

Merlin™ Patient Care System

Merlin™ PCS, Model 3650

Merlin™ Antenna, Model 3638

Merlin™ PSA, Model EX3100

USER'S MANUAL



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Introduction

The Merlin™ Patient Care System (Merlin™ PCS) Model 3650 User's Manual describes the components, setup, maintenance, accessories, and technical data of the Merlin PCS. For information on St. Jude Medical implantable devices, select the ? button from any device session screen.

Indications

The Merlin™ PCS Model 3650 programmer is indicated for use for patients with bradyarrhythmias, tachyarrhythmias or heart failure undergoing implantation, lead revision, explant or device follow-up of a cardiac monitor, pacemaker, implantable cardioverter defibrillator, or cardiac resynchronization therapy system.

Intended Use

The St. Jude Medical Merlin™ PCS Model 3650 is a portable, dedicated system designed to interrogate, program, display data from, and test St. Jude Medical implantable devices during implant and follow up. At time of implant, it is intended to assess the pacing and sensing performance of the lead after it is connected to the pulse generator.

The Telemetry Wand Model 3630 is intended to provide inductive communication between the programmer and the pulse generator during a programming session.

The Merlin PCS ECG function when using the ECG cable Models 3617, 3626 and EX3001 is intended to display the patient electrocardiogram and used to support activities related to implanting, programming, and monitoring St. Jude Medical implantable pulse generators.

The Merlin Antenna Model 3638 is a dedicated radio antenna accessory intended to enable wireless radio frequency (RF) communication between the Merlin PCS and St. Jude Medical implantable pulse generators with RF communication capability during a programming session.

The Merlin PSA Model EX3100 and the PSA Patient Cable Model 3150 are pacing analyzer systems intended for use with the Merlin PCS to evaluate implanted leads for integrity, and for pacing and sensing performance during surgical procedures related to the implanted system.

The Magnet Model 3630M is intended to support inductive communication with specific pulse generators or to enable device-specific magnet settings, such as high voltage therapy inhibition or asynchronous mode activation, when placed over an implanted pulse generator.

Contraindications

There are no contraindications to the use of the St. Jude Medical Merlin™ PCS Model 3650 to interrogate, program, display data from, and test implantable devices during implant and follow up.

Technical Support

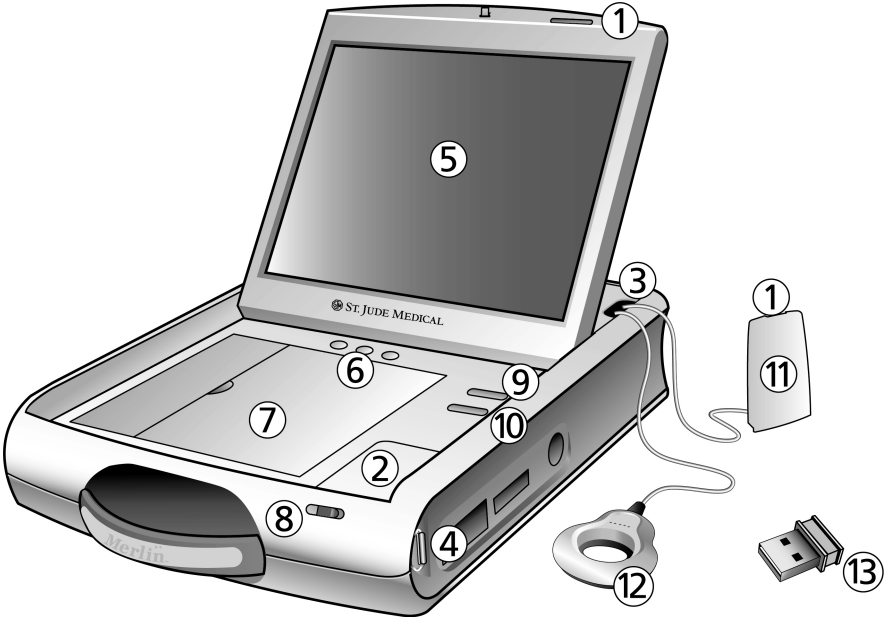
St. Jude Medical maintains 24-hour phone lines for technical questions and support:

- 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.

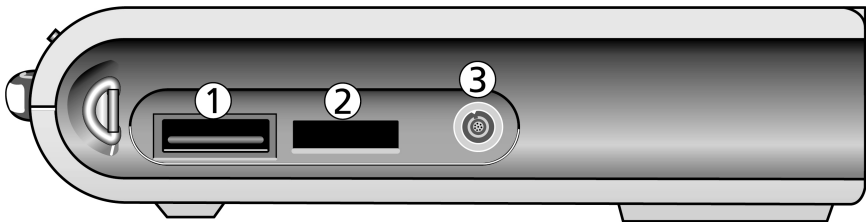
Features

Figure 1. Merlin™ Patient Care System



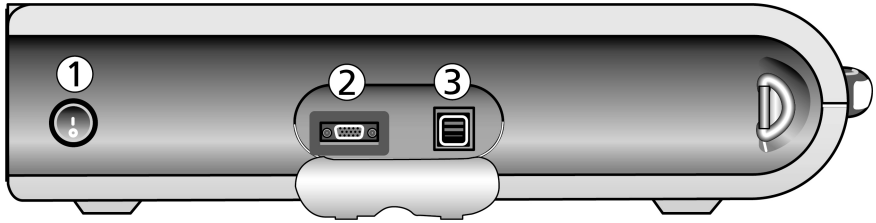
1. **Telemetry Strength Indicators.** For the Merlin™ PCS and Merlin™ Antenna. See Merlin™ PCS Setup (page 7) and RF Communication Setup (page 14).
 2. **Flash Drive Compartment** (USB Port 1). See External Device Connection (page 18) and Bluetooth Wireless Communication Setup (page 17).
 3. **Storage Compartment.** Connect ECG cable and inductive telemetry wand. Install the Merlin™ PSA Model EX3100 (page 10) or connect the Merlin Antenna (page 14).
 4. **Carrying Strap Loops.**
 5. **Touchscreen.** Use the pad of your finger to activate the screen. Do not use pencils, pens, fingernails, or other sharp objects.
 6. **Rhythm Strip Print Buttons.** Select one of these buttons to begin continuous printing of markers and ECG and EGM waveforms.
 7. **Paper Tray Door.** See Printer Paper (page 20).
 8. **Display Latch.**
 9. **Shock Button.** Select this button to display the Shock screen. See Emergency Operation (page 18).
 10. **VVI Button.** Select this button to reprogram a device to high-output Emergency VVI settings. See Emergency Operation (page 18).
 11. **Merlin Antenna.** See RF Communication Setup (page 14).
 12. **Inductive Telemetry Wand.**
 13. **Bluetooth®** Low Energy wireless communication USB dongle. See Bluetooth Wireless Communication Setup (page 17).
-

Figure 2. Right side



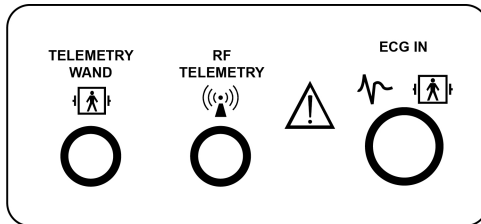
1. **Wi-Fi port**
 2. **Ethernet port**
 3. **PSA port.** Connect the PSA Wand Model 3150 or an additional telemetry wand here. Do NOT connect the Merlin PSA Model EX3100 here. See Setup Instructions (page 7).
-

Figure 3. Left side



1. **On/Off switch**
2. **Display Out port.** Connect an external video monitor here. See External Device Connection (page 18).
3. **Two USB ports.** Connect an external floppy drive, keyboard, mouse, Merlin Antenna, or connectivity accessory here. Top port is Port 2; bottom port is Port 3. See External Device Connection (page 18), RF Communication Setup (page 14), and Bluetooth Wireless Communication Setup (page 17).

