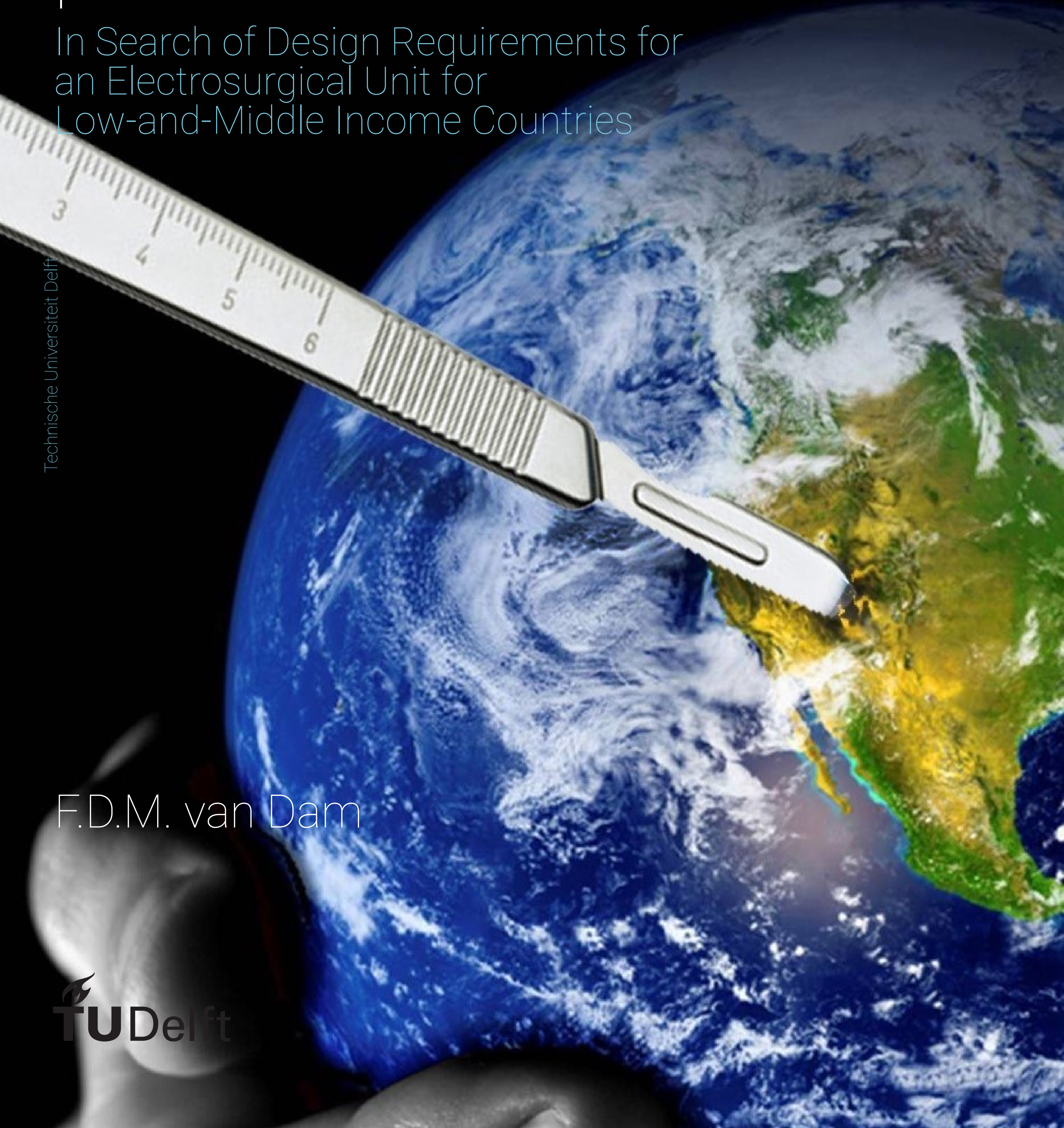
# Designing a test set-up to measure electrosurgical parameters

## In Search of Design Requirements for an Electrosurgical Unit for Low-and-Middle Income Countries



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# Designing a test set-up to measure electrosurgical parameters

## In Search of Design Requirements for an Electrosurgical Unit for Low-and-Middle Income Countries

by

F.D.M. van Dam

to obtain the degree of Master of Science
at the Delft University of Technology,
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*This thesis is confidential and cannot be made public until December 18th, 2023.*



TU Delft

# Summary

Safe surgical and anesthetic care is not available to 5 billion people worldwide. Many problems that are encountered when providing surgical care are related to surgical equipment. A lot of surgical equipment is designed for the use in High Income Countries (HICs) and not specifically for Low-and-Middle Income countries (LMICs). One appliance, used in every operation room worldwide, is an electrosurgical unit (ESU). Electrosurgery is the use of a high-frequency (HF) alternating current (AC) to raise tissue temperature, making it possible to cut and coagulate this tissue. There is a large variety of ESUs available to HICs, but these do not meet the requirements for safe and proper use in LMICs. The Biomedical Engineering department at the TU Delft is currently working on a project to create an ESU for LMICs. This thesis aims to compose a list of requirements for this ESU, design a protocol and test set-up to measure electrosurgical parameters and perform an experiment to measure these electrosurgical parameters.

During the development of the list of requirements, there was a lack in the knowledge about the thermal effects of electrosurgery was found. In order to be able to fill this gap, a testing set-up was created as well as a protocol to perform measurements on electrosurgical units. Throughout the process of designing this set-up different obstacles were found which had to be overcome. These obstacles consisted of the influence of light on thermal camera measurements, the influence of a smoke extractor on thermal measurements in general, measuring simultaneously or separately with a thermal camera and a thermocouple and measuring inside the tofu or on top of the tofu with the thermocouples. Experiments provided data which concluded that light had an effect on the measurements, using the FLIR E75 camera. Therefore these experiments should be performed in the dark. Furthermore, it was found that a smoke extractor affected the surface temperature during measurements, so the smoke extractor should not be used. Other external influences did not seem to influence the measurements drastically.

Taking these factors into account, a testing set-up and protocol are created. This set-up is used to perform experiments comparing two ESUs and comparing different power settings of the ESUs. The result of these experiments show that for the Valleylab Force Fx, higher powers created higher temperatures (starting at 60 Watts). For the ERBE ICC 300 there is no significant difference in maximum temperatures per power settings. There is a large difference between the maximum temperatures of the Valleylab and the ERBE. This is probably because the Valleylab uses a power controlled system and the ERBE uses a voltage controlled system.

In conclusion, the set-up and prototype were validated and can be used to measure electrosurgical parameters. This information can guide us into making further decisions in the design requirements for the new ESU.

# Acknowledgements

This thesis could not have become what it is without the people around me. I would like to thank my supervisor Roos Oosting for encouraging me through this project and helping me to keep believing in the bigger picture. Our meetings guided me through this project and provided me with new energy to continue every time. I would also like to thank Jenny Dankelman for the helpful critique and ideas to complete this project and help met through the obstacles which occured. Additionally a huge thanks to Arjan van Dijke, who helped me with such a large part of my experimental set-up and was always ready to answer my questions.

I also would like to thank the "zomer thesis Pluks" for their support and helping me keep up the spirit during the summer. Also thanks to all my other friends who patiently listened to all my talk about this thesis.

And lastly I would like to thank my family, who have supported me throughout my entire studies and helped me through the tough moments and celebrated the good ones. Dad, thanks for all the sparring sessions and the explanations, I think I finally understand many of the things we discussed and that is mainly thanks to you.

# Contents

# List of Abbreviations

| | |
|---|---|
| AC | Alternating Current |
| COSECSA | College of Surgeons of East, Central and Southern Africa |
| ERBE | ERBE ICC 300 |
| ESU | Electrosurgical Unit |
| FUSE | Fundamental use of Surgical Energy |
| HICs | High Income countries |
| LMICs | Low-and-Middle Income Countries |
| RDE | RDE Electrocut 100 |
| RF | Radio-Frequency |
| Valleylab | Valleylab Force FX |

# 1

# Introduction

In today's world, not every individual has the same healthcare opportunities. This is largely dependent on the place you live. Every individual should be able to receive basic medical treatment, regardless of the country they live in. To improve this situation, this thesis focuses on designing a test set-up to measure electrosurgical parameters in Low-and-Middle Income Countries [1] (LMICs).

Countries that are affected most by deaths due to surgical conditions are LMICs [2]. If surgical conditions in these countries are improved, the global burden of disease could be greatly decreased [3]. Shrime et al. (2015) conclude in their survey that 30% of all deaths worldwide consist of surgical conditions. And Meara et al. (2015) state that access to safe surgical and anesthetic care is not available to 5 billion people worldwide [4]. While there has been a large focus on infectious diseases in LMICs. Up until now, the number of deaths due to infectious diseases is lower than that of deaths due to conditions needing surgical care [5]. This indicates that the focus needs to be more on surgical care and equipment.

One considerable obstacle in hospitals in LMICs is the shortage of working equipment. A survey conducted in Africa demonstrated that 20% of the surgeries in district and referral hospitals are canceled due to malfunctioning equipment [6]. The most common reason for this was the lack of maintenance and the use of old and overused equipment [6]. Currently, many surgical devices are designed solely for High Income Countries (HICs), not taking into account that they are also used in LMICs [7]. The devices from HICs are donated to LMICs where they are not used, due to the lack of knowledge on the use and the maintenance of the devices [8]. This could be overcome by redesigning specific surgical appliances which are easier to maintain [6]. One appliance, which is used in nearly all surgeries worldwide is an Electrosurgical Unit (ESU) [9].

Electrosurgery is "the use of radiofrequency (RF) alternating current (AC) to raise the intracellular temperature in order to achieve vaporization or the combination of desiccation and protein coagulation"[10]. An electrosurgical unit consists of a generator which produces a cutting or a coagulation waveform. This is applied to a patient by a scalpel which is connected to the generator. In the case of monopolar electrosurgery, a return plate is necessary so that the current can run through a completed circuit [10]. More detailed information on the basics of electrosurgery is provided in Chapter 2. Unfortunately, there is not a lot of knowledge about the specific effects of electrosurgery [11]. In surgery, the settings for use of this device are passed down from teacher to student. But the differences between settings are not necessarily known to the surgeons [12]. Knowledge about the settings of electrosurgery and their effects are of great importance for clinicians as well as for the design of a new ESU.

Due to the vast amount of electrosurgical units available in HICs, designing a new unit for LMICs might seem unnecessary. However, these devices for HICs do not comply with the needs of LMICs. The devices used

[1] "low-income economies are defined as those with a GNI per capita of $1,005 or less in 2016; lower-middle-income economies are those with a GNI per capita between $1,006 and $3,955; upper-middle-income economies are those with a GNI per capita between $3,956 and $12,235; high-income economies are those with a GNI per capita of $12,236 or more"[1]

in HICs have many unnecessary settings, are complicated to use, are not robust and are difficult to repair [13]. There is an ESU on the market which is designed for LMICs by Recherche Développement Electronique. Unfortunately, this device does not have a CE marking and does not provide the same outputs and settings as surgeons are used to. In addition, this device does not comply with many of the needs of the user, as indicated by surgeons in LMICs [13].

Because of the absence of proper electrosurgical units suitable for LMICs on the market, the Department of Biomedical Engineering at the TU Delft is currently working on designing an ESU specifically for LMICs. This thesis is part of this project. The aim of this thesis is divided into three categories:

1. Providing a list of design requirements
2. Designing a protocol and test set-up to measure electrosurgical parameters
3. A validation of the test set-up and protocol by performing experiments. With these experiments the question "What is the difference in thermal effects between different electrosurgical cutting settings and different electrosurgical units during cutting?" is answered.

In the next chapter of this thesis, the working principles of an ESU are described. Further requirements for a new ESU are elaborated on in Chapter 3. From this list of requirements, several gaps in the knowledge on electrosurgery come to light, specifically on the effect of different settings on an ESU. To establish the effect of different settings a testing set-up and a protocol are developed and described in Chapter 4. This protocol and testing set-up is used for experiments to gain more insight into different power settings and comparing two ESUs. In Chapter 5 the results of these experiments are documented in the form of a paper. This paper can be read as a separate document. In Chapter 6 the results are discussed and recommendations for future research are made. Finally, the conclusions of this thesis are described in chapter 7.

# 2
# Background

In this chapter, general information on electrosurgery is discussed. The basic settings, additional components and the different ESUs available at the TU Delft are introduced below.

Electrosurgery uses "radio frequency (RF) alternating current (AC) to raise the intracellular temperature in order to achieve vaporization or the combination of desiccation and protein coagulation"[10]. An electrosurgical unit (ESU) has two main settings; cutting and coagulation. Many high-end devices have more settings. In this thesis, these two main settings will be discussed as these settings are used most often [13]. Cutting and coagulation can be performed with either the monopolar or the bipolar method. For the monopolar method a return electrode is necessary.

## 2.1. Cutting

In the cutting mode of the electrosurgical generator, the tissue is heated rapidly up to a boiling point. When this occurs, the cells are vaporized through which a cutting process occurs[14], this is illustrated in figure 2.1. Using high currents causes heat which is focused in one place to create a clean cut with little thermal damage through a higher current density. This higher current density is not possible with any other waveform. The power of the alternating waveform is higher than other waveforms with the same voltages [15]. The sinusoidal waveform produces a higher average power and a higher current density. The temperature causes intracellular fluid to vaporize and thus causes the cell membrane to rupture [16]. At a temperature of 100°C or higher, focused cellular vaporization occurs and a plasma cloud of steam, ions, and organic matter is created [10].

## 2.2. Coagulation

During coagulation, the temperature of the tissue is between 60-95°C. At this temperature cellular proteins are altered but not destroyed (protein coagulation and dehydration or desiccation occurs) this is illustrated in figure 2.1. This also happens if the temperature is kept at 50°C for 6 minutes or longer [10], which also occurs when an egg is boiled. In coagulation the pulses of the current are short, in this way the tissue is able to cool down between bursts and the heat can spread over a larger area [14]. The high voltages produce high temperatures in the tissue creating a lot of thermal impact [15]. Because the sine waves are produced in pulses, there is less heat generated, but this is done at high peak voltages. Because less heat is generated, the cells are disrupted due to evaporation of intracellular fluid, causing protein denaturation[16]. The duty cycle is usually 6%. This entails that instead of 100% during cutting, there is a pulse of only 6% of the time, as shown in figure 2.2.

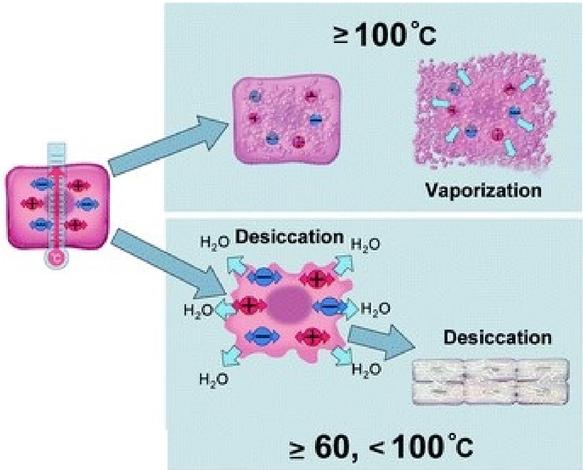



Figure 2.1: Tissue effects at different temperatures [10]

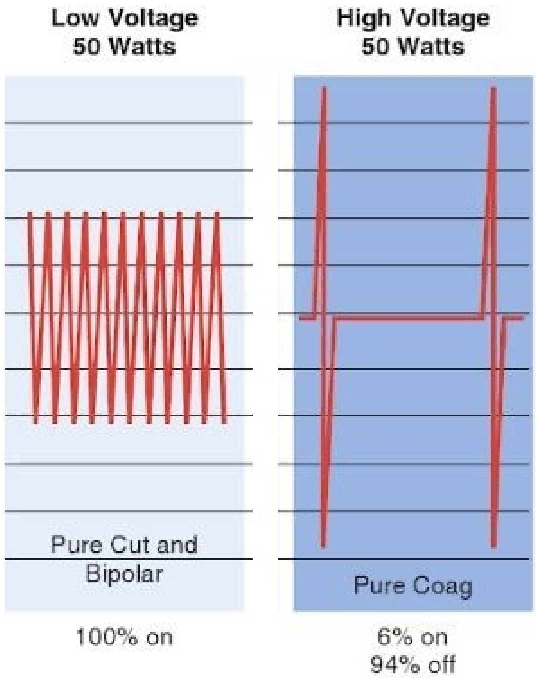



Figure 2.2: Different waveforms for Cutting, and coagulation [10]

## 2.3. Monopolar and bipolar

In electrosurgery, there are two kinds of methods to heat the tissue, monopolar and bipolar [10][17]. For monopolar surgery, the current runs through the entire patient, whereas in bipolar surgery the current only runs through the tissue between the two electrode tips of the instrument [10]. In monopolar surgery, there is one active electrode (scalpel) and a dispersive electrode attached to the patient. The current is concentrated in the active electrode and disperses to the dispersive electrode as shown in figure 2.3. In bipolar instruments, the current runs between the two electrodes at the tip of the instrument [10].

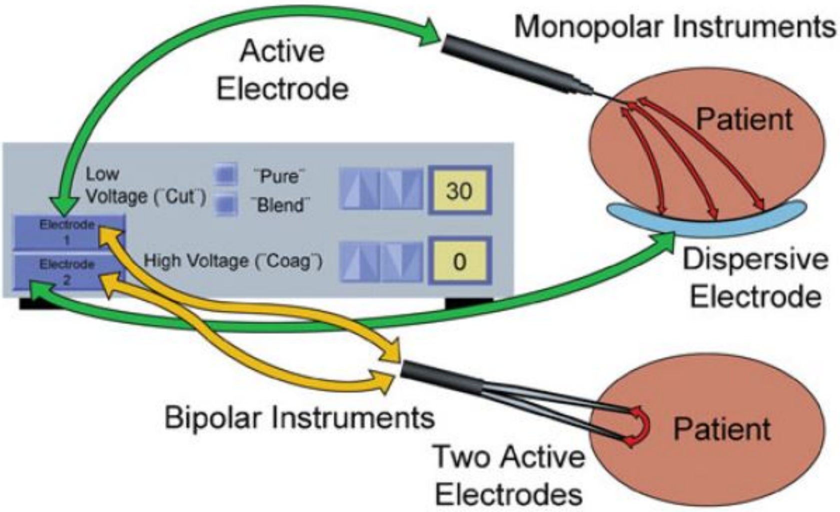



Figure 2.3: The difference between monopolar and bipolar [10]

## 2.4. Return electrode

The return electrode is necessary to perform monopolar surgery [10]. The scalpel is the active electrode and the current returns through the return (dispersive) electrode. In HICs, single-use split electrodes are used. This entails that two dispersive electrodes are placed next to each other on the patient, but not in contact with one another. A picture of a split electrode can be found in figure 2.4. This split electrode consists of an extra safety feature. If there is a difference in measured impedance between the two split electrodes due to for instance partial detachment, the machine will stop working [10]. Unfortunately, these split electrodes are not reusable. Of course, a return plate consisting of one dispersive electrode can also be used, but this is not without risks. A single dispersive electrode can cause capacitive coupling. What this means is that a stray current can cause burns to the patient, because the return electrode is not properly attached [18]. These burns can occur because the pathway with the least capacitive resistance to the ground is usually taken [15]. If the ground plate is not attached properly or fully this could result in the current flowing through another path, not to the dispersive electrode. These safety hazards are eliminated when a split electrode is used.

