Boston Scientific
Advancing science for life™

LUX-Dx™

ICM System

Quick Reference Guide

It's time for a different ICM.

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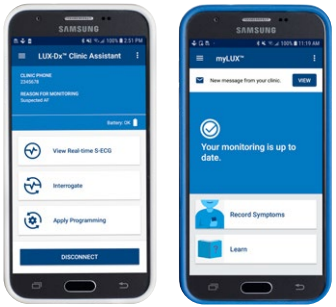
LUX-Dx™ ICM



myLUX™ Patient App
LUX-Dx™ Clinic Assistant App

Diagnostic view on
LATITUDE Clarity™
Data Management System

LUX-Dx™
Insertable Cardiac Monitor System

- Integrates advanced technologies across the ICM system
- Uses a dual-stage algorithm capable of rejecting false positives, which combined with the LATITUDE Clarity™ Data Management System, maximizes your time
- Is designed to accelerate critical decision making, enhance data quality and increase clinic efficiencies

With remote programming, the LUX-Dx ICM System allows for device programming changes without requiring the patient to be present in the clinic. And with mobile technologies, the LUX-Dx ICM System can manage programming and patient compliance remotely, which allows for improved workflow and satisfied teams.

Familiar ICM Implant Experience

Incision Tool

- Steel blade
- 1 cm width for small pocket size
- Sharp, blade cover included

Insertion Tool

- Four-step visual process
- All-in-one, sturdy design
- Pocket-forming tip
- Device preloaded in tool
- Easy device reload process

Insertion Steps

1. Insert Tool
2. Rotate 180 degrees
3. Pull the plunger back until the blue line is exposed
4. Push plunger forward

LUX-Dx™ ICM

- 3-year battery life
- MR-Conditional for 1.5T and 3T
- Detections for:
  - ✓AF
  - ✓Pause
  - ✓Brady
  - ✓VT
  - ✓AT

When monitoring for AF, false positives from ICM devices can be overwhelming

- Real world experience suggests that false positives can be as high as 85% of alerts[1]
- This may cause inefficiencies and can take up valuable clinic time

1. Afzal MR, Mease J, Koppert T, et al. Incidence of false-positives during remote rhythm monitoring with implantable loop recorders. Heart Rhythm. 2020 Jan;17(1):75-80.

LUX-Dx™ ICM System

Utilizes a dual-stage algorithm for AF detection

- The first stage uses a two-minute window to analyze R-R variability and heart rate density index to detect potential AF rhythms
- The second stage verifies potential AF utilizing adaptive morphology, noise discrimination and pattern detectors to identify and reject false positives, providing more accurate data

Is highly programmable

- The AF algorithm has five programmable settings for the sensitivity parameter settings (Least, Less, Balanced, More, Most) to provide important flexibility to fine-tune your patient's ICM settings

Provides a separate programmable AT algorithm

- No need to choose between short-duration AF or AT/flutter to monitor patients
- The algorithm is intended to detect short-duration AT, long-duration AT, AF and AT/flutter and short-duration atrial flutter

LUX-Dx AF Nominal Settings

Duration: 4 min.
Response: More

Determining if alerts are real can be a difficult challenge for the clinic staff

- False-positives when monitoring for pause are typically due to the ICM under sensing
- This can mean the ICM is experiencing small signal amplitude, variable signal amplitude, dynamic noise algorithm, or non-physiologic flatline from loss of electrode contact

LUX-Dx™ ICM System

Is designed to reject false positives

- The system filters out excessive noise during a pause episode
- Excessive noise may increase the sense threshold via the DNA algorithm, leading to R-wave under sensing and false pauses

Has a programmable response parameter

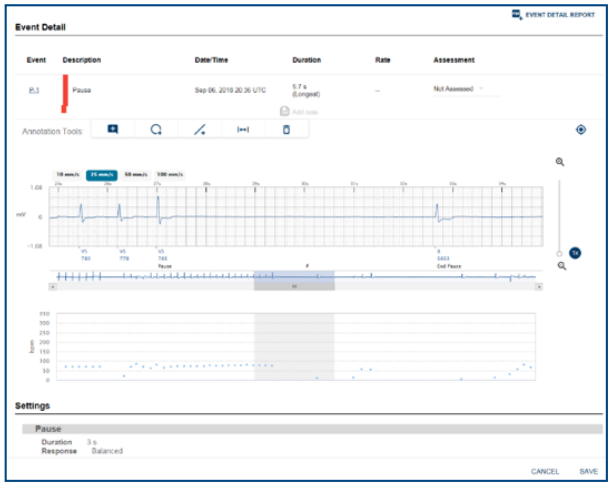
- Allows for flexibility for individual patients
- The parameter is initialized according to the programmed reason for monitoring

Uses signal to noise ratio 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-post R-waves and rejects the false positive if the criteria are not met

In addition:

