A Context-specific Design of an Electrosurgical Unit and Monopolar Handheld to Enhance Global Access to Surgical Care

a Design Approach Based On Contextual Factors

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A Context-Specific Design of an Electrosurgical Unit and Monopolar Handheld to Enhance Global Access to Surgical Care: A Design Approach Based on Contextual Factors

To comply with the large global need for surgery, surgical equipment that fits the challenging environment in low- and middle-income countries (LMICs) should be designed. The aim of this study is to present a context-specific design of an electrosurgical unit (ESU) and a monopolar handheld to improve global access to surgery. This paper presents both a detailed description of electrosurgery in clinical practice in LMICs and the design of an ESU generator and monopolar handheld for this specific setting. Extensive fieldwork (by means of surveys, interviews, observations, and collection of maintenance records) was done by authors RO, KO, and LH. Feedback from users working in Kenya on the first demonstrator designs was obtained, after which the designs were adapted into conceptual prototypes. These were further evaluated by surveying respondents who attended the annual meeting of the College of Surgeons of East, Central, and Southern Africa (COSECSA) in Kigali, Rwanda in December 2018. Conceptual prototypes were developed for (a) an affordable ESU that is compact and battery powered and (b) a robust reusable monopolar handheld that can be cleaned in the autoclave and by chemicals (e.g., glutaraldehyde solution). The conceptual prototypes were positively received by the 51 respondents of the survey. The findings from the field work and the feedback from users during the design phase have led to a clear understanding of the specific needs and potential solutions. The presented conceptual prototypes need to be further developed into functional prototypes, which could be implemented in Kenya and other settings for further evaluation. [DOI: 10.1115/1.4045966]

Keywords: surgical equipment, electrosurgery, global surgery, low- and middle-income countries

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1 Introduction

There is a large unmet need for surgery in low- and middle-income countries (LMICs), as five billion people do not have access to safe and affordable surgical care for conditions, such as appendicitis, hernia, fractures, obstructed labor, and breast and cervical cancer [1]. To increase global access to surgical care, increased workforce capacity is required. However, the availability of surgical equipment is equally important to achieve these targets. Shortages of equipment for essential surgical care were identified by previous surgical capacity studies conducted in Sub-Saharan Africa [2–8]. To increase availability, medical device companies, nongovernmental organizations (NGOs), and academia are addressed in various publications to work on innovations to improve access to surgical care and medical equipment in LMICs [9,10]. Sarvestani and Sienko indicated that less than 15% of the commercially available medical devices designed for global health were targeting noncommunicable diseases (cardiovascular diseases, cancer, and diabetes), and even less were surgical devices [11]. This shows an urgent need for innovations targeting the large global need for surgery.

The context in which surgical equipment is used in LMICs differs from high-income countries (HICs). For example, the higher temperatures, eruptive power supplies, and dust demand that equipment can withstand these more challenging environments in LMICs [12]. Additionally, factors, such as lack of spare parts and consumables, limited access to maintenance, bad roads to reach rural hospitals, complex procurement systems, and limited financial resources all contribute to the complexity of using surgical equipment [1,13,14].

Design in the domain of biomedical engineering is traditionally done from a technical perspective, with a limited focus on the context of use. The context in which surgical equipment is used in LMICs is unfamiliar for the majority of biomedical engineers (BMEs) originating from HICs. What differs from traditional biomedical engineering design projects is that an extensive use of qualitative context research is required to gather and to analyze information of the context [15].

Aim of this study is to present a multidisciplinary project that the Delft University of Technology started in 2016 to design an electrosurgical unit (ESU) and a monopolar handheld to improve global access to electrosurgery by using a context-driven design approach [16]. We developed this design approach to guide biomedical engineering design teams when designing equipment for global surgery, to ensure that this equipment fits the context of use in LMICs. Additionally, design teams are encouraged to involve users during the design process to receive feedback in an early stage. The rationale to focus on electrosurgery is because it is used during almost all general surgeries. Electrosurgery is time efficient, reduces blood loss, and facilitates wound healing [17]. Moreover, the need for developments of electrosurgery for LMICs is highlighted in several publications [13,18]. Electrosurgery requires a generator, an ESU, and either a combination of a monopolar handheld and patient plate, or a bipolar handheld. In this study, we present the process of applying this context-driven design approach during the development of ESU equipment for LMICs.

2 Method

This study contains three parts: (1) a field study of the surgical context in LMICs by the use of our context-driven design approach [16], (2) the translation of the collected information into a list of design requirements that were used to design an ESU generator and monopolar handheld, and (3) an evaluation of the designs by surgeons working in Sub-Saharan Africa.

2.1 Study of the Surgical Context. A context-driven design approach for surgical equipment for safe surgery worldwide [16] that we developed was used to collect contextual factors to determine context-specific design requirements for the ESU and monopolar handheld. The contextual factors included in the context-driven design approach are: (A) type of hospitals and type of surgeries performed, (B) availability of equipment, (C) procurement, (D) infrastructure (water, electricity, etc.), (E) team composition and availability of training, (F) maintenance, (G) sterilization, (H) storage, and (I) daily usage (settings, modes, etc.).

2.1.1 Fieldwork. Qualitative and quantitative research methods were used to identify contextual factors of electrosurgery in Kenya and other African countries. Extensive fieldwork (by means of interviews, observations, collection of maintenance records) was done by the main researcher (RO, study 1, 2, and 3, Table 1).

Complimentarily, industrial design engineering master student KO conducted interviews with surgeons during hospital site visits in Kenya, gaining feedback on the demonstrator designs of the ESU and monopolar handheld (study 4, Table 1). Industrial design engineering master student LH observed the practice of electrosurgery during 14 surgical procedures in Kenya to detail the "equipment journey," meaning that every step involving electrosurgery during daily use was observed and recorded in detail (study 5, Table 1). All data, such as transcripts of interviews, notes, pictures, and survey data, were analyzed using MAXQDA 2018.

2.2 Design of an Electrosurgical Unit Generator and a Monopolar Handheld. The contextual factors that were studied based on the context-driven design approach were translated into a set of context-specific design requirements for both the ESU and the monopolar handheld. After the ideation phase, demonstrator designs (Fig. 1) of the ESU and the monopolar handheld were taken on a field trip to Kenya (study 4, Table 1) to receive feedback from surgeons in the early stage of the design trajectory. After receiving the feedback, the designs of the ESU and monopolar handheld were further developed into nonfunctional concept prototypes for further evaluation (Fig. 2). Calculations on the design and of the electrical hardware of the ESU were done in Jupyter Notebook and simulations were done in LTspice.

