Empowering the accessibility of safe global electrosurgery

Safe electrosurgery should be available for **everyone**, **everywhere.**

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MSc. Integrated Product Design

TU Delft

Empowering the accessibility of global electrosurgery

Master of Science Thesis

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Empowering the accessibility of global electrosurgery
Msc. Integrated Product Design – Master Thesis

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Executive **summary**

of graduation project

Project scope

Roos Oosting and the Global Health Design Lab initiated development of affordable and high-quality electrical surgery units (ESU) as a step towards improving surgical care. The ESU is used as an operating tool to assist the surgeon for a high variety of essential surgical procedures. The ESU consists of a high frequency generator with an interface to adjust power settings, a return electrode and an a monopolar handheld that is used to perform the surgery. The main advantages of electrosurgery for low and middle income countries (LMICs) settings is that it is widely applicable, helps to stop and prevent bleeding, allows for precise cutting, facilitates better wound healing in less hygienic environments and has a valuable contribution to time efficient execution of surgical procedures.

A few low-end devices also exist that—due to their stripped down, fully analogue and simple design— do not fully meet the demands that are needed for safe global usage of the ESU. As a result, the devices are used inappropriately and this can have serious clinical consequences for the patient, even more in low-resource settings like East-Africa (Oosting, 2018).

“The design goal of the project has been the development of a reliable, safe and intuitive user-interaction with the ESU system and a tailored design for maintenance in a variety of use-contexts in LMICs”

The new design of the electrosurgery unit should be understandable for all electrosurgery users, thus surgeons with limited electrosurgery experience as well as specialists and surgical assistances. The ESU system should be affordable and therefore the design focus will be solely on essential functionalities for safe electrosurgery.

Analysis

Quantitative research conducted by R.Oosting and the R&D team of 3ME along with desktop research has been used to create a better understanding on the technology of electrosurgery and problems and needs in regard of electrosurgery in the LMICs healthcare context. Moreover, for situations where existing equipment and devices cannot fulfil the unique needs of LMICs, the process of designing tailored solutions should involve extensive consultation with end-users, as this is critical to promoting correct device use and protecting patient safety (Ng-Kamstra, 2016).

Consequently, substantial qualitive research has been done by interviewing 15 Dutch surgeons that work or have worked in developing countries. This created an holistic view on the user-interactions and barriers with the electrosurgical unit prior, during and after a surgical procedure and legit assumptions on required functionalities in use and sustainable maintenance prior to designing. Besides, the ideation phase has been conducted in close collaboration with the Dutch surgeons. This co-creative design approach resulted in efficient iteration steps and well-founded assumptions concerning the intended target group in LMICs.

Concept development

A final concept has been designed with the input of Dutch surgeons and translated to various boundary objects that could be iteratively tested on intuitive and safe user-interaction with the surgeons in Kenya. Qualitive research has been conducting an explorative studies with interviews and user tests with around 23 electrosurgery operators in and around Nairobi, Kenya. Furthermore, various boundary objects/trade-offs have been made to verify design decisions with the intended target group (surgeons, operation assistances and local technicians) and to increase knowledge on barriers in LMICs and the various post-treatment procedures of the surgical equipment.

Executive **summary**

of graduation project

In general, the underlying principles of electrosurgery are not widely known and the experience with the ESU is limited. Hence, this forms a potential risk for the operator as well as the patient. Even more in LMICs where a routine surgery does not exists and a broad spectrum of surgery knowledge is required, according to the majority of the interviewed surgeons.

Final design

The user interaction of the high frequency generator is extensively tested with the intended target group in LMICs on intuitiveness, acceptance and reliability. Accordingly, the newly developed high frequency generator is tailored designed to the knowledge of the operator, increases safety for patient and operator and designed to be modular concerning a future product family. The high frequency generator is designed to be affordable and therefore solely focusses on essential functionalities and interactions to perform safe and basic electrosurgery.

One of the main barriers encountered during the field trip in Kenyan hospitals is the lack of reliable monopolar handhelds and the safety risks because of the various used cleaning procedures in LMICs in which the available handhelds are not resistant. The new design of the monopolar handheld increases safety, intuitiveness and the feeling of control along the surgery. Furthermore, the handheld has been designed to be resistant against frequent re-sterilization with the variety of used cleaning procedures in LMICs.

The electrode tip connected with the monopolar handheld has been designed as a multitool to be sufficient for execution of all basic electrosurgery interventions. Furthermore, the increased insulation design will reduce safety risks and enhance confidence along the surgery.

Evaluation

Even though the developed ESU system requires future improvements to create a sustainable success, the designed system empowers the future accessibility of electrosurgery for LMICs. The ESU system increases safety and an intuitive user interaction concerning the limited electrosurgery experience and enhances reliability for maintenance in the variety of use contexts in LMICs. The developed trade-off has shown the great potential this designed ESU system can have on global surgery. Hopefully, this ESU system can in all sincerity make global electrosurgery accessible for everyone and everywhere.

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of the thesis report

Surgery in LMICs (source: Capacare)

Introduction

to the design project

About one-third of the global disease burden is surgical, yet five billion people around the world do not have access to safe, timely, affordable surgery (Raykar, 2016). Some reasons for this shortage in medical equipment are a lack of funding, maintenance, training, educated procurement and infrastructure. In low- and middle-income countries (LMICs) improved surgical care can be used to save millions of lives and this will significantly reduce the number of disability adjust life years (Westra, 2016).

In 2010 it has been estimated that a provision of basic surgery could have prevented 16.9 million deaths due to illness and injuries. Moreover, new evidence has emerged showing that surgical conditions are responsible for nearly one-third of the world's burden of disease, and that providing surgical treatment can be highly cost-effective (Ng-Kamstra, 2016). In the last decades the global focus has been on diagnostic diseases such as Aids and Malaria, however, the sum of lives lost as a consequence of bad surgical conditions is almost five times higher (Westra, 2016).

More than a half of medical equipment in LIMCs hospitals is donated. However, the WHO estimates that 70% of medical devices designed for use in the developed world, do not work when they reach the developing world (Malkin, 2006). Factors contributing to this are: lack of needs assessment, appropriate design, robust infrastructure, lack of spare parts, lack of consumables, and a lack of information for procurement and maintenance, as well as trained health-care staff (WHO, 2010). This lack of existing or functioning medical equipment is a major factor preventing reliable diagnostics and surgical interventions (Malkin, 2006).

In this regard, MSc. Roos Oosting of the Department of Biomechanical Engineering (3ME) is executing her PhD on high quality and robust surgical equipment for safe surgery world-wide. For her research, she visited East Africa (Kenya) various times to see how surgical equipment does(not) function in the local healthcare context. Hence, this project has come to life among the Faculty of Applied Science (Biomechanical Engineering (3ME)) and Industrial Design Engineering as a part of The Global Health Lab.

Roos Oosting initiated development of affordable and high-quality electrical surgery units (ESU) as a step towards improving surgical care. The ESU is used as an operating tool to assist the surgeon for a high variety of essential surgical procedures. The main advantages of electrosurgery for LMIC settings is that it is widely applicable, helps to stop and prevent bleeding, allows for precise cutting, facilitates better wound healing in less hygienic environments and has a valuable contribution to time efficient execution of surgical procedures.

The challenge of this project is to create a comprehensive understanding of the problems and needs in LMICs in regards of electrosurgery by incorporating use conditions, user-interactions, available knowledge & experience of the target group and costs constraints. This knowledge should be used as design input for product development. Hence, the goal is to empower the accessibility of global electrosurgery by developing an electrical surgery unit that enables an effective implementation in the LIMCs healthcare system.

Problem **definition**

problems to tackle

Today's market is dominated by high-end ESUs characterized by high prizes, large number of settings and computer control systems. A few low-end devices also exist that—due to their stripped down, fully analogue and simple design— do not fully meet the demands that are needed for safe global usage of the ESU. As a result, the devices are used inappropriately and this can have serious clinical consequences for the patient, even more in low-resource settings like East-Africa (Oosting, 2018).

In general, the underlying principles of electrosurgery are not widely known and the experience with the ESU is limited. Hence, this forms a potential risk for the operator as well as the patient. Even more in LMICs where a routine surgery does not exists and a broad spectrum of surgery knowledge is required according to the majority of the interviewed surgeons. Besides, the existing devices are complex due to the lack of standardization in user-interface, the brand specific names for power settings and waveform outputs and the wide range of available instruments.

Moreover, apart from problems in use, maintenance, the replacement of parts, transportability to remote regions, no functionality at high ambient temperature and no toleration of grid fluctuations can also be barriers in developing countries (Diaconu, 2017). Hence, this project will focus on a reliable, safe and intuitive user-interaction with the ESU system and a tailored design for use and maintenance of a variety of use-contexts in LMICs.

ESU in operation theatre of Kenya

Design **approach**

of the project

The design approach of the project is based on the Creative Problem Solving Method (Boeijen, 2013), which consists of a three-stage process: explore the challenge, generate ideas and prepare for action. This approach can be seen as creative and pragmatic, something that embraces the challenges within this project.

The design approach has been adjusted to a design process of four phases as can be seen in figure 1. The four project phases are: analysis (technology and context), co-creative ideation & conceptualization with target group and experts, verification of the design and detailing.

Phase 1: Analysis (technology and context)
Quantitative research conducted by R.Oosting and the R&D team of 3ME along with desktop research has been used to create a better understanding on the technology of electrosurgery and problems and needs in regard of electrosurgery in the LMICs healthcare context. In addition, substantial qualitive research has been done by interviewing 15 Dutch surgeons that work or have worked in developing countries. This created an holistic view on the user-interaction with the electrosurgical unit prior, during and after a surgical procedure and legit assumptions prior to designing.

Accordingly, a comprehensive view concerning the problems and needs has been created and concluded with a design brief (design goal, scope of the project, requirements and challenges of the project).

Phase 2: Ideation and conceptualization
The design brief has been the starting point of ideation, what included mock ups to verify design decisions, creation of safe and intuitive user interaction with the ESU and component & material selection for maintenance in local context. To verify design decisions and pre-assumptions this phase included multiple co-creation sessions with Dutch surgeons and medical clinical technicians, all with experience in the LMICs healthcare context. This phase has been concluded with a final concept that has been prototyped for user-testing in the intended use context, Kenya (sub-Saharan).

Phase 3: Verification
For situations where existing equipment and devices cannot fulfil the unique needs of LMICs, the process of designing tailored solutions should involve extensive consultation with end-users, as this is critical to promoting correct device use and protecting patient safety (Ng-Kamstra, 2016). Consequently, a boundary object/trade-off has been made to verify design decisions with the intended target group (surgeons, operation assistances and local technicians). Qualitive research has been conducted by interviewing and user testing with around 23 electrosurgery operators in and around Nairobi, Kenya. The prototypes have been tested on safe and intuitive user interaction, acceptance and reliability in local context. The information received during the user test and interviews has been used as design input and requirements for final design decisions.

Phase 4: Detailing
Insights of the field trip have been implemented in a final iteration/detailing phase. Changes in user-interaction have been made to increase intuitiveness of usage, patient safety and operator safety. Furthermore, final iterations have been made concerning materialization and manufacturability of the high frequency generator and monopolar handheld. Accordingly a sustainable, safe and reliable design of the ESU system is accomplished. At last recommendations are provided on future implementation and future development of the ESU system.

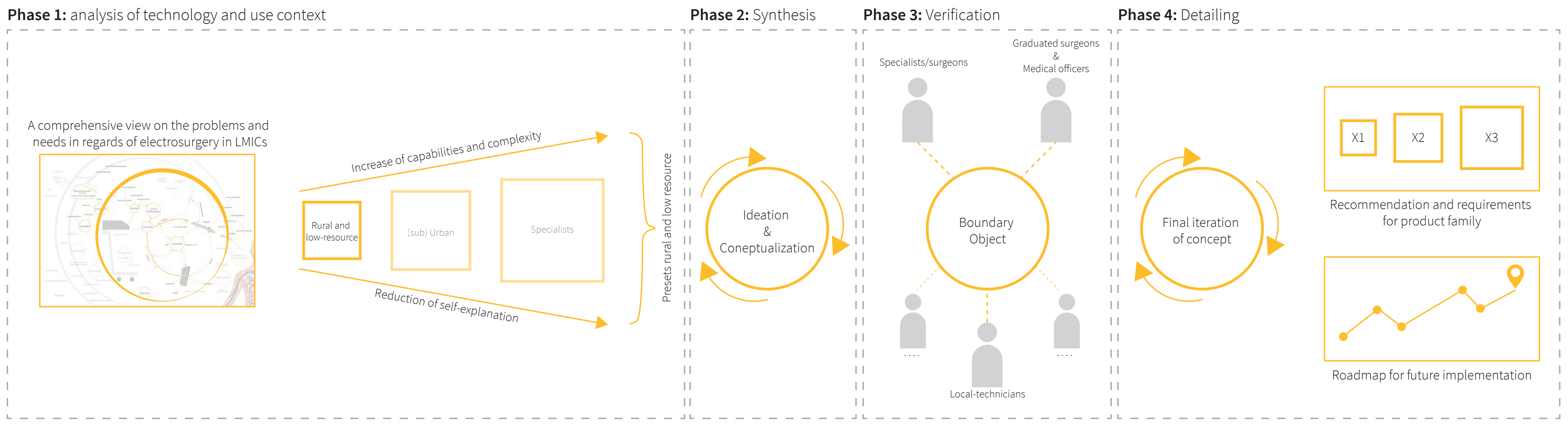
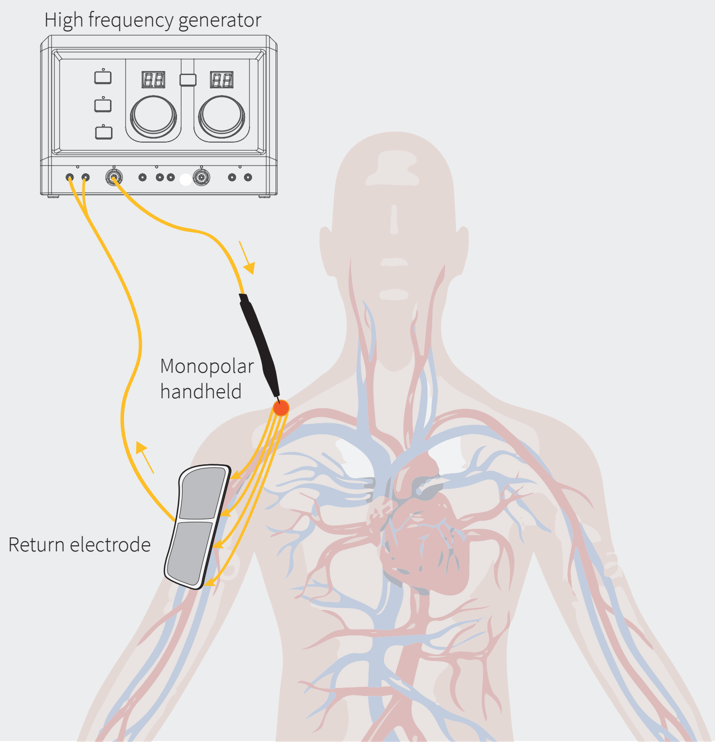


Figure 1: design approach of the project

1.1 The **principles**

of electrosurgery

Electrosurgery is the application of high-frequency current on biological tissue to raise intercellular temperature which is used in a high variety of medical surgeries to precisely cut tissue and to reduce blood loss during a surgical procedure. In this chapter an explanation and overview of the physical principles of tissue heating with electric current will be discussed. Furthermore, the technological functioning and important influencing factors for the clinical electrosurgical effect on human tissue will be discussed.



Electrosurgery can be divided in monopolar and bipolar application, reflecting the number of active electrodes that are used (van den Berg, 2012). During monopolar electrosurgery, a handheld with a single cutting electrode is attached to the high frequency generator and a return electrode plate - large enough to avoid local tissue heating - is attached to the patient's body to close the electrical circuit (see figure below). Whereas during bipolar electrosurgery, two active electrodes are used in close proximity and both affect the intermediate tissue (van den Berg, 2012).

The electrosurgery principle will be explained more extensively by using the monopolar application. The high-frequency generator creates a high-frequency alternating current (AC) that flows from the active electrode to the least path of resistance; the return electrode plate, and consequently the electrical circuit is closed. The active electrode consists of an electrode tip with a small cross sectional area, which results in converging of current in the form of heat, that is proportional to the square of the current density. Contrarily, the size of the return electrode plate provides a substantial cross sectional area, which decreases heat generation within the tissue.

The high frequency alternating current wave properties are the main cause for tissue heating (Hawthorne, 2004). Inside the human cell, there are positively as well as negatively charged ions and particles. An alternating current will result in a migration of ions towards their opposite pole. During a high frequency alternating current a fast change in polarity arises, which make the positive and negative start oscillate, causing frictional heat, thus a raise of intercellular temperature. This thermal effect can be used for tissue desiccation (cutting of tissue) and coagulation (stop bleeding by creating a coagulation effect), joint capsular tightening, corneal curvature alteration, venous closure, and cardiac ablation (Crantz, 2017).

Electrosurgery is often explained similar to electrocautery although both techniques differ as with electrosurgery heat is generated within the tissue instead of the instrument. The electrode tips of electrosurgical tools are the poles that can generate a potential difference, whereas the electrocautery is a closed loop - often battery powered - circuit in which heat is generated (direct current) (van den Berg, 2012). The advantage of electrosurgery over electrocautery is that, aside from the superficial layer, the underlying tissues will be reached as well (Westra, 2016).

The advantages of electrosurgery reside primarily in the controllability of the electrosurgical effect, the versatile, partly new and unique applications, and the variety of supported instruments and instrument forms (Erbe, 2015). Furthermore, electrosurgery makes a valuable contribution to time efficient execution of surgical procedures, reduction of blood loss and facilitates better wound healing, which can be highly beneficial in less hygienic environments.

A small lecture on physical terms

The fundamentals of physical terms will briefly be discussed as an understanding of the used terminology. For an electrical circuit to exist there are positive and negative electrons that are attracted to each other, thus providing the potential difference for ions to move. The required energy (unit: Joule [J]) for separation per charge quantity is the electrical voltage (unit: Volt [V]), which pushes the current through the conductor(the human tissue) (Vilos, 2013). An electrically conductive connection will move the ions towards each other and electrical current starts flowing (unit Ampere [A]). Herein, current is the measure of the electron movement through a point over time(Crantz, 2017).

All conductors have a resistance/impedance (unit: Ohm [Ω]) against the current flow based on material characteristics and geometry. In example, if the resistance is increasing (more tough biological tissue), current flow will decrease at a constant voltage or constant current requires an increase of voltage. These variables are related to each other by Ohm's law: V =I·R

There are two types of current: direct current (DC) and alternating current (AC). Direct current always flows in the same direction. A periodically change of the current direction is called alternating current, wherein one period consists of two changes in polarity (positive and negative). The number of periods per second is called frequency (unit: Hertz [Hz])
In electrosurgery typically a sinusoidal alternating current is used to make the cells start to oscillate. The maximum peak voltages required for general electrosurgery is 3000 [V] by a power of 70 Watts. Consequently, components exposed to these high peaks should be resistant for a short time frame. Generally, these high peaks are generated in a duty cycle of 6%, which means the voltages over the components is not continuously this high.

Therefore, it is important to consider the actual effective power that is flowing through the exposed components, the Root Means Square (RMS). The RMS is the absolute voltage over the sinusoid, averaging the peak values with the lower values, also known as the square root of the peak voltage($\sqrt{2}*V_{peak}$) that is often used to measure resistance of electrical components against high voltages.

The effect of this power on human tissue is depending on the current density. The current density is the current per cross-section of the conductor, which is in contact or adjacent with the electrode tip. Nearly all of the electrodes have a positive resistance, which results in an abduction of power in the form of heat, that is proportional to the square of the current density (Crantz, 2017).

$H= j^2/\sigma$
σ exemplifies the conductivity with $\sigma = 1/R$. Consequently, an increase of the current density will increase the temperature of the electrode tip exponentially.

Hence, the current density is limited since too much heat damages the material of the resistors/electrodes. In example of electrosurgery, a high current density can cause tissue burns if the tissue or body is caught in the circuit. In that instance, the tissue acts as the resistor with a very low positive resistance, resulting in the heating and damaging of cells caught in the stream of the high density current (Crantz, 2017)

1.2 Influencing **factors**

of electrosurgery effect on tissue

Settings such as waveform, current density, speed of heating, exposure time and tissue impedance are decisive for the surgical effect of the ESU (Malcolm, 2012). With an increased power, tissue heats quicker as larger current flows through the tissue. Thus, the speed of heating and the exposure time to an increased temperature are determined by the time and power delivered to the tissue. Besides, the local distribution of heat depends on the electrode size (current density) and the tissue resistance/impedance. These various factors all have influence on the electrosurgical clinical effect and consequently possible future design decisions.

Size and shape of the electrodes

A small cross sectional area and the material impedance of the electrode tip are of high influence on the intensity and the speed of heating. Since the rate of heating is proportional to the squared current density (as explained in the small lecture), a small cross sectional area will exponentially increase the temperature of the electrode tip. In example, a cutting electrode typically has a line shaped leading edge, to allow for a high current density. However, the current density is limited since too much heat damages the material of the electrodes, where the possible danger arises of melted material inside of the human body or tissue.

In opposition, an increased contact area with a similar power output will have no impact on the cells, by virtue of a low current density (Malcolm, 2012). Consequently, the design size and shape of both the active electrode tip and the return electrode plate is of high influence on the surgical effect of the ESU.

Tissue exposure time

The achieved temperature and exposure time is influenced by the length of time of the contact between the electrode tip and the tissue (van den Berg, 2012). The longer the activation results in wider and deeper tissue damage. Contrarily, a short activation time can lead to an absence of the desired tissue effect (Wang, 2007). Likewise, the electrode tip movement speed will result in either less or more thermal spread. Recent guidelines concerning the application of electrosurgery describe that to enhance patient's safety a brief and intermittent activation is recommended (Meeuwsen et all, 2017).

Tissue properties

The human body consists of various tissue types with different thermal and electrical properties that respond differently to heat (Wicker, 1990). Each type of tissue has its own distinctive impedance, as can be seen in figure 3. The impedance depends on the fluid concentration within the tissue and consequently the tissue impedance is different for each person by virtue of age and lifestyle . A high concentration of fluid results in an increased conductivity, thus a reduction of impedance (e.g. blood) (Crantz, 2017).

Furthermore, the properties of tissue will change its impedance depending on the pressure (e.g. tweezers during bipolar surgery) exerted on the tissue. A more compressed material and an increased surface result in an increased impedance (Doddle, 2011). Besides, once tissue is desiccated or coagulated the concentration of fluid decreases and consequently tissue becomes less conductive not allowing deep heat penetration (Crantz, 2017). Subsequently, differences in electrical properties of to-be-processed tissue types affects the performance of the electrical surgery unit (van den Berg,

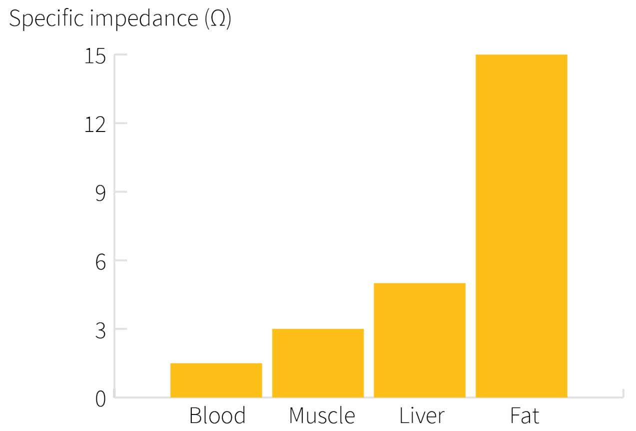


Figure 3: differences in tissue impedance

Waveform output

The impact on the tissue effect is highly related to the waveform output of the electrosurgical generator. Most electrosurgical generators operate with two main waveform modes: continuous and intermittent, also known as the cut mode and coagulation mode, which is roughly the desired tissue result (uniformly labelled with the colours yellow for cutting and blue for coagulation) (van den Berg, 2012).

Cut mode

The continuous mode is generally characterized by sine waves which incorporates higher current but lower voltage than intermittent waveforms at the same power setting (see figure 4). The continuous waveform is primarily used to vaporize cells, and therefore to cut or remove tissue (Crantz, 2017). If the temperature within the cells reaches above the boiling point (100°C) the intracellular water evaporates. This evaporation leads to a quick and enormous expansion of steam which cannot be retained by the cellular wall. The cellular wall will burst, giving way for the active electrode tip to get through the targeted tissue (Malcolm, 2012).

In general, the continuous mode produces less charring and tissue damage in comparison with the intermittent mode since the thermal spread is less deep (Wang, 2007). Besides, cutting tissue by means of electrosurgery instead of the surgery scalpel will provide interim coagulation on the walls of the incision, thus reducing blood loss during the surgery (Westra, 2017).

Typically, a clean cut is achieved by selecting a high power and pulse duration longer than the tissue's thermal recovery time. This allows structures to retain their rest state after impact, preventing heat build-up and reducing the thermal dissipation to surrounding tissue (van den Berg, 2012).

Coagulation mode

The intermittent mode is characterized by high peaks sine waves which have a higher voltage and lower current than the continuous mode. The intermittent mode has a duty cycle of 5–6 % of the continuous mode giving the tissue time to cool down, thus producing the coagulation effect during 94% of the waveform cycle. The high voltage is required for current to pass through high tissue impedance or desiccated tissue(Wang, 2007).

The intermittent/coagulation mode is mainly used to achieve haemostasis through coagulation and desiccation. Furthermore, to seal lumen-containing

structures such as the fallopian tube to destroy volumes of soft tissue like cancer cells (Crantz, 2017). Coagulation can be performed in two manners; direct contact with the tissue (desiccation) or without contacting the tissue (fulguration).

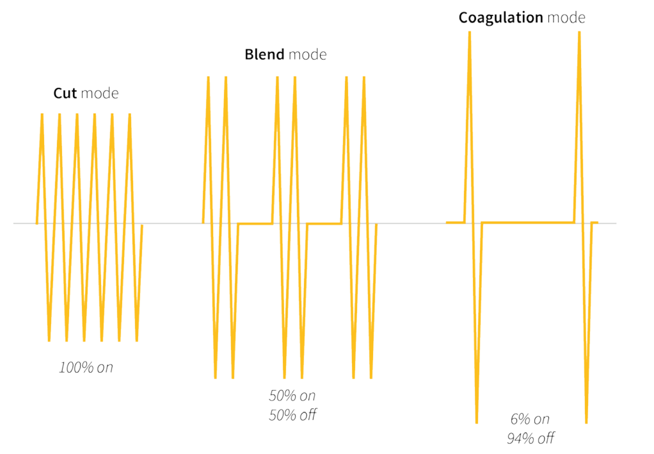


Figure 4: A graphic representation of the waveform modes. A continuous waveform is initially used to cut tissue. A intermittent high voltage waveform is initially used to coagulate tissue. The blend waveform is a mix and used in situations where both cut and coagulation is required because of possible high blood loss while cutting tissue.

1.2 Influencing **factors**

of electrosurgery effect on tissue

Desiccation

Contact coagulation is primarily suitable for coagulation of vessels and localized bleeding. During contact coagulation cells within the tissue gradually lose their fluid content through vaporization out of the cellular wall. This will increase tissue impedance as dried top layers make it harder to reach adequate tissue depth (Westra, 2017). Contact of the active electrode with tissue results in a full conversion of electrical energy to heat within the tissue (Wang, 2007). This is contrary to fulguration where a significant amount of electrical energy is lost during creation of the spark gap between the active electrode and the tissue. Consequently, contact coagulation results in deeper destructiveness and greater thermal spread (Westra, 2017).

Desiccation is achieved most efficiently with the cut mode waveform. By touching the tissue with the electrode tip, the current concentration is reduced, thus less thermal spread and no vaporization of the tissue. Hence, coagulating with the cut waveform will accomplish the task with less voltage. This is an important consideration during minimally invasive procedures as well as a surgical procedure with delicate organs nearby the targeted tissue (Covidien, 2008).

Fulguration

Fulguration is non-contact coagulation technique where the active electrode tip is positioned above the targeted tissue. To overpass the emerged air gap between the tissue and the electrode tip the electric current releases an electric discharge arc that can be identified as a spark (Westra, 2017). The result is a relatively diffuse, inhomogeneous zone of elevated tissue temperature that is limited to the superficial tissue layers, by virtue of an increase of tissue impedance. Consequently, this type of coagulation is most preferred for the arrest of capillary or small arteriolar bleeding over a large surface area and has implications during minimally invasive surgery (Malcolm, 2007).

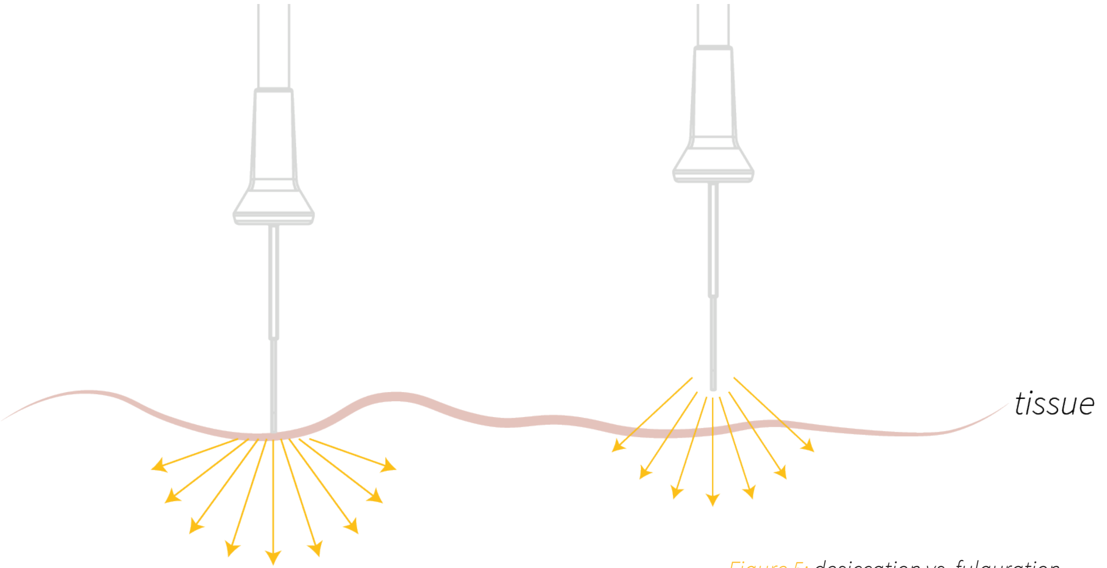


Figure 5: desiccation vs. fulguration

Operating power

The electrosurgical generator can keep the operating parameters constant or change them by virtue of control on the interface to achieve the desired tissue effect. This enables the surgeon to compensate for differences in tissue properties, or react to transmissions in tissue properties due to desiccation.

In most cases, the appropriate operating power output will be the minimum power density at the active electrode to create the desired vaporization or coagulation. Nonetheless, a clear description or guidelines of the tissue contact area is frequently missing, which disables the determination of appropriate power density. Using too high power settings and inappropriate waveform modes can result in tissue trauma or trauma on the surrounded sensitive organs.

Information concerning power guidelines may be of great value in a broader, comparative context (van den Berg, 2012). According to Theo Wiggers (director of Incision care), providing these guidelines will be of great attention in the coming years since global legislation will arise where qualification and capability of using medical equipment cannot do without one another.

Thermal effects on human tissue

When heating tissue various processes take place that generate changes in human tissue, which can be seen in figure 5. The essential processes for electrosurgery are denaturation of the proteins (coagulation) starting at around 60 °C and vaporization(desiccation/cutting) of the tissue fluid at 100 °C.

From 60-100 °C

In the range of 60–80 °C tissue proteins start denaturalizing. The intramolecular hydrogen bonds of proteins are broken, the triple-helix structure unwinds and the highly organized crystalline structure transforms into an amorphous state, which is also known as coagulation (van den Berg, 2012). Hereupon, an increased tissue temperature will ensure vaporization of cell content and tissue starts to dehydrate or "dessicate" which increases tissue impedance (van den Berg, 2012).

From 100 °C

At approximately 100 °C cells explode in a process called vaporisation. Cell walls tend to rupture, which enables the steam to escape causing it to explode, leading to cellular membrane rupture: cutting (Westra, 2017)(van den Berg, 2012).

37 °C - **40** °C

None

40 °C - **60** °C

Hyperthermia
initial tissue damage, edema formation, depending on the durati-on of application, the tissue can recover or die (devitalization)

60 °C - **100** °C

Devitalization (destruction)
of the cells, shrinkage of the connec-tive tissue through denaturation

From **100** °C

Vaporization
of the tissue fluid, depending on the speed of vaporization:

- Tissue shrinkage through desiccation (drying out) or
- Cutting due to mechanical tearing of the tissue

From **200** °C

Carbonization

Figure 6: thermal effect on tissue

1.3 Electrosurgical **procedures**

monopolar vs. bipolar

During electrosurgery a potential difference is generated between two electrodes, providing a "path of least resistance." Two main techniques, respectively monopolar and bipolar electrosurgery, referring to the amount (1 or 2) of active cutting electrodes used, will subsequently be discussed, see figure 7 (van den Berg, 2012).

Monopolar vs. Bipolar

In monopolar electrosurgery, tissue is cut and coagulated by completing an electrical circuit that includes a high-frequency generator, the return electrode plate, the connecting cables, and the monopolar handheld. Electric current from the ESU is conducted through the surgical site with an electrical cable to the monopolar handheld. The electrosurgical current is then dispersed through the patient to a return electrode pad returning the energy to the generator to complete the electrical circuit. In bipolar electrosurgery, two electrodes (generally the tips of a pair forceps or scissors) serve as the equivalent of the active and dispersive leads in the monopolar mode. Thus, bipolar electrosurgery does not require a dispersive electrode plate to close the circuit.

In contrast to monopolar electrosurgery the bipolar modality was found to be associated with a more efficient performance and less thermal spread (van den Berg, 2012). The current density is focused and confined between the two electrodes. In this way a misguided electric return pad, also known as direct coupling of other conductive surgical equipment is largely eliminated (explanation in chapter 1.5).

Accordingly, bipolar surgery is often presented as more safe and affords greater control over the area to be coagulated. Moreover, damage to sensitive tissue in close proximity to the instrument can be avoided and therefore bipolar surgery is mostly used for neurological surgery, plastic surgery and infants surgery (superficial tissue).

Contrarily, monopolar surgery results in a more radial pattern around the active electrode and consequently the power requirements in monopolar surgery are significantly higher for application of the targeted tissue, see figure 7 (Crantz, 2017).

In general, the applicability of monopolar instruments is considered to be more diverse. Monopolar surgery can be used to coagulate and cut tissue and a high variety of active electrode designs are available, which will be explained in chapter 1.4.

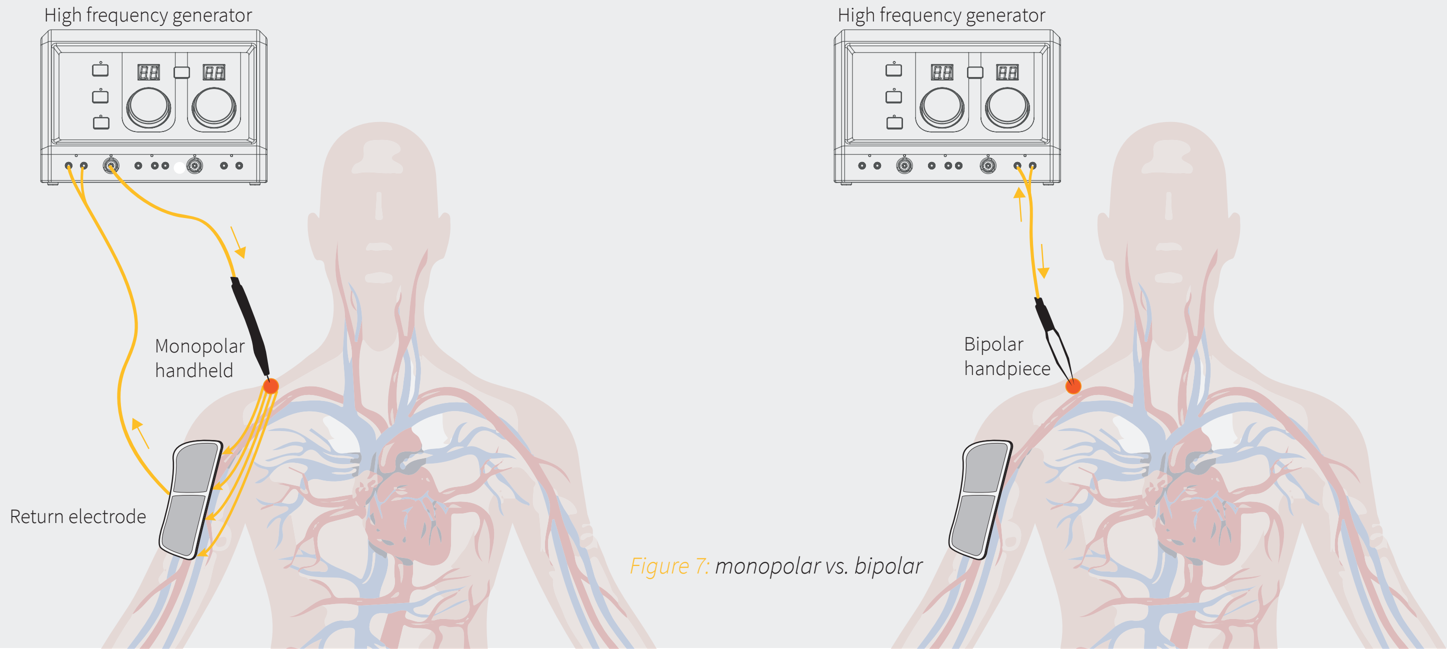


Figure 7: monopolar vs. bipolar

Whereas bipolar instruments can solely be used to coagulate tissue, mainly blood vessels. The used electrical energy of currently marketed bipolar instruments is insufficient to effectively cut tissue since it is hard to design and manufacture a bipolar instrument that is narrow enough to compete with monopolar cutting (Crantz, 2017). Some bipolar cutters exists, however, this requires contact with tissue resulting in deeper thermal damage compared to monopolar cutting (van den Berg, 2012). An overview of the differences between monopolar and bipolar surgery can be found in figure 9.

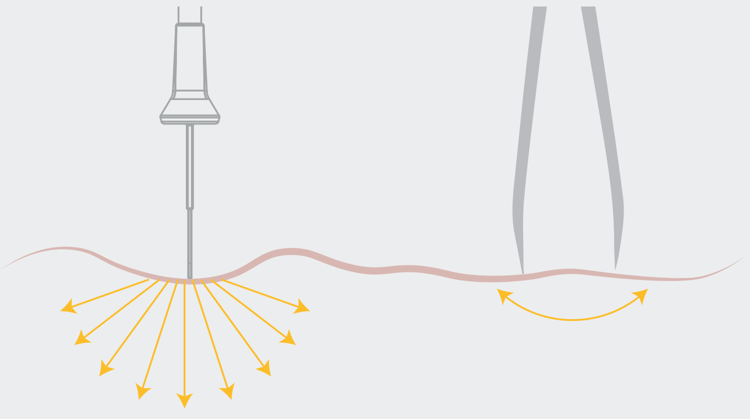


Figure 8: thermal spread of monopolar and bipolar

Monopolar surgery	**Bipolar surgery**
Can be used for coagulation and desiccation	Can solely be used for coagulation
Can be operated with high voltages as well for desiccation and fulguration	Uses low voltages because there is solely contact coagulation (low impedance)
Uses high(er) power settings	Uses low power settings
Possibilities for misguided electric return path	Misguided electric return path is eliminated
Risk of fire due to high voltages	Low risk of fire due to low voltages
Hand or pedal activated	Pedal activated or instant response technology when in contact with tissue
High variety in electrode tips	Tweezers, scissor or laparoscopic instruments
Highly difficult to measure differences in tissue impedance	Possibility measurement differences in tissue impedance
Problems operating in conductive environment	More efficient performance
Higher possibility for unintended tissue damage	Low possiblity for unintended tissue thermal due to less thermal spread
Thermal spread around active electrode	Thermal spread in between electrodes

Figure 9: differences between monopolar and bipolar electrosurgery

1.4 Electrosurgery **instruments**

of monopolor electrosurgery

Users of electrosurgery have a high variety of electrode instruments at their disposal for the various applications. This chapter provides an overview of these instruments and explanation of applications.

The electrosurgical instruments can be subdivided in cutting instruments and coagulation instruments. The instruments can also be classified according to their area of application in regard to their design. Instruments for minimally invasive surgery require a shaft that can be rigid or flexible depending on the kind of application, e.g. laparoscopic surgery or flexible endoscopy. For open surgery, instruments generally consist of a handheld with an electrode attachment in example of monopolar electrosurgery (see figure 10). And lastly, instruments can be disposable (one-time usage) as well as reusable (Erbe, 2015).

Cutting instruments

The power density required to vaporize tissue must be high, which requires the use of an electrode with a very small surface area (Malcolm, 2012). Accordingly, electrodes with a line-shaped leading edge are essential for incisions. Typical forms of cutting electrodes are spatulas, needles, hooks and wire snare (for examples see image on the right). These electrodes are available in a monopolar version which include an electrode attachment for handhelds with a rigid or flexible shaft (Erbe, 2015).

Bipolar cutting instruments normally have a neutral electrode ring that has to be in contact with the tissue during the incision. Therefore, the required contact result in deeper thermal tissue damage compared to monopolar cutting instruments (van den Berg, 2012).

Coagulation instruments

There are various instruments for the following coagulation effects: haemostasis, vessel sealing and ablation. Haemostasis in open surgery is generally achieved by using an instrument with a large contact area, such as the spatula electrode or a ball electrode during monopolar surgery. For vessel sealing bipolar tweezers and clamps of various sizes and shapes are used (Erbe, 2015). Lastly, puncture needles are used for tissue ablation and devitalization of for instance tumour cells. The small cross sectional area of the needle will require less power for similar reaction on the tissue as with the spatula electrode.

Additionally, some electrodes serve a dual purpose. For instance, the spatula electrode may be employed for a cutting procedure if the line edge blade is held near to the tissue, which will create a higher power density. Alternatively, by positioning the breadth of the blade in contact with the tissue, a lower power density is created which can be used for coagulation purposes (Malcolm, 2012).

Besides, while the leading edge of the spatula blade is used for cutting purposes, the breadth of the blade may contact the edge of the incision, creating interim coagulation on the adjacent tissue. Depending on the clinical situation, this effect may be either an advantage or disadvantage (Malcolm, 2012).

Figure 10: open surgery monopolar instruments

1.5 Electrosurgery **risks**

that should be prevented for

The use of the electrosurgery unit includes many risks the user should be aware of. In case of ignorance these risks can have serious consequences for the user as well as the patient. Prior to usage it is highly important that the user is not only qualified to use the ESU but also competent of what to do in case of these risks. Within this chapter the main possible risks will be explained and the understanding and prevention of risks will be used as design requirements and input for the design phase. Other risks can be found in appendix A.

Direct application
Direct application is closely related to being competent as a surgeon to use the surgical product but not being capable of appropriate usage. Direct application describes sustained damage through wrong positioning of the electrodes (return electrode or active electrode) or device misuse, as in wrongly used power settings, waveform modes and active electrodes(van den Berg, 2012). Localised overheating or accidental activation of the active electrode can cause unwanted tissue damage, which can have negative impact on the clinical outcome of the surgery (Crantz, 2017).

Direct coupling
Direct coupling refers to the unintended contact of the active electrode to other conductive materials within the abdomen. Direct coupling occurs when the user accidentally activates the ESU while the active electrode is in close proximity to another metal instrument (Wang, 2007). Current from the active electrode flows through the adjacent instrument (e.g. surgical scissor) through the pathway of least resistance. Consequently, structures and organs out of the visual field which are in direct contact with the adjacent instrument will be potentially damaged (Wang, 2007).

Furthermore, electromagnetic interference caused by the ESU can influence diagnostic interference with Implanted Electrical Devices such as pacemakers (Crantz, 2017). Direct coupling can be prevented by enhancing the visibility of the electrode in contact with the targeted tissue and avoiding contact with any other conductive instruments prior to activating the electrode (Wang, 2007). Subsequently, in case of high power settings, more attention is required with metal objects in close proximity to the surgical field.

Insulation failure
Insulation failure is the risk of alternate current pathways out of breaks in the insulation material that cover the electrosurgery accessories. Hence, with a high current concentration, injury to adjacent tissue and organs is possible (Wang, 2007). Insulation failure often results from excessive use an frequent re-sterilization of instruments, what leads to material degradation (van den Berg, 2012). This occurs primarily when the comparatively high coagulation waveform mode is used by virtue of its high voltage output. This high voltage can spark through compromised insulation or can blow holes in weak insulation.

Accidental burns caused by insulation failure can be prevented by a proper selection of insulation material (dielectric strength of at least 3 MV/m and thermal breakdown of at least 150 °C), by lowering the needed current concentration or by coagulating with the cut current, as explained in chapter 1.3 (Wang, 2007). Accordingly, this will increase reliability of the instruments and enhance patient and operator safety.

Capacitive coupling
Capacitive coupling arises when two conductive instruments, the active electrode and another conductive instrument, are separated by an insulator layer and form an electric potential build-up without making actual contact (Wang, 2007). The electric charge that has built up in adjacent tools will eventually be dispersed to surrounding tissue, causing unintended tissue damage (van den Berg, 2012).

Warning signals that can signify coupling abnormalities include a reduced efficiency of the active electrode, a ‘‘snow storm’’ on the monitor caused by coupling to the laparoscope or other surgical equipment, and a generation of arcing sounds within the cannula (Crantz, 2017). The use of an active electrode monitoring system and limiting the amount of time that a high voltage setting is used can eliminate concerns about capacitive coupling (Wang, 2007). Hence, an appropriate material selection of the electrode tip and monopolar handheld will prevent for capacitively coupled noise (relative permittivity).

Residual heat of the electrode tip
If the active electrode is activated for a longer period of time, the electrode tip will most likely increase temperature. The lower the conductivity of the used material the higher the resistance for current pass through and consequently faster increase of the electrode tip temperature.

Nevertheless, continued activation will heat the electrode tip, which will require the prevention for contact of other tissue than the targeted tissue (e.g. when laying down the handheld during the surgery). This risks occurs for monopolar as well as bipolar surgery.

The danger of Eschar build-up
Eschar is a piece of dad tissue cast off from the surface of the skin, specifically after a burn injury. During the surgical procedure Eschar can amass on surgical instruments, such as the electrode tip, and this can create two risks. Firstly, the eschar build-up can impede the flow of electrical current in the active electrode. Secondly, eschar can ignite and cause a fire (Covedien, 2008). Scratching off the eschar roughens the surface of the electrode tip, which promotes the build-up for more eschar (Megadyne, 2010). Hence, the creation of scratches, thus adhesive wear should be minimized.

Electrosurgical smoke
Surgical smoke is created when tissue is heated and cellular fluid is vaporized causing membranes to rupture and particles to be dispersed into the surrounding air. Although the presence of surgical smoke may not always be (visually) apparent, special illumination techniques have been used to demonstrate their existence during electrosurgery, ultrasonic surgery, and laser surgery (van den Berg, 2012).

Viral DNA, bacteria, carcinogens, irritants and sometimes even viable tumour cells are known to be present in electrosurgical smoke (Covedien, 2008). Pathological risks range from irritated eyes and headaches to tumour recurrence and bacterial or viral infections (van den Berg, 2012). Consequently, smoke evacuation systems should be valuable to reduce potential risks to patients and user of the electrosurgery unit.

1.6 **Function** analysis

of ESU system

A function analysis has been developed to create a better understanding of the ESU's sub-functions, parts, and their inter-relations. The function diagram will be used to identify the main internal components that are needed to provide safe electrosurgery. Several assumptions have been made by analysing functions and components of two competitive products: Valleylab Force FX and RDE 100 (see appendix A).

Power supply

Prior to usage, power supply is needed, so the high frequency generator is connected to grid power (240 V or 50 Hz, alternating current) by using a power cable and power connector. In some situations an separate cable is connected to the a fuse connection in the surgery room, since sockets in the Sub Sahara are not always grounded. From the cable the power is transferred to a battery and a power transformer. The battery is used to catch grid fluctuations. A power transformer is used to transform grid power to a lower voltage which ensures affordability and safety for the internal electrical components.

The brain of the ESU system

All electrical components are in connection with the brain of the ESU; the main micro controller. The main controller regulates all the input and output and translates this into signals to other components.

Interaction feedback

To provide appropriate feedback to the user multiple components are included. The serial ports function as a connection of the accessories of the ESU to the high frequency generator, including a return electrode plate port, monopolar handheld port, bipolar handheld port and a pedal port.

The user interface of the ESU consists of a keyboard that provides the opportunity to change output power settings and create the desired vaporization or coagulation. On the display this change in power can be broadcasted to the users.

Electrosurgery output

To provide electrosurgery a high frequency waveform has to be achieved. An output waveform module (PWM) is used to control the desired waveform output: cut mode or coag mode. This signal is transferred to the amplifier to increase the frequency to approx. 400 KHz (desired frequency is being studied by 3ME on clinical effect on human tissue).

This signal is transferred to the handheld, which can be used monopolar and bipolar. In case of monopolar usage, the desired waveform output signal can be controlled on the control panel on the handheld which is button activated. When activating the monopolar handheld the desired waveform signal is transferred to the electrode tip and the main controller activates the speaker that has two frequency tones to differentiate the waveform choice (coagulation mode has higher tone than cut mode). It is standardized in all ESU equipment to provide this audio feedback.

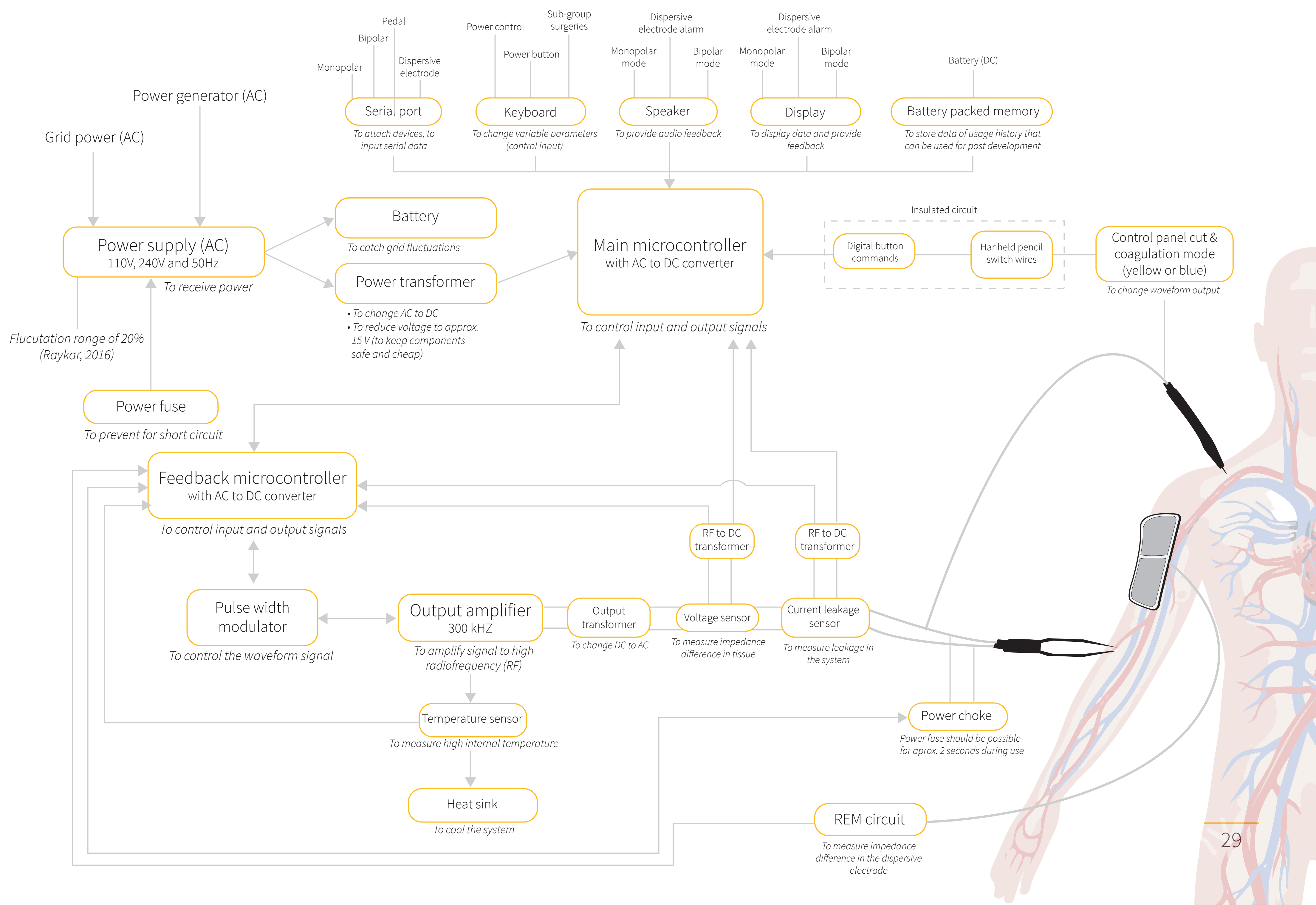
Heat reduction

As the ESU is activated, voltage and current flow through the electrical components. As result of resistance the temperature of the electrical components increases, which is even of greater chance in the high ambient temperature in Sub-Saharan countries.

In terms of safety a heat sink and temperature sensor are used to inform the main micro controller in case the internal temperature exceeds limits. A heat sinks should be used instead of an electronic air fan, since an air fan might emerge clinical risks since unsterile air can blow from the machine to the sterile operation area.

Leakage

To prevent for current or voltage leakage the feedback micro controller will continuously check the output and - in case of voltage or current leakage - inform the main microcontroller that will activate the alarm. This alarm will be used as well when the return electrode plate does not measure a sufficient safe contact area with the tissue.



1.6 **Function** analysis
of ESU system

Since a power fuse frequently arises in Sub-Saharan countries a memory module is needed to reset the system to the last used power setting to reduce the unnecessary tissue damage as a consequence of repetitive pre-setting/testing the power output of the ESU. Hence, a small battery is needed to overcome the power fuse time.

The knowledge obtained concerning functions and components have been used to identify the needed external and internal measurements of the high frequency generator, which can be found in chapter 4.

Obsolete equipment in sub-Saharan Africa

2. Surgical **product development**
in LMICs

About one-third of the global disease burden is surgical, yet five billion people around the world do not have access to safe, timely, affordable surgery (Raykar, 2016). Some reasons for this shortage in medical equipment are a lack of funding, maintenance, training, educated procurement and infrastructure. Urgent and immediate attention is required to make safe, affordable and timely surgical care global available to the billions currently without and consequently this will significantly reduce the number of disability adjust life years (Raykar, 2016) (Ng-Kamstra, 2016).

In the last decades the global focus has been on diagnostic diseases such as Aids and Malaria, however, the sum of lives lost as a consequence of bad surgical conditions is almost five times higher (Westra, 2016). In 2015, surgical conditions accounted for 11 % of the global burden of diseases. Certainly, trauma could soon overtake infectious diseases as the major cause of death in Sub-Saharan countries. In LMICs, surgical services are almost exclusively situated in major cities and only available to those who can afford to pay for the surgery. The poor who live in rural areas can rarely afford to travel, let alone pay for surgical care (Gnanaraj, 2015).

Technology plays a central role in the delivery of modern surgical care, but designing for the global world market presents unique challenges not seen elsewhere (Gnanaraj, 2015). The clearest evidence of these challenges are the current problems with implementing medical devices; the WHO estimates that 70% of medical devices designed for use in the developed world, do not work when they reach the developing world (Malkin, 2006). Accordingly, most of the essential basic surgery equipment is not accessible in most LMICs hospitals according to Dr. Pankaj Jani, president of COSECSA.

There are four salient issues with respect to optimal use of surgical equipment in LMICs: problematic equipment donations, a mismatch between government and NGO purchase requirements and context of use, the challenge of consumables, and the challenge of long-term maintenance (Ng-Kamstra, 2016). Surgical equipment is usually designed to operate in a relatively constant environment, with stable, controlled temperatures and humidity, dust and insect free conditions, uninterrupted electrical supply and unlimited medical consumables. This ideal environment also includes expert users with knowledge on correct usage of these products, advanced technical support and stack equipment capacity. Change these basic fundamental conditions, for example as in LMICs, and the design process does not need modification – it needs to be turned upside down (Neighbour, 2012).

LMICs do not just require equipment as good as that used in developed countries, they require something better, in that it not only needs to function safely for both patient and user, it needs to function in the challenging environments frequently found in developed countries, and all of this in a sustainable manner (Neighbour, 2012).

Hence, this also applies for development of the electrosurgery unit. As mentioned before, the main advantages of electrosurgery for LMIC settings is that it is widely applicable, helps to stop and prevent bleeding, allows for precise cutting, facilitates better wound healing in less hygienic environments and has a valuable contribution to time efficient execution of surgical procedures. However, to create a sustainable implementation of the new design a tailored fit solution should be created which involves extensive consultation with end-users throughout the design process.

Hence, together with the target group a better understanding should be created about the problems and needs in regards of electrosurgery, the variety in experience levels with the ESU, the use context and problems during the use phase prior, during and after the surgery. This knowledge will be used as design input and requirements for the design phase. In the following chapters, the qualitative knowledge gained by the interviews in the Netherlands as well as Kenya is integrated to create theory on ESU usage in LMICs (see appendix G and H).

2.1 **Healthcare providers**
in LMICs

In LMICs surgical care is often provided by a combination of public, mission and private providers, where the public healthcare sector is roughly subdivided in health canters, district and referral hospitals (Oosting, 2018). Within this section, Kenya will be used as a case study to explain the healthcare providers and their differences.

According to the Kenya Health Policy 2014-2030, a document issued by the government of Kenya in 2014, health services are provided in over 4700 facilities across Kenya. Approximately, half of them are public hospitals and the other half includes private (for-profit), mission or NGO hospitals. Private, mission and NGO hospitals strive independent of the government but have to follow national guidelines in terms of equipment procurement and regulations (Oosting, 2018).

The public healthcare system of Kenya can be divided in 6 levels, see figure 11. These hospitals include mission hospitals, district hospitals and university hospitals. The differences in levels can be found in the services that are provided in the hospitals and consequently this involves the level of healthcare knowledge within the hospital. The surgical healthcare providers differ in regards of financial, geographic and cultural barriers. Rural healthcare providers (generally level 4) experience a lack of trained staff, insufficient infrastructure, equipment, consumables and supplies. Urban providers (generally level 4-6) face overcrowding, exacerbated by minimal clinical and administrative support, and limited inter hospital care coordination (Raykar, 2016). Generally, the rural healthcare providers can be classified as district, mission and private hospital whereas the urban hospital are regularly (educational) public and private hospitals.

In order to be classified as a level 6 hospital, the hospital should not only provide sophisticated services but also operate as an educational facility. Additionally, within level 6 there are two classes; level 6A and level 6B what indicates the variety of sophisticated services a hospital provides. A high number of various sophisticated services will shift a level 6B hospital to a level 6A hospital.

Level	Type	Goal
1	Community	First line contact: provision of preventive healthcare services
2	Dispensaries	First line contact: provision of preventive healthcare services
3	Health centers	Ambulatory health services adapter to local needs
4	Primary referral facilities	Delivery of health services, plans and buget by county government
5	Secondary referral facilities	Referral hospital for level 1-4 provision of specialized care, plans and buget by county government
6 A-B	Tertiary referral facilities	Apex of the healthcare system providing sophisticated services , plans and buget by county government
Private or for profit	Healthcare systems & hospitals	Independent of the government, have to follow nation guidelines

Figure 11: *various levels of healthcare providers in Kenya*

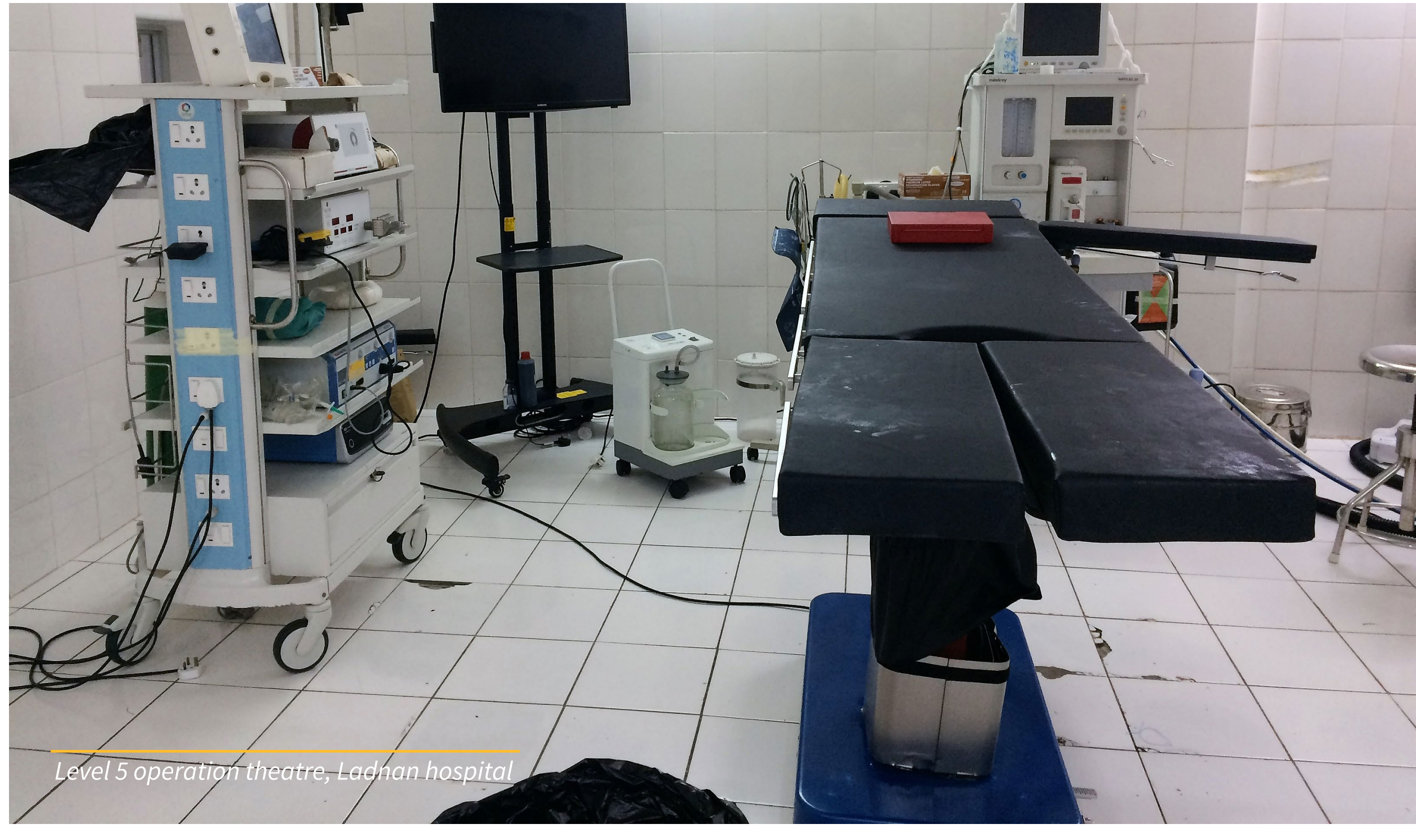
The two level 6A hospitals are the Kenyatta National Hospital in Nairobi and the Moi Referral and Teaching Hospital in Eldoret. Equivalent private referral hospitals are the Nairobi Hospital and Aga Khan Hospital in Nairobi.

In respect of electrosurgery differences among the healthcare providers can be found in variety of surgical treatments and the knowledge level/surgical experience of the surgerical staff. For instance, level 5 and 6 hospitals provide sophisticated services aside from general services, in regard of electrosurgery this means that specialist surgery is provided by a specialist surgeon whereas in a level 4 hospitals this is solely general surgery provided by a general surgeon or medical officer, according to the interviewees (see appendix G and H).

Accordingly, as general surgeon there is no such thing as a routine surgery, which means extensive knowledge in regards of the required power setting for the wide spectrum of surgeries should be present, as stated by Dr. Wanjeri.

Furthermore, different levels of healthcare providers results in differences in the executed surgical procedures. The electrosurgical procedures for sophisticated surgery – as provided in some of the hospitals in Nairobi – include open surgery (monopolar and bipolar) and laparoscopic surgery. Hence, there is more variety in required waveform modes and electrode tips of the ESU system. Whereas in level 4 district hospitals the surgery is in 95% of the cases monopolar open surgery, according to the majority of the interviewed Kenyan surgeons.

Within this project the focus will be on the healthcare providers from level 4 on, since these facilities provide surgical care in which the accessibility of the ESU is be essential. The goal of the project is to empower basic surgery for low resource hospitals because here the biggest impact on global surgical care can be established, according to the president of COSECSA. Hence, the focus should be on monopolar basic electrosurgery.


Level 5 operation theatre, Ladnan hospital

2.2 **Operation theatre**
in LMICs

The use environment of the ESU is composed by the users and the surgical tools within the operation theatre. Within this project the focus will be on the operators performing the surgery and the operation room (OR) assistances that assist the operator in safe surgery execution. In the developed world, the operation theatre is composed by the surgeon, surgical assistance (1 or 2), runner(1 or 2) and the anaesthetist. For an example of the theatre personnel and equipment, see figure 12.

The surgical team
The surgeon is the leader of the surgery and responsible for the clinical outcome of the surgery. He or she is the main user of the ESU and other surgical tools. The surgeon provides working orders to the team all along the surgery. The surgical assistance(s) prepares the needed equipment for the surgery according to the briefing with the surgical staff prior to the surgery. The surgical assistance is located in the surgical area and provides the surgeon with the needed surgical tools such as the scalpel or monopolar handheld and partly performs surgery.

The circulation assistance(s), also known as the runner(s), is located in the "unsterile" area in the theatre and assists the surgeon and surgical assistance with additional sterilized medical equipment, monitored information of the patient and power adjustments on

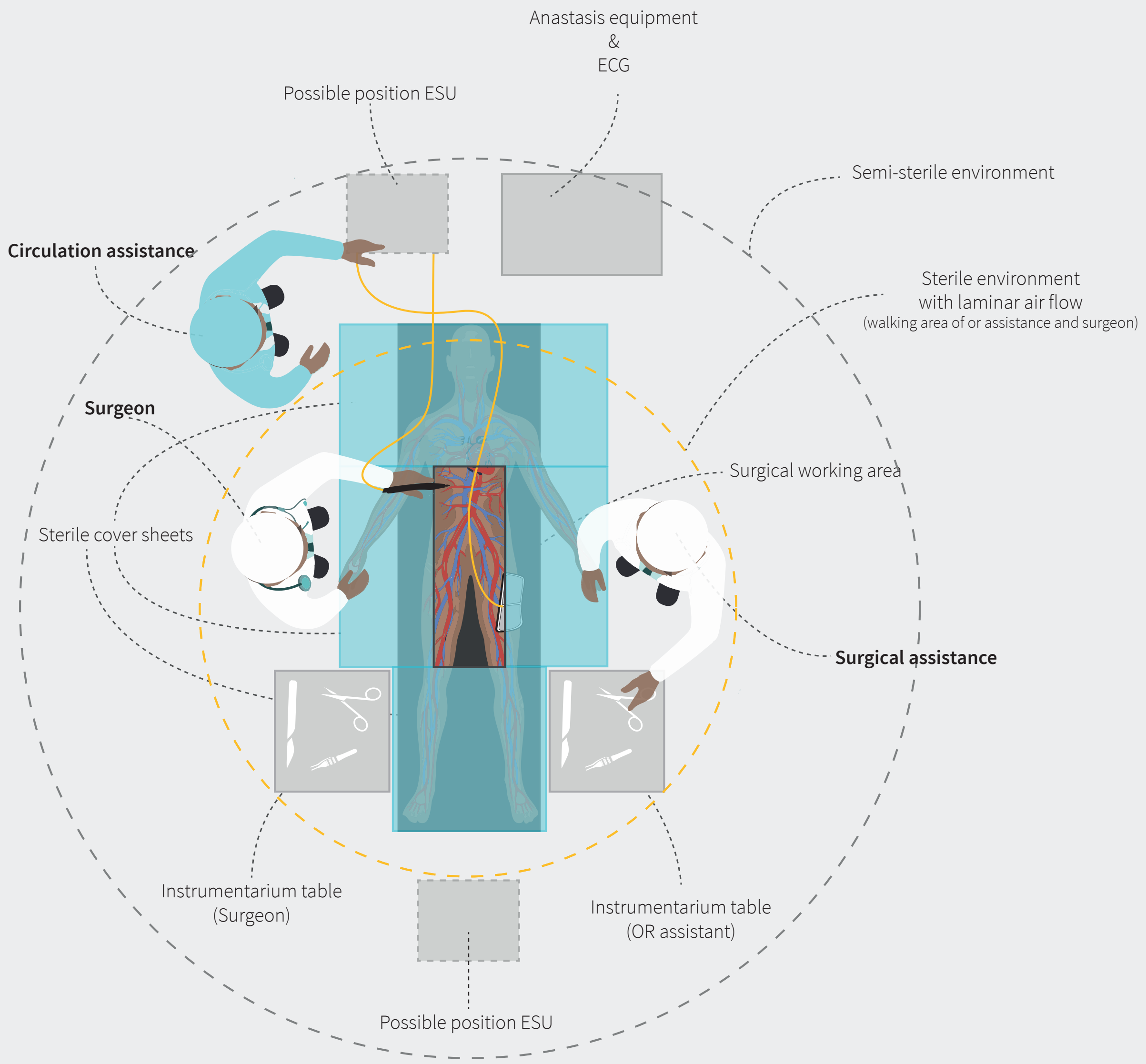


Figure 12: *overview of operation theatre in LMICs*

the ESU. The anaesthetist arrives prior to the surgery to anesthetize the patient with the appropriate anaesthetic, checks whether the anaesthetic equipment performs properly and awakens the patient after surgery.

Ideally this would be the staffing and task division during each surgery. However, one of the main problems encountered in LMIC is the shortage of qualified personnel. Besides, when qualified staff are competent, they are often lost to 'brain drain'. Brain drain refers to educated workers emigrating from their developing world nations (Malkin, 2007). This shortage of skilled medical professionals in many LMICs results in less qualified personnel operating surgical equipment and less surgical assistances during the surgery (Neighbour, 2016).

Task shifting
An approach to remedy this is also known as task shifting or task sharing (WHO, 2018). To deal with the shortage of surgeons, non-doctors are trained to perform general surgeries without supervision of a surgeon. The partnership between the Royal College of Surgeons of Ireland (RCSI) and the College of Surgeons of East, Central, and Southern Africa (COSECSA), for example, has led to the implementation of basic surgical skills courses with a train-the-trainer approach, an online surgical curriculum designed to meet the needs of COSECSA trainees, and a training programme for COSECSA surgeon–scientists (Ng-Kamstra, 2016).

The particulars of this training and whom is deemed qualified to fulfil such a position is different for each country (Westra, 2016). These health workers that are specifically trained to diagnose and treat certain surgical conditions are referred to as:

- Clinical Officers
- Associate clinicians
- Non-physician clinicians
- Mid-level providers
- Assistant medical officers
- Medical assistants

Most staff is trained on the job, given the absence of training programmes that prepare trainees for the broad spectrum of general surgery can take on significant risk to care for their patients, sometimes jeopardising their own safety (Raykar, 2016).

Furthermore, the lack of qualified personnel often leads to heavy workloads. For instance, the runner will have to monitor whether the anaesthetic equipment performs properly and simultaneously provide the surgeon with additional equipment and changes in the power setting of the electrosurgery unit. Consequently, tasks execution will take longer, resulting in a longer surgery, increased blood loss and increased stress for the surgeon, according to the surgical staff of the Kiambu District hospital.

The surgical theatre in LMICs
To perform basic surgery the theatre should be equipped with an operation table, operation light, electrosurgery unit, suction machine and anaesthetic equipment. However, in most theatres parts of the equipment do not always function properly according to the majority of the interviewed Kenyan surgeons. The ESU is mostly positioned at the ends of the bed on a table or chair next to the anaesthetic equipment and ECG, all connected to the ground grid sockets.

The patient is covered with operation sheets, which unfortunately, are not always sterile (semi-sterile). After the sheets being sterilized in the washing machine they will be dry hanged outside of the hospital as consequence of the lack of equipment, according to Dr Hubach. In the "sterile" operation area, within reach of hand of the surgeon and surgical assistance,

2.2 **Operation theatre**
in LMICs

the instrumentation table can be found. The table is equipped with all sorts of surgical tools such as a scalpel, surgical scissor and tweezer. The return electrode is positioned on the patient body in eye sight of the surgical team and in close proximity of the surgical working area. The handheld is used within the surgical working area and the electronic wire is located on the operation sheets.

Preferably, there is always a backup sterilized monopolar handheld in case of breakage of the handheld during the surgery or when falling on the floor. Unfortunately, as result of low resources, this is not always possible resulting in fast sterilization solutions with cleaning detergents such as CIDEX, Steranios or Chlorine. Consequently, there is a container with cleaning detergent available in the theatre. A more broad explanation of this cleaning procedure and differences in healthcare facilities will be discussed in the following chapter.

2.3 **Surgical procedures**
in LMICs

Whereas in the Netherlands most surgeons are specialists within their field of surgery (e.g. neurosurgery), surgeons in Sub-Saharan countries are mostly general surgeons, which means a routine surgery does not exist. Accordingly, a more broad spectrum of knowledge on tailored power settings related to a certain surgery is essential.

As mentioned before the shortage of skilled medical professionals and the unknown theory of electrosurgery power settings results in less qualified personnel operating surgical equipment and less surgical assistances during the surgery (Neighbour, 2016). Hence, it is important to understand what the basic surgical procedures are, what their theoretical needed power settings are and how frequently they arise in LMICs.

15 essential surgeries
In consultation with Roos Oosting the focus of the project has been on providing the accessibility for general surgery particularly focussed on the 15 essential surgeries stated by the World Health Organization (WHO), see figure 13. According to Botman et all, essential care is defined as 'Basic surgical procedures that save lives and prevent permanent disability or life-threatening complications. Such surgery should be of appropriate quality and safety, accessible at all times and affordable to the community'.

Conditions	**Interventions**
Obstructed labour	Caesarean section, Symphysiotomy, assisted or manipulative delivery
Severe uterine bleeding	Evacuation of retained products of the placenta, B-lynch suture, repair of uterine perforation
Surgical infections	Incision and drainage of abscess, fasciotomy, dental extraction, tympanotomy, bone drilling, arthotomy
Severe wounds (including burns)	Debridement, hemostasis, suturing, escharotomy, skin grafting
Severe head injury	Management of head injury, cranial burr holes, elevation of depressed skull fracture
Airway obstruction	Management of compromised airway, tracheostomy, cricothyroidotomy, removal of foreign body
Chest injury and infections	Intercostal drainage, thoracostomy
Acute Abdomen	Emergency laparotomy including appendicectomy
Fractures and dislocations	Reduction of fractures and dislocations casting and splinting, external fixation
Severe limb ischemia, sepsis and injury	Amputations
Urinary outflow obstruction	Suprapubic catheterizaion
Hernia	Hernia repair
Cataract	Cataract extraction and intra-ocular lens insertion
Club foot	Casting and splinting, tenotomy
Simple cleft lip	Cleft lip repair

Figure 13: 15 essential surgeries (WHO, 2018)

The most common surgeries found in LMICs are trauma surgery (e.g. traffic accidents) and surgical care in the abdomen such as a caesarean section, according to the interviewees. African surgeon prepares the patient for a caesarean section (source: Capacare).

2.3 **Surgical procedures**
in LMICs

The 15 essential surgeries basic interventions can provide coverage for approximately 80 percent of the most basic surgical needs of a community; particularly in rural and low-resource areas where doctors and equipment are scarce (WHO, 2018). According to all interviewed surgeons, 95 percent of all these surgeries can be covered by using monopolar surgery with waveform functions cut and coagulation. Besides, a spatula electrosurgery instrument will be sufficient in executing these surgical procedures.

These interventions can be provided general surgeons (various levels of experience) or by non-physician providers and medical officers who receive specific and narrow training in targeted surgical procedures (WHO, 2018). In general, for none of these essential surgeries usage of the electrosurgery unit is mandatory. However, it provides an increase of clinical outcomes and time efficient execution of surgical procedures, according to all interviewed surgeons. Something of major influence knowing that approximately two-thirds of all surgical patients will get infections', according to a rural surgeon in sub-Saharan Africa (Raykar, 2015).

Power setting guidelines
As mentioned before, in general, for most provided basic surgical procedures in LMICs the knowledge of the operator on power settings related to a certain surgery is unknown. Around 80% of the interviewed Kenyan surgeons admitted to not know most of the basic electrosurgical theory in terms of appropriate power settings related to a certain surgery. The majority of the surgeons follow the use settings taught by a visiting doctor or former supervisor who is again mostly a specialist surgeon that performs routine surgeries and likewise did not receive the power setting theory on the broad spectrum of surgery, according to Professor Dr. Moses Obimbo. Consequently, the majority of surgeons surgeons are qualified to use the ESU but not competent on how to use the ESU in an appropriate way, which can be dangerous for both patient and operator (Wiggers, 2018).

Accordingly, the ESU should not only be capable of performing electrosurgery but should empower the knowledge of the operator by providing power setting guidelines. The effect of these guidelines should be an increased feeling of confidence for the operator and an increased safety for the patient and operator throughout the surgery.

The surgical effect of the ESU is influenced by a number of factors, which makes it impractical to create exact tailored guidelines of power settings for a certain surgery (Malcolm, 2012). However, despite the variety in influencing factors, the appropriate power settings for a certain surgery can always be found within a specific bandwidth, according to the all interviewees. Hence, in consultation with the interviewees in the Netherlands and Kenya (for interviews see appendix G and H) a list could be created with the most common surgical procedures in LMICs and the approximate needed power settings, see figure 14.

Besides, to perform these most common surgeries cut mode and coagulation mode are more than sufficient and blend modes (e.g. mix of 50% cut waveform and 50% coagulation waveform) are solely used in sophisticated surgery and mostly ineffective according to the majority of Kenyan surgeons. The surgical procedures have been subdivided in three sub-groups related to the depth of the surgery and the sensitivity of the surrounding organs and tissue, which are the used criteria's of the Kenyan surgeons as recently researched with Kenyan surgeons in an unpublished study by Roos Oosting.

Some of the surgeries can be found in multiple groups as a result of infants surgery (sensitive tissue) or surgeries with a high possibility of blood loss such as an amputation (vasectomies) where a high power is mandatory. Thus, a macro surgery group with higher power settings is needed in the more rare situations of the 15 essential surgery but is mandatory in performing safe surgery, according to surgeon Erik Hansen.

2.3 **Surgical procedures**
in LMICs

By means of these power setting guidelines, theory will be provided to the operator of the ESU and consequently this will improve safety for patient and user, improve clinical surgical outcomes and increase confidence of the operator on correct usage of the ESU. These guidelines will be integrated in the interface of the high frequency generator which will be explained in chapter 4.1.

** can be found in more sub-groups as a result of infants surgery or the possibility of high blood loss*

Figure 14: guidelines of power settings

2.4 **Use journey** of ESU

in LMICs

A use journey of the ESU prior, during and after the surgery could be created by means of extensive co-creation sessions with the electrosurgery users in the Netherlands and Kenya (see appendix G and H). This surgery journey has been created to increase understanding on the handlings and interaction in between the surgical team and with the ESU throughout a surgical procedure in LMICs, and how this affects future design decisions. Additionally, to create a better understanding on what feedback interaction of the ESU is required for a trustworthy, intuitive and safe surgery execution.

The surgery journey will be explained within each phase of usage (prior, during and after). Besides, another surgery journey has been created with more extensive explanation on a surgery treatment in LMICs not only focussing on the ESU including other used equipment and task divisions, see appendix B.

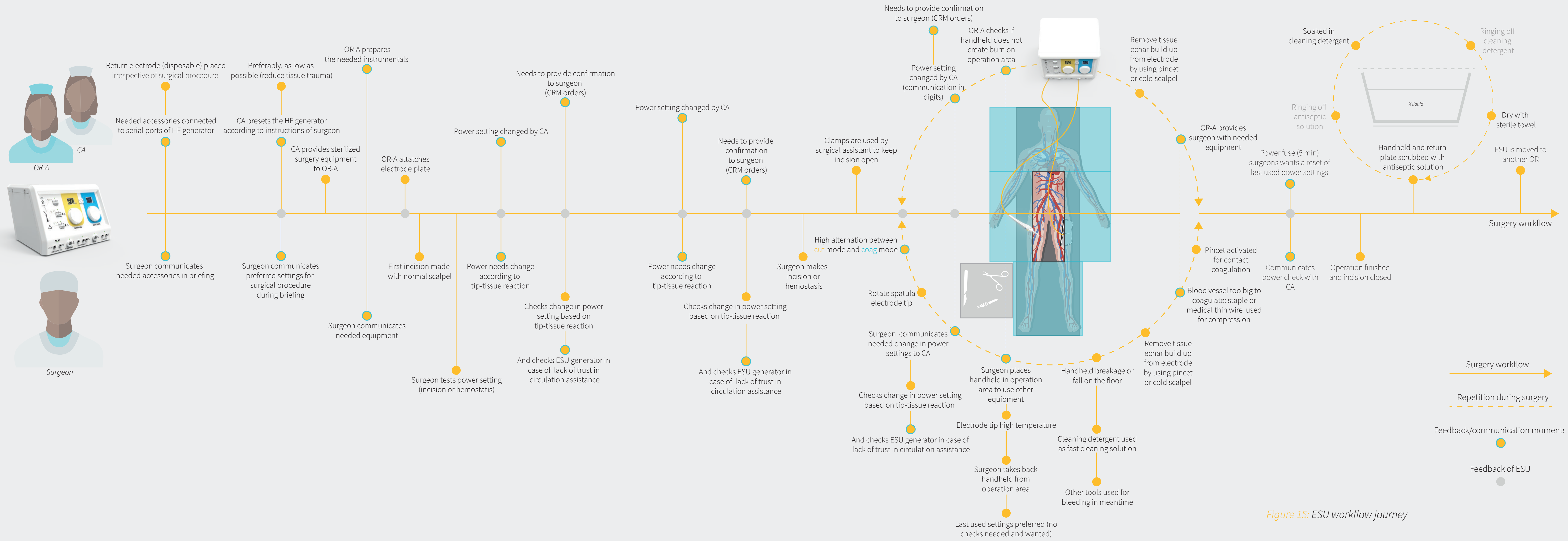


Figure 15: ESU workflow journey

2.4 **Use journey** of ESU

in LMICs

Prior to the surgery

The first part of the preparation phase of the surgery involves a briefing with the surgical team wherein the patient information, surgical procedure and the to use surgical equipment are discussed. Since the operation theatre is a sterile environment the surgeon and assistances have to dress prior to entering. The surgery team is clothed with an operation jacket, operation pants, (disposable) hat, mouth cap, (disposable) rubber gloves and boots, all cleaned sterile before entering to maintain sterility in the operation theatre. The circulation and surgical assistance prepare the operation theatre and medical equipment according to the information of the surgeon during the briefing session (e.g. monopolar handheld, electrode tips, medical scissor, tweezers, etc.).

In case electrosurgery will be used the high frequency generator is often transported from another theatre because frequently not all operation theatres incorporate an ESU. Hence, it is important that the high frequency generator is movable, thus includes for instance a hand grip, is lightweight and has no protruding elements, as stated by the majority of the interviewed surgeons. Out of experience almost all protruding elements of surgical equipment break after a period of time, according to biomedical engineering technicians of the Kenyatta hospital. In most well equipped theatres the ESU is stationed on a cart or inside the laparoscopic tower.

Nonetheless in most rural low resource hospitals the ESU is stationed in any possible position in the theatre such as a table, chair or even a window counter.

The patient is prepared for the surgery by shaving and cleaning the surgical area with disinfectant (e.g. betadine). The monopolar handheld and return electrode are connected to the ESU by the circulation assistant and handed over the surgical assistance. The surgical assistant prepares the monopolar handheld by connecting the needed electrode tip. The spatula electrode tip (explained in chapter 1.4) is sufficient for all basic surgeries in LMICs because of its variety of application, according to all interviewed surgeons. The return electrode plate is positioned in close proximity to the surgical area and the monopolar handheld is placed on the surgical sheets.

Surgery with the ESU

In most cases, the superficial tissue layers are firstly cut by using the cold scalpel since thermal spread of the electrode tip can permanently destroy these sensitive tissue layers. Hereupon clamps are used to open up the incision to enhance visibility. Next the electrosurgery equipment is used to make a first cut or coagulation. Prior to electro tip-tissue contact the surgeon communicates the needed power settings – based on practical experience – to the circulation assistance. Out of experience of multiple surgeons in Kenya, these power settings are often higher than required for a certain surgery. Most surgical equipment is not well maintained or not resistant against corrosion (e.g. connection adapter of electrode tip in monopolar handheld) and this requires an increase of power to attain the needed output, according to the surgeons of the Kiambu District hospital.

Set the power

As a consequence of responsibility of the surgeon, the power setting communicated with the circulation assistance is first checked on the interface of the high frequency generator prior to electrode tip-tissue contact. Thus, this requires excellent visibility from a distance of at least 2 meters and in a variety of angles (CRM orders are used by the team).

Hereupon the surgeon checks the appropriateness of the power setting by the electrode tip-tissue reaction. Usually the power setting needs some changes after this first check or during the surgery by changing either the cut mode or coagulation mode (5-10% of maximum power) and consequently these two modes need a separate adjustment. The more adjustments needed, the more unintended tissue damage as a consequence of trying, so this should be limited, according to all interviewees.

In case additional equipment is needed, the surgeon is dressed by the circulation assistant to maintain sterility (source: Capacare)

2.4 **Use journey** of ESU
in LMICs

Use of monopolar handheld
During the surgery there is a high alternation between the cut mode and coagulation mode. In case the pedal is used to activate both modes the surgeon has to use his feet and activate the correct pedal. The pedal is regularly located underneath the operation bed which requires a check, underneath the sterile sheets, to secure correct activation. Hence, it is preferred by all surgeons to alternate between these two modes by using a control panel on the monopolar handheld and retain vision on the surgical area. Furthermore, the pedal is an unsterile object in close proximity to the sterile area which is undesired.

The monopolar handheld is preferably used as a pencil to enhance precision and the buttons are activated by the index finger or thumb. In case the to cut or coagulate tissue is in a difficult angle the hand of the surgeon or the electrode tip is rotated. Not all electrode tips serve for rotation since there is no insulation material around the electrode tip. Thus, the possibility of rotating the electrode tip will increase ergonomics and control, according to the majority of the Kenyan surgeons.

A surgery introduces a lot of blood and saline and consequently the rubber gloves of the operator get wet. Accordingly, the monopolar handheld gets slippery resulting in a cutback of control and precision, and in frequent drying of the hands and surgical equipment with a sterile towel. Furthermore, this can lead to a stumble of the handheld onto the unsterile floor.

Preferably, there is always a backup handheld in case the handheld breaks or drops on the floor during the surgery. However, in most low resource hospitals this is not the case and consequently the monopolar handheld needs a fast sterilization solution. The used sterilization solutions are surgical alcohol (see appendix C) or a quick dip of the handheld in an antiseptic solution to take away blood stains and eschar build up prior to soaking the handheld into cleaning detergents such as chlorine, see image on page 53 of an example of the cleaning box in the operation theatre.

As mentioned before, monopolar surgery is most important in providing basic interventions. However, in some general surgeries it is beneficial to reduce thermal spread. Most times, the tweezers are used as bipolar electrodes by activating them with the electrode tip. The operator grasps tissue or a vessel between the tweezers and (button) activates the monopolar handheld that is in contact with the tweezers. Consequently, a sophisticated contact area on the electrode tip is essential (flat side of spatula electrode).

Other activities
Obviously, the ESU is not the only product used throughout a surgical treatment. To perform safe surgery various equipment is needed and consequently the monopolar handheld is often unused. In this case, the monopolar handheld is laid down in the surgical area. Logically, frequent activation heats up the electrode tip introducing cauterization risks (unintended tissue damage) with tissue in adjacent to the electrode tip, which is something to avoid in the future design.

When retracting the monopolar handheld after approximately five minutes of other surgical activities, the surgeon will always want to continue with the last used power settings since these settings have been pre-set and experienced to be appropriate for this patient/treatment.

Subsequently, the unstable grid power in LMICs can lead to a power fuse during the surgery. Therefore, the ESU should be equipped with a memory to reset the ESU to the last used power settings. Hence, unintended tissue damage by recurrently adjusting power will be prevented.

Wet rubber gloves during the use of the monopolar handheld
(source: Capacare)

Cleaning area in the Nazareth level 6 hopsital, Kiambu county

2.4 **Use journey** of ESU

in LMICs

After the surgery, the ESU high frequency generator is cleaned by using an antiseptic solution such as surgical alcohol or Dettol (methylated spirit) and in some cases moved to another operation theatre. The cleaning procedure of the accessories (e.g. monopolar handheld) in LMICs have variations as result of a lack of resources concerning machinery and cleaning detergents.

During the field trip in and around Nairobi an extensive study has been conducted on the cleaning procedures of the accessories within a variety of hospital levels. This knowledge is essential input for the design of the accessories in regards of reliability and materialization.

Steam autoclavation

In most high resource LMICs hospitals, electric steam autoclavation machines are available and used in a high frequency throughout the day. The electric steam autoclavation machine is reliable in terms of output parameters, so the temperature or pressure does not exceed limits after the pre-set (134 °C and 2 bar).

However, in most low resource hospitals a gas steam autoclavation machine is available, which means fire is used to heat up the autoclave. Hence, the output of these autoclaves are close to the required temperature but might exceed limits with around 5-10% of the initial temperature, according to surgical assistances of The Nazareth Hospital. Most monopolar handhelds are not reliable against the high temperatures of steam autoclavation, thus material degrades which can cause possible use risks. Furthermore, in most low resource hospitals the autoclave is not used on a frequent base but mostly used during the night, according to the majority of interviewed surgeons.

In case the monopolar handheld is autoclavable and largely available, three handheld per theatre are adequate. One handheld is used for the surgery, the second handheld is used as back up during the surgery and the third handheld is cleaned along the surgery to be used in the following surgery. When the autoclave is solely used ones a day (nigh time) approximately 7-10 handhelds will be sufficient to use an adequate number of monopolar handhelds throughout the day and clean them at the end of the day.

