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LUX-Dx™ Insertable Cardiac Monitor (ICM) System*

DEVICE CLINIC RESOURCE GUIDE

A device clinic's guide to managing LUX-Dx ICMs and the LATITUDE Clarity™ Data Management System

*LUX-Dx™ ICM System refers to LUX-Dx™, LUX-Dx II™, or LUX-Dx II+™ System, depending on what the patient is prescribed.

CLICK TO BEGIN

Here is a comprehensive list of the guide's contents.
Click on a topic below to go to that page.

Welcome to the Device Clinic Resource Guide for the LUX-Dx Insertable Cardiac Monitor (ICM) System.

This guide is designed to equip device clinics with important information and recommendations to successfully integrate LUX-Dx ICMs, and patients, into existing clinic workflows. It contains relevant information for clinic managers as well as anyone following LUX-Dx ICMs.

Within this guide, you'll find resources to help you:

- Prepare your clinic to follow LUX-Dx ICMs
- Configure the LATITUDE Clarity™ Data Management System to fit with your clinic users and workflow
- Understand the insertion procedure
- Enroll and educate patients
- Activate and interrogate devices using clinic and patient mobile apps
- Optimize patient data review and follow-up using the LATITUDE Clarity System
- Understand LUX-Dx ICM programming and how you might adjust detection parameters and alert settings to meet clinic and patient needs

The recommendations throughout this guide have been developed based on conversations with allied health professionals (AHPs), clinic managers, physicians, patients, and other health professionals who interact with ICMs and existing data management systems.

How to use this guide:

This guide is meant to introduce you to key concepts and parts of the LUX-Dx ICM System and then offer steps for practical application in your clinic. It is meant to be easy for you to find information when you need it without having to read it cover to cover.

Throughout the guide, the main sections will stay on the left side to aid your navigation. If you are using the digital (PDF) version of this guide, it is interactive, which means you can navigate by clicking buttons.

Many sections in this guide are meant to be used alongside the LATITUDE Clarity™ Data Management System.

If you don't find what you need in this guide, please visit Boston Scientific's EDUCARE site at ***luxdxtraining.com*** or call Boston Scientific at 1-800-CARDIAC (1-800-227-3422).

You'll also see three other helpful callouts:

Go to: *Activate & Educate*

more information paths: These *Go to* callouts tell where you can go in the guide to find more information on a topic. The image will indicate which section to look for in the left navigation.

notes: Be sure to read these callouts for important information.

workflow tips: These tips are ideas that may help you integrate LUX-Dx ICMs into your clinic's workflow.

If you have access to the system, we recommend you keep the website open to follow along.

LUX-Dx System Overview

This overview section familiarizes you with how the LUX-Dx System works, as well as indications for use. You'll learn about the five parts of the system: insertable cardiac monitor (ICM), myLUX™ Patient App, magnet, LATITUDE Clarity™ Data Management System, and the LUX-Dx Clinic Assistant App.

Click to navigate to a section.

Indications

The LUX-Dx™ Insertable Cardiac Monitor (ICM) is intended to monitor and record subcutaneous electrocardiogram (S-ECG). The recorded S-ECG is used for the clinical evaluation and diagnosis of cardiac arrhythmias. The LUX-Dx is indicated for use in patients that have a known heart condition and are at risk of developing an abnormal heart rhythm, or have symptoms that may suggest a cardiac arrhythmia, such as dizziness, palpitations, syncope, chest pain, and/or shortness of breath. The LUX-Dx has not been tested specifically for pediatric use.

The LUX-Dx ICM is indicated for use in patients who:

- Have a known heart condition
- Are at risk of developing an abnormal heart rhythm
- Have symptoms that may suggest a heart condition, such as dizziness, palpitations, syncope, chest pain, and/or shortness of breath

note: Licensed health care practitioners trained or experienced in device insertion may prescribe the LUX-Dx II and LUX-Dx II+ ICMs.

note: Need HEMA resources and reimbursement support for the LUX-Dx ICMs? Find them here:

- Coding Resources for Rhythm Management:

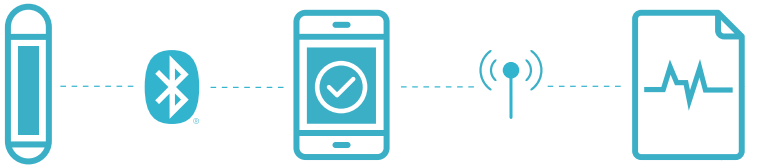
http://www.bostonscientific.com/en-US/reimbursement/rhythm-management.html

- Reimbursement Help Desk:

CRM.Reimbursement@bsci.com

1-800-CARDIAC (227-3422) EXT. 24114

System Introduction



The Devices
LUX-Dx™ ICM
LUX-Dx II™ ICM
LUX-Dx II+™ ICM

The App
myLUX™ Patient App
LUX-Dx™ Clinic Assistant App

The Data
LATITUDE Clarity™
Data Management System

System components are described in more detail later in this section.

Go to: *How the System Works > System Components*

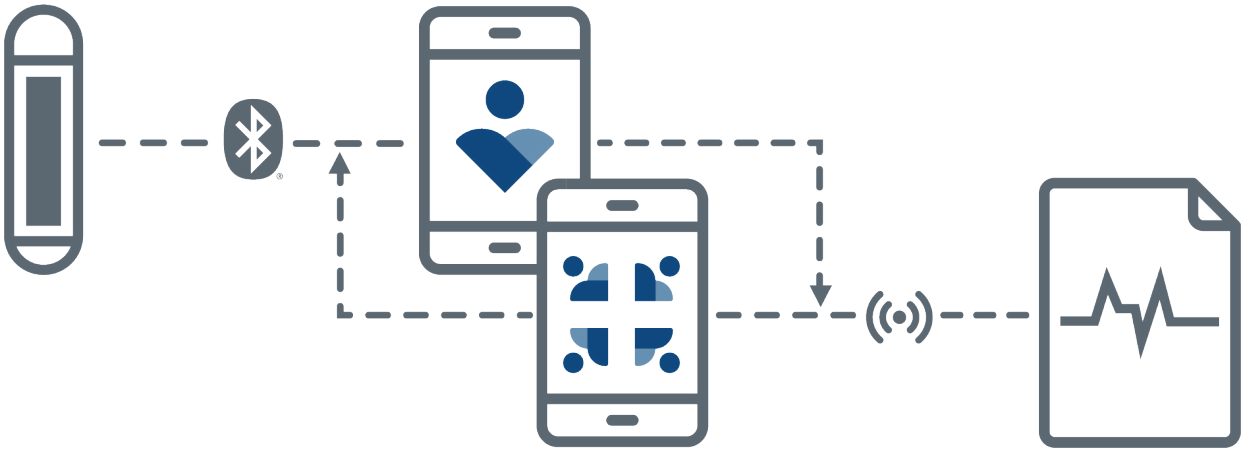
The LUX-Dx ICM is designed to monitor and record heart rhythms for clinical evaluation. It does not provide clinical diagnoses and is not meant to assist in health emergencies.

The ICM system consists of the following components:

SYSTEM COMPONENT	MODEL NUMBER	KIT NUMBER
LUX-Dx ICM LUX-Dx II ICM LUX-Dx II+ ICM	M301 M302 M312	N/A
myLUX Patient App on a Boston Scientific provided mobile device myLUX Patient App for patient's own Android™ Mobile Device myLUX Patient App for patient's own Apple™ Mobile Device	2925 2929 2939	6259, 7259
LATITUDE Clarity System	N/A	N/A
Magnet	6386	Included with 6385, 6259 & 6256
LUX-Dx Clinic Assistant App	2935	6256, 7256

KIT	MODEL NUMBER
Boston Scientific provided myLUX Mobile Device Kit (for M301)	6259 (not compatible with M302 & M312; includes phone preloaded with the myLUX app, magnet, stand, charger and literature)
Boston Scientific provided myLUX Mobile Device (for M301, M302 & M312)	7259 (phone preloaded with myLUX app, and charger)
myLUX Patient Kit (for M302 & M312)	6385 (1:1 for all M302 and M312; includes magnet and patient literature)
LUX-Dx Clinic Assistant Mobile Device (for M301, M302 & M312)	7256 (Boston Scientific provided phone preloaded with the Clinic Assistant app, stand, and charger)
LUX-Dx Clinic Assistant Kit with Mobile Device (for M301)	6256 (Boston Scientific provided phone preloaded with the Clinic Assistant app, magnet, stand, and charger;compatible with M302 & M312 once the app version is updated to version 2.0 or higher)

How the System Works



System Overview

- Once inserted and activated, the LUX-Dx ICM automatically records and stores arrhythmias based on programming parameters configured in the LATITUDE Clarity™ System.
- 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 happens each night as long as the myLUX Patient App is properly connected.
- Patients have the options of either downloading the myLUX Patient App onto a personal smart phone (Android OS or Apple iOS) or using a mobile device provided by Boston Scientific with the myLUX app pre-installed.
- 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 or in clinic using the LUX-Dx Clinic Assistant App.
- The LUX-Dx Clinic Assistant App connects to any of the LUX-Dx ICMs and can be used during insertion and clinic follow-ups for ICM device activation, device checks and interrogations, and firmware update delivery.

Reasons for Monitoring & Programmable Settings

The LUX-Dx ICM monitors a patient's heart rate for arrhythmias based on programmed parameters. Programmed parameters are initially based on the Reason for Monitoring selected during the enrollment process. Parameters can be adjusted at any time.

Available Reasons for Monitoring include:

- Syncope
- Palpitations
- Cryptogenic Stroke
- Suspected AF
- Post-AF Ablation
- AF Management
- Ventricular Tachycardia
- Other

note: Reasons for monitoring and individual parameters can be adjusted remotely without the patient coming in for a visit.

Arrhythmia Type and Programmable Options

	LUX-Dx II+ ICM M312	LUX-Dx II ICM M302	LUX-Dx ICM M301
Pause	Yes	Yes	Yes
Brady (bradycardia)	Yes	Yes	Yes
Tachy (tachycardia)	Yes	Yes	Yes
AF (atrial fibrillation)	Yes	Yes	Yes
AT (atrial tachycardia)	Yes	Yes	Yes
PVC burden	Yes	Yes	No
Pause nighttime programming	Yes	No	No
Pause programable duration extensions	Yes (2, 3, 4, 5, 6, 7, 8, 9, 10 seconds)	No (1.5, 3 and 4.5 seconds)	No
Brady nighttime programming	Yes	No	No

System Components

There are five components of the system. Each is explained in this section:

ICM Devices | myLUX™ Patient App | Magnet | LATITUDE Clarity™ System | LUX-Dx Clinic Assistant App

ICM Devices

Model Number: M301, M302, M312

The LUX-Dx ICM is a leadless electronic device inserted just under the skin in the left pectoral region. It uses two electrodes to monitor the patient's S-ECG data when specific arrhythmias are detected.

ICM Quick Specs:

SIZE

Volume: 1.2 cm^3 | Weight: 3 grams

STORAGE

The ICM stores a maximum of five events of each type (AT, AF, Pause, Brady, Tachy, Symptom) per day. The event data is stored in an event logbook which includes up to 40 events of each type. When the log is full, data from the most recent event may overwrite the oldest stored event data of that type.

Highest-priority events

Event Type	Priority	Special Criteria
AF	1	Longest
Pause	1	Longest
Tachy	1	Fastest
AT	2	N/A
Brady	2	Slowest
Symptom	3	N/A

The ICM's memory can store up to 60 minutes of S-ECG recordings. When the available memory is full, a new S-ECG recording will overwrite older SECG data. The event logbook in LATITUDE Clarity will attempt to preserve the most recent and special events of highest priority.

BATTERY LIFE

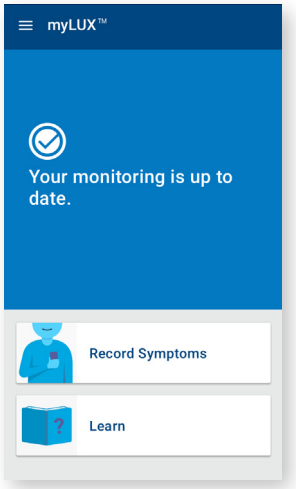
The LUX-Dx ICM has three years of projected longevity, under the following usage:

- Average of one auto-detected event per day
- Average of one patient initiated event per month
- PVC Burden disabled*
- Less than or equal to 6 months shelf life (between device manufacture and insertion)

* For LUX-Dx II (M302) and LUX-Dx II+ (M312) only

myLUX™ Patient App

Model Number: 2925, 2929, 2939



The myLUX Patient App is a mobile application, if enabled by the clinic, that allows the patients to be remotely monitored and transmit data between the ICM and the LATITUDE Clarity server. Patients now have the option of accessing the myLUX Patient App by:

- Downloading the patient app from the Apple App Store (model 2939) or Google Play Store (model 2929) and installing it on their personal smartphones*
- Using a mobile device provided by Boston Scientific with the patient app pre-installed (model 2925)

The myLUX Patient App also contains other features that will help patients interact with the system and their clinic and stay connected. These features include:

- **Symptoms:** If enabled by the clinic, patients will be allowed to record a finite number of symptomatic events per day. The number of events is configurable by the clinic.
- **Connection:** The app will display the current connection status on the main screen.
- **Compliance:** The app will prompt and help patients to troubleshoot connection problems.
- **Education:** The app provides access to online educational materials directly from the main screen.
- **Communication:** Patients can receive read-only messages on their app from clinics sent via LATITUDE Clarity.

The myLUX Patient App on a Boston Scientific provided mobile device (Model 2925) contains clinician tools** to support the ICM insertion procedure. These tools allow clinicians to view the current ICM device status and view real-time S-ECGs.

More information on the myLUX Patient App is included in the Patient Education section.

Go to: *Activate & Educate > Using the myLUX Patient App*

*The downloadable myLUX Patient App is only available for LUX-Dx II ICM and LUX-Dx II+ ICM. It is not available for the LUX-Dx ICM.
**Clinician tools are only available on the provided version of the myLUX app (model 2925). It is not available for the downloadable versions of the app (model 2929, model 2939).

Magnet

Model number: 6386, or in kits 6256, 6259 and 6385

The magnet is an accessory used to initiate communication between the ICM and the mobile applications. It comes in a shielded box in the Bostion Scientific provided mobile device kits (6256 or 6259), in the myLUX™ patient kit (6385), or as a standalone (6386).

In most cases, the magnet should be attached to the back of both the patient and clinic mobile devices. Provided mobile device cases will come with an adhesive circle already applied to the back of the case for attaching the magnet to the case.

For patients using the myLUX Patient App on their own smartphone, advise them to attach the magnet to their keychain, on the back of their smartphone, or keep it at a place where it can easily be found.

Use of the magnet is required in order to:

- ✓ Initiate communication between the ICM and myLUX™ Patient App:
  - At initial device activation and pairing
  - When using clinician tools
  - When sending manual transmissions or recording symptoms (If you would like your patient to record symptoms, instruct them to carry the myLUX app and magnet with them throughout the day)
- ✓ Initiate communication between the LUX-Dx Clinic Assistant App and the device

note: Keep the magnet at least 15 cm (6 inches) away from items sensitive to magnetic fields, including the ICM device when the magnet is not being used to initiate communication between the device and the patient app or LUX-Dx Clinic Assistant App. Remind patients DO NOT carry the magnet in a shirt or jacket pocket over their inserted ICM.

LATITUDE Clarity™ Data Management System

Overview

The LATITUDE Clarity System is a separate section of the existing LATITUDE website: ***latitude.bostonscientific.com***. LATITUDE Clarity is dedicated to the monitoring and programming of ICM devices exclusively. All remotely transmitted data from a LUX-Dx ICM is sent to the LATITUDE server and made available on the LATITUDE Clarity website to authorized health care providers.

If you already use the LATITUDE™ NXT Patient Management System in your clinic, you will notice LATITUDE Clarity was built from that same foundation, but it includes many features specific to ICM workflows. These features were built based on feedback from AHPs currently managing ICM devices.

Using LATITUDE Clarity, authorized personnel will be able to:

- ✓ Enroll a patient in the LATITUDE Clarity System before, during, or after the insertion procedure

Information on enrolling a patient is included in the Activate & Educate section.

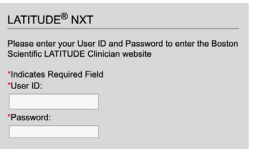
Go to: *Activate & Educate > Patient Enrollment in the LATITUDE Clarity System*

- ✓ Access and assess data transmitted from a patient's ICM
- ✓ Analyze patient data using enhanced ECG and annotation tools
- ✓ Monitor patient heart health trends
- ✓ Generate reports and send data to EMR systems (if configured)
- ✓ Adjust device programming and apply changes remotely from the website

Accessing LATITUDE Clarity™

If you are an *existing* LATITUDE user:

1. Navigate to ***latitude.bostonscientific.com***.
2. Select *LATITUDE Clarity*.
3. Enter your existing username and password.



4. Once logged in, if you are seeing LATITUDE™ NXT, select the *LATITUDE Clarity* link in the upper-right corner of the site.

note: If you are an existing LATITUDE user but are accessing the website from a computer that has never used LATITUDE before, you will be asked to select your country and language.

If you are a *new* LATITUDE user:

Please work with your Boston Scientific representative to get set up on the system.

note: A session will time out if you are inactive for more than 60 minutes. After that, the session is automatically closed and you are logged out. When this happens, the site will direct you back to the login page.

The LATITUDE website works with the latest versions of the following internet browsers: Microsoft Edge, Safari, and Google Chrome.

You will not be able to view device and patient data directly from the LUX-Dx Clinic Assistant App. After an interrogation, you will log into the LATITUDE Clarity™ Data Management System to view any data transmitted from the device.

LUX-Dx Clinic Assistant App

Model Number: 2935

The LUX-Dx Clinic Assistant App is a mobile application preinstalled on a mobile device provided by Boston Scientific (model 7256). The mobile device and app will also come in kit 6256 with accessories (white case, charger, magnet, and stand) and product literature in the kit.

The LUX-Dx Clinic Assistant App will connect to any LUX-Dx ICM within a range of 6 feet (2 meters) and can be used during insertion and clinic follow-ups for the following tasks.

It will be used during insertion to:

- Check ICM device status
- Display a real-time S-ECG to confirm placement
- Activate device

note: The Clinic Assistant App will be utilized during insertion for patients who use the downloadable myLUX Patient App, because the patient app does not have Clinician Tools available. Reference the Insertion Procedure tab for more details.

It will also be used during in-clinic follow-ups to:

- Interrogate LUX-Dx™ devices and transmit data to LATITUDE Clarity for review
- Apply programming updates made in LATITUDE Clarity to the ICM device
- Deliver ICM device firmware updates when available

Learn more about setting up and managing the LUX-Dx Clinic Assistant App.

Go to: *Prepare Clinic*

Learn more about using the LUX-Dx Clinic Assistant App during in-clinic follow-up appointments.

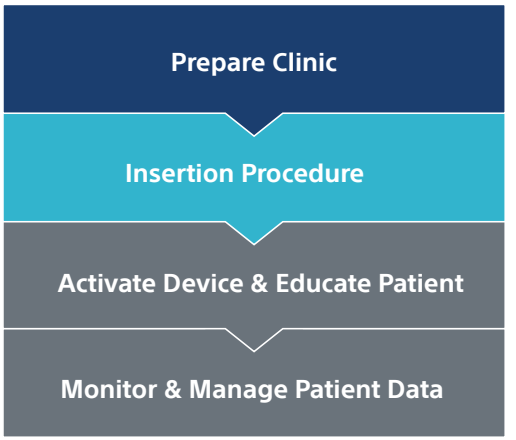
Go to: *In-Clinic Follow-Up Visits*

Workflows

The LUX-Dx™ ICM System was designed to be flexible to fit into existing clinic workflows. Now that you have reviewed the components of the system, this workflow summary can help you think through how these tools and steps might fit into your existing routines and staff assignments. Not all clinics or users of this guide will participate in each of these workflow steps, so they are separated for easy navigation throughout this guide.

Click to navigate to a section.

The rest of this guide will follow the steps of a typical ICM workflow and will include workflow tips when the LUX-Dx ICM System may present new opportunities in your existing workflow:



Prepare Clinic

These steps ideally occur before you manage LUX-Dx ICM patients and are most often led or determined by the clinic manager or super-user:

- Assign roles in workflow
- Configure LATITUDE Clarity™ (clinic and patient group settings)
- Set up LUX-Dx Clinic Assistants
- Review device detection parameters, programming, alerts, and alert notifications (and establish any necessary protocols)
- Prepare for the downloadable app and the RhythmCARE™ Assist service

Insertion Procedure

Steps of the insertion procedure:

- Determine patient monitoring method
- Use the Clinic Assistant App or the myLUX Patient app on a Boston Scientific provided mobile device to check ICM battery
- Insert device using four-step process (tunnel, rotate, pull back, insert)
- Use mobile apps to verify R-Wave sensing
- Close the incision

note: To help with your planning, there is a workflow worksheet that contains more in-depth information on each task as well as the tools and information required at each step.

See the worksheet.

Go to: *Additional Resources > Workflow Worksheet*

Activate Device & Educate Patient

These steps are **required** to activate the patient's ICM – ideally these steps are taken before the patient is discharged after the procedure:

- Enroll the patient in LATITUDE Clarity™
  - Sign up for supplemental RhythmCARE™ Assist service if patients choose to use the downloadable version of the myLUX™ Patient App
- Set up the myLUX™ Patient App to pair with the ICM (must happen *after* enrollment in LATITUDE Clarity)
- Educate the patient

Monitor & Manage Patient Data

Steps involved in ongoing follow-up and review of patient data and adjusting programming parameters:

- Review alerts
- Assess events
- Generate reports
- Communicate with patients
- Send data to EMR
- Dismiss alerts
- Adjust programming (as desired)
- Use the LUX-Dx Clinic Assistant App for in-clinic follow-up (as desired)

workflow tip:

If you already have an ICM workflow in place, you may want to review a few sections in this guide first, because they are potentially different:

- Use the my LUX™ Patient App Pre-Insertion Card to discuss and confirm the preferred monitoring method
- Use mobile apps during insertion
- Enroll patients in LATITUDE Clarity
- Use mobile apps for device activation
- Message patients and manage compliance in LATITUDE Clarity
- Adjust programming remotely (as desired)
- Use the LUX-Dx™ Clinic Assistant App for in-clinic follow-ups
- Configure EMR settings for when to send information

Prepare Clinic

This section is meant to help clinics prepare to manage LUX-Dx™ ICM patients and their data. It primarily applies to clinic managers or anyone who makes decisions for an entire clinic or group of users when integrating new devices and workflows.

This section covers four key aspects of setup and configuration to help integrate the LUX-Dx ICM with your existing clinic workflows and protocols:

1) Assign roles in the workflow.
2) Set up and configure the LATITUDE Clarity™ System to best fit your patients and staff.
3) Set up the LUX-Dx™ Clinic Assistant App.
4) Review detection parameters and programming.
5) Prepare for the downloadable app and the RhythmCARE™ Assist service.

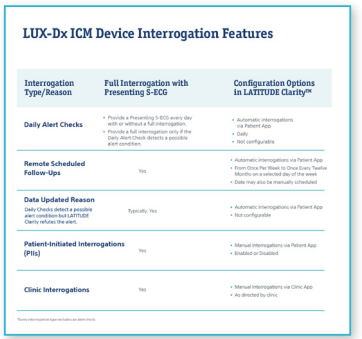
If possible, think through these decisions and get these settings in place for your clinic prior to your first LUX-Dx ICM patient.

Click to navigate to a section.

Assigning Roles in Workflow

In the appendix, you will find a worksheet to help you understand each step of a typical LUX-Dx ICM workflow so you can think about staffing and assigning roles. The worksheet includes tasks, tools, and information required for each step of the workflow to make sure the entire process is covered. You can use this chart to discuss with your team who will do each task when you start inserting or following LUX-Dx ICMs.

note: For a LUX-Dx ICM to be actively monitoring a patient with the appropriate detection parameters, you must enroll a patient in LATITUDE Clarity and *then* activate a patient's ICM as well as wet up the myLUX™ Patient App. It will be critical to identify who is responsible for these steps to make sure all ICMs are set up properly and these steps are completed in the right order.



LUX-Dx ICM Device Interrogation Features

Interrogation Type/Reason	Full Interrogation with Presenting S-ECG	Configuration Options in LATITUDE Clarity™
Daily Alert Checks	• Provide a Presenting S-ECG every day with or without a full interrogation. • Provide a full interrogation only if the Daily Alert Check detects a possible alert condition.	• Automatic interrogations via Patient App • Daily • Not configurable
Remote Scheduled Follow-Ups	Yes	• Automatic interrogations via Patient App • From Once Per Week to Once Every Twelve Months on a selected day of the week • Date may also be manually scheduled
Data Updated Reason Daily Checks detect a possible alert condition but LATITUDE Clarity refutes the alert.	Typically, Yes	• Automatic interrogations via Patient App • Not configurable
Patient-Initiated Interrogations (PIIs)	Yes	• Manual interrogations via Patient App • Enabled or Disabled
Clinic Interrogations	Yes	• Manual interrogations via Clinic App • As directed by clinic

See the worksheet.

Go to: *Additional Resources* > *Workflow Worksheet*

Setting Up and Configuring the LATITUDE Clarity™ System

As you think about integrating LUX-Dx ICM patients into your clinic, it will be helpful to understand how the LATITUDE Clarity website is organized and what might be different from the current data management systems you are using.

System Organization

LATITUDE Clarity uses two primary designations to organize patients and device programming: Patient Groups and Reasons for Monitoring. The system requires that, at the time of enrollment, every patient in the system be assigned both one Patient Group and one Reason for Monitoring. These two designations can be modified, but they are always required to organize patients and structure programming and alert configurations.

Patient Groups: Patient Groups are used for organizing patients in LATITUDE Clarity. Patient Groups are unique to, and controlled by, each clinic.

- Examples of how some clinics organize Patient Groups include by location, by physician, or by device type.
- Patient Groups can be modified at any time by specific user types.
- Some programming and alert settings can be manually changed and applied across an entire Reason for Monitoring within a Patient Group. This concept is covered throughout various sections of this guide.

Reasons for Monitoring: Initial default programming and configuration values are automatically supplied with the selection of a Reason for Monitoring in LATITUDE Clarity. These values can be revised anytime.

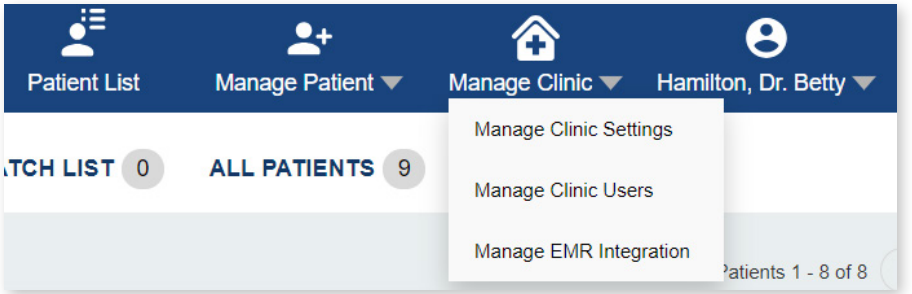
At enrollment, a Reason for Monitoring from this preset list must be selected:

- Syncope
- Palpitations
- Cryptogenic Stroke
- Suspected AF
- Post-AF Ablation
- AF Management
- Ventricular Tachycardia
- Other

note: Patient Groups are shared between LATITUDE Clarity and LATITUDE™ NXT. This means if you already have Patient Groups set up in LATITUDE NXT, you will see these Patient Groups in your LATITUDE Clarity Patient Group list. Additional considerations for Patient Groups are covered later in this section.

Using LATITUDE Clarity Alongside This Section

This section follows the same structure as the Manage Clinic section you will see in the LATITUDE Clarity System. You can use this section alongside the website, as you see here, to ensure you are addressing each option for configuring clinic settings prior to managing LUX-Dx ICM patients.



For full context, follow along with LATITUDE Clarity.

As you work through these various configurations, there are a few helpful things to remember:

- Some of your clinic settings are shared between the LATITUDE™ NXT and LATITUDE Clarity sides of the LATITUDE system.

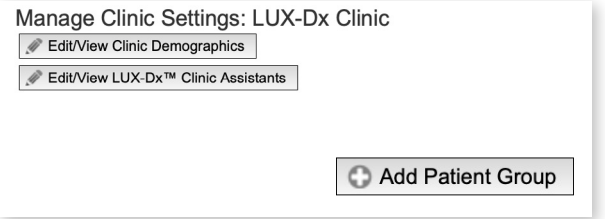
  When that is the case, it's noted with this symbol

- Anytime you make a change you wish to keep in the system, you need to click *Save* or *Save and Close* at the bottom of the page or window before moving on in order for your changes to be applied.
- The system automatically logs you out after 60 minutes of inactivity.
- Some of the steps on the following pages require using the LUX-Dx Clinic Assistant App at the same time you are logged in to LATITUDE Clarity, so make sure you have the app available when working through this section.

Manage Clinic Settings

In the Manage Clinic Settings section of LATITUDE Clarity, you can:

- ✓ Edit/View Clinic Demographics
- ✓ Edit/View LUX-Dx Clinic Assistants
- ✓ Add/Edit/View Patient Groups and Patient Group Default Settings



For full context, follow along with LATITUDE Clarity.

Edit/View Clinic Demographics

MANAGE CLINIC > *MANAGE CLINIC SETTINGS* > *EDIT/VIEW LUX-DX CLINIC DEMOGRAPHICS*

In the Edit/View Clinic Demographics section, you will be able to manage information about your clinic, including the name and contact information associated with your clinic. If you are an existing LATITUDE™ NXT user, this information is likely already populated in this section. If it is correct, you do not need to do anything.

Please note that any changes you make to your Clinic Demographic information will be reflected in both LATITUDE Clarity and LATITUDE NXT.

