

USER'S MANUAL

LUX-Dx™

Insertable Cardiac Monitor System

REF M301, 2925, 2935

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ABOUT THIS MANUAL

This manual contains information about the LUX-Dx Insertable Cardiac Monitor system, which includes an insertable cardiac monitor, two mobile applications (one for the patient and one for the clinician), and the LATITUDE Clarity Data Management System.

Throughout the manual, the following terminology conventions are used:

Term	Definitions
Device	LUX-Dx Insertable Cardiac Monitor
Mobile device	Hardware on which the clinic app or patient app is installed
Patient app	myLUX patient app (mobile application)
Clinic app	LUX-Dx Clinic Assistant app (mobile application)
Server	LATITUDE server
ICM system	LUX-Dx Insertable Cardiac Monitor system
LATITUDE Clarity	LATITUDE Clarity Data Management System (includes LATITUDE server and LATITUDE Clarity website)

The figures used in this manual are intended as examples only and may not match what you see when using the ICM system. Figures and instructions that describe the mobile device are representative. Your actual mobile device may vary slightly in appearance.

Patient names displayed in figures are fictitious. Any resemblance to a real person, living or dead, is purely coincidental.

Unless serving as a heading or for emphasis, bold words are intended to represent the actual words appearing on screens within the apps or LATITUDE Clarity.

The following abbreviations may be used in this manual:

Abbreviation	Definition
AF	Atrial Fibrillation
AT	Atrial Tachy
BSC	Boston Scientific Corporation
EMI	Electromagnetic interference
EMR	Electronic Medical Record
EOS	End of Service
ESWL	Extracorporeal shock wave lithotripsy
HBOT	Hyperbaric oxygen therapy
ICM	Insertable Cardiac Monitor
ID	Identification or Identifier
MR	Magnetic resonance
MRI	Magnetic Resonance Imaging
PII	Patient Initiated Interrogation
RF	Radio Frequency

Abbreviation	Definition
RRT	Recommended Replacement Time
S-ECG	Subcutaneous Electrocardiogram
TENS	Transcutaneous electrical nerve stimulation
VAD	Ventricular assist device

All intervals, rates, and durations have a tolerance of ± 5 milliseconds.

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INTRODUCTION

CHAPTER 1

This chapter contains the following topics:

- "System Overview" on page 1-2
- "System Limitations" on page 1-3
- "Clinical Benefits of the Device" on page 1-4
- "Intended Use" on page 1-4
- "Summary of Safety and Clinical Performance" on page 1-5
- "Warranty Information" on page 1-5
- "Warnings" on page 1-5
- "Precautions" on page 1-7
- "Potential Adverse Events" on page 1-12
- "Patient Counseling Information" on page 1-12

SYSTEM OVERVIEW

The LUX-Dx Insertable Cardiac Monitor system (“ICM system”) is designed to monitor and record heart rates for clinical evaluation. The ICM system may be prescribed for patients with clinical syndromes, patients at increased risk of cardiac arrhythmias, or patients who experience symptoms such as dizziness, palpitation, syncope, and chest pain that may suggest a cardiac arrhythmia. It does not treat cardiac arrhythmias. The ICM System is not for active patient monitoring or for use with patients requiring attended, in-hospital monitoring for life threatening arrhythmias.

The ICM system consists of the following components:

System Component	Description	Model Number
Device	LUX-Dx Insertable Cardiac Monitor	M301
Mobile Applications	myLUX software	2925
	LUX-Dx Clinic Assistant software	2935
Server and Website	LATITUDE Clarity Data Management System	N/A
Accessory	Magnet	6386

The device constitutes the insertable portion of the ICM system. The mobile applications and LATITUDE Clarity constitute the external portion of the ICM system.

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.

Use of the patient app and use of the magnet by patients are optional. These components may be used if a health care provider wants to follow a patient remotely.

Boston Scientific provides each of the mobile applications pre-installed on a mobile device:

Kit	Model Number
myLUX Patient Kit with mobile device	6259
LUX-Dx Clinic Assistant Kit with mobile device	6256

CAUTION: The ICM system is not meant to assist with health emergencies. Patients who need immediate medical attention, should call their health care provider or seek emergency provider medical services.

The ICM System does not provide any diagnosis and is not intended to be used as the sole means for making decisions about patient medical care.

Insertable Cardiac Monitor

The insertable cardiac monitor is a small, leadless electronic device inserted just under the skin in the chest area. Its primary function is to monitor, record, and store data related to cardiac arrhythmias. The device uses two electrodes on the body of the device to monitor the patient’s subcutaneous ECG (S-ECG) data when specific arrhythmias are detected. In addition, the sensor will record S-ECG data when the patient initiates or triggers the device to record S-ECG. The device memory can store up to 60 minutes of S-ECG recordings. Arrhythmia detection parameters are based on Reason for Monitoring information entered during patient enrollment. Arrhythmia detection parameters can also be programmed manually by the clinician.

Mobile Applications

The mobile applications (apps) are used to interrogate the device and transmit data between the device and the LATITUDE server. The patient app also allows patients to record S-ECGs of symptomatic events to be sent to the server.

Both apps communicate with the device using Bluetooth Low Energy technology, and with the LATITUDE server using a Wi-Fi or cellular connection (Figure 1-1 ICM System Diagram on page 1-3).

LATITUDE Clarity Data Management System

LATITUDE Clarity is used to periodically monitor both patient and device status, program the device, and review and evaluate clinical data. All remotely transmitted data is sent to the LATITUDE server and made available on the LATITUDE Clarity website to authorized health care providers.

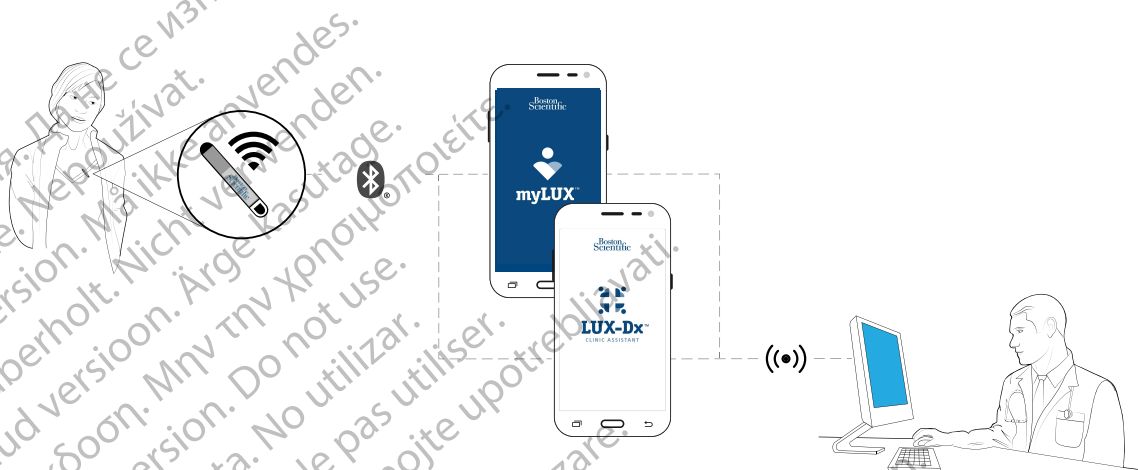


Figure 1-1. ICM System Diagram

SYSTEM LIMITATIONS

Network and data security. The ICM system uses industry-accepted protocols for authenticating users and encrypting transmitted data. It is considered good practice to connect only to managed, secure networks.

There are many internal and external factors that can hinder, delay, or prevent acquisition and delivery of device information. These factors include:

- **Programming** – Proper reporting of the device and alert notifications by the LATITUDE Clarity System depends on accurate programming. (See "Patient Group, Clinic Configuration, and Programming Options" on page 4-10.) The device receives programming changes during interrogations (from either the patient app or clinic app) or when applied by clinicians via the clinic app.
- **Patient environment** – To transmit data, the mobile device must be charged and Bluetooth must be enabled. The mobile applications must also maintain Wi-Fi or cellular connection with the LATITUDE Clarity System. Patients must be within 2 meters (6 feet) of the mobile device at the time of the transmission. For more information, see the *myLUX Patient App for Insertable Cardiac Monitor Patient Handbook*. Radio frequency (RF) interference from electronic products may interfere with communication between the device and the patient app.

NOTE: Boston Scientific personnel may contact the clinic if a device uses too much telemetry to perform remote interrogations.

- **Method of connection to the LATITUDE Clarity System:**

- **Cellular data service plus Wi-Fi** – Actual coverage may be affected by such things as terrain, weather, foliage, buildings and other construction, signal strength, timely payment (as applicable), and other factors. Coverage is not guaranteed.

- **Internet** – Variations in the quality of internet infrastructure and internet service providers can affect the delivery of device information.
- **Device memory capacity** – Device memory used to store data may reach its capacity if the patient app cannot connect to the device for an extended period.
 - If this occurs, the device may delete older stored episode data (see "Arrhythmia Event Data and S-ECG Storage" on page 2-16).
- **Clinician environment** – Delays in contacting clinicians may occur for a variety of reasons, including computer equipment that may be down or offline, cell phones that may not be able to receive alert text messages, and the unavailability of clinical staff.
- **Clinic app environment** – To transmit data, the mobile device containing the clinic app must be charged and Bluetooth must be enabled. The clinic app must also maintain Wi-Fi or cellular connection with LATITUDE Clarity and patients must be within 2 meters (6 feet) of the mobile device at the time of the transmission. Radio frequency (RF) interference from wireless electronic products may interfere with communication between the device and the clinic app.
- **Data processing** – Data acquisition and delivery can be delayed or prevented due to:
 - Temporary, scheduled, and unscheduled downtime of computer servers.
 - Variations in server loads and processing times.
 - Other data processing issues.

CLINICAL BENEFITS OF THE DEVICE

The primary benefit of the LUX-Dx ICM System is to provide long-term monitoring and remote transmission of subcutaneous electrocardiogram (S-ECG) recordings triggered by arrhythmic events 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 system automatically detects and records a variety of events, including pause (asystole), bradycardia, tachycardia, atrial fibrillation, and atrial tachycardia, with an additional option for the patient to trigger an event (S-ECGs) recording, from their patient app, in response to symptoms. Given the long-term monitoring, the ICM device enables detection of arrhythmias that due to their sporadic occurrence might be missed by short-term monitoring and allows the ability to correlate these events with the patient's symptoms. The resulting S-ECGs recordings and their correlation with patient symptoms can help physicians provide accurate diagnoses and guide the therapeutic decisions that might follow. The system is designed with programmable parameters that can be tailored based on the patient's medical condition and the clinician's cardiac monitoring strategy. The system has remote monitoring capabilities which allows the clinician to have access to recorded events and to perform routine follow-ups without requiring an in-office visit. In addition, the ICM device and system diagnostic parameters can be programmed remotely, providing the capability to potentially allow for more timely decision making when tailoring the device diagnostic features according to the patient's clinical need as events occur.

INTENDED USE

Indications / Patient Target Group

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.

Intended Audience

This literature is intended for use by a variety of health care providers, including those who

- Are trained or experienced in device implant and/or follow-up procedures
- Provide follow-up care for patients who have a LUX-Dx insertable cardiac monitor
- Are authorized to use LATITUDE Clarity

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

For customers in the European Union, use the device name found in the labeling to search for the device's Summary of Safety and Clinical Performance, which is available on the European database on medical devices (Eudamed) website:

<https://ec.europa.eu/tools/eudamed>

WARRANTY INFORMATION

This product has a limited warranty. See www.bostonscientific.com/warranty for warranty information.

WARNINGS

General

- **Co-implanted device interaction.** 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.

Following completion of the interaction testing, thorough follow-up evaluation of all co-implanted devices should be performed to ensure that device functions have not been compromised. If operational settings of the co-implanted devices change or if patient conditions change which may affect ICM sensing, re-evaluation of the co-implanted devices may be required.

- **Labeling knowledge.** Read this manual thoroughly before using the ICM system to avoid damage to the device. Such damage can result in patient injury or death.
- **For single patient use only.** Do not reuse, reprocess, or resterilize the insertable cardiac monitor or insertion tools. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient. The medical professional may reposition or re-insert the device within a single procedure.

- **Sharp object.** Incision tool is sharp. Take precautions to ensure that it is handled properly. Dispose of incision tool directly into a sharps disposal container labeled with a biological hazard symbol. Sharps waste should be safely disposed of using available sharps waste channels in accordance with hospital, administrative, and/or local government policy.

Insertion

- **Tunneling.** The insertion tool is intended to be used in the subcutaneous space. Always be aware of the location of the tool tip relative to the patient anatomy. Hold the insertion tool at a narrow angle while tunneling. Unintended tissue damage may result if the device is inserted at a large angle.
- **Incision tool blade placement.** Always be aware of the location of the incision tool blade relative to the patient anatomy. Unintended tissue damage may result if the incision tool is inserted beyond the blade.

Post Insertion

- **Diathermy.** 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.
- **Firmware update must be completed.** Once a firmware update begins, the patient will not be monitored until the update is completed. If the firmware update is skipped, the patient is still monitored.
- **Interrogate device, save data, and check device function.** 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 compatibility.** 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.
- **Magnet use.** 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.
- **Mobile devices and magnet are MR Unsafe.** 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 on MR Safe Practices¹. Under no circumstances should the mobile device or magnet be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.
- **MR conditional requirements.** 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 with other devices.** 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.
- **Protected environments.** 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.

1. Kanal E, Barkovich AJ, Bell C, et al. ACR guidance document on MR safe practices: 2013. J. Magn. Reson. Imaging 2013;37:501-530.

PRECAUTIONS

General

- **Not a medical alert system.** The ICM system is not meant to assist with health emergencies. Patients who need immediate medical attention, should call their health care provider or seek emergency provider medical services.
- **Patient Settings.** Ensure that each patient's alert configuration and programming settings are appropriate when the patient is enrolled and, if applicable, after the device is replaced.

Clinical Considerations

- **Check device battery before insertion.** Check the device battery prior to insertion. If a low battery condition is indicated, do not insert the device.
- **Device does not alert patient.** The device cannot alert the patient to emergency situations.
- **Magnet use impact on longevity.** Use of the magnet to initiate communication has been accounted for in the projected battery life of the inserted device. Using this feature more often than directed may lead to a decrease in the battery life of the device.

Sterilization and Storage

- **If package is damaged.** The blister trays and contents are sterilized with ethylene oxide gas before final packaging. When the device is received, it is sterile provided the container is intact. If the packaging is wet, punctured, opened, or otherwise damaged, return the device to Boston Scientific.
- **If device is dropped.** Do not insert a device which has been dropped while outside of its intact shelf package. Do not insert a device which has been dropped from a height of more than 24 inches (61 cm) while within its intact shelf package. Sterility, integrity, and/or function cannot be guaranteed under these conditions, and the device should be returned to Boston Scientific for inspection.
- **Mobile device and magnet.** The mobile device and magnet are non-sterile. Do not sterilize the mobile device or magnet. These items must be contained in a sterile barrier before use in the sterile field.
- **Use by date.** Insert the device before or on the USE BY date on the package label because this date reflects a validated shelf life. For example, if the date is January 1, do not insert on or after January 2.
- **System protection.** Store mobile devices containing Boston Scientific mobile applications in a secure location when not in use and take appropriate measures to prevent theft or unauthorized access.
- **Device storage.** Store the insertable cardiac monitor in a clean area away from unshielded magnets, kits containing unshielded magnets, and sources of EMI to avoid device damage.
- **Magnet storage.** Store the magnet between -20 to 70° C (-4 to 158° F) to avoid risk of de-magnetization or damage to the magnet case.
- **Device storage temperature and equilibrium.** Recommended storage temperatures are 0°C–50°C (32°F–122° F). Allow the device to reach an ambient temperature before using telemetry communication capabilities, programming, or inserting the device because temperature extremes may affect initial device function.

Insertion

- **Breast implant rupture or leaking.** Use extra care in patients with breast implants when inserting an ICM device. Breast implant rupture or leaking may result if the breast implant is damaged during the ICM insertion procedure.

- **Mobile device battery.** Verify that the mobile device is sufficiently charged for the implant procedure; if not sufficiently charged, difficulty with set-up and system initialization may occur.
- **Expected benefits.** Determine whether the expected device benefits provided by programmable options outweigh the possibility of more rapid battery depletion.
- **Evaluate patient for surgery.** There may be additional factors regarding the patient's overall health and medical condition that, while not related to device function or purpose, could render the patient a poor candidate for insertion of this system. Cardiac health advocacy groups may have published guidelines that may be helpful in conducting this evaluation.
- **Handling the device.** Use caution when using medical surgical instruments to remove the device during a repositioning as they could damage the device.

Magnet

- **Magnet replacement.** If you lose your magnet or if the plastic coating surrounding the magnet cracks, contact Boston Scientific for a replacement.
- **Magnet cleaning.** Clean your magnet with only the following cleaning agents as needed to avoid risk of damage to the magnet case: warm tap water, Isopropyl alcohol (70% concentration), or a weak concentration of mild detergent mixed with warm water. Apply cleaning agents to a soft cloth and use gentle pressure to avoid damaging the markings. Do not submerge the magnet or place under running water to prevent risk of water getting inside the magnet case.

Device Programming

- **Device communication.** Use only the designated mobile devices and apps to communicate with this device.
- **Sensing adjustment.** Following any adjustments to sensing parameters, always verify appropriate sensing. Programming Sensitivity to the highest value (lowest sensitivity) may result in delayed detection or undersensing of cardiac activity. Likewise, programming to the lowest value (highest sensitivity) may result in oversensing of non-cardiac signals.
- **Patient app use restriction.** The patient app is paired with a patient's specific inserted device. It will not work with other inserted devices and should only be used as directed by the patient's healthcare provider. Unauthorized use could interrupt the prescribed operation of the device.

Environmental and Medical Hazards

- **Avoid electromagnetic interference (EMI).** Advise patients to avoid sources of EMI, including but not limited to radio frequency interference (RFI) from wireless electronic products, which may have the potential to temporarily interfere with the device's ability to detect and monitor the patient's heart rate. It could also delay or prolong communication between the device and the patient or clinic apps.

Moving away from the source of the EMI or turning off the source usually allows the sensor device to return to normal operation.

Examples of potential EMI sources are:

- Electrical power sources, arc welding or resistance welding equipment, and robotic jacks
- High voltage power distribution lines
- Electrical smelting furnaces
- Large RF transmitters such as radar

- Radio transmitters, including those used to control toys
- Electronic surveillance (antitheft) devices
- An alternator on a car that is running
- Medical treatments and diagnostic tests in which an electrical current is passed through the body, such as TENS, electrocautery, electrolysis/thermolysis, electrodiagnostic testing, electromyography, or nerve conduction studies
- Any externally applied device that uses an automatic lead detection alarm system (e.g., an EKG machine)
- **External defibrillation.** It can take a few seconds for sensing to recover after an external shock is delivered. External defibrillation or cardioversion can damage the device. To help prevent damage to the device, consider the following:
 - Avoid placing a pad (or paddle) directly over the device. Position the pads (or paddles) as far from the device as possible.
 - Set energy output of external defibrillation equipment as low as clinically acceptable. Following external cardioversion or defibrillation, verify device function.
- **Cardiopulmonary resuscitation.** Cardiopulmonary resuscitation (CPR) may temporarily interfere with sensing and may damage the device.
- **Electrical interference.** Hospital medical equipment or equipment in home or occupational environments may cause damage to the device or could lead to oversensing. To reduce the potential of damage, ensure there is minimum separation between the device and other medical equipment and verify operation of the device following any patient procedure. Examples of equipment are as follows:
 - Diathermy
 - High levels of radiation
 - Electrosurgical cautery
 - Lithotripsy
 - Ultrasound
 - Radio frequency ablation
 - Electronic article surveillance (EAS)
- **Ionizing radiation therapy.** It is not possible to specify a safe radiation dosage or guarantee proper device function following exposure to ionizing radiation. Multiple factors collectively determine the impact of radiation therapy on an inserted device, including proximity of the device to the radiation beam, type and energy level of the radiation beam, dose rate, total dose delivered over the life of the device, and shielding of the device. The impact of ionizing radiation will also vary from one device to another and may range from no changes in function to a loss of monitoring.

Sources of ionizing radiation vary significantly in their potential impact on an inserted device.

Several therapeutic radiation sources are capable of interfering with or damaging an inserted device, including those used for the treatment of cancer, such as radioactive cobalt, linear accelerators, radioactive seeds, and betatrons.

Prior to a course of therapeutic radiation treatment, the patient's radiation oncologist and cardiologist or electrophysiologist should consider all patient management options, including increased follow-up and device replacement. Other considerations include:

- Shielding the device with a radiation-resistant material, regardless of the distance between the device and the radiation beam.
- Determining the appropriate level of patient monitoring during treatment.

Evaluate device operation during and following the course of radiation treatment to exercise as much device functionality as possible. The extent, timing, and frequency of this evaluation relative to the radiation therapy regimen are dependent upon current patient health, and therefore should be determined by the attending cardiologist or electrophysiologist.

The effects of radiation exposure on the implanted device may remain undetected until some time following exposure. For this reason, continue to monitor device function closely and use caution when programming a feature in the weeks or months following radiation therapy.

