



OPERATING MANUAL



UE/CR/01/01-01

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1 SYSTEM OVERVIEW

iBreastExam™ (iBE) is a non-invasive, hand-held, fully wireless mHealth point-of-care solution for breast lesion detection. iBE scanner uses our proprietary capacitive pressure sensor technology that differentiates variances in tissue elasticity in breast tissue. iBE enables a trained user to administer and record breast exams objectively, consistently and with the ability to share the results easily using a mobile scanner. In clinical studies, iBE has shown high sensitivity and specificity to detect non-palpable lesions at an early stage.

Key Facts about iBE:

- Completely safe & radiation free
- Quick & painless
- Accuracy to detect clinically relevant breast lesions >84%
- Usable by any health-worker/doctor
- Results available instantly, at site



Figure 1-A

2 SYSTEM COMPONENTS

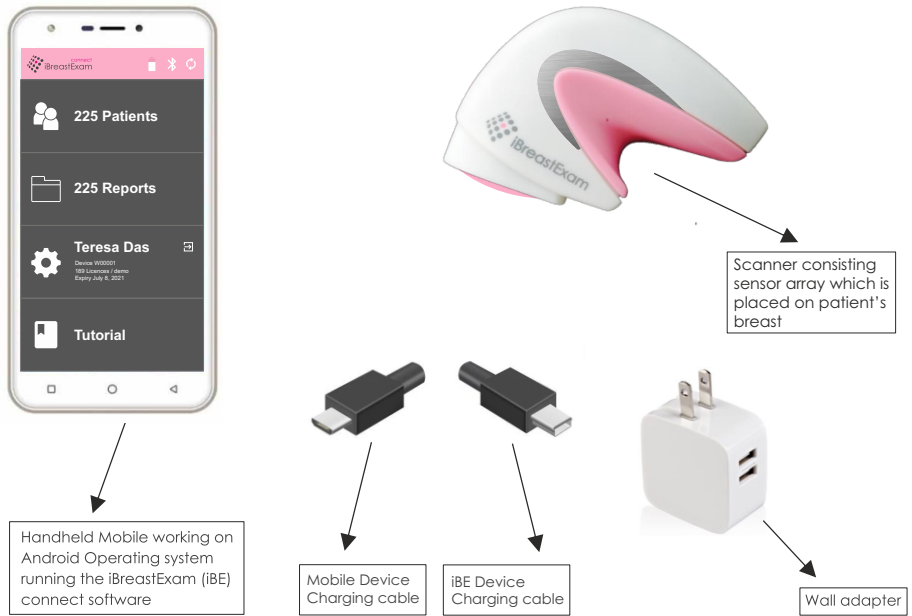


Figure 2-A

The iBE system consists of a scanner, mobile device, and charging accessories, Refer Figure 2-A.

The Mobile device runs on Android operating system and has the iBE Connect App pre-installed. The Scanner houses 648 Dynamic Co-Planar Capacitive sensors and is connected to the mobile device through a dedicated bluetooth connection. It also consists of 2 charger cables and a wall charger to re-charge the Scanner and the mobile device.

3 HOW TO PREPARE A PATIENT FOR SCANNING

The following are a set of suggested guidelines to prepare a woman for the test before the iBE system can be used to document the breast lesions:

1. The patient must be disrobed from waist up and lie down, face-up on a patient table, Refer Figure 3-A.
2. The patient table should be stationary. Table should not be on wheels to avoid movement. Necklaces should not hang down obstructing breast tissue and nipple rings (if present) must be removed.
3. Ask the patient to place her hands on the hips with elbows facing out. The side of the breast tissue should not be obstructed by the arms and there should be no folds in the breast tissue.
4. Before you start the test, explain to the patient that the test is painless radiation-free.

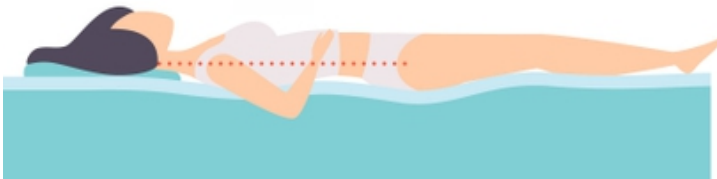


Figure 3-A

4 HOW TO USE iBE CONNECT HARDWARE

iBE Hardware includes the Scanner and a mobile device. Mobile device used is typical like any other device using Android Operating system 8.0 Oreo with a minimum screen size of 5.2 inches, and so in this section we will be mainly focusing on topics related to Scanner usage like charging, screening and maintaining.

4.1 CHARGING THE SCANNER

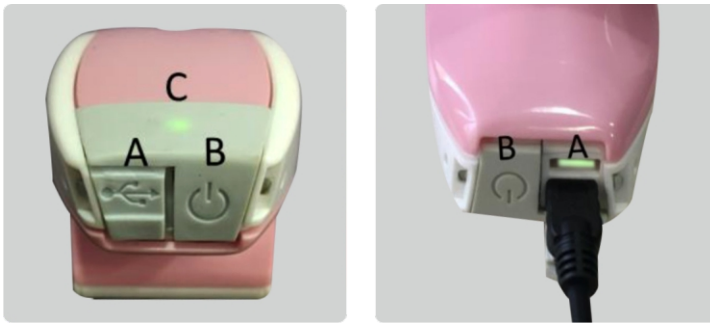


Figure 4.1-A

Refer Figure 4.1-A; it shows the location of the **(A)** charging point, **(B)** Scanner ON/OFF switch and **(C)** indicator light.

Point A is the charging point and is located at the bottom of the Scanner.

Point B is ON/OFF switch located next to charging Point A.

Point C is the indicator light which lights up when the Scanner is ON. The green indicator light will not light up if the Scanner battery is drained.

Light inside Point A turns ON when the device is plugged in to charge. If it fails to turn ON, it indicates that the scan head is not getting charged. When the device is completely charged, the light goes off.

Make sure the device is properly charged before starting any new scan (there is a battery life indicator in the iBE Connect App). Ideally the device needs to be charged for over five (5) hours.

