LUX-Dx™
ICM Systems

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Nominal Programming Settings

The following table displays the nominal values for programming based on each reason for monitoring for the family of LUX-Dx™ Insertable Cardiac Monitor Systems (ICMs)*

Parameter Name	Configurable Options	Cryptogenic Stroke Suspected AF	Post AF Ablation	AF Management	Syncope	Palpitations	VT	Other
Detection Algorithm Nominal Parameters								
AF Detection	On, Off	On						
AF Response	Least, Less, Balanced, More, Most	More	More	Balanced	Less	Balanced	Less	Balanced
AF Duration	2, 4, 6, 10, 20, 30, 60 (minutes)	4	4	10	10	10	10	6
AT Detection	On, Off	On						
AT Duration	2, 6, 10, 20, 30, 60 (minutes) and 2, 3, 4, 6, 8, 10, 12, 16, 24 (hours)	4 hours						
AT Rate	70, 80, 90, 100, 110, 120, 140, 160, 180 (bpm)	110						
Brady Detection	On, Off	On						
Brady Duration	1, 2, 3, 5, 7, 10, 15, 20, 30 (seconds)	1						
Brady Rate	30, 40, 50, 60 (bpm)	40						
Brady Nighttime Rate (M312 only)	30, 40, 50, 60 (bpm)	30						
Brady Nighttime Duration (M312 only)	1, 2, 3, 5, 7, 10, 15, 20, 30 (seconds)	1						
Pause Detection	On, Off	On						
Pause Response	Less, Balanced, More	Less	Less	Less	More	Balanced	Less	Balanced
Pause Duration	M301, M302 – 1.5, 3, 4.5 (seconds) M312 – 2, 3, 4, 5, 6, 7, 8, 9, 10 (seconds)	3						
Pause Nighttime Duration (M312 only)	2, 3, 4, 5, 6, 7, 8, 9, 10 (seconds)	5						

Parameter Name	Configurable Options	Cryptogenic Stroke / Suspected AF	Post AF Ablation	AF Management	Syncope	Palpitations	VT	Other
Detection Algorithm Nominal Parameters								
Tachy Detection	On, Off	On						
Tachy Duration	0, 1, 2, 3, 4, 5, 10, 15, 20, 25, 30, 40, 50, 60 (seconds)	5						
Tachy Rate	115- 220 in steps of 5 bpm	170						
Tachy Response	Less, Balanced, More	Less	Less	Less	More	Balanced	More	Balanced
PVC Burden Detection (M302, M312 only)	On, Off	Off						
PVC Burden Monitoring Duration (M302, M312 only)	Continuous, Short Term	Continuous						
PVC Burden Monitoring Days (M302, M312 only)	2, 3, 7, 14, or 30 days	N/A						
PVC Burden Monitoring Frequency (M302, M312 only)	Every week, month, 3 months, or 6 months	N/A						
Blank After Sense	130-400 ms @ 10 ms increments	160						
Sensitivity	0.025, 0.037, 0.05, 0.075, 0.1, 0.15, 0.2 mV	0.037						
Morphology Assessment	On, Off	On						
Symptom Recording	On, Off	On						
Symptom Recordings Allowed Per Day	3 (10 minutes/event) 4 (7.5 minutes/event) 6 (5 minutes/event)	4 (7.5 minutes/event)						
Telemetry Related								
Manual Bluetooth® Connection	Require Magnet, No Magnet	Require Magnet						

***References to LUX-Dx ICMs Includes LUX-Dx™ (M301), LUX-Dx II™ (M302) and LUX-Dx II+™ (M312) 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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Cardiology
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

Medical Professionals:
1.800.CARDIAC (227.3422)
Patients and Families:
1.866.484.3268

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