DEVICE TO AID EARLY DETECTION OF BREAST CANCER

PRODUCT DESIGN PROJECT III

ARCHANA SONAVANE
176130010

GUIDE: PROF. PURBA JOSHI

IDC School OF DESIGN
INDIAN INSTITUTE OF TECHNOLOGY, BOMBAY

2017 -19

ACKNOWLEDGEMENT

I would like to sincerely thank my project guide Professor Purba Joshi for her invaluable guidance and encouragement throughout my project.

I am grateful to Professor V.P. Bapat, Professor Kumeresan, Professor R. Sandesh, Professor Chakravarthy , Professor Sadhu and Professor Avinash for their inputs during presentations.

I am extremely grateful to ColMed, Amol Thube and Drashti Gandhi for their guidance in prototyping through this project.

A large credit goes to my family and my batch mates for their help and support.

Thanks to all the workshop staff at IDC for their cooperation and help. Thanks to IDC, IIT Bombay for providing me with the infrastructure and support of all kind.

APPROVAL SHEET

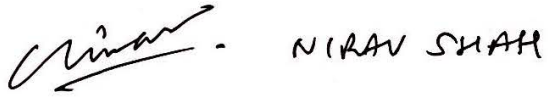
Industrial Design Project 03
Device To Aid Early Detection of Breast Abnormalities

By : Archana Sonavane
M.Des Product Design 2017-19
176130010

Is approved as a partial fulfillment of requirement of post graduate degree in Industrial Design.

Professor Purba Joshi:
(Project Guide)

External Examiner:



Internal Examiner:

Chairperson:

DECLARATION

I declare that this written submission represents my ideas in my own words and where other ideas or words are included, I have adequately cited and referenced the original sources. I also declare that I have adhered to all principles of academic honesty and integrity and have not misrepresented or fabricated or falsified any idea / data / fact / source in my submission. I understand that any violation of the above will cause for disciplinary action by the institute and can also evoke penal action from the sources which have thus not been properly cited or from whom proper permission has not been taken when needed.

(Signature)

Archana Sonavane

(Name of the Student)

176130010

(Roll. No)

05.06.2019

Date:

ABSTRACT

The primary aim of this project is to design a portable self scanning device to check for breast abnormalities in women in the age group of 20 years and above to aid early detection of Breast Cancer.

Breast Cancer used to be a disease associated with women in the age group of 50 years and above. However in the last decade there has been a considerable rise in the number of Breast Cancer cases in younger age groups (30-40 years). Also most cancers tend to show no symptoms until a very advanced stage after which the patient cannot be saved and therefore early detection is the key to survival. Hence there is a need for awareness regarding regular monitoring of breast tissue to identify abnormalities.

As a part of the process, studies were conducted on the existing technologies used for initial scanning of breast for cancer detection. Mammography is currently the gold standard for detection of Cancer lesions in the breast tissue after which patient is sent for further confirmation tests. However mammography is well suited for women in age groups of 50 years and above as the breast tissue is not as dense as the younger age groups and the incidence of breast cancer is on a rise in younger age group (30-40 years). Also it tends to expose a healthy individual to the harmful X-rays.

This project aimed at designing a device using a harmless technology that is equally effective in all age groups and can be used by women in the comfort of their homes as a part of the process of self examination. This device would not only help women scan for abnormalities but also help them become aware of their bodies to identify these abnormalities.

Contents

A | Introduction.....1 - 31

Cell Structure.....3
Cancer.....5
Breast Anatomy.....7
Breast Cancer.....9
i. About Breast Cancer
ii. Breast Cancer in India
Breast Cancer Detection.....17
i. Current Techniques
ii. New Developments

B | Study.....33 - 43

Trans-illumination.....35
Why Trans-illumination?.....37
Study of existing devices.....39 - 43

C | Design Statement And brief.....45 - 47

D | Device.....49 - 155

Insights from the Study.....51 - 53
Mind Mapping.....55 - 57
Initial Ideation.....59 - 69
Proof of Concept.....71 - 73
Brainstorming.....75
Concept Development.....77 - 87
Grip Development.....89 - 95
Form Development.....97 - 99
Mood Board.....101
Final Concept.....103 - 155
i. Device
ii. Interface
iii. Packaging

E | Conclusion.....157 - 159

References.....160 - 161

Bibliography.....161

Project Timeline

January to March

Studying other developing technologies
Talking to doctors to get feedback on existing technologies
Narrowing down on a technology to proceed with Ideation
User testing with mock ups
Concept Development
Concept Detailing

April to May

Final Concept
Detailing of the final concept
Prototyping
Testing of the final concept

June

Final Product
Branding
Packing
Final Jury

A | Introduction

A.1 Structure of a Cell

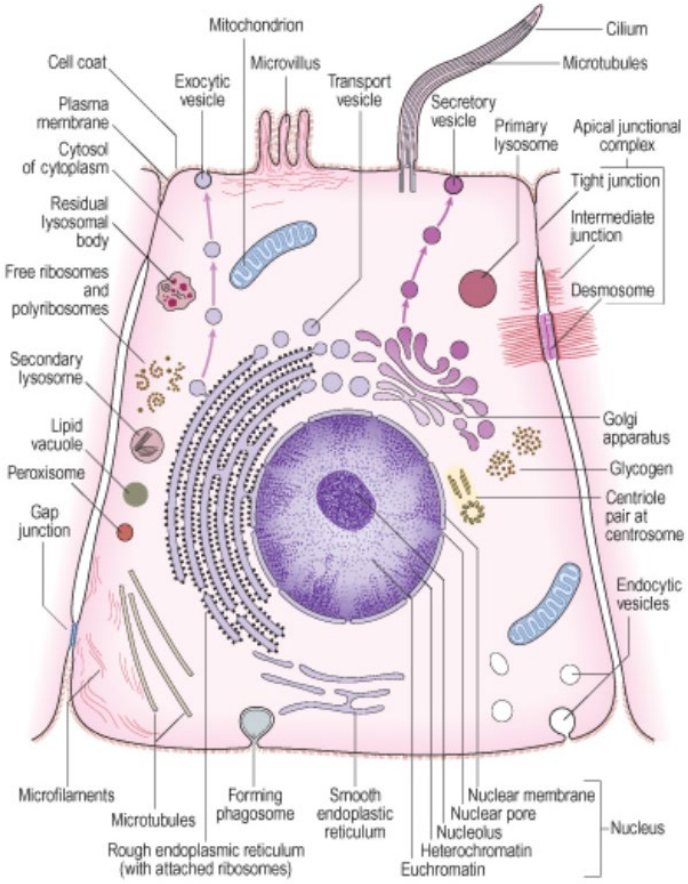


Fig. A.1 shows the cell structure.[2]

A cell is the smallest structural and functional unit of a living body or an organism. It can be defined as a mass of protoplasm containing nucleus or nuclear material. The cells are of multiple types according to the function of the organ that they form. The cells have a definite structure, which consists mainly a cell wall, a cell membrane, cytoplasm and a central nucleus.

A typical cell has a nucleus surrounded by cytoplasm. The nucleus is bounded by a double layered nuclear membrane, and contains the chromosomes which are made of DNA and protein. One or more nucleoli, made of protein, RNA and DNA maybe present, these are sites of ribosome formation. [1]

In a healthy functional body the cells are constantly dividing, growing and dying. This process continues throughout our lifespan. The dead cells are excreted by the body.

A.2 Cancer

Cancer is a group of diseases that cause cells in the body to change and grow out of control. Most types of cancer cells eventually form a lump or mass called a tumor, and are named after the part of the body where the tumor originates. [3]

Sometimes due to some external irritants the cells of the body undergo a change in the nucleic structure. These cells do not follow the divide, grow and die pattern. They do not follow a programmatic death pattern and grow uncontrollably. This leads to an abnormal mass known as a tumor, except in the case of blood cancer where the cells flow in the blood stream. The cancer is named according to area of the body that has been affected.

The cancer cells deprive the surrounding healthy cells of nutrition and grow like a parasite. This uncontrolled growth can result into spread of the cells into the body leading to organ failure and eventual death of the affected human if not treated in time.

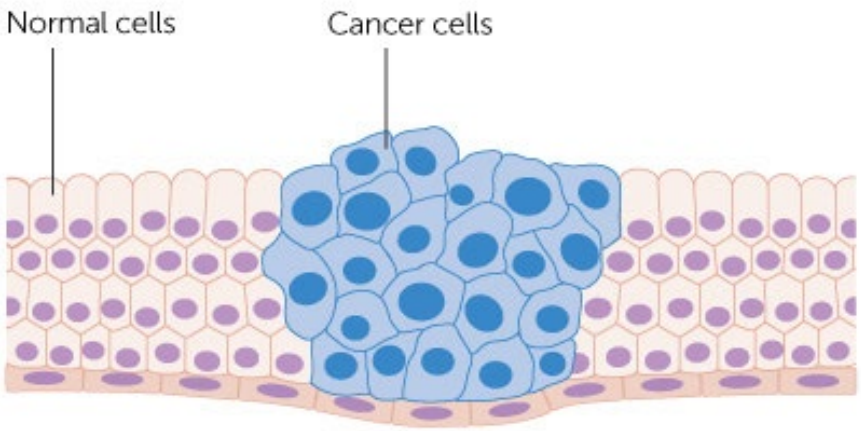


Fig. A.2 Growth of cancer cells [4]

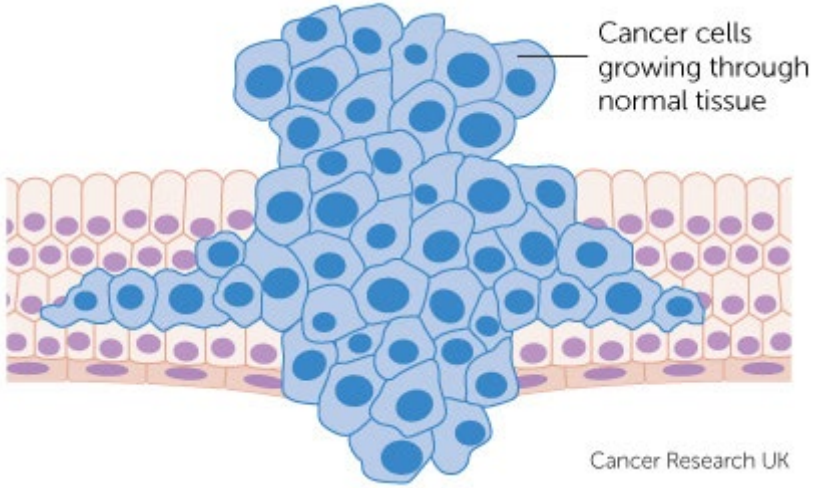


Fig. A.3 Growth of cancer cells [4]

A.3 Breast Anatomy

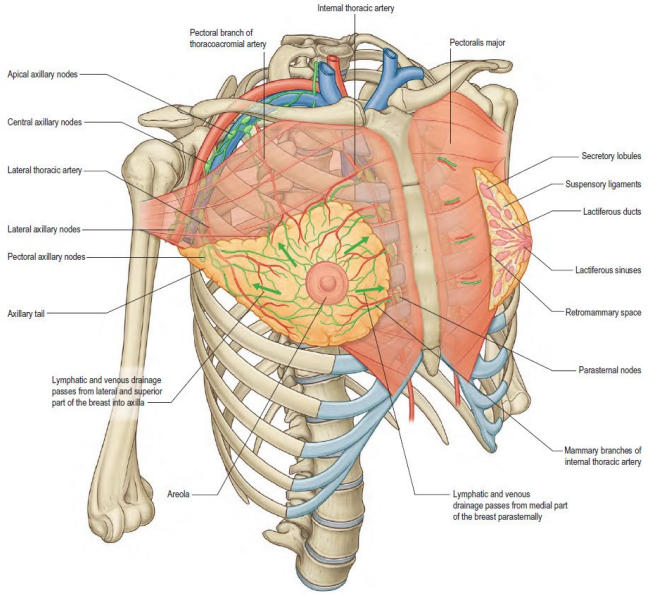


Fig. A.4 Anatomy of a breast [2]

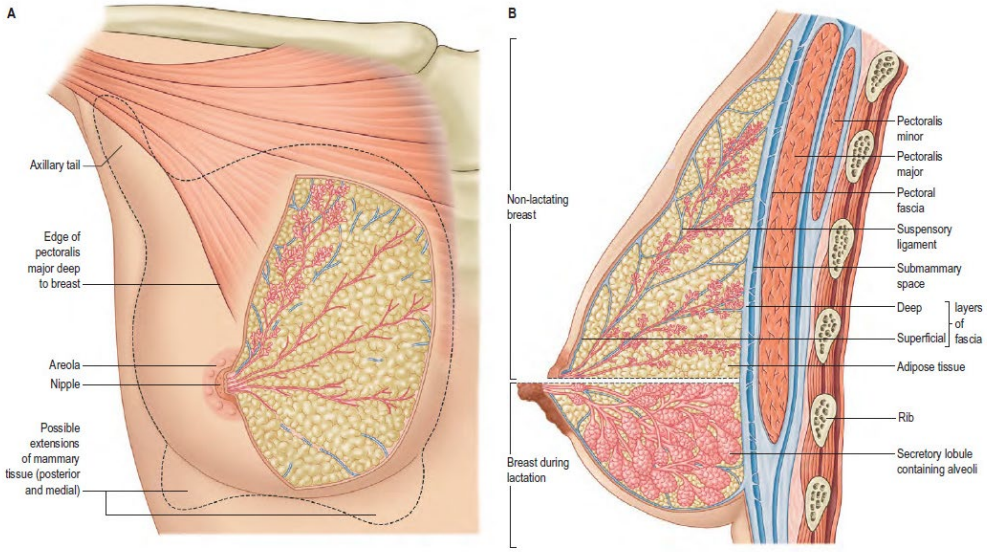


Fig. A.5 Anatomy of a breast [2]

To understand the breast cancer and the tumor location it is essential to understand the anatomy of the breast.

The breast is the tissue overlying the chest (pectoral) muscles. Women's breasts are made of specialized tissue that produces milk (glandular tissue) as well as fatty tissue. The amount of fat determines the size of the breast.[5]

The breast is composed of the adipose tissue, the milk producing parts organized in 15-20 sections called as the lobes, which branch out into lobules, ducts that store the milk, nipple through which the milk comes out, connective tissue, ligaments to provide support to the breast, nerves, blood vessels, lymph vessels and lymph nodes.

A.4a Breast Cancer

Breast cancer is the most common type of cancer in female and the second most common type of cancer overall. The cancer affecting the breast is known called breast cancer. The cells affect the adipose tissue in the breast region leading to a tumor.

The vast majority of breast cancers begin in the parts of the breast tissue that are made up of glands for milk production, called lobules, and ducts that connect the lobules to the nipple. [3]

The cancer can be classified according to the site and the extent of its spread and the site or origin:

Invasive breast cancer

Invasive lobular breast cancer

Triple negative breast cancer

Ductal carcinoma in Situ (DCIS) [Fig no. A.6]

Lobular carcinoma in Situ (LCIS) [Fig no. A.7]

Male breast cancer

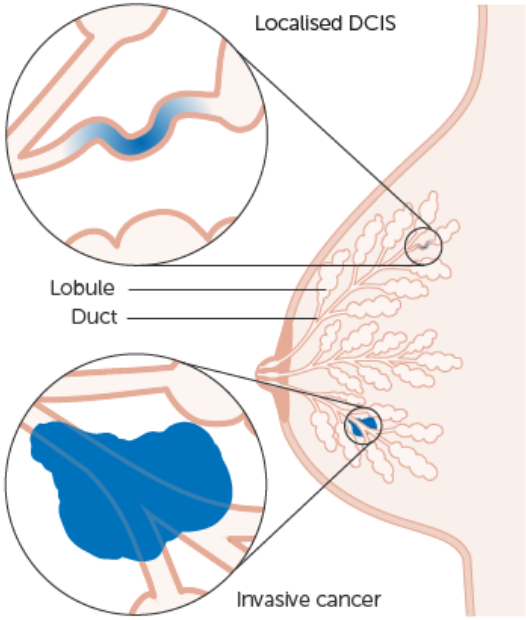


Fig. A.6 Ductal carcinoma in Situ [4]

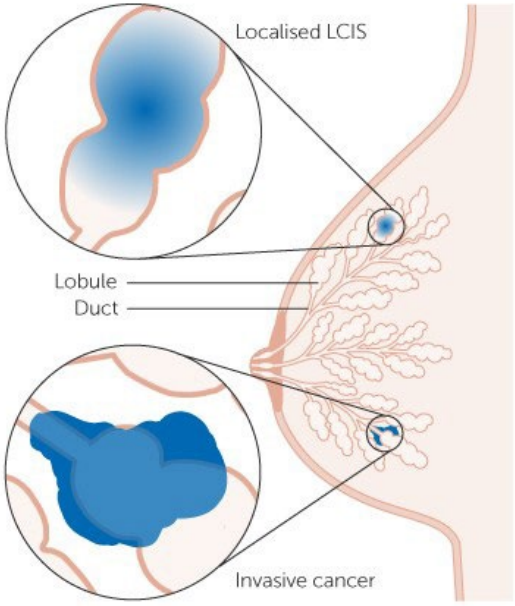


Fig. A.7 Lobular carcinoma in Situ [4]

A.4b Breast Cancer in India

The majority of underlying causes, and other features are usually uniform around the world, every region has its own uniqueness for that cancer. These are discussed under the following headings:

- Increasing incidence of Breast Cancer in younger age groups (30 - 40 years)

In India, we are now witnessing more and more numbers of patients being diagnosed with breast cancer to be in the younger age groups (in their thirties and forties). Please consider Fig A.8 (This is only a rough representation of the data):

The horizontal line lower down represents the age groups: 20 to 30 years, 30 to 40 yrs and so on. And the vertical line represents the percentage of cases. The blue colour represents the incidence 25 years back, and maroon colour represents the situation today. 25 years back, out of every 100 breast cancer patients, 2% were in 20 to 30 years age group, 7% were in 30 to 40 and so on. 69% of the patients were above 50 years of age. Presently, 4% are in 20 to 30 yrs age group, 16% are in 30 to 40, 28% are in 40 to 50 age group. So, almost 48% patients are below 50. An increasing numbers of patients are in the 25 to 40 years of age, and this definitely is a very disturbing trend.

Of course, one particular reason for higher numbers of younger patients is our population pyramid, which is broad at the base and middle and narrow at top, which means that we have a huge population in the younger age group and much lesser in older age group. [6]

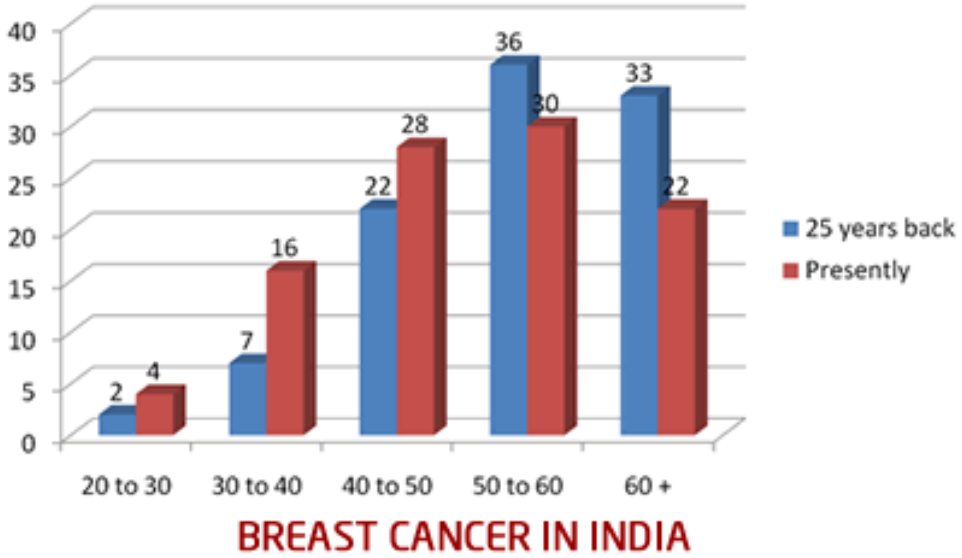


Fig. A.8 Breast Cancer in India [6]

- Rising incidence of breast cancer in India

Breast cancer is now the most common cancer in most cities in India, and 2nd most common in the rural areas. Please have a look at the Fig A.10 about percentage distribution of top ten cancers in females in Mumbai.
The complete details of cancers in various cities like Mumbai, Delhi, Bengaluru, Bhopal, Kolkata, Chennai, Ahmedabad etc. can be found on the PBCR (Population Based Cancer Registry) Website. After going through all the graphs, the point worth noting is that, breast cancer accounts for 25% to 32% of all female cancers in all these cities. This implies, practically, one fourth (or even approaching one thirds) of all female cancer cases are breast cancers. [6]

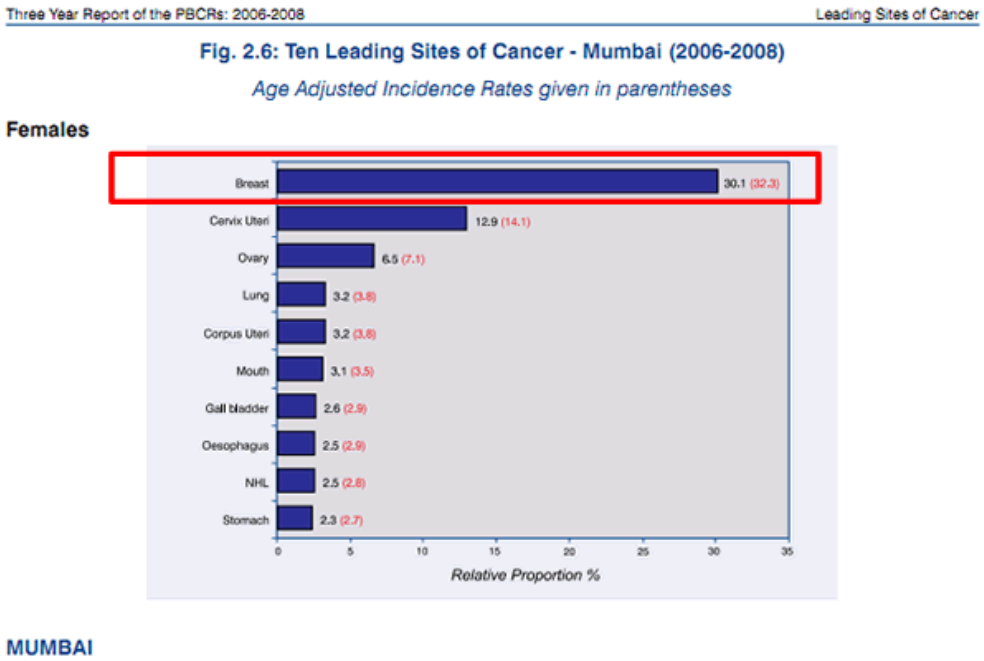
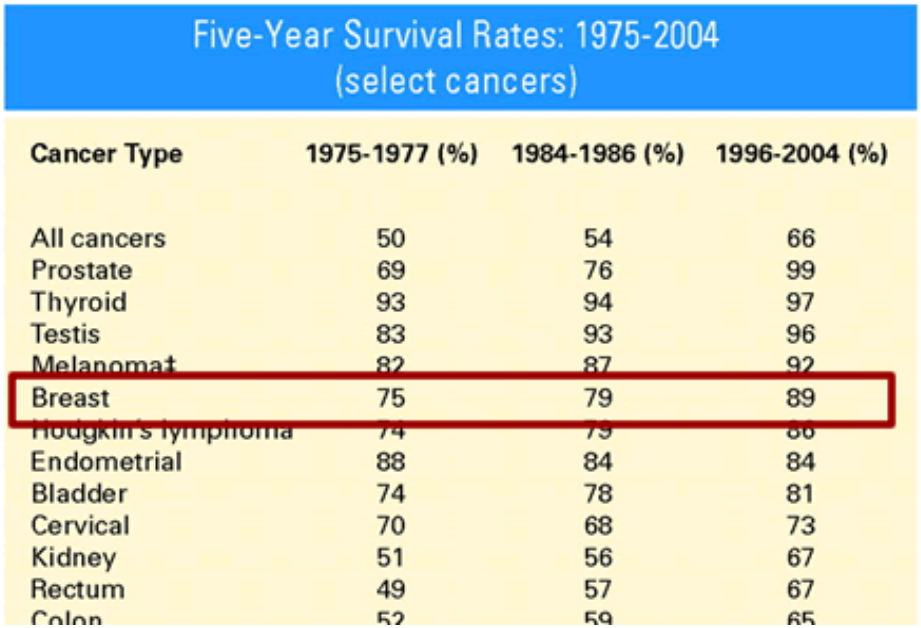


Fig. A.10 Percentage of Breast Cancer Incidences in India [6]

- Late presentation and decreased survival

Consider the Fig A.11. This was published by ASCO (American Society of Clinical Oncology) in 2009, and shows the improvements in the overall five year survival for various cancers in the United States. If you see, the over all 5 year survival for breast cancer has increased from 75% in 1970's to almost 89% presently. This means that, out of every 100 women with breast cancer in the US, 89 women are likely to survive for atleast 5 years. There are barely any similar statistics for India available, but a rough estimate from the PBCR and HBCCR reports is that, this figure is not even more than 60%. The most important reason being lack of awareness about breast cancer and screening of the same; more than 50% patients of breast cancer present in stages 3 and 4, and outcome is not as good as earlier stages, however aggressive the treatment may be. The western nations have achieved a steadily improving and good survival mainly because of screening of breast cancer.[6]



Cancer Type	1975-1977 (%)	1984-1986 (%)	1996-2004 (%)
All cancers	50	54	66
Prostate	69	76	99
Thyroid	93	94	97
Testis	83	93	96
Melanoma‡	82	87	92
Breast	75	79	89
Hodgkin's lymphoma	74	79	86
Endometrial	88	84	84
Bladder	74	78	81
Cervical	70	68	73
Kidney	51	56	67
Rectum	49	57	67
Colon	52	59	65

Fig. A.11 Percentage of Breast Cancer Incidences in India [6]

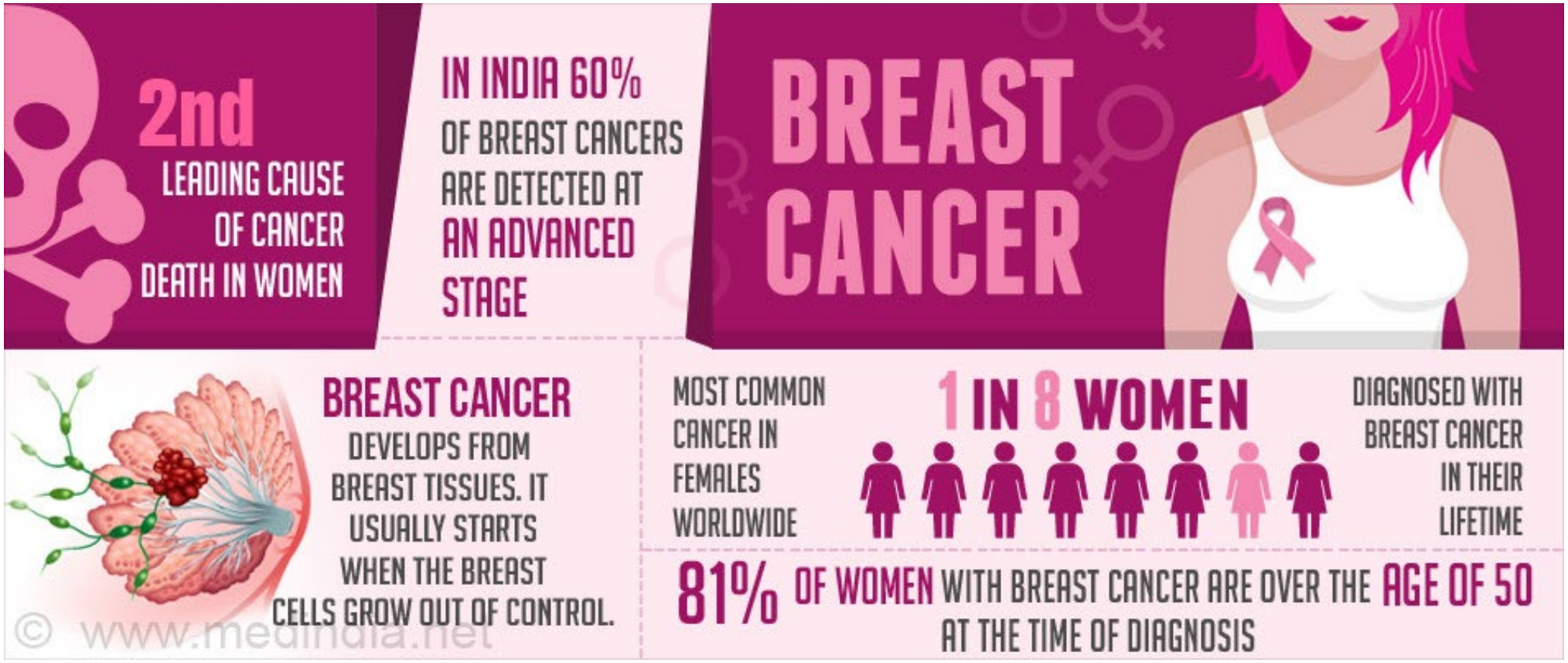


Fig. A.12 Percentage of Breast Cancer Incidences
Source:[7]

Breast Awareness.

