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LUX-Dx Insertion Workflow

This presentation summarizes the steps of LUX-Dx ICM Insertion Workflow

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CRM-1561502-AA

DESIGNED TO DO WHAT TODAY'S ICMS CAN'T

THE DEVICE

LUX-Dx ICM

- Intuitive implant procedure
- Dual-stage algorithm
- Clear signal quality
- Remotely programmable

THE APP

myLUX™ Patient App

- Helps keep patients connected
- Designed to ease clinic burden

THE DATA

LATITUDE Clarity™ System

- Innovative interface
- Streamlined team workflow

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LUX-Dx Insertion

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Preparing for LUX-Dx ICM Insertion

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LUX-Dx ICM Kit — Model M301

- Lux-Dx ICM
- ICM Cutting Tool
- ICM Insertion Tool

myLUX Patient Kit with Mobile Device — Model 6259

- BSC Mobile Device with myLUX Patient app installed
- Power adapter
- Magnet

Preparing for LUX-Dx ICM Insertion

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Getting the patient app ready for ICM implant:

1. Remove mobile device from packaging.

2. Power on mobile device and verify it's sufficiently charged.

Mobile device used to check LUX-Dx battery and R-wave amplitude once implanted

Preparing for LUX-Dx ICM Insertion

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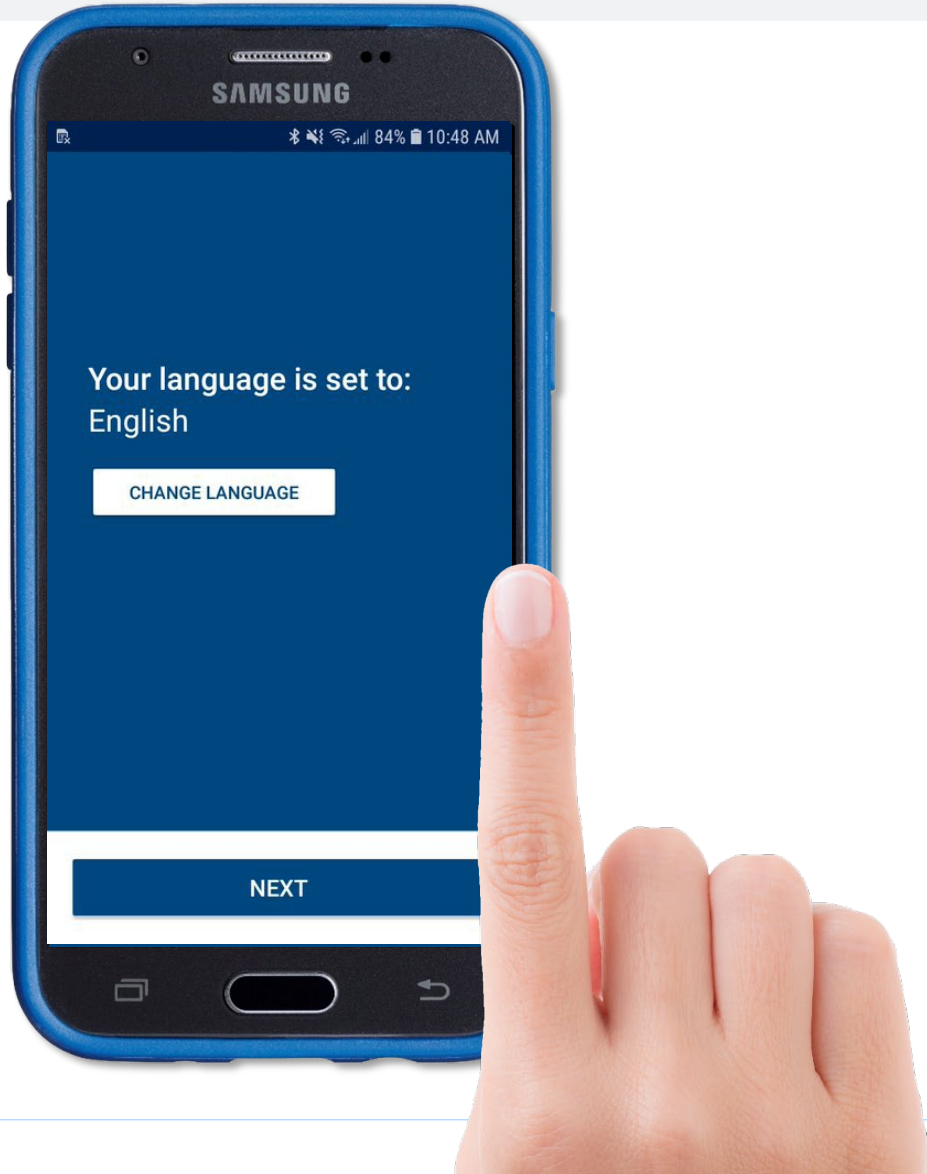
3 Select myLUX app icon on home screen and confirm language.



Preparing for LUX-Dx ICM Insertion

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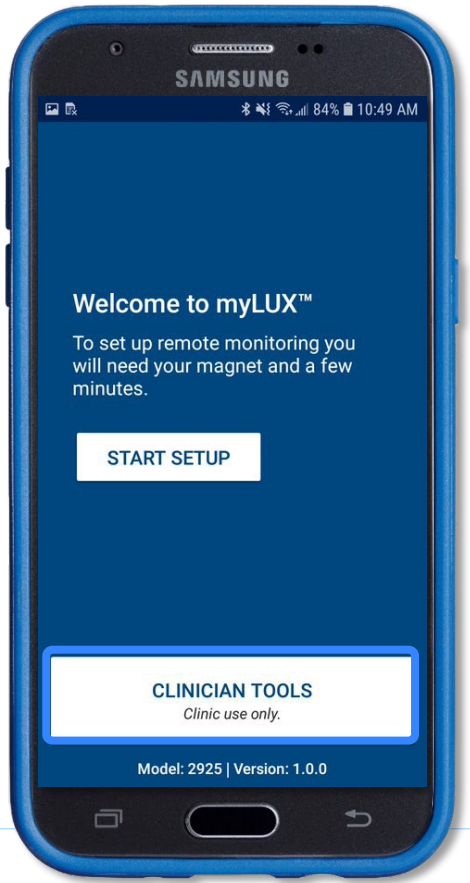
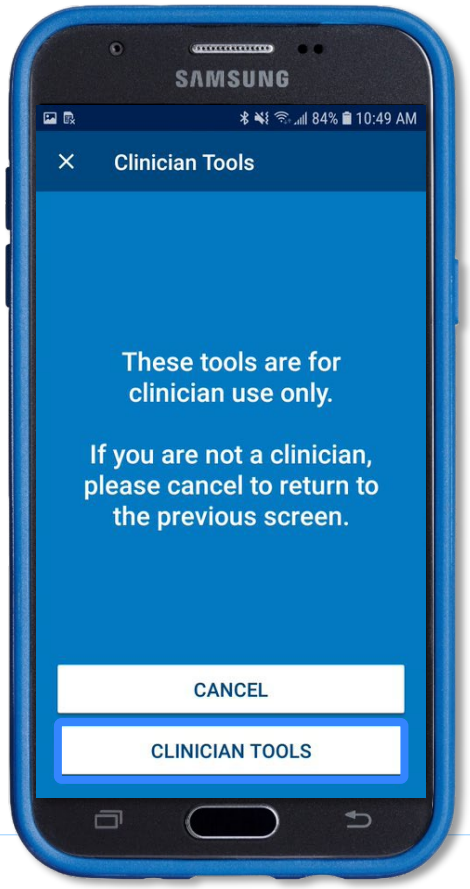
4 Choose the Clinician Tools button and follow prompts.

