

Target Product Profile

Lifebox Light



Figure 1.1: Surgeons at a national hospital in Ethiopia use a cell phone light to complete an operation. Photo CC BY-SA 4.0 Lifebox

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For more information, or for headlight manufacturers who wish to express interest in partnering with Lifebox, please send your inquiries to:

headlight@lifebox.org

1. Introduction

1.1. Opportunity

The purpose of this target product profile is to enter into an agreement with a partner vendor who can deliver an affordable and fit-for-purpose surgical headlight to address the lighting gap in operating rooms in low and middle-income countries (LMICs). Lifebox (<http://www.lifebox.org/>) is a charity focused on improving surgical safety globally. We estimate there are 24 million patients annually at risk from poor surgical lighting and over 400,000 surgeons in need of a surgical headlight (based on 40% of the 1 million surgical providers living and working in under-resourced health systems) (Holmer et al. 2015).

Based on the decreasing costs and increasing quality of LED lights and rechargeable batteries, we believe there is an opportunity to deliver a high quality surgical headlight at affordable costs while leaving room for profits that can benefit Lifebox safer surgery programs and our manufacturing partner. Together, we will build on Lifebox's past success and world class brand in delivering over 18,000 purpose-built pulse oximeters to hospitals in more than 100 countries. Lifebox brings experience in navigating international customs rules and regulations, forming relationships with surgery and anesthesia professional organizations, and developing a globally accepted standard-of-care to assist in delivering quality technologies to healthcare professionals and facilities in LMICs. Our work in the safe surgery space positions us to challenge the market to provide a fit-for-purpose surgical headlight and distribute it globally.

1.2. Scope

In this Surgical Headlight Target Product Profile, Lifebox provides details about the intended uses, users, use environments, concept of operation, needs, and requirements for a high quality headlight to serve the needs of communities in LMICs. We have taken a unique approach to this TPP in collaborating with expert surgeons and healthcare professionals from low and middle-income contexts, as well as integrating wisdom from technology, manufacturing, and human-centered design perspectives. The goal is to create a TPP that best enables an affordable surgical headlight to be made available to surgeons in LMICs that meets the quality standards of surgical headlights used in the U.S. or EU while being well-suited to the more challenging environment of an operating room in the developing world. For more information or for headlight manufacturers who wish to express interest, please send your inquiries to headlight@lifebox.org.

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2. Background

2.1. Need

Reliable, high quality lighting is essential for safely performing an operation. In low and middle-income countries (LMICs), electricity outages are disruptive and dangerous (Adair-Rohani et al. 2013); they are also unfortunately common. The following figures illustrate three aspects of the lighting gap Lifebox has identified in operating rooms in low and middle-income countries. We look forward to addressing these gaps with the right surgical headlight manufacturing partner.

Lighting Gap # 1: Intermittent Lighting Due to Power Outages



Figure 2.1: A surgical team in India uses cell phone lights to continue an operation during a power outage.
Photo CC BY-SA 4.0 Lifebox

In a survey of 100 surgeons in 39 low or middle-income countries, 48% indicated their facility experienced frequent power outages (Forrester et al. 2017). Even in facilities with a functioning and fueled backup generator, there is a lighting gap when switching from mains to generator power. One surgeon shared his story of working at a national hospital in Ethiopia:

“During a surgery to remove esophageal cancer, once the patient was asleep and the belly was open, the power went out. People quickly pulled out cellphones but the operation was on hold. Power returned, but, over the course of the case, the power went out another 3 times.”

During a power outage, patients on the table can be injured, disabled or die. Lifesaving emergency operations are often delayed or cancelled.

Lighting Gap # 2: Substandard or Broken Surgical Lighting



Figure 2.2: Surgeons at a tertiary referral hospital in Ethiopia using portable exam lights (foreground) not designed for use in surgery because overhead installed surgical lights (background) had burnt out. Photo CC BY-SA 4.0 Lifebox

Most of the medical equipment in the developing world is broken with estimates ranging from 40% to 96% out of service (Perry and Malkin 2011).

Almost all devices present in developing countries have been designed for use in industrialized countries. [...] Factors contributing to this are: lack of needs assessment, appropriate design, robust infrastructure, spare parts when devices break down, consumables, and a lack of information for procurement and maintenance... In some countries, nearly 80 percent of healthcare equipment is funded by international donors or foreign governments. [...] Used or refurbished equipment is often donated and can also prove problematic. In many cases, such equipment does not work for any significant length of time or when it does, local arrangements for training and accessories are needed to keep it working. (World Health Organization 2010; “WHO | Medical Device Donations: Consideration for Solicitation and Provision” 2016).

This pattern holds true for surgical lighting. Even at national-level hospitals in low and middle-income countries, burnt-out bulbs in surgical lights are often not replaced. Power surges in excess of international design requirements can easily damage lights, rendering them useless. Biomedical engineering maintenance staff are typically unavailable to fix the equipment. Tight budgets, limited supply chains, and discontinued parts for older model products leave these lights unrepairable.

Lighting Gap # 3: No Surgical-Quality Lighting



Figure 2.3: Medical staff perform an operation by the light of a window and a flashlight due to lack of surgical lighting. Photo CC-BY-SA 4.0 Lifebox, Nick Boyd

There are many operating theaters in low and middle-income countries where no surgical lighting is available. This is especially true for cesarean sections; the most prevalent surgery in low and middle-income countries. Cesarean sections are performed at a wide variety of facilities by both surgeons and clinical officers. Many of these facilities depend on ambient light from windows and assistants holding flashlights or cell phones to light the surgery. Given the low staff to patient ratio, this is a very expensive solution. In other cases, surgeons use headlights designed for recreational use which often are not bright enough, not focused enough, or not uniform enough to differentiate arteries, veins, nerves, and other important structures. The situation becomes even more dire at night when healthcare professionals are left to decide whether the surgery must be performed in the dark or risk waiting until daylight.

2.2. Market

A variety of ambient lights, overhead surgical lights, surgical task lights, and surgical headlights are currently used to light operating rooms in high-income countries, but many of these lighting solutions are unavailable or quickly break down in LMICs. Providing a high-quality headlight will dramatically improve the quality of illumination for all types of surgery, including deep cavity procedures. In addition, individual surgeons instead of facilities can own and care for a headlight, increasing the likelihood that it stays in-use and functional in a low-resource setting.

There is a significant market of clinicians who could benefit from using a personal headlight during procedures in low-resource settings. In 2015, LMICs – representing 70.6% of all countries and 82.0% of the global population – were served by 1,010,000 surgical providers: 720,000 surgeons and 290,000 obstetricians (Holmer et al. 2015). Based on our prior field work (Forrester et al. 2017), we estimate that at least 40% of surgical providers in LMICs operate with inadequate or substandard surgical lighting. This equates to an estimated 404,000 surgical providers: 288,000 surgeons and 116,000 obstetricians.

Notably, these figures likely underestimate the total potential market as they do not account for emergency health officers performing many cesarean sections, office-based procedures, and other health services such as labor and delivery that that could be dramatically safeguarded by improved lighting. It also does not consider the future market given the expansion of the surgical workforce outpacing the development of reliable surgical infrastructure.

2.3. TPP Development Process

After reviewing the technical specifications of over 100 existing surgical, dental and recreational rechargeable LED lights, Lifebox procured eight unique models for testing. We tested all lights outside the operating room to quantify light quality, longevity, and generate qualitative data on overall design features and usability. We measured illumination intensity using a digital lux meter every hour until complete discharge, as well as maximum and minimum spot size from a standardized working distance of 38 cm (15") from the light source. Afterwards, battery recharge time was quantified from complete discharge to full charge. Headlights that did not meet their own specification were eliminated.

From May 2017 to January 2018, we field tested these lights during surgery at three tertiary referral hospitals in Ethiopia and a well-resourced facility in the USA. Participating surgeons completed a standardized feedback form on lighting quality, mounting, battery charge, overall fit, and general use. In addition, we shadowed several surgeons in Ethiopia

to better understand charging, storage, and transport of the headlight outside of the operating room. We also performed controlled illuminance testing in the UK to determine maximum and minimum acceptable light intensity under no light, ambient light, and overhead surgical light conditions.

To understand the business case, we analyzed the likely cost of materials and components used in existing surgical and recreational headlights. We also gathered advice from experts who are experienced in finding manufacturing partners.

Based on this work, Lifebox has developed this target product profile (TPP) for a headlight that does not compromise standards and serves the needs of clinicians in diverse, low-resource settings. This TPP format is inspired by medical device TPPs issued by UNICEF, WHO, and FIND, as well as the medical device TPP workbook from MaRS Innovation (“[No Title]” n.d. MaRS 2011)((“[No Title]” n.d. UNICEF 2014)(World Health Organization 2016)(“[No Title]” n.d. FIND 2017). In addition, Lifebox has included extensive detail about the intended users and intended use environments in addition to the needs and requirements in hopes of arriving at the most affordable and appropriate headlight for LMICs.

3. Terms, Acronyms, and Definitions

- 3.1. **Color temperature** - an indication of the color of a light source generally expressed in degrees kelvin where higher degrees kelvin is light that appears more blue and lower degrees kelvin is light that looks more red.
- 3.2. **Color Rendering Index (CRI)** - is a quantitative measure of the ability of a light source to reveal the colors of various objects faithfully in comparison with an ideal or natural light source (“Color Rendering Index - Wikipedia” n.d.).
- 3.3. **Headlight kit** - all components of the headlight system including but not limited to all battery packs, charging systems, cables, headlight, mount, bag or carrying case, and instructions for use.
- 3.4. **Human Factors Engineering** - also known as usability engineering. This is the application of knowledge about human behavior, abilities, limitations, and other characteristics to the design of medical devices (including software), systems, and tasks to achieve adequate usability (“IEC 62366-1:2015 - Medical Devices -- Part 1: Application of Usability Engineering to Medical Devices” 2015).
- 3.5. **Illuminance** - is the total luminous flux incident on a surface, per unit area. It is a measure of how much incident light illuminates a surface, generally measured in Lux..
- 3.6. **LBLED** - A “less blue” light-emitting diode is a semiconductor device that emits visible light when an electric current passes through it. LBLEDs appear “white”. Whereas the most prevalent white LEDs are built by adding a yellow phosphor

layer to a blue LED, LBLEDs are built by adding a yellow phosphor to a violet LED which lessens the amount of blue wavelength light contained in the final white light output.