Edit/View LUX-Dx Clinic Assistants

MANAGE CLINIC > *MANAGE CLINIC SETTINGS* > *EDIT/VIEW LUX-DX CLINIC ASSISTANTS*

In the Edit/View LUX-Dx Clinic Assistants section, you will be able to add, remove, and edit your LUX-Dx Clinic Assistants that are used to connect to and interrogate LUX-Dx ICMs.

To Add a LUX-Dx Clinic Assistant

MANAGE CLINIC > *MANAGE CLINIC SETTINGS* > *EDIT/VIEW LUX-DX CLINIC ASSISTANTS* > *ADD LUX-DX CLINIC ASSISTANT*

note: This process requires that you use the LUX-Dx Clinic Assistant App at the same time to complete setup.

Go to the Setting Up LUX-Dx section for instruction on adding a Clinic Assistant.

Go to: *Prepare Clinic* > *Setting Up LUX-Dx Clinic Assistants*

To Edit or Remove a Clinic Assistant

MANAGE CLINIC > *MANAGE CLINIC SETTINGS* > *EDIT/VIEW LUX-DX CLINIC ASSISTANTS*

If you need to reassign, rename, or delete a Clinic Assistant, you will do that from the Edit/View LUX-Dx Clinic Assistants page in LATITUDE Clarity. On the far right of the list of Clinic Assistants, you will see both a pencil and a trash icon.

- **Pencil icon:** Use to edit Clinic Assistant information.
- **Trash icon:** Use to delete Clinic Assistant entirely.

note: If a Clinic Assistant is lost or stolen, please contact Boston Scientific for more information.

Review Patient Groups

MANAGE CLINIC > *MANAGE CLINIC SETTINGS*

If you use LATITUDE™ NXT, review the below considerations when thinking about how to organize ICM patients in LATITUDE Clarity.

note: As you think about how you want your ICM patients organized, keep in mind that patients can be assigned to only one Patient Group at a time in LATITUDE Clarity.

BY LOCATION OR PHYSICIAN

If NXT Patient Groups are organized by location or physician, consider adding ICM patients to these same established groups.

OR

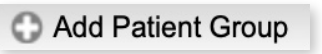
BY DEVICE TYPE

If NXT Patient Groups are organized by device type, consider creating a **new** group exclusive to ICM patients.

note: You will not see NXT patient names in this shared group viewing it from the LATITUDE Clarity site.

To Add a Patient Group

MANAGE CLINIC > *MANAGE CLINIC SETTINGS* > *ADD PATIENT GROUP*



1. If you wish to add a new Patient Group entirely, click *Add Patient Group* in the upper right of the Manage Clinic Settings page of LATITUDE Clarity.
2. Complete the Name and Description fields.
3. Click *Save Patient Group.*

Patient Groups: If you add, delete, or rename a Patient Group, this will be reflected on both sites.

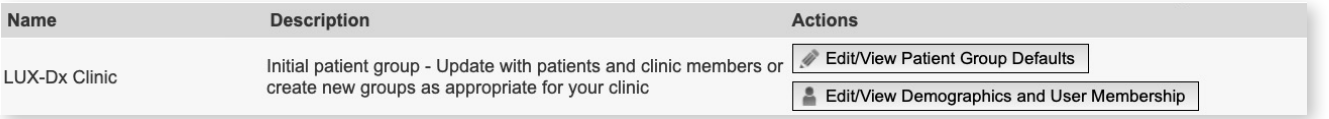
If you have questions about adjusting Patient Groups, please call Boston Scientific at 1-800-CARDIAC (1-800-227-3422).

To Edit Patient Group Defaults

MANAGE CLINIC > *MANAGE CLINIC SETTINGS* > *EDIT/VIEW PATIENT GROUP DEFAULTS*

Adjusting Patient Group default settings can be a way of customizing the LATITUDE Clarity System to your clinic's workflow and needs. Default settings you select in each Patient Group are applied to all patients within that group and any patients you add going forward.

To view and edit Patient Group settings, start on the Manage Clinic Settings page of LATITUDE Clarity. Find the Patient Group you wish to review and select *Edit/View Patient Group Defaults* on the far right.



For full context, follow along with LATITUDE Clarity.

Continue to the next page to learn more about adjusting Patient Group default settings.

Once you've selected a certain Patient Group, you will have the ability to configure many settings for that Group by Reason for Monitoring.

Below is a list of options you will find in Patient Group Defaults. Each of these sections in blue will allow you to establish settings for each Reason for Monitoring. On the next pages you'll find a few things to consider when making your default selections. Many of these features are also covered in the Monitor & Manage Patient Data Section of this guide.

Patient Group Default Section:

Remote Scheduled Follow-Ups

Patient-Initiated Interrogations (PIIs)

Connection Status Notification

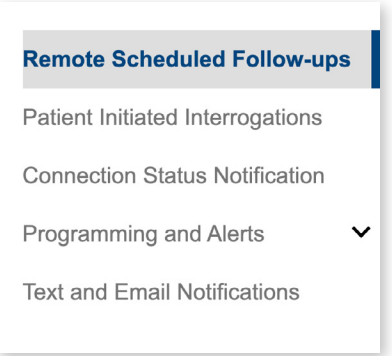
Programming and Alerts

Remote Scheduled Follow-Ups

CONFIGURATION OPTIONS

In this section, you can adjust Follow-Up Schedules for when you wish to receive regular reports from your ICM patients. The schedules can be set differently for each Reason for Monitoring within a given Patient Group. Options include:

- Set *Schedule* to either **Automatic** or **Manual**.
- Select *Frequency* of follow-up from the drop-down list (options range from Once Per Week to Once Every Twelve Months).
- Select *Day of the Week* the follow-up data will be available (from Monday to Friday).



For full context, follow along with LATITUDE Clarity.

CONSIDERATIONS

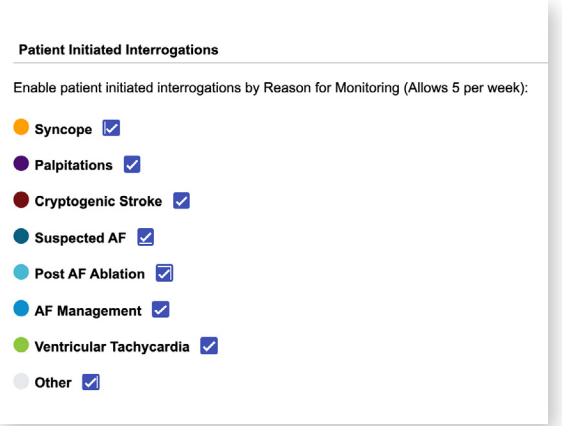
The day of the week you select will be the day the report shows up in LATITUDE Clarity.

Patient-Initiated Interrogations (PIIs)

CONFIGURATION OPTIONS

The LUX-Dx ICM system supports PIIs, which provide the same data as a scheduled follow-up interrogation with a presenting S-ECG.

- *Enable* or *disable* PIIs by selecting or clearing the check box next to each Reason for Monitoring.
- If enabled, patients are allowed 5 PIIs per week.



For full context, follow along with LATITUDE Clarity.

CONSIDERATIONS

One additional PII (beyond the allowed 5 per week) can be enabled at any time for an individual patient. This can be done on the Programming tab of a patient's profile.

Patients initiate an interrogation by following the instructions for sending a "Manual Transmission" on their myLUX™ Patient App. If PIIs are disabled, or the limit has been reached, the patient will not be able to perform a Manual Transmission.

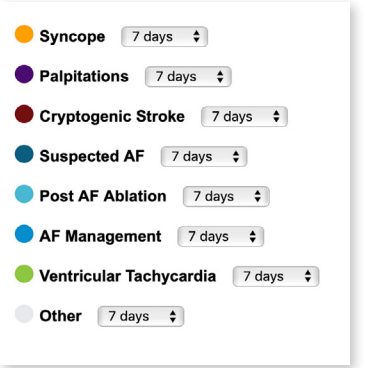
Connection Status Notification

CONFIGURATION OPTIONS

The Connection Status Notification setting can help manage patient compliance. The LUX-Dx ICM System will attempt to notify patients via the myLUX™ Patient App when they are disconnected. The app will offer troubleshooting tips to help patients get reconnected.

In the Connection Status Notification section, you will be able to configure when patients within a Reason for Monitoring are added to the Not Monitored list on the Patient List page if not connected for the selected timeframe.

- Options include from 1 to 7 days and 14 days.
- The default is 7 days.



For full context, follow along with LATITUDE Clarity.

CONSIDERATIONS

This setting is connected to the myLUX Patient App. Whatever timeframe you choose will indicate when the patient may see a notification on their app to help them get reconnected.

Programming and Alerts

CONFIGURATION OPTIONS

Within Patient Group Defaults, you can configure device programming and alert configuration settings for each Reason for Monitoring.

Find more information on configuration.

Go to: *Prepare Clinic > Reviewing Detection Parameters and Programming*

CONSIDERATIONS

If you make modifications in this Patient Group Defaults section, these changes will be applied at the next device connection. The changes will be applied to all patients following the Patient Group defaults within that Reason for Monitoring and in the selected Patient Group. These updated settings will also be selected for any newly enrolled patients assigned to both this Patient Group and Reason for Monitoring.

Please note, changes can also be made at the individual patient level, which is covered in the Monitor & Manage Patient Data section.

More information on reviewing and adjusting programming is found within the Monitor & Manage Patient Data section.

Go to: *Monitor & Manage Patient Data > Reviewing and Adjusting Programming Settings*

To Edit/View Patient Group Demographics and User Membership

MANAGE CLINIC > *MANAGE CLINIC SETTINGS* > *EDIT/VIEW DEMOGRAPHIC AND USER MEMBERSHIP*

If you need to edit the name, description, or user membership of a Patient Group, follow these steps:

1. **From the Manage Clinic Settings page in LATITUDE Clarity, identify the name of the Patient Group you wish to edit.**
2. **Select *Edit/View Demographic and User Membership.***
3. **Make the desired changes.**

   If you are trying to edit user membership for users not listed on this page, you may need to adjust their *access level* in their individual user profile. This is covered in the next section.
4. **Click *Save and Close.***

note: Changes made to Patient Group Demographics and User Membership will be reflected in both LATITUDE™ NXT and LATITUDE Clarity. If you need to remove a group entirely, consider calling Boston Scientific at 1-800-CARDIAC (1-800-227-3422).

Manage Clinic Users

There are three types of privilege levels that can be assigned to clinic users in LATITUDE Clarity.

These privilege levels are shared with LATITUDE™ NXT, which means that if users access both systems, their access level must be the same for both sites.

The privilege level is set when a new user is added and can be changed at any time by someone with clinic account manager (CAM) privileges. The intended use for each user type and the functions each user can perform are shown in the table to the right.

Find more information on Viewing Another Clinic's Patient

Go to: *Monitor & Manage Patient Data > Viewing Another Clinic's Patient*

USER TYPE: READ-ONLY ACCESS

Intended For

Users who need to work with or **view patient data** but are not responsible for managing the patients within the system

Limitations

- Access is limited to patients in assigned Patient Groups
- Cannot edit Watch List
- Cannot enroll patients
- Cannot add and register LUX-Dx Clinic Assistant App
- Cannot update programming
- Unable to view another clinic's patient

USER TYPE: LIMITED ACCESS

Intended For

Users who are **responsible for managing patients**.

This access will likely be the access you assign to the majority of your clinic users

Limitations

- Access is limited to patients in assigned Patient Groups
- Can perform all patient review functions
- Access to view another clinic's patient

USER TYPE: COMPLETE ACCESS

(CLINIC ACCOUNT MANAGERS)

Intended For

The user who is **responsible for managing the clinic,** including other clinic users and patients

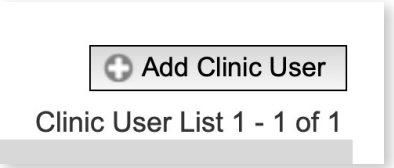
No Limitations

Note: User accounts can be created or deleted only by the Clinic Account Manager.

To Add a Clinic User

MANAGE CLINIC > *MANAGE CLINIC SETTINGS* > *MANAGE CLINIC USERS* > *ADD CLINIC USER*

1. From the Manage Clinic Users page, click *Add Clinic User* in the upper right.
2. Complete the user form with the appropriate demographic information for that user.



For full context, follow along with LATITUDE Clarity.

To Edit Individual User Demographics and Access Settings

MANAGE CLINIC > *MANAGE CLINIC SETTINGS* > *MANAGE CLINIC USERS* > *EDIT/VIEW DEMOGRAPHICS AND ACCESS SETTINGS*

1. From the Manage Clinic User page, select the user you wish to edit.
2. Click *Edit Individual User Demographics and Access Settings*.
3. Make the desired changes.
4. Click *Save and Close*.

workflow tip: Within each individual user profile, there is a place to select which homepage (LATITUDE™ NXT or LATITUDE Clarity) each user sees when they first log in to the system. Regardless of selection, users will still be able to use both sites; however, the **default selection** will appear first. This setting can be changed by the CAM or individual user at any time.

Manage EMR Integration

MANAGE CLINIC > *MANAGE EMR INTEGRATION*

If your clinic is new to EMR integration with LATITUDE Clarity, ask your clinic IT staff to contact Boston Scientific's LATITUDE EMR Integration Support Group at 1-888-283-8713 to assist with the configuration and/or installation of EMR integration software.

If your clinic already uses EMR integration with LATITUDE™ NXT, enabling EMR integration for LATITUDE Clarity is an easy option. To set up EMR integration for LATITUDE Clarity, follow the instructions to the right.

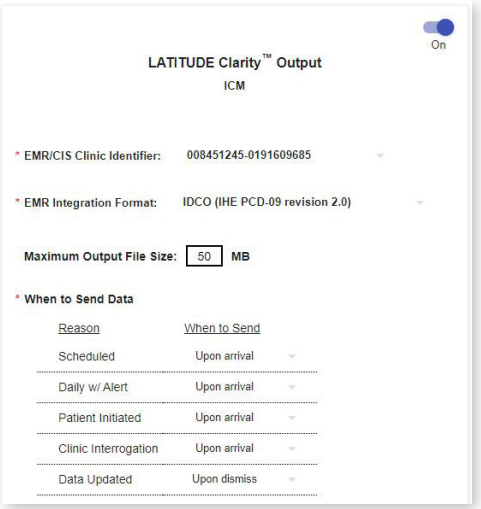
note: If you have specific security questions or security request forms, please contact us at ProductCyberSecurity@bsci.com.

Steps to Set Up EMR Integration in LATITUDE Clarity:

workflow tip: Prior to setting up EMR integration, review the list in step 4 on the next page with your clinic IT department.

1. Navigate to Manage Clinic in top navigation bar and select *Manage EMR Integration* from the drop-down menu.
2. Click *Edit/View EMR Configuration* in the upper left.
3. In the Options for LATITUDE Clarity section on the right, click the slider on the gray box for LATITUDE Clarity so it reads On.

4 Once the slider is in the On position, you will see a list of items you can configure.



For full context, follow along with LATITUDE Clarity.

- **EMR/CIS Clinic Identifier:** This is used as an ID to verify that LATITUDE Clarity is sending your patient data to the correct EMR software installed at your clinic.
  - If this is already set up in LATITUDE™ NXT and you wish to send data to the *same EMR system*, select the same ID number and it will send data to your current EMR system.
  - If you would like ICM patient data to be sent to a *different EMR or device management system*, select the other identifier.
- **EMR Integration Format:** This option is the type of file LATITUDE Clarity is able to send to your clinic's EMR system. The only format LATITUDE Clarity supports is IDCO. IDCO is a standard for cardiac devices supported by the Heart Rhythm Society (HRS).
- **Maximum Output File Size:** This option can be left as configured unless you encounter an issue. If you need help troubleshooting, please work with your clinic IT department or the LATITUDE EMR Integration Support Group at 1-888-283-8713.

note: If you decide to send your ICM data to a different EMR system than what is set up in LATITUDE NXT, it may require additional configuration or software. To get set up, ask your clinic IT staff to contact the LATITUDE EMR Integration Support Group at 1-888-283-8713 to assist with the configuration and/or installation of the appropriate EMR integration software.

- **When to Send Data:** This feature allows you to decide which types of interrogations are sent to your EMR and when.

See the Interrogation Chart.

Go to: *Additional Resources > Interrogation Chart*

For each reason, you can select one of the following:

Upon Arrival: Data will be sent as is to EMR immediately when an interrogation arrives to LATITUDE Clarity.

- This setting is typically best for clinics that review information first in an EMR system.

Upon Dismissal: Data will be sent to EMR when the Dismiss button is selected.

- This setting is typically best for clinics that begin their review in LATITUDE Clarity and like to use ECG annotation tools for review and reporting.

Manual: Data will be sent to EMR manually only by clicking *Send to EMR* on a patient's profile.

workflow tip: If your clinic uses EMR integration, it might be best to select the same "When to Send" method for all interrogation types until you get used to different reasons for review in the system.

- **Report Configuration:** This feature allows you to select which PDF reports are sent to the EMR along with discrete data. Options include:

PDF Format: Combined File or *Separate Files*

You can also decide which PDFs to include as part of the IDCO file.

Type of Report: Follow-Up, *Event Detail*, and/or *Presenting S-ECG reports*

Additional Data for Reports:

- Trends and Histograms
- For Event Detail Reports with "Symptom + Device Detected" events, trim S-ECG to display only the portion from the device-detected event.

5 **Once you have your configuration set, you can click *Save and Close.***

Setting Up LUX-Dx Clinic Assistants

When you receive your LUX-Dx Clinic Assistant mobile device (standalone model 7256 or in kit model 6256), it will include a Quick Start Guide.

note: For this process to be successful, you will also need to access LATITUDE Clarity.

Here is a summary of the steps included in the Quick Start Guide:

1

Attach the magnet to the mobile device case.

Remove the blue magnet from the silver box. You will see a two-sided adhesive circle already on the back of the mobile device. Use the tab to peel off the backing to reveal the adhesive part. Place the logo side of the magnet on the adhesive and press firmly.

2

Power on the device.

Press and hold the power key located on the right side of the mobile device.

3

Open the app.

When the screen turns on, you will see only one app icon in the center of the screen. Tap on this image.

4

Set your language preference.

The app is set to English. If this is your preferred language, tap *Next* when prompted to change the language.

If you need to change the language, tap *Change Language* and refer to the Quick Start Guide for instructions.

note: The magnet is provided with the model 6256 LUX-Dx Clinic Assistant Kit. The magnet (model 6386) is provided separately for the model 7256 LUX-Dx Clinic Assistant Mobile Device.

5

Start setup.

1. After confirming your language, you will see a Welcome screen.
2. Tap *Start Setup* in the middle of the screen.
3. The instructions on the screen will tell you to enter a registration code from LATITUDE Clarity.

6

Sign in to LATITUDE Clarity using a different smartphone with internet access.

7

From the top navigation bar, under Manage Clinic, select *Manage Clinic Settings*.

8

Select *Edit/View LUX-Dx Clinic Assistants*.

9

Select *Add LUX-Dx Clinic Assistant*.

10

Before generating a registration code, the system will ask you to enter a name and description for the LUX-Dx Clinic Assistant. The name you enter here will serve as an identifier in LATITUDE Clarity anytime this mobile device is used for an interrogation of a LUX-Dx ICM.

11

Select *Save and Close*. This action will generate a registration code.

12

Return to the app and enter the 12-digit registration code in the space provided on the app screen.

13

On the app, tap *Next*. You should arrive at a home screen for the LUX-Dx Clinic Assistant with a button that says Scan and Connect.

workflow tip: Here are a few options you can consider for where to keep your LUX-Dx Clinic Assistant once it is set up.

- You may choose to keep it in the room or on the cart where the other programmers are located.
- If you have access to the Boston Scientific 3300 LATITUDE Programmer, you may consider keeping the Clinic Assistant with the 3300 equipment if LUX-Dx ICM patients will be in the same area.
- If you are located in an acute-care setting or you use LATITUDE Consult on a regular basis, you might consider keeping the LUX-Dx Clinic Assistant in the LATITUDE Consult case.

note: If your LUX-Dx Clinic Assistant is ever lost or stolen, please talk to your Boston Scientific representative.

note: The LUX-Dx Clinic Assistant is a critical tool for clinics before, during, and post ICM insertion. Ensure you have it set up, store it where you can find it easily, connect it to hospital WiFi, power it on periodically to check its connection, and keep the app version up-to-date.

Find information on using the LUX-Dx Clinic Assistant App before and during ICM insertion and the follow-up visits.

Go to: • *Using the LUX-Dx Clinic Assistant before and during insertion*

Go to: • *In-Clinic Follow-Up Visits*

Reviewing Detection Parameters and Programming

The LUX-Dx ICM monitors a patient for arrhythmias based on programmed parameters. Programmed parameters are assigned based on a patient's Reason for Monitoring selected during the enrollment process in LATITUDE Clarity. These parameters may be modified at any time remotely to meet your clinic's preferences or individual patient needs.

To help you and your team understand the specific detection and programming parameters for the LUX-Dx ICM, in this section you will find:

- A short summary of detection parameters you can review with your team
- A programming chart that can help as a reference for nominal settings as well as parameter options

Summary of Detection Parameters

This section summarizes how the LUX-Dx ICMs utilize dual stage algorithms to detect arrhythmias. The ICM can be programmed to detect any of the following:

- ***Pause***
- ***Brady***
- ***Tachy***
- ***Atrial Fibrillation*** *(AF)*
- ***Atrial Tachy*** *(AT)*
- ***PVC Burden*** *(M302 and M312 only)*

Pause

DETECTION:

A potential event is detected when the R-R interval exceeds the user programmed Pause duration. The algorithm then verifies a true Pause event by re-assessing the S-ECG signal during the pause interval looking for reasons for undersensing, like the presence of noise, changes in R-wave amplitude or flatline segments.

LUX-Dx II/II+ ICMs (M302 and M312) have additional verification step that further rejects false positives due to low signal-to-noise ratios.

The LUX-Dx II+ ICM (M312 only) also offers unique nighttime programming applied from 11:00 pm - 7:00 am, giving clinicians the flexibility to fine tune settings to focus on clinically actionable events.

PROGRAMMABLE PARAMETERS:

- **Detection:** On/Off
- **Duration (seconds):** M301, M302 - 1.5, 3, 4.5 M312 - 2, 3, 4, 5, 6, 7, 8, 9, 10
- **Pause Nighttime Duration (seconds)** M312 only: 2, 3, 4, 5, 6, 7, 8, 9, 10 between 11:00 pm-7:00 am
- **Response:** Less, Balanced, More

Brady

DETECTION:

- A potential event is detected when 4 out of 5 beats are slower than the programmed rate
- If a slow pattern (2 out of 5 beats) is maintained for the programmed duration, additional criteria are applied to verify that the slow-rate event is not the result of undersensing

PROGRAMMABLE PARAMETERS:

- **Detection:** On/Off
- **Rate (bpm):** 30, 40, 50, 60
- **Duration (seconds):** 1, 2, 3, 5, 7, 10, 15, 20, 30
- **Brady Nighttime Rate (bpm)**
  M312 only: 30,40, 50, 60 between 11:00 pm-7:00 am
- **Brady Nighttime Duration (seconds)**
  M312 only: 1, 2, 3, 5, 7, 10, 15, 20, 30 between 11:00 pm-7:00 am

Tachy

DETECTION:

- A potential event is detected when 8 out of 10 beats are faster than the programmed rate threshold
- If a fast pattern (3 out of 10 beats) is maintained for the programmed duration, additional criteria are applied to verify that the high-rate event is not the result of oversensing

PROGRAMMABLE PARAMETERS:

- **Detection:** On/Off
- **Rate (bpm):** 115–220 in increments of 5
- **Duration (seconds):** 0, 1, 2, 3, 4, 5, 10, 15, 20, 25, 30, 40, 50, 60
- **Response:** Less, Balanced, More

Atrial Fibrillation (AF)

DETECTION:

- The first stage uses a 2-minute window to analyze R-R variability and the heart rate density index to detect potential AF rhythms
- The second stage computes a number of metrics to verify if the window is AF or not. The criteria verify that the variability is not the result of oversensing, noise, regular patterns, ectopic beats or other confounders
- The LUX-Dx II+ ICM (M312 only) has additional verification step that identifies sequential heart rate patterns to further reject false positives. The AF algorithm was also enhanced to merge adjacent AF episodes to reduce episodes for review which may improve clinic workflow and expedite clinical decision making

PROGRAMMABLE PARAMETERS:

- **Detection:** On/Off
- **AF Response:** Least, Less, Balanced, More, Most
- **AF Duration (minutes):** 2, 4, 6, 10, 20, 30, 60
- **Alert for AF Burden:** On/Off
- **AF Burden Threshold (hours):** >0, 0.5, 1, 2, 3, 6, 12, 18, 23

Atrial Tachy (AT)

DETECTION:

- The AT algorithm analyzes heart rate over each 2-minute window. The algorithm will detect an AT episode when the heart rate exceeds the programmed AT rate for the programmed duration
- If the AT Duration is programmed to 2 hours or longer, an AT episode is stored once a series of windows satisfy the programmed duration
- If the AT Duration is less than 2 hours, the algorithm also assess R-R variability in the rhythm to aid in distinguishing AT from sinus rhythms
- The LUX-Dx ICMs AT algorithm is separately programmable from the AF algorithm, allowing flexibility to tailor settings to detect clinically relevant sustained arrhythmias

PROGRAMMABLE PARAMETERS:

- **Detection:** On/Off
- **Rate (bpm):** 70–110 by increments of 10; 120–180 by increments of 20
- **Duration (minutes and hours):**
  - Minutes: 2, 6, 10, 20, 30, 60
  - Hours: 2, 3, 4, 6, 8, 10, 12, 16, 24

PVC Burden (M302, M312 Only)

DETECTION:

- The PVC Burden algorithm is capable of detecting multiple sequence types, including singlets, couplets and triplets, to provide a daily PVC Burden value and trend
- R-R intervals and changes in R-wave amplitude are used to detect potential PVCs
- The verification stage then utilizes a morphology assessment that determines if the potential PVCs should be counted towards the PVC burden
- The LUX-Dx II/II+ ICMs offer a unique and programmable PVC Burden Alert, allowing clinicians to be alerts for PVC burdens they deem clinically actionable
- The alert level and preferred PVC burden threshold and duration are configurable

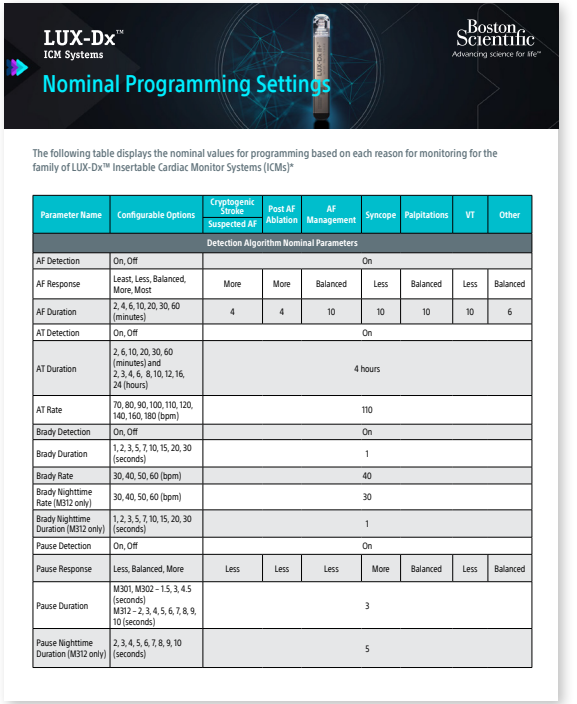
PROGRAMMABLE PARAMETERS:

- **Detection:** On/Off
- **Monitoring Duration:** Continuous, Short Term
- **Monitoring Days:** 2, 3, 7, 14, 30
- **Monitoring Frequency:** Every week, every month, 3 months, 6 months
- **Alert for PVC Events:** On or Off/Red or Yellow
- **PVC Burden Threshold (percentage):** 5, 10, 15, 20, 30, 40
- **PVC Burden Threshold (days):** 1, 3, 5, 7

Programming and Alert Nominal Chart

This chart in the appendix is meant to be a quick reference for how parameters are nominally set and also the configuration options available. Some clinics like to use a document like this in two ways:

- As a quick reference at workstations
- As a tool to document preferred parameters across an entire clinic



LUX-Dx™ ICM Systems

Nominal Programming Settings

Boston Scientific

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The following table displays the nominal values for programming based on each reason for monitoring for the family of LUX-Dx™ Insertable Cardiac Monitor Systems (ICMs)*

Parameter Name	Configurable Options	Cryptogenic Stroke / Suspected AF	Post AF Ablation	AF Management	Syncope	Palpitations	VT	Other
Detection Algorithm Nominal Parameters								
AF Detection	On, Off	On						
AF Response	Least, Less, Balanced, More, Most	More	More	Balanced	Less	Balanced	Less	Balanced
AF Duration	2, 4, 6, 10, 20, 30, 60 (minutes)	4	4	10	10	10	10	6
AT Detection	On, Off	On						
AT Duration	2, 6, 10, 20, 30, 60 (minutes) and 2, 3, 4, 6, 8, 10, 12, 16, 24 (hours)	4 hours						
AT Rate	70, 80, 90, 100, 110, 120, 140, 160, 180 (bpm)	110						
Brady Detection	On, Off	On						
Brady Duration	1, 2, 3, 5, 7, 10, 15, 20, 30 (seconds)	1						
Brady Rate	30, 40, 50, 60 (bpm)	40						
Brady Nighttime Rate (M312 only)	30, 40, 50, 60 (bpm)	30						
Brady Nighttime Duration (M312 only)	1, 2, 3, 5, 7, 10, 15, 20, 30 (seconds)	1						
Pause Detection	On, Off	On						
Pause Response	Less, Balanced, More	Less	Less	Less	More	Balanced	Less	Balanced
Pause Duration	M301, M302 – 1.5, 3, 4.5 (seconds) M312 – 2, 3, 4, 5, 6, 7, 8, 9, 10 (seconds)	3						
Pause Nighttime Duration (M312 only)	2, 3, 4, 5, 6, 7, 8, 9, 10 (seconds)	5						

Find more in-depth information on adjusting programming parameters in LATITUDE Clarity.