Figure 2.4: Split return electrode [19]

## 2.5. Different types of electrosurgical units

At the Delft University of Technology (DUT) there were three devices at our disposal. Two high-end devices, the Valleylab Force FX and ERBE ICC 300, and one low-end device, the RDE Electrocut 100. The Valleylab Force FX and the ERBE ICC 300, shown in Figure 5.1, are devices which contain many different settings. In addition to cutting and coagulation, it is also possible to have a combination of these two settings, called blend. Both devices also have a REM system which is later described in appendix B. The RDE Electrocut 100 is a simplified device with only the basic settings of electrosurgery. To find the differences in set-up the components of this device are analyzed.


Figure 2.5: Top: ERBE ICC 300, Bottom: Valeylab Force FX

## 2.6. Set-up of the RDE

The RDE Electrocut 100 from the company Recherche Développement Electronique (RDE) is also created for use in LMICs. However, this device is not CE marked. In order to find what aspects of the current electrosurgery units need to be integrated in the current one, the basics of the existing ESUs need to be found. This is why it was very interesting to find what components are used in this electrosurgical unit. In collaboration with Arjan van Dijke, Technician at the MISIT lab at the TU Delft, the components were taken apart and analyzed. The Electrocut 100 consists of many of the shelf products. Unfortunately, it was not possible to find exactly how all components connected to one another. To do this, it was necessary to completely take it apart and find out how the circuit boards worked and because the RDE still had to be used this was not an option. In figure 2.6 the components of the RDE are highlighted. One remarkable difference between this device and high-end devices was that the waveforms for coagulation and cutting are very similar [20]. This is confirmed by examining the components. There is one transformer which divides its output into two. One of these outputs flows into the part of the circuit where the coagulation and cutting waveforms are created, while the other part is used for the interface of the ESU. How the waveforms are created exactly is not clear. Nonetheless, it is speculated that a waveform is created and that a filter is placed over this waveform to create the other waveform. For the cutting and coagulation signals in the new ESU to be different signals, the set-up as shown in figure 2.6 is too simplified. However, it is possible to use similar off the shelf components.

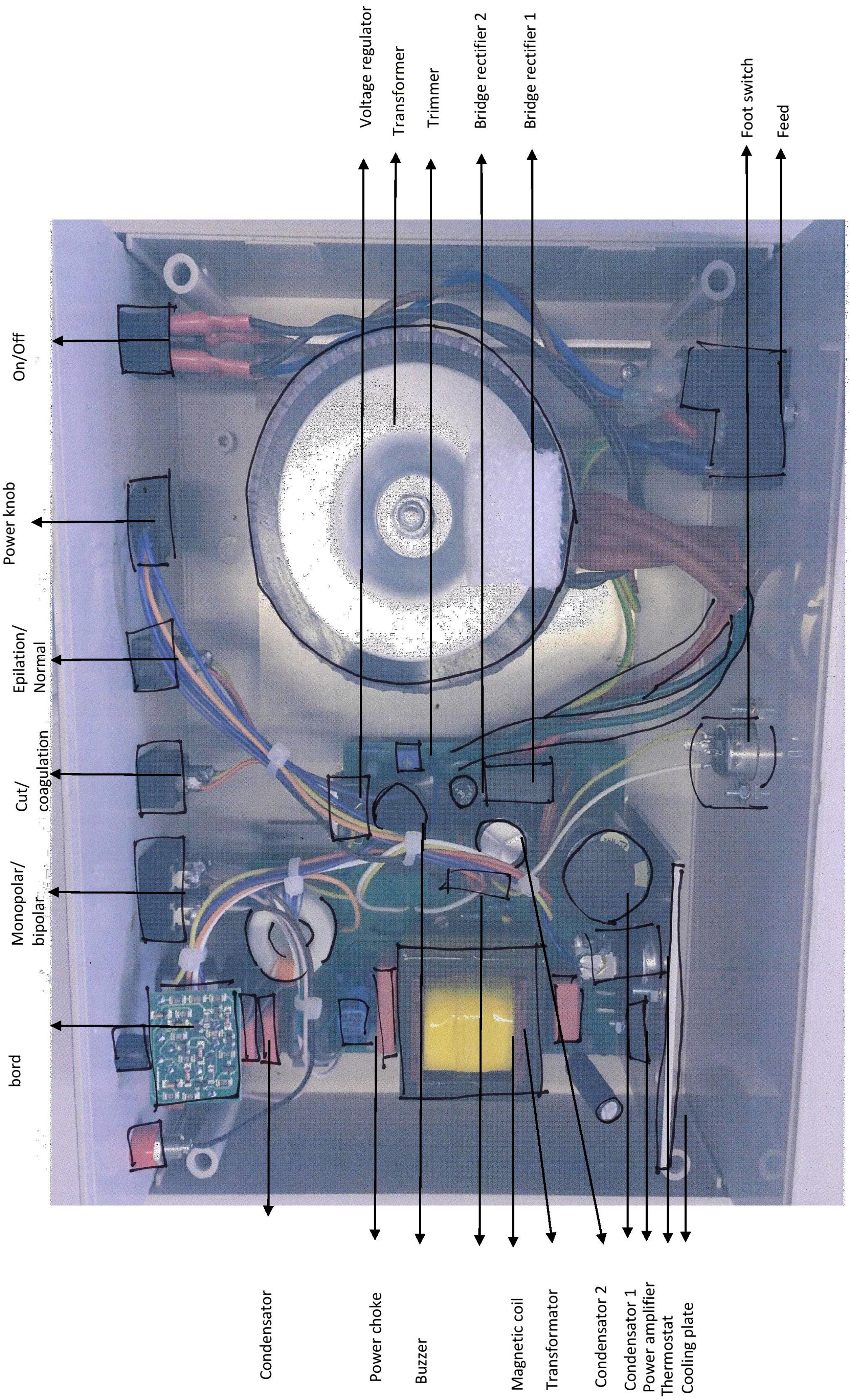



Figure 2.6: Set-up of parts of the RDE

# 3
# Redesign of the ESU

## 3.1. Introduction

In order to design a new ESU for the use in Low-and-Middle Income settings, it is important to construct a list of requirements. In this chapter the different design criteria are summarized, a method for quantification is shown and the priorities of the criteria are allocated.
In the paper "Design requirement of surgical equipment to enhance safe surgery in Low-and-Middle Income Countries: case studies of electrosurgical devices and laparoscopic equipment" by Oosting et al. (2018) [13] some of the design requirements for the ESU came forward. In this paper, questions from the survey conducted at the Annual meeting of COSECSA [1] in Mozambique was filled in by 35 surgeons from different origins. The requirements which were found to be of great importance to the surgeons are that medical equipment is sterilizable by steam, that it is repairable by local technicians and that it is robust. Specific for the ESU the requirements found are that there should be an alarm when the ground plate is not properly attached, the electrodes should be reusable and the ESU should be portable.

In another survey which was conducted in Kenya, surgeons found design requirements which took the settings in LMICs into consideration, such as the high temperatures of the environment and humidity important [6]. Combining these design requirements and those of the paper by Oosting et al. (2018) a basis was made for the general requirements. Also from the recommendations of the thesis of Felix Cranz (2018) [20] some requirements were obtained. These requirements consist of the more technical side of the ESU. The design requirements are classified into four categories as listed below.

1. Safe
2. User-friendly
3. Robust
4. For LMICs

Within these categories, there are different criteria which have to be met. A method to quantify these criteria is given as well as the priority of the criteria. This priority has 3 scales, 1 is must have, this option is not negotiable. 2 is nice to have, meaning that it is of great added value. 3 is a wish for the product, this means that it does not have any priority but if it fits into the concept it would be nice. In table 3.1 the list of requirements can be found.

[1] College of Surgeons of East, Central and Southern Africa

### 3.1.1. List of requirements

Table 3.1: List of requirements for new ESU

| **Category** | **Criteria** | **Quantification** | **Priority (1-3)**<br>**1: must**<br>**2: nice to have**<br>**3: wish** |
|---|---|---|---|
| **Safe** | Linear power settings | Voltage | 1 |
| | Power control system | * | 1 |
| | Sufficient power settings | High enough to perform all surgeries[1] | 1 |
| | Reusable split electrode | * | 1 |
| | Alarm when ground plate not properly attached | * | 1 |
| | Sufficient frequency settings | Frequency[1] | 1 |
| | Max leakage | Voltage | 1 |
| | Compliant with ISO | * | 1 |
| | Alarm if malfunctioning | * | 1 |
| | Varying Frequency settings | * | 3 |
| **User-friendly** | Bi polar and monopolar | | 1 |
| | Sterilizable (by steam) | * | 1 |
| | Same connection as Valleylab + ERBE | * | 1 |
| | Reusability | Number of single-use parts | 2 |
| | Spare parts (local) | Amount of spare parts locally available | 2 |
| | Easily repairable/taken apart | Time | 2 |
| | Intuitive | Training time | 2 |
| | Easy to clean | Cleaning time per use | 2 |
| | | Additional cleaning time | 2 |
| | Portable | Weight | 2 |
| | | Compact | 2 |
| | Quick set up | Time to set up | 3 |
| **Robust** | 220V | Voltage fluctuation | 1 |
| | Battery | Safety | 1 |
| | | Time (lifetime) | 2 |
| | | Recharge time | 2 |
| | | Indicator | 2 |
| | Mechanical impact | IP 3rd number | 2 |
| | Dust | IP 1st number | 2 |
| | Exchangeable cables | Components of general mechanics in cable | 2 |
| **For LMICs** | Low cost | Price | 1 |
| | Function at high temp | Temperature | 1 |
| | Stabilizer | Voltage range | 2 |
| | Easy to maintain | Maintenance time | 2 |
| | | Availability of spare parts | 1 |

* Cannot be quantified, is either Yes or No
[1] To be determined

The rationale behind the choices for the design requirements can be found in Appendix A. One very important design requirement consisted of a reusable split electrode. Further suggestions on how this could be designed can be found in Appendix B.

## 3.2. Discussion & Conclusion

There are many requirements which have to be incorporated into the design of the new ESU. Unfortunately, some of the design requirements could not be quantified because there was not enough information available to make educated decisions. The design requirements in which this was the case were the power settings and the frequency settings. In order to gain more insight into what these settings should entail, a testing set-up and protocol was developed. With this set-up and protocol it should be possible to find information to complete the design criteria for the new ESU. How this protocol and set-up was developed is discussed in chapter 4.

# 4
# Development of protocol

## 4.1. Introduction

In the previous chapter, which discusses the design requirements for a new ESU, a gap in literature about the effect of different settings is found. With an electrosurgical scalpel, a high-frequency current is applied to the tissue. Due to this current, the tissue heats up and has the desired effect for the surgeon: the coagulation or cutting of tissue. A combination of different settings results in a specific reaction on the tissue. The only settings a surgeon can change on an ESU are the mode and the power. The mode necessary for a surgery is known to the surgeon, but there is less knowledge about the power settings and their effects on tissue. Knowing how much power is necessary to achieve the goal of the surgeon is important information for the design.

Several studies have investigated the thermal effects of similar devices [21][22][23][24]. Unfortunately, these studies do not clearly indicate their methods nor the obstacles they encountered.

The goal of this chapter is to provide a clear protocol which can be used by any researcher to perform experiments with ESUs. Within this chapter, the particular choices that can be made in designing this experimental set-up are tested and discussed.

Thermal measurements can be performed by many different devices. The two devices used in this study are thermocouples and a thermal camera [1]. Both of these thermal measuring methods are influenced by their surroundings, for instance by light, air flow, surrounding temperature, positioning, shadow effects, wavelength dependence of emissivity, wind speed and thermal reflection [25]. Some of these factors are believed to affect this measurement set-up. After careful consideration of the surroundings, experiments consisting of the following factors will be performed:

1. Using a smoke extractor
2. Measuring simultaneously and separately with the thermal camera and thermocouples[2]
3. The location of the measurement
4. The presence of light

Several external influences are expected to have an effect on both measurement techniques (1,2,3) while other external influences are only expected to affect the thermal camera measurements (4).

Besides these 3 experiments, due to the generosity of Dirk Faber from Acal BFi Netherlands BV, it was possible to perform 3 measurements with a FLIR X6901sc thermal camera. This camera is very fast and sensitive due to the fact that it is cooled, making it possible to capture events with a frequency of 1000Hz [26]. This camera is very expensive and it was very special that it was possible to use it for a few experiments. As discussed before, with the camera available at the TU Delft, many external effects have to be taken into account. This is not the case with the FLIR X6901sc camera because it works with photon sensors[27].

[1] The thermocouples which are used are type T thermocouples and the thermal camera is the FLIR E75 camera
[2] To find whether there is interference

Therefore, aspects such as reflection, distance to object and effects from outside the visual zone are not a problem according to Dirk Faber (personal communication, October 10th, 2018, Acal BFi Netherlands BV).

In addition to gaining insight into different external effects on measurements, the thermal effects created by an electrosurgical unit were analyzed. Guided by this information, choices regarding the final protocol could be made.

## 4.2. Methods

Five different experiments have been performed to find the influence of external effects. For the first four experiments, the Valleylab Force FX electrosurgical unit was used. The scalpel was turned on for 2.5 seconds [11] and the total measurement time was 8-10 seconds. All test specimens consisted of tofu of $1cm^3$ at room temperature. Tofu was chosen due to its similarities with human tissue and because it is prohibited to work with human or animal tissue at the TU Delft. The resistance of tofu lies between the resistances of skin (255-424 Ohm-cm), muscle (135-216 Ohm-cm) and fat (3046-4868 Ohm-cm) [28]. How this resistance is measured can be found in Appendix C.

All measurements were performed 5 times, with the exception of the smoke extractor measurements, which were performed 10 times. This was because with 5 measurements only a small increase was found. With more measurements, the factor that the mean temperature differed would become clearer. More measurements were performed to further investigate this difference.

For each experiment, unless discussed differently below, the smoke extractor was turned on, the thermocouples were placed 1mm into the tofu [3], the scalpel was placed 1mm into the tofu and the measurements were performed in the dark at a setting of 40W.

In Figure 4.1, the placement of the thermocouples and scalpel into the tofu is shown in the thermal camera images.

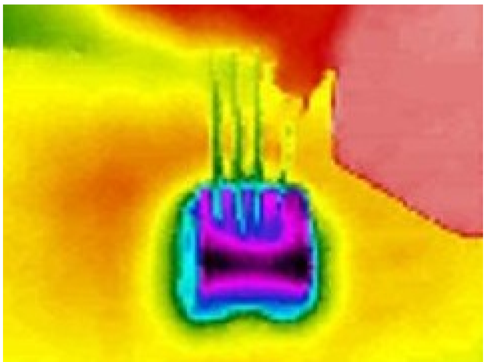


Figure 4.1: Tofu with placement of thermocouples and scalpel made with the thermal camera

For each experiment the different variables were:

1. turning the smoke extractor on and off
2. measuring simultaneously or separately
3. thermocouples placed on top or 1mm into the tofu
4. light turned on or in the dark
5. 20W, 30W or 40W settings with the FLIR X6901sc camera

For all measurements with the thermal camera, the data were filtered with a Low-pass Butterworth filter with a cut-off frequency of 0.5 Hz[4]. Statistical analysis, using a two-sided t-test and a Mann-Whitney U test, was performed with SPSS Statistics 25 (iBM, North Castle, NY, USA) and MS Excel 2016. The data analysis and

[3] This was performed by the researcher consistently

[4] The reasoning behind this is explained in the Discussion of this Chapter

visualisation is performed with Matlab Release 2015b, The MathWorks, Inc., Natick, Massachusetts, United States.

The measurement set-up used a thermal camera (FLIR E75) which was connected to a laptop, the results were analyzed in the research IR software. The thermocouples were connected to the MGC plus, which collected all the thermocouple data, this data was analyzed by Catman Easy software on the connected laptop. Furthermore, the ESU was connected to the ground plate and the scalpel was plugged into the ESU. The ESU was turned on by an instrument timing box, more information about this can be found in Appendix F. A schematic sketch of the measurement set-up is shown in Figure 4.2.

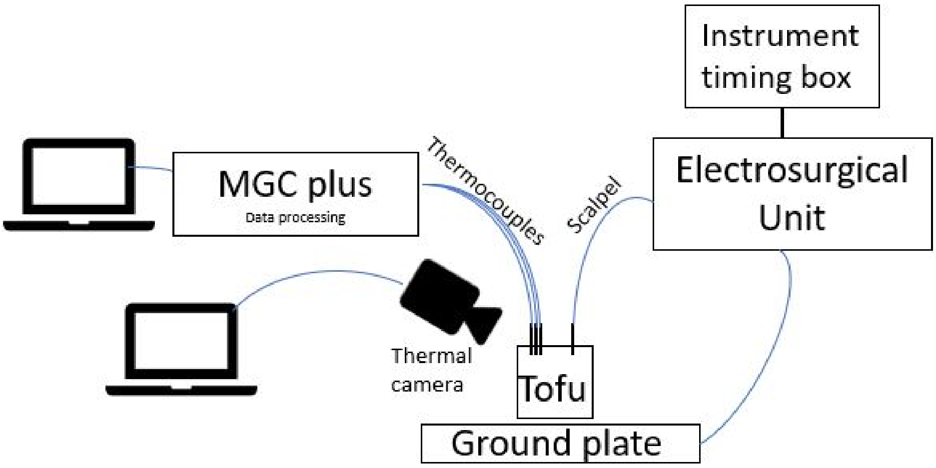



Figure 4.2: Measurement set-up

For the measurements with the FLIR X6901sc camera, the scalpel was turned on for 2.5 seconds and the smoke extractor was turned on. These measurements were not performed in the dark because these measurements were not influenced by reflection. The set-up is shown in Figure 4.3.


Figure 4.3: FLIR X6901sc camera

## 4.3. Results

The results of the experiments described in the methods are displayed in this section. For every experiment, the maximum reached temperature at a point 2mm from the scalpel are shown.

All measurements were performed with a smoke extractor, at 40W, 2mm from the scalpel, in the dark, with thermocouples placed 1mm into the tofu, the thermal camera measurements and thermocouple measurements were performed simultaneously and the scalpel was turned on for 2.5 seconds.

For all experiments, the results of the maximum temperatures are portrayed in boxplots, comparing the thermocouples (left plot) and the thermal camera (right plot). All tests are substantiated with statistical tests. Because the data of the thermal camera without a smoke extractor and the data with a thermocouple measuring separately are not normally distributed [5] these comparisons are performed with a Mann-Whitney U test. The other comparisons are performed with a one- or two-sided t-test.

