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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

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 implant 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 LUX-Dx Clinic Assistant App.

Click to navigate to a section.

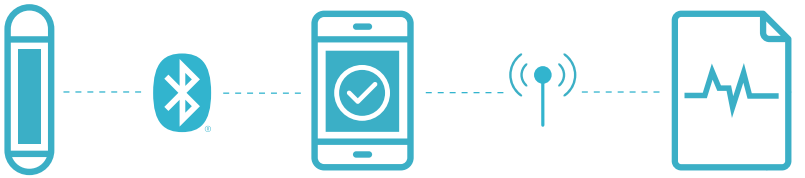
Indications

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
- Or have symptoms that may suggest a heart condition, such as dizziness, palpitations, syncope, chest pain, and/or shortness of breath

System Introduction



The Device
LUX-Dx™ ICM

The App
myLUX™

The Data
LATITUDE Clarity™

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

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

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

The ICM system consists of the following components:

SYSTEM COMPONENT	MODEL NUMBER	KIT NUMBER
LUX-Dx ICM	M301	N/A
myLUX Patient App	2925	6259
LATITUDE Clarity System	N/A	N/A
Magnet	6386	Included w/6259 and 6256
LUX-Dx Clinic Assistant App	2935	6256

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.

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

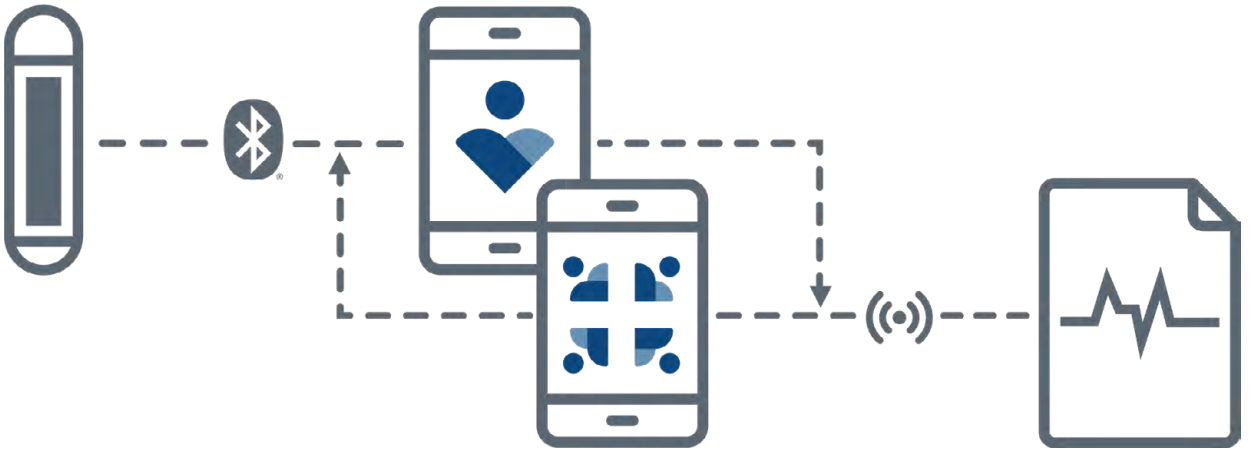
Available Reasons for Monitoring include:

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

The ICM device can be programmed to detect the following types of arrhythmia events:

- Pause
- Brady (bradycardia)
- Tachy (tachycardia)
- AF (atrial fibrillation)
- AT (atrial tachycardia)

How the System Works



System Overview

- Once implanted 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 usually happens each night as long as the myLUX Patient App is properly connected.
- 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.

System Components

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

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

Insertable Cardiac Monitor

Model Number: M301

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) per day. The five events include an S-ECG; if more than five events occur, a summary of each without S-ECG is saved.

Highest-priority events include:

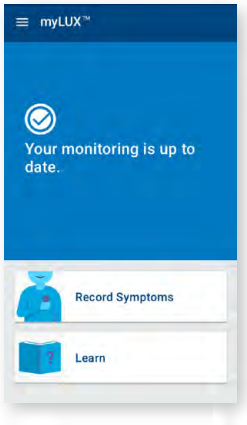
- **AF:** longest
- **AT:** no special priority
- **Brady:** lowest average rate
- **Pause:** longest
- **Tachy:** highest average rate

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 S-ECG 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 scenarios:

- Average of one auto-detected event per day
- Average of one patient-initiated event per month



myLUX™ Patient App *Model Number: 2925*

The myLUX Patient App is a mobile application pre-installed on a mobile device provided by Boston Scientific. The mobile device and app will come with device accessories (blue case, charger, magnet, and stand) and product literature in Kit #6259.

The primary purpose of the app is to activate the patient's implanted ICM and transmit data between the ICM and the LATITUDE Clarity™ server. 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.

While the myLUX Patient App is primarily intended for patient use, it also contains clinician tools to support the ICM implant 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*

Magnet

Model Number: 6386

The magnet is an accessory that comes in a shielded box. It is used to initiate communication between the ICM and the mobile applications. It is available as a separately packaged accessory in addition to being packaged in Kit #6256 or #6259 for the provided mobile devices.

In most cases, the magnet should be attached to the back of the mobile device case on *both* patient and clinic mobile devices. Mobile device cases will come with an adhesive circle already applied to the back of the case that is used to attach the magnet to the case.

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 depending on programming of the device's Bluetooth® Manual Connection parameter
- ✓ 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 or LUX-Dx Clinic Assistant App.

LATITUDE Clarity™ Data Management System

Overview

The LATITUDE Clarity System is a new and 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 healthcare 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 implant procedure

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

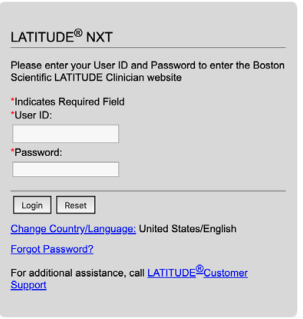
Go to: *Activate & Educate > Patient Enrollment in the LATITUDE Clarity System*

- ✓ 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: Internet Explorer, Microsoft Edge, Mozilla Firefox, Safari, Google Chrome

LUX-Dx Clinic Assistant App

Model Number: 2935

The LUX-Dx Clinic Assistant App is a mobile application pre-installed on a mobile device provided by Boston Scientific. The mobile device and app will come with accessories (white case, charger, magnet, and stand) and product literature in Kit #6256. The Clinic Assistant App is intended for use primarily during in-clinic follow-ups with patients to transmit data from their LUX-Dx ICM to LATITUDE Clarity™ or to apply any programming changes made from the website.

With the LUX-Dx Clinic Assistant App, you can perform the following functions:

- Connect to any LUX-Dx ICM within a range of 6 feet (2 meters)
- View device status
- View a real-time S-ECG
- Interrogate devices and transmit data to LATITUDE Clarity for review
- Apply programming changes made in LATITUDE Clarity to the ICM

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.

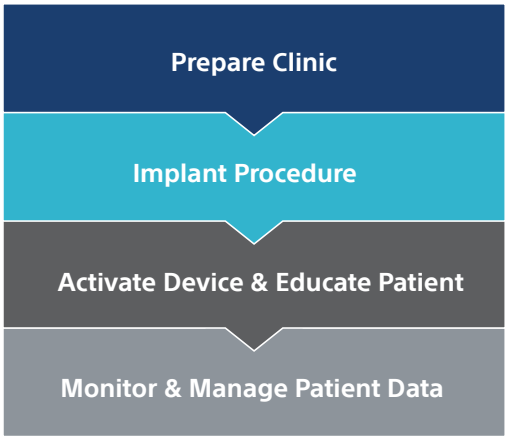
Go to: *In-Clinic Follow-Up Visits*

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, patient group, and individual user settings)
- Set up LUX-Dx Clinic Assistants
- Review device detection parameters, programming, alerts, and alert notifications (and establish any necessary protocols)

Implant Procedure

Steps of the implant procedure:

- Use mobile apps 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™ (complete online form).
- 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:

- Using mobile apps during implant
- Enrolling patients in LATITUDE Clarity
- Using mobile apps for device activation
- Messaging patients and managing compliance in LATITUDE Clarity
- Adjusting programming remotely
- Using the LUX-Dx Clinic Assistant App for in-clinic follow-ups
- Configuring 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.

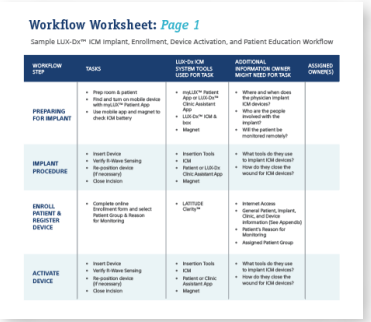
If possible, think through these decisions and get these settings in place for your clinic prior to your first LUX-Dx ICM patient.

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 as well as a space for you to assign an owner 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 implanting or following LUX-Dx ICMs.

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 using the myLUX™ Patient App. It will be critical to identify who is responsible for these two steps to make sure all ICMs are set up properly and these steps are completed in the right order.


Workflow Worksheet: *Page 1*

Sample LUX-Dx™ ICM Implant, Enrollment, Device Activation, and Patient Education Workflow

WORKFLOW STEP	TASKS	LUX-Dx ICM SYSTEM TOOLS USED FOR TASK	ADDITIONAL INFORMATION OWNER MIGHT NEED FOR TASK	ASSIGNED OWNER(S)
PREPARING FOR IMPLANT	• Prep room & patient • Unbox and turn on mobile device with myLUX™ Patient App • Use mobile app and magnet to check ICM battery	• myLUX™ Patient App • Patient or LUX-Dx Clinic Assistant App • LUX-Dx™ ICM & box • Magnet	• Where and when does the patient want to implant ICM device? • Who are the people involved with the implant? • Will the patient be monitored remotely?	
IMPLANT PROCEDURE	• Insert Device • Verify R-Wave Sensing • Re-position device (if necessary) • Close incision	• Insertion Tools • ICM • Patient or LUX-Dx Clinic Assistant App • Magnet	• What tools do they use to implant ICM devices? • How do they close the wound for ICM devices?	
ENROLL PATIENT & REGISTER DEVICE	• Complete online Enrollment form and select Patient Group & Reason for Monitoring	• LATITUDE Clarity™	• Internet Access • General Patient, Implant, Clinic, and Device information (See Appendix) • Patient's Reason for Monitoring • Assigned Patient Group	
ACTIVATE DEVICE	• Insert Device • Verify R-Wave Sensing • Re-position device (if necessary) • Close incision	• Insertion Tools • ICM • Patient or Clinic Assistant App • Magnet	• What tools do they use to implant ICM devices? • How do they close the wound for ICM devices?	

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.

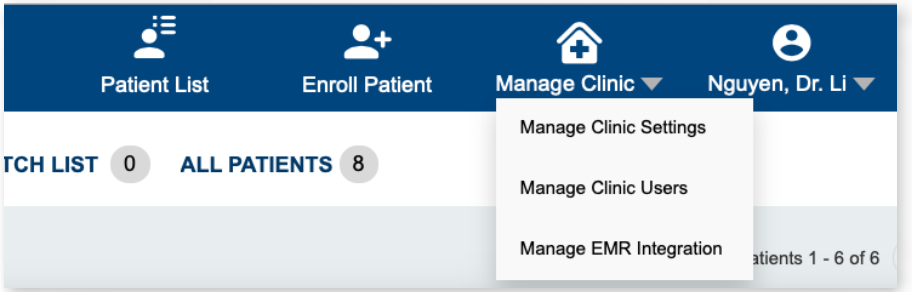
At enrollment, a Reason for Monitoring from this preset list must be selected:

- 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.