2.3 Evaluation. Respondents who attended the annual meeting of the College of Surgeons of East, Central, and Southern Africa (COSECSA) in Kigali, Rwanda in December 2018 were surveyed (Table 1, study 6). The surveys were conducted after the presentation of the nonfunctional prototypes during an oral presentation at the annual meeting of COSECSA, and photos of the designs were provided within the survey. Respondents were asked to indicate if they currently had access to an ESU and to score the following aspects of the redesigned ESU and monopolar handheld from 0 (lowest score) to 5 (highest score): dimensions, portability, the three different presettings for low, medium, or high voltage settings and the reusable monopolar handheld. In addition, they were asked if they will use the battery, if the provided modes (cut and coagulation) are sufficient, and if they expect this device to improve their surgical practice. Additionally, respondents were asked if they would prefer these devices over the current ESUs and monopolar handhelds currently available in their hospital and if they had additionally feedback that should be included in the design of the devices.

3 Results

To ensure that the designs of the ESU generator and monopolar handheld comply with the context of use in LMICs, this study was divided into three parts: (1) study of the surgical context, (2) design of the ESU generator and monopolar handheld, and (3) evaluation by surgeons working in LMICs (Fig. 1). A total number of 120 surgeons and 40 biomedical equipment technicians (BMETs) working in 12 different countries in Sub-Saharan Africa were surveyed or interviewed to detail the surgical context, that

Table 1 Fieldwork conducted to identify contextual factors that influence the design of the electrosurgical unit and monopolar handheld

	Type of study	Region	Date	Type of hospital	Number of participants	Published
1	Survey COSECSA[a] in Mombasa, Kenya (conducted by RO)	9 countries in Sub Saharan Africa	December 2016	10 private hospitals 14 public referral hospitals 9 public district hospitals	42 surgeons	Yes [18]
2	(a) Survey COSECSA[a] in Maputo, Mozambique (b) Survey Society of Surgeons of Kenya (SSK), Mombasa, Kenya (c) Survey of 21 biomedical equipment technicians (BMETs) (d) Collection of 36 maintenance records in Kenya (conducted by RO)	12 countries in Sub Saharan Africa	December 2016 April 2017 February–April 2018 February–April 2018	28 public hospitals 1 mission hospital 2 unknown 14 public hospitals 8 private hospitals 4 mission hospitals 2 unknown 4 public hospitals 1 private hospital 1 mission hospital 2 public hospitals 1 mission hospital	31 surgeons 28 surgeons 21 BMETs[b]	Submitted
3	Semistructured in-depth interviews (conducted by RO)	Kenya	December 2016 to December 2018	5 public hospitals 1 private hospital 1 mission hospital	17 BMETs[b]	Yes [19]
4	(a) Semistructured in-depth interviews (b) Feedback on the demonstrator designs (Conducted by KO)	Kenya	June 2018	9 public hospitals 2 private hospitals	19 surgeons 2 BMETs[b]	No
5	Observation of 14 surgical procedures (Conducted by LH)	Kenya	October 2018	1 public hospital		No
6	Survey COSECSA[a] in Kigali, Rwanda (conducted by RO)	12 countries in Sub Saharan Africa	December 2018	35 referral hospitals 5 district hospitals 2 private hospitals 9 mission hospitals	51 surgeons	No

[a]COSECSA: College of Surgeons of East, Central, and Southern Africa.
[b]BMET: biomedical equipment technician.

led to a list of engineering specifications for both the ESU generator and monopolar handheld. Fourteen surgical procedures were observed in one large hospital in Kenya. Another 51 surgeons working in Sub-Saharan Africa evaluated the designs in part 3 of this study.

3.1 Surgical Context Study. The data collected during the five different field studies (Table 1) that were conducted to study the context of use of electrosurgery in LMICs were combined, resulting in the following insights per contextual factor of the context-driven design approach.

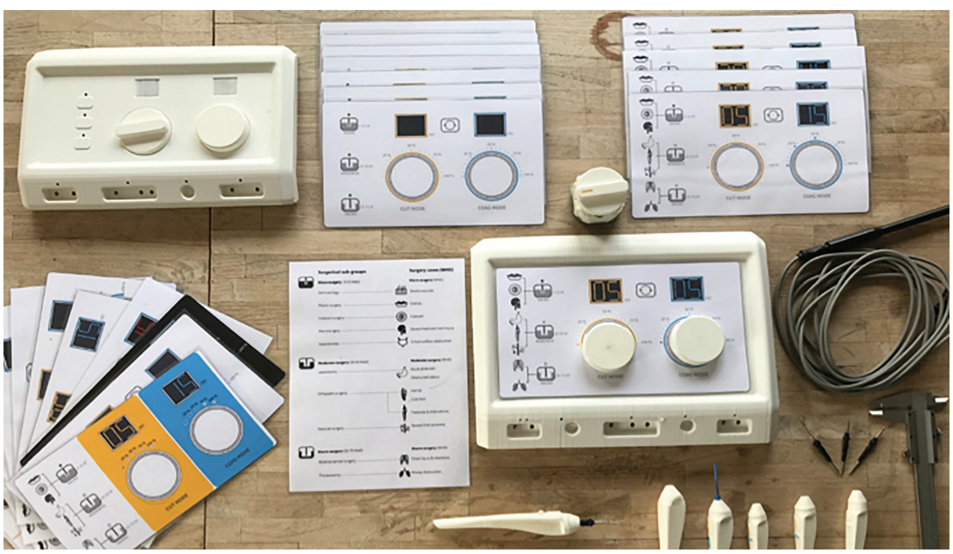


Fig. 1 Demonstrator designs of the ESU interface and the monopolar handheld that were evaluated by 19 surgeons and 2 BMETs working in Kenya (study 4, Table 1)

3.1.1 Type of Hospital & Type of Surgery. We conducted our fieldwork in Kenya in public and private (for- or not-for profit) hospitals where they had at least one operating theater (Table 1). Two surgeons mentioned different aspects concerning their daily practice that we should be aware of in our design process:

> *Most of the surgeries that I do are pediatric surgery which is around 40% of all my surgeries. This involves a lot of child surgery. From my experience each child in Africa by the age of 16 has had a surgery wherein the ESU was needed. The awareness on child surgery should therefore be highly visible in the design*. Surgeon 22, Study 4

> *Think about laparoscopic surgery as well. Within five years this will be more and more available. So, make your design flexible to make the product more sustainable and not obsolete within five years*. Surgeon 11, Study 4

3.1.2 Equipment Availability. Study 1 (Table 1) revealed that 60% of district hospitals, 75% of public referral hospitals, and 82% of private hospitals had access to an ESU. Study 2 (Table 1) showed that there was at least one working and one used ESU per hospital for all surgeons that participated. Also, all 21 BMETs that participated had access to an ESU (study 2, Table 1). This in contrast to laparoscopic equipment, which was only available for 49% of surgeons included in study 2 (Table 1).

Despite the large availability that we found, ESUs and (disposable) accessories were not always sufficiently available for every operating theater:

> *Not every theatre has an ESU, so we cannot always use the ESU for each surgery, sometimes it is already used by someone else*. Surgeon 1, Study 4

> *Mostly we just had one handheld to use for the entire day*. Surgeon 15, Study 4

> *Most times, the handheld can be used several times by cleaning them in chemicals but after a while the buttons start to break. As a solution we changed the attachment point so that we can use the same handheld by using the pedal to be able to use them a bit longer*. Surgeon 22, Study 5

At places were split-patient plate stickers were available, they were reused (study 5, Table 1). Other hospitals (study 3 and study 4, Table 1) had patient plates without a monitoring system indicating if the patient plate is not properly attached, often made from rubber or aluminum.

