

Merlin™ PSA

Pacing System Analyzer
Model EX3100

HELP MANUAL



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Introduction

Contents:

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- Operator Profile (page 1)
- Indications for Use (page 1)
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- Warnings (page 2)
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System Description

The Merlin™ Pacing System Analyzer (PSA) Model EX3100 system provides you with the ability to assess the electrical performance of a lead system during pulse generator implantation or invasive lead-system troubleshooting. The Merlin PSA system uses the St. Jude Medical™ Merlin™ Patient Care System (PCS).

In addition to the Merlin PCS, the Merlin PSA system consists of:

- a sterilizable patient cable
The Merlin PSA Patient Cable Model EX3150 connects the Merlin PSA with one to three implanted leads.
- patient-cable adapters
The Merlin PSA Cable Adapter Model EX3170 and the Merlin PSA "M" Adapter Model EX3180 connect the Merlin PSA to commonly used PSA patient cables (see Connect the Leads to the Merlin™ PSA). The PSA patient cables are then connected to the implanted leads.

For information on the Merlin PCS, refer to the Merlin PCS Model 3650 or Merlin 2 PCS MER3700 User's Manual. For technical data and other information on the Merlin PSA and accessories, refer to Technical Data.

NOTE:

- Only persons properly trained to operate the Merlin PSA should do so.
- If the user connects both the Merlin PSA Model EX3100 and the PSA Wand Model 3150 to the Merlin PCS, the programmer only enables the Merlin PSA Model EX3100.
- Refer to the Merlin PCS Model 3650 or Merlin 2 PCS Model MER3700 User's Manual for Merlin PSA installation instructions.

Operator Profile

The intended operators of the Merlin™ PSA system include trained Abbott Medical employees and clinical personnel trained in pacing and electrophysiology, such as nurses, technicians, or physicians.

Indications for Use

The Merlin™ Pacing System Analyzer (PSA) is indicated for use at the time of surgery in patients

with bradyarrhythmias, tachyarrhythmias, and/or heart failure undergoing implantation or lead revision of a pacemaker, implantable cardioverter defibrillator, or cardiac resynchronization therapy system.

Intended Use

The Merlin™ PSA is intended to assess the pacing and sensing performance of the lead system prior to pulse generator implantation, or during invasive lead system troubleshooting.

The Merlin PSA Patient Cable EX3150 is a three-channel resterilizable patient cable intended to connect the Merlin PSA to as many as three IS-1, DF-1, or DF4 leads.

The Merlin PSA Patient Cable Adapter EX3170 is a three-channel adapter intended to connect the Merlin PSA to as many as three disposable patient cables. The EX3170 Cable Adapter can connect to the Model 4051L disposable patient cable for IS-1 leads or to the Model 4161 disposable patient cable for DF4 leads. The opposite ends of the disposable patient cables connect to implantable pacing leads.

The Merlin PSA "M" Adapter Model EX3180 is intended to connect the Merlin PSA to the two-channel Medtronic Model 2292 re-sterilizable patient cable. The opposite end of the Medtronic Model 2292 cable connects to implantable pacing leads.¹

Following use, the patient cables must either be disposed or re-sterilized, depending on the requirements of the cable.

Only use the Merlin PSA with the Merlin PCS.

Contraindications

There are no contraindications to the use of a lead-analysis device. The patient's age and medical condition, however, may dictate the pacing modes and lead assessment activities appropriate for the patient.

The Merlin™ PSA is not intended for use as a temporary pacemaker or for life sustaining pacing support.

The Merlin PSA is not intended for diagnostic purposes.

Warnings

Line-powered Equipment. An implanted lead or a lead with an extension cable constitutes a direct, low-resistance current pathway to the myocardium. Due to the danger of tachyarrhythmias resulting from alternating current leakage, extreme caution must be taken to only use line-powered equipment according to its intended use as properly grounded line-powered Class I equipment used on or in the vicinity of the patient.

Electrosurgical Cautery. Electrosurgical cautery could induce ventricular arrhythmias and/or fibrillation, or may cause device malfunction or damage. If electrocautery is necessary, keep the current path and groundplate as far away from the leads as possible.

Burst Pacing. Use of atrial or ventricular burst pacing may result in ventricular tachycardia or fibrillation. Defibrillation equipment should be readily available during the PSA session.

Handling Inserted Leads. Do not touch the terminal pins or exposed metal when handling inserted leads. Do not allow the terminal pins or exposed metal to unintentionally contact electrically conductive or wet surfaces.

Unconnected Atrial Leads. Do not operate the Merlin™ PSA in the DDD or VDD pacing mode with only the ventricular pacing lead connected. Interference detected at the unconnected atrial

¹ The Medtronic Model 2292 re-sterilizable patient cable has an embedded resistor connected via connector pins P3 and P5 that enables Medtronic equipment to distinguish between different supported PSA cables. However, pins P3 and P5 are not connected to the Merlin PSA which does not support this functionality.

input of the Merlin PSA can result in false sensing and can drive the ventricular pacing rate to the Max Track Rate setting.

Asystole. During threshold tests, asystole may result due to loss of capture.

Electromagnetic Interference (EMI). At high sensitivity (low numerical settings) and in the presence of excessive levels of interference, the Merlin PSA may inhibit completely or revert to asynchronous operation, pacing at the Base Rate. Additional sources of strong EMI that can temporarily affect the operation of the Merlin PSA include the following:

- Electrosurgical equipment
- Diathermy equipment
- Some medical telemetry equipment, when operated within one meter of the Merlin PSA
- Communication transmitters such as cellular phones and "walkie talkies".

Move the source of EMI as far from the Merlin PSA as possible.

Asynchronous Pacing. During asynchronous pacing operation, pacing stimuli may be inadvertently delivered within the vulnerable period of the T-wave. This may be hazardous to patients with acute myocardial infarction or who are otherwise predisposed to arrhythmias.

Precautions

Temporary Pacing. Do not use the Merlin™ PSA as a temporary pacemaker. It should not be used to provide extended external pacing in situations where the patient is left unattended. Testing has not been performed to support this function.

Power Loss. In the event of a power loss to the programmer, the Merlin PSA continues to pace in the safe pacing mode for the length of backup battery life. Do not use the Merlin PSA as an external temporary pacemaker. Connect the patient to an external temporary pacemaker as soon as possible. For more information, see Safe Pacing.

High Output and Maximum Sensitivity. In the presence of large depolarization potentials or large output pulses, use of high sensitivity settings (low numerical settings) may allow potentials to inappropriately inhibit (or trigger) the output.

Connecting the Lead System. Connect the Merlin PSA to the Merlin PCS or Merlin 2 PCS. (For installation instructions, see the Merlin PCS Model 3650 User's Manual or Merlin 2 PCS Manual) Then connect the sterile patient cables (and accessories, as necessary) to the Merlin PSA before connecting the lead to the sterile patient cable.

Electrostatic Discharge (ESD). Pacing leads provide a low-impedance pathway to the heart. Therefore, discharge any static electricity prior to touching the patient, the cables, or the leads.

Termination of Pacing. Abrupt termination of pacing stimuli may result in intervals of asystole before an intrinsic rhythm is reestablished. Prior to terminating pacing, set the pacing mode to a demand mode and then gradually reduce the pacing rate below the patient's intrinsic rate. Once a spontaneous rhythm is established, you can turn off pacing.

Defibrillation/Cardioversion. The Merlin PSA may be damaged by defibrillation shocks when it is connected to an implanted lead system. Test the Merlin PSA after it has been exposed to such charges by launching the PSA application and verifying that the Merlin PSA is functional. Whenever possible, for the safety of the patient, disconnect the Merlin PSA from the lead system before defibrillation or cardioversion. After a typical defibrillation shock, the Merlin PSA will recover in less than five seconds.

Environmental Precautions. The Merlin PSA has been carefully designed and tested to ensure reliability during normal use. However, electronic devices are susceptible to many environmental stresses. Take precautions to avoid damaging the device, including (but not limited to) the following examples:

- do not expose the Merlin PSA to extreme temperatures and/or humidity as that may result in inaccurate measurements
- do not expose the Merlin PSA to mechanical shock as it may damage the Merlin PSA and result in unreliable measurements
- do not store the Merlin PSA near magnets or magnetic-field-inducing coils as it may shorten its lifetime.

Other environmental factors may affect proper performance of the device in the hospital setting. Use of appropriate environmental health and safety practices helps prevent environmental damage to the device.

Heart-Rate Monitoring. Monitor the patient's heart rate with an ECG monitor while using the Merlin PSA.

Liquid Immersion. Do not immerse the Merlin PSA in liquid or damage will result.

Adverse Events

Potential adverse events include:

- Prolonged surgery
- Arrhythmia
- Discomfort
- Additional surgical procedure
- Infection

Tools Menu

Contents:

- ? Button (page 1) (Help)
- Tools (page 1)
- Preferences (page 1)
- **Customer Support.** Provides contact information for Technical Support representatives. See Technical Support (page 31).
- Print Screen (page 2)
- Export Screen (page 2)

? Button

The ? button opens a window that provides context-sensitive help. You can also get help if you select Tools > Educational Materials > Help.

Accessed From: Help button

Tools

The Tools menu provides access to a number of programmer tools, including:

- **PSA.** Opens the PSA application (inactive during the PSA session).
- **Session Records:** Opens archived data (inactive during the PSA session).
- **Educational Materials:**
 - **Help.** Opens links for on-line Help for all supported devices.
 - **Demos.** Opens device demonstrations (inactive during the PSA session).
- **Maintenance.** Opens utilities for programmer maintenance (for use by Abbott Medical personnel only).
- **Clinical Studies.** Opens information for studies (for use by Abbott Medical personnel only; inactive during the PSA session).
- **Preferences** (page 1). Opens the Merlin™ PCS or Merlin™ 2 PCS settings.
- **Customer Support.** See Technical Support (page 31).
- Print Screen (page 2).
- Export Screen (page 2). Exports an image to a USB flash drive.

Accessed From: Tools menu

Preferences

The Preferences window sets the following for the programmer:

- **Date** (inactive during the PSA session)
- **Time** (inactive during the PSA session)
- **Language for Display and Help** (inactive during the PSA session)
- **Date, Time, and Number Formats** (inactive during the PSA session)
- **ECG Notch Filter Frequency** . The ECG Notch Filter Frequency reduces ECG interference from the programmer's AC power line. Check with your local authorities for your power line

frequency.

- Audio Preferences (page 2)
- Printer Preferences. (inactive during the PSA session)²

Accessed From: Tools menu > Preferences button

NOTE: It is important to set an accurate date and time because the device's functions use the date and time from the programmer. You must exit the PSA session to set the date and time from the Tools menu.

Audio Preferences

The Audio Preferences window contains two panels:

- **General Audio.** Select the On button to allow audio cues for programmer activity. You can also select a volume level. The Off button turns all sounds off (except Charging Audio).
- **Charging Audio.** Select the On button for an audio cue when the capacitors charge during a programming session. An audio cue is always emitted during charging for an Emergency Shock, regardless of the Charging Audio setting.

Accessed From: Tools menu > Preferences button > Audio tab

Print Screen

The Print Screen button prints an image of the current screen to a PDF.

For more information on printing, see Print Menu (page 32).

Accessed From: Tools menu > Print Screen button

Export Screen

The Export Screen button opens a window which allows you to save the current screen as an electronic (.png) file and send the file to any storage device (flash drive) connected to one of the programmer's USB ports. The Merlin™ PCS and Merlin™ 2 PCS detect all connected devices and asks you to select the device to receive the data.

Accessed From: Tools menu > Export Screen button

Rhythm Display

Contents:

- Rhythm Display (page 3)
- ECG (page 3)
- Markers (page 4)
- EGM (page 6)
- Waveform Control (page 7)
- Rhythm Display Setup Instructions (page 7)
- Adjust Display (page 8)
- ECG Configuration (page 8)

² The reports printed during a PSA session are always saved as a PDF file and may be printed to an external printer.

- EGM Configuration (page 8)
- Freeze Capture (page 8)

Rhythm Display

The Rhythm Display, seen on the Main Programming Window (page 31), can show up to five concurrent waveforms (or channels) that can be individually configured and adjusted. You can also freeze the display or print it in real time.

