LUX-Dx II™

ICM System

Models M302, 2925, 2929, 2935, 2939, 6386

▶▶ | Focused on what matters.

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.

The LUX-Dx II introduces a new PVC burden algorithm that identifies single, couplet and triplet PVC sequence types in one actionable alert. Enhanced Pause algorithms 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	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	M302
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
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 (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

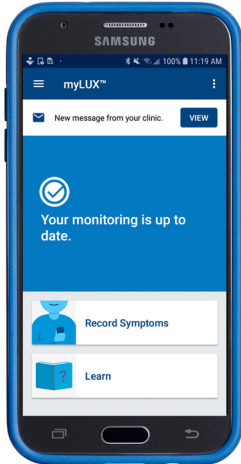| Magnet Use	
Bluetooth® Low Energy Technology	Require Magnet, No Magnet

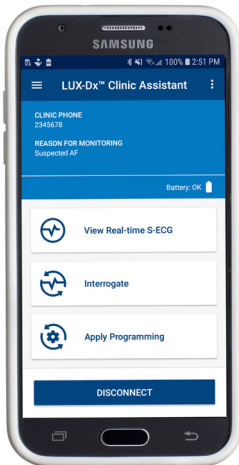| Device Data Collection	
Reason for Monitoring	Syncope; Palpitations; Cryptogenic Stroke; Suspected AF; Post AF Ablation; AF Management; Ventricular Tachycardia; Other

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LUX-Dx II ICM System uses four mobile applications, three app options for patients and one for clinicians. 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
- 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

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