3.1.3 Procurement. Study 2 (Table 1) revealed that almost half of the surgeons had ESUs that were procured by the hospitals and 37% relied on a combination of both donations and procured equipment. In study 1 (Table 1), high costs were identified as one of the main barriers why equipment was unavailable. The use of disposable accessories has to be paid by the patient on top of other costs for surgery, which can result in financial difficulties for many patient groups since surgeries are often out of pocket payments (study 4, 5, Table 1). In addition, it is expensive for hospitals to obtain consumables from outside Kenya (study 3, Table 1).

During our hospital's visits, we encountered ESUs developed by large European, American, and Chinese brands. Most Chinese brands were procured by the hospitals itself; large European and American brands are often too expensive and mostly obtained by donation (study 3, 4, and 5, Table 1).

3.1.4 Infrastructure. Kenya has, like many other LMICs, an instable electricity network. Hospitals in Kenya often have a generator to provide electricity during power cuts. However, this does not mean in practice that the generator provides electricity for the entire hospital, often only for a few areas (for example, the intensive care unit and large operating theaters). In addition, voltage peaks often occur when the power goes back on, which can cause damage to equipment (study 2, 3, Table 1).

> *The power goes off frequently in rural areas so it is important to have a reset button for the last setting used. This will take away a lot of frustration of the surgeon and will reduce unnecessary damage on the tissue*. Surgeon 15, Study 4

In some areas, the electricity network is not stable enough to run all equipment, so other energy sources are used:

> *The autoclave that we use is not powered on electricity but by fire. This can result in a fluctuating temperature range*. Surgeon 19, Study 4

Donated equipment does not always match with the local power supply rating, resulting in damaged equipment:

> *For example, the user can put it in a 240 V which is supposed to run by a 110 V. As such, the power supply gets burned, when this happens the machine is not working*. BMET 2, Study 3

3.1.5 Team Composition and Training. In most of the large hospitals, the surgical team consists of the following members:

> *The surgery staff consists of the surgeon, one or two surgical assistants, one or two circulation assistants (nurses) and one anesthetist*. Surgeon 13, Study 4

However, in some rural areas, it is difficult to find health care staff. As a result, medical officers are often performing small general surgical procedures in these areas.

Limited training on electrosurgery is provided during medical school for surgeons, 45% of 59 surgeons that were included in study 2 (Table 1) were trained during their medical education. Those not receiving training learned about electrosurgery practice on the job:

> *Currently all surgeons just follow what they have learned from their supervisory surgeon. In the rural areas there is no supervisor so*

(*a*) (*b*) (*c*)

Fig. 2 Conceptual prototypes of the ESU generator and monopolar handheld

guidelines can create confidence and will prevent that the ESU will not be used as consequence of a lack of confidence or control. Surgeon 22, Study 4

During the study we just learn some basic theory and one or two practical examples. This means we are not acquainted with what power settings to use for a certain surgery. Surgeon 6, Study 4

The nurses that worked in the operating theater explained that they do not learn about electrosurgery during their education.

We do not learn a lot about electrosurgery at school, more on the job. The BMETs can teach us a lot because they know more. But I know that one needs to place the return electrode on vascularized mass and close as possible to the surgical site. Nurse 2, Study 5

Two surgeons explained that the provision of guidelines on safe electrosurgery could be helpful:

Guidelines should be positioned on the wall of the theatre, because while preparing the surgery room and the machines, we always look at the posters on the wall. Surgeon 8, Study 4

I would decide to put the guidelines attached with a chain to the ESU and put the guidelines on the cart that is used. In case they want to be sure they can take the guidelines and check them. If you would attach them to the top of the ESU they will break or eventually fall of. A pamphlet in the surgery room will also always help. So, this is a thing that you can do additionally! Surgeon 23, Study 4

3.1.6 Maintenance. Eighty percent of the in total 101 surgeons we surveyed had access to maintenance within their facility (study 1, 2, Table 1). In addition, all interviewed and surveyed BMETs performed maintenance on the ESU. Half of the 21 BMETs learned about electrosurgery during their education (study 2, Table 1). Additionally, we noticed during our field visits that BMETs have a lot of knowledge about the working principles of the devices. When new equipment is procured, they sometimes get additional training from the medical device company. However, this does not always mean that BMETs can practice maintenance work on models that can be opened up to learn how to trouble shoot in case of an error or how to replace parts (study 3, Table 1).

Based on the 36 maintenance records that we collected in three large hospitals in Kenya (study 2, Table 1), we identified that most of the maintenance was related to the soldering of parts of the accessories (7 out of 20 maintenance records on the accessories). However, when the ESU generator required repair, this sometimes (4 out of 13 cases) could not be repaired by the BMETs themselves. In addition, all 21 BMETs (study 2, Table 1) indicated that accessories (cables, connectors, patient plates, and monopolar handhelds) break easily. Additionally, more than half (57%) of 21 surveyed BMETs indicated that power boards of the ESU generator are prone to breaking. We found that BMETs perform relatively more in-house repairs on the ESU than, for example, on laparoscopic equipment. Laparoscopic equipment is often too delicate and requires a servicing contract with the medical device company. An electrical analyzer can be used to evaluate the functioning of the ESU, for example, to measure the current leakage. However, there are no electrical analyzers in most of the hospitals in Kenya, only one large hospital that we visited had access to one.

Suggestions for the design of a new ESU generator given by the 21 BMETs that we surveyed included:

- Prevention of insulation failure of the handhelds
- Reduce the number of printed circuit boards in the generator
- Separate power supply boards for easy diagnosing. Power filters should be easy to procure from local stores.
- Install power stabilizers into the equipment for protection during large power peaks

3.1.7 Sterilization. The ESU accessories that are in contact with tissue need to be sterile. Many hospitals in HICs use disposable one-time use ESU accessories. However, 24% of 59 surgeons in our survey mentioned that they reuse these disposable accessories as much as possible (study 2, Table 1), mostly because of financially and structural barriers. It is difficult to get the ESU accessories in some countries (study 2, 3, Table 1). We noticed during our field trips that only a small number of hospitals had reusable accessories. The disposable accessories cannot withstand the high temperatures in the autoclave and are therefore cleaned by heavy chemicals (including cidex).

We use the autoclave during the whole day, but when you quickly need a handheld, we always use cidex detergent. Surgeon 1, Study 4

There are some problems with getting the cidex out after usage because there is not a long drying time. They normally shake the handheld to get the water out. Surgeon 10, Study 4

The sterilization room is far from the theatres, so in a lot of cases the accessories are cleaned quickly to reuse a handheld that has been used in the surgery prior to the new surgery. This is a fast method to sterilize the handheld (10 min). However, there are problems with electricity and the liquid that stays in the handheld. The risk of this is that the high-power settings can cause insulation failure in the cables as well as the exterior of the handheld. It happened that a hole was blown in the exterior after frequent sterilization. Surgeon 1, Study 4

3.1.8 Storage. During our field visits, we noticed that equipment was placed on the floor, chairs, tables, or in the windowsill. The patient plate was frequently kept close to the ESU; however, the cables were often still on the floor and hospital beds were moved over these cables frequently.

