LUX-Dx II+™
ICM System

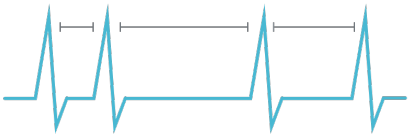
Boston Scientific
Advancing science for life™

Algorithm Overview

The LUX-Dx II+ ICM System uses new and enhanced dual-stage algorithms that detect and then verify data before sending results. Developed in collaboration with ICM implanters and care teams to sharpen algorithm performance where it matters most.

Atrial Fibrillation (AF) Algorithm:

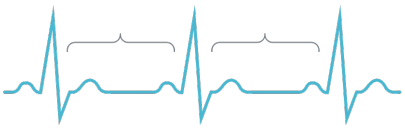
Monitors R-R variability in 2-minute windows to detect potential AF rhythms. The verification stage uses adaptive morphology, noise discrimination and pattern detectors to identify and reject false positives.



New! Additional verification step to identify sequential heart rate patterns and updated to merge adjacent AF episodes.

Bradycardia Algorithm:

Uses rate and duration parameters during the detection stage to identify potential Brady episodes. During the verification stage, episodes are further examined for under-sensing to reject false positives.



New! Nighttime detection parameters allow programming of Brady Rate and Duration separately for daytime and nighttime. Nighttime programming applies from 11:00 pm – 7:00 am.

Pause Algorithm:

Monitors R-R duration to detect potential pause episodes. The verification stage rejects false positives by using a dynamic noise-reduction filter, signal-to-noise ratio and loss-of-signal conditions.

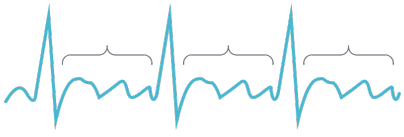
New! Enhanced verification step to further reject false positives due to low Signal-to-Noise ratio.

New! Nighttime detection parameters allow programming of Pause Duration separately for daytime and nighttime. Nighttime programming applies from 11:00 pm – 7:00 am.

New! Pause Duration programmability options expanded.

Atrial Tachycardiac (AT) Algorithm:

Separately programmable from the AF algorithm, the AT Algorithm uses rate, duration and built-in flexibility to detect either short or long duration AT/Atrial flutter based on heart rate and R-R variability. The family of LUX-Dx™ Insertable Cardiac Monitors (ICMs)* are the only ICMs on the market with an AT duration independent of the AF algorithm duration.[1]



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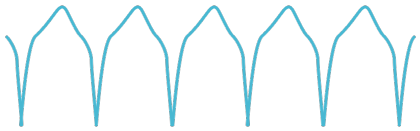
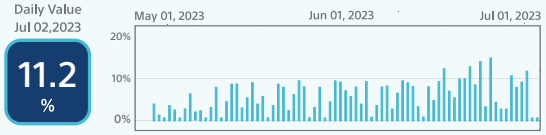
Tachycardia Algorithm:

Uses traditional ICD-based rate and duration parameters during the detection stage. The verification stage uses a machine-learning-based decision tree to classify Tachy episodes as VT, SVT or to reject as noise.



New! PVC Burden:

A new PVC Burden algorithm that identifies singlet, couplet and triplet PVCs to provide a daily PVC Burden trend and programmable alerts. Monitors R-R variability and change in R-wave amplitude, as well an adaptive morphology assessment in the verification step.



Learn more at bostonscientific.com/LuxDxICM

1. 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

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

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

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 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.

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