

## INDUSTRIAL DESIGN PROJECT-2

# BREAST CANCER EARLY DETECTION DEVICE

Project guide Prof. Purba Joshi

Submitted by-Mugdha Dengle 216130012

# **Approval sheet**

This is to certify that the industrial design project entitled "Device for early detection of Breast Cancer" by Mugdha Dengle is approved for partial fulfillment for the Master of Design degree in Industrial Design.

Approval

Signature of the Project Guide:

Signature of the Chair Person:

Signature of the Internal Examiner:

# **Acknowledgment**

I would like to take this opportunity to sincerely express my deepest gratitude to the people who have wholeheartedly supported and helped me achieve success in this project.

firstly i would like to thank my guide Prof. Purba Joshi for her constant feedbacks, invaluable advice and motivation. Her guidance and time-to-time inputs gave me a larger perspective to look at.

Also, I like to convey great respect and gratitude to Prof. Avinash Shende, Prof. BK. Chakravarthy, and Prof. Sandesh for such invaluable insights and ideas. Deepest gratitude to the medical staff and the patients of the hospitals and clinics that I visited during the tenure of this project.

I would like to give special thanks to my friends Susovan, Snehdeep, Shivangi, Abhishek, Kunal and my colleagues for supporting me throughout this project journey. Furthermore, I would like to extend my deepest heartfelt gratitude and love to my family for supporting me through this creative process and help me undertake various academic endeavors that have led me to the place I am today.

# **Declaration**

This written submission is a part of my report, "Designing a Device for early detection of Breast Cancer is done as a part of Project - 2 for post-graduation program at IDC, IIT Bombay, under the guidance of Prof. Purba Joshi.

I hereby declare that the thoughts, ideas, and words in this document are original, and appropriate references have been adequately cited wherever due. I also declare that I have adhered to all principles of academic honesty and integrity and have not misrepresented 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.

Mugdha Dengle 216130012 (2021-2023) M.Des, Industrial Design IDC School of Design

## **Abstract**

This project's main goal is to create a portable detector that can be used to evaluate breast anomalies in women 35 years of age and older in order to help with early breast cancer detection. Breast cancer was once thought to be a condition that only affected women over the age of 50. The incidence of cases of breast cancer in younger age groups has, however, increased significantly during the past ten years (30-40 years).

Studies on the current technologies employed for the initial scanning of breast tissue for cancer diagnosis were done as part of the procedure. The gold standard for diagnosing breast cancer is mammography, which is followed by additional confirmation tests for the patient. However all the tests are to be done in a hospital. This can only be apparent during regular health checkups or self testing.

Additionally, the majority of malignancies tend to go undetected until an advanced stage, after which the patient survival probability is poor, making early detection essential for survival. Therefore, there is a need for education on the importance of regularly checking breast tissue for abnormalities.

The goal of this project was to create a device that can be used by women in the comfort of their homes as a part of the self-examination process and is beneficial for the target user group. Without anyone's assistance, users would be able to understand this unaided. Women could use this equipment to not only check for anomalies but also to become more cognizant of these irregularities in their bodies.

## **Table of Contents**

#### **INITIAL BRIEF**

#### INTRODUCTION

Structure of cell

What are cancer cells?

**About Breast Cancer** 

Structure of Breast Tissues

Anatomy of Breast

#### INDIAN STATISTICS

Epidemiology of breast cancer

- i. In Indian women
- ii. In Indian men
- iii. Inferences

#### **DETECTION TESTS**

**Breast Cancer** 

**Detection Tests** 

- i. Breast self-examination
- ii. Mammography
- iii. 3D Mammography
- iv. Breast Ultrasound
- v. Magnetic Resonance Imaging (MRI)
- vi. Confirmation Test

#### **DETECTION TESTS**

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#### MARKET RESEARCH

Current technologies

- i. Piezoelectric Fingers iBreastexam
- ii. GE VSCAN portable ultrasound
- iii. Breast-i
- iv. Breastlight
- v. Eclipse
- vi. Sure touch

#### **TECHNOLOGY STUDY**

Portable Ultrasound

Microwave imaging

Trans-illumination

#### **Infrared Imaging**

#### PRIMARY RESEARCH

Informal Interviews
Google survey
Documents study

#### **DESIGN**

Design Brief

Process of Use

Mindmap for accessories

Ergonomic study

Ideation based on modes of using

Comparative Evaluation

Final Design Objective

Anthropometric dimensions

Ergonomic gripping study

Moodboard

Ideations based on Form

Mockups

Power button interface

Final Concept

Concept mockup
Testing mockup

CMF

Final product render

Exploded view

Technical Specs

Manufacturing

Technical drawing

Final product in

making

User Interaction

User environment

Branding & Packaging

#### **REFERENCES**

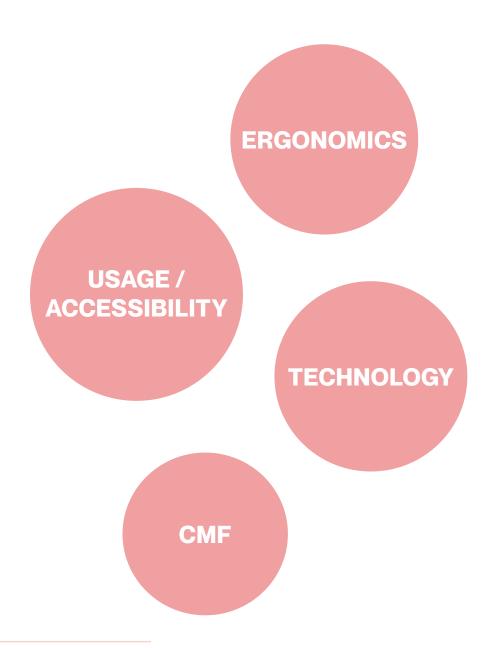
# **Initial Brief**

Design a portable screening solution for the earlier detection of breast cancer. The design should be simple and easy to operate as well as economically viable for all stakeholders.

The design solution in end can be essentially used by individual women, who don't have medical knowledge at their own personal space.

This design has to empower women to enable them to monitor their health on time and make it a part of their regular checkup cycle.

This was initial idea when the topic was selected



# INTRODUCTION

# Structure of cell

#### Healthy cell

"A cell is defined as the smallest, basic unit of life that is responsible for all of life's processes."

Cell is the basic membrane-bound unit that contains the fundamental molecules of life and of which all living things are composed. It is the structural and fundamental unit of life. Robert Hooke was the first Biologist who discovered cells.

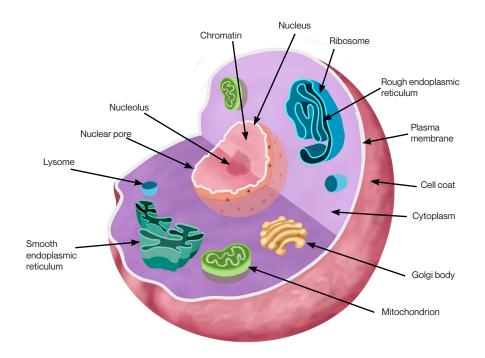
All organisms are made up of cells. They may be made up of a single cell (unicellular), or many cells (multicellular). Cytoplasm are the smallest known cells. Cells are the building blocks of all living beings. They provide structure to the body and convert the nutrients taken from the food into energy.

Cells are complex and their components perform various functions in an organism. They are of different shapes and sizes, pretty much like bricks of the buildings. Our body is made up of cells of different shapes and sizes.

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.

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.



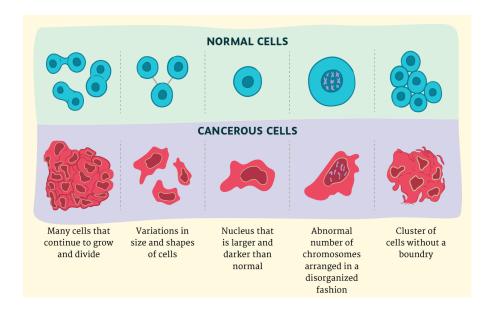
# What are cancer cells?

Cancer is a disease caused when cells divide uncontrollably and spread into surrounding tissues.

Four main types of cancer are:

- Carcinomas- A carcinoma begins in the skin or the tissue that covers the surface of internal organs and glands. Carcinomas usually form solid tumors. They are the most common type of cancer. Examples of carcinomas include prostate cancer, breast cancer, lung cancer, and colorectal cancer.
- Sarcomas- A sarcoma begins in the tissues that support and connect the body. A sarcoma can develop in fat, muscles, nerves, tendons, joints, blood vessels, lymph vessels, cartilage, or bone.
- Leukemias- Leukemia is a cancer of the blood. Leukemia begins when healthy blood cells change and grow uncontrollably.
  The 4 main types of leukemia are acute lymphocytic leukemia, chronic lymphocytic leukemia, acute myeloid leukemia, and chronic myeloid leukemia.

Lymphomas- Lymphoma is a cancer that begins in the lymphatic system. The lymphatic system is a network of vessels and glands that help fight infection. There are 2 main types of lymphomas: Hodgkin lymphoma and non-Hodgkin lymphoma.



#### What is breast cancer?

The breast is an organ that sits on top of the upper ribs and chest muscles. There is a left and right breast and each one has mainly glands, ducts, and fatty tissue.

The breast has different parts:

Lobules are the glands that make breast milk. Cancers that start here are called lobular cancers.

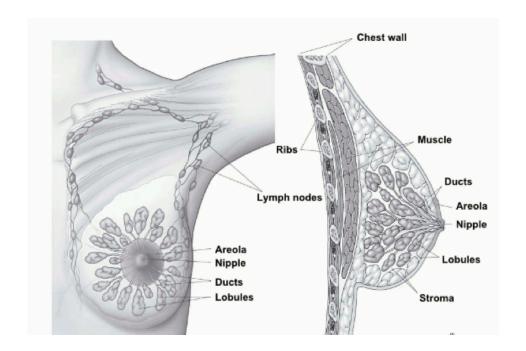
Ducts are small canals that come out from the lobules and carry the milk to the nipple. This is the most common place for breast cancer to start. Cancers that start here are called ductal cancers.

The nipple is the opening in the skin of the breast where the ducts come together and turn into larger ducts so the milk can leave the breast. The nipple is surrounded by slightly darker thicker skin called the areola. A less common type of breast cancer called Paget disease of the breast can start in the nipple.

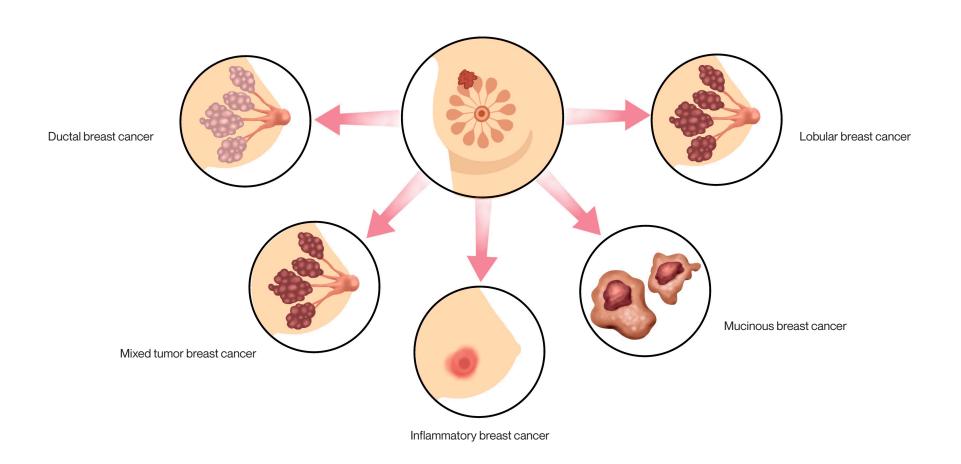
The fat and connective tissue (stroma) surround the ducts and lobules and help keep them in place. A less common type of breast cancer called phyllodes tumor can start in the stroma.

Blood vessels and lymph vessels are also found in each breast.

Angiosarcoma is a less common type of breast cancer that can start in the lining of these vessels. The lymph system is described below.



## Types of breast cancer



#### Extent and spread of breast cancer

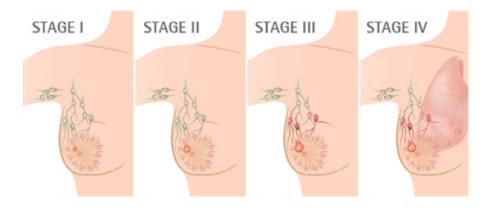
Breast cancer can spread when the cancer cells get into the blood or lymph system and then are carried to other parts of the body. Cancer can spread through tissue, the lymph system, and the blood.

