iBreastExam
early detection. for all

OPERATING MANUAL

FDA UNICERT ISO 13485 UNICERT MHLW-GMP CE

UELSIPL/Training/28/F-03-00

CONTENTS

1 SYSTEM OVERVIEW

iBreastExam™ (iBE) is a non-invasive, hand-held, fully wireless mHealth point-of-care solution for breast lesion detection. It uses patented piezoelectric ceramic sensor technology that electro-mechanically palpates the breast tissue to differentiate variances in tissue elasticity. 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 device. 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

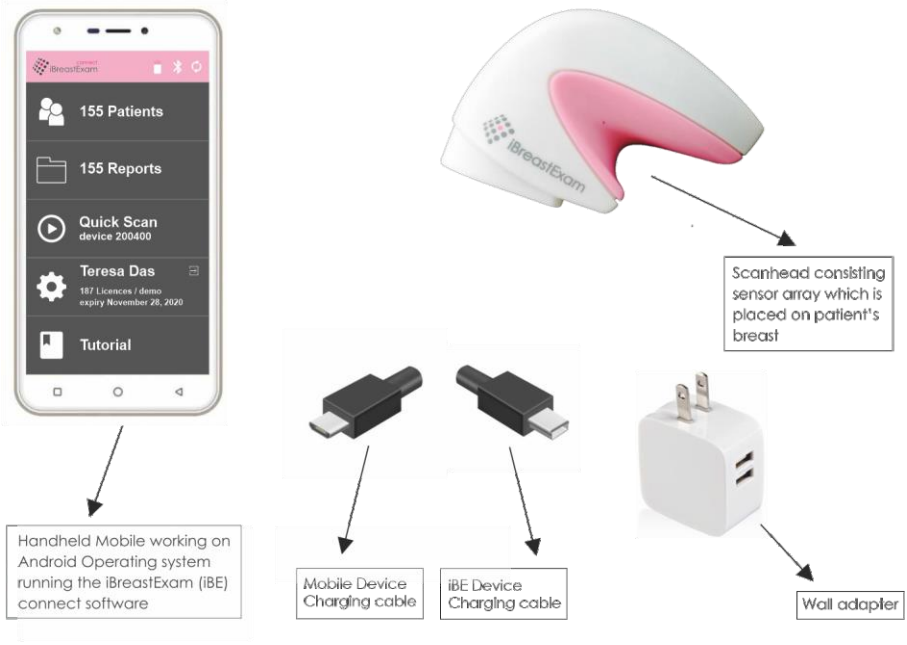

Figure 2-A

The iBE system consists of a Scanhead, 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 Scanhead houses 16 piezoelectric 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 Scanhead 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. Make patients put their arms above their head and ask if they will be comfortable in the same position for 3-5 minutes. If patient cannot hold her arms above her head for 3 – 5 minutes, she can 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 but they may feel mild vibrations of the sensors during the test.

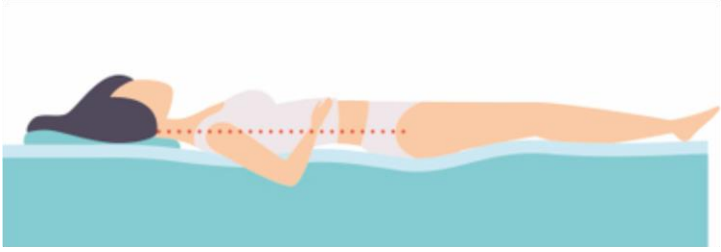

Figure 3-A

4 HOW TO USE iBE CONNECT HARDWARE

iBE Hardware includes the Scanhead 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 Scanhead usage like charging, screening and maintaining.

4.1 CHARGING THE SCANHEAD

Figure 4.1-A

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

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

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

Point C is the indicator light which lights up when the Scanhead is ON. The green indicator light will not light up if the Scanhead 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 SCANHEAD

