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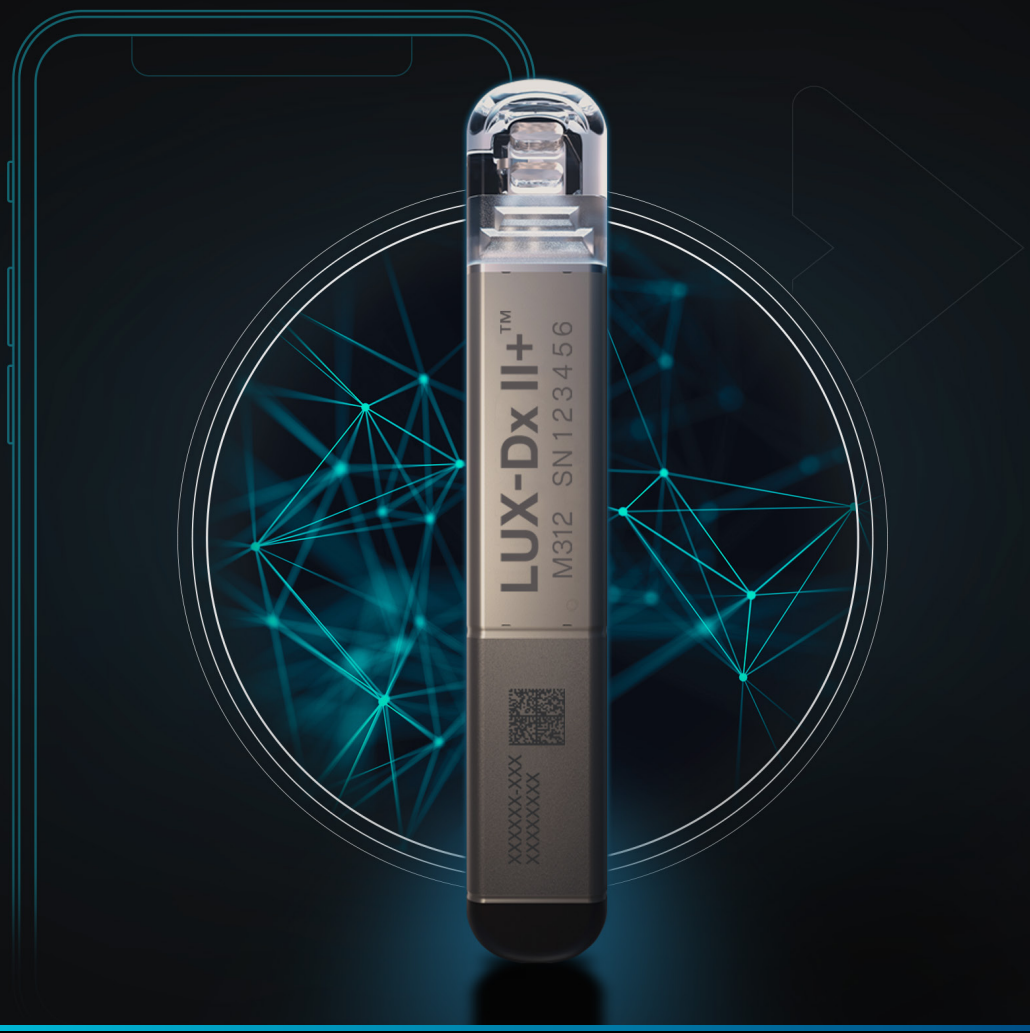
LUX-Dx II/II+™ ICM Systems*

Quick Reference Workflow Guide



LUX-Dx II/II+™ Insertable Cardiac Monitoring Systems (ICMs)*

myLUX™ Patient App

RhythmCARE™ Assist Service

*References to "LUX-Dx II/II+™ ICMs" includes LUX-Dx II™ and LUX-Dx II+™ ICM Systems

PRE-INSERTION

Direct the patient to download the myLUX™ Patient App prior to the procedure using the **myLUX™ Patient App Pre-Insertion Card.**

The card may be provided to the patient by:

- The clinicians at consult
- The scheduler
- The hospital/clinic staff or Boston Scientific Representative on the insertion day prior to the procedure

If the manufacturer is unknown, encourage the patient to bring their app store username and password.

INSERTION

Prepare: Monitoring Method

Meet with the patient and use the **myLUX™ Patient App Pre-Insertion Card** to confirm the preferred monitoring method.

If the patient is using the downloadable myLUX app:

- Download the app if the patient hasn't done so already
- Review the **RhythmCARE™ Assist Service Guide**, get consent to sign the patient up, and get the patient's contact information for the RhythmCARE™ Assist service

Follow the steps for this patient's monitoring method:

A Downloadable myLUX™ Patient App (or if method is unknown)

1. Prepare: Inventory

- M302 or M312 ICM
- 6385 myLUX™ Patient Kit
- 6256 LUX-Dx™ Clinic Assistant*

2. Insertion: View S-ECG

- On the LUX-Dx™ Clinic Assistant

3. Enroll: LATITUDE Clarity™

- During LATITUDE Clarity™ enrollment, sign the patient up for RhythmCARE™ Assist emails and (optional) text messages

  Tip: For all patients using the downloadable app, it is recommended to sign them up for RhythmCARE™ Assist and to send the Welcome Communication.