4.2 CLEANING THE SCANNER

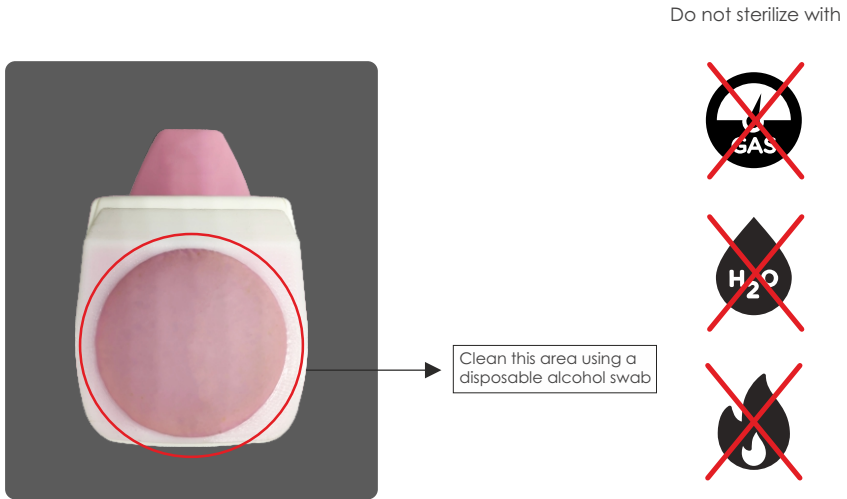


Figure 4.2-A

Before every breast examination, it's important to wipe the breast tissue with antibacterial wipes. Also, after every breast examination, wipe the Scanner using an alcohol swab to sanitize. (For cleaning area Refer Figure 4.2-A).

It's important to sanitize the Scanner every single time before it is used. Effective cleaning and sanitizing prevents exposing product users to potential health hazards.

Always disconnect the system from power supply prior to cleaning or using the system.

DO NOT sterilize the Scanner using gas, heat or liquid.

DO NOT autoclave the Scanner.

These methods may permanently damage the Scanner.

4.3 HOW TO HOLD THE SCANNER

During the use of iBE, the Scanner must remain in full contact with the breast tissue. While calibrating and scanning the breast tissue, the Scanner must be held as shown in Figure 4.3-A. Maintain continuous contact with the grip pads throughout - while calibrating and scanning.



Figure 4.3-A

5 HOW TO USE iBREASTEXAM CONNECT APPLICATION

This section mainly covers steps required to connect iBE Scanner device to iBE Connect Application and the way to do a scan.

The topics covered are as follows:

- 1) Launch iBE Connect Application on the device
- 2) Understand iBE Connect Application layout and its features
- 3) Entering Organizational Information
- 4) Connecting the Scanner to Mobile device
- 5) Entering Patient Information
- 6) Way to do a Scan & View Report

5.1 LAUNCH iBE CONNECT APPLICATION ON THE DEVICE

Switch on the mobile device. Do confirm if the time and date displayed on the mobile device matches the actual local time. If the time and date does not match, the user should manually change it as it will be used to time stamp the scans and reports created.

On the home screen of the device there will be **iBE Connect App**. Click on the iBE App logo to launch the App. The first screen on the app is the login screen.

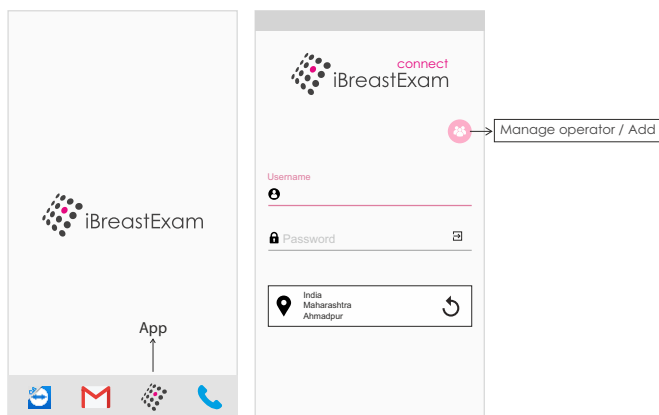


Figure 5.1-A

Operator is required to enter User Name and Password to continue Refer Figure 5.1-A.

If it's a first-time user, and the operator has no login or password, then the operator will need to create a login and password. This can easily be done through the "**Manage/Add Operator**" icon. This option also allows you to '**Edit**' an existing operator information.

Location Settings – If the Mobile device is connected to the Wifi / internet, the app will automatically locate the current location using GPS. If the location is not appropriate, the user should manually change the location by clicking on and set the current location manually

In case an incorrect user name or password is entered, the following pop up message is displayed, Refer Figure 5.1 B-C

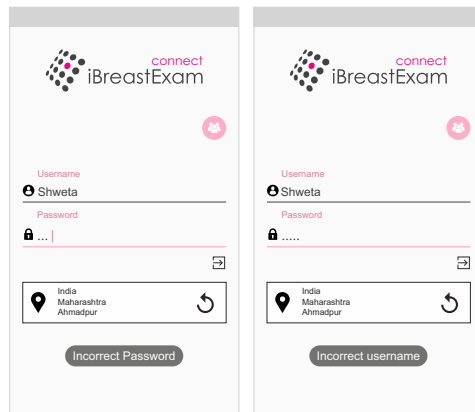


Figure 5.1 B-C

CREATING A NEW USER/EDITING USER

In order to create a new user, click on  button and fill in all the required information for user creation, Refer Figure 5.1 D-G.

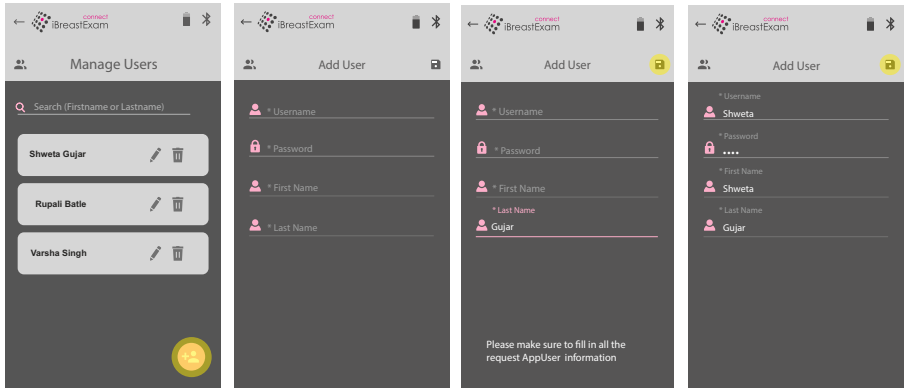


Figure 5.1 D-G

In order to edit information for existing users, Refer Figure 5.1 H-J.