Two surgeons described why the ESU should be compact:

The ESU should be as small as possible because we do not always have a good table for this. Surgeon 19, Study 4

The ESU is moved a lot from place to place so it should be small, light and have a handgrip. Surgeon 15, Study 4

3.1.9 Daily Usage (Settings, Modes, Etc.). The 59 surgeons that participated in study 2 (Table 1) mostly used coagulation (100%) and cut (97%) as settings to perform their surgeries. Twenty-six percent only used the ESU in monopolar mode, 5% only in bipolar, and 68% used both modes. Sixty percent indicated that they experience complications during use, burns were encountered by 27%, and electrical shocks by 12% (study 3, Table 1). During our conversations with surgeons and observations, we noticed that the most frequently used settings were between 20 and 50 W. Also, a few surgeons used higher settings (more than 70 W) to perform certain procedures (study 4 and study 5, Table 1). Most surgeons were aware that they should use the lowest settings as possible and adjust the settings according to the tissue response.

Coagulation and cut are more than sufficient for the surgeries in Africa. Surgeon 4, Study 4

The surgeon checks the power setting by seeing the reaction on the tissue. When the cut function does not do much, they will increase. When there is too much smoke they will decrease. Most times, the power setting will stay the same for the rest of the surgery. Surgeon 23, Study 4

Most times when I use high power is when the machine is not working properly. I can see this within this hospital that I use way more higher power settings than in the other hospital where I work. The power setting for a surgery should always start as low as possible. Surgeon 5, Study 4

You should only focus on the spatula electrode because this electrode is mainly used and is multifunctional. Normally we do not like to change electrodes during the surgery so if you focus on one please focus on the spatula electrode. Surgeon 23, Study 4

When the power needs to be adjusted during surgery, this is often done by the circulation assistant (nurse). Two surgeons explained why a clear display is important:

Sometimes the ESU is positioned on a chair lower than the bed, which makes it harder to see the ESU interface and the power setting. So, it is highly important that this is properly visible. Surgeon 5, Study 4

The display should be visible from at least two meters away, I want to check if the power setting has changed. Surgeon 8, Study 4

We described in detail the equipment use during each step when electrosurgery was used, based on 14 observations in Kenya (study 5, Table 1). This resulted in 84 steps (during procurement, presurgical treatment, surgical treatment, postsurgical treatment, maintenance, repair, and disposal) revealing details of electrosurgery in clinical practice. It was also during this study that the input on electrosurgery practice of (circulation) nurses was obtained and that the involvement of anesthetists and cleaning staff was observed. The entire equipment journey can be accessed via the footnote.[2]

Overall, detailing the equipment journey revealed that the nurses are mostly responsible for the installation of the ESU and the accessories prior to surgery, and it revealed the following issues: improper placement of the patient plate, a missed alarm sound given by the ESU, the cleaning of monopolar handhelds in chemicals that are not properly dried, delays during surgery because a monopolar handheld suddenly does not function anymore, and reuse of the patient plate sticker. Although these aspects were also identified during studies 1–4, the equipment journey provides information on the specific phase during use of electrosurgery during which they occur, and revealed which users are involved during each phase of the equipment journey.

3.2 Designs of the Electrosurgical Unit Generator and a Monopolar Handheld. Based on the surgical context study, we developed a context-specific set of design requirements for the ESU generator (Table 2) and the monopolar handheld (Table 3).

3.2.1 Demonstrator Designs. After establishing the context-specific set of design requirements, the following two design directions were chosen:

- An affordable ESU generator that is compact, has a clear user interface, and is battery powered and can be operated in both cut and coagulation mode, and
- A robust reusable monopolar handheld that can be cleaned in the autoclave and by chemicals.

During the ideation phase, several demonstrator designs for the ESU and the monopolar handheld were generated (Fig. 1). Two rotating buttons to control the power levels for both cut and coagulation, together with a division of the power between 0 and 70 Win three different levels (micro, moderate, and macro), were chosen as a base for the interface of the ESU generator. For the monopolar handheld, a pen-shaped design with two different buttons, both in terms of color and orientation, were chosen as a base for the design of the monopolar handheld. Several mock-up models were developed and evaluated with 19 surgeons and 2 BMETs working in Kenya (Table 1, study 4).

3.2.2 Evaluation Demonstrator Designs

ESU generator interface. Comments given on the two rotating buttons to adjust the settings included:

+ *Having a limited bandwidth within a subgroup will be a great safety precaution for wrong power setting by the circulation assistance.* Surgeon 13, Study 4

+ *There will be more awareness and attention when moving to another subgroup.* Surgeon 15, Study 4

± *The maximum macro power that you used is rarely used. For adults I go maximum up to 70 W if I need to cauterize the liver (a lot of blood). Normally I will not go higher than 50 W. Macro is now according to your design a generic setting that is normal to use. Create more precaution for this subgroup to avoid for it to become normal to use.* Surgeon 22, Study 4

± *Creating a distinction between the cut and coagulation mode by adding color will make it easier to see what mode has been changed and can be better understood by the surgical assistance.* Surgeon 8, Study 4

Monopolar handheld. Comments given on the pen-shaped monopolar handheld included:

+ *The pen shaped grip in the handheld will maintain grip when activating the handheld and when the rubber gloves are wet. Most handhelds will start to slide away when the rubber gloves are wet which increases the risk to drop them and does not give the feeling of confidence and precise examination of for instance a cut.* Surgeon 23, Study 4

+ *I really like to hold the handheld like this with this design. It is actually really comfortable and gives me good grip when I hold it as a pen. It makes me feel more secure that the handheld will not drop.* Surgeon 13, Study 4

+ *It is very nice that your buttons have a different sensation that means that when my fingers are used to the difference I will not have to check the button colors and I can keep my focus on the surgery. This will ensure less checks.* Surgeon 14, Study 4

+ *What is a really important advantage of your handheld is that you have a controlled feeling in the hand. During the surgery my gloves often get wet and with the smoother surfaces' handheld, for instance rounded once they often slide out of the hand so I will have to dry my hands a couple of time during the surgery.* Surgeon 19, study 4

3.2.3 Conceptual Prototypes of the ESU Generator and the Monopolar Handheld. The demonstrator designs were further finalized into conceptual prototypes of both the ESU and the monopolar handheld (Fig. 2), incorporating the feedback obtained from surgeons working in Kenya.

