



OPERATING GUIDE

UE/CR/01/01-04.03



Contents

- 1. iBreastExam 1**
 - iBreastExam Components 1
 - Charge the Scanner 1
 - Log in to the App 1
 - Connect the Scanner to the App..... 2

- 2. Breast Scans..... 3**
 - Register and Select a Patient 3
 - Prepare the Patient 3
 - Position the Patient..... 3
 - Place the Scanner..... 4
 - Understand the Pressure Map and the Breast Grid 4
 - Scan the Breast Tissue 4
 - Enable or Disable Automatic Tile Selection 6
 - Scan Special Cases..... 6
 - Replace the Sensor Cartridge..... 6
 - Maintain and Store the Scanner 7
 - Check the Sensor Cartridge and the Connection Pins..... 7
 - Dispose of the Scanner 7

- 3. Understand and Confirm Findings..... 8**
 - Understand Negative Findings 8
 - Understand Positive Findings 8
 - Avoid Inconclusive Findings 8
 - Confirm Findings 9
 - Avoid Excess Pressure..... 9
 - What iBreastExam Can(not) Detect 9

- 4. Reports 10**
 - View Reports 10
 - View and Add Patient Consent Forms to Reports 11
 - Share Reports..... 11
 - Auto-Share Reports via Email 11
 - Manage Un-Synced Scans 12
 - Add Clinical Findings to Reports 12
 - Enable or Disable Auto Download 13

- 5. Troubleshooting 14**
 - Scanner 14
 - iBreastExam App 16
 - Scanning 18
 - Reports 20
 - Mobile Phone 21

- 6. Warnings and Precautions..... 23**
- 7. Technical Specifications..... 25**
- 8. Regulatory Clearances and Approvals..... 26**

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:
- Device Serial number:
- Sensor Serial number:

Format:

- W123456 / T12345678
- iBExx_[Device number]
- i1234-56789
- S-1234-5678

Location:

- App main menu
- Bluetooth settings
- Pink underside of scanner
- Backside of sensor cartridge

Charge the Scanner

1. For the first-time use, charge the scanner for at least 6 hours. After that, charge the scanner depending on the 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.

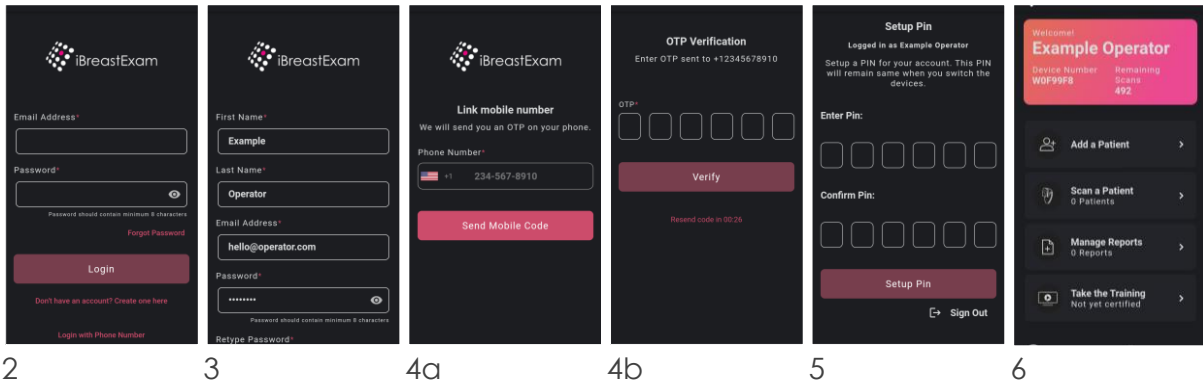
Log in to the App

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.

Note: Only your organization's admin can edit your username.

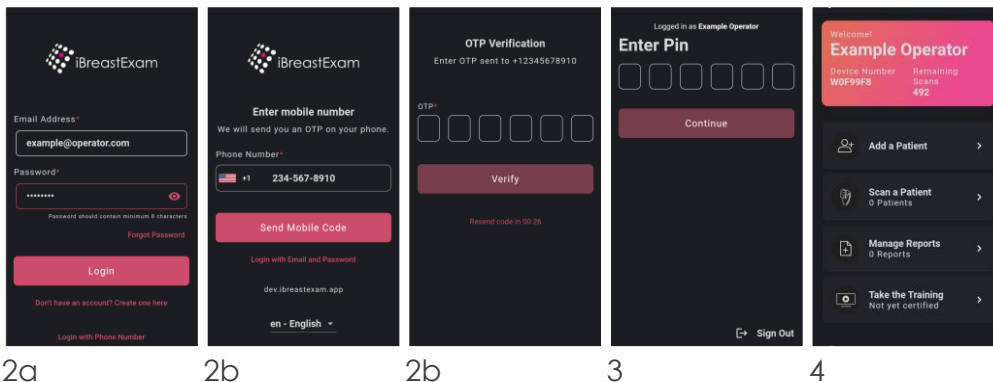
Note: The same user can be logged in to multiple mobile phones.



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 5 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

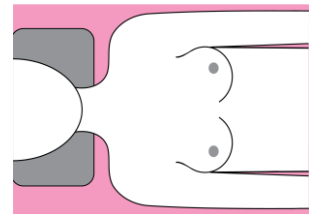
Register and Select a Patient

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, by searching the patient's name in the search bar.
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. If enabled by your org admin in the iBreastExam Dashboard settings, you can check or uncheck *Automatic Tile Selection* (see → [Enable or Disable Automatic Tile Selection](#)).
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.

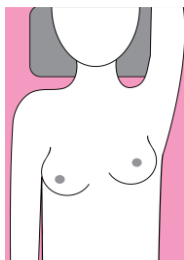


Position the Patient

Use these patient positions to always place the sensor i) on sufficient breast tissue and ii) evenly on tissue, without any obstructions such as tissue folds:

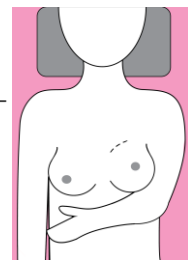
Arm Position – Stretch:

To ensure the sensor is placed evenly on breast tissue, place the patient's arm above the head to better access e.g., the inframammary fold.