Cleaning detergents

Nonetheless, most used handhelds are disposable, so not resistant against steam autoclavation or in low availability. Consequently, re-sterilization of the handhelds is done by using cleaning detergents indicated as CIDEX (general used term for cleaning detergent in sub-Saharan countries). However, CIDEX is an expensive detergent and as a consequence of low resources a variety of detergents is used (see appendix C for used cleaning detergents). The strongest alkalis used can be found in the more rural areas where chlorine (PH 11) is used to sterilize surgical equipment.

Although the materials of the ESU accessories are not reliable against the aggressive alkalis it ensures re-usage of around 10 times, according to the interviewed Kenyan surgical staff. Accordingly, this is of high risk since frequent re-sterilization leads to insulation failure. As stated by E. Hansen, the handheld buttons often fail first but to enhance the life time of the handheld the pedal is used to activate the handheld until insulation failure. The cleaning procedure with cleaning detergent can be seen in figure 16.

2.4 **Use journey** of ESU

in LMICs

At first, the accessories are cleaned by using an antiseptic solution that is used to remove eschar build up and blood stains. Second, the handheld is ringed with distilled or (boiled) filtered tap water (mostly used because of costs and run out of distilled water). Third, the handheld is cleaned in an alkalis cleaning detergent to sterilize the medical equipment (see appendix C for variation of used cleaning detergents). The medical equipment has been ringed prior to this cleaning step to assure the cleaning detergent solution will remain sterile.

Fourth, the medical equipment is ringed in saline, distilled water or (boiled) filtered tap water to take away the cleaning detergent which fumes and liquid can be irritating for the operator as well as the patient. At last, the equipment is dry cleaned by using a sterile towel.

Indeed this should be the cleaning procedure but as a consequence of little time during the surgery step 2 and 5 are often skipped. Consequently, water will stay in and around the handheld which affects the output of the handheld since monopolar tools have trouble operating in a conductive (e.g., saline) medium, as this will alter the path of least resistance (van den Berg, 2012).

Subsequently, as long as the ESU accessories are resistant against steam autoclavation and the variety of cleaning detergents, three handheld per theatre will be sufficient for daily surgeries.

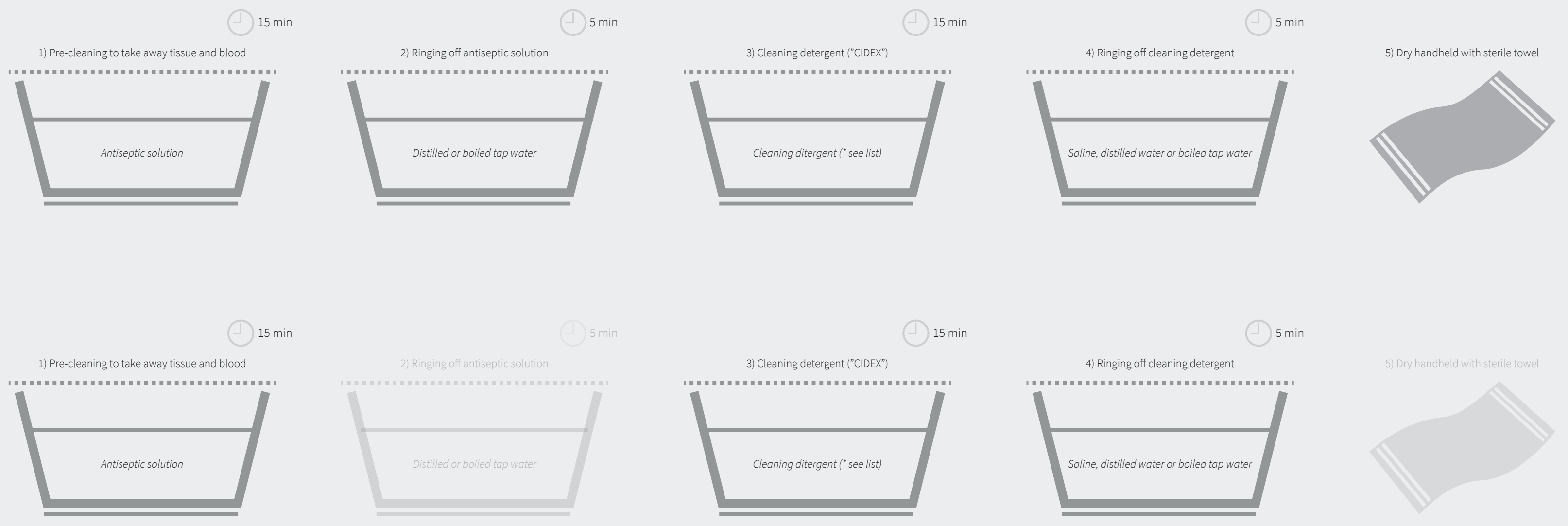


Figure 16: *sterililizing with cleaning detergent*

Cleaning box in the operation theatre, Ladnan hopsital

2.5 **Procurement**
in LMICs

An essential part of a successful implementation of the ESU system in LMICs are exposing possible procurement barriers. Currently there is a big gap in the availability of ESU systems which limits the provision of safe surgery. As could be seen in the previous chapter, the ESU system is currently functioning unsatisfactory and to prevent for implementation problems in the future of the design a better understanding of the procurement journey of medical (surgical) equipment in LMICs has been established. Increased knowledge on the procurement journey is part of a successful and sustainable strategy for the accessibility of the ESU as well as the accessories (monopolar handheld, return electrode, etc.)

Accordingly, the situation of Kenya is used as a case study to understand possible barriers to a functional ESU system in LMICs. This study aims to identify the different phases surgical equipment regularly goes through during its lifespan, the surgical equipment journey (see appendix F for use phase and disposal phase). Herein, the focus lies on the possible barriers during the procurement phase of the ESU as well as the accessories, see figure 17.

Identification of the surgical equipment journey revealed differences between public level 1-5 hospitals and level 6 or private hospitals in Kenya. The largest difference is the role of the 47 district counties in policies and budget allocation for surgical equipment. Public level 1-5 hospitals procure and dispose in consultation with the district county, whereas public level 6, private, mission, and NGO hospitals are an entity on its own (Oosting, 2018). Donated equipment is brought directly to all categories of hospitals, but for public hospitals (level 1-5) this can again be in consultation with the county government. Hence, the focus will lie on a better understanding of the surgical equipment journey for public level 1-5 hospitals.

In the beginning of the year a list with resources and consumables is created by the surgical team and discussed with the procurement officer or directly with the country government. In this list the required supplies have to be specified as explicit as possible (to prevent for wrong procurement), and a list with three possible competitive companies should be included. The county government prequalifies the companies according to the regulation of the Kenyan Bureau of Standards (follow ISO norms) and provides tenders to the companies that can supply the goods, according to Dr. Laktabai.

Procurement is often done regarding the lowest bid and based on initial procurement costs and consequently these costs should be as low as possible. Running costs and required maintenance of equipment are not included in the tendering process (Oosting, 2018). Hence, to increase sustainable procurement of surgical equipment, biomedical engineering technicians of the hospital should be consulted to define the specifications of equipment prior to procuring. In this way, the equipment will correspond to both the wishes of the surgical team as well as the technical team, whom are often excluded which results in piles of useless equipment when arriving or just after the first use months.

In case of goods that are low-cost such as the monopolar handheld (300 dollar or less) the hospital is allowed to directly procure from the prequalified company. Nonetheless, according to the law, the hospital has to initially identify and contact three qualified companies for quotations even if just a single company supplies the goods (Kenyan Bureau of Standards, 2018). Ones accepted the hospital is allowed to directly procure from this company and to bypass the tendering process. Hence, it is essential to become a qualified supplier by certifying the ESU system with the ISO norms. Besides, barriers in becoming a qualified company can be bypassed by collaborating with a qualified supplier in Kenya such as Harleys, according to Dr. Laktabai.

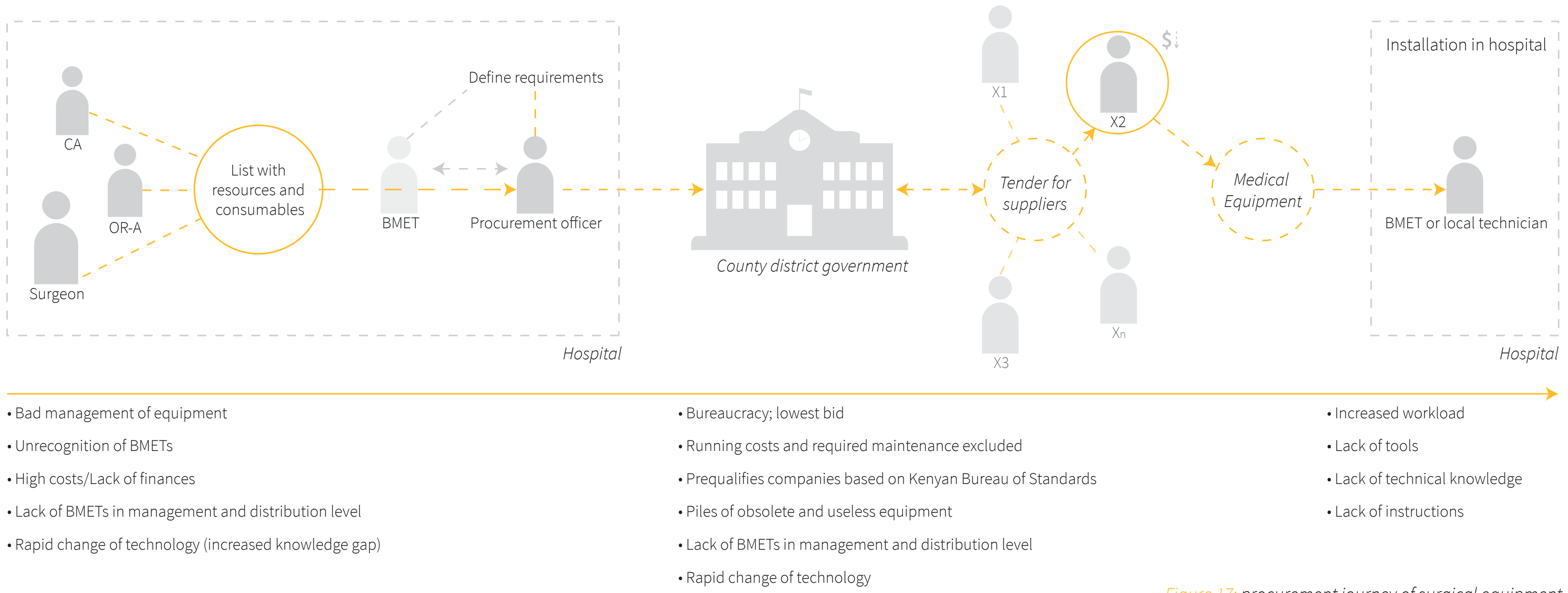


Figure 17: *procurement journey of surgical equipment*

2.6 **Barriers** of ESU
in LMICs

As explained in the user journey and context, the use of the ESU includes many barriers within the LMICs setting. In this chapter a summary will be provided about main barriers for implementation of surgical devices in LMICs, which will be used as design input and requirements for the design phase. The barriers within LMICs needs to be known to create a novel context appropriate development of the ESU system that decreases the availability and failures of the equipment.

A product system view of these barriers with the electrosurgery unit is summarized in an infographic that can be found in appendix D. This infographic shows the origin and focus of the problem and relations of problems within the ESU system.

Lack of knowledge in (Electro)surgery
Providers noted that contextually inappropriate policies extend to professional standards and guidelines, including training systems, which are often blindly adopted from high-income environments. Oftentimes, trainees are not taught a generalist skill set but instead follow specialty surgical skillset, irrelevant to the low-resource setting (Raykar, 2016). Apart from irrelevant theory, most teaching professor do not always adequately understand the theory behind electrosurgery, according to interviewed professors in Kenya.

Most surgical staff is trained on the job, given the absence of training programmes that prepare trainees for the broad spectrum of electrosurgery experience that low-resource providers can expect to encounter (Raykar, 2016). In example of Kenya, graduated surgeons are send to rural district hospital without supervision and with limited surgical experience, let alone experience with electrosurgery. Or under supervision of a specialist foreign surgeon that provides supervision according to his routine surgery experience.

As prior stated, the shortage of skilled medical professionals in many LMICs results in less qualified personnel operating surgical equipment and less surgical assistances during the surgery (Neighbour, 2016). Consequently, on top of the lack of knowledge in electrosurgery of local surgeons, an increase of the knowledge gap will arise, which is something that should be incorporated in product development of the ESU by increasing intuitive and knowledge adaptable user interaction.

"According to the president of COSECSA the gap between medical technology from the developed countries and the developing countries is expanding, which will result in an even bigger knowledge gap between these two worlds (Jani, 2018)."

Consumables
One of the most common problem encountered during the field trip in Kenyan hospitals is the lack of consumables. Consumables are liquids or supplies required for when using medical equipment, but allowing only limited, or no, reuse (e.g. test strips, ECG electrodes, blood pressure transducers or rubber gloves) (Malkin, 2006). In general, these consumables are components that are intended to be discarded after every use, which in a developed context might even include surgical instruments and sensor probes (Ng-Kamstra, 2016). For the ESU system these consumables are the electrode tip, monopolar handheld (incl. cables) and return electrode (incl. cables).

The unattainability of consumables leads to improvisation extends where single-use materials are frequently re-sterilised for repeated use (Raykar, 2016). This forms a potential danger for the user and the patient since parts may no longer function as intended. In general, the ESU accessories are not resistant against the cleaning procedures used in the LMIC settings (no watertight design, low melting point and material degradation because of used alkalis detergent). However, a lack of resources makes it impossible for healthcare facilities to change their cleaning procedures. Accordingly, design for reuse of consumables will, by necessity, be the norm for many years to come (Neighbour, 2012).

Consumables needed to perform surgery
(source: Capacare)

2.6 **Barriers** of ESU

in LMICs

Spare parts
Any device designed for the developing world will be likely to stop working as soon as the first replacement part is required. For instance, if a filter that is required to evacuate the electrosurgical smoke needs to be replaced every 6 months, then the device will likely only last for 6 months when placed in a developing world hospital (Malkin 2016).

Since most equipment used in these settings is manufactured in the high-income environment, and it is either purchased by or donated to hospitals in these settings, the ability to service equipment locally is a core challenge (Raykar, 2016). This can be because of locally unavailable spare parts in the developing world, because the manufacturer no longer produces spare parts for that particular device, or the spare part may require a credit card to purchase (almost all people own mobile payment, few people own a credit card).

Besides, the cost for the spare parts might be prohibitive or the hospital might lack the expertise or tools required to execute the repair. Most hospitals do not have a technician with more than a high school education (Malkin, 2016). Accordingly, the newly developed ESU should consists of general used spare parts that are locally available and can be separately replaced without replacing a full module.

Cleanability and sterilization
According to Maite Guardiola – a biomedical engineering technician working with infection control at MSF in and around Kenya – there is inadequate post-treatment of the surgical devices which negatively affects the quality of infection control. Most surgical equipment is designed to be disposable or resistant against the regulative cleaning procedures of an autoclave. However, as prior stated in most LMICs hospitals an autoclave is or not available or solely used ones a day as a consequence of costs, according to the interviewees.

Besides, most surgical equipment designed for the developing world consists of disposable consumables that are designed for single use and consequently cannot be sterilized by using the autoclave. Thus, this leads to improvised cleaning procedures as temporary solutions to sterilize for instance the monopolar handheld of the ESU, according to E. Hansen, surgeon of Kijabe mission hospital. Accordingly, a reusable monopolar handheld that is resistant against the harsh cleaning procedures is mandatory for a sustainable success of the ESU system, according to the president of COSECSA.

Cultural barriers
Cultural barriers include a family role in decision making that is influenced by adverse attitudes and beliefs about available care (Grimes, 2001). Many of the barriers are more pertinent, although not restricted to surgical disciplines. They include fear of undergoing surgery, fear of having an anaesthetic, and fear of bad outcomes as a result of surgery (Raykar, 2016).In many cultures, family and social support networks play an important role in health care decisions. Family and social support networks are needed to raise funds for surgery and other costs associated with the inpatient stay, cover household responsibilities during the absence, and provide an escort (Raykar, 2016).

Politics
As prior stated in the procurement journey the government can affect a sustainable implementation of the ESU system. A lack of proper device management both at government level and within healthcare facilities is one of the barriers for optimal use of the ESU system. In case of Kenya, the government influences the ESU system in regulations of procurement by following the norms of the Kenyan Bureau of Standards.

Accordingly, the ESU system should follow and update these norms to prevent for possible barriers while implementing the developed system. When upscaling the project to the sub-Saharan countries it will be of great importance to follow the international norms of medical product development (e.g. Medical Design Directive, ISO). Something that should be researched extensively in the future development phase.

"In some cultures, childbirth is seen as a natural event, and a difficult birth carries the stigma of the woman having a defective body or is thought to be the result of infidelity or an extramarital affair. (Raykar, 2016)" (source: Capacare)

An impression of the workplace to maintain surgical equipment in the Kiambu District hospital where solely basic tools such as screwdrivers are available

2.6 **Barriers** of ESU

in LMICs

Infrastructure

Another barrier stated by all interviewees that have worked or still work in LMICs are the many shortcomings in and around the operation theatre. In many hospitals the lack of reliable and continuous power, running water, blood banks, oxygen supply, an area for emergency care and supplies needed for postoperative care are not available (Westra, 2016). The lack of a steady electricity network is particularly challenging for a functional ESU system.

A recent study of Alkire et all revealed that out of the 231 district hospitals assessed in 12 sub-Saharan countries only 81 (35%) of the hospitals possessed a steady electricity network. This data is comparable to the 31% of facilities without a reliable electricity network presented in the WHO SAT database research roughly 800 medical services in LMICs on the availability of a steady electricity network (Westra, 2016).

With a view to the ESU, most components break just after arrival since they are not resistant against these grid fluctuations. Furthermore, a different power output can arise in case the internal components are resistant against the fluctuations according to technicians of 3ME at the TU Delft. This can possibly negatively affect the clinical outcome of the surgery, reliability of the ESU system and consequently the ESU should include a voltage stabilization system. Hence, it is important for long-term growth, devices should be able to accommodate the present infrastructure (Ng-Kamstra, 2016).

Lack of technical knowledge

Current medical equipment often requires highly skilled technicians to operate and maintain them (Malkin, 2006). After hospitals adopt the donated ESU devices into practice, most times maintenance must be performed to ensure ongoing availability; in a study of over 110 000 pieces of biomedical equipment in LMICs, 40% was found to be non-functioning (Ng-Kamstra, 2016). However, the demand for technicians is often not present in the hospitals and the repair manuals and tools are frequently unavailable (Westra, 2016). Besides, most developing on donating companies do not provide service or the needed training for service in LMICs.

Most problems with equipment can be solved with a limited set of basic skills and a minimum of spare parts (Ng-Kamstra, 2016). Accordingly, for a successful future implementation the ESU system should be easy to maintain with a limited number of tools, include an intuitive user manual and include the spare parts that are most likely to fail after a period of time (e.g. power fuse). Moreover, include a specific training for the local technicians and BMETs to create understanding on failures and errors.

Financial barriers

Surgical providers in Kenya reported that poverty limits access to care most directly through hospital fees. They noted that their patients are frequently required to pay cash deposits or provide letters of guarantee of payment before providing treatment even in countries where universal health coverage systems exist (Eastern sub-Saharan Africa, South Asia, Western sub-Saharan Africa) (Ng-Kamstra, 2016).

Financial barriers to care included both direct and indirect costs. Direct costs are those directly related to care, such as surgical fees, anaesthetics, monopolar handheld supplies, transport, stay at hospital, etcetera. Indirect costs are the costs accumulated because of the sickness or absence of the patient. Indirect costs identified the loss of income/ wages and costs of bringing a caregiver (Grimes, 2011).

An affordable ESU system might positively influence the reduction of financial barriers. As prior stated, the ESU contributes to time efficient surgery execution, reduction of blood loss and better wound healing, which might decrease the direct and indirect costs of the surgery. However, the ESU system should include reusable accessories to reduce direct costs and include low maintenance.

3. **Design brief**

focus of the design

Desktop research and extensive co-creation with the end-user resulted in the foundation for the design phase and further development of the ESU. The ambition of the project will be discussed and the program requirements for safe, intuitive and reliable electrosurgery will be used as boundaries and an evaluation tool for the developed ESU.

Design goal

The goal of the project will be the development of a reliable, safe and intuitive user-interaction with the ESU system and a tailored design for maintenance in a variety of use-contexts in LMICs. The new design of the electrosurgery unit should be understandable for all electrosurgery users, thus surgeons with limited electrosurgery experience as well as specialists and surgical assistances. The ESU system should be affordable and therefore the design focus will be solely on essential functionalities for safe electrosurgery.

"The world of electrosurgery has many capabilities of power setting and waveform modes. However, nearly all of this is needed to perform basic surgery. The design approach should be compared with the functionalities of your Iphone. At maximum 15 percent of the functionalities is used. For a tailored and intuitive ESU system you should only focus on this essential 15 percent (Jani, 2018)."

The developed ESU system will be part of a product family that differs in the knowledge and experience of the operator with the ESU system and the required capabilities and complexity of the ESU system, see figure 18. The focus within this project will be on a trade-off for rural and low resource healthcare facilities since here substantial global impact can be achieved.

The feedback of the interface should be adaptive to the knowledge of the target group and provide the user with guidelines on the power setting theory. Consequently, this will improve safety for patient and user, improved clinical outcomes and increase confidence of the operator on correct usage of the ESU.

The design will be modular for all product families to enhance a sustainable implementation in the long term and cost reduction in the short term. Accordingly, the flexibility of the design mainly affects the differences highlighted in figure 18. The modularity of the system will have most influence on the internal components used in the high frequency generator.

The increase of capabilities, such as waveform modes and the required range of power settings for sophisticated surgery, leads to an increase of internal components and measurements and needed user feed-back information. The goal is to create a single design that creates flexible component change responding to these different needs, and is compatible to other used competitive accessories.

Scope

The development focus of the ESU system will be on rural and low-resource healthcare providers in the sub-Saharan countries that accommodate an operation theatre. The ESU system should fulfil the demand of the 15 essential surgeries stated by the World Health Organization and preferably beyond. Thus, focus on safe and reliable provision of monopolar electrosurgery with waveform modes cut and coagulation and by using the spatula electrosurgery instrument. The return electrode pad design is not included since this will be developed by another student of the faculty of 3ME.

Differences in product family	**Rural and low-resource**	**Urban**	**Specialists**
Surgical treatments	Basal surgery (15 essential surgeries)	General surgery (15-specialism)	General surgery (15-specialism) Laporascopic surgery
Surgical procedures	Monopolar and limited bipolar	Monopolar and bipolar	Mainly bipolar
Connected handhelds	Monopolar handheld Limited bipolar handheld	Monopolar handheld Bipolar handheld	**Simultaneous usage of monopolar handheld and bipolar handheld + Laporascopic device(s)**
Power settings	Limited 10-70 [W]	**Range of settings (5-100 [W]) Presettings based on preferences surgeon**	**Precise changes in power (5-120 [W]) Presettings based on preferences surgeon**
Waveforms	Coagulation and cut	**Coagulation, cut and blend cut**	**Coagulation, cut, blend cut and other**
Variety in electrode tips	1	**5 or more**	**> 10**
Knowledge level surgery	Graduated doctor or medicine students Medical officers with with surgery degree	**Experienced surgeons & Doctors with some year of experience in district hospitals**	**Specialized and experienced surgeons**
Knowledge level technical support	Employee with some feeling with technique	Local biomedical technician	Local biomedical technician
Type of hospitals	District hospitals Mission hospitals Public hospitals	Mission hospitals Public hospitals Private hospitals	Private hospitals University hospitals
Healtcare system level (i.e. Kenya)	4	4 and 5	6
Ambient atmosphere	High ambient temperature and humidity High presence of dust (windows open in OR)	Semi controlled environment (windows sometimes opened)	Controlled environment (humidity and temperature)
Infrastructure	Grid fluctuations Generator fluctuations Frequent power cuts	Grid fluctuations (semi-stable) Stable solar panel battery	Stable network
Safety and regulations in hospital	No clear structure or regulations in hospital	**Local medical standards**	**European/American standards**
Internal logistiscs	Small number of ORs Moves from OR to OR	Moves from OR to OR	Each OR has an ESU
Cleaning procedures	Steralization (ones a day) Chlorine	Steralization after each treatment Chlorine and Steranios	Steralization after eacht treatment or disposables CIDEX
Storage of accessories	No storage of sterilized cables and electrodes (accesoires)	Storage in ESU cart Sterile cabinets or drawers	**Laporascopic tower** Sterile cabinets or drawers
Service (preventive)	None	Limited to none	Limited
Procurement of devices	Government and municipality Donated medical equipment	Government and municipality Self-procurement by hospitals	Mainly self-procurement by hospital
Availability spare parts	None	Limited	Frequently

Figure 18: differences in needs and procedures of healthcare providers

3. **Design brief**

focus of the design

Program of requirements
Based on all the gained knowledge, a program of requirements has been formulated. These requirements will be used as an evaluation tool for the concepts and as a future tool in product development for developing countries. The complete program of requirement can be found in appendix E. The main requirements will be subdivided according to the product group of the ESU system and can be found in chapter 4. The main requirements that are generally applicable for the ESU system can be found below.

- The ESU includes an electrical high frequency electric generator, monopolar handheld and return electrode plate
- The ESU is capable of performing monopolar surgery
- The provided information by the ESU is compatible to the variety of electrosurgery experience in sub-Saharan countries
- The ESU should be able to provide the required power settings to assist the surgical staff with the 15 essential surgeries proposed by the WHO thus provide a power setting range of at least 10 Watt to 70 Watt
- Medical certified electronic components and software are used
- Durability and reliability of the ESU is more important than local repairability
- All parts of the ESU have a dielectric strength high enough to prevent for insulation breakage when performing electrosurgery at a maximum power of 70 Watt.
- All conductors of the ESU should be resistant against RMS values with a maximum of 529 V at a power of 70 W
- All conductors of the ESU are resistant against maximum peak voltage of 3kV
- All conductor components are highly resistant against corrosion as a result of the cleaning procedures used in LMICs
- The electric conductors of the ESU do not have any sharp edges which can enhance ionisation of air that can create breakage of the insulation.
- The ESU components must function normally despite of grid fluctuations of 15% above or 20% below nominal mains rating (Neighbour, 2012)
- The shape of the high frequency generator, monopolar handheld and electrode tip should facilitate in smooth surfaces for ease of cleanability
- The ESU does not use service related parts that have to be replaced within 1 year (filters, additional liquids, etc.)
- The ESU can be operated by surgeons, clinical officers and OR assistances with all levels of experience with electrosurgery
- The electrosurgery unit should be designed modular for future implemented design features

Challenges
Following from the program of requirements, challenges have been formulated in order to demarcate the project focus. These challenges will be used as input for the ideation and conceptualisation phase, and as design proposal of the ESU.

"To develop an sustainable and affordable ESU system by capturing the primary needs and functionalities to perform basic electrosurgery"

"To create a safe and intuitive user interaction with the high-frequency generator that is accepted and understood by operators with a variety of experience levels. The user interaction should increase electrosurgery knowledge and confidence of the operator and consequently confine risks and increase the clinical outcome of the surgical procedures"

"To develop a reliable monopolar handheld including electrode tip that enhances safety, intuitiveness and control during surgical procedures, and is resistant against the cleaning procedures used in LMICs"

4. **Development** phase

of the ESU system

All the expansion of knowledge related to the project made it possible to start with the ideation phase. The focus of the development phase has been on the previous stated challenges. At first, a wide ideation phase has been done with the knowledge gained through quantitative and qualitative research, see next page for a small impression.

As stated before, in situations where existing equipment and devices cannot fulfil the unique needs of LMICs, the process of designing tailored solutions should involve extensive consultation with end-users, as this is critical to promoting correct device use and protecting patient safety (Ng-Kamstra, 2016). Consequently, the ideation phase has been conducted in close collaboration with the Dutch surgeons that work or have worked in LMICs and with several Brazilian surgeons, see appendix G. Moreover, brainstorm sessions have been conducted on understanding and intuitive interactions with master students of the TU Delft that have zero experience with electrosurgery.

This co-creative approach resulted in efficient iteration steps and well-founded assumptions concerning the intended target group. A final concept has been designed with the input of Dutch surgeons and translated to various boundary objects that could be iteratively tested on intuitive and safe user-interaction with the surgeons in Kenya (see appendix H for the explorative study, research protocol and interviews). The retrieved information has been integrated into design decisions as can be seen in the following chapters.

The following chapter will be subdivided in the development of three parts of the ESU system: design of the HF generator, design of the monopolar handheld and design of the electrode tip. For each product design decisions will be discussed.

"Using boundary objects instead of a visually finished prototype created a more critical attitude of the interviewed surgeons. When using a visually finished prototype the surgeons will be less critical on the design because they are scared to be disrespectful, which is even more present in the African culture. Besides, by explaining that most Dutch surgeons lack the knowledge on the broad spectrum of electrosurgery, the Kenyan surgeon dared to position themselves uncertain about the knowledge of power settings. This enhanced the critical attitude during the explorative study and removed the risks of solely perceiving positive feedback."

An impression of the drawings made in collaboration with the Dutch and Brazilian surgeons

The prototypes used for the explorative study with surgeons in and around Nairobi, Kenya

4.1 Design of the **HF generator**

user-interaction

The high frequency generator is the brain of the ESU system and provides the user with essential feedback on the used power settings. The main design goal for the high frequency generator has been on the adaptability to the knowledge of the operator and a modular design concerning the product family. The high frequency generator is designed to be affordable and therefore solely focusses on essential functionalities and interactions for safe electrosurgery.

Main design requirements

The main design requirement influencing the design of the high frequency generator can be found below. The complete program of requirements can be found in appendix E.

- The high frequency generator includes a hand grip that enhances movability
- The power setting of the interface is based on power instead of voltages, since this will be the criterion in the near future, according to the CEO of Incision care
- The interface enables power change between a bandwidth of 10 to 70 Watt.
- The interface of the high frequency generator enables an intuitive pre-setting of power according to the limited electrosurgery experience in LMICs.
- The interface of the HF generator consists of generic serial ports that are globally available
- The high frequency generator will solely produce the waveforms of cut and coagulation and no other intermittent settings, since these waveforms are sufficient for general surgery, according to the majority of the interviewees
- The interface of the high frequency generator should be visible from a distance of 2,5 meters and an angle of 20 degrees of eye-direction
- The high frequency generator does not consist of any protruding components
- The material of the high-frequency generator should be resistant against the surgical alcohol and antiseptic solutions found in appendix C
- The high frequency generator is designed IP54 to be resistant against high ambient dust in rural operation theatres and a possible drop of water on the exterior.
- The ESU interface components consists of basic electronics that are globally available
- Mechanical strength and accessibility of internal components is tested with a standard test finger (30N of pressure), while penetrating the finger no unearthed components can be touched
- The electrosurgery unit should be designed modular for future implemented design features

User-interaction

The most important design challenge has been the creation of a reliable and intuitive user interaction of the high frequency generator with the surgical team. These user-interactions should be tailored designed for the context in LMICs and the variety of experience levels with electrosurgery.

Movability

Not all operation theatres in LMICs accommodate an ESU and consequently the high frequency generator is transported by the surgical team from operation theatre to operation theatre prior to the surgery. It has been stated by all surgical teams in LMICs that the current ESU equipment is too bulky to transport by hand and most operation theatres do not have a transportable surgical equipment cart with wheels. Therefore, the ESU should be lightweight designed and include a handle for individual transportation. The handle has been integrated in the exterior of the ESU since all protruding elements will break, according to the biomedical technicians in Kenya.

The angled design of the high frequency generator creates the possibility to integrate a handle box with an ergonomic size for P5 and P95 hands (DINED, 2018).

4.1 Design of the **HF generator**

user-interaction

The light weight and equal weight distribution as explained the next section 'component selection' will enable an ergonomic transportation. The bumper on the front of the interface will protect the protruding interface components of breakage while the high frequency generator is being transported or falls on the floor.

The centre of mass of the internal components should be in close proximity to the applied force on the handle to create an ergonomic balance while transporting the model, see figure 20. As can be seen in section 'component selection' , the transformer and heat sink will have the most influence on the centre of mass and consequently these two components should be positioned in a strategic manner by the student of 3ME that focusses on the internal components.

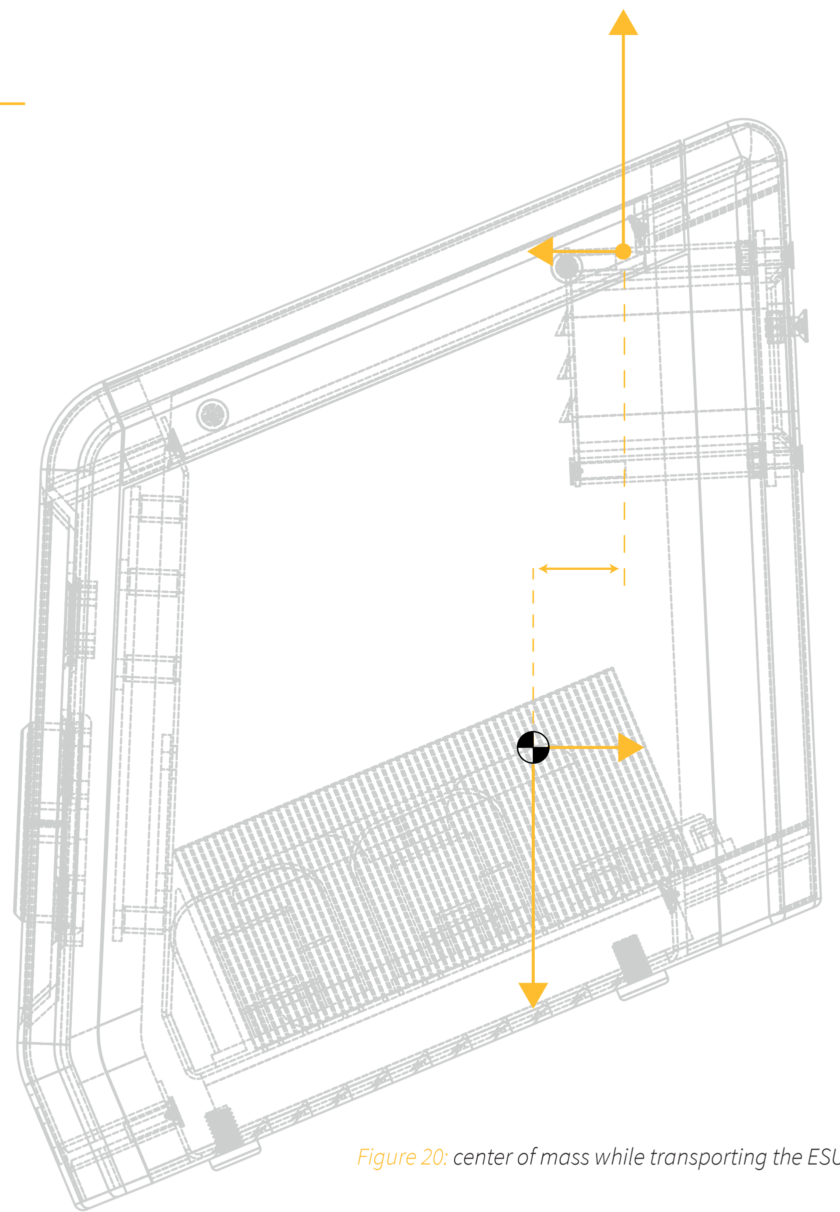


Figure 20: *center of mass while transporting the ESU*

4.1 Design of the **HF generator**

user-interaction

Pre-setting the ESU

As explained in chapter 2.3, almost all surgeons in LMICs do not have the appropriate power setting knowledge that is needed to safely perform general surgery. However, the operator of the ESU should possess the knowledge of the spectrum of power settings to adequately perform a safe surgery.

Guidelines on appropriate power settings related to a certain surgical procedure have been created in consultation with the interviewed surgeons, see chapter 2.3. The goal of providing these guidelines is to improve safety for patient and operator, improve clinical surgical outcomes and increase confidence of the operator on correct usage of the ESU.

As stated in chapter 2.3, the surgical effect of the ESU is influenced by a number of factors (e.g. age and lifestyle of patient, cross sectional area of electrode, etc.) which makes it impractical to create exact tailored guidelines of power settings for a certain surgery (Malcolm, 2012). However, despite the variety in influencing factors, the appropriate power settings for a certain surgery can always be found within a specific bandwidth, according to all interviewed surgeons. Accordingly, the surgical procedures have been subdivided in three sub-groups related to the depth of the surgery and the sensitivity of the surrounding organs and tissue (micro surgery, moderate surgery and macro surgery). Furthermore, the thermal spread concerning higher power settings is integrated in the sub-group symbol.

Each sub-group has his own distinctive safe bandwidth that is required for the differences in surgical procedures and tissue impedance amongst patients. The limits of the bandwidth have been selected based on the electrosurgery theory and by co-creative sessions with Kenyan surgeons on the effective used power settings.

As prior stated in chapter 1.2, the appropriate operating power output will be the minimum power density at the active electrode to create the desired vaporization or coagulation effect(van den Berg, 2012). Thus, the desired power setting for a certain surgery should constantly start as low as possible but in a close range to the definite power setting, as stated by all interviewed surgeons.

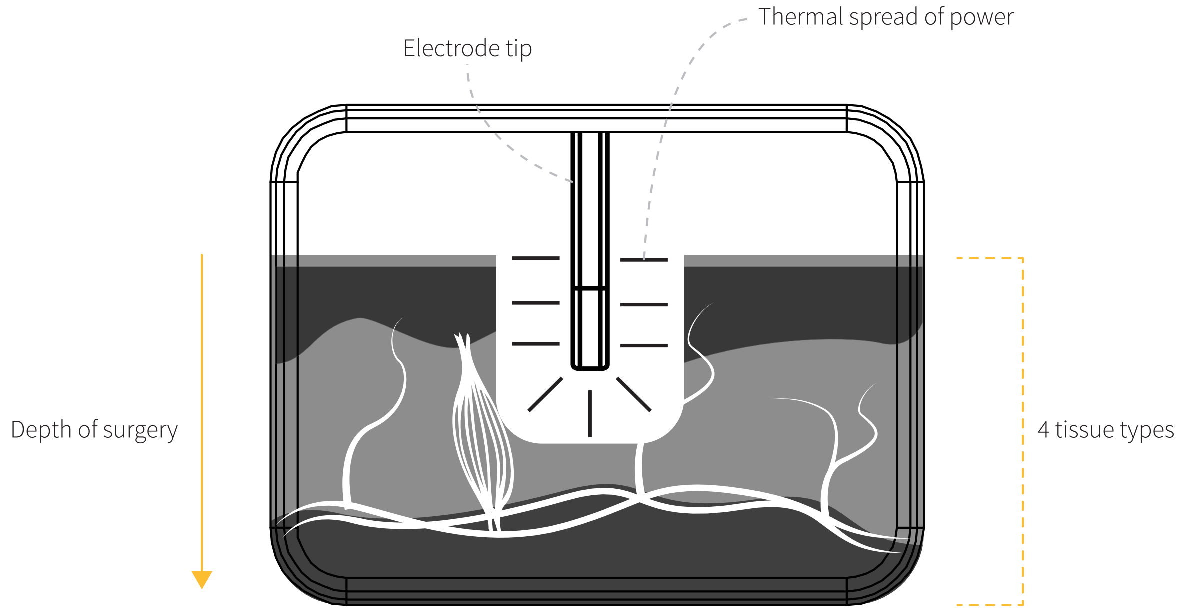


Figure 21: sub-group icon

“An essential part of providing these guidelines is the understandability and acceptance by the high variety of knowledge levels in LMICs. Besides, the guidelines should be experienced as an innovative approach that contributes to a positive added value compared to the current ESU use approach. Accordingly, an explorative study has been conducted with the operators of the ESU, in and around Nairobi (Kenya), on acceptance, intuitiveness and safety, see appendix H for the interviews.

Various surgery scenarios have been presented to study whether providing the power setting guidelines is accepted and increases control, confidence and trustworthiness. All interviewed Kenyan surgeons stated that providing guidelines on the interface will enhance safety for the operator and patient, and increases confidence in use. Besides, the guidelines have been accepted as a positive added value by the surgeons with a variety of electrosurgery experience levels.

Most surgeons are taught on how to use the product by the surgical team of the hospital, which means in general all operators follow the majority in terms of power settings for a certain surgery. However, most times the surgical team or even the surgical professor does not know the theory concerning appropriate use, according to professor Obimbo. Hence, the interface should be self-explanatory and increase the capability of the surgeon to safely perform general surgery but yet provide the feeling of control and responsibility to the operator. “

Dr. Wanjeri testing the intuitiveness of the interface in a semi-outdoor hallway in the Thika level 5 hospital

4.1 Design of the **HF generator**
user-interaction

Prior to the surgery, the interface will instruct the surgical team with the to connect electrosurgical instruments by blinking LEDs above the serial ports, see image on the right page. Ones the electrosurgery instruments are appropriately attached – for instance in case of monopolar electrosurgery; the return electrode and the monopolar handheld – the sub-group LEDs will start blinking.

The interfaces will instruct the surgical team with information on common surgeries found in LMICs and consequently what sub-group to select. The language differences within the sub-Saharan countries demanded for an ordinary symbol language and consequently explorative studies have been performed on understandability of the symbols among the variety of ESU operators. Initially, the symbol guidelines have been designed to display the essential surgeries stated by the WHO as can be seen in figure 22.

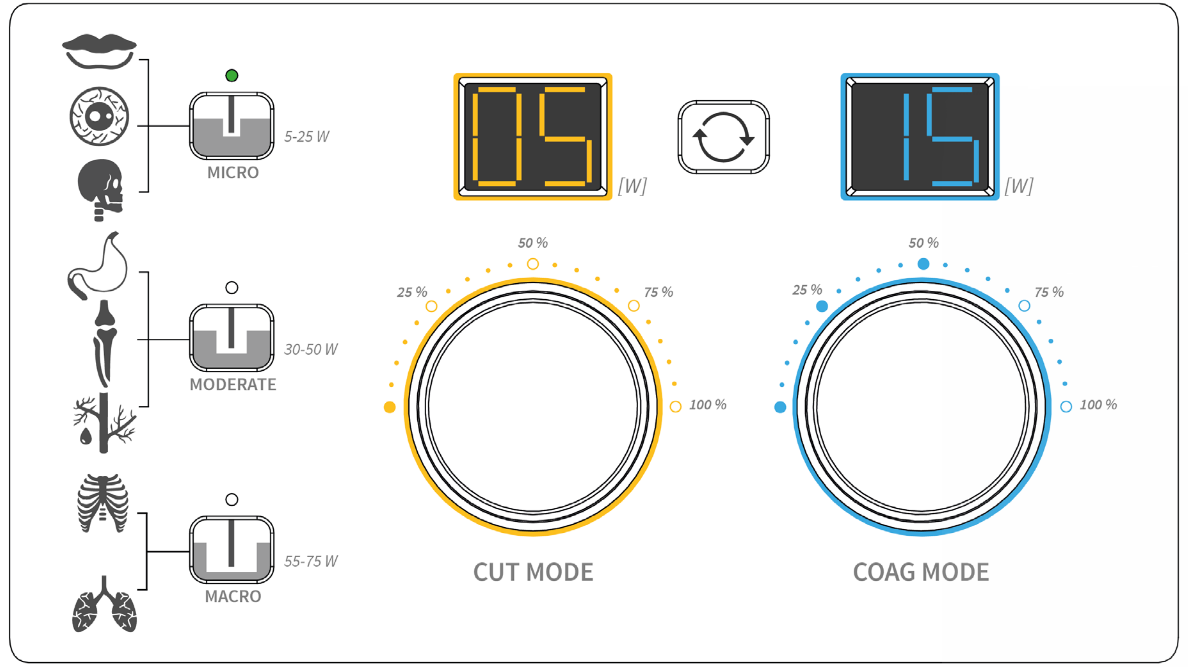


Figure 22: example of interface used for explorative study in Kenya

However, providing guidelines on specific surgeries will or need an extensive explanation of power limits for a specific surgery – since most surgeons will literally interpret guidelines and not think about their approach – or designed more interpretable, thus in a generic and interpretable manner, according to the majority of the interviewed Kenyan surgeons. An extensive explanation of the to use power settings and handlings will take away the responsibility and control of the surgeon and consequently the provided guidelines on the interfaces will be designed more generic. The pre-setting user interaction can be compared with the washing machine principle, where the user selects the settings based on the sensitivity of the fabric but yet has the possibility to change the program according to for instance the level of dirt.

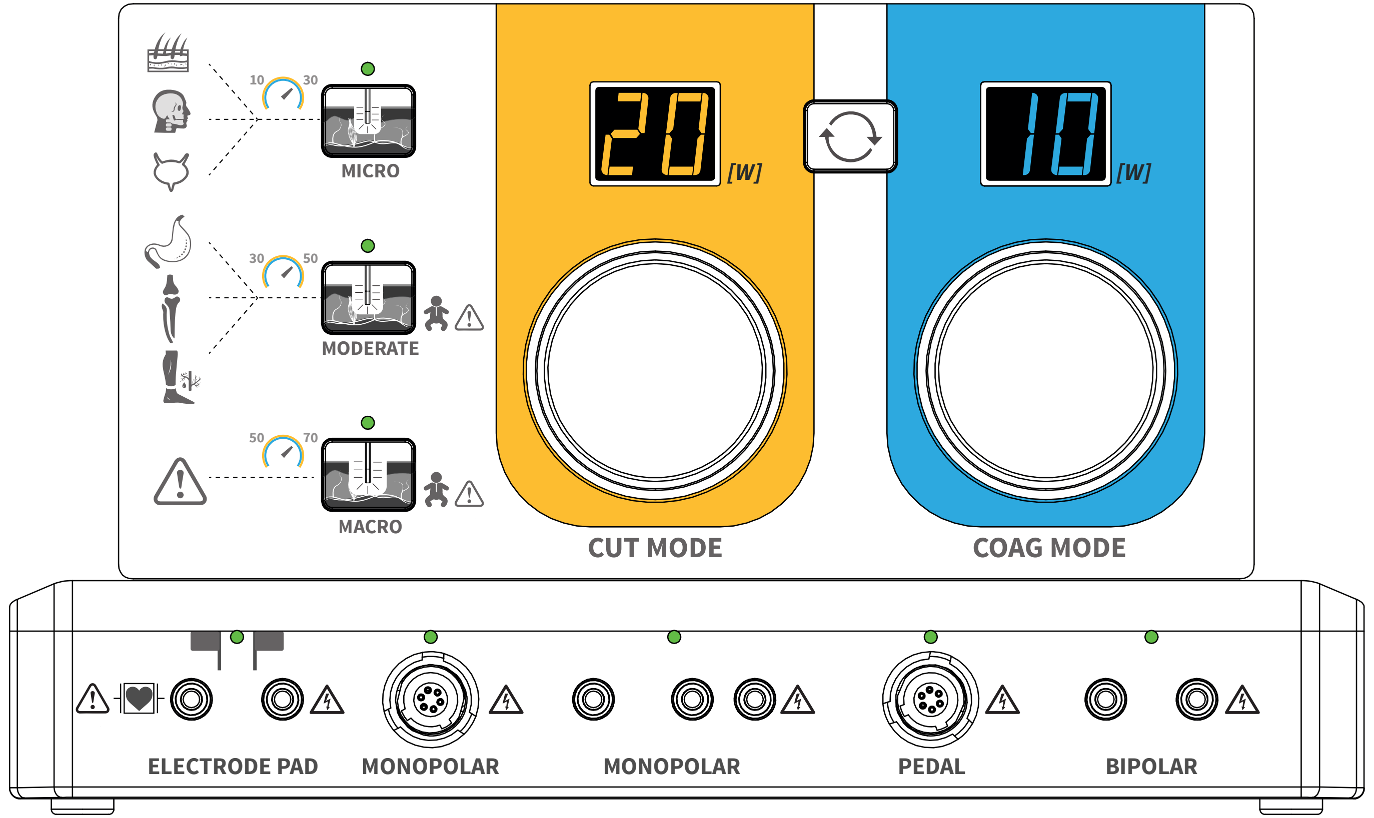
"It is sometimes better to make the surgeon think a bit instead of struggling with a guideline that you provide that might not work for another similar surgery"
(Dr. Wanjeri – Kenyatta National hospital)

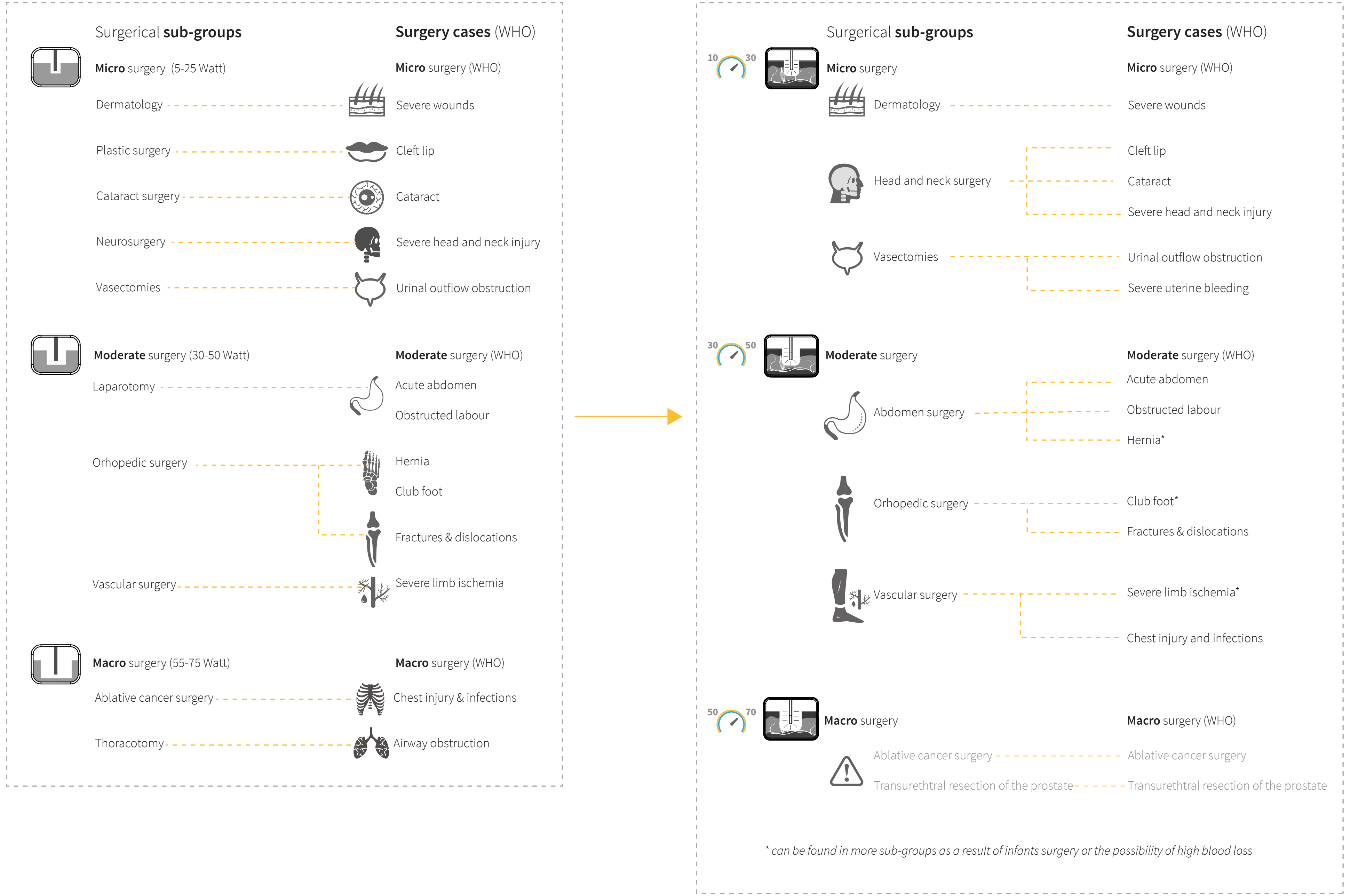
4.1 Design of the **HF generator**

user-interaction

According to the target group, various surgeries can be found in multiple sub-groups. For instance infants surgery with more sensitive tissue will regularly require a lower power setting. Accordingly, it is inevitable to create more awareness and prevention on the interpretation of the moderate and macro sub-group as being ordinary, as stated by Dr. Hansen. This will take away product/brand risks of being misguided but will remain the confidence and control of correctly performing the surgery.

Along with the guidelines on the interface a more extensive explanation of the guidelines will be provided on a separate sheet that can be positioned on the walls or door in the operation theatre in case extensive information is desired. These guidelines have been set up by co-creative sessions in the Netherlands and reorganized with a variety of surgeons in LMICs, see image on the right page.





4.1 Design of the **HF generator**

user-interaction

At the start of the surgery the surgeon will instruct the circulation assistance with the desired sub-group concerning the surgical procedure. In respect of responsibility, the surgeon always wants to check the pre-setting of the high frequency generator prior to activation of the monopolar handheld.

Accordingly, through user testing essential feedback during the surgery has been analysed and integrated in the design. The sub groups and displayed power should be sufficiently visible from a distances up to 2 meters to increase the feeling of control. Furthermore, an increased presence and contrast of waveform mode colours is required to enhance visibility, according to all surgeons.

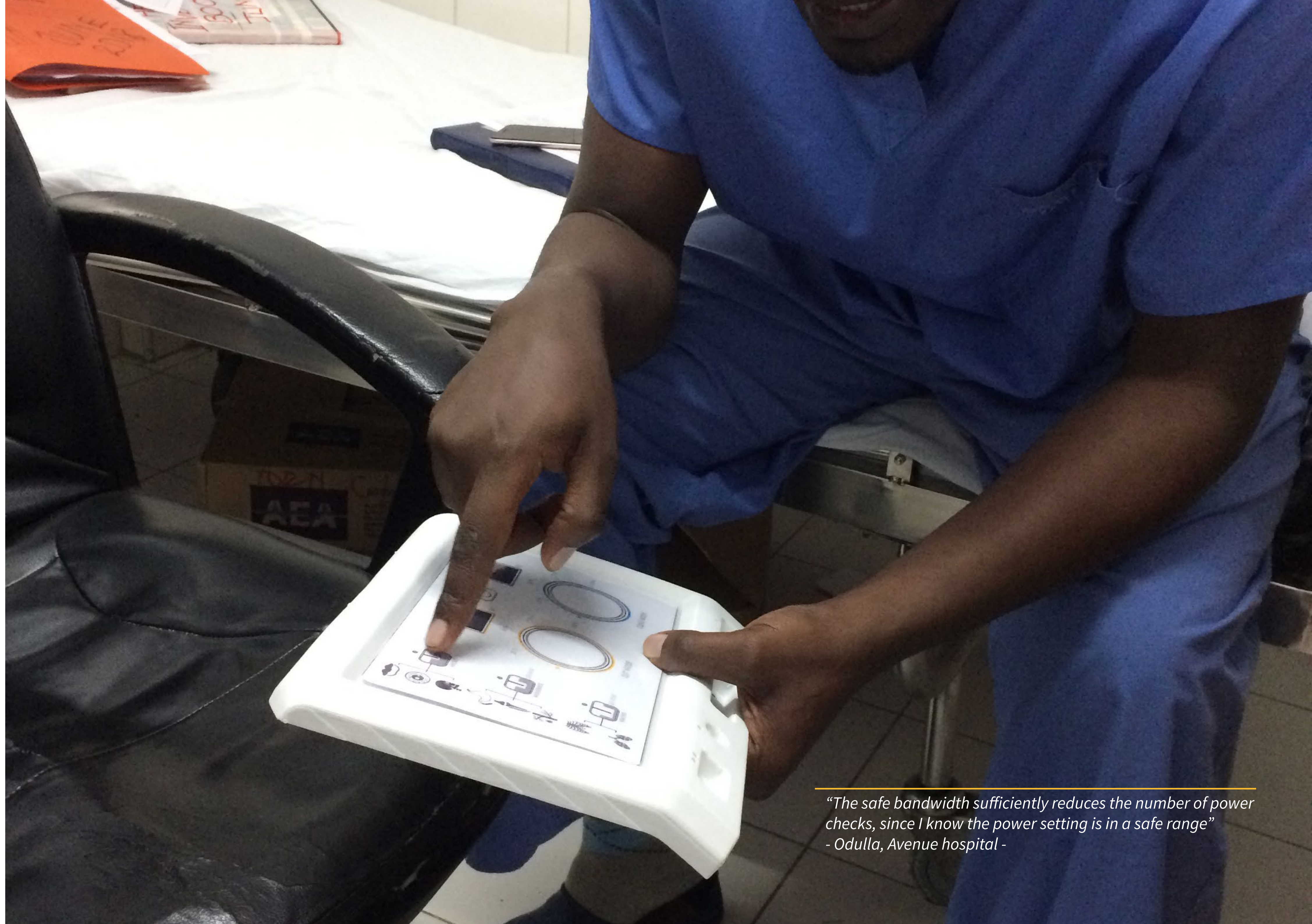
After approval of the sub-group, the minimum power of the sub-group will be used by the surgeon to perform the first cut or coagulation. According to differences in tissue impedance the operator can change the power by instructing the circulation assistance with an increase of either the cut power or coagulation power. In practice, the power is changed in steps of 1 Watt in the micro sub-group and 5 Watt in the moderate and macro sub-group. However, the limited rotation snaps of the rotary encoder will demand for a power change of 1 Watt in all sub-groups to remain intuitive.

In view of risk management, the power setting of a sub-group can be found in a safe bandwidth for a certain surgical procedure and consequently limits cannot be exceeded without alternating between sub-groups. Therefore, the number of power checks after an ordered change of power will be diminished and consequently this will enhance viewpoint on the surgical area, according to Dr. Odulla, member of the Society of Kenyan Surgeons.

Furthermore, the sub-group creates an increased boundary to move to risky power settings related to a certain surgery, thus this will either diminish the use of too high power settings for a certain surgery, or increase attention awareness when moving to a possible dangerous power setting, as stated by the majority of the surgeons.

Grid fluctuations

Subsequently, in the more remote areas in the sub-Saharan countries there is a high probability of grid fluctuations and power cuts. In case a power cut appears, all surgical equipment will most probably stop working until the power generator is activated. Ones the generator is activated the high frequency generator will at all times roll back to the starting feedback where all sub-groups will light up in hold for a sub-group selection. In this degree, the surgical team will again have to pre-set the product and this will result in unintended tissue damage. Nonetheless, by integrating a reset button the surgical team can at any time go back the last used power settings, which will remove the trial and error period of the electrode tip reaction on tissue and increase a boundary to use power settings of a previous surgery.



“The safe bandwidth sufficiently reduces the number of power checks, since I know the power setting is in a safe range”
- Odulla, Avenue hospital -

4.1 Design of the **HF generator**

component selection & functionality

All components of the high frequency generator have been selected on reliability and availability in the LMICs context. Accordingly, all components should be resistant against the high ambient humidity of 95 % and a temperature range of -40°C to + 70°C. The lack of controlled hospital environments require the need of an IP 54 degree of protection against contact and penetrating objects.

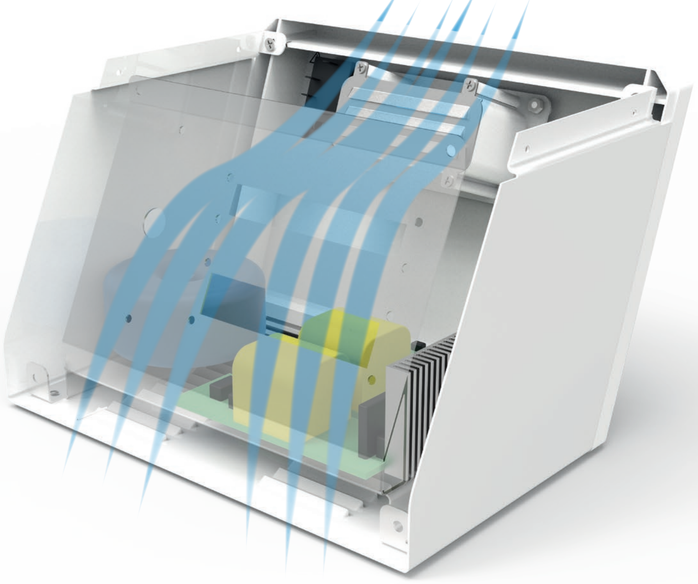
Internal components

The components are selected based on the knowledge gained during the function analysis. This could set-up a foundation of space claim for the internal components of the high frequency generator, see figure 23. As mentioned before, the ESU should be flexible for the capabilities of the other product families. Therefore, the trade-off model will be increased in size to fit the additional component that are needed for the functionalities and differences of the other product families.

This mostly affects the needed system power output that is required for sophisticated surgery. The power setting range for general surgery has been set from 10-70, whereas in sophisticated surgery higher power settings are mandatory (up to 120 [W]). Consequently, the transformer and coil need to be specified for a higher power setting and this increases the size of both components. The height of the design is sufficient for the internal components and required for the intuitive user interaction as explained in the previous section 'user interaction'.

The required power for sophisticated surgery requires a serious heat sink that is in close proximity to the thermostat of the high frequency generator. In case critical temperatures are achieved the high frequency generator will block and shut down. A sufficient air flow around the internal components is created by air grills in the bottom sheet metal and the handle. Heated air will move upwards and flows through the handgrip to the outside of the embodiment.

The heat sink is positioned contra to the transformers since these two components will have most influence on the weight distribution of the high frequency generator. Thus, the centre of mass will be close to the middle of the high frequency generator and take away movability problems.



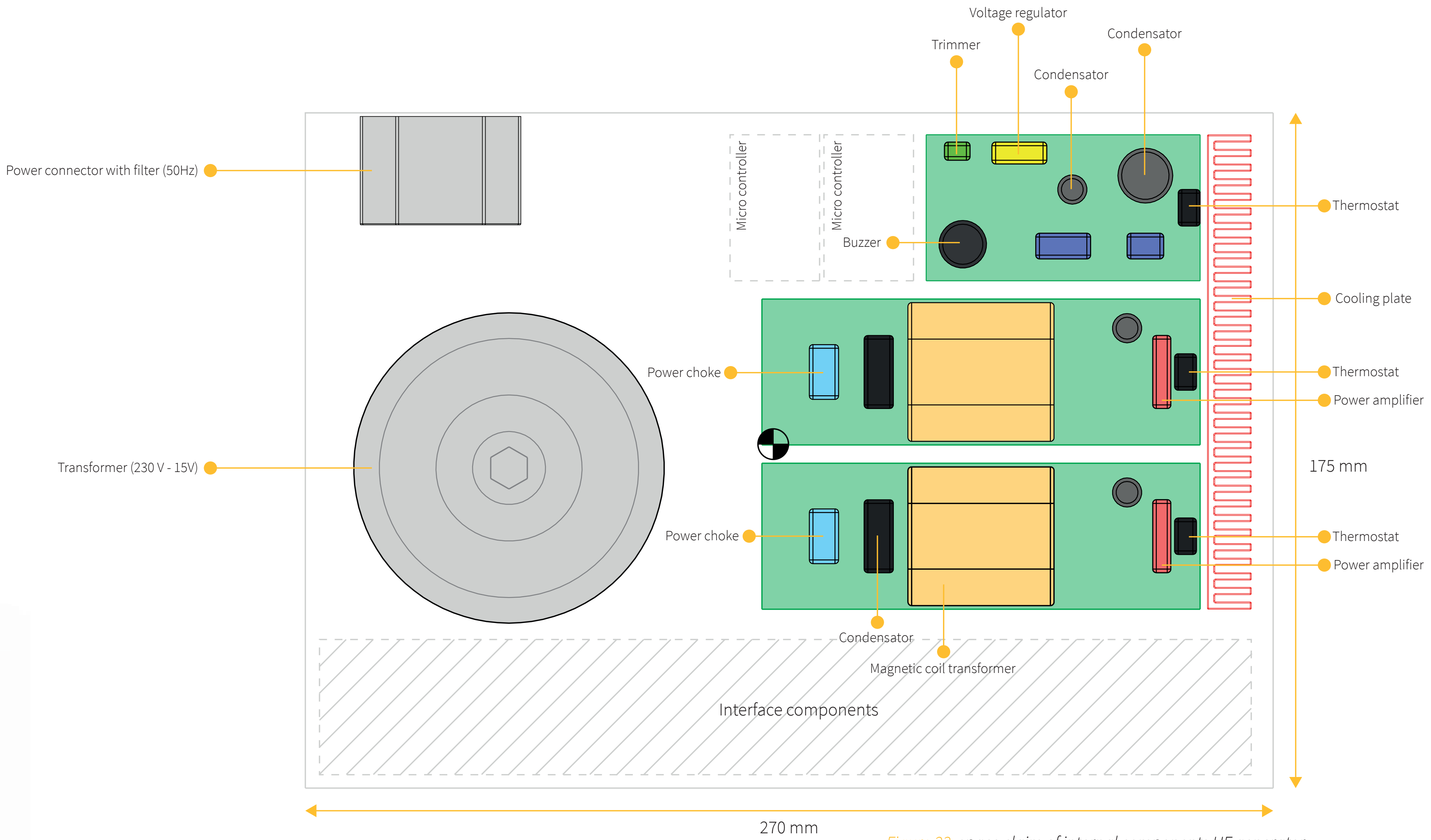


Figure 23: space claim of internal components HF generator

4.1 Design of the **HF generator**

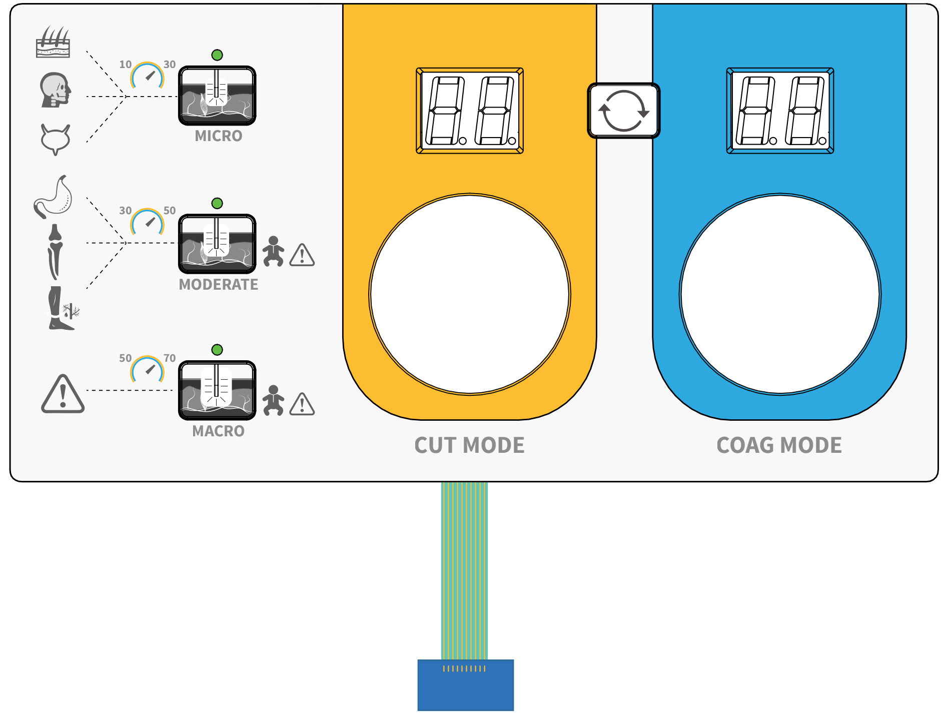
component selection & functionality

Component selection interface
The increased capabilities of the high frequency generators affects different capabilities of the interface. For the design of the interface a polycarbonate white membrane foil is used to enhance modularity of the interface without fully replacing the full mechanisms of the internal components. These polycarbonate stickers are frequently used in the medical world and allow for integration of the needed LEDs and buttons. These polycarbonate stickers acquire an integrated electronic connection on the back of the sticker which can easily be passed through the internal structure of the high frequency generator.

The power setting of both waveform modes will be displayed by using 7 segment LEDs that are often used in industrial appliances because of its reliability in harsh environment and its global availability. These displays are globally available with an mcd value of 3000 or higher, so bright enough to read from a distance up to 2 meters and a view angle of 30 degrees.

The component selection of the rotary encoder is based on intuitive and safe usage. The rotary encoder has no maximum rotation distance or a fixed position as seen in potentiometers. Consequently, this enables software to roll back both waveform modes powers to the lowest power setting within a sub-group after each surgery. This will take away the risk of using power settings that have been previously used by another surgeon, which might be incorrect for the next surgery. Besides, the rotary encoder will enhance reliability by eliminating possible breakage while rotating.

Both the seven segment display and the rotary encoder are selected based on local availability to retain standards and norms certifications (ISO and Medical Design Directive) when replacing components by virtue of breakage, according to Arjo Loeve, expert of 3ME.



Serial ports
Extra serial ports are added for compatibility with competitive products (e.g. other monopolar handheld, laparoscopic handheld, etc.) to increase use sustainability of the high frequency generator in the long term. As will be explained in section 'design of the monopolar handheld', the developed monopolar handheld will be connected to the serial ports by using a REDEL connector.

However, most competitive products use 4 millimetres banana plug connectors in a certain distance between each jacket as incorporated in the serial port design for the monopolar handhelds of Valleylab that are regurarly used in LMICs.

Competitive monopolar handhelds include single pin or 3 pin connectors. A single pin monopolar handheld should be connected with the red active pin and needs a pedal as additional accessory to activate the two waveform modes. A 3 pins button activated handheld includes: left - the active pin, middle - the coagulation pin and right - the cut mode pin, which is integrated in the design with compatible measurements.

The electrode pad can also be used as a single pin connection. This will remove the possibility of monitoring the tissue impedance along the surgery (see appendix A for an explanation of the REM system)but will enhance sustainability in case the developed return electrode will break and solely a single pin electrode pad is available. The compatibility with other electrosurgical equipment required rearrangement of the PCB and microcontroller and increased measurements as can be seen in the space claim.

Power connection
A certified power connector with integrated 5x20 mm power fuse will be connected to the back exterior. It is almost compulsory to position the power fuse on the exterior of the high frequency generator since the power fuse can easily break. The power fuse should be in accessible reach to enhance replicability. The 5x20 mm power fuse is easily available in the urban as well as rural areas according to the interviewed technicians in the Kenyatta hospital.

4.1 Design of the **HF generator**

Materialization and manufacturing

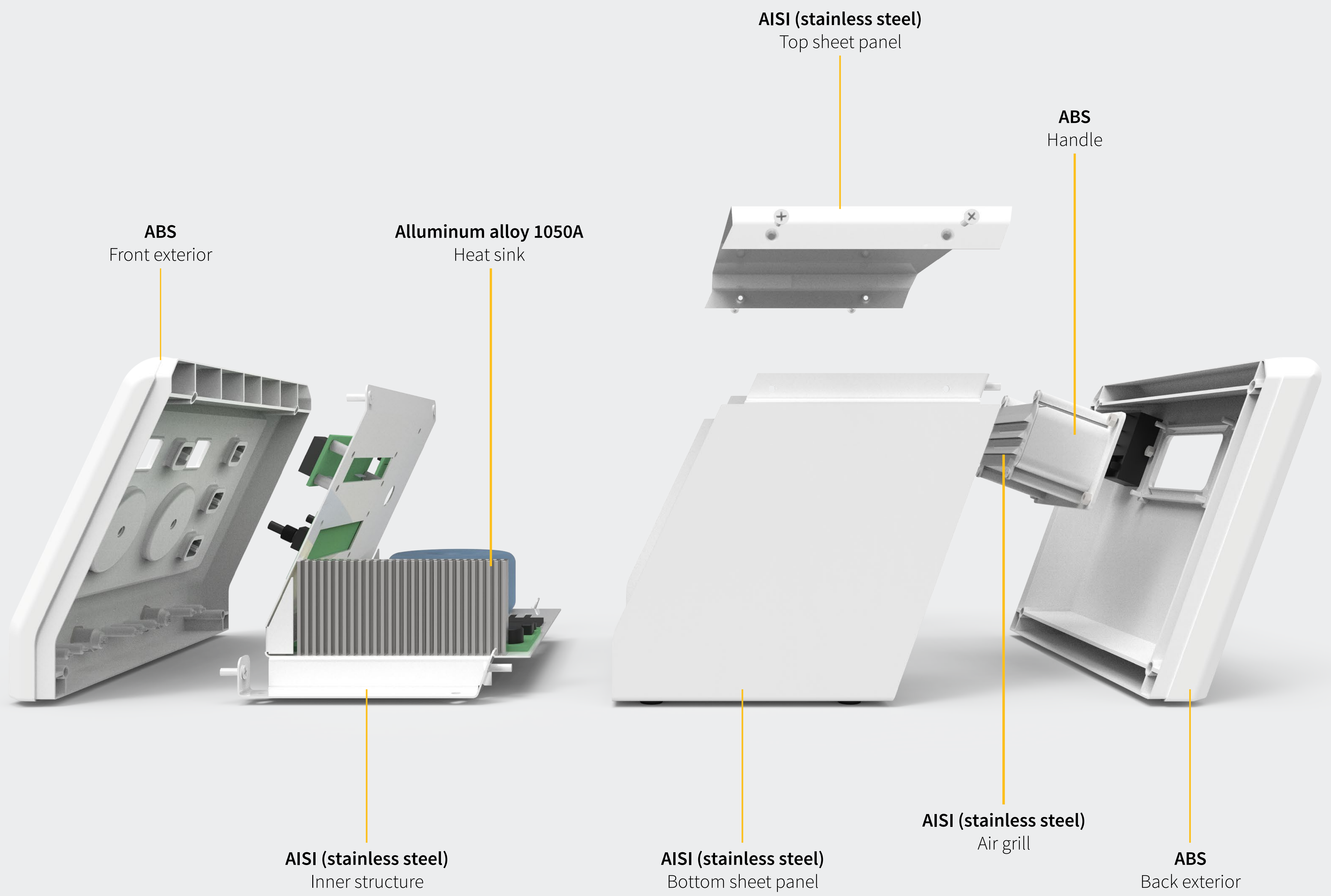
Materialization and finishing
The high frequency generator will not be exposed to aggressive alkalis as analysed in the post-treatment of the ESU journey, see appendix C for used detergents. After a surgical treatment the high frequency generator will either not be cleaned or cleaned with an antiseptic solution (e.g. Dettol) or surgical alcohol, since the generator is not positioned in the sterile surgical area. Accordingly, the plastic parts of the high frequency generator can be materialized with a high variety of materials. The material of the plastic parts have been selected with ABS because of its low cost and excellent processing properties for injection moulding, see appendix K for specifications.

The sheet metal parts will be made of stainless steel (AISI) and coated with a matt white paint to prevent for any possibility of wear and corrosion. All exterior steel parts will be bonded and grounded to limit the voltage-to-ground — thus preventing destruction of electrical components as well as electric shocks that can occur from superimposed voltage from lightning and voltage transients (Holt, 2001).

The heat sink that is located on the side of the internal structure will be made of aluminium alloy 1050A because of it high thermal conductivity, cast ability and its relatively light weight characteristics. However, heat simulations should be done to determine the needed measurements and cut outs for sufficient cooling in LMICs without using an internal van.

As explained before the interface will be made of a polycarbonate foil. A polycarbonate foil is highly reliable and resistant against the used cleaning detergents that are used to clean the high frequency generator. All ink of the symbols and text is applied on the back of the polycarbonate sticker and ones attached the symbols and texts cannot be harmed by excessive use. Besides, the sticker will ensure a dust free seal since the buttons are integrated in the foil.

Manufacturability
The production size has been estimated on 1000 pieces which enables the possibility for injection moulding. However, injection moulding the entire exterior (e.g. consisting of two mould) will ensure high mould costs. Furthermore, this will need draft angles that will affect the geometric design of the high frequency generator. Accordingly, the injection moulded front exterior and back exterior are separated by metal components that are laser cut prior to cold forming (bending). The handle and power knobs are injection moulded by using a family mould since the materials are similar and this will lower costs.



4.1 Design of the **HF generator**

Assembling

All parts of the high frequency generator can be found in the bill of materials (BOM) in appendix I. Not all internal components can be found in the BOM, solely the parts that have most influence on the design of the high frequency generator in terms of measurements and weight.

The ***internal structure*** is the main assembly with all internal (electronic) components of the high frequency generator. The planar level of the internal structure has been designed to be above ground level to prevent for possible water damage. As consequence of the polycarbonate membrane foil the PCB attached to the angular plan of the internal structure are limited to a display and rotary encoder. The internal structure assembly will be connected with the bottom sheet panel by screws that simultaneously function as feet.

The ***front exterior*** is used to connect the panel mount serial port connectors and to guide the power knobs. The electronic wire connection of the serial ports is connected to the PCB on the internal structure prior to connecting both assemblies. Accordingly, the cables should have a sufficient length to not have problems while assembling. The front exterior and internal structure are connected with Allen screws because of the reduced length of this tool.

The ***back exterior*** is used to connect the ***handle*** and power connector to the high frequency generator. The electronic wiring of the power connector is assembled with the PCBs on the internal structure prior to attachment with the internal structure and bottom sheet penal. Likewise to the front panel this will be done by using allen screws.

The ***top sheet panel*** is used as exterior enclosure and creates the possibility for internal checks without disassembling the full product. The parting line between the top sheet panel and the bottom sheet panel is positioned at the top to create an attachment opportunity of the bottom sheet panel with the top of the back exterior without adding parts.

4.1 Design of the **HF generator**

Safety and reliability in LMICs
The fundamental design measures integrated in the high frequency generator to increase safety and reliability of the electrode tip are presented below.

• All protruding elements are eliminated which will increase the reliability of the ESU system in the long term

• The provided guidelines on the interface will increase electrosurgery knowledge for all experience levels within LMICs. Consequently, this will increase clinical outcome of the surgery, confidence of appropriate surgery execution for the operator and enhanced safety for the patient as well as the operator.

• A consistent roll back to the lowest power setting within a sub-group will empower the user to always start with the lowest power related to a certain surgery, which will result in less thermal spread, reduced safety risks and improved clinical outcomes of the surgery.

• The safe bandwidth for the most common surgical procedures enhances the feeling of confidence of an appropriate and safe power change by the circulation assistance and consequently, the viewpoint of the operator can remain on the surgery.

• The establishment of boundaries and precautions when shifting between sub-groups increases the attention of the operator when operating with possible risky power settings.

• The possibility to reset the high frequency generator to the last used power settings after a power cut will remove the trial and error period of finding the correct power setting and will take away unintended tissue damage.

• The used heat sink cooling system of the high frequency generator will take away clinical risks within the sterile operation theatre.

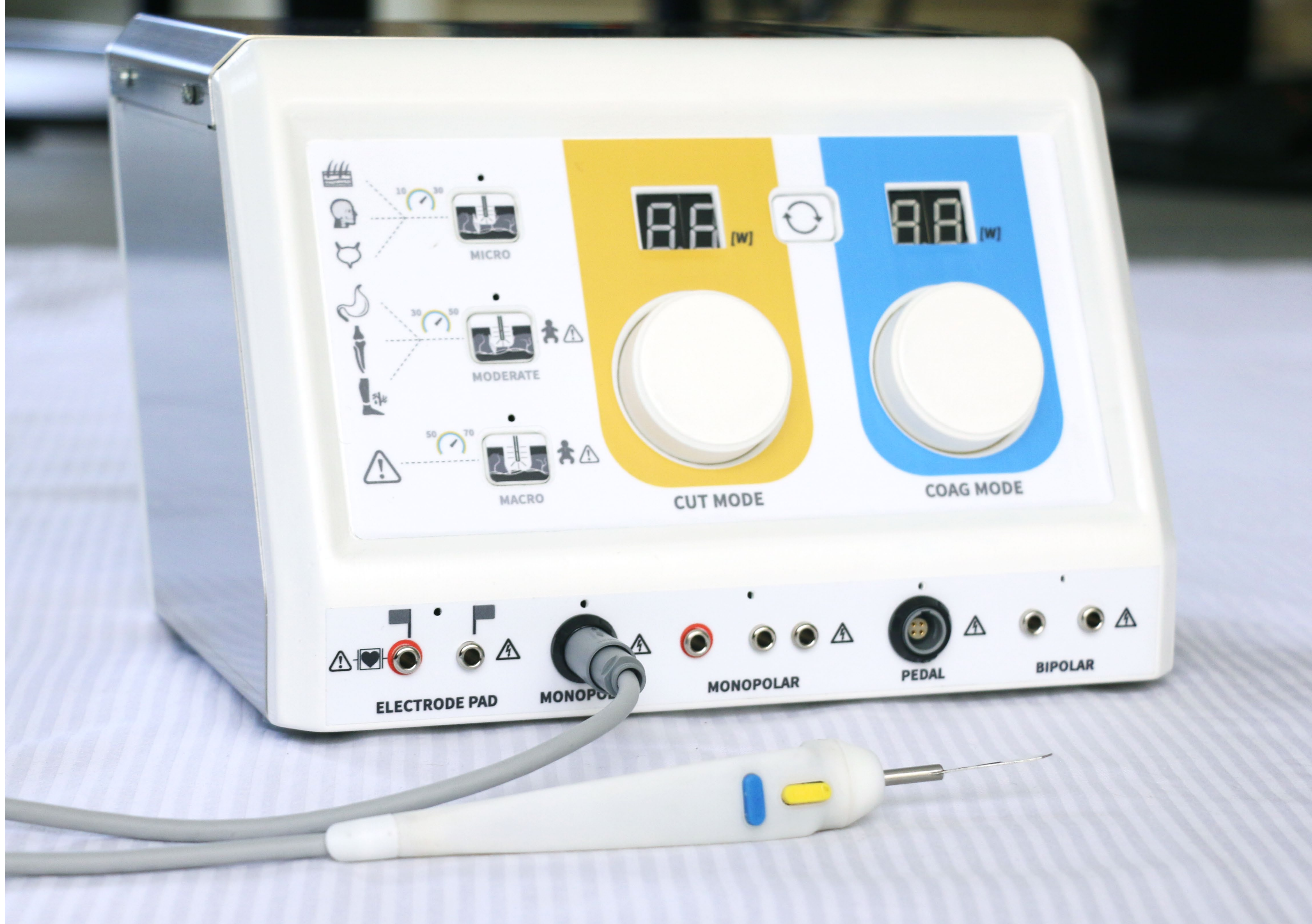
• In regard of local repairability the ISO regulation state that a component should at all times be replaced with an identical component. Therefore, all used electronic components are basic electronics that are globally available.

Cost price estimation
The costs for the high frequency generator have been roughly estimated by using the cost estimation framework of Hals and the BOM. Furthermore, the most valuable components have been estimated by desktop research. The estimated cost price of the high frequency generator will be approximately 290 euros, see appendix I for BOM. However, more in depth cost estimation should be made based on the selected internal electronics by 3ME. Besides, the additional certification costs should be included in the detailing phase after this project.

Prototyping
The essential design measures are integrated in the prototype of the high frequency generator. All designed parts have been prototyped to experience the aesthetics, measurements, assembling and movability of the design. Furthermore, the user-interaction of the high frequency generator has been designed by incorporating the designed interface sticker, the interface components and by programming the intended interactions of the interface (see appendix J for the comprehensive Arduino code).

This prototype cannot be used for actual electrosurgery since internal components are yet under development and the metal parts are currently not grounded. However, this prototype can be used as a foundation of space when incorporating the internal components and by examining lab tests on dielectric strength, insulation breakage and frequency radiation. Henceforth, the components can be changed according to the required standards. The displays are currently not sufficiently visible from a distance because the 7 segment displays with an mcd of 3000 have a lead time of approximately 6 weeks, which has been impractical in the short time frame of the project.

This functional and visual realistic prototype can be used as a showcase for the upcoming field trips to sub-Saharan countries to receive feedback on the aesthetics and a safe and intuitive use interaction.



4.2 Design of the **Monopolar handheld**

user-interaction

The focus of the electrosurgical procedure has been on monopolar surgery since this is the most frequently used procedure in general surgery and consequently empowering the accessibility of monopolar surgery will have the biggest impact on global surgery. The design goal of the monopolar handheld will be on increased safety, intuitiveness and feeling of control along the surgery. Furthermore, the lack of resources experienced in LMICs require design for reliability against frequent re-sterilization with the variety of used cleaning procedures.

Main design requirements

The main design requirement influencing the design of the monopolar handheld can be found below. The complete program of requirements can be found in appendix E.

- The handheld consists of two buttons one for activation the cut mode and one for activation the coagulation mode
- The handheld provides a secure grip to increase the feeling of control and precision when being activated
- The handheld is IP 67 to be resistant against the steam autoclave
- The material of the monopolar handheld is resistant against high temperatures of the steam autoclave which is around 145 °C
- Monopolar handheld can only function when the patient is attached to the dispersive electrode
- The monopolar handheld should provide a tactile difference between the cut mode and coagulation mode
- Each reusable monopolar handheld has a product life span of approximately 500 autoclavation cycles, thus 500 surgical procedures
- The material of the monopolar handheld should be resistant against the cleaning procedures and cleaning detergents in LMICs, see appendix C
- The monopolar handheld, including electronic wire, is fully autoclavable
- The costs of a single monopolar handheld will not exceed 50 euros
- The shape of the monopolar handheld should prevent for the electrode tip to contact human tissue or surgical sheet when laying down the handheld during the surgery procedure
- The materials insulating the high voltage electronic should have a dielectric strength of at least 3 MV/m at a power of 70 W to ensure safety
- The shape and measurements of the monopolar handheld should be compatible to P5 and P95 ergonomic activation of both waveform buttons

User-interaction

As analysed during the use phase of the ESU system, the monopolar handheld will be most frequently used to perform general surgery. In chapter 2.4 the use of the monopolar handheld has been analysed to enhance an intuitive and reliable user-interaction during the surgery.

Control during usage

In my vision, the monopolar handheld should create a reliable and controlled surgery execution, since the monopolar handheld is used to precisely cut tissue or coagulate blood vessels. As noticed during the use of the monopolar handheld, the hands of the operator often get wet because of saline or blood. Consequently, the hands need to be frequently cleaned since the monopolar handheld becomes slippery. This is time demanding, frustrating and is undesired in regard of sterility.

Likewise, slipperiness can contribute to a decrease of control and this might cause unintended tissue damage. Accordingly, the handheld has been designed to create a secured grip that take away problems in case the handheld becomes slippery. The ergonomic shape is symmetrical for right and left handed operators and will not contribute to clinical problems since the secured grip is designed with smooth surfaces.

The size of the monopolar handheld has been chosen by showing various design sizes to the Kenyan surgeons. In general, African people have bigger hands compared to western operators and consequently an increased size of the handheld has been required. Hence, this increased reliability and control, according to the majority of Kenyan surgeons.

The angled back exterior will ensure a descending positioned cable during usage. In addition, the clean design lines and angled lines of the controlled grip and back exterior create unity with the ESU high-frequency generator.

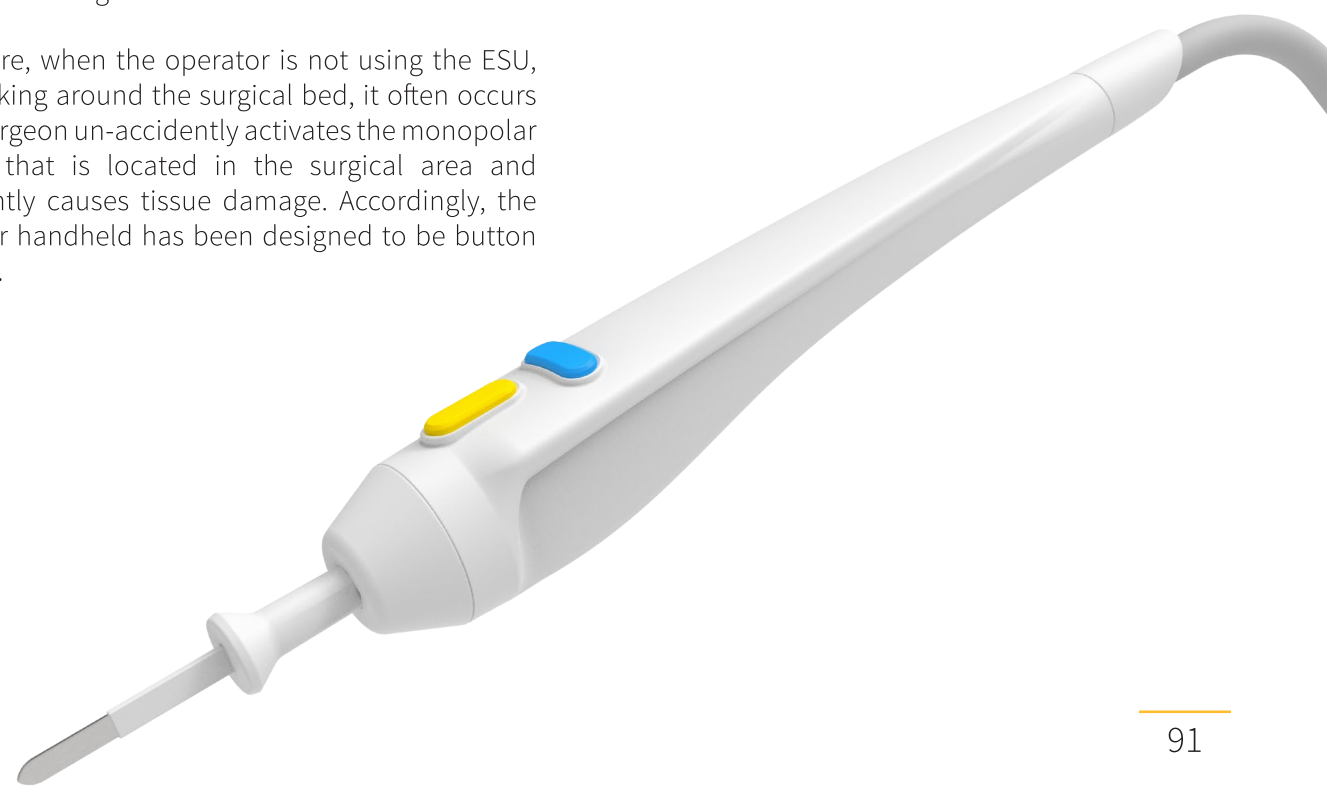
The desired waveform activation

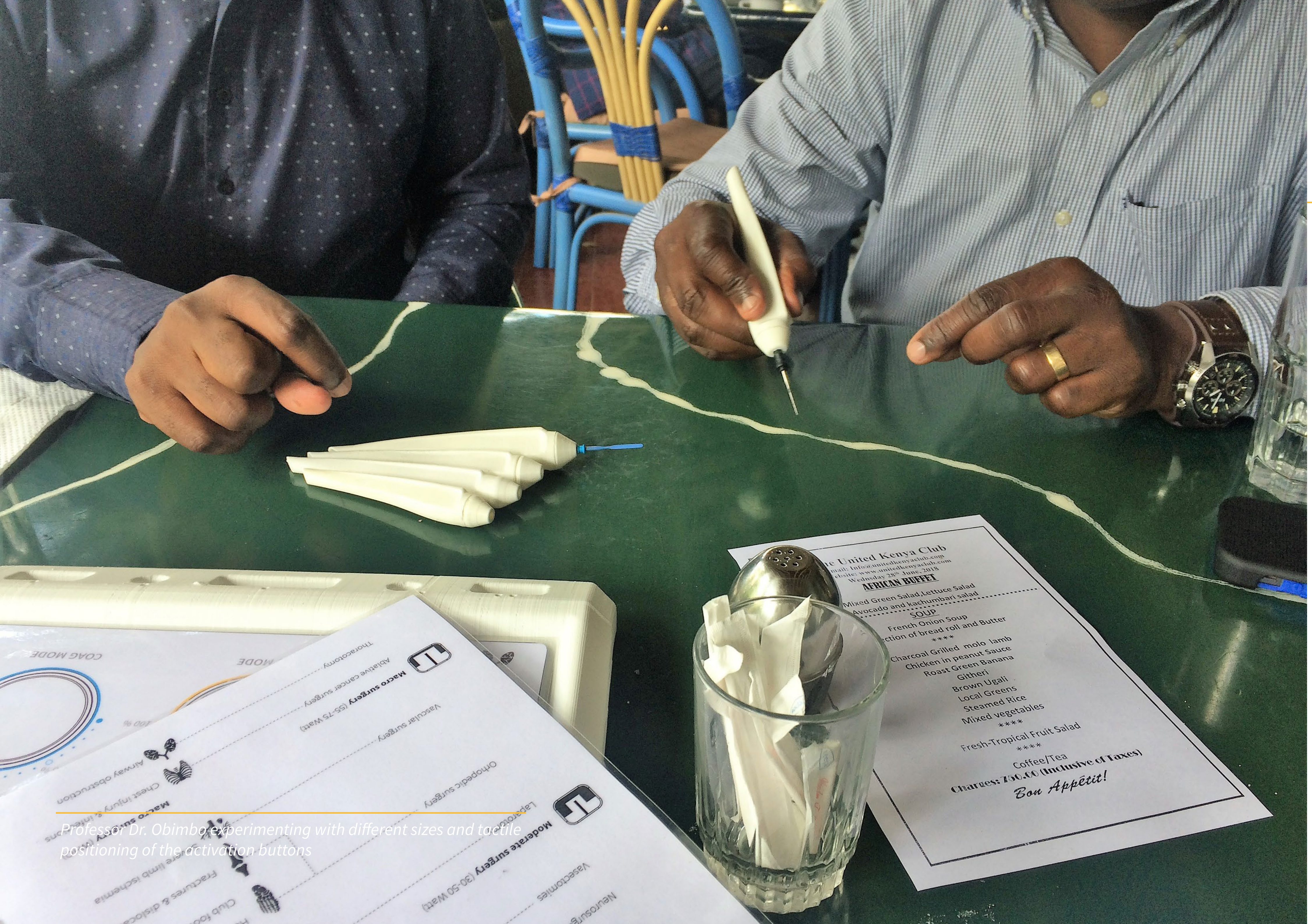
As explained in the design of the high frequency generator, the monopolar handheld will be activated by using two waveform modes: cut mode (yellow) and coagulation mode (blue). This activation is possible in two manners: pedal activation or button activation.

