Assurity™, Assurity MRI™, Endurity™, Endurity™ Core, Endurity MRI™, Zenex™, Zenex™ MRI, Zenus™, Zenus™ MRI
Pulse Generator

Allure™ RF, Allure Quadra™ RF, Quadra Allure™, Quadra Allure MP™, Quadra Allure MP™ RF
Cardiac Resynchronization Therapy Pulse Generator

User's Manual

ST. JUDE MEDICAL

Device Description

This manual describes the St. Jude Medical™ pulse generators listed in the table below[1].

These devices can be programmed with Merlin™ Patient Care System (Merlin PCS) equipped with Model 3330 version 21.2.2 (or greater) software. For information on programming, refer to the programmer's on-screen help.

CAUTION: Not all device models are available in all countries.

Not all of the products listed as MR Conditional are approved for MR Conditional use in all countries or regions.

Before performing an MRI scan on patients implanted with any of these devices, contact St. Jude Medical or consult your regulatory authorities to determine if the products have been certified as MR Conditional.

Table 1. Pulse generator descriptions

Name	Model Number	Description	Connector Type	MRI Status
Endurity™ Core	PM1140	Single-chamber pulse generator	IS-1	MR Conditional

[1] Not all device models are available in all countries.

Table 1. Pulse generator descriptions

Name	Model Number	Description	Connector Type	MRI Status
Endurity™ Core	PM1152	Single-chamber pulse generator	IS-1	MR Conditional
Endurity™	PM1160	Single-chamber pulse generator	IS-1	Untested
Endurity™	PM1162	Single-chamber pulse generator	IS-1	MR Conditional
Zenus™	PM1170	Single-chamber pulse generator	IS-1	Untested
Endurity MRI™	PM1172	Single-chamber pulse generator	IS-1	MR Conditional
Zenus™ MRI	PM1182	Single-chamber pulse generator	IS-1	MR Conditional
Assurity™	PM1240	Single-chamber pulse generator with RF telemetry	IS-1	Untested
Zenex™	PM1250	Single-chamber pulse generator with RF telemetry	IS-1	Untested
Assurity MRI™	PM1272	Single-chamber pulse generator with RF telemetry	IS-1	MR Conditional
Zenex™ MRI	PM1282	Single-chamber pulse generator with RF telemetry	IS-1	MR Conditional

Table 1. Pulse generator descriptions

Name	Model Number	Description	Connector Type	MRI Status
Endurity™ Core	PM2140	Dual-chamber pulse generator	IS-1	MR Conditional
Endurity™ Core	PM2152	Dual-chamber pulse generator	IS-1	MR Conditional
Endurity™	PM2160	Dual-chamber pulse generator	IS-1	Untested
Endurity™	PM2162	Dual-chamber pulse generator	IS-1	MR Conditional
Zenus™	PM2170	Dual-chamber pulse generator	IS-1	Untested
Endurity MRI™	PM2172	Dual-chamber pulse generator	IS-1	MR Conditional
Zenus™ MRI	PM2182	Dual-chamber pulse generator	IS-1	MR Conditional
Assurity™	PM2240	Dual-chamber pulse generator with RF telemetry	IS-1	Untested
Zenex™	PM2250	Dual-chamber pulse generator with RF telemetry	IS-1	Untested
Assurity MRI™	PM2272	Dual-chamber pulse generator with RF telemetry	IS-1	MR Conditional

Table 1. Pulse generator descriptions

Name	Model Number	Description	Connector Type	MRI Status
Zenex™ MRI	PM2282	Dual-chamber pulse generator with RF telemetry	IS-1	MR Conditional
Allure™	PM3120	CRT-P	IS-1	Untested
Allure™ RF	PM3222	CRT-P with RF telemetry	IS-1	Untested
Allure Quadra™ RF	PM3242	CRT-P with RF telemetry	IS-1/IS4-LLLL	Untested
Quadra Allure MP™ RF	PM3262	CRT-P with RF telemetry	IS-1/IS4-LLLL	Untested
Quadra Allure™	PM3542	CRT-P	IS-1/IS4-LLLL	MR Conditional
Quadra Allure MP™	PM3562	CRT-P	IS-1/IS4-LLLL	MR Conditional

Indications

Implantation of a single-chamber pulse generator, dual-chamber pulse generator, or CRT-P (Cardiac Resynchronization Therapy Pacemaker) is indicated in one or more of the following permanent conditions or any combination of these symptoms[2,3,4]:

- Syncope
- Presyncope
- Fatigue
- Disorientation due to arrhythmia or bradycardia

Implantation of a CRT-P is indicated for patients who:

- Would benefit from resynchronization of the right and left ventricles.
- Have one or more conventional indications for the implantation of a pacemaker.

MR Conditional pulse generator is conditionally safe for use in the MRI environment when used in a complete MR Conditional pacing system and according to the instructions in the MRI-Ready System manual for the St. Jude Medical™ MR Conditional Pacing System.

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[2] Brignole M, Auricchio A, Baron-Esquivias G. et al. 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy: The Task Force on cardiac pacing and resynchronization therapy of the European Society of Cardiology (ESC). Developed in collaboration with the European Heart Rhythm Association (EHRA). Eur Heart J. 2013;34(29):2281-329.

[3] Tracy CM, Epstein AE, Darbar D, et al. ACCF/AHA/HR Focused Updated of the 2008 Guidelines for Device Based Therapy of Cardiac Rhythm Abnormalities. Circulation 2012;126:1784-1800.

[4] Epstein AE, DiMarco JP, Ellenborgen KA, et al. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities. J Am Coll Cardiol 2008;51:e1-62.

Rate-modulated pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity.

Dual-chamber pacing (dual-chamber pulse generators, CRT-Ps) is indicated for those patients exhibiting:

- Sick sinus syndrome
- Chronic, symptomatic second- and third-degree AV block
- Recurrent Adams-Stokes syndrome
- Symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out

Atrial pacing is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems.

Ventricular pacing is indicated for patients with significant bradycardia and:

- Normal sinus rhythm with only rare episodes of AV block or sinus arrest
- Chronic atrial fibrillation (AF)
- Severe physical disability

AF Suppression™ pacing (dual-chamber pulse generators, CRT-Ps) is indicated for suppression of paroxysmal or persistent atrial fibrillation episodes in patients with one or more of the above pacing indications.

AT/AF Detection Algorithm. The AT/AF detection algorithm is indicated for detecting atrial tachyarrhythmias which have been found to be associated with an increased risk of stroke in elderly, hypertensive, pacemaker patients without prior history of AF.