5 Scan the QR code on outside of LUX-Dx ICM packaging





Preparing for LUX-Dx ICM Insertion

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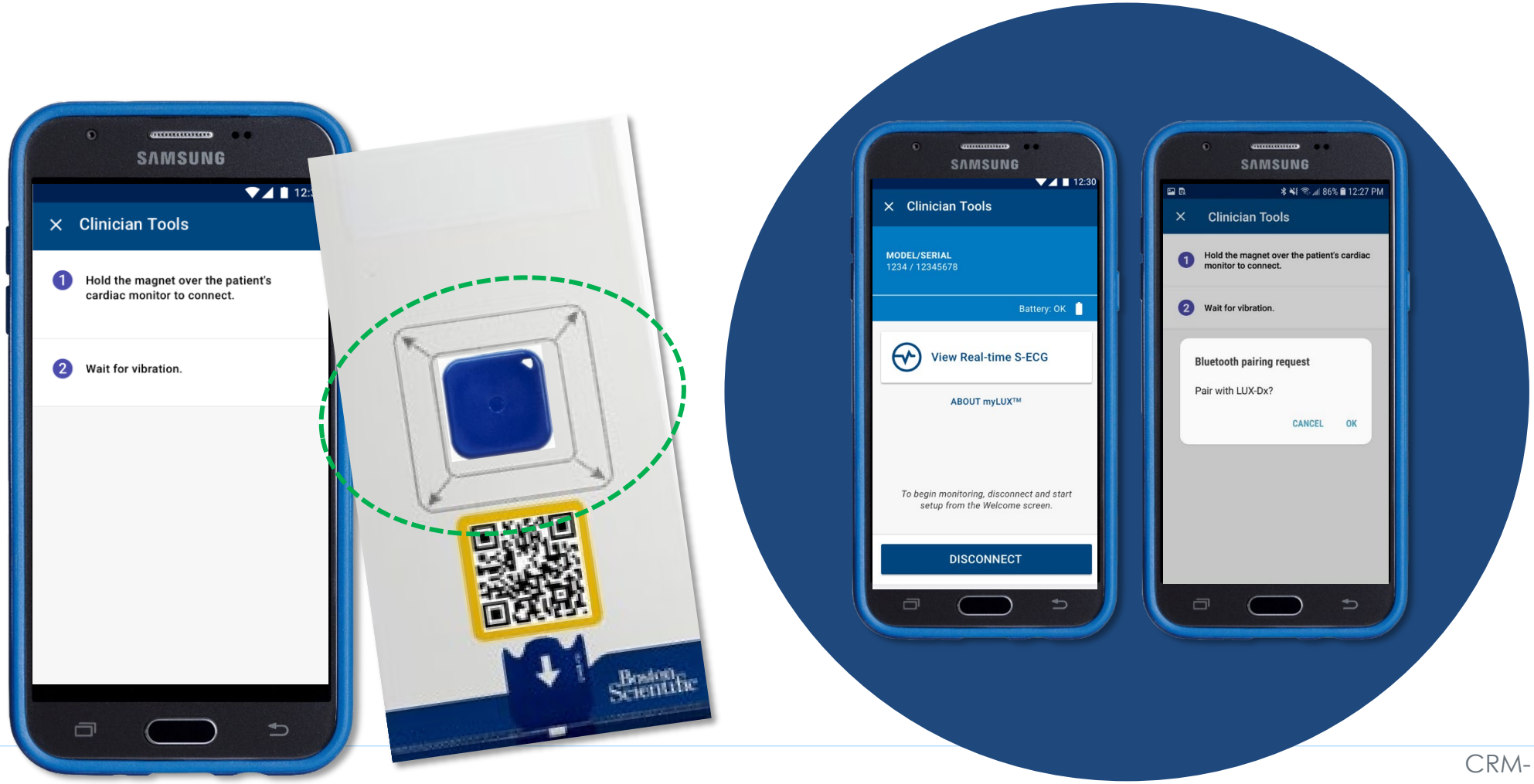
6 Hold the Magnet over the image on the implant box to connect to LUX-Dx ICM.



Preparing for LUX-Dx ICM Insertion

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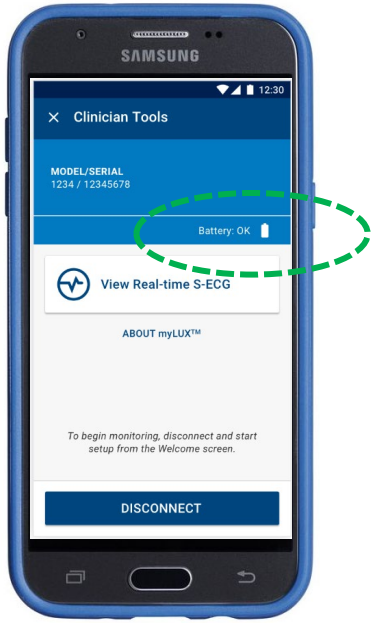
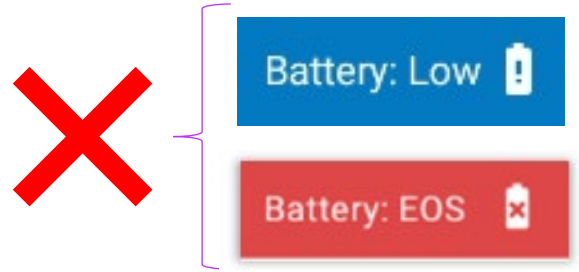
7 Check the battery level of LUX-Dx ICM.

If the battery status says Low or EOS, do not implant the device and instead contact Boston Scientific using the information on the back of the device packaging





8 Hand off LUX-Dx ICM Kit to implanter.

LUX-Dx Device Placement

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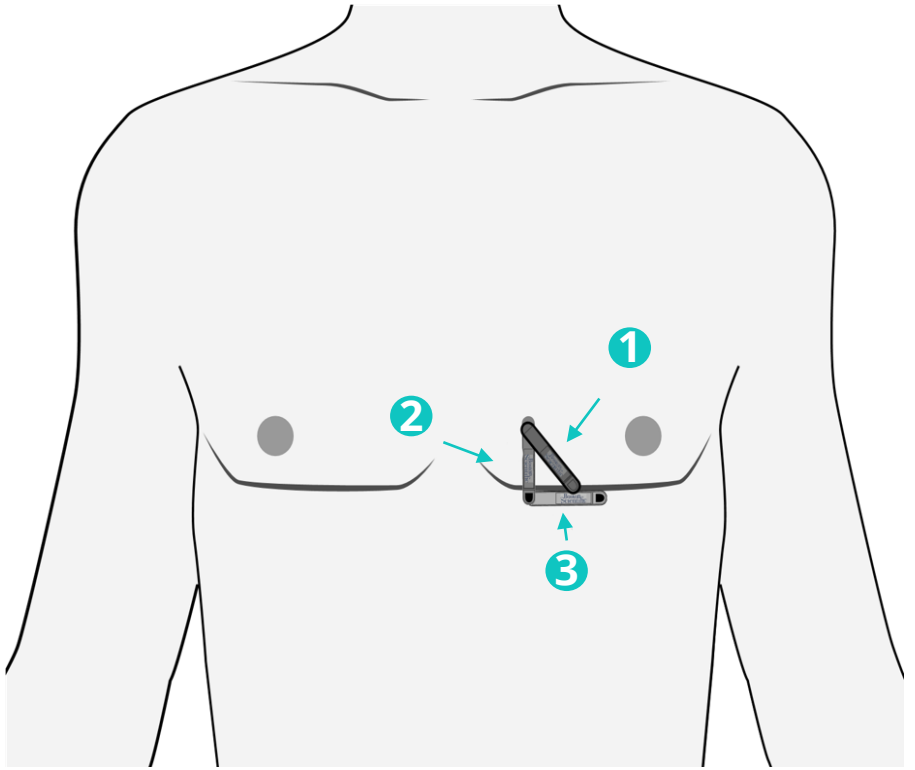
Typically positioned under skin in the left pectoral region

1. **4th intercostal space, 45 degree relative to sternum**
2. **4th intercostal space, parallel to sternum**
3. **Optional locations — anterolateral, inframammary between 5th and 6th intercostal space**



- Optional Surface Mapping
  - Recommended for optional locations
  - Utilize pediatric-size ECG patches, space 4 cm apart (center to center)
  - Position patches to correspond to desired insertion site
  - Use surface ECG to examine position with largest R-wave amplitude
  - Minimum R-wave = 0.3 mV (when viewed on an ECG)

Implant Steps

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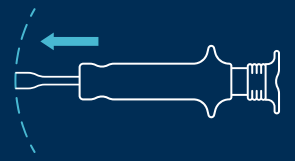
INTUITIVE IMPLANT PROCEDURE