Go to: *Monitor & Manage Patient Data > Reviewing Individual Patient Data > Programming Tab*

Preparing Patient for App and Service

Pre-insertion Card

Boston Scientific prepared a Pre-insertion Card to help facilitate your workflow. Providing the printed Pre-Insertion Card at consult or scheduling to patients will make the insertion day smooth for the patient and you.

This card describes the remote monitoring options that are available for the patients and explains the basic criteria for each option. It provides information for patients to download the myLUX Patient App ahead of the insertion and ensures patients to bring their smartphone, app store ID and passwords on the insertion day. It also allows patients to fill in contact information for the RhythmCARE Assist service.

RhythmCARE Assist Service

RhythmCARE Assist is an automated, supplemental service that communicates directly with patients who choose to download the myLUX app on their own phones. The service will help them set up the myLUX™ Patient App when needed, and resolve technical troubleshooting issues if monitoring becomes disconnected.

The service notifies the patient via email or text message when connectivity issues arise and provides educational content to guide the patient through reconnecting.

This is a free service to patients and clinics.

Service sign up for the patient occurs during the LATITUDE Clarity™ enrollment process at time of ICM insertion. Service is dependent on patient attestation and clinic agreement that they want RhythmCARE™ Assist service. Patients may unsubscribe at anytime, which would stop automated messaging.

The LUX-Dx™ ICM System*

Finding the Right Monitoring Option

Boston Scientific

Advancing science for life™

The patient app on a mobile device collects information about irregular heart rhythms stored on your Insertable Cardiac Monitor (ICM) device and automatically sends that information to your health care team. You have two options: downloading an app onto your own smart device or using the app on a Boston Scientific Provided Mobile Device.

Downloadable myLUX™ Patient App**

Download the myLUX™ Patient App on your own smartphone to deliver vital cardiac data to your health care team. This option enables you to seamlessly integrate the app into your lifestyle. The downloadable app is free to download and use.

This option may be best if you:

- Own a smartphone
- Keep your smartphone powered on and near you a considerable portion of time each day
- Are comfortable using a smartphone or have a family member who can support you

If you choose this option, please refer to the back of this page.

OR

Boston Scientific Provided myLUX™ Mobile Device

The Boston Scientific provided mobile device has the myLUX™ patient app pre-installed. This device delivers vital cardiac data to your health care team.

This option may be best if you:

- Do not own a smartphone

If you choose this option, the mobile device will be provided at your procedure and you will learn more then.

RhythmCARE™ Assist

The service is available exclusively to patients who have downloaded the myLUX™ Patient App on their personal smartphone. RhythmCARE Assist is an optional and automated service that provides connectivity or app set up help via email or text message. This service is available to you at no cost. RhythmCARE Assist may give you peace of mind knowing you have additional support to keep connected to your clinic.

note: Reach out to your Boston Scientific Rep to integrate the Pre-insertion card to your workflow!

note: In addition to the automated RhythmCARE Assist service, patients may call RhythmCARE Patient Services for live assistance at 1-866-484-3268, Monday through Friday during business hours.

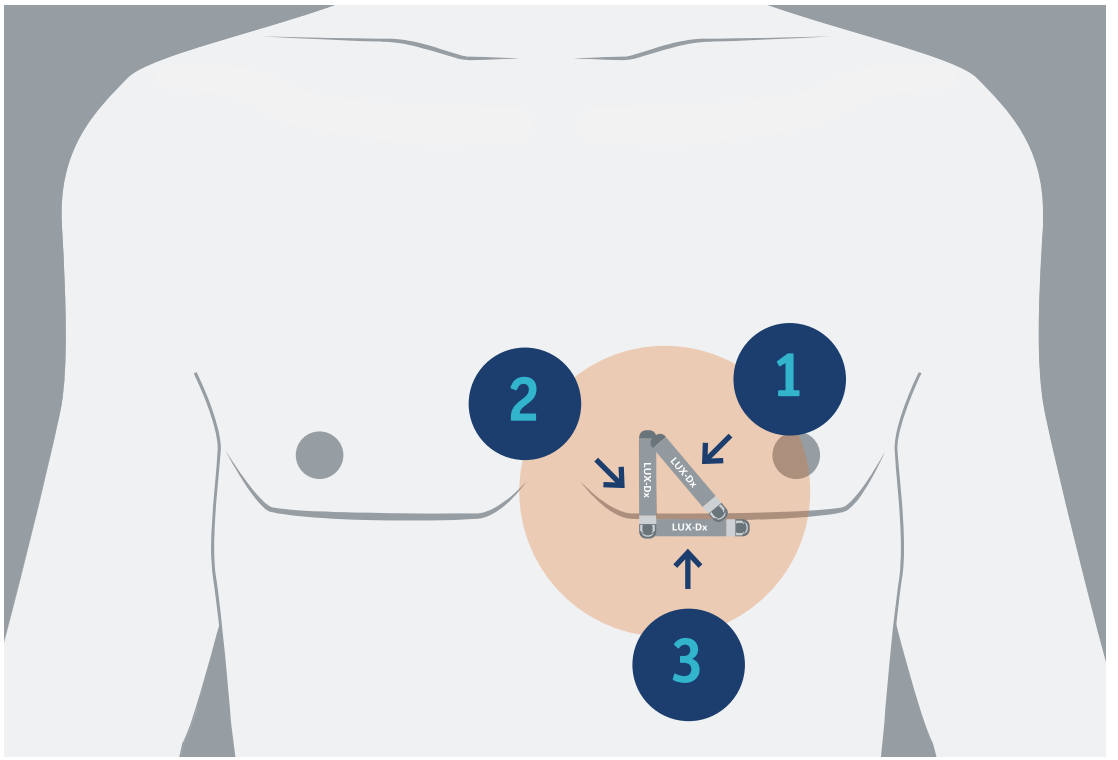
Insertion Procedure

Whether you are directly involved in the insertion procedure or working with patients who already have a LUX-Dx™ ICM, this section can help you understand the basics of the procedure.

Click to navigate to a section.

Insertion Locations

The device is typically positioned under the skin in the left pectoral region. Insertion locations are:



1. 4th intercostal space, 45° relative to the sternum, along axis of the heart (recommended).
2. 4th intercostal space, parallel to the sternum (recommended).
3. Optional insertion locations may be considered, such as anterolateral or inframammary between the 5th and 6th ribs.

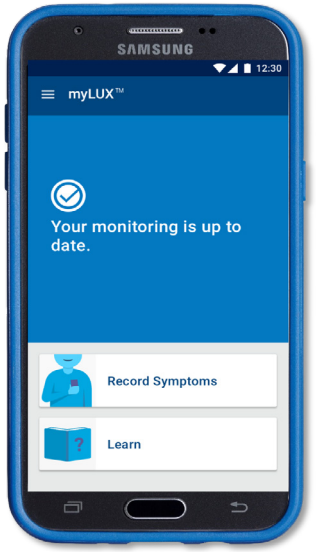
note: For optional locations, preinsertion surface mapping with clinic ECG equipment is recommended to determine if the location provides reliable signal quality and R-wave amplitude sensing.

Determine Patient Monitoring Method

If your clinic partners with your Boston Scientific Rep to implement the printed Pre-insertion card at consult or scheduling the patient may bring back the card with information filled in and the myLUX app downloaded.

On the day of insertion, ensure the patient has confirmed if they would like to download the myLUX app on their own phone, or rather have a Boston Scientific provided mobile device. If they choose to download the app, check if the app has been downloaded, and you have the patient's contact information for the RhythmCARE Assist service enrollment.

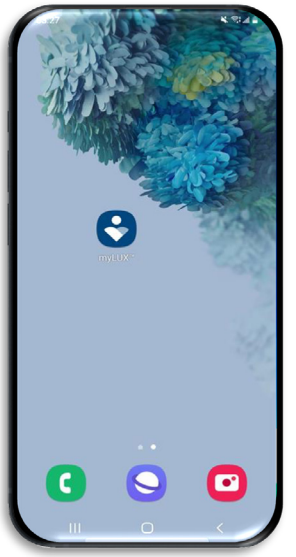
Boston Scientific Provided myLUX™ Mobile Device



Patient can bring the phone with them or leave it next to their bed

OR

New! Downloadable myLUX™ Patient App*



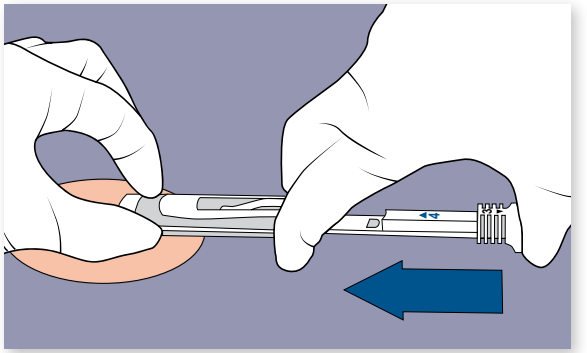
Patient Convenience

Additional support from RhythmCARE™ Assist**

*The downloadable myLUX™ Patient App is only available for LUX-Dx II™ ICM and LUX-Dx II+™ ICM. It is not available for the LUX-Dx™ ICM.
**RhythmCARE™ Assist is available exclusively to patients who have downloaded the myLUX Patient App on their personal smartphone.

Insertion Procedure

The LUX-Dx ICM insertion procedure involves 4–5 steps, depending on the patient and insertioning physician preference. Prepare the selected insertion site using local anesthetic and aseptic procedures. Use the insertion tools provided to insert the device.



Steps include:

1. **Checking the device**
2. **Inserting the ICM**
3. **Verifying R-Wave sensing**
4. **Repositioning the device (if needed)**
5. **Closing the incision**

note: Boston Scientific recommends retaining the insertion tools in the sterile field during the procedure in case device repositioning is required.

If you may be directly involved in the insertion procedure, it will be important for you to also understand how the Boston Scientific provided mobile devices for the LUX-Dx™ ICMs are used to support the procedure. These include the myLUX™ mobile device for patients and the LUX-Dx Clinic Assistant for clinics.

Using Boston Scientific provided myLUX mobile Device before and during insertion

Follow the steps below if patients choose the Boston Scientific provided myLUX mobile device for remote monitoring.

- **Pre-Insertion:** ***Check Battery***

  Use the myLUX Patient App and magnet (provided in kit 6259 for M301, or 6385 and 7259 for M302 and M312) to check the ICM battery before removing it from the box.

  1. Locate appropriate kit/kits.
  2. Power on the mobile device.
  3. Open the myLUX Patient App.
  4. Follow the prompts on screen to confirm the preferred language.
  5. Tap *Clinician Tools*.
  6. Follow the instructions to locate the QR code on the LUX-Dx ICM box.
  7. Hold the magnet over the marked space on the ICM box to connect to the ICM.
  8. Confirm the pairing request on the myLUX Patient App.
  9. Check the battery level displayed in the header.

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

- **During Insertion Procedure:** ***Verify R-Wave Sensing***

  Use the myLUX Patient App to verify R-Wave sensing and confirm placement of the ICM before closing to check the device battery and in preparation for performing an R-Wave check during the insertion. It is recommended to establish communication between the device and the myLUX Patient app prior to passing the device into the sterile field.

  1. From the main screen of the myLUX Patient App, or from the menu, tap *Clinician Tools* and follow instructions on the screen.

     Wait for a vibration on the mobile device to indicate connection.

2. Tap *View Real-Time S-ECG*.
3. Use the amplitude information on the screen to confirm that:
   - ✓ Amplitude is greater than or equal to 0.2mV
   - ✓ Peak-to-peak R-Wave amplitude is at least 2x peak of T-Wave or P-Wave (whichever is greater)
4. Once confirmed, tap *Disconnect* to end the session.

Important! After the insertion procedure, you must complete two critical tasks before a LUX-Dx ICM is actively monitoring and recording data for evaluation:

1. Enroll the patient in LATITUDE Clarity™.
2. Activate the patient's device using the myLUX™ Patient App or LUX-Dx™ Clinic Assistant App.

note: For patients who choose to use the myLUX Patient App on their own smartphone, the downloadable version of the myLUX app does not include Clinician Tools. This means you will need to utilize the LUX-Dx Clinic Assistant during insertion to check battery status and view real-time S-ECG by using the Scan and Connect feature.

See more information on using the LUX-Dx Clinic Assistant App before and during insertion.

Go to: *Next page*

See more information on using the LUX-Dx Clinic Assistant App during follow-up visits.

Go to: *In-Clinic Follow-up Visits*

note: A sterile bag may be used to pass the magnet into the sterile field should communication need to be re-established with the ICM after it has been passed into the sterile field.

Using Clinic Assistant Before and During Insertion

Conduct the following steps using the LUX-Dx™ Clinic Assistant for patients who use the myLUX™ Patient App on their personal smartphone or who are unsure what remote monitoring method they will choose at the time of insertion.

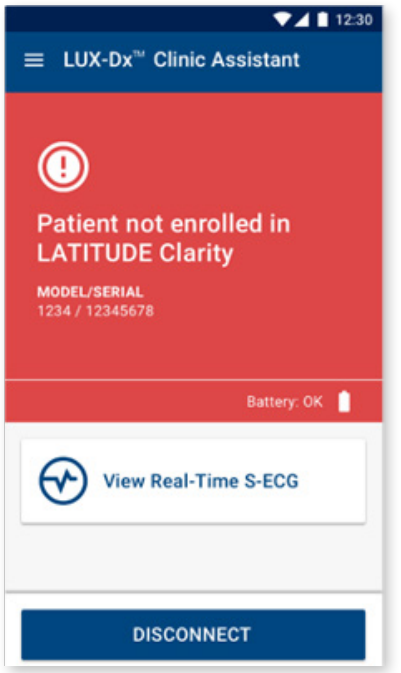
- **Step 1:** ***Connect the ICM***

  Connect to the M302 or M312 with a Clinic Assistant by tapping "Scan and Connect". You will be promoted to hold the magnet over the ICM. Wait for vibration and select ok to pair. Select the ICM device when it appears on the screen.
- **Please note:** In the case you have multiple ICMs in the room with you, it's possible multiple ICMs could be picked up by the Clinic Assistant.
- **If this occurs:** Ensure you are selecting the correct model and serial number.

note: Once you have interrogated the ICM, you will see a red screen. This is because the ICM is not currently enrolled in LATITUDE Clarity, which will be done after the device insertion. Even with the red screen, you will be able to perform the tasks needed at insertion, which are confirming the battery status and viewing real-time S-ECGs.

- **Step 2:** ***Confirm the battery status of the ICM device***

  Always check the battery status of the ICM prior to insertion. If a low battery condition is indicated, like “Battery: Low” or “Battery: EOS”, do not insert the device. Once the battery status has been confirmed as “OK”, the ICM can be handed off into the sterile field, and the ICM insertion can occur.
- **Please call:** RhythmCARE™ Technical Services to appropriately document this instance and use a different ICM with proper battery status.



Contact:
Boston Scientific RhythmCARE™ Technical Services Support at 1-800-CARDIAC (1-800-227-3422).

See more information on insertion location and procedure.

Go to: *Insertion Procedure*

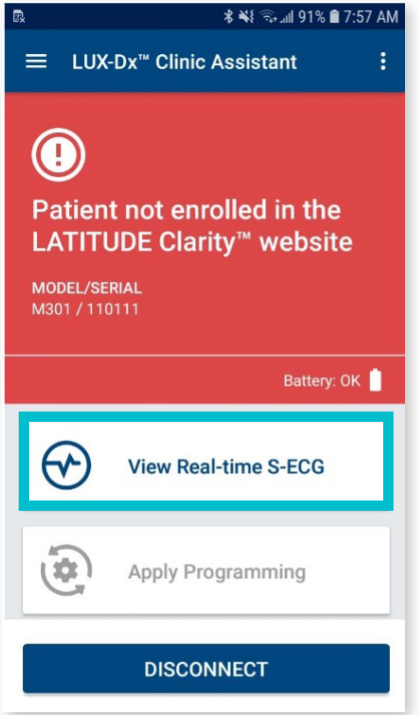
- **Step 3:** ***View Real-time S-ECGs for device signal and position verifications***

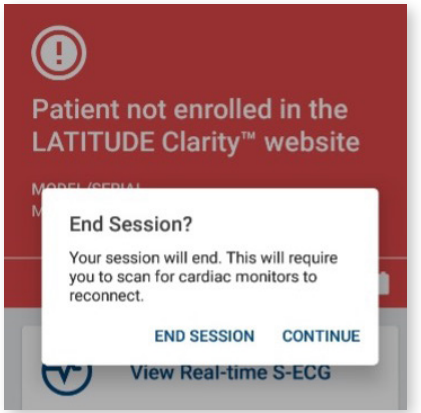
  Once the ICM has been inserted, verify device sensing performance requirements are met by selecting "View Real-time S-ECG" on the Clinic Assistant, as pictured here.

- **As a reminder:**
  - ✓ The R-wave amplitude should be a minimum of 0.2 mV when viewed on the patient or clinic app
  - ✓ The peak-to-peak R-wave amplitude should be at least twice the peak T-wave or P-wave amplitude, whichever is greater

- **Step 4:** ***End Session***

  Once adequate sensing is confirmed, select "DISCONNECT" on the LUX-Dx Clinic Assistant and "END SESSION".





note: *An ICM is only as good as the signal it receives. If the device sensing performance requirements are not met, the device may be removed from the previous insertion location and repositioned.*

Activate ICM & Educate Patient

To make sure a LUX-Dx™ ICM is actively monitoring and recording data, these two critical steps must be performed in this order during or after insertion:

1. The patient must be enrolled in the LATITUDE Clarity™ Data Management System.
2. The patient's inserted ICM must be activated with the appropriate programming settings using the myLUX™ Patient App or the LUX-Dx Clinic Assistant App.

This section will cover these tasks as well as suggestions for educating patients on the LUX-Dx™ ICM System and home monitoring with the myLUX™ Patient App.

Click to navigate to a section.

Patient Enrollment in the LATITUDE Clarity System

Every LUX-Dx ICM patient *must* be enrolled in LATITUDE Clarity to be actively monitored. Enrollment is completed using one online form per patient in LATITUDE Clarity. By completing this form, you are accomplishing three critical tasks required to set up a LUX-Dx ICM:

- ✓ Enrolling the patient in LATITUDE Clarity
- ✓ Registering the LUX-Dx ICM with Boston Scientific
- ✓ Selecting device programming parameters by choosing a Reason for Monitoring

Completing the Enrollment form can happen at any time during or after the patient's procedure, after confirming the right ICM device is with the right patient. It must be completed before activating the patient's device with the myLUX Patient App.

workflow tip:

The Enrollment form is available online and accessible via the LATITUDE Clarity website, which should allow some additional flexibility when assigning this task in clinic workflows.

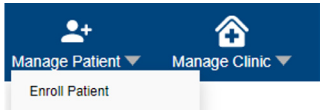
To be successful with enrollment, the person completing the form should meet the following criteria:

- ✓ Have access to a PC, laptop, or tablet where they can access the website: *latitude.bostonscientific.com*
- ✓ Have the necessary login credentials to access the LATITUDE Clarity System and access the appropriate clinic Patient Groups
- ✓ Have access to insertion and patient information required on the Enrollment form
- ✓ Give attention to detail so data is entered properly at this stage

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

1. Navigate to the LATITUDE website: *latitude.bostonscientific.com*
2. Log in to the LATITUDE Clarity System.
3. 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.

4. Click *Manage Patient* on the top navigation bar, then click Enroll Patient



5. Complete the Enrollment form.
   - Complete all required fields.
   - You will see some optional fields. These fields include information that may help in data review. For example, information included in the Clinical Context section will show up as part of a patient's report header, which can help to provide additional context for the reviewer.

(continued)

note: ***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.

See required fields for enrollment.

Go to: *Additional Resources > Enrollment Form Fields*

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

- You will fill out the RhythmCARE™ Assist service patient communication preferences during this enrollment process
  - In the top portion, you will see an overview of the service
  - The next portion, you will choose one of the three options for each patient according to their remote monitoring method and service preference

a. The first option is for patients who are using the downloadable myLUX app on their own phone and agree to the service

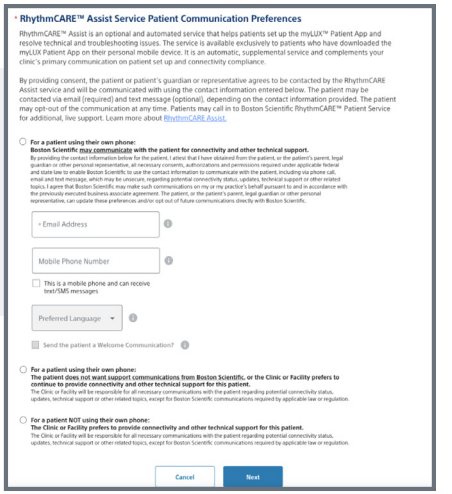
b. The second option is for patients who are using the app on their own phone but opt out of the service

c. The third option is for patients who use the Boston Scientific provided mobile device and are not eligible for the service

d. If the patient's monitoring method is unknown, it is recommended to enroll the patient in the first option, opting in for the RhythmCARE Assist service. This is because signing up for the service is only available during this enrollment process.

- Once enrollment is complete, you will see a confirmation page with an option to generate a PDF file of the completed Enrollment form.
- By adding an email address, the patient will receive emails from the service; by adding a mobile phone number, the patient will receive text messages. It is recommended to select the optional Welcome Communication to all patients signed up for RhythmCARE Assist service, so they get information on the service and proactive education on connectivity.

note: Refer to the Pre-insertion Card to get the patient's contact information for the RhythmCARE Assist service enrollment, if you have this implemented into your workflow.



Activating a Patient's LUX-Dx ICM

After a patient has been enrolled in LATITUDE Clarity, you can activate their ICM in one of two ways to make sure programming is properly applied to the ICM and it is actively monitoring.

1. Use the myLUX Patient App. You can use this if the patient already has the app downloaded on their personal smartphone or they are choosing to use the myLUX app on the Boston Scientific provided myLUX mobile device.

2. Use the LUX-Dx Clinic Assistant App. You can use this for a patient who wants to use the downloadable version of the myLUX Patient App but can't set up the app at time of insertion.

This section covers instructions for both options.

Using the myLUX Patient App to Activate a LUX-Dx ICM

note: ***Important!*** Even if the myLUX Patient App was used during the insertion procedure, this part of the process is still *required* after enrollment to activate the ICM.

If you intend to monitor a LUX-Dx ICM patient remotely, you will typically activate the ICM by pairing it with the myLUX Patient App using Bluetooth® wireless technology. By completing this process, you are also helping the patient get their home-monitoring equipment set up simultaneously.

Steps to Set Up the myLUX Patient App and Activate ICM

workflow tip: Setting up the myLUX Patient App requires:

- An active internet connection via a cellular or Wi-Fi network.
- The patient's personal smartphone with the myLUX app downloaded, or a Boston Scientific provided myLUX mobile device
- Bluetooth® turned on
- The magnet

Prep:

1. Attach the magnet to the provided mobile device's case or personal smartphone. If patients don't want to attach the magnet to their phone, have them attach it to their keychain.
2. Turn on the mobile device or smartphone and check that it is sufficiently charged.

Check out tips for the magnet

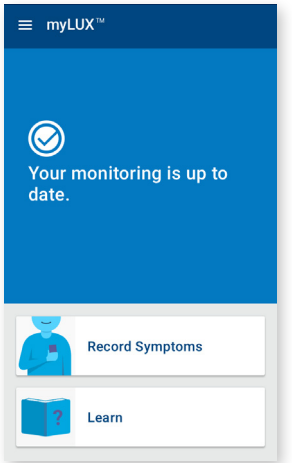
Go to: *LUX Dx System Overview > Magnet*

Want to learn more on how the myLUX Patient App works? Please check out the myLUX Patient App Tutorial.

Go to: *https://mylux-tutorial.bsci.com*

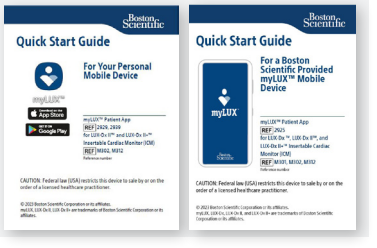
Set Up:

1. Open the myLUX app by tapping the icon.
2. Confirm the language selection (only on provided mobile device).
3. Tap Start Setup.
4. Ask that the patient agree to the privacy policy and terms of use on screen.
5. Enter the patient's date of birth.
6. Follow the instructions on the screen:
   - Tap Allow or OK as they show up.
   - Hold the magnet over the patient's inserted ICM and wait for a vibration on the smartphone or mobile device. Tap Pair and then move the magnet away from their chest. You may see multiple pairing requests throughout the setup process – tap Pair each time it comes up.



The ICM is activated when you see a screen that says "Your monitoring is up to date." This is the main screen of the app.

note: This process is also covered in the Quick Start Guide For Your Personal Mobile Device, provided in the myLUX Patient Kit (model 6385), or in the Quick Start Guide for a Boston Scientific Provided myLUX Mobile Device, provided in the myLUX mobile device box (model 6259, 7259).



Using the LUX-Dx Clinic Assistant App to Activate a Patient's ICM

If you intend to use the LUX-Dx Clinic Assistant App to activate LUX-Dx ICMs, you will need to confirm the following before you begin:

- ✓ The LUX-Dx Clinic Assistant App must be activated and registered in LATITUDE Clarity.
- ✓ The mobile device must be charged.
- ✓ The mobile device must be connected to a Wi-Fi or cellular network.
- ✓ You must have access to the blue magnet that is part of the LUX-Dx ICM System. This will be either attached to the mobile device case or available somewhere else in your clinic.

Once you have all these items ready, follow these steps to activate the patient's ICM:

1. From the main screen of the LUX-Dx Clinic Assistant App, tap *Scan and Connect*.
2. Follow the instructions on the screen to hold the magnet over the patient's ICM. The mobile device will vibrate when the connection is successful.
3. The app will provide a list of ICMs available for connection.
4. Select the ICM you are attempting to activate. You may be prompted more than once to accept the pairing request with that particular ICM.
5. Once connected, the app will display information about the ICM and the patient along with available actions that can be performed.
6. Select *Program & Activate* and accept the pairing request.
7. Follow the instructions on the screen until you see a screen confirming that activation was successful.

Want to learn more on how the LUX-Dx Clinic Assistant activates the ICM?

Go to: *Additional Resources > LUX-Dx ICM System Clinic Assistant App Demo*

note: If the patient's ICM has not been activated, on the Clinic Assistant App, you will see the model and serial number of the ICM only and no patient information.

Using the myLUX Patient App

If you would like to go into more detail on the myLUX Patient App during patient education, this section will help outline the various functions of the myLUX Patient App and workflow tips related to the app.

There are two options for patients to use the myLUX Patient app – on a Boston Scientific provided mobile device, or downloading the app onto their own smartphone.

Functions of the myLUX Patient App:

For the most part, the two options of the myLUX app have similar functions and features. The primary purpose of the app is to activate the patient's inserted ICM and transmit data between the ICM and the LATITUDE server. The myLUX Patient App also contains many other features that will help patients interact with the ICM system and the clinic and stay connected.

These features include:

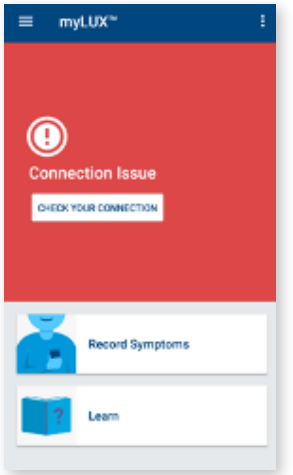
- **Monitoring Status**
- **Record Symptoms**
- **One-way messages**
- **Education**
- **Manual Transmission**
- **Connection notification on home screen***
- **RhythmCARE Assist service***

**Exclusive to the downloadable app monitoring option, a connection issue notification feature and the supplemental RhythmCARE™ Assist service are offered to patients to support patient connectivity.*

Monitoring Status

- Displays current monitoring status AND notifies patient of connection issues on the main screen of the app.

Remind the patient to open the app periodically to check if it is connected. If they see a screen with an exclamation point, they should follow the instructions on the screen to resume the connection. In this example, they would tap the *Check Your Connection* button.

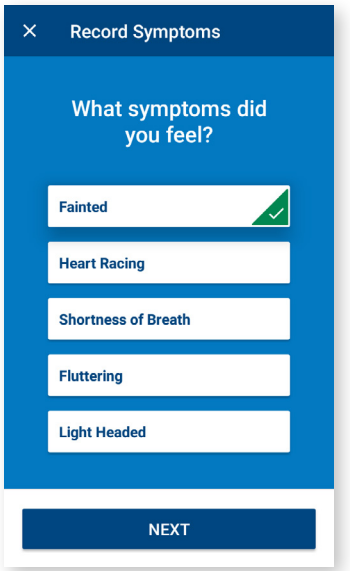


workflow tip: Clinics can adjust connection status timeframes in LATITUDE Clarity to determine when a patient is added to the Not Monitored list. This setting is connected to when a patient might see a Connection Issue screen to help them get reconnected.

