Boston Scientific
Advancing science for life™

LUX-Dx II+™
ICM System

Focused on what matters.

You don’t have time to be distracted by extraneous data.

The LUX-Dx II+™ ICM System builds upon the advanced dual-stage algorithms and unparalleled signal quality of the original LUX-Dx™ system—while also adding enhanced detection algorithms and monitoring capabilities to help reduce false alerts, encourage patient compliance, and prioritize clinically actionable events.

The LUX-Dx II+™ ICM system is focused on what matters:

MEANINGFUL ALERTS

CLEAR S-ECG SIGNALS

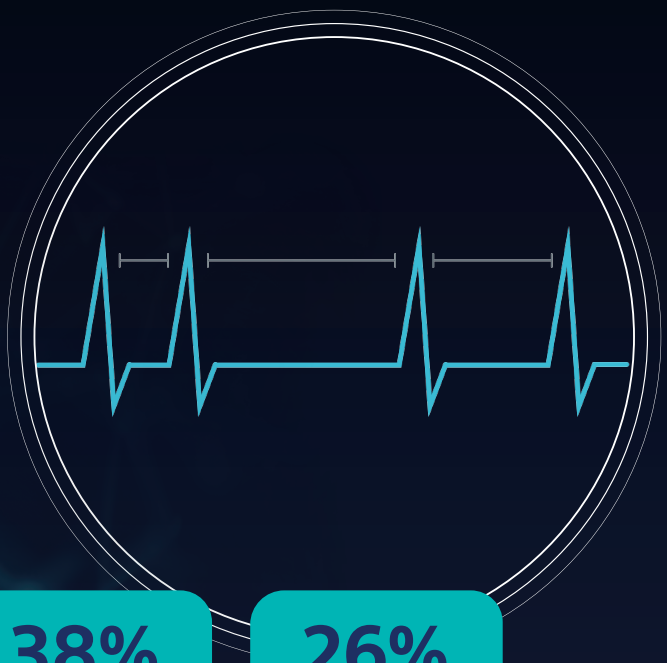
SEAMLESS PATIENT EXPERIENCE

EFFICIENT WORKFLOWS

Meaningful alerts

Reduce false positives without missing a beat.

Powered by enhanced detection algorithms, the LUX-Dx II+™ ICM System is focused on providing clinically actionable event alerts and rejecting false positives.



38%

reduction in false positives while maintaining high relative sensitivity[1†]

26%

fewer AF S-ECG episodes for review[2†]

Enhanced atrial fibrillation algorithm

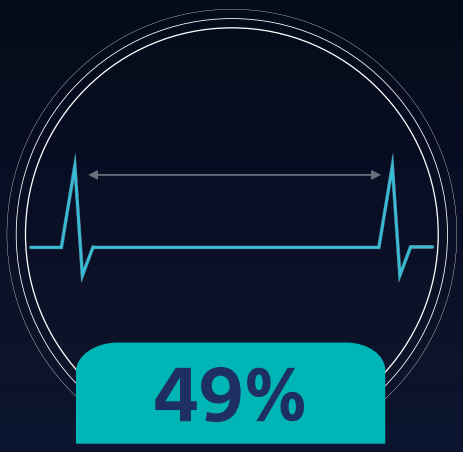
Continues to use R-R variability to detect potential AF rhythms and merge adjacent episodes, which was found to reduce 26% of AF S-ECG episodes for review.[2†] The algorithm also includes an additional verification step to identify repeating sequential patterns and reduced false positives by 38% while maintaining high relative sensitivity.[1†]

Watch the enhanced AF algorithm in action

Enhanced where it matters most.

The original LUX-Dx™ ICM set the standard in monitoring with dual-stage algorithms that automatically detect and verify events before sending alerts. The LUX-Dx II+ ICM is equipped with enhanced versions of those powerful algorithms, further improving its ability to reject false positives across multiple arrhythmia types.

