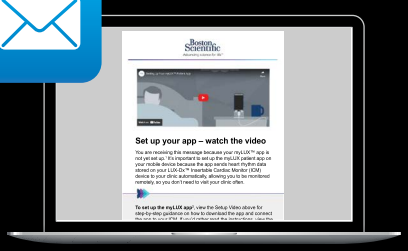
Boston Scientific
Advancing science for life™

RhythmCARE™ Assist Service

For the LUX-Dx II/II+™ Insertable Cardiac Monitor Systems*

Automated Text Messages

Automated Email Messages



Seamless Connectivity

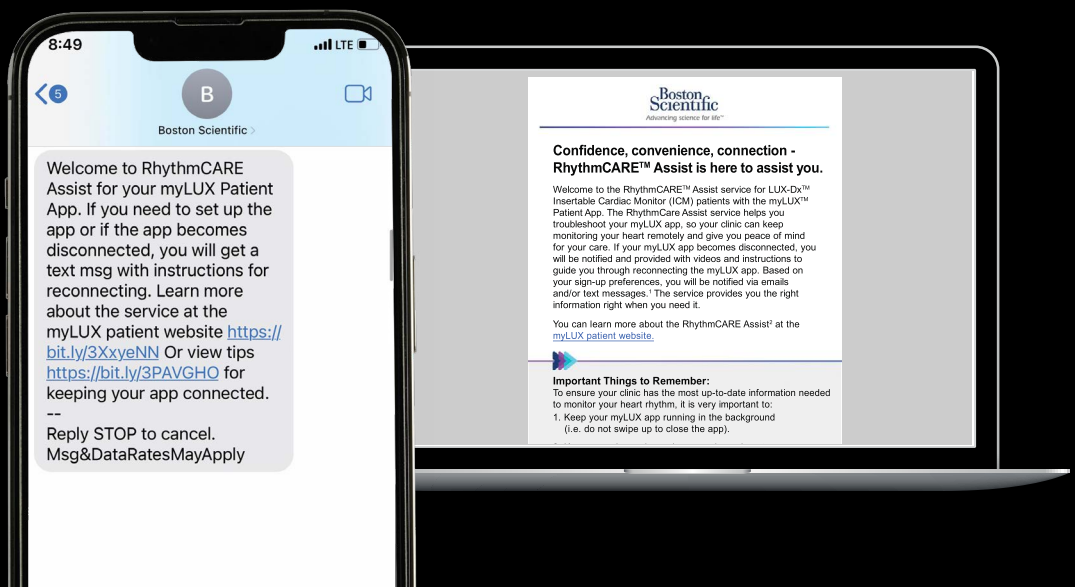
*References to "LUX-Dx II/II+ ICMs" Includes LUX-Dx II™ and LUX-Dx II+™ ICM Systems. RhythmCARE Assist is available exclusively to patients who have downloaded the myLUX™ Patient App on their smartphone.

RhythmCARE™ Assist is an automated service that communicates directly with LUX-Dx™ ICM patients to help set up the myLUX™ Patient App and resolve technical troubleshooting issues.

The service is available exclusively to patients who have downloaded the myLUX™ Patient App on their personal smartphones. Patients may be signed up for the service during LATITIDUE Clarity™ enrollment. The service notifies the patient via email or text message if the patient needs to set up the app or when connectivity issues arise and provides educational content to guide the patient through reconnecting.

The communication is automatic, requiring no action from the clinic to initiate so less time is spent filling out forms.

RhythmCARE™ Assist is a supplemental service at no extra cost to you or your patients, and complements your clinic's primary communication on patient set up and compliance, providing an efficient workflow and seamless connectivity.



Confidence.

RhythmCARE™ Assist sends automated messages to patients.

The patient may be contacted via email and/or text message, depending on the contact information provided when signing up for the service.

The email messages are sent from **RhythmCAREassist@bostonscientificemail.com**
The text messages are **sent from the number 58984.** The patient will receive a contact card sent within the opt-in message with this 5-digit number for Boston Scientific.
If the patient saves the contact card, future messages will come from Boston Scientific.

