Accent™, Accent™ RF, Accent MRI™, Accent™ ST, Accent™ ST MRI, Assurity™, Assurity™ +, Endurity™

Pulse Generator

Allure™, Allure™ RF, Allure Quadra™, Allure Quadra™ RF, Anthem™, Anthem™ RF

Cardiac Resynchronization Therapy Pulse Generator

User's Manual

St. Jude Medical
More control. Less risk.

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 equipped with Model 3330 version 17.2.1 (or greater) software. For information on programming, refer to the programmer's on-screen help.

Table 1. Pulse generator descriptions

Name	Model Number	Description	Connector Type	MRI Status[2]
Accent SR	PM1110	Single-chamber pulse generator	IS-1	MR Unsafe
Accent ST	PM1122	Single-chamber pulse generator	IS-1	MR Unsafe
Accent MRI	PM1124	Single-chamber pulse generator	IS-1	MR Conditional
Accent ST MRI	PM1126	Single-chamber pulse generator	IS-1	MR Conditional
Endurity	PM1160	Single-chamber pulse generator	IS-1	MR Unsafe
Accent SR RF	PM1210	Single-chamber pulse generator with RF telemetry	IS-1	MR Unsafe
Accent ST	PM1222	Single-chamber pulse generator with RF telemetry	IS-1	MR Unsafe
Accent MRI	PM1224	Single-chamber pulse generator with RF telemetry	IS-1	MR Conditional
Accent ST MRI	PM1226	Single-chamber pulse generator with RF telemetry	IS-1	MR Conditional
Assurity	PM1240	Single-chamber pulse generator with RF telemetry	IS-1	MR Unsafe
Assurity+	PM1260	Single-chamber pulse generator with RF telemetry	IS-1	MR Unsafe
Accent DR	PM2112	Dual-chamber pulse generator	IS-1	MR Unsafe
Accent ST	PM2122	Dual-chamber pulse generator	IS-1	MR Unsafe
Accent MRI	PM2124	Dual-chamber pulse generator	IS-1	MR Conditional
Accent ST MRI	PM2126	Dual-chamber pulse generator	IS-1	MR Conditional
Endurity	PM2160	Dual-chamber pulse generator	IS-1	MR Unsafe
Accent DR RF	PM2212	Dual-chamber pulse generator with RF telemetry	IS-1	MR Unsafe
Accent ST	PM2222	Dual-chamber pulse generator with RF telemetry	IS-1	MR Unsafe
Accent MRI	PM2224	Dual-chamber pulse generator with RF telemetry	IS-1	MR Conditional
Accent ST MRI	PM2226	Dual-chamber pulse generator with RF telemetry	IS-1	MR Conditional
Assurity	PM2240	Dual-chamber pulse generator with RF telemetry	IS-1	MR Unsafe
Assurity+	PM2260	Dual-chamber pulse generator with RF telemetry	IS-1	MR Unsafe
Anthem	PM3112	CRT-P	IS-1	MR Unsafe
Anthem RF	PM3212	CRT-P with RF telemetry	IS-1	MR Unsafe
Allure	PM3120	CRT-P	IS-1	MR Unsafe
Allure Quadra	PM3140	CRT-P	IS-1/IS4-LLLL	MR Unsafe
Allure RF	PM3222	CRT-P with RF telemetry	IS-1	MR Unsafe
Allure Quadra RF	PM3242	CRT-P with RF telemetry	IS-1/IS4-LLLL	MR Unsafe

Indications

Implantation of a single-chamber pulse generator, dual-chamber pulse generator, or CRT-P is indicated in one or more of the following permanent conditions:

- Syncope
- Presyncope
- Fatigue
- Disorientation due to arrhythmia/bradycardia
- Or any combination of those symptoms.

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

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

[1] Not all device models are available in all countries.
[2] As defined by the American College of Radiology.

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 Procedure Information document for the St. Jude Medical™ MR Conditional Pacing System.

