



# OPERATING GUIDE

UE/CR/01/01-04



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# 1. iBreastExam

## iBreastExam Components

Scanner\* with removable sensor cartridge  
(\*actual colors may vary)



Smartphone (optional) with iBreastExam app



Charging cables (for scanner and phone) and wall adapter(s) (optional)



### Number Types:

- Device number:
- Bluetooth number:
- Serial number:

### Format:

- W123456 / T12345678
- iBExx\_[Device number]
- i1234-56789

### Location:

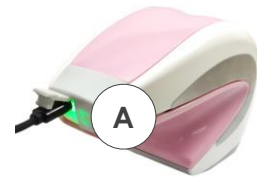
- App main menu
- Bluetooth settings
- Pink underside of scanner

## Charge the Scanner

1. For the first-time use, charge the scanner for at least 6 hours. After that, charge the scanner depending on usage (a full charge takes 6 hours).

**Battery light** (A, inside the charging port):

- Green light while being charged → Device is charging.
- No light while being charged → Device is fully charged.



2. Turn on the device using the power button (⏻).

**Power light** (B, on the back of the device):

- Green light → Device is on.
- No light → Device is off.



**Important:** Turn off the scanner after use, as it does not turn off automatically.

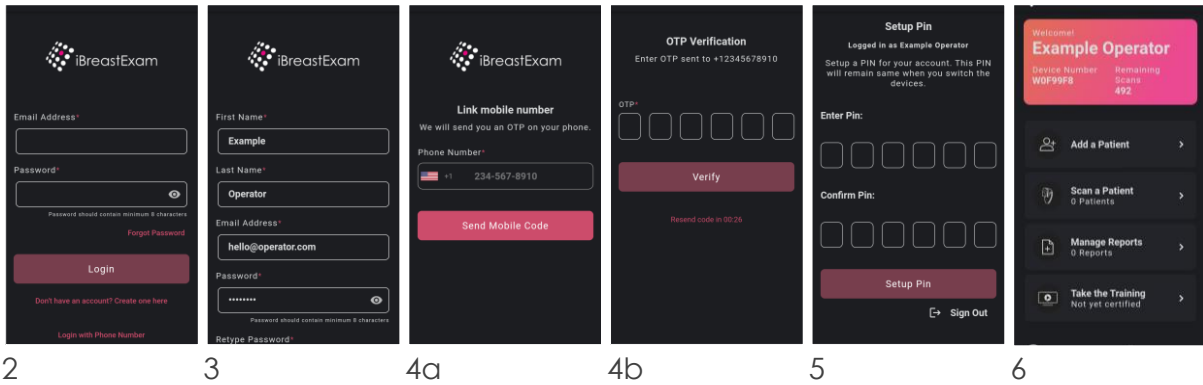
## Log in to the App

### First-time Use (Sign-up):

1. Open the iBreastExam app on your mobile phone.
2. Tap on *Don't have an account? Create one here.*
3. Enter your account details. Adding your mobile number is optional but highly recommended, as you cannot add it later. Select *Sign up.*
4. If you added a mobile number, verify it with a one-time password (OTP):
  - a) Enter your mobile number and select *Send Mobile Code.*
  - b) Enter the OTP that was sent to your mobile phone and select *Verify.*
5. Enter and confirm your own PIN code. Select *Setup Pin.*
6. The app takes you to the main menu.

**Important:** Only your organization's admin can edit your username.

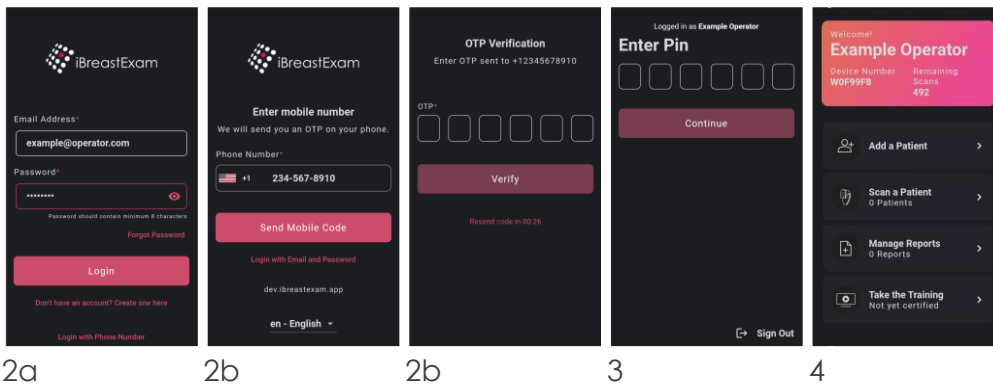
**Note:** The same user can be logged in to multiple mobile phones.



### Regular Use (Sign-in):

1. Open the iBreastExam app on your mobile phone.
2. Sign in via entering your
  - a. Email address and password. Select *Login*.
  - b. Mobile number and OTP. Select *Send Mobile Code*. Enter the OTP sent to your phone and select *Verify*.
3. Enter your PIN and select *Continue*.
4. The app takes you to the main menu.

**Note:** If the app is closed or inactive for more than 3 minutes, you must re-enter your PIN code.



### Connect the Scanner to the App

1. Ensure the scanner is turned on.
2. Ensure the phone's Bluetooth is turned on.
3. Open the iBreastExam app and login to your account.
4. The scanner automatically connects to the app.

**Connection light** (C, below the pink or silver cover):

- Light blinking → Device is looking for a connection.
- Light stops blinking → Device is connected.



5. Tap on *Done* in the *Bluetooth Connection Status* pop-up message.

**Tip:** If the green light does not stop blinking, tap on the Bluetooth icon (📶) in the top right corner of the main menu or see → [Troubleshooting](#).

## 2. Breast Scans

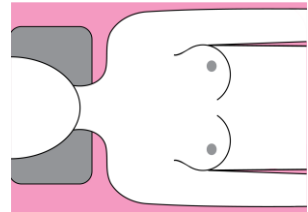
### Register and Select a Patient

1. In the main menu, select *Add a Patient*.
2. Add and save the patient information.
  - If you want to proceed with scanning the patient, select *Start Scan*.
  - If you don't want to proceed with scanning the patient, select *Done*.
3. To scan a previously registered patient, tap on *Scan a Patient* in the main menu and select a patient from the list.
4. The app takes you to the *Patient Consent Form*. Ensure the patient reads, understands, and signs the form.
5. Select the appropriate breast size for the patient.
6. Confirm that the patient's breast tissue and the sensor area have been cleaned.
7. Proceed to the scanning page.