Three types of waveforms can be shown in the Rhythm Display:

- ECG (electrocardiogram) (page 3)
- Markers (page 4)
- EGM (intracardiac electrogram) (page 6)

The controls for the Rhythm Display include the:

- **Channel Control** buttons. Indicates the current waveform for each channel. Select this button to show the Marker Control buttons or the Marker Control buttons.
- **Waveform Control** (page 7) buttons. Select the Channel Control buttons on the left side of the waveform to show the Waveform Control buttons. Top view shows buttons for ECG. Bottom two views show buttons for EGM. See also Current of Injury (page 6).
- **Marker Control** buttons. Select the Channel Control buttons on the left side of the Marker Control buttons. Select the desired configuration or select the "?" button to show help for Markers (page 4).
- **Adjust Display** (page 8) button
- **Freeze Capture** (page 8) button



See also:

- Rhythm Display Setup Instructions (page 7)

ECG

The Rhythm Display shows up to five ECG waveforms simultaneously from seven possible ECG vectors. There are two ways to change the ECG display:

- Adjust Display (page 8) button. Selects the waveform source and configuration and the ECG filter.
- Waveform Control (page 7) buttons, which set the gain and the waveform source.

For an example of a typical ECG setup, refer to the Merlin™ PCS Model 3650 User's Manual or

the Merlin™ 2 PCS Model MER3700 User's Manual.
 For more information, see ECG Configuration (page 8).

Markers

Markers are symbols that represent paced and sensed events, intervals, and refractory periods. You can choose markers as one of the five channels. Markers can be configured either as:

- **Basic.** Basic Event Markers (page 4) appear along a time line.
- **Full.** In addition to the Basic Event Markers, the Interval and Refractory Markers (Full Markers) (page 5) appear.

The following markers always appear in both the Basic and Full marker configurations:

- Special Event Markers (page 5)
- Full-Display Markers (page 6)
- Waveform Channel Markers (page 6)



There are two ways to change the marker configuration:

- Select the Adjust Display (page 8) button and select the desired configuration.
- Select the marker's Waveform Control (page 7) button on the left of the Rhythm Display and select the desired configuration.

The following markers always appear in both the Basic and Full marker configurations:

Basic Event Markers

Table 1. Basic event markers

Marker	Description	Example
AR	Atrial event sensed in refractory period	
AS	Atrial sensed event	
AP	Atrial paced event	
VS	Ventricular sensed event	
VP	Ventricular paced event	

For CRT-Ds and CRT-Ps, when the V. Pacing (page 24) or V. Sensing (page 24) parameter is set to:

- **RV Only.** The VP or VS marker has a right-pointing tick mark.
- **LV Only.** The VP or VS marker has a left-pointing tick mark.
- See below for **RV->LV**, **LV->RV**, and **Simultaneous**.





Ventricular sensed event within the refractory period



Table 3.

BP	Biventricular paced event	<p>For CRT-Ds and CRT-Ps, when the V. Pacing parameter is set to:</p> <ul style="list-style-type: none"> ▪ Simultaneous; RV->LV with a 10 ms delay. The BP marker points down. ▪ RV->LV with a 15 ms or greater delay. The BP marker points right. ▪ LV->RV with a 15 ms or greater delay. The BP marker points left.
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Table 4.

Interval and Refractory Markers (Full Markers)

Interval and refractory markers are shown in the following diagram.

Figure 1. Interval and refractory markers (full markers)




Special Event Markers

Table 5. Special event markers

Marker	Description	Example
--> A-Noise or --> V-Noise	Entry into noise reversion mode	
A-noise or V-Noise	Continuation of noise reversion mode	
<-- A-Noise or <-- V-Noise	Exit from noise reversion mode	
Burst---	Burst stimulation	



Full-Display Markers

Table 6. Full-display markers

Marker	Description	Example
Pulse Amplitude	Updated Pulse Amplitude setting	
A. Burst or RV Burst Started	Starting burst stimulation delivery	
A. Burst or RV Burst Ended	Ending burst stimulation delivery	

Waveform Channel Markers

Table 7. Waveform channel markers

Marker	Description	Example
Signal Amplitude Measurement	Intrinsic signal amplitude measurements above the associated complex	
Impedance Measurement	Lead impedance measurement above the associated complex	

EGM

EGMs (intracardiac electrograms) show the sensed electrical activity of the heart. The shape and size of the waveform depend on the available EGM Configuration (page 8) and the Gain setting.

The configurations available are Unfiltered or Sense Amp (narrow band filtered data). The Sense Amp filtering characteristics of the Merlin™ PSA are designed to match those of Abbott Medical pulse generators. The default configuration is Unfiltered, and once it's changed, the new configuration is saved for future sessions.

Select the Adjust Display (page 8) button to select the waveform source and configuration, and also the sweep speed and the ECG Filter.

Current of Injury

The Current of Injury view shows an unfiltered view of the EGM and an amplitude value measured from peak-to-peak of the waveform. (The filtered EGM view measures the Sense Amp waveform from baseline-to-peak.) The peak-to-peak amplitude of the unfiltered EGM is shown in the upper left corner of the Current of Injury view. The Current of Injury view updates with every sensed beat.

Use the Plus (+) and Minus (-) buttons to manually set the gain. AutoGain is not available in the Current of Injury view.

Select the Current of Injury button to return to the Rhythm Display.

Accessed From: Rhythm Display > Channel Control button

Waveform Control

The Waveform Control buttons on the left side of the Rhythm Display control the waveform's appearance. To open the controls, select one of the buttons. The buttons shown depend on the selected Source for that channel.

Figure 2. Waveform control buttons



1. **Current of Injury** (page 6) button (EGM only). Toggles from the filtered baseline-to-peak view of the EGM (pictured) to the unfiltered, peak-to-peak Current of Injury view of the EGM.
2. **Configuration** button. Opens the ECG Configuration (page 8) or the EGM Configuration (page 8) window.
3. **AutoGain** button. Allows the programmer to automatically set an appropriate gain.
4. **Plus (+)** and **Minus (-)** buttons allow you to set the gain manually.

Accessed From: Rhythm Display > Channel Control button

Rhythm Display Setup Instructions

1. Select the Adjust Display button to the right of the Rhythm Display.
The Adjust Display (page 8) window appears.
2. Locate position 1.
3. Select the Source you want to see in position 1 (ECG (page 3), EGM (page 6), Markers (page 4), or Off).
The programmer selects a default Configuration for the Source.
4. Select the Configuration button.
If you selected ECG or EGM for the Source, the ECG Configuration (page 8) or EGM Configuration (page 8) window opens. If you selected Markers (page 4), select the Basic or Full button.
5. Choose the configuration.
6. Repeat these steps for the remaining waveforms.
7. Select the Sweep Speed button and choose a speed.
8. Select the ECG Filter button to enable the ECG filter
Electromagnetic interference is reduced when the ECG filter is enabled.
9. Select the AutoGain All button to refresh the AutoGain settings.

Adjust Display

The Adjust Display window changes the:

- **Source** for each waveform in the Rhythm Display window (ECG (page 3), Markers (page 4), or EGM (page 6))
- **Configuration** of the waveform
- **Sweep Speed**
- **ECG Filter** to reduce electromagnetic interference

The following buttons are also available:

- **AutoGain All**. Sets all waveforms to AutoGain and recalculates the gain of waveforms currently displayed in the Rhythm Display.

See also:

- ECG Configuration (page 8)
- EGM Configuration (page 8)
- Rhythm Display Setup Instructions (page 7)

Accessed From: Rhythm Display > Adjust Display button

ECG Configuration

The ECG Configuration window changes the ECG vector on the Rhythm Display (page 2).

For an example of a typical ECG setup, refer to the Merlin™ PCS User's Manual or Merlin™ 2 PCS User's Manual.

To achieve the ECG vectors, select the following electrodes:

- **I**. L(+) to R(-)
- **II**. F(+) to L(-)
- **III**. F(+) to R(-)
- **aVR**. R(+) to [L(-) + F(-)]
- **aVL**. L(+) to [R(-) + F(-)]
- **aVF**. F(+) to [R(-) + L(-)]
- **Chest**. C

Accessed From: Adjust Display > Configuration button

EGM Configuration

The EGM Configuration window changes the EGM source on the Rhythm Display (page 3).

Accessed From: Adjust Display > Configuration button

Freeze Capture

The Freeze button captures the most recent 30 s of the waveform and shows the data in the Freeze Captures window. Up to six Freeze Captures are saved in the programmer memory. The controls on the Freeze Captures window include the:

- **Waveform Control** (page 7) buttons, including the **Hide** button, which hides the selected waveform
- **Restore Channels** button, which restores the hidden waveforms
- **Sweep Speed** button

- **Show Calipers** button, which shows calipers that can be moved with button controls to display time measurements for a portion of the freeze
- **Hide Calipers** button, which toggles to the Show Calipers button
- **Scroll** buttons

You can also print the frozen waveforms immediately (select the Print button) or print all Freeze Captures with the Freezes report. See Reports (page 32).

Accessed From: Freeze button

Merlin™ PSA Session Information

Contents:

- Insert the PSA in the PSA Case (page 9)
- Connect the Leads (page 12)
- Start a Merlin™ PSA session (page 14)
- End a Merlin™ PSA Session (page 15)
- Suspend the Merlin™ PSA Session (page 15)

Merlin™ PSA Setup Information

When used with the Merlin™ PCS Model 3650, you must insert the Merlin™ PSA Model EX3100 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. For more information, see Merlin™ PSA Model EX3100 Setup in the Merlin™ PCS User's Manual.

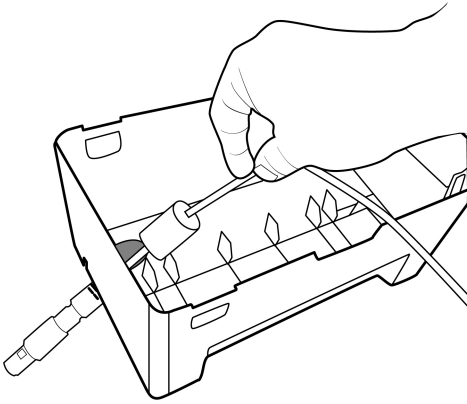
When used with the Merlin™ 2 PCS Model MER3700, it is a best practice to enclose the Merlin™ PSA Model EX3100 in the PSA case.

Insert the PSA in the PSA Case

If you want to connect to the Merlin 2 Programmer, please complete the following instructions to properly place the PSA in the PSA case.

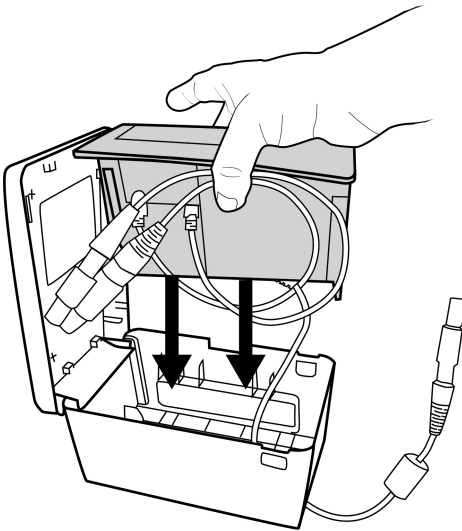
Step 1: Insert the PSA Cable

Figure 3. Inserting the PSA cable



Step 2: Coil the Remaining Cables and Place the PSA on the Tracks in the PSA Case

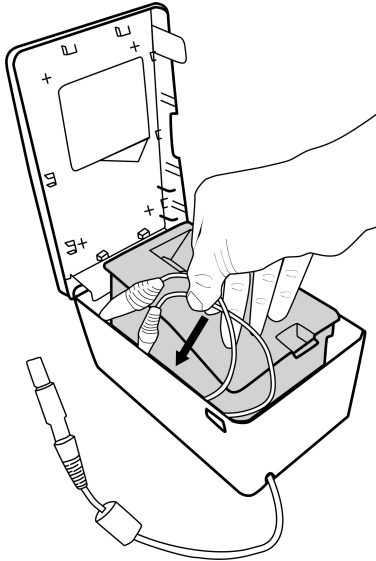
Figure 4. Coiling remaining cables and placing the PSA on the tracks in the PSA Case.



NOTE: Tracks are located next to the window.