- **Electrocautery and radio frequency (RF) ablation.** If electrocautery or RF ablation is medically necessary, observe the following to minimize risk to the patient and device:
 - Avoid direct contact between the electrocautery equipment or ablation catheters and the device.
 - Keep the path of the electrical current as far away as possible from the device.
 - If RF ablation and/or electrocautery is performed on tissue near the device, verify device function.
 - For electrocautery, use a bipolar electrocautery system where possible and use short, intermittent, and irregular bursts at the lowest feasible energy levels.
- **Lithotripsy.** Extracorporeal shock wave lithotripsy (ESWL) may cause electromagnetic interference with or damage to the device. If ESWL is medically necessary, focus the ESWL beam at least 15 cm (6 in) away from the device to minimize the potential for encountering interaction.
- **Ultrasound energy.** Therapeutic ultrasound (e.g., lithotripsy) energy may damage the device. If therapeutic ultrasound energy must be used, avoid focusing near the insertion site. Diagnostic ultrasound (e.g., echocardiography) is not known to be harmful to the device.
- **Conducted electrical current.** Any medical equipment, treatment, therapy, or diagnostic test that introduces electrical current into the patient has the potential to interfere with device function. Medical therapies, treatments, and diagnostic tests that use conducted electrical current (e.g., TENS, electrocautery, electrolysis/thermolysis, electrodiagnostic testing, electromyography, or nerve conduction studies) may interfere with or damage the device. After the treatment, verify device function.
- **Transcutaneous electrical nerve stimulation (TENS).** TENS involves passing electrical current through the body, and may interfere with device function. If TENS is medically necessary, evaluate the TENS therapy settings for compatibility with the device. The following guidelines may reduce the likelihood of interaction.
 - Place the TENS electrodes as close together and as far away from the device as possible.
 - Use the lowest clinically-appropriate TENS energy output.
 - Additional steps can be taken to help reduce interference during in-clinic use of TENS:
 - If interference is suspected during in-clinic use, turn off the TENS unit.
 - Do not change TENS settings until you have verified that the new settings do not interfere with device function.

- If TENS is medically necessary outside the clinical setting (at-home use), provide patients with the following instructions:
 - Do not change the TENS settings or electrode positions unless instructed to do so.
 - End each TENS session by turning off the unit before removing the electrodes.
- **Magnetic fields.** Advise patients to avoid extended exposure to strong (greater than 10 gauss or 1 mTesla) magnetic fields. Examples of magnetic sources include:
 - Industrial transformers and motors
 - Large stereo speakers
 - Telephone receivers if held within 1.27 cm (0.5 inches) of the device
 - Magnetic wands such as those used for airport security
- **Elevated pressures.** The International Standards Organization (ISO) has not approved a standardized pressure test for implantable devices that experience hyperbaric oxygen therapy (HBOT) or SCUBA diving. However, Boston Scientific developed a test protocol to evaluate device performance upon exposure to elevated atmospheric pressures. The following summary of pressure testing should not be viewed as and is not an endorsement of HBOT or SCUBA diving.

Elevated pressures due to HBOT or SCUBA diving may damage the device. During laboratory testing, all devices in the test sample functioned as designed when exposed to more than 200 cycles at a pressure up to 3.0 ATA. Laboratory testing did not characterize the impact of elevated pressure on device performance or physiological response while implanted in a human body.

Pressure for each test cycle began at ambient/room pressure, increased to a high pressure level, and then returned to ambient pressure. Although dwell time (the amount of time under elevated pressure) may have an impact on human physiology, testing indicated it did not impact device performance. Pressure value equivalencies are provided in the following table.

Table 1-1. Pressure Value Equivalencies

Atmospheres Absolute	3.0 ATA
Sea water depth	20 m (65 ft)
Pressure, absolute	42.7 psia
Pressure, gauge	28.0 psig
Bar	2.9
kPa Absolute	290

- a. All pressures were derived assuming sea water density of 1030 kg/m³.
 b. Pressure as read on a gauge or dial (psia = psig + 14.7 psi).

More frequent device follow-up may be warranted in conjunction with HBOT or SCUBA diving. Evaluate device operation following high pressure exposure. The extent, timing, and frequency of this evaluation relative to the high pressure exposure are dependent upon current patient health and should be determined by the attending health care provider. If you have additional questions, or would like more detail regarding the test protocol or test results specific to HBOT or SCUBA diving, contact Boston Scientific using the information on the back cover.

- **Mammography procedure.** During a mammography procedure, manipulation or angular stress of the device between the plates could cause tissue trauma, vascular trauma, or pain, or affect device sensing. Before scheduling a mammogram, the health care provider should weigh the potential risks against the benefits and evaluate other diagnostic options. Allow sufficient time for the incision to heal before performing a mammography procedure.

Follow-up

- **Follow-up considerations for patients leaving the country.** Patients can travel globally and still be followed remotely by their primary clinician if there is a Wi-Fi or cellular connection to the patient app. There are countries that will not be able to provide in-clinic follow-up services. Contact Boston Scientific, using the information on the back cover, for help in determining feasibility of device follow-up in the patient's destination country.

Device Removal and Disposal

- **Handling at time of disposal.** Clean and disinfect the device using standard biohazard handling techniques.
- **Incineration.** Remove the device before cremation and incineration as temperatures might cause the device to explode.

POTENTIAL ADVERSE EVENTS

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

Transient procedural adverse events are expected in some patients. These include, but are not limited to discomfort, pain 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 *MRI Technical Guide* at www.bostonscientific-elabeling.com.

If any adverse events occur, invasive corrective action and/or ICM system modification or removal may be required.

Any serious incident that occurs in relation to this device should be reported to Boston Scientific and to the relevant local regulatory authority.

PATIENT COUNSELING INFORMATION

The patient should be advised to consult with his/her health care provider before traveling for extended periods of time if they will not have access to a cellular network or Wi-Fi to discuss how they will be monitored. The *myLUX Patient App for Insertable Cardiac Monitor Patient Handbook* provides a place to write instructions in the section, "When to call your health care provider."

The following topics should be discussed with the patient:

- Signs and symptoms of infection
- Symptoms that should be reported

- Protected environments—the patient should 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
- Avoiding devices that generate a strong electric or magnetic interference (EMI) in home, work, and medical environments
- Reliability of their device ("Product Reliability" on page 2-20)
- Activity restrictions (if applicable)
- Use of the patient app (if applicable)
- Use of the magnet, including risks associated with magnet use
- Frequency of follow up for both in-clinic and remote appointments
- Travel or relocation—Follow-up arrangements should be made in advance if the patient is leaving the country where the device was inserted
 - Implant Card—the patient should be advised to carry their Implant Card at all times
 - The ICM system is not meant to assist with health emergencies. Patients who need immediate medical attention should call their health care provider or seek emergency provider medical services.
 - Advise the patient to report any serious incident that occurs in relation to their ICM device to Boston Scientific and the relevant local regulatory authority.
 - Advise the patient to tell their healthcare professionals, such as their doctor, dentist, or technician, that they have an implanted medical device.
 - Inform the patient that there is information regarding their ICM device available from Boston Scientific and direct them to the website noted on the back of the Implant Card for a copy of the information.
 - Expected lifetime of the ICM device is typically a minimum of 3 years based on test data. A healthcare professional will monitor the long-term performance of the device to determine if and when it may need to be replaced.
 - The implanted device contains materials and substances that come in contact in contact with the body. See Table 2-4 Patient-contacting Materials on page 2-19.
 - Discuss pertinent warnings including "MR conditional requirements" and "Diathermy." See "Warnings" on page 1-5.
 - Discuss any pertinent precautions. See "Precautions" on page 1-7.
 - Discuss any potential adverse events that may occur. See "Potential Adverse Events" on page 1-12.

NOTE: Availability of Patient Information on the website varies by region.

Patient Handbook

The *myLUX Patient App for Insertable Cardiac Monitor Patient Handbook* is provided with each device.

It is recommended that you discuss the information in the *myLUX Patient App for Insertable Cardiac Monitor Patient Handbook* with patients both before and after insertion so they are fully familiar with ICM system operation.

For additional copies, contact Boston Scientific using the information on the back cover.

Patient App

If you want to monitor the patient remotely, give them the patient app. Explain the function of the patient app and instruct the patient to set up according to information provided in the *myLUX Patient App for Insertable Cardiac Monitor Patient Handbook*. Instruct the patient on how to use the patient app, explaining how to view connectivity information, how to perform a manual transmission, and if they will be able to record symptoms, which symptoms they should record.

Patient App Quick Start Guide

A Quick Start Guide is provided for each mobile device on which the patient app comes pre-installed. Give this to the patient along with the mobile device. It contains abbreviated instructions on using the patient app. For detailed information on using the patient app and magnet, see the *myLUX Patient App for Insertable Cardiac Monitor Patient Handbook*.

Magnet

The magnet is required to set up the patient app. Use of the magnet with other features, such as recording symptoms or sending manual transmissions, is required unless Bluetooth Manual Connection is programmed to No Magnet. Instruct the patient how you want them to use the magnet with their patient app, cautioning them as follows:

- Keep the magnet at least 15 cm (6 inches) from other implanted devices sensitive to magnet use
- Use the magnet as instructed. Using more often may lead to a decrease in the battery life of the device

WARNING: 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.

For more information, see "Magnet Use" on page 2-17.

Magnet IFU

Give the patient the Magnet IFU which contains important safety information. Information for patients on using the magnet with the patient app is included in the *myLUX Patient App for Insertable Cardiac Monitor Patient Handbook*.

INSERTABLE CARDIAC MONITOR

CHAPTER 2

This chapter contains the following topics:

- “Overview” on page 2-2
- “Device Insertion” on page 2-2
- “Implant Card for Patient” on page 2-10
- “R-wave Sensing” on page 2-10
- “Diagnostics” on page 2-11
- “Magnet Use” on page 2-17
- “Device Removal and Disposal” on page 2-18
- “Product Specifications” on page 2-19

OVERVIEW

The device is the inserted portion of the ICM system.

This section of the manual provides instructions for insertion and removal, information about device functions, features, and specifications. It also contains information about the magnet used to initiate communication between the device and mobile applications.

DEVICE INSERTION

Pre-insertion Information

Before removing the device from the box, check the battery by using one of the mobile applications to connect to the device. If the device is not recommended for insertion due to a low battery condition, a message will display (Figure 2-1 Low Device Battery on page 2-2). Contact Boston Scientific using the information on the back cover.

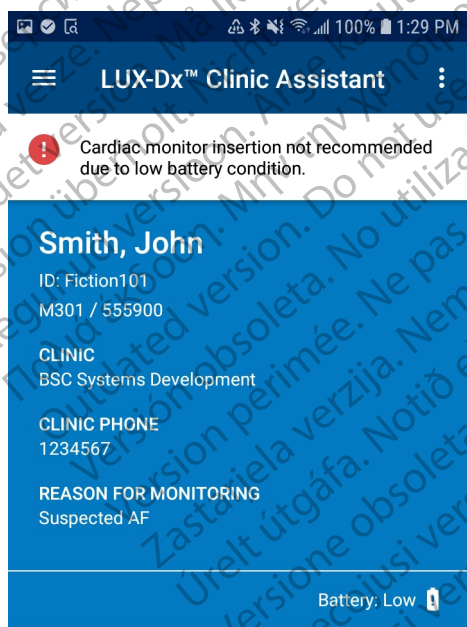


Figure 2-1. Low Device Battery

CAUTION: Check the device battery prior to insertion. If a low battery condition is indicated, do not insert the device.

Consider the following prior to the insertion procedure:

- The patient must be enrolled in LATITUDE Clarity to enable monitoring.
- Enrollment of the patient in LATITUDE may be performed prior to, during, or after insertion. For information on enrolling patients, see "Enrolling New Patients" on page 4-7.
- Verify that the mobile device being used is sufficiently charged. If not sufficiently charged, difficulty with device set-up and system initialization may occur.
- To check the device battery and in preparation for performing an R-wave check during the insertion, it is recommended to establish communication between the device and the patient app prior to passing the device into the sterile field. See "Patient App" on page 3-2 for more information on establishing communication.

- Retain the QR code on the device packaging; this will be used to enable features on the patient app used during insertion.
- The clinic app may be used in place of the patient app during insertion.

Items Included in Package

The following sterile items are included in the package:

- Insertable Cardiac Monitor device preloaded in the insertion tool
- Incision tool
- Sterile pouch

Additional Tools

The following is a list of items used during insertion of the device, but not packaged with it:

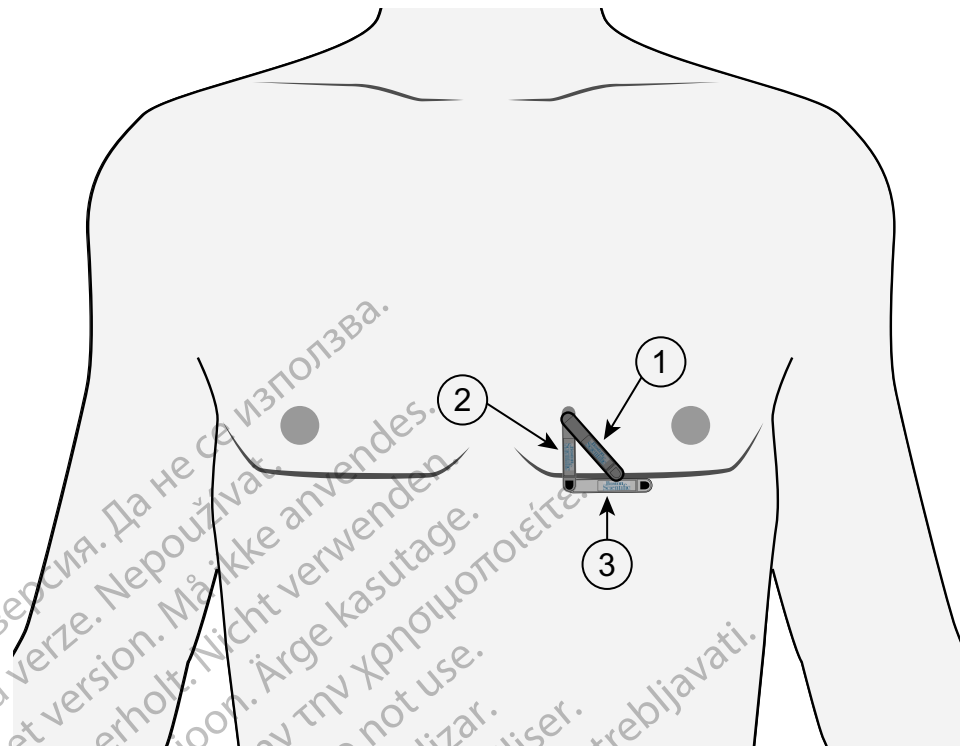
- Mobile device with patient app or clinic app installed
- Magnet
- Mobile device power adapter with USB cable (as needed)

Insertion Locations

The device is typically positioned under the skin in the left pectoral region. Recommended insertion locations are:

- 4th intercostal space, 45° relative to the sternum, along axis of the heart (location 1 in Figure 2-2 Common Insertion Locations on page 2-4)
- 4th intercostal space, parallel to the sternum (location 2 in Figure 2-2 Common Insertion Locations on page 2-4)

Optional insertion locations may be considered such as Anterolateral, inframammary between the 5th and 6th ribs, (location 3 in Figure 2-2 Common Insertion Locations on page 2-4). For optional locations, pre-insertion surface mapping is recommended to determine if the location provides reliable signal quality and R-wave amplitude sensing. See "Surface mapping to qualify an optional insertion location" on page 2-4



[1] 4th intercostal space, 45° relative to the sternum (recommended); [2] 4th intercostal space, parallel to the sternum (recommended); [3] Anterolateral, inframammary between the 5th and 6th ribs (optional)

Figure 2-2. Common Insertion Locations

Surface mapping to qualify an optional insertion location

Conduct surface mapping with clinic ECG equipment.

- Use pediatric-size ECG conductive patches to approximate the device electrode size.
- Space the ECG conductive patches 4 cm apart, center-to-center, to approximate the device electrode spacing.
- Position and orient the ECG electrodes to correspond with the desired insertion site and orientation.

Examine the R-wave amplitude from available insertion locations to find a position with the highest and most stable R-wave amplitude possible. The R-wave amplitude should be a minimum of 0.3 mV when viewed on external ECG equipment.

Insertion Instructions

This section presents the information necessary for inserting and testing the device, including:

- Inserting the device
- Verifying R-wave sensing
- Repositioning the device, if needed, until R-wave sensing is verified
- Closing the incision

Inserting the Device

Prepare the selected insertion site using local anesthetic and aseptic procedures. Use the insertion tools provided to insert the device.

NOTE: *Boston Scientific recommends retaining the insertion tools in the sterile field during the procedure in case device repositioning is required.*

To insert the device, complete the following steps.

WARNING: Always be aware of the location of the incision tool blade relative to the patient anatomy. Unintended tissue damage may result if the incision tool is inserted beyond the blade.

1. **Cut.** While applying tension on the skin away from the incision location, cut at the intended angle until the blade is fully inserted (Figure 2-3 Cut on page 2-5). Technique may vary based on clinician preference and patient assessment.

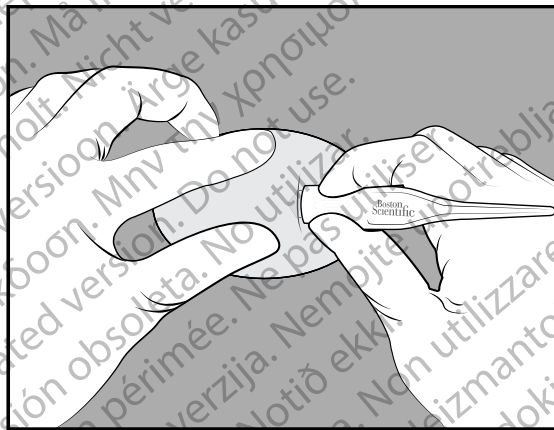


Figure 2-3. Cut

WARNING: The insertion tool is intended to be used in the subcutaneous space. Always be aware of the location of the tool tip relative to the patient anatomy. Hold the insertion tool at a narrow angle while tunneling. Unintended tissue damage may result if the device is inserted at a large angle.

2. **Tunnel.** At the incision location, fully insert the tunneling portion of the insertion tool parallel to the skin approximately 8mm (0.31 inches) under the surface (Figure 2-4 Tunnel on page 2-5).

NOTE: *If tunneling towards the patient's head, the orientation of the inserted device may produce inverted S-ECGs.*

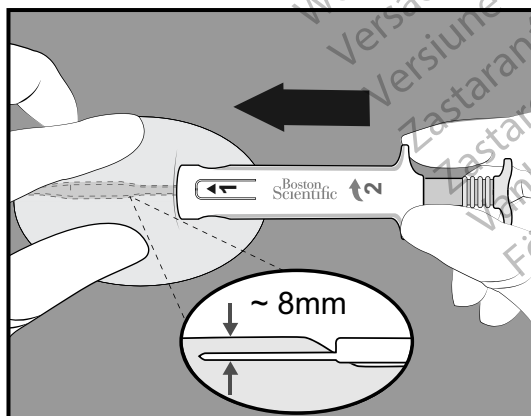


Figure 2-4. Tunnel

3. **Rotate.** Rotate the insertion tool 180° in either direction, creating a pocket for the device to be inserted (Figure 2-5 Rotate on page 2-6).

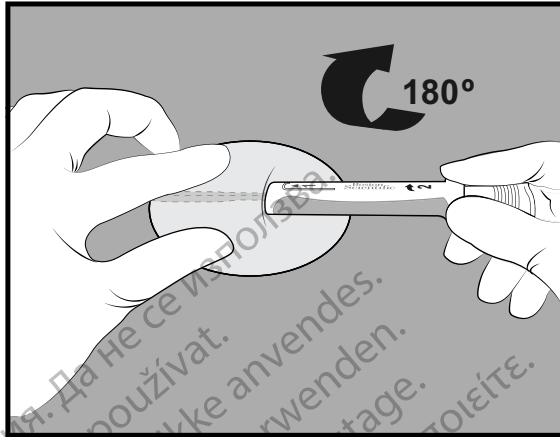


Figure 2-5. Rotate

4. **Pull back.** Hold the base of the insertion tool to the incision site and pull back the plunger until you feel a hard stop or until the blue line is visible (Figure 2-6 Pull Back on page 2-6). This ensures that the device has dropped down into the channel.

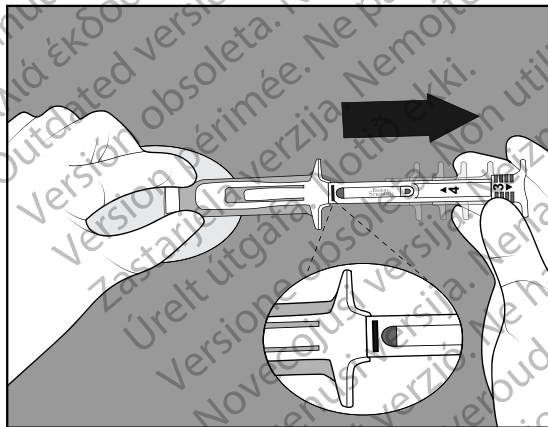


Figure 2-6. Pull Back

5. **Insert.** Lower the body of the tool close to the skin. **Firmly hold the base of the insertion tool at the incision site** while pushing the plunger in completely (Figure 2-7 Insert on page 2-7).

NOTE: The tool and the device may back out during insertion if the base of the insertion tool is not secured.

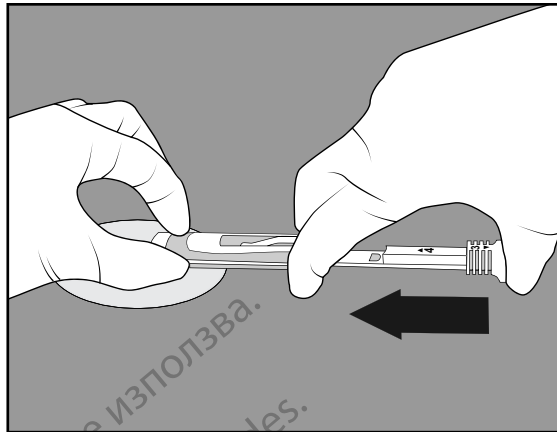


Figure 2-7. Insert

6. **Remove.** Pinch at the incision site to hold the device in place while removing the insertion tool (Figure 2-8 Remove on page 2-7).