### Prepare the Patient

To perform a scan, the patient should:

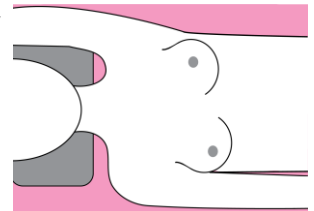
- ✓ be disrobed from the waist up,
- ✓ lie down on the back on a stable surface, and
- ✓ have the breast tissue wiped with wet wipes.



### Position the Patient

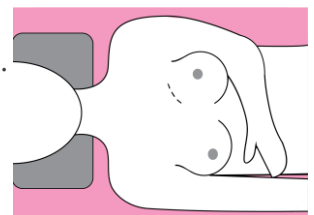
- ✓ To place the sensor evenly on **breast tissue that is not easily accessible**, such as the inframammary fold, place the patient's arm above the head. This is especially useful for:

- Better accessing lower and outer breast areas.
- Larger breast sizes that fall down or to the side.
- Saggy breast tissue that falls down or to the side.



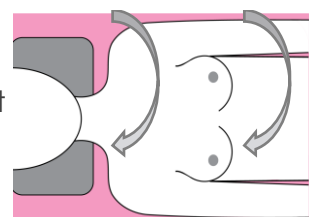
- ✓ To **increase the volume of the (inner) breast tissue underneath the sensor**, fold the patient's arm across the rib cage. This pushes the tissue upwards or towards the middle of the chest. This is especially useful for:

- Increasing the tissue volume in upper and inner breast areas with low tissue volume.
- Small breast sizes, especially in bony areas (rib cage).
- Saggy breast tissue that falls down or to the side.



- ✓ To **increase the volume of the (outer) breast tissue underneath the sensor**, slightly tilt the patient to let the breast fall towards the middle of the chest. This keeps the outer breast area accessible. This is especially useful for:

- Increasing the tissue volume in outer areas that cannot be pushed using the positions above.
- Small breast sizes with low tissue volume.
- Saggy breast tissue that falls down or to the side.



**Tip:** Ask patients to adjust the position themselves but provide additional tissue support by hand if needed.

**Tip:** If possible, stand next to the breast side which you are scanning.

## Place the Scanner

When performing a scan:

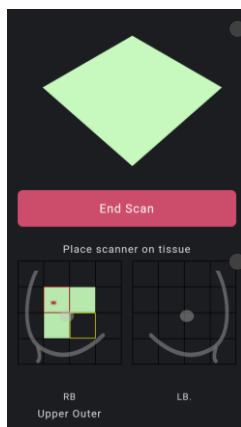
- ✓ place the sensor evenly on the breast tissue,
- ✓ ensure the whole sensor area remains in full contact with the breast tissue,
- ✓ free the breast from obstructions, such as tissue folds, and
- ✓ increase the tissue volume underneath the sensor.

**Important:** To ensure proper functioning of the sensor, hold the scanner without gloves by its conductive elements, either the silver pads on the sides (D) or the silver cover on top (E).



## Understand the Pressure Map and the Breast Grid

Once you start a scan, you will see the following page:



### Pressure Map

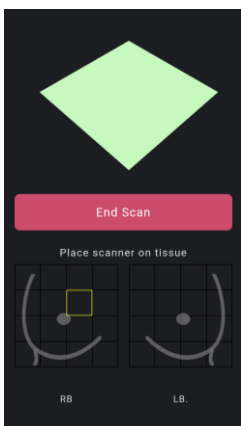
The Pressure Map displays the sensor reading in real time, as it scans the breast tissue.

### Breast Grid

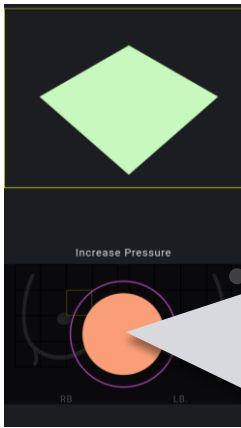
Each breast is divided into multiple tiles (depending on the selected breast size) to guide you through the scan.

- Yellow border: Selected tile.
- Green tile: Scanned, no finding.
- Green tile with red border: Scanned, positive finding.

## Scan the Breast Tissue



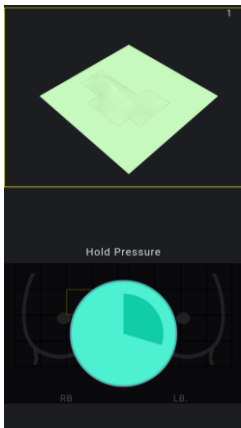
1. Hold the scanner in the air and select a tile on the Breast Grid.
  - **Important:** Do not place the scanner on the tissue while selecting a tile (hold it in the air instead).
  - **Important:** Always start with the tile next to the nipple in the upper-inner quadrant and proceed in a spiral movement across the Breast Grid.
2. Wait for 2 seconds before placing the scanner on the corresponding location of the breast tissue for the Pressure Meter to appear.



### Pressure Meter

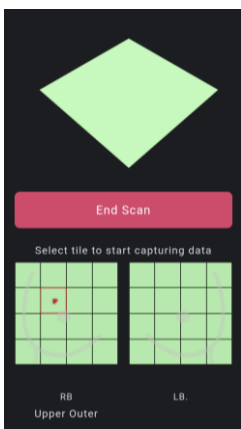
The Pressure Meter indicates the pressure with which you place the scanner on the tissue.

- The size of the circle increases with pressure.
- If you apply insufficient or excess pressure, the Pressure Meter instructs you to increase or reduce the pressure accordingly.



3. Aim for the ideal pressure level, where the Pressure Meter will turn green, and a timer will start.
4. Hold the scanner steadily in place for 3 seconds for the reading to be captured automatically. If the scanner is not held steadily, the timer will restart.

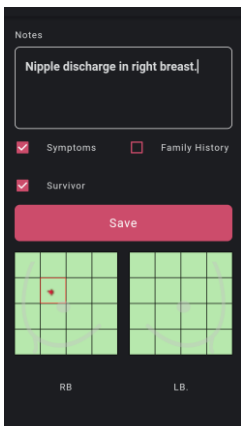
- **Tip:** If the Pressure Meter seems discordant with the amount of pressure applied:
  - Ensure that you apply pressure evenly.
  - Re-select the tile on the Breast Grid while holding the scanner in the air to re-set the sensor.



5. Once the tile is captured, lift the scanner in the air and then select a new tile. Repeat the process for the rest of the breast tissue.

- **Tip:** It is not possible to delete a reading, but you can re-capture a tile, which overwrites the previous capture.
- **Tip:** If findings of the same shape and size and in the same tile position appear in different tiles, see → [Troubleshooting](#).

6. Once you have captured all tiles, tap on *End Scan* and on *Ok* to confirm.



7. On the next screen, you can include notes and additional patient information (symptoms, family history, breast cancer survivorship). These notes will automatically appear in the report.