ESU. The design of the ESU consists of an interface with two large rotating buttons, which can be used to adjust the power for both cut (left (in yellow)) and coagulation (right (in blue)). Two light-emitting diode (LED) screens provide the currently used power setting of the device and in case of failure, error codes will be displayed to assist health care staff and BMETs. These LED screens are bright enough to be read from a distance of three meters and a view angle of 30 deg. On the left side of the interface, the user can choose between three different presettings for the output power, low (5–25 W), medium (30–50 W), or high (50–70 W). The rotating buttons can be used to adjust the setting of cut and coagulation within this bandwidth of the three different presettings of the output power (low, medium, or high) in steps of 1 W. When the device is switched on, it will always be set to the lowest setting (5 W), the reset button in the middle of the two LED displays can be used to set the device back to the previous used setting. The rotation button has no maximum rotation angle as seen in potentiometers. Consequently, this enables software to start at to the lowest power setting when the device has been switched off.

The connections for the patient plate, both monopolar and bipolar electrodes, and the foot pedal are placed on the bottom of the device. Prior to the surgery, the interface will instruct the surgical team when connecting the accessories by blinking LEDs above the ports. Once the accessories are appropriately attached, for instance, in case of monopolar electrosurgery, the return electrode and the monopolar handheld, the subgroup LEDs will start blinking.

The ESU is designed for cutting and coagulation, so the wave generator used in the design provides two different alternating currents: a continuous waveform for cutting and an intermitted waveform for coagulation. For both modes, the maximum output voltage is set to 70 W. The electrical hardware (Fig. 3(*a*)) consists of two parts: the power supply board and the main board (with the

[2]https://projects.invisionapp.com/share/7DQ2GTEQGJB#/screens/342674421

wave generator and microcontroller). The two boards can be replaced separately, when maintenance is required. The power supply board includes a power stabilizer that is compatible between 85 and 164 AC power (VAC) (and for 15 s at 300 VAC) and 45–65 Hz. The 2×12 V 0.8 Ah lithium batteries provide enough energy to continue working for 90 min, including at least 9 min of activation on the highest power setting of 70 W. The main part of the electrical hardware consists of a microcontroller and custom-built wave generator. Transformers will be used to control the power output with changing impedances of tissue. The microcontroller will be programmed to control: the output of the wave generator (cutting or coagulation), LED lights, alarms during activation and in case of an error and the rotating buttons. In addition, the temperature, the current leakage between the source and the load (to prevent unintended burns because of direct coupling), and the resistance between both sides of the split patient plate will be measured and the ESU will stop functioning when an unwanted situation occurs. A heat sink is used for cooling of the device. Also, all components are able to operate between temperatures of 0 and 60 °C. All components, except the custom-built

Table 2 Context-specific design requirements for the ESU generator

Design requirements ESU generator	Engineering specifications	Rationale
Portable	• Contain a handle • <8 kg[a]	The ESU generator must be easy to move between operating theaters due to insufficient numbers of devices per hospital *(contextual factor B, H)*
Durability	• Lifetime of the device >5 years • Casing made from 100% nonabsorbent material • Able to operate at temperatures between 10 and 45 °C and 0–90% relative humidity[b] • Resistant against high ambient dust in rural operation theaters and a possible drop of water on the exterior (IP54)	The ESU generator must function in operating theaters that do not have temperature or humidity control systems *(contextual factor D and F)* The ESU generators must withstand cleaning with water and chemical solutions that are used to clean the device in between surgeries or at the end of the day *(contextual factor I)*
Safe and efficient use	• Power 0–70 W • Cut and coagulate • Monopolar and bipolar mode • Power stabilizer (AC/DC converter)[c] • Audible alarm when patient plate is not properly attached • Audible indication when activated Clear interface that can be read from 3 m distance of the device Consistent power delivery with changing tissue impedance[d] • High quality components of manufacturers that are ISO9001 certified or have a history of Conformité Européenne (CE) marking	The ESU should operate with a power up to 70 W, since this is the maximum power used in clinical practice according to our participants *(contextual factor I)* The ESU generator must operate in cut and coagulation mode, since these are sufficient to perform majority of surgeries according to our participants *(contextual factor I)* The ESU generator must be able to withstand large power fluctuations since the electricity infrastructure in many LMICs is unstable *(contextual factor D and F)* The ESU generator must contain an interface that enhances intuitive use since not all staff are properly trained on installation and use of the ESU generator *(contextual factor E an I)* The ESU generator must comply with CE marking regulation *(contextual factor C)*
Battery powered	• Battery required for 90 min inactive use, 5 min of active use at largest power setting (70 W)[e] • Compatible with 100–240 VAC and 50–60 Hz[f] • Compatible with airplane regulations on batteries	The ESU generator must accommodate the variety of electricity infrastructures from LMICs that can contain large electricity peaks *(contextual factor D)* The ESU generator must be enable use during power interruptions *(contextual factor D and I)*
Easy to maintain	• Easily replaceable power board Clear error codes for maintenance issues	BMETs must be able to provide in-house maintenance on the ESU generator avoiding timely out sourced repairs *(contextual factor F)*
Low costs	• 0–1500 US dollar[g]	The ESU generator must be affordable and should not cost more than competing models from China *(contextual factor C)*

[a]The dimensions and weight of a Valleylab Force Fx were chosen as benchmark values, participants indicated that they were able to carry this device from one operating theater to the other, but larger than this will become difficult for one person [20].
[b]Chosen according to publication of Neighbour and Eltringham [12]and Forrester et al. [21] and the World Federation of Societies of Anaesthesiologists (WFSA) performance standards for anesthesia equipment for LMICs [22].
[c]Chosen according to our own data supported by the publication of Neighbour and Eltringham [12].
[d]The resistance in the human body can differ from 25 Ω to 4 k Ω and full power should be delivered over the entire resistance span. During use of the ESU, the resistance will vary a lot when different type of tissue is cut. It is preferred to keep the power that is delivered to the load (tissue in this case) as constant as possible to enhance optimal use. The voltage needs to be regulated according to the Ohm's law in order to keep the output power, the same, by a changing resistance [17].
[e]Meeuwsen et al. [23] indicated a mean activation time of 2.5 min of the ESU during laparoscopic cholecystectomies performed by experience surgeons during procedures with an average time of 44 min. According to the WFSA performance standards, procedures should be able to continue for at least 90 min.
[f]According to the publication of Forrester et al. [21].
[g]This amount was specified based on experience of our participants that indicated that this is the price range of equipment that is currently procured and is manageable by the hospitals (study 4, Table 1).