Nearly all comparisons resulted in a $p>0.05$. Thus showing there is no significant difference in mean between the thermal camera and thermocouples for all the measurements [29]. There was a difference in the thermocouple measurements and the thermal camera when they were measured apart. This can be explained by the difference in positioning and one high outlier.

[5] Kolmogorov-Smirnov tests for normality showed that data of the thermal camera measurement without smoke extractor and Thermocouples measuring separately were not normally distributed

### 4.3.1. Thermocouple and thermal camera experiments

In the following section, the maximum reached temperatures per measurement of the 5 previously discussed experiments are portrayed in boxplots. These boxplots will be explained and more information on the data will be provided.

*Experiment 1*

The boxplots in Figure 4.4 show the differences between measuring with and without a smoke extractor. The boxplots visualize that the median decreases for both the thermocouple, from 43°C to 35°C, and the thermal camera, from 38°C to 33°C, when the smoke extractor is turned on. By performing an unpaired one-sided t-test on the data between the thermocouples, and a Mann-Whitney U test between the data of the thermal camera, a difference between the data sets is found. The results of a one-sided, paired t-test between the thermocouples are $t(18)=-2.12$, $p=0.024 < 0.05$, and the results of the Mann-Whitney test is $U=16$, $n1=n2=10$, $p<0.05$.

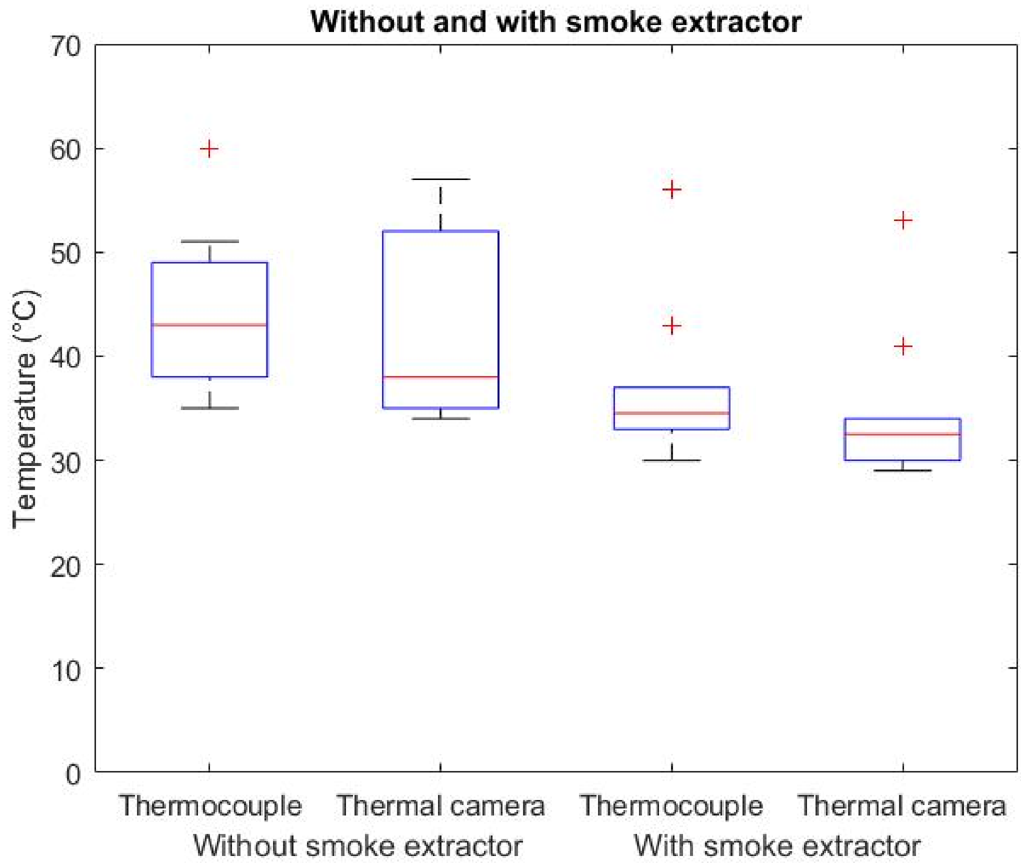



Figure 4.4: **Box plot of smoke extractor on and off.** The median of all the maximum temperatures regarding measurements with a smoke extractor are higher than measurements without the smoke extractor. This is for both the thermocouples and the thermal camera.

*Experiment 2*
The boxplots in Figure 4.5 show only a slight difference between the measurements performed simultaneously or separate. The difference between the median of the thermocouples (simultaneous= 39°C, separate = 37°C) , and the median of the thermal camera (simultaneous= 36°C, separate = 34°C) is only 2°C. To evaluate the means of the thermal camera a two-sided, unpaired, t-test was performed resulting in t(6)=-.056, p=0.0.59. To compare the data sets of the thermocouples, a Mann-Whitney U test was performed. This resulted in U=11.5, n1=n2=5, p>0.05. This shows that there is no significant difference between the two data sets.

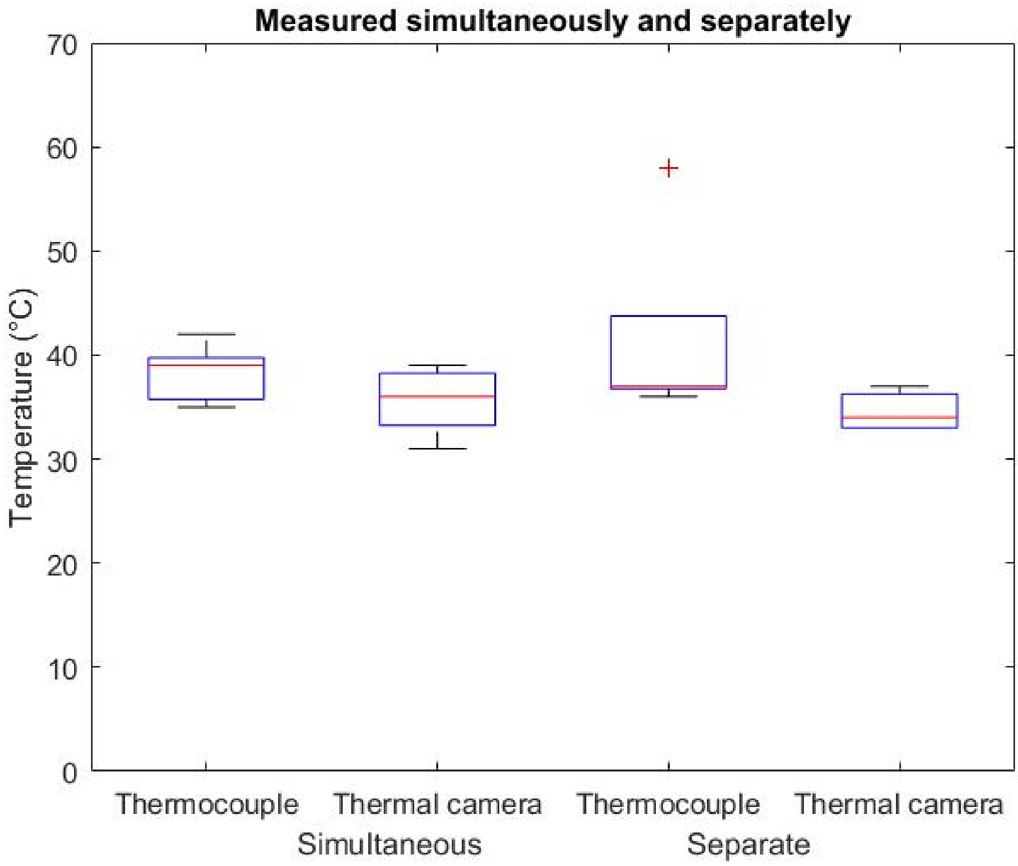



Figure 4.5: **Measuring simultaneously and separate with thermal camera and thermocouples.** Conducting measurements with the thermocouples at the same time as conducting measurements with the thermal camera could result in interference between the measurements. This data shows that the medians of the maximum temperatures measured lie very close to each other, both for the thermocouples as for the thermal camera.

*Experiment 3*

The boxplots for the measurements inside and on top of tofu are displayed in Figure 4.6 below. The difference between the median of the thermocouples (1mm inside= 39°C, top = 37°C) , and the median of the thermal camera (1mm inside= 39°C, top = 37°C) is 0°C. The range of the measured maximum temperatures is larger for the measurements on top of tofu than for the measurements 1mm inside the tofu. The mean of the maximum temperatures measured by placing the thermocouples on top of the tofu and into the tofu have a mean difference of 2.1 °C. The mean±standard deviation for the thermocouples was 38.3 ±2.7°C for simultaneous and 40.4 ±4.9°C for separate measurements. For the measurements with the thermal camera was 35.5 ±3.3°C for simultaneous and 37.2 ±6.1°C for separate measurements. The range in which measurements fall is larger for the measurements done on top of the tofu. After performing a two-sided, unpaired t-test to compare the thermal camera $t(6) = -0.55$, $p=0.60$ and the thermocouples, $t(6)=-0.86$, $p=0.42$, the null hypothesis was not rejected, in other words, there is no significant difference between measuring 1mm inside the tofu or on top of tofu.

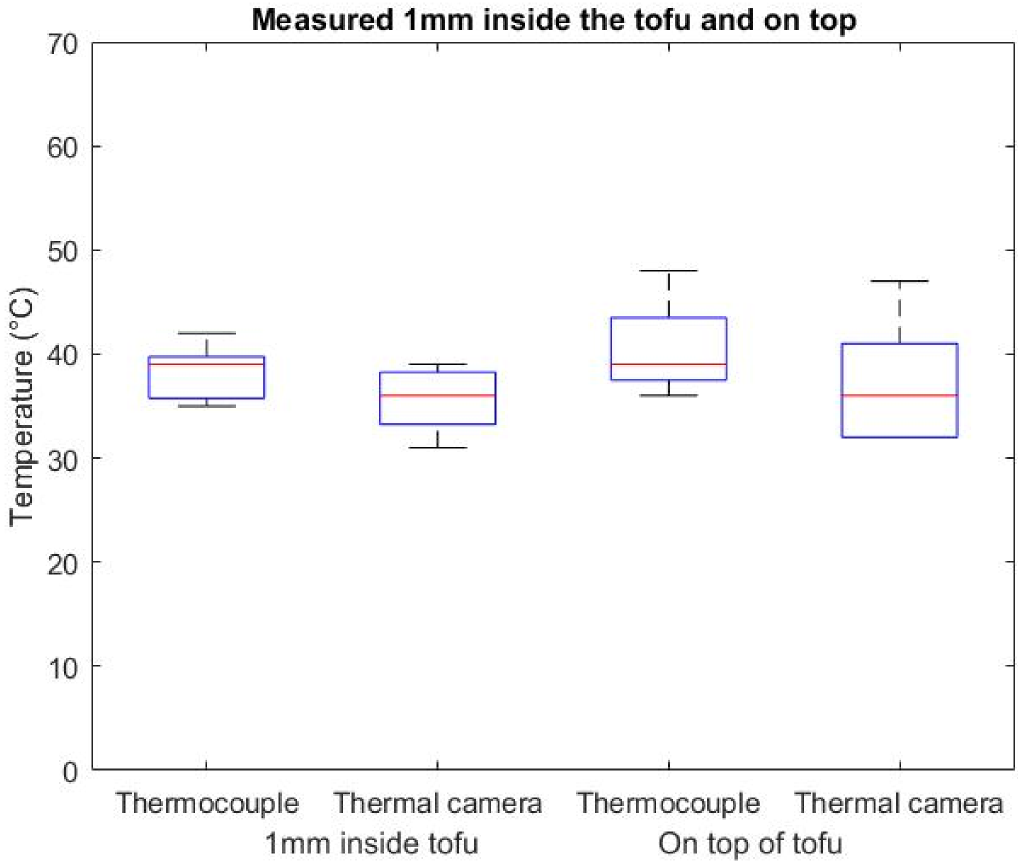



Figure 4.6: **Thermocouple measurements inside and on top of tofu.** Measurements with the thermocouples placed on top of the tissue show a larger spread in data points. The median of the thermocouples measuring simultaneous or separately and the thermal camera data measuring simultaneous or separately is the same.

*Experiment 4*
In Figure 4.7 the maximum measured temperatures of the experiment performed with natural light and with natural light blocked out from the set-up are shown. The boxplots portraying measurements in the dark show a smaller range than measurements performed in natural light. The median of the thermal camera is also higher (45°C) than that of the thermocouple (43°C). When looking at the mean ±standard deviation, it is found that for the thermocouple this increases from 38.3 ±2.7°C to 48.9 ±11.2°C. And for the thermal camera measurements this only increases from 35.5 ±3.3°C to 43.8 ±8.3°C. When comparing the thermal camera measurements to the thermocouple measurements there is a mean difference of 5.1 °C. For the measurements done in the dark, this difference is only 2.8 °C. A one-sided t-test was performed and resulted between the thermal camera temperatures, resulting in $t(5)=-2.05$, $p=0.048$ showing the results have a difference. The thermocouples do not show this significant difference as their corresponding t-test results show $t(4)=-2.05$, $p=0.055$.

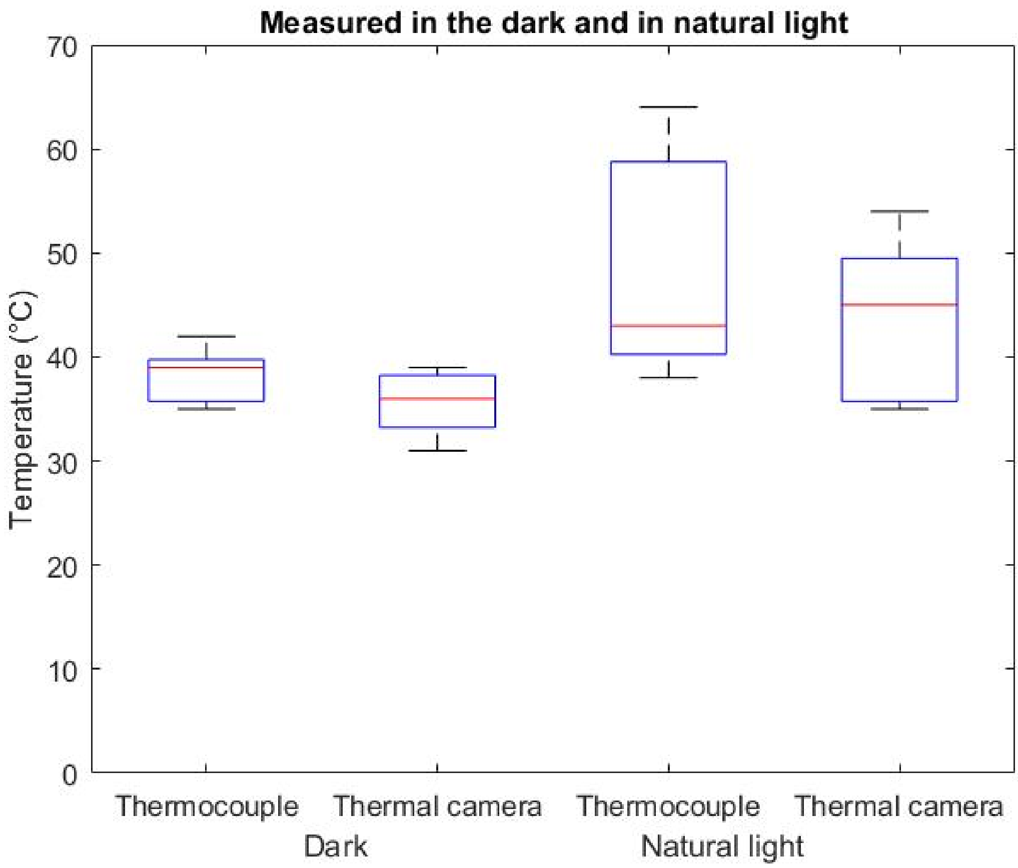



Figure 4.7: **Dark vs natural light.** For the measurements where the light was turned on and natural light was not blocked, the median for both the thermocouple measurements and the thermal camera is higher than when this light is blocked out. The range of the measurements also increases with light being let into the set-up.

For a summary of the above-discussed results see Table 4.3.1.

| | | Thermocouple | Thermal camera |
|---|---|---|---|
| | Difference | p value | p value |
| Experiment 1 | Yes | 0.01 | 0.024 |
| Experiment 2 | No | 0.59 | 0.51 |
| Experiment 3 | No | 0.42 | 0.60 |
| Experiment 4 | Yes* | 0.055 | 0.048 |

Table 4.1: Summary of results
* Only a difference for thermal camera measurements

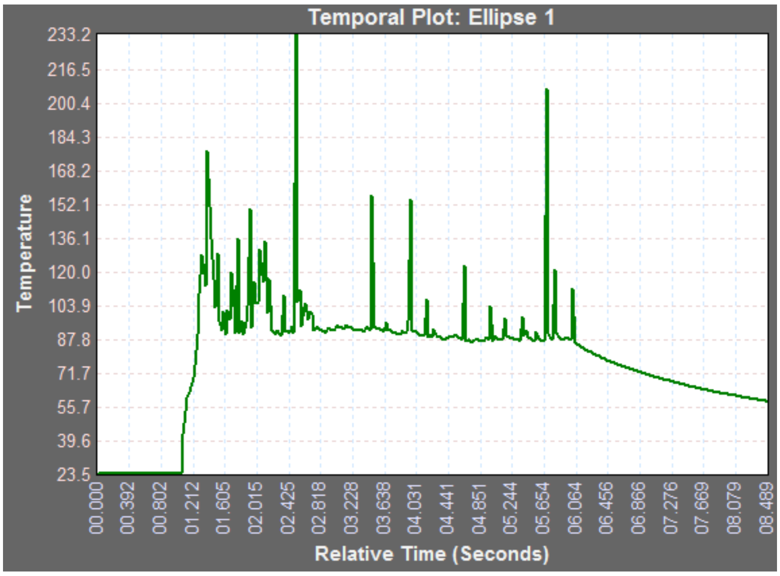
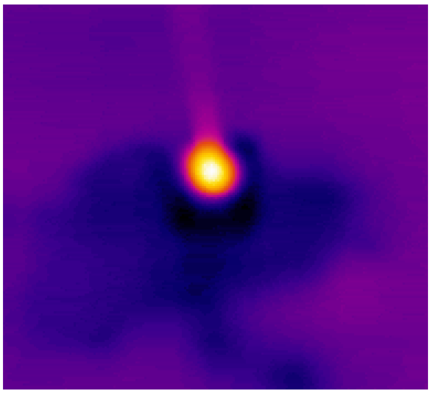



Figure 4.8: Graph of FLIR X6901sc camera with sparks

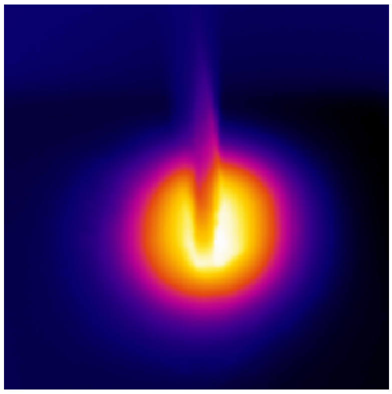
*Experiment 5*

The measurement data obtained by the FLIR X6901sc camera is too large to export to a computer and process in MATLAB 2015b, The MathWorks, Inc., Natick, Massachusetts, United States. However it is possible to plot figures within the Research IR software. In Figure 4.8 a plot of the maximum temperature within the thermal affected area is shown.