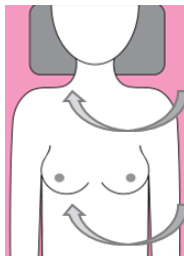
Arm Position – Push:

To increase tissue volume in inner areas, fold the patient's arm across the rib cage to push tissue upwards / towards the middle of the chest.



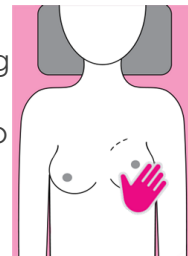
Tilting:

When scanning outer areas, it can help to slightly tilt the patient to let the breast fall towards the middle of the chest.



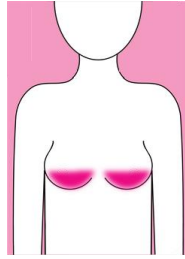
Support by Hand:

If arm positions don't bring enough tissue to the required area, it can help to provide additional tissue support by hand.



Sitting Up:

For very small breast sizes, it can help sitting up the patient to have enough tissue fall towards the lower breast areas.



Tips:

- If possible, stand next to the breast side which you are scanning.
- Ensure not to strain your back while leaning over the patient. If helpful, sit down during the scanning.

Place the Scanner

When performing a scan:

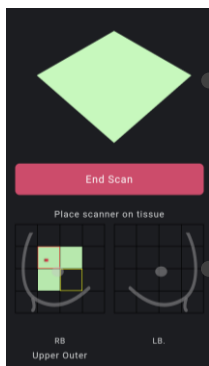
- ✓ place the sensor evenly on the breast tissue,
- ✓ ensure the whole sensor area remains in full contact with the breast tissue,
- ✓ free the breast from obstructions, such as tissue folds, and
- ✓ increase the tissue volume underneath the sensor.

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

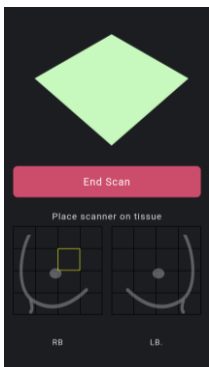
The Pressure Map displays the sensor reading in real-time, as it scans the breast tissue.

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, negative finding.
- Green tile with red border: Scanned, positive finding.

Scan the Breast Tissue



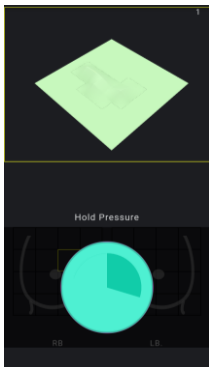
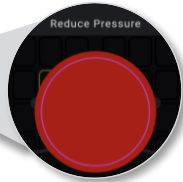
1. Hold the scanner in the air and select a tile on the Breast Grid.
 - **Important:** Hold the scanner in the air while selecting a tile.
 - **Important:** Start with the tile next to the nipple in the upper-inner quadrant and proceed in a spiral movement.
 - **Tip:** If *Automatic Tile Selection* is checked when selecting the patient's breast size, the app auto-selects tiles.
2. Wait for 2 seconds before placing the scanner on the correct location of the breast tissue for the Pressure Meter to appear.



Pressure Meter

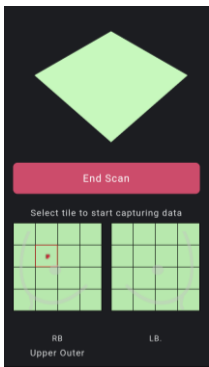
The Pressure Meter indicates the pressure with which you place the scanner on the tissue.

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

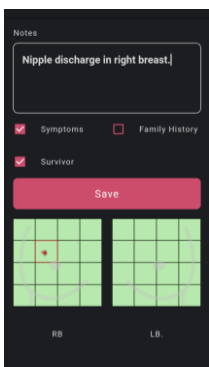


3. Aim for the ideal pressure level, where the Pressure Meter will turn green, and a timer will start.
4. Hold the scanner steadily in place for 3 seconds for the reading to be captured automatically. If the scanner is not held steadily, the timer will restart.

- **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 reset the sensor.



5. Once the tile is captured, lift the scanner in the air and 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.

Enable or Disable Automatic Tile Selection

1. If enabled by the org admin in the iBreastExam Dashboard, the automatic tile selection feature automatically selects tiles in a spiral movement.
2. The automatic tile selection feature follows the standard confirmation protocol (see → [Confirm Findings](#)).
 - If the 1st capture is negative, the next tile is selected.
 - If the 1st capture is positive, the same tile is re-selected.
 - If the 2nd capture is positive, the next tile is selected.
 - If the 2nd capture is negative, the same tile is re-selected.
 - After the 3rd capture, the next tile is selected.
3. Users can manually override the automatic tile selection at any point during the scan by tapping on another tile on the Breast Grid.
4. Users can disable this feature:
 - For an individual exam, by unchecking the *Automatic Tile Selection* checkbox during the breast size selection before an exam, or
 - In general, by opening the settings and toggling *Automatic Tile Selection* to *Off*.

Scan Special Cases

<p>In cases of</p> <ul style="list-style-type: none"> • freckles or pimples, • dense breast tissue, • periods, • pregnancy, or • after radiotherapy, <p>you can scan as usual.</p>	<p>In cases of</p> <ul style="list-style-type: none"> • implants and filler, • scar tissue, • elevated birthmarks, • nipple discharge, • metal clips and ports, • orange peel skin ("peau d'orange"), or • pacemakers, <p>you can scan as usual. In case of a positive finding, add a note to the report to mention the condition.</p>	<p>In cases of</p> <ul style="list-style-type: none"> • open wounds, • mastectomies, <p>or on</p> <ul style="list-style-type: none"> • axillary regions, or • bony areas, <p>only scan around that area and if needed, add a note to the report.</p>
		<p>In cases of</p> <ul style="list-style-type: none"> • skin infections, or • lumpy breast tissue due to breastfeeding, <p>do not scan the patient.</p>

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 and aligned correctly before applying any pressure to avoid breaking the connection pins.

Important: Only remove the sensor cartridge when the device is turned off.

Maintain and Store the Scanner

- ✓ Sanitize the sensor area with an alcohol swab before and after every scan.
- ✓ UV light is safe to use to clean the scanner but is not required.
- ✗ DO NOT sterilize the scanner using gas, heat, or liquid.
- ✗ DO NOT autoclave the scanner.