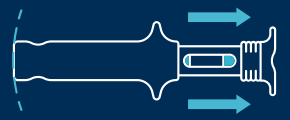
Incision

Insertion

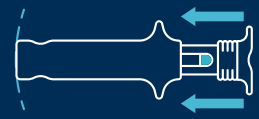


Rotate

Pull Plunger



Push Plunger



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LUX-Dx Insertion Steps

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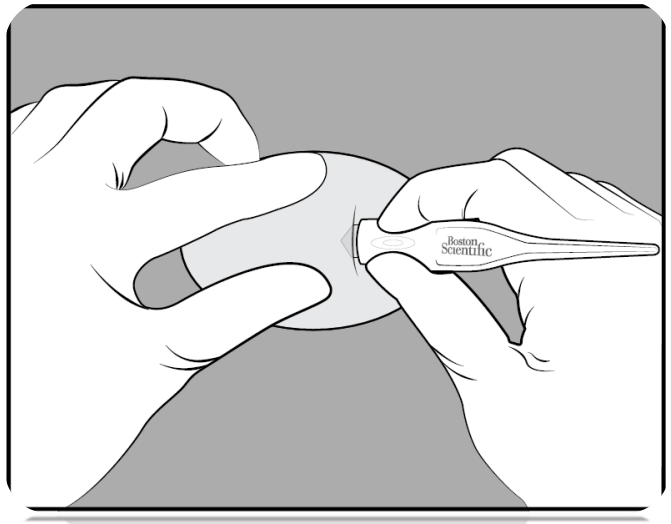
Step 1 CUT

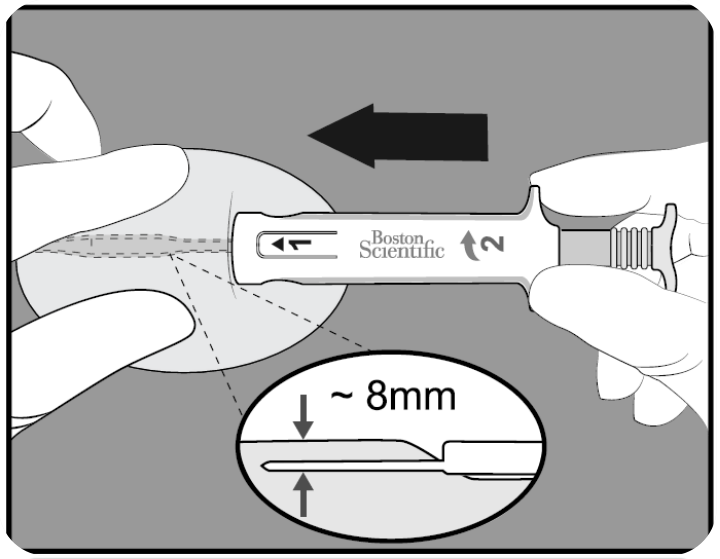
- With logo facing up, insert the tunneling portion of the insertion tool parallel to the skin approximately 8 mm under the surface of skin.

NOTE: If tunneling toward the patient's head, the orientation of the device may produce inverted S-ECGs.



Step 2 TUNNEL

- Apply tension on skin away from incision location.
- Using ICM Cutting Tool, cut at the intended angle until blade is fully inserted.



LUX-Dx Insertion Steps

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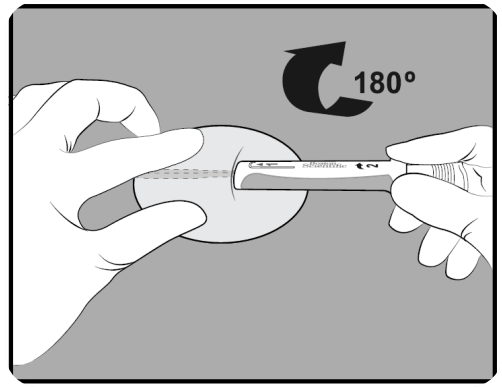
Step 3 ROTATE

Rotate the insertion tool 180 degrees in either direction to create pocket for the LUX-Dx ICM.

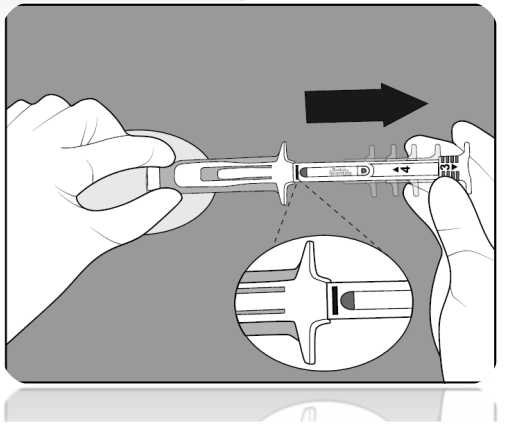


Step 4 PULL BACK PLUNGER

Hold base of the Insertion Tool to the incision site and PULL BACK PLUNGER ALL THE WAY until you feel a hard stop and the blue line is visible.

This ensures the LUX-Dx ICM has dropped down into the channel.

NOTE: If not pulled back completely, the LUX-Dx ICM may jam and not deploy.



TIP: Implanters used to competitive two-piece systems may hesitate pulling plunger all the way back.

LUX-Dx Insertion Steps

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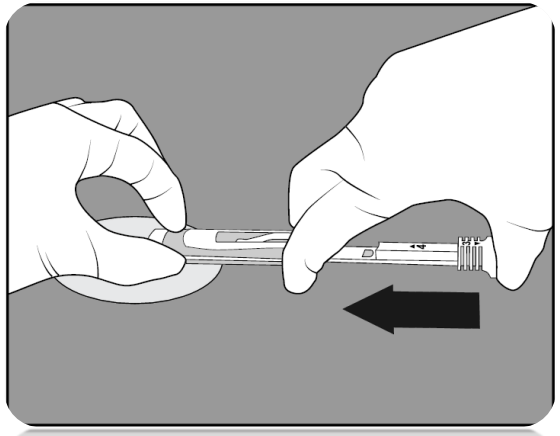
Step 5 INSERT

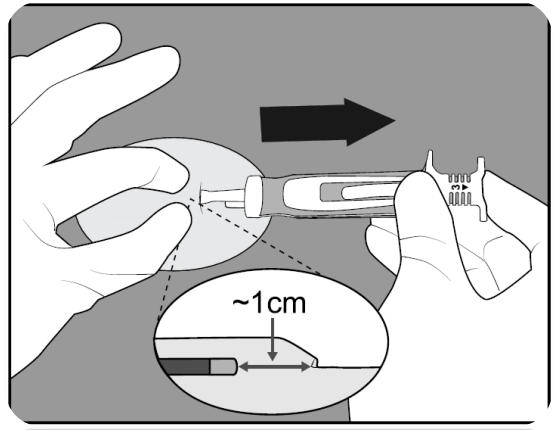
Lower the body of tool close to the skin, and FIRMLY HOLD base of the Insertion Tool at the incision site while pushing the plunger in completely.

NOTE: The tool and device may back out during insertion if the base of Insertion Tool is not secured.



Step 6 REMOVE

- Pinch at the incision site to hold the device in place while removing the Insertion Tool.
- There should be 1 cm of space between edge of device and insertion site.