- The Patient Summary page displays the longest pause in the current set of data being reviewed. This feature prioritizes reviews and allows viewing of data more efficiently
- Loss of signal or flatline episodes are due to loss of electrode contact; these signals are rejected by the LUX-Dx ICM pause algorithm, which compares the R-wave amplitudes over a very short period



LUX-Dx ICM Pause Algorithm Nominal Settings

Duration: 3 sec.
Response: More

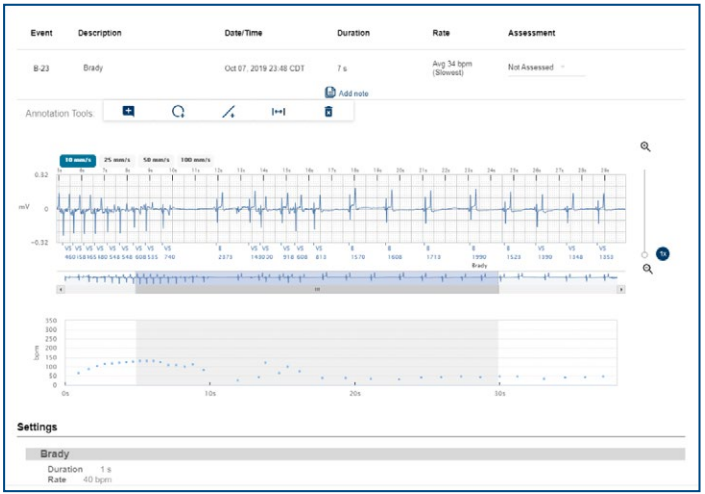
False positives when monitoring Brady episodes are due to:

- Under sensing because of small signal amplitude
- Variable signal amplitude
- Dynamic noise algorithm or non-physiologic flatline from loss of electrode contact
- Saturated sense amplifiers

This may result in poor device performance and wasted time to manage the false positives.

LUX-Dx™ ICM System

- Uses a dual-stage algorithm capable of detecting and rejecting false positives due to under sensing
- Uses rate and duration parameters during the detection stage to identify potential brady episodes
- Further examines potential episodes during the verification stage for under sensing before being rejected



LUX-Dx ICM Brady Algorithm Nominal Settings

Rate: 40 BPM
Duration: 1 sec.

False positives from ICMs when monitoring for both AF and AT may lead to frustration and inefficiencies due to the inability to set AT duration independently

- As a result, long-duration AT often goes undetected because the algorithm detection has been turned off due to the high volume of false positives that can be generated.

LUX-Dx™ ICM System

- The AT/AF algorithm was designed to be more flexible with separate programmability
- Allows for program changes for both AF and AT independently, including rate and duration choices
- Can be set to detect only high rate rhythms sustained for a prolonged (pathophysiologic) period (4 hours ≥ 110 bpm)
- Can be programmed to detect short-duration AT/AFL, if desired

LUX-Dx ICM AT Algorithm Nominal Settings

Rate: 110 bpm
Duration: 4 hrs.

When monitoring for tachy episodes, low detection and false positives from under sensing and over sensing due to noise can cause frequent false positives

LUX-Dx™
ICM System

- Uses a dual-stage algorithm capable of detecting and rejecting false positives due to under sensing and over sensing
- Utilizes the traditional ICD-based rate and duration parameters in addition to a morphology assessment
- Detects a potential tachy episode at onset when 8 out of 10 beats are faster than the programmed rate threshold
- Monitors tachy episodes to determine if the fast pattern is maintained for the programmed duration. If the pattern is maintained, additional criteria are automatically applied to verify that the high rate episode is not the result of under sensing or over sensing according to the programmed sensitivity
- During the verification step of the algorithm, classifies episodes as SVT, VT/VF, VF or noise based on detection

LUX-Dx ICM Tachy Algorithm Nominal Settings

Rate: 170 bpm
Duration: 5 sec

ICMs can produce a high volume of data that can be challenging and time consuming to review

- Current data management systems can be challenging to navigate and often lack tools that aid in ECG review
- Reviewing false positives is often time consuming, and there are limited options for filtering through data and modifying device settings to reduce alerts
- ICMs can add complexity to established workflows due to an unpredictable amount of data and time spent communicating with patients

LATITUDE Clarity™
Data Management System

Designed with workflow efficiencies built in

- A dashboard view with organized navigation can help clinics plan and prioritize their workload
- Zoom and annotation tools that are designed to improve and accelerate ECG review
- Ability to modify device programming and alerts remotely without bringing patients back in saves valuable time
- Optional one-way messaging to patients can reduce call volume and provide patient assurance

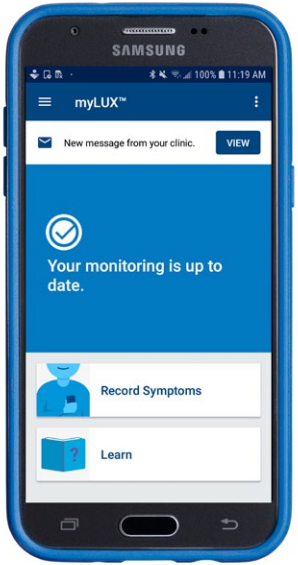
Remote monitoring can be confusing and frustrating to patients