Since the number of cases are rising, more younger women are getting affected, most are presenting only after symptoms develop (so usually stage 2B and beyond, rarely earlier stage) and we cannot prevent this cancer, all we can do is to detect this cancer early. BREAST AWARENESS is the way to go.

- Lack of awareness of breast cancer, lack of screening

Breast cancer is a non existent entity for a majority of population till a near and dear one suffers from it. Healthcare is low on priority and even in major cities, screening is also an 'alien' word for most people. So naturally, this results in most people presenting only when symptomatic, and on an average, most 'symptomatic' cancers are stage 2B and beyond (significant numbers in stages 3 and 4). So the breast cancer patients do not tend to survive for a longer time, as their western counterparts.

In the West, majority of breast cancers (read more than 75%) present in stages 1 and 2, resulting in good survival; and there is an ever increasing numbers of patients presenting with mammography detected cancer, with no symptoms. India needs to reach this achievement, and it is only with aggressive promotion of screening and awareness and proper treatment that India will achieve this; and will take atleast a few decades to reproduce similar results.[6]

- Aggressive cancers in the young

Cancers in the young, tend to be more aggressive (Most, but not all). Many of these cancers are HER2 positive and ER/PR negative, or HER2/ER/PR all three negative, and they have a worse prognosis than those who have ER/PR positive tumors. So all the more reason to catch these cancers early, since chances of long survival decrease fast with increasing stage of these tumors. [6]

A.5 Breast Cancer Detection

5a. Currently used Techniques

Detection of breast cancer involves initial screening and confirmation tests.

Screening Test include -
a. Mammography
b. Breast Ultrasound
c. MRI

Mammography is a gold standard test in the screening of breast cancer. Most doctors swear by Mammogram scans. However Mammography does not work with same efficiency for denser breast tissues. In these cases breast Ultrasound or MRI are prescribed along with mammography.

Clinical Examination and Self examination are also a part of the initial screening process, however the reliability of these exams is questionable.

Confirmation Tests include Biopsy which is done to check if the lesion detected in the initial screening is Malignant or Benign.

Screening Tests

a. Mammography

The current standard of care for breast cancer screening is x-ray mammography for women over the age of 40. A technician that compresses the breast and takes pictures from different angles, creating a set of images of each breast, usually performs this technique. In the set of images, called a mammogram, breast tissue appears white and opaque, while fatty tissue appears darker and translucent. X-rays travel unimpeded through soft tissues; however, cancerous tissue absorbs x-rays and can show up on the film as white areas. In a screening mammogram, the breast is x-rayed from center to side.

However, a diagnostic mammogram focuses in on a particular lump or area of abnormal tissue. This examination usually takes about 30 minutes. Yearly screening mammography results in sensitivity (proportion tests that correctly indicate a woman has cancer) ranging from 71 to 96 percent and specificity (proportion of tests that correctly indicate that a woman does not have cancer) ranging from 94 to 97 percent. However, several factors influence the correct detection of breast cancer, such as age, breast density, hormone replacement therapy, image quality, and experience of the radiologist

Although X -ray mammography is the standard and the most reliable technique for the diagnosis of a breast cancer, it has some limitations. Its detectability of a breast tumor is decreased in so called “dense breast “. Noninvasive lesions called intraductal carcinoma or lobular carcinoma in situ are not detectable on mammography if they do not have visible micro-calcifications. And it has the risk of cancer induction from X -ray exposure. Therefore, other modalities have been given more attention. [10]

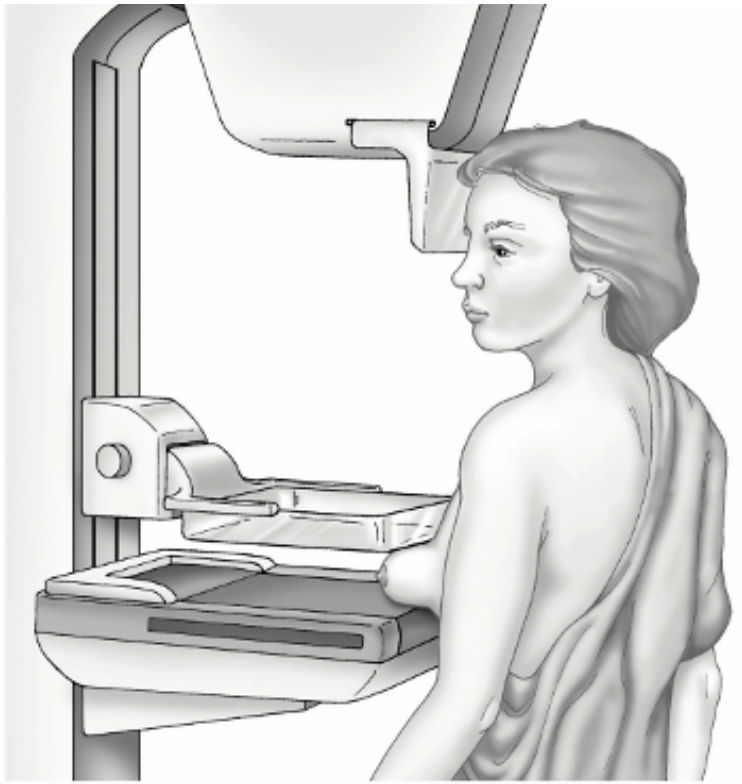


Fig. A.13 Mammography [8]

b. Breast Ultrasound

Sonography, also known as ultrasound, is an imaging technique in which high-frequency sound waves are reflected from tissues and internal organs. Their echoes produce a picture called a sonogram based upon the properties of the tissue. Ultrasound can be used as an adjunct to mammography to evaluate suspicious areas on a mammogram, increasing the accuracy of the combined technologies.17 It can be of particular use in distinguishing between solid tumors and fluid-filled cysts because differences in reflective characteristics between the tissues are discernible on the sonograph.

Ultrasound does not use any radiation and is usually pain-free. The exam may take between 15 and 30 minutes to complete depending on how difficult it is for the operator to find the breast abnormalities being examined, such as a lesion deep within the breast. Ultrasound is not currently used for routine breast cancer screening because it does not consistently detect certain early signs of cancer such as micro-calcifications, which are deposits of calcium in the breast that cannot be felt but can be seen on a conventional mammogram, and are the most common indicator of ductal carcinoma in situ (DCIS). However, the technique is quite useful in conducting image-guided biopsy.26,33 Many techniques are being developed to enhance the capability of ultrasound to detect cancer single-handedly; however, they are still under clinical investigation and will require further study to determine their utility.

Fig. A.14 Breast Ultrasound [8]

c. Breast MRI

In MRI, a powerful magnet linked to a computer creates detailed images of the breast without the use of radiation. Each MRI produces hundreds of images of the breast from side-to-side, top-to-bottom, and front-to-back. A radiologist then interprets the images to identify abnormal regions that may require further investigation.

During an MRI of the breast, the patient lies on her stomach on the scanning table. The breast hangs into a depression or hollow in the table, which contains coils that detect the magnetic signal. The table is moved into a tube-like machine that contains a powerful magnet.

After an initial series of images has been taken, the patient may be given a contrast agent intravenously to enhance the visibility of tissue characteristics. The contrast agent is not radioactive; and can be used to improve the visibility of a tumor. Additional images can be taken after administering the contrast agent. The entire imaging session takes about one hour.

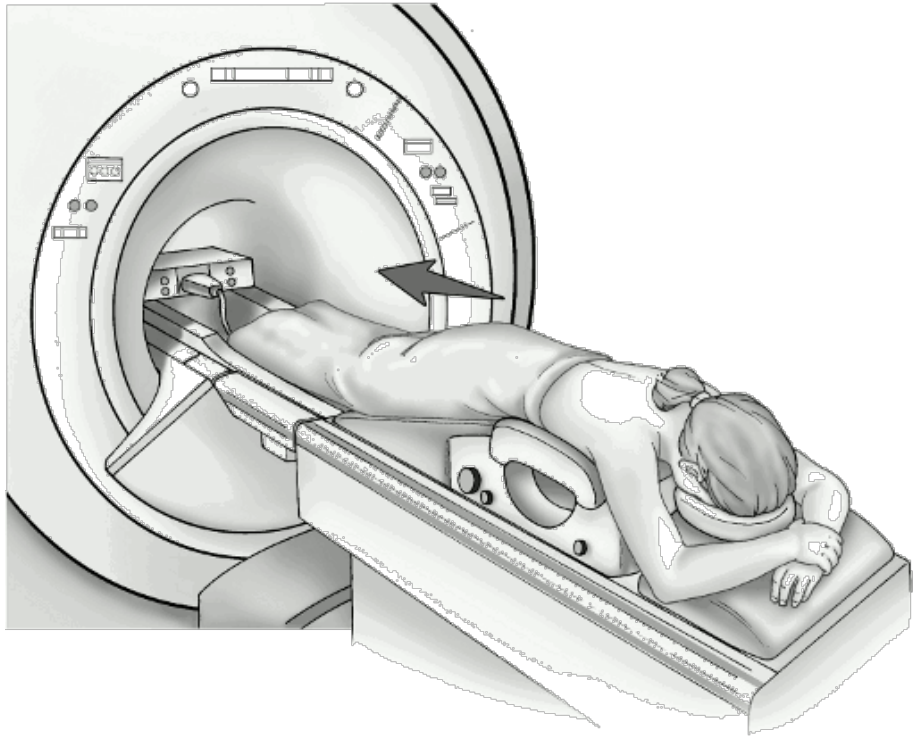


Fig. A.15 Breast MRI [8]

Confirmation Test

Biopsy

Biopsy has four major types -

Surgical Biopsy
The gold standard in breast biopsy. Requires a surgical incision to completely remove the lesion (excisional biopsy) or obtain a sample from the lesion (incisional biopsy) to allow the pathologists to make a definitive diagnosis.

Core Needle Biopsy
Larger needle used to obtain tissue samples from a breast lesion. This procedure usually obtains enough tissue to allow a pathologist to make a definitive diagnosis.

Fine Needle Aspiration Biopsy
Small needle used to collect fluid or a small sample of cells from a breast lesion. This minimally invasive procedure allows for a pathologist to make a diagnosis; however, a larger sample size obtained through a more invasive biopsy procedure may be required.

Image Guided Biopsy
Subset of needle biopsy procedures that use imaging techniques to guide needles into lesions and obtain samples from non-palpable lesions. These imaging techniques typically include mammography, ultrasound, and MRI.

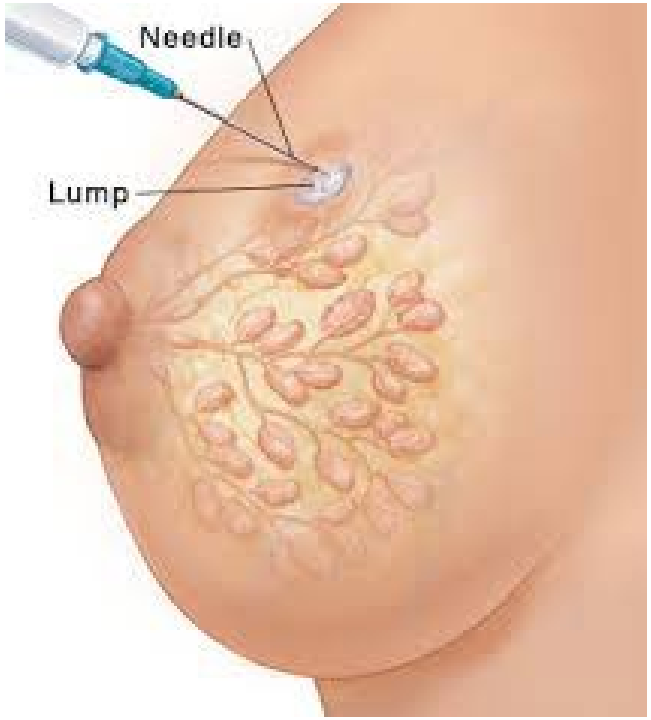


Fig. A.16 Breast Biopsy [8]

5b. Newer Technologies

These include -

Piezoelectric Fingers
Nipple Aspirate Fluid
Thermography
Electrical Conductivity of Tissues
Trans - illumination

Piezoelectric Fingers

Device - iBreast Exam

iBreastExam uses patented ceramic sensors developed at Philadelphia's Drexel University, Mihir Shah's (Founder, UE Lifesciences) alma mater, to detect subtle variations in breast tissue. Mihir Shah developed his first breast scan device while abroad in the U.S.

- Available in India, made by UE Life Sciences
- Cloud Based system
- Mostly installed in Hospitals and used by NGOs for mass scanning.
- The iBE device was developed as a 16 finger array with a rapid wireless mobile processor algorithm and durable battery powered hand piece.
- Uses tactile sensor technology originally invented at Drexel University in Philadelphia. The specialized ceramic material (patented), enables the device to assess tissue elasticity from the surface of the breast.
- Developed to be operated by a technician or health care worker.

Fig. A.17 iBreast Exam [11]

Nipple Aspirate Fluid

Atossa Genetics - Breast Cancer Detector

- Available in U.S.
- Used a breast pump-like device and a micro-filter, to extract and collect tiny amounts of fluid.
- Analyzed the cells from that fluid directly on the micro-filter.
- Hyperplasia and other abnormalities, cancer, genetic mutations.
- FDA approved.
- Difficult for self-examination.
- Difficult to take Nipple fluid sample.

Fig. A.18 Antossa Genetics - Nipple Fluid Aspirator [12]

Thermography

BRASTER - Breast Screening Device

- Available in Poland.
- It works on the basis of contact thermography. Patented themographic matrix detects abnormal changes in breast.
- The examination is performed in accordance with instructions on the mobile application.
- Difficult to understand Thermographic image.
- Need to rely on Application for performing the screening.

Fig. A.19 Braster [13]

Electrical Conductivity of Tissues

MEIK Device

- Available in Canada
- Based on the principles of Electro Impedance Tomography (EIT)
- Uses advanced digital imaging reconstruction algorithms to identify, locate and size different female breast abnormalities
- Less than 35 seconds to perform scanning and display images
- Not meant for self-examination.
- Requires software to get the report.

Fig. A.20 MEIK Device [14]

Infra red LEDs (Trans - Illumination)

Breastlight / Breast-i

- Uses Infrared Leds to illuminate the breast tissue
- Available in UK
- No. of LEDs used: 3 (Medical Grade Leds)
- Wavelength: 620 nm
- Brightness adjustment option with display of the same.

Fig. A.21 Breastlight [15]

Fig. A.22 Breast- i [15]

B | Study

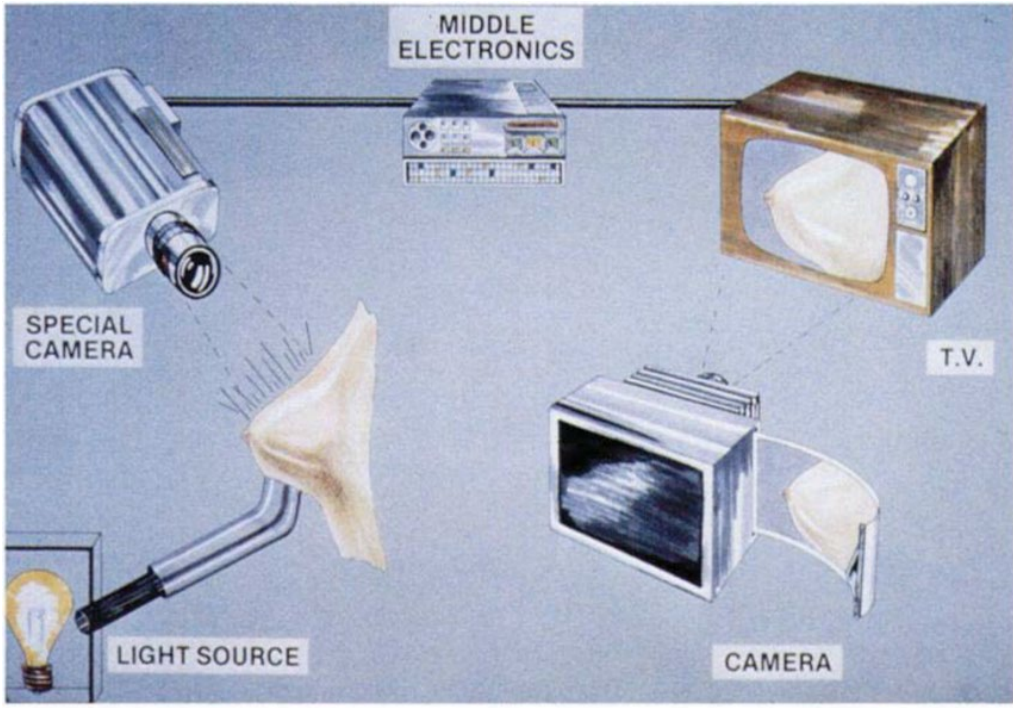


Fig. B.1 Trans-illumination [16]

B.1 Trans - Illumination of Breast

Dr. Max Cutler was one of America's pioneers in the campaign against cancer. He first did experiments using infra red light for checking breast tissue in 1929. [16]

The principle of trans-illumination is simple:

- A light source is placed behind the breast, and the light transmitted through the breast tissue is viewed.
- As light passes through living tissue, it is reflected, scattered and absorbed.

How does it work?

- Light falling on the breasts undergoes scattering, absorption and reflection.
- When light hits the blood vessels it is absorbed by hemoglobin in the blood, this causes them to appear as shadows.
- Malignant lumps have increased blood supply (angiogenesis) to feed them and hence they appear as shadows too.
- Fluid filled cysts and fibrosis let the light pass.
- Can be used with higher intensity for denser breasts

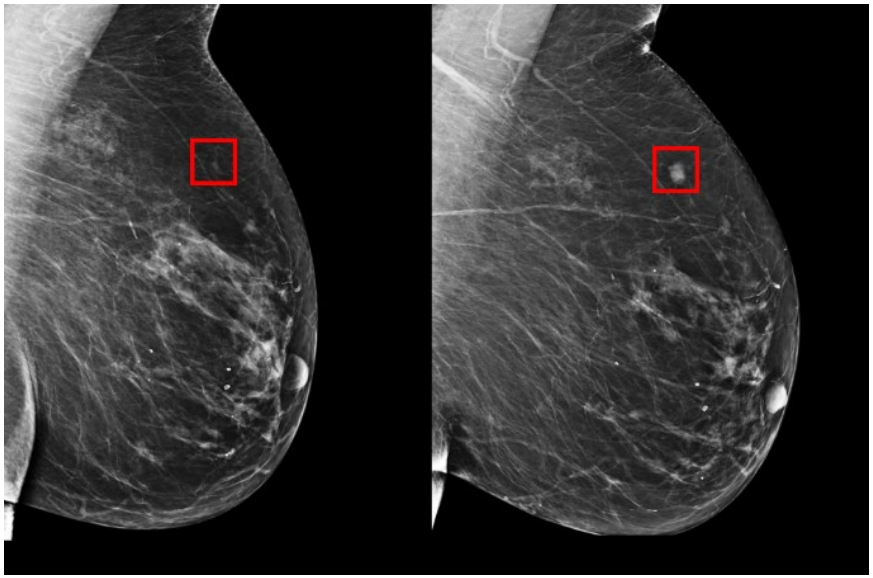


Fig. B.2 Mammography [17]

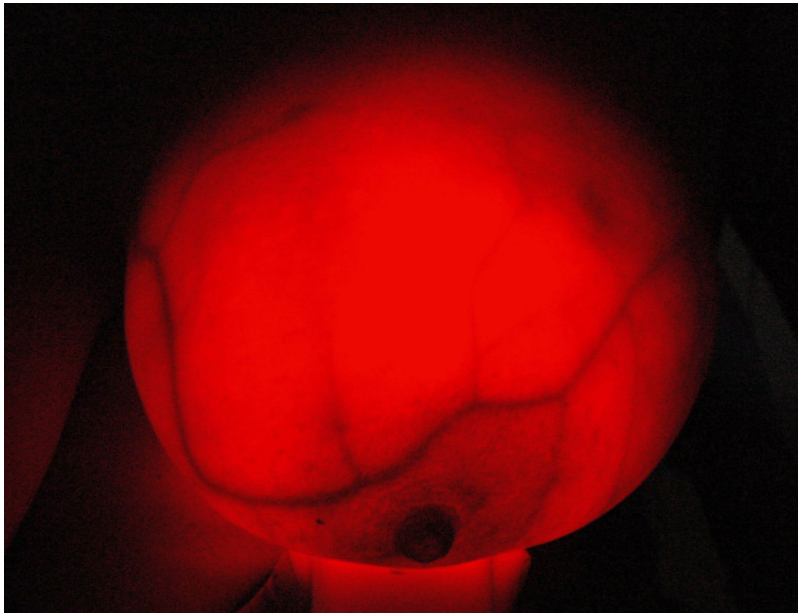


Fig. B.2 Trans-illumination [15]

B.2 Why Trans - Illumination?

Mammography is the Gold Standard Test for breast screening. However as discussed earlier mammography has it drawbacks and hence trans-illumination is one technique that has started to gain importance lately.

Drawbacks of Mammography

- Peak age incidence age for breast cancer is 40 – 45 years and above, hence screening needs to begin at 25.
- Mammography is not prescribed for younger age groups as breast tissue is dense.
- Small but significant risk of ionizing radiation.
- Picks up significant changes in breasts – even non cancerous ones.
- Equipment cost is high.
- Lack of skilled technicians and radiologists in India.

In case of trans-illumination the equipment cost can be reduces drastically and a device as simple as a torch can be designed using Infra red LEDs which women can use at home. This device need not have a complex learning curve and will also help women develop and awareness of their own bodies to differentiate normal from abnormal.

B.3 Study of Existing Devices

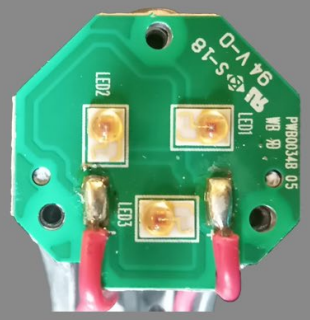
Breastlight

- INR 60,000 /- (Amazon)
- INR 11000 - 15000 /- (Supplier)
- Uses led light to trace shadows of abnormalities
- Can be used at home

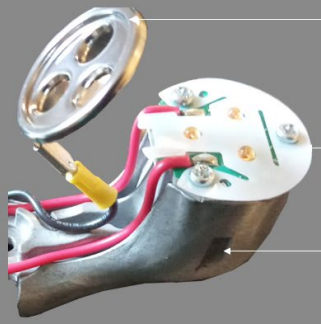
Fig. B.3 Breastlight

Breastlight

- This device was purchased from a supplier for the purpose of study.



Circuit without the foam



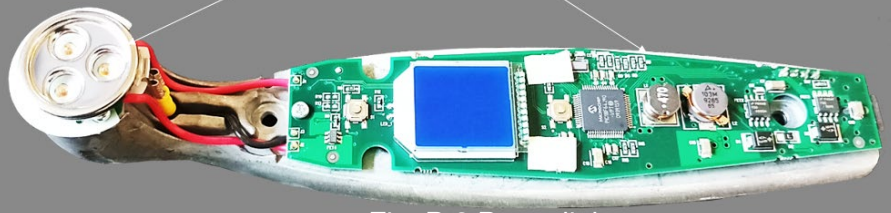
S.S. Capacitive Sensor

Silicon Foam

Grooves for cooling purpose

S.S. Ring to fill the gap between Sensor & Silicon Foam

Fig. B.4 Breastlight



LED Circuit Separated from main circuit

Fig. B.6 Breastlight

Battery connected to the circuit

Rechargeable 4.8V Battery

Aluminum Heat Sink

Fig. B.5 Breastlight

2 hidden screws used to fasten the outer cover

Snap fit for external flap

Fig. B.7 Breastlight

Fig. B.8 Trans-illumination Devices [15]

Fig. B.9 Breast- i [15]

Other Similar Devices

Most of these devices are manufactured by the chinese to be sold for cheaper rates in other parts of the world

However these devices lack background study and can be dangerous.

Some of these devices have Vibration modes which may be linked with causing spread of the tumor.

Out of the devices mentioned above fig B.9 shows Breast-i which is an advanced version of Breastlight.

C | Design Brief

To design a self scanning device to aid early detection of breast abnormalities using Trans-Illumination Technology

Device

- It should be a medical grade device (using leds and safety prescribed as per medical standards).
- The device should be simple and easy to use for the women themselves.
- Should allow use for women with varied skin tones and breast sizes.
- There should be a feedback system.
- It should have an Ergonomic grip.
- The device should be easy to clean.
- Since the device does not have a regular use, it should have a proper storage provision.
- It should come with a manual to guide the user and facilitate efficient use.
- It is to be sold in Indian Market at an affordable price.

D | Device

D.1 Insights from the Study

1a. The Device needs to have -

- Combination of Red and Orange LEDs (red to near infra red)
- Wavelength – 615 – 630 nm (medical grade).
- Rechargeable battery with accessible compartment.
- Good quality heat sink.
- Sensors to suppress light unless device is in contact with the skin.
- Sensors to remember the intensity of light used so breasts appear same each time.
- User Interface for feedback and operation.

1b. Potential Problems

- Heating up of the LEDs.
- Heat causes -
  Reduction in light output
  Color changes by altering the wavelength
  Decreased life expectancy
  Worst case – Failure
- Good heat sink increases the weight of the device.
- Complex forms increase the overall cost of
- manufacturing.
- Intensity of light varies with decrease in charge.
- Wide intensity adjustment needed to cater to different skin tones and tissue density.

1c. Essentials to Remember

Ergonomics

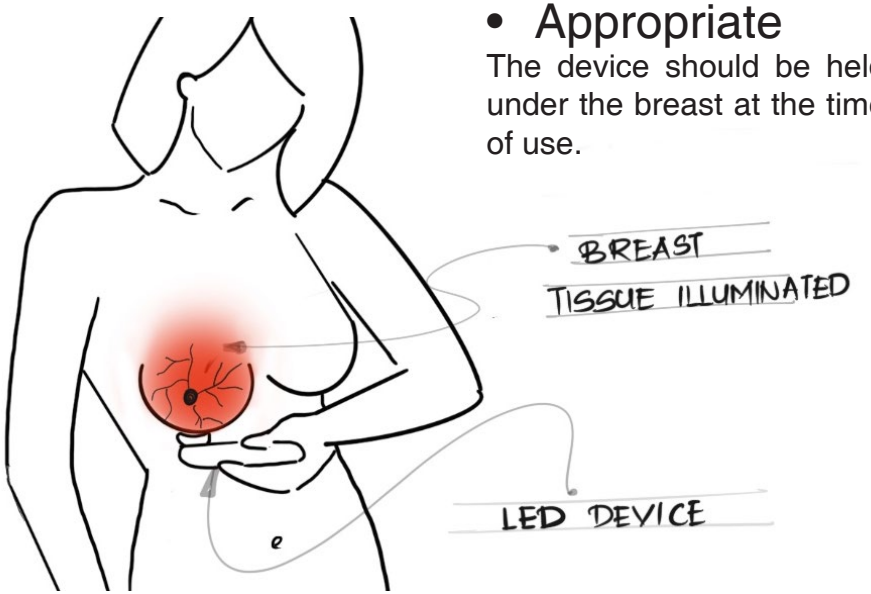
- Weight of the device plays a major role as the device needs to be held in hand.
- Use of opposite hand for scanning to be able to conveniently use the device.
- Total time taken for the scan is not more than 10 minutes.
- Interface plays a major role in giving a feedback of the intensity that is being is used and also the battery status of the device. The interface must be visible in the dark.

Visibility

- The device needs to be used in a dark room for maximum visibility.
- Use of mirror is essential to be able to view the breast from all angles.
- Light intensity adjustments are crucial to have the right amount of clarity in the shadows.
- One needs to be aware of what the breast normally looks likes to be able to understand unwanted growths.

