Boston Scientific
Advancing science for life™

LUX-Dx™
ICM System

It's Time for an ICM Like No Other

Here.

Excessive false positives can mean frustration for you and your staff. And time you spend analyzing and adjudicating false positives isn't time well spent.

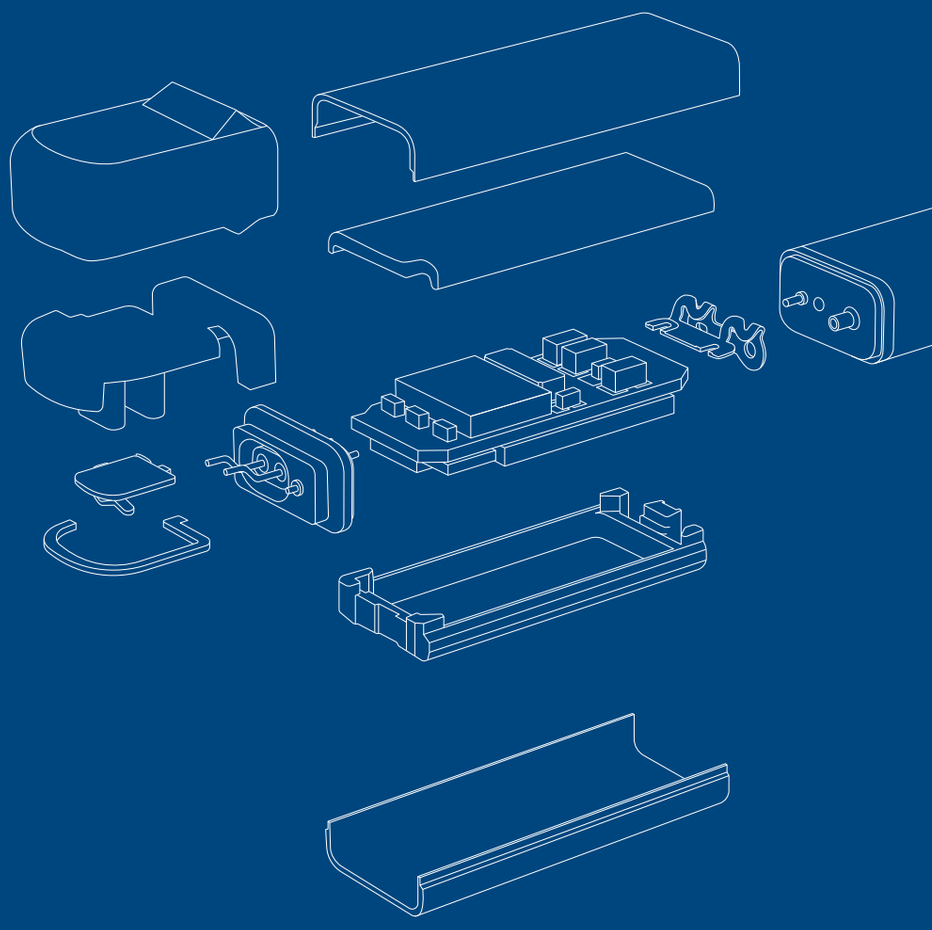
Now. **LUX-Dx™**
ICM System

Capable of reducing false positives by 53%.*

* Bench testing showed a relative reduction of 53.1% in false positives when QRS morphology was turned on.

Bench test results may not be indicative of clinical performance.

Bench data for this research was provided by Telemetric and Holter ECG Warehouse (THEW), University of Rochester, NY.



It's Time for Actionable High-Quality Data

An ICM system that puts you in control.

Now, there's an insertable cardiac monitor that works differently to make the most of your time. The LUX-Dx™ ICM System uses state-of-the-art sensor technology along with a dual-stage algorithm to detect and verify potential arrhythmias, rejecting false positives, for reliable data. It's also remotely programmable, so you don't need to have a patient come in to make critical adjustments. It's time for something different. It's time for the LUX-Dx™ ICM.

An ICM that checks its work.

The LUX-Dx™ ICM uses dual-stage algorithms that detect and verify each potential arrhythmia before you get an alert. Detection parameters can be adjusted for each algorithm based on the chosen reason for monitoring. The LUX-Dx™ ICM can be programmed to detect AF, pause, brady, tachy and AT, and the LUX-Dx™ ICM is uniquely programmed to separate AT from AF, resulting in a meaningful clinical benefit to capturing both AT and AF.

AF DETECTION ALGORITHM

R-R VARIABILITY
BEAT VALIDATION
VENTRICULAR SCATTER
HEART RATE DENSITY INDEX

DETECT

Using R-R variability and other discrete filters, the LUX-Dx™ ICM detects arrhythmias and alerts each time the set threshold is exceeded.

