LUX-Dx™
ICM Systems

Models M301, 2925, 2935, 6386

It's time for a different ICM.

- AF algorithm uses morphology to expand detection beyond simple R-R variability from Lorenz plots and looks to reject false alerts caused by PVCs and noise artifacts
- Pause algorithm utilizes a two-stage detection and verification mechanism to identify under-sensing due to low amplitude, over-sensing and missing signal (flatline)
- AT algorithm is untethered from the AF algorithm and can be programmed separately to identify pathophysiologic high-rate/long-duration rhythms that would normally go undetected
- LATITUDE Clarity™ Data Management System is used to monitor and program a patient's device remotely
- The myLUX™ Patient App is used by patients to transmit device data, record symptoms and check connection status

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	M301
Chemistry	Lithium-manganese dioxide
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 **Note:** At the maximum shelf storage time of 18 months, longevity is reduced by approximately 4 months **Note:** Projected longevity is 2 years when the Bluetooth Manual Connection is configured to not require a magnet

System Component	Description	Model Number
Device	LUX-Dx Insertable Cardiac Monitor	M301
Mobile Applications	myLux Patient App LUX-Dx™ Clinic Assistant App	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 provided mobile devices.

Kit	Model Number
myLUX Patient Kit with mobile device	6259
LUX-Dx Clinic Assistant kit with mobile device	6256

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

Brady	Programmable Settings
Pause On/Off	On, Off
Rate (bpm or min -1)	30, 40, 50, 60
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)	1.5, 3, 4.5
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 (min); 2, 3, 4, 6, 8, 10, 12, 16, 20, 24 (hours)

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

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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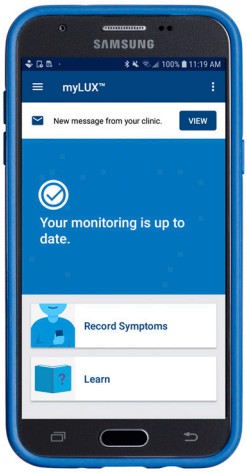
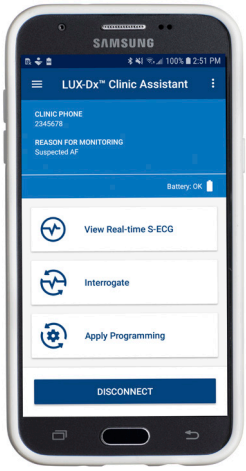
LUX-Dx ICM System uses two mobile applications, one for patients and one for clinicians.
Model 2925 (Patient App), Model 2935 (Clinic App), Magnet Model 6386.



myLUX Patient Mobile App

- Transmits device data
- Records symptoms
- Displays monitoring status
- Connects to educational resources
- Displays messages from clinic



LUX-Dx Clinic Assistant Mobile App

- View a patient's real-time S-ECG
- Interrogate LUX-Dx ICM devices
- Apply programming changes to a LUX-Dx ICM device

Magnet

- Can be attached to back of mobile device
- Initiates communication between device and mobile apps

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LUX-Dx 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™ Insertable Cardiac Monitor System

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.

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.

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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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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