8. Tap on *Save* to record the scan and automatically generate a report.

## Scan Special Cases

In cases of

- implants,
- freckles or pimples,
- dense breast tissue,
- periods,
- pregnancy, or
- after radiotherapy,

you can **scan as usual**.

In cases of

- scar tissue,
- elevated birthmarks,
- nipple discharge,
- metal clips and ports,
- orange peel skin ("peau d'orange"),
- pacemakers, or
- if the patient is breast-feeding,

you can **scan as usual**. In case of a positive finding, **add a note to the report** to mention the condition.

In cases of

- open wounds,
- mastectomies,
- axillary regions, or
- bony areas such as ribs, collar bones, and sternums,

**only scan around that area** and if needed, add a note to the report to mention the condition.

In cases of skin infections, do **not scan the patient**.

## Replace the Sensor Cartridge

**Removing:** Wedge your finger in the notch at the top of the scanner to pull out the cartridge.

**Inserting:** Align the notches and ensure the latch is at the top. Insert the cartridge at the bottom and push it at the top to snap it in.



**Important:** Make sure the cartridge is inserted correctly before applying any pressure to avoid breaking the connection pins.

## Maintain and Store the Scanner

- ✓ Sanitize the sensor area with an alcohol swab before and after every scan.
- ✗ DO NOT sterilize the scanner using gas, heat, or liquid.
- ✗ DO NOT autoclave the scanner.

**Important:** Disconnect the device from the power supply prior to cleaning it.

- ✓ Turn off the device before putting it back into the box.
- ✓ Keep the sensor cartridges in the provided storage boxes.
- ✗ DO NOT rest the scanner on the sensor.
- ✗ DO NOT apply excessive pressure to the sensor surface.

## Dispose of the Scanner

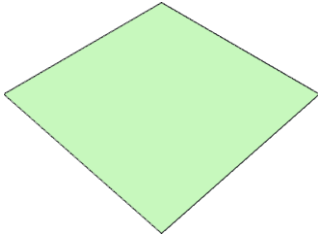
At the end of their life cycle or in case of irreparable damage, the scanner and the sensor cartridges can be disposed of.

**Important:** The scanner contains a lithium-polymer battery, which must be properly disposed of. If preferred, send it back to the manufacturer to ensure proper disposal.

### 3. Understand and Confirm Findings

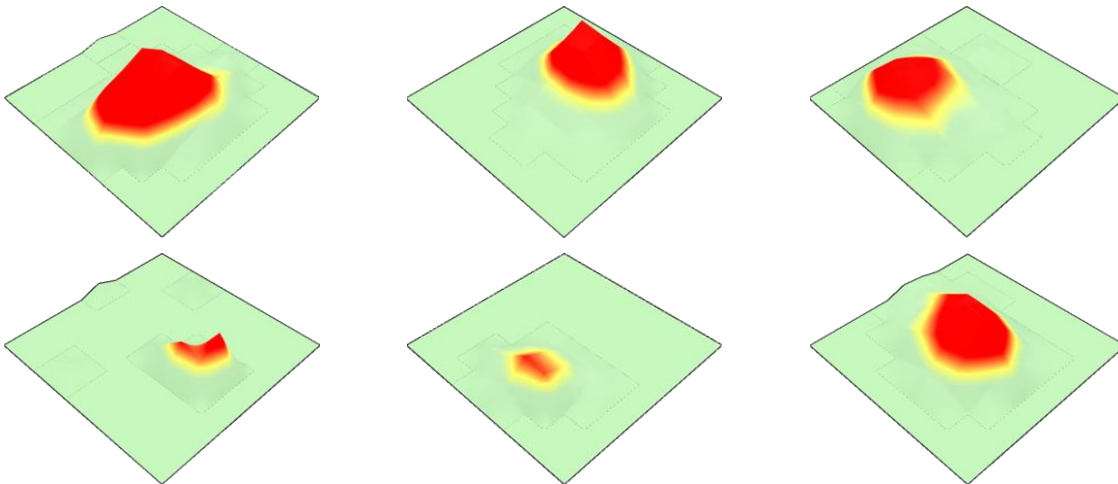
#### Understand Negative Findings

Negative findings present as flat green on the Pressure Maps.



#### Understand Positive Findings

Positive findings present as well-defined red spots of varying sizes and shapes with yellow borders.

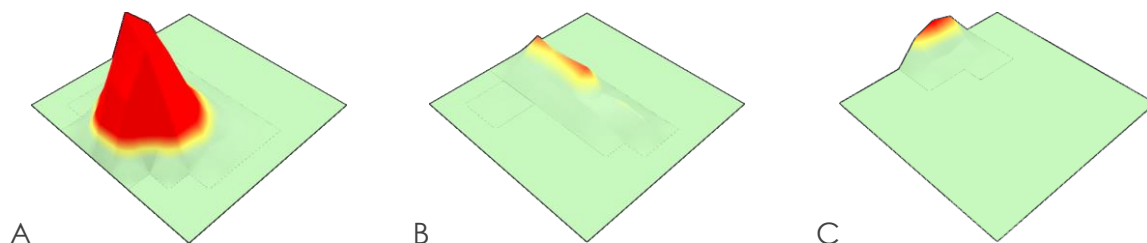


**All positive findings must be confirmed** (see → [Confirm Findings](#)).

#### Avoid Inconclusive Findings

Some findings may not present clearly as negative or positive, but as:

- Red spikes (A), which occur due to overpressure or placement of the scanner on insufficient breast tissue volume, such as bony areas.
- Red stripes (B), which indicate stiffer tissue, such as scars or tissue folds.
- Findings on the edge of the sensor (C), which can occur due to uneven pressure.

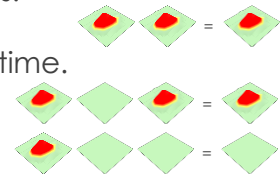


**All inconclusive findings must be confirmed** (see → [Confirm Findings](#)).

## Confirm Findings

Confirm positive and inconclusive findings as follows:

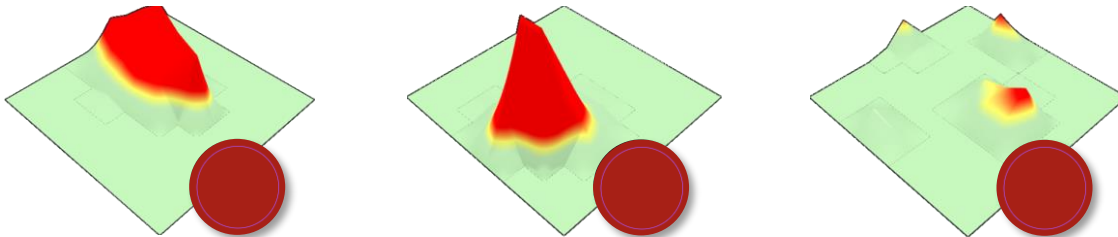
1. Lift the scanner, re-select the same tile, and scan that area again.
2. Ensure that:
  - you wait 2 seconds before placing the sensor on the breast tissue,
  - the sensor is placed evenly on the breast tissue,
  - the whole sensor area is in contact with the breast tissue,
  - the tissue is free from tissue folds,
  - the scanner is placed on sufficient tissue volume, and
  - the red spot is stationary and well within the sensor area.
3. Let the app capture the reading automatically after 3 seconds.
4. If the second reading is positive, label the file as positive.
5. If the second reading is negative, capture the reading a third time.
  - If the third reading is positive, label the file as positive.
  - If the third reading is negative, label the file as negative.