- 3.7. **LED** - A light-emitting diode (LED) is a semiconductor device that emits visible light when an electric current passes through it.
- 3.8. **LMIC** - Low and middle-income countries. These are the countries Lifebox is targeting for the headlight project. As of 1 July 2016, low-income economies are defined as those with a GNI per capita, calculated using the World Bank Atlas method, of \$1,025 or less in 2015; lower middle-income economies are those with a GNI per capita between \$1,026 and \$4,035; upper middle-income economies are those with a GNI per capita between \$4,036 and \$12,475 ("The World Bank Atlas Method - Detailed Methodology – World Bank Data Help Desk" n.d.).
- 3.9. **Lumen** - the SI unit of luminous flux, equal to the amount of light emitted per second in a unit solid angle of one steradian from a uniform source of one candela.
- 3.10. **Lux** - the SI unit of illuminance, equal to one lumen per square meter.
- 3.11. **Scrubbing In** - The process of washing hands, gowning and gloving. All members of the surgical team must scrub in before every operation. In the surgical scrub, the hands and forearms are decontaminated. A sterile surgical gown and pair of gloves are subsequently donned; creating an aseptic environment.
- 3.12. **Lighting Uniformity** - a measure of how even the illuminance is across an area.
- 3.13. **Lighting Wavelength** - in physics, a measure of the distance from trough to trough of a wave. Visible light is usually defined as having wavelengths in the range of 400–700 nanometres (nm), or 4.00×10^{-7} to 7.00×10^{-7} m, between the infrared (with longer wavelengths) and the ultraviolet (with shorter wavelengths).
- 3.14. **Working distance** - the distance from the headlight to the surgical area. This can vary based on the type of surgery and the height of the surgeon. In this document, we will use 16 inches (41 cm) as representing an average surgeon and the most common surgical procedures which involve the surgeon standing over the patient.

4. Context of Use

Following best practices of human factors engineering in medical device design, Lifebox has documented the intended uses of the headlight, the intended users, the intended environments of use, and the concept of operation. This information will help headlight manufacturers assess and mitigate risks associated with the correct use and use errors of a surgical headlight during normal use following best practices from international standards. (“IEC 62366-1:2015 - Medical Devices -- Part 1: Application of Usability Engineering to Medical Devices” 2015).

4.1. Intended Uses

The Lifebox Light is for use in illuminating the surgical field when operating on patients ranging from newborns to adults in hospital operating rooms in low and middle-income countries.

Notably, a headlight could be useful in other use cases and settings such as examining a patient while in labor, counting a child’s breath rate to determine whether they have pneumonia, or for operations in a well-outfitted, highly developed operating room. Users are not prohibited from using the Lifebox Light in alternative contexts, but the information in this target product profile is focused on surgical use in hospitals in low and middle-income countries that may be challenged by resource, power, lighting gaps, and shortfalls.

4.2. Intended Users

All intended headlight users are literate adults who have good vision or corrected vision using glasses. The intended users’ cognitive, memory, fine motor, vision, hearing and other abilities will be equivalent to or exceed an average healthy adult as these abilities are fundamental to their performance in the operating room. All users will be familiar with using other medical devices including interpreting Arabic numerals and common medical device iconography such as the power button symbol. Only some users will read English. Instructions for Use and other print material should be available in multiple languages to reach the widest audience.

4.2.1. Surgical Providers

The headlight’s primary users will be surgeons, obstetricians, and emergency health officers performing a range of procedures. For example, in Ethiopia, surgeons and obstetricians typically proceed from high school to 6-7 years of medical school and 3-7 years of residency in order to receive an MD. Emergency

health officers follow a different educational model that enables them to perform cesarean sections without receiving an MD.

In addition to enabling safer surgery through better lighting, we expect headlight ownership may also increase surgeons' perceptions of self-efficacy leading to higher quality surgery. The combination of health education and training programs with ownership of a well-functioning medical device have been shown to increase health professionals' view of their self-efficacy in other instances such as a novel newborn resuscitation program in Indonesia that combined ownership of a bag valve mask with resuscitation education (Olson et al. 2015).

4.2.2. Nurses

Staff / circulating / runner nurses will not be primary headlight users. During surgery, nurses may assist the surgeon in turning the headlight on and off, adjusting the headlight tilt, spot diameter, or headband fit. Very rarely, the surgeon may ask the nurse to swap out the battery; nurses are in short supply, so the surgeon will not always have enough surgical assistance if they asked the nurse to leave the operating room to fetch a backup battery.

4.2.3. Patients

Although patients will not directly use the headlight, equipping surgeons with this modern, medical device will become a mark of a well-trained surgeon and a high-quality facility. Provision of high-quality medical devices with modern medical aesthetic has been documented to increase patients' rate of care-seeking and influence choice of healthcare professional or facility (Olson et al. 2015).

4.2.4. Other Important Stakeholders

Members of the surgical team and observers will be affected by the use of the headlight even though they will not be headlight users. Most notably, their vision could be damaged if the light is too intense and/or too blue. In addition, surgical team members may bump into the headlight when leaning over the patient.

4.2.5. Not Target Users

Maintenance staff and biomedical engineers are not expected to interact with the surgical headlight in any way because we anticipate individual surgeons instead of facilities will own and maintain the headlights.

4.3. Intended Environments of Use and Storage

The environment in which a device is used (e.g., OR, hospital bed, home) can affect the actual use of the device because of variations in conditions such as noise, lighting, and

temperature (“ANSI/AAMI HE75:2009/(R)2013” n.d.). The majority of operations in low and middle-income countries take place in hospitals. Primary-level hospitals generally have capacity to perform cesarean sections, a variety of general surgery procedures, and injury repair. Secondary and tertiary referral hospitals typically have the capacity to do the same procedures as the primary level with the addition of some specialty operations such as obstetric fistula repair and repair of congenital abnormalities such as cleft lip and palate. (Mock et al. 2016, 4–5) At the hospital, the surgical headlight will be used in the operating room and stored or charged in hospital offices, hallways and (rarely) in homes. Some surgeons work at multiple hospitals. In these cases, the headlight will be transported between hospitals.

In terms of climate, unlike hospitals in the U.S. or EU, many operating rooms in low-resource hospitals will not have air conditioning and will often have windows that open to the outside. For this reason, temperatures inside the hospital are much more variable, mirroring general environmental temperatures outside. Wall heaters are present in many hospital rooms, preventing the temperature from dipping too low in colder climates. Designing the surgical headlight to function within 10-40 deg C and 30-95% relative humidity will accommodate the majority of low and middle-income country hospital environments. In addition, headlights in low-resource hospitals will be exposed to more dust as the hospital air is frequently not filtered as it is in hospitals in the U.S. or EU. Floors in low-resource hospitals are typically cement covered with linoleum or ceramic tile. Electricity will be available at all hospitals with surgical capacity, but can be intermittent with spikes and dips as mentioned in Surgical Lighting Gap #1.

4.3.1. Operating Room at Hospital

Operating rooms in low-resource hospitals vary widely in size, equipment, and facilities. The following four photos depict this range.



Figure 4.1: An operating room at a tertiary referral hospital in a large city in Sierra Leone including room fans, wall heating unit, ambient lighting from the window and a portable exam light used for surgical lighting. Photo CC BY-SA 4.0 Lifebox



Figure 4.2: An operating room at a Primary Health Centre in India that accommodates two operations simultaneously using low-power antiquated surgical lights and limited ambient lighting from the window. Photo CC BY-SA 4.0 Lifebox



Figure 4.3: An operating room at a Primary Health Centre in India with limited lighting from a nearby window and hanging lamp. Photo CC BY-SA 4.0 Lifebox

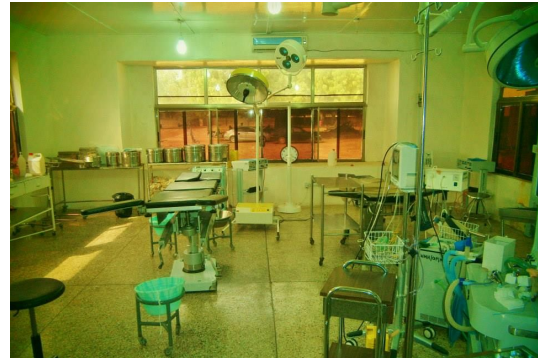


Figure 4.4: An operating room in Ghana that uses portable exam lights and ambient lighting from the window to light operations. Photo CC BY-SA 4.0 Lifebox

4.3.2. Scrub Sink Area at Hospital

Surgeons will wear the headlight while they are scrubbing in on the way to surgery. Scrub sinks in low-resource hospitals are often located closely adjacent to or in the operating room.



Figure 4.5: Scrub sink in operating room in Guinea. Photo CC BY-SA 4.0 Lifebox



Figure 4.6: Scrub sink outside an operating room at a private hospital in India. Photo CC BY-SA 4.0 Lifebox

4.3.3. Office or Charging Zone at Hospital

Lifebox asked eight surgeons in Ethiopia to use several existing headlights. Between operations and when off-shift, the surgeons stored and charged the headlights in their offices at the hospital. The headlight might also be stored in other locations where medical devices and mobile phones are charging such as in hallways. Sometimes the headlight charging cable will be plugged directly into the outlet and other times it would be plugged into a power strip that may or may not provide surge protection.



Figure 4.7: Surgeon office in a hospital in Ethiopia (top) and in Zambia (bottom); a place to store and charge the headlight. Photo CC BY-SA 4.0 Lifebox



Figure 4.8: Example charging station in an office in Ethiopia. Photo CC BY-SA 4.0 Lifebox

4.3.4. Transport Outside Hospital

A good number of surgeons working in low-resource settings perform operations at multiple institutions. Our current assumption is that surgeons will personally own their headlight and bring it with them to all the facilities where they work. The surgeon will want to ensure they have all the parts to the headlight kit when moving between facilities. Given the wide range of possible transportation methods including walking, biking, bus, and car, the headlight kit could easily be

exposed to the weather during transport including heavy rain. In addition, the kit could be dropped on dirt, mud, asphalt, or cement during travel.