Figure 4. Storage compartment connectors (with Merlin PSA not installed)¹



1. **Telemetry wand (inductive) port.** For inductive telemetry devices. See Merlin PCS Setup (page 7).
2. **RF telemetry port.** For connection to the Merlin Antenna. See RF Communication Setup (page 14).
3. **ECG In port.** See Merlin PCS Setup (page 7).

¹ See Merlin™ PSA Model EX3100 Setup for connections with the Merlin PSA installed.

Setup Instructions

Merlin™ PCS Setup

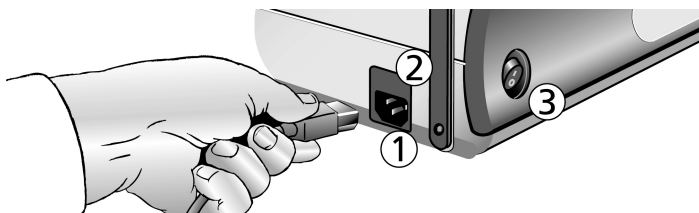
CAUTION: Do not bring any external control devices, such as a programmer, into the scanner magnet room (Zone IV). These devices are considered MR Unsafe.

To set up the Merlin™ PCS to communicate with a device that uses inductive telemetry, follow these instructions. For instructions to set up the Merlin PCS with devices that use RF communication, see RF Communication Setup (page 14). For instructions to set up the Merlin PCS with devices that use Bluetooth® Low Energy wireless communication, see Bluetooth Wireless Communication Setup (page 17).

1. Remove cables from storage compartment.
2. Plug the power cord into the power receptacle and then into grounded mains outlet.

CAUTION: The Merlin PCS must be connected to a grounded mains outlet with a hospital-grade cable.

Figure 5. The power receptacle, the fuse holder, and the On/Off switch



1. Power receptacle
2. Fuse holder
3. On/Off switch

3. You can attach a 5-lead or 3-lead ECG to the Merlin PCS. With the 5-lead ECG cable, attach up to five ECG electrodes to the patient: Right Arm, Left Arm, Right Leg, and Left Leg. For the fifth or chest electrode, choose one C location.

With the 3-lead ECG cable, attach electrodes to the Right Arm, Left Arm, and Right Leg.

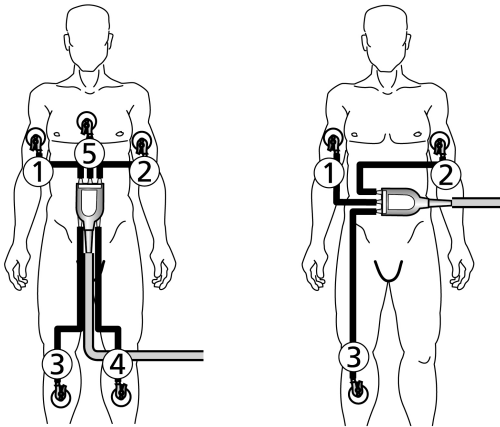
CAUTION: Use only the ECG cables listed in the Accessories section (page 34) of this manual to protect the Merlin PCS against possible damage from defibrillator shock.

The Merlin PCS ECG function is intended to support activities related to implanting, programming, and monitoring St. Jude Medical implantable pulse generators. The programmer is not intended for use as an ECG monitor or general diagnostic device.

NOTE: With the 3-lead ECG cable, only the Lead I vector is displayed on the Merlin PCS programmer screen.

4. Attach the ECG leads to the appropriate electrodes.

Figure 6. Color codes and positions of ECG cable connections for 5-lead ECG (left) and 3-lead ECG (right)

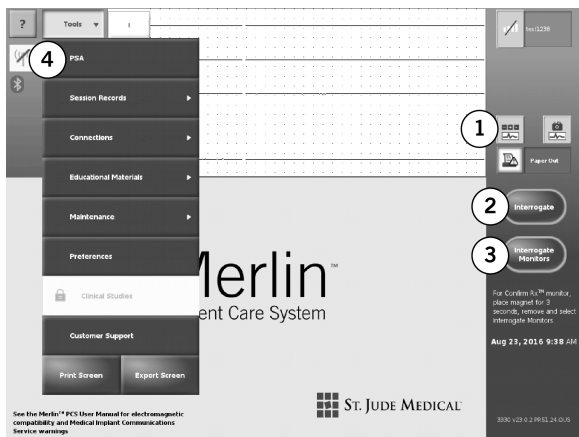


1. R (Red)
 2. L (Yellow)
 3. N (Black)
 4. F (Green)
 5. C (White)
-

WARNING: Do not allow conductive parts of electrodes or connectors to come into contact with other conductive parts, including Earth ground.

5. Turn on the power.
6. Open the screen display.
7. On the Merlin PCS screen, select the Adjust Display button to configure the ECG waveform. For more information, select the ? button at the top of the screen when the Adjust Display window appears.

Figure 7. The Adjust Display button, the Interrogate button, the Interrogate Monitors button, and the Tools Menu



1. Adjust Display button
2. Interrogate button
3. Interrogate Monitors button
4. Tools menu

8. Place the inductive telemetry wand over the patient's device. Do not insert the magnet into the wand.

NOTE: For devices that use inductive telemetry, use only the Model 3630 wand with the Merlin PCS. The Model 3530 telemetry wand, used with the Model 3510/3500 programmer, cannot be used with the Merlin PCS.

The telemetry wand can be connected to a wand extension cord, see Accessories (page 34). However, use of more than one wand extension cord may degrade the telemetry signals and range.

Do not place the inductive wand on top of the Merlin™ PSA Model EX3100.

9. Select the Interrogate button for pacemakers, ICDs, and CRTs, or select the Interrogate Monitors button for cardiac monitors. Use the telemetry strength indicators above the screen and on the telemetry wand to position the wand over the device. A single lighted LED indicates telemetry is established. A greater number of lighted LEDs indicates greater signal strength.

CAUTION: Telemetry may be compromised if the wand and device are less than 0.3 m from the Merlin PCS.

10. If the interrogated device requires a magnet, a message suggests that you insert the magnet into the telemetry wand. Insert the magnet so that it is flush with the wand.

Shut Down

To power down the Merlin™ PCS:

1. Remove any cables connecting the Merlin PCS to the patient.
2. Either:
 - Move the On/Off switch to the Off position, or
 - Detach the power cable from the unit.

The Merlin PCS has a power switch that, when shut off, isolates both conductors of the supply mains simultaneously.

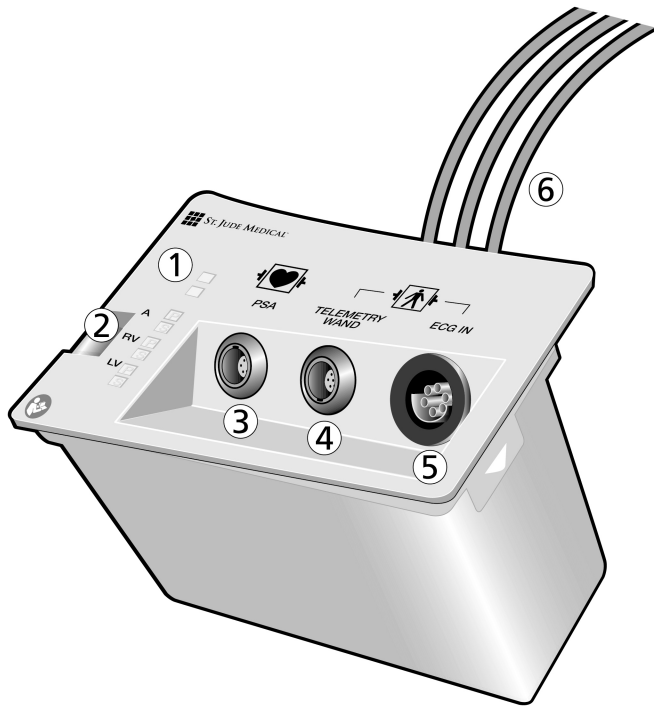
Merlin™ PSA Model EX3100 Setup

The Merlin™ PSA Model EX3100 must be inserted into the Merlin™ PCS storage compartment. It contains ports for the Merlin PSA patient cables or patient-cable adapters, the ECG input, and the inductive telemetry wand. The items previously stored in the compartment can be stored in the Merlin PCS storage pouch, see Accessories (page 34).