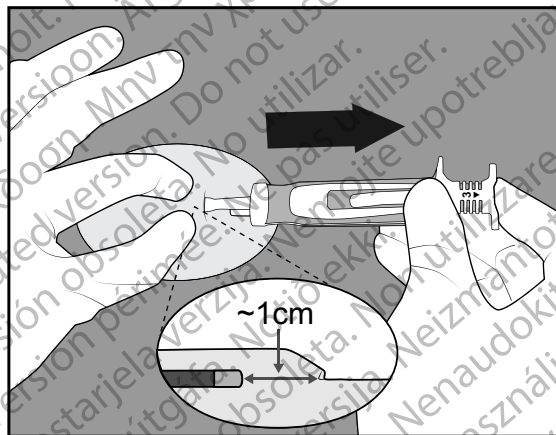


Figure 2-8. Remove

Verifying R-wave Sensing

Verify that the following device sensing performance requirements are met:

- The R-wave amplitude should be a minimum of 0.2 mV when viewed on the patient or clinic app.
- The peak-to-peak R-wave amplitude should be at least twice the peak T-wave or P-wave amplitude, whichever is greater.

For more information on using the patient app to verify R-wave sensing, see "View Real-time S-ECG" on page 3-3. Once the sensing performance requirements are met, proceed with closing the incision.

Repositioning the Device

If device sensing performance requirements are not met, the device may be removed from the previous insertion location and repositioned. If the insertion tools have been retained within the sterile field, they may be reused for device reloading and repositioning.

CAUTION: Use caution when using medical surgical instruments to remove the device during a repositioning as they could damage the device.

Reloading the Device

To reload the device in the insertion tool, complete the following steps:

1. Pull the plunger back to expose the loading surface (Figure 2-9 Expose Loading Surface on page 2-8).

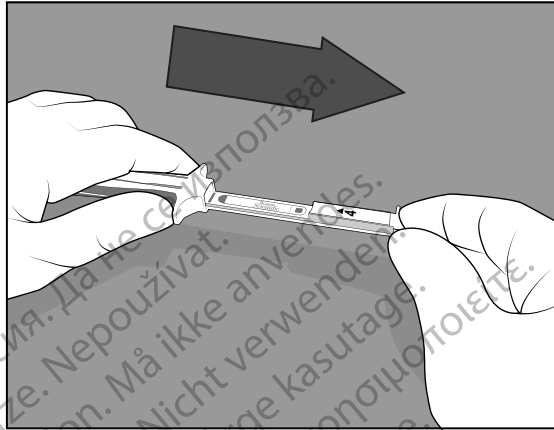


Figure 2-9. Expose Loading Surface

2. Place the black end of the device onto the loading surface exactly as shown in Figure 2-10 Place Device on Loading Surface on page 2-8. The Boston Scientific logo and black square should be visible and facing up.

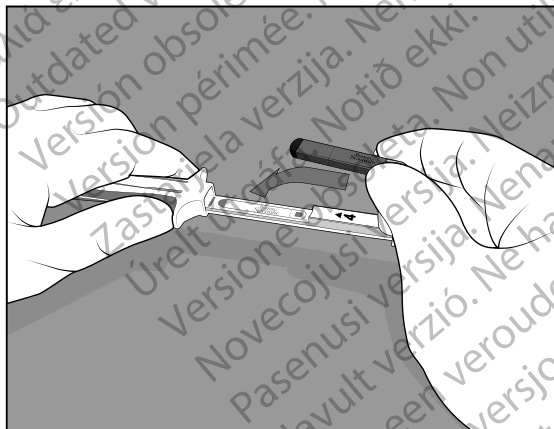


Figure 2-10. Place Device on Loading Surface

3. Firmly press the plunger in until you feel a hard stop and the number 4 marking is no longer visible (Figure 2-11 Press Plunger to Load Device on page 2-9 and Figure 2-12 Device Loaded in Tool on page 2-9).

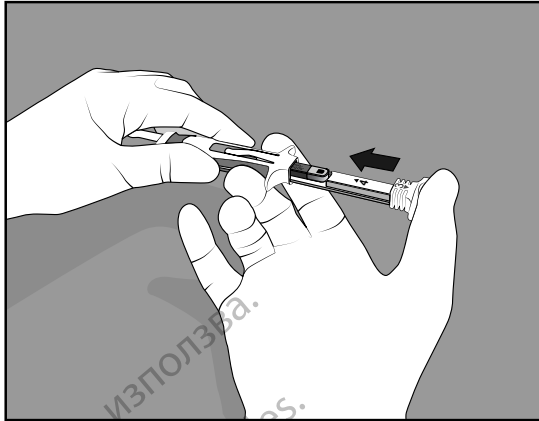


Figure 2-11. Press Plunger to Load Device

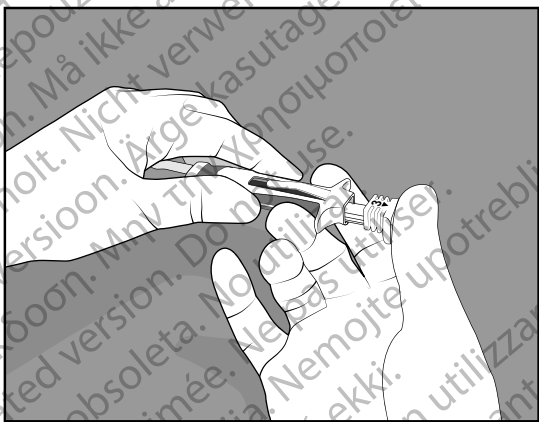


Figure 2-12. Device Loaded in Tool

4. The device is reloaded and ready to be repositioned. See "Inserting the Device" on page 2-5.

Closing the Incision

After the device has been inserted and sensing performance requirements have been met, close the incision. Use standard surgical techniques to achieve good tissue contact with the device. For information on disposal of insertion tools and packaging, see "Device Removal and Disposal" on page 2-18.

Post-Insertion Information

Patient Enrollment

Enroll the patient in LATITUDE Clarity if not completed earlier. LATITUDE Clarity is used by clinicians to manage patient data, to adjust programmable parameters on the device, and to monitor device sensing.

For information on enrolling patients, see "Enrolling New Patients" on page 4-7.

Device Activation

The device needs to be activated before it begins monitoring the patient's heart rate. To activate the device, complete one of the following:

- Complete the patient app setup as described in the *myLUX Patient App for Insertable Cardiac Monitor Patient Handbook*.
- Use the clinic app to program and activate the device. See "Using the Clinic App" on page 3-5.

Patient App Setup

The patient app will not be able to start monitoring until setup is complete. See the *myLUX Patient App for Insertable Cardiac Monitor Patient Handbook* for information about app setup.

IMPLANT CARD FOR PATIENT

An Implant Card and peel-off labels are supplied in the packaging with this device. The Implant Card (Figure 2-13 Implant Card for Patient on page 2-10) must be filled out and provided to the patient receiving the implanted device. Complete the Implant Card as follows:

1. Remove one of the peel-off labels that matches the dimensions of the designated location on the Implant Card and place it on the Implant Card. The card may include space for more than one peel-off label.
2. Write the following information in the spaces provided using permanent ink:



Name of Patient

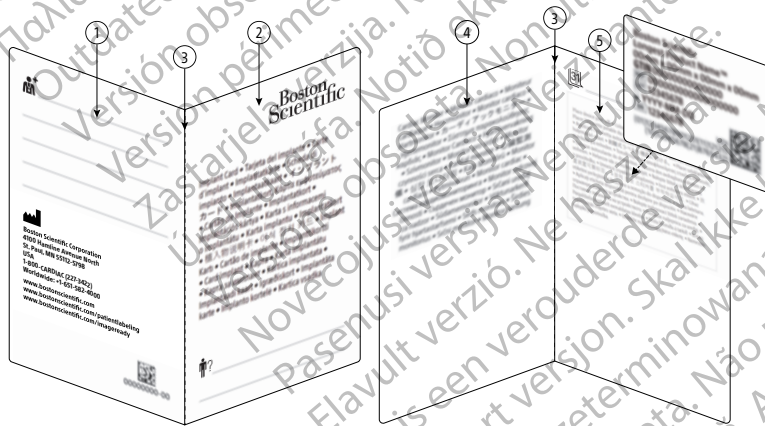


Date of implant



Name and contact information of healthcare institution or clinician

3. Fold the Implant Card and place it in the sleeve provided.
4. Give the Implant Card to the patient and counsel the patient as described in "Patient Counseling Information" on page 1-12.



[1] Back page; [2] Front page; [3] Fold; [4] Inside left page; [5] Inside right page

Figure 2-13. Implant Card for Patient

R-WAVE SENSING

The ICM device automatically detects arrhythmias based on R-wave sensing. The cardiac signal for R-wave detection is filtered to remove noise and reduce the amplitude of T-waves and P-waves so they are not sensed. The device detects an R-wave when the amplitude of the filtered cardiac signal rises above a dynamically-adjusted sensing threshold. The sensing threshold does not decay below the programmed Sensitivity (Figure 2-14 Sensing Threshold on page 2-11). After a sensed R-wave, the device waits for a programmable period of time (Blank After Sense) before looking at the signal for the next R-wave. This ensures that each R-wave is detected only once. The Blank After Sense consists of two parts; an absolute refractory and a noise window. The absolute refractory is the total period minus the last 40 milliseconds. The noise window is the last 40 milliseconds. R-waves cannot be detected during the absolute refractory. During the noise window, if the signal

exceeds the detect threshold, it is deemed noise and the noise window is extended another 40 milliseconds. Following the absolute refractory window, the sensing threshold decays down until either it reaches the programmed floor, or the signal again crosses the threshold.

A clinician can assess R-wave detection by monitoring a patient's real-time S-ECG using the patient or clinic app. For information about when this feature is used at the time of insertion, see "Insertion Instructions" on page 2-4. For instructions on viewing real-time S-ECGs, see "View Real-time S-ECG" on page 3-6.

Parameters:

- **Sensitivity** – Program to the minimum R-Wave amplitude and greater than the P-Wave amplitude.
- **Blank After Sense** – Program to the period of time the device ignores the signal after detecting an R-wave.

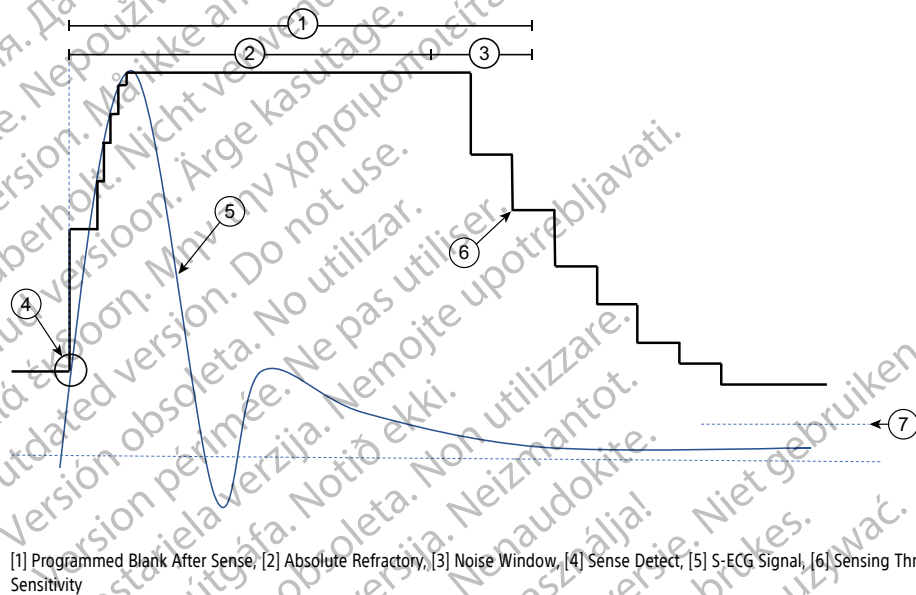


Figure 2-14. Sensing Threshold

DIAGNOSTICS

Arrhythmia Detection

The device monitors a patient's heart rate for arrhythmias based on programmed parameters. Programmed parameters are based on the Reason for Monitoring selected by the patient's clinician during the enrollment process. These parameters may be modified by the patient's clinician according to their preference. Both the Reason for Monitoring and individual parameters can be changed after insertion, for example, during a follow-up. For a list of programmable parameters, see "Programmable Parameters: Arrhythmia Detection" on page B-1.

The ICM device can be programmed to detect the following types of arrhythmia events:

- Pause
- Brady
- Tachy
- AF

- AT

Events stored on the device will be uploaded to the LATITUDE Clarity server at the next device interrogation (see Table 4-3 Device Interrogation Features on page 4-8 for types of information transmitted). Once uploaded, the patient's clinician can review and evaluate the data ("Viewing Patient Detail" on page 4-16. Clinicians can be alerted when arrhythmias are detected ("Alerts" on page 4-9).

The ICM device is designed to monitor and record heart rhythms (i.e., tachycardia, bradycardia, pauses) potentially associated with the patient's symptoms or clinical events. The R-wave sensing and arrhythmia recording algorithms contain filters to reject episodes that meet criteria associated with a high likelihood of false positive detection for a given arrhythmia. Therefore, the filtering may result in a true arrhythmia episode not being recorded (false negative). Examples of arrhythmia data that may not be recorded include, but are not limited to, arrhythmias that occur in the setting of noise or low amplitude R-waves, fine ventricular fibrillation, or atrial fibrillation with frequent premature ventricular contractions.

Pause (asystole)

The device detects a potential Pause event when the R-R interval exceeds the user-programmed Pause Duration. Once a potential event is detected, the device confirms that the Pause is not the result of undersensing, according to the programmed Response.

Parameters:

- **Duration** – Select the length of the pause interval that must occur for the event to be classified as a Pause event.
- **Response** – Select the level to use in detecting a pause event. The levels determine the amount of contrast required between the signal during the pause and the R-waves on both sides of it. Nominal is the default setting. Programming to "More Response" allows for less contrast, which may result in more false-positive detections of Pause events. Programming to "Less Response" requires more contrast to be detected, which may result in fewer Pause events.

S-ECG data delivered to the clinician for Pause events includes 30 seconds before and up to 30 seconds after the detection event.

If there are Pause events, the Patient Detail page displays the longest pause in the current set of data being reviewed.

Brady

The device detects a potential Brady event when the 4 out of 5 beats are slower than the programmed Brady Rate. This is called onset. Once a potential event is detected, it is monitored to see if the slow pattern is maintained for the programmed Duration. If the pattern is maintained, additional criteria are automatically applied to confirm that the low rate event is not the result of undersensing.

Parameters:

- **Rate** – Select the rate threshold; beats below this threshold will be considered slow.
- **Duration** – Select the period of time the Brady event must be maintained to be considered a potential event.

Each Brady event contains 30 seconds of annotated S-ECG data centered around the onset (15 seconds before and up to 15 seconds after) and up to 30 seconds of annotated S-ECG data at the end where the heart rate is no longer slow.

If there are Brady events, the Patient Detail page displays the one with the slowest average heart rate in the current set of data being reviewed.

Tachy

The device detects a potential Tachy event when 8 out of 10 beats are faster than the programmed Tachy Rate. This is called onset. Once a potential event is detected, it is monitored to see if the fast pattern is maintained for the programmed Duration. If the pattern is maintained, additional criteria are automatically applied to verify that the high rate event is not the result of oversensing according to the programmed Response.

If the rate is sustained above 230 min^{-1} , the event may be annotated in LATITUDE Clarity as VF or accelerated to VF.

Parameters:

- **Rate** – Select the rate threshold; beats above this threshold will be considered fast.
- **Duration** – Program to “0” to prevent duration from being considered. Otherwise, select the period of time the Tachy must be maintained to be considered a potential event.
- **Response** – Select the level to use in detecting Tachy event. Balanced is the default setting. Programming to “More” may result in more false-positive detections of Tachy events. Programming to “Less” may result in fewer detections of Tachy events.
- **Morphology Assessment** – Select the level at which the algorithm uses morphology to screen out PVCs or non-sinus detections. This applies to both Tachy and AF.

S-ECGs delivered to clinician for Tachy events include annotated S-ECG data 15 seconds before and up to 15 seconds after the onset and annotated S-ECG data at the termination, 30 seconds before the heart rate is no longer fast.

If there are Tachy events, the Patient Detail page displays the one with the fastest average heart rate in the current set of data being reviewed.

AF (Atrial Fibrillation)

The device detects a potential AF event based on R-wave variability. The algorithm analyzes 2-minute windows to assess variability. Additional criteria are automatically applied to verify that the variability is not the result of under or over sensing, according to the programmed Response. Each 2-minute window is declared as either AF or not AF. Short runs of AF or runs that span across multiple 2-minute windows, but do not meet the criteria for a single window, may be missed. When the number of consecutive 2-minute periods that have been identified and verified for AF meets the programmed event Duration, the event is stored.

Parameters:

- **Duration** – Select the persistent amount of time in AF required before an AF event is stored (relates to the number of 2-minute windows).
- **AF Response** – Select the level to use in detecting AF event. Programming to “Most” may result in more false-positive detections of AF events. Programming to “Least” may result in fewer AF events.
- **Morphology Assessment** – Select the level at which the algorithm uses morphology to screen out PVCs or non-sinus detections. This applies to both Tachy and AF.

Each AF event contains 3 minutes of intervals before the start, 1 minute of annotated S-ECG data after the start, and up to 3 minutes of annotated S-ECG at the end. The average V-Rate and maximum V-Rate during the event are displayed, along with the time/date the event started and the duration.

AT (Atrial Tachy)

The device detects a potential AT event when there is an elevated ventricular rate for a user-programmable duration. The algorithm analyzes 2-minute windows to assess the ventricular rate over each window.

If the AT duration is programmed to 2 hours or longer, the V-rate of each 2-minute window is evaluated for AT. Once a series of windows declare AT for the programmed duration, an AT event is stored.

If the AT duration is programmed to less than 2 hours, the algorithm also looks for instability in the heart rate. The stability criteria aids in distinguishing AT from normal sinus rhythms for shorter arrhythmias. For shorter duration AT (less than 2hrs), a series of windows that are over the user programmable AT rate and with some instability must indicate AT for the user-programmed duration before an event is stored.

Parameters:

- **Rate** – Select the rate threshold; beats above this threshold will be considered fast.
- **Duration** – Select the persistent amount of time of AT required before an AT event is stored.

Each AT event contains 1.5 minutes of intervals at the point where event duration is met, including 30 seconds of annotated S-ECG data. The average ventricular rate during the event is displayed, along with the time/date the event started and ended and the duration of the event.

Symptom Recorded Event

Symptom recorded events are S-ECGs recorded in response to a patient selecting the Record Symptoms option on their patient app.

When Symptom Recording is configured On, the patient can use their patient app to record symptoms. The S-ECG that is recorded is sent to the server along with the symptom information collected from the patient by the patient app. For information on recording symptoms, see the *myLUX Patient App for Insertable Cardiac Monitor Patient Handbook*.

NOTE: *When you use LATITUDE Clarity to configure Symptom, the change will take effect when the patient app next connects to the server.*

The maximum number of symptom recorded events allowed per day is programmable. If the maximum daily number has been reached, patients will receive a message on their app indicating that their limit has been reached and the feature will be temporarily unavailable.

For a list of programmable parameters, see "Programmable Parameters: Arrhythmia Detection" on page B-1.

S-ECGs delivered to the clinician for confirmed symptom recorded events include 1 minute after the event was triggered and up to 9 minutes preceding the event, depending on the programmed Events Allowed Per Day.

Symptom + Device Detected Event

Symptom + Device Detected Events help the clinician to determine if symptoms recorded by a patient are related to a cardiac condition or a different cause.

If a symptom recorded event starts within 30 minutes of the start of a device-detected event, then the system correlates the two events. For example, if a Brady event is detected and then 10 minutes later the patient records symptoms, the server correlates the two events, capturing them in a single S-ECG. Symptom information collected from the patient is listed along with the S-ECG.

If a single device-detected event has more than one symptom event that starts within 30 minutes, the symptom recorded event start time that is closest to the device-detected event is the correlated event. The non-correlated symptom recorded event will be displayed separately.

Presenting S-ECGs

Presenting S-ECGs capture a snapshot of the patient's heart rate even if no episodes are being detected. These S-ECGs are used to establish a baseline of the patient's normal heart rate to compare to any events that may

occur. Presenting S-ECGs are automatically recorded daily. Additional Presenting S-ECGs may be recorded as a result of a patient initiated interrogation or clinic interrogation.

- **Daily** – The device records and stores a 10-second Presenting S-ECG at a fixed time every day. The time is not programmable. The S-ECG is stored for up to five days until it can be transmitted to the LATITUDE Clarity server during the next interrogation.
- **Patient Initiated Interrogation or Clinic Interrogation** – When a patient or clinic initiates an interrogation, the device records a 10-second Presenting S-ECG that is bundled and sent with the interrogation data.

The Presenting S-ECG for the current day is displayed under Presenting S-ECG on the Data for Review page. S-ECGs for previous days are also available at the same location for clinicians to review. For more information about review of patient data, see "Viewing Patient Detail" on page 4-16.

S-ECG Markers

The following table identifies and defines the S-ECG markers.

Table 2-1. S-ECG Markers

Marker	Definition
VN	Noise has been detected in the system indicating sensing may be compromised.
[VS]	A signal was seen following a ventricular sense that was above the detection threshold but within the refractory period after the previous VS; considered noise.
VS n	A ventricular sense. If the Brady and/or Tachy features are enabled, this may be replaced with a B, T, or F marker, depending on the rate. The number below the VS marker represents the interval (in milliseconds) since the previous VS/B/T/F marker.
B n	If the Brady feature is enabled, a ventricular sense where the rate (with respect to the previous ventricular sense) is slower than the programmed Brady rate threshold. This does not necessarily mean the device has detected a Brady event. (See "Brady" marker.) The number below the marker represents the interval (in milliseconds) since the previous VS/B/T/F marker.
T n	If the Tachy feature is enabled, a ventricular sense where the rate (with respect to the previous ventricular sense) is higher than the programmed Tachy rate threshold. This does not necessarily mean the device has detected a Tachy event. (See "Tachy" marker.) The number below the marker represents the interval (in milliseconds) since the previous VS/B/T/F marker.
F n	If the Tachy feature is enabled, this marks a ventricular sense where the rate (with respect to the previous ventricular sense) is in the non-programmable VF zone (230 bpm and higher). This does not necessarily mean the device has detected a Tachy event. (See "Tachy" marker.) The number below the marker represents the interval (in milliseconds) since the previous VS/B/T/F marker.
Pause	Labels the VS at the beginning of a device-confirmed cardiac pause.
P	Ventricular pause (interval without a VS). The marker is positioned at the point where the user-programmed pause duration expired from the previous VS.
End Pause	Labels the VS at the end of a device-confirmed cardiac pause.
Brady	Labels the VS in a Brady event where four out of five beats were slow.
End Brady	Labels the VS in a Brady event where there were no longer at least two slow beats out of five.
Tachy	Labels the VS in a Tachy event where eight out of ten beats were fast.
End Tachy	Labels the VS in a Tachy event where there were fewer than three fast beats out of ten.
AF	Labels the point at which the device determined the presence of AF.
End AF	Labels the point at which the device determined AF was no longer present.