Meaningful alerts



49%

fewer false positives with 100% relative sensitivity[3†]

Enhanced pause algorithm

Continues to use R-R interval to detect pause episodes, and the enhanced verification step further rejects false positives due to undersensing of low amplitude signals.

Watch the pause algorithm in action

Bradycardia algorithm

Uses rate and duration parameters during the detection stage to identify potential brady episodes, with separate programmable parameters for daytime and nighttime. During the verification stage, episodes are further examined and rejected if undersensing is identified.

Watch the brady algorithm in action

The difference is night and day.

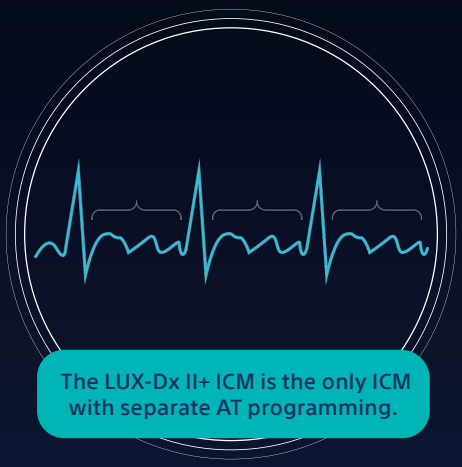
Advanced nighttime programming can detect, differentiate and record only specified nighttime brady and pause events between 11 pm - 7 am. The LUX-Dx II+ ICM is the only ICM with nighttime pause programming.**

75%

reduction in brady S-ECG episodes for review[2†]

57%

reduction in pause S-ECG episodes for review[2†]



The LUX-Dx II+ ICM is the only ICM with separate AT programming.

Atrial tachycardia algorithm

Uses rate, duration and built-in flexibility to detect high-rate rhythms sustained over time or short-duration AT/atrial flutter.

Watch the atrial tachycardia algorithm in action

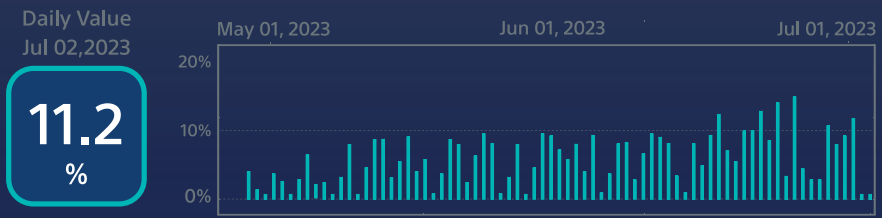
Tachycardia algorithm

Uses a machine-learning decision tree to identify potential tachy episodes and reject events outside rate zone.

Watch the tachycardia algorithm in action

Novel PVC burden algorithm

Uses a patient-specific morphology assessment in the verification step that enables detection of PVC sequence types like couplets and triplets. The LUX-Dx II+ ICM provides a daily burden percentage with advanced programming and is the **only ICM with an actionable alert.****