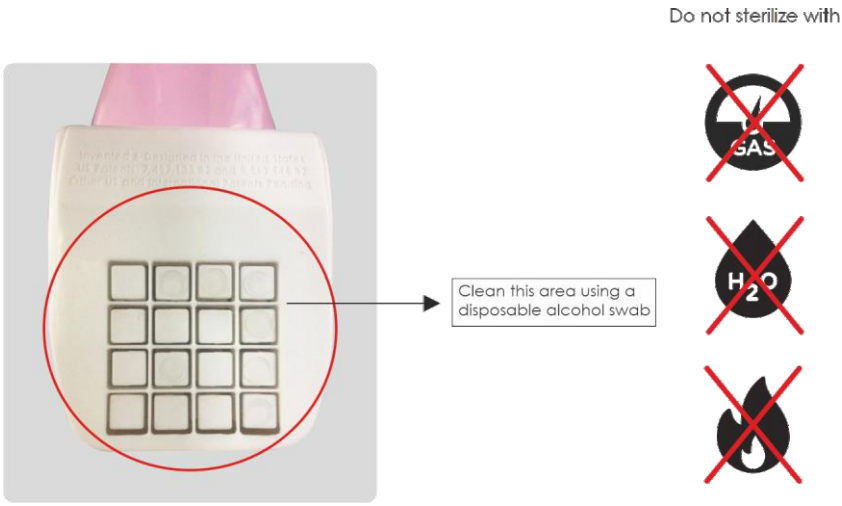

Figure 4.2-A

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

It's important to sanitize the Scanhead 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 Scanhead using gas, heat or liquid.

DO NOT autoclave the Scanhead.

These methods may permanently damage the Scanhead.

4.3 HOW TO HOLD THE SCANHEAD

Figure 4.3-A

During the use of iBE, the Scanhead sensors must remain in full contact with the breast tissue as shown in Figure 4.3-A. While scanning the breast tissue, the Scanhead must be held at an angle such that all 16 sensors are in contact with the breast tissue with *optimal pressure*.

The breast may not be correctly mapped if there is an error in the positioning of the Scanhead.

5 HOW TO USE iBREASTEXAM CONNECT APPLICATION

This section mainly covers steps required to connect iBE Scanhead 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) Connecting the Scanhead to Mobile device
4) Entering Organizational Information
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.

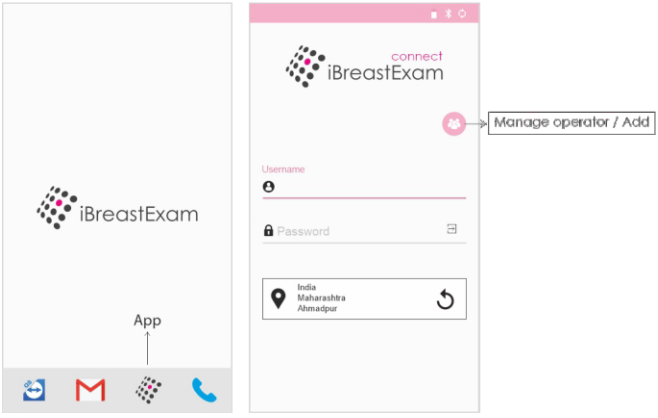

Figure 5.1-A

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

5.2 iBE CONNECT APPLICATION HOMEPAGE LAYOUT AND ITS FEATURES

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

There are five main sections listed on the homepage:

1. Patients
2. Reports
3. Quick Scan
4. Settings
5. 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.

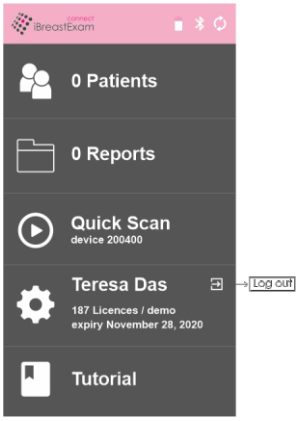

Figure 5.2-A

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. Quick Scan: As the name suggests, this function is meant to be used to perform a scan on a New Patient. Selecting this, takes the operator directly to "Add Patient Information" screen and from thereon to consent form and scan.

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

Scanhead 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.

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

5.3 TO CONNECT iBE SCANHEAD TO THE MOBILE DEVICE

The steps to follow are:

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

To Pair a New Scanhead:

1. To begin pairing you will need obtain the Bluetooth number of the Scanhead. The Bluetooth (RNBT) number of the Scanhead is registered with iBE Customer Support team against the Scanhead serial number.
2. Once you have the Scanhead BT number, select 'Settings' on homepage.
3. Select 'Connect to device' (Refer Figure 5.3-A).
4. This will display list of Bluetooth devices. Select the Scanhead BT number from the list and pair.
5. Once paired successfully Bluetooth icon will indicate successful connection, Refer Figure 5.3-A. Also, **"Connection established"** will pop-up at the bottom of the screen.
6. Once paired, the device needs to be enrolled to reflect the licences. Connect to Wi-Fi and select 'Enroll Device' to update Licences.