There are 4 reasons the service will send communications:

Opt-in | **Welcome** | **Get Set Up** | **Keep Connected**

Opt-In Message

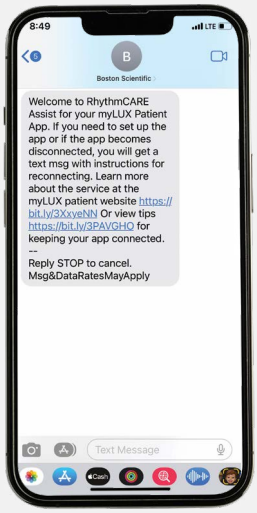
This message is only for patients who chose to be contacted by SMS. The patient must reply "YES" to the opt-in text message to receive further text communications.

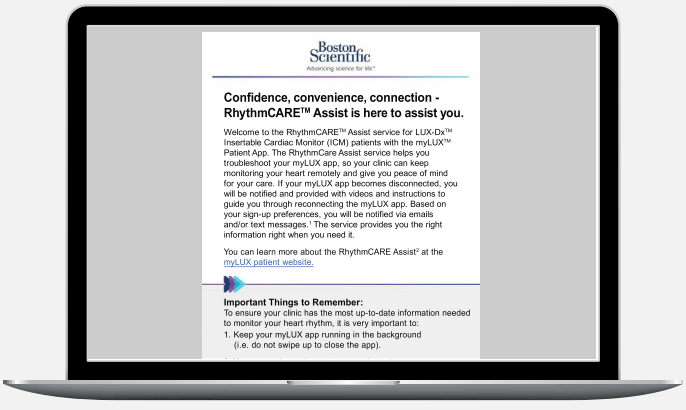
15 minutes
post-ICM activation

Welcome Message

This message provides information on RhythmCARE™ Assist and proactive education on connectivity.

15 minutes
post-ICM activation

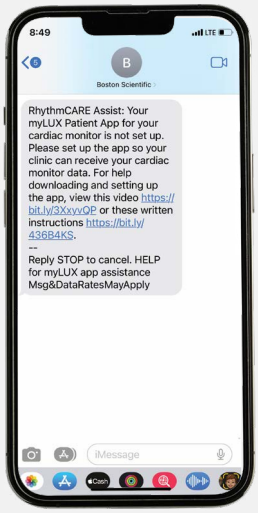




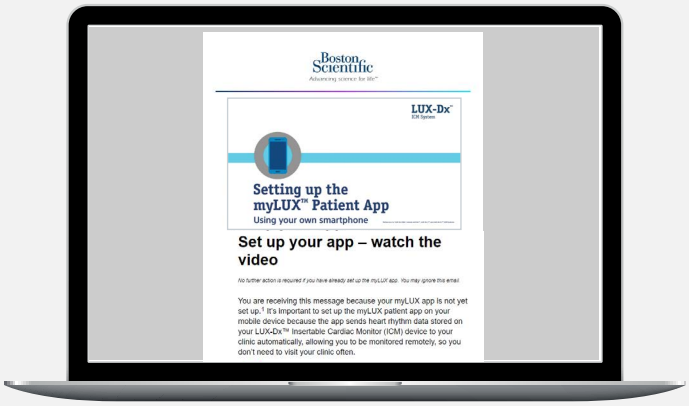
Convenience.

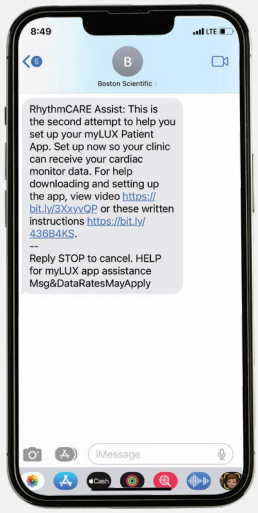
Get Set Up Messages
These messages are only sent to patients who have not yet downloaded and set up the myLUX™ Patient App. The messages provide step by step instructions, in video and written formats, on how to download the app and pair their ICM.

For patients who are Not Set Up, the service will conclude its communication 9-10 business days after the patient appears on the LATITUDE Clarity™ Not Monitored list.