Table 2-1. S-ECG Markers (continued)

Marker	Definition
AT	Labels the point at which the device determined the presence of AT.
Symptom	Labels the point at which the patient initiated a symptom recorded S-ECG.

Arrhythmia Event Data and S-ECG Storage

The device stores event data and S-ECGs for each event type which has detection enabled. The event logbook provides access to the following information about all events:

- Event Number
- Date and Time of event
- Type of event
 - Event Duration
 - Event Parameter Settings
- S-ECGs with annotated markers (if available)
- Intervals (if available)

The event data is stored in an event logbook which includes up to 40 events of each type. When the log is full, data from the most recent event may overwrite the oldest stored event data of that type.

The device stores a max of 5 events of each type per day unless a special event occurs which is always saved making it possible to get more than 5 events in a day for types that have a special event.

The device reserves 60 minutes of S-ECG storage for all events. When the available memory is full, a new S-ECG recording will overwrite older S-ECG data. The event logbook attempts to preserve the most recent and special events of highest priority. When an event is read from the device the memory used by that event is made available.

Event Type	Priority	Special Criteria
AF	1	Longest
Pause	1	Longest
Tachy	1	Fastest
AT	2	N/A
Brady	2	Slowest
Symptom	3	N/A

Trends

Trends provide a graphical view of specific patient and device data. This data can be useful when evaluating a patient's condition and the effectiveness of programmed parameters. Unless otherwise noted below, data for all trends is reported every 24 hours. The device stores 6 months' worth, but the LATITUDE Clarity server displays historical data for up to one year. Trends are viewable only on the Health tab of the Patient Detail page on the LATITUDE Clarity System.

For many trends, a value of **N/R** is reported if there is insufficient or invalid data for the collection period.

The following trends are available:

- **Night Heart Rate**—A trend of the patient's average heart rate between midnight and 6 am. The data from this trend can be affected if the device clock is incorrect, such as if the patient travels to another time zone and the device clock is not updated accordingly. There are two lines on the viewable graph: one is the nightly average and the other is a three-night average.
- **Day Heart Rate**—A trend of the patient's average heart rate for 24 hours. The data from this trend can be affected if the device clock is incorrect, such as if the patient travels to another time zone and the device clock is not updated accordingly. There are two lines on the viewable graph: one is the daily average and the other is the three-day average.
- **AF Burden**—Each two-minute window that is determined to be AF is added to the AF burden for that day. For the AF burden trend, since 0 is a valid value, there is no N/R.
- **V Rate during AF**—A trend of the patient's maximum and average V rates during any AF. This trend has an Off value, which may be displayed if the feature is turned off.

Histograms

Histograms display the heart beats sensed at different rates. The histograms show heart rate data from the current follow-up period and the previous follow-up period side by side. There is one pair of histograms for all-inclusive V Rate and another pair for V Rate during AF.

Each histogram shows 22 rate ranges that are each 10 min⁻¹ wide. In addition, rates slower than 30 min⁻¹ are included in the <30 min⁻¹ range; rates at or above 250 min⁻¹ are included in the ≥ 250 min⁻¹ range.

To view the histograms, select the Patient Diagnostics tab from the Patient Detail page. All four histograms show the rate distribution of ventricular events as the percentage of the total number of events in the follow-up period. In V Rate during AF, only beats during device-detected AF are considered.

MAGNET USE

The magnet feature allows a patient or clinician to initiate communication between the device and the patient or clinic app. The magnet is required to do the following:

- Set up the patient app
- Initiate communication between the patient app and the device when using Clinician Tools (e.g., after scanning QR code)
- Initiate communication between the patient app and the device when sending manual transmissions or recording symptoms if the device's Bluetooth Manual Connection parameter is programmed to Magnet Required
- Initiate communication between the clinic app and the device

WARNING: 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.

No magnet is required to send manual transmissions or record symptoms unless Bluetooth Manual Connection on the patient's device is programmed to Magnet Required. When a magnet is required, the patient or clinic app will provide instructions for magnet use as needed.

If you need to replace the magnet because of damage, contact Boston Scientific to learn how to return and replace it.

DEVICE REMOVAL AND DISPOSAL

Contact Boston Scientific when any of the following occur:

- When a product is removed from service
- In the event of patient death (regardless of cause), along with an autopsy report, if performed
- For other observation or complication reasons

Consider the following items when removing and returning the device:

- Turn detection algorithms off
- Interrogate the device and upload data
- Avoid removing the device with hemostats or any other clamping tool that may damage it
- Resort to tools only if manual manipulation cannot free the device
- Use a Boston Scientific Returned Product Kit to properly package device, and send it to Boston Scientific

WARNING: Incision tool is sharp. Take precautions to ensure that it is handled properly. Dispose of incision tool directly into a sharps disposal container labeled with a biological hazard symbol. Sharps waste should be safely disposed of using available sharps waste channels in accordance with hospital, administrative, and/or local government policy.

CAUTION: Clean and disinfect the device using standard biohazard handling techniques.

Return all devices removed from patients to Boston Scientific. For a Returned Product Kit, contact Boston Scientific using the information on the back cover.

NOTE: Examination of these devices can provide information for continued improvement in system reliability and warranty considerations.

For all components that are not returned to Boston Scientific, to minimize risk of infection or microbial hazards after use, dispose of product and packaging as follows:

- After use, all explanted components are considered biohazardous. Other components may also contain biohazardous substances
- Components that contain biohazardous substances should be disposed in a biohazard container that is labeled with the biological hazard symbol and taken to a designated facility for biohazardous waste for proper treatment in accordance with hospital, administrative, and/or local government policy
- Biohazardous substances should be treated with an appropriate thermal or chemical process

NOTE: Untreated biohazardous substances should not be disposed of in the municipal waste system.

NOTE: Disposal of explanted devices is subject to applicable laws and regulations.

CAUTION: Remove the device before cremation and incineration as temperatures might cause the device to explode.

This product and associated electrical and electronic equipment should not be incinerated. Do not incinerate any device or component containing a battery or electronics. Improper disposal could result in an explosion.

WARNING: Do not reuse, reprocess, or resterilize the insertable cardiac monitor or insertion tools. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device

failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient. The medical professional may reposition or re-insert the device within a single procedure.

PRODUCT SPECIFICATIONS

Mechanical Specifications

Table 2-2. Device

Parameter	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

Table 2-3. Materials

Parameter	Value
Can	Titanium
Electrodes	Titanium nitride
Header	Implantable Grade Polymer
Coating	Parylene

Table 2-4. Patient-contacting Materials

Material	% of Total Exposed Surface Area
Cured epoxy	13%
Titanium (with titanium nitride coating)	10%
Parylene coating	77%

Table 2-5. Battery

Parameter	Value
Manufacturer	Boston Scientific
Model	LUX-Dx
Material	Lithium-manganese dioxide
Longevity	<p>3 years projected longevity, under the following usage scenarios:</p> <ul style="list-style-type: none"> • 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) <p>NOTE: At the maximum shelf storage time of 18 months, longevity is reduced by approximately 4 months.</p> <p>NOTE: Projected longevity is 2 years when the Bluetooth Manual Connection is configured to not require a magnet.</p>
Status	<p>Status is displayed, with dates for the following</p> <ul style="list-style-type: none"> • RRT— Recommended Replacement Time • EOS — End of service (30 days after RRT) <p>After EOS is reached, monitoring is disabled.</p>

Characteristics as Shipped

Refer to the table for device settings at shipment.

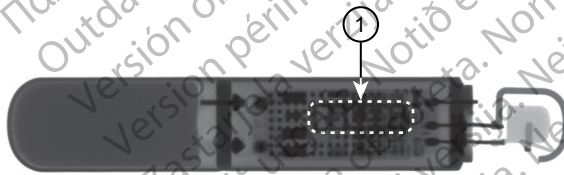
Table 2-6. Characteristics as Shipped

Parameter	Setting
Sensing	Off
Blank After Sense	160 ms
Sensitivity	0.037 mV

X-Ray Identifier

The device has an identifier (ID) that is visible on x-ray film or under fluoroscopy. This ID provides noninvasive confirmation of the manufacturer and consists of the following:

- The letters, BSC, to identify Boston Scientific as the manufacturer
- The number, 301, to identify the device as a LUX-Dx device
- The x-ray identifier is inside the device case (Figure 2-15 X-ray ID location on page 2-20).
- The ICM device model and serial number are stored in the device memory. This information is displayed in the ID field on the main screen of the clinic app after connecting to an ICM device using Scan and Connect (see "Scan and Connect" on page 3-6). Additional information such as date of manufacture can be obtained by contacting Boston Scientific and providing the model number and serial number.



1) Location within case

Figure 2-15. X-ray ID location

Communications Compliance

The device operates with a transmit frequency of 2400.0-2483.5 MHz.

Product Reliability

It is Boston Scientific's intent to provide implantable and insertable devices of high quality and reliability. However, these devices may exhibit malfunctions that may result in lost or compromised ability to monitor and record. These malfunctions may include the following:

- Premature battery depletion
- Sensing issues
- Error codes
- Loss of telemetry

Sometimes device malfunctions result in the issuance of product advisories. Boston Scientific determines the need to issue product advisories based on the estimated malfunction rate and the clinical implication of the malfunction. When Boston Scientific communicates product advisory information, the decision whether to replace a device should take into account the risks of the malfunction, the risks of the replacement procedure, and the performance to date of the replacement device.

Остаряла версия. Да не се използва.
Zastaralá verze. Nepoužívat.
Forældet version. Må ikke anvendes.
Version überholt. Nicht verwenden.
Version obsolete. Ärge kasutage.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Outdated version. Do not use.
Version périmée. Ne pas utiliser.
Zastarjela verzija. Ne uporabljavati.
Úreлт útgáfa. Notið ekki.
Versione obsolete. Non utilizzare.
Pasenusi versija. Nenaudokite.
Elavult verzió. Ne használja!
Dit is een verouderde versie. Niet gebruiken.
Wersja przeterminowana. Nie używać.
Versão expirada. Não utilize.
Utdatert versjon. Skal ikke brukes.
Wersja przeterminowana. Nie używać.
Zastaraná verzia. Nepoužívať.
Zastarela različica. A nu se utiliza.
Vanhentunut versio. Älä käytä.
Föråldrad version. Använd ej.
Güncel olmayan sürüm. Kullanmayın.

Остаряла версия. Да не се използва.
Zastaralá verze. Nepoužívat.
Forældet version. Må ikke anvendes.
Version überholt. Nicht verwenden.
Version obsolete. Μην την χρησιμοποιείτε.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Outdated version. Do not use.
Version périmée. Ne pas utiliser.
Zastarjela verzija. Nemojte upotrebljavati.
Úrejt útgáfa. Notið ekki.
Versione obsoleta. Non utilizzare.
Zastarjela verzija. Neizmantot.
Pasenusi versija. Nenaudokite.
Elavult verzió. Ne használja!
Dit is een verouderde versie. Niet gebruiken.
Utdatert versjon. Skal ikke brukes.
Wersja przeterminowana. Nie używać.
Versão obsoleta. Não utilize.
Zastaraná verzia. Nepoužívat.
Zastarela različica. A nu se utiliza.
Vanhentunut versio. Älä käytä.
Föråldrad version. Använd ej.
Güncel olmayan sürüm. Kullanmayın.

MOBILE APPLICATIONS

CHAPTER 3

This chapter contains the following topics:

- “Overview” on page 3-2
- “Patient App” on page 3-2
- “Clinic App” on page 3-3
- “Replacing a Boston Scientific Mobile Device” on page 3-8
- “Disposing of a Boston Scientific Mobile Device” on page 3-8
- “Deactivation Due to Inactivity” on page 3-9

OVERVIEW

The ICM system uses two mobile applications (apps), one for patients and one for clinicians. Boston Scientific provides each of the apps pre-installed on a mobile device. This manual contains information regarding the use of the apps by clinicians. For specifications or other information about the mobile device on which the apps run, see the literature provided by the mobile device manufacturer. For instructions on how to use patient app features intended to be used by patients, see the *myLUX Patient App for Insertable Cardiac Monitor Patient Handbook*.

CAUTION: Store mobile devices containing Boston Scientific mobile applications in a secure location when not in use and take appropriate measures to prevent theft or unauthorized access.

PATIENT APP

The patient app is intended primarily for patient use. However, it also contains Clinician Tools to support the insertion process. These tools allow clinicians to view the current ICM device status and view real-time S-ECGs.

Items Included in the Package

The following items are included in the package:

- myLUX patient app pre-installed on a mobile device in a case
- Mobile device power adapter(s) with USB cable
- Mobile device stand
- Magnet in shielded box with extra adhesive strips
- Product literature

Using Clinician Tools on the Patient App

This section of the manual describes Clinician Tools available on the patient app. The following are required to access Clinician Tools:

- Magnet
- QR code provided on the ICM device packaging (only if the patient app has not been set up)

Access features as follows:

1. Power on the mobile device.
2. Tap the **myLUX** icon.

If the patient app hasn't been set up yet, a message will indicate that the language is set to English. To change the language, see "Change language setting" on page 3-7. Tap **NEXT**.

3. Tap the **CLINICIAN TOOLS** button. If the patient app has been set up, this will be an option on the menu. Otherwise, it will be available on the Welcome screen.

NOTE: The Clinician Tools option will only be available for a limited amount of time.

4. Tap **CLINICIAN TOOLS** again.
5. Follow the instructions on the screen to connect to the ICM device.
6. To view S-ECGs, tap **View Real-time S-ECG**.

To end the session, tap the **DISCONNECT** button.

View Real-time S-ECG

This feature is used by clinicians during insertion to verify that the insertion location provides adequate sensing amplitude.

The Real-time S-ECG screen displays the following information:

- S-ECG with markers
- Amplitude of the signal with indication of whether the signal is adequate for R-wave sensing
- Heart rate

NOTE: *The ICM S-ECG should not be used to interpret ST segment deviation.*

The S-ECG displays at a sweep speed of 25mm/s. To restart real-time S-ECG streaming once it has stopped, tap the pause and play buttons.

Because this feature relies on telemetry, it is susceptible to radio frequency interference. Significant interference may cause a break or drop-out of real-time S-ECGs. See "System Limitations" on page 1-3.

CLINIC APP

The clinic app is intended for use during in-clinic follow-up sessions with patients who have an ICM device. It can also be used at insertion to view current device status and view real-time S-ECG.

Unlike the patient app, the clinic app can connect to any ICM device within a range of 2 meters (6 feet).

Items Included in the Package

The following items are included in the package:

- LUX-Dx Clinic Assistant app pre-installed on a mobile device in a case
- Mobile device power adapter(s) with USB cable
- Mobile device stand
- Magnet in shielded box with extra adhesive strips
- Product literature

Installation

If Boston Scientific provided you with a mobile device, the clinic app will be pre-installed. For information on software and firmware updates, see "Maintenance" on page 3-8.

Setup

The clinic app must be registered in LATITUDE Clarity before it can be used. The following are required to complete the setup:

- Wi-Fi or cellular connection
- Registration code
- Access to LATITUDE Clarity

NOTE: You will be prompted to log on to LATITUDE Clarity to generate the registration code during the app setup process.

To set up the clinic app:

1. Power on the mobile device.
2. Tap the **LUX Clinic** app icon to open the app. A screen will display, indicating that the language is set to English.
Touchscreen Tip: Gently and quickly tap the screen with your fingertip. Do not use your fingernail.
3. To continue with English as the language setting, tap **NEXT** and proceed to the next step. To change the language setting, tap **CHANGE LANGUAGE** and complete the following:
 - a. Select the preferred language by dragging the up/down arrows to move it to the top of the list and then tap **DONE**. A screen will display in the selected language, indicating the language you selected.
 - b. Tap **NEXT**.
4. Tap the **START SETUP** button on the **Welcome!** screen.
5. Follow the instructions on the screen.
NOTE: If the app is not able to connect to the server using a cellular connection, the app will prompt the user to connect to Wi-Fi to complete the setup.
6. A message will confirm when the setup is complete. Tap **CONTINUE**.

Attaching the magnet to the mobile device case

To ensure that the magnet is readily available when needed to use with the app, you may choose to attach the magnet to the back of the mobile device case.

To attach the magnet to the mobile device case:

1. Remove the blue magnet from the silver box labeled "Magnet in shielded box."
2. Locate the adhesive circle pre-applied to the back of the mobile device case.
3. Use the tab to peel off the adhesive backing (see Figure 3-1 Remove Adhesive Backing on page 3-5).



Figure 3-1. Remove Adhesive Backing

4. Place the back side of the magnet (the side with the Boston Scientific logo) on the adhesive and press firmly (Figure 3-2 Magnet Attached to Mobile Device Case on page 3-5).



Figure 3-2. Magnet Attached to Mobile Device Case

Using the Clinic App

This section of the manual describes clinic app features. Availability of each feature is based on the current status of the ICM device, the patient, and connectivity. For example, Interrogate and Apply Programming will not be available until after the patient is enrolled.

A Wi-Fi or cellular connection is required to use all features on the clinic app except for:

- View current ICM device status
- View Real-time S-ECG

Connect to Wi-Fi

Connect to Wi-Fi at any time by completing the following steps:

1. Press the Home button on the mobile device.
2. Tap the down arrow in the upper right corner of the screen.
3. Tap the Settings icon.
4. Tap **Wi-Fi**.
5. If a list of available Wi-Fi networks displays, tap to select a network from the list.
6. Follow the instructions on the screen. You may be prompted to enter a network password to connect.
7. The screen will indicate when the mobile device is connected to Wi-Fi.
8. Press the Home button on your mobile device.
9. Tap the **LUX Clinic** icon to return to the app.

Scan and Connect

The first step when using the clinic app is to scan for and connect to a patient's device. The app provides a list of nearby devices available for connection. After the clinician selects a device and is connected, the app will display patient information (if available), device information, device status, and a menu of available features.

NOTE: The magnet is required to connect to a device.

NOTE: If your clinic app cannot connect to a device or to the server or if it loses connection during a session, a message will appear on the app screen instructing you to check your connection. Follow the instructions on the screen. A message will confirm when your app is connected.

View Real-time S-ECG

The clinic app may be used to view real-time S-ECGs. This feature allows clinicians to verify that the device sensing amplitude is adequate.

This feature is also temporarily available on the patient app. For more information about this feature, see "View Real-time S-ECG" on page 3-3.

Program & Activate

If a device has not been activated, this feature allows the clinic app to apply initial programmed settings to the device and activate it so that it begins monitoring the patient's heart rate. A message on the clinic app screen confirms that the device was successfully programmed and activated.

Interrogate

This feature performs a manual interrogation of a device. During an interrogation, the clinic app collects data from the device and uploads it to the server.

When the interrogation is complete, any programming changes downloaded from the server at the time the app connected to the device will be applied. A message on the app screen confirms that the interrogation was successful.

Apply Programming

Changes to programmed settings are made on the LATITUDE server. The **Apply Programming** feature allows the clinic app to send the changes to a patient's device. A message on the clinic app screen confirms that the programming was successfully applied.

For information on applying firmware updates, see "Firmware Update to ICM Device" on page 3-8.

Secure the mobile device screen

On a Boston Scientific mobile device, there is an option to lock the mobile device screen to prevent unauthorized users from accessing the clinic app:

1. Press the Home button on the mobile device.
2. Tap the down arrow in the upper right corner of the screen.
3. Press the Settings icon.
4. Tap **Screen Lock**.
5. Tap to select the method to be used (e.g., PIN, Password) and follow the instructions on the screen.
6. Press the Home button on the mobile device.
7. Tap the **LUX Clinic** icon to return to the app.

Change language setting

On a Boston Scientific mobile device, the language setting is selected during app setup. Change the language setting at any time using the following steps:

1. Press the Home button on the mobile device.
2. Tap the down arrow in the upper right corner of the screen.
3. Press the Settings icon.
4. Tap **Language** on this screen and on the next screen.
5. Select the preferred language by dragging the up/down arrows to move it to the top of the list and then tap **DONE**.
6. Press the Home button on the mobile device.
7. Tap the **LUX Clinic** icon to return to the app.

Additional Features

The following additional features are also available from the clinic app menu:

- **Connection Check.** Manually connect to the server in order confirm the connection is working.
- **Clinic Resources.** Access education and training content related to use of the ICM system and the types of cardiac conditions it monitors.

Disconnect

To end a session:

1. Tap the **DISCONNECT** button to end the session.

All data related to the device is deleted from the clinic app and it can now connect to a new device.

Maintenance

To ensure successful connections and transmissions of data between the clinic app and the LATITUDE server, keep the mobile device containing your clinic app charged and use it in a location that receives a cellular or Wi-Fi signal.

Firmware Update to ICM Device

The clinic app will indicate when a firmware update is ready to be applied to a patient's device. This indication occurs when the clinic app connects to the device.

To perform a firmware update:

1. Tap **APPLY** to perform the update.
2. Follow the instructions on the screen. A message will confirm when the update is complete.

During the update process, patient monitoring is interrupted. After the update is complete, monitoring will resume.

NOTE: Connectivity between the app and the device and connectivity between the app and server are required throughout the update process. If the connection is interrupted, reconnect and begin the firmware update again.