When the Merlin PSA is placed in the Merlin PCS, the Merlin™ Antenna can no longer be connected through the storage compartment. Instead, the Merlin Antenna can be connected to the USB port on the side of the Merlin PCS by connecting the antenna to the Merlin Antenna adapter (Model EX3190). See connection instructions (page 14).

For more information on the Merlin PSA Model EX3100, including connection of the patient cables and patient-cable adapters, refer to the on-screen help on the Merlin PCS.

Figure 8. Merlin PSA Model EX3100

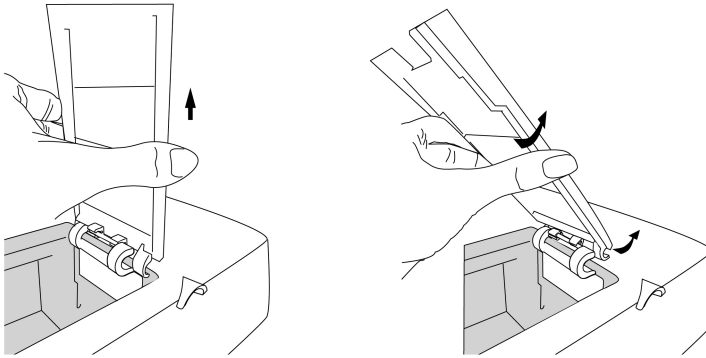


1. Functional Status LEDs
 2. Pace and Sense LEDs
 3. Receptacle for patient cable or patient-cable adapter
 4. Receptacle for inductive telemetry wand
 5. Receptacle for ECG input
 6. Connectors to Merlin PCS
-

To place the Merlin PSA into the storage compartment, follow the steps below. To remove the Merlin PSA from storage compartment, reverse the steps.

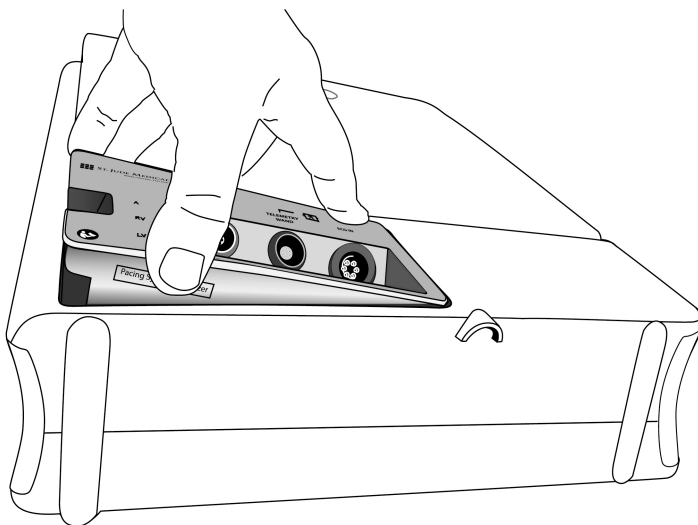
1. Turn off the Merlin PCS.
2. Remove the Merlin PCS storage compartment door by raising it at a 90 degree angle.
3. Grip the lid so you can pull on one side and push on the other side.
4. Loosen the lid from the hinge on one side.

Figure 9. Storage compartment door removal



5. Loosen the hinge on the other side and pull the hinge and lid free.
Save the lid and hinge for future use.
6. Disconnect all cables and remove them from the storage compartment.
7. On the back of the Merlin PSA, locate the gray Merlin PSA connector and connect it to the gray RF Telemetry port in the storage compartment.
8. Locate the blue telemetry wand connector on the back of the Merlin PSA and connect it to the blue telemetry wand port in the storage compartment.
9. Locate the black ECG cable on the back of the Merlin PSA and connect it to the black ECG port in the storage compartment.
10. Orient the Merlin PSA over the storage compartment so its ports and LEDs are facing up and the ports are facing away from the Merlin PCS screen. Gently lower the Merlin PSA into the storage compartment.
11. Facing the back of the programmer, tilt the right side of the Merlin PSA into the compartment so that the hinge hooks grip inside the storage compartment.
12. Push down on the Merlin PSA to snap it into place. It should fit securely and flush with the surface of the Merlin PCS.

Figure 10. Insertion of the Merlin PSA



13. Connect the inductive telemetry wand into the blue port on the Merlin PSA and the ECG into the black port.

14. Connect the Merlin Antenna to a USB port on the left side of the programmer using the Merlin Antenna cable adapter (Model EX3190). See RF Communication Setup (page 14).

15. Turn on the Merlin PCS.

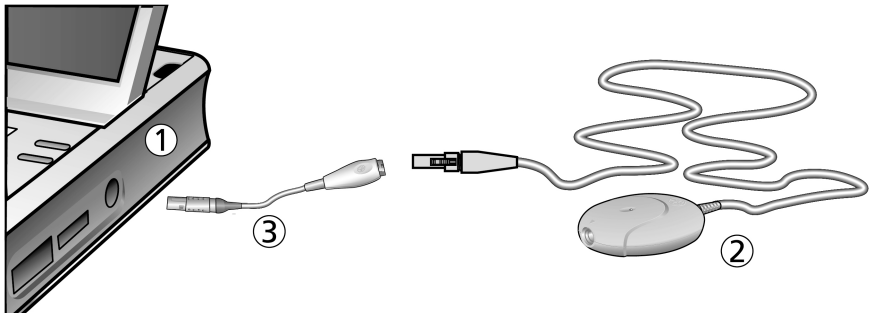
The blue LED on the Merlin PSA should be illuminated within 10 seconds, indicating the unit is powered and operational. If it is not on, the PSA has not been placed correctly or the Merlin PSA is not functioning properly.

16. Select Tools > PSA.

You are now ready to begin a PSA session. Consult the Merlin PSA on-screen help for instructions on the Merlin PSA operation and maintenance, backup battery replacement, and connections between the PSA, the patient cables, and the implanted leads.

NOTE: The Merlin PCS operates only one pacing system analyzer at a time. If both the Merlin PSA Model EX3100 and the PSA Wand Model 3150 are connected to the Merlin PCS, the Merlin will only operate the Merlin PSA, and the PSA Wand will not function.

Figure 11. Connection between the Merlin PCS and the PSA Wand Model 3150 using the PSA Wand adapter Model 3615



1. Merlin PCS
 2. PSA Wand Model 3150
 3. PSA Wand adapter Model 3615
-

PSA Wand Model 3150 Setup

1. Connect the PSA Wand adapter Model 3615 to the PSA Wand Model 3150.²
2. Insert the adapter into the PSA port on the right side or into the inductive telemetry port inside the storage compartment.
3. When the Start-Up screen appears, select the Tools button, and then select the PSA button. The Merlin™ PCS detects the presence of the PSA Wand Model 3150 and starts the program.

NOTE: The Merlin PCS operates only one pacing system analyzer at a time. If both the Merlin™ PSA Model EX3100 and the PSA Wand Model 3150 are connected to the Merlin PCS, the Merlin will only operate the Merlin PSA, and the PSA Wand will not function.