The lymph (or lymphatic) system is a part of your body's immune system. It is a network of lymph nodes, ducts /vessels, and organs that work together to collect and carry clear lymph fluid through the body tissues to the blood. The clear lymph fluid inside the lymph vessels contains tissue by-products and waste material, as well as immune system cells.

In the case of breast cancer, cells can enter those lymph vessels and start to grow in lymph nodes. Most of the lymph vessels of the breast drain into:

Auxillary (under arm) lymph nodes

Internal mammary (near breast bone inside chest) lymph nodes Around collar bone lymph nodes

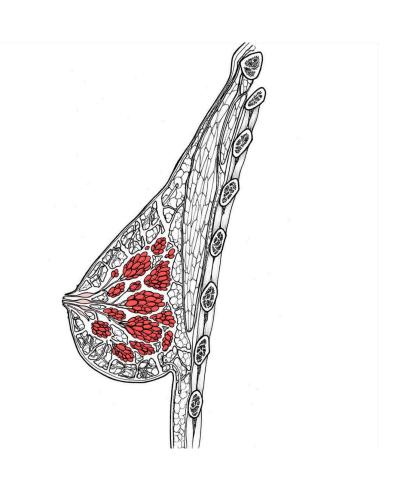


Active Cancer Cells Double in Number Every 90 Days			
90 days 1 year 2 years 3 years 4 years 5 years 6 years	16,777,216 cells	ndetectable)	
7 years 268,435,456 cells 8 years 4,294,967,296 cells (doubled 32 times) *  *Normally detectable by Mammogram at this stage 40 Doublings (Aprox 10 Years) considered lethal.			

#### Causes of breast cancer

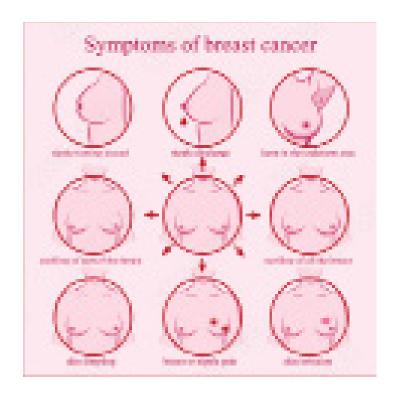
It is not known what causes breast cancer, but risk factors are linked to the disease include:

- Family history
- Certain inherited genes
- · History of malignant or benign (non-cancerous) breast disease
- · Early onset of menstruation
- Late menopause
- Physical inactivity
- Having fewer children or no children
- · Being on hormone replacement therapy
- Drinking too much alcohol
- · Being overweight or obese
- Dense breast tissue
- Radiation to breast



### Symptoms of breast cancer

- Swelling or thickening of the breast
- Dimpling of the breast skin
- Nipple crust
- Redness or heat of breast skin.
- · New nipple discharge that is not breast milk, including blood
- Skin sores
- Bumps
- · Growing veins on the breast.
- Sunken nipple
- · Changes in the size or shape of the breast
- "Orange peel" skin
- Hard lump in the breast
- Skin changes on the breast: scaliness or flaky skin
- Pain in any area of the breast
- Nipple pain
- Lump in the underarm area (armpit)

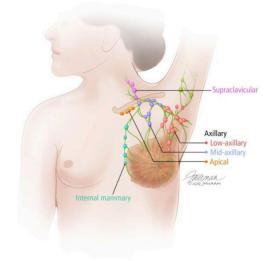


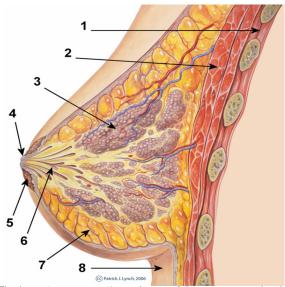
# Structure of Breast Tissues

The blood supply from the breast comes primarily from the internal mammary artery, which runs underneath the main breast tissue. The blood supply provides nutrients, such as oxygen, to the breast tissue. The lymphatic vessels of the breast flow in the opposite direction of the blood supply and drain into lymph nodes. It is through these lymphatic vessels that breast cancers metastasize or spread to lymph nodes. Most lymphatic vessels flow to the axillary (underarm) lymph nodes, while a smaller number of lymphatic vessels flow to internal mammary lymph nodes located deep to the breast. Knowledge of this lymphatic drainage is important, because when a breast cancer metastasizes, it usually involves the first lymph node in the chain of lymph nodes. This is called the "sentinel lymph node," and a surgeon may remove this lymph node to check for

metastases in a patient with breast cancer.

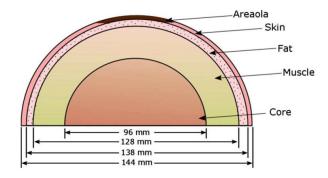
Many additional changes are seen in the breast tissue during pregnancy and lactation due to the changes in hormones during those times.





The breast: cross-section scheme of the mammary gland.

- Chest wall
- 2. Pectoralis muscles
- 3. Lobules
- 4. Nipple
- 5. Areola
- 6. Milk duct
- 7. Fatty tissue
- 8. Skin

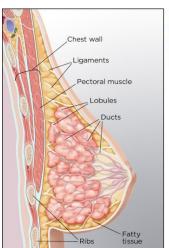


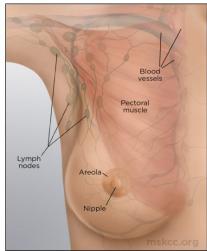
# **Anatomy of Breast**

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.

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.





In women, the breasts overlie the pectoralis major muscles and extend on average from the level of the second rib to the level of the sixth rib in the front of the rib cage; thus, the breasts cover much of the chest area and the chest walls. At the front of the chest, the breast tissue can extend from the clavicle (collarbone) to the middle of the sternum (breastbone). At the sides of the chest, the breast tissue can extend into the axilla (armpit), and can reach as far to the back as the latissimus dorsi muscle, extending from the lower back to the humerus bone (the bone of the upper arm). As a mammary gland, the breast is composed of differing layers of tissue, predominantly two types: adipose tissue; and glandular tissue, which affects the lactation functions of the breasts.

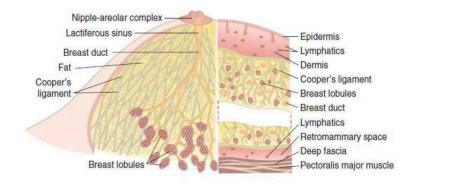
Morphologically the breast is tear-shaped. The superficial tissue layer (superficial fascia) is separated from the skin by 0.5–2.5 cm of subcutaneous fat (adipose tissue). The suspensory Cooper's ligaments are fibrous-tissue prolongations that radiate from the superficial fascia to the skin envelope. The female adult breast contains 14–18 irregular lactiferous lobes that converge at the nipple. The 2.0–4.5 mm milk ducts are immediately surrounded with dense connective tissue that support the glands. Milk exits the breast through the nipple, which is surrounded by a pigmented area of skin called the areola. The size of the areola can vary widely among women. The areola contains modified sweat glands known as Montgomery's glands. These glands secrete oily fluid that lubricate and protect the nipple during breastfeeding. Volatile

# Anatomy of Breast

compounds in these secretions may also serve as an olfactory stimulus for the newborn's appetite.

The dimensions and weight of the breast vary widely among women. A small-to-medium-sized breast weighs 500 grams (1.1 pounds) or less, and a large breast can weigh approximately 750 to 1,000 grams (1.7 to 2.2 pounds) or more. The tissue composition ratios of the breast also vary among women. Some women's breasts have a higher proportion of glandular tissue than of adipose or connective tissues. The fat-to- connective-tissue ratio determines the density or firmness of the breast. During a woman's life, her breasts change size, shape, and weight due to hormonal changes during puberty, the menstrual cycle, pregnancy, breastfeeding, and menopause.

#### Situation and extend

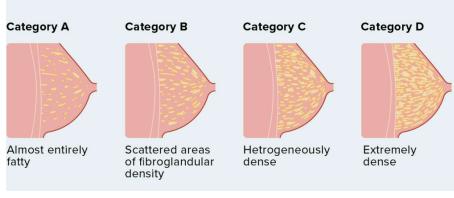


# Structure of Breast Tissues

#### Different categories of breast density

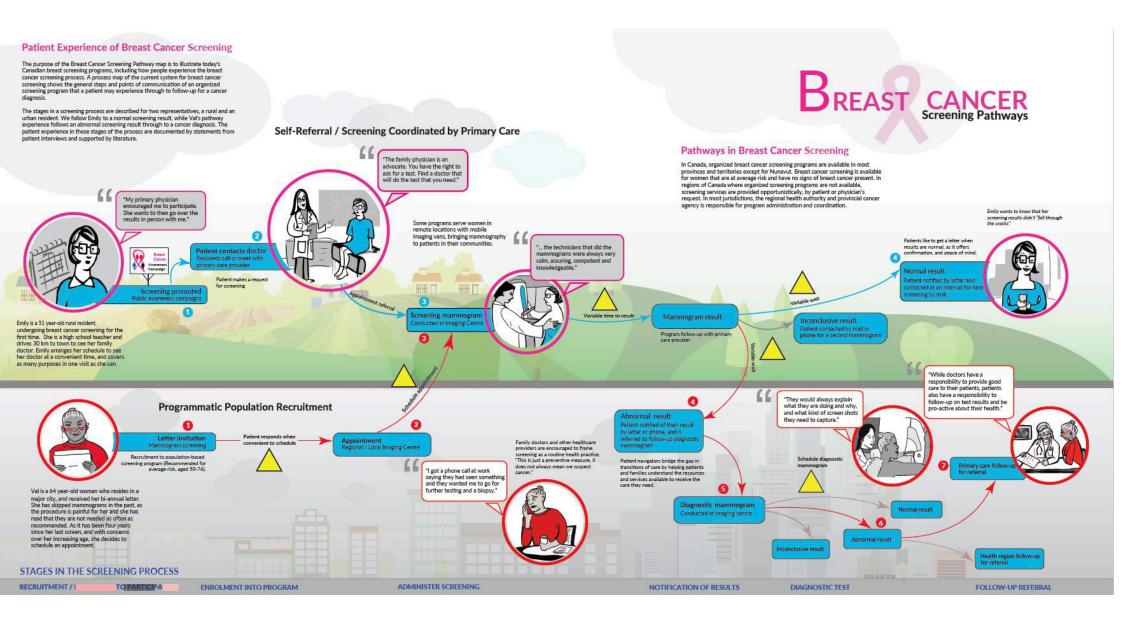
Radiologists use something called the Breast Imaging Reporting and Data System (BI-RADS) to categorize breast tissue density. This system was developed by the American College of Radiology. BI-RADS groups breast density into four different categories. In order of least to most dense, these breast tissue categories are:

- Fatty breast tissue. Fatty breast tissue is when your breasts are composed almost entirely of non-dense fatty tissue. About 10 percent of women have fatty breast tissue.
- Scattered fibroglandular breast tissue. This category includes breasts that have scattered areas of dense tissue, but have a higher ratio of non-dense fat. About 40 percent of women have scattered fibroglandular breast tissue.
- Heterogeneously dense breast tissue. For this category, the breast includes some non dense fat, but much of the tissue in the breast is fibro glandular. About 40 percent of women have heterogeneously dense breast tissue.
- Extremely dense breast tissue. When most of the tissue in your breast is dense, the density is considered "extreme." About 10 percent of women have extremely dense breast tissue.



4 Categories of breast densities.

Fatty breast tissue	Scattered fibroglandular breast tissue	Heterogeneously or extremely dense breast tissue
<b>Ages 65 to 74:</b> 11.3 per 1,000 women	<b>Ages 65 to 74:</b> 17.2 per 1,000 women	<b>Ages 65 to 74:</b> 23.7 per 1,000 women
Ages 75 and older: 13.5 per 1,000 women	Ages 75 and older: 18.4 per 1,000 women	Ages 75 and older: 22.5 per 1,000 women



# INDIAN STATICS

#### In Indian women

Breast cancer occurs more frequently in the left breast than the right. The left breast is 5%-10% more likely to develop cancer than the right breast.

