DESIGN OF AN ELECTROSURGICAL UNIT FOR LOW- AND MIDDLE-INCOME COUNTRIES

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DESIGN OF AN ELECTROSURGICAL UNIT FOR LOW- AND MIDDLE-INCOME COUNTRIES

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Design of an electrosurgical unit for low- and middle-income countries

MSc Biomedical Engineering – Master Thesis

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Executive Summary

With the provision of essential surgical care millions of lives can be saved and this realization has reached the international agenda. There are however many obstacles that make it hard to provide safe, qualitative, affordable and accessible surgical care to the more than 4.8 billion people for whom this is currently out of reach. One of the obstacles is the lack of medical equipment that is suitable for use in the harsh environment found at the district hospitals. Problems that could be expected at the district hospital are the shortage of consumables, the lack of spare parts, the lack of a steady electricity network, financing problems and a shortage of qualified surgeons and technicians.

The goal of this project is to: DESIGN A USER-FRIENDLY, ROBUST AND EASY TO MAINTAIN ELECTROSURGICAL UNIT THAT CAN SAFELY BE USED BY SURGEONS AND CLINICAL OFFICERS AT THE DISTRICT HOSPITALS IN LOW- AND MIDDLE-INCOME COUNTRIES

The electrosurgical unit (ESU) is a device that can be used during many surgical procedures and it would be a welcome addition to the operating rooms (ORs) in these district hospitals. The ESU is however accompanied with its own set of problems. A problem with electrosurgery is that the underlying principles of electrosurgery are not widely known, even though it is a very common surgical technique. In addition to the lack of knowledge, there is the problem that the existing devices are very complex due to the lack of standardization in user-interface, the brand specific names for power and waveform outputs and the wide range of available instruments. To aid personnel in low- and middle- income countries (LMIC) that have limited training possibilities, the focus has been on reducing the complexity of the ESU by only providing the necessary functions on the interface.

The minimum set of requirements necessary for an ESU to be safe and effective is unknown. However, data from surgeries performed at Reinier de Graaf Gasthuis (RdGG) and Leiden University Medical Center (LUMC) made it possible to get some insight in how the power settings and modes are used during surgery. It showed that surgeons are free to use the instrument, mode and power setting they prefer. No rules or strict guidelines exist on its use. At LUMC different settings were used for similar surgeries performed at RdGG, so the assumption can be made that the preference for certain power settings is hospital specific.

To simplify the interface it was chosen to introduce pre-set power settings. In the new design only four different power settings can be selected that do not show its corresponding value in Watt, but an intensity level. The interface also provides the option to connect a monopolar instrument, a dispersive electrode, a bipolar instrument, a foot pedal and a choice between two coagulation modes.

A questionnaire was used to determine if the users would trust the new interface design, if they perceive it as safe and to find out whether the interface has been simplified too much. Two surgeons, one resident and 13 OR assistants have filled out the questionnaire. It could be concluded that staff from RdGG had trouble trusting the new design due to the inability to set precise values. Whether this is because of the limited power settings or because they do not like to see a device they are used to change was not clear.

More research is needed to identify the functions that are truly indispensable on the ESU and which ones could be eliminated in order to reduce the complexity of the ESU. To get meaningful feedback from the intended users it would be best to speak to them directly and on scene.

During this project it was decided to focus on only one component of the ESU. To make the ESU more suitable for use in LMIC there should be done more research for each component separately. It should also be noted that the differences in resources and such between LMIC are enormous. If the challenges in designing an appropriate ESU have been overcome, there are still problems to expect. To be successful local support and training is needed.

Table of Contents

1 Introduction

1.1 Need for surgery in low- and middle-income countries

Within a healthcare system, surgical care is an important aspect that may not be overlooked. Yet, it has only recently been recognized that surgery also has a crucial part to play in global health care. Surgical care can greatly enhance the quality of life for patients with certain conditions. In low- and middle-income countries (LMIC) surgical care can be used to save millions of lives and it will also significantly reduce the number of disability-adjusted life years (DALYs)[1-5].

In 2010 it has been estimated that there were 16.9 million deaths due to illnesses and injuries that could have been prevented by the provision of basic surgical care and it is expected that this number will only drastically increase in the next 20 years. While the global focus has been on diseases such as Aids, the sum (3.57 million) of lives lost from HIV/Aids (1.20 million), malaria (1.17 million) and tuberculosis (1.20 million) does not come near the number of lives lost by surgical conditions[6].

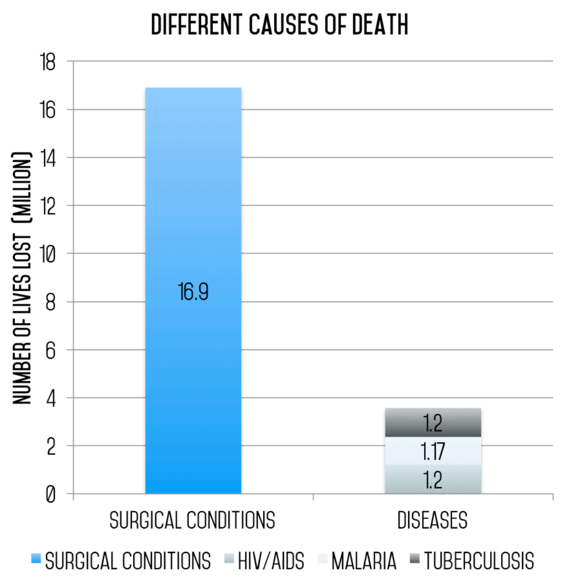

Figure 1. The number of lives lost due to surgical conditions surpasses the deaths due to well-known diseases

In section 2.2 this need for essential surgical care and the implications for global health will be further explained. To realize this global goal of offering affordable surgical care that can be provided in a timely manner to even the poorest people in the world, a lot of steps still have to be taken. Within this project the focus will lie on a small part of the wide variation of problems that have to be overcome, namely the design of a context appropriate electrosurgical unit.

1.2 Medical devices in low- and middle-income countries

It is important to realize that it does not work to implement medical technologies designed for the developed world in the developing world[7]. An affordable technology that has proved its effectiveness in other areas is not necessarily guaranteed to be a success when introduced in LMIC. Conditions in which the medical equipment has to function are not comparable to the conditions found in the western world. Obtaining the necessary accessories, consumables and spare parts is often challenging. In addition, there is also the lack of reliable power and water supply, lack of a functioning infrastructure and a shortage of technical know-how that is needed for the equipment to function properly[7]. As a result of these problems, about 70% of medical equipment in LMIC does not function[8, 9].

1.3 Electrosurgery

1.3.1 Electrosurgical units

Electrosurgical units (ESUs) are one of the most useful and most frequently used tools in surgery. They are used in practically every surgical procedure, are efficient and contribute to safe surgery im various ways. It should however be recognized that it can also cause severe complications[10, 11]. An ESU consists of a high-frequency electrical generator and an active and dispersive electrode. The high-frequency electrical current produced by the generator can achieve different tissue effects. The tissue effects can be roughly divided into the groups of cutting and coagulation, which can be achieved by either a monopolar or bipolar technique[12, 13]. Because of the great versatility with respect to the surgical procedures in which the ESU can be used, the device can have a positive influence on the provision of surgical care in LMIC. In the developing world this ESU is however faced with design-related barriers, such as the costs of the technology, the lack of spare parts and the need for consumables[7].

1.3.2 Complexity electrosurgery

Problems with electrosurgery are not limited to the developing world. The wide range of ESUs available, from different brands and with different generators, settings, interfaces and energy platforms make the use of electrosurgery also complex in the developed world. This variety of devices in combination with the demanding environment of the operating room (OR) and potential safety hazards due to heat and the electrical current demands knowledge and training from its user[10].

1.4 Problem definition

Surgery has been recognized to be an aspect that cannot be ignored in global health care. The number of people that can be saved by high-quality surgical care provides an international incentive to look into the problems surrounding surgical care in LMIC. ESUs are very useful in many different surgeries and can therefore be a helpful tool in achieving the goal of making essential surgeries available to everyone. One of the problems encountered in LMIC however, is a lack of medical devices that are suitable to function in the harsh conditions found at the district hospitals there. In addition to the context related problems, there are the problems surrounding electrosurgery and the ESU in general. The complexity of the current ESUs forms a barrier for effective and safe use by staff in LMIC. While the many unknowns encountered during electrosurgery and the complexity of the devices form a problem for the surgeons and other OR personnel, in the end it is the patient who will be most at risk if it is not possible to safely work with the ESU.

1.5 Project goal

The goal of this project is to design a user-friendly, robust and easy to maintain electrosurgical unit that can safely be used by surgeons and clinical officers at the district hospitals in low- and middle-income countries.

1.6 Report structure

This section provided a brief introduction to both the context and electrosurgery. Some of the problems that have to be dealt with to achieve the goal are context related (so specific to LMIC), while others are specific to electrosurgery and the ESU.

Section 2 provides information about what is known about surgical care and medical devices in LMIC and section 3 offers background information on electrosurgery and the ESU. Section 4 complements the previous theoretical section about electrosurgery with how the ESU is actually used in practice. In section 5 the information from the analysis about the context and electrosurgery is combined to create requirements that help achieve the goal. The design process is described and several concepts are presented. The sixth section presents the final design and how it has been evaluated. The report ends with a discussion (section 7) about aspects to consider and certain limitations during this project. Finally it will conclude with a description of the main findings and recommendations for further research (section 8).

2 Analysis Context

The ESU has to function within an environment that is not comparable to the developed world. This section provides some background information on this context. First on essential surgery and the problems surrounding the provision of surgery in LMIC. Secondly, on the factors that hinder the performance of medical devices at the district hospitals in LMIC.

2.1 Low- and middle-income countries

Low- and middle-income countries often referred to as developing countries, get their classification by the World Bank. The World Bank derives these classifications from the Gross National Income (GNI) per capita[14]. The classifications for the year 2015 are listed in table 1.

WORLD BANK CLASSIFICATION 2015	
LOW INCOME COUNTRY	$1,045 OR LESS
LOWER MIDDLE INCOME COUNTRY	$1,045 TO $4,125
UPPER MIDDLE INCOME	$4,125 TO $12,746
HIGH INCOME COUNTRY	$12,746 OR MORE

Table 1. Classifications based on the GNI [14]

2.2 Essential surgery

2.2.1 Millennium development goals

The millennium development goals (MDGs), established in 2000 during the Millennium Summit of the United Nations, were focused on several topics. Main incentive was to provide clear objectives to be able to eradicate extreme poverty in the world by 2015. Now the attention is shifted to what are called the sustainable development goals for 2030[15]. However, the base is still the MDGs and from a surgical perceptive, improving surgical care in LMIC can help achieve MDG 4, 5 and 6 (see Figure 2). Currently, there are enormous gaps in the provision of essential surgical care and a lot has to be done to close these gaps[16].

Figure 2. Millennium development goals

2.2.2 Need for essential surgery

The majority of the world's population (over 4.8 billion people) has no access to safe surgical care[17]. This enormous deficiency of surgical care in the developing world, results in a high mortality rate for common and easily treatable surgical conditions. Take for instance complications encountered during pregnancy and childbirth, which led to the death of around 270,000 women in 2012[2, 6, 18]. These surgical conditions, which lead to deaths or life-long disabilities that could have been prevented, have a big impact on society regarding both human and economic aspects. Disabilities often make it hard or even impossible for a person to get a well-paid job. This makes them dependent on both family and the community[2]. The international community has finally recognized the need for surgical care and its important place within healthcare delivery. Efforts are now made by a growing number of people to make surgical care available to the people in LMIC[1-4, 18].

2.2.3 Essential surgical procedures

Essential surgery refers to a series of surgical conditions and the necessary procedures to treat these conditions. Debas et al. (2015) define essential surgical conditions based on three criteria. First the condition has to be treated mainly by surgery. Second, the condition has to impose a large burden on global health and third, the surgical procedures to treat the condition have to be cost-effective and realistic to implement on a global scale[18].

Most of the essential conditions that are proposed can be treated at district hospitals. These 28 procedures provide a starting point for many countries for the provision of an essential surgical package[18]. See Table 2 for the complete list.

With the growing awareness that surgery should be available to everyone, a similar list was proposed during the final session of the symposium 'Surgery in Low Resource Settings' on November the 15th 2014 in Amsterdam[19, 20]. This list contains many conditions also mentioned by Debas et al (2006)[2].

The Essential Surgery Package

		Platform for delivery procedure	
Type of procedure	Community facility and primary health center	District hospital (a.k.a. first-level hospital)	Second- and third-level hospitals
Dental procedures	1. Extraction 2. Drainage of dental abscess 3. Treatment for caries		
Obstetric, gynecologic and family planning	4. Normal delivery	1. Cesarean birth 2. Vacuum extraction/forceps delivery 3. Ectopic pregnancy 4. Manual vacuum aspiration and dilation and curettage 5. Tubal ligation 6. Vasectomy 7. Hysterectomy for uterine rupture or intractable postpartum hemorrhage 8. Visual inspection with acetic acid and cryotherapy for precancerous cervical lesions	1. Repair obstetric fistula
General surgical	5. Drainage of superficial abscess 6. Male circumcision	9. Repair of perforations: for example, perforated peptic ulcer, typhoid ileal perforation 10. Appendectomy 11. Bowel obstruction 12. Colostomy 13. Gallbladder disease, including emergency surgery 14. Hernia, including incarceration 15. Hydrocelectomy 16. Relief of urinary obstruction: catheterization or suprapubic cystostomy	

INJURY	7. RESUSCITATION WITH BASIC LIFE SUPPORT MEASURES 8. SUTURING LACERATION 9. MANAGEMENT OF NON-DISPLACED FRACTURES	17. RESUSCITATION WITH ADVANCED LIFE SUPPORT MEASURES, INCLUDING SURGICAL AIRWAY 18. TUBE THORACOSTOMY (CHEST DRAIN) 19. TRAUMA LAPAROTOMY 20. FRACTURE REDUCTION 21. IRRIGATION AND DEBRIDEMENT OF OPEN FRACTURES 22. PLACEMENT OF EXTERNAL FIXATOR, USE OF TRACTION 23. ESCHAROTOMY/FASCIOTOMY (CUTTING OF CONSTRICTING TISSUE TO RELIEVE PRESSURE FROM SWELLING) 24. TRAUMA-RELATED AMPUTATIONS 25. SKIN GRAFTING 26. BURR HOLE	
CONGENITAL			2. REPAIR OF CLEFT LIP AND PALATE 3. REPAIR OF CLUB FOOT 4. SHUNT FOR HYDROCEPHALUS 5. REPAIR OF ANORECTAL MALFORMATIONS AND HIRSCHSPRUNG'S DISEASE
VISUAL IMPAIRMENT			6. CATARACT EXTRACTION AND INSERTION OF INTRAOCULAR LENS 7. EYELID SURGERY FOR TRACHOMA
NON-TRAUMA ORTHOPEDIC		27. DRAINAGE OF SEPTIC ARTHRITIS 28. DEBRIDEMENT OF OSTEOMYELITIS	

Table 2. The essential surgery package: Procedures and platforms, proposed by Debas et al[18]

2.2.4 Access to safe, affordable surgery

The lack of access to safe and affordable surgical care is one of the issues that needs to be addressed to make surgery available to everyone. For a patient to receive much needed high-quality surgical care there should first, be some sort of surgical delivery system in place. Secondly, very important is the ability for the patient to reach this surgical facility in a timely manner. Access is not only limited to whether a patient is able to get transport to the facility, but there are other aspects involved that also affect the ability of a patient to get access to surgical care[6, 18]. See Figure 3 for other obstacles that influence the ability to receive the necessary care.

The last obstacle is the possibility of high costs of the surgery and its follow-up care. This often proves to be problematic for the patients and their family, since they already struggle to get by on a low income[6, 17, 18]. The problems presented in Figure 3 cannot be solved all at once, but it illustrates the scope and complexity of providing surgical care to even the poorest in the world. Within this project the focus will be on the design of an ESU that is suitable for safe use in LMIC. It will help facilitate safe and appropriate surgery and hopefully it will help keep the costs of surgery low.

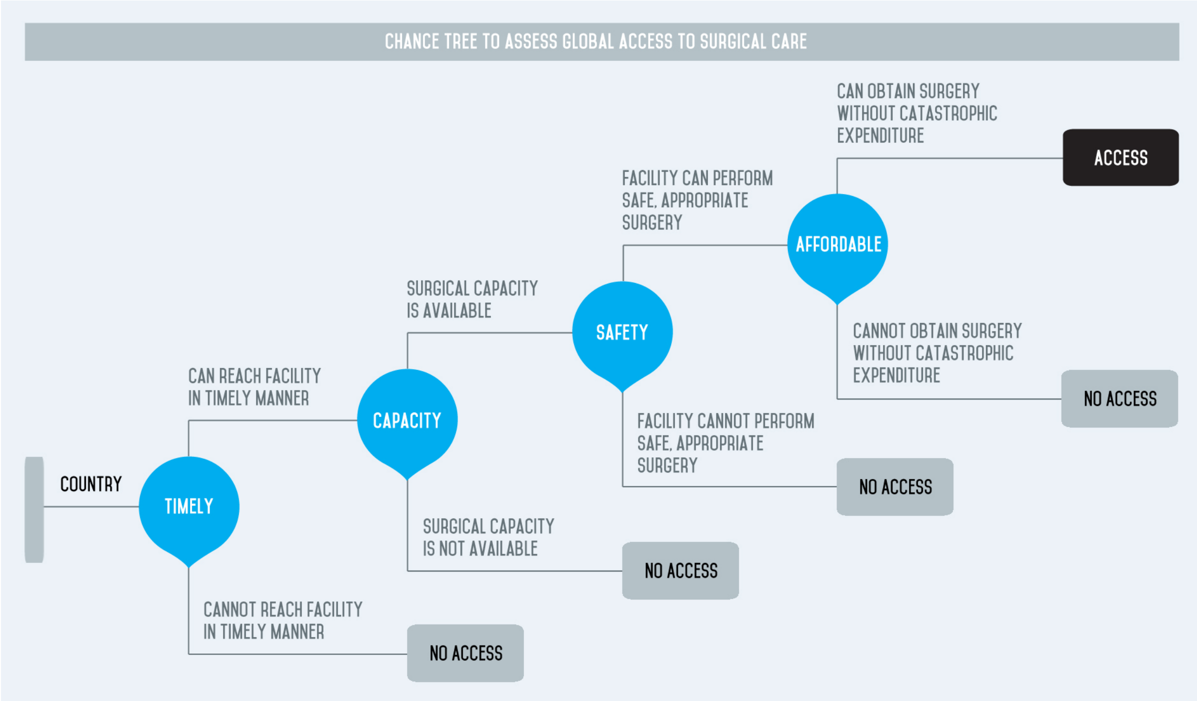

Figure 3. A an overview of the different aspects that need to be considered when talking about access to surgical care[17]

With this broad concept of access to safe surgical and anesthesia care the Institute for Health Metrics and Evaluation region developed a map to illustrate the distribution of access to surgery around the world (see Figure 4)[6, 18]. The figure shows that 93% of the people living in sub-Saharan Africa have no access to safe surgery and 97% of the population in South Asia[6]. More recent numbers published by Rose et al. (2015) show that the need for surgery is highest in sub-Saharan Africa[21].

2.3 Healthcare system in low- and middle-income countries

Within every healthcare system in the world you can identify three main stakeholders: the patients, the providers and the people and agencies paying for healthcare. In a western country such as The Netherlands, hospitals, doctors and nurses would be the provider and the health insurers would be the paying agency. In African nations, the providers are for instance the public and private hospitals with both their own payment system for healthcare[22]. This section gives some insight in the main players and consequently where and by whom the ESU will most likely be used.

2.3.1 Patients

The list of essential surgeries presented in Table 2, gives a good impression of the type of surgical conditions found among patients in LMIC. Note that for the different LMIC, the most prominent surgical needs are also different. The focus of this project will be on sub-Saharan Africa, because of the high surgical need within this region. The needs within this region vary from those in for instance Asia, but can still be very different between the various sub-Saharan African countries.

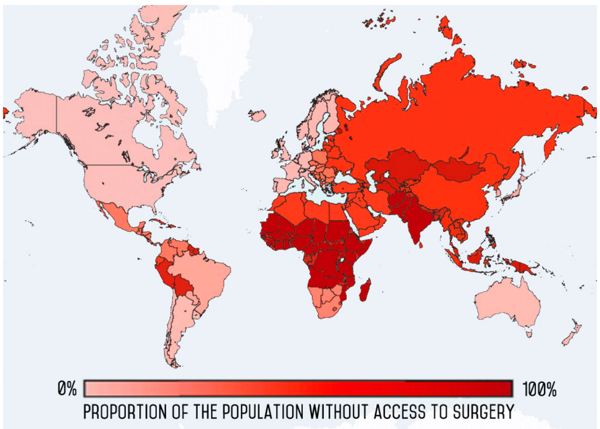

Figure 4. Proportion of the population without access to surgery[6]

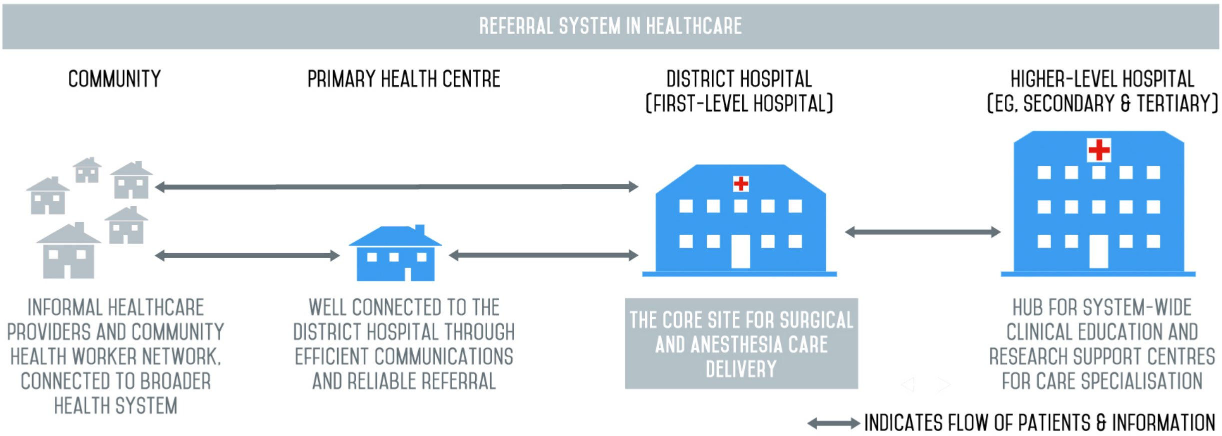

Figure 5. Referral system common in healthcare[6]

2.3.2 Providers

A lot of different aspects have an influence on the quality of healthcare and with this also on the quality of surgical care that can be delivered. For surgical care, Alkire et al. (2015) identified four main components that have to be in good order to be able to provide high-quality surgical care[17]:

- Space – The space in which the care is provided, such as the OR
- Staff – The different healthcare professionals who carry out the work, such as the surgeons
- Stuff – The equipment and other resources needed to deliver high-quality surgical care
- System – The management and logistical structure that match the right stuff with the staff and make a facility function properly

Unfortunately, in LMIC the availability of any of these elements on their own is often already limited, making the delivery of good surgical care very challenging[17].

Space

Surgical Facilities and referral system

The level of complexity of the medical care required determines at what type of facility the patient should receive this care. See Figure 5 for an overview of the flow of patients from and to the different facilities that are in a healthcare system. In LMIC surgical care is often provided by a combination of public and private providers[6]. The healthcare system depends on a good referral system to get patients from one facility to the other. In LMIC however, referral to another facility proves to be difficult.

One of the main problems is the limited availability of affordable transport between the various facilities. People with a low income cannot afford to transport their family member or friend from one facility to the next. If transport can be arranged, a new problem arises. It is common for a family member to care for the patient during its stay in a medical center. However, this family also has to pay for their own transport and stay, while missing work and consequently their income[6, 18].

The problems with transport and the high costs that accompany a referral have as result that if the needed surgical care cannot be provided at a district hospital within reach of the patient and his or her family, the patient can most likely not receive the necessary treatment. In sub-Saharan Africa about 80% of the population encounters this problem[6, 18].

District hospital

The district hospital plays a significant role in the delivery of surgical care, because this type of hospital is more likely to be in reach for the patient than a higher-level hospital that is often located in larger cities. Table 3 gives a short overview of how a district hospital can be defined. Note that this serves as a guide and that in reality, for every region in the world the district hospital differs in size, number of physicians and size of population it serves. It shows that steps have to be made in terms of staff and specializations to be able to provide the proper care for the surgical conditions listed in Table 2. Other terms for district hospital that are also often used are[18]:

- First-level hospital
- Primary-level hospital
- Rural hospital
- Community hospital
- General hospital

Of the different level of facilities delivering essential surgical care, the district hospital has proven to be the most cost-effective. The surgical care provided at this particular platform can prevent costs of US$ 10 - US$ 220 per DALY. These hospitals should theoretically have the staff and resources to provide surgical care for a large range of surgical conditions[18]. Good district hospitals are not only necessary in the rural areas, but can also provide a solution to the third-level hospitals in large cities that are often overcrowded.
In theory this all seems an ideal solution. However, there are still many problems that these facilities have to face. Take for instance the simple fact that in sub-Saharan Africa the budget is often less than US$ 30 per day per patient, making it financially difficult to provide the much needed surgical care or follow-up treatments[18]. See section 2.4.2. for other barriers that affect the functionality and effectiveness of the hospital.

DEFINITION DISTRICT HOSPITAL
FEW SPECIALTIES – MAINLY INTERNAL MEDICINE, OBSTETRICS AND GYNECOLOGY, PEDIATRICS AND GENERAL SURGERY
OFTEN ONLY ONE GENERAL PRACTICE PHYSICIAN OR A NON-PHYSICIAN CLINICIAN
LIMITED LABORATORY SERVICES AVAILABLE FOR GENERAL ANALYSIS BUT NOT FOR SPECIALIZED PATHOLOGICAL ANALYSIS
50-250 BEDS

Table 3. Description of a district hospital[18]

Surgical staff

The surgeons and OR assistants are not the only ones crucial in providing high-quality surgical care. The surgical staff is supported by personnel such as those performing the preoperative assessment or the nurses who provide care during the recovery of the patient[18]. Relevant for this particular project is the staff using the ESU. Focus will therefore be on the operators performing the surgery and the OR assistants that change the settings as directed by the surgeon during surgery.
One of the problems encountered in LMIC is the shortage of qualified personnel. An approach to remedy this is also known as task shifting or task sharing. To deal with the shortage of surgeons, non-doctors are trained for three or four years to be able to perform certain surgical procedures without the supervision of a surgeon[2, 23, 24]. The particulars of this training and who is deemed qualified to fulfill such a position is different for each country. These health workers that are specifically trained to diagnose and treat certain surgical conditions are referred to as[6]:

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

To keep the clinical officers satisfied and motivated within the rural areas there are still improvements to be made. Take the example of receiving proper training. After completing their training period it is difficult for them to get additional training because of the heavy workload[18].
While the system of task sharing provides a solution for the shortage of human resources it should be recognized that it is only one of the factors influencing the accessibility and quality of surgical care.

Stuff and system

A known reason for the inability to provide high-quality surgical care is a lack of resources. Still, this is only part of the problem, since how good a hospital functions is also depended on how well the distribution of these resources is organized. It is important that the right resources reach the surgeon who requires these resources for safe surgery on its patient in time. Within the hospitals in LMIC there is often no properly defined structure, making it firstly hard to provide the right resources at the right time and secondly also problematic to see who is responsible for which part. For instance, without a clear structure it is nearly impossible to find out at which point and under whose supervision it went wrong when an instrument is not properly cleaned but still ends up in the OR[6]. See section 2.4.2. for other problems related to the resources.

2.4 Designing for low- and middle-income countries

2.4.1 Need for frugal technology

There is a need for medical equipment specifically designed for the harsh environments found in the developing world. Technology that is especially designed for the developing world and the poorest people is also known as frugal technology[25]. Frugal technology can have the potential to be a disruptive innovation. This term is introduced by Harvard professor Clayton Christensen and describes the process where a simple technology designed for the bottom of a market moves to a more prominent place within this market[25, 26]. A medical technology specifically designed for the developing world can therefore have the potential benefit of also bringing a change in healthcare in the developed world.

2.4.2 Barriers

For a medical device or new medical technology to be effective in LMIC, it is essential that it is tailored to that demanding environment. Different problems arise that are specific for that harsh environment and a design should ideally be able to overcome these problems. The main barriers that make designing for LMIC difficult can be found in the following section.

Spare parts

What proves to be problematic is the lack of spare parts for medical equipment in these areas. A device that is designed to withstand the harsh conditions in which it has to function, is still likely to be discarded when the first part breaks[9]. According to Han Knol (chairman of the organization Passion for People) many donations of medical equipment consist of devices that are discarded from western hospitals. In some cases the manufacturer no longer produces spare parts for that particular device, making the procuring of spare parts nearly impossible.

The most obvious reason for the inability to fix equipment that is broken down is the lack of spare parts in the area. Although it is a problem often encountered, a study of Engineering World Health (EWH) shows that this is a relatively smaller problem than frequently thought[7, 9]. Other reasons why the broken part is not replaced are the lack of know-how due to missing manuals and a shortage of technicians qualified to repair medical devices, the lack of tools necessary to make the repair or in some cases the in ability to obtain the spare part due to its high cost[7].

Consumables

Acquiring the necessary consumables is a common problem in LMIC. Often this shortage is due to poor management, bad infrastructure and insufficient information[6]. Consumables are the additional supplies that are needed for the medical devices to function. These supplies are often limited in their use. For the ESU the electrosurgical tips that need to be implemented in the instrument count as consumables. The study by EWH mentions the example of a donated electrosurgical unit. With the donation disposable surgical tips were also provided but when the tips of this original donation had been used, the device has simply been discarded by the staff[7]. The unattainability of consumables also leads to reuse of disposables (parts that are intended for single-use). This forms a potential danger to the patient since the part may no longer function as intended. The donations of medical equipment needing consumables should be discouraged[6, 7].

Infrastructure

Another problem stated by J.J.Beltman, H.Knol and others familiar with the working environment in African countries, are the many shortcomings in and around the OR[7]. In many hospitals cannot be counted on a steady electricity network, running water, availability of extra blood, enough oxygen supply, an area for emergency care and supplies needed for postoperative care. The lack of a steady electricity network is especially challenging for working with the ESU. Of 231 district hospitals assessed in 12 sub-Saharan countries only 81 (35%) of the hospitals possessed a steady electricity network[17]. This percentage is comparable to the 31% of facilities without a reliable electricity network presented in the WHO SAT database that surveyed almost 800 medical services in low-income countries on the dependability of the electricity network. For the design of the ESU this unreliable power supply should be taken into account and possibly compensated for in the new design. Medical electrical devices should have a feature for voltage stabilization and some sort of power backup to be suitable for LMIC[27].

Lack of technical knowledge

Current medical devices are often complex and need highly skilled technical staff for maintenance and repairs. These much needed technicians however are often not present in the hospital and also the lack of manuals is a problem frequently encountered.[7] For a design to be successful the device should be easy to maintain, durable and local technicians should be trained to work with the device.[6] An additional problem to the lack of technical staff is the problem of brain drain. When technicians and engineers have received enough training to work with the medical equipment they see opportunities elsewhere. There is a trend of excessive migration of trained staff from the developing world to the developed world[6, 7, 18, 23].

Costs

When medical equipment is functional it can still be difficult for the patient to receive care with that type of equipment. In some cases the equipment is only available for use when the patient can pay and preferably up front. They not only have to pay for the surgical services, but also the expenses that come from the necessary surgical supplies. This makes that for many patients who need that service, it is simply unavailable[6, 18].

Low-cost innovations are needed to make surgery available for everyone. Note that for a medical device it not enough to that the purchase price is low and this should be kept in mind while designing the ESU. If the consumables or maintenance needed for the device to function are too expensive this medical device is still not attractive for use in low-income countries[7, 18].

Corruption

The study conducted by EWH showed that even when necessary spare parts were available and the staff had valuable technical skills and proper tools, frustration was created by the corruption encountered in the government, hospitals and biomedical engineering services. This frustration often led to the loss of incentive to do maintain and fix the medical equipment[7].

The technicians are not the only ones to experience frustration about corruption and the inefficiency it brings. Patients and other staff at the hospital also encounter the problem of corruption. In LMIC the number of people who come in contact with some sort of corruption when seeking medical attention or other services related to health care is over 80%. Most obvious are bribes people need to pay to be able to receive medical attention. Other examples are that certain people receive priority because they know the right people. This is both in receiving care as in getting a well-paid job at the hospital[6].

Regulations and standards

Besides the engineering challenges there is the matter of international standards that needs to be considered. Often the international legislative and regulatory authorities demand standards that are composed for high-tech medical environments as found in the developed world. This does not agree with the actual need in the typical LMIC[27].

Cleaning and sterilization

According to Lizette van der Kamp (a biomedical engineer working for Médecins Sans Frontières (MSF)) there is generally a huge lack in maintenance of medical devices.

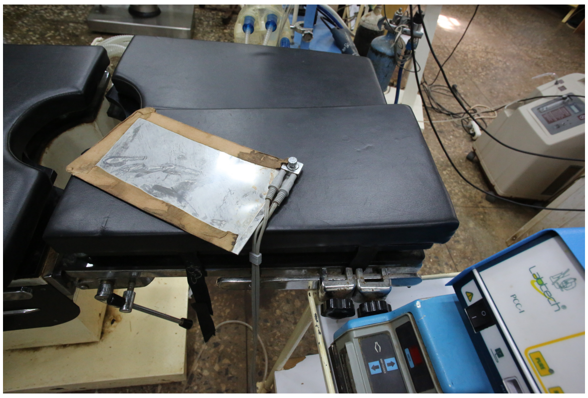

Figure 6. The self-made dispersive electrode used in a hospital in Nigeria[28]

This negatively affects the quality of infection control. The reason for this lack in user maintenance is not only a lack of knowledge in how to correctly handle the equipment, but also an absence in accountability. It is not clear who is responsible for which device or for which part of the cleaning and/or sterilization process.

Some examples of observations made by L. van der Kamp in a non-MSF hospital in Sokoto, Nigeria[28]:

- There was blood to be found on the sensor of the pulse oximeter, because the device has never been cleaned. This lack of cleaning between use on different patients leads to the risk of cross-contamination.
- The dispersive electrode (see Figure 6) used during electrosurgery is self-made, which increases the risk of burn wounds for the patient and again the lack in cleaning may lead to cross-contamination.
- Cross-contamination is also a risk with the patient monitors, since the cables and sensors are never cleaned.
- The tubes and filters of the suction units are never cleaned or changed and there can even be found ants in the filter.

2.4.3 Examples medical devices for LMIC

While designing medical devices for LMIC is challenging, there are certain examples of projects that were successful. See Appendix D for a description of some of these projects. Within these examples, different design strategies can be seen. First, there is the approach taken by Design that Matters that made an incubator build up from car parts. With this approach the focus was on designing the medical device with parts that are widely available in the area, thereby eliminating the problem of spare parts that are hard to come by. In addition there is the increased chance that local technicians know how to fix the device once broken. A second approach is eliminating the features that are not necessary for the device to perform its main function, such as done by D. Zurovick who designed a simplified wound pump. A third approach is that of the English company Diamedica. This company produces anesthetic machines that are robust and can withstand the conditions in LMIC, partly because of its backup power supply. It is one of the few companies that has as its core business designing and producing medical equipment for LMIC.

2.4.4 Need for solid business models and partnerships

There are many opportunities for innovation regarding medical technologies for LMIC. The problem is however not limited to creating a solution such as the NeoNurture Incubator (see Appendix D). For manufacturers it is difficult to develop a product that is on the one hand affordable and on the other capable to function in rough conditions[6]. A good business model and establishing solid business partnerships in LMIC is a key attribute, but proves to be a difficult task. Major barriers for new medical technologies are manufacturing, financing, distribution and getting the necessary regulatory approval. For a new medical technology that is tailored to LMIC to be successful it is crucial that there are the means to provide the products on a larger scale[6, 29]. To expand the business and to be a successful project it is essential that partnerships be formed between the public and the private sector. The medical device industry, government authorities, NGOs, knowledge institutions and local partners should work closely together to promote the development of these much needed context appropriate medical devices[6, 29].

2.5 Conclusion

It has been established that there is a need for surgical care in LMIC and that the international community is aware of this need. This recognition is a good step towards providing high-quality surgical care to the population of LMIC. Yet, surgical care is still inaccessible for too many of the world's population. Especially in sub-Saharan Africa access remains a problem. There are however opportunities when focusing on strengthening the district hospitals in the provision of surgical care. Providing appropriate medical devices is part of this solution, but many barriers still exist. Problems associated with medical devices in LMIC are:

- Failure due to user errors
    - Lack of training
- Lack maintenance and repairs
    - No qualified technicians
    - No access to spare parts
    - No preventive maintenance
- Infrastructure and climate
    - No tools
    - No test equipment
    - No service manuals
    - Donations of already broken equipment
    - Humidity
    - Dust
    - Temperature
- Hospitals have often no access to AC power
- Limited budgets of the hospital
- Every country has its specific standards and regulations
    - Standards and regulations are often based on standards in developed world
- Corruption
- Difficult to scale up an appropriate design businesswise

3 Analysis Electrosurgery

The ESU is a device that is present in many ORs around the world and it can assist in countless surgeries. The ESU consists of three main components: the generator, the active electrode and the dispersive electrode. When adding the patient and the various wires to connect all these different elements, a closed electrical system is formed, making electrosurgery possible. This section provides an overview of the basic principles behind electrosurgery, how the various tissue effects are achieved and an explanation about the functions of the different components of the ESU.