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

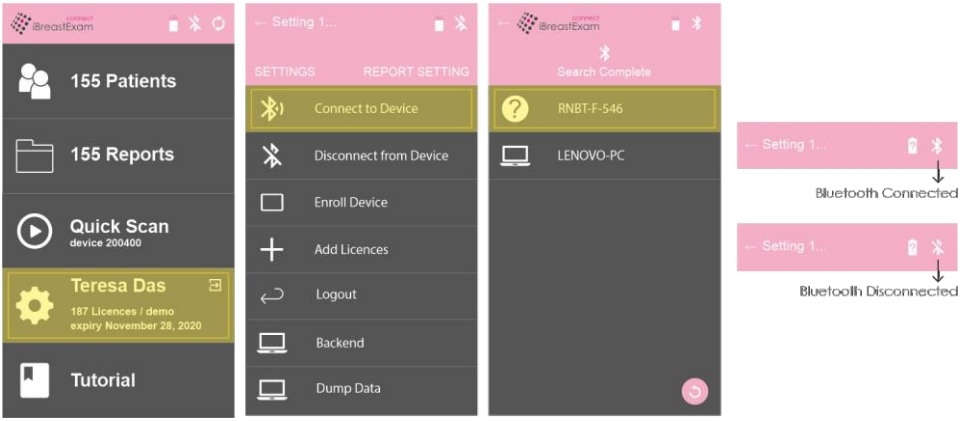

Figure 5.3-A

5.4 ENTERING ORGANIZATIONAL INFORMATION

Before beginning a scan, it is important to add the organizational details that will be used in report generation.

1. Select '**Settings**' from homepage, go to '**Report Settings**'.
2. Enter the company information in the given fields, Refer Figure 5.4-A. It will automatically get saved.

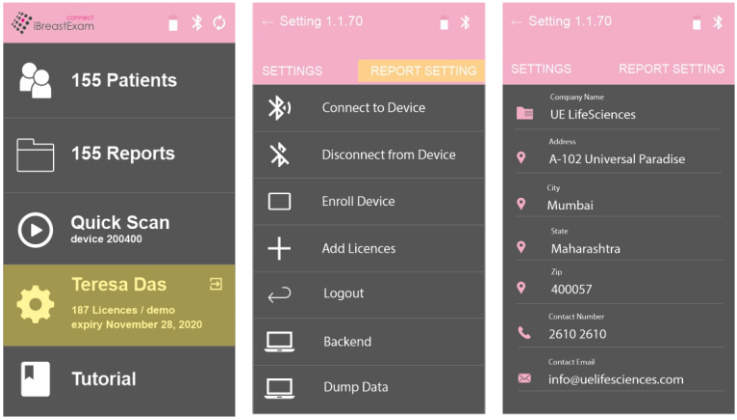

Figure 5.4-A

1. TO ADD ORGANIZATION LOGO

The next step is to upload organization's logo. To add the logo:

1. Save the logo in png format in the phone gallery/ file manager.
2. Select '**Settings**' from homepage, go to '**Report Settings**'.
3. Click on '**Edit Picture**' (highlighted in yellow in Figure 5.4- B Screen 1)
4. This will display the current logo, Now click on the logo above and select 'gallery' option for adding the desired logo from gallery.
5. Logo can be cropped as per requirement. Click on ✓ icon and save the changes. Logo will get successfully saved.