Table 3 Context-specific design requirements for the monopolar handheld

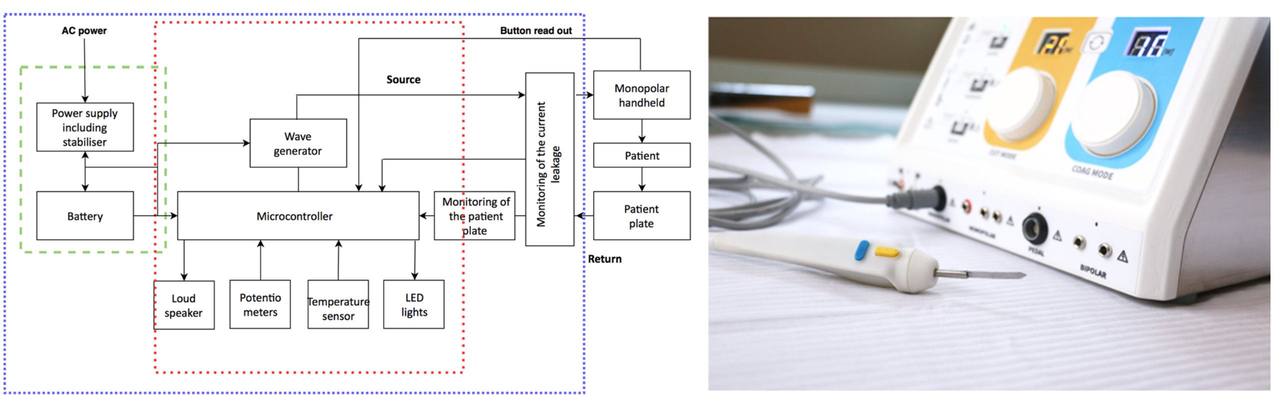
Design requirements monopolar handheld	Engineering specifications	Rationale
Compatibility should be ensured with different ESU brands that are currently on the market	• Standard 3 plug for monopolar handheld • Monopolar handheld should be button activated and compatible to work with a foot pedal	The monopolar handheld must contain a standard 3×4 mm banana plug connector that is used by large international brands, since hospitals have various brands of ESU generators *(contextual factor B, C, and I)* The monopolar handheld must be activated by a button because it is mostly preferred by the participating surgeons, but in case of failure of the buttons, compatibility with a foot pedal is desirable *(contextual factor B and I)*
Reusability	• Scapula electrode • 100% noncorrosive material • Compatible with heavy chemical cleaning solutions (such as glutaraldehyde solution and chlorine) • Withstand temperature of the autoclave >150 °C • Watertight design of the handpiece to prevent corrosion of internal components	The monopolar handheld must contain a scapula electrode that is sufficient for most general surgeries *(contextual factor I)* The monopolar handheld must withstand cleaning by sterilizers, and for when accessories or sterilizers are of limited availability, they must withstand cleaning by heavy chemicals *(contextual factor B, F, G and I)*
Durability	• Cables with at least two isolation mantels • Strain relief between the connections of the handheld and the cable and the connector to the ESU • Tip of the instrument can be replaced when contaminated with eschar	The monopolar handheld must withstand the fact that hospital beds are moved over cables *(contextual factor H and I)* The monopolar handheld should be designed as such that repair of the connection points between the handheld and the cable is not necessary *(contextual factor H)*
Low costs	• 0–50/100 U.S. dollar[a]	The monopolar handheld must be affordable and should not cost more than competing models from China *(contextual factor C)*

[a]This amount was specified based on experience of our participants that indicated that this is the price range of equipment that is currently procured and is manageable by the hospitals (study 4, Table 1).

wave generator, are made by high quality manufactures with ISO9001 certification and a history with CE marking that have distributors in Kenya and other African countries.

The heaviest part of the internal hardware are the power stabilizers, the batteries, and the heat sink: with a combined weight of approximately 4 kg. The dimensions of the device including a handle to tilt the device that is placed on the backside (Fig. 2) will allow for transport between operating theaters. A raster to provide cooling to the device is placed inside the handle to prevent water and dust getting in. The exterior is made from acrylonitrile butadiene styrene and stainless steel, which are 100% nonabsorbent and therefore able to withstand cleaning by chemicals [24]. The interface made of a polycarbonate foil is highly reliable and resistant against the cleaning detergents that are used for cleaning. All ink of the symbols and text is applied on the back of the polycarbonate sticker and cannot be harmed by excessive use. Besides, the sticker ensures a dust free seal since the buttons are integrated in the foil.

Monopolar handheld. The monopolar handheld has a pen-shaped design with two buttons, one in the front for cutting (yellow) and one behind for coagulation (blue) that are placed in a



(*a*) (*b*)

Fig. 3 (*a*) Flowchart of the electrical hardware of the ESU (in the round dotted square) containing the power supply board (rectangled dotted square) and the main board (in the square with squared dots) and (*b*) Nonfunctional conceptual prototypes of the ESU and monopolar handheld that were used for further evaluation of the designs. * A redel connector was used for this prototype since it was easily available during the manufacturing of this prototype, the 3 × 4 mm banana plug will be used for future prototypes.

different orientation. The handheld consists of two parts, the pen and the tip. The tip can be replaced, for example, when too much eschar has built up. The monopolar handheld is designed as such that when the handheld is laid down, the tip will not come into contact with the surface, in case the ESU is accidentally activated. The monopolar handheld has a watertight design, allowing it to be cleaned in one piece for reuse. The tip is made from stainless steel. It was chosen to use a strain relief connection made from polymers between the handheld and the cable to ensure durability and to make the design watertight. Materials used for the pen should be highly resistant against chemicals and high temperatures, as, for example, polysulfone. The monopolar handheld has a connection with 3×4 mm banana plugs, similar to the design of commonly used international brands.

Conceptual prototypes. We have developed the designed into nonfunctional conceptual prototypes with working LED lights to demonstrate what we envision for the design in the future (Fig. 3(*b*)). Due to budget constraints, it was not possible yet to build full functioning prototypes including the electrical hardware.

3.3 Evaluation of the Electrosurgical Unit and Monopolar Handheld by Surgeons Working in Sub-Saharan Africa. A total number of 51 surgeons participated in our survey to evaluate the design of the ESU generator and the reusable monopolar handheld (Table 1, study 6). Surgeons represented hospitals in Angola (1), Botswana (1), Cameroon (1), Congo (2), Ethiopia (4), Kenya (20), Malawi (2), Uganda (3), Rwanda (10), Tanzania (2), Zambia (4), Zimbabwe (1) and one surgeon specified to work in various countries. More than half ($n = 35$) of the surgeons worked in referral hospitals, 5 in district hospitals, 2 in private hospitals and 9 in NGO/mission hospitals.

Forty-seven (94%) of the participants currently had access to an ESU in the hospital they work in, three respondents had no access, and one did not respond to this question. Of the 46 participants that responded to the question if they would prefer this prototype over the current ESU, they have in their hospitals, 40 participants (87%) responded with yes. Table 4 shows the rating participants gave to different aspects of the conceptual prototypes. The participants indicated to especially like the use of reusable accessories (score of 4.6 out of 5), followed by the portability of the device (4.5 out of 5).

4 Discussion

Despite the large global need for surgery, only a few efforts have been made to develop surgical equipment specifically targeting this specific need for surgery in challenging environments in LIMCs. The goal of this paper was to design a context-specific ESU and monopolar handheld to increase global access to electrosurgery. To ensure that the newly designed ESU and monopolar handheld comply with the context of use in LMICs, we used the context-driven design approach that we developed [16]. By the use of quantitative and qualitative research methods (surveys, interviews, and observations) in Kenya and other African countries, we collected contextual factors influencing use. We translated these findings into context-specific design requirements and into new designs of both the ESU and the monopolar handheld. The conceptual prototypes were evaluated by surgeons attending a large surgical conference in Rwanda in December 2018.