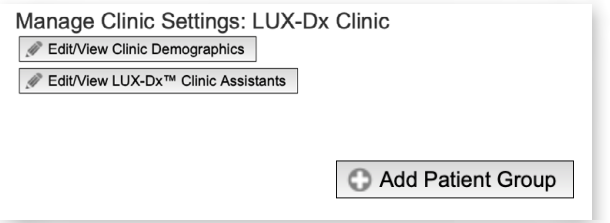
  When that is the case, it's noted with this symbol

- 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 and 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

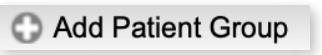
BY DEVICE TYPE

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 when 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.

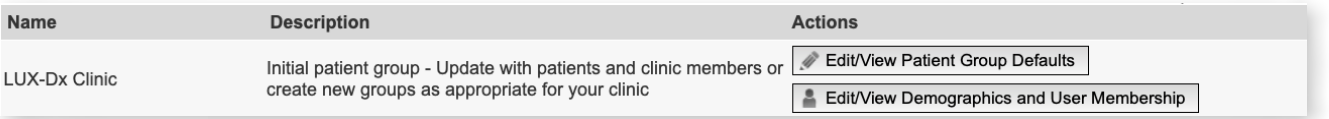
If you have questions about adjusting Patient Groups, please call Boston Scientific at 1-800-CARDIAC (1-800-227-3422).

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

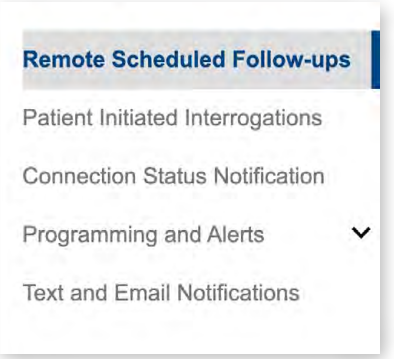
Text and Email Notifications

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

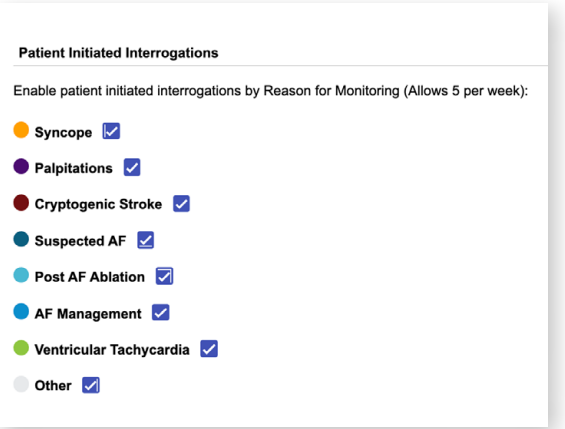
The day of the week you select will be the day the report shows up in LATITUDE Clarity.

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.

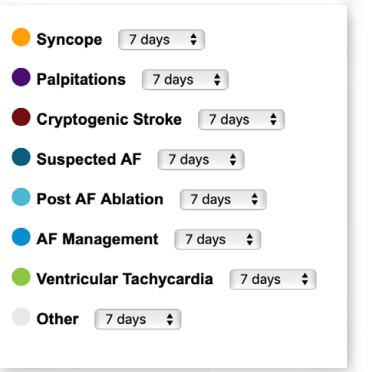
Connection Status Notification

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 to patients inheriting group settings within that Reason for Monitoring in this particular 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, select 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.

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

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

USER TYPE: **COMPLETE ACCESS**

(CLINIC ACCOUNT MANAGERS)

Intended For

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

Limitations

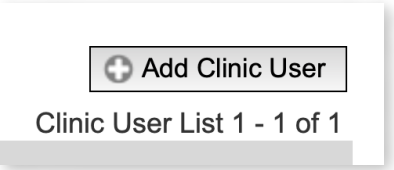
Access is open to all patients in all Patient Groups. No limitations.

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.

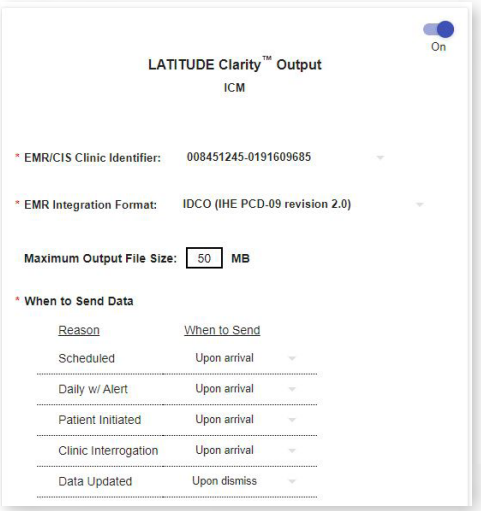
If your clinic already uses EMR integration with LATITUDE® NXT, enabling EMR integration for LATITUDE Clarity is an easy option. To set up EMR integration for LATITUDE Clarity, follow the instructions to the right.

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 Kit #6256, it will include a Quick Start Guide to help you get started.

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.

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 device.

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.

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

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

- *Pause*
- *Brady*
- *Tachy*
- *Atrial fibrillation (AF)*
- *Atrial tachy (AT)*

Pause

DETECTION:

The LUX-Dx ICM utilizes a dual-stage algorithm for Pause detection. A potential event is detected when the R-R interval exceeds the user-programmed Pause duration AND the device confirms that the Pause is not the result of under sensing.

- The LUX-Dx ICM uses signal noise ratio (SNR) to dynamically adjust the Pause interval under-sensing threshold to the surrounding R-Wave amplitude detections. Separate SNRs are computed using pre-Pause and post-Pause R-Waves, and will reject the data if the criteria are not met.
- Loss of signal or flatline episodes may be due to loss of electrode contact; the LUX-Dx ICM Pause algorithm attempts to reject these signals.

PROGRAMMABLE PARAMETERS:

- **Detection:** On/Off
- **Duration (seconds):** 1.5, 3, 4.5
- **Response:** Less, Balanced, More

Brady

DETECTION:

The LUX-Dx ICM utilizes a dual-stage algorithm for 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 under sensing.

PROGRAMMABLE PARAMETERS:

- **Detection:** On/Off
- **Rate (bpm):** 30, 40, 50, 60
- **Duration (seconds):** 1, 2, 3, 5, 7, 10, 15, 20, 30

Tachy

DETECTION:

The LUX-Dx ICM utilizes a dual-stage algorithm for 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 over sensing.

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 LUX-Dx ICM utilizes a dual-stage algorithm for 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 then verifies potential AF utilizing adaptive morphology, noise discrimination, and pattern detectors to minimize false positives, providing more accurate data.

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:

When there is an elevated ventricular rate for a user-programmable duration, the algorithm analyzes 2-minute windows to assess ventricular rate.

- Duration > 2 hours: 2-minute windows evaluated for V Rate
- Duration < 2 hours: 2-minute windows evaluated for V Rate and instability in heart rate to distinguish AT from normal sinus rhythms for shorter arrhythmias

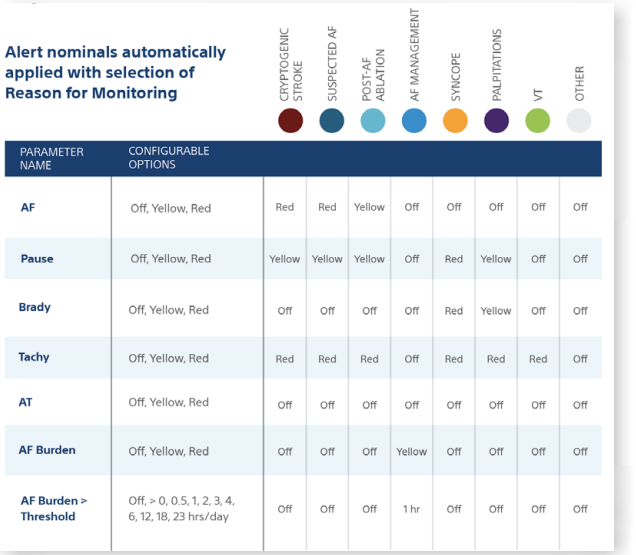
PROGRAMMABLE PARAMETERS:

- **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

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



Alert nominals automatically applied with selection of Reason for Monitoring		CRYPTOGENIC STROKE	SUSPECTED AF	POST-AF ABLATION	AF MANAGEMENT	SYNCOPE	PALPITATIONS	VT	OTHER
PARAMETER NAME	CONFIGURABLE OPTIONS								
AF	Off, Yellow, Red	Red	Red	Yellow	Off	Off	Off	Off	Off
Pause	Off, Yellow, Red	Yellow	Yellow	Yellow	Off	Red	Yellow	Off	Off
Brady	Off, Yellow, Red	Off	Off	Off	Off	Red	Yellow	Off	Off
Tachy	Off, Yellow, Red	Red	Red	Red	Off	Red	Red	Red	Off
AT	Off, Yellow, Red	Off	Off	Off	Off	Off	Off	Off	Off
AF Burden	Off, Yellow, Red	Off	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	Off	1 hr	Off	Off	Off	Off

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

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

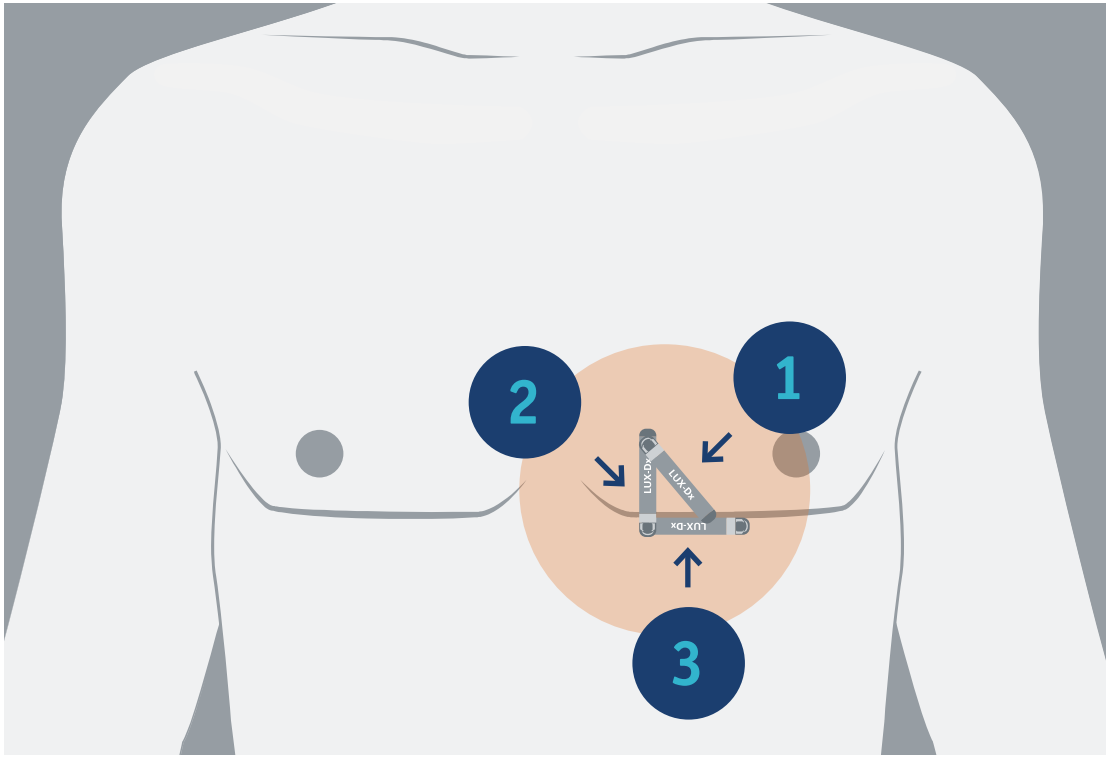
Implant Procedure

Whether you are directly involved in the implant 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.