As stated by all surgeons the monopolar handheld is preferably activated by using a button control panel, because in this way the viewpoint of the surgeon can be fully focussed on the surgical area.

The pedal activation is regularly positioned underneath the surgical bed which often gets lost from the feet of the surgeon. Consequently, the surgeon has to search beneath the surgical bed prior to correct activation of the waveform modes. This relocation of view point on the surgery leads to frustration, increased blood loss and possible wrong activation of the waveform mode.

Furthermore, when the operator is not using the ESU, and is walking around the surgical bed, it often occurs that the surgeon un-accidently activates the monopolar handheld that is located in the surgical area and consequently causes tissue damage. Accordingly, the monopolar handheld has been designed to be button controlled.

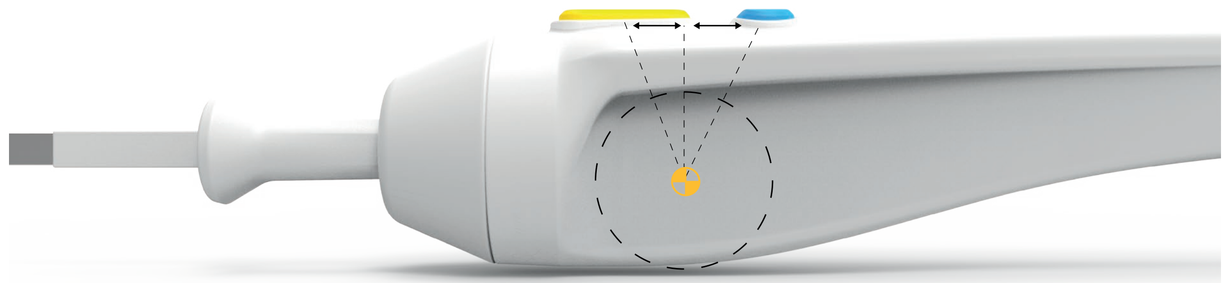




Professor Dr. Obimbo experimenting with different sizes and tactile positioning of the activation buttons

4.2 Design of the **Monopolar handheld**

user-interaction



Design of the control panel
Although button controlled systems already exist in the world of electrosurgery, the waveform modes are often misused as a result of improper button activation and a lack of knowledge. Despite the fact that the buttons have a contrasting standardized colours (yellow for cut and blue for coagulation), the operator often activates the button that is in most ergonomic reach. Therefore, the newly developed monopolar handheld will include an integrated control grip to secure the hand position in such way that the activation fingers are in ergonomic reach of both buttons.

Additionally, this controlled grip is positioned in such way that when activating either the cut or coagulation button, the centre of mass will remain stable and will not tilt forward or backward, as could be experienced in competitive products for either one of the activation buttons. Nevertheless, the distance between both buttons should be sufficient enough to prevent for incorrect activation. In general, African surgeons have substantial hand and finger sizes and a sufficient distance is required without losing this ergonomic reach, according professor Obimbo.

During surgery, the operator consistently cuts prior to coagulation. The cut mode is used for precise procedures which intuitively demands for a close distance between the activation finger and the electrode tip. The coagulation mode is used to coagulate blood vessels that have just been cut. Consequently, the Kenyan surgeons experienced the cut mode in front as being more intuitive in use.

The waveform buttons will have tactile differences related to their thermal effect on tissue. A different sensation between the buttons will – after a small learning curve – reduce the number of checks on correct button activation, according to the majority of surgeons. Hence, this creates a retained focus on the surgical area.

4.2 Design of the **Monopolar handheld**

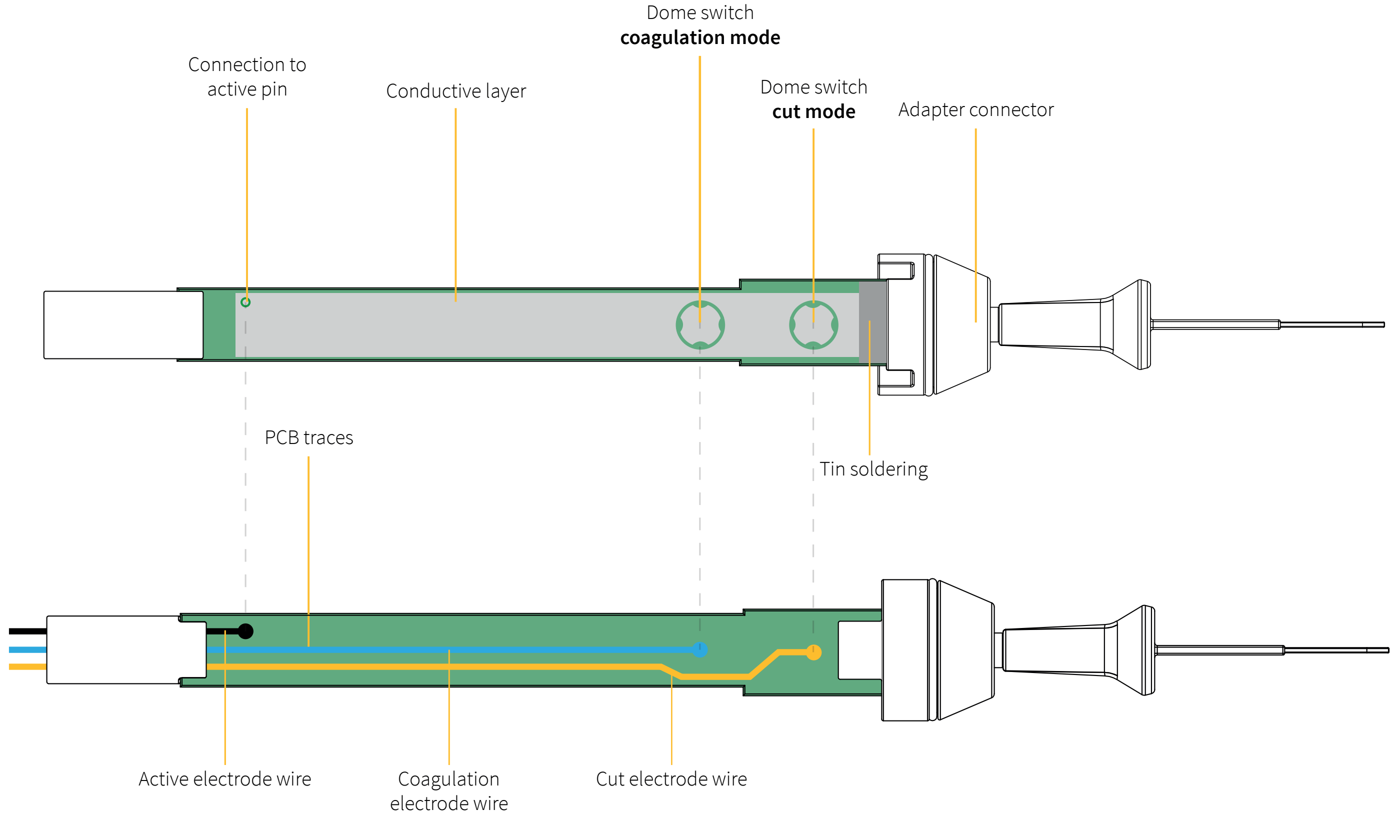
component selection and functionality

The space claim of the handheld has been designed by incorporating the ergonomic and intuitive user interaction of the operator with the handheld. The initial space has been designed based on the preferred size and shape to enhance control and intuitive activation of the buttons. In case the operator activates one of these buttons, for instance cut mode, the dome switch underneath this button will be pressed and deformed until contact with the printed circuit board (PCB).

The PCB will send this signal from the electronic wire and 3 pins REDEL connector (cut mode pin, coagulation mode pin and active pin) to the high frequency generator which processes this signal into the desired waveform output and appurtenant sound (cut mode low frequency sound, coagulation mode high frequency sound).

This waveform output is transferred from the high frequency generator to the active electronic wire that is connected to the PCB. The adapter connector is connected with soldering tin to the traces on the PCB, that are connected to the active electronic wire. From here the output is transferred from the plug connector to the electrode tip and electrosurgery is achieved.

The component selection of the handheld has been based on reliability and consequently dome switches have been selected. Dome switches are known for their long life, tactile feedback and low contact resistance (ARC-USA, 2009). However, the desired tactile feedback of these dome switches should still be researched based on deflection force characteristics.



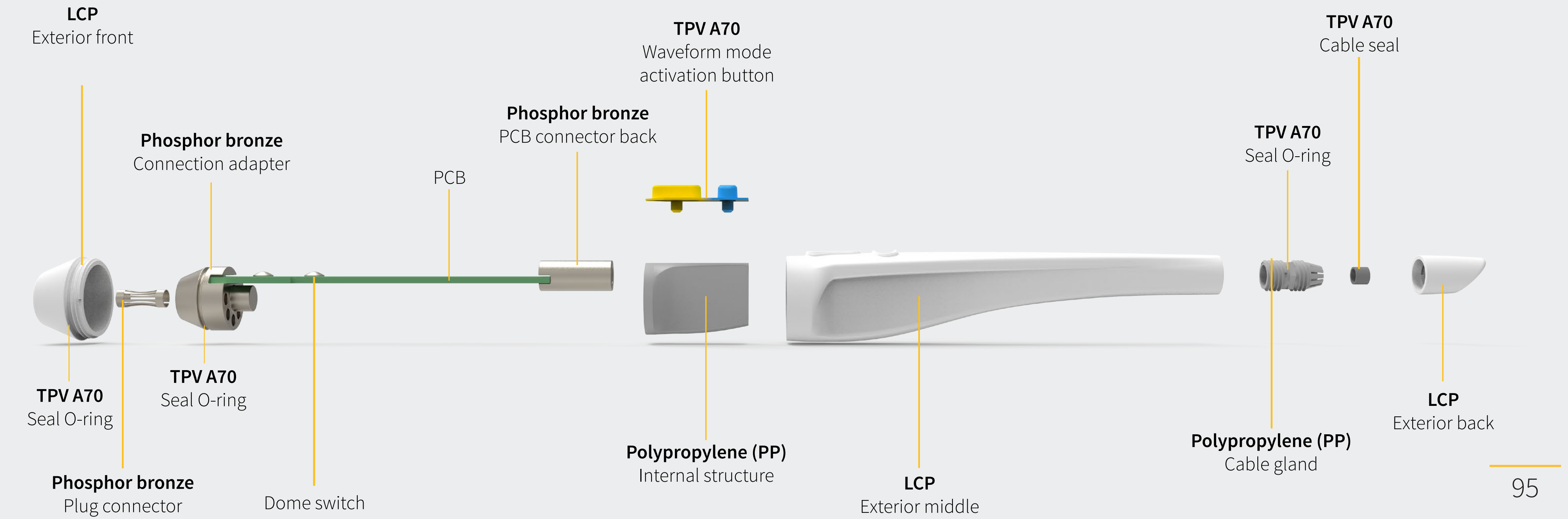
4.2 Design of the **Monopolar handheld**

materialization

One of the key challenges of sustainable success of the ESU system is a reliable design of the monopolar handheld against the high voltages and cleaning procedures used in LMICs. Consequently this has considerable impact on material selection of the parts that are exposed to these cleaning procedures. For all parts exposed to the aggressive cleaning detergents it is important that the material will not degrade after frequent re-sterilization.

The strong alkalis used to clean the monopolar handheld and the required high melting point of steam autoclavation enormously reduced the available materials. Besides, the material should have a sufficient dielectric strength to prevent for insulation breakage because of the high voltage peak. Accordingly, all conductors should have rounded edges to prevent for high current concentration. The material selection can be found in the section below. The specification sheets of the used materials can be found in appendix K.

The selected material for the exterior parts (front, middle and back) is LCP due to its excellent chemical resistance against strong alkalis (PH>10), the availability as medical grade plastic (semi-invasive use) and its sufficient dielectric strength against high currents used in electrosurgery. The dielectric strength of 47 MV/m ensures a resistivity against insulation breakage up to voltage peaks of 70,5 kV.



4.2 Design of the **Monopolar handheld**

materialization

Likewise, the button foil will be exposed to the cleaning detergent but needs a sufficient flexibility to watertight seal the handheld and to create the required travel to activate the PCB dome switches. The material chosen is TPV A70 because of its flexible characteristic, its excellent chemical resistance and frequent use in the medical field. The button foil has been prototyped with shore A80 to experience the elasticity and consequently the button foil required a slight increase of flexibility. In addition, the button foil is an open end in the exterior middle so needs sufficient dielectric strength to prevent for insulation breakage. TPV is resistant up to voltage peaks of 20,3 kV/mm, so sufficient for the used settings of the ESU system. Nonetheless, extensive research is needed to perfectly define the needed flexibility and tactile feedback of the button foil.

Inside the monopolar handheld you can find an internal structure for the button foil which is made of PP to create flexibility for compression of the part and the button foil within the LCP middle exterior. Furthermore, the cable gland is made of PP to create the flexibility needed to seal and compress the insulated electronic Northwire cable.

The adapter connector of the PCB is connected with the PCB and transfers the voltage from the PCB to the plug connector. Both connectors should include excellent electrical conductance (low resistance) to reduce heat generation. As explained in chapter 2.4, the electrode tip will continuously be rotated in contact with the adapter plug connector, thus both parts should include excellent resistance against adhesive wear. Thus, the selected material is phosphor bronze because of its frequent application in RF components, excellent galling resistance and chemical resistance against the used cleaning detergents. Furthermore, this material is available in sheet metal and can be cold formed to the desired shape of the plug connector.

For the soldering connection of the PCB with the front connector tin will be sufficient against the high temperatures of the steam autoclavation. Subsequently, the Northwire cable and REDEL connector will be supplied by LEMO and have excellent resistance against autoclavation and the alkalis cleaning detergents, according to the representative of LEMO. See appendix K for all selected materials.

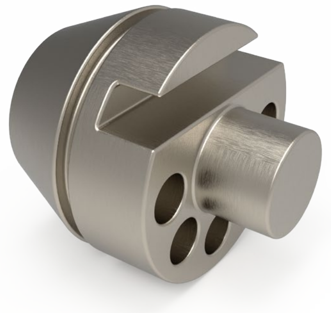
4.2 Design of the **Monopolar handheld**

manufacturability

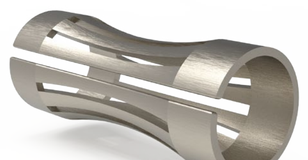
The main challenge is a watertight connection between the middle exterior of the monopolar handheld and the activation buttons. These buttons have to be flexible enough to generate motion – to achieve the needed travel to activate the dome switches – and maintain sealed against the pressure during the autoclavation process.

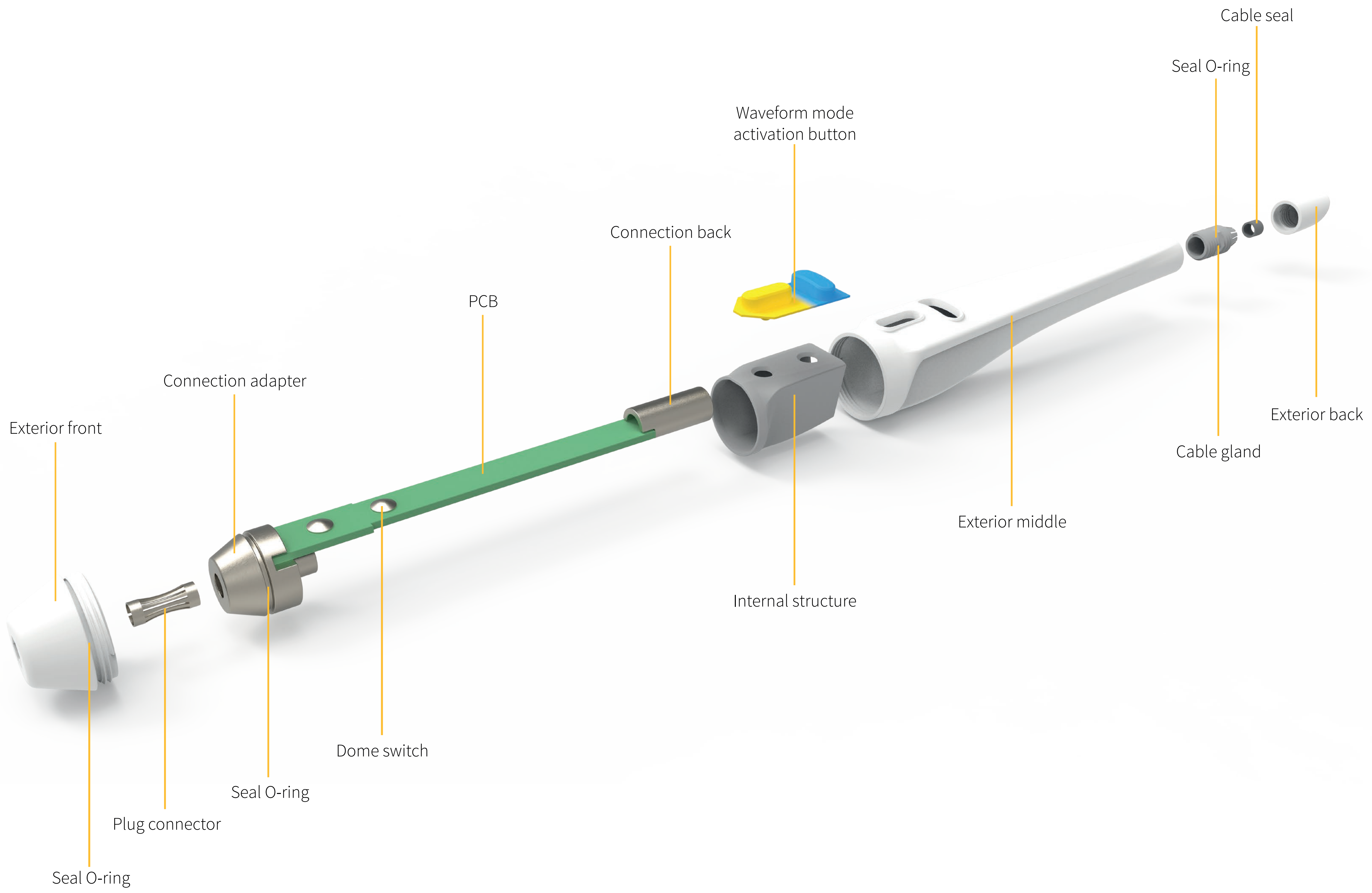
The initial idea has been to seal the two buttons by multi component injection moulding. However, three different materials will be needed (exterior LCP, yellow TPV A70 and blue TPV A70) and consequently this will result in high production costs of the monopolar handheld. Accordingly, a button foil will be created with the material TPV A70. The button foil will be 2K injection moulded, which will lead to a gradient between both components which will be covered by the exterior of the monopolar handheld. The exterior parts (front, middle and back), cable gland and internal structure will be injection moulded as well.

The electrical connection parts (adapter connection and PCB back connection) will be manufactured by turning and milling. The adapter connection part will be used to transfer the electricity from the electric cables to the connector plug and electrode tip and therefore the adapter connection part should not consist of sharp edges that can create current concentrations.



The adapter plug will be manufactured by laser cutting, roll forming and cold forming. At first the leaf springs will be laser cut out of the phosphor bronze sheet metal. Hereafter, the sheet will be roll formed to the desired shape with an open end. Contrarily to radio frequency banana plug connectors, the roll formed shape will be cold formed in such manner that the leaf springs will be formed inside.



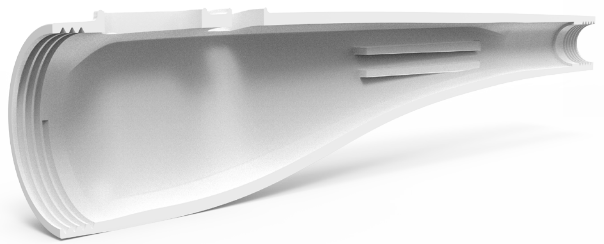


4.2 Design of the **Monopolar handheld**

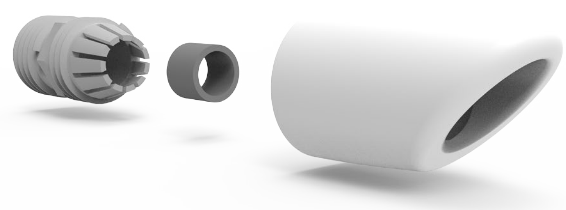
assembling

The middle exterior is connected with the cable gland, internal structure and the button foil. The brain of the monopolar handheld can be found in the internal electronic components consisting of the parts that can be seen in figure component selection and functionality. The plug connector is pressed inside the adapter connector by compressing the open ends and ones located the plug connector will be locked by virtue of expansion against the walls of the adapter connector. The adapter connector is assembled with the PCB by a guiding edge which is soldered with tin.

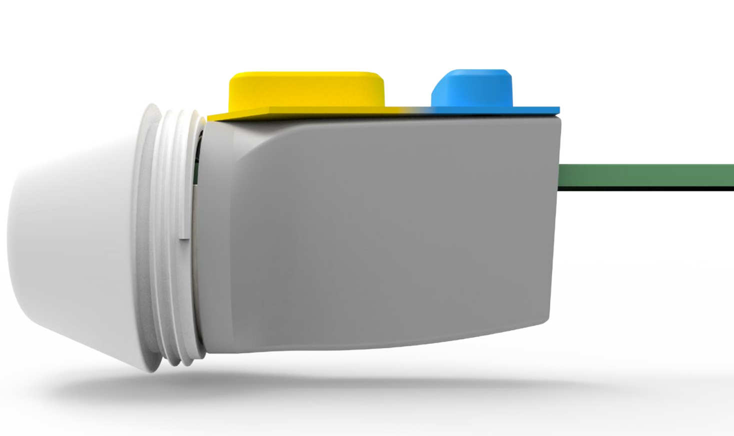
The electronic cable will be connected to the PCB prior to assembling the internal components with the middle exterior part. Henceforth, the PCB will be slid and positioned into the middle exterior by virtue of guiding edges at the end of the middle exterior part. These guiding edges are positioned in the back of the middle exterior to provide for the needed freedom while assembling.



The biggest challenge has been to seal the open ends of the monopolar handheld against the extreme conditions of the steam autoclave. Accordingly, the handheld middle exterior has been designed to be axial at both ends of the handheld, to ensure a watertight seal by using (O-) seal rings that are resistant against the high pressure (2 bar) of steam sterilization. The electronic cable is mechanically compressed between the cable gland and the seal ring and locked by screwing the back exterior against the cable gland. This cable gland functions as a seal as well as a strain relief. To seal the open end between the middle and back exterior an O-ring is used that is compressed while assembling.



The button foil of the handheld will be sealed by compression of the internal structure part. Hence, the top shape of the handheld should be relatively flat to create a sufficient seal. The front exterior parts is used to close the assembly and compress the internal structure and button foil against the walls of the middle exterior



Nonetheless, the seal rings and flexible button foil will require more testing and engineering on the material flexibility and tolerance between the inter enclosures to fully ensure a resistance against the pressure of the steam autoclave. However, the technology is proven and assumed to be reliable.

4.2 Design of the **Monopolar handheld**

safety & reliability

The design measures integrated in the monopolar handheld to increase safety and reliability of the electrode tip are presented below.

Clinical risks & insulation failure

Perhaps the most important requirement for a sustainable ESU system is a reliable monopolar handheld against frequent re-sterilization with the various cleaning procedures during or after the surgery. This will take away the risk of insulation failure and infection risks between patients and the operator. The challenge has been to develop a monopolar handheld (including cable and connector) that is resistant against the extreme cleaning conditions explained in chapter 2.4.

Most times, either the handheld, cable or connector is not resistant against these extreme conditions which means if one of these parts break the ESU system will stop working. Besides, when one of these parts is not resistant against the various cleaning procedures, there is a high probability that hospitals will improvise with cleaning methods what can increase possible contamination risks (Raykar, 2016).

Hence, a reliable system has been designed wherein the electronic Northwire cable is fully integrated in the handheld by using a cable gland system that water tights the cable with a sealing sleeve and lock by virtue of the back exterior part. The back exterior has been designed as perfect fit for the cable diameter and the outer radius will prevent for a dirt trap. The end of the cable is sealed in a similar manner by using the REDEL connector that is resistant against the chemical detergents and reliable for frequent sterilization. For specification of this component, see appendix K.

Another advantage of the REDEL connector is the self-latching system that ensures absolute security against vibration, shock or pull on the cable and facilitates in a limited space. This will ensure that the cable will not fall out during the surgery or will be improperly connected, something experienced by various Kenyan surgeons.

Cauterization risks of the electrode tip

The handheld is designed to be tapered to increase ergonomics when positioned in the hand and to take away the risk of cauterization burns. As explained in the user journey of the ESU system, the handheld is often not used during the surgery because other surgical equipment is needed. Frequent activation of the handheld, heats up the electrode tip, introducing cauterization risks with tissue in adjacent to the electrode tip. The tapered design of the handheld will eliminate this risk since the electrode tip will at all times be positioned upward. This will result in less checks of the surgical team on possible cauterization risks and confidence of laying down the handheld. Besides, the triangular shape results in a stable position of the handheld on the surgical area, so reduces the possibility to roll off during the surgery.

Furthermore, the adapter connection is designed to minimize heat up by introducing cooling holes. Accordingly, the electrode tip will heat up less rapidly. Besides, these cooling holes will function as weight reduction of the handheld, which should be as lightweight as possible.

Corrosion risks

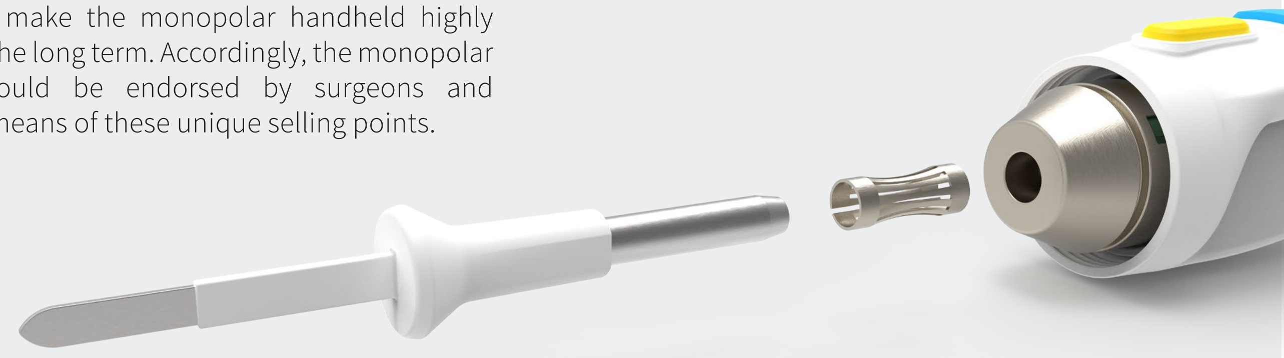
One of the essential reliability issues connected to the design of the high frequency generator is the prevention of corrosion on the connectors. Corrosion increases the resistance for current to pass through the connectors and consequently a higher power setting is required for a similar electrode tip output. During field study in the Kiambu District hospital, it has been experienced that the starting power of the high frequency generator is regularly set with 40 W, which is extremely high for sensitive general surgeries. By means of corrosion the surgical team has to use unnecessary high power settings which can result in material degradation of the electrode tip and insulation failure.

Besides, corrosion failure will make the provided guidelines on the high frequency generator useless, which will be counter intuitive and a big risk for clinical outcomes. Accordingly, the adapter connector and connector plug have been designed to take away corrosion when rotating the electrode tip. The leaf springs will function as a scraper of corrosion on the electrode tip.

Cost price estimation

The costs for the monopolar handheld have been roughly estimated by using the cost estimation framework of Hals and the bill of materials. The total price of a single monopolar handheld is estimated on €40,30 based on a total badge size of 3000 (3 handheld mandatory per operation theatre), see appendix I for BOM.

The monopolar handheld has been designed with the vision to have lower running costs than competitive products. The monopolar handhelds initial procurement costs are similar to competitive products but the intuitive and ergonomic interaction and excellent resistance against cleaning procedures in LMICs will make the monopolar handheld highly affordable in the long term. Accordingly, the monopolar handheld should be endorsed by surgeons and marketed by means of these unique selling points.



4.2 Design of the **Monopolar handheld**

prototyping

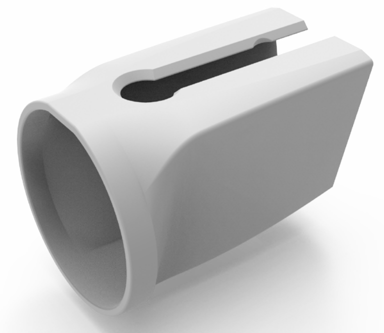
Throughout the project multiple prototypes have been made of the monopolar handheld and iterated by means of co-creation with surgeons in the Netherlands and Kenya. These iterations steps included space claim, ergonomics, intuitiveness and feeling of reliability. Subsequently, this extensive iteration resulted in two final prototypes: a functional model which includes all internal electronics to perform electrosurgery and a visual model which included the intended aesthetics and internal components, see image on the lef for the functional prototype.

The functional model has been prototyped to solely present the user-interaction throughout a surgery and not to perform actual surgery. Although the functional prototype is designed to perform actual surgery, the handheld should be tested in a lab setting on dielectric strength and possible insulation breakage prior to electrosurgery.

The internal switches of the cut and coagulation mode have been connected with the REDEL connector, so the high frequency generator can receive activation input and activate the speaker accordingly. Hence, this prototype can certainly be tested with the target group on user interaction. The functional model is not watertight because the pressure of the O-rings will result in breakage of the brittle 3D print material.

Subsequently, the cable gland did not create a sufficient compression partly because of the 3D print material and partly because of the design. Accoringly, the cable gland has been redesigned for an enhanced compression of the cable.

The internal structure created a sufficient compression of the button foil but should be redesigned for assembly by including a guiding line for the button foil. Otherwise, the bulges on the button foil will either block or break while assembling. However, this guiding line introduces problems with compression since the back of this parts will start to compress. Accordingly, a small rib at the end of this guiding lines is introduced to maintain a sufficient compression.



In the prototype an electronic cable has been used – with a comparable elasticity as the intended Northwire cable – to experience the impact on use ergonomics. Consequently, the metal connection back has been experienced as redundant since the electronic cable provides a sufficient force to balance the monopolar handheld while operating. Moreover, a possible future development could be a rotating back exterior – as experienced when not using an O-ring – to remove the counterforce while rotating the handheld. However, this might involve a possible dirt trap thus this will need further research. For more photos of the prototypes see appendix L.

4.3 Design of the **electrode tip**

user-interaction

As mentioned before, the focus of the electrode tip has been on the 15 essential surgeries. During the field study in Kenya the most generally used electrode tip has been discussed by showing the four most commonly used electrode tips (spatula, needle, loop and ball electrode). All surgeons explained that the spatula electrode is most frequently used and sufficient for all general surgeries. The spatula electrode has the benefit that it is multifunctional by means of its shape. The thin edge is used to cut tissue and the flat side is used to coagulate tissue. The electrode tip has been innovated by analysing the usage during a surgical procedure and how this might benefit intuitiveness and risk reduction.

Main design requirements

The main design requirement influencing the design of the electrode tip can be found below. The complete program of requirements can be found in appendix E.

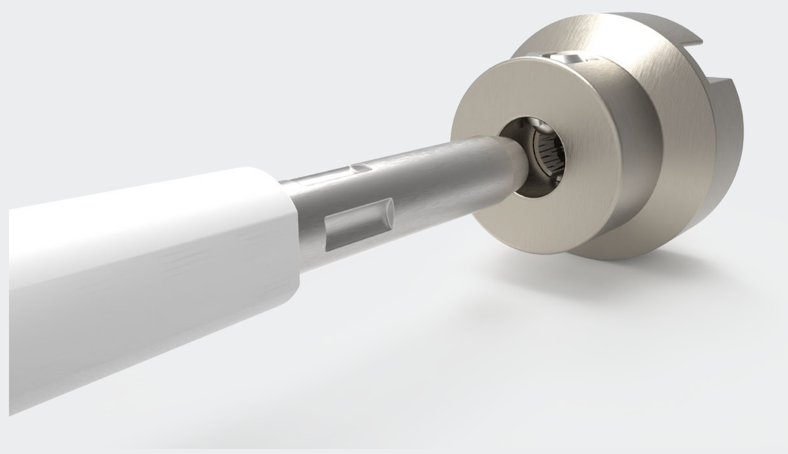
- The reusable electrode tip should be easy and quick to replace without being loose when performing a surgery
- The electrode tip should be rotatable when connected to the monopolar handheld
- The electrode tip includes a plastic surface which enables rotation of the electrode tip
- The electrode tip should enable a cut surface, coagulation surface and micro cross sectional area surface
- Each reusable electrode tip has a product life span of approximately 500 autoclavation cycles, thus 500 surgical procedures
- The adapter connection, plug connector and electrode tip should be resistant against adhesive wear and corrosion because of the agressive cleaning procedures used in LMICs
- The materials of the electrode tip should be resistant against the cleaning procedures and cleaning detergents in LMICs, see appendix C
- The electrode tip should prevent eschar build-up, which increases resistance and contributes to arcing
- All invasively used parts should include medical grade material according to Medical Design Directive (MDD)
- The connection shaft of the electrode tip is standardized with a diameter of 4 millimetres
- The spatula electrode should have similar measurements as the competitive spatula electrodes, thus a length of 25-40 millimetres and a thickness of 0,5 millimetres

User-interaction

The user interaction with the electrode tip should be intuitive and safe. As analysed during the use phase, the electrode tip can preferably be rotated during the surgery. In some cases the needed hand rotation to cut is unergonomic and consequently the operator wants to rotate the electrode tip. Besides, the controlled grip that is created in the design of the monopolar handheld will increase the need to rotate the electrode tip, since rotating the monopolar handheld will be impractical. As explained in the design of the monopolar handheld, the adapter connection includes a connector plug with leaf springs. Accordingly, these leaf springs will function as a scraper of corrosion and consequently will automatically take away corrosion during use.

Snap clicks while rotating

One of the concepts to increase control while rotating the electrode tip is by integrating rotation snap clicks of a ball plunger. In this way the operator will at allt imes receive a control feedback that the electrode tip is rotated in the required 0 and 90 degrees position instead of guessing the position with the naked eye. The ball plunger will be screw connected to the connection adapter and sealed with an O-ring. These micro ball plungers are low cost, easily available and experienced as added value by the Kenyan surgeons. However, during the explorative study there were many concerns regarding clinical risks of dirt inside the camber of the ball plunger. Therefore this concept has been neglected for now although this is worth researching for future development.



Increased current density

Simply the top part of the spatula electrode is used to cut and coagulate tissue during surgical procedures. When performing a surgery deeply in the abdomen it often happens that the sides of the electrode tip start arcing on the tissue walls. Therefore, it will be highly beneficial for clinical outcomes to insulate all the surfaces that are unused for surgery, according to Dr. Hansen.

During the surgery the flat side of the spatula electrode is regurarly used to connect with the surgical tweezers. In this way, tissue can be grasped in between the tweezers and activated in contact with the electrode tip. The tweezers are mostly activated on the top, thus to enhance a sufficient contact area the electrode tip should at least provide a contact area of 10 millimetres, since this is the regular width of the surgical tweezer. Accordingly, the spatula electrode can be insulated up to 10 mm from the top.

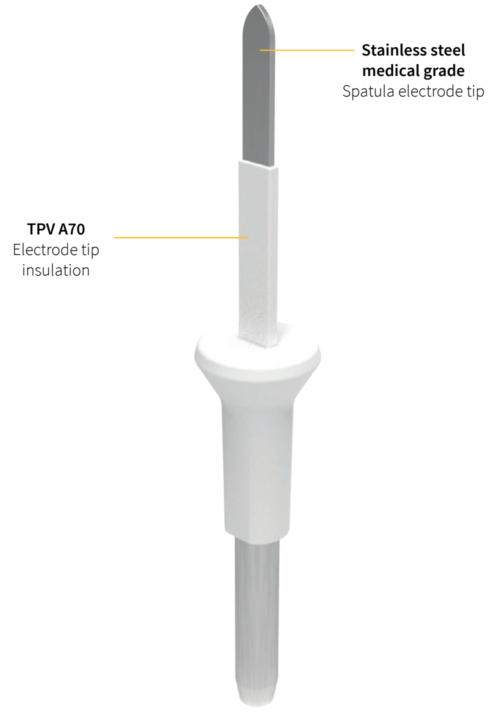
The maximum power of the ESU system will not exceed 70 watt since this is sufficient for the 15 essential surgeries. However, in some cases a higher current concentration is preferred to increase coagulation effect without increasing the power. In such cases the needle electrode is used because of its small cross sectional area. However, during surgery the operator often gets hurt by the needle through the rubber gloves when grasping the monopolar handheld. This is a tremendous risk in sub-Saharan countries considering the high presence of AIDS, HIV and other harming diseases. Consequently, the Kenyan surgeons never use the needle electrode because of the possible cross-contamination risks. Accordingly, a multifunctional electrode tip is created by integrating a small cross sectional top area on the electrode tip that is stump enough to not harm the operator.

4.3 Design of the **electrode tip**
technical information

Component selection & functionality
The shaft diameter of the electrode tip in contact with the connection adapter and connection plug is decided to be 4 millimetres because of the compatibility with other electrode tip. This enhances the possibility to use other electrode tips and increases sustainability of the handheld in case the hospital stocks out of our electrode tip (consumables).

Materialization and finishing
Similar to most parts of the monopolar handheld the electrode tip is exposed to high current and the aggressive cleaning procedures. During surgery the electrode tip will be frequently rotated when in contact with the connection adapter, thus prevention of adhesive wear and chemical resistance are of high importance. Subsequently, the electrode tip enters the body into a body cavity and consequently the electrode tip is invasively used according to the Medical Design Directive (MDD). Hence, the electrode tip both materials of the electrode tip should be medical grade to meet the MDD standards.

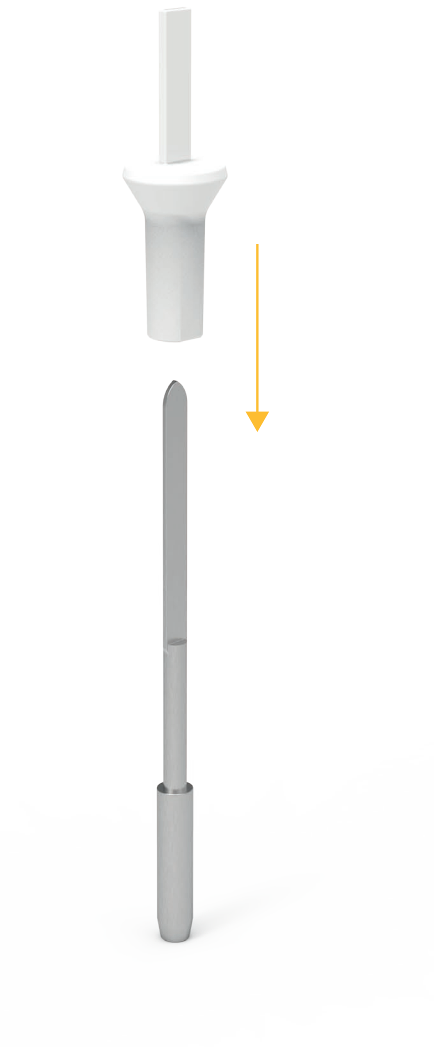
There is a high possibility that other electrode tips will be used beside our designed spatula electrode since there is a huge variety of electrode tips available in the market. These competitive electrode tips are made of medical grade stainless steel and consequently our developed electrode tip will be made of equal material. Despite the fact that phosphor bronze has a better electrical conductance, so less electrical resistance and less heat generation within the part, a change of material will result in a different system output. Hence, the reliability of the provided guidelines on the high frequency generator will be maintained when using compatible electrode tips.



Furthermore, phosphor bronze is currently not used as a medical grade metal. Other possible material to use is titanium due to its high resistance and frequent use in the medical world. However, titanium has more than double the electrical resistivity of stainless steel which will lead to an increase of heat generation when activating the handheld and will again result in an unreliable system output when using competitive electrode tips.

The material of the electrode tip insulation will be TPV A70 because of the availability as medical grade plastic and rubber like resistance which is desired in regard of wet gloves during the surgery. The thickness of the insulation layer should be at least 0,5 millimetres to be resistant against the voltage peaks of 3 MV/m.

Manufacturability
The medical grade stainless steel parts of the electrode tip will be casted, hardened and polished to prevent for edges that can lead to eschar build-up. The insulation of the electrode tip will be injection moulded. Henceforth, the plastic parts will slide over the metal electrode tip and will be connected by vibration welding. The metal and plastic part are frictionally heated by pressing them together and vibrating the metal part. During vibration welding a pressure tight joint is created, which is important for clinical risks between the metal and plastic part.



Assembling with monopolar handheld
The electrode tip will be assembled to the monopolar handheld by connecting the bottom part of the electrode tip with the monopolar handheld connection adapter. As explained in the design of the monopolar handheld, the electrode tip will be clamped by the pressure of the plug connector into the adapter connector. The leaf springs exert pressure to the electrode tip which creates a sufficient and safe resistance for no drop out while operating.

Safety and reliability in LMICs
The design measures integrated in the electrode tip to increase safety and reliability of the electrode tip are presented below.

- The hardened and polished stainless steel has excellent reliability against the cleaning procedures and adhesive wear and consequently this will take away the contamination risks and uncomfortable build-up of eschar during the surgery.
- The increased insulation of the electrode tip will reduce the risk of direct coupling and unintended tissue damage since the tissue spread will be solely focussed on the targeted tissue.
- The additional small cross sectional area will take-away the need of higher power settings, thus less risk of unintended tissue trauma or trauma on the surrounded sensitive organs.

Furthermore, a small cross sectional area will be achieved without possible cross contamination between the patient and the operator.

Cost price estimation
The costs for the electrode tip have been estimated by using the cost estimation framework of Hals and the bill of materials. The total price of a single electrode tip is estimated on €7,00 based on a total badge size of 10000 pieces, see appendix I for BOM.

4.3 Design of the **electrode tip**

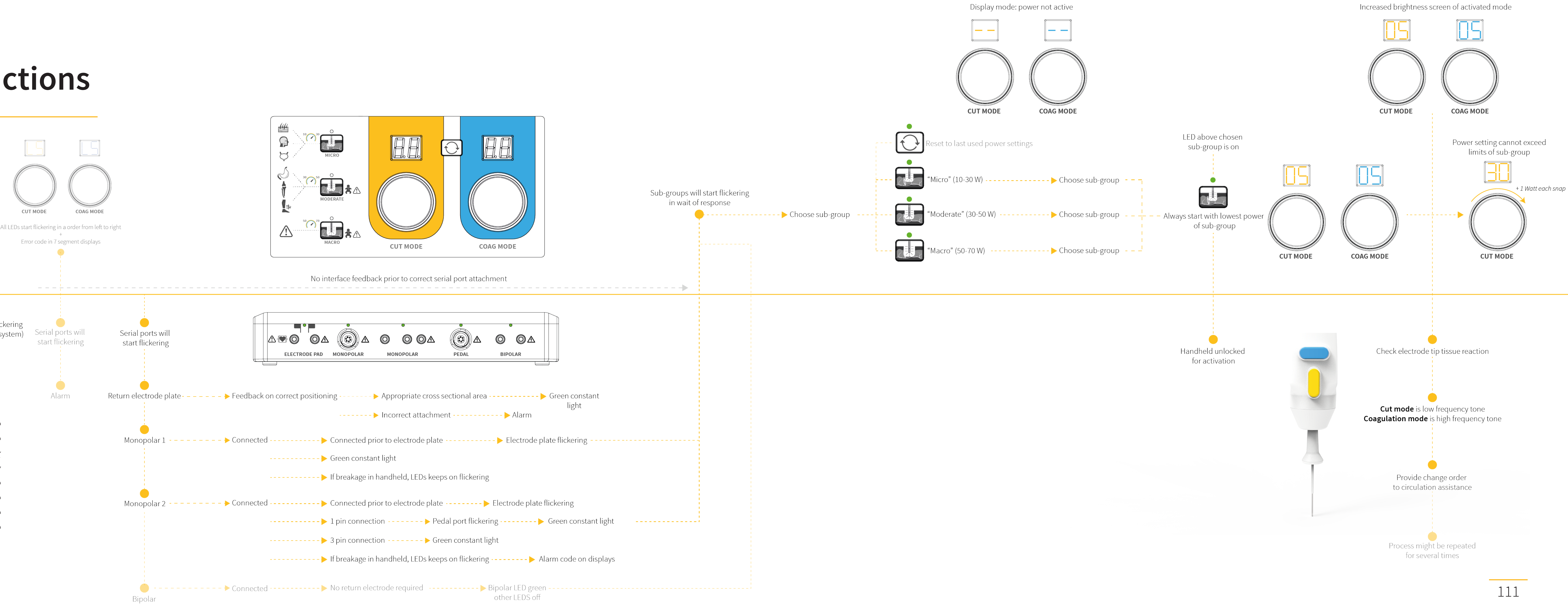
prototyping

Several trial and error tests have been prototyped to find the optimal pressure between the electrode tip and connection adapter by iteratively milling the inner diameter of the connection adapter. The pressure should create enough resistance to prevent for a slide out of the electrode tip during surgery and should be smooth enough to empower rotation of the electrode tip. The spring leaf part of the conventional banana plugs is used and attached around the electrode tip to reproduce the reversed banana plug. A diameter of 4,7 millimetres with an integrated reversed banana plug connector with a thickness of 0,3 millimetres will create the desired resistance.

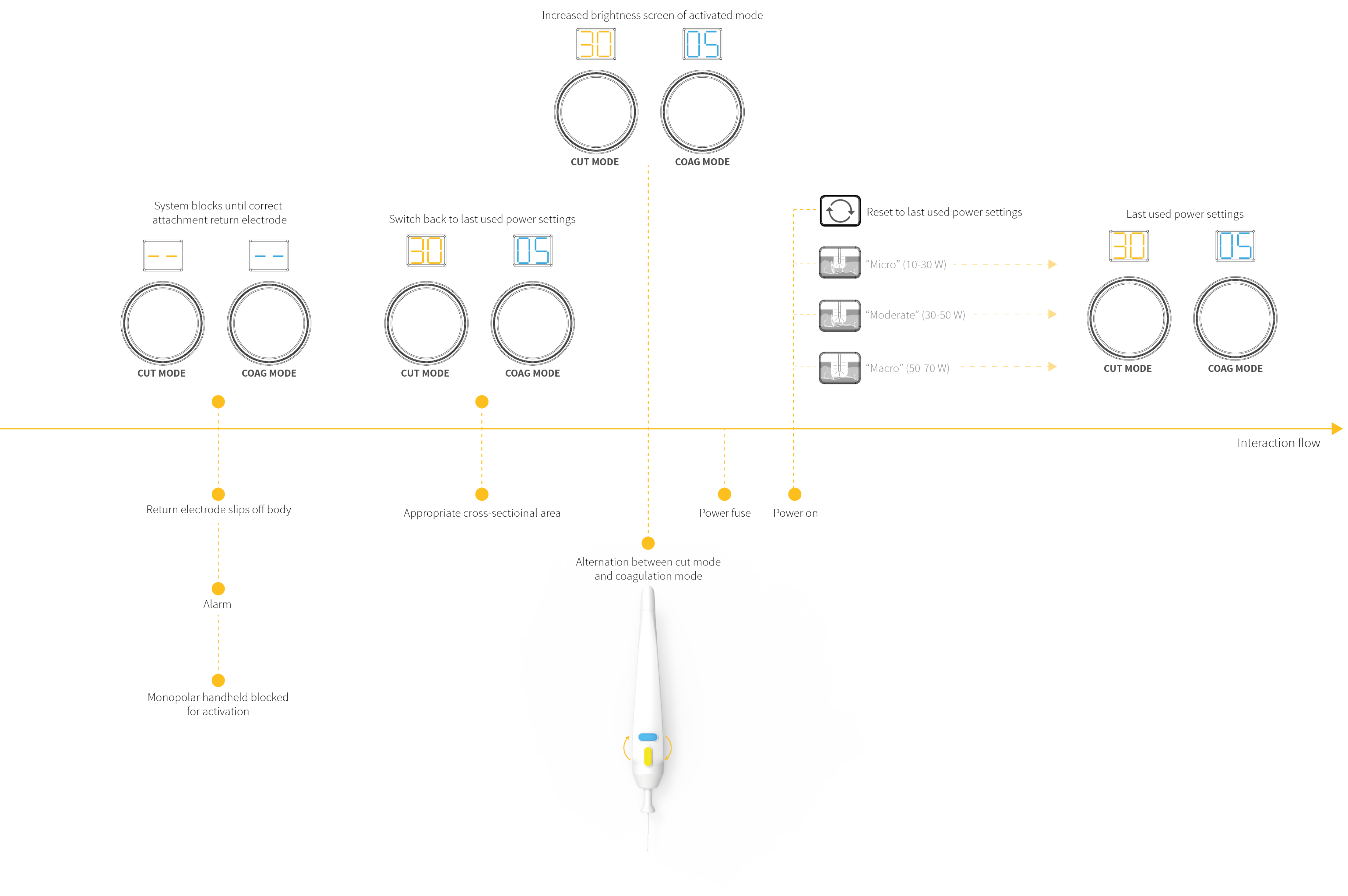
Furthermore, the spatula electrode has been visually prototyped to experience the measurements and total visibility of the monopolar handheld. The electrode tip has been prototypes by milling the shaft and by filing sheet metal to the required shape. These parts are interconnected with glue since the parts have been too superficial to weld and consequently the electrode tips cannot be used for electrosurgery tests.

5. ESU system **interactions**

how does the total system interact



In this section an explanation will be provided on how the ESU system works during a surgical procedure by virtue of a workflow. This will show what essential feedback moments will be provided to the user and how the new ESU system increases safety and intuitiveness. The middle line illustrates the surgical workflow in time. The interactions above this line are provided by the interface and the interactions below the line are provided by the serial ports or products connected to the serial ports.



6. Recommendations

for future development

According to the results of prototyping and the corresponding field study in Kenya, the design has been adjusted as described in the chapter "Development of the ESU system". Nonetheless, there are more future improvements and recommendations for the ESU system to create a sustainable success. Suggestions discussed in this section have been derived from the prototypes, explorative study in Kenya and the final design of the ESU.

Strategy for successful future implementation

During the field trip in Kenya there has been contact with the president of COSECSA and multiple members of the Society of Surgeons in Kenya. From a strategy perspective it is recommended to conceive endorsement of these surgical organisations that have a substantial power in LMICs. A successful example has been the anaesthesia machine developed by Diamedica that is endorsed by the WHO. Accordingly, this resulted in the best marketing conceivable and a successful implementation of the product to the global market of LMICs. The first seeds have been planted, soon it will be time to continue the growth of future collaborations.

Moreover, it is recommended to dismiss possible procurement barriers of the qualification by the (county) governments by means of collaboration with a qualified supplier of the targeted LMIC (e.g. Harleys in Kenya). Hence, this will dismiss issues with bureaucratic tenders of the government. Furthermore, it is suggested to expand the market of the ESU system to other LMIC countries around the globe or disaster and war areas because of its portability and reliability against harsh contextual conditions.

Subsequently, create a focus on educational purposes since the developed ESU system expands knowledge on correct usage of power settings. In the end, educational systems are the roots of future surgery thus a possible foundation of early stage brand bonding.

Future engineering improvement of the design

The goal of this project has been the creation of a trade-off ESU system that makes electrosurgery accessible for LMIC and consequently the new phase of development of the ESU system will need several detailed engineering adjustments prior to production.

High frequency generator

In view of the high frequency generator, the next step will be on design for manufacturing and assembly of the exterior parts based on the regulations of medical product development. This includes development in such manner that water can never enter the electronic through parting lines between connected parts.

A potential way to solve this is to not create a guiding edge on the plastic exterior parts but by creating a guiding edge on the sheet metal parts that move inside the front and back panel (see appendix A for a likewise approach of Valleylab). This will take away the non-uniform wall thickness of the front and back panel as consequence of the currently guiding edges. This will cause problems with sink marks when being injection moulded.

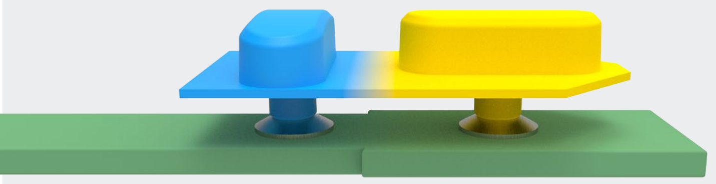
Monopolar handheld

The main challenge concerning manufacturability of the monopolar handheld will be the development of the correct elasticity shore of the button foil to create the required travel for an intuitive activation of the dome switches on the PCB. This elasticity should be high enough to create a sufficient travel for tactile feedback and should be strong enough to withstand the conditions of the high steam pressure of the steam autoclave. Besides, the designed connection seals should be engineered to ensure a resistance against steam autoclavation. Subsequently, for all autoclavable accessories the expansion ratio should be researched to see whether the high temperatures of autoclavation affect the design.

6. Recommendations

for future development

In addition, it is recommended to further analyse the REDEL connector on full resistance against all used cleaning detergent in LMICs. The manufacturer indicated that the REDEL connector is highly resistant against strong alkalis but could not fully promise resistance for over 100 cleaning procedures.



"For all products of the ESU system it will be highly interesting to further explore the possibilities of producing or assembling in one of the sub-Saharan countries (e.g. Kenya). In this way, all spare parts will be centrally available and this will empower national labour. For the future brand this can result in positive marketing and possibly remove import and regulation problems"

Changes in user interaction

High frequency generator

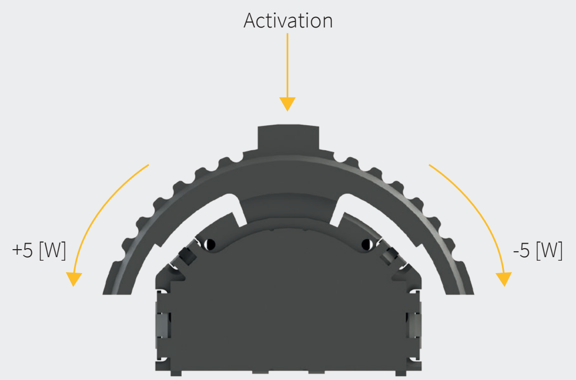
The resistance of the snap gears inside the rotary encoders should be researched and increased to create a better tactile feedback for the user while changing the power settings. This tactile feedback is currently provided by an integrated gear inside of the rotary encoder which is determined by the manufacturer. Besides, the resistance is influenced by the diameter of the power knobs, a larger diameter will lead to an increase of momentum and consequently a decrease of tactile feedback. Various rotary encoders should be studied on the intended tactile feedback and selected accordingly.

Furthermore, the selected surgery symbols on the interface could be analysed more extensively by setting up a quantitative research on understanding with a variety of cultures. Accordingly, iterations on the symbols might empower the intuitiveness of the design.

Monopolar handheld

The used Northwire cable connected to the monopolar handheld is more tough than the available disposable monopolar handhelds, so this could be experienced as less freedom of movement by the target group. However, the cable provides an ergonomic equilibrium of mass when positioned in the hand. Therefore, it is recommended to further analyse the possibility of creating more elasticity in the cable and experience how this affects the weight distribution. Nonetheless, the material should at all times be resistant against the used cleaning procedures in LMICs

Subsequently, along the field trip in Kenya it is often announced by the intended target group that individual power change by the operator might be of great benefit because of the lack of surgical staff, thus increased time for power change, and an increased control over the surgical procedure. A concept has already been developed on power change by using a multifunctional jog lever switch (see appendix M). The possible intuitive power change and limited measurements make it a worthy problem to tackle.



Return electrode

The user interaction with the return electrode has been analysed although the return electrode has not been part of this development project. The return electrode is positioned at all times prior to the surgery despite monopolar or bipolar surgery (not required). Therefore, it is recommended to include safety precautions on both sides of the return electrode to attend the surgical staff on possible risks prior to each surgery.

Internal components

The development of the internal electronics has another time schedule as my graduation project and consequently after this project knowledge sharing is needed to create a total functional concept which can be easily manufactured and assembled.

The weight of the internal components of the high frequency generator should be optimized for easy movability with the high frequency generator. The internal components are developed by another graduation student of 3ME in consultation with DEMO and consequently the system architecture might need changes according to weight distribution for ergonomic use. Therefore, there will be more knowledge sharing between Koen Ouweltjes, DEMO and 3ME after graduating.

Furthermore, heat simulations along the surgery should be examined on both the high frequency generator and monopolar handheld. By incorporating the high temperatures in sub-Saharan countries it can be studied whether the current cooling block, air flow and adapter connection are reliable against a maximum power continuous activation period of 30 seconds. If not, make design changes on the heat sink and airflow accordingly.

ESU system selection

When bringing the ESU system to the market it is important to know what products should be included for a sustainable functioning ESU system in various LMICs operation theatres. To provide a consistent workflow of used equipment it is important that each operation theatre that uses the ESU system can be equipped with at least three of the reusable accessories (monopolar handheld, return electrode, etc.). Accordingly, one accessory can be used during the surgical procedure, one accessory can be used as back-up if for instance the accessory breaks or drops on the floor during the surgery and one accessory will be cleaned with cleaning detergent of an autoclave at the time of the surgery.

Moreover, the ESU system should include at least ten extra 5x20 millimetres power fuses because of possible breakage, include the assembly allen key for maintenance of internal components and include an intuitive user manual that will be developed by another student of the faculty Industrial Design Engineering.

User testing on conference Kenya

At the end of this year Roos Oosting will attend various congresses in Kenya to show the developed ESU system as promotion of her PhD and for feedback on reliability, user-interaction and functionality. The prototype of the high frequency generator has been designed as a boundary object to show the visual appearance and an intuitive and safe user interaction. However, the high frequency generator model is not a fully functional prototype when incorporating the regulations of testing electronic devices with high voltages.

The metal exterior parts should be grounded and the system should be checked on possible insulation breakage through the 3d printed layers. Thus, for functional testing with the high frequency generator it is recommended to create two models: a finalized visual model with user interaction as already prototypes and a to build functional prototype that consists of the internal components and an electrical justified junction box.

6. **Recommendations**

for future development

The junction box should be selected in consultation with DEMO on needed measurements and insulation. The user interface can be integrated in the junction box by laser cutting one of the exterior panels to assemble the needed power knobs, sub-group buttons, LEDs and designed sticker.

Furthermore, the RF connector 6 millimetres serial ports should be replaced with insulated test banana female connectors because of the insufficient RMS values of the used connectors. The current RF connectors are solely suitable for the lowest power mode of the high frequency generator.

In view of the monopolar handheld it is recommended to insulate the internal components with a rubber like insulation tube to prevent for insulation breakage as consequence of the layer build up of the 3d printer. Besides, build extra prototypes because of possible breakage of the fragile SLA 3D print material.

"In general it is recommended to solely test functionality of the ESU system on the micro power setting bandwidth to prevent for possible insulation danger of both the high frequency generator and monopolar handheld."

Regulations

For a successful implementation of the ESU system to LMICs it will be essential to research the national and international regulations and standards for medical product development. Extensive research should be done by a new graduation student on which norms and standards to incorporate in the design in terms of component selection, functionality, repairability (Medical Design Directive, ISO norms, FDA, etc.). Accordingly, mandatory design changes should be incorporated. Additionally, a Failure Modes and Effects Analysis (FMEA) should be made to uncover possible risks.

Design guide for surgical device development for LMICs

It is recommended to create a design guide based on the established knowledge on surgical equipment development for LMICs after this graduation project. This design guide can be used for future development of the ESU system and other possible innovations connected to the product portfolio of a future brand. Besides, this can be interesting for future publications or university projects concerning global health.

As prior stated, LMICs do not just require surgical equipment as good as that used in more developed countries, they require something better, in that it not only needs to function safely for both patient and user, it needs to function in the challenging environments frequently found in developed countries, and all of this in a sustainable manner (Neighbour, 2012).

As experienced during the field trip and researched by Kamstra et all, for situations where existing equipment and devices cannot fulfil the unique needs of LMICs, the process of designing tailored solutions should involve extensive consultation with end-users, as this is critical to promoting correct device use and protecting patient safety (Ng-Kamstra, 2016).

Therefore, the design guide should include various design approaches of co-creating a tailored fit solution with the target group in LMICs. Furthermore, it should include design requirements and boundaries, do's and don'ts when designing for LMICs and various successful approaches on user testing with the intended target group in LMICs.

Sustainability

Empowering the accessibility of electrosurgery for LMICs can positively or negatively affect the three pillars of sustainability: Planet, Prosperity and People. Facts regarding sustainability should be analysed to compare the consequences of the developed ESU system in comparison with existing ESU system and surgery without an ESU system.

The accessibility of a sustainable ESU system will have a positive effect on sustainable development goal 3 of good health and well-being. The ESU system possibly increases life expectancy by reducing the common killers associated with child and maternal mortality as a consequence of no available surgical equipment, blood loss, infections or surgery costs. Hence, facts should be compared which can possibly be used as marketing.

Furthermore, the accessibility of a sustainable ESU system will have a positive effect on sustainable development goal 8 and 10 of decent work and reduced inequalities. The availability of the ESU promotes productive employment and consequently has a valuable contribution to time efficient execution of surgical procedures.

Nonetheless, extensive research is required to uncover positive and negative consequences of the situation with the developed ESU system compared with the existing ESU system and surgery without an ESU system. In example, a life cycle analysis (LCA) should be made and the ESU system will be possibly redesigned accordingly.

Internet of things

As experienced during the field trip in Kenya various innovations are built around the mobile network because of the substantial mobile infrastructure in sub-Saharan countries. To possibly enhance inclusion of the surgical staff and technical staff on a sustainable accessibility of the ESU system it is recommended to analyse possibilities concerning the connection with the internet of things.

An imaginable future step could be an integration of algorithms in the software of the high frequency generator that indicates certain use changes in power setting as a consequence of for instance corrosion on the electronics. This warning could provide the surgical staff with a message and user manual on what procedures to follow. Besides, the information saved about practical use of the ESU system can be used for future development and improvement of the product.

An developed approach and proven technology by Incision care provides the user with 3D animations on the smartphone showing possible safety errors during a surgery and use this info to explain the origin of these problems and how this can be prevented in future surgery. In view of electrosurgery, this will not only enhance safety but increase the knowledge on the principles of electrosurgery as well, according to the interviewed CEO Theo Wiggers of Incision care. It is recommended to exploit knowledge with Incision care and perhaps create a future collaboration since Incision care is interested in expansion of their service to emerging markets.

Expansion of the product portfolio

During the field trip it has been often announced by the president of COSECSA that the development of the ESU system should be the beginning of something big. According to Pankaj Jani, a tailored designed operation theatre should be established with all essential equipment to perform basic surgery. Consequently, it is recommended to use the ESU system as a trade-off to expand the product portfolio. Nonetheless, it is important that at all times the future brand will stay with an initiated vision on for instance empowering the accessibility of safe surgery for everyone and everywhere.

6. **Recommendations**
for future development

Compatible adapter
The biggest problem encountered in LMICs is an unreliable monopolar handheld as a consequence of no resistance against cleaning procedures in LMICs, insulation failure and cable breakage. As could be seen in chapter 2.6, the developed trade off monopolar handheld will solve these problems for the developed ESU system. Consequently, to expand the market of the monopolar handheld and future brand it will be highly interesting to develop a compatible adapter for the available systems in LMICs (Erbe and Valleylab) and future developed high frequency generators. Moreover, this cannot only increase the end of life of competitive products in LMICs but can also be interesting for developed countries since more and more healthcare providers shift to reusable goods.

This compatible adapter will consists of two connectors on opposite sides: a REDEL female connector for the developed monopolar handheld and a 3 pin banana plug connector for competitive machines. Valleylab and Erbe are the most frequently used ESU systems in LMICs. Accordingly, the distances between the banana plug connectors or other type of competitive connectors should be researched more extensively to ensure a compatible system for most ESUs in LMICs.

The adapter will be connected to the high frequency generator thus the material has to be reliable in terms of insulation against the high voltage peaks during electrosurgery. The adapter does not have to be resistant against the harsh cleaning procedures used in LMICs since the adapter is not located in the sterile surgical area during the surgery.

Other possible future products
In this project the focus has been on monopolar surgery. However, the high frequency generator has been designed for connection with other electrosurgery products such as the bipolar handheld and basic laparoscopic devices to be sustainable for a change in used technology in the future. Consequently, to expand the product portfolio of the possible future brand it is recommended to develop such tools by using the established knowledge and design requirements when designing surgical products for LMICs.

Conclusion
of graduation project

The project goal has been to develop a reliable, safe and intuitive user-interaction with the ESU system and a tailored design for maintenance in a variety of use-contexts in LMICs. The developed ESU system is designed to capture the primary needs and functionalities to perform the prior stated 15 essential surgeries. These functionalities have been integrated in a safe and intuitive user interaction with both the high frequency generator as well as the monopolar handheld.

The high frequency has been designed to enhance a safe and intuitive user interaction by integrating co-created guidelines on appropriate power settings related to a certain surgery. The integrated safety precautions on pre-setting the high frequency generator and the designed sub-group bandwidths empowered the knowledge and confidence of the operator, according to the majority of interviewed Kenyan surgeons. Consequently, this will confine risks and increase the clinical outcome of the surgical procedures. As researched in an explorative study in Kenya, the design has been accepted and experienced as a significant positive added value on safe electrosurgery in LMICs.

The monopolar handheld and electrode tip have been designed to enhance control, safety and intuitiveness during the surgical procedure. The extensive co-creation sessions with Dutch and Kenyan surgeons on use problems and ergonomics have enhanced the feeling of control and reliability during the surgery. The design has been experienced as visually appealing and a significant improvement in comparison with the available monopolar handhelds in LMICs, according to all interviewed surgeons. The monopolar handheld is resistant against the various used cleaning procedures in LMICs and consequently this has a significant impact on the sustainability of the ESU system.

Even though the developed ESU system requires future improvements to create a sustainable success, the designed system empowers the future accessibility of electrosurgery for LMICs. The ESU system increases safety and an intuitive user interaction concerning the limited electrosurgery experience and enhances reliability for maintenance in the variety of use contexts in LMICs. The developed trade-off has shown the great potential of a sustainable and successful implementation of the designed ESU system in LMICs. Hopefully, this ESU system can in all sincerity make global electrosurgery accessible for everyone and everywhere.

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Glossary
of thesis report

Ablation Removal reduction or destruction of tissue

Active electrode The part of the electrosurgical instrument that transmits the electrosurgical current along a surgical procedure to the targeted tissue of the patient

Alternating current Current that regularly changes its direction from positive to negative (AC)

Bipolar electrosurgery Electrosurgical procedure in which two active electrodes are integrated in one electrosurgery instrument

Capacitive coupling Contactless transmission of AC between two electrical conductors with alternating voltage applied between them

Carbonization Charring of human tissue

Electrocautery Procedure for cutting and haemostasis using heated surgical instruments. Frequently this procedure is used as a synonym for electrosurgery

Coagulation mode Electrosurgical effect in which proteins start to coagulate and the tissue shrinks

Current Electrical charge quantity that moves past a certain point in one second, Unit: ampere (A)

Current density Amount of current flow per cross-section area. The higher the current density, the more heat is generated

Cutting mode Electrosurgical effect in which the intracellular fluid is explosively vaporized and the cell walls burst

Desiccation Drying out of biological tissue

Devitalization Destruction of biological tissue

Electric arcing Electrical discharge in the form of a flash, mainly needed for cutting procedures

Electrical resistance / impedance Describes the electrical conductivity of a material. The greater the conductivity the lower the electrical resistance. The resistance of a conductor is the product of the material dependent specific resistance and the length, divided by the cross-section area, Unit: ohm (Ω)

Electrosurgery Application of high-frequency electric current on biological tissue with the goal of creating a surgical effect through heating

Frequency Rate of periods per second during which the direction of, for example, the current changes, Unit: hertz (Hz)

Fulguration Non-contact coagulation with arcings above biological tissue

Haemostasis Blocking blood flow out of the surgical area

High-frequency generator Device that converts direct current or low-frequency AC into a high-frequency surgical current

Hyperthermia Heating of the tissue to higher than its normal temperature

Monopolar electrosurgery Electrosurgical procedure during which the active electrode is used at the surgical site and the electrical circuit is closed by a return electrode plate

Return electrode plate Conductive electrode which is attached to the patient during a monopolar application in order to receive the electrosurgical current and close the circuit

Peak voltage Maximum value of a voltage varying in time, in positive or negative direction starting from zero voltage

Power Electrical power is the product of current and voltage, Unit: Watt (W)

Root mean square value Square root of the mean square (RMS) value of a parameter varying in time (current, voltage). In regard to the delivered power, the root mean square is the value with equivalent effect of a direct current or direct voltage.

Vaporization Vaporization of the entire tissue

Voltage Energy for separating charges, relative to the charge quantity. Unit: volt (V)

Appendix **A**
additional info ESU technology

Return electrode burns

In case the return electrode pad is placed improperly on the human tissue this can be a severe risk for tissue burn. As explained before, the current throughput and the electrode surface in contact with the tissue determine the current density (van den Berg, 2012). Hence, to reduce current density the return electrode pad should have a sufficient cross-sectional area. This will prevent the skin underneath the return electrode to heat. In case of a too small contact area or if the impedance of that contact area decreases, a dangerous condition can develop as the temperature at the return electrode site will increase (Covidien, 2008). As previously explained, this risk is solely related to monopolar electro surgery.

As a power density of 7.5 W/cm2 or more is said to cause thermal damage, the cross sectional area of the return electrode should be large enough to avoid this (van den Berg, 2012). The general accessible resorbing energy of the tissue is 1.5-2.2 W/cm2, which means by a maximum power of 100 W, the return electrode pad attachment surface should be at least 45 cm2. However, a risk percentage of surface should be incorporated for situations where the electrode pad might lose conductivity as a consequence of movement or slipping off the human tissue. Moreover, the surface area impedance can be compromised by excessive hair, adipose tissue, bony prominences, fluid invasion, adhesive failure, scar tissue and many other variables (Covidien, 2008). Consequently, to retain a low cross-sectional area it would be beneficial to have a flexible return electrode pad with an understandable theory of positioning, as the human body curves are organic.

Return Electrode Monitoring

In case the return electrode will have inadequate contact, a system should alarm the user and block the output of the active electrode tip until the return electrode plate is replaced with an appropriate cross sectional surface. In the last years many of these contact quality monitoring systems have been developed to protect patients from burns. An example of such a system is the Return Electrode Monitor (REM) system that actively monitors the amount of impedance at the return electrode because there is a relationship between this impedance and the contact area . By incorporating such a system a split return electrode is mandatory to measure and compare input and output power that is necessary to calculate the impedance.

Additional safety precautions

Flammable substances

Explosion and fire can occur if electrical sparks ignite flammable gases or solutions. Although, fire hazards have been greatly reduced over the years, lack of appropriate safety measures are still causes for concern. Inadvertent activation of an active electrode positioned on sponges, drapes, or in an oxygen-enriched atmosphere can result in fires (McCauley, 2010).

• The ESU should not be used in presence of flammable agents (i.e. alcohol and/or tincture-based agents)
• Avoid oxygen-enriched environments

Electrode(s)

• Do not use rubber catheters or other materials as a sheath on active electrodes
Red rubber and other plastic materials may ignite with high power settings and in the presence of an oxygen enriched environment
• Use manufacturer-approved insulated tips

Disrupting other devices

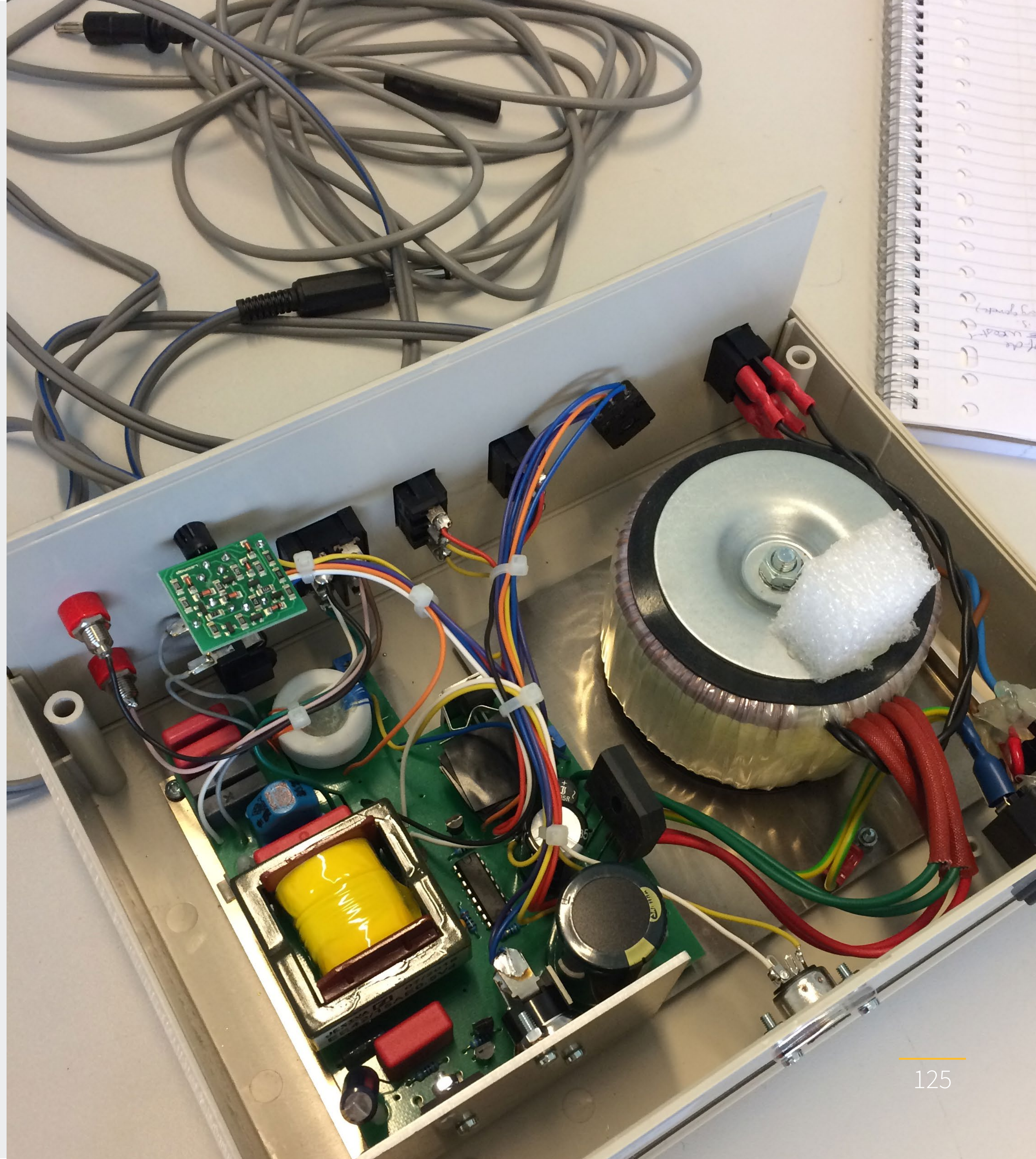
It is recommended that:
• Electrical cords of the ESU should not be wrapped around metal instruments
• Electrical cords should not be bundled together

Infants and children

In case of surgery on infants and children more attention is required on the used power settings and a sufficient contact area of the return electrode. In general, infants tissue is more sensitive than adult tissue and consequently the surgical effect between these patients is highly different. At all times, more attention is required on used power settings when performing electrosurgery on infants.

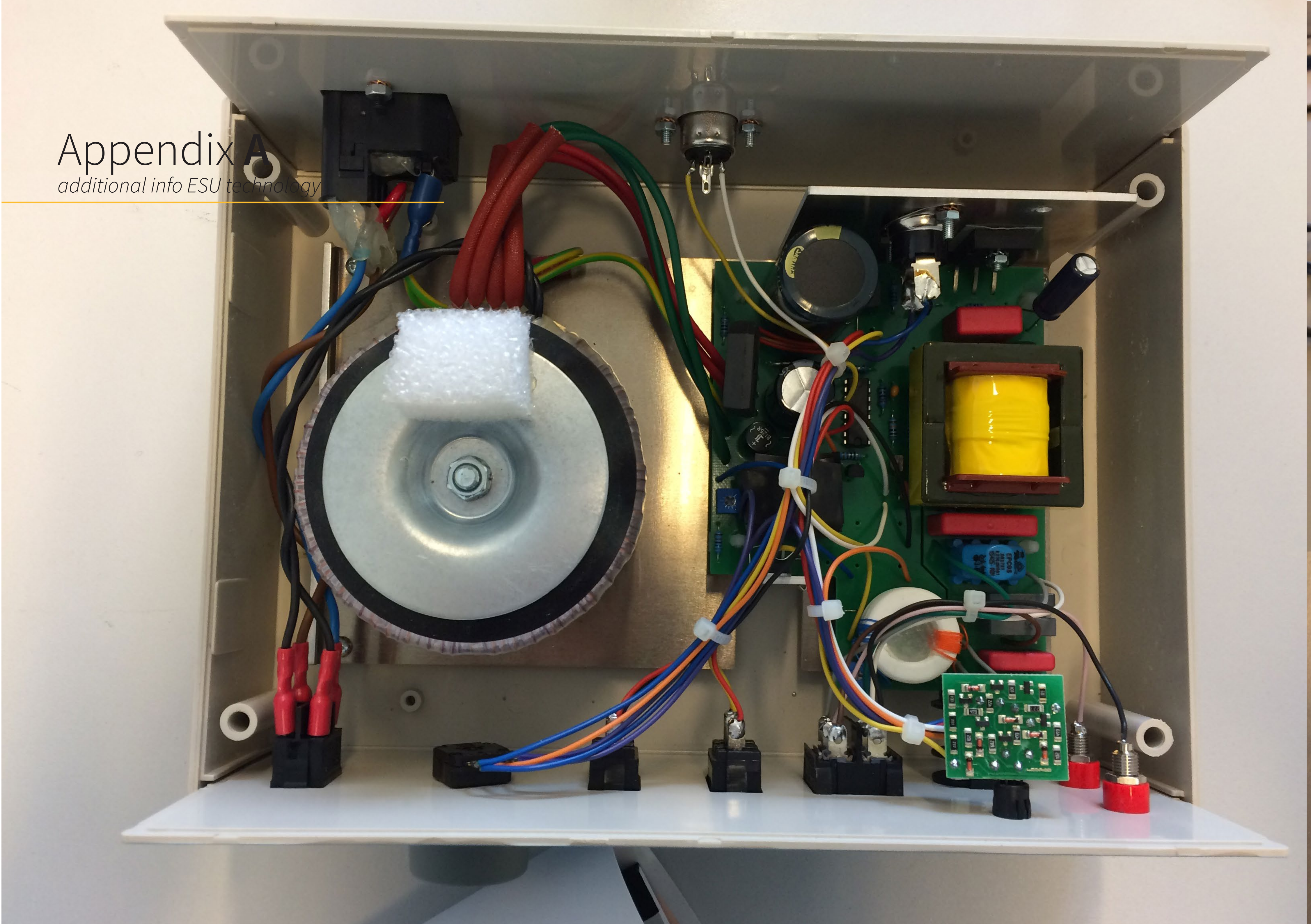
Furthermore, on the infants or children's body the current is distributed over a smaller cross-sectional area. To prevent for burns caused by higher current density, the used power settings should be limited. Another measure is to decrease the contact area at the active electrode through careful cutting and/or by using a small-area coagulation electrode (higher current density).