New figures spell a startling future – it's time we took preventive measures

There's no escaping the fine print – Breast cancer is the most common form of cancer in the country, having overtaken cervical cancer. In cities like Mumbai, Delhi, Bengaluru, Bhopal, Kolkata, Chennai, Ahmedabad, breast cancer accounts for 25% to 32% of all female cancers, more than 1/4th of all female cancers.

It's also more common in the younger age group. Almost 50% of all cases are in the age group of 25-50. And more than 70% of the cases present in the advanced stage had poor survival and high mortality.

The numbers are staggering and constantly rising. The Indian Council for Medical Research recently published a report which stated that in 2016 the total number of new cancer cases is expected to be about 14.5 lakhs. This figure will likely increase to 17.3 lakhs in 2020.

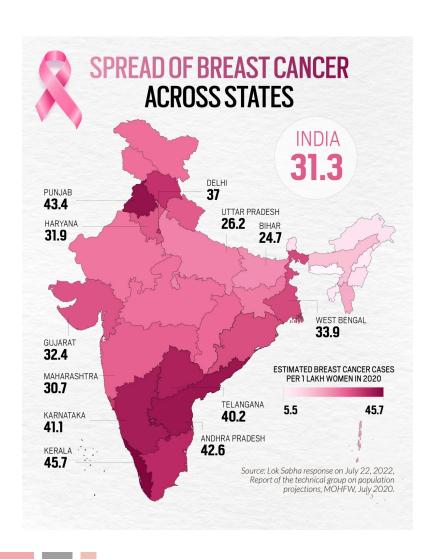
The survival rates of breast cancer in India are low because the detection takes place late. The only way to change these numbers is by increasing awareness. Breast cancer is a treatable disease and chances of survival are higher if it's detected in time. The only way to do so is by being aware of how it can be detected and early diagnosis can be done.

With being the most common type of cancer in women, breast cancer accounts for 14% of cancers in Indian women. It is reported that with every four minutes, an Indian woman is diagnosed with breast cancer. Breast cancer is on the rise, both in rural and urban India. A 2018 report of Breast Cancer statistics recorded 1,62,468 new registered cases and 87,090 reported deaths.

Cancer survival becomes more difficult in higher stages of its growth, and more than 50% of Indian women suffer from stage 3 and 4 of breast cancer. Post cancer survival for women with breast cancer was reported 60% for Indian women, as compared to 80% in the U.S.

India's highest cancer rate is listed in the state of Kerala. Other states with high cancer rates in India include Mizoram, Haryana, Delhi & Karnataka. Mizoram accounted for the highest cancer death rates in the

country, followed by Kerala and Haryana.



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.

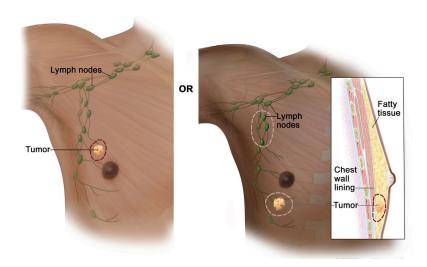


#### In Indian men

Breast cancer may occur in men at any age, but it usually occurs in men between 60 and 70 years of age. Male breast cancer makes up less than 1% of all cases of breast cancer.

Survival for men with breast cancer is similar to that for women with breast cancer when their stage at diagnosis is the same. Breast cancer in men, however, is often diagnosed at a later stage.

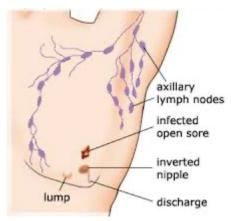
The most common type of breast cancer in men is infiltrating ductal cancer. It in both men and women are assessed in the same way to determine the prognosis.



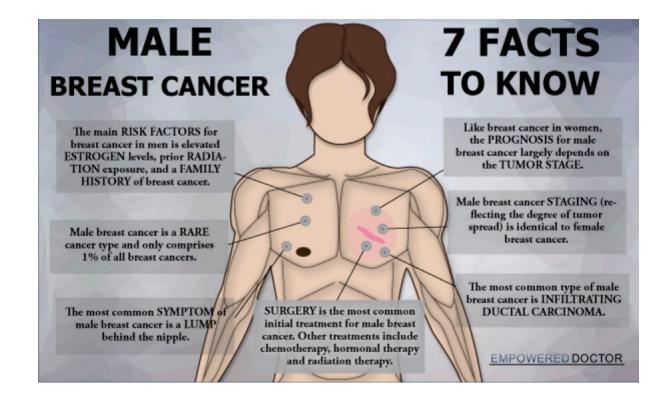
Survival for men with breast cancer is similar to that for women with breast cancer when their stage at diagnosis is the same. Breast cancer in men, however, is often diagnosed at a later stage. Cancer found at a later stage may be less likely to be cured.

#### **Key Points**

- Male breast cancer is a disease in which malignant (cancer) cells form in the tissues of the breast.
- A family history of breast cancer and other factors can increase a man's risk of breast cancer.
- Male breast cancer is sometimes caused by inherited gene mutations (changes).
- Men with breast cancer usually have lumps that can be felt.
- Tests that examine the breasts are used to diagnose breast cancer in men.
- If cancer is found, tests are done to study the cancer cells.
- Survival for men with breast cancer is similar to survival for women with breast cancer.
- Certain factors affect prognosis (chance of recovery) and treatment options.



Symptoms of male breast cancer



#### Inferences

Most 'symptomatic' cancers are stage 2B and beyond (significant numbers in stages 3 and 4).

In India there is no promotion of screening and awareness and proper treatment. Those who know about this are embarrassed to go to doctors for manual checkups. Regular checkups are important to know cancer in stage 1 itself, so that death mortality rate of Indian women is reduced.

Substantial support for breast cancer awareness and research funding has helped create advances in the diagnosis and treatment of breast cancer. Breast cancer survival rates have increased, and the number of deaths associated with this disease is steadily declining, largely due to factors such as earlier detection, a new personalized approach to treatment and a better understanding of the disease.

#### Lack of awareness of breast cancer, lack of screening

Most people don't think much about breast cancer until someone close to them acquires it. Healthcare is low on priority and even in major cities, screening is also an 'alien' word for most people. Because of this, most patients only seek medical attention when they are experiencing symptoms, and most malignancies that are considered to be "symptomatic" are stage 2B or later (significant numbers in stages 3 and 4). As a result, patients with breast cancer tend not to live as long as their counterparts in the west.

The majority of breast cancers in the West (about more than 75%) present in stages 1 and 2, leading to reasonable survival; nevertheless, more and more people are showing up with cancer that has been diagnosed by mammography but has no symptoms. India must attain this goal, and the only way to do so is by promoting vigorous screening, education, and treatment. It will take at least a few decades to achieve similarly successful results in other countries.

#### Aggressive cancers in the young

Cancers tend to be more aggressive in young people (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. The likelihood of extended survival decreases quickly with rising stage of malignant tumors, which is all the more incentive to detect these cancers early.

#### Traveling to healthcare

Breast cancer diagnosis and treatment could involve repeated visits of patients to fully equipped medical centers. It has been shown that living in rural areas can affect the access to breast cancer diagnostic tools, potentially resulting in delays in cancer diagnosis. Additionally, being far from primary health centers and hospitals, prevents the availability of treatment, surgery, or appropriate interventions, decreasing the possibility of positive outcomes and patient.

# DETECTION TESTS

# Breast Cancer Detection

## **Currently used Techniques**

Screening usually involves checking your breasts for cancer even before there are any signs and symptoms. While screening cannot prevent breast cancer, it can help you to detect the cancer early, so that it can be treated earlier.

In general, screening tests include:

- Breast self-examination (BSE)
- Mammogram
- Ultrasound scan
- Breast MRI

• Biopsy-confirmation test

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 question-able.

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

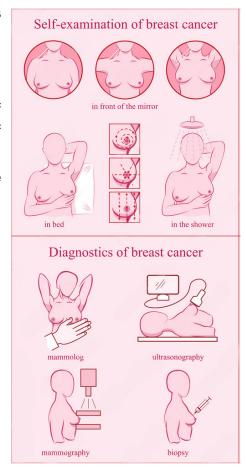
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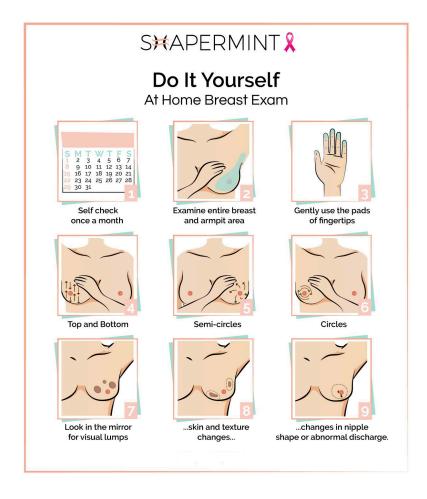
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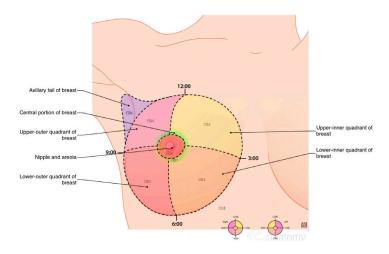
#### **Breast self-examination**

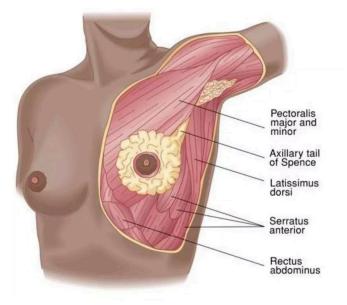
Women may perform breast self exams to help detect changes in their breasts to call to their physicians' attention. Performing regular breast self exams can help women become familiar with the individual characteristics of their breasts and notice any changes. n recent years, organizations such as the American Cancer Society have changed their positions, no longer recommending that women perform self exams on a monthly basis. This decision was made after several studies revealed that the exams do not increase the chances that women will survive breast cancer. Despite the change in position, the American Cancer Society and other organizations suggest that self exams can be performed to help detect changes in the breasts to call to a physician's attention. Women who perform self exams should consult a healthcare professional to determine how to correctly perform the exam. If women learn to perform BSE correctly, they can help detect changes and bring them promptly to a medical professional. Finding a breast cancer tumor when it is smaller improves the chances of saving a breast by avoiding a mastectomy, and may reduce the need for chemotherapy.



However, cancerous tumors are more likely to be found in some parts of the breast than in others. Approximately half of all breast cancers occur in the upper, outer region of the breast toward the armpit. Some physicians refer to this upper outer region as the "tail" of the breast and encourage women to examine it with great care.

Approximate percentage of breast cancers found in each area: 41% in the upper, outer quadrant 14% in the upper, inner quadrant 5% in the lower, inner quadrant 34% in the area behind the nipple 6% in the lower, outer quadrant





#### Mammography

A mammogram is an X-ray of the breast. For many women, mammograms are the best way to find breast cancer early, when it is easier to treat and before it is big enough to feel or cause symptoms.

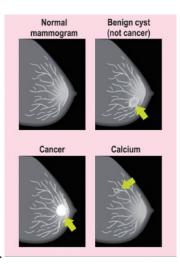
Most women find a mammogram a bit uncomfortable, while some find it painful. The good news is that the test itself only takes a few moments and the discomfort is over soon enough.

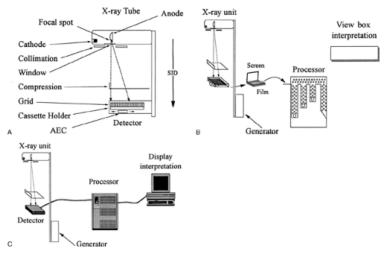
X-ray mammography is currently the gold standard for screening of breast cancer. This method is often carried out by a technician who uses the mammogram machine to compress the breast and takes photos from various angles to provide a series of images of each breast. Breast tissue appears white and opaque in the series of images known as a mammogram, while fatty tissue appears

darker and more translucent. Soft tissues do not interfere with X-rays, but malignant tissue absorbs them and can appear as white patches on the film. The breast is imaged from the centre to the sides during a screening mammography.



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 % 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. It exposes the breasts to small amounts of radiation. The benefits outweigh any possible harm from the radiation exposure.

#### 3D Mammography

This is a new type of mammography. Traditional mammography produces just two images of each breast, a side-to-side view and a top-to-bottom view. 3D mammography produces many X-ray images of the breasts from multiple angles to create a digital three dimensional rendering of internal breast tissue.





3d mammography machine which rotates around the breast for screening.