For specific indications associated with individual modes, refer to the programmer's on-screen help.

Accessories, Intended Use

Only the accessories listed here are approved for use with the pulse generators described in this manual.

Table 2. Accessories and their intended uses

Accessory	Intended use
Torque driver	To secure lead connectors and port plugs within the device header.
IS-1 lead receptacle plug	To insulate and protect unused lead receptacles.
IS4/DF4 port plug	To seal unused lead receptacles

Contraindications

Implanted Cardioverter-Defibrillator (ICD). Single-chamber pulse generators, dual-chamber pulse generators, and CRT-Ps are contraindicated in patients with an implanted cardioverter-defibrillator.

Rate-Adaptive Pacing may be inappropriate for patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerated by the patient.

AF Suppression (dual-chamber pulse generators, CRT-Ps) stimulation is not recommended in patients who cannot tolerate high atrial-rate stimulation.

Dual-Chamber Pacing (dual-chamber pulse generators, CRT-Ps), though not contraindicated for patients with chronic atrial flutter, chronic atrial fibrillation, or silent atria, may provide no benefit beyond that of single-chamber pacing in such patients.

Single-Chamber Ventricular Demand Pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction, or suffer a drop in arterial blood pressure with the onset of ventricular pacing.

Single-Chamber Atrial Pacing is relatively contraindicated in patients who have demonstrated compromise of AV conduction.

MRI Scan. Patients who do not have a complete St. Jude Medical™ MR Conditional pacing system, which includes a St. Jude Medical MR Conditional pulse generator and St. Jude Medical MR Conditional leads, are contraindicated for an MRI scan.

For specific contraindications associated with individual modes, refer to the programmer's on-screen help.

Warnings

To prevent permanent damage to the device and tissue damage at the electrode/tissue interface, avoid exposure to the following:

- **Electrosurgery**. Do not use electrosurgical devices in the vicinity of an implanted device. If electrocautery is necessary, use a bipolar cauterizer or place the indifferent electrode as far from the device as possible.
- **Lithotripsy**. Do not focus a lithotripsy beam within 16 cm of the device. Program the device to Sensor Off prior to lithotripsy to prevent inappropriate increases in pacing rate. A thorough assessment of device function with special attention to the sensor should be performed following exposure to lithotripsy.
- **Therapeutic Radiation**. Do not use therapeutic ionizing radiation in the vicinity of an implanted device. Radiation therapy may damage the electronic circuitry of the device. Any damage to the device by therapeutic ionizing radiation may not be immediately detectable.
- **Ultrasound Treatment**. The device should not be exposed to therapeutic levels of ultrasound energy, as the device can inadvertently concentrate the ultrasound field and cause harm that might not be immediately detectable. Diagnostic ultrasound treatment is not known to affect the

function of the device.

- **Ventricular Sensing**. In CRT-Ps, Ventricular Sensitivity should be programmed to the highest setting (lowest sensitivity) that will provide ventricular sensing with adequate sensing margin. Left ventricular lead dislodgement, to a position near the atria, can result in atrial oversensing and ventricular inhibition.

Perform a thorough assessment of device function following exposure to any of the above.

Magnetic Resonance Imaging (MRI).

- **MR Conditional pulse generators**. Testing has demonstrated that the St. Jude Medical™ MR Conditional pacing system is conditionally safe for use in the MRI environment when used according to the instructions in the MRI-Ready System manual. The St. Jude Medical MR Conditional pacing system includes a St. Jude Medical MR Conditional pulse generator connected to one or more St. Jude Medical MR Conditional leads.
- **MR Untested pulse generators**. Untested indicates that the device has not been tested and its use in an MR environment is not determined. For more information, please consult the MRI-Ready System manual.

Backup VVI Operation. In rare instances, the device may revert to Backup VVI operation at the settings listed in the table below. These values are not programmable.

When the device has reverted to Backup VVI operation, the programmer displays a pop-up message indicating that the device is operating at the Backup VVI values. Press the Continue button and follow

the on-screen instructions.

Table 3. Backup VVI settings

Parameter	Setting	
	Single-chamber pulse generators Dual-chamber pulse generators	CRT-Ps
Mode	VVI	VVI
Base rate	67 min^{-1}	67 min^{-1}
Ventricular pacing chamber	NA	LV —> RV
Pulse configuration	Unipolar	RV Unipolar Tip LV Unipolar Tip
Sense configuration	Unipolar Tip	RV Unipolar Tip
Pulse amplitude	5.0 V	5.0 V
Pulse width	0.6 ms	0.6 ms
Refractory period	337 ms	337 ms
Sensitivity	2.0 mV	2.0 mV
Interventricular delay	NA	16 ms

Elective Replacement Indicator (ERI) (page 42). At ERI, the nominal life of the device is three or six months. When the device exhibits signs of ERI it should be replaced expeditiously.

Patient follow-up visits should be scheduled at an appropriate frequency so that ERI can be detected well before end-of-life (EOL).

Noninvasive Programmed Stimulation (NIPS). Life-threatening ventricular tachycardia or fibrillation may occur during NIPS. During NIPS testing, (1) closely monitor the patient and (2) make defibrillation and resuscitation equipment, and trained personnel, readily available during testing. Only physicians trained in tachycardia induction and reversion protocols should use NIPS. For more information on NIPS, refer to the programmer's on-screen help.

Ventricular Support Pacing during NIPS testing (dual-chamber pulse generators, CRT-Ps) is delivered in the VOO mode. The specific indications and contraindications for VOO mode can be found on the programmer's on-screen help.

Precautions

For single use only.

Device Communication. Communication with the device can be affected by electrical interference and strong magnetic fields. If this is a problem, turn off nearby electrical equipment or move the electrical equipment away from the patient and the programmer. If the problem persists, contact St. Jude

Medical.

Suboptimal RF Communication. The Merlin™ Patient Care System (Merlin PCS) indicates the quality of the RF communication by the telemetry strength indicator LEDs on both the programmer and the Merlin™ antenna. Below is a list of potential causes to suboptimal radio communication:

Table 4. Possible causes and solutions for suboptimal RF communication

Possible Causes	Solutions
The Merlin antenna orientation/location is suboptimal.	Move or reorient the Merlin antenna slightly. Make sure that the front of the Merlin antenna faces the implantable device.
People or objects interfere with the communication between the Merlin antenna and the device.	Make sure that the space between the Merlin antenna and the device is free from interfering objects/people.
The Merlin antenna is too far away from the device.	Move the Merlin antenna closer to the device.
Someone is holding the Merlin antenna.	Place the Merlin antenna on a flat surface. Do not hold the Merlin antenna.
Other products in the vicinity are causing electromagnetic interference (EMI).	Power off or remove equipment that could cause EMI.