Internal components of Valleylab and RDE



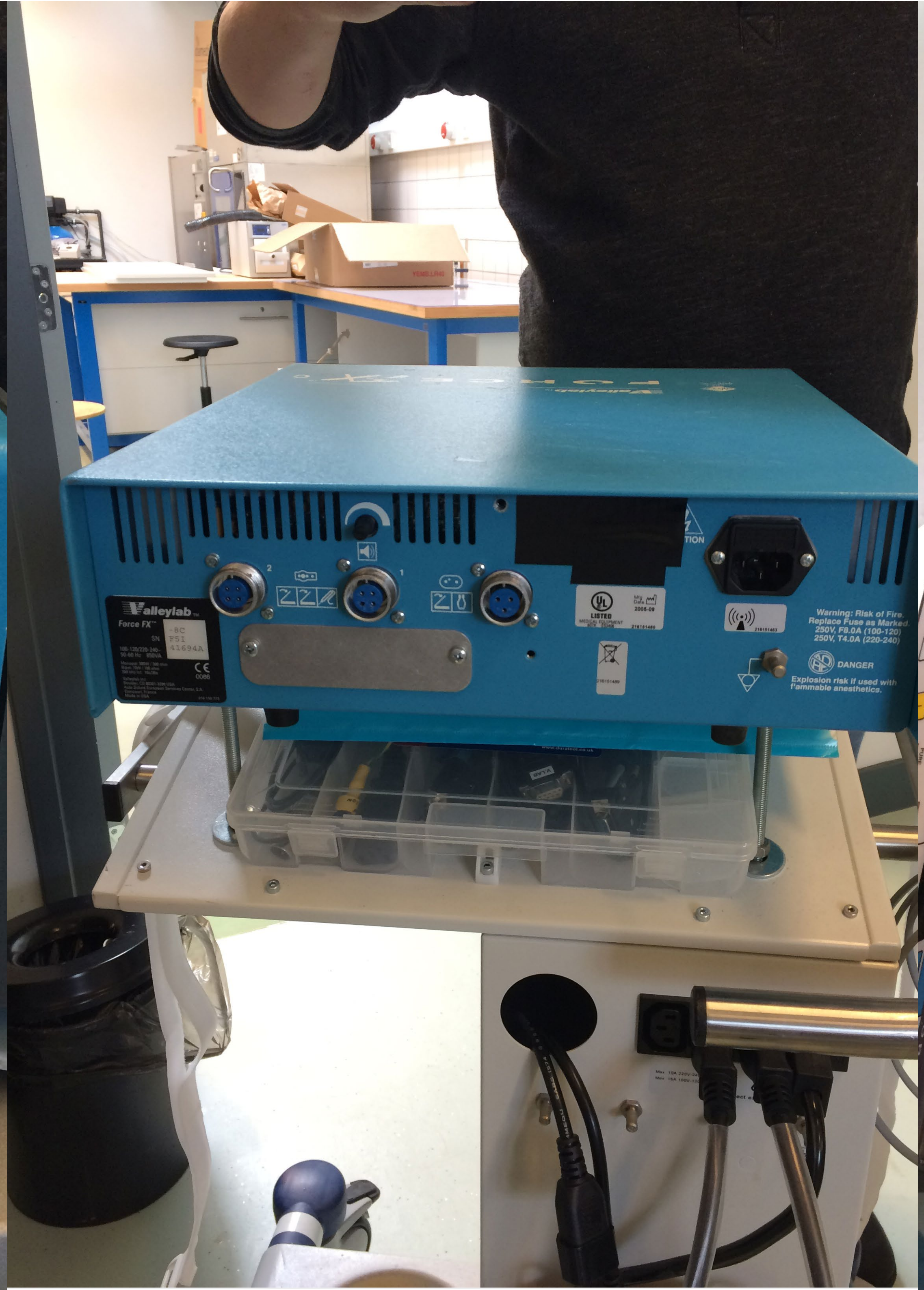
Appendix A

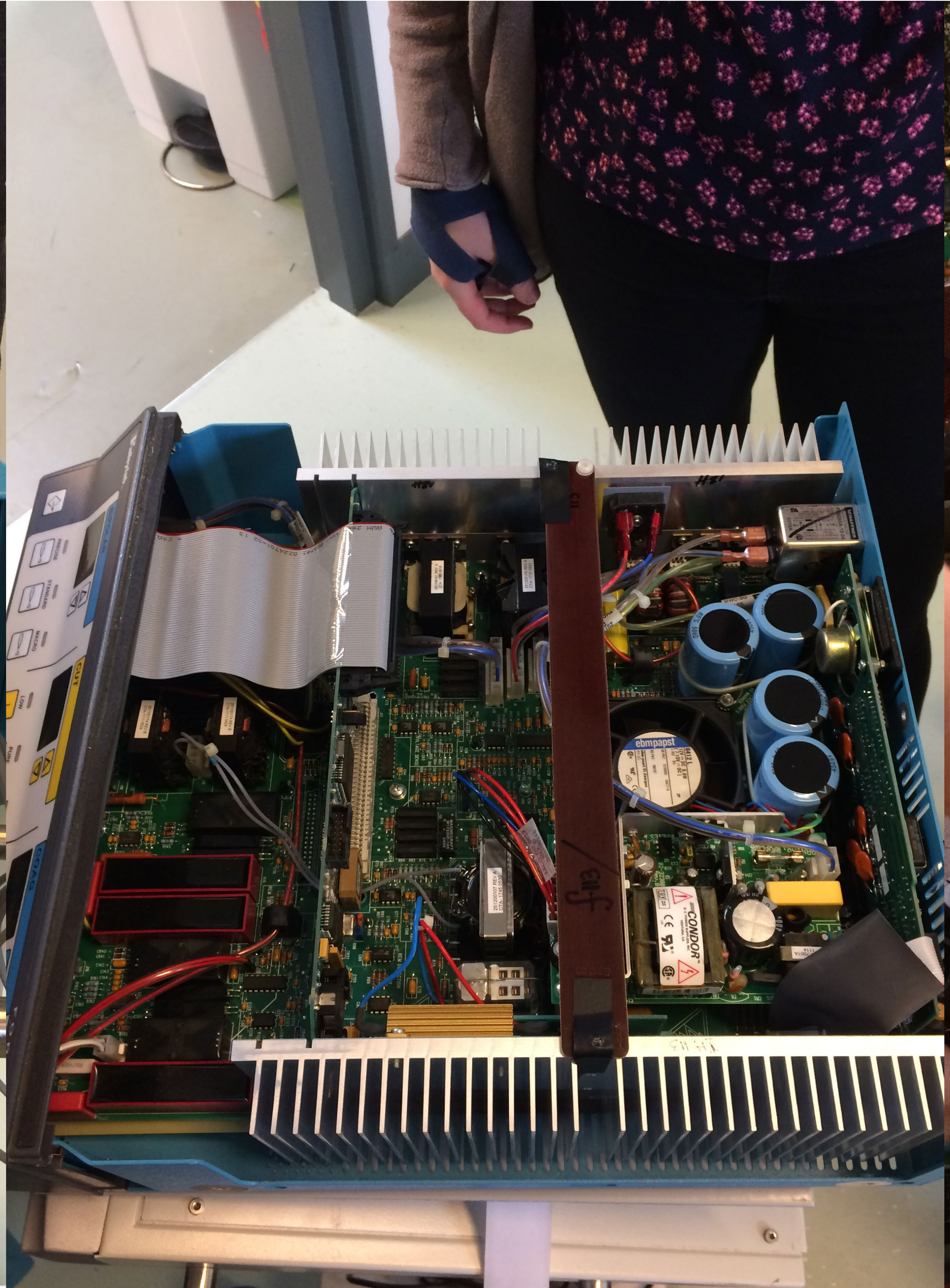
additional info ESU technology

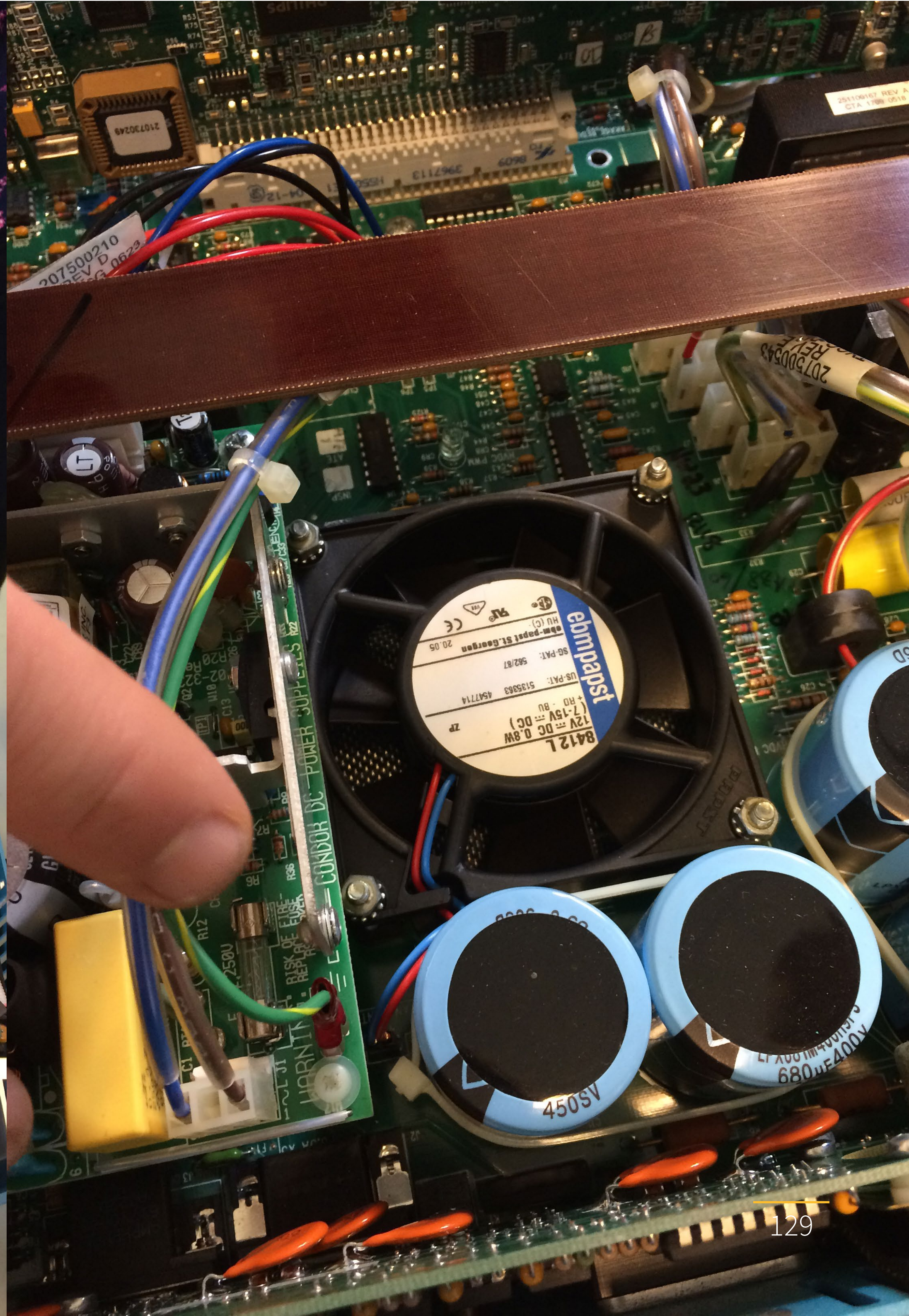


Appendix **A**

additional info ESU technology

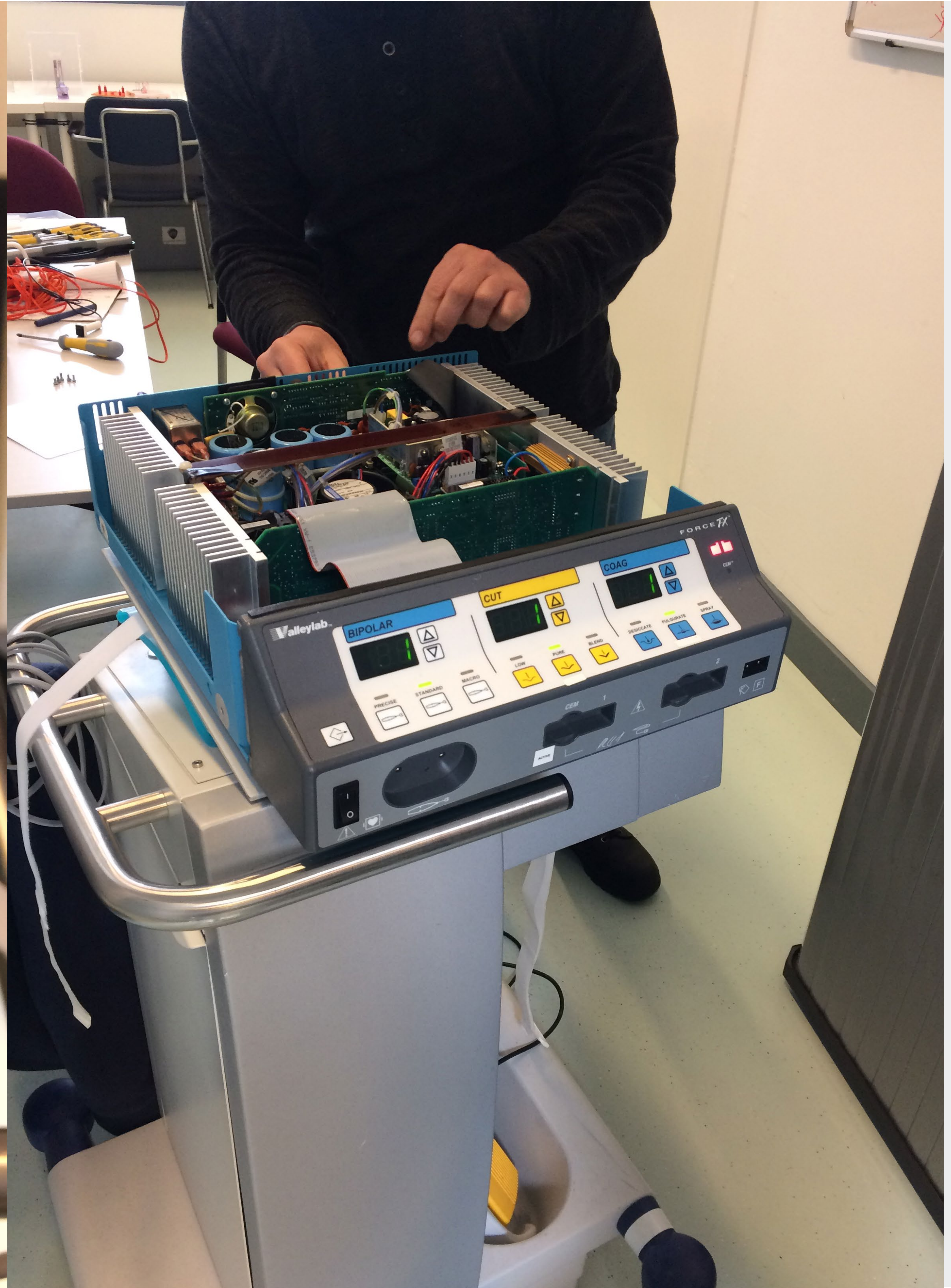


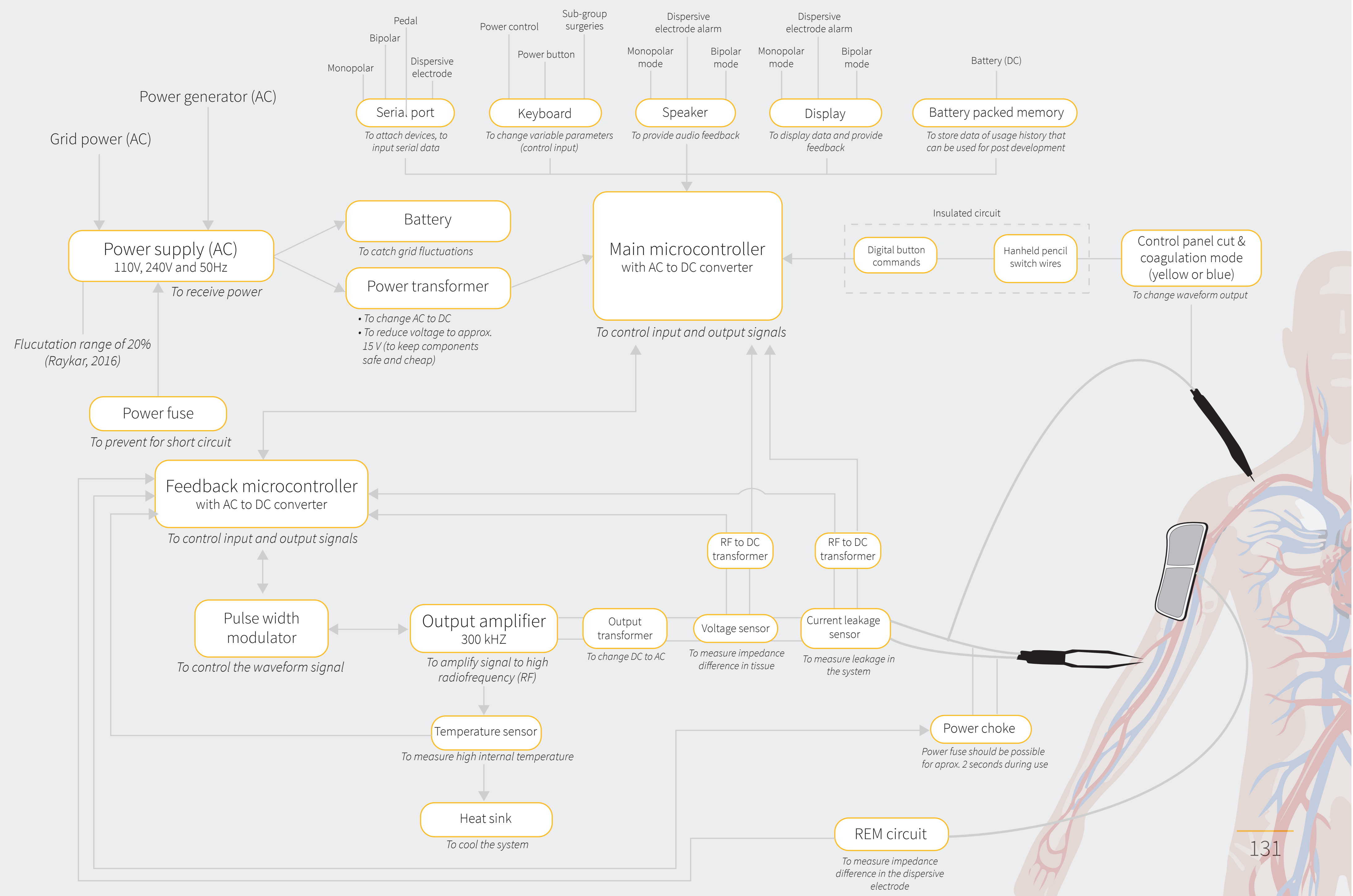




Appendix A

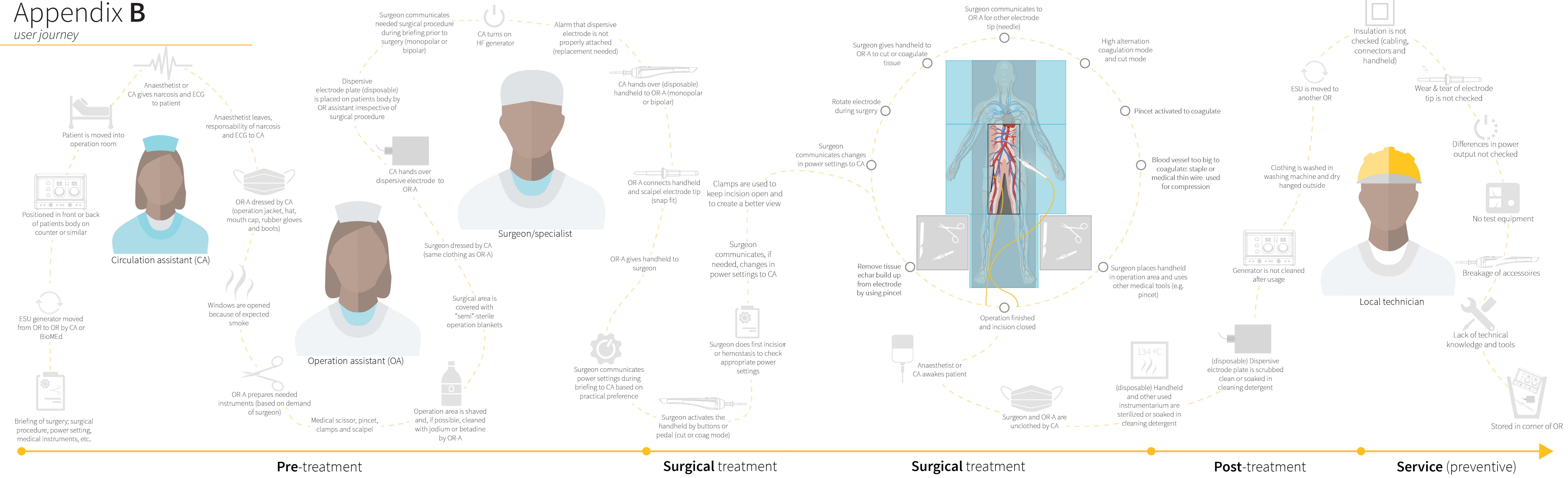
additional info ESU technology





Appendix **B**

user journey



STERANIOS 2%

STERANIOS 2% NG - STERANIOS 2% ECS

Appendix C

*Cleaning detergents - monopolar handheld - **Steranios - PH 6***

High level disinfectant / Cold sterilant

- Solution ready to use: absence of activator
- Active against bacteria, yeasts, moulds, virus and mycobacteria in 10 minutes
- Active against spores of bacteria in 1 hour
- Possible control of disinfectant solution's conformity with test-strips
- Stability of the bath during use: 30 days

READY TO USE

INDICATIONS

High level disinfection/Cold sterilization of medical devices, surgical, medical, endoscopic and heatsensitive equipment.

CHARACTERISTICS

- Clear green solution.
- Active against Helicobacter pylori.
- 2% glutaraldehyde solution buffered at pH 6 (sodium citrate).
- STERANIOS 2%NG and STERANIOS 2%ECS contain compounds limiting and controlling glutaraldehyde evaporation.
- Complete efficacy against spores of bacteria (5 log reduction).
- Wide compatibility with all kind of materials.
- Shelf-life: 3 years from the production date.
- Can be used in association with any kind of cleaning predisinfectant product.

laboratoires ANIOS
Le professionnel de la désinfection

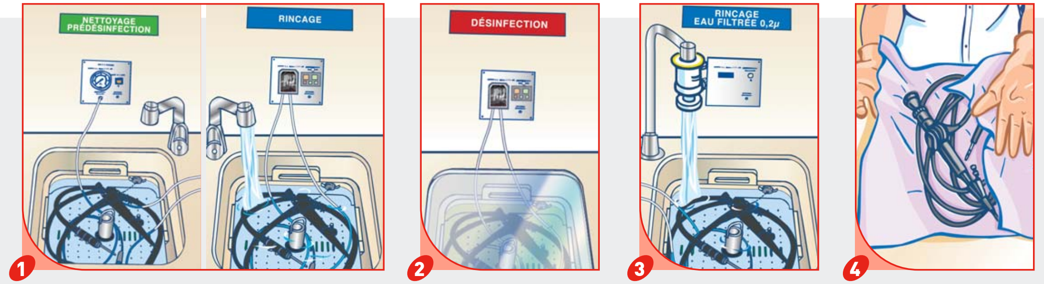
AFAQ ISO 9001

STERANIOS 2%

STERANIOS 2% NG - STERANIOS 2% ECS

High level disinfectant / Cold sterilant

INSTRUCTIONS FOR USE



1. **Pre-disinfection step :** Clean the medical device with a detergent or a pre-disinfectant product like ANIOSYME DD1, ANIOSYME DLT PLUS, HEXANIOS G+R or ANIOSYME PLA II. Rinse thoroughly.
   For endoscopic equipment : the internal and external parts of the medical device.
2. **Disinfection step :** Pour the solution. Cover the tank. **Contact time : 10 min. or 1 hour** according to the requested activity. **Maximum use duration of soaking solution: 30 days**
3. **Rinse thoroughly** the medical device with sterile or filtered water (0.2 µm) the internal and external parts of the medical device.
4. **Dry with a single-use towel.** Keep the medical device as aseptically as possible up to use it again.

QUALITATIVE COMPOSITION

STERANIOS 2% is a 2% glutaraldehyde solution (expressed in 100% active compound), buffered at pH 6 in the presence of surface effects catalysor.
STERANIOS 2% NG and STERANIOS 2% ECS contain two compounds limiting glutaraldehyde evaporation, when associated.

PRECAUTIONS FOR USE

Dangerous. Follow the instructions for use (in accordance with Directive 99/45/EC and its adapted versions).
Storage : from +5°C to +35°C.
Class IIb medical device (Directive 93/42/EEC as amended)

PACKAGINGS

1. STERANIOS 2% 4 cans de 5L........................Ref 382.034
2. STERANIOS 2% NG 4 cans de 5L........................Ref 383.034
3. STERANIOS 2% ECS 4 cans de 5L........................Ref 710.034

MICROBIOLOGICAL PROPERTIES

Active against	Standards	Contact time
Bacteria	EN 1040, EN 13727, NF T 72-171 EN 14561	5 minutes
	Helicobacter pylori	10 minutes
Mycobacteria	Mycobacterium tuberculosis (TB)	5 minutes
	EN 14348 (M. terrae, M. avium) pr EN 14563 (M. terrae)	10 minutes
Yeasts / Moulds	EN 1275,	10 minutes
	EN 13624, EN 14562	10 minutes
Viruses	HIV-1, HBV, Herpesvirus, BVDV (surrogate of HCV)	5 minutes
	EN 14476	10 minutes
Spores of bacteria	T 72-301 (C. difficile)	30 minutes
	NF T 72-230	1 hour
	Urogenital mycoplasma	5 minutes

laboratoires ANIOS
Le professionnel de la désinfection
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www.anios.com

G80382 - 120523 - Noncontractual photographies

ASP

CIDEX®

ACTIVATED GLUTARALDEHYDE SOLUTION

Appendix C

*Cleaning detergents - monopolar handheld - **CIDEX - PH 9,2***

HIGH-LEVEL DISINFECTION

For over 45 years, CIDEX® Activated Glutaraldehyde Solution has been used and recognized as a worldwide trusted brand for effective high-level disinfection of flexible endoscopes and other medical devices.

EXPERIENCE THE BENEFITS

CIDEX® Activated Glutaraldehyde Solution contains 2.4% glutaraldehyde and has been tested and cleared as a high-level disinfectant.

- **Effective**
- **High compatibility with materials**

ASP

CIDEX®

ACTIVATED GLUTARALDEHYDE SOLUTION

FEATURES & BENEFITS

- **EFFECTIVE** – achieves high-level disinfection in 20 minutes at 20°C.
- **LONG-LASTING EFFICACY** – reusable for up to 14 days when monitored with CIDEX® Solution Test Strips.
- **EXCELLENT MATERIALS COMPATIBILITY** – can be used safely to disinfect a wide range of instruments, reducing risk of damage and associated cost of repairs.
- **EASY CONTROL OF EFFICACY** with CIDEX® Solution Test Strips.

MATERIALS COMPATIBILITY

CIDEX® Activated Glutaraldehyde Solution offers excellent materials compatibility and can therefore be used to disinfect a wide range of medical instruments, made of aluminum, brass, copper, stainless steel, plastics and elastomers. Refer to instructions for use for complete details.

MICROBICIDAL ACTIVITY

CIDEX® Activated Glutaraldehyde Solution provides a wide spectrum efficacy against bacteria, mycobacteria, viruses and fungi. The solution can also achieve some sporicidal activity with longer exposure time.

TECHNICAL INFORMATION

MEDICAL DEVICE CLASSIFICATION	Class IIb according to MDD 93/42/EEC
IN-USE CONCENTRATION	2.4% Glutaraldehyde
SOAK TIME	High-level Disinfection: 20 minutes at 20°C Sporicidal activity: 10 hours at 25°C
USE LIFE	Up to 14 days
SHELF LIFE	12 months
OPEN BOTTLE SHELF LIFE	14 days (when open and activated)
STORAGE	15-30°C
DISPOSAL	Drain or as per hospital policy. Flush thoroughly with water.

ORDERING INFORMATION

REORDER NO.	DESCRIPTION	CASE CONTENTS
SCX145	CIDEX® Activated Glutaraldehyde Solution	4 x 5 liters
MCX001	CIDEX® Solution Test Strips	12 x 60/bottle
MCX002	CIDEX® Solution Test Strips	2 x 15/bottle

CIDEX® Activated Glutaraldehyde Solution may also be used for instrument reprocessing in automated equipment, in accordance with equipment manufacturers' recommendations.

Please read and follow the Instructions for Use prior to using CIDEX® Activated Glutaraldehyde Solution for detailed information, including contraindications, warnings and proper directions for use.

FOR MORE INFORMATION, CONTACT YOUR LOCAL ADVANCED STERILIZATION PRODUCTS SALES REPRESENTATIVE

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ADVANCED STERILIZATION PRODUCTS
Division of Cilag GmbH International
a Johnson & Johnson company

AD-110030-01-CT_B

Appendix C

*Cleaning detergents - monopolar handheld - **CIDEX OPA - PH 9,2***

CIDEX® OPA

Proven. Trusted. Safe.

Since its introduction in 1999, CIDEX OPA® Solution has become the world-leading solution for high-level disinfection used by thousands of healthcare facilities. It protects both patients and technicians with a demonstrated safety profile.

EXPERIENCE THE BENEFITS

CIDEX® OPA Solution has been cleared as a high-level disinfectant for use with the most widely used endoscopes

- Multiple studies have shown the efficacy of CIDEX® OPA Solution against bacteria, fungi, and viruses[1,2]
- Low vapor pressure for minimal inhalation exposure risk
- Specially designed test strips make it easy to check the minimum effective concentration (MEC) of CIDEX® OPA Solution

References
1. Akamatsu T, Minemoto M, Uyeda M. Evaluation of the antimicrobial activity and materials compatibility of orthophthalaldehyde as a high-level disinfectant. J Int Med Res. 2005;33:178-187.
2. Rutala WA, Weber DJ. New disinfection and sterilization methods. Emerg Infect Dis. 2001;7:348-353.

CIDEX® OPA

ORTHO-PHTHALALDEHYDE SOLUTION FOR HIGH-LEVEL DISINFECTION OF THE MOST WIDELY USED ENDOSCOPES

FEATURES	BENEFITS
GLUTARALDEHYDE FREE	In-use solution has low odor Effective against glutaraldehyde-resistant mycrobacteria
EFFECTIVE	Effective against a wide array of microorganisms
FAST ACTING	Rapid disinfection improves productivity, allowing more endoscopes to be processed in less time
LONG LASTING UP TO 14 DAYS REUSE LIFE	Long lasting efficacy allows reprocessing of more devices per gallon than with glutaraldehyde[2]
EASE OF USE	CIDEX OPA® Solution can be used straight from the bottle for extra efficiency. Requires no activation or mixing
DISPOSAL	Discard down healthcare facility drains in accordance with local regulations

Materials Compatibility

CIDEX® OPA SOLUTION HAS BEEN TESTED WITH A WIDE RANGE OF MATERIALS COMMON TO FLEXIBLE ENDOSCOPES INCLUDING:
Aluminum, brass, copper, stainless steel, polyurethane, natural rubber latex, silicone rubber.
Refer to instructions for use for complete details.
Near neutral pH level ensures compatibility with endoscopic instruments.

System Use

VALIDATED FOR USE IN THE ENDOCLENS-NSX™ AUTOMATIC ENDOSCOPE REPROCESSOR (AER)
DESIGNED FOR EITHER MANUAL OR AUTOMATIC REPROCESSING

USE-LIFE	Up to 14 days
SHELF-LIFE	24 months
STORAGE INFORMATION	15-30°C
OPEN BOTTLE SHELF LIFE	75 days

ORDERING INFORMATION

REORDER NO.	DESCRIPTION	CASE CONTENTS
20391	3.785 l container	4 x 3.785 l containers
20392	CIDEX® OPA Solution Test Strips	2 bottles (60 strips/ea.)
20393	CIDEX® OPA Solution Test Strips	2 bottles (15 strips/ea.)

Please read and follow the CIDEX OPA® Solution instructions for use prior to using this product for complete usage information, including contraindications and warnings.

FOR MORE INFORMATION PLEASE VISIT WWW.ASPJJ.COM/EMEA OR CONTACT YOUR ASP LOCAL REPRESENTATIVE

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A Division of J&J Medical Middle East
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South Africa

T: +27 11 265 1120
F: +27 11 265 1189

ADVANCED STERILIZATION PRODUCTS
Division of Cilag GmbH International
a Johnson & Johnson company

AD-110141-01-CT_F

MATERIAL SAFETY DATA SHEET

1. Product and Company Identification

Material name	**CIDEX Activated Dialdehyde Solution**
Issue date	9/14/12
Change Order #	1005190
CAS #	Mixture
Revision #	F
MSDS Number	006
Synonym(s)	CIDEX Solution
Manufacturer/Supplier	Advanced Sterilization Products 33 Technology Drive, Irvine CA 92618
Telephone number	1-800-755-5900
Emergency	24-Hour phone (Access code): 1-760-476-3962 (333623)

2. Hazards Identification

Physical state	Liquid.
Appearance	Unactivated, colorless liquid; Activated, green liquid.
Emergency overview	WARNING Causes skin, eye and respiratory tract irritation. May cause sensitization by skin contact.
OSHA regulatory status	This product is considered hazardous under 29 CFR 1910.1200 (Hazard Communication).
Potential health effects	
Routes of exposure	Inhalation. Ingestion. Skin contact. Eye contact.
Eyes	Risk of serious damage to eyes.
Skin	May cause skin irritation. May cause allergic skin reaction.
Inhalation	Vapor may cause irritation of the upper respiratory tract (nose and throat) and lungs. May cause asthma-like symptoms in sensitive individuals.
Ingestion	Ingestion may cause severe irritation of the mouth, the esophagus and the gastrointestinal tract. Ingestion of this product may cause nausea, vomiting and diarrhea.
Target organs	Eye Skin
Chronic effects	Not known.
Signs and symptoms	Sensitization. Irritation of eyes and mucous membranes. Skin irritation. Upper respiratory tract irritation.
Potential environmental effects	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

3. Composition / Information on Ingredients

Components	CAS #	Percent
Glutaraldehyde	111-30-8	2.55

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First Aid Measures

First aid procedures	
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops or persists.
Skin contact	Wash skin thoroughly with soap and water. Get medical attention if irritation develops and persists.
Inhalation	Remove victim to fresh air. If breathing is difficult, give oxygen. Get medical attention.

Ingestion	Immediately rinse mouth and drink plenty of water. Keep person under observation. Do not induce vomiting. If vomiting occurs, keep head low. If person becomes uncomfortable seek medical advice.
Notes to physician	If the product is ingested, probable mucosal damage may contraindicate the use of gastric lavage. Treat the affected person appropriately.
General advice	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire Fighting Measures

Flammable properties	Fire or high temperatures create:
Extinguishing media	
Suitable extinguishing media	Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.
Unsuitable extinguishing media	None.
Protection of firefighters	
Protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do it without risk.
Hazardous combustion products	Carbon oxides.

6. Accidental Release Measures

Personal precautions	Avoid inhalation and contact with skin and eyes. Use personal protection as recommended in Section 8 of the MSDS.
Environmental precautions	Avoid discharge into storm drains, water courses or onto the ground.
Methods for containment	Stop leak if you can do so without risk.
Methods for cleaning up	Contain spill by placing suitable absorbent material around the edges of the spill and work inward. Carefully scoop up into waste container for disposal. For each estimated gallon of spill disperse about 228g of sodium bisulfite powder (CAS 7631-90-5) or 25g of glycine (56-40-6) on spill. Thoroughly blend into CIDEX Solution. Allow 5 minutes for neutralization. Dispose of in accordance with applicable Federal, State and Local Regulations. Following product recovery, flush area with water.
Other information	Clean up in accordance with all applicable regulations.

7. Handling and Storage

Handling	Provide adequate ventilation. Avoid inhalation of vapors/spray and contact with skin and eyes. Use in well-ventilated area and use with appropriate exhaust ventilation, for example a minimum of 10 air exchanges per hour or as defined by state and local regulations. Use appropriate Personal Protective Equipment. Wash thoroughly after handling. Observe good industrial hygiene practices.
Storage	Store in closed original container at temperatures at 15 - 30°C (59 - 86°F). Store away from incompatible materials.

8. Exposure Controls / Personal Protection

Occupational exposure limits

US. ACGIH Threshold Limit Values

Components	Type	Value
Glutaraldehyde (111-30-8)	Ceiling	0.05 ppm

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Type	Value
Glutaraldehyde (111-30-8)	Ceiling	0.2 mg/m3 0.05 ppm

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Type	Value
Glutaraldehyde (111-30-8)	Ceiling	0.05 ppm

Canada. Ontario OELs. (Ministry of Labor - Control of Exposure to Biological or Chemical Agents)

Components	Type	Value
Glutaraldehyde (111-30-8)	Ceiling	0.05 ppm

Canada. Quebec OELS. (Ministry of Labor - Regulation Respecting the Quality of the Work Environment)

Components	Type	Value
Glutaraldehyde (111-30-8)	Ceiling	0.41 mg/m3
		0.1 ppm

Mexico. Occupational Exposure Limit Values

Components	Type	Value
Glutaraldehyde (111-30-8)	Ceiling	0.7 mg/m3
		0.2 ppm

Exposure guidelines Use personal protective equipment as required. Keep working clothes separately.

Engineering controls Provide adequate ventilation and minimize the risk of inhalation of vapors and mists. Use in well-ventilated area and use with appropriate exhaust ventilation, for example a minimum of 10 air exchanges per hour or as defined by state and local regulations.

Personal protective equipment

Eye / face protection Wear safety glasses with side shields.

Skin protection Wear chemical-resistant, impervious gloves. Suitable gloves can be recommended by the glove supplier. Wear suitable protective clothing.

Respiratory protection In case of risk of inhalation of vapour/aerosols: Use high efficiency particulate respirator with appropriate filter.

General hygiene considerations Wash thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice.

9. Physical & Chemical Properties

Appearance	Unactivated, colorless liquid; Activated, green liquid.
Color	Unactivated, colorless; Activated, green.
Odor	Characteristic aldehyde.
Odor threshold	Not available.
Physical state	Liquid.
Form	Liquid.
pH	3 - 4.6 (unactivated) 8.2 - 9.2 (activated)
Melting point	Not available.
Freezing point	Not available.
Boiling point	Not available.
Flash point	Not available.
Evaporation rate	1
Flammability limits in air, upper, % by volume	Not available.
Flammability limits in air, lower, % by volume	Not available.
Vapor pressure	0.0012 mmHg (68°F/20°C)
Vapor density	1.1
Specific gravity	1.003
Solubility (water)	Completely Soluble.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	212 °F (100 °C)
Decomposition temperature	Not available.

10. Chemical Stability & Reactivity Information

Chemical stability Stable under normal temperature conditions.

Conditions to avoid Extremes of temperature, direct sunlight and prolonged heating at temperature above 40°C.

Incompatible materials Strong oxidizers, strong acids, and strong bases.

Hazardous decomposition products Carbon oxides.

Possibility of hazardous reactions Hazardous polymerization does not occur.

11. Toxicological Information

Toxicological data

Product	Test Results
CIDEX Activated Dialdehyde Solution (Mixture)	Acute Dermal LD50 Rabbit: > 2000 mg/kg
	Acute Oral LD50 Rat: 4250 mg/kg

Acute effects Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Local effects Causes skin and eye irritation. May cause irritation of respiratory tract.

Sensitization May cause allergic skin reaction.

ACGIH Sensitizer

Glutaraldehyde (CAS 111-30-8) Sensitiser.

Chronic effects Not known.

Carcinogenicity Not classified.

ACGIH Carcinogens

Glutaraldehyde (CAS 111-30-8) A4 Not classifiable as a human carcinogen.

Mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Reproductive effects Not classified.

Symptoms and target organs Sensitizing. Skin irritation. Irritation of eyes and mucous membranes. Upper respiratory tract irritation.

Further information No other specific acute or chronic health impact noted.

12. Ecological Information

Ecotoxicity Not expected to be harmful to aquatic organisms.

Environmental effects An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulation / Accumulation No data available.

Partition coefficient (n-octanol/water) Not available.

Mobility in environmental media The product is soluble in water.

13. Disposal Considerations

Disposal instructions Any disposal practice must be in compliance with local, state and federal laws and regulations (contact local or state environment agency for specific rules). Do not dump in sewers, any body of water or on the ground.

14. Transport Information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

TDG

Not regulated as dangerous goods.

15. Regulatory Information

US federal regulations This product is hazardous according to OSHA 29 CFR 1910.1200. All components are on the U.S. EPA TSCA Inventory List.

TSCA Section 12(b) Export Notification(40 CFR 707, Subpt. D)

Not regulated.

CERCLA (Superfund) reportable quantity (lbs) (40 CFR 302.4)

None

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

Section 302 extremely hazardous substance (40 CRF 355, Appendix A) No

Section 311/312 (40 CFR 370) No

Drug Enforcement Administration (DEA) (21 CFR 1308.11-15) Not controlled

WHMIS status Controlled

WHMIS classification D1B - Immediate/Serious-TOXIC
D2B - Other Toxic Effects-TOXIC
E - Corrosive

WHMIS labeling

Inventory status

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

State regulations

US - California Hazardous Substances (Director's): Listed substance

Glutaraldehyde (CAS 111-30-8) Listed.

US - Massachusetts RTK - Substance: Listed substance

Glutaraldehyde (CAS 111-30-8) Listed.

US - New Jersey RTK - Substances: Listed substance

Glutaraldehyde (CAS 111-30-8) Listed.

US - Pennsylvania RTK - Hazardous Substances: Listed substance

Glutaraldehyde (CAS 111-30-8) Listed.

16. Other Information

HMIS® ratings Health: 2
Flammability: 0
Physical hazard: 0

NFPA ratings Health: 2
Flammability: 0
Instability: 0

Disclaimer The information in the sheet was written based on the best knowledge and experience currently available.

Appendix C

*Cleaning detergents - monopolar handheld - **Descoton - PH 5,5***

SECTION 1: Identification of the substance/mixture and of the company/undertaking

Use of the substance/mixture
Instrument disinfectant

1.3. Details of the supplier of the safety data sheet

Company name:	Dr. Schumacher GmbH
Street:	Am Roggenfeld 3
Place:	34323 Malsfeld / DEUTSCHLAND
Telephone	+49 (0) 5664/9496-0
Telefax	+49 (0) 5664/8444
e-mail:	post@schumacher-online.com
Internet:	www.schumacher-online.com

Responsible for the safety data sheet: sds@gbk-ingelheim.de

1.4. Emergency telephone number: INTERNATIONAL: +49 - (0) 6132 - 84463, GBK GmbH (24h - 7d/w - 365d/a) England and Wales: NHS Direct - 0845 4647; Scotland: NHS 24 - 08454 24 24 24

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Indications of danger: Xn - Harmful
R phrases:
Harmful by inhalation and if swallowed.
Irritating to respiratory system and skin.
Risk of serious damage to eyes.
May cause sensitisation by inhalation and skin contact.

GHS classification
Hazard categories:
Acute toxicity: Acute Tox. 4
Skin corrosion/irritation: Skin Irrit. 2
Serious eye damage/eye irritation: Eye Dam. 1
Respiratory/skin sensitization: Resp. Sens. 1
Respiratory/skin sensitization: Skin Sens. 1
Specific target organ toxicity - single exposure: STOT SE 3
Hazardous to the aquatic environment: Aquatic Chronic 3
Hazard Statements:
Harmful if swallowed.
Causes skin irritation.
May cause an allergic skin reaction.
Causes serious eye damage.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause respiratory irritation.
Harmful to aquatic life with long lasting effects.

2.2. Label elements

Hazardous components which must be listed on the label
Ethane-1,2-diol
Glutaraldehyde

Signal word:	Danger
Pictograms:	GHS05-GHS07-GHS08

Hazard statements

H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H412	Harmful to aquatic life with long lasting effects.

Precautionary statements

P261	Avoid breathing vapour.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P302+P352	IF ON SKIN: Wash with plenty of water.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312	Call a POISON CENTER/doctor if you feel unwell.

2.3. Other hazards
Not known.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization
Aqueous preparation of the following substances with non-hazardous admixtures

Hazardous components

EC No	Chemical name	Quantity
CAS No	Classification	
Index No	GHS classification	
REACH No		
203-473-3	Ethane-1,2-diol	< 10 %
107-21-1	Xn - Harmful R22	
603-027-00-1	Acute Tox. 4, STOT RE 2; H302 H373	
01-2119456816-28		
203-856-5	Glutaraldehyde	< 5 %
111-30-8	T - Toxic, C - Corrosive, N - Dangerous for the environment R23/25-34-42/43-50	
605-022-00-X	Met. Corr. 1, Acute Tox. 3, Acute Tox. 3, Skin Corr. 1B, Resp. Sens. 1, Skin Sens. 1, Aquatic Acute 1 (M-Factor = 1), Aquatic Chronic 1 (M-Factor = 1); H290 H301 H331 H314 H334 H317 H400 H410	
01-2119455549-26		

Full text of R-, H- and EUH-phrases: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information
Remove contaminated soaked clothing immediately.
If you feel unwell, seek medical advice.

After inhalation
Move to fresh air in case of accidental inhalation of vapours or decomposition products.
In the event of symptoms refer for medical treatment.

After contact with skin
Wash off immediately with soap and plenty of water.
Consult a doctor if skin irritation persists.

After contact with eyes
Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
Consult (eye) doctor immediately.

After ingestion
Do not provoke vomiting. Consult physician. Attention in case of vomiting - acute danger of suffocating, produced by foaming ingredients. Rinse mouth. Make drink some glasses of water. The decision whether to provoke vomiting is to be taken by a physician.

4.2. Most important symptoms and effects, both acute and delayed
Harmful if swallowed or if inhaled.
Causes serious eye damage.
Causes skin irritation.
May cause an allergic skin reaction.
May cause respiratory irritation.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.

4.3. Indication of any immediate medical attention and special treatment needed
Treat symptoms.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media
Product does not burn, fire-extinguishing activities according to surrounding.

Unsuitable extinguishing media
Full water jet.

5.2. Special hazards arising from the substance or mixture
Fire may produce:
Irritant/corrosive, flammable as well as toxic distillation gases (carbonization gases).
Carbon monoxide, carbon dioxide, sulphur oxides and nitrogen oxides (NOx).

5.3. Advice for firefighters
Use breathing apparatus with independent air supply.
Protective suit.

Additional information
Cool containers at risk with water spray jet.
Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
In case of vapour formation use respirator.
Avoid contact with skin, eyes and clothing.
Ensure adequate ventilation.
Use personal protective clothing.

6.2. Environmental precautions
Do not discharge into the drains/surface waters/ground water.

6.3. Methods and material for containment and cleaning up
Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder).
Shovel into suitable container for disposal.

6.4. Reference to other sections
Observe protective instructions (see Sections 7 and 8).
Information for disposal see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling
Keep container tightly closed.
Use only in thoroughly ventilated areas.
Avoid contact with skin, eyes and clothing.

Advice on protection against fire and explosion
No special protective measures against fire required.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels
Keep containers tightly closed in a dry, well-ventilated place.

Advice on storage compatibility
Incompatible with:
Oxidizing agents
Acids and bases.

Further information on storage conditions
Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)
Instrument disinfectant

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m³	fibres/ml	Category	Origin
107-21-1	Ethane-1,2-diol, vapour	20	52		TWA (8 h)	WEL
		40	104		STEL (15 min)	WEL
111-30-8	Glutaraldehyde	0.05	0.2		TWA (8 h)	WEL
		0.05	0.2		STEL (15 min)	WEL

8.2. Exposure controls

Appropriate engineering controls
Ensure adequate ventilation, especially in confined areas.

Protective and hygiene measures
Do not inhale vapours.
Wash hands before breaks and immediately after handling the product.
When using do not eat or drink.
Remove and wash contaminated clothes before re-use.
Avoid contact with eyes, skin or mucous membrane.

Eye/face protection
Safety goggles with side protection (EN 166).
Eye wash bottle with pure water (EN 15154).

Hand protection
PVC or other plastic material gloves.
This recommendation refers exclusively to the chemical compatibility and the lab test conforming to EN 374 carried out under lab conditions.
Requirements can vary as a function of the use. Therefore it is necessary to adhere additionally to the recommendations given by the manufacturer of protective gloves.

Skin protection
Long sleeved clothing (EN 368).

Respiratory protection
In case of insufficient ventilation wear suitable respiratory equipment (gas filter type A) (EN 141).

VAH listed · IHO list for virucidal disinfectants · ÖGHMP listed · virucidal acc. to RKI/DVV · 5 min. · 0482

Instrument disinfection

PERFEKTAN® active

Powder concentrate for instrument disinfection based on peracetic acid

- virucidal according to RKI/DVV
- extensive material compatibility
- superior cleaning performance
- completely soluble

Product properties

PERFEKTAN® active is a highly effective powder concentrate for manual disinfection of all kinds of medical instruments. This product is a low dusting powder which dissolves fast and complete in water for a reliable and safe application.

PERFEKTAN® active is based on the active agent peracetic acid generated in mild alkaline solution. This product combines excellent antimicrobial properties and superb material compatibility.

Use of **PERFEKTAN® active** avoids protein fixation and enables safe disinfection even in difficult conditions. **PERFEKTAN® active** masters difficult cleaning conditions.

Range of application

For manual pre-cleaning of endoscopes preceding thermo-chemical treatment.

For manual disinfection of medical devices of all kinds (surgical instruments, anesthetic equipment) as well as for rigid and flexible endoscopes.

Concentrations and application times

Antimicrobial properties		1 min.	5 min.	15 min.	30 min.	60 min.
instrument disinfection acc. DGHM/VAH (bactericidal, yeasticidal)	dirty conditions		1,0 %			
instrument disinfection acc. DGHM/VAH (tuberculocidal)	dirty conditions				2,0 %	1,0 %
instrument disinfection acc. DGHM/VAH (fungicidal)	dirty conditions				3,0 %	2,0 %
active against all enveloped and non-enveloped viruses incl HBV/HIV/HCV (virucidal, Aspergillus brasiliensis)	acc. RKI/DVV				2,0 %	1,0 %
	Polio virus				2,0 %	1,0 %
	Adeno virus			0,5 %		
	Papova virus / SV40		1,0 %	0,5 %		
	Vaccinia virus	0,25 %				
sporicidal (Clostridium difficile)	acc. EN 13704			2,0 %	1,0 %	0,5 %

10/2014

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PERFEKTAN® active

Powder concentrate for instrument disinfection based on peracetic acid

Concentrations and application times

Antimicrobial properties		1 min.	5 min.	15 min.	30 min.	60 min.
EN 1040	bactericidal	0,5 %				
EN 1275	yeasticidal	0,5 %				
EN 1275 (A. brasiliensis)	fungicidal			1,5 %		
EN 13727	bactericidal, dirty conditions	1,0 %				
EN 13624	yeasticidal, dirty conditions	1,0 %				
EN 13624 (A. brasiliensis)	fungicidal, dirty conditions			2,0 %	1,5 %	1,0 %
EN 14348 (M. terrae)	tuberculocidal, dirty conditions				2,0 %	1,0 %
EN 14561	bactericidal, dirty conditions	0,5 %				
EN 14562	yeasticidal, dirty conditions	0,5 %				
EN 14562 (A. brasiliensis)	fungicidal, dirty conditions				1,5 %	1,0 %
EN 14563 (M. terrae)	tuberculocidal, dirty conditions				1,5 %	1,0 %
EN 13704 (C. difficile)	sporicidal, clean conditions			2,0 %	1,0 %	0,5 %

Dosage	1 %	2 %
4 litres	2x 20g	4x 20g
4 litres	1x 40g	2x 40g
8 litres	4x 20g	8x 20g
8 litres	2x 40g	4x 40g
	1 x = 20 g	1 x = 40 g

Application

Prepare ready-to-use solution according to dosage chart under aid of the attached measuring spoon using < 30 °C water.

PERFEKTAN® active is suitable for disinfection by immersion and for use in ultrasonic baths. Choose sonication times according to manufacturer's recommendation and don't exceed temperatures of 30 °C. Compatible with all water hardness types.

Disinfection and cleaning of endoscopes

Immerse instruments directly after use and clean mechanically based upon the type of device and manufacturer's recommendations. Ensure complete wetting of all surfaces and cavities, avoiding air bubbles.

Ensure that contact time, solution concentration and the manufacturer's recommendation for manual reprocessing conforms to DIN EN ISO 17664. Rinse instruments with deionised water after use.

The working solution must be replaced after 8 h or if visibly contaminated.

Virucidal disinfection of all types of medical instruments

Rinse instruments after manual cleaning thoroughly with water. Immerse in the **PERFEKTAN® active** working solution with all surfaces and cavities accessible to the solution. Remove instruments after the recommended contact time and rinse with water thoroughly, dry instruments and sterilise if needed. The manufacturer's instruction and recommendations for reprocessing must be followed.

The working solution has to be replaced on a daily basis (8h).

Antimicrobial properties

- bactericidal (incl. MRSA)
- tuberculocidal
- yeasticidal
- fungicidal
- virucidal acc. to RKI/DVV guidelines
- sporicidal

Delivery units

Single unit	Delivery unit	REF
1 kg container	6	00-155-010
40 g sachet	100	00-155-0004

Dosage aids

Measuring spoon (20 g).

Listings/Product status

Listed in the current disinfectant list of the DGHM/VAH.

Listed in the current disinfectant list of the ÖGHMP.

Listed in the IHO list for virucidal disinfectants (www.iho-viruzidie-liste.de).

Conforms to the guideline 93/42/EC for medical devices.

Material compatibility

PERFEKTAN® active has excellent material compatibility; it is suitable for glass, metals, plastics and endoscope-materials. Not suitable for anodized aluminium and polycarbonate.

Expert opinions

Prof. H.-P. Werner, hygienist, Schwerin:
Expert´s report on virucidal activity acc. RKI/DVV guidelines 2008 incl. Polio-, Adeno-, Papova/Polyoma-, Vaccinia viruses.
Expert´s report on sporicidal activity (Clostridium difficile) acc. EN 13704.

Dr. M. Suchomel, hygienist, Vienna:
Expert´s report on instrument disinfection acc. to DGHM/VAH guidelines/EN 13727/EN 13624/EN 14561/EN 14562.

Dr. Schumacher GmbH is certified according to DIN EN 13485, DIN EN ISO 9001, DIN EN ISO 14001 & BS OHSAS 18001 and has a validated eco management system (according to EMAS).

We are members of IHO, VCI, BAH, DGSV and DGKH.

Instrument disinfection

PERFEKTAN® active

Powder concentrate for instrument disinfection based on peracetic acid

Dipl. Biol. T. Koburger, hygienist, Greifswald:
Expert´s report on instrument disinfection acc. to DGHM/VAH guidelines.
Expert´s report on bactericidal, yeasticidal, tuberculocidal and fungicidal activity acc. to EN 13727, EN 13624, EN 14348, EN 14561, EN 14562, EN 14563.

Composition

Active ingredients: Peracetic acid (in-situ) > 850 ppm (1 % solution).

Ingredients acc. to Detergents Regulation 648/2004/EC:

PERFEKTAN® active contains
< 5% non-ionic surfactants, phosphonates
> 30% sodium percarbonate

Chemical-physical data

Appearance: off-white powder
Bulk density: approx. 800 g/L
pH (1% solution): approx. 9

Storage information

Stable up to 2 years when stored appropriately.
Do not store above 25°C.
Disposal of residual content: see MSDS

Additional information

May intensify fire; oxidiser. Causes skin irritation. Causes serious eye damage. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Take any precaution to avoid mixing with combustibles. Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN: Wash with plenty of soap and water.IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF exposed or concerned: Get medical advice/attention. Dispose of contents/container to a hazardous waste collection point. Dispose of completely empty containers to recycling. For professional use only.

Environmental Information

The products of Dr. Schumacher GmbH are manufactured according to modern, safe and environmentally friendly processes in compliance with high quality standards.

Dr. Schumacher GmbH is certified according to DIN EN 13485, DIN EN ISO 9001, DIN EN ISO 14001 & BS OHSAS 18001 and has a validated eco management system (according to EMAS).

We are members of IHO, VCI, BAH, DGSV and DGKH.

Appendix C

Cleaning detergents - monopolar handheld - **Sodium hypochlorite - PH 6**

Special Remarks on Explosion Hazards:
Anydrous Sodium Hypochlorite is very explosive. Primary amines and calcium hypochlorite or sodium hypochlorite react to form normal chloroamines, which are explosive. Interaction of ethyleneimine with sodium (or other) hypochlorite gives the explosive N-chloro cmpd. Removal of formic acid from industrial waste streams with sodium hypochlorite soln becomes explosive at 55 deg C. Several explosions involving methanol and sodium hypochlorite were attributed to formation of methyl hypochlorite, especially in presence of acid or other esterification catalyst. Use of sodium hypochlorite soln to destroy acidified benzyl cyanide residues caused a violent explosion, thought to have been due to formation of nitrogen trichloride. (Sodium hypochlorite)

Section 6: Accidental Release Measures

Small Spill:
Dilute with water and mop up, or absorb with an inert dry material and place in an appropriate waste disposal container.

Large Spill:
Corrosive liquid. Oxidizing material. Stop leak if without risk. Absorb with DRY earth, sand or other non-combustible material. Do not get water inside container. Avoid contact with a combustible material (wood, paper, oil, clothing...). Keep substance damp using water spray. Do not touch spilled material. Use water spray curtain to divert vapor drift. Prevent entry into sewers, basements or confined areas; dike if needed. Call for assistance on disposal. Be careful that the product is not present at a concentration level above TLV. Check TLV on the MSDS and with local authorities.

Section 7: Handling and Storage

Precautions:
Keep locked up.. Keep container dry. Keep away from heat. Keep away from sources of ignition. Keep away from combustible material.. Do not ingest. Do not breathe gas/fumes/ vapor/spray. Never add water to this product. In case of insufficient ventilation, wear suitable respiratory equipment. If ingested, seek medical advice immediately and show the container or the label. Avoid contact with skin and eyes. Keep away from incompatibles such as reducing agents, combustible materials, organic materials, metals, acids.

Storage:
Keep container tightly closed. Keep container in a cool, well-ventilated area. Separate from acids, alkalies, reducing agents and combustibles. See NFPA 43A, Code for the Storage of Liquid and Solid Oxidizers. Air Sensitive Sensitive to light. Store in light-resistant containers.

Section 8: Exposure Controls/Personal Protection

Engineering Controls:
Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective threshold limit value.

Personal Protection:
Face shield. Full suit. Vapor respirator. Be sure to use an approved/certified respirator or equivalent. Gloves. Boots.

Personal Protection in Case of a Large Spill:
Splash goggles. Full suit. Vapor respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits:
Sodium hypochlorite TWA: 1 CEIL: 1 (ppm as Cl2) STEL: 1 (ppm as Cl2) from ACGIH (TLV) [United States] Sodium hydroxide STEL: 2 (mg/m3) from ACGIH (TLV) [United States] TWA: 2 CEIL: 2 (mg/m3) from OSHA (PEL) [United States] CEIL: 2 (mg/m3) from NIOSH Consult local authorities for acceptable exposure limits.

Section 9: Physical and Chemical Properties

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Physical state and appearance: Liquid.

Odor: Characteristic. Chlorine-like (Slight.)

Taste: Not available.

Molecular Weight: Not applicable.

Color: Colorless to light greenish yellow

pH (1% soln/water): Neutral.

Boiling Point: Decomposition temperature: 40°C (104°F)

Melting Point: Not available.

Critical Temperature: Not available.

Specific Gravity: 1.07 - 1.093 (Water = 1)

Vapor Pressure: 2.3 kPa (@ 20°C)

Vapor Density: The highest known value is 0.62 (Air = 1) (Water).

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: Not available.

Ionicity (in Water): Not available.

Dispersion Properties: See solubility in water.

Solubility: Easily soluble in cold water.

Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Incompatible materials. light, air, heat

Incompatibility with various substances: Reactive with reducing agents, combustible materials, organic materials, metals, acids.

Corrosivity:
Extremely corrosive in presence of aluminum. Corrosive in presence of stainless steel(304), of stainless steel(316). Non-corrosive in presence of glass.

Special Remarks on Reactivity:
Decomposed by carbon dioxide from air. Slowly decomposes on contact with air. Unstable in air unless mixed with sodium hydroxide. Incompatible with ammonium acetate, ammonium carbonate, ammonium nitrate, ammonium oxalate, and ammonium phosphate. Decompostion of sodium hypochlorite takes place within a few seconds with these salts. Also incompatible with primary amines, phenyl acetonitrile, ethyleneimine, methanol, acidified benzyl cyanide, formic acid, urea, nitro compounds, methylcellulose, celloluse, aziridine, ether, ammonia. Mixing this product with chemicals (e.g. ammonia, acids, detergents, etc.) or organic matter (e.g. urine, feces, etc.) will release chlorine gas. Chloramine gas may be evolved when ammonia and bleach are mixed. Decomposed by hot water. Sensitive to light. Exposure to light accelerates decompositon.

Special Remarks on Corrosivity:
Sodium Hypochlorite is extremely corrosive to brass, and moderately corrosive to bronze. There is no corrosivity information for copper.

Polymerization: Will not occur.

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Appendix C

Cleaning detergents - monopolar handheld - **Chlorine - PH 12**

Liquid Bleach

6.2. Environmental precautions

Do not discharge into drains, water courses or onto the ground. Collect and dispose of spillage as indicated in section 13.

6.3. Methods and material for containment and cleaning up

Absorb with inert, damp, non-combustible material, then flush area with water.

6.4. Reference to other sections

For personal protection, see section 8.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Read and follow manufacturer's recommendations.

7.2. Conditions for safe storage, including any incompatibilities

Store at moderate temperatures in dry, well ventilated area.
Storage Class
Chemical storage.

7.3. Specific end use(s)

The identified uses for this product are detailed in Section 1.2.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Ingredient Comments
WEL = Workplace Exposure Limits

8.2. Exposure controls

Protective equipment


Respiratory equipment
No specific recommendation made, but respiratory protection may still be required under exceptional circumstances when excessive air contamination exists.
Hand protection
Use protective gloves.
Eye protection
Wear approved safety goggles.
Other Protection
Wear appropriate clothing to prevent any possibility of skin contact.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	Liquid
Colour	Water-white.
Odour	Chlorine.
Solubility	Soluble in water.
Initial boiling point and boiling range (°C)	
Not determined.	
Melting point (°C)	
Not determined.	
Relative density	1.06 @20
Bulk Density	
Not determined.	

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Liquid Bleach

Vapour density (air=1)	
Not determined.	
Vapour pressure	
Not determined.	
Evaporation rate	
Not determined.	
Evaporation Factor	
Not determined.	
pH-Value, Conc. Solution	12.0
pH-Value, Diluted Solution	
Not determined.	
Viscosity	
Not determined.	
Solubility Value (G/100G H2O@20°C)	
Not determined.	
Decomposition temperature (°C)	
Not determined.	
Odour Threshold, Lower	
Not determined.	
Odour Threshold, Upper	
Not determined.	
Flash point (°C)	
Not determined.	
Auto Ignition Temperature (°C)	
Not determined.	
Flammability Limit - Lower(%)	
Not determined.	
Flammability Limit - Upper(%)	
Not determined.	
Partition Coefficient (N-Octanol/Water)	
Not determined.	
Explosive properties	
Not determined.	
Other Flammability	
Not determined.	
Oxidising properties	
Not determined.	

9.2. Other information

Not known.	
Volatile By Vol. (%)	Actives 4.5 Av Cl2

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

Generates toxic gas in contact with acid.

10.2. Chemical stability

Avoid Contact with acids.

10.3. Possibility of hazardous reactions

Not known.

10.4. Conditions to avoid

Generates toxic gas in contact with acid.

10.5. Incompatible materials

Materials To Avoid
Strong acids.

10.6. Hazardous decomposition products

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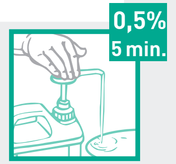
ANIOSYME DD1

Cleaning and pre-disinfection of instrumentation

Appendix C

Cleaning detergents - HF generator - ***Aniosyme - PH 6***

- Patented formula
- First tri-enzyme liquid detergent with disinfecting properties
- Especially developed for collecting of soiled instrumentation: no crossed contamination



PRODUCT
TO BE DILUTED
25 ml › 5L

INDICATIONS

- Reinforced cleaning and pre-disinfection of medico-surgical instrumentation, medical devices and endoscopic equipment.
- Cleaning in ultrasonic bins.
- Collecting of soiled instrumentation.

CHARACTERISTICS

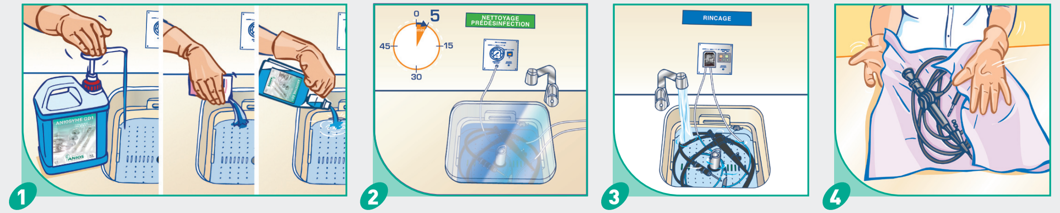
- First enzymatic liquid detergent with disinfecting properties.
- Tri-enzyme complex : protease, lipase, amylase, combined with surfactants
- Proved efficacy (DCP*) *Degreasing Cleaning Power
- Chlorine free formulation: no oxydization of materials.
- Aldehyde free formulation: no fixation of proteins.
- Stability of soaking bath: 8 hours (operating working day).
- Enzymatic stability proved.
- Neutral pH: compatible with alloys.
- Absence of chloride (ammonium propionate): non corrosive effect with materials.
- Compatible with ultra-sonic process.
- Clear liquid, blue perfumed

laboratoires ANIOS
Le professionnel de la désinfection

ANIOSYME DD1

Cleaning and pre-disinfection of instrumentation

INSTRUCTIONS FOR USE



1. **0.5 % dilution:** Pour a 25 ml dose in 5 litres of cold or tepid water.
2. Totally immerse the medical device. **Advised soaking time: 5 minutes.** Brush when necessary. For endoscopic equipment: brush channels.
3. Rinse thoroughly with tap water (of good microbiological properties) For endoscopic equipment: both internal and external parts of the medical device.
4. Dry with a clean towel. Proceed to the next step (see protocol established by the service).

COMPOSITION

Quaternary ammonium propionate, polyhexamethylene biguanide hydrochloride, enzymatic complex (protease, lipase and amylase), surface-active agents, stabilising agents, sequestrating agents, fragrance, colouring.

PRECAUTIONS FOR USE

Dangerous – respect the precautions for use (Drawn up according to the European rules in force regarding the classification and labelling of chemical products).
Storage: from +5°C to +35°C.
Class IIb medical device (Directive 93/2/EEC as amended).

PACKAGING

1. Box of 200 dosis, 25 ml each............................ Ref. 1200.097
2. 12 dosing bottles, 1 litre each............................ Ref. 1200.095
3. 4 cans, 5 litres each with a 25 ml dosing pump............................ Ref. 1200.036

MICROBIOLOGICAL PROPERTIES

Active against	Standards	Contact time
Bacteria	EN 1040, EN 13727 (dirty conditions : albumine and erythrocytes MRSA (EN 13727)	**5 minutes**
Mycobacteria	Mycobacterium tuberculosis (Tb)	**5 minutes**
Yeasts	EN 1275, EN 13624	**5 minutes**
Viruses	HIV-1, PRV (surrogate of HBV), BVDV (surrogate of HCV), Herpes virus, Influenza virus A [H1N1], Vaccinia virus	**5 minutes**

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GB1200-140224-Non contractual photographies

Appendix C

Cleaning detergents - HF generator - ***Hybitane - PH 6***

Hibitane Disinfectant category:
Disinfectants for agents used on object

Active ingredients:
Chlorhexidine Acetate

Hibitane Disinfectant companies and manufacturers:
Wyeth

Hibitane Disinfectant forms, composition and dosages:
Liquid; Disinfectant, Barn; Chlorhexidine Acetate 2%

Indications, usages and classification codes:
V07AV - Technical Disinfectants

There is an additional general information about this medication active ingredient chlorhexidine:

Pharmacological action

Antiseptic agent. chlorhexidine is active against vegetative forms of gram-negative and gram-positive bacteria and yeasts, dermatophytes and lipophilic viruses. This medicine has effect for bacterial spores only at elevated temperatures. It cleans and disinfects the skin without causing damage.

Why is Hibitane Disinfectant prescribed?

For local use: trichomonas coleitis, cervical erosion, itching of the vulva, prevention of sexually transmitted diseases (including gonorrhea, syphilis, trichomoniasis, chlamydia, ureaplasmosis); gingivitis, stomatitis, aphthae, paradont, alveolitis, disinfection of removable dentures, sore throat; postoperative care for patients in ENT and dentistry.
Treatment of wounds, burn wounds and surfaces, disinfection of the patient's skin.
Treatment of surgeons', nurses' hands and operating field before diagnostic manipulation operation.
Disinfection of work surfaces of devices (including thermometers) and equipment which heat treatment is not desirable.

Dosage and administration

The dose and method of application depend on the testimony and dosage form of chlorhexidine.
Use only locally. 0,5% alcohol or 1% aqueous solution for 2-5 min is applied to the corresponding surface. In dentistry solution for mouthwash and gel are prescribed 2-3 times a day.

Hibitane Disinfectant side effects

Perhaps allergic reaction. Dry and itchy skin, dermatitis, stickiness of hands for 3-5 min, stained teeth, the deposition of tartar, breach of taste (in the treatment of gingivitis).

Contraindications

Hypersensitivity to chlorhexidine, dermatitis, allergic reactions.

Special instructions

Remains active in the presence of impurities of blood and organic matter. Should not enter the chlorhexidine in the eye (except for special dosage form prescribed for washing the eye), as well as contact with the meninges and the auditory nerve.
Avoid using with iodine preparations.

Hibitane Disinfectant drug interactions

chlorhexidine is incompatible with the soap, and detergents containing anionic group (saponins, sodium lauryl sulfate, sodium carboxymethyl cellulose).
This medicine is compatible with any medication containing cationic group (cetrimonium bromide, benzalkonium chloride).

PLEASE, BE CAREFUL!
Be sure to consult your doctor before taking any medication!

Similar drugs | Analog drugs

1 Stroke Environ (STERIS Corporation)
14 Antibacterial All Purpose Cleaner and Disinfectant (Ecolab)
2 + 2 Nettoyant Desinfectant Liquide (Produits Sanitech)
2005 Pine Detergent Disinfectant (GH G.H.Wood)
2005 Pine Disinfectant (Wood Wyant)
2030 Bio-Cidol Neutral Germicidal Detergent (Seccure)
2312 Germicidal Detergent (Rebco Chemicals)
3 in 1 Disinfecting All Purpose and Glass Cleaner (Avmor)
3-D (Dustbane Products)
3129 Quat-10 (Les Laboratoires Choisy)
3133 Eclips No. 1 Disinfectant Detergent (Les Laboratoires Choisy)
3134 Eclips No. 2 Disinfectant Detergent (Les Laboratoires Choisy)
3D All Purpose Cleaner (Admiral)
3D Special (Admiral)
3D Super (Admiral)
3D Ultra 4 SCS (Delitek SCS)
3D Ultra-4 (Admiral Environmental Solutions)
3M Bathroom Disinfectant Cleaner Concentrate (3M)
3M Neutral Quat Disinfectant Cleaner Concentrate N23 (3M)
3M Quat Disinfectant Cleaner Concentrate (3M)

More Hibitane Disinfectant similar drugs »

	TWA: 260 mg/m³		Stunden TWA: 260 mg/m³ 8 Stunden	TWA: 260 mg/m³	STEL: 5 ppm 15 minute

Component	Russia	Slovak Republic	Slovenia	Sweden	Turkey
Ethyl alcohol	TWA: 1000 mg/m³ STEL: 2000 mg/m³ vapor	Ceiling: 1920 mg/m³ TWA: 500 ppm TWA: 960 mg/m³	TWA: 1000 ppm 8 urah TWA: 1900 mg/m³ 8 urah STEL: 4000 ppm 15 minutah STEL: 7600 mg/m³ 15 minutah	STV: 1000 ppm 15 minuter STV: 1900 mg/m³ 15 minuter LLV: 500 ppm 8 timmar. LLV: 1000 mg/m³ 8 timmar.	
Methyl alcohol	TWA: 5 mg/m³ Skin notation STEL: 15 mg/m³ vapor	Potential for cutaneous absorption TWA: 200 ppm TWA: 260 mg/m³	TWA: 200 ppm 8 urah TWA: 260 mg/m³ 8 urah Koža	STV: 250 ppm 15 minuter STV: 350 mg/m³ 15 minuter LLV: 200 ppm 8 timmar. LLV: 250 mg/m³ 8 timmar. Hud	Deri TWA: 200 ppm 8 saat TWA: 260 mg/m³ 8 saat

Biological limit values
List source(s):

Component	European Union	United Kingdom	France	Spain	Germany
Methyl alcohol			Methanol: 15 mg/L urine end of shift	Methanol: 15 mg/L urine end of shift	Methanol: 30 mg/L urine (end of shift) Methanol: 30 mg/L urine (end of several shifts for long-term exposures)

Component	Italy	Finland	Denmark	Bulgaria	Romania
Methyl alcohol					Methanol: 6 mg/L urine end of shift

Component	Gibraltar	Latvia	Slovak Republic	Luxembourg	Turkey
Methyl alcohol			Methanol: 30 mg/L urine end of exposure or work shift Methanol: 30 mg/L urine after all work shifts for long-term exposure		

Monitoring methods
BS EN 14042:2003 Title Identifier: Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents.
MDHS70 General methods for sampling airborne gases and vapours
MDHS 88 Volatile organic compounds in air. Laboratory method using diffusive samplers, solvent desorption and gas chromatography
MDHS 96 Volatile organic compounds in air - Laboratory method using pumped solid sorbent tubes, solvent desorption and gas chromatography

Derived No Effect Level (DNEL) See table for values

Route of exposure	Acute effects (local)	Acute effects (systemic)	Chronic effects (local)	Chronic effects (systemic)
Oral				
Dermal				328 mg/kg bw/day
Inhalation		915.5 mg/m³		1818 mg/m³/day

Predicted No Effect Concentration (PNEC) See values below.
Fresh water 0.96 mg/L
Fresh water sediment 3.6 mg/kg
Marine water 0.79 mg/L
Soil (Agriculture) 0.63 mg/kg

8.2. Exposure controls

Engineering Measures
Use only under a chemical fume hood. Ensure that eyewash stations and safety showers are close to the workstation location. Use explosion-proof electrical/ventilating/lighting/equipment. Ensure adequate ventilation, especially in confined areas.
Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous materials at source

Personal protective equipment
Eye Protection Safety glasses with side-shields (European standard - EN 166)
Hand Protection Protective gloves

Glove material	Breakthrough time	Glove thickness	EU standard	Glove comments
Butyl rubber	> 480 minutes	0.38 mm - 0.56 mm	Level 6	As tested under EN374-3 Determination of
Neoprene	> 480 minutes	0.45 mm	EN 374	Resistance to Permeation by Chemicals
PVC	< 60 minutes	0.18 mm		
Viton (R)	> 480 minutes	0.7 mm		

Skin and body protection Long sleeved clothing

Inspect gloves before use.
Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)
Ensure gloves are suitable for the task: Chemical compatability, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.
Remove gloves with care avoiding skin contamination.

Respiratory Protection When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

Large scale/emergency use Use a NIOSH/MSHA or European Standard EN 136 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced
Recommended Filter type: Organic gases and vapours filter Type A Brown conforming to EN14387 Brown

Small scale/Laboratory use Use a NIOSH/MSHA or European Standard EN 149:2001 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. Maintain adequate ventilation
Recommended half mask:- Valve filtering: EN405; or; Half mask: EN140; plus filter, EN 141

Environmental exposure controls Prevent product from entering drains. Do not allow material to contaminate ground water system.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	Colorless	
Physical State	Liquid	
Odor	Alcohol	
Odor Threshold	No data available	
pH	No information available	
Melting Point/Range	-114.1 °C / -173.4 °F	
Softening Point	No data available	
Boiling Point/Range	78.2 °C / 172.8 °F	760 mmHg
Flash Point	14 °C / 57.2 °F	**Method -** No information available
Evaporation Rate	No data available	
Flammability (solid,gas)	Not applicable	Liquid
Explosion Limits	Lower 3.3	

Appendix C
Cleaning detergents - HF generator - Mehylated spirit - PH 6

Upper 19 %
Vapor Pressure 5.8 kPa @ 20 °C
Vapor Density No information available (Air = 1.0)
Specific Gravity / Density 0.787 - 0.791
Water Solubility Soluble in water
Solubility in other solvents No information available

Partition Coefficient (n-octanol/water)

Component	**log Pow**
Ethyl alcohol	-0.32
Methyl alcohol	-0.74

Autoignition Temperature	365 °C / 689 °F	
Decomposition Temperature	No data available	
Viscosity	1.52 cSt 20 °C	
Explosive Properties	No information available	Vapors may form explosive mixtures with air
Oxidizing Properties	No information available	

9.2. Other information

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity
None known, based on information available

10.2. Chemical stability
Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous Polymerization Hazardous polymerization does not occur.
Hazardous Reactions None under normal processing.

10.4. Conditions to avoid
Incompatible products. Excess heat. Keep away from open flames, hot surfaces and sources of ignition.

10.5. Incompatible materials
Oxidizing agents. Acids. Acid anhydrides.

10.6. Hazardous decomposition products
Carbon monoxide (CO). Carbon dioxide (CO_2).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Product Information

(a) acute toxicity;
Oral No data available
Dermal No data available
Inhalation No data available

Toxicology data for the components

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Ethyl alcohol	3450 mg/kg (Mouse)		20000 ppm/10H (Rat)
Methyl alcohol	**Calc. ATE 60 mg/kg** LD50 > 1187 – 2769 mg/kg (Rat)	**Calc. ATE 60 mg/kg** LD50 = 17100 mg/kg (Rabbit)	**Calc. ATE 0.6 mg/L (vapours) or 0.5 mg/L (mists)** LC50 = 128.2 mg/L (Rat) 4 h
Water	-		

(b) skin corrosion/irritation; No data available

(c) serious eye damage/irritation; No data available

(d) respiratory or skin sensitization;
Respiratory No data available
Skin No data available

(e) germ cell mutagenicity; No data available

(f) carcinogenicity; No data available

The table below indicates whether each agency has listed any ingredient as a carcinogen

Component	EU	UK	Germany	IARC
Ethyl alcohol				Group 1

(g) reproductive toxicity; No data available

(h) STOT-single exposure; No data available

Results / Target organs Eyes.

(i) STOT-repeated exposure; No data available

Target Organs Optic nerve, Central nervous system (CNS).

(j) aspiration hazard; No data available

Symptoms / effects,both acute and delayed Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity
Ecotoxicity effects Contains no substances known to be hazardous to the environment or that are not degradable in waste water treatment plants.

Component	Freshwater Fish	Water Flea	Freshwater Algae	Microtox
Ethyl alcohol	Fathead minnow (Pimephales promelas) LC50 = 14200 mg/l/96h	EC50 = 9268 mg/L/48h EC50 = 10800 mg/L/24h	EC50 (72h) = 275 mg/l (Chlorella vulgaris)	Photobacterium phosphoreum:EC50 = 34634 mg/L/30 min Photobacterium phosphoreum:EC50 = 35470 mg/L/5 min
Methyl alcohol	Pimephales promelas: LC50 > 10000 mg/L 96h	EC50 > 10000 mg/L 24h		EC50 = 39000 mg/L 25 min EC50 = 40000 mg/L 15 min EC50 = 43000 mg/L 5 min

12.2. Persistence and degradability
Persistence Persistence is unlikely, based on information available.

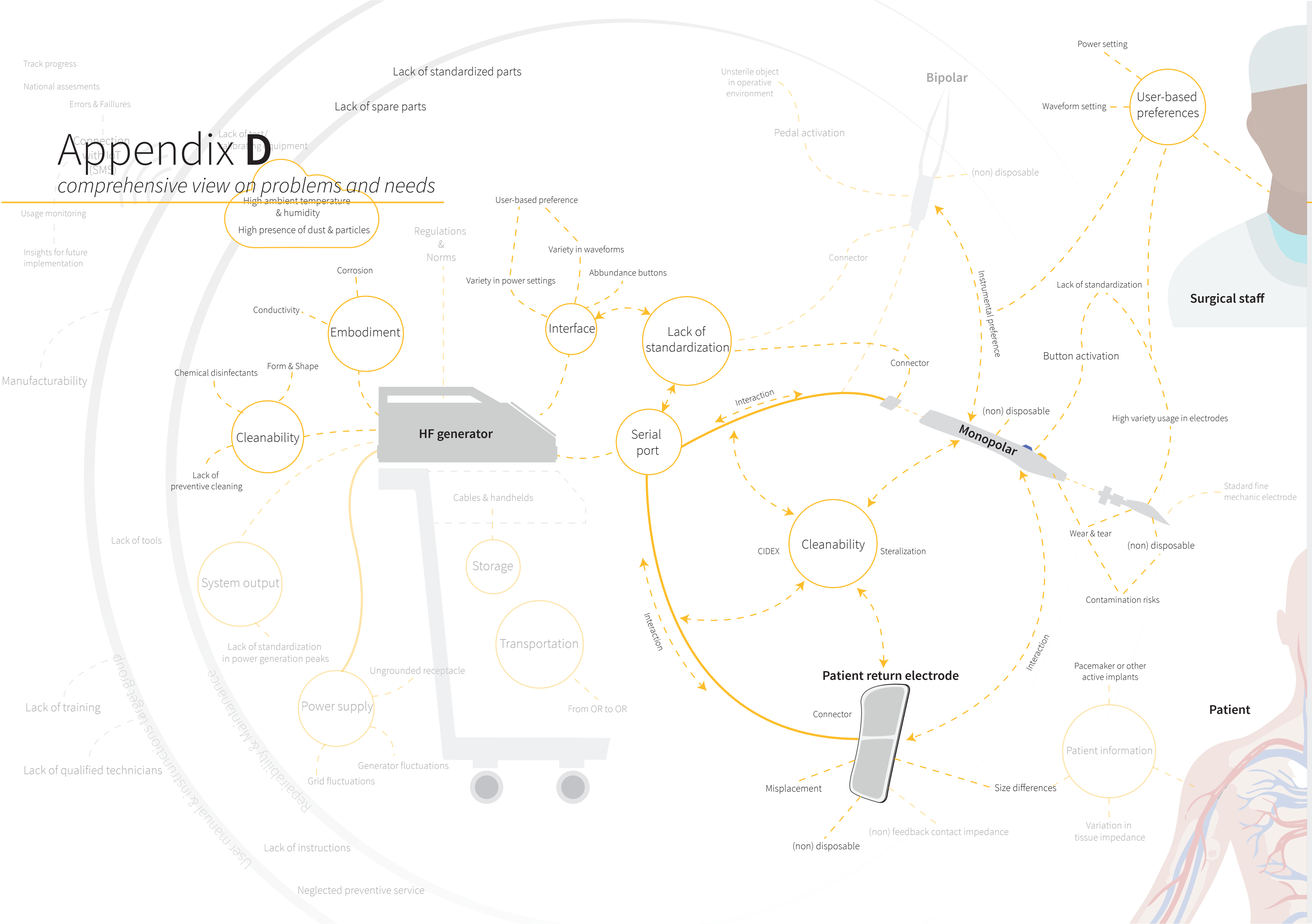
12.3. Bioaccumulative potential Bioaccumulation is unlikely

Component	log Pow	Bioconcentration factor (BCF)
Ethyl alcohol	-0.32	No data available
Methyl alcohol	-0.74	10 (fish)

12.4. Mobility in soil
The product contains volatile organic compounds (VOC) which will evaporate easily from all surfaces. Will likely be mobile in the environment due to its volatility. Disperses rapidly in air

Appendix D

comprehensive view on problems and needs



Appendix E

program of requirements

The extensive research, interviews and observations have contributed to input for design requirement. These requirement will be the foundation for the design phase and future development of the electrosurgery unit. The most important design requirements can be found below.

The design requirements that contain a (W) are wishes the ESU should have. From this point on the design requirements will be used as an evaluation tool for future ideas and concepts. Furthermore, these requirements can be used for future guidelines on development of surgical devices for LMICs

Function of ESU system

General purposes

- The ESU includes an electrical high frequency electric generator, active electrode (handheld) and return electrode plate
- The ESU is capable of performing monopolar surgery as well as bipolar surgery
- The provided feedback/information by the ESU is compatible to the variety of electrosurgery experience in Sub-Saharan countries
- The ESU enables the surgeons of LMICs to perform safe and intuitive electrosurgery
- The ESU should be able to provide the required power settings to assist the surgical staff with the 15 essential surgeries proposed by the WHO thus provide a power setting range of at least 10 Watt to 70 Watt
- Medical certified electronic components and software are used
- The ESU must remain safe and usable in face of a complete power outage of at least 90 minutes
- The output of the power control of the system is linear
- (W) The ESU should be as cheap as possible
- (W) The ESU should be endorsement for global safe surgery by the WHO and Society of Surgeons in Sub-Saharan Africa
- Durability and reliability of the ESU is more important than local repairability
- The components of the ESU should enable repair and reuse (Neighbour, 2012)
- The device must be manufactured in such a way that, when used under the conditions and for the purposes intended, it will not compromise the clinical condition or the safety of patients. This shall include:
- Reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and
- Consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users, (design for lay, professional, or other users). (Neighbour, 2012)
- All parts of the ESU have a dielectric strength high enough to prevent for insulation breakage when performing electrosurgery at a maximum power of 70 Watt.
- All conductors of the ESU should be resistant against RMS values with a maximum of 529 V at a power of 70 W
- All conductors of the ESU are resistant against maximum peak voltage of 3kV
- The electric conductors of the ESU do not have any sharp edges which can enhance ionisation of air that can create breakage of the insulation.

High frequency generator

- The high frequency generator includes a hand grip that enhances movability
- The system includes an internal power control (IPC) to prevent for current and voltage leakage
- (W) Within the range of tissue impedance, the output power should vary as little as possible between high and low or should at least be stable
- The interface consists of a linearly increasing power control
- The interface enables power change between a bandwidth of 10 to 70 Watt.
- The interface of the high frequency generator enables an intuitive pre-setting of power according to the limited electrosurgery experience in LMICs.

Appendix **E**

program of requirements

• The system output should be a clean sinusoid for the cut waveform and a clear duty cycle for the coagulation waveform to ensure an effective thermal output
• There is a difference in audio frequency of cut mode and coagulation mode (cut mode - low frequency, coagulation mode - high frequency)
• (W) The design of the generator should be modular in case of future addition of laparoscopic surgery. Consequently, the exterior measurements of the casing will not exceed the internal space within the laparoscopic tower.
• The interface of the HF generator consists of generic serial ports that are locally available all around the world. In addition the used connectors are standardized for all competitive electrosurgery accessories
    • Monopolar handheld (single and button activated)
    • 3 x 4 millimetres banana female connector
    • Bipolar handheld
    • 2 x 4 millimetres banana female connector
    • Split return electrode as well as 1 pin return electrode
    • 2 x 4 millimetres banana female connector
• The interface of the serial ports should provide a clear input for a single pin monopolar electrode and return electrode
• (W)The interface of the high-frequency will provide the user with basic theory of electrosurgery to increase feeling of confidence and control when using the electrosurgery unit during a surgery
• The high frequency generator will solely produce the waveforms of cut and coagulation and no other intermittent settings, since these waveforms are sufficient for general surgery
• The interface of the high frequency generator should be visible from a distance of 2,5 meters and an angle of 20 degrees of eye-direction
• A display brightness is required of at least 3000 mcd
• The sub-group LEDs should be clearly visible from a distance of 2,5 meters and an angle of 20 degrees of eye direction
• The high frequency generator should include feet to prevent the bottom exterior for wear and tear/damage and entering of water from the placement area
• The PCB and internal electronics must be assembled off ground to prevent for contact with water
• The cut mode and coagulation mode should have separate power adjustments, since the power setting can differ per patient
• The power setting should by all means start as low as possible for the intended surgical procedure
• The power setting of the waveform modes will be changed in steps of 1 W since this is required for superficial surgeries
• The high frequency generator should include memory to reset the last used power settings in case of a power fuse
• All steel parts should be grounded
• The high frequency generator includes a battery back up to function as a voltage stabilization
• The high frequency generator does not consist of any protruding components

Monopolar handheld
• The handheld consists of two buttons one for activation the cut mode and one for activation the coagulation mode
• The handheld provides a secure grip to increase the feeling of control and precision when being activated
• The handheld is IP 67 to be resistant against the steam autoclave
• Monopolar handheld can only function when the patient is attached to the dispersive electrode
• The monopolar handheld should provide a tactile difference between the cut mode and coagulation mode
• (W)The active electrode adapter includes a feedback-controlled instrument where the resistance in the tissue is measured and monitored to prevent for differences in impedance as a consequence of haemostasis.
• When one of the activation buttons stops working the product can still be activated by using a pedal system

Electrode tip
• The reusable electrode tip should be easy and quick to replace without being loose when performing a surgery
• The electrode tip should be rotatable when connected to the monopolar handheld
• The electrode tip includes a plastic surface which enables rotation of the electrode tip
• The electrode tip should be sufficiently designed to perform basic electrosurgery
• (W) The electrode tip should include a snap rotation at 0 and 90 degrees
• The electrode tip should enable activation with a tweezer or similar
• The electrode tip should enable a cut surface, coagulation surface and micro cross sectional area surface

Return electrode pad
• The return electrode has a 2 pin connection to enable for a REM system that measures a sufficient tissue impedance of the patient with the return electrode pad
• The return electrode pad should be flexible to create a better contact with the human body
• The return electrode should include fast attachment snaps for a quick attachment on the human body
• The return electrode should contain a manual with possible attachment locations
• The return electrode should include information on both sides on possible hazards during electrosurgery
• The attachment of the return electrode should not exceed pressure high enough to create decubitus during a surgery
• The system consists of a split return electrode to measure changes in tissue impedance

Bipolar handheld
• The bipolar handheld will be activated by using a pedal
• The bipolar handheld should include two electrodes that can be compressed together
• (W) The bipolar handheld should be capable of cutting tissue

Environment

The ESU must function normally despite of grid fluctuations of 15% above or 20% below nominal mains rating (Neighbour, 2012)
• During transport and storage the ESU should withstand -40°C to + 70°C[44]
• During transport and storage, the ESU withstands relative humidity of 10% - 100 % including condensation
• The should withstand operating temperature range 0 – 45°C
• The monopolar handheld is designed IP67 to be resistant against the high ambient dust in rural operation theatres (windows in operation theatre are opened)
• The dispersive electrode is designed IP67 to be resistant against high ambient dust in rural operation theatres
• The high frequency generator is designed IP54 to be resistant against high ambient dust in rural operation theatres and a possible drop of water on the exterior.

Product life span
• Each reusable monopolar handheld has a product life span of approximately 500 autoclavation cycles, thus 500 surgical procedures
• Each reusable electrode tip has a product life span of approximately 500 autoclavation cycles, thus 500 surgical procedures
• Each reusable return electrode pad has a product life span of approximately 500 autoclavation cycles, thus 500 surgical procedures
• All internal components of the high frequency generator have a product life span of approximately 7-10 years with intensive use
• The ESU should include at least 10 extra power fuses to enhance a sustainable system
• (W) The reusable monopolar handheld can be autoclaved as much as possible
• (W) The reusable electrode tip can be autoclaved as much as possible
• (W) The reusable return electrode can be autoclaved as much as possible

Appendix **E**

program of requirements

Maintenance

• The monopolar handheld and electrode tip should withstand the process of steam sterilization
  •134-140 degrees
  •2 bar
• The materials of the monopolar handheld, electrode tip and return electrode are resistant against high temperatures of the steam autoclave which is around 145 °C because of fluctuations
• The monopolar handheld (including electronic wire and seals), electrode tip and return electrode should be resistant against the cleaning detergents used in LMICs, see appendix C
• The adapter connection, plug connector and electrode tip should be resistant against adhesive wear and corrosion because of the agressive cleaning procedures used in LMICs
• The material of the high-frequency generator should be resistant against the surgical alcohol and antiseptic solutions found in appendix C
• The electrode tip is fully autoclavable
• The monopolar handheld, including electronic wire, is fully autoclavable
• The return electrode, including electronic wire, is fully autoclavable
• The ESU interface components consists of basic electronics that are globally available
• The electrical / interface components must be positioned in such a way that treatment or cleaning water does not fall directly on the interface or can remain on either one of the parts
• The electronic connections and wiring consist of universal spare parts
• The maintenance of the ESU will mostly be performed by the BMET so inclusion of training and clear user manuals will be mandatory
• The ESU does not use service related parts that have to be replaced within 1 year (filters, additional liquids, etc.)
• (W)The ESU does not require preventive service

Production

• In consultation with client Roos Oosting, the proposed badge size of the ESU will be 1000 pieces
• The costs of the high frequency generator will not exceed 250 euros
• The costs of a single monopolar handheld will not exceed 50 euros
• The costs of the electrode tip will not exceed 10 euros
• (W) The production costs should be as low as possible
• (W) Consider manufacturing locally to produce more affordable products, improved profit margins and greater benefit to local economies (Ng-Kamstra, 2016)
  • Reduction of problems with importing regulations when assembling the ESU locally

Colours, form and materials

• The shape of the high frequency generator, monopolar handheld and electrode tip should facilitate in smooth surfaces for ease of cleanability
• The HF generator shape includes a bumper to protect the interface components after a fall
• The material of the return electrode is an intrinsically conducting flexible polymer (ICPs) to create sufficient contact with the human body
• The monopolar handheld shape provides hold grips in close proximity both activation buttons
• The shape of the monopolar handheld should prevent for the electrode tip to contact human tissue or surgical sheet when laying down the handheld during the surgery procedure
• The shape of the electrode tip should facilitate in rotation with two fingers
• The coagulation function should be indicated with the colour blue in all parts
• The cut function should be indicated with the colour yellow in all parts
• The colour of the ESU is white because to enhance acceptance and create a professional attitude, according to the majority of surgeons in LMICs
• The materials of the monopolar handheld, electrode tip and return electrode should be resistant against the cleaning procedures and cleaning detergents in LMICs, see appendix C
• The material of the high frequency generator should be resistant against surgical alcohol and antiseptic solutions, see appendix C
• Prevent for grooves in electrode tip since they contribute to eschar build up
• All invasively used parts should be medical grade according to Medical Design Directive (MDD)
• The material of the return electrode is bio compatible for long contact with skin
• (W) The materials of the monopolar handheld and electrode tip should have an expansion ratio as low as possible
• The materials insulating the high voltage electronic should have a dielectric strength of at least 3 MV/m at a power of 70 W to ensure safety
• (W) The contrast of yellow and blue on the white exterior should be a visible as possible
• (W) The ESU exudes a medical product that has high performance and is safe in usage
• (W) The ESU is mobile and stable
• (W) Visible (purchasing) components have a reticent character with respect to the exterior of the ESU.
• (W) Structural elements and fasteners must not be in the field of view
• (W) The future branding of ESU should fit on the product and must be clearly visible
• (W) Meaning of controls should be explained (power button, power setting sub-groups, etc.)
• (W) The visible parts of the product must have a high optical quality

Measurements

• The maximum size of the ESU is 300 mm x 200 mm x 200 mm
• The ESU has a maximum weight of 6 kilogram
• (W) The high frequency generator should be as light as possible
• The connection shaft of the electrode tip is standardized with a diameter of 4 millimetres
• The spatula electrode should have similar measurements as the competitive spatula electrodes, thus a length of 25-40 millimetres and a thickness of 0,5 millimetres
• The return electrode should have a size of at least 45 cm2 to create a sufficient and safe cross sectional contact area

Norms and standards

• All parts that are exposed to the operation area are sterilisable
• The high frequency generator does not consist of a fan but a heat sink to prevent for clinical risks since the high frequency generator is in close proximity to the sterile surgical area
• The electronic cables and connectors of the monopolar handheld and return electrode
• The internal power supply must be equipped with a means of determining the state of the power supply.
• The ESU must include an alarm system to signal any power failure or hazard
• The ESU must avoid the risk of accidental electric shocks during normal use and in single fault condition
• Mechanical strength and accessibility of internal components is tested with a standard test finger (30N of pressure), while penetrating the finger no unearthed components can be touched
• Openings in the housing are tested with a test hook (tensile force 20N for 10 seconds perpendicular to the plane)
• Incorrect connection of plugs (use) or sub-plugs (service) may not cause hazardous situations or cause damage
• The function of the controls and indicators must be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.
• The parts of the monopolar handheld that have a high frequency in breakage (e.g. power fuse) should be easy to disassemble and replaced with similar components

Appendix **E**
program of requirements

Ergonomics
- An intuitive user interface with an easy power control is important for the management of an ESU
- (W) The recommended pre-operative checks take as little time as possible and is easy to perform
- The shape and measurements of the monopolar handheld should be compatible to P5 and P95 ergonomic activation of both waveform buttons

Target group
- The ESU can be operated by surgeons, clinical officers and OR assistances with all levels of experience with electrosurgery
- The ESU interface design should be accepted by surgeons, clinical officers and OR assistances with all levels of experience with electrosurgery
- (W) The surgeon should feel in control when using the product
- (W) The surgeon should feel confident when using the product
- The interface should provide the surgeon with extra confidence on correct examination of the surgery and correct power adjustment of the circulation assistance

Safety
- The high frequency generator interface consists of three sub-group functions (micro, moderate and macro) to increase safety by reducing the possibility of tissue trauma by misuse
- The pre-set of the sub-group will always start as low as possible
- A split return electrode should be used for safety to measure impedance during before and during treatment
- (W) design a dispersive electrode that is more conductive (e.g. by using a gel)
- The dispersive electrode has a safety margin in terms of measurements of 5%
- HF leakage needs to be below 100mA to prevent burns to the user, staff and patient.
- The monopolar handheld insulation, electrode tip insulation and electric cable are not allowed to conduct electricity
- Safe use of medical technology represents a safe product, in the hands of a trained user, in an environment that can guarantee safe surgery
- The ESU consist of an isolated generator technology that will deactivate when the return electrode is broken
- The electrode tip should prevent eschar build-up, which increases resistance and contributes to arcing
- The patient return electrode must be equipped with an appropriate alarm system to alert the user for situations that can lead to unintended tissue trauma
- An isolated power system utilizes a transformer to isolate power with no voltage reference to ground. This is an important safety feature because it reduces the risk of alternate path burns.
- Utilise available technology, such as tissue response generator to reduce capacitive coupling or an active electrode monitoring system, to eliminate concerns about insulation failure and capacitive coupling.
- To avoid inadvertent coupling and/or shunting of RF currents around the resistor elements, keep the resistors at least 10.2 cm (4 in.) away from any metal surface including table tops and other resistors. This is especially true if several resistors are connected in series or parallel to obtain a specified value. Do not allow the resistor bodies to touch each other.
- A metal generator embodiment includes a equipotential grounding lug
- Polymeric insulation materials must go through component plastics testing for properties such as flame rating (UL94, UL746), arcing resistance (HAI, CTI), hot wire ignition resistance (HWI) and relative thermal index (RTI)
- If the internal temperature of the generator is too high, an alarm tone sounds and an error will be generated on the displays
- The high frequency generator includes different sound for the cut mode and coagulation mode
- All exterior parts can be directly touched by the operator and patient
- The user cannot get in contact with charged parts
- During use, the high frequency generator cannot be easily shifted by means of resistance of the feet

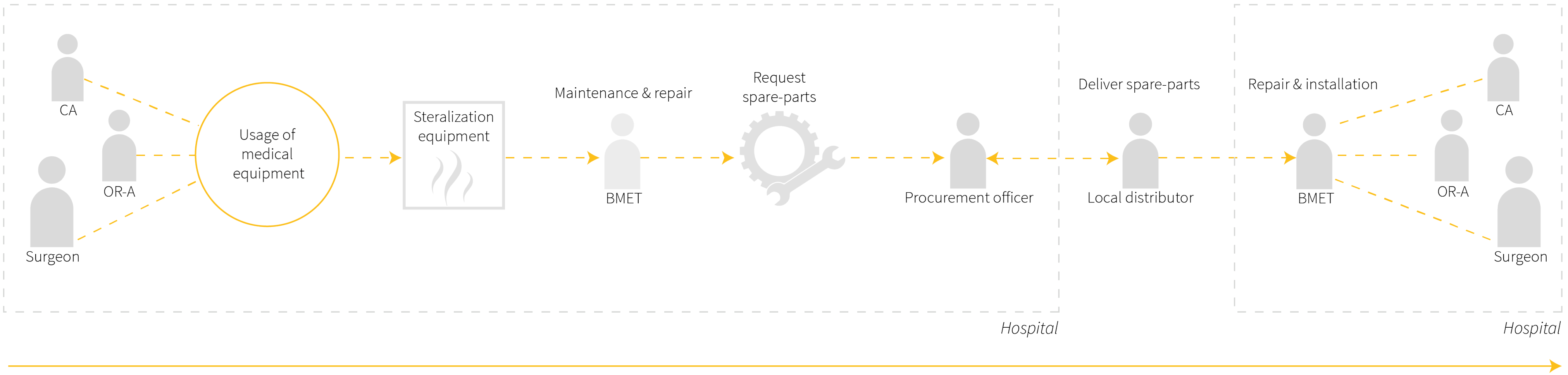
Installation and commissioning
- The ESU includes a clear and visual instruction manual for usage as well as maintenance.