WARNING: Once a firmware update begins, the patient will not be monitored until the update is completed. If the firmware update is skipped, the patient is still monitored.

Software App Updates

When software updates are needed, they will be sent to the mobile device automatically. If the updates include a mobile device system update, a Wi-Fi connection may be needed in order to complete the update.

REPLACING A BOSTON SCIENTIFIC MOBILE DEVICE

If you need to replace the mobile device or any accessories (e.g., USB cable) because of damage or malfunction, contact Boston Scientific to learn how to return and replace them.

To replace a mobile device that is used with a patient app or a clinic app, the following steps need to occur:

1. Contact Boston Scientific using the number on the back of this manual for replacement options.
2. For patient apps, release the current myLUX pairing from the patient on LATITUDE Clarity. See "Changing Patient Demographic and Equipment Information" on page 4-23.
3. For clinic apps, remove the current LUX-Dx Clinic Assistant from the clinic on LATITUDE Clarity. Then, add the new LUX-Dx Clinic Assistant to the clinic. See Edit/View LUX-Dx Clinic Assistants in "Patient Group, Clinic Configuration, and Programming Options" on page 4-10.
4. Complete app setup on the new mobile device.

DISPOSING OF A BOSTON SCIENTIFIC MOBILE DEVICE

If you no longer need to use your clinic app or any electronic accessories, contact your local authorities to learn how to dispose of electronic items.

Electrical and electronic equipment should not be incinerated. Do not incinerate any device or component containing a battery or electronics. Improper disposal could result in an explosion.

Dispose of a Boston Scientific mobile device only as directed as it may contain encrypted health data.

There are no special requirements for disposal of the Patient Kit or Clinic Assistant Kit packaging.

NOTE: For information on disposal of the magnet provided with a Boston Scientific mobile device, see the Instructions for Use provided with the magnet.

DEACTIVATION DUE TO INACTIVITY

Boston Scientific reserves the right to disable monitoring if a mobile device provided by Boston Scientific has been inactive for a substantial period of time. Any patient data stored on the mobile device will be deleted at the time of deactivation.

Остаряла версия. Да не се използва.
Zastaralá verze. Nepoužívejte.
Forældet version. Må ikke anvendes.
Version überholt. Nicht verwenden.
Aegunud versioón. Ärgе kasutage.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Outdated version. Do not use.
Version obsolete. Ne pas utiliser.
Zastarjela verzija. Nemojte upotrebljavati.
Úreлт útгáфа. Notið ekki.
Versione obsolete. Non utilizzare.
Pasenjela verzija. Neizmantot.
Úreлт útгáфа. Notið ekki.
Novcojusi versija. Nenaudokite.
Elavult verzió. Ne használja!
Dit is een verouderde versie. Niet gebruiken.
Wersja przeterminowana. Nie używać.
Versão obsoleta. Não utilize.
Versiune expirată. A nu se utiliza.
Zastaraná verzia. Nepoužívať.
Zastarela različica. Ne uporabite.
Vanhentunut versio. Älä käytä.
Föråldrad version. Använd ej.
Güncel olmayan sürüm. Kullanmayın.

Остаряла версия. Да не се използва.
Zastaralá verze. Nepoužívát.
Forældet version. Må ikke anvendes.
Version überholt. Nicht verwenden.
Aegunud versioón. Myn þyn Χρησιμοποιείτε.
Παλιά έκδοση. Μην την Χρησιμοποιείτε.
Outdated version. Do not use.
Versión obsoleta. No utilizar.
Version périmée. Ne pas utiliser.
Zastarjela verzija. Nemojte upotrebljavati.
Úreлт útγάfa. Notið ekki.
Versione obsoleta. Non utilizzare.
Pasenusi versija. Neizmantot.
Elavult verzió. Ne használja!
Wersja przeterminowana. Niet gebruiken.
Dit is een verouderde versie. Niet gebruiken.
Utdatert versjon. Skal ikke brukes.
Wersja przeterminowana. Nie używać.
Versão expiratã. A nu se utiliza.
Zastaraná verzia. Nepoužívát.
Zastarela različica. Ne uporabite.
Vanhentunut versio. Älä käytä.
Föråldrad version. Använd ej.
Güncel olmayan sürüm. Kullanmayın.

THE LATITUDE CLARITY DATA MANAGEMENT SYSTEM

CHAPTER 4

This chapter contains the following topics:

- "Overview" on page 4-2
- "Getting Started" on page 4-2
- "System Setup" on page 4-6
- "Saving Settings" on page 4-6
- "Enrolling Patients" on page 4-7
- "Reason for Monitoring" on page 4-8
- "Device Interrogation" on page 4-8
- "Patient Group and Clinic Options" on page 4-10
- "Organization of Patient Information and Programming Options" on page 4-12
- "Managing Patients" on page 4-23
- "Managing Patient Groups" on page 4-24
- "Clinic Account Management" on page 4-24
- "Managing User Accounts" on page 4-25
- "Passwords" on page 4-27
- "EMR System Integration" on page 4-28
- "Troubleshooting" on page 4-32

OVERVIEW

LATITUDE Clarity enables authorized personnel to periodically monitor both patient and device status, as well as to program a patient's device. LATITUDE Clarity also provides tools to analyze a patient's data sent from their device in order to develop an informed understanding of their cardiac monitoring status. Patients may come into the office when clinically appropriate.

NOTE: The LATITUDE website contains separate sections for LATITUDE NXT (Therapy) and LATITUDE Clarity (Diagnostic). When information in this manual is specific to one or the other, LATITUDE NXT and LATITUDE Clarity are referenced. When information applies generally to both, LATITUDE website, or simply LATITUDE, is referenced.

Secure Server

The LATITUDE server is a centralized computer database that stores patient and device data sent from the patient or clinic app. Collected patient data are protected health information. LATITUDE also stores clinic and clinic user configuration information.

Access to patient data is provided only to clinic users authorized by the clinic that enrolled the patient. (For additional access information, see "Clinic User Privileges" on page 4-25.) The data is available via the internet and includes the most recently received patient and device data, as well as historical data related to previous follow-ups. Designated Boston Scientific personnel also have access to patient data. All user access of LATITUDE patient data is logged.

LATITUDE Customer Support

LATITUDE Customer Support provides technical and general maintenance support to customers using LATITUDE Clarity.

LATITUDE Customer Support telephone numbers are listed in the following table.

Table 4-1. LATITUDE Customer Support Telephone Numbers

Country	Number
Austria	0800 202289
Belgium	0800 80697
France	0805 5404 22
Germany	069 51709 481
Ireland (Republic)	1800 851861
Italy	848 781164
Netherlands	0800 0292077
Spain	900 806108
Switzerland	0844 000110
United Kingdom	0800 678 16 44

Boston Scientific may contact the clinic regarding LATITUDE Clarity and/or patients managed in the system.

GETTING STARTED

LATITUDE Clarity provides authorized personnel with a convenient and secure way to:

- Enroll patients.
- Access data from a patient's ICM device.

- Program the patient's ICM device to record desired data.
- Analyze patient data using included analysis and trending tools.

Mobile Application

Personnel authorized to use LATITUDE Clarity may also have the option of using the clinic app, a mobile application, to enable, apply programming to, or interrogate a patient's device. See "Clinic App" on page 3-3 for more information.

Requirements

The LATITUDE website was developed to support the following internet browsers¹:

- Internet Explorer™ internet browser

NOTE: While Internet Explorer 8 and 9 are supported for most website functions, users may experience some performance issues, including diminished graphing capabilities. To avoid this, the latest version of Internet Explorer is strongly recommended.

- Microsoft Edge internet browser
- Mozilla Firefox™ internet browser
- Apple™ Safari™ on the Mac™, iPad™, and iPhone™ internet browsers
- Google Chrome™ browser

If using an unsupported browser, the LATITUDE website may not work as intended.

Adobe™ Reader™ software or compatible PDF viewer is required to view reports that are in PDF format.

A current anti-virus program is recommended.

Logging In and Out

Log in to the LATITUDE website by doing the following:

1. Launch your web browser and enter the LATITUDE web address:

<http://www.latitude.bostonscientific.com>

The initial access page will display, as represented by the following figure.

1. The LATITUDE website was developed with browsers that were current at that time and may not function properly when using browser versions that were subsequently released. Call LATITUDE Customer Support for a list of supported internet browsers.



Figure 4-1. LATITUDE Initial Access Page

2. The first time you access the LATITUDE website or the first time you access the website from a different computer, select your country and language, as applicable.
 - During subsequent logins, country and language can be changed by clicking **Change Country/ Language** on the login page, as shown in the following figure. This will bring you back to the initial access page.
 - Language may also be changed by accessing **My Profile** either:
 - At the top of all pages for **LATITUDE NXT** or
 - In the drop-down list from the clinic user name at the top of all pages for **LATITUDE Clarity**.
3. Click the **LATITUDE NXT** or **LATITUDE Clarity** button to display the login page shown in the following figure.

(*) Click this link to change your country or language.

Figure 4-2. Login Page

4. Enter your **User ID** and **Password** and click the **Login** button.

NOTE: Clicking the link for *LATITUDE Customer Support* provides a list of phone numbers to call for help.

Users accessing the LATITUDE website for the first time are prompted to change their temporary password and complete a set of personal security questions. The security questions can be used at a later time by the user to reset a forgotten password. (See "Resetting Your Forgotten Password" on page 4-28.)

An announcement or broadcast message may be displayed when you login.

Login Session Time Out – An individual session is started each time a user logs on to the LATITUDE website. If a user remains logged in but is inactive for more than 60 minutes, the session is automatically closed, effectively logging the user out. The user is redirected to the login page.

5. If two factor authentication (TFA) is required, the first time you click the **Login** button, select the method for receiving the TFA verification code (SMS text message or email), then enter either your phone number (mobile phone only) or email address. When you receive the verification code, enter it on the Two Factor Authentication page. At subsequent logins, you will automatically receive the verification code to enter on the Two Factor Authentication page.

NOTE: TFA authentication, as well as SMS text message and email, may not be available in all geographies.

To change how verification codes are sent, on the **Update Clinic User** page, scroll down to **Login Information and Security**, and click **View/Edit Two Factor Authentication**.

The Clinic Account Manager or LATITUDE Customer Support may create a one-time verification code for a clinic user to use at their next login. See "Other Patient Group Management Functions" on page 4-24.

6. The default homepage (**LATITUDE NXT** or **LATITUDE Clarity**) is selected when the user is created by the Clinic Account Manager. It may be changed by accessing **My Profile** as described in step 2 above, and then from the **Homepage** section, selecting the desired homepage.
7. Log out of the LATITUDE website by clicking **Logout**, available at the top of all pages for **LATITUDE NXT** or in the drop-down list under the user's name in the upper-right corner of the screen for **LATITUDE Clarity**. Users are advised to close their web browsers to complete the log-out process.

Navigating the Site

The following figure shows the top banner and navigation buttons that appear on the LATITUDE Clarity website. Descriptions are listed in the following table.

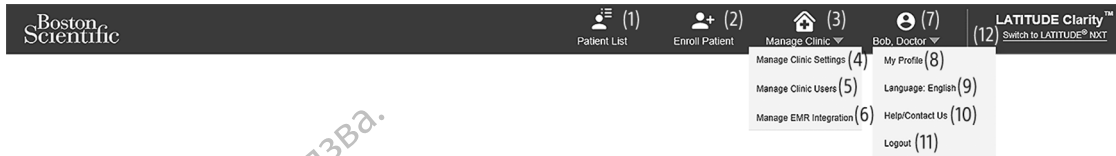


Figure 4-3. LATITUDE Clarity System Banner

Table 4-2. Navigating the Site

(1)	Patient List	The first page displayed after logging on to LATITUDE Clarity; provides a list of patients to which the current user has access. (See "Patient List Page" on page 4-12.)
(2)	Enroll Patient	Links to an enrollment form that enables authorized personnel to enroll new patients. (See "Enrolling New Patients" on page 4-7.)
(3)	Manage Clinic	Displays clinic-related action links 4-6.
(4)	Manage Clinic Settings	Links to clinic and Patient Group demographics, membership, and associated configuration information. (See "Managing Patient Groups" on page 4-24.)
(5)	Manage Clinic Users	Links to a list of clinic users and associated configuration information. (See "Managing User Accounts" on page 4-25.)
(6)	Manage EMR Integration	Links to a page that enables authorized personnel to configure integration with their clinic's electronic medical record (EMR) system, access and download necessary software for EMR integration, and view the export status of their EMR files. (See "EMR System Integration" on page 4-28.)
(7)	Name of current clinic user	Displays clinic user-related action links 8-11.
(8)	My Profile	Links to the Update Clinic User page for the current user. (See "Update Clinic User Page" on page 4-26.)
(9)	Language	Displays selected language; links to the Update Clinic User page for the current user where the selected language can be changed.
(10)	Help/Contact Us	Links to contact information, troubleshooting guides, and other resources. (See "Troubleshooting" on page 4-32.)
(11)	Logout	Ends the user's session.
(12)	LATITUDE Clarity Switch to LATITUDE NXT	Links to View Patient List page of LATITUDE NXT.

SYSTEM SETUP

The patient must be enrolled in LATITUDE Clarity before the device can be activated. For more information, see "Enrolling New Patients" on page 4-7. The device may be activated using either the patient app or clinic app. See "Post-Insertion Information" on page 2-9.

NOTE: Before the clinic app can be used, it must be registered in LATITUDE Clarity. See "Setup" on page 3-3.

SAVING SETTINGS

The **Save and Close** or **Save** button must be selected to ensure any setting changes are stored in LATITUDE Clarity. Select the **Close Without Saving** button to discard any changes and revert to the settings from the previously saved version.

Changes to programming settings are updated on the affected patient's device the next time the patient app or clinic app communicates with the device after either has connected with LATITUDE Clarity. **Assuming availability of a good connection, it could take up to 36 hours for the patient app to connect to LATITUDE Clarity and apply any pending changes to the device. Until then, the device will continue to operate using the previous configuration.**

NOTE: Changes to programming settings on the patient's device may be updated immediately using the clinic app while the patient is in the clinic. See "Apply Programming" on page 3-7.

ENROLLING PATIENTS

This section provides information for enrolling patients in the ICM system. As a result of the enrollment and set-up process:

- The patient is enrolled in LATITUDE Clarity.
- Initial default programming and configuration values are supplied based on the Reason for Monitoring. These values can be revised for a Patient Group ("Patient Group, Clinic Configuration, and Programming Options" on page 4-10) or individual patient ("Viewing Patient Detail" on page 4-16), as desired by the clinician.

CAUTION: Ensure that each patient's alert configuration and programming settings are appropriate when the patient is enrolled and, if applicable, after the device is replaced.

Enrolling New Patients

Enrollment of the patient in LATITUDE Clarity may be performed before, during, or after implant of the device but must be performed before the device can be activated. Clinic users enroll new patients by clicking **Enroll Patient** available at the top of any page. Patients are identified in LATITUDE Clarity by their date of birth and the model and serial number of their device.

Figure 4-4. Enroll Patient Page

Clinic users must assign a Patient Group and Reason for Monitoring from a selectable list before submitting the multiple webpage form. A confirmation of enrollment is displayed and can be printed.

See "Post-Insertion Information" on page 2-9 for information on device activation and patient app setup. Patients may be monitored remotely or in clinic.

NOTE: The ICM system is designed for remote monitoring; however, an option of in-clinic-only monitoring is available. In those cases, the patient will not use the patient app.

Enrollment of the patient, activation of the device, and setup of the patient app (if patient will be followed remotely) must be complete in order for the device to connect to LATITUDE Clarity.

Enrolling Existing Patients

If a patient was previously enrolled in LATITUDE Clarity, re-enrollment is required before data can be sent to the new clinic. Follow the same process as the initial enrollment process (via **Enroll Patient**). During re-enrollment, the patient's date of birth must be the same date entered during initial enrollment. The patient's existing data will be available to the new clinic after enrollment is complete.

Users in the new clinic will see the last patient data sent but may see limited prior follow-up or alert history. Contact LATITUDE Customer Support if you need assistance.

If a patient's device is replaced, the model, serial number, and implant date must be updated. See "Changing Patient Demographic and Equipment Information" on page 4-23.

If the mobile device containing the patient app is replaced, before set up of the replacement mobile device can occur, the existing mobile device must be released. See "Changing Patient Demographic and Equipment Information" on page 4-23.

REASON FOR MONITORING

Programming Options for Each Reason for Monitoring

When a patient is enrolled in LATITUDE Clarity, a Reason for Monitoring based on the patient's medical condition must be selected. Depending on the selected Reason for Monitoring, default programming values and alert and schedule configuration settings are automatically set. See "Programmable Parameters: Arrhythmia Detection" on page B-1 for programming options for each parameter and "Default Programming Values per Reason for Monitoring" on page C-1 for default values for each Reason for Monitoring. These values may be manually changed for the:

- Patient Group for each Reason for Monitoring. See "Patient Group, Clinic Configuration, and Programming Options" on page 4-10, or
- Individual patient through the **PROGRAMMING** tab in Patient Detail. The Reason for Monitoring for the individual patient may also be changed on this page. See "Viewing Patient Detail" on page 4-16.

DEVICE INTERROGATION

Device Interrogation

The ICM system can perform several types of device interrogations, initiated automatically through configuration settings or manually via the patient app or clinic app. Each interrogation type varies in the amount and type of data that are collected, as shown in the following table:

Table 4-3. Device Interrogation Features

Interrogation Type/Reason ^a	Full Interrogation with Presenting S-ECG	Configuration Options
Automatic Interrogations via Patient App		
Daily Alert Checks For more information, see "Alerts" on page 4-9.	<ul style="list-style-type: none"> • Provide a Presenting S-ECG every day with or without a full interrogation. • Provide a full interrogation only if the Daily Alert Check detects a possible alert condition. 	<ul style="list-style-type: none"> • Daily. • Not configurable.
Data Updated Reason Typically occurs when Daily Alert Checks detect a possible alert condition but LATITUDE Clarity determines that there is no new alert condition for the patient	Typically yes.	Not configurable.

Table 4-3. Device Interrogation Features (continued)

Interrogation Type/Reason ^a	Full Interrogation with Presenting S-ECG	Configuration Options
Remote Scheduled Follow-ups For more information, see "Patient Group, Clinic Configuration, and Programming Options" on page 4-10 and "Viewing Patient Detail" on page 4-16.	Yes.	<ul style="list-style-type: none"> From Once Per Week to Once Every Twelve Months on a selected day of the week. Date may also be manually scheduled.
Manual Interrogations via Patient App		
Patient Initiated Interrogations For more information, see "Patient Initiated Interrogations" on page 4-10.	Yes.	<ul style="list-style-type: none"> Enabled. Disabled.
Manual Interrogations via Clinic App		
Clinic Interrogations See "Interrogate" on page 3-6.	Yes.	As directed by clinician.

a. Every interrogation type includes an alert check.

NOTE: The patient app provides troubleshooting steps for the patient in case there are connection issues.

Alerts

Alerts are designed to notify clinic users of potential health conditions, device clinical events, or system alerts. Alert conditions are detected as determined by the alert configuration and are checked during **Remote Scheduled Follow-ups**, daily alert checks, **Clinic Interrogations**, or **Patient Initiated Interrogations**.

NOTE: In patient-facing literature, the term "interrogation" is referred to as "transmission."

Alerts are based on the Reason for Monitoring for a Patient Group or can be manually set for a Patient Group ("Patient Group, Clinic Configuration, and Programming Options" on page 4-10) or individual patient ("Viewing Patient Detail" on page 4-16). LATITUDE Clarity can generate an Alert for each condition included on the **PROGRAMMING** tab in Patient Detail. For each condition, an Alert may or may not be selected. If selected, Alerts can be set as a **Red Alert** or a **Yellow Alert**. Red Alerts are treated as a higher priority than Yellow Alerts in LATITUDE Clarity.

The primary means of alert notification is through the **Patient List** page. See "Patient List Page" on page 4-12. LATITUDE Clarity issues one notification for an alert condition detected by the system. For most Alerts, it does not issue alert notifications for the same condition unless the condition is no longer detected and then reoccurs during a following data collection activity. Alert notifications are not intended to be used as the sole basis for making decisions about patient medical care.

Designated Boston Scientific personnel may provide notification of alert conditions in place of the notifications provided by LATITUDE Clarity. If LATITUDE Clarity is unable to display device data, LATITUDE Clarity or Boston Scientific personnel may provide alert notification. The clinic may be contacted regarding data that is currently not available on LATITUDE Clarity. For example, if there is an alert condition that cannot be retrieved and displayed automatically by LATITUDE Clarity, Boston Scientific personnel may contact the clinic to inform them of that Alert.

Additional Alert Notification to the Clinician

Additional Alert Notification is available through text (SMS) and email messages. (SMS text messages are not available in all geographies.) These messages can only be configured at the Patient Group level. For more information, see the **Text and Email Notifications** section of "Edit/View Patient Group Defaults" on page 4-10.

Patient Initiated Interrogations

The ICM system supports non-scheduled Patient Initiated Interrogations (PIIs), which provide the same data as a scheduled follow-up interrogation with a presenting EGM/S-ECG.

The number of PIIs is limited to five per week if enabled or zero when disabled.

Clinic users who are assigned to a Patient Group and have complete or limited access can enable or disable PIIs. PIIs are configured for:

- All patients in a Patient Group on the **Edit/View Patient Group Defaults** page ("**Edit/View Patient Group Defaults**" on page 4-10) or
- An individual patient through the **PROGRAMMING** tab in Patient Detail ("Tabs" on page 4-17).

Patients initiate an interrogation by following the instructions on their patient app. (See the appropriate Patient Manual for more information about the patient app.) The device will not be interrogated if this feature is not enabled or the limit has been reached.

If the PII configuration setting is changed, it will take effect the next time the patient app connects to LATITUDE Clarity. If PIIs are disabled on the patient app and the patient attempts to interrogate, the patient app will connect to LATITUDE Clarity to check for updated information.