Implant Locations

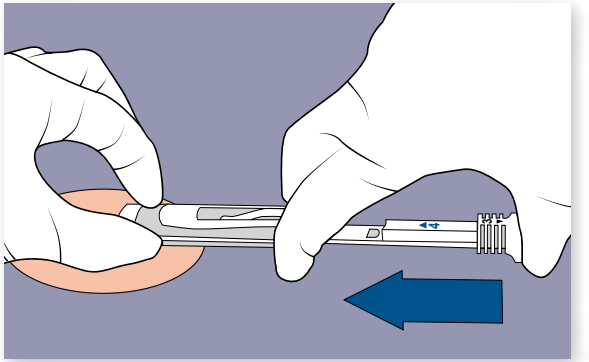
The device is typically positioned under the skin in the left pectoral region. Recommended implant locations are:



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

Implant Procedure

The LUX-Dx ICM implant procedure involves 4–5 steps, depending on the patient and implanting physician preference.



Steps include:

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

If you may be directly involved in the implant procedure, it will be important for you to also understand how the myLUX™ Patient App is used to support the procedure. The following steps are completed using the myLUX Patient App:

- **Pre-Implant:** ***Check Battery***

  Use the myLUX Patient App and magnet (provided in Kit #6259) to check the ICM battery before removing it from the box.

  1. Locate Kit #6259.
  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 implant the device and instead contact Boston Scientific using the information on the back of the device packaging.**

- **During Implant 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 implant 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: If necessary, these steps during implant can also be done with the LUX-Dx Clinic Assistant App using the Scan and Connect feature to view real-time S-ECG.

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.

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 implant:

1. The patient must be enrolled in the LATITUDE Clarity Data Management System.
2. The patient's implanted 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 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, but 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 implant and patient information required on the Enrollment form

See required fields for enrollment.

Go to: *Additional Resources > Enrollment Form Fields*

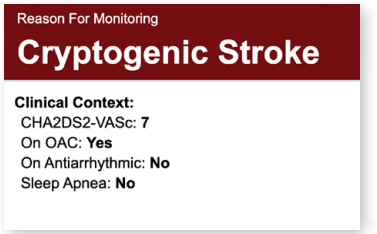
- ✓ Attention to detail so data is entered properly at this stage

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 *Enroll Patient* on the top navigation bar.

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.



For full context, follow along with LATITUDE Clarity.

Once enrollment is complete, you will see a confirmation page with an option to generate a PDF file of the completed Enrollment form.

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.

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. You will most often do this using the myLUX Patient App; however, there may be times you have to use the LUX-Dx Clinic Assistant App instead. 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 implant procedure, this part of the process is still *required* after enrollment to activate the ICM.

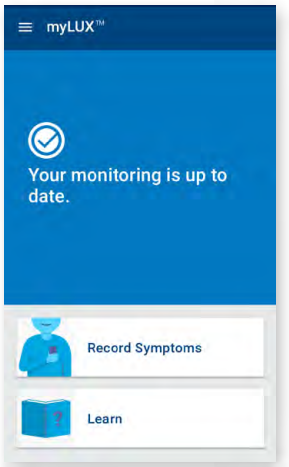
If you intend to monitor a LUX-Dx ICM patient remotely, you will typically activate the ICM by pairing it with the myLUX Patient App using Bluetooth® wireless technology. By completing this process, you are also helping the patient get their home-monitoring equipment set up simultaneously.

workflow tip: Setting up the myLUX Patient App requires an active internet connection via a cellular or Wi-Fi network.

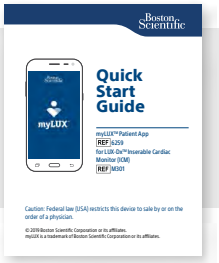
Steps to Set Up myLUX Patient App and Activate ICM

1. Attach the magnet to the mobile device case (if not already done during implant procedure).
2. Press the power button on the right side of the mobile device. You may have to plug the device in if it isn't sufficiently charged.
3. Open the myLUX Patient App by tapping the app icon in the middle of the first screen.
4. Confirm the language selection.
5. Ask that the patient agree to the privacy policy and terms of use on screen.
6. Tap *Start Setup*.
7. Follow the instructions on the screen that ask you to hold the magnet over the patient's implanted ICM. When it connects, the mobile device will vibrate briefly.

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



note: This process is also covered in the Quick Start Guide provided in the patient's mobile device box.



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.

note: If the patient's ICM has not been activated, you will see the model and serial number of the ICM only.

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-implant procedure, you may consider covering the following topics at least once with every patient.

note: In Kit #6259 you will find product literature (Handbook and Quick Start Guide) that you may find useful in conversations with patients.

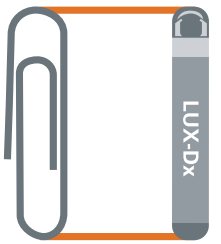
- ☑ **Introduce Function of ICMs**
- ☑ **Discuss Procedure and Wound Care**
- ☑ **Explain the LUX-Dx ICM System and Its Parts**
- ☑ **Set Expectations for Remote Monitoring and Follow-Up**
- ☑ **Set Up the myLUX Patient App and Discuss App Uses**
- ☑ **Discuss Home-Monitoring Reminders**
- ☑ **Review 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 healthcare 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

The LUX-Dx ICM is about the length of a paper clip.



Discuss Procedure and Wound Care

- Review any required pre-implant preparation.
- Discuss what will happen during the procedure, including implant technique, size of device, and possible location for implant.
- After the procedure, review recovery expectations, wound care, and discharge instructions.

note: In materials specifically for patients, the procedure will be called an insertion procedure (not an implant procedure) to help them understand this device is simply inserted beneath the skin.

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 mobile device must be powered on, connected to Wi-Fi or a cellular network, and located within 6 feet of the patient for an extended period of time. Many providers recommend that the patient keep the mobile device by their bedside just like a typical home monitor for other device types.
- 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, confirm the magnet is attached to the back of the provided mobile device case.
- Turn on the mobile device using the power button on the right side of the device. The device may need to be plugged in if it isn't sufficiently charged.
- The myLUX Patient App will be the only app available; open the app.
- Confirm the language selection.
- Ask that the patient agree to the privacy policy and terms of use on screen.
- Tap *Start Setup*.
- Follow the instructions on the screen that ask you to hold the magnet over the patient's implanted ICM. When it connects, the mobile device will vibrate briefly.
- Once you see the screen that says "Your monitoring is up to date," you may want to point out a few things about the app to the patient. You can use the next section as a guide on what to review with the patient.

Discuss Home-Monitoring Reminders

- To help patients stay connected, you can offer them a few simple reminders:
  - Keep the mobile device powered on and charged.
  - Set the mobile device within 6 feet of where they sleep.
    - If this is not possible, help the patient identify a place where they spend a considerable amount of time each day (60 minutes or more) in the same spot. Some ideas may be where they eat a meal, read, or watch television.
  - 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.
- 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 mobile device at all times unless you'd like the patient to record symptoms.

Review Available Resources

- See the list on the next page.

Patient Education Resources

To support LUX-Dx ICM patients pre- and post-implant 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
Patient Brochure	• Overview of Reasons for Monitoring, the LUX-Dx ICM, and the insertion procedure • Basic steps to get started with the myLUX Patient App	Contact your Boston Scientific representative
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 Guide	• **Handbook:** Describes ICM system and how to use myLUX Patient App as well as covers warnings and safety precautions • **Quick Start Guide:** myLUX Patient App setup instructions	Product literature provided in Kit #6259 or ordered directly from Boston Scientific

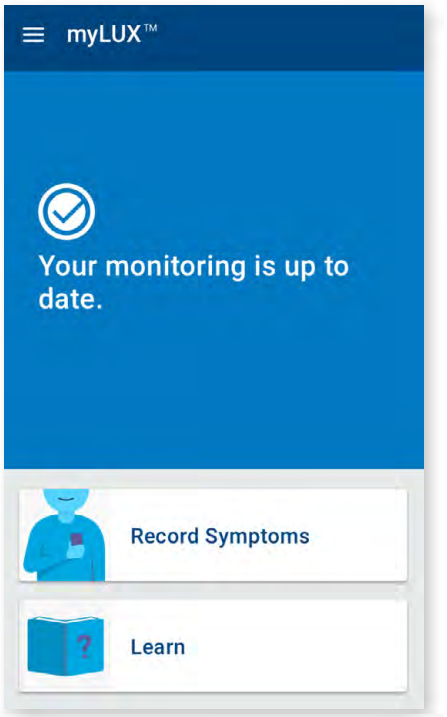
In addition to what is listed here, you will find similar information and patient education videos on both ***bostonscientific.com/luxdx*** and the LUX-Dx ICM training site for clinicians on EDUCARE at ***luxdxtraining.com***. Boston Scientific will continue to add to these sites as necessary with new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

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.

Functions of the myLUX Patient App:

The primary purpose of the app is to activate the patient's implanted 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 system and the clinic and stay connected.

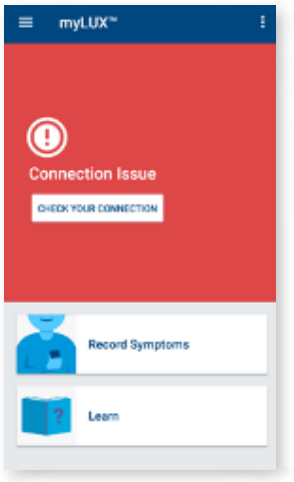


These features include:

- **Monitoring Status**
- **Record Symptoms**
- **Messages**
- **Education**
- **Manual Transmission**

Monitoring Status

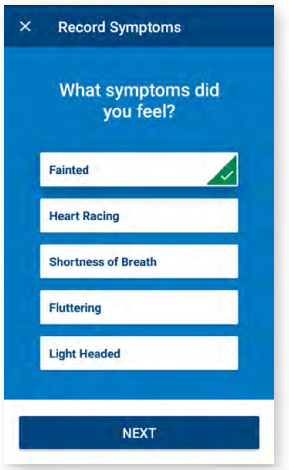
- Displays current monitoring status AND notifies patient of connection issues on the main screen of the app. Remind the patient that if they see a screen with an exclamation point, they should follow the instructions on the screen. In this example, they would tap the *Check Your Connection* button.



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

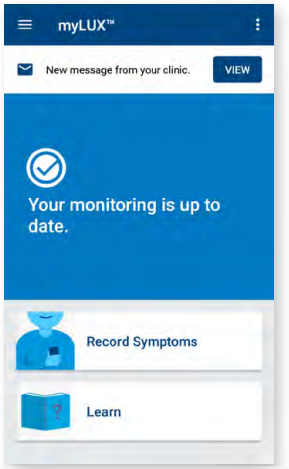
If enabled by the clinic, this feature helps patients track symptoms by recording what they were feeling and the activity they were doing when they felt their symptom.



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.