In addition to this thermal effect, the scalpel and tofu could be distinguished clearly from one another on the thermal images of the FLIR X6901sc camera. The difference in the images is shown in Figure 4.9.



(a) FLIR E75 Camera)



(b) FLIR X6901sc camera

Figure 4.9: Images made with different camera's

The images with the FLIR X6901sc camera made it possible to analyze the temperatures of the scalpel and the tissue just beside the scalpel. At the point of maximum impact, the maximum temperatures of the scalpel and the point just beneath the scalpel on the tofu have been measured. This is performed for all of the measurements with this camera.

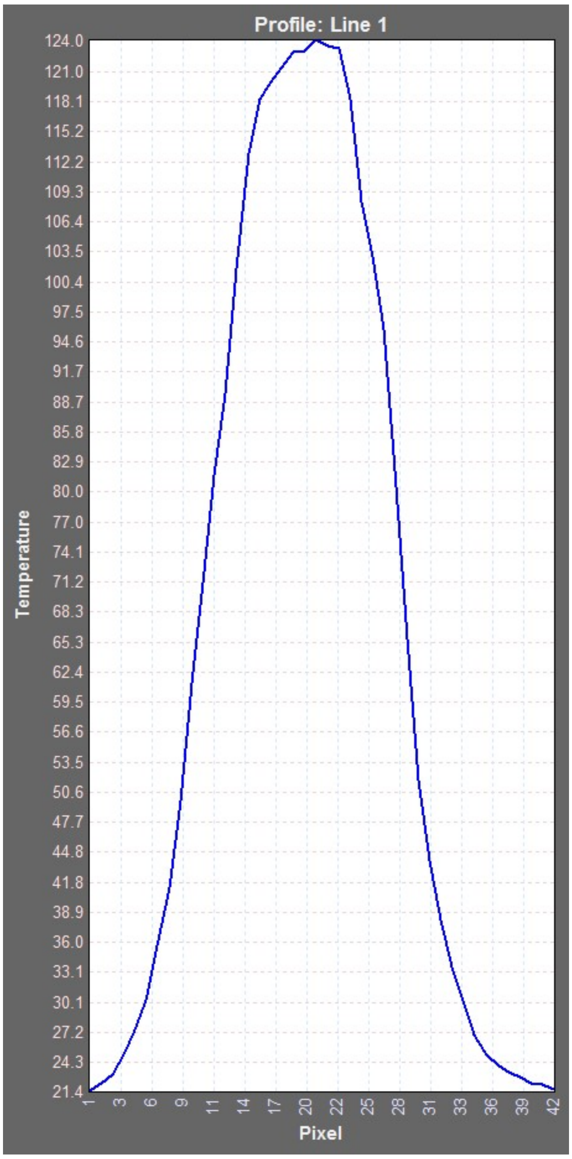
| | **Scalpel** | **Tofu, next to scalpel** |
|---|---|---|
| **20 Watt** | 90.9°C | 104.9°C |
| **30 Watt** | 71.4°C | 101°C |
| **40 Watt** | 92.9°C | 135.4°C |

Table 4.2: Maximum temperature of scalpel and just beside the scalpel

### 4.3.2. Temperature effects

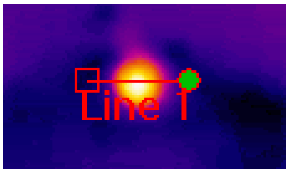
Besides finding external effects which influenced the measurements, more insight was also created into the electrosurgical effects during the performance of these experiments. The most interesting findings are discussed in this part of the results.

The temperature curve found around the scalpel is parabolic. At the point just next to the scalpel, the temperature is the highest, moving off to the sides the temperature decreases as shown in Figure 4.10a below. This profile plot was obtained by placing a line through the thermal measurement as shown in Figure 4.10b in the Research IR software.




(a)

Temperature curve in a line just next to the scalpel at 100W




(b) line in thermal camera software

Figure 4.10: Profile plot of line at maximum temperature with FLIR E75 camera

The rapid temperature increase per pixel can also be seen from this picture. The FLIR E75 thermal camera, measures temperatures at 320x240 pixels. The difference per pixel also became evident when comparing pixels from different measurements to one another. In Figure 4.11 the difference in temperature of measuring one pixel to the right is demonstrated.

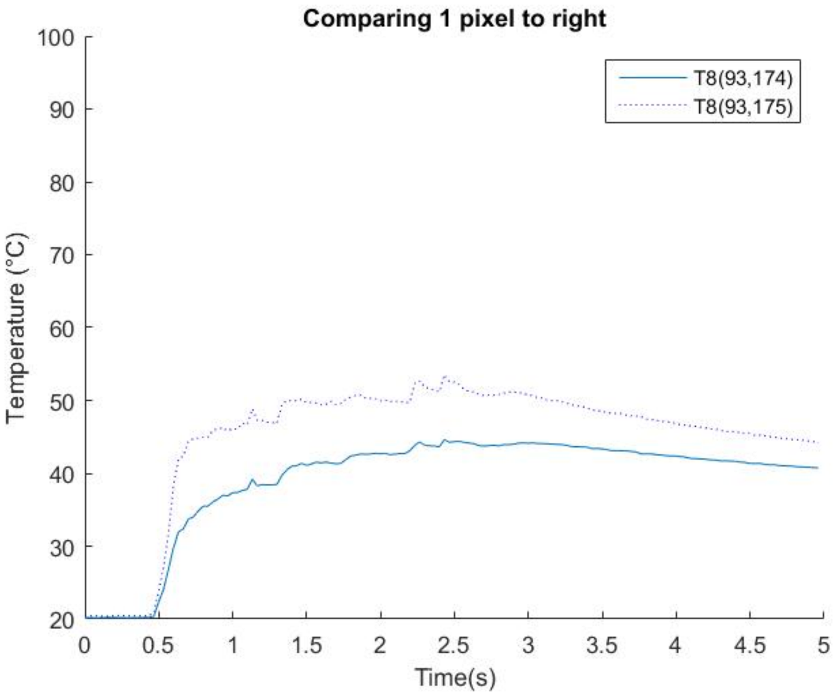



Figure 4.11: Temperature 1 pixel difference

### 4.3.3. Temperature spread

Thermal measurements performed at 4mm and 6mm, two of the three thermocouples, were found to not be very high. In an experiment with 5 measurements for 20Watts, 30Watts and 40 Watts the maximum temperature at 4mm found was 43.4 °C. At 6mm from the scalpel the maximum temperature found was 25.3 °C.

From the experiments, there was a difference for measurement in the light and with a smoke extractor. Measurements performed separately and on top of the tofu did not seem to have a difference in the mean. Additionally, information from the FLIR X6901sc camera provided information on what exactly the thermal camera finds and where the thermal effect takes place. Moreover, the difference in measurements with the FLIR E75 thermal camera and thermocouples are discussed and the results of these experiments are compared to those of other studies.

## 4.4. Discussion

In this section, the different experiments and the potential reasons for the differences in temperature are evaluated. Temperature effects measured with the FLIR X6901sc camera are observed and the differences between performing measurements with thermocouples and a thermal camera are discussed.

### 4.4.1. Thermocouple and thermal camera experiments

*Experiment 1*

Although a difference in the median is found for measuring with a smoke extractor and measuring in the dark, there was not a lot of repetition within the experiments. For a more solid proof of this difference, more repetitions have to be performed.

A median temperature increase of 8°C (thermocouples) and 5°C (thermal camera) is found between measuring with and without a smoke extractor. This could be due to the airflow cooling the top of the tofu. The air is blown past it in close proximity and affects the surface temperature. Unfortunately, these experiments create smoke and this could be a potential health hazard. Therefore, it is wise to make use of a smoke extractor. In conclusion, it would be better for the measurements to put the smoke extractor in the same room as the measurement set-up, but not near the tofu, to prevent the air flow from affecting the measurements.

*Experiment 2*
The maximum temperatures measured during simultaneous or separate measurements did not show a significant difference. The median of the thermal camera and thermocouples for simultaneous measurements and separate measurements are not far apart. However, the range of measurements for measuring separately is larger, including one outlier. This could be due to the fact that the thermocouples are not always positioned the same. Positioning could have had an effect on the measured temperature because, as shown in the results, just one pixel away from or towards the scalpel can impact the measured temperature. During the separate measurements, the thermocouples were placed at 2mm from the scalpel. When placing them into the tofu, the tofu sometimes deformed slightly causing the thermocouples to move as well, resulting in other temperatures. This was not a problem when measuring simultaneously because the pixel the thermal camera measured was chosen by finding the exact placement of the thermocouple. Thus comparing them was not a problem. But it was a problem for comparing different measurements because the placing the thermocouple in the exact same spot was a challenge. For the thermal camera, this was not a challenge because the spot to be measured could be calculated exactly. If the outlier of the thermocouple is eliminated, it does not seem to matter whether the measurements are done simultaneously or separately. This indicates that the interference between these measurements is probably minimal.

*Experiment 3*
The measurements of thermocouples placed on top of the tofu and 1 mm within the tofu show that the top of the tofu varies 2°C on average from 1mm inside the tofu. The difference in temperature between the thermal camera measurement and thermocouples is probably due to the scalpel which is also placed 1mm into the tofu. The temperature spread of the scalpel just beneath the surface could be higher than on the top. Measurements performed with the thermal camera can only see the temperature spread on the surface and not on in the rest of the tofu. This is probably also the reason for the difference between the thermocouples and the thermal camera in all measurements. The thermocouple always measures a slightly higher temperature. Concerning the thermocouples, the difference in temperature measured on top and 1mm into the tofu is minimal. Given the stabilization of the thermocouples and the smaller range, placement just underneath the surface is best for conducting these measurements.

*Experiment 4*
The effect of measuring in the dark is clearly portrayed in the boxplots of Figure 4.7. As reflection can have such a large impact on measurements it is important to make this impact as small as possible. These measurements were performed at the end of the day when there was not a lot of sunlight, which could also have an effect on measurements. Measuring on a sunny day, even though a box is placed around the set-up could still have an effect on the measurements. This is why it is of great importance to perform measurements on one day or be aware of the surroundings when performing measurements. Other measurements were also performed where the effect seemed less. However, to make sure that the measurements with the thermal camera are not affected it is important to minimize the light in the set-up. Because thermocouples do not have to overcome this challenge, measurements performed with the thermal camera were validated to check if the designed set-up is effected by reflection. For these measurements, the thermocouples do seem to measure higher temperatures under the same circumstances. This could be due to interference in the circuit or other factors, such as the placement of the thermocouples. There is also one data point which is much higher than the other data points. Because of this, the result portrayed in the boxplot look as if the thermocouple is more influenced by the light. Which is not the case.

*Experiment 5*
The thermal camera data from this more advanced camera provides more insight into how electrosurgery affects tofu. The main insight is the circular effect of the temperature around the scalpel, which was the case for all three measurements. Besides this information, it is possible to see sparks or gases during the visualization of the measurement. In Figure 4.8 very high peaks are seen in the maximum temperature at 40 Watts. An explanation for this could be that the camera measures gas and sparks which are emitted when the scalpel is in contact with the tofu. The peaks increase and decline with a gradient at which it is impossible to heat tofu. In order to eliminate these peaks, a first-order low-pass Butterworth filter was used with a cut-off frequency of 0.5. More information on this filter can be found in Appendix G. The filter results in the probable temperature of tofu and removes the steep peaks. If the researcher is interested in the temperature of the tofu,

the filter is important. However, if the researcher is interested in the possible temperature that the tofu could get because a spark comes in contact with the tofu, it is of great importance not to filter the obtained data. This choice is for the researcher to make, depending on the research question.

Additionally, from these great images, data from the temperatures of the scalpel and tofu just next to it were obtained, to provide more insight into the temperature. It is found that in these measurements the temperature of the scalpel is lower than the temperature of the tofu. Because the number of tests done with this set-up is low, it is not possible to conclude that this is true for all measurements. This is interesting information that could be further explored. This information is also in contrast with a paper written by Sutton et al.(2010) [21]. In this study, the temperatures found at the tip of the scalpel are higher than those adjacent to the scalpel. Because it is unclear what the adjacent measurement in this study entails, it is possible that this is not at the exact position underneath the scalpel where the highest temperature is found. The maximum temperature found at the tip in their study at 40W was 80°C. In the experiment performed with the FLIR X6901sc camera at 40W this was 92.9°C. And just beneath the scalpel, 135.4°C was recorded. Considering that the experiment with the FLIR X6901sc camera only has one measurement per setting, no definitive statement can be made.

### 4.4.2. Temperature effects

The designed set-up for measuring effects of different types of ESUs has given many insights into how an ESU works and what methods can be used to evaluate the effect of electrosurgery.

A recurring problem in various measurements was that the range of temperature was remarkably large. There are different reasons for this, factors which probably influence the measurements are shown below.

| | |
|---|---|
| Measurement set-up | Placement of thermocouples/cursor |
| | Light/Reflection of light |
| | Depth of scalpel into the tissue |
| | Size of the tissue |
| | Temperature of the surroundings |
| | Temperature of the tissue |
| ESU | Not all the energy can be put into the tofu |
| | Static and not dynamic testing |
| | Interaction with water |
| | Sparks and gas |
| | Temperature of scalpel |
| | Power drop at a certain resistance |

### 4.4.3. Temperature spread

The temperature increase in tofu is relatively small between 4mm and 6mm from the scalpel. In order to find whether the temperature increase is in line with theory, a calculation of heat capacity was performed. For this calculation we take the mean specific heat $Cp = 3.105KJ * Kg^{-1} * K^{-1}$ and the mean density of tofu $\rho = 1152kg/m^3$ [30]. In the experiments the ESU is set to 40W for 2.5 seconds. Therefore the heat capacity input can be calculated as follows,

$$Q = Power * time \tag{4.1}$$

$$Q = 40W * 2.5s \tag{4.2}$$

$$Q = 100 Joules \tag{4.3}$$

This heat is used to increase the temperature of the tofu:

$$Q = Cp * Mass * \delta T \tag{4.4}$$

This is equal to:

$$Q = Cp * \rho * Volume * \delta T \tag{4.5}$$

This can be rewritten to:

$$\delta T = Q/(Cp * \rho * Volume) \tag{4.6}$$

If the volume of the heated area is seen as half a sphere with a radius of 5mm, the volume can be calculated as follows:

$$V = 1/2 * 4/3 * \pi * r^3 = 2.62e^{-7} m^3 \tag{4.7}$$

Combining the results into equation 4.6

$$\delta T = 100J/(3.105KJ * Kg^{-1} * K^{-1} * 1152kg/m^3 * 2.62e^{-7}m^3) = 106 \quad (4.8)$$

From this a δT of 106 is calculated. This temperature difference has the same magnitude as the temperature difference that is found through the experiments. However, in the experiments this temperature is lower. This is to be expected given losses inside the ESU, around the scalpel and in the connection between the ESU and the scalpel. Further calculations could be performed or simulations can be done, but this does not fall into the scope of this thesis.

### 4.4.4. Comparison of thermocouples to thermal camera temperatures

Besides the above aspects having an effect on measurements, after trial and error, it became evident that comparing one pixel to the same pixel in different measurements was complicated. This is because the temperature changes per pixel, this can even be a change of 10°C. For this reason, it is complicated to compare one pixel of one measurement to one pixel of another measurement as the scalpel might have shifted slightly during different measurements and the pixel will give different measurements.

Finding the correct place also influenced the thermocouple measurements as it was a challenge to precisely place the thermocouples in the exact same place each measurement. When placing the thermocouples into the tofu the resistance of the tofu resulted in the thermocouples moving sometimes. The large range in measurements could be the result of slightly placing the thermocouples to the left or right and finding a different pixel.

The large difference in pixels is also illustrated in Figure 4.10a. A similar curve is found in measurements where forceps were applied to a Fallopian tube in vivo [23].

While the thermal camera and thermocouples give comparable data there is one drawback in using thermocouples. With a thermal camera the temperature change is visualized and very clear. On the contrary, this is not the case when using thermocouples. With thermocouples, the temperature just underneath the top tofu layer is measured. The temperature measured at 4mm and 6mm is not very different from the initial temperature of 22°C.

### 4.4.5. Comparing results to other experiments

As discussed in the introduction, the papers discussing experiments on thermal effects by electrosurgical interventions do not address the challenges in designing a measurement set-up. Nonetheless, they do find similar tissue effects. In the paper of Sutton et al. (2010), there is no temperature change at distances 1 cm from the tip. This coincides with our finding of only a slight temperature effect. The curves of the temperatures are also comparable to each other, showing a steep peak [21]. Koch et al. (2003) [22] and Wallwiener et al. (2010) also show similar curves. Wallwiener et al. (2010) also has a distribution of the mean surface temperature. This coincides with the distribution that is found during our measurements [23]. None of the papers mention troubles with the reflection of the surroundings when measuring temperatures with the thermal camera. This could be because the camera they used was for instance cooled and not affected by this. However, there is no mention of in their papers.

Within this study, there are some limitations. There is not a lot of repetitions within the experiments. With more repetitions, the differences could be more visible. Besides this, it was only possible to perform one measurement per setting with the FLIR X6901sc camera. The information provided by these experiments was interesting but it is not possible to give definitive results. Another limitation is that no animal or human tissue could be used to perform this study. Tofu is not homogeneous and has different characteristics than human tissue does. Besides the difference in characteristics, live human tissue is 37°C, while the tofu which was used was at room temperature (22°C), the higher temperature of live huma tissue could result in different tissue effects. For future research, it would be of considerable value to use a camera which has a higher resolution so that the thermal effects can be examined in more detail. It would be best to use the FLIR X6901sc camera because it is hardly influenced by light and other external factors. Unfortunately, this camera is very expensive. If researchers wish to continue measuring with thermocouples it is recommended to perform more research in this area. The thermocouples that are used within this set-up are 1mm in diameter. It would be interesting to look into using smaller thermocouples if these are used for future measurements. Thermocouples which are smaller in size have a higher conductivity and thus will react faster.

The results of all these findings are combined into a protocol for measuring thermal effects. This protocol can be found in Appendix D.

## 4.5. Conclusion

The aim of this chapter was to make a protocol and testing set-up for measuring electrosurgical parameters. This is achieved by looking at different external factors that can influence the measurements. To perform measurements with this set-up, it is important to keep all conditions constant. It was found that measuring simultaneously and separately do not seem to affect each other. It is possible to measure simultaneously with this set-up. When thermocouples are used, placing the thermocouples slightly into the tofu might give slightly higher temperatures than the thermal camera measurements but the measurements are more stable. For this reason, it is advised to place the thermocouples slightly into the tofu when performing measurements with them. Another critical finding was that measurements should be performed in the dark to minimize the possible effects of reflection. The full protocol on how to use this set-up step-by-step can be found in Appendix D.