85.4%

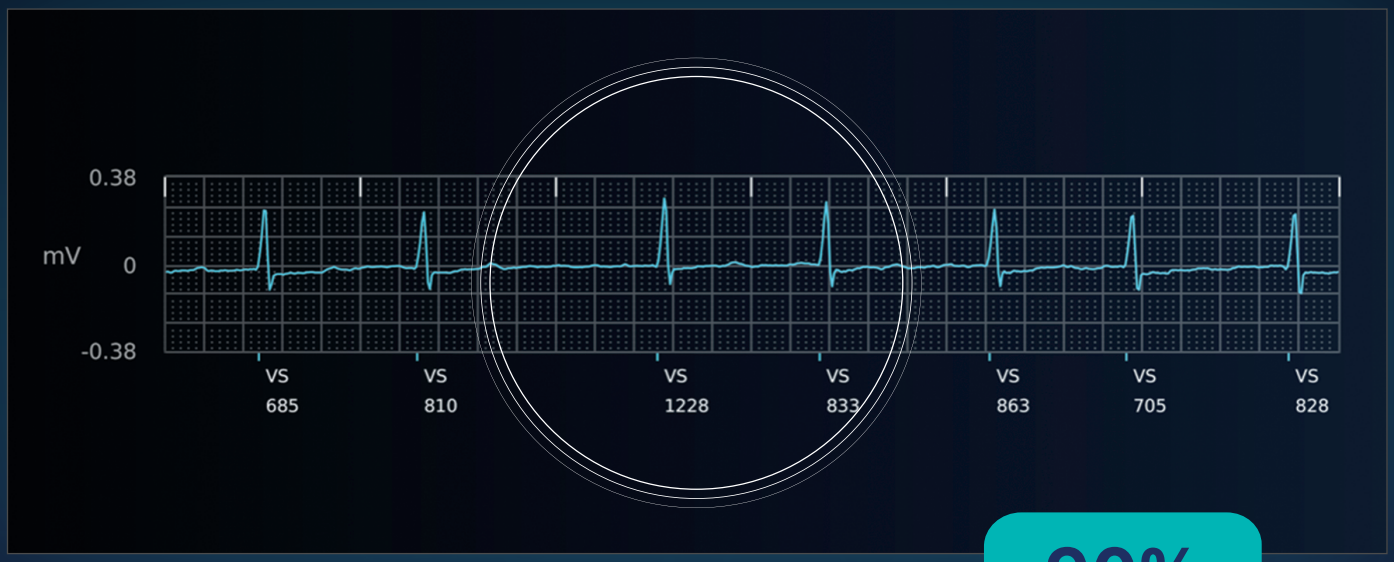
PPV in detecting singlet, couplet and triplet PVCs[4 †]

Watch the PVC burden in action

Clear S-ECG signals

Visible P-waves. It's as clear as that.

The LUX-Dx II+™ ICM System is focused on reducing analysis time by providing astoundingly clear S-ECG signals from day one.



90%

of P-waves visible in heart cycles over time[5*]

Clinic Assistant App

With the LUX-Dx™ Clinic Assistant app, you only need one device to connect to and interrogate devices, minimizing the need for additional monitoring equipment.

- View real-time patient S-ECGs
- Interrogate any LUX-Dx ICM*
- Apply LATITUDE Clarity™ parameter changes

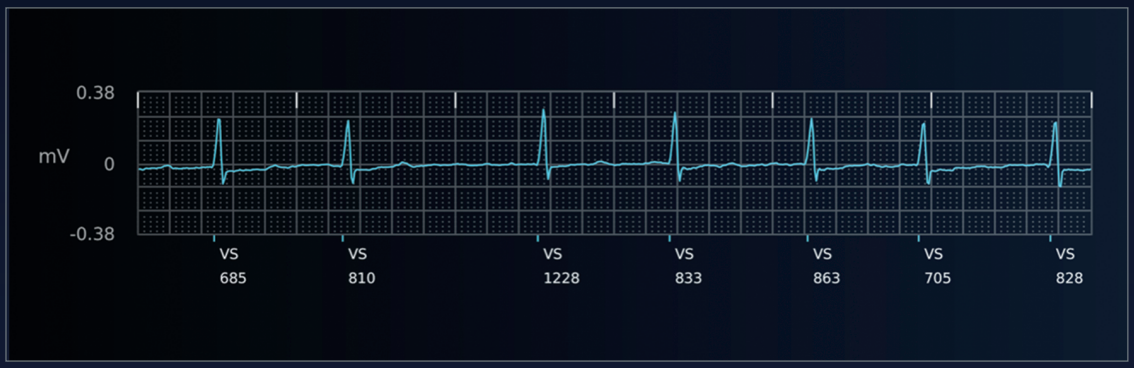
Clarity from day one.

Right from the start, the LUX-Dx II+ ICM makes it easy to verify correct placement and connection confidence by transmitting real-time S-ECGs in sharp resolution.