Accessibility

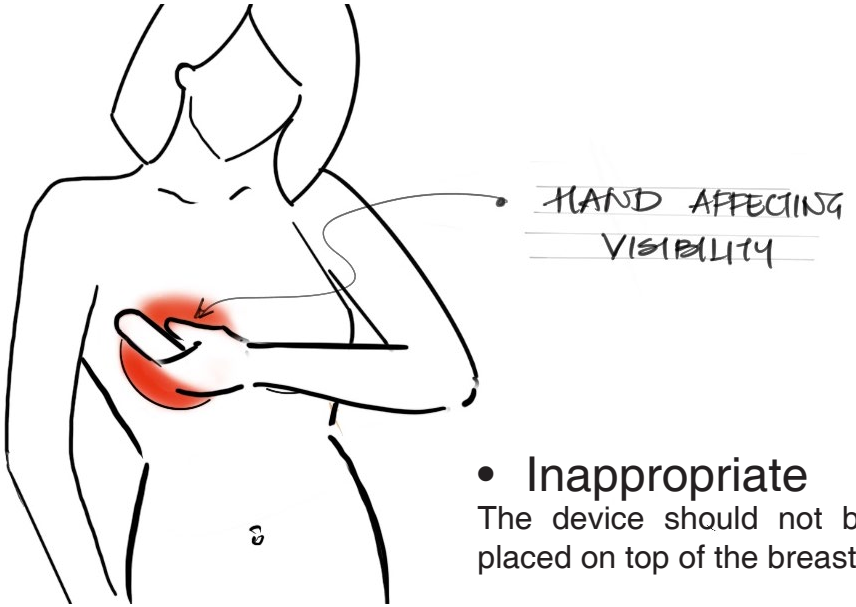
- One might want to take help in case of obesity to be able to view better and be sure.



- **Appropriate**

The device should be held under the breast at the time of use.

Fig. D.1 Trans-illumination



- **Inappropriate**

The device should not be placed on top of the breast.

Fig. D.2 Trans-illumination

1d. Process of Use

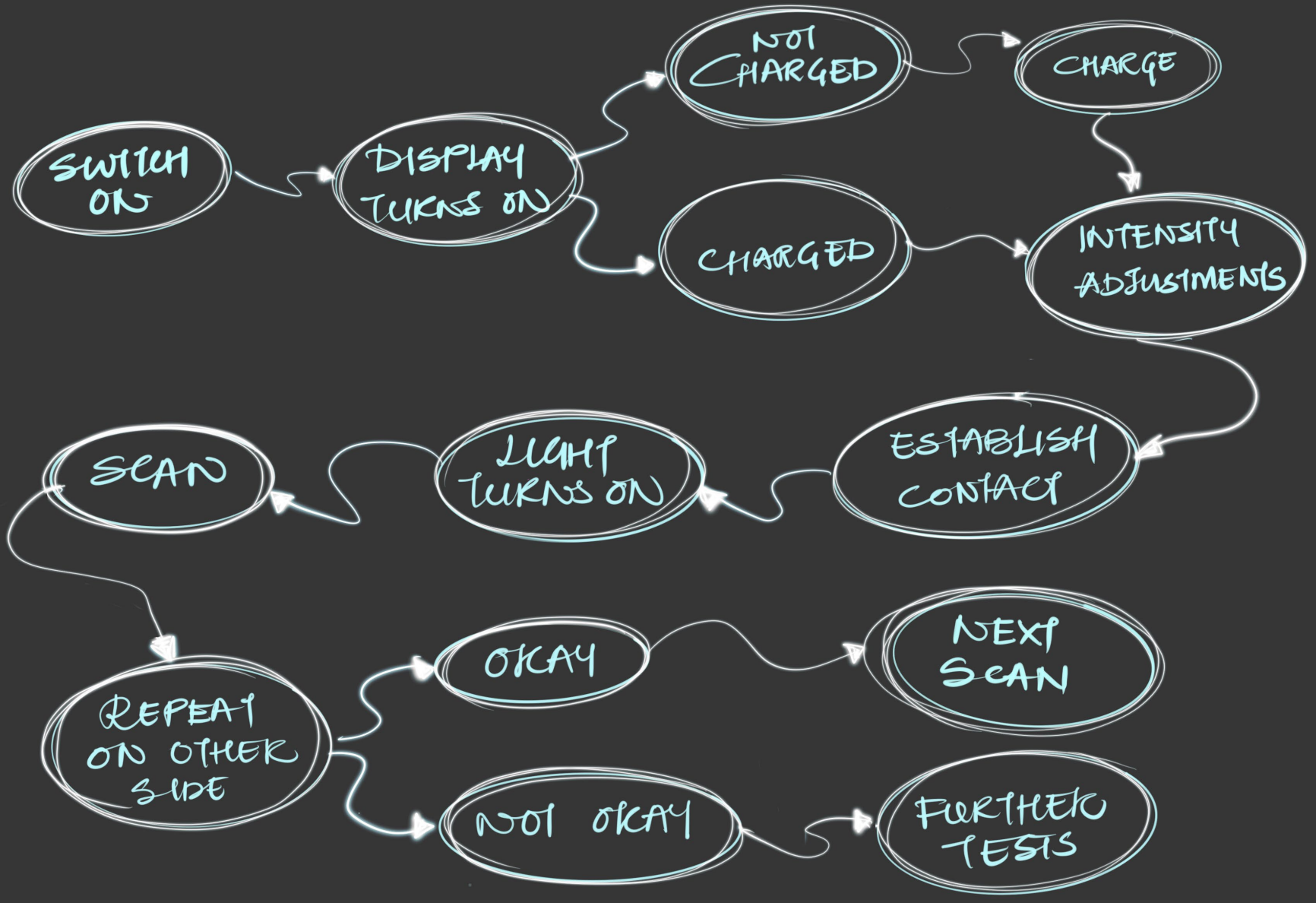
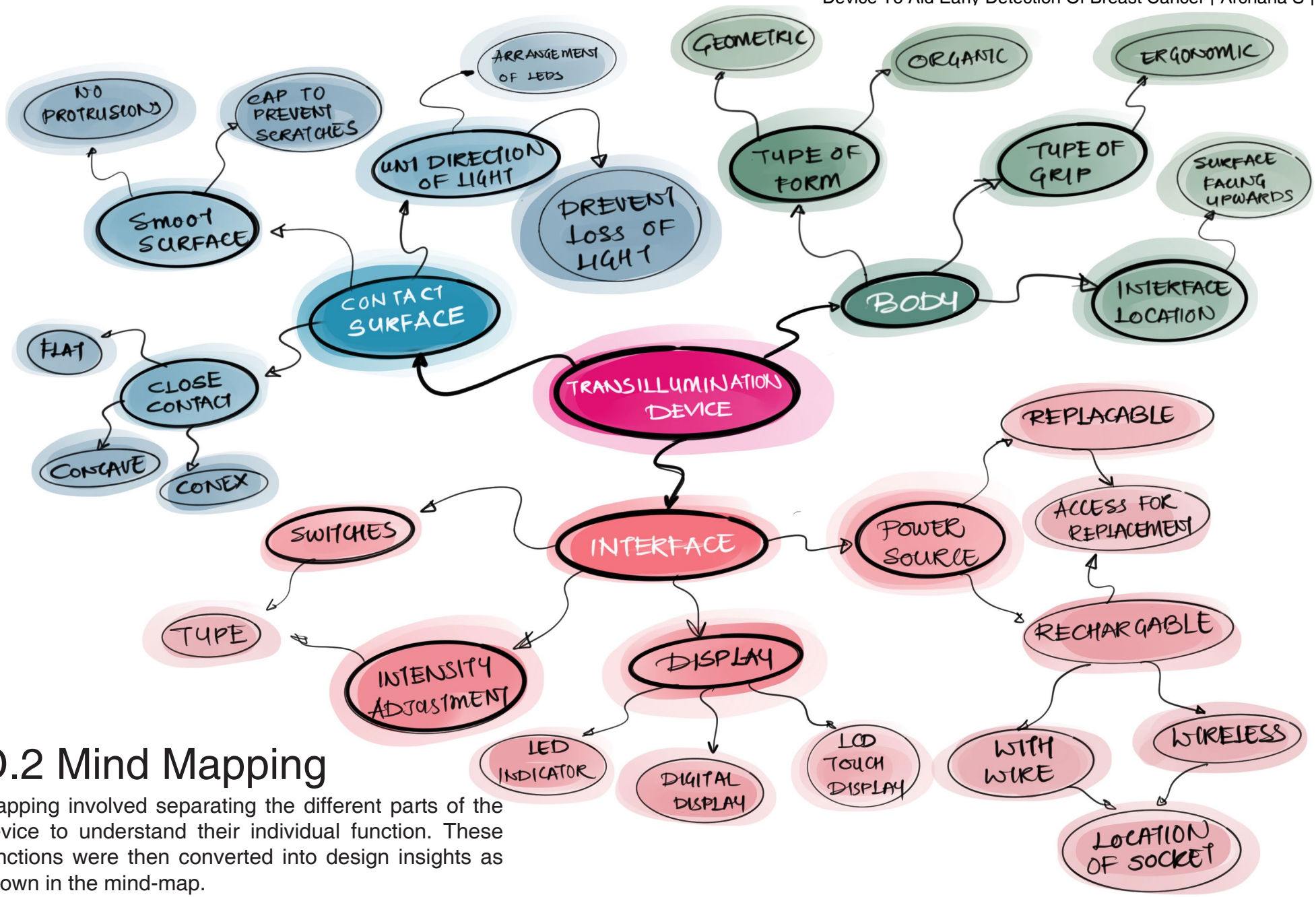


Fig. D.3 Process of Using the Device



D.2 Mind Mapping

Mapping involved separating the different parts of the device to understand their individual function. These functions were then converted into design insights as shown in the mind-map.

Fig. D.4 Brainstorming

D.3 Initial Ideation

Contact Surface

Fig D.5 shows the various possibilities of form that the contact surface (head) could have to establish better contact with the skin. How do concave, convex or flat surface help to maximize transmission of light into the breast is explored here.

Another important aspect to consider while designing the head would be to not allow light to escape from the sides for maximum visibility.

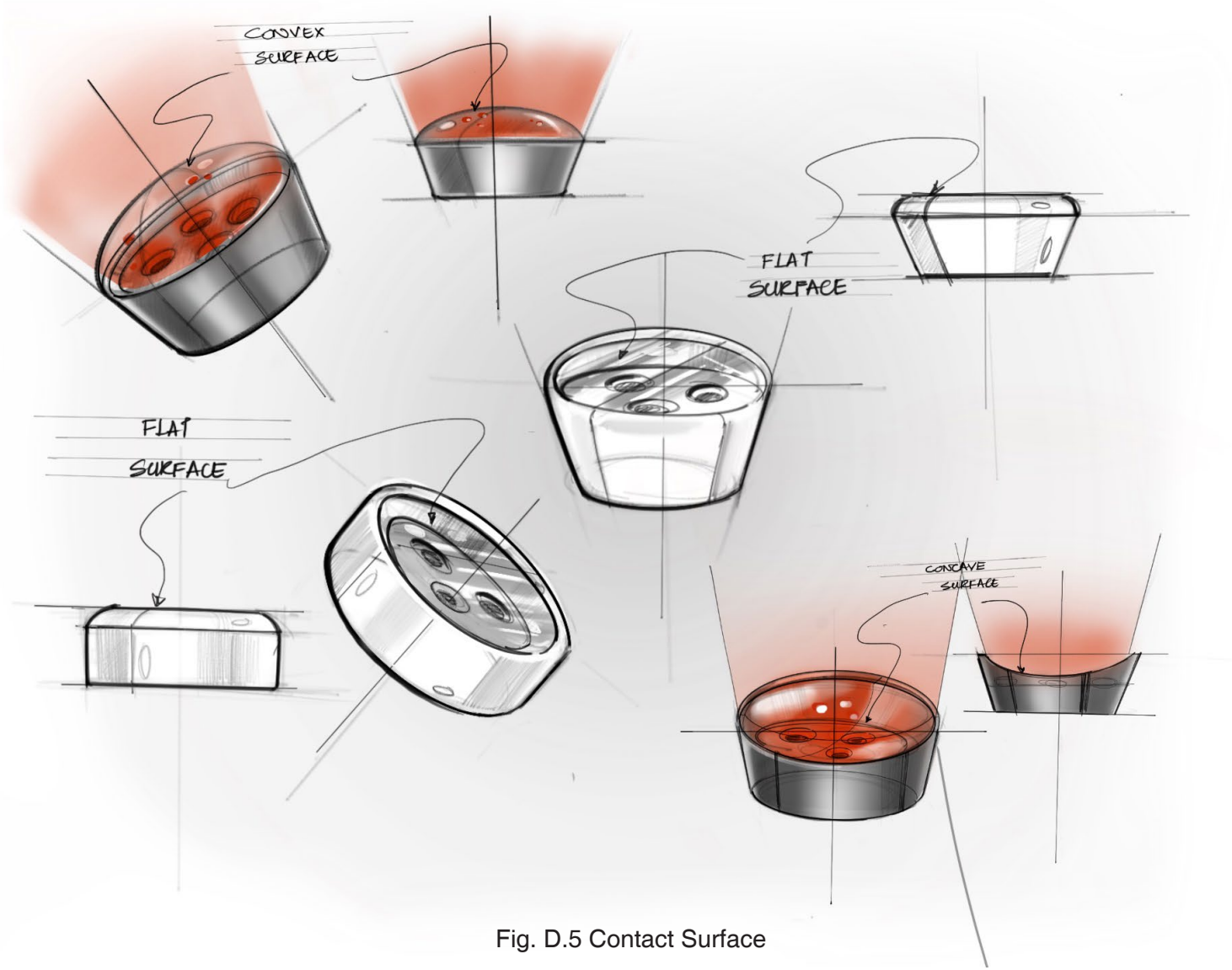


Fig. D.5 Contact Surface

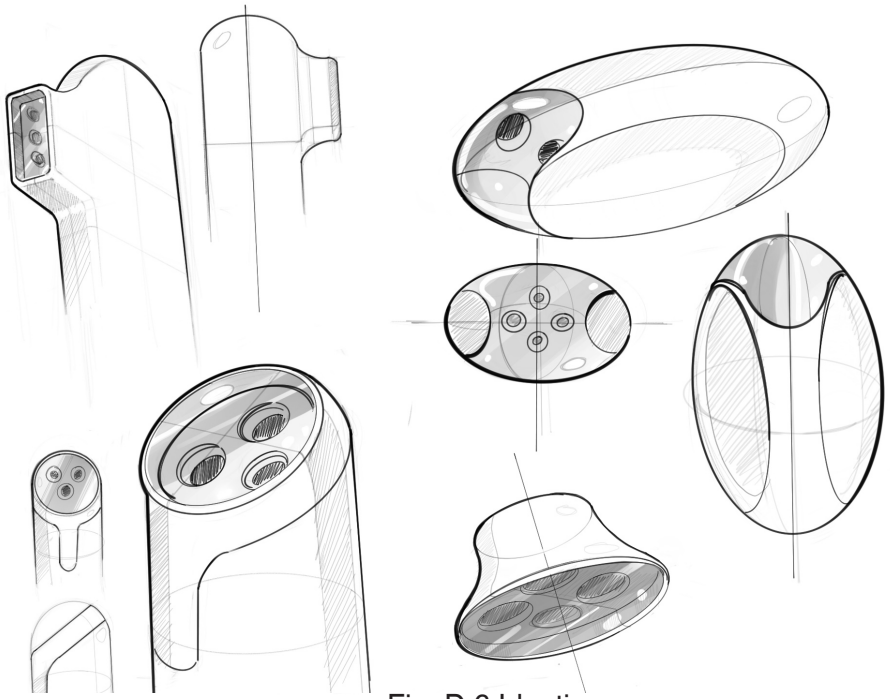


Fig. D.6 Ideation

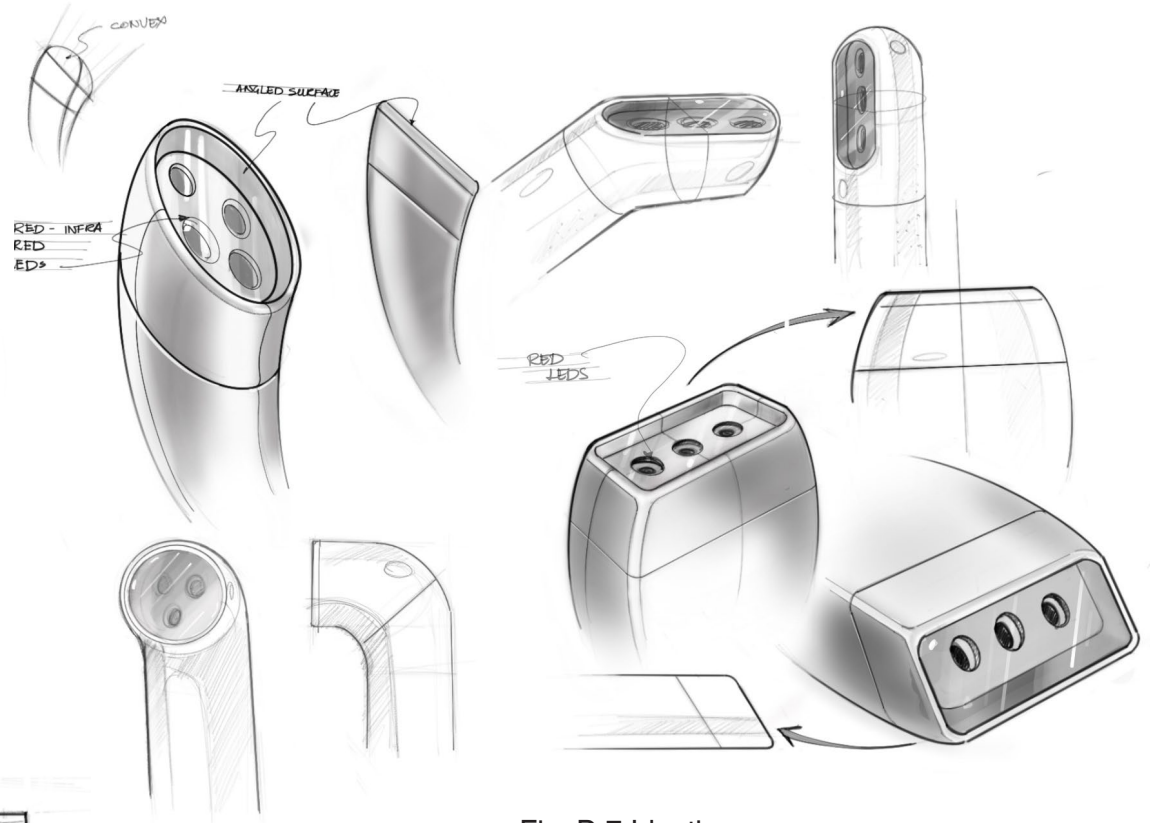


Fig. D.7 Ideation

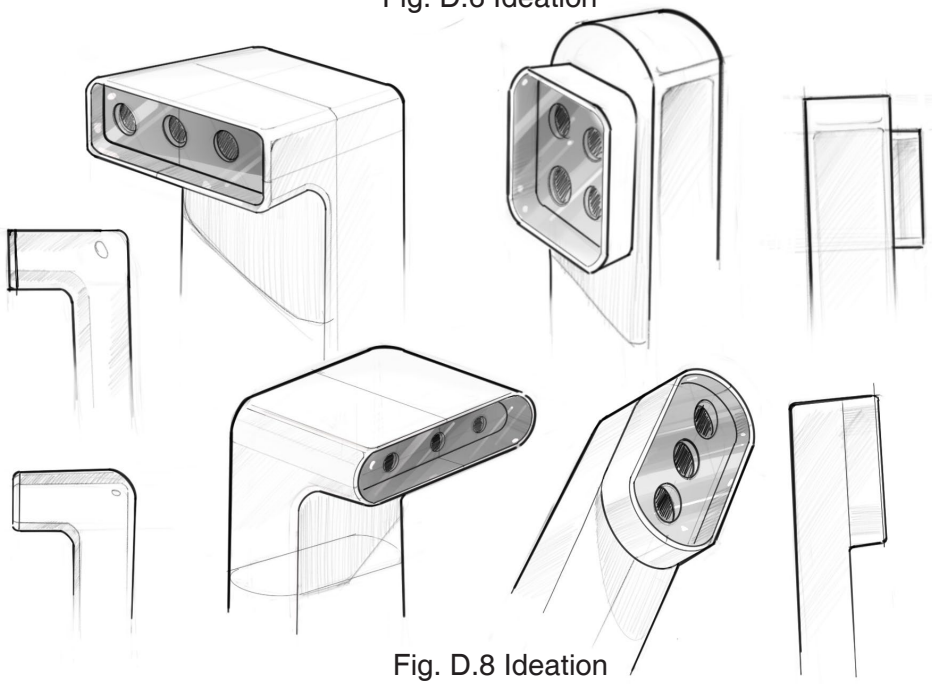


Fig. D.8 Ideation

Head

The sketches here show exploration for different types of heads. The head could be protruded or flushed with the surface. It could also be at suitable angles that help establish better contact and also make it easy to hold the device.

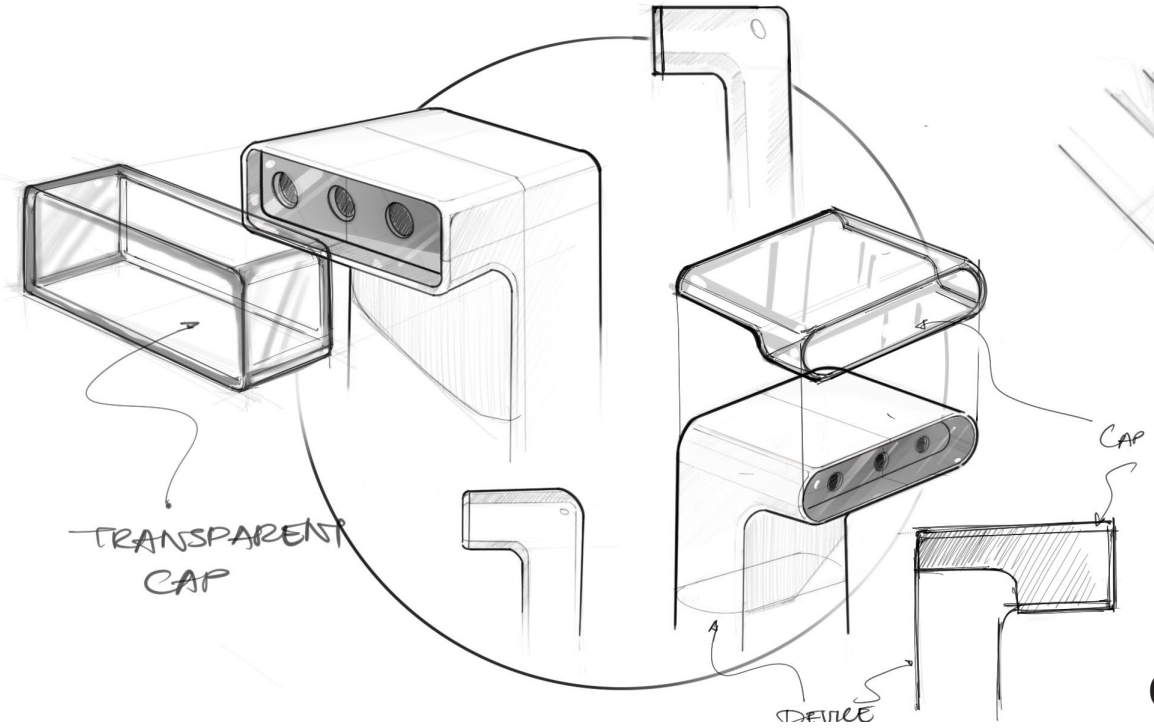


Fig. D.9 Ideation

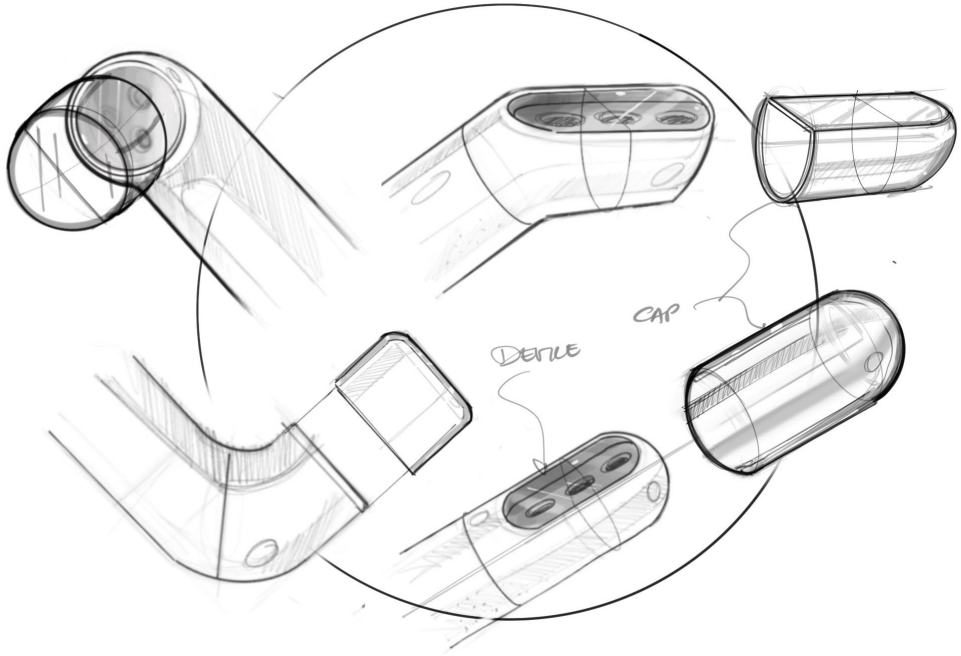


Fig. D.10 Ideation

Cover

Thought was given to idea of having a cover to protect the contact surface from scratches, dust and other damage that may affect the efficiency of the device with time.

