Merlin™ 2 Patient Care System

Merlin™ 2 PCS, Model MER3700

User's Manual

Abbott

Contents

Introduction

The Merlin™ 2 Patient Care System (Merlin™ 2 PCS) Model MER3700 User's Manual describes the components, setup, maintenance, accessories, and technical data of the Merlin 2 PCS. For information on St. Jude Medical implantable devices, select the ? button from any device session screen.

The Merlin™ Antenna Model 3638 is a dedicated radio antenna accessory that enables radio frequency (RF) communication between the Merlin 2 PCS and St. Jude Medical implantable devices with RF communication capability. This manual describes the components, setup, maintenance, and technical data of the Merlin Antenna together with the Merlin 2 PCS.

The Merlin™ PSA Model EX3100 is a pacing analyzer for use with the Merlin 2 PCS to evaluate St. Jude Medical implantable devices and leads. More information on this device can be found in the on-screen help.

Indications

The Merlin™ 2 PCS (Merlin 2 PCS Programmer, Model MER3700, and Merlin 2 PCS Software, Model MER3400) 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 resynchornization therapy system.

Intended Use

The Merlin™ 2 PCS (Merlin 2 PCS Programmer, Model MER3700, and Merlin 2 PCS Programmer Software, Model MER3400) is a portable, dedicated programming system designed to interrogate, program, display data from, and test St. Jude Medical implantable medical devices during implant and follow up.

The Telemetry Wand Model 3630W is intended to provide inductive communication between the programmer and the implantable medical device during a programmer session.

The Merlin 2 PCS ECG function when using the ECG cable Models 3617, 3626, and EX3001 is only intended to support activities related to implanting, programming, and monitoring St. Jude Medical implantable medical devices.

The Merlin Antenna Model 3638 is a dedicated radio antenna accessory intended to enable wireless radio frequency (RF) communication between the Merlin 2 PCS and St. Jude Medical implantable medical devices with RF communication capability during a programmer session.

The Merlin PSA Model EX3100 is a pacing analyzer system intended for use with the Merlin 2 PCS to evaluate St. Jude Medical implanted leads for integrity, and for pacing and sensing performance during surgical procedures related to the implanted system. Refer to the Merlin PSA Help Manual for additional details.

Contraindications

There are no contraindications to the use of the Merlin™ 2 PCS (Merlin 2 PCS Programmer, Model MER3700, and Merlin 2 PCS Software, Model MER3400) to interrogate, program, display data from, and test implantable medical devices during implant and follow up.

Potential Adverse Events

Possible adverse events include:

- Arrhythmia
- Electric Shock
- Prolonged Surgery
- Discomfort
- Infection
- Injury (for example, Burn)

Technical Support

Abbott 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)
- medical.abbott/manuals

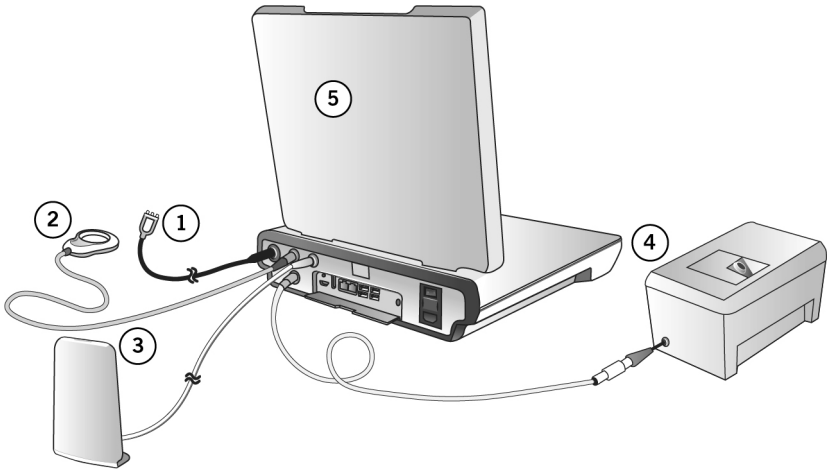
For additional assistance, call your local Abbott Medical representative.