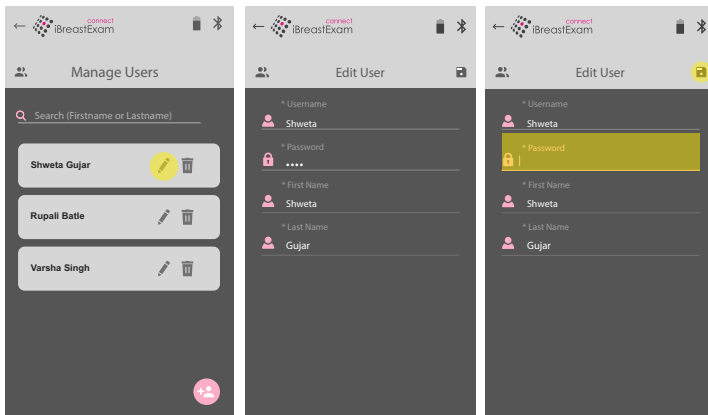


Figure 5.1 H-J

5.2 iBE CONNECT APPLICATION HOMEPAGE LAYOUT AND ITS FEATURES

Figure 5.2-A shows the Homepage layout of iBE Connect App.

There are four main sections listed on the homepage:

1. Patients
2. Reports
3. Settings
4. Tutorial

1. Patients: This function contains list of Patients. From here the Operator can:

- Select an existing Patient for screening
- Add New Patient/s
- Edit Patient information

This also allows one to save patient details in advance prior to scheduling the scans.

2. Reports: This function is used to:

- Add/Update Clinical Findings in a Report
- View Report
- Replay Scan
- Print/Share Reports

Clinical Findings on a patient include Mammography, Ultrasound and Clinical Breast Exam findings. All these can be recorded on the report for correlation purpose.

3. Settings: This is the third tile on the homepage. It displays the name of the operator and the number of scans available on the connected Scanner and its expiry date. Before screening it's important to make sure that there are enough scans available.

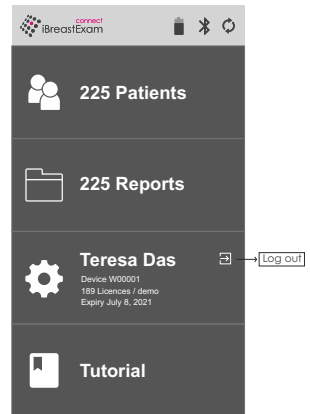


Figure 5.2-A

Scanner will not work if the Scan count is Zero or past Expiry Date.

There are sub sections listed under Settings:

1. Connect to Device
2. Disconnect from device
3. Enroll Device
4. Add Licenses
5. Logout
6. Backend
7. Dumpdata

The operators need not access / change this option unless troubleshooting.

This tab also displays Logout option, using which the user can log off the app.

4. Tutorial: This tab contains soft copy of the Operating Manual.

5.3 ENTERING ORGANIZATIONAL INFORMATION

Before beginning a scan, it is important to add the organizational details that will be used in report generation. Organizational details include Organizational Logo, and Name and Address of the organization.

TO ADD ORGANIZATION LOGO

1. Save the logo in png format in the phone gallery/ file manager.
2. Click on '**Edit Picture**' (highlighted in yellow in Figure 5.3- A Screen 1)
3. This will display the current logo, Now click on the logo above and select '**Gallery**' option for adding the desired logo from gallery.
4. Logo can be cropped as per requirement. Click on icon and save the changes. Logo will get successfully saved.

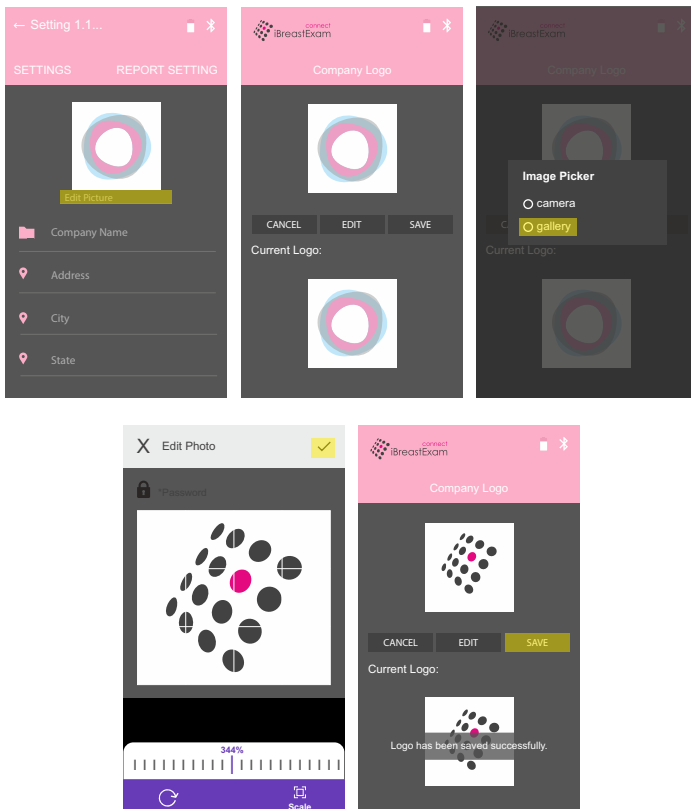


Figure 5.3 - A

1. Select 'Settings' from homepage, go to 'Report Settings'.
2. Enter the company information in the given fields, Refer Figure 5.3-B. It will be saved automatically