Interface

Initial thoughts on what kind of switches or feedback the interface could have in order to make operating the device easy and ergonomic

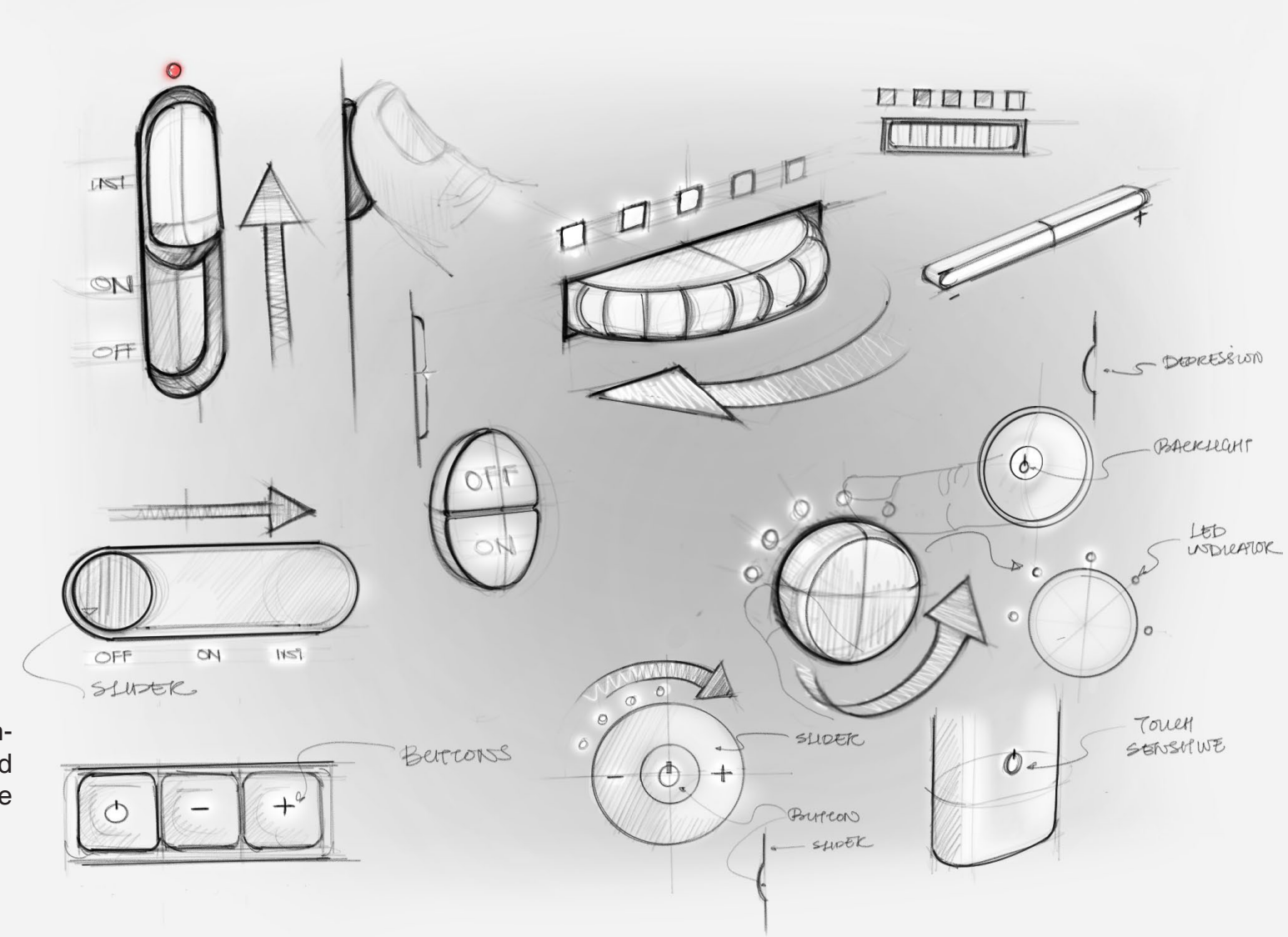
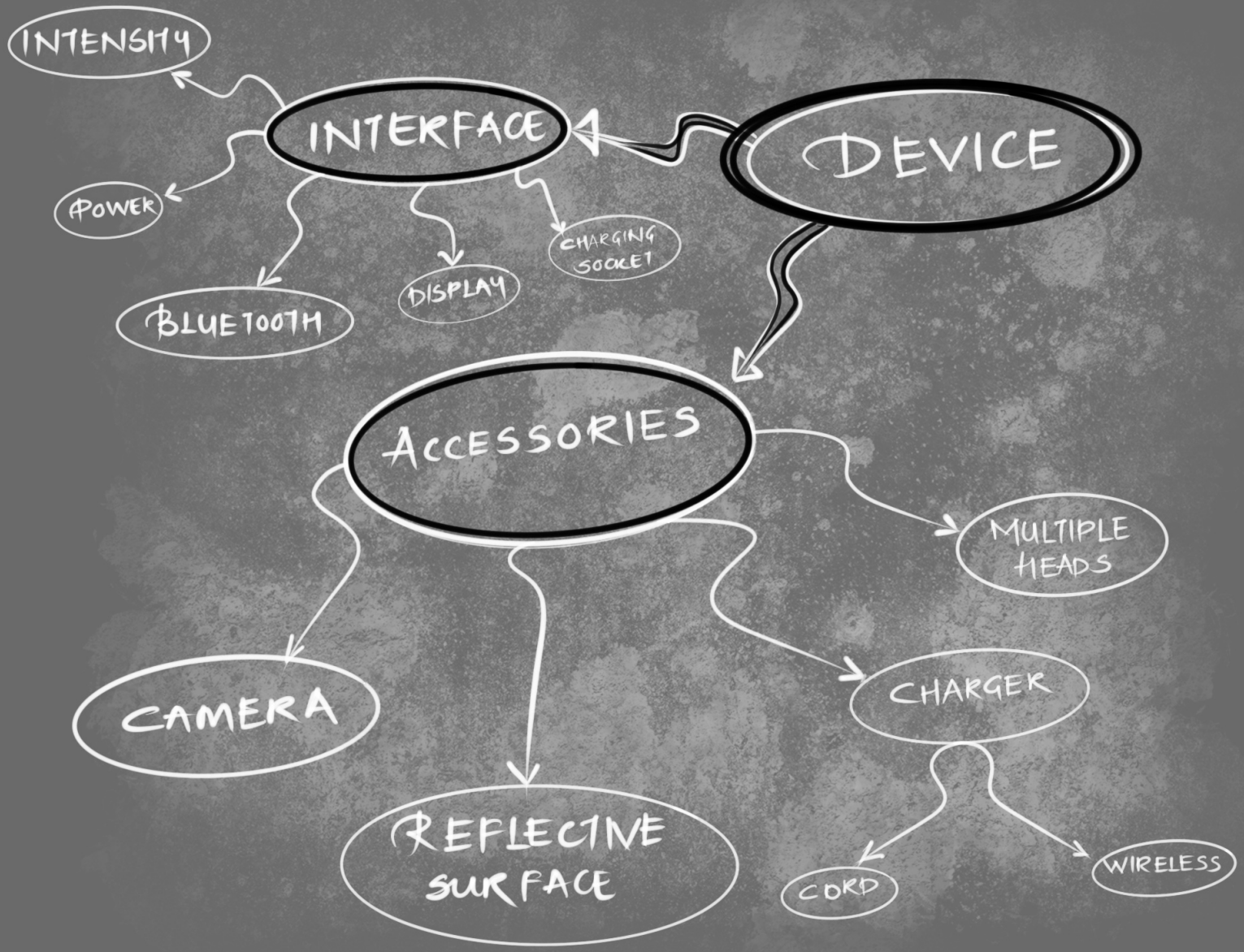


Fig. D.11 Interface Ideation



Idea Generation for Possible Accessories

Mapping to explore the various accessories that could be provided with the device to improve functionality and desirability of the product.

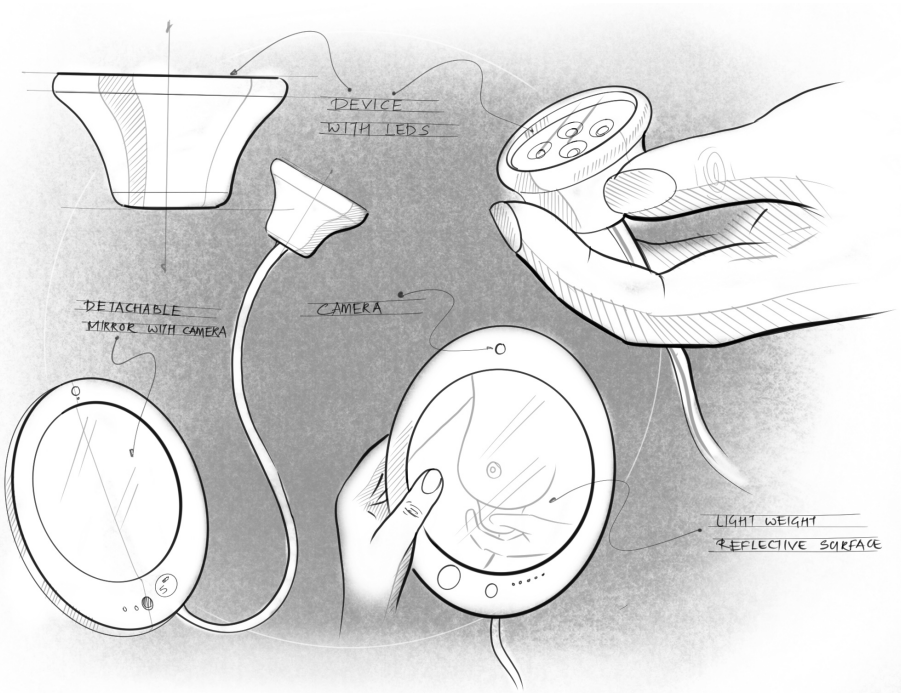


Fig. D.12 Reflective Surface

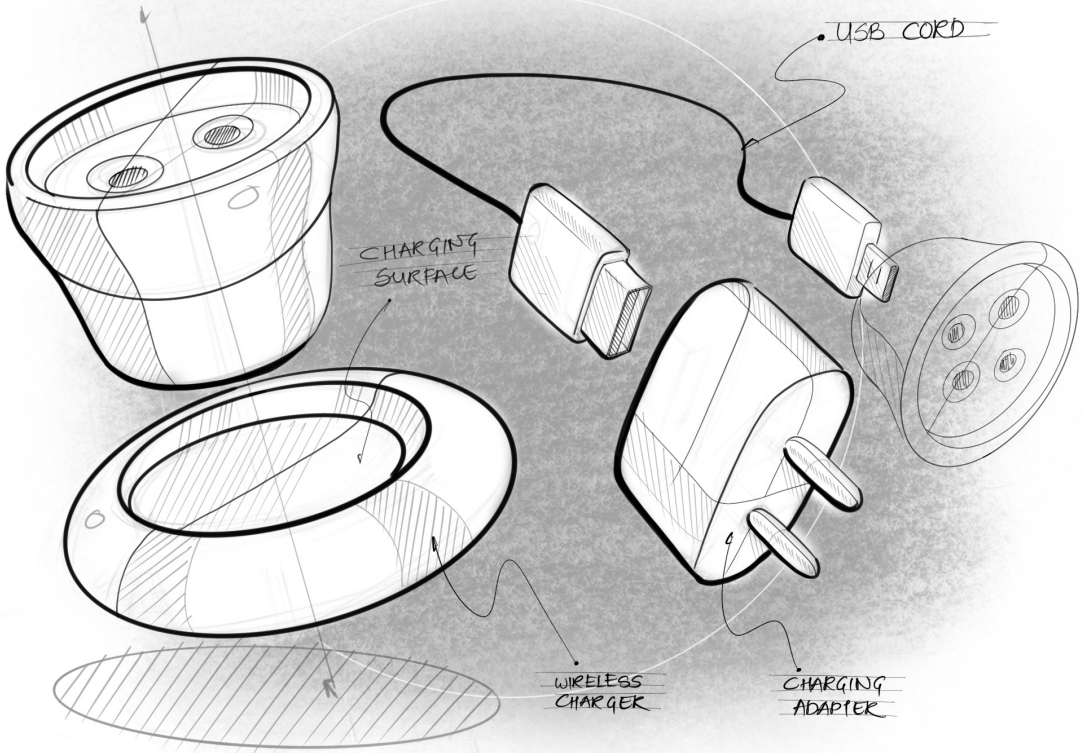


Fig. D.13 Dock For Charging

Accessories

Fig D.12 explores the possibility of providing a light weight reflective surface along with the device for better visibility and portability.

Fig D.13 explores the options for charging the device.

Fig D.14 explores the possibility of having a camera for capturing images to keep a record or forward it to a physician for advice.

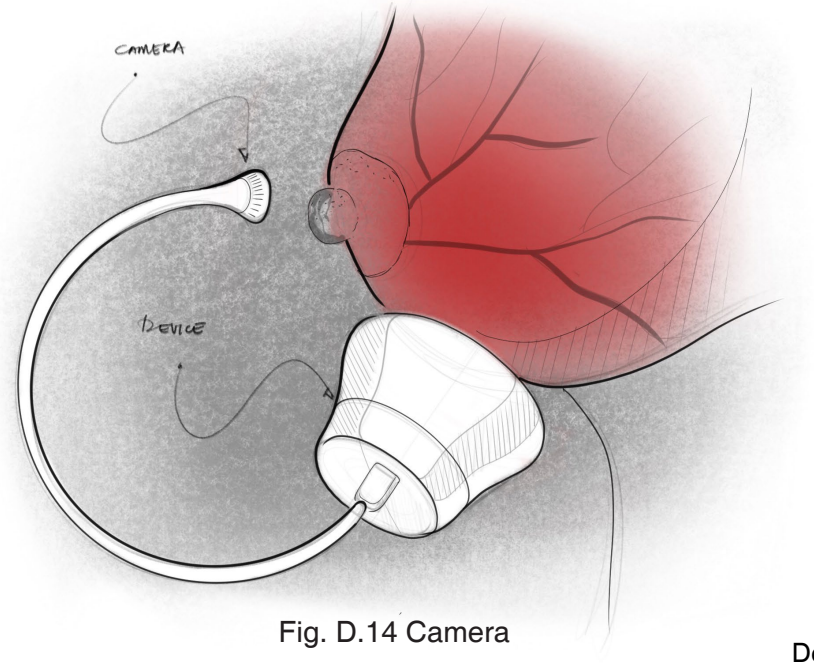
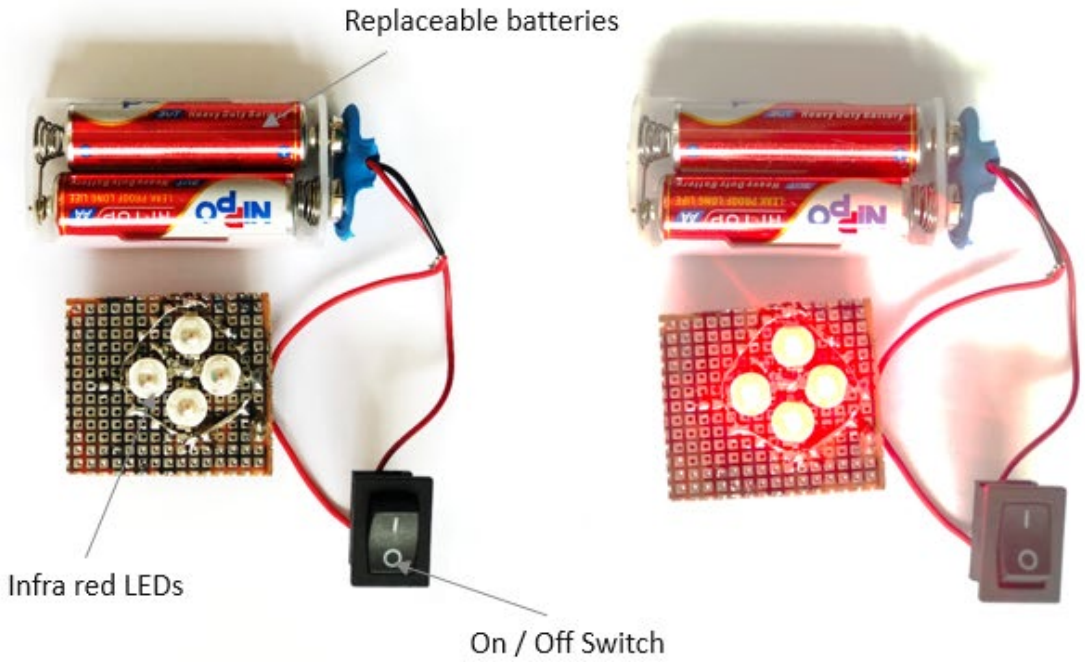
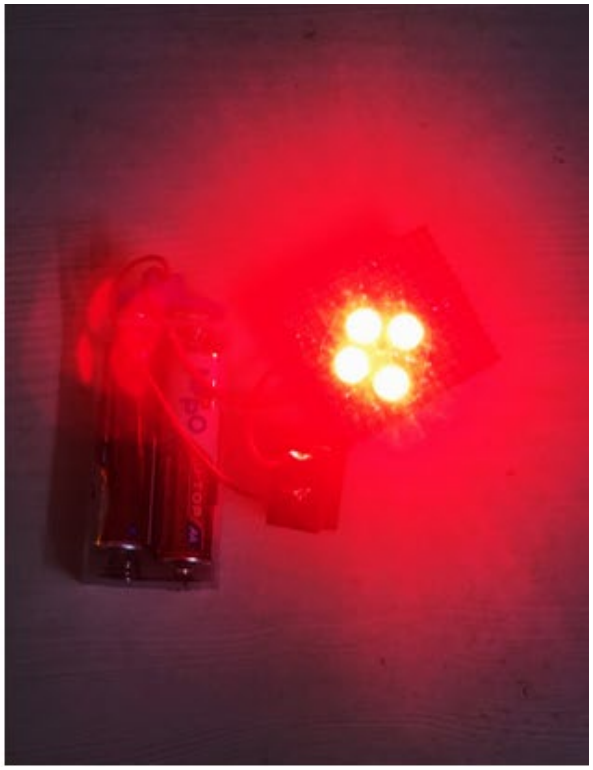


Fig. D.14 Camera

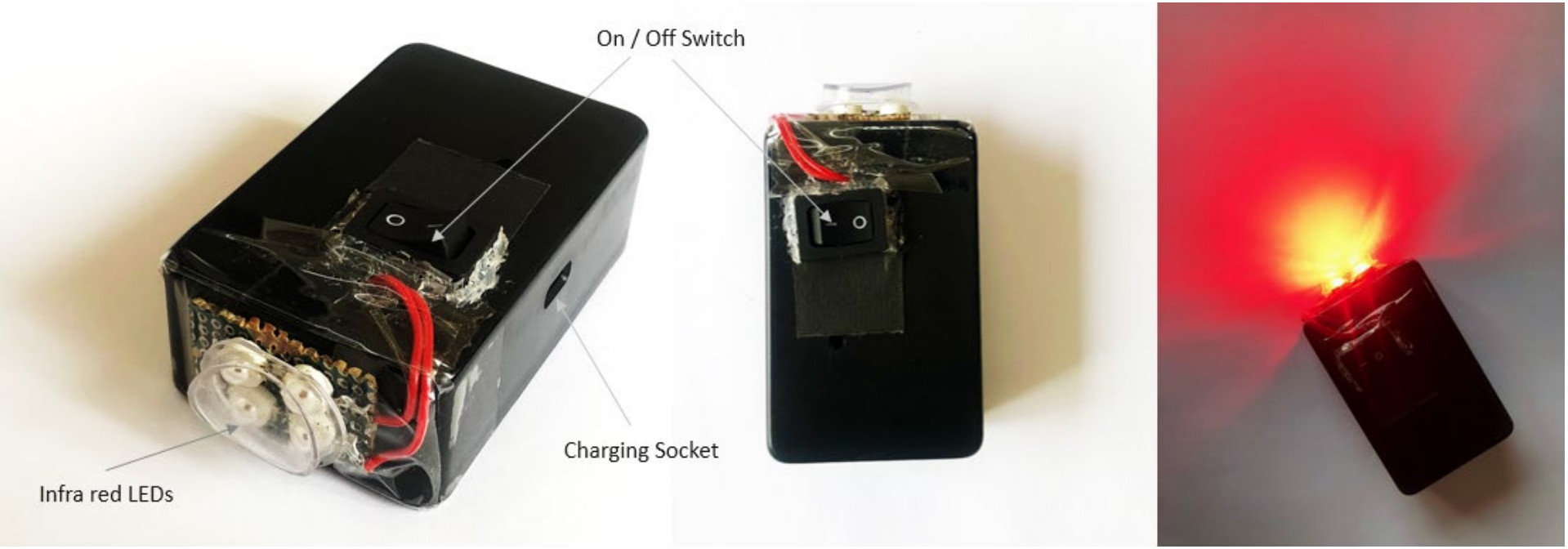
D.4 Prototyping





Specifications – Prototype 1

- 4 LEDs of 1 watt each
- Total 200 lumen – 50 lumen each
- Wavelength – 620 – 625nm
- Replaceable battery source
- No intensity adjustments



Specifications – Prototype 2

- 4 LEDs of 4 watt each
- 200 lumen – 50 lumen each
- Wavelength – 620 – 630nm
- Rechargeable battery source
- No intensity adjustments

User Testing

Observations based on user feedback

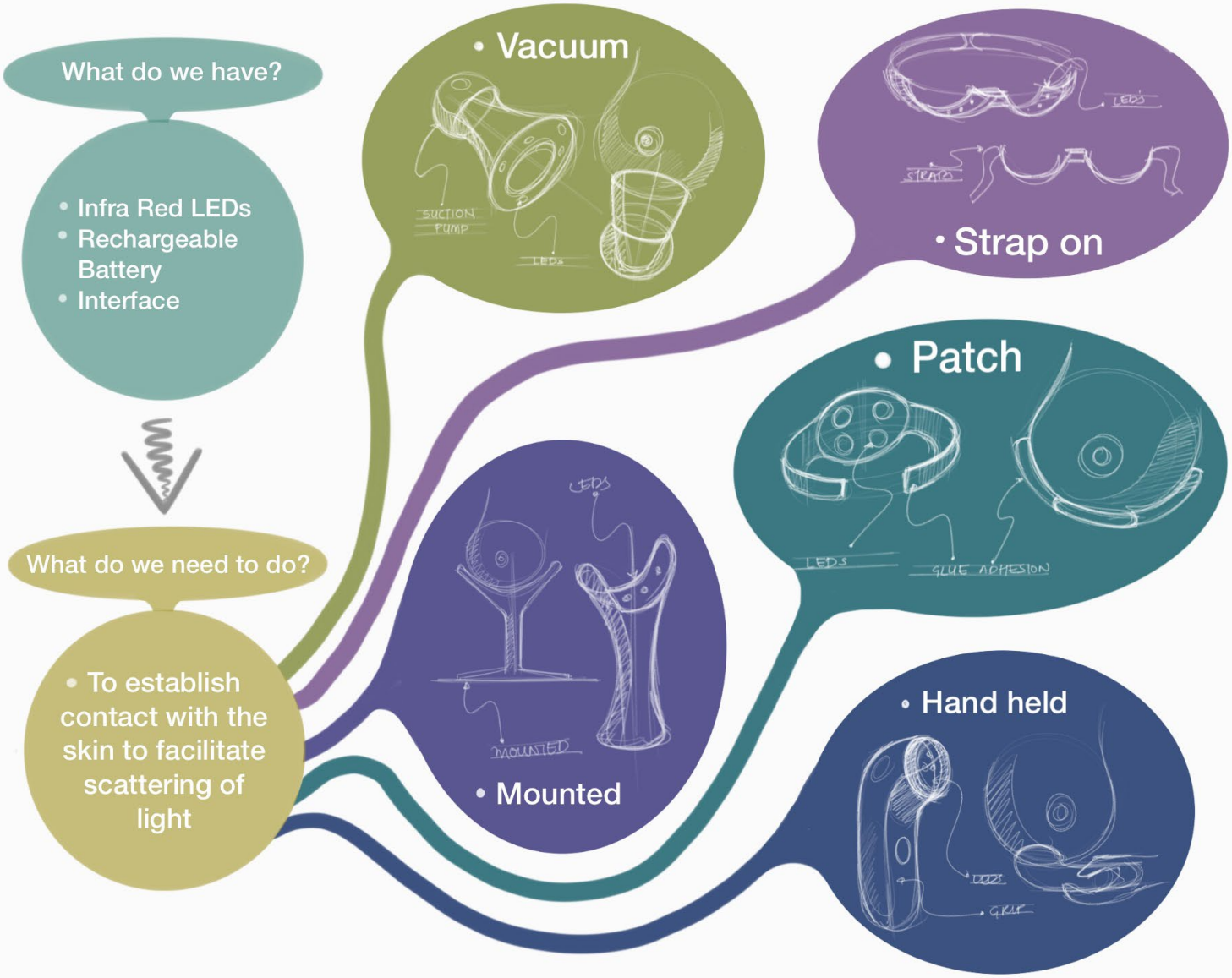
Physical Aspects

- Insufficient intensity for some subjects hence there is a need to provide multiple intensity adjustments in the device.
- Availability and proximity of the mirror.
- Heating of device.
- Lack of feedback from the device in terms of battery level and intensity.
- Loss of light from the sides hindering vision when reflected in the mirror.
- Device worked equally well on all skin types.
- Sensors needed to supress light when device is not in use to prevent hurting the users eyes.
- Where and how is the device being placed after the use in the dark implied that there are chances of the device falling and getting damaged.
- The operation switches are not visible in the dark.
- Provision for capturing and storing images for future reference and comparison.

Emotional Aspects

- Anxiety associated with the idea of using a device designed to aid detection of cancer.
- Some of the users preferred ignorance over awareness and others understood the importance of awareness.
- Most users agreed to try the prototype when explained that early detection reduces the amount of treatment required and greatly increases the chances of survival.

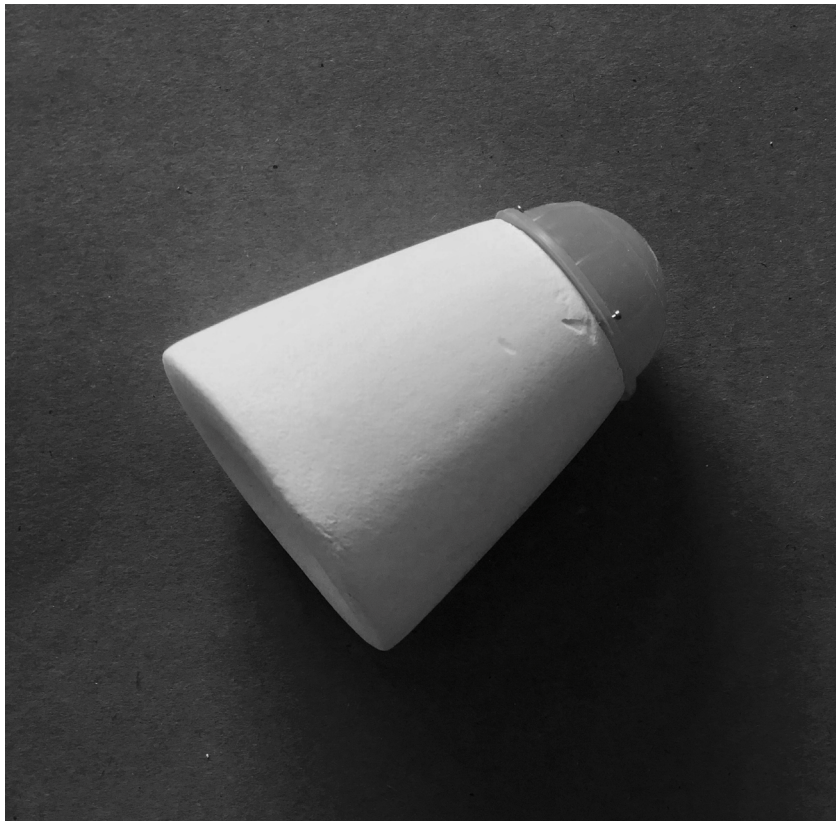
These aspects were key drivers to the idea of having a device that women could use in the comfort of their homes rather than visiting a hospital facility which can be an intimidating experience.



D.5 Brainstorming

Brainstorming involved understanding the function that needed to be achieved and in how many ways can it be done.

D.6 Concept Development

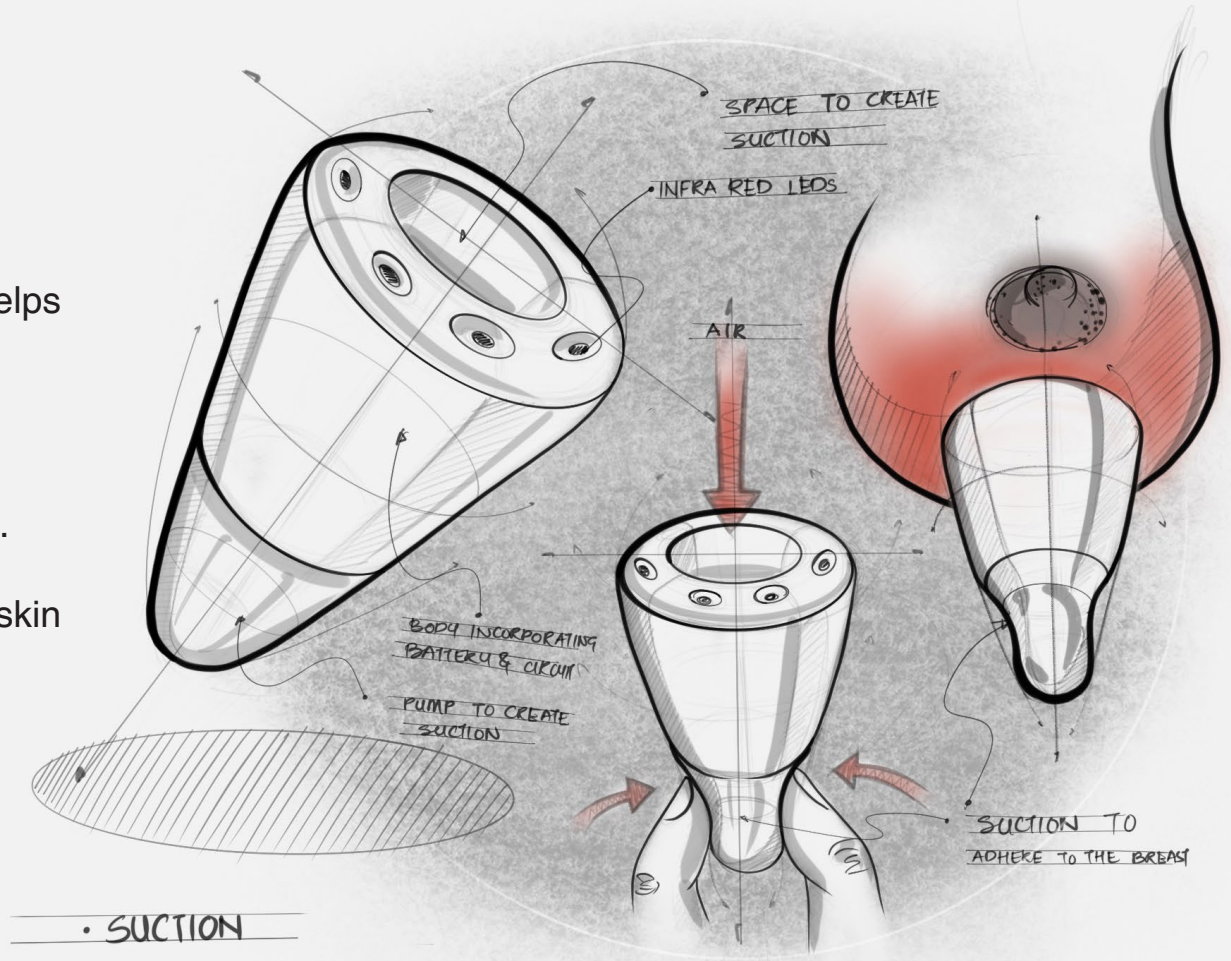


Mockup

1. Vacuum

Uses suction to create pressure which helps in adhesion to the skin.