Table 4. Possible causes and solutions for suboptimal RF communication

Possible Causes	Solutions
The Merlin antenna cable is wound around the Merlin antenna.	Make sure the Merlin antenna cable is not wound around the Merlin antenna.

CT Scans. CT scans, due to their increased power levels and long exposure times, have the remote possibility of interfering with implanted devices. The potential interference is transient and occurs only when the X-ray signal is present. Continuous exposure may cause a temporary sensor rate increase. In addition, there is a remote possibility for a device to intermittently oversense while the CT scanning beam is directly over the implanted device.

Sterilization

The package contents have been sterilized with ethylene oxide before shipment. This device is for single use only and is not intended to be resterilized.

If the sterile package has been compromised, contact St. Jude Medical.

Storage and Handling

Mechanical Shock. St. Jude Medical™ devices are ruggedly constructed. However, if you suspect the device has been damaged, do not implant and return it to St. Jude Medical.

Temperature. Store the device at temperatures between -5°C (23°F) and 50°C (122°F). Do not subject the device to temperatures below -20°C (-4°F) or over 55°C (131°F). After cold storage, allow the device to reach room temperature before programming or implanting the device because cold temperature may affect initial device function.

Incineration. Do not incinerate the device. Return explanted devices to St. Jude Medical.

Preparation for Implantation

Package Label. Before opening the sterile package, carefully read the label and verify that the package contains the desired device. **Do not implant the pulse generator if:**

- The package is damaged or wet.
- The dot on the ethylene oxide label is purple. Purple indicates that the package has not been sterilized.
- The Use Before Date on the outer box and the tray has been exceeded. The Use Before Date reflects the minimum battery voltage required to support the calculated battery longevity shown in the programmer's on-screen help.

Verifying Operation. Before opening the sterile package, verify that the device is operating properly by interrogating it in the package. Remove the magnet from the programmer telemetry wand and establish communication:

- Inductive communication. Position the Merlin™ Patient Care System (Merlin PCS) telemetry wand over the package and select Interrogate.
- RF communication. To establish RF communication between the device and the programmer and to troubleshoot communications problems, you must first attach the Merlin antenna to the programmer. Refer to the Merlin PCS User's Manual that accompanies the programmer and the Merlin antenna. Use the telemetry strength indicators to evaluate the communication.

  If the device is RF-compatible, an icon in the upper left-hand corner of the screen during the programming session indicates the status of the RF communication link. If an RF icon does not appear on the screen during the session, the device is not RF-compatible. Once you have established telemetry, select Interrogate.

The unit's Measured Data will be displayed on the FastPath™ Summary screen and should indicate normal voltage and battery status, and the programmed parameters should be identical to the Shipped Settings displayed on the programmer's on-screen help.

Package Integrity. Ensure that the package has not been opened or in any way compromised. If damage is suspected, return it to the manufacturer.

Use Before Date. Do not implant the device after the Use Before Date printed on the label.

Opening the Package. If interrogation of the device in its sterile packaging indicates normal

functioning, remove it from the package. The package's outer tray can be opened in nonsterile surroundings. However, when opening the inner tray, complete sterile technique must be observed.

Pre-Implant Testing

Pacing System Analyzer. Before implantation, you may wish to test the device using a compatible pacing system analyzer (PSA) with calibrated sensitivity and output settings. When the probe is attached to the device's connector, the programmed parameters should be identical to the Shipped Settings displayed on the programmer's on-screen help.

Adaptor Probes. Use only IS-1 PSA cable adaptor probes when testing the device. Other probes may damage the connector. Do not use IS-1 adaptor probes in the IS4-LLLL connector.

Compatible Pacing Leads. Devices with IS-1 connectors accept unipolar or bipolar IS-1 short terminal pin leads. Devices with IS4-LLLL connectors accept IS4-LLLL quadripolar leads. Prior to implantation, make sure leads fit easily and snugly into the device header.

Capture/Sensing Thresholds. Capture and sensing thresholds should be determined with a PSA before implanting the device. Connect the negative (black) PSA terminal to the portion of the lead terminal pin corresponding to the tip electrode. Connect the positive (red) terminal to the ring electrode portion of the lead pin for bipolar leads or to an indifferent electrode. For more information on conducting capture and sensing threshold tests, please consult the PSA technical manual.

Establishing Baseline Capture/Sensing Thresholds. After the leads have been implanted and before

they are connected to the device, establish and document the baseline morphology for capture and sensing thresholds for each lead using a suitable recording system, such as a 12-lead electrocardiogram (ECG) or an intracardiac electrogram (IEGM).

Implantation

Physician Preparation. The physician should be familiar with all components of the system and the material in this manual before beginning the procedure.

External Defibrillator. Ensure that a separate standby external defibrillator is immediately available.

Data Transmission. Implant the pulse generator no deeper than 5 cm to ensure reliable data transmission with the Merlin™ PCS inductive telemetry wand. For MR Conditional pulse generators, implant the pulse generator no deeper than 4 cm to ensure reliable data transmission with the SJM MRI Activator™ handheld device.

Patient Comfort. For patient comfort, do not implant the pulse generator within 1.25 cm of bone unless you cannot avoid it.

Case Markings. Examine the markings on the device case and verify proper atrial and ventricular connection.

Setscrew. Exercise caution when turning the setscrew, which may be backed out of the connector if turned counter-clockwise for more than two rotations.

Programming

Programmer. These devices can be interrogated and programmed with the Merlin™ Patient Care System (Merlin PCS) equipped with Model 3330 version 21.2.2 (or greater) software.

For a list of programmable parameters and their programmable values, refer to the programmer's on-screen help.

Setting Lead Type. When you interrogate the device for the first time, the programmer will prompt you to set the Lead Type. (In CRT-Ps, the right and left ventricular lead types are independently set.) Because some parameters are determined by the Lead Type (for example, Pulse Configuration), you should set this parameter when the device is implanted. Devices with Auto Lead Polarity Detection (ALPD) will automatically detect and program the lead type and sensing configurations. This feature will be suspended during telemetry and for one minute after telemetry is completed.

Lead Impedance Values. In CRT-Ps, independent lead impedance values are displayed for the RV and LV leads.