Rate-modulated pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. Chronotropic incompetence[3] has not been rigorously defined. A conservative approach, supported by the literature, defines chronotropic incompetence as the failure to achieve an intrinsic heart rate of 70% of the age-predicted maximum heart rate or 120 min^{-1} during exercise testing, whichever is less, where the age-predicted heart rate is calculated as 197 — (0.56 x age).

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 A-V block or sinus arrest
- Chronic atrial fibrillation
- 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	Seal unused lead receptacles

Contraindications

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.

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.

Atrial Fibrillation. CRT-Ps are contraindicated in patient's having chronic atrial fibrillation or intermittent atrial fibrillation that does not terminate.

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:

- 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.

[3] Gwinn N, Leman R, Kratz J, et al. Chronotropic incompetence: A common and progressive finding in pacemaker patients. American Heart Journal 1992; 123:121619.

- 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 ionizing radiation in the vicinity of an implanted device. Radiation therapy may damage the electronic circuitry of the device.
- Ultrasound Treatment. Do not use therapeutic ultrasound within 16 cm 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 (page 1). St. Jude Medical™ MR Conditional pulse generators are safe for use in the MRI environment when used in a complete MR Conditional pacing system and according to the instructions in the MRI Procedure Information document for the St. Jude Medical™ MR Conditional Pacing System.
- MR Unsafe pulse generators. MRI for patients with implantable devices has been contraindicated by MRI manufacturers.

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 [Continue] 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). At ERI (page 9), 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, therefore: (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 it away from the patient and the programmer. If the problem persists, contact St. Jude Medical.

Suboptimal RF Communication. The 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.
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 it; return it to St. Jude Medical.

Temperature. Store the pulse generator at temperatures between -5°C/23°F and 50°C/122°F. Do not subject it to temperatures below -20°C or over 55°C. 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.

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

- Inductive communication. Position the 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 RF Antenna to the programmer. Please refer to the Merlin™ Patient Care System 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. The positive (red) terminal should be connected 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 ECG or 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 equipped with Model 3330 version 17.2.1 (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.

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 220 min^{-1} (± 10 min^{-1}) for PM1160, PM1240, PM1260, PM2160, PM2240, PM2260, PM3120, PM3140, PM3222, PM3242 devices. For all other devices, the rate threshold is 210 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, the patient notifier within the pulse generator is permanently disabled when in or near an MRI scanner.

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 electromagnetic interference (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 EMI fields that may interfere with device operation.

Communication Equipment, such as microwave transmitters[4], 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 handtools 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, 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 the Electronic Article Surveillance/Anti-theft systems or Electronic Article Surveillance (EAS) systems such as those at the point of sale and entrances/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.

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

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.[5]

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.

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** 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.

MR Conditional Pacing System

The St. Jude Medical™ MR Conditional pulse generator is part of the St. Jude Medical MR Conditional pacing system.

Patients with an implanted St. Jude Medical™ MR Conditional pacing system can have an MRI scan if the conditions for use, as described in the MRI Procedure Information document, are met.

Potential Adverse Events

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

- Arrhythmia
- Heart block
- Thrombosis
- Threshold elevation
- Valve damage
- Pneumothorax
- Myopotential sensing
- Vessel damage
- Air embolism
- Body rejection phenomena
- Cardiac tamponade or perforation
- Formation of fibrotic tissue; local tissue reaction
- Inability to interrogate or program a device because of programmer malfunction
- Infection
- Interruption of desired device function due to electrical interference
- Loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface, or lead malfunction (fracture or damage to insulation)
- Loss of normal device function due to battery failure or component malfunction
- Device migration, pocket erosion, or hematoma
- Pectoral muscle stimulation
- Phrenic nerve or diaphragmatic stimulation
- Cardiac/coronary sinus dissection (CRT-Ps only)
- Cardiac/coronary sinus perforation (CRT-Ps only)
- Coronary sinus or cardiac vein thrombosis (CRT-Ps only)

The following, in addition to the above, are potential complications associated with the use of rate-modulated pacing systems:

- Inappropriate, rapid pacing rates due to sensor failure or to the detection of signals other than patient activity
- Loss of activity-response due to sensor failure
- Palpitations with high-rate pacing.