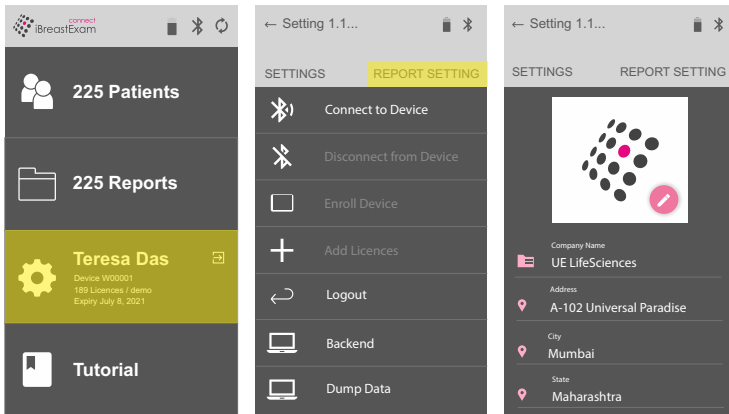


Figure 5.3-B

5.4 TO CONNECT iBE SCANNER TO THE MOBILE PHONE

The steps to follow are:

- 1) Switch **ON** the Scanner.
- 2) Make sure the iBE Connect App is launched and ready on Mobile phone. Connect the Scanner to mobile phone via Bluetooth connection. In most cases, the Scanner will be already paired with the Mobile Bluetooth.
- 3) In case Mobile Bluetooth is not paired with Scanner then follow the steps listed below:

To Pair a New Scanner:

1. To begin pairing you will need obtain the Bluetooth number of the Scanner. The Bluetooth (RNBT) number of the Scanner is registered with iBE Customer Support team against the Scanner serial number.
2. Once you have the Scanner BT number, select '**Settings**' on homepage.
3. Select 'Connect to device', Refer Figure 5.4-A.
4. This will display list of Bluetooth scanner. Select the Scanner BT number from the list and pair.
5. Once paired successfully Bluetooth icon will indicate successful connection, Refer Figure 5.4-A. Also, "**Connection established**" will pop-up at the bottom of the screen.
6. Once paired, the scanner needs to be enrolled to reflect the licences. Connect to Wi-Fi and select 'Enroll Scanner' to update Licences.

Make sure the mobile scanner is connected to Wi-Fi to enable and continue scanner enrollment and backup of data.

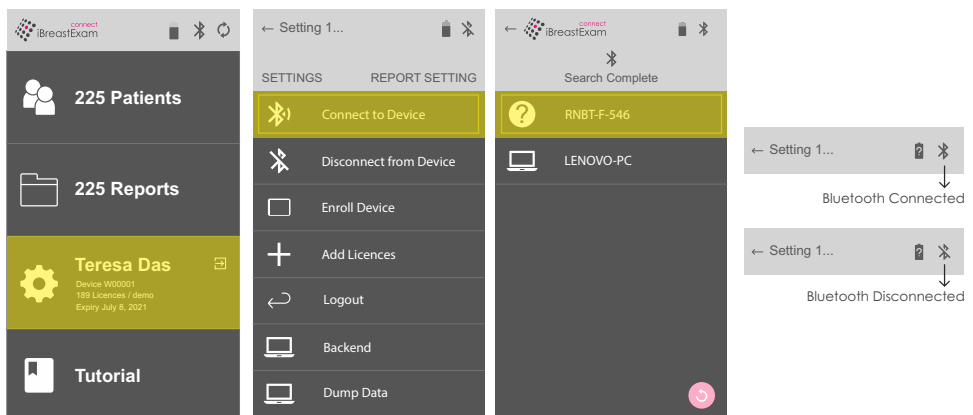


Figure 5.4-A

5.5 ENTERING PATIENT INFORMATION

To add new Patient, Refer Figure 5.5-A.

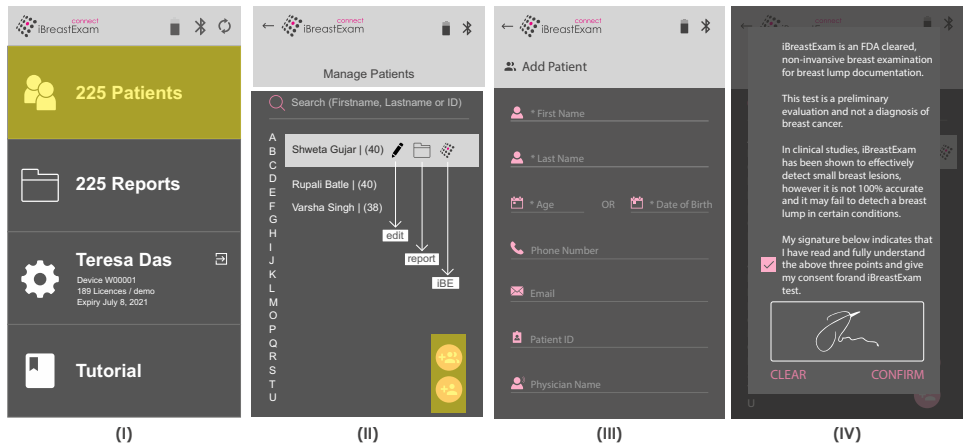


Figure 5.5-A

Once the patient details are entered and saved, it will take you to Consent Form, Refer Figure 5.5-A(IV).

Make sure the patient reads, acknowledges and signs off this form in the space provided before proceeding with the scan. Once the Consent Form is saved it will take you to the screening page.

To Edit an existing Patient's Information, go to Manage Patients and select the edit option.

5.6 STEPS TO DO THE SCAN

The screening page consists of a surface pressure map and the breast map. Each breast is divided into 16 squares which are referred to as tiles. Refer Figure 5.6A

The procedure consists of the following steps:

1. Air Calibration
2. Tissue Calibration
3. Breast Scan

STEP 1) Air Calibration: Hold the scanner in air & click on “**CALIBRATE**”

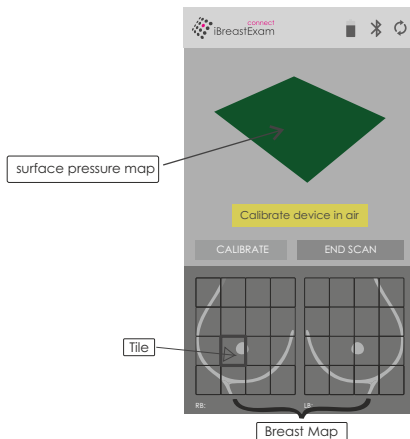


Figure 5.6-A

- The entire surface pressure map will be green.