Step 3: Tuck the Remaining Cables into the PSA Box

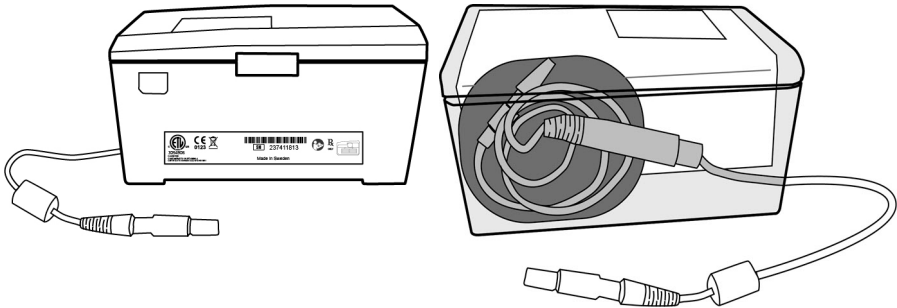
Figure 5. Tucking the remaining cables into the PSA Case.



NOTE: The Wand (blue cable) and ECG (black cable) are the cables to go inside of the PSA box.

Step 4: Close the PSA Case Lid

Figure 6. Closing the PSA Case Lid.



NOTE: Grayed out cable represents portion inside of case.

Connect the Leads

1. Turn on the Merlin™ PCS or Merlin™ 2 PCS programmer and check that the blue LED on the Merlin™ PSA is lit.³
2. Select one of the three approved patient cables or cable adapters you are going to use to connect to the implanted lead(s).

The three cables that can be connected to the Merlin PSA include:

- Merlin PSA Patient Cable Model EX3150 (terminates to three sets of connector clips for three channels: A, RV, LV)⁴
- Merlin PSA Cable Adapter Model EX3170 (terminates to a connection for Models 4051L and 4161 patient cables)
- Merlin PSA "M" Cable Adapter Model EX3180 (terminates to a connection for a Medtronic™ Model 2292 patient cable)⁵

For more details on the cables and adapters, see Merlin™ PSA Accessories.

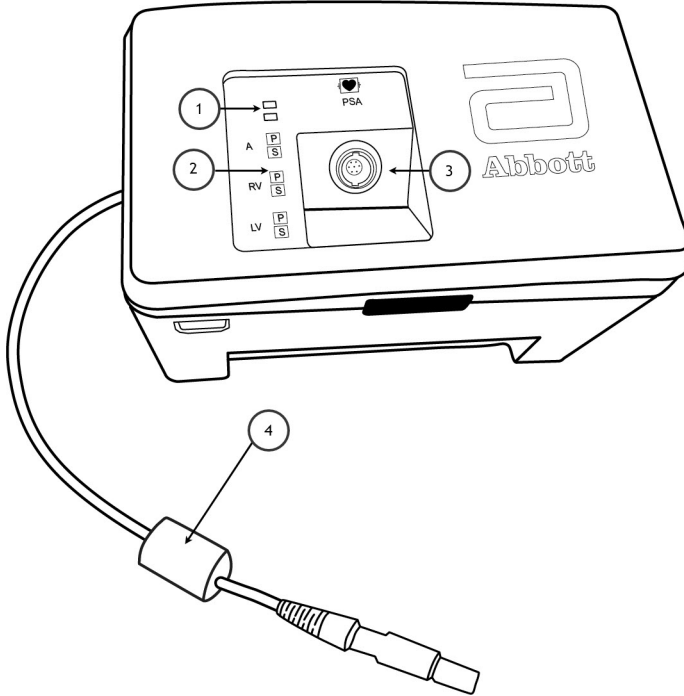
CAUTION: Do not attempt to connect the Medtronic™ patient cable Model 5436 to the Merlin PSA. This patient cable is not electrically compatible and will result in inaccurate impedance measurements and an inability to pace or sense.

³ It may take up to 10 seconds for the blue LED to illuminate.

⁴ The connector clips on the Model EX3150 are compatible with IS-1, DF-4, and DF-1 lead connectors.

⁵ Medtronic is a trademark of Medtronic, Inc.

Figure 7. Merlin PSA



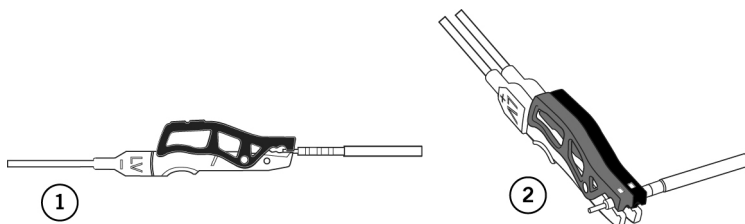
1. Functional Status LEDs
 2. Pace and Sense LEDs
 3. Receptacle for patient cable or patient-cable adapter
 4. Connector to Merlin PCS or Merlin 2 PCS
-

3. Inspect the Merlin PSA, cable, or cable adapter for any visual damage.
4. Insert the connector on the cable or cable adapter into the green PSA port on the Merlin PSA.
Ensure that you have a secure connection.
CAUTION: Do not attempt to insert a patient cable or cable adapter into the PSA port.
5. If not already connected, insert the ECG into its port on the Merlin PSA.
6. If you are using a cable adapter (Models EX3170 or EX3180), connect the cable adapter to its respective patient cable.
7. Connect the patient cable connectors to the implanted lead you wish to test.
For appropriate measurements:
 - Connect the lead to the appropriate channel

- Connect the (+) and (-) patient-cable to the appropriate connection on the lead. Refer to the appropriate lead manual for information on the lead configuration.

The clips on the Model EX3150 patient cable can be positioned side by side, with the lead electrodes visible through the clip.

Figure 8. Two views of the Model EX3150 clips connected to an DF4 lead: 1) Single clip connected to the lead connector electrode, approached from the front; 2) Two clips connected to the lead connector electrode rings, approached from the side. Use the window on the top of the clip to visualize the connection to the electrode.



NOTE: Use care when connecting the sterile patient cable to the lead. Avoid contamination of or damage to the sterile connectors or leads. See *Cleaning, Disinfecting, and Sterilization Methods* (page 47).

CAUTION:

- Do not allow conductive parts of leads or connectors to come into contact with other conductive parts, including Earth ground.
- Ensure that the leads are connected to the appropriate channel. Incorrect connections could result in inappropriate or harmful stimulation as well as inaccurate intrinsic signal amplitude and slew rate measurements.
- In the event of power loss or communication failure, the Merlin PSA switches to battery power to continue operation. If this occurs, the Merlin PSA operates in Safe Pacing mode for as long as the battery life permits or until power is restored to the Merlin PCS or Merlin 2 PCS and a PSA session is started. To ensure that the battery life is sufficient, the Merlin PCS or Merlin 2 PCS measures the Merlin PSA battery voltage when it is turned on. If the batteries cannot sustain PSA operation for at least 30 minutes, you will see an alert indicating that the batteries are near depletion and should be changed. See *Safe Pacing* (page 33) and *Battery Information* (page 45).
- Leaving the atrial connector disconnected when the Merlin PSA is in DDD or VDD modes may result in the unit sensing external noise and increasing the ventricular pacing rate to the Max Track Rate.

Start a Merlin™ PSA Session

You can start a PSA session from the Start-Up Screen or during a device programmer session. The Merlin™ PSA imports patient and device data from the ongoing device session into the PSA session.

To begin a PSA session:

1. From the Start-Up Screen or during a device programming session, select Tools > PSA.

If you started from the Start-Up Screen, you will be prompted to select the device implant type. This enables the Merlin PSA to use appropriate filters, default Pulse Width settings, and the correct number of test channels.

2. Select the Start PSA button.
The PSA session starts.
3. Begin the leads tests or burst pacing procedures.

For information on use of the Merlin PSA, see:

- Lead Tests (page 15)
- Burst Pacing (page 20)
- Parameters (page 21)
- Additional Information.

End a Merlin™ PSA Session

To end a PSA session:

1. Select the End Session button.
Select the Print selected reports check box to print reports prior to ending the PSA session. Select the Resume Session button to close the End Session window and return to the PSA session.
2. Select the End Session button to end the PSA session.

The Merlin™ PSA clears all test results and patient data. Pacing from the PSA ends.

NOTE: It is important to end the PSA Session by selecting the End Session button. If the Merlin PSA is pacing and if you turn the Merlin™ PCS or Merlin™ 2 PCS programmer off before selecting the End Session button, the Merlin PSA will switch to battery power and continue pacing, thereby draining the batteries.

- In addition, if you select the End Session button, you reduce the chance of mistakenly using the previous session's patient data for the current session.
- PSA reports are not stored as Session Records.

Suspend the Merlin™ PSA Session

You can suspend the PSA session and return to other programmer functions by selecting the Programmer button. If a device session is not already suspended, you can interrogate a device and later return to the PSA session. When you exit the programmer session, the suspended PSA session is resumed.

NOTE: When the PSA session is suspended, the Merlin™ PSA continues its pacing operation at the current PSA settings.

Lead Tests

When the Lead Tests window appears, the Merlin™ PSA begins sensing and measuring the intrinsic signal amplitude and slew rate.

From the Lead Tests window you can:

- Enable/Disable Pacing (page 16).
- Reset the Mode (page 23), Base Rate (page 22), and Additional Parameters (page 20).
- View and Store Intrinsic Signal Amplitude and Slew Rate Measurements (page 17).

- View and Store Lead Impedance Measurements (page 17).
- Open the Capture Test (page 18) window. Perform a Capture Test (page 18).
- Perform a Phrenic Nerve Stimulation Check (page 19).
- Annotate Test Results (page 19).
- In CRT devices, select the connected Ventricular Sensing Buttons (page 20) channel.
- Print a report. Select the Print button. See Print Menu (page 32).
- End a Merlin™ PSA Session (page 15).
- Return to the device session with the Programmer button. See Suspend the Merlin™ PSA Session (page 15).

Accessed From: Lead Tests button

NOTE: Pacing. Stimulation applied during the PSA session is ONLY intended for use during short-term lead evaluation tests and IS NOT intended for long term life-sustaining pacing support.

Enable/Disable Pacing

Select the Pacing toggle button to turn pacing on or off for the corresponding channel. When you enable or disable pacing for a particular channel with the Pacing button, the Merlin™ PSA automatically changes the Mode and V. Pacing settings, depending on the pacing status of other channels (see Table 1 and Pacing, Mode, and V. Pacing Parameter Autoprogramming below). You can also select a different setting for the Base Rate and Additional Parameters.

You must enable pacing to measure lead impedance and capture threshold.

To enable pacing with the Pacing button, the Mode must be set to ODO, VVI, AAI, or DDD. The Pacing button does not operate in AOO, VOO, VDD, DOO, or DDI modes.

See also: Mode Descriptions (page 24).

NOTE: When noise, defined as activity sensed by the Merlin PSA in a refractory period, is detected, the Merlin PSA switches to asynchronous pacing at the programmed Base Rate in that channel until noise disappears.

CAUTION: Leaving the atrial connector disconnected when the Merlin PSA is in DDD or VDD modes may result in the unit sensing external noise and increasing the ventricular pacing rate to the Max Track Rate.

Pacing, Mode, and V. Pacing Parameter Autoprogramming

The Pacing, Mode, and V. Pacing parameters are linked, so that a change to one parameter results in automatic changes to the other two. For example, enabling Pacing in the atrial channel (when ventricular pacing is off) changes the Mode setting from ODO to AAI. Similarly, changing the Mode from AAI to DDD will turn on Pacing in the ventricular channel (or in a CRT device, the ventricular channels designated by the V. Pacing parameter). In CRT devices, changing the V. Pacing setting from RV Only to Simultaneous enables pacing in the LV channel (if the Mode parameter is set to DDD or VVI).

The following table shows how the Merlin™ PSA is programmed for all combinations of the Pacing, V. Pacing, and Mode parameters.

Table 8. Changes to Mode and V. Pacing settings when pacing is enabled (On) or disabled (Off) in a particular channel

A Pacing	RV Pacing	LV Pacing	Mode Setting	V. Pacing Setting
Off	Off	Off	ODO	n/a
Off	Off	On	VVI	LV Only
Off	On	Off	VVI	RV Only
Off	On	On	VVI	Biventricular
On	Off	Off	AAI	n/a
On	Off	On	DDD	LV Only
On	On	Off	DDD	RV Only
On	On	On	DDD	Biventricular

Accessed From: Lead Tests button

Intrinsic Signal Amplitude and Slew Rate Measurements

CAUTION: Ensure the lead is connected to the appropriate channel. If you inadvertently reverse the connections, the Merlin™ PSA may deliver inappropriate or harmful stimulation and display inaccurate intrinsic signal measurements.