Record Symptoms

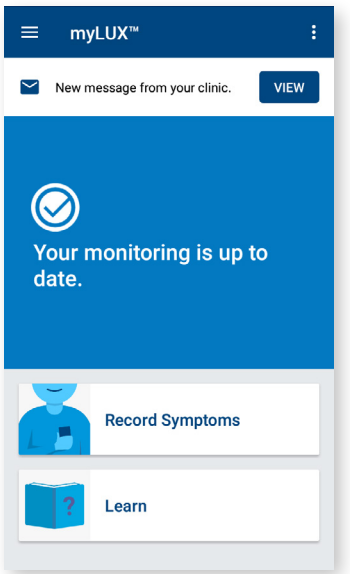
If enabled by the clinic, this feature helps patients track symptoms by recording what they were feeling and the activity they were doing when they felt their symptom.

workflow tip: If a patient no longer needs to record symptoms, edit symptom configuration in the programming section of LATITUDE Clarity. If the configuration is disabled completely, the patient will no longer see the Record Symptoms button on their app.



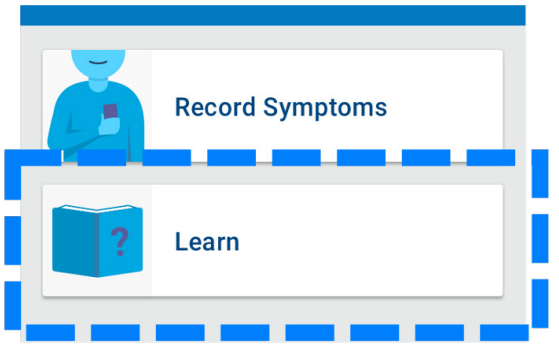
Messages

Patients can receive messages from their clinic. This message will stay on their screen until they have read it. The only option will be to read the message; no other action can be taken. For more information on Patient Messaging, refer to the Monitor & Manage Patient Data section.



Education

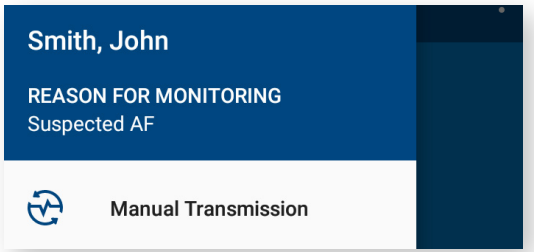
The Learn button on the main screen of the app gives the patient access to educational resources. Patients can tap the Learn button at any time to learn more about heart monitoring, the ICM system, and using the myLUX Patient App.



workflow tip: These features were available with our first-generation LUX-Dx™ ICM and continue to be important features of the LUX-Dx II/II+™ ICMs.

Manual Transmission

When requested by the clinic, patients can send a manual transmission using the option in the app menu.



note: The term *Manual Transmission* is used in patient materials. This term is the same as a patient-initiated interrogation in LATITUDE Clarity.

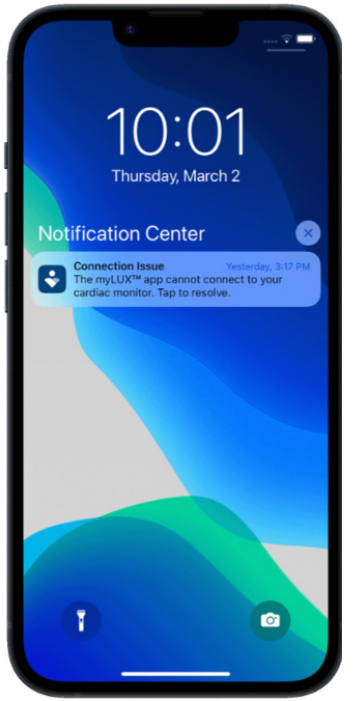
Exclusive Features and Service for Downloadable myLUX App

There are a few new features that support patient connectivity for the LUX-Dx II/II+ ICMs.

If the patient has chosen to download the myLUX Patient app on their own phone, there are a few additional ways they may be prompted to resolve their connection issue.

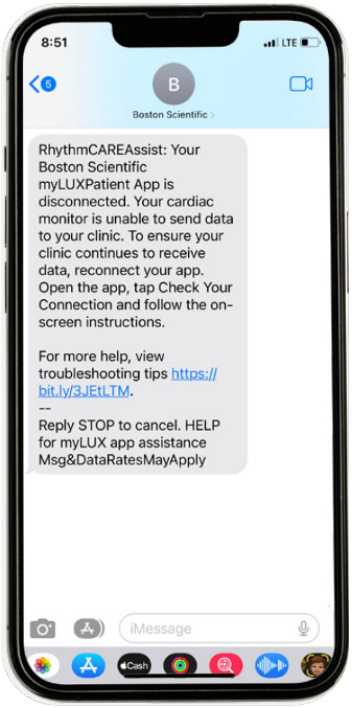
Connection Notification on Home Screen

For patients using the downloaded app, they will receive a notification on their home screen if there is a connection issue, including if the patient closed the app.
The notification timing is based on their settings in LATITUDE Clarity, and will appear at the same time when the red connection issue screen displays within the myLUX Patient app.



RhythmCARE™ Assist Service

For patients using the downloadable app who are signed up for the RhythmCARE Assist service, the patient will be notified by the service via email or text message if the patient needs to set up the app or when connectivity issues arise. The communication includes educational content to guide the patient through reconnecting. The communication is automatic, so it requires no action from the clinic in order for it to be sent to patients.



To learn more about the RhythmCARE Assist Service:

Go to: *Prepare Clinic > Preparing Patient for App and Service*

Patient's Monitoring Method Preference

Release Current myLUX Pairing

If a patient ever loses their Boston Scientific provided myLUX mobile device, you will need to find the Monitoring Information section under the patient's profile in LATITUDE Clarity and click Release current myLUX™ pairing. To secure data, this action will clear all data and deactivate the app. For questions about replacing the provided myLUX mobile device please contact Boston Scientific.

You will need to click "Release current myLUX pairing" on LATITUDE Clarity for patients who would like to set up the app on a mobile device different than their current one:

- Patients using the app on the provided mobile device wants to switch to having the app on their own smartphones, or vise versa
- Patient using the app on a personal phone needs to set the app up on another personal phone with a new phone number or a new email address
- Patient using a provided mobile device needs to switch to a new provided mobile device

How to Manage Monitoring Method Preference Changes:

- If the patient needs to switch monitoring method, please call Boston Scientific Patient Support at 866-484-3268.
- For patients who use the downloadable myLUX Patient App and get a new phone, the patient will need to set up the myLUX™ app on their new phone following the same process used during initial set up.
- If the patient gets a new phone and phone number they will need to download and install the myLUX app. In the set up process select the option to "Change Phone Number" during the verification code step. This will allow set up of the myLUX app on the new phone with the new number. At this time, RhythmCARE™ Assist communications will not go to the new number.
- If the patient would like to unsubscribe from RhythmCARE™ Assist communications, direct the patient to tap the "unsubscribe" link in the email and/or reply "STOP" to the text message. Patients must unsubscribe to both if they'd like all communication to cease.

Patient Education

Every clinic will have a preferred way of discussing ICMs, remote monitoring, symptoms, and heart conditions with patients. This section will offer a simple checklist of topics that you may find useful to cover with ICM patients, as well as the resources that may help you educate patients on the LUX-Dx ICM specifically.

Patient Education Checklist

Whether you are educating patients pre- or post-insertion procedure, you may consider covering the following topics at least once with every patient.

note: In kit 6259 and kit 6385, you will find product literature (handbooks) that you may find useful in conversations with patients.

- ☑ **Introduce Function of ICMs**
- ☑ **Discuss Procedure and Wound Care**
- ☑ **Explain the LUX-Dx ICM System and Its Parts**
- ☑ **Set Expectations for Remote Monitoring and Follow-Up**
- ☑ **Set Up the myLUX Patient App and Discuss App Uses**
- ☑ **Discuss Home-Monitoring Reminders**
- ☑ **Review RhythmCARE Assist Service for downloadable app patients**
- ☑ **Review Available Resources**

Introduce Function of ICMs

Review with the patient why their provider has recommended an ICM.

- Share that an ICM is used for the long-term monitoring of heart rhythms for the health care team to use in evaluating symptoms or concerns. It is a monitoring device; it does not treat cardiac arrhythmias.
- Discuss the patient's specific Reason for Monitoring, including:
  - Possible symptoms (if relevant)
  - What types of events the clinic might be alerted for
  - Why these events may be related to a heart condition

note: Patient education is critical to keep ICM patients compliant and connected. We've made patient education accessible in numerous ways including directly from the myLUX Patient App Learn button and easy to find from home for patients, caregivers.

To learn more:

Go to: *Patient Education Resources*

Discuss Procedure and Wound Care

Review any required pre-insertion preparation.

- Help the patient determine which monitoring options is best for them.
- If the patient chooses the downloadable myLUX app, inform them the steps and information they need to download the app
- Discuss what will happen during the procedure, including insertion technique, size of device, and possible location for insertion.
- After the procedure, review recovery expectations, wound care, and discharge instructions.

The LUX-Dx™ ICM System*

Finding the Right Monitoring Option

Boston Scientific

The patient app on a mobile device collects information about irregular heart rhythms stored on your Insertable Cardiac Monitor (ICM) device and automatically sends that information to your health care team. You have two options: downloading an app onto your own smart device or using the app on a Boston Scientific Provided Mobile Device.

Downloadable myLUX™ Patient App**

Download the myLUX™ Patient App on your own smartphone to deliver vital cardiac data to your health care team. This option enables you to seamlessly integrate the app into your lifestyle. The downloadable app is free to download and use.

This option may be best if you:

- Own a smartphone
- Keep your smartphone powered on and near you a considerable portion of time each day
- Are comfortable using a smartphone or have a family member who can support you

If you choose this option, please refer to the back of this page.

OR

Boston Scientific Provided myLUX™ Mobile Device

The Boston Scientific provided mobile device has the myLUX™ patient app pre-installed. This device delivers vital cardiac data to your health care team.

This option may be best if you:

- Do not own a smartphone

If you choose this option, the mobile device will be provided at your procedure and you will learn more then.

RhythmCARE™ Assist

The service is available exclusively to patients who have downloaded the myLUX™ Patient App on their personal smartphone. RhythmCARE Assist is an optional and automated service that provides connectivity or app set up help via email or text message. This service is available to you at no cost. RhythmCARE Assist may give you peace of mind knowing you have additional support to keep connected to your clinic.

Use the pre-insertion card to help with your conversation.

Ask your Boston Scientific rep for the card (CRM-1614204-AA).

Explain the LUX-Dx ICM System and Its Parts

- Introduce each part of the LUX-Dx ICM System and how they work together.
  - The ICM automatically records and stores data on arrhythmias.
  - The myLUX Patient App collects data from the ICM (usually at night) and sends available data to the clinic for review.
    - In order to do this, the provided mobile device or personal smartphone with the app installed must be powered on, connected to Wi-Fi or a cellular network, with Bluetooth® turned on, and located within 6 feet of the patient for an extended period of time. Many providers recommend that the patient keep the mobile device/ smartphone by their bedside as they sleep at night, just like a typical home monitor for other device types.
  - Magnet is used for the app's connections to the ICM device:
    - Set up
    - Symptoms
    - Manual transmission
    - Resolving device connection issues
- The clinic reviews data and contacts the patient if there is a need for further follow-up.

Set Expectations for Remote Monitoring and Follow-Up

- Discuss your clinic's preferred review and follow-up schedule to help the patient understand how they will be monitored.
- Encourage the patient to contact their insurance provider to better understand how monitoring may be billed.
- Confirm that the patient understands that remote monitoring equipment does not alert emergency services. In an emergency, they still need to contact emergency services using other means.

Set Up the myLUX Patient App and Discuss App Uses

note: When you are setting up the myLUX Patient App for the first time, it is best to make sure you are in an area with a reliable Wi-Fi or cellular connection before you begin.

- If you intend for the patient to use the magnet, recommend them to attached it to the back of the mobile device case, or carry it with a key chain. Alternatively, they can carry it in their pants pocket or purse, but keep it away from credit cards or other cards with magnetic strips
- Explain to patients that the myLUX app is used to transmit their heart rhythm data (stored in their LUX-Dx device) to their clinic.

note: To avoid draining your ICM battery, DO NOT carry the magnet in a shirt or jacket pocket over their inserted device.

- Remind patients should routinely check to verify that the app's connection and reconnect so their clinic can continue monitoring their heart rhythm remotely.
- For patients using the BSC provided mobile device, instruct them on how to:
  - POWER it ON, keep it plugged in and charged at all times
  - CHECK the myLUX app connections
  - CONNECT to home WiFi
  - RESTART the mobile device
- Set up the myLUX patient app following the step-by-step instructions:

Go to: *Activating a Patient's LUX-Dx ICM > > Steps to Set Up the myLUX Patient App and Activate ICM*

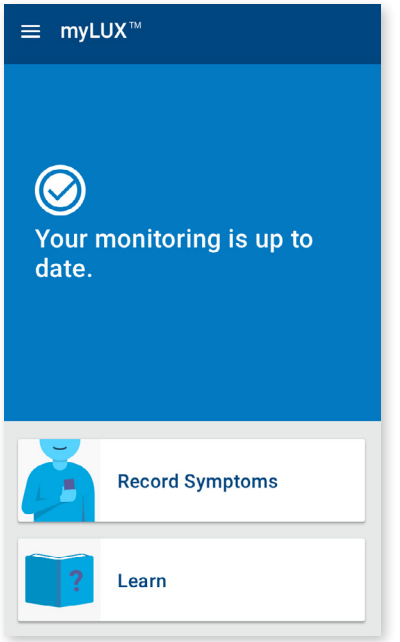
- If the patient will set up the app at home, walk them through the steps. Remind them the patient education resources (Step-by-Step Setup Guide, Quick Start Guides) available to guide them through the steps. In addition, explain what they should expect from the RhythmCARE Assist service to help them set up the app at home. The patient will receive an email and/or a text from the RhythmCARE Assist service in 3-4 days to remind them to set up if they haven't done so already.

Go to: *Patient Education Resources*

Discuss Home-Monitoring Reminders

- To help patients stay connected, you can offer them a few simple reminders:
  - Keep the personal or provided mobile device with the myLUX Patient App powered on and charged, and connected to the Internet via cellular signal or Wi-Fi connection.
  - When possible, connect the mobile device to a home Wi-Fi network. Setting the mobile device up with Wi-Fi at home will help ensure a consistent monitoring experience.
  - Set the mobile device within 6 feet (2 meters) of where they sleep overnight, or place it within 6 feet of a spot where they spend a considerable amount of time each day (60 minutes or more) in the same spot.
  - Keep Bluetooth® ON
  - Keep the app running and connected:
    1. Do not quit the app. Remember to reopen the app if they restart their mobile device.
    2. Open the app every once in a while to look for a blue screen with a check mark to confirm the monitoring is up to date.
- Discuss with the patient when you would like them to carry their mobile device. You can cover things like everyday activities, traveling, and/or in-clinic follow-up visits.

note: During the patient's regular routine, it is not necessary to carry the provided magnet or mobile device at all times unless you'd like the patient to record symptoms. Have patients notify your team before traveling for an extended period of time or relocating.



Review RhythmCARE Assist Service for downloadable app patients

- To help patients get set up (if they will set up the app at home) and stay connected:
  - Explain to the patients who are using the downloadable app on the benefits of the RhythmCARE Assist Service and what to expect. Refer to the RhythmCARE Assist Service Guide in the Patient Information Packet (CRM-1640305-AA)
  - Stress the importance of reading and taking action on the RhythmCARE Assist Service communications
  - Instruct patients to call RhythmCARE Patient Services when help is needed;. e.g., setting up, getting reconnected, phone replacement, or unresolved issues
  - Instruct patients to call their health care team or seek emergency medical services if they need immediate medical attention

note: Boston Scientific RhythmCARE™ Patient Services phone number is in all the patient education materials:

Call 1-866-484-3268, Monday - Friday during business hours, and select the option for LUX-Dx™ ICM.

Review Available Resources

- Ensure you familiarize yourself with the Patient Education Resources that are listed on the next page (page 77)

Patient Education Resources

To support LUX-Dx ICM patients pre- and post-insertion procedure, Boston Scientific has developed a few resources you may find useful when educating patients. Here is a short list of resources, what they include, and where they are located.

RESOURCE	CONTENTS	LOCATION
Pre-Insertion Card	• Key criteria to help patients determine to download the myLUX app or not • RhythmCARE Asssist service overview • Steps to download the app • Information to bring for the app and RhythmCARE Assist service set up	• The tear-off sheets can be sent home with the patient at consult or scheduling • Contact your Boston Scientific representative to order
Patient Information Packet	Four important patient brochures in one folder: 1. The LUX-Dx ICM System Patient Brochure 2. myLUX Step-by-Step Setup Guide 3. Staying Connected Tip Card 4. RhythmCARE Assist Service Guide	Contact your Boston Scientific representative to order the Patient Information Packet (CRM-1640305-AA)
The Learn button on the myLUX Patient App	Website to explain the LUX-Dx ICM, app uses, heart monitoring, and patient FAQ	Website accessed by clicking Learn button in myLUX Patient App
Patient Handbook and Quick Start Guides	• **Handbook:** Describes ICM system and how to use myLUX Patient App as well as covers warnings and safety precautions • myLUX App Quick Start Guide for patient's personal mobile device • myLUX App Quick Start Guide for Boston Scientific provided mobile device	Product literature provided in kit 6259 and kit 6385
myLUX™ Patient App Tutorial	A demo tool with screenshots to illustrate what the myLUX™ app looks like	https://myluxtutorialbsci.com/

In addition to what is listed here, you will find similar information and patient education videos on both ***bostonscientific.com/luxdx*** and the LUX-Dx ICM training site for clinicians on EDUCARE at ***luxdxtraining.com***. Boston Scientific will continue to add to these sites as necessary with new resources for patient education.

Monitor & Manage Patient Data

This section will introduce and explain how to use the LATITUDE Clarity™ Data Management System to review and manage patient data from LUX-Dx ICMs. **If you have access to the LATITUDE Clarity System, we strongly recommend you keep the website open to follow along throughout this section.**

If you oversee ICM decisions for your clinic, please first review the ***Prepare Clinic section*** to learn more about how the site is organized and ways to configure the system to meet your needs.

Throughout this section you will see images of the LATITUDE Clarity System. All patient information included is not real and was created for purposes of demonstration.

Click to navigate to a section.

Overall Site Navigation

Using the LATITUDE Clarity™ System to Manage Patients

Using LATITUDE Clarity, you will be able to:

- Enroll new LUX-Dx ICM patients
- Access data transmitted from a patient's ICM device
- Analyze patient data using included analysis and trending tools
- Generate reports for review
- Send read-only messages to patients
- Adjust detection parameters and device settings remotely

If you need help enrolling new patients, please review the LATITUDE Clarity section.

Go to: *Activate & Educate > Patient Enrollment in the LATITUDE Clarity System*

To help you get the most out of LATITUDE Clarity, this section will review the features of the system in order of a typical review workflow.

Managing the patient list
(triaging new data)

↓

Reviewing individual patient data

↓

Generating reports for review

↓

Communicating with patients

↓

Dismissing data

↓

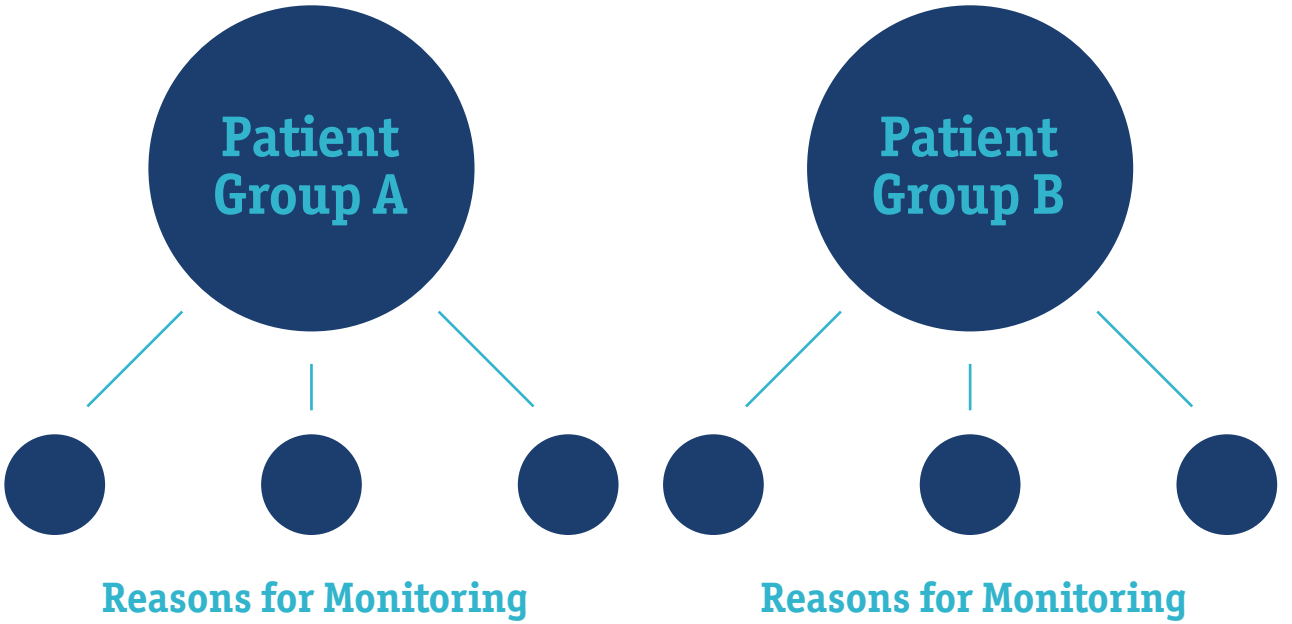
Sending information to EMR systems

↓

Reviewing or adjusting programming settings and alerts

System Organization

LATITUDE Clarity™ uses two primary designations to organize patients and device programming: Patient Groups and Reasons for Monitoring. The system requires that every patient in the system be assigned both a Patient Group and a Reason for Monitoring at the time of enrollment. These two designations can be modified, but they are always required as a way to organize patients and structure programming and alert configurations.



Patient Groups: Patient Groups are used for organizing patients in LATITUDE Clarity™. Patient Groups are unique to, and controlled by, each clinic.

- Examples of how some clinics organize Patient Groups include by location, by physician, or by device type.
- Patient Groups can be modified at any time by specific user types.
- Some programming and alert settings can be manually changed and applied across an entire Reason for Monitoring within a Patient Group. This concept is covered throughout various sections of this guide.

Reasons for Monitoring: Initial default programming and configuration values are automatically supplied with the selection of a Reason for Monitoring in LATITUDE Clarity. These values can be revised anytime.

At enrollment, a Reason for Monitoring from this preset list must be selected:

- Syncope
- Palpitations
- Cryptogenic Stroke
- Suspected AF
- Post-AF Ablation
- AF Management
- Ventricular Tachycardia
- Other

note: Patient Groups are shared between LATITUDE Clarity and LATITUDE™ NXT. This means that if you already have Patient Groups set up in LATITUDE NXT, you will see these Patient Groups in your LATITUDE Clarity Patient Group list; however, NXT patients will not appear in LATITUDE Clarity and vice versa.

Find more information on organizing Patient Groups.

Go to: *Prepare Clinic* > *Setting Up and Configuring the LATITUDE Clarity System* > *Manage Clinic Settings*

Regardless of where you are on the LATITUDE Clarity™ website, you will always have access to the navigation bar at the top, which has five key sections to help you move through your review.

Top Navigation

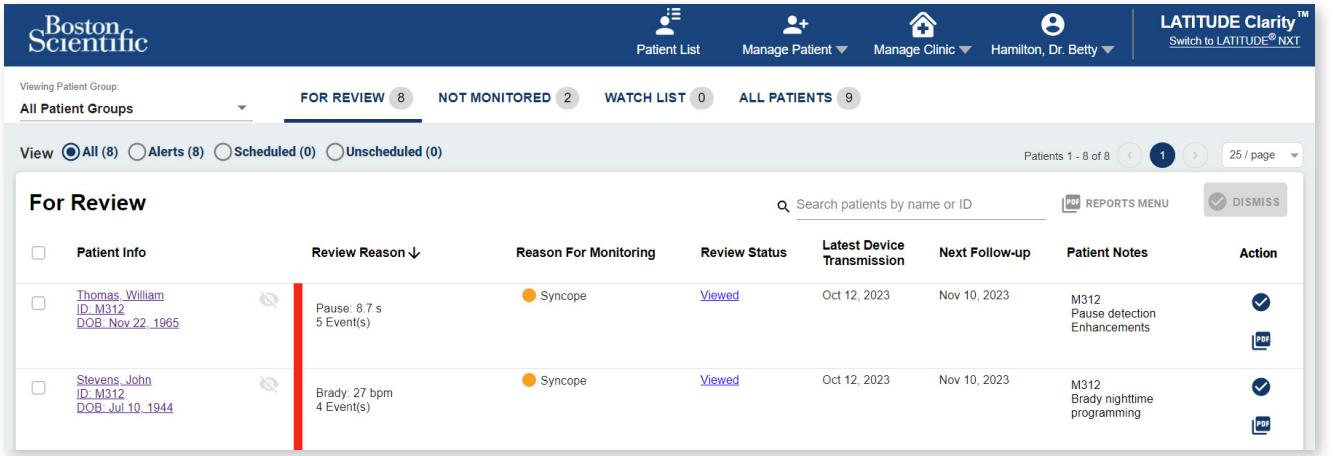
For full context, follow along with LATITUDE Clarity.

1. **Patient List:** This will be the first page displayed upon login. It will display a complete list of patients to which you have access (covered in detail on the next page) and information about their status and data for review.
2. **Manage Patient:** This links to the online Enrollment form used to enroll new ICM patients in LATITUDE Clarity and View Another Clinic's Patient which will be discussed in Viewing Another Clinic's Patient section.
3. **Manage Clinic:** This links to various clinic-wide settings, including Patient Groups, Clinic Users, and EMR Integration. Depending on your level of access, you may see different options.
4. **User Profile:** This links to your personal information. You will navigate here to edit your personal information, change language, find additional help information, and log out when you are done using the system.
5. **Switch to LATITUDE™ NXT:** This links to the View Patient List page of LATITUDE NXT.

Managing the Patient List

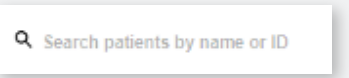
When you log in to, or switch over to, LATITUDE Clarity™, the first page displayed is called the Patient List. This page provides a list of all the ICM patients to which you have access. The Patient List will be your guide to planning and prioritizing your day and understanding at a high level which data is available for review across all your ICM patients.

To give you a working knowledge of what is included on the Patient List page, this section will highlight some key features that can help you streamline your workflow as you navigate the system.



For full context, follow along with LATITUDE Clarity.

workflow tip: If you are looking for a specific patient, you can use the search bar on the Patient List to enter their name or ID.



Primary View Filters

On the Patient List page, you will see a set of primary and secondary view filters at the top that can help you organize your view and the patients listed below.

For full context, follow along with LATITUDE Clarity™.

1 **Viewing Patient Group:** This is a drop-down menu of all the Patient Groups to which you have access. By default, it will display All Patient Groups, but you can jump to a specific Patient Group at any time using this drop-down menu. The Patient List will filter accordingly.

2 **For Review:** This filter displays patients with new data available for review that has not yet been dismissed. Data listed here could be data from alerts and/or remote follow-ups (both scheduled and unscheduled).

3 **Not Monitored:** This filter displays patients who are not currently being monitored because they are not connected or because of another reason.

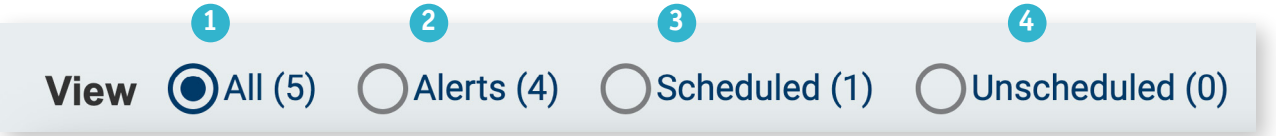
- Patients displayed within this filter are listed in order of when their Not Monitored status was determined, with the most recent listed first.

4 **Watch List:** This filter is a custom list of patients that users within your clinic have selected. This list is visible to, and shared by, all users within your clinic. With certain user permissions, you can add or remove patients from the Watch List by clicking the Watch List icon anywhere it appears on the site.

5 **All Patients:** This filter lists all patients within the selected Patient Group regardless of review or monitoring status.

Secondary View Filters

These filters are located just under the primary view filters and offer even more ways to organize your patients. Secondary view filter options will change based on primary view filter. In this guide we will focus on these secondary view filters used on the For Review primary view filter:



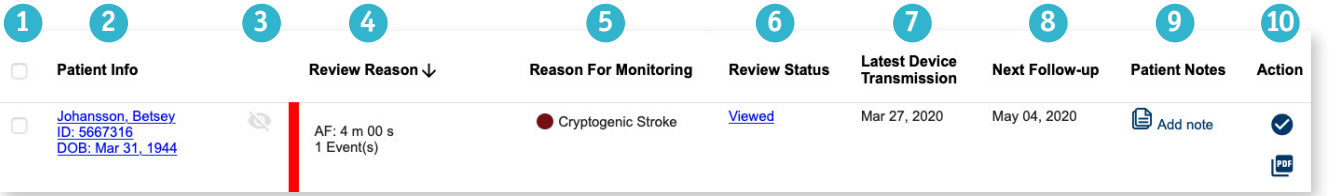
For full context, follow along with LATITUDE Clarity™.

1. **All:** This is the default view. This filter will show you all patients within the primary view filter selected above.
2. **Alerts:** This filter will display any new data for review that met the alert criteria configured.
3. **Scheduled:** This filter includes only new data that was received as part of a scheduled follow-up.
4. **Unscheduled:** This filter displays clinic interrogations and patient-initiated interrogations.

For Review Filter

For full context, follow along with LATITUDE Clarity™.

Data that is listed on this page as For Review is associated with new data that has not yet been dismissed. The For Review page provides a summary of more in-depth data included throughout the site. You can think of this page as a preview of your day.