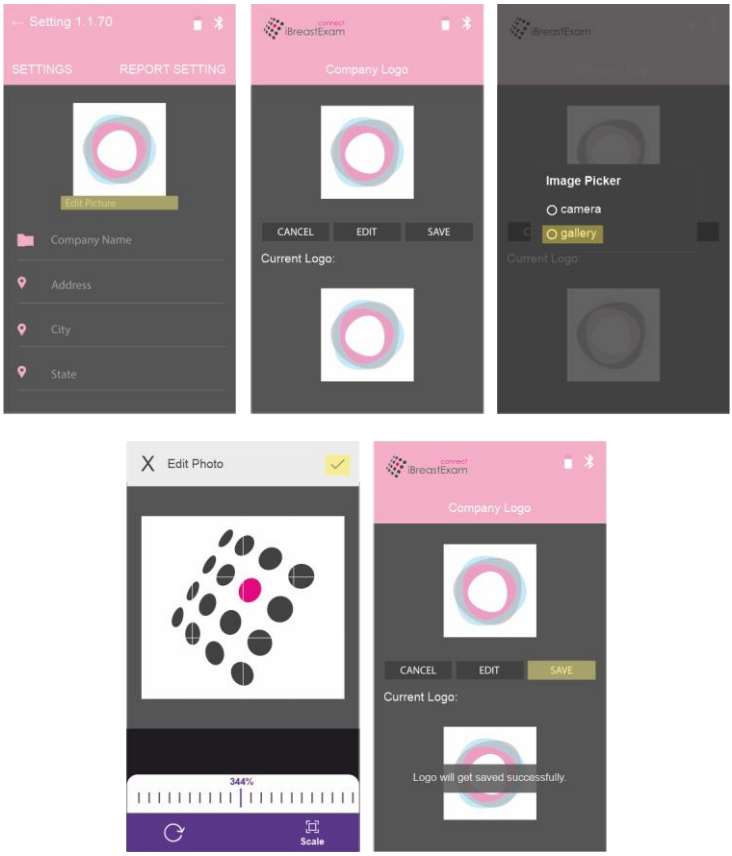

Figure 5.4-B

5.5 ENTERING PATIENT INFORMATION

Use '**QUICK SCAN**' to add new Patient, Refer Figure 5.5-A.

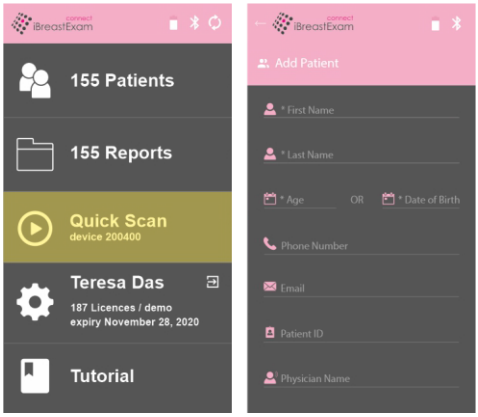

Figure 5.5-A

Information such as Patients First Name, Last Name and age are mandatory fields that need to be filled in before proceeding. Once the patient details are entered and saved, it will take you to Consent Form, Refer Figure 5.5-B.

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.

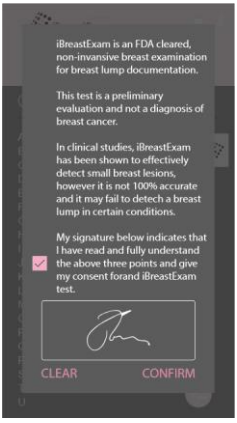

Figure 5.5-B

If a scan is to be performed on a patient whose name already exist in the Patient lists, then the operator will have to follow these steps (Refer Figure 5.5- C):

- Select **Patients** option on the homepage
- Under Manage Patients list search for that existing patient.
- Selecting the patient will display options, Refer Figure 5.5-C.
- Select iBE icon to begin a scan.
- Select edit icon to edit patient details.
- Select report icon to view any scans if done in past, Refer Figure 5.5-C.

- Select icon to add multiple patients at a time
- Select icon to add single patients at a time

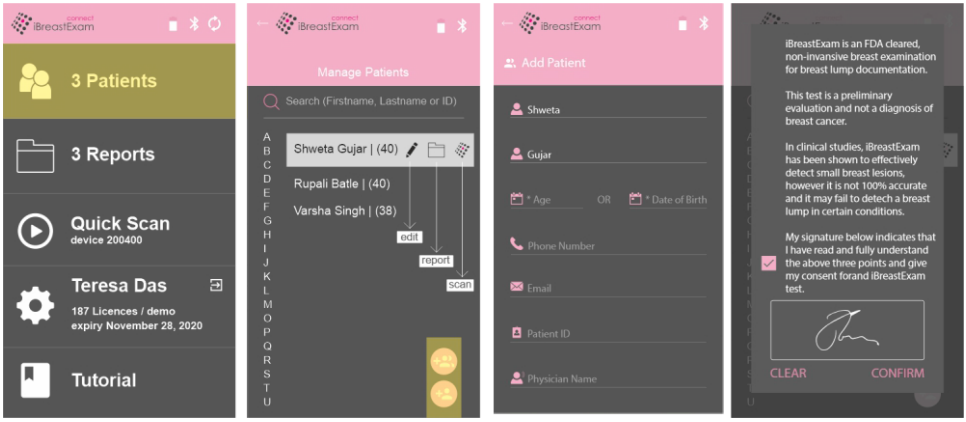

Figure 5.5-C

5.6 STEPS TO DO THE SCAN

Once the patient information is entered and "Consent form" signed, it will take you to the scanning page.