The Intrinsic Signal Amplitude measures the P/R-wave baseline-to-peak. To retrieve an intrinsic signal amplitude and a slew rate measurement:

1. Confirm that the patient has intrinsic activity.

The real-time intrinsic signal amplitude and slew rate measurements are shown on the P/R-wave Slew Rate button and as Markers on the Rhythm Display. If an intrinsic rhythm is not sensed within 2 seconds, the button shows "---".

2. Press the P/R-wave Slew Rate button.

The Merlin PSA saves the measurements and displays them to the right of the button. Each time you press the P/R-wave Slew Rate button, the saved measurement is shown to the right of the button.

You can view and store intrinsic signal amplitude and slew rate measurements for each channel as many times as desired. Up to five measurements for each channel are saved and can be included in the PSA report. Once five measurements for a single channel are saved, the next measurement saved for that channel replaces the oldest saved measurement for that channel.

When you initially enable pacing for a particular channel, the Merlin PSA measures and saves the most recent intrinsic signal amplitude and slew rate, unless the measurements have been previously saved.

Accessed From: Lead Tests button

Lead Impedance Measurements

When you initially enable pacing for a particular channel, the Merlin™ PSA measures and saves the lead impedance result.

The Merlin PSA displays the real-time impedance measurements on the Impedance button and the most recently saved measurements to the right of the button. You can also see the impedance measurement in the Rhythm Display. The Merlin PSA updates the measurement with every beat. If there is no paced pulse within two seconds, the button shows "---".

You can also measure impedance in an asynchronous mode, such as AOO, VOO, and DOO.

To save a lead impedance measurement, select the impedance button. You can update a lead impedance measurement for each channel as many times as desired. Up to five measurements for each channel are saved and can be included in the PSA report. Once five measurements for a single channel are saved, the next measurement retrieved for that channel replaces the oldest saved measurement for that channel.

NOTE: To obtain the most accurate lead impedance measurement, ensure that the Pulse Amplitude is set to a minimum of 2.0 V.

Accessed From: Lead Tests

Capture Test

From the Capture Test window you can Perform a Capture Test for each channel as many times as desired. The Merlin™ PSA saves up to five measurements, which are included in the PSA report. Once five measurements for a single channel are saved, the next measurement retrieved for that channel replaces the oldest saved measurement for that channel.

You can adjust the following parameters:

- Pulse Amplitude
- Mode
- Base Rate
- Pulse Width
- AV Delay

You can also:

- Select the See Additional Parameters button to open the Additional Parameters window and adjust any of the parameters associated with a capture test.
- Perform a Phrenic Nerve Stimulation Check.
- Review the saved thresholds.

Accessed From: Lead Tests button > Run Test button

Perform a Capture Test

To perform a Capture Test:

1. Enable Pacing for the desired channel.
2. Check the Rhythm Display to ensure that you have capture.
3. Select the Run Test button.

The Capture Test window opens, showing the current Pulse Amplitude setting, the pulse current measurement, and settings for additional parameters.

4. Select the Pulse Amplitude and other parameter settings for the test. To adjust any additional parameter settings, select the Additional Parameters (page 20) button.

To adjust the Pulse Amplitude, use one of the following methods:

- Select a toggle button to select a specific setting shown on the button.
- Select the + and - buttons to increase or decrease the pulse amplitude step by step.
- Select the Pulse Amplitude button listing the current setting to open a window showing all available settings.

5. Decrement the Pulse Amplitude setting.
Watch the Rhythm Display for signs of loss of capture.
6. When loss of capture occurs, increase the Pulse Amplitude to restore capture.
7. Select the Save as Threshold button to save the threshold measurements.

NOTE: The Merlin™ PSA reverts back to the originally programmed settings for the Pulse Amplitude and Pulse Width parameters when the test results are saved or the Capture Test window is closed.

Phrenic Nerve Stimulation Check

To ensure that there is no phrenic nerve stimulation due to suboptimal lead placement, perform a 10 V stimulation check, which applies 10 V through the lead.

During the test, all parameter settings except the Pulse Amplitude parameter remain unchanged.

To perform a stimulation check:

1. Press and hold the 10 V press & hold button.
The Pulse Amplitude is increased to 10 V. Observe the patient for extracardiac stimulation.
2. Release the 10 V press & hold button to end the test.

When a phrenic nerve stimulation check is performed and phrenic nerve stimulation is not observed, select the check-box next to the 10 V press & hold button to add this information to the PSA report.

Accessed From: Lead Tests > Run Test button

Annotate Test Results

After you have performed a test, the Merlin™ PSA displays the Annotate Test Results button. Use this button to review test results, to note the polarity configuration used to conduct the lead tests, and to add annotations to your printed report.

The Annotate Test Results window has a tab for each channel. Each window consists of three columns for the three available tests (P/R-wave slew rate, Impedance, and Capture). Each column can contain up to five test results (and a time/date stamp), with the most recent results at the top of the window. If six or more tests were recorded, the oldest result is overwritten by the latest. To view other available channels, select the tabs at the top of the window.

The Merlin PSA provides three choices for annotations:

- Bipolar or Unipolar to indicate the polarity used in the test
- Custom, which allows you to indicate multisite polarity (you are allowed up to four characters entered from an on-screen keyboard)
- No Annotation.

To annotate your results:

1. Select the box next to the result or results.
A check-mark appears next to each test result.
2. Select either the Unipolar, Bipolar, or Custom button.

If you select Custom, an on-screen keyboard appears. Type in four characters and close the window. All the checked results will be annotated with the same annotation.

If you select Unipolar, all the checked results are annotated "Uni."

If you select Bipolar, all the checked results are annotated "Bi."

Once you select the button, the check-marks are erased, and the annotations are added to the printed report.

3. Repeat this procedure for different chambers and for different annotations.
4. To erase any annotations, check the desired results and select the No Annotation button.
5. Close the window to save the results and annotations.

Accessed From: Lead Tests > Annotate Test Results button

Additional Parameters

From the Additional Parameters window you can select settings for the following parameters:

- Pulse Amplitude (page 23)
- Pulse Width (page 23)
- Refractory (page 23)
- Sensitivity (page 24)
- Mode (page 23)
- Base Rate (page 22)
- Max Track Rate (page 22)
- AV Delay (page 22)
- V. Pacing (page 24)
- V. Sensing (page 24)
- Advanced Settings. Select the Advanced Settings button to access the Low Frequency Attenuation (page 22) parameter.

Accessed From: Lead Tests > Additional Parameters button

Ventricular Sensing Buttons

In CRT devices, ventricular sensing occurs in a single chamber. To select the chamber to be sensed, select the appropriate V. Sensing radio button at the bottom of the Lead Tests window.

When the V. Pacing parameter (page 24) is changed, the V. Sensing parameter is autoprogrammed to match the chamber selected for V. Pacing.

CAUTION: For CRT devices, if only one ventricular channel is connected to the Merlin™ PSA, ensure that the Ventricular Sensing button on the Lead Tests window corresponds to the connected channel. Failure to do so may result in asynchronous pacing.

See also: V. Sensing (page 24).

Accessed From: Lead Tests

Burst Pacing

You can use the Burst Pacing function to terminate an arrhythmia.

From the Burst Pacing window you can adjust the following parameters:

- Chamber

- S1S1 (page 23)
- Pulse Amplitude (page 23)
- Pulse Width (page 23)
- Ventricular Support Rate (VOO) (page 24)

See also:

- Burst Pacing Instructions (page 21)
- Parameter Settings and Availability (page 34)

Burst Pacing Instructions

WARNING:

- **Always have a separate standby external defibrillator immediately available.**
- **Burst pacing should be performed only by physicians trained in tachycardia induction and reversion protocols.**

To deliver burst pacing:

1. Select the radio button indicating the chamber you wish to examine (Atrium or Right Ventricle).

NOTE: Burst Pacing is not available in the Left Ventricle.

2. Select the S1S1 parameter to select the burst pacing interval.
 - Select the S1S1 button to open the parameter selection window.
 - Select the + and - buttons to increment and decrement the setting.
3. Select the Pulse Amplitude, Pulse Width, and Ventricular Support Rate (VOO) settings.

The Pulse Amplitude and Pulse Width settings selected for Burst Pacing are temporary settings. When Burst Pacing is completed, the Merlin™ PSA restores the original Pulse Amplitude and Pulse Width settings.
4. Select the Enable Burst button.
5. Press and hold the Hold to Apply Burst button to deliver burst pacing.

Burst markers (STIM) are shown on the Rhythm Display. The timer starts counting and continues counting until you release the Hold to Apply Burst button. If you hold the button for more than 20 seconds, the Burst Pacing automatically ends.
6. Release the Hold to Apply Burst button to end the burst pacing.

Parameters

- AV Delay (page 22)
- Base Rate (page 22)
- Interventricular Delay (page 22)
- Low Frequency Attenuation (page 22)
- Max Track Rate (page 22)
- Mode (page 23)
- Pacing (page 23)
- Pulse Amplitude (page 23)
- Pulse Width (page 23)

- Refractory (page 23)
- S1S1 (page 23)
- Sensitivity (page 24)
- V. Pacing (page 24)
- V. Sensing (page 24)
- Ventricular Support Rate (VOO) (page 24)

AV Delay

The AV Delay parameter determines the interval between a sensed or paced atrial event and a paced ventricular event.

See also:

- Parameter Settings and Availability (page 34)

Base Rate

The Base Rate parameter sets the minimum stimulation rate.

See also:

- Parameter Settings and Availability (page 34)

Interventricular Delay

The Interventricular Delay parameter determines the interval between the pulses delivered to the ventricles when the V. Pacing parameter is set to either LV→RV or RV→LV.

See also:

- Parameter Settings and Availability (page 34)

Low Frequency Attenuation

The Low Frequency Attenuation parameter enables and disables the Low Frequency Attenuation filter for tachycardia devices. The Low Frequency Attenuation filter increases the R to T wave amplitude ratio, which may enhance sensing performance and may reduce oversensing T waves. Turning the Low Frequency Attenuation filter On or Off changes the device's sensing performance and may impact the reported R wave amplitude. For more information on how turning the Low Frequency Attenuation filter On or Off affects the sensing ability of the device, refer to the device manual.

For best results, the Low Frequency Attenuation setting on the PSA should match that of the selected device.

The default setting for the Low Frequency Attenuation filter is On for all tachycardia devices except for CRT-D devices. The default can be changed by selecting the Save as Default button on the Advanced Settings screen.

See also:

- Parameter Settings and Availability (page 34)

Max Track Rate

The Max Track Rate parameter determines the maximum ventricular stimulation rate allowed in atrial tracking modes.

See also:

- Parameter Settings and Availability (page 34)

Mode

The Mode parameter determines the stimulation and sensing method. The selected mode is in effect at all times except during Burst Pacing (page 20). Details of each mode can be found in Mode Descriptions (page 24).

See also:

- Parameter Settings and Availability (page 34)

Pacing

The Pacing parameter enables stimulation for the corresponding channel. For the Merlin™ PSA, this parameter is linked to the Mode and V. Pacing parameters. See Pacing, Mode, and V. Pacing Parameter Autoprogramming (page 16).

See also:

- Parameter Settings and Availability (page 34)

NOTE: **Pacing.** Stimulation applied during the PSA session is **ONLY** intended for use during short-term lead evaluation tests and IS NOT intended for long term life-sustaining pacing support.

Pulse Amplitude

The Pulse Amplitude parameter determines the voltage applied to the myocardium during the stimulation pulse.

See also:

- Parameter Settings and Availability (page 34)

Pulse Width

The Pulse Width parameter determines the duration of the pacing pulse applied to the myocardium.

See also:

- Parameter Settings and Availability (page 34)

Refractory

The Refractory parameter determines the amount of time that the device is unresponsive to signals following a sensed or paced event for the corresponding channel. The refractory period for the corresponding channel is initiated by a sensed or paced event on that channel and either ends when the period times out or is reset when another sensed or paced event occurs on that channel.