LUX-Dx Insertion Steps

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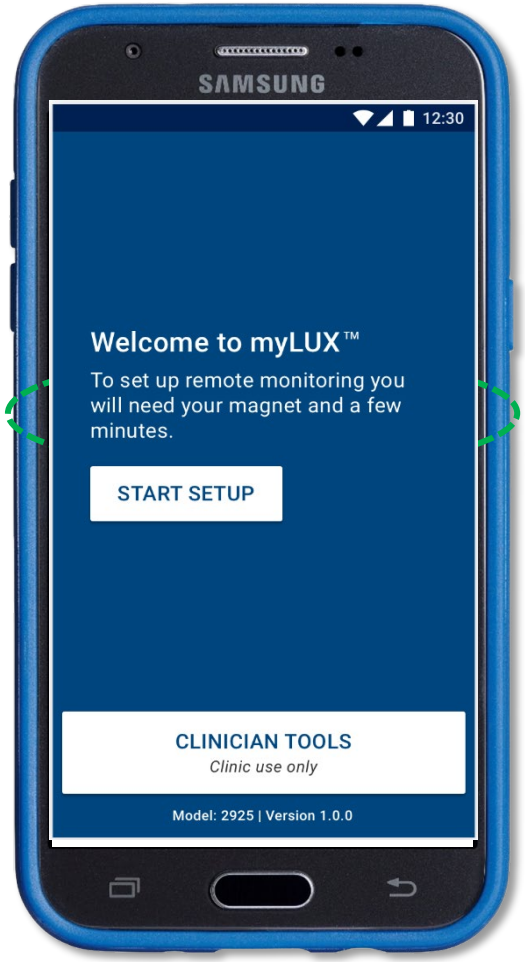
Step 7 VERIFY R-WAVE

Utilizing the patient monitor that accompanies the LUX-Dx device, verify R-wave sensing
(prior to closing incision)



Note: If communication has been lost between BSC Mobile Device and the LUX-Dx ICM:

1. Open “CLINICIAN TOOLS” again.
2. Place the Magnet in the sterile sleeve and hand to the implanter to hold over the implanted LUX-Dx ICM.
3. Wait for vibration on the mobile device.
4. Select “View Real-Time S-ECG.”

Implant Steps

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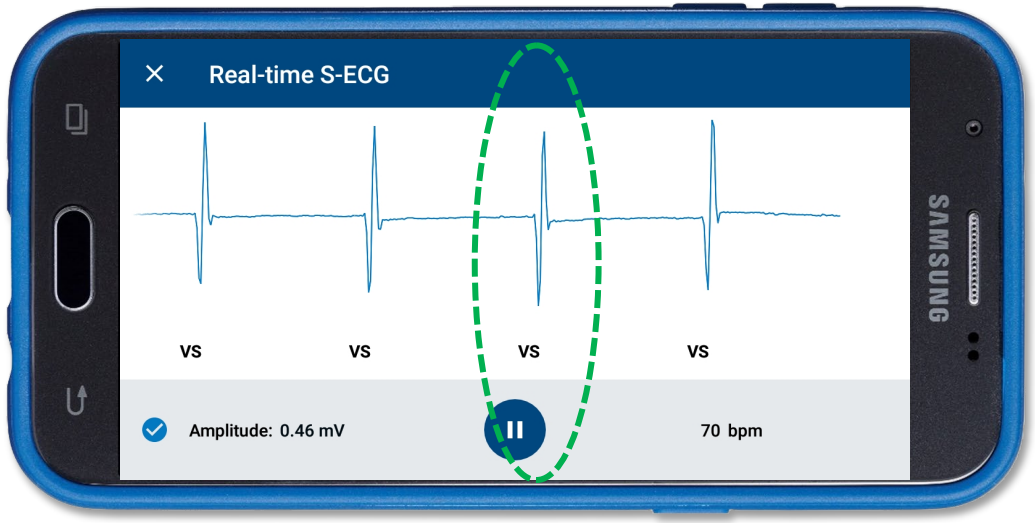
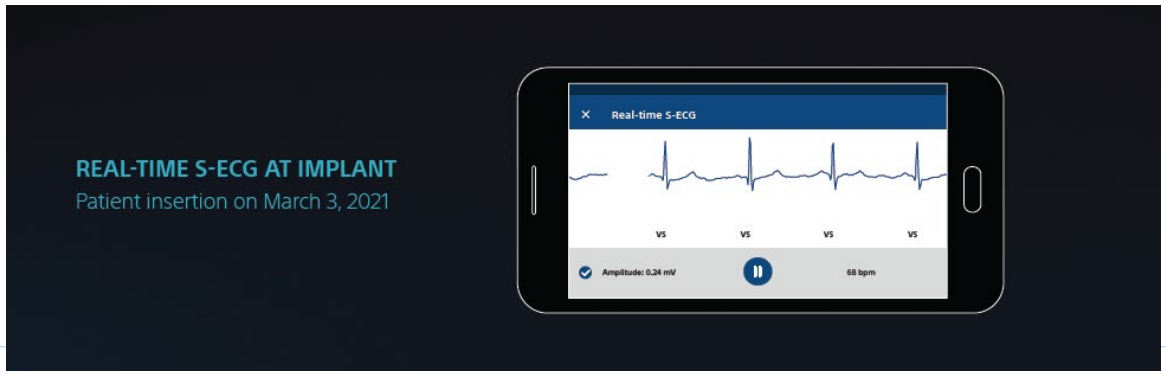
Step 7 VERIFY R-WAVE

Utilizing the patient monitor that accompanies the LUX-Dx device, verify R-wave sensing
(prior to closing incision)

- View S-ECG and verify that R-wave amplitude is ≥ 0.2mV.
- Peak-to-peak R-wave amplitude is at least 2x peak of T-wave or P-wave (whichever is greater).
- Once confirmed, select Disconnect and End Session.





The S-ECG signal quality of the LUX-Dx™ ICM is designed to emulate Lead II. It puts the power of astoundingly clear signals in your hands from the very moment of implant, giving confirmation of proper device location and confidence in algorithm performance.

LUX-Dx Insertion Steps

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Step 8 CLOSE INCISION

Use standard surgical techniques to achieve good tissue contact with the device.

Step 9 COMPLETE FOLLOWING CHECKLIST BEFORE PATIENT DISCHARGE

- ☑ If not yet already done, attach the Magnet to the back of the patient's mobile device case.
- ☑ Confirm the patient's language. If not English, change language on mobile device.
- ☑ Enroll the patient in the LATITUDE Clarity™ System.
- ☑ If cellular connection is possible, complete the myLUX™ Patient App set up on the patient's mobile device. **This will activate the patient's LUX-Dx ICM implanted device.**

NOTE: The patient must be enrolled in LATITUDE Clarity and the myLUX Patient App must be set up and paired on the patient's mobile device in order for the LUX-Dx to become active.

Repositioning the LUX-Dx ICM

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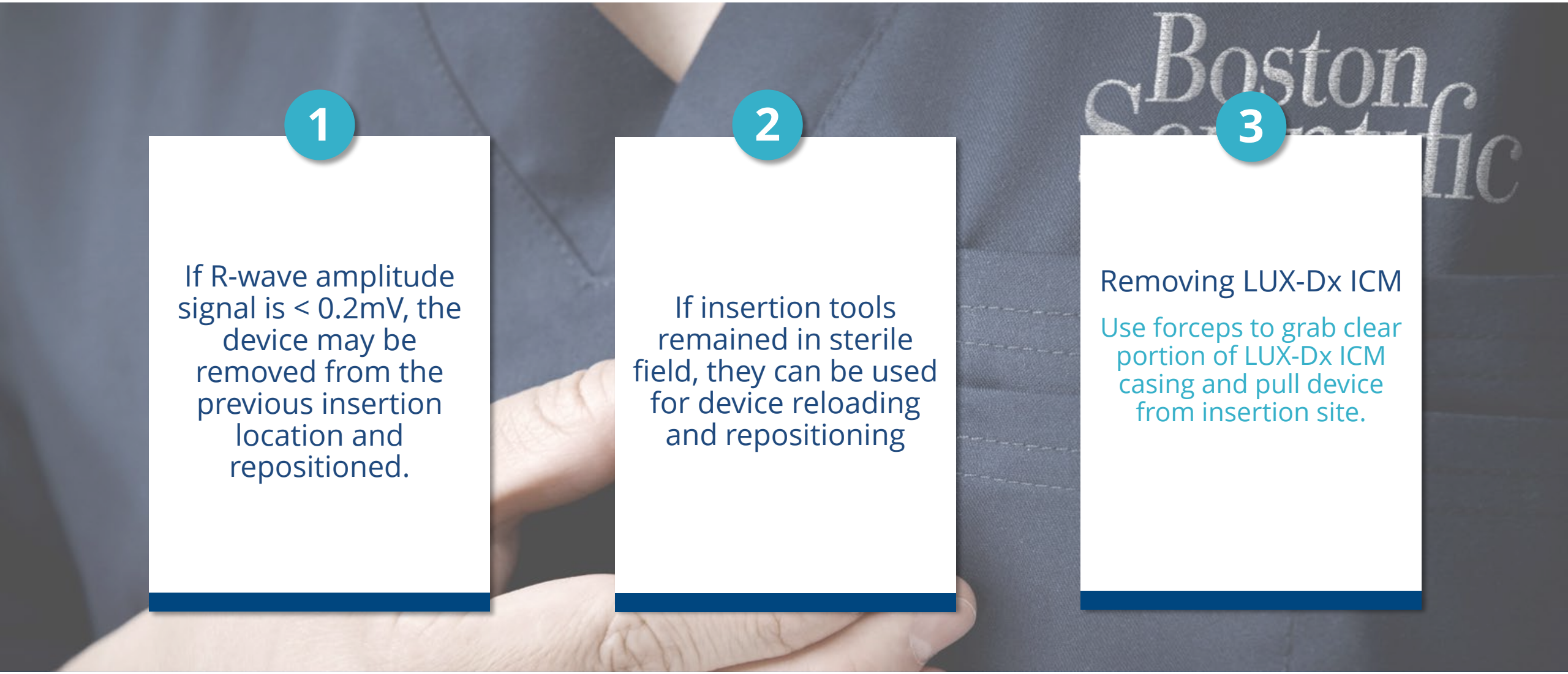

1

If R-wave amplitude signal is < 0.2mV, the device may be removed from the previous insertion location and repositioned.