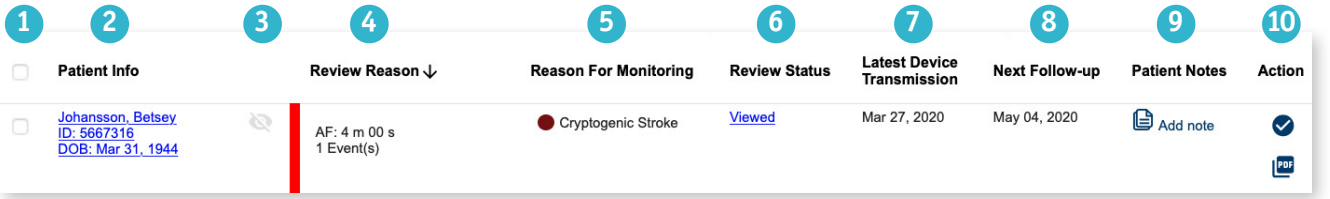


To better understand this page and how you can use it, please review the summary of each column included below and on the next pages.

1 **Check Box:** This column is used to select a patient(s) when preparing to perform an action. When a box is checked, options for "reports menu" and "dismiss" will appear in the upper right of the For Review page.

2 **Patient Info:** This column displays the patient's name, ID (determined by clinic), and date of birth.

note: Patient Info can be edited at any time by going into the individual patient's profile.

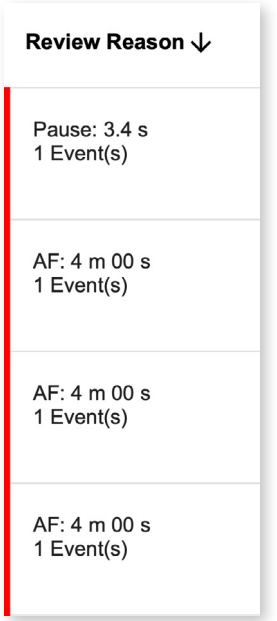


For full context, follow along with LATITUDE Clarity™.

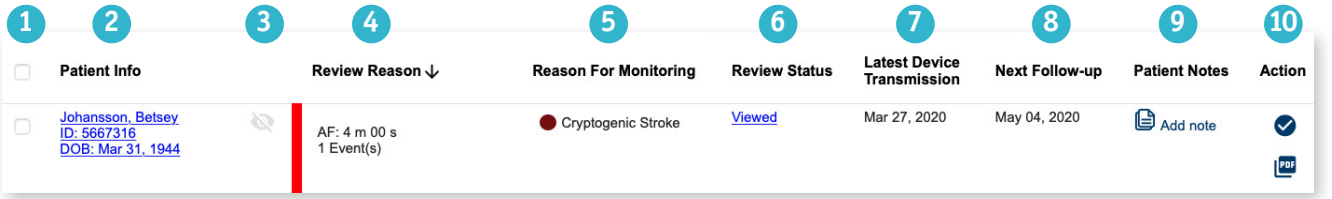
3 **Watch List Icon:** This column will indicate if a particular patient is currently assigned to the Watch List. The Watch List icon will appear filled in next to the patient's name if they are currently on the Watch List. If the patient is not on the Watch List, the icon will appear gray with a slash through it.

4 **Review Reason:** This column summarizes much of the critical information you may be looking for to begin your review or prioritize your day. Five categories of information will be summarized in this column.

Vertical Colored Bar (either red or yellow): This bar will appear when there is at least one undismissed red or yellow alert for review.



workflow tip: With the exception of the check box column, each column can be **sorted** by clicking on the column header. When the column header is clicked, an arrow will appear to indicate how the column is being sorted.



4

Review Reason (continued):

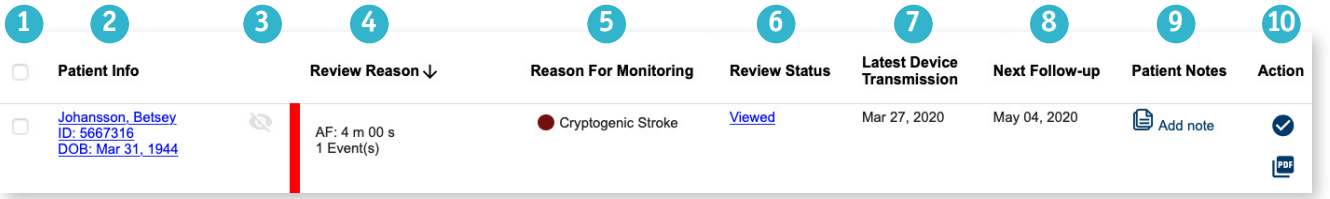
- If more than one alert condition is met, the colored bar will indicate the more severe condition that was met.
- Data may appear on this list that doesn't include a colored bar. This means there is new data for review, but that data doesn't have an alert associated with it.
  - ***Example:*** A manual transmission or clinic interrogation may appear on this list, but there is not a red or yellow alert associated with it.

Type of Interrogation: This column will display the type of interrogation associated with the data available for review. If interrogation is due to an alert only, you will not see an interrogation type listed here.

See the Interrogation Table for more information on each type of interrogation.

Go to: *Additional Resources > Interrogation Chart*

Highest-Priority Alert: This column will display highest-priority event and/or non-event alerts.



4 **Review Reason (continued):**

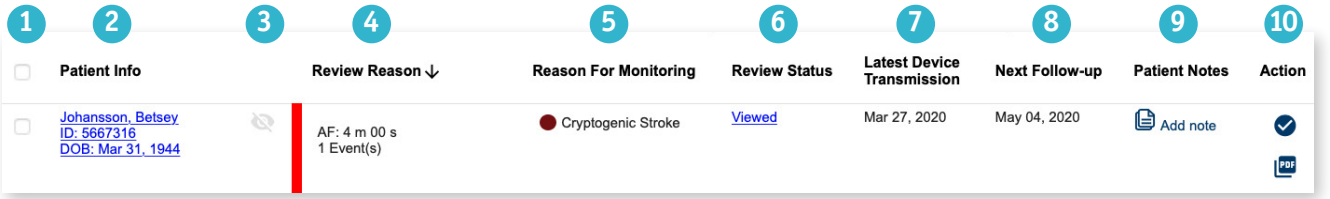
Number of Undismissed Events: This is a simple count of events for review that have not yet been dismissed.

Symptoms: This line will note if any of the undismissed events have been correlated with patient-recorded symptoms. Symptoms will not be described on this line, but a note will appear that says "incl. detected w/ symptoms." Symptom detail will be available once you click on an individual patient to review their data.

5 **Reason for Monitoring:** This column displays a patient's currently selected Reason for Monitoring. Reasons for Monitoring are color coded throughout the entire LATITUDE Clarity™ site and patient reports, for easy identification.

6 **Review Status:** This column displays whether data has been viewed. If someone has either viewed the data or generated reports, the status will read "Viewed." By clicking the link in this column, you can view the user review history right from a pop-up window on this page to track user activity.

note: "Viewed" data does not mean the alert has been dismissed. If no one has viewed the data, this column will say "New Data."



7 **Latest Device Transmission:** This column displays the date of the last full interrogation collected from the patient's device.

8 **Next Follow-Up:** This column displays the date of the patient's next scheduled remote follow-up. This can be modified.

9 **Patient Notes:** This column is a place for users to view, add, or edit notes on a patient.

> ***workflow tip:*** To delete a note, click on the note, select all text, then delete and save.

10 **Action:** This column will display two available actions the user can select.

- ***Dismiss:*** Dismisses data that was new and for review.
- ***Reports Menu:*** Generates a pop-up window with a Reports Menu where you can select which data you'd like to export to a PDF report.

Not Monitored Filter

For full context, follow along with LATITUDE Clarity™.

Patients that appear within this filter are not currently being monitored for one of the following reasons:

- Patient Has Been Transferred
- LUX-Dx Device Not Connecting
- LUX-Dx Device Not Set Up
- Monitoring Is Disabled due to:
  - ✓ Battery at End of Service
  - ✓ Incomplete Device Firmware Upgrade
  - ✓ Possible Device Malfunction
- Patient Monitor (myLUX™ Patient App) Not Connecting
- Patient Monitor (myLUX Patient App) Not Set Up

By default, patients will be listed in order of when Not Monitored was determined, with the most recent listed first.

workflow tip: You can use the **Monitoring Status/Date** column to find more information about what a connection issue might be. Click on the link provided in this column to investigate the issue further. The system will attempt to identify the issue in this pop-up window. One common issue you may see is "Patient Monitor Not Connecting." This could mean a patient's mobile device isn't on, charged, or connected to a Wi-Fi or cellular network.

See more information on how to modify when patients are added to the Not Monitored list.

Go to: *Prepare Clinic > Setting Up and Configuring the LATITUDE Clarity System > Connection Status Notification*

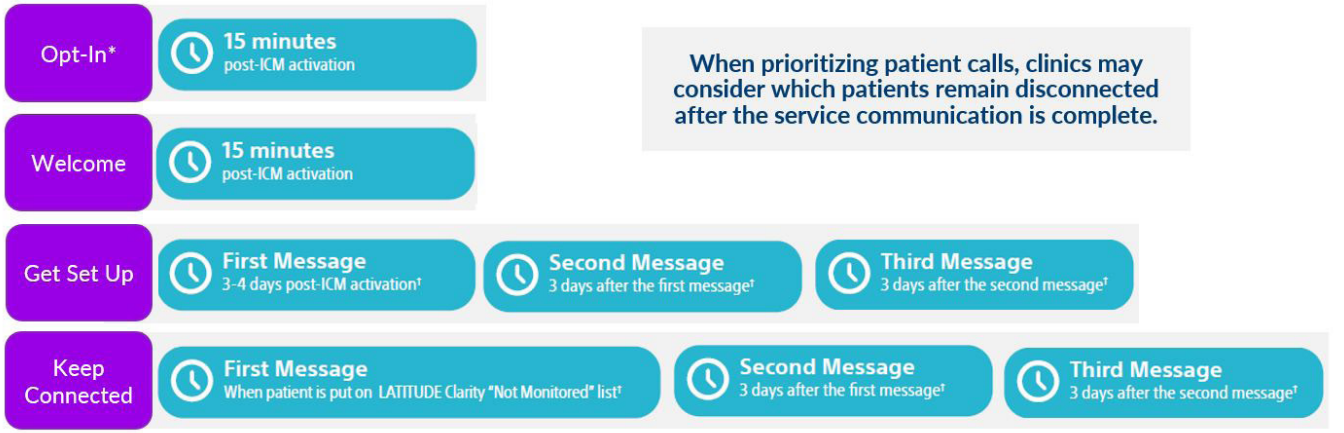
Not Monitored Filter (continued)

workflow tip: **Not Monitored List and RhythmCARE Assist communication**

1. **Get Set-up:** For patients who signed up for the RhythmCARE Assist service but have not yet downloaded and set up the myLUX patient app, get set-up messages will send out to help them set up the app. The service will conclude its communication 9-10 business days after the patient appears on the LATITUDE Clarity Not Monitored list.
2. **Keep Connected:** RhythmCARE Assist patients will also receive Keep Connected messages when they become not monitored at any point during their patient journey. The messages provide step by step instructions to help them resolve connectivity issues. The service will conclude its communication 6 business days after the patient appears on the LATITUDE Clarity Not Monitored list.

note: If the scheduled communication day falls on a weekend, it will go out on Monday.

Once the patient has downloaded the myLUX™ app, the communication messages will be sent using the timing below.



When prioritizing patient calls, clinics may consider which patients remain disconnected after the service communication is complete.

† Messages cease if the patient sets up their app, resolves their connection issue or opts out of communications. If the scheduled communication day falls on a weekend, it will go out on Monday.
Note: Patients may call Boston Scientific RhythmCARE Patient Services for live assistance. Patients may unsubscribe at any point which would cease any automated messaging.

Want to learn more about what is included in the RhythmCARE Assist Service?

Go to: *RhythmCARE Assist Clinician Brochure (CRM-1634701-AA)*

Watch List Filter

The Watch List is a custom list of patients the clinic determines need to be watched more closely. Use of this list is entirely optional, and criteria for placing patients on this list is defined by each clinic or user.

For full context, follow along with LATITUDE Clarity™.

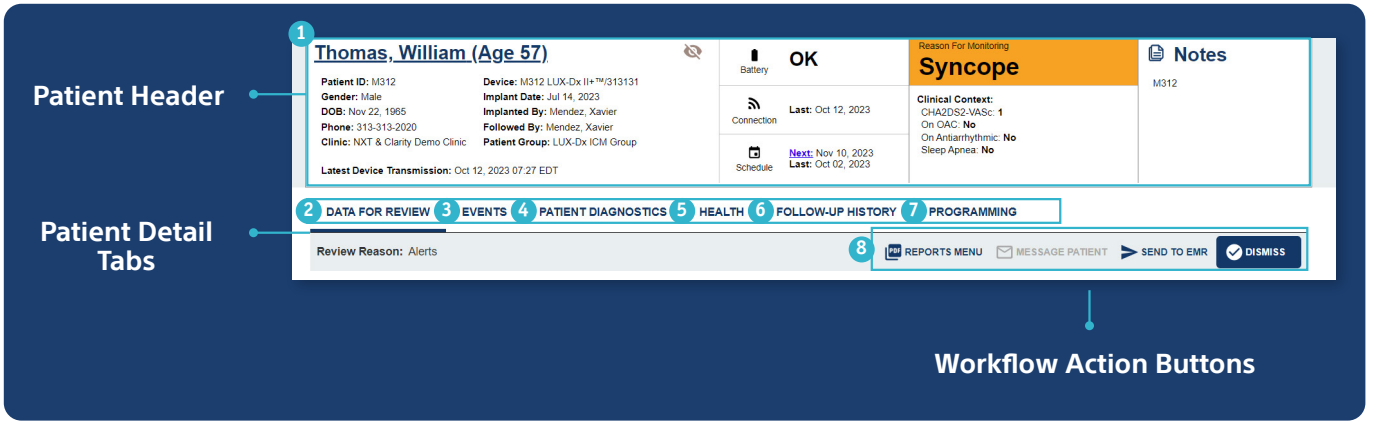
Within the same clinic, all users will be able to see which patients are on the Watch List. Users with CAM or Limited access will be able to modify the Watch List, and users with Read Only access will not be able to modify this list. When on the Watch List, patients will be listed in order of new alert severity as the default, but columns can be sorted by clicking on the column header. The system does not notify a patient if they are added to the Watch List.

To add or remove a patient from the Watch List, click the *Watch List* icon. The icon will become dark if the patient is on the Watch List. If the patient is not on the Watch List, the icon will appear gray with a slash through it.

Reviewing Individual Patient Data

To review a specific patient's data, simply click on their name in the Patient Info column from the Patient List page. Once you click on a patient's name, you will see the Patient Detail section.

There are three distinct subsections here you can use for your review:



For full context, follow along with LATITUDE Clarity™.

The following section will explain in depth each of these subsections, including what information is included and how you might use each subsection in your review. It will also highlight areas in which you might consider adjustments based on workflow.

Use this menu to skip ahead to a specific tab.

1 Patient Header

2 Data for Review

3 Events

4 Patient Diagnostics

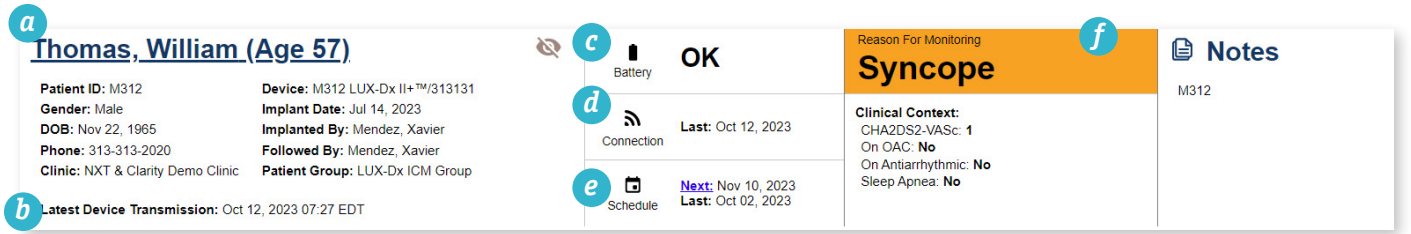
5 Health

6 Follow-Up History

7 Programming

8 Workflow Action Buttons

Patient Header: *Summary of Patient and Device Information*



For full context, follow along with LATITUDE Clarity™.

The Patient Header is the top section of a Patient Detail section. This header will stay visible regardless of which Patient Detail tab you navigate to in your review. This header will also appear on the first page of exported reports.

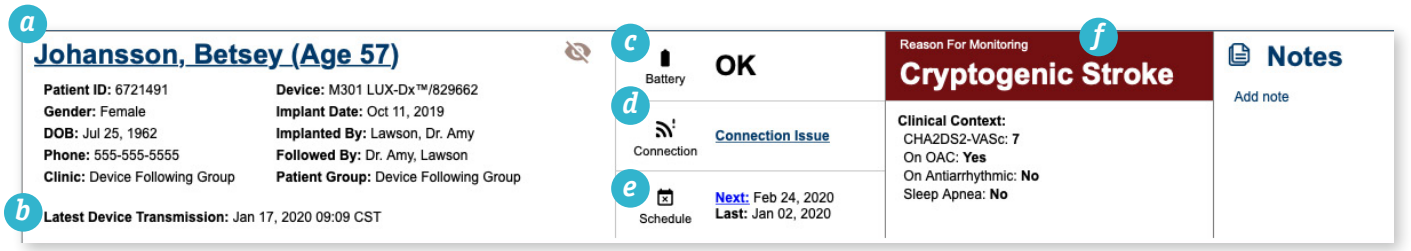
Much of the information included in the Patient Header is pulled directly from information entered into the Enrollment form. Patient information can be edited by clicking the patient's name in the Patient Header.

The following information will be displayed in the Patient Header:

a **Patient Name and Summary of Patient Information:** This section includes patient personal information and information about their insertion, device, and care team.

- This section is where you will find the patient's assigned Patient Group.
- If a patient is on the Watch List, you will see the Watch List icon highlighted here.

b **Latest Device Transmission:** Clearly displays the date of the last full interrogation collected from the patient's device.



Battery, Connection, and Scheduling Information: In the middle section of the Patient Header, you will find information about battery and connection status of the device as well as the patient's follow-up schedule.

c **Battery:** A visual indicator of battery status. Options will include:

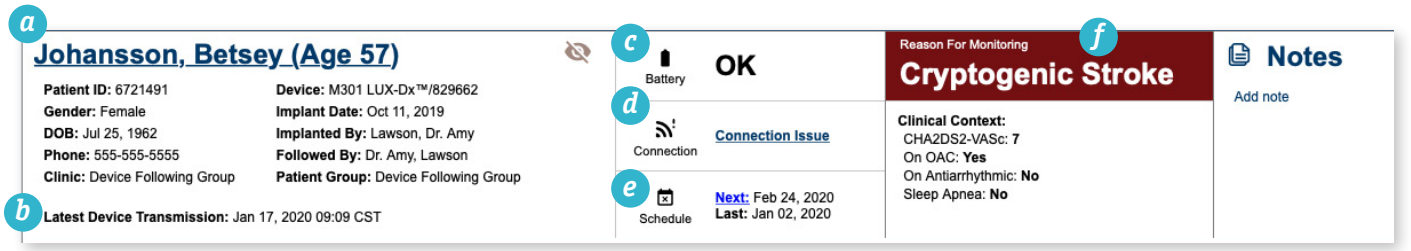
- Battery is OK
- RRT (recommended replacement time) with a date that indicates a 30-day window for replacement
- EOS (end of service) with a date this occurred

d **Connection:** Indicates if the patient is Monitored or Not Monitored.

- If the patient is Monitored, this section will provide the date of last connection to the patient's device.
- If the patient is Not Monitored, you will see a link. You can click on this to view a pop-up window that lists the most likely issue and troubleshooting help.

e **Schedule:** Displays dates for the last and next scheduled follow-ups. You can adjust scheduling right from this section by clicking the *Next* link and selecting a date from the calendar.

workflow tip: You can change a patient's follow-up schedule using the calendar option here or from the Programming tab.



f

Reason for Monitoring: Displays the current Reason for Monitoring selected for this patient.

- In this section, you will also see an area called Clinical Context. This section is optional but can include a patient's CHA2DS2-VASc score, oral anticoagulant and antiarrhythmic history, and sleep apnea diagnosis.

workflow tip: Clinical context information can be entered during enrollment or changed by clicking on the patient's name in the Patient Header. Information entered into Clinical Context will appear on the first page of PDF reports.

note: In the Patient Header, you will be able to add, view, edit, or delete notes about a patient. These notes are visible from the Patient Header and For Review sections of the Patient List page.

- These notes do not show up on exported reports or in your EMR system.

Patient Detail Tabs

Below the Patient Header, all patient data is organized by a series of Patient Detail tabs to help organize data review workflows. This section will explain each tab in detail.

For full context, follow along with LATITUDE Clarity™.

Data for Review: Primary page you will use to review *new* data that has not yet been dismissed or assessed

Events: List of all events captured by the device

Patient Diagnostics: Up-to-date histograms, counters, and settings

Health: Detail on atrial fibrillation and other rate trends

Follow-Up History: List of past interrogations

Programming: Section to view and modify detection parameters, symptom configuration, and alert settings

Data for Review Tab: *New Data Available for Review*

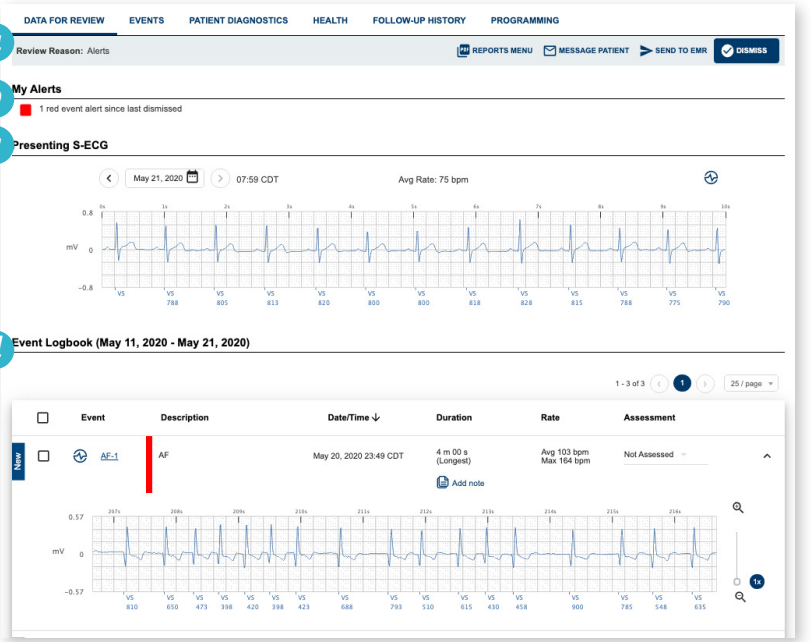
You can use the Data for Review tab for much of your review of new patient data. This tab summarizes information from multiple other tabs but summarizes the information you need on new events specifically. **As you scroll through the page from top to bottom, you will see the following information:**

Review Reason (a)

My Alerts (b)

Presenting S-ECG (c)

Event Logbook (d)



For full context, follow along with LATITUDE Clarity™.

Find these farther down the page:

Counters & Settings (e)

AF Overview (f)

PVC Burden (g)

a **Review Reason:** This section will display one or more interrogation types related to why there is new data for review.

See the Interrogation Table for more information on each type of interrogation.

Go to: *Additional Resources > Interrogation Chart*

b **My Alerts:** This section will display a few pieces of information depending on what data is available for review.

Events: Displays the number of new red or yellow alerts since you last dismissed data for this patient.

Burden: If you have chosen to be alerted for burden and there is an event beyond the configured threshold, that will be marked here.

System: Any system alerts you've configured will appear here.

c **Presenting S-ECG:** This section displays the patient's most recent 10-second presenting S-ECG.

- The presenting S-ECG is automatically captured each day and is unrelated to a specific event. The date and time it was collected and average heart rate will be displayed above the S-ECG. You can use the calendar icon to view presenting S-ECGs recorded on previous days.
- For more detail, you can click the rhythm icon to view the S-ECG more closely or generate a presenting S-ECG report.

d **Event Logbook:** This section will display the events available for review that occurred during the timeframe shown next to the Event Logbook title. Event types will include:

- All undismissed events
- Previously dismissed events *if* a scheduled follow-up is undismissed

For more information on how to review event details in the Event Logbook, see the next page.

e **Counters & Settings:** This section will display a summary of recent, previous, and lifetime counters and settings for each type of event. It will also display a Programming Summary of the device settings at the time of the last interrogation.

For more information on this section, see the Patient Diagnostics tab.

Navigate below to: *4: Patient Diagnostics*

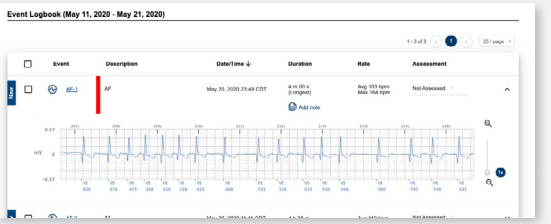
f **AF Overview:** This section will display a summary of trends related to atrial fibrillation events such as Burden and V Rate during AF.

g **PVC Burden Overview:** This section will display a summary of trends related to PVC Burden.

For more information on AF or PVC Overview, see the Health tab.

Navigate below to: *5: Health*

Data for Review Event Logbook: *All new events*



Using the Data for Review tab, you will be able to view the Event Logbook and Event Details directly from this summary page rather than navigating to multiple pages to gather the data you need.

As you are reviewing the Event Logbook on the Data for Review tab, there are a few things to note:

- Some Event Details will already be expanded to display an S-ECG. The system will automatically expand the events deemed most severe by the system:
  - Pause: longest
  - Tachy: highest average rate
  - AT: no special criteria
  - Brady: lowest average rate
  - Symptom: no special criteria
- If you wish to expand and contract events in the Event Logbook, use the arrows on the far right of each event to expand and contract event details.
- When events are expanded, you will be able to zoom in on S-ECGs. To zoom in on an S-ECG, click the corresponding magnification/zoom icon on the far right of the S-ECG strip.

For full context, follow along with LATITUDE Clarity™.

The Event Logbook contains the following columns:

a **New Flag:** Events that have not yet been dismissed and assessed will appear with a blue "New" flag on the left.

b **Event:** Lists events available for review. Events that include S-ECG data will display an image next to the Event Identifier.

c **Description:** This column may include a colored bar to indicate a red or yellow alert, and it will note the Event or Alert type (e.g., AF or Symptom).

d **Date/Time:** This column lists the date and time of the *start* of the event available for review.

e **Duration:** This column lists the duration of the events. You may see notes like "longest" below the duration. This descriptor will be listed for the most severe event within a set of new data for review.

f **Rate:** This column lists the average and maximum or minimum heart rate during the event timeframe.

g **Assessment:** This column presents a drop-down list of choices to assess each event.

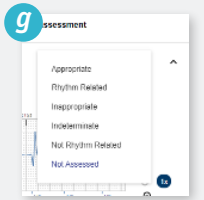
h **Zoom:** Use the magnification/zoom icon on the right side of an S-ECG to zoom in or out on the S-ECG.

i **Arrows:** Arrows on the far right of the Event Logbook can be used to expand or hide further Event Detail.

note: Each event displayed in LATITUDE Clarity™ is assigned an Event Identifier that is presented in the form of a link. The ID consists of an acronym for the event type and a number that indicates a lifetime event count for that patient.

For example: AF-11 means the event detected is atrial fibrillation and this is the 11th AF event recorded by the device for this patient.

note: Assessment options will include options titled Rhythm Related and Not Rhythm Related. These options can be useful when assessing symptom events. Assessing events can help with documentation across clinic users and serve as a reference when reviewing data.



Event Detail

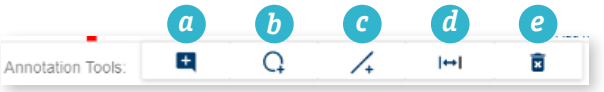
As you are reviewing events in the Event Logbook, you may see an S-ECG symbol, which means you can click on this event to view additional event detail. Clicking will generate an Event Detail pop-up window that will include the same event summary included in the expanded Event Logbook plus some additional information.

note: Event Detail pop-up windows are available only for events that have an S-ECG available.

S-ECG symbol

For full context, follow along with LATITUDE Clarity™.

Annotation Tools:



For full context, follow along with LATITUDE Clarity™.

These are tools that can help with your data review, collaboration with your team, reporting, and documentation. The tools available include:

- **a** ***Text/Note:*** Add a note anywhere on the S-ECG to yourself or your team.
- **b** ***Circle:*** Circle any area of interest on the S-ECG.
- **c** ***Line:*** Add a vertical line as a marker anywhere on the S-ECG.
- **d** ***Calipers:*** Expand and measure time in milliseconds (ms) as you move across the S-ECG.
- **e** ***Trash:*** Use this tool to delete an existing annotation.

workflow tips for using annotation tools:

- After selecting a tool, you will need to **click and drag** it on top of the S-ECG strip to expand the tool to where you want it.
- After you have finished making a note, circle, etc., you can click again directly on the mark and drag it around the S-ECG.
- If you choose *Save Annotations and Close*, your annotations will appear on the report.
- To delete an annotation, click once on the annotation to select it. You will see a dashed outline; then click the trash icon.