Clear S-ECG signals

Presenting S-ECG

S-ECG from Atrial fibrillation alert

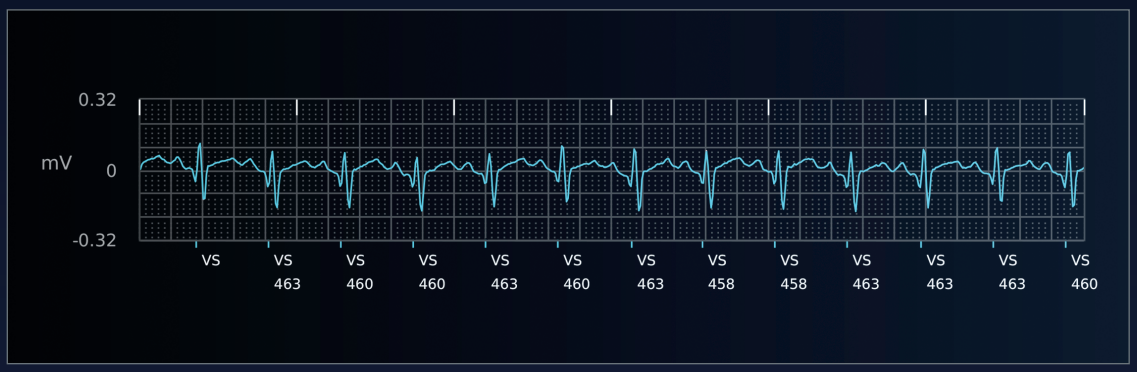


S-ECG from Pause alert

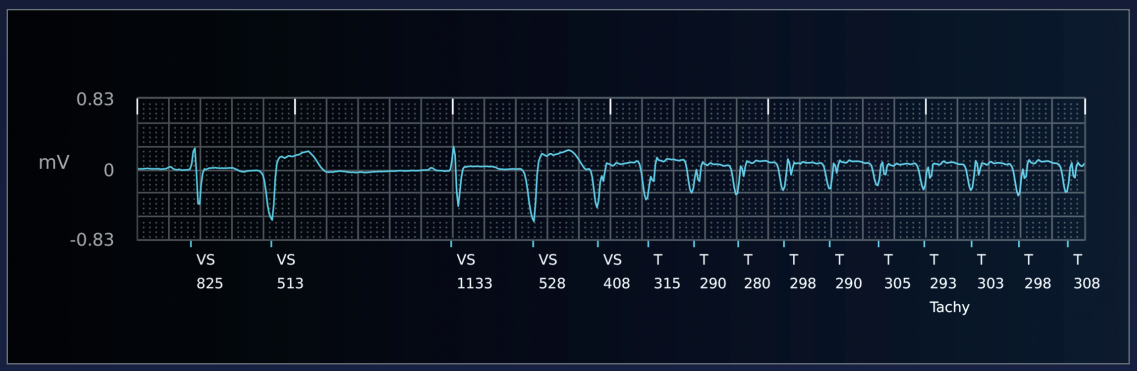
Cases shown are from real LUX-Dx™ ICM patients.

S-ECG from Bradycardia alert

S-ECG from Atrial tachycardia alert



S-ECG from Tachycardia alert



Review additional cases

Simple choices for seamless connectivity.