In AAI Mode, the Refractory parameter determines the atrial refractory period. In dual-chamber modes, the Refractory parameter determines the post-ventricular atrial refractory period.

See also:

- Parameter Settings and Availability (page 34)

S1S1

The S1S1 parameter determines the interval at which the Burst Pacing stimulation pulse is applied.

See also:

- Parameter Settings and Availability (page 34)

Sensitivity

The Sensitivity parameter determines the threshold above which the device responds to intrinsic cardiac events.

See also:

- Parameter Settings and Availability (page 34)

V. Pacing

The Ventricular Pacing parameter determines which ventricles receive stimulation and the order in which the stimulation is applied. When you select the LV→RV or RV→LV settings, you can also set the Interventricular Delay parameter.

See also:

- Parameter Settings and Availability (page 34)

V. Sensing

The V. Sensing parameter determines the channel in which ventricular sensing occurs when the selected device implant type is CRT-D or CRT-P.

When the V. Pacing parameter is changed, the V. Sensing parameter is autoprogrammed to match the chamber selected for V. Pacing.

See also:

- Ventricular Sensing Buttons (radio buttons on Lead Tests window) (page 20)
- Parameter Settings and Availability (page 34)

CAUTION: For CRT devices, if only one ventricular channel is connected to the Merlin™ PSA, ensure that the Ventricular Sensing button on the Lead Tests window corresponds to the connected channel. Failure to do so will result in asynchronous pacing.

Ventricular Support Rate (VOO)

The Ventricular Support Rate (VOO) parameter determines the stimulation rate applied to the ventricle during atrial Burst Pacing.

See also:

- Parameter Settings and Availability (page 34)
- VOO mode description (page 29).

Mode Descriptions

The Merlin™ PSA may be programmed to the following operating modes.

Table 9. Available Modes

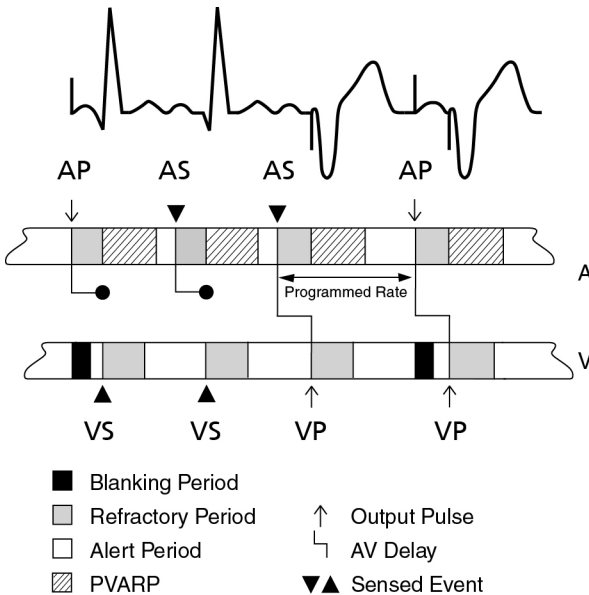
Dual-Chamber	Atrial	Ventricular	Off Modes
DDD	AAI	VVI	ODO
DDI	AOO	VOO	
DOO			
VDD			

DDD

(Dual-Chamber Pacing, Sensing, and Inhibition; Atrial Tracking)

The DDD Mode is a dual-chamber, atrial-based timing mode in which increases or decreases in the sensed atrial rate are duplicated by similar changes in the ventricular rate. Sensed P-waves or R-waves inhibit output pulses, while no intrinsic activity during the alert periods result in delivered pulses.

Figure 9. DDD Mode timing diagram

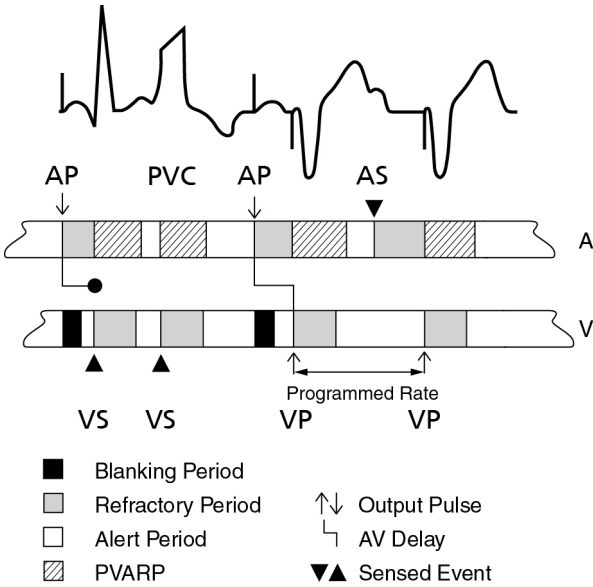


DDI

(Dual-Chamber Pacing, Sensing, and Inhibition; No Atrial Tracking)

The DDI mode is a non-tracking, dual-chamber mode in which sensed atrial activity does not cause a change in timing. Atrial tachycardias do not result in increased pacing rates.

Figure 10. DDI Mode timing diagram



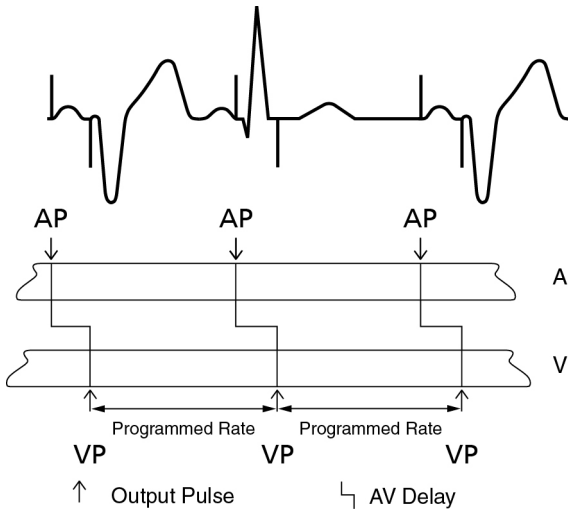
DOO

(Dual-Chamber Asynchronous Pacing)

In DOO mode, the device paces in the atrium and ventricle(s) at the programmed Base Rate and AV Delay regardless of intrinsic activity.

CAUTION: DOO mode is primarily intended for temporary use. Long-term use may result in competitive pacing, which may induce potentially dangerous tachyarrhythmias.

Figure 11. DDD Mode timing diagram

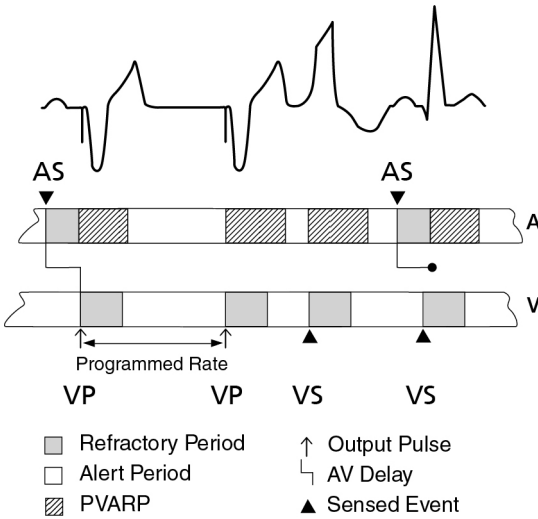


VDD

(Ventricular Pacing; Dual-Chamber Sensing and Inhibition; Atrial Tracking)

The VDD mode is a dual-chamber, atrial-tracking mode with no atrial output in which ventricular pacing is synchronized to intrinsic atrial activity. The device senses in the atrium and ventricle(s) but only paces in the ventricle(s).

Figure 12. VDD Mode timing diagram

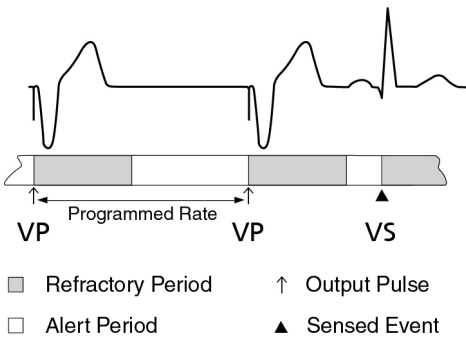


VVI

(Ventricular Pacing, Sensing, and Inhibition)

In VVI mode, the device paces the ventricle(s) at the programmed rate if it does not detect a sensed event. If the device detects a sensed event during the alert period, it withholds the pulse and it resets the timing period to the start of the Ventricular Refractory Period.

Figure 13. VVI Mode timing diagram



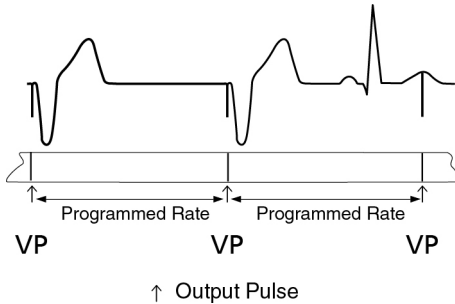
VOO

(Ventricular Asynchronous Pacing)

In VOO mode, the device paces the ventricle(s) at the programmed rate regardless of the intrinsic rhythm.

CAUTION: VOO mode is primarily intended for temporary use. Long-term use may result in competitive pacing, which may induce potentially dangerous tachyarrhythmias.

Figure 14. VOO Mode timing diagram

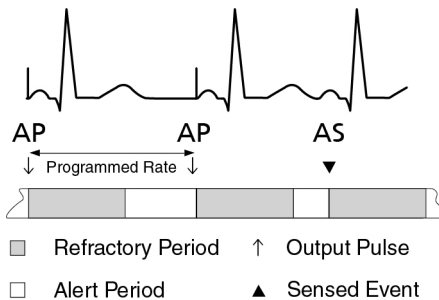


AAI

(Atrial Pacing, Sensing, and Inhibition)

In AAI mode, the device paces the atrium at the programmed rate if the atrial events are not sensed. If the device detects a sensed event during the alert period, it withholds the pulse and resets the timing to the start of the Atrial Refractory Period.

Figure 15. AAI Mode timing diagram



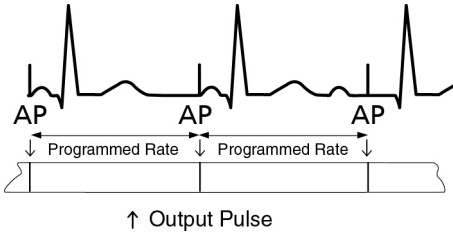
AOO

(Atrial Asynchronous Pacing)

In AOO mode, the device paces the atrium at the programmed rate regardless of intrinsic rhythm.

CAUTION: AOO mode is primarily intended for temporary use. Long-term use may result in competitive pacing, which may induce potentially dangerous tachyarrhythmias.

Figure 16. AOO Mode timing diagram



ODO

CAUTION: ODO mode is not recommended for pacemaker-dependent patients or patients who might be affected by even a short cessation of the device's operation.

In this mode, pacing is turned off while the device continues to detect and record sensed events. This mode is useful primarily for temporary diagnostic evaluation and recording of intrinsic activity.

Additional Information

NOTE: Only persons properly trained to operate the Merlin™ PSA system should do so. See Operator Profile (page 1).

Contents:

- Technical Support (page 31)
- Main Programming Window (page 31)
- Patient Data (page 31)
- On-Screen Keyboard (page 32)
- Device Parameters and Settings Selection (page 32)
- Print Menu (page 32)
- Reports (page 32)
- Settings (page 33)
- Safe Pacing (page 33)
- Emergency VVI Pacing (page 33)

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.

Main Programming Window

The Main Programming window is the upper portion of the screen that contains the following buttons and indicators:

- **? button.** Opens the context-sensitive on-screen help menu.
- **Tools menu.** Opens a menu for the Merlin™ PSA application, preferences, and other functions.
- **Patient Data (page 31).** Patient data is either entered directly in the PSA session or imported from a device programming session. Select the Patient Data button to view or edit patient information.
- **Measured Heart Rate**
- **Rhythm Display (page 2).** Shows the real-time waveforms and Markers.
- **Adjust Display button (page 8).** Opens a window to adjust the Rhythm Display.
- **Freeze Capture button (page 8).** Freezes the Rhythm Display and opens a window to adjust and print the frozen waveform.
- **Print Menu button (page 32).** Opens the Reports and Print Settings windows.