Ventricular Pulse Amplitudes and Pulse Widths. In CRT-Ps, the right and left ventricular pulse amplitudes and pulse widths are independently programmable. The pulse amplitude should be evaluated in each chamber accordingly. Typically, capture thresholds are higher in the left ventricle.

Follow-up Capture Threshold Measurements. In CRT-Ps, the RV and LV capture threshold measurements are evaluated independently. During an RV or LV capture test, you may be able to determine when capture is occurring by noting changes in the ECG morphology. Capture tests are not

performed in triggered ventricular pacing modes. Upon initiation, the pacing mode is temporarily programmed to the corresponding inhibited mode. For additional information, refer to the programmer's on-screen help.

AOO(R), VOO(R), and DOO(R) Modes are primarily intended for temporary diagnostic use. Long-term use may result in competitive pacing, inducing potentially dangerous arrhythmias.

Off mode is not recommended for patients who would be adversely affected by even a short cessation of device function.

Pulse Amplitude. If the AutoCapture™ pacing system or Cap Confirm pacing system are not in use, determine the capture threshold before programming the Pulse Amplitude. Program Pulse Amplitude to yield a suitable safety margin for reliable, long-term capture. Reassess capture thresholds periodically.

Noninvasive Program Stimulation (NIPS). Atrial or ventricular tachycardia or fibrillation may occur during NIPS. Therefore, (1) closely monitor the patient, and (2) have emergency equipment for cardioversion/defibrillation readily available while conducting NIPS.

High-Output Settings. Programming high-output settings or a high Base Rate may shorten the time to ERI.

Runaway Protection. Hardware circuitry in the device prevents it from stimulating at rates higher than the runaway protection rate, listed below.

Table 5. Runaway protection for all devices

Device	Runaway protection rate
PM1140, PM1152, PM1160, PM1162, PM1170, PM1172, PM1182, PM1240, PM1250, PM1272, PM1282, PM2140, PM2152, PM2160, PM2162, PM2170, PM2172, PM2182, PM2240, PM2250, PM2272, PM2282, PM3120, PM3222, PM3242, PM3262, PM3542, PM3562	220 min^{-1} (± 10 min^{-1})

Sensing Configuration. Sensing tests should be performed whenever changes are made to the sensing configuration.

Patient Notifier. Before setting Patient Notifier On, test and ensure patient awareness of the Patient Notifier feature. For MR Conditional pulse generators with Patient Notifier capability, the Merlin PCS programmer permanently disables the Patient Notifier when the pulse generator is programmed to MRI settings.

NOTE: For a list of devices with Patient Notifier capability, refer to the programmer's on-screen help.

Environmental and Medical Therapy Hazards

Environmental and Medical Therapy Hazards

St. Jude Medical™ devices are equipped with special shielding and filters which significantly reduce the adverse effects of electromagnetic interference (EMI) on the operation of the device.

Patients should be directed to exercise reasonable caution in avoidance of strong electric or magnetic fields. If the device inhibits or reverts to asynchronous operation while in the presence of EMI, the patient should move away from the EMI source or turn the source off.

Advise patients to seek medical guidance before entering environments which could adversely affect the operation of the device, including areas protected by a warning notice preventing entry by pacemaker patients.

Medical Procedures and Environments

In general, pacemaker patients should not be exposed to hospital equipment that produces high electromagnetic field strength signals, such as diathermy machines and electrosurgical units.

- **External Defibrillation**. The electronic circuitry in the device provides protection from defibrillation discharges. Nevertheless, do not place defibrillator paddles directly over the device or pacing lead. Following defibrillation, ensure that the device is operating correctly.
- **Ionizing Radiation.** Therapeutic ionizing radiation (for example, used in linear accelerators and

cobalt machines) can permanently damage the device's circuitry. The effect of ionizing radiation is cumulative; the potential for damage to the device is proportional to the patient's total radiation dosage. If the patient must be exposed to ionizing radiation, protect the device during the procedure with local radiation shielding. If tissue near the implant site must be irradiated, it may be necessary to move the device to another area. Before and after exposure to radiation, evaluate the device operation to identify any adverse consequences.

- **Transcutaneous Electrical Nerve Stimulation (TENS).** To reduce the possibility of interference with device function, place the TENS electrodes close to one another and as far from the device as possible. Before allowing unrestricted use of TENS in a home or other setting, screen the patient in a monitored environment for possible interaction.
- **Therapeutic Diathermy.** Avoid diathermy, even if the device is programmed off, as it may damage tissue around the implanted electrodes or may permanently damage the device.
- **Electrosurgical Cautery** can induce ventricular arrhythmias and/or fibrillation or may cause asynchronous or inhibited device operation. If use of electrocautery is necessary, the current path and ground plate should be kept as far away from the device and leads as possible. A bipolar cauterizer may minimize these effects. Following electrocautery, conduct a thorough assessment of the device.
- **RF Ablation.** Radiofrequency (RF) ablation in patients with a device may cause any of the following: asynchronous pacing above or below the programmed rate; reversion to an asynchronous operation; device electrical reset; or premature triggering of the elective

replacement indicator.

RF ablation risks may be minimized by: programming a non-rate responsive, asynchronous pacing mode prior to the RF ablation procedure; avoid direct contact between the ablation catheter and the implanted lead or device; positioning the ground plate so that the current pathway does not pass through or near the device system, i.e., place the ground plate under the patient's buttocks or legs; having a programmer available; or having external defibrillation equipment available.

Patient Environment

High-voltage transmission lines and equipment, arc or resistance welders, induction furnaces, and similar equipment may generate substantial electromagnetic interference (EMI) that may interfere with device operation.

Communication equipment, such as microwave transmitters[5], linear power amplifiers, or high-power amateur transmitters may generate sufficient EMI to interfere with the operation of the device. Advise patients to move away from this equipment to resume normal device operation.

Home appliances that are in good working order and properly grounded do not usually produce enough EMI to interfere with device operation. Electric vibrators, razors, and hand tools held directly over the device may disturb its operation.

Twiddler's syndrome. Caution patients against manipulating the implanted device since it may result in lead damage or lead displacement.

Patient activities. Any activities that involve repetitive impacts or jarring (such as horseback riding,

[5] Home appliance microwave ovens do not interfere with device operation.

jackhammer use, etc.) may increase the pacing rate when the device's Sensor is programmed On. Caution patients against such activity and program Sensor parameters with these activities in mind.