QRS MORPHOLOGY
NOISE DISCRIMINATION
PATTERN DETECTION

VERIFY

Adaptive algorithms, QRS morphology, noise discriminators and pattern detection provide additional filters to reject false positives.

ALERT

False positives can be rejected, resulting in time saved.

Advanced control on your terms.

The remotely programmable ICM system.

The LUX-Dx™ ICM System is remotely programmable, so you can make key adjustments to programming and detection from the LATITUDE Clarity™ Data Management System website, streamlining workflow for your whole team.

Device parameters for individuals, patient groups and reasons for monitoring can be updated at any time after implant, so physicians and care teams can make necessary adjustments without requiring a patient appointment. This can increase not just efficiency but also data quality.

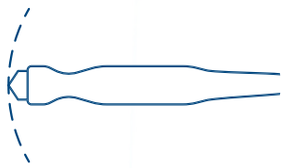
Stay connected, stay ahead.

Patients are provided with a Boston Scientific Mobile Device including the preloaded myLUX™ app that connects via Bluetooth® to their LUX-Dx™ ICM device. Each night—or as needed—the myLUX™ Patient App transmits device data to the LATITUDE Clarity™ Data Management System.

You and your team can view and analyze patient data, plus make key adjustments to detection programming that will update each time the app connects.

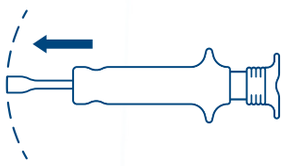
Intuitive procedure.

The LUX-Dx™ ICM uses a familiar implant procedure. The device comes pre-loaded in its own reloadable, single-piece insertion tool.



1. INCISION

Make a small incision with the included incision tool



2. INSERTION

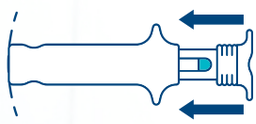
Then, fully insert the tunneling portion of the insertion tool

3. ROTATE BY 180°

Rotate the insertion tool 180° to create a pocket for the device

4. PULL PLUNGER

Pull the plunger back until the blue line is visible to load the device...



5. PUSH PLUNGER

...then push the plunger completely to insert the device into the incision

An efficient data management system exclusively for LUX-Dx™ ICMs.

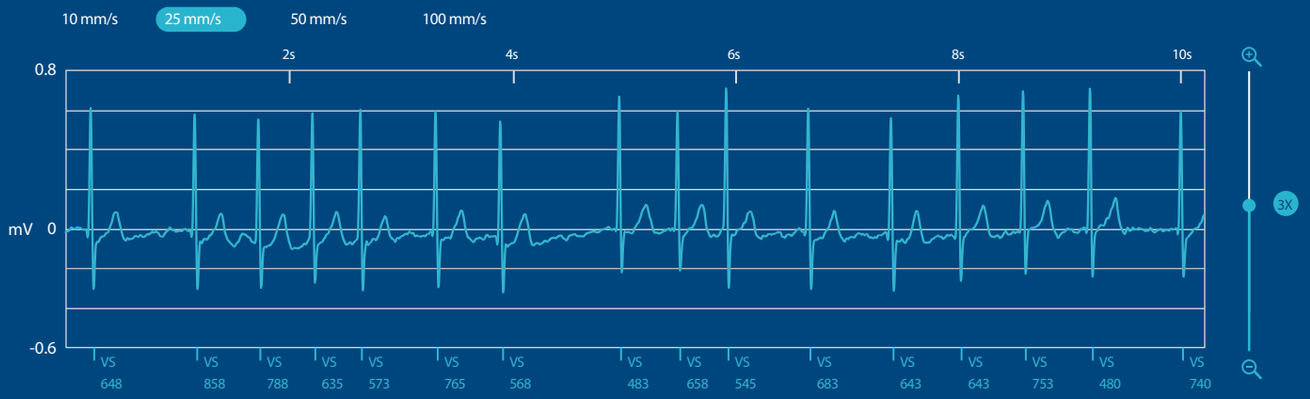
Once programmed, the LUX-Dx™ ICM System sends data directly to the LATITUDE Clarity™ Data Management System, where alerts and comprehensive data are just a click away. Clear S-ECGs with advanced zooming and annotation tools save time for your whole team. And consolidated and flexible reporting gives you all the information you need to see, the way you want to see it, all in one place.

Event Detail

Event	Description	Date/Time	Duration	Rate	Assessment
AF-2	AF	Jan 15, 2020 1:27 EST	12h 12m (Longest)	Avg 102 bpm Max 208 bpm	Not Assessed

Add note

Annotation Tools



Settings

AF	
Response	More
Duration	2 min

For further information, please visit
bostonscientific.com/LUXDxICM

LUX-Dx™ INSERTABLE CARDIAC MONITOR SYSTEM

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.

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

General

• **Co-implanted device interaction.** 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.