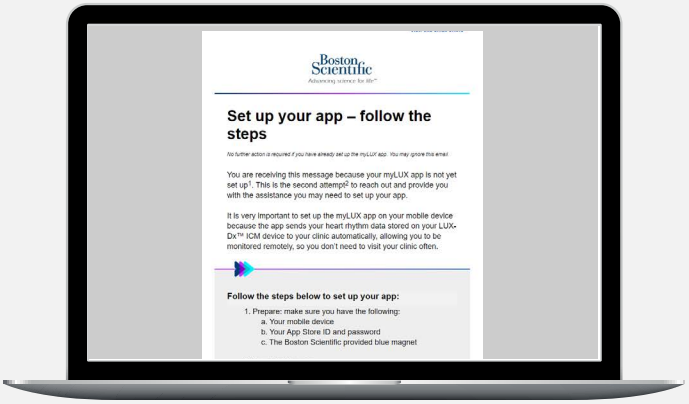


First Message
3-4 days post-ICM activation†

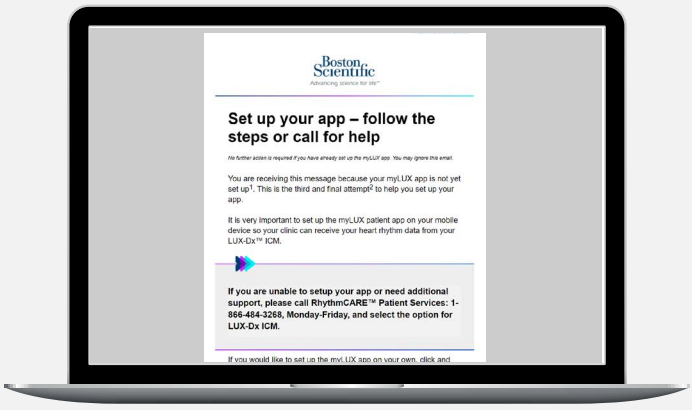




Second Message
3 days after the first message†



Third Message
3 days after the second message†

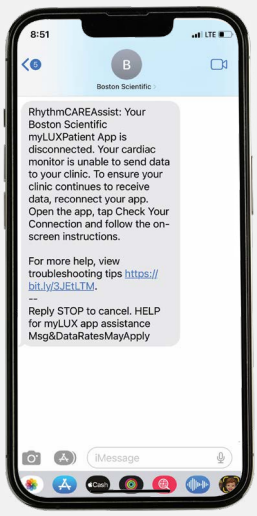


† Messages cease if the patient sets up their app, resolves their connection issue or opts out of communications. If the scheduled communication day falls on a weekend, it will go out on Monday.
Note: Patients may call Boston Scientific RhythmCARE Patient Services for live assistance. Patients may unsubscribe at any point which would cease any automated messaging.

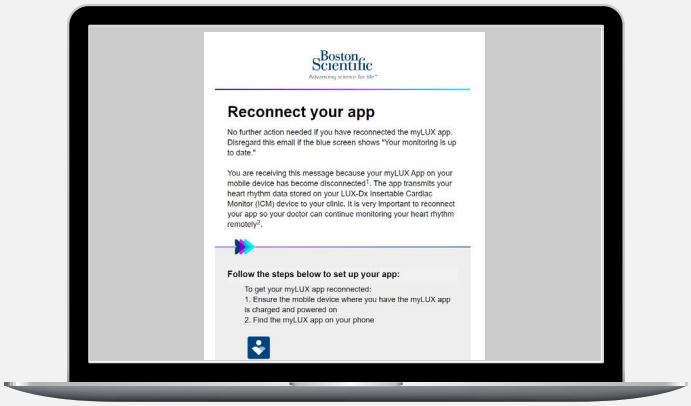
Connection.

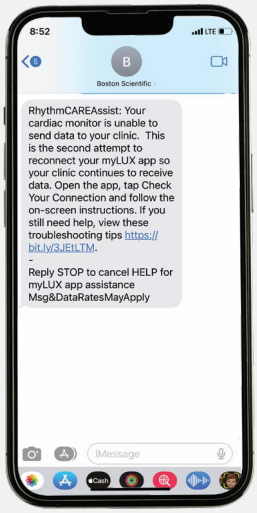
Keep Connected Messages
These messages are only sent to patients who become not monitored. It provides step by step instructions, in video and written formats, on how to resolve connectivity issues.