Performing thermal measurements can be done through using thermocouples and a thermal camera. The positive and negative aspect of using these methods are concluded below.

| | | | |
|---|---|---|---|
| Thermocouples | + measures inside tofu<br>+ measures only tofu temperature<br>+ less data<br>- has a delay in measurement<br>- trouble positioning the exact place<br>- cannot give full overview of thermal effects | Thermal camera | + measures all thermal effects<br>+ no trouble positioning<br>- measures top of tofu<br>- measures sparks or gas as well<br>- a lot of data<br>- affected by reflection<br>- measuring preferably in the dark |

When deciding which method to use, it is advised to take these positive and negative effects into account and find which data is necessary to answer the research question.

## 4.6. Choices validation experiment

For the research question of the paper in the following chapter, it was important to find the maximum temperature. This is not possible to do with a thermocouple because it just measures a few points. Thus in order to answer this specific research question, the method of using a thermal camera has been chosen. By using the protocol provided by the experiments and findings in this chapter, a comparison of different settings and different ESUs has been performed. This experiment, documented in paper form, can be found in paper form in Chapter 5.

# 5

# Thermal impact of electrosurgical power settings in different Electrosurgical Units (Paper)

***Abstract***- **Electrosurgery is used in nearly every surgical department worldwide. However, there appears to be a lack of knowledge about the thermal effects of electrosurgery and differences between different electrosurgical units (ESUs). Therefore, there is a need to gain more insight into what effects occur in tissue during electrosurgery. To do this, it is important to find the difference in thermal effects between different electrosurgical cutting settings and different electrosurgical units during cutting. Within this paper the maximum temperature at 40W, 60W,100W and 120W for the Valleylab Force FX is analyzed and compared to the maximum temperature at 40W, 60W and 100W settings of the ERBE ICC 300. These two ESUs seem to differ from one another, especially at higher powers. The maximum temperature created by the Valleylab Force FX increases significantly from 60W and higher. This is not the case for the ERBE ICC 300. Another interesting finding is that the thermal affected area is similar for all the settings.**

## 5.1. Introduction

Since the end of the 19$^{th}$ century procedures using electrical energy have been performed [10]. However, it was not until the invention of Bovie's electrosurgical unit (ESU), which could superficially dehydrate, cut and coagulate that this method became popular to use [31]. Nowadays, electrosurgery is one of the most commonly used systems in laparoscopy [32], and is used in nearly every surgical procedure around the world [9]. Unfortunately, there is still a gap in the knowledge about the effect of energy based devices [11]. The settings that surgeons use in the operating room are passed down from teacher to student and therefore surgeons often do not know the reason for applying specific settings.

These settings are of great importance to the patient because higher settings could cause unnecessary damage to the tissue around the incision site. Damage can instantly occur at temperatures between 60 °C and 100°C [33]. When the temperature is kept at 50°C for 6 minutes, coagulation occurs which also damages the tissue [33]. At 90°C the water in the cells completely evaporates and at 100°C the cell walls rupture [34][35]. These tissue effects are very useful in electrosurgery, when specific areas need to be coagulated or cut. The thermal effects also have an effect on surrounding, healthy tissue, which should be affected as little as possible. The range of the thermal effects from the scalpel and the differences between settings is unknown to clinicians but also to researchers.

Besides varying settings, there are also many different brands of electrosurgical units available to hospitals worldwide. Some surgeons have preferences for a specific ESU, but the differences between ESUs have not, to the knowledge of the author, been discussed in literature. There is a clinical relevance for this, as this would be extremely valuable information for the surgeons when they choose which device they want to use in their operating room.

To gain more insight into the differences the research question to be answered is "What is the difference in thermal effects between different electrosurgical cutting settings and different electrosurgical units during cutting? "

The hypothesis is that if the power of the electrosurgical unit is increased, the temperature and temperature spread around the scalpel will increase with higher settings for both of the electrosurgical units. To find these effects the maximum temperature of the different settings and different ESUs is measured and the radius of the spread (in pixels) is compared.

## 5.2. Methods

To perform this experiment, a test set-up was designed. In order to measure the temperature as accurately as possible, a strict protocol was followed, which can be found in Appendix D. To perform the measurements, a thermal camera (FLIR E75), sampling at 30Hz, with an emissivity factor of 0.95[1], was used. Due to the effect of reflection on the thermal camera, a surrounding with as little light as possible was chosen to measure in [2]. The Valleylab Force FX and the ERBE ICC 300 electrosurgical units were used to perform the measurements at 40 Watts, 60 Watts and 100 Watts. These ESUs were used because they were available at the TU Delft. A picture of both generators can be found in Figure 5.1.


Figure 5.1: The Valleylab Force FX (bottom) and the ERBE ICC 300 (top)

Due to restrictions of the TU Delft, it was not possible to test on animal tissue. Tofu [3] was chosen as an alternative because its properties are comparable to human tissue [4].

This tofu was cut into cubes of $1cm^3$ and these cubes were left at room temperature for a minimum of 30 minutes. The size was chosen because it was large enough to see the thermal effects and the resistance was low enough to not cause a power drop in the ESUs, as this power drop occurs at around $1700\Omega$ for the Valleylab Force FX (Valleylab), but already at $500\Omega$ for the ERBE ICC 300 (ERBE) [20].

The cubes of tofu were placed on a ground plate which was connected to mimic a return electrode[5]. A SafeAir smoke pencil was used to perform the cutting for both electrosurgical units. The electrosurgical scalpel was placed approximately 1mm into the tofu for every measurement. By using an instrument timing box, which activated the scalpel for a specific amount of time, measurements could accurately last for the set amount of time. A drawing of the set-up can be found in Figure 5.2.

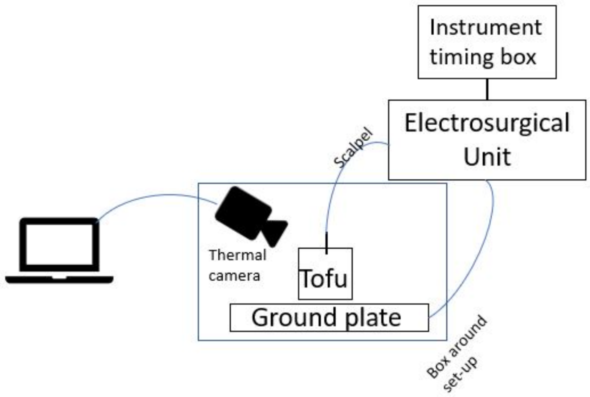



Figure 5.2: Test set-up

Every measurement was performed five times per ESU in a randomized order, to avoid potential heating effects of the scalpel, which could affect the measurements. The scalpel was turned on for 2.5 seconds and the thermal camera measured for a total time of 5 seconds. The maximum temperatures recorded by the thermal camera are used. To find if there is a significant difference between the experiments a one-way and two-way ANOVA are performed. For the results which showed a significant difference a two-sided, unpaired t-test was performed to find between which settings a significant difference could be found. The statistical analysis and the visualization of data was performed with SPSS Statistics 25 (iBM, North Castle, NY, USA) and MS Excel 2016.

[1]This number was calculated within the research IR data
[2]More information about this can be found in chapter 4
[3]Veggie Chef- Jumbo
[4]Measurements performed on the resistance of tofu are performed in Appendix C
[5]More information can be found in Appendix E

## 5.3. Results

*Maximum temperature*

The temperature curve during the activation of the electrosurgery scalpel is similar for all the settings. On the combined data of the maximum reached temperature of the Valleylab and the ERBE, a two-factor ANOVA was performed. This showed that there is a significant difference between the ESUs and the different powers. The most notable difference in the data is the maximum measured temperature at different powers for the Valleylab. There is also quite a large range in maximum temperatures. The results are visualized in Figure 5.3.

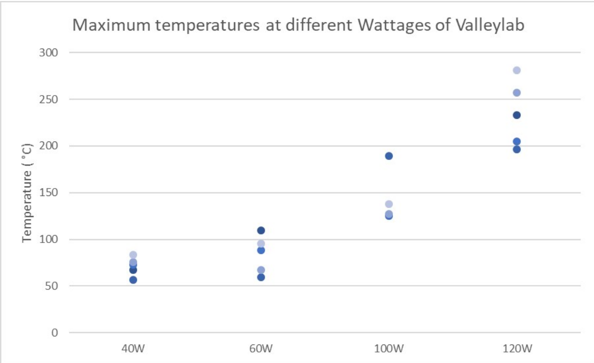



Figure 5.3: **Maximum temperatures at 40,60,100 and 120 Watts of the Valleylab Force FX.** The maximum temperature increases remarkably between 60W and higher powers.

The maximum temperatures of the Valleylab lie close to one another for 40 and 60 Watts. The mean ±standard deviation for the 40W measurements is 71.2 ±10.5°C and for 60W is 84.04 ±20.64°C. However, when the power is increased to 100 Watts, the maximum temperature increases substantially above the 100°C to a mean of 151.48 ±29.89 °C. For the 120 Watts setting the maximum temperature increases even more to well over 200°, with a mean of 234.6 ±35.5 C. There is a significant effect of power on the temperature at the $p<0.05$ level for the 4 powers [$F(3,16)=41.91$, $p=0.0000000835$][6]. To find the difference between specific powers a two-sided, unpaired t-test was performed [7]. The results of the unpaired, two-sided t-test are shown in table 5.3 below.

| Difference between | T-test results |
|---|---|
| 40W and 60W | t(6) = -1.25, p=0.26 |
| 40W and 100W | t(5) = -5.69, p=0.002 |
| 40W and 120W | t(5) = -9.90, p= 0.00018 |
| 60W and 100W | t(7) = -4.15, p= 0.004 |
| 60W and 120W | t(6) = -8.2, p= 0.0018 |
| 100W and120W | t(8) = -4.00, p = 0.004 |

Table 5.1: Results of t-test

Within this data set, the Bonferroni-correction is used. This is used when more statistical tests are performed simultaneously [36] to avoid finding a difference when there is no difference. This correction adjusts the alpha for the number of comparisons. An alternative alpha is calculated with the formula $\alpha_{\text{altered}} = \alpha/n = 0.05/6 = 0.008$. Taking this in consideration, for every condition, except the difference between 40 and 60 Watts, there is a significant difference in maximum temperature between different powers for the Valleylab.

The results of the ERBE are within the same range for measurements at 40 Watts, 60 Watts and even 100 Watts. The respective means ±standard deviations are; 76.86 ±3.58°C, 70.74 ±10.9°C and 74.27 ±3.47°C. There is no significant effect of power on the temperature at the $p>0.05$ level for the 3 powers [$F(2,12) = 1.044$, $p=0.38$][6]. This was confirmed by performing an unpaired, two-sided t-test. Between 40W and 60W: t(5)=1.19, p=0.14, between 60W and 100W: t(5)=-0.87, p=0.21 and between 40W and 100W: t(8)=0.74, p=0.24.

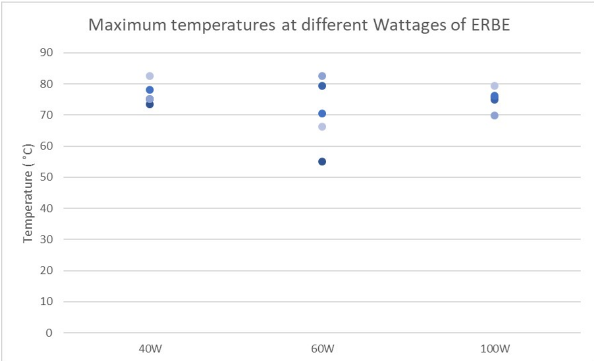



Figure 5.4: **Maximum temperatures at 40,60 and 100 Watts of the ERBE ICC 300.** The maximum temperatures do not seem to change at these powers.

In Figure 5.5 the experiments with both ESUs are shown in a bar chart. In this figure, the mean of the maximum temperatures is displayed, with an error bar showing standard deviation per experiment. A two-way ANOVA was performed on the influence of

[6] Calculated by a one-factor Anova
[7] All data was normally distributed according to the Kolmogorov-Smimov test in SPSS 25

two independent variables (power and type of ESU) on the maximum temperature reached. All effects are statistically significant at the 0.05 significance. There is a significant difference between the Valleylab and the ERBE [$F(1,24)=22.51$, $p=0,000079$], there is also a significant difference between the power [$F(2,24)=18.21$, $p=0,000015$]. And there is a significant interaction between power and ESU [$F(2,24)=17.65$, $p=0,000019$]. Taken together, these results suggest that there is a difference between the Valleylab and the ERBE. It also shows that there is a significant difference between set power and the output power for both ESUs. This is why for both of the ESUs a one-way ANOVA was performed in the previous sections.

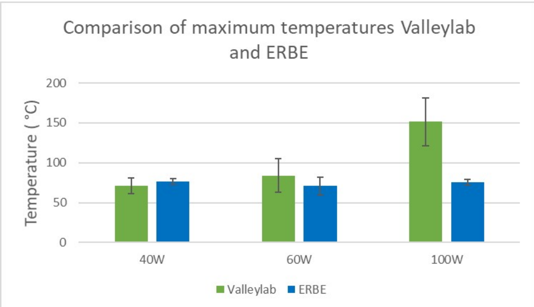



Figure 5.5: **The comparison of maximum temperatures of the Valleylab and the ERBE.** At 40W there does not seem te be a difference in mean temperature. However, at higher powers the machines do not give the same output temperatures.

*Temperature analysis*

A small experiment was performed with another camera. This camera was the FLIR X6901sc camera. This camera is cooled and performs measurements using photons sensors instead of infrared energy like the camera used in the previous experiments[27]. Through measurements with this camera it became evident that during the electrosurgical process, sparks or gas is released. The high peaks can be seen in Figure 5.6. These temperature effects also occurred during the experiments performed for this paper.

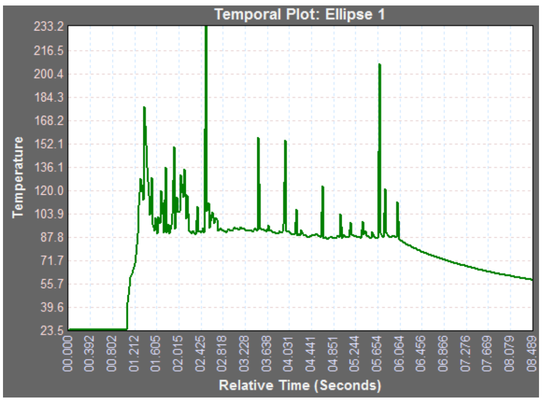



Figure 5.6: Graph of FLIR X6901sc camera with sparks

*Temperature spread*

Through the thermal camera images, it can be seen that the thermal spread occurs in a circular manner around the scalpel. In Figure 5.7 the scalpel is in contact with the tofu in the middle of the circle.

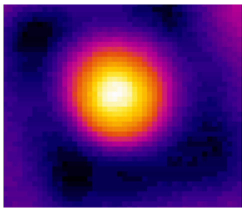


Figure 5.7: Circular thermal effects by FLIR E75 camera

To find the temperature spread, the amount of pixels from the highest temperature (just next to the scalpel in the middle) to the area at the same temperature as the room temperature was measured. This resulted in the radius of the thermal spread. The results show that there is a range in the spread but this is not necessarily correlated to the power. For all settings, there is no significant difference in the number of pixels. This was calculated with an unpaired, two-sided t-test where for all comparisons $p>0.05$. This is also illustrated in Figure 5.8.

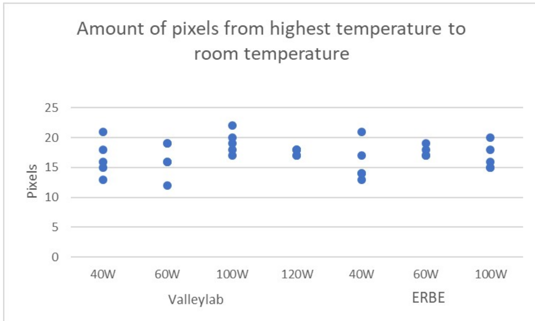



Figure 5.8: **Spread of pixels from middle highest temperature to side.** The thermal spread does not seem to increase with higher powers for both of the ESUs.

## 5.4. Discussion

With these results, it is possible to answer our research question which consists of two parts. The first part of the research questions focuses on the difference in thermal effects at different settings, and the second part focuses on the difference between different electrosurgical units.

The most important finding from the experiments is the rise in maximum temperature between the settings of 60W, 100W and 120W with increasing power in the Valleylab. A significant difference is found between all settings except between 40W and 60W. For the ERBE, there is no significant difference between the maximum temperatures.

In figure 5.5 the maximum temperatures of both ESUs are compared to each other. At the two higher powers, there is a difference between the maximum temperatures of both ESUs. The reason for the difference in maximum temperature for different settings could be allocated to the fact that the ERBE produced fewer sparks during the cutting process than the Valleylab.

Another reason for the difference could be that the increased power created more heat within the tofu. The temperatures or effect inside the tofu are not measured with the thermal camera. This is an interesting aspect to look into further with future research.

Furthermore, the difference in temperature could be explained by the difference in frequency of the electrosurgical generators. The frequency of the Valleylab is 390 kHz [37]. While the frequency of the ERBE ICC 300 is 330 kHz [38]. The higher frequency of the Valleylab could account for the larger differences in maximum temperature.

Besides these reasons, an explanation for the difference between these two electrosurgical generators can be that they have a different variable they keep constant in their system. Doctors assume that the Valleylab uses a power control generator, where the power is kept constant and the voltage and current change [39]. While the ERBE uses a constant voltage generator. The power coincides with a voltage which is kept constant and the current changes with the impedance of the tissue. Meaning that the set power is the maximum power that can be reached [39]. While this is not confirmed by the companies themselves, this difference in operating principle coincides with the results. Previous findings in the thesis of Felix Cranz (2018) confirm these findings. In his thesis, the highest power in both ESUs is used at different resistances. In the Valleylab the power drops at around 1000 Ω. While the ERBE only has its peak power with a very low load (100-200Ω) [20]. This coincides with a constant voltage system. If the resistance becomes higher, the current decreases if the voltage has to be kept constant, as can be seen in $U = I * R$. If the current decreases, the power can never reach the set power, as shown in $P = U * I$. This means higher power settings are necessary to reach the same temperatures with a constant voltage system. This coincides with the results of our experiment.

The results also show a large range. This range in maximum temperature can be allocated to different reasons. The first possibility is that the scalpel is placed into the tissue slightly different every time. The second possibility is that there is a slight difference in the homogeneity of each tofu piece, the structure, size and amount of water in the tofu could have differed slightly. Finally, even though measurements are performed in the dark, it is possible that small rays of light are introduced into the measuring set-up, causing reflection.