Within this project, adaptations to conventional designs of the ESU and monopolar handheld were made to design context-specific surgical equipment that complies with the context of use in LMICs. To overcome current barriers to use, we have designed: (1) an ESU that is portable and has a clear user interface and a backup battery for at least 90 min of usage and (2) a robust reusable pen shaped monopolar handheld and that can be cleaned in the autoclave and by heavy chemicals. Current ESUs available on the market are expensive, difficult to maintain and have complex interfaces. In addition, there are, to our knowledge, no ESUs on the market that are battery powered. Chawla et al. reported that in 21 LMICs, less than two-thirds of the hospitals had access to a continuous electricity source or a generator, demonstrating the wide impact that battery-powered surgical equipment might have [25].

As reported before [1,13,26], we also identified the reuse of disposable monopolar handhelds during our fieldwork. Reusable monopolar handhelds are available on the market, often with a disposable tip. These reusable monopolar handhelds are

Table 4 Average ratings and comments on the conceptual prototypes given by 51 surgeons participants in this study

Comment on the device	Average rating by the participants (0 = lowest, 5 = highest ranking)
I like the dimensions of the prototype	4.3
I like the portability of the prototype	4.5
I will use the option to operate the device on a battery	3.8
I believe that cut and coagulation (both monopolar and bipolar) are enough to perform most of the surgeries	4.3
The three different presettings for minor, moderate, and major surgery will help me to select the right setting	4.0
I would like to use reusable accessories (that are intended to be reused)	4.6
I believe the device could improve the way I perform surgery on a daily basis	4.3
Comments on the devices	**Excerpt**
Back-up power	*It is portable and can be used in rural areas without electricity, perhaps look into incorporating solar for remote areas without stable power*. Participant 16
Reusability	*The reusable aspect of the monopolar handheld is the main appealing component*. Participant 32
Back-up power	*Battery mode is a game changer*. Participant 39
Robust	*Will it stand when dropped by 1 m?* Participant 41
Portability	*Can it come with a portable light weight foldable stand?* Participant 7

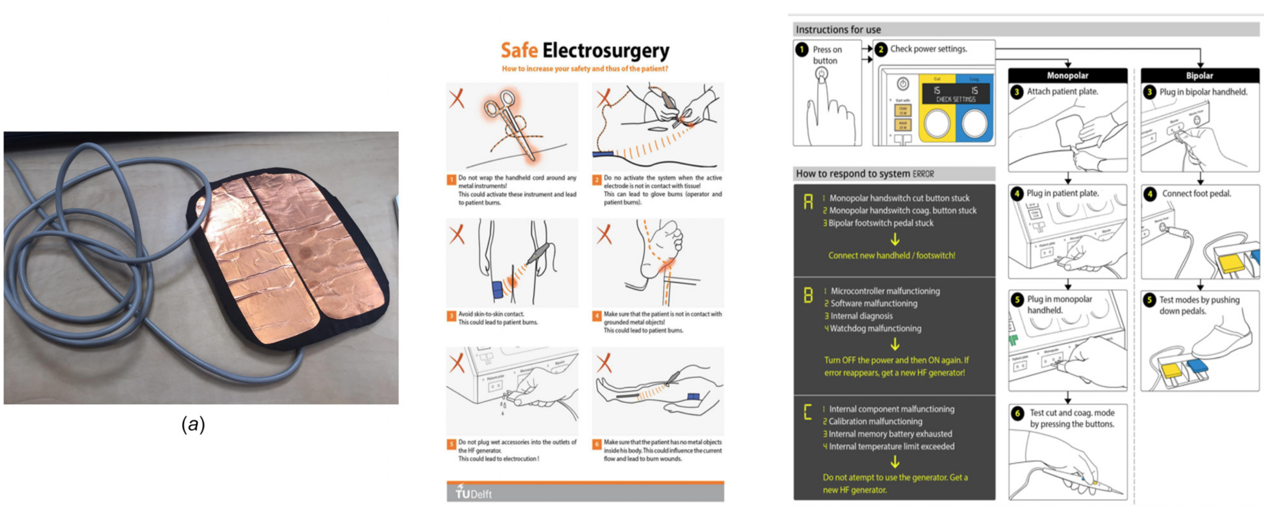
expensive, prone to breaking (especially the cables) and do not, based on the experiences of our participants, withstand cleaning by heavy chemicals. Reuse of both, disposable and reusable, monopolar handhelds by cleaning with heavy chemicals can lead to insulation failure possibly leading to unintended burns [17] or electrical shocks. Some commercially available reusable monopolar handhelds have to be dismantled before cleaning, resulting in parts that get lost, leading to unavailability of the equipment. We have chosen to focus on durability for the design of the monopolar handheld rather than its reparability, because to support maintenance, adaptations had to be made that would reduce its durability. We have, therefore, chosen to focus on a durable design that when overused or broken will need to be replaced in total.

Besides the introduction of a battery and the design of a durable reusable monopolar handheld, other features to increase global accessibility of electrosurgery were introduced as well. First, an interface with two rotating buttons and three different presettings for the power output was designed, ensuring that the power can only be adjusted within the bandwidth of the selected category (low, medium, or high). The use of the presettings will ensure that users are more aware of using higher power settings because they actively have to move to the higher presetting. Second, the interface aims to provide guidance for the users during installation of the ESU, by the blinking LED lights on the interface. Thirdly, to enhance in-house maintenance performed by BMETs, it is easy to dismantle the ESU, and the power board is a separate component that is accessible if replacement is required. Maintenance will be supported by error codes that are displayed in the LED screens and will be explained in the manual of the ESU. Previously described adaptations can be especially helpful for users with limited training on how to use electrosurgery. Additionally, a pen-shaped monopolar handheld was designed, which provides more grip while holding the handheld with wet gloves and prevents contact with tissue or other materials when laying down, while not in use. Finally, the different orientation of the two buttons on the monopolar handheld provides feedback to the user during activation of cut or coagulation. These adaptations could be useful in any setting worldwide. The use of a power stabilizer and battery, and the choice for materials that can withstand cleaning by heavy chemicals are features that are probably not valuable in HICs, but can have a large impact in LMICs.

In addition to the designs presented in this paper, we are working on the development of a reusable patient plate that supports safety monitoring system in ESU generators that are currently available on the market (Fig. 4(*a*)), guidelines for use (Fig. 4(*b*)) and installation that can be placed on top of the ESU, a poster with safety instructions for use in the operating theater (Fig. 4(*c*)), and a manual that explains the error coding displayed on the LED-screens. Future projects will involve the design of a cart to store and easily transport the ESU between operating theaters and a drying tripod for the monopolar handhelds after cleaning by chemicals. Another increasing unmet need is the development of low-cost robust laparoscopic equipment, to enhance widespread implementation of laparoscopic surgery. Within the department of Bio-Mechanical Engineering of the Delft University of Technology, recently some projects started to develop affordable laparoscopic equipment. We see this project as a first step in this direction, since the ESU is an essential equipment also for laparoscopic surgery. Additionally, we believe that many of the insights obtained during the various field studies will be very valuable during these future design projects.