Merlin™ 2 PCS Features

Figure 1. Merlin™ 2 Patient Care System

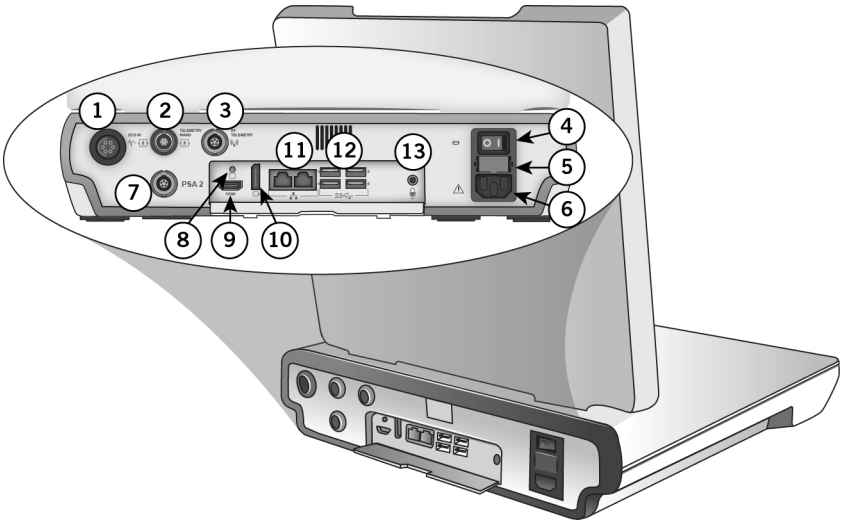
1. **NFC (Near Field Communication) Logo.**
2. **Fold-away Handle.**
3. **Two USB Ports.** For connection to any USB compatible accessory supported by the system. Top port is Port 1; bottom port is Port 2.
4. **VVI Button.** Select this button to reprogram a device to high-output Emergency VVI settings. See Emergency Operation (page 15).
5. **Shock Button.** Select this button to display the Shock screen (for ICDs). See Emergency Operation (page 15).
6. **Display Latch.**

Figure 2. Connections between the Merlin™ 2 PCS, and the Merlin Antenna, Telemetry Wand, Merlin PSA, and ECG Cables



1. **ECG Cable connected to the ECG input port.** See Merlin 2 PCS Setup (page 7).
2. **Inductive Telemetry Wand connected to the telemetry wand inductive port.** See Merlin 2 PCS Setup (page 7).
3. **Merlin Antenna connected to the RF telemetry port.** See RF Communication Setup (page 10).
4. **Merlin PSA connected to the PSA port.** See Merlin 2 PCS Setup (page 7).
5. **Merlin 2 PCS**

Figure 3. Back side



1. **ECG input port.** See Merlin™ 2 PCS Setup (page 7).
2. **Telemetry wand (inductive) port.** For connection to inductive telemetry devices. See Merlin 2 PCS Setup (page 7).
3. **RF telemetry port.** For connection to the Merlin™ Antenna. See RF Communication Setup (page 10).
4. **On/Off switch**
5. **Fuse holder**
6. **Power receptacle**
7. **PSA port.** For connection to the Merlin PSA Model EX3100. See Merlin 2 PCS Setup (page 7).
8. **Function button.** For use by Abbott Medical personnel only.
9. **HDMI port.** For connection to an external video monitor. See External Device Connection (page 15).
10. **Display port connector** (DVI connection)
11. **Ethernet ports**
12. **Four USB ports.** For connection to any USB compatible accessory supported by the system. Top left port is Port 3; bottom left port is Port 4; top right port is Port 5; bottom right port is Port 6. See External Device Connection (page 15), RF Communication Setup (page 10), and Bluetooth® Wireless Communication Setup (page 13).
13. **Microphone jack input port**

Setup Instructions

Merlin™ 2 PCS Setup

WARNING: 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™ 2 PCS to communicate with a device that uses inductive telemetry see Setup for Inductive Telemetry Devices (page 9). To set up the Merlin 2 PCS with a device that uses RF communication, see RF Communication Setup (page 10). To set up the Merlin 2 PCS with a device that uses Bluetooth® Low Energy wireless communication, see Bluetooth Wireless Communication Setup (page 13).

CAUTION: Do not use if the programmer, cable, or any accessories that connect to the programmer show visible signs of damage.

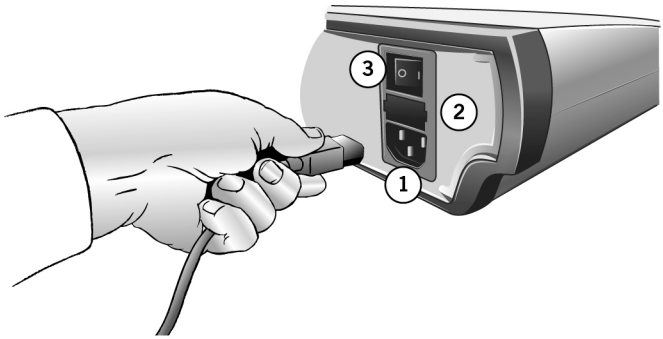
1. Place the programmer and accessories on a clean, stable, and well-lit surface. Do not place any implantable devices on the inside surface of the programmer when the lid is in the open position and you are attempting to communicate with the Merlin 2 PCS. See the Figure "Merlin 2 Patient Care System" (page 3).

   CAUTION: Ensure the programmer is positioned so the vents are not blocked. Blocking the vents may lead to overheating, which may cause the programmer to shut down.

2. Plug the power cord into the power receptacle and then into grounded mains outlet.

   CAUTION: The Merlin 2 PCS must be connected to a grounded mains outlet with a hospital-grade cable.

Figure 4. 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 2 PCS (see below).

   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 (see figure below).

With the 3-lead ECG cable, attach electrodes to the Right Arm, Left Arm, and Right Leg (see figure below).