Sweep Speed

- The sweep speed of the S-ECG will display 25 mm/s; however, you can use the options listed above the S-ECG to adjust the sweep speed while reviewing. Options include:
  - 10 mm/s
  - 25 mm/s (default)
  - 50 mm/s
  - 100 mm/s

Event S-ECG

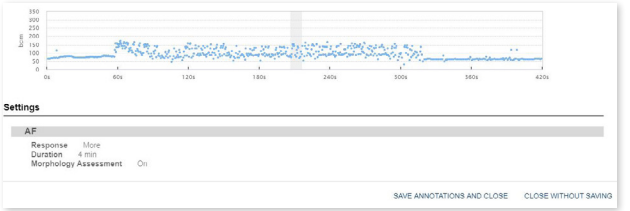
- The S-ECG will automatically display the most relevant portion of the S-ECG based on event type. You can use the scroll bar at the base of the S-ECG to move backward or forward in time from this point. The S-ECG will move with your adjustment.
- Event time in seconds will be displayed at the top of the S-ECG.
- Amplitude in mV will be displayed on the left side of the S-ECG. Amplitude markers will automatically adjust when you click the magnification/zoom icon.
- Relevant markers for the rhythm and event will be displayed at the bottom of the S-ECG.

For more information on markers, see the chart in the appendix.

Go to: *Additional Resources > S-ECG Markers Chart*

- Use the magnification/zoom icon on the right side of an S-ECG to zoom in or out on it.
- The total amount of time displayed in the S-ECG will vary by event type.

Rate Plot



For full context, follow along with LATITUDE Clarity™.

- This displays a rate plot to help with your review of the event.
- As you adjust the scroll bar of the S-ECG, a gray bar on the rate plot will indicate the corresponding point in time displayed on the S-ECG.

Settings

- Current detection parameters will be displayed at the bottom of the Event Detail window.

Options to Save Annotations and Close or Close Without Saving

- If you want any of your magnifications or annotations to appear in the system for other users or on reports, you must click *Save Annotations and Close*.
- If you want to leave Event Detail blank after your review, click *Close without Saving*.

Event Detail Report

By selecting this option in the upper-right corner of the pop-up window, you can generate a PDF report of this specific event and its full corresponding S-ECG data.

EVENT DETAIL REPORT

Events Tab: *Events Captured by the Device*

The Events tab in the Patient Detail section will display all events captured by the device (new and dismissed).

The Events tab has two main sections:

Presenting S-ECG

Event Logbook

The information for the Presenting S-ECG and the Event Logbook follows the same structure described in the Data for Review Tab section (#2 below).

A few reminders about the Event Logbook on this tab:

- It lists all events collected by the device.
- It shows "New" flags for any events not yet dismissed and assessed.
- It has the same sorting capabilities, accessed by clicking on each column header.
- It displays an icon when an event includes S-ECG data.
- It generates Event Detail pop-up windows for events that contain an S-ECG.
- It may contain multiple pages. You can browse pages using the page list at the bottom of the Event Logbook. You can also adjust how many events are shown per page using the drop-down menu.

Patient Diagnostics Tab: *Counters, Settings, and Histograms*

The Patient Diagnostics tab will provide a working view of Counters, Settings, and Histograms.

Counters and Settings

The Counters and Settings section gives you a look at the Recent, Previous, and Lifetime historical count for each type of event.

Each column of the Counters and Settings section indicates a timeframe for the data displayed below the column header that corresponds to configured follow-up settings.

The date listed under the Programming Summary indicates the date of the last full interrogation that corresponds to the device programming settings listed in the table.

note: Recent counters will be reset when configured scheduled follow-ups occur.

Counters and Settings

	Recent Apr 25, 2020 - May 05, 2020 *11 day(s)*	Previous Feb 25, 2020 - Apr 25, 2020 *61 day(s)*	Lifetime Feb 25, 2020 - May 05, 2020 *71 day(s)*	Programming Summary May 05, 2020
Symptom (Total)	1	0	1	4 (7.5 min/event)
Tachy	0	0	0	≥ 170 bpm, > 5 s
Pause	0	0	0	≥ 3 s
Brady	0	0	0	< 40 bpm, > 1 s
AT	2	0	2	≥ 110 bpm, ≥ 4 hrs
AF	1	0	1	≥ 4 min
Sensing Parameters				Sensitivity: 0.037 mV Blank After Sense: 300 ms

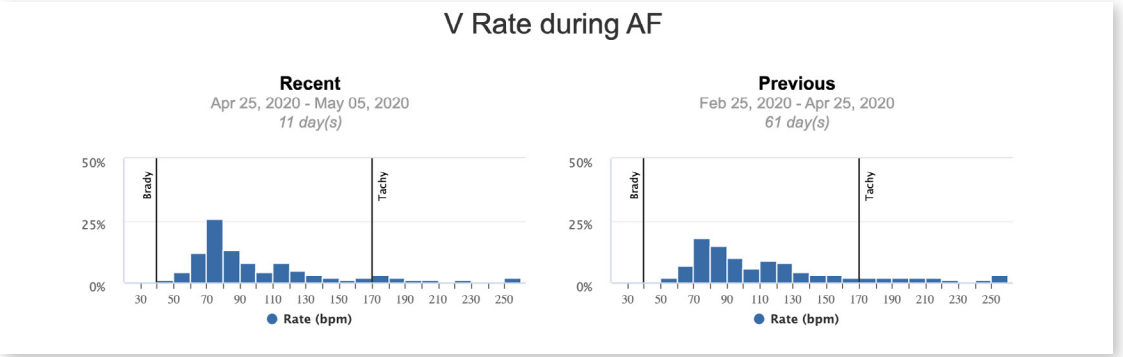
For full context, follow along with LATITUDE Clarity™.

Histograms

Histogram charts will display heartbeats sensed at different rates from the current, and previous, follow-up period for both V Rate and V Rate during AF. There are four charts in total.

A few things to note about histograms in this section:

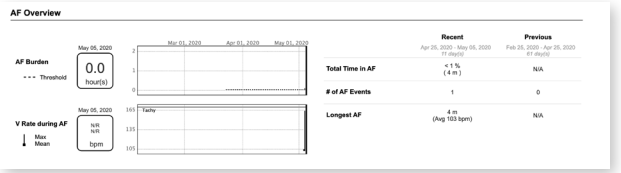
- All four histograms show the rate distribution of ventricular events as the percentage of the total number of events in the follow-up period.
  - On the V Rate during AF chart, only beats during device-detected AF are considered.
- Each histogram shows 22 rate ranges that are 10 bpm wide.
- Rates slower than 30 bpm or faster than 250 bpm are included in range sections on either side of the histogram.



For full context, follow along with LATITUDE Clarity™.

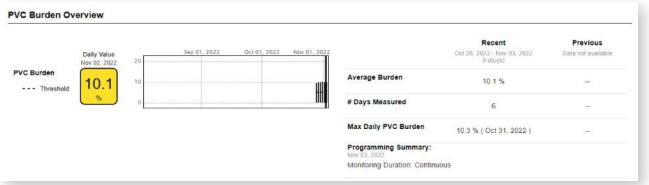
Health Tab: *Details About AF, PVC Burden Trends, and Heart Rate*

The Health tab gives you a more detailed look at a patient's AF information as well as their heart rate and burden trends. On this tab, you will find an AF Overview section and a Trends section.



For full context, follow along with LATITUDE Clarity™.

workflow tip: Hover your cursor over charts on the Health tab to view information on a given day or about an individual data point.



AF Overview

This section will show you key details about AF Burden and V Rate during AF, as well as an AF Summary.

AF Burden: The system measures AF burden by assessing each 2-minute window that is determined to be AF and adding it to the AF burden for that day.

- The system displays the AF burden threshold (if configured) for this patient as well as the AF burden in hours as of the date of the latest full interrogation. The chart displayed will plot the total time in AF and the burden threshold for each point.

PVC Burden Overview (M302 and M312 only):

This section will show you key details about PVC Burden, as well as a Summary.

PVC Burden: The system measures PVC burden as the number of detected PVCs out of the total number of detected ventricular beats for each 24-hour period.

- When the PVC Burden is enabled, the system will display a trend of the patient's daily PVC burden values. Additionally, information on the patient's PVC burden percentage on a given day, the average PVC burden over the number of days measured, max daily PVC burden during measured days, and the PVC burden programming summary will be displayed.

V Rate during AF: The system shows a trend of the patient's maximum and mean or average V Rate during AF episodes.

AF Summary: To the right of the charts is an AF Overview section. This table summarizes Total Time in AF, Number of AF Events, and Longest AF for recent and previous timeframes.

PVC Burden Summary: To the right of the charts is an PVC Burden Overview section. This table summarizes Average Burden, Number of Days Measured, Max Daily PVC Burden and a Programming Summary.

Trends

Trends are listed below the PVC Burden Overview and will provide a graphical view of specific patient and device data. This data can be useful when evaluating a patient's condition and the effectiveness of programmed parameters. This data is typically reported every 24 hours, and the system will display historical data for up to one year.

At the top of the Trends section are view buttons that allow you to adjust your view to see trends over the previous 1 month, 3 months, 6 months, and 1 year. With one click, these buttons will adjust the time frame. You can also use the scroll bar to navigate to a certain point in time based on the calendar displayed.

These trends are updated as of the last full interrogation with the ICM:

Night Heart Rate: The patient's average heart rate (bpm) between midnight and 6 a.m.

Day Heart Rate: The patient's average heart rate (bpm) for 24 hours.

AF Burden: The patient's total time (in hours) in AF each day.

V Rate during AF: The patient's maximum and mean or average V Rates during AF episodes in a given day.

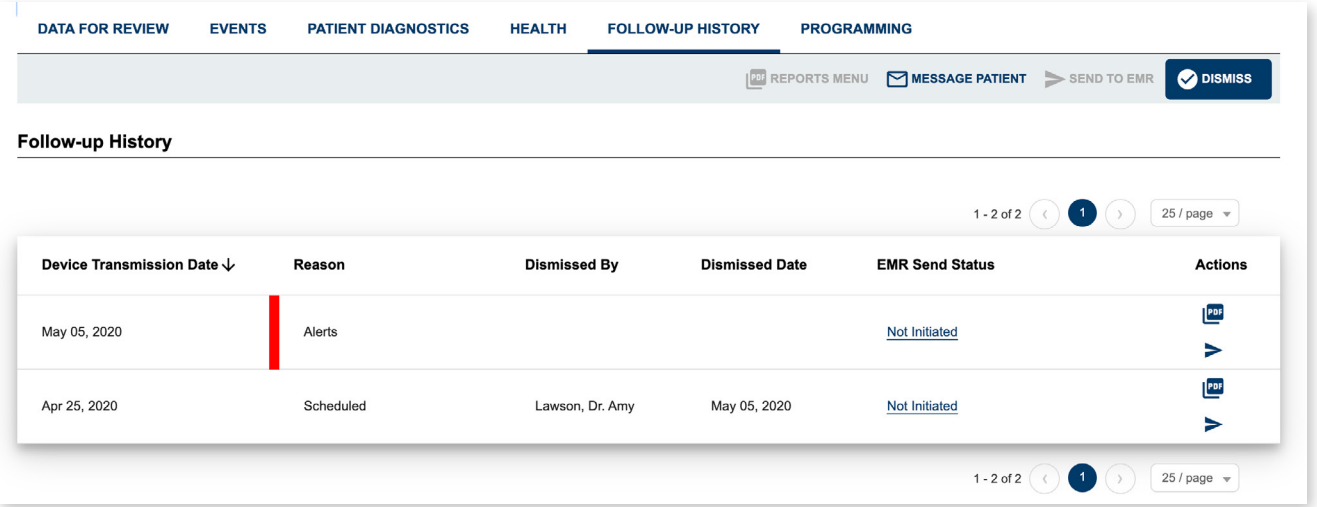
PVC Burden (M302/M312): The patient's PVC Burden percentage for each 24-hour period measured.

note: All heart rate trends in this section contain two lines: one for the daily average and one for the 3-day average.

Follow-Up History Tab: *List of Past Interrogations*

This tab displays a record of past interrogations (of all types) for the device. With each record on this page, you will see a transmission date, a reason (alert, scheduled, etc.), which user dismissed the data, the date the data was dismissed, and whether data was already sent to the EMR system. You will be able to generate a report for each listed follow-up.

workflow tip: If you need to check on the EMR send status, click the status link to display a pop-up window with EMR transfer history for that patient.



For full context, follow along with LATITUDE Clarity™.

1 Patient Header | 2 Data for Review | 3 Events | 4 Patient Diagnostics | 5 Health | **6 Follow-Up History** | 7 Programming | 8 Workflow Action Buttons

Programming Tab: *Modify Reason for Monitoring, Detection Parameters, and Alerts*

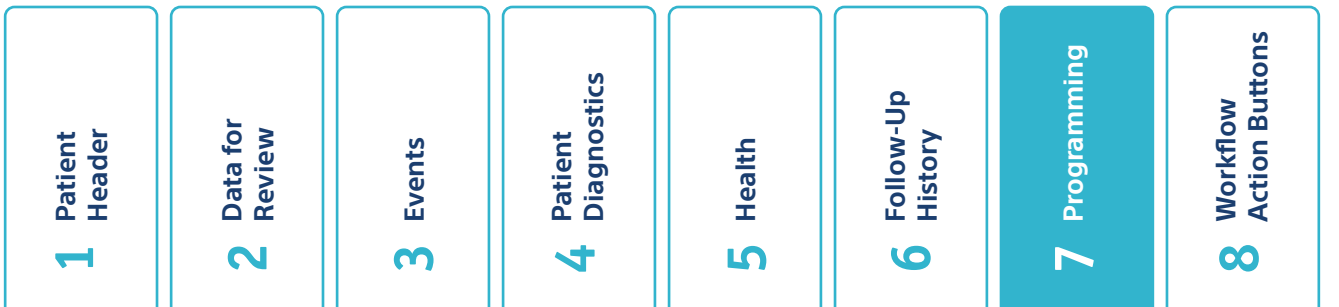
The Programming tab is where you can view or modify a patient's Reason for Monitoring as well as adjust device parameters related to sensing, event detection, symptoms, and alerts, including:

- Reason for Monitoring
- Sensing parameters (Blank After Sense, Sensitivity, and Morphology)
- Brady
- Tachy
- Pause
- Symptom
- AT
- AF
- PVC Burden
- System alerts (Monitoring Disabled and Battery)
- Magnet requirements
- Remote scheduled follow-ups
- Connection status notifications
- Patient-initiated interrogations

notes: To apply any change on this tab, you must scroll to the bottom of the page and click *Save* for changes to be saved. Changes will be applied to the patient's ICM at the next connection to their myLUX™ Patient App. This can take up to 36 hours depending on the schedule and connection status.

For more detailed information about adjusting these programming settings, please view the Adjusting Programming Settings section.

Go to: *Monitor & Manage Patient Data > Reviewing and Adjusting Programming Settings*



Workflow Action Buttons

When reviewing each tab of detailed individual patient information, you will see optional action buttons (located below the tabs) designed to help you with review workflow. These actions will be visible from most tabs within the Patient Detail section and will include:

For full context, follow along with LATITUDE Clarity™.

- **a** **Reports Menu:** Displays a menu from which one or more PDF reports can be generated
- **b** **Message Patient:** Generates two pre-written options for a one-way (read-only) message to be sent to the patient's myLUX™ Patient App
- **c** **Send to EMR:** Depending on configuration, sends discrete data as well as reports to EMR system
- **d** **Dismiss:** Clears all undismissed data and alerts for that patient

workflow tip: Reports Menu and Dismiss actions can be performed directly from the Patient List page as well as from this Patient Detail section.

note: The details of these options, as well as the implications of each action, are described in later sections about each action button.

Viewing Another Clinic's Patient

The Latitude Clarity Temporary Healthcare Provider Access allows health care clinicians read-only data access to another clinic's ICM patient for up to 24 hours.

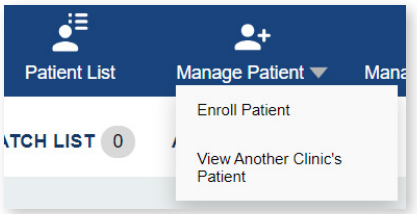
This observer access is meant for health care providers and allied health professionals who would like to review another clinic's ICM patient for clinic consultations, ER visits or hospital admissions.

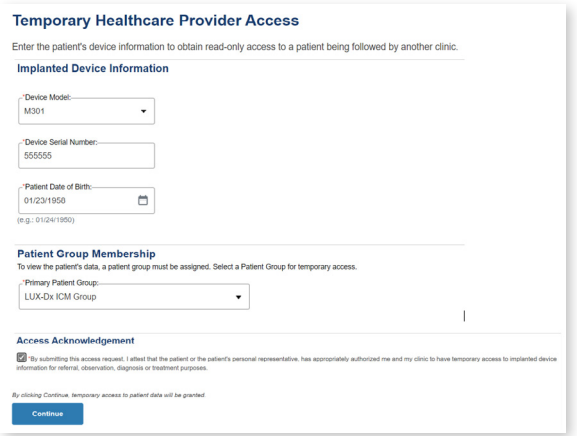
Clinicians will need:

- ☑ Any smart device (smartphone, tablet, laptop, or desktop) to visit LATITUDE Clarity™ website
- ☑ Access to secure Wi-Fi or cellular connection
- ☑ LATITUDE Clarity account access (must have Limited Access or Complete Access)
- ☑ LATITUDE Clarity website login and password
- ☑ LUX-Dx™ Clinic Assistant with magnet or the patient's own myLUX™ Patient App with magnet
- ☑ Patient ICM device model number, serial number and date of birth
  - Patients must be currently enrolled in LATITUDE Clarity and under the care of a primary physician with a device that is already set up

Device Interrogation: Clinicians can either use the LUX-Dx Clinic Assistant and magnet to interrogate the ICM device, or have the patient do a manual transmission on the myLUX™ Patient App. This step is recommended to get the latest transmission data.

Data Access: To view the data transmission, log in to the LATITUDE Clarity website. Select "Manage Patient" > "View Another Clinic's Patient" and input the patient's ICM Device Model number, Device Serial Number, and Patient Date of Birth to find the patient.





Review information:

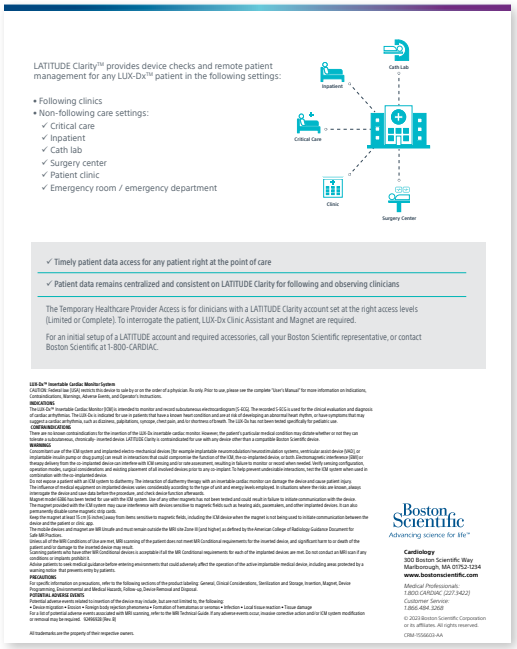
The patient data is now ready for the read-only review. This includes latest transmission, event history, trends, and counters.

- Patient will be available on the All Patients list and not on For Review
- Monitoring Status will be "Observing Only"
- Changes to schedule, alerts and programming are not available

End Access: The temporary observer data access to this patient will automatically expire after 24 hours; observing clinicians will no longer see this patient shown on their patient list.

- ☑ Timely patient data access for any patient right at the point of care
- ☑ Patient data remains centralized and consistent on LATITUDE Clarity for following and observing clinics

note: If the patient will be followed permanently at this clinic, the patient may be transferred instead of using this temporary access.



Reporting

In LATITUDE Clarity™ you can generate PDF reports of an individual patient's data or for a group of patients.

You can also send reports to your EMR system, if configured.

See more information on sending reportings to your EMR.

Go to: *Monitor & Manage Patient Data > Sending Information to EMR Systems*

In this section, you can review the types of reports you will have access to, report configuration options, and the various ways to generate reports throughout your review workflow.

ALL REPORTS IN LATITUDE CLARITY, REGARDLESS OF TYPE, INCLUDE:

- ✓ Patient Header (page 1 only)
  - Patient Name, ID (if complete), Date of Birth, and Reason for Monitoring are included at the top of every subsequent page
- ✓ Report Creation Date (all pages)
- ✓ Space for Reviewer Comments, Signature, and Date (page 1 only)

In addition to this standard information, the table on the next page shows which information will be included by report type and the configuration options you will have for each.

REPORT NAME	CONTENTS	CONFIGURATION OPTIONS
Follow-Up Report	Alerts, Presenting S-ECG, Event List, Counters & Settings, and AF Overview	Event List Timeframe, Trends & Histograms
Event Detail Report	Event Details for each event manually selected from Event Logbook	Must first manually select events to include from Event Logbook
Most Recent Presenting S-ECG Report	Only most recent Presenting S-ECG	N/A
Programming Report	Latest Device Programming, Alert Configuration, System Configuration (Symptoms & Connection Notification)	N/A

Generating Reports:

Once you have reviewed a patient's data, you can navigate to three different locations on the site to generate a report.

Patient List: From the For Review section, you can click the PDF icon under the Action column on the far right of the page.

Patient Detail: Reports Menu is one of the Workflow Action buttons you will see on each tab of a Patient's Detail section.

When you select either of these options, the system will generate a Reports Menu pop-up window.

Follow-Up History: From this tab, you will be able to generate a PDF report of each follow-up listed.

workflow tip: If you are trying to generate reports for more than one patient at a time, you must select multiple patients from the Patient List page before selecting Reports Menu.

When you see the Reports Menu pop-up window, the Follow-Up Report may be auto-selected. This is meant to help with workflow by pre-selecting information that captures new events from the Data for Review section.

From this window, you can select all the other information you wish to configure for your reports, including the timeframe of the report. To do this, use the drop-down menu to choose an Event Timeframe of either *Since Last Dismissed* or *Since Last Scheduled*.

Once your selections are made, click *Generate Report(s)*. This will open a PDF file in a new window/tab of your browser.

View a sample report from LATITUDE Clarity™

Go to: *Additional Resources* > *Sample Report*

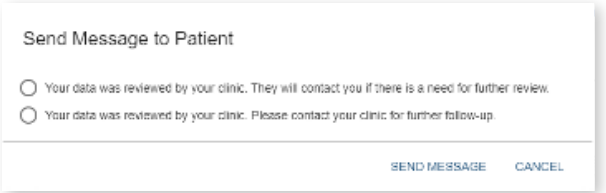
note: If you wish to include the Event Detail Report in the PDF file you generate, you must first select individual events from the Event Logbook for that patient and then select the Reports Menu option. The Event Detail Report check box will then be available to select.

For full context, follow along with LATITUDE Clarity.

Communicating with Patients

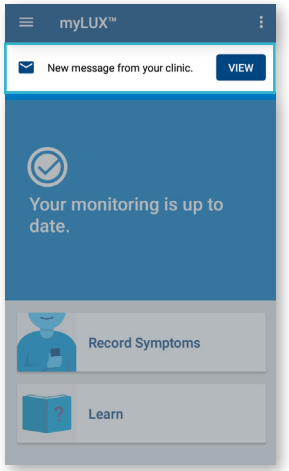
LATITUDE Clarity™ gives you the option to send a one-way (read-only) message to a patient's myLUX™ Patient App confirming your review.

To do this, you must be in the Patient Detail section of the site. Here you will see a workflow action button labeled *Message Patient*. When you click this option, you will then see two message options. Whichever option you select will be exactly what is sent and what the patient views on their app.



For full context, follow along with LATITUDE Clarity.

This is how the message notification will appear on the patient's app.



A few notes on this feature:

- This feature is entirely optional.
- If you have sent multiple messages to a patient's app that they haven't viewed, the most recent message will be what the patient sees when they finally open the message.
- At this time, messages cannot be customized.

Sending Information to EMR Systems

If your clinic has chosen to integrate LATITUDE Clarity™ with your EMR system, you will have options to send discrete data and reports directly to your EMR systems.

If LATITUDE Clarity is configured to export data manually to an EMR system, you can do this from the Patient Detail section by clicking *Send to EMR*. This action will send one or more interrogations (collections of events) to the configured EMR system. Each interrogation selected is sent as an individual record.

For more information on how to configure EMR options, view the Manage EMR Integration section.

Go to: *Prepare Clinic* > *Setting Up and Configuring the LATITUDE Clarity System* > *Manage EMR Integration*

workflow tip: If your clinic has configured EMR integration to send data "Upon Dismiss," you do not need to also use the *Send to EMR* button unless you want to send data to your EMR manually.

Dismissing Alerts Data

Once you are ready to dismiss the new data you've reviewed, you can do this from either the Patient List page or the Patient Detail section. When you select *Dismiss*, it clears all undismissed alerts for that patient.

The following will happen throughout the system when you select *Dismiss*:

- If your system is configured to send data to EMR "Upon Dismiss," it will send data to EMR as soon as you click *Dismiss*.
- The patient you dismissed will be removed from the For Review list until they have new data again for review.
- Alerts will be dismissed from the Data for Review page. Dismissed event data will still be available in the Events tab of a patient's profile.
- The Review Reason associated with the dismissed data will be cleared on the Data for Review tab in the Patient Detail section.
- The Event Logbook will be cleared on the Data for Review tab for that particular patient.
- A record of the dismissed date and the user who dismissed the alert will be recorded on the Follow-Up History tab.

Reviewing and Adjusting Programming Settings

Initial default programming and configuration values are supplied in LATITUDE Clarity™ based on the Reason for Monitoring. Programming is applied to the patient's ICM when it is paired with the myLUX™ Patient App.

Get a detailed view of Nominal Settings by Reason for Monitoring.

Go to: *Additional Resources* > *Alert Nominals Chart*

While detection parameters are selected by Reason for Monitoring, LATITUDE Clarity also allows clinicians to adjust parameters remotely from the website at any time without bringing patients back in for an appointment.

Adjustments in LATITUDE Clarity are flexible in the following ways:

- Changes can be made for a Patient Group (multiple patients at once with the same Reason for Monitoring)
- Changes can be made at the individual patient level (one patient at a time)
- Changes can be made at any time in your workflow

Once changes are made and saved, they will be applied to a patient's device at the next connection with the ICM; this typically happens within 36 hours.

note: If you would like changes to be applied at a certain time, you can call the patient and ask them to perform a connection check, followed by a manual transmission, and attempt to update programming settings that way.

Each clinic will have its own reasons for making programming adjustments. Here is a list of scenarios in which it might make sense to review detection parameters closely and consider adjustments:

- ✓ A patient's Reason for Monitoring has changed (example: Suspected AF to AF Management).
- ✓ The alerts you are receiving are not the types of alerts or events that require review for that patient's Reason for Monitoring.
- ✓ You are receiving more alerts than you would like to, and it is clinically acceptable for your team to see different information that could reduce the burden of alerts.
- ✓ You only want to track changes in AF burden.
- ✓ You no longer need to detect, or be alerted for, a certain type of event.
- ✓ Your clinic has decided to adjust protocols (and therefore detection parameters) for all patients within a certain Reason for Monitoring (example: duration for all AF detection moves from 2 minutes to 4 minutes).
- ✓ You would like to turn off symptom tracking for a patient.

This section will give you a working knowledge of all the available options to adjust programming as well as the instruction you will need to make and save changes.

As a reminder, a chart of nominal settings is available in the appendix that you may find helpful to print and use at your workstation.

Get a detailed view of Nominal Settings by Reason for Monitoring.

Go to: *Additional Resources* > *Alert Nominals Chart*

Device Programming and Alert Configuration

Whether you are making changes to an entire Patient Group or an individual patient, you will see the same options in the Device Programming and Alert Configuration section outlined here. **This section will focus on changes at the individual patient level.**

For more information about how to make changes for multiple patients within the same Reason for Monitoring, see the Prepare Clinic section.

Go to: *Prepare Clinic*

note: To change programming for an individual patient, navigate to the Programming tab within the Patient Detail section of the system.

Moving from top to bottom of the Programming page, you will have the following options:

Reason for Monitoring:

Definition: A designation given to each patient in LATITUDE Clarity™ upon which arrhythmia detection parameters are based.

Options:

- Syncope
- Palpitations
- Cryptogenic Stroke
- Suspected AF
- Post-AF Ablation
- AF Management
- Ventricular Tachycardia
- Other

Instructions: To change a patient's Reason for Monitoring:

1. Click the existing Reason for Monitoring visible on the Programming tab.
2. When the drop-down menu is displayed, select the new desired Reason for Monitoring from the list.
3. At the confirmation screen, click *Apply Changes*.

For full context, follow along with LATITUDE Clarity™.

View Programming Status:

Definition: A link to a pop-up window meant to provide a quick way to see a full list of current and pending programming settings. The Pending Delivery to Device column will display any adjustments that have been made and saved in LATITUDE Clarity but have not yet been applied to the patient's ICM. These changes will be applied at the next connection.

Options: N/A – This is a status update, not a programmable setting.

Use Patient Group Defaults Check Box:

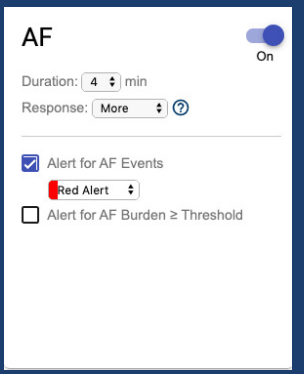
Definition: This box will determine whether the patient's ICM is inheriting settings from the broader Patient Group settings or if settings should be considered custom to this patient.

Options:

- **Checked** = Use Patient Group Defaults
- **Unchecked** = Do Not Use Patient Group Defaults

Instructions: Uncheck this box to make adjustments to an individual patient's ICM programming or alert configuration.

Key to symbols you will see on the Programming tab:



- A toggle switch for each arrhythmia event turns detection on or off. This switch will be in color when on and gray when off.
- Drop-down menus list options for programmable parameters.
- The Alert check box turns alerts on or off.
- Question marks – Click directly on a question mark to get more information about the parameter it is next to.