If PIIs are disabled or the weekly limit is reached, a clinic user can allow one PII by selecting the **Allow one Patient Initiated Interrogation** button via the **PROGRAMMING** tab in Patient Detail. Before recommending a PII, clinicians may want to verify that the patient is stable, not symptomatic, and able to perform the PII. See "Precautions" on page 1-7 and "System Limitations" on page 1-3.

PATIENT GROUP AND CLINIC OPTIONS

The following tables show LATITUDE Clarity locations and types of information that can be configured separately for each Patient Group or the clinic via the **Manage Clinic > Manage Clinic Settings >** corresponding buttons. For individual patient configuration, see "Viewing Patient Detail" on page 4-16.

Edit/View Patient Group Defaults

The following table describes programming and configuration options that can be changed from the default for each **Reason for Monitoring** (except for **Text and Email Notifications**) for the selected Patient Group on the **Edit/View Patient Group Defaults** page:

Section	Description
Remote Scheduled Follow-ups	<ul style="list-style-type: none"> • Set Schedule for either Automatic or Manual. • Select Frequency from the drop-down list (from Once Per Week to Once Every Twelve Months). • Select Day of the Week from the drop-down list (from Monday to Friday).
Patient Initiated Interrogations ("PIIs")	<ul style="list-style-type: none"> • Enable (five per week) or disable by selecting or clearing each check box. <p>NOTE: One additional PII can be configured at any time for an individual patient. See "Patient Initiated Interrogations" on page 4-10 and "Viewing Patient Detail" on page 4-16, PROGRAMMING tab, Patient Initiated Interrogations section.</p>
Connection Status Notification	Configure number of days to add the patient to the Not Monitored filter on the Patient List page by selecting a time interval from the drop-down list (from 1 to 14 days).
Programming and Alerts	Configure Device Programming and Alert Configuration settings: <ul style="list-style-type: none"> • Sensing Parameters are always enabled. Select values for Blank After Sense and Sensitivity from the drop-down menu. Morphology Assessment may be selected On or Off.

Section	Description
	<ul style="list-style-type: none"> For event alerts, first press the toggle key to enable each event, as applicable, and then select the desired values and alerts. The individual patient settings for event alert configuration provide three options: <ul style="list-style-type: none"> Toggle key to the Off position: No alert or event detection. Clear alert check boxes: Event detection with no alert. Select Red Alert or Yellow Alert: Event generates selected alert. System Alerts: Monitoring Disabled and Battery Recommended Replacement Time (RRT) may be selected or cleared and designated as red or yellow, as appropriate for the Patient Group. Bluetooth® Manual Connection provides a selection of Require Magnet or No Magnet for the Patient Group. See "Programmable Parameters: Arrhythmia Detection" on page B-1 for programming options for each parameter and "Default Programming Values per Reason for Monitoring" on page C-1 for default values for each Reason for Monitoring.
Text and Email Notifications	<ul style="list-style-type: none"> The primary means of alert notification is through the Patient List page in LATITUDE Clarity ("Patient List Page" on page 4-12). Additional Alert Notification through email and/or SMS text messages may be configured based on settings for Alert Severity and Hours of Notification. (SMS text messages are not available in all geographies.) If an email address or text message number is entered in After Business Hours & Holidays, notification still occurs even if conflicting with selected Custom Business Hours (except Holidays). Additional Alert Notification can only be configured at the Patient Group level. When an alert is detected, a notification is sent to each configured email address and text message number. The notifications do not include patient-identifying information. The user must check the Patient List page in LATITUDE Clarity for the alert information. Messages are sent at the selected time even if a patient's alert has already been dismissed. Delivery of email and text messages is not guaranteed as described in "System Limitations" on page 1-3. If a patient has multiple alerts resulting from the same interrogation, one notification is sent for all.

A **Last Updated By** link provides the date and name of the user who last updated **Edit/View Patient Group Defaults**.

Edit/View Demographics and User Membership

The following table describes the **Edit/View Demographics and User Membership** page:

Remove Patient Group button	For more information, see "Deleting Patient Groups" on page 4-24.
Demographics	View or change the Patient Group Name or Description .
Clinic Member Assignment	Provides check boxes to select or clear members of the Patient Group.



Edit/View Clinic Demographics

The following table describes the **Edit/View Clinic Demographics** page.

General Information	<ul style="list-style-type: none"> Provides access to change Name, Language, and Time Zone, as applicable, for the clinic. View the Clinic ID. Provides check box to select or clear User passwords expire every 180 days.
Contact Information	Provides access to change the clinic's contact information.
Include Additional Information in Alert Notification	Provides check box to select or clear Clinic Name in Alert Notification .

Edit/View LUX-Dx™ Clinic Assistants

The following table describes the **Edit/View LUX-Dx™ Clinic Assistants** page:

Add LUX-Dx™ Clinic Assistant button	<ul style="list-style-type: none"> Click to add a mobile device containing the clinic app. Complete Name and Description, which serves as an identifier any time this mobile device is used for an interrogation of an ICM device. Click the Save and Close button. The resulting LUX-Dx™ Clinic Assistant Added page provides a temporary registration code required for clinic app setup. <p>For more information, see "Clinic App" on page 3-3.</p>
List of LUX-Dx Clinic Assistants	<ul style="list-style-type: none"> View the Name, Description, Status, and Version of each assigned mobile device containing the clinic app. Provides access to edit  information for an assigned mobile device containing the clinic app or remove  to delete it.

ORGANIZATION OF PATIENT INFORMATION AND PROGRAMMING OPTIONS

This section explains the organization of patient information in LATITUDE Clarity, as well as programming options that can be configured for an individual patient. See the PROGRAMMING section of "Viewing Patient Detail" on page 4-16 for more information. For Patient Group configuration, see "Patient Group, Clinic Configuration, and Programming Options" on page 4-10.

Patient List Page

The **Patient List** page (shown as follows) is the first page displayed after logging on to LATITUDE Clarity. Upon login, by default, the page uses the **For Review** filter to display patients for **All Patient Groups**. However, within a single session, the page remembers the filters chosen by the user.

Clicking a patient's name on the **Patient List** page directs the user to Patient Detail. See "Viewing Patient Detail" on page 4-16. Much of the information from the **Patient List** page is duplicated in Patient Detail; however, Patient Detail contains expanded details and access to the **Event Detail** viewer. See "Event Detail Viewer" on page 4-21.

Patient Info	Review Reason	Reason For Monitoring	Review Status	Latest Device Transmission	Next Follow-up	Patient Notes	Action
Flores, Hailey ID: pid407486 DOB: 15 Oct 2019	Patient Initiated + More 6 Event(s)	Other	New Data	13 Oct 2019	None	Add note	✓
Foster, Tyler ID: pid659884 DOB: 15 Oct 2019	Patient Initiated + More 5 Event(s)	Other	New Data	13 Oct 2019	None	Add note	✓
Paraz, Sydney ID: pid199204 DOB: 15 Oct 2019	Patient Initiated 2 Event(s)	Ventricular Tachycardia	New Data	13 Oct 2019	None	Add note	✓
Bailey, Christian ID: pid81218 DOB: 18 Oct 2019	Clinic Interrogation + More 1 Event(s)	Ventricular Tachycardia	New Data	13 Oct 2019	None	Add note	✓
Collins, Brooklyn ID: pid91204 DOB: 16 Oct 2019	Patient Initiated + More 5 Event(s) (incl. detected w/ symptoms)	Ventricular Tachycardia	Viewed	13 Oct 2019	None	Add note	✓
Darlington, Ella ID: pid516414 DOB: 16 Oct 2019	Patient Initiated 8 Event(s)	AF Management	New Data	13 Oct 2019	None	Add note	✓
Miller, Gabriel ID: pid151118 DOB: 15 Oct 2019	Patient Initiated 4 Event(s) (incl. detected w/ symptoms)	Post AF Ablation	Viewed	13 Oct 2019	None	Add note	✓
Ortiz, Matthew ID: pid57229 DOB: 15 Oct 2019	Patient Initiated 0 Event(s)	Suspected AF	Viewed	13 Oct 2019	None	Add note	✓

Figure 4-5. Patient List Page

The following subsections describe the filtering and organizational tools available to efficiently navigate the Patient List page:



Viewing Patient Group

The Viewing Patient Group drop-down list provides a list of Patient Groups to which the user is assigned. All Patient Groups is the default. Select from the drop-down list to select a specific Patient Group. Within a single session, the page remembers the last Viewing Patient Group selection.

Filters

Each filter category may be used to organize the view of patients within a selected Patient Group or for All Patient Groups. The number of patients for each filter category is displayed. See the Columns table later in this section for more information about each category.

Filter	Description
For Review	<ul style="list-style-type: none"> Lists patients with reviewable data that have not been dismissed. Reviewable data includes data associated with alerts, scheduled, and unscheduled remote follow-ups. The Review Reason column on the Patient List page is the default sort when the For Review list is displayed. Patients are listed in order of alert severity, followed by the date of the latest device transmission, with the most recent listed first.
Not Monitored	<ul style="list-style-type: none"> Lists patients that currently are not being monitored due to not being connected or for another reason. The Monitoring Status / Date column on the Patient List page is the default sort when the Not Monitored list is displayed. Patients are listed in order of when Not Monitored was determined, with the most recent listed first.

Filter	Description
Watch List	<ul style="list-style-type: none"> Custom list of patients who need to be monitored more closely. To add a patient to the Watch List, simply click the inactive icon , which will become dark to indicate activation . To remove a patient from the Watch List, simply click the active icon, which will become grey to indicate inactivation. The Review Reason column on the Patient List page is the default sort when the Watch List filter is displayed. Patients are listed in order of alert severity, followed by the date of the latest device transmission, with the most recent listed first.
All Patients	<ul style="list-style-type: none"> Lists all patients in the selected Patient Group or for All Patient Groups. The Patient Info column on the Patient List page is the default sort when the All Patients list is displayed, with patients listed in alphabetical order by last name.

View Secondary Filters



Each filter listed above provides the option of selecting a secondary filter to further limit the list of patients. **All** is the default **View** for all secondary filters.

Search Patients by Name or ID

Click in the **Search patients by name or ID** field and begin typing any part of a patient's name or ID. As keystrokes are entered, the system displays text matches from the list of patients in the current filter of the **Patient List** page.

Action

The following **Action** functions can be performed for selected patients from the **Patient List** page:





Action	Description
Dismiss	<ul style="list-style-type: none"> Dismisses the patient from the For Review list. An individual patient can also be dismissed from For Review by clicking the Dismiss icon  from their Action column (using the For Review filter only) or from the Dismiss button in Patient Detail. Clears all alerts for the patient. Clears the Review Reason on the DATA FOR REVIEW tab in Patient Detail. Clears the Event Logbook on the DATA FOR REVIEW tab in Patient Detail. If configured, sends data to EMR. Once dismissed, the patient is removed from For Review until new reviewable data is transmitted.
Reports Menu	<ul style="list-style-type: none"> Provides a Reports Menu from which one or more reports can be generated. Reports can also be generated for an individual patient by clicking the Reports Menu icon  from their Action column (using the For Review filter only) or from the Reports Menu icon in Patient Detail. See "Generating and Printing Patient Reports" on page 4-22 for more information.

Columns

With the exception of check box, any one of the following columns can be used to sort the **Patient List** page. An arrow in the column header indicates which column is being sorted. Columns vary depending on the filter being used. Except as noted, the referenced column is displayed for all filters.

Column	Description
<input checked="" type="checkbox"/> Check box	<ul style="list-style-type: none"> Select the check box for one or more patients. A selection from the Action menu is performed for all selected patients.
Patient Info	Click on a patient's name in the Patient Info column to see Patient Detail for that patient. (See "Viewing Patient Detail" on page 4-16.)

Column	Description
Review Reason	<p>Displays a vertical colored bar on the left of the column to indicate at least one undismissed red or yellow alert. If more than one alert condition is met, the colored bar will indicate the more severe condition that was met. For example, the colored bar will be red if both red and yellow alert conditions are met. No colored bar indicates no alert detected.</p> <ul style="list-style-type: none"> Summarizes undismissed interrogations in four rows: <ul style="list-style-type: none"> Type of interrogation: <ul style="list-style-type: none"> Indicates if an interrogation is Scheduled, Patient Initiated, or Clinic Interrogation; displays "+ More" for multiple interrogations of different types. Row is blank if interrogation is not one of the three listed above. Highest-priority alert. Provides the number of undismissed events. Indicates symptoms, if any, associated with the undismissed events. <p>Displays for all filters except Not Monitored.</p>
Reason for Monitoring	<ul style="list-style-type: none"> Displays the Reason for Monitoring selected for the patient. Each Reason for Monitoring is color coded throughout LATITUDE Clarity for easier identification.
Review Status	<ul style="list-style-type: none"> Displays the patient's Review Status, which can be New Data or Viewed. Clicking a patient's Review Status link displays their Review History, with Date, Action, and User information. Viewing patient data or generating reports will record the action and may update Review Status from New Data to Viewed, even if using Read-Only Access. The status reverts to New Data when a new interrogation is recorded. Displays only when using the For Review filter.
Monitoring Status / Date	<ul style="list-style-type: none"> Indicates the current monitoring status of the patient: Monitored, Monitored In Clinic, Not Set Up, Patient Transferred, Connection Issue, or Monitoring Disabled. Patients monitored remotely: Considered monitored once their device has been activated and the patient app has been set up. Patients monitored in clinic: Considered monitored once their device has been activated and Monitoring Method has been set to Monitor in clinic only on the Edit/View Patient and Equipment Information page "Edit/View Patient and Equipment Information Page" on page 4-20. Dates are shown only for Not Set Up, Connection Issue, and Monitoring Disabled. When multiple dates are involved, only the most recent date is shown. All monitoring statuses, except Monitored, provide a link to a page with additional information, which may include an Edit link to the patient's Edit/View Patient and Equipment Information page, as applicable. See "Viewing Patient Detail" on page 4-16. Displays for all filters except For Review.
Last Connection	<ul style="list-style-type: none"> Displays the last date of connection to the patient's device or None. Displays only when using the Not Monitored filter.
Latest Device Transmission	<ul style="list-style-type: none"> Displays the date of the last full interrogation collected from the patient's device. Displays for all filters except the Not Monitored filter.
Next Follow-up	<ul style="list-style-type: none"> Displays the date of the patient's next scheduled remote follow-up. Displays an icon  for a missed follow-up.









Column	Description
Patient Notes	<p>Displays either Patient Notes entered by the user or  Add note.</p> <ul style="list-style-type: none"> Patient Notes are initially created by clicking  Add note. Patient Notes are also available in the Notes section in Patient Detail ("Viewing Patient Detail" on page 4-16). Clicking an existing note opens a window from which Patient Notes can be revised and saved. <p>NOTE: An existing note can be deleted by revising, deleting all text, and saving.</p> <ul style="list-style-type: none"> Hovering over a long note reveals a longer version in a pop-up window.
Action	<ul style="list-style-type: none"> Displays available action icons for an individual patient: Dismiss  and Reports Menu . Displays for individual patients only when using the For Review filter.



Viewing Patient Detail

Clicking the patient's name on the **Patient List** page brings the user to a page containing detailed patient information (referred to as "Patient Detail" in this document). Each time Patient Detail is accessed, the **DATA FOR REVIEW** tab is the default view. Each section of Patient Detail is explained in the following tables.

Patient Header

The top section (referred to as "Patient Header" in this document) remains constant throughout all functions of Patient Detail. The following information is displayed in the Patient Header:

Function	Description
Summary of patient information	<p>The summary includes:</p> <ul style="list-style-type: none"> Patient personal data. Watch List icon, showing active  or inactive . Clinic and Patient Group information. Device and clinician information. Latest Device Transmission date. <p>Clicking the patient's name from the Patient Header opens a page providing editable patient and patient-related information (referred to as "Edit/View Patient and Equipment Information Page" in this document). See "Edit/View Patient and Equipment Information Page" on page 4-20.</p>
Battery status	<p>In addition to a visual indicator of battery status, one of the following status indicators is shown:</p> <ul style="list-style-type: none"> -- status unknown. OK . RRT (Recommended Replacement Time)  with date that RRT occurred. EOS (End of Service)  with date that EOS occurred.
Connection	<ul style="list-style-type: none"> Monitored  provides last date of connection to the patient's device or Not Monitored  displays highest priority reason for not being monitored; clicking the reason displays a page providing additional information, troubleshooting help, and may provide an Edit link to the Edit/View Patient and Equipment Information page. <p>NOTE: For patients in LATITUDE Clarity who are monitored in clinic only, messages for Connection may vary.</p>
Schedule 	<ul style="list-style-type: none"> Dates for the Next and Last scheduled follow-ups for normal patients with an activated device. Clicking the Next link displays a calendar from which to select the Next Scheduled Remote Follow-up; may also be selected as described in the PROGRAMMING portion of the Tabs table, later in this section. For patients in LATITUDE Clarity who are monitored in clinic only, Clinic Only is displayed, with no schedule.
Reason for Monitoring	<ul style="list-style-type: none"> Displays the Reason for Monitoring selected for the patient. Each Reason for Monitoring is color coded throughout LATITUDE Clarity for easier identification.

Function	Description
Clinical Context	Displays corresponding optional data entered on the Edit/View Patient and Equipment Information page; maintained by the clinic if deemed useful; may remain blank.
Notes 	<ul style="list-style-type: none"> Notes are initially created by clicking  Notes or the Add note link. Notes are also available in the Patient Notes section of the Patient List page ("Patient List Page" on page 4-12). Clicking an existing note or Notes opens a window from which Notes can be revised and saved. <p>NOTE: An existing note can be deleted by revising, deleting all text, and saving.</p> <ul style="list-style-type: none"> Hovering over a long note reveals a longer version in a pop-up window.

Function Buttons

The following function buttons are shown on all tabs and are active or inactive, as applicable per tab.





Function Button	Description
REPORTS MENU	See "Generating and Printing Patient Reports" on page 4-22.
MESSAGE PATIENT	<ul style="list-style-type: none"> Click to select a message to be delivered and displayed on the patient app. If multiple messages are sent, only the most recent message will appear on the patient app.
SEND TO EMR	<ul style="list-style-type: none"> Appears only if there is at least one undismissed interrogation. EMR must be enabled and configured before interrogations can be sent. See "Setting Up EMR Integration" on page 4-29. If there are multiple undismissed interrogations, the user has the option to select one or more to be sent to EMR. Each interrogation selected is sent as an individual record.
DISMISS	<ul style="list-style-type: none"> Appears only if there is at least one undismissed interrogation. Click to dismiss patient from the For Review list. Clears all alerts for the patient. Clears the Review Reason on the DATA FOR REVIEW tab. Clears the Event Logbook on the DATA FOR REVIEW tab. If configured, sends data to EMR. Once dismissed, the patient is removed from For Review until new reviewable data is transmitted.

Tabs

Patient Detail is organized by tabs. The details for each tab are listed in the following table. See "Diagnostics" on page 2-11 for information about the diagnostics provided on LATITUDE Clarity.

Tab	Description
DATA FOR REVIEW: Primary page providing information to the clinician.	Review Reason – displays one or more of the following reasons for interrogations that have not yet been dismissed; data shown are for those interrogations. <ul style="list-style-type: none"> Alerts Scheduled Patient Initiated Clinic Interrogation Displays None if the patient is dismissed or if the DATA FOR REVIEW is other than the above four interrogations.
	My Alerts – displays information for red or yellow alerts not yet dismissed.
	Presenting S-ECG , not dismissed when patient is dismissed. For more information, see the EVENTS portion of this table.
	Event Logbook – displays the following events: <ul style="list-style-type: none"> All undismissed events.

Tab	Description
	<ul style="list-style-type: none"> Previously dismissed events if a scheduled follow-up is undismissed, shown to provide a complete view of events in a scheduled follow-up period. <p>For more information, see the EVENTS portion of this table.</p> <p>Counters and Settings:</p> <ul style="list-style-type: none"> Matrix displaying counters data from the device for Recent, Previous, and Lifetime time frames³ for each type of event. The Programming Summary column displays programmed settings from the last full interrogation. A link to View Current Settings is displayed to flag users when programming shown in the Programming Summary column differs from the most recent device programming. Clicking the link bring the user to the PROGRAMMING tab, which contains the current settings. <p>AF Overview</p> <ul style="list-style-type: none"> Provides trends related to AF and summary data related to AF events for Recent and Previous time frames³. Hovering over each trend data point reveals corresponding information.
<p>EVENTS: Provides a list of all events captured by the device.</p>	<p>Presenting S-ECG:</p> <ul style="list-style-type: none"> Displays the patient's most recent 10-second S-ECG. Previous S-ECGs can be viewed by adjusting the date. Unrelated to an event; automatically captured daily; additionally may be commanded by a Patient Initiated or Clinic Interrogation. Displays the patient's average heart rate for the displayed date and time. Clicking the Access Event Detail icon  provides enhanced viewing options and tools. See "Event Detail Viewer" on page 4-21. <p>Event Logbook:</p> <ul style="list-style-type: none"> May contain multiple pages. Lists all events for the life of the device. Events not yet assessed and not dismissed are flagged on the left as New. An Event Detail Report may be generated for: <ul style="list-style-type: none"> One or more events by selecting the check box of each desired event, scrolling up and clicking the REPORTS MENU button, selecting additional desired reports, and then clicking GENERATE REPORT(S) or A specific event by clicking the event ID link (e.g., P-23) or Access Event Detail icon  and then clicking the EVENT DETAIL REPORT button. Clicking a column heading sorts the events; an arrow indicates which column and order is being displayed. If S-ECG data is available for an event, the Access Event Detail icon  displays. See "Event Detail Viewer" on page 4-21 for information about viewing and annotating the Event Detail viewer. Explanation of Event Logbook columns: <ul style="list-style-type: none"> Event: Each event has an ID link composed of the acronym for the type of event and a sequential number. Description: <ul style="list-style-type: none"> Displays a vertical colored bar on the left of the column to indicate a red or yellow alert is associated with the event. If more than one alert condition is met, the colored bar will indicate the most severe condition that was met. For example, the colored bar will be red if both red and yellow alert conditions are met. No colored bar indicates no alert detected. <p>NOTE: <i>The colored bar by the event remains after the patient is dismissed.</i></p> <ul style="list-style-type: none"> Displays a short description of the event. If the event is a recorded symptom, lists one or more patient-selected symptoms associated with the event and may include an icon for the patient-selected position when the symptoms occurred. <ul style="list-style-type: none"> Date/Time of the start of the event. Duration of the event.