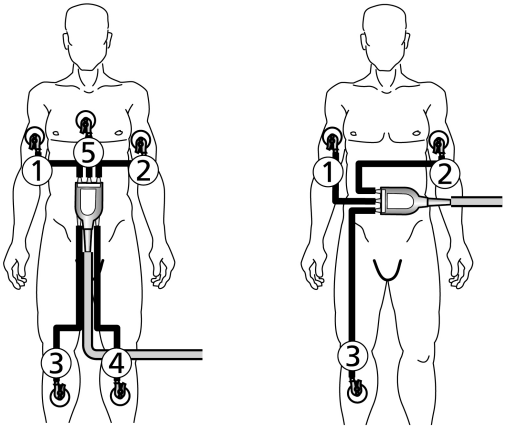
CAUTION: Use only the ECG cables listed in the Accessories table (page 30) of this manual to protect the Merlin 2 PCS against possible damage from defibrillator shock.

Do not use the programmer 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 2 PCS programmer screen.

4. Attach the ECG leads to the appropriate electrodes.

Figure 5. 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)

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

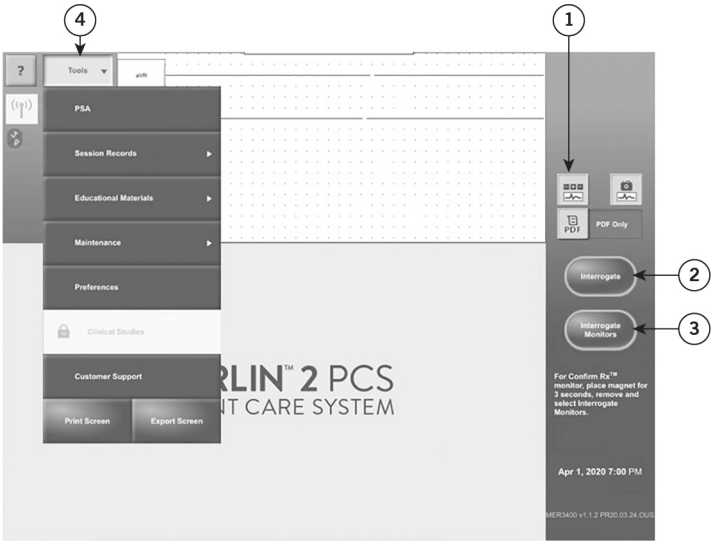
5. Turn on the power.
6. Open the screen display by releasing the latch.

   Use your fingertip or a soft-tip stylus to contact the touchscreen. Do not use pens or pencils

to contact the touchscreen. The touchscreen has a special coating that can be damaged by contact with other hard surfaces.

7. On the Merlin™ 2 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 6. The Adjust Display button, the Interrogate button, and the Tools Menu



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

Setup for Inductive Telemetry Devices

1. Place the inductive telemetry wand over the patient's device.

   NOTE: For devices that use inductive telemetry, use only the Model 3630W telemetry wand with the Merlin™ 2 PCS.

2. Select the Interrogate button for pacemakers, ICDs, and CRTs.

3. Use the telemetry strength indicator 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 stronger signal strength.

Setup for Insertable Cardiac Monitors

1. Place the magnet on the patient's device for 3 seconds and remove.

2. Select the Interrogate Monitors button.
3. The programmer will look for advertising pulses from the Confirm Rx™ Insertable Cardiac Monitor.

Merlin™ PSA Model EX3100 Setup

Connect the Merlin™ PSA Model EX3100 into the PSA port on the Merlin 2 PCS

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 2 PCS and to the Merlin PSA user's manual.

Figure 7. Merlin™ PSA Model EX3100

1. Functional Status LEDs
2. Pace and Sense LEDs
3. Receptacle for patient cable or patient-cable adapter
4. Connector to Merlin 2 PCS

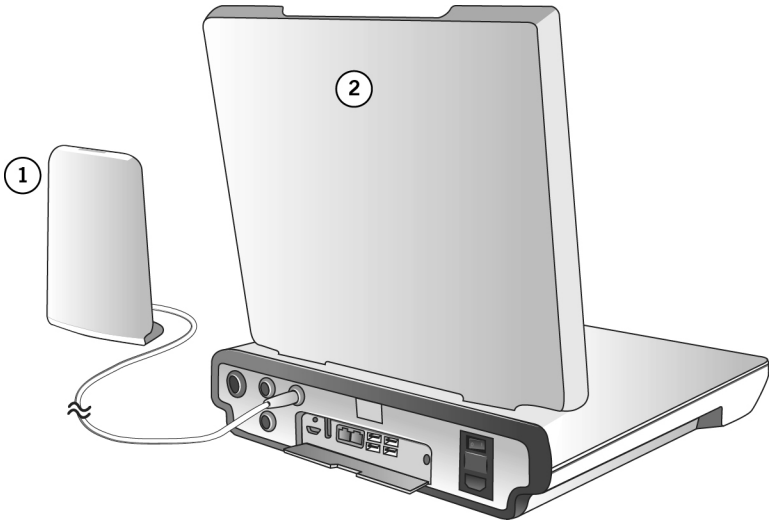
RF Communication Setup

Some St. Jude Medical implantable devices can communicate with the Merlin™ 2 PCS via radio frequency (RF), which allows for a greater distance between the device and the Merlin 2 PCS. To establish RF communication, follow the instructions below.