Important: Disconnect the device from the power supply before 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.

Check the Sensor Cartridge and the Connection Pins

Before performing scans, check that the sensor cartridge has:

- ✓ no palpable dents,
- ✓ no large folds in its cover, and
- ✓ puffy foam (which is not flattened).

When changing the sensor cartridge, or in case of an error message stating the cartridge has been inserted incorrectly, check that the connection pins are:

- ✓ clean (otherwise clean them with an alcohol swab), and
- ✓ straight (not bent or broken).

Important: If there are any issues with the sensor cartridge or the connection pins, please contact our customer support before performing any scans.

Dispose of the Scanner

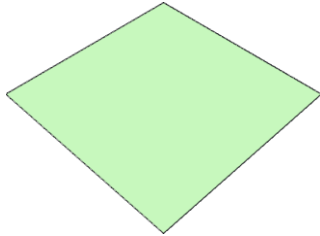
At the end of their life cycle or in case of irreparable damage, the scanner and the sensor cartridges can be disposed of.

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

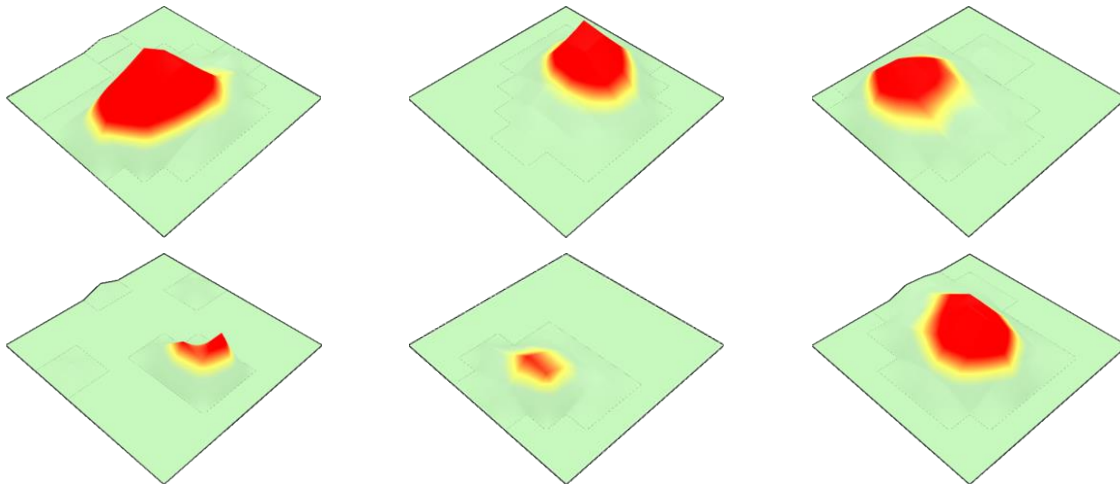
Understand Negative Findings

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.

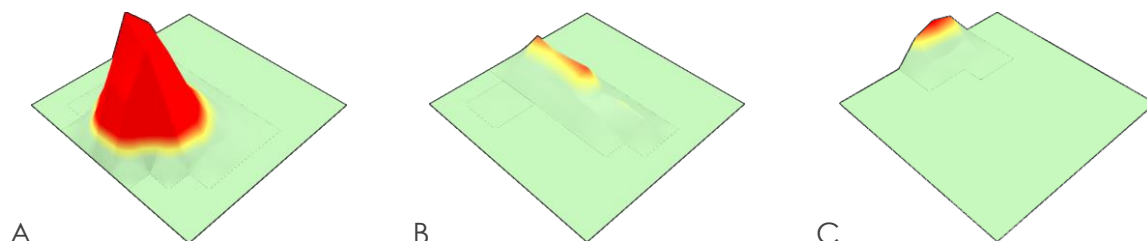


All positive findings must be confirmed (see → [Confirm Findings](#)).

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.

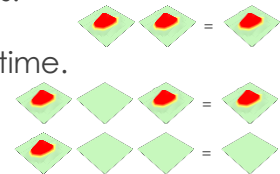


All inconclusive findings must be confirmed (see → [Confirm Findings](#)).

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 tile as negative.

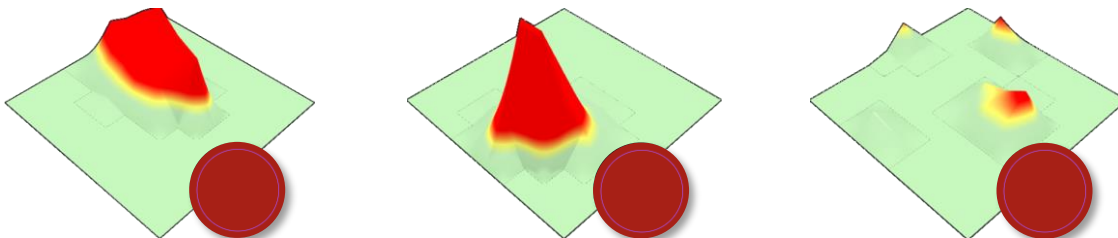


Important: Do not use manual palpation to determine the presence of a lump.

Tip: If *Automatic Tile Selection* is checked when selecting the patient's breast size, the app auto-selects tiles according to this confirmation protocol.

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 (centralized) tumors, granular cell (decentralized) tumors, complex cysts (with debris), macro-calcifications (>5mm), fat necrosis, hyperplasia, fibrosis, fibroadenoma, or phyllodes tumors.