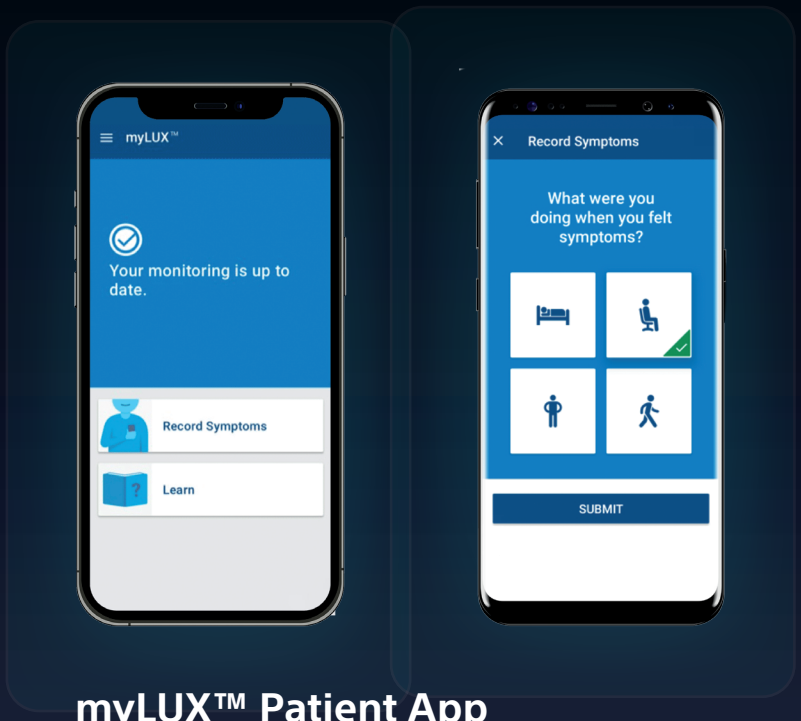
The LUX-Dx II+™ ICM System is focused on supporting every step along the cardiac monitoring journey—for both physicians and patients alike.

Flexible patient monitoring

The LUX-Dx II+ ICM system now offers a choice for patients to use their own mobile phone with the downloadable myLUX patient app for monitoring.

Available on the App Store

ANDROID APP ON Google Play



myLUX™ Patient App

The primary connection point between a patient's LUX-Dx II+ ICM device and the LATITUDE Clarity™ server, the user-friendly myLUX Patient App helps empower patients to play an active role in recording symptoms and connecting their device.

- Current monitoring status
- One-way clinic messaging
- Programmable symptom tracking
- Patient education tools

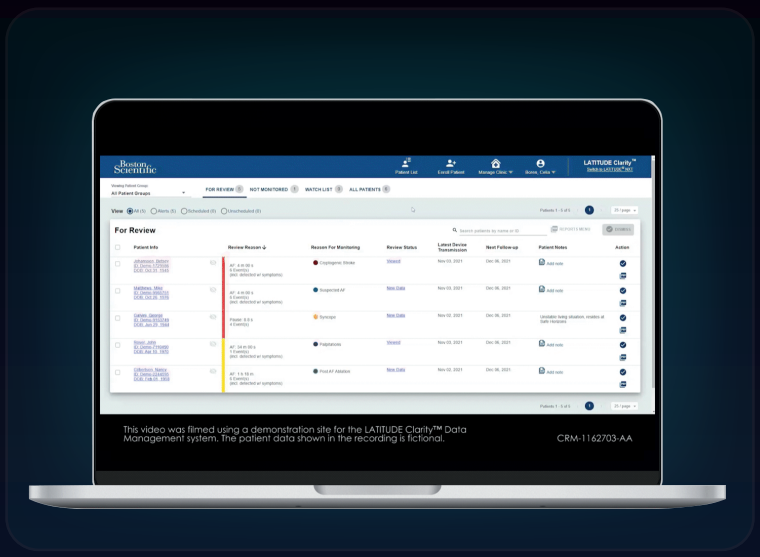
RhythmCARE™ Assist

Patients using the downloadable myLUX app on their smartphone can sign up for a supplemental support service. This automated service communicates directly with patients via email or text messages to help set up the myLUX app and resolve technical troubleshooting issues.

Efficient workflows

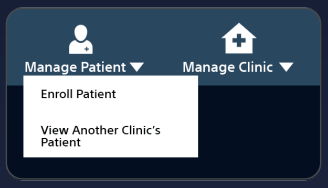
Designed to accelerate clinical decision-making.

The LUX-Dx II+™ ICM System is focused on maximizing workflow efficiency by streamlining data management and simplifying common review procedures.



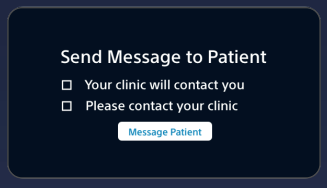
LATITUDE Clarity™ Data Management System

Built specifically to meet the needs of ICM management teams, LATITUDE Clarity helps to increase efficiencies, enhance workflows and fine-tune monitoring. It's equipped with powerful tools to help you see the bigger data picture—without losing the detail to back it up.