CAUTION: Do not plug the PSA Wand directly into the PSA port on the right side of the Merlin PCS without first connecting it to the PSA Wand adapter Model 3615.

Do not plug the PSA Wand into the PSA port on the Merlin PSA.

RF Communication Setup

Some St. Jude Medical™ implantable devices can communicate with the Merlin™ PCS via radio frequency (RF), which allows a greater distance between the device and the Merlin PCS. To establish RF communication, follow the instructions below.

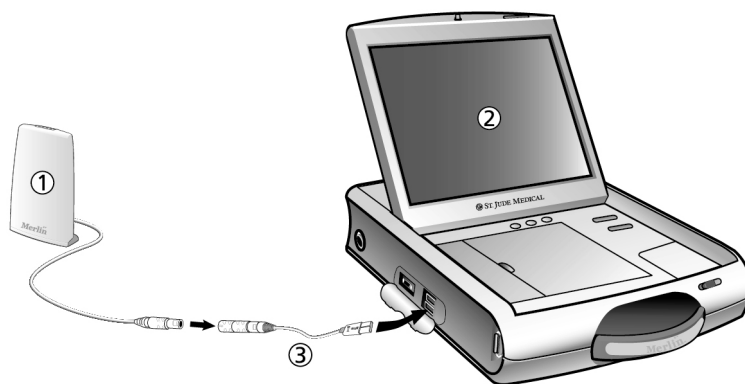
1. Turn off the Merlin PCS.
2. If the Merlin PSA Model EX3100 is not in place in the storage compartment, open the storage compartment door and locate the RF Telemetry port. Connect the cable from the Merlin Antenna to the RF Telemetry port.

² For information, consult the PSA Model 3150 Reference Manual or press the ? button from the PSA program.

If the Merlin PSA Model EX3100 is already placed in the storage compartment, locate the Merlin Antenna USB adapter (Model EX3190) provided with the Merlin PSA. Connect the USB connector on the adapter to one of the USB ports on the left side of the Merlin PCS. Then, connect the Merlin Antenna to the remaining connector on the adapter.

NOTE: Connect the Merlin Antenna only to the USB ports on the left side of the programmer. Do not connect the Merlin Antenna to the USB port in the flash drive compartment.

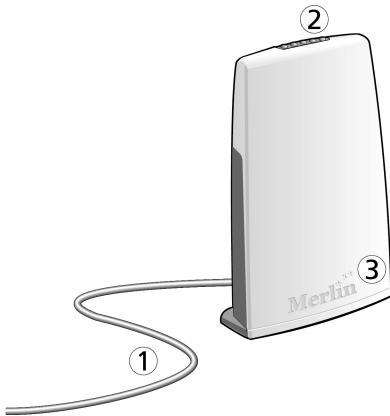
Figure 12. Connection between the Merlin Antenna and the Merlin PCS using the Model EX3190 cable adapter



1. Merlin Antenna
 2. Merlin PCS
 3. Model EX3190 cable adapter
-

1. Place the Merlin Antenna on a flat surface approximately 1 – 2 m (2 – 6 ft) from the implanted device. The front panel should face the device.
2. Follow steps 1 through 7 in the Merlin PCS Setup (page 7).
3. When the Merlin PCS is turned on, the telemetry strength indicator LEDs and the status LEDs on the Merlin Antenna will light, indicating the unit is powered and operational.

Figure 13. Merlin Antenna, showing the antenna cable, the green telemetry strength indicator LEDs, and the blue status LEDs



1. Antenna cable
 2. Green telemetry strength indicator LEDs
 3. Blue status LEDs
-

4. When the programmer startup screen appears, the "Ready to Connect to Device" icon appears under the Tools menu button. See RF Telemetry Icons (page 16).
5. Place the inductive telemetry wand over the patient's device.
6. On the programmer, select the Interrogate button. After the interrogation is complete, the Merlin PCS displays the FastPath™ Summary Screen. The "Active RF Telemetry connection" icon appears under the Tools menu button. See RF Telemetry Icons (page 16).
7. The telemetry strength indicators on the Merlin Antenna and the Merlin PCS indicate RF telemetry communication between the Merlin Antenna and the device. A single lighted LED indicates telemetry is established. A greater number of lighted LEDs indicates greater signal strength. If necessary, relocate the Merlin Antenna for better communication. See Suboptimal RF Communication (page 23).
8. Once RF telemetry is established, you may remove the inductive telemetry wand from the patient. Begin the programming session.

CAUTION: Position the Merlin Antenna at least 20 cm (8 in) from the patient and from any device connected to the Merlin PCS wireless port.

Do not use the Merlin Antenna if its enclosure is damaged.

Do not connect the Merlin Antenna to any device other than the Merlin PCS.

RF Telemetry Icons

Table 1. RF telemetry icons for tachycardia devices

Table 1. RF telemetry icons for tachycardia devices










Start-Up Screen Icons		Application Icons	
Disconnected Antenna/Not Working	Ready to connect to device	Active RF telemetry connection	Inactive RF telemetry connection
			

Table 2. RF telemetry icons for bradycardia devices

Start-Up Screen Icons		Application Icons		
Disconnected Antenna/Not Working	Ready to connect to device	Active RF telemetry connection	Inactive RF telemetry connection	Only wand telemetry is available
				

Bluetooth Wireless Communication Setup

Some St. Jude Medical™ implantable devices can communicate with the Merlin™ PCS via Bluetooth® Low Energy wireless communication. This allows communication at a greater distance between the Merlin PCS and an implanted device. To establish Bluetooth Low Energy wireless communication, follow the instructions below.

1. Turn on the Merlin PCS.
2. Insert the USB dongle in one of the available USB ports (either on the side of the programmer or in the Flash Drive compartment).

NOTE: It is recommended that the USB dongle be left in place for repeated ease of use. If the USB dongle is inserted into a side USB port, the port compartment cover flap may not fully close.

3. Confirm that the Bluetooth icon is visible on the Merlin PCS Start-up screen. The icon indicates detection of the USB dongle by the Merlin PCS.
4. Follow the instructions provided below the Interrogate Monitors button on the Start-Up screen to start communication between the Merlin PCS and an implanted device that supports Bluetooth Low Energy wireless communication.

The Merlin PCS may be powered down with the USB dongle in place.

CAUTION: For optimal Bluetooth Low Energy wireless communication, the Merlin PCS and SJM implantable devices should be within 2 m (6.6 ft) in normal use. Do not operate a device that may generate interference, such as a powerful microwave oven, while Bluetooth Low Energy wireless communication is attempted.

Emergency Operation

Figure 14. Emergency buttons (displayed in red)



The console has two red emergency option buttons:

- **SHOCK.** Select this button to display the Shock screen (for ICDs). From this screen, you can deliver therapy.³
- **VVI.** Select this button to automatically reset the device to predefined high-output settings.⁴

External Device Connection

The Merlin™ PCS can be connected to three types of external devices: storage devices; input devices; and output devices. Ports for the wireless card, modem, and ethernet are not currently supported.

NOTE: Not every commercially available external device is guaranteed to operate with the Merlin PCS. External devices that have been tested and verified to operate are listed in the Accessories table (page 34).

WARNING: The ports on the Merlin PCS are not isolated. Only connect external devices that provide proper isolation from the power supply or use the external device with an isolation transformer. Close the cover after disconnecting the device.

Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards. Furthermore, all configurations must comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3.1Ed. of IEC 60601-1, respectively).

Anyone who connects additional equipment to the input or output ports is configuring a medical system and is therefore responsible for the compliance of the system with the requirements of system standard IEC 60601-1-1. If in doubt, consult the Technical Support department (page 1) or your local St. Jude Medical representative.

³ Emergency Shock is not available during Merlin PSA session.

⁴ Emergency VVI settings for each device are defined in the device's User's Manual.