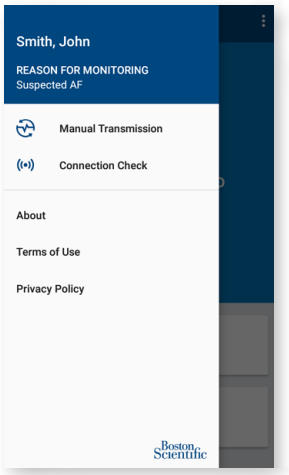


Education

The Learn button included on the main screen of the app gives the patient access to educational resources directly from the app. Patients can tap the Learn button at any time to learn more about the system and app.

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.

workflow tip: If a patient ever loses their 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 a patient's mobile device, please contact Boston Scientific.

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.

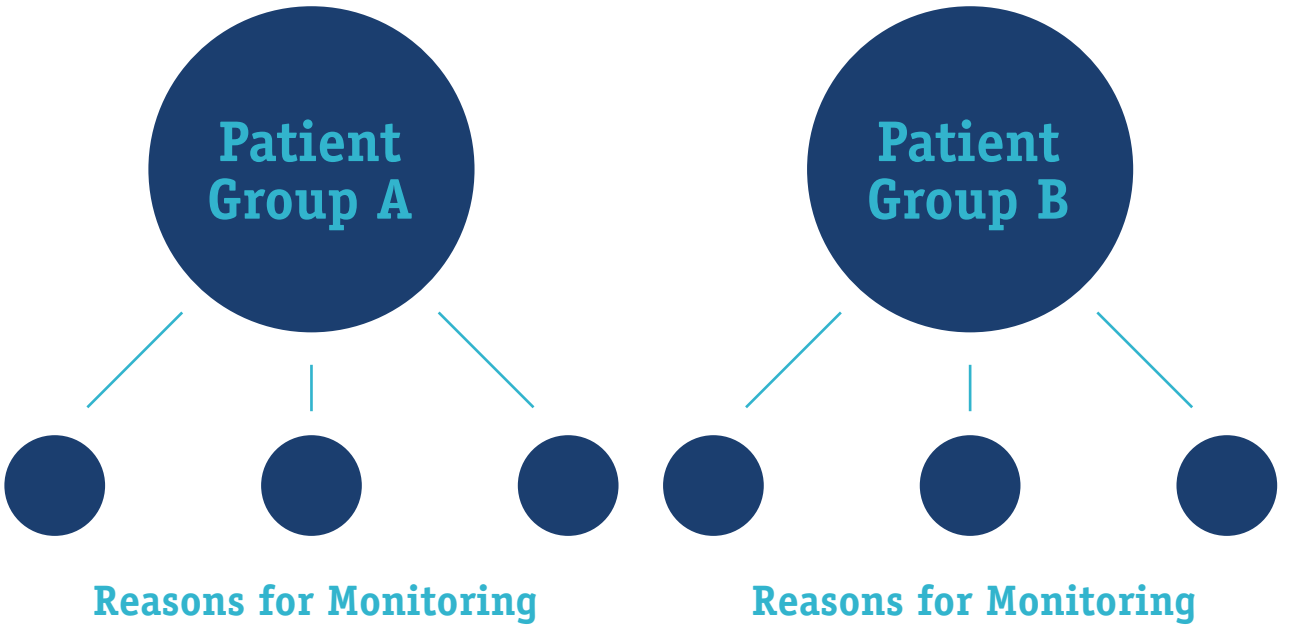
Go to: *Activate & Educate > Patient Enrollment in the LATITUDE Clarity System*

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

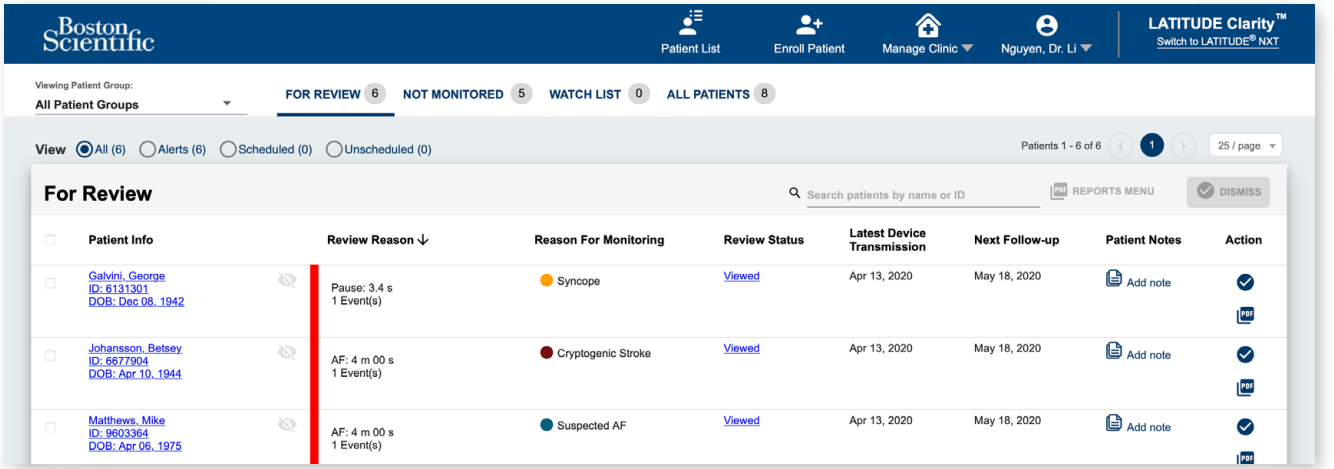
For full context, follow along with LATITUDE Clarity.

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. **Enroll Patient:** This links to the online Enrollment form used to enroll new ICM patients in LATITUDE Clarity.
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

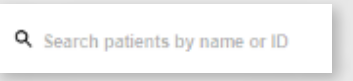
When you log in to, or switch over to, LATITUDE Clarity™, the first page displayed is called the Patient List. This page provides a list of all the ICM patients to which you have access. The Patient List will be your guide to planning and prioritizing your day and understanding at a high level which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

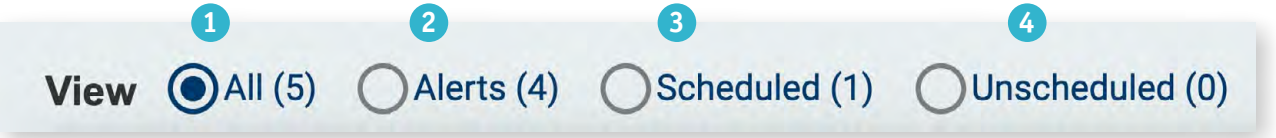
For full context, follow along with LATITUDE Clarity™.

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 or assessed. 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:



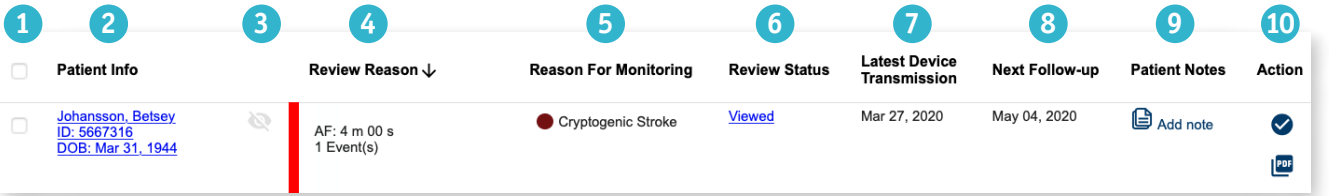
For full context, follow along with LATITUDE Clarity™.

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.

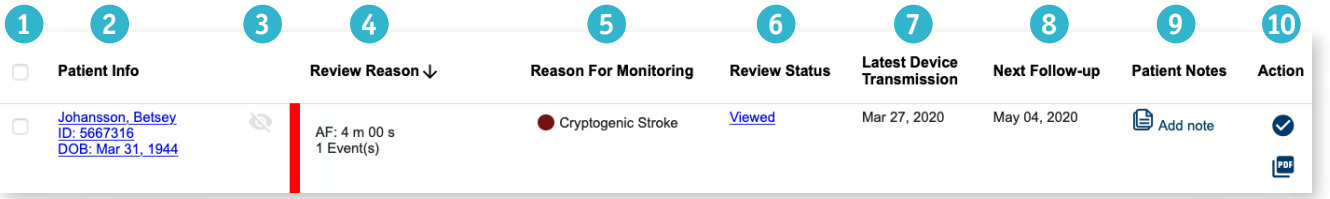


To better understand this page and how you can use it, please review the summary of each column included below and on the next pages.

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.

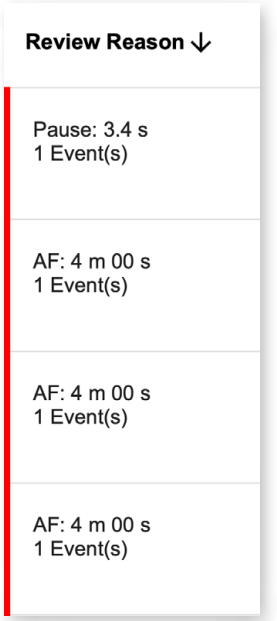


For full context, follow along with LATITUDE Clarity™.

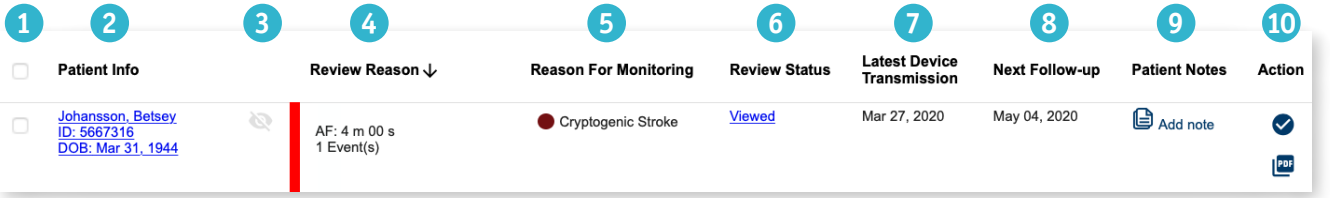
3 **Watch List Icon:** This column will indicate if a particular patient is currently assigned to the Watch List. The Watch List icon will appear filled in next to the patient's name if they are currently on the Watch List. If the patient is not on the Watch List, the icon will appear gray with a slash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

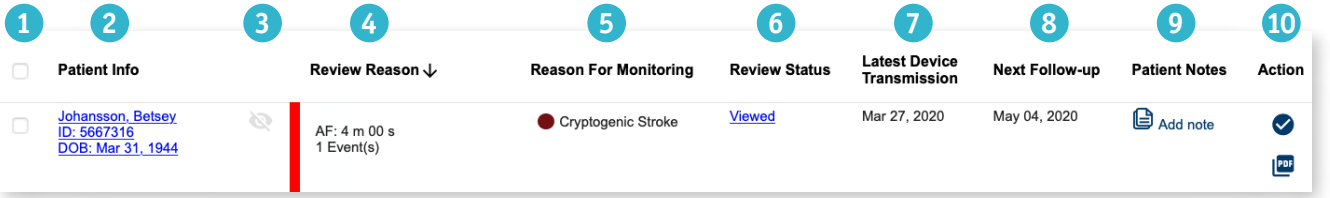
- If more than one alert condition is met, the colored bar will indicate the more severe condition that was met.
- Data may appear on this list that doesn't include a colored bar. This means there is new data for review, but that data doesn't have an alert associated with it.
  - ***Example:*** A manual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

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



4 **Review Reason (continued):**

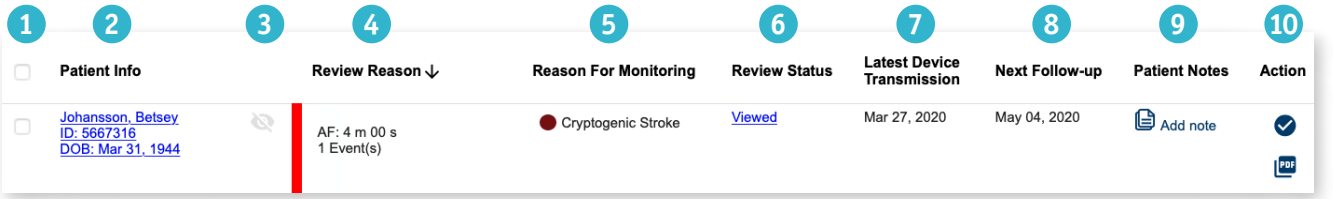
Number of Undismissed Events: This is a simple count of events for review that have not yet been dismissed or assessed.