2

If insertion tools remained in sterile field, they can be used for device reloading and repositioning

3

Removing LUX-Dx ICM

Use forceps to grab clear portion of LUX-Dx ICM casing and pull device from insertion site.

Reloading LUX-Dx ICM Device

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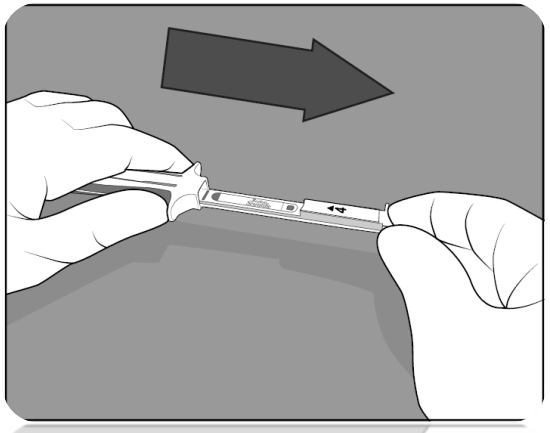
Step 1

PULL PLUNGER BACK TO EXPOSE THE LOADING SURFACE

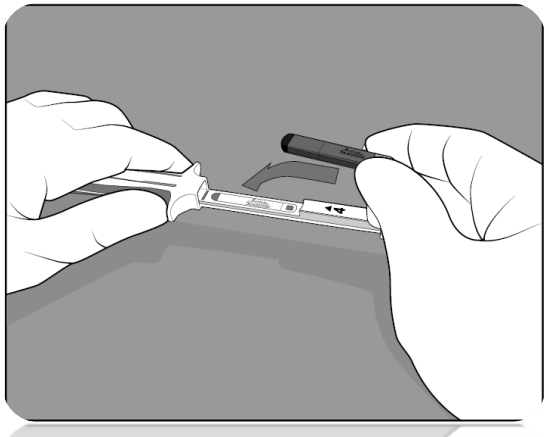
- Ensure to pull back to hard stop



Step 2

PLACE DEVICE INTO ICM INSERTION TOOL

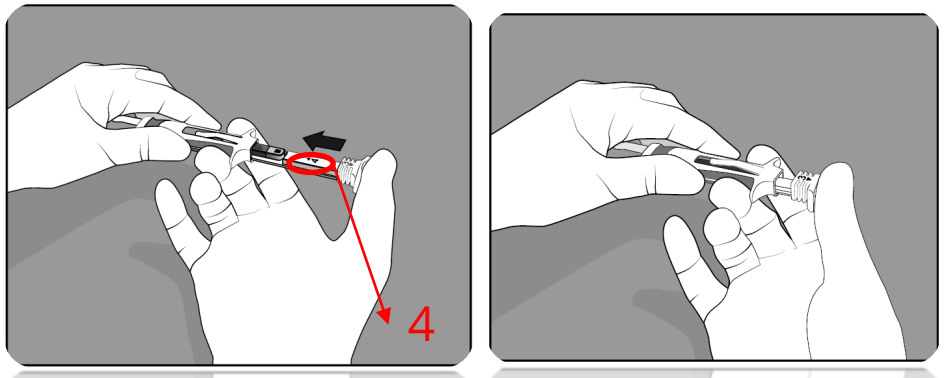
- Place black end of the device on the loading surface exactly as in picture.
- The BSC logo and black square should be visible and facing up.



Step 3

PRESS PLUNGER TO LOAD DEVICE

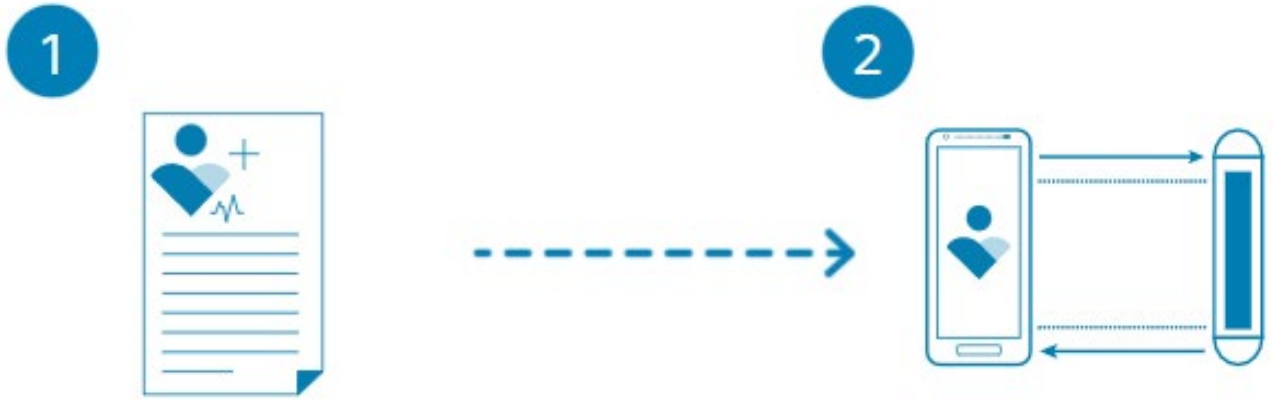
- Firmly press the plunger in until you feel a hard stop and the number 4 marking is no longer visible.
- The device is reloaded and ready to be repositioned.



LUX-Dx Patient Enrolment and Device Activation

Workflow Overview

- For the LUX-Dx ICM to be actively monitoring, the **2 steps below are required**.
- Both these steps must be completed in the right order to make assure the ICM is set up properly.



Step 1: Enroll the patient in LATITUDE Clarity™ (complete online form)

- **Patient Enrolment can be done by anyone who has access to LATITUDE Clarity**
- **It is recommended to be done during or after insertion**

Step 2: Set up the myLUX™ Patient App to pair with the ICM

Required for Activation:

- **myLUX Patient app and magnet**
- **Wi-Fi or cellular connection**
- **Patient's Date of Birth**