3.1 Introduction to electrosurgery

3.1.1 History of electrosurgery

Thermal- and electrocautery

Since the prehistory energy in the form of heat was used to control bleedings. By putting a hot instrument to a wound, people stanched the bleeding, a method that is also known as thermal cautery[11, 30]. As technology evolved, the tools and devices used for thermal cautery evolved alongside. Eventually, this led to the introduction of electrocautery in the 19th century. With electrocautery, an electrical current is used to heat the tip of the instrument instead of for instance a flame. When the tip is properly heated, it can be used to obtain hemostasis by putting it to the wound[11, 30, 31].

Introduction of electrosurgery

Electrocautery is a different technique than electrosurgery. The difference is that with electrosurgery, a high-frequency alternating current is guided through the tissue to get the desired effect. The first concept of electrosurgery was introduced in the early 20th century[11, 30, 31]. It took some time however until it evolved into electrosurgery, as we know today. It was when William T. Bovie (physicist) and Harvey Cushing (neurosurgeon) started to cooperate in the late 1920's that the true forerunner of the now commonly used ESU was created[11, 12, 32]. Initially, there was only the possibility to use monopolar electrosurgery with the device made by Dr. Bovie. It took a couple of decennia for bipolar electrosurgery to find its way into neurosurgery and finally around 1955 onto the commercial market as well. Improving the technique, the ESUs and its instruments is still an ongoing process[30].

3.1.2 Electrosurgery, a misunderstood technology

Lack basic knowledge electrosurgery

Electrosurgery has evolved since the introduction in the 1920's into a technology found in almost every clinic and OR. While the basic principle has not changed significantly since first introduced, the variations in the design of ESUs itself has increased drastically in number and complexity[10, 33]. Despite its extensive use, the technology is often misunderstood. Most of the users of the ESU do not possess the basic knowledge of the principles behind electrosurgery and the accompanying equipment[10, 33, 34]. Research conducted by Feldman et al. (2012) shows that there are several gaps in the knowledge of the users. They were not familiar with the electrosurgical terminology and there was a lack of knowledge about the settings available on the generator, how the electrical current interacts with implanted medical devices and how OR personnel should respond to a fire in the OR[10].

Need for training

Most hospitals do not require their surgeons to follow a training program about the surgical techniques that involve some form of energy (except laser techniques), despite the potential dangers accompanying these technologies. It is crucial in the prevention of complications that each member of the surgical team is aware of the risks associated with the surgical technique being used during a certain surgical procedure[10, 30, 34]. As a patient you are relying completely on the competences of the surgical team and it is therefore reasonable to expect that they have proper knowledge about the equipment used during surgery[10, 30].

Figure 7. Electromagnetic spectrum with electrosurgery within the range 0.3 - 5 MHz[12]

Surgeons should receive training about electrosurgery and hospitals should be made more aware of this necessity. Note also that the ESU used during the education period as resident might be different than the ESU used in the hospital where one ends up working.

3.1.3 Operating principles electrosurgery

With electrosurgery a high frequency alternating current (AC) is put through the tissue to cut or coagulate a particular target area[11, 12, 30]. The advantage of this coagulation technique over cautery is that not only the superficial layers of the tissue will be affected, but the underlying tissues will be reached as well[12].

Factors influencing the tissue effect

The actual tissue effect that is obtained using an electrosurgical technique is influenced by various factors. First, there are the electric properties of the tissue that is targeted during the procedure. Each type of tissue within the body has its own distinctive impedance (see Table 4). A higher concentration of fluid within the tissue results in better conductivity[35-37].

CUT MODE APPLICATION	IMPEDANCE RANGE (Ω)
PROSTATE TISSUE	400 - 1700
ORAL CAVITY	1000 - 2000
LIVER TISSUE	
MUSCLE TISSUE	
GALL BLADDER	1500 - 2400
SKIN TISSUE	1700 - 2500
BOWEL TISSUE	2500 - 3000
PERIOSTEUM	
MESENTERY	3000 - 4200
OMENTUM	
ADIPOSE TISSUE	3500 - 4500
SCAR TISSUE	
ADHESIONS	
COAG MODE APPLICATION	
CONTACT COAGULATION TO STOP BLEEDING	100 - 1000

Table 4. Characteristic impedance ranges for various types of tissue[37]

Besides the tissue characteristics there are the following factors that also influence the effect electrosurgery has on the target tissue[11, 30, 35, 36]:

- Power setting
- Waveform
- Size of the electrode surface
- Shape of the electrode surface
- Tissue exposure time
- Pressure exerted on the tissue

How the alternating current influences the cells and tissue

Electrosurgical generators generally produce an AC between 0.3 and 5 MHz (see Figure 7). In this range, the high frequency current can take advantage of the heating effects of the electrical current, but it avoids neuromuscular stimulation, which causes pain, causes muscles to contract and in severe cases may even lead to cardiac arrhythmia[12, 35, 38].

Figure 8 provides an illustration of the effect a direct current (DC) and an AC have on a cell. Within a cell, there are anions and cations to be found. Anions are ions with a negative charge and ions with a positive charge are called cations. With a DC, the anions will go towards the positive pole, while the cations tend towards the negative pole. If an AC is applied, the ions will still tend to migrate towards their opposite pole. The fast changing polarity now makes that the anions and cations start to oscillate.

This oscillation due to the polarity change at 5 MHz will convert the electromagnetic energy into mechanical energy and the high speed combined with friction will then convert the mechanical energy into thermal energy[30]. This process stands at the base of the rise in temperature within the cell, whose effects will be further explained in section 3.1.4.

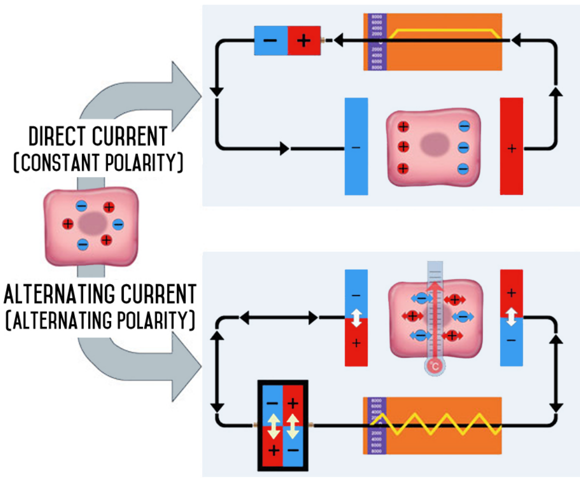

Figure 8. Effect DC and AC on the cell content[30]

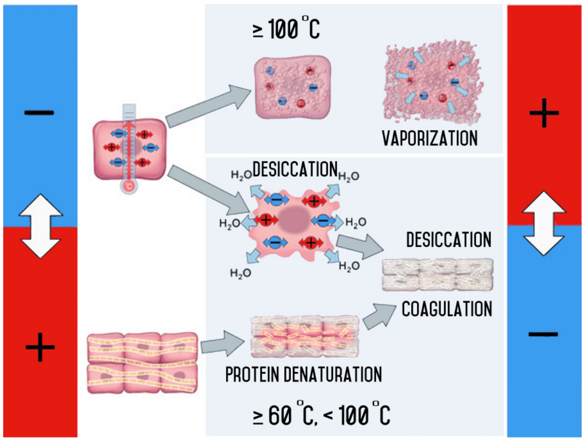

Figure 9. The effect of rise in temperature on tissue[30]

3.1.4 How temperature influences cells and tissue

The high frequency AC that is used during electrosurgery causes changes on a cellular level. Within the cells the electromagnetic energy converts into kinetic energy and from kinetic energy into thermal energy (see section 3.1.3) causing the water within the cell to heat[30]. See Table 5 and Figure 9 for an overview of the effects of increasing temperature within the cells. This section will elaborate on these effects.

Coagulation, desiccation and fulguration

A healthy person has a body temperature of about 37°C and only during an infection the body will raise the temperature to approximately 40°C to fight off the infection. This slightly raised temperature has some effect on the cells, but it does not damage the structural integrity of the cells. Even if the rise in temperature occurred very rapidly and reached about 45°C or 50°C, there is still the ability for the cells to return to their normal state when the temperature is brought down again[30, 37]. The structural integrity will, however, be compromised when the temperature in the cells rises above 50°C. With this cellular temperature the cells begin to degrade and will be dead in about 6 minutes. With a temperature of 60°C or higher this dead will be immediate[30].

Coagulation

Between 60°C and 95°C cells die instantaneously, but there are two processes that occur alongside each other that are significant for electrosurgery. First, between the protein molecules within the cell hydrothermal bonds exist, which are instantaneously broken when they reach a temperature of about 60°C. At this temperature these bonds can quickly reform, resulting in protein denaturation. This first process is also known as coagulation[30].

Desiccation

The second process is known as desiccation and it signifies the drying of cells when they gradually lose their water content through their damaged cellular wall[12, 30]. Desiccation will increase the impedance of the tissue due to the dried out top layers and this makes it harder to reach adequate tissue depth[12].

TEMPERATURE	EFFECT
40°C	REVERSIBLE CELLULAR DAMAGE
≥50°C	IRREVERSIBLE CELLULAR DAMAGE
60-80°C	COAGULATION: DENATURALIZING OF PROTEINS; COLLAGEN CHANGES TO GLUCOSE; A COAGULUM IS FORMED
80-100°C	SLOW VAPORIZATION OF CELL CONTENT, LEADING TO CELL DEHYDRATION AND SHRIVELING: DESICCATION
>100°C	RAPID VAPORIZATION OF CELL CONTENT, LEADING TO CELLULAR MEMBRANE RUPTURE: CUTTING
≥200°C	CARBONIZATION

Table 5. The effects different temperatures have on a cell[35]

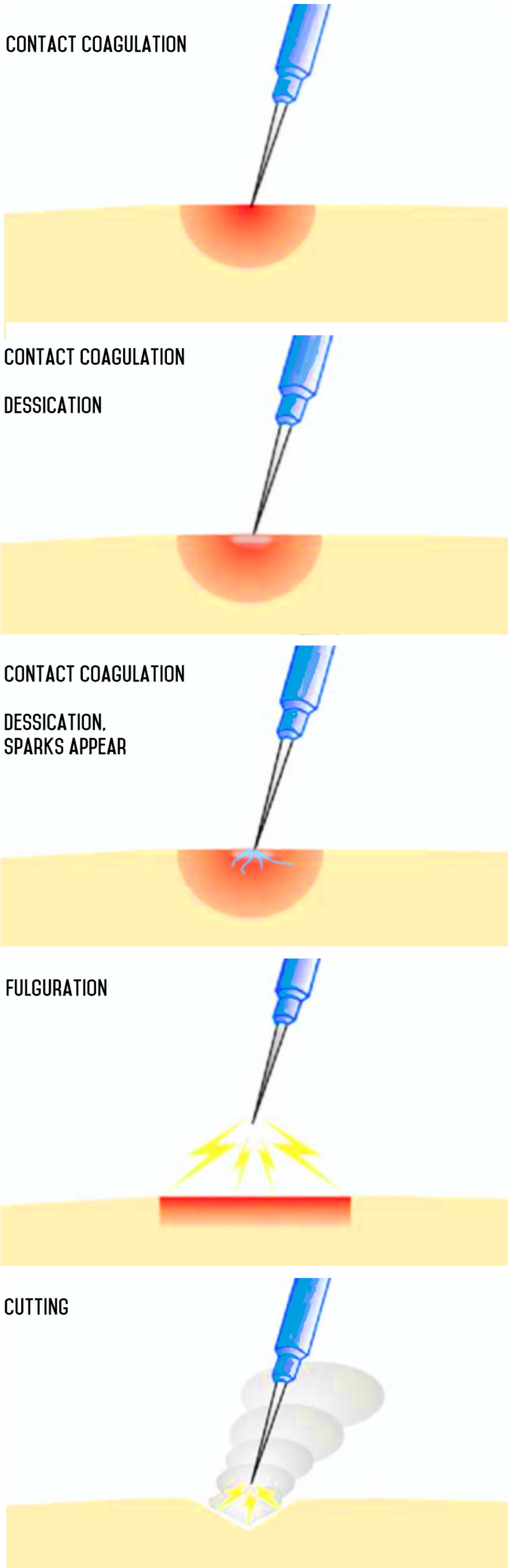

Figure 10. The effect of different waveforms on tissue [11]

Fulguration

With fulguration, which is often also referred to as spray or non-contact coagulation, the tip of the monopolar instrument is held above the target tissue, creating an air gap of a few millimeters. To bridge this gap, the electric current releases an electric discharge arc that can be seen as a spark [11, 12, 37]. Fulguration is a technique that also results in coagulation, but local temperatures can rise above 400°C so carbonization will also occur. The advantage of this method is that a large area can be quickly coagulated. The depth of coagulation is however limited, because the tissue impedance of the superficial layer is rapidly increased, leaving it hard to reach deeper layers of the tissue[30].

Cutting

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 the content of the cell, which cannot be hold by the cellular walls. The cell will burst, demolishing the cellular wall hereby giving way to the active electrode to get through the target tissue[12, 30].
The advantage of cutting tissue by means of electrosurgery instead of by scalpel is that coagulation can occur on the walls of the incision. This is especially the case with smaller blood vessels; larger vessels are likely to need additional coagulation to obtain hemostasis[12].

Carbonization

Carbonization occurs when the temperature rises above 200°C. With this process the tissue will become brown and/or black. The color is the result of the organic molecules that come apart at this high temperate, leaving only the carbon molecules behind. It is often the result of using a too high power setting[30, 37].

3.2 Electrosurgical unit

The generator is there to convert the low-frequency AC of the power grid into a higher voltage radiofrequency output. It can produce several types of current waveforms that allow the different tissue effects in electrosurgery.

3.2.1 Operating principle generator

There are two ways to control the generator of the ESU. The voltage controlled generators, the power controlled generators and some generators that make use of a control system that combines these two principles to get the desired tissue effect. This section will give an explanation on the different forms of control and the various waveforms that can be produced.

Voltage controlled generator

When using a voltage controlled generator a certain voltage and mode have to be chosen. The generator will vary the power to keep this chosen voltage constant during surgery regardless of the type of tissue or the pressure that the surgeon applies to the tissue. For safety reasons the user should choose a maximum power output to prevent extreme heating when dealing with tissue that has very low impedance. [39].

Power controlled generator

Power controlled generators are used most often in practice. The principle behind this type of generator is that it regulates the voltage to keep the output power constant[37, 39]. The generator creates the same power output regardless of the type of tissue operated on or the pressure applied by the surgeon[39].
Table 4 shows that the impedance of adipose tissue is one of the highest and it might occur that it is no longer possible to cut through this tissue due to the inability to create the cutting spark. The surgeon should apply less pressure to the tissue, thereby decreasing the contact area of electrode and tissue, to increase the heating effect making cutting possible again[39].

Combination of power and voltage controlled

The third type of generator uses a combination of voltage and power control. These generators have the ability to switch between the two types of control to get the best tissue effect[39].

Waveforms

By varying the waveform, different tissue effects can be achieved. See for the basic waveforms Figure 11. The waveform a generator produces is often related to the brand of the ESU.

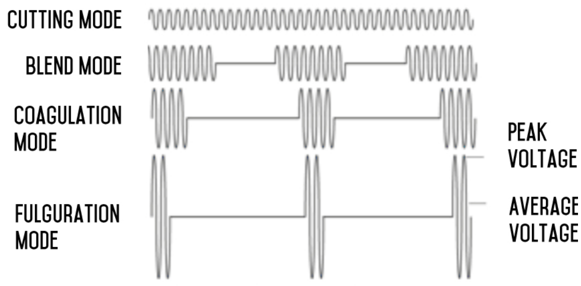

Figure 11. The different types of waveforms[12]

Cutting mode

For cutting tissue a continuous wave is used. This continuous waveform is also referred to as the pure cutting mode[12, 31].

Coagulation and fulguration mode

The waveform used for coagulation is damped between sine bursts, hereby allowing the cells briefly to cool down to achieve a greater zone of coagulation. The percentage of the total time that there is actually an electrical current produced by the generator is also known as the duty cycle. For instance if there is only a current flowing for 8% of the time, this is called an 8% duty cycle. The coagulation mode has a lower current than while cutting, but contains a higher voltage at a similar power setting. In fulguration, a gap between the instrument and the tissue has to be overcome so a very high voltage is used. This helps create the spark needed for fulguration[12, 30, 31, 40]. Next to the duty cycle another term is used to describe the waveform, namely the crest factor or also referred to as the peak-to-average power ratio. It indicates the ratio of the peak amplitude of the waveform compared to the average amplitudes[40].

Blend mode

Blend mode uses an altered version of the cutting waveform causing coagulation on the section walls of the tissue while cutting. The type of blend used is determined by the duty cycle and is different for each brand of ESUs[30]. For ESUs there is no standardization within the market to promote ease of use. Each ESU has its own characteristic interface and characteristic way of displaying the chosen power output. Some brands work with an indication of power

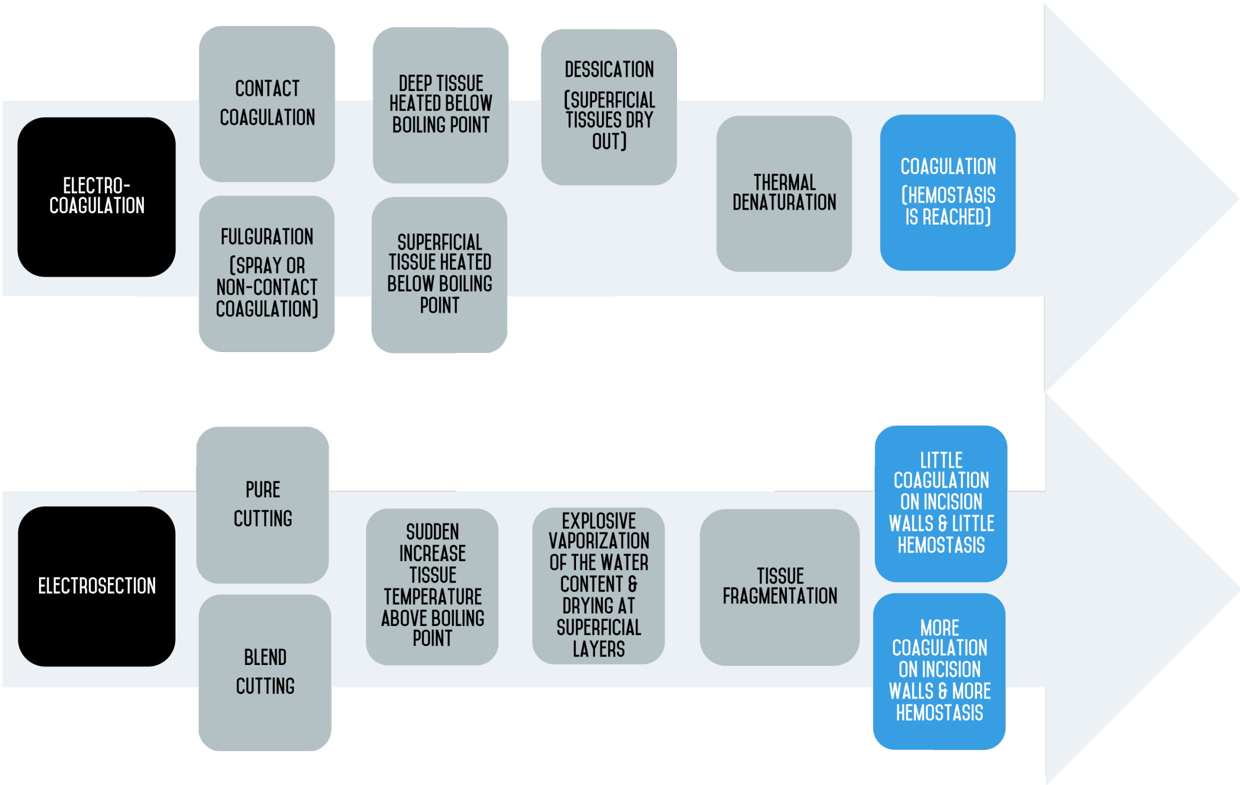

Figure 12. Overview of the different tissue effects as result of a certain mode

in Watt, while others simply use an arbitrary numerical indication such as from 1 to 10[40]. There is also a great range in what other functions the ESU has to offer next to the different waveforms, think for example of an incorporated water pump or some type of smoke evacuation system.

3.2.2 Importance of using low-voltage output

There are many manufacturers of ESUs and as mentioned earlier, they come with their own set of waveforms and names for these modes. There are many outputs that can be used to achieve tissue coagulation, but where a continuous low-voltage waveform (also known as the cutting mode) will lead to a predictable and qualitatively good area of coagulation, the actual coagulation mode will result in less consistent coagulation of lesser quality [30].

There are three reasons that can be distinguished for this occurrence. First, the bonds that are reformed between the proteins are not evenly distributed. Secondly, some of the waveforms only result in coagulation of the superficial layers of the tissue, such the fulguration mode (see section 3.1.4.). The next spark will be diverted to an area with less impedance resulting in an incoherent area of coagulation[30].

The third reason is the high temperature that will be generated near the tip of the electrode. This tissue will likely carbonize and the molecules will come apart making it easy for the tissue to adhere to the electrode tip. By moving the electrode the just sealed tissue will be ripped open again, causing bleedings[30].

3.2.3 Monopolar electrosurgery

The electrosurgical current can be delivered either monopolar or bipolar. With monopolar electrosurgery there is one active electrode and a dispersive electrode to close the circuit that also consists of the body of the patient (see Figure 13). For minor surgical procedures outside the operating room, such as certain small dermatological procedures, monopolar electrosurgery can be used without the placement of an dispersive electrode[12, 13]. However, these are the exception and for most surgical procedures it is crucial to properly place the dispersive electrode.

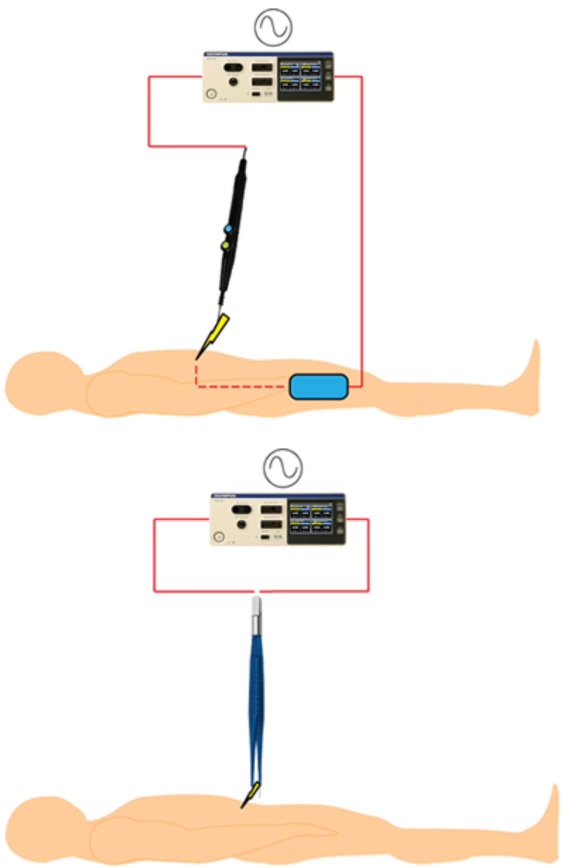

Figure 13. Above: Monopolar Electrosurgery with active electrode and dispersive electrode. Below: Bipolar Electrosurgery with instrument consisting of two electrodes [35]

3.2.4 Bipolar electrosurgery

In bipolar electrosurgery the electric current flows from one forceps tine through the tissue between the tips, to the other forceps tine and then back to the generator. Only the tissue grasped between the tips of the bipolar forceps takes part in the electrical circuit. These forceps act as two active electrodes [12, 13].

3.2.5 Dispersive electrode

The dispersive electrode, also known as the return electrode or neutral electrode is a large electrode that is connected to both patient and generator, hereby closing the electrical circuit. This dispersive electrode is often placed on the thigh, a muscular location that has a good blood supply. This electrode basically acts as the opposite pole and deals with the same current as the active electrode. Due to the dimensions of this electrode the current is spread over a large surface area, thereby preventing the temperature beneath the electrode to rise too high[30, 33].

There are two main types of electrodes, the single-plate dispersive electrode and the split-plate dispersive electrode. This split electrode consists of two components and by measuring the resistance between these components it is possible to check how well the dispersive electrode is connected to the skin. With this type of electrode it is possible to monitor the quality of the contact between skin and electrode and serves as a safety feature, since the ESU is able to deactivate when contact with the skin is poor and starts to pose a risk for the patient[13, 41].

3.2.6 Electrosurgery and argon plasma

With conventional fulguration a spark is used to achieve coagulation (see section 3.1.4.)[12, 38]. It is also possible to use argon gas during fulguration. This gas prevents oxygen from getting to the target tissue. The advantage of this is less smoke production compared to normal electrosurgery, it provides a clearer surgical field and there is less chance of carbonization of the tissue[38].

3.2.7 Feedback controlled bipolar electrosurgery

Next to the monopolar and bipolar electrosurgical techniques as described in this section, there are more advanced techniques. Bipolar electrosurgery is safer than monopolar electrosurgery, but it is limited in certain functions (see section 3.3.7). The Ligasure™ has been developed to include a cutting function in the bipolar instrument. This mechanical cutting mechanism is used to separate the coagulated tissue when optimal coagulation in sensed by this feedback-controlled instrument. (The resistance in the tissue is measured and the electric current is switched of automatically when the desired effect has been reached) [38].

3.3 Risks electrosurgery

Electrosurgery is a useful technique, but it is not without its risks. This section briefly describes the different complications that are common with electrosurgery.

3.3.1 Dispersive electrode burns

The site on which the dispersive electrode is placed is prone to skin burns if placed improperly. The dispersive electrode consists of a large area to make sure the current density is low, hereby preventing the skin underneath to heat. If the contact area between skin and electrode is too small, the patient will experience burns at this site[11, 31, 35]. This risk is related to monopolar electrosurgery.

3.3.2 Alternate site burns

The current will always seek the path of least resistance. If a patient comes in contact with a conductive material while monopolar electrosurgery is used, it is likely that the current will pass through this alternative path. If the contact area is small, the current density will be high and lead to skin burns at this site[31].

3.3.3 Residual heat

If used for a longer period of time, the tip of the instrument will likely heat during electrosurgery. It should be prevented that this tip comes in contact with other tissue than the target tissue to avoid unintentional damage. This risk is exists for both monopolar and bipolar techniques[35].

3.3.4 Insulation failure

As the current will seek the path of least resistance, a defect in the instruments insulation can lead to the current following an alternative path. If the current density is high enough, there will be damage to the surrounding tissue. Repeated sterilization of the instrument and/or the use of a high voltage are two of the causes that lead to insulation failure[11, 31, 35].

3.3.5 Direct coupling

When during activation of the electrosurgical instrument, the tip comes in contact with another instrument of conductive material; the current might follow this alternative path. If somewhere this instrument comes in contact with tissue, burns will occur at this site[11, 31, 35].

3.3.6 Capacitive coupling

With capacitive coupling there is a thin insulating layer between the active electrosurgical instrument and another conductive instrument. The insulating layer can however not prevent the current to 'flow over' from the active tip to the conductive element such as for instance a steel trocar. If this steel trocar comes in contact with tissue in the abdomen for example, this can cause damage to the tissue[11, 31, 35].

3.3.7 Monopolar vs bipolar electrosurgery

Advantages bipolar electrosurgery

As the previous section about the risks of electrosurgery illustrates, monopolar electrosurgical techniques are more likely to cause complications than the use of bipolar electrosurgery. Bipolar electrosurgery is safer, partly because less power is needed to achieve the same tissue effects and because of the current that flows only between the two electrodes and the target tissue instead of the entire body[13, 35].
Bipolar electrosurgery also reduces the damage surrounding the target tissue. It is more precise and makes it therefore suitable for delicate surgery such as neurosurgery[30, 40].

Disadvantages bipolar electrosurgery

Disadvantages of bipolar electrosurgical techniques are that it is hard to use on larger surfaces and that it in general cannot be used for cutting[30]. For these purposes monopolar electrosurgery is more useful. There are some bipolar devices and accessories available that provide a cutting ability on a small scale, but these devices are not commonly used and hard to find. The complex design of these devices and accessories causes high manufacturing costs, especially when compared to the costs of the monopolar devices that ensure a similar tissue effect[40]. Due to the immediate contact between the bipolar tips and the tissue it is more likely that tissue will stick to the tip of the instrument.
Due to this tissue that is stuck to the instrument, the electrical current will be obstructed causing an irregular area of coagulation and another disadvantage is that by removing the instrument the tissue can be ripped open again.

3.3.8 Laparoscopic electrosurgery

With laparoscopic procedures the field of vision of the surgeon is limited and only the tip of the electrosurgical instrument is in view. If complications occur, such as burns to non-targeted tissue, the surgeon will not notice this if it occurs along the instruments' shaft outside is field of view. Only after the procedure, when a patient begins to shows signs of for instance hemorrhage or infections, is the injury sustained during electrosurgery detected[34]. But even if the surgical team is aware of an injury sustained by electrosurgery during the operation, the depth and impact of the injury is hard to assess[10].

4 Electrosurgery in Practice

While previous sections focused on literature and background information about the topic, this section will explain more about the use of electrosurgery in practice. Some notable observations made at Leiden University Medical Center (LUMC) are described and an overview given of the problems that have been found thus far regarding ESUs and electrosurgery. Next to this, there will also be elaborated on the power settings and modes used during several surgeries at Reinier de Graaf Gasthuis (RdGG) and LUMC.

4.1 Observations surgeries at LUMC

To get an understanding of the current use of the ESU, observations have been made at the departments Gynaecology, Surgery, Otorhinolaryngology and at Trauma Surgery of Leiden University Medical Centre (LUMC). The observations made can be found in Appendix B. The department OR's visited were derived from the list of 15 proposed essential surgeries that should be available to everyone composed during the symposium 'Surgery in Low Resource Settings' on November 15th 2014 in Amsterdam.

4.1.1 Electrosurgical units at LUMC

In every OR an ESU can be found, but the brand is not always the same. In OR 2, OR 9, OR 15 and OR 16 the Erbe VIO 300D is present. In OR 7 the Valleylab Force Triad with the option of a LigaSure™. This is in line with what Jos van Hameren (staffmember of the Technical Department at LUMC) mentioned; of the 20 OR's at LUMC, 4 OR's are equipped with Valleylab, the others with Erbe VIO 300D. For neurosurgery a special device is available and a device with argon gas can also be requested. The technical department can add new programs on request by a surgeon/physician.

4.1.2 Common problems electrosurgical units LUMC

The most commons problems that occur with the ESU are cable breaks or a bad connection due to a not proper put in plug or broken socket. This corresponds to the most common failure of technical equipment found in the study by EWH. The power supply was in 29.9% of the cases the reason for broke down medical equipment[7].

4.1.3 Notable observations LUMC

Before surgery is started, the surgeon chooses a certain pre-set program. This chosen program and setting is based on the type of surgery to be performed and the preference of the surgeon. Once a program is set, it is almost never changed during surgery. It became clear that the surgeon does not really understand what the setting stands for. They almost always use the program they are familiar with.
For cleaning of the instrument tip a special scourer is provided. Most often the surgeon however uses other means to clean the tip, such as forceps or gauze. Noteworthy is also the use of a tweezers or forceps to seal a vessel by putting the tip of the activated monopolar instrument against the tip of the instrument they or the OR assistant are holding.

4.2 Overview problems electrosurgical unit

Electrosurgery is a commonly used surgical technique, but during the analysis phase of the project it became clear that it is not without its risks. The underlying causes for the problems related to electrosurgery were not clear in literature or widely known by the users in the OR. This section provides an overview of the detected problems.

4.2.1 Problems associated with electrosurgery

Problem Tree

To create an overview of what the underlying causes of the risks in electrosurgery are and what it eventually means for the user and, most importantly, for the patient being operated on, a problem tree was created. To be able to serve as a clear guide in designing a safer ESU the overview contains only the problems related to electrosurgery and not yet how the problems specific to medical equipment in LMIC relate to this. This overview helps to incorporate solutions for problems encountered in the developed world in the design that should be appropriate for use in LMIC. See Figure 14 for the problem tree.

Problems with electrosurgery

The study conducted by Mayooran et al. (2004) shows that the main reason for complications that commonly occur during electrosurgery is the lack in basic knowledge of electrosurgical principles and the lack of effective training programs that would provide the surgeons with the necessary knowledge and skills[34]. This has also been seen in other studies and became apparent during observations made at LUMC.

Another problem of electrosurgery are the unknowns. It is not clear for specific types of surgery, which waveform and which power setting should be used to get the best result. In addition there are many companies, which all have their own brand-specific names for the modes available on the ESU. There are no large studies that compare the effect that different types of ESUs and their associated power settings and modes have on human tissue. It is therefore hard to identify which power setting and waveform proves most effective during a certain surgical procedure. The choice of the type of waveform and the power setting is almost solely based on the experience of the user and their preference[40, 42].

The complexity of the ESUs, the gaps in available data on electrosurgery and the lack of knowledge that the users have about the basic underlying principles of electrosurgery increase the risk of complications during use in developed countries. LMIC have their own set of problems related to the use of medical equipment (see section 2.4) and this in combination with the problems that occur in a fully functional OR in the developed world, proves that a lot of improvements should be made for an ESU so that it can be safely used in LMIC.

Problem Tree

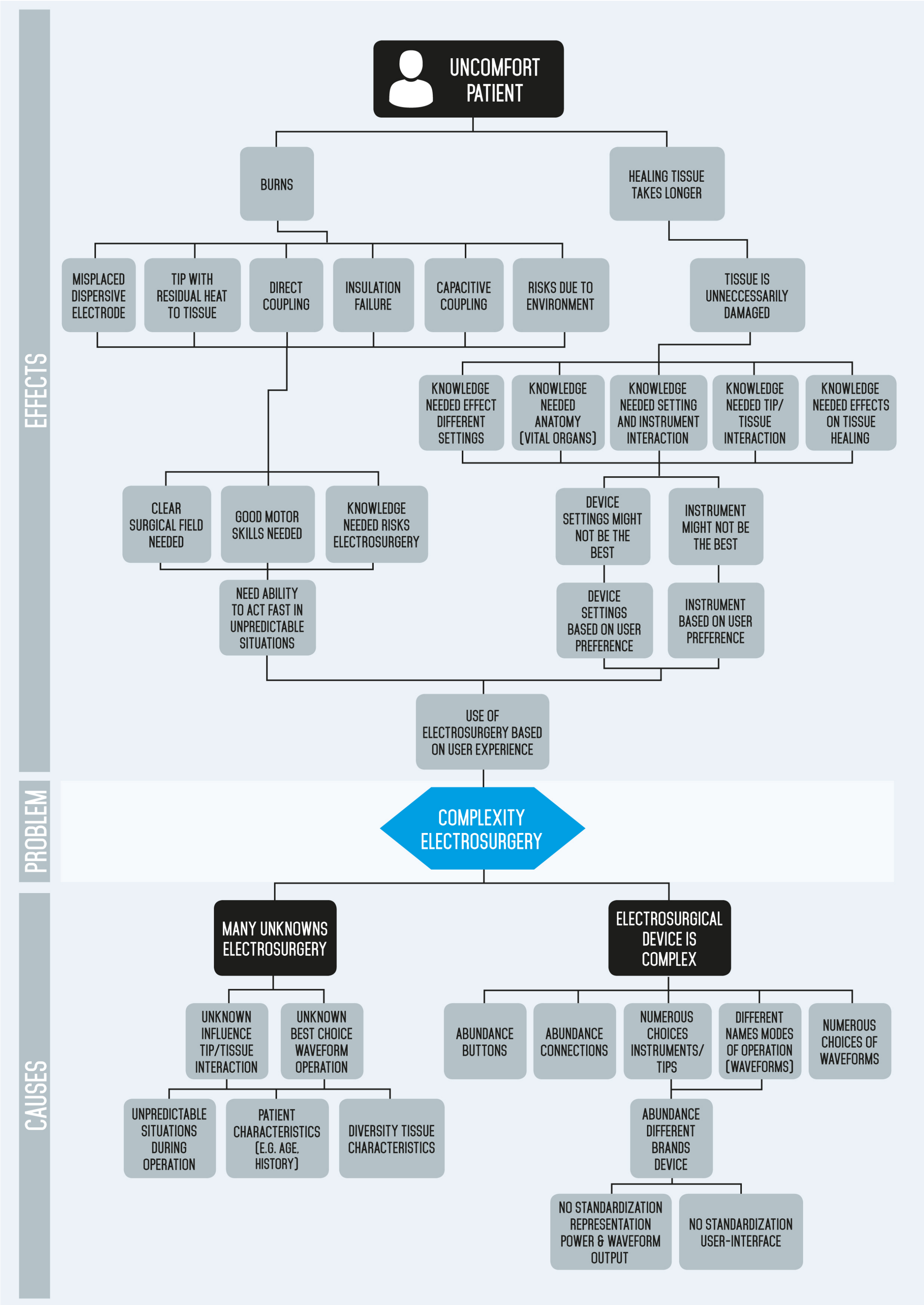

Figure 14. An overview of the problems associated with electrosurgery, causes and their effects.

4.3 ESU power settings

Key finding in the preceding analysis phase was that the settings of the ESU are based on the preference of the surgeon, while research showed that they often lack the basic understanding of the underlying principles of electrosurgery. A solution to this problem could be to give the surgeon setting options that do not provide a wide range, but instead are fixed on certain pre-set values. According to literature the effect that electrosurgery has on the tissue, depends on various factors.
The goal of this section is to provide a discussion of what is expected during surgery regarding the settings and what actually happens in the ORs of RdGG and LUMC.

TYPE OF HOSPITAL	
RDGG	GENERAL HOSPITAL
LUMC	ACADEMIC HOSPITAL

Table 6. RdGG and LUMC are different types of hospitals

4.3.1 Expectations

Literature describes different factors that influence the tissue effect and it is expected that during surgery the surgeons will act accordingly (see section 3.1).
The generators used at RdGG and LUMC are the Valleylab Force Triad, Valleylab Force FX and the ERBE VIO300D. The power settings and mode should be chosen to suit the surgery that has to be performed, the patient characteristics and the type of electrode that will be used.
For an electrode that has a shape and surface area that concentrates the current, such as a needle electrode, a lower power setting should be used than for instance a blade electrode.
During observations at LUMC at the start of the project however, it was noted that the setting was almost never adjusted during surgery. If in practice the change is not needed, it could be possible to limit the range of the power settings, consequently simplifying the design.