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 or assessed. 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.

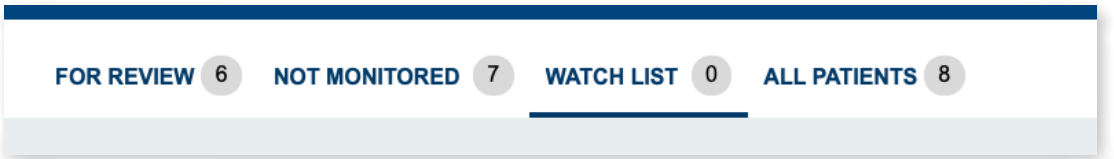
workflow tip: You can use the **Monitoring Status/Date** column to find more information about what a connection issue might be. Click on the link provided in this column to investigate the issue further. The system will attempt to identify the issue in this pop-up window. One common issue you may see 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*

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™.

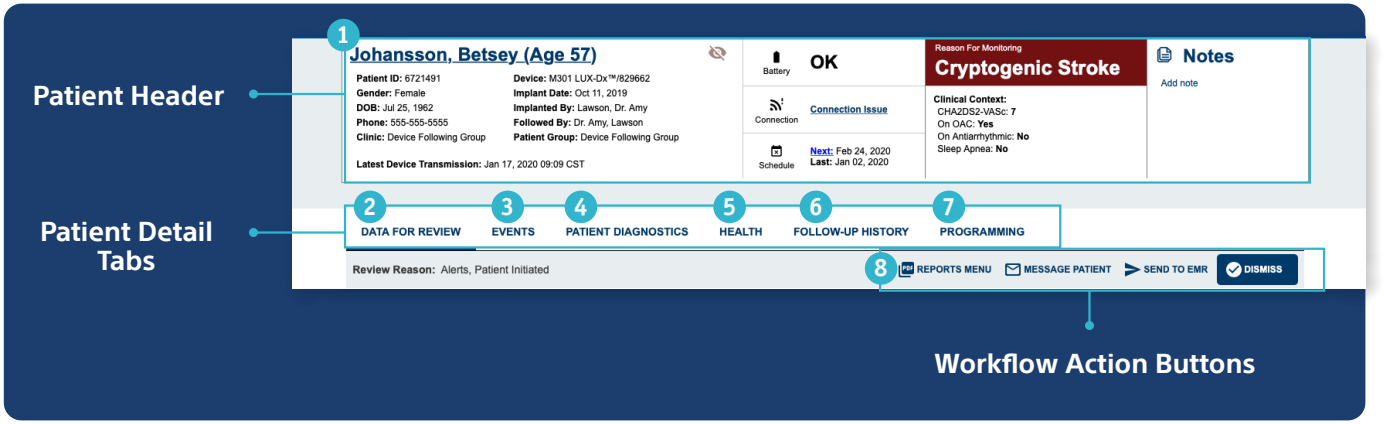
Within the same clinic, all users will be able to see which patients are on the Watch List. Users with CAM or Limited access will be able to modify the Watch List, and users with Read Only access will not be able to modify this list. When on the Watch List, patients will be listed in order of new alert 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:



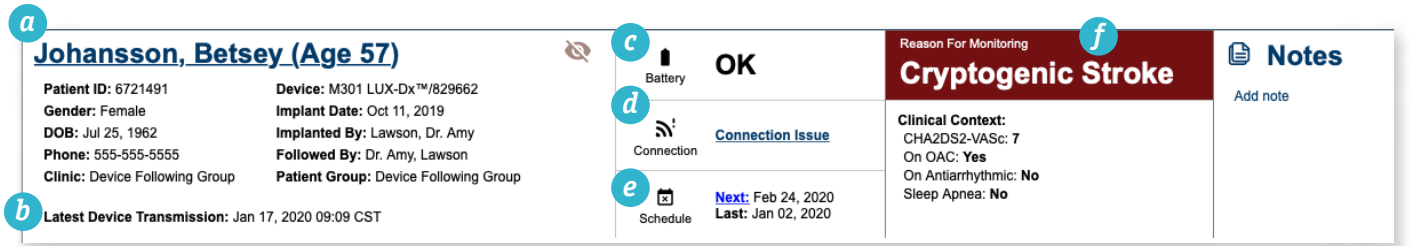
For full context, follow along with LATITUDE Clarity™.

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.

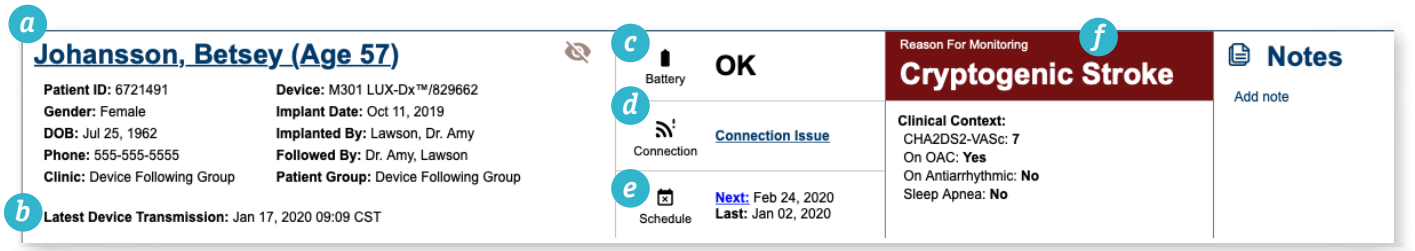
Much of the information included in the Patient Header is pulled directly from information entered into the Enrollment form. Patient information can be edited by clicking the patient's name in the Patient Header.

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 implant, 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:

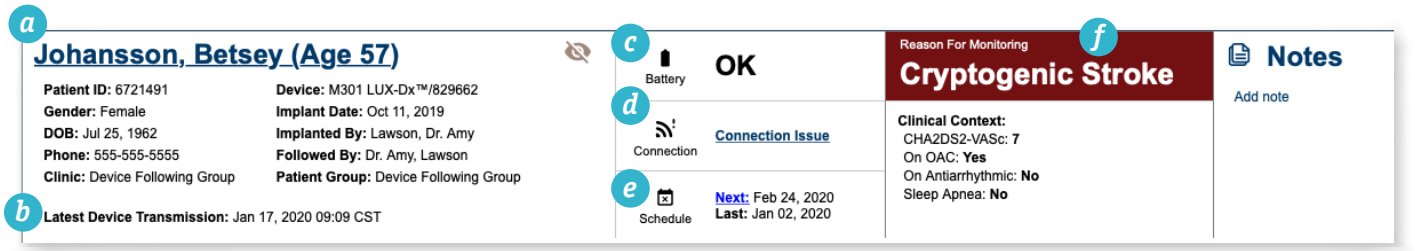
- Battery is OK
- RRT (recommended replacement time) with a date that indicates a 30-day window for replacement
- EOS (end of service) with a date this occurred

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.

Below the Patient Header, all patient data is organized by a series of 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)

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

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 Table*

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.

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

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.

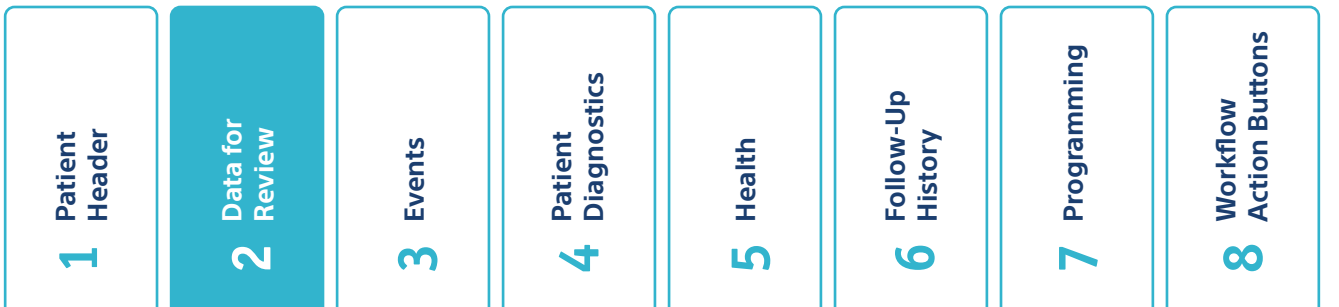
For more information on this section, see the Patient Diagnostics tab.

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.

For more information on this section, see the Health tab.

Navigate below to: *5: Health*



Data for Review Event Logbook: *All new events*

d

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:
  - AF: longest
  - AT: no special priority
  - Brady: lowest average rate
  - Pause: longest
  - Tachy: highest average rate
- 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.

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.

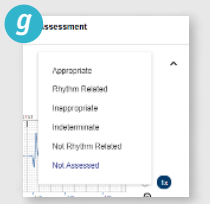
For example: AF-11 means the event detected is atrial fibrillation and this is the 11th AF event recorded by the device for this patient.

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: 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.

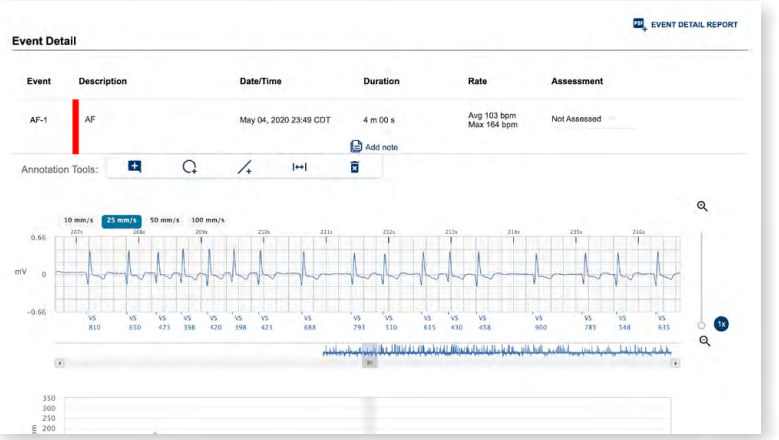


Event Detail

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.

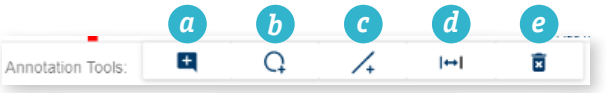
note: Event Detail pop-up windows are available only for events that have an S-ECG available.