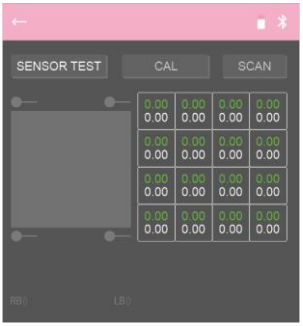

Figure 5.6-A

Scanning comprises of three main Steps:

1) Sensor Test
2) Calibrate
3) Breast Scan

STEP 1) Sensor Test: *Sensor test* is done by selecting 'Sensor Test'. Refer Figure 5.6-B. This step checks the sensors to see if they are healthy and working fine. Once the sensors pass the test, the operator can now Calibrate. ***If a Scanhead fails sensor test, please reach out to iBE Customer Support Team (contact details listed on last page) for further instructions.*** A Scanhead with failed sensor test will not be allowed to perform calibration or the scan.

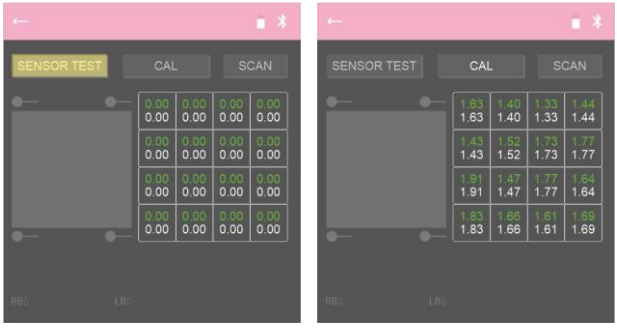

Figure 5.6-B

STEP 2) Calibrate: *Tissue calibration* is done to set the reference/base reading for the sensors. 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 new screening.

A good Tissue calibration will range anywhere between 0.25-0.80

In Figure 5.6-C, you will notice a blank square with highlighted horizontal bars bordering on upper and lower side. These are Pressure Sensors;

- They indicate the amount of pressure applied on the sensors.
- Pressure sensor bars have points that move, and change colour based on the amount of pressure.
- There are three colours: red (indicates no pressure & high pressure), yellow & green (indicates mid & normal pressure respectively)

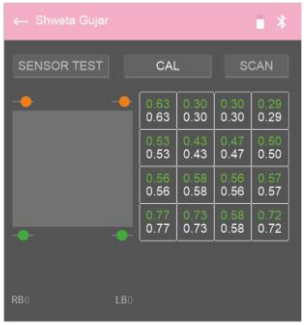

Figure 5.6-C

<u>To do Tissue Calibration:</u>

- Select CAL (Refer Figure 5.6-C) and simply put the Scanhead on the breast such that every sensor touches the breast tissue. Adjust the placement of the device on breast tissue so that all the pressure sensors are either yellow or green (never a red).
- Now hold it there steadily for a few seconds. Once the desired pressure is achieved and the numbers are within calibration range; keep hand stable; in a few seconds the software will auto calibrate.
- Once the calibration is successful it will display '**Calibration Complete**' at the bottom.
- If the calibration is not completed in 2 minutes, it will suggest to proceed with **'Manual Calibration**' mode. If you select '**NO**', it will revert back to Auto calibration.
- If you wish to proceed with Manual Calibration, select '**YES**'. Now simply, repeat the tissue calibration steps. Once the desired pressure is achieved, and the numbers are within calibration range, Select **'Manual Cal**' (Refer Figure 5.6-D) to freeze the reference readings.

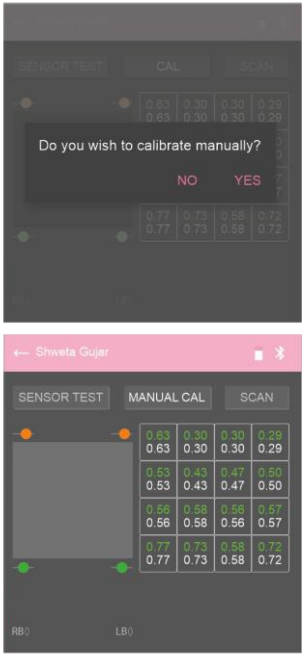

Figure 5.6-D

Step3) Breast Scan: Begins post Tissue Calibration.