4.3.2 Results surgical data

In Appendix G data can be found of 25 cholecystectomies and 18 breast surgeries at RdGG and 15 procedures conducted at LUMC. This data was used to check what happens with the settings and modes in practice.

25 Cholecystectomies

The surgeries are performed on a Valleylab Force FX or a Valleylab Force Triad. See Table 4 for the different tissues in the human body and its impedance. For the gallbladder the impedance is between 1500 Ω and 2400 Ω. Figure 15 shows the settings each surgeon has used during the cholecystectomy. In appendix G can be found that S1 has performed 58% of the 25 surgeries, S2 19%, S3 11%, A2 4% and A4 8%. The S stands for surgeon and the A for an assistant.

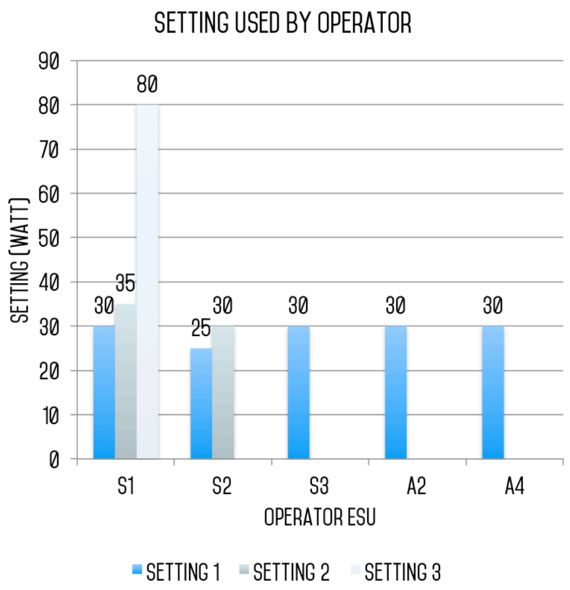

Figure 15. The setting each operator uses during the cholecystectomies

Noteworthy is that during the 6th cholecystectomy the setting is increased from 30 to 35 Watt. For the 7th cholecystectomy this setting is not adjusted and also performed with a 35 Watt power setting. This situation is repeated during the 23rd, 24th and 25th cholecystectomy. This can also be seen with the mode. At the 30th of April the mode is set to spray in the first surgery of the day and the mode stays the same for all surgeries that day. This might imply that the setting and mode are not always consciously chosen for each new patient.

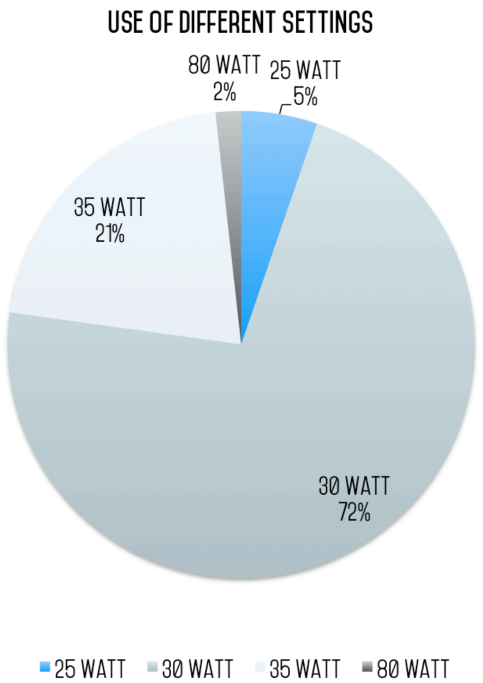

Figure 16. Diagram of how often a certain setting is used during the 25 cholecystectomies

Setting

As Figure 15 and Figure 16 show, the power setting of 30 Watt is used most often. Only surgeon S1 uses the 35 and 80 Watt settings. There seems to be some common practice at RdGG to use the setting of 30 Watt, but it is clear that each surgeon can make its own decision on which setting will be used.

Mode

During these surgeries it can be derived from Figure 17 that coagulation is the most important mode, since the blend mode (cutting mode) is used in only 9% of the cholecystectomies. However, no clear preference can be distinguished between the different coagulation modes available on the ESU. This raises the question if it is necessary for the ESU to have these different coagulation modes or if only one mode will also suffice.

Instrument

Figure 18 shows the hook instrument (haakje) is used most often. The tables in Appendix G show that the power setting is not adjusted for the blade electrode or the hook electrode. Possible explanation is that the hook electrode is chosen, because of its ability to concentrate the current better than the blade electrode, which makes it unnecessary to change the power setting while still achieving higher temperatures of the tissue.

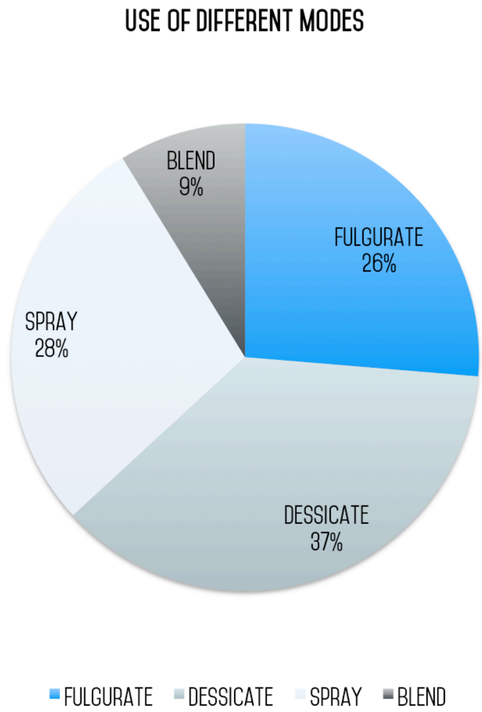

Figure 17. Diagram of how often a certain mode is used during the 25 cholecystectomies

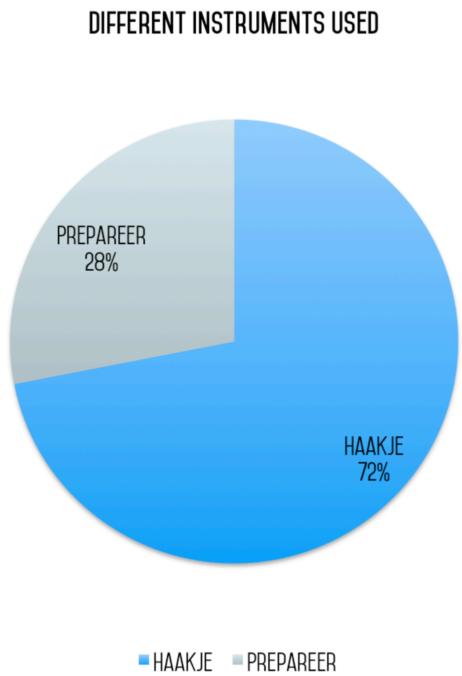

Figure 18. Instrument used during surgery

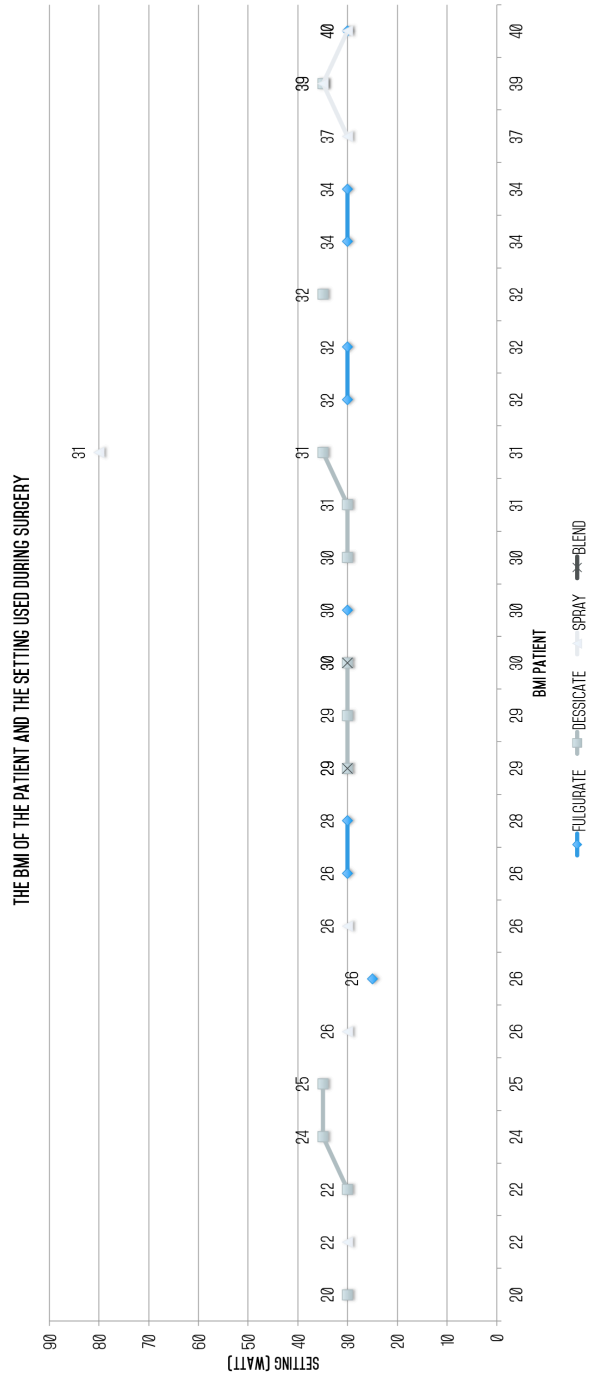

Figure 19. Patients BMI and the setting used during that surgery

Influence BMI on setting

The data on the cholecystectomies includes the BMI and age of the patients operated on. This has been used to check if patient characteristics are considered when choosing the height of the power setting. See Table 7 for the BMI classification as given by the WHO.

Adipose tissue has a high impedance of between 3500 Ω and 4500 Ω. It could be expected that with a higher BMI, especially in the overweight and obese range, the power settings should be set accordingly. It is very likely that with a power setting that is too low for the patient it will take too long to achieve either cutting or coagulation, plus there is also the possibility that the intended effect will not happen at all.

CLASSIFICATION	BMI (KG/M^2)
UNDERWEIGHT	< 18.50
NORMAL RANGE	18.50 – 24.99
OVERWEIGHT	≥ 25.00
OBESE	≥ 30.00

Table 7. BMI Classification[43]

Figure 21 shows the BMI of each patient and the setting that is used with that patient. What can be seen is that there is no increase in power even if the patient is classified as obese. Where in theory a change in setting would be expected, in the OR itself the power setting is not changed in accordance with the BMI of the patient.

18 Breast Surgeries

From the breast surgeries found in Appendix G there are 9 Ablatio's, 7 Lump surgeries, one GRM surgery and one FAD surgery. The surgeries are performed on a Valleylab Force FX and Force Triad. Part of the breast consists of adipose tissue with impedance between 3500 Ω and 4500 Ω.

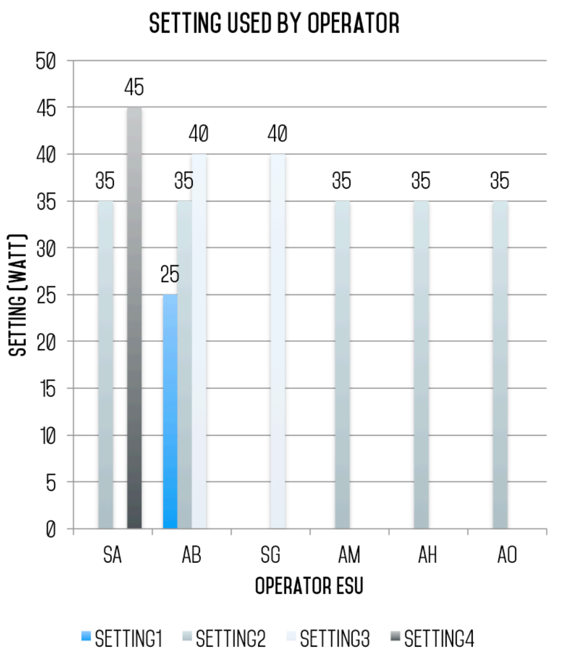

Figure 20. The setting each operator uses during the breast surgery

Setting

In Figure 20 the power settings used by different operators performing breast surgery is presented. Surgeon SA performs 33% of the surgeries, AB 11%, SG 39%, AM 6%, AH 5% and AO also 5 %. During surgery the settings of 35 and 40 Watt are used most often as can be seen in figures 20 and 21.
Operators SA and AB are the only ones using different settings. It should be noted that the 45 Watt power setting is only used 5% of the time and 25 Watt 2%. Operator AB is the only operator using 3 different settings and it could be plausible that this assistant uses the setting that is set in a previous surgery by a surgeon. The first surgery AB performs is after SA who uses a 35 Watt setting and the second surgery after SG, who uses a 40 Watt setting as can be seen in the tables in Appendix G. It is always recommended by manufacturers to use the lowest possible power setting and the 25 Watt setting might be a safety precaution by this assistant.
During the cholecystectomies each operator has used the setting of 30 Watt, but during these breast surgeries SG shows a clear preference for a setting that is further only used by AB who performs a consecutive surgery. Each operator is free to choose his or her preferred setting.

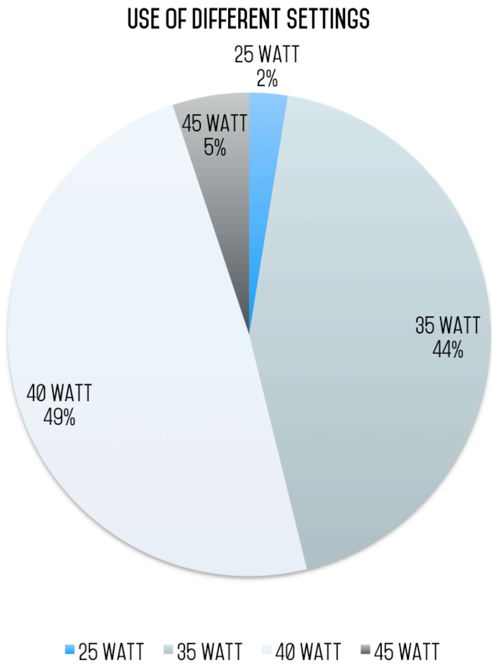

Figure 21. How often each power setting is used

Modes

These breast surgeries have an almost equal distribution of the use of cutting modes and coagulation modes. However, the blend cut mode seems preferred over the pure cut mode. For the coagulation mode the distinction between fulgurate and spray mode is less. This can imply that it is possible for a new design to only incorporate one coagulation mode.

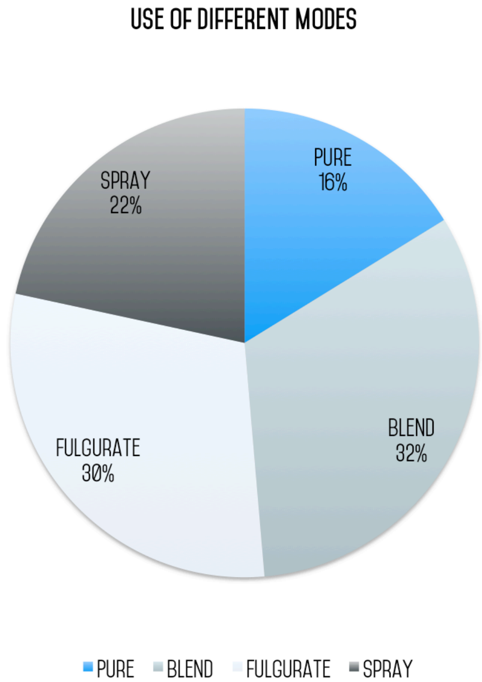

Figure 22. Diagram of how often each mode is used

Comparison RdGG and LUMC

The cholecystectomies and the breast surgeries are both performed at RdGG and gave an indication that there is some common practice, but that each operator can choose its own mode and power setting.
Since the height of the power setting is based on preference of the user, there might be large differences between hospitals. From observations made during surgeries at LUMC, an overview was created about which settings were used during different types of surgery. See Appendix K for the table. In section 6.2.1. and in section 6.2.2 a description is given about how the design was evaluated and on which points. During this evaluation the participants at RdGG were also asked to provide information about the power settings they used for surgeries performed most often (see Appendix J for the results). This information made it possible to check for surgeries that were performed both at RdGG and LUMC and it provided the opportunity to compare the power settings used in each hospital, since both hospitals use ESU's that are controlled by the same principle. The comparison is shown in Figures 23, 24 and 25.

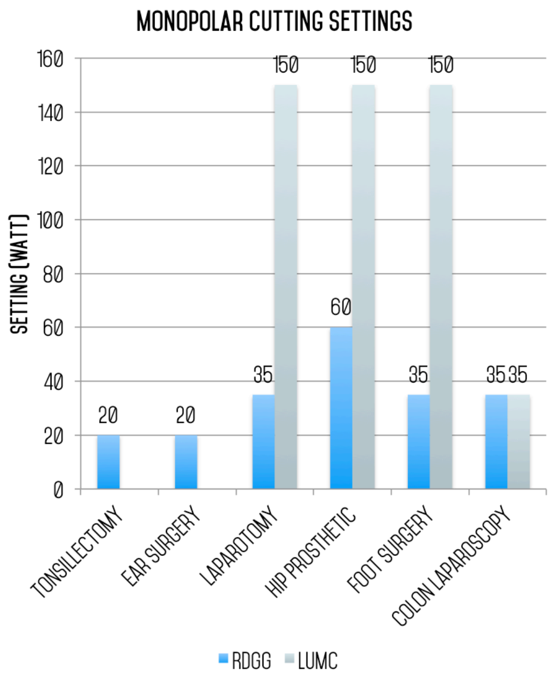

Figure 23. The difference in power settings for monopolar cutting between RdGG and LUMC

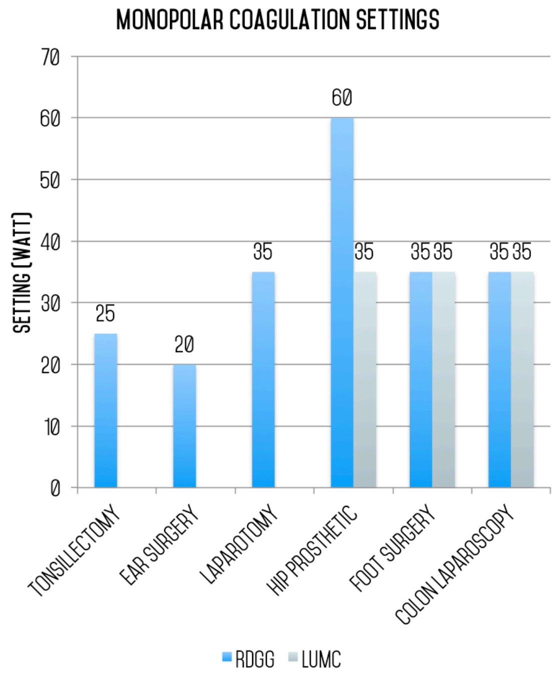

Figure 24. The difference in power setting for monopolar coagulation between RdGG and LUMC

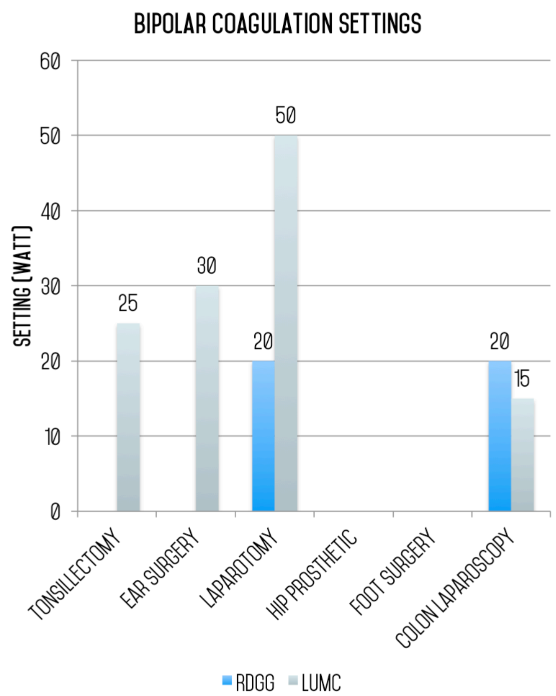

Figure 25. The difference in power setting for bipolar coagulation between RdGG and LUMC

Remarkable is that for the tonsillectomy and for ear surgery LUMC chose to only use a bipolar technique, while the RdGG also makes use of a monopolar technique. The data is however limited and the data of the RdGG surgeries might be incomplete so it is imprudent to draw real conclusions from this. Looking purely at the

power settings it could be observed that for ear surgery a higher power setting of 25 Watt is used at LUMC.
For laparotomy, placement of a hip prosthetic and foot surgery LUMC uses a very high setting of 150 Watt for monopolar cutting. RdGG uses 35, 60 and 35 respectively. The monopolar coagulation settings at LUMC are the same for foot surgery and colon laparoscopy. The data shows that at LUMC the surgeons are more likely to use high power settings than at RdGG.

4.3.3 Limitations during analysis

Only the data about the surgeries was provided. The tables are not accompanied with information on why the surgeon makes the decision in mode, setting or for a certain instrument. Spray mode is for instance known to be useful to quickly coagulate a large surface area, but it is not clear if it served this purpose during the cholecystectomies.
Most data presented in this section is on cholecystectomies and breast surgeries. Both surgeries are however soft tissue surgeries and are not representable for the wide range of surgeries were the ESU should be able to assist in. To get a good impression of appropriate settings for the ESU, it is important to collect data on different types of surgeries. Table 2 with essential surgeries can provide a good starting point.
It is interesting to see that there is a difference in settings between RdGG, a general hospital, and LUMC, an academic hospital. This comparison is made, however, on the basis of only one surgery in each category. This gives an impression, but forms no basis for drawing real conclusions.

4.3.4 Conclusion

While it is expected that the surgeon will choose and change the setting and mode in accordance with the instrument type and patient characteristics, this does not show in practice. For each type of surgery it shows that the surgeon is completely free to choose the modes and settings to his or her liking. Preferences seem to vary between hospitals. This implies that the surgery can be successfully performed with different power settings.
The data provided during this project was limited however, and it is recommended that more research will be done on a wider range of surgical procedures and with more surgeons from different hospitals. With that input it would be easier to determine which power settings and modes are crucial for the ESU to function and which functions might be eliminated to reduce the complexity of the current ESU designs.

5 Design

The goal was to design a user-friendly, robust and easy to maintain electrosurgical unit that can safely be used by surgeons and clinical officers at the district hospitals in LMIC. This section describes the design focus, which requirements were chosen as a guide and the evolution from ideas to concepts.

5.1 Design focus

During the analysis phase, the complexity of electrosurgery became apparent. It is also interesting that the settings chosen for a particular surgery are mainly dependent on the experience of the user, especially since research showed that the user often lacks the knowledge of the basic principles behind electrosurgery. The focus chosen for this project was therefore on reducing the complexity of the ESUs for surgeons, clinical officers and OR assistants and consequently hopefully also lessen the amount of training needed to operate the ESU safely.

5.2 List of requirements

This section shows the lists of requirements that have to be met by the new design. It will be explained how these requirements, which are listed in Table 8, are the result of what has been discovered during the analysis phase of the project.

LIST OF REQUIREMENTS	
1.	THE ESU SHOULD BE SUITABLE FOR USE IN DISTRICT HOSPITALS
2.	THE ESU SHOULD BE ABLE TO BE OPERATED BY SURGEONS, CLINICAL OFFICERS AND OR ASSISTANTS
3.	THE ESU SHOULD BE ABLE TO ASSIST WITH THE ESSENTIAL SURGICAL SURGERIES PROPOSED BY DEBAS ET AL.
4.	ELECTROSURGERY SHOULD BE AVAILABLE FOR EVERYONE
5.	THE ESU SHOULD BE SAFE IN USE
6.	THE ESU SHOULD BE INTUITIVE
7.	INITIAL COSTS AND RUNNING COSTS OF THE ESU SHOULD BE LOW
8.	MAINTENANCE AND REPAIRS SHOULD BE ABLE TO BE DONE BY LOCAL TECHNICIANS

Table 8. List of requirements for a new design

5.2.1 List of requirements

1. THE ESU SHOULD BE SUITABLE FOR USE IN DISTRICT HOSPITALS

The first requirement defines the type of facility in which the ESU should be able to be used. In section 2.3.2. the referral system commonly used in healthcare has been briefly explained. A critical aspect for the patients in LMIC is the inability to reach a higher-level facility where specialized care can be received. The private hospitals in LMIC are often similar in standard as those in the western world, but often out of reach for the poor population due to the high costs. Although in real practice the district hospitals frequently have to deal with the barriers elaborated on in section 2.4.2, the district hospitals are vital in providing the necessary surgical care for an extensive range of surgical conditions. According to the experts that have proposed the essential surgical package (see Table 2), most of the essential surgical conditions can be delivered at the district hospital. As the most likely facility that can still be reached by the patients and the notion of the experts that it should be possible for 28 essential surgeries to be performed at the district hospital, it has been chosen to strive for a design of the ESU that can be used at the district hospital.

2. THE ESU SHOULD BE ABLE TO BE OPERATED BY SURGEONS, CLINICAL OFFICERS AND OR ASSISTANTS

The second requirement takes into account which operators should be able to use the ESU. To establish whom these people are there has to be looked into who currently perform surgeries in LMIC.
First, there are the surgeons that originate from the LMIC and who received their training as surgeon either in their home country or some country in the developed world. Another group is surgeons originating from developed countries that provide surgery in LMIC. They have their own motives for doing this, such as wanting to help the less fortunate in the world.

They can be performing surgery in the LMIC, either on the short or the long term. Thirdly clinical officers should be taken into account. These operators of the ESU have not received the surgical training that surgeons have, but are trained in performing one or more specific surgical procedures without the supervision of a surgeon. Lastly, there are the OR Assistants that do not carry out the surgery, but who have to be able to operate the ESU based on the wishes of the performing surgeon or clinical officer.
The extent of knowledge about electrosurgery, the surgical procedure and the skills in operating medical devices (see Figure 14 for other aspects) varies between the different operators in LMIC. The use of electrosurgery is based on the experience of the user so each of them has to be considered.

3. THE ESU SHOULD BE ABLE TO ASSIST WITH THE ESSENTIAL SURGERIES PROPOSED BY DEBAS ET AL.

The third requirement focuses on the surgical procedures in which the ESU should be able to be used. As has been explained in section 3.1.3., the effect of electrosurgery is influenced by many factors and these can be different for each type of surgery and each patient, all having its own implications for what the ESU should be able to deliver. To have some notion of which surgical procedures the ESU should be suitable for, the proposed essential surgical package is taken into account (see Table 2). This list of surgeries that have the potential to make a significant difference in patients' lives and that are likely to be able to be performed in the district hospital can be used as a framework. It serves as a guide in setting some realistic boundaries for the ESU in reducing its complexity.

4. ELECTROSURGERY SHOULD BE AVAILABLE FOR EVERYONE

The injuries and illnesses that could have been helped through surgical intervention caused over 16 million deaths in 2010. Among these deaths are both children and adults of all kinds of postures. To save lives in both groups, it is important that appropriate equipment is available, not only for the difference in child and adult, but also for differences in BMI or for instance for patients with a medical history.
People requiring surgical care should be able to receive this at the district hospital with its limited resources, regardless of their physical properties or very limited budget.

5. THE ESU SHOULD BE SAFE IN USE

During surgery, it should be avoided that the patient gets new injuries. Electrosurgery has certain risks (see section 3.3) and the new design should eliminate as many potential safety hazards as possible. Although some difficulties will remain due to the nature of electrosurgery, it should be safe in use for both the patient and the person operating the ESU.

6. THE ESU SHOULD BE INTUITIVE

The people that operate the ESU in LMIC do not all have the same level of training regarding the device or the use of electrosurgery and its potential dangers. Additionally, there is the abundance of different ESUs that all have their own interface and characteristic names for settings and waveforms. It is not guaranteed that the ESU used during the training, will also be the device used when training is completed.
To ensure the safety of both user and patient, it should be obvious how the ESU has to be operated, regardless of lack in previous experience with that particular device or level of training that has been received. To put it differently, the device should be intuitive. Intuitive means that you can understand, in this particular case, how the device should be operated without rational thought. An intuitive design makes it easier and possibly safer to operate even if knowledge about it is limited. To promote safe use by staff lacking the proper knowledge the sixth requirement is that the ESU should be intuitive.

7. INITIALS COSTS AND RUNNING COSTS OF THE ESU SHOULD BE LOW

What generally can be said about the population in LMIC is that they are poor. The patients are not the only ones with very limited purchasing power; the ministries of health and different types of facilities delivering surgical care are often also bound by a very tight budget. For these hospitals to be able to acquire the ESU, it is important to keep the purchasing costs of the device low. The running costs of the ESU should also be kept low. Think for instance of the consumption of power that costs the hospital and indirectly the patient and his or her family money. Another example is the parts that have to be replaced when broken down. If the parts are too expensive, the device will likely be put out of use.

8. MAINTENANCE AND REPAIRS SHOULD BE ABLE TO BE DONE BY LOCAL TECHNICIANS

Section 2.4.2. has shown that there is a lack of technical staff and among them, there is not always the knowledge necessary to properly maintain and fix the medical devices. For the design of the ESU, it should be kept in mind that there are not many highly skilled technicians to fix the medical devices, but also that it is hard to acquire complex parts or all the tools required to deal with complex connections. In the design process, these aspects should be taken into account, to ensure that the device can easily be maintained and fixed with the tools and knowledge available in LMIC.

5.2.2 Environment district hospital and transport

The first requirement already implies that the ESU should be able to withstand conditions that can be encountered in and around the district hospitals. To make a realistic assumption of what could be expected of the ESU regarding these harsh conditions, several existing devices were used as a guideline.

- During transport and storage the ESU should withstand -40°C to + 70°C[44]
- During transport and storage, it should withstand relative humidity of 10% - 100 % including condensation[45]
- It should withstand operating temperature range 0 – + 40°C [44, 46]
- It should withstand operating in relative humidity of 15% - 80% noncondensing
- The ESU should withstand transport across rough terrain

5.2.3 Users whishes

Maintenance is often neglected in LMIC, which can lead to potentially dangerous situations for the patient and the user. Besides the safety aspect, the device is also more likely to break down without proper maintenance. It is therefore important that the device is designed for durability. If possible, the aspects requiring maintenance should be replaced by a solution that gets around elements requiring maintenance. The wish of the users is an ideal situation:

- Working equipment that requires no maintenance

5.3 Ideation

The ESU consists of several elements, each with their particular set of problems. The main component is the generator and if focused on the user (the surgeon, clinical officer or OR assistant) the interaction with the generator is with its interface. The other components are the monopolar instruments, the dispersive electrode and the bipolar instruments. One of the accessories is a footswitch, but during this project, it was not taken into account to redesign. This section explains the process of idea generation and its outcomes.

5.3.1 Idea generation

The generation of ideas started with the use of the 'How To' brainstorm method. This method was chosen for its ability to support idea generation from different perspectives. The How Tos are open questions that give an opportunity to look creatively at several issues that came forward during the problem analysis phase. With the help of a group of people, ideas were generated.

The selection of How Tos used for the first brainstorm session are:

- How to ensure that minimal maintenance is required
- How to reduce the complexity of an interface
- How to inspire safe use of a device without the user having the proper knowledge

The How Tos of the second brainstorm session are:
- How to design a device so it will not break down
- How to ensure reparability of a device without the user having the proper knowledge
- How to make the device more intuitive

The results of these brainstorms that followed the rules of postponing judgment, stimulating the associations of ideas by other group members and with the focus on quantity rather than on quality can be found in Appendix E. In the first session two PhD candidates were asked to provide the extra input. In the second session, two Industrial Design Engineers participated.

5.3.2 Ideas for the components of the ESU

With the input of own experience with LMIC, the brainstorm, the suggestions made in papers and of the interviewed experts, an overview was created. For each component ideas for possible solutions were found on how to fulfil the requirements that are stated in section 5.2. and some background is given on what other themes are associated with these main requirements. The main requirements serve as a guide within this process. In this section, the ideas for the interface can be found. The ideas generated for the other components can be found in Appendix F.

Interface

The figures in this subsection are about the interface of the generator. They show different approaches on how to take the requirements into account for this particular component of the ESU.

1. The ESU should be suitable for use in district hospitals

The district hospital where the ESU should be used has to deal with the problems mentioned in section 2.4.2. First, the environment in which the interface should function was taken into account. It is not as organized and clean as private hospitals or the hospitals in the western world. What most likely can be expected is an environment where the temperature and humidity are not controlled, not in the OR where the ESU is used and not in the storage area (if a proper storage area is even available).
With the shortage of working medical devices at the hospital it is common that, if there are more ORs found in the hospital, the ESU will be transported between the ORs. To deal with the environment in the district hospital, it is important that the interface can withstand variations in humidity, changes in temperature, dust and the frequency with which the ESU is moved from one place to another.
Another aspect to consider is the cleaning techniques used at the hospital. More primitive cleaning methods and chemicals will be used to clean the interface. The interface should withstand these methods of cleaning. Besides, there is often a lack of user maintenance and to lower the chance of accumulating filth on the interface the use of grooves and ridges should be avoided.

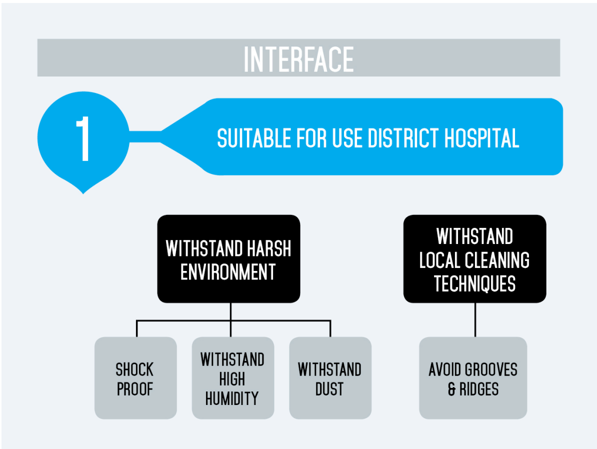

Figure 26. Aspects to consider when making the interface suitable for use in a district hospital

2. The ESU should be able to be operated by surgeons, clinical officers and OR assistants

The interface should be clear to all users of the ESU. The aspects that should be considered and possible solutions can be seen in Figure 27. The prior knowledge about the device and the effect of changes in settings can vary for each one of them. There are different ways to deal with the differences in knowledge and the complexity of some of the current ESUs. There is the option of providing an explanation about what each button, mode and setting does. This can be done in various ways, such as through providing a written manual or some quick start guide. There is, however, the risk that the manual is not in the language of the users. A more universal explanation can be given IKEA style. What this means, is the use of pictograms and some kind of flow chart that explains the order in which different steps have to be taken. If the interface is a digital one, a help option can be given where the user can browse for the particular problem he or see has encountered.

To be able to go around the lack of knowledge about the effects of different settings, an option is the use of pre-sets. By indicating the type of tissue that you are operating on, or the type of surgery that has to be done the ESU will provide the associated setting. Currently, the range of power that can be chosen is very wide and the need for such a broad range needs to be looked into. If the ESU can still safely and efficiently be used when the choice in settings is reduced, this could be a feasible solution. How the design can be made more intuitive will be explained in a next subsection.

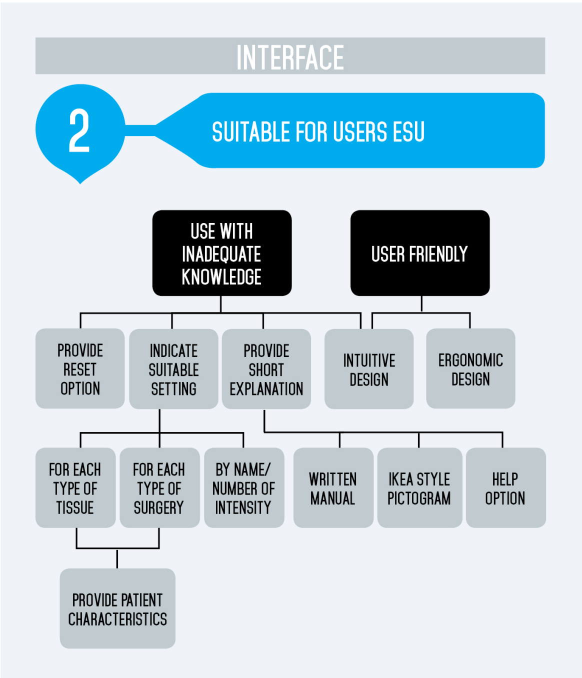

Figure 27. Aspects to consider and possible solutions to make the interface suitable for the users of the ESU

3. The ESU should be able assist with the essential surgeries proposed by Debas et al.

The list of essential surgeries (see Table 2) shows that the 28 surgical interventions that are proposed for the district hospitals are of quite a different nature. Within the 28 interventions, various types of tissue will be encountered and different actions are required from the ESU to be helpful. To deal with this and with unexpected situations that can occur during surgery, it is necessary for the interface to have changeable power settings, connections for a monopolar instrument, a dispersive electrode, a bipolar instrument and a connection for a footswitch. Further, it should minimally have a cutting waveform mode and a coagulating waveform mode. There are several options for the design of the buttons that make switching between functions and settings possible. A choice has to be made between knobs, the use of a touchscreen or feather touch controls.