Sustainability
- The handheld and electrodes are reusable
- No disposables will be used
- No glue will be used for connection of parts
- The electrosurgery unit and additional accessories can be repaired with basic repair tools that are globally and locally available
- The ESU includes an Allen key suitable for all incorporated screws
- The electrosurgery unit should be designed modular for future implemented design features
- The serial ports of the high frequency generator are compatible for competitive products to enhance sustainability in the long term

Appendix **F**

procurement journey - surgical equipment

Use phase of surgical equipment

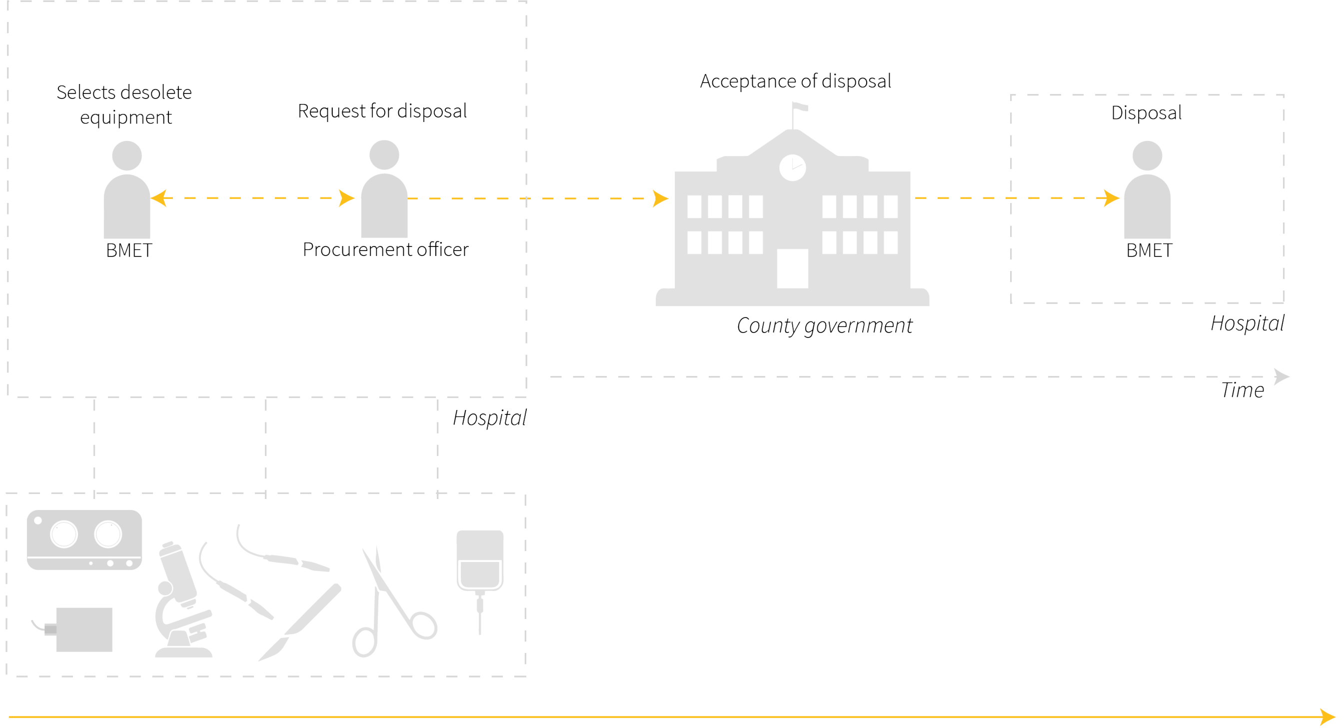


- Lack of spare parts
- Lack of training on maintenance of specific devices
- Bad management of equipment
- Unrecognition of BMETs by hospita management
- High costs/lack of finances
- No guidelines on preventive maintenance
- Lack of BMETS in management and districutor levels
- Unintended use

- Bureaucracy
- Manufacturers outside of the country
- Rapipd change of technology
- Design is used in a different context than it is designed for
- Delay of parts and treatments because of infrastructure

- Increased workload
- Lack of tools
- Lack of technical knowledge
- Lack of instructions

Disposal phase of surgical equipment



- Bad management of equipment
- High costs/lack of finances
- Lack of BMETs in management and distributor level
- Piles of obsolete and useless equipment

- Bureaucracy
- No polices on donations

- Increased workload

Appendix **G**

Interviews Dutch and Brazilian surgeons

Name: Rinse Meester
Date: 15/03/2018
Profession: Orthopedic surgeon
Experience with electrosurgery: Experienced
Experience in LMICs: Missions to Congo

Rinse Meester worked from 2010 to 2012 as AIGT/MD Global Health in the rural north of Congo Brazzaville. Pokola, the little town in the jungle where he was based, has a medical health post, offering medical facilities to 30.000 Congolese people. Rinse's work consisted of diagnosing and treating (tropical) infectious diseases, supervising mother&child care, performing surgical procedures, conducting ultrasounds, hospital logistics and out-of-hospital care for HIV patients.

The most important aspects for an ESU in LMICs will be:

- Easy and intuitive in use related to the knowledge in Sub-Sahara (try to research this)
- Resistant to power cuts and current fluctuations
- Reusable materials for the accessories of the ESU
  - o Dispersive electrode should be easy to clean, preferably flexible for easy attachment on the legs
- Cheap in purchase
- Long lifespan
- Reliable in system output and long lasting

In other words, the preputium mobile!

Name: Stichting Medic
Date: 15/03/2018
Profession: Donation company for LMICs
Experience with electrosurgery: Experienced
Experience in LMICs: Missions all over Africa

- Wat voor soort apparaten (Elektrochirurgie) sturen jullie weg en hoe maken jullie hierin de selectie? (veiligheid, merk, CE markeringen)
- Wat zijn de problemen met medische hulpmiddelen in lage lonen landen?
- Doen jullie aanpassingen aan de apparaten voordat jullie de apparaten toesturen (refurbished)
- Wat is de werkwijze als een van de onderdelen kapot is gegaan? Is daar een soort service systeem voor?
- Zijn er politieke problemen bij het doneren van medische hulpmiddelen?
- Zijn er problemen met certificeringen bij het doneren van medische hulpmiddelen?
- Wat zijn de problemen met huidige elektrochirurgie apparatuur
  - o Repareren van kapotte onderdelen?
  - o Tekort aan apparatuur?
  - o Niet bestendig tegen luchtvochtigheid en temperatuur?
  - o Ouderwetse apparatuur?
  - o Fouten in gebruik door gebrek aan kennis specialisten?
- Wat is de behoefte m.b.t. elektrochirurgie
  - o Type behandelingen?
  - o Meer voor basale behandelingen?
- Wat zijn de faciliteiten in ontwikkelingslanden met betrekking tot infrastructuur (elektriciteit, distributie, spare parts, etc.) en hoe spelen jullie hierop in?
- Is het mogelijk om electrodes mee te krijgen om ervan te leren? (handhelds die niet meer werken)
- Wat gebeurt er wanneer er een apparaat kapot gaat?
  - o Technici in lage lonen landen repareren het product met spare parts uit de omgeving?
  - o Wat doen jullie om deze problemen te verhelpen?
- Apparaat wordt teruggestuurd of toesturen onderdelen met een uitleg?
  - o Apparaat wordt niet meer gebruikt?
  - o Wat doen jullie ten aanzien van end of life van het product?
- Verbranden?
- Terugsturen?

Het gebruik

- Hoe ziet een dag van het elektrochirurgie apparaat eruit in ontwikkelingslanden?
  - o Wat zijn de voorbereidingen?
- Wordt het apparaat verplaats van operatiekamer naar operatiekamer?
- Hoe wordt het apparaat geïnstalleerd voor gebruik?
- Wordt er een check gedaan om te zien of het apparaat werkt?
  - o De behandeling:
- Welke extra tools worden er gebruikt?
- Wordt er veel geswitcht tussen monopolair en bipolair?
  - o Nabehandeling
- Welke onderdelen worden schoongemaakt en op wat voor manier?
- Welke onderdelen worden gesteriliseerd?
- Waar wordt het product na gebruik gestationeerd?
- Wat zijn de schoonmaakfaciliteiten in lage lonen landen en hoe wordt er omgegaan bij een gebrek aan die faciliteiten(wat voor vloeistoffen worden er dan gebruikt)?

De behandeling:

• Welke extra tools worden er gebruikt?
• Wordt er veel geswitcht tussen monopolair en bipolair?

Nabehandeling

• Welke onderdelen worden schoongemaakt en op wat voor manier?
• Welke onderdelen worden gesteriliseerd?
• Waar wordt het product na gebruik gestationeerd?
• Wat zijn de schoonmaakfaciliteiten in lage lonen landen en hoe wordt er omgegaan bij een gebrek aan die faciliteiten(wat voor vloeistoffen worden er dan gebruikt)?

Remarks

- Stichting MEDIC bevindt zich op de laatste cyclus van de apparatuur
  - o Apparatuur wordt gerestaureerd en verkocht voor een klein bedrag
  - o De apparaten die gedoneerd zijn voldoen niet altijd aan de standaarden. Er wordt ook niets gedaan m.b.t. regulering van de apparatuur.
- Hierdoor wordt de veiligheid niet altijd gewaarborgd
  - o Target group is de ziekenhuizen in rurale gebieden
- Apparaat moet robuust zijn
  - o Moet tegen een schok kunnen of kleine val
- Standaardisatie
  - o User interface (instellen van de settings)
  - o Gebruikte electrodes
  - o Elektronica
- Er zit verschil in aansluitingen van verschillende merken
- De ESU moet functioneren op 50 Hz of 220 V

Context

- Het elektrochirurgie apparaat moet bestendig zijn voor fluctuaties in de voedingsspanning
  - o Moet zowel op 50Hz als iets daaronder kunnen werken (bijvoorbeeld 48 Hz of 52 Hz)
- Er is een gebrek aan kennis m.b.t. tot de functie van de apparatuur en de componenten
- Er ontstaat een steeds groter tendens voor het leasen van de apparatuur met een service systeem ingebouwd voor controle van componenten en functionaliteit
- Er is een gebrek aan onderhoud en technische kennis
- Chirurgen weten alleen de functie van de apparatuur, maar weten niets over de technische werking
  - o Dit is meer de verantwoordelijkheid van de OK assistenten
- Het doneren van producten vermoord plaatselijke economie
- Binnen de cultuur moet het gevoel van samenhorigheid en vertrouwen groeien
  - o Geen vertrouwen in de politiek
  - o Geen vertrouwen in andere ziekenhuizen
- In de urban gebieden wordt wel gebruik gemaakt van laparoscopische chirurgie, hier is bipolair dus ook wel interessant. In de rurale gebieden wordt nauwelijks tot geen bipolaire chirurgie uitgevoerd, hier voldoet het

Appendix **G**

Interviews Dutch and Brazilian surgeons

meer basale en is monopolair voldoende.
- De LMICs chirurgen leren tijdens de opleiding werken met de apparatuur (elektrochirurgie).
- In Twente is er een werkweek waarin chirurgen die op uitzending gaan naar de tropen leren repareren, banden plakken, elektronica, etc. Om dit toe te passen in de rurale gebieden.
  o Zodat ze meer feeling krijgen met de techniek
- Vaak nemen artsen vanuit HIC fijn instrumentarium mee om eventueel apparatuur mee te repareren. Grof instrumentarium (hamer, waterpomptang, etc.) is vaak aanwezig in de rurale gebieden, maar niet het fijne instrumentarium (kleine schroevendraaier, imbussleutel, etc.)
- Ziekenhuizen die apparatuur lenen zullen dit nooit teruggeven.
- Wanneer bezoekers het ziekenhuis verlaten, worden zij gefouilleerd om te kijken of er geen spullen meegenomen zijn.
  o Er zit in sommige ziekenhuizen zelfs prikkeldraad om de TL buizen
- In de meeste operatie ruimtes in de rurale gebieden staat een hoop apparatuur, maar dit is bijna allemaal kapot.
- Standaardisatie in de apparatuur is van groot belang kijkend naar mogelijkheid tot reparatie en onderhoud
- De meeste apparatuur in kleine ziekenhuizen wordt in de OK schoongemaakt. Hier bevindt zich dan ook de autoclaaf. In grotere ziekenhuizen is er een aparte sterilisatieruimte.
- De eisen m.b.t. schoonmaken en steriliseren van de apparatuur wordt niet gevalideerd.
- In de kleine ziekenhuizen zijn maar een klein aantal OKs, hier worden de elektrochirurgie apparaten ook niet verplaatst van OK naar OK.
- De apparatuur moet tegen een stootje kunnen.
  o De elektronica gaat vaak als eerst kapot en is ook moeilijk om te repareren aangezien de kennis ontbreekt.
- De apparatuur moeten geen naden of ribbels hebben, omdat dit moeilijk is schoon te maken.
- Buisjes en kanalen op de handheld moeten absoluut voorkomen worden i.v.m. cleanability en steriliteit.
- Van het elektrochirurgie apparaat worden alleen de actieve elektrodes gesteriliseerd (invasief gebruik). De rest van het apparaat wordt schoongemaakt met een ontsmettingsmiddel zoals alcohol.
- Jassen en handschoenen worden in de wasmachine gegooid en buiten gehangen, niet bepaald steriel.
- De BMETs kunnen de apparatuur niet repareren
  o Tools voor fijn gebruik niet aanwezig
- Er wordt alleen monopolair gebruikt voor de rurale gebieden.
  o Met name de scalpel wordt gebruikt
- BOWA Duitse elektrochirurgie apparatuur catalogus
- Er staan met name veel ERBE en Valleylab apparaten omdat deze het meest ingekocht worden door de ziekenhuizen en wellicht langer meegaan.

Electrochirurgie
- Wordt met name gebruikt voor het meer basale werk
  o Alleen monopolair wordt gebruikt
  o Bipolair is te precies werk en wordt met name bij laproscopie gebruikt. Wordt geen gebruik van gemaakt in ontwikkelingslanden
- Dispersive electrode
  o Platen die reusable zijn gebruiken silicone. Zijn erg duur om te kopen vanuit het ontwikkelingsland.
  o In westerse cultuur is alles disposable, dit werkt niet in ontwikkelingslanden (te duur)
  o Moet zowel ontwikkeld worden voor volwassenen als kinderen (2 maten)
- Electrodes
  o Geen disposables, worden hergebruikt in de ontwikkelingslanden
  o Vaak wordt alleen de mes electrode gebruikt (spiraal of bol niet)
  o Moeten gesteriliseerd kunnen worden
- De generator heeft nooit problemen alleen als zij hem vaak laten vallen.
- Artsen willen liever geen pedaal tijdens het gebruik van de ESU
  o Zoeken naar het pedaal
  o Ligt tussen de rommel bij ziekenhuizen in ontwikkelingslanden
- Apparaat moet bestendig zijn tegen de luchtvochtigheid van de ontwikkelingslanden
- Handheld
  o Schakelaar voor coaguleren en snijden
  o Moet in de autoclaaf kunnen

Name: Pieter Spiering
Date: 20/03/2018
Profession: Secretaris en cie Materialen – Werkgroep Orthopedie Overzee
Experience with electrosurgery: Limited

- Werkgroep Orthopedie is een overleg orgaan met 65 leden die in kleine groepen naar landen in nood verstuurd worden.
- Zij opereren dan in landen waar geen hulp en toegang is tot gezondheidszorg.
- Hierbij voeren zij eenvoudige chirurgie uit en het meer basale werk.
- In de LMICs ontbreekt het aan infrastructuur en nabehandeling
- Zijn werkgroep doet met name de verwaarloosde fracturen
- Er zijn daar vaak geen middelen voor elektrochirurgie omdat er ook geen OKs zijn ingericht
- Af en toe zijn er missie posten die het begeleiden en waar wel wat apparatuur en of OKs aanwezig zijn.
- Er is vaak geen technische dienst
- De meeste ziekenhuizen hebben een autoclaaf
- De werkgroepen nemen vaak geen diathermie apparatuur mee, maar wel scalpels en standaard medische apparatuur van de chirurg.
- In de meeste gevallen wordt de OK kleding gewassen en buiten gehangen.. Niet bepaald steriel.
- Zoek contact op met mijn kennis Peter Hubach | Orthopedisch chirurg met veel ervaring in Kameroen – 0227 547 108
- Zoek contact op met mijn kennis Bas van Faassen | Orthopedisch chirurg met veel ervaring in Oeganda – 0113 301 769

Name: Bas van Fraassen
Date: 23/03/2018
Profession: Orthopedic surgeon
Experience with electrosurgery: Experienced
Experience in LMICs: Multiple missions Cameroon and Uganda

De moderne diathermy apparaten hebben veel functies, iets wat zo eenvoudig mogelijk gehouden moet worden. Het liefst 2 of 3 standen. Hierbij wordt alleen coaguleren en cutting als functies gebruikt.
- Snoeren en handheld zijn kwetsbaar, deze worden gesteriliseerd door ze te plaatsen in een roestvrijstalen bak vol met CIDEX.
- Het scalpel wordt het meest gebruikt tijdens operaties (dit is natuurlijk wel afhankelijk van type chirurgie)
- Snoeren moeten degelijk zijn.
- Het diathermy apparaat wordt alleen gebruikt als er OK ruimtes zijn, dit kan bijvoorbeeld al in ziekenhuizen zijn met 40 bedden. Bas van Fraassen werkt in een ziekenhuis met ongeveer 300 bedden.
  o Grote ziekenhuizen hebben zeker elektriciteit
- Netspanning fluctueert, dus hiervoor moet een veiligheid ingebouwd worden.
- De werknemers daar zijn niet persé dommer dan ons, maar hebben een andere achtergrond.
- De chirurgische ingrepen bevinden zich in een beperkt palet, iets meer op basis chirurgie
- De primaire incisie tijdens een operatie gaat met een normaal scalpel
- Betrouwbaarheid in het product is ontzettend belangrijk
- De omgeving van het product zijn
  o Hoge temperaturen
  o Hoge luchtvochtigheid

Appendix **G**

Interviews Dutch and Brazilian surgeons

o Fluctuerende netspanning
- De hygiene in de ziekenhuizen is minder dan in westerse culturen. Er wordt geroeid met de riemen die ze hebben.
- Tijdens de behandeling gebeurt het regelmatig dat de plaat verschuift. Hierdoor stopt het apparaat met werken. Dokter van Fraassen heeft nog een problemen gehad met brandwonden.
- Bipolaire tweezer gebruikt hij niet, omdat dit niet aanwezig is in de ziekenhuizen waar hij werkt en hij heeft hier zelf geen behoefte aan. Coaguleren van een ader kan ook met monopolair gebruik en door de huid met een pincet te pakken en daar de scalpel op te zetten voor coagulatie.
- Voor de meer subtiele chirurgie (urologie, neurologie, plastische chirurgieetc.) worden er dokters ingevlogen, ook doen de chirurgen dit zelf in de praktijken.
- De ziektebeelden zijn daar heel anders. Kijkend naar klompvoet; dit wordt niet op tijd behandeld.
- Het ESU apparaat
o Niet te ingewikkeld in gebruik
o Robuust
o Moet resistent zijn tegen de fluctuaties in netspanning
o Simpel te bedienen (2 of 3 functies)
o Moet voor een redelijk bedrag te koop zijn
- In Oeganda betalen de mensen met hun mobiel:
o Veilig
o Veel gedaan door vertegenwoordigers en markt kooplui
- Iedereen heeft daar een mobiel.
- Moet een verschil zitten tussen operaties van volwassen en kinderen
o Kinderen moeten geopereerd worden met lagere voltages i.v.m. met massa verschillen en gevoeligheid. Aantasten van omliggende weefsel kan meer gevolg hebben. Het moet niet zo zijn dan bij het coaguleren van de vaatjes in de enkel, de halve enkel meegenomen wordt
- De werknemers in de ziekenhuizen daar zijn heel praktisch, er wordt geroeid met de riemen die ze hebben.
- Snoeren van het apparaat zijn erg kwetsbaar
- Er wordt schoongemaakt met CIDAX
- Elke OK heeft een autoclaaf, dus daar kan je vanuit gaan.
- Een keer hebben zij een autoclaaf in Afrika gekocht, omdat er daardoor ook continue service aanwezig kan zijn.
- De mesjes/scalpels worden na een paar keer vervangen, omdat ze niet tegen hergebruik kunnen.
- Disposables worden in deze landen nog wel 10x meer gebruikt dan wat kan en mag
- ESU staat altijd gepositioneerd in de OK als een aparte machine en wordt verplaatst van OK naar OK.
- Belangrijk is dat er een onderscheid is tussen coaguleren en cutting
- Hoe simpeler het product, des te minder kans op oneigenlijk gebruik
- Standaardisatie van de onderdelen is super belangrijk.
- Protheses worden niet geplaatst omdat dit niet veilig is kijken naar steriliteit in de ontwikkelingslanden
- De Nederlandse chirurgen nemen vaak klein gereedschap en jassen mee
o Eigen handschoenen
o Eigen mondkapjes
o Eigen petjes
- Als je een batterij gebruikt zal het gewicht en de prijs toenemen (lithium ion batterij)
- Robuustheid van de ESU is reuze belangrijk
- Technici heeft geen kennis om de kapotte onderdelen daar te repareren
- Als een medisch apparaat het niet meer doet, wordt deze in de hoek gelegd en gewacht tot dokter van Fraassen volgend jaar weer een nieuwe meeneemt.
- Zoek contact op met Goovert van Nieuwenhuizen van stichting MEDIC
- Het betere is de vijand van het goede

Het gebruik van de ESU

Voorbereiding

- Het ESU apparaat wordt vaak verplaatst van OK naar OK, net waar er een nodig is.
- De ESU wordt achter de chirurg in de OK geplaatst, buiten het operatieveld op een tafel met wieltjes
- De afstand tot en met de patiënt is +/- 2,5 tot 3 meter
- De ESU wordt van de tevoren ingesteld op de verwachte soort behandeling
- De ESU wordt van tevoren altijd op cutting ingesteld
- Instellingen worden van te voren verhoogd aan de hand van het te behandelen type weefsel
- De handheld en snoer worden uit het CIDEX gehaald en op het operatieveld gepositioneerd. Het restant van het snoer wordt doorgegeven aan de omloop ter bevestiging aan de ESU
- De return plaat wordt altijd van tevoren gekoppeld aan de patient (in dit geval een stalen plaat)
o De OK assistente (diegene die de narcose uitvoert) plaatst de electrode
o Snoer gaat van de generator om de chirurg heen naar de patient toe
o Deze wordt onder de rug of zij geplaatst van de patient, afhankelijk van de positie waarop de patient ligt)
o Mocht dit niet goed zitten zal het apparaat alarmeren
o Dokter van Fraassen heeft geen problemen ondervonden met brandwonden
o Er wordt geen gel of ander conductie materiaal op de huid gesmeerd, het lichaam wordt ook niet geschoren.
- De return plaat is bij voorkeur
o Flexibel zodat deze makkelijk op het lichaam geplaatst kan worden
o Moeilijk te verschuiven
o Banden of iets dergelijks eromheen zodat deze vastgemaakt kan worden aan benen of armen
o Snoer langer ongeveer 3-4 meter
- Dokter en OK assistente worden steriel aangekleed en gedesinfecteerd

De behandeling

- Tijdens de behandeling gebruikt dokter van Fraassen vaak een pincet, schaar of scalpel
- De chirurg draagt handschoenen, een jas, mondkapje en muts
- Tijdens de behandeling wordt er door hem niet geswitcht van monopolair naar bipolair
- Hij gebruikt altijd het de scalpel electrode, de andere gebruikt hij niet voor zijn operaties
- Tijdens de behandelingen worden er niet twee actieve handhelds/electrodes gebruikt, dit is niet nodig.
- De kabels moeten ongeveer 4 meter zijn om genoeg flexibiliteit te hebben
- De settings worden af en toe tijdens de behandeling aangepast als de chirurg niet door het weefsel komt (dus stugger materiaal)
- Tijdens het gebruik wordt de handheld regelmatig weggelegd, deze ligt dan in het operatieveld, dus op de patient
o Er kan dan per ongeluk op het pedaal getrapt worden waardoor de handheld geactiveerd wordt en er dus een brandwond ontstaat
- Des te minder beweging tijdens de behandeling des te sterieler kan je werken, dus de chirurg veranderd absoluut de settings niet, dit doet de omloop assistente
- Meestal worden de settings niet aangepast tijdens de behandeling alleen als er te weinig power is.
- Wat gebeurt er tijdens een powercut
o Ziekenhuis heeft altijd wel een generator voor stroom
o Dit schommelt nog iets meer
o Zonnepanelen op het dak voor een buffer

De nabehandeling

- Allereerst wordt de stroom eraf gehaald en worden alle snoeren losgekoppeld
- De snoeren worden in een bak met CIDAX gelegd
- De generator wordt schoon gepoets met een doekje, met name als er erg veel gespetterd is. Waarschijnlijk is dit met alcohol gedaan, dit weet Dokter van Fraassen niet zeker
- Het schoonmaak protocol is hier minder strikt dan in Nederland

Appendix **G**

Interviews Dutch and Brazilian surgeons

Name: Gery Selissen
Date: 24/03/2018
Profession: Technical team MCA
Experience with electrosurgery: Experienced

- Binnen de medische dienst zijn er 3 risico klassen met betrekking tot medische apparatuur wat te maken heeft met het gevolg van een mankement in de medische apparatuur (high risk = levenbedreigend bij problemen
- Het ESU/diathermy apparaat valt onder de high risk
  o Het ziekenhuis heeft graag de technische kennis over dit apparaat in huis
  o Hieronder vallen certificaten om de apparaten te repareren
    ▪ Hiervoor krijgen zij een certificaat bij de fabrikant
    ▪ Jaarlijks moeten zij hiervoor op training komen
  o Dit betekend dat de technici meer weet over de functie van het apparaat i.p.v. de chirurg. Die weet alleen hoe hij zijn functies uit moet voeren
- De medische specialisten moeten bekwaamheden t.a.v. diathermy aantonen
  o Hoe de spullen te gebruiken?
  o Niet op patienten oefenen
- De apparaten die in bruikleen of op zich getest worden mogen niet kritisch gebruikt worden
- De chirurg moet de FMEAs maken voor het diathermy apparaat
- Technische dienst is 24/7 bereikbaar voor eventuele problemen
  o Zuster oproep tot röntgen installatie
  o Raadpleegt collega's wanneer de kennis niet aanwezig is
- Belangrijke vraag is waarom is er een defect getoond
  o Horen van gebruiker hoe het apparaat defect is gegaan (grondslag)
  o Dialoog is belangrijk en er wordt direct gecommuniceerd met de medische dienst
- De gebruiker is diegene die het apparaat in zet en moet dus alvorens bekijken wat de status van het apparaat is.
- Als apparaat wel onderhoud heeft gehad zegt dit niet dat het apparaat het hele jaar blijft functioneren.
- Er zijn tijdens de OK allemaal time out procedures waarin ze de apparatuur testen.
- Dit wordt allemaal gedocumenteerd en functioneert als het controle middel. Soort van vliegtuig principe.
- Sommige ziekenhuizen zijn alleen gebaseerd op onderhoud
  o Buiten firma's doen kritieke reparaties
  o Hoge kosten
- De OK is steriel
- Belangrijk dat ze back up apparaten hebben mocht er iets kapot gaan tijdens een kritieke operatie
- Medische technici participeren mee in de keuze naar apparaten
- Jaarlijks wordt de status van de apparatuur besproken en wordt besloten of en apparaat wel of niet vervangen wordt en dit wordt dan meegenomen in de begroting.
- Standaardisatie is het tover woord
- Voor diathermy hebben zij 6 merken staan en elk apparaat heeft zijn eigen karakter en eigenschappen. Jarenlang met ERBE gewerkt en dan Valleylab dan gaat de chirurg de mist in.
- Bij het ene apparaat lis op het weefsel zetten (ERBE) valleylab eerst power op de electrode zetten. Andere opstart curve. Die hoge puls van Valleylab kan dan het weefsel gelijk carboniseren.
- De lis mag maar 2kV hebben. Snijtechnieken en sproeien gebruiken in de lucht af en toe 9000V waarin de lis gewoon verdampt. Dus door verkeerd gebruik ontstaan dit soort zaken.
- Materialen kennis in relatie met apparatuur is ontzettend belangrijk
- Bij regelmatig steriliseren moet er goed getest worden op functie. (bekabeling)
- Isolatie om de disposable moet altijd intact blijven! (kunststof)
- Wordt getest bij 10kV dus dan kan de apparatuur al perforeren tijdens de testsituaties.
- Van alle instrumenten moet je weten wat er fout kan gaan en dit moet je kunnen dekken.
- Standaardisatie in stekkering is er nu wel! Hier moet je bij de aanschaf goed op letten
- Zij willen geen snoeren meer vinden met bananenstekkers omdat je die overal in kan stoppen (veiligheid)
- Monopolair meer vermogen nodig (plaat nodig en stroom gaat door het hart heen etc.)
- Bipolair heeft lager vermogen en mooier hanteerbaar
- Technieken worden vaak tegelijk gebruikt tijdens behandeling
- Er zijn technieken om een darm door te knippen met laparoscopische pen
- Overstappen van het ene merk naar het andere merk dan werkt de tang weer anders waardoor er grote fouten kunnen ontstaan – STANDAARDISATIE
- Dit hoort terug te komen in een risico analyse van de arts
- Focus je op de gebruiker die veilig moet werken
- Stroom is waarschijnlijk niet geaard in Afrika
- Bij basale diathermy hebben je wel veel vermogen nodig +/- 400 W
- Het plakken van de return electrode gaat vaak fout, omdat het toestel de impedantie niet meet
- Er moeten genoeg controle middelen in het apparaat zitten
- Het liefst een REM installatie voor de elektrode plaat
- Return electrode moet groot genoeg zijn. Er zijn nieuwe kleinere platen ontwikkeld die boller lopen
- Voor kinderen is er minder vermogen nodig, het is allemaal veel directer.
- Per mensen is de huid ook verschillend (tougher, vochtiger, etc.)
- Bij diathermy moet de huid eigenlijk wel schoon gemaakt worden met alcohol zodat er goed contact gemaakt kan worden.
- Bij kinderen worden er waarschijnlijk ook kleinere technieken gebruikt worden
- Als je de plaat vlak maakt, moet hij groter zijn.
- Valleylab heeft remplaat met meer bolling voor warmteafvoer en deze is ook dikker
- Zorg dat de bekabeling en contacten goed zijn
- Alle tussenliggende kabels worden gesteriliseerd
- Alle pencils zijn disposables
- Als je steriliseren in goed doet gaan je instrumenten stuk (in zulke landen wordt misschien wel 200 graden gebruikt..)
- De keten voor het goed uitvoeren moet je zo goed mogelijk dekken
- De apparatuur moet een afstemming krijgen waarvoor het gebruikt wordt
- Kijk goed welke power er nodig is
- Check de Martin 100 die misschien afgestemd is voor de discipline
  o Zijn redelijk goed voor elke discipline toepasbaar
- Methodes uitvoeren alvorens de arts begint met chirurgie
- Eindtrappen kunnen gemakkelijk breken
- Er staat nooit een vermogen op de knop aangegeven
- Door disposables is alles veiliger geworden
- Als je instrumentarium gebruikt moet je vragen hoe je kan controleren dat het product toch goed blijft.
- Wat is minimaal nodig om het meeste impact te creëren
  o Standaardiseer en kijk wat er nodig is
  o Wat ga jij nou allemaal met het product doen
- Als het met bananenstekkers fout gaat, gaat het goed fout

Appendix **G**

Interviews Dutch and Brazilian surgeons

Name: Peter Hubach
Date: 26/03/2018
Profession: Orthopedic surgeon
Experience with electrosurgery: Experienced
Experience in LMICs: Multiple missions Kenya and Uganda

- Sterk wisselende stroom (soms oplopend tot 240V)
- Ziekenhuis Kameroen
o Nieuwe elektriciteit aangelegd met spanningsregelaar
o Generator wordt gebruikt als de stroom uitvalt
 Fluctueert ook veel
 Het zijn vaak oude generators die gebruikt worden
- Meestal zijn de mensen al heel blij als er elektriciteit is
- Het snijden met de diathermy pen is het belangrijkst
- Ook is het belangrijk om bloedvaten dicht te schroeien
o Kan met de zijkant van het mes
o Wordt door meneer Hubach veel gedaan door met het de monopolair bol elektrode een pincet te activeren en dan te coaguleren
- Fijne chirurgie is er eigenlijk niet (precieze instellingen)
o Groot verschil in settings is niet nodig
o Mocht dit wel nodig zijn dan zijn er enkele universitaire ziekenhuizen die wel de juiste apparatuur hebben om dit uit te voeren
- De ziekenhuizen zijn al lang blij met een apparaat waarmee ze basale chirurgie uit kunnen voeren
- Wanneer de instellingen niet goed zijn:
o anastasis medewerker past power aan
o Dood weefsel (gecarboniseerd) wat achter blijft geeft veel problemen met infecties
- Handvat (pen) moet gemakkelijk gesteriliseerd kunnen worden
o Moet zoveel mogelijk uit 1 deel bestaan
o Alle extra verbindingen geven problemen
- Alle onderdelen moeten robuust zijn
- Mocht bipolair wel nodig zijn dan wordt dit vaak gedaan door een monopolaire bol tegen een pincet aan te zetten en deze onder stroom te zetten
o Mocht er toch een handvat komen dan moet deze apart zijn van het monopolaire handvat
- Snoeren moeten robuust zijn
- De scalpel electrode wordt veel gebruikt
- Alles wat uitwisselbaar is raakt weg of gaat stuk
- Het gesteriliseerde gedeelte van de ESU moet hittebestendig zijn (>100 graden)
o Moet voldoen aan de sterilisatie eigenschappen van andere gebruikte apparatuur tijdens de operaties
- Pen met 2 knoppen is niet nodig. 1 knop voor het activeren is genoeg
- Scalpel electrode moet 2 cm lang zijn en dan het liefst aan de bovenkant iets dikker, met dat gedeelte kan je dan tegen het pincet aan
- Er wordt tijdens de behandeling niet veel gewisseld van elektrode
- Het gebeurt af en toe dat je bij het snijden meer of minder power nodig hebt. De anastasis assistente past dan de power aan. De setting wordt dus veel aangepast
- De generator staat altijd bij het hoofdeind omdat de anastasis medewerker hier ook aanwezig is
- De benodigde kabel lengtes zijn 3-4 meter zodat je ook bij de voeten van de patiënt kunt komen
- De generator staat dus in het omloop gedeelte en niet in het operatie gedeelte
- Het snoer moet geheel steriel zijn
- OK assistente pakt stekker beet en zet deze in het apparaat
- De stekker heeft een goed handvat nodig en een goede klik in het apparaat
- Na gebruik wordt de generator afgesopt. Het liefst met zo min mogelijk water
o Moet hufter proef zijn
o Moet water proef zijn
- Kijk hierbij naar Valleylab, deze is degelijk afgesloten
- De ESU gaat van OR naar OR en moet daarom zo licht mogelijk zijn met eventueel een handvat
- Behuizing van zwaar metaal wel robuust, maar erg zwaar.
- Wanneer de artsen op missie gaan nemen zij vaak een werken diathermy apparaat mee zodat zij zeker weten dat er iets werkt als zij er zijn.
- Op de OK zijn de stopcontacten wel geaard
o Dit is nodig omdat de OR ook schoongemaakt wordt en vochtig kan zijn

Name: R. Mollema
Date: 26/03/2018
Profession: gynecologist surgeon
Experience with electrosurgery: Experienced

- Er wordt veel gewerkt met ERBE, Valleylab en Covedian (overgenomen door Medtronic)
- Keuze wordt gemaakt op basis van kwaliteit en prijs
- Testen met apparatuur wordt op patiënten gedaan
- Apparatuur dat disposable is wordt af en toe meegegeven aan dierenartsen om mee te opereren aangezien de mens dier transitie geen hele grote problemen geeft.
- Alle westerse landen gebruiken disposables, dit is ook een vastgestelde eis.
- In Afrika zullen er weinig kijk operaties nodig zijn, waardoor alle nieuwe technieken niet nodig zijn (denk aan Ligasure)
- Voor kijkoperaties is bipolair een must
- Basale chirurgie is niet persé slecht, kijk goed wat de behoefte is m.b.t. instellingen en elektrodes
- Producten als laparoscopische Ligasure worden daar niet gebruikt.
- Oncologie chirurgie
o Melononen (diathermy, basic surgery)
o Kijk operaties (Laparoscopisch)
o Longen (Laparoscopisch)
o Borst operaties (diathermy, basic surgery)
- Er zijn grote ontwikkelingen op het gebied van minimaal invasief gebruik. Minimaal invasieve chirurgie zal minder voorkomen in Afrikaanse landen.
- Door gebruik te maken van de nieuwe technieken duren de operaties korter
- Bij apparatuur waarbij er een impedantieverschil wordt gemeten worden de power settings niet meer aangepast
- De arts heeft zelf weinig problemen met verwondingen omdat hij/zij rubberen handschoenen draagt, dus insullation faillure heeft vaak invloed op de patiënt.
- Bipolaire scharen meten geen impedantie verschillen
- Bipolair wordt met name gebruikt voor neurochirurgie en plast chirurgie
o Bij neuro chirurgie wil je lokale microchirurgie uitvoeren
o Monopolair zal bij dit soort chirurgie teveel omliggend weefsel aantasten wat problemen kan veroorzaken.
- R. Mollema gebruikt altijd dezelfde stand 35W cut en 35 W coaguleren, voor kinderen zet hij dit wel lager i.v.m. met gevoeliger weefsel en weinig vet, 25W cut en 25W coaguleren.
- Voor plastische chirurgie wordt vaak 25W cut en 25W coaguleren gebruikt.
- Het diathermy apparaat is van essentieel belang binnen de chirurgie, zonder kan er niet netjes geopereerd worden.
- In culturen waar en weinig of slechte apparatuur beschikbaar is, is de techniek van de artsen vaak erg goed, omdat zij leren roeien met de riemen die ze hebben.
- Tijdens de operatie wordt af en toe een electrode verwisseld. R. Mollema gebruikt vaak de naald electrode om nog fijner en subtieler mee te opereren (naald wordt gebruikt door hem om mee te snijden).
- Tijdens de operatie komt er wel eens dood weefsel op de electrode. Dit wordt schoongemaakt tijdens de operatie met de achterkant van het pincet.
- Tijdens de operatie bevinden zich meerdere mensen in de OK
o Anesthesie (Alleen voor de operatie en aan het einde van de operatie)
o Anesthesie assistente

Appendix **G**

Interviews Dutch and Brazilian surgeons

o 2 OK verpleegkundige
o 1 aan de operatietafel
o 1 als omloop (regelt instellingen van diathermie apparaat)
o Eventueel een arts in opleiding
o Chirurg
- Des te langer de operatie duurt, des te meer kans op infecties
- Grootste bron van infectie is de chirurg zelf
- Basis apparatuur bij operatie
o Mes
o Pincet
o Schaar
- Bekijk Baxter Nederland als je meer wilt weten over disposables en autoclavable onderdelen
- Draadbreuk komt nog wel eens voor, maar dan wordt er gewoon een nieuwe disposable geopend.
- Electrode wordt altijd vastgemaakt aan het bovenbeen
- Wanneer de patiënt een pacemaker heeft, wordt er een magneet bovenop de pacemaker gelegd.
- De chirurg heeft er een hekel aan om vette mensen te opereren, minder mooie vlakken en het gaat heel langzaam.
- Steriliseren kost ook geld, neem dit mee in eventuele business case
- Er is binnen de OK een "steriele" berging voor de disposables
- Steriele afdeling kost ook ruimte in het ziekenhuis
- Veranderen van materiaal en werkprocedures is vervelend
o Ander maatvoering
o Communicatie in de OK
o Standaardisatie is niet altijd makkelijk
- Meestal passen de pennen van een bepaald merk, maar op één soort generator (ook van dat merk)
- Soms worden bloedvaten dicht geniet, omdat deze te groot zijn. Hierdoor ontstaat er een te hoge druk op de bloedvaten, wat gevaarlijk kan zijn.

ESU journey | Westers ziekenhuis

Voorbereiding

- Er staat standaard een diathermie apparaat in elke OK deze wordt gepositioneerd buiten het operatie gedeelte (aan het voeteneind of hoofdeind van de patiënt)
- Diathermie apparaat staat op een kar met wieltjes
- De instellingen voor het apparaat worden van te voren ingesteld afhankelijk van de operatie en patiënt
o Leeftijd
o Type weefsel
- De elektrodes worden in de pen geklikt
- De return electrode wordt altijd op het bovenbeen van de patiënt geplaatst
o Groot spierweefsel
o Wanneer de patiënt harig is wordt de huid geschoren voor een beter conductiviteit
o Bij een patiënt met een pacemaker wordt er een magneet boven de pacemaker geplaatst. Zo kan de stroom hier niet doorheen lopen
o Op de disposables zit al een conductieve gel
- Er worden geen duidelijke checks gedaan voordat de operatie begint. Als er iets stuk is ziet de arts dit snel genoeg aangezien de elektrode dan niet werkt.

De behandeling

- Tijdens de behandeling maakt de chirurg gebruik van een medische schaar, pincet en een scalpel
- Tijdens de operatie bevinden zich meerdere mensen in de OK
o Anesthesie (Alleen voor de operatie en aan het einde van de operatie)
o Anesthesie assistente
o 2 OK verpleegkundige
o 1 aan de operatietafel
o 1 als omloop (regelt instellingen van diathermie apparaat)
o Eventueel een arts in opleiding
o Chirurg
- De arts draagt de volgende producten
o Steriele jas
o Steriele mond kap
o Steriele muts
o Rubberen handschoenen
- Tijdens de behandeling wordt er door de heer Mollema nooit geswitcht van monopolair naar bipolair
- Tijdens de behandeling wordt er nog wel eens geswitcht van elektrode (scalpel naar naald)
- De power settingen worden nauwelijks aangepast tijdens de operatie.
- Wanneer het apparaat impedantie verschillen zou meten, zal het niet meer nodig zijn om de power settings aan te passen.
- De handheld wordt af en toe weggelegd binnen het operatie gedeelte
- Er zijn geen problemen met slijtage, omdat er alleen maar gebruik wordt gemaakt van disposables.

Nabehandeling

- Welke onderdelen worden er schoongemaakt en op wat voor manier?
o De disposables worden weggegooid (handheld, kabels en elektrodes)
o Diathermie apparaat wordt niet schoongemaakt
- De handheld en kabel moeten gesteriliseerd worden
- Het ziekenhuis heeft een tijd met een non disposable handheld gewerkt, deze werd gesteriliseerd en de actieve elektrode tip werd na elke behandeling weggegooid.

Name: Peter Hubach
Date: 28/03/2018
Profession: Orthopedic surgeon
Experience with electrosurgery: Experienced
Experience in LMICs: Multiple missions Kenya and Uganda

- Reusables are not done
- Gaas en handschoenen die gebruikt worden tijdens de operaties zijn vaak wel steriel. Dit was niet altijd zo en kan dus in sommige ziekenhuizen nog steeds niet zo zijn
- Diathermie apparatuur is een essentieel apparaat kijkend naar tijdwinst en een reductie bloedverlies
- Het is moeilijk om te grote vaten te stollen omdat de druk op deze vaten te hoog is. Deze bloedvaten worden dan afgebonden met touw
- In Afrika is tijd geen geld, alles gaat er erg langzaam
- Het is belangrijk dat het apparaat alle operatieve behandelingen kan uitvoeren
- Het grootste probleem zijn spare parts
o Handheld connecties gaan vaak kapot
- Het product moet simpel en degelijk zijn en goed te steriliseren
- Het product moet bestaan uit eenvoudige onderdelen en simpel zijn
o Onderdelen die moeilijk kapot gaan
- Techniek van de lokale artsen is goed aangezien ze om leren gaan met minieme middelen
- OK assistenten zijn niet allemaal even geleerd, messen worden zelfs verkeerd aangegeven
o Zij stellen het diathermy apparaat in
o Communicatie tussen chirurg en OK assistente moet hierin goed zijn
o Standen van 0-10, omdat iedereen dit snapt
- Er moet altijd gecheckt worden op aids i.v.m. gevaar voor de chirurg
- Het diathermy apparaat wordt vaak in het begin ingesteld. Dan wordt er een incisie gedaan en wordt er gekeken of hij op de goede stand staat voor het persoonlijke weefsel van de patiënt
- Ook wordt de stand tijdens de operatie nog regelmatig aangepast met namen voor het snijden (cut mode)
- Soms staat het apparaat te hoog en vliegen de vonken er vanaf
- De disposables worden net zo lang gebruikt tot dat deze niet meer werken
- Elke OK moet een autoclaaf hebben, dit hebben ze daarom dus ook altijd
o Hij wordt niet vaak na elke behandeling gebruikt, dus er moeten meer onderdelen op voorraad liggen
- Alle verbindingen tussen onderdelen geven

Appendix **G**

Interviews Dutch and Brazilian surgeons

problemen. Zorg er daarom voor dat er zo min mogelijk verbindingen in tussen de pen en de bekabeling zitten
o Het liefst bestaat dit uit 1 deel
- Tijdens de behandeling worden er af en toe elektrodes verwisseld. Binnen Orthopedie is dit de bolle tip en de mes tip.
- De stekker verbinding blijft een zwak punt
- Tijdens de behandeling gebruikt de heer Hubach af en toe een pincet om bipolair mee te coaguleren. Door de monopolaire pencil te connecten met de pincet werkt deze als een soort van bipolaire elektrode.
o De chirurg is zelf niet geaard dus dit geeft geen problemen voor de chirurg.
o De chirurg draagt handschoenen en dit geeft dus geen problemen, alleen als er een gaatje in de handschoen zit.
- Het is in gebruik handiger om buttons op de handheld te hebben i.p.v. een voetpedaal:
o Moeilijk te vinden onder de steriele lakens (daardoor ook sneller een foute keuze tussen coag en cut
o Gaat stuk op de grond, omdat bedden erover heen rijden
- Het liefst kan de handheld snijden en branden tegelijk
- Tijdens het gebruik blijft de handheld aardig schoon en wordt deze dus ook niet glad. Dit komt mede door de handschoenen die de gebruiker draagt.
- Het snoer, stekker, handheld en elektrode moeten autoclaveerbaar zijn.
- Specialisatie of plastische chirurgie is daar niet aanwezig
- Belangrijk is dat het een eenvoudig en degelijk apparaat is dat lang mee gaat
- Het apparaat moet zo licht mogelijk zijn
o Eventueel meenemen op missie in koffer, dus zo klein mogelijk is fijn
- Valleylab is bijvoorbeeld loodzwaar
- Meestal zijn er wel karretjes in de OK, mochten deze er niet zijn, timmeren de technici dit zelf wel
- Diathermie apparaat staat in de omloop van de OK en hoeft daardoor niet steriel te zijn.
- De generator wordt daarom ook niet steriel schoongemaakt.
- Schoonmaakmiddelen zijn de autoclaaf en CIDAX
- In de grotere ziekenhuizen is er vaak meer apparatuur beschikbaar
- Focus: ziekenhuizen met een redelijke operatieruimte
- Infectie geeft extra kans op bloedingen
- De bipolaire tangen zijn al zo modern voor de afrika context en gaan gemakkelijk stuk
- Bipolair is te duur omdat het vervolgens wordt weggegooid.
- Vaak wordt er een metalen plaat met elastiek gebruik om dit vast te maken
o Moet goed om het lichaam blijven zitten
- Het maakt niet zo heel veel uit waar de elektrode geplaatst wordt
o Liefst op gebied met veel spierweefsel
- De power output van het diathermie apparaat wordt lager gezet bij kinderen, omdat het weefsel van kinderen gevoeliger is
- De return elektrode moet gemakkelijk schoon maakbaar zijn. Deze is niet steriel.
- Handheld kan gemakkelijk op de grond vallen, dus moet tegen een stootje kunnen
- Wanneer het apparaat te hoog staat, brand alles sneller door
- Wanneer er weefsel achterblijft op de elektrode pin wordt dit schoongemaakt met een mes of achterkant van pincet. Ook wordt er wel eens een gaasje gebruikt om de elektrode schoon te maken
- De meeste patiënten hebben geen pacemaker in Afrika, dus daar hoef je je niet druk om te maken
- Voor instellingen op het apparaat (presets) zijn onzin in die context
- Het apparaat moet zo primair mogelijk worden voor de tropen
- Ook oorlogsgebieden zijn interessant
- De apparatuur in de Westerse landen wordt steeds extremer en intelligenter waardoor ze ook moeilijker te repareren zijn en dit geeft de grootste problemen in de LMICs context
- Cut mode en coagulation mode is voldoende
- Precieze instellingen is niet nodig. Laparoscopisch wordt daar zelden uitgevoerd.
- Belangrijk dat er een schaal op de interface zit zodat je weet wat meer en minder power is.
- Het apparaat moet stevig zijn, goede functies hebben en financieel haalbaar zijn
- Leasen wordt zelden gedaan in Afrika
- Schakel elementen gaan vaak stuk
- Belangrijk is dat het apparaat een degelijke stekker aansluiting heeft
- In het ziekenhuis bevindt zich een generator ook voor acute power drops midden in de nacht
- In de operatieruime is wel vaak een airco, airco filter zorgt voor steriliteit
- Ook wordt er veel gebruik gemaakt van UV straling om bacteriën te doden
- Er is een apart iemand in het ziekenhuis die werkt als technici (vaak veredelde timmerman)
- Het operatiegedeelte wordt schoongemaakt met Jodium (met alcohol) of betadine Jodium (zonder alcohol)
- Patiënten worden bij veel haar onthaard door de OK assistente daarna wordt er alcohol en jodium gebruikt om de patiënt te steriliseren
- Het apparaat wordt regelmatig verplaatst van OK naar OK
- Het snoer moet genoeg lengte hebben (3-4 meter)
- Tijdens de eerste snede wordt gekeken of de power settings goed staan.
- Tijdens spoedgevallen worden de settings nog wel eens hoger gezet voor snelheid, veel rook en carbonisatie.
- In Afrika worden de power settings iets hoger gezet, omdat het allemaal iets basaler is
- Wanneer er een weefsel lap teruggezet moet worden, wordt er zo min mogelijk power gebruikt om zo de bloedvaten in tact te houden. Dit zorgt voor een sneller herstel en dit voorkomt dat er dood weefsel ontstaat
- De orthopedisch chirurg plaatst vaak de return elektrode op het lijf, aangezien hij vaak met been operaties bezig is.
- Er moet een duidelijk verschil zijn in toonhoogte voor coaguleren en cut modes
o Cut modes: hoge toon
o Coag modes: lage toon
- De equipment die de arts altijd bij de operatie heeft zijn:
o Pincet
o Medische schaar
o Mes/scalpel (klein formaat)
- De arts draag de volgende equipment:
o Steriele muts
o Steriele rubber handschoenen
o Steriel mondkapje
o Steriele operatie jas
o Operatie sloffen (makkelijk schoon te maken)
o Schoongemaakt met desinfecterend middel zoals CIDAX
- De elektrode pin wordt steeds vervangen, hierdoor moet er druk op de handheld uitgeoefend worden, dit kan middels een rand creëren voor de power knop.
- Wanneer je een schroefdraad connectie gebruikt, kan er snel rommel tussen de pin en handheld zitten (in het schroefdraad)
- Kijkend naar slijtage tussen de handheld en de elektrode pin, slijt de adapter van de handheld het snelst. Dit heeft uiteraard met materiaal keuze te maken.
- Voor een betere connectie is de elektrode pin iets aangeruwd
- De anastasis medewerker blijft altijd bij de operatie (dit is in Nederland wel anders, na de narcose verlaat de anastasis medewerker de operatie ruimte en houdt de OK assistente toezicht)
- Bipolair is een luxe probleem voor de orthopeed. Wellicht is dit voor neurochirurgie of plastische chirurgie van meer belang.
- Vaak is er in de OK een aanrecht waar instrumentarium op kan staan zoals het diathermy apparaat.
- Wanneer er vergeten was om een van de instrumenten te steriliseren, werd het instrument in de

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jodium gelegd (+/- 10 min)
- In de OK bevindt zich een airco. Wanneer de artsen op missie gaan nemen zij altijd een filter mee ter vervanging. Zo niet, wordt het filter in de airco niet vervangen. Iets wat een grote bacterie bron kan worden.

Technische problemen in ziekenhuis
- Repareren van kapotte onderdelen beginnen ze niet aan. De onderdelen zijn vaak niet te verkrijgen en ze hebben niet de tools om deze onderdelen te vervangen.
- De generator moet een simpele zekering hebben die ook in de rurale gebieden te verkrijgen is. Het is regelmatig gebeurd dat het apparaat de gehele tijd niet werkte, dat alleen de zekering vervangen moest worden.
- Wanneer je het apparaat zo klein mogelijk maakt kunnen de missie artsen het apparaat meenemen naar Nederland voor reparatie. Daarnaast is het handig om er altijd een extra mee te nemen zodat zij zeker weten dat er diathermie aanwezig is in de OK.
- Wanneer er spare parts moeten komen, worden deze vaak wel naar de hoofdsteden getransporteerd. Vanuit daar komt het vaak niet in de periferie.
- Zekeringen en bananen stekkers zijn wel te verkrijgen.
- In de operatie ruimtes bevindt zich bijna altijd geaarde stopcontacten voor de medische apparatuur.
- Ook als er niet geaarde stopcontacten zijn, moet het apparaat nog steeds werken.
- Technici krijgen geen trainingen ter reparatie van de apparatuur (zijn meer klusjesmannen)
- Het autoclaveren van onderdelen gaat vaak goed. Zij hebben nog nooit problemen gezien met kromme onderdelen of iets dergelijks.
- Er zijn geen protocollen op het gebied van sterilisatie in de missie ziekenhuizen. Elk ziekenhuis heeft zijn eigen systeem. Dit kan in overheidsziekenhuizen wel anders zijn, maar dat weet ik niet.
- De generator hoeft niet water dicht te zijn. Hooguit vloeistof wat over het apparaat valt (infuus)
- Bij het apparaat hoeft niet persé een kar geleverd te worden, omdat wanneer deze niet aanwezig zij dit zelf wel bouwen (timmerman)
- Hetgeen wat kapot gaat zijn altijd de snoeren en handhelds
- Draaiknoppen op de generator zijn van degelijke kwaliteit
- Het is misschien een idee om een keuze te maken in het type nozzle wat je gebruikt, zodat hier geen verbinding meer nodig is. Dit hangt wel af van het feit of andere type chirurgen wel vaak wisselen tussen elektroden.
- Het gebruik van een pedaal is ontzettend onhandig
  - o Zit een veersysteem in, dus spring weg na indrukken
  - o Alles is afgedekt in de OK dus het is erg moeilijk om het pedaal te zien
  - o Tijdens het bewegen rondom de patiënt kan het gebeuren dat de pen geactiveerd wordt.
- Alle handigheden gaan kapot
- Het bed is net zo breed als normale mensen hun heupbreedte
- Naast de chirurg ligt basic instrumentarium die de chirurg gebruikt. De instrumentarium tafel wordt opgemaakt door de OK assistente afhankelijk van de type operatie.
- De handheld wordt wanneer deze niet gebruikt wordt, op de patiënt gelegd.
- Het personeel kent niet alle knoppen en settings.
- Het is gemakkelijk om met de omloop assistente te communiceren wanneer de standen van 0-10 zijn. Dit begrijpt iedereen en voorkomt fouten.
- De operaties duren nooit langer dan 2 uur.
- Het kan handig zijn om in het systeem een veiligheidsmarge te hebben van 4 uur. Apparaat moet dus 4 uur gebruikt kunnen worden en hier geen problemen mee ondervinden (temperatuur)
- OK heeft vaak 220 V
- Kleinere ziekenhuizen schommelen tussen de 180 en 240 V. Dit moet dus gestabiliseerd worden door het systeem.
- Display in het apparaat gaat gemakkelijk kapot?
- Als missie arts ben je al blij dat er iets werkt als je aankomt
- Wanneer je lage power settings gebruikt, gaat het snijden ook langzamer, maar beschadig je zo min mogelijk weefsel.
- LED is alleen handig voor kleine holtes, bij bijvoorbeeld laparoscopisch werk. Dit is voor het monopolair en bipolair niet van toepassing.
- Ga met het product terug naar de basis.
- Implantaten zijn daar voor de patiënten niet te betalen, aangezien dit er ook weer uitgehaald moet worden.
- Kijk naar de koppeling van de zaag en boor die gebruikt wordt tijdens operaties
- Het apparaat mag maximaal 3000 euro kosten
- Wanneer de handheld kapot is, wat dan ook, wordt deze gelijk weggegooid en wordt er een nieuwe gebruikt.

Name: Rens Huizinga
Date: 29/03/2018
Profession: Plastic surgeon
Experience with electrosurgery: Experienced
Experience in LMICs: Multiple missions to Nigeria

- Plastisch chirurg heeft over het algemeen weinig apparatuur nodig
- Diathermie apparaat wordt met name gebruikt om bloed verlies te voorkomen.
- In Afrika worden de jongen en gezonde mensen geopereerd
- Diathermie is niet altijd nodig als plastisch chirurg, omdat zij liever incisies maken met het mes, om zo een mooiere incisie te realiseren en minder schade aan het weefsel aan te richten.
- Tijdens de plastisch chirurgische ingreep is anastasis niet nodig
- In de tropen wordt vaak ketamine gebruikt ter verdoving (werkt als spier verslapper) en een plaatselijke verdovingsvloeistof
- Tijdens de behandeling ademen de patienten zelfstandig
- In Afrika zijn alle behandelingen die hij gedaan heeft onder te verdelen in twee groepen: hazenlippen en brandwonden
  - o Er wordt veel vuur gestookt waar in de nacht kinderen zich ernstig aan kunnen verbranden
- Bij kleine kinderen wordt er vaak wel diathermie gebruikt, om bloedverlies te voorkomen. Dit is bij kinderen van groter belang, omdat alle organen, weefsel, etc. gevoeliger is.
- Met het diathermie apparaat wordt alleen gebruik gemaakt van de cut mode en coagulation mode. Hierin is de coagulation mode de belangrijkste (hemostasis = minder bloedverlies)
- Kijkend naar elektrode tips wordt er binnen de plastische chirurgie allen het zwaard en af en toe de naald voor het fijnere werk (is niet van grote behoefte in tropen)
- Bij brandwonden operaties wordt littekenweefsel verwijderd (hij doet dit met name met het normale scalpel/mes
- De behoefte in dit soort landen is niet het precisie werk
- Jonge afgestudeerde artsen (Afrika) moeten eerst 2-3 jaar in de arme meer afgelegen public ziekenhuizen werken om ervaring op te doen en toch deze omliggende gebieden te helpen.
- Er is ontzettend veel corruptie in het land
- Belangrijke operaties met diathermie apparaat
  - o Keizersneden
  - o Navelbreuk
  - o Liesbreuk
  - o Brandwonden
  - o Hazenlip
  - o Acute blindedarm ontsteking
  - o Verkeersongevallen (amputaties)
- Er zijn daar geen bloedbanken dus vaak geeft een familielid ter plekke bloed
- Grote bloedvaten kunnen niet gecoaguleerd worden, hier wordt een klem opgezet om af te dichten
- Monopolair is het belangrijkste om te gebruiken
- Bipolair is gering nodig
- Aluminium plaat wordt onder bil van patiënt

Appendix **G**

Interviews Dutch and Brazilian surgeons

geplaatst om stroomkring te voltooien
- De verfijnde monopolair pincetten blijven niet heel, er wordt super grof met instrumentarium zoals scharen en pincetten omgegaan.
- Focus je daarom vooral op de monopolaire handheld
- Tijdens de operatie wordt de powersetting regelmatig aangepast. Belangrijk dat dit in het product blijft
  - o Keuze zou kunnen zijn om 4 standen te hebben
- In de OK gaat de apparatuur vaak stuk
  - o Elektriciteit generator gaat snel stuk
  - o De OK lampen gaan vak kapot
  - o Anastasis apparaat
  - o Diathermie apparaat
  - o Draadbreuken
  - o Stekker connecties
  - o Overgang stekker naar kabel
- Er is ontzettend veel onkunde bij de artsen en assistentes
- Preventieve onderhoud wordt niet gedaan, dus verwacht dit ook niet
- Het missie team nam altijd een technisch iemand mee om daar de technische zaken te regelen
- Draadbreuk en corrosie veroorzaakte de grootste problemen, maak hier dus slimme ontwerp en materiaalkeuzes in.
- Let op: artsen in tropenlanden accepteren niet altijd eenvoud in producten omdat zij dondersgoed weten wat er op de markt te bevinden is.
- Apparatuur dat gedoneerd wordt is vaak te storingsgevoelig. Hierdoor staat er veel niet werkzame apparatuur in de OKs
- In de komende jaren gaat de bevolkingsgroei verdubbelen, waardoor er nog meer problemen zullen ontstaan
- Grootste gedeelte van de plastisch chirurg operaties is brandwonden
- Het indicatiegebied van operaties is niet zo groot
- Ga in je ontwerp voor unipolair gebruik
- De afrikanen hebben allemaal mobieltjes
- In de omgeving waren daarom ook vaak spanning stabilisators omdat de mensen toch hun telefoon op willen laden
- De artsen en chirurgen die congressen bijwonen bevinden zich in de toplaag van de healthcare sector
- Wanneer er echt grote en precieze operaties worden gedaan, gaan de patienten vaak naar Amerika of UK
- Neem een kijkje naar de sovjet apparatuur wat jaren geleden gebruikt is. Het is sowieso interessant naar apparatuur van vroeger te kijken.
- Less is more!

Name: Cees Spronk
Date: 30/03/2018
Profession: Plastic surgeon
Experience with electrosurgery: Experienced
Experience in LMICs: Mission all over Africa

- Vanaf 1974 op missie naar ontwikkelingslanden
- Probleem is dat er een hoop afgedankte apparatuur naar de landen wordt gestuurd dat niet resistent is aan de context
- Ook wordt er veel apparatuur uit China gehaald wat waardeloos is en snel kapot gaat
- Het apparaat moet simpel, licht en robuust zijn
- Het zou handig zijn als je het apparaat mee kunt nemen op en neer zodat er op die manier ook service geleverd kan worden.
- Belangrijk is dat het apparaat zowel monopolair als bipolair gebruikt kant worden
- Eenvoudige bipolaire pincet ontwikkelen
- Het zou fijn zijn als het apparaat ook afzuiging heeft voor de rook die ontstaat bij het opereren
- Vaak wordt er voor plastische en iets fijnere chirurgie monopolair gebruikt
- Het snijden van het weefsel wordt ook vaak elektrisch gedaan
- Het grootste voordeel van het diathermie apparaat is bloedverlies zodat er geen bloedtransfusie nodig is.
- Spanning fluctuaties is een groot probleem
- Meneer Spronk heeft zelf in de OKs spanning stabilisatoren neergezet (niet alle stopcontacten)
- Als een van de medewerkers het verkeerde stopcontact gebruikt, stop het apparaat er vaak snel mee
- Het apparaat moet fluctuaties tussen de 100 en 250 [V] aankunnen
- De elektrode plaat die hij gebruikt was reusable en ging lang mee
- Voor de handheld werden er disposables vanuit Nederland meegenomen. Die werden een aantal keer gebruikt en na draadbreuk werden deze weggegooid
- Voor bipolaire activatie ga dan terug naar het ouderwetse, waarbij de pincet geactiveerd wordt door het voetpedaal
- De huidige apparatuur heeft een automatische activatie of wordt 1 seconde na contact geactiveerd, dit vind hij niet handig in gebruik
- Bij de handheld stopt vaak de kabel ermee door kabelbreuk
- De kabel moet vervangbaar zijn met simpele stekkers
- Jan Heeringa (medisch klinische techniek) van het MCL in Leeuwarden heeft veel in Tanzania gewerkt.
- De techniek wereld heeft in de tropenlanden een stap overgeslagen; telecommunicatie gaat heel goed, maar basistechniek is een groot probleem
- Het apparaat moet zo simpel mogelijk worden
- Zekeringen moeten gepositioneerd worden op een duidelijke plek
- Zo min mogelijk gecompliceerde mechaniek
- Stevige kabels en robuust exterieur
- Naar mijn idee is voor geen van deze 15 essential surgeries diathermie echt essentieel; het is alleen bij veel ingrepen een heel plezierig hulpmiddel.
- Verder is het een kwestie van voorkeur welke coagulatie je wilt gebruiken, bipolair of monopolair. Met een zwaardje kun je in principe alles doen, maar soms is een bolletje of een naald prettiger. Snijden doe je met cut, met zwaardje (of naald, maar een naald verbrandt snel) Een lis gebruik ik nooit; wordt dink ik alleen bij endoscopische chirurgie gebruikt.
- Het benodigde vermogen kan ik zo niet zeggen, maar met de Erbe kom ik eigenlijk nooit boven stand 40; tot stand 50 is ruim genoeg.
- Nogmaals: als je een apparaat ontwerpt, hou het simpel, gemakkelijk te vervangen onderdelen, licht (aluminium behuizing?) en klein. Bestand tegen voltageschommelingen en gemakkelijk te vervangen zekering.
- De Erbe icc50 is een apparaat dat ik zo in de koffer meegenomen heb; alleen de voetpedaal is erg zwaar.

Name: Wiebe Henstra
Date: 30/03/2018
Profession: Biomedical technician
Experience with electrosurgery: None
Experience in LMICs: Missions to Tanzania

- Twee keer in Tanzania geweest om apparatuur mee te nemen en instructies te bieden aan technici in lokale ziekenhuizen
- Instructies werden gegeven op gebruiks- en instructieniveau
- Belangrijk hierin is om de lokale BMET te betrekken
  - o Groot gedeelte van het personeel kende de medewerker niet eens
  - o Westerse technici helpt het personeel en de BMET kijk lijdzaam toe
  - o Zij stelde dan de technici voor aan het personeel
  - o Alle spare parts werden bij hem gestationeerd om hem meer te betrekken in het proces en een belangrijkere rol te bieden
- Belangrijk is dat het apparaat een stroom stabilisator heeft
- Er leeft veel onzekerheid over het repareren van de apparatuur
- Wanneer het ziekenhuis hoort dat er westerse technici aanwezig is, worden er allemaal vragen gesteld over apparatuur dat kapot is en of zij dit willen repareren.

Appendix **G**

Interviews Dutch and Brazilian surgeons

Terwijl de lokale BMET van het ziekenhuis hier nooit in betrokken wordt. Het gros van het personeel wist niet eens dat er een technici aanwezig is in het ziekenhuis.
- Er heerst een andere verhouding tussen de verpleging en specialist in vergelijking met de westerse cultuur. De verpleging neemt zelf geen beslissingen en wacht altijd af wat de specialist gaat doen. Als er bijvoorbeeld een probleem is wordt er net zo lang gewacht totdat de specialist dit opvalt en er iets mee doet. In Nederland zijn wij veel mondiger en worden problemen gelijk door de mondige verpleging aangekaart.
- De printplaat en transformatoren gaan vaak kapot
- Alle onderdelen van de apparatuur is op module niveau, hier zijn daar geen spare parts voor.
- Trekontlasting is vaak verkeerd ontwikkeld waardoor er een hoop kabelbreuken ontstaan
- Belangrijk is dat het apparaat bestaat uit discrete componenten die voorradig zijn in de LMICs.
- Het apparaat moet op component niveau gerepareerd kunnen worden
- De spare parts van gedoneerde apparatuur is nooit te verkrijgen (fabrikant heeft de setjes niet meer)
- Belangrijk is dat er bij het apparaat een goede manual met gebruiksonderhoud zit
- Het moeilijkste is om de medewerkers zover te krijgen om hiervan gebruik te maken.
- Preventieve onderhoud wordt daar niet uitgevoerd
- Bijvoorbeeld: een van de anastasis apparatuur had een vocht opvang en wanneer deze vol zat werkte het apparaat niet meer. Door deze alleen te legen werkte het apparaat niet meer, iets wat beschreven stond in de manual (die nog in het folie zat).
- Het apparaat moet zo simpel mogelijk zijn en toch werken

Name: Jonathan vas Nunes
Date: 02/04/2018
Profession: Medical officer
Experience with electrosurgery: Limited
Experience in LMICs: Mission to Sierra Leone

- Groot gebrek aan Afrikaanse artsen
- Jonathan is in dienst van het ziekenhuis, de westerse artsen worden ondersteund door een aantal internationale NGO's die de salarissen betalen
- Hij werkt daar in een public hospital. Het is begonnen als een missie ziekenhuis, maar het heeft nu niets meer maken met de religie.
- Over 10 jaar willen zij een overheidsziekenhuis worden; vanuit duurzaamheid oogpunt, zodat zij langzaam het stokje overgeven aan Sierra Leone. Financiën zijn nu niet aanwezig.
- Zij zijn een van de weinige ziekenhuizen die wel diathermie gebruiken. In de meeste ziekenhuizen is de apparatuur of kapot gegaan, niet onderhouden, missen disposables, etc.
- Om de maand komt er een Nederlandse of Engelse chirurg die apparatuur mee kunnen nemen
- De handhelds zijn reusable, net zoals de elektrodes
- Elk ziekenhuis met een OK heeft een autoclaaf (de meeste gangbare zijn de cookingpots)
- Zij gebruiken de diathermie erg spaarzaam. Alleen gebruik voor hydroseals of bloederige hernias, dus met name ingrepen waarbij een hoop bloedverlies verwacht wordt. Ze hebben te weinig pennen en ze zijn bang dat hij kapot gaat dat wanneer zij hem gebruiken (bang voor brandplekken en voor brandveiligheid)
- Er is weinig kennis aanwezig over het gebruik van diathermie.
- Ook geen kennis over hoe je de apparatuur moet onderhouden
- Medische apparatuur gaat vaak kapot en wordt dan ergens in een schuur gezet
- Geen technici aanwezig met kennis die de appratuur kan onderhouden of repareren
- Ze kunnen ook het solar systeem niet teveel belasten
- Meeste ziekenhuizen zijn afhankelijk van het instabiele netwerk van de overheid
- Er is een technici aanwezig, maar die heeft geen opleiding t.a.v. medische apparatuur
- Ik heb het idee om ook een kennis programma bij het apparaat te geven, dit vind hij heel interessant.
- Bij het ziekenhuis hebben zij een college opgezet, waarin zij nieuwe artsen willen opleiden (nurses, fysiotherapeuten, verloskundige, etc.)
- Willen ook graag een technisch pakket aanreiken, omdat niemand hier verstand van heeft.
- Zij hebben een perfect functionerend digitale X-Ray machine die communiceert met de computer, maar nu is de computer kapot en werkt het apparaat niet. Netwerkkaart is gekoppeld aan de computer en zij weten nu niet hoe zij die om moeten zetten naar een andere computer.
- Komt ook omdat zij geen service pakket bij het apparaat hebben
- Hij is het er helemaal mee eens dat het apparaat de 15 essential surgeries moet uit kunnen voeren en dat de behoefte absoluut niet bij het precieze laparoscopisch chirurgie ligt.
o Het basale is precies wat nodig is
- 80% van de chirurgie is nog steeds niet laparoscopisch (dit zal het komende decennia nog zo blijven)
- Als je het aan Jonathan vraagt twijfelt hij helemaal niet aan het feit dat de behoefte ligt bij het meer basale werk
- De artsen die naar een congres gaan werken vaak in de meer established ziekenhuizen (private of universiteitsziekenhuizen)
- De absolute grootste markt en groots groeiende populatie zal behoefte hebben aan het meer basale werk
- In het ziekenhuis doen zij ongeveer 1000 ingrepen per jaar
- In een verdere fase willen zij graag samenwerken en wij kunnen daar eventueel testen doen
- De connectoren en handhelds gaan vaak kapot
- Het apparaat moet veilig zijn in een omgeving waar veel power drops, fluctuatie en bliksem is
- Tijdens de opleiding als tropenarts krijgen zij geen standaardisatie in de power settings die je in moet stellen. Door mee te lopen zie je hoe het apparaat gebruikt wordt en welke settings er worden gebruikt (dit is toch deels gebaseerd op de voorkeur van de arts)
- Grote precisie in power settings niet nodig (hoe meer vrijheid des te meer kan er fout gaan)
- De doelgroep is niet de Europese arts, maar meer de lokale artsen, die weinig kennis hebben verkregen over diathermie.
- Op het gebied van diathermie wordt in hun opleiding bijna niets gegeven, omdat dit niet sustainable is (niet aanwezig is de ziekenhuizen)
- De artsen werken allemaal erg ruraal en hier is dus geen diathermie aanwezig
- Er is heel veel behoefte aan diathermie en dit gaat waarschijnlijk alleen nog maar meer worden
- Een conferentie is volgens hem niet de plek om je apparaat te testen op gebruik of implementatie, omdat dit naar zijn idee niet de doelgroep wordt
- Kenya zit wel meer geld om het project op te starten
- Mensen die naar een congres komen hebben minder de intentie om een afordable oplossing te hebben. Ze kunnen zich veroorloven om er naartoe te gaan.
- Zij zijn veel bezig met de overheid om te kijken waar de behoefte ligt in apparatuur, dus misschien zou dit een leuk project zijn om te onderzoeken of dit feasible is voor rurale ziekenhuizen.
- Als je uiteindelijk het apparaat wilt testen (op functie) is het gemakkelijk om in Sierra Leone te testen kijkend naar ethische commissie.
- Het is goed om te testen of de artsen er mee om kunnen gaan, of ze dit willen implementeren in hun operaties, etc.
- Zij hebben elk half jaar een groep die zij opleiden waar je mee zou kunnen testen
- Op een congres kom je niet de gemiddelde arts tegen (private artsen en goed opgeleide chirurgische artsen)
- De meeste artsen hebben geneeskunde gedaan en gaan vervolgens chirurgie doen, omdat daar de behoefte ligt in de landen.

Appendix **G**

Interviews Dutch and Brazilian surgeons

Name: Ralph Lenior
Date: 04/04/2018
Profession: Biomedical technician
Experience with electrosurgery: None
Experience in LMICs: Missions to Tanzania

- Tijdens de missies richt hij zich met name op de IC
- Zij brengen afgedankte spullen van het MCL naar het ziekenhuis in Tazania (Moshi)
- De gedoneerde apparatuur komt vanuit alle windstreken waardoor standaardisatie in connectoren een groot probleem is
- ValleyLab en Erbe zijn de grootste merken op het gebied van diathermie
- De medewerkers van het ziekenhuis zijn met elk gedoneerd apparatuur tevreden
- Het grootste probleem van niet werkende diathermie apparatuur is het gebrek aan accessoires of het kapot gaan van de accessoires
- Kabels en aansluitingen gaan regelmatig kapot
- Binnen het ziekenhuis in Tanzania zijn wel technici aanwezig die zich ook steeds beter ontwikkelen. Zij zijn heel kundig met de middelen die zij hebben, maar hebben vaak geen medische achtergrond
- Tijdens hun bezoeken nemen zij de BMET mee om hem meer in de picture te brengen. Wanneer er westerse artsen op missie zijn, worden zij als eerste gevraagd om apparatuur te repareren terwijl de lokale technici hier nooit in is betrokken. Dit proberen zij te verbeteren.
- Er zijn geen spare parts aanwezig. Hetgeen dat zij wel vervangen zijn kabels door van twee, een te maken
- De stekkers in Tanzania zijn Engels
- Preventief onderhoud van apparatuur wordt niet gedaan. Dit is ook een grote oorzaak van het kapot gaan door bijvoorbeeld vuil.
- Kunststof krijgt het zwaar te verduren
- Er is geen klimaatbeheersing in het ziekenhuis
  - Vaak droog en veel zand
- Pencelen gaan regelmatig kapot door het klimaat of ze raken kwijt
- Elektrodes met rubber gaan kapot door uitdroging
- ECG kabels gaan kapot
- Handheld kabel gaat eerder kapot dan de adapter waardoor slijtage van de adapter in de handheld moeilijk te beoordelen is.
- Werkzaamheden van medewerkers verander je niet zo snel
- Regelgeving t.a.v. reparatie is niet aanwezig in het ziekenhuis
- De technici roeien met de riemen die ze hebben, iets wat niet altijd veilig is voor de apparatuur.

Name: Tim Middelberg
Date: 10/04/2018
Profession: Plastic surgeon
Experience with electrosurgery: Experienced
Experience in LMICs: Missions to Sierra Leone

- Medische apparatuur wordt verzonden die wel functioneert in de westerse culturen, maar niet in Afrikaanse context
- Onderhoud is een groot probleem. In Nederland heb je simpelweg een vertegenwoordiger of technici die dit repareert, maar wanneer er iets kapot gaat wordt het vervolgens in de hoek gezet.
- Er is vaak geen technicus of elektricien aanwezig
- De medische apparaten die gedoneerd worden, zijn vaak oud en afgedankt vanuit westerse ziekenhuizen (deze hebben dus al een hogere kans op falen).
- Vorig jaar hebben zij een diathermie apparaat verstuurd naar Sierra Leone zodat zij er dit jaar weer mee kunnen werken, maar deze functioneert nu al niet meer en de oorzaak is onduidelijk.
- Een simpele kabelbreuk kan er al voor zorgen dat het apparaat voor een langere tijd niet gebruikt kan worden.
- De sterilisatie wordt niet altijd goed gecontroleerd en kan dus hoger uitvallen dan nodig (te heet)
- Spanning is niet stabiel en kan soms zomaar uitvallen, hier moet het apparaat tegen bestand zijn. Dit geldt met name voor de generator.
- Over het algemeen hebben de artsen en technici een laag opleidingsniveau
- Zij kunnen niet goed genoeg Engels schrijven en spreken
- De technici weten vaak wel alles over de generator bij stroomuitval, maar niet over de medische apparatuur.
- Het zou interessant zijn als er een bureau aanwezig is die alles lokaal repareert.
- Transport van onderdelen is lastig door invloed van de douane. Dit komt met name door corruptie. Ondanks dat een apparaat de juiste standaarden en normeringen heeft kan dit toch blijven hangen, omdat er mensen aan willen verdienen.
- Tim erkent dat er een onderverdeling is tussen rural and low resource hospitals, urban hospitals en specialists. Hierin moet allereerst de focus liggen op de meer rurale gebieden aangezien hier de grootste problemen zijn en de grootste impact gemaakt kan worden.
- Het product moet robuust zijn, low maintenance en werken op een stabiel netwerk.
- Mochten er problemen mee zijn, moet dit lokaal opgelost kunnen worden.
- Precieze chirurgie zoals ligasure is daar niet aan de orde. Met name monopolair en bipolair.
- Qua kennis weten de artsen maar net hoe het elektrochirurgie apparaat werkt, kennis over instellingen hebben zij niet.
- Belangrijk is dat het apparaat in ieder geval hoger of lager gezet kan worden
  - Verschil in weefsel weerstand
  - Hier getallen aan koppelen maakt niet zoveel uit
- De bandbreedte van power instellingen van de huidige apparatuur moet aangehouden worden
- Kabelbreuken zijn de problemen die het vaakst voorkomen
- Het apparaat moet minimaal bipolair en monopolair kunnen uitvoeren. Hierbij is een bipolair pincet nodig en een monopolair zwaard electrode tip. Andere elektrodes zoals het bolletje of de naald worden niet gebruikt.
- Op de markt zijn een hoop disposable elektrode tips met bijvoorbeeld een teflon laag. Dit slijt bij het afschrapen van weefsel tijdens de behandeling.
- Voor extra vragen kan ik Tim altijd mailen.

Name: Dick van der Schaaf
Date: 12/04/2018
Profession: Orthopedic surgeon
Experience with electrosurgery: Experienced
Experience in LMICs: Missions all over Africa

- Het is belangrijk dat het apparaat onderhoudsvrij is aangezien er geen preventieve onderhoud uitgevoerd wordt
- Als er een onderdeel van het apparaat kapot is blijft het staan en wordt dit vaak niet gerepareerd
- Het apparaat moet simpel zijn in gebruik
- Het apparaat moet geen bewegende onderdelen hebben aangezien deze het vaakst kapot gaan
- De electrode pad en electrode tips mogen niet disposable zijn, omdat dit tot in den treure hergebruikt wordt
  - Risico's op contaminatie
  - Risico's onnodig weefsel aantasten
- In de ziekenhuizen staan vaak de deuren gewoon open, dus het is in de operatie ruimtes niet altijd even steriel
- De huidige diathermie apparaten hebben een verdienmodel op de disposables, dit werkt absoluut niet in de Afrika context.
- Er zijn over het algemeen veel problemen met sterilisatie (deze apparaten werken ook niet altijd)
  - Verkapte snelkookpan met een verkalkt hitte

Appendix **G**

Interviews Dutch and Brazilian surgeons

element

- Het is belangrijk dat het apparaat stofvrij is (hogere stof aanwezigheid in OK)
- Belangrijkste waveforms zijn coaguleren en snijden. Dit zijn ook de enige waveforms die je nodig hebt
- Het verschil tussen beide standen is meer klinisch. Meneer van der Schaaf snijdt regelmatig met de coagulatie mode.
- Bij het behandelen van kinderen gebruikt hij standaard 25 W en volwassen standaard 50 W
- Precisie in wattage is niet belangrijk aangezien dit puur op gevoel gaat. Belangrijk is wel dat de power setting hoger of lager ingesteld kan worden
- Een optie kan zijn laag, midden en hoog (met bijvoorbeeld icoontjes voor kinderen en volwassenen)
- Tijdens de behandeling wordt de powersetting regelmatig aangepast
- Als het apparaat het maar een beetje doet is het vaak al goed..
- Bipolair is niet nodig voor orthopedie aangezien dit iets grover werk is. Dit wordt wel gebruikt voor fijne handchirurgie en plastische chirurgie (cleft lip)
- Heel af en toe gebruikt hij bipolair, maar dan gebruik hij gewoon zijn pincet en activeert hij deze met de monopolaire handheld.
- Neem contact op met Interplast – plastische chirurgie organisatie die vaak op missie gaat
- Electrode tip
  o Zwaard electrode is genoeg om alle behandeling uit te voeren
  o Naald wordt nog wel eens gebruikt, maar er zijn veel problemen met het door de handschoen heen prikken.
- Het is toch wel belangrijk dat cut and coagulation apart ingesteld kunnen worden
- Het is een aantal keer voorgekomen dat de diathermie generator op de grond is gevallen: knoppen breken af en worden niet vervangen
- Kijkend naar de technici is er veel apathie, rotzooi en troep in het ziekenhuis
- Lokale technici zien regelmatig het probleem, maar doen er vervolgens niet aan
- In de steden zijn spare parts goed te verkrijgen, niet in de rurale gebieden
- Lokaal produceren is een goede optie i.v.m. spare parts en regelgeving
- Wat regelmatig kapot gaat zijn de draden en handstukken
- Handstukken
  o Barst in embodiment
  o Verbogen tips of embodiment
  o Draad breuk of per ongeluk geknipt
- Het draad moet robuust gemaakt worden
- Het voordeel van elektrochirurgie
  o De operatie gaat sneller
  o Minder stress voor de arts, omdat bloedingen een klein probleem worden
  o Bloedingen zijn makkelijker te verhelpen
   Nu worden er vaak disposables gebruik voor het dichtknijpen van bloedvaten
  • Prijzig op lange termijn
  o Het is veiliger
  o Minder bloedverlies
  o Eventueel geen mes nodig

Power settings

- De instelling baseer ik nu op grootte van de patiënt, dus bij kinderen 25 en bij volwassenen 40 a 50, geldt zowel voor coagulatie als voor snijden.
- De instellingen worden gedaan vanuit praktische ervaring en geleerd door andere artsen
- Coagulation and Cut moeten beide apart ingesteld kunnen worden
- De power setting wordt heel praktisch ingesteld door te kijken naar de reactie op het weefsel. Bij teveel rook zet je het apparaat lager. Wanneer het snijden of coaguleren te langzaam gaat vraag je om dit wat te verhogen. Helaas is hier geen exact getal aan te koppelen omdat dit per merk en per chirurg verschillend is.
- De power instellingen veranderen met stappen van 5 is meer dan prima. Hij laat zowel coagulation als cut tegelijk veranderen.
- Naar zijn ervaring is er geen variatie in de impedantie van het weefsel wanneer de huid gecomprimeerd wordt of na het creëren van hemostasis.
- Dick probeert de operaties altijd zo simpel mogelijk te houden en veranderd daarom de power setting niet heel veel tijdens de behandeling
- Het aanpassen van de power setting door knoppen op het penceel lijkt Dick geen goed idee, omdat dit nog meer afleidt van het werkveld en daardoor stress of precisie verlies veroorzaakt.
- In het menselijk lichaam zijn er heel veel soorten weefsel en tijdens de behandeling kom je verschilleden type weefsels tegen. De power setting aanpassen a.d.h.v. het type weefsel is daardoor erg lastig. Keep it simple, zou ik zeggen. Ik heb aan die cijfertjes tot nog toe meer dan genoeg gehad.
- Daarnaast worden de nummers gebruikt voor communicatie met de omloop assistente

Name: Carmelio Carvalho
Date: 24/04/2018
Profession: Neurological surgeon
Experience with electrosurgery: Experienced
Experience in LMICs: Working in Brazil

- The power setting is based on the type of tissue that needs to be operated on and not on the type of surgery that needs to be performed (caesarean, club foot, etc.). The settings is depending on the precision and subtlety of the tissue. In example, when doing neurosurgery the surrounding tissue is highly sensitive for unintended tissue damage, so lower power settings are used. This is also used when doing plastic surgery when the superficial tissue should be damaged the least as possible. For the more tough tissue higher power/ temperature is used during for example a caesarean.
- The choices in power settings are based on practical experience and personal preferences.
- The coagulation power setting and the cut power settings differ from each other so they should both be adjusted separately.
- The power setting for the kind of surgery are communicated from the surgeon to the circulation assistant.
- To whether the used power setting is appropriate a first contact with the tissue is made to see the reaction. If needed, the power setting is adjusted based on result. If for example the tissue does not react to hemostasis a higher power is needed. If the power is too high and the tissue starts to smoke, a lower power setting will be used.
  o In comparison with the power setting prior to the surgery the changes of the power setting after the first check up are not much different (difference of +/- 5 Watt)
  o 30 W to 25 W or 25 W to 30 W
- Each patient has a different tissue impedance which will normally differ with around +/- 5 Watt. However there are cases where a power setting of 8 was even enough to create hemostasis.
- The least power is needed the better the effect on the surrounding tissue (no unintended tissue damage)
- The power setting is continuously changed during the surgery according to the tissue that is operated on.
- Choosing the power settings can be compared with using a iron for clothing. For jeans a higher temperature can be used compared to silk. So there is a continuous shift from one to the other
- Most medical devices power settings can be changed from 0-40 by changing the watt of the electrosurgery generator although the surgeon talks about temperature. The watt power from 0-10 is never used since this does not have effect on the tissue (which is ofcourse depending on the used brand). 10-15 watt is used for the sensitive tissue such as nerves and the superficial layers. When using such a setting the process

Appendix **G**

Interviews Dutch and Brazilian surgeons

is not in particular slow in compared to higher settings.
- Cutting tissue with the electosurgery unit will not be used for highly sensitive tissue then a scalpel is used.
- The closer the surgeon get to the deeper tissue layers the lower the power setting because of sensitivity of the tissue and the surrounding organs.
- In order to see whether the used power setting is correct, the surgeon checks if the blood can create an hemostasis.
- The surgeon pre sets the electrosurgery generator based on experience. When he has to change the power settings he is more concerned about the patient and he will be very careful.
- For neurological surgeries the surgeon uses 15-20 W for coagulation, not more. For the cut mode the neurological surgeon uses 30 W which can differ with +/- 5 Watt.
- For cut mode the surgeon uses the button on the handheld and for the coagulation mode a pedal is used.
- The surgeon does not prefer to change the power on the handheld because he needs to pay a lot of attention to the operational field instead of the power settings, so he prefers to let the power settings be changed by the circulation assistant.