To begin scanning,

- Select 'Scan' Refer Figure 5.6-C. This will activate the sensors.
- Now place the Scanhead on the breast tissue and select the corresponding square in the breast diagram on the mobile screen. Refer Figure 5.6-D & follow the numbering for screening guidance.
- Allow the scan head to be stabilized for a few seconds, such as the pressure bars are either yellow or green, all the sensors are touching the tissue and hold your hand steady for a few seconds.
- Once stabilized there will be a message that says, 'Ready to Record'. At this point operator can click on the capture square to record the reading.
- Once captured the selected Square will flash BLUE indicating a successful capture.
- Operator must repeat the above-mentioned steps to complete screening for the whole breast.

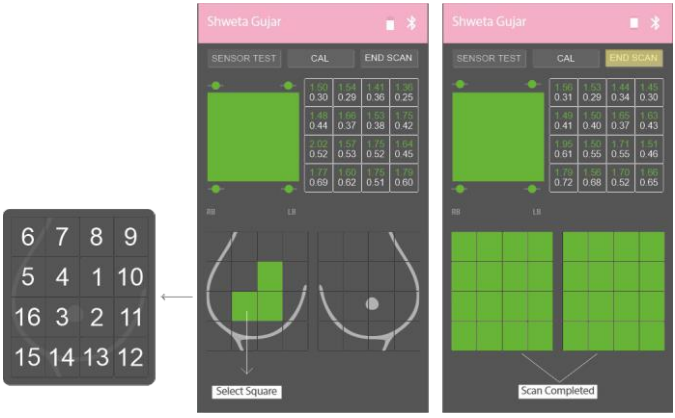

Figure 5.6-D

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

Once the scan is saved, the screen will revert back to home page.

Operator can enter notes and capture other patient information such as Symptoms, Family History and Survivor (Refer Figure 5.6-E).

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.

Figure 5.6-E

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

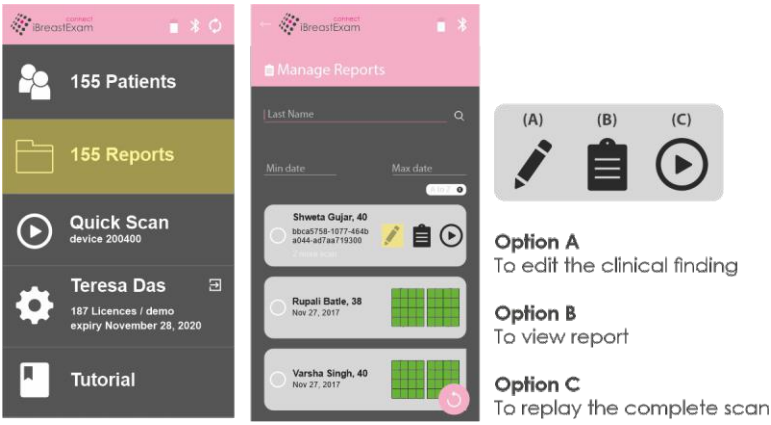

Figure 6-A

6.1 ADD/EDIT CLINICAL FINDINGS

Refer Figure 6.1-A, go to **Reports** on Homepage. Select patient, c lick 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**".

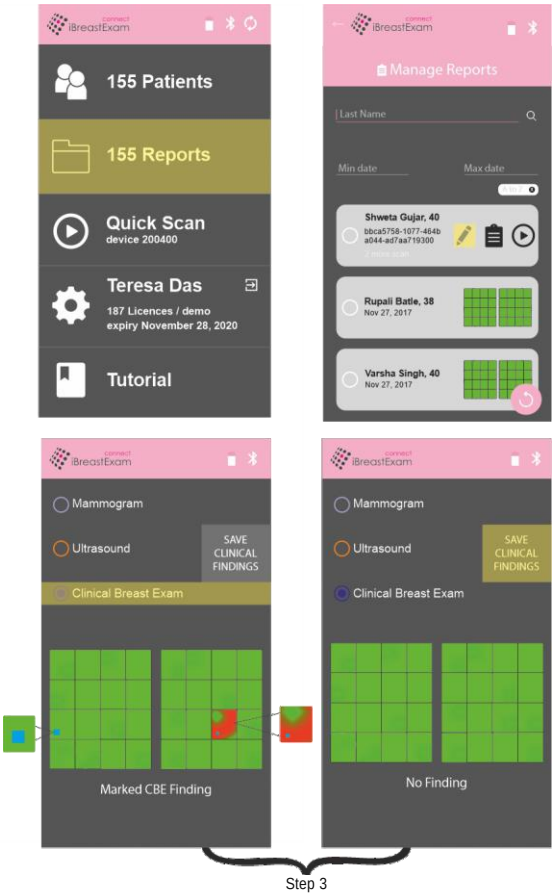

Figure 6.1-A

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.

