Boston Scientific
Advancing science for life™

# LUX-Dx™
# ICM System

## NOW, AN ICM THAT CHECKS ITS WORK.

The LUX-Dx™ ICM System uses a dual-stage algorithm to detect AF and other arrhythmias. Dual-stage means it detects and then verifies data before sending results; rejecting false positives, improving efficiency and maximizing your time.


## IN BENCH TESTING*, THE UNIQUE LUX-DX ICM ALGORITHM DESIGN HAS SHOWN:

| ALGORITHM | DESCRIPTION | RESULTS |
|---|---|---|
| AF | R-R variability vs. R-R+Morphology | **53.1%** relative reduction in false positives; AF burden PPV ranged from 73% - 99%[1] |
| | Dual-Stage | **PPV improved from 54.4% to 99.2%** with minimal changes to sensitivity[2] |
| Pause | Filter signal using dynamic noise reduction, signal to noise ratio, signal loss | **Performance for 3-second pauses from the 4 settings ranged from 82% - 98% PPV%[3]** |
| AT | Algorithm allows AT detection and duration programmed separately | **PPV improved from 54% to 97%** with higher rates and longer durations[4] |
| Tachy | Machine learning used to optimize tachycardia detection algorithm | **Correctly rejected noise 96% of the time. PPV improved from 23% to 86%[5]** |

*Bench Test results may not necessarily be indicative of clinical performance.
*Bench data for this research was provided by Telemetric and Holter ECG Warehouse (THEW), University of Rochester, NY.

1. Mittal S, Saha S, Perschbacher D, Siejko K. Improved AF Rhythm Discrimination with an Implantable Cardiac Monitor Using QRS Morphology. Poster presented at: 2019 Heart Rhythm Society; May, 2019; San Francisco, CA
2. Richards M, Perschbacher D, Herrmann K, Siejko K, Saha S. A Novel Algorithm Reduces False Positives for Pause Detection in Implantable Cardiac Monitors. Poster presented at: 2019 Heart Rhythm Society; May, 2019; San Francisco, CA
3. Richards, M. Perschbacher, D, Herrmann, K, Saha, S, Siejko, K. A Novel Algorithm to Reduce False Positives for Pause Detection in Implantable Cardiac Monitors. Poster presented at Heart Rhythm Society May 2018, Boston, MA
4. Richards, M. Perschbacher, D, Saha, S. A Novel Algorithm Improves Detection of Arrythmias With Regular R-R Intervals. Poster Presented at Heart Rhythm Society May 2019 San Francisco, CA
5. Mittal, S. Siejko, K, Saha, S, Herrmann, K, Perschbacher, D. Can Machine Learning Be Used to Optimize Tachycardia Detection Algorithm in an Implantable Cardiac Monitor. Poster presented at ESC, June 2018, Munich, Germany

**LUX-Dx™ Insertable Cardiac Monitor**

**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.
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**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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