After Air calibration, a message appears “**Calibrate device with tissue**”.

STEP 2) Calibrate: Tissue calibration is done to set the reference/base reading for the scanner. This reference reading will be used during the scan to compare and locate an area that is biologically stiffer than the reference reading. Tissue Calibration is necessary before starting any screening.

To do Tissue Calibration:

Place the scanner on tissue and apply a small amount of pressure.

A good Tissue calibration will give an even, complete red dome like structure.

Refer Figure 5.6-B for examples of correct and incorrect calibration.

Correct Calibration



Incorrect Calibration

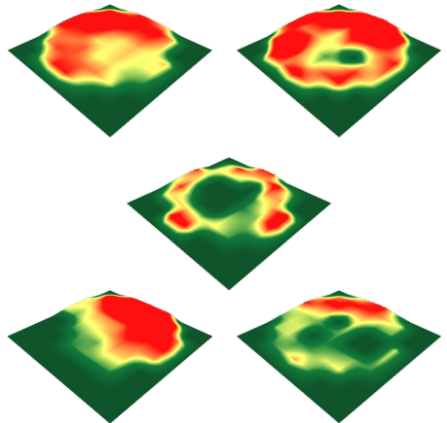


Figure 5.6-B

When you see an even, complete red dome like structure, press “**CALIBRATE**” . Wait for 3-4 seconds until the **surface pressure map** turns green and then pick up the scanner.

Calibration guide:

Breast Tissue Type	Calibration on	Scan on
For most types including droopy breasts (Here hold up the tissue throughout)	LB 12 o clock or 3 o clock (whichever has more tissue)	RB
	RB 12 o clock or 9 o clock (whichever has more tissue)	LB
Bony breasts (less tissue)	LB Inner RB Inner LB Outer RB Outer	RB Inner LB Inner RB Outer LB Outer

Figure 5.6-C

Calibration FAQs

How do I avoid a poor calibration?

- Maintain continuous contact with the grip pads throughout - while calibrating and scanning.
- Ensure the scanner is making uniform contact with breast tissue.

I put the scanner on the tissue but I don't see a dome. What do I do?

- Hold the scanner in air & press "**CALIBRATE**". After air calibration, a message appears- "**Calibrate device with tissue**"
- Next place it on tissue & wait for a dome to appear. When you see an even, complete red dome like structure, press "**CALIBRATE**". Wait for 3-4 seconds until the surface pressure map turns green and then pick up the scanner. This indicates that tissue calibration is complete.

Note : If you hold the tissue while calibrating, you should hold it while scanning as well.

Step 3) Breast Scan: First select the appropriate tile on the breast map. Refer Figure 5.6-D & follow the numbering for screening sequence. Now place the Scanner on the breast tissue.

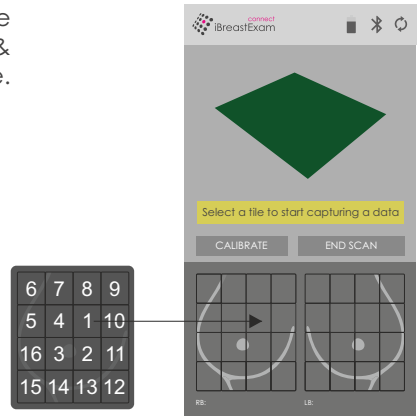


Figure 5.6-D

- Allow the scanner to be stabilized for a few seconds, there will be a message '**Capturing Data**', Refer Figure 5.6 E-(I). Ensure that the scanner is touching the tissue.

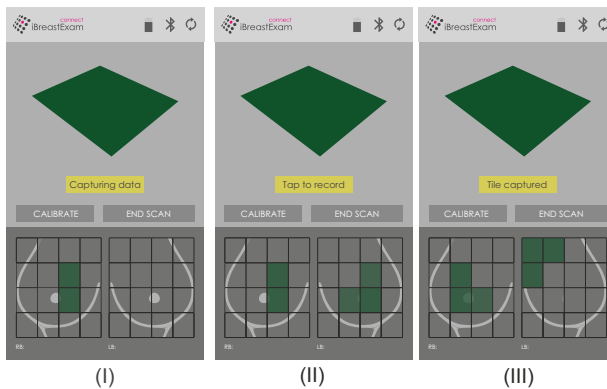


Figure 5.6-E

- Once stabilized there will be a message that says, '**Tap to Record**', Refer Figure 5.6 E(II). Hold the scanner in position for at least 5 seconds and then tap on the surface pressure map to record the reading.
- A message appears '**Tile Captured**': Refer Figure 5.6 E-(III).
- Operator must repeat the above-mentioned steps to complete screening for both the breasts as described in Figure 5.6E.

Frequent Appearance of Patchy Flares:

- Frequent appearance of disconnected yellow-red patches (Refer Figure 5.6 F), with shadows indicates poor tissue calibration &/or loss of Tissue calibration.
- Hold up the breast tissue firmly to ensure that the scanner has enough tissue to calibrate on.
- Recalibrate and then continue screening for the rest of the breast tissue.

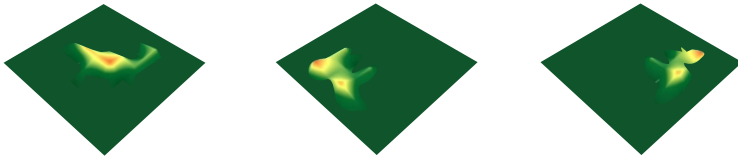


Figure 5.6-F

POSITIVE FINDING:

A well circumscribed structure with significant redness & limited yellow indicates positive finding.

Steps to confirm a positive finding:

Its mandatory to follow these steps before recording a positive finding.