#### **Breast Ultrasound**

X-ray mammograms are frequently followed by ultrasound imaging to determine whether a mass that appeared on a mammogram is solid tissue or a harmless cyst containing fluid. Ultrasound imaging devices emit high-frequency sound waves, which penetrate the body. When these waves bounce off the boundaries between tissues in the body, they generate distinctive echoes that a computer uses to generate images known as a sonogram. Ultrasound can be used as a complement to mammography to assess areas of suspicion on mammography, increasing the accuracy of the combined technique. Cysts can be distinguished on ultrasound.

Because ultrasound uses no radiation, it is usually painless. The examination takes 15 to 30 minutes, depending on how difficult it is for the surgeon to find the breast abnormalities being examined, such as: B. Deep chest lesions. Ultrasound is not currently used for routine breast cancer screening because it fails to consistently detect certain early signs of cancer, including Micro calcifications. The most common indicator of ductal carcinoma in situ (DCIS). However, this technique is very useful when performing imageguided biopsies. However, they are still under clinical investigation and further studies are needed to determine their usefulness.



#### Magnetic Resonance Imaging (MRI)

Physicians have been using MRI for a wide variety of medical applications since it was FDA-approved for body imaging in 1985. MRI, generally considered to be a safe procedure, generates an image by measuring the responses of tissue components to a magnetic field. Specialized MRI systems, designed for breast imaging and approved by the FDA, show promise as a detection method to be used with mammography, especially for dense breasts.

The patient is placed on the scanning table with her stomach facing up during an MRI of the breast. The breast hangs into a depression or hollow in the table, which contains coils that detect the magnetic signal. The table is lowered into a device that resembles a tube and is equipped with a strong 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, which is not radioactive, can be used to make a tumor more visible. After giving the contrast agent, more pictures can be taken. The whole imaging process lasts roughly an hour.

In an MRI, powerful magnets connected to a computer make detailed pictures of the breast without using radiation. Each MRI produces hundreds of side-to-side, top-to-bottom, and front-to-back images of the breast. A radiologist then interprets the images to identify abnormal areas that may require further investigation.

Studies suggest that although MRI is highly sensitive at detecting tissue abnormalities that indicate cancer, it is sometimes unable to distinguish malignancies from other harmless tissue abnormalities in the breast. Also, like ultrasound, it cannot detect microcalcifications.



# **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 (incision biopsy) to allow the pathologists to make a definitive diagnosis.

#### Core Needle Biopsy

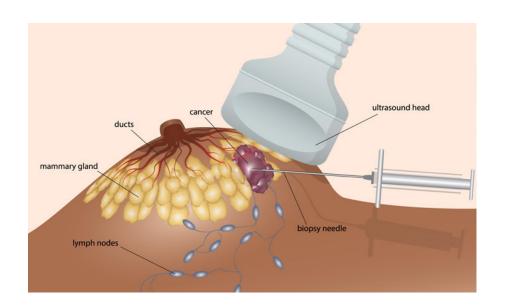
Larger needle used to obtain tissue samples from a breast lesion. This procedure usually obtains enough tissue to allow a pathologist to make a definitive diagnosis.

#### 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.



# MARKET RESEARCH

### Current technologies

### Piezoelectric Fingers iBreastexam

Available in India, made by UE Life Sciences

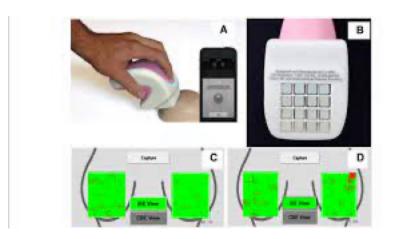
Cloud Based system

Mostly installed in Hospitals.

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.



### GE VSCAN portable ultrasound

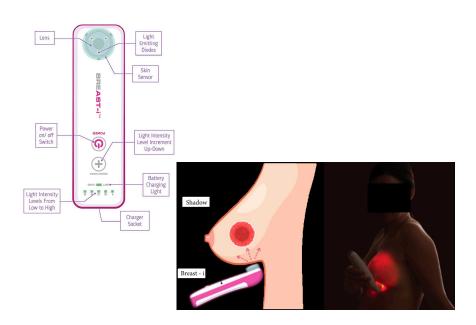
It's only the size of a mobile ultrasound! This innovative pocket-sized ultrasound is the first to house two transducers in one probe – enabling a non-invasive look inside the body, with both shallow and deep views. Alternatively, the GE Vscan Extend is available for between \$6,000 and \$7,000 refurbished, on average.



### Current technologies

#### Breast-i

Breast-i when fully charged can be used to examine the breasts of about 70 women making it useful and accessible in areas with unreliable electricity. Usage requires just a dark room and a well-trained handler; hence it is inexpensive to use. Breast-i is equipped with five adjustable light intensities that enable usage on various skin tones, breast sizes and densities, and pregnant and lactating women. The advance sensor technology also protects the eyes of users



### Breastlight

Available in UK

Uses led light to trace shadows of abnormalities. Can be used at home. Breast-i is equipped with five adjustable light intensities that enable usage on various skin tones, breast sizes and densities, and pregnant and lactating women. The advance sensor technology also protects the eyes of users. Requires complete darkness to follow this process of observing for abnormalities.



### **Eclipse**

Indiegogo to test and eventually bring to market a wireless sensor meant to aid in the early detection of breast cancer and the tracking of patients being treated for the disease that kills 40,000 U.S. women each year.

The Eclipse uses "low level photons" to image the breast, which we assume to mean infrared or near-infrared light frequencies that can penetrate tissue well below the skin. A woman would move the device across the breasts as the device does its sensing while recording a density map of the volumes. After finishing an exam the user would be able to compare maps from previous rounds and see whether any areas are getting denser and larger over time.



#### Sure touch

SureTouch was developed to provide a comfortable accurate breast exam to the millions of women in the US and the world. The patented Sure Touch tactile sensing technology is more accurate at detecting and determining a mass within the breast and also if the mass is cancerous than manual methods.

The physician holds the small Sure Touch tactile sensing while touching the breast during a clinical breast examination. The Sure-Touch system provides an electronic "map" from objective data including suspicious masses and surrounding tissue of the breast. As such, Sure Touch is non-invasive, painless and its results may ultimately help guide future decisions for additional radiologic tests.

No pain, no radiation, and a small device that can be used almost anywhere because of which in every country and culture, Sure-Touch has become a tremendous hit!



# TECHNOLOGY STUDY

#### Portable Ultrasound

Portable ultrasound machines are mobile ultrasound systems designed to be used in small spaces, at a patient's bedside, or in the field. They can be cart-based, tablet-based, or hand-carried.

Mostly installed in Hospitals. In most cases these mobile ultrasound systems could be carried by hand and in some cases even operated for a time on battery power alone. The first portable ultrasound machines arrived in the early 1980s but battery powered systems that could be easily carried did not arrive until the late 1990s.

Portable ultrasound machines are typically used in situations where space is limited, mobility is important, or the scanning must be done in the field. OB/GYN doctors were the first to start using portable ultrasound systems as these could be brought bedside or were affordable enough to be purchased by a private practice.

by emitting sound waves into the body and rendering an image with the echoes sent back to the transducer.

However, it is very costly. And it has to be operated by a technician or health care worker.



### Microwave imaging

In general, a microwave imaging system is made up of hardware and software components. The hardware collects data from the sample under test. A transmitting antenna sends EM waves towards the sample under test.

Microwave imaging is a science which has been evolved from older detecting/ locating techniques in order to evaluate hidden or embedded objects in structure using electromagnets.

a transmitter antenna sends EM waves toward sample under test.

if sample is made of only homogeneous material which extend to infinity, no EM wave will be reflected.

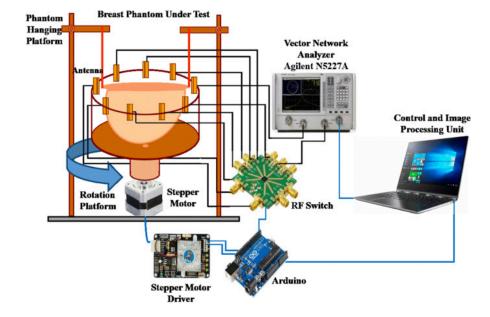
if sample has any anomaly, in comparison with the surrounding homogeneous medium may reflect a portion of EM wave.

this reflection will be collected and measured by the same antenna or a different rec3iver antenna.

when the antenna finishes scanning the entire sampling area, one can put together collected data all over the sampling area and process them together, simultaneously.

the collected data is fed into software to get processed.

It is not feasible for a personal use product.

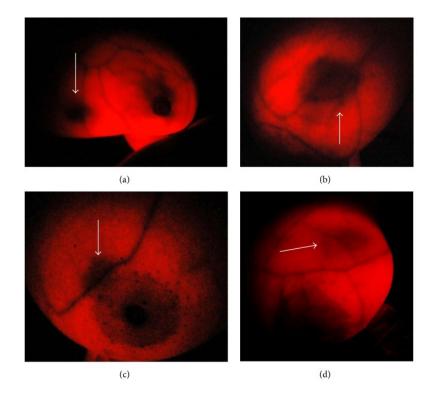


### Trans-illumination

Trans-illumination is the shining of a bright light through a body cavity or organ for diagnostic purposes. Trans-illumination can be used on the head, scrotum, or chest in the premature or newborn infant, or the breast in an adult female. It is bed side test that can be done by getting room lights dark so that the glow of light can be seen easily.

Transillumination of hand tumors or masses is a physical examination tool which ostensibly helps the examiner to distinguish between solid and cystic lesions. The premise of transillumination is that cystic lesions transilluminate while solid tumors do not. A transillumination test is a way of diagnosing certain conditions. It's often used along with other procedures and tests to confirm a diagnosis. For instance, transillumination may be used with ultrasound and a biopsy.

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.



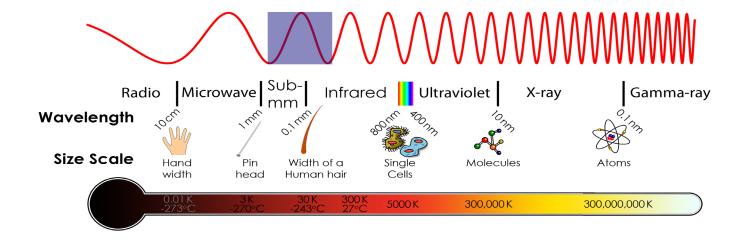
# Infrared Imaging

### Selected technology

Infrared light is beyond the light range that is visible to the human eye, and falls between the visible light and microwave regions (the wavelength is longer than visible light). The longest wavelengths are red, which is where infrared got its name ("beyond red"). Infrared waves are electromagnetic waves, which is also present in heat; campfires, sunlight, etc., is actually infrared radiation. Infrared proximity sensors work by sending out a beam of infrared light, and then computing the distance to any nearby objects by employing the characteristics of the returned signal. The infrared region of the spectrum includes electromagnetic radiation that can alter the vibrational and rotational states of covalent bonds in organic molecules.

The main principle of IR image diagnosis is that the unregulated growth of cells generates a higher metabolic rate and requires more blood flow than the surrounding tissue. The additional heat generated is delivered to the tissue surrounding the tumor, causing a temperature spike on the breast surface. Infrared (IR) spectroscopy is an absorption method widely used in both qualitative and quantitative analyses.

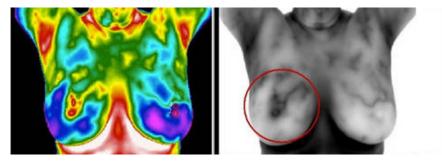
Webcams and digital cameras are able to see that infrared light. Our eyes just can see wavelengths between 400-700 nm. Infrared light has wavelengths between 700 nm - 1 mm.



# Infrared Imaging

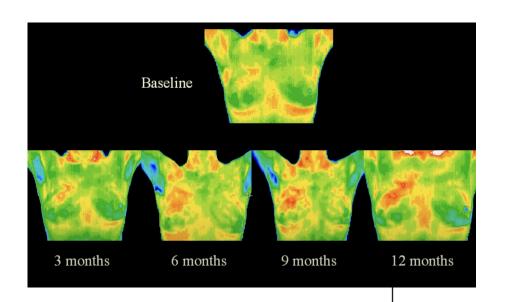
A clinical study by Gamagami reported that 15% of non-palpable carcinomas went undetected by mammography but were detected by IR thermography. Gautherie and Gross, studied 1245 patients with abnormal IR image profiles and found that 35% of patients with abnormal thermograms developed cancer within the next 5 years. They noted that IR imaging may be useful for early detection of breast cancer and fast-growing neoplasms. However, the approach was unable to distinguish the cancerous region of the breast from areas of inflammation.