1. Connect the Merlin™ Antenna to the RF Telemetry port on the back of the Merlin 2 PCS (see figure below).

   NOTE: Connect the Merlin Antenna only to the RF Telemetry port on the back of the programmer. Do not connect the Merlin Antenna to any other ports.

Figure 8. Connection between the Merlin™ Antenna and the Merlin™ 2 PCS

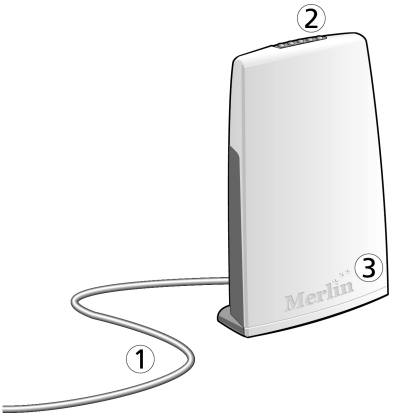


1. Merlin Antenna
2. Merlin 2 PCS

2. 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.
3. Follow steps 1 through 6 in the Merlin 2 PCS Setup (page 7).

When the Merlin 2 PCS is turned on, the green telemetry strength indicator and blue status LEDs on the Merlin Antenna will light, indicating the unit is powered and operational.

Figure 9. 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

When the programmer startup screen appears, the "Ready to Connect to Device" icon appears under the Tools menu button. See RF Telemetry Icons (page 13).

4. Place the inductive telemetry wand over the patient's device.
5. On the programmer, select the Interrogate button.

   After the interrogation is complete, the Merlin™ 2 PCS displays the FastPath™ Summary Screen. The "Active RF Telemetry connection" icon appears under the Tools menu button. See RF Telemetry Icons (page 13).

   The telemetry strength indicators on the Merlin Antenna 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 stronger signal strength. If necessary, relocate the Merlin Antenna for better communication. See Suboptimal RF Communication (page 19).
6. Once RF telemetry is established, you may remove the inductive telemetry wand from the patient.
7. Begin the programming session.

   CAUTION: Position the Merlin Antenna at least 20 cm (8 in) away from the patient and any other devices that might interfere with the Merlin Antenna's operation.

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

RF Telemetry Icons

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

The Merlin™ 2 PCS is Bluetooth® Low Energy wireless compatible. Bluetooth is built into the Merlin 2 PCS. This allows for communication between the Merlin 2 PCS and an implanted device that supports Bluetooth Low Energy wireless communication without the need for a dongle.

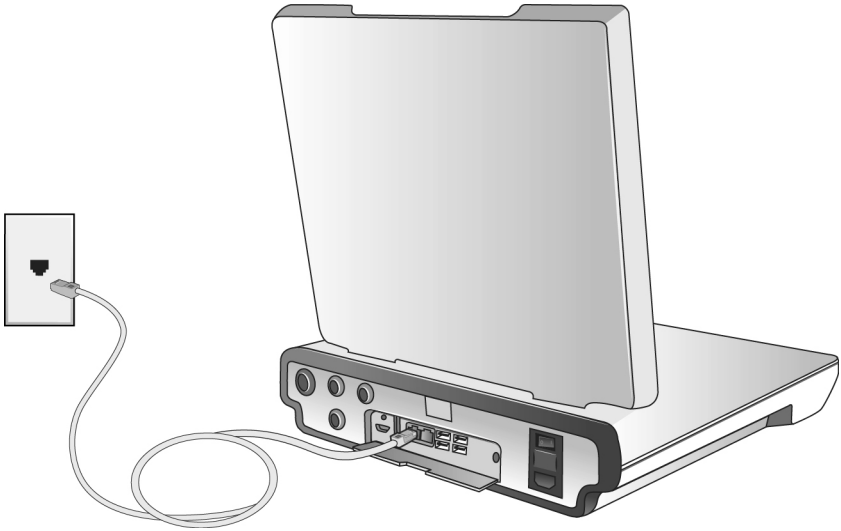
- Do not put anything between the Merlin 2 PCS and the implanted device. People and objects may interfere with communication between the Merlin 2 PCS and the device.
- Confirm that the Bluetooth icon is visible on the Merlin 2 PCS Start-up screen.
- Follow the instructions provided on the Start-up screen to begin communication between the Merlin 2 PCS and an implanted device that supports Bluetooth Low Energy wireless communication.
- Do not use a Bluetooth dongle.

CAUTION: For optimal Bluetooth Low Energy wireless communication, the Merlin 2 PCS and St. Jude Medical implantable devices should be within 2 m (6.6 ft) of each other in normal use. Do not operate a device that may generate interference, such as a powerful microwave oven, when utilizing Bluetooth Low Energy wireless communication.