- The LEDs on the periphery
- Suction needed to facilitate adhesion.
- Suction causes pressure on the skin causing discomfort.
- No easy adjustment.
- Portable

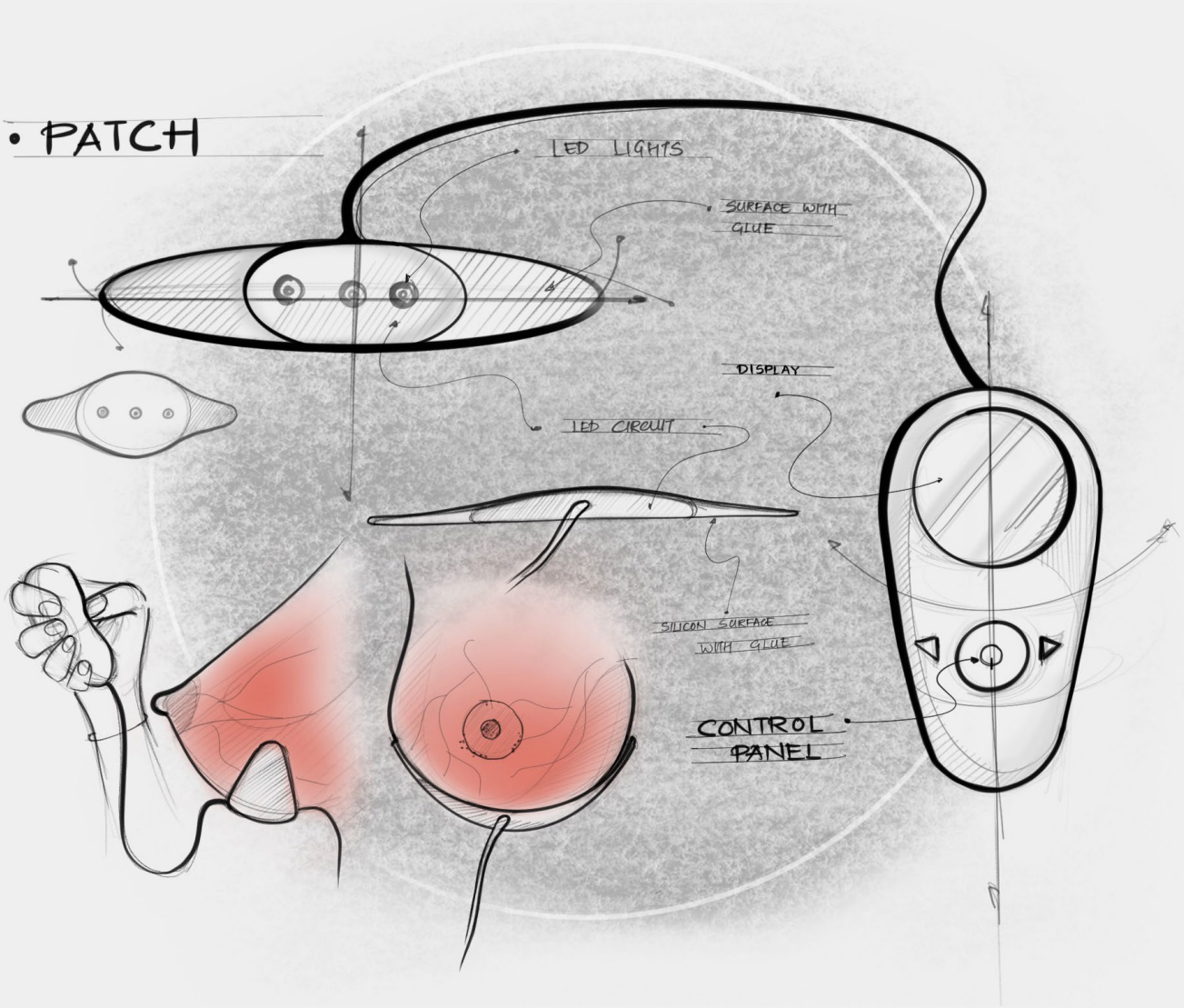


Mockup

2. Patch

Uses glue to be adhered to the skin.
The patch is made of silicone with the led unit snap fitted on it.

- Glue helps adhesion and can be reused around 50 times.
- Patch is made in silicone and can be re-placed.
- Heat sink cannot be provided.
- Portable

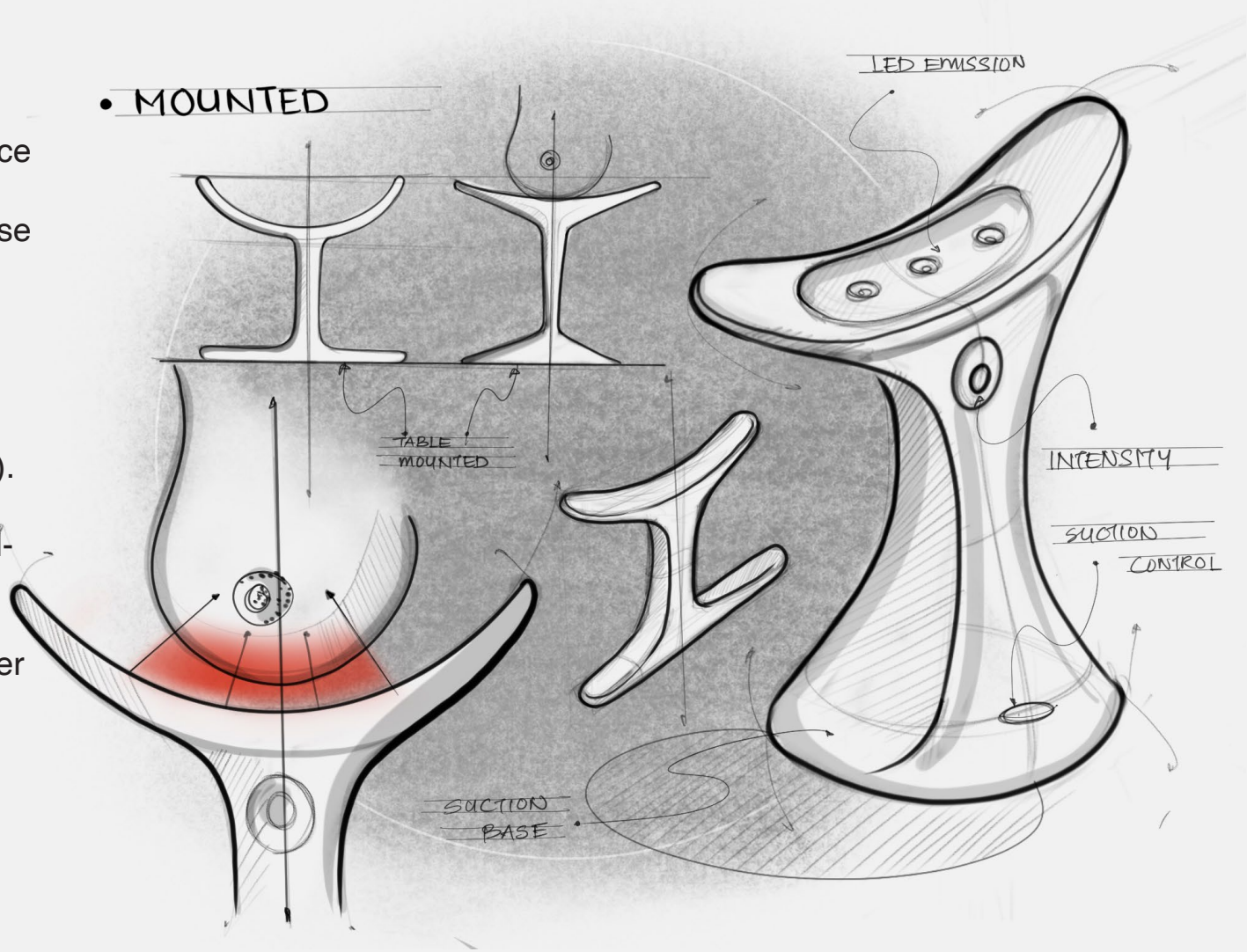


Mockup

3. Mounted

The device is mounted on a plane surface such as a table using suction.
One needs to place the breast on it to use the device.

- Flat surface is needed for mounting.
- Portability is an issue (size and weight).
- Will require multiple height and size adjustments.
- Can have a good heat sink due to larger surface area

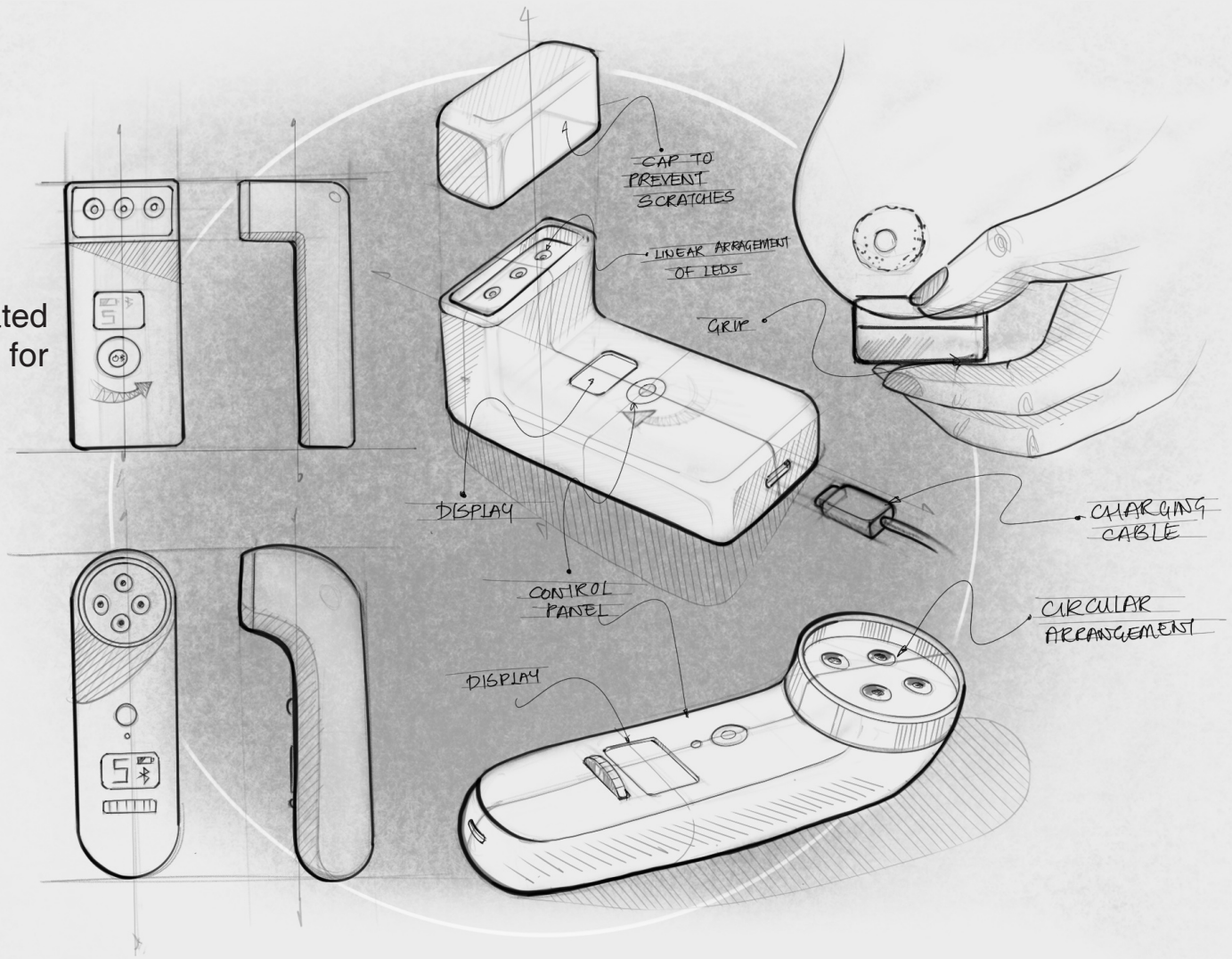


Mockups

4. Hand Held

The device is held in the hand and operated manually as it is pressed against the skin for better visibility.

- Device has to be held in the hand.
- Can be moved around to adjust.
- Portable.
- Heat sink can be provided.
- Easy to use.



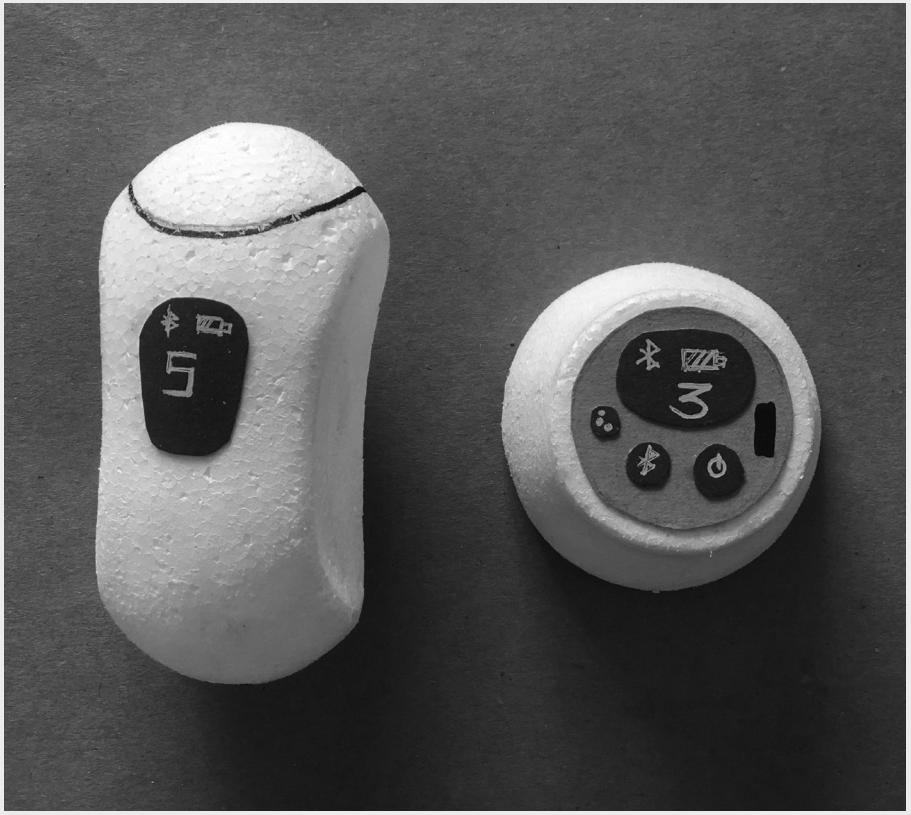
USABILITY EVALUATION

	VACUUM	PATCH	MOUNTED	HANDHELD
EASE OF USE	●●	●●●	●	●●●●
COMFORT	●	●●●●	●	●●●●
HEAT SINK	●●●●	●	●●●●	●●●●
PORTABILITY	●●●●	●●●●	●	●●●●●
INTERFACE	●●●	●●●●	●●●●	●●●●
STABILITY	●●	●●●	●●●●	●●●●

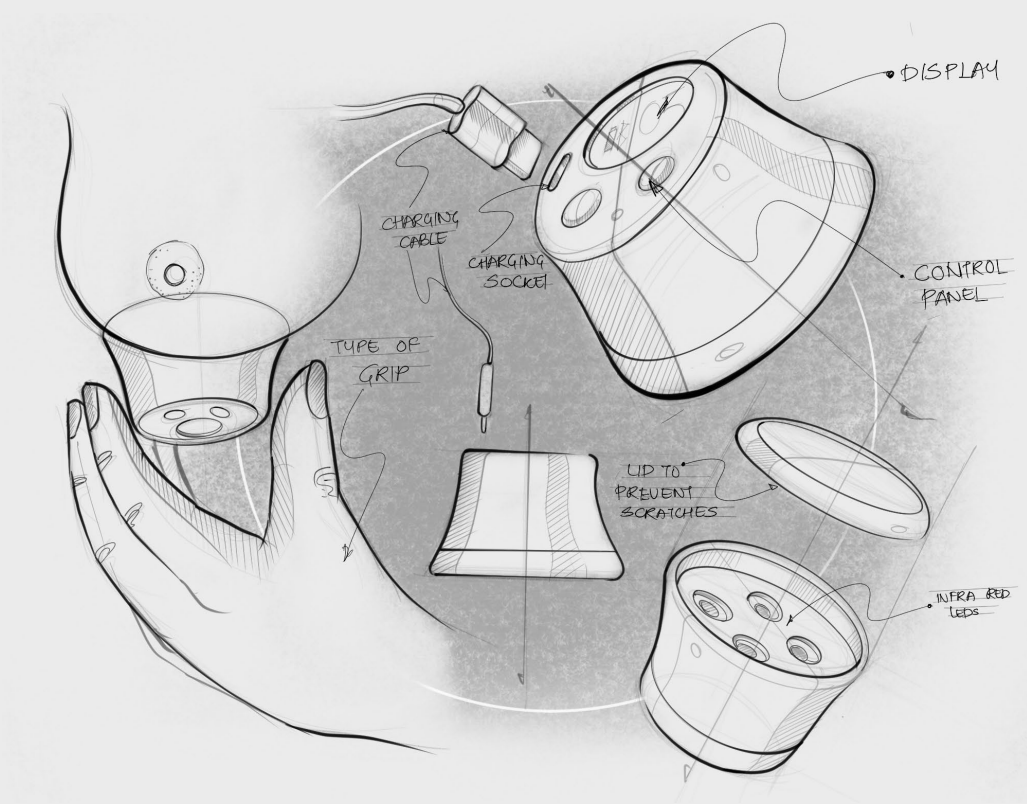
RATING ON SCALE ON 1-5, ONE BEING THE LOWEST

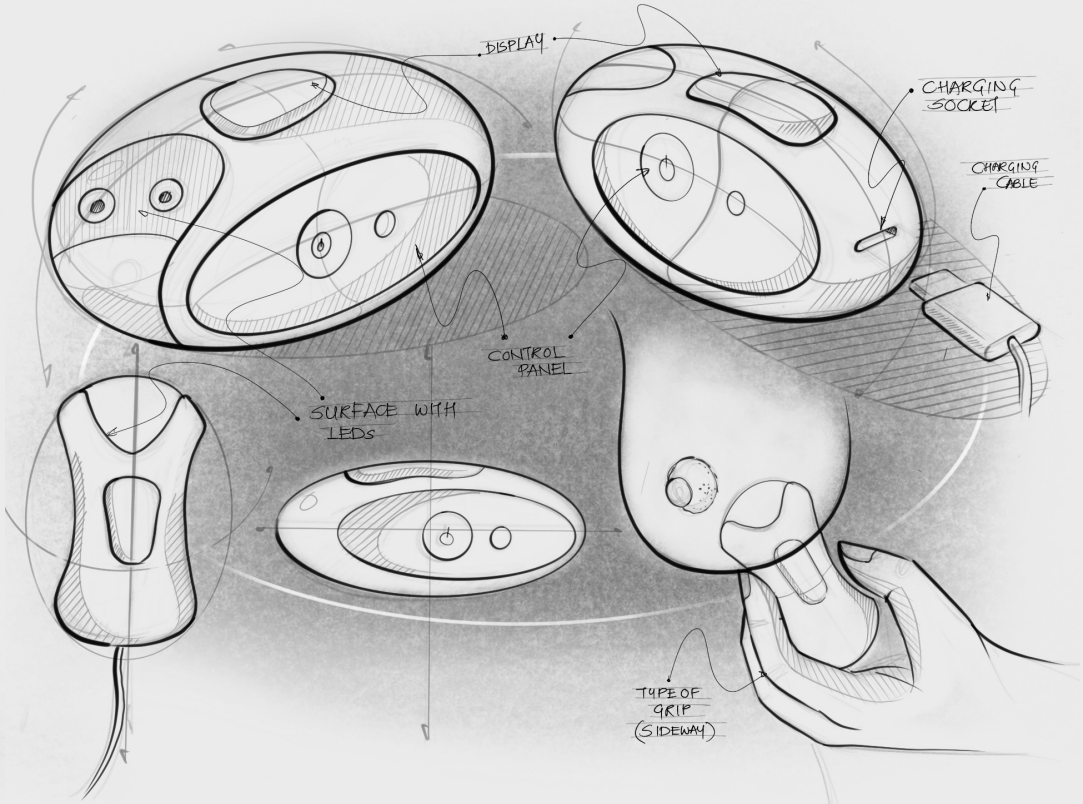
The chart above shows the various parameters used to evaluate the four concepts mentioned above.
This evaluation involved role play exercises using the mock-ups developed in order to get a better understanding of usability and the aspects that hinder the flow of actions.
Based on this evaluation it was decided to proceed further with the concept of a hand Held Device.

D.7 Grip Development for Hand Held Device



Mockups



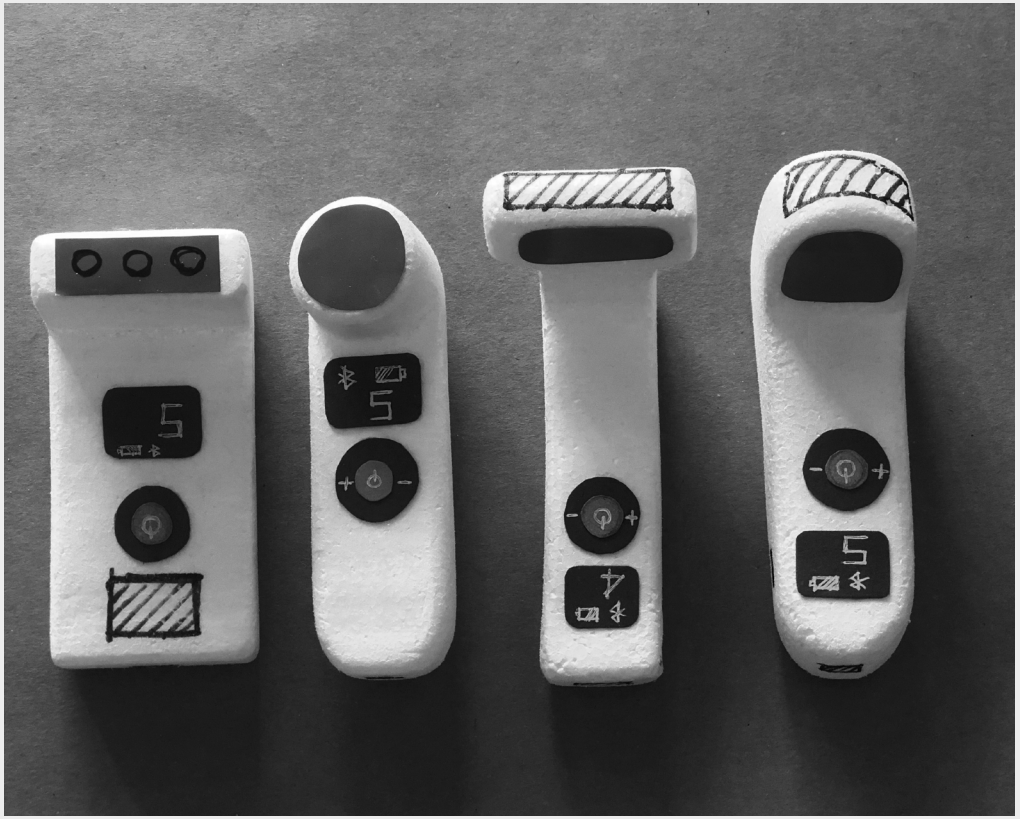


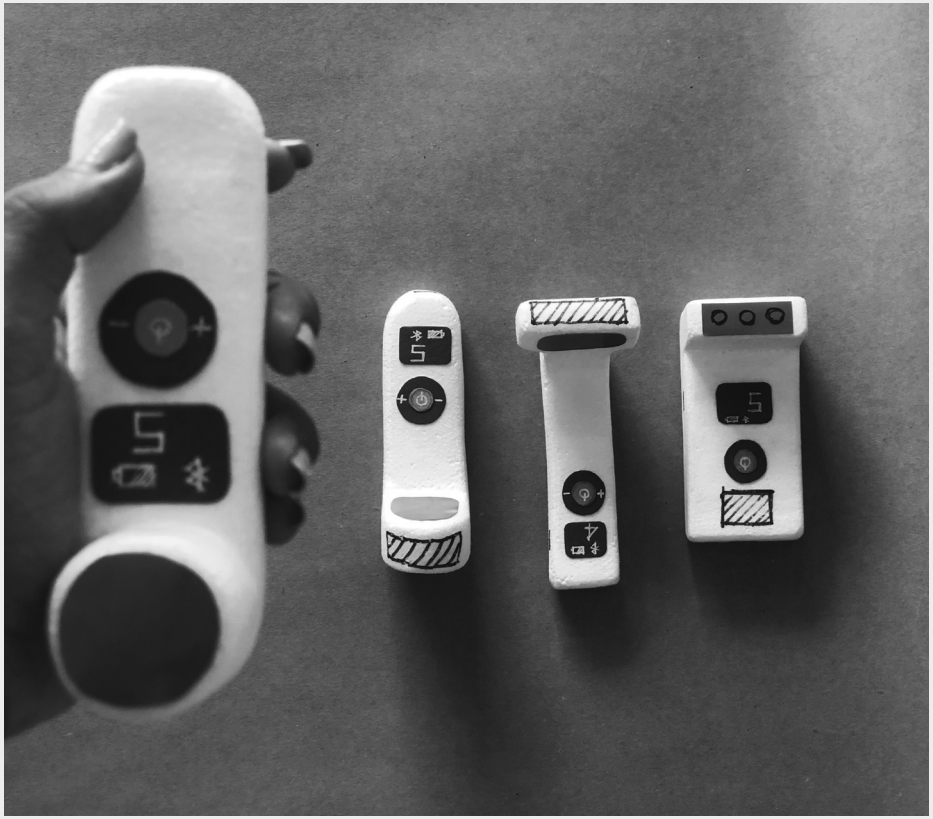
D.7a Grip Type I

This grip type is inspired from the stethoscope used by doctors. The grip allows the device to held firmly against the skin.

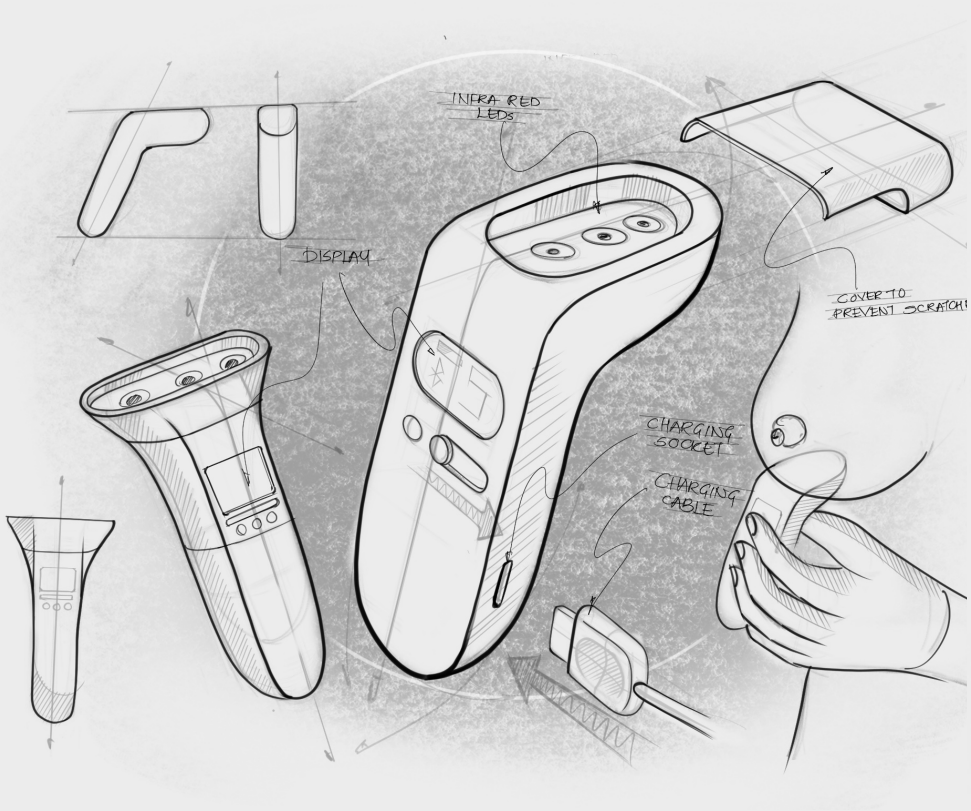
This grip type does not provide interface accessibility while the device is in use.