Following completion of the interaction testing, thorough follow-up evaluation of all co-implanted devices should be performed to ensure that device functions have not been compromised. If operational settings of the co-implanted devices change or if patient conditions change which may affect ICM sensing, re-evaluation of the co-implanted devices may be required.

• **Labeling knowledge.** Read this manual thoroughly before using the ICM system to avoid damage to the device. Such damage can result in patient injury or death.

• **For single patient use only.** Do not reuse, reprocess, or resterilize the insertable cardiac monitor or insertion tools. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient. The medical professional may reposition or re-insert the device within a single procedure.

• **Sharp object.** Incision tool is sharp. Take precautions to ensure that it is handled properly. Dispose of incision tool directly into a sharps disposal container labeled with a biological hazard symbol. Sharps waste should be safely disposed of using available sharps waste channels in accordance with hospital, administrative, and/or local government policy. 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.

Insertion

• **Tunneling.** The insertion tool is intended to be used in the subcutaneous space. Always be aware of the location of the tool tip relative to the patient anatomy. Hold the insertion tool at a narrow angle while tunneling. Unintended tissue damage may result if the device is inserted at a large angle.

• **Incision tool blade placement.** Always be aware of the location of the incision tool blade relative to the patient anatomy. Unintended tissue damage may result if the incision tool is inserted beyond the blade. Document for Safe MR Practices.

Post Insertion

• **Diathermy.** 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.

• **Firmware update must be completed.** Once a firmware update begins, the patient will not be monitored until the update is completed. If the firmware update is skipped, the patient is still monitored.

• **Interrogate device, save data, and check device function**. 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 compatibility.** 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.

• **Magnet use.** 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.

• **Mobile devices and magnet are MR Unsafe.** 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 on MR Safe Practices1. Under no circumstances should the mobile device or magnet be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

• **MR conditional requirements.** 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 with other devices.** 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.

• **Protected environments.** 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 Precautions section of the User's Manual or the following sections of the product labeling: General, Clinical Considerations, Sterilization and Storage, Insertion, Magnet, Device Programming, Environmental and Medical Hazards, Follow-up, Device Removal and Disposal.

POTENTIAL ADVERSE EVENTS

Insertion and usage of this product may result in adverse events which may lead to injury, death, or other serious adverse reactions. If any adverse events occur, invasive corrective action and/or ICM system modification or removal may be required.

Potential adverse events related to insertion of the device may include, but are not limited to, the following: • Device migration • Erosion • Foreign body rejection phenomena • Formation of hematomas or seromas • Infection • Local tissue reaction • Tissue damage

Potential adverse events related to device operation may include, but are not limited to, the following: • Premature battery depletion • Sensing issues • Error codes • Loss of telemetry

Transient procedural adverse events are expected in some patients. These include, but are not limited to discomfort, pain, anxiety, and other systemic symptoms that might be related to medications or other interventions performed during implant.

For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide at www.bostonscientific-elabeling.com.

Any serious incident that occurs in relation to this device should be reported to Boston Scientific and to the relevant local regulatory authority.

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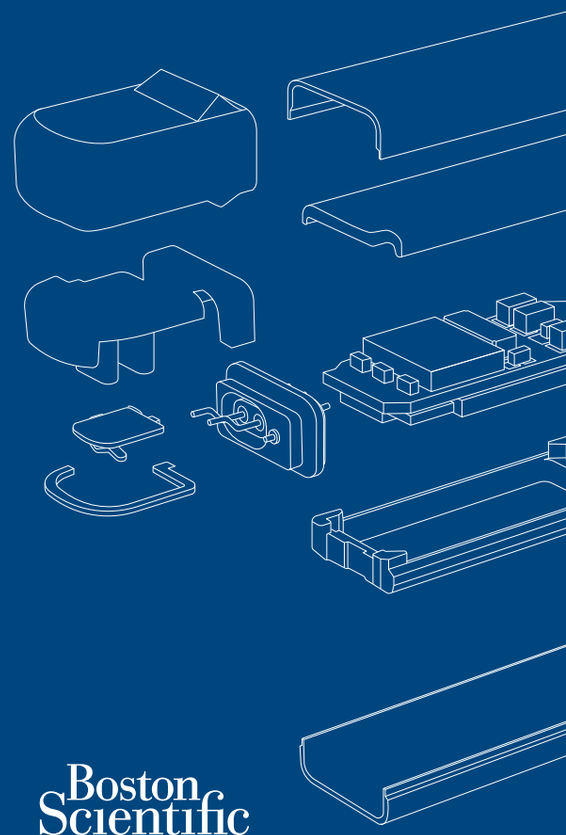

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Medical Professionals:
1.800.CARDIAC (227.3422)
Patients and Families:
1.866.484.3268

CRM-745003-AA

EDUCARE

More information, training resources and CEU credits available on LUXDxTraining.com