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

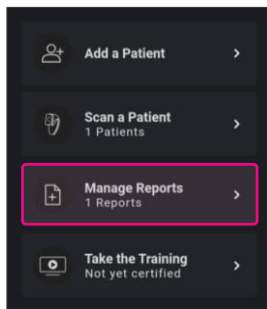
- Simple, fluid-filled cysts (same elasticity as breast tissue)
- Micro-calcifications (too small)
- Ductal carcinoma in-situ (DCIS) and lobular carcinoma in-situ (LCIS) (too small)
- Inflammatory breast cancer, mucinous cancer, colloid carcinoma (do not present as lumps)
- Large findings (>2,5 cm) covering the majority of the sensor area (stiff elasticity is registered as baseline elasticity and the lesion is not detected as anomaly)

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

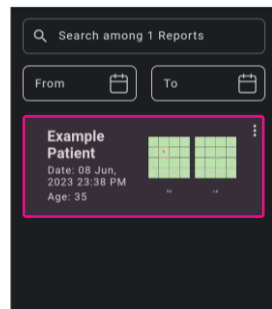
4. Reports

View Reports

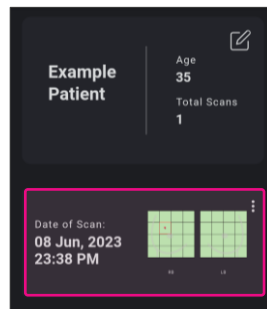
1. In the main menu, select *Manage Reports*.
2. Search for a patient and tap on the patient's name or the thumbnail report.
3. Search for a scan and tap on the scan date or the thumbnail report.
4. View the detailed report.



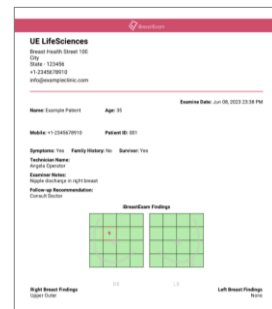
1



2



3

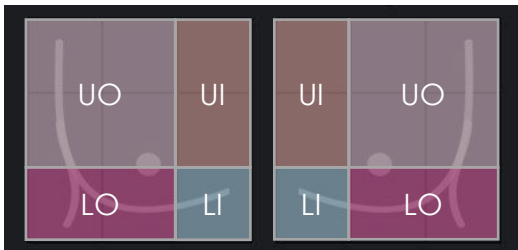


4

Quadrant Indicator:

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

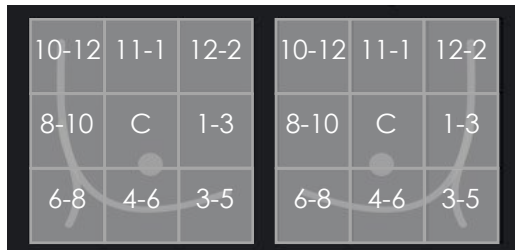
Small Breast – Quadrants



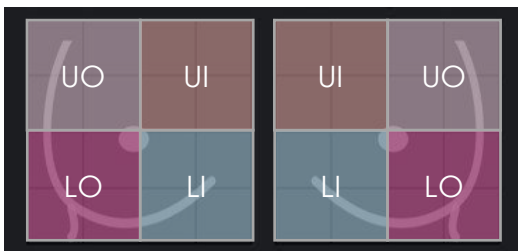
Clock Indicator:

If required, you can add a clock-based indicator by opening the settings and toggling the *Clock Indicator* to On.

Small Breast



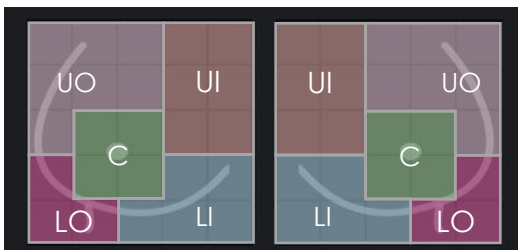
Medium Breast – Quadrants



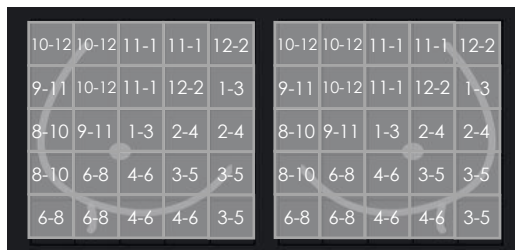
Medium Breast



Large Breast – Quadrants

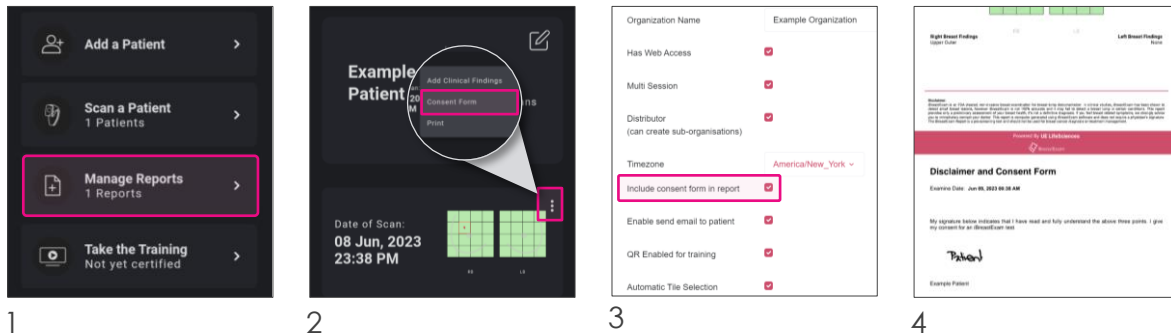


Large Breast



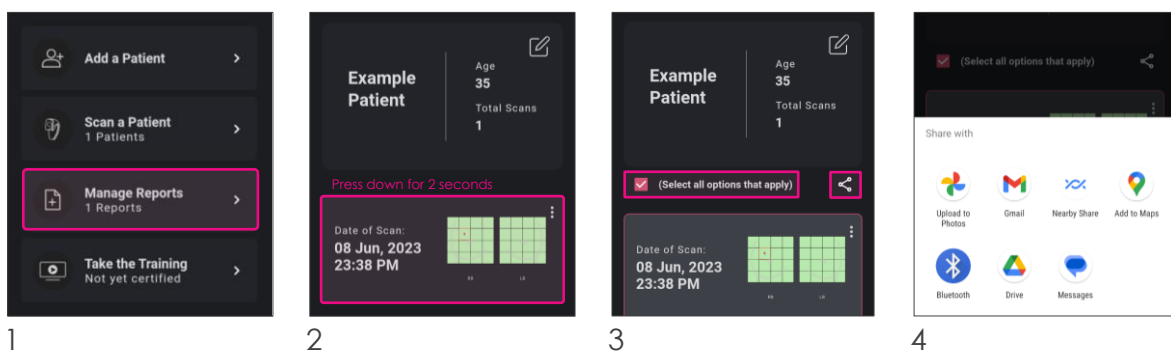
View and Add Patient Consent Forms to Reports

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, open the iBreastExam Dashboard, click on your name in the top-right corner and the edit icon next to your organization, and check the box *Include consent form in report*.
4. The Patient Consent Form will appear on the second page of all future reports.