Electronic Article Surveillance (EAS). Advise patients that Electronic Article Surveillance (EAS) systems such as those at the point of sale and entrances or exits of stores, libraries, banks, etc., emit signals that may interact with pacemakers and CRT-Ps. It is very unlikely that these systems will interact with their device significantly. However, to minimize the possibility of interaction, advise patients to simply walk through these areas at a normal pace and avoid lingering near or leaning on these systems.

No Pacer symbol. Caution patients implanted with this device to avoid areas marked with the No Pacer symbol.

Figure 1. No Pacer symbol

Cellular Phones. A St. Jude Medical-designed protective filter in the device prevents cellular phone-generated electromagnetic signals from interfering with the operation of the device[6].

The device has also been tested for compatibility with handheld wireless transmitters in accordance with the requirements of AAMI PC69. This testing covered the operating frequencies (450 MHz-3 GHz) and pulsed modulation techniques of all of the digital cellular phone technologies in worldwide use today. For more information, you or your patient may wish to contact Technical Support (page 45).

Explantation and Disposal

Do not reuse explanted devices and leads.

Clean explanted equipment with +1% sodium hypochlorite, rinse with water, dry.

Return the explanted device to the manufacturer.

Explant the device with standard surgical tools.

Explant the device before cremation of a deceased patient.

Hex wrenches are available for disconnecting a previously implanted device from the indwelling leads. To obtain the wrenches, contact your local St. Jude Medical representative.

[6] Carrillo R, Williams DB, Traad EA, Schor JS. Electromagnetic filters impeded adverse interference of pacemakers by digital cellular telephones. JACC 1996; 27(2A):15A Abstract 901-22.

MRI Safety Information

MR Conditional pacemakers and CRT-Ps are conditionally safe for use in the MRI environment when used in a complete MR Conditional system and according to the instructions in the St. Jude Medical™ MRI-Ready Systems Manual. Scanning under different conditions may result in severe patient injury or death or device malfunction.

Potential Adverse Events

The following are potential complications associated with the use of any pacing system:

- Additional Surgery
- Allergic Reaction
- Arrhythmia
- Cardiovascular Injury such as Thermal Injury
- Decompensated Heart Failure
- Death
- Embolism
- Erosion

- Extra-Cardiac Stimulation
- Hematoma
- Infection
- Loss of Cardiac Pacing
- Loss of Synchrony
- Pneumothorax

Pulse Generator Header

The pulse generator headers are shown in the table below, followed by the legend for the lead receptacles. (page 31)

Table 6. Pulse generator headers. See lead receptacle legend (page **31**)

	
Assurity PM2240	Assurity MRI PM1272
Assurity MRI PM2272	Assurity PM1240
Endurity PM2160, PM2162	Endurity PM1160
Endurity MRI PM2172	Endurity MRI PM1172, PM1162
Endurity Core PM2140, PM2152	Endurity Core PM1140, PM1152
Zenex PM2250	Zenex PM1250
Zenex MRI PM2282	Zenex MRI PM1282
Zenus PM2170	Zenus PM1170
Zenus MRI PM2182	Zenus MRI PM1182

Table 6. Pulse generator headers. See lead receptacle legend (page 31)

	
Allure PM3120 Allure RF PM3222	Allure Quadra RF PM3242 Quadra Allure PM3542 Quadra Allure MP PM3562 Quadra Allure MP RF PM3262

Lead Receptacle Connector Types

Table 7. Lead receptacles

Legend	Receptacle	Lead type	Connector
1	V (IS-1 BI) SENSE/PACE	Bipolar endocardial	IS-1 in-line bipolar
2	A (IS-1 BI) SENSE/PACE OR PLUG	Bipolar endocardial; IS-1 plug (when no atrial lead is used)	IS-1 in-line bipolar
3	RV (IS-1 BI) SENSE/PACE	Bipolar endocardial in right ventricle (CRT-P)	IS-1 in-line bipolar
4	LV (IS-1 BI) SENSE/PACE OR PLUG	Bipolar endocardial in left ventricle (CRT-P); IS-1 plug (when no LV lead is used)	IS-1 in-line bipolar
5	S (A/V) (IS-1 BI) SENSE/PACE	Bipolar endocardial; single-chamber, designated A or V based on programming	IS-1 in-line bipolar

Table 7. Lead receptacles

Legend	Receptacle	Lead type	Connector
6	LV (IS-4 Quad) SENSE/PACE OR PLUG	Quadripolar endocardial; IS-4/DF4 plug (when no LV lead is used)	IS4-LLLL

NOTES:

- When connecting leads to the pulse generator, make sure that you plug the correct lead into the correct lead receptacle. For sensing and pacing, this is important to ensure that atrial and ventricular signals are correctly recorded and that pacing pulses are delivered in the desired chamber.
- The IS4-LLLL lead receptacle can only be used with IS4-LLLL left heart leads.

Programming Guidelines

General

For a list of all programmable parameters and settings, refer to the programmer's on-screen help.

Magnet Use

To interrogate the device, remove the magnet from the programmer telemetry wand. A magnet will interfere with proper telemetry.

Temporary Programming

These devices feature Temporary Programming to aid the clinician in diagnosing and treating the patient. The clinician can temporarily program parameters to assess their effects with the ability to quickly cancel or permanently program the setting. For more information, refer to the programmer's on-screen help.

Preset Programmed Settings

Shipped Settings

The device's parameter settings are preset when the device is manufactured. For additional information, refer to the programmer's on-screen help.

Emergency Settings

The device is equipped with standard, high-output settings that can be quickly programmed using the programmer's Emergency VVI function. Settings for Emergency VVI can be found in the programmer's on-screen help.

> NOTE: When Emergency VVI is selected, diagnostic data are cleared from memory without a warning.

Radiopaque Identification

Each device has an X-ray absorptive marker for noninvasive identification. The marker consists of the St. Jude Medical logo (SJM) and a model code.[7]

[7] Models PM1172, PM1272, PM2172, and PM2272, may have a SJM HM MRI tag due to global distribution.

Table 8. X-ray ID codes for the devices described in this manual

Device model	X-ray ID Model Code
PM1160, PM1170, PM1172, PM1182, PM1240, PM1250, PM1272, PM1282, PM2160, PM2170, PM2172, PM2182, PM2240, PM2250, PM2272, PM2282, PM3120, PM3222, PM3242, PM3262	HI
PM1140, PM1152, PM1162, PM2140, PM2152, PM2162	HM MRI
PM3542, PM3562	SJM HM

Implantation and Lead Connection

Package Contents

Devices are shipped in a sterile box containing:

- One device
- Connector kit containing:

- #2 torque wrench

- Literature

Lead Connection

Devices with IS-1 connectors accept unipolar or bipolar IS-1 short terminal pin leads. Devices with IS4-LLLL connectors accept IS4-LLLL quadripolar leads. Prior to implantation, make sure leads fit easily and snugly into the device header.