Storage Devices

These devices can be connected to any of the three USB ports on the Merlin™ PCS. The devices can be used to save session records, screen captures, and database records for patient-tracking software to other media. The media include:

- **Flash drive.** See Accessories (page 34) for Flash drive requirements.
- **Floppy drive.** This device must be powered through the USB port and cannot use an external power supply.
- **PC Database.** Connect the Merlin PCS to a PC Database by plugging a USB-to-9-pin serial adapter into any one of the USB ports and then connecting a 9-pin serial cable from the PC Database computer to the adapter.

Input Devices

Keyboard. A USB keyboard can be connected to any of the three USB ports for use in conjunction with the on-screen keyboard.

Mouse. A USB mouse can be connected to any of the three USB ports for use in conjunction with the on-screen keyboard. For a list of compatible mice, contact your St. Jude Medical representative or Technical Support (page 1).

ECG Input Cable. The ECG Input Cable, supplied by your St. Jude Medical Representative, can be used to display an ECG waveform generated by an external ECG device on the Merlin PCS, see Accessories (page 34). Plug the cables 6-pin connector into the ECG IN port in the storage compartment and the 3.5 mm mini-plug into the Signal Out port on the external unit. The cable also comes with adapters for a 1/4-inch phone plug and a BNC connector.

NOTE: For the best display, select Lead 1 from the ECG Configuration window on the programmer.

The signal attenuation is 1000:1. A 1.0 V signal from the source presents a 1.0 mV signal to the ECG Input port.

Output Devices

Video Out. The screen display of the Merlin™ PCS can be sent to any VGA video monitor that has a "VGA In" or "Line In" port. Connect the male end of a 15-pin video cable into the Display Out port on the left side of the Merlin PCS and plug the female end into the monitor port. Use a male/male adapter if the monitor uses a male connector plug.

External Printer. The Merlin PCS can print to some laser printers with USB connectors⁵. For a list of compatible printers, contact your St. Jude Medical Representative or Technical Support (page 1). To print to an external printer:

1. Connect the printer's USB cable to any of three USB ports on the Merlin PCS.
2. Turn on the printer and the Merlin PCS.
3. On the Merlin PCS screen, select the Tools button.
4. On the drop-down menu, select the Preferences button, then select the Printer tab.
5. Under "Selected Printer," select the External button.
6. Close the window and begin the device session.

⁵ The Merlin PSA cannot print to an external printer.

Printer Paper

The paper tray on the top of the Merlin™ PCS holds 200 sheets of fan-fold thermal paper (21 x 14 cm) (8.25 x 5.5 in)⁶. It is not necessary to advance the paper once it is loaded. The printer autofeeds the paper after a two-second delay.

The paper tray cover contains instructions on loading printer paper.

When the paper supply runs low, a paper-low mark can be seen on the paper and the Merlin PCS displays a paper-low message.

CAUTION: The thermal paper is heat-sensitive. Store it in a cool, dark environment.

The paper will last approximately 30 days under direct fluorescent light. The paper may discolor if it is stored at temperatures above 65°C or if it is exposed to high humidity, acetone, alcohol, ammonia, or other organic compounds. Make a photocopy of the printed report if you want to store it.

Software Download

Only St. Jude Medical personnel is authorized to perform a software download. If at any time you require a software download, contact Technical Support.

⁶ The printer also accepts 100-sheet paper packs.

Maintenance and Troubleshooting

Maintenance

Merlin™ PCS and Merlin PSA: Service must be performed at the factory or by an authorized service representative only. The Merlin PCS and its accessories, including the Merlin PSA, contain no user-serviceable parts.

NOTE: For information on the Merlin PSA maintenance and troubleshooting, see the Merlin PSA on-screen help.

Cleaning

To clean the exterior of the Merlin PCS, Merlin PSA, Merlin Antenna, and ECG cables, wipe the exterior surfaces with a damp cloth moistened with a mild soap.

To clean the Merlin PCS touch-screen display, spray a small amount of diluted glass cleaner on a soft cloth and gently wipe the screen. Dilute the glass cleaner by adding an equal amount of water.

CAUTION: Keep liquid out of the system's interior. Never spray liquid directly onto the Merlin PCS or its accessories.⁷

WARNING: Do not modify the Merlin PCS without the authorization of the manufacturer.

Programmer Self Test/Preventive Maintenance

When you turn on the Merlin™ PCS, the device performs a self-test of the internal hardware and software. If the test fails, the programmer displays a message explaining the cause of the failure.

Should the self-test fail, turn off the programmer, wait 30 seconds, and then restart the programmer. If the self-test fails again, contact Technical Support (page 1).

The programmer and its electronic accessories have been designed with digital circuitry and does not require calibration.

Telemetry Wand Sterilization

To sterilize the telemetry wand and/or cables, place the item in a gas-permeable package and sterilize it in ethylene oxide. Do not exceed 50°C (122°F). After sterilization, allow sufficient time for complete aeration of ethylene oxide prior to use. This process may be shortened by forced ventilation. Use biological controls to verify the effectiveness of sterilization.

CAUTION: Do not autoclave, radiation sterilize, or clean ultrasonically or with chemical solutions.

Do not attempt to sterilize the Merlin™ PSA, the PSA Wand, the Merlin™ Antenna, or the Merlin™ PCS itself.

NOTE: You can place the PSA Wand, the Merlin Antenna, or the inductive telemetry wand inside a sterile glove or bag.

⁷ Some PSA patient cables can be immersed in liquid. See the Merlin PSA on-screen help.

Troubleshooting

Start-Up Problems

Possible Causes

Failure to start is most commonly caused by a lack of power.

Solutions

- Check that the outlet is working and that the appropriate power cord is plugged in properly.
- Check that the appropriate power cord is plugged into the back of the Merlin™ PCS and that the power switch is on.
- Check both fuses. Remove the power cord, place a finger under the middle of the fuse holder (page 7), and lift the catch until the fuse holder clicks and pops out. If either fuse is blown, replace it with the appropriate fuse (see Electrical Specifications (page 25)), plug the unit in, and turn the power on. If the fuse blows again, contact St. Jude Medical's Technical Support department (page 1).

System Errors

If a software problem occurs, the Merlin™ PCS displays a message indicating that a system error has occurred and information indicating the origin of the problem. The system displays this message until you reboot by turning the Merlin PCS off and then on. Before turning the Merlin PCS off, record the information. All data from the current programming session will be lost. If the problem persists, contact St. Jude Medical's Technical Support department (page 1).

Power Failure

If power to the Merlin™ PCS is lost during a critical telemetry operation (for example, parameter programming), check the parameter settings and reprogram the device to ensure that the settings are at the desired values.

Lock-Up

If the screen freezes during normal operation or if the screen blacks out, a lockup may have occurred.

Possible Causes

Lockup may be caused by a variety of software execution problems, voltage transients, or input errors.

Solutions

If you suspect a lockup:

1. Remove the telemetry wand from the patient's chest to break telemetry.
2. Re-boot the Merlin™ PCS: Turn the power off. Wait five full seconds. Then turn the power on again.
3. If the Merlin PCS locks up again, reboot again. If the problem continues, contact your St. Jude Medical representative.

RF Communication Problems

RF Communication problems may be present if you interrogate an RF-enabled implantable device and:

- The Merlin™ PCS does not display the Ready To Connect to Device or Active RF Telemetry

icons (page 16).

- Few or no telemetry strength indicator LEDs are lit on the Merlin PCS and Merlin™ Antenna.
- The Merlin PCS displays a communication alert.

Make sure that the cable from the Merlin Antenna to the Merlin PCS is properly connected and the blue status LEDs on the Merlin Antenna are on. Follow the steps in RF Communication Setup (page 14). If the problem persists, consider the options in the section Suboptimal RF Communication (page 23) below.