Name: Ederson Ussami
Date: 25/04/2018
Profession: General surgeon
Experience with electrosurgery: Experienced
Experience in LMICs: Working in Brazil

- After years of experience he uses the settings that he likes and that are in his experience good (more practical approach)
- In practical they change the setting after the first check up on the human tissue with small differences
- Since he already has a lot of experience the surgeon does not have to test on the human tissue because he knows a certain setting will work
- The power settings are based on the to cut tissue, which is again in his situation based on experience.
- In example, the skin tissue is highly sensitive so you do not want penetration of the skin due to high power settings. So low power settings are used for superficial tissue.
- The coagulation setting is more localized and the cut setting penetrates
- For bipolar surgery water or saline is used to increase the conductivity
- For stronger tissue such as muscle a higher power setting can be used
- Each brand has a different indication of what the power is..
- For superficial skin a lower power setting is used
- All the time when using electrosurgery you create a burn on the surrounding tissue, however, this burn should be as low as possible to create less tissue trauma.
- The higher the energy the bigger the burn, no matter the nature of the tissue
- The use of the electrosurgery is basically on practical intuition and on experience
- There is no general table that shows what measurements to use for a certain type of surgery
- He usually uses 20-30 for cut and 30-40 for coag and with this he can perform all the surgeries.
- For children a lower power setting is used because they have a more sensitive tissue
- Fragile skin means lower power
- The power is changed depending on the tissue and the patient situation
- When performing surgery on the liver a high power setting for coagulation is used because there is a lot of bleeding
- There is a high variation between brands, so the surgeon first has to get used to the product and interface because he learned to work with another brand
- A regular surgeon does not need the reference of what a certain power setting means. It is based on what you practically see on the tissue
- Tissue impedance is depending on the clinical situation of the patient. So this means for the same type of tissue you will need a different type of power setting.
- In example, when using a washing machine you do not check in between how it is going with the shirts and if something goes wrong, you know that it will go right. However, during electrosurgery the situation is continuously changing so you have to change the power setting. A pre setting is good to have a first indication but during the surgery this will eventually change
- The electrosugery unit is mainly used after the first fragile skin, so from the skin after the fragile skin until the abdominal cavity
- When burning the outer lesion of the tissue this will not heal well because it will be traumatized compared to the situation before.
- Cut mode is used to cut massive organs such as kidney, liver and splint. Cause a lot of blood so high power settings
- After the superficial skin you start to open the acces to the caveties with cutting from 20-30
- There is a high alternation between coagulation and cut so having this on the pencil is a must
- The communication between the circulation assistance and the surgeon is numerical. So a scale is always needed to create good communication and a reference for both users
- For the superficial fragile outer skin a scalpel is used to create less tissue damage.
- Because of the numerical scale there is not much training needed for the circulation doctor. Everyone can increase or decrease a scale by number
- This is usually done by using buttons or a potential meter
- Pre settings are not necessarily needed because multiple doctors will use the same product.
- Important that the handheld which is used invasive is easy to sterilize

Name: Peter Hubach
Date: 25/08/2018
Profession: Orthopedic surgeon
Experience with electrosurgery: Experienced
Experience in LMICs: Multiple missions Kenya and Uganda

- Electrode tip moet enkel 180 graden kunnen draaien
o Wordt met name gebruikt voor moeilelijkere hoeken of voor het gemakkelijk maken van gebruikerergonomie
- Het zou kunnen werken om de tip massiever te maken zodat dit gebruikt kan worden om de pincet aan te linken. Ondanks dat dit niet nodig is om de stroomkring af te maken, geeft dit toch bij geen kennis het idee dat de stroom beter overgezet wordt naar het pincet
- De breedte van het ontwerp van de scalpel moet tussen het huidige ontwerp en de breedte van valleylab inzitten om de meeste behandeling uit te kunnen voeren.
- Plastisch chirurg gebruikt niet snel de cut tool, hij doet dit met een koud scalpel zodat je zo min mogelijk weefsel aantast.
- Orthopeed gebruikt altijd hogere settings in vergelijking met de plastisch chirurg, doordat er meer spierweefsel is.
- Belangrijk dat er geluid wordt gegeven bij het activeren van coaguleren en snijden (verschillende frequenties)
- De handheld wordt regelmatig 5 min weggelegd. Bij opnieuw gebruik wilt de chirurg altijd de laatst gebruikte power settings
- Tijdens de operatie komt het af en toe voor dat de power setting omhoog moet. Wanneer de orthopeed bijvoorbeeld dichtbij het bot komt, is er botvlies, wat een hogere power setting vraagt.
- Handheld wordt altijd weggelegd op de lakens en niet op weefsel. De handheld blijft altijd in het steriele gebied. Wordt weggelegd door de chirurg op een plek die gemakkelijk voor handen is.
- De generator wordt alleen met een doek schoongemaakt
- De handhelds worden schoongemaakt met stoom sterilisatie of met desinfectans. Einde van de dag wordt de apparatuur gesteriliseerd.

Appendix **G**

Interviews Dutch and Brazilian surgeons

- Tijdens de operatie zijn er altijd twee handhelds nodig. 1 voor gebruik en 1 als reserve. Het gebeurt regelmatig dat er een handheld op de vloer valt en daardoor niet meer steriel is. Ook gebeurt het dat de handheld kapot gaat en dat er een reserve nodig is.
- Gebruik in het ontwerp zo min mogelijk bewegende delen.
- In afrika wordt er altijd meegekeken bij het verhogen van de power setting.
- Na het instellen van de power setting wordt de power setting gecheckt op basis van de reactie op het weefsel.
- Om de huid open te snijden wordt nooit het elektrochirurgie apparaat gebruikt, maar een koud scalpel, omdat dit minder het weefsel aantast.
- Het elektrochirurgie apparaat staat altijd tegenover de chirurg
- In Nederland is er weinig hierarchie in de operatie kamer. Dit is in Afrika veel meer aanwezig. Ook is de communicatie meer kort af in Afrika.
- Elke patient is anders dus elke patient heeft andere power settings nodig. Voor dezelfde operatie blijft dit wel vaak in dezelfde range.
- Als er order worden gegeven voor het verhogen of verlagen van de power settings wordt dit altijd middels communicatie bevestigd.
- OR-A rijkt de instrumenten aan voor de chirurg. Zij staat dichtbij de instrumenten tafel. Ook geeft de chirurg al het gebruikte instrumentarium weer terug aan de OR-A
- Na de eerste incisie worden er klemmen gebruikt om de incisie open te houden.
- Het is belangrijk dat coaguleren en snijden apart ingesteld moet kunnen worden. Maar de power verschilt niet veel van elkaar. (dit kan dus in dezelfde sub groep blijven)
- Als er weefsel op de electrode tip zit, wordt dit weggehaald met het koude scalpel (deze is namelijk disposable) of met het pincet. Niet met bijvoorbeeld de schaar, want deze moet scherp blijven.
- Tussen kinderen en volwassenen kan wel een groot power verschil zitten.
- Wees voorzichtig met de indeling van standen (het geven van richtlijnen), arts wilt zelf bepalen op welke setting hij staat.
- Knop maken van 1-10 i.p.v. zo een grote variatie.
- In de handleiding eventueel de richtlijnen benoemen.
- Bij het verslepen van de generator moet je oppassen dat door het handvat het apparaat niet snel omvalt.
- Persoonlijk zal de heer Hubach een handvat bovenop het apparaat willen die aan een kant vastzit, omdat zo het apparaat (de bovenkant) nog makkelijk schoonmaakbaar is.
- Oostbloklanden is ook eventueel een interessante markt.
- Metaal exterieur gaat minder snel kapot bij vallen. Plastic breekt snel.
- De sterilisator staat vaak dichtbij de operatie kamer.
- Wanneer je weet dat een operatie zich tussen de standen 3 en 5 bevindt. Altijd op 3 beginnen zodat je zo min mogelijk tissue aantast.
- Op de knop van de handheld moet een rand zitten zodat je voelt dat je bij de knop zit. Het gebeurt vaak dat de chirurg gladde handschoenen heeft en daardoor het tactiel verschil niet goed kan voelen.

Name: Theo Wiggers
Date: 18/06/2018
Profession: CEO of Incision Care
Experience with electrosurgery: Experienced
Experience in LMICs: Mission all over Africa

Theo Wiggers is oud chirurg en probeert nu middels de interactieve video's van incision care het niveau of het ontbreken van kennis te verbeteren. Femke van der Gaag is bezig met business development voor incision en kijkt hierin naar wat voor producten Incision zou moeten aanbieden.
Our ambition is to have a global impact on surgical training, operations and patient safety because we believe everyone deserves the best surgical care. The provided content is trustworthy (accredited by the Royal College of Surgeons of England) which covers most of the relevant procedures pertaining to a surgical discipline in one digital platform. The Academy is developed according to international guidelines and it is supervised by senior surgeons. We are accredited as an institution by leading establishments such as the RCSE.

We see a future where the best surgical knowledge is available for everyone, everywhere.

- Grote vraag vanuit de markt over de hele wereld naar theorie achter elektrochirurgie is niet altijd bekend, maar wordt door regelgeving in de komende jaren steeds belangrijker. Doel van Incision is om de theorie op een interactieve manier over te brengen.
- Fouten worden besproken om vanuit hier uit te leggen waar dit vandaan komt en hoe dit voorkomen kan worden.
- Wanneer moet je nou bipolair i.p.v. monopolair gebruiken? Wat is het effect van het pincet activeren middels de handheld, etc.
- Er zit een groot verschil in ervaringsniveaus wat de verhouding tussen bevoegd en bekwaam belangrijk maakt
- Zonder bevoegd geen bekwaam en vice versa
  - o Dit wordt in de komende jaren wetgeving over heel de wereld, wat het dus nog belangrijker maakt dat de juiste kennis overgedragen wordt.
- Focus ligt zowel op open chirurgie als laparoscopisch. Nederland is alles laparoscopisch, maar in andere landen zijn de procedures met name open chirurgie.
- Guidelines van Erbe worden naar verwachting wel de standaard (check handleiding van nieuwste apparaat voor informatie)
- Belangrijk is dat power settings niet overschreden worden voor een bepaalde type procedure
- Meer attention nodig bij minimaal invasief gebruik
- Power settings worden gebaseerd op type procedure (ERBE) waarbij er een ondergrens en bovengrens gegeven wordt voor een type chirurgische procedure
- Apparaten zijn spannings gestuurd en wattage gestuurd, check wat de toekomst focus wordt
- Belangrijk is dat de power setting altijd zo laag mogelijk begint
- Wat is er minimaal nodig voor de juiste tip tissue reactie
- Refereer bij gesprek Moses Obimbo naar Theo Wiggers of Femke van der Gaag
- NIVEL heeft eindtermen opgesteld waar de chirurg en assistente op getoetst wordt op het gebied van elektrochirurgie

Appendix **H**

Explorative study Kenya - research protocol

Empowering the accessibility of global electrosurgery
Koen Ouweltjes | +31623452696 | TU Delft | Industrial Design Engineering | Landbergstraat 15, Delft (Netherlands)

My name is Koen Ouweltjes and I am a graduate student of the study Integrated Product Design at the Technical University of Delft. The goal of my graduation project is: empowering the accessibility of global electrosurgery.
As a step towards improving surgical care and global access to affordable medical equipment, high quality and low-cost Electrosurgical Units (ESUs) are essential. The ESU is used as an operating tool to assist the surgeon for many surgical procedures. The electrosurgery unit is widely applicable for all surgical procedures, helps to stop and prevent bleeding, allows for precise cutting, and facilitates better wound healing in less hygienic environments.

Today's market is dominated by high-end ESUs characterized by high prizes, large number of settings and computer control systems. A few low-end devices also exist that—due to their stripped down, fully analogue and simple design— do not fully meet the demands that are needed for safe global usage of the ESU. As a result, the devices are used inappropriately and that can have serious clinical consequences for the patient.

Our research & development team of the TU Delft is testing with a variety of cultures and context settings on the user-interactions, understandability and acceptance of the electrosurgery unit and by means of this study increase patients safety. The information received during the user test and interviews will be used as input and requirements for future development of the electrosurgery unit. Furthermore, the result of my graduation project will be part of Roos Oosting her PHD project concerning high quality and robust surgical equipment for safe surgery world-wide.

Explorative study

The new design of the electrosurgery unit should be understandable for all electrosurgery users, thus surgeons with limited electrosurgery experience, specialists and surgical assistances.

Methodology

Research A

Prior to the user test, the research participant (surgeon or surgical assistance) will be provided with a variety of surgery scenarios and asked to set the provided interface with the, to his or her knowledge, correct power settings. Multiple 2D interfaces will be shown and the researcher will observe the interaction with the interfaces. In between tasks the researcher will ask questions about the interactions and understandability. This research will take approximately 15 minutes.
In case of more time, the researcher will ask more in depth questions about user-interaction (prior, during and after surgery) with the electrosurgery unit and by means of co-creation make future design decisions with the research participants.

Research participants

- Surgeons with all levels of experience
- Surgical assistances
- Medical students

Research B

Another part of the interview/research will concern short questions to create a better understanding on the cleaning procedures of the electrosurgery accessories within the hospital, local repairability of medical equipment and the procurement of electrosurgery accessories. This with the aim to make proper design decisions on the monopolar handheld part of the electrosurgery unit.
Research participants

- Surgical assistances
- Medical students
- Biomedical engineers
- Procurement officer (hospital)
- Local technicians

Apparatus

- Lenovo tablet
- 2D scale paper versions of the user interfaces
- Variety of interface designs
- Questionnaire
- 3D prototype model of the electrosurgery unit
- 3D models of monopolar handheld

Appendix **H**
Explorative study Kenya

My name is Koen Ouweltjes and I am a graduate student of the study Integrated Product Design at the Technical University of Delft. The goal of my graduation project is: empowering the accessibility of global electrosurgery. This study aims to find insights on the user interactions and understandability of the interface of the electrosurgery unit. The outcome of this study will be used as design input and requirements for future development of the electrosurgery unit.
You will be provided with a variety of surgery scenario's and asked to set the interface with the correct power settings. Hereafter, the researcher will ask you more in depth questions about the performed task.

Please think out loud and motivate your answers.

Gender:	Male / Female
Profession	____________
Years of experience in profession	________ years
Experience with electrosurgery	Yes / No
If yes, how many year of experience	________ years

Pre-setting the product

1) Pre-set the power settings of the provided electrosurgery unit interface according to the following three surgery scenarios:

- Patient A is a 70 year old man that just broke his skull and needs an urgent head surgery. Please pre-set the electrosurgical unit on the provided interface

- Patient B is a 35 year old pregnant woman with an obstructed labour. Therefore, a caesarean surgery is mandatory. Please pre-set the electrosurgical unit on the provided interface

- Patient C is a 13 year old boy that is diagnosed with club foot since he was 3 years old and this will finally be remedied. Patient has a low percentage of body fat and has a low body mass for his age. Please pre-set the electrosurgical unit on the provided interface

Interface sub-group pre-set (Main questions)

- Considering the acceptance of the design; do you experience the positive value of this new design, what are good and bad aspects of the design?
- What are possible barriers concerning the acceptance of the novel interface design?
o Problems of acceptance as a consequence of no integration within electrosurgery studies?
o Missing features?
- Do you believe in the added value of the novel interface compared with the current available electrosurgery unit(s), if yes, why?
o Do you think the new design is an improvement on what is available?
- In case of the provided scenario, what kind of surgery sub-group has been chosen and why?
- Has the power setting been changed for one of the waveform modes? If yes, why?
- How confident are you of using the correct power settings? (1=total lack of confidence, 5= confident) and explain why?
- Please rate the trustworthiness of the interface (1= dangerous, 5=highly trustworthy) and explain why?
- Please rate the understandability of the provided interface(1=complicated 5=easy to use) and explain why?
- Name another surgical procedure that can be found in the sub-group micro
- Name another surgical procedure that can be found in the sub-group moderate
- Name another surgical procedure that can be found in the sub-group macro
- Would you change any of you filled in sub-groups after doing all the tests?
- Do you like any of the other designed interface and why would you prefer another design?
o Do you prefer another background colour for a better contrast
o Do you prefer the text of the surgery examples on the interface? Or do you prefer them somewhere else?
o Do you prefer stronger colour indications/ separation of the cut and coag mode?
- Are there any buttons or icons of which you do not know the meaning?
- What kind of power button do you prefer on the provided 3D printed interface (control, visibility, size)?
- Would you like to have the power setting guidelines in the surgery room? On the ESU? Or would you position it somewhere else?

Interface sub-group pre-set (Sub-questions)

- Should the power setting of a sub-group always start on the lowest power or in the middle of the sub group bandwidth?
- Does the power needs to be visible during the surgery, what information is wanted?
- Does the sub-group pre-set needs to be visible for the surgeon during the surgery or is the provided information during the briefing of the surgery sufficient?
- Is there any theory taught concerning electrosurgery during the study?
- What feedback/knowledge is wanted when performing the pre-setting?
- Do you miss any features on the interface?
- How do you check if the used power setting is correct (what are signs that show that this is the appropriate power setting to continue the surgery with)?
- What do you think is the meaning of the sub-group symbols?
- What is the meaning of each symbol on the interface?
- Is a screen that indicates the wattage mandatory?

Adjusting the power setting (Sub-questions)

2) The power setting needs some adjustment because of the low coagulation effect when activating the coagulation button. Please increase the coagulation power with the – to your opinion – needed value.

- Does the research participant changes the correct waveform mode? If not, show other examples and see if this helps.
- With how much Watt is the power setting changed and why did the research participant make this change? (where did the participant look at? Rotations? LEDs?)
- Test three power buttons and check what button gives the best feeling of control (1= no control, 5= full control) (round button without click, round button with click, cut round button with click)
- What kind of power button is preferred, and why?
- In the micro group there is a bandwidth of 5-25, would you like to change the power per 1 [W] or per 5 [W]?
- Show the monopolar handheld and ask what they think are the cut mode and coagulation mode buttons and ask them why?

During the surgery (sub-questions)

- How many monopolar handhelds are used during a surgery? Is there a back-up handheld during the surgery?
- Is the sound of cut mode and coagulation mode mandatory?
- How often do you normally change the power setting during the surgery (prior and during the surgery)?
- Do you always check the power setting yourself on the interface after giving the order of a power change?
- Show the monopolar handheld and ask what they think are the cut mode and coagulation mode buttons and ask them why?
- How do you hold the handheld while doing an incision of coagulation (ask the surgeon to show this)
- Do you rotate your hand when using the other side of the electrode tip or do you rotate the electrode tip?
- How visible can the LEDs be on the handheld?

Appendix **H**
Explorative study Kenya

Will they distract you while doing a surgery?
- Do you want to hear a sound when activating the handheld?
- Would it be interesting to change the power settings on the handheld instead of being changed by the surgical assistance?
- During the surgery it often happens that you have to use other equipment than the monopolar handheld. After 5 minutes you take back the monopolar handheld, do you check the power setting? Should the power setting similar as the last used power setting?
- There has been a power fuse, please set the power on the last used power setting.
- What kind of electrode tips do you use during the surgery (scalpel, bulb, needle, etc.)?

Interview on the cleaning procedure of the monopolar handheld and other accessories
To make the monopolar handheld and other electrosurgical accessories resistant against the cleaning procedures used in a variety of healthcare settings, we would like to map the used cleaning procedures of the electrosurgery accessories within the hospital.

Research participants
- Surgeons
- Surgical assistances
- People that clean medical equipment within Sub-Saharan hospitals

Cleaning procedure (Main questions)
- What kind of cleaning procedures are used to clean the electrosurgery accessories(monopolar handheld, cable and electrode tip)?
- Is cleaning detergent used to clean any of the accessories, if yes, what kind of cleaning detergent (spec sheet)?
- How often are the monopolar handhelds and accessories cleaned on a regular day?

a. Autoclaved after each treatment?
b. Autoclaved at the end of the day?
c. Is there a difference between the monopolar handheld and other accessories?

- What are the standard autoclave settings?

a. Temperature?
b. Pressure?
c. Time?
d. Humidity ratio?

- In what kind of situations is cleaning detergent used instead of steam autoclavation?
- Imagine a monopolar handheld with integrated cable that is autoclavable, what will be the difference with the current cleaning procedures? Will this fit the autoclave?
- How many monopolar handhelds are used during a surgery? Is there a back-up handheld during the surgery? Who cleans the accessories (surgical assistance, biomedical engineer, other)?

Cleaning procedure (sub-questions)
- Is there a cleaning protocol within the hospital?
- How are the electronic cables of the monopolar handheld cleaned?
- If the autoclave is in use and a monopolar handheld needs urgent cleaning since the handheld dropped on the floor during the surgery, how will the cleaning procedure be?
- How will the accessories be cleaned in case of no autoclave?
- Do you clean the handhelds just before the surgery or are all handhelds sterilized and stationed in a sterilized area?
- If you run out of cleaning detergent and the monopolar handheld or electrode tip needs to be cleaned, what do you do? Is there any final course of action when you run out of cleaning detergent
- How is the HF generator cleaned after a surgical procedure?

a. How often is the HF generator cleaned?

Procurement of the electrosurgery accessories

Research participants
- Board of hospitals
- Procurement officers of hospital
- Procurement officers of the government

1) When procuring new monopolar handhelds, what are the most important requirements?

a. Costs
b. Reusability
c. Service
d. Features (button activation, standardized connectors, etc.)
e. Cleanability

2) Is there a maximum procurement size of the monopolar handhelds or electrode tips (e.g. 10 handhelds each time)?
3) Does the government also creates tenders for electrosurgery accessories such as the monopolar handheld? If yes, what will be the procurement procedure?
4) How many handhelds will you buy if the price of the handheld is 40 euros?

Repairability of medical equipment

Research participants
- Biomedical engineer
- Local repairmen
- Engineers of Makerspace

- Is there any medical equipment repaired in the hospital, if yes, what kind of equipment?
- Who repairs the medical equipment?
- What kind of repair tools are available in the hospital or at the local repair office?

o Pictures and measurements

- What is the experience of the local repairmen concerning electronics?
- What does the local repairmen often repairs in the hospital?
- Are there any standardized spare parts available in the hospital?
- What is the procurement procedure if a spare part is missing?
- Where does the local repairmen buys his spare parts, is it possible to buy them online?
- Is a power fuse easily available
- How about repairing electronic cables, are there spare parts and are the tools locally available?
- Does Makerspace provide any service for hospitals if medical equipment is broken?
- Are there any local production or assembly facilities in Kenya?
- Ask questions about locally available electronics (Makerspace, local electronic store, etc.) Do you have any view on the used cleaning detergents in a variety of healthcare settings?

Appendix **H**

Explorative study with Kenyan surgeons

Name: Kiambu District hospital
Date: 22/06/2018
Profession: Master students
Experience with electrosurgery: None

Kiambu is a district hospital just out of Nairobi. It can be classified as a low resource urban hospital (public). At the Kiambu district hospital I have been able to talk with a university professor and medicine students that are in their final year prior to become a medical officer.
These students receive a practical course about electro surgery wherein one of the teachers shows the skill for a type of surgery and with that information the students are expected to work with the product. They are familiar with the different waveform modes and that there can be a difference in power settings. However, just one type of surgery is shown in practice. As explained by professor Pankaj Jani; in many hospitals the electro surgery equipment is used by medical officers since there is a lack of surgeons, something becoming more important in the future.

Prior to the user test, I explained what my goal is with the project and showed them the prototypes. Hereafter the scenario's were sketched in order to see if they understand the user interface and whether this is intuitive.

- All knowledge is not taught by using guidelines based on the preference of the visiting teacher.
- All of the 4 students discussed the power settings and they all seem to really understand the interface
- The icons were highly understandable and the way of changing the power settings was easily understood as well.
- In all three scenarios the correct power setting has been chosen.
- Hereafter, I asked them to explain what the symbols meant and ask them for other surgeries that might fit the sub-group. This was all understood and some examples were given. I was not expecting this but this outcome was really nice to me.
- The symbols in their opinion works really well especially taking into account the other African countries where no English is spoken. After I showed the examples with text the agreement was even stronger.
- "This really gives me the confidence of at least being in the range of the correct power setting. We just got shown a surgery with power setting 40 W, wherein we got taught to use this setting. Apparently this is way too high!"
- "When I will do a similar surgery as the cleft lip then I will know what the power settings have to be, super nice!"
- It makes me feel more secure for myself as well as for the patient
- One thing that was not understood has been the percentages of changing the power setting after the pre-set. They all said that it is way to hard to sort of calculate this, which can also be caused by not having a working screen that properly shifts when turning the power knob. It was preferred to have a simple identification of +5 or +10, which was the best option to all students.
- The button that has been preferred more in terms of feeling of control has been the tactile feedback of the small button. However the bigger button has been preferred since it to there opinion provided more reliability. "the small button will break instantly, is what one of the students said"
- The power setting guidelines were shown and the students preferred to have this guidelines attached on the ESU. Putting it on the door or on the wall of the surgery room will not help since this will not be seen and the briefing of the surgery is mostly in another room.
- After the briefing the power is set by the surgical assistances and by giving these guidelines they are more aware of what power settings to use and they can more easily attend the surgeon on mistakes.
- Not exceeding a certain power setting really provides the feeling of confidence and safety that is not present in current equipment.
- What the students did know is to always have the power as low as necessary. They loved the fact that the power button always automatically shifts to the lowest power within a sub-group.
- The screen on the interface was to them mandatory because this will increase fast and easy communication instead of communicating about a percentage of +10 or +15 watt. Moreover, it gave them the feeling of precision.
- It has been preferred to change the power setting with +5 instead of +1 because this will go faster and is still more precise then as indicated during the practical class where the surgeon easily changed the power with 10 Watt.
- The students were shown the monopolar handheld and asked which of the two buttons would be the cut button. They all agreed that the thin lined button really shows what the waveform mode does. Furthermore, the handheld was immediately held in the correct manner and the feeling looked ergonomic to them.
- Multiple designs of the interface were shown and they preferred to have a strong distinction between the two colours of cut and coagulation. In this way it will be more clear on what waveform mode you are changing and this is also more easy to see from a distance. By seeing a visual difference is better then just having some text.
- The product handle should be integrated within the product to prevent for breakage. To them it feels more convenient. However they should be placed on the side of the product instead of on the back by having a cut out.
- The hospital is separated into women resting places and men resting places.
- The hospital just has 2 surgery rooms so movability is not that big on an issue but this is much more important in a hospital such as the Kenyatta University Hospital

Cleaning procedure in the hospital

- For all surgical equipment the autoclave has been used
- In case of an emergency CIDEX cleaning detergent is used but not for the surgical equipment is what they explained.
- During the surgery there is normally a back-up handheld in case of droppage on the floor or breakage. Only in case that there are enough available in the hospital.
- The autoclave is mostly used ones a day but in case of an emergency it is also used throughout the day in case the hospital runs out of sterilized equipment.
- The autoclave looked really sophisticated

Biomedical engineer

- The most common breakage are the cables of the accessories and the connection parts with the electrosurgery unit.
- Normally they will not fix these cables and just buy another handheld. Mainly because they will not want to take the risk of repairing it where after the handheld might not be autoclavable/watertight anymore.
- They have all the more basic tools such as a screwdriver, hammer, imbus set equipment but no current/voltage measurements equipment since this is too expensive.
- They think in case of the handheld that durability is more important than local repairability
- Until now no parts of the electrosurgery unit broke in the hospital, mainly the electrode (return plate and active)
- The monopolar handheld equipment that lasted the longest are the one that are autoclavable but without the wire. The wire can be detached prior to autoclavation.
- The spare parts of the equipment is mostly not locally available and the guide is often missing. Buying them online is mostly too expensive.

Appendix **H**

Explorative study with Kenyan surgeons

Name: Professor Pankaj Jani (president of COSECSA)
Date: 22/06/2018
Profession: General surgeon - Nairobi Women's hospital
Experience with electrosurgery: None

Professor Pankaj Jani is a general surgeon at the Nairobi Women's hospital Hurlingham and also the president of COSECSA, college of surgeons in East, Central and Southern Africa. He has over 30 years' experience as a surgeon and knowledge about low resource settings all over Africa.

- Coagulation and cut is more than sufficient for the surgeries in Africa
- I will send you a logbook with the most common surgeries because it would be great to implement this within the interface
- The sub-division of sub-groups feels safe and provides the needed information.
- Symbols will work better than words
- The clef lip symbol should include a cleft
- The caesarean section is the most common surgery
- Drawings are better to understand
- Caesarean section should include a section
- Professor Pankaj Jani easily understand the symbols and the surgeries within a sub-group
- The most important thing of this product will be costs, high quality and safety
- Important to understand is that we have to go back to the basics. All new technology make the gap between wealthy countries and Africa even bigger. The new technology is for the rich countries.
- Cheap and high quality, that's the key!
- We do not need any unnecessary function. Look at your Iphone; you do not use 80% of all features because you simply do not need or understand them.
- In the last decades technology has changed extremely, previously we could not even see microscopic changes on the tissue during a surgery. Now, with laparoscopic surgery everything is seen more easily. I see blood vessels that I have never seen before. With all the improvement of antibiotics we do not need precise settings of power..
- There is a strong hierarchy between the assistances and the surgeon. This can already be seen with entering an office. The surgeon gently lets you wait before he tells her to come in.
- The electrosurgery product is mostly used to coagulate. Cut is done with the scalpel or scissor.
- Koen what you have to understand is that in Afrika we are no specialists as in the Netherlands. Were are mostly general surgeons that need to examine the full spectrum of surgeries
    - o Medical officers are currently doing a lot of surgeries (caesarean, laparotomy).
    - o Other low educated people that are not even medical officers examine surgeries since there is a big lack of surgeons.
- In the future more and more will be laparoscopic but that will probably be in 10-15 years.
- Basic surgery is the most important thing for Afrika
- Handheld should really be able to withstand 1000-2000 sterilizations and still be cheap in order to succeed.
- Surgeon has the idea to put plastic over the handheld and not the electrode tip to prevent for contamination. The plastic will be thrown away after each surgery and the electrode tip will be sterilized.
- All sockets in the surgery room of the Nairobi Women's Hospital are grounded
- Durability is more important than local repairability
    - o Some parts are being bought online but this is very expensive
- Professor likes the symbol approach and easily understands this. He is not sure if there should be a different power setting for both waveform modes. Keep it simple!! You will not see the difference between the coag and cut mode is what he says.
- The goal should be IKEA for surgery; affordable and good quality
- Regulations are not a big issue in Kenya because there not many rules like in Europe
- The surgery rooms within the private hospital looks sophisticated. However, really old fashion and we could simply walk in while there was a surgery. Pretty rare haha.
- What I would really want to have in the future is someone like you to work on a Theatre (surgery room) with basic equipment without any unnecessary features that is as cheap as possible.
- The electrosurgery unit cannot cost more than 500 euros.
- The surgeon did not know the difference between cauterizing machine and the electrosurgery unit. He thought cauterizing would be more cheap
- Why do you need to change the cut mode as well as the cut mode, I think it can be simpler to include this in one button
- The blend mode is useless.
- The world of electrosurgery has many capabilities of power setting and waveform modes. However, nearly all of this is needed to perform basic surgery. The design approach should be compared with the functionalities of your Iphone. At maximum 15 percent of the functionalities is used. For a tailored and intuitive ESU system you should only focus on this essential 15 percent
- The ESU unit should only include functions that are necessary to perform the basic functions of electrosurgery. All additional features such as automatic measurement of tissue impedance, smoke evacuation and lights should be eliminated. They increase the possibility of breakage and do not empower the basic needs (Jani, 2018)
- In basic surgery those extra features are just useless.
- Difference cut and coag in general for Africa does not make a difference. If the extra feature for coag and cut is just 10% more expensive than it is fine. Costs is super important.
- Absolutely good outcome for the sub group and changing power within the sub group because you have to change the power for the difference in tissue and patients have different tissue impedance
- If I need to cut I just increase the power of coag
- Professor always uses the coagulation function
- A caesarean section is done by a medical officer. In Holland a specialists does this.
- In Malawi the caesarean section is done by a clinical officer
- The electrosurgery unit is hardly used for cutting
- The product should be cheap and less sophisticated.
- The idea is very good if the handheld can be autoclaved 2000 times.
- As I said the last time, the gap between surgical care in rich countries and in poor countries is becoming bigger and bigger because of the of the shift of technology to the rich countries. Therefore, all equipment is too expensive and not reliable in the African conditions
- The product should me reliable, cheap, durable, high quality and safe
- In the last years the procurement phase has become better and better. Kenya is subdivided in 47 counties with each a separate procurement government. This counties are spread over Kenya. Within each county government there is a board that decides what will be procured. This means that the voice of the surgeon and engineers is also heard in the more rural areas and not just in Nairobi because previously there was just one government in Nairobi that decided over all the equipment. This has been changed six years ago and finally the system work. The first 5 years the system did not work so well.

Appendix **H**

Explorative study with Kenyan surgeons

Name: Dr. Wilson Navagwa - Coptic hospital
Date: 25/06/2018
Profession: General surgeon
Experience with electrosurgery: Experienced

Dr. Wilson Navagwa works at the Coptic mission hospital and has been a surgeon for over 15 years. The Coptic hospital is a private hospital for the middle-class of society. It is a well maintained hospital with new surgical equipment and a hygienic environment.

- The cleaning detergent used within the hospital are CIDEX and aniosyme dd1 which are both used as solutions in case a surgical tool is needed quickly or in case disposable equipment needs to be used for another time. (5-10 min steralization)
- For a surgery they will ideally use just one monopolar handheld but they mostly need two or more.
- Within the surgery they use both reusable and disposable monopolar handheld. In case when they run out of sterilized reusable handhelds they will use disposables and charge the patient for using this. This is based on bad luck for the patient..
- On a normal day they will perform 7-10 surgeries per operation room. This means that for each operation room in a hospital you will need at least 5-10 handhelds.
- The autoclave is used each hour, so on a continuous base
- The first incision during the surgery is always made with the normal scalpel to prevent for tissue damage on the superficial sensitive top layer of tissue.
- Hereafter the monopolar handheld is used for cutting and coagulation.
- For almost all surgeries the spatula electrode is used, so this will be sufficient within the project.
- The power settings during the surgery is increased when there is for example a lot of fat tissue. This is just to increase the surgery time because the same effect can also be achieved with lower power settings but this will take longer
- The maximum power setting that the surgeon has ever used is during a TURP (Transurethral resection of the prostate) surgery. Where cut 70 W has been used and coag 120 W. Furthermore when having prosthetic tissue also higher power settings are used.
- When using lower power settings the surgery will take more time which is also not wanted because this will maybe lead to more blood loss during the surgery.
- The user of the ESU should be acquainted on how to use the product because it can be a very dangerous product.
- The idea that you have on explaining what power should be used for a certain surgery will really help to make surgeons more capable of using the correct power settings. This knowledge is almost always missing.
- Most surgeons do not know what power settings to change when they have never performed a surgery
- The solution that you have will mainly be of high benefit in the more rural area where there the spectrum of surgeries is so diverse and the electro surgery experience is limited.
- If is see your guidelines there is not something missing. The 75 W is high and I think in 95% of the cases not necessary.
- Using this kind of interface will for sure give more feeling of confidence of using the correct power setting. And most important this will be more safe for the user as well as the patient.
- The sub groups and icons were easily understandable by the surgeon
- Important is to always start as low as possible with the power settings and increase from there on.
- I always make a first coag or cut to see the effect and after that I change the power setting
- I always change this in steps of 5W and after I give the order to the runner I always check the power setting. I have had cases where the runner accidentally changed the power with 50 W instead of 5 W. In the end I am responsible so I always want to see the change in power. Therefore this should be easily visible from a distance. The interface with more colour will also improve this contrast and better visibility of the power settings of both waveform modes
- The screen is mandatory for me to see that the correct power settings are used and gives me the feeling of control and precision.
- Most important when using the product we should always pay attention and want to receive the needed feedback.
- An orange LED on the handheld in cases where high power settings are used or more attention is required will be a good add on, especially in case you do not understand how to use the product in the correct manner in terms of power settings.
- During the study we just learn some basic theory and one or two practical examples. This means we are not acquainted with what power settings to use for a certain surgery, so the guidelines will be a great add on.
- By looking at the handheld the cut mode is in front and the coag mode is in the back because the coag mode is always in the direction of the surgeon and the cut mode is always in the direction of the patient.
- Coag and cut are sufficient enough to perform all surgeries
- Coag and cut are always in close proximity to each other in terms of power
- This surgeon really based the usage of the ESU on the waveform modes provided by valleylab; spray for this kind of surgery and pure cut for this kind of surgery, etc.
- During the surgery I rotate my hand and the electrode. It would be a great add on to have control clicks in the straight and 90 degrees positions
- The autoclavable handheld is autoclaved together with the cable
- The pedal activation is not preferred. Better to always have a view on the operation.
- The used product within the hospital were the Valleylab Force X, Covidien Ligasure (laparoscopic) and the covidien Force Triad with all functions and possible simultaneous usage.

Name: Derrick Mugasia
Date: 25/06/2018
Profession: Co-owner of Makerspace
Experience with electrosurgery: None

- My experience with medical product development is that a lot of experienced surgical assistances are very conservative (scared for technology). They are used to work with a certain product so they do not want to learn many new things. This is different compared to students that are very willing to learn and adapt to new things.
- The most important thing for medical product development is co creation with the end-user. By making them part of the process, they will be more willing to use the product because they have been part of the development.
- It is important to create strong confidence of using the product and map out the necessary feedback
- This is also important for sustainability in the long run
- The used cleaning detergents that I saw in the urban as well as rural areas are GIK detergent and CIDEX
- Make sure that you use stainless steel for all metal products and that you do not use paint. This will make the product wear or corrodes over time which makes the product unsterile.
  - o After a while the product will not feel safe anymore and they will throw it away
- Since there is a lack of surgeons a lot of times medical officers perform the surgery. In the more rural area this is sometimes even a clinical officer.
- Banana plugs are locally available in each electronic shop. For electronics in Nairobi check the following website of Kenyan shops
  - o Nirokas Electronics
  - o Ktechnics
- The PCBs are mostly coming out of China since it is cheaper to get them from there
- If you want the product to be regulated in Kenya it should pass the Kenyan Bureau of Standards the will have to approve the product. Ones a product is approved you will not have any more problems.
- If you want to transport electronics that are locally available in Nairobi it will take around a day for it to get there. This works pretty well.
- Important to use basic electronics within your

design to create a successful implementation
- So far I really like both designs and I think especially the handheld is great in terms of simplicity and durability.
- If you look at the grid cable that is attached to the ESU it should not be integrated in the design but needs an external connector. This is needed for safety in case someone walks against the cable, the cable will fall out.
- Most basic tools are available locally such as a screw driver, allen key, pipe wrench, etc.
- All components should be able to be replaced/ repaired separately, so no usage of modules.

Name: Dr. Wobenjo Adili - Kiambu District hospital
Date: 27/06/2018
Profession: General surgeon
Experience with electrosurgery: Experienced

- Most times wen I use high power is when the machine is not working properly. I can see this within this hospital that I use way more higher power settings than in the other hospital where I work.
- The interface sub division in groups will surely help to increase safety for patients and the surgeon.
- The sub group division was easily understood by the surgeon and well accepted!
- The power setting for macro are too high in his opinion. He has never exceeded 40-50 W with a good working machine, unless the machine was not working properly.
- He thinks two subgroups, micro and macro would be sufficient.
- For cancer surgery (macro) he never used these high power settings
- If the sub group has a function of being more safe, then it should always be visible for the surgeon. He wants to know whether the runner chooses the correct sub-group so therefore this should always be visible from a distance.
- Sometimes the ESU is positioned on a chair lower than the bed, which makes it harder to see the ESU interface and the power setting. So it is highly important that this is properly visible.
- The screen is mandatory for the feeling of control and confidence and should be visible from a distance. The surgeon always wants to see the power so it should be visible from a distance. This is also important to check whether the runner has changed the power correctly.
- The power setting for a surgery should always start as low as possible.
- The icons of the surgeries are easily understood and the information is sufficient
- A better colour visibility of the sub-groups would help to create a better distinction. The more yellow and blue blocks are preferred because this is better visible so gives the surgeon a better feeling of control and understanding.
- The surgeon check the correctness of the power setting by looking at the tissue reaction.
- The power is changed on most machines with +5 but I prefer a change with +1 because if the machine works properly these small changes can already make the difference that I want. Furthermore, this gives me a better feeling of precision.
- The power settings is only adjusted in the beginning of the surgery and ones or twice during the surgery
- The change in power setting by the runner is always checked by the surgeon because in the end he is responsible for the clinical outcome.
- Preferably the surgeon always want 1 or 2 back up handheld but this is not always available, not even in our hospital. Especially in rural areas where you mostly have just one per theatre.
- The handheld is hold like a pen. This gives the best feeling of precision.
- The cut button is the one in the front because by intuition and usage I always first cut something and then I coagulate. So this feels more logic to me.
- An orange LED on handheld is will be distracting during the surgery and not in my field of view. I am focusing on the surgery and do not want to focus on anything else. I would rather want an increase in sound when going to a higher power settings, thus more attention is required. This could be or a different sound from the waveform activation sounds or an increase of volume of the waveform sounds.
- I use all different kinds of electrodes since they all have their advantages. However, if you have to choose one more multifunctional electrode then you should use the spatula electrode since this will be sufficient for all general surgeries.
- I prefer activating the electrode by button but these buttons are not always working so in that case I used the pedal.
- Throughout the day the autoclave is used on a frequent base in our hospital. However, in the more rural areas it can just be used ones a day. So in most cases for quick sterilization CIDEX is used for the accessories. I think in a ratio of 40% CIDEX to 60% water.
- The handheld should be resistant against CIDEX. Currently, most cables stop working or a hole is blown in the exterior of the handheld after frequent cleaning.
- Most times in rural areas there a no back up handhelds so a surgeon uses one handheld throughout the whole day. It is being reused by using CIDEX detergent.
- The handheld and cables are first cleaned with normal soap to take the eschar and blood off before they are cleaned with CIDEX (10 min).
- Prior to the surgery we take sterilized equipment from the cleaning area and after that if there is a good cleaning service with multiple handheld we use steam sterilized handhelds, otherwise we quickly clean them with CIDEX.

Name: Salome - Nairobi County Government
Date: 27/06/2018
Profession: BMET
Experience with electrosurgery: Medium

- The purchased product are mostly designed for different weather and humidity conditions.
- In the rural area there is normally no AC which means windows are opened and the products are more exposed to dust.
- Most times, the AC is hanging but not working
- The current level of infection control in Kenya is like 5% of what it should be.
- When the equipment is not properly working during a surgery the BMET is asked to take a look. This is mostly done after the surgery and not during the surgery.
- Caesarean sections are often performed by medical officers
  - o Surgery takes at most 30 min
- The generator never breaks, always the pencil or the return plate
  - o The active knife or the electronics inside break
- Suppliers of ESU always give extra fuses
  - o Cheap
  - o Frequently changed in Africa
- Autoclave is available in most hospitals
- CIDEX is mainly used in theatres
- In cleaning room besides autoclave they use JIK bleach detergent.
- Tenders are mainly used for bulks of products
- For the accessories there is an annual tender wherein the hospitals buy equipment for the whole year on the facility level. They only pay for what they use.
  - o E.g. if they supply for 3 months and then run out of equipment they can get more.
- Consumables are bought on the facility level
- There are three levels
  - o Facility
  - o County level
  - o National level
- I will bring you in contact with the Machachos hospital and the Mbagathe hospital.
- Reusables is a must because of costs
- Orthopaedic surgeries are the most common surgeries here because of all the traffic accidents.
- Kenya is divided by 47 counties that all have their examination board for procurement

Appendix **H**

Explorative study with Kenyan surgeons

Name: Professor dr. Obimbo & Dr. Babi
Date: 28/06/2018
Profession: Specialist surgeons
Experience with electrosurgery: Experienced

- The restart power button looks like it's the blend mode
- The maximum power setting that I have ever used is 80W
  - o More because the reaction felt better and probably the equipment was not working appropriately
- There are a lot of brand differences which makes it hard for us to know what is the meaning of a certain power. In example on a scale from 1-10 I know what the reaction will be but if the scale is from 0-80 then I do not know what the tissue effect will do. We change a lot between products which makes it hard for us to know if we are on the right move.
- This guidelines will for surely help me to understand the usage of the ESU better especially with all the differences in brands and the differences in surgeries
- The icons are well understood prior to choosing a sub-group
- The power settings should always be as low as possible
- Guidelines should be positioned on the wall of the theatre because while preparing the surgery room and the machines we always look at the posters on the wall.
- Dr. Obimbo's first time he operated was on a patient so he did not have any theory prior to the surgery. He just experienced the tissue effect.
- Most surgeons are taught on how to use the product by the surgical team, which means in general everyone follows the majority in terms of pre settings for a certain surgery.
- There are currently no standards in the power guidelines which would be very nice to have. Even I do not always know what power settings to use. Its just based on practical experience.
- Some of the scales on electrosurgery unit interfaces I simply do not understand.
- The clinical outcome could be much better when these guidelines are supplied
  - o More ease to use the product
  - o More confidence
  - o More safe for me and the patient
- It is important to know what set-up to use prior to the surgery therefore the wall would be interesting. The theatre is being organized which gives us times to read these kind of posters.
- The patients safety is becoming more and more important. Especially in the more rural areas where infection control is lower.
  - o Problems with the ESU are getting more and more attention
- I really like the ergonomics of the handheld
- It can be used for right as well as left handed people
- It is good that there is an angle at the end of the handheld because this will not cause obstruction with the cable during usage
- The space between the buttons should be bigger because then it is less likely to make a mistake with using the wrong power button
  - o Some surgeons have big/fat fingers so you should take this into account to prevent for misuse
- Interesting would be to have a triangle button for the cut mode and a round button for the coag button. In this way you will still have to good surfaces to touch but still it refers to the tissue effect. Triangle is sort of a knife and coagulation is sort of a round spread.
- The design of the handhelds were shown and they all preferred the bigger handhelds because this makes them feel more in charge and increases confidence and control by having the better grip.
- The handheld was not too big
- The handheld has been used in two manners, or as a pencil or by activating it with the thumb. In both manners, the pencil seems very ergonomic for both situations.
- When we buy a new product the technician will tell us what the meaning is of the scale
- Normally when we buy a new product we always discuss the usage of this product with the surgical team and the BMETs
- It is very important that the display is visible from at least 2 meters because we always want to check the surgical assistance when we change the power during a surgery.
- Creating a better distinction between the cut and coag mode by adding more colour will make it easier to see what mode has been changed and can be better understood by the surgical assistance (interface).
- To make the interface accepted you should also have the blend mode. The general surgeons use the blend mode a lot because they do not want to continuously switch between the two buttons.
- The guidelines and colour codes on the interface will make our lives much easier and will increase the feeling of control over the surgery situation.
- Blend causes more tissue damage
  - o Less trauma than the coag function
  - o More trauma than the cut function
- I want to make sure sometimes that I cut and at the same time coag
- Again it is important to state why and for what you use the blend mode (guide) just as how you do this with the power settings
- Ones you are using the blend function it does not matter which button of the two (cut and coag) you activate. They will both work for this waveform
- When we buy a new product we mostly read the manual and discuss the product with the team.
- For general surgery the spatula electrode is more than sufficient. It is multifunctional and preferred by all surgeons. The ball can be handy but should be bigger than the example. This is only used for coagulation.
- For sure you should not include the needle. We often hurt ourselves with this needle and this can be highly dangerous in terms of the patients that we operate that are infected with for example HIV or Hepatitis
- During the surgery we preferably have more handhelds to use, but they are not always available so when a handheld drops on the floor and we need fast sterilization we use CIDEX cleaning detergent
- It would be of great add when the electrode tip has a snap function on the two rotation points because in this way I am always sure that the knife is in the correct direction and that is more probable to create a clean cut. Especially when you have a controlled grip of the handheld this is even more important.
- During a surgery I sometimes saw that the electrode tip burned the patient when the handheld was put away during the surgery. The tapered design is a great solution, really love it.
- Durability is more important than local repair because in most cases the handhelds are not being repaired. The knowledge and BMETs are mostly not available.

Appendix **H**

Explorative study with Kenyan surgeons

Name: Dr. Sajabi - The Nairobi hospital
Date: 28/06/2018
Profession: General surgeon
Experience with electrosurgery: Medium

The Nairobi hospital is a level 5 hospital. Dr. Sajabi has previously worked at the Aga Khan hospital as well as a rural hospital.

- In the Nairobi hospital they use monopolar, bipolar and ligasure.
- The Ligasure is a disposable consumable so they use this for 3 times by cleaning it in CIDEX.
- Preferably the surgeons will always want to use the autoclave regarding safety but this is not possible with the disposable consumables. In that case they will always use CIDEX cleaning detergent.
- In the low resource hospitals Dr. Sajabi experienced that there are not always enough handhelds so they will use CIDEX since this is a faster procedure (5-10 min) to sterilize than the autoclave (1 hour).
    - o There are some problems with getting the CIDEX out after usage because there is not a long drying time. They normally shake the handheld to get the water out..
- The spatula electrode is sufficient for all general surgeries
- During the surgery both sides of the electrode need to be used so most times the surgeon rotates his hand but in case that this rotation is too hard or not ergonomic, he will rotate the electrode
    - o This is not always possible with the competitive products
    - o Some of the surgeons prefer the hold the handheld as a pencil in any case so they will prefer to rotate the handheld.
    - o However, not all electrodes have a tip plastic rotation point..
- The yellow cut button is always close to the electrode tip. This also gives a better feeling of precision. The blue coagulation button is always the second button.
- The surgeon hold the handheld as a pen and sometimes uses his thumb to activate the handheld.
- In rural areas, general surgery covers most of the surgeries
- Orthopaedic surgeries are the most common surgeries in Africa because of all the traffic accidents.
- The subdivision would work really well in terms of guidelines. Important is that we can still change the power settings accordingly. This is because there can be a difference in tissue resistance between patients.
- The symbols on the interface were well understood and by giving the scenario the correct power setting has been chosen.
- During the surgery the surgeon always play around with the power settings and check the reaction on the tissue to see if the power settings is appropriate.
- I always tell myself do not use the extremes. This is never necessary and this can be dangerous for the patients and for me.
- The highest power setting that I have used is 40 W. Mostly I am operating between 30-35 Watt.
- When operating a child or more sensitive tissue I will lower the power to 15 for example.
- Also when operating a cleft lip; this is more superficial tissue so a lower power is required
- The most common operations for children are: orthopaedic hernia's and cleft lips
- 80% of the children is a cleft lip 20% is adults with cleft lip
- Even if they are adults the 5-25 W is still sufficient
- Dr Sajabi prefers to always have the power setting as low as possible for the type of surgery.
- So starting from low with the power setting is mandatory! This is better for the clinical outcome as well as for danger of the ESU.
- When the power setting is changed the surgeon always checks if the runner changed the power settings in the appropriate way. Otherwise if he does not check the damage can already be made This means that the power setting should be visible from a distance of at least 3 meters. The brightness should be high enough.
- Generally the power setting is changed with +5 because the difference with +1 is hardly visible.
- During the surgery it is not mandatory to have the sub groups visible because I can already see what the numbers of the power setting is.
- It would be better if the subdivision between the cut mode and coagulation mode has more contrast to make it better to distinguish from a distance. Preferably the blocked colours with yellow and blue should be visible in a strong way. This will also make communication more easy. I can simply say; yellow, +5.
- Most times the cables of the handhelds cannot withstand sterilization and because of that they will be cleaned with CIDEX cleaning detergent
- Important is that the cables are as sterile as possible to prevent for infections and increase infection control
- The surgeons learn how to operate the ESU by practical experience. The theory is not known but this is not always mandatory.
- Many surgeons are still very conservative so by showing them the guidelines might cause unacceptance. Therefore, the symbols on the ESU interface will be sufficient.
- For me the guidelines would give me more confidence, since I will know what power to use and what would work for a certain surgery. This can be especially important in the more rural areas.
- The guidelines can always be placed in the training of the equipment instead of the ESU because when new equipment is bought, there is always a discussion in the team for everyone that will be involved with the product (Surgeon, BMET, surgical assistances).
- If the guidelines are positioned on the equipment then I am not sure if they will look at it.
- During the surgery the surgical team always has back up handhelds in case they break or fall on the floor. In the rural areas I am not sure if this is available. When I worked there we mostly had one handheld for each surgery. When the handheld fell on the floor, it was cleaned with CIDEX for 10 min because if they would have to wait for the autoclave the surgery would take too long which could be dangerous for the patient.
- So far, no necessary features are missing on the interface (e.g. blend is not needed at all). The waveforms cut mode and coag mode are sufficient as well and it is important that you can change them separately.
- I consulted our theatre. The CIDEX used is not diluted and is used without change from the manufacturer. No other solutions are currently being used for the sterilization. I am also made to understand that they are able to autoclave the diathermy equipment. I am not sure, though, how easy or difficult the process may be.

Appendix **H**

Explorative study with Kenyan surgeons

Name: MSF Nairobi
Date: 28/06/2018
Profession: Innovation team Kenya
Experience with electrosurgery: Limited

- The product will be used in highly different settings then how they are used in the western countries
- In India for example you are send just after graduation to the rural area where they have literally nothing, which makes it hard to follow the protocols in terms of usage and sterility.
o During a surgery they even had to cut with a razor because the equipment was not available.
- When designing think about all the worse situation that can happen.
- There is a big task shifting trend because there is a lack of professionals, so lack of medical care.
- Primary facility is just rural, not your focus, there should be a surgery room.
- 3rd level you will find operating theatres, from level 3 on is your scope.
- Blood banks are mostly not available so this is another advantage for the electrosurgery since there will be less blood loss.
- You should have clear guidelines which show why you use the product and how you use the product to prevent for problems with safety.
- Waste management is also very important for your product in example of using reusables and how to deal with this.
- In the rural areas you often see power cuts
- You could use a battery in case of the power cuts and to prevent for this (does not make sense, because if the anaesthetics are not working you cannot continue with the surgery.
- You should visit more low-resource settings because this will be more the reality of your project instead of visiting the hospitals in Nairobi
o Surgeons all have experience in the rural areas so this is not completely true.
- You should incorporate something for blood and smoke suction this can be easily without a filter.
- Important to make a risk assessment
o Vulnerability of tissue
- The output of the system should always be consequent even when even when they are grid fluctuations.
- Try to increase the estimated life of the product
- What I saw in the more rural areas is that they often use Hexanios
o First in hexanios and afterwards in water. This cannot be reversed!
- Think about how to source components
o In example, in Kenya people use a lot of Toyota because spare parts are cheap to get.
- Supply in each country is different
- In some countries they want you to buy from someone local
- In Kenya you can buy from wherever you want (America, Europe, etc.)
- In your market study try to see what or who is your benchmark
- Sterilization methods in the rural areas are gas sterilization like a cooking pot and electricity sterilization.
- Gas sterilization is not always consequent in terms of temperature.
- Email lifebox to get more information on their projects

Name: Dr. Paul Odulla - Avenue hospital
Date: 29/06/2018
Profession: General surgeon
Experience with electrosurgery: Experienced

- The interface was easily understood and guidelines are experienced as a great benefit (icons are easy to understand and are partly the most common surgeries)
- The sub groups make the user more confident on what he does and I think that this indeed can be much more safe for the patient. Lots of surgeons do not know the theory, which can cause bad tissue damage.
- The sub groups will ensure that I do not have to check the runner when he or she changes the power settings because I am sure that the bandwidth is safe for the type of surgery.
o In this way, I can have more focus on the surgery without having to continuously check. Hence, this will decrease stress for me.
- The sub group will be chosen prior to the surgery so this should be visible for the surgeon. I do not care about the number of power anymore because I will know I am in the safe bandwidth for the surgery. However, it can happen that during the surgery I will have to change of sub-group because I will need higher power. This is a critical decision for the surgeon, so therefore the sub-groups have to be visible for communication.
o The power setting does not have to me visible to my opinion when using this interface design.
- Having these guidelines would especially be better for rural areas. Most surgeons do not have experience with the electrosurgery and even in many cases a medical officer performs the surgery that never had the theory about electrosurgery.
- Using the blend mode is not necessary. This is not often used an in case of general surgery these function are more than sufficient.
- The control grips of the handheld are really nice and this will give me more control than how the current handhelds are. I do not think the handheld looks very beautiful but the practical functioning is much more important than this
o Consequence of this design is that I cannot nicely rotate the handheld, so it is important that the electrode tip can be nicely rotated because in some cases you need this.
o A click within the design for the two important sides of the spatula electrode would be a good add on but watch out with problems of sterilization. The holes or click can cause problems with cross contamination.
 This can lead to problems with the design, which will make the product fail if this does not work in the proper manner.
- The activation buttons on the handheld are preferred by most of the surgeons. I prefer the pedal because in this way the handheld will not move during activation. An interesting outcome could be to choose the waveform mode on the handheld but activating the handheld by using a pedal with just one activation according to the chosen waveform mode.
- Think about laparoscopic as well. Within 5 years this will be more and more available so make your design flexible to make the product more sustainable and not obsolete within 5 years.
- The sound is important when activating the handheld. All machines have this, so you should include this as well.
- The scalpel electrode is more than sufficient enough for general surgery. In rare cases the needle is used for eye surgery.
- The handhelds are often cleaned with CIDEX, I am not sure if they mix this with water, I am not aware of these procedures.

Appendix **H**

Explorative study with Kenyan surgeons

Name: Dr. Steven - Ladnan hospital
Date: 02/07/2018
Profession: Senior surgical assistant
Experience with electrosurgery: Experienced

The Ladnan hospital is a level 5 private hospital mainly focussing on the middle class of society. Dr. Steven is experienced with surgeries within urban hospitals as well as in the low-resource rural hospitals. During the interview we could talk about cleaning procedures within both settings and discuss the prototypes.

- The interface has been well understood and seen as a better solution for especially rural areas where the experience with the electrosurgery unit is limited to none.
- Having a limited bandwidth will be a great safety precaution for wrong power setting by the circulation assistance.
- In the rural area there are just view facilities with the electrosurgery unit and most operators are medical officers because most surgeons move to the cities or urban areas.
- This interface will give me more confidence of choosing the correct power mode
- During my career I saw many surgeons using incorrect power settings. Even the really experience ones
- During the surgery the sub-group needs to be visible because just before the surgery starts the surgeon always looks at the electrosurgery unit to check whether the settings are correct. This also counts for the power set on the product. This needs to be visible from a distance or under an angle (rural areas sometimes chair used).
- The power should always start as low as possible to prevent for fatigue to the patient
- The blend mode is totally unnecessary for general surgery and what you have is more than sufficient. The only time I see usage of the blend mode is when performing a TURP
- For open surgery we use 95% monopolar surgery. The only time that we use bipolar surgery is during neurosurgery. In example of a head injury as consequence of a traffic accident it depends on the depth of the injury. When the injury is deep and close to nerves and the brain we prefer to use bipolar. Otherwise monopolar can be used. Important is that the power settings are always low! Maximum 15 W.
- When we start we look at the reaction on the tissue and see whether the reaction is as expected. If needed we increase or decrease power.
- The symbols are well understood.
- The power setting should be changed with +5W, changing it with +1 W does not make any difference.
- We do not often change the power setting after the pre-setting. In some cases it is needed so we change accordingly.
- The surgeon always checks the power setting after the runner changes the power. He feels responsible so he always wants to check this. The interface should be visible in a good way.
- Using more orange and blue colours to create a better distinction would be very helpful. In most theatres the assistances have already experience with the electrosurgery unit so we can communicate by saying; cut higher with 5 and coag higher with 10. In the rural areas most assistances are or just students or not experienced with the electrosurgery unit, so communicating in colour would be more safe: blue 5 up, etc.
- Preferably we always have more than one handheld. In our hospital we always have enough handhelds to use during the surgery. 10 handheld per theatre would be sufficient enough.
- Normally I use the thumb to activate the monopolar handheld, this is not very comfortable with this design of the handheld. This design is more used as a pencil, which is not my preference but most surgeons use it like this. After a while talking about the handheld Dr. Steven explained; actually I really like to hold the handheld like this with this design. It is actually really comfortable and gives me good grip when I hold it as a pen. Change what I said before, I really think the design works well. This size is the best one compared to the other. Most African like me have big hands so the small ones will make you fingers feel tensed after long usage. This design feels really good. It makes me feel more secure that the handheld will not drop.
- When using the handheld we always want to hear the sound when we activate it. There should be a difference between coag and cut.
- During the surgery I rarely rotate the electrode tip. I always rotate my hand. In case this is not ergonomic at all I will rotate the tip but only in this case. First choice will always be to rotate the hand.
- The design feel very comfortable and because I can hold it in this controlled position I have the feeling that this will cause less fatigue on tissue. When activating the buttons the electrode tip does not move as much as with the ones we have here. Really nice.
- During the surgery we often position the handheld away because we are not using it. It is always placed on the surgical sheet and I did not see any accidents of activating the tip while it is positioned on the sheets.
- In case of general surgery the spatula electrode should be the focus. This is most often used and is multifunctional.
- I really like the difference in buttons on the handheld because now I do not have to look at the handheld to differentiate which button I am holding. I can even feel the difference when using the surgical glove. Different shapes will prevent me for choosing the wrong button.
- The front one is the cut button because that's the button that we use most often for cutting and contact coagulation. Therefore it feels logic to put this on the front. The other button is the coag button.
- The guidelines poster should be more coloured so that surgeons will be more attracted to look at it.
- I should recommend to put the guidelines on the machine because in this way the user will have the choice whether he will check them. I would not recommend to put them on the wall because in example of our theatre. The walls are also cleaned from time to time which will make them become bad or fall of. Besides, they will be to far away from the viewpoint.
- The ESU is normally positioned around 2-3 meter from the bed so the cables need to be long enough
- What I see a lot are differences in interfaces between brands. If this happens most of the time the surgeon will ask the assistances on how to set the machine. Here it often goes wrong because if the assistance does not know how to set the machine there can be big tissue trauma problems.
- The surgery staff consists of the surgeon, 1 or two surgical assistances, 1 or 2 circulation assistances and 1 anaesthetist.
- In rural areas the runner is also the anaesthetist which will be instructed by the surgeon on how much anaesthetic should be used and when there is more needed the surgeon will give instructions on how much he want to be add (mostly the runner is a student or someone with limited experience).

- For cleaning the surgical equipment we have the following procedures. When the equipment can be autoclaved we will always autoclave them. In case the handheld are disposable and not resistant against autoclavation we use the following procedure:
  - o First the equipment decontaminated by using chlorine (5% bleach and 95% water) or hexanios (mostly too expensive) (20 min)
  - o Second, we clean the instrumental with soap and water to take away blood and eschar
  - o Third, we dry the equipment with a sterile towel
  - o Fourth, we put the equipment in a box of steranios or CIDEX (15 min)
  - o Fifth, ringed the equipment with water
  - o At last, we dry them with a sterile towel similar as the sterile surgery sheets.
- In rural areas the procedure is mostly seen as:
  - o First the equipment is decontaminated by using chlorine (5% bleach and 95% water) (20 min) or hexanios (mostly too expensive)
  - o Second, we clean the instrumental with soap and water to take away blood and eschar
  - o Third, we dry the equipment with a sterile towel
  - o Fourth, we put the equipment again in chlorine (15 min)

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Explorative study with Kenyan surgeons

o Fifth, ringed the equipment with water
o At last, we dry them with a sterile towel similar as the sterile surgery sheets.
- In case of no back up handheld and quickly needing one:
o Quickly cleaning in chlorine
o Cleaning with soap – no drying time
o Put in steranios – in case of no steranios, chlorine is used
o Ringed with water and dry with a sterile towel
- Every instrument will be first cleaned in a bath of chlorine
- For the cleaning container we always use similar type of instrumentarium
- Even if we use steranios the people always talk about CIDEX. Even the assistances that already work here for 5 years since we changed to steranios talk about CIDEX. This is even written on the plastic boxes. Check at Kijabe what they use!!
- We stopped using CIDEX because there were some problems that the flumes are toxic. Now CIDEX has changed to CIDEX OPA which is also used by a lot of hospitals. The difference in PH values between steranios and CIDEX are not so big.
- The most important substance to sterilise is glutaraldehyde, which is part of CIDEX or steranios. In case one of these is to expensive some hospitals use chlorine with a bit of glutaraldehyde that is added in a powder. For some hospitals even this is too expensive so just chlorine will be used.

Name: Dr. Jeremiah Laktabai - Webuye district hospital
Date: 04/07/2018
Profession: Medical officer
Experience with electrosurgery: Medium

- I really like that you can see what kind of mode to choose for a certain type of surgery
- This can be very important especially by taking into account our hospital where most of the time the surgery is performed by an unqualified doctor because there is a lack of surgeons in this area.
- The sub groups and added symbols can assist the surgeon with low experience
- The ESU should be as small as possible to put in order to station it in the surgery room. We do not always have a good table for this.
- Sometimes the plug connections are not working well so it is important that the connections are reliable.
- In our setting we mostly lack personnel which means that most of us have to perform more functions then in a regular setting
- The good thing about the symbols is that this is an ordinary language so easy understandable for all.
- It is important that you can adjust the power instead of having just 3 power options (micro, moderate and macro) because there are differences in tissue during the surgery and sometimes a patient have more tough tissue then the other (e.g. more fat).
- I prefer to have the power visible during the surgery to give me more feeling of control. This also counts for the possibility to change the power of the cut mode and coag mode.
- The symbols of surgery were all easy understood. Explained as ordinary symbols according to Dr. Laktabai.
- We try to always have a back up handheld during the surgery but most of the time this is not possible within our hospital. It even happens that if a handheld breaks and we do not have a backup, we have to go to the other theatre to get one of them. Which can cause an unsterile object during the transport from theatre to theatre.
- What is a really important advantage of your handheld is that you have a controlled feeling in the hand. During the surgery my gloves often get wet and with the more smooth surfaces handheld, for instance rounded once they often slide out of the hand so I will have to dry my hands a couple of time during the surgery.
- The handheld should be button activated to give me more focus on the surgery. With the pedal I sometimes have to find it under the bed which takes away my view on the operation. I do not like this..
- The spatula electrode is the electrode you should work with because this is used in almost all surgeries .
- The flat side is also often used to activate the tweezer to grasp the tissue between the tweezer and activate the handheld. Normally I do this with the broad side of the spatula electrode.
- During surgery I always rotate my hand and not the electrode tip. Most of the handheld that I use cannot be rotated.

- The cleaning procedures used within the rural district hopsitals are unfortunately not steam sterilization. If we are lucky we will be able to use the autoclave ones or twice a day and in regard of the handhelds of the electrosurgery unit we do not have enough to wait for that so we have to clean it with cleaning detergent. Besides, most of the handhelds are not autoclavable so we have to clean them with cleaning detergent anyway.
- Besides the autoclave that we use is not powered on electricity but by fire this means that the temperature is more fluctuating. I do not no the maximum power of this.
- What we mostly use in between surgeries to clean the handheld is chloride (JIK).
- First the blade is used to take away tissue from the electrode
- Second, the electrode is cleaned in an antiseptic solution such as Dettol. We use Hibitane or Savlon. This is done to take away remaining tissue and blood
- Hereafter it is cleaned in chloride (JIK) for around 15 min
- At last the JIK is ringed off the handheld by preferably saline or distilled water. But in most cases we use boiling water from the tap that is available in the surgery room since saline and distilled water are expensive. We always try to improvise with what we have.
- In comparison with the Eldoret hospital. They are sure that they will always get good supplies. The government does not always adequately resource around 50% of the needed goods.

- In terms of procuremt for our hospital. In the beginning of the year we have to let the county know what resources and consumables we will approximately need for the upcoming year.
- First we have to create a list with the amount of supplies we need and we need to specify this exact as possible. So provide this with 3 possible companies and with as much detail about the product as possible.
- This first goes to the hospital management and then to the county in the headquarters.
- The county will give out tenders that are able to supply the good
- The county pre qualifies the companies.
- The county pick the components mainly based on costs.
- Sometimes there is just one company that can supply the goods then you are allowed to go to them because there are no competitors to hold the tender for.
- Our hospital is allowed to make the procurement and give a list of needs for the government. The county government has to okay the list.
- Good that are cheap so this means up to 30.000 kenyan shilling (300 dollar) means that as a hospital you can contact companies yourself and ask for quotations. By law (PUBLIC PROCUREMENT AND ASSET DISPOSAL ACT) you have to always ask for 3 companies with quotations. Even if they do not have exactly what you want and there is just one competitor then you have to contact 3 companies as well. The two companies will say that they do not have the supplies so you are able to buy supplies from the company that is left. This is the easiest way to supply for goods that are cheap such as the handhelds for electrosurgery
- Important is that the company is qualified by the county
- So if there are no competitors you first have to make 3 quotations of 3 different companies. Some will respond that they do not have the supply so this gives you evidence that you have used 3 quotations and after this you can contact the company that has your supplies. This is all stated in the procurement rules of Kenya.
- Part of your marketing of you product should be to interact with companies such as the WHO or society of surgeons (Kenya). If they will endorse the use of your

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handheld because with your design they will be able to perform more surgeries for less money then this will be the best marketing you can get. These companies will help you in tender qualification because costs of the handheld might be too high when you first see it but they are more reliable and sustainable in the long term

- Another important part of your strategy has to be to become a qualified supplier by the government. What you could do is to collaborate with companies such as Harleys that supply good to hospitals all over Kenya. They can easily add you product in their portfolio and since they are already qualified by the county this will make it more easy to make your product be chosen by the counties. Besides, these companies are actively responding to tenders and send representatives to hospitals to show the product they have.

Name: Steve - Kenyatta national hospital
Date: 05/07/2018
Profession: BMET
Experience with electrosurgery: Medium

- In regards of durability we always specify the ESU with higher power capabilities, e.g. 300 W instead of the 75W that is needed. This will increase the durability since our machines in for example the emergency theatres are used 24/7.
- At the Kenyatta National hospital we always provide 3 handhelds during a surgery per theatre. In this way there is always one back up and the other handheld will be autoclaved in between surgeries to use it for the next surgery, which takes approximately 50 minutes.
- Most of the time the theatres also have a back up generator in case one of the generators stops working
- In the Kenyatta National hospital the grid is stable so almost all equipment just breaks because of over use. The transistor should be specified with higher capabilities
  - o Check this in specified transistor of BOM
  - o Especially necessary in cases where the machine is used 24/7
- The handheld should also be resistant against the high power and voltage peaks. So good insulation of the cable and PCB is important.
- In regards of the pedal, sometimes the transistors within the pedal break. Take this into account when designing the pedal.
- The Kenyatta National hospital is not the best example for the product because here almost all equipment is available.

Name: Dr. Wanjeri - Thika hospital
Date: 05/07/2018
Profession: Professor and general surgeon
Experience with electrosurgery: Experienced

- The sub division of the micro, moderate and macro mode is a really good way to go. Most of the time we do not know in what ranges we have to stay and for sure the limited experienced surgeons will not know this.
- The symbols that you use within a sub group are not always correct. Be very careful for this because this might be interpreted as literal, which means in cases the surgery is not on the ESU interface they might not know what to do or are not sure which power settings to use.
- Important when providing the guidelines is to not give straight guidelines but also make sure that the surgeon will think themselves on how to perform the surgery. It is sometimes better to make them think a bit instead of struggling with a guideline that you provide that might not work for another similar surgery. So it is important to keep with good bandwidths so that the surgeon is still flexible in his choice. A good idea could be to or leave the example surgeries out of the interface and just continue working with the sub groups. Most surgeons will know that if a surgery is on more sensitive tissue that they will have to use the micro mode, etc. Another idea could be to extend the guidelines with more surgeries. For instance, all surgeries that we find in general surgery. Why is this needed? For orthopaedic surgery you might think you should always be moderate to high in the used power but for children this can be the opposite wherein you have to use lower power settings than for adults. Take this into account!
- The colour distinction between coag and cut could be more visible to create a better difference. For us this is still fine since we know well the differences between both waveform modes but if you do not have the experience then it could be better to change this.
- In conclusion, the sub division between micro moderate and macro is really better then what we have now. It will give us more safety of using the correct power setting and makes us sure that a surgical assistances will not exceed limits. Furthermore ones we have to change power to a higher degree so higher sub group we will automatically be more aware of our decision. So this means a surgeon will pay more attention on power settings when changing in sub group.
- It is very hard to sub divide surgeries because orthopaedic surgery for a child is different than orthopaedic surgery for an adult.
- The hernia in the guidelines are not correct. The hernias that we do for general surgery are mainly in the abdominal so similar power setting to use as for a caesarean section.
- With the guidelines symbol you have to watch out because some surgeons will might take this to literal whereas they should function as guides that can still be changed because of differences in tissue impedance. They should be based on the sensitivity of the tissue and the sensitivity of the surrounded organs.
- The symbol designed for the subgroup has been well understood but the new sub group has been understood in a better way, since in this symbol you see the layers of tissue that are important in the depth of the surgery and the tissue spread.
- The power setting and sub groups should be visible from a distance because these are references for the surgeon in this design.
- Micro group: Clef lip, sensitive tissue, eye, children is generally lower, the skull now looks like a bone surgery which requires higher powers than a head wound.
- Moderate: laparotomy, hernia in the abdominal wall, orthopaedics, tumours that are positioned in the neck or other more sensitive parts.
- Macro: TURP(which is already not really general surgery anymore), sometimes you can find orthopaedic surgery here but again this does not count for children. The lungs should not be in this group because to reach the lungs you need higher powers but when being close to the lungs the power should decrease because the

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lungs are sensitive.

- So maybe it will be better to focus more on general parts of the body and general sub groups of surgeries instead of providing literally the symbol of a surgery. For instance, the abdominal will include caesarean section, laparotomy, hernia. In this way it is more generalised which result in the fact that the surgeon has to think as well.
- It is hard for us to say what the highest power setting is that we have ever used, since there are big differences between machines. 25W for one machine is not similar for the other.. so in this case guidelines will be good to have a better feeling of control and confidence of what you are doing.
- If you make the surgery symbols to literally the surgeon might argue that he was mislead by the machine in case something goes wrong.
- Although other symbols should maybe be used for the guidelines, the symbols were well understood by all surgeons.
- It is important that the ESU is as small as possible and portable because now they are too bulky which makes it difficult to move them from room to room. Furthermore there is not always enough space for the machine, since there are not always tables etc.
- When I use the monopolar handheld I normally rotate the hand instead of the electrode tip. An important thing to add might be to have an extra spatula electrode which is longer. This means it can be used deeper in de abdomen in case this is needed.
- As mentioned before, having the power settings more separated from the machine and maybe with more explanation but then positioned on the wall might be a better idea. In this way you have more space for explanation and in this case the surgeons can take a look at this in case they need it.
- The hernia surgery should be a separate one and is not part of orthopaedic surgery
- For club foot we do not use the ESU most of the time. Nowadays we fix the club foot by stretching it and putting it in a cast and do this several time. In this way the club foot is cured and most of the time the outcome is better than doing surgery.
- The hand injuries that we see are mostly cuts as a consequence of sharp objects. With hand surgery we mostly coagulate because if you destroy the important vessels then this might lead to a death hand.
- When performing hand surgeries we always use low power settings since the tissue is more sensitive
- For TURP we use high power settings
- Our recommendation is to go more in depth about the theory of power settings to create the perfect guidelines. You are almost there.
- The severe wounds that we see are mostly cut wounds and burns. Every nurse is also trained to surgery those because they are so frequent that this will overcrowd the surgery room.
- For the caesarean section we mostly not use the ESU to get the baby out. Most surgeons are scared to hurt the baby. Ones the baby is out we immediately take the ESU to coagulate the wounds. For the sections to get the baby out we use medical wires to close the vessels.
- Every doctor should know how to perform a caesarean section because this is so common and just as the severe wounds if not all people would know how to do this then this will overcrowd the surgery rooms.
- For the hernia use the same powers used as for the other surgeries in the abdomen.
- So as advice, keep the sub group guidelines more general to let the surgeon still think instead of trying to perform something that is not working on each patient.
- The thoracotomy surgery can be found more in the moderate mode. Parts of the surgery include tough muscle so higher power settings should be used. Ones you get close to the lungs the power setting should be as low as the lowest power in the moderate mode.
- Cancer surgery that you see the most in general surgery is removal of tumours in the abdomen and breast tumours. We always remove the cancer around 2 cms of the tumour to be sure that the cancer is gone. In case of neck cancer we can for sure not do this without the ESU because this will get messy!
- For TURP the high power settings are needed because most of the times the surgery area is wet which needs higher power settings especially when performing monopolar surgery. Besides, bone surgeries need high power such as removing linings on the joint.
- In general surgery you can also find bone surgery wherein you might use a macro setting
- An option could be to just have two sub groups which will maybe make it more easier to subdivide but less save then your design..
- Preferably for surgeries wherein we have to go deep in the abdomen we prefer to use the pedal because our hand needs to be very stable..
- For general surgery for sure we prefer to use power activation by using the handheld. This ensures a better focus on the surgery.
- The big handheld feels more bulky to me and I think I will get tired when using it for a while.. The thin one is better and will give me more precision (surgeon had really small hands..). My fingers might get cramped after a while.
- It is very nice that your buttons have a different sensation which means ones my fingers are used to the difference I will not have to check the button colours and I can keep my focus on the surgery. This will ensure less checks..
- A button differences with a triangle and a round will ensure less sensitive differences so I prefer how you have them now. For me the distance between the buttons does not need to have a change.
- Another thing that you could include is the usage of a power bank in case there is a fuse. Most of the equipment in rural areas have a power bank so they will continue the surgery whenever this is possible.
- In terms of cleaning we use CIDEX sometimes in between surgeries when the handhelds cannot be sterilized. We have tried to dilute the CIDEX but in this case we are not sure whether the equipment is properly sterilized. So we always use 100% CIDEX

Name: Dr. Mathenge Maina - Kenyatta national hospital
Date: 05/07/2018
Profession: Graduated general surgeon
Experience with electrosurgery: Limited

The Kenyatta University hospital is the only level 6 hospital within the country (public hospital). This means that the hospital also provides specialist surgery and not just general surgery. Accordingly, this is one of the richest hospital.

- I really think that this can have a positive value. I have just been taught in university to always use 30 W to start with and change this power. Sometimes this really causes tissue damage. I think this can be a very good way to understand what power settings to use and feel comfortable using this power.
- The lights around the turning knob do not add so much to the design because I will always look at the screen while turning the knob.
- The interface has all the features that I normally use, no extra features needed.
- To me the interface is an improvement because in Kenya we are mostly general surgeons that have to do operations in the full spectrum of all surgeries. By using this interface I will know what power settings to use instead of the power setting that was taught during university which gives me confidence to operate.
- In case of providing the scenario the correct power setting has been chosen.
- After this the surgeon will not change the power setting but he will first do a pre test on the human tissue to see if this is the correct tissue reaction. Hereafter, he might change the power.
- During the surgery the power has to be visible because after the power change I always automatically check if the assistant (runner) changed the power setting in the correct manner.
- The power setting is always being changed by changes of 5 Watt and the order is always given to the runner by using numbers. So increase with 5 W or decrease with 10 W.
- The power should always start at the lowest power within the sub group, better for safety.
- I do not understand the sub-group but when you

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explained this I understand it. Anyway, as a surgeon I do not care much about how good this symbol is. I just want to know if I am using the correct power settings.

- The symbols on the interface have been properly explained.
- Ones the correct power setting has been found, the surgeon does not change the power setting very often.
- During the surgery we always have multiple monopolar handhelds. Most times the first handheld does not work so we often have like 4 handhelds for a surgery.
- The surgeon used his thumb to activate the waveform modes. However, when giving him the pen prototype he used it as a pen.
- Normally I rotate my hand for a difficult surgery angle. But the fact that the electrode tip will be rotatable with a snap was something the surgeon really liked. He said in this way there will be more control in difficult angles
- When activating the handheld I always hear a sound. I am used to this. An extra LED would be nice but not necessary.
- The power reset button was understood instantly.
- During the surgery the surgeon solely uses the scalpel electrode. He never used other ones.
- The cleaning procedures used in the Kenyatta University hospital is just the autoclave and CIDEX for the surgical equipment.
- Each ward in the Kenyatta University hospital has an autoclave which is used throughout the whole day.
- In case of a break of fall on the floor of the monopolar handheld there are always multiple backups.
- All accessories are already autoclaved and stored so they are not sterilized just before the surgery.
- Important thing the surgeon said that in low resource settings there are no 'routine operations', surgery is urgent and in the full spectrum of surgery
- I prefer to work bipolar because there is less thermal spread
- The maximum power setting that I have used is 40-45 W

During the tour around the Kenyatta University hospital I passed by a surgical assistances and asked more questions. Did not ask for her name..

- We normally know what power settings to use for a certain surgery because we always use sort of the same power. It might sometimes differ when there is a fat or old person in the surgery room.
- It would be nice for you to explore with the medical team what the guidelines should be for the power settings.
- We do not have a briefing prior to the surgery but during the surgery the surgeon tell us what the power settings should be.
- If the power settings are in our case very high we ask the surgeon if he really wants and then the surgeon will explain why he wants this kind of power setting.
- During the surgery we mostly have multiple handhelds in case they break or fall on the floor.
- All these handhelds are already organized in the sterile area so that we can immediately take them in case we need them.
- All handhelds are disposable but we mostly reuse them for a couple of times.
- The highest power setting that I have seen used by a surgeon is 50 W

Anisha | Student medical officer | Kenyatta University hospital

Showed me the log book of surgeries in the hospital and showed me around all wards within the hospital.

The most common surgeries are:

- Minor head injury as a consequence of a traffic accident
- Orthopaedic surgeries as consequence of a traffic accident
- Caesarean section

Name: Dr. Jana Macload - Kenyatta national hospital
Date: 05/07/2018
Profession: Professor and general surgeon
Experience with electrosurgery: Medium

- Honestly, I am not sure how to always use the power settings although I am already using the electrosurgery unit for many year.
- The problem is that residents teach residents and the general electrosurgery theory is in this sense unknown
- Whenever people are not sure they will always follow the majority within the hospital whereas I really want to know the theory behind the power settings, so it would be very nice for you to help me with that. I do want to be part of the minority and help the others.
- I am a lecturer at the Kenyatta University as well so I also teach others how to use the electro surgery unit and the way I teach them is with how I learned to use the technique by a residential. God knows, whether his theory is right..
- I was wondering, when I am using the handheld to activate a scissor or pincet, is it better to use coagulation mode or better to use cut mode to stop the bleeding. Coagulation is better against bleeding because in this way the tissue gets time to rest in between high peaks. However, the thermal spread is deeper. It is important to know that this way of activating is not the same as using a bipolar tool. The current circuit is still closed with the return electrode so there will be spread around the activated tissue instead of solely in between the electrodes. So in this sense to create less tissue damage it will be better to use the cut mode.

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Name: Dr. Erik Hansen - Kijabe hospital
Date: 06/07/2018
Profession: specialist pediatric surgeon
Experience with electrosurgery: Experienced

Dokter Erik Hansen is a surgeon from the United States that started working at the Kijabe hospital 7 years ago.

- The handhelds that we currently use are disposable but we use them a couple of times by putting them into a container of CIDEX.
- Most times, they can be used several times by cleaning them in CIDEX but after a while the buttons start to break. As solution we changed the attachment point so that we can use the same handheld by using the pedal to be able to use them a bit longer.
- Director of clinical services is not aware of the fact that there are reusable button handhelds manufactured by Valleylab, which can be used for around 70 cycles.
- Disposables can normally not be heat autoclaved which is a big issue for the hospital
- We also have problems with the return electrode which do not seem to work appropriately. This has effect on the output of the handheld.
- Level 6b hospital means specialist surgeries are provided but level 6a hospitals provide a higher variety of surgeries.
- Procurement of mission hospital is directly with the supplier.
- Sub division of the surgery groups is a really good idea in terms of safety and confidence of the surgeon and patient but the bandwidth should change slightly according to my experience.
- By using this interface there is a bigger boundary to go to higher power settings that are needed in the more rare occasions. On normal machines you do not feel this boundary because you can change the power from 0-100. When you move into another surgery group you will create more attention on what you are doing. Besides, it will give me more confidence of operating within the needed bandwidth.
- Every patient is different so variation in power is needed for similar surgeries.
- It is beneficial to provide the surgeons with guidelines because most of the surgeons have no feeling at all about what power settings to use. However, it is important to still let them think about how to use the power instead of making them struggle with a to you provided power setting for a surgery. The surgery symbols should therefore be more generic.
- Currently all surgeons just follow what they have learned from their supervisory surgeon. In the rural areas there is no supervisor so guidelines can create confidence and will prevent that the ESU will not be used as consequence of a lack of confidence or control.
- If you could create high quality ESUs for a price of around 1000 dollar, we would buy this right away for all our surgery rooms.
- Important is that the ESU is movable because it will for sure be moved from OR to OR. Besides, protruding parts will break for sure, so take this into account. Your bumper should be bigger because right now the knobs still protrude.
- Most of the surgeries that I do are paediatric surgery which is around 40% of all my surgeries. This involves al lot of child surgery. From my experience each child in Africa by the age of 16 has had a surgery wherein the ESU was needed. The awareness on child surgery should therefore be highly visible in the design and precautions.
- The maximum macro power that you used is rarely used. For adults I go maximum up to 70 W if I need to cauterize the liver (a lot of blood). Normally I will not go higher than 50 W. Macro is now according to your design a generic setting that is normal to use. Create more precaution for this sub group to avoid for it to become normal to use.
- The problem with the understanding the needed power settings is that there are so many differences in power between brand so that we do not have any idea of what power means. It is al relevant to us. Everything is relative, I do not think about the device and its technology.
- Take into account that everything that is protruding will break!
- The ESU should be as intuitive as an apple wherein you do not need any guidelines for use. You are getting close but you should include more precautions.
- For the superficial layer of tissue (epidermis) I always use the cold scalpel. For the second layer (dermis) where there are the vessels I start using the ESU to cut. I normally use the needle but there are problems of using this considering HIV and AIDS. So when using the scalpel electrode you need normally a bit higher power settings then with the needle because of less current concentration.
- It is important that the surgeon will still have to think himself but give him some guidelines to create confidence. Therefore, your symbols should be more generic than using a specific surgery. This might be approached as to literal which will result in trying with a setting that is maybe not working for another patient because of difference in impedance.
- Infants and children are important in the sub-division of sub-groups. They need more attention concerning the used power settings.
- More generic serial ports for usage of multiple brands of handhelds will make the design more sustainable in the long term!
- I would change the sub group names more to low, medium and high because this indicates more what it is about. You talk about power settings and not about surgeries.
- The lowest power for micro is too low. This is never enough to cut through tissue. I would suggest to start from 10 on to have effect. Especially in general surgery.
- The electrode tip should be insulated all the way to almost the tip to prevent for tissue burns or arcing when being deeper in the human body. This will be a good safety precaution.
- Instead of having a round scalpel the end of the scalpel could be more pointy. Not pointy enough to hurt yourselves as a user but pointy enough to create current density more close to the needle electrode. This will strengthen the variety of use of the tip.
- I have never exceeded 25 W on a very young kid.. (needle tip 12 W and spatula 15-18 W).
- 25-40 is mostly used for general surgery.
- Clinical officers and medical officers also perform surgery and are not always acquainted with the power settings that they should use.
- Create more precaution for the macro surgery. Watch out that in this way it will never be used. But actually that would not be a bad thing.
- I would suggest you to create power steps of +1 within the micro surgery because here small changes might have effect and to change the power in steps of 5 in the moderate and macro surgery. To my opinion this will not influence intuitiveness and will give more control and confidence.
- The sub group choice has to be visible from a distance to have feeling of control
- The power setting display should also be visible from the distance. This is mandatory! We do not care about the percentages around the power setting because we only look at the screen.
- The sub division symbols were unclear and need arcing to make it clear that it is the electrode tip.
- I always use my thumb to activate the buttons on the handheld I simply do not like to use my other finger for this.
- I prefer to activate the handheld with my finger because then I do not have to look for the pedal and I can keep my focus on the surgery.
- I always rotate the electrode tip because in this way I can always preserve the controlled grip
- Some surgeons prefer the pedal because while activating the electrode tip might move when there is not enough control.
- Monopolar surgery is used for over 95% of all surgeries.
- We often activate tweezers with the monopolar handheld but we do not need a big surface to do this. A small contact is enough and if surgeons really want a bigger contact then this is purely out of laziness.

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- Make a contact area that is just big enough to contact with the tweezer by using the flat side of the electrode
- The power setting knob should be endless to prevent for breakage. This will also increase durability.
- A change of +1 W will give me more feeling of precision and control..
- As mentioned before a lot of surgeries are applied to children to my experience and even more in low resource settings

Name: Dr. Dimingo Gomez - Kijabe hospital
Date: 06/07/2018
Profession: General surgeon
Experience with electrosurgery: Medium

Worked for a long time in the rural are of Liberia and worked there as a medical officer. He often explained that I will be more of his target group in terms of knowledge level.