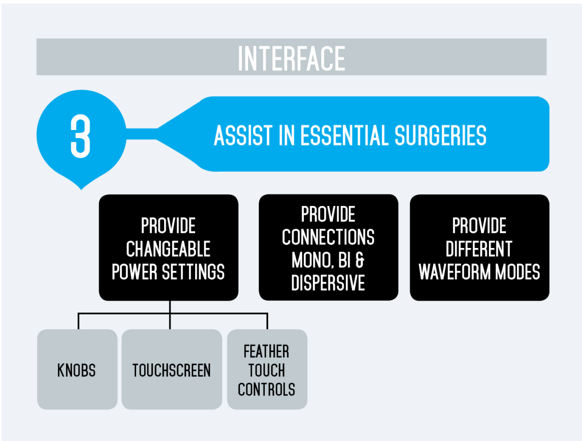

Figure 28. Aspects to consider and possible solutions to make the interface suitable for the essential surgeries

4. Electrosurgery should be available for everyone

Figure 29 shows that to be able to perform surgery on various types of patients, it should be suitable for different kinds of tissue and different types of patient characteristics. These things could also be found in the preceding subsection. Because each type of tissue has its particular physical properties, the interface should provide the option to change power setting, waveform and instrument to get the best possible outcome for the patient.

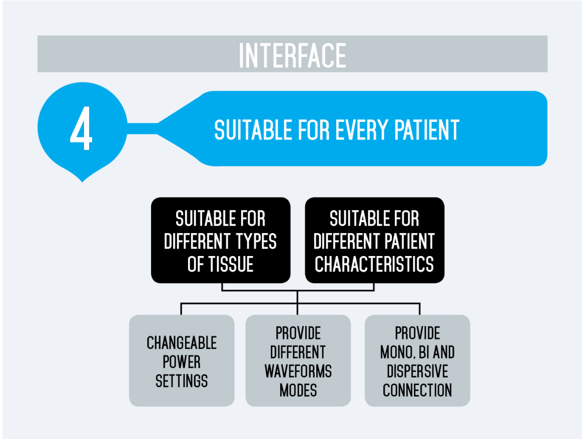

Figure 29. Aspects to consider when designing an ESU suitable for every patient

5. The ESU should be safe in use

In the analysis phase, Figure 14 was presented, which gives an overview of problems related to electrosurgery. There are the risks that can lead to burns, such as misplacement of the dispersive electrode and there are the aspects that lead to a longer recovery period due to poor choices of the user. Figure 30 shows aspects that should be considered and possible solutions on how to make it happen. To make the ESU safer, the interface could indicate the progress (of cutting or coagulation) made during activation of the instrument. With this solution it will be avoided that the tissue is unnecessarily damaged, hereby shortening the time it takes for the tissue to heal again. It can be done with haptic feedback, alarm, an indication by lights or a combination of those. The downside of this option is the complexity of the technology. The ESU should have advanced technology to deal with instruments (that are also more complex) that provide this solution. Both the ESU and the instruments will be more expensive.
Other potential dangers, such as misplacement of the dispersive electrode can be notified to the user by using an alarm or a light indication. To check the quality of the connection between skin and the dispersive electrode, a more advanced design of the dispersive electrode is necessary. This will likely not be feasible if you consider that it is not uncommon that the hospital fabricates its own dispersive electrode because of the lack of even a conventional dispersive electrode.

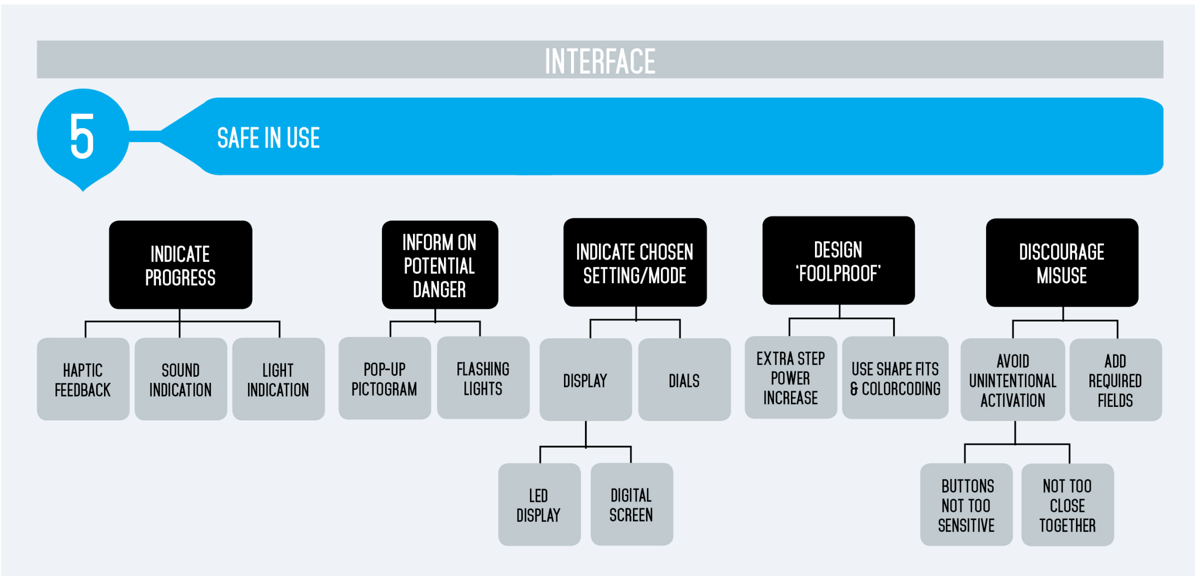

Figure 30. Aspects to consider and possible solutions for safe use of the ESU

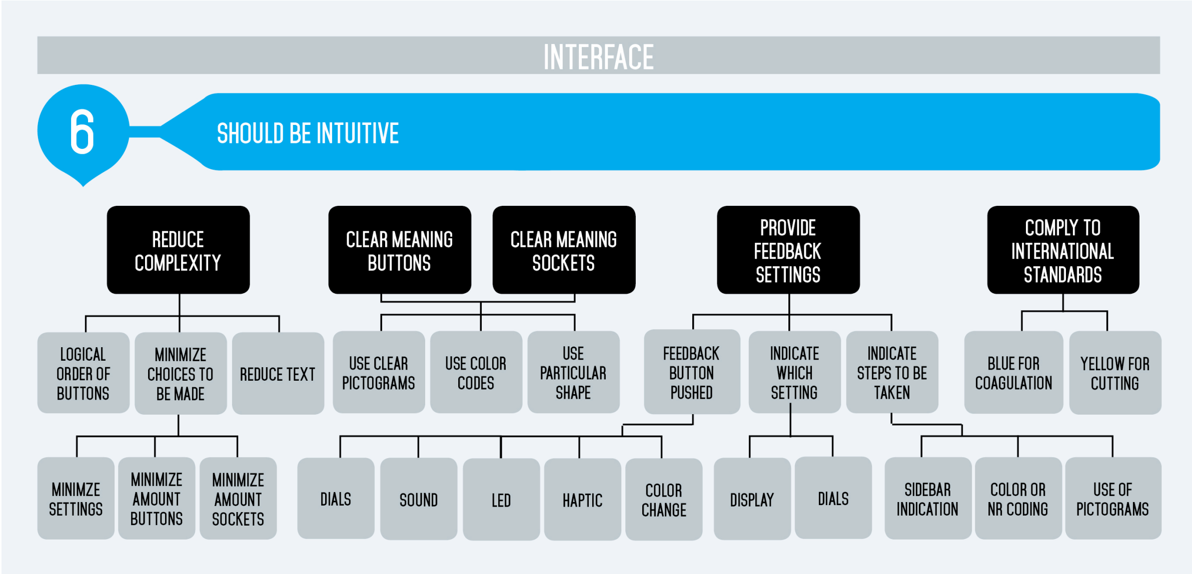

Figure 31. Solutions for making the interface more intuitive

In the preceding figures it became apparent that there should be adjustable power settings and other functions available, but to be safe in use it has to be clear to the user which setting or instrument is activated at that moment. Several options to do so are presented in Figure 30.

To make the design safer an option is to make the user more aware of the fact that he or she is about to increase the power. It should be promoted that the lowest possible power setting is used during electrosurgery; thereby avoiding that tissue is unnecessarily damaged. Unintentional activation can also damage tissue. A solution to this is the use of buttons that are not placed too close together and are not too sensitive.

6. The ESU should be intuitive

For safe and effective use of the ESU it is important to reduce the complexity. All solutions that can be found in Figure 31 are there to make the interface design more comprehensible and more intuitive. From the brainstorm it could be deducted that to make a design simpler, a good step is to minimize the choices that have to be made before use. The problem tree (see Figure 14) shows that a lot of buttons, connections and other factors that demand a choice add to the complexity of electrosurgery. At the mini-symposium Global Health at the TU Delft on July 10th 2015, professor Eddy Rahardjo (an anesthesiologist from Indonesia) also argued that there is a need for simpler designs of medical devices in LMIC. He implemented a most basic solution to simplifying the anaesthetic machine used during his surgeries, by taping functions and settings he deemed unnecessary. A good start can therefore be to go back to a more basic design, but a design that has all the options that make it possible to adhere to the requirements stated in section 5.2.

By using pictograms, shapes or colors to make the function of a button or socket known, the language barrier that might exist can be avoided and it also add to the intuitiveness of the interface.

An important aspect to work safe is to provide feedback on choices that have been made by the user, such as the indication of the settings. Some solutions on how to give this feedback can be found in Figure 31.

The problem tree (see Figure 14) shows that there is no international standard on the aspects of the interface. There is however the agreement that blue should be used to indicate the coagulation function and yellow that of cutting.

7. Initial costs and the running costs of the ESU should be low

The initial costs of the interface can be kept low by the use of parts that are widely available and to use a front that can be made with standard production techniques (see Figure 32). The use of standard and widely available parts is also

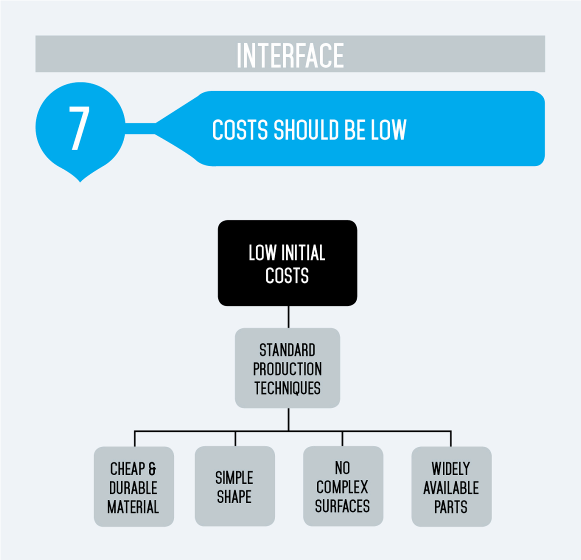

Figure 32. How to keep the costs of the interface low

useful in keeping the costs low during maintenance and repairs.

8. Maintenance and repairs should be able to be done by local technicians

To make it possible for local technicians to maintain and repair the ESU when necessary, it is important to make it possible to reach the parts. Easy access to the broken part and the use of standard connections are part of the solution to enable local personnel in repairing the ESU. Standard connections do not require the use of special tools that might not be readily available in the region. It diminishes the chance that the ESU ends up with the 70% of medical devices that does not work in LMIC.
The parts that most often break down are the sockets, because of the rough handling and the

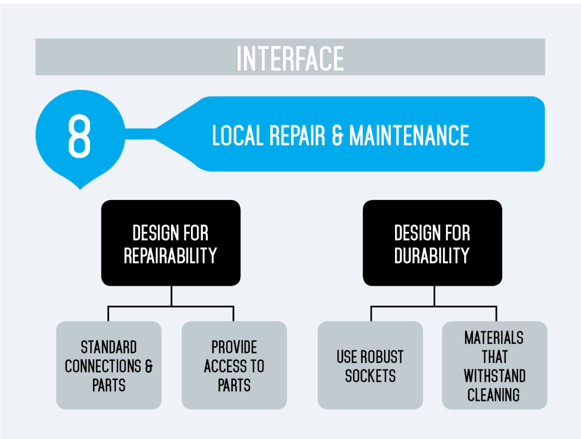

Figure 33. Solutions to making the interface repairable for local technicians

frequency with which the instruments and power cords are connected and disconnected. The sockets should be made robust in order to prevent damage when plugs are roughly handled.

5.3.3 Interface of the ESU

For this project the ESU has been considered as existing of several different components: the monopolar instrument, the dispersive electrode, the bipolar instrument and the generator which was divided into two parts, namely the generator itself and the interface of the generator that makes the interaction between the generator and the user possible.

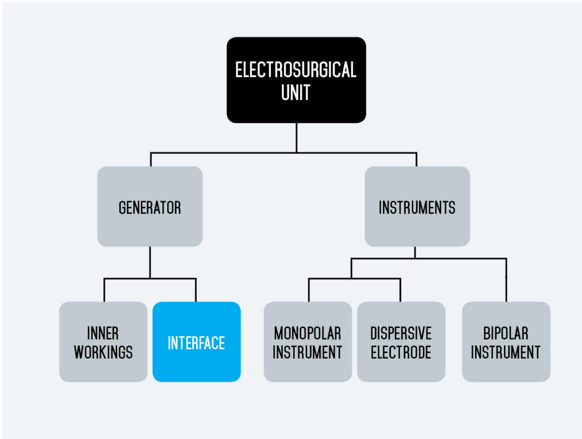

Figure 34. The interface as part of the ESU

After generating ideas for each component, the choice has been made to continue this project with the focus on the interface.
While for each component steps have to be made to make it more suitable for use in LMIC, a lot of problems concerning electrosurgery can be led back to the many choices that have to be made on the interface. Figure 14 shows the causes that add to the complexity of electrosurgery and while for instance the generator itself is responsible for creating the different waveforms, the choice that has to be made by the user is presented on the interface. The challenge is to design an ESU that has the minimum amount of functions, but one that will still be effective and safe.

5.4 Conceptualization

The aim of the new design is to make the interface more intuitive. A more intuitive and simpler design will provide a solution to the surgeons and clinical officers in LMIC, who often lack the possibility to receive extensive training about the device. It might encourage safer use, hereby limiting the potential risks for the patient being operated on.

The surgical data (see section 4.3.) showed that surgeons are free to use a power setting of their own choosing. For each hospital it is also different what kind of setting is used. It suggests that a particular type of surgery can be successfully performed with different power settings, regardless of the BMI of the patient or the mode used. The concepts presented in this section give the surgeon a limited option in power settings to provide a start in exploring the possibility of using only certain pre-set power settings, hereby making the design easier to use.

5.4.1 Phase 1

This section shows the first sketches made after the idea generation phase. Figure 35 and Figure 36 show an interface that has a monopolar cutting function, a monopolar coagulation function and a bipolar coagulation function as is necessary to adhere to the requirements set earlier in the project. During this project, problems and possible solutions regarding the design of the footswitch were not addressed. However, many bipolar instruments work with foot activation and it is therefore necessary to provide the connection on the interface. The sockets are slightly sunken into the interface to clearly indicate by the shape which instrument corresponds to that particular socket.

One of the ideas generated was to provide the option to select the type of tissue or the option to select a certain surgery that has to be performed. After this choice, the generator would provide the correct setting for the surgery that needs to be performed. This idea presented some problems. During surgery, the instrument goes through different layers of tissue and it would be very inconvenient if another button has to be pushed each time this occurred. For the second option, there are a lot of different kinds of surgery and by asking the user to go through a menu to select the one they are about to perform, adds to the complexity of the design. Another problem that has to be faced with this option is the lack of data about which settings should best be used for a certain type of surgery.

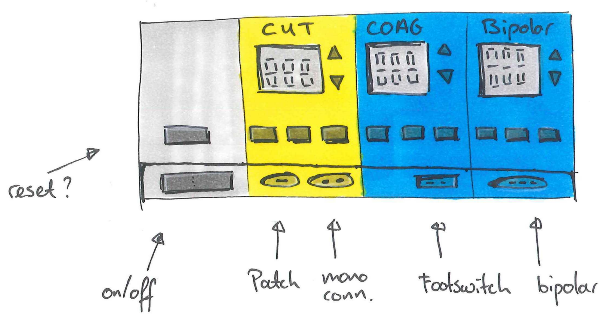

Figure 35. First design of the interface of the ESU

The idea presented in Figures 35 and 36 makes use of three options: Low, Medium and High. A particular power setting is associated with each option and is different for monopolar cutting, monopolar coagulation and bipolar coagulation. The LED screen will show this value and the buttons next to the screen make it possible for the user to increase or decrease this provided setting with steps of 5 Watt. For cutting there is only the option of pure cutting and coagulation can also only be done by one type of waveform.

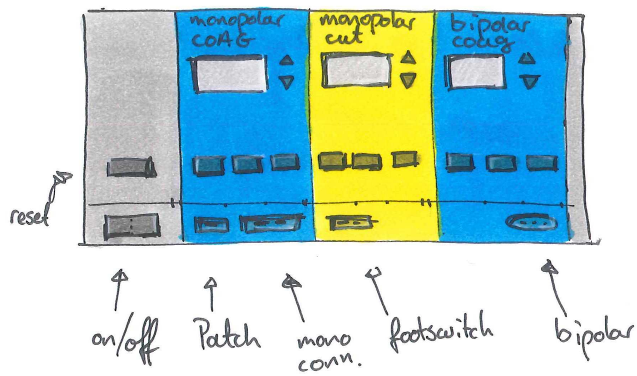

Figure 36. Second design of the interface of the ESU

To indicate the distinction between cutting and coagulation, the international standard of yellow and blue is used. The buttons, screens and sockets for each function are presented within the corresponding colored area. The buttons that have a general purpose, the power button and a possible reset button are within an area of neutral color.

5.4.2 Phase 2

To make the design more robust and more straightforward, it has been chosen to use an analog system instead of a digital system as can be found at the ERBE VIO 300D. While it is possible to save the settings for a certain surgery with those digital options, it also makes the device less intuitive and more complex. During the observations at LUMC, it became clear that the user itself does not know how to put in the presets, but only how to select it when somebody from the technical department has already put in the right program with the requested settings. Within the boundaries set for this project, an analog system is more suitable for its simplicity both in use and reparability.

DEGREE	MONOPOLAR CUT	MONOPOLAR COAGULATION	BIPOLAR COAGULATION
LOW	30 WATT	15 WATT	15 WATT
MEDIUM	80 WATT	30 WATT	30 WATT
HIGH	150 WATT	70 WATT	50 WATT
EXTREME	200 WATT	120 WATT	70 WATT

Table 9. Suggestion of power settings in Watt to correspond with a certain degree

The choice has been made to add an extra option, Extreme, for situations where it is necessary for coagulation or cutting to occur very quickly to be able to guarantee the safety of the patient.
Table 9 shows a suggestion of power settings that can be used for each degree of power. For all concepts to adhere to the requirements, it has been decided that the interface of the ESU should at least contain the aspects presented in Table 10.

CATEGORY	SPECIFIC
BUTTONS	POWER POWER SETTING MONO/BI FOOTSWITCH OPTION
CONNECTION POSSIBILITIES	DISPERSIVE ELECTRODE MONOPOLAR INSTRUMENT BIPOLAR INSTRUMENT FOOTSWITCH
MODES	MONOPOLAR CUTTING MONOPOLAR COAGULATION BIPOLAR COAGULATION
INDICATION	POWER DISPERSIVE ELECTRODE ALARM WHICH SETTING SELECTED WHICH MODE ACTIVATED ACTIVATION FOOTSWITCH YELLOW/BLUE INTERNATIONAL STANDARD

Table 10. Options needed on the ESU

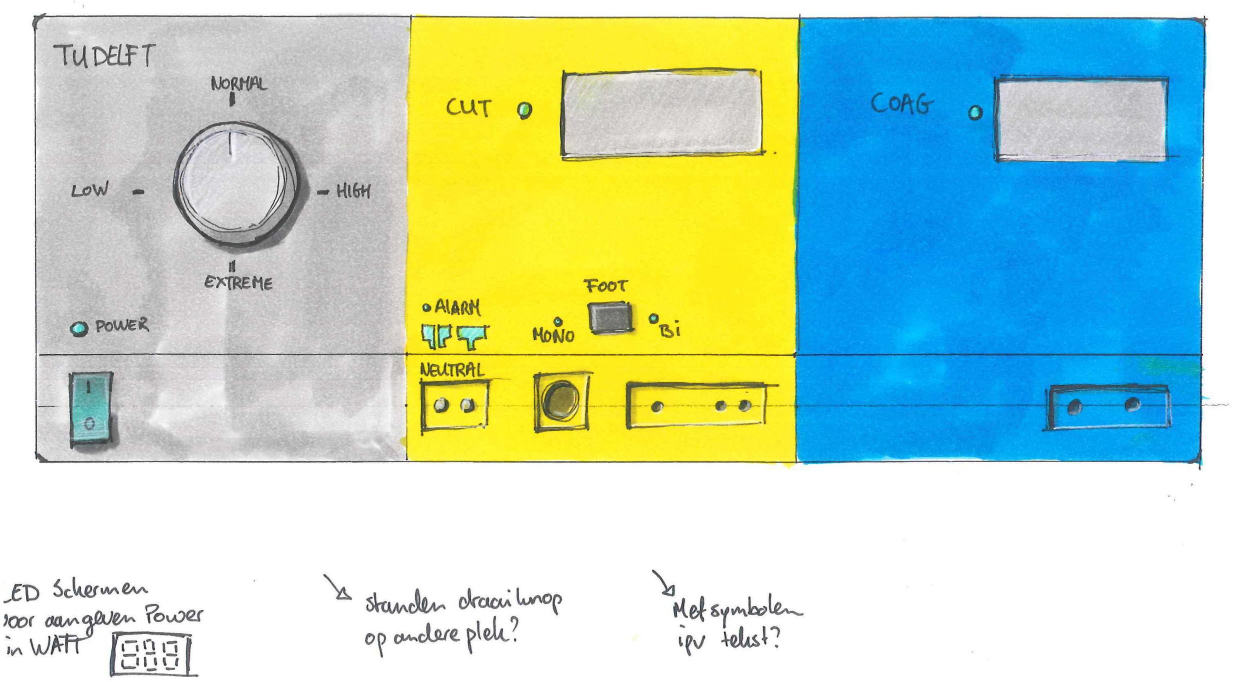

Figure 37. Concept #01

Concepts phase 2

Concept #01

Concept #01 (see Figure 37) has less buttons than the preceding ideas. With one knob different power intensities can be chosen. In this design, if the coagulation function of the monopolar instrument is activated, the LED screen will show this corresponding value. If the bipolar instrument is used, it will show the setting corresponding to bipolar coagulation.
The interface indicates if a dispersive electrode is connected and what kind of electrode this is. It has been chosen to present the dispersive electrode indication within the section of monopolar cutting. A dispersive electrode is necessary for safe monopolar electrosurgery.

Concept #02

The second concept (see Figure 38) is very similar to the first concept. It has the same features with the exception that in this design the corresponding value is now indicated separately for monopolar and bipolar coagulation. Each section is narrow and because of this, the monopolar socket is presented in the monopolar coagulation section.

Concept #03

This third concept (see Figure 39) shows a clear separation between the monopolar and bipolar section. In this design the power setting for cutting and coagulation each have an own knob in the corresponding section. Making it possible to choose a different strength for both. The Wattage is shown on the relevant screen.

Concept #04

The fourth design (see Figure 40) can be compared to the second design presented in Figure 38. Different is the type of knob used to turn the power on/off and the button used to set the power setting. The slider that is used to set the power shows an indication of the range and that Extreme is a significantly higher power setting.
Figure 40 shows an additional idea, based on giving each function its own knob and indication of the power range. The next section will elaborate more on this type of idea.

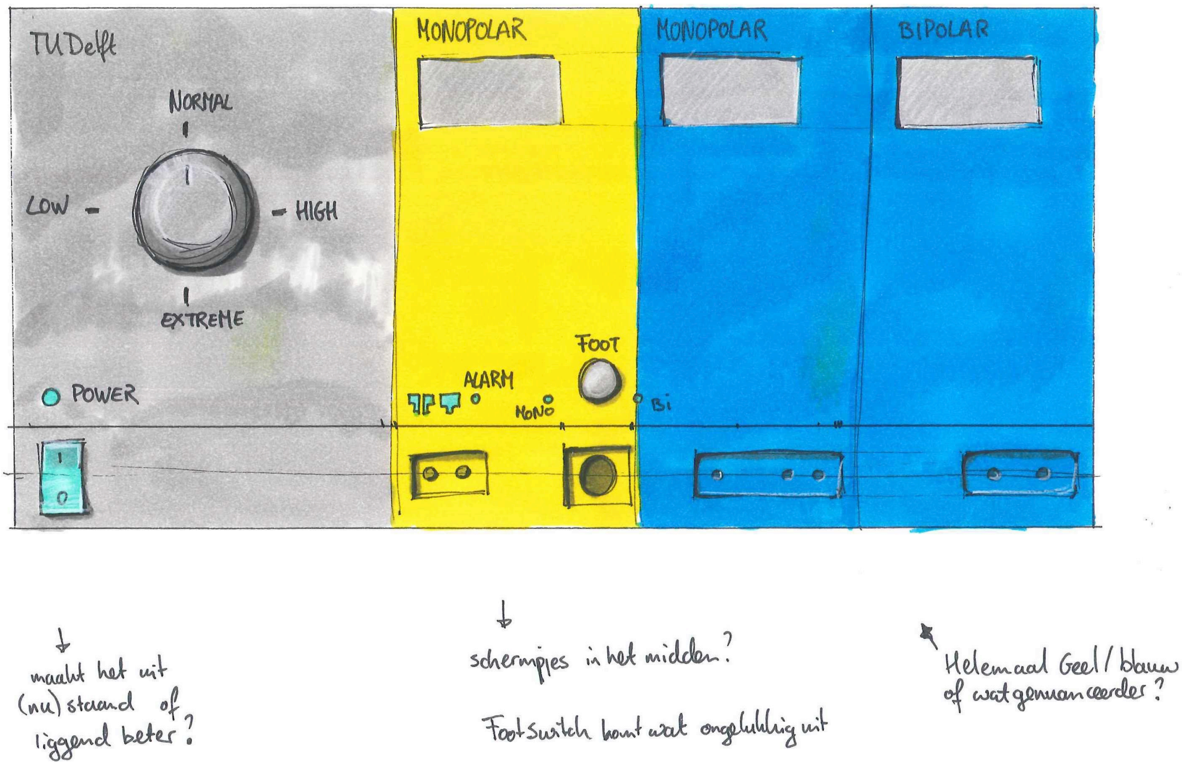

Figure 38. Concept #02

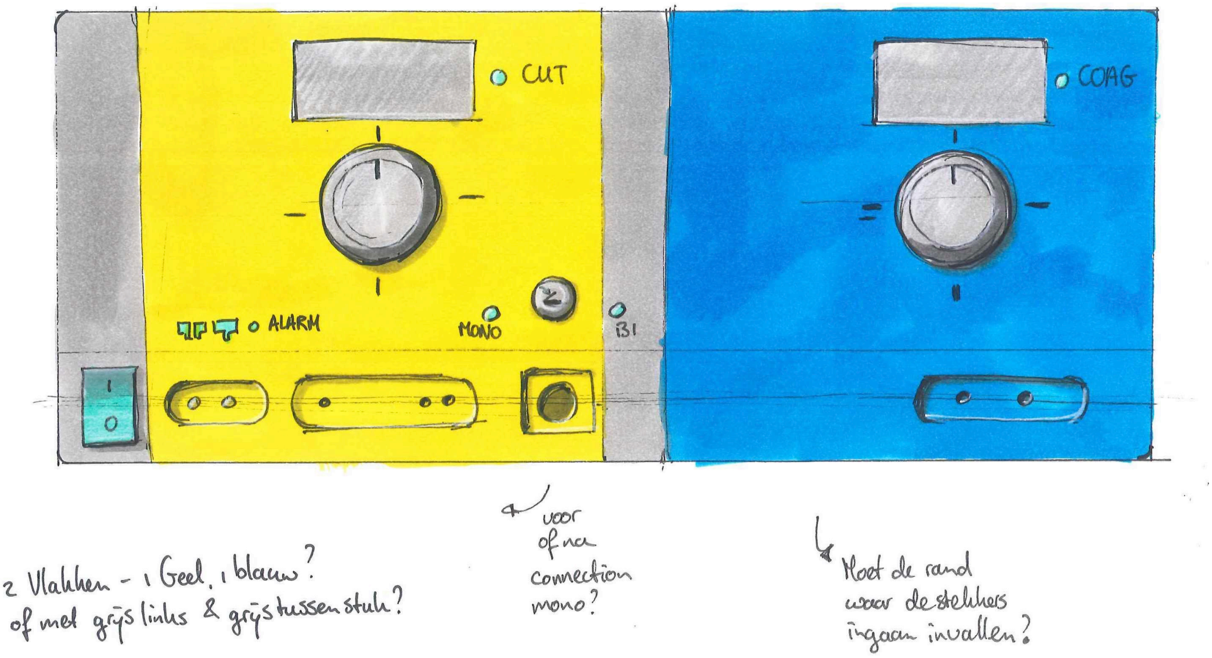

Figure 39. Concept #03

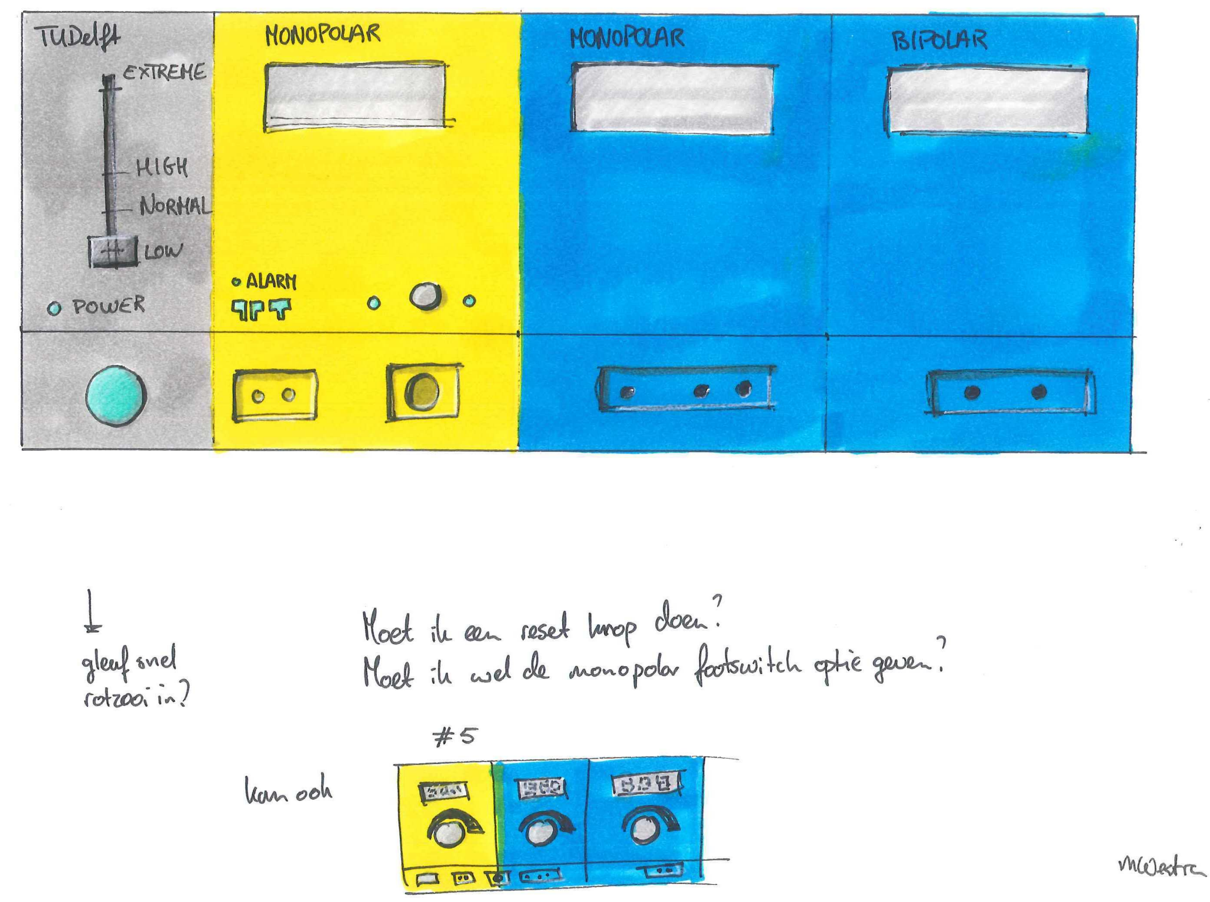

Figure 40. Concept #04 and an additional idea

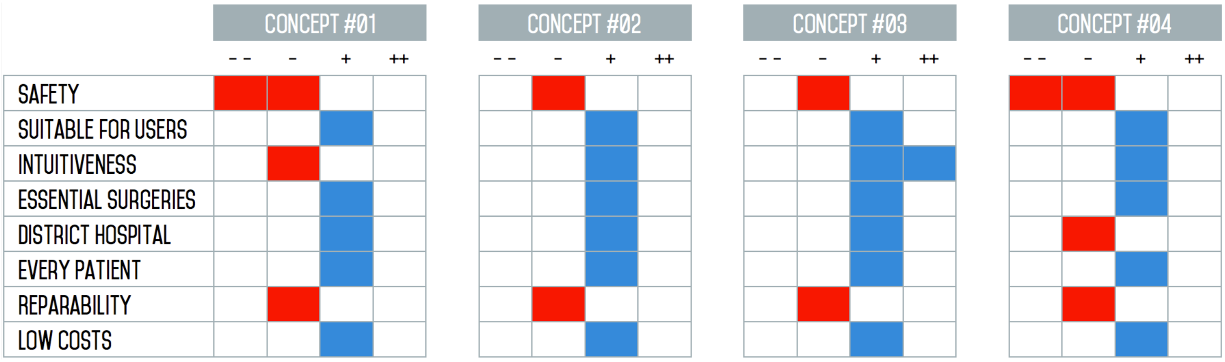

Figure 41. Harris profile of concepts #01 - #04

Evaluation concepts phase 2

To evaluate the different concepts the Harris Profile method is used. This method presents a visual presentation on how well the concepts score on the requirements set in section 5.2. It should be realized that it shows the expected performance of the concepts. The costs and reparability are hard to predict for the interface.
The Harris Profile (see Figure 41) has the requirements ranked in order of importance. The most important requirements are that the ESU should be safe in use, that it is suitable to be used by the staff in LMIC and that it can assist in the essential surgeries. As can be seen in Figure 27, an intuitive design is one of the aspects that make the interface more suitable for use by local staff. Figure 28 and 29 show that the essential surgeries in which the ESU should assist and the different patients that should be able to be operated on have similar solutions.

Indication power setting

The most prominent change in the interface compared to the existing ESUs is the use of only a limited amount of power settings. In the previous designs, the actual value of the chosen setting was still shown, but it is the question if the operators know what these numbers stand for. Research done by Feldman et al. (2010) showed that only 20% of the participants correctly identified the different input and output functions presented on the electrosurgical generator[10]. During observations made this became also known. It has therefore been decided only to show intensity without the actual corresponding value in Watt in de next designs.

Location buttons

The disadvantage of working with just one button is that is not possible to have different intensities for monopolar cutting and coagulation. The monopolar instrument has buttons for both and it might lead to dangerous situations if cutting is set to High power, while coagulation requires a low setting. It will be best to be able to adjust the intensity separately for monopolar cutting, monopolar coagulation and bipolar coagulation.
To avoid confusion the button that indicates whether the footswitch controls the monopolar or the bipolar instrument will be placed in a neutral section of the interface. When putting it in the monopolar section, it might be perceived as a function only related to monopolar electrosurgery, instead of relating to both types of electrosurgery.
The fourth concept has a sliding knob, which is not appropriate enough for the district hospital since filth will get stuck in the groove.

5.4.3 Phase 3

The evaluation of the preceding concepts resulted in new insights for the positioning of the buttons and way of indicating the level of intensity. This section shows two other designs that took these aspects into consideration.