Figure 4.9: Riding a motorbike in the rain is one way the headlight may be transported between hospital sites.
Photo CC BY-NC 2.0 Denis De Mesmaeker, flickr.com



Figure 4.10: Riding a bicycle in the rain is one way the headlight may be transported between hospital sites.
Photo CC BY-NC 2.0 bricoleurbanism, flickr.com

4.3.5. At Home

In the case of surgeons who work at multiple facilities, some may bring the headlight home with them to charge while they are off shift. Especially if, for example, the two facilities are far apart and the surgeon is leaving one facility for the day and going to another facility the next day. In terms of environment, we assume that the home will experience the same range of temperature and humidity with more exposure to dust.

4.3.6. During International Shipping & Storage

The headlight kit will be subjected to a range of shipping conditions including vibrations, drops, and temperature extremes when packed in its shipping packaging as described in the requirements. In addition, it may be stored for up to 1 year at a variety of storage temperatures before being deployed at a hospital.

4.4. Concept of Operation

4.4.1. Headlight User Interface

Headlight User Interface

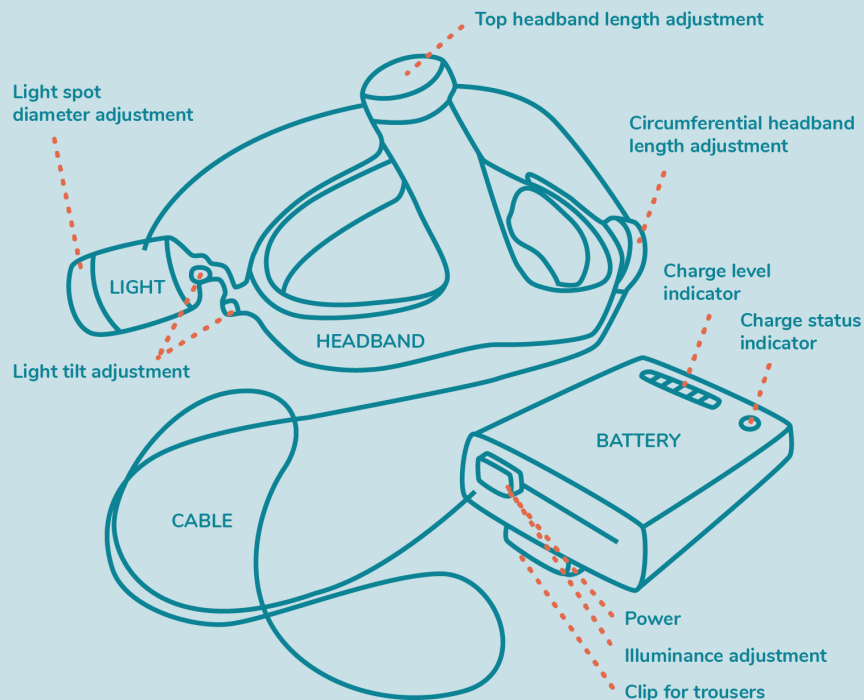


Figure 4.11: Desired headlight user interface features. All features are required, but could be implemented in a different way from how they are shown in this figure. Figure CC BY-SA 4.0 Lifebox

A. Light

1. Light tilt adjustment - adjusts tilt of light with respect to headband.
2. Light spot diameter adjustment - adjusts light spot diameter.

B. Headband

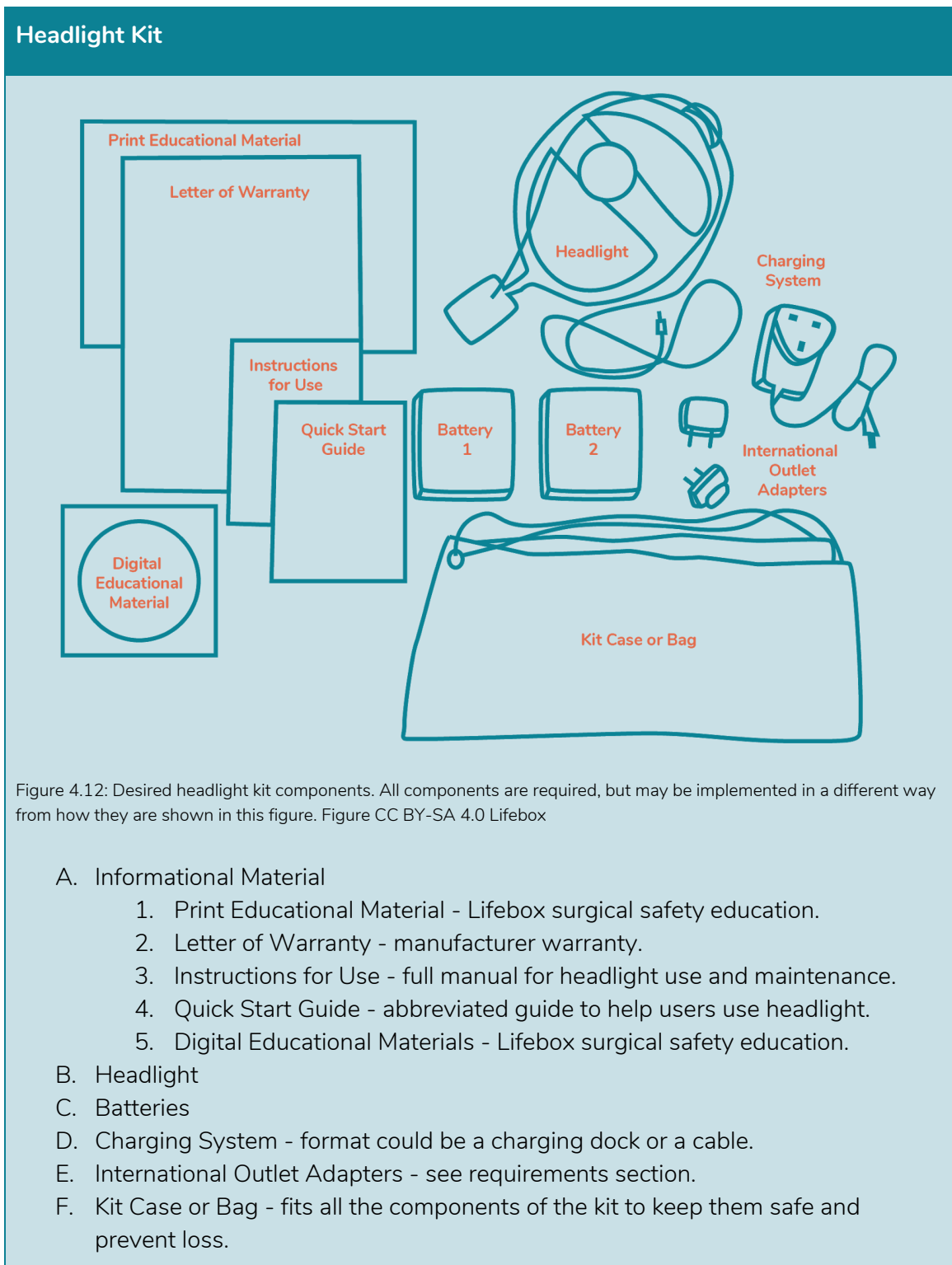
1. Top headband length adjustment - ensures headband does not move down on head over time.
2. Circumferential headband length adjustment - fits to various size heads.

C. Cable

D. Battery

1. Charge level indicator - shows current battery charge level; typically located on battery, but may be more convenient if located on more easily visible areas such as the headband or light.
2. Power switch - turns headlight on and off; may be integrated with illuminance adjustment, typically located on battery.
3. Illuminance adjustment & readout - controls illuminance level; typically located on battery, but may also be located on headband or light.
4. Clip for trousers - enables battery to be clipped to scrub bottoms.

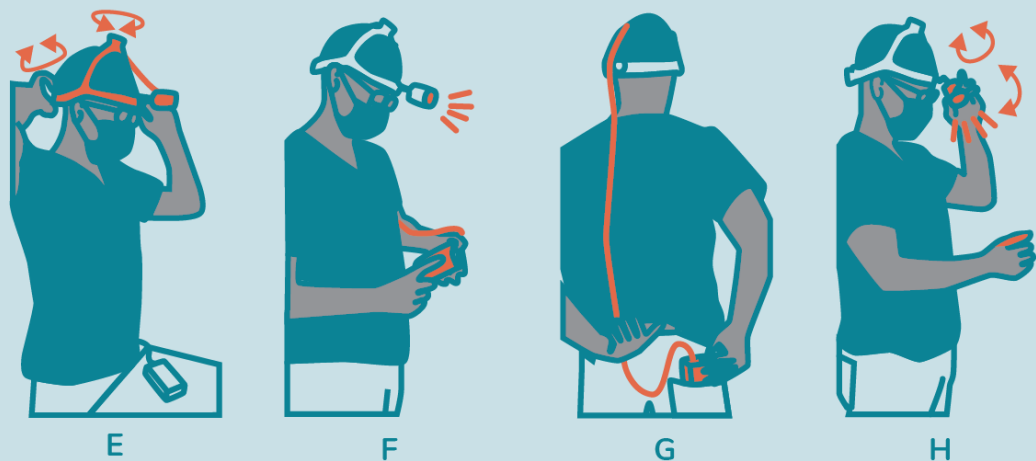
4.4.2. Headlight Kit



4.4.3. Headlight Use Steps

The following figures illustrate the steps to use the surgical headlight. Some of these steps may be performed in a slightly different order depending on the surgeon's preference, hospital layout, and hospital habits.