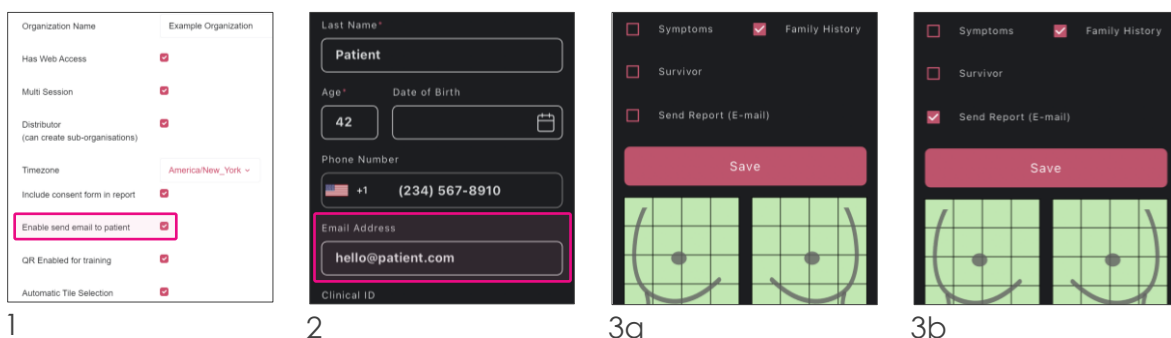
Share Reports

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) that you want to share or tap on *Select all*.
4. Tap on the *Sharing* icon and select the format and sharing mode.



Auto-Share Reports via Email

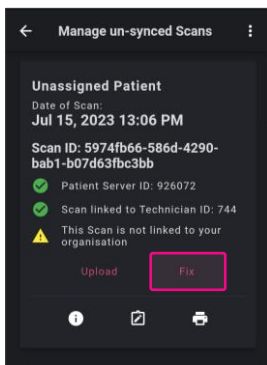
1. When registering a patient, include their email address and perform the scan.
2. If enabled by your org admin in the iBreastExam Dashboard settings, tick the checkbox *Send Report (E-Mail)* after ending the scan and then save the scan.
3. This will automatically send the report to the patient in PDF format.



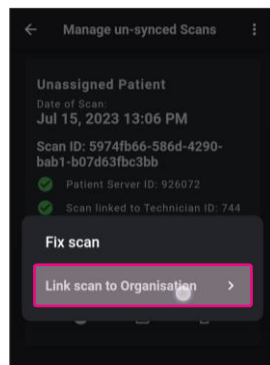
Manage Un-Synced Scans

Reports (along with patients) are automatically uploaded to the online iBreastExam Dashboard (see *Dashboard Guide* for more information). If issues block this automatic upload, you can manually manage un-synced scans from within the app.

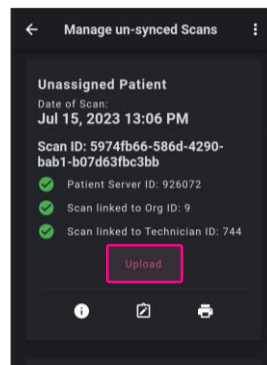
1. Tap on the *Settings* icon in the top-right corner of the main menu.
2. Select *Manage un-synced Scans*, which opens a list of un-synced scans on this mobile device (if any), including the name of the patient, the date and ID of the scan, and a checklist with potential issues blocking the automatic upload.
3. From there, you can:
 - a. View and/or print the report and/or the patient consent form.
 - b. Manually fix the issue(s) blocking the automatic scan upload by tapping on *Fix*, namely uploading the patient details to the Dashboard, linking the scan to a technician, and linking the scan to an organization.
 - c. Once all checkboxes are checked, manually upload un-synced scans to the iBreastExam Dashboard by tapping on *Upload*.



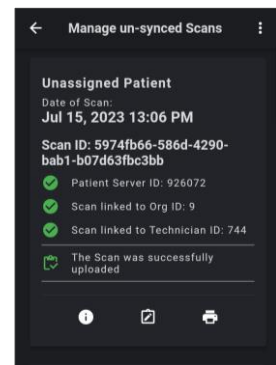
3b



3b



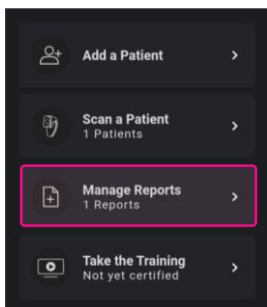
3c



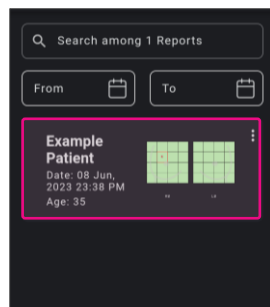
3c

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.



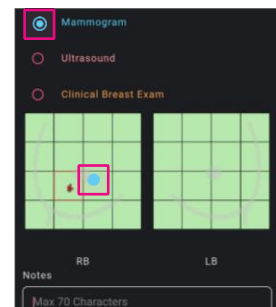
1



2



3




4

Enable or Disable Auto Download

Downloading large numbers of reports that have been performed on other mobile devices from the iBreastExam Dashboard can consume a significant amount of mobile device storage, potentially impacting the app's performance and operational speed. To prevent this, *Auto Download* is turned off by default.

To access reports from previous devices on your mobile device, *Auto Download* can be enabled.

1. Tap on the *Settings* icon in the top-right corner of the main menu.
2. Select *Auto Download* and toggle to *On* to enable the downloading of reports.
3. Alternatively, in the *Manage Reports* section, tap on the *Downloading* icon .

Note: Reports from previous mobile devices will only be downloaded to a new mobile device if they have been synced to the iBreastExam Dashboard.


5. Troubleshooting

Scanner


Scanner not charging / Charging light not turning on

1. Make sure you are using the charging accessories provided with the scanner.
2. Check if the scanner's charging cable is plugged in correctly to the scanner as well as the electrical outlet. Make sure the electrical outlet is turned ON.
3. Check the charging cable/charging adapter to rule out damage to either of those accessories.
4. Check if the scanner and charging port are damaged on the surface.
5. If the issue persists, contact customer support.