1. Ensure that the finding persists for 4-5 seconds.
2. Lift the sensor & repeat #1.
3. Complete the rest of the breast exam.
4. Return to the locations that experienced any flares. Recalibrate & repeat #1.
5. Re-examine a previously examined normal area to ensure it looks normal as before. If not, recalibrate & repeat #1-4

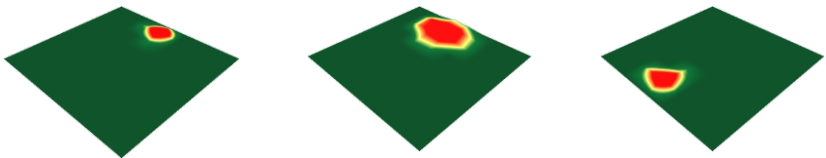


Figure 5.6-G

NOT A POSITIVE FINDING :

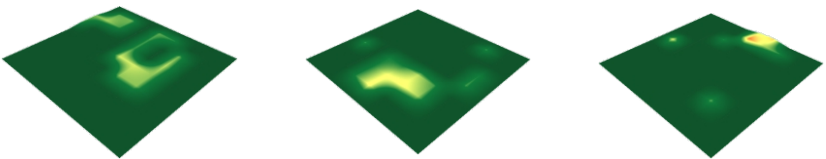


Figure 5.6-H

Please note : If the scanner is inactive for over 10 seconds, repeat air recalibration.

At any point during the scan, the operator can recalibrate by performing air calibration followed by tissue calibration.

- To conclude the scan, the user must click on '**END SCAN**' at the top corner, Refer Figure 5.6-I. Message showing '**CANCEL**' or '**CONFIRM**' pops up. To save scan, click on '**CONFIRM**' and wait for few seconds.

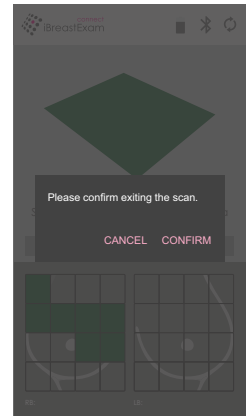


Figure 5.6-I

- Operator can enter notes and capture other patient information such as Symptoms, Family History and Survivor, Refer Figure 5.6-J.
- The operator can also record CBE, Mammography and Ultrasound findings, later if any, using Reports function. To do so follow the steps listed under Add/Edit Clinical Findings process listed under 'Reports' home page.
- Once the scan is saved, the screen will revert to home page.

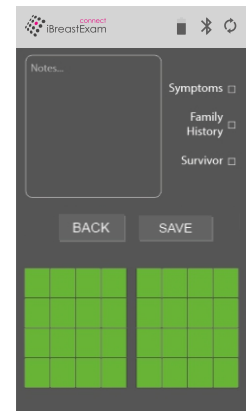


Figure 5.6-J

6 REPORTS

All scans are recorded and saved both as a record and pdf file. All reports can be viewed, replayed and printed through the 'Reports' option on the homepage, Refer Figure 6-A. On selecting '**Reports**', it displays list of patients screened. Further on selecting a patient, it lists the options, Refer Figure 6-A. These options include:

- A) Edit Clinical Findings
- B) View Report
- C) Replay scan

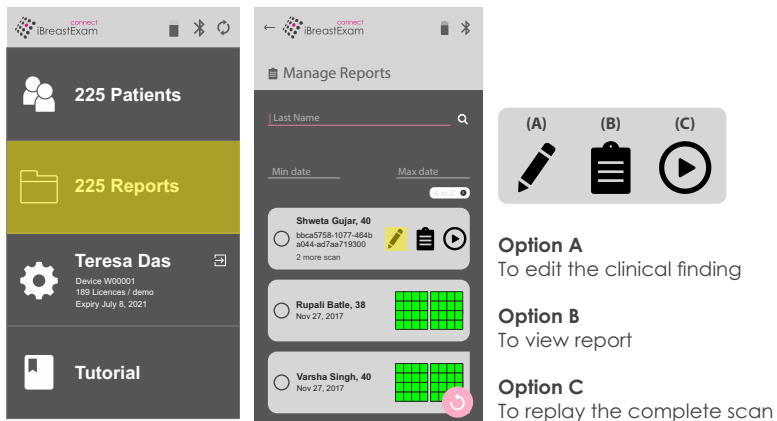


Figure 6-A

6.1 ADD/EDIT CLINICAL FINDINGS

Refer Figure 6.1-A, go to **Reports** on Homepage. Select patient, click on “**Add/Edit Clinical Findings**” icon. This will take you to the Clinical Findings page of that patient.

To mark, select the modality and single tap the appropriate quadrant. This process highlights the quadrant with a coloured square dot.

To unmark, simply tap modality, and the quadrant.

Because each modality is represented by a distinct colour; findings from all three aspects can be documented.

If there are no Clinical findings, leave the screen unmarked and proceed by selecting “**Save Clinical Finding**”.

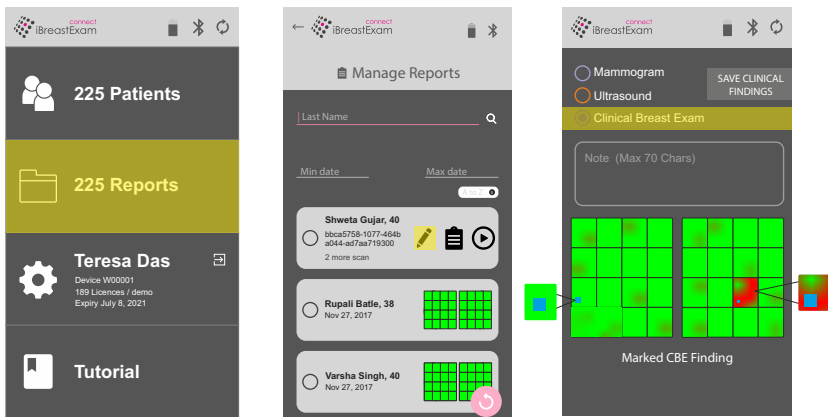


Figure 6.1-A

6.2 VIEW REPORT

All reports are listed by '**Patient Name**' and '**Report Date**'. This report list can easily be filtered to view all the positive scans and sorted either by alphabetical order and by date. This is done by using the '**Search**' icon, Refer Figure 6.2-A.