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

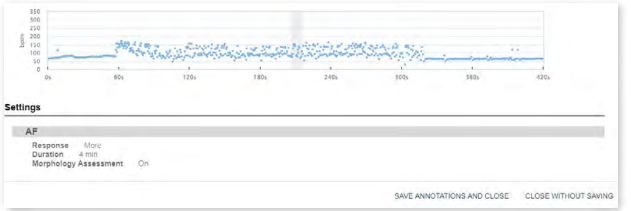
- The S-ECG will automatically display the most relevant portion of the S-ECG based on event type. You can use the scroll bar at the base of the S-ECG to move backward or forward in time from this point. The S-ECG will move with your adjustment.
- Event time in seconds will be displayed at the top of 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.

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

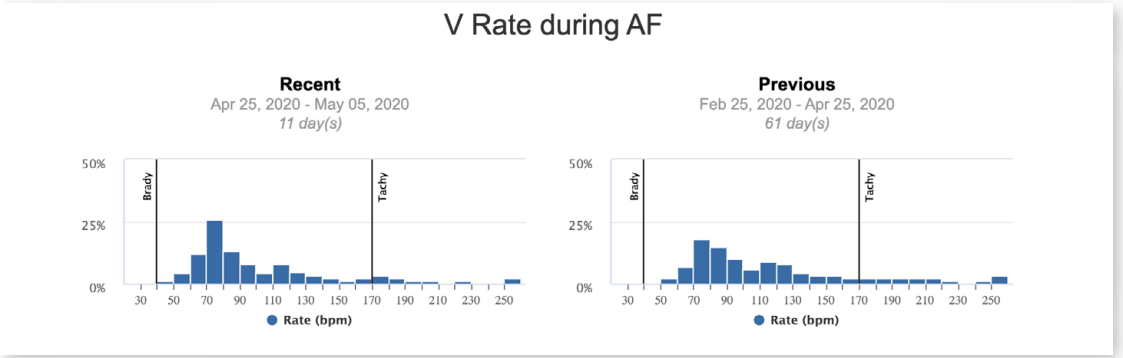
For full context, follow along with LATITUDE Clarity™.

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:

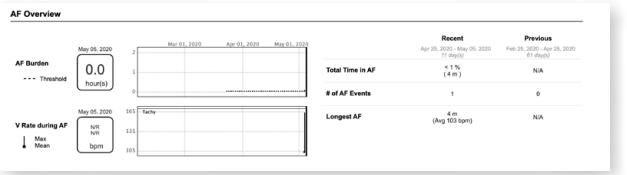
- All four histograms show the rate distribution of ventricular events as the percentage of the total number of events in the follow-up period.
    - On the V Rate during AF chart, only beats during device-detected AF are considered.
- Each histogram shows 22 rate ranges that are 10 bpm wide.
- Rates 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, 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.

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.

Trends

Trends are listed below the AF 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 timeframe. 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

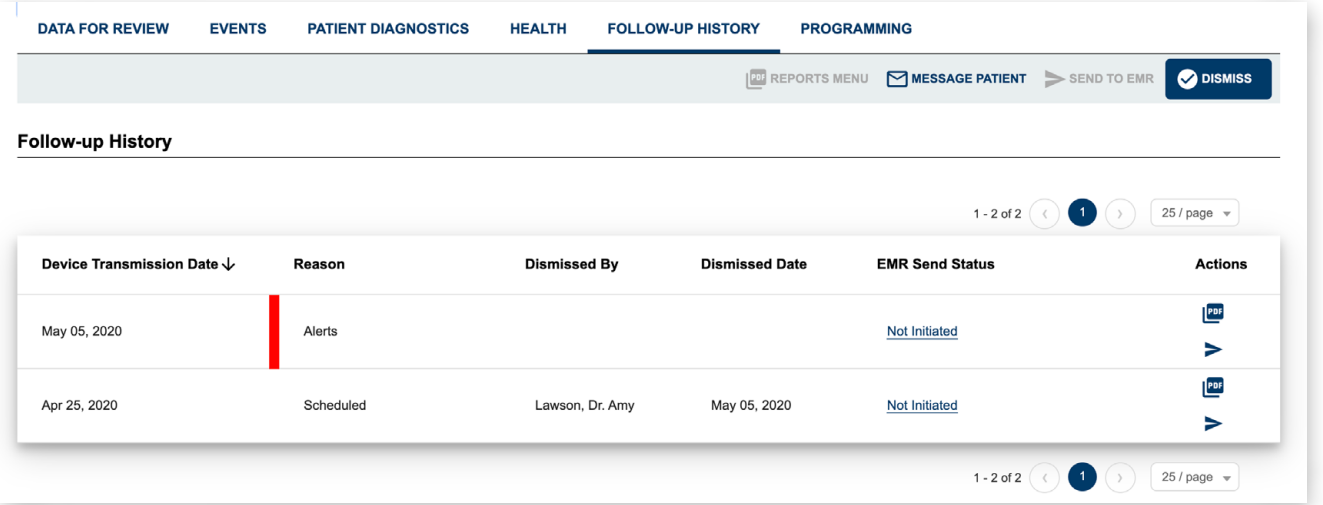
V Rate during AF: The patient's maximum and mean or average V Rates during AF episodes in a given day

note: All charts 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*

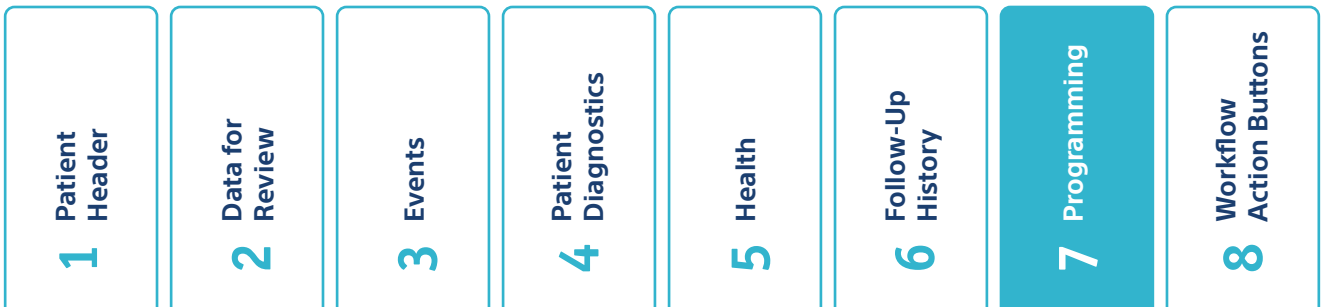
The Programming tab is where you can view or modify a patient's Reason for Monitoring as well as adjust device parameters related to sensing, event detection, symptoms, and alerts, including:

- Reason for Monitoring
- Sensing parameters (Blank After Sense, Sensitivity, and Morphology)
- Brady
- Tachy
- Pause
- Symptom
- AT
- AF
- 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

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

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

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.

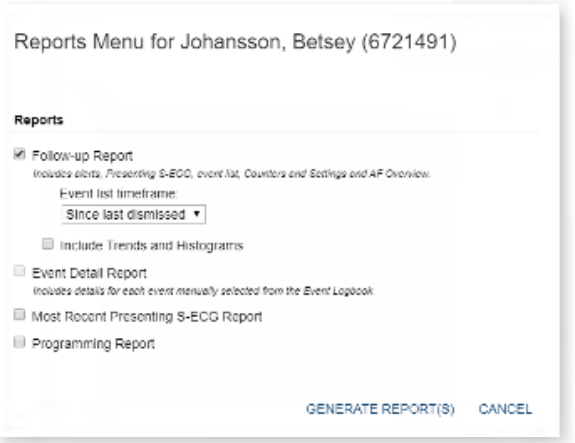
From this window, you can select all the other information you wish to configure for your reports, including the timeframe of the report. To do this, use the drop-down menu to choose an Event Timeframe of either *Since Last Dismissed* or *Since Last Scheduled*.

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.

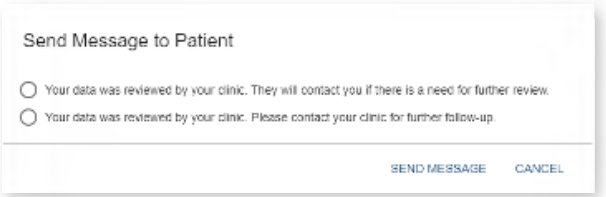


For full context, follow along with LATITUDE Clarity.

Communicating with Patients

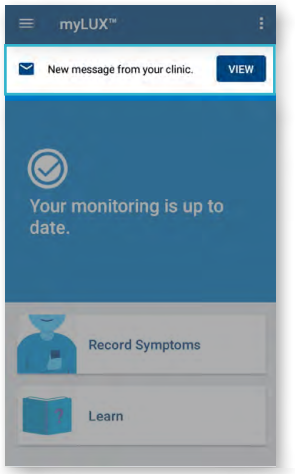
LATITUDE Clarity™ gives you the option to send a one-way (read-only) message to a patient's myLUX™ Patient App confirming your review.

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*

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:

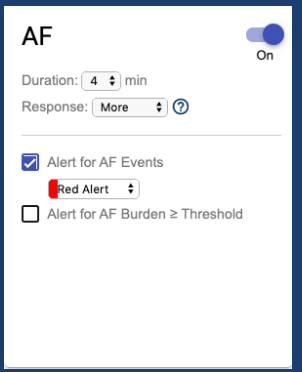
Definition: This box will determine whether the patient's ICM is inheriting settings from the broader Patient Group settings or if settings should be considered custom to this patient.

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 the minimum R-Wave amplitude and greater-than P-Wave amplitude. Only program to the most sensitive setting if R-Wave amplitudes are less than 0.15 mV.
- **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 Tachy detection – Will use R-Wave morphology to discriminate noise and to categorize VT/VF and SVT

Note/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.*

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 (2 out of 5 beats) is maintained for programmed duration, additional criteria are applied to verify that the slow-rate event is not the result of under sensing.

Programmable Parameters:

Detection: On/Off

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

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

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 (3 out of 10 beats) is maintained for programmed duration, additional criteria are applied to verify that the high-rate event is not the result of over sensing.

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: Dual-stage algorithm for detection

Detection occurs when the R-R interval exceeds the user-programmed Pause duration and the device confirms that the Pause is not the result of under sensing.

- Uses signal noise ratio (SNR) to dynamically adjust the Pause interval under-sensing threshold to the surrounding R-Wave amplitude detections. Separate SNRs are computed using pre-Pause and post-Pause R-Waves, and the algorithm rejects the false positive if the criteria are not met.
- Loss of signal or flatline episodes may be due to loss of electrode contact; these signals are rejected by the LUX-Dx ICM Pause algorithm.

Programmable Parameters:

- **Detection:** On/Off
- **Duration (seconds):** 1.5, 3, 4.5
- **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: When the device detects an elevated ventricular rate for a user-programmable duration, an algorithm analyzes 2-minute windows to assess ventricular rate.

- Duration > 2 hours: 2-minute windows evaluated for V Rate
- Duration < 2 hours: 2-minute windows evaluated for V Rate and instability in heart rate to distinguish AT from normal sinus rhythms for shorter 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: Dual-stage algorithm for detection.

- The first stage uses a 2-minute window to analyze R-R variability and a heart rate density index to detect potential AF rhythms.
- The second stage then verifies potential AF utilizing adaptive morphology, noise discrimination, and pattern detectors to minimize false positives.

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

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*.