Network Hardware Connection

You can connect the Merlin™ 2 PCS to a network using the wired ethernet network connection on the back of the programmer.

Figure 10. Network hardware connection



Shut Down

To power down the Merlin™ 2 PCS:

1. Remove any cables connecting the Merlin 2 PCS to the patient.
2. Move the On/Off switch to the Off position.

The Merlin 2 PCS has a power switch that, when shut off, isolates both conductors of the supply mains simultaneously.

Emergency Operation

Figure 11. 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[1].
- **VVI.** Select this button to automatically reset the device to predefined high-output settings.[2]

External Device Connection

The Merlin™ 2 PCS can be connected to three types of external devices: data storage devices, input devices, and output devices.

NOTE: Not every commercially available external device is guaranteed to operate with the Merlin 2 PCS. External devices that have been tested and verified to operate are listed in the Accessories table (page 30).

WARNING: The ports on the Merlin 2 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.

CAUTION: Additional non-medical electrical equipment connected to medical electrical equipment, which includes equipment connected to the input or output ports, 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, Clause 16). Anyone who connects additional equipment to medical electrical equipment is configuring a medical system and is responsible for the compliance of the system. If in doubt, contact the Abbott Medical Technical Support department or your local Abbott Medical representative.

Data Storage Devices

Only external storage devices can be connected to the six USB ports on the Merlin™ 2 PCS. The devices can be used to save session records, screen captures, and database records that will be uploaded to patient-tracking software.

Flash drive. A flash drive can be plugged into the Merlin 2 PCS to store data from patient devices.

[1] Emergency Shock is not available during a PSA session.
[2] Emergency VVI settings for each device are defined in the device's User's Manual.

Data Export. Data Export applies to data that displays patient information, such as screen captures, data base records, and pdf reports. Data Export is nominally set to encrypt exported data (see Personal Identification Number). Session Records and Programmer Logs are automatically encrypted, and only Abbott Medical personnel can access the data.

You can view Data Export settings in Preferences from the Tools menu To adjust the patient data export setting, contact Technical Support.

Personal Identification Number (PIN). To export data you must create a Personal Identification Number. The PIN cannot:

- Repeat a number six times in succession, for example 555555
- Have consecutive numbers in either ascending or descending order, for example 123456 or 654321

  NOTE: Be sure to document the PIN selected. The PIN will be required later to access the data from the flash drive.

Input Devices

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

Mouse. A USB mouse can be connected to any of the six USB ports for use in conjunction with the on-screen keyboard while in the presence of a patient. Do not use a third-party device that enables long range control to send remote mouse input, for example over the Internet. For a list of compatible mice, contact your Abbott Medical representative or Technical Support (page 2).

ECG Input Cable. The ECG Input Cable, supplied by your Abbott Medical Representative, can be used to display an ECG waveform generated by an external ECG device on the Merlin™ 2 PCS. See the Accessories table (page 30). Plug the cable's 6-pin connector into the ECG IN port in the back of the Merlin 2 PCS, and the 3.5 mm mini-plug into the Signal Out port on the external unit.

NOTE: For the best display, select Lead 1 from the ECG Configuration window on the Merlin 2 PCS.

Output Devices

Video Out. The screen display of the Merlin™ 2 PCS can be sent to a video monitor that supports HDMI capabilities for use while in the presence of a patient. Connect one end of the video cable into the HDMI port on the rear of the Merlin 2 PCS, and plug the other end into the monitor port.

External Printer. The Merlin 2 PCS can print to some external printers with USB connectors. For a list of compatible printers, contact Technical Support (page 2).

1. Connect the printer's USB cable to any of the six USB ports on the Merlin 2 PCS.
2. Turn on both the printer and the Merlin 2 PCS.
3. On the Merlin 2 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 & PDF button.
6. Close the window and begin the device session.

Maintenance and Troubleshooting

Maintenance

Merlin™ 2 PCS and Merlin PSA: Service must be performed at the factory or by an authorized service representative only. The Merlin 2 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 or Disinfecting

To clean or disinfect the exterior of the Merlin™ 2 PCS, Merlin PSA, Merlin Antenna, and ECG cables:

- Wipe the case with a damp micro-fiber cloth moistened with a mild cleaning solution. Recommended solutions include: Hand soap or dishwashing soap, isopropyl alcohol (concentration less than or equal to 90%), chlorine beach, or hydrogen peroxide.

To clean or disinfect the Merlin 2 PCS touch-screen display:

- To clean: Gently wipe the touchscreen with a damp micro-fiber cloth.
- To disinfect: Wipe the touchscreen with a damp micro-fiber cloth moistened with a mild cleaning solution. Recommended solutions include: Isopropyl alcohol (concentration less than or equal to 90%), chlorine beach, or hydrogen peroxide.

NOTE: High concentration alcohol is not recommended because it could damage the touchscreen.