- Patients may be confused by separate home monitors and symptom trackers
- In many cases, patients consistently want to know if they are connected and want reassurance their data was received and reviewed
- Patients don't know where to find answers to their questions, so they call clinics for answers

myLUX™
Patient App

Interactive mobile experience that empowers patients and can improve compliance

- Transmits data between ICM device and clinic, records symptoms and helps patients access useful information all in one place
- Displays connection status and offers connection troubleshooting help right from the main screen
- Symptom recording includes simple selection of a symptom description and activity and is done directly from the app
- Patients can receive read-only messages from their clinic confirming their data has been reviewed
- Features a "Learn" button on the main screen where patients can access educational information



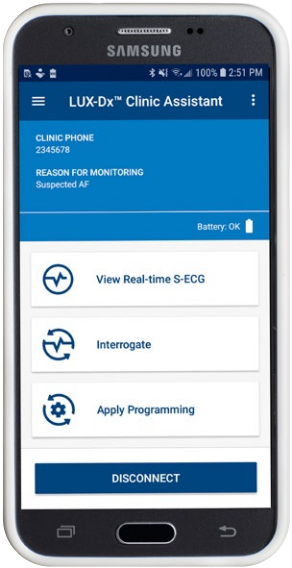
Current equipment can be bulky and may restrict where and when device checks happen

- ICM devices aren't always checked in the same clinic
- Interrogating devices can be challenging, or take a long time, if the right equipment isn't set up

LUX-Dx™
Clinic Assistant App

Portable mobile technology that can travel with you for device checks and programming adjustments

- Offers a convenient mobile solution for interrogating devices and updating programming
- Can connect to any LUX-Dx ICM device wherever there is a reliable Internet connection
- Can be used for all LUX-Dx ICM in-clinic tasks, including viewing real-time S-ECGs, interrogating devices and applying new programming parameters

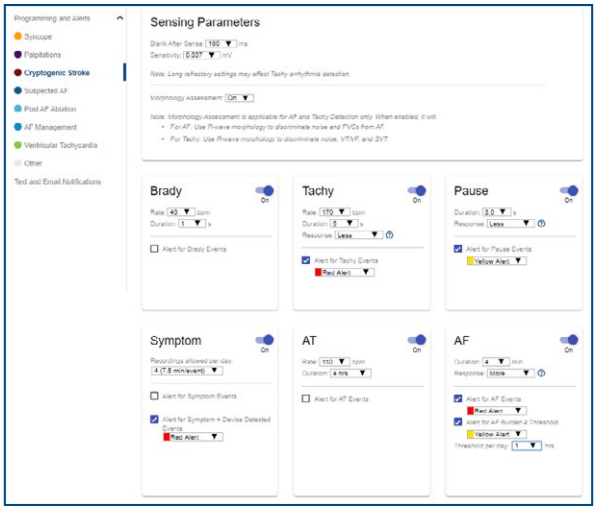


- Real-world clinic data by Dr. Afzal et al. indicated the incidence of false positives with ICM nominal setting's during the study period was 46% for AF, 86% for cryptogenic stroke and 71% for syncope[1]
- As reported by Medicare (2012-2015), only 25% of all ICMs have their settings changed in the initial 90 days post-implant[2]
- Requiring patients to come to the clinic for ICM programming changes is time consuming for clinics and may be inconvenient for patients

1. Afzal MR, Mease J, Koppert T, et al. Incidence of false-positives during remote rhythm monitoring with implantable loop recorders. Heart Rhythm. 2020 Jan;17(1):75-80.
2. Rate of in-person programming analyzed by creating annual cohorts of device implant claims from 2012-2015 using the 5% Medicare Standard Analytic File (SAF) physicians data file and counting for in-person programming claims for one year in 90-day increments post-implant using 2012-2016 5% Medicare SAF physician data file.

LATITUDE Clarity™
Data Management System

- Remote programming through the LATITUDE Clarity website provides clinicians the ability to adjust a patients' LUX-Dx™ ICM device settings without requiring the patient to be present in the clinic
- Each algorithm is independently programmable to desired settings for diagnostic groups or individual patient needs



- LUX-Dx ICM System was built with remote programming in mind
- Designed to accelerate critical decision making and enhance data quality
- Potential to Increase efficiency through fewer patient appointments

Boston Scientific is committed to the privacy of health information

- Data from the LUX-Dx™ ICM System is securely gathered, transferred and stored for the healthcare team
- During each transmission, the connection is first secured with the device
- As data are transferred, critical data are encrypted to provide an additional layer of security

LUX-Dx™ Insertable Cardiac Monitor System

INDICATIONS The LUX-Dx™ Insertable Cardiac Monitor (ICM) is intended to monitor and record subcutaneous ECG (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. A)

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

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