These devices have a single setscrew for each lead pin. The setscrew makes contact with the pin securing the lead within the connector while an annular spring makes contact with the proximal rings.

NOTE: Enter the lead types for each lead on the Patient Information screen. For additional information, refer to the programmer's on-screen help.

CAUTION: After all leads have been implanted and before they are connected to the device, establish and document the baseline morphology for capture and sensing thresholds for each lead using a suitable recording system, such as a 12-lead electrocardiogram (ECG) or an intracardiac electrogram (IEGM)

To connect the device to the leads:

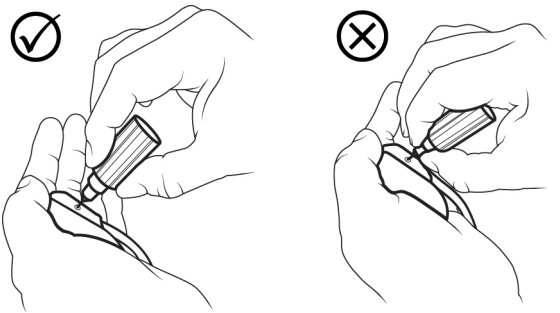
1. Remove blood and body fluids from the terminal pins of the implanted leads.
2. Check the markings on the device case and verify proper atrial and ventricular connections.

CAUTION: Exercise caution when turning the setscrew, which may be backed out of the connector if turned counterclockwise for more than two rotations.

NOTE: In CRT-Ps: For proper sensing and pacing, it is important to ensure that left and right ventricular signals are correctly detected and that pacing pulses are delivered in the desired chamber.

3. Use the #2 torque wrench packaged with the device to retract the setscrews in the device connector so that the pacing lead terminal pins can be fully inserted.
4. Insert a lead firmly into the connector until the lead pin is immobile and visible in the viewport at the opposite end of the connector.
5. Grip the torque wrench by the large part of the handle as shown in the figure on the left below. On applicable wrench models, do not grip the torque wrench by the smaller, narrower part of the handle as shown on the right.

Figure 2. Correct vs. incorrect use of torque wrench



6. Insert the #2 torque wrench through the aperture on the header and into the setscrew on the side of the connector.
7. Turn the wrench clockwise until it clicks. The wrench is torque-limited and when used correctly will not allow excessive tightening.

8. Repeat the steps above for additional leads.
9. Tug gently on the leads to ensure they are secured in the connector.

In order to minimize device migration, secure the device to the subcutaneous pocket via the suture hole in the device header.

After the device has been implanted and the pocket is closed, interrogate the device and set the Lead Type to the correct setting. Lead Type settings are described on the programmer's on-screen help. For MR Conditional pulse generators, set the Additional Hardware parameter to the correct setting.

NOTE:

- In CRT-Ps, the right and left ventricular pulse amplitudes and pulse widths are independently programmable. The pulse amplitude and pulse width should be evaluated in each chamber accordingly.
- In CRT-Ps, independent lead impedance values are displayed for the RV and LV leads.

Device Registration

An Implantable Device Registration Form is enclosed with each device to serve as a permanent record of information pertaining to the implanted device. The completed original should be returned to the manufacturer in the postage-paid, addressed envelope provided. Copies of the registration form are

provided for the hospital and the physician.

Device Longevity

For estimated longevity calculations, see the programmer's on-screen help.

At nominal conditions (100% pacing, 2.5 V/0.5 ms in each chamber, 60 ppm, 500 ohm lead impedance), estimated longevity is as follows:

Table 9. Estimated device longevity

Model name	Model number	Device type	Estimated longevity
Endurity Core	PM1140, PM1152	SR	14.3 years
Endurity	PM1160, PM1162	SR	14.3 years
Zenus	PM1170	SR	14.3 years
Endurity MRI	PM1172	SR	14.3 years
Zenus MRI	PM1182	SR	14.3 years
Assurity	PM1240	SR	13.8 years
Zenex	PM1250	SR	13.8 years
Assurity MRI	PM1272	SR	13.8 years

Table 9. Estimated device longevity

Model name	Model number	Device type	Estimated longevity
Zenex MRI	PM1282	SR	13.8 years
Endurity Core	PM2140, PM2152	DR	9.5 years
Endurity	PM2160, PM2162	DR	9.5 years
Zenus	PM2170	DR	9.5 years
Endurity MRI	PM2172	DR	9.5 years
Zenus MRI	PM2182	DR	9.5 years
Assurity	PM2240	DR	9.3 years
Zenex	PM2250	DR	9.3 years
Assurity MRI	PM2272	DR	9.3 years
Zenex MRI	PM2282	DR	9.3 years
Allure	PM3120	CRT-P	7.7 years
Allure RF	PM3222	CRT-P	7.6 years
Allure Quadra RF	PM3242	CRT-P	7.6 years

Table 9. Estimated device longevity

Model name	Model number	Device type	Estimated longevity
Quadra Allure MP RF	PM3262	CRT-P	6.3 years
Quadra Allure	PM3542	CRT-P	7.6 years
Quadra Allure MP	PM3562	CRT-P	6.3 years

Elective Replacement Indicator (ERI)

ERI (or Recommended Replacement Time) is the point at which battery voltage has dropped to the lowest capacity that will maintain adequate pulse generator operation for a nominal period of before end of life (EOL). See the table below for the nominal period between ERI and EOL.

When the device reaches ERI, a number of indicators alert the clinician to this condition. For information on these conditions, refer to the programmer's on-screen help.

Table 10. Nominal time between ERI and EOL for all devices

Device	Nominal time period between ERI and EOL
PM1140, PM1152, PM1160, PM1162, PM1170, PM1172, PM1182, PM1240, PM1250, PM1272, PM1282, PM2140, PM2152, PM2160, PM2162, PM2170, PM2172, PM2182, PM2240, PM2250, PM2272, PM2282, PM3120, PM3222, PM3242, PM3262, PM3542, PM3562	6 months

Clearing ERI

When the programmer displays a message that the device has reached ERI, you are able to clear ERI. For additional information on clearing ERI, refer to the programmer's on-screen help.