Prepare for Enrolment

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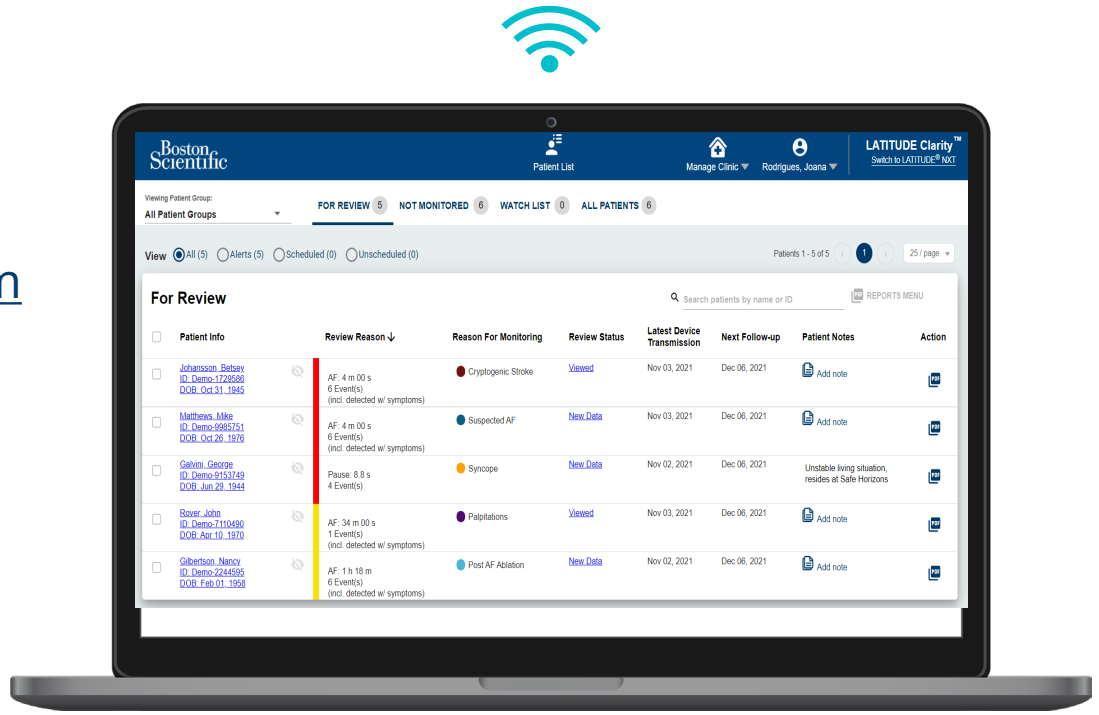
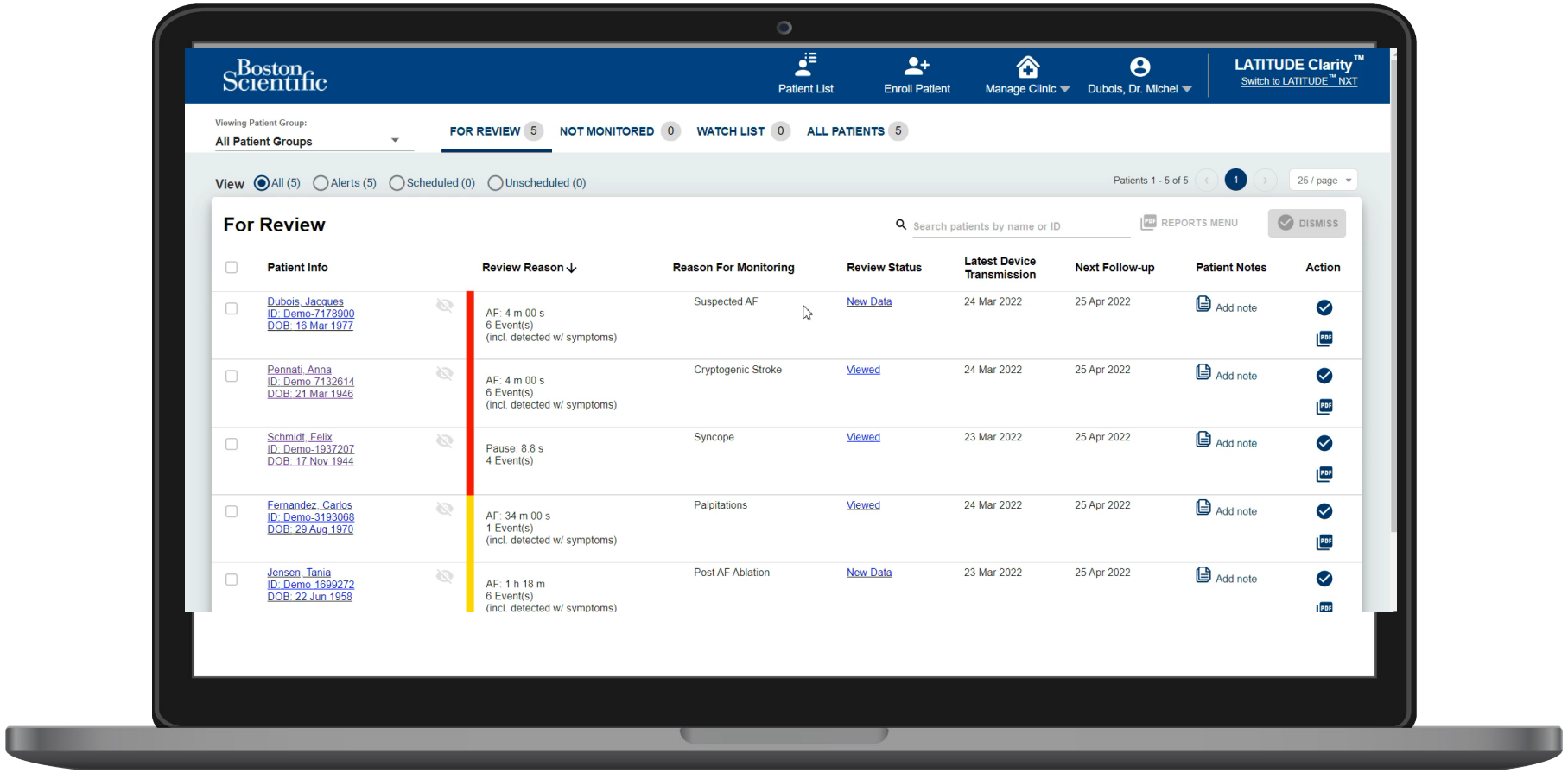
To perform the Patient Enrolment, you will need access to:



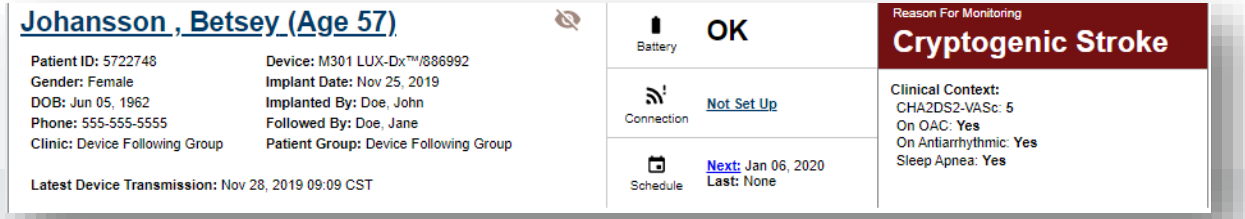
- PC, laptop, or tablet with internet connection
- LATITUDE website: http://www.latitude.bostonscientific.com
- Patient's Date of Birth
- Assigned Patient Group in LATITUDE Clarity™
- ICM Model and Serial Number
- Patient's Reason for Monitoring
- Programming settings — if default settings (nominals) are not preferred

Complete the Enrolment Form

The video below will give you a sense of what the Enrolment Form contains.
All the information you will see entered is completely fictitious for purposes of demonstration.



Enrollment Summary

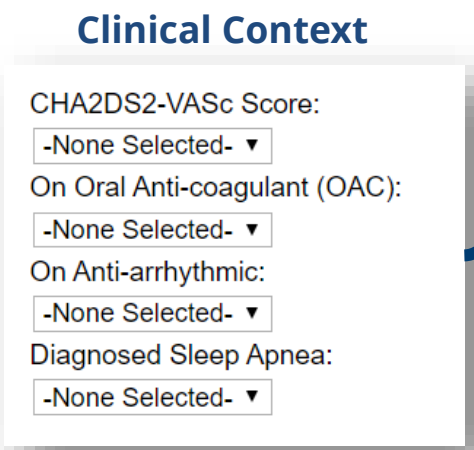


To enroll a LUX-Dx ICM patient, follow these steps:

- Navigate to the LATITUDE website and Log into LATITUDE Clarity™. Note: Confirm that you see the LATITUDE Clarity main screen. If you see the LATITUDE® NXT main page, click the link in the upper-right corner to switch to the LATITUDE Clarity site.

- Click Enroll Patient on the top navigation bar.

- Complete the Enrollment form.
  - Complete all required fields (marked with red asterisks).
  - You will see some optional fields. These fields include information that may help in data (ex: Clinical Context).
- Save confirmation page for proof of service (if relevant).