Sensing Parameters:

Definition: The ICM detects arrhythmias based on R-Wave sensing. Sensing parameters can be adjusted to fine-tune thresholds the device uses to sense R-Waves and therefore detect arrhythmias.

Options: Sensing parameters are always on but contain the following programmable options:

- **Blank After Sense (ms):** Programmable period of time the device ignores the signal after detecting an R-Wave and before looking at the signal for the next R-Wave.
- **Sensitivity (mV):** Program to the minimum R-Wave amplitude and to greater-than P-Wave amplitude.
- **Morphology:** An assessment of R-Waves used as an additional screening tool to confirm arrhythmias. Can be programmed on or off.

  WHEN ON:
  - For AF detection – Will use R-Wave morphology to discriminate noise and PVCs from AF
  - For PVC detection – Will use R-wave morphology to improve PVC detection performance
  - For Tachy detection – Will use R-Wave morphology to discriminate noise and to categorize VT/VF and SVT

Consideration: *Programming sensitivity to the highest value (lowest sensitivity) may result in delayed detection or under sensing of cardiac activity. Likewise, programming to the lowest value (highest sensitivity) may result in over sensing of noncardiac signals.*

Summary of Programming Parameters

LUX-Dx ICMs utilize dual stage algorithms to detect arrhythmias.

The ICM can be programmed to detect any of the following:

- *Brady*
- *Tachy*
- *Pause*
- *Atrial Tachy (AT)*
- *Atrial Fibrillation (AF)*
- *Symptom*
- *PVC Burden (M302, M312 only)*
- *System Alerts*
- *Bluetooth® Manual Connection*

Brady

Detection: Dual-stage algorithm for detection.

- Potential event is detected when 4 out of 5 beats are slower than the programmed rate.
- If slow pattern is maintained for programmed duration, additional criteria are applied to verify that the slow-rate event is not the result of undersensing.

Programmable Parameters:

Detection: On/Off

Rate (bpm): 30, 40, 50, 60

Duration (seconds): 1, 2, 3, 5, 7, 10, 15, 20, 30

Brady Nighttime Rate (bpm)
M312 only: 30,40, 50, 60 between 11:00 pm-7:00 am

Brady Nighttime Duration (seconds)
M312 only: 1, 2, 3, 5, 7, 10, 15, 20, 30 between 11:00 pm-7:00 am

Alert for Brady Events: On or Off/Red or Yellow

Tachy

Detection: Dual-stage algorithm for detection.

- Potential event is detected when 8 out of 10 beats are faster than the programmed rate threshold.
- If fast pattern is maintained for the programmed duration, additional criteria are applied to verify that the high-rate event is not the result of oversensing.
- If the rate is sustained above 230 bpm, the event may be annotated in LATITUDE Clarity as VF.

Programmable Parameters:

- **Detection:** On/Off
- **Rate (bpm):** 115–220 in increments of 5
- **Duration (seconds):** 0, 1, 2, 3, 4, 5, 10, 15, 20, 25, 30, 40, 50, 60
- **Response:** Less, Balanced, More
- **Alert for Tachy Events:** On or Off/Red or Yellow

Additional Considerations:

Duration: By increasing the duration, you may see fewer events (both true events and false events).

Response:

- When *Less* is selected, detection is less aggressive. You may see fewer false positives, but you may miss some real cardiac events.

- When *More* is selected, detection is more aggressive. You may see more false positives, but you are less likely to miss real events.

> ***note:*** Click the **?** symbol throughout the Programming page to find helpful definitions of settings.

Pause

Detection: A potential event is detected when the R-R interval exceeds the user programmed Pause duration. The algorithm then verifies a true Pause event by re-assessing the S-ECG signal during the pause interval looking for reasons for undersensing, like the presence of noise, changes in R-wave amplitude or flatline segments.

- LUX-Dx II/II+ ICMs (M302 and M312) have additional verification step that further rejects false positives due to low signal-to-noise ratios.
- The LUX-Dx II+ ICM (M312 only) also offers unique nighttime programming applied from 11:00 pm - 7:00 am, giving clinicians the flexibility to fine tune settings to focus on clinically actionable events.

Programmable Parameters:

- **Detection:** On/Off
- **Duration (seconds):** M301, M302 - 1.5, 3, 4.5; M312 - 2, 3, 4, 5, 6, 7, 8, 9, 10
- **Pause Nighttime Duration (seconds) M312 only:** 2, 3, 4, 5, 6, 7, 8, 9, 10 between 11:00 pm-7:00 am
- **Response:** Less, Balanced, More
- **Alert for Pause Events:** On or Off/Red or Yellow

Additional Considerations:

Duration: By increasing the duration, you may see fewer events (both true events and false events).

Response:

- When *Less* is selected, detection is less aggressive. You may see fewer false positives, but you may miss some real events.
- When *More* is selected, detection is more aggressive. You may see more false positives, but you are less likely to miss real events.

Atrial Tachy (AT)

Detection: The AT algorithm analyzes heart rate over each 2-minute window. The algorithm will detect an AT episode when the heart rate exceeds the programmed AT rate for the programmed duration.

- If the AT Duration is programmed to 2 hours or longer, an AT episode is stored once a series of windows satisfy the programmed duration.
- If the AT Duration is less than 2 hours, the algorithm also assess R-R variability in the rhythm to aid in distinguishing AT from sinus rhythms.
- The LUX-Dx ICMs AT algorithm is separately programmable from the AF algorithm, allowing flexibility to tailor settings to detect clinically relevant sustained arrhythmias.

Programmable Parameters:

- **Detection:** On/Off
- **Rate (bpm):** 70–110 by increments of 10; 120–180 by increments of 20
- **Duration (minutes and hours):**
  - Minutes: 2, 6, 10, 20, 30, 60
  - Hours: 2, 3, 4, 6, 8, 10, 12, 16, 24
- **Alert for AT Events:** On or Off/Red or Yellow

Atrial Fibrillation (AF)

Detection:

- The first stage uses a 2-minute window to analyze R-R variability.
- The second stage computes a number of metrics to verify if the window is AF or not. The criteria verify that the variability is not the result of oversensing, noise, regular patterns, ectopic beats or other confounders.
- The LUX-Dx II+ ICM (M312 only) has additional verification step that identifies sequential heart rate patterns to further reject false positives. The AF algorithm was also enhanced to merge adjacent AF episodes to reduce episodes for review which may improve clinic workflow and expedite clinical decision making.

Programmable Parameters:

- **Detection:** On/Off
- **AF Response:** Least, Less, Balanced, More, Most
- **AF Duration (minutes):** 2, 4, 6, 10, 20, 30, 60
- **Alert for AF Events:** On or Off/Red or Yellow
- **Alert for AF Burden:** On or Off/Red or Yellow
- **AF Burden Threshold (hours):** > 0, 0.5, 1, 2, 3, 6, 12, 18, 23

Atrial Fibrillation (AF) (continued)

Additional Considerations:

Duration: By increasing the duration, you may see fewer events (both true events and false events).

Response:

- When *Least* is selected, detection is less aggressive. You may see fewer false positives, but you may miss some real events.
- When *Most* is selected, detection is more aggressive. You may see more false positives, but you are less likely to miss real events.

Symptom

Detection: Symptoms are recorded when a patient initiates a symptom recording from their myLUX™ Patient App. If symptom recording is configured as *On*, patients can use their app to record symptoms. If configured as *Off*, the symptom recording option is removed from the myLUX Patient App entirely.

Programmable Parameters:

- **Recording:** On/Off
- **Recordings Allowed per Day:**
  - 3 symptoms at 10 min/event
  - 4 symptoms at 7.5 min/event
  - 6 symptoms at 5 min/event
- **Alert for Symptom Events:** On or Off/Red or Yellow
- **Alert for Symptoms Correlated with Device-Detected Events:** On or Off/Red or Yellow

PVC Burden (M302, M312 only)

DETECTION:

- The PVC Burden algorithm is capable of detecting multiple sequence types, including singlets, couplets and triplets, to provide a daily PVC Burden value and trend
- R-R intervals and changes in R-wave amplitude are used to detect potential PVCs
- The verification stage then utilizes a morphology assessment that determines if the potential PVCs should be counted towards the PVC burden
- The LUX-Dx II/II+ ICMs offer a unique and programmable PVC Burden Alert, allowing clinicians to be alerts for PVC burdens they deem clinically actionable
- The alert level and preferred PVC burden threshold and duration are configurable

PROGRAMMABLE PARAMETERS:

- **Detection:** On/Off
- **Monitoring Duration:** Continuous, Short Term
- **Monitoring Days:** 2, 3, 7, 14, 30
- **Monitoring Frequency:** Every week, every month, 3 months, 6 months
- **Alert for PVC Events:** On or Off/Red or Yellow
- **PVC Burden Threshold (percentage):** 5, 10, 15, 20, 30, 40
- **PVC Burden Threshold (days):** 1, 3, 5, 7

System Alerts

In this section, you can choose if you'd like to receive alerts when:

- Monitoring has been disabled
- The device battery reaches the threshold for recommended replacement time (RRT)

Bluetooth® Manual Connection

With the LUX-Dx ICM, the magnet is required for initial setup, but you will have options for how the patient will use the magnet after setup. The magnet is used to initiate communication between the ICM and the myLUX™ Patient App at non-scheduled times. On the Programming tab, you can either choose *Require Magnet* or switch a patient's status to *No Magnet Required*.

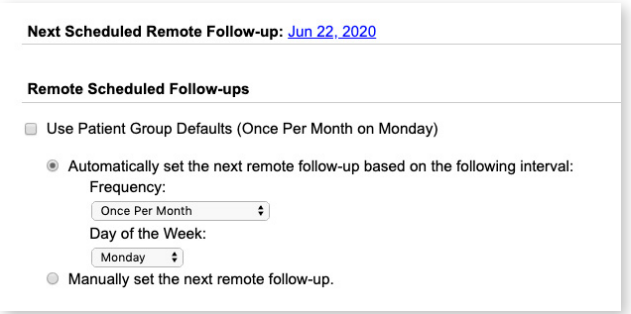
- **Require Magnet:** In this mode, the patient must apply the magnet close to the ICM before recording symptoms and resolving some connection issues. This will be your default setting, as this will apply to most patients followed remotely. This mode will help preserve battery longevity.
- **No Magnet Required:** In this mode, no magnet is needed for the myLUX Patient App to interact with the ICM to record symptoms or perform a manual transmission. This mode will reduce battery life of the ICM.

Follow-Up Schedules

Toward the bottom of the Programming page, you will see information about the patient's follow-up schedule. Again, here you will need to select whether you are using Patient Group Defaults or modifying settings for this patient individually.

First, you will see a date with a link. Click this link to see a pop-up calendar where you can adjust the schedule for the patient's next follow-up only.

Next, you will see options to adjust regular schedule frequency. You can choose to automatically set the frequency of the next follow-up or manually schedule it.



For full context, follow along with LATITUDE Clarity™.

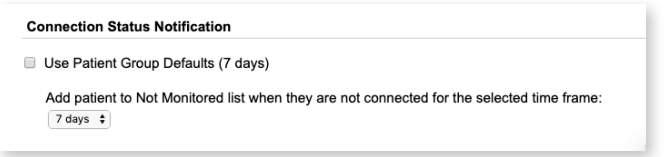
note: The link will say *Missed* if a patient has missed the remote scheduled follow-up.

Connection Status Notification

In this section, you can make choices about when the patient is added to the Not Monitored list. You can use Patient Group Defaults for this or modify for the individual patient with the Use Patient Group Defaults check box.

The individual patient is added to Not Monitored on the Patient List page if not connected for the selected timeframe.

This setting is also related to when a disconnection message will be displayed on the myLUX™ Patient App. Options include 1–7 days or 14 days. Ideally the app will help the patient get reconnected within this timeframe before they are added to the Not Monitored list in LATITUDE Clarity™.



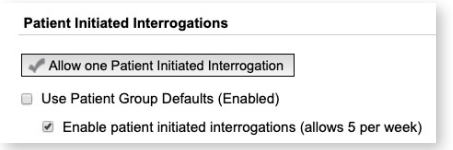
For full context, follow along with LATITUDE Clarity.

To learn more about Connection Status Notifications, view the Prepare Clinic section.

Go to: *Prepare Clinic > Setting Up and Configuring the LATITUDE Clarity System > Connection Status Notification*

Patient-Initiated Interrogations

In this section, you can enable or disable patient-initiated interrogations. If enabled, these interrogations are automatically limited to five per week. In this section, you can also allow one additional patient-initiated interrogation if the patient has already reached the maximum of five in one week.



note: Patient-initiated interrogations are called Manual Transmissions in patient materials and in the myLUX Patient App.

Saving and Verifying Programming and Alert Changes

Saving Changes

Important! After you have made changes on the Programming page, you must click *Save* at the bottom of the page for any change to take effect. If you navigate away from this page without saving your changes, they will not be applied.Once you select *Save*, changes will be applied to the patient's device at the next connection with the ICM.

Verifying Changes

You will have a few options throughout the system to check the status of your programming changes:

Programming Tab: Within a patient's Programming tab, you can check the status of changes in one of two ways:

- Click the *View Programming Status* link at the top of the page. This will show current and pending settings.
- Look for a symbol next to the parameters on the Programming page. If you see the symbol shown below next to any options, it means this parameter has been changed in LATITUDE Clarity™ but is still pending delivery to the device at the next connection with the myLUX™ Patient App.

Patient Diagnostics Tab: Use the Counters & Settings table to view a summary of programming settings as of the last full interrogation.

Programming Report: If you generate a programming report from the Reports Menu, the Setting column will include a note that says "Pending Delivery to Device" if that setting has not yet taken effect.

† = Pending Delivery To Device

In-Clinic Follow-Up Visits

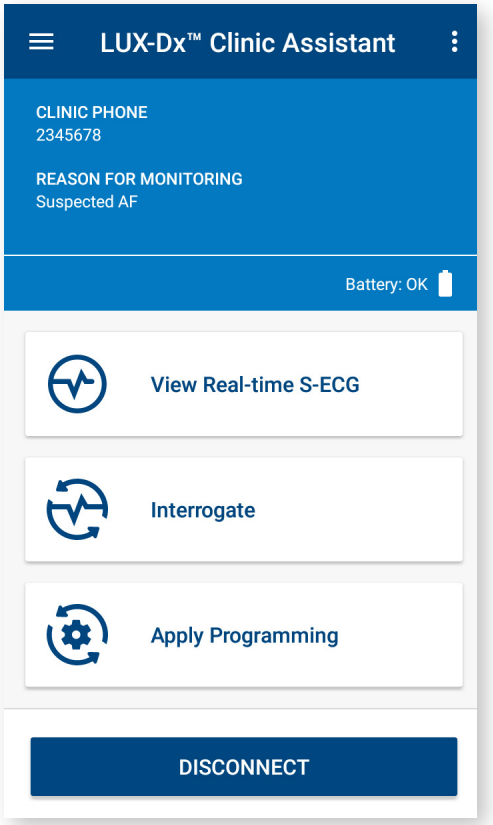
When LUX-Dx ICM patients come into the clinic or ER for a scheduled or unscheduled visit, the LUX-Dx Clinic Assistant App will be able to connect to, and interrogate, any LUX-Dx ICM, regardless of where that patient is followed. To perform some of the tasks to the right, you will need access to the LUX-Dx Clinic Assistant App and the magnet provided as part of the LUX-Dx ICM System.

Click to navigate to a section.

Using the LUX-Dx Clinic Assistant App

Regardless of the visit type, you can perform three main tasks during a follow-up using the LUX-Dx Clinic Assistant App:

- **View Real-Time S-ECG**
- **Interrogate**
- **Apply Programming**



note: View Real-Time S-ECG will be the only task you are able to perform if the patient isn't yet enrolled in LATITUDE Clarity™.

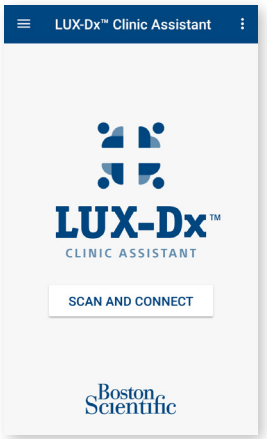
Connecting to Wi-Fi

With the exception of viewing a real-time S-ECG, you will need access to the internet via a Wi-Fi or cellular connection for all tasks on the LUX-Dx™ Clinic Assistant.

1. Press the home button on the mobile device.
2. Tap the down arrow in the upper-right corner of the screen.
3. Tap the *Settings* icon.
4. Tap *Wi-Fi*.
5. Select the network you are trying to connect to from the list of available networks.
6. Follow instructions on the screen; you may be prompted to enter a network password to connect. The screen will indicate when you are connected.
7. Press the home button on your mobile device.
8. Tap the *LUX Clinic* icon to return to the app.

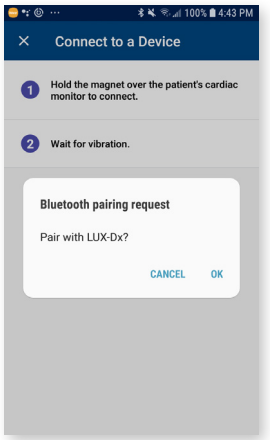
Connecting to a LUX-Dx ICM

To connect to a LUX-Dx ICM, you will follow these steps:



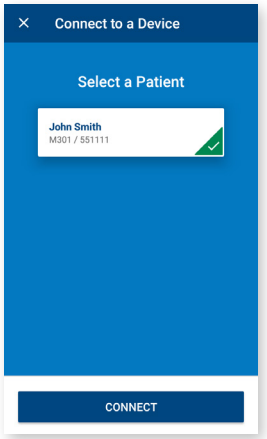
1

Select *Scan and Connect* from the main screen of the app.



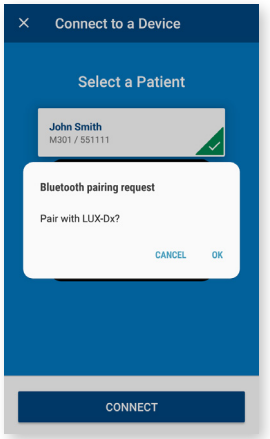
2

Follow the connection instructions on screen and confirm the pairing request.



3

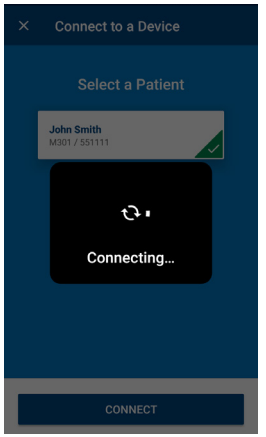
Select the patient from the patient list, then select *Connect*.



4

Confirm the second pairing request.

Connecting to a LUX-Dx ICM (continued)

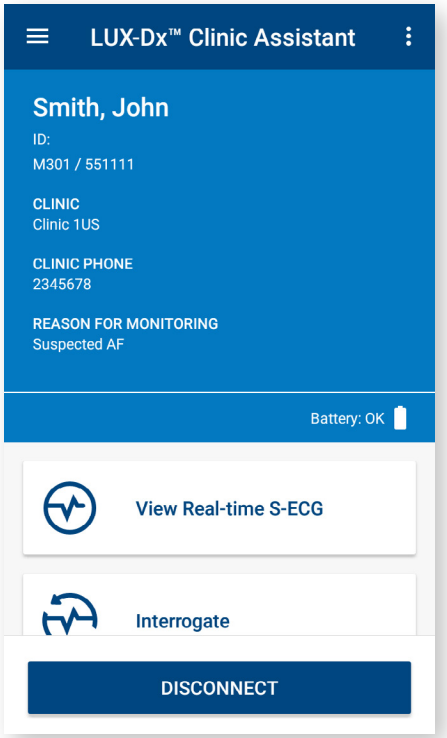


5

Wait for the app to connect and patient information to appear as well as options for what to do next.

Viewing Real-Time S-ECG

Once you are connected to a patient's device, the screen will show you an option to view a real-time S-ECG. You can use this feature to verify that the device-sensing amplitude is adequate or simply to view a live rhythm.

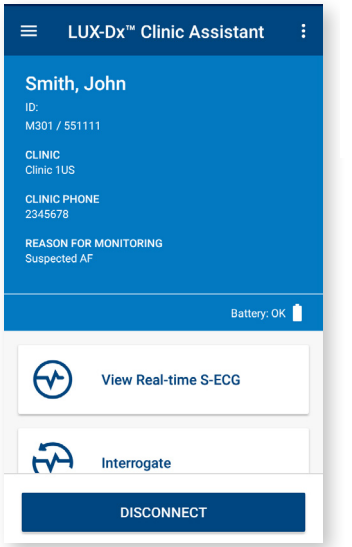


note: You will be able to perform this function without an internet connection.

Interrogating LUX-Dx ICMs

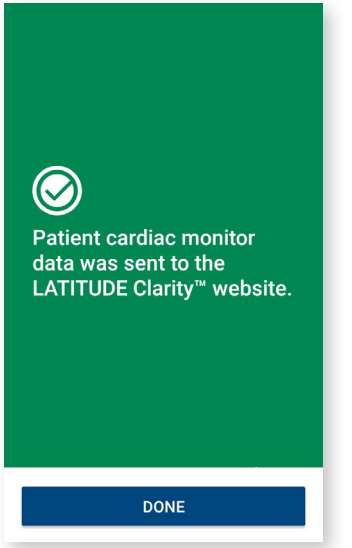
Once you are connected to a patient's ICM, the screen will show you an option to interrogate the device. This feature performs a manual interrogation of the ICM and uploads data to the LATITUDE server. A message will appear once the interrogation is successful.

note: LUX-Dx Clinic Assistant App will be able to interrogate ANY LUX-Dx ICM. You will not be able to view the interrogation data directly from the LUX-Dx Clinic Assistant App



To view a patient's data from this interrogation, you must log in to LATITUDE Clarity™. The interrogation you just performed will show up as new Data for Review*, and Clinic Interrogation will show up as the Review Reason*.

note: With the new Temporary Healthcare Provider Access feature on LATITUDE Clarity, clinics now are able to view ANY LUX-Dx patient data, including those who they do not follow (i.e. who visit from other clinics). The Temporary Healthcare Provider Access is for clinicians with a LATITUDE Clarity account set at the right access levels (Limited or Complete). For an initial setup of a LATITUDE account and required accessories, call your Boston Scientific representative, or call 1-800-CARDIAC.



**When reviewing a visiting patient page in Temporary Healthcare Provider (i.e. observer) mode, you may notice several changes because your access to this patient is temporary and read-only. The primary followup clinic remains the owners of key actions within the system for the patient, such as Dismiss Alerts or Events, classify new episodes, or change programing. For this reason, you don't see the tabs "Data for Review" and "Programming" from an observer perspective.*

Applying Programming

There may be times when you choose to adjust programming settings during a visit with the patient. To do this, **follow the steps below:**

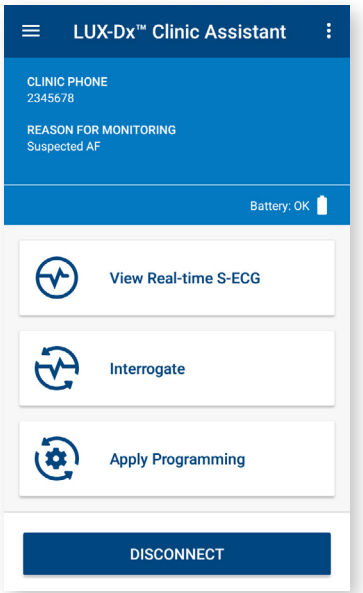
For more information on adjusting programming settings, go to the Adjusting Programming section.

Go to: *Monitor & Manage Patient Data > Adjusting Programming*

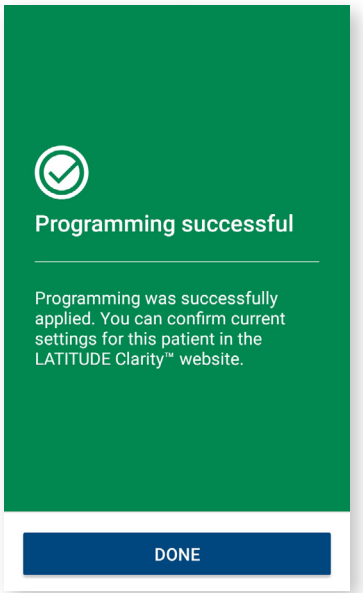
1. Connect to and interrogate the ICM.
2. Log in to LATITUDE Clarity™ using a different device with access to *latitude.bostonscientific.com*.
3. Navigate to the appropriate patient. The patient should show up on the For Review page with a Review Reason of Clinic Interrogation.
4. Review the patient's programming settings on the Programming tab and make any desired adjustments.
5. Click *Save* on the Programming page.
6. Return to the LUX-Dx Clinic Assistant App.

Applying Programming (continued)

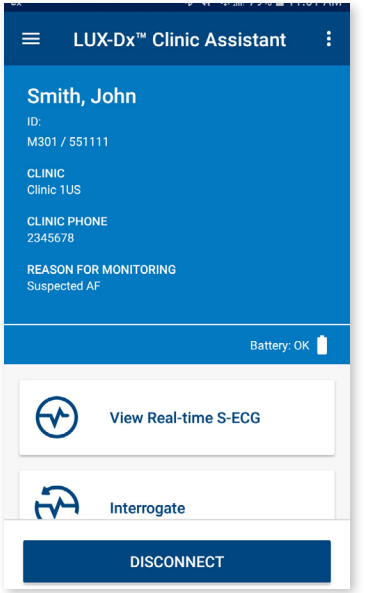
7 Select *Apply Programming.* (If the app has timed out, you may need to connect to the patient's device again.)



8 Follow the instructions on the app screen until you see this screen confirming that programming was successful.



9 When you have finished your follow-up, you can select *Disconnect* to end the session.



Additional Resources

If you didn't find what you need in this guide, you can find additional resources on the LUX-Dx ICM and LATITUDE Clarity™ at the following places:

- From the LUX-Dx Clinic Assistant App menu, you can access Clinic Resources, which includes educational information related to the use of the Clinic Assistant App during insertion and follow-up visits.
- The LUX-Dx ICM System has a dedicated section on Boston Scientific's LUX-Dx Learning Center hosted on EDUCARE. This site can be found at ***luxdxtraining.com***.
- Talk to your Boston Scientific representative.
- Contact Boston Scientific Support, at 1-800-CARDIAC (1-800-227-3422).

Click to navigate to a section.

LUX-Dx ICM Device Interrogation Features

Interrogation Type/Reason	Full Interrogation with Presenting S-ECG	Configuration Options in LATITUDE Clarity™
Daily Alert Checks	• Provide a Presenting S-ECG every day with or without a full interrogation. • Provide a full interrogation only if the Daily Alert Check detects a possible alert condition.	• Automatic interrogations via Patient App • Daily • Not configurable
Remote Scheduled Follow-Ups	Yes	• Automatic interrogations via Patient App • From Once Per Week to Once Every Twelve Months on a selected day of the week • Date may also be manually scheduled
Data Updated Reason Daily Checks detect a possible alert condition but LATITUDE Clarity refutes the alert.	Typically, Yes	• Automatic interrogations via Patient App • Not configurable
Patient-Initiated Interrogations (PIIs)	Yes	• Manual Interrogations via Patient App • Enabled or Disabled
Clinic Interrogations	Yes	• Manual Interrogations via Clinic App • As directed by clinic

*Every interrogation type includes an alert check.

LATITUDE Clarity™ Data Management System
S-ECG Markers: *Page 1*

Marker	Definition
VN	Noise has been detected in the system, indicating that sensing may be compromised.
[VS]	A signal was seen following a ventricular sense that was above the detection threshold but within the refractory period after the previous VS; considered noise.
VS n	A ventricular sense. If the Brady and/or Tachy features are enabled, this may be replaced with a B, T, or F marker depending on the rate. The number below the VS marker represents the interval (in milliseconds) since the previous VS/B/T/F marker.
B n	If the Brady feature is enabled, a ventricular sense where the rate (with respect to the previous ventricular sense) is slower than the programmed Brady rate threshold. This does not necessarily mean the device has detected a Brady event. (See “Brady” marker.) The number below the marker represents the interval (in milliseconds) since the previous VS/B/T/F marker.
T n	If the Tachy feature is enabled, a ventricular sense where the rate (with respect to the previous ventricular sense) is higher than the programmed Tachy rate threshold. This does not necessarily mean the device has detected a Tachy event. (See “Tachy” marker.) The number below the marker represents the interval (in milliseconds) since the previous VS/B/T/F marker.
F n	If the Tachy feature is enabled, this marks a ventricular sense where the rate (with respect to the previous ventricular sense) is in the non-programmable VF zone (230 bpm and higher). This does not necessarily mean the device has detected a Tachy event. (See “Tachy” marker.) The number below the marker represents the interval (in milliseconds) since the previous VS/B/T/F marker.

LATITUDE Clarity™ Data Management System S-ECG Markers: *Page 2*

Marker	Definition
Pause	Labels the VS at the beginning of a device-confirmed cardiac Pause.
P	Ventricular Pause (interval without a VS). The marker is positioned at the point where the user-programmed Pause duration expired from the previous VS.
End Pause	Labels the VS at the end of a device-confirmed cardiac Pause.
Brady	Labels the VS in a Brady event where 4 out of 5 beats were slow.
End Brady	Labels the VS in a Brady event where there were no longer at least 2 slow beats out of 5.
Tachy	Labels the VS in a Tachy event where 8 out of 10 beats were fast.
End Tachy	Labels the VS in a Tachy event where there were fewer than 3 fast beats out of 10.
AF	Labels the point at which the device determined the presence of AF.
End AF	Labels the point at which the device determined AF was no longer present.
AT	Labels the point at which the device determined the presence of AT.
Symptom	Labels the point at which the patient initiated a symptom-recorded S-ECG.