Programmer. Select the Programmer button to suspend the ongoing PSA session and interrogate a device to begin a device programmer session or return to a suspended session. See [Suspend the Merlin™ PSA Session \(page 15\)](#).

- **End Session.** Select the End Session button to end the PSA session. Patient data entered during the PSA session is not retained in the programmer. See [End a Merlin™ PSA Session \(page 15\)](#).

Patient Data

The Patient Data window displays patient, lead, and device information. For data fields that open an on-screen keyboard, you can alternatively use a USB keyboard connected to one of the USB ports.

When you are finished entering data, close the window to store the data for the duration of the PSA session. The Patient Data information is included in the PSA report.

When you launch or resume the PSA application from a device programmer session, the Patient Data panel on the Main Programming window displays the information on the device and patient. However, you cannot export data entered during the PSA session to a device programmer session.

The data fields include:

- **Patient Name and ID buttons.** Opens an on-screen keyboard for data entry.
- **Lead Information buttons.** Opens the Patient Data: Lead Information window to set the manufacturer, model, length, serial number, and lead implant date for each lead.
- **Device Model and Serial Number buttons.** Opens an on-screen keyboard for data entry.

- **Implant Notes** button. Opens a field for entering implant notes.

Accessed From: Main Programming window

Patient Data: Lead Information

The Patient Data: Lead Information window allows you to set the following characteristics for all implanted leads:

- **Manufacturer**
- **Lead Model**
- **Lead Length**
- **Lead Serial Number**
- **Lead Implant Date**

The information from the Patient Data: Lead Information window is included in the PSA report, but is not saved when the PSA session ends.

Accessed From: Main Programming window > Patient Data button > Lead Information button

On-Screen Keyboard

Use the On-Screen Keyboard to enter data.

- **Special Char key.** Select the Special Char key and then select another key to display the special character (labeled in green on the key).
- **Inactive Keys.** Unsupported characters.
- **Repeating Keys.** If you press and hold most keys on the on-screen keyboard, they are not repeatedly typed. The exceptions are the arrow keys, the Space key, the Enter key, and the Backspace key.
- **External Keyboard.** You can use an external keyboard connected to the programmer through any of its USB ports. Both keyboards can operate simultaneously.

Device Parameters and Settings Selection

To change the setting for any parameter, select the desired parameter button. A setting selection window appears or the setting toggles between two settings.

Print Menu

The Print Menu window contains two tabs:

- Reports (page 32)
- Settings (page 33)

Reports

The Reports window allows you to configure the report and to print the selected reports.

To select a report to print, select the check-box on the left.

The available report types include:

- **PSA Report.** Select the PSA Report button to open the Report Settings window to include all test results or only the latest test results.
- **Freezes.** All Freeze Captures are included in the report. To print individual Freeze Captures select the Freeze button to open the Freeze Capture window. Select a Freeze Capture. Select the Print button.

The reports are saved as a PDF file. PDF files can be exported using the tools menu only after exiting the PSA session or from within the device session.

Accessed From: Print Menu button > Reports tab

Settings

The Settings window allows you to set print preferences for the PSA and Freezes reports. Select the check-box to the left to include the following in the report headers or footers:

- Patient Name
- Patient ID
- Clinic Name

To configure the export settings, exit the PSA session and select Preferences > Printer from the Tools menu.

NOTE: The reports generated during PSA sessions are internally printed and available for PDF export on Model 3650 only.

Accessed From: Print Menu button > Settings tab

Safe Pacing

The Merlin™ PSA switches to Safe Pacing Mode if pacing is enabled and there is a loss of power or other programmer error that prevents normal programmer function. In Safe Pacing Mode, the Merlin PSA is powered by its backup batteries. The unit continues to operate at the last programmed settings, with the exception of the Pulse Amplitude parameter, which is set to 10 V, and the Pulse Width parameter, which is set to 1.5 ms. At the start of each session, the Merlin PSA measures the battery life and alerts the user if the batteries cannot support Merlin PSA operation for at least 30 minutes. See Battery Information (page 45).

The Merlin PSA continues to operate in Safe Pacing mode until the batteries are depleted or until the Merlin PSA has counted 60 consecutive cycles with no impedance load (that is, the leads have been disconnected).

Emergency VVI Pacing

Emergency VVI pacing can be initiated using the programmer.

To begin emergency VVI pacing:

- Press the red VVI hard key on the Merlin™ PCS or Merlin™ 2 PCS console.
All other Merlin™ PSA system activities are terminated when Emergency VVI Pacing is in progress.
The Merlin PSA displays a message that emergency VVI pacing is in effect.

You cannot change the settings associated with Emergency VVI pacing. These settings are as follows:

Table 10. Emergency VVI settings for the Merlin PSA

Parameter	EWI Setting
Mode	VVI
Base Rate	70 min ⁻¹
V. Pulse Amplitude	7.5 V

Table 10. Emergency VVI settings for the Merlin PSA

Parameter	EWI Setting
V. Pulse Width	1.5 ms
V. Sensitivity	2.0 mV
V. Refractory	400 ms
V. Pacing ¹	Simultaneous
V. Sensing ¹	RV

1. CRT devices only.

NOTE:

- Pressing the VVI hard key from the Start-Up screen initiates Emergency VVI pacing parameters in the implanted device if the wand is within the necessary telemetry distance.
- To initiate Emergency VVI pacing for the Merlin PSA system, launch the PSA application, then press the VVI hard key.
- The Merlin PSA only delivers Emergency VVI Pacing through the ventricular channel. EVVI pacing is not delivered through the atrial channel.

CAUTION: The Emergency Shock function is not available during a PSA session.

Parameter Settings and Availability

Parameters below are described in this help manual.

Table 11. Parameter settings and availability

Parameter	Availability	Settings	Nominal
AV Delay	All sessions	25; 30; 35; 40; 50; ... 200; 225; ... 450 ms	150 ms
Base Rate	All sessions	30; 35; ... 100; 110; ... 220 min ⁻¹	90 min ⁻¹
Interventricular Delay	CRT-P, CRT-D sessions	10; 15; ... 80 ms	n/a
Low Frequency Attenuation	CRT-D, ICD sessions	On; Off	ICD: On CRT-D: Off
Max Track Rate	All sessions	90; 95; ... 130; 140; ... 230 min ⁻¹	110 min ⁻¹
Mode	All sessions	AAI; AOO; VVI; VDD; VOO; DDI; DDD; DOO; ODO	ODO
Pacing	All sessions	On; Off	Off
Pulse Amplitude	All sessions	0.1; 0.2; ... 4.0; 4.5; ... 8.0; 9.0; 10.0 V	5.0 V (7.5 V for Burst Pacing Pulse Amplitude)

Table 11. Parameter settings and availability

Parameter	Availability	Settings	Nominal
Pulse Width	All sessions	CRT-Ds, ICDs: 0.1; 0.2; ... 1.5 ms	0.5 ms (1.0 ms for Burst Pacing Pulse Width)
		CRT-Ps, Pacemakers: 0.1; 0.2; ... 1.5 ms	0.4 ms (1.0 ms for Burst Pacing Pulse Width)
A. Refractory	All sessions	100; 125; ... 500 ms	400 ms for AAI, AOO modes; 275 ms for ODO, DDD, DDI, DOO, VDD modes
V. Refractory	All sessions	100; 125; ... 500 ms	250 ms
S1S1	All sessions	100; 110; ... 800 ms	600 ms
Sensitivity	All sessions	0.1; 0.2; ... 0.5; 0.75; 1.0; ... 2.0; 2.5; ... 5.0; 6.0; ... 20.0 mV	Atrial channel: 0.5 mV Ventricular channel: 2.0 mV
V. Pacing	CRT-P, CRT-D sessions	RV only; LV only; LV->RV; RV->LV; Simultaneous	RV only
V. Sensing	CRT-P, CRT-D sessions	RV; LV	RV
Ventricular Support Rate (VOO)	All sessions	Off; 30; 35; ... 95 min ⁻¹	Off

Technical Data

For information on the Merlin™ or Merlin™ 2 Patient Care System (PCS), refer to the Merlin PCS Model 3650 User's manual or the Merlin 2 PCS Model MER3700 User's manual.

- Mechanical Specifications (page 36)
- Electrical Specifications (page 39)
- LED States (page 39)
- Measurement Ranges and Tolerances (page 39)
- Essential Performance (page 40)
- Electromagnetic Compatibility (page 40)
- Battery Information (page 45)
- Merlin™ PSA Accessories (page 46)
- Storage and Operating Conditions (page 46)
- Cleaning, Disinfecting, and Sterilization Methods (page 47)
- Maintenance (page 51)

- Disposal (page 51)
- Troubleshooting (page 51)

Mechanical Specifications

Figure 17. Top dimensions PSA only

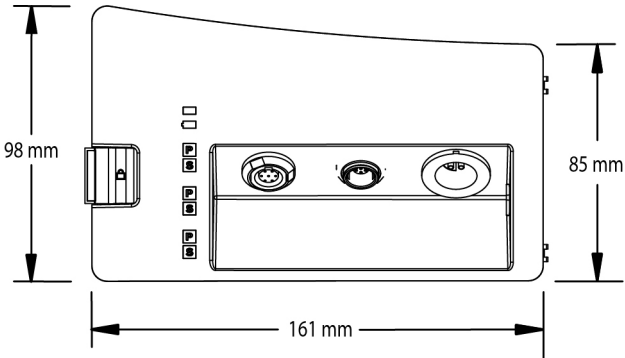


Figure 18. Top dimensions PSA in case

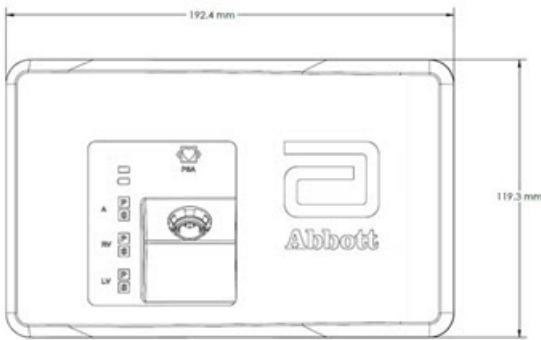


Figure 19. Front dimensions PSA only

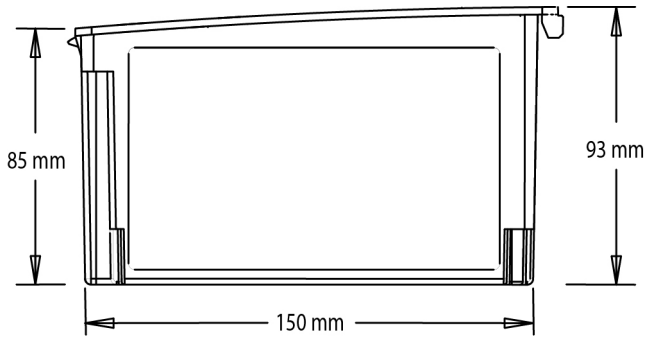


Figure 20. Side dimensions PSA only

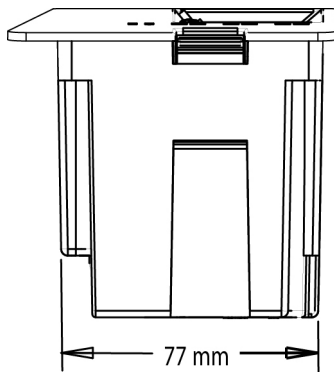


Figure 21. Front and side dimensions PSA in case

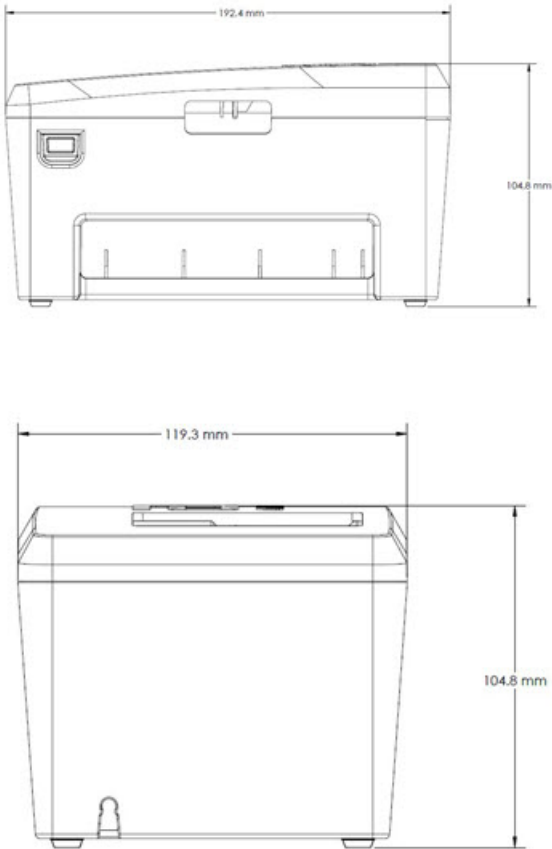


Table 12. Merlin PSA mechanical specifications

	Specification
Weight (PSA only)	0.52 kg (including batteries) 0.44 kg (excluding batteries)
Weight (PSA in case)	0.84 kg (includes batteries and case)
Materials (PSA and case)	PC/ABS Polymer
Battery	Four (4) AA-size LR6 (alkaline) batteries ¹