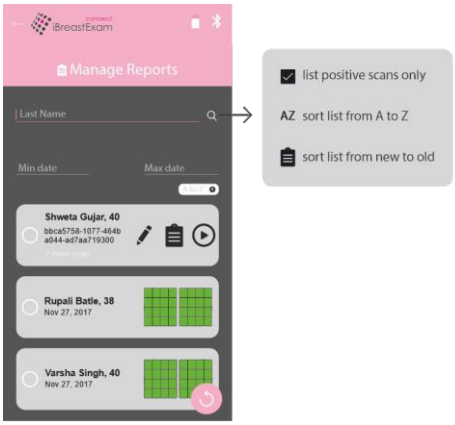

Figure 6.2-A

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.

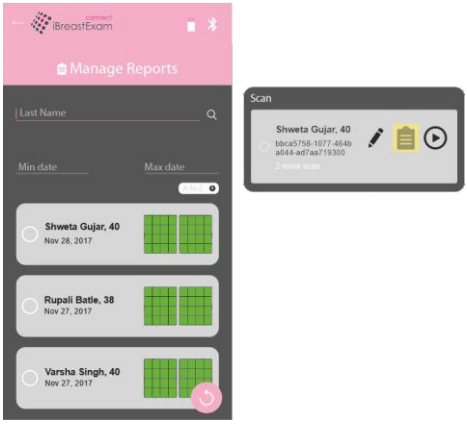

Figure 6.2-B

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.

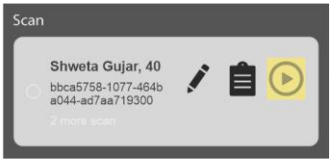

Figure 6.3-A

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

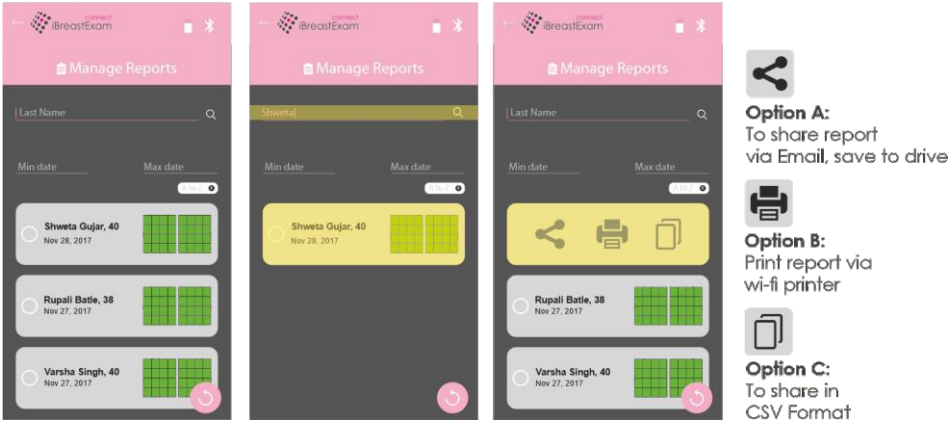

Figure 6.4-A

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.

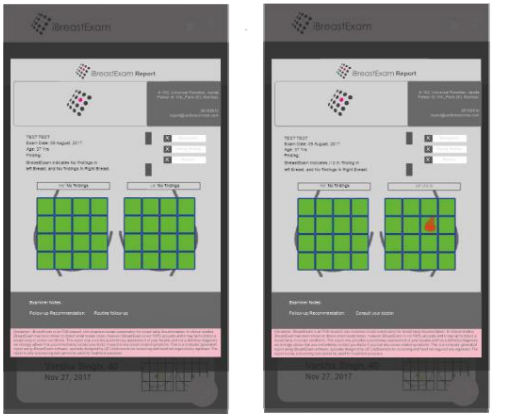

Figure 6.4-B

6.5 SYNCHRONIZING DATA

Refer Figure 6.5-A shows how to sync the data from the mobile device. Connect mobile device 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.