In the 2000s, IR cameras significantly improved their performance, especially when used in conjunction with a blackbody, and nominal accuracy could be varied from 0.1 to 1 °C and a scan time of 0.8 s. This improvement in the performance of the cameras allowed deeper tumors to be detected and less pronounced temperature variations to be observed on the breast surface. This also led to the development of breast tumor detection methods such as dynamic infrared thermography (DIT). DIT reveals temperature differences on the surface of the breasts to detect breast tumors.



Thermography (R) produces an infrared image that shows the patterns of heat on or near the surface of the body. (L) is an scanned image of the breast tin which we can see the abnormality in left hemisphere of breast.

It is proven that this method can be used as supplementary tool together with other gold standard methods as mammography, ultrasound and MRI.



#### **Active Cancer Cells Double in Number Every 90 Days** 90 days 2 cells 16 cells 1 year 2 years 256 cells -3 years 4,896 cells 4 years 65,536 cells 1,048,576 cells (still undetectable) 5 years 16,777,216 cells 6 years 268,435,456 cells 7 years 4,294,967,296 cells (doubled 32 times) \* 8 years \*Normally detectable by Mammogram at this stage 40 Doublings (Aprox 10 Years) considered lethal.

# PRIMARY RESEARCH

### Informal Interviews

Older woman or who are having menopause are more in numbers compared to other age groups.

It is genetically there is my family. So i have to do mammography every year as part of health checkup. It would be helpful i there was a device to check every month. I wouldn't have to go for frequent checkups and face embarrassment.

The whole process is scary. First time doing mammography was very awkward and there was discomfort felt.

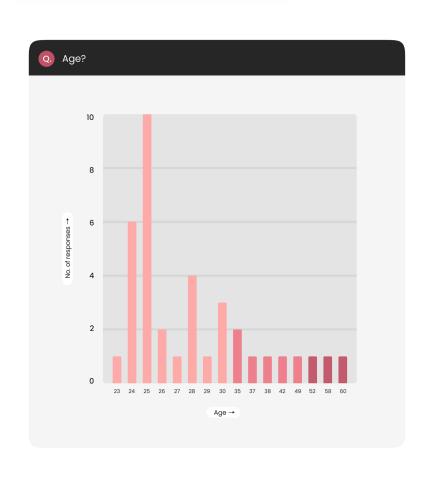
Very uncertain how to do. the process of detecting and diagnosis is very cumbersome. My mom died of breast cancer. She used to do self testing, but still she got to know very late. the lump was felt when it was in stage 3. I feel this device should be there to help to know tumors before they become fatal.

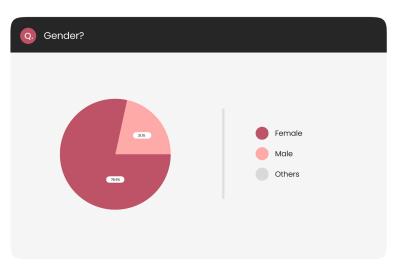


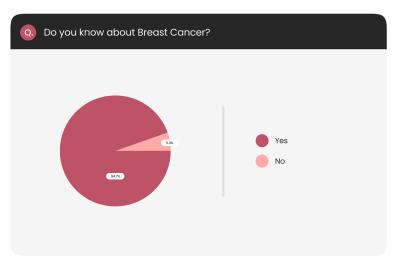


Above images are taken in 1 of the hospitals i visited for research. However, due to privacy that I had to sign to do interviews with radiologists and oncologists. I have to refrain from putting those interviews here. But inferences were drawn from these interviews and accordingly design decisions were made.

# Google survey

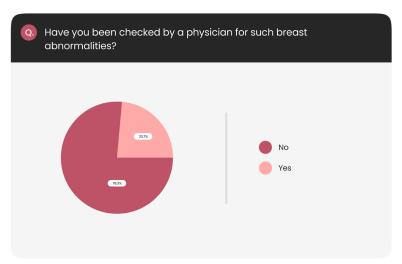


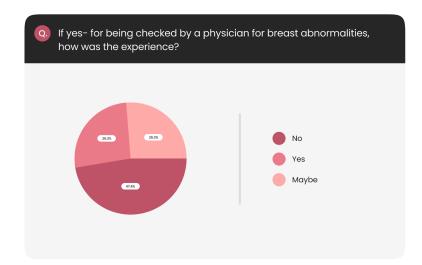


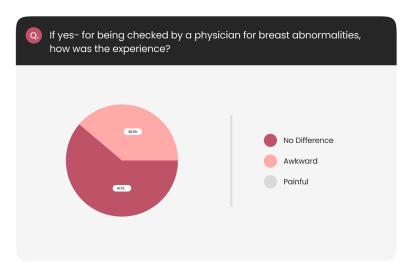


### Google survey

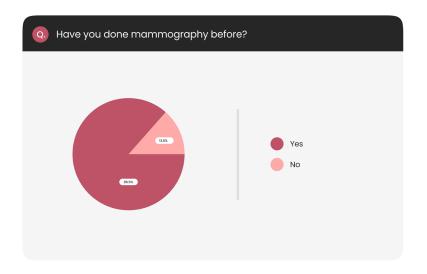


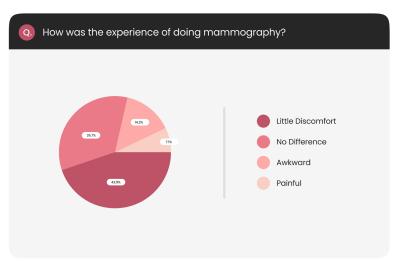






### Google survey





# Documents study







Different documents were read with regards to current and new technologies used for detecting tumors. And also study specific to IR imaging for medical purposes was done.

# DESIGN

# Design Brief

To design a self scanning device for the early detection of breast abnormalities using infrared imaging technology (thermograpgy).

- It is a personal use device.
- It should be simple, easy to use and without needing medical knowledge.
- Device has to be portable and lightweight to carry and use.
- It has to be compact for storage.
- Should allow different anatomies of women such as ages and breast sizes to use without hindrance.
- Ergonomic grip for handling different postures.
- It can be connected to phone for quick imaging.
- Easy to operate device and understand image results.

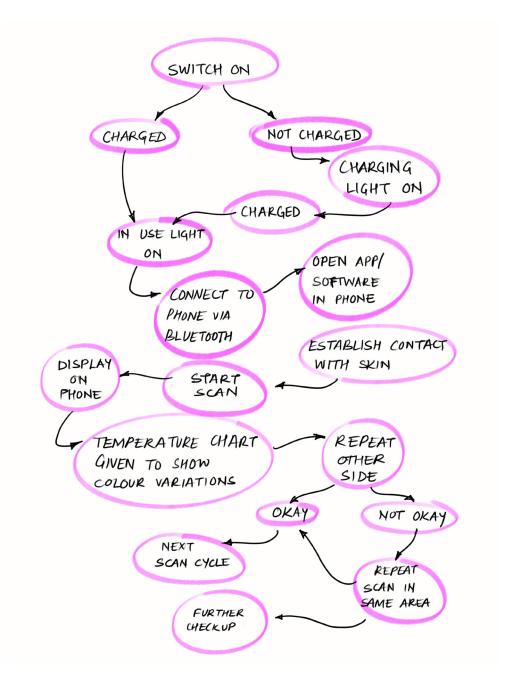
#### Target user-

- Hereditary
- Women above 35 <</li>

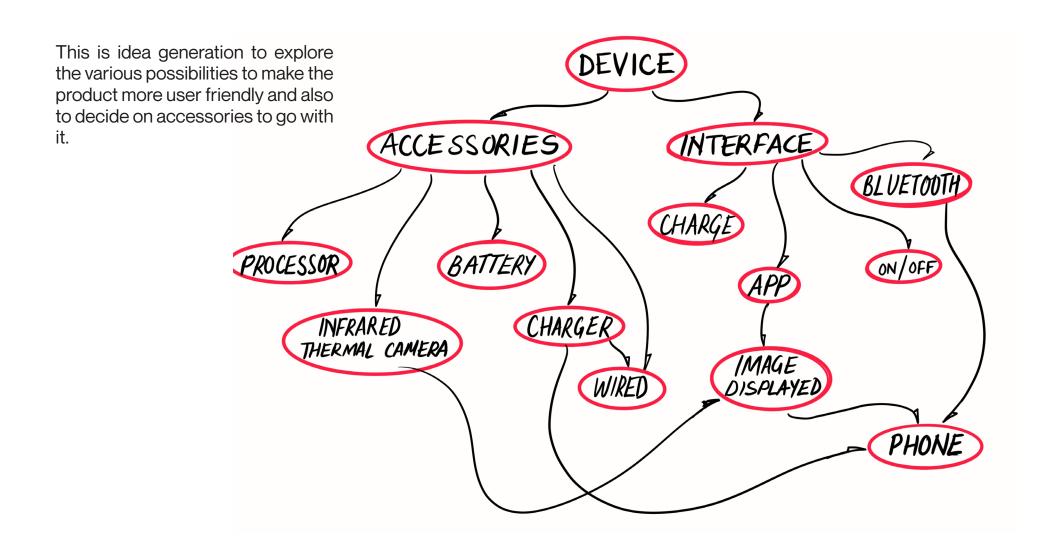
#### Tertiary user-

• Men above 60 yrs having history in family

### **Process of Use**

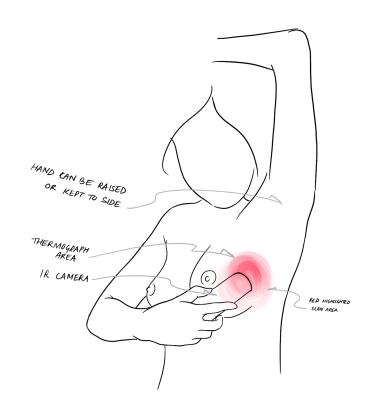


# Mindmap for accessories

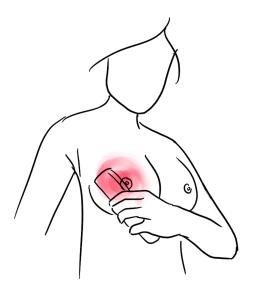


# **Ergonomic study**

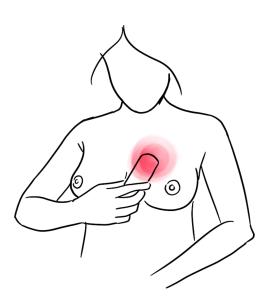
- The device has to be lightweight to hold, use and carry.
- Use of opposite hand for scanning should be convenient as well for use.
- Cold press is required to get unaffected imaging of thermal mapping.
- Total time taken for imaging is not more than few minutes.
- Interface plays a major role in giving a feedback of the temperature that is being is used and also the battery status of the device. The interface must be visible and easy to decipher.
- The device can be used in light or dark room.
- Use of mirror is not crucial, as imaging results will be visible in phone.
- In case of someone having obesity, it would not affect the imaging, as placement of phone is changeable.

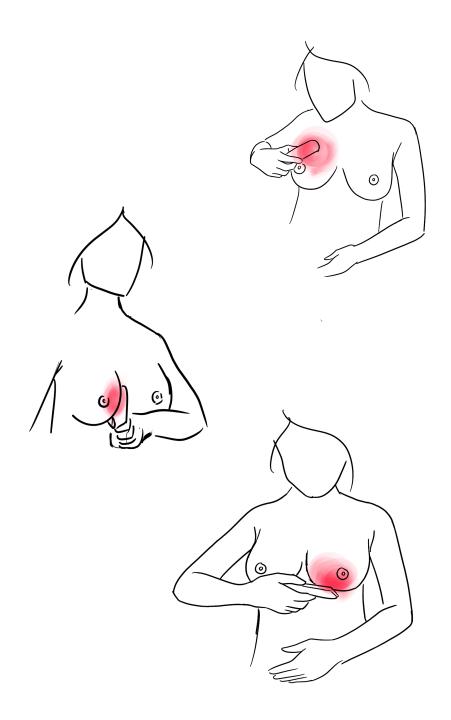






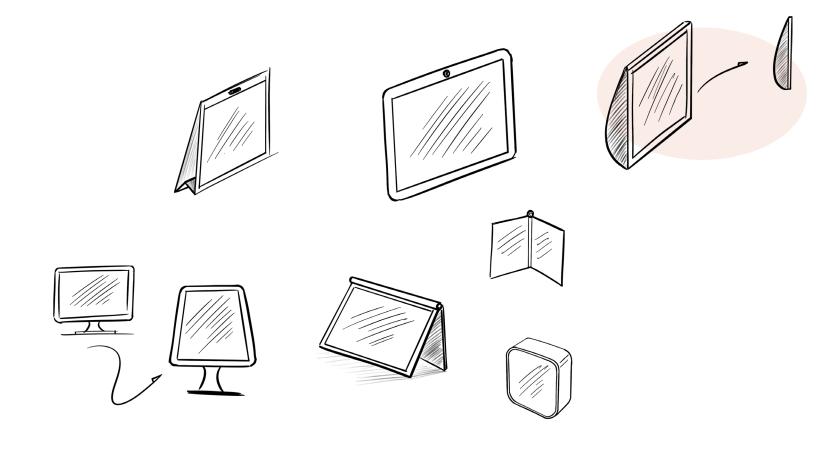
Use of both hands can be achieved. Hand should be kept stable.