Tab	Description
	<ul style="list-style-type: none"> - Click  Add note for any event to add a note. Notes are included in generated reports. See "Generating and Printing Patient Reports" on page 4-22 for more information. • Rate: Heartrate. • Assessment drop-down list with choice of options. Any changes to the assessment from the default value of Not Assessed displays the user and date of the most recent assessment. • An arrow shows or hides an S-ECG of the event. A magnification slider to the right of the S-ECG provides clinicians with the ability to increase or decrease magnification of the S-ECG.
<p>PATIENT DIAGNOSTICS: Provides a working view of histograms and counters.</p>	<ul style="list-style-type: none"> • Matrix displaying counters data from the device for Recent, Previous, and Lifetime time frames^a for each type of event. • The Programming Summary column displays programming at the time of the last interrogation. • A link to View Current Settings is displayed to flag users when programming shown in the Programming Summary column differs from the most recent device programming. Clicking the link brings the user to the PROGRAMMING tab, which contains the current settings. • Histograms may be displayed for Recent and Previous time frames^a.
<p>HEALTH: Provides detail about AF, trends, and heart rate.</p>	<ul style="list-style-type: none"> • Displays AF Overview and Trends for Recent and Previous time frames^a. • Hovering over a data point in any of the Trends charts for Night Heart Rate, Day Heart Rate, AF Burden, and V Rate during AF reveals corresponding information for each data point in all charts.
<p>FOLLOW-UP HISTORY: Provides a list of past interrogations for the patient.</p>	<ul style="list-style-type: none"> • Clicking the Print Report icon  generates a report for the selected interrogation. • The SEND TO EMR icon is active  only if EMR integration is enabled. Clicking the active icon requests data be sent to EMR. If not enabled, an inactive icon  is displayed. Each interrogation lists the EMR Send Status. Clicking the link provides EMR Transfer History. See "Setting Up EMR Integration" on page 4-29.
<p>PROGRAMMING: Provides ability to change Reason for Monitoring for the patient and program sensing, events and alerts.</p>	<ul style="list-style-type: none"> • For all sections of the PROGRAMMING tab: <ul style="list-style-type: none"> • When the check box for Use Patient Group Defaults is selected, parameter values are inherited from the Patient Group. See "Patient Group, Clinic Configuration, and Programming Options" on page 4-10. • When the check box is cleared, parameter values may be customized for the individual patient.
	<p>Reason for Monitoring:</p> <ul style="list-style-type: none"> • May be changed for the individual patient by clicking the current Reason for Monitoring and selecting the new one. Once selected, a Warning page appears providing consequences of the change. Select APPLY CHANGES to continue with the change or CANCEL to revert to the original Reason for Monitoring. • When the Reason for Monitoring is changed, the default parameter values will change accordingly. • See "Programmable Parameters: Arrhythmia Detection" on page B-1 for programming options and "Default Programming Values per Reason for Monitoring" on page C-1 for default values for each Reason for Monitoring.
	<p>Device Programming and Alert Configuration:</p> <ul style="list-style-type: none"> • Clicking the View Programming Status link provides a list of Current and Pending programming. Pending programming has not yet been received by the device. • Sensing Parameters are always enabled. Select values for Blank After Sense and Sensitivity from the drop-down menu. Morphology Assessment may be selected On or Off. • For event alerts, first press the toggle key to enable each event, as applicable, and then select the desired values and alerts. • The individual patient settings for event alert configuration provide three options: <ul style="list-style-type: none"> • Toggle key to the Off position: No alert or event detection. • Clear alert check boxes: Event detection with no alert. • Select Red Alert or Yellow Alert: Event generates selected alert. • System Alerts: for Monitoring Disabled and Battery Recommended Replacement Time (RRT) may be selected or cleared and designated as red or yellow, as appropriate for the individual patient. • Bluetooth® Manual Connection provides a selection of Require Magnet or No Magnet for the individual patient. • See "Programmable Parameters: Arrhythmia Detection" on page B-1 for programming options and "Default Programming Values per Reason for Monitoring" on page C-1 for default values for each Reason for Monitoring.

Tab	Description
	<p>Next Scheduled Remote Follow-up:</p> <ul style="list-style-type: none"> Clicking the date link displays a calendar from which to select the Next Scheduled Remote Follow-up; may also be selected as described above in the Schedule section of Additional Patient Header information. Even with automatic scheduling, you can always manually select a new follow-up date for an individual patient by using the scheduling calendar as described above.
	<p>Remote Scheduled Follow-ups:</p> <ul style="list-style-type: none"> Can be scheduled manually as described above in Next Scheduled Remote Follow-up or set automatically. For automatic scheduling, the next follow-up is automatically scheduled by using the configured interval and day of the week. Even with automatic scheduling, you can always manually select a new follow-up date for an individual patient by using the scheduling calendar as described above. The scheduled date is calculated by taking the date the remote scheduled interrogation was received and adding the configured interval and the number of days of the configured day of the week (scheduled date = interrogation date + interval + configured week days). If a patient's follow-up schedule (interval or day of the week) is changed, the date of the next follow-up does not change unless you specifically change that date. <p>NOTE: The number of days used for a monthly interval is 30 times the number of months selected except for 1 month and 3 months, which are 31 and 91 days respectively. The number of days for 1 through 12 months equals 31, 60, 91, 120, 150, 180, 210, 240, 270, 300, 330, and 360.</p>
	<p>Connection Status Notification:</p> <ul style="list-style-type: none"> The individual patient is added to Not Monitored on the Patient List page if not connected for the selected time frame of 1 to 14 days.
	<p>Patient Initiated Interrogations ("PII"):</p> <ul style="list-style-type: none"> Can be enabled (five per week) or disabled for the individual patient. One additional PII can be configured at any time for an individual patient by clicking the Allow one Patient Initiated Interrogation button.

a. The following definitions of time frames apply throughout Patient Detail for patients monitored remotely; for patients monitored in clinic, the definitions are for every interrogation:

- Recent:** From the prior scheduled follow-up to the most recent full interrogation.
- Previous:** The period between the prior two scheduled follow-ups.
- Lifetime:** From beginning of monitoring to the most recent full interrogation.

Edit/View Patient and Equipment Information Page


Clicking the patient's name from the Patient Header brings the user to an Edit/View Patient and Equipment Information page. The following table shows the type of information that can be entered or configured for the patient on this page. Some of the information entered on the Edit/View Patient and Equipment Information page is displayed in the Patient Header.


Function	Description
Unenroll Patient button	Removes the patient from the primary Patient Group and discontinues monitoring.
Last Updated By link	For each section of the page, provides the section name, date, and name of the user who last updated the section.
General Information	<ul style="list-style-type: none"> Patient Information, provides patient name, ID, gender, phone numbers, and date of birth. Patient Time Zone may be set to a selected fixed or Auto Detected time zone to facilitate the time-sensitive functions of the patient app and device. <ul style="list-style-type: none"> Auto Detected is the default setting for patients monitored remotely. If a patient moves or travels to a different time zone, the time zone in the device is automatically updated based on the time zone of the patient or clinic app. If desired, a fixed time zone may be selected for patients who frequently travel to different time zones so that the timing of interrogations are more uniform. A fixed time zone is the default setting for patients monitored in clinic. Monitoring Information, provides:




Function	Description
	<ul style="list-style-type: none"> • Monitoring Method choice of Monitor remotely or Monitor in clinic only; selecting Monitor remotely also provides the following: <ul style="list-style-type: none"> - Remote Monitoring Equipment. - myLUX™ Application Version. - Release current myLUX pairing button, required to allow setup of a replacement mobile device. • Clinical Context, provides: <ul style="list-style-type: none"> • Reason for Monitoring (informational only; see PROGRAMMING tab section above to change Reason for Monitoring). • Option to select several diagnostic conditions of the patient.
Patient Group Membership	<p>Primary Patient Group</p> <ul style="list-style-type: none"> • Option to change the patient's Primary Patient Group and • Link to Remove Patient From Group.
Implanted Device	<p>Implanted Device Information</p> <ul style="list-style-type: none"> • Model • Serial Number • Implant Date <p>Information in this location is changed when a patient's device is replaced. See "Replacing Patient Equipment" on page 4-23 for more information.</p>
Additional Information	<ul style="list-style-type: none"> • Clinician Information includes: <ul style="list-style-type: none"> • Implanting Clinician, Following Clinician, and Referring Clinician. • Implanting Facility Information. • Explanted Device Information. • Registration Information, provides option to enter Registration Comments.

A **Last Updated By** link for each section of the Edit/View Patient and Equipment Information page provides the date and name of the user who last updated the patient settings.

Event Detail Viewer

An **Event Detail** viewer provides enhanced viewing options and tools and is available from Patient Detail for **Presenting S-ECG** data and **Event Logbook** events. Click the Access Event Detail icon  from either the **DATA FOR REVIEW** or **EVENTS** tab.

From either **Event Detail** viewer, select the  button to create a PDF report of the page being viewed (**Presenting S-ECG Report** or **Event Detail Report**). See "Generating and Printing Patient Reports" on page 4-22 for more information.

Event Detail	Description
Presenting S-ECG	<ul style="list-style-type: none"> An Access Event Detail icon  displayed above the Presenting S-ECG indicates S-ECG data that can be seen on the Event Detail viewer. Click either the icon for the event to open the Event Detail viewer. The patient's average heart rate during the S-ECG is also displayed. The default time scale is 25 mm/s but may be adjusted to 50 or 100 mm/s. A magnification slider to the right of the S-ECG provides clinicians with the ability to increase or decrease magnification of the S-ECG. A mini viewer displays a selected point in time to the corresponding S-ECG. Adjusting the time in the mini viewer displays a different time value in the S-ECG, providing the user with a view of changes over the selected period of time. There is no option to annotate the Presenting S-ECG Event Detail viewer. See the following Event Logbook portion of this table for annotation information.
Event Logbook	<ul style="list-style-type: none"> An Access Event Detail icon  displayed in the Event column of the Event Logbook indicates S-ECG data that can be seen and annotated on the Event Detail viewer. Click either the icon or the ID link for the event to open the Event Detail viewer. The first section of the Event Detail viewer is a duplicate of the information contained in the Event Logbook section of Patient Detail for that event.  Add note is an optional tool to add a note associated with the event. Notes are included in generated reports. See "Generating and Printing Patient Reports" on page 4-22 for more information. Annotation Tools are available to mark up the S-ECG on the Event Detail viewer. A description of each tool can be viewed by hovering over the icon. SAVE ANNOTATIONS AND CLOSE must be selected before closing the Event Detail viewer in order to save the annotations. The default time scale is 25 mm/s but may be adjusted to 50 or 100 mm/s. A magnification slider to the right of the S-ECG provides clinicians with the ability to increase or decrease magnification of the S-ECG. A mini viewer displays a selected point in time to the corresponding S-ECG. Adjusting the time in the mini viewer displays a different time value in the S-ECG, providing the user with a view of changes over the selected period of time. A rate plot for the event is shown below the mini viewer. The device programmed settings specific to the event type are shown at the bottom of the page.

Generating and Printing Patient Reports

One or more reports, using data from the latest device transmission, can be generated for individual patients or for several patients at a time. When printing reports, report information is retrieved, and a single PDF file is generated for each report request. Once the selected report(s) are generated, the user can print and save the reports.

Reports may be generated by clicking the **Reports Menu** icon from either the **Patient List** page, after selecting one or more patients, or from Patient Detail.

Multiple individual reports may be printed at one time. If attempting to print more than the maximum number of reports allowed, the system will advise to print fewer reports.

The following reports are available:

- **Follow-up Report**, including trends and histograms if selected, and events since last dismissed and events since last scheduled, as applicable
- **Event Detail Report**
- **Most Recent Presenting S-ECG Report**
- **Programming Report**

Select one or more reports, then click **GENERATE REPORT(S)**.

The date, time, and user who generated the reports is logged in the **Review Status** link for the patient on the **Patient List** page.

MANAGING PATIENTS

The following information is provided to help clinic users manage their LATITUDE patients.

Changing Patient Demographic and Equipment Information

Users can view and edit patient demographic and device information on the Edit/View Patient and Equipment Information page by clicking the patient's name on the **Patient List** page, then clicking the patient's name again in the Patient Header. See "Patient Header" on page 4-16 for more information.

Replacing Patient Equipment

When a patient's device is replaced, the patient app is automatically released and needs to be set up again. The patient app will prompt the user for set up. In addition, patient information needs to be updated on LATITUDE Clarity via the Edit/View Patient and Equipment Information page ("Edit/View Patient and Equipment Information Page" on page 4-20) with new model and serial numbers and implant date before the patient can set up their mobile device.

NOTE: *When the patient's device is replaced, all uploaded data, follow-up history, and alert history for the previous device are no longer viewable. We recommend printing any desired reports before updating the device.*

When a patient's mobile device is replaced, click the **Release current myLUX pairing** button on the Edit/View Patient and Equipment Information page to allow setup of the replacement mobile device.

The device, as well as the mobile device, are intended to be used by a single patient.

Changing Patient Groups

Clinics can change the Patient Group of a patient on the Edit/View Patient and Equipment Information page by clicking the patient's name on the **Patient List** page, then clicking the patient's name again in the Patient Header. The patient can be moved from one Patient Group to a new Patient Group by selecting the new Patient Group from the drop-down menu in the **Patient Group Membership** section of the **Edit/View Patient and Equipment Information** page. Only clinic users associated with the new Patient Group will have access to the patient.

This change does not affect the patient's data or status on the **Patient List** page; however, programming values and alert and schedule configuration settings may change if the patient is using Patient Group defaults and the new Patient Group has different settings.

Transferring Patients

Patients can be transferred from an existing clinic to a new clinic, based on patient consent. When a new clinic enrolls a patient, the user in the previous clinic will see an indication that the patient is being followed by a different clinic. Once the user in the new clinic indicates that the patient has authorized the transfer, the enrollment can be completed and the patient is immediately transferred to the new clinic.

Users in the new clinic will see the patient's current data and will also see any undismissed alerts and interrogations from the previous clinic.

Users in the previous clinic will see the patient's status as **Patient Transferred**. The existing follow-up history information is available to print any desired reports. No new data will be visible to users in the previous clinic. The previous clinic can unenroll the patient by clicking the **Unenroll Patient** button on the Edit/View Patient and Equipment Information page.

Unenrolling Patients

Patients can be unenrolled on the Edit/View Patient and Equipment Information page by clicking the **Unenroll Patient** button. Unenrolling the patient immediately discontinues monitoring and removes access to the patient records.

NOTE: Clinics are responsible for unenrolling patients if a clinic is no longer in practice. If a clinic dissolves, Boston Scientific personnel may contact patients enrolled in that clinic.

MANAGING PATIENT GROUPS

The list of existing Patient Groups can be viewed via **Manage Clinic > Manage Clinic Settings**. Clinic users only see the Patient Groups to which they are assigned.

Adding Patient Groups

A Clinic Account Manager can add a Patient Group by selecting the **Add Patient Group** button on the **Manage Clinic Settings** page. Adding a Patient Group automatically assigns all Clinic Account Managers to that Patient Group. A second screen is displayed that allows assigning additional clinic users to the Patient Group.

Deleting Patient Groups

Patient Groups can be removed by Clinic Account Managers, but only if there are no patients enrolled in the Patient Group. To delete a Patient Group, click the **Edit/View Demographics and User Membership** button associated with a Patient Group on the **Manage Clinic Settings** page. Then click the **Remove Patient Group** button.

Other Patient Group Management Functions

Other Patient Group management functions are available from the **Manage Clinic Settings** page:

- **Edit/View Patient Group Defaults** – selecting this button associated with a Patient Group allows clinic users to manage **Remote Scheduled Follow-ups**, **Patient Initiated Interrogations**, **Connection Status Notification, Programming and Alerts**, and **Text and Email Notifications** settings. See "Patient Group, Clinic Configuration, and Programming Options" on page 4-10 for more information.
- **Edit/View Demographics and User Membership** – selecting this button associated with a Patient Group allows clinic users to update the Patient Group's name and description and to see the other users assigned to the Patient Group. Clinic Account Managers can assign clinic users to, or remove clinic users from, the Patient Group. Note that Clinic Account Managers are assigned to all Patient Groups and cannot be removed from a Patient Group.

CLINIC ACCOUNT MANAGEMENT

The following sections explain clinic account management in LATITUDE Clarity.

Registered Users

Boston Scientific reserves the right to deactivate any user or account that uses or accesses LATITUDE Clarity contrary to the LATITUDE Licensing Agreement, any policies related to LATITUDE, or any relevant privacy and data protection laws or regulations.

Users who have not logged in for an extended period of time are considered inactive and may be deleted.

Patient, Clinician, and Clinic Relationships

Patient monitoring on LATITUDE Clarity is based on the relationship of patients to clinics. Each LATITUDE Clarity clinic user has a user account that is associated with a specific clinic.

Each ICM system patient must have an assigned clinic in order to be monitored and must be associated with one Patient Group in their assigned clinic.

Patient Groups

A clinic is organized into one or more Patient Groups created for the efficient management of patients. For example, patient groups can be organized by physician and/or location. Clinic users can be assigned to any number of Patient Groups. Clinic users assigned to a Patient Group have access to all patients enrolled in that Patient Group. Clinic Account Managers have access to all patients in all Patient Groups.

Patient Groups provide default programming and alert and schedule configuration settings for their associated patients. A patient can have customized settings that differ from the Patient Group default settings.

Clinic User Privileges

There are three types of privilege levels assigned to clinic users that control access to patient data, described as follows. The functions that each can perform are shown in the following table.

- **Read-Only Access** – Intended for users who need to work with patient data but are not responsible for managing the patients within the system. Access is limited to patients in assigned Patient Groups.
- **Limited Access** – Intended for users who are responsible for managing patients. These users have full capability to manage patients, but access is limited to patients in assigned Patient Groups.
- **Complete Access** (Clinic Account Managers) – Intended for the user who is responsible for managing the clinic and the clinic users and patients. Access is open to all patients in all Patient Groups. User accounts can be created by the Clinic Account Manager.

Table 4-4. Functions Permitted for Clinic Users by Privilege

Function	Complete Access (Clinic Account Manager)	Limited Access	Read-Only Access
	All Patient Groups	Assigned Patient Groups	Assigned Patient Groups
Add/Manage Patient Groups	✓		
Add/Manage clinic users	✓		
Enroll/Manage patients	✓	✓	
Manage schedule and alert configurations	✓	✓	
Program ICM device	✓	✓	
View patients on the Patient List page	✓	✓	✓
Dismiss patients on the Patient List page	✓	✓	
View patient data and reports ^a	✓	✓	✓
Edit EMR integration configuration	✓		
Send data to EMR	✓	✓	

a. Viewing patient data or reports will record the action and may update **Review Status** from **New Data** to **Viewed**, even if using **Read-Only Access**.

MANAGING USER ACCOUNTS

Clinic Account Managers have access to all account management functions for each clinic user (except themselves) via **Manage Clinic > Manage Clinic Users > Edit/View Demographics and Access Settings** button > **Update Clinic User** page. The Clinic Account Manager can access their own **Update Clinic User** page by clicking the **My Profile** link associated with their name at the top of every page on the LATITUDE website.

Adding User Accounts

Clinic user accounts can be added by Clinic Account Managers. To add a user, select the **Add Clinic User** button on the **Manage Clinic Users** page. The **Add Clinic User** page provides a set of required and optional data entry fields. Adding an account includes selecting the user's privileges and assigning them to the desired Patient Groups.

Deleting User Accounts

Clinic user accounts can be removed by Clinic Account Managers. To delete a user, click on the **Edit/View Demographics and Access Settings** button associated with that user on the **Manage Clinic Users** page, then click on the **Remove Clinician** button. Removing an account removes that user from all access to patients and deletes that user's account.

It is the responsibility of the clinic to ensure that accounts are deleted for users who are no longer employed by the clinic or who should no longer have access to patient data in LATITUDE Clarity.

Users who have not logged in for an extended period of time are considered inactive and may be deleted.

Update Clinic User Page

Additional account management functions are available for both the Clinic Account Manager and clinic user on the **Update Clinic User** page.

- The Clinic Account Manager can access this page by selecting **Manage Clinic > Manage Clinic Users**, then selecting the **Edit/View Demographics and Access Settings** button associated with a user.
- A clinic user can access the **Update Clinic User** page by clicking **My Profile**, associated with their name at the top of every page.

The following table shows the functions available on the **Update Clinic User** page:

Function	Description	Clinic Account Manager For All Clinic Users (Except Themselves)	Clinic User (and Clinic Account Manager via My Profile)
User Information	Includes name, phone number, and e-mail address.	X	X
Website Language and Country	Can also be changed on the login page. See "Logging In and Out" on page 4-3.		X
Login Information, User ID and Password	Change User ID	X	X
	Reset Password <ul style="list-style-type: none"> • If a user forgets their password, this function can be used by the Clinic Account Manager to assign a temporary password. Clicking the Reset Password link assigns a temporary password and displays it in a pop-up window. The user will use the temporary password at the next login attempt but then will be required to create a new password. 	X	
	Change Password		X
Login Information, Security	View/Edit Security Questions		X

Function	Description	Clinic Account Manager For All Clinic Users (Except Themselves)	Clinic User (and Clinic Account Manager via My Profile)
Login Information, Security	Get Two Factor Verification Code - (not available in all geographies) If two factor authentication is required, the Clinic Account Manager may create a one-time verification code for a clinic user to use at their next login, which must be within 10 minutes. The link to create the verification code is in the Login Information / Security section. Also see "Logging In and Out" on page 4-3.	x	
Access Settings	Provides ability to assign Privileges and Assigned Patient Groups .	x	
Heart Failure Patient View	LATITUDE NXT function only: Provides check box to Enable Heart Failure Patient View , which sends the user directly to the Health tab when selecting the patient name from the Patient List page.	x	x
Homepage	Allows user to select LATITUDE Clarity as the default homepage instead of LATITUDE NXT, which otherwise is the default homepage.	x	x

PASSWORDS

Passwords cannot be retrieved, even by an administrator. Password rules and suggestions for creating a good password are provided on the LATITUDE website.