1. See also Battery Information (page 45).

Electrical Specifications

Table 13. Merlin PSA electrical specifications

	Specification
Supply voltage	5 Vdc (+/- 5%)
Power dissipation	3 W

LED States

Figure 22. LED status indicators (for explanations, see table below)



Table 14. LED Status Indicator Descriptions

	LED	Color/Status	Description
1	PSA Status Indicator	Blue/On	PSA is on, powered through Merlin PCS.
		Blue/Off	PSA is not on or is using batteries.
2	Battery Status	Yellow/Off	Not operating on batteries.
		Yellow/On	PSA is operating on batteries.
		Yellow/Flashing	PSA is operating on batteries near depletion. Replace the batteries immediately.
3	A/RV/LV Pace	Green/On	Paced event
		Green/Off	No paced event
4	A/RV/LV Sense	Amber/On	Sensed event
		Amber/Off	No sensed event

Measurement Ranges and Tolerances

Table 15. Ranges and tolerances for Merlin™ PSA measurements

Measurement	Range	Tolerance
ECG	±5 mV	0 to -20% of the vertical display gain
EGM	±35 mV	0 to -10% of the vertical display gain
Sensed intervals	100-1991 ms	±10 ms
Measured heart rate	30 - 300 min ⁻¹	±1 min ⁻¹ or ± 1% ¹

Table 15. Ranges and tolerances for Merlin™ PSA measurements

Measurement	Range	Tolerance
Intrinsic signal amplitude	0.1 - 35.0 mV	±0.1 mV or ± 10% ¹
Slew rate	0.1 - 8.0 V/s	±0.1 V/s or \hat{A} ± 10% ¹
Pacing lead impedance	200 - 4000 Ω	±10% for impedances in the range of 200 - 2499 Ω (at 5.0 V) \hat{A} ±15% for impedances in the range of 2500 - 4000 Ω (at 5.0 V)
AV Delay	25 - 450 ms	±5 ms
Base Rate	30 - 220 min ⁻¹ (2000-273 ms)	±5 ms
Interventricular Delay	10 - 80 ms	±5 ms for nominal pulse width
Pulse Amplitude	0.1 - 10.0 V	±5% or 0.08 V, whichever is greatest for pace intervals > 400 ms (with a pacing load of 500 Ω) ±20% or 0.4 V, whichever is greatest for pace intervals of 40-400 ms (with a pacing load of 500 Ω)
Pulse Width	0.1 - 1.5 ms	±0.015 ms

1. Whichever is greater.

Essential Performance

The Merlin™ PSA provides diagnostic information related to the implanted lead and provides pacing pulse at a rate and amplitude set by the operator.

The Merlin PSA operates in conjunction with the Merlin™ PCS Model 3650 and Merlin™ 2 PCS Model MER3700; therefore, the essential performance defined for the Merlin PCS and Merlin 2 PCS governs and limits the available performance that is exhibited by the Merlin PSA Model EX3100.

NOTE: For single fault conditions, see Troubleshooting.

Electromagnetic Compatibility

The Merlin™ PSA requires special precaution with regard to electromagnetic compatibility (EMC) and should be used in accordance with the EMC information provided in this section of the manual.

Do not use the Merlin PSA near other electronic equipment. In particular, avoid portable and mobile RF communication equipment, such as mobile phones, as well as equipment emitting strong magnetic fields. This may affect the operation of the Merlin PSA.

The Merlin PSA complies with the requirements of the international EMC standard IEC 60601-1-2 when used with the cables listed in the accessories table (page 46).

The Merlin PSA is intended for use in the electromagnetic environment specified in the tables below.

The Merlin PSA is intended for use in an electromagnetic environment where radiated RF disturbances are controlled. Maintain a reasonable distance between portable and mobile RF

communications equipment (transmitters) and the Merlin PSA.

Table 16. Guidance & manufacturer's declaration - electromagnetic emissions

Test	Compliance	Electromagnetic Environment - Guidance
RF Emission CISPR 11	Group 1	The Merlin PSA uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emission CISPR 11	Class A	The Merlin PSA is 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	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Table 17. Guidance & manufacturer's declaration - electromagnetic immunity

Test	IEC 60601 Test Level (Compliance Level)¹	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)	Pacing leads provide a low-impedance pathway to the heart. Discharge any static electricity prior to touching the patient or cables. Whenever possible, disconnect the patient cable from the Merlin PSA before moving the cables.
Electrical fast transient/burst IEC 61000-4-4	±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)	

Table 17. Guidance & manufacturer's declaration - electromagnetic immunity

Test	IEC 60601 Test Level (Compliance Level) ¹	Electromagnetic Environment - Guidance
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)	
Voltage dips, shorts, interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T ² [>95% dip in U_T] for 0.5 cycle (<5% U_T [>95% dip in U_T] for 0.5 cycle)	Mains power quality should be that of a typical commercial or hospital environment. In the event of a power loss to the programmer, the Merlin PSA continues to pace in the safe pacing mode for the length of backup battery life. See Battery Information.
	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)	
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.

Table 17. Guidance & manufacturer's declaration - electromagnetic immunity

Test	IEC 60601 Test Level (Compliance Level) ¹	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms (3 Vrms) [V1=3] 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the Merlin PSA, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. ³
Radiated RF IEC 61000-4-3	3 V/m (3 V/m) [E1=3] 80 MHz to 2.7 GHz	

Recommended separation distance:

$$d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$$

80 MHz to 800 MHz⁴

$$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$$

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,⁵ should be less than the compliance level in each frequency range⁶. Interference may occur in the vicinity of equipment marked with the following symbol:



Table 17. Guidance & manufacturer's declaration - electromagnetic immunity

Test	IEC 60601 Test Level (Compliance Level) ¹	Electromagnetic Environment - Guidance
		<ol style="list-style-type: none"> Figures in parentheses are the immunity compliance levels for each test. U_T is the a.c. mains voltage level prior to application of the test level. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. 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. Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than [V1]/m

NOTE: The Merlin PCS and Merlin 2 PCS are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Merlin PCS or Merlin 2 PCS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Merlin PCS or 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 18. Recommended separation distances between portable and mobile communications equipment and the Merlin PCS and the Merlin PSA

Rated maximum output power of transmitter (W)	Recommended separation distance according to frequency of transmitter (m) ¹		
	150 kHz to 80 MHz	80 MHz to 800 MHz ²	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

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

Battery Information

In case of power failure or other system error, the batteries in the Merlin™ PSA support operation of the unit at the maximum Pulse Amplitude settings in all channels and at the maximum Base Rate setting for at least 30 minutes.⁶ The batteries do not power the screen of the Merlin™ or Merlin™ 2 PCS. The yellow Battery LED on the Merlin PSA lights up when the unit is operating on battery power and pacing is enabled.

When the yellow battery LED is flashing, the batteries are near depletion. They should be replaced immediately.

During a power or system failure, the Merlin PSA operates in Safe Pacing mode for as long as the battery life permits. To ensure that the battery life is sufficient, the Merlin PCS or Merlin 2 PCS measures the Merlin PSA battery voltage when the Merlin PCS or Merlin 2 PCS is turned on. If the batteries cannot sustain PSA operation for at least 30 minutes, you will see an on-screen alert at the beginning of a session that indicates the batteries are near depletion and should be changed.

To install new batteries:

1. Disconnect any leads and patient cables from the Merlin PSA.
2. End the PSA Session and turn off the Merlin PCS or Merlin 2 PCS programmer.
3. Remove the connections from the Merlin PSA to the Merlin PCS or Merlin 2 PCS.
NOTE: As needed, remove the PSA from the PSA case.
4. Locate the blue battery compartment hatch (door) on the bottom of the Merlin PSA.
5. Push down the tabs on the door and lift the door open.
6. Remove all four batteries.
7. Insert four new, high-quality AA-size LR6 (alkaline) batteries into the compartment. Install the batteries according to the polarity symbols (+ and -) marked inside.
8. Close the battery compartment door.

NOTE: If necessary, put the PSA back in the PSA case.

9. Reconnect the Merlin PSA to the Merlin PCS or Merlin 2 PCS.
10. Turn on the Merlin PCS or Merlin 2 PCS and start a PSA session.

NOTE:

If the system alerts you that the batteries still need to be replaced after you have replaced the batteries, then:

- You did not turn the Merlin PCS or Merlin 2 PCS off before changing the batteries
- You installed the batteries incorrectly
- The batteries have insufficient voltage.

Repeat this procedure, paying close attention to the polarity symbols in the battery compartment.

CAUTION:

- **Use only high-quality AA-size LR6 (alkaline) batteries in the Merlin PSA.**

⁶ The 30minute estimate assumes an operating temperature of 2040°C and the use of high quality alkaline batteries. Battery performance is reduced at temperatures below 20° C.

- To ensure that the batteries are not inadvertently depleted, end every PSA session by selecting the End Session button. See End a Merlin™ PSA Session (page 15).
- Remove the batteries from the unit if you do not plan to use the Merlin PSA.
- Do not touch the patient while you are changing the batteries.

Accessories

NOTE: The Merlin™ PSA is an accessory to the Merlin™PCS and Merlin™ 2 PCS. While connected to the Merlin PCS or Merlin 2 PCS, the Merlin PSA system is a Class I system and complies with EN 60601-1 and EN 60601-1-2.

The Merlin PSA Model EX3100 should only be used with accessories listed in the table below. The use of other accessories has not been tested and may affect patient safety.

For information on cleaning and sterilizing these accessories, see Cleaning, Disinfecting, and Sterilization Methods (page 47). Operating and storage characteristics can also be found in Storage and Operating Conditions (page 46).

Table 19. Accessories for use with the Merlin PSA system

Accessory Description	Model Number
Merlin PSA Patient Cable, Sterilizable patient cable, 4 m	EX3150
Merlin PSA Cable Adapter, Disposable patient cable adapter, 0.25 m	EX3170
Merlin PSA "M" Adapter, Medtronic patient cable adapter, 0.25 m	EX3180
Single-use patient cable, alligator clip (connects IS-1 lead to Merlin PSA Cable Adapter Model EX3170), 3.7 m	4051L
Single-use patient cable, plunger clip (connects IS-1 or DF4 ¹ lead to Merlin PSA Cable Adapter Model EX3170), 2.4 m	4161

1. SJ4-LLHH is equivalent to DF4-LLHH. SJ4 and DF4 connectors comply with ISO 27186:2010(E).

Storage and Operating Conditions

Table 20. Storage and operating conditions for Merlin™ PSA and accessories

Model	Property/Parameter	Storage		Operating
		Min	Max	
Merlin PSA Model EX3100	Temperature	Min	-40°C	10°C ¹
		Max	70°C	40°C
	Humidity	Min	10% (non-condensing)	30% (non-condensing)
		Max	90% (non-condensing)	75% (non-condensing)
EX3150	Temperature	Min	-10°C	10°C
EX3170		Max	50°C	40°C
EX3180	Humidity	Min	10% (non-condensing)	30% (non-condensing)
		Max	90% (non-condensing)	75% (non-condensing)

1. Battery performance is reduced at temperatures below 20°C.

CAUTION: Allow the unit to warm to ambient temperature when transporting from a

cold environment.

Cleaning, Disinfecting, and Sterilization Methods

NOTE: Do not immerse the Merlin™ PSA in any liquid.