CAUTION:

- Programming to high output settings or a high Base Rate may shorten the time to

ERI. Programming to lower rates and outputs may restore normal battery status.

- If the programmer displays an ERI warning message, the clinician should fully evaluate the device.

WARNING: At ERI, the nominal life of the device is three or six months (page 42). When the device exhibits signs of ERI (described on the programmer's on-screen help), it should be replaced expeditiously.

End-of-Life

End-of-life (EOL) occurs when the battery voltage has fallen to a level designated in the table below. For additional information, refer to the programmer's on-screen help.

Table 11. Approximate EOL battery voltage for all devices

Device	Approximate EOL battery voltage
PM1140, PM1152, PM1160, PM1162, PM1170, PM1172, PM1182, PM1240, PM1250, PM1272, PM1282, PM2140, PM2152, PM2160, PM2162, PM2170, PM2172, PM2182, PM2240, PM2250, PM2272, PM2282, PM3120, PM3222, PM3242, PM3262, PM3542, PM3562	2.47 V

Technical Support

St. Jude Medical maintains 24-hour phone lines for technical questions and support:

- 1 818 362 6822
- 1 800 722 3774 (toll-free within North America)
- + 46 8 474 4147 (Sweden)
- + 61 2 9936 1200 (Australia)
- manuals.sjm.com

For additional assistance, call your local St. Jude Medical representative.

Additional Information

For additional information on this device, refer to the programmer's on-screen help.

Physical Specifications

Device Measurements

Table 12. Device measurements[8]

Model	Dimensions (h x l x t) (mm)[9]	Weight (g)	Displaced volume (cm^3)[10]
PM1140	41 x 50 x 6	19	9.7
PM1152	41 x 50 x 6	19	9.7
PM1160	41 x 50 x 6	19	9.7
PM1162	41 x 50 x 6	19	9.7
PM1170	41 x 50 x 6	19	9.7
PM1172	41 x 50 x 6	19	9.7
PM1182	41 x 50 x 6	19	9.7
PM1240	47 x 50 x 6	20	10.4
PM1250	47 x 50 x 6	20	10.4
PM1272	47 x 50 x 6	20	10.4

[8] Device measurements are nominal values.
[9] Nominal values based on engineering model measurements.
[10] Nominal values based on engineering model measurements.

Table 12. Device measurements[8]

Model	Dimensions (h x l x t) (mm)[9]	Weight (g)	Displaced volume (cm^3)[10]
PM1282	47 x 50 x 6	20	10.4
PM2140	46 x 50 x 6	19	10.4
PM2152	46 x 50 x 6	19	10.4
PM2160	46 x 50 x 6	19	10.4
PM2162	46 x 50 x 6	19	10.4
PM2170	46 x 50 x 6	19	10.4
PM2172	46 x 50 x 6	19	10.4
PM2182	46 x 50 x 6	19	10.4
PM2240	47 x 50 x 6	20	10.4
PM2250	47 x 50 x 6	20	10.4
PM2272	47 x 50 x 6	20	10.4
PM2282	47 x 50 x 6	20	10.4
PM3120	55 x 59 x 6	24	14

Table 12. Device measurements[8]

Model	Dimensions (h x l x t) (mm)[9]	Weight (g)	Displaced volume (cm^3)[10]
PM3222	55 x 59 x 6	24	14
PM3242	55 x 59 x 6	27	15
PM3262	56 x 59 x 6	27	15
PM3542	56 x 59 x 6	26	15
PM3562	56 x 59 x 6	26	15

Device Materials

Table 13. Device materials

Model	Can	Case coating	RF antenna[11]	Connector material
All devices	Titanium	None	Titanium	May contain one or more of the following: Epoxy, Thermoplastic Polyurethane, Polysulfone

[11] For devices with RF telemetry capability.

Lead Compatibility

Table 14. Lead compatibility

Model	Lead compatibility
PM3242 PM3262 PM3542 PM3562	IS-1 and IS4-LLLL
All other devices	IS-1[12]

[12] Accepts IS-1 short terminal pin leads.

Battery Information

Table 15. Battery information

Model	Power source	Manufacturer; Model	Voltage at Beginning of Life	Voltage to trigger Estimated Replacement Indicator
PM3120 PM3222 PM3242 PM3262 PM3542 PM3562	1 QMR[13] cell	Greatbatch Medical; Model 2662	3.20 V	2.62 V
All other devices				2.60 V

[13] QMR is a trademark of Greatbatch Medical.

RF Operating Frequencies

Nearby equipment emitting strong magnetic fields can interfere with RF communication, even if the other equipment complies with CISPR emission requirements. The operating characteristics are as follows:

MICS band: 402-405 MHz. The effective radiated power is below the limits as specified in:

- Europe: EN ETSI 301 839
- USA: FCC 47 CFR Part 95; 95.601-95.673 Subpart E, 95.1201-95.1221 Subpart I
- FCC ID: RIASJMRFB
- Harmonized with the FCC

The following is applicable to Canada only:

This device may not interfere with stations operating in the 400.150-406.000 MHz band in the meteorological aids, meteorological-satellite, and earth exploration-satellite services and must accept any interference received, including interference that may cause undesired operation.

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Detection Performance in the Presence of Electromagnetic Interference

When the Sense Configuration is set to Bipolar, the Atrial Sensitivity setting of 0.2 mV or more sensitive settings may be more susceptible to electromagnetic interference (EMI). The devices comply with the electromagnetic compatibility requirements of CENELEC standard EN45502-2-1[14], clause 27.5, at Atrial Sensitivity settings of 0.3 mV and less sensitive settings.

When the Sense Configuration is set to Unipolar, the Atrial and Ventricular Sensitivity settings more sensitive than 2.0 mV may be more susceptible to EMI. The devices comply with the electromagnetic compatibility requirements of CENELEC standard EN45502-2-1, clause 27.5, at Atrial and Ventricular Sensitivity settings of 2.0 mV and less sensitive settings. (CENELEC standard EN45502-2-1, clause 27.5.1, requires that the implantable pulse generator be constructed so that commonly encountered electromagnetic signals are unlikely to be confused with sensed beats and change the therapeutic behavior of the implantable pulse generator.)

As required by EN45502-2-1 Clause 27.4, the device interference mode of operation is characterized as follows:

- The atrial noise mode is “pacing off” for EMI frequencies below approximately 30 Hz and “fixed rate pacing” for frequencies above approximately 30 Hz.
- The ventricular noise mode is “fixed rate pacing” for EMI frequencies of 16.6 Hz-167 kHz.