Scanner not connecting to app and Connection light blinking

1. Check if the scanner is charged properly (a full charge takes at least 6 hours).
2. Make sure the phone has Bluetooth and GPS (location) activated (Turned ON).
3. Make sure the scanner has been paired with the Bluetooth (BT) of the mobile phone (which is separate from connecting it to the iBreastExam app).
4. Restart the scanner and the app, and re-connect the scanner with the app.
5. Try connecting it manually using the following steps:
 - On the main menu of the iBreastExam app, tap on the *Settings* icon  in the top right corner to open the settings. Select 'Connect to Device.'
 - Select your scanner's BT number from the 'Nearby Bluetooth Devices.' (see below → [Unable to find Bluetooth / Device number](#))
 - Once the BT connection is successful, the connection light becomes steady, and a pop-up message will appear showing the success of the *Bluetooth Connection Status*. Tap on 'Done.'
6. If the issue is still present, go to the mobile phone's Bluetooth settings and Unpair/Forget all iBreastExam scanners.
7. Pair the scanner again with the mobile phone and restart the app. Now try connecting again.


Scanner not connecting to app and Connection light stable

1. This could be because the scanner is already paired to a different mobile phone.
2. To ensure we are connecting the correct pair of scanner and mobile phone: Manually disconnect the device from the other mobile phone's iBreastExam app. To do this, tap on the *Settings* icon  in the top right corner, then tap on 'Disconnect'. The connection light should now be blinking.
3. Restart the scanner and 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. Restart the scanner and tap on the refresh icon in the top-right corner of the scanning page.
3. If the issue is still present, leave the scanning page. Re-select the patient and restart the scan. The app will redirect to the *Connect to Device* page, then tap on the device Bluetooth number.
4. If the issue persists, see above → [Scanner not connecting to app](#).

Unable to find Bluetooth / Device number

1. Device Bluetooth number starts with W or T and has 7 or 8 digits (numbers and letters).
2. Find the device number in the main menu of the app (if the scanner is connected).
3. If not connected, turn on the scanner and ensure all other scanners (if present) are turned off.
4. In the main menu of the iBreastExam app, tap on the *Settings* icon  in the top right corner and tap on *Connect to Device*.
5. Search for *Nearby Bluetooth Devices* to see the Bluetooth number, which includes the device number in (iBExx_[Device Number]).

Firmware Upgrade via Over-the-Air (OTA)

To maintain optimal performance and security of the iBreastExam scanner, users can update the device firmware directly through the iBreastExam app using the Over-the-Air (OTA) feature.

Note: This feature only applies if your Bluetooth number starts with T.

1. The OTA update process requires a stable internet connection, a fully charged scanner and mobile phone, and specific mobile device compatibility.
2. Users can initiate the update by navigating to the 'Firmware Update' option in the app's settings and following the on-screen instructions.
3. It is crucial to keep the scanner close to the mobile phone throughout the process and ensure that no other Bluetooth devices are connected.

For detailed instructions, refer to the [iBreastExam OTA upgrade document](#).

iBreastExam App

iBreastExam app freezing or crashing

1. Restart the iBreastExam app and the mobile phone
2. If using Android mobile:
 - Long Press iBreastExam app icon
 - Select *App Info*
 - *Force Stop*, and re-start the app.
3. If available, update the iBreastExam app from the Google Play Store / App Store.
4. If available, update the phone's Android/iOS version.

Forgotten iBreastExam PIN / Password

1. In case of a forgotten PIN or password, please contact your organization's administrator, who can reset them from the Dashboard.
2. Once you receive confirmation from your organization administrator, follow the instructions below:
 - In case of reset PIN, restart the iBreastExam app. This will require an internet connection, 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 (which was initially used to set up the account) 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


This message appears when you try to sign up with a phone number that's already linked to an existing account. Each phone number or email address can only be used for one account.

If you have already created an account using your mobile number, creating an account using your email address will create a second account. You cannot link a previously registered mobile number/email to a new account. New users can create a single account with both their mobile number and email address.

Banner showing “User does not exist” during login

1. This message appears when you try to log in with a mobile number that is not registered by the system.
2. Contact your organization administrator or Customer Support

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 *Settings* icon  in the top right corner.
2. Tap on *Disconnect* and then tap on *Connect to Device*.
3. Go back to the main menu to see if the balance scans and device number/battery percentage should be visible.

Remaining Scans showing ~NA~

1. Turn off the scanner, close the app, then remove and re-insert the sensor cartridge. Finally, restart both the scanner and the app.
2. If the issue is still present, turn off the scanner, close the app, and replace the sensor cartridge. Restart the scanner and the app.


Remaining Scans showing zero

1. This happens when you have used all the scans on the sensor cartridge. Replace the sensor cartridge with a new one (if available) 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 “Your sensor cartridge seems to be disconnected...”

1. Turn off the scanner, close the app, and remove and reinsert the sensor cartridge. Restart the scanner and the app.
2. If the issue persists, repeat Step 1, after delicately wiping the pogo pins and the backside of the sensor cartridge with wet wipes.
3. If the issue persists, then you need to replace the sensor cartridge. Please ensure that the device is switched off while removing and inserting the cartridge.

Company Information missing in the app (after entering it from the Dashboard)

1. Check if your account is assigned to your organization. Tap on the *Settings* icon  in the top right corner, go to ‘*About Application*’ and ‘*Org Information*’.
2. If you notice ‘NA’ next to ‘*Org Information*’ it means your account is not assigned. Connect your phone to the internet and your scanner. Restart iBreastExam app. Log in again to see if the company information is updated.
3. If your account is still not assigned, inform your organization’s administrator that your device is not assigned to your organization.


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 up to 20 scans before this notification will block you from doing any more scans. To solve this issue:

1. Connect your phone to the internet and to your scanner.
2. Restart iBreastExam app, and log back in.
3. If the issue continues, tell your organization administrator that your device is not assigned in the Dashboard.

Unable to find device and software details for raising a customer support ticket

To help our customer support team solve any issues you might face as efficiently as possible, always share details of the device and software you are using when raising a customer support ticket.

1. Tap the *Settings* icon  in the top right corner and scroll down to ‘*About Application*’ to view device and software details.
2. The pop-up window will display information such as the app version.