- To me the sub-division of groups can have a major impact on the level of surgery.
- The visibility of the sub-groups is very important since this will give me the confidence and control of knowing what to do and where I am with my power setting.
- The power should always start the lowest within the sub-group and from here on we increase power and try. Out of experience we decide whether the power setting is sufficient enough to continue with.
- I do not always check the surgical assistance whether she changed the power setting in the correct manner because when I worked with a surgical assistance for already a year I know what to expect and I can trust on her.
- In all hospital that I have worked for there has been a cart to station the ESU.
- The ESU is moved a lot from place to place so should be small, light and have a handgrip.
- I prefer the button activation because then I can have more focus on the surgery.
- I prefer to use the smaller handheld because this gives me more feeling of precision.
- I normally rotate the handheld to change the position of the electrode
- It is important that the machine has all the necessary features because then the use will be more effective and understandable
- A sensitive difference between the buttons will help me to differentiate the buttons without looking at them.
- In the more rural area we used betadine to wipe clean the handheld after it dropped on the floor during the surgery.
- Mostly we just had one handheld to use for the entire day..
- There should be more colour distinction between the cut and coag to create a better feeling of control.
- The power goes of frequently in rural areas so it is important to have a reset button. This will take away a lot of frustration of the surgeon and will reduce unnecessary damage on the tissue.
- It is important to provide this guidelines because otherwise if the surgeon is not comfortable enough he will not even use this machine…
- 10-25 W is at most what we use for children surgery.
- Create more attention and awareness for children because a lot of children have had a surgery by a young age.
- In practice a power step difference of 5W is sufficient enough. We never have to need power steps of +1 W.
- Paediatric surgery is mainly on children's until the age of 16
- Your idea is the way to go. Otherwise I will be trying and going higher then what I should use for a type of surgery and will still keep going with a higher range while this is not necessary and even worse for clinical outcome.
- It is similar to medication. When I know I am already in the maximum dose I will pay more attention when giving more medication.
- There will be more awareness and attention when moving to another sub-group.
- This will have great impact speaking from my personal point of view. Knowing the range and limits is so important as a surgeon. Knowing the limits is important in general. For instance, when I make jokes I also know now out of experience what is the range but if no one has ever told me what the ranges are I will keep on using it.
- The new design according to what you have discussed with other surgeons is exactly what I meant and what was missing in the interface design.

Name: Dr. James Nyabanda, Dr. Julius Gisone and Dr. Isaac Mwangik - The Nazareth hospital
Date: 07/07/2018
Profession: General surgeon
Experience with electrosurgery: Experienced

The Nazareth hospital is a "rural" hospital outside of Nairobi. It is a mission hospital with around 250 beds performing general surgery as well as specialist surgery. It is a referral as well as a teaching hospital. I interviewed multiple surgeons at the same time which gave great sparring sessions between the surgeons.

- For open surgery we mainly use the monopolar pencil. This will be for around 95% of the surgeries.
- Important with the ESU is that you should be capable of using the product. Most specialists know how to use the product and how to use correct power settings. Other surgeons not always know. Especially in the rural area most surgeons will not have the correct theory or experience.
- The interface is simple and very easy to understand. I like the symbols of type of surgeries because it shows me what type of surgeries I can expect within the sub-groups. Most surgeons always want to refer to something to know that they are using the correct settings. Sometimes this will be a supervisory surgeon but in case they are not available they want to have the security of using the correct power settings/bandwidth.
- It is important to be able to change the power setting of coag and cut within the bandwidth because this gives is important for patients with different tissue resistance and gives me more feeling of control.
- The sub-division of surgeries is seen as more safe because they have had problems where an assistance highly exceeded the power which can cause big problems with the tissue.
- It is important to remain a certain bandwidth wherein you can still change the power setting because there are differences between patients.
- In the rural areas there is no surgeon to guide the graduated surgeon or medical officer so in this case it is very important to have a referral system that will show you what type of power settings to use.
- I would decide to put the guidelines with a chain on the ESU and put the guidelines on the cart that is used. In case they want to be sure they can take the guidelines and check them. If you would attach them to the top of the ESU they will break or eventually fall of. A pamphlet in the surgery room will also always help so this is a thing that you can do additionally!
- The surgeon checks the power setting by seeing the reaction on the tissue. When the cut function does not do much they will increase. When there is too much smoke they will decrease.

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- Most times, the power setting will stay the same for the rest of the surgery.
- When the power settings is changed the surgeon will always check the assistances of correct change. The surgeon is responsible so wants to always have the feeling of control. So for sure the display power should be visible from a distance of around 2 meters and the sub group setting should be visible as well. An LED would be sufficient.
- The power is always changed with +5 because +1 does not make a difference at +10 will be too much. Of course this depends per machine. Some have a more sensitive effect then others.
- There should be a better colour distinction between the cut and coag mode. A good option would be to change the colour of the dials. So the cut dial is yellow and the coag dial is blue.
- The background of the interface should be white instead of grey or black because this shows more a professional machine and is easier to keep clean.
- Sometimes the assistances do not have much experience with the ESU theory so they will not always know what coag or cut is (more in rural areas). So colours would help to differentiate the different modes and will be easier in terms of communication.
- The cord of the monopolar handheld should be long enough because the machine can have a distance from the patient of around 2 meters.
- Most surgeons prefer button activation because they can keep a better view on the surgery. One of the surgeons prefers the pedal because in this way he will have more freedom with the pencil. When he has to activate the pencil he will feel cramped within the hand and feels less control. By showing my new design he thought it was great.

o The grip in the handheld will maintain grip when activating the handheld and when the rubber gloves are wet. Most handhelds will start to slide away when the rubber gloves are wet which increases the risk to drop them and does not give the feeling of confidence and precise examination of for instance a cut.

- All surgeons really liked the differences in buttons between cut and coag because in this way they will not have to check the handheld to see what waveform they are using. It is way nicer when the buttons are different in terms of shape because then we do not have to think.
- The ergonomic shape and size is really good. In general African have bigger hands and most surgeons are men. The bigger size gives me a more reliable feeling and more control over the pencil. In all cases the handheld that was bigger has been chosen as most preferred.
- When I want to use the other side of the spatula electrode I move my hand. Another surgeon prefers to rotate the electrode tip to remain the same position of the hand. All of them stated that a click function for the 0 and 90 degrees is not needed at all. This will only increase problems with contamination and is really not something mandatory.
- For all the pencil felt really stable when activating the buttons. This is very important to all surgeons.
- Some of the surgeons activated the buttons with the thumb. After I showed the handheld used by RDE they all explained that when the pencil is much smaller and for example round. The handheld can easily slip out of the hands when the gloves get wet. Therefore, we use the thumb to create a better grip. For your design this is not needed anymore and the grip feels more controlled and the hand feels less tensioned which is better in terms of ergonomics. Especially when we have long surgeries.
- Within the project you should only focus on the spatula electrode because this electrode is mainly used and is multifunctional. Normally we do not like to change electrodes during the surgery so if you focus on one please focus on the spatula electrode.
- A TURP is the surgery where the highest power settings should be used and this is still a general surgery that quite often occurs. I would put this one in the macro sub-group and will take away the lungs because I think for this the power settings are too high.
- Not all symbols were understood. The vascular surgery has to change in more like an amputation because this is mostly what is done. The laparotomy they would change with the belly in general because this will include more surgeries and not only the caesarean section.
- The symbols of the sub-group were not understood, just after I explained it. One of the surgeons would recommend to just use a sort of power bar. The higher the sub group the higher the power.
- The symbols next to the sub-group really add value in terms of safety and confidence of the surgeon
- Most of the times the surgeon has to work with another brand machine which means that the surgeon first has to get to know the machine by asking the assistances that are not always experienced enough to explain him. This can cause tissue damage when the surgeon is testing with the machine.
- When using a thumb activation for the handheld, which is what some surgeons want, the handheld is still stable and ergonomic according to the surgeons.
- An idea or extra electrode tip could be a longer spatula electrode in case you have to perform the surgery deep inside the abdomen. Important is that the rod will be covered with plastic to prevent for tissue damage.
- The spatula electrode will be sufficient for all general surgeries.
- It is important that the surgeon can always adjust the coag and cut button separately. One of the machines just had one button which is not easy accepted by the surgeons
- The surgeons always want to check the change in power setting of the assistances for the security of the patient and for their own security
- The blend mode is not necessary at all!
- When the power goes off it will be important to go back to the last used power settings. A button will be more safe than always going back to the last used power settings because then the power setting can be used to high for a certain type of surgery.
- We always want to see the power on the screen. This is very important for the convenience of the machine and eventually for acceptance and the willingness to use.
- The highest power setting that I have used is during a TURP surgery where the cut is 130 and the coag is 80. For the rest almost all surgeries are in between 25-40 W.
- The color distinction of cut and coag should be stronger in the design. Better visible from a distance.
- The percentages or information around the turning knob are not needed at all. We will only look at the power on the screen. It will add more costs and can be more distracting.
- The cut and coag text should be visible on the interface this is important in terms of convenience and acceptance.
- The reset button should include words that are related to reset to make it more clear
- The cut mode is most often used for cutting and contact coagulation and should therefore be in front of the buttons. The coag button is used when you need to create more superficial spread.
- The symbols of surgery examples do not have to be visible during the surgery only the sub-group will be sufficient enough.
- While I was at the Nazareth hospital there was a power fuse during the surgery. It took approximately 5 seconds before the generator went on.
- In this hospital we always have back up handheld in case one of them breaks or drops on the floor. In most rural areas you just have one for the whole day so they will be cleaned in between surgeries or during the surgery.

Cleaning

- All staff members within the hospital talk about CIDEX as a general name for the cleaning detergent used to clean the surgical equipment. However, they use different kinds of brands and detergents than the original CIDEX.
- Most handhelds within the Nazareth hospital are disposables that are being reused by cleaning them in cleaning detergent. Some of them are reusable and autoclaved but most times they are also cleaned with cleaning detergent.

o First soap is used to clean the instruments. In the Nazareth hospital they will use Sodium hypochlorite (Chlorisscrub) or Perfectan extra to take away dirt and blood from the handheld. (15-20 min)

o The handheld is ringed with normal tap water

Appendix **H**

Explorative study with Kenyan surgeons

o Hereafter the handheld is cleaned with CIDEX which is in their hospital Steranios (PH 6) or this is Perfectan powder (PH 9 when using 1 % with water) that is mixed with water in a ratio of 1% detergent to 99% water. (15 min)

o Then the handheld is ringed with saline or water

o Made dry by using a sterile towel

- Sometimes during the surgery when the handheld drops on the floor Surgical spirit is used (Methilated spirit (PH 5,5-6)) which is wiped on a towel to clean the handheld and continue the surgery. This is a fast but still safe solution.

- The hospital does not prefer to use Gluteraldehyde that is also in CIDEX because of the flumes that irritate the skin or eyes of the staff

- In some settings JIK (bleach water) is used to clean the handhelds but in most cases this causes corrosion. The ratio is cleaning is 4% jik and 96% water.

- If the autoclave is used for the equipment the hospital uses 121 degrees as temperature and 2 bar. The heat takes around 30 minutes and the drying procedure around 20 min. Most times this is too long so they prefer to use the cleaning detergent procedure

- CIDEX OPA cleaning detergent has a PH value of around 9.

Name: Dr. Carmen Orlotti - rural hospital
Date: 19/07/2018
Profession: General surgeon
Experience with electrosurgery: Experienced

- What kind of cleaning procedures are used to clean the electro surgery accessories(monopolar handheld, cable and electrode tip)?

WASHING AND CIDEX

- Is cleaning detergent used to clean any of the accessories, if yes,
what kind of cleaning detergent?

CHLOREXIDINE

- How often are the monopolar handhelds and accessories cleaned on a
regular day?

ONCE AFTER SURGERY, SEVERAL HANDLES AVAILABLE

Autoclaved/cleaned after each treatment? *NO*

Autoclaved/cleaned at the end of the day? *YES*

- Is there a difference between the cleaning procedure of the
monopolar handheld and other accessories?

THE HANDLES ARE SOACKED THE OTHER ITEMS NO

- In what kind of situations is cleaning detergent used instead of steam
autoclavation?

IN CASE AUTOCLAVE IS NOT ABLE TO PROCESS RUBBER

- How many monopolar handhelds are used during a surgery? Is there a
back-up handheld during the surgery?

ONE, YES

- If the autoclave is in use and a monopolar handheld needs urgent
cleaning since the handheld dropped on the floor during the surgery, how
will the cleaning procedure be?

WASH AND KEPT IN CIDEX, BUT I HAVE SEEN SURGEONS USING SPIRIT 90%

- How will the accessories be cleaned in case of no autoclave?

CHLOREXIDINE.....:-(

- If you run out of cleaning detergent and the monopolar handheld or
electrode tip needs to be cleaned, what do you do? Is there any final course
of action when you run out of cleaning detergent

YOU JUST DO NOT USE !!!

ELECTOSURGERY IN MANY THEATRES IS STILL A LUXURY !

Appendix **I**

technical data package

Trade off ESU system

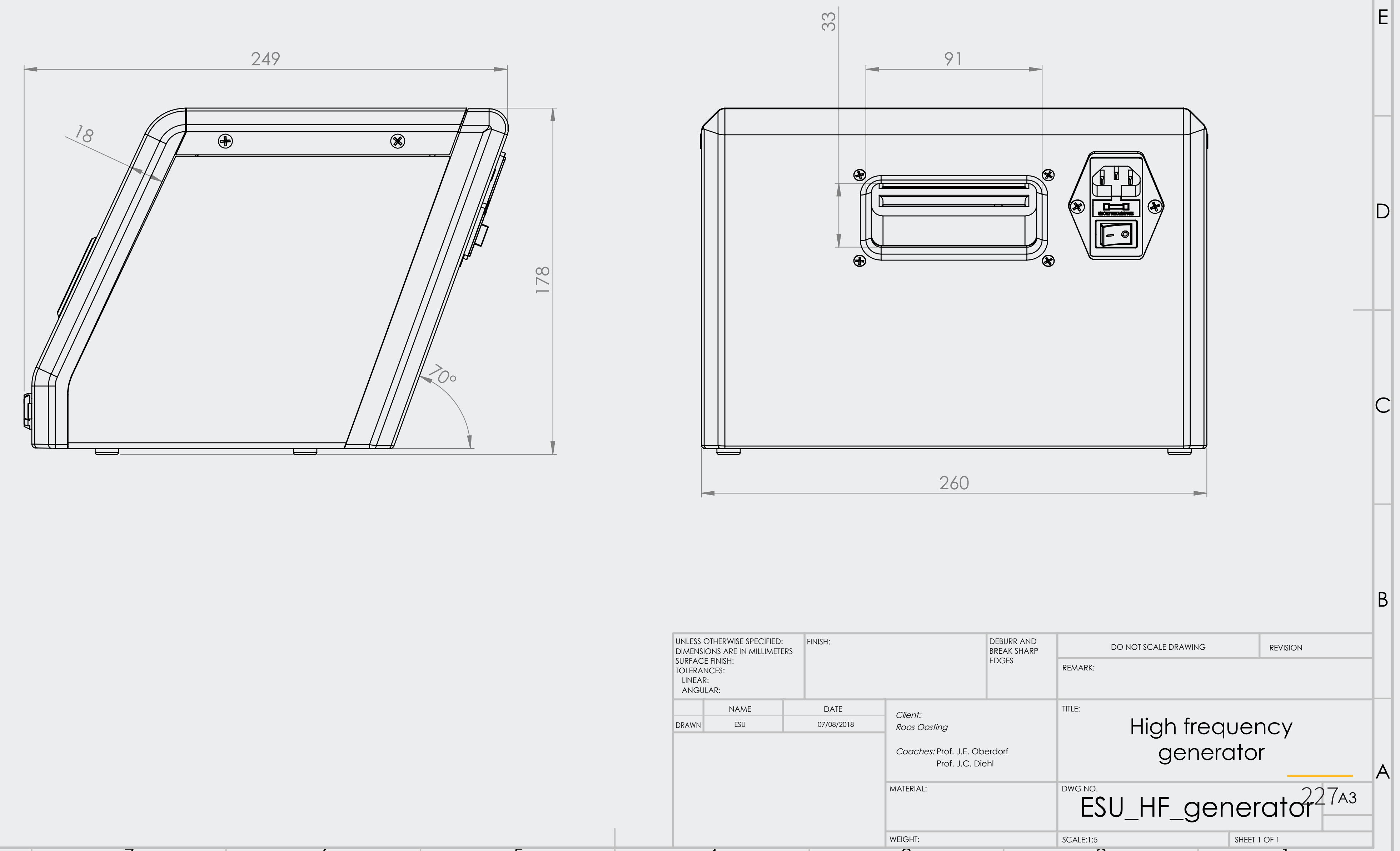
High frequency generator

	Part-assembly name	*Pieces*	*Costs*	*Mold costs*	*Availability in LMICs*	*Material*	*Production process*	Supplier
1.0	***Internal components***							
1.1	Internal sheet metal connection frame	*1*	*€ 5,00*	*x*		*AISI*	*Laser cutting + Bending*	Singeling BV
1.2	Main micro controller (with AC-DC converter)	1	€ 20,00					In wait of consulation with DEMO
1.3	Feedback micro controller (with AC-DC converter)	1	€ 10,00					In wait of consulation with DEMO
1.4	Memory micro controller	1	€ 4,00					In wait of consulation with DEMO
1.5	Battery (stabilization of grid fluctuations)	1	€ 5,00		Medium			In wait of consulation with DEMO
1.6	Speaker (buzzer cut and coag mode)	1	€ 2,00		Good			In wait of consulation with DEMO
1.7	Bridge rectifier (KBU8G & BI25R)	2	€ 4,00					In wait of consulation with DEMO
1.8	Condensator	2	€ 2,00					In wait of consulation with DEMO
1.9	Trimmer	1	€ 1,00					In wait of consulation with DEMO
1.10	Capacitor	2	€ 1,00					In wait of consulation with DEMO
1.11	Voltage regulator (L78S12CV3)	1	€ 0,60					In wait of consulation with DEMO
1.12	Output waveform micro controller	1	€ 5,00					In wait of consulation with DEMO
1.13	PWM (waveform modes)	1	€ 0,50					Operational amplifier\lpc660.pdf
1.14	Heat sink (also used as contra weight)	1	€ 5,00	€ 2.500,00		Alluminum Alloy 1050A	*Die casting*	
1.15	Thermostat	1	€ 2,00					In wait of consulation with DEMO
1.16	Output transformer coil (EE42) (300 kHz) (100-200 Watt) over specified for reliability	3	€ 15,00					In wait of consulation with DEMO
1.17	Power choke (B82721 EPCOS)	3	€ 4,00					In wait of consulation with DEMO
1.18	Condensator	3	€ 2,00					In wait of consulation with DEMO
1.19	Power transformer (240 V to 15 V and 40 V) (50-60 Hz)	1	€ 35,00		Good			Vigortronix
1.20	Current leakage	-						
1.21	RF to DC converter	-						
2.0	**Interface**							
2.1	Embodiment A	*1*	*€ 11,00*	*€ 10.000,00*		*ABS*	*Injection moulding*	
2.2	Serial port monopolar handheld (banana 4 mm jack panel mount)	3	€ 3,00		Good			
2.3	Serial port bipolar handheld (banana 4 mm jack panel mount)	2	€ 2,00		Good			
2.4	Serial port dispersive electrode plate (banana 4 mm jack panel mount)	2	€ 2,00		Good			
2.5	REDEL 3 pin female connector (monopolar handheld)	2	€ 11,00					LEMO
2.6	Rotary encoder	2	€ 6,00		Good			
2.7	Power setting rotational knob	2	€ 2,50	*€ 1.000,00*		*ABS*	*Injection moulding*	
2.8	Power setting sub group foil	1	€ 10,00					
2.9	LED 3mm (dispersive electrode, monopolar, bipolar, pedal and sub-groups)	9	€ 12,00		Good			
2.10	Light guide	9	€ 10,00					
2.11	Sticker information	1	€ 4,00					
2.12	SMD 2 digit 7 segment display (blue) - mcd > 3000	1	€ 1,50		Good			LUMEX
2.13	SMD 2 digit 7 segment display (yellow/orange) - mcd > 3000	1	€ 1,50		Good			LUMEX
2.14	Display cover	2	€ 4,00				Thermoforming	
	Exterior back							
3.1	Embodiment B	*1*	*€ 10,00*	*€ 10.000,00*		*ABS*	*Injection moulding*	
3.2	Handgrip	*1*	*€ 3,00*	*€ 3.000,00*		*ABS*	*Injection moulding*	
3.3	Sheet metal grid	*1*	*€ 3,00*			*AISI*	*Laser cutting*	Singeling BV
3.4	Power cable (C14-female) (110 V, 240V, 50Hz)	1	€ 7,56		Good			Schaffner
3.5	Power adapter connector (C14)	1	€ 15,94		Good			Schaffner / Schurter
4.1	Nut cover (used as feets of the HF generator)	4	€ 1,00		Medium			
5.1	*Sheet metal exterior 1*	*1*	*€ 7,00*	*x*		*AISI*	*Laser cutting + Bending*	Singeling BV
6.1	*Sheet metal exterior 2*	*1*	*€ 4,00*	*x*		*AISI*	*Laser cutting + Bending*	Singeling BV
	Assembly costs (including assembly components)		*€ 35,00*					
	Total price HF generator		€ 290,10					

Appendix I
technical data package

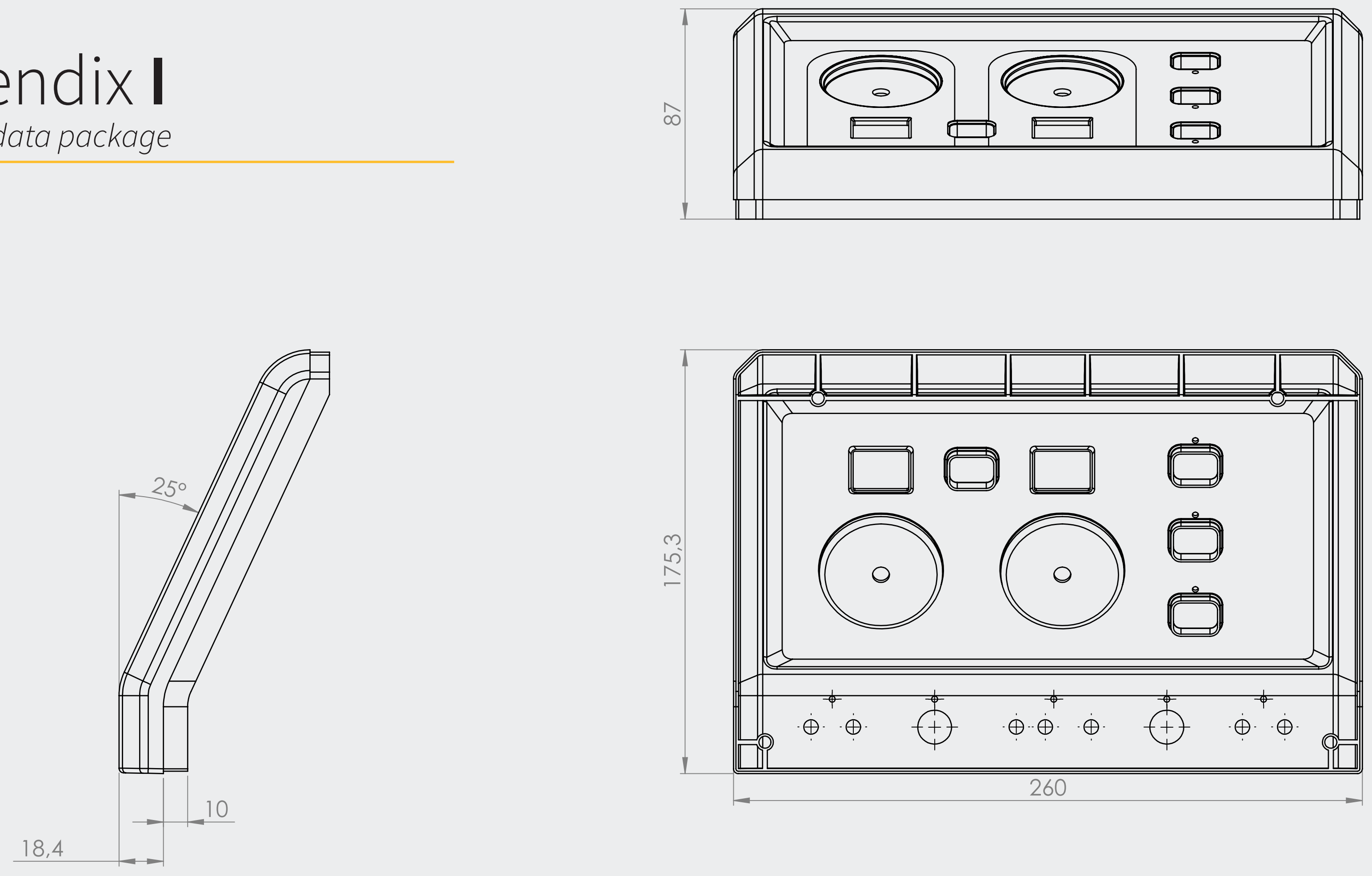
Monopolar handheld	1.1	Handheld exterior A	1	€ 5,00	€ *5.000,00*		LCP medical grade	*Injection moulding*	
	1.2	Activation button foil	1	€ 1,00	€ *1.000,00*		TPV shore A75	*Injection moulding*	
	1.3	Compression frame of button foil	1	€ 1,00	€ *1.000,00*		PP	*Injection moulding*	
	2.1	PCB connection front	1	€ 5,00			Phosphor bronze	*Turning*	
	2.2	Adapter electrode tip	1	€ 3,00			Phosphor bronze	*Lasercutting + Rolling*	
	2.3	O-ring front 1 mm x diameter 15 mm	1	€ 1,00			TPV shore A55		ERIKS
	2.4	Printed circuit board with dome swithces	1	€ 3,00					
	2.5	Active switch electrode wire	1	€ 0,50		Good			
	2.6	Coagulation switch electrode wire	1	€ 0,50		Good			
	2.7	Cut switch electrode wire	1	€ 0,50		Good			
	2.8	Cable (Northwire, LEMO)	1	€ 3,30					
	2.9	O-ring cable gland 1 mm x diameter 6 millimetres	1	€ 1,00			TPV shore A55		ERIKS
	3.1	Cable gland	1	€ 3,00	€ *2.000,00*		PPP	*Injection moulding*	
	3.2	Seal cable gland	1	€ 1,00			TPV shore A55		
	4	Handheld exterior B	1	€ 2,00	€ *2.000,00*		LCP medical grade	*Injection moulding*	
	5	O-ring exterior A-C 0,5 mm x diameter 18 millimetres	1	€ 1,00			TPV shore A55		ERIKS
	6	Handheld exterior C	1	€ 3,00	€ *3.000,00*		LCP medical grade	*Injection moulding*	
	7	REDEL 3 pin connector	1	€ 5,50		Good			LEMO
		Total price monopolar handheld		€ 40,30					
Electrode tip	1	Reusable scalpel electrode (4 mm inlet diameter)	1	€ 4,00	€ 2.500,00		Stainless Steel - Medical grade	Casting	
	2	Insulation electrode tip	1	€ 3,00	€ *3.000,00*		TPV shore A70	Injection moulding and welding	
		Total price electrode tip		€ 7,00					
Bipolar handheld	1	Pincet embodiment	1				Stainless Steel - Medical grade		
	2	2 pin connector	1						
	3	Electronic wire(s)	2						
	4	Insulation wire	1						
	5	2 pin standardized connector for serial port	1						
Dispersive electrode plate	1	Electrode pad	1				TPV shore A75		
	2	Electrode pad attachment(s)	2						
	3	Electrode pad wire adapter (banana female connector)	2						
	4	Electrode wire(s)	2						
	5	Insulation wire	1						
	6	2 pin connector (split return measurements)	1						

Appendix I
technical data package



Appendix I

technical data package



Remarks:
- All surfaces to be textured with: Matt gloss
- Nominal wall thickness: 2 mm
- Draft angle of 0,5 degrees
- Product definition according to the to provide 3D file

UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS SURFACE FINISH: TOLERANCES: LINEAR: ANGULAR:

FINISH:

DEBURR AND BREAK SHARP EDGES

DO NOT SCALE DRAWING

REVISION

REMARK:

	NAME	DATE
DRAWN	ESU	07/08/2018

Client: Roos Oosting

Coaches: Prof. J.E. Oberdorf, Prof. J.C. Diehl

TITLE: Front panel

MATERIAL: ABS

DWG NO. Front panel

A3

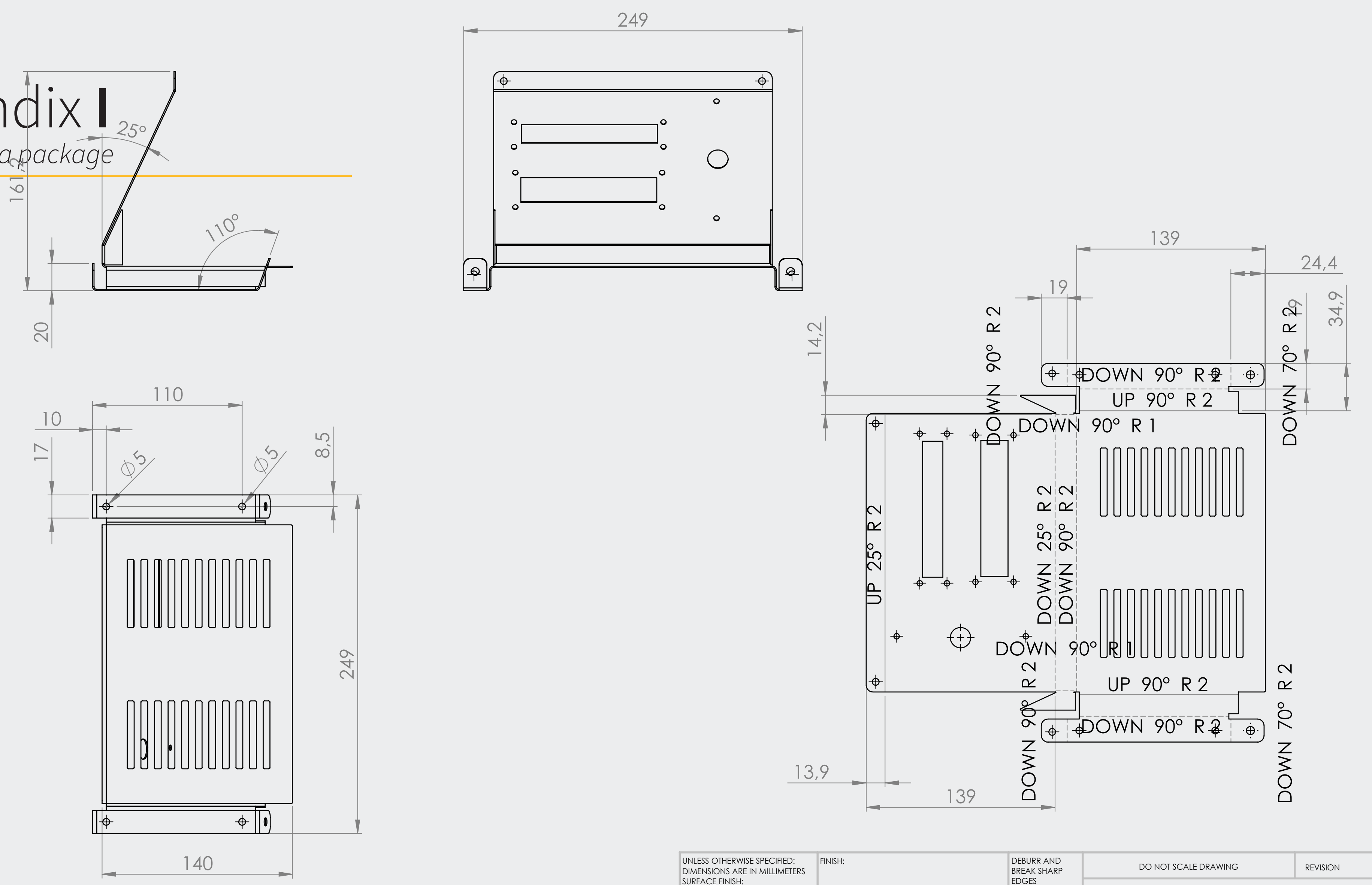
WEIGHT:

SCALE:1:2

SHEET 1 OF 1

Appendix I

technical data package



Remarks:
- Sheet wall thickness: 1 mm
- Product definition according to the to provided 3D file

UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS SURFACE FINISH: TOLERANCES: LINEAR: ANGULAR:

FINISH:

DEBURR AND BREAK SHARP EDGES

DO NOT SCALE DRAWING

REVISION

REMARK:

	NAME	DATE
DRAWN	ESU	07/08/2018

Client: Roos Oosting

Coaches: Prof. J.E. Oberdorf, Prof. J.C. Diehl

TITLE: Internal structure

MATERIAL: AISI

DWG NO. Internal structure

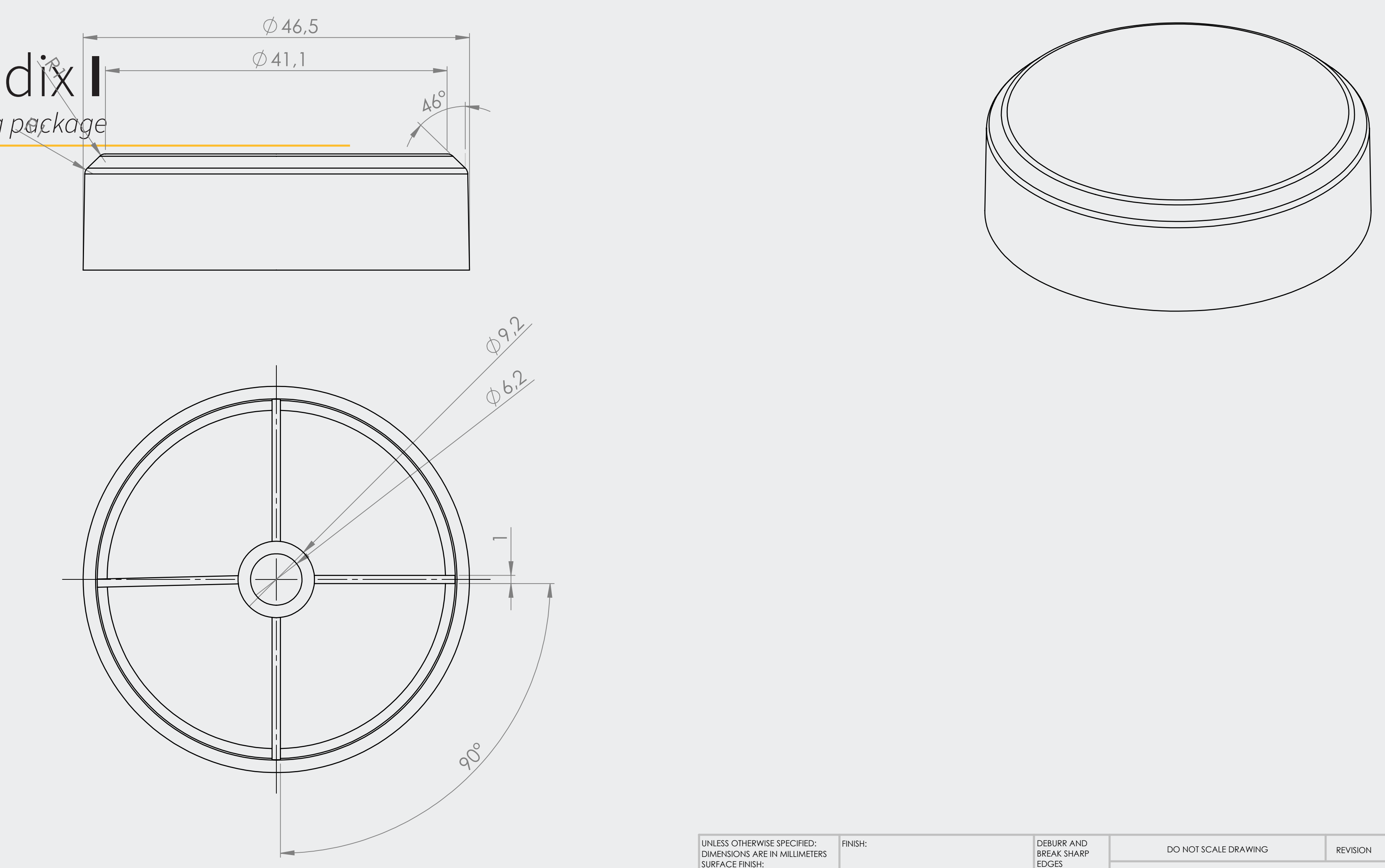
A3

WEIGHT:

SCALE:1:3

SHEET 1 OF 1

Appendix I
technical data package



Remarks:
- All surfaces to be textured with: Matt gloss
- Nominal wall thickness: 1 mm
- Draft angle of 0,5 degrees
- Product definition according to the to provide 3D file

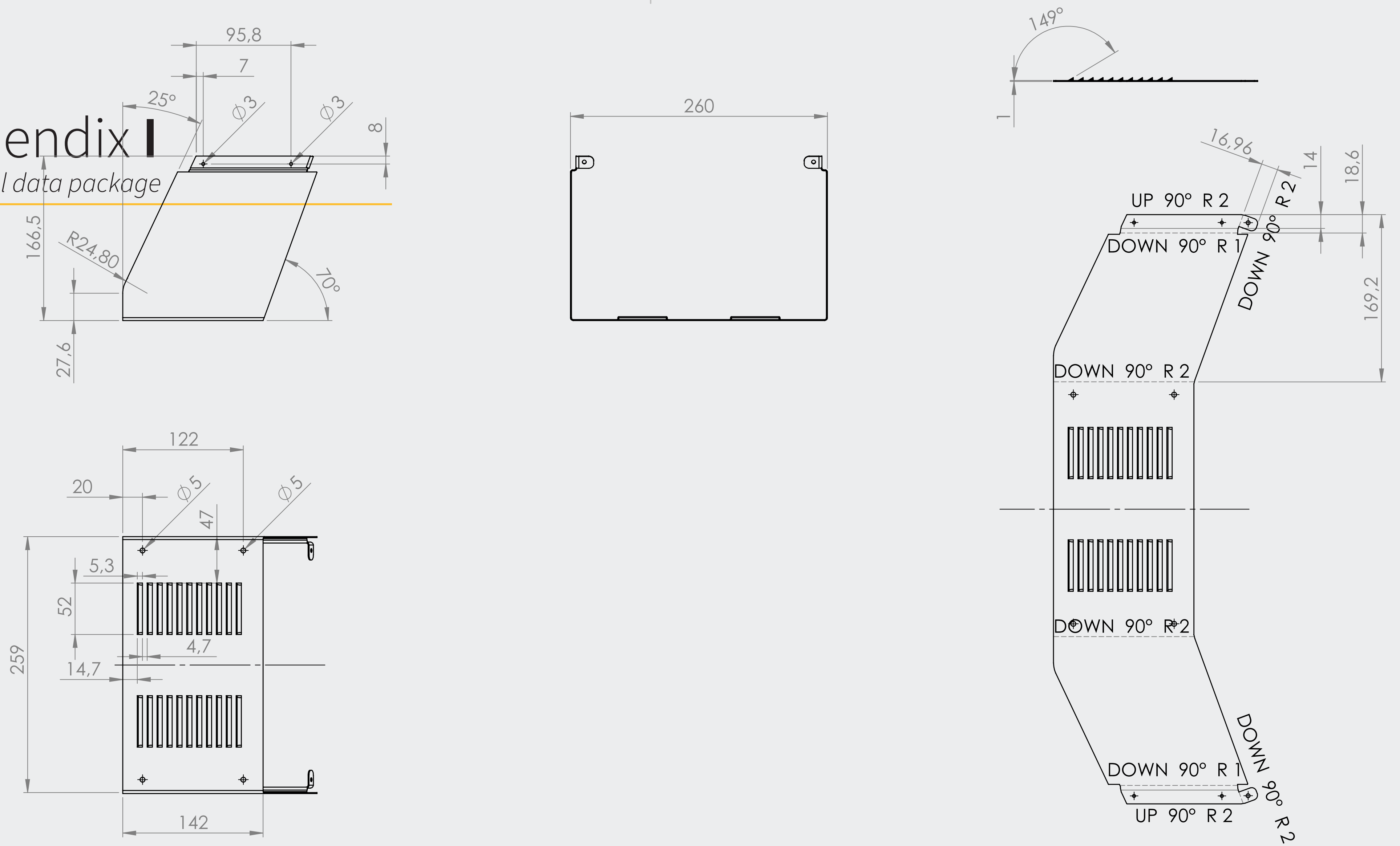
UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS SURFACE FINISH: TOLERANCES: LINEAR: ANGULAR:
FINISH:
DEBURR AND BREAK SHARP EDGES
DO NOT SCALE DRAWING
REVISION
REMARK:

	NAME	DATE
DRAWN	ESU	07/08/2018

Client: Roos Oosting
Coaches: Prof. J.E. Oberdorf, Prof. J.C. Diehl

TITLE: Turning knob
MATERIAL: ABS
DWG NO. Turning knob
A3
WEIGHT:
SCALE:2:1
SHEET 1 OF 1

Appendix I
technical data package



Remarks:
- Sheet wall thickness: 1 mm
- Product definition according to the to provided 3D file

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FINISH:
DEBURR AND BREAK SHARP EDGES
DO NOT SCALE DRAWING
REVISION
REMARK:

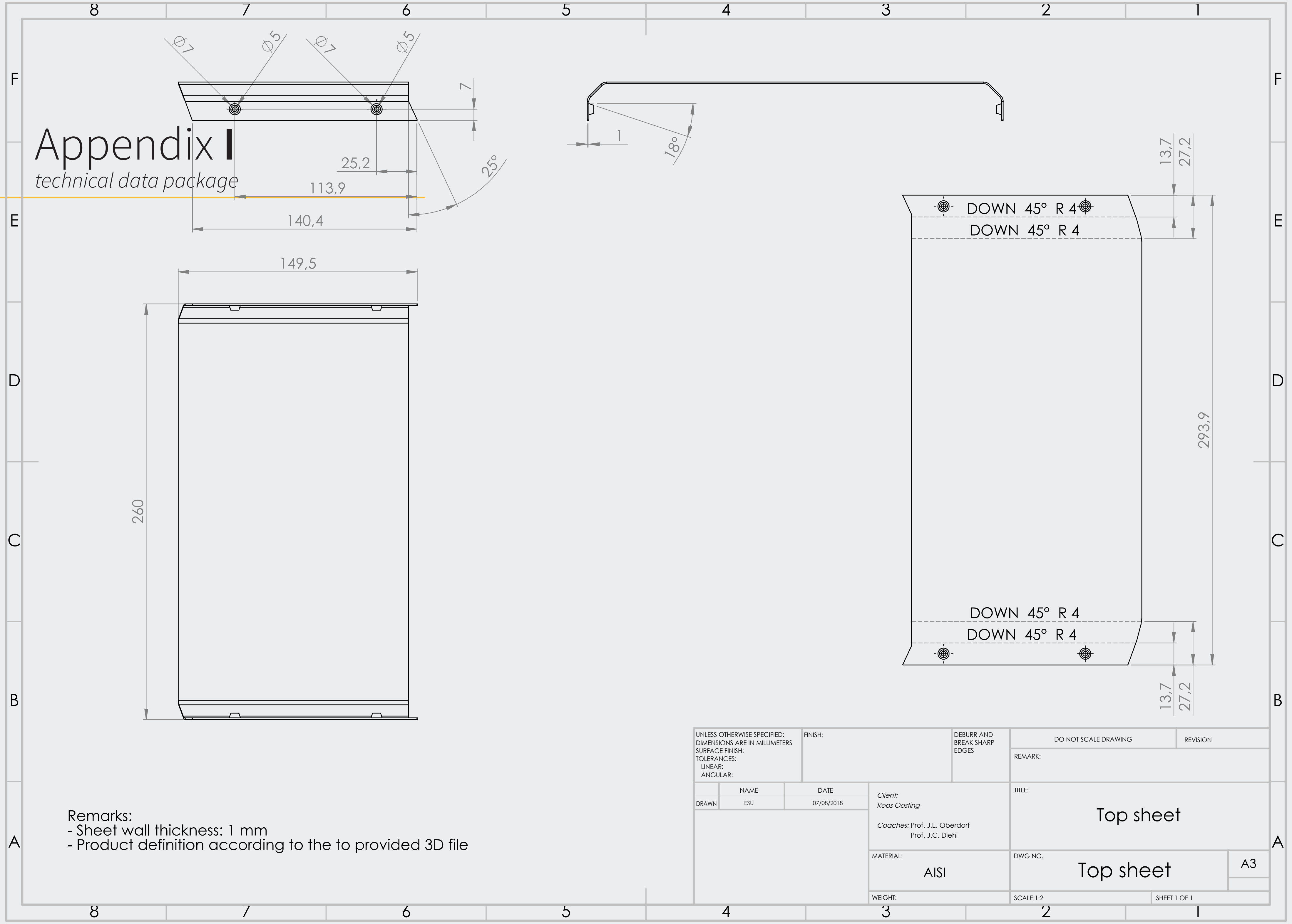
	NAME	DATE
DRAWN	ESU	07/08/2018

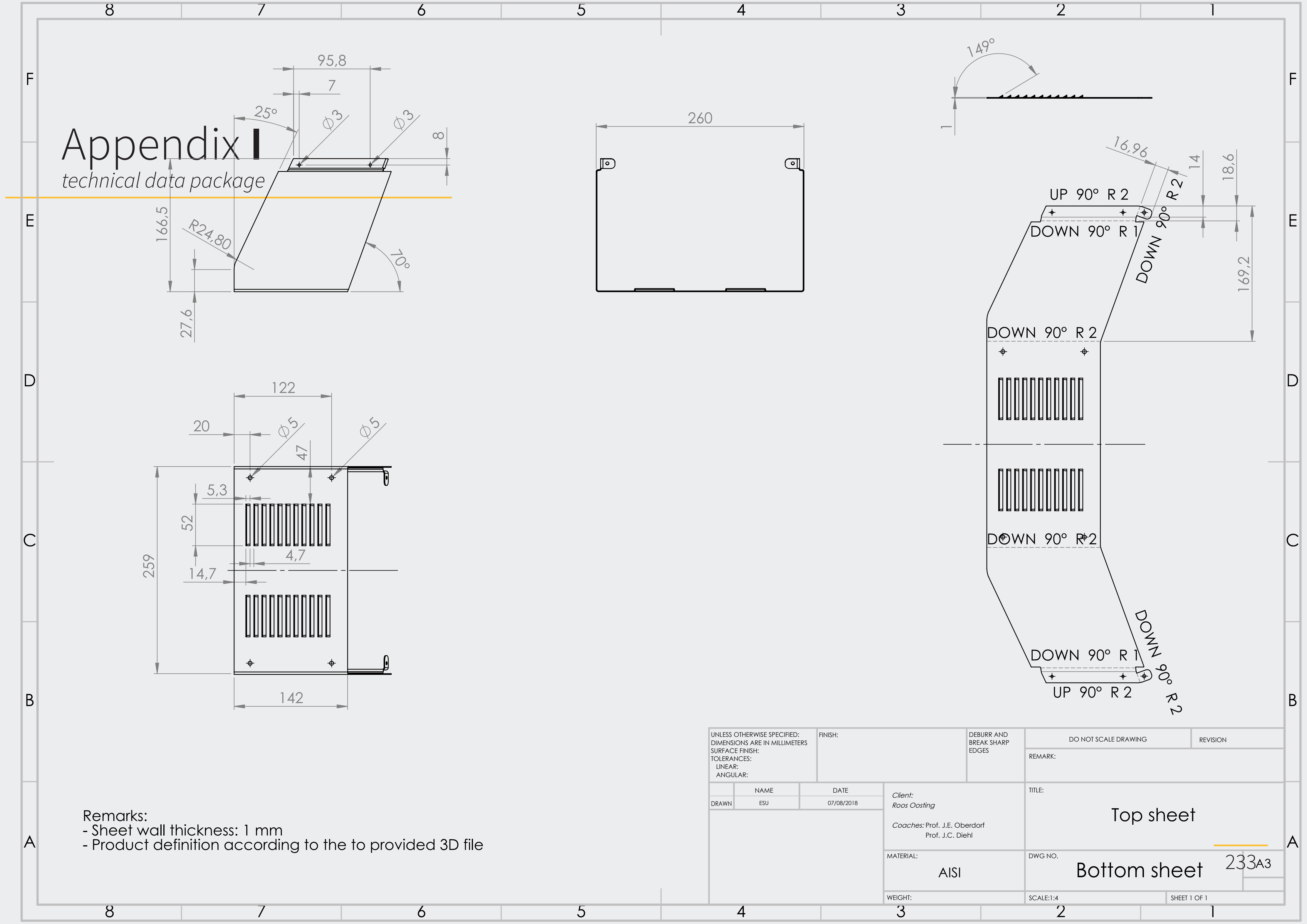
Client: Roos Oosting
Coaches: Prof. J.E. Oberdorf, Prof. J.C. Diehl

TITLE: Top sheet
MATERIAL: AISI
DWG NO. Bottom sheet
A3
WEIGHT:
SCALE:1:4
SHEET 1 OF 1

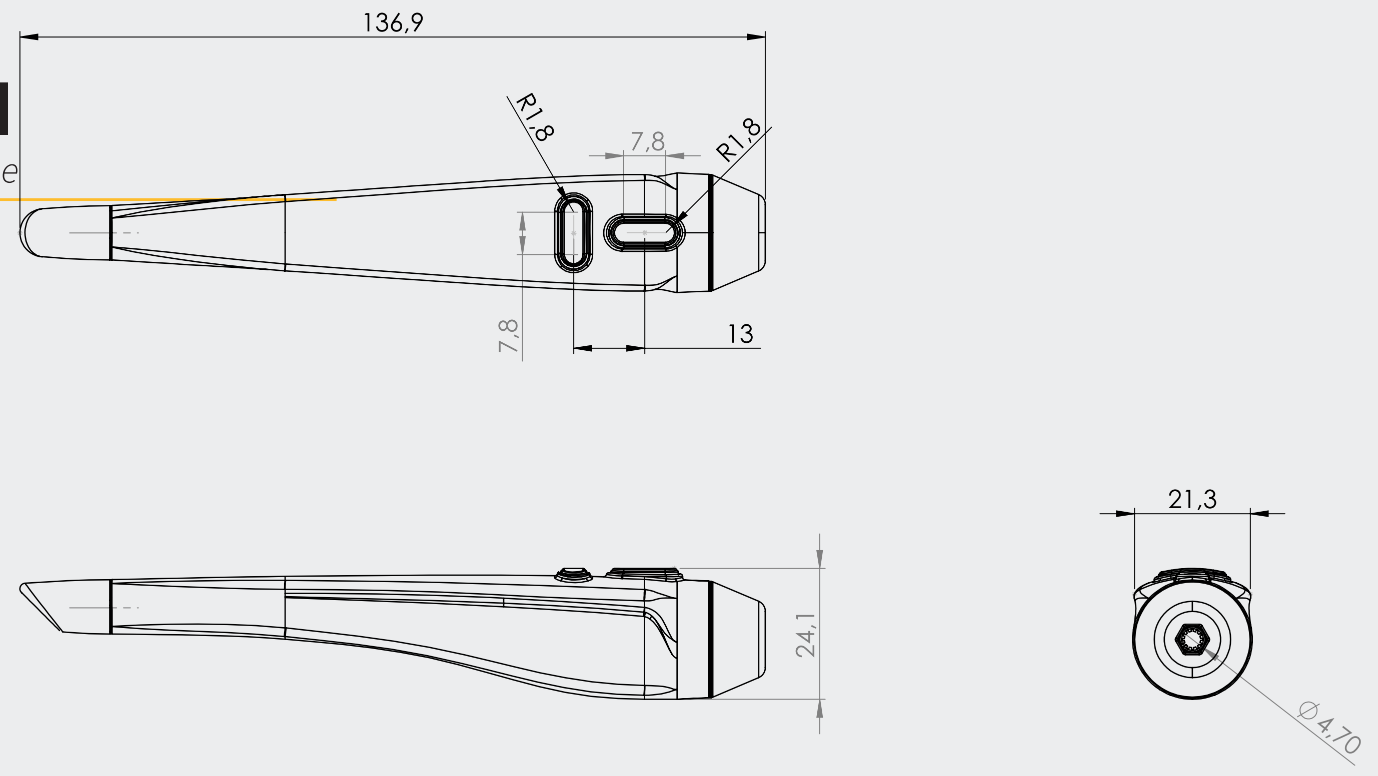
Appendix I

technical data package





Appendix I
technical data package



ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	Front exterior		1
2	Back exterior		1
3	Internal electronics		1
4	Back exterior		1
5	Cable gland		1
6	Electrode tip		1
7	Cable seal		1
8	O-ring back		1
9	Cut mode button		1
10	Coag mode button		1
11	O-ring exteriors		1

UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS SURFACE FINISH: TOLERANCES: LINEAR: ANGULAR: | FINISH: | DEBURR AND BREAK SHARP EDGES | DO NOT SCALE DRAWING | REVISION

REMARK:

	NAME	DATE
DRAWN	ESU	07/08/2018

Client: *Roos Oosting*

Coaches: Prof. J.E. Oberdorf, Prof. J.C. Diehl

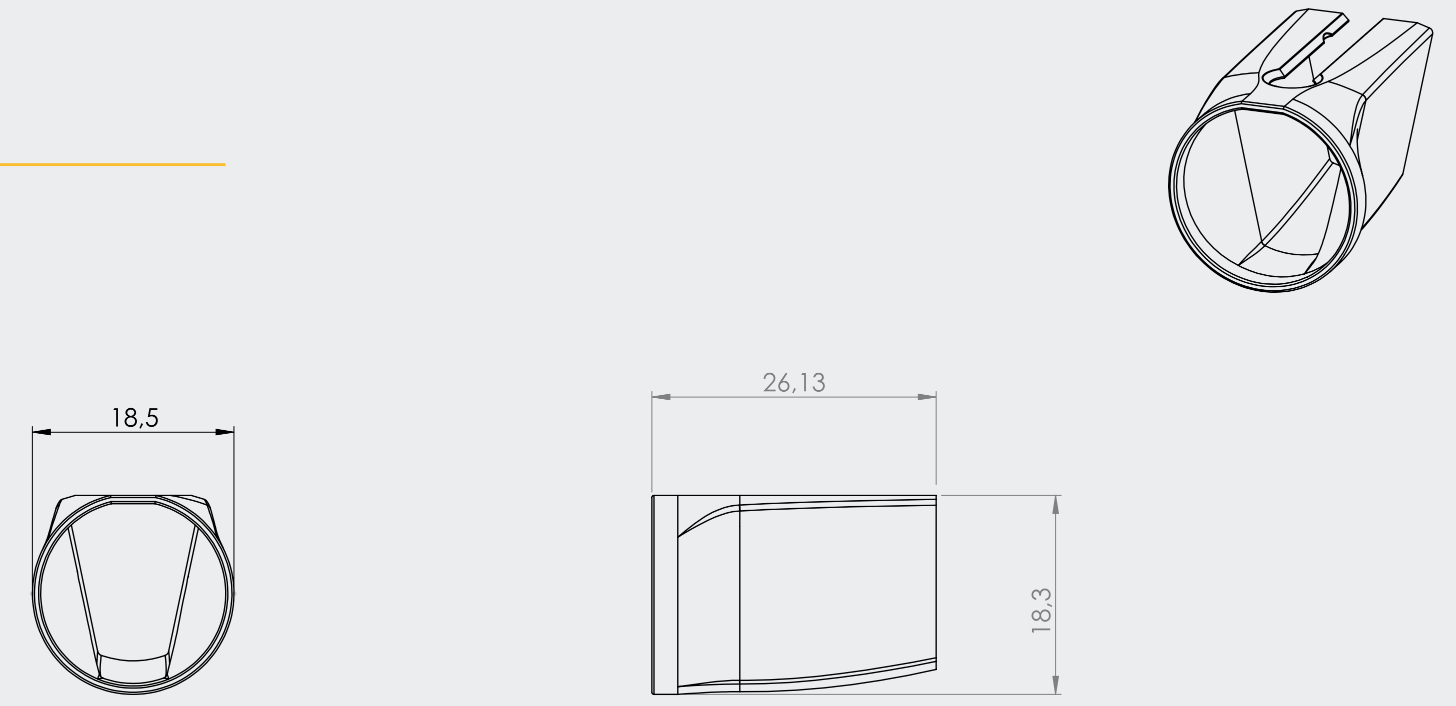
TITLE: Monopolar handheld

MATERIAL:

DWG NO. ESU_Handheld A3

WEIGHT: SCALE:1:1 SHEET 1 OF 1

Appendix I
technical data package



Remarks:
- All surfaces to be textured with: Matt gloss
- Nominal wall thickness: 1 mm
- Draft angle of 0,5 degrees
- Product definition according to the to provide 3D file

UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS SURFACE FINISH: TOLERANCES: LINEAR: ANGULAR: | FINISH: | DEBURR AND BREAK SHARP EDGES | DO NOT SCALE DRAWING | REVISION

REMARK:

	NAME	DATE
DRAWN	ESU	07/08/2018

Client: *Roos Oosting*

Coaches: Prof. J.E. Oberdorf, Prof. J.C. Diehl

TITLE:

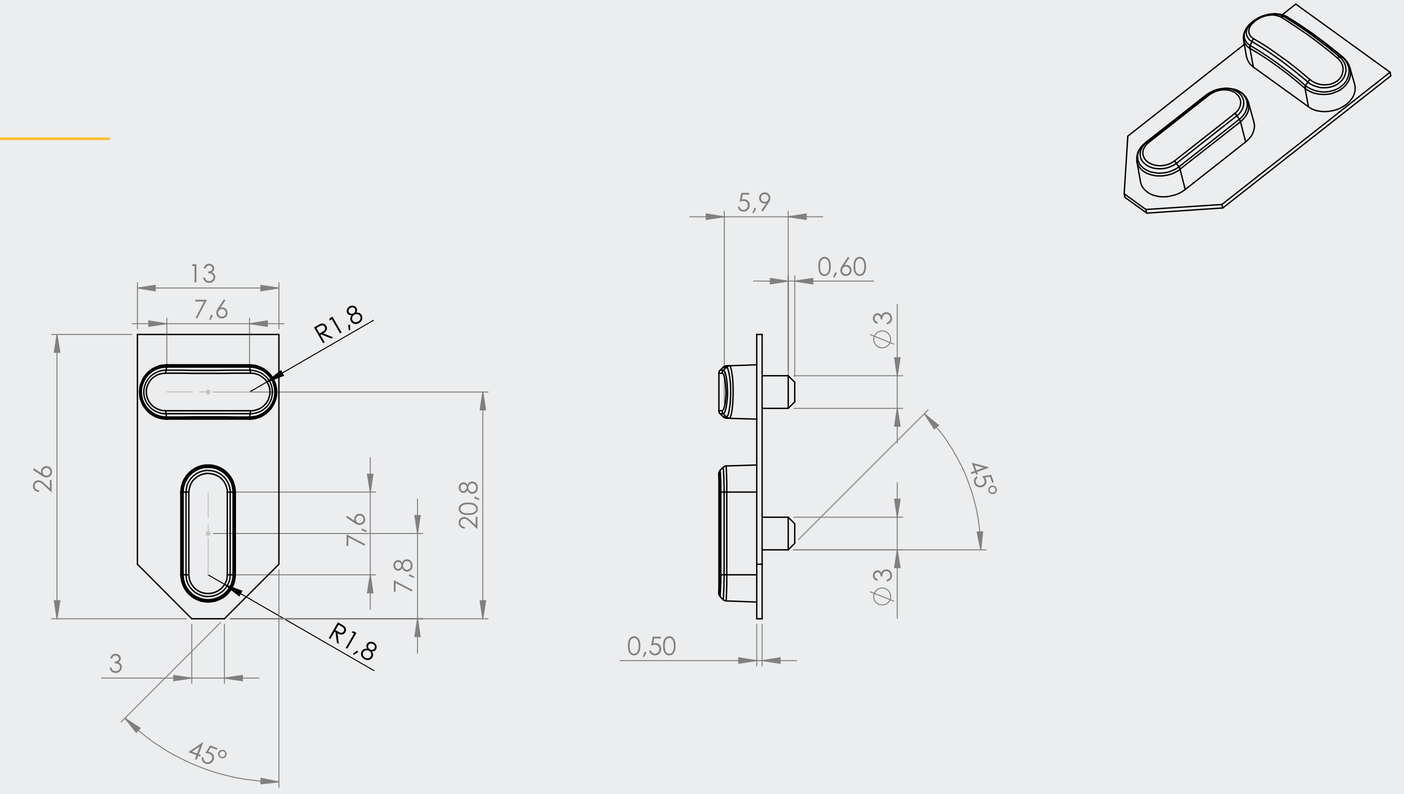
MATERIAL: PP

DWG NO. Compression part A3

WEIGHT: SCALE:1:1 SHEET 1 OF 1

Appendix I

technical data package



Remarks:
- All surfaces to be textured with: Matt gloss
- Nominal wall thickness: 0,5 mm
- Draft angle of 0,5 degrees
- Product definition according to the to provide 3D file

UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS SURFACE FINISH: TOLERANCES: LINEAR: ANGULAR:

FINISH:

DEBURR AND BREAK SHARP EDGES

DO NOT SCALE DRAWING

REVISION

REMARK:

	NAME	DATE
DRAWN	ESU	07/08/2018

Client: *Roos Oosting*

Coaches: Prof. J.E. Oberdorf, Prof. J.C. Diehl

TITLE: Button foil

MATERIAL: TPV A70

DWG NO. Button foil

A3

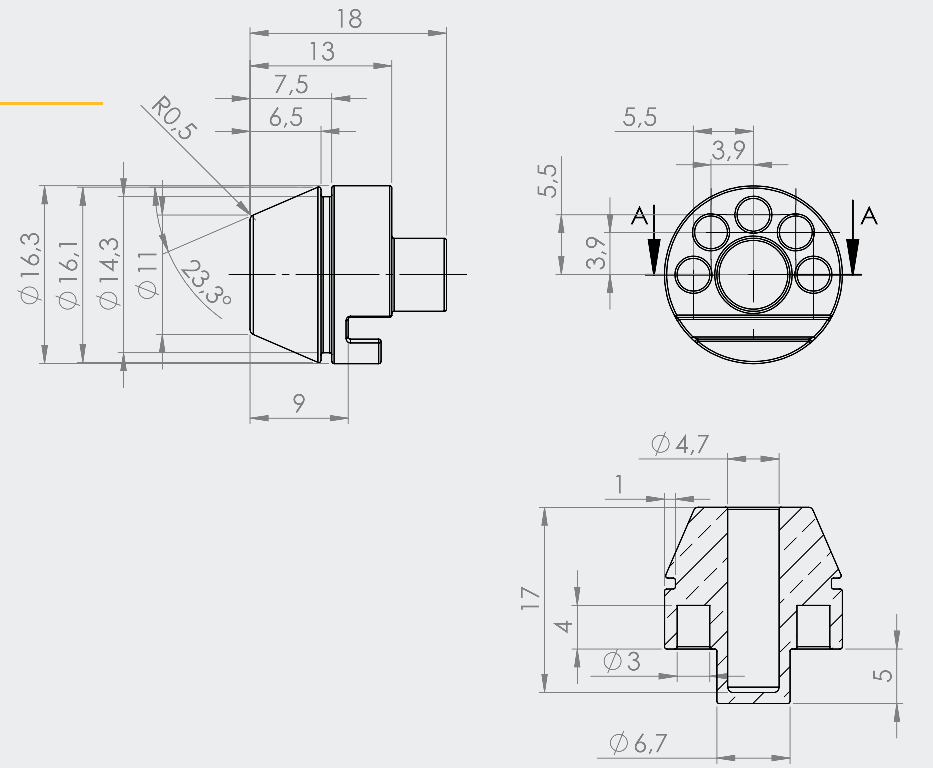
WEIGHT:

SCALE:1:1

SHEET 1 OF 1

Appendix I

technical data package



SECTION A-A

UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS SURFACE FINISH: TOLERANCES: LINEAR: ANGULAR:

FINISH:

DEBURR AND BREAK SHARP EDGES

DO NOT SCALE DRAWING

REVISION

REMARK:

	NAME	DATE
DRAWN	ESU	07/08/2018

Client: *Roos Oosting*

Coaches: Prof. J.E. Oberdorf, Prof. J.C. Diehl

TITLE: Connection adapter

MATERIAL: Phosphor bronze

DWG NO. Connection adapter

A3

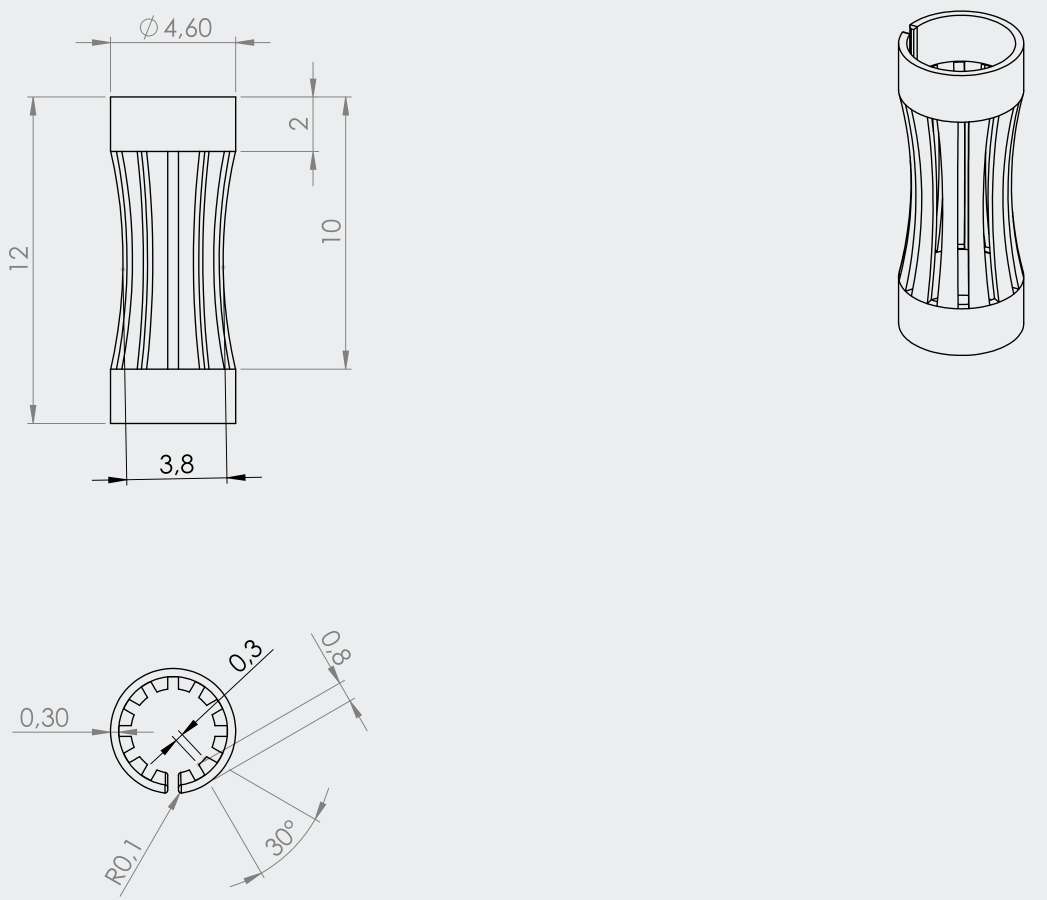
WEIGHT:

SCALE:2:1

SHEET 1 OF 1

Appendix I

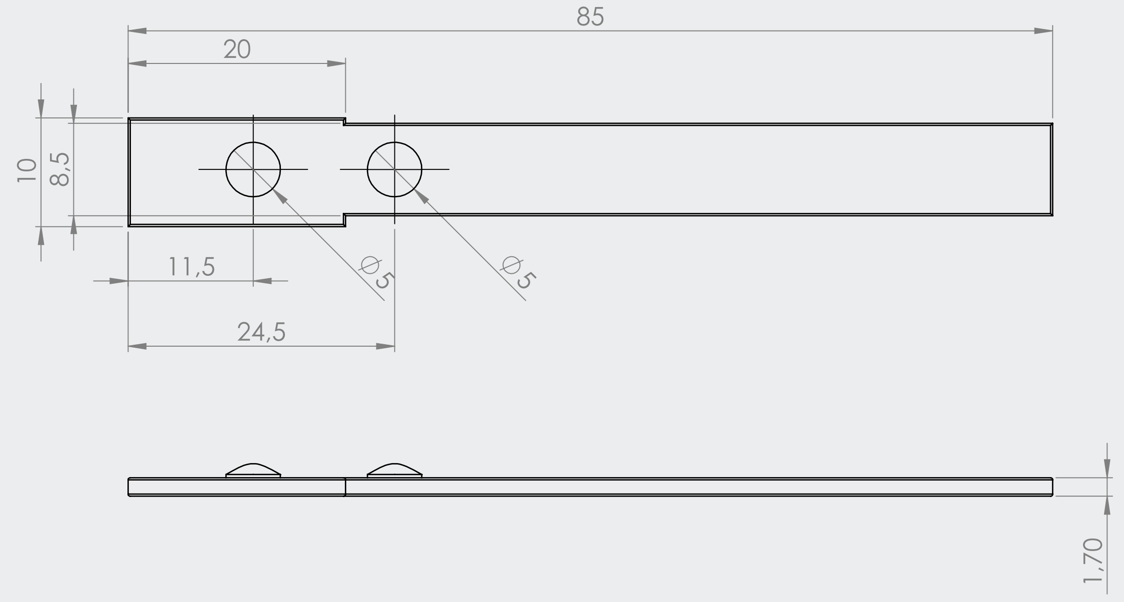
technical data package



UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS SURFACE FINISH: TOLERANCES: LINEAR: ANGULAR:	FINISH:	DEBURR AND BREAK SHARP EDGES	DO NOT SCALE DRAWING	REVISION	
			REMARK:		
NAME	DATE	Client: Roos Oosting Coaches: Prof. J.E. Oberdorf Prof. J.C. Diehl	TITLE: Plug connector		
DRAWN ESU	07/08/2018				
		MATERIAL: Phosphor bronze	DWG NO. Plug connector	A3	
		WEIGHT:	SCALE:5:1	SHEET 1 OF 1	

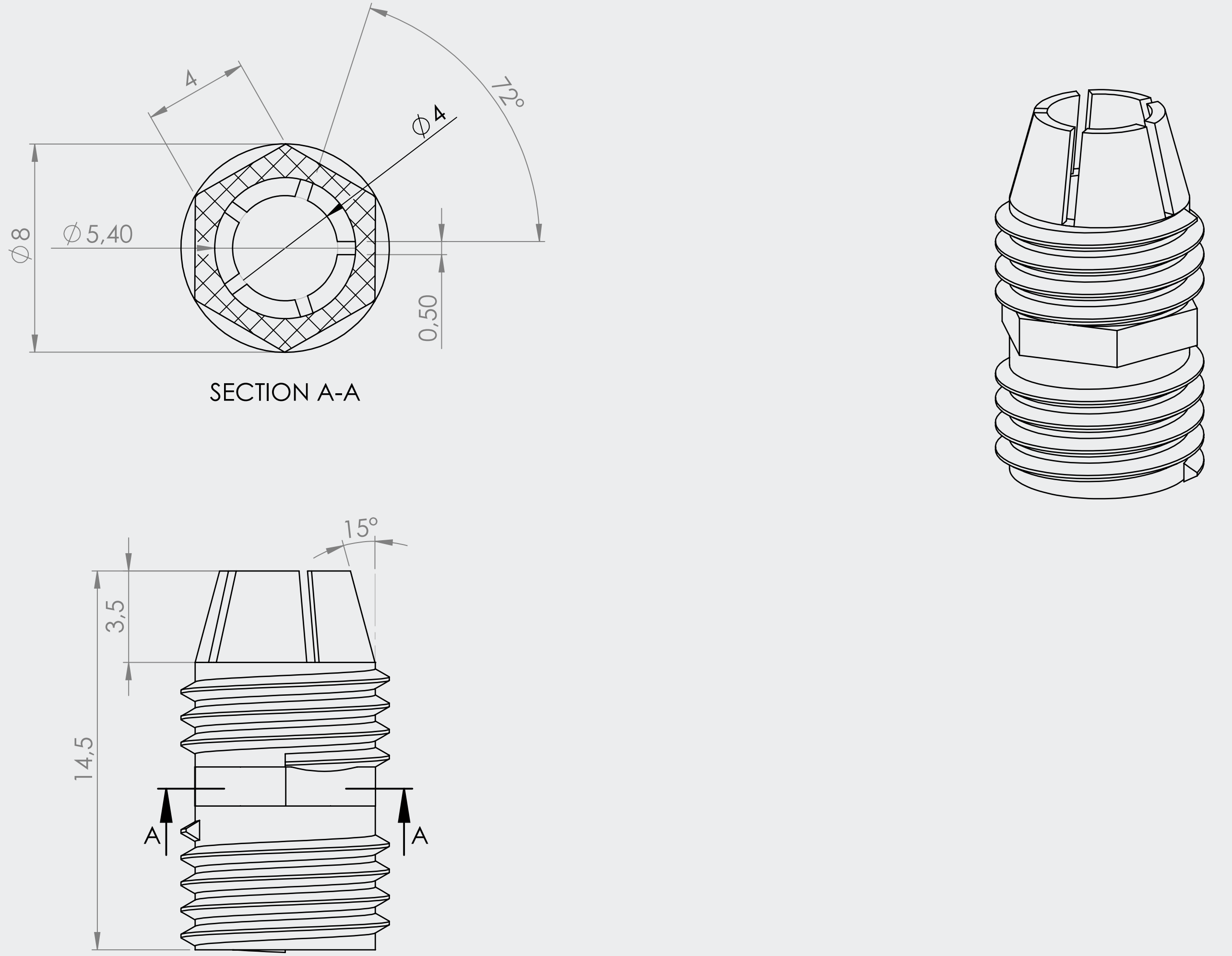
Appendix I

technical data package



UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS SURFACE FINISH: TOLERANCES: LINEAR: ANGULAR:	FINISH:	DEBURR AND BREAK SHARP EDGES	DO NOT SCALE DRAWING	REVISION	
			REMARK:		
NAME	DATE	Client: Roos Oosting Coaches: Prof. J.E. Oberdorf Prof. J.C. Diehl	TITLE: PCB internal conmponents		
DRAWN ESU	07/08/2018				
		MATERIAL:	DWG NO. PCB outline	A3	
		WEIGHT:	SCALE:2:1	SHEET 1 OF 1	

Appendix I
technical data package



Remarks:
- All surfaces to be textured with: Matt gloss
- Nominal wall thickness: 1 mm
- Draft angle of 0,5 degrees
- Extruded metric tap of M6 x 1 mm
- Product definition according to the to provide 3D file

UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
SURFACE FINISH:
TOLERANCES:
LINEAR:
ANGULAR:

FINISH:

DEBURR AND BREAK SHARP EDGES

DO NOT SCALE DRAWING

REVISION

REMARK:

	NAME	DATE
DRAWN	ESU	07/08/2018

Client:
Roos Oosting

Coaches: Prof. J.E. Oberdorf
Prof. J.C. Diehl

TITLE: Cable gland

MATERIAL: PP

DWG NO. Cable gland

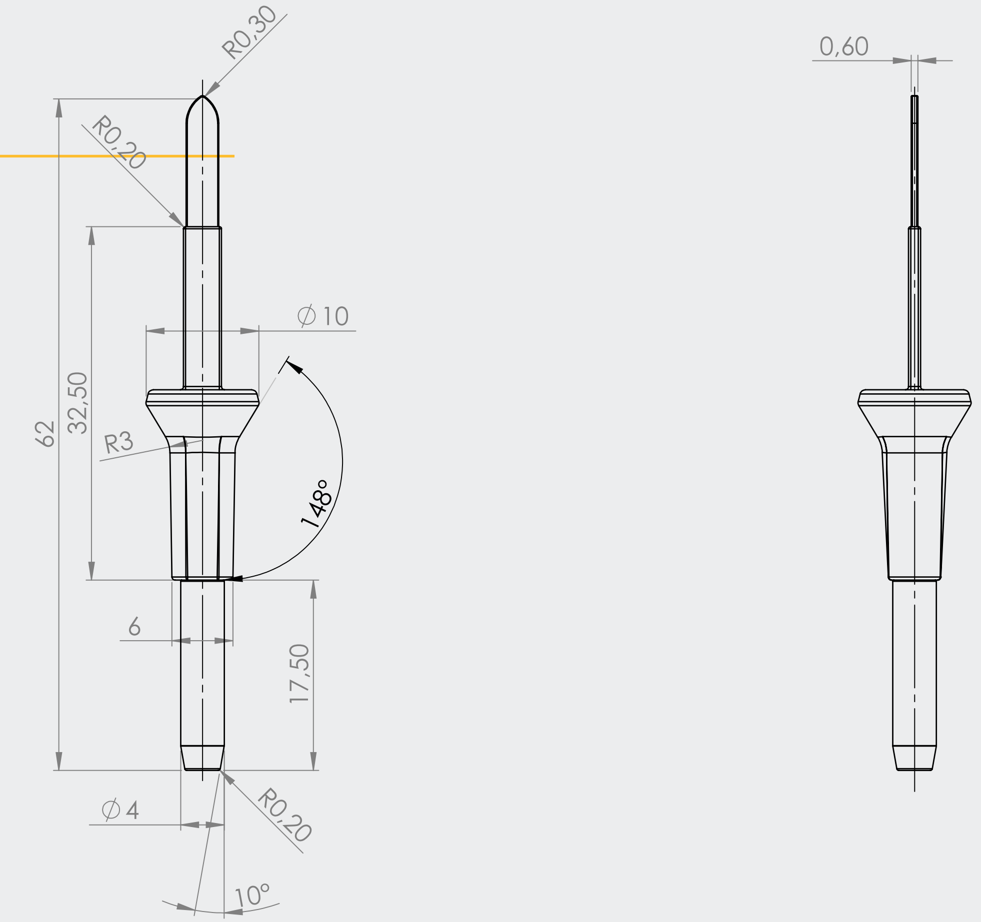
A3

WEIGHT:

SCALE:5:1

SHEET 1 OF 1

Appendix I
technical data package



UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
SURFACE FINISH:
TOLERANCES:
LINEAR:
ANGULAR:

FINISH:

DEBURR AND BREAK SHARP EDGES

DO NOT SCALE DRAWING

REVISION

REMARK:

	NAME	DATE
DRAWN	ESU	07/08/2018

Client:
Roos Oosting

Coaches: Prof. J.E. Oberdorf
Prof. J.C. Diehl

TITLE: Electrode tip

MATERIAL:

DWG NO. ESU_Electrode tip

A3

WEIGHT:

SCALE:2:1

SHEET 1 OF 1

POWER TRANSFORMER CHASSIS MOUNT : TOROIDAL MEDICAL SERIES

TRIAD MAGNETICS

Appendix I
technical data package

VPM12-20800

Description:
The toroidal construction inherently reduces stray fields, increases efficiency and minimizes size compared to traditional EI transformers. The addition of a Flux Band further reduces the remaining stray fields. The shield between Primary and Secondary improves safety, reduces common mode signals and minimizes leakage current. Built with a Class F (155°) insulation system. A 140°C self-resetting thermal switch is included in each primary.


Photo for illustration only

RoHS 2011/65/EU

Electrical Specifications (@25C)
1. Maximum Power: 250VA
2. Input Voltages: 100, 120, 220, 240VAC, 50/60Hz
3. Output Voltages: 6VAC @41.60A or 12VAC CT @ 20.8A
4. Voltage Regulation: 6.2% TYP from full load to no load
5. Temperature Rise: 55°C TYP
6. Hipot: 4000VAC, Primary to Secondary, Primary & Secondary to Shield & mounting surface
7. Efficiency: 93% TYP. @ full load

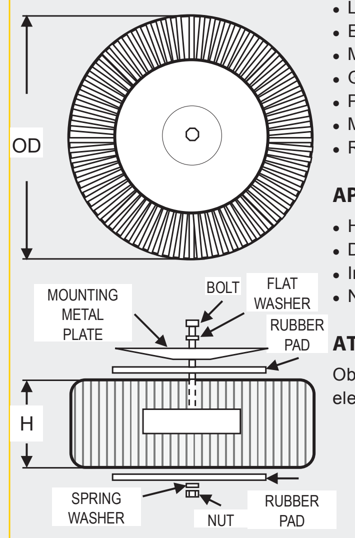
Agency File:
UL: File E122529, UL 60601-1/(R) 2012 Medical Electrical Equipment – Part 1
CE: ES 60601-1 (IEC 60601-1:2005, MOD)
cUL: C22.2 No. 60601-1:14, Medical Electrical Equipment – Part 1
CB Certified.

Dimensions: Inches (mm)

O.D.	I.D.	HT.*
4.8 (123)	1.8(45)	2.4(60)

*Add 0.188 (3) to the height for mounting hardware

Weight: 2.5Kg



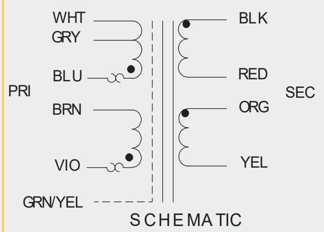
Mounting:
Transformer is provided with one metal mounting plate, two rubber pads, M6 x 65mm bolt, nut, spring and flat washer.

Connections:
Transformer is provided with 8" (203mm) long, 0.25" (6.35mm) stripped and tinned, stranded UL 1015 lead wire. Primaries are 20AWG, Secondaries are 12AWG, and Shield is 20AWG.
The GRN/YEL shield lead is typically grounded. Do not lift transformer by leads!

Input Options:
- **100VAC:** Input to Gray & Blue, jumper White & Brown, jumper Blue & Violet.
- **120VAC:** Input to White & Blue, jumper White & Brown, jumper Blue & Violet.
- **220VAC:** Input to Gray & Violet, jumper Blue & Brown
- **240VAC:** Input to White and Violet, jumper Blue & Brown

Output Options:
- **120VAC:** Output from Black & Red, jumper Black & Orange, jumper Red to Yellow
- **240VAC:** Output from Black & Yellow, jumper Red & Orange

Primary and secondary windings are designed to be connected in series or parallel. Windings are not intended to be used independently.



RoHS Compliance: Meets the requirements of 2011/65/EU, known as the RoHS 2 initiative.

* At printing, this document is considered "uncontrolled". Contact Triad Magnetics' website for current version

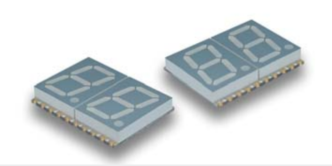
Web: www.TriadMagnetics.com
Phone 951-277-0757
Fax 951-277-2757

460 Harley Knox Blvd.
Perris, California 92571

Publish Date: June 19, 2015

Kingbright

ACDA56-41SEKWA-F01
Surface Mount Display



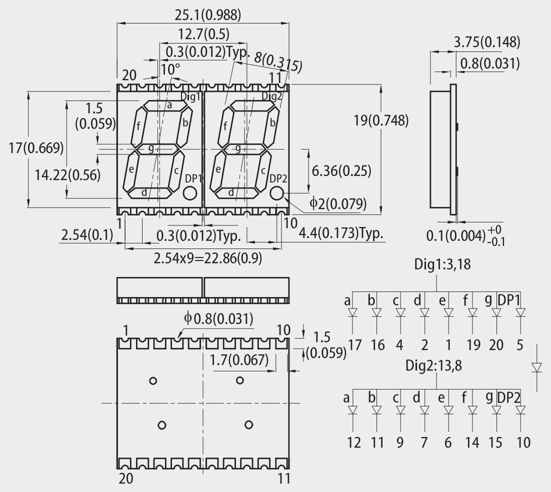
DESCRIPTIONS
- The Super Bright Orange device is made with AlGaInP (on GaAs substrate) light emitting diode chip
- Electrostatic discharge and power surge could damage the LEDs
- It is recommended to use a wrist band or anti-electrostatic glove when handling the LEDs
- All devices, equipment and machineries must be electrically grounded

FEATURES
- 0.56 inch digit height
- Low current operation
- Excellent character appearance
- Mechanically rugged
- Gray face, white segment
- Package: 200 pcs / reel
- Moisture sensitivity level: 2a
- RoHS compliant

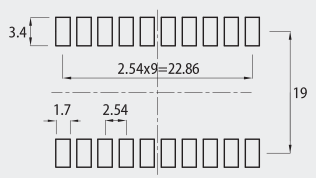
APPLICATIONS
- Home and smart appliances
- Display time and digital combination
- Industrial and instrumental applications
- Numeric status

ATTENTION
Observe precautions for handling electrostatic discharge sensitive devices

PACKAGE DIMENSIONS



RECOMMENDED SOLDERING PATTERN
(units : mm; tolerance : ± 0.15)



Notes:
1. All dimensions are in millimeters (inches), Tolerance is ±0.25(0.01")unless otherwise noted.
2. The specifications, characteristics and technical data described in the datasheet are subject to change without prior notice.
3. The gap between the reflector and PCB shall not exceed 0.25mm.

SELECTION GUIDE

Part Number	Emitting Color (Material)	Lens Type	Iv (ucd) @ 10mA [1]		Description
			Min.	Typ.	
ACDA56-41SEKWA-F01	Super Bright Orange (AlGaInP)	White Diffused	31000	78000	Common Anode, Rt. Hand Decimal
			*14000	*23000	

Notes:
1. Luminous intensity / luminous Flux: +/-15%.
* Luminous intensity value is traceable to CIE127-2007 standards.

ELECTRICAL / OPTICAL CHARACTERISTICS at T_A=25°C

Parameter	Symbol	Emitting Color	Value		Unit
			Typ.	Max.	
Wavelength at Peak Emission I_F = 10mA	λ_{peak}	Super Bright Orange	610	-	nm
Dominant Wavelength I_F = 10mA	λ_{dom} [1]	Super Bright Orange	605	-	nm
Spectral Bandwidth at 50% Φ REL MAX I_F = 10mA	$\Delta\lambda$	Super Bright Orange	29	-	nm
Capacitance	C	Super Bright Orange	15	-	pF
Forward Voltage I_F = 10mA	V_F [2]	Super Bright Orange	2.0	2.35	V
Reverse Current (V_R = 5V)	I_R	Super Bright Orange	-	10	uA

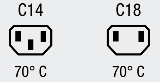
Notes:
1. The dominant wavelength (λd) above is the setup value of the sorting machine. (Tolerance λd : ±1nm.)
2. Forward voltage: ±0.1V.
3. Wavelength value is traceable to CIE127-2007 standards.
4. Excess driving current and / or operating temperature higher than recommended conditions may result in severe light degradation or premature failure.

ABSOLUTE MAXIMUM RATINGS at T_A=25°C

Parameter	Symbol	Value	Unit
Power Dissipation	P_D	75	mW
Reverse Voltage	V_R	5	V
Junction Temperature	T_j	115	°C
Operating Temperature	T_{op}	-40 to +85	°C
Storage Temperature	T_{stg}	-40 to +85	°C
DC Forward Current	I_F	30	mA
Peak Forward Current	I_{FM} [1]	195	mA
Electrostatic Discharge Threshold (HBM)	-	3000	V

Notes:
1. 1/10 Duty Cycle, 0.1ms Pulse Width.
2. Relative humidity levels maintained between 40% and 60% in production area are recommended to avoid the build-up of static electricity – Ref JEDEC/JESD625-A and JEDEC/J-STD-033.

IEC Appliance Inlet C14 or C18 with Line Switch 2 pole and Fuseholder 1- or 2-pole



Approvals and Compliances

Description
- Panel Mount :
  Screw-on version from front or rear side , Appliance Inlet , protection class I or II , Fuseholder for fuse-links 5 x 20 mm , Line Switch 2-pole
- Meets the requirements of IEC 60335-1 for appliances in unattended use. This includes the enhanced requirements of glow wire tests acc. to IEC 60695-2-12 and -13.
- Solder terminals or quick connect terminals

Characteristics
- Line switch non-illuminated or illuminated

References
Alternative: version with line filter FKID

Weblinks
pdf datasheet, html-datasheet, General Product Information, Distributor-Stock-Check, Accessories, Detailed request for product

Technical Data

Ratings IEC	10 A / 250 VAC; 50 Hz
Ratings UL/CSA	10 A / 250 VAC; 60 Hz
Dielectric Strength	> 1.5 kVAC between L-N > 3 kVAC between L/N-PE (1 min/50 Hz)
Allowable Operation Temperature	-25 °C to 70 °C
IP-Protection	from front side IP 20 acc. to IEC 60529
Insulation cover	Suitable for appliances with protection class I or II acc. to IEC 61140
Terminal	Solder terminals or quick connect terminals
Material: Housing	PA6, black, UL 94V-0
appliance inlet/-outlet	C14 / C18 acc. to IEC 60320-1 UL 498, CSA C22.2 no. 42 (for cold conditions) pin-temperature 70 °C, 10 A, Protection Class I or II
Fuseholder	1 or 2 pole, acc. to IEC 60127-6, for fuse-links 5 x 20 mm
Power Acceptance @ Ta > 23°C	Admissible power acceptance at higher ambient temperature see derating curves
Line Switch	Rocker switch 2-pole, non-illuminated or illuminated black, acc. to IEC 61058-1 Technical Details

Approvals and Compliances

Detailed information on product approvals, code requirements, usage instructions and detailed test conditions can be looked up in Details about Approvals

Approvals
The approval mark is used by the testing authorities to certify compliance with the safety requirements placed on electronic products.
Approval Reference Type: 6765

Approval Logo	Certificates	Certification Body	Description
	SEMKO Approvals	SEMKO	Certificate Number: SE/09137-1A
	UL Approvals	UL	UL File Number: E93617
	CSA Approvals	CSA	CSA Certification Record: 27324
	CSA Approvals	CSA	CCC File Number: 27324

Appendix I
technical data package

Product standards

Product standards that are referenced

Organization	Design	Standard	Description
IEC	Designed according to	IEC 60320-1	Appliance couplers for household and similar general purposes
IEC	Designed according to	IEC 60127-6	Miniature fuses. Part 6. Fuse-holders for miniature fuse-links
IEC	Designed according to	IEC 61058-1	Switches for appliances. Part 1. General requirements
UL	Designed according to	UL 498	Standard for Attachment Plugs and Receptacles
CSA Group	Designed according to	CSA C22.2 no. 42	General Use Receptacles, Attachment Plugs, and Similar Wiring Devices

Application standards

Application standards where the product can be used

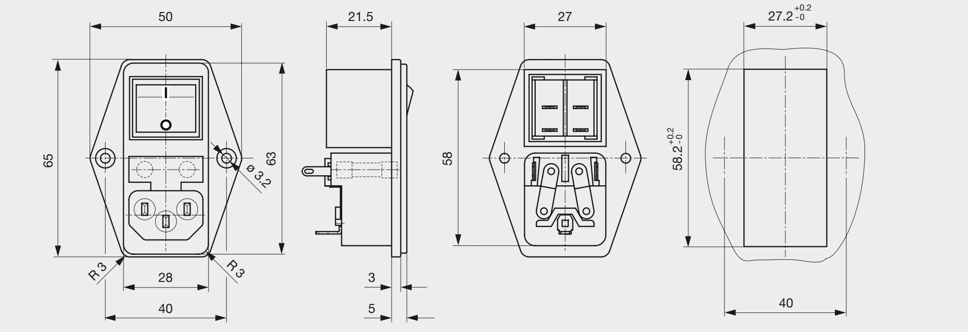
Organization	Design	Standard	Description
IEC	Designed for applications acc.	IEC/UL 60950	IEC 60950-1 includes the basic requirements for the safety of information technologyequipment.
IEC	Designed for applications acc.	IEC 60335-1	Safety of electrical appliances for household and similar purposes. Meets the requirements for appliances in unattended use. This includes the enhanced requirements of glow wire tests acc. to IEC 60695-2-12 and -13.