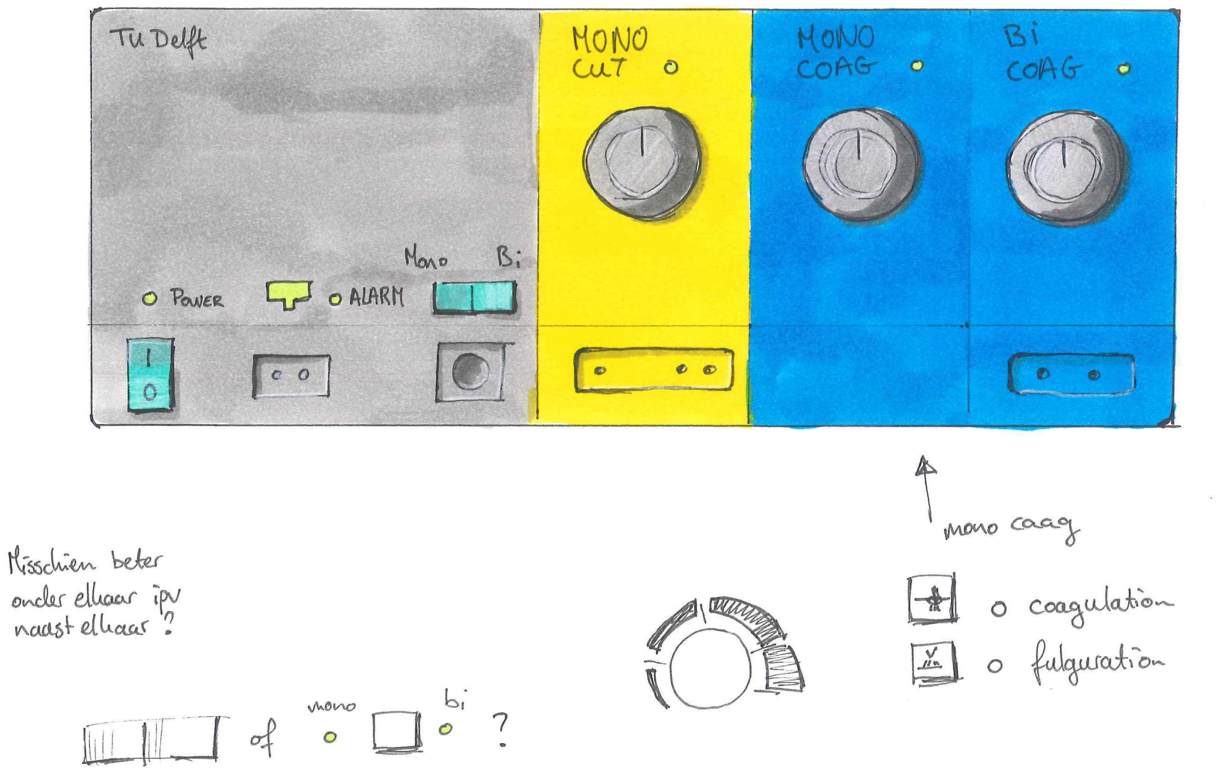

Figure 42. Concept #05

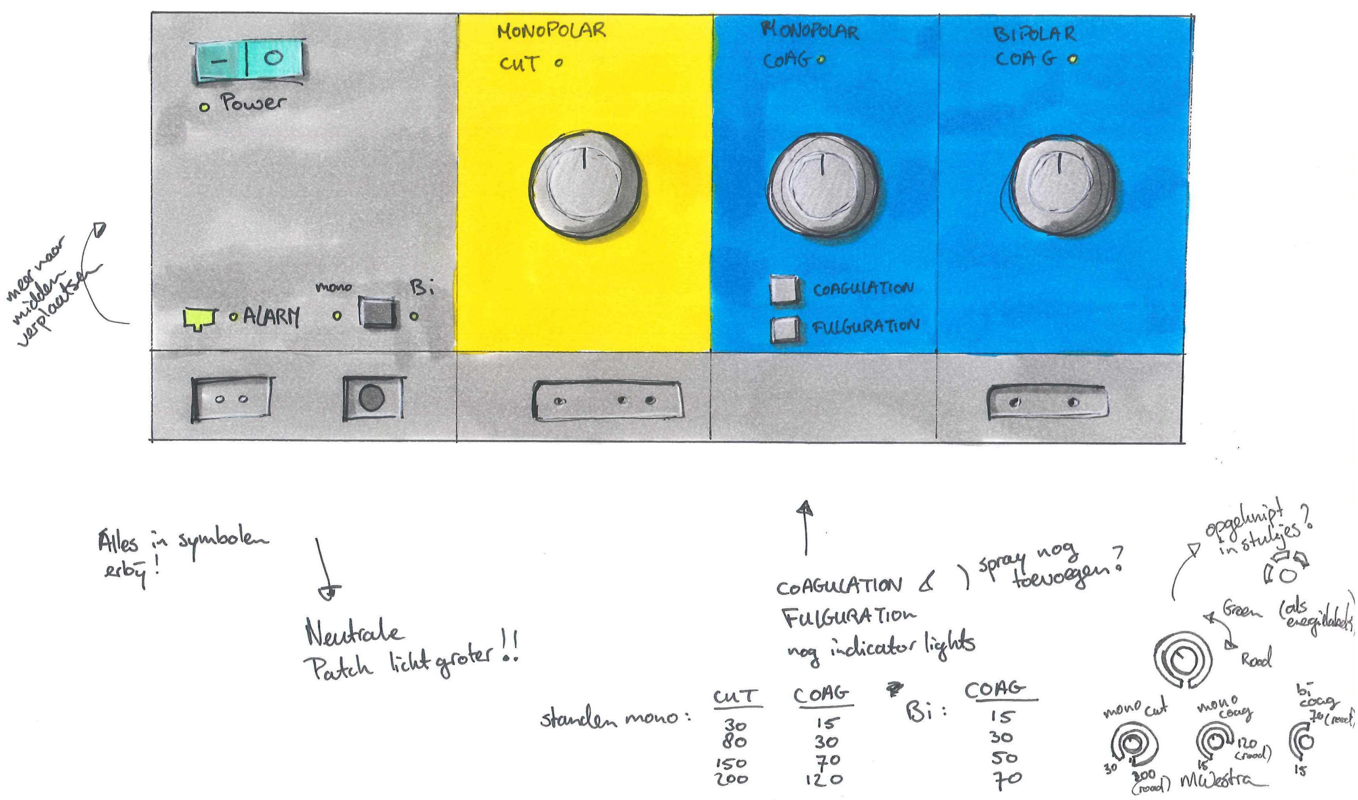

Figure 43. Concept #06

Concepts phase 3

Concept #05

Figure 42 shows the fifth concept. The interface has three turning knobs to be able to choose the power setting for each function. Not shown in figure 42, but part of the design will be the four settings that are presented in the previous concepts. It has been chosen only to show a single-plate dispersive electrode since these are used most often in LMIC.

Concept #06

The sixth concept (see Figure 43) shows all the sockets in a section with neutral color. The monopolar instrument connection and the bipolar instrument connection are positioned beneath the section that corresponds with either monopolar or bipolar electrosurgery.
Fulguration mode can also be used to achieve coagulation. The advantage of this technique is the possibility to coagulate a large target area quickly. Since during surgery, quick coagulation in some cases adds significantly to the safety of the patient it has been chosen to add this additional coagulation mode.

Evaluation concepts phase 3

The Harris Profile of concept #05 and #06 can be seen in figure 44. Both interface designs have three turning knobs, one for each function, making these designs safer than the designs in phase 2.
By eliminating the use of numbers to indicate the power settings, the designs are more intuitive.

Concept #05 has few buttons and the buttons are standard switches that can also be found in a lot of other devices, such as coffeemakers. Also, these buttons give a clear indication on which side is activated and this is an advantage over concept #06.
It is important to have both a desiccation and fulguration mode on the ESU as presented in concept #06.

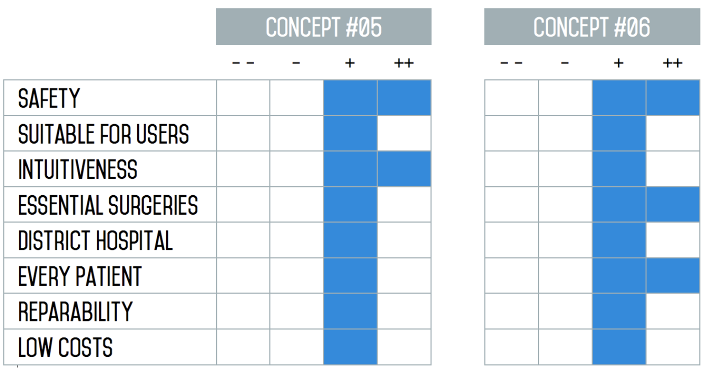

Figure 44. Harris Profile concepts #05 and #06

6 Final Design

The circumstances found at district hospitals in LMIC present problems for safe surgery and in addition to this, electrosurgery has still many unknowns even in the developed world. The interface design presented in this section aims to simplify the ESU, hereby making it easier for the user to safely operate on the many different patients seeking assistance at the district hospital. The design can be seen in figure 45 and the necessary features and specifications are further explained in this section.

6.1 Specifications

The interface (see Figure 45) has evolved from the earlier concepts. The evaluations showed that the final design should have the features that are listed in Table 12.

6.1.1 Dimensions

The dimensions of the interface are 280 x 140 mm. These dimensions are derived from existing ESUs of different brands and this compact form makes it also suitable for use in district hospitals. The generator itself was not included in this project and it might be necessary to somewhat deviate from the current dimensions to fit all the components behind this front panel.

COMPONENT		DIMENSIONS
INTERFACE		280 X 140 MM
BUTTONS	TURNING KNOBS	Ø 30 MM
	SWITCHES	25 X 8 MM

Table 11. Dimensions of the interface and buttons

6.1.2 Connection possibilities

For the sockets no particular brand has been chosen to fit these connections. It gives an indication of where the sockets should be placed and which symbols can be used to indicate the accessory that should be connected to this socket.

The socket for the monopolar instrument displayed in Figure 45 can be used to either connect a single-pin foot activated instrument or a three-pin hand activated instrument.

The socket for the bipolar instrument can receive an instrument with a two-pin connector.

To use a footswitch activated instrument a footswitch should be connected. This connection would be on the rear panel of the generator. The power entry would also be placed on the rear panel.

6.1.3 Modes

The fulguration mode provides faster coagulation of larger tissue surfaces. In certain situations this mode will be safer for the patient than the desiccation mode. For the cutting mode the current design has only incorporated a continuous cutting waveform and no blend mode in order to provide only the primary functions.

CATEGORY	SPECIFIC
BUTTONS	POWER POWER SETTING • MONOPOLAR CUTTING • MONOPOLAR COAGULATION • BIPOLAR COAGULATION DESICCATE/FULGURATE OPTION MONO/BI FOOTSWITCH OPTION
CONNECTION POSSIBILITIES	DISPERSIVE ELECTRODE MONOPOLAR INSTRUMENT • HAND ACTIVATED INSTRUMENT • FOOT ACTIVATED INSTRUMENT BIPOLAR INSTRUMENT • HAND ACTIVATED INSTRUMENT • FOOT ACTIVATED INSTRUMENT
MODES	MONOPOLAR CUTTING MONOPOLAR COAGULATION • DESICCATION MODE • FULGURATION MODE BIPOLAR COAGULATION
INDICATION	POWER INDICATOR DISPERSIVE ELECTRODE ALARM SINGLE-PLATE INDICATOR POWER SETTING SELECTED (3X) • LOW • MEDIUM • HIGH • EXTREME WHICH MODE ACTIVATED • MONOPOLAR CUTTING • MONOPOLAR COAGULATION ○ DESICCATE ○ FULGURATE MONO/BI FOOTSWITCH CONTROL YELLOW/BLUE ACCORDING TO STANDARD

Table 12. Features of the interface

Final Design of the Interface

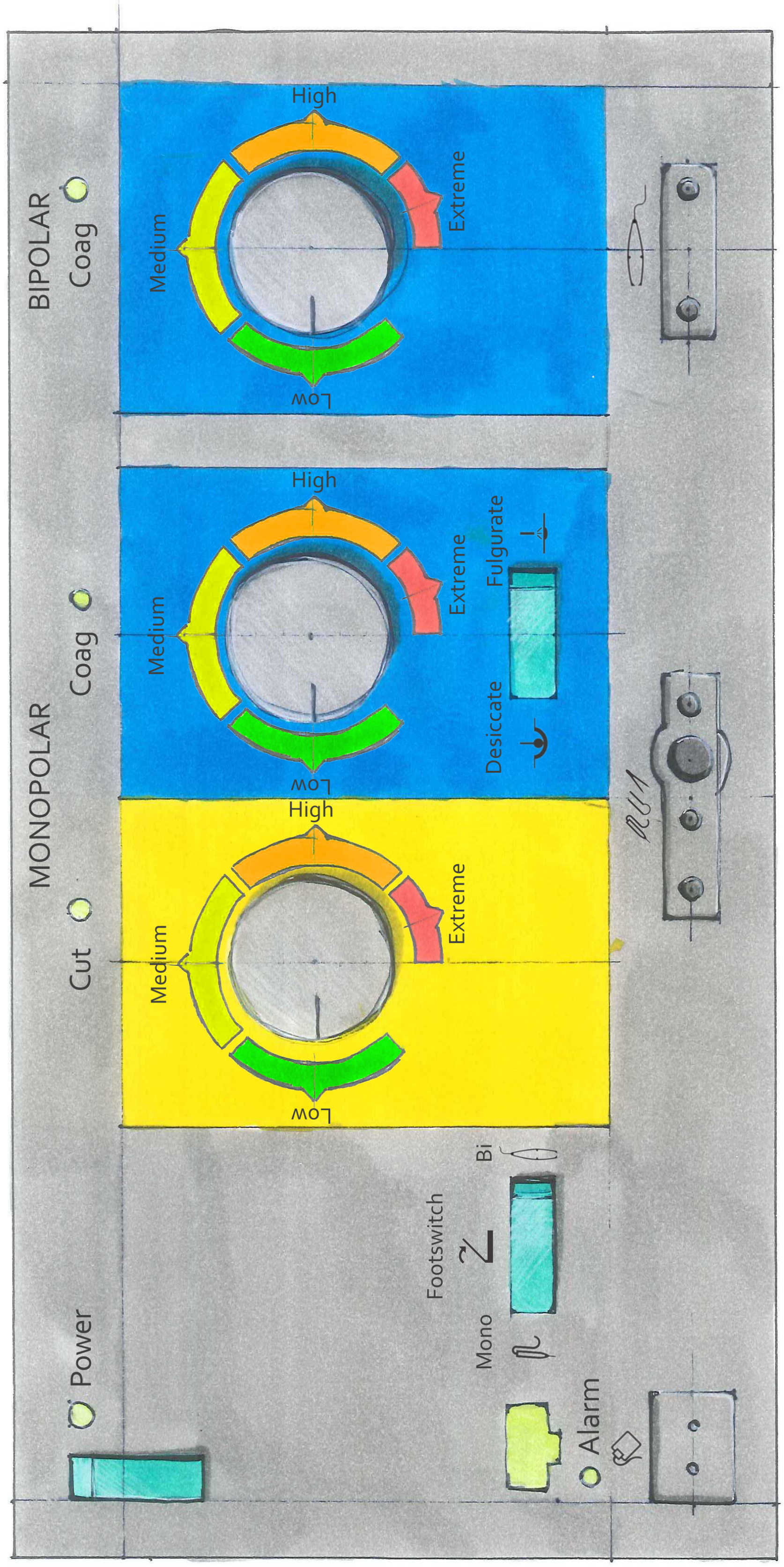

Figure 45. The new design of the interface of the ESU

6.1.4 Indication

The intensity of the power setting is indicated both by text and by color indicator. The other functions presented at the interface are indicated by text and by symbols. Advantage of the color-coding and the symbols is that staff that does not speak English could still use the ESU. It is a solution to the language barrier that might exist.

The LED indicators of monopolar cutting, monopolar coagulation and bipolar coagulation will illuminate when that particular mode is activated. The power indicator illuminates when the ESU is on, the dispersive electrode symbol will illuminate when a dispersive electrode is connected and the alarm indicator illuminates if there is an unsafe situation related to the dispersive electrode is detected by the system.

6.2 Evaluation Design

A questionnaire was used to evaluate the new design. The questionnaire that has been used for the pilot study can be found in Appendix H and the evaluation form used for the study is presented in Appendix I. This section describes the objectives of the evaluation and the method used to acquire this information.

6.2.1 Objectives

The main objective of the evaluation was to get insight in how well the new interface meets the requirements set in section 5.2.1. The focus has been especially on the following requirements:

- The ESU should be safe in use
- The ESU should be able to be operated by surgeons, clinical officers and OR assistants
- The ESU should be intuitive
- The ESU should be able to assist with the essential surgeries

Another objective was to find out if the users of the ESU trust the new interface. The new design does no longer show the value of the setting in Watt and the options for different power settings are also limited. The aim has been to get the opinion of the users on these changes and to find out if the new design might be too simplified.

6.2.2 Method

The questionnaire consisted of both open-ended and closed-ended questions. The open-ended questions have been used to get some background information on the participant, to ask the participants' opinion on the new interface design and to obtain the settings they use most during surgeries they perform most often. The closed-ended questions were used to get some insight in how the participants would score the ESU they work with now and how they would score the new design.

The questionnaire (that was appropriate for handwritten answers) was presented to Dutch surgeons and OR assistants. The complete questionnaire can be found in Appendix I and was administered at the OR department of the RdGG on November 12th 2015.

6.2.3 Results questionnaire

Two surgeons, one resident and 13 OR assistants have filled out the questionnaire. The values of the power settings these participants use most often and the values they suggest to match the power settings given in text are presented in the tables found in Appendices J and L. Background information about the participants can be found in Appendix M.

Training

A remarkable thing to see was that all OR assistants (A1-A13) have received training about the ESU about a year before filling out the questionnaire and the resident (AIO1) 1.5 year before. The first surgeon (S1) has however not received training in about six years and the second surgeon (S2) did not receive any training at all. The second surgeon had also no notion of which brand or type of ESU he used. Yet, the surgeons are the ones that tell the OR assistants how to set up the ESU before and during surgery. It is another indication that the surgeons should receive more training about the devices they work with.

Power settings

Of the 16 participants, there are 13 who stated that they would like to see power settings that could be set more precisely. They did not like the intensities and indicated that this was the reason they thought the new design less safe and/or less trustworthy than the ESUs they worked with. Some interesting answers about why they perceived the ESUs they worked with safe and trustworthy are:

AIO1 : “Werkt prima, is het apparaat waarmee ik opgeleid ben, ik ken dus geen andere.”
A3: “Ben eraan gewend”

The other answers were in the spirit of:
A7:”Ze werken prima, weinig storingen”

From this questionnaire it was hard to derive whether the limited power settings are truly a step in the wrong direction regarding simplifying the design, or whether the participants just did not like the change of a design that they are so accustomed to. Only A9 indicates that she would like these settings and that she thinks it would be suitable for use during different surgeries.

Modes

The interface provides the choice between desiccate or fulgurate when it comes to the coagulation modes. In the questionnaire A2, A3, A8, A11 and A12 indicated that they would like to add the spray function to the design. This is a clear example of the confusion that arises with brand-specific names for power settings and modes, because the spray function is in fact the fulgurate waveform. In the design there is only a continuous cutting waveform available. A11 and A12 are the only two to indicate that they miss a blend mode on the ESU.

Second monopolar socket

The OR assistants A1, A6, A11 and A12 said that the design misses an extra monopolar socket. This is for instance an answer to question 11 about whether they think the design suitable for use on different types of surgeries:

A6: ”Is wel bijna overal te gebruiken, maar door gebrek aan 2^{e} monopolaire ingang niet handig voor ingrepen die zowel laparoscopisch als open gaan. Moet je steeds snoer wisselen.”

During this project the assumption was made that laparoscopic surgery is too advanced to perform in LMIC. There could however be advantages of laparoscopic surgery in LMIC, such as less chance of a wound getting infected when performing surgery in a dusty OR. Before adding an extra monopolar socket there should be looked into the possibility of laparoscopic surgery at the district hospital. Another aspect that an assistant would like to add was the option for smoke evacuation. During this project it seemed not to be an essential function of the ESU, but more research about this option might be needed.

Additional findings

Five of the participants did not check a box about how intuitive they think the ESU is they work with or about the new design. It is likely that they do not know what was meant by the term intuitive.
A6 does not think that turning knobs are practical. She wrote that they are hard to keep clean and they are prone to changing setting when they are accidentally nudged.

6.2.4 Conclusion questionnaire

Two surgeons, one resident and 13 OR assistants have filled out the questionnaire. Staff from RdGG had trouble trusting the new device, because it no longer has the option to set precise values. Whether this is because of the limited power settings or because they do not like to see a device they are used to change was not clear. More research is needed on which functions can be eliminated on the ESU and to get more meaningful feedback it is necessary to talk to the users in LMIC directly.

7 Discussion

The aim was to design a user-friendly, robust and easy to maintain ESU that can safely be used by the staff at the district hospitals in LMIC. This section gives an overview of what has been found during this project, what its implications are and which limitations during this study should be considered.

7.1 Context

Surgical care plays a crucial role in the healthcare system and its value in saving lives has now been recognized on a global scale. There are however many obstacles that stand in the way of providing essential surgical care to everyone. In section 2 an overview is given of the factors that influence the provision of surgical care in LIMC. One aspect within this complex problem is the lack of appropriate medical equipment that can successfully function at the district hospitals in LMIC. The focus has been on the ESU, which is a helpful device that is commonly used during many different types of surgery.

7.1.1 Barriers

There was no information to be found about the ESU in LMIC specifically and therefore there was looked into medical equipment in general. As section 2.4.2 describes, there are problems of different natures that make it difficult for medical devices in LMIC to function properly. Some are directly related to the device itself, while others such as corruption indirectly affect the use of medical devices and the quality of surgery. The main problems found surrounding medical devices in LMIC were the lack of spare parts, the inability to acquire consumables, lack of technical knowledge and the shortage of other necessities such as running water, extra blood and important for the ESU, a steady electricity network.

7.1.2 Differences among countries

Some experts, such as J.J. Beltman are skeptical about the use of an ESU at district hospitals because of its need for electricity and the risk for patient burns, while others such as A.M. Worm have not encountered problems with the ESU at their district hospital in a LMIC. An important aspect to keep in mind is that the conditions found at district hospitals vary greatly among different countries and regions. Each country has its own healthcare system, standards and regulations and deals with is own set of problems. It is essential to know all stakeholders involved, how they operate and what their opinion is on the subject.

7.2 Electrosurgery

7.2.1 Training about electrosurgery

Electrosurgery is a commonly used technique during surgery, but research showed that many users do not know the basic principles behind this technique. Surgeons and clinical officers in LMIC do not have the training possibilities that surgeons in the developed world have access to.
What would be expected is that with the potential risks that accompany this surgical technique, the surgeons working in advanced western hospitals would have received proper training about the ESU and electrosurgery. This is however not the case and hospitals should be made more aware of the necessity of proper training. Especially since electrosurgery has proven to be very complex and its use is mainly based on the preference and experience of the user.

7.2.2 Complexity electrosurgery

The complexity of electrosurgery can be brought back to two basic causes. First there are the aspects that, such as the patient characteristics and different tissue characteristics make it hard to determine the best power setting and mode for each surgery. There are still a lot of unknowns about these factors. Secondly there is the lack of standardization of the user-interface and lack of standardization in representation of waveforms and power outputs. Aspects such as mode names, connections and instruments are all brand specific. This makes the ESU a complex device.

7.2.3 Design opportunity ESU

To make the ESU more suitable for use by surgeons, clinical officers and OR assistants in district hospitals in LMIC, there was chosen to focus on reducing the complexity of the ESUs interface. Simplifying the design would reduce the amount of training necessary to safely operate the device. To reduce the complexity, the new ESU would have to contain only the minimum amount of functions necessary for the device to adhere to the requirements set in section 4.2.

7.3 Essential functions ESU

7.3.1 Many unknowns electrosurgery

There are no large studies that looked into the effect that the various types of ESUs with their brand specific modes and power settings have on the human tissue. It is also not clear which waveform and which power setting are best for specific types of surgery, making it hard to determine which functions of the ESU could be simplified.

7.3.2 Data analysis

To get some insight in the power settings and modes used during surgery there was looked into data on cholecystectomies and breast surgeries performed at RdGG.

It showed that there are no strict rules and that surgeons can set-up the ESU to their own preference. The instrument, mode and patient characteristics did not seem to influence the choice for a certain power setting.

Also interesting to see were the differences in power setting between the two different types of hospitals. LUMC showed a tendency towards using higher power settings than RdGG. The reason for these differences is not clear, but it showed that preferences differ between hospitals.

7.3.3 Research needed

There were however limitations to the data. Section 3.7.3. explained these limitations in more detail. More research is needed on a wider range of surgical categories and with more surgeons from different hospitals, to find out which settings and modes are best for particular types of surgery. There should also be done more extended research to identify the functions that are truly indispensable on the ESU and which ones could be eliminated to reduce the complexity of the ESU.

7.4 Final Design

While more research is still needed to better identify the best and the necessary functions on the ESU, it was chosen to design an interface that has certain pre-set power settings. The final design does not show the value of the power setting in Watt, but only an intensity level since the number also seemed to be just an indication for the surgeon.

7.4.1 Limitations evaluation final design

The users of the interface will be surgeons, clinical officers and OR Assistants. Ideally this would also be the people that would help evaluate the final design. The questionnaire was chosen as a method to be able to reach these users that live in LMIC. It was initially a form in PDF format that could be e-mailed to surgeons, clinical officers and OR assistants residing in these LMIC. During this study there were unfortunately no participants found that lived and worked in LMIC and that would be willing to answer the questions.

The participants working at RdGG have had different training opportunities and are accustomed to working in a hospital with high standards. A hospital that does not have to deal with the problems found in section 2.4.2. In addition more surgeons should fill out the questionnaire. While it has been useful to get some insight in how the new design is perceived by people who work with the existing devices, these people do not represent the actual users in LMIC. This target group is very hard to reach through e-mail or other means that could be used to contact them from The Netherlands. To get meaningful feedback from the intended users it would be best to speak to them directly and on scene.

7.4.2 Interface design

How people interact with a product and how in this case the users will perceive the interface of the ESU depends on many different aspects. During this project an interface has been designed, but it should be noted that for the best choice in for instance saturation of colors or size of the buttons, more research is needed on the effect that the aesthetics and ergonomics of the design have on the users in LMIC. This has been beyond the scope of the project as the aim was to reduce the complexity of the interface by only providing the necessary functions.

7.5 Design opportunities ESU

7.5.1 Power source

Fact remains that the ESU requires electricity to function. It would be wise to incorporate an uninterruptible power supply (UPS) in the generator to deal with the unsteady electricity networks in LMIC. More research is needed on how to deal with the unpredictable electricity network and the use of an alternative (backup) power source if the electrical network fails. One of the aspects that could also be looked into is in making the ESU more power efficient.

7.5.2 ESU components

During the idea-generating phase suggestions were given for the interface, but also for the monopolar instrument, bipolar instrument, dispersive electrode and the generator (see Appendix F). To make the ESU suitable for use in district hospitals in LMIC it is important to meet all requirements and to look for the best possible solution for each component.

7.5.3 Bipolar electrosurgery

Bipolar electrosurgery is a safer technique than monopolar electrosurgery, but has the large disadvantage that it cannot be used for cutting and it is limited in its ability to coagulate large tissue areas. If an instrument could be designed that makes it possible to also use bipolar electrosurgery for both these purposes, this much safer bipolar technique could be used to replace monopolar electrosurgery. Especially in LMIC where they often have dispersive electrodes of lesser quality it would greatly add to the delivery of safe surgical care. The existing advanced bipolar instruments such as the Ligasure™ that make cutting possible are too expensive for use in LMIC.

7.5.4 Accessories

The connection type of instruments and other accessories are brand specific. In LMIC they often use donated accessories. There are adapters on the market to facilitate the use of a generator of one brand with the instrument of another brand. Loose parts as these are likely to get lost, assuming they are available at the district hospital at all. There should be looked into a solution for more universal sockets for the interface.

7.5.5 Barriers to expect

A new ESU that is appropriate for use in district hospitals does not solve all problems. Major barriers that can be expected after creating an ESU that is suitable for use in district hospitals are in manufacturing and financing the ESU, in the distribution (which distribution channels are used, who are the stakeholders and how can you use these to your advantage?) of the ESU and in getting the necessary regulatory approval.

To get necessary funds, H. Knol advised to check what major healthcare issue is trending in a certain country. If for instance dealing with complications around childbirth have the main attention of the population and government, it would be wise to especially focus their attention on the ability of the ESU to provide aid during these complications.

It should be kept in mind that the initial costs of the ESU are only a small portion of the total costs that are needed for the ESU to operate.

8 Conclusion

There are problems that are related to the circumstances found at the district hospitals in LMIC and problems related to electrosurgery, regardless of context. Electrosurgery is a complex technique and even though it is widely used, there are still many unknowns. Data on several surgeries performed at RdGG and LUMC was analysed. This data made it apparent that the use of the ESU is solely based on the preferences of its operators, since no strict rules or guidelines exist on the use of the ESU. It is therefore remarkable to see that these users do not possess enough knowledge about the most basic principles behind electrosurgery. More training is needed on the theory of electrosurgery and about the device itself. This training is hard to come by in LMIC and to help these surgeons, clinical officers and OR assistants the complexity of the ESUs should be reduced. During this project an interface was designed that offered pre-set power settings. However, there is more research needed to identify the functions that are truly indispensable on the ESU and which functions could be eliminated, in order to reduce the complexity of the ESU more successfully. This became clear after administering a questionnaire about the new design at the OR department of RdGG. To get meaningful feedback from the intended users it would be best to speak to them directly and on scene in LMIC. During this project the main focus has been on only one component of the ESU. To make the ESU more suitable for use at the district hospitals in LMIC, there should be done more research for each component separately. For the newly designed ESU to be successful, local support and training is needed.

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Appendices

A Abbreviations

AC	-	Alternating Current
DC	-	Direct Current
ESU	-	Electrosurgical Unit
LMIC	-	Low- and Middle-income Countries
LUMC	-	Leiden University Medical Center
MDG	-	Millennium Development Goals
MSF	-	Médecines Sans Frontières
OR	-	Operating Room
RdGG	-	Reinier de Graaf Gasthuis
UN	-	United Nations
UPS	-	Uninterruptible Power Supply
WHO	-	World Health Organization

B Observations LUMC

I Gynaecology

#1 Date: 24-11-2014
LUMC OR: 9
Physician: S1
Surgical Intervention: Conization of the cervix
(Excision of a cone-shaped wedge from the cervix uteri to be able to diagnose how far the cancer has spread)
Model Electrosurgical unit: Erbe VIO 300D
Patient: Overweight woman

Open surgery
Technique: Monopolar coagulation
Instrument: Bulb electrode

Noteworthy:
- Giving the epidural took a long time. The anaesthetist had to search for the right spot.
- The stitches that were used to create a clear operating field ripped and had to put in place again.
- To clean the bulb electrode a scourer that was stuck to the patient was used. The physician went off the scourer causing some minor burns to the patients skin.

#2 Date: 24-11-2014
LUMC OR: 9
Physician: S1
Surgical Intervention: Laparoscopic removal of one ovary and cyst of other ovary
Model Electrosurgical unit: Erbe VIO 300D
Patient: woman of normal posture

Laparoscopic surgery
Technique: Bipolar coagulation
Instrument: Bipolar forceps

Noteworthy:
- The electrosurgical unit did not work when using the bipolar laparoscopic forceps. The technical service was paged and discovered a loose connecting in the instrument. When tightened, the device worked.
- The physician used foot pedals to activate the electrode.

#3 Date: 24-11-2014
LUMC OR: 9
Physician: S1
Surgical Intervention: Hysterectomy
(Curettage, remains placenta that were left after a previous operation had to be removed)
Model Electrosurgical unit: Erbe VIO 300D
Patient: woman of normal posture, about 33 years old

Noteworthy:

- The electrosurgical unit was not used.
- The device that was used leaked water, but no one in the OR knew why.
- Complication due to the fact that there was much more placenta left than initially expected.
- The patient started bleeding vigorously due to the use of too much water, which was the effect of above complication.
- The symbol that appeared on the device was not understood
- The alarm given by the device was not understood
- The operation had to finish before all placenta remains were removed for the safety of the patient

#4 Date: 24-11-2014

LUMC OR: 9
Physician: S1
Surgical Intervention: Removal Vulvar Intraepithelial Neoplasia (VIN)
(A laser is used to remove unhealthy spots on the vulva)
Model Electrosurgical unit: Erbe VIO 300D
Patient: woman of normal to large posture

Noteworthy:

- The electrosurgical unit was not used
- The patient was already put under, but no one knew how to turn on the laser device. About 15 minutes later an OR assistant was paged who could tell them were to put which cable.
- No complications

#1 Date: 01-12-2014

LUMC OR: 9
Physician: Surgeon in training 1 (ST1)
Surgical Intervention: Curettage
Model Electrosurgical unit: Erbe VIO 300D
Patient: woman of slim posture

Noteworthy:

- The electrosurgical unit was not used
- The bucket that had to catch the sucked blood hung askew, which made reading the amount of blood inaccurate and hard.

#2 Date: 01-12-2014

LUMC OR: 9
Physician: S1
Surgical Intervention: Removal Vulvar Intraepithelial Neoplasia (VIN) and placement IUD (spiraaltje)
(A VIN can often be seen as a preliminary stage of vulvar cancer)
Model Electrosurgical unit: Erbe VIO 300D
Patient: woman of normal posture

Open surgery
Technique: Monopolar cutting
Instrument: Needle electrode

Noteworthy:

- The needle electrode had to be put on the tissue several times, but resulted in a clean cut.
- No complications

#3 Date: 01-12-2014
LUMC OR: 9
Physician: S1
Surgical Intervention: Conization of the cervix
(Excision of a cone-shaped wedge from the cervix uteri to be able to diagnose how far the cancer has spread)
Model Electrosurgical unit: Erbe VIO 300D
Patient: woman of normal posture

Open surgery
Technique: Monopolar coagulation
Instrument: Bulb electrode

Noteworthy:

- Before the procedure the electrosurgical unit does not work. The OR assistant expects a cable break and gets a new ones. New monopolar instrument with cable, new patch and cable to dispersive patch.
- Instead of using a scourer, the physician uses a normal forceps to clean the electrode tip.
- No complications

#4 Date 01-12-2014
LUMC OR: 9
Physician: S1
Surgical Intervention: laparoscopic exploratory operation
(The woman is in a lot of pain, most likely has blood in the abdomen)
Model Electrosurgical unit: Erbe VIO 300D
Patient: woman of slim posture, in early twenties

Laparoscopic surgery
Technique: Bipolar coagulation
Instrument: Bipolar forceps

Noteworthy:

- After suction of the blood in the abdomen it became clear that the tube was already closed due to blood clotting.
- The electrosurgical unit was used, but first did not work because no monopolar dispersive patch was placed. Only after placement of the patch the bipolar function could be used. This let to a lot of frustration among the OR personnel.

#5 Date 01-12-2014
LUMC OR: 9
Physician: S1
Surgical Intervention: laparoscopic exploratory operation
(The woman is in a lot of pain, caution advised because of an IVF treatment that might or might not be successful)
Model Electrosurgical unit: Erbe VIO 300D
Patient: woman of slim posture, in early twenties

Noteworthy:

- No complications or interventions

#1 15-12-2014
LUMC OR: 9
Physician: S1
Surgical Intervention: Laparotomy
(A cyst has to be removed and send away to be diagnosed)
Model Electrosurgical unit: Erbe VIO 300D
Patient: woman of normal posture

Open surgery
Technique: Monopolar coagulation and cutting
Instrument: Blade electrode
Technique: Bipolar coagulation
Instrument: Bipolar forceps

Program:

- Gyn. Grote Chirurgie
- Bipolar Soft – Effect 4 – 50 Watt
- Mono Dry Cut – Effect 5 – 150 Watt

Noteworthy:

- To cut through the skin, a scalpel is used. When the next layer is reached monopolar cutting is used.
- The smoke extractor is connected and used.
- The OR assistant creates a channel for the cables by using two normal forceps and the cloth.
- To stop suction the OR assistant simply pushes the tube through the eyes of the forceps to lock the tube.
- (Not surgery related) The OR assistant complains about the many menus she has to scroll through in the electrosurgical unit.
- The use of scissors, mono coagulation and cutting with the monopolar blade are interspersed.
- Two wound clips and the tweezers that S1 are holding are very close to the monopolar instrument ST1 uses.
- The removal of the cyst (which has the size of a football) has to be very careful, because of its very thin outer layer.
- The ureter is close and should not be damaged.
- To remove the cyst from the ovary a small incision is made by monopolar cutting. This allows the use of two normal forceps (the area is to wide for one forceps).
- The monopolar blade is put against normal tweezers to achieve the bipolar effect.

II Surgery (Heelkunde)

#1 02-02-2015
LUMC OR: 7
Physician: S2 & S3
Surgical Intervention: Check anal fistula and application of new setons
(Patient has Crohn's disease)
Model Electrosurgical unit: Valleylab Force Triad (standard in this OR)
Patient: Man of normal to large posture, about 70

Open surgery
Technique: Monopolar
Instrument: Blade electrode

Program:

- Mono std – cut 25 – coag 25

Noteworthy:

- For splitting the fistula channel monopolar cutting is used.
- No ligasure is used
- S2 is very pleased about the ligasure. No better device possible according to him.
- No complications

#2 02-02-2015

LUMC OR: 7
Physician: S2 &S3
Surgical Intervention: Stoma and check anal fistula and setons
Model Electrosurgical unit: Valleylab Force Triad (standard in this OR)
Patient: Woman of normal to large posture, 58 years old

Laparoscopic surgery
Technique & Instrument: Ligasure
Technique: Monopolar
Instrument: Blade electrode

Program:

- Mono std – pure cut 25 – fulg. Coag. 25 (is changed during surgery to 35 -35)
- Bi std – cut 15 – coag 15 – Eff 3 (not used)

Noteworthy:

- They use a Velcro patch to channel all the cables.
- Ligasure arrives completely sealed (5 mm – 37 cm) with purple cable
- Use ligasure: Clamp the tissue, then push the button till the valleylab gives the signal it is finished and pull the trigger. Release the clamp.
- The ligasure is used to get some of the colon free of the surrounding tissue and to pierce the colon.
- The use monopolar cutting to widen one of the holes used for laparoscopy.
- The colon is pulled through the hole and yet again the ligasure is used.
- Outside the abdomen monopolar cutting is used on the colon. The device is set to pure cut 35 and fulg. Coag. 35.
- One doctor focuses on the stoma, one doctor checks the fistula.
- No complications

#3 02-02-2015

LUMC OR: 7
Physician: S2
Surgical Intervention: Laparoscopic resection of the sigmoid
Model Electrosurgical unit: Valleylab Force Triad (standard in this OR)
Patient: Man of normal to large posture, 70 years old
Position patient: Trendenburg

Laparoscopic surgery
Technique & Instrument: Ligasure
Technique: Monopolar
Instrument: Needle electrode

Program:

- Mono std – pure cut 35 – fulg. Coag. 35

Noteworthy:

- The use monopolar cutting to create a hole to inject the CO2
- The footrests are not good connected. Two OR assistants need to go under the cloth to fix this.
- They use a Velcro patch to channel all the cables.
- The ligasure is used to loosen the bowel from surrounding tissue
- The camera keeps getting dirty.
- Patient is put in more trendenburg to reach other piece of bowel, but this leads to problems with ventilation pressure.
- A Covidien stapler (80 mm - 3.8 mm) is used to seal and cut a large piece of the bowel (larger area possible than the ligasure)
- Scalpel is used to cut the skin, monopolar cutting is used on underlying tissue (cut of about 4cm)
- Coagulate is used to cut through the fat tissue
- The pull the bowel through a plastic flexibele tube.
- Outside the body coagulate and ligasure is used to remove extra tissue
- The stapler is used

III Otorhinolaryngology

#1 03-02-2015
LUMC OR: 16
Physician: S4
Surgical Intervention: Removal of cartilage in the ear to widen meatus (gehoorgang)
(Surgery is already started before I entered)
Model Electrosurgical unit: Erbe VIO 300D

Technique: Bipolar
Instrument: Forceps

Program:

- 2. Chirurgie Klein
- Bipolar Soft – Effect 3 – 30 Watt

Noteworthy:

- Did not see electrosurgery
- No patch attached to patient

#2 03-02-2015

LUMC OR: 15
Physician: S4
Surgical Intervention: Tonsillectomy
Model Electrosurgical unit: Erbe VIO 300D
Patient: Man of normal posture

Technique: Bipolar
Instrument: Bipolar tweezers (during surgery switch to longer tweezers)

Program:
- 17. KNO TE
- Bipolar soft coag. – Effect 4 – 25 Watt

Noteworthy:
- Note on the Erbe: Intraduraal Effect 4 – 10 Watt
- Patch is attached, but no mono will be used
- The tweezers are cleaned by OR assistant with gauze
- Bleeding doesn't stop
  - One side the tonsil was easily removed, two 'sisjes' and it was done
  - Other site the tonsil was deeper and therefore harder to remove
- New set of longer tweezers is used
- Physician does not want to coagulate too much, because this can cause damage to tissue at another spot that was already closed. Gauze is also used to stop the bleeding.
- This is why she did not use the monopolar bulb electrode (risk of damaging tissue is greater)
- Vessel eventually sealed

#3 03-02-2015

LUMC OR: 15
Physician: S5 & S6
Surgical Intervention: Parotidectomy
Model Electrosurgical unit: Erbe VIO 300D
Patient: Woman of normal posture

Technique: Monopolar
Instrument: Blade electrode
Technique: Bipolar
Instrument: Bipolar tweezers (curved end)

Program:
- 18. Hals KL/Parotid
- Bipolar soft coag. – Effect 4 – 40 Watt

Noteworthy:
- Monopolar instrument is connected to generator, but no patch is attached to the patient
- S6 wants a simpler device, an electrosurgical unit that is more intuitive.
- To cut through the skin a scalpel is used
- Bipolar coagulation is used to seal blood vessels when cut with normal scalpel and to cut through small pieces of tissue
- Bipolar is connected to a foot pedal on request physician

- He uses bipolar coagulation preventive before cutting with scissors.
- With forceps he isolates a small piece of tissue, which then can be cut by the use of bipolar coagulation, if this does not works he also uses scalpel.
- S6: Coagulation does more damage than cutting with scissors
- They continue bipolar coagulation, normal cutting, bipolar coagulation, normal cutting, etc.
- The tumor is removed
- Sutures to close the wound
- S6: Normally you try to work around different layers of tissues, but in this case they had to go through several layers, which has the potential of a lot of blood.
- Erbe instructions hang at the back of the device. Cannot be reached and read.