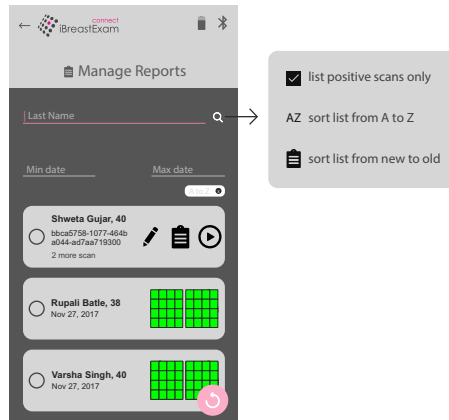


Figure 6.2-A

A report can be filtered based on Patient Name as well. To search a report simply type the patient name in the 'Search Reports' box, Refer Figure 6.2-B. Select a report by tapping on the patient name and this will display report options, Refer Figure 6.2-B. Select the '**View Report**' icon. This will display patient report.

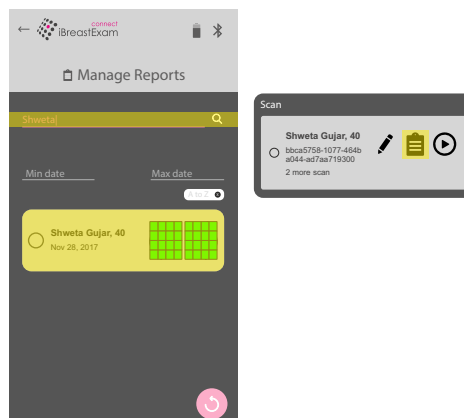


Figure 6.2-B

6.3 REPLAY SCAN

Replay Scan is the third option, Refer Figure 6.3-A. This option replays the scan, thus helping us to review calibration and other details about the scans for quality check and other verifications.

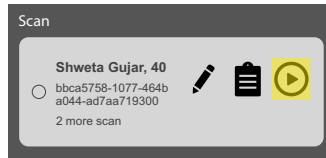


Figure 6.3-A

6.4 PRINTING/SHARING REPORT

At end of the screening, a pdf version of the report file is automatically generated at the backend in the Reports Folder, Refer Figure. 6.4-A

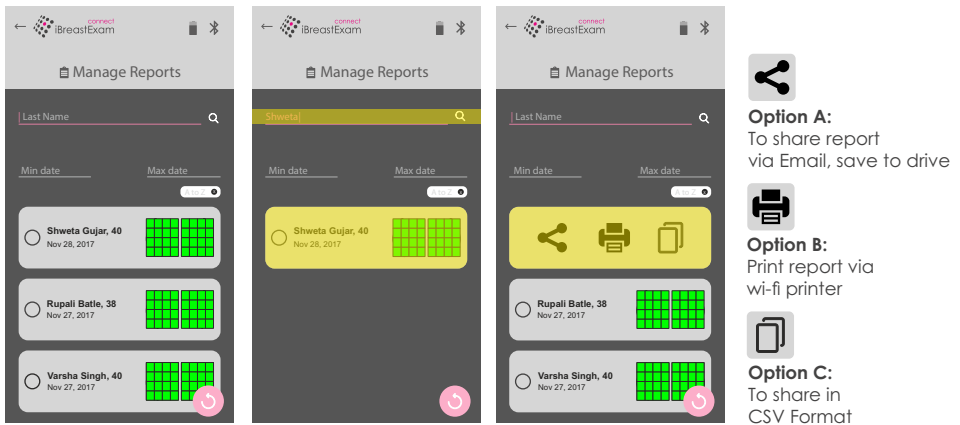


Figure 6.4-A

To select the report simply click on the patient's name. This will display report sharing options. The operator can then opt to print the patient's report through a Wi-Fi printer or share it via email as soon as the scan is finished. The reports can also be shared in CSV format via email.

Refer Figure 6.4-B shows two sample reports. The Report on the first Screen has **No Findings** or in other words there was no lump or lesion detected during the scanning process. The Report on the second Screen indicates a **Positive Finding** which means there was an area within the breast tissue that appeared biologically stiffer than the normal breast tissue and thus the follow up recommendation is “Consult Doctor”.

These reports are designed such as to schematically show the location/area of stiffness within the breast tissue. Thus, making the reports self-explanatory. Also, being a preliminary health check, the follow-up recommendation for all positive findings is the same i.e. Consult a Doctor. As there is no diagnosis/interpretation of the findings listed, it is possible to release these reports without a Doctor's signature.



Figure 6.4-B

6.5 SYNCHRONIZING DATA

Refer Figure 6.5-A shows how to sync the data from the mobile scanner. Connect mobile scanner to the internet. Open iBE Connect App and login with your credentials. On the homepage, select the synchronizing icon '↻'.

'**Synchronization Success**' will show up on the screen once the synchronization is complete.

Ensure complete synchronization before disconnecting the Wi-Fi.

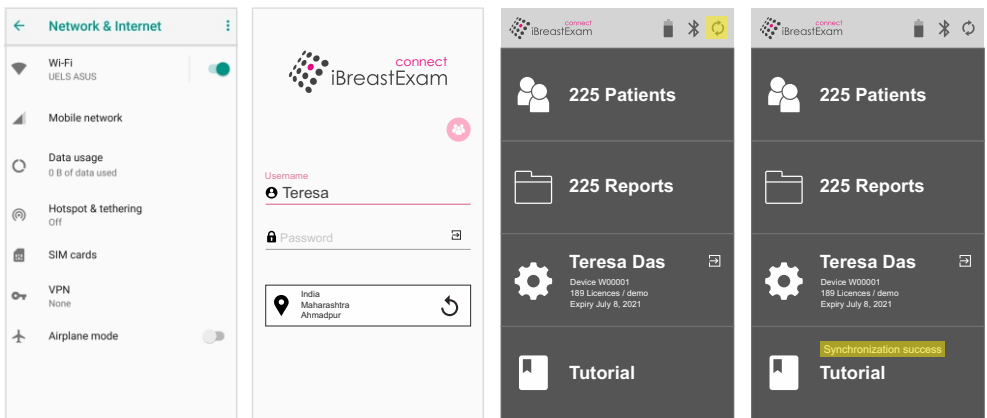


Figure 6.5-A

7 IBREASTEXAM FAQ

What do the colors in the report mean?