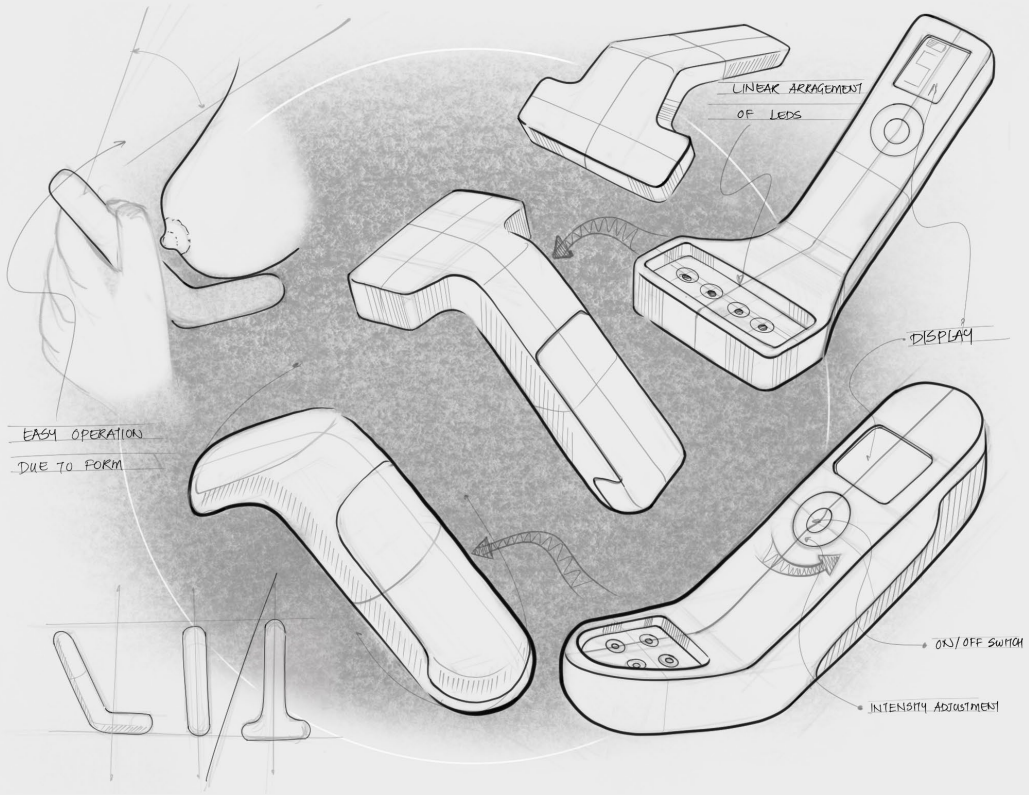
Also the aspect of being able to incorporate all the internal components in this type of a form would make the form too big





Mockups





D.7b Grip Type II

This grip type allows use of the interface even while the device is in use such as intensity adjustment etc.

It also improves the visibility of the interface as compared to the previous grip type.

The grip is bigger and more comfortable.

Mockup

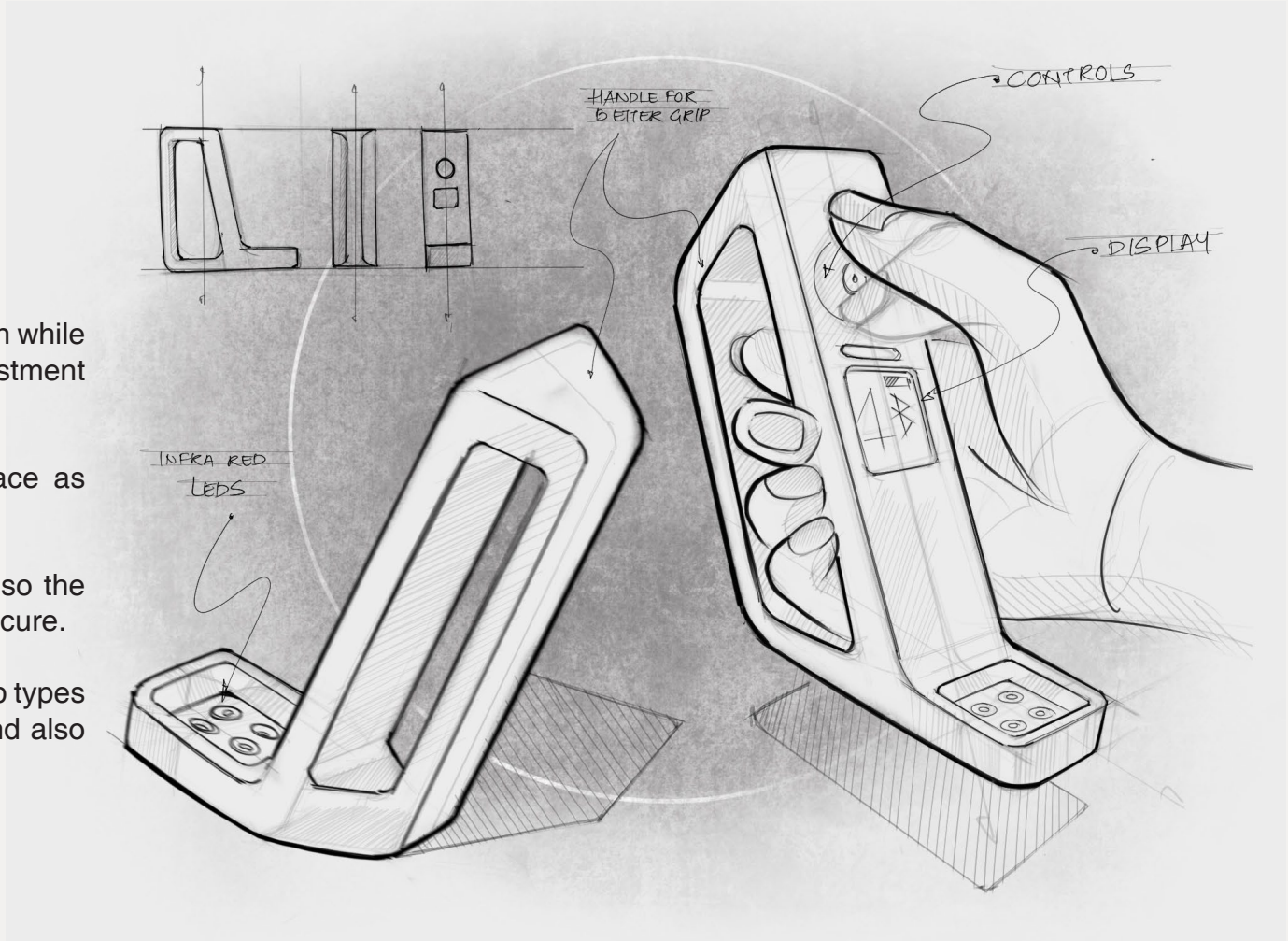
D.7c Grip Type III

This grip type allows use of the interface even while the device is in use such as intensity adjustment etc.

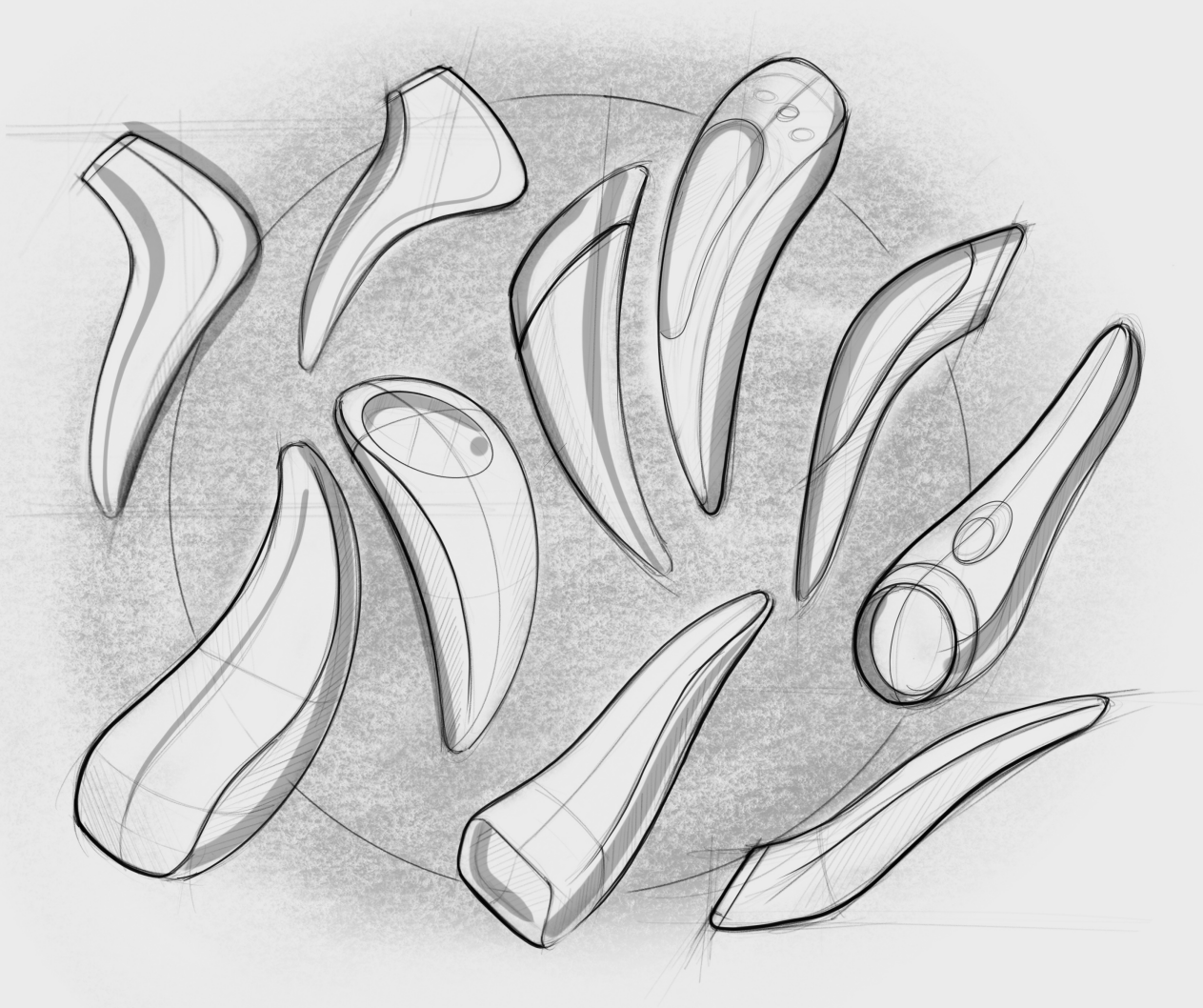
It also improves the visibility of the interface as compared to the previous grip type.

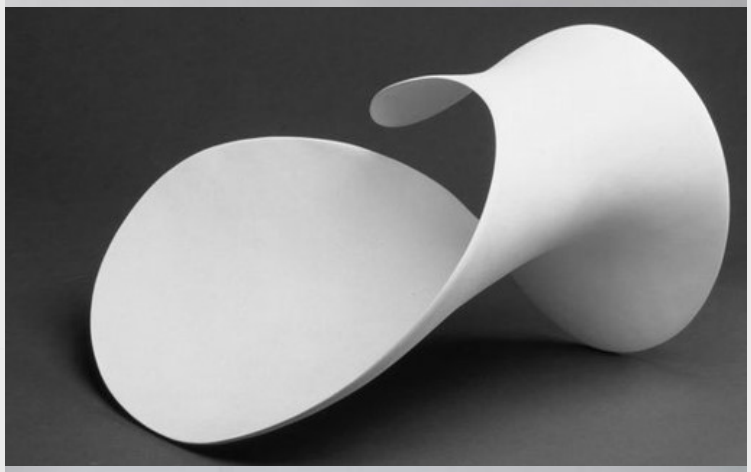
The grip is bigger and more comfortable also the possibility of handle makes the grip more secure.

From the mock models made for all three grip types this one felt the most comfortable to use and also gave better visibility and accessibility.

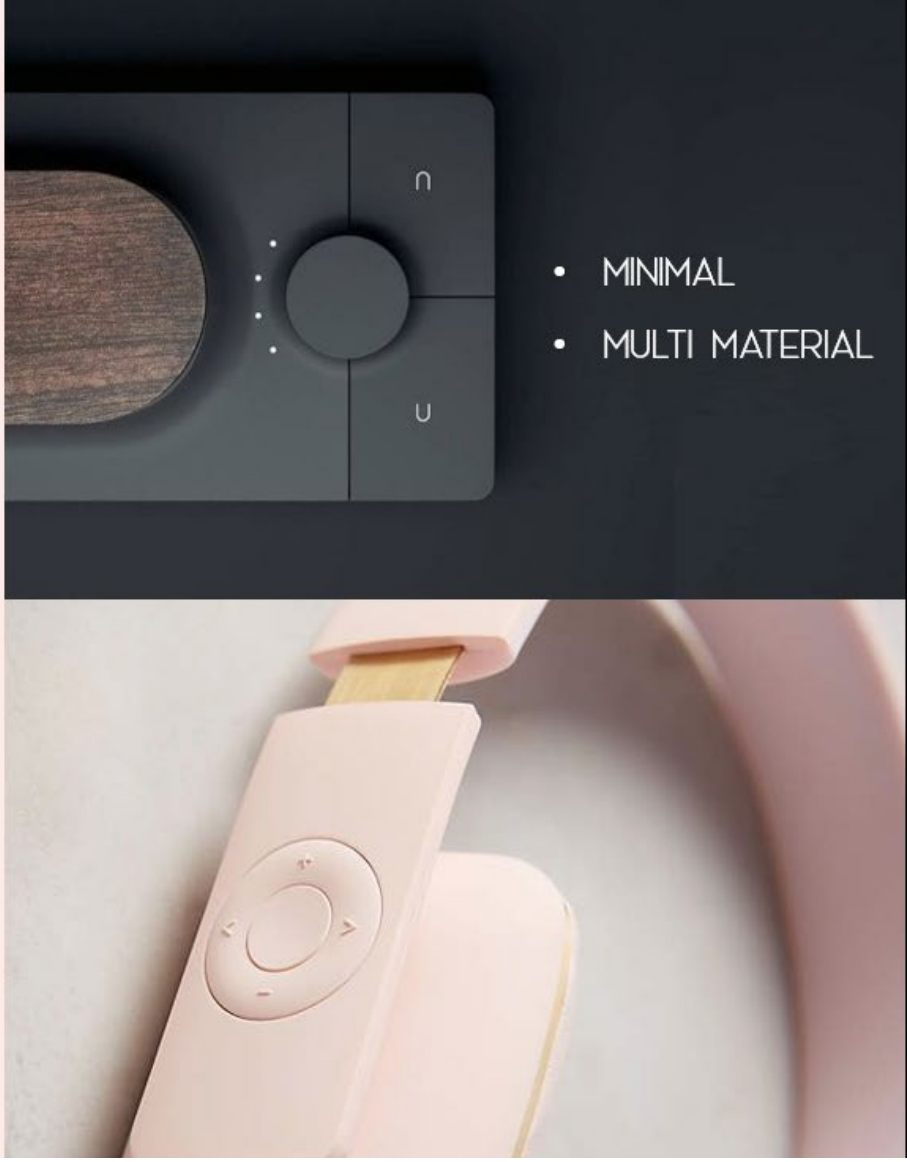


D.8 Form Development





The final form of the device was to be sleek yet ergonomic. The form had to be Soft as it comes in contact with a delicate body part but had to also have a dynamism or movement to create interest and desirability. All this had to be achieved without compromising on the functionality aspect.



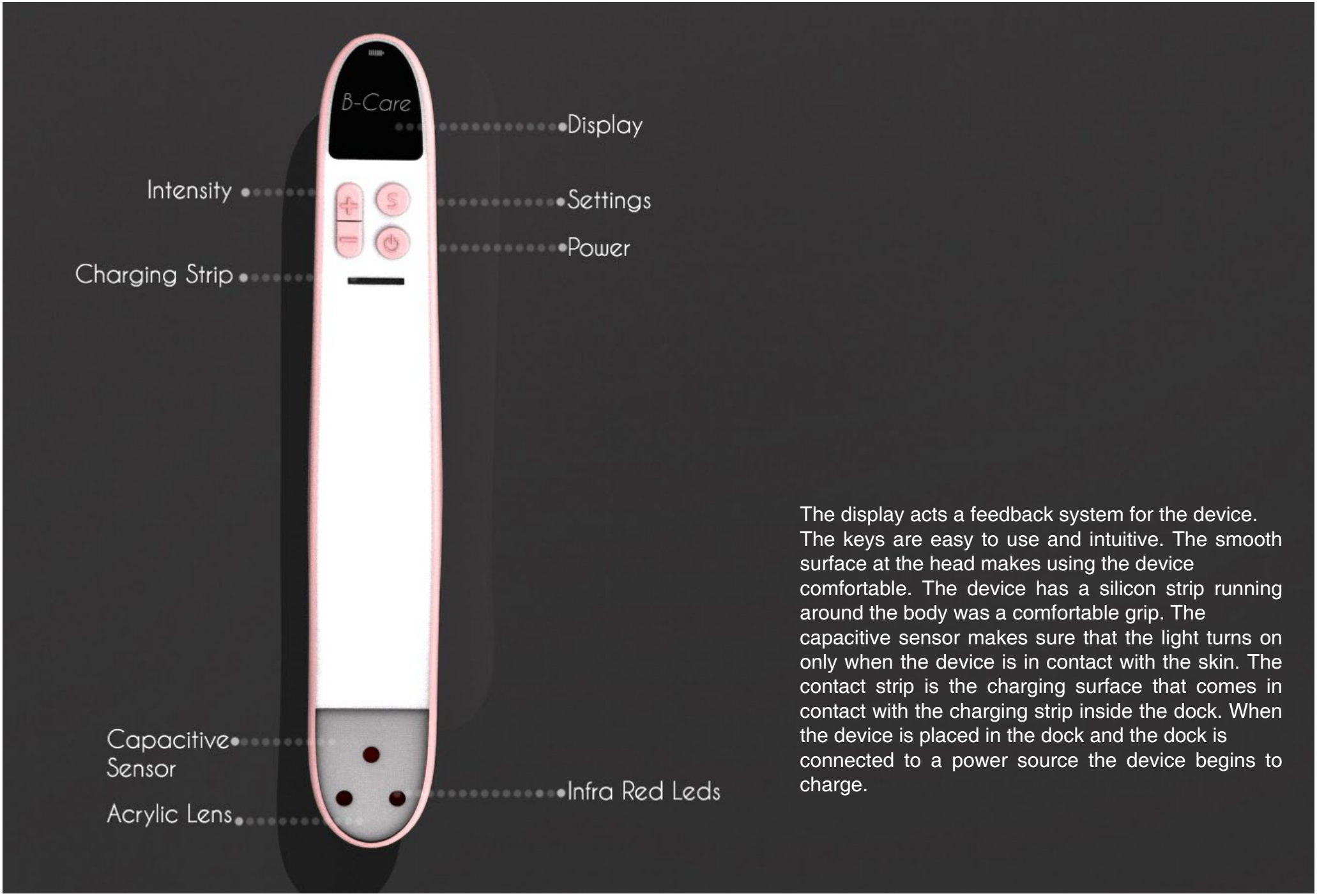
D.9 Mood Board

The Mood Board sticks to idea of having a minimal sleek device.
The pastel Pink signifies Breast Cancer Awareness.

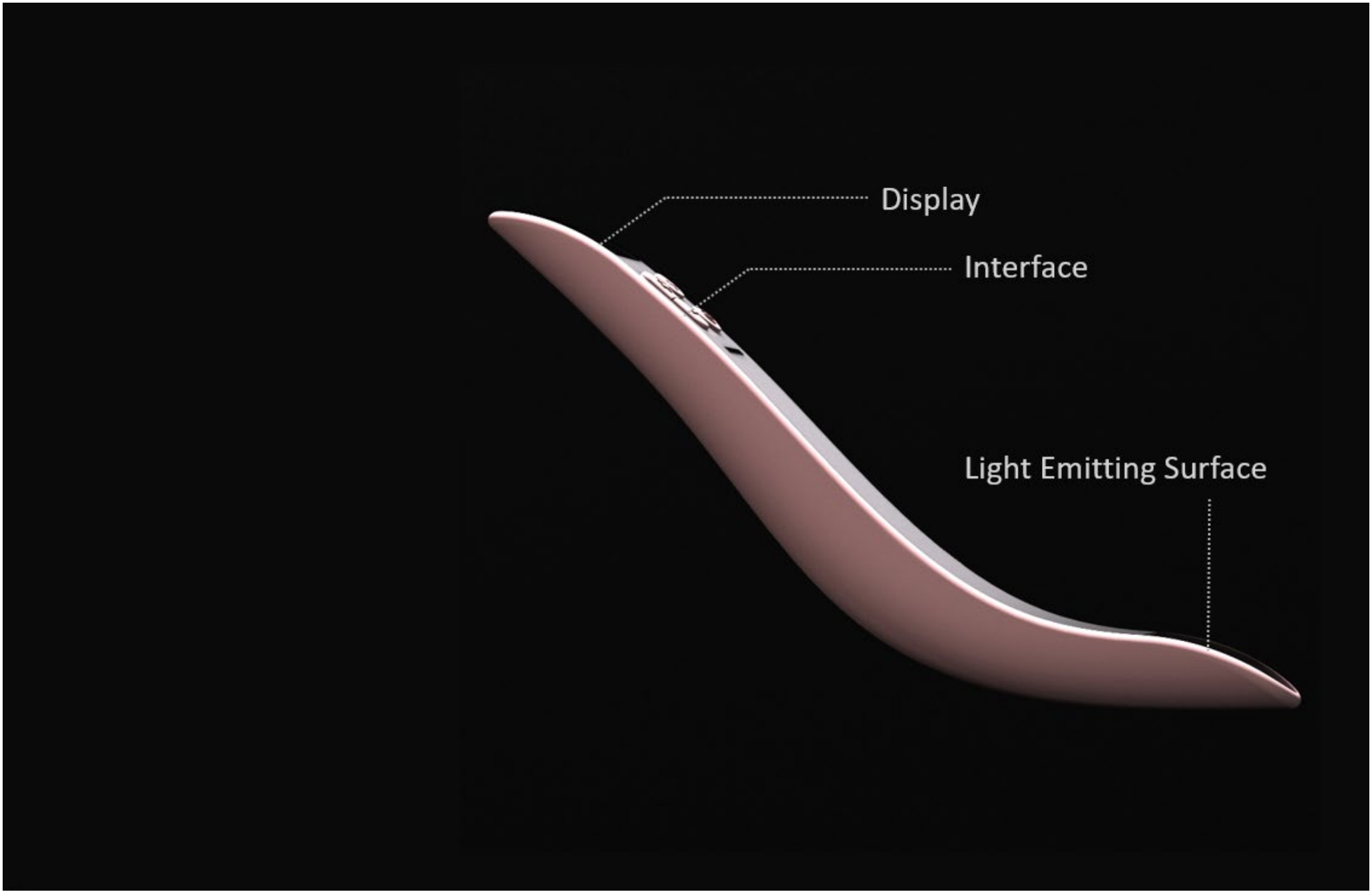
D.10 Final Concept


B-Care
Your at home breast scan device
B-Care
B-Care

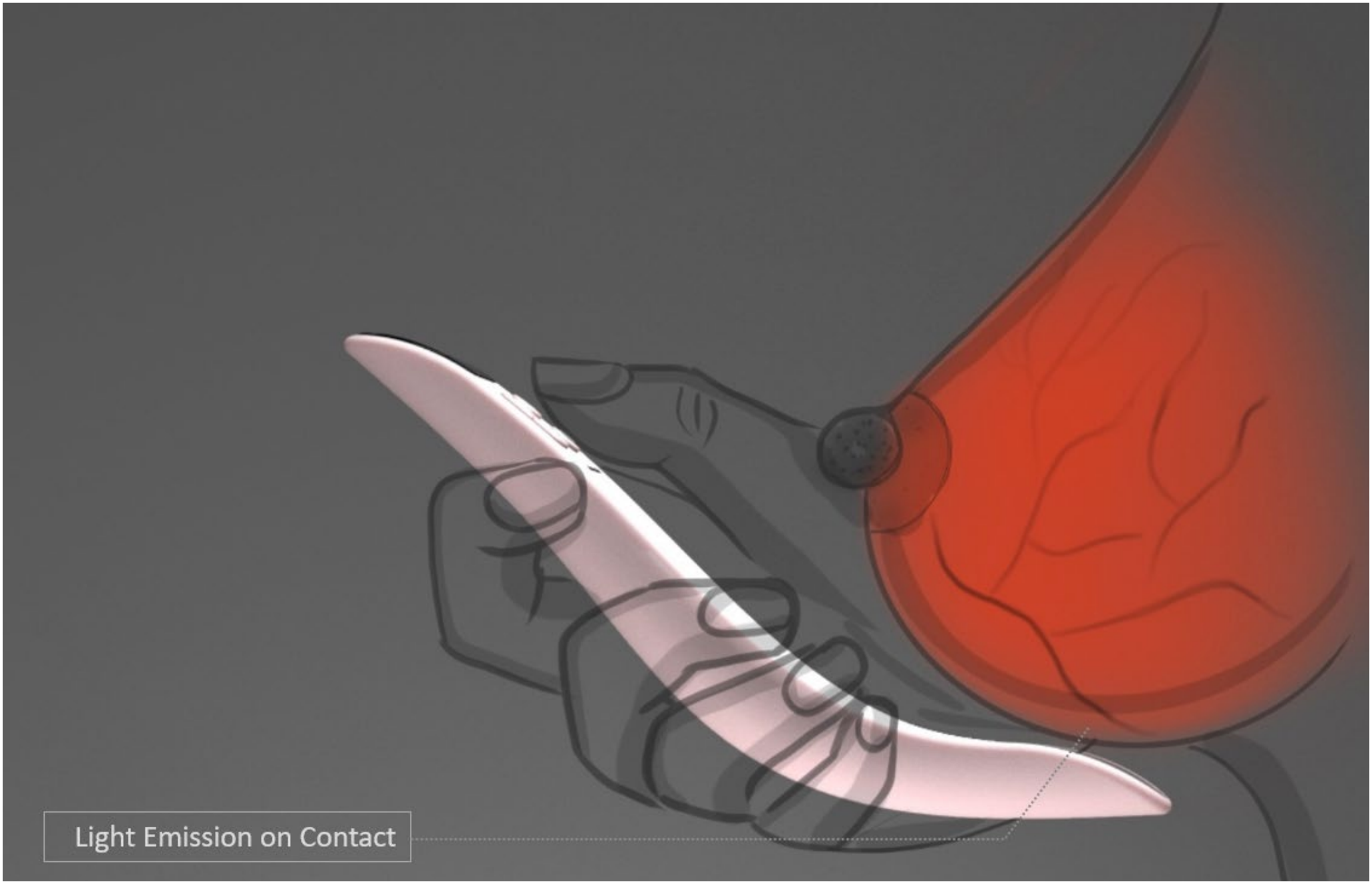
B-Care stands for Breast Care and for the idea of Be Aware that the device aims to promote.
The device has been designed to be a part of the self breast scanning routine for women in the comfort of their homes.