IV Trauma Surgery

#1 10-02-2015

LUMC OR: 2
Physician: S7 & S8
Surgical Intervention: Placement of plate and screws ankle fracture
Model Electrosurgical unit: Erbe VIO 300D
Patient: man

Technique: Monopolar coagulation and cutting
Instrument: Blade electrode

Program:

- 1. Chirurgie groot
- Monopolar dry cut – Effect 5 – 150 Watt
- Monopolar forced coag. – Effect 3 – 35 Watt

Noteworthy:

- No electrosurgery was used
- Because of the use of rontgen everyone had to were a lead apron
- A scalpel is used to cut the skin and other tissue layers to reach the fracture. The blood is removed by suction.
- To get a clean fraction the scalpel, water solution and suction is used
- Before putting in a screw the fraction is kept in place and checked with rontgen.
- First a pulling screw is placed
- The plate is put in place and 6 screws are put in. (first they drill, then they check dept, then they put in the screw)
- With rontgen they check the screws on length and position and put new ones in when not pleased
- Remarks OR assistant:
    - With surgery (heelkunde) and transplantation the doctors love to use spray coagulation.
    - At orthopaedics always the highest setting is used
    - In OR 2 the setting is almost always chirurgie groot
    - In some cases they use a strap around the leg to minimize the blood that flows through. (not with this patient) It is a consideration of the physician.

#2 10-02-2015
LUMC OR: 2
Physician: S7 & S8
Surgical Intervention: Zuggurtung (at the elbow)
Model Electrosurgical unit: Erbe VIO 300D
Patient: Woman

Open surgery
Technique: Monopolar coagulation and cutting
Instrument: Blade electrode

Program:
- 1. Chirurgie groot
- Monopolar dry cut – Effect 5 – 150 Watt
- Monopolar forced coag. – Effect 3 – 35 Watt

Noteworthy:
- The skin is cut with a scalpel
- To coagulate the blade electrode is put on normal tweezers
- S7: With wound clips they tighten the tissue, which closes small blood vessels. Coagulation is not always necessary.
- Cutting all happens with normal scalpel
- A hole is drilled and wire is pulled through
- Another two holes and two pins are placed
- The wire is bend and with a hammer the bend ends of the pins are put in the bone

#3 10-02-2015
LUMC OR: 2
Physician: S8 &S9
Surgical Intervention: Head neck prosthesis for hip
Model Electrosurgical unit: Erbe VIO 300D
Patient: Woman, 97 years old

Open surgery
Technique: Monopolar coagulation and cutting
Instrument: Blade electrode

Program:
- 1. Chirurgie groot
- Monopolar dry cut – Effect 5 – 150 Watt
- Monopolar forced coag. – Effect 3 – 35 Watt

Noteworthy:
- The operation has to be as quick as possible
- No one is allowed in or out during the operation
- A scalpel is used to cut through the skin
- Dry cut and coagulate are interspersed when cutting through underlying tissues.
- Suction is used to remove blood
- Dry cut is activated a long time to work as fast as possible to get to the bone

- With a saw right under the head they cut the head loose. Small pieces are cut loose from the 'kapsel' with a scalpel and pulled out with tweezers.
- They drill a hole and with several rasps they create a bigger cavity to put the stem in. Because of the old age the bone is brittle and it doesn't take a lot of force and time.
- The head is pulled out of the wound and with dry cut they cut the remaining pieces loose.
- Coagulation is needed when the wound clips are tightened to open the wound and to cut away tissue to allow space for the new head
- Bone cement is made and the stem is pushed in. We wait 12 min.
- The head is put in place.
- Even though nobody should enter or leave the OR, an anaesthetist enters.
- Time: 45 min
- No complications
- Remarks OR assistant:
    - At transplantations the Valleylab is used
    - The technical service puts in new programs on request by a physician
    - At thorax they use an old Valleylab that has only one setting
    - A problem that often occurs is that the patch stutters. This is always a cable problem, or it there is a cable break or the connection with the device is not good.
    - The blade and patch are disposable, but the instrument and cable are reusable.
    - Once a program is set, it is almost never changed during surgery

C Interviews and Correspondence

This appendix presents key points and tips from interviews that have been conducted and e-mails that have been exchanged during this project. (Presented in Dutch)

Jogchum Beltman – Gynaecologist LUMC and experience tropical medicine (Malawi)

- Check See and Treat van de female cancer foundation - cryotechnologie
- Misschien hebben we meer aan fatsoenlijkere hechtmaterialen dan een coagulatie apparaat
- Kabels moeten ook gesteriliseerd worden
- Zorg dat het apparaat zelfvoorzienend is – zonder netstroom en met backup kunnen werken
- De milleniumgoals zijn een hot topic, kan je hier wat mee doen?

Frenk Stokman – MSc student (IDE at TU Delft) with master thesis subject: 'Water efficient sterilization for humanitarian aid - a redesign of the Robustex 90L (autoclave)'

- Definieer goed de context. Voor welk type ziekenhuis of medical centers ga je het maken?
- Uit zijn ervaring in Oeganda: Er is alleen elektra als de patiënt diesel mee neemt voor de generator
- Check bij de verschillende stakeholders wat zij willen in/met de ESU
- Zonnecellen worden vaak gestolen en is dit überhaupt voldoende om de ESU te laten draaien?
- Maak het product zo transparant mogelijk – Waarom gebeurt er wat er gebeurt. Laat ze begrijpen wat er kapot is
- Zorg dat lokaal onderhoud mogelijk is, maar laat het niet lokaal produceren
- Houd rekening met de wetgeving en regulaties specifiek voor dat land
- Voor Afrika is het bijna onmogelijk een gecertificeerd product te maken

Alex Vernooij – Instrumental affairs LUMC

- Veiligheid staat bij het LUMC op de eerste plaats
- Check wie worden de gebruikers en welke instellingen zijn er nodig
- Wat is het potentiele gevaar voor deze gebruikers en met deze instellingen
- Bij het LUMC streeft hij naar zo veel mogelijk bipolaire elektrochirurgie vanwege de veiligheid
- Check waar monopolaire elektrochirurgie echt voor nodig is en wat met bipolair kan opgelost
- Streef naar uniformiteit – OK assistenten werken veel met deze apparatuur en ze werken op verschillende afdelingen (bij verschillende specialisaties)
- Bij het LUMC moet er meer training komen voor de artsen, zodat ze beter met de apparatuur om kunnen gaan waar ze mee werken en meer weten over de achterliggende principes
- Check Diamedica

Jos van Hameren – Technical departement LUMC

- Diathermie apparatuur word 1x per jaar gecheckt
- Een deel van het onderhoud kan zelf gedaan, maar een deel moet ook bij de firma's
- Bij dermatologie wordt een apparaat gebruikt waar geen patch voor nodig is
- Bij de maag/darm afdeling gebruiken ze vaak elektrochirurgie met argon gas
- Voor de Thorax operaties word Valleylab i.p.v. Erbe gebruikt, "Ze willen vonken zien". Dit is puur de voorkeur van de artsen, want de apparaten kunnen exact hetzelfde als de Erbe
- Bij Thorax open chirurgie is echt monopolaire elektrochirurgie nodig
- Na 1 minuut stopt het apparaat. Deze safety zit op alle apparatuur, dus er is ergens een standaard hiervoor
- Het merk diathermie apparaat word gekozen uit traditie
- De onderdelen die kapot gaan: aansluitingen en bussen slijten en worden af en toe vervangen, maar meest mechanisch iets kapot. Een bus moet bijvoorbeeld vervangen omdat de stekker te grof in/uit is gedaan
- Het is belangrijk dat er geen stof en vocht in de generator komt
- Voor de ERBE VIO300D worden insteek printen gebruikt, het piepschuim rondom isoleert direct de stroom en kanalen in het schuim zorgen voor goede luchtstroom
- Er zitten hele unieke onderdelen in – de software moet ook weer compatible zijn met de printplaten die vervangen worden
- Er zit een overbrenging mechanisme in om te voorkomen dat er netspanning bij het frontje kan komen
- In de ERBE kunnen programma's toegevoegd worden. Dit wordt gedaan op verzoek van een arts
- Hoe hoger het vermogen, hoe meer koolproductie
- De neutrale patch is disposable, maar de draad ernaartoe is reusable

Han Knol – Founder/Director of Novymed International BV. & Chair of Passion for People

- Maak een apparaat dat heel eenvoudig te bedienen is, zo min mogelijk 'toeters en bellen'
- Apparatuur dat hier is afgedankt wordt naar ontwikkelingslanden gestuurd. Een groot probleem is dat er vaak geen onderdelen meer geproduceerd worden, waardoor als iets kapot gaat er geen vervanging nodig is
- Zorg voor een lokale partner die wat opleiding of training heeft gehad. Zonder lokale partner geen tot weinig kans van slagen
- Het apparaat moet nog steeds kunnen functioneren als fluctuaties in stroom optreden
- Check hoe werken ze daar, is het nodig en wat doen ze anders dan hier met elektrochirurgie
- Zorg voor een unique selling point. Toon aan dat jouw apparaat super nuttig is, bijvoorbeeld het ideale apparaat om te helpen bij obstetrische complicaties. Dan willen ministeries etc wel betalen
- In Afrika wordt er veel naar de FDA gekeken, omdat het geld vaak uit die kant komt, maar hangt ook erg per land af
- Check https://www.cordaid.org/nl/nieuws/innovatie-ontwikkelingslanden/ and http://www.tfhc.nl

Arjan van Dijke – Technician at MISIT TU Delft

- Maak gebruik van een UPS, zitten gewoon loodaccu's in, net anders dan auto accu's
- Standaard battery powered maken
- Stel dat je het apparaat gedurende een half uur aan zou hebben staan en gemiddeld wordt er 350 mA gebruikt (de basis van 250 en de pieken van 500 gemiddeld – bij de galblaas operaties). Dan wordt er 350 / 0.5 = 700 mAh = 0.7 Ah gebruikt.
  Dat lijkt niet zoveel (een gemiddelde oplaadbare penlite-batterij heeft 5x die capaciteit), maar je moet er rekening me houden dat dit bij 230V wisselspanning gemeten is. Er is dus 230 * 0.7 = 161 Watt-uur gebruikt.
  Dat is trouwens nog steeds iets wat prima met een (iets grotere) accu geleverd kan worden. En die bijvoorbeeld met een zonnepaneel van 250 Watt ook weer goed op te laden is.
- Check http://frankshospitalworkshop.com/

Anne-Marije Worm – Healthcare technology advisor (work experience Africa)

Door een te slechte connectie in Benin was er geen Skype gesprek mogelijk. Correspondentie ging via e-mail. (Onderstaande geschreven vanuit oogpunt Anne)

- Marc (mijn vriend die hier als BME werkt) heeft vorige week 5 district ziekenhuizen bezocht en allen gebruiken ESUs.
- Wie de ESU gebruiken: Er zijn hier weinig specialisten. Dus basis artsen doen bijna alles
- De ESU wordt blijkbaar zowel in district ziekenhuizen als referentie ziekenhuizen gebruikt (meestal universiteits ziekenhuizen). Ik denk dat als er geopereerd wordt, het geschikt is om een ESU te hebben. Misschien is de vraag eerder voor wie jij een ESU wilt ontwikkelen
- De meeste problemen zijn gerelateerd aan gebrek aan onderhoud en reparatie en infrastructuur/klimaat.
- Volgens R. Malkin wordt trouwens minstens de helft (of was het 75%?) van de medische apparatuur 'failure' veroorzaakt door user errors.
- Check R. Malkin's papers
- Gebrek aan onderhoud en reparatie: geen gekwalificeerde techneuten, geen (access to) reserveonderdelen, geen Preventive Maintenance Plan (alleen reactief),
- Infrastructuur/klimaat: geen tools en test equipment, geen service manuals, donaties van apparatuur die al half kapot was, vochtigheid, stof, temperatuur. Ziekenhuizen hebben vaak geen AC.
- De ESUs die Marc is tegengekomen vorige week werkten allemaal.
- De generator wordt aangezet als de stroom uitvalt. Als er geld is voor Diesel. En zijn meestal geen Voltage Regulators oid. UPS?
- Rekening houden met: Ease of Use. Vergeet niet de trots van de artsen, die vaak alleen dat willen wat ze op congressen tegenkomen.
- Maar heel eerlijk gezegd weet ik niet of ESUs problemen opleveren, gezien de observaties van Marc vorige week

Uit een facebook gesprek tussen Anne en haar student uit Rwanda die werkt als BMET in Butaro in een PiH ziekenhuis waar het behoorlijk goed geregeld is kwam het volgende:

- In general the surgeons use the ESU
- Had 2 breakdowns in 4 years
- He has classified the ESUs as critical equipment and pays much attention to them
- They can be used from the district hospital to the referral hospital

- He has 2 units, a Valleylab and a Cooper Surgical. They are very good, but expensive and hard to maintain
- The planned preventive maintenance he performs is: check electrical leakage, check grounding, check vacuum pressure and he performs function tests every 3 months

Joke van Leersum – OR assistant at RdGG (work experience Bangladesh – mission to provide plastic surgery)

- Maak het diathermie apparaat zo basic mogelijk
- Rookafzuiging zou handig zijn, omdat de geur na dagen in de OK staan irritant word
- Ze gebruikten de ERBE ICC 200, die had alleen monopolair
- Er is een bipolaire optie nodig
- Maak gebruik van kleuren om de taalbarrière te omzeilen
- Nuttig: zorg dat onderdelen lokaal te vervangen zijn
- Het diathermie apparaat is een essentieel apparaat bij brandwonden
- Het alternatief van elk bloedvaatje apart dichtbranden of afbinden oid werkt niet goed
- De diathermiesnoeren hebben ze zelf meegenomen
- Maak gebruik van reusables ipv disposables
- Alle disposable snoeren/instrumenten werden in een sterilisatie trommel met stoom gesteriliseerd
- Gebruikten een neutrale plaat die jaren terug ook in NL standaard was, werkte goed
- Zorg voor genoeg snoerlengte, want in de krappe OK staat het apparaat op soms gekke plekken
- Zorg dat het met minimale technische kennis gerepareerd kan worden
- Ze hebben lang gezocht om tot de beste setting te komen, waar een goede snijlijn is maar geen verbranding
- Werk met plaatjes ipv van tekst op het apparaat
- Gebruik onderdelen die het makkelijkst te vervangen zijn en minst snel kapot gaat
- Houd rekening met dat het lang duurt om te steriliseren (ketel op stoom te brengen)
- 8 ingrepen per dan met 5/6 snoeren, wat je bij de 1e operatie gebruikt pas weer bij de 4e opnieuw beschikbaar
- Gebruik zo min mogelijk naden, uitstekende delen en min mogelijk losse onderdelen
- Er is een opzetstuk nodig om de generator compatible te maken met instrumenten van ander merk
- De overheidsziekenhuizen zijn duur en slecht

D Examples Design Medical Devices LMIC

The NeoNurture car-parts incubator

Within the first days of their life many infants die, about 4 million within the first month and one million even within their first day. Hypothermia is for almost half of these infants the cause of death. This is the result of inability of the neonates' body to maintain the necessary body temperature[47]. The nonprofit design company Design that Matters investigated this problem with support from several initiatives and accepted the challenge to design an incubator that consists of parts that are abundant in LMIC. With this approach they sought to avoid the problem of the incubator being discarded due to the lack of parts and the lack of knowledge on how to repair the incubator once broken[29, 47].

Figure 46. NeoNurture Incubator[47]

The observation had been made that even the smallest and most remote areas in LMIC had the means to maintain and repair cars. The focus was on the Toyota 4Runner and the usefulness of all the parts within the car was explored. The result of the project was a robustly build incubator with a pair of headlights as heat source, car door alarm signals to indicate emergencies and a climate control system consisting of motor blowers and dashboard fans[29, 47].

The MOM inflatable incubator

James Robert, a student from the Loughborough Univeristy was, after seeing a documentary about premature child deaths within refugee camps, inspired to find a solution for this problem. The WHO states that 75% of the deaths in neonates could be prevented if an incubator is available to help the child maintain the necessary body temperature[48, 49]. During his research it became clear that the incubators used in the western world have a lot of additional functions next to its main function, such as the ability to measure the brain activity of the child. Partly because of these features the costs of an incubator are extremely high. The people in LMIC are not trained to handle such complex technology and donated equipment is often not used, also because of the unreliable power grid. His solution is the inflatable incubator that can provide the necessary care for the neonates through the use of ceramic heating elements, cheap computer ventilators, a humidifier and blue LED lights for the provision light therapy[49]. The costs of this design are considerably lower than the common incubators, is more power efficient and it is much easier to transport[48, 49].

Figure 47. The MOM inflatable incubator[48]

Simplified negative pressure wound therapy device

A successful method for treating open wounds is negative pressure wound therapy. With this method a controlled vacuum source is applied to an open wound, which has several advantages such as promoting the healing of the wound and the removal of interstitial fluid. Current techniques are however not suitable for use in LMIC, in disaster relief or for military purposes. It is limited by the lack of portability, the high consumption of electrical power and the high costs of the equipment [33. Danielle Zurovcik and her team at MIT focused on designing a mechanical system that is human powered and which is affordable. To achieve this they identified the inefficiencies in the current systems and eliminated the features that do not contribute to the main functions of the device. The result was a bellows pump that met all the functional requirements and had low costs. The initial prototype was tested in Haiti after the 2010 earthquake and its results were promising [50-52].

Figure 48. Prototype of the wound pump in a field test in Haiti

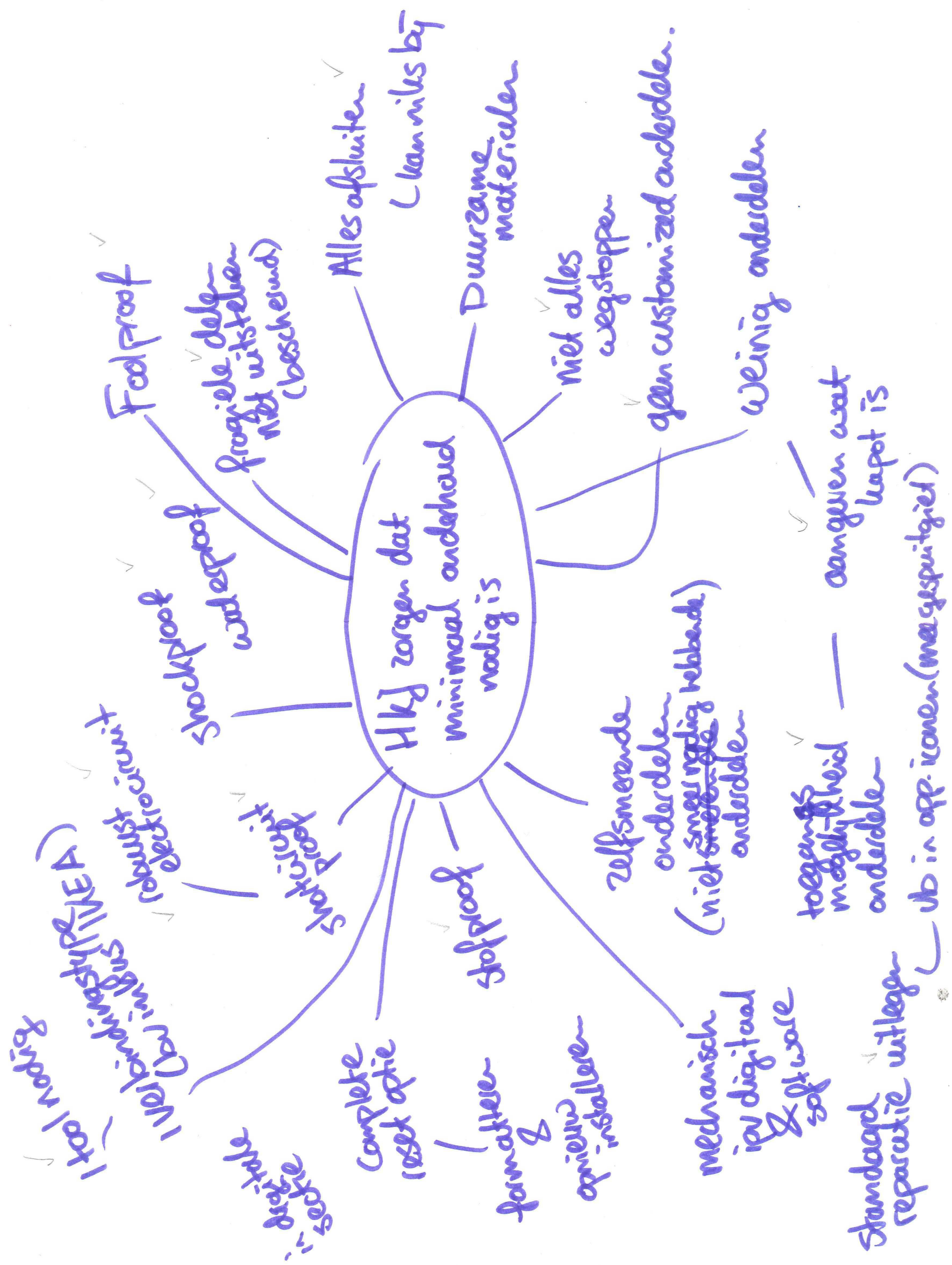
Diamedica anaesthetic equipment

The English company Diamedica is one of the few manufacturers that have focused its business primarily on providing medical devices for challenging environments. Their anesthetic machines are designed in such a way that it deals with many of the barriers mentioned in section 2.4.2. The Glostavent Anaesthetic Machine for instance is very useful in remote settings, because of its battery backup system and incorporated uninterruptible power supply (UPS)[53]. The devices are easy to use and come with simple, but clear instructions that assist staff in setting up the equipment. The factors that play a key role in the success of their aneasthetic machines are the provision of long-term service contracts and their assistance in training local biomedical technicians[6, 53].

E Brainstorms

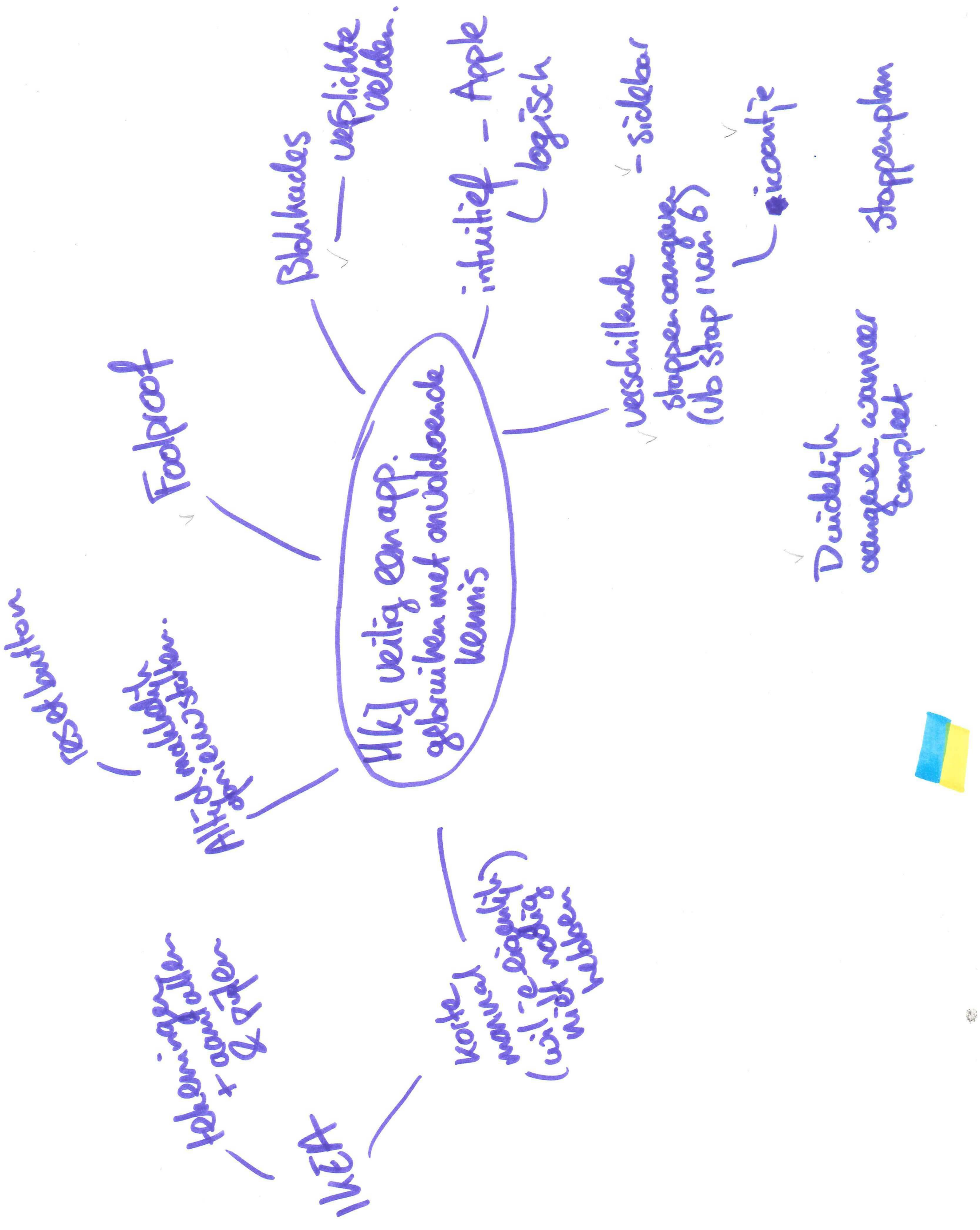
First session

How to ensure that minimal maintenance is required



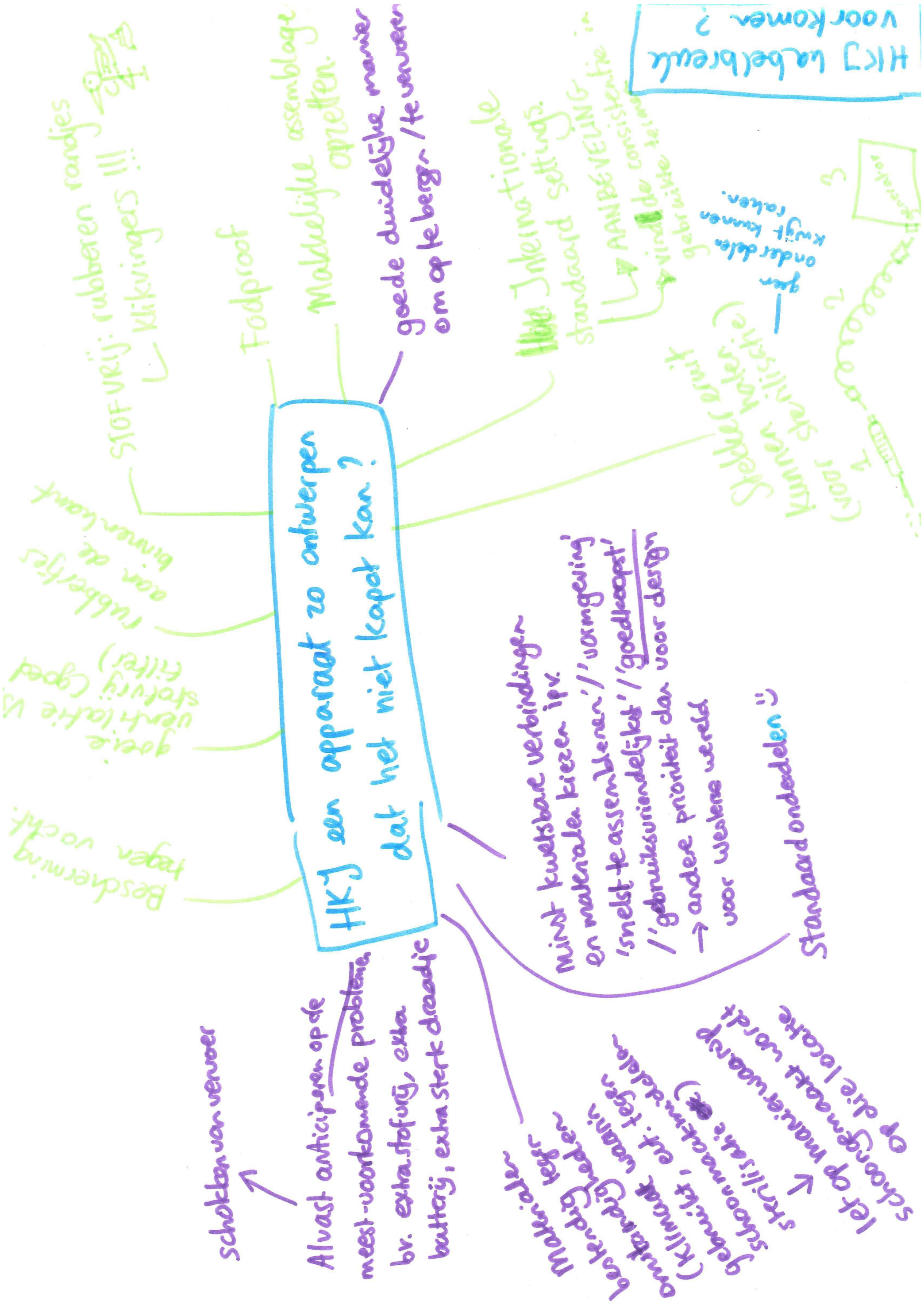
How to reduce the complexity of an interface

How to encourage safe use of a device without the user having the proper knowledge



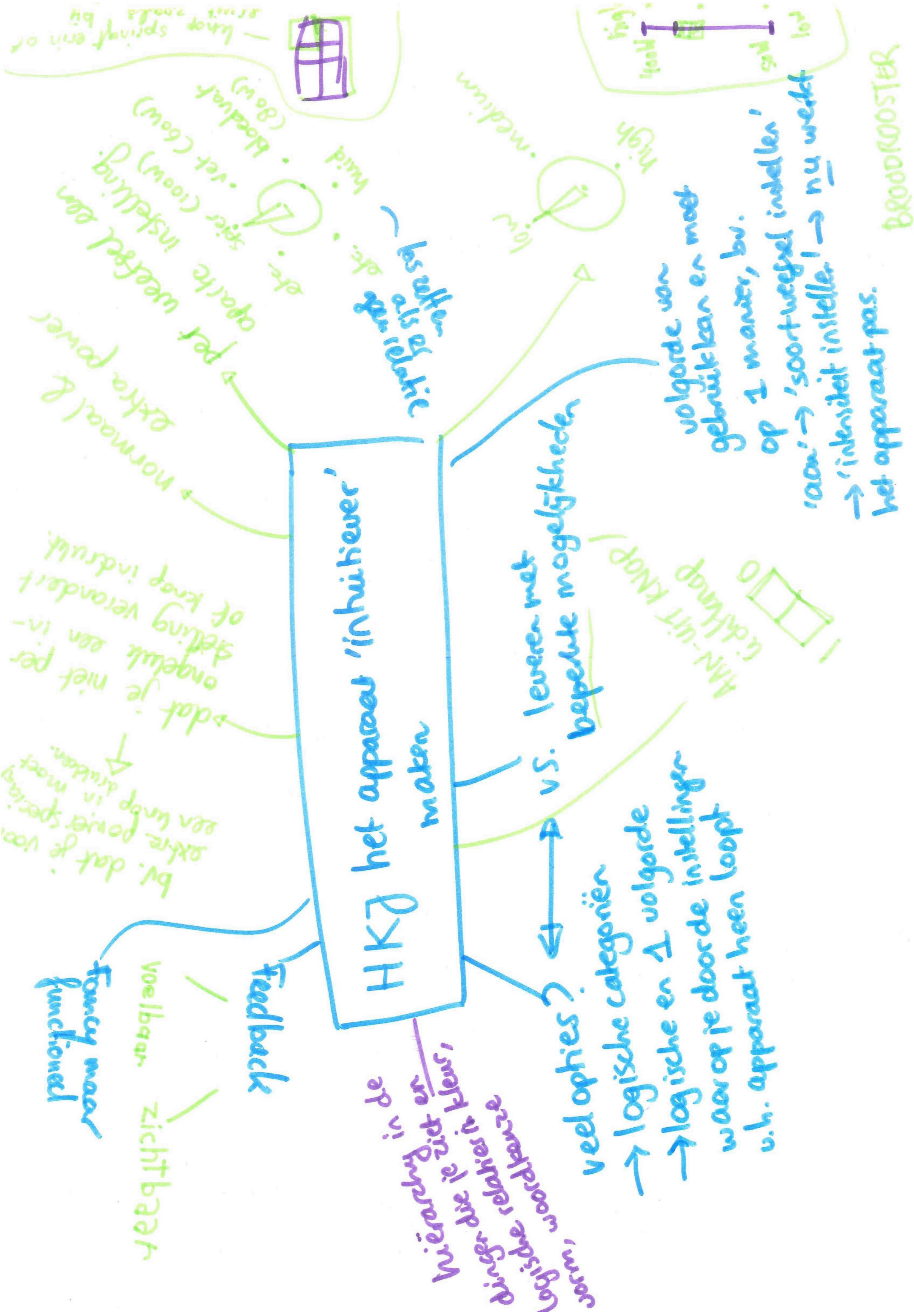
Second Session

How to design a device so it will not break down



How to ensure reparability

How to make the device more intuitive



F Overview Solutions

This appendix presents the solution schemes of the other components of the ESU (see section 5.3.2. for those of the interface). These schemes were made with input of my own experience in LMIC (Kenya and Albania), the brainstorms, suggestions that were made in literature and tips given by the interviewed experts (see Appendix C). The requirements that are stated in section 5.2. have been used as guide. The schemes give more detail on what the requirement means for that particular component and provides ideas on possible solutions.