To request support, tap on the ‘*Get Support*’ button in the bottom-left corner of the main menu, and share this information either as a screenshot or via *Notes* sections.

Viewing Release Notes After App Update (“What’s New” Section)


After updating the iBreastExam app, a banner appears on the main menu with the message: “*You’ve updated the app to version [app version]. See what’s new.*”

1. Click on this banner to read the release notes, including the latest features, updates, and bug fixes included in the current release.
2. Close the pop-up by clicking the ‘*Ok*’ button to return to the main menu.

Scanning

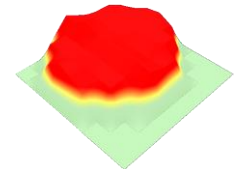
Pressure Meter not appearing/reacting properly

The Pressure Meter might not appear or react properly if the sensor area is not fully in contact with the tissue; if the scanner is placed on tissue without (re-)selecting a tile or if the scanner is rushed and placed on the breast tissue within the 2-second timer.

1. Make sure your fingers are in contact with the silver strip on the top/side of the scanner.
2. Hold the scanner in the air, re-select the tile to reset the sensor, wait for two seconds, and then apply the scanner again.
3. Place the scanner evenly on the tissue, ensuring the whole sensor area is in contact with the breast tissue. For example, avoid placing the scanner on deep scars, which might prevent parts of the sensor from touching the tissue.
4. If the issue persists, turn off the scanner, remove and reinsert the sensor cartridge, then turn it on and click the refresh icon  on the scanning page.

Pressure Map turning completely red

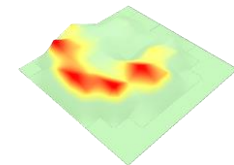
The Pressure Map might briefly turn red after placing the scanner on the tissue. This large red "dome" occasionally appears, indicating that the sensors are still stabilizing between the air and tissue readings. and does not indicate a finding.



1. Reselect the tile, wait for two seconds, keep the scanner in position on the tissue, and wait for the red "dome" to disappear.
2. If the red dome persists, hold the scanner in the air, re-select the tile to reset the sensor, wait for two seconds, and then apply the scanner again.

Pressure Map showing red areas

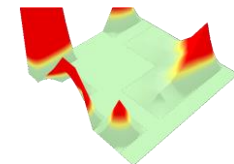
The Pressure Map might light up red in the (partial) shape of the sensor if the scanner is rushed and put on the tissue after selecting a tile.




1. Hold the scanner in the air, re-select the tile, wait for two seconds, and then apply it on the tissue.

Finding "dancing" on Pressure Map

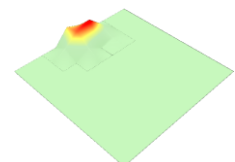
The Pressure Map might show red "dancing" spikes if the sensor cartridge is replaced during a scan.



1. Turn off the scanner and remove the sensor cartridge. Clean the pogo pins and the backside of the sensor cartridge with wet wipes. Ensure that the sensor is dry and reinsert the sensor cartridge.
2. Click the refresh icon  on the scanning page and apply the scanner again.

Finding appearing at very edge of the Pressure Map

If a finding appears at the very edge of the Pressure Map, it may not be a real finding but the result of applying uneven pressure on the tissue.

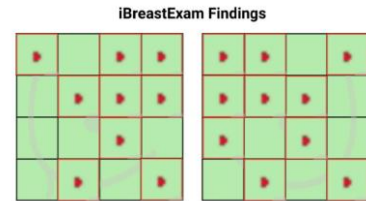


1. Ensure that you apply the sensor evenly on the tissue.

2. Slightly move the sensor to make sure the lump is positioned in the center of the sensor area.
3. If the tissue is bony, follow the steps listed in the operating guide to scan a bony area.

Same finding appearing in different tiles

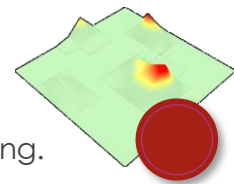
If findings of the same shape and size appear in the same tile position across different tiles, the sensor cartridge might be damaged.



1. Replace the sensor cartridge and apply the scanner again. If the 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 with ideal pressure level, it may not be a real finding but the result of applying the scanner incorrectly.



1. Follow the scanning process as indicated in the iBreastExam training.

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 balance, even if you do not save the scan or generate a report.

Unable to access all files on Android Tablet

This issue may arise due to the screen resolution or zoom settings of the tablet.

1. Go to Tablet Settings > Display.
2. Click on Screen Zoom and ensure the zoom level is set to the minimum.
3. Return to the iBreastExam scan page and check if the issue is resolved.
4. If the issue persists, go to Settings > Display > Screen Resolution and change it to the smallest setting.

Disable Automatic Tile Selection

1. To disable Automatic Tile Selection for a single scan, uncheck the checkbox when selecting Breast size before beginning each scan.
2. To disable this feature for all scans, contact your Organization Administrator.

Reports

Reports not uploading to Dashboard

1. To upload scans that were performed offline, connect the mobile phone to the internet (once available).
2. Restart iBreastExam 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 the main menu / showing an incomplete list

This can happen when you log in from a new mobile device.

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

Performed scan not showing in the 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. Once you click on the *Save* button, wait for the progress bar to complete.
2. If the progress bar is stuck for more than a few minutes, restart the iBreastExam 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.

Report generated with incorrect date and/or time

This issue occurs when the mobile date and time are not set correctly or have been changed.

1. Open the mobile phone settings. Tap on *Date & Time*.
2. Set the correct date and time. You can check these changes on the mobile home screen.

Open the app and proceed with the scanning. The correct date and time will be displayed in all future reports.

Mobile Phone

Mobile Bluetooth not switching on/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 the 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 menu across the screen from the top (Android) or top-right corner (iOS).
3. Ensure that Wi-Fi is turned ON and that the Airplane Mode is turned OFF.
4. Install system updates (if available):
 - Android:*
 - In *Settings*, near the bottom, tap *System* and then *System Update*. Follow the steps displayed on the screen.
 - iOS:*
 - In *Settings*, tap on *General* and then *Software Update*. Follow the steps displayed on the screen.
5. In the Wi-Fi settings, select the network you're trying to connect to, tap *Forget* or *Forget This Network*, and then reconnect to the Wi-Fi.
6. Open the web browser on the mobile phone and enter a sample search. In case your clock is behind, you will get asked to *Update the 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; under Mobile phone not connecting to Wi-Fi → [Install system updates](#)).
3. Reboot the mobile phone (see above; under Mobile Bluetooth not switching on → [Reboot the mobile phone](#)).