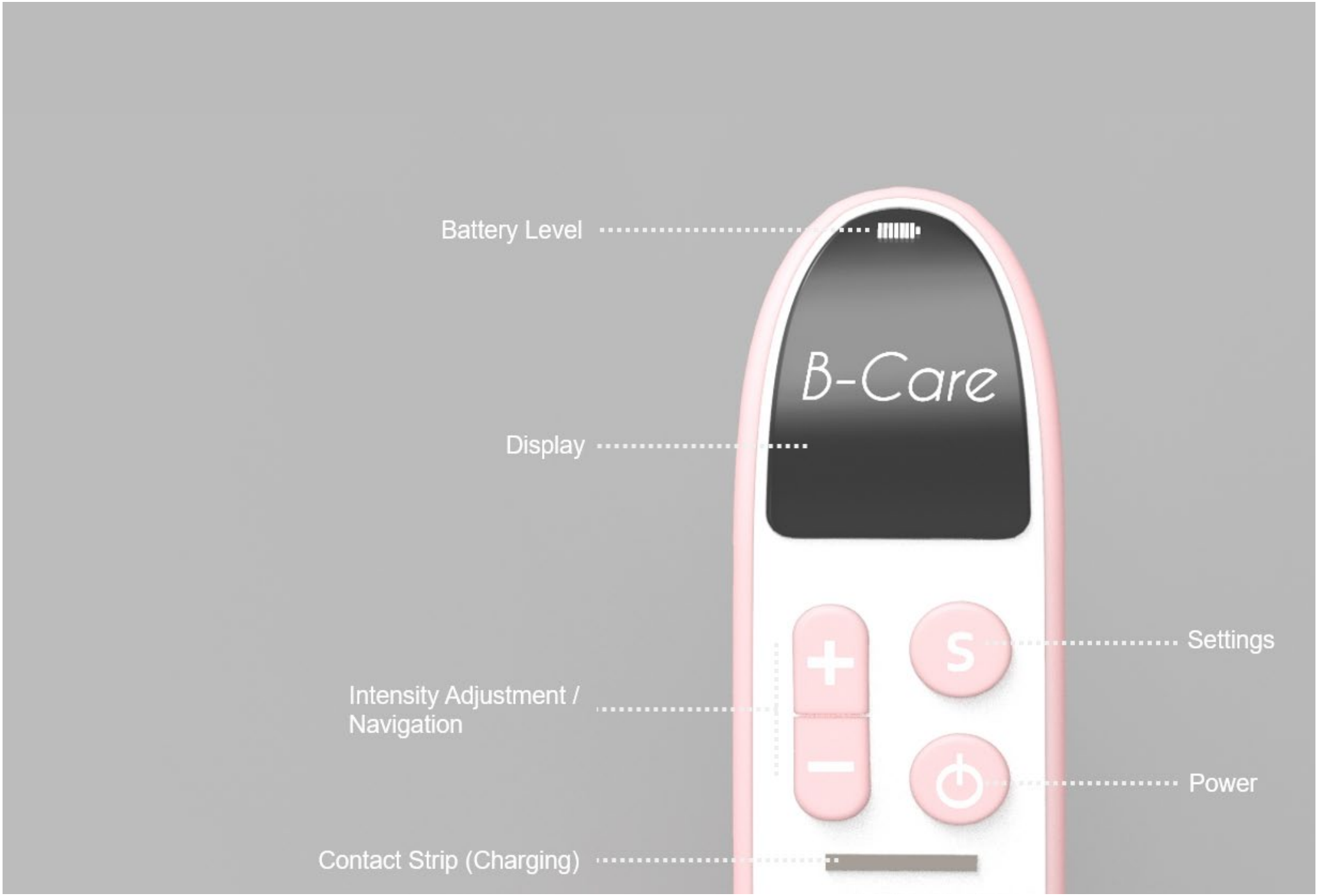
The display acts a feedback system for the device. The keys are easy to use and intuitive. The smooth surface at the head makes using the device comfortable. The device has a silicon strip running around the body was a comfortable grip. The capacitive sensor makes sure that the light turns on only when the device is in contact with the skin. The contact strip is the charging surface that comes in contact with the charging strip inside the dock. When the device is placed in the dock and the dock is connected to a power source the device begins to charge.


Display
Interface
Light Emitting Surface

Back-lit keys make it easy to use the device in the dark.


Light Emission on Contact

D.10a Interface and Operation

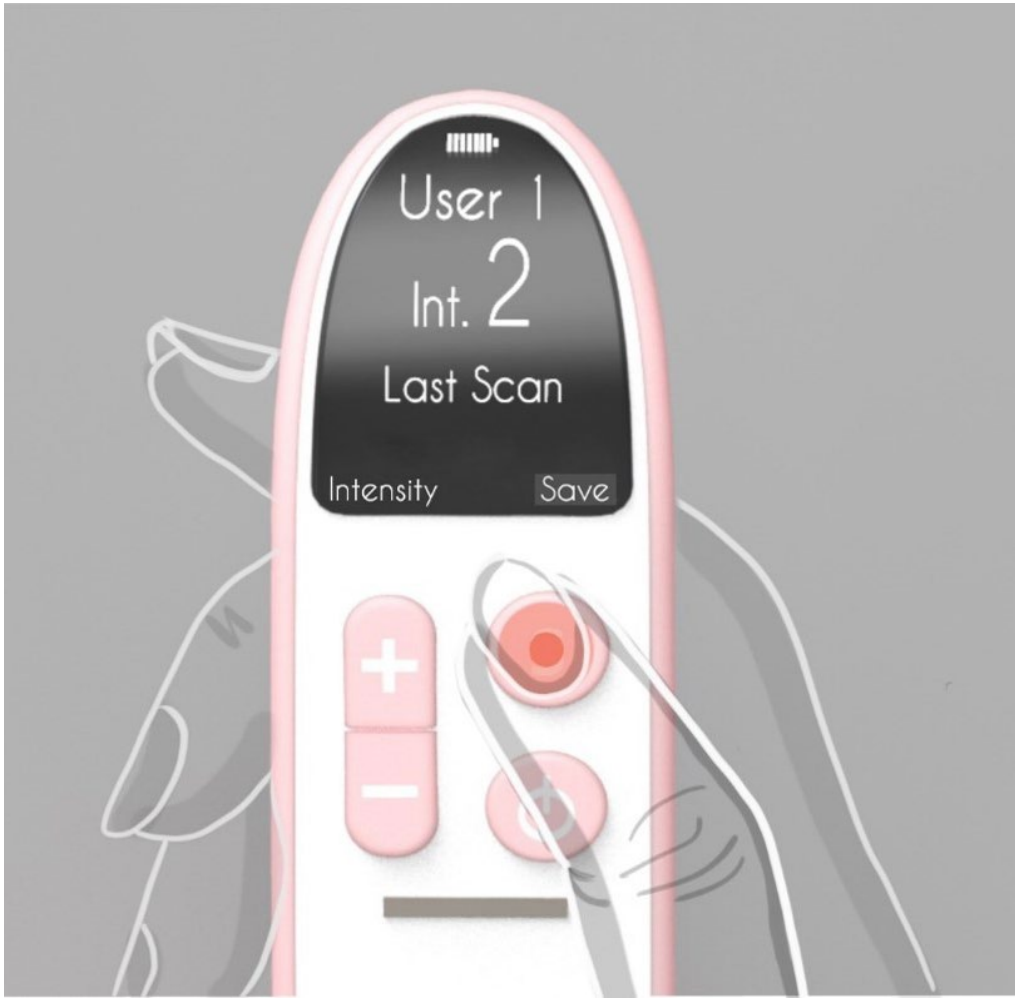

Battery Level
B-Care
Display
Settings
Intensity Adjustment /
Navigation
Power
Contact Strip (Charging)

1.
Turn on the device using the power button.

2.
Choose an option best suited.

3.
New user for someone who is using the device for the first time.

4.
The device will generate a user number.
Set the intensity and use the device. Modify the intensity if needed.



5.

Save the setting for next use.

6.

On pressing save on previous step the device will update the last scan date. On saving now the settings will be saved for next use.

7.

You may now turn off the device or go to options to repeat the above process.

1.

For users who have used the device before.

2.
Select the user number given by the device on last usage. Use the intensity / navigation key to navigate through saved users.

3.
Adjust intensity if needed and use the device. Save the settings after use.

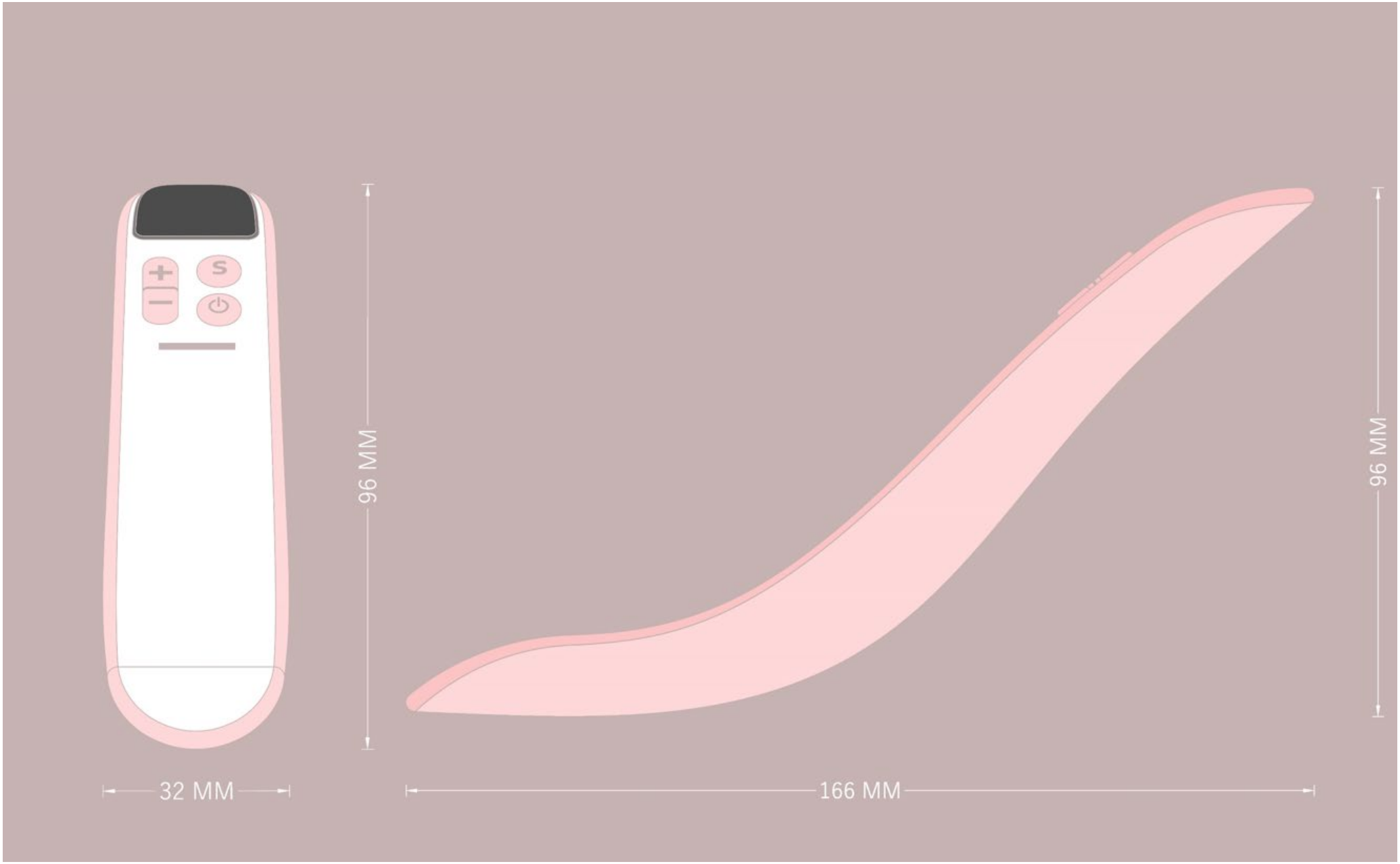
4.

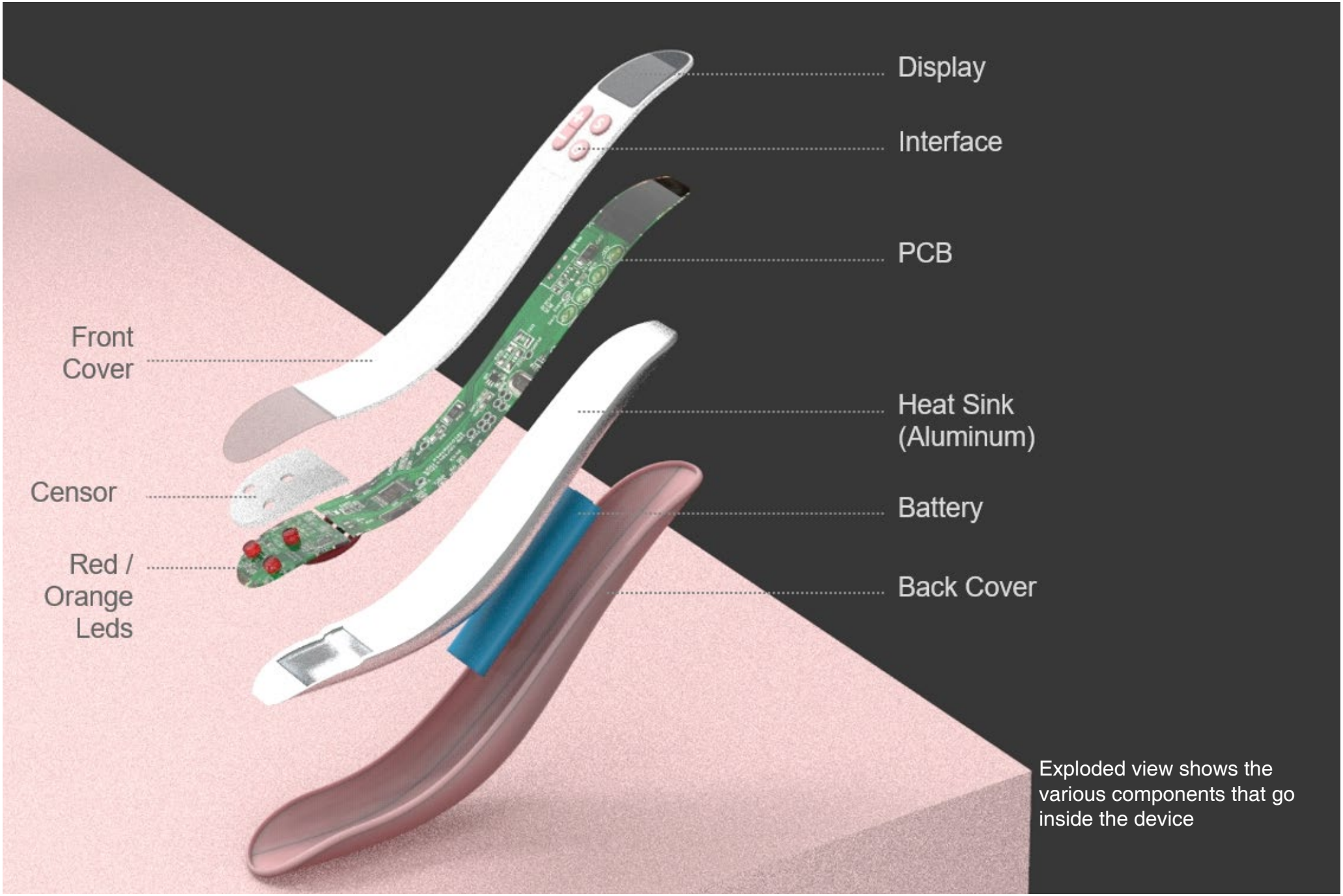
Return to home. The device can now be turned off.

Warning.

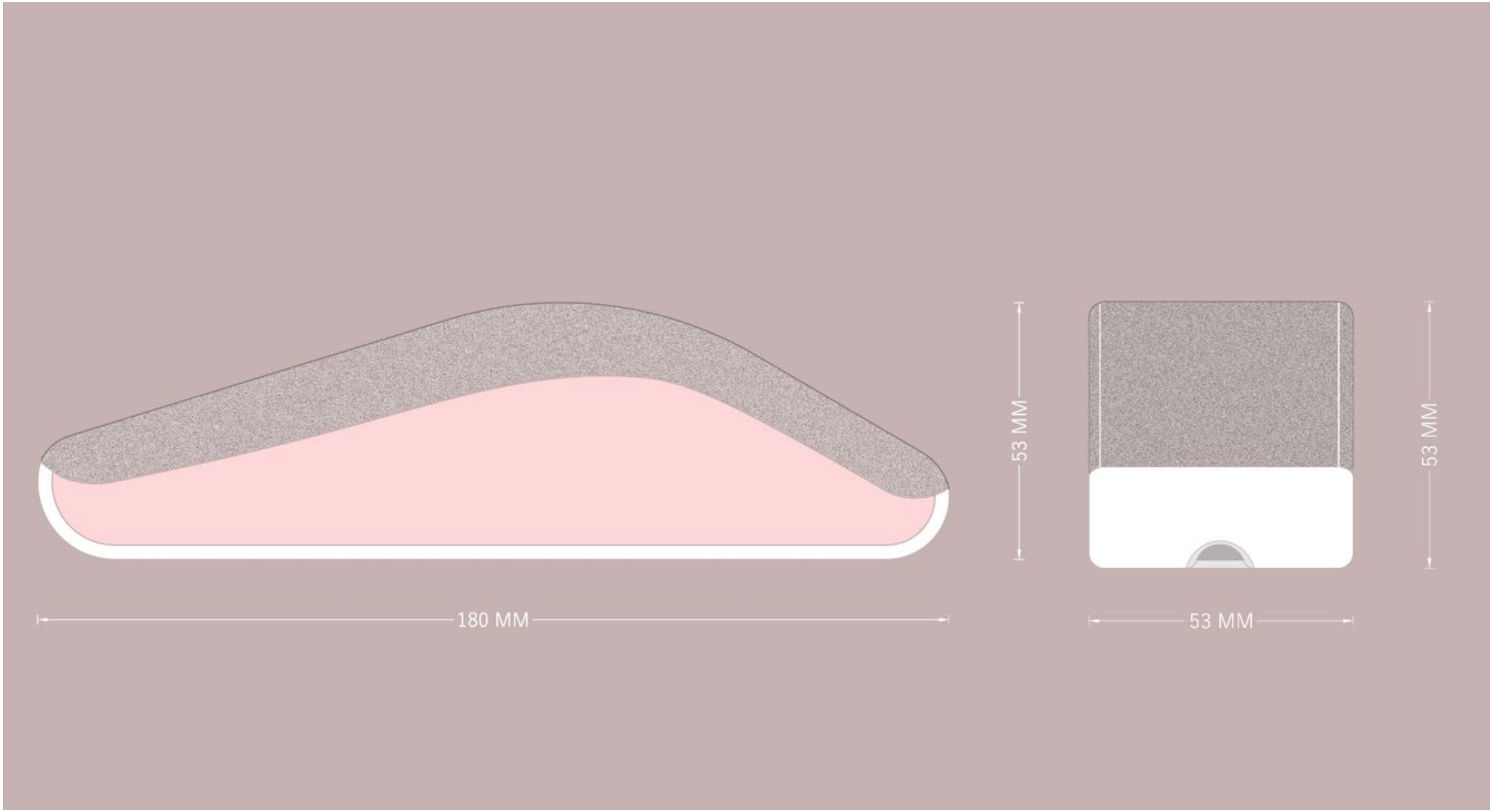
If the device gets overheated the power light will turn red and blink thrice before the device shuts down until it cools. The device can then be turned on and used normally. This is a safety feature even though there are rare chances of such heating occurrences.

D.10a Product Detailing


96 MM
96 MM
32 MM
166 MM



Exploded view shows the various components that go inside the device

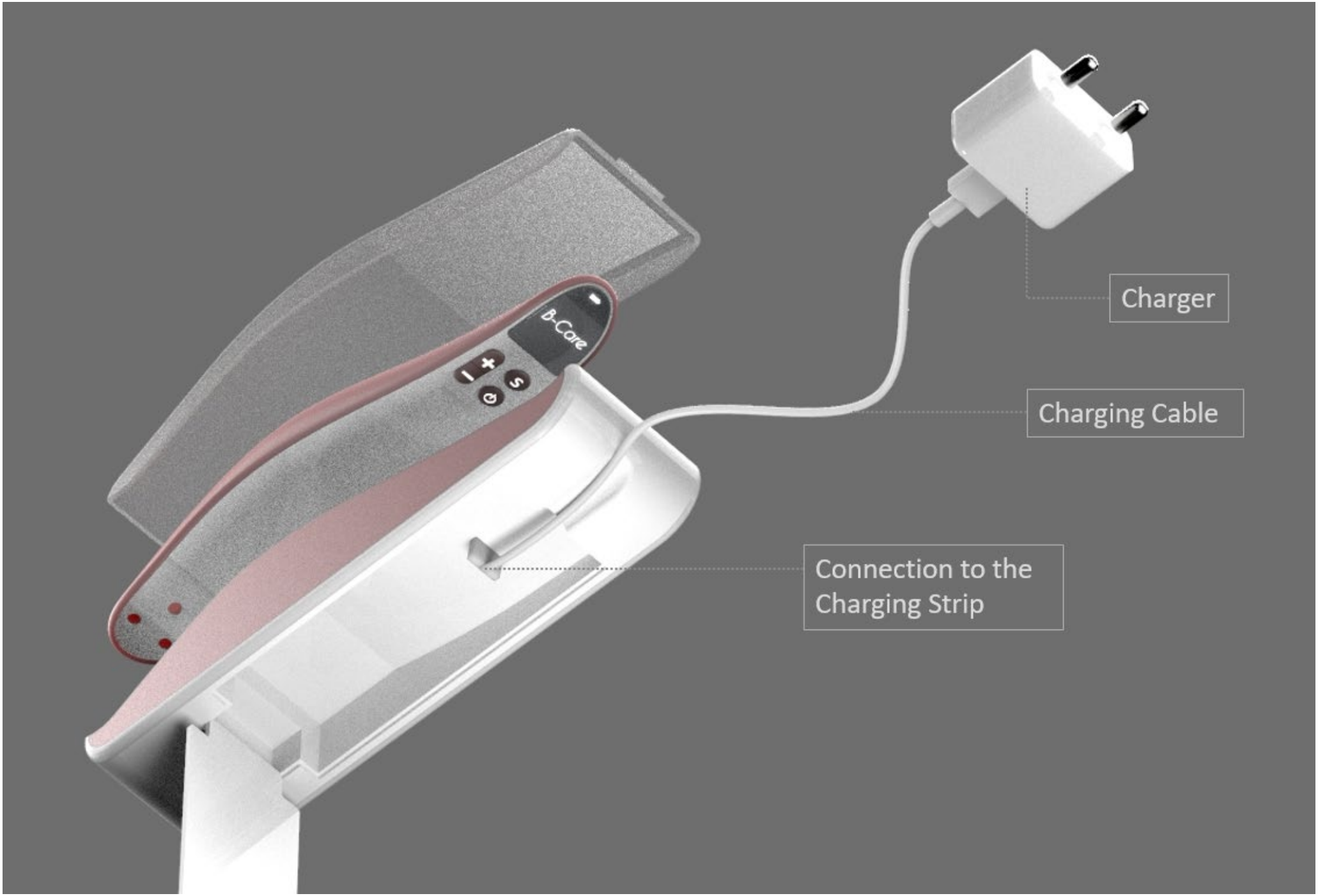

53 MM
53 MM
180 MM
53 MM

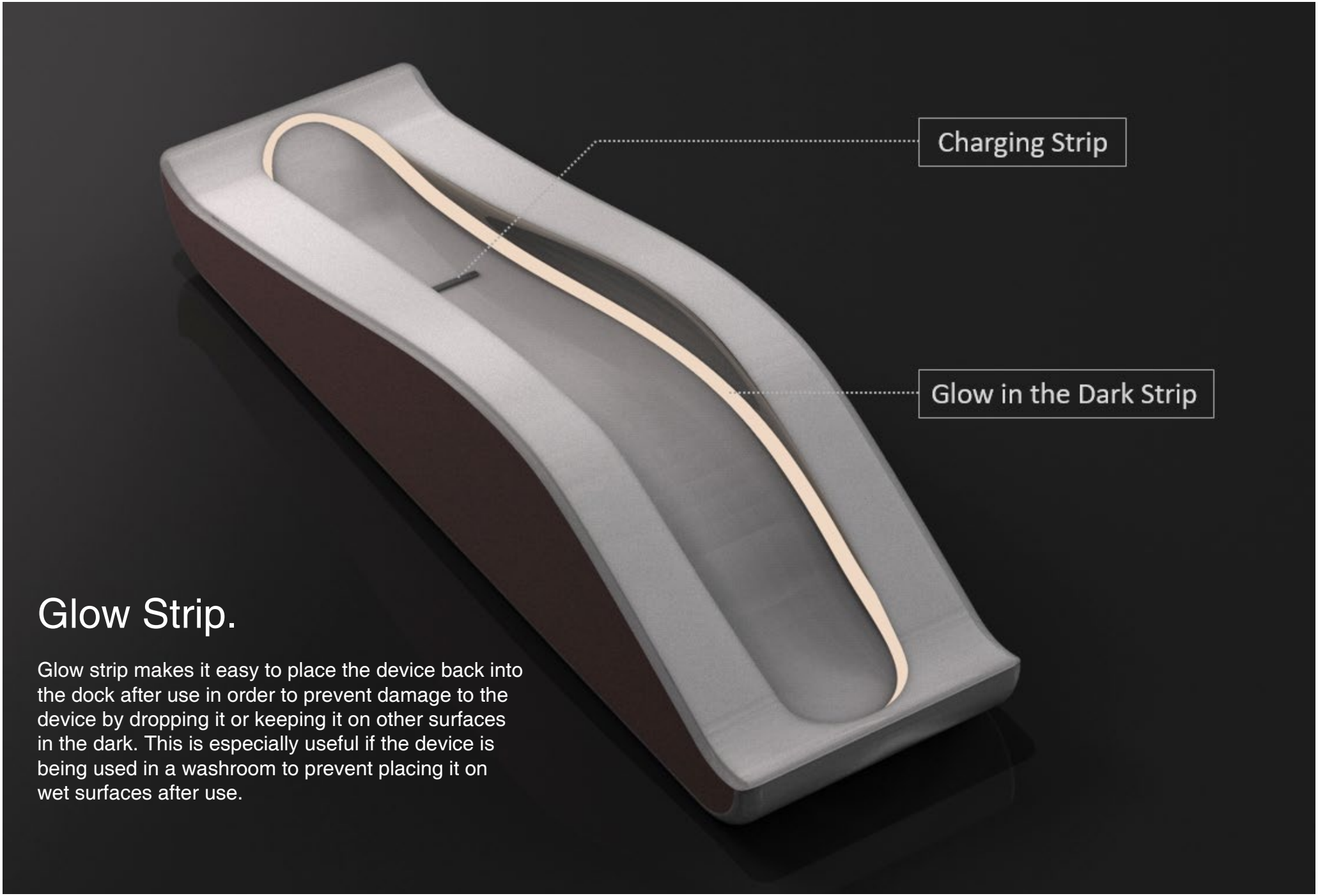
Storage for Charger

Charge and Store.

Considering the fact the device was not designed for everyday use, the packaging had to be something that can help store the device in good condition.

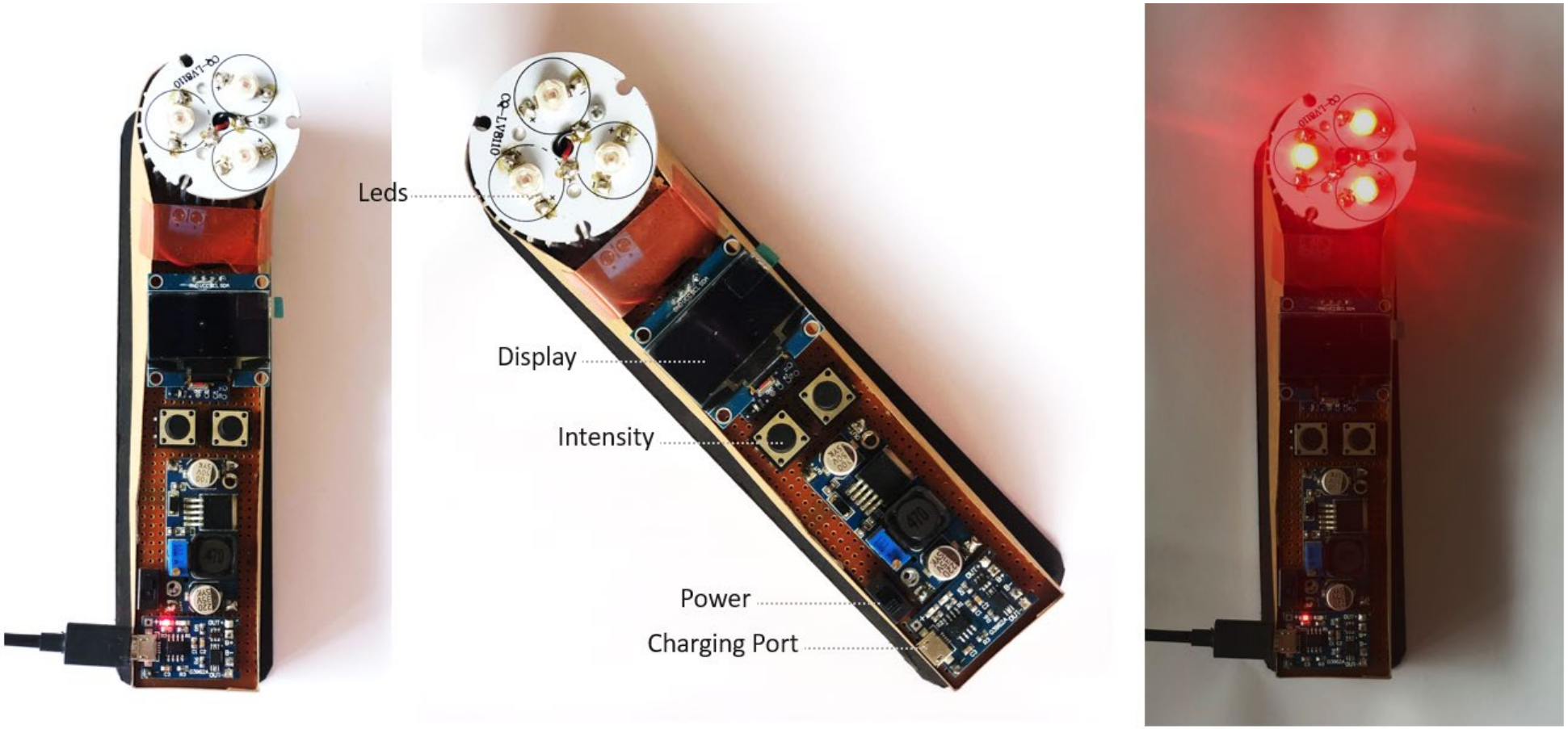
The packaging designed functions as a dock for charging the device as well as a storage case not just for the device but also the charging adapter and chord.


b-Care
Charger
Charging Cable
Connection to the
Charging Strip



Glow Strip.