**Important:** Do not use manual palpation to determine the presence of a lump.

## Avoid Excess Pressure

In case of excess pressure (= red Pressure Meter ●), the Pressure Map may eventually show red spots. To prevent incorrect readings, the app only allows capturing readings at the ideal pressure level.



## What iBreastExam Can(not) Detect

iBreastExam **can detect** breast lesions (malignant and benign), such as:

- Solid tumors
- Granular cell tumors
- All major breast carcinomas
- Complex cysts (debris)
- Fat necrosis
- Hyperplasia
- Fibrosis
- Fibroadenoma
- Phyllodes tumors

iBreastExam is **limited in its ability** to detect breast conditions with no elastic modulus differential detectable from surface, such as:

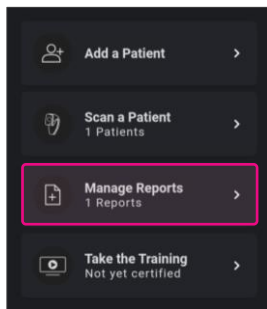
- Simple, fluid-filled cysts (same elasticity as breast tissue)
- Micro-calcifications (too small)
- Ductal carcinoma in-situ (DCIS) and lobular carcinoma in-situ (LCIS) (usually too small)
- Inflammatory breast cancer, mucinous cancer, colloid carcinoma (decentralized, do not present as lumps)

**Important:** All symptomatic patients must follow up with a doctor.

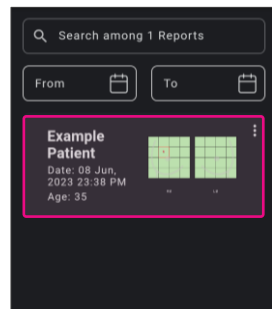
## 4. Reports

### View Reports

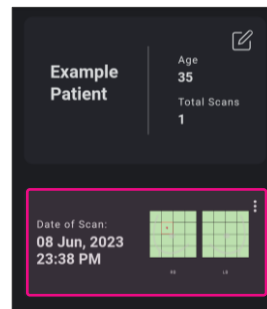
1. In the main menu, select *Manage Reports*.
2. Search for a patient and tap on the patient's name or the thumbnail report.
3. Search for a scan and tap on the scan date or the thumbnail report.
4. View the detailed report.



1



2



3

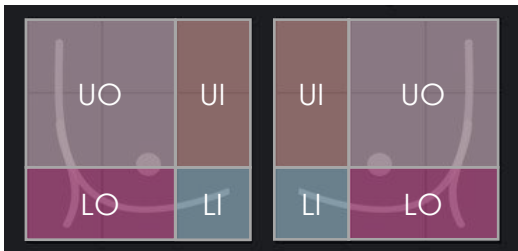


4

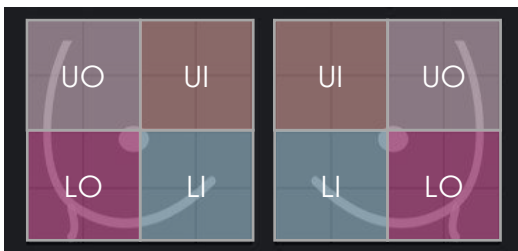
### Quadrant Indicator:

To locate the findings on the Breast Grid, tiles are labelled using:  
U = Upper; L = Lower; O = Outer; I = Inner; C = Central.

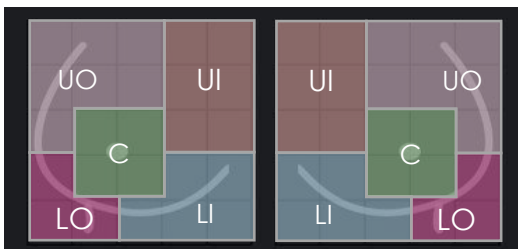
#### Small Breast



#### Medium Breast

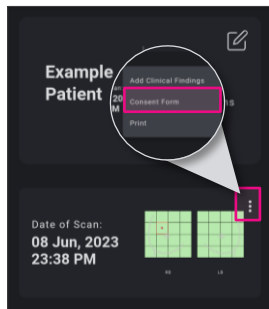


#### Large Breast

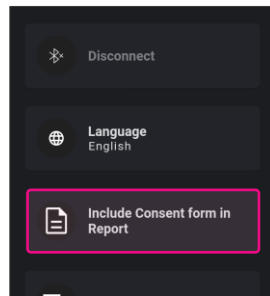


## View and Add Patient Consent Forms to Reports

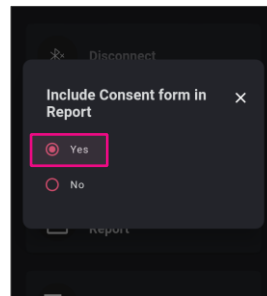
1. To view a Patient Consent Form: In the main menu, select *Manage Reports*.
2. Search for a patient and report, tap on the three dots, and select *Consent Form*.
3. To add Patient Consent Forms to future Reports: As an org admin, tap on the gear icon in the top-right corner of the main menu to go to settings.
4. Select *Include Consent Form in Report* and toggle *Yes*.
5. The Patient Consent Form will appear on the second page of all future reports.



2



3



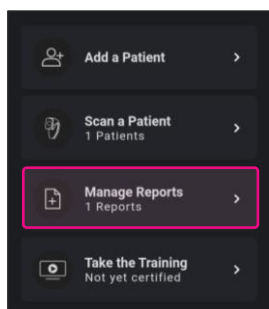
4



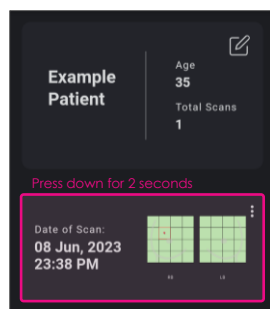
5

## Share Reports

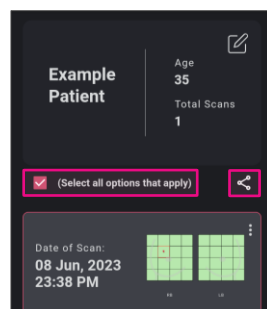
1. In the main menu, select *Manage Reports*. Search for a patient or a report.
2. Press down on the patient or report thumbnail for 2 seconds.
3. Select the patient(s) or report(s) which you want to share or tap on *Select all*.
4. Tap on the sharing icon and select a sharing mode or directly print the report.