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 the 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; under Mobile phone not connecting to Wi-Fi → [Install system updates](#)).
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 scanner when it is plugged into the charger. Ensure that the scanner is not connected to the charger when switching on the scanner.
12. iBreastExam utilizes a Bluetooth Wireless radio that exchanges data between the scanner and the iBreastExam computer system. The Bluetooth radio may be connected to other non-iBreastExam computer systems. The iBreastExam scanner is only intended to be connected and paired with an iBreastExam computer system. If the scanner 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 scanner 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

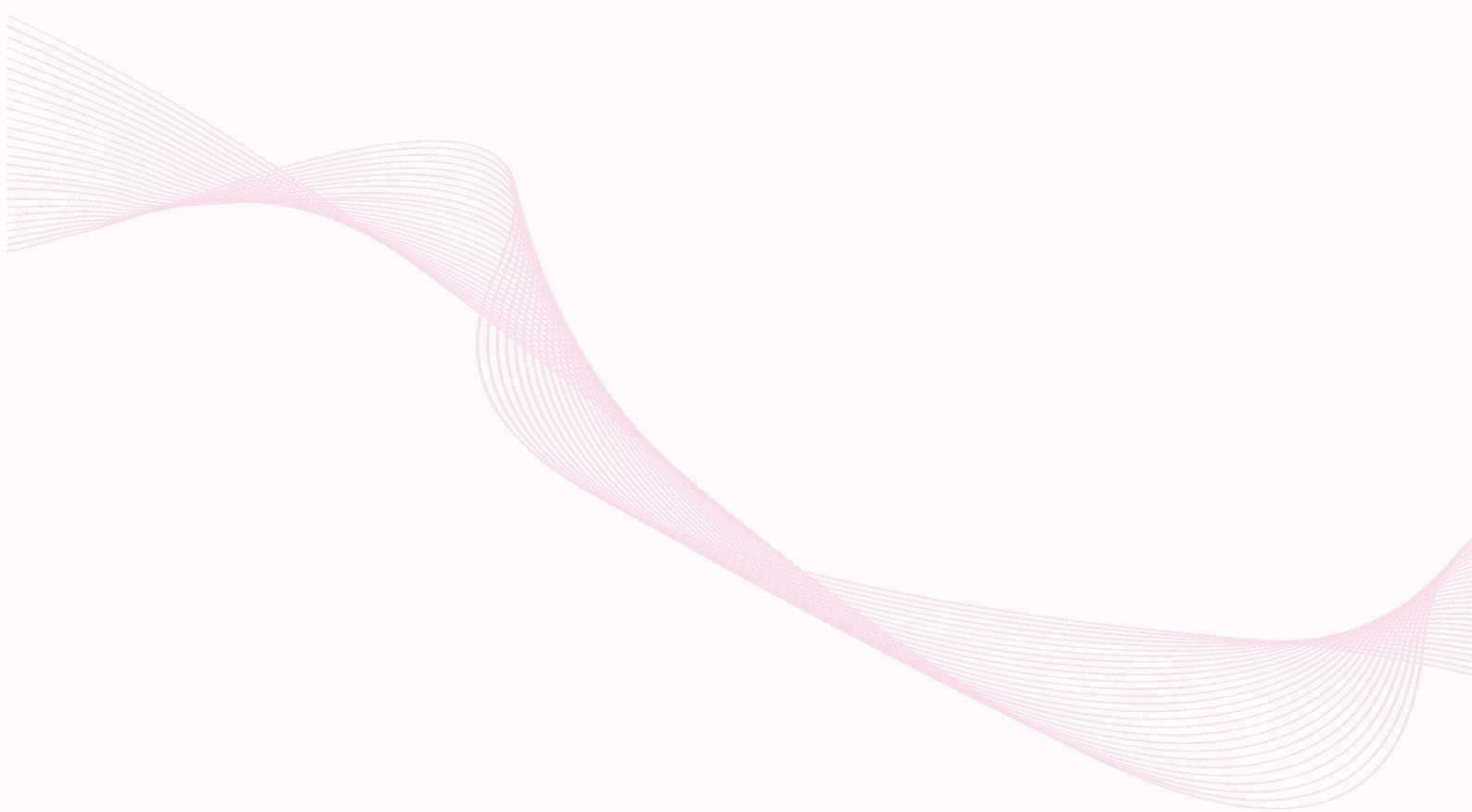
1. Non-invasive, radiation-free, breast examination.
 2. Ultra-Portable and light-weight probe.
 - Probe size: 13 x 6.5 x 8.5cm, weight: 0.5kg.
 - Full system with case size: 27 x 26 x 11cm, weight: 2kg.
 3. Operable with rechargeable battery (1000 to 2000 mAh). Recharging Power: Input 110-220v 50/60Hz at 0.3-0.5A and Output 5v at 2A.
 4. Sensor Technology:
 - 648 Dynamic Co-Planar Capacitive (DCPC) Sensor
 - Measurement of tissue elasticity 20 times per second
 5. Wireless operation using Bluetooth 2.0 standard protocol
 6. Regulatory Clearances & 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
 7. Storage capacity up to 50000 breast examination scans and full reports. Storage capacity based on the selection of the Mobile device.
 8. Custom Mobile Application for Breast Examination with capabilities to:
 - Perform breast examination
 - Store the breast examination data and
 - Print the final report
 9. Replay feature enables the physician to replay a breast examination performed in the past, frame by frame.
 10. 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)
 11. 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
12. Clinical study validation performance characteristics**:
 - Sensitivity is 84%
 - Specificity is 94%
 - Negative Predictive Value is 98%
 - Positive Predictive Value is 60%
 13. Storage, Transport and Operating Conditions:
 - Temperature range in Use:10°C to 40°C
 - Maximum relative humidity: 90%
 - Atmospheric pressure range: 700- 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



USA | India | Malaysia | Colombia | Chile

www.ibreastexam.com
www.uelifesciences.com

support@uelifesciences.com