- Do not spray the solution directly onto the touchscreen, and do not allow the cleaning solution to puddle at the edges of the touchscreen.

WARNING: Keep liquid out of the system's interior, and never spray liquid directly onto the Merlin 2 PCS or its accessories; otherwise damage may result. If liquid should get into the system's interior, contact your local Abbott Medical representative. Damage could occur that is not visible.

CAUTION: Do not modify the Merlin 2 PCS without the authorization of the manufacturer.

Programmer Self Test/Preventive Maintenance

When you turn on the Merlin™ 2 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 2).

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

Telemetry Wand Sterilization

To sterilize the telemetry wand 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.

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

Do not attempt to sterilize the Merlin™ PSA, the Merlin Antenna, or the Merlin 2 PCS itself.

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

Troubleshooting

Start-Up Problems

Possible Causes

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

Solutions

- Check that the grounded mains outlet is working and the Merlin™ 2 PCS power cord (or other medical grade power cord) is plugged in properly.
- Check that the Merlin 2 PCS power cord (or other medical grade power cord) is plugged into the back of the Merlin 2 PCS and the Merlin 2 PCS power switch is on.
- Check both fuses. Remove the power cord, place a finger under the middle of the fuse holder, 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 21)), plug the unit in, and turn on the power. If the fuse blows again, contact the Abbott Medical Technical Support department (page 2).

System Errors

If a software problem occurs, the Merlin™ 2 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 2 PCS off and then on. Before turning the Merlin 2 PCS off, record the information. All data from the current programming session will be lost. If the problem persists, contact the Abbott Medical Technical Support department (page 2).

Power Failure

If power to the Merlin™ 2 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™ 2 PCS: Turn off the power. Wait five full seconds. Turn on the power

again.

3. If the Merlin 2 PCS locks up again, reboot again. If the problem continues, contact your Abbott Medical representative.

RF Communication Problems

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

- The Merlin™ 2 PCS does not display the Ready To Connect to Device or Active RF Telemetry icons (page 13).
- Few or no telemetry strength indicators are lit on the Merlin™ Antenna.
- The Merlin 2 PCS displays a communication alert.

Make sure that the cable from the Merlin™ Antenna to the Merlin 2 PCS is properly connected, and the blue status LEDs on the Merlin Antenna are on. Follow the steps in RF Communication Setup (page 10). If the problem persists, consider the options in the section Suboptimal RF Communication (page 19) below.

Suboptimal RF Communication

The Merlin™ 2 PCS indicates the quality of the RF communication by the telemetry strength indicators on both the programmer and the Merlin™ Antenna. Below is a list of possible causes of suboptimal radio communication:

Possible Causes

- The Merlin™ Antenna orientation or location is suboptimal.
- People or objects are interfering 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 nearby 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 or 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 nearby 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.

BLE Communication Problems

BLE Communication problems may be present if you interrogate a BLE-enabled implantable device and:

- The Merlin™ 2 PCS does not display the Ready To Connect to Device or Active BLE

Telemetry icons.

- The Merlin 2 PCS displays a communication alert.

Follow the steps in Bluetooth® Wireless Communication Setup (page 13). If the problem persists, consider the options in the section Suboptimal BLE Communication below (page 20).

Suboptimal BLE Communication

Below is a list of possible causes of suboptimal radio communication:

Possible Causes

- The Merlin™ 2 PCS orientation or location is suboptimal.
- People or objects are interfering with the communication between the Merlin 2 PCS and the device.
- The Merlin 2 PCS is too far away from the device.
- Other products nearby are causing electromagnetic interference (EMI).

Solutions

Try to optimize BLE communication:

- Move or reorient the Merlin™ 2 PCS slightly.
- Make sure that the space between the Merlin 2 PCS and the device is free from interfering objects or people.
- Move the Merlin 2 PCS closer to the device.
- Power off or remove equipment nearby that could cause EMI.

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

NOTE: If you disable the BLE to use the inductive telemetry wand it may take up to seven seconds to connect. You cannot deliver emergency shock during that time.

Inductive Communication Problems

If there are any communication problems with the inductive telemetry wand:

- Try re-orienting the wand.
- Avoid holding the wand.
- Try moving the wand farther away from the implanted device.
- Move away or turn off the power from equipment that could generate electromagnetic interference or strong magnetic fields.

Transportation

To move the Merlin™ 2 PCS:

1. Turn off the Merlin 2 PCS.
2. Disconnect the external devices.
3. Disconnect the power cord.
4. Close the display. Make sure that the cover latch is closed.

CAUTION: To avoid breakage, do not lift the Merlin 2 PCS by its display.

Technical Data

Merlin™ 2 PCS Specifications

The Merlin™ 2 PCS is Class I, Type BF defibrillation-proof medical equipment.