4. Set Up the myLUX™ Patient App

If the patient was able to successfully download the app:

- Complete app set up by following prompts on the screen (which also activates their ICM)*

If the patient was NOT able to download the app:

- Educate the patient to complete the app download and set up at home
- Use the LUX-Dx™ Clinic Assistant to activate ICM

If the monitoring method unknown:

- Use the LUX-Dx™ Clinic Assistant to activate ICM*
- Once you've met with the patient, determine their monitoring method. Then either download/set up the app or set up the provided phone

B 7259 myLUX™ Mobile Device

1. Prepare: Inventory

- M302 or M312 ICM
- 6385 myLUX™ Patient Kit
- 7259 myLUX™ Mobile Device

2. Insertion: View S-ECG

- On 7259 myLUX™ Mobile Device

3. Enroll: LATITUDE Clarity™

- No change to the enrollment process as this monitoring method is not eligible for service

4. Set Up the myLUX™ Patient App

- Complete set up on 7259 myLUX™ Mobile Device (which also activates their ICM prior to patient going home)

*6256 LUX-Dx™ Clinic Assistant will require a software to be compatible with M302/312

Ask your Boston Scientific Representative for these resources.

POST-INSERTION

Follow the steps for this patient's monitoring method. If the monitoring method is unknown, determine method prior to patient education.

A Downloadable myLUX™ Patient App

Additional Patient Education

If the patient was able to successfully download and set up the app:

- Review the **RhythmCARE™ Assist Service Guide** and **Connectivity Tip Card**

If the patient was NOT able to download the app:

- Refer them to the **myLUX™ Patient App Step-by-Step Set Up Guide**
- Review the **RhythmCARE™ Assist Service Guide**, highlight they will receive communication in 3-4 days to remind them to set up the myLUX app if they haven't done so by that time

Opt-In to RhythmCARE™ Assist Text Messages

- If the patient provided a mobile number during RhythmCARE™ Assist sign up in the LATITUDE Clarity™ enrollment process, guide the patient to reply "YES" to the text message

B 7259 myLUX™ Mobile Device

Additional Patient Education

All information in the Patient Education Folder will be relevant to these patients with the exception of the RhythmCARE™ Assist Service Guide; you can point out this service is exclusively for patients using the downloadable app for monitoring and would be available if they switch to the downloadable app in the future.

Opt-In to RhythmCARE™ Assist Text Messages

- N/A

Post-Discharge: RhythmCARE™ Assist Communications

Information in this section is only applicable to patients using the downloadable myLUX™ Patient App

Welcome

- Patients will receive this communication if "Send the patient a Welcome Communication" was selected during service sign-up in LATITUDE Clarity™
- No additional action from the clinic is needed

Get Set Up

- The Get Set Up message is sent to patients who need to set up the downloadable myLUX™ Patient App at home
- For patients who are Not Set Up, the service will reach out up to three times and will conclude its communication 9-10 business days post-ICM activation
- *See information below on considerations for prioritizing patient calls*

Keep Connected

- The Keep Connected message is sent to patients who become disconnected
- For patients with a Connection Issue, the service will reach out up to three times and will conclude its communication in 6 business days
- *See information below on considerations for prioritizing patient calls*

Clinics may consider this information when prioritizing calls to patients:

- On the "Not Monitored" list in LATITUDE Clarity™, click "Connection Issue" to view the patient's monitoring method and last connection date
- The monitoring method helps you understand if the patient is eligible for the service
- The Last Connection date and communication timelines described above help you understand which patients remain disconnected after the service communication is complete

Review the RhythmCARE™ Assist Brochure for more information

How to Manage Preference Changes:

- *If the patient needs to switch monitoring method,* please call Boston Scientific Patient Support at 866-484-3268.
- *If the patient gets a new phone,* the patient will need to set up the myLUX™ Patient App on their new phone following the same process used during initial set up.
- *If the patient gets a new phone and phone number,* install the myLUX app. In the set up process select the option to "change phone" number during the verification code step. This will allow set up of the myLUX app on the new phone with the new number. At this time, RhythmCARE™ Assist communications will not go to the new number.
- *If the patient would like to unsubscribe from RhythmCARE™ Assist communications,* direct the patient to tap the "unsubscribe" link in the email and/or reply "STOP" to the text message. Patients must unsubscribe to both if they'd like all communication to cease.

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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Rhythm Management
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

Medical Professionals:
1.800.CARDIAC (227.3422)
Customer Service:
1.866.484.3268

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