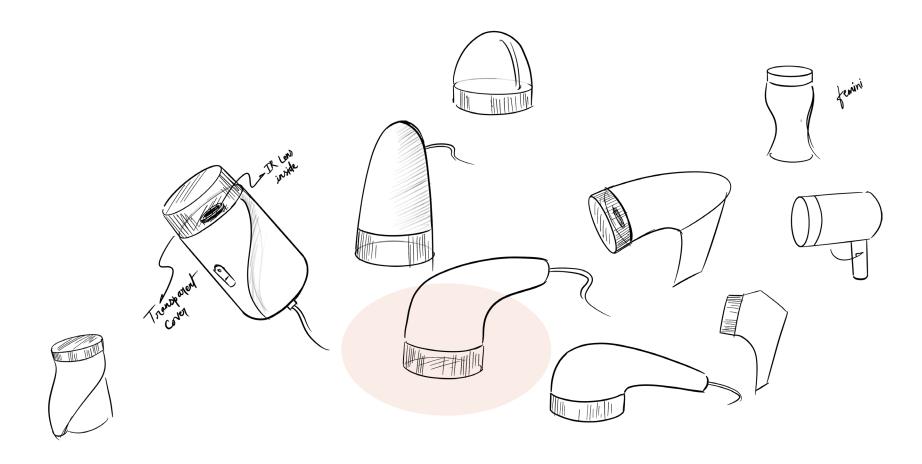
# Ideation based on modes of using

Stationary camera and display

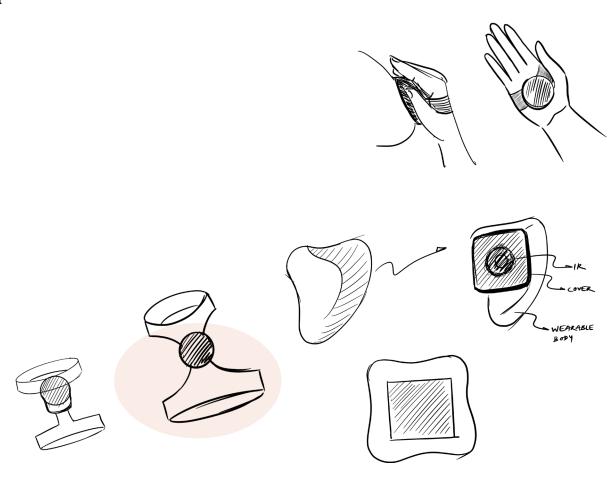




### Hand held device with phone display



### Wearable device in hand



### **Comparative Evaluation**

Ideation based on Modes of Using





Lighter in weight	more time taking	Looks high tech	takes time to change hands	instruction manual needed	can take form of palm
charging issue	interaction	older people	wearing it		
Criaiging issue	with product hard for elderly	find it hard	looks task	dependency on others	
how to charge?	how to operate?	feels like cumbersome process	requires both hands	takes more time to change	hard to follow instructions
easy	for 5 min why wear device?	cleaning issue	easy to store	gripping	how to do with shaky hands?
cleaning issue	too many parts that come off to clean	how to sanitize?	does not require much space to store	costly	cost would be higher
looks comfortable	confusing to use	Doubtful about device capability	harder access areas		
hand change takes more time	free flow on skin				

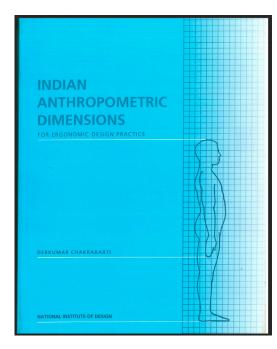
# Final Design Objective

To design a breast cancer detecting, hand-held device for personal use which uses infrared technology and is rechargeable and can be connected to phone for imaging results display.

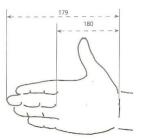
# Anthropometric dimensions

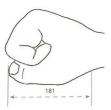
Human beings have assorted body sizes and rates of growth that follows certain patterns, but physical development from birth to adulthood does not show the same proportional growth of all parts of the body. The basic structure and shape of the human body are identical among the human race all over the world, but sizes differ. Bone, muscle and other minute detailed dimensions of the anatomy are mostly referred to for medical and other necessities. But even while designing products for human use, the external body dimensions are of importance and the anthropometry has to

be considered. While designing individual items or products, one has to take into consideration the dimensions of the product/ items, their layout pattern in a given space, the ease of reach, their use, etc., to match with the anthropometry of the users.



The following is book referred to for anthropometric data study.





#### Hand dimensions

179 Hand length

Distance (at palmar surface) from the base of the palm to the tip of the middle finger, when hand is held straight and stiff, with fingers together and extended.

180 Palm length 181 Fist length Distance from the base of the palm to the base of the middle finger (at the palmar surface).

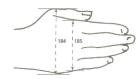
Length of the hand grip in the same line of the long axis of the hand from the base of the

palm to the tip of the fist, wherever found.

R.No.	Parameters		Min		F	ercent	iles	Max	Mean	±SD	Ratio	
				5th	25th	50th	75th	95th				
179	Hand length	Male	119	163	173	180	187	198	229	181	12	0.11
.,,	riana iengai	Female	150	154	160	166	170	181	190	167	8	0.11
		Combined	119	158	168	176	184	197	229	178	12	0.11
180	Palm length	Male	86	92	99	103	107	114	176	104	8	0.06
	-	Female	84	. 86	91	94	97	103	113	95	5	0.06
		Combined	84	89	96	101	106	114	176	103	8	0.06
181	Fist length	Male	73	85	93	99	105	115	127	101	9	0.06
		Female	52	61	87	93	101	106	117	92	13	0.06
		Combined	52	81	92	98	104	115	127	99	11	0.06

Even though it is said that man is highly adaptive to any situation, where comfort is concerned, optimization is required.







R.No.	Parameters	Definition ( brief )
182	Hand grip, length	Length of the hand grip, from the base of the palm to the centre of the grip, while holding a rod of 30 mm diameter.
183	Hand grip, breadth	Maximum breadth of the hand grip, wherever found, perpendicular to the long axis of the hand.
184	Hand breadth, with thumb	Maximum breadth across the palm with the thumb at right angle to the long axis of the hand.
185	Hand breadth, without thumb, at metacarpal	Maximum breadth across the palm at the distal ends of the metacarpal bones (where the fingers join the palm) of the index and the little finger.
186	Finger-tip depth	Maximum distance between the dorsal and the palmar surfaces of the tip of the middle finger.

R.No.	Parameters		Min		P	ercent	iles		Max	Mean	±SD	Ratio
				5th	25th	50th	75th	95th				6
182	Hand grip length	Male	36	39	45	50	55	65	95	51	8	0.03
		Female	40	41	46	50	55	63	64	51	7	0.03
	*	Combined	36	40	45	50	55	64	95	51	8	0.03
183	Hand grip breadth	Male	65	82	91	99	104	109	130	98	9	0.06
		Female	51	70	82	86	91	96	104	86	9	0.06
		Combined	51	79	89	96	102	109	130	96	10	0.06
184	Hand breadth	Male	78	86	93	99	104	111	117	99	7	0.06
	with thumb	Female	75	77	82	86	90	95	100	87	6	0.06
		Combined	75	81	89	95	102	109	117	96	9	0.06
185	Hand breadth	Male	60	72	77	81	85	90	100	82	6	0.05
	without thumb	Female	60	66	69	71	75	79	92	73	5	0.05
	at metacarpal	Combined	60	68	74	79	84	90	100	80	7	0.05
186	Finger-tip depth	Male	10	11	12	13	14	15	18	14	1	0.01
		Female	8	8	9	10	11	13	15	11	1	0.01
		Combined	8	10	12	13	14	15	18	14	2	0.01









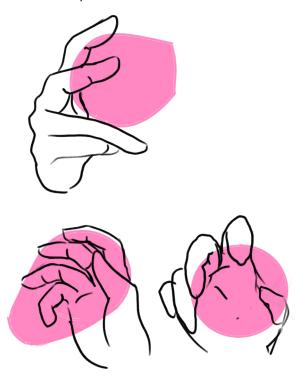
R.No.	Parameters	Definition ( brief )							
187	Finger-tip breadth	Maximum distance across the lateral surfaces of the tip of the middle finger.							
188	Hand depth at metacarpal	Maximum thickness between the dorsal and the palmar surfaces of the palm, across the knuckle of the middle finger, where it joins the palm.							
189	Hand depth, at thumb base	Maximum thickness of the palm, on the fleshy pad at the base of the thumb.							
190	Fist circumference	Maximum circumference of the fist, wherever found, encompassing the knuckles of the middle finger and the thumb.							
191	Grip inside diameter, maximum	Maximum inside grip diameter, measured by sliding the hand down a graduated cone until the tips of the thumb and the middle finger remain touched to each other.							

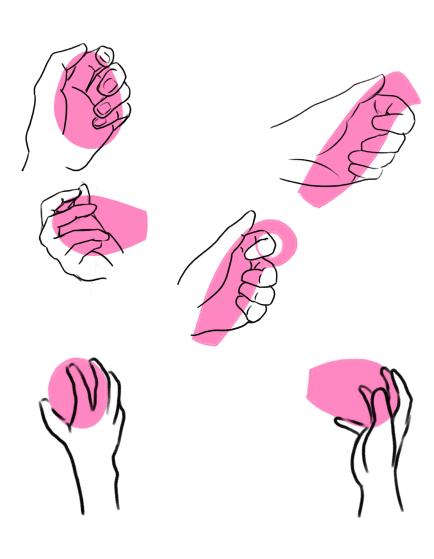
R.No.	Parameters		Min		P	ercent	iles		Max	Mean	±SD	Ratio
0				5th	25th	50th	75th	95th				
187	Finger-tip breadth	Male	13	13	14	15	16	17	20	16	1	0.01
		Female	10	11	12	12	13	15	16	13	1	0.01
		Combined	10	12	13	14	15	17	20	15	2	0.01
188	Hand depth	Male	15	18	21	24	27	31	39	25	4	0.02
	at metacarpal	Female	17	17	20	23	25	29	37	24	4	0.02
		Combined	15	18	21	23	26	31	39	25	4	0.02
189	Hand depth	Male	26	34	37	40	44	50	65	42	5	0.03
	at thumb base	Female	29	30	34	37	38	43	44	37	4	0.02
		Combined	26	34	37	40	43	50	65	41	5	0.03
190	Fist circumference	Male	220	240	252	264	279	294	373	266	19	0.16
		Female	200	205	219	229	237	249	250	227	13	0.15
		Combined	200	219	247	259	275	294	373	260	23	0.16
191	Grip inside diameter,	Male	39	42	46	49	51	56	60	50	4	0.03
	maximum	Female	39	40	42	46	49	52	57	47	5	0.03
		Combined	39	41	46	49	51	56	60	49	4	0.03

# Hand Grip study

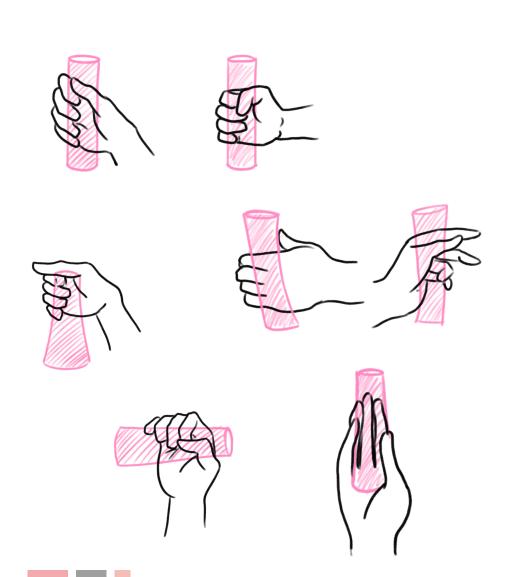
What is ergonomics in handheld items?