Surgeon's Office or
Operating Room

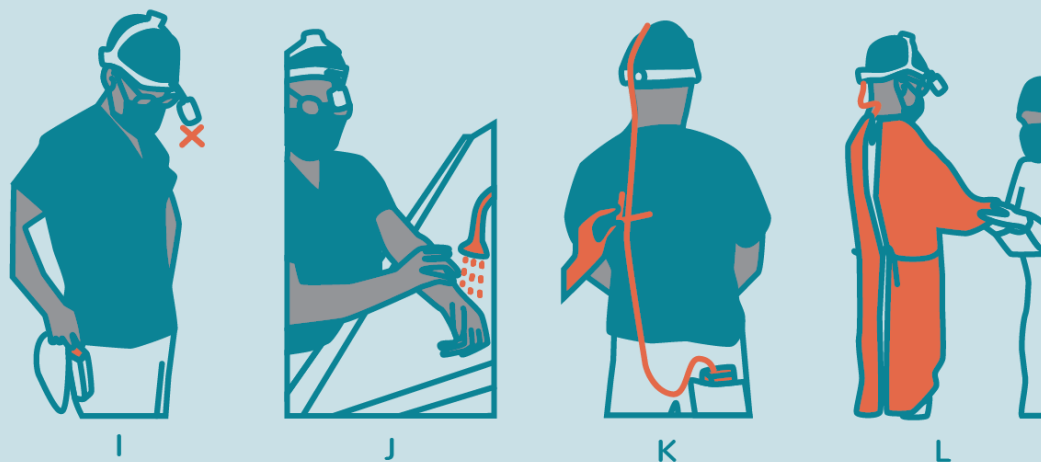
Surgeon's Office or
Operating Room

Surgeon's Office or
Operating Room

Surgeon's Office or
Operating Room

Figure 4.14: Headlight use steps before surgery. Figure CC BY-SA 4.0 Lifebox

- E. Place headlight on head and adjust to fit
- F. Turn headlight on, adjust illuminance
- G. Place battery in back pocket or clip to waistband of scrub bottoms
- H. Adjust light tilt angle and light spot diameter



Surgeon's Office or
Operating Room

Scrub Sink Next to or in
Operating Room

Operating Room or
Room Next to it

Operating Room or
Room Next to it

Figure 4.15: Headlight use steps before surgery. Figure CC BY-SA 4.0 Lifebox

- I. Turn headlight off
- J. Scrub (wash hands) and dry with sterile towel
- K. Circulating nurse attaches headlight cable to scrub shirt (if clip is available)
- L. Put on sterile gown and gloves

Headlight Use Steps - During Surgery

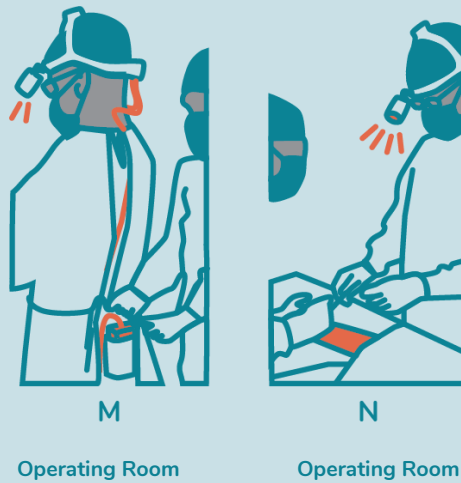
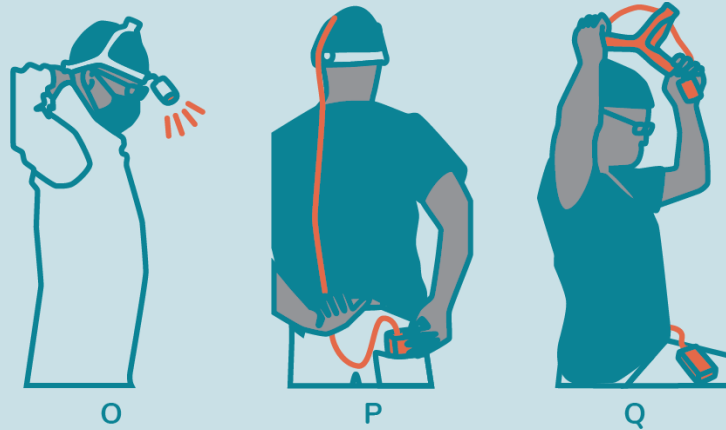


Figure 4.16: Headlight use steps during surgery. Figure CC BY-SA 4.0 Lifebox

- M. Circulating nurse turns headlight on and adjusts illuminance
- N. Use headlight to light surgical field

Headlight Use Steps - After Surgery



Operating Room

Operating Room or Room
Next to it

Operating Room or Room
Next to it

Figure 4.17: Headlight use steps after surgery. Figure CC BY-SA 4.0 Lifebox

- O. Remove gloves, gown, and face mask
- P. Remove battery from pocket or waistband and turn headlight off
- Q. Remove headlight from head



Operating Room or Room
Next to it

Hallway

Surgeon's Office or Other
Charging Location

Figure 4.18: Headlight use steps after surgery. Figure CC BY-SA 4.0 Lifebox

- R. Disconnect battery from headlight
- S. Carry headlight and battery to storage
- T. Plug battery into charging system

4.4.4. Headlight Use Scenarios

Use scenarios in low and middle-income countries inform the required features and components of a surgical headlight kit. The type of surgery, length of surgery, length of time between operations, location of headlight storage and use as well as the journey of the headlight between these spaces effects features such as light tilt angle, battery duration, battery charge time, type of charging system, and method for packaging the kit.

In low and middle-income countries, common operations include cesarean sections, laparotomies (opening of the abdominal cavity), external fixation for open long bone fractures, and obstetric fistula repair. The following case studies illustrate two typical operations in LMICs and the required light tilt angle to accommodate each.

Headlight Use Scenario 1: Cesarean Section



Figure 4.19: A surgical team in Rwanda performs a cesarean section, one of the most common operations performed in LMICs. Photo CC BY-SA 4.0 Lifebox

A study of 17 surgical programs in 13 countries in Africa, Asia and South America found that 40% of the surgical procedures conducted were obstetric-related, including cesarean sections (Chu, Ford, and Trelles 2010). Rate of cesarean delivery has a direct effect on reducing maternal and newborn mortality (Molina et al. 2015). Lack of quality, consistent lighting can be a danger to the mother and newborn.

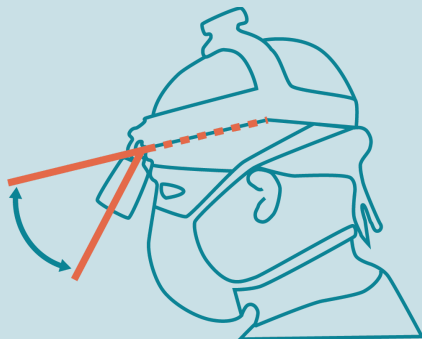


Figure 4.20: Surgical headlight tilt angle required to provide light during cesarean section and most operations. Figure CC BY-SA 4.0 Lifebox

During a cesarean section, a surgeon typically stands next to the patient looking downward as seen in the image above. This posture is also used with most other common operations performed in LMICs. To provide adequate lighting during cesarean sections and other common operations, the headlight should ideally enable a tilt angle measured from the headband as shown in the adjacent figure. See requirements for more information.

Headlight Use Scenario 2: Obstetric Fistula Repair



Figure 4.21: An obstetric fistula repair is performed by Dr. Itengre Ouedraogo (foreground) with assistance by operating room nurse Haoua Terah at Danja Fistula Center in Niger. Photo courtesy Worldwide Fistula Fund. <https://worldwidefistulafund.org/getmedia/e952e45b-e6a9-4eda-bc68-4f3b97ff02b9/IMG_4108.jpg>

An estimated 3 million women suffer from obstetric fistula worldwide (Wall 2006). One of the major effects of not having access to safe cesarean delivery is obstetric fistula resulting from obstructed labor. An obstetric fistula refers to a hole between the urinary tract or the gastrointestinal tract and the genital tract. Women with obstetric fistula report genital soreness; painful intercourse; constipation; and unpleasant odor, despite frequent washing and pad changes. These women endure social isolation, economic deprivation, and depression (Turan, Johnson, and Polan 2007; Weston et al. 2011).

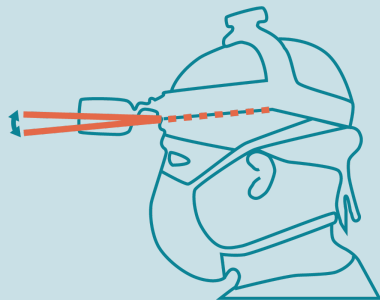


Figure 4.22: Surgical headlight tilt angle required to provide adequate light during obstetric fistula repair. Figure CC BY-SA 4.0 Lifebox

To perform obstetric fistula repair, the surgeon is usually sitting with their head level with the patient as seen in the photo above. To properly light the surgical field, a headlight needs to accommodate an upward tilt angle measured from the headband as seen in the adjacent figure. See requirements for more information.

There is no expected standard headlight use pattern as there is no typical day for many surgeons. Surgeons have a variety of schedules depending on the speciality, stage of career, and country. For example, at Lifebox partner facilities in Ethiopia, operations are performed by consultant surgeons, residents, and emergency surgical officers. Consultant surgeons perform elective operations generally starting in the morning and finishing by early afternoon. Consultant surgeons may work at multiple sites during one day, or alternate between sites on different days. Residents and emergency surgical officers perform the majority of cesarean sections and emergency operations. They work at all hours of day and night sometimes for 24-36 hours in a row until they have addressed the full caseload assigned to them for the shift. During these shifts, there may be less than 50% down time, and a string of operations could cluster together to exceed 6 hours of use with no significant break in between for charging batteries.

The following diagram illustrates three possible headlight use patterns that should be supported by the headlight including battery life and charge time. Use pattern 1 represents a consulting surgeon's schedule with four typical-length operations performed at two different hospitals where they work. Use pattern 2 represents a consultant surgeon's schedule for a rare, long surgery followed by a short surgery. Use pattern 3 represents a resident or emergency health officer's schedule including many short operations such as cesarean section mixed with other operations.