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 of suboptimal radio communication:

Possible Causes

- The Merlin™ Antenna orientation/location is suboptimal.
- People or objects interfere with the communication between the Merlin Antenna and the device.
- The Merlin Antenna is too far away from the device.
- Someone is holding the Merlin Antenna.
- Other products in the vicinity are causing electromagnetic interference (EMI).
- The Merlin Antenna cable is wound around the Merlin Antenna.

Solutions

Try to optimize RF communication (increase the number of telemetry strength indicator LEDs):

- Move or reorient the Merlin™ Antenna slightly.
- Make sure that the space between the Merlin Antenna and the device is free from interfering objects/people.
- Move the Merlin Antenna closer to the device.
- Make sure that the front of the Merlin Antenna faces the implantable device.
- Power off or remove equipment that could cause EMI.
- Make sure the Merlin Antenna cable is not wound around the Merlin Antenna.
- Do not hold the Merlin Antenna.

If none of the above solutions solve the problem, avoid using RF communication and use the inductive telemetry wand instead.

Transportation

To move the Merlin™ PCS:

1. Make sure that all disk activity has stopped (the hard disk becomes silent).
2. Turn off the Merlin PCS.
3. Disconnect the external devices.
4. Disconnect the power cord.
5. Close the display. Make sure that the cover latch is closed.
6. Store the wand, Merlin™ Antenna, and ECG cables in the storage compartment or the pouch. Carefully wind the cables to avoid damage.

CAUTION: To avoid breakage, do not lift the Merlin PCS by its display or by the storage compartment lid.

Technical Data

Merlin™ PCS Specifications

The Merlin™ PCS is Class I, Type BF defibrillation-proof medical equipment⁸.

Mechanical

Length	50.8 cm (20.0 in)
Width	38.1 cm (15.0 in)
Height	13.3 cm (5.2 in)
Case material	High-impact plastic

Electrical

Input power (mains)	100-240 V~, 50/60 Hz, 3-wire (grounded)
Power supply	Medical grade (shielded)
AC power cord	3 m (10 ft)
Current consumption	3 A - 1.7 A
Fuse (2)	5x20 mm, fast-acting, 6.3 A, 250 V~, high-breaking capacity, cartridge fuse

Screen

Display	Active-matrix, thin-film transistor LCD, with backlight
Color	16-bit color
Screen type	Touch-screen
Screen size	38.1 cm (15 in) diagonal
Resolution	VGA (1024 x 768 pixels)

Printer

Printing method	Thermal
Thermal paper	21 x 14 cm (8.25 x 5.5 in) fanfold, 200 sheets
Printing speed	50 mm/s (1.97 in/s) (maximum speed)

ECG Cables

5-lead cable	4.14 m (13.6 ft) (Model 3626)
3-lead cable	4.14 m (13.6 ft) (Model EX3001)
ECG input cable	7.62 m (25.0 ft) (Model 3617)

Telemetry Wand

Cord	3.1 m (10.8 ft)
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⁸ The Merlin PCS, RF antenna and Merlin PSA comply with IEC 60601-1: 2005, ANSI/AAMI ES 60601-1: 2005 as well as UL60601-1: 2003, and CAN/CSA-C22.2 No. 601.1-M90, CAN/CSA-C22.2 No. 60601-1: 2008 (Inclusion of ANSI/AAMI ES 60601-1:2005 does not infer acceptance of the standard by OSHA).

Extension cord	1.22 m (4.0 ft)
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Merlin™ Antenna Specifications

The Merlin™ Antenna Model 3638 is Class I medical equipment⁹.

Mechanical

Length	5.0 cm (2.0 in)
Width	10.3 cm (4.0 in)
Height	15.3 cm (6.0 in)
Case material	High-impact plastic

Electrical

Input power (mains)	Powered by Merlin™ PCS
Input voltage	5.0 V
Maximum power consumption	0.5 A

Merlin™ Antenna Cable

Cable to Merlin™ PCS	2.9 m (9.5 ft)
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Essential Performance

The Merlin™ PCS provides access to SJM active implantable medical devices (pacemakers, CRT-Ps, ICDs, and CRT-Ds) but does not provide therapy. All therapy is delivered via the implanted device.

The Merlin PCS communicates with SJM implantable devices enabling operations such as programming, and the sending and retrieval of data between the Merlin PCS and the implanted device.

The Merlin PCS provides visual and mechanical interfaces to medical professionals so they may assess patient conditions and enable and assess the functioning of the implanted device.

NOTE: For single fault conditions, see Troubleshooting (page 22).

Data Security

St. Jude Medical takes a broad and deep approach to ensuring the safety, security and privacy of the patient information and data on our devices and systems connecting patients to healthcare providers and clinics. Patients, clinical staff, and hospital IT staff do not need to configure the pulse generator or take any special action, for example firewall use, to safeguard patient information and device data.

- The Merlin PCS programmer logs security events, for example a failed installation of programmer software, and stores these log files on disk. These files can then be analyzed by St. Jude Medical personnel during system forensics. They are not meant to be analyzed by the clinic's information technology personnel.

⁹ The Merlin PCS, RF antenna and Merlin PSA comply with IEC 60601-1: 2005, ANSI/AAMI ES 60601-1: 2005 as well as UL60601-1: 2003, and CAN/CSA-C22.2 No. 601.1-M90, CAN/CSA-C22.2 No. 60601-1: 2008 (Inclusion of ANSI/AAMI ES 60601-1:2005 does not infer acceptance of the standard by OSHA).

All safeguards for the devices will be provided throughout the stated warranty period or until a replacement product is available. In the rare event of a cybersecurity attack on the programmer that affects its ability to program the pulse generator, implanted device therapy will continue. St. Jude Medical encourages the clinics to allow only authorized healthcare providers to use the Merlin™ PCS, for example by requiring badged access to programmer locations. The cybersecurity bill of materials (CBOM) is available upon request.

Bluetooth Communication

For Bluetooth® Low Energy wireless communication, the Merlin PCS and St. Jude Medical implantable devices should be within 2.5 meters in normal use.

The programmer uses BLE with authentication methods to ensure that the programmer communicates only with St. Jude Medical authorized products. The integrity and confidentiality of all data-in-transit during BLE communication is protected by multiple levels of encryption.

Inductive Communication

Inductive Communication is a short-range communication channel that protects patient information by the proximity of the telemetry wand to the device.

Only authorized healthcare providers should place the inductive wand over the device.

RF Communication

To begin Merlin™ PCS use, the clinician places the programmer's inductive telemetry wand over the patient's implanted device and initiates communication. The inductive wand has a range of less than 7 centimeters in normal use. The Merlin PCS then switches to Medical Implant Communications Service (MICS)-based (RF) telemetry if the implanted device supports it. The RF telemetry range is less than 2.5 meters in normal use.

St. Jude Medical implantable devices introduced in 2010 and later use proprietary communications protocol based on magnetic induction and, for certain models, an MICS-based protocol. This protocol prevents unauthorized device communication and recording and protects sensitive patient information using:

- An authentication algorithm
- Data encryption

NOTE: The implanted device authenticates telemetry communication before accepting changes to programmed therapy.

Electromagnetic Compatibility

The Merlin™ PCS and the Merlin™ Antenna require special precautions with regard to electromagnetic compatibility (EMC) and should be used in accordance with the information provided in this manual.

The Merlin PCS and the Merlin Antenna comply with the requirements of the EMC international standard IEC 60601-1-2 when used with the cables listed in Accessories (page 34).

The Merlin PCS and the Merlin Antenna are intended for use in the electromagnetic environment specified in the following tables. The user should ensure that it is used in such an environment.

WARNING: The Merlin PCS and the Merlin Antenna are intended for use only by healthcare professionals. They comply with the limits for medical devices contained in IEC/EN 60601-1-2.