[14] As referenced in this section, the CENELEC standard EN45502-2-1:2003 is equivalent to ANSI/AAMI PC69:2007.

Temperature Effects

Pacing parameters such as Pulse Rate, Pulse Width, Pulse Amplitude and Sensitivity meet the nominal tolerances defined in the programmer's on-screen help over the temperature range of 25°C to 45°C (±2°C).

Input Impedance

Table 16. Input impedance

Measurement	Range
Input impedance	30-75 kΩ

Effective Pacing Capacitance

Table 17. Effective pacing capacitance

Measurement	Range
Effective pacing capacitance	4.7 µF±10%

Test Pulse Sensitivity

Sensitivity was measured using the test pulse shown in the figure below.

Table 18. Test pulse sensitivity (mV)—Positive signals, ventricular channel, 37°C

Programmed nominal	Min	Typical	Max
0.5	0.35	0.40	0.65
1.0	0.7	1.0	1.3

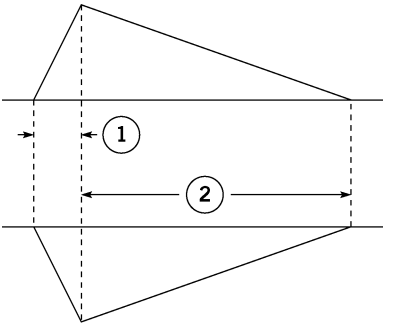
Table 18. Test pulse sensitivity (mV)—Positive signals, ventricular channel, 37°C

Programmed nominal	Min	Typical	Max
7.0	4.9	7.3	9.1
12.5	8.75	12.9	16.25

Table 19. Test pulse sensitivity (mV)—Negative signals, ventricular channel, 37°C

Programmed nominal	Min	Typical	Max
-0.5	-0.35	-0.40	-0.65
-1.0	-0.7	-1.0	-1.3
-7.0	-4.9	-7.3	-9.1
-12.5	-8.75	-12.9	-16.25

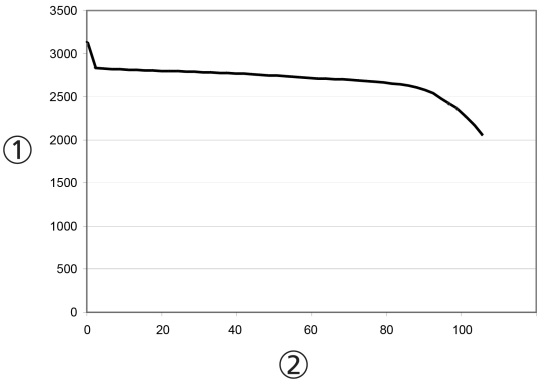
Figure 3. Test pulse description



1. 2.0 ms
2. 13 ms

Battery Discharge Curve

Figure 4. Battery discharge curve



1. Voltage (mV)
2. % Depth of Discharge (mAh)

Symbols

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at https://manuals.sjm.com.

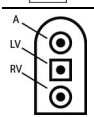
Symbol	Description
SR	Single chamber, rate modulated device
DR	Dual chamber, rate modulated device
SC	Single chamber, communicating device
DC	Dual chamber, communicating device
CRT-P	Cardiac resynchronization therapy pacemaker, right atrial, right ventricular, left ventricular
	Bipolar Sensing/Bipolar Pacing
	Unipolar Sensing/Unipolar Pacing
DDDR	NBG - dual-chamber pacing, dual-chamber sensing, dual-chamber response, rate-modulated

Symbol	Description
DDDRV	NBG - dual-chamber pacing, dual-chamber sensing, dual-chamber response, rate-modulated, biventricular sensing and pacing
SSI	NBG - atrial or ventricular pacing, atrial or ventricular sensing, inhibited response, no rate-modulation
SSIR	NBG - atrial or ventricular pacing, atrial or ventricular sensing, inhibited response, rate-modulated
IS-1	Lead connector accepts unipolar or bipolar IS-1 (International Standard-1) short terminal pin leads.
IS4-LLLL	Lead connector accepts quadripolar IS4-LLLL leads. SJ4-LLLL is equivalent to IS4-LLLL. St. Jude Medical SJ4 and IS4 connector cavities comply with ISO27186:2010(E).
VVI	NBG - ventricular pacing, ventricular sensing, inhibited response
DDD	NBG - dual-chamber pacing, dual-chamber sensing, dual-chamber response, no rate-modulation
	Follow instructions for use on this website

Symbol	Description
	Manufacturing facility
CE 0123	European conformity, affixed according to the relevant provisions of AIMD directive 90/385/EEC and RE directive 2014/53/EU Annex II. Hereby, St. Jude Medical declares that this device complies with the essential requirements and other relevant provisions of these directives. The full text of the European Union RE directive 2014/53/EU declaration of conformity is available at the following internet address: www.sjmglobal.com/euconformity. This product operates in the 402-405 MHz band with an effective radiated power of less than 25 µW ERP. This product operates between 9 and 200 kHz with an H-field strength of less than 25 dBµA/m at 10 m.

Symbol	Description
	The device contains a battery and the label is affixed to this device in accordance with European Council Directive 2006/66/EC. Return the device to St. Jude Medical when explanted or dispose as potentially biohazardous material in accordance with medical practice and applicable local, state, and federal laws and regulations.
	For prescription use only
	This equipment is certified for type certification pursuant of Article 38-24 of the Japan Radio Law
	Korea Certification mark for electrical devices
	Australian Communications and Media Authority (ACMA) and New Zealand Radio Spectrum Management (RSM) Regulatory Compliance Mark (RCM)
BOL >95 min^{-1}	Beginning of life

Symbol	Description
	Left ventricle parameter
	Right atrium and right ventricle parameter
	Indication of an interval or delay. When an interval or delay is present between two chambers, the image is modified to include a space or gap.
	Sensed atrial to ventricular interval
	AV Delay: Paced/Sensed
	Pulse amplitude and pulse width
	Pulse amplitude/width, right ventricular, left ventricular
	Sensitivity
	Refractory period
	Sensing
	Therapy delivered

Symbol	Description
	Auto polarity detection
	S (A/V)- Single chamber (A or V) IS-1connector
	A- Atrial IS-1 connector; V- Ventricular IS-1 connector
	A- Atrial IS-1 connector; LV- Left ventricular IS-4 connector; RV- Right ventricular IS-1 connector
	Accessories
	Product literature

Symbol	Description
Made in Malaysia	Made in Malaysia
Made in USA	Made in USA

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