Measuring the temperature with the more detailed FLIR X6901sc camera, it became evident that not only the scalpel causes high temperatures. During the process, sparks are caused by the interaction of the high-frequency current with the tissue. These sparks cause a higher maximum temperature than the temperature which the tissue reaches. With a low-pass Butterworth filter, the abrupt increases in data can be removed, leaving only the temperature of the tofu. Because in this paper the actual thermal effects were of interest to the researcher, no filter was placed over the data. Due to irregularity in the temperature curve and very low temperature, one data set of 100W of the Valleylab was removed from the data. Reason for a different curve could be a misplaced scalpel into the tofu, less water in the tofu, a difference in the consistency of the tofu or there was a power drop in the machine.

Besides the difference between the settings, there were also similarities. For every measurement, there is a circular tissue effect. This circular tissue effect is confirmed by thermal measurements with the FLIR X6901sc camera. A picture of this is shown in Figure 5.9.

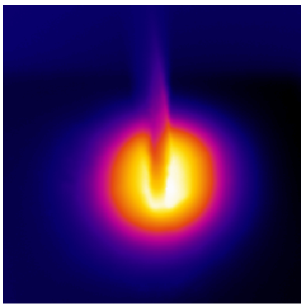


Figure 5.9: Circular thermal effects by FLIR X6901sc camera

The similarities continue in analyzing the spread of the thermal effect, as shown in Figure 5.8. The spread of the temperature seems to not increase with an increased power. This is interesting for clinicians, knowing that the temperature spread does not increase with increasing Power. It is also interesting for clinicians that the difference in maximum temperatures between 40W and 60W are not significant within the Valleylab.

A similar study, researching the thermal effects of different types of electrosurgical units presents different temperatures than the temperatures we have measured. The experiments performed in this study by Sutton et al. (2010) [21], are done on porcine tissue, at lower powers than used in this experiment and they leave the scalpel on for 5 seconds instead of 2.5 seconds. However, the measured maximum temperatures in our experiment are larger than their measurements at the tip of the monopolar instrument and adjacent to the tip. Another study discussing thermal effects on tissue is that of Koch et al.(2003) [22]. In this study, measurements are performed on live animals and separate tissue samples. Similar thermal effects are found and the same peak in measurements is seen. In a study by Wallwiener et al. (2010) [23], similar curves were also found. One large gap in these studies is that their method sections did not contain a lot of detail. The studies of Koch et al. (2003) and Wallwiener et al. (2010) both use a thermal camera, but, there is no description of the obstacles that occur due to the reflection of the scalpel.

Furthermore, a previous study performed by Felix Cranz (2018) also examined the differences between thermal effects. However, the study did not take external influences like reflection into account. The results of his study are comparable to this study. The temperature increased between 40W and 110W for the Valleylab. Similar to the results we found, but he did not look at the steps in between. In the ERBE he found a slight temperature increase in the maximum temperature between 40W and 110W, this does not coincide with our results from the ERBE, this could have something to do with the effects of reflection or other external influences this study has taken into account.

*Limitations*

The experimental set-up used in this study had its limitations. This is primarily due to the factors which are difficult to keep consistent. One of these factors is the scalpel placement, it is difficult to find the exact placement of the scalpel, because the scalpel changes temperature when turned on, and is at room temperature just like the tofu before being turned on. Secondly, the placement of the scalpel into the tofu is performed by hand, limiting the ability to place it specifically at 1mm into the tofu. Thirdly, the experiments are performed on tofu at room temperature of 22°C. Living tissue is 37°C. Therefore, it is possible that the temperature in human tissue is higher. Furthermore, tofu is similar to human tissue but is not the same. This experiment is done on a piece of tofu with low resistance, using pieces of tofu with a higher resistance would most likely find higher temperatures. Fourthly, the experiments are only performed 5 times per setting. Because the range in the maximum temperatures is quite large, more repetitions could result in an even clearer evaluation of the differences. Finally, the camera that was used is very accurate, but could not zoom in as much as necessary to give specific information. Therefore, it is difficult to determine the exact distance of one pixel and converting this back to the thermal spread in mm. A better suitable camera would also give more specific temperatures.

*Recommendations*

For further research, there are a few recommendations. Firstly, it is recommended to use a better camera for further measurements. With a better camera, the external influences have less effect on the measurements and the thermal effects can be recorded with a higher resolution. It is also easier to calculate the actual size of pixels because the images can be interpreted more precisely. Secondly, performing experiments with more settings, on different modes (for instance coagulation) and on different ESUs would provide more insights. Thirdly, as became clear in the results, there is a large range in the measurements. To make sure that the differences found are substantiated with enough measurements, more measurements could be performed. Fourthly, in order to make a better comparison with previous papers, measurements with a longer duration can be performed. Fifthly, more research could be done to find if the power output settings of the ERBE and the Valleylab indeed keep a different variable constant. It would also be interesting to find whether the newer ESUs also show this difference, and how these new ESUs differ from the ESUs tested in this experiment. Finally, experiments can be performed on real tissue to find real tissue effects. The results of this experiments should be discussed with clinicians to find the settings necessary for operations. In collaboration with these clinicians optimal settings for different surgeries can be found.

## 5.5. Conclusion

The research question in the introduction stating "What is the difference in thermal effects between different electrosurgical cutting settings and different electrosurgical units during cutting" has been answered. There is a correlation between the maximum temperature and an increased power on the ESU for the Valleylab. This effect is not seen in the ERBE. The hypothesis that the thermal spread from the scalpel would increase, does not seem to hold for these two machines for the settings used. Both electrosurgical units seem to have a different working principle to create an output power, resulting in different thermal reactions to tissue. With this information, end users can make well informed decisions when choosing which ESU they want to use.

# 6 Discussion

This thesis consists of three main chapters, which are all necessary in reaching the final objective, designing a new electrosurgical unit for low-and-middle-income countries. Within chapter 3, an extensive list of requirements has been discussed. For several of the design requirements, literature could not provide enough information to make an informed decision for the new ESU. In order to make it possible to make this informed decision, it was necessary to build a testing set-up for ESUs. This information is relevant for designing a new electrosurgical unit and also for the clinical use of the ESU.

The most important findings from this thesis are summarized per chapter. In chapter 3 a gap in knowledge about electrosurgery is found. This gap consists of a lack of knowledge about the thermal effects of electrosurgery; what power settings are necessary and what frequency is necessary. Filling this gap was found to be more complicated than initially expected. The results of chapter 4 show that measuring without a smoke extractor, in the dark and with a thermal camera provides the most comprehensive results when measuring thermal effects during electrosurgery. Using these findings, in chapter 5 experiments concluded that at different powers, the Valleylab Force FX produces higher temperatures (starting at 60W). The ERBE ICC 300 does not produce higher temperatures with increasing power. Another finding was that there is no difference in the thermal spread around the scalpel between these settings for both of these devices. Guided by this information, choices on the necessary power can be made with the help of clinicians. The information on the differences between the two ESUs also provides us with a choice between constant power and constant voltage systems. Keeping this in mind, the thermal effects of the novice ESU could differ between all devices, including the new ESU.

With these results, we are one step closer to finding the specific design requirements for the new ESU and in finding more information on thermal effects in electrosurgery. Unfortunately, we are not there yet and there is a need for more research. Fortunately, we are not alone in wanting to provide more information. Often surgeons are unaware of the basic principles and functions of energy based devices such as electrosurgery [11][40]. They have a sub-optimal understanding of electrosurgical nomenclature and generator settings [9]. For this reason, the FUSE[1] program has been initiated by SAGES [2][9]. Information, such as that being obtained through this set-up, will one day be part of this program to create more awareness for surgeons through which patients will profit.

This testing set-up is not only necessary for testing current available ESUs but can also be used to test the new ESU once it is built. With the experiment performed in chapter 5, a small part of the gap in literature was filled. It also generated questions about the different types of systems that are used to create the output of the ESU. More transparency in the design choices of ESU manufacturers and the reasons behind them can guide us in making our design choices. Unfortunately, transparency is not probable because all companies want to be the first or have the best innovations and tend not to favor transparency. Besides transparency

[1] Fundamental Use of Surgical Energy
[2] The Society of American Gastrointestinal and Endoscopic Surgeons

being a problem, the complexity of measuring thermal effects is also presumed to be a reason for the lack in literature.

*Limitations*
In this research, it was not possible to test on (live) tissue of humans or animals [3]. For this reason, the temperatures cannot be compared to measurements on real tissue. However, the tissue effects will likely be similar because of similar consistency and resistance. Aside from this, it was difficult to interpret precise information using the camera at our disposal. With a camera that has more pixels, more detailed evaluations can be performed such as with the FLIR X6901sc camera. The experiments performed are all focused on cutting and not yet on coagulation.

*Future research*
This set-up is a gateway to gaining more insight into the different settings in electrosurgery and into differences in different types of electrosurgical units.

The waveforms are the reason for the effects on the tissue when the electrosurgical device is in use. In order to make the electrosurgical unit as cheap and as easily repairable as possible, it was necessary to find why certain choices have been made in electrosurgical devices. Unfortunately, not a lot of documentation on the choices that are made for specific settings can be found. This is also a recurring statement in many papers about electrosurgery. To find whether the choices that have become a standard in electrosurgery are also the choices which are best for an electrosurgical unit for LMICs more tests have to be performed.

One interesting starting point is to find the effect of frequency. The oldest versions of ESUs make use of a lower frequency than the ESUs which are newer. This could mean that there is an effect to increasing the frequency with 100 kHz or more. Unfortunately not a lot of information can be found what these effects are.

| | Valleylab FX[1] | Valleylab FT 10 [2] | RDE Electrocut 100 [3] | RDE Electrocut 400 [4] |
|---|---|---|---|---|
| Frequency | 390 kHz | 434 kHz | 300 kHz | 400 kHz |

Eventually, it would be of great value to perform tests on (live) tissue. This will create even more valuable information on the thermal effects of electrosurgical units. However, before this is done it is important to fully understand what factors have which effect and to analyze the temperature curves at specific points more thoroughly. Looking into the effects that happen inside the tissue, underneath the top layer, at specific points will provide more insight. Another way to do this is looking at the different voltages and currents which run through the body. Calculations into the thermal effects can also be performed and comparisons can be made to the real tissue effects.

The experiments performed in this thesis only look at the effects of cutting by using electrosurgery. It is recommended to perform similar tests with coagulation settings, to find how these thermal effects differ and what settings are necessary for the new ESU in coagulation. Furthermore, the experiments have only compared two different ESUs. These ESUs are older editions, therefore it would be very interesting to perform similar experiments on newer ESUs. This would also provide insight for clinicians who are using the devices in the operation room.

[3]Due to restrictions of the TU Delft

# 7 Conclusion

In this master thesis project, a protocol was designed for testing different ESUs. Many different external influences are taken into account and a step-by-step protocol is made to guide any user through the steps of measuring ESUs. Using this protocol an experiment was performed. The results of this experiment show that different ESUs have a different reaction if set at the same powers in the cutting mode. At low powers (40W-60W) there is no significant difference in maximum temperature, while at higher powers the maximum temperature only increases for the Valleylab Force Fx and not for the ERBE ICC 300.

This experiment was a proof of principle for the protocol and resulted in interesting findings. In the future, more experiments should be performed with this set-up in order to finalize the list of requirements for designing an electrosurgical unit for Low-and-Middle Income Countries. With the information provided by this thesis, the different effects of a power controlled and a voltage controlled system can be compared and the choice between these settings can be made. In addition to this, it is shown that the temperature does not increase significantly between 40 and 60 Watts. This should be taken into account in the design requirements, and this should be discussed with clinicians. The differences in maximum temperature for higher powers are shown and with this information it is possible to find the power necessary for surgeries.

These findings are not solely important for designing an ESU for LMICs but are also clinically relevant for HICs. Through performing more experiments with the designed protocol, electrosurgery will be more deeply understood. By using this knowledge our novice electrosurgical unit will have great potential in ensuring every citizen in the world receives the healthcare they deserve.

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# Appendices

# A

# Rationale Design requirements ESU

## A.1. Safe

### A.1.1. Must have

*Linear power settings:*
The power settings of the RDE Electrocut 100 have a setting from 1-10. In the thesis of Felix Cranz, it is described that this power setting is exponential and not linear [20]. This is very counter-intuitive, as the user might expect that the power will gradually increase as in the other ESU's that were tested. To make sure that the use of the ESU is intuitive and easy to use. According to the thesis of Cranz, a voltage display was not necessary as the surgeon will most likely not know the implications of the different voltages and this also changes with load.

*Power control system:*
A power control system could be useful for users as the user will know what effect to expect, unrelated to the load [20].

*Sufficient power settings:*
In the thesis of Felix Cranz, experiments showed that the RDE has power settings which are not high enough. However, the details of the thermal effects of using different settings are not very well known. To gain more insight into what effects different power settings have, experiments have to be performed.

*Split electrode:*
To eliminate virtually all burns which happen during electrosurgery, a split electrode can be used [20]. Unfortunately, a reusable split electrode has not been found, thus it could be a possibility to provide the option of using a reusable and a disposable split electrode. This is also done in the RDE Electrocut 100 at the moment. More information on a reusable return electrode can be found in Appendix B.

*Alarm when the ground plate is not properly attached:*
To prevent burns with a regular ground plate, an alarm should be given when this is not properly attached [10].

*Sufficient frequency:*
The frequency settings of the waveform of the newer ESU models are increasing. The Valleylab FX had a frequency of 390 kHz [37], while the newer version had a frequency of 434 kHz [41]. For the company RDE this is also the case, the RDE Electrocut 100 uses a frequency of 300 kHz [42], while the Electrocut 400 uses a frequency of 400 kHz [43]. More information behind the reasoning of the increase in frequency must be performed.

*Maximum leakage:*
To have a safe environment for both the patient and the operating room personnel it is important for the maximum leakage to be lower than 100 mA [20].

*Compliant with ISO:*
In order to be able to use the device in Europe, it should comply with the ISO and receive a CE marking. All the ISO standards should be integrated into the design. The ISO requirements which have to be integrated are the ISO for electrical devices, biomaterials, instruction manuals, symbols, clinical tests, ISO 13485, usability test, safety analysis, sterilization and standard connectors (personal communication with Arjo Loeve, MISIT Lab, TU Delft).

*Alarm if malfunctioning:*
When one or more of the components of the ESU are not functioning properly, this should be indicated. A wish would be to indicate where exactly the ESU is malfunctioning but this is not necessary.

### A.1.2. Wish

*Varying frequency settings:*
It could be possible to integrate a varying frequency setting. However, experiments must first find whether there is a need for this in surgery.

## A.2. User-friendly

### A.2.1. Must have

*Bipolar and monopolar:*
The electrosurgical unit must have a bipolar and monopolar function, as both of these functions are frequently used [13].

*Sterilizable (by steam):*
All components that can come in contact with the patient have to be sterilizable. The components which do not come in contact with the patient have to be able to be cleaned and disinfected properly. The rules to comply with can be found in the ISO standards about sterilization.

*Same connection as Valleylab + ERBE:*
It would be very useful to have the same three-point connection as is used in the Valleylab and the ERBE [13]. This is a universal plug-in and donated items will fit also fit into this. Also, it would mean that these plug-ins would not have to be designed specifically for this ESU.

### A.2.2. Nice to have

*Reusability:*
Because this product will be used in LMICs, it is important for it to have as many reusable parts as necessary. If the product does have many parts that are for one time use, they will be used as reusable anyway. To make sure this does not happen, the things that can be made reusable should be [13].

*Spare parts:*
From surveys performed in Nairobi [7], it became clear that some parts of the ESU that were broken took a long time to order and get shipped. This is a problem, which could be fixed by making sure that many spare parts are locally available.

*Easily repairable /taken apart:*
Any time the ESU is not running, it is costing money. The product should be easy to repair so that it can easily be fixed and quickly be in service again.

*Intuitive:*
As with any other ESU, it is important that it is clear how it works. The surgeon should not need a lot of training time and mistakes in the settings should be avoided [12].

*Easy to clean:*
The ESU is used in nearly every surgery. Therefore it should be cleaned often but this should not take a lot of time. The time it takes for the machine to be cleaned, is time that it cannot be in use.

*Portable:*
From interviews performed in Nairobi, it was found that there are hospitals in which there are not enough ESU's to have one in every OR. This means that they are carried around and put in places which are not ideal. To make sure that for instance wires are not broken due to the circumstances that they are put into when being transported, a cart could be helpful and an easy way to store everything that is necessary close together [13].

### A.2.3. Wish

*Quick to set up:*
The ESU is carried around from different OR's and when it is brought from another room, it should be easy to set-up for the operating room personnel.

## A.3. Robust

### A.3.1. Must have

*220V:*
In the EU 220V is used for every device. Unfortunately, in the USA this is not the case. We want to make this device for use in Kenya, where there is 240V and devices with 220V outlet can be used [13].

### A.3.2. Nice to have

*Battery:*
From the survey preformed in Mozambique [13], it became evident that some surgeons wanted the device to have a battery in case of a power outage. The device will not stop and the surgery can continue. However all the other devices will probably not have a battery thus the surgery cannot fully continue.

*Mechanical impact:*
Due to different circumstances in LMICs, the device will be used very frequently and it will be moved between different Operation Rooms. This can be evaluated with an IP number [44].

*Dust:*
In operation rooms in HICs, the air is as dust free as possible [45]. Unfortunately in hospitals in LMICs this cannot be guaranteed so the impact of dust should be kept in mind [44].

*Exchangeable cables:*
This requirement overlaps slightly with the requirement of using local supplies as the requirement is to use general components in the cables so that they can easily be replaced. This requirement is also from the survey in Nigeria [13].

## A.4. For in LMICs

### A.4.1. Must have

*Low cost:*
The price of the Valleylab force 1 is $3500 [46] and of the ERBE is $1250[47] and of the RDE varies between 1049 euro [48] and 3588 euro [49]. The price of the new device should be lower than these devices.

*Function at high temperature:*
Because in temperatures in LMICs can be higher within hospitals it is important to take this into account in the design [6].

### A.4.2. Nice to have

*Stabilizer:*
From questions answered in a survey conducted in Mozambique[13] it became clear that sometimes devices broke due to the current of the grid fluctuating. This problem should be taken seriously because whole pieces of hardware have to be replaced when the wrong current is applied to the device.

*Easy to maintain:*
In LMICs there are less resources at our disposal. This means that if the device is not very complicated and does not need a lot of extra work this would be a great advantage. There is not enough money to have an ESU in every OR so it is important that the ESUs which are available are not out of service for too long [13]. Sometimes technicians do not know how to fix very complex ESUs, for this ESU this should not be a problem.

# B
# Suggestions for designing a reusable split electrode

## B.1. Introduction

One of the requirements of the ESU in chapter 3 was a reusable split electrode. The design of a reusable split electrode would be a considerable addition to the new ESU [13]. The reason for this is that in LMICs, there are two options. The first option is using a return plate; with this electrode, it is difficult to create constant contact and burns occur on patients. This happens due to a capacitive coupling which can create stray current in area's where they are not attached to the electrode [18][50]. The second option, is using a single-use split electrode for more than one patient. This is unhygienic and the return electrodes are made to last for only one surgery, besides this it is also unsafe. A solution to this problem would be to use a reusable split electrode. After an extensive search in literature, the author could not find commercially available reusable return electrodes. This Appendix describes the necessity of a return electrode and suggests concept solutions.