However, the Merlin PCS and the Merlin Antenna may cause radio interference or may

disrupt the operation of nearby equipment. It may be necessary to mitigate this effect by reorienting or relocating the receiving device or shielding the location.

Table 3. Guidance and manufacturer's declaration — electromagnetic emissions

Test	Compliance	Electromagnetic Environment — Guidance
RF Emission CISPR 11	Group 1	The Merlin™ PCS and the Merlin™ Antenna use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	Class A	The Merlin PCS and the Merlin Antenna are suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	The Merlin PCS and the Merlin Antenna are suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 4. Guidance and manufacturer's declaration — electromagnetic immunity

Test	IEC 60601 Test Level (Actual Level) ¹⁰	Electromagnetic Environment — Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact (±8 kV contact)	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	±15 kV air (±15 kV air)	
Electrical fast transient/burst IEC 61000-4-4 ¹¹	±1 kV for input/output lines (±1 kV for input/output lines)	Mains power quality should be that of a typical commercial or hospital environment.
	±2 kV for power supply lines (±2 kV for power supply lines)	
Surge IEC 61000-4-5	±1 kV line[s] to line[s] (±1 kV line[s] to line[s])	Mains power quality should be that of a typical commercial or hospital environment.
	±2 kV line[s] to earth (±2 kV line[s] to earth)	
Power Frequency	30 A/m	Power frequency magnetic fields

¹⁰ Figures in parentheses are the immunity compliance levels for each test.

¹¹ Applies only to the Merlin PCS.

Table 4. Guidance and manufacturer's declaration — electromagnetic immunity

Test	IEC 60601 Test Level (Actual Level) ¹⁰	Electromagnetic Environment — Guidance
(50/60 Hz) Magnetic Field, IEC 61000-4-8	(30 A/m)	should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, shorts, interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<p><5% U_T¹² [>95% dip in U_T] for 0.5 cycle (<5% U_T [>95% dip in U_T] for 0.5 cycle)</p> <p>40% U_T [60% dip in U_T] for 5 cycles (40% U_T [60% dip in U_T] for 5 cycles)</p> <p>70% U_T [30% dip in U_T] for 25 cycles (70% U_T [30% dip in U_T] for 25 cycles)</p> <p><5% U_T [>95% dip in U_T] for 5 s (<5% U_T [>95% dip in U_T] for 5 s)</p>	<p>Mains power quality should be that of a typical commercial or hospital environment.</p> <p>If the user of the Merlin™ PCS requires continued operation during power mains interruptions, it is recommended that the Merlin PCS be powered from an uninterruptible power supply or a battery.</p>

Table 5. Guidance and manufacturer's declaration - electromagnetic immunity (conducted RF and radiated RF)

Test	IEC 60601 Test Level ¹³	Immunity Compliance Level	Electromagnetic Environment - Guidance ¹⁴
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	(3 Vrms) [V1=3]	Portable and mobile RF communications equipment should be used no closer to any part of the Merlin™ PCS, RF Antenna, and Merlin™ PSA, including cables, than the recommended separation distance ¹⁵ calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m [E1=3]	


Recommended separation distance:

¹² U_T is the a.c. mains voltage level prior to application of the test level.

¹³ At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

¹⁴ These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 5. Guidance and manufacturer's declaration - electromagnetic immunity (conducted RF and radiated RF)

Test	IEC 60601 Test Level ¹³	Immunity Compliance Level	Electromagnetic Environment - Guidance ¹⁴
			$d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$
			<p>80 MHz to 800 MHz¹⁶</p>
			$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$
			<p>800 MHz to 2.7 GHz</p>
			$d = \left[\frac{7}{E_1} \right] \sqrt{P}$
			<p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p>
			<p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey*, should be less than the compliance level in each frequency range.** Interference may occur in the vicinity of equipment marked with the following symbol:</p>
			
			<p>*Electromagnetic site survey- Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength of the location in which the Merlin PSA is used exceeds the applicable RF compliance level above, the Merlin PSA should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Merlin PSA.</p>
			<p>**Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than $[V_1]/m$.</p>
			<p>NOTE: The Merlin PCS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Merlin PCS can help prevent electromagnetic interference by maintaining a minimum distance between portable and</p>

¹⁵ These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

¹⁶ At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

mobile RF communications equipment (transmitters) and the Merlin PCS as recommended in the table below, according to the maximum output power of the communications equipment. For transmitters rated at a maximum output power not listed in the table below, the recommended separation distance (**d**) in meters can be estimated using the equation applicable to the frequency of the transmitter, where **P** is the maximum output power rating of the transmitter in watts (**W**) according to the transmitter manufacturer.

Table 6. Recommended separation distances between portable and mobile communications equipment and the Merlin™ PCS

Rated maximum output power of transmitter (W)	Recommended separation distance according to frequency of transmitter (m) ¹⁷		
	150 kHz to 80 MHz	80 MHz to 800 MHz ¹⁸	800 MHz to 2.7 GHz
	$d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	$d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1.0	1.2	1.2	2.3
10.0	3.8	3.8	7.3
100.0	12	12	23

RF Operating Frequencies

Nearby or hidden equipment emitting strong magnetic fields, such as Radio-Frequency Identification (RFID) emitters, other medical and radio devices, etc., can interfere with the Merlin™ PCS inductive and RF communication, even if the other equipment complies with applicable emission requirements. If interference occurs, you can minimize its effect by reorienting or relocating the Merlin PCS or by shielding its location.

The operating characteristics of the Merlin PCS and its accessories are as follows:

Inductive Telemetry Wand

- RF Transmission – Carrier frequency below 100 kHz (inductive telemetry).
- RF Reception – Below 100 kHz (inductive telemetry).

Merlin™ Antenna

- 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, 95.1201-95.1219

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.

¹⁷ These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

¹⁸ At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE: Maintain a reasonable distance between other electronic equipment and the Merlin™ PCS and its accessories.

WARNING: This transmitter is authorized by rule under the Medical Implant Communications Service (part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids (that is, transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such aids, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Implant Communications Service.

Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

Operation of the Merlin™ Antenna requires that it is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device. Please refer to other parts of this manual for operating precautions and suggestions on how to minimize any interference to or from other electronic devices in the area.

Bluetooth Wireless Communication

- 2.402 to 2.4835 Ghz: The effective radiated power is below the limits as specified in:
 - Europe: EU EN 300 328
 - USA: FCC Part 15 Subpart C paragraph 15.247 FCC 47 CFR Part 95; 95.601-95.673 Subpart E

Table 7. Bluetooth® Low Energy wireless communication specifications

Power Supply Rating	3.2V DC
Modulation Type	GFSK
Modulation Technology	Bluetooth Low Energy
Transfer Rate	Up to 1Mbps
Operating Frequency	2.402 ~ 2.480GHz
Number of Channels	40
Output Power	3mW
Antenna Type	Type F printed on PCB
Antenna Connector	N/A
Purpose	Communication between implant and external control device
Type Symbol	LARN8-IO2A2402/2480TRO.003F1D40

Wireless Security

To begin Merlin™ PCS use, the clinician places the programmer's inductive telemetry wand over the patient's implanted device and initiates communication. The inductive wand has a range of

less than 7 centimeters in normal use. The Merlin PCS then switches to Medical Implant Communications Service (MICS)-based (RF) telemetry if the implanted device supports it. The RF telemetry range is less than 2.5 meters in normal use.

For Bluetooth® Low Energy wireless communication, the Merlin PCS and St. Jude Medical implantable devices should be within 2 meters in normal use.

St. Jude Medical implantable devices introduced in 2010 and later use proprietary communications protocol based on magnetic induction and, for certain models, an MICS-based protocol. This protocol prevents unauthorized device communication and recording and protects sensitive patient information using:

- An authentication algorithm
- Data encryption

NOTE: The implanted device authenticates telemetry communication before accepting changes to programmed therapy.