A Clinic Account Manager can designate whether passwords expire 180 days after being issued or never expire via **Manage Clinic > Manage Clinic Settings > Edit/View Clinic Demographics** page. A user's account is locked after six consecutive login attempts with an incorrect password (or verification code in Europe). If their account is locked, a user can unlock it by providing their answer to a security question, or a Clinic Account Manager can reset the user's password. See "Update Clinic User Page" on page 4-26 and "Resetting Your Forgotten Password" on page 4-28.

NOTE: Passwords expire three months after being issued in Italy.

Temporary Passwords

When a Clinic Account Manager creates an account or resets the password for a clinic user, a temporary one-time password is assigned. The Clinic Account Manager gives this password to the clinic user. The clinic user must change this password when logging in for the first time.

Temporary passwords expire six months after being issued.

NOTE: In Italy, temporary passwords expire three months after being issued.

Security Questions

A clinic user is prompted to change their password the first time they log in with their temporary password. The clinic user must enter answers to three selected security questions.

A clinic user is prompted for their answer to one of these security questions if they forget their password and need to reset it. Clinic users can also ask their Clinic Account Manager to reset their passwords. Refer to "Resetting Your Forgotten Password" on page 4-28.

Changing Your Password

A clinic user can change their own password by clicking the **My Profile** link associated with their name at the top of every page on the LATITUDE website, and then by clicking the **Change Password** link in the **Login Information** section. Enter the old and new passwords as shown in the following figure. Click the **Save and Close** button. The new password will take effect at the next login.

Boston Scientific LATITUDE Clarity™
Switch to LATITUDE® NXT

- Password must be between 8 and 32 characters in length
- Password must contain at least one character (a-zA-Z) and either one number (0-9) or one special character (!@#%&*()_+!~=:{}|'";<>?.,))
- Password is case-sensitive
- The new password cannot be the same as any of the previous three
- Passwords cannot contain your username

*Indicates Required Field

*Old Password:

*New Password:

*Confirm New Password:

Figure 4-6. Change Password

Resetting Your Forgotten Password

If a clinic user forgets their password or their login account is locked, the password can be reset any time by using the **Forgot Password?** link (shown in the following figure). An answer to one of the security questions is required in order to reset the password. The Clinic Account Manager may also reset a password.

LATITUDE™ NXT / LATITUDE Clarity™

Please enter your User ID and Password to enter the Boston Scientific LATITUDE Clinician website

*Indicates Required Field

*User ID:

*Password:

Change Country/Language: United Kingdom/English

[Forgot Password?](#)

For additional assistance, call LATITUDE™ Customer Support

Figure 4-7. Forgot Password? Link

EMR SYSTEM INTEGRATION

The optional LATITUDE Electronic Medical Record (EMR) system integration feature, if enabled, provides an automated way to export patient device data to a clinic's internal EMR application. Clinicians may want to refer to the Implantable Device Cardiac Observation (IDCO) integration specification of Boston Scientific for details on how device data are converted into IDCO messages, which are used to deliver patient data to the EMR application.

If EMR integration is enabled, individual patient data can also be manually sent to the EMR application by clicking **Send to EMR** from Patient Detail. Notes from the **Event Logbook > Event Detail** viewer are also sent to the EMR application within generated reports.

If EMR integration is not enabled, patient data is still captured and can be sent manually once EMR integration is enabled.

The data may include PDFs of the **Follow-up Report**, **Event Detail Report**, **Most Recent Presenting S-ECG Report**, if available. Not all EMR applications accept these types of data. When enabled, EMR integration exports data for all patients in all Patient Groups within your clinic.

NOTE: Annotations or notes added to **Events** or the **Event Detail Report** are more easily included when sent to the EMR application if either **Manual** or **Upon Dismiss** is selected when enabling EMR integration.

The EMR integration feature provides the following functions:

- Enables and disables EMR integration as needed (default is disabled).
- If enabled (see "Setting Up EMR Integration" on page 4-29), allows automatic export of available patient data to your EMR application. The data provided is associated with all device interrogations (e.g., alerts, **Remote Scheduled Follow-ups**, **Patient Initiated Interrogations**, or **Clinic Interrogations**).
- If disabled, the **Send to EMR** button, which can be found in the **Actions** column of the EMR log or in Patient Detail, is not active. Entries are created but not sent. When enabled, the **Send to EMR** button becomes active and the entries can be selected and sent. (See "View EMR Log" on page 4-31 or "Viewing Patient Detail" on page 4-16.)
- Allows selection of the data format for your EMR application.
- Displays details of each data export including time stamps and export status.
- Allows EMR data to be resent.

NOTES:

- *Connection difficulties may delay or prevent EMR file delivery to the EMR application. LATITUDE Clarity is the system of record for remote patient management. Clinicians should not rely on the presence of data in the EMR application to determine if a remote follow-up or alert has occurred.*
- *Any changes to data from within the EMR application will not change data in LATITUDE Clarity.*
- *Some EMR applications may not directly import LATITUDE Clarity data. Additional software may be required to import LATITUDE Clarity data into your EMR application. Technical information is located separately in the Boston Scientific IDCO integration specification.*
- *If an attempt to export an EMR file fails, LATITUDE Clarity continues to attempt to export the file to the EMR application for up to 30 days. The export status at this time will be **Waiting for Clinic Computer**. LATITUDE Clarity will then discontinue the attempt to export the EMR file and report a **Failed** status. If this occurs, the data may be resent using the **Send to EMR** button located in the **Actions** column of the EMR log. See "View EMR Log" on page 4-31.*

Setting Up EMR Integration

The LATITUDE EMR integration feature must be enabled and configured before EMR files can be exported to a clinic's internal EMR application.

Installing, Configuring, and Registering EMR Integration Software

The EMR integration software will typically be installed on the clinic's EMR application server or another clinic server rather than on an individual's workstation. In order to install the EMR integration software, administrative access may be needed on the target system. If unfamiliar with the setup of the target system or EMR application, please consult the information technology (IT) professional responsible for administering the clinic's systems.

Complete the following steps to install the EMR integration software (numbers in the figures refer to the related step):

1. Navigate to the **Manage EMR Integration** page from the **Manage Clinic** drop-down list.
2. Click the **Edit/View EMR Configuration** button:

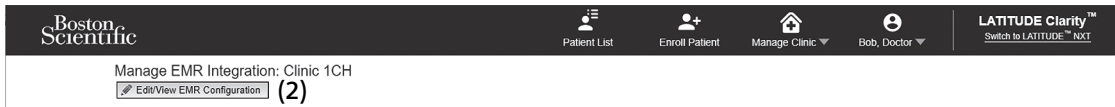


Figure 4-8. Edit/View EMR Configuration Button

3. Press the applicable toggle key for **LATITUDE NXT Output** or **LATITUDE Clarity Output**:



Figure 4-9. Edit/View EMR Configuration Page

4. For **LATITUDE Clarity Output**, select a clinic identifier from the **Select clinic identifier** drop-down list.
 - If you want the exports to go to the same output location as LATITUDE NXT, select the first identifier, which should be identical to the **EMR/CIS Clinic Identifier** shown in the **LATITUDE NXT Output** section.

- If you want the exports to go to a separate output location from LATITUDE NXT output, select the second identifier.

Record the **EMR/CIS Clinic Identifier** identifier for the desired output.

Important: The identifier is required to complete the registration of the EMR integration client software. The identifier is used to route LATITUDE clinic records to the clinic's EMR application.

5. Click the **click here** link to download the EMR integration software.
6. A website for the EMR integration software that needs to be installed is provided. Follow the installation and setup instructions available on this website.
7. Before enabling EMR Integration, complete installation and registration of the software.

NOTE: *Once installation and registration are complete, no further EMR integration software configuration should be required. However, Boston Scientific personnel may contact you regarding additional configuration tasks.*

Enabling EMR Integration for LATITUDE

8. Return to the **Edit/View EMR Configuration** page and press the applicable toggle key for **LATITUDE NXT Output** or **LATITUDE Clarity Output** to enable EMR integration.
9. Select the appropriate **EMR Integration Format** from the drop-down list. The format selected must be appropriate for your EMR application. Supported formats are listed in the drop-down list.
10. Revise the **Maximum Output File Size** as appropriate for your clinic's EMR.
11. **When to Send Data** selections of either **Manual**, **Upon arrival**, or **Upon dismiss** are required for each reason listed.

NOTE: *Annotations or notes added to **Events** or the **Event Detail Report** are more easily included when sent to the EMR application if either **Manual** or **Upon Dismiss** is selected.*

12. Check boxes for options of **Report Configuration** can be selected.
13. Click the **Save and Close** button.

Notice: By enabling EMR, you agree and assert to the following terms and conditions:

- You have installed the EMR integration software on your organization's system in order to download LATITUDE data to your organization's medical record system.
- You will not use the EMR integration software for any other purpose without Boston Scientific's written approval.
- You accept responsibility for the security of the data you are receiving from Boston Scientific.

Clicking the **Last Updated By** link at the top of the page opens a pop-up window that displays the date and time the EMR configuration was last changed and the name of the user who changed it.

View EMR Log

The **View EMR Log** window in the bottom section of the **Manage EMR Integration** page (shown as follows) lists EMR files for which EMR transmission applies. The log only lists patients that are in Patient Groups of which the clinic user has access. Clinic Account Managers will see entries for all patients in the clinic.

The log may optionally be filtered by entering dates in one or both date fields of the **Filter by Device Transmission Date** section and then clicking the **Filter** button.

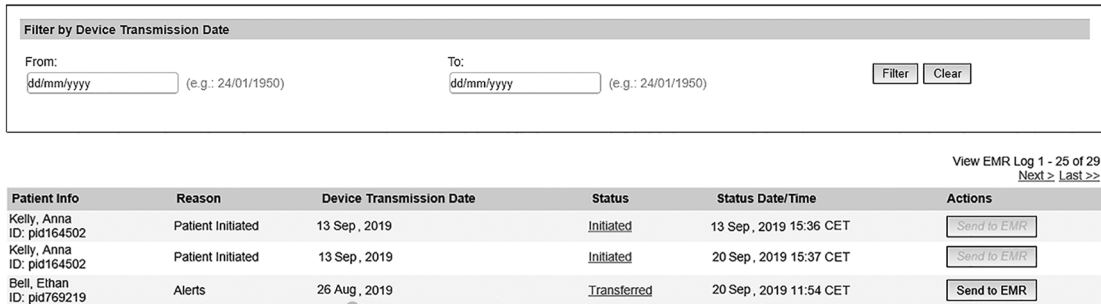


Figure 4-10. View EMR Log Window

The EMR log is sorted by **Device Transmission Date**. The following table provides a description of each column of the **View EMR Log** window:

Column	Description
Patient Info	Provides a list of patient names and identifiers for whom EMR transmission applies.
Reason	Provides the reason that the EMR export was initiated. Options are: <ul style="list-style-type: none"> • Scheduled • Alerts • Patient Initiated • Clinic Interrogation • Data Updated
Device Transmission Date	Provides the date the device interrogation associated with the EMR file was initiated.
Status	<ul style="list-style-type: none"> • Provides the current status of the export. • Clicking the status link opens an EMR history pop-up window that provides detailed information of the export processes for that EMR export. • The options for Status are: <ul style="list-style-type: none"> • Initiated – The EMR export has been initiated. • Waiting for Clinic Computer – All data for the file has been processed and the file is ready to be exported to your EMR application. Typically, file delivery will occur within 30 minutes. If this status persists for more than 30 minutes, please contact the IT professional responsible for monitoring EMR integration software or EMR application. • Transferred – The EMR file has been successfully exported. • Manual Send – An export attempt of the EMR file has been requested. • Failed – The attempt to export the EMR file failed. No further attempt will be made to export the EMR file. Once the reason for failure has been determined, the EMR data may be resent. • Not Initiated – The EMR export has not been initiated based on the EMR export configuration settings. • Dismissed – The EMR export attempt of the EMR file has been initiated due to patient dismissal. • Refer to the troubleshooting section of the installation instructions document available on the LATITUDE EMR Integration software (EMR client) webpage for help with diagnosing and troubleshooting failures.
Status Date/Time	Provides the date and time of the last change in status.
Actions	If EMR is enabled, provides an active Send to EMR button. If EMR is not enabled, the button is inactive.

TROUBLESHOOTING

The **Help/Contact Us** section of LATITUDE Clarity is available in the drop-down list under the user’s name. This page provides:

- Contact information for assistance
- Both patient and clinician educational information

- Troubleshooting Guides

Остаряла версия. Да не се използва.
Zastaralá verze. Nepoužívat.
Forældet version. Må ikke anvendes.
Version überholt. Ärge kasutage.
Aegunud versioon. Mην την χρησιμοποιείτε.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Outdated version. Do not use.
Version obsolete. Ne utilizar.
Version périmée. Ne pas utiliser.
Zastarjela verzija. Nemojte upotrebljavati.
Úrejt útgáfa. Notið ekki.
Versione obsoleta. Non utilizzare.
Zastarjela verzija. Neizmantot.
Úrejt útgáfa. Notið ekki.
Pasenusi versija. Nenaudokite.
Elavult verzió. Ne használja!
Utdatert versjon. Niet gebruiken.
Wersja przeterminowana. Nie używać.
Versão obsoleta. Não utilize.
Versione expirată. A nu se utiliza.
Zastaraná verzia. Nepoužívat.
Zastarela različica. Nie używać.
Vanhentunut versio. Älä käytä.
Föråldrad version. Använd ej.
Güncel olmayan sürüm. Kullanmayın.

Остаряла версия. Да не се използва.
Zastaralá verze. Nepoužívát.
Forældet version. Må ikke anvendes.
Version überholt. Nicht verwenden.
Aegunud versioón. Myn þyn Χρησιμοποιείτε.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Outdated version. Do not use.
Version obsoleta. Ne utilizar.
Version périmée. Ne pas utiliser.
Zastarjela verzija. Nemojte upotrebljavati.
Úreлт útγάfa. Notið ekki.
Versione obsoleta. Non utilizzare.
Pasenusi versija. Neizmantot.
Elavult verzió. Ne használja!
Wersja przeterminowana. Niet gebruiken.
Dit is een verouderde versie. Niet gebruiken.
Utdatert versjon. Skal ikke brukes.
Wersja przeterminowana. Nie używać.
Versão expiratã. A nu se utiliza.
Zastaraná verzia. Nepoužívát.
Zastarela različica. Ne uporabite.
Vanhentunut versio. Älä käytä.
Föråldrad version. Använd ej.
Güncel olmayan sürüm. Kullanmayın.

SYMBOLS ON PACKAGING

APPENDIX A

The following symbols may be used on packaging and labeling (Table A-1 Symbols on packaging on page A-1):

Table A-1. Symbols on packaging


































Symbol	Description
	Reference Number
	Serial Number
	Use By
	Date of Manufacture
	Sterilized using ethylene oxide
	Do Not Resterilize
	Single use. Do not re-use
	Single patient-multiple use
	Do not use if package is damaged and consult instructions for use.
	Implantable device, coated
	Temperature limitation
	MR Conditional
	MR Unsafe
	Consult instructions for use on this website: www.bostonscientific-elabeling.com
	Consult instructions for use
	Consult instructions for use
	Bluetooth®
	Place magnet here
	Manufacturer

Table A-1. Symbols on packaging (continued)

Symbol	Description
	Authorized Representative in the European Community
	Australian Sponsor Address
	LUX-Dx Clinic Assistant app icon
	Warning; Sharp element (color is yellow)
	Open Here
	Recyclable Package
	Medical Device under EU Legislation
	Double sterile barrier system
	Person identification
	Date
	Health care center or doctor
	myLUX patient app icon
	Unique Device Identifier
	Separate Collection

PROGRAMMABLE PARAMETERS

APPENDIX B

Table B-1. Programmable Parameters

	User Programmable Parameter	Programmable values
Sensing Parameters ^a	Blank After Sense (ms)	130 – 400, 10 ms intervals
	Sensitivity (mV)	0.025, 0.037, 0.05, 0.075, 0.1, 0.15, 0.2
	Morphology Assessment	On, Off
Brady ^a	Brady On/Off	On, Off
	Rate min ⁻¹	30, 40, 50, 60
	Duration (seconds)	1, 2, 3, 5, 7, 10, 15, 20, 30
Tachy ^a	Tachy On/Off	On, Off
	Rate min ⁻¹	115 – 220 in increments of 5
	Duration (seconds)	0, 1, 2, 3, 4, 5, 10, 15, 20, 25, 30, 40, 50, 60
	Response	Less, Balanced, More
Pause ^a	Pause On/Off	On, Off
	Duration (seconds)	1.5, 3, 4.5
	Response	Less, Balanced, More
Symptom ^a	Symptom On/Off	On, Off
	Recordings Allowed Per Day	6 events of 5 minutes, 4 events of 7.5 minutes, 3 events of 10 minutes
AT ^a	AT On/Off	On, Off
	Rate min ⁻¹	70 – 110 by 10, 120 to 180 by 20
	Duration (minutes/hour)	2, 6, 10, 20, 30, 60 (minutes) 2, 3, 4, 6, 8, 10, 12, 16, 24 (hours)
AF ^b	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 Manual Connection	Require Magnet, No Magnet
System Alerts	Alerts may or may not be selected; if selected, choose either Red Alert or Yellow Alert	

a. Alerts may or may not be selected; if selected, choose either Red Alert or Yellow Alert.

b. Alerts may or may not be selected for AF Event; if selected, choose either Red Alert or Yellow Alert. Alerts may or may not be selected for AF Burden; if selected, choose either Red Alert or Yellow Alert with a user-selectable threshold, in hours.

Остаряла версия. Да не се използва.
Zastaralá verze. Nepoužívat.
Forældet version. Må ikke anvendes.
Version überholt. Nicht verwenden.
Aegunud versioón. Myn þyn Χρησιμοποιείτε.
Παλιά έκδοση. Μην την Χρησιμοποιείτε.
Outdated version. Do not use.
Version obsoleta. Ne utilizar.
Version périmée. Ne pas utiliser.
Zastarjela verzija. Nemojte upotrebljavati.
Úrelt útgáfa. Notið ekki.
Versione obsoleta. Non utilizzare.
Pasenusi versija. Neizmantot.
Elavult verzió. Ne használja!
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Föråldrad version. Använd ej.
Güncel olmayan sürüm. Kullanmayın.

DEFAULT PROGRAMMING VALUES PER REASON FOR MONITORING

APPENDIX C

The following table displays the default values for parameters based on the reason the patient is being monitored.

Table C-1. Default Programming Values per Reason for Monitoring

Parameter Name	Values (User Visible Names)	Reason for Monitoring							
		Suspected AF	Crypto-genic Stroke	Post AF Ablation	AF Management	Syncope	Palpitations	Ventricular Tachycardia	Other
Detection Algorithm Parameters									
Blank After Sense	130-400 ms @ 10 ms increments	160							
Morphology Assessment	On, Off	On							
AF Detection	On, Off	On							
AF Response	Least, Less, Balanced, More, Most	More	More	More	Balanced	Less	Balanced	Less	Balanced
AF Duration	2, 4, 6, 10, 20, 30, 60 (minutes)	4	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							
AT Rate	70, 80, 90, 100, 110, 120, 140, 160, 180 (min ⁻¹)	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 (min ⁻¹)	40							
Symptom	On, Off	On							
Recordings Allowed Per Day	3 (10 min./event), 4 (7.5 minutes/event), 6 (5 minutes/event)	4 (7.5 minutes/event)							
Pause Detection	On, Off	On							
Pause Duration	1.5, 3, 4.5 (seconds)	3							
Pause Response	Less, Balanced, More	Less	Less	Less	Less	More	Balanced	Less	Balanced
Sensitivity	0.025, 0.037, 0.05, 0.075, 0.1, 0.15, 0.2 mV	0.037							
Tachy Detection	On, Off	On							

Table C-1. Default Programming Values per Reason for Monitoring (continued)

Parameter Name	Values (User Visible Names)	Reason for Monitoring							
		Suspected AF	Cryptogenic Stroke	Post AF Ablation	AF Management	Syncope	Palpitations	Ventricular Tachycardia	Other
Tachy Duration	0, 1, 2, 3, 4, 5, 10, 15, 20, 25, 30, 40, 50, 60	5							
Tachy Rate	115 - 220 in steps of 5 min ⁻¹	170							
Tachy Response	Less, Balanced, More	Less	Less	Less	Less	More	Balanced	More	Balanced
Telemetry Related									
Manual Bluetooth Connection	Require Magnet, No Magnet	Require Magnet							

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Forældet version. Må ikke anvendes.
Version überholt. Nicht verwenden.
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Παλιά έκδοση. Μην την Χρησιμοποιείτε.
Outdated version. Do not use.
Version obsoleta. No utilizar.
Zastarjela verzija. Nemojte upotrebljavati.
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Versione obsolete. Non utilizzare.
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Versão expiratã. A nu se utiliza.
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Boston Scientific Corporation
4100 Hamline Avenue North
St. Paul, MN 55112-5798 USA

EC REP

Guidant Europe NV/SA; Boston Scientific
Green Square, Lambroekstraat 5D
1831 Diegem, Belgium

AU REP

Boston Scientific (Australia) Pty Ltd
PO Box 332
Botany NSW 1455 Australia
Free Phone 1 800 676 133
Free Fax 1 800 836 666

www.bostonscientific.com

1.800.CARDIAC (227.3422)

+1.651.582.4000

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