Mechanical

Length	36.3 cm (14.3 in)
Width	34.9 cm (13.75 in)
Height	7.4 cm (2.9 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	0.5 / 0.25 A
Fuse	5x20 mm, slow-acting, 2.5 A, 250 V~, low-breaking capacity, cartridge fuse

Screen

Display	LED
Color	16-bit color
Screen type	Touchscreen
Screen size	38.1 cm (15 in) diagonal
Resolution	VGA (1024 x 768 pixels)

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)
Extension cord	1.22 m (4.0 ft)

Merlin™ Antenna Specifications

The Merlin™ Antenna Model 3638 is Class I medical equipment[3].

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™ 2 PCS
Input voltage	5.0 V
Maximum power consumption	0.5 A

Merlin™ Antenna Cable

Cable to Merlin™ 2 PCS	2.9 m (9.5 ft)

Essential Performance

The Merlin™ 2 PCS communicates with implantable devices (Implantable Cardioverter-Defibrillators (ICDs), pacemakers, Cardiac Resynchronization Therapy (CRT) devices, and Implantable Cardiac Monitors (ICMs)). Communication enables operations such as programming, and the sending and retrieval of data between the Merlin 2 PCS and the implanted device. The Merlin 2 PCS provides access to the implantable device but does not provide therapy: all therapy is delivered via the implantable device.

The Merlin 2 PCS provides visual and mechanical interfaces to medical professionals so that they may assess patient conditions and the functioning of the implantable device.

As per the risk analysis, there have been no unacceptable risks identified in evaluating the clinical functions of the product and associated risks. The following safety guidelines should be kept under consideration:

- During external interference, such as electromagnetic interference, the programmer will not undergo any permanent damages that prevents it from communicating with the implantable device, although the programmer display and communication speed may be affected. The programmer is able to reestablish and recover display and communication speeds, either automatically or with manual intervention, once the external interreference is removed.
- The programmer is not expected to function if the unit is damaged.

  NOTE: For single fault conditions, see Troubleshooting (page 18).

[3] The Merlin 2 PCS, Merlin RF antenna, and Merlin PSA comply with IEC 60601-1 + A1: 2012, Ed 3.1, ANSI/AAMI ES60601-1: 2005/A1: 2012 in addition to UL60601-1: 2003, and CAN/CSA - C22.2 NO. 60601-1:14. (Inclusion of ANSI/AAMI ES 60601-1:2005 does not infer acceptance of the standard by OSHA).

Data Security

Abbott 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™ 2 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 Abbott Medical personnel during system forensics. They are not meant to be analyzed by the clinic's information technology personnel.

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. Abbott Medical encourages the clinics to allow only authorized healthcare providers to use the Merlin 2 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™ 2 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™ 2 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 2 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™ 2 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 2 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 the Accessories table (page 30).

The Merlin 2 PCS and the Merlin Antenna are intended for use in the electromagnetic environment specified in the following tables. The user should ensure that they are used in such an environment.

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

However, the Merlin 2 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™ 2 PCS and the Merlin Antenna use RF energy only for its internal function. Therefore, the RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	Class A	The Merlin 2 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 2 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)[4]	Electromagnetic Environment — Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact (±8 kV contact) ±15 kV air (±15 kV air)	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

[4] Figures in parentheses are the immunity compliance levels for each test.

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

Test	IEC 60601 Test Level (Actual Level)[4]	Electromagnetic Environment — Guidance
Electrical fast transient/burst IEC 61000-4-4[5]	±1 kV for input/output lines (±1 kV for input/output lines) ±2 kV for power supply lines (±2 kV for power supply lines)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line[s] to line[s] (±1 kV line[s] to line[s]) ±2 kV line[s] to earth (±2 kV line[s] to earth)	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency (50/60 Hz) Magnetic Field, IEC 61000-4-8	30 A/m (30 A/m)	Power frequency magnetic fields 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	<5% U_T [6][>95% dip in U_T] for 0.5 cycle (<5% U_T [>95% dip in U_T] for 0.5 cycle) 40% U_T [60% dip in U_T] for 5 cycles (40% U_T [60% dip in U_T] for 5 cycles) 70% U_T [30% dip in U_T] for 25 cycles (70% U_T [30% dip in U_T] for 25 cycles) <5% U_T [>95% dip in U_T] for 5 s (<5% U_T [>95% dip in U_T] for 5 s)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Merlin™ 2 PCS requires continued operation during power mains interruptions, it is recommended that the Merlin 2 PCS be powered from an uninterruptible power supply or a battery.

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

Test	IEC 60601 Test Level[7]	Immunity Compliance Level	Electromagnetic Environment - Guidance[8]

[5] Applies only to the Merlin 2 PCS.
[6] UT is the a.c. mains voltage level prior to application of the test level.
[7] At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
[8] 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[7]	Immunity Compliance Level	Electromagnetic Environment - Guidance[8]
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™ 2 PCS, RF Antenna, and Merlin PSA, including cables, than the recommended separation distance[9] calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ **80 MHz to 800 MHz[10]** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ **800 MHz to 2.7 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 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). 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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m [E1=3]	

*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

[9] These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
[10] At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

Test	IEC 60601 Test Level[7]	Immunity Compliance Level	Electromagnetic Environment - Guidance[8]
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.			
**Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than [V_1]V/m.			
NOTE: The Merlin 2 PCS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Merlin 2 PCS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Merlin 2 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™ 2 PCS

Rated maximum output power of transmitter (W)	Recommended separation distance according to frequency of transmitter (m)[11]		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz[12] $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.7 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
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™ 2 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 2 PCS or by shielding its location.