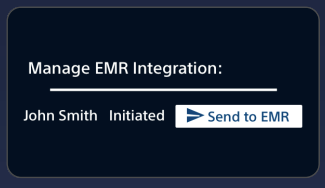


Temporary read-only access

Intuitive S-ECG review tools

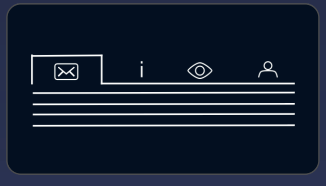


One-way patient messaging



Easy EMR integration

Customizable patient reports



Organized dashboard view

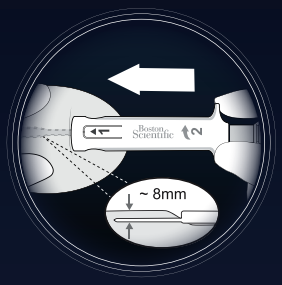
Efficient remote programming

Efficiency is a familiar feeling.

The intuitive insertion process of the LUX-Dx II+™ ICM is designed for reliable placement, rapid validation, and confident completion.

1. Incision

Create a small incision using the included LUX-Dx Incision Tool.

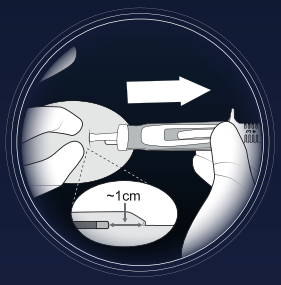


2. Tunnel

Insert the included LUX-Dx Insertion Tool into opening.

3. Rotate

Twist the Insertion Tool 180 degrees to create a pocket.

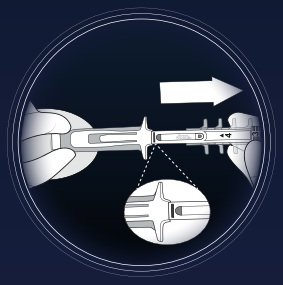


4. Pull back

Pull back on Insertion Tool plunger to the pre-marked blue line.

5. Insert

Push in the Insertion Tool plunger all the way to place device in pocket.



6. Remove

Remove Insertion Tool and close using standard surgical techniques.

Insertion tools

The LUX-Dx II+ ICM includes a reloadable, all-in-one insertion tool and incision tool to simplify the device insertion procedure.

Let’s advance cardiac care together.

The Cardiac Diagnostic Solutions portfolio elevates cardiac care with solutions for a range of patient needs, helping you diagnose and monitor across the care continuum with ease.

Short-term holter
24-48 hrs

Medium-term and long-term holter
48 hrs - 15 days

BodyGuardian™ MINI Family of Monitors are waterproof devices, ideal for both short-term and mid-term cardiac monitoring.

Depending on their clinical condition, patients may require short or long-term monitoring.
The BodyGuardian™ products and affiliated services are associated with Boston Scientific Cardiac Diagnostics, Inc., a wholly owned subsidiary of Boston Scientific.

Cardiac event monitor
Up to 30 days

Mobile cardiac telemetry
Up to 30 days

Insertable cardiac monitor
Up to 3 years

Learn more about the portfolio

1. Richards M, Frost K, Mahajan D, et al. Novel run-test algorithm for improved AF detection in insertable cardiac monitors. Poster presented at 2022 Heart Rhythm Society; April 2022; San Francisco, CA

2. Rajan A, Perschbacher D, Mahajan D, et al. Improving clinic workflow and diagnosis for the LUX-Dx Insertable Cardiac Monitor. Poster Presented at Heart Rhythm Society; April 2022; San Francisco, CA

3. Burke M, Ravikumar V, Siejko K, et al. Enhanced pause algorithm for insertable cardiac monitor reduces clinical review burden. Poster presented at 2023 Heart Rhythm Society; May 2023; New Orleans, LA

4. Nair D, Herrmann K, Mahajan D et al. Novel PVC burden algorithm for insertable cardiac monitors (ICMs) detects all PVC sequence types. Poster presented at: 2021 Heart Rhythm Society; July 2021; Boston, MA.