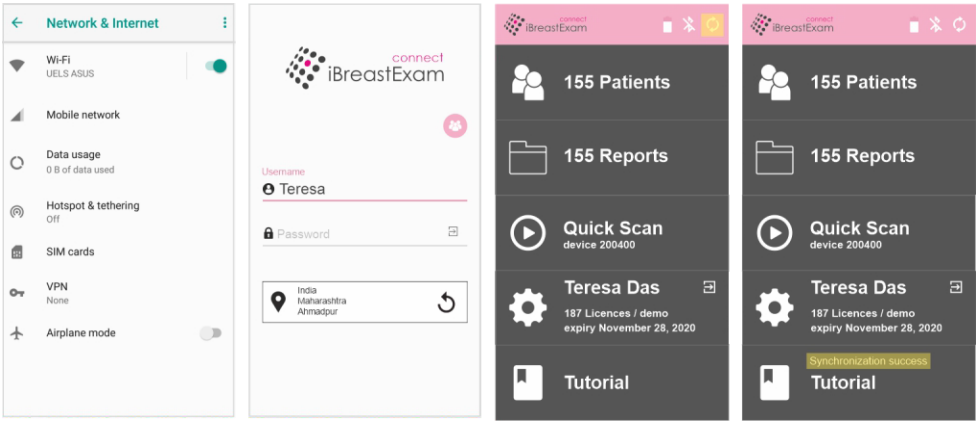

Figure 6.5-A

7 WHAT iBREASTEXAM CAN/CANNOT DETECT?

iBE can detect abnormalities such as tumors both malignant and benign which include:

- hyperplasia
- fibrosis
- fibroadenoma
- phyllodes tumors
- macro calcifications
- fat necrosis (oil cysts)
- granular cell tumors
- all major types of breast carcinomas

iBE is limited in its ability to detect breast conditions such as:

- Small cysts (fluid-filled sacs within the breasts); most women with fibrocystic changes and no bothersome symptoms do not need treatment but closer follow-up may be advised.
- LCIS (cells that look like cancer cells are growing in the lobules of the milk-producing glands of the breast. Does not cause a tumor that can be felt or changes that can be seen on a mammogram and it doesn't become an invasive cancer if it isn't treated)
- Inflammatory Breast Cancer (has no lump)
- Micro-calcifications
- Mucinous cancer (colloid carcinoma) a rare form of invasive ductal carcinoma; here the tumor is made up of abnormal cells that 'float' in pools of mucin, a key ingredient in the slimy, slippery substance known as mucus.

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 device 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 device 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 device with care. Sensors are delicate in nature.

10. As per the Warranty Certificate, Damage like Mechanical shock due to fall of device 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 device. Also, this is highly recommended as use of device 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	· 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	· Restart mobile phone and the device · 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	· 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 device · Connect the device to the mobile phone · Login into the iBE connect application · Go to settings in the dashboard · Tap on enroll device only once · Go back to the dashboard and wait for around 10-20 seconds · License and device number will appear on the software · If problem is not resolved by above solution, then kindly contact our technical support team
4	Scanhead is not charging	· Check if the green LED light of the scanhead glows while it is plugged in for charging · If not, verify that the device 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	Not able to perform scans using "Quick scan"	· Check if the device is connected to the iBE connect app or not · Check the dashboard of the software to see if any licenses are available · If not, please connect the mobile to the Wi-Fi/ data and enroll the device. Once the licenses are credited you can start scanning · Check if all the checkboxes in the consent form are selected and signed.
6	Failed Sensor Test Calibration option is greyed out	· iBE Scanhead with failed sensor test will not be allowed to do patient scan, thus calibration option will not be available or greyed out · Contact iBE Customer Support Team for further assistance
7	Device is disconnected during "Scanning"	· Turn OFF the device 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
8	Takes long time for "Calibration"	· Tissue must be tight, rub the tissue to loosen it · Try on another side 3/9 o'clock · Apply optimum pressure for calibration · Ensure that all the sensor should touch the tissue and range of the tissue calibration is between 0.25 to 0.80 · If the issue persists, Manual calibration is available (if calibration is not done by above method then try manual calibration)

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 device and identify potential issues.

11 CUSTOMER SUPPORT CONTACTS

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


iBreastExam
early detection. for all
UE LifeSciences