For a hand tool to be considered ergonomic, it should be safe to operate with one hand. The center of the tool's gravity should be aligned with the gripping hand, making it feel comfortable to hold in the position intended for use. Ergonomic handles for hand tools should be cushioned and non-slip.





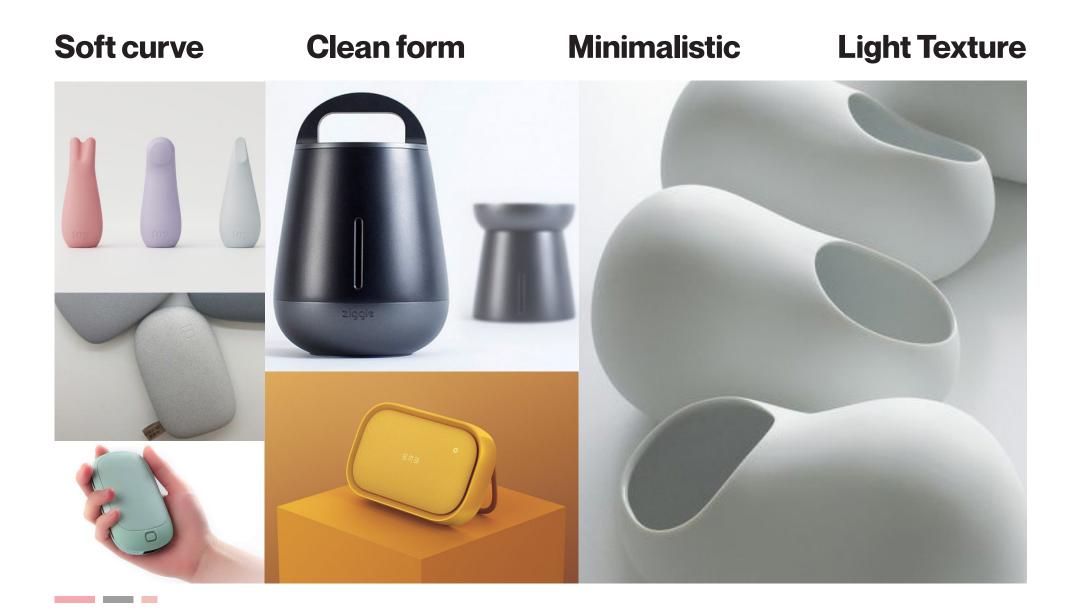
# Ergonomic gripping study





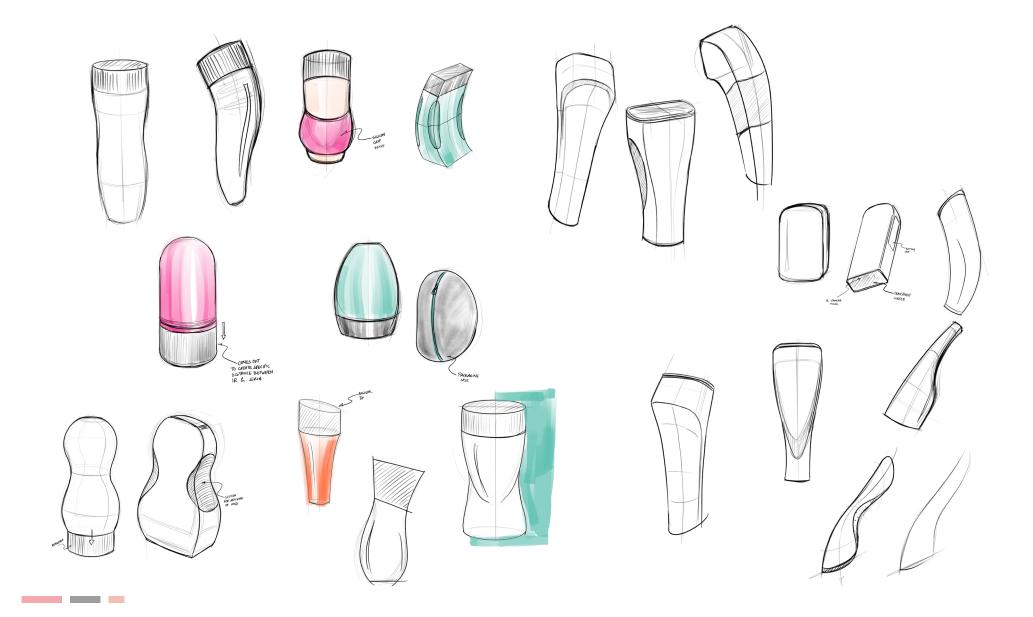
Different positions of hand holding an object.

### Moodboard



# Ideations based on Form





# Mockups









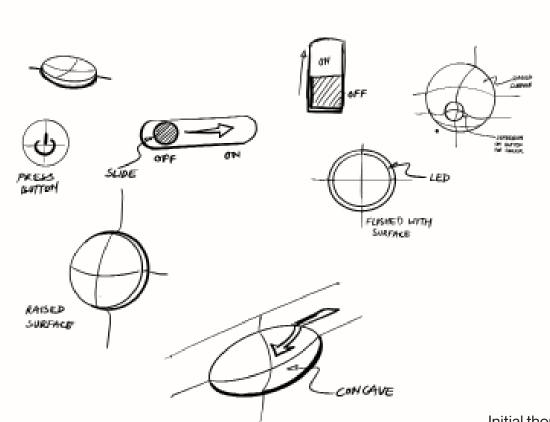
Mockups of hand grips were made of clay to study holding patterns of women of different hand sizes. This led to understanding the forms which are easy to hold for any hand size.







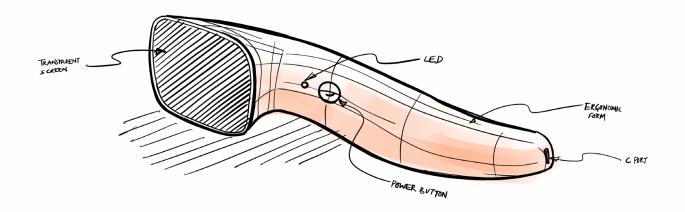
#### Power button interface

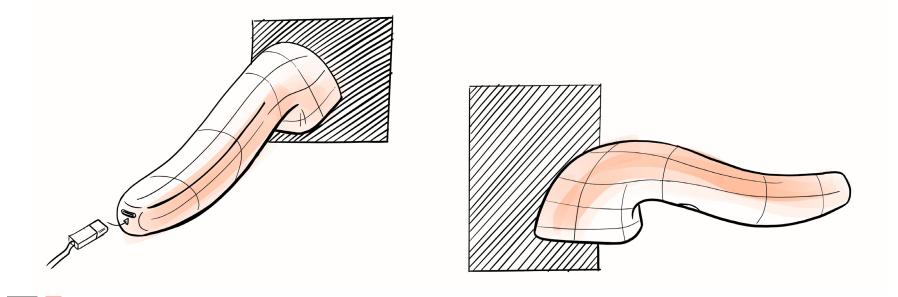


Initial thoughts on what kind of buttons or feedback the interface could have in order to make operating the device easy and ergonomic. It should be understandable enough without needing instruction every time someone wants to use the device.

# Less, but better | Dieter Rams

# Final Concept





### Concept mockup

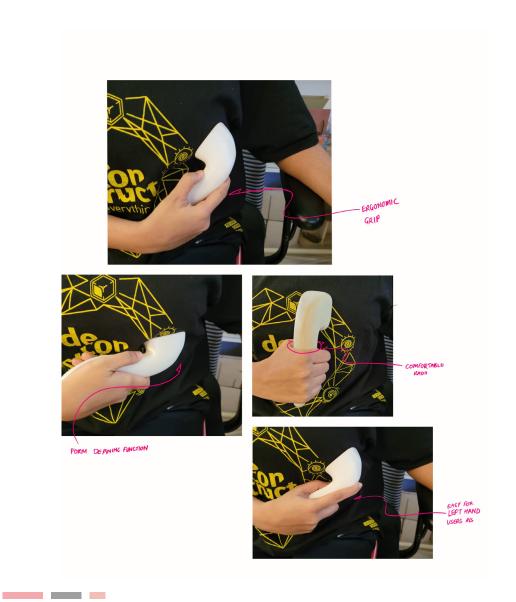
# Iterations based on ergonomic form factor

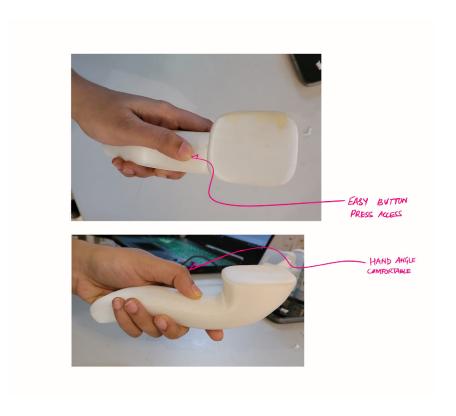




These are iterations of final form. After ergonomic testing with users, the form was refined further. Above is the final form with specific curves defined.