5. Frazier-Mills C, Rahan A, Saleeby R, et al. Consistent visibility in P-waves observed in patients implanted with LUX-Dx Insertable Cardiac Monitor. Poster presented at: 2021 Heart Rhythm Society; July 2021; Boston, MA

*Evaluated using the LUX-Dx™ ICM System.

†Simulated performance tested on real-world LUX-Dx ICM events

*References to "LUX-Dx ICMs" Includes LUX-Dx™, LUX-Dx II™ and LUX-Dx II+™ ICM Systems

**As of 7.20.23: REVEAL LINQ™ Clinician Manual, LINQ II™ Clinician Manual, BIOMONITOR III™ Technical Manual, BIOMONITOR IIIm™ Technical Manual, BIOMONITOR IV™ Technical Manual, Merlin Patient Care System for SJM Confirm™ ICM, Confirm Rx™ ICM and Jot Dx™ ICM Help Manual, Merlin Patient Care System Assert-IQ™ ICM Help Manual

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

INDICATIONS LUX-Dx II™ and LUX-Dx II+™ Insertable Cardiac Monitor (ICM) Systems are 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 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 bostonscientific-elabeling.com. MRI Technical Guide at www.bostonscientific-elabeling.com Any serious incident that occurs in relation to this device should be reported to Boston Scientific and to the relevant local regulatory authority. 97104968 (Rev. A)

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

BodyGuardian™ MINI and MINI PLUS INTENDED USE The BodyGuardian MINI is intended for use in clinical long-term ambulatory ECG monitoring, data transfer and analysis. BodyGuardian MINI is indicated for adult and pediatric patients who require ECG monitoring inside or outside hospital or healthcare facility environments. The sensor does not provide interpretive statements. Final interpretation and diagnosis is the responsibility of a physician.

CONTRAINDICATIONS The sensor is contraindicated for those patients requiring attended, in-hospital monitoring for life threatening arrhythmias and for use on pediatric patients weighing 22 lbs. (10kgs) or less.

SAFETY PRECAUTIONS The sensor does not directly provide diagnosis as a supervising physician is responsible for ECG data interpretation. Do not disassemble, try to repair, or modify sensor. Sensor does not have any electrical stimulation capabilities.

WARNINGS Do not attempt self-diagnosis or self-treatment based on acquired data. Not suitable for use in MRI environment. Patients with known skin allergies or hypersensitivities to adhesives or hydrogel may experience reactions. Patients should consult with their health care professional to select a BodyGuardian MINI Strip or alternate electrode option that is most appropriate for their needs. Apply the BodyGuardian MINI Strip or alternate electrode only to intact, clean skin. Do not apply over open wounds, lesions, infected or inflamed areas. The BodyGuardian MINI Strips are for single patient use only. The device is not intended to be used at the same time with high frequency (HF) surgical equipment or with a defibrillator. Patients who have active implantable medical device (for example a heart pacemaker), should consult supervising physician or doctor before use. When using the MINI ECG monitor connected in Bluetooth mode (in the MINI Plus configuration) the monitor should be kept within 10 feet (approximately 3 meters) to the companion device (smartphone) to facilitate wireless communication. To avoid danger of electrical shock and electromagnetic disturbances, the computer and associated equipment used with the ECG Sensor should comply with IEC/EN 60950 (IT and office equipment safety) or EN60601-1 (Medical electrical equipment safety) standard. If a computer that does not comply with the IEC/EN 60601-1 requirements is used in the patient environment, the computer and peripherals must be plugged in using an isolation transformer that fulfills the requirement. CRM-1424006-AA.

CAUTION U.S. Federal law restricts this device to sale by or on the order of a physician.

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Patients and Families:
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