## B.2. List of requirements

To find what is necessary in a return electrode a list of requirements was composed.

Table B.1: List of requirements for return electrode

| **Category** | **Criteria** | **Quantification** | **Priority (1-3)**<br>**1: must**<br>**2: nice to have**<br>**3: wish** |
|---|---|---|---|
| **Safe** | Split<br>electrode | | 1 |
| | Possible<br>to place close to the active electrode | | 1 |
| | Compliant<br>with ISO | | 1 |
| **User-friendly** | Reusability | Number of<br>uses before replacement | 1 |
| | Bends<br>with different places of the body | Can be<br>placed on different body parts | 2 |
| | Spare<br>parts (local) | Amount<br>of spare parts locally available | 3 |
| | Easily<br>repairable/taken apart | Time for repair | 2 |
| | Sterilizable<br>(by steam) | | 2 |
| | Intuitive | Training<br>time | 2 |
| | Easy<br>to clean | Cleaning<br>time per use | 1 |
| | | Compact | 2 |
| | Quick<br>set up | Time<br>to set up | 3 |
| **Robust** | Mechanical<br>impact | IP 3rd<br>number | 2 |
| | Water<br>resistant | IP 2nd<br>number | 1 |
| **For LMICs** | Low<br>cost | Price | 1 |
| | Function<br>at tropical temperatures | Temperature | 1 |
| | Easy<br>to maintain | Maintenance<br>time | 2 |
| | | Availability<br>of spare parts | |

## B.3. Concept ideas

Keeping the list of requirements in mind, different concept ideas were made.

In order for the split electrode to work properly, it is important that the conductive material, which is placed against the skin, is covered by a dielectric material. This dielectric material will make sure that the high-frequency current which runs through the split electrodes will not diffuse to other areas. The dielectric material is also necessary to make sure that when the electrodes touch, the current does not run through the person in question. Not only for safety reasons but also to make sure that it works properly and no current can escape through other channels.

The conductive electrode can be made from a thin metal plate. Because there are two conductive electrodes it is possible to place the pads around a leg or other body part as there is a bendable space through the middle. According to Malkin (2006), the side of the thigh is a very common location. Placing the return electrode in a place where fat can be built up is not practical, because there should be enough blood flow [50]. It is also of great importance for the electrodes to be the same size [51].

## B.4. Concepts

Both sides of the split electrode need to be in contact with the patient at all time. To accomplish this, Velcro or elastic material are good options.

Besides this, it is important to position the return electrode close to the operation site. This can be done on the thigh or around the torso. Concepts can be found in figure B.1.

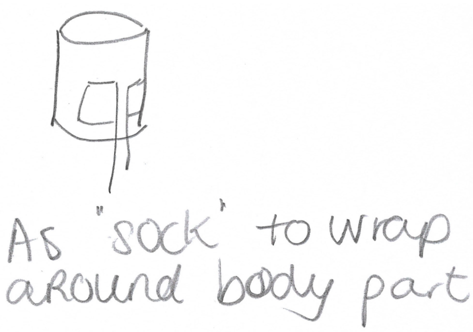
**Concept 1:**
A split electrode with rubber around it that can be strapped to the torso of the patient.

**Concept 2:**
A split electrode with rubber around it to keep the current from going to other places in the body. On the outside of this rubber, Velcro is placed so that it can be wrapped around the upper thigh.

**Concept 3:**
Depending on where the surgery is taking place on the body, it is possible to make a split electrode with rubber around it. This is made into a circular shape, similar to a sock without the part for the toes. This can be pulled over the foot or arm (whichever is closest to the incision site). It will not move during surgery as it is wrapped tightly around the body part through elastic.


(a) Velcro around leg [52])

(b) Velcro around torso [53]




(c) Elastic around limb

Figure B.1: Different return electrode concepts

## B.5. Discussion

The concepts at this moment are still very broad and do not entail many details. Further research should be done into different materials, which can be cleaned properly. More research should also be performed into making sure that the electronics can be connected to different ESU connections.

## B.6. Conclusion

In conclusion, a framework for designing a reusable return electrode is made. There are concepts ideas but these have not been conceptualized at this moment. Using these ideas and the design requirements a student of Industrial design has continued this project for her master Thesis.

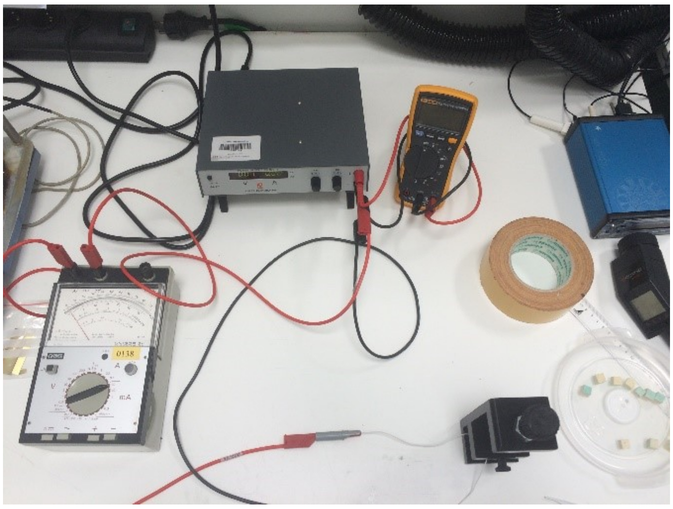
# C
# Resistance of Tofu

## C.1. Introduction

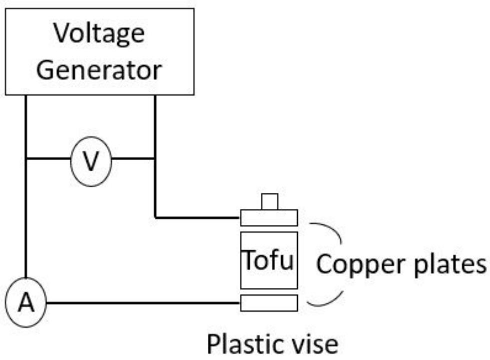
Due to restrictions of the lab at the TU Delft it was necessary to find an alternative to real tissue to perform tests on. Due to similarities found between the resistance of tofu [20] this option was further explored. The goal of this experiment was to find the resistance of tofu.

## C.2. Method

To perform these measurements a set-up was created. A vice was 3D printed and two copper plates were attached to it, so that the tofu could be placed exactly between these two copper plates. Furthermore, an ampere meter, a voltmeter and a volt producer were used. These were set-up in a circuit as shown in Figure F.1. The volt producer was connected to the voltmeter, the voltmeter was connected to the vice. The vice was connected to the ampere meter and this returned back to the volt producer. A schematic drawing of the



(a) Testing set-up




(b) Schematic drawing of circuit

Figure C.1: Testing set-up

One piece of tofu (1 $cm^3$) was used for 5 measurements where the voltage was increased up to 5 V in steps of 1 Volt. After the voltmeter was set, there was a 10 second waiting period before reading the ampere meter. The results are evaluated with the formulas:

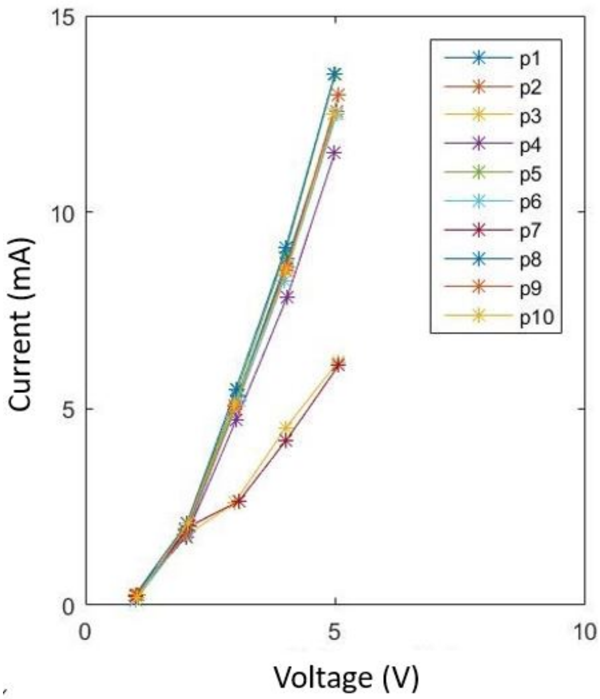
$$p = R * A / l \tag{C.1}$$

$$R = V / I \tag{C.2}$$

Combining formula C.1 and C.2 creates

$$p = (V/I) * (A/l) = (V/I) * 1cm \quad \text{(C.3)}$$

## C.3. Results




(a) Set-up

| Experiment | 1V | 2V | 3V | 4V | 5V |
|---|---|---|---|---|---|
| 1 | 3885 | 1053 | 576 | 460 | 399 |
| 2 | 3714 | 1097 | 598 | 469 | 402 |
| 3 | 3923 | 1138 | 1150 | 891 | 817 |
| 4 | 4208 | 1154 | 643 | 516 | 435 |
| 5 | 4039 | 109 | 556 | 447 | 371 |
| 6 | 8333 | 1103 | 590 | 482 | 403 |
| 7 | 4591 | 1040 | 1162 | 959 | 833 |
| 8 | 3607 | 971 | 549 | 442 | 370 |
| 9 | 3778 | 1111 | 594 | 470 | 391 |
| 10 | 495 | 981 | 588 | 474 | 400 |

(b) Resistance at different voltages in Ωcm

Figure C.2: Results of the experiment

## C.4. Discussion & Conclusion

There is a wide range of resistance at different voltages, while a linear relation was expected. This could be due to different reasons; firstly because the Voltage at which is measured is not high enough. Secondly, this could be due to the slowly heating of the tofu during the experiment. In order to find if this was the reason for the decreasing resistance, another experiment should be performed where a new piece of tofu should be used every time. This will however give the problem that tofu is not homogeneous and that this will also have an effect on the resistance. Every piece of tofu will have a slightly different resistance. There are two measurements with very different results to the rest, these are therefore not taken into account.

Because in the experiments a high voltage is used as well, the resistance at higher voltages are taken as a benchmark. For future research, higher voltages should be tested to see if the resistance drops even more. The measurements of 3, 4 and 5V show that the resistance of tofu varies between 370 Ωcm and 435 Ωcm. This is similar to skin, where the resistance lies between the 255 and the 424 Ωcm [28].

# D

# Protocol for performing measurement with electrosurgical units

This protocol is designed for measuring simultaneously with thermocouples and a thermal camera. Based on the research question the researcher must decide which measurement devices should be used. The steps for thermocouples and the thermal camera have been pointed out.

## D.1. Material list

**General Material:**

- Scalpel
- Ground plate
- 1cm x1cmx 1cm blocks of Tofu (Veggie Chef)
- Smoke extractor (optional)
- Box around measurement set-up
- Ruler
- Electrosurgery unit (Valleylab Force FX/ERBE)
- Mounting arm (x2)
- Black cardboard
- Lab-Jack
- Instrument timing box (Appendix F)
- Return circuit for REM (Appendix E)

**Measurements with the thermal camera:**

- Thermal Camera (FLIR E75) [1]
- Tripod for camera
- Laptop + Research IR software
- Charged battery thermal camera

**Measurements with thermocouples:**

[1] The emissivity settings should be put to 0.95 for tofu, this was calculated in the ResearchIR software

- 3 Thermocouples (type T)
- Thermocouple wood mount
- Thermocouple measuring device (MGCPlus)
- Laptop + Catman Easy software

The thermal camera, FLIR E75, samples at 30 Hz. The thermocouples, type T, sample at 50 Hz.

## D.2. Measurement protocol

Setting up the test set-up:

1. Let the tofu become room temperature for at least 30 minutes.
2. Attach the ground plate to a lab-jack.
3. Attach the ground plate to itself before attaching it to the ESU. This is described in Appendix B.
4. Place a mounting arm with the thermocouples and the electrosurgical scalpel above the ground plate.
5. Place another mounting arm to hold the piece of wood with the thermocouples on it in place.
6. Place the smoke extractor somewhere outside the box and away from the measurement set-up (if necessary).
7. Place a small piece of cardboard over the ground plate, leaving a 1cm x 1cm area for the tofu.
8. (Thermal camera) Place the camera on a tripod at a height that it is facing down on the tofu as shown in fig D.1.

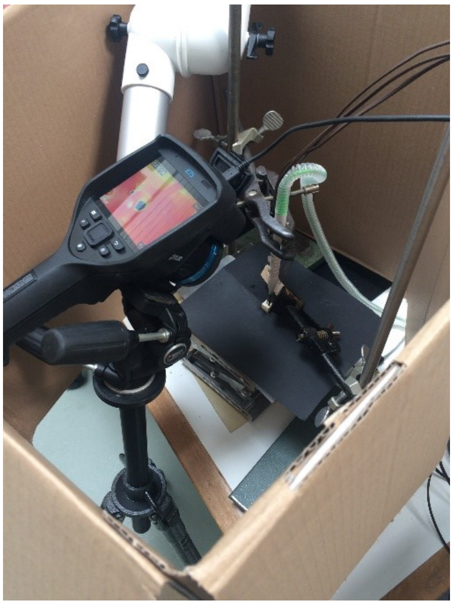


Figure D.1: Camera facing tofu

9. (Thermal camera) Place a battery in the camera and connect the camera to a computer.
10. (Thermal camera) Connect the computer to the camera with Research IR software.
11. (Thermal camera) Place the camera at a distance of minimally 4cm to be able to bring everything in focus. As shown in the figure D.2 below.

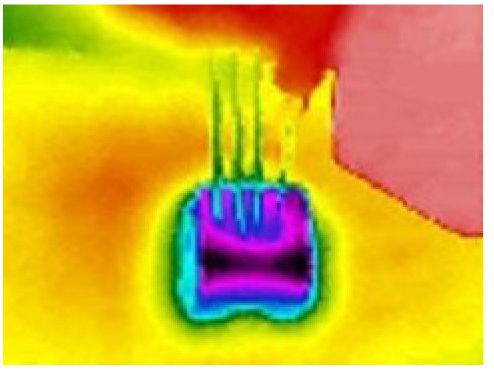


Figure D.2: Focus of thermal camera

12. Place a box around the testing set-up.

Figure D.3: Cardboard box around the set-up

13. Place the black cardboard over the box in order to make the inside completely dark.

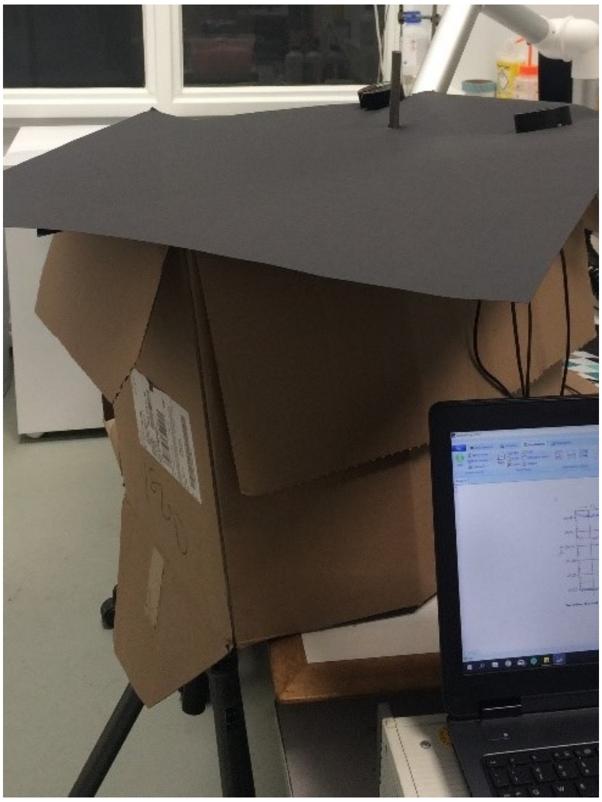


Figure D.4: Cardboard on top of the set-up

14. (Thermocouples) Connect the thermocouples to the MGC Plus. Within the program make sure all settings are complete.

Before starting the experiment first:

1. Check the set-up if it is correct and properly connected.
   (a) (Thermal camera) The laptop is connected to the thermal camera
   (b) (Thermocouple) The thermocouples are connected to the MGC Plus
   (c) (Thermocouple) The laptop is connected to the MGC Plus
2. Ensure all devices are charged sufficiently.
   (a) (Thermal camera) The batteries of the thermal camera have to be charged
3. Take a picture of the setup.
4. Pick a letter to give the experiment so all the measurements can be given this letter.
5. (Thermal camera) Make sure that all area's you want to measure are in focus. [2]

Before starting the experiment:

1. (Thermocouples) Place the thermocouples 2 mm away from the scalpel. (The thermocouples have been placed on a piece of wood so that they are equally spaced and will always be 2mm apart from one another).

[2]For my placement the thermal camera was facing at an angle of 44°down. At a distance of 4 cm from the tofu.

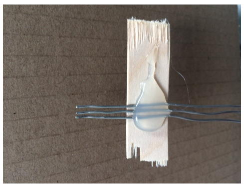


Figure D.5: Thermocouples mounted on wood

2. Ensure all devices are turned on.
3. Make sure all connections to computers are correct.
4. Place the tofu in the designated place.

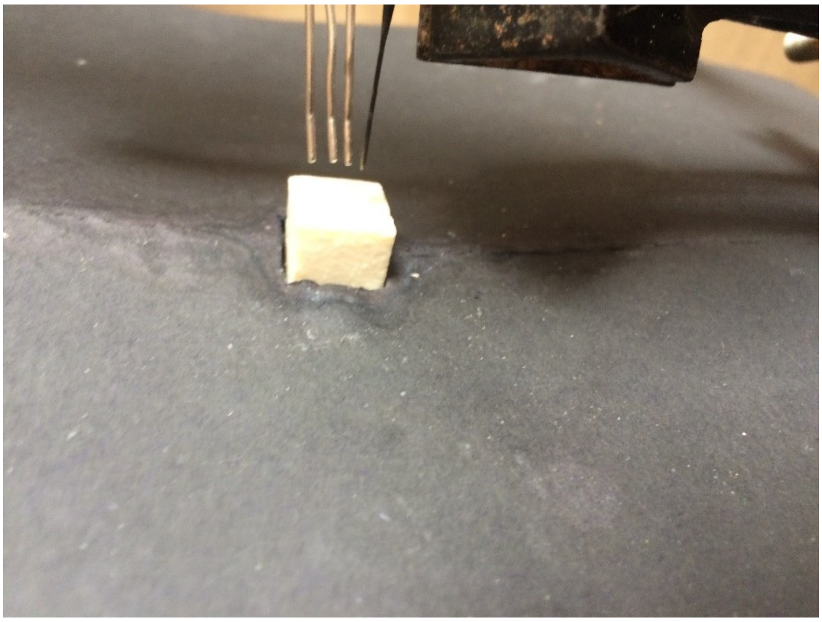


Figure D.6: Placement of Tofu

5. Move the lab-jack so that
   (a) (Thermocouples) The thermocouples are slightly inserted in the tofu
   (b) The scalpel is slightly inserted in the tofu 4
   (c) (Thermocouple) The scalpel and thermocouples are placed 2 mm from the middle
6. Close the top lid of the box to make the set-up dark.
7. Plug the scalpel into the ESU.