The next step is to build the designs presented in this study into working prototypes for further evaluation. The design requirements seem technically feasible and we also expect to stay below the maximum costs for the device. However, working prototypes that can be evaluated in a lab setting and clinical practice are required to ensure that all context-specific design requirements are met. Heat simulations should, for example, be conducted to determine whether a heat sink provides sufficient cooling for the temperatures reached in LMICs, or if a carbon heat pad should be included. Additionally, the number of times that the monopolar handhelds can be safely reused and if a battery backup time of 90 min is sufficient enough to bridge power interruptions should be tested in clinical practice. In addition, acceptance by users and if the device can be maintained by BMETs should be evaluated. Based on the feedback we received during the evaluation of the nonfunctional prototypes, we should consider renaming the different presets from low, medium and high into: low, standard and high to avoid unnecessary use of high voltage settings.

This was the first design project that used the context-driven design approach to research contextual factors influencing context-specific surgical equipment. Sarvestani and Sienko showed that engaging end users in the design process is essential to ensure successful adoption [11]. Mohedas et al. also showed that a combination of different qualitative research methods is valuable to collect contextual factors during design projects [27]. We provided a practical example of the context-driven design approach and the contextual factors that we studied in this design project through surveys, observations, and interviews in Kenya and other African countries. The data collected during the first



(*a*) (*b*) (*c*)

Fig. 4 (*a*) Reusable patient plate including a safety monitoring system, (*b*) guidelines on safe electrosurgery that are developed in addition to the ESU and monopolar handheld, and (*c*) poster with instructions for use

three field studies (Table 1) led to the preliminary list of context-specific design requirements; this was a solid base to develop the demonstrator designs of the ESU and monopolar handheld. These were used to get feedback from surgeons working in Kenya (study 4, Table 1) in the early stage of the design. Studies 4 and 5 (Table 1) were used to finalize the context-specific design requirements that were used for the conceptual prototypes. The design requirements were for a large majority based on input from both surgeons and BMETs, and to a lesser extent by nurses and other healthcare professionals. We believe that users of the context-driven design approach that we used in this study should be encouraged to include a wide variety of healthcare workers while studying the context. Detailing the equipment journey, as was done during study 5 in this paper, has shown to be a great tool in identifying all different healthcare professionals that are involved during equipment use.

The first evaluation of the conceptual prototypes by the 51 surgeons showed that 87% preferred the redesigned ESU and monopolar handheld over the equipment they currently have in the hospital they worked in. The portability of the ESU and the reusable monopolar handhelds received the highest scores of the respondents (4.6 and 4.5, respectively). This indicates that the ESU and monopolar handheld are expected to be adopted by end users. However, this needs further evaluation by implementation of working prototypes in hospitals in different LMICs. This further evaluation is especially required since the respondents of the evaluation study were surveyed after an oral presentation without the possibility to test case the nonfunctional prototype, meaning that this evaluation study showed a positive response on the first impressions of the nonfunctional prototypes. Additionally, these results can also be partly influenced by respondents' biases or socially desirable answers that were given to our questions regarding the acceptability of the device. Future research with functional prototypes in clinical practice in LMICs and evaluation done, for example, by structured interviews is therefore highly recommended.

The high front-end costs for the developments of the prototypes were an important barrier during the design project described in this study. This barrier needs to be overcome to move to next phases of obtaining CE or U.S. Food and Drug Administration certification, manufacturing, testing, and widespread implementation. There are different routes for implementation of context-specific surgical equipment that should be explored when proceeding with the development of the context-specific designs presented in this study. Either via a route such as done by Diamedica (Devon, UK), Arbutus (Vancouver BC, Canada), Lifebox (London, UK), or SISU Global Health (Baltimore, MD), that are examples of enterprises and NGOs that developed and distributed equipment on a large scale for medical needs in LMICs. Or in collaboration with large medical device companies (such as Philips, General Electrics, and WISAP) have a few products that are specifically targeting LMICs. Other medical device companies are currently leasing equipment to hospitals in LMICs, where they provide servicing and have contracts whereby hospitals buy a fixed number of consumables on a yearly basis. Emmerling et al. propose a pay-per-use model to ensure that both the medical device company and the hospital share responsibility in that equipment is used [28]. This is, to our knowledge, currently not done by any medical device company and could be an interesting test case. Some medical device companies directly sell equipment to hospitals; however, the role of distributors cannot be neglected when aiming to implement equipment in LMICs. Especially since we expect difficulties in patenting the designs presented in this study, it is key to start collaborations with the right (commercial) partners to ensure that the designed surgical equipment will reach hospitals in LMICs in the way it was intended during the design process.

We envision the context-specific designs presented in this study as a set of surgical equipment that is bought by the hospitals with a certain number of reusable accessories, depending on the number of operating theaters and surgeries performed on a daily basis. A strong relationship between the user and the medical device company must be established to ensure the supply chain of the accessories. Additionally, BMETs should be able to contact the device company for large repairs. Calibration devices that are required to check, for example, if the voltage of the ESU is still in range, were not available in the hospitals that we visited. An affordable calibration device should be developed and, in the meantime, the medical device company should ensure that these checks will be done on a six monthly or yearly basis. We hope that when the designs of the ESU and monopolar handheld are available on the market, they will eventually be adopted by surgical organizations such as COSECSA and SSK and will be included in the compendium of technologies for low resource settings that is issued by the World Health Organization.

We provided a list of context-specific design requirements for the ESU, which can hopefully be used in other design projects as an example. This list, which shows to a great extend similarities to the list of design requirements published by Forrester et al. [21] (Lifebox) on a context-specific surgical headlight, could be a starting point of a general list of design requirements for surgical equipment in LMICs to guide procurement, design, and implementation. The World Federation of Societies of Anaesthesiologists (WFSA) published a general list of performance standards for anesthetic equipment in LMICs for the same purposes [22]. Organization such as the World Health Organization or COSECSA, together with biomedical engineers, should take the lead in establishing of standards for surgical equipment for safe surgery worldwide. Research on the implementation of our designs and the surgical head light of Lifebox could support in the developments of these standards.

Despite the assumption that all context-specific design requirements presented in Tables 2 and 3 are technically feasible, it is a limitation of this study that we were not able to build full functioning prototypes of the designs. In the future, users and BMETs should evaluate the design while using them in clinical practice. Contextual factors were collected in areas where ESUs are already implemented, and the use of our designs in locations without previous experience with ESUs should be evaluated, to indicate how successful translation between different settings in LMICs is.

We hope that this paper can provide an example to other design teams that are working on innovations for surgical, or other medical equipment, for LMICs. Within the Biomechanical Engineering department of the Delft University in the Netherlands, other projects have started on the design of a video laryngoscope and equipment for laparoscopic surgery, using a similar approach. We hope that successful implementation of the presented designs in this study marks the start of increased global access to electrosurgery, and paves a path for the implementation of context-specific designs of surgical equipment.

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