LUX-Dx ICM System Programming:
Page 1

The following table displays the nominal values for programming based on each reason for monitoring for the family of LUX-Dx™ Insertable Cardiac Monitor Systems (ICMs)*

Parameter Name	Configurable Options	Cryptogenic Stroke / Suspected AF	Post AF Ablation	AF Management	Syncope	Palpitations	VT	Other
Detection Algorithm Nominal Parameters								
AF Detection	On, Off	On						
AF Response	Least, Less, Balanced, More, Most	More	More	Balanced	Less	Balanced	Less	Balanced
AF Duration	2, 4, 6, 10, 20, 30, 60 (minutes)	4	4	10	10	10	10	6
AT Detection	On, Off	On						
AT Duration	2, 6, 10, 20, 30, 60 (minutes) and 2, 3, 4, 6, 8, 10, 12, 16, 24 (hours)	4 hours						
AT Rate	70, 80, 90, 100, 110, 120, 140, 160, 180 (bpm)	110						
Brady Detection	On, Off	On						
Brady Duration	1, 2, 3, 5, 7, 10, 15, 20, 30 (seconds)	1						
Brady Rate	30, 40, 50, 60 (bpm)	40						
Brady Nighttime Rate (M312 only)	30, 40, 50, 60 (bpm)	30						
Brady Nighttime Duration (M312 only)	1, 2, 3, 5, 7, 10, 15, 20, 30 (seconds)	1						
Pause Detection	On, Off	On						
Pause Response	Less, Balanced, More	Less	Less	Less	More	Balanced	Less	Balanced
Pause Duration	M301, M302 – 1.5, 3, 4.5 (seconds) M312 – 2, 3, 4, 5, 6, 7, 8, 9, 10 (seconds)	3						
Pause Nighttime Duration (M312 only)	2, 3, 4, 5, 6, 7, 8, 9, 10 (seconds)	5						

LUX-Dx ICM System Programming:

Page 2

Parameter Name	Configurable Options	Cryptogenic Stroke / Suspected AF	Post AF Ablation	AF Management	Syncope	Palpitations	VT	Other
Detection Algorithm Nominal Parameters								
Tachy Detection	On, Off	On						
Tachy Duration	0, 1, 2, 3, 4, 5, 10, 15, 20, 25, 30, 40, 50, 60 (seconds)	5						
Tachy Rate	115- 220 in steps of 5 bpm	170						
Tachy Response	Less, Balanced, More	Less	Less	Less	More	Balanced	More	Balanced
PVC Burden Detection (M302, M312 only)	On, Off	Off						
PVC Burden Monitoring Duration (M302, M312 only)	Continuous, Short Term	Continuous						
PVC Burden Monitoring Days (M302, M312 only)	2, 3, 7, 14, or 30 days	N/A						
PVC Burden Monitoring Frequency (M302, M312 only)	Every week, month, 3 months, or 6 months	N/A						
Blank After Sense	130-400 ms @ 10 ms increments	160						
Sensitivity	0.025, 0.037, 0.05, 0.075, 0.1, 0.15, 0.2 mV	0.037						
Morphology Assessment	On, Off	On						
Symptom Recording	On, Off	On						
Symptom Recordings Allowed Per Day	3 (10 minutes/event) 4 (7.5 minutes/event) 6 (5 minutes/event)	4 (7.5 minutes/event)						
Telemetry Related								
Manual Bluetooth® Connection	Require Magnet, No Magnet	Require Magnet						

LUX-Dx ICM System Alert Nominals:

Page 1

The following table displays the alert nominals based on each reason for monitoring for the family of LUX-Dx™ Insertable Cardiac Monitor Systems (ICMs).*

Parameter Name	Configurable Options	Suspected AF / Cryptogenic Stroke	Post AF	AF Management	Syncope	Palpitations	VT	Other
Alert nominals automatically applied with selection of Reason for Monitoring.								
PVC Alert (M302, M312 only)	Off, Red, Yellow	Off	Off	Off	Off	Off	Off	Off
PVC Alert Threshold (M302, M312 only)	5, 10, 15, 20, 30, 40%	15	15	15	15	15	15	15
Days to PVC Alert** (M302, M312 only)	1, 3, 5, 7 Days	5	5	5	5	5	5	5
AF	Off, Yellow, Red	Red	Yellow	Off	Off	Off	Off	Off
Pause	Off, Yellow, Red	Yellow	Yellow	Off	Red	Yellow	Off	Off
Brady	Off, Yellow, Red	Off	Off	Off	Red	Yellow	Off	Off
Tachy	Off, Yellow, Red	Red	Red	Off	Red	Red	Red	Off
AT	Off, Yellow, Red	Off	Off	Off	Off	Off	Off	Off
AF Burden	Off, Yellow, Red	Off	Off	Yellow	Off	Off	Off	Off
AF Burden > Threshold	Off, > 0, 0.5, 1, 2, 3, 4, 6, 12, 18, 23 hrs/day	Off	Off	1 hour	Off	Off	Off	Off
Symptom (patient recorded)	Off, Yellow, Red	Off	Off	Off	Yellow	Yellow	Off	Off
Symptom + Device Detected Episode	Off, Yellow, Red	Red	Red	Off	Red	Yellow	Red	Yellow
Monitoring Disabled	Off, Yellow, Red	Red	Red	Red	Red	Red	Red	Red
Battery Recommended Replacement Time (RRT)	Off, Yellow, Red	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow

*References to "LUX-Dx™ ICMs" include LUX-Dx™, LUX-Dx II™ and LUX-Dx II+™ ICM Systems.
**Number of days above the PVC burden threshold applies since the last triggered alert or alert configuration change.

Workflow Worksheet: *Page 1*

WORKFLOW STEP	TASKS	LUX-Dx ICM SYSTEM TOOLS USED FOR TASK	ADDITIONAL INFORMATION OWNER MIGHT NEED FOR TASK
Sample LUX-Dx ICM Insertion, Enrollment, Device Activation, and Patient Education Workflow			
PREPARING FOR INSERTION	• Prep room and patient • Use the pre-insertion card to determine the patient's remote monitoring method (downloadable myLUX app vs. provided mobile device) and, if applicable, download the app and gather contact information for RhythmCARE Assist sign-up. • Turn on and update provided patient and clinic mobile devices. • Use the provided Clinic Assistant or the myLUX mobile devices and magnet to check ICM battery • Keep track of device serial number (used in enrollment later)	• myLUX Patient App or LUX-Dx Clinic Assistant App • LUX-Dx ICM and Patient Kit box • Magnet • LUX-Dx Pre-insertion card	• Where and when does the physician insertion ICM devices? • Who are the people involved with the insertion? • Will the patient be monitored remotely? • What remote monitoring method is best for them? • Will they opt in for RhythmCARE Assist service should they choose using the myLUX app on their personal phones?
INSERTION PROCEDURE	• Insert device • Verify R-Wave sensing • Reposition device (if necessary) • Close incision	• Insertion tools • ICM • myLUX Patient App or LUX-Dx Clinic Assistant App • Magnet	• What tools do they use to insertion ICM devices? • How do they close the wound for ICM devices?
ENROLL PATIENT AND REGISTER DEVICE	• Complete the online Enrollment form, sign up for the RhythmCARE Assist service when suited, and select Patient Group and Reason for Monitoring	• LATITUDE Clarity™ • LUX-Dx Pre-insertion Card	• Internet access • General patient, insertion, clinic, and device information (see Appendix: Enrollment Form Fields) • Patient's email address and phone number to enroll in RhythmCARE Assist service • Patient's Reason for Monitoring • Assigned Patient Group
SET UP & ACTIVATE DEVICE	• The inserted ICM device is activated either through setting up the provided myLUX mobile device, setting up the downloadable myLUX app on the patient's personal smartphone, or using the LUX-Dx Clinic Assistant.	• LUX-Dx Clinic Assistant App • myLUX Patient App • Magnet	• Internet Access • Patient's date of birth • Patient must agree to the Privacy Policy and Terms of Use on app

Workflow Worksheet: *Page 2*

WORKFLOW STEP	TASKS	LUX-Dx ICM SYSTEM TOOLS USED FOR TASK	ADDITIONAL INFORMATION OWNER MIGHT NEED FOR TASK
Sample LUX-Dx ICM Insertion, Enrollment, Device Activation, and Patient Education Workflow			
EDUCATE PATIENT	• Cover key topics, including: – How ICM and remote monitoring work – What to do with the magnet and how to carry it – Cover when to record symptoms or send manual transmissions (if relevant) – Set expectations for data review and follow-up – Explain the benefits of RhythmCARE Assist service and remind patient to save the contact card, read communications coming from the service, and don't unsubscribe the service. If the patient signed up for text messages, guide the patient to reply YES to the opt-in text message. – Ensure patient knows all the connectivity best practices for the myLUX app: • Keep Bluetooth® on • Keep powered on and charged • Connected to Wi-Fi if possible • Place within 6 feet of where patient sleeps or spends considerable amount of time • Tap into the myLUX app to check on the bluescreen periodically • Do not swipe up to close/quit the app • Recommend patient to contact insurance to understand billing • Remind patient where to find additional educational resources	• myLUX Patient App • LUX-Dx ICM Patient Information Packet • Patient Handbook • myLUX Quick Start Guide for personal phones • myLUX Quick Start Guide for Boston Scientific Provided Mobile Device	• Will patient be allowed to record symptoms? If so, which ones and when? • What is clinic review and follow-up schedule? • What is patient's Connectivity situation at home? • Will patient be using the RhythmCARE Assist service? If so, what should you remind them about before you send them home?

Workflow Worksheet: *Page 3*

WORKFLOW STEP	TASKS	LUX-Dx ICM SYSTEM TOOLS USED FOR TASK	ADDITIONAL INFORMATION OWNER MIGHT NEED FOR TASK
Sample LATITUDE Clarity™ Data Management System Patient Data Review Workflow			
DAILY OR SCHEDULED ALERT REVIEW	• Check Patient List for new data available for review • Choose patient to review • On Patient Detail page, review new Event Details on Data for Review page • Use expandable arrows and/or Event Detail option to view and annotate S-ECG and compare rate plots • Review Counters & Settings on Data for Review page • See additional Trends and Histograms in Patient Diagnostics and Health sections • Use Reports Menu to generate reports for review or documentation • Check Follow-Up Schedule and contact patient (if required) • Send reports to EMR (if preferred) • Dismiss reviewed events	• LATITUDE Clarity™	• If enabled, helpful to know when EMR integration is configured to send data to EMR system – manually, upon dismiss, etc. • Physician report preferences
Sample LATITUDE Clarity™ Data Management System Patient Data Review Workflow			
ADJUST DEVICE PROGRAMMING OR EVENT ALERTS (BY INDIVIDUAL PATIENT)	• Select individual patient • Navigate to Programming tab • Adjust desired parameters • Select *Save and Close* at bottom of page • Verify change in 3 ways: **Programming page** • View *Programming Status* • Look for "†" symbol next to settings that are pending delivery to device **Patient Diagnostics page** **Programming summary**	• LATITUDE Clarity	• Clinic protocols by Reason for Monitoring • Clinic protocols for remote programming • Nominal programming settings and adjustable parameters • Changes to desired device programming parameters • ***Tip:*** Use "?" button to see descriptions of certain parameters

Workflow Worksheet: *Page 4*

WORKFLOW STEP	TASKS	LUX-Dx ICM SYSTEM TOOLS USED FOR TASK	ADDITIONAL INFORMATION OWNER MIGHT NEED FOR TASK
Sample LUX-Dx ICM In-Clinic Follow-Up Workflow: Using the LUX-Dx Clinic Assistant App			
IN-CLINIC FOLLOW-UP	• Locate LUX-Dx Clinic Assistant and magnet (should be attached to mobile device) • Move to a place with a Wi-Fi or cellular connection • Turn on mobile device • Open app (if necessary) • Tap Scan and Connect • Follow instructions on screen to confirm pairing • View list of nearby devices and select appropriate Patient Name • Follow instructions on screen to confirm pairing and connect to device. Once connected, app will display patient information and possible actions • (If desired) Select View Real-Time ECG. This can be used to confirm amplitude of signal. • Select Interrogate and follow the instructions on screen. Once complete, data is uploaded to LATITUDE Clarity™ **For visiting patients from another clinic who are not followed by your clinic:** • To view the data transmission, log in to the LATITUDE Clarity website. Select "Manage Patient" > "View Another Clinic's Patient" and input the patient's ICM model number, serial number, and date of birth to find the patient. **For patients that your clinic follows:** • Use computer or tablet to log in to LATITUDE Clarity • Search for Patient Name • Select alert that lists Review Reason as Clinic Interrogation to view new data • Perform any actions required for review or programming adjustments in LATITUDE Clarity. Save changes. • If interrogating device only: Select Disconnect when session is complete	• LUX-Dx Clinic Assistant App • Magnet • LATITUDE Clarity	• Any desired changes to device programming parameters and relevant clinic protocols • Location with best connectivity • Password if LUX-Dx Clinic Assistant App is password protected • LATITUDE Clarity login and password • Patient's ICM model number, serial number and date of birth

Workflow Worksheet: *Page 5*

WORKFLOW STEP	TASKS	LUX-Dx ICM SYSTEM TOOLS USED FOR TASK	ADDITIONAL INFORMATION OWNER MIGHT NEED FOR TASK
Sample LUX-Dx ICM In-Clinic Follow-Up Workflow: Using the LUX-Dx Clinic Assistant App (continued)			
IN-CLINIC FOLLOW-UP	**If changes were made to Programming:** • Return to LUX-Dx Clinic Assistant App and select Apply Programming from patient's summary screen • Follow instructions on screen until you reach confirmation that programming was applied successfully • When successful, select Disconnect to end session		
Sample LUX-Dx ICM In-Clinic Follow-Up Workflow: Using myLUX™ Patient App			
IN-CLINIC FOLLOW-UP	• Move to a place with a Wi-Fi or cellular connection • Open patient's myLUX Patient App and confirm that you have access to the magnet (should be attached to mobile device) • Select Menu in upper-left corner of main screen • Select Manual Transmission from menu • Follow instructions on screen • Once you reach confirmation screen, select Done • Use computer or tablet to connect to LATITUDE Clarity™ • Search for Patient Name • Select alert that lists Review Reason as Patient Initiated to view new data • Perform any actions required for review or adjustments in LATITUDE Clarity. Save changes. • If changes were made to Programming, they will be applied within the next 36 hours at scheduled connection times. • If you need to apply changes immediately, try performing a connection check and second manual transmission using the myLUX Patient App	• myLUX Patient App • Magnet • LATITUDE Clarity	• Any desired changes to device programming parameters and relevant clinic protocols • Location with best connectivity

Sample Report: *Page 1*

Boston Scientific

LATITUDE Clarity™ Follow-up Report | Created: Oct 25, 2023

Stevens, John (Age 79)

ID: M312
Gender: Male
DOB: Jul 10, 1944
Phone: 323-323-2020
Clinic: NXT & Clarity Demo Clinic

Device: M312 LUX-Dx II+™/323232
Implant Date: Jul 14, 2023
Implanted By: Mendez, Xavier
Followed By: Mendez, Xavier
Patient Group: LUX-Dx ICM Group

Latest Device Transmission: Oct 12, 2023 07:19 EDT

OK

Last: Oct 12, 2023

Next: Nov 10, 2023
Last: Oct 02, 2023

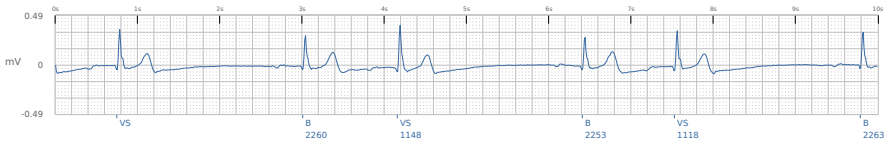
Reason For Monitoring
Syncope

CHA2DS2-VASc: 3
On OAC: Yes
On Antiarrhythmic: No
Sleep Apnea: No

My Alerts

4 red event alerts since last dismissed

Presenting S-ECG (Oct 12, 2023 07:59 EDT) **Avg Rate: 33 bpm**



Event Logbook (Oct 02, 2023 - Oct 12, 2023)

Event	Description	Date/Time	Duration	Rate	Assessment
B-4	Brady	Oct 12, 2023 05:44 EDT	6 s	Avg 27 bpm	Not Assessed
B-3	Brady	Oct 12, 2023 05:39 EDT	7 s	Avg 27 bpm	Not Assessed
B-2	Brady	Oct 12, 2023 05:31 EDT	6 s	Avg 29 bpm	Not Assessed
B-1	Brady	Oct 12, 2023 05:26 EDT	14 s	Avg 29 bpm	Not Assessed

Counters and Settings

	Recent Oct 02, 2023 - Oct 12, 2023 *11 day(s)*	Previous Jul 14, 2023 - Oct 02, 2023 *81 day(s)*	Lifetime Jul 14, 2023 - Oct 12, 2023 *91 day(s)*	Programming Summary Oct 12, 2023
Symptom (Total)	0	0	0	4 (7.5 min/event)
Tachy	0	0	0	≥ 170 bpm, > 5 s
Pause	0	0	0	
Brady	4	0	4	
AT	0	0	0	≥ 110 bpm, ≥ 4 hrs
AF	0	0	0	
Sensing Parameters				Sensitivity: 0.037 mV Blank After Sense: 160 ms

Comments & Interventions

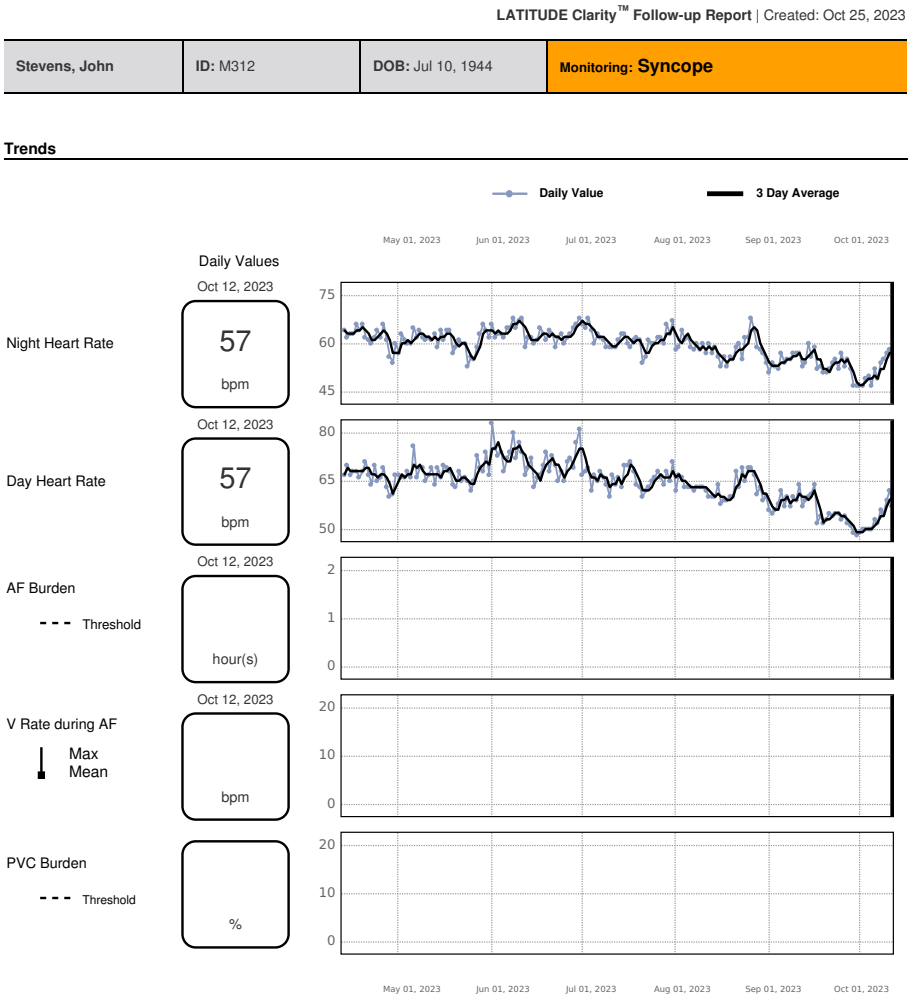
Signature

Date

M312 Firmware Version: BA_v1.00.00 (1.00)

Patient and case details are not real. The sample report is for demonstration purposes.

Sample Report: *Page 2*



LATITUDE Clarity™ Follow-up Report | Created: Oct 25, 2023

Stevens, John	ID: M312	DOB: Jul 10, 1944	Monitoring: Syncope

Trends

Daily Value — 3 Day Average

May 01, 2023 | Jun 01, 2023 | Jul 01, 2023 | Aug 01, 2023 | Sep 01, 2023 | Oct 01, 2023

Daily Values

Night Heart Rate — Oct 12, 2023: 57 bpm (75 / 60 / 45)

Day Heart Rate — Oct 12, 2023: 57 bpm (80 / 65 / 50)

AF Burden — Oct 12, 2023: hour(s) (2 / 1 / 0)
--- Threshold

V Rate during AF — Oct 12, 2023: bpm (20 / 10 / 0)
Max
Mean

PVC Burden — (20 / 10 / 0)
--- Threshold
%

May 01, 2023 | Jun 01, 2023 | Jul 01, 2023 | Aug 01, 2023 | Sep 01, 2023 | Oct 01, 2023

M312 Firmware Version: BA_v1.00.00 (1.00)

Page 4 of 4

Patient and case details are not real. The sample report is for demonstration purposes.

Enrollment Form Fields

REQUIRED	OPTIONAL
Insertioned Device Model and Serial Number	Patient ID
Patient's Date of Birth	Patient's Gender
Patient's First and Last Name	Patient's Weight
Patient's Email Address	Patient's CHA2DS2-VASc Score
Patient's Phone Number	Patient's Oral Anticoagulant and Antiarrhythmic History
Patient's Social Security Number (or they must decline to provide)	Patient's Sleep Apnea Diagnosis
Patient's Street Address	Inserting Clinician Specialty
Monitoring Method (Remote or In-Clinic)	Inserting Clinician Email Address
Remote Monitoring Equipment	Following Clinician Specialty
Reason for Monitoring	Following Clinician Email Address
Patient's Assigned Patient Group	Referring Clinician First and Last Name, Specialty, Email, Phone Number, City, and State
Insertion Date	Explanted Device Information
Inserting Clinician First and Last Name	Registration Comments
Inserting Clinician Phone Number	
Inserting Clinician City and State	
Following Clinician First and Last Name	
Following Clinician Phone Number	
Following Clinician City and State	
Inserting Facility Name	
Inserting Facility Phone Number and Street Address	
Acknowledgment of Agreement to Be Responsible for This Patient	

LUX-Dx™ Insertable Cardiac Monitor System

INDICATIONS: The LUX-Dx™ Insertable Cardiac Monitor (ICM) is intended to monitor and record subcutaneous electrocardiogram (S-ECG). The recorded S-ECG is used for the clinical evaluation and diagnosis of cardiac arrhythmias. The LUX-Dx is indicated for use in patients that have a known heart condition and are at risk of developing an abnormal heart rhythm, or have symptoms that may suggest a cardiac arrhythmia, such as dizziness, palpitations, syncope, chest pain, and/or shortness of breath. The LUX-Dx has not been tested specifically for pediatric use. **CONTRAINDICATIONS:** There are no known contraindications for the insertion of the LUX-Dx insertable cardiac monitor. However, the patient's particular medical condition may dictate whether or not they can tolerate a subcutaneous, chronically- inserted device. LATITUDE Clarity is contraindicated for use with any device other than a compatible Boston Scientific device. **WARNINGS:** Concomitant use of the ICM system and inserted electro-mechanical devices [for example insertionable neuromodulation/neurostimulation systems, ventricular assist device (VAD), or insertionable insulin pump or drug pump] can result in interactions that could compromise the function of the ICM, the co-inserted device, or both. Electromagnetic interference (EMI) or therapy delivery from the co-inserted device can interfere with ICM sensing and/or rate assessment, resulting in failure to monitor or record when needed. Verify sensing configuration, operation modes, surgical considerations and existing placement of all involved devices prior to any co-insertion. To help prevent undesirable interactions, test the ICM system when used in combination with the co-inserted device. Do not expose a patient with an ICM system to diathermy. The interaction of diathermy therapy with an insertable cardiac monitor can damage the device and cause patient injury. The influence of medical equipment on inserted devices varies considerably according to the type of unit and energy levels employed. In situations where the risks are known, always interrogate the device and save data before the procedure, and check device function afterwards. Magnet model 6386 has been tested for use with the ICM system. Use of any other magnets has not been tested and could result in failure to initiate communication with the device. The magnet provided with the ICM system may cause interference with devices sensitive to magnetic fields such as hearing aids, pacemakers, and other inserted devices. It can also permanently disable some magnetic strip cards. Keep the magnet at least 15 cm (6 inches) away from items sensitive to magnetic fields, including the ICM device when the magnet is not being used to initiate communication between the device and the patient or clinic app.The mobile devices and magnet are MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices. Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the inserted device, and significant harm to or death of the patient and/or damage to the inserted device may result. Scanning patients who have other MR Conditional devices is acceptable if all the MR Conditional requirements for each of the inserted devices are met. Do not conduct an MRI scan if any conditions or insertions prohibit it. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active insertionable medical device, including areas protected by a warning notice that prevents entry by patients. **PRECAUTIONS:** For specific information on precautions, refer to the following sections of the product labeling: General, Clinical Considerations, Sterilization and Storage, Insertion, Magnet, Device Programming, Environmental and Medical Hazards, Follow-up, Device Removal and Disposal. **POTENTIAL ADVERSE EVENTS:** Potential adverse events related to insertion of the device may include, but are not limited to, the following: • Device migration • Erosion • Foreign body rejection phenomena • Formation of hematomas or seromas • Infection • Local tissue reaction • Tissue damage. For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide. If any adverse events occur, invasive corrective action and/or ICM system modification or removal may be required. 92496928 (Rev. B)

LUX-Dx II™ and LUX-Dx II+™ Insertable Cardiac Monitor Systems

INDICATIONS: The LUX-Dx Insertable Cardiac Monitor (ICM) is intended to monitor and record subcutaneous electrocardiogram (S ECG). The recorded S-ECG is used for the clinical evaluation and diagnosis of cardiac arrhythmias. The LUX-Dx is indicated for use in patients that have a known heart condition and are at risk of developing an abnormal heart rhythm, or have symptoms that may suggest a cardiac arrhythmia such as dizziness, palpitations, syncope, chest pain, and/or shortness of breath. The LUX-Dx has not been tested specifically for pediatric use. **CONTRAINDICATIONS:** There are no known contraindications for the insertion of the LUX-Dx insertable cardiac monitor. However, the patient's particular medical condition may dictate whether or not they can tolerate a subcutaneous, chronically inserted device. LATITUDE Clarity is contraindicated for use with any device other than a compatible Boston Scientific device. **WARNINGS:** Concomitant use of the ICM system and inserted electro-mechanical devices [for example insertionable neuromodulation/neurostimulation systems, ventricular assist device (VAD), or insertionable insulin pump or drug pump] can result in interactions that could compromise the function of the ICM, the co-inserted device, or both. Electromagnetic interference (EMI) or therapy delivery from the co-inserted device can interfere with ICM sensing and/or rate assessment, resulting in failure to monitor or record when needed. Verify sensing configuration, operation modes, surgical considerations and existing placement of all involved devices prior to any co-insertion. To help prevent undesirable interactions, test the ICM system when used in combination with the co-inserted device. Do not expose a patient with an ICM system to diathermy. The interaction of diathermy therapy with an insertable cardiac monitor can damage the device and cause patient injury. The influence of medical equipment on inserted devices varies considerably according to the type of unit and energy levels employed. In situations where the risks are known, always interrogate the device and save data before the procedure, and check device function afterwards. Magnet model 6386 has been tested for use with the ICM system. Use of any other magnets has not been tested and could result in failure to initiate communication with the device. The magnet provided with the ICM system may cause interference with devices sensitive to magnetic fields such as hearing aids, pacemakers, and other inserted devices. It can also permanently disable some magnetic strip cards. Keep the magnet at least 15 cm (6 inches) away from items sensitive to magnetic fields, including the ICM device when the magnet is not being used to initiate communication between the device and the patient or clinic app. The mobile devices and magnet are MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices. Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the inserted device, and significant harm to or death of the patient and/or damage to the inserted device may result. Scanning patients who have other MR Conditional devices is acceptable if all the MR Conditional requirements for each of the inserted devices are met. Do not conduct an MRI scan if any conditions or insertions prohibit it. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active insertionable medical device, including areas protected by a warning notice that prevents entry by patients. **PRECAUTIONS:** For specific information on precautions, refer to the following sections of the product labeling: General, Clinical Considerations, Sterilization and Storage, Insertion, Magnet, Device Programming, Environmental and Medical Hazards, Follow-up, Device Removal and Disposal. **POTENTIAL ADVERSE EVENTS:** Insertion and usage of this product may result in adverse events which may lead to injury, death, or other serious adverse reactions. If any adverse events occur, invasive corrective action and/or ICM system modification or removal may be required. Potential adverse events related to insertion of the device may include, but are not limited to, the following: Device migration, Erosion, Foreign body rejection phenomena, Formation of hematomas or seromas, Infection, Local tissue reaction, Tissue damage. Potential adverse events related to device operation may include, but are not limited to, the following: Premature battery depletion, Sensing issues, Error codes, Loss of telemetry. Transient procedural adverse events are expected in some patients. These include, but are not limited to discomfort, pain, anxiety, and other systemic symptoms that might be related to medications or other interventions performed during insertion. For a list of potential adverse events associated with MRI scanning, refer to the bostonscientific-elabeling.com. MRI Technical Guide at www.bostonscientific-elabeling.com Any serious incident that occurs in relation to this device should be reported to Boston Scientific and to the relevant local regulatory authority.
97104968 (Rev. A)

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner trained or experienced in device insertion.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "User's Manual" for more information on Indications, Contraindications, Warnings, Adverse Events, and Operator's Instructions.

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