During the experiment:

1. Make sure all connections between the computers and the measuring devices are secure after every test.

For each measurement:

1. Check if the settings are correct[3].
   (a) Time set on timing box = 2.5 seconds or 5 seconds

[3] These settings can be chosen per experiment

   (b) Timer measurements Catman Easy = 8 seconds
   (c) Timer measurement FLIR = 8 seconds

2. Plug the scalpel into the ESU.
3. Start the measurement.
   (a) Turn on both measurement computer simultaneously by clicking with the mouse on the start.
   (b) Using the instrument timing box press the button to activate the scalpel

After every measurement:

1. Save the measurements, the method for saving the measurements is elaborated on in the chapter data retrieval.
2. Unplug the scalpel from the ESU before touching the tofu.
3. Lower the lab-jack and remove the tofu.
4. Remove any tofu residue from the scalpel.

After the experiment:

1. Take pictures of the tofu samples.

## D.3. Data retrieval Thermal camera

Per experiment, a letter was chosen to indicate which experiment it coincided with. Once this letter is chosen the experiments can be saved per number, for example: P1,P2. Thermal camera data has to be exported in the Research IR program to a CSV file. It is necessary to export the whole file due to the fact that it is not possible to only export certain points or areas of interest. The process of exporting can be timely, depending on the measurement time. Because the export file can become very large it is advised to keep the measurement time to a minimum (depending on the experiment). The measurements are automatically given a number. When saving the data, a file can be made with the experimental number. If all experiments are saved in a different folder with the coinciding name, the measurements can be kept together. Per time step a measurement is saved. At the end of the export process, there should be a file with the name of the experiment, for instance: P1. Within this file, all the measurements per time step can be found, for example P1_1 P1_2. When the data is exported the three points where the thermocouples measure the temperature have to be found. This is performed by the researcher by finding the middle pixel by hand in the software. When finding a pixel in the data the x and y have to be switched. This is due to the conversion from FLIR data to CSV files.

### D.3.1. Finding the middle pixel

**Introduction**

In order to compare measurements of thermocouples to the data of the thermal camera the same measurement point has to be found. Because the camera has 320 x 240 pixels it is important to repeatedly preform this process in the same way. Depending on the distance of the camera to the measurement site there are 2 or more pixels which can be chosen to compare with the thermocouple measurements. The middle of the thermocouple is chosen because the thermocouple measures temperature at the point were the two metals, which it consists of, are connected, this should be the middle of the thermocouple[54]. Thermocouples are a very cost-effective way to measure temperature. At the junction, as shown in figure D.7 a voltage is created, which corresponds to a temperature[54].

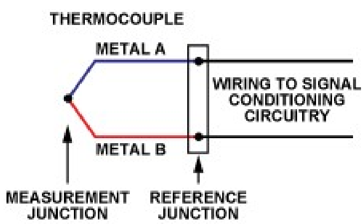
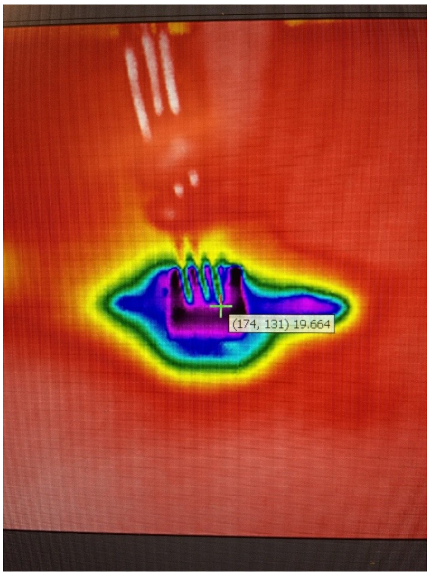


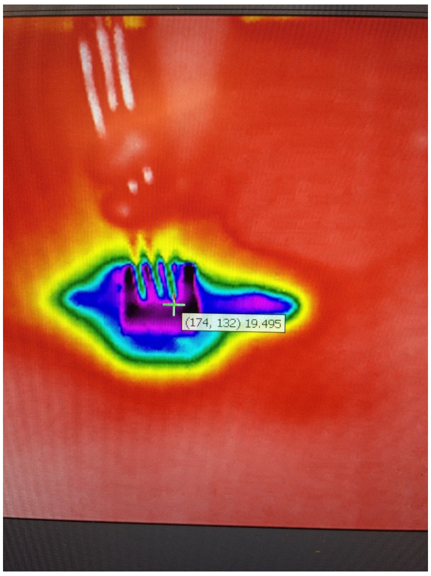

Figure D.7: Schematic drawing of thermocouple [54]

**Method**

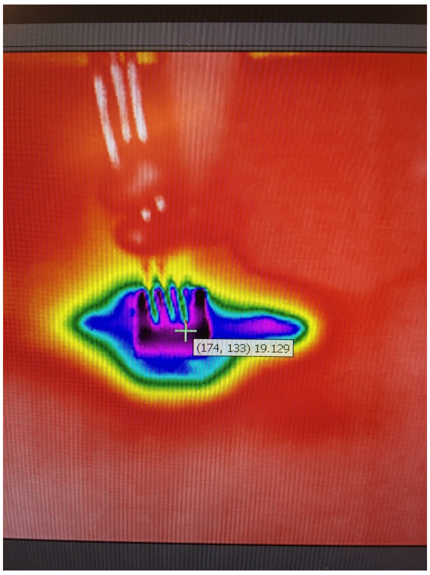
The pixel is chosen just underneath where the thermocouple is placed. In the example below in figure D.8, finding the point with the cursor is shown. Finding the pixel is performed manually and the middle pixel is chosen.



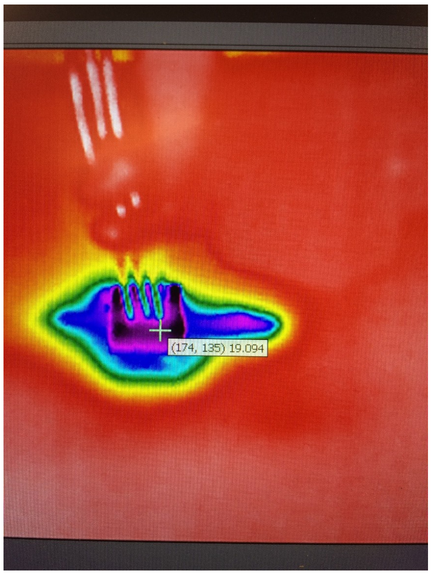

(a) Point (174,131)




(b) point(174,132)




(c) point (174,133)




(d) point (174,135)

Figure D.8: Finding a pixel in thermal camera measurements

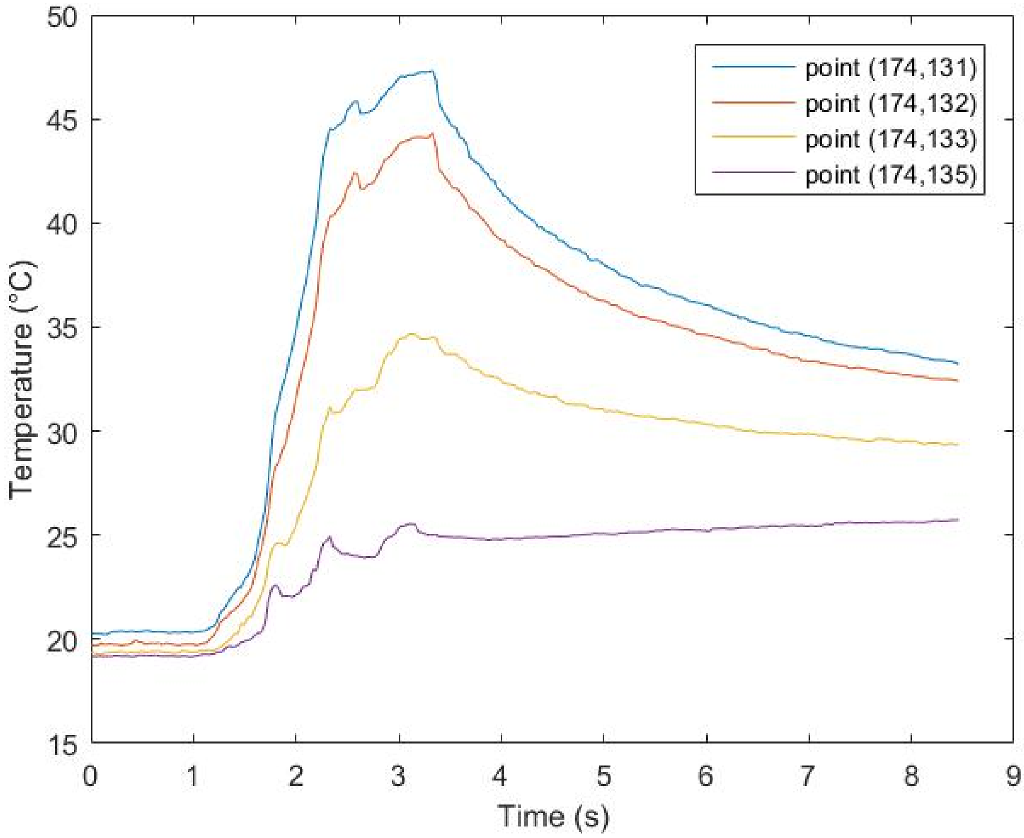



Figure D.9: Plot of temperature over time of different pixels

Even if the mean of the different pixels is chosen this could give a misguided representation as the temperature can differ substantially per pixel. Calculating a mean with one pixel which has a temperature which is much higher than the other pixels will give a false representation of the temperature on this spot.

**Results**

In figure D.9 the temperature curves of the different points are shown. From this data, it becomes clear that choosing the proper pixel is very important in order to properly compare the measurements. The pixels closest to the point of interest are in a range of 4 degrees to each other. For pixels further away the temperature decreases significantly. Thus showing the importance of carefully choosing the pixel.

**Conclusion**

Comparing the data of the thermocouple and the thermal camera can be done when a correct pixel is chosen. One pixel difference will already give a difference in maximum and mean temperatures of a measurement. This is the reason that the pixel used for data should always be carefully chosen with the same method.

## D.4. Data retrieval Thermocouples

The data acquired by MGC Plus can be saved to a Matlab file. This data can directly be analyzed through MATLAB 2015b, The MathWorks, Inc., Natick, Massachusetts, United States. The first column is the time column, the second column corresponds to the thermocouple plugged into the first input channel, the third column corresponds to the second output channel and so on. During the data analysis, the input channels and the time vector can be put into one file[4].

[4]The file for data processing can be obtained from the author

# E

# Return electrode bypass system

## E.1. Introduction

The Valleylab FX has a built-in Return Electrode Monitoring (REM) system. This system measures the resistance at the site of the return electrode between the two halves. By measuring the resistance the machine finds if it is properly attached or not. How this is done is schematically shown in figure E.1.


Figure E.1: Schematic drawing of the return electrode, based on [19]

This resistance can lie between the 5 ohm and 135 ohm. This is the resistance of the skin of a patient when a split electrode is attached. When this does not function properly the machine stops producing output power[55]. In the test set-up this REM system has to be bypassed because instead of a split electrode, a single return electrode is used. Therefore, the REM system cannot measure an impedance between the two electrodes and does not let the ESU turn on.

## E.2. Method

A bypass system was created by using a resistance of 47 ohm for the Valleylab and no resistance for the ERBE. A picture of this circuit is shown in figure E.2a and a systematic drawing is shown in figure E.2b below.

(a) Picture of the bypass system


(b) Schematic bypass system, based on [19]

Figure E.2: Bypass system for return electrode

The bypass system is only necessary when measurements are performed with the Valleylab Force FX. In order to perform measurements with the ERBE the resistance needs to be taken out, however, the circuit still needs to be closed.

## E.3. Conclusion

In order for the REM system within the ESUs to work it is necessary to create a bypass system. By using this bypass system the ESU is deceived and functions properly.

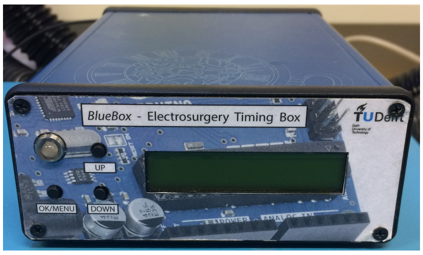
# F

# Instrument timing box

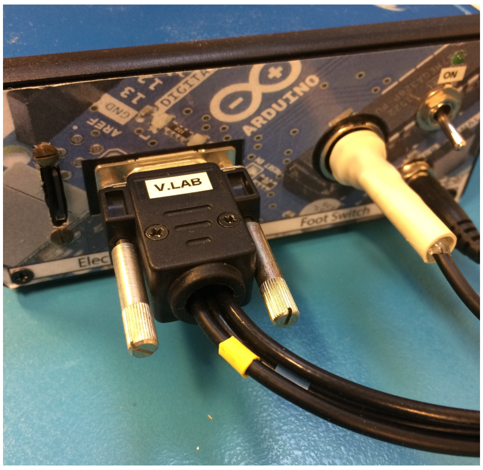
## F.1. Introduction

During experiments, it is essential to keep variables constant. One of the variables which has to be kept constant is the time that the scalpel is on during experiments. To make sure this is done properly an instrument timing box is used.

## F.2. Method




(a) Instrument timing box




(b) Connection part timing box

Figure F.1: Timing box

The instrument timing box is a box which can be connected to different ESUs and is shown in Figure F.1a. It is designed by Arjan van Dijke, technician at the MISIT lab. It consists of an Arduino which can be set to different settings. These settings are cutting, coagulation and blend. Besides this, a time can also be set. A button is connected to the instrument timing box. When this button is pressed it starts the ESU, similar to how a foot paddle would activate the ESU. This way specific times can be set for activating the scalpel. For different ESUs there are different connection parts to ensure that the timing box works properly. An example of such a connection part is shown in Figure F.1b.

## F.3. Conclusion

Making use of the instrument timing box ensures timing accuracy during the measurement, making it an essential item of the testing set-up.

# G

# Filtering thermal camera data

## G.1. Introduction

In the thermal camera data, very high peaks are found. The temperature increases and decreases with such a high slope that it is impossible for the measurement to be of tofu. Speculations about this are made after measurements with another very precise camera as described in Chapter 4.

## G.2. Method

For filtering a low- pass Butterworth filter with a cut-off frequency of 0.5 was chosen. This was done by analyzing the spectral density of the data. At 0.5 Hz the spectral density decreased a lot, for this reason, the cut-off frequency was chosen there.

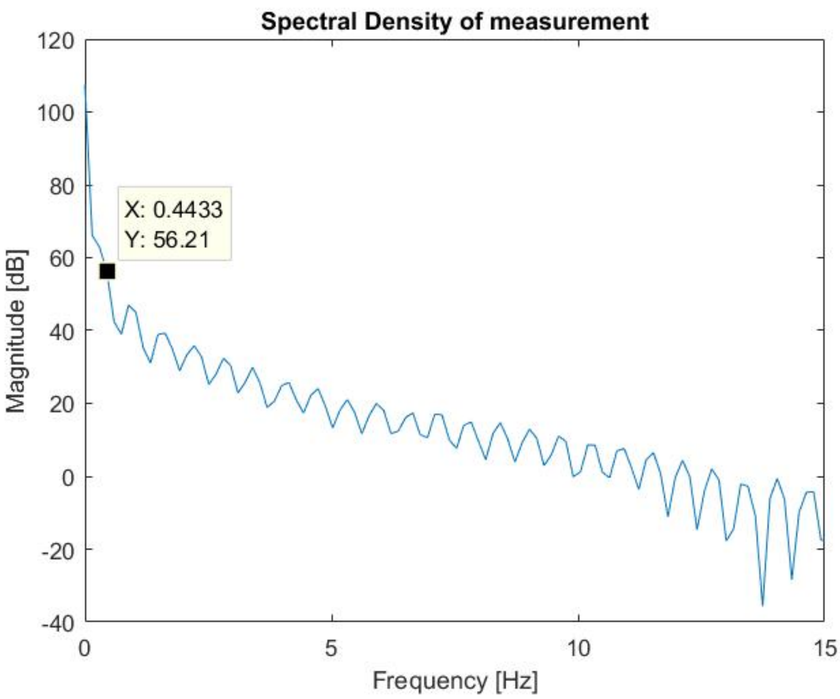



Figure G.1: The spectral density plot of one set of data

## G.3. Discussion

With this filter peaks with a very high slope were filtered and smoothed. The filtered plots follow the same temperature curve as that of the thermocouples. This is how the filter was chosen.

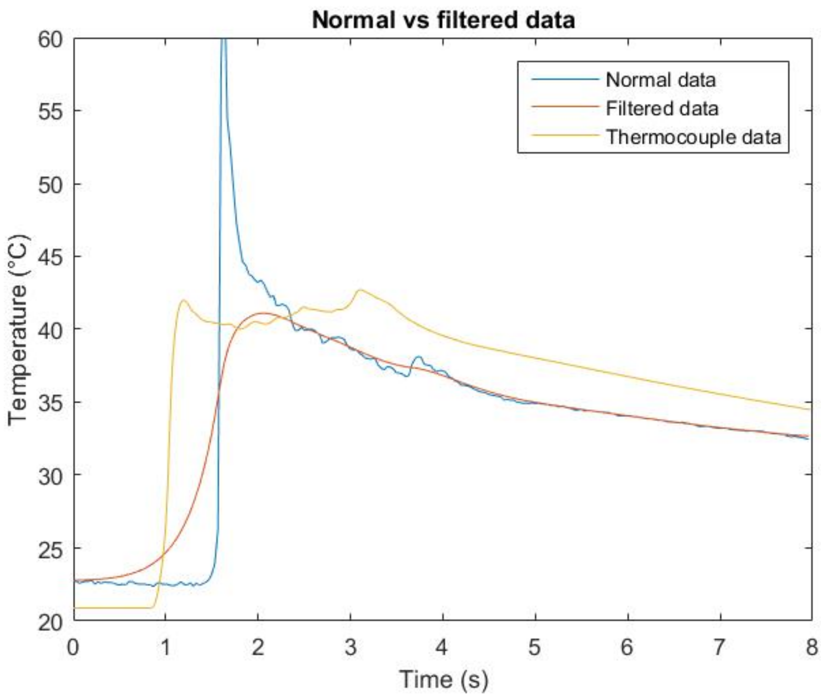



Figure G.2: Comparison of filtered, unfiltered and thermocouple data

## G.4. Conclusion

With this filter, it is possible to eliminate the sparks or gases measured on the surface by the thermal camera. However, depending on the goal of the measurement the filter can be used or not.

*“You cannot change the wind,*
*but you can adjust the sails.”*

ELIZABETH EDWARDS