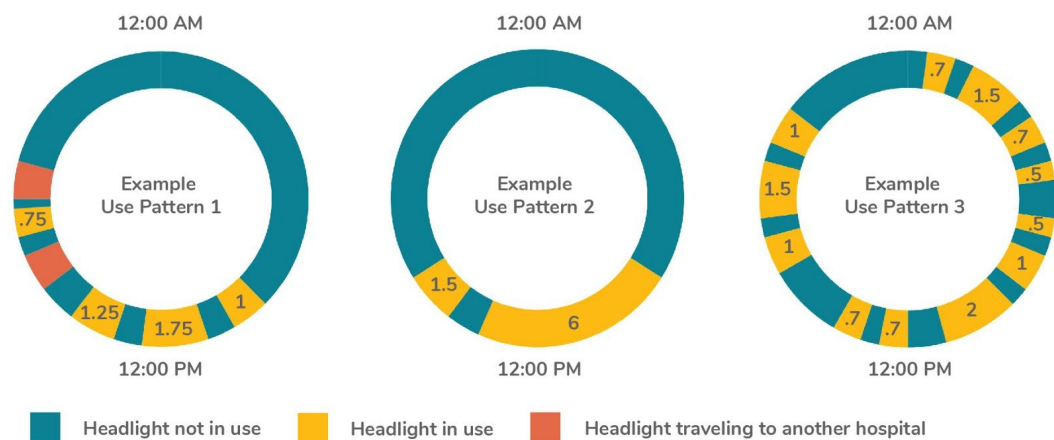


Figure 4.23: Example 24-hour headlight use patterns. Numbers on circles represent hours. Diagram CC BY-SA 4.0 Lifebox

In terms of operations, cesarean sections represent some of the shortest operations, taking 30-45 minutes. Lifebox estimates the average surgery in low and middle-income countries is approximately 1.5 hours long. Operations that last over 6 hours are rare and would represent the upper bound for surgery length. Given the headlight will sometimes be the only source of good lighting, we plan

for the case where surgeons would use the headlight for the duration of each surgery. The wait time for surgeons between operations can be as short as 30 minutes with the exception of a teaching facility where wait time can be closer to 1.5 hours.

4.4.5. Light Quality

Currently, some surgeons, dentists, and veterinarians use recreational headlamps to light surgical procedures in low and middle-income countries (Wu et al. 2008). Though a variety of durable and high-power recreational headlamps exist and can be used in absence of higher quality sources of light, Lifebox was unable to find a recreational headlight that could provide the high-quality lighting we need to provide to support safe and effective surgery. Specifically, many recreational headlamps are designed to illuminate a wide field and do not provide the range of focused light spot diameters useful for typical operations performed in low and middle-income countries. In addition, some recreational headlights provide a high illuminance setting, but the battery life is not long enough to last through a longer surgery. Finally, the optics used with recreational headlights tend to lead to poor lighting uniformity. Typical issues are a bright spot at the center, or varied dim and bright spots throughout the lighting field. Poor lighting uniformity leads to inability to distinguish small but important anatomical structures such as arteries, veins, and nerves. A comparison of lighting uniformity in two recreational headlights and one surgical headlight appears below.



Figure 4.24: Headlight lighting uniformity comparison. From left to right: recreational headlamp using a reflector; recreational headlamp using a gross fresnel lens and diffuser; surgical headlamp using a fine fresnel lens.

Notably, recreational headlights could be an asset in many medical applications in low and middle-income countries. The wide field of illumination may be helpful to light up a dark room at night or support performing a patient exam. These applications also may not require a high level of light uniformity and illuminance.

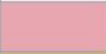
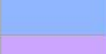
In addition to lighting uniformity, color rendering index (CRI), especially CRI R9, is an important indicator of light quality for surgical headlights. However, most surgical and recreational headlight manufacturers do not measure CRI. To

measure basic CRI, the light source is evaluated as to how well it illuminates the first eight color samples of eighteen proposed in (Nickerson 1960) compared to daylight. These first eight color samples are relatively low saturated pastel colors and are evenly distributed over the complete range of hues. The resulting eight measurements are combined to calculate the general color rendering index R_a . A higher R_a number means the light is closer to performing like natural sunlight.

For surgical applications, CRI R9 is an additional recommended measurement to characterize how well the light source renders red colors typical in the human body. The measurement involves including a ninth color swatch which is a strong red (see Table 4.1).

Skin tones, for example, are very much influenced by the redness of the blood that flows right beneath our skin. Therefore, a light that lacks red will make a person look pale, or even green. This can be problematic for medical applications where color appearance is critical for accurate assessment (“What Is CRI R9 and Why Is It Important? | Waveform Lighting” n.d.).

Table 4.1: CRI Test Color Samples Including R9

Name	Appr. Munsell	Appearance under daylight	Swatch
TCS01	7,5 R 6/4	Light greyish red	
TCS02	5 Y 6/4	Dark greyish yellow	
TCS03	5 GY 6/8	Strong yellow green	
TCS04	2,5 G 6/6	Moderate yellowish green	
TCS05	10 BG 6/4	Light bluish green	
TCS06	5 PB 6/8	Light blue	
TCS07	2,5 P 6/8	Light violet	
TCS08	10 P 6/8	Light reddish purple	
TCS09	4,5 R 4/13	Strong red	

Source: (“Color Rendering Index - Wikipedia” n.d.)

Recently, some LED manufacturers have been able to increase their R9 values from the low 70s to the mid 90s. This ought to make red colors appear more bold and vivid, helping make tissue identification and diagnosis faster and more accurate (Steris “[No Title]” n.d.).

5. User Needs

The following sections list the needs the surgical headlight should fulfill when in operation and the constraints that must be met. They serve to convey the needs of the intended users and other stakeholders affected. The fulfillment of the needs listed will help ensure the device is successful when used. The needs have been categorised into sections describing the performance, user interface, and design needs. There may be overlap in the needs between categories. The needs are mapped to requirements in the next section.

5.1. Performance Needs

This section details how well the device needs to perform to satisfy the needs of the intended users.

Table 5.1: Performance Needs

Need	Rationale
Continuously Ready for Use - The headlight should be ready for its owner operator to use at any time. Specifically, this means the parts of the headlight kit such as light, charging system, cables, mount, and battery should be easy to find and assemble. At least one battery should always be charged and ready. The operator should be able to bring the headlight kit to multiple sites and home during a given day without losing or breaking any components.	Operating theaters in LMICs can have unexpected power outages at any time. The headlight can be used to provide light during these power outages to avoid delaying or cancelling urgent operations. Surgeons may also work long shifts with an unpredictable flow of operations and down time. Assuming surgeons, not hospitals, will own the headlights, they will stay with the surgeon. Many surgeons perform operations at multiple sites in a single day. Surgeons may walk, or use bicycle or motorbike transportation to get between these locations in any kind of weather. Most surgeons will leave the headlight kit at a work site when they are at home. In some rare cases, surgeons may bring the headlight kit home with them between working hours if their work locations are far apart.

Functions After Dropped - The operator will want to continue to use the light after being dropped.	As a hand-held item, the headlight, battery pack, and charging components will be dropped from time to time. In addition, the headlight kit may be transported between sites by walking, riding a bicycle or motorbike, or other methods. During travel, it may be dropped while inside its carrying case. In a survey, 90% of cell phone users dropped their phone one time per month (Blandford 2013). Given phones are handled more often than the headlight, it may be safe to estimate all elements of the headlight kit may be dropped 2 times per year.
Light Position is Secure - Headlight must not shift significantly during surgery. Specifically, it must not shift side to side when surgeon looks left or right, headband must not move downward on the operator's head over time, and light tilt and spot size must not easily move from set position when bumped.	Steady lighting is key to safe surgery. If the light shifts on the surgeon's head during use, an area that was previously illuminated may no longer be illuminated. In addition, if the headband shifted down over time, it will come in front of the surgeon's eyes and block the view of the surgery. If this happened at a critical point in the surgery, this could lead to injury, or even disability and death. The headlight can be readjusted during surgery by the surgeon or scrub nurse, but ideally this is minimized to reduce risk of contaminating the sterile field by touching the unsterile headlight.
Functions for Entire Shift - The light must function the length of typical operations in a single LMIC work day without the need for charging.	The headlight is used in cases where additional lighting is needed, or where it may be the only lighting for the surgery. Based on observations of workflow in several hospitals in Ethiopia, consulting surgeons typically perform about 6 hours of surgery during a day/shift. Residents and emergency health officers may work for 24-36 hour shifts where they may be in surgery 25% - 50% of the time. Given down time between operations may be close to 50% and down time between operations fluctuates depending on the flow of cases, there may be insufficient time to recharge a single battery between cases. Most likely, the kit should include at least 2 batteries for this purpose so one can charge while the other is in-use. See Use Scenarios for more information about

	typical workflow.
Functions for Entire Surgery - The light must function for the full length of a surgery in LMICs without the need for battery swapping.	The headlight is used in cases where additional lighting is needed, or where it may be the only lighting for the surgery. A typical surgery in LMICs is commonly 1-2 hours, however rare operations may last 5-6 hours. Given the staff to patient ratio is low in LMIC facilities, ideally, the headlight would function for the duration of a longer surgery without the need to find personnel who could swap out the battery during the surgery. See Use Scenarios for more information about typical workflow.
Distinguish Anatomical Features - The operator needs to see important anatomical features of the patient's body. Some examples of important, but challenging, aspects to see include bleeding vessels "bleeders", nerves, and bowel perforations.	In surgery, the surgeon needs to cut or repair some anatomical features, but not others. Many of these features such as veins, arteries, and nerves, are slightly different shades of red or blue and hard to distinguish from adjacent red or blue anatomical features. The inability to distinguish anatomical features from each other can lead to patient injury, disability, or death.
Does not Touch Patient - The operator needs the headlight to avoid contact with the patient.	The surgical headlight is not sterile. Patient contact with a non-sterile item can lead to surgical site infection. The headlight should be designed to have the cable and battery worn under the sterile gown. Parts should be securely attached to the surgeon to ensure they do not fall out of place and contact the patient or interfere with the surgeon's work.
Minimize Bumping the Assistant - The operator needs the light to be small enough that it does not frequently hit their assistant and easy to readjust into the proper position.	The operator's assistant is often asked to put their head close to the operator to visualize the same part of the body. In addition, the surgical team will reposition themselves from time to time and hand instruments back and forth which can lead to inadvertent light bumping. In testing some existing surgical headlights, bumping into the assistant's head was a complaint with some headlight models whose light protruded further from the head, but not with others.

Promote Good Posture - To preserve the operator's ability to work long-term, the headlight should enable ideal posture for any given surgery.	Common operations in LMICs include cesarean section and obstetric fistula repair. These two operations require the surgical light to be at very different angles to the surgeon's head to accommodate ideal posture.
Protect Eyes - To preserve the surgical team's ability to work long-term, the eyes should be protected from damage by lighting that is too intense or too blue.	The use of elevated blue spectrum and extreme cool LED for long durations may be harmful to eyes (Stamatacos and Harrison 2013). Specifically, it can induce or aggravate macular degeneration. LBLEDs are preferred.
Protect Ears - To preserve the surgical team's ability to work long-term, the ears should be protected from damage by a headlight that is too loud.	Sounds over 85 dBA are known to cause hearing damage. Sounds lower than 85 dBA can also cause damage when people are exposed for long periods of time. The headlight should avoid exceeding these thresholds. In addition, it's important for the surgical team to be able to communicate well with each other and hear the patient monitoring devices. The headlight should not interfere with these tasks.
Continues Working If Splashed - The operator needs the light to continue working even if splashed with bodily fluids including blood, fat, amniotic fluid, stool, pus, bile, and other bodily secretions.	In rare cases (estimated less than 5% of the time), bodily fluids may land on the headlight. This should not lead to any interruption in lighting. Interruptions at critical moments in a surgery can lead to patient injury, or even disability or death.
Continues Working in Dusty Environment - The operator needs the light to continue working even in the presence of dust.	Hospitals in LMICs typically do not have air filtration systems. In addition, most operating rooms have windows that can be opened to the outside. Open windows lead to dust in the operating room and in the locations where the headlight may be stored. Some electronic cooling systems rely on air movement over the electronics. Cooling system air intake might be prevented by dust leading to overheating and damaging the device. In addition, dust could land on the internal optical components dimming the light over time.
Long-Lasting Device - The operator needs the headlight to function for at least several years.	Devices designed for the U.S. or EU hospital context often do not last long in a low-resource hospital. Read more under Lighting Gap #2. This headlight must work out of the box and not require any replacement parts for several

	years to be useful. This means none of the parts are lost, wear out, or break.
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5.2. User Interface Needs

This section details the user interface features the device needs to enable the functionality desired by intended users.

Table 5.2: User Interface Needs

Need	Rationale
Find Own Headlight - the operator must be able to determine which headlight and headlight kit parts are their own.	In a hospital where multiple surgeons may have the same model of headlight in various states of charging and repair, it will be important to know which parts belong to which surgeon. In addition, this will help in differentiating the headlight from equipment owned by the hospital. In addition, the surgeon must be able to identify the appropriate battery and avoid using inappropriate batteries that either do not provide enough power or could damage the device.
Know Charge Status - The operator must be able to know if the battery is charging.	The battery will need to be charged between uses. The operator could have a loose connection, a broken power charging system, or a broken battery and not know until hours later when they retrieve the headlight for an imminent surgery and battery charge has not increased. This could lead to delays or cancellations of urgent life-saving operations if no other lightings is available.
Know Charge Level - The operator must be able to determine how long the headlight will last before scrubbing into a surgery and during a surgery. Specifically, this means being able to determine the level of charge for rechargeable batteries and how that charge level relates to hours of light at a given illuminance.	The headlight is used in cases where additional lighting is needed, or where it may be the only lighting for the surgery. To ensure the light lasts through a surgery, the operator must choose a battery that has sufficient charge. Surgeons move from case to case during the day and must check battery level in between cases even when not powering the light or charging. There should be a way to draw attention to the headlight when the battery is getting close to depletion. Note, if the battery level visual indicator is located on the waist battery, it will be hidden by the surgeon's gown during

	surgery. If the battery is unexpectedly depleted and the light suddenly turns off at any point in the surgery, this could lead to injury, or even disability and death.
Power On & Off - The surgeon and surgical nurse must be able to turn the device on and off before, during, and after scrubbing in.	To ensure the headlight is on when needed and to avoid having the device on at inappropriate times.
Adjust Fit to Head - Headlight must fit on the operator's head.	The headlight will be mounted to the surgeon's head as this is the best way to illuminate the area at which the surgeon is currently looking. Mount must take into account a range of head sizes, hair will be pulled up, and must fit over a cloth head covering. Mount must be intuitive and easy for operator to secure onto their own head. In most cases, the operator will prepare themselves for surgery without assistance, so headband adjustment method must be easy for a surgeon to do, but also easy for an assistant.
Adjust Illuminance - The operator must be able to easily adjust the light to the desired illuminance before scrubbing in and during surgery.	Operating room lighting can range from no lighting to powerful overhead surgical lights. The illuminance must be adjustable to ensure the light is bright enough for the type of surgery the operator is doing and the type of ambient lighting. A surgeon who is new to the headlight may not know the ideal illuminance until they are in surgery, requiring adjustment at that time. In addition, the operating room lighting levels or nature of the surgery could change during the course of surgery and require a change in illuminance. In addition, illuminance effects battery use time. During operations that take longer than originally planned, surgeons can turn down the illuminance to prolong light use. When adjusting illuminance during surgery, gloves must not come in contact with the light to ensure the gloves remain sterile and do not carry an infection the patient. The circulating nurse would most likely do this if illuminance is adjusted using a switch on the battery.
Adjust Spot Diameter - The operator needs to be able to easily adjust the	The light spot diameter should be adjustable to be able to concentrate the light on the surgical

light to the desired spot size diameter before scrubbing in and during surgery.	site based on the type of surgery. The most common essential operations in LMICs benefit from a wider field of lighting than the average surgery in the U.S. or EU where headlights are used. Examples of common operations in LMICs include cesarean section and obstetric fistula repair. In addition, a wider spot diameter is preferable when ambient lighting is low to provide light to peripheral areas near the surgical site. operations deep in the body benefit from a more concentrated, small diameter light but are less frequent in LMICs. A surgeon who is new to the headlight may not know the ideal spot diameter size until they are in surgery. In addition, the light could be bumped out of the ideal setting or the nature of the surgery could change during the course of surgery and require a different spot size. This is typically performed by a circulating nurse who can help adjust the light focus and spot location. However, some surgeons may use a sterile towel draped over their sterile gloves to adjust the light, then discard the towel with other soiled items for wash.
Adjust Light Tilt - Before scrubbing in and during surgery, the operator needs to be able to adjust the tilt of the light downward to accommodate standing over a patient (such as cesarean section). The operator needs to be able to easily adjust the tilt of the light slightly upward to accommodate sitting at the level of the patient (such as obstetric fistula).	Many operations are performed with the surgeon standing next to the patient and looking down. One example is a cesarean sections, one of the most common surgical procedures in LMICs. Other operations may require the surgeon's head positioned closer to the same level as the patient's body. For example, obstetric fistula repair is a common surgery in LMICs that benefits from this head position. Given the varying heights of surgeons and varying angle between surgeon and patient for different operations, it is best to provide continuous instead of discrete tilt angle adjustment. The adjustment will be made initially before scrubbing in. However, a surgeon who is new to the headlight may not realize what is the ideal light tilt until they are in the surgery. In addition the nature of the surgery could change

	during the course of surgery and require a different lighting tilt, or the headlight could be bumped out of position and need readjustment. When adjusting light tilt during surgery, gloves must not come in contact with the light to ensure the gloves remain sterile and do not carry an infection to the patient. This is typically performed by a circulating nurse who can help adjust the spot location and light angle. However, some surgeons may use a sterile towel draped over their sterile gloves to adjust the light, then discard the towel with other soiled items for wash. See Use Scenarios for more information.
Wipe Down -Rarely, the operator or surgical nurse must be able to wipe bodily fluids off of the device during or after surgery.	It is unlikely that bodily fluids would touch the light in the majority of operations. In most cases, the light would not need to be cleaned or sterilized between uses. In perhaps 5% of cases, (more or less for particular specialists), the light would need to be wiped with a towel or gauze after surgery to remove bodily fluids. In addition, the light should be able to withstand wiping with typical local sanitizers including mild detergent and water, 70% isopropyl alcohol, 70% denatured ethanol, chlorhexidine gluconate 73 µg/ml, or a mix of these disinfectants ("Chlorhexidine - Wikipedia" n.d.). In some cases, these cleaning solutions may be colored with dye to differentiate them from other fluids in the hospital which could be taken into account when choosing product color and material as porous or light-colored materials could become discolored over time.
Allows Battery Replacement - If the battery is lost or stops working for some reason, another battery should be able to swap into its place.	The battery is likely detachable from the headlight and could be misplaced in the hospital or during transit. During handling, it could be dropped one too many times or exposed to a power surge beyond the design limits that leads it to be non-functional. In these cases, the headlight battery component should be replaceable instead of requiring the entire

	headlight to be replaced.
Comfortable to Wear - The operator will need to remain comfortable for the duration of surgery while using the headlight during a full day of operations. This includes not digging into the head, not too hot, and not too heavy on the head or on the scrub bottoms.	Surgeons must be able to maintain focus on their surgical tasks and maintain energy to complete multiple operations every day. In some facilities in LMICs, the headlight will be the only reliable light source for surgery. Due to this, the headlight is likely to be used for more hours of surgery per day in LMICs than is typical of use in settings in the U.S. or EU. Uncomfortable lighting can lead to neck strain over time, burns on skin of the head or body, or lack of headlight use.
Avoid Accidental Power Down - The light must not unintentionally be turned off during the surgery.	The headlight is used in cases where additional lighting is needed, or where it may be the only lighting for the surgery. If the light stopped working during the surgery without warning, this could lead to injury, or even disability and death. For example, the power switch must not be activated by accident, and the battery must stay connected securely to the light.
Requires no Training - The users must be able to learn how to operate the headlight safely and effectively on their own.	The headlight should be simple enough to use that the intended users can teach themselves to use it safely and effectively using the provided print instructions for use. Though all headlight users will have good vision, be literate, and will be familiar with the use of more complex medical devices including some markings in English, not all users will speak or read enough English to interpret the full instructions for use in English. For this reason, it is very important to provide the print instructions in languages familiar to the users. Ideally, instructions would be available in all six official languages of the WHO; Arabic, Chinese, English, French, Russian, and Spanish. In addition, Amharic and Hindi would be useful as Ethiopia and India are regions where Lifebox frequently works. Providing additional content such as instructional videos online or a CD or USB drive can help, but not all users will be able to access this content. The print instructions for use must be comprehensive.

Keep Kit Together - The operator has a need to keep track of all parts of the kit.	There will be multiple parts to the headlight kit including battery, headlight, charging system, outlet adapters, and print materials that will not always be physically attached to each other. It could be easy to lose some of these parts when moving the headlight kit between different rooms in the hospital and between different hospitals.
Bring Kit Between Places - The operator has a need to bring the kit between rooms in the hospital and between hospitals.	As described in prior sections, surgeons will bring the kit with them between operating room and storage location in the hospital and between multiple hospitals where they work.

5.3. Design Needs

This section details the design needs separate from user interface or performance that must be fulfilled to enable the intended users to use the device.

Table 5.3: Design Needs

Need	Rationale
Trust the Device - Operators must trust the device to feel confident in using it. Purchasers must feel confident they are buying a high quality device.	Users globally know how high-quality medical equipment looks and feels. If the headlight looks cheap, low-quality, or does not have design cues indicating it is made for medical purposes, surgeons won't be as likely to trust and use the headlight and purchasers will be less likely to buy the headlight, even if its performance meets other requirements.
Convey Lifebox Brand - The headlight must include Lifebox branded touchpoints.	Lifebox is a globally-renowned brand that stands for quality, safety, and efficacy. The headlight kit should deliver the same branded experience surgeons and anesthesiologists have come to know and trust. This will enable the headlight to scale more quickly worldwide and lead to more lives saved through providing quality lighting

5.4. Purchaser Needs

This section details the needs related to procurement, transportation, and logistics.

Table 5.4: Purchaser Needs

Need	Rationale
Predictable, Low Ex-Works Price - Lifebox needs to be able to plan budgets for purchasing the light from the manufacturing partner.	Stable, low pricing enables Lifebox's mission of ensuring operating theaters in low and middle-income countries have quality lighting. Lifebox is aiming for the same sale price as the successful pulse oximeter program which has attained scale of 18,000 units sold. All Lifebox Light purchases will go through Lifebox. About 20% of the sale price must be allocated to logistics of getting the device to its purchaser.
Continuously Available for Purchase - the purchaser needs the headlight kit to be available ongoing for procurement.	This will enable additional purchasers including governments, hospitals, and individual surgeons to purchase the device as needed after a Lifebox roll-out. In this way, the impact of Lifebox programs are amplified through further sales and use of an excellent surgical tool.
Available in Quantity - The purchaser needs the headlight to be available in quantities that support their programs.	To be able to support the quantities needed for maintaining existing programs and implementing new programs.
No Need for Training - The purchaser of the headlight needs the headlight to be easy enough to use such that an operator can train themselves to use it well.	When the headlight is distributed through implementation programs by Lifebox, governments or NGOs, the total cost of the program includes the headlight cost, shipping cost, and training cost. An easy to use headlight with no training costs presents a cost savings.
Low Total Cost of Ownership - The purchaser needs the headlight to have a low cost of ownership. Specifically, prevent requirement for repair or replacement of headlight system parts, especially parts not affordable and available locally.	Repairs are unlikely to be possible in LMIC hospitals due to few trained biomedical engineering staff. There are limited resources among purchasers, surgeons, and hospitals to fund purchase of replacement parts, especially parts which must be shipped from outside the country of use.
Kit Packaging Services - The purchaser needs all components of the headlight kit to be packaged in	Any quantity of headlight kits from one to many may be shipped internationally directly to hospitals and/or surgeons. Lifebox does not have

individual kit packaging that can withstand international shipping.	the logistical resources to buy batches of headlight kit parts in bulk and assemble kits.
Small Kit Size - The operator and the purchaser need the components of the headlight kit to be packaged in as small a space as possible.	A smaller kit is easier for an operator to bring between rooms and between hospitals. Smaller packaging leads to lower shipping costs. In addition, many Lifebox partners bring equipment to LMICs through personal airline travel. Larger shipping box sizes restrict the number of headlights Lifebox partners will purchase due to airline limitations in baggage size.
Lightweight Kit - The purchaser needs the components of the headlight kit to weigh as little as possible in total.	A lighter weight kit reduces shipping costs and enables Lifebox partners to pack more headlight kits in their baggage during airline travel leading to higher sales. However, a durable and fully-functional headlight is more important than reducing weight for shipping.
Lasts in Storage and Shipping - The purchaser needs the headlight to function after up to 12 months in storage.	Logistics are complex and can require a long time in various storage locations during transit to LMICs.
Warranty - The purchaser wants to protect themselves and their beneficiaries from loss of use of product due to manufacturer defects.	Despite manufacturer best efforts, there could be some product that does not perform according to specification.

6. Product Requirements

The following section lists the minimal requirements the headlight should meet to fit the needs of the intended users in the intended uses and intended contexts. These requirements are based on the needs the Lifebox team has identified in collaboration with our partners globally.

6.1. Lighting

Most existing headlights on the market use LED technology for lighting in combination with lenses and/or reflector. LED performance continues to increase while cost continues to decrease. For these reasons, Lifebox assumes LEDs will be the lighting technology used in this headlight.

Table 6.1: Lighting Requirements

ID	Characteristic	Minimal	Needs Addressed
6.1.1	Light component quality	Lighting component shall be sourced from a trusted, quality, leading LED manufacturer with ISO 9001 quality certification.	Long-lasting device
6.1.2	Illumination spot diameter at working distance	Spot diameter shall be adjustable between $\leq 7\text{cm}$ - $\geq 12\text{ cm}$ where 12 cm is the most important diameter to achieve.	Adjust spot diameter,
6.1.3	Acceptable range of minimum illuminance with 12 cm spot diameter at working distance	There shall be at least one (low) setting at which illuminance shall be no less than 8,000 lux at the end of required battery pack run time using a light and battery pack at end of operational life expectancy and no more than 18,000 lux using a fully-charged battery pack and a light used for less than 100 hours total.	Adjust illuminance, functions for entire surgery
6.1.4	Acceptable range of maximum illuminance with 12 cm spot diameter at working distance	There shall be at least one (high) setting at which illuminance shall be no less than 35,000 lux at the end of required battery pack run time using a light and battery pack at end of operational life expectancy	Adjust illuminance, protect eyes
6.1.5	Illuminance adjustment	Illuminance adjustment shall be located on battery pack. Force required to change illuminance shall be high enough and oriented such that it is unlikely to be accidentally triggered.	Adjust illuminance, avoid accidental power down
6.1.6	Lighting color	LED color temperature shall be between 4500 - 6500K. Ideally, light would have a CRI value ≥ 90 and CRI R9 value ≥ 90 .	Distinguish anatomical features, protect eyes,
6.1.7	Lighting tilt angle	Light must be able to be adjusted between + 5 deg and - 60 deg measured from the the bottom	Promote good posture, adjust light tilt

		edge of the headband around circumference of head.	
6.1.8	Lighting tilt mechanism	Light shall be adjustable with one hand and shall not require a second action to hold in place such as a set screw. The force to adjust tilt shall be easy for surgeons and nurses to apply, yet hold the light in place during normal use in surgery.	Promote good posture, light position is secure, minimize bumping the assistant, adjust light tilt
6.1.9	Lighting life expectancy	Lighting component lifetime shall at meet or exceed required device life expectancy .	Long-lasting device, low total cost of ownership,
6.1.10	Lighting uniformity	Within required ranged of illumination spot diameter , illuminance measurements (lux) shall not vary by more than <u>25%</u> . In addition, there shall be no pronounced dark areas visible to the naked eye when illuminating a white piece of paper at working distance and with max required spot diameter .	Distinguish anatomical structures,
6.1.11	Light component temperature	Light component shall be maintained within manufacturer-recommended operating temperatures while operating in the range of required use temperatures .	Long-lasting device,

6.2. Mounting

Lifebox is looking for a head-mounted headlight with the light is positioned on the forehead. Other mounting locations on or off the body will not be considered.

Table 6.2: Mounting Requirements

ID	Characteristic	Minimal	Needs Addressed
6.2.1	Light mounting position	Light shall be mounted on the head, positioned in the middle of	Comfortable to wear,

		forehead (close coaxial mounting).	
6.2.2	Headband material durability	Headband shall be constructed of a material that is durable including avoiding changes in headband length more than 5% over device life expectancy according to calculations.	Trust the device, low total cost of ownership
6.2.3	Headband configuration	Headband shall be constructed of two bands: one around circumference of head and the other over the top of the head.	Light position is secure, adjust fit to head, comfortable to wear, does not touch patient
6.2.4	Headband circumference	Headband internal circumference shall range from 52 cm to 62 cm to leave room for hair and cloth head covering (Catapan et al. 2015; R. Ball et al. 2010; R. M. Ball 2011).	Light position is secure, adjust fit to head, comfortable to wear, does not touch patient
6.2.5	Headband top strap length	Headband top strap length shall accommodate a 5th percentile Chinese woman and a 95th percentile African male plus room for hair and a cloth hair covering.	Light position is secure, adjust fit to head, comfortable to wear, does not touch patient
6.2.6	Headband size for transport	Headband shall be collapsible to 17cm W x 21cm L x 13 cm H	Small kit size, bring kit between places
6.2.7	Strap adjustment	Strap adjustment shall be a mechanism that is easy and intuitive to use for surgeons, ensures strap shall stay secure on the head during use, and shall hold securely in place for the device life expectancy .	Light position is secure, adjust fit to head, comfortable to wear,
6.2.8	Weight on the head	Weight of headband assembly (all components worn on the head) shall not exceed 300g.	Comfortable to wear, lightweight kit, bring kit between places
6.2.9	Compatibility with other equipment	The headlight shall not interfere with glasses at any required lighting tilt angle .	Comfortable to wear,

6.2.10	Headband pads or coverings	Headband shall be comfortable for 12 hours of surgery per 24 hour period, 5 days a week when worn on the head, with hair pulled up and headlight placed over a cloth head covering over the course of device life expectancy .	Comfortable to wear, long-lasting device
6.2.11	Length of cable from headband to power source	The cable from light to battery pack shall be at least 135 cm as measured from back bottom edge of the headband to the top surface of the battery pack.	Comfortable to wear, avoid accidental power down,
6.2.12	Cable connector between light and power source	Cable connector between light and power source shall be easy and intuitive to use and provide sufficient force to ensure cable will not work itself free during battery pack run time .	Allows battery replacement, avoid accidental power down
6.2.13	Cable restraint	Ideally, cable would include a clip that enables the cable to be secured to the surgeons' scrub shirt.	Comfortable to wear, avoid accidental power down, does not touch patient,

6.3. Battery System

Lifebox is looking for a battery-powered device that includes rechargeable batteries worn in the pocket or on the waist. Based on our current knowledge, lithium ion batteries are preferred for their discharge curve. Headlights that require wall power during use will not be considered. Headlights with battery packs mounted on the head will not be considered as it is very important to minimize surgeon neck strain.

Table 6.3: Battery Requirements

ID	Characteristic	Minimal	Needs Addressed
6.3.1	Battery type	Headlight kit shall include two rechargeable battery packs.	Continuously ready for use, functions for entire shift, functions for entire surgery,

6.3.2	Battery pack form factor	Battery pack(s) shall connect to headlight through detachable cable. Ideally battery(s) shall be enclosed in a housing that cannot be easily opened by user, or battery type is only useful for this device and hard to lose.	Allows battery replacement, comfortable to wear, keep kit together, small kit size, bring kit between places
6.3.3	Battery pack dimensions	Battery pack and holder assembly circumference (2* Width + 2*Thickness) shall not exceed 30 cm. Ideally, height of battery shall not extend too much over pocket height of 15.5cm.	Comfortable to wear, small kit size, bring kit between places
6.3.4	Battery pack weight	Battery pack weight shall not exceed 600 g.	Comfortable to wear, lightweight kit, bring kit between places
6.3.5	Battery pack run time	2 battery packs shall each run for at least 3 hrs on maximum illuminance setting after being used for required battery lifetime . Ideally, another battery pack shall be available for purchase that runs for at least 6 hrs on maximum illuminance setting after being used for required battery lifetime .	Continuously ready for use, functions for entire shift, functions for entire surgery,
6.3.6	Power discharge curve	Batteries shall maintain illuminance above required minimum illuminance during required battery pack run time .	Continuously ready for use, functions for entire shift,
6.3.7	Charging system	Charging system shall be a system that shall not easily lost or is easily replaced locally (such as USB cable).	Continuously ready for use,
6.3.8	Wall adapter	Headlight kit shall include wall power adapter compatible with customer's country including options for U.S., UK, EU, and Australian/WPRO ("Plug & Socket Types - World Standards" n.d.)	Continuously ready for use,

6.3.9	Charging time	Battery charge time to reach 90% at required range of charging temperatures shall be less than or equal to battery pack run time on maximum illuminance with provided charging equipment.	Continuously ready for use,
6.3.10	Charging voltage	Charging system shall be compatible with at least 100 - 240 VAC, 50-60 Hz ("Complete List: Plug, Socket & Voltage by Country - World Standards" n.d.)	Continuously ready for use,
6.3.11	Charging in unstable power	Charging system shall automatically continue charging when voltage returns to required charging voltage range	Continuously ready for use,
6.3.12	Protection from power surges	Highly desirable to have resettable surge protection, but not required	Long-lasting device,
6.3.13	Mounting position	Includes features to clip to waistband or fit in hip pocket of surgical scrub bottoms	Comfortable to wear,
6.3.14	Charge level indication during use	Device shall have a continuous visual display of charge remaining when powering headlight. Display could be located on battery, but is ideally located on the headlight.	Know charge level, avoid accidental power down
6.3.15	Charge depletion warning	Device shall provide visual indication when there is estimated to be less than 10 minutes of battery life left. Estimation can be based on maximum illuminance level.	Continuously ready for use, know charge level, avoid accidental power down
6.3.16	Charge level indication between uses	Charge level indication shall be accessible on-demand when not powering headlight.	Know charge level, avoid accidental power down
6.3.17	Charge status indication	Device shall provide visual indication of whether the device is currently charging.	Continuously ready for use, know charge status
6.3.18	Power on/off location	Power on/off shall be located on	Power on and off,

		battery pack.	avoid accidental power down,
6.3.19	Power on/off force	Force required to activate power shall be high enough and oriented such that it is unlikely to be accidentally triggered on and especially off.	Avoid accidental power down,
6.3.20	Hot-swappable	Battery shall be able to be replaced with another battery during use in the operating room.	Functions for entire surgery

6.4. Durability

Enhanced durability is important to endure the more rugged conditions of a low-resource hospital environment.

Table 6.4: Durability Requirements

ID	Characteristic	Minimal	Needs Addressed
6.4.1	Device operational life expectancy	Device shall continue to operate according to specification for 3500 hours without need for repair or replacement parts (6hrs/day x 5 days/week x 48 weeks/year x 2 years + 20%).	Long-lasting device, low total cost of ownership
6.4.2	Battery lifetime	Headlight kit shall include enough battery packs to operate for the number of charging cycles required to achieve device life expectancy assuming battery(s) is recharged every time it is depleted to 50%. For example, a kit that must last for 3500 hours with two 3 hour batteries, each battery will experience $3500 / 2 \text{ batteries} / (3 \text{ hours} * 50\%) = 1200$ charging cycles.	Continuously ready for use, long-lasting device, low total cost of ownership
6.4.3	Device storage life expectancy	Device shall operate according to specification after being stored for	Lasts in storage and shipping,

		12 months at storage temperature and humidity.	
6.4.4	Impact resistance	Ideally, headlight battery and headlight would continue to operate according to requirements after withstanding six drops at different angles onto cement surface from 1m height.	Functions after dropped, long-lasting device
6.4.5	Impact resistance in shipping packaging	Battery and light shall continue to operate according to requirements and are visually intact after shipping. Desired but not required to pass ASTM or ISTA testing.	Lasts in storage and shipping,
6.4.6	Moisture & particulate resistance	Ideally, device would meet IP54 standard “splash resistant and dust protected”; battery and light would continue to operate according to requirements after being wiped 100 times with a wet cloth with potentially water, mild detergent, or isopropyl alcohol (5% x 4 operations/day x 5 days/week x 48 weeks/year x 2 years).	Continues working if splashed, continues working in dusty environment, easy to wipe down, avoid accidental power down, long-lasting device,
6.4.7	Use temperature and humidity	Device shall operate according to specification at temperatures 10 degC - 40 degC, and humidity 30 - 90% RH.	Avoid accidental power down, long-lasting device,
6.4.8	Storage temperature and humidity	Device shall function according to specification after up to 12 months of storage in shipping packaging at range of temperatures -20 degC to 50 degC, and humidity 30 - 95% RH (“Medical Device Transit Testing” n.d.).	Lasts in storage and shipping,
6.4.9	Shipping temperature and humidity	Device shall function according to specification after 8 hours in shipping packaging at range of temperatures -20 degC to 50 degC and humidity 30 - 95% RH	Lasts in storage and shipping,

		("Medical Device Transit Testing" n.d.).	
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6.5. Health and Safety

These requirements focus on protecting the surgeons and bystanders from harm.

Table 6.5: Health & Safety Requirements

ID	Characteristic	Minimal	Needs Addressed
6.5.1	Headlight temperature - surfaces touching the body	Surfaces of the headlight and battery assembly that lay against the body when worn shall not exceed 48 degC when operating normally within required use temperatures ("ANSI/AAMI ES60601-1:2005/(R)2012, (IEC 60601-1:2005, MOD)" n.d.).	Comfortable to wear,
6.5.2	Headlight temperature - other surfaces	Outer surfaces of the headlight assembly shall not exceed 60 degC for plastics and rubber, or 51 degC for metal when operating within required use temperatures ("ANSI/AAMI ES60601-1:2005/(R)2012, (IEC 60601-1:2005, MOD)" n.d.).	Comfortable to wear,
6.5.3	Noise when headlight is powered on	Noise from headlight shall not exceed 90 dBA ("Occupational Noise Exposure. - 1910.95 Occupational Safety and Health Administration" 2018) and is ideally less than 30 dBA ("ANSI/AAMI HE75:2009/(R)2013" n.d.)	Protect ears, comfortable to wear,
6.5.4	Protection from battery acid	Battery(s) shall be sourced from a trusted, quality, battery manufacturer with ISO 9001 quality certification, ideally with CE marking.	Long-lasting device, comfortable to wear,

6.6. Other

Table 6.6: Other Requirements

ID	Characteristic	Minimal	Needs Addressed
6.6.1	Instructions for Use	Headlight kit shall include a comprehensive, printed instructions for use available in the following languages; English, French, and Spanish. Ideally it would also include instructions for use in all WHO official languages including Arabic, Chinese, and Russian, as well as Amharic and Hindi to cover Lifebox partnership countries.	Requires no training,
6.6.2	Kit branding	Headlight kit shall display Lifebox brand elements on carrying case or bag and on headlight.	Trust the device, convey Lifebox brand, keep kit together
6.6.3	Kit container	Headlight kit shall include a reusable carrying case or bag that protects all kit parts including space for 2 batteries, can be carried securely while walking or riding a bicycle or motorbike, and will last for device life expectancy .	Continuously ready for use, find own headlight, long-lasting device, bring kit between places, keep kit together, convey Lifebox brand

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