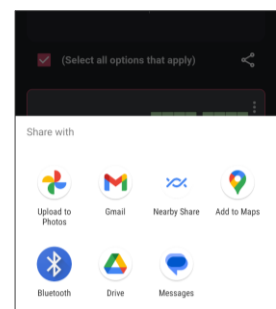
1



2



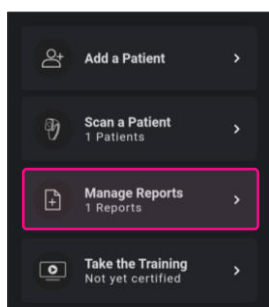
3



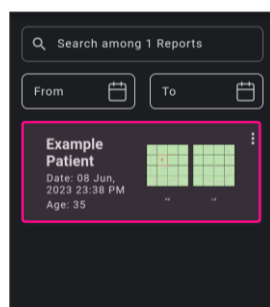
4

## Add Clinical Findings to Reports

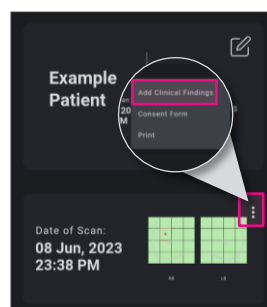
1. In the main menu, select *Manage Reports*.
2. Search for a patient and tap on the patient's name or the report thumbnail.
3. Search for a scan, tap on the three dots, and select *Add Clinical Findings*.
4. Select a scanning modality and add its findings by tapping on the Breast Grid.



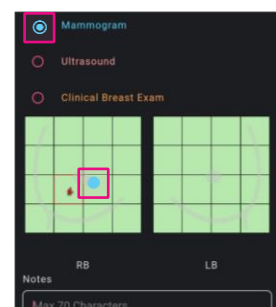
1



2



3



4

## 5. Troubleshooting

### Scanner

#### Scanner not charging / Charging light not turning on

1. Check if the cable is plugged in correctly and if the outlet is turned on.
2. If available, exchange the cable and adapter.
3. Check if the scanner and charging port are damaged on the surface.

#### Scanner not connecting to app / Connection light blinking

1. Check if the scanner is charged (a full charge takes at least 6 hours).
2. Check if the scanner has been paired via Bluetooth with the mobile phone (which is separate from connecting it to the app).
3. Check if the phone has Bluetooth and GPS (location) activated.
4. Turn the scanner off and on again, close and restart the app, and try re-connecting.
5. If the scanner still does not connect to the app, connect it manually:
  - In the main menu of the iBreastExam app, tap on the gear icon in the top right corner to open the settings and tap on *Connect to Device*.
  - Select your scanner's Bluetooth number in *Nearby Bluetooth Devices*.
  - If successful, the connection light becomes steady, and a pop-up message will confirm the *Bluetooth Connection Status*.
6. If the issue persists, go to your mobile phone's Bluetooth settings, and unpair / forget all iBreastExam scanners.
7. Pair the scanner again with your mobile phone, close and restart the app, and try connecting again.

#### Scanner not connecting to app / Connection light stable

1. The scanner seems to be connected to another phone.
2. Manually disconnect the device from that phone's iBreastExam app by tapping on the gear icon in the top right corner to open the settings and tap on *Disconnect*. The connection light should now be blinking.
3. Turn the scanner off and on again, close and restart the app, and try connecting again.

#### Scanner disconnecting from app / Banner showing "The device is disconnected!"

1. Tap on the refresh icon in the top-right corner of the scanning page.
2. Turn the scanner off and on again and tap on the refresh icon in the top-right corner of the scanning page.
3. Leave the scanning page. Re-select the patient and restart the scan. The app will re-initiate a Bluetooth connection with the scanner.
4. If the issue persists, see → [Scanner not connecting to app](#).

#### Unable to find Bluetooth / Device number

1. Find the device number in the main menu (if the scanner is connected).
2. If not, turn on the scanner and ensure no other scanner is turned on.
3. In the main menu of the iBreastExam app, tap on the gear icon in the top right corner to open the settings and tap on *Connect to Device*.
4. Search for *Nearby Bluetooth Devices* to see the Bluetooth number, which includes the device number in (iBExx\_[Device Number]).

## iBreastExam App

### **iBreastExam app freezing or crashing**

1. Close and restart the app.
2. In Android: Press down on the iBreastExam app, select *App Info* and then *Force Stop*, and re-start the app.
3. If available, update the iBreastExam app from the Google Play Store or the App Store.
4. Restart the mobile phone.
5. If available, update the phone's system software.

### **Forgotten PIN / Password**

1. In case of forgotten PIN or password, please contact your organization's administrator, who can reset them in the Dashboard.
  - In case of reset PIN, close and restart the app, which will prompt you to set and confirm a new PIN.
  - In case of reset password, you will receive a link on your registered email address to set and confirm a new password (please note that this link is only valid for 10 minutes).

### **Banner showing “Mobile number already exists” during signup**

You seem to try signing up with a previously used number that is already linked to a registered account. Each mobile number and/or email address can only be used for signup once.

If you have already created an account using your mobile number, creating an account using your email address will create a second account. It is not possible to link the previously registered mobile number to this newly created account (as both your mobile number and email address are used as the unique identifier for the two different accounts).

1. If you have already created an account using your mobile number and wish to create an email-based login, you can create a second account using your email address and a password (without entering your mobile number).
2. New users can create a single account with both their mobile number and email address.

### **Banner showing “User does not exist” during login**

You seem to try logging in with a mobile number that is not recognized by the system.

1. Contact your organization administrator to add your (new) phone number to your account.

### **Remaining Scans and Device Number showing ~NA~ and/or Device Battery showing 0%**

1. In the main menu of the iBreastExam app, tap on the gear icon in the top right corner to open the settings.
2. Tap on *Disconnect* and then on *Connect to Device*.
3. Go back to the main menu where the fields should be updated.

### **Remaining Scans showing ~NA~**

1. Ensure the scanner is connected to the app (see → [Scanner not connecting to app](#)).
2. Turn off the scanner, close the app, and remove and re-insert the sensor cartridge. Restart the scanner and the app.
3. If the issue persists, turn off the scanner, close the app, and replace the sensor cartridge. Restart the scanner and the app.

