



## LUX-Dx™ ICM System

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
<b>Volume</b>	1.2 cm <sup>3</sup>
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 <sup>2</sup>
Surface area of header electrode	10.2 mm <sup>2</sup>

#### 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	<p>3 years projected longevity, under the following usage scenarios:</p> <ul style="list-style-type: none"> <li>• Average of 1 auto-detected event per day</li> <li>• Average of 1 patient-initiated event per month</li> <li>• Less than or equal to 6 months shelf life between device manufacture and insertion</li> </ul> <p><b>Note:</b> At the maximum shelf storage time of 18 months, longevity is reduced by approximately 4 months</p> <p><b>Note:</b> Projected longevity is 2 years when the Bluetooth Manual Connection is configured to not require a magnet</p>

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 <sup>a</sup>	
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



**CAUTION:** The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device or at [www.IFU-BSCI.com](http://www.IFU-BSCI.com). Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.

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