Compliances

The product complies with following Guide Lines

Identification	Details	Initiator	Description
CE	CE declaration of conformity	SCHURTER AG	The CE marking declares that the product complies with the applicable requirements laid down in the harmonisation of Community legislation on its affixing in accordance with EU Regulation 765/2008.
RoHS	RoHS	SCHURTER AG	EU Directive RoHS 2011/65/EU
50	China RoHS	SCHURTER AG	The law SJ / T 11363-2006 (China RoHS) has been in force since 1 March 2007. It is similar to the EU directive RoHS.
REACH	REACH	SCHURTER AG	On 1 June 2007, Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals 1 (abbreviated as "REACH") entered into force.

Dimensions [mm]



Length of the terminal please find at the order code configuration table

HEYCO Liquid Tight Cordgrips

This product is RoHS compliant.

HEYCO LIQUID TIGHT STRAIGHT-THRU CORDGRIPS

Cordgrips are for flexible cords. Install in either clearance or threaded holes.

For quantities greater than listed, call for quote.

Cable Dia. Range (In.)		Black		Gray				Dimensions: in.			Price Each			
Min.	Max.	MOUSER STOCK NO.	Heyco Part No.	MOUSER STOCK NO.	Heyco Part No.	Fig.	Description	A	B	C	1	10	50	100
Cordgrips for PG Hubs • Locknuts are Included														
0.064	0.210	836-3444	3444	836-3445	3445	A	RLTF 7	0.492	1.170	0.330	.85	.67	.63	.59
0.114	0.250	836-3207	3207	836-3208	3208	A	LTF 7	0.492	1.170	0.330	.85	.67	.63	.59
0.069	0.187	836-3446	3446	--------	---	A	RLTF 9	0.599	1.300	0.340	.89	.70	.58	.50
0.181	0.312	836-3210	3210	836-3211	3211	A	LTF 9	0.599	1.300	0.340	.89	.70	.58	.50
0.069	0.250	836-3448	3448	836-3449	3449	A	RLTF 11	0.733	1.460	0.390	1.07	.85	.70	.61
0.230	0.395	836-3213	3213	836-3214	3214	A	LTF 11	0.733	1.460	0.390	1.07	.85	.70	.61
0.170	0.450	836-3216	3216	836-3217	3217	A	LTF 13.5	0.804	1.530	0.410	1.61	1.27	1.04	.89
0.230	0.530	836-3219	3219	836-3220	3220	A	LTF 16	0.886	1.660	0.450	1.35	1.07	.93	.86
0.250	0.490	836-3454	3454	--------	---	A	RLTF 21	1.115	1.870	0.520	1.89	1.49	1.24	1.07
0.450	0.705	836-3222	3222	836-3223	3223	A	LTF 21	1.115	1.870	0.520	1.89	1.49	1.24	1.07
0.590	0.990	836-3225	3225	836-3226	3226	A	LTF 29	1.470	2.230	0.590	3.36	2.65	2.19	1.90
Cordgrips for NPT Hubs • Locknuts are not Included.														
0.069	0.187	836-3458	3458	--------	---	A	RLTF 3/8	0.670	1.490	0.530	.80	.63	.53	.45
0.181	0.312	836-3228	3228	836-3229	3229	A	LTF 3/8	0.670	1.490	0.530	.80	.63	.58	.54
0.170	0.470	836-3231	3231	836-3232	3232	A	LTF 1/2	0.875	1.720	0.620	1.07	.85	.70	.65
0.230	0.546	836-3200	3200	836-3201	3201	A	LLTF 1/2	0.875	1.830	0.620	1.22	.97	.89	.83
0.450	0.709	836-3234	3234	836-3235	3235	A	LTF 3/4	1.068	1.970	0.630	1.70	1.34	1.20	1.11
0.250	0.485	836-3460	3460	836-3461	3461	A	RLTF 3/4	1.068	1.970	0.630	1.70	1.34	1.11	.97
0.590	1.000	836-8437	8437	836-8438	8438	A	LTF 1	1.375	2.420	0.750	3.02	2.38	1.97	1.71

"HEYCO TITE" LIQUID TIGHT STRAIGHT-THRU CORDGRIPS

"Ratchet design" of sealing nut assembly provides superior anti-vibration protection and ensures a firm grip on the cable. Integral "Sealing Ring" ensures a superior seal at mounting location every time.

For quantities greater than listed, call for quote.

Cable Dia. Range (In.)		Black		Gray				Dimensions: in.			Price Each			
Min.	Max.	MOUSER STOCK NO.	Heyco Part No.	MOUSER STOCK NO.	Heyco Part No.	Fig.	Description	A	B	C	1	10	50	100
Cordgrips for PG Hubs • Locknuts are Included														
0.065	0.220	836-M3444	M3444	836-M3445	M3445	B	RLTCG 7	0.492	1.160	0.320	.96	.87	.80	.76
0.115	0.250	836-M3207	M3207	836-M3208	M3208	B	LTCG 7	0.492	1.160	0.320	.96	.87	.80	.72
0.105	0.312	836-M3210	M3210	836-M3211	M3211	B	LTCG 9	0.599	1.250	0.320	1.02	.92	.83	.76
0.230	0.395	836-M3213	M3213	836-M3214	M3214	B	LTCG 11	0.733	1.480	0.380	1.22	1.11	1.02	.92
0.095	0.260	836-M4500	M4500	--------	---	B	RLTCG 13.5	0.804	1.500	0.410	1.34	1.22	1.11	1.02
0.170	0.450	836-M3216	M3216	836-M3217	M3217	B	LTCG 13.5	0.804	1.500	0.410	1.34	1.22	1.11	1.02
0.180	0.440	836-M4502	M4502	--------	---	B	RLTCG 16	0.886	1.680	0.440	1.54	1.40	1.27	1.16
0.260	0.546	836-M3219	M3219	836-M3220	M3220	B	LTCG 16	0.886	1.680	0.440	1.54	1.40	1.27	1.16
0.250	0.485	836-M3454	M3454	836-M3455	M3455	B	RLTCG 21	1.115	1.890	0.520	2.14	1.94	1.77	1.61
0.485	0.709	836-M3222	M3222	836-M3223	M3223	B	LTCG 21	1.115	1.890	0.520	2.14	1.94	1.77	1.61
0.490	0.787	836-M4504	M4504	--------	---	B	RLTCG 29	1.470	2.230	0.580	3.81	3.47	3.15	2.86
0.590	1.000	836-M3225	M3225	--------	---	B	LTCG 29	1.470	2.230	0.580	3.81	3.47	3.15	2.86
Cordgrips for NPT Hubs • Locknuts are not Included														
0.105	0.315	836-M3228	M3228	836-M3229	M3229	C	LTCG 3/8	0.680	1.410	0.490	.91	.82	.75	.68
0.095	0.260	836-M4518	M4518	836-M4519	M4519	C	RLTCG 1/2	0.875	1.700	0.610	1.22	1.11	1.02	.95
0.170	0.450	836-M3231	M3231	836-M3232	M3232	C	LTCG 1/2	0.875	1.700	0.610	1.22	1.11	1.02	.95
0.256	0.485	836-M3460	M3460	--------	---	C	RLTCG 3/4	1.040	2.000	0.620	1.92	1.75	1.59	1.45
0.485	0.709	836-M3234	M3234	--------	---	C	LTCG 3/4	1.040	2.000	0.620	1.92	1.75	1.59	1.45
0.490	0.787	836-M8439	M8439	--------	---	C	RLTCG 1	1.326	2.410	0.760	3.42	3.11	2.83	2.57
0.590	1.000	836-M8437	M8437	--------	---	C	LTCG 1	1.326	2.410	0.760	3.42	3.11	2.83	2.57

HYBRID LIQUID TIGHT CORDGRIPS

NEW PRODUCT

• Locknuts not Included

For quantities greater than listed, call for quote.

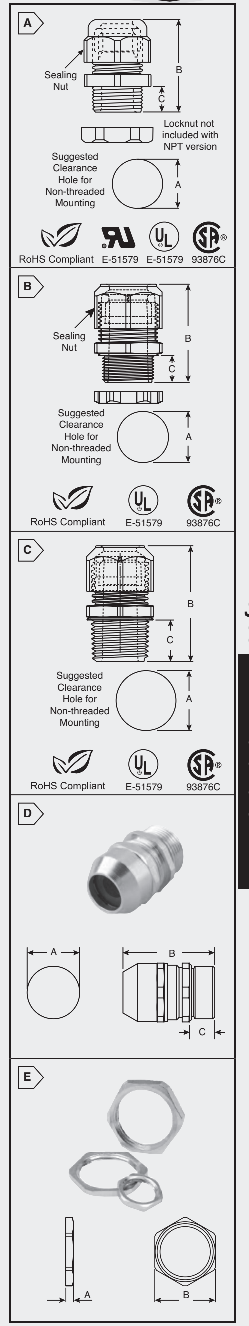
Cable Dia. Range (In.)		MOUSER STOCK NO.	Heyco Part No.	Fig.	Thread Size	Dimensions: in.			Price Each			
Min.	Max.					A	B	C	1	10	50	100
Cordgrips for PG Hubs												
0.04	0.20	836-4450	4450	D	PG 7	0.50	0.87	0.20	3.62	3.43	3.27	3.10
0.12	0.28	836-4451	4451	D	PG 7	0.50	0.87	0.20	3.62	3.43	3.27	3.10
0.08	0.24	836-4452	4452	D	PG 9	0.61	1.02	0.24	4.66	4.43	4.21	3.99
0.18	0.39	836-4453	4453	D	PG 9	0.61	1.02	0.24	4.66	4.43	4.21	3.99
0.14	0.31	836-4454	4454	D	PG 11	0.75	1.22	0.24	6.31	5.99	5.69	5.41
0.28	0.51	836-4455	4455	D	PG 11	0.75	1.22	0.24	6.05	5.75	5.46	5.19
0.14	0.31	836-4456	4456	D	PG 13.5	0.83	1.24	0.26	6.31	5.99	5.69	5.41
0.28	0.51	836-4457	4457	D	PG 13.5	0.83	1.24	0.26	6.31	5.99	5.69	5.41
0.14	0.31	836-4458	4458	D	PG 16	0.91	1.24	0.26	6.31	5.99	5.69	5.41
0.28	0.51	836-4459	4459	D	PG 16	0.91	1.24	0.26	10.54	10.00	9.51	9.04
0.20	0.43	836-4460	4460	D	PG 16	0.91	1.48	0.26	10.98	10.44	9.91	9.42
0.39	0.67	836-4461	4461	D	PG 16	0.91	1.48	0.26	10.99	10.42	9.91	9.42
0.28	0.59	836-4462	4462	D	PG 21	1.14	1.57	0.28	15.17	14.41	13.70	13.00
0.51	0.83	836-4463	4463	D	PG 21	1.14	1.57	0.28	15.17	14.41	13.70	13.00
0.59	0.91	836-4464	4464	D	PG 29	1.48	1.89	0.31	23.77	22.58	21.45	20.38
0.75	1.10	836-4465	4465	D	PG 29	1.48	1.89	0.31	23.77	22.58	21.45	20.38
Cordgrips for Metric Hubs												
0.04	0.20	836-4472	4472	D	M12 x 1.5	0.50	1.14	0.47	3.90	3.69	3.52	3.34
0.12	0.28	836-4473	4473	D	M12 x 1.5	0.50	1.14	0.47	3.90	3.69	3.52	3.34
0.08	0.24	836-4474	4474	D	M16 x 1.5	0.64	1.26	0.47	5.22	4.96	4.71	4.48
0.18	0.39	836-4475	4475	D	M16 x 1.5	0.64	1.26	0.47	5.01	4.76	4.52	4.30
0.14	0.31	836-4476	4476	D	M20 x 1.5	0.80	1.46	0.47	6.47	6.15	5.84	5.55
0.28	0.51	836-4477	4477	D	M20 x 1.5	0.80	1.46	0.47	6.47	6.15	5.84	5.55
0.20	0.43	836-4478	4478	D	M25 x 1.5	1.00	1.69	0.47	10.93	10.37	9.86	9.37
0.39	0.67	836-4479	4479	D	M25 x 1.5	1.00	1.69	0.47	10.93	10.37	9.86	9.37
0.28	0.59	836-4480	4480	D	M32 x 1.5	1.27	1.89	0.59	15.73	14.94	14.20	13.49
0.51	0.83	836-4481	4481	D	M32 x 1.5	1.27	1.89	0.59	16.39	15.57	14.80	14.06

Accessories - Locknuts

NEW PRODUCT

For quantities greater than listed, call for quote.

Thread Size	MOUSER STOCK NO.	Heyco Part No.	Fig.	Description	Dimensions: in.		Price Each			
					Thickness A	Wrenching B	1	10	50	100
PG Thread-Nickel Plated Brass										
PG 7	836-2257	2257	E	PG 7	0.110	0.591	.47	.43	.40	.37
PG 9	836-2258	2258	E	PG 9	0.110	0.709	.70	.66	.63	.60
PG 11	836-2259	2259	E	PG 11	0.118	0.827	.77	.73	.66	.57
PG 13.5	836-2260	2260	E	PG 13.5	0.118	0.906	.83	.771	.709	.657
PG 16	836-2261	2261	E	PG 16	0.118	1.024	.96	.88	.81	.75
PG 21	836-2262	2262	E	PG 21	0.138	1.261	1.32	1.21	1.12	1.03
PG 29	836-2263	2263	E	PG 29	0.158	1.615	2.06	1.89	1.74	1.60
Metric Thread-Nickel Plated Brass										
M12	836-2246	2246	E	LN M12	0.118	0.591	.59	.54	.49	.46
M16	836-2247	2247	E	LN M16	0.118	0.748	.82	.771	.709	.657
M20	836-2248	2248	E	LN M20	0.138	0.945	1.01	.93	.85	.79
M25	836-2249	2249	E	LN M25	0.138	1.181	1.34	1.23	1.11	1.04

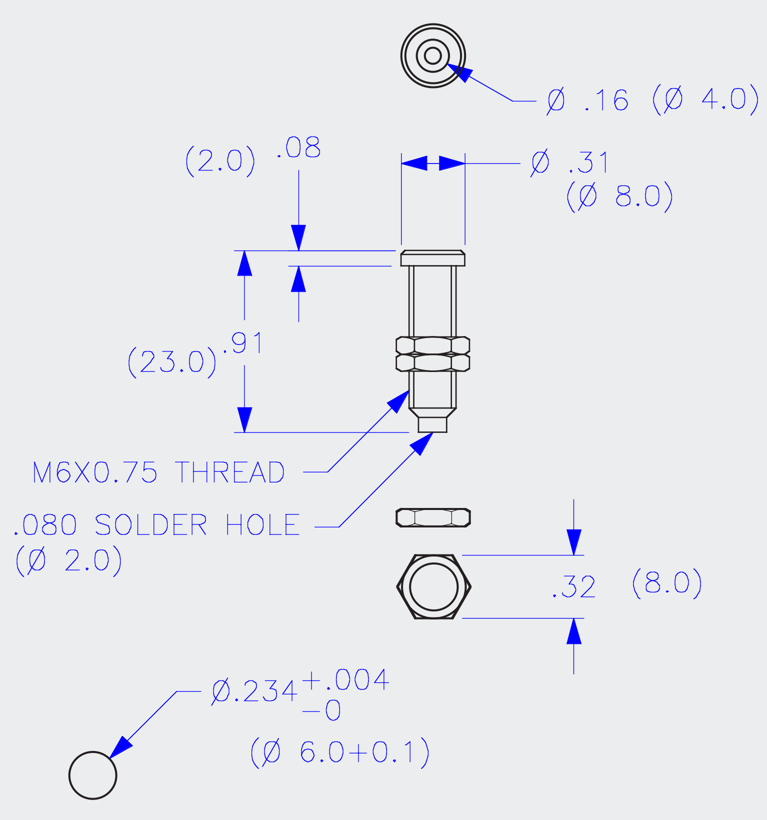


Heyco Hardware

REVISIONS			
REV.	DESCRIPTIONS	DATE	APPROVED
—	CLASS A RELEASED	7/12/99	

1. 4mm UNINSULATED SOCKET (JACK) w/Ø .080 (Ø 2.0) SOLDER HOLE.
2. SPECIFICATIONS:
   SOCKET BODY: BRASS, NICKEL PLATED.
3. RATING:
   CURRENT: 36A MAX.
   TEMPERATURE: −20° C TO +150° C.
4. MOUNTING HOLE: REFERENCE DIAGRAM.
5. MAXIMUM PANEL THICKNESS: .50 (12.7)

PART NUMBER
CT2220



MOUNTING HOLE

THIRD ANGLE PROJECTION	UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES TOLERANCES ARE: FRACTIONS ± 1/32; DECIMALS .XX ± .02, .XXX ±.005; DO NOT SCALE DRAWING	CONTRACT NO.	Cal Test Electronics, 22820 Savi Ranch Parkway, Yorba Linda, CA 92887-4610
NEXT ASSY / USED ON	MATERIAL	APPROVALS / DATE	TITLE: 4mm SOCKET, UNINSULATED
APPLICATION	FINISH	DRAWN: WDH 7/12/99	SIZE: A; CAGE CODE; DWG. NO.: P222000; REV.
		CHECKED	SCALE: 1:1; SHEET 1 OF 1
		ENGR.	
		DESIGN ACTIVITY	

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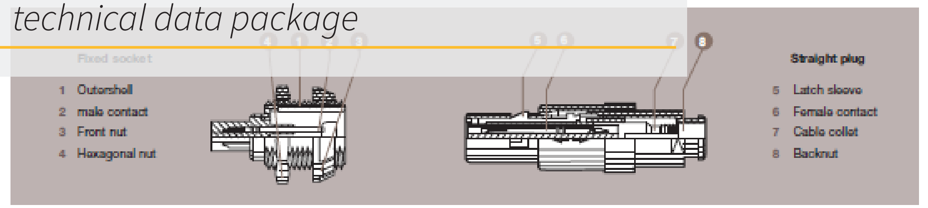
Appendix I

technical data package

REDEL

Mains power configuration

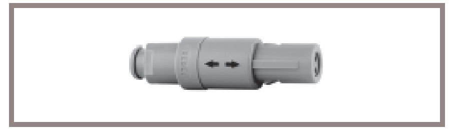
The new PA● and PK● models are used for mains power in medical applications. The design of a special insulator offers the required creepage distance. The 3 contacts are only solder type with a maximum AWG 18 (wire size max 1.35 mm). The connectors are UL certified to be used at 250 Volt AC (9 Amps). See UL approval file number N°E242949 (only valid for 3 contact configuration).

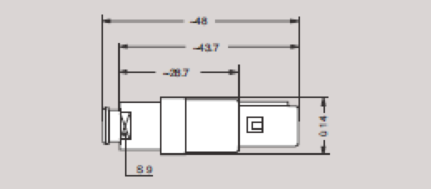


Characteristics	Value	Standards
Test voltage (rms)	1.5 kV	IEC 60512-2 test 4a
Rated voltage (rms)	250 V	IEC 60601/UL 60601-1
Average retention force when pulling on the cable 1N = 0.102 kg	90 N	IEC 60512-8 test 15f

Characteristics	Value	Standards
Cable retention force (depends on cable construction) 1N = 0.102 kg	50 – 150 N	IEC 60512-9 test 17c
Endurance (latching)	> 2000 cycles	IEC 60512-5 test 9a
Working temperature range (PSU)	-50/+150°C	–
UL file number	E242949	–

PA● Straight plug, key (H or G), with cable collet and nut for fitting a bend relief

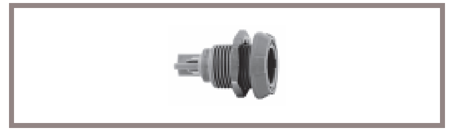


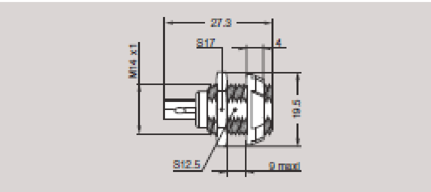


Part Number	Cable ø min	Cable ø max
PAH.N0.3GL.LC52GZ	4.0	5.2
PAH.N0.3GL.LC65GZ	5.3	6.5
PAG.N0.4GL.AC52GZ	4.0	5.2
PAG.N0.4GL.AC65GZ	5.3	6.5

Note: The bend relief must be ordered separately (see page 22).

PK● Fixed socket, key (H or G), with two nuts (back panel mounting)





Part Number
PKH.N0.3GL.AG
PKG.N0.4GL.LG

Note: For front nut colour replace last digit (see table page 20). Not available with print contact.

Note: all dimensions are in millimeters

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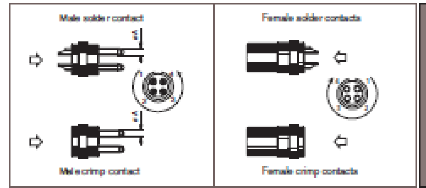
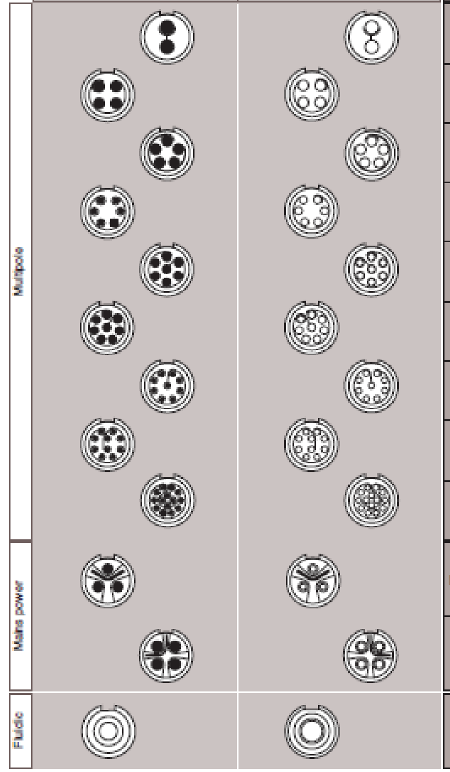
REDEL

Insert configuration





Reference	Number of contacts	Contact ø (mm)	Solder bucket ø (mm)[5]	Crimp bucket ø (mm)[5]	Contact type: Solder	Crimp	Print (straight)	Print (elbow)	Test voltage (kV rms)[1] Contact-contact	Air clearance min[2] (mm) Creepage distance min[3] (mm)	Rated current (A)
M0.2	2	1.3	1.10	1.4	•	•	•	•	1.20	1.30	10.0
M0.4	4	0.9	0.80	1.1	•	•	•	•	1.20	1.20	8.0
M0.5	5	0.9	0.80	1.1	•	•	•	•	1.05	0.80	7.0
M0.6	6	0.7	0.60	0.8	•	•	•	•	1.05	0.85	6.0
M0.7	7	0.7	0.60	0.8	•	•	•	•	1.05	0.85	5.0
M0.8	8	0.7	0.60	0.8	•	•	•	•	1.05	0.80	5.0
M0.9	9	0.5	0.45	-	•	-	•	•	0.85	0.80	3.0
M1.0	10	0.5	0.45	-	•	-	•	•	0.85	0.45	3.0[4]
M1.4	14	0.5	0.45	-	•	-	•	•	0.60	0.50	2.0
N0.3[6]	3	0.9	1.40	-	•	-	-	-	1.50	2.00 / 6.00	9.0[6]
N0.4	4	0.9	1.40	-	•	-	-	-	2.50	1.30 / 3.50	8.0
A0.1	1 Fluidic (monotube) up to 2 bars										

Note: 1) depending on specific application and related standard, more restrictive operating voltage may apply. We suggest operating voltage = 1/3 test voltage, see page 68.
2) shortest distance in air between two conductive parts.
3) shortest distance along the surface of the insulating material between two conductive parts.
4) for PPG and PXG (with 10 contacts) electrical characteristics, please contact factory.
5) for a given AWG, the diameter of some stranded conductor design is larger than the solder cup diameter (see page 69).
6) UL file number: E242949

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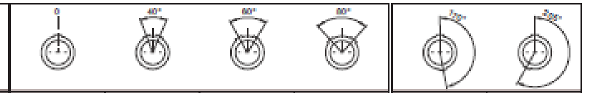
REDEL

Alignment key

Verify the third digit of the part number in order to select the right keying.
The standard keying is «G» coded.



Keying (plug front view)						
Reference	G	A	B	C	H	J
Contact type for plug	male	male	male	male	female	female
Contact type for socket	female	female	female	female	male	male
Number of contacts	2 to 14				8, 10 or 14	

Outer shell material

Material	Ref.	Colour	Temperature
PEI	S	Grey	-50° / +170°C
PEI	T	Black	
PSU	G	Grey	-50° / +150°C
PSU	N	Black	

Note: for extensive sterilization use PEI. For complete connector in PEI (collet nut, front nut or flange also in PEI), available colours are grey or black only. Use colour coding grey or black according to colour coding table (see below)

Contact type

Select the type of contact: solder or crimp?

Plug

Type	Male	Female
solder	A	L[1]
crimp	C	-

Socket

Type	Male	Female
solder	A[1]	L
crimp	-	M
print	D	N
print 90°	V	V

Note: 1) only for H and J keying with 8, 10 or 14 contacts
For complete connector in PEI (collet nut, front nut or flange also in PEI), available colours are grey or black only. Use colour coding grey or black according to colour coding table (see below)

When should I use crimp rather than solder contacts ?

Soldering

- recommended for small volumes
- requires little amount of tooling (soldering iron)
- requires more time

Crimping

- recommended for large volumes
- no heat is required to make the connection
- for contacts with high density
- for use in high temperature environment
- requires extra tooling (crimping tools)

Colour coding

	Colours: grey	blue	yellow	black	red	green	white
Reference	G	A	J	N	R	V	B
RAL code	7001	5002	1016	9005	3020	6024	9003

Note: the RAL colours are indicative and depend on raw material and production process. Colour may differ.

Easy identification with the assistance of colour coding.
Outershell is only available in grey or black.

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Appendix J

Arduino code

```
#define SENSITIVITY 4

#include "SevSeg.h"
SevSeg sevsegA; //Instantiate a seven segment controller object
SevSeg sevsegB; //Instantiate a seven segment controller object


//From bildr article: http://bildr.org/2012/08/rotary-encoder-arduino/
const int encoderAPin1 = 19;               // rotary pin A (interrupted)
const int encoderAPin2 = 18;               // rotary pin B (interrupted)
volatile int lastEncodedA = 0;
volatile long encoderValueA = 0;
long lastencoderValueA = 0;
int lastMSBA = 0;
int lastLSBA = 0;

const int encoderBPin1 = 21;               // rotary pin A (interrupted)
const int encoderBPin2 = 20;               // rotary pin B (interrupted)
volatile int lastEncodedB = 0;
volatile long encoderValueB = 0;
long lastencoderValueB = 0;
int lastMSBB = 0;
int lastLSBB = 0;

//Speaker for cut mode and coagulation mode


const byte pinBuz=13;
unsigned long lastPeriodStart;
const int onDuration=1000;
const int periodDuration=6000;

const int cutmodePin = 38; // Push-button cut mode
const int coagmodePin = 39; // Push-button coag mode


// mode pins
const int switch1 = 30;
const int switch2 = 32;
const int switch3 = 34 ;
int switchMode = 0;     // to store mode
int switchModeOld = 0;     // to store old mode
int switchModeOffset = 0;    // to store mode offset

const int micromodeLED =  31;
const int moderatemodeLED =  33;
const int macromodeLED =  35;

// encoder interrupt handler
void updateEncoderA(){
  int MSB = digitalRead(encoderAPin1); //MSB = most significant bit
  int LSB = digitalRead(encoderAPin2); //LSB = least significant bit

  int encoded = (MSB << 1) |LSB; //converting the 2 pin value to single
number
  int sum  = (lastEncodedA << 2) | encoded; //adding it to the previous
encoded value

  if(sum == 0b1101 || sum == 0b0100 || sum == 0b0010 || sum == 0b1011)
encoderValueA ++;
  if(sum == 0b1110 || sum == 0b0111 || sum == 0b0001 || sum == 0b1000)
encoderValueA --;

  // limit to >=0 and <= SESITIVITY*20
  if (encoderValueA < 0) encoderValueA = 0;
  if (encoderValueA > SENSITIVITY * 20) encoderValueA = SENSITIVITY * 20;

  lastEncodedA = encoded; //store this value for next time
}


// encoder interrupt handler
void updateEncoderB(){
  int MSB = digitalRead(encoderBPin1); //MSB = most significant bit
  int LSB = digitalRead(encoderBPin2); //LSB = least significant bit

  int encoded = (MSB << 1) |LSB; //converting the 2 pin value to single
number
  int sum  = (lastEncodedB << 2) | encoded; //adding it to the previous
encoded value

  if(sum == 0b1101 || sum == 0b0100 || sum == 0b0010 || sum == 0b1011)
encoderValueB ++;
  if(sum == 0b1110 || sum == 0b0111 || sum == 0b0001 || sum == 0b1000)
encoderValueB --;

 // limit to >=0 and <= SESITIVITY*20
  if (encoderValueB < 0) encoderValueB = 0;
  if (encoderValueB > SENSITIVITY * 20) encoderValueB = SENSITIVITY * 20;

  lastEncodedB = encoded; //store this value for next time
}


void setup() {
  bool resistorsOnSegments = false; // 'false' means resistors are on digit
pins
  byte hardwareConfig = COMMON_ANODE; // See README.md for options
  bool updateWithDelays = false; // Default. Recommended
  bool leadingZeros = false; // Use 'true' if you'd like to keep the
leading zeros
  byte numDigits = 2;

  // digit A
  byte digitPinsA[] = {2, 3};
  byte segmentPinsA[] = {6, 7, 8, 9, 10, 11, 12, 37};

  // digit B
  byte digitPinsB[] = {4, 5};
  byte segmentPinsB[] = {22, 23, 24, 25, 26, 27, 28, 29};

   sevsegA.begin(hardwareConfig, numDigits, digitPinsA, segmentPinsA,
resistorsOnSegments, updateWithDelays, leadingZeros);
   sevsegA.setBrightness(5);
   sevsegA.setNumber('MM', 1);
   sevsegA.refreshDisplay();

   sevsegB.begin(hardwareConfig, numDigits, digitPinsB, segmentPinsB,
resistorsOnSegments, updateWithDelays, leadingZeros);
   sevsegB.setBrightness(100);
   sevsegB.setNumber('MM', 1);
   sevsegB.refreshDisplay();

  // encoders
   pinMode(encoderAPin1, INPUT_PULLUP);
   pinMode(encoderAPin2, INPUT_PULLUP);
   pinMode(encoderBPin1, INPUT_PULLUP);
   pinMode(encoderBPin2, INPUT_PULLUP);

  //call updateEncoder() when any high/low changed seen
  //on interrupt 0 (pin 2), or interrupt 1 (pin 3)
    attachInterrupt(digitalPinToInterrupt(encoderAPin1), updateEncoderA,
CHANGE);
    attachInterrupt(digitalPinToInterrupt(encoderAPin2), updateEncoderA,
CHANGE);
    attachInterrupt(digitalPinToInterrupt(encoderBPin1), updateEncoderB,
CHANGE);
    attachInterrupt(digitalPinToInterrupt(encoderBPin2), updateEncoderB,
CHANGE);

  // mode pins
   pinMode(switch1, INPUT_PULLUP);
   pinMode(switch2, INPUT_PULLUP);
   pinMode(switch3, INPUT_PULLUP);

   //LEDs of sub-groups

   pinMode(micromodeLED, OUTPUT);
   pinMode(moderatemodeLED, OUTPUT);
   pinMode(macromodeLED, OUTPUT);

   // Buzzer for coag and cut mode

Serial.begin(9600); // Opens Serial communication
pinMode(pinBuz,OUTPUT); //Defines pinBuz as an Output
  pinMode(cutmodePin,INPUT_PULLUP); // Defines cut mode button as an input
  pinMode(coagmodePin,INPUT_PULLUP); // Defines coag mode as an input

}

void loop() {

  // read buttons and set mode
  if (digitalRead(switch1) == LOW) {
    sevsegA.refreshDisplay(); // Must run repeatedly
    sevsegB.refreshDisplay(); // Must run repeatedly
      // set to mode 1
      switchMode = 1;
      switchModeOffset = 10;
      encoderValueA = 0;
      encoderValueB = 0;
      switchModeOld = switchMode;

  }
  else if (digitalRead(switch2) == LOW) {
    sevsegA.refreshDisplay(); // Must run repeatedly
    sevsegB.refreshDisplay(); // Must run repeatedly
      // set to mode 2
      switchMode = 2;
      switchModeOffset = 30;
      encoderValueA = 0;
      encoderValueB = 0;
      switchModeOld = switchMode;
```

```
}
else if (digitalRead(switch3) == LOW) {
  sevsegA.refreshDisplay(); // Must run repeatedly
  sevsegB.refreshDisplay(); // Must run repeatedly
    // set to mode 3
    switchMode = 3;
    switchModeOffset = 50;
    encoderValueA = 0;
    encoderValueB = 0;
    switchModeOld = switchMode;

  }


 //LED output for sub-groups


 if (switchMode==1){

 digitalWrite(micromodeLED, HIGH);
 } else {
 // turn micro mode LED off:
 digitalWrite(micromodeLED, LOW);
 }

 if (switchMode==2){

 digitalWrite(moderatemodeLED, HIGH);
 } else {
 // turn micro mode LED off:
 digitalWrite(moderatemodeLED, LOW);
 }

 if (switchMode==3){

 digitalWrite(macromodeLED, HIGH);
 } else {
 // turn micro mode LED off:
 digitalWrite(macromodeLED, LOW);

}

if (switchMode != switchModeOld) {
  // mode has changed, so set encoderValues to 0
  encoderValueA = 0;
  encoderValueB = 0;
  }



  //Buzzer frequency differences of cut mode and coag mode

      int cutmode; // To save the last logic state of the button
      int coagmode; // To save the last logic state of the button
      cutmode = digitalRead(cutmodePin); //Put the reading value of the
switch on cutmode pin
      //Serial.println(cutmode); //Shows the logic state of the input on
Serial Monitor
      coagmode = digitalRead(coagmodePin); //Put the reading value of the
switch on coagmode pin
      //Serial.println(coagmode); //Shows the logic state of the input on
Serial Monitor

      if (cutmode == LOW) // Pressed button, logic State HIGH (5V)
      {
        digitalWrite(pinBuz,HIGH); //Switch pressed, buzzer on
        delayMicroseconds(200);
        sevsegA.refreshDisplay(); // Must run repeatedly
        sevsegB.refreshDisplay(); // Must run repeatedly
        digitalWrite(pinBuz,LOW);
        delayMicroseconds(200);
        sevsegA.refreshDisplay(); // Must run repeatedly
        sevsegB.refreshDisplay(); // Must run repeatedly
       }

      //Coag mode pin
      if (coagmode == LOW) // Pressed button, logic State HIGH (5V)
      {
        digitalWrite(pinBuz,HIGH); //Switch pressed, buzzer on
        delayMicroseconds(400);
        sevsegA.refreshDisplay(); // Must run repeatedly
        sevsegB.refreshDisplay(); // Must run repeatedly
        digitalWrite(pinBuz,LOW);
        delayMicroseconds(400);
        sevsegA.refreshDisplay(); // Must run repeatedly
        sevsegB.refreshDisplay(); // Must run repeatedly
      }

  // read and set displays, with correct offsets
  int displayValueA = encoderValueA / SENSITIVITY + switchModeOffset;
  int displayValueB = encoderValueB / SENSITIVITY + switchModeOffset;

  // mode 1: 10-30
  // mode 2: 30-50
  // mode 3: 50-70

  if (switchMode != 0) {
    // only display new value when a mode is chosen
    sevsegA.setNumber(displayValueA, 1);
    sevsegB.setNumber(displayValueB, 1);
  }


  // refresh displays
  sevsegA.refreshDisplay(); // Must run repeatedly
  sevsegB.refreshDisplay(); // Must run repeatedly
}

/// END ///
```

Appendix K

material of high frequency generator

General information

Designation

Acrylonitrile Butadiene Styrene (Injection Molding, platable)

Tradenames

Abistir, Abscom, Absolac, Abstron, Accucomp, Alcom, Allen, Altech, Anjacom, Ashlene, Astalac, Badalac, Bulksam, Certene, Cevian, Cevian-V, Cheng, Claradex, Clariant, Colorrx, Cycolac, Delta, Diamond, Dynacom, Edgetek, Electrafil, Elix, Encom, Epitec, Estadiene, Evosource, Excelloy, Ghaed, Hival, Hylac, Isopak, Jackdaw, Jamplast, Kaneka, Kralastic, Kumho, Kumhosunny, LNP Stat-Loy, Lustran, Magnum, Malecca, Micholac, Neftekhim, Next, Next Signature, Nexus, Nilac, Novakral, Novalloy-E, Novodur, Omnitech, Permastat, Plaslube, Polimaxx, Polyabs, Poly-Elek, Polylac, Polylan, Polyman, Ponacom, Pryme, Radici, Ramshine, Retelan, Ronfalin, Rotec, Royalite, Santac, Sattler, Saxalac, Shinko-Lac, Sicoflex, Sindustris, Sinkral, Spartech, Starex, Stylac, Tairilac, Taitalac, Tarodur, Techno, Tenogel, Terez, Terluran, Toyolac, Trilac, Tynab, Tyne, Veroplas, Zgpc

Typical uses

Safety helmets; camper tops; automotive instrument panels and other interior components; pipe fittings; home-security devices and housings for small appliances; communications equipment; business machines; plumbing hardware; automobile grilles; wheel covers; mirror housings; refrigerator liners; luggage shells; tote trays; mower shrouds; boat hulls; large components for recreational vehicles; weather seals; glass beading; refrigerator breaker strips; conduit; pipe for drain-waste-vent (DWV) systems.

Composition overview

Compositional summary

Block terpolymer of acrylonitrile (15-35%), butadiene (5-30%), and Styrene (40-60%).

Material family	Plastic (thermoplastic, amorphous)
Base material	ABS (Acrylonitrile butadiene styrene)
Polymer code	ABS

Composition detail (polymers and natural materials)

Polymer		100			%

Price

Price	*	2,15	-	2,54	EUR/kg
Price per unit volume	*	2,24e3	-	2,72e3	EUR/m^3

Physical properties

Density		1,04e3	-	1,07e3	kg/m^3

Mechanical properties

Young's modulus		2,21	-	2,62	GPa
Yield strength (elastic limit)		42	-	46	MPa
Tensile strength		42	-	46	MPa
Elongation	*	15,3	-	20,9	% strain
Compressive modulus	*	2,21	-	2,62	GPa
Compressive strength	*	52,8	-	58,2	MPa
Flexural modulus		2,34	-	2,68	GPa
Flexural strength (modulus of rupture)		72,4	-	79,3	MPa
Shear modulus	*	0,79	-	0,937	GPa
Bulk modulus	*	3,86	-	4,06	GPa
Poisson's ratio	*	0,391	-	0,407	
Shape factor		5,6			

Hardness - Vickers	*	13	-	15	HV
Hardness - Rockwell M	*	66	-	72	
Hardness - Rockwell R		103	-	109	
Fatigue strength at 10^7 cycles	*	14	-	18,2	MPa
Mechanical loss coefficient (tan delta)	*	0,0153	-	0,0181	

Impact & fracture properties

Fracture toughness		1,9	-	2,1	MPa.m^0.5
Impact strength, notched 23 °C		10,7	-	23,1	kJ/m^2
Impact strength, notched -30 °C		4,88	-	10,9	kJ/m^2
Impact strength, unnotched 23 °C		110	-	132	kJ/m^2
Impact strength, unnotched -30 °C		64,3	-	77,2	kJ/m^2

Thermal properties

Glass temperature		100	-	110	°C
Heat deflection temperature 0.45MPa		102	-	106	°C
Heat deflection temperature 1.8MPa		88	-	106	°C
Maximum service temperature		63	-	77	°C
Minimum service temperature		-45	-	-35	°C
Thermal conductivity	*	0,254	-	0,264	W/m.°C
Specific heat capacity	*	1,68e3	-	1,75e3	J/kg.°C
Thermal expansion coefficient		84,6	-	95,4	µstrain/°C

Electrical properties

Electrical resistivity		3,3e21	-	3e22	µohm.cm
Dielectric constant (relative permittivity)		2,8	-	3,2	
Dissipation factor (dielectric loss tangent)		0,003	-	0,006	
Dielectric strength (dielectric breakdown)		16,5	-	21,7	MV/m
Comparative tracking index		400	-	600	V

Magnetic properties

Magnetic type	Non-magnetic

Optical properties

Refractive index		1,53	-	1,54	
Transparency		Opaque			

Critical materials risk

Contains >5wt% critical elements?	No

Absorption & permeability

Water absorption @ 24 hrs	*	0,2	-	0,45	%
Water vapor transmission		2,04	-	3,2	g.mm/m².day
Permeability (O2)		47,3	-	78,5	cm³.mm/m².day.atm

Processing properties

Polymer injection molding	Excellent
Polymer extrusion	Acceptable
Polymer thermoforming	Excellent

Linear mold shrinkage		0,5	-	0,8	%
Melt temperature		137	-	260	°C
Mold temperature		50	-	70	°C
Molding pressure range		55	-	172	MPa

Durability

Water (fresh)	Excellent
Water (salt)	Excellent
Weak acids	Excellent
Strong acids	Limited use
Weak alkalis	Acceptable
Strong alkalis	Excellent
Organic solvents	Unacceptable
Oxidation at 500C	Unacceptable
UV radiation (sunlight)	Poor
Flammability	Highly flammable

Primary production energy, CO2 and water

Embodied energy, primary production		90,6	-	99,9	MJ/kg

Sources
95 MJ/kg (Kemna et al. 2005); 95 MJ/kg (Franklin Associates, 2008); 95.3 MJ/kg (PlasticsEurope, 2010); 95.3 MJ/kg (Hammond and Jones, 2008)

CO2 footprint, primary production		3,45	-	3,81	kg/kg

Sources
3.32 kg/kg (Kemna et al. 2005); 3.76 kg/kg (Hammond and Jones, 2008); 3.8 kg/kg (PlasticsEurope, 2010)

Water usage	*	167	-	185	l/kg

Processing energy, CO2 footprint & water

Polymer extrusion energy	*	5,81	-	6,42	MJ/kg
Polymer extrusion CO2	*	0,436	-	0,481	kg/kg
Polymer extrusion water	*	4,82	-	7,23	l/kg
Polymer molding energy	*	18,3	-	20,2	MJ/kg
Polymer molding CO2	*	1,37	-	1,52	kg/kg
Polymer molding water	*	12,4	-	18,6	l/kg
Coarse machining energy (per unit wt removed)	*	0,974	-	1,08	MJ/kg
Coarse machining CO2 (per unit wt removed)	*	0,0731	-	0,0808	kg/kg
Fine machining energy (per unit wt removed)	*	5,47	-	6,04	MJ/kg
Fine machining CO2 (per unit wt removed)	*	0,41	-	0,453	kg/kg
Grinding energy (per unit wt removed)	*	10,5	-	11,6	MJ/kg
Grinding CO2 (per unit wt removed)	*	0,784	-	0,867	kg/kg

Recycling and end of life

Recycle		✓			
Embodied energy, recycling	*	30,7	-	34	MJ/kg
CO2 footprint, recycling	*	1,17	-	1,29	kg/kg
Recycle fraction in current supply		3,8	-	4,2	%
Downcycle		✓			
Combust for energy recovery		✓			
Heat of combustion (net)	*	37,6	-	39,5	MJ/kg
Combustion CO2	*	3,06	-	3,22	kg/kg

Landfill	✓
Biodegrade	✗

Notes

Warning

HDT 1.8 covers unannealed to annealed samples. HDT 0.45 is for annealed

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material of REDEL connector

General information

Designation

Polysulfone (Extrusion and Injection Molding)

Tradenames

Altech, Dynapath, Hifill, Lasulf, LNP Colorcomp, Starglas, Thermalux, Udel, Ultrason, Vampsulf

Typical uses

Medical components; food processing equipment; electrical and electronics; valve bodies; under-bonnet components; housings.

Composition overview

Compositional summary

(C6H4-SO2-C6H4-O-C6H4-CH3-C-CH3-C6H4-O)n

Material family	Plastic (thermoplastic, amorphous)
Base material	PSU (Polysulfone)
Polymer code	PSU

Composition detail (polymers and natural materials)

Polymer	100	%

Price

Price	*	8,88	-	12,8	EUR/kg
Price per unit volume	*	1,09e4	-	1,6e4	EUR/m^3

Physical properties

Density		1,23e3	-	1,25e3	kg/m^3

Mechanical properties

Young's modulus		2,62	-	2,76	GPa
Yield strength (elastic limit)		75,5	-	83,3	MPa
Tensile strength	*	94,4	-	104	MPa
Elongation		40	-	80	% strain
Compressive modulus	*	2,62	-	2,76	GPa
Compressive strength	*	125	-	280	MPa
Flexural modulus		2,48	-	2,61	GPa
Flexural strength (modulus of rupture)		115	-	127	MPa
Shear modulus	*	0,939	-	0,989	GPa
Bulk modulus	*	4,2	-	4,41	GPa
Poisson's ratio	*	0,388	-	0,404	
Shape factor		4,4			
Hardness - Vickers	*	23	-	25	HV
Hardness - Rockwell M		66	-	73	
Hardness - Rockwell R	*	101	-	111	
Fatigue strength at 10^7 cycles	*	34,8	-	45,3	MPa
Mechanical loss coefficient (tan delta)	*	0,0145	-	0,0153	

Impact & fracture properties

Fracture toughness	*	1,89	-	4,69	MPa.m^0.5

Impact strength, notched 23 °C		5,17	-	5,7	kJ/m^2
Impact strength, notched -30 °C		4,95	-	5,46	kJ/m^2
Impact strength, unnotched 23 °C		590	-	600	kJ/m^2
Impact strength, unnotched -30 °C		154	-	185	kJ/m^2

Thermal properties

Glass temperature		186	-	192	°C
Heat deflection temperature 0.45MPa		161	-	205	°C
Heat deflection temperature 1.8MPa		150	-	193	°C
Maximum service temperature	*	147	-	172	°C
Minimum service temperature	*	-47	-	-27	°C
Thermal conductivity	*	0,277	-	0,288	W/m.°C
Specific heat capacity	*	1,5e3	-	1,56e3	J/kg.°C
Thermal expansion coefficient		54,7	-	56,9	µstrain/°C

Electrical properties

Electrical resistivity		3,3e21	-	3e22	µohm.cm
Dielectric constant (relative permittivity)		3,4	-	3,65	
Dissipation factor (dielectric loss tangent)		7,6e-4	-	8,4e-4	
Dielectric strength (dielectric breakdown)	*	16,3	-	19,5	MV/m
Comparative tracking index		125	-	180	V

Magnetic properties

Magnetic type	Non-magnetic

Optical properties

Refractive index	1,63	-	1,64	
Transparency	Transparent			

Critical materials risk

Contains >5wt% critical elements?	No

Absorption & permeability

Water absorption @ 24 hrs	*	0,27	-	0,33	%
Water vapor transmission		5,37	-	35,9	g.mm/m^2.day
Permeability (O2)		59,3	-	138	cm^3.mm/m^2.day.atm

Processing properties

Polymer injection molding		Acceptable			
Polymer extrusion		Acceptable			
Polymer thermoforming		Acceptable			
Linear mold shrinkage		0,5	-	0,7	%
Melt temperature		273	-	360	°C
Mold temperature		90	-	160	°C
Molding pressure range	*	34,4	-	138	MPa

Durability

Water (fresh)	Excellent
Water (salt)	Acceptable

Weak acids	Acceptable
Strong acids	Limited use
Weak alkalis	Excellent
Strong alkalis	Acceptable
Organic solvents	Unacceptable
Oxidation at 500C	Unacceptable
UV radiation (sunlight)	Fair
Flammability	Self-extinguishing

Primary production energy, CO2 and water

Embodied energy, primary production	*	182	-	201	MJ/kg
CO2 footprint, primary production	*	9,72	-	10,7	kg/kg
Water usage	*	372	-	411	l/kg

Processing energy, CO2 footprint & water

Polymer extrusion energy	*	6,02	-	6,66	MJ/kg
Polymer extrusion CO2	*	0,452	-	0,499	kg/kg
Polymer extrusion water	*	4,91	-	7,37	l/kg
Polymer molding energy	*	24,3	-	26,9	MJ/kg
Polymer molding CO2	*	1,83	-	2,02	kg/kg
Polymer molding water	*	15	-	22,4	l/kg
Coarse machining energy (per unit wt removed)	*	1,91	-	2,11	MJ/kg
Coarse machining CO2 (per unit wt removed)	*	0,143	-	0,158	kg/kg
Fine machining energy (per unit wt removed)	*	14,8	-	16,4	MJ/kg
Fine machining CO2 (per unit wt removed)	*	1,11	-	1,23	kg/kg
Grinding energy (per unit wt removed)	*	29,1	-	32,2	MJ/kg
Grinding CO2 (per unit wt removed)	*	2,19	-	2,42	kg/kg

Recycling and end of life

Recycle		✓			
Embodied energy, recycling	*	61,8	-	68,3	MJ/kg
CO2 footprint, recycling	*	3,29	-	3,64	kg/kg
Recycle fraction in current supply		0,1			%
Downcycle		✓			
Combust for energy recovery		✓			
Heat of combustion (net)	*	33,3	-	35	MJ/kg
Combustion CO2	*	2,94	-	3,09	kg/kg
Landfill		✓			
Biodegrade		✗			

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material of cable gland

General information

Designation

Polypropylene (Copolymer, 10% talc)

Tradenames

Bergaprop; Acclear; Accpro; Acctuf; Achieve; A[illegible]lene; Adflex; Adpro; Akrolen; Alphacan; Aplax; Appryl; Aqualoy; Arcoplen; Armlen; Arpak; Arpro; Astryn; Atofina Polypropylene; Azdel; Bapolene; Bicor; Borstar; Bras-Tec; Bynel; Capilene; Carboplene; Carmelstat; Cefor; Clyrell; Compel; Compotene; Comshield; Corton; Cosmoplene; Cotene; Cuyolen; Daelimpoly; Dafnelen; Daicelpp; Danapro; Daplen; Denilen; Dep; Dexflex; Digilyte; Dow; El-Pro; Eltexp; Endura; Epsilon; Equistarpp; Escalloy; Esdash; Estaprop; Eticourt; Extron; Exxpol Enhance; Exxtral; Ferrexnewfoamer; Ferrolene; Fiberfil; Finapro; Flametec; Formolene; Fortilene; Grand Polpro; Haiplen; Halene; Hi-Fax; Hi-Glass; Hishiplate; Hms; Hopelen; Hostacen; Hostacom; Hostalen Pp; Hyosung Pp; Hypro; Inertec; Inspire; Isplen; Jazz; Kelburon; Kopelen; Koylene; Latene; Lupol; Luvogard; Mafill; Magnacomp; Malen-P; Marlex; Maxbatch; Maxpro; Maxxam; Metallyte; Metocene; Microthene; Moplen; Mosten; Multipro; Neviprop; Newstren; Niplene; Nissen; Noblen; Nortuff; Novatec; Novolen; Oleform; Olehard; Olesafe; Oppalytetrespaphan; Osstyrol; Palprop; Percom; Permastat; Petoplen; Petrothene; Piolen; Plastiflam; Polene; Polifor; Polycom; Polyfill; Polyflam; Polyfort; Polystone; Polyvance; Ponalen; Pre-Elec; Procom; Pro-Fax; Prolen; Propak; Propilven; Propylux; Protec; Proteus; Ranplen; Refax; Repol; Repolen; Reptol; Retpol; Rexene; Rotothon; Sanalite; Sanren; Saxene; Scolefin; Seetec; Sequel; Simona; Sinpolene; Spolen; Stamax; Stamylan; Starpylen; Strandfoam; Sunlet; Syntegum; Taboren; Taffen; Taipolene; Tairipro; Talcoprene; Tatren; Tecafine; Teknoplen; Terez; Thermolen; Thermylene; Tipplen; Topilene; Torayfan; Tracolen; Trapylen; Trilen; Trilene; Umastyr; Valmax; Valtec; Vamplem; Vylene; Vyon; Wintec; Wpp; Xenopren; Yuhwa; Zeral; Accutech; Albis PP; Muehlstein Compounds; Delta; Ecoplast Pp; Primefin; Rhetech PP; Spartech Polycom; Matrixx; Tipcolene

Typical uses

Furniture; Automotive Interior Parts; Automotive Under the Hood; General Purpose; Electrical; Wire & Cable Applications; Automotive Interior Trim; Automotive Instrument Panel; Buckets; bowls; general mechanical parts; bottle crates; toys; medical components; washing machine drums; pipes; battery cases; bottles; bottle caps; bumpers; films for packaging; fibers for carpeting and artificial sports surfaces.

Composition overview

Compositional summary

Copolymer from propylene and max. 15 wt% ethylene or other comonomer(s) + 10% talc filler

Material family	Plastic (thermoplastic, semi-crystalline)	
Base material	PP (Polypropylene)	
% filler (by weight)	10	%
Filler/reinforcement	Mineral	
Filler/reinforcement form	Particulate	
Polymer code	PP-MD10	

Composition detail (polymers and natural materials)

Polymer	90	%
Talc	10	%

Price

Price	*	1,92	-	2,03	EUR/kg
Price per unit volume	*	1,84e3	-	1,99e3	EUR/m^3

Physical properties

Density		956	-	977	kg/m^3

Mechanical properties

Young's modulus		1,07	-	1,27	GPa

Yield strength (elastic limit)		23,7	-	27,6	MPa
Tensile strength		14,1	-	17,2	MPa
Elongation		30,5	-	63,3	% strain
Elongation at yield		9,77	-	10,6	% strain
Compressive modulus	*	1,07	-	1,27	GPa
Compressive strength	*	29,9	-	31,5	MPa
Flexural modulus		1,33	-	1,58	GPa
Flexural strength (modulus of rupture)		27,3	-	36,3	MPa
Shear modulus	*	0,413	-	0,424	GPa
Bulk modulus	*	1,83	-	1,88	GPa
Poisson's ratio	*	0,391	-	0,399	
Shape factor		5			
Hardness - Vickers	*	7	-	8	HV
Hardness - Rockwell M	*	40	-	45	
Hardness - Rockwell R		60	-	71	
Hardness - Shore D		68	-	71	
Hardness - Shore A		91	-	95	
Fatigue strength at 10^7 cycles	*	6,09	-	6,4	MPa
Mechanical loss coefficient (tan delta)	*	0,035	-	0,0368	

Impact & fracture properties

Fracture toughness	*	1,08	-	1,14	MPa.m^0.5
Impact strength, notched 23 °C		6,48	-	10,9	kJ/m^2
Impact strength, notched -30 °C		1,94	-	3,1	kJ/m^2
Impact strength, unnotched 23 °C		79,7	-	95,6	kJ/m^2
Impact strength, unnotched -30 °C		33,2	-	34,9	kJ/m^2

Thermal properties

Melting point	*	156	-	165	°C
Glass temperature		-24	-	-16	°C
Heat deflection temperature 0.45MPa		89,9	-	108	°C
Heat deflection temperature 1.8MPa		47,2	-	63,4	°C
Vicat softening point	*	133	-	154	°C
Maximum service temperature	*	71,8	-	89,2	°C
Minimum service temperature	*	-25	-	-10	°C
Thermal conductivity	*	0,234	-	0,24	W/m.°C
Specific heat capacity	*	1,79e3	-	1,83e3	J/kg.°C
Thermal expansion coefficient		98,7	-	101	µstrain/°C

Electrical properties

Electrical resistivity	*	7,07e23	-	7,21e23	µohm.cm
Dielectric constant (relative permittivity)	*	2,25	-	2,35	
Dissipation factor (dielectric loss tangent)	*	0,00294	-	0,00306	
Dielectric strength (dielectric breakdown)	*	19,6	-	20,4	MV/m
Comparative tracking index		600			V

Magnetic properties

Magnetic type	Non-magnetic

Optical properties

Transparency	Opaque

Critical materials risk

Contains >5wt% critical elements?	No

Absorption & permeability

Water absorption @ 24 hrs		0,0195	-	0,0205	%

Processing properties

Polymer injection molding		Excellent			
Polymer extrusion		Limited use			
Polymer thermoforming		Acceptable			
Linear mold shrinkage		1,12	-	1,41	%
Melt temperature		197	-	247	°C
Mold temperature		24,7	-	51,5	°C
Molding pressure range		3,33	-	7,8	MPa

Durability

Water (fresh)	Excellent
Water (salt)	Excellent
Weak acids	Excellent
Strong acids	Excellent
Weak alkalis	Excellent
Strong alkalis	Excellent
Organic solvents	Excellent
Oxidation at 500C	Unacceptable
UV radiation (sunlight)	Poor
Flammability	Highly flammable

Notes

Currently NOT UL tested but expected to pass the HB test

Primary production energy, CO2 and water

Embodied energy, primary production	*	65,5	-	72,3	MJ/kg
CO2 footprint, primary production	*	2,95	-	3,25	kg/kg
Water usage	*	34,8	-	38,5	l/kg

Processing energy, CO2 footprint & water

Polymer extrusion energy	*	5,91	-	6,53	MJ/kg
Polymer extrusion CO2	*	0,443	-	0,49	kg/kg
Polymer extrusion water	*	4,86	-	7,29	l/kg
Polymer molding energy	*	21,1	-	23,3	MJ/kg
Polymer molding CO2	*	1,58	-	1,75	kg/kg
Polymer molding water	*	13,6	-	20,4	l/kg
Coarse machining energy (per unit wt removed)	*	0,777	-	0,858	MJ/kg
Coarse machining CO2 (per unit wt removed)	*	0,0583	-	0,0644	kg/kg
Fine machining energy (per unit wt removed)	*	3,49	-	3,86	MJ/kg
Fine machining CO2 (per unit wt removed)	*	0,262	-	0,289	kg/kg
Grinding energy (per unit wt removed)	*	6,51	-	7,19	MJ/kg

Grinding CO2 (per unit wt removed)	*	0,488	-	0,54	kg/kg

Recycling and end of life

Recycle		✓			
Embodied energy, recycling	*	22,2	-	24,6	MJ/kg
CO2 footprint, recycling	*	1	-	1,11	kg/kg
Recycle fraction in current supply		0,1			%
Downcycle		✓			
Combust for energy recovery		✓			
Heat of combustion (net)	*	39,6	-	41,6	MJ/kg
Combustion CO2	*	2,76	-	2,9	kg/kg
Landfill		✓			
Biodegrade		✗			

Links

ProcessUniverse

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Appendix K

material of button foil and seals

General information

Designation

Thermoplastic Vulcanizate

Tradenames

Actymer, Alfater, Dryflex, Elastron, Enflex, Epigum, Excelink, Ezprene, Flexiteq, Forprene, Gelast, Geolast, Innoprene, Invision, Kebaflex, Keyflex, K-Prene, Micriflex, Milastomer, Neoplast, Novalast, Onflex-V, Primoprene, Salflex, Santoprene, Sarlink, Solplast, Taroprene, Tectron, Tivilon, Tpsiv, Trexprene, Uniprene, Viprene, Vyram, Zeotherm

Typical uses

Construction Applications; Expansion Joint; Glazing; Industrial Applications; Profiles; Sheet; Tubing; Appliance Components; Automotive Applications; Hinges, Living; Overmolding; Blow Molding Applications; Diaphrams; Gaskets; General Purpose; Seals; Cable Jacketing; Hose, Garden; Weatherstripping; Pump Parts; Valves/Valve Parts; Foam; Medical Applications; Lawn and Garden Equipment; Marine Applications; Outdoor Applications; Fluid Handling; Irrigation Applications; Appliances; Connectors; Coverings, Protective; Housing, Electrical; Wheels; Automotive Interior Parts; Plumbing Parts; Automotive Exterior Parts; Grips, Flexible; Parts, Thin-walled; Sporting Goods; Tools, Power/Others; Closures; Containers, Food; Cookware, Microwave; Food Applications, Non-specific; Food Service Applications; Kitchenware; Consumer Applications; Hospital Goods; Hypodermic Syringe Parts; Medical Appliances; Prosthetics; Automotive Bumper; Automotive Exterior Trim; Belts/Belt Repair; Electrical/Electronic Applications; Household Goods; Insulation, Electronic; Panels, Reinforced; Piping; Toys; Business Equipment

Composition overview

Compositional summary

Blend of PP (~40%) and vulcanized EPDM rubber (~60%). EPDM particles encased in a continuous matrix of PP.

Material family	Elastomer (thermoplastic, TPE)
Base material	TPV (Thermoplastic vulcanizate)
Polymer code	TPV

Composition detail (polymers and natural materials)

Polymer		100			%

Price

Price	*	3,43	-	3,51	EUR/kg
Price per unit volume	*	3,22e3	-	3,45e3	EUR/m^3

Physical properties

Density		939	-	981	kg/m^3

Mechanical properties

Young's modulus		0,0158	-	0,0162	GPa
Yield strength (elastic limit)		3,9	-	4,1	MPa
Tensile strength		6,31	-	8,95	MPa
Tensile stress at 100% strain		2,5	-	3,71	MPa
Tensile stress at 300% strain		4,27	-	5,36	MPa
Elongation		428	-	550	% strain
Elongation at yield		53	-	57,1	% strain
Compressive modulus	*	0,0152	-	0,0168	GPa
Compressive strength	*	4,57	-	5,04	MPa
Flexural modulus		0,0257	-	0,027	GPa

Flexural strength (modulus of rupture)	*	15	-	18,9	MPa
Shear modulus	*	0,00525	-	0,00551	GPa
Shear strength	*	5,05	-	8,95	MPa
Poisson's ratio	*	0,48	-	0,495	
Shape factor		1,7			
Hardness - Vickers		1			HV
Hardness - Rockwell M	*	2	-	6	
Hardness - Rockwell R	*	2	-	6	
Hardness - Shore D	*	16	-	26	
Hardness - Shore A		65	-	75	
Fatigue strength at 10^7 cycles	*	2,53	-	3,58	MPa
Mechanical loss coefficient (tan delta)		0,08	-	0,1	
Compression set at 23°C		21,2	-	25,8	%
Compression set at 70°C		33,4	-	38,6	%
Compression set at 100°C		37,5	-	44,6	%
Tear strength		26,5	-	33,3	N/mm

Impact & fracture properties

Fracture toughness		0,405	-	0,462	MPa.m^0.5
Impact strength, notched 23 °C		590	-	600	kJ/m^2
Impact strength, notched -30 °C		590	-	600	kJ/m^2
Impact strength, unnotched 23 °C		590	-	600	kJ/m^2
Impact strength, unnotched -30 °C		590	-	600	kJ/m^2

Thermal properties

Melting point	*	144	-	164	°C
Glass temperature	*	-115	-	-99	°C
Maximum service temperature		130	-	140	°C
Minimum service temperature		-66	-	-56	°C
Thermal conductivity	*	0,118	-	0,128	W/m.°C
Specific heat capacity	*	1,8e3	-	1,86e3	J/kg.°C
Thermal expansion coefficient	*	263	-	277	µstrain/°C

Electrical properties

Electrical resistivity	*	4,3e23	-	6,6e24	µohm.cm
Dielectric constant (relative permittivity)		2,25	-	2,35	
Dissipation factor (dielectric loss tangent)	*	2,6e-4	-	4,4e-4	
Dielectric strength (dielectric breakdown)		19,5	-	20,3	MV/m
Comparative tracking index		600			V

Magnetic properties

Magnetic type	Non-magnetic

Optical properties

Transparency	Opaque

Critical materials risk

Contains >5wt% critical elements?	No

Absorption & permeability

Water absorption @ 24 hrs	*	0,044	-	0,0535	%
Water absorption @ sat	*	0,269	-	0,327	%
Humidity absorption @ sat	*	0,0809	-	0,0982	%
Water vapor transmission		0,451	-	0,521	g.mm/m².day
Permeability (O2)		469	-	542	cm³.mm/m².day.atm

Processing properties

Polymer injection molding		Acceptable			
Polymer extrusion		Excellent			
Polymer thermoforming		Acceptable			
Linear mold shrinkage		1,52	-	1,72	%
Melt temperature		191	-	213	°C
Mold temperature		7	-	44	°C
Molding pressure range		80,5	-	128	MPa

Durability

Water (fresh)	Excellent
Water (salt)	Excellent
Weak acids	Excellent
Strong acids	Excellent
Weak alkalis	Excellent
Strong alkalis	Excellent
Organic solvents	Limited use
Oils and fuels	Unacceptable
Oxidation at 500C	Unacceptable
UV radiation (sunlight)	Poor
Flammability	Highly flammable

Primary production energy, CO2 and water

Embodied energy, primary production	*	116	-	127	MJ/kg
CO2 footprint, primary production	*	5,74	-	6,33	kg/kg
Water usage	*	267	-	295	l/kg

Processing energy, CO2 footprint & water

Polymer extrusion energy	*	5,87	-	6,48	MJ/kg
Polymer extrusion CO2	*	0,44	-	0,486	kg/kg
Polymer extrusion water	*	4,85	-	7,27	l/kg
Polymer molding energy	*	19,9	-	22	MJ/kg
Polymer molding CO2	*	1,49	-	1,65	kg/kg
Polymer molding water	*	13,1	-	19,7	l/kg
Grinding energy (per unit wt removed)	*	1,43	-	1,58	MJ/kg
Grinding CO2 (per unit wt removed)	*	0,107	-	0,118	kg/kg

Recycling and end of life

Recycle		✓			
Embodied energy, recycling	*	39,2	-	43,3	MJ/kg
CO2 footprint, recycling	*	1,95	-	2,15	kg/kg

Recycle fraction in current supply		0,1			%
Downcycle		✓			
Combust for energy recovery		✓			
Heat of combustion (net)	*	44	-	46,2	MJ/kg
Combustion CO2	*	3,06	-	3,22	kg/kg
Landfill		✓			
Biodegrade		✗			

Links

ProcessUniverse

Producers

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Shape

Appendix **K**

material connection adapter and plug connector

General information

Designation

CuSn8, wrought

Condition	Extra hard
UNS number	C52100
EN name	CW453K
ISO name	CuSn8
JIS (Japanese) name	C5210 / C5212

Typical uses

Heavy-duty springs and washers; pinions; gears; pump parts; bushings; clutch plates; bridge bearings; items for chemical & textile plant.

Composition overview

Compositional summary

Cu90-93 / Sn7-9 / P0.03-0.35 (impurities: Zn<0.2, Fe<0.1, Pb<0.05)

Material family	Metal (non-ferrous)
Base material	Cu (Copper)

Composition detail (metals, ceramics and glasses)

Cu (copper)	90,3 - 93	%
Fe (iron)	0 - 0,1	%
P (phosphorus)	0,03 - 0,35	%
Pb (lead)	0 - 0,05	%
Sn (tin)	7 - 9	%
Zn (zinc)	0 - 0,2	%

Price

Price	* 5,69 - 6,59	EUR/kg
Price per unit volume	* 4,83e4 - 5,61e4	EUR/m^3

Physical properties

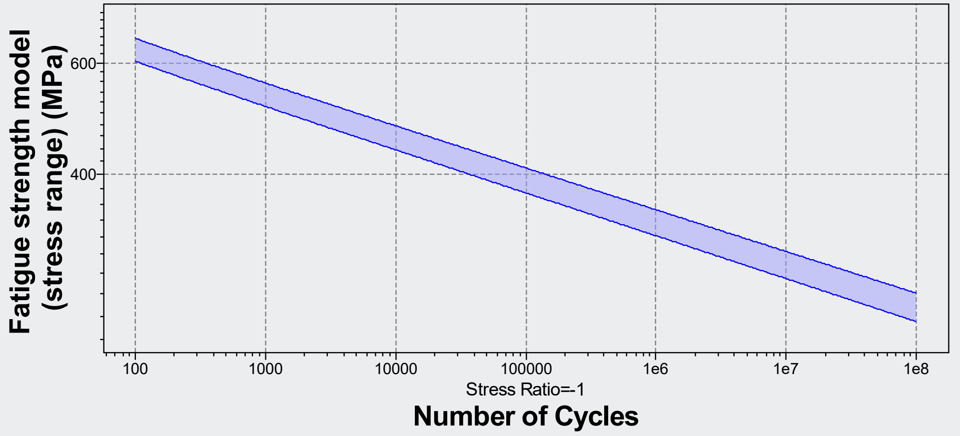
Density	8,5e3 - 8,52e3	kg/m^3

Mechanical properties

Young's modulus	105 - 110	GPa
Yield strength (elastic limit)	700 - 720	MPa
Tensile strength	830 - 870	MPa
Elongation	3,5 - 4	% strain
Compressive strength	* 700 - 720	MPa
Flexural modulus	* 105 - 110	GPa
Flexural strength (modulus of rupture)	700 - 720	MPa
Shear modulus	* 38,9 - 40,7	GPa
Bulk modulus	* 113 - 119	GPa
Poisson's ratio	0,34 - 0,35	
Shape factor	13	
Hardness - Vickers	245 - 250	HV
Fatigue strength at 10^7 cycles	* 284 - 293	MPa

Fatigue strength model (stress range)	* 411 - 449	MPa

Parameters: Stress Ratio = -1, Number of Cycles = 2,5e4cycles



Mechanical loss coefficient (tan delta)	8e-6	

Impact & fracture properties

Fracture toughness	* 21,8 - 22,4	MPa.m^0.5

Thermal properties

Melting point	887 - 1,04e3	°C
Maximum service temperature	160 - 170	°C
Minimum service temperature	-273	°C
Thermal conductivity	62 - 64	W/m.°C
Specific heat capacity	* 384	J/kg.°C
Thermal expansion coefficient	16,5 - 17,5	µstrain/°C
Latent heat of fusion	* 220 - 240	kJ/kg

Electrical properties

Electrical resistivity	14,8 - 16,6	µohm.cm
Temperature dependence of resistivity	* 2 - 2,5	/°C
Galvanic potential	* -0,23 - -0,15	V

Magnetic properties

Magnetic type	Non-magnetic

Optical properties

Transparency	Opaque

Critical materials risk

Contains >5wt% critical elements?	Yes

Processing properties

Metal casting	Unsuitable
Metal cold forming	Acceptable
Metal hot forming	Unsuitable

Metal press forming	Acceptable	
Metal deep drawing	Limited use	
Machining speed	30,5	m/min
Weldability	Excellent	
Notes	Preheating and post weld heat treatments are required	

Durability

Water (fresh)	Excellent
Water (salt)	Excellent
Weak acids	Acceptable
Strong acids	Unacceptable
Weak alkalis	Excellent
Strong alkalis	Excellent
Organic solvents	Excellent
Oxidation at 500C	Limited use
UV radiation (sunlight)	Excellent
Galling resistance (adhesive wear)	Excellent
Flammability	Non-flammable

Corrosion resistance of metals

Stress corrosion cracking	Slightly susceptible
Note	Rated in ammoniacal; Other susceptible environments: Water, amine, dinitrogen tetroxide

Primary production energy, CO2 and water

Embodied energy, primary production	* 70,1 - 77,3	MJ/kg
CO2 footprint, primary production	* 4,44 - 4,89	kg/kg
Water usage	* 1,15e3 - 1,27e3	l/kg

Processing energy, CO2 footprint & water

Rough rolling, forging energy	* 5,57 - 6,15	MJ/kg
Rough rolling, forging CO2	* 0,418 - 0,462	kg/kg
Rough rolling, forging water	* 3,93 - 5,9	l/kg
Extrusion, foil rolling energy	* 10,9 - 12	MJ/kg
Extrusion, foil rolling CO2	* 0,814 - 0,9	kg/kg
Extrusion, foil rolling water	* 6,19 - 9,28	l/kg
Wire drawing energy	* 39,9 - 44,1	MJ/kg
Wire drawing CO2	* 2,99 - 3,31	kg/kg
Wire drawing water	* 15 - 22,6	l/kg
Metal powder forming energy	* 22,3 - 24,6	MJ/kg
Metal powder forming CO2	* 1,78 - 1,97	kg/kg
Metal powder forming water	* 24,3 - 36,4	l/kg
Vaporization energy	* 9,17e3 - 1,01e4	MJ/kg
Vaporization CO2	* 688 - 760	kg/kg
Vaporization water	* 3,82e3 - 5,73e3	l/kg
Coarse machining energy (per unit wt removed)	* 1,27 - 1,4	MJ/kg
Coarse machining CO2 (per unit wt removed)	* 0,0951 - 0,105	kg/kg
Fine machining energy (per unit wt removed)	* 8,4 - 9,28	MJ/kg
Fine machining CO2 (per unit wt removed)	* 0,63 - 0,696	kg/kg

Grinding energy (per unit wt removed)	* 16,3 - 18	MJ/kg
Grinding CO2 (per unit wt removed)	* 1,22 - 1,35	kg/kg
Non-conventional machining energy (per unit wt removed)	* 91,7 - 101	MJ/kg
Non-conventional machining CO2 (per unit wt removed)	* 6,88 - 7,6	kg/kg

Recycling and end of life

Recycle	✓	
Embodied energy, recycling	* 15,2 - 16,7	MJ/kg
CO2 footprint, recycling	* 1,19 - 1,31	kg/kg
Recycle fraction in current supply	40,8 - 45	%
Downcycle	✓	
Combust for energy recovery	✗	
Landfill	✓	
Biodegrade	✗	

Notes

Other notes

(s)=soft; (1/2 h)=half hard; (h)=hard; (xh)=extra hard; (hr) = hot rolled; (w)=soln heat-trtd; (wh)=soln heat-trtd & work hdnd; (wp)=soln heat-trtd & precip hdnd; (whp)=precip hdnd after cold-wkng; (wph)=work hdnd after precip hdng.

Keywords

MILLER 200PLUS, Miller Company (USA); ALL-STATE NO. 24, All-State Welding Products, Inc. (USA); WATERBURY PBC, Waterbury Rolling Mills Inc. (USA); PHOSPHOR BRONZE, Little Falls Alloys, Inc. (USA); BRONZE DEVIL, Champion Welding Products (USA); CARO, Manufacturer unknown (); ANACONDA (C) 521, Anaconda Industries (USA); NAVIBRONZE, Le Bronze Industriel (FRANCE); CARBOBRONZE, English manufacture (UK); ;

Standards with similar compositions

- Canada:
HC.4.TJ80(521) to CSA
- Czech Republic:
CuSn8 to CSN 423015
- Europe:
CW453K to CEN EN 12163, CW453K to CEN EN 12166, CW453K to CEN EN 12167, CW453K to CEN EN 12449, CW453K to CEN EN 1652, CW453K to CEN EN 1654, CW459K to CEN EN 12163, CW459K to CEN EN 12449
- Germany:
2.101 to DIN, CuSn8 to DIN
- USA:
C52100, C52100 to ASTM B103/B103M, C52100 to ASTM B139M, C52100 to ASTM B159M, C52100 to ASTM B888, ECuSn-C to AWS A5.6, MIL CuSn-C to MIL E-23765/3A, UNS C52100
- Tradenames:
5210, ANACONDA (C) 521, BOLTON NO. 15 PHOSPHOR BRONZE, BRONZE DEVIL, C PHOSPHOR BRONZE, CARO, CUPRONAR 920C, ELEPHANT BRAND NO. 170 METAL, HARRIS PHOSPHOR BRONZE C, MILLER 200 PLUS GR. C, PHOSPHOR BRONZE, PHOSPHOR BRONZE (C) 353, PHOSPHOR BRONZE 8% C 521, PHOSPHOR BRONZE GRADE C, PHOSPHORBRONZE SN BZ 8, REVERE ALLOY NO. 521, RIVERSIDE PHOSPHOR BRONZE NO. 47, SEYMOUR 9230, SEYMOUR NO. 9225, SEYMOUR NO. 928, SUPER X PHOSPHOR BRONZE GR. C ALLOY 113, WATERBURY PBC, WIELAND FW8, ZINNBRONZE SNBZ8

Links

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Producers
Reference
Shape

Appendix K
material handheld

General information

Designation

Polyester Liquid Crystal (Unfilled)

Tradenames

Coolpoly, Fregtis, Sepaz, Sumikasuper, ThermaTech, Vectra

Typical uses

Medical equipment; [illegible]; electrical connectors; surgical devices; syringes.

Composition overview

Compositional summary

Wholly aromatic polyesters - typical compostion is a linear copolymer of hydroxybenzoic acid and hydroxynaphthoic acid (C6H4COO)n (C10H6COO)m

Material family	Plastic (thermoplastic, semi-crystalline)
Base material	LCP (Liquid crystal polyester)
Polymer code	LCP

Composition detail (polymers and natural materials)

Polymer	100			%

Price

Price	* 6,63	-	9,85	EUR/kg
Price per unit volume	* 9,22e3	-	1,4e4	EUR/m^3

Physical properties

Density	1,4e3	-	1,42e3	kg/m^3

Mechanical properties

Young's modulus	15	-	15,4	GPa
Yield strength (elastic limit)	117	-	125	MPa
Tensile strength	120	-	127	MPa
Elongation	1,55	-	2,38	% strain
Compressive modulus	* 15	-	15,4	GPa
Compressive strength	* 85	-	95	MPa
Flexural modulus	9,73	-	10,9	GPa
Flexural strength (modulus of rupture)	135	-	145	MPa
Shear modulus	* 5,22	-	5,49	GPa
Shear strength	* 40,7	-	45	MPa
Poisson's ratio	* 0,4	-	0,43	
Shape factor	9,6			
Hardness - Vickers	* 35	-	38	HV
Hardness - Rockwell M	* 62	-	68	
Hardness - Rockwell R	* 97	-	107	
Fatigue strength at 10^7 cycles	46,7	-	51,7	MPa
Mechanical loss coefficient (tan delta)	* 0,0026	-	0,0027	

Impact & fracture properties

Fracture toughness	* 1,89	-	1,97	MPa.m^0.5

Impact strength, notched 23 °C	90	-	100	kJ/m^2
Impact strength, notched -30 °C	* 18,2	-	22	kJ/m^2
Impact strength, unnotched 23 °C	250	-	600	kJ/m^2
Impact strength, unnotched -30 °C	50	-	56	kJ/m^2

Thermal properties

Melting point	280			°C
Glass temperature	116	-	124	°C
Heat deflection temperature 0.45MPa	* 199	-	223	°C
Heat deflection temperature 1.8MPa	176	-	198	°C
Vicat softening point	143	-	147	°C
Maximum service temperature	157	-	227	°C
Minimum service temperature	* -50	-	-30	°C
Thermal conductivity	* 0,54	-	0,58	W/m.°C
Specific heat capacity	* 1,02e3	-	1,1e3	J/kg.°C
Thermal expansion coefficient	* 10	-	20	µstrain/°C

Electrical properties

Electrical resistivity	1e21	-	1e22	µohm.cm
Dielectric constant (relative permittivity)	3	-	3,4	
Dissipation factor (dielectric loss tangent)	0,015	-	0,02	
Dielectric strength (dielectric breakdown)	45	-	47	MV/m
Comparative tracking index	150	-	225	V

Magnetic properties

Magnetic type	Non-magnetic

Optical properties

Transparency	Translucent

Critical materials risk

Contains >5wt% critical elements?	No

Absorption & permeability

Water absorption @ 24 hrs	* 0,00428	-	0,00473	%
Water absorption @ sat	* 0,03	-	0,04	%
Humidity absorption @ sat	0,025	-	0,035	%
Water vapor transmission	0,0219	-	0,041	g.mm/m².day
Permeability (O2)	0,0184	-	0,0326	cm³.mm/m².day.atm

Processing properties

Polymer injection molding	Excellent			
Polymer extrusion	Limited use			
Polymer thermoforming	Limited use			
Linear mold shrinkage	0,03	-	0,064	%
Melt temperature	230	-	295	°C
Mold temperature	90	-	110	°C
Molding pressure range	* 48	-	69	MPa

Durability

Water (fresh)	Excellent
Water (salt)	Excellent
Weak acids	Excellent
Strong acids	Acceptable
Weak alkalis	Excellent
Strong alkalis	Excellent
Organic solvents	Excellent
Oxidation at 500C	Unacceptable
UV radiation (sunlight)	Good
Flammability	Self-extinguishing

Primary production energy, CO2 and water

Embodied energy, primary production	* 209	-	231	MJ/kg
CO2 footprint, primary production	* 11,3	-	12,5	kg/kg
Water usage	* 582	-	644	l/kg

Processing energy, CO2 footprint & water

Polymer extrusion energy	* 5,76	-	6,37	MJ/kg
Polymer extrusion CO2	* 0,432	-	0,478	kg/kg
Polymer extrusion water	* 4,8	-	7,2	l/kg
Polymer molding energy	* 17	-	18,8	MJ/kg
Polymer molding CO2	* 1,27	-	1,41	kg/kg
Polymer molding water	* 11,9	-	17,8	l/kg
Coarse machining energy (per unit wt removed)	* 1,08	-	1,19	MJ/kg
Coarse machining CO2 (per unit wt removed)	* 0,081	-	0,0896	kg/kg
Fine machining energy (per unit wt removed)	* 6,53	-	7,22	MJ/kg
Fine machining CO2 (per unit wt removed)	* 0,49	-	0,541	kg/kg
Grinding energy (per unit wt removed)	* 12,6	-	13,9	MJ/kg
Grinding CO2 (per unit wt removed)	* 0,944	-	1,04	kg/kg

Recycling and end of life

Recycle	✓			
Embodied energy, recycling	* 71	-	78,4	MJ/kg
CO2 footprint, recycling	* 3,84	-	4,24	kg/kg
Recycle fraction in current supply	0,1			%
Downcycle	✓			
Combust for energy recovery	✓			
Heat of combustion (net)	* 26,9	-	28,3	MJ/kg
Combustion CO2	* 2,58	-	2,71	kg/kg
Landfill	✓			
Biodegrade	✗			

Links

ProcessUniverse

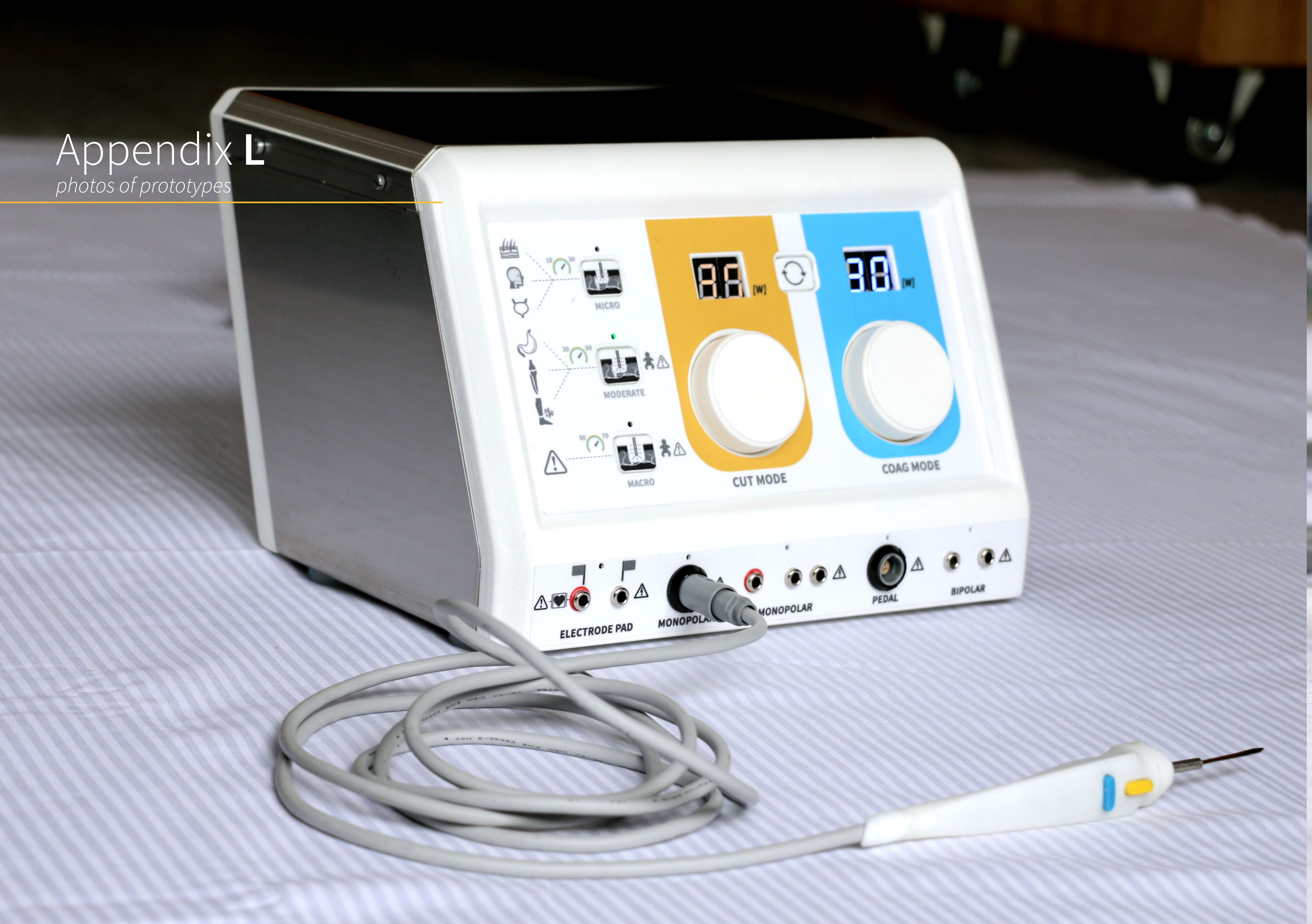
Producers

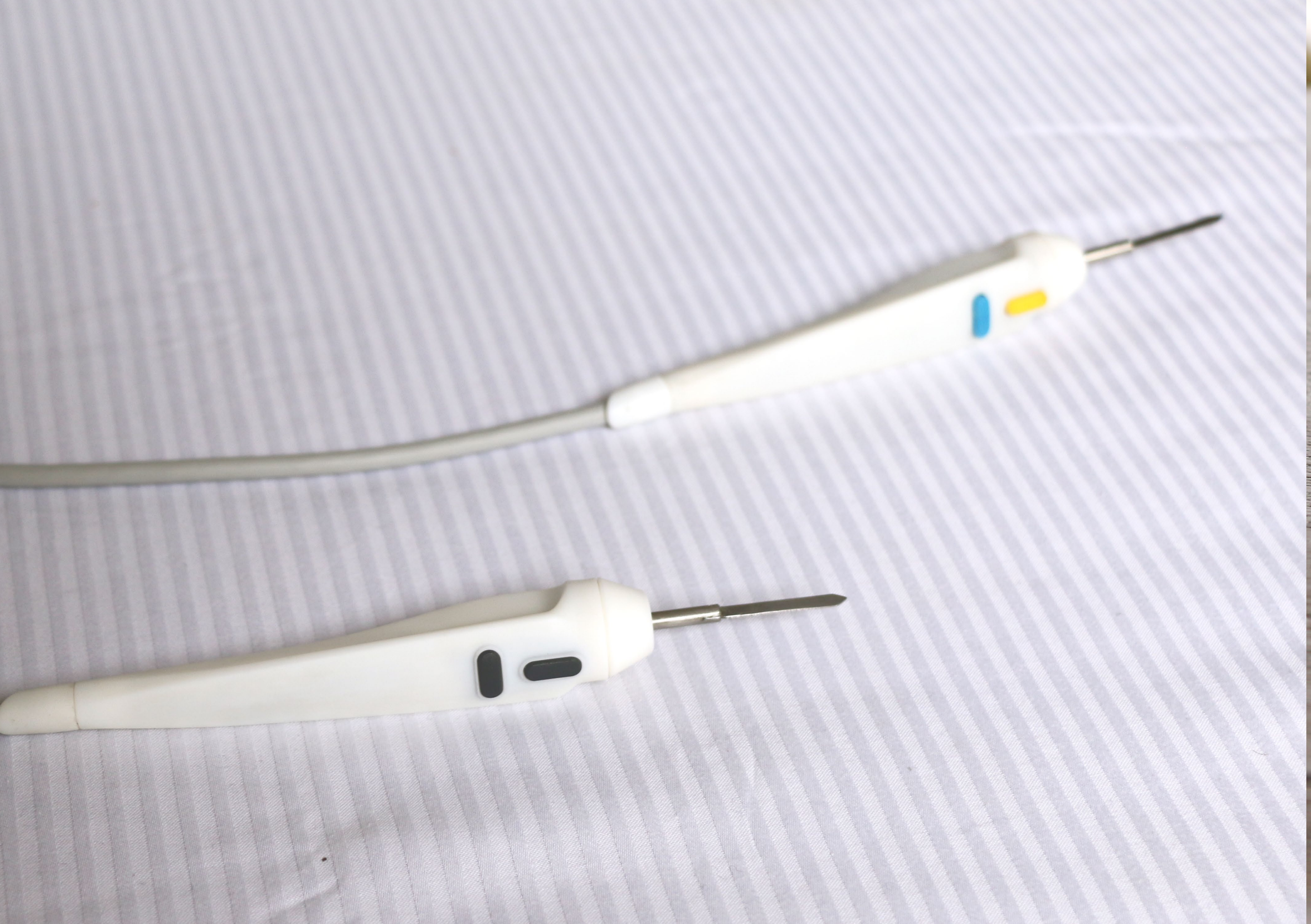
Reference

Shape

Appendix L

photos of prototypes





Appendix **M**

power setting change on handheld

As explained in the design of the high frequency generator, a change in power will lead to a check of the surgeon on the interface by most of the surgeons. Furthermore, the lack of surgical assistances results in sometimes more time demanding power changes because of other activities. Consequently, this will take away the viewpoint from the surgical area. Hence, one of the concepts that will be interesting for future development is a monopolar handheld that enables power change on the handheld. Multiple activation switches have been compared and a jog lever switch was found to increase intuitiveness and reliability during usage.

The jog lever switch is a multifunctional switch that has three signal possibilities. The lever makes it possible to rotate the switch forward and backward which will be used to increase or decrease power with 1 W and when holding the rotation the power will rise up to quickly change power. The jog creates a tactile switch that will be used to activate the waveform mode.

Nevertheless, this concept will have a substantial impact on the use of the ESU and therefore it should be research whether it is safe, reliable and intuitive to change power in such manner. Furthermore, the reliability of the jog lever should be studied more extensively. The jog lever has been sterilized 5 cycles without misfunctioning but this should be tested further to assume that the jog lever is reliable for frequent sterilization cycles.

The button foil should be flexible enough to enable a power increase by using the lever switch. Therefore, more research should be conducted on the relation between elasticity and reliability against steam autoclavation.