### Testing mockup





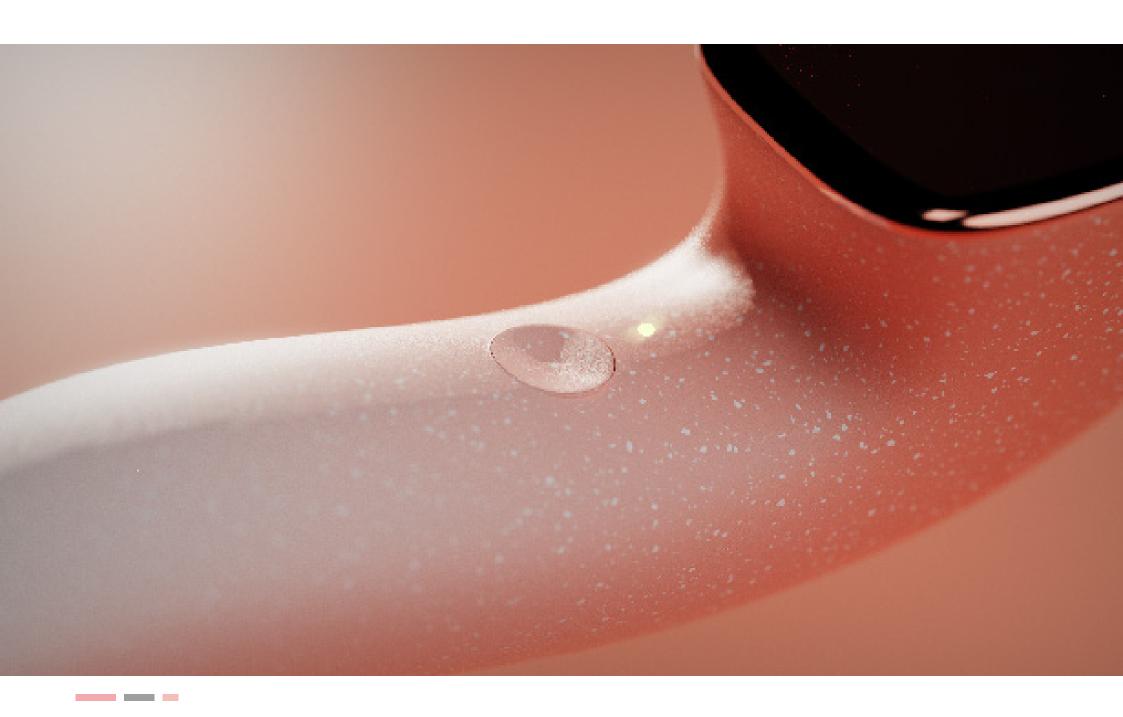
#### **CMF**



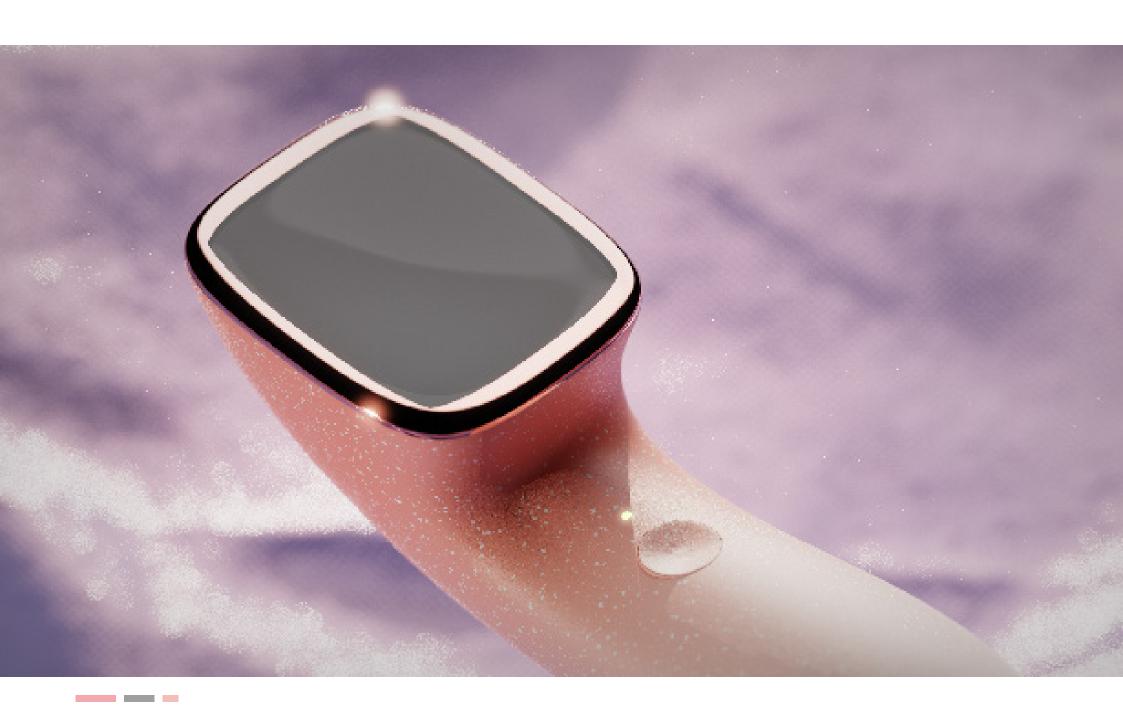
Healthcare related products generally give a cold feel.
Also most breast cancer related products are pink. They make it look too specific and feminine. I chose to use a gradated surface and textures to give the product a warm, inviting and soothing look. The color palette will be peach, corals, greys with base tone of white to give a refreshing look.

# Final product render

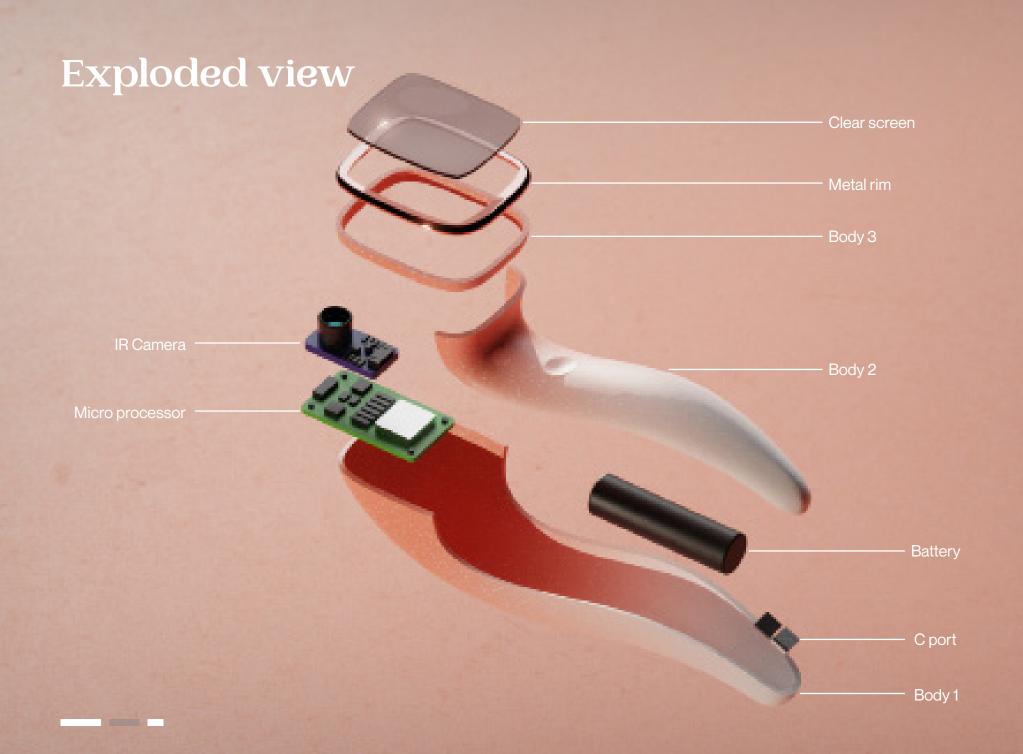








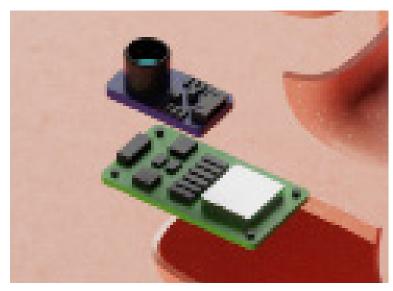


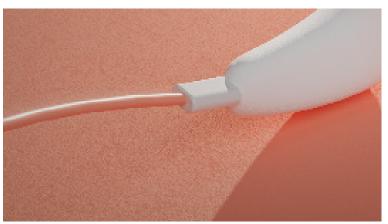


# **Technical Specs**



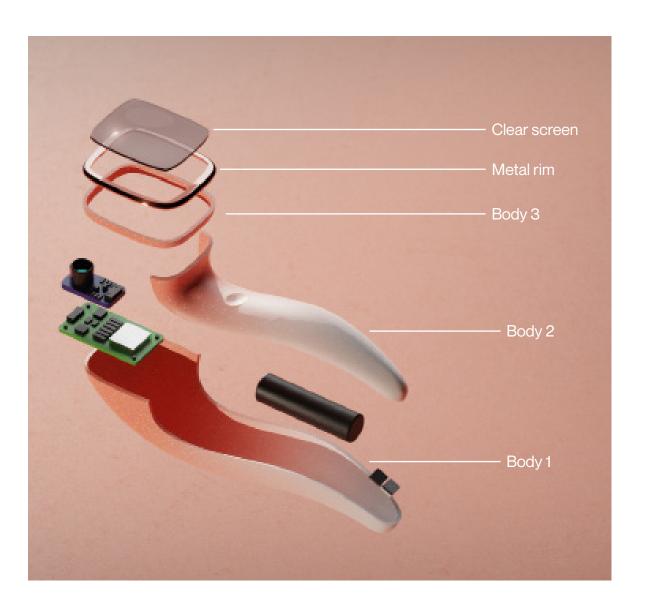
IR camera along with its processor to convert all the data into thermographs and send it to phone by Bluetooth wirelessly.



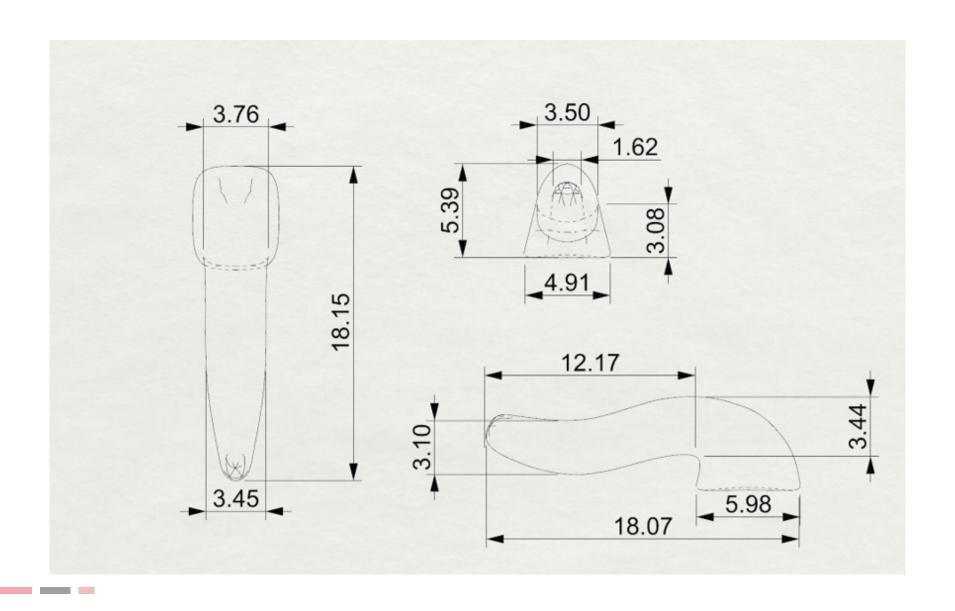


### Manufacturing

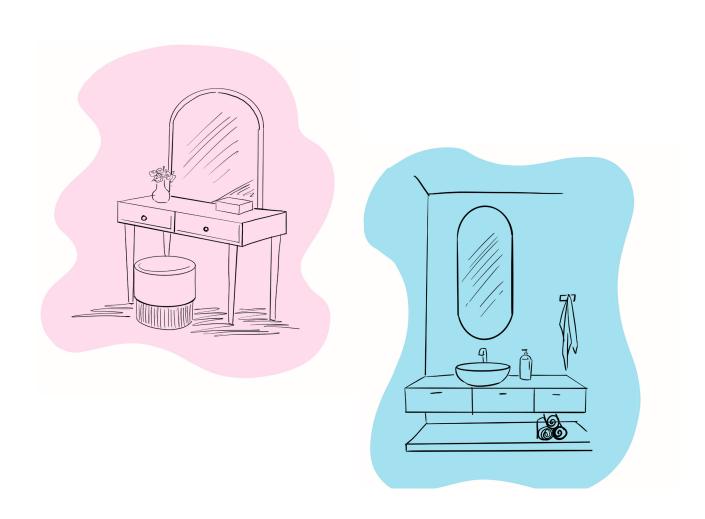
- Bodies (1,2&3) will be made in ABS by injection molding process.
- The front screen will be in clear plastic.
- Metal rim will be done by forging process.



### Technical drawing



#### User environment



The user can use this device in any personal space at the comfort of their homes. This device does not require to be in dark like its counter parts. Hence user can comfortably do test in front of mirror or that also is not required as long as a phone is connected and in front of user.

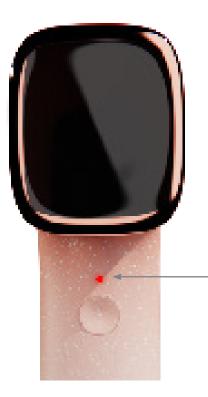
#### **User Interaction**



Blue light to show initial thermal reading is on.
Press on button once to start scanning body temperature of person and room.

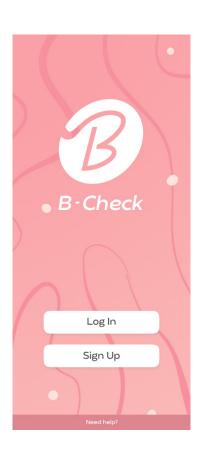


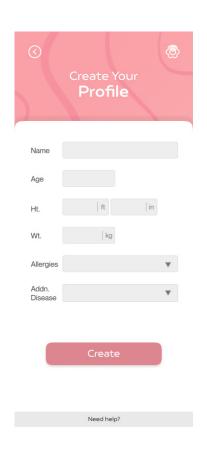
White light shows its ready to start detecting process. Press on button twice to start screening.



Red light means low battery or that its charging mode is on.

# User Interaction on phone

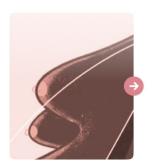












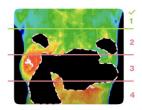
#### STEP 1

Your breast tissue covers the area from your armpits up to your collarbones, so when you're feeling your boobs make sure to check your armpits and upper chest as well.

. . . .

Need help?



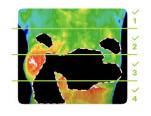




Move the controller towards left, try to cover all the regions.

Need help?





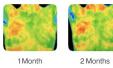
Your scan is now complete!

Done

Need help?

















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# THANK YOU