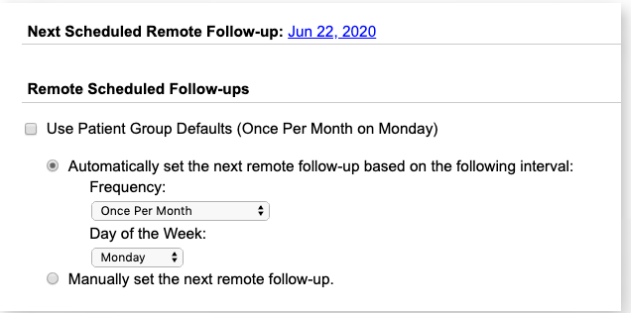
- **Require Magnet:** In this mode, the patient must apply the magnet close to the ICM before recording symptoms and resolving some connection issues. This will be your default setting, as this will apply to most patients followed remotely. This mode will help preserve battery longevity.
- **No Magnet 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™.

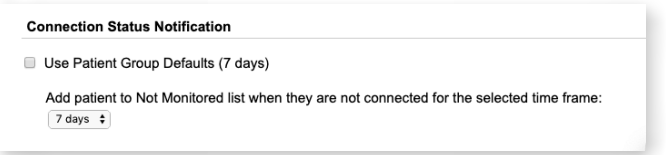
note: The link will say *Missed* if a patient has missed the remote scheduled follow-up.

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™.



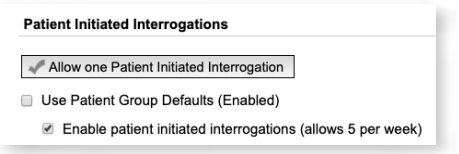
For full context, follow along with LATITUDE Clarity.

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.

† = Pending Delivery To Device

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.

In-Clinic Follow-Up Visits

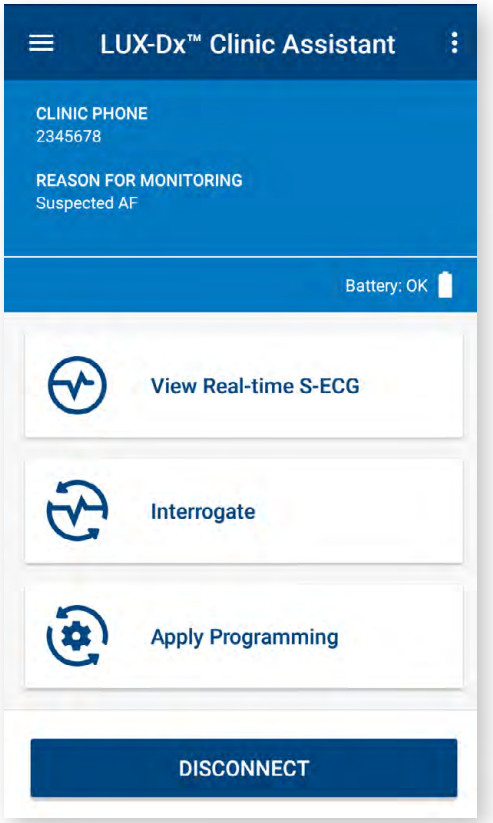
When LUX-Dx ICM patients come into the clinic or ER for a scheduled or unscheduled visit, the LUX-Dx Clinic Assistant App will be able to connect to, and interrogate, any LUX-Dx ICM, regardless of where that patient is followed. To perform some of the tasks to the right, you will need access to the LUX-Dx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

Click to navigate to a section.

In-Clinic Follow-Up Visits: 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. To connect to Wi-Fi, follow these instructions:

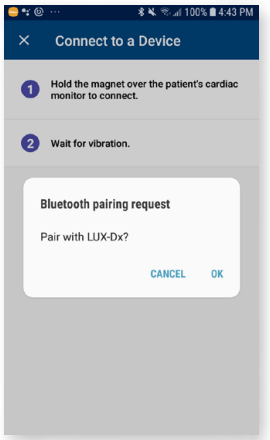
1. Press the home button on the mobile device.
2. Tap the down arrow in the upper-right corner of the screen.
3. Tap the *Settings* icon.
4. Tap *Wi-Fi*.
5. Select the network you are trying to connect to from the list of available networks.
6. Follow instructions on the screen; you may be prompted to 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.

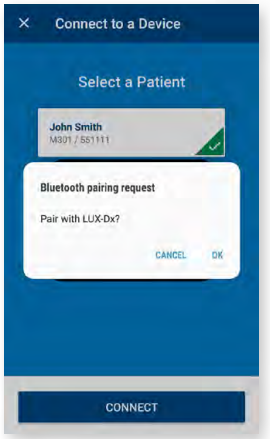


2

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.

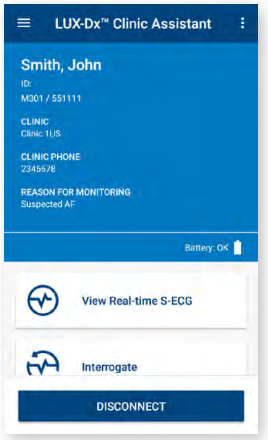
Connecting to a LUX-Dx ICM (continued)

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

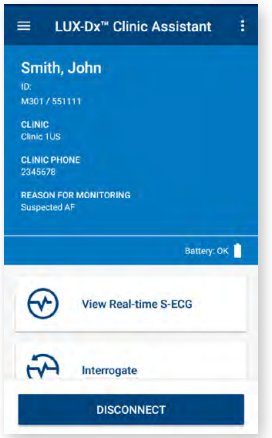
Once you are connected to a patient's device, the screen will show you an option to view a real-time S-ECG. You can use this feature to verify that the device-sensing amplitude is adequate or simply to view a live rhythm.



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

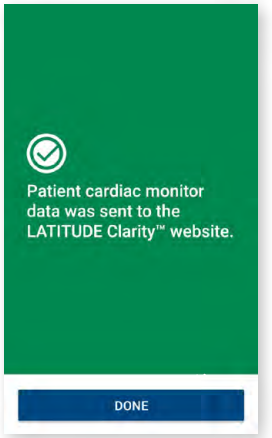
Interrogating LUX-Dx ICMs

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: 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: Clinics will be able to view patient data only for the patients they follow. The LUX-Dx Clinic Assistant App will be able to interrogate any LUX-Dx ICM, but to view that data from a LUX-Dx ICM you do not follow, you must work directly with the patient's following clinic or call Boston Scientific at 1-800-CARDIAC (1-800-227-3422).

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*

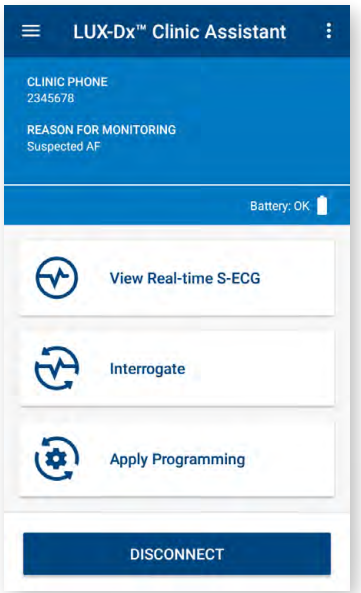
1. Connect to and interrogate the ICM.
2. Log in to LATITUDE Clarity™ using a different device with access to ***latitude.bostonscientific.com***.
3. Navigate to the appropriate patient. The patient should show up on the For Review page with a Review Reason of Clinic Interrogation.
4. Review the patient's 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.

Continued on the next page

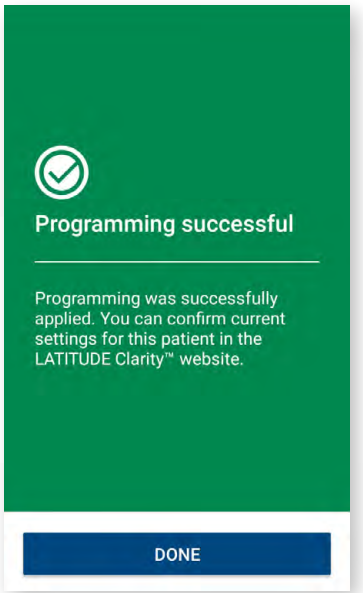
Applying Programming

Continued from the previous page

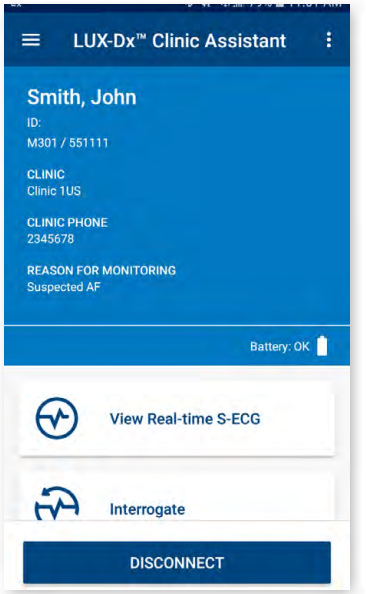
7 Select *Apply Programming.* (If the app has timed out, you may need to connect to the patient's device again.)



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 implant and follow-up visits.
- The LUX-Dx ICM System has a dedicated section on Boston Scientific's Rhythm Management Learning Center hosted on EDUCARE. This site can be found at ***luxdxtraining.com***.
- ***bostonscientific.com/luxdxicmsystem***
- Talk to your Boston Scientific representative.
- Contact Boston Scientific Support, available 24/7 at 1-800-CARDIAC (1-800-227-3422).

Click to navigate to a section.

LUX-Dx ICM Device Interrogation Features

Interrogation Type/Reason	Schedule	Configuration Options in LATITUDE Clarity™
Daily Alert Checks	• Attempted daily • Will always provide S-ECG even if the system does not detect an alert and therefore perform full interrogation	**Not configurable**
Remote Scheduled Follow-Ups	As configured	• **From Once Per Week to Once Every Twelve Months on a selected day of the week** • **Date may also be manually scheduled**
Patient-Initiated Interrogations (PIIs)	• Manual (as requested by clinic) • Performed by myLUX™ Patient App	**Enabled or Disabled**
Clinic Interrogations	• Manual • Performed by LUX-Dx Clinic Assistant app	**As directed by clinic**
Data Updated Reason	Typically occurs when Daily Alert Checks detect a possible alert condition but LATITUDE Clarity determines that there is no new alert condition for the patient	**Not configurable**

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

Detection Algorithm Nominal Parameters

PARAMETER NAME	CONFIGURABLE OPTIONS	CRYPTOGENIC STROKE	SUSPECTED AF	POST-AF ABLATION	AF MANAGEMENT	SYNCOPE	PALPITATIONS	VT	OTHER
Blank After Sense	130–400 @ 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							
AF Detection	On, Off	On							
AF Response	Least, Less, Balanced, More, Most	More	More	More	Balanced	Less	Balanced	Less	Balanced
AF Duration	2, 4, 6, 10, 20, 30, 60 (mins)	4	4	4	10	10	10	10	6
AT Detection	On, Off	On							
AT Duration	2, 6, 10, 20, 30, 60 (mins) 2, 3, 4, 6, 8, 10, 12, 16, 24 (hrs)	4 hrs							

LUX-Dx ICM System Programming:
Page 2

Detection Algorithm Nominal Parameters

PARAMETER NAME	CONFIGURABLE OPTIONS	CRYPTOGENIC STROKE	SUSPECTED AF	POST-AF ABLATION	AF MANAGEMENT	SYNCOPE	PALPITATIONS	VT	OTHER
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							
Pause Detection	On, Off	On							
Pause Duration	1.5, 3, 4.5 (secs)	3							
Pause Response	Less, Balanced, More	Less	Less	Less	Less	More	Balanced	Less	Balanced
Tachy Detection	On, Off	On							