For patients with a Connection Issue, the service will conclude its communication 6 business days after the patient appears on the LATITUDE Clarity™ Not Monitored list.

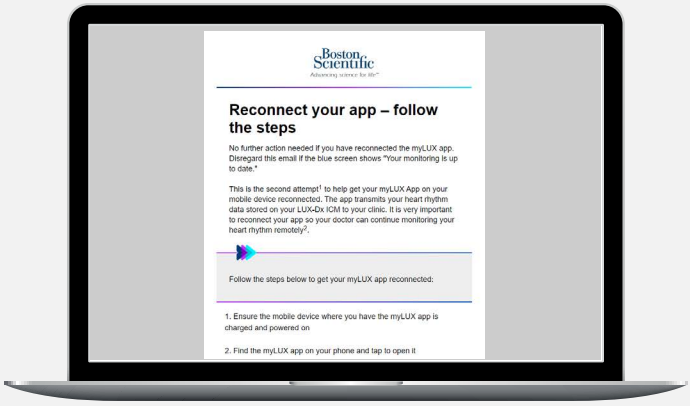


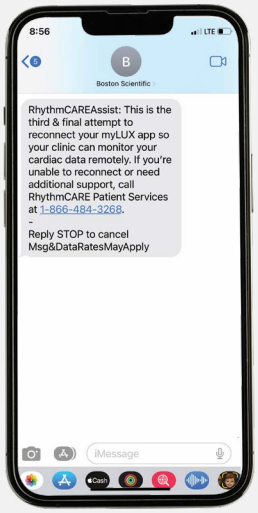
First Message
When patient is put on LATITUDE Clarity "Not Monitored" list†



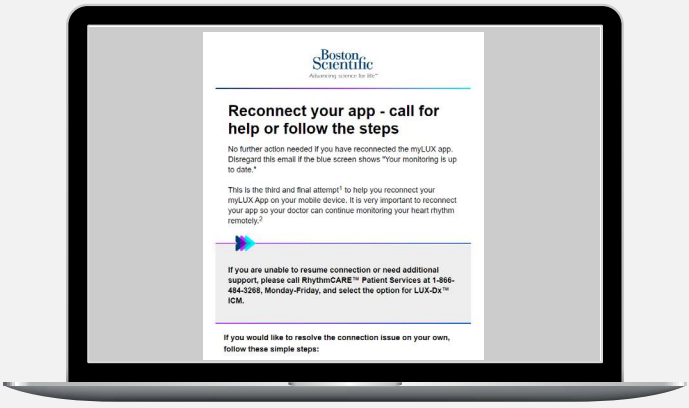


Second Message
3 days after the first message†





Third Message
3 days after the second message†



Clinics may consider this information when prioritizing calls to patients:

- Review the "Not Monitored" list in LATTTUDE Clarity™, click "Connection Issue" to view the patient's monitoring method and last connection date.
- First, determine whether the patient is eligible for the RhythmCARE Assist Service based on the Mobile Device Information provided.
  - If the patient is using the downloadable myLUX Patient App, the type of smartphone the patient is using will be displayed. These patients are eligible for the service since they are using the downloadable app.*
  - If the patient is using a Boston Scientific mobile device, the patient is not eligible for the service.
- Then, review the Connection Issue alert date to help you determine which patients remain disconnected after the service communication is complete.
  - For patients with a **Connection Issue**, the service will conclude Keep Connected communication within 6 business days.
  - For patients who are **Not Set Up**, the service will conclude the Get Set Up communication within 9-10 business days.

If the patient would like to unsubscribe from RhythmCARE Assist Communications, direct the patient to tap the link at the bottom of the email to unsubscribe and/or reply "STOP" to the text message. Patients must unsubscribe to both if they'd like all communication to cease.

Patients will receive RhythmCARE Assist communications if they were signed up for the service during LATITUDE Clarity enrollment, have an active LUX-Dx II/II+ ICM, and have remained opted-in to the communications.

If patients need additional support, they may call into RhythmCARE Patient Services: 1-866-484-3268 Monday – Friday.

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.

Boston Scientific
Advancing science for life™

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

CRM-1634701-AA