Green color in the report represents uniform elasticity of the breast tissue, indicating no areas of focal stiffness being detected by iBreastExam.

Red color in the report represents areas of the breast that indicate increased stiffness (higher elastic modulus) compared to the surrounding breast tissue. Clinically, this occurs due to breast lumps/lesions that are harder/stiffer than normal breast tissue.

What iBreastExam can/can't detect?

iBreastExam can detect abnormalities such as tumors both malignant and benign which include: Hyperplasia, Fibrosis, Fibroadenoma, Phyllodes Tumors, Macrocalcifications, Fat necrosis (oil cysts), Granular cell tumors and all major types of breast carcinomas.

iBreastExam is limited in its ability to detect certain breast conditions that do not provide an elastic modulus differential that is detectable from skin surface. These are simple cysts, Micro-calcifications, Lobular carcinoma in-situ, Inflammatory Breast Cancer (has no lump) and Mucinous cancer (colloid carcinoma).

In various published clinical studies, iBreastExam has demonstrated sensitivity of 84 – 87%, specificity of 88 – 94% and negative predictive value of 96 - 98% to detect clinically relevant breast lesions. To learn more about iBreastExam, please visit www.iBreastExam.com/doctors. This webpage is specifically designed for clinicians to learn more about iBreastExam clinical evidence, regulatory approvals and answer other clinical questions you may have.

8 INDICATIONS AND CONTRAINDICATIONS

Indications:

- The iBE is intended to document breast lesions as an adjunct to the CBE.
- iBE is intended to be used in the hospital, acute care settings, outpatient surgery and health care practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel. iBE is used as an aid to document palpable breast lesions identified and/ or monitored during a clinical breast exam.
- This scanner is intended for use by qualified healthcare personnel trained in its use.
- The iBE system is not a substitution or replacement for mammography or clinical breast examination.

Contraindications:

- iBE should not be used as a diagnostic scanner to confirm the presence of breast cancer, rather it should only be used as a breast lesion documentation system.
- iBE should not be used on animals or birds for any purpose.
- iBE should not be used on open wounds and skin infections on breast.
- iBE should not be used in/around an MRI field.

9 WARNINGS AND PRECAUTIONS

1. iBE is a preliminary breast health check or a screening test. It is not a confirmatory diagnostic test.
2. iBE is not compatible for use in an MRI magnetic field.
3. Do not operate this system without proper training.
4. Please report malfunctioning or damaged components to iBE Customer Support team immediately.
5. There are no adverse reactions or contraindications. There is no harmful exposure (x-rays, ionizing radiation) from the iBE system. This is a safe test.
6. Do not operate this system in the presence of inflammable gases or anesthetics. Explosions can occur.
7. Do not attempt to fix any broken parts or sensors.
8. All internal adjustments and replacements must be made only by a qualified technician from UE LifeSciences (India) Pvt. Ltd.
9. Handle the scanner with care. Sensors are delicate in nature.
10. As per the Warranty Certificate, Damage like Mechanical shock due to fall of scanner or due to application of over pressure while screening is not covered under warranty because it is caused due to mishandling.
11. Do not use pen/any sharp object to adjust the sensors. If the sensors get stuck in the grid or anything happens to the sensors, please contact iBE Support Team for further assistance.
12. Kindly note that only iBreastExam trained operators are authorized to use the scanner. Also, this is highly recommended as use of scanner by untrained professionals can lead to damage of the sensors and improper results.

10 BASIC TROUBLESHOOTING GUIDE

Sr. No.	Problem	Solution
1	Android app shows "Software needs to be updated"	<ul style="list-style-type: none"> · Connect the mobile phone to internet · Go to phone settings · Search for system updates · Install system update (if update is available)
2	Application crashes/shuts down on its own	<ul style="list-style-type: none"> · Restart mobile phone and the scanner · Update System Software (if update is available) · Update the iBE connect V2.0 application from Play store (if update is available)
3	License not appearing on the software	<ul style="list-style-type: none"> · Connect the mobile phone to the internet using mobile data/ Wi-Fi · Check the strength of the internet connection by just searching iBE on google · Switch on the scanner · Connect the scanner to the mobile phone · Login into the iBE connect application · Go to settings in the dashboard · Tap on enroll scanner only once · Go back to the dashboard and wait for around 10-20 seconds · License and scanner number will appear on the software · If problem is not resolved by above solution, then kindly contact our technical support team
4	Scanner is not charging	<ul style="list-style-type: none"> · Check if the green LED light of the scanner glows while it is plugged in for charging · If not, verify that the scanner and charging port are not damaged on the surface · If the issue persists, change the adaptor and check again · If problem is not resolved by above solution, then kindly contact our technical support team

5	Scanner does not connect	<ul style="list-style-type: none"> · Check if the scanner is charged (it takes 5 hours for full charging) · Check the Bluetooth in the mobile phone is switched on or not
6	Not able to login to iBE connect application	<ul style="list-style-type: none"> · Please verify that the correct login id and password has been used · If the user has forgotten the password & is unable to login: · Go to manage users · Choose the existence name>click on edit button>change the password>click on save button which is on right side · Go back to the login
7	Scanner is disconnected during "Scanning"	<ul style="list-style-type: none"> · Turn OFF the scanner and ON it again · Stay on scanning mode · Click on Bluetooth symbol which on right side top corner. A Bluetooth connected message will appear and continue the scan

Please Note:

The mobile phone should be connected to the internet via a local Wi-Fi 4G network on a weekly basis to sync data. This will enable the service team to get regular updates on the working of the scanner and identify potential issues.

11 CUSTOMER SUPPORT CONTACTS

iBreastExam Customer Support Team
Email: support@uelifesciences.com
Phone: +91 22 26636266 | +91 70454 57056



USA | India | Malaysia