

Pacing System Analyzer

Model 3150

HELP MANUAL

Unless otherwise noted, ™ indicates that the name is a trademark of, or licensed to, St. Jude Medical or one of its subsidiaries. ST. JUDE MEDICAL and the nine-squares symbol are trademarks and service marks of St. Jude Medical, Inc. and its related companies.

© 2010 St. Jude Medical, Inc. All Rights Reserved.

Contents

Welcome to the PSA	1-1
Introduction	1-1
Typographic Conventions	1-1
Technical Assistance	1-1
Pacing System Analyzer Overview	2-1
System Description	2-1
Intended Use	2-2
Contraindications	2-2
Warnings	2-2
Precautions	2-3
Fundamentals of PSA Operation	2-4
Setting Up the PSA System	2-4
User Interface	2-8
Navigating the Screen Display	2-9
System Message Bar	2-10
The PSA Session	2-10
Beginning a Session	2-10
Moving Between PSA and Programming Sessions	2-10
Ending a Session	2-11
ECG/EGM Display	3-1
Viewing Surface ECGs and Real-Time EGMs	3-1
Adjusting the ECG/EGM Display	3-2
Surface ECG Vector Selection	3-2
Assessing the Lead	4-1
Retrieving Lead Measurements	4-1
Performing a Capture Threshold Test	4-3
Selecting Capture-Threshold Test Settings	4-4
Performing a Stimulation Check	4-4
Adjusting Lead Tests Parameters	4-5
Using NIPS	5-1
Printing	6-1
Printing a Report	6-1

Printer Preferences (Merlin™ PCS only)	6-1
PDFs	6-2
Continuous ECG/EGM Printing	6-2
Emergency Operation	7-1
Emergency VVI Pacing	7-1
Technical Data	A-1
PSA Wand	A-1
Mechanical Specifications	A-1
LED	A-1
Electromagnetic Compatibility	A-1
RF Operating Frequencies	A-3
Maintenance	A-3
PSA Wand Battery	A-3
Cleaning	A-3
Storage and Operating Conditions	A-4
Disposal	A-4
Initial Values	A-4
PSA System Parameters	A-5
PSA Accessories	A-6
Cleaning	A-7
Symbols	A-8
Using On-Screen Help	B-1
Accessing On-Screen Help	B-1
From the Start-Up Screen	B-1
During a Session	B-2
Navigating On-Screen Help	B-2
Navigation Buttons	B-2
Moving from Page to Page with the Scroll Bar	B-2
Cross-References	B-3
Table of Contents and Index	B-3
Search	B-3
Printing On-Screen Help Pages	B-4
Index	1-1

1. Welcome to the PSA

Introduction

This manual describes the St. Jude Medical™ Pacing System Analyzer (PSA) system.

For descriptions of specific St. Jude Medical pulse generators, warnings, precautions, and implantation instructions, refer to the user's manual for the applicable model.

The PSA system consists of the Model 3150 PSA wand along with either the Model 3307 software (version 4.7 or greater) that runs on the Model 3510 programmer or the Model 3330 software (version 1.0 or greater) that runs on the Merlin™ Patient Care System (PCS).

Typographic Conventions

This manual uses different formats to distinguish tasks, notes, cautions and warnings.

1. Numbered paragraphs contain instructions.

Paragraphs like this one provide an explanation of the paragraph above it as well as additional information that might be useful at that point in the procedure.

[CONSOLE] button names are written in uppercase and enclosed in brackets.

Screen button names are written in upper and lower case letters, for example, Base Rate.

Note

Notes provide information that is particularly useful or important.

CAUTION

Cautions flag conditions that may damage the PSA system or pulse generator or that may prevent their safe and effective use.

WARNING

Warnings call attention to potential safety hazards and situations that may cause personal injury.

Technical Assistance

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

- 1 818 362 6822
- 1 800 722 3774 (toll-free within North America)
- + 46 8 474 4147 (Sweden)

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

2. Pacing System Analyzer Overview

This chapter provides an overview of the Pacing System Analyzer (PSA) system, including:

- Intended use, contraindications, warnings, and precautions
- Setting up the PSA system
- Start-up sequence
- Navigating the screen display
- System messages
- Beginning and ending a session, including moving between a PSA session and programming session.

Refer to Appendix A for technical data and additional information about the PSA wand and accessories.

System Description

The PSA Model 3150 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 PSA Model 3150 system uses the St. Jude Medical™ Model 3510 programming system or the Merlin™ Patient Care System (PCS).

In addition to the Model 3510 programming system or the Merlin PCS, the PSA Model 3150 system consists of:

- the PSA Model 3150 wand
The wand has sensing and pacing capabilities and a port for connecting a patient-cable adapter. Additionally, