

Automated Surgical Headlight

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I am thankful to IDC, IIT Bombay for providing me with the infrastructure and support of all kind.

A handwritten signature in black ink, followed by the date '29.05.2019' written below it.

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Primary Research

Introduction

Surgical Lights are medical devices intended to assist medical personnel during a surgical procedure by illuminating a local area or cavity of the patient.

Usually a combination of several surgical lights are used in operation theatres and is referred to as a 'surgical light system.' [Fig. 01]

The market share of Surgical Lights is “forecasted to reach \$859 million by 2024...with Asia-Pacific expected to grow at a CAGR of 5.2%” as reported in the Global Surgical Lamp Market Report by Variant Market Research.

Some of the top manufacturers of surgical lights are DRE, BFW, Welch Allyn, Burton and Stryker.



Fig. 01

Light Sources

Light sources commonly used in surgical lighting are:

- Halogen
- Metal-Halide
- Optical Fibre with LED Light Source
- LB LED
- Xenon

Though halogen surgical lights have long been the industry standard, they are becoming quickly outpaced by newer LED models [Fig. 02] as they have major advantages such as:

- Reduced Energy Requirement
- Longer-rated Battery Life
- Low-heat Radiation
- Consistent Illumination

The development of smaller LEDs have eliminated the need for optical fibres and proven to be a tough competitor for the more expensive xenon lights.

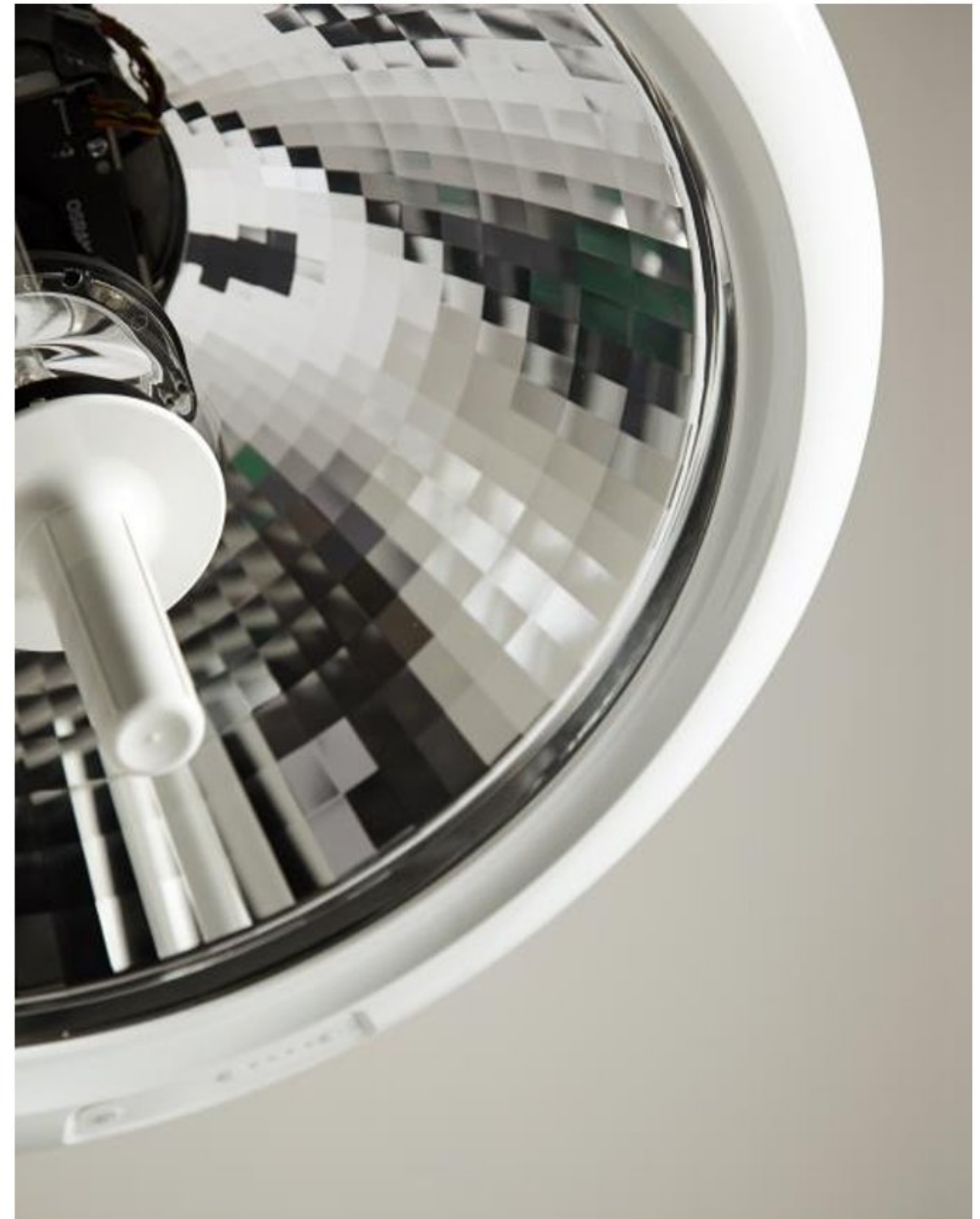


Fig. 02

Types of Surgical Light

The types of surgical light that are available in the market are:

- Ceiling / Wall Mounted Light [Fig. 03]
- Mobile On-floor Light Stand [Fig. 04]
- Portable Headlight [Fig. 05]

Eventhough they are generally used in conjunction with each other, there are specific scenarios for which they are designed for.

Ceiling / wall mounted & mobile floor lights are suitable for minimally invasive surgeries as they provide diffused ambient light. However, headlights are used for open surgeries as they provide a uniform spotlight to illuminate the body cavity.



Fig. 03



Fig. 04



Fig. 05

Advantages of Headlight

Advantages of using a Surgical Headlight [Fig. 06] are:

- **Uniform & Shadow-free Illumination:**
Overhead lights cast shadows of the surgeon and the instrument on the operating field which is absent in the case of headlights. They also produce an ultra-bright central illumination with dull edges causing colour distortion on the lighted operating field while surgical headlights produce light with uniform brightness.
- **Ease of Use:**
Being worn on the head, headlights can be moved around to focus light without interruptions for manually adjusting the direction.
- **Portability:**
Being compact and portable, headlights allow for freedom of movement and don't occupy storage space.
- **Economical:**
LEDs are cheaper, reduce energy consumption and last longer than the bulbs used in overhead lamps.



Fig. 06

Types of Headlight

Surgical Headlights can be classified based on how the lighththead is mounted:

- Loupe Mounted [Fig. 07]
- Headband Mounted [Fig. 08]

Headband Mounted Lights have several advantages over the other as they provide:

- Occipital Support to balance and distribute the weight and reduce neck strain
- Cranial Support to stabilize the headlight position
- Adjustability for right fit without temporal compression

Various headbands made of fabric (wears out over time), elastic band (creates pressure and discomfort over time) or flexible plastic are available in the market.



Fig. 07



Fig. 08

Headlight Accessories

Surgical Headlights are generally sold with a set of essential accessories [Fig. 09]:

- Li-ion/LiPo Battery Packs + USB Cable & Charger/Multi-bay Charger
- Secure Hard Carrying Case

along with optional secondary accessories:

- Padding Set (used as and when the buttoned-up / velcro padding wears out)
- Sterile Handle Cover (as surgical lights are not sterile equipments)
- Curing Light Filter (used in dentistry to prevent light from polymerising light-activated materials)

Additional features are provided by compatible equipments:

- Coaxial Headlight Imaging System
- Magnifying Loupes Set



Fig. 09

Context

Usage Scenarios

Headlight systems could be used in any one of the following scenarios:

- Examination
- Dental
- Surgical

The usage scenario defines the specifications that are required like illumination level, colour temperature or presence of filters.

Surgical Headlights are used in open surgeries where illumination of a cavity is required. It could be used in General, Cardio-thoracic & Vascular, Neuro & Spinal and Transplant surgeries to name a few.

In most cases, surgeons stand next to patient looking downward like in Caesarean Section [Fig. 10]. The lighthead is hence given a downward tilt angle [Fig. 11].

Rarely, surgeons sit down with their head level with the patient like in Obstetric Fistula Repair [Fig. 12]. Hence the lighthead given a little upward tilt [Fig. 13].



Fig. 10



Fig. 11



Fig. 12



Fig. 13

Users

The users of surgical headlight can be viewed as:

- **PRIMARY** - surgeons, clinicians, proceduralists
- **SECONDARY** - first assists, scrub nurses, circulating nurses
- **TERTIARY** - servicing technicians

However, there is no standard daily usage pattern as they are dictated by the day-to-day clinical duties of the surgeon. While a resident general surgeon may have multiple procedures during the day of shorter duration [Fig. 14], a specialist surgeon may have fewer yet longer critical operations to attend [Fig. 15]. On the other hand, a consulting surgeon will have to travel between clinics/hospitals to attend to patients [Fig. 16].

Generally surgeries last for a minimum of 30-45 min to a maximum of over 6 hrs. Hence a fully charged battery should atleast cater to the average duration of 1.5 hrs.

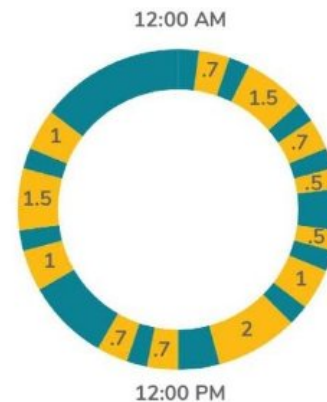


Fig. 14

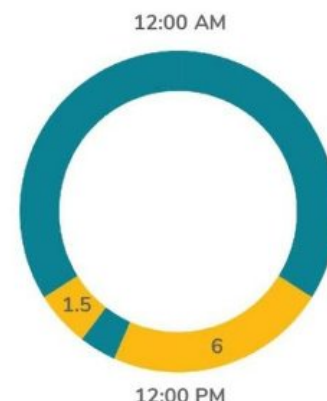


Fig. 15

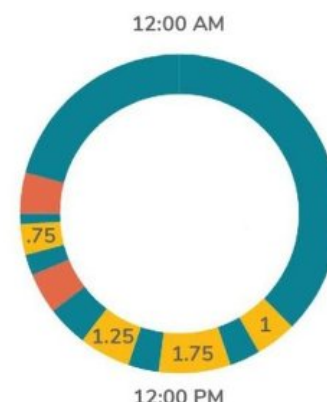


Fig. 16

LEGEND:

Not in Use



In Use



In Transit



User Study

Interviews were carried out with Dr. Manish Agarwal and Dr. Manit Gundavda, orthopedic oncologists at P. D. Hinduja National Hospital in Mahim, Mumbai, along with inputs from Prof. B. Ravi & Dr. Rupesh Ghyar from BETiC-OrthoCAD Lab, IIT Bombay. A summation of the same are as follows:

- Purchased by hospitals as well as by doctors for personal use.
- Quite expensive as they are all imported – lack of indigenously made products.
- Primary light source in open surgeries and could replace surgical lights in future.
- Illuminates the surgeon's point of view and hence only one headlight is required in OT.
- Surgeons face neck and/or back pain from prolonged usage.
- Not a sterile equipment and nurses' help is required to operate after scrubbing.
- Surgeons move in & out of OTs to refer scans, consult doctors, attend other procedures, etc.
- Equipments & instruments tend to get passed over the surgical area in the OT.

The design insights gained are as follows:

- Provide provision for attaching loupes and/or integrating cameras.
- Prevent misalignment from occurring between the loupes, headlight and line of vision.
- Intelligent/smart systems could be an added feature.
- Brightness & spot size of the light are usually not adjusted and used at the maximum level.
- Provide uniform lighting over varying working distances.
- Light angle is fixed before surgery & the set position needs to be secure.
- Separate out the battery pack in the pocket/waist to reduce weight & fatigue.
- Provide battery indicator as light sometimes switches off without warning.

Task Analysis

To better understand the role of the Surgical Headlight from a system design perspective, Task Analysis was done to document the end-to-end usage of the product by user(s) in the real world environment for the 3 phases of an operation and to gain insights for intervention.

Pre-Op:

- Wear scrubs including scrub cap and surgical mask. [Fig. 17]
- Select battery with sufficient charge, disconnect from charger and connect headlight to battery. [Fig. 18]
- Place and adjust headlight to fit on head. [Fig. 19]
- Turn headlight on to adjust illuminance, tilt angle and spot diameter. [Fig. 20]
- Place battery in back pocket or clip to waistband. [Fig. 21]
- Scrub hands, dry with sterile towel and put on sterile gown and gloves. [Fig. 22]



Fig. 17



Fig. 18



Fig. 19



Fig. 20



Fig. 21



Fig. 22

Task Analysis

During Operation:

- Circulating nurse makes adjustments in headlight and swaps batteries if required. [Fig. 23]

Post-Op:

- Remove gloves, gown and face mask. [Fig. 24]
- Switch headlight off and remove it from head and battery from pocket or waistband. [Fig. 25]
- Disconnect the battery and plug it into charger. [Fig. 26]



Fig. 23

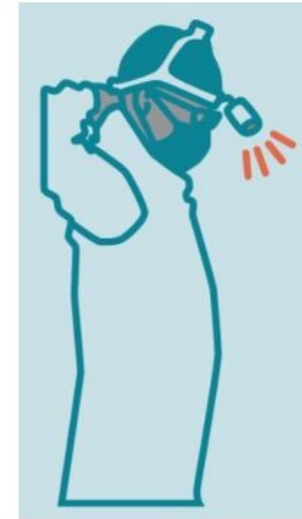


Fig. 24



Fig. 25



Fig. 26

Biomechanics

Using the headlight requires surgeons to hold their heads in a fixed, flexed position [Fig. 27] for long periods of time. Research in the 'Journal of Spine' correlated frequent headlight use with increase in severity and frequency of neck pain with the fixed, flexed posture being the main contributing factor.

Biomechanical studies show that axial loads are dispersed through an instantaneous axis of rotation (IAR) centered within the vertebral bodies. In a flexed posture, a moment (M) is generated by each component, determined by their weight times the distance (d) of the Centre of Mass from the IAR. This increases disc pressures within the cervical spine which may lead to degenerative neck disease.

Hence it is required to redesign the headlight to be light-weight with its centre of mass closer to the cervical disc when surgeon's head is in the flexed position.

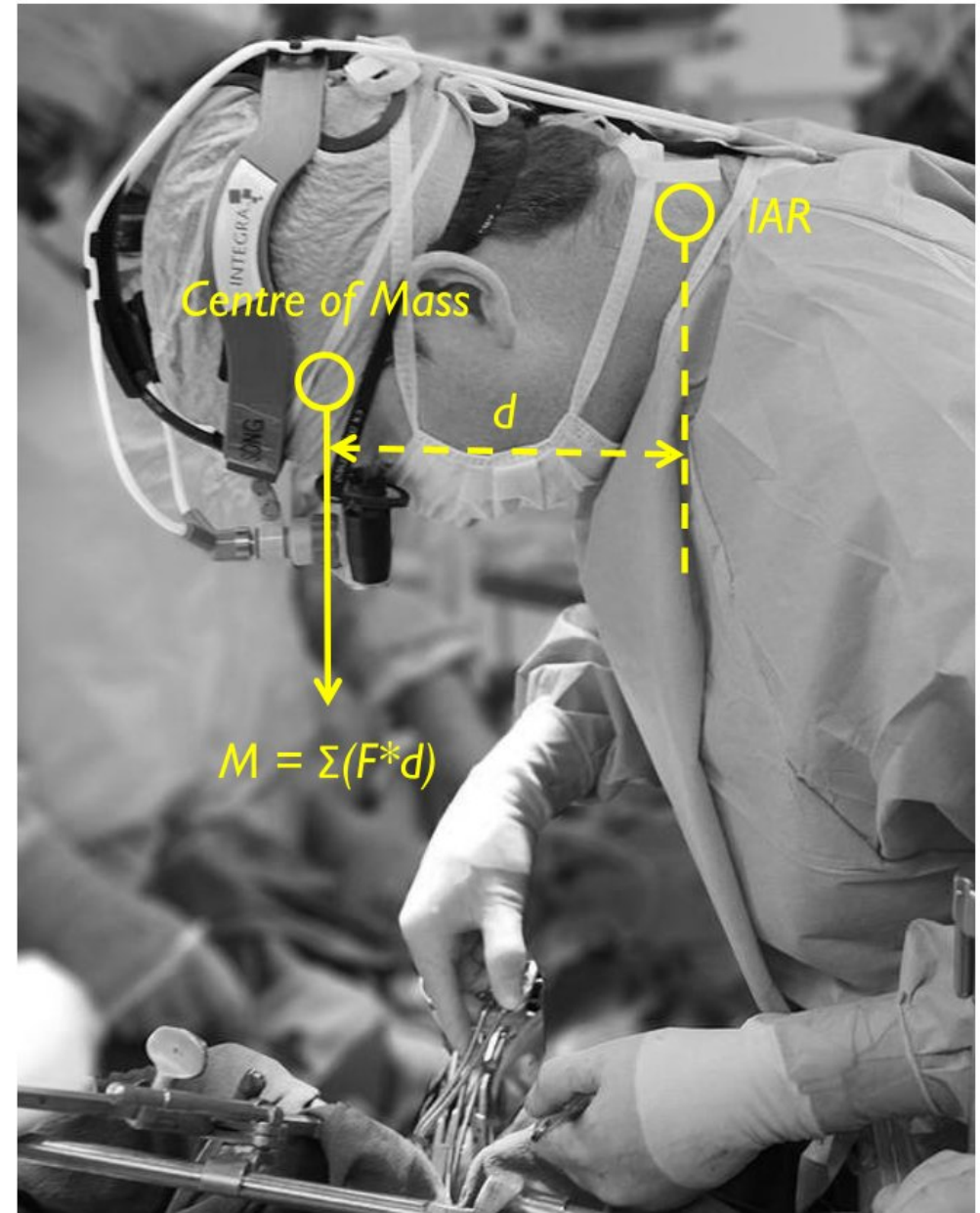


Fig. 27

Secondary Research

Patents

Patents were referred to map the new trends in innovation in surgical lighting. Some patents which incorporated novel design interventions were:

- **US8348448B2** [Fig. 28, 29, 30]
Provision for a removable stabilizer at the rear of the headband to cradle the occipital bone of the head when worn for improved stability and maximizing comfort.
- **US20120259178A1** [Fig. 31]
A smart illumination system by automatic tracking of an optical marker on a surgical glove worn by a clinician to provide consistent illumination during a surgical procedure.

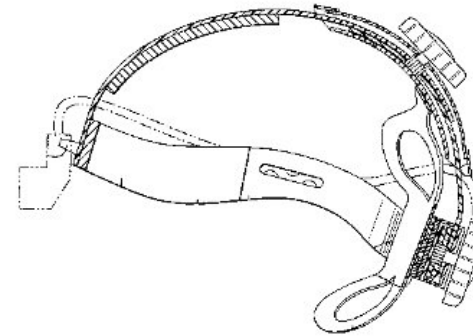


Fig. 28

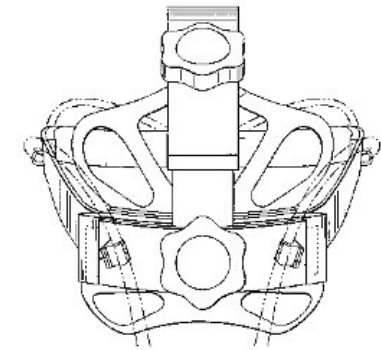


Fig. 29

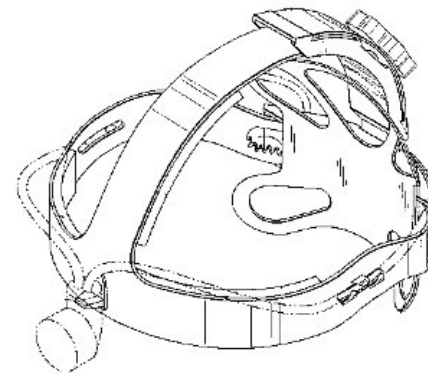


Fig. 30

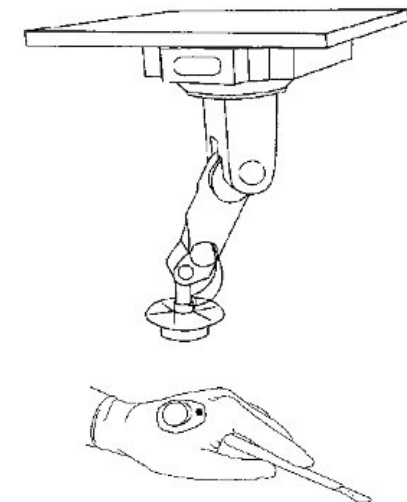


Fig. 31

Existing Smart Systems

The market was studied for intelligent systems in surgical lighting for their incorporation of technology into their features. Two significant existing systems are:

iLED 7, Trumpf Medical [Fig. 32]

- **Eliminates Shadows:**
 - a. Sensors identify obstacles in illumination field.
 - b. Individual LED modules are accordingly automatically activated / deactivated.
- **Consistent Lighting Conditions:**
 - a. Sensors identify the current working distance.
 - b. Illumination level and light field size are automatically adjusted to maintain uniformity.



Fig. 32

FlexInLight, Telstar [Fig. 33]

- **Promotes Surgical Asepsis:**
 - a. Nurse identifies the point of illumination using a remote pointing device.
 - b. Motorized spotlights automatically reorient themselves to the said point



Fig. 33

Parallel Products

Headlights feature quite prominently in other fields of use as well, namely:

- Rescue / Response
- Govt. / Military
- Industrial / Tech
- Sport / Recreational

Two innovative products available in the market to cater to the above fields are:

- **Halo, ILLUMAGEAR [Fig. 34]**

This industrial headlight connects securely around any standard hard hat to produce a ring of light. It provides both 360° flood and task lighting to enable the wearer to see and be seen.

- **HeadLamp 330, BioLite [Fig. 35]**

This trekking headlight has a strap with moisture-wicking fabric to keep it dry for any activity. It integrates the light and wiring into the strap allowing for a one-piece design where the lighthouse sits flushed without bouncing or slippage.



Fig. 34



Fig. 35

Industry Specification

The IEC 60601-2-41 [2009] by the International Electro-technical Commission outlines the requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis. The prescribed specifications are three-fold:

Homogenous Light:

- Central illuminance - 40,000 to 160,000 lux
- Light field diameter D50 – min. 50% of D10
- Colour rendering index (Ra) – 85 to 100

Power Backup:

- Within 5s, light restored to 50% intensity [min. 40,000 lux]
- Within 40s, light restored to original brightness

Appended Information:

- Voltage & power consumption marked near the light-head
- Instructions for use should include:
 - a. Cleaning of surgical light
 - b. National rules for hygiene and disinfecting
 - c. Safety aspects of optical filter
 - d. Specifications of light used - central illuminance, light field diameter, depth of illumination, shadow dilution, total irradiance, colour temperature and colour rendering index

Incorporating Automation

Product Interface

Several adjustments can be done to the lighthouse position based on the number present:

- Adjustable Declination Angle [Fig. 36]
- Adjustable Convergence Angle (Dual Head) [Fig. 37]
- Adjustable Pupil Distance (Dual Head) [Fig. 38]
- Flip-up when not in use

However only a single lighthouse is considered for the project based on user feedback.

The headlight interface also allows for the following adjustments for the light:

- Power: ON / OFF
- Brightness: 4 Illumination Levels + Turbo
- Spot Size: 3-4 Sizes
- Colour Temperature: Cool White / Neutral White / Warm White

In the case of an integrated Coaxial Headlight Imaging System, the following adjustments can also be made:

- Upto 2.5x Manual / 16x Digital Magnification
- Photograph Images



Fig. 36

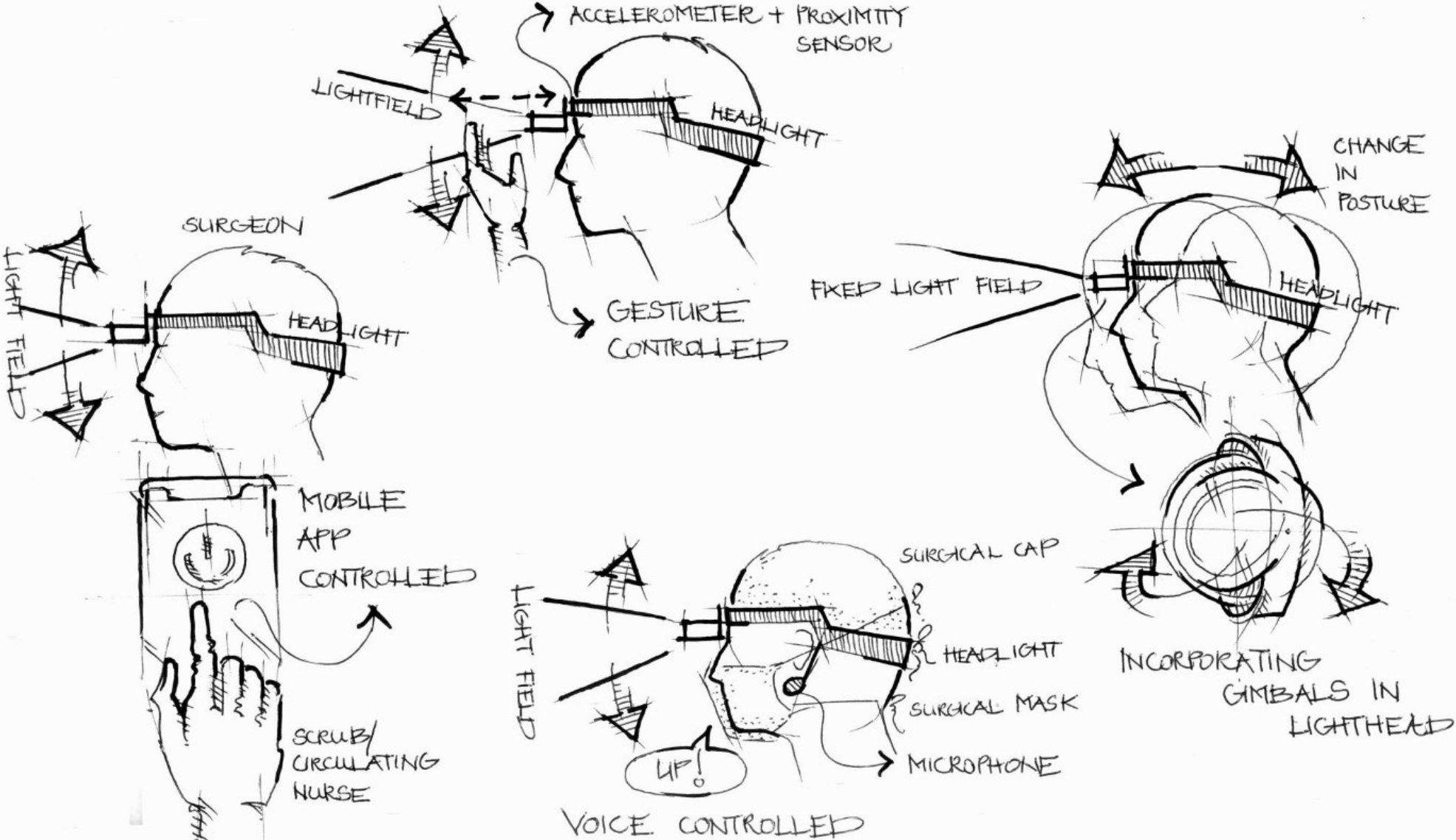


Fig. 37

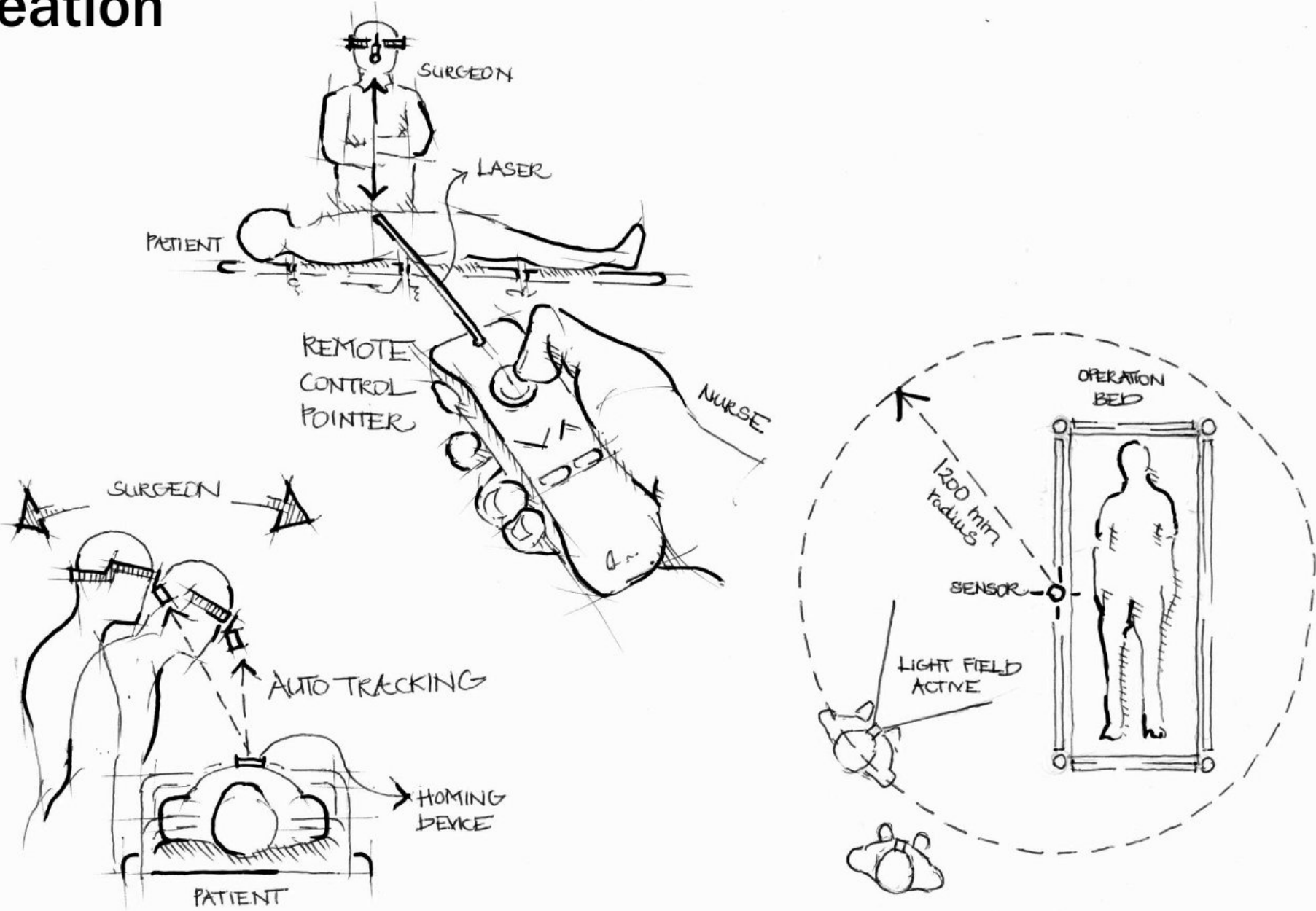


Fig. 38

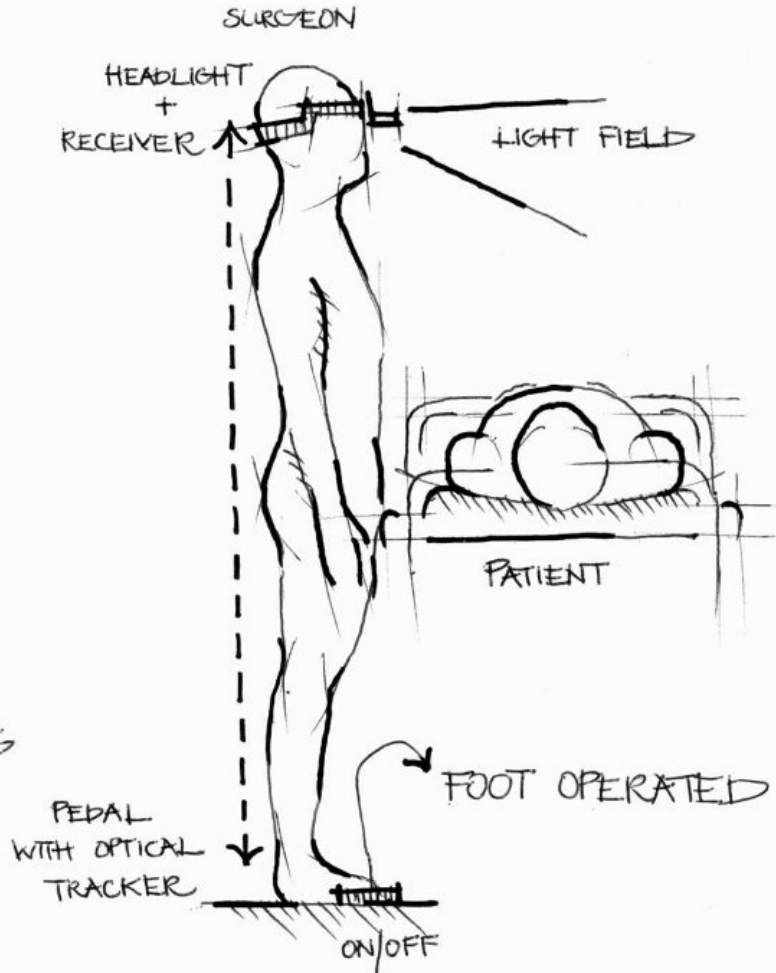
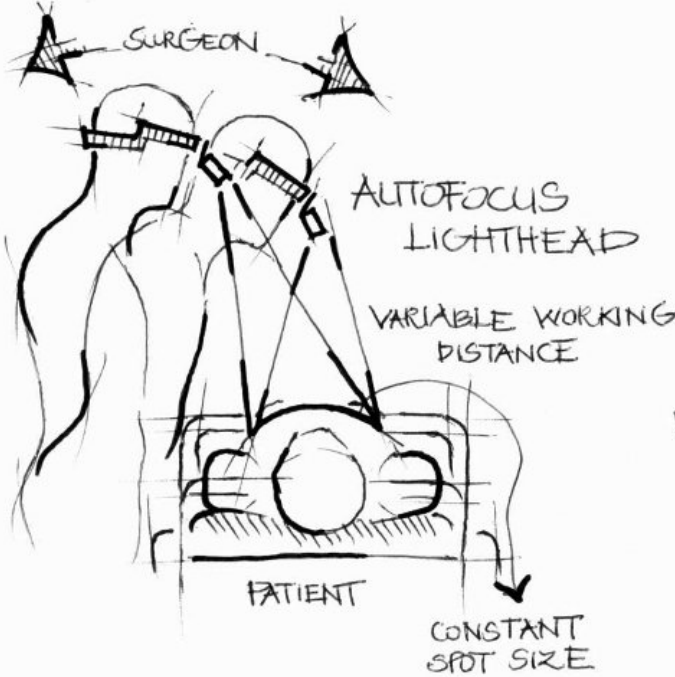
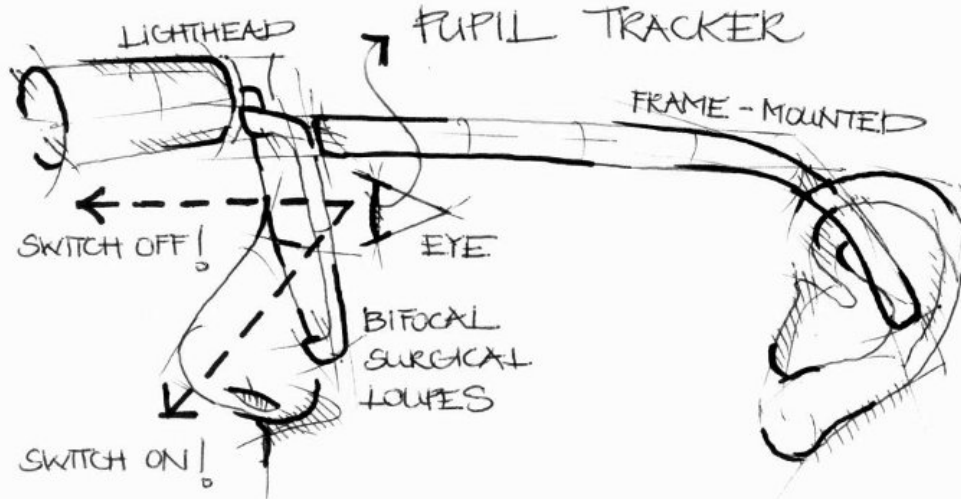
Ideation



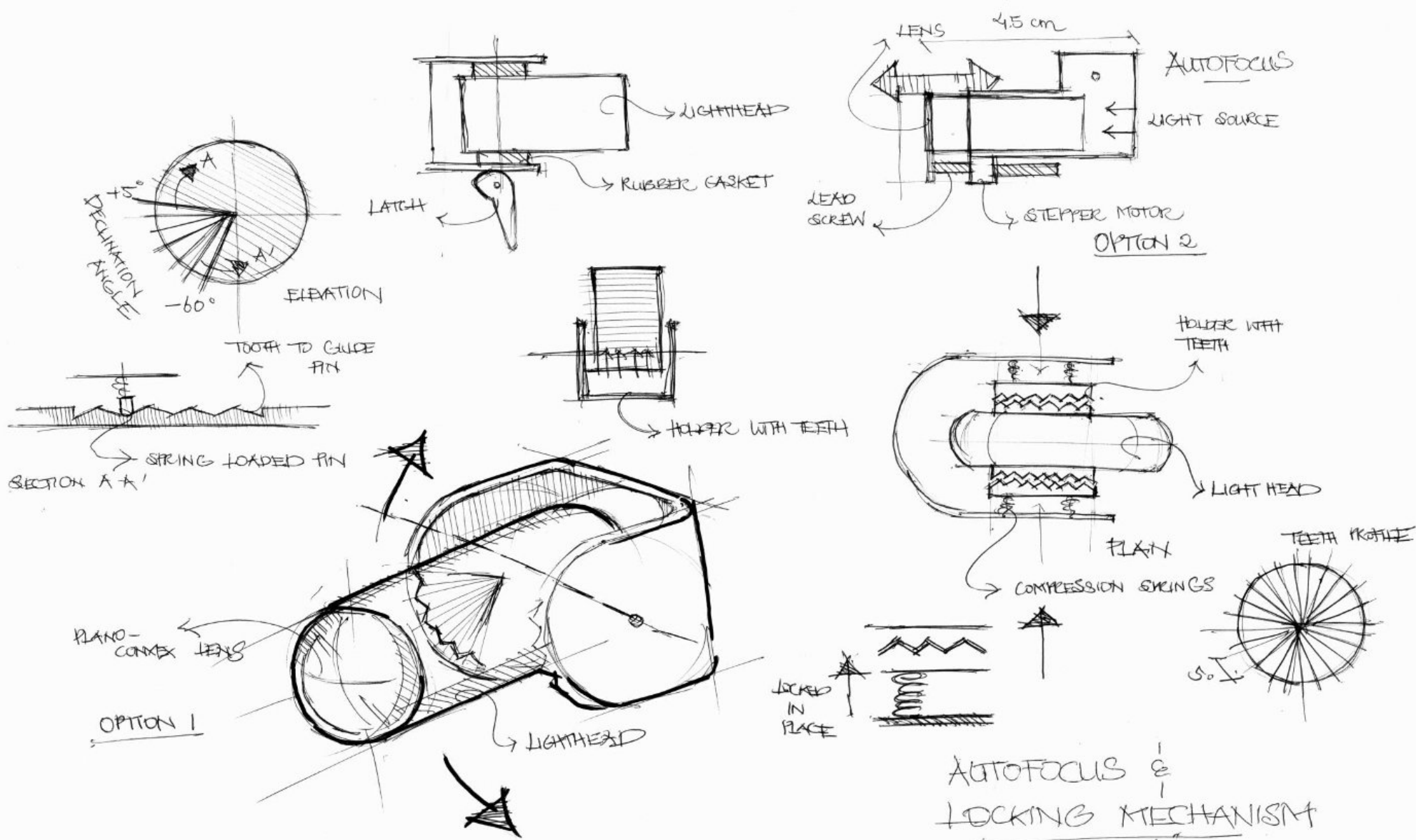
Ideation



Ideation



Ideation



Optics

For a better understanding of optics, Prof. Parinda Vasa in the Dept. of Physics, IIT Bombay, was consulted.

A combination of three plano-convex lenses [Fig. 49] of 12mm dia. and focal length 15mm will be used in the lighthouse. Lenses L1 & L2 are placed adjacent to each other, with the LED at the focus of one. This collimates the light beam and makes it a point source at the focus of the other lens.

By moving lens L3 such that the point source lies within its focus, the angle of divergence of the light beam is varied such that a constant spot size of 10cm is created over a varying working distance of 35cm to 45cm [Fig. 50].

Using the three lens configuration reduces diffusion to create a consolidated light spot as well as removes the need for a parabolic reflector which allows for light losses.

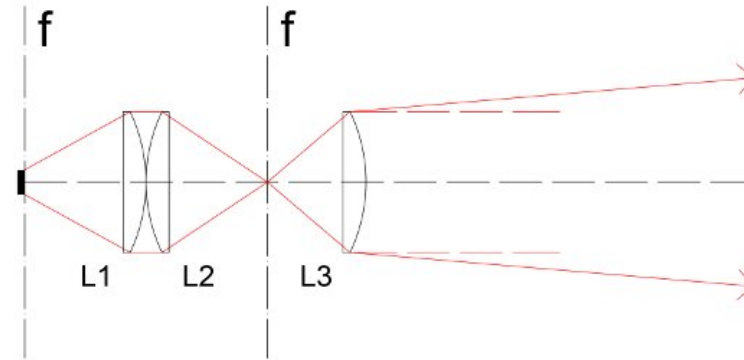
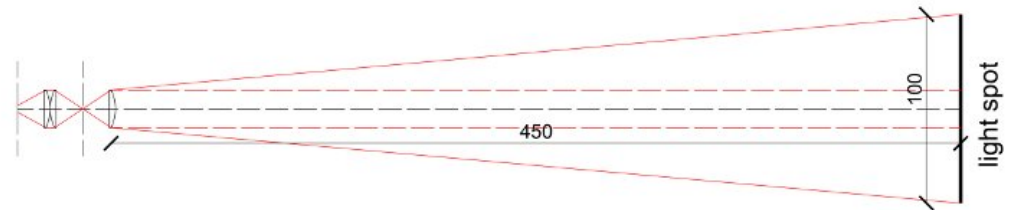
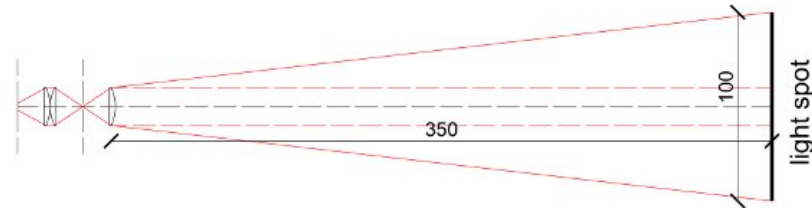


Fig. 49



*all dimensions are in mm.

Fig. 50

Product Specification

A Chip On Board (COB) LED, paired with a heat sink of size 20mm dia. X 15mm, with the following specifications shall be used:

- Colour: White, Neutral
- Colour Rendering Index (CRI): 97
- Illuminance: Min. 35,000 lux
- Luminous Flux: Min. 1100 lm.
- Light Emitting Surface (LES): 3mm dia.
- Size: 20mm dia. X 1.50mm

The lens will be moved using a servo motor of size 22mm X 14mm X 13mm with feedback received from an IR sensor of size 30mm X 13mm X 13mm – both connected to an Arduino Nano. A camera module of size 25mm X 25mm X 4mm will be connected to a Raspberry Pi Mini.

The LED, R-Pi and Arduino will be powered by a rechargeable Li-ion battery of size 75mm X 55mm X 20mm via suitable voltage converters and LED driver as shown in the circuit diagram [Fig. 51]. All the above components amounted to ₹10,000.

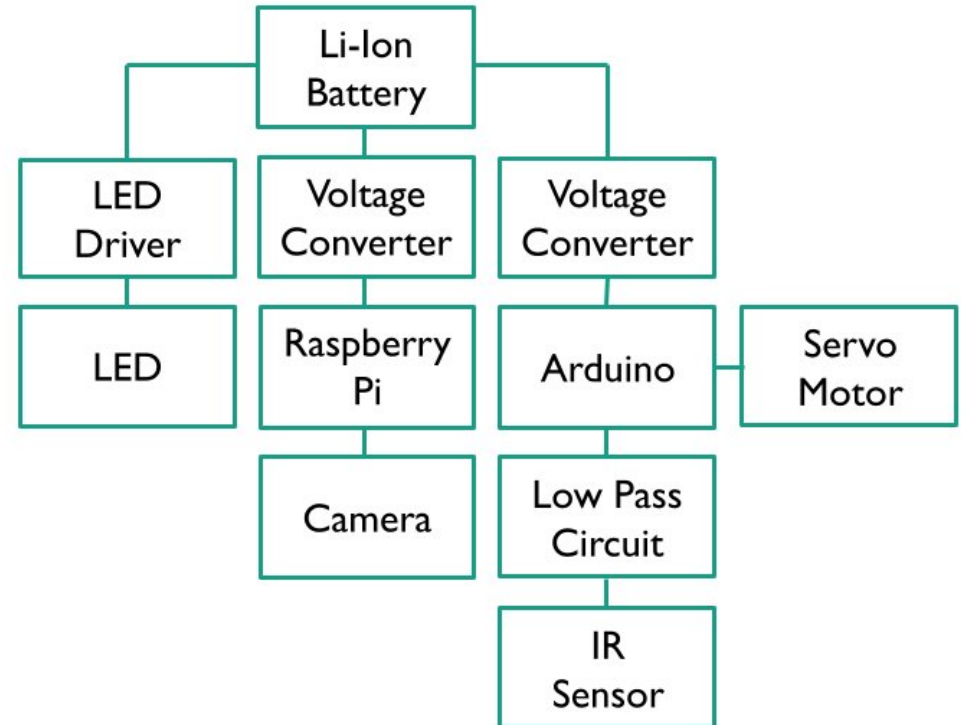


Fig. 51

Proof-of-Concept

A proof-of-concept was made using three optical lenses in order to produce a constant spot size over a varying working distance.

A servo motor was also used to move the lens in relation to the feedback from an IR sensor. A camera was added to wirelessly stream HD video to a laptop and mobile phone [Fig. 52].

The proposed automation was well received by surgeons and medical personnel, with feedback to incorporate varying illuminance based on the working distance and/or the ambient lighting conditions. This can be done with appropriate coding of the existing components used.



Fig. 52

Design Language

Design Framework

Design Statement

To design a wearable device for **automated illumination of surgery area** in operation theatre.

Design Framework

Design Brief – ‘must haves’

- Should provide uniform & shadow-free illumination, where lux does not vary by more than 25% at a working distance of 350 - 450mm.
- Should promote good posture by allowing light tilt angle to be adjustable between $+5^{\circ}$ & -60° .
- Should provide adjustability for correct fit, accommodating 5th & 95th percentile indian men & women 20 years old or more.
- Should be lightweight, not exceeding 300g if components are worn on head.
- Should provide steady lighting by securing the set position of lighthouse.
- Should promote efficient dissipation of generated heat such that surfaces in contact with the body do not exceed 48° C.



Fig. 53

Design Framework

Design Brief - *'may haves'*

- Can be **automated to be easily operable** by user with little-to-no assistance.
- Can be **compatible with other surgical equipments** such as coaxial headlight imaging systems and/or surgical loupes.
- Can **provide 'hot-swap' batteries** for uninterrupted usage while swapping batteries during procedures.



Fig. 54

Ergonomics

The Indian Anthropometric Dimensions for Ergonomic Design Practice by Debkumar Chakrabarti was referred, to determine the sizing and variation in adjustability of the headband based on:

- Head Breadth – 133mm (5th percentile)
[Fig. 55 a.] 157mm (95th percentile)
- Head Length – 170mm (5th percentile)
[Fig. 56 b.] 199mm (95th percentile)
- Head Circumference – 509mm (5th percentile)
[Fig. 55 c.] 569mm (95th percentile)

The lighthouse should be designed so as to not hinder vision as given by the average intercanthal distance [Fig. 57 d.] of 30mm.

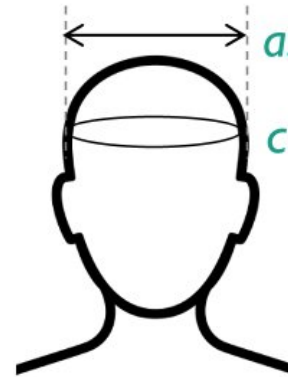


Fig. 55

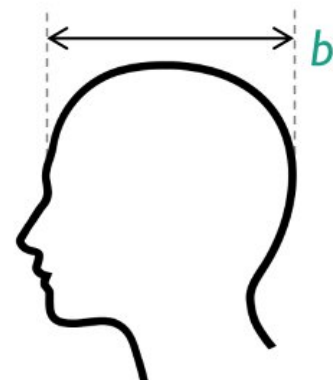


Fig. 56

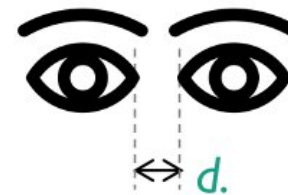


Fig. 57

Mood Board

'Clean & Clinical'

The first mood board is depicted by derivatives of simple forms defined by their edge profiles. They are characterized by polished, textured or brushed finished stainless steel or chrome used alone or in combination with each other to create a sterile look.



Fig. 58



Fig. 59



Fig. 60



Fig. 61



Fig. 62



Fig. 63

Mood Board

'Light & Minimal'

The second mood board is depicted by smooth transitions of platonic forms with curves and rounded edges to create a soft look. They are characterized by white, off-white or translucent volumes with a smooth finish for a 'less is more' visual palette.



Fig. 64



Fig. 65



Fig. 66



Fig. 67



Fig. 68

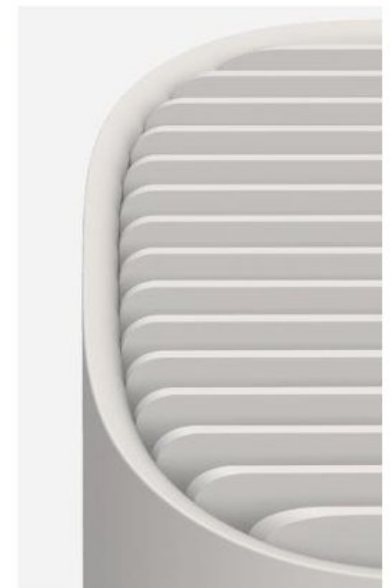


Fig. 69

Mood Board

'Sleek & Smart'

The third mood board is depicted by articulation of sleek and elongated forms and silhouettes with dynamic lines and edges. They are characterized by incorporating streaks of light with muted metallic or glossy surfaces to give a hi-tech look.



Fig. 70



Fig. 71



Fig. 72



Fig. 73

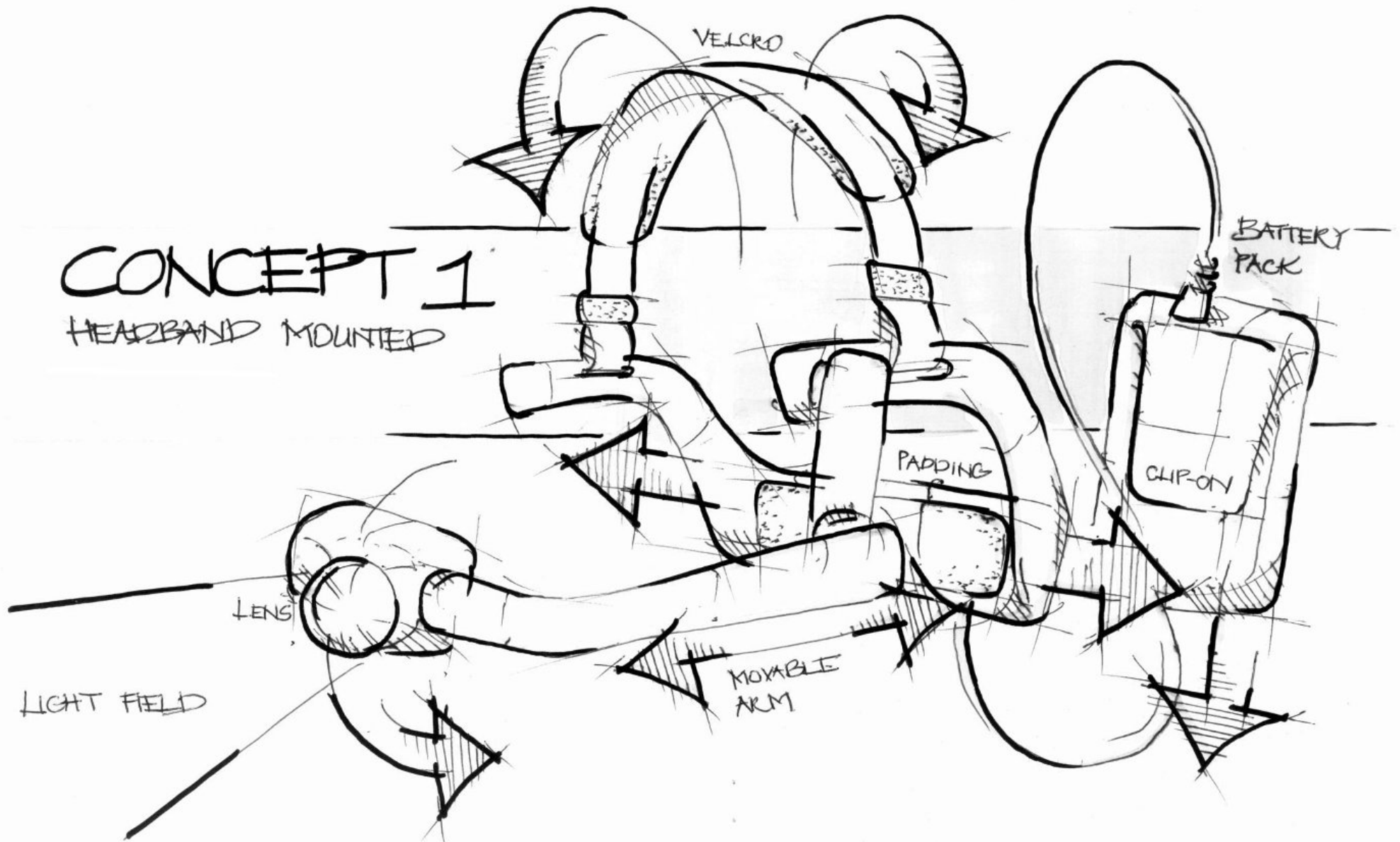


Fig. 74

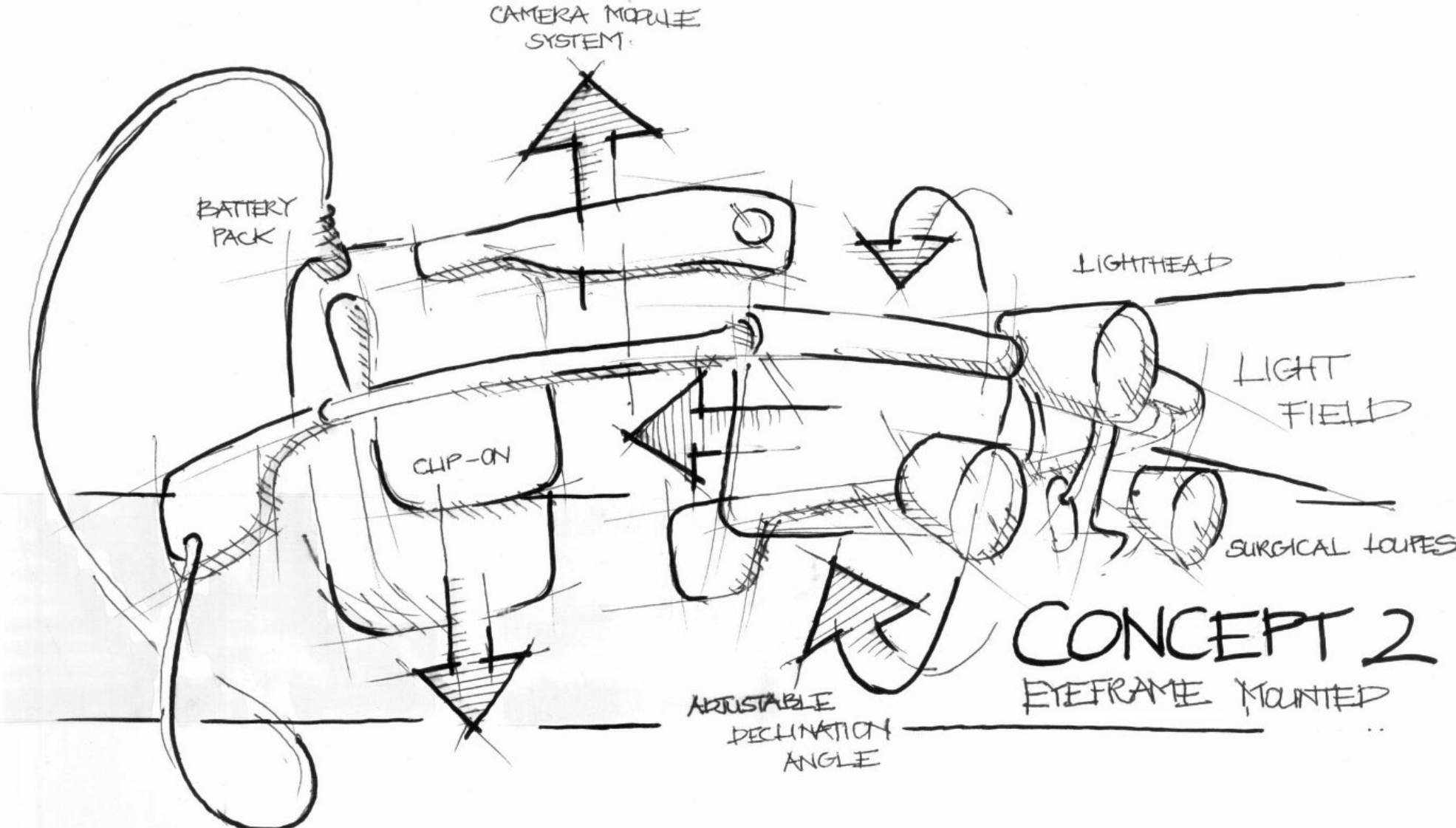


Fig. 75

Initial Concept



Initial Concept



Lighthouse Configuration

Along with the lenses, LED and heat sink, the lighthouse also holds the camera, motor and IR sensor as they also need to be aligned to the tilt angle. They are mounted on a hinge with a pin-locking mechanism to secure the set position of the lighthouse. Several configurations for the lighthouse were looked at: one with components arranged on top at an angle [Fig. 76], another where they are arranged vertically above and below [Fig. 77] and where they are arranged horizontally on either side [Fig. 78].

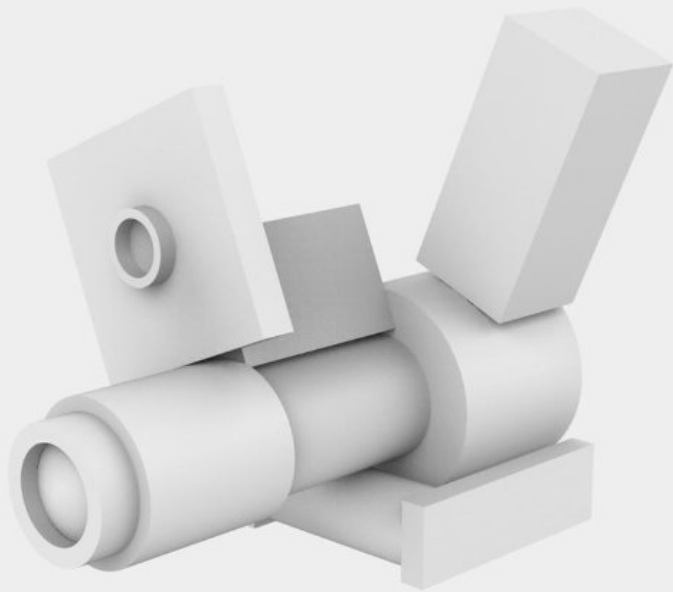


Fig. 76

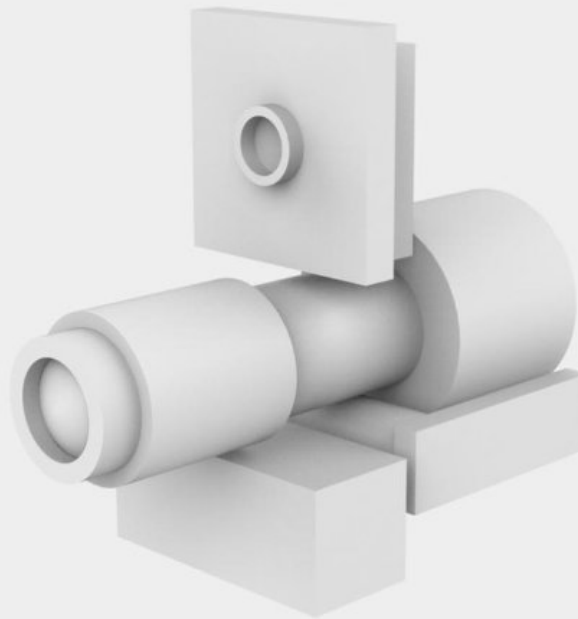


Fig. 77

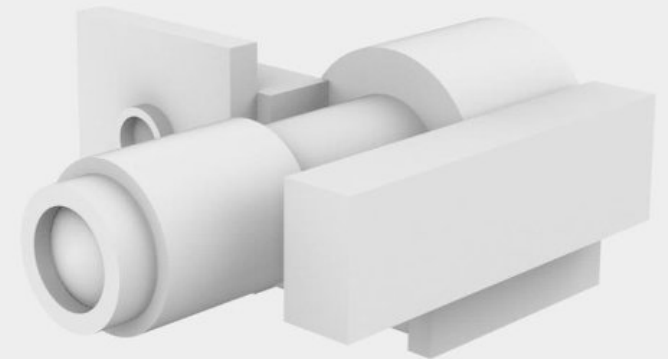


Fig. 78

Lighthouse Configuration

Based on the configurations discussed earlier, three forms for the lighthouse were designed to accommodate the components. The first form [Fig. 79] did not integrate the various components together well and is visually disjointed. The second form [Fig. 80] has undercuts which will be difficult to clean. The last lighthouse form [Fig. 81] based on the third configuration is the most simple and compact of the three, allows for easy cleanability and its horizontal form sits well with the adjoining headband.

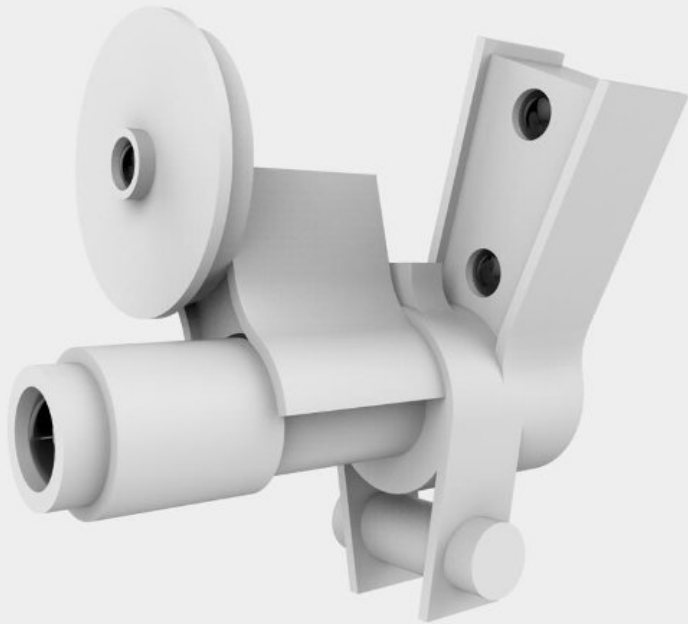


Fig. 79



Fig. 80

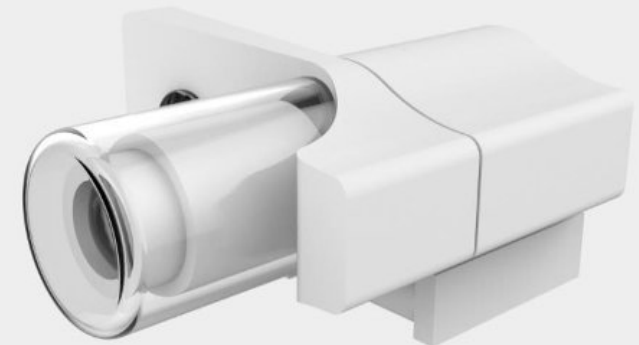


Fig. 81

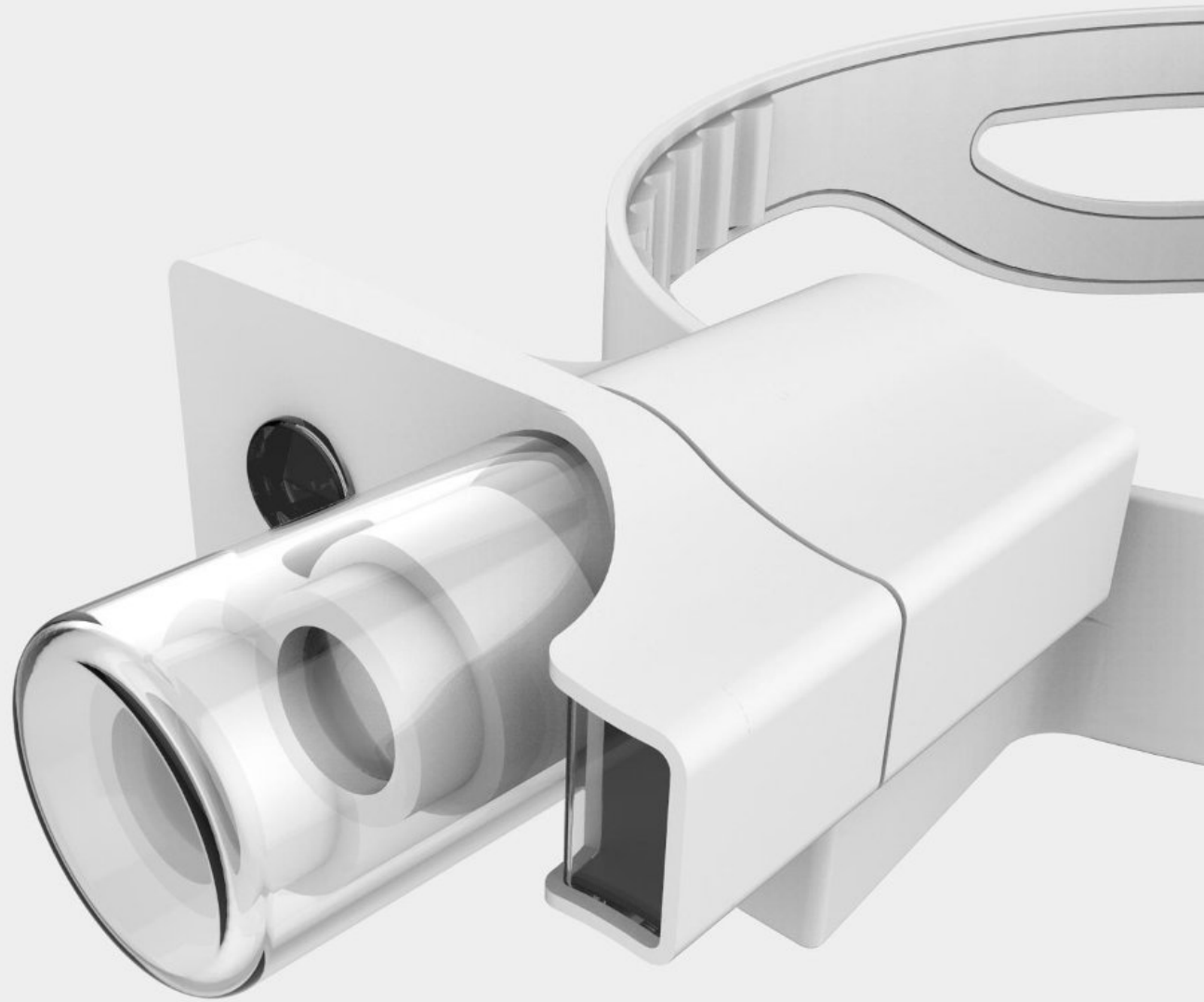


Final Concept

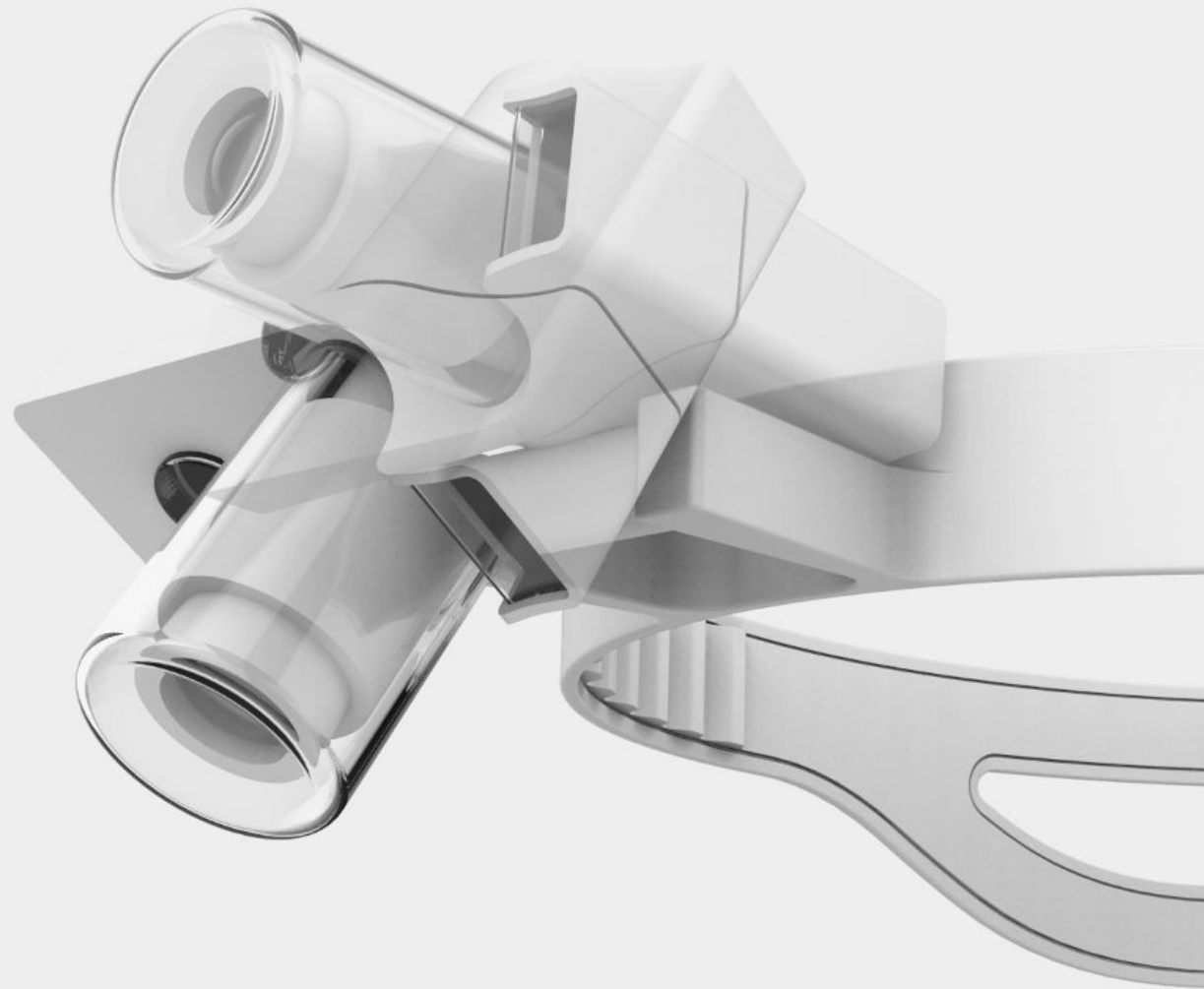
The final form of the lighthouse is horizontally articulated, with the IR sensor to its left, with the transmitter and receiver oriented to the front. The camera sits to its right with the servo motor placed behind it.

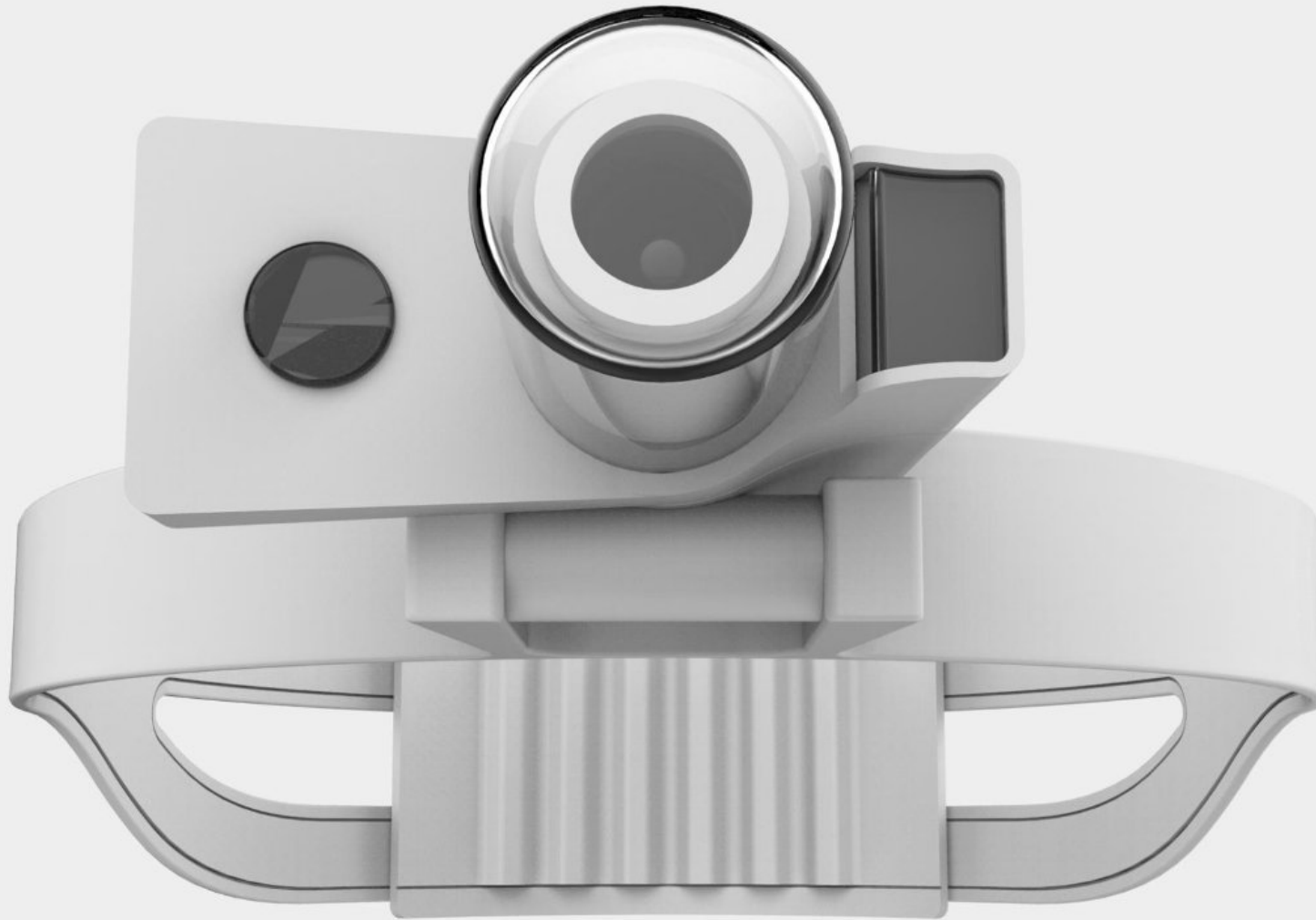
The front portion of the lighthouse holding a single lens moves linearly by 1 cm with a rack and pinion mechanism to translate the rotational motion of the motor into a linear one.

This is enclosed within a transparent removable cover to prevent direct contact with the moving part as well as to allow for easy cleanability. It can also double up as a sterile handle to allow the surgeon to change the tilt angle.



The lighthouse is mounted on a hinge to allow for an adjustable declination angle between $+5^\circ$ & -60° . The hinge has a pin locking mechanism to secure the set position of the lighthouse at 5° intervals.



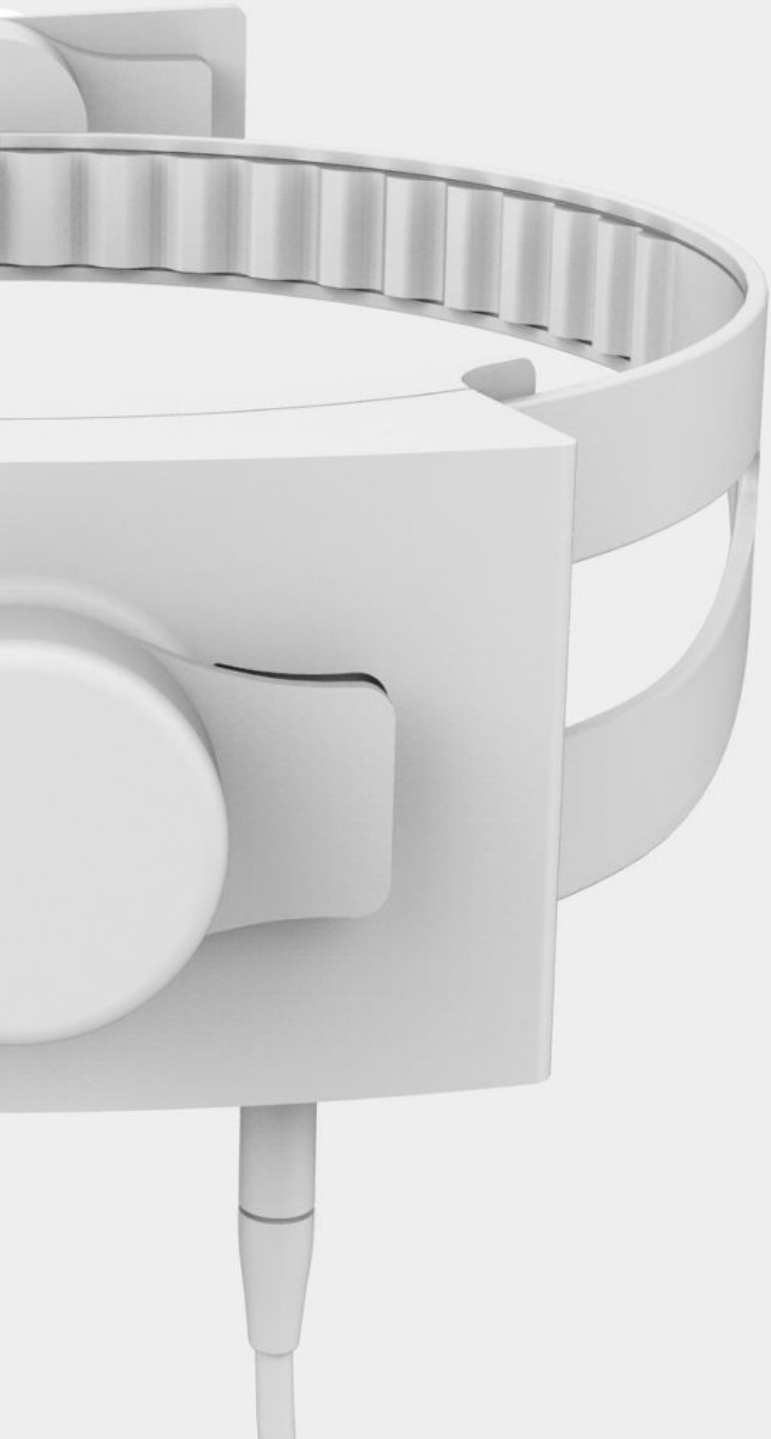


The lighthead is attached to a moulded flexible PU / Silicone / Fluoro Rubber strap that is easy to clean and maintain. It extends out below at the rear to stabilize the headlight and provide occipital support to the head.

The inner surface of the rubber strap has an indented profile at the front and back. This allows for additional grip and prevents slippage as well as allows for breathability and prevent sweat accumulation.

Cut-outs are provided in the rear end of the strap to accommodate a toothed profile – on the top edge of the cut-out at one end of the strap and on the bottom edge at the other end.





The processor, voltage controller and LED driver are placed within a casing at the rear to make the headlight back-heavy.

The two ends of the head strap pass within the casing with a turnable knob to allow for adjustability for correct fit using a rack and pinion mechanism.

The headlight comes with a pair of rechargeable battery packs, to be carried in the surgeon's pocket or waistband with the clip provided. A detachable cord powers the processor mounted on the headlight.

The battery interface has three options: Power OFF, Power ON & Camera ON, along with an LED display for the battery level and charging status.





Oc.LUX

Automated Surgical Headlight

The surgical headlight is branded as 'Oc.LUX', a derivative of two words: 'Oculus' - the Latin word for 'Eye' as well as referring to a circular opening - and 'Lux' - the Latin word for 'Light' and the SI unit for illuminance.

Learnings

Working on this project in collaboration with BETiC-OrthoCAD Lab, has allowed me to step outside my comfort zone in IDC by coordinating and collaborating with engineers from the Electronics, Mechanical and Biomedical departments.

As designing a medical device was a first for me, it was required that I gained the necessary domain knowledge by talking to surgeons to understand various scenarios and operations involved in the working of an OT in addition to reading patents, journals, research papers and prescribed industry specifications.

The product also required an understanding of optics in order to ideate, select and incorporate the appropriate automation as well as to choose the right LED and lenses to design the lighthouse. The various technical qualities of light also was understood in order to provide the necessary interface for operation.

Making a working prototype proved to be challenging as it involved being up-to-date with the technology available, understanding and choosing the appropriate electronic components in order to find the right configuration to design the product.

Annexure

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Questionnaire

Automated Surgical Headlight

This survey is part of the 'Collaborative Engineering' course at BETIC, IIT Bombay as well as the Semester Design Project at IDC, IIT Bombay.

The survey is meant to qualify the need for and to gain insights for designing the above mentioned product. The responses will not be shared with anyone else. Thanks for sparing your time.

- Vinod Louis Joseph Swamy, Industrial Design Centre (IDC), IIT Bombay
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* Required

1. Name *

2. Do you use surgical headlights? *

Mark only one oval.

- Yes
 No

3. Has the surgical headlight you are currently using obstructed/hindered your line of vision of the surgery area? *

Mark only one oval.

- Yes
 No

4. Has any misalignment occurred between the headlight, surgical loupes & your line of vision during surgery? *

Mark only one oval.

- Yes
 No

5. Has the light-head position moved out of the set position during surgery? *

Mark only one oval.

- Yes
 No

6. Does the lighting condition provided by your surgical headlight deteriorate when you move closer to the surgery area? *

Mark only one oval.

- Yes
 No

7. Has the surgical headlight switched off unexpectedly during surgery due to lack of battery charge? *

Mark only one oval.

- Yes
 No

8. Have you ever needed to rely on a nurse to make adjustments in the surgical headlight during surgery? *

Mark only one oval.

- Yes
 No

9. Has the headlight caused discomfort to other medical personnel by flashing light in their eyes? *

Mark only one oval.

- Yes
 No

10. Have you faced neck/back pain from prolonged usage of surgical headlight? *

Mark only one oval.

- Yes
 No

11. Any other problems you faced with the existing product?

12. Any feedback/suggestions?