### **Remaining Scans showing zero**

1. You seem to have used all the scans on the sensor cartridge. Replace the sensor cartridge with a new one and dispose of the old one.
2. If this seems unlikely, turn off the scanner, close the app, and remove and re-insert the sensor cartridge. Restart the scanner and the app.

### **Banner showing “Session Expired!”**

You seem to have logged in to a second mobile phone using the same account. This causes the session on the first mobile phone to expire, disabling data upload and download from that device.

1. If you want to use the app on the first mobile phone, tap on the refresh icon in the banner.
2. The “Session Expired!” banner now appears on the second mobile phone until you sign out from the app on that device.

### **Banner showing “You’re not connected to Scanner!” when registering a patient**

1. Connect to the scanner before registering a patient (see → [Scanner not connecting to app](#)).

### **Pop-up message showing “Organization not assigned”**

Usually, your scanner is automatically assigned to your organization in the Dashboard. If this is not the case, you are still allowed to do 20 scans before this notification will hinder you from doing any more scans. To solve this issue:

1. Connect your mobile phone to the internet and to your scanner.
2. Close and restart the app and log back in.
3. If the issue persists, notify your organization administrator that your device is not assigned to your organization in the Dashboard.

### **Finding current app version**

1. To see the current app version you are using, go to the gear icon in the top right corner and scroll down to *About Application*.
2. The app version is displayed on the first line of the pop-up window.

### **App requiring update of the phone’s operating system**

1. Connect the mobile phone to the internet.
2. Open the phone settings, search for system updates, and install the available updates.

## Scanning

### Pressure Meter not appearing

The Pressure Meter might not appear if not enough of the sensor area is in contact with the tissue.

1. Place the scanner evenly on tissue with the whole sensor area in contact with the breast tissue (for example, avoid placing the scanner on deep scars, which might prevent parts of the sensor from being in contact with the tissue).

### Pressure Meter not reacting properly

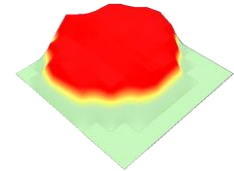
The Pressure Meter might not react properly to the amount of pressure applied if the scanner is placed on tissue without (re-)selecting a tile or if the scanner is placed too quickly on tissue after selecting a tile.

1. Hold the scanner in the air, re-select the tile to reset the sensor, wait for two seconds, and apply the scanner again.

### Pressure Map turning completely red

The Pressure Map might briefly turn red after placing the scanner on tissue. This red "dome" indicates the difference in sensor reading between air and tissue and does not indicate a finding.

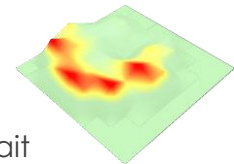
1. Keep the scanner in position and wait for the red "dome" to disappear.



### Pressure Map showing red areas

The Pressure Map might light up red in the (partial) shape of the sensor circle if the scanner is placed too quickly on tissue after selecting a tile.

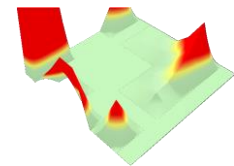
1. Hold the scanner in the air, re-select the tile to reset the sensor, wait for two seconds, and apply the scanner again.



### Finding "dancing" on Pressure Map

The Pressure Map might show red "dancing" spikes if the sensor cartridge is replaced during a scan.

1. Turn off the scanner, close the app, and remove and re-insert the sensor cartridge.
2. Restart the app, reconnect the scanner, and apply the scanner again.

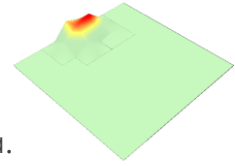


To avoid this situation:

- In scanners with device numbers starting with W: Do *not* replace sensor cartridges during an ongoing scan.
- In scanners with device numbers starting with T: Do replace sensor cartridges during an ongoing scan (if needed) and do *not* exit the scan.

### Finding appearing at very edge of Pressure Map

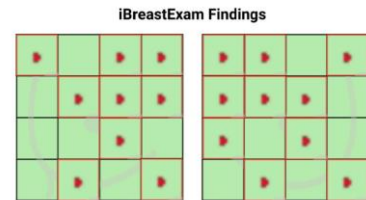
If a finding appears at the very edge of the Pressure Meter, it may not be a real finding but the result of applying the scanner unevenly.



1. Ensure that you apply the sensor evenly on the tissue.
2. Slightly move the sensor to center the lump within the sensor area.

### Same finding appearing in different tiles

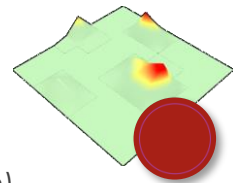
If findings of the same shape and size and in the same tile position appear in different tiles, the sensor cartridge might be damaged.



1. Replace the sensor cartridge and apply the scanner again. If findings are no longer visible, the old sensor cartridge was damaged and should not be used again.
2. Contact our customer support team.
3. To avoid damage to the sensor cartridge, do not apply excessive pressure to the sensor surface, do not rest the scanner on the sensor, and keep sensor cartridges in the provided storage.

### Finding disappearing after reducing pressure level

If a finding only appears with over-pressure (= red Pressure Meter) and disappears after the pressure has been reduced to the ideal level, it may not be a real finding but the result of applying the scanner incorrectly.



1. Follow the scanning process as indicated and capture the (green) Pressure Map at the ideal pressure level without the finding.

### Losing scan count after performing test scan

1. To test the sensor without losing a scan count, ensure that you select and scan no more than 3 tiles and do not save the scan.
2. If you scan more than 3 tiles, a scan will be deducted from your Remaining Scans, even if you do not save the scan and do not generate a report.

## Reports

### Reports not uploading to Dashboard

1. To upload scans that were performed offline to the Dashboard, connect the mobile phone to the internet (once available).
2. Close and restart the app and go to the main menu. In the background, the iBreastExam app states "Uploading Data to Cloud...".
3. Once all reports are uploaded, a notification appears stating "Uploaded Scans to Cloud!".

### Patients and Reports showing 0 in main menu / showing incomplete list

You seem to have logged in from a new device.

1. Ensure your mobile phone is connected to the internet.
2. Close and restart the app.
3. Visit both the *Scan a Patient* and the *Manage Reports* sections. Your data will appear shortly.

### Performed scan not showing in Manage Reports section

1. Ensure that you tap on *End Scan* > *Ok* > *Save* before exiting the scanning page.
2. Visit the *Manage Reports* section and wait for a few minutes.
3. If the report is still not showing, re-perform the scan.

### Report generation taking a long time

1. Wait for the progress bar to complete.
2. If the progress bar is stuck for more than a few minutes, close and restart the app.
3. Check if the report is shown in the *Manage Reports* section.
4. If the report is still not showing, re-perform the scan.