LUX-Dx ICM System Programming:
Page 3

Detection Algorithm Nominal Parameters

PARAMETER NAME	CONFIGURABLE OPTIONS	CRYPTOGENIC STROKE	SUSPECTED AF	POST-AF ABLATION	AF MANAGEMENT	SYNCOPE	PALPITATIONS	VT	OTHER
Tachy Duration	0, 1, 2, 3, 4, 5, 10, 15, 20, 25, 30, 40, 50, 60 (secs)	5							
Tachy Rate	115–220 bpm (increments of 5)	170							
Tachy Response	Less, Balanced, More	Less	Less	Less	Less	More	Balanced	More	Balanced
Symptom Recording	On, Off	On							
Symptom Recordings Allowed per Day	3 (10 mins/event) 4 (7.5 mins/event) 6 (5 mins/event)	4 (7.5 minutes/event)							
Manual Bluetooth® Connection	Require Magnet, No Magnet	Require Magnet							

LUX-Dx ICM System Alert Nominals:

Page 1

Alert nominals automatically applied with selection of Reason for Monitoring

PARAMETER NAME	CONFIGURABLE OPTIONS	CRYPTOGENIC STROKE	SUSPECTED AF	POST-AF ABLATION	AF MANAGEMENT	SYNCOPE	PALPITATIONS	VT	OTHER
AF	Off, Yellow, Red	Red	Red	Yellow	Off	Off	Off	Off	Off
Pause	Off, Yellow, Red	Yellow	Yellow	Yellow	Off	Red	Yellow	Off	Off
Brady	Off, Yellow, Red	Off	Off	Off	Off	Red	Yellow	Off	Off
Tachy	Off, Yellow, Red	Red	Red	Red	Off	Red	Red	Red	Off
AT	Off, Yellow, Red	Off	Off	Off	Off	Off	Off	Off	Off
AF Burden	Off, Yellow, Red	Off	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	Off	1 hr	Off	Off	Off	Off

LUX-Dx ICM System Alert Nominals:

Page 2

Alert nominals automatically applied with selection of Reason for Monitoring

PARAMETER NAME	CONFIGURABLE OPTIONS	CRYPTOGENIC STROKE	SUSPECTED AF	POST-AF ABLATION	AF MANAGEMENT	SYNCOPE	PALPITATIONS	VT	OTHER
Symptom (patient-recorded)	Off, Yellow, Red	Off	Off	Off	Off	Off	Yellow	Yellow	Off
Symptom + Device-Detected Episode	Off, Yellow, Red	Red	Red	Red	Off	Red	Yellow	Red	Yellow
Monitoring Disabled	Off, Yellow, Red	Red	Red	Red	Red	Red	Red	Red	Red
Battery Recommended Replacement Time (RRT)	Off, Yellow, Red	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow

Workflow Worksheet: *Page 1*

WORKFLOW STEP	TASKS	LUX-Dx ICM SYSTEM TOOLS USED FOR TASK	ADDITIONAL INFORMATION OWNER MIGHT NEED FOR TASK	ASSIGNED OWNER(S)
Sample LUX-Dx ICM Implant, Enrollment, Device Activation, and Patient Education Workflow				
PREPARING FOR IMPLANT	• Prep room and patient • Find and turn on mobile device with myLUX™ Patient App • Use mobile app 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 box • Magnet	• Where and when does the physician implant ICM devices? • Who are the people involved with the implant? • Will the patient be monitored remotely?	
IMPLANT 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 implant ICM devices? • How do they close the wound for ICM devices?	
ENROLL PATIENT AND REGISTER DEVICE	• Complete online Enrollment form and select Patient Group and Reason for Monitoring	• LATITUDE Clarity™	• Internet access • General patient, implant, clinic, and device information (see Appendix: Enrollment Form Fields) • Patient's Reason for Monitoring • Assigned Patient Group	
ACTIVATE DEVICE	• Pair implanted ICM device with myLUX Patient App	• myLUX Patient App • Magnet	• 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	ASSIGNED OWNER(S)
Sample LUX-Dx ICM Implant, Enrollment, Device Activation, and Patient Education Workflow				

EDUCATE PATIENT	• Set up myLUX™ Patient App
	• Cover key topics, including:
	How ICM and remote monitoring work
	What to do with monitor:
	  • 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
	Cover when to record symptoms (if relevant)
	Set expectations for data review and follow-up
	  • Recommend patient contact insurance to understand billing
		• myLUX Patient App
		• Patient Handbook
		• myLUX Quick Start Guide
			• 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?	

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) *Can be done with Message Patient directly to myLUX Patient App* • 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	

Workflow Worksheet: *Page 3*

WORKFLOW STEP	TASKS	LUX-Dx ICM SYSTEM TOOLS USED FOR TASK	ADDITIONAL INFORMATION OWNER MIGHT NEED FOR TASK	ASSIGNED OWNER(S)
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	
Sample LUX-Dx ICM In-Clinic Follow-Up Workflow: Using LUX-Dx Clinic Assistant App				
IN-CLINIC FOLLOW-UP *(continued on the next page)*	• 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	• 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	

Workflow Worksheet: *Page 4*

WORKFLOW STEP	TASKS	LUX-Dx ICM SYSTEM TOOLS USED FOR TASK	ADDITIONAL INFORMATION OWNER MIGHT NEED FOR TASK	ASSIGNED OWNER(S)
Sample LUX-Dx ICM In-Clinic Follow-Up Workflow: Using LUX-Dx Clinic Assistant App				

IN-CLINIC FOLLOW-UP *(continued from the previous page)*	• 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 instructions on screen
	Once complete, data is uploaded to LATITUDE Clarity™
	• 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
	• **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
		• 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	

Workflow Worksheet: *Page 5*

WORKFLOW STEP	TASKS	LUX-Dx ICM SYSTEM TOOLS USED FOR TASK	ADDITIONAL INFORMATION OWNER MIGHT NEED FOR TASK	ASSIGNED OWNER(S)
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: May 08, 2020

Johansson, Betsey (Age 76)

ID: 9665101
Gender: Female
DOB: May 02, 1944
Phone: 555-555-5555
Clinic: LUX-Dx Clinic

Device: M301 LUX-Dx™/951571
Implant Date: Feb 25, 2020
Implanted By: Mendez, Xavier
Followed By: Mendez, Xavier
Patient Group: LUX-Dx ICM Group

Latest Device Transmission: May 05, 2020 09:09 CDT

OK

Last: May 05, 2020

Next: Jun 08, 2020
Last: Apr 25, 2020

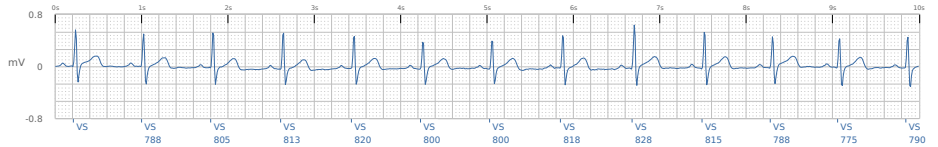
Reason For Monitoring
Cryptogenic Stroke

CHA2DS2-VASc: 7
On OAC: Yes
On Antiarrhythmic: No
Sleep Apnea: No

My Alerts

1 red event alert since last dismissed

Presenting S-ECG (May 05, 2020 07:59 CDT) **Avg Rate: 75 bpm**



Event Logbook (Apr 25, 2020 - May 05, 2020)

Event	Description	Date/Time	Duration	Rate	Assessment
AF-1	AF	May 04, 2020 23:49 CDT	4 m 00 s	Avg 103 bpm Max 164 bpm	Not Assessed
AT-2	AT	May 04, 2020 11:11 CDT	4 h 30 m	Avg 112 bpm	Not Assessed
AT-1	AT with symptoms (Fluttering)	May 04, 2020 07:44 CDT	14 h 54 m	Avg 127 bpm	Not Assessed

Demo Note: This Event only includes the device detected ECG and not the Symptom ECG.

Comments & Interventions

Signature

Date

M301 Firmware Version: BA_v0.29.01

Page 1 of 2

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

Sample Report: *Page 2*

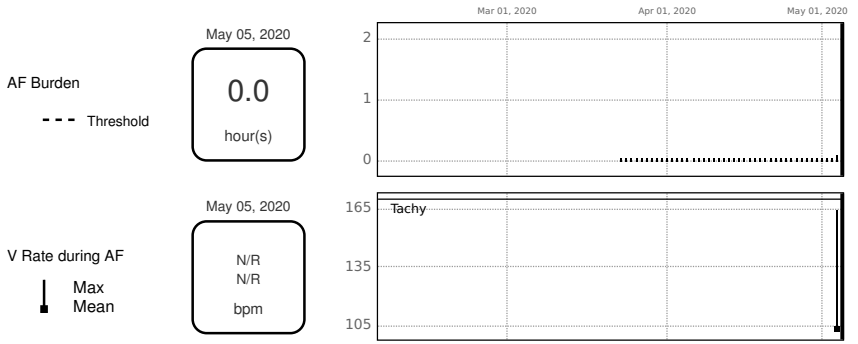
LATITUDE Clarity™ Follow-up Report | Created: May 08, 2020

Johansson, Betsey	ID: 9665101	DOB: May 02, 1944	Monitoring: Cryptogenic Stroke

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

AF Overview



	Recent Apr 25, 2020 - May 05, 2020 *11 day(s)*	Previous Feb 25, 2020 - Apr 25, 2020 *61 day(s)*
Total Time in AF	< 1 % (4 m)	N/A
# of AF Events	1	0
Longest AF	4 m (Avg 103 bpm)	N/A

M301 Firmware Version: BA_v0.29.01

Page 2 of 2

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

Enrollment Form Fields

REQUIRED	OPTIONAL
Implanted 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 Phone Number	Patient's CHA2DS2-VASc Score
Patient's Social Security Number (or they must decline to provide)	Patient's Oral Anticoagulant and Antiarrhythmic History
Patient's Street Address	Patient's Sleep Apnea Diagnosis
Monitoring Method (Remote or In-Clinic)	Implanting Clinician Specialty
Remote Monitoring Equipment	Implanting Clinician Email Address
Reason for Monitoring	Following Clinician Specialty
Patient's Assigned Patient Group	Following Clinician Email Address
Implant Date	Referring Clinician First and Last Name, Specialty, Email, Phone Number, City, and State
Implanting Clinician First and Last Name	Explanted Device Information
Implanting Clinician Phone Number	Registration Comments
Implanting Clinician City and State	
Following Clinician First and Last Name	
Following Clinician Phone Number	
Following Clinician City and State	
Implanting Facility Name	
Implanting 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 implanted electro-mechanical devices [for example implantable neuromodulation/neurostimulation systems, ventricular assist device (VAD), or implantable insulin pump or drug pump] can result in interactions that could compromise the function of the ICM, the co-implanted device, or both. Electromagnetic interference (EMI) or therapy delivery from the co-implanted 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-implant. To help prevent undesirable interactions, test the ICM system when used in combination with the co-implanted 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 implanted 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 implanted 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 implanted devices are met. Do not conduct an MRI scan if any conditions or implants prohibit it.

Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable 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)

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.*

Boston Scientific

Advancing science for life™

Rhythm Management
4100 Hamline Avenue North
St. Paul, MN 55112-5798
www.bostonscientific.com

Medical Professionals:
1.800.CARDIAC (227.3422)
Patients and Families:
1.866.484.3268

CRM-741701-AB