Glow strip makes it easy to place the device back into the dock after use in order to prevent damage to the device by dropping it or keeping it on other surfaces in the dark. This is especially useful if the device is being used in a washroom to prevent placing it on wet surfaces after use.



WORKING PROTOTYPE

D.10a Instructions of Use

Breast Awareness

Most women look out for changes in their breasts – both by feeling for lumps and looking at them carefully.
It is recommend that women make an effort to know how their breasts look and feel normally. This is called “breast awareness”.

In addition to lumps there are other changes to the breasts that one should look out for as well. These include:

- A change in the size or shape of the breast
- A change in the skin – particularly dimpling or puckering
- A change in the appearance of the nipple or a discharge from the nipple.
- Breast pain that does not go away after a period
- Lumpy areas or thickening of the breast tissue

Getting Started

B-Care is a health and wellbeing product for women. It helps women notice any changes in their breasts over time.
B-Care shines a powerful light through the breast tissue so that one can see some of the details inside. That way one can get to know what's normal and spot any changes.

B-Care is a simple and easy to use product. Important things to remember are:

- Charge your B-Care before using it.
- Make the room as dark as possible.
- Hold B-Care under one of your breasts and look down.
- Keep your B-Care pressed tightly against your skin.
- Use a mirror so you can see more.
- Check all areas – including under the arms and high on the chest.

What you will see…

Veins and other blood vessels as dark lines in the breast. These are totally normal.

Around the nipple you may see a circle of small dots – these are part of your mammary glands. These are also totally normal.

Over a number of months you will learn what your breasts look like when lit by B-Care.
This internal view will become as familiar as the look and feel of your breasts on the outside.
As with all the aspects of breast awareness, the important thing is to look out for any changes.

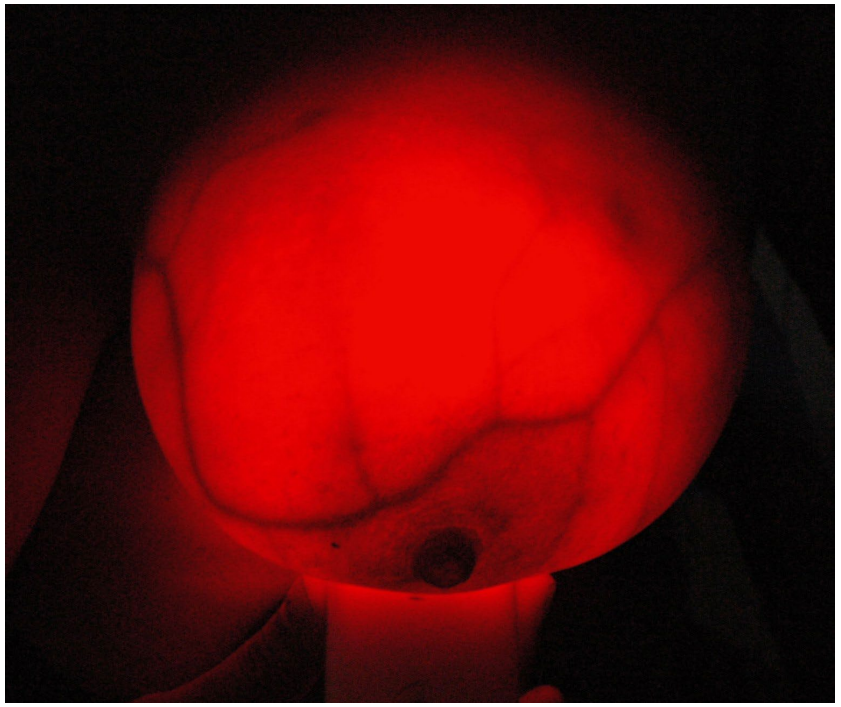


Fig. D.15 Using B-Care [15]

Using B-care

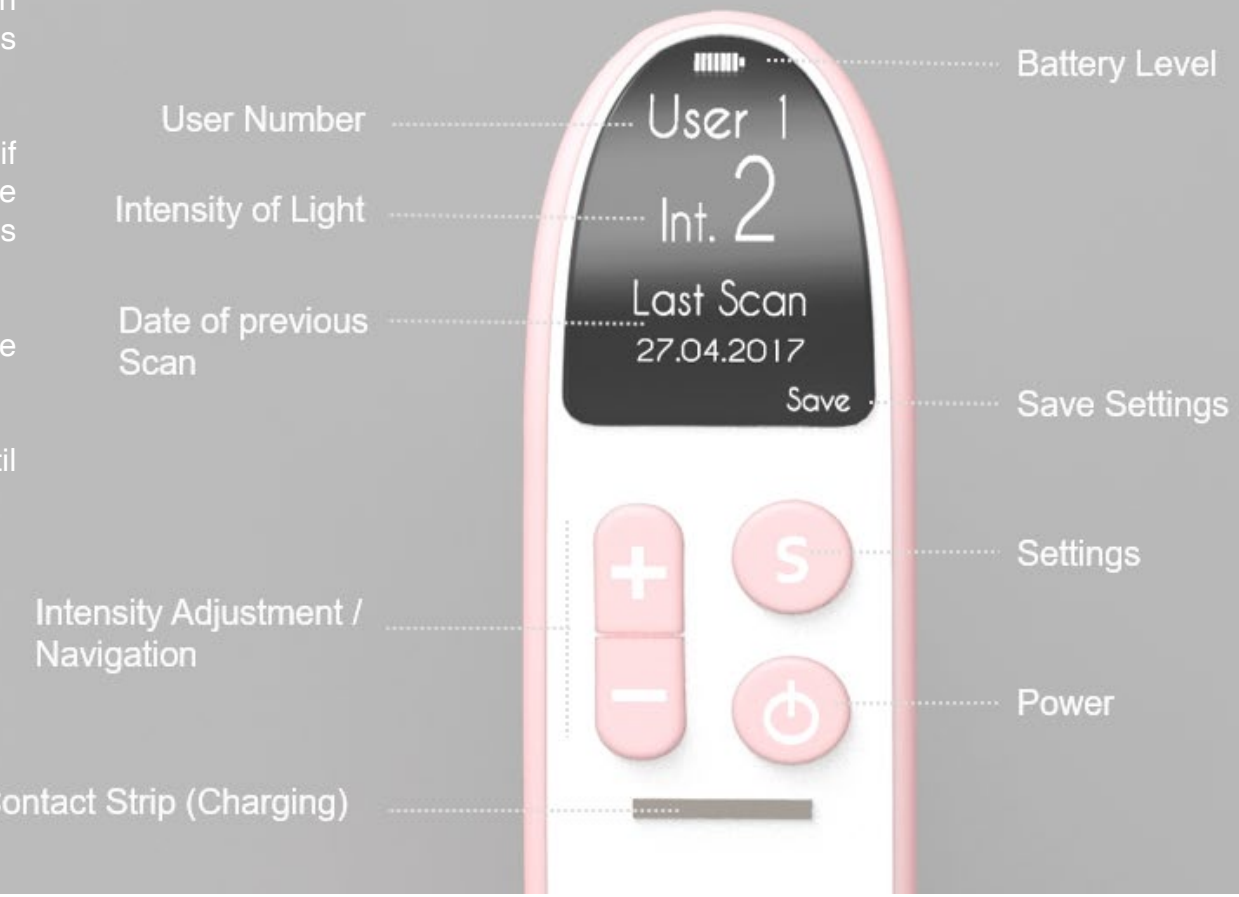
The brightness setting indicator shows you the level of brightness that you have selected. There are four settings to choose from.

The battery charge symbol will show you how much battery life is left and will flash when the battery needs charging.

The Power symbol will turn red and blink thrice only if the product has overheated. In this unlikely event the unit will cut out, the symbol will flash until B-Care has cooled down sufficiently and is ready to use again.

The last scan indicator shows the date on which the previous scan was done.

After the device is used the settings can be saved until next use.



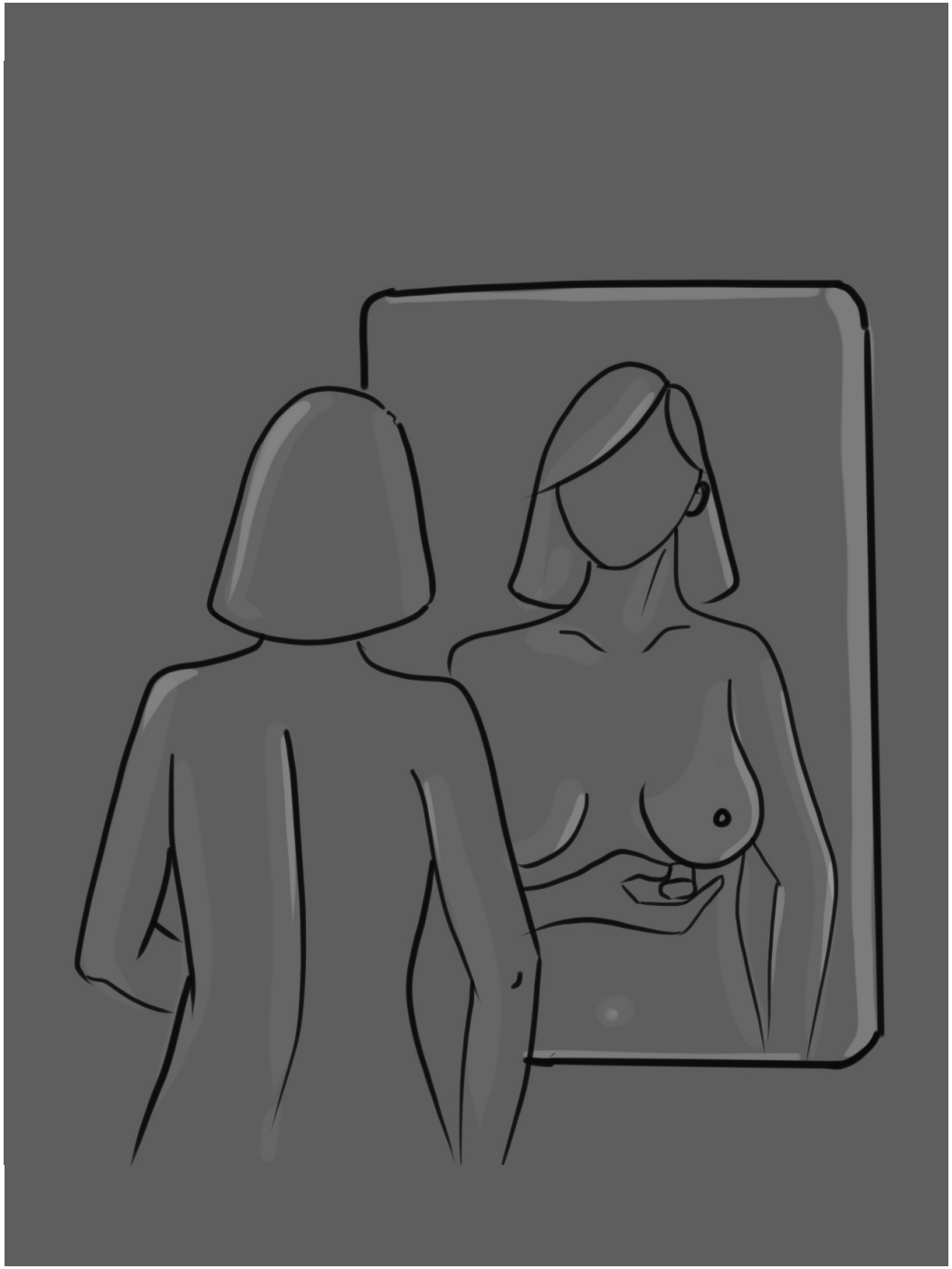
Using B-care

1.

Find a room in the house where you can turn off the lights and make it as dark as possible. The darker the room, the easier it is to use B-Care.

It is good to be able to see yourself in a mirror as you use the product – so make sure there is one in the room that you can see.

Make yourself comfortable – sitting or standing are both fine.

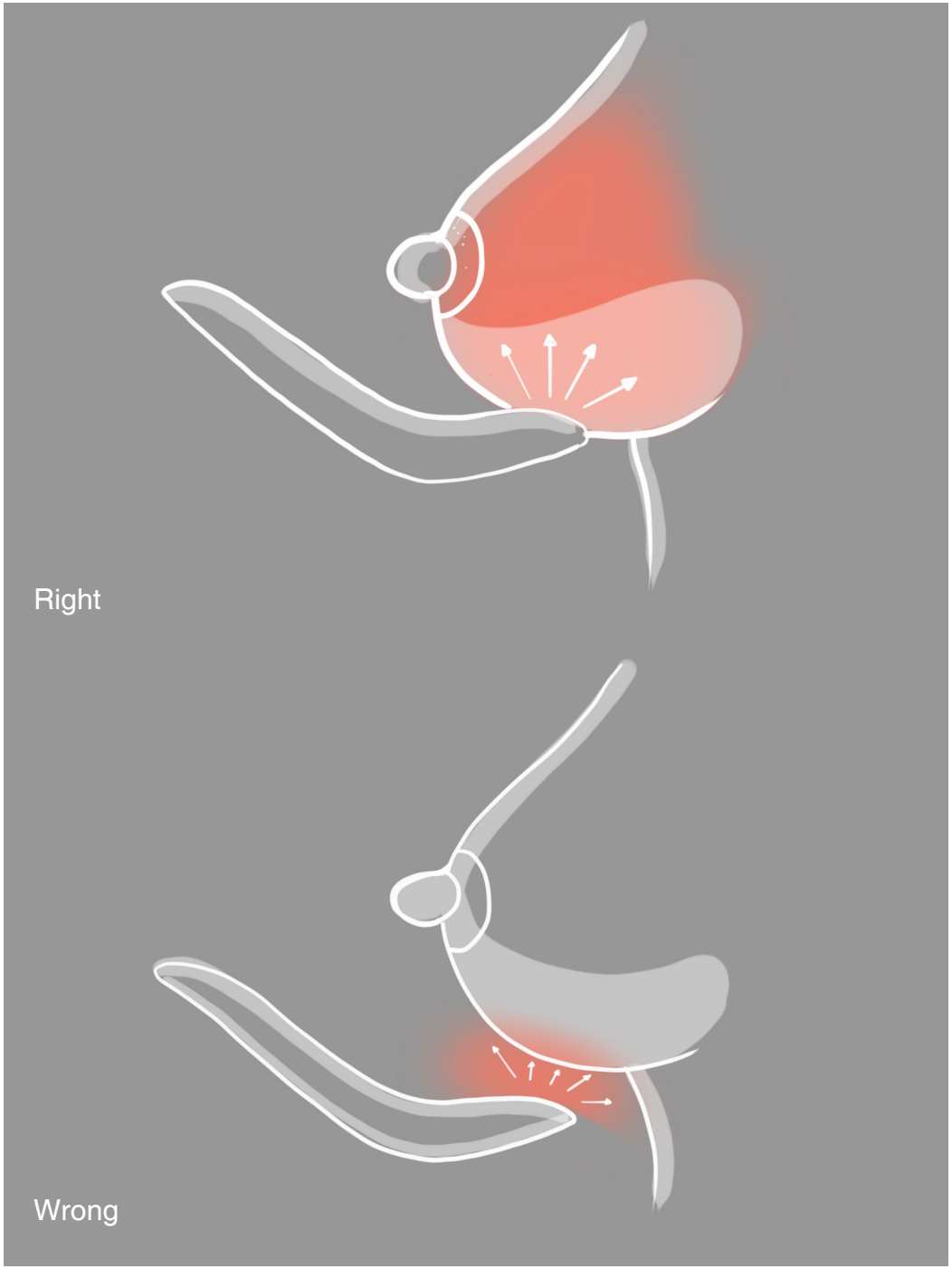


2.

Turn off the lights and wait for a couple of minutes to allow your eyes to get used to the dark.

Turn on your B-Care . The light will turn on only when it is in contact with your skin.

Hold B-Care underneath one of your breasts and push it firmly against the skin. If you have a good light seal there will be no significant escape of light from under the breast and the breast itself will suddenly appear brighter. The dark lines are veins and other blood vessels in silhouette.



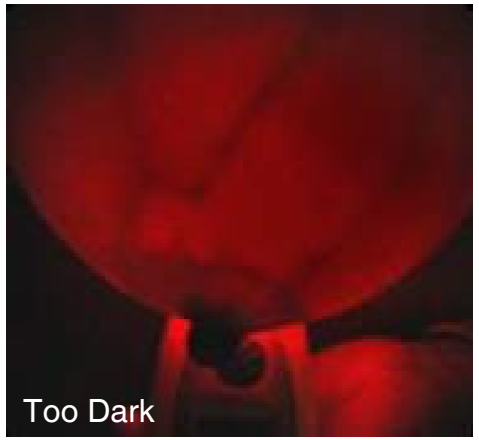


Fig. D.16 Using B-Care [15]

Fig. D.17 Using B-Care [15]

3.

There are four different brightness settings.

Generally larger or firmer breasts will require a higher brightness setting. Try all the brightness settings until you find the setting that is right for you.

If the light is too low then you will not be able to see the veins in your breast. If it is too high you won't be able to see the fine details.

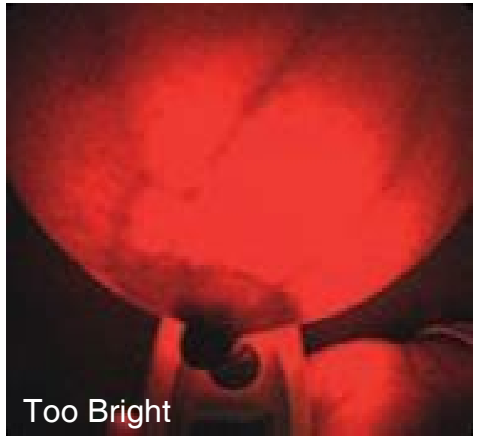


Fig. D.18 Using B-Care [15]

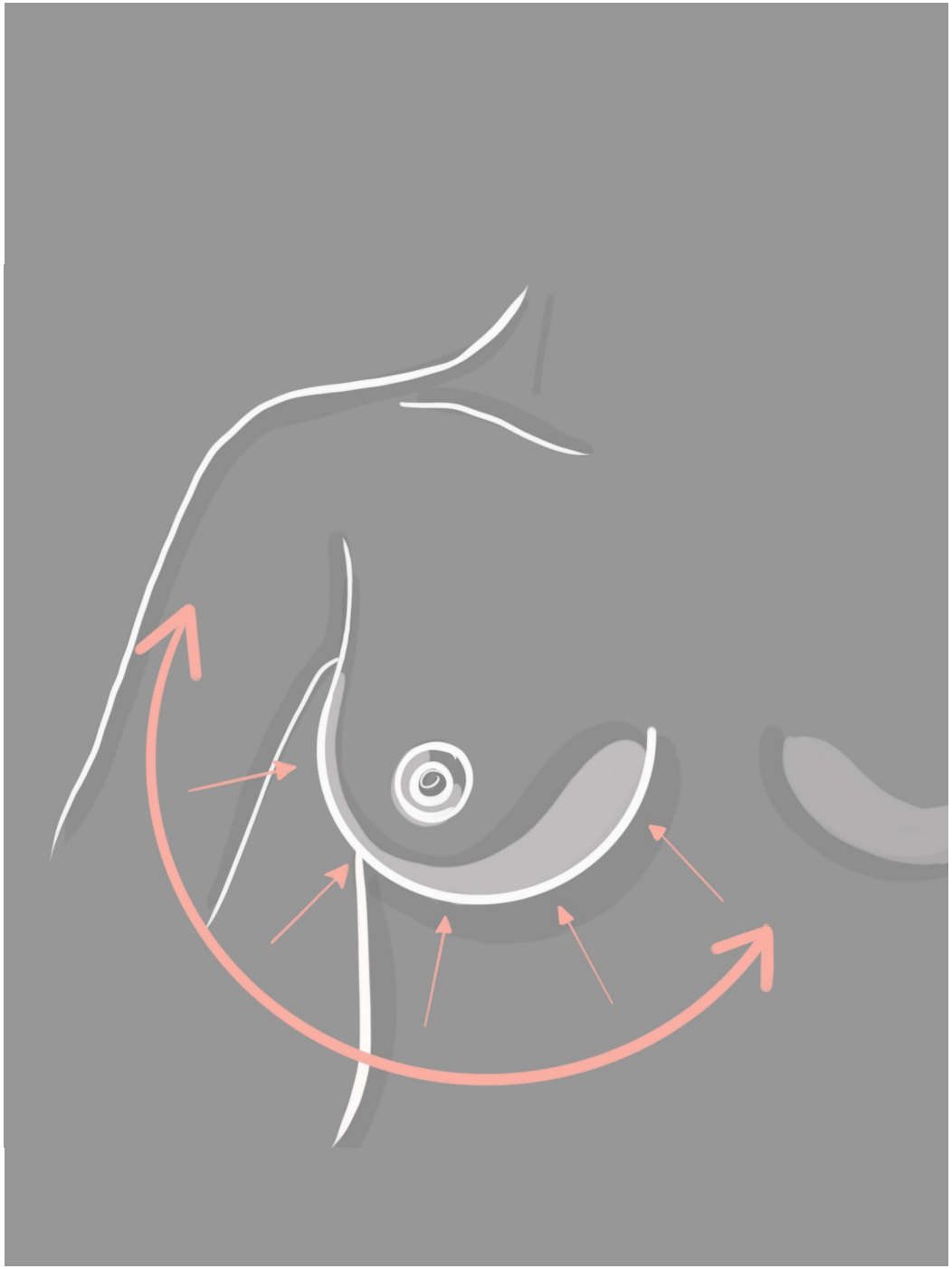
4.

Slowly move the device around and you will be able to see other parts of your breast. You should continue to do this until you have seen as much as you can. As you move around you may find it easier to switch hands as you change position.

The breast tissue goes right around under the arms and high up on the chest toward your shoulder – so be sure to look here as well.

By either looking down on your breast or at the reflection in the mirror you will get a good view of all these areas. Take time to check all areas of your breast, including the area just behind the nipple.

There is no set way to complete the examination. There is quite a variation in breast shapes and sizes and you know yourself best. Just make sure that you have a good look around.



What to look for ?

When you are looking at your breasts with B-Care you may see some dark spots or shadowy areas.
It is possible that these are abnormalities in the breast. If you see these you should go to your doctor for advice.
These pictures are some examples of what to look out for.

Fig. D.19 Using B-Care [15]

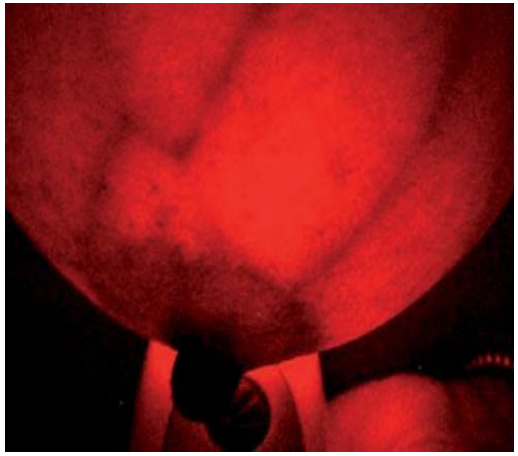


Fig. D.20 Using B-Care [15]

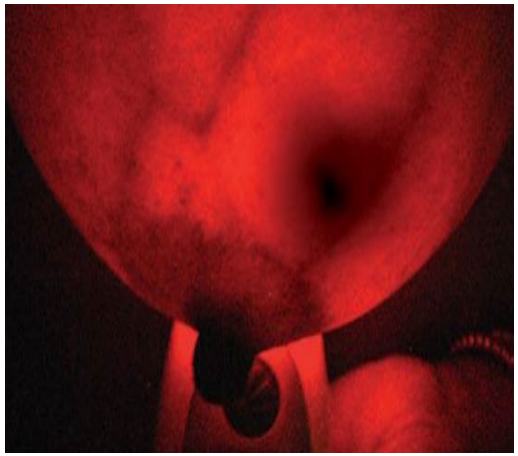


Fig. D.21 Using B-Care [15]

Fig. D.22 Using B-Care [15]

Note

B-Care is designed to aid breast awareness, however it is not capable of detecting all sizes, positions and types of breast abnormalities. It is not intended for use as a diagnostic device.

B-Care should be used as an additional part of a normal breast awareness routine. It is not a replacement. Women who are invited for a routine breast screening are strongly advised to attend. B-Care is not a substitute for mammogram screening.

It may highlight a potential abnormality that subsequently turns out to be normal or requires minimal medical intervention. For example blood filled cysts and haemotomas will appear as dark areas. However it is recommend that any suspicious signs are investigated by a doctor.

B-Care is not suitable for use when breast feeding. B-Care can be used by women with implants.

E | Conclusion

Final Form Model

With over 2 million new cases in 2018 alone, Breast cancer is one of the most common forms of cancer. The most viable solution to combat this, is to aggressively spread awareness and promote screening. Using portable screening devices is arguably the best way to detect early stage cancerous tumors and expedite treatment.

This study has identified that devices using the technology of “Trans-illumination” are cheaper to manufacture, easy to use and provides a fairly accurate detection of breast abnormalities at an early stage. However, these are not readily available in the Indian market.

This design proposal, uses the technology of trans-illumination but is designed to be cost effective and have an easy learning curve, hence enabling use by a larger demographic. Making the device accessible, only promotes awareness and can significantly aid in detection of breast abnormalities that may or may not be cancer.

Learnings

Project 3 has been a tremendous learning experience as it was my first time working on medical devices.

I was able to experiment and visualize the various aspects of product design - research, ideation, prototyping, and manufacturing.

The project has also been a good opportunity to understand empathic design and the importance of paying attention to user needs.

It has also enlightened me on how important regular screenings and body awareness are for women my age.

References

Sr. No	Link	Accessed on
3	Breast Cancer facts and Figures 2015-2016 https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/breast-cancer-facts-and-figures/breast-cancer-facts-and-figures-2015-2016.pdf	8.02.2019 , 10.50PM
4	Cancer Research UK http://www.cancerresearchuk.org/about-cancer/what-is-cancer	11.02.2019 , 11.34PM
5	Breast Anatomy http://www.webmd.com/women/picture-of-the-breasts#1	12.02.2019, 4.11PM
6	Breast Cancer trends in India http://www.breastcancerindia.net/statistics/trends.html	12.02.2019, 6:15PM
7	https://www.womenfitness.org/breast-cancer-rising-india/	12.02.2019, 6:30PM
8	https://www.cancer.org/cancer/breast-cancer/screening-tests-and-early-detection/mammograms/mammograbasics.html	15.02.2019, 11:50 AM
9	https://www.ncbi.nlm.nih.gov/books/NBK22310/	14.02.2019, 1:30 AM
10	https://www.spiedigitallibrary.org/conference-proceedings-of-spie on	1/29/2019, 10.30 AM
11	https://www.forbes.com/sites/suparnagoswami/2016/12/12/this-handheld-breast-scan-is-revolutionizing-how-indians-detect-cancer/#6e7365593b34	16.08.2018, 3.45 PM

Sr. No	Link	Accessed on
12	https://www.medgadget.com/2013/03/testing-breast-cancer-interview-with-atossa-genetics-ceo-steven-quay-md-phd.html	16.08.2018, 4.30 PM
13	https://www.braster.eu/en/technology	16.08.2018, 4.45 PM
14	https://www.indiegogo.com/projects/meik-global-breast-cancer-awareness-campaign#/	16.08.2018, 5.10 PM
15	https://www.breastlight.com/	18.08.2018, 6.30 PM
16	https://pubs.rsna.org/doi/pdf/10.1148/radiographics.4.6.989	18.08.2018, 7.15 PM
17	https://www.csail.mit.edu/news/using-ai-predict-breast-cancer-and-personalize-care	21.08.2018, 3.30 PM

Bibliography

Sr. No	Title	Author	Edition
1	Taber's Cyclopedic Medical Dictionary		Edition 21st
2	Gray's Anatomy	Elsevier, Churchill and Livingstone	Edition 39th 6