## Mobile Phone

### Bluetooth not switching on or automatically turning off

1. Restart the mobile phone.
2. Open the mobile phone settings. Find the *Apps* section, tap on the three dots in the top-right corner, select *Show system apps*, and select *Bluetooth*.
3. Tap on *Clear Cache*.
4. Reboot the mobile phone:  
*Android:*
  - Press and hold the power and the volume-down button until the phone vibrates.
  - To turn the device back on, press and hold the power and the volume-up button until the phone restarts.*iOS:*
  - Press and hold either volume button and the side button until the power-off slider appears.
  - Drag the slider, then wait 30 seconds for your device to turn off.
  - To turn your device back on, press and hold the side button until you see the Apple logo.

### Mobile phone not connecting to Wi-Fi

1. Restart the mobile phone.
2. Open the mobile phone settings (or pull-down across the screen from the top (Android) or top-right corner (iOS)).
3. Ensure that Wi-Fi is turned on and that Airplane Mode is turned off.
4. Install any available system updates:  
*Android:*
  - In *Settings*, near the bottom, tap *System* and then *System update*. Follow any steps on the screen.*iOS:*
  - In *Settings*, tap on *General* and then *Software Update*. Follow any steps on the screen.
5. In the Bluetooth settings, select the Wi-Fi network you try connecting to, and tap *Forget / Forget This Network*. Reconnect with this Wi-Fi network.
6. Open the web browser on your mobile phone and enter a sample search. In case your clock is behind, you will get asked to *Update date and time* to establish a connection.

### **Mobile phone freezing or crashing**

1. Restart the mobile phone.
2. Open the mobile phone settings and install any available system updates, if any (see above).
3. Reboot the mobile phone (see above).

### **Unable to install app updates / Google Play Store showing error (“Something went wrong”)**

1. Ensure that you have a strong internet connection.
2. Ensure that you have sufficient storage space on your mobile phone.
  - *Android:* In *Settings*, check *Storage*.
  - *iOS:* In *Settings*, select *General* and check *iPhone Storage*.
3. Install any available system updates, if any (see above).
4. *Android:* Re-install Play Store updates:
  - Press down on the Play Store app.
  - Tap on the app info button (i).
  - Tap on the three dots in the top-right corner.
  - Tap on *Uninstall updates*.
  - If asked to replace the Play Store app with the factory version, select *OK*.
5. *Android:* Clear Data/Storage and Cache of the Google Play Store:
  - Press down on the Play Store app.
  - Tap on the app info button (i).
  - Tap on *Storage* and then select *Clear Data/Storage* and *Clear Cache*.
6. *Android:* Clear Storage and Cache of the Google Play Services:
  - Open the mobile phone settings.
  - In the *Apps* section, find *Google Play Services*.
  - Tap on *Storage* and then select *Clear Data/Storage* and *Clear Cache*.

For more information, tap on the **?** *Get Help* button in the bottom-left corner of the main menu of the iBreastExam app. Select *Operating Guide* to see a digital copy of this manual or select *Help Desk* to raise a customer support ticket if issues persist.

## 6. Warnings and Precautions

### **General**

1. Do not operate this system without reading this manual in its entirety.

### **Indications & Contraindications**

2. The iBreastExam is designed to be an aid in the documentation of the self-breast exam. If the device's measured size of the lesion does not agree with the manual estimate of size made by the user's self-exam, the user should re-examine themselves both manually and with the device to ensure that the device is correctly documenting the user's self-exam. If the device still does not agree with the exam, the user should rely on a clinical exam measurement made by a qualified physician but may want to note any discrepancy in the device file before saving or printing it.
3. This device may not document every lesion by clinical breast exam in every user, including some deep-seated lesions.
4. The device should not be used on users with open wounds of the breast, as this may increase the risk of tissue trauma, bleeding, and infection.
5. The device has not been shown to be effective in users who have undergone breast augmentation, reconstructive surgery, radiation therapy, or chemotherapy for prior breast cancer.
6. The number of lesions should not be determined based on the mapping using the device.
7. This device has not been shown to be useful as a diagnostic or management tool, i.e., the device should not be used to track changes in the size of a lesion.

### **Potential Damages**

8. Report malfunctioning or damaged components to UE LifeSciences immediately.
9. Users should inspect the device before each use and replace the device if any signs of wear or damage are noted.
10. Do not remove the protective covers on the system; hazardous voltages are present inside. All internal adjustments and replacements must be made by a qualified technician.

### **Usage**

11. Do not use the scan head when it is plugged into the charger. Ensure that the scan head is not connected to the charger when switching on the scan head.
12. iBreastExam utilizes a Bluetooth Wireless radio that exchanges data between the scan head and the iBreastExam computer system. The Bluetooth radio may be connected to other non-iBreastExam computer systems. The iBreastExam scan head is only intended to be connected and paired with an iBreastExam computer system. If the scan head is connected to another computer system, the iBreastExam device may not function as intended. Users should not provide third-party or unauthorized wireless capabilities to the device via and remote interface including USB dongles.

### **Warnings**

13. Any deviations from the specified electrical accessories and their use may result in electrical shock.
14. Do not operate this system in the presence of flammable gases or anesthetics. Explosions can occur.
15. The iBreastExam is MR unsafe.

16. A distance of at least 3 feet / 1m should be maintained between any portable and mobile radio frequency (RF) equipment and the iBreastExam device.
17. Do not use the iBreastExam device in the presence of increased electric magnetic fields, as this may impact the essential performance of the device.
18. The device should not be used in conjunction with other known electromagnetic interference (EMI) sources, security systems (metal detectors and EAS), RFID systems, or any RF emitters including other medical devices such as CT or diathermy. These EMI sources may or may not be visible. Coexistence with other EMI devices has not been tested, and therefore iBreastExam should not be used in the presence of any EMI emitting devices.
19. Stacking/adjacent devices may increase EMI. Use of other cables or any other accessories could result in increased emissions or decreased immunity.
20. iBreastExam should not be used in the presence of other transmitting iBreastExam units or any electrical equipment utilizing the same frequency band, including wireless telephones, cell phones, z-wave, zigbee wireless X10 devices, or computer systems utilizing a wireless technology that may interfere with iBreastExam such as Bluetooth or Wi-fi. If interference is encountered and the connection to the iBreastExam scan head is lost as indicated by the connection light in the iBE software, the unit should be turned off and not used until the interference is eliminated. The presence of RF emitting devices might cause the loss of data.
21. The EMC test programs for iBreastExam were performed in accordance with the applicable requirements of IEC 60601-1-2:2007 (3rd Edition) & IEC 60601-1-2:2014 (4th Edition). All tests were performed at Keystone Compliance New Castle, PA EMC test facility. All tests were performed using the test set-ups of the relevant standard for tests performed in laboratory conditions.
22. If at any time the connections status indicates 'Not Connected', the user shall turn off iBreastExam and leave it off until the source of radio interference is identified and eliminated. The sources may be, but are not limited to, cell phones, EMI sources, MRI, security systems, RFID, cellphones, other computer systems utilizing wireless radios (Wi-Fi or Bluetooth) or other medical devices with wireless radios.
23. The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.

