LUX-Dx II+™
ICM System

Models M312, 2925, 2929, 2935, 2939, 6386

Boston Scientific
Advancing science for life™

Focused on what matters.

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.

LUX-Dx II+ introduces a new PVC burden algorithm that identifies single, couplet and triplet PVC sequence types in one actionable alert. Enhanced AF and enhanced Pause algorithms, along with advanced nighttime brady and pause programing, deliver clinically meaningful, actionable insights that reduce time wasted reviewing false positives and irrelevant episodes.

Product Specifications - Device

Parameters	Value
Volume	1.2 cm^3
Mass	3 g
Dimensions W x H x D	7.2 mm x 44.8 mm x 4.0 mm
Surface area of can electrode	75.3 mm^2
Surface area of header electrode	10.2 mm^2

Materials

Parameters	Value
Can	Titanium
Electrodes	Titanium nitride
Header	Implantable Grade Polymer
Coating	Parylene

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Battery

Parameters	Value
Manufacturer	Boston Scientific
Model	LUX-Dx
Chemistry	Lithium-manganese dioxide
Longevity	Longevity 3 years projected longevity, under the following usage scenarios: • Average of 1 auto-detected event per day • Average of 1 patient-initiated event per month • Less than or equal to 6 months shelf life (between device manufacture and insertion) • PVC Burden disabled Note: At the maximum shelf storage time of 18 months, longevity is reduced by approximately 4 months.

System Component	Description	Model Number
Device	LUX-Dx II+ Insertable Cardiac Monitor	M312
Mobile Applications	myLUX™ Patient App for an Android™ Mobile Device myLUX Patient App for an Apple™ Mobile Device myLUX Patient App LUX-Dx™ Clinic Assistant App	2929 2939 2925 2935
Server and Website	LATTITUDE™ Clarity Data Management System	N/A
Accessory	Magnet*	6386

*Magnet Model 6386 is an accessory used to initiate communication between the device and the mobile applications. It is available as a separately packaged accessory in addition to being packaged with the 6385 myLUX™ Patient Kit.

Kit	Model Number
myLUX™ Patient Kit	6385
myLUX™ Mobile Device	7259
LUX-Dx™ Clinic Assistant Mobile Device	7256

Default Settings

Sensing Parameters	Setting
Blank After Sense	160 ms
Sensing	Off
Sensitivity	0.037 mV

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Programmable Parameters

Sensing	Programmable Settings
Blank After Sense	130-400; 10 ms intervals
Sensing (mV)	0.025, 0.037, 0.05, 0.075, 0.1, 0.15, 0.2
Morphology Assessment	On, Off

Brady	Programmable Settings
Brady On/Off	On, Off
Rate (bpm or min -1)	30, 40, 50, 60
Night Rate (bpm or min -1)	30, 40, 50, 60
Duration (seconds)	1, 2, 3, 5, 7, 10, 15, 20, 30
Night Duration (seconds)	1, 2, 3, 5, 7, 10, 15, 20, 30

Tachy	Programmable Settings
Tachy On/Off	On, Off
Rate (bpm or min -1)	115 -220 in increments of 5
Duration (seconds)	0, 1, 2, 3, 4, 5, 10, 20, 25, 30, 40, 50, 60
Response	Less, Balanced, More

Pause	Programmable Settings
Pause On/Off	On, Off
Duration (seconds)	2,3,4,5,6,7,8,9,10
Night Duration (seconds)	2,3,4,5,6,7,8,9,10
Response	Less, Balanced, More

Symptoms	Programmable Settings
Symptoms	On, Off
Recordings Allowed Per Day	6 events of 5 minutes 4 events of 7.5 minutes 3 events of 10 minutes

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AT	
AT On/Off	On, Off
Rate (bpm)	70 -110 by 10; 120 -180 by 20
Duration (min/hr)	2, 6, 10, 20, 30, 60 (minutes); 2, 3, 4, 6, 8, 10, 12, 16, 20, 24 (hours)

AF	
AF On/Off	On, Off
AF Response	Least, Less, Balanced, More, Most
AF Duration (minutes)	2, 4, 6, 10, 20, 30, 60

PVC Burden	
PVC Burden On/Off	On, Off
PVC Burden Monitor	Continuous, Short Term (2, 3, 7, 14, or 30 days)
PVC Burden Monitoring Frequency	Every week, month, three months, six months

Magnet Use	
Bluetooth® Low Energy Technology	Require Magnet, No Magnet

Device Data Collection	
Reason for Monitoring	Syncope; Palpitations; Cryptogenic Stroke; Suspected AF; Post AF Ablation; AF Management; Ventricular Tachycardia; Other

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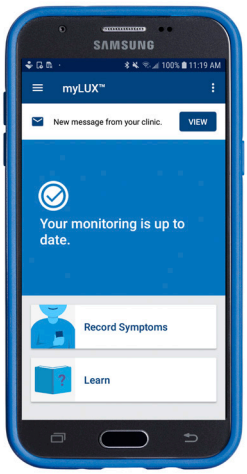
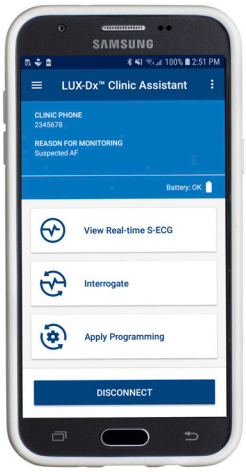
LUX-Dx II+ ICM System uses four mobile applications, three app options for patients and one for clinicians. For patients, the app options are Model 2925 (Patient App on provided device), Model 2929 (Downloadable Patient App for Android™) Model 2939 (Downloadable Patient App for Apple™)



myLUX™ Patient Mobile App

- Transmits device data
- Records symptoms
- Displays monitoring status
- Connects to educational resources
- Displays messages from clinic
- Available as a downloadable app for patient's own smartphone or on a Boston Scientific provided mobile device



LUX-Dx™ Clinic Assistant Mobile App

- View a patient's real-time S-ECG
- Interrogate LUX-Dx ICM™ devices
- Activate and apply programming changes to a LUX-Dx ICM device

Magnet

- Can be attached to the back of a mobile device, to a keychain, or carried in a purse or pants pocket
- Initiates communication between device and mobile apps

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LUX-Dx II+ ICM ECG Storage Data

Up to 30 minutes of patient-triggered event tracking

- Four episodes at 7.5 minutes each
- Three episodes at 10 minutes each
- Six episodes at 5 minutes each

60 minutes of S-ECG storage for all event types; AF, AT, Pause, Brady, Tachy
(includes patient-initiated events)
Automatic detection: Five events of each type per day unless a special event occurs

Event Type	Priority	Special Criteria
AF	1	Longest
Pause	1	Longest
Tachy	1	Fastest
AT	2	N/A
Brady	2	Slowest
Patient Triggered	3	N/A

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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