[11] These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
[12] At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

The operating characteristics of the Merlin 2 PCS and its accessories are as follows:

Inductive Telemetry Wand

- RF Transmission – Carrier frequency 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.

NOTE: Maintain a reasonable distance between other electronic equipment and the Merlin™ 2 PCS and its accessories.

CAUTION: 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

Quality of Service for Wireless Technology

The Merlin™ 2 PCS communicates with St. Jude Medical implanted devices using inductive, RF, or BLE telemetry. All 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)

Bluetooth® Low Energy wireless communication operates:

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

During use, the Merlin 2 PCS inductive telemetry wand 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.

Transportation and Handling Conditions

Table 7. Transportation and handling conditions

Minimum Temperature (°C (°F))*	-25 (-13)
Maximum Temperature (°C (°F))*	70 (158)
Minimum Humidity (% non-condensing)*	10
Maximum Humidity (% non-condensing)*	90
Minimum Atmospheric Pressure (hPa)	500
Maximum Atmospheric Pressure (hPa)	1060

*Found on box label

Operation and Storage Conditions

Table 8. Operation and storage conditions

Minimum Temperature (°C (°F))*	10 (50)
Maximum Temperature (°C (°F))*	35 (95)
Minimum Humidity (% non-condensing)*	30
Maximum Humidity (% non-condensing)*	75
Minimum Atmospheric Pressure (hPa)	700
Maximum Atmospheric Pressure (hPa)	1060

*Found on Merlin™ 2 PCS label

Disposal

Return the Merlin™ 2 PCS and the Merlin Antenna to Abbott Medical at the end of their operating lives.

The crossed-out trash can symbol marked on the Merlin 2 PCS and the Merlin Antenna indicates that Abbott 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

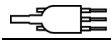
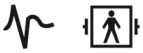
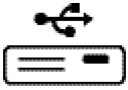
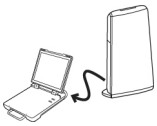
Accessory	Model Number	Ordered Separately	Intended Use
5-lead ECG Cable	3626	Yes	Provides surface ECG signals for real-time viewing on the Merlin™ 2 PCS
3-lead ECG Cable	EX3001	Yes	Provides surface ECG signals for real-time viewing on the Merlin 2 PCS
ECG input Cable	3617	Yes	Provides surface ECG signals for real-time viewing on the Merlin 2 PCS
Merlin Antenna	3638	Yes	Provides wireless radio frequency communication between the programmer and the device during a programmer session
Merlin PSA	EX3100	Yes	Assess the pacing and sensing performance of the lead system prior to implantable medical device implantation, or during invasive lead system troubleshooting
Telemetry Wand	3630W	No	Provides inductive communication between the Merlin 2 PCS and the device during a programmer session

Symbols

For information on symbols pertaining to the Merlin™ PSA Model EX3100 and its accessories, 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://medical.abbott/manuals.

Symbol	Description
PN	Part number

Symbol	Description
CE 0123	European conformity, affixed according to the relevant provisions of European Council Regulation 2017/745 (NB 2797) and RE directive 2014/53/EU Annex II. Hereby, Abbott Medical declares that this device complies with the relevant provisions of this regulation and directives. The full text of the European Union RE directive 2014/53/EU declaration of conformity is available at the following internet address: sjmglobal.com/euconformity. This product operates between 9 and 200 kHz with an H-field strength of less than 25 dBµA/m at 10 m.
	Affixed to this device in accordance with European Council Directives 2002/96/EC. 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. Return the device to Abbott Medical at the end of its operating life.
	Display Out port
	ECG Cable
ECG IN	ECG IN cable port
	
	Ethernet port (non-functional)
	Flash drive
 T2.5AL250V~	Fuse
	Merlin 2 Patient Care System Model MER3700
	An accessory to Merlin 2 Patient Care System Model MER3700

Symbol	Description
	Off
	On
PSA	Pacing system analyzer port
	Power cord
	Follow instructions for use on this website
	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
RF TELEMETRY	RF Telemetry port
	Telemetry wand
	Connect to the RF Telemetry port on the Merlin 2 PCS
	Conforms to AAMI Std ES60601-1 IEC Std 60601-1-11 Certified to CAN/CSA std C22.2 No. 60601-1
Made in USA.	Made in USA
	Unique device identification number
FCC ID: XXXX TBD	FCC Identification Number

Symbol	Description
IC: XXXX-XXX TBD	Industry Canada certification
	USB port
	Product literature
	Manufacturing facility
	Importer
WI-FI	Wi-Fi port
MD	Medical Device

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