## 7. Technical Specifications

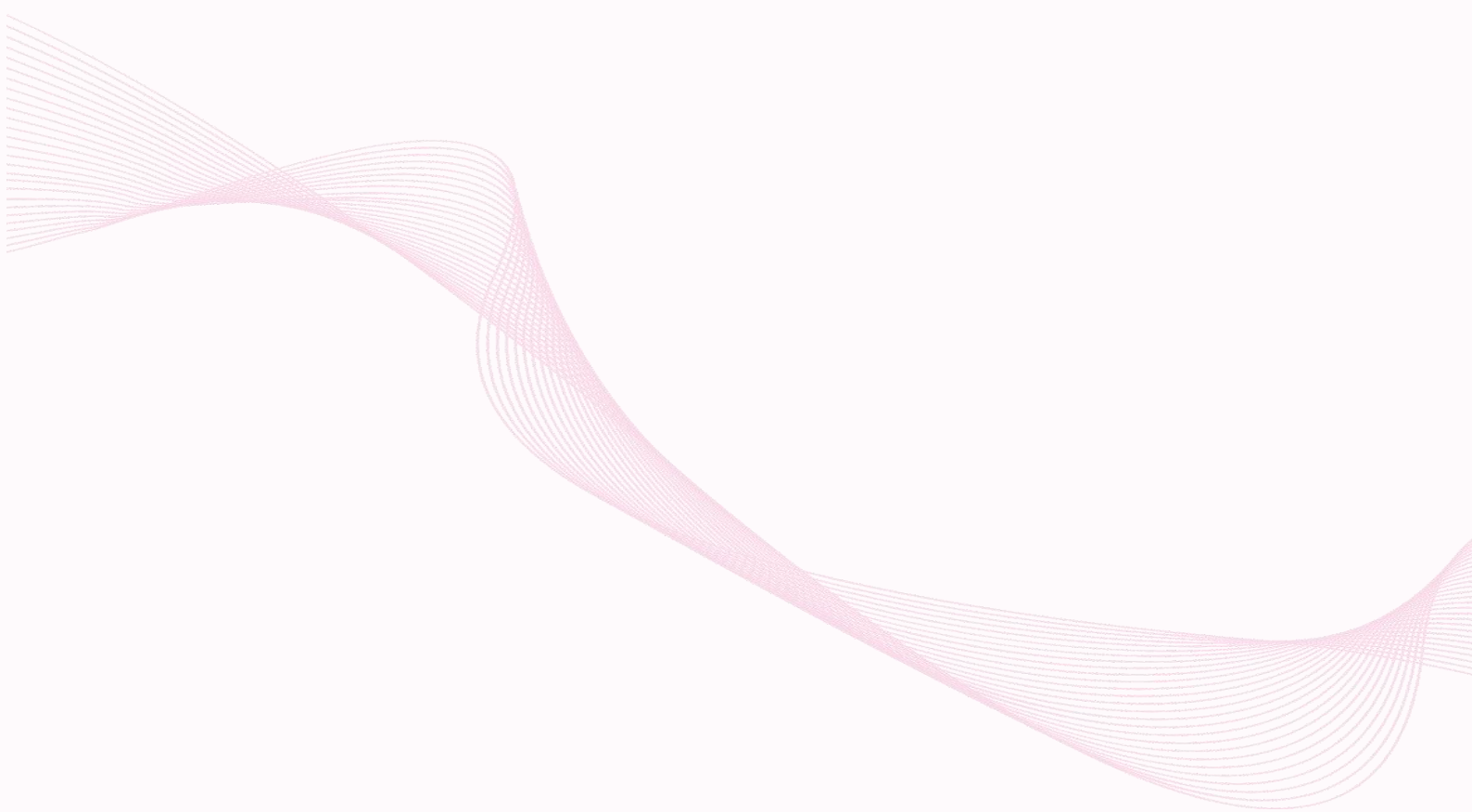
1. Non-invasive, radiation-free breast examination.
2. Ultra-portable and light-weight probe:
  - Probe: Size: 13 x 6.5 x 8.5cm; Weight: 0.5kg.
  - Full system with case: Size: 27 x 26 x 11cm; Weight: 2kg.
3. Operable with rechargeable battery (1000 to 2000 mAh). Recharging Power: Input 110-220v 50/60Hz at 0.3-0.5A and Output 5v at 2A.
4. Sensor Technology:
  - 648 Dynamic Co-Planar Capacitive (DCPC) sensors.
  - Measurement of tissue elasticity 20 times per second.
5. Wireless operation using Bluetooth 2.0 standard protocol.
6. Storage capacity of up to 50,000 breast examination scans with full reports. Storage capacity is based on the selection of the mobile device.
7. Custom mobile application for breast examination with capabilities to:
  - Perform breast examinations.
  - Store the breast examination data.
  - Print the final report.
8. Replay feature enabling the physician to replay a previously performed breast examination frame by frame.
9. Approved for Electromagnetic Compatibility (EMC) Test 1409-054EA REV. A TEST STANDARDS: IEC 60601-1-2:2007 (3RD EDITION) & IEC 60601-1-2:2014 (4TH EDITION).
10. Approved for the following electrical and mechanical safety tests:
  - IEC 60601-1 Ed.3 (2005) + Am.1 (2012) = IEC 60601-1 Ed.3.1 (2012)
  - The following National Deviations were included in the evaluation: - AAMI/ANSI ES 60601-1:2005(R) 2012/A1
  - EN 60601-1 Ed.3 (2007) + Am.1 (2013)
  - CSA C22.2 No. 60601-1:2014
11. Clinical study validation performance\*\*: Sensitivity is 84%; Specificity is 94%; Negative Predictive Value is 98%; Positive Predictive Value is 60%.
12. Storage, Transport and Operating conditions:
  - Temperature range in Use: -10°C to 50°C.
  - Maximum relative humidity: 90%.
  - Atmospheric pressure range: 700 to 1060 hPa.
  - Store in a dry, cool place away from heat, humidity, and direct sunlight.

\*Storage capacity can be higher based on mobile device storage.

\*\*Based on 2016 IJGO study.

## 8. Regulatory Clearances and Approvals

- US FDA cleared Registration# K190575/S001
- CE Marked Certificate # CE-BV-2212-5889
- ISO 13485 Certificate # IN97607H
- ISO 9001 Certificate # IN97607A
- GMP Certificate # IN97607U



Developed and Manufactured by

UE LifeSciences

USA | India | Malaysia | Colombia | Chile

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