[5] 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.

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.

Table 5. X-ray ID codes for the devices described in this manual

Device Model	X-ray ID Model Code
PM1110, PM1122, PM1160, PM1210, PM1222, PM1240, PM1260, PM2112, PM2122, PM2160, PM2212, PM2222, PM2240, PM2260, PM3112, PM3120, PM3140, PM3212, PM3222, PM3242	HI
PM1124, PM1126, PM1224, PM1226, PM2124, PM2126, PM2224, PM2226	HM MRI

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 ring(s).

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 ECG or 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. Insert the #2 torque wrench through the aperture on the header and into the setscrew on the side of the connector.
6. Turn the wrench clockwise until it clicks. The wrench is torque-limited and will not allow excessive tightening.
7. Repeat the steps above for additional lead(s).
8. 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.

Elective Replacement Indicator

ERI (or Recommended Replacement Time) is the point at which battery voltage has dropped to the lowest capacity that will maintain adequate device operation for a nominal period before EOL. The nominal period is six months for PM1160, PM1240, PM1260, PM2160, PM2240, PM2260, PM3120, PM3140, PM3222, PM3242. The nominal period for all other devices is three months.

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.

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 (page 9), the nominal life of the device is three or six months. 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 approximately 2.50 V for all devices except PM1160, PM1240, PM1260, PM2160, PM2240, PM2260, PM3120, PM3140, PM3222, PM3242 devices. EOL for the listed devices is 2.47 V.

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

Technical Support

St. Jude Medical Cardiac Rhythm Management Division 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)

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 6. Device Measurements[6]

Model	Dimensions (h x l x t) (mm)	Weight (g)	Displaced volume[7] (cm^3)
PM1110	42 x 52 x 6	18	9.5
PM1122	42 x 52 x 6	18	9.5
PM1124	52 x 46 x 6	22	12.0
PM1126	52 x 46 x 6	22	12.0
PM1160	41 x 50 x 6	19	9.7
PM1210	52 x 52 x 6	23	12.8
PM1222	52 x 52 x 6	23	12.8
PM1224	52 x 53 x 6	24	13.1
PM1226	52 x 53 x 6	24	13.1
PM1240	47 x 50 x 6	20	10.4
PM1260	47 x 50 x 6	20	10.4
PM2112	46 x 52 x 6	19	10.5
PM2122	46 x 52 x 6	19	10.5
PM2124	52 x 53 x 6	23	13.1
PM2126	52 x 53 x 6	23	13.1
PM2160	46 x 50 x 6	19	10.4

[6] The dimensions and weight are nominal values.
[7] ±0.5 cm^3

Table 6. Device Measurements[6]

Model	Dimensions (h x l x t) (mm)	Weight (g)	Displaced volume[7] (cm^3)
PM2212	52 x 52 x 6	23	12.9
PM2222	52 x 52 x 6	23	12.9
PM2224	52 x 53 x 6	24	13.1
PM2226	52 x 53 x 6	24	13.1
PM2240	47 x 50 x 6	20	10.4
PM2260	47 x 50 x 6	20	10.4
PM3112	52 x 52 x 6	21	11.5
PM3212	58 x 52 x 6	25	13.7
PM3120	55 x 59 x 6	24	14
PM3140	56 x 59 x 6	26	15
PM3222	55 x 59 x 6	24	14
PM3242	56 x 59 x 6	27	15

Device Materials

Table 7. Device Materials

Model	Can	Case Coating	RF antenna[8]	Connector Material
All devices	Titanium	None	Titanium	Epoxy, Polysulfone

Lead Compatibility

Table 8. Lead compatibility

Model	Lead compatibility
All devices	IS-1[9]
PM3140	IS-1 and IS4-LLLL
PM3242	

Battery Information

Table 9. Battery Information

Model	Power source	Manufacturer; Model	Voltage at BOL	Voltage at ERI
PM3120	1 QMR[10] cell	Greatbatch Medical; Model 2662	3.20 V	2.62 V
PM3140				
PM3222				
PM3242				
All other devices				2.60 V

[8] For devices with RF telemetry capability.
[9] Accepts IS-1 short terminal pin leads.
[10] 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 301 839-2
- 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.