Important! When enrollment is complete in LATITUDE Clarity, the patient is NOT yet actively monitored. After the patient is enrolled, their ICM must be activated with the appropriate programming by pairing the ICM with the myLUX Patient App

Reason for Monitoring

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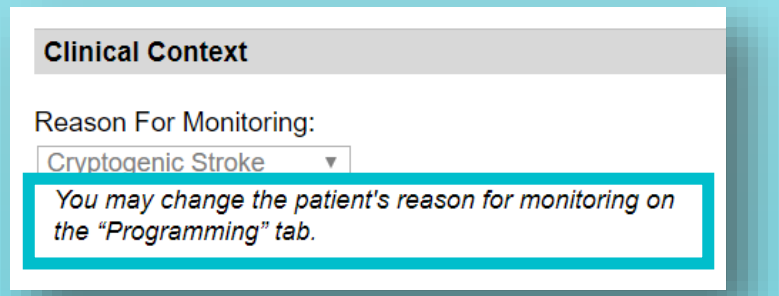
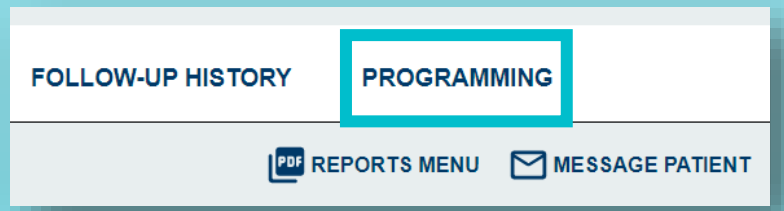
As part of enrollment, **you MUST select the patient's Reason for Monitoring**. With this selection, programming settings specific to that Reason for Monitoring are selected to be applied to the device.

Select a Reason for Monitoring During the Enrolment Process



Then adjust Reason for Monitoring or Programming in Patient's profile by deselecting patient group defaults



NOTE: There are default settings by each Reason for Monitoring, but If desired, programming changes can be performed by Patient Group or Individual Patient.

Assign a Patient Group

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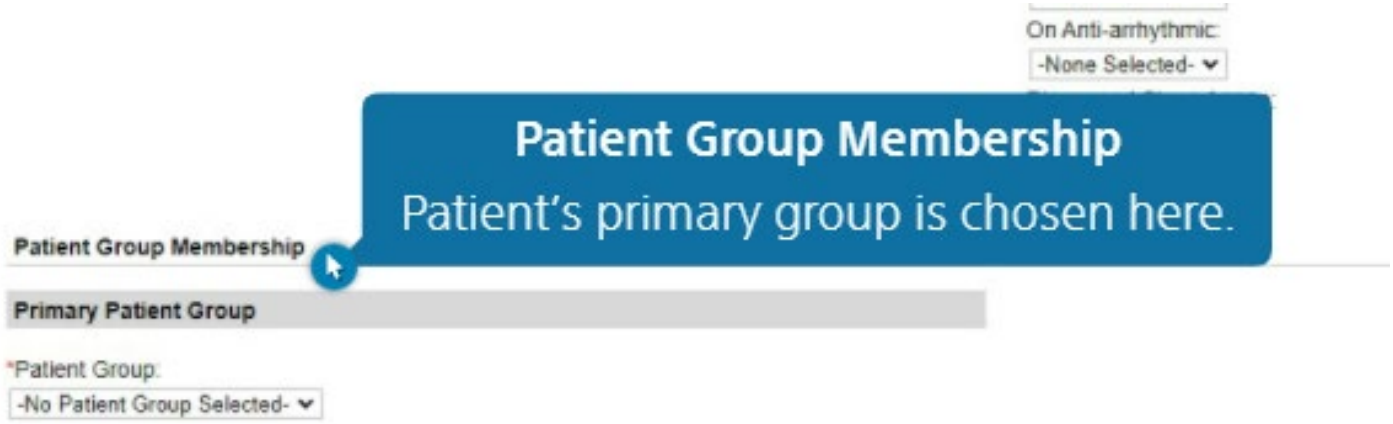
During the enrollment process, **patients MUST be assigned to a Patient Group** in LATITUDE Clarity™.



NOTE

Patient Groups are SHARED across NXT and Clarity. It is critical to help your clinic plan how they want their ICM patients organized so they are set up for success. Note that you can add new groups and edit the default group settings in the "Manage Clinic Settings " section of LATITUDE Clarity

Overview of Enrolment

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1 Enroll patient in LATITUDE Clarity™

Patient is **enrolled** in LATITUDE Clarity.

Device is **registered** with Boston Scientific.

Programming parameters are automatically selected with the required selection of a Reason for Monitoring.

2 Pair ICM with myLUX™ Patient App

Note

This part of the process is **ALWAYS** required even if you used the myLUX™ patient app during implant to view a real-time ECG.

How the system works?

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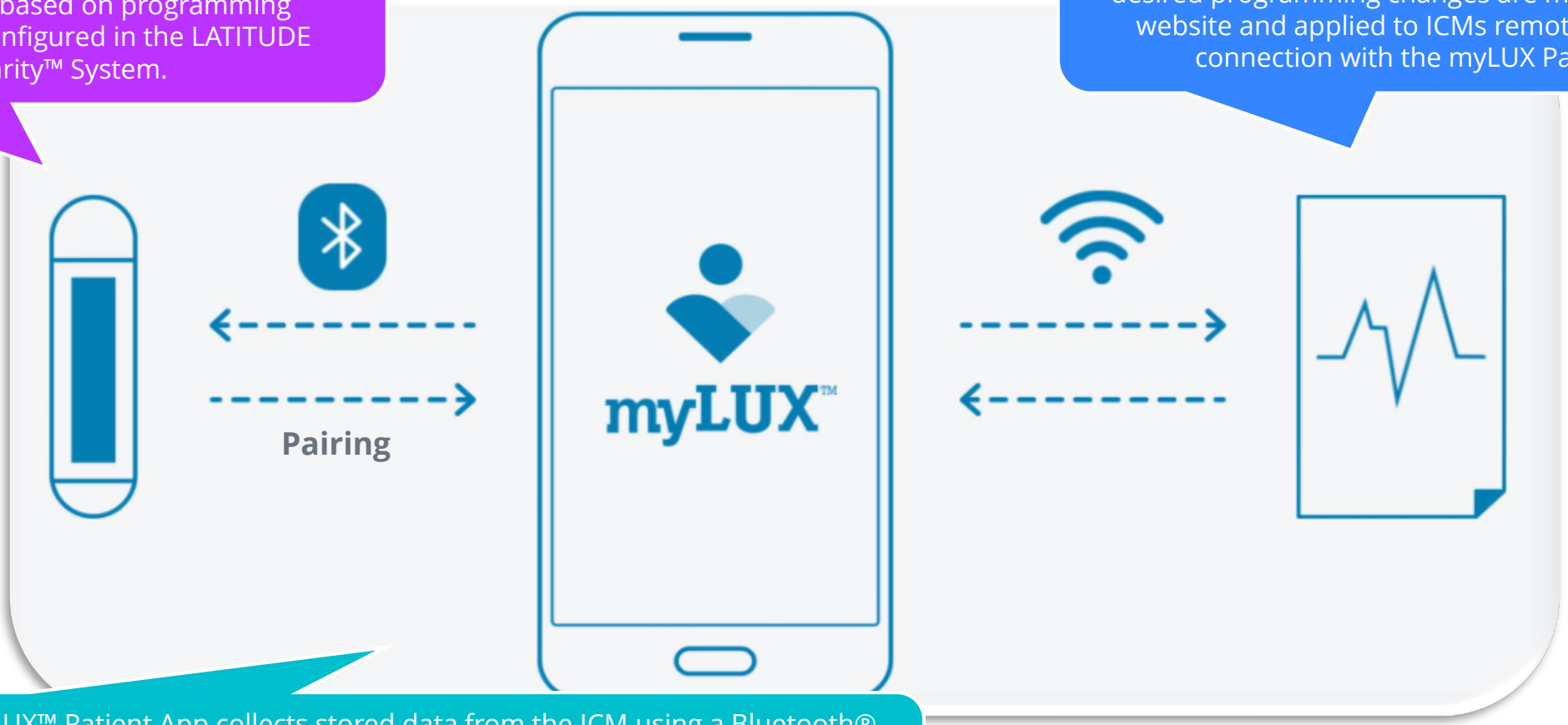
Once **implanted and activated,** the LUX-Dx ICM automatically records, and stores arrhythmias based on programming parameters configured in the LATITUDE Clarity™ System.