Monopolar Instrument

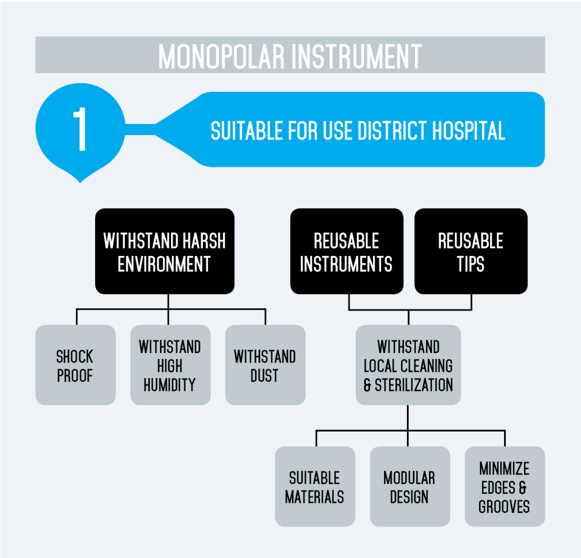


Figure 49. Aspects to consider and possible solutions to make the monopolar instrument suitable for use in a district hospital

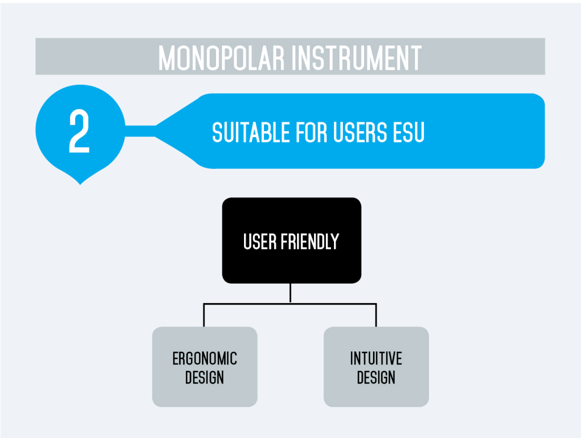


Figure 50. Aspects to consider and possible solutions to make the monopolar instrument suitable for the users of the ESU

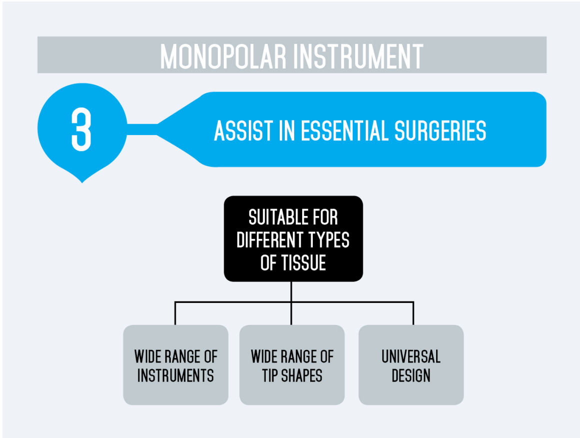


Figure 51. Aspects to consider and possible solutions to make the monopolar instrument suitable for the essential surgeries

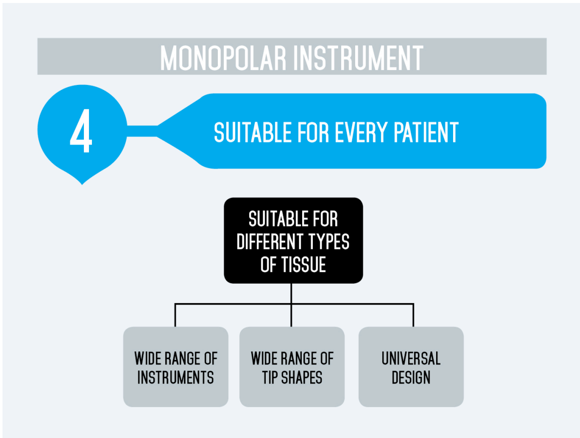


Figure 52. Aspects to consider and possible solutions to make the monopolar instrument suitable for every patient

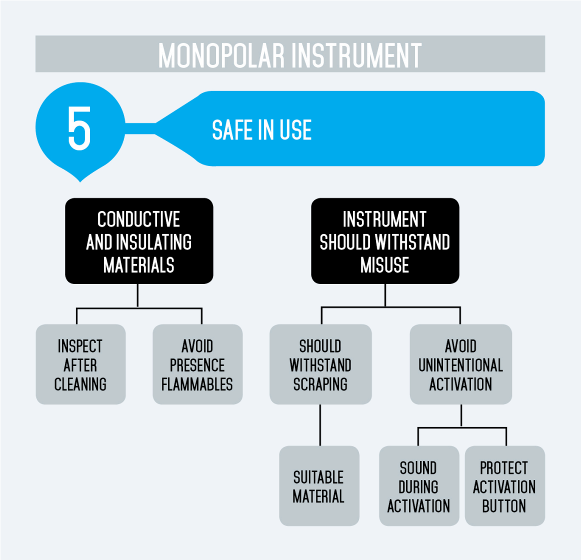


Figure 53. Aspects to consider and possible solutions for making the monopolar instrument safe in use

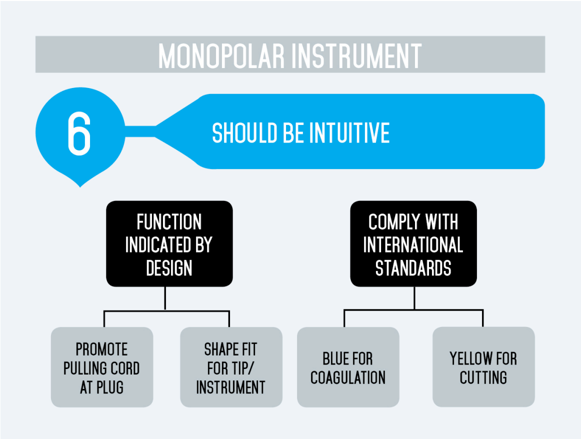


Figure 54. Aspects to consider and possible solutions to make the monopolar instrument intuitive

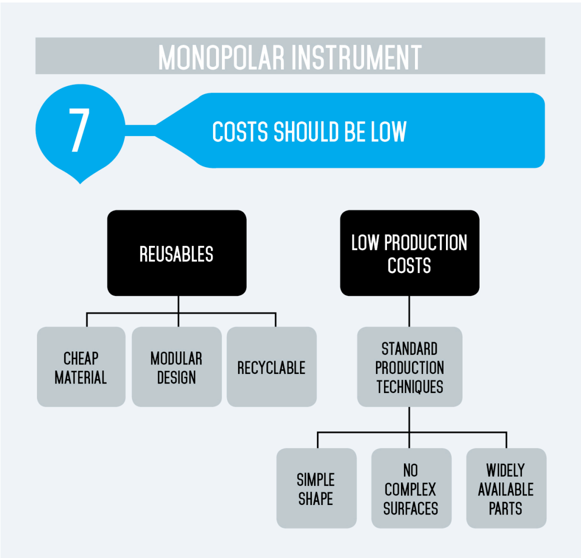


Figure 55. Aspects to consider and possible solutions to keep the costs of the monopolar instrument low

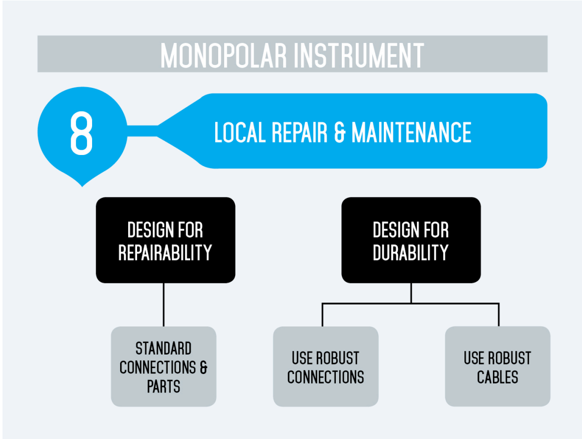


Figure 56. Aspects to consider and possible solutions to making the monopolar instrument suitable for local repair and maintenance

Dispersive Electrode

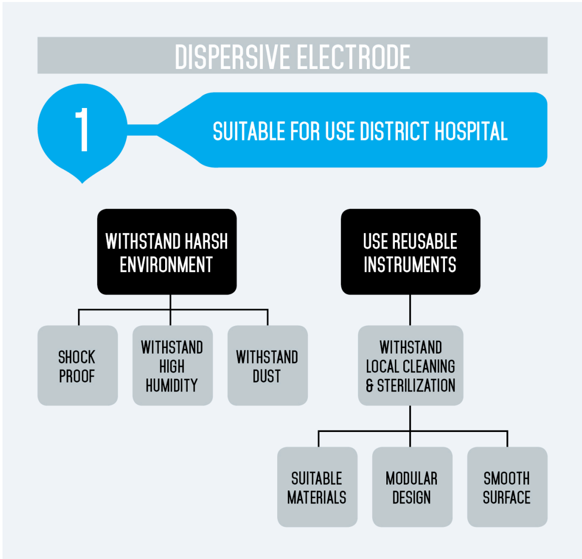


Figure 57. Aspects to consider and possible solutions on how to make the dispersive electrode suitable for use in a district hospital

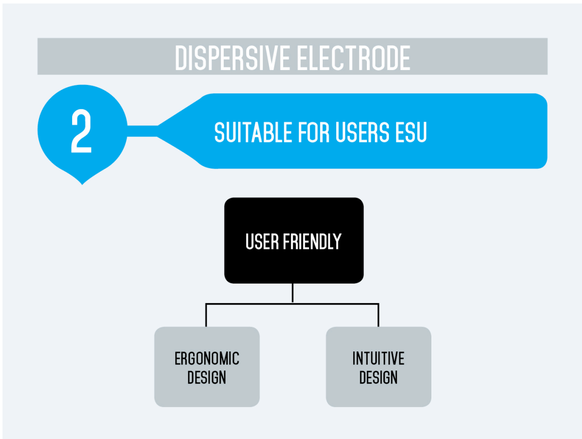


Figure 58. Aspects to consider and possible solutions to make the dispersive electrode suitable for the users of the ESU

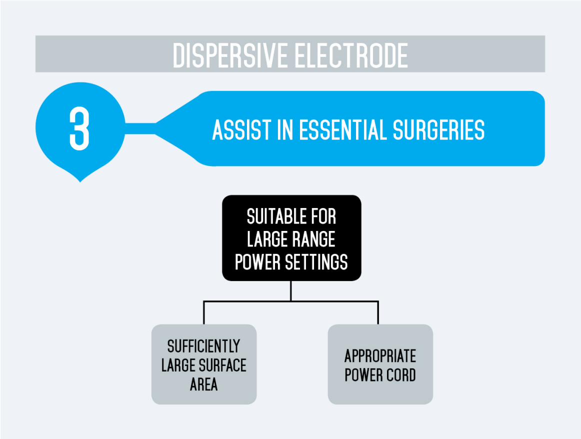


Figure 59. Aspects to consider and possible solutions to make the dispersive electrode suitable for the essential surgeries

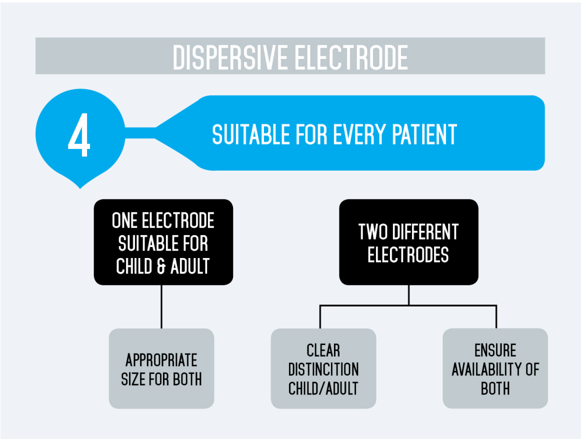


Figure 60. Aspects to consider and possible solutions to make the dispersive electrode suitable for every patient

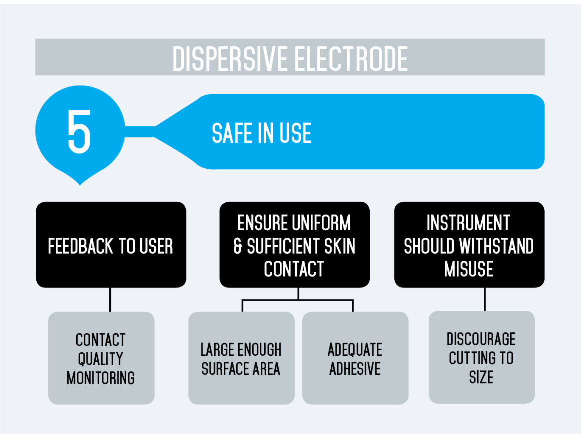


Figure 61. Aspects to consider and possible solutions to make the dispersive electrode safe in use

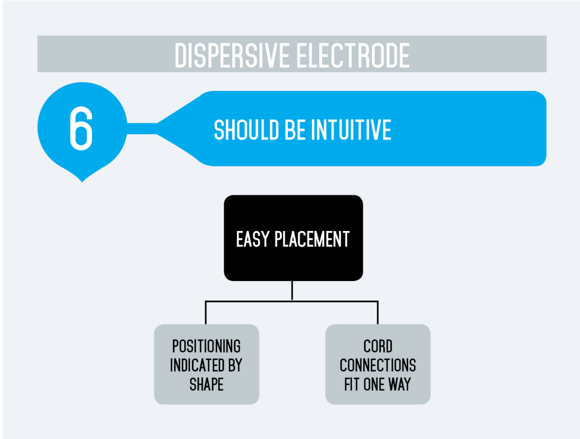


Figure 62. Aspects to consider and possible solutions to make the dispersive electrode more intuitive in use

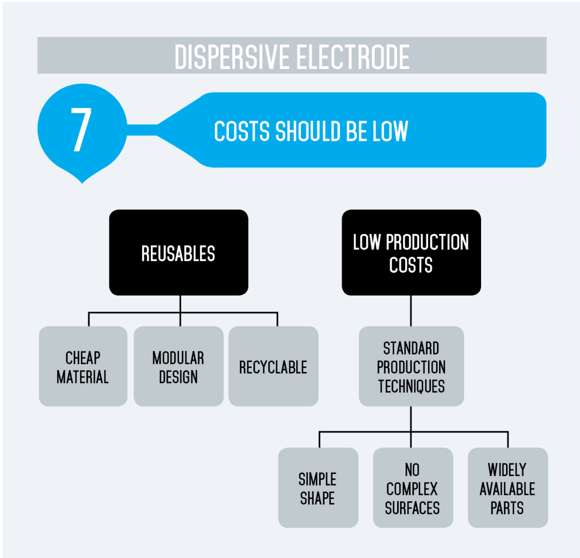


Figure 63. Aspects to consider and possible solutions to keep the costs of the dispersive electrode low

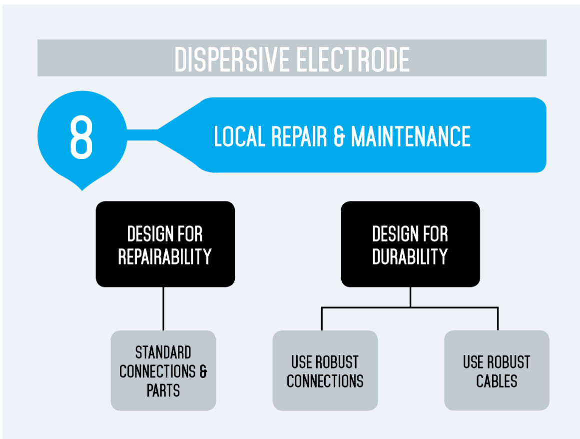


Figure 64. Aspects to consider and possible solutions to make the dispersive electrode suitable for local repair and maintenance

Bipolar Instrument

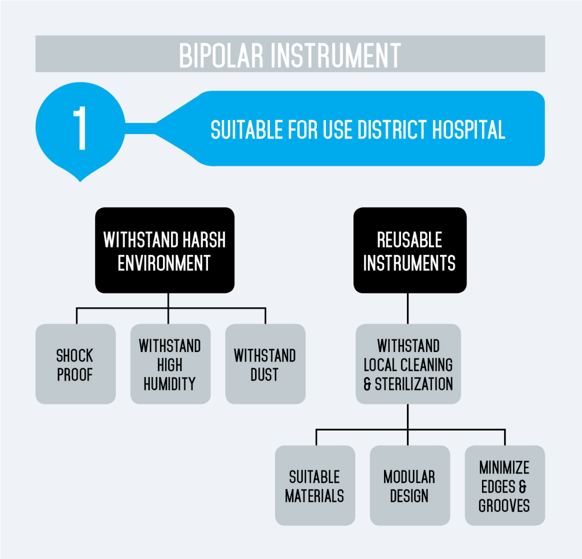


Figure 65. Aspects to consider and possible solutions to make the bipolar instrument suitable for use in a district hospital

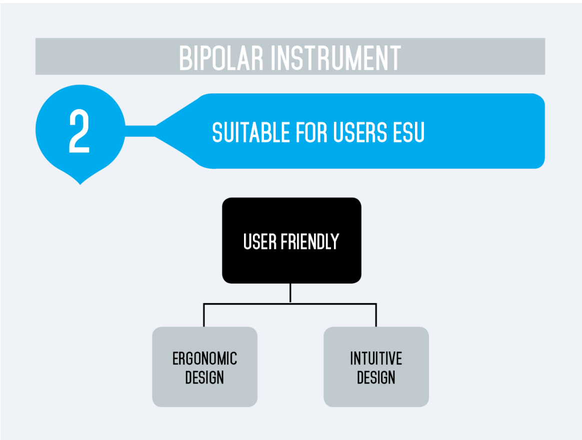


Figure 66. Aspects to consider and possible solutions to make the bipolar instrument suitable for the users of the ESU

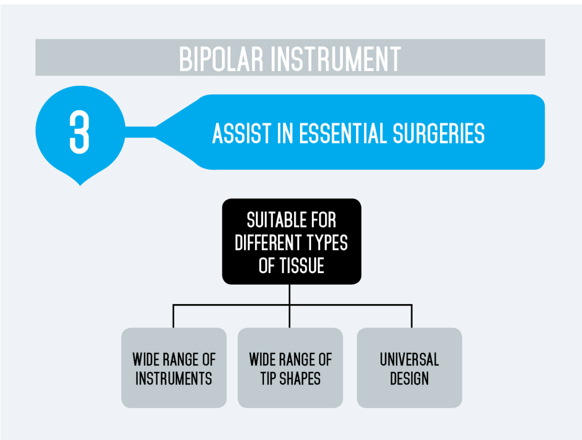


Figure 67. Aspects to consider and possible solutions to make the bipolar instrument suitable to assist in the essential surgeries

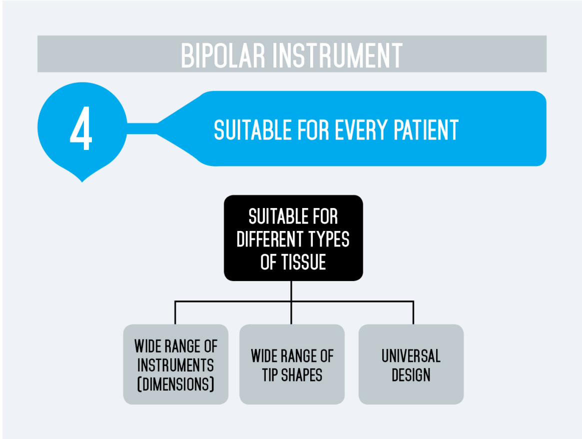


Figure 68. Aspects to consider and possible solutions to make the bipolar suitable for use on every patient

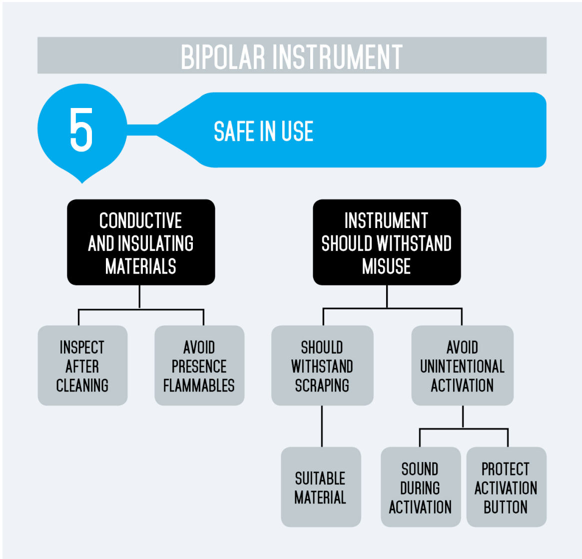


Figure 69. Aspects to consider and possible solutions to make the bipolar instruments safe in use

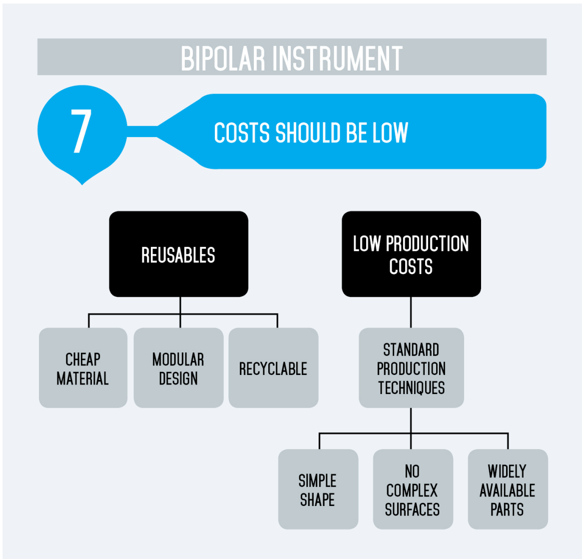


Figure 70. Aspects to consider and possible solutions to keep the costs of the bipolar instrument low

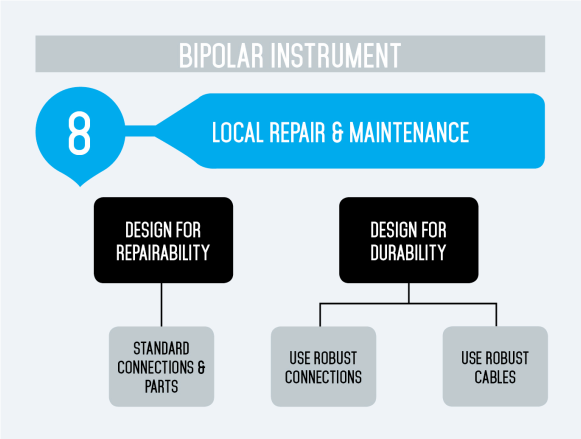


Figure 71. Aspects to consider and possible solutions to make the bipolar instrument suitable for local repair and maintenance

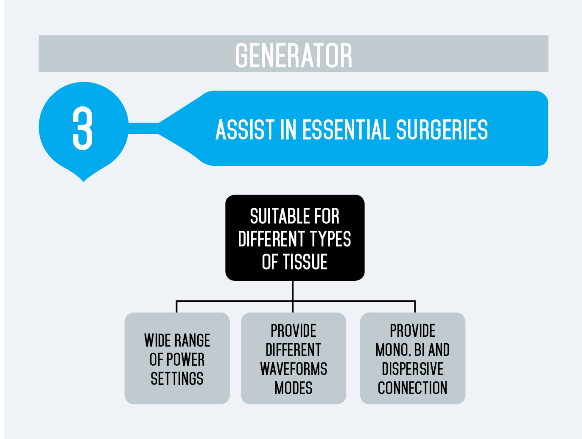


Figure 74. Aspects to consider and possible solutions to make the generator suitable to assist in the essential surgeries

Generator

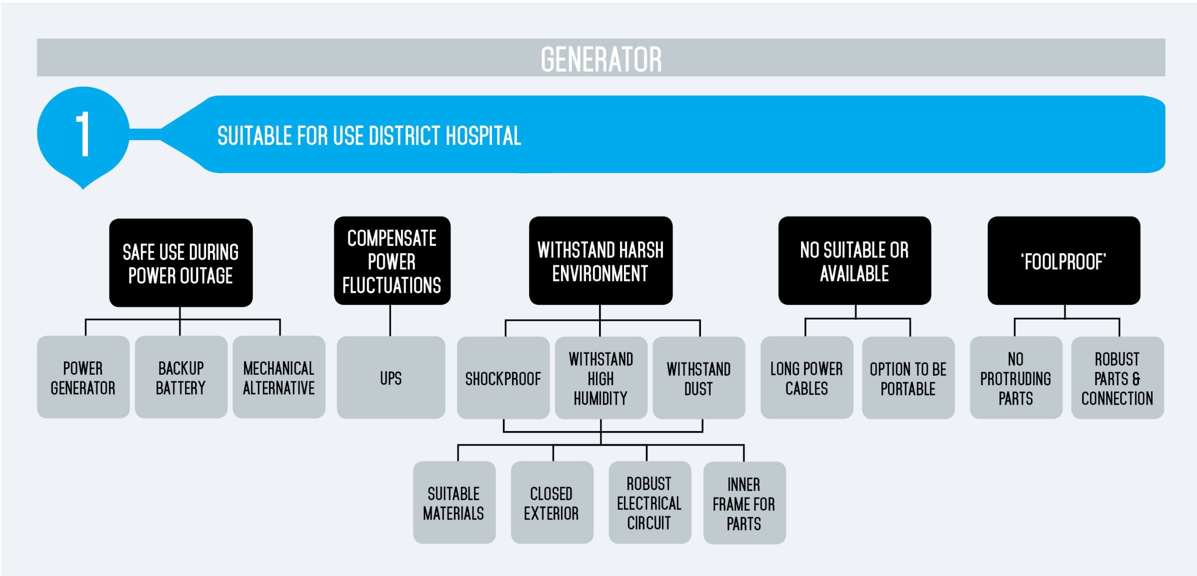


Figure 72. Aspects to consider and possible solutions to make the generator suitable for a district hospital

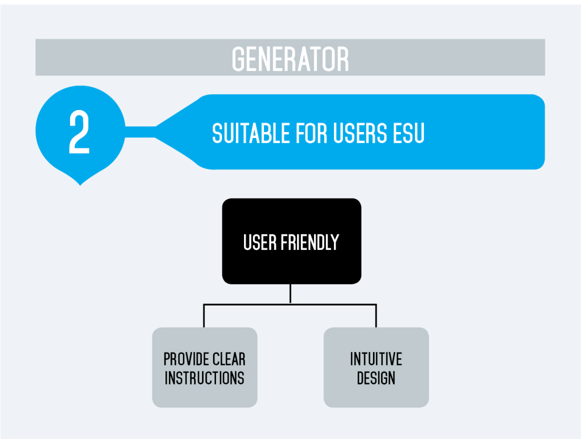


Figure 73. Aspects to consider and possible solutions to make the generator suitable for the users

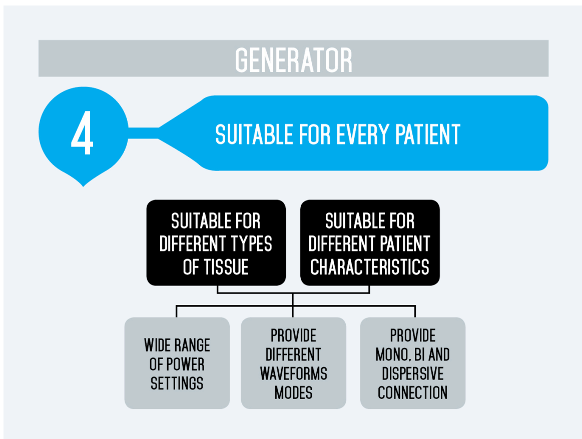


Figure 75. Aspects to consider and possible solutions to make the generator suitable for every patient

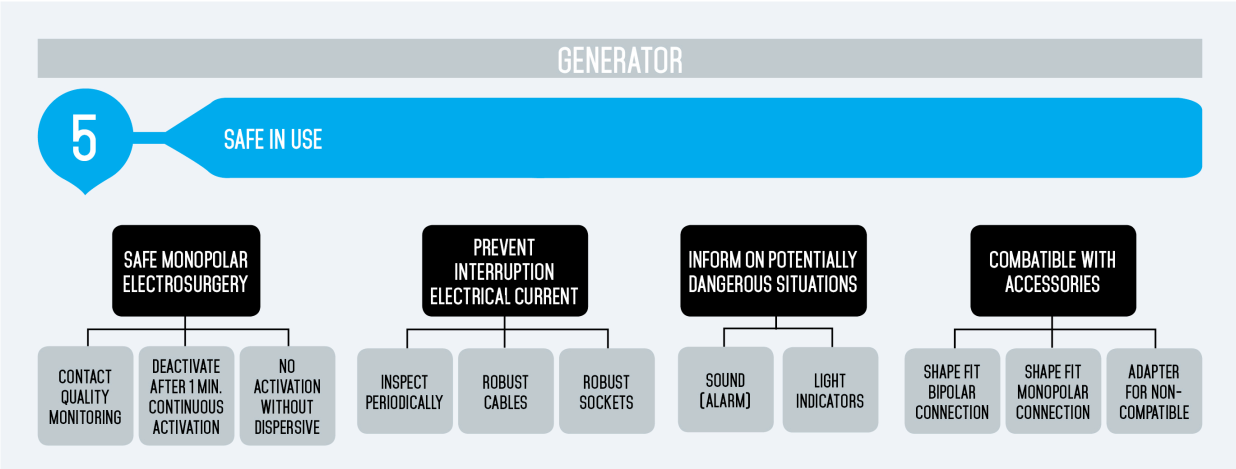


Figure 76. Aspects to consider and possible solutions to make the generator safe

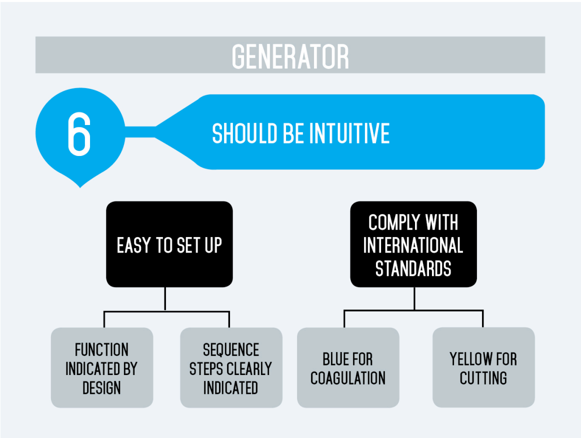


Figure 77. Aspects to consider and possible solutions to make the generator more intuitive

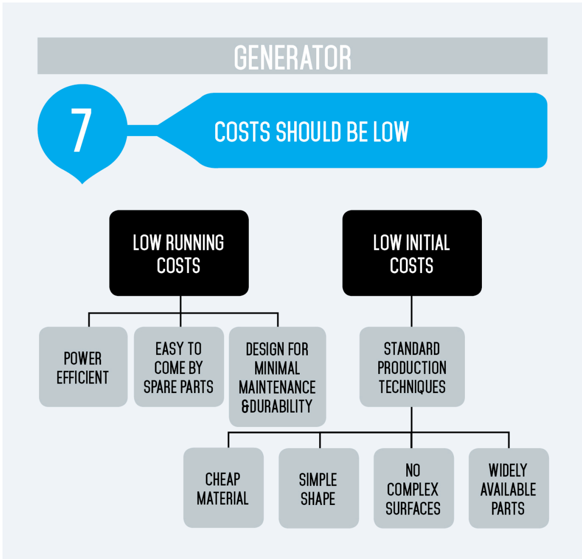


Figure 78. Aspects to consider and possible solutions to keep the costs of the generator low

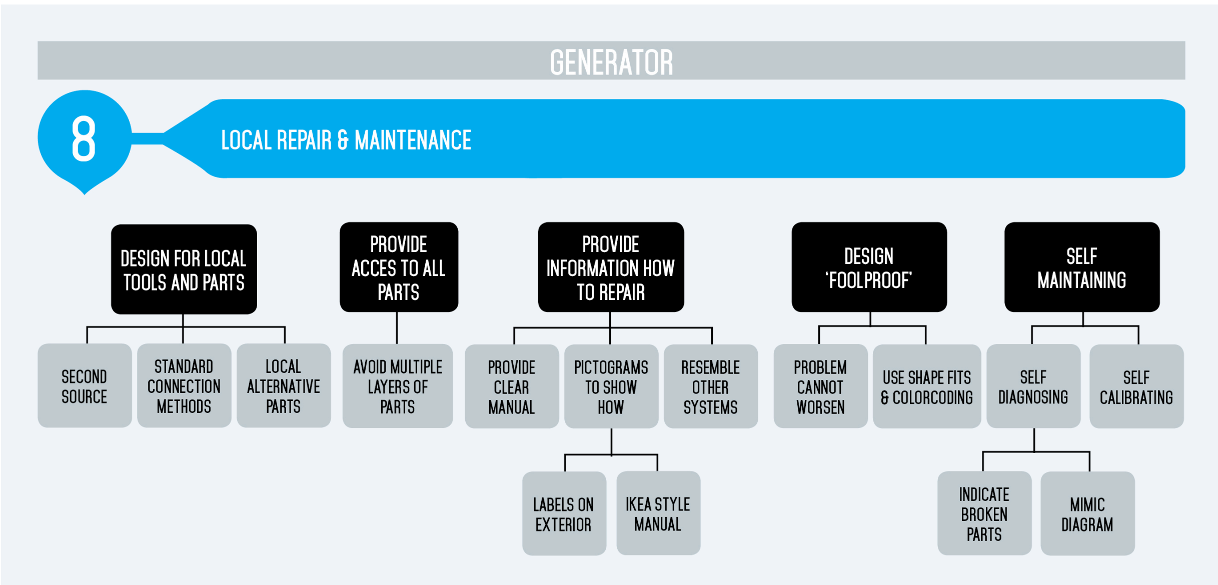


Figure 79. Aspects to consider and possible solutions to make the generator suitable for local repair and maintenance

G Setting Specifics

Data of 25 Cholecystectomies performed at Reinier de Graaf Gasthuis (Setting in Watt)

SURGERY	DATE	TIME	SURGEON	ASSISTANT	CUT/COAG	MODE	SETTING (WATT)	INSTRUMENT	PERCENTAGE ASSISTANT	DIFFICULTY	AGE PATIENT	BMI PATIENT
01		08.27.00 – 09.22.59	S1	A1	COAG	FULGURATE	30	HAAKJE	5	1	1963	29.9
02	05/03/14	10.00.00 – 11.04.59	S1	A1	COAG	FULGURATE	30	HAAKJE	15	2	1953	26.3
03	05/03/14	11.38.00 – 12.38.59	S1	A1	COAG	FULGURATE	30	HAAKJE	50	0	1969	28.4
04	05/03/14	13.13.00 – 13.37.59	S1	A1	COAG	FULGURATE	30	HAAKJE	10	0	1980	31.8
05	05/03/14	14.10.00 – 14.58.58	A2	A1	COAG	FULGURATE	30	HAAKJE	5	0	1991	34.4
06	12/03/14	10.37.00 – 10.50.59	S1	A3	COAG	DESSICATE	30	HAAKJE	60	0	1946	31.9
		10.51.00 – 11.14.59			COAG	DESSICATE	35	HAAKJE				
07	12/03/14	12.07.00 – 12.37.59	S1	A3	COAG	DESSICATE	35	HAAKJE	80	0	1967	23.9
08	12/03/14	13.20.00 – 14.36.59	S1	A3	COAG	DESSICATE	30	HAAKJE	5	2	1956	29.4
09	19/03/14	09.35.00 – 10.08.59	S1	A4	COAG	DESSICATE	30	HAAKJE	0	0	1980	22.2
10	19/03/14	11.05.00 – 11.45.07	S1	A4	COAG	DESSICATE	30	HAAKJE	10	1	1971	29.5
		11.45.07 – 11.45.11			CUT	BLEND	30	HAAKJE				
		11.45.11 – 11.47.41			COAG	DESSICATE	30	HAAKJE				
		11.47.41 – 12.07.59			CUT	BLEND	30	HAAKJE				
11	19/03/14	12.38.00 – 13.20.59	S1	A4	COAG	DESSICATE	30	HAAKJE	90	0	1995	20.4

SURGERY	DATE	TIME	SURGEON	ASSISTANT	CUT/COAG	MODE	SETTING (WATT)	INSTRUMENT	PERCENTAGE ASSISTANT	DIFFICULTY	AGE PATIENT	BMI PATIENT
12	19/03/14	14.02.00 – 14.37.59	S1	A4	COAG	DESSICATE	30	HAAKJE	5	1	1942	30.1
13	08/04/14	10.47.00 – 12.03.58	S2	A4	COAG	FULGURATE	25	PREPAREER	0	1	1936	25.7
		12.04.00 – 12.29.38			COAG	FULGURATE	25	HAAKJE				
		12.29.38 – 12.37.59	S1	A1	COAG	FULGURATE	25	HAAKJE				
14	08/04/14	13.12.00 – 13.49.59	S2	A4	COAG	DESSICATE	30	PREPAREER	60	2	1940	30.8
		13.50.00 – 14.29.59			COAG	DESSICATE	30	HAAKJE				
		14.30.00 – 14.44.59			COAG	DESSICATE	30	PREPAREER				
15	08/04/14	15.20.00 – 15.24.34	S2	A4	CUT	BLEND	30	PREPAREER	0	1	1952	28.9
		15.24.34 – 15.26.43			COAG	DESSICATE	30	PREPAREER				
		15.26.43 – 15.34.59			CUT	BLEND	30	PREPAREER				
		15.35.00 – 15.47.50			CUT	BLEND	30	HAAKJE				
		15.47.50 – 15.56.59			COAG	DESSICATE	30	HAAKJE				
16	10/04/14	08.31.00 – 09.31.59	S2	A5	COAG	FULGURATE	30	PREPAREER	0	2	1930	33.7

SURGERY	DATE	TIME	SURGEON	ASSISTANT	CUT/COAG	MODE	SETTING (WATT)	INSTRUMENT	PERCENTAGE ASSISTANT	DIFFICULTY	AGE PATIENT	BMI PATIENT
17	10/04/14	10.18.00 – 10.25.59	S2	A5	COAG	FULGURATE	30	PREPAREER	90	1	1969	31.7
		10.26.00 – 10.44.59			COAG	FULGURATE	30	HAAKJE				
		10.45.00 – 10.56.59			COAG	FULGURATE	30	PREPAREER				
		10.57.00 – 11.15.59			COAG	FULGURATE	30	HAAKJE				
18	30/04/14	10.21.00 – 10.34.59	S3	A6	COAG	FULGURATE	30	PREPAREER	0	1	1945	39.8
		10.35.00 – 10.44.59			COAG	FULGURATE	30	HAAKJE				
		10.45.00 – 10.47.59			COAG	SPRAY	30	HAAKJE				
		10.47.59 – 10.49.59			COAG	SPRAY	30	PREPAREER				
19	30/04/14	11.39.00 – 12.05.00	S3	A6	COAG	SPRAY	30	HAAKJE	0	0	1950	25.5
20	30/04/14	12.37.00 – 12.56.59	S3	A6	COAG	SPRAY	30	PREPAREER	95	0	1952	26.0
		12.57.00 – 13.20.00			COAG	SPRAY	30	HAAKJE				
21	30/04/14	13.59.00 – 14.21.59	A4	A6	COAG	SPRAY	30	PREPAREER	0	0	1970	22.0
		14.22.00 – 14.24.59			COAG	SPRAY	30	HAAKJE				
		14.25.00 – 14.29.59			COAG	SPRAY	30	PREPAREER				
		14.30.00 – 14.53.00			COAG	SPRAY	30	HAAKJE				