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 EMI. The devices comply with the electromagnetic compatibility requirements of CENELEC standard EN45502-2-1[11], 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 settings 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 EN 45502-2-1 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.

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 10. Input Impedance

Measurement	Range
Input Impedance	30 – 75 kΩ

Test Pulse Sensitivity

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

Table 11. Test Pulse Sensitivity (mV) – Positive and Negative Signals, Ventricular Channel, 37°C

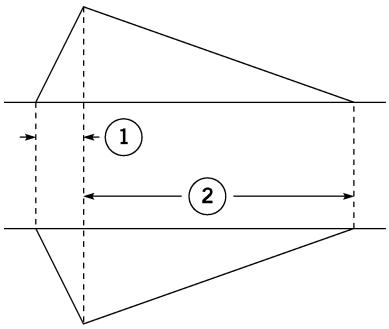
Programmed Nominal	Positive Signals		
	Min	Typical	Max
0.5	0.35	0.4	0.65
1.0	0.7	1.0	1.3
7.0	4.9	7.3	9.1
12.5	8.75	12.9	16.25

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

Table 11. Test Pulse Sensitivity (mV) – Positive and Negative Signals, Ventricular Channel, 37°C

Programmed Nominal	Positive Signals		
	Min	**Typical**	**Max**
	Negative Signals		
-0.5	-0.35	-0.46	-0.65
-1.0	-0.7	-1.2	-1.3
-7.0	-4.9	-8.4	-9.1
-12.5	-8.75	-15.1	-16.25

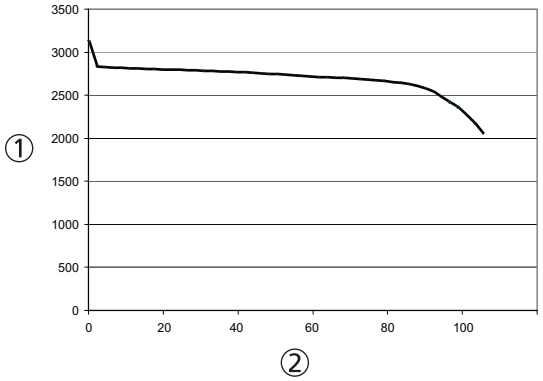
Figure 2. Test Pulse Description



1. 2.0 ms
2. 13 ms

Battery Discharge Curve

Figure 3. Battery Discharge Curve



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

Symbols

The following symbols may appear on St. Jude Medical™ pulse generator labels.

Table 12. Symbols

Symbol	Description
DDDR	NBG - dual-chamber pacing, dual-chamber sensing, dual-chamber response, rate-modulated
DDDRV	NBG - dual-chamber pacing, dual-chamber sensing, dual-chamber response, rate-modulated, biventricular sensing and pacing
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's SJ4 and IS4 connector cavities comply with ISO27186:2010(E).
	Sterilized using ethylene oxide
	Authorized Representative in the European Community
	Caution, Consult Accompanying Documents
	Consult instructions for use
	Date of Manufacture
	Manufacturer
	Country of manufacture; BE- Belgium, MY- Malaysia, US- United States
	Use by
	Do not reuse
	Do not use if package is damaged
	Serial number
CE 0123 0413	Affixed in accordance with European Council Directive 90/385/EEC ("0123") and 1999/5/EC ("0413"). Hereby, St. Jude Medical declares that this device is in compliance with the essential requirements and other relevant provisions of these Directives[12].
	Temperature limits
	The device contains a battery and the label is affixed to this device in accordance with European Council Directive 2002/66/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.

[12] "0413" applies only to RF devices.

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