CAUTION: Do not sterilize the Merlin PSA Patient-Cable Adapters Models EX3170 and EX3180.

Table 21. Cleaning, disinfecting, and sterilization methods

Product	Cleaning Method	Disinfecting Method	Sterilization Method
Merlin PSA Model EX3100	Wipe with a damp cloth moistened with a mild soap	Cannot be disinfected	Cannot be sterilized
Merlin PSA Patient Cable Model EX3150	See Special Instructions for the Patient Cable Model EX3150 (page 47).		
Merlin PSA Disposable Cable Adapter Model EX3170	Wipe with a damp cloth moistened with a mild soap	Cannot be disinfected	Cannot be sterilized
Merlin M Adapter Model EX3180	Wipe with a damp cloth moistened with a mild soap	Cannot be disinfected	Cannot be sterilized

Special Instructions for the Patient Cable Model EX3150

Abbott Medical has validated the procedures outlined below as adequate preparation for re-use of the Patient Cable Model EX3150. It remains the responsibility of the processor to ensure that the procedures are properly performed to completely clean, disinfect, and sterilize the patient cable. Processors must validate and routinely monitor their processes. The processor should fully evaluate any deviation from these procedures for effectiveness and potential adverse consequences.

The patient cable can be reprocessed up to 100 times, but its end-of-life is normally determined by wear and damage due to use.

WARNING:

- **Chlorine-based, Phenol-based, and Peroxide-based cleaning and disinfecting detergents and solutions can damage the patient cable.**
- **Do not sterilize the patient cable with gamma radiation.**
- Preparation for Cleaning (page 47)
- Automated Cleaning and Disinfection (page 48)
- Manual Cleaning (page 49)
- Manual Disinfection (page 50)
- Sterilization (page 50)
- Storage (page 51)
- Before Using (page 51)

Preparation for Cleaning

- Immediately after using the Patient Cable Model EX3150, remove excess soil from the

patient cable with a disposable cloth or paper wipe.

- Do not attempt to disassemble the patient cable.
- Carefully release the clips to separate the three pairs of connectors.
- Within an hour of its last use, soak the patient cable in potable water and Cidezyme™⁷ enzymatic detergent solution for at least one hour according to manufacturer's instructions.⁸
- Rinse the cable thoroughly in potable water after soaking it to remove any residual detergent.

You can clean the cable either through an automated system (Automated Cleaning and Disinfection) or manually (see Manual Cleaning).

Automated Cleaning and Disinfection is recommended over Manual Cleaning for optimal results.

NOTE:

- Soak for at least 60 minutes in Cidezyme enzymatic detergent solution. Prolonged exposure to detergent may reduce the expected life of the product. If soaking for longer periods than two hours, soak in water until further processing. Do not soak the cable for longer than 24 hours.
- Minimize the time between presoak and cleaning to prevent the cable from drying.
- Do not exceed concentration recommended by the manufacturer of the detergent.
- Follow the detergent's instruction for use to optimize cleaning efficiency.

Automated Cleaning and Disinfection

The goal in cleaning the Patient Cable Model EX3150 is to remove any surface contamination on the product to facilitate the disinfection and sterilization of the cable. Thus, cleaning must be viewed as the first step in the process that includes disinfection and sterilization for eventual re-use of the cable.

The goal of disinfection is reduce the bioburden to a level so that the sterilization process will reach a sterility assurance level (SAL) of 10⁻⁶.

Equipment:

- Washer/disinfector complying with ISO 15883-1
- Detergent and neutralizer: Neodisher™ FA & Neodisher™ Z⁹, or
- Detergent: Neodisher™ MediClean⁴

Instructions:¹⁰

1. Load the Patient Cable Model EX3150 into the washer/disinfector. Position the patient cable so that all surfaces are exposed.
2. Pre-wash using cold, potable water (15°C) for five minutes.
3. Clean at 55°C for five minutes using Neodisher FA detergent or Neodisher MediClean detergent according to the manufacturer's instructions.

⁷ Cidezyme™ is a trademark of Advanced Sterilization Products.

⁸ St. Jude Medical has validated the following challenge parameters for cleaning efficiency: Cidezyme enzymatic detergent solution 0.8% v/v, 20° C ± 2°C, 60 min soak.

⁹ Neodisher™ FA, Neodisher™ Z, and Neodisher™ MediClean are trademarks of Chemische Fabrik DR. WEIGERT GmbH & Co. KG.

¹⁰ St. Jude Medical has validated the following challenge parameters for cleaning and disinfection efficiency: Pre-wash water one minute. Cleaning temperature 55°C (-0°C +3°C), Neodisher FA detergent 0.2% v/v, Neodisher MediClean detergent 0.2% v/v. Rinse Neodisher Z detergent 0.1% v/v, two minutes. Rinse water one minute. Disinfection temperature 93°C (-0°C +5°C) corresponding to AO value of 3000.

4. If you use Neodisher FA detergent, rinse with cold, potable water (15°C) for five minutes using Neodisher Z detergent according to the manufacturer's instructions.
5. Rinse with cold, potable water (15°C) for five minutes.
6. Begin thermo-disinfection at 93°C for five minutes.
7. Unload the patient cable and check for complete removal of soil.

If necessary, repeat the steps above or use the Manual Cleaning method (page 49).

NOTE:

- Do not exceed 120°C in the drying cycle.
- Load washer disinfection such as the water and detergent can reach all surfaces.
- Do not overload the washer disinfectant.
- Do not exceed concentration recommended by the manufacturer of the detergent.
- Follow the detergent's instruction for use to optimize cleaning efficiency.

Manual Cleaning

The goal in cleaning the Patient Cable Model EX3150 is to remove any surface contamination on the product to facilitate the disinfection and sterilization of the cable. Thus, cleaning must be viewed as the first step in the process that includes disinfection and sterilization for eventual re-use of the cable.

Equipment:

- Ultrasonic cleaner sized to fully immerse the Patient Cable Model EX3150
- Potable water
- Cidezyme enzymatic detergent solution

Instructions:¹¹

1. Clean the Patient Cable Model EX3150 ultrasonically for 10 minutes using Cidezyme enzymatic detergent solution according to the manufacturer's instructions.
2. Rinse the patient cable thoroughly in lukewarm potable water or until no visual signs of the detergent is left on the cable.
3. Wipe dry with a lint-free cloth.

NOTE:

- Do not exceed 30 minutes of ultrasonic cleaning.
- The ultrasound must achieve a minimum of 35 kHz.
- The temperature of the cleaning solution should not exceed 35°C.
- Make sure no residues of soil can be seen on the cable.
- Do not exceed concentration recommended by the manufacturer of the detergent.
- Follow the detergent's instruction for use to optimize cleaning efficiency.

¹¹ St. Jude Medical has validated the following challenge parameters for cleaning efficiency: Ultrasonic frequency 35 kHz, Cidezyme enzymatic detergent solution 0.8% v/v, 20° C ± 2°C. Rinse 30 s potable water 30°C ± 3°C followed by rinse 10s in cold demineralized water.

- After rinsing, ensure that no visible residue of detergent is left.

Manual Disinfection

The goal of disinfection is reduce the bioburden to a level so that the sterilization process will reach a SAL of 10^{-6} .

Equipment:

- Cidex™ OPA¹² (Orthophthalaldehyde (OPA)-based disinfection solution)
- Demineralized water

Instructions:¹³

1. Visually inspect the Patient Cable Model EX3150 for any trace of soil and repeat Manual Cleaning (page 49) if necessary.
2. Immerse the patient cable in Cidex OPA solution for 12 minutes according to the manufacturer's instructions.
3. Rinse the patient cable thoroughly in lukewarm demineralized water for at least one minute or until no visual signs of the solution is left on the cable.
4. Wipe dry with a lint-free cloth.

NOTE:

- Make sure no visual residues of detergent are seen on the cable.
- Do not exceed concentration recommended by the manufacturer of the detergent.
- Follow the detergent's instruction for use to optimize cleaning efficiency.
- Prolonged exposure to disinfection agent may reduce the expected life of the product.

Sterilization

The goal is to render a device free from all forms of viable microorganism with a SAL of 10^{-6} .

Equipment: Autoclave with vacuum complying with EN 285 or ANSI/AAMI ST8.

Instructions:

1. Seal the cable in a sterilization pouch suitable for moist heat sterilization.
2. Sterilize the Patient Cable Model EX3150 a minimum of four minutes at 134°C. Do not exceed six minutes or 137°C.

NOTE:

- The sterilization process must be validated according to ISO 17665-1.
- Prolonged sterilization time or increased temperature will reduce the expected life of the product.
- Use demineralized water (less than 20 µS).
- Ensure that the autoclave's maximum load is not exceeded.

¹² Cidex™ OPA is a trademark of Advanced Sterilization Products, Johnson & Johnson.

¹³ St. Jude Medical has validated the following challenge parameters for disinfection efficiency: Cidex OPA solution delivered ready for use, OPA 0.55%, 20° C ±2°C. Immerse cold demineralized water one min.

Storage

Store the Patient Cable Model EX3150 in its sealed sterile pouch. See also Storage and Operating Conditions (page 46).

Before Using

- Visually inspect for soil, damage, wear and corrosion.
- Check the connector to the Merlin™ PSA for smooth movement and proper locking.
- Ensure that lead connector clip functions well before starting the procedure.

Maintenance

Before using the Merlin™ PSA and any of its accessories, visually inspect the items for any damage.

The Merlin PSA and its accessories do not contain any user-serviceable parts. Preventive maintenance, including periodic safety checks, is not required. Do not modify the Merlin PSA or its accessories. If there is a problem with the Merlin PSA or its accessories, contact Technical Support (page 31).

Disposal

The device contains a battery and the label is affixed to this device in accordance with European Council Directives 2002/96/EC and 2006/66/EC. These directives call for separate collection and disposal of electrical and electronic equipment and batteries. 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.

Troubleshooting

Loss of Communication

If communication between the PSA software and the Merlin™ PSA device is broken, for example, due to a cable disconnection, burst stimulation is terminated and you will no longer be able to change any parameter settings. In case of a communication loss, the Merlin PSA stores the current parameter settings and restores them when communication is restored. The Merlin PSA displays a lost communications alert message. Programming is not possible when a break is detected.

To remedy a communications loss, turn off the Merlin™ PCS or Merlin™ 2 PCS, disconnect and then reconnect the Merlin PSA cable to the PSA port on the Merlin PCS or Merlin 2 PCS.

System Failure

Each time the Merlin™ PCS or Merlin™ 2 PCS is turned on, the Merlin™ PSA conducts a self-test. If the test fails, the Merlin PCS or Merlin 2 PCS will not begin a PSA session and the blue LED on the unit will not illuminate. Contact Technical Support (page 31).

If the Merlin PCS or Merlin 2 PCS fails during an ongoing PSA session, the unit will resort to Safe Pacing mode. See Safe Pacing (page 33) for more information.

Low Batteries

Batteries are required for backup operation in case of a system failure. See Battery Information (page 45) for information on replacing the batteries.










EGM Noise

To reduce noise on the EGM display caused by interference with the mains power:

- Do not coil the patient cable or patient cable adapters.
- Keep the patient cable and patient cable adapters away from the power cord.

Symbols

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

Symbol	Description
	Affixed in accordance with European Council Directive 90/385/EEC. Hereby, Abbott declares that this device is in compliance with the essential requirements and other relevant provisions of these Directives.
	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 at the end of its operating life.
	Prescription only
	Manufacturing facility
 <small>medical.abbott/manuals</small>	Consult instructions for use on this website
	Part number
	Product literature
	TÜV Listed, US and Canada. Conforms to UL60601-1. Certified to CAN/CSA C22.2 No.601.1-M90
	Type BF applied part Defibrillation-proof
Made in USA.	Made in USA



St. Jude Medical
Cardiac Rhythm
Management Division
15900 Valley View Court
Sylmar, CA 91342 USA
+1 818 362 6822



EC REP

St. Jude Medical
Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11



St. Jude Medical Puerto Rico LLC
Lot A Interior - #2 Rd Km. 67.5
Santana Industrial Park
Arecibo, PR 00612
USA



St. Jude Medical Operations (M) Sdn. Bhd.
Plot 102, Lebuhraya Kampung Jawa,
Bayan Lepas Industrial Zone
11900 Penang
Malaysia

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