Quality of Service for Wireless Technology

The Merlin™ PCS communicates with St. Jude Medical implanted devices using both inductive and RF telemetry. Both telemetry methods operate within worldwide limits for emitted power.

Inductive telemetry operates:

- At 64 kilobits/s or lower
- Over a short range (less than 7 centimeters in normal use)

RF telemetry operates:

- Using the MICS band (402-405 MHz)
- At 200 kilobits/s or lower
- Over a short range (less than 2.5 meters in normal use)

During use, the Merlin PCS displays a signal strength indicator to help clinicians optimize telemetry wand placement. The transmitter automatically monitors and recovers from most communication errors, including data integrity errors and excessive latency. If wireless Quality of Service (QoS) is inadequate, the programmer automatically switches to inductive telemetry.

Bluetooth® Low Energy wireless communication operates:

- 2.402 to 2.4835 Ghz at 1 megabits/s or lower
- Over a short range (within 2 meters in normal use)

In order to comply with FCC/ISED RF Exposure requirements, the USB dongle must be installed to provide at least 7.5 mm separation from the human body at all times.

Wireless Communication Troubleshooting

If the Merlin™ PCS is unable to communicate with a St. Jude Medical implanted device:

- If using inductive telemetry or the RF wand, try re-orienting the wand.
- If using Bluetooth® Low Energy wireless communication, try plugging the USB dongle into a different USB port.
- Minimize the number of objects or people between the programmer and the patient.
- Avoid holding the inductive telemetry or RF wand.
- Move away from or turn the power off of equipment that could generate electromagnetic interference or strong magnetic fields.

Storage and Operating Conditions

Table 8. Storage and operating conditions

Property	Storage	Operating
Minimum Temperature (°C (°F))	-40 (-40)	10 (50)
Maximum Temperature (°C (°F))	70 (158)	40 (104)
Minimum Humidity (% non-condensing)	10	30
Maximum Humidity (% non-condensing)	90	75
Minimum Atmospheric Pressure (hPa)	500	700
Maximum Atmospheric Pressure (hPa)	1060	1060

CAUTION: Allow the unit to warm to ambient temperature after transporting it from a cold environment. If the unit was stored below 10°C (50°F), it may not function properly.

Disposal

Return the Merlin™ PCS and the Merlin™ Antenna to St. Jude Medical at the end of their operating lives.

The crossed-out trash can symbol marked on the programmer and the Merlin Antenna indicates that St. Jude Medical complies with the European Union's Waste Electrical and Electronic Equipment (WEEE) directive. That directive calls for separate collection and disposal of hazardous waste from electrical and electronic equipment. Sorting such waste and removing it from other forms of waste lessens the contribution of potentially toxic substances into municipal disposal systems and into the larger eco-system.

Accessories

Table 9. Clinical Accessories

Accessory	Model Number	Ordered Separately	Intended Use
5-lead ECG Cable	3626	Yes	Provide surface ECG signals for real-time viewing on the Merlin™ PCS
3-lead ECG Cable	EX3001	Yes	Provide surface ECG signals for real-time viewing on the Merlin PCS
ECG input Cable	3617	Yes	Provide surface ECG signals for real-time viewing on the Merlin PCS
Magnet	3630M	Yes	ICDs & CRT-D: Inhibits therapy when placed over the device Pacemakers & CRT-Ps: Used in battery voltage evaluation.
PSA Wand	3150	Yes	Assess the pacing and sensing performance of the lead system prior to pulse generator implantation, or during invasive lead system troubleshooting

Table 9. Clinical Accessories

Accessory	Model Number	Ordered Separately	Intended Use
PSA Wand Adapter	3615	Yes	Connect the PSA Wand to the Merlin PCS
Merlin™ Antenna	3638	Yes	Provides wireless radio frequency communication between the programmer and the device during a programmer session
Merlin Antenna Adapter ¹⁹	EX3190	No	Connect the PSA Wand model 3150 to the Merlin PCS
Merlin™ PSA	EX3100	Yes	Assess the pacing and sensing performance of the lead system prior to pulse generator implantation, or during invasive lead system troubleshooting
Telemetry Wand	3630	No	Provide inductive communication between the programmer and the device during a programmer session

Table 10. Non-Clinical Accessories

Accessory	Model Number	Ordered Separately
Bluetooth® USB dongle	BLU2000	Yes
Bluetooth® Low Energy USB dongle	BLU1000	Yes
Carrying Bag	3631	Yes
Flash Drive, USB	3621-XXX ²⁰	Yes
Floppy Drive, External	3620	Yes
Keyboard, External	3618-XX ²¹	Yes
Power Cord	3145	No
Merlin Storage Pouch	EX3160	Yes
Shoulder Strap	3622	Yes
Thermal Paper	3643	No
USB to Serial 9-pin Adapter	3623	Yes
Video Cable and Gender Adapter	3134	Yes

¹⁹ Included with Merlin PSA.






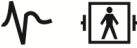

²⁰ XXX indicates the available memory in MB.


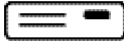

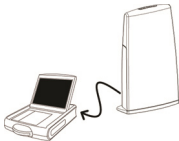







²¹ XX indicates the keyboard's country code.











Symbols

For information on symbols pertaining to the Merlin™ PSA Model EX3100 and its accessories, please refer to the Merlin PSA on-screen help.

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
	Part number
	<p>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.</p> <p>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.</p> <p>This product operates between 9 and 200 kHz with an H-field strength of less than 25 dBµA/m at 10 m.</p> <p>This product operates in the 2.4-2.4835 GHz band with an RF output power of less than 0.45 mW EIRP.</p> <p>This product operates in the 402-405 MHz band with an effective radiated power of less than 25 µW ERP.</p>
	<p>Affixed to this device in accordance with European Council Directives 2002/96/EC.</p> <p>These directives call for separate collection and disposal of electrical and electronic equipment. Sorting such waste and removing it from other forms of waste lessens the contribution of potentially toxic substances into municipal disposal systems and into the larger ecosystem.</p> <p>Return the device to St. Jude Medical at the end of its operating life.</p>
	Display Out port
	ECG Cable
ECG IN	ECG IN cable port
	Ethernet port
	

Symbol	Description
	Flash drive
 F6.3AH250V~	Fuse
	Merlin Patient Care System Model 3650
	An accessory to Merlin Patient Care System Model 3650
	Off
	On
PSA	Pacing system analyzer wand port
	Power cord
	Printer paper
 manuals.sjm.com	Follow instructions for use on this website
RF TELEMETRY	RF Telemetry port
	Telemetry wand
TELEMETRY WAND	Telemetry wand port
	

Symbol	Description
RF TELEMETRY 	Connect to the RF Telemetry port on the Merlin PCS
	TÜV Listed, US and Canada. Conforms to UL60601-1. Certified to CAN/CSA C22.2 No.601.1-M90 (Symbol is colored blue.)
	Manufacturing facility
Made in USA.	Made in USA
	Malaysian Communication and Multimedia Commission (MCMC) certification mark for products meeting applicable MCMC Technical Codes
	Australian Communications and Media Authority (ACMA) and New Zealand Radio Spectrum Management (RSM) Regulatory Compliance Mark (RCM)
	This equipment is certified for type certification pursuant of Article 38-24 of the Japan Radio Law
	Korea Certification mark for electrical devices
FCC ID: RIASJMRFANT	FCC Identification Number for Merlin Antenna, Model 3638
IC: 7067A-SJMRFANT	Industry Canada certification for Merlin Antenna, Model 3638
	USB port
	Product literature
	Importer
WI-FI	Wi-Fi port
FCC ID: RIA-MRLN3650ACC	FCC Identification Number for BLU2000
IC: 7067A-MRLN3650ACC	Industry Canada certification for BLU2000



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