Once available on the LATITUDE Clarity website, data from the ICM is reviewed by authorized personnel. Any desired programming changes are modified from the website and applied to ICMs remotely at the next connection with the myLUX Patient App



The myLUX™ Patient App collects stored data from the ICM using a Bluetooth® Low Energy (BLE) connection and transmits that data to the LATITUDE website for review. This usually happens each night as long as the myLUX Patient App is properly connected.

Activate the LUX-Dx ICM

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After a patient has been enrolled in LATITUDE Clarity, you must activate his ICM to make sure programming is properly applied to the ICM and it is actively monitoring. **The following list is required to set up myLUX™ patient app and pair it with the patient's ICM device:**

- Kit 6259
  - Mobile device with myLUX app
  - Magnet
  - Quick Start Guide
  - Patient Handbook
  - Stand and charger
- Patient's Date of Birth
- Reliable Internet Connection via Wi-Fi or Cell Network
- Must be within close proximity to patient

Set Up the myLUX Patient app

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Steps to Set Up myLUX Patient App and Activate ICM

Note! Setting up the myLUX Patient App requires an active internet connection via a cellular or Wi-Fi network

1. The Magnet provided is required for set up. You will need to attach the magnet to the mobile device case (if not already done during implant procedure).

2. Press the power button on the right side of the mobile device. You may have to plug the device in if it isn't sufficiently charged.

Set Up the myLUX Patient app

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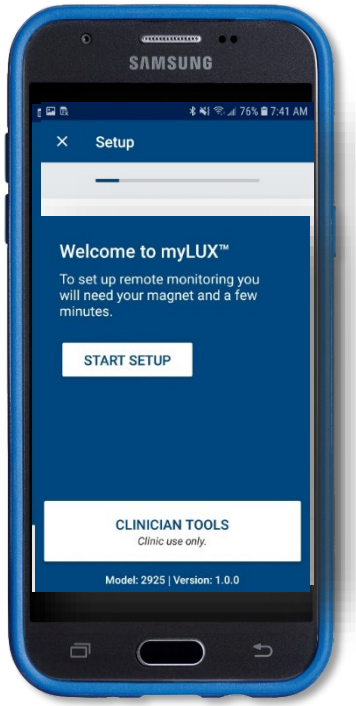
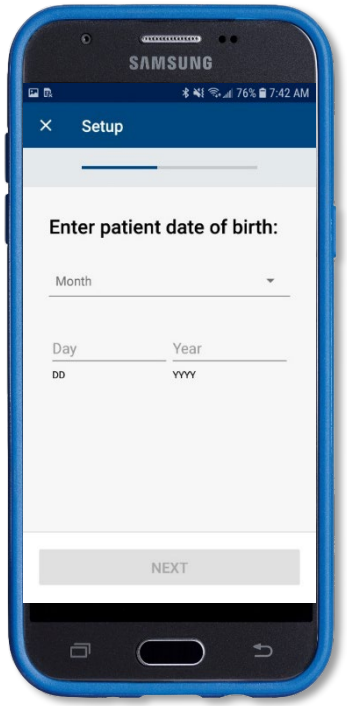
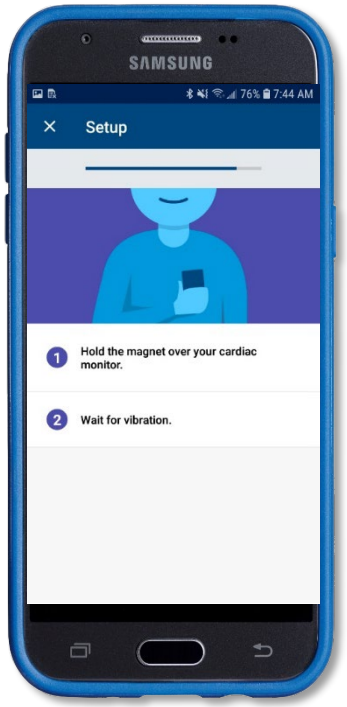
3. Open the myLUX Patient App by tapping the app icon in the middle of the first screen

4. Confirm the language selection. Ask the patient to agree to the privacy policy and terms of use on screen. Tap Start Setup. Enter the Patient's Data of Birth.



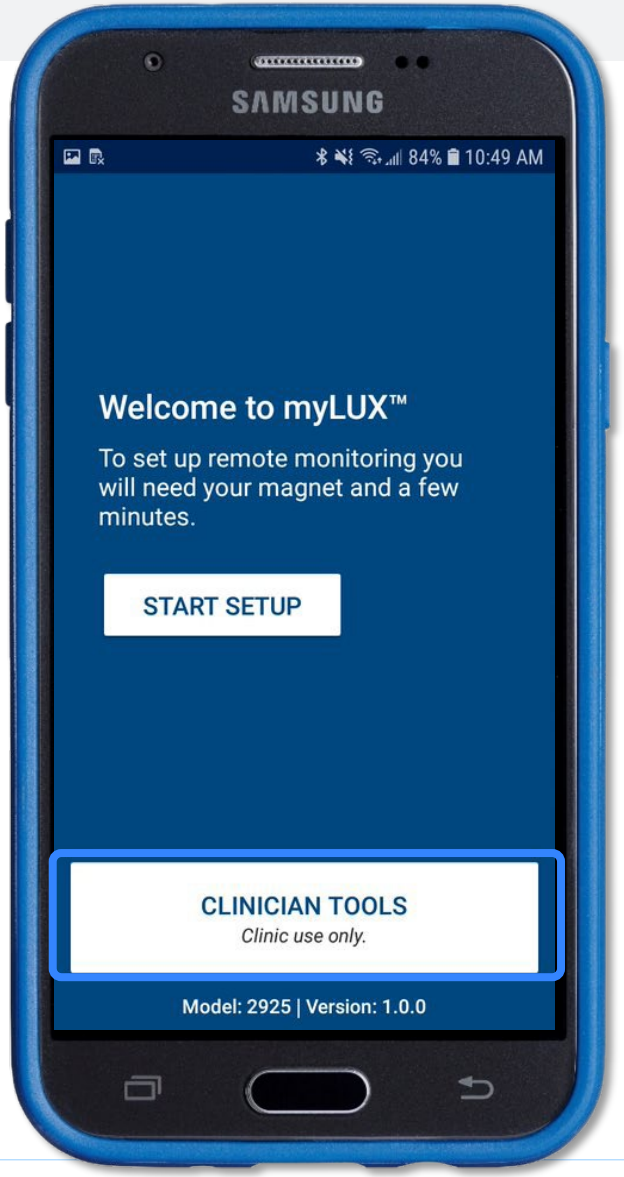


5. Keep following the instructions on the screen that ask you to hold the magnet over the patient's implanted ICM. When it connects, the mobile device will vibrate briefly.



The ICM is activated when you see a screen that says "Your monitoring is up to date."

Clinician Tools



Note

The Clinician Tools button on the myLUX™ patient app will go away once the app is set up. This button is only visible for implant purposes.

LUX-Dx Assistance Clinic App

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The LUX-Dx Clinic Assistant App can also be used to activate the LUX-Dx ICM. In that case, you must check if:

- The LUX-Dx Clinic Assistant App is activated and registered in LATITUDE Clarity.
- The mobile device is charged.
- The mobile device is connected to a Wi-Fi or cellular network.
- You have access to the blue magnet that is part of the LUX-Dx ICM System.

From the main screen of the LUX-Dx Clinic Assistant App, tap Scan and Connect.

Follow the instructions and hold the magnet over the patient's ICM device until it vibrates

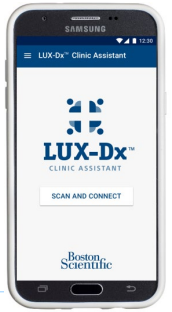
The app will provide a list of ICMs available for connection.

Select the ICM you are prompt to activate

Once connected the app will display the information about the ICM and available actions

Select Program & Activate and accept the pairing request

Follow the instructions on the screen, until a conformation that the activation was successful appears.



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CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device or at www.IFU-BSCI.com. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.
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