SURGERY	DATE	TIME	SURGEON	ASSISTANT	CUT/COAG	MODE	SETTING (WATT)	INSTRUMENT	PERCENTAGE ASSISTANT	DIFFICULTY	AGE PATIENT	BMI PATIENT
22	30/04/14	15.25.00 – 15.44.59	A4	A6	COAG	SPRAY	30	PREPAREER	0	0	1992	36.9
		15.45.00 – 16.21.00			COAG	SPRAY	30	HAAKJE				
23	14/05/14	08.24.00 – 08.36.59	S1	A7	COAG	DESSICATE	30	HAAKJE	0	0	1959	24.9
		08.37.00 – 08.43.59			COAG	DESSICATE	35	HAAKJE				
24	14/05/14	09.13.00 – 09.19.59	S1	A7	COAG	DESSICATE	35	HAAKJE	0	1	1932	31.1
		09.20.00 – 09.21.59			COAG	DESSICATE	35	PREPAREER				
		09.22.00 – 09.23.59			COAG	DESSICATE	35	HAAKJE				
		09.24.00 – 09.26.59			COAG	SPRAY	35	HAAKJE				
		09.27.00 – 09.29.59			COAG	DESSICATE	35	HAAKJE				
		09.30.00 – 09.36.46			COAG	SPRAY	35	HAAKJE				
		09.36.46 – 09.47.59			COAG	SPRAY	80	HAAKJE				
25	14/05/14	10.15.00 – 10.24.59	S1	A7	COAG	SPRAY	35	HAAKJE	0	0	1981	39.0
		10.25.00 – 10.34.59			COAG	DESSICATE	35	HAAKJE				
		10.35.00 – 10.48.59			COAG	SPRAY	35	HAAKJE				

Data of 18 breast surgeries performed at Reinier de Graaf Gasthuis (Setting in Watt)

SURGERY	SURGICAL PROCEDURE	TIME	OPERATOR	CUT/COAG	MODE	SETTING (WATT)
01	ABLATIO	08.48 – 09.27	SA	CUT	PURE	35
				COAG	FULGURATE	35
02	ABLATIO	10.21 – 11.28	AB	CUT	BLEND	35
				COAG	FULGURATE	25
03	LUMP	14.04 – 14.46	SA	CUT	BLEND	45
				COAG	FULGURATE	45
04	GRM	15.33 – 16.42	SA	CUT	BLEND	35
				COAG	FULGURATE	35
05	LUMP	08.42 – 09.28	SG	CUT	BLEND	40
				COAG	SPRAY	40
06	LUMP	10.21 – 11.25	AB	CUT	BLEND	40
				COAG	FULGURATE (SN)	40
				COAG	SPRAY (LUMP)	40
07	LUMP	12.12 – 12.50	SG	CUT	BLEND	40
				COAG	FULGURATE (SN)	40
				COAG	SPRAY (LUMP)	40
08	ABLATIO	14.00 – 14.51	SG	CUT	BLEND	40
				COAG	FULGURATE (SN)	40
				COAG	SPRAY (ABLATIO)	40
09	TS ABLATIO	15.30 – 16.39	SG	CUT	BLEND	40
				COAG	SPRAY	40
10	FAD	08.24 – 08.48	AM	CUT	BLEND	35
				COAG	FULGURATE	35
11	ABLATIO BDZ	13.34 – 15.05	SA	CUT	BLEND	35
				COAG	FULGURATE	35

SURGERY	SURGICAL PROCEDURE	TIME	OPERATOR	CUT/COAG	MODE	SETTING [WATT]
12	LUMP	08.39 – 09.25	SA	CUT	PURE	35
				COAG	FULGURATE	35
13	ABLATIO	10.25 – 11.16	AH	CUT	PURE	35
				COAG	FULGURATE	35
14	ABLATIO BDZ	13.26 – 14.21	SG	CUT	PURE	40
				COAG	SPRAY	40
15	LUMP	11.36 – 12.15	SG	CUT	BLEND	40
				COAG	SPRAY	40
16	ABLATIO	13.30 – 14.28	SG	CUT	PURE	40
				COAG	SPRAY	40
17	ABLATIO	13.29 – 14.35	AO	CUT	BLEND	35
				COAG	FULGURATE	35
18	LUMP	08.45 – 09.44	SA	CUT	PURE	35
				COAG	FULGURATE	35

Data of several types of surgery performed at Leiden University Medical Center

SURGICAL PROCEDURE	DATE	DEVICE	SURGEON	MONOPOLAR/ BIPOLAR	CUT/COAG	MODE	SETTING (WATT)	EFFECT	INSTRUMENT	AGE PATIENT	GENDER PATIENT	POSTURE PATIENT
CONIZATION OF THE CERVIX	24/11/2014	ERBE VIO 300D	SL1	MONO	COAG				BULB		WOMAN	OVERWEIGHT
LAPAROSCOPIC REMOVAL OF ONE OVARY, REMOVAL CYST OTHER OVARY	24/11/2014	ERBE VIO 300D	SL1	BI	COAG				FORCEPS		WOMAN	NORMAL
REMOVAL VIN AND PLACEMENT IUD	01/12/2014	ERBE VIO 300D	SL1	MONO	CUT				NEEDLE		WOMAN	NORMAL
CONIZATION OF THE CERVIX	01/12/2014	ERBE VIO 300D	SL1	MONO	COAG				BULB		WOMAN	NORMAL
LAP. EXPLORATORY OPERATION	01/12/2014	ERBE VIO 300D	SL1	BI	COAG				FORCEPS	21	WOMAN	SLIM
LAPAROTOMY	15/12/2014	ERBE VIO 300D	SL1	MONO	CUT	DRY CUT	150	5	BLADE		WOMAN	NORMAL
				MONO	COAG				BLADE			
				BI	COAG	SOFT	50	4	FORCEPS			
CHECK ANAL FISTULA AND APPLICATION NEW SETONS	02/02/2015	VALLEYLAB FORCE TRIAD	SL2/SL3	MONO	CUT	STANDARD	25		BLADE	70	MAN	NORMAL/LARGE
				MONO	COAG	STANDARD	25		BLADE			
STOMA AND CHECK ANAL FISTULA AND SETONS	02/02/2015	VALLEYLAB FORCE TRIAD	SL2/SL3	MONO	CUT	PURE CUT	25		BLADE	58	WOMAN	NORMAL/LARGE
				MONO	COAG	FULGURATE	25		BLADE			
				BI	COAG	STANDARD	15	3	FORCEPS			
				MONO	CUT	PURE CUT	35		BLADE			
				MONO	COAG	FULGURATE	35		BLADE			
LAPAROSCOPIC RESECTION OF THE SIGMOID	02/02/2015	VALLEYLAB FORCE TRIAD	SL2	MONO	CUT	PURE CUT	35		NEEDLE	70	MAN	NORMAL/LARGE
				MONO	COAG	FULGURATE	35		NEEDLE			
REMOVAL CARTILAGE IN EAR	03/02/2015	ERBE VIO 300D	SL4	BI	COAG	SOFT	30	3	FORCEPS		WOMAN	
TONSILLECTOMY	03/02/2015	ERBE VIO 300D	SL4	BI	COAG	SOFT	25	4	TWEEZERS		MAN	NORMAL
PAROTIDECTOMY	03/02/2015	ERBE VIO 300D	SL5/SL6	BI	COAG	SOFT	40	4	TWEEZERS (CURVED)		WOMAN	NORMAL
PLACEMENT PLATE AND SCREWS, ANKLE FRACTURE	10/02/2015	ERBE VIO 300D	SL7/SL8	MONO	CUT	DRY	150	5	BLADE		MAN	
				MONO	COAG	FORCED	35	3	BLADE			
ZUGGURTUNG	10/02/2015	ERBE VIO 300D	SL7/SL8	MONO	CUT	DRY	150	5	BLADE		WOMAN	
				MONO	COAG	FORCED	35	5	BLADE			
HEAD-NECK PROSTHESIS FOR HIP	10/02/2015	ERBE VIO 300D	SL9/SL8	MONO	CUT	DRY	150	5	BLADE	97	WOMAN	SLIM

Analysis of surgical data Cholecystectomies RdGG

Remarkable is that during the 6th cholecystectomy the setting is increased from 30 to 35 Watt. For the 7th cholecystectomy this setting is not adjusted. This situation is repeated during the 23rd, 24th and 25th cholecystectomy. Both situations occur when S1 is the surgeon. He is the only surgeon that uses setting of 80 Watt. This can imply that the surgeons do not choose the setting according to the patient characteristics. The other operators are more consistent in their use of setting. This can also be seen with the mode. At the 30th of April the mode is set to spray in the first surgery of the day and the mode stays the same for all surgeries that day.

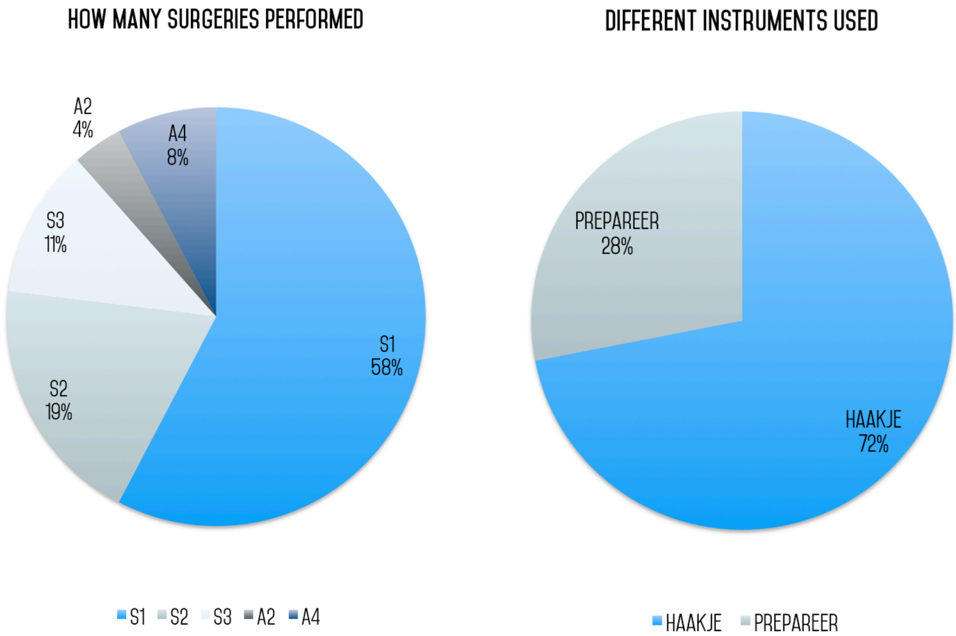


Figure 80. Left: Percentage of 25 cholecystectomies per surgeon, Right: How often each instrument is used during the 25 cholecystectomies

Analysis of surgical date Breast surgery RdGG

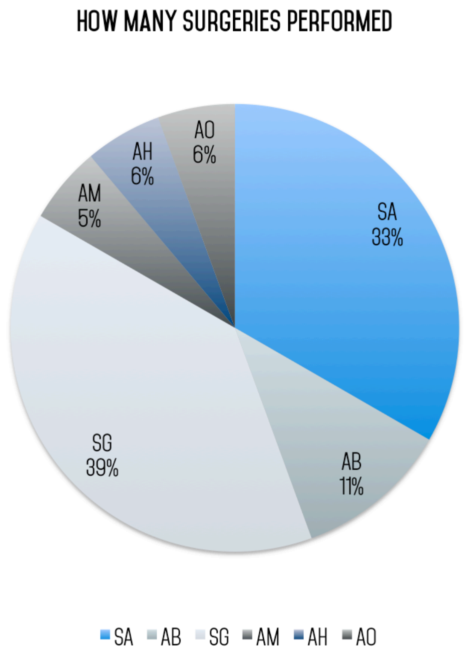


Figure 81. Percentage of the 18 breast surgeries performed by each surgeon

Typical Power Settings according to Valleylab[44]

POWER	SURGICAL PROCEDURE
LOW POWER < 30 WATTS	DERMATOLOGY LAPAROSCOPIC STERILIZATION (BOTH BIPOLAR AND MONOPOLAR NEUROSURGERY (BOTH BIPOLAR AND MONOPOLAR) ORAL SURGERY PLASTIC SURGERY VASECTOMIES
MEDIUM POWER CUT: 30-100 WATTS COAG: 30-70 WATTS	GENERAL SURGERY HEAD AND NECK SURGERY (ENT) LAPAROTOMY ORTHOPEDIC SURGERY (MAJOR) POLYPECTOMY THORACIC SURGERY (ROUTINE) VASCULAR SURGERY (MAJOR)
HIGH POWER CUT: >100 WATTS COAG: > 70 WATTS	ABLATIVE CANCER SURGERY, MASTECTOMIES, ETC (CUT 180-300 WATT; COAG 70-120 WATTS) THORACOTOMY (HEAVY FULGURATION, 70-120 WATTS) TRANSURETHRAL RESECTIONS (CUT 100-170 WATTS; COAG 70-120 WATTS, DEPENDING ON THE THICKNESS OF THE RESECTION LOOP AND THE TECHNIQUE

H Evaluation Design – Pilot Form

Marije Westra M.Westra@student.tudelft.nl

Vragenlijst Ontwerp Diathermie apparaat

Beste deelnemer,

Ik ben Marije Westra, master student Biomedical Engineering aan de TU Delft en werk momenteel aan mijn afstudeerproject over elektrochirurgie. Het doel van mijn project is het ontwerpen van een diathermie apparaat dat geschikt is voor gebruik in ontwikkelingslanden. Ik wil u verzoeken de onderstaande vragenlijst in te vullen en mij zo te helpen het ontwerp te evalueren. Voor vragen over dit onderzoek of mijn project kunt u me mailen op M.Westra@student.tudelft.nl .

Naam	fw jansen
Beroep	gynaecoloog
Specialisatie	idem
Aantal jaar ervaring in uw vakgebied	>25 jaar
Hoeveel operaties per week voert u uit?	4-6
Welke operatie(s) voert u het meeste uit?	laparoscopische
Hoeveel jaar werkt u al met het diathermie apparaat?	>25 jaar
Wanneer heeft u voor het laatst training ontvangen over het diathermie apparaat?	onbekend
Welk diathermie apparaat werkt u vaak mee?	1. Merk: erbe Type: 2. Merk: valleylab Type:

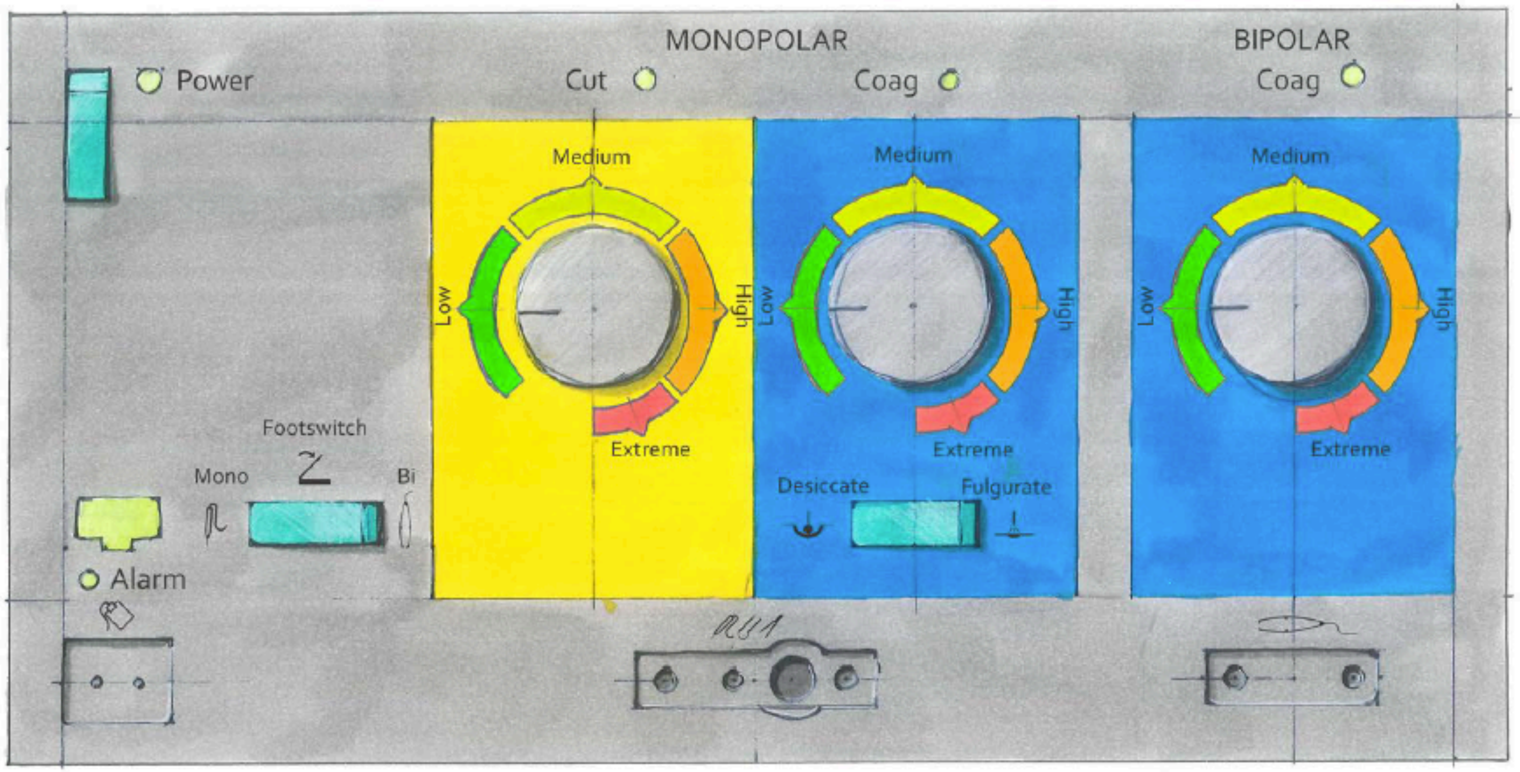
Op de volgende pagina (2) vind u het ontwerp. De bijbehorende vragen 1 t/m 11 zijn op pagina 3 t/m 5 te vinden.

1

Marije Westra

M.Westra@student.tudelft.nl

Ontwerp Diathermie apparaat



De vragenlijst gaat verder op de volgende pagina

Marije Westra M.Westra@student.tudelft.nl

1. Vindt u het ontwerp duidelijk? Waarom wel/niet?

ja

2. Vindt u het ontwerp geschikt voor de operaties die u vaak uitvoert? Waarom wel/niet?

nee
waar is de blend techniek?

3. Welke standen stelt u in bij operatie(s) die u veel uitvoert?

1. Operatie: hysteroscopie

Cut: Watt Coag: Watt Bipolar Coag: Watt

2. Operatie:

Cut: Watt Coag: Watt Bipolar Coag: Watt

3. Operatie:

Cut: Watt Coag: Watt Bipolar Coag: Watt

4. Welke waardes in Watt zou u voor de afgebeelde settings in het ontwerp geven?

Monopolar Cut			Monopolar Coag			Bipolar Coag		
Low:		Watt	Low:		Watt	Low:		Watt
Medium:		Watt	Medium:		Watt	Medium:		Watt
High:		Watt	High:		Watt	High:		Watt
Extreme:		Watt	Extreme:		Watt	Extreme:		Watt

5. Hoe tevreden bent u met de diathermie apparaten waar u nu mee werkt en waarom?

Zeer ontevreden ○ ○ ○ ○ ● ○ Zeer tevreden

De vragenlijst gaat verder op de volgende pagina

Marije Westra M.Westra@student.tudelft.nl

6. Hoe tevreden zou u zijn met de bediening van het diathermie apparaat zoals afgebeeld op pagina 2 en waarom?

Zeer ontevreden ○ ○ ○ ○ ◉ ○ Zeer tevreden

kleurtjes geven veoiligheid weer, maar niet de stand

7. Hoe beschouwt u het diathermie apparaat afgebeeld op pagina 2?

Niet veilig	○	○	○	◉	○	○	Veilig
Onbetrouwbaar	○	○	○	◉	○	○	Betrouwbaar
Niet intuitief	○	○	○	○	◉	○	Intuitief

8. Kunt u uitleggen waarom u de antwoorden bij vraag 7 zo heeft gekozen?

9. Denkt u dat het diathermie apparaat afgebeeld op pagina 2 geschikt is voor veel verschillende type operaties? Waarom wel/niet?

ja en nee
details
verschillende ingrepen vergen verschillende standen

De vragenlijst gaat verder op de volgende pagina

TU Delft Delft University of Technology

10. Zou u nog een andere instelling of functie toe willen voegen aan het ontwerp? Zo ja, welke en waarom?

11. Heeft u nog verdere opmerkingen over het ontwerp?

Hartelijk dank voor het invullen van deze vragenlijst! U kunt de ingevulde lijst opsturen naar:

M.Westra@student.tudelft.nl

I Evaluation Design – Form

(Dutch version)

Marije Westra M.Westra@student.tudelft.nl

Vragenlijst Ontwerp Diathermie apparaat

Beste deelnemer,

Ik ben Marije Westra, master student Biomedical Engineering aan de TU Delft en werk momenteel aan mijn afstudeerproject over elektrochirurgie. Het doel van mijn project is het ontwerpen van een diathermie apparaat dat geschikt is voor gebruik in ontwikkelingslanden. Ik wil u verzoeken de onderstaande vragenlijst in te vullen en mij zo te helpen het ontwerp te evalueren. Voor vragen over dit onderzoek of mijn project kunt u me mailen op M.Westra@student.tudelft.nl .

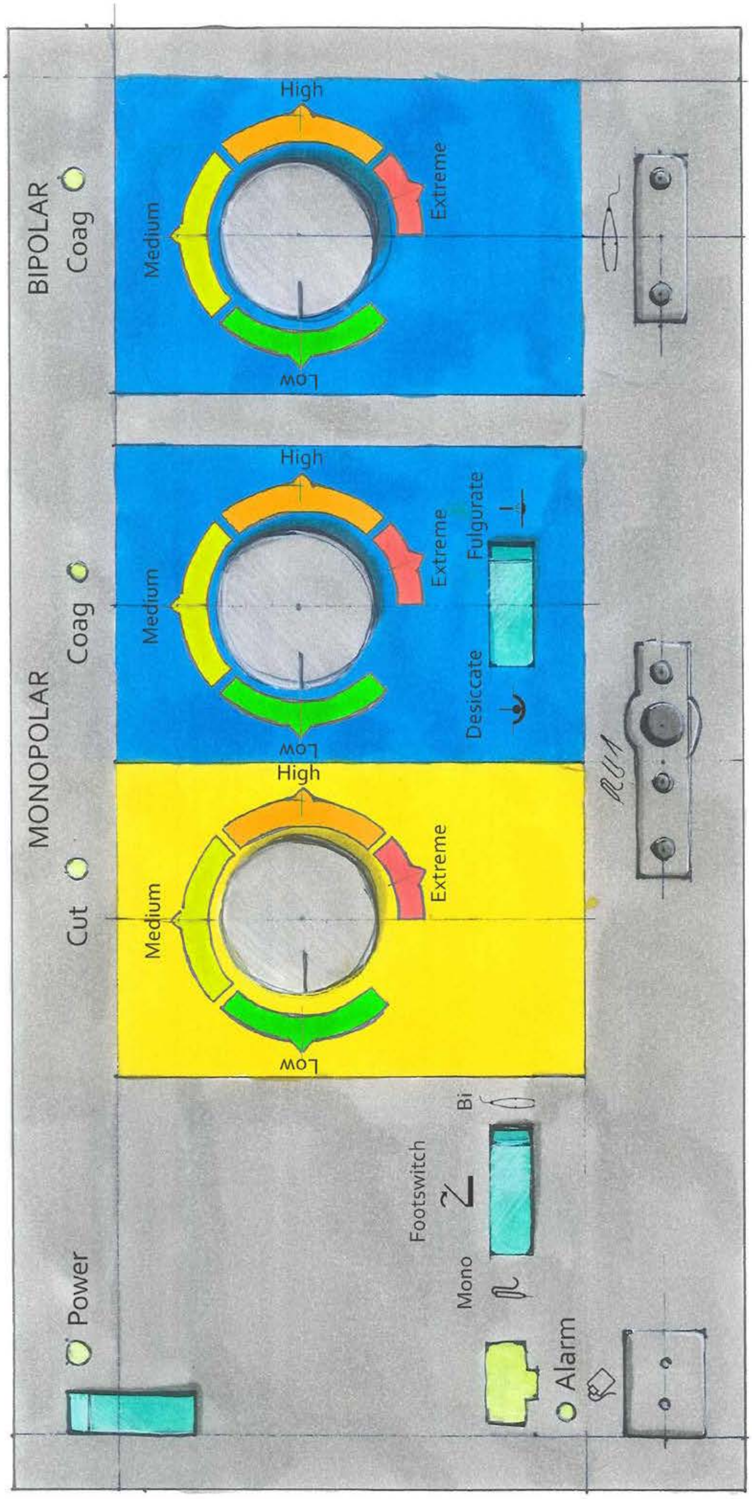
Naam	
Beroep	
Specialisatie	
Aantal jaar ervaring in uw vakgebied	
Hoeveel operaties per week voert u uit?	
Welke operatie(s) voert u het meeste uit?	
Hoeveel jaar werkt u al met het diathermie apparaat?	
Wanneer heeft u voor het laatst training ontvangen over het diathermie apparaat?	
Welk diathermie apparaat werkt u vaak mee?	1. Merk: Type: 2. Merk: Type:
Heeft u ervaring met werken in ontwikkelingslanden?	

Op de volgende pagina (2) vind u het ontwerp. De bijbehorende vragen 1 t/m 13 zijn op pagina 3 t/m 6 te vinden.

1

Marije Westra
M.Westra@student.tudelft.nl

Ontwerp Diathermie apparaat



De vragenlijst gaat verder op de volgende pagina

Marije Westra M.Westra@student.tudelft.nl

1. Vindt u het ontwerp duidelijk? Waarom wel/niet?

2. Vindt u het ontwerp geschikt voor de operaties die u vaak uitvoert? Waarom wel/niet?

3. Welke standen stelt u in bij operatie(s) die u veel uitvoert?

1. Operatie:

Cut: Watt Coag: Watt Bipolar Coag: Watt

2. Operatie:

Cut: Watt Coag: Watt Bipolar Coag: Watt

3. Operatie:

Cut: Watt Coag: Watt Bipolar Coag: Watt

☐ De waardes zijn bij u niet bekend

4. Welke waardes in Watt zou u voor de afgebeelde settings in het ontwerp geven?

Monopolar Cut		Monopolar Coag		Bipolar Coag	
Low:	Watt	Low:	Watt	Low:	Watt
Medium:	Watt	Medium:	Watt	Medium:	Watt
High:	Watt	High:	Watt	High:	Watt
Extreme:	Watt	Extreme:	Watt	Extreme:	Watt

☐ De waardes zijn bij u niet bekend

De vragenlijst gaat verder op de volgende pagina

TU Delft Delft University of Technology

Marije Westra M.Westra@student.tudelft.nl

5. Hoe tevreden bent u met de diathermie apparaten waar u nu mee werkt en waarom?

Zeer ontevreden ○ ○ ○ ○ ○ ○ Zeer tevreden

6. Hoe beschouwt u de diathermie apparaten waar u nu mee werkt?

Niet veilig	○	○	○	○	○	○	Veilig
Onbetrouwbaar	○	○	○	○	○	○	Betrouwbaar
Niet intuitief	○	○	○	○	○	○	Intuitief

7. Kunt u uitleggen waarom u de antwoorden bij vraag 6 zo heeft gekozen?

8. Hoe tevreden zou u zijn met de bediening van het diathermie apparaat zoals afgebeeld op pagina 2 en waarom?

Zeer ontevreden ○ ○ ○ ○ ○ ○ Zeer tevreden

De vragenlijst gaat verder op de volgende pagina

Marije Westra M.Westra@student.tudelft.nl

9. Hoe beschouwt u het diathermie apparaat afgebeeld op pagina 2?

Niet veilig	○	○	○	○	○	○	Veilig
Onbetrouwbaar	○	○	○	○	○	○	Betrouwbaar
Niet intuitief	○	○	○	○	○	○	Intuitief

10. Kunt u uitleggen waarom u de antwoorden bij vraag 9 zo heeft gekozen?

11. Denkt u dat het diathermie apparaat afgebeeld op pagina 2 geschikt is voor veel verschillende type operaties? Waarom wel/niet?

12. Zou u nog een andere instelling of functie toe willen voegen aan het ontwerp? Zo ja, welke en waarom?

De vragenlijst gaat verder op de volgende pagina

TU Delft Delft University of Technology

Marije Westra M.Westra@student.tudelft.nl

13. Heeft u nog verdere opmerkingen over het ontwerp?

Hartelijk dank voor het invullen van deze vragenlijst! U kunt de ingevulde lijst opsturen naar:

M.Westra@student.tudelft.nl

J Setting Data Questionnaire

Data provided by staff working at Reinier de Graaf Gasthuis

PARTICIPANT	TYPE OF SURGERY	CUTTING (WATT)	COAGULATION (WATT)	BIPOLAR COAG (WATT)
AIO1	SURGERY	30 - 35	30 - 35	30 - 35
S1	TUR – P	(CUT 6) 200	(COAG 2) 80	-
S1	TUR – B	(CUT 5) 200	(COAG 1) 60	-
S1	CIRCUMCISIE KIND	(CUT 2) 20	(COAG 1) 15	-
S2	TONSILLECTOMIE	20	25	-
S2	UPPP ("ANTISNURK")	25	25	-
S2	OOROPERATIE	20	20	-
A1	OPEN CHIRURGIE	35	35	20
A1	LAPAROSCOPISCH	30	30	20
A2	BUIK OK	35	35	
A2	GYN LAPAROSCOPIE	35	35	40
A3	BUIK OK	35	35	20
A3	GYN LAPAROSCOPIE	35	35	40
A4	-	35	35	-
A5	-	NB	NB	NB
A6	ASI	60	60	-
A6	THP/TKP	45	45	-
A6	LAPTOMIE/SCOPIC	35	35	20
A7	LAP DARM	(BLEND) 35	35	20
A7	LAPAROTOMIE	(PURE) 35	35	20
A7	KHP	35	35	20
A8	HERNIA	35	35	-
A8	STRUMA	30	30	25
A8	VAAT	35	35	-
A9	TOTALE HEUP PROTHESE	60	60	-
A9	TOTALE KNIE PROTHESE	45	45	-
A10	KNIE PROTHESE	45	45	-
A10	HEUP PROTHESE	60	60	-
A10	VOET CHIRURGIE	35	35	-
A11	DARM LAP.	35	35	20
A11	LAP CHOL	30	30	-
A12	LAPAROSCOPIE	30	30	-
A12	OPEN BUIK	35	35	40
A12	HEUP	45	45	
A13	MAMMA	25	25	15
A13	OOR	15	15	-
A13	TE	-	-	18

Table 13. AIO = Resident, S = Surgeon, A = OR Assistant, NB = Niet Bekend (Not known by participant)

K Comparison: Similar Surgeries, Different hospital

Data from Reinier de Graaf Gasthuis and from Leiden University Medical Center

	Monopolar cutting (Watt)		Monopolar coagulation (Watt)		Bipolar coagulation (Watt)	
Surgery	RdGG	LUMC	RdGG	LUMC	RdGG	LUMC
Tonsillectomy	20	-	25	-	-	25
Ear surgery	20	-	20	-	-	30
Ear surgery	15	-	15	-	-	-
Laparotomy	35	150	35	-	20	50
Hip prosthetic	60	150	60	35	-	-
Hip prosthetic	45	-	45	-	-	-
Foot surgery	35	150	35	35	-	-
Colon laparoscopy	35	35	35	35	20	15

L Settings Recommended by the Participants Questionnaire

Suggestions for settings LOW

PARTICIPANT	MONO CUTTING (WATT)	MONO COAG (WATT)	BIPOLAR COAG (WATT)
AIO1	1 -15	1 -15	1 -15
S1	-	-	-
S2	5	5	5
A1	15	15	10
A2	0 – 30	0 – 30	0 – 15
A3	0 – 30	0 – 30	0 – 20
A4	-	-	-
A5	NB	NB	NB
A6	15	15	10
A7	10 – 15	0 – 15	0 – 15
A8	25	25	15
A9	0 – 30	0 – 30	-
A10	20	20	20
A11	20	20	-
A12	25	25	20
A13	10	10	10

Table 14. AIO = Resident, S = Surgeon, A = OR Assistant, NB = Niet bekend (Not known by participant)

Suggestions for settings MEDIUM

PARTICIPANT	MONO CUTTING (WATT)	MONO COAG (WATT)	BIPOLAR COAG (WATT)
AIO1	15 – 35	15 – 35	15 – 35
S1	-	-	-
S2	15	15	15
A1	35	35	20
A2	30 – 40	30 – 40	15 – 30
A3	30 – 40	30 – 40	20 – 30
A4	-	-	-
A5	NB	NB	NB
A6	30	30	20
A7	20 – 40	20 – 40	20 – 35
A8	35	35	25
A9	35 – 40	35 – 45	-
A10	35	35	35
A11	35	35	-
A12	35	35	20
A13	15	15	15

Table 15. AIO = Resident, S = Surgeon, A = OR Assistant, NB = Niet bekend (Not known by participant)

Suggestions for settings HIGH

PARTICIPANT	MONO CUTTING (WATT)	MONO COAG (WATT)	BIPOLAR COAG (WATT)
AIO1	35 - 45	35 - 45	35 - 45
S1	-	-	-
S2	25	25	25
A1	75	75	30
A2	40 - 50	40 - 50	30 - 50
A3	40 - 50	40 - 50	30 - 40
A4	-	-	-
A5	NB	NB	NB
A6	45	45	30
A7	45 - 60	45 - 60	40 - 60
A8	45	45	30
A9	40 - 60	40 - 60	-
A10	60	60	60
A11	45	45	-
A12	45	45	60
A13	25	25	18

Table 16. AIO = Resident, S = Surgeon, A = OR Assistant, NB = Niet bekend (Not known by participant)

Suggestions for settings EXTREME

PARTICIPANT	MONO CUTTING (WATT)	MONO COAG (WATT)	BIPOLAR COAG (WATT)
AIO1	> 45	> 45	> 45
S1	-	-	-
S2	-	-	-
A1	100	100	40
A2	> 50	> 50	> 50
A3	> 50	> 50	> 40
A4	-	-	-
A5	NB	NB	NB
A6	60	60	40
A7	65 - 100	65 - 100	65 - 100
A8	60	60	35
A9	> 60	> 60	-
A10	80	80	80
A11	60	60	-
A12	60	60	
A13	40	40	25

Table 17. AIO = Resident, S = Surgeon, A = OR Assistant, NB = Niet Bekend (Not known by participant)

M Background Information Participants Questionnaire

PARTICIPANT	SPECIALISATIE	AANTAL JAAR ERVARING VAK	AANTAL OPERATIES PER WEEK	MEEST UITGEVOERDE OPERATIES	AANTAL JAAR ERVARING ESU	LAATST ONTVANGEN TRAINING ESU	TYPE ESU	ERVARING ONTWIKKELINGSLAND
AIO1	CHIRURGIE	2	± 10	VERSCHILT PER DAG	5	1 ½ JAAR GELEDEN	?	JA
S1	UROLOGIE	2 AGNIO 6 OPLEIDING 2 KLAAR	± 10	TUR – P & TUR – BLAAS CIRCUMCISIE ENDO STEENBEHANDELING	10	± 6 JAAR GELEDEN	ERBE 300D VALLEYLAB	NEE
S2	KNO	12	± 10	TONSILLECTOMIE "ANTISNURK OPERATIE" UPPP OOROPERATIE	12	NIET	"DIE VAN HET ZIEKENHUIS"	NEE
A1	GASTRO-ENTEROLOGIE	25	20	BUIKOPERATIES OPEN & LAPAROSCOPISCH	25	1 JAAR GELEDEN	VALLEYLAB FORCE TRIAD & FORCE FX	JA (MAAR WESTERSE SPULLEN)
A2	UROLOGIE	20	± 15	UROLOGISCHE INGREPEN BV. TUR-P	20	± 1 JAAR GELEDEN	VALLEYLAB ERBE	NEE
A3	-	25	3 DAGEN	WISSELEND WERK	25	± 1 JAAR GELEDEN	VALLEYLAB	NEE
A4	TRAUMA	23	20	VAN ALLES	23	1 JAAR GELEDEN	VALLEYLAB	JA (GHANA)
A5	CHIRURGIE	20	± 20	DIVERSEN	20	-	VALLEYLAB	NEE
A6	ORTHOPEDIE	± 20	5 – 10	THP/TKP	± 20	2014	VALLEYLAB FORCE TRIAD & FORCE FX	NEE
A7	GE – CHIRURGIE	13	± 15/20	GE – CHIRURGIE BV. LAPDARMEN	13	½ JAAR GELEDEN DMV E-LEARNING	VALLEYLAB FORCE TRIAD & FORCE FX	NEE
A8	VAATCHIRURGIE	12	± 20	HERNIA'S	12	2014	VALLEYLAB FORCE	NEE
A9	ORTHOPEDIE	14	16	HEUP EN KNIEPROTHESES PLAATSEN	14	VORIG JAAR	VALLEYLAB FORCE TRIAD & FORCE FX	NEE
A10	ORTHOPEDIE	6	± 16	KNIE EN HEUPPROTHESES	6	1 JAAR GELEDEN	VALLEYLAB FORCE TRIAD & FORCE FX	NEE
A11	GE	15	± 10	DARM	20	2014	VALLEYLAB FORCE TRIAD	NEE
A12	CHIRURGIE	7	10 - 15	DARMOPERATIES	7	2014	VALLEYLAB FORCE TRIAD	NEE
A13	KNO	17	-	OOROPERATIES	17	2000 PRAKTIJK 2014 E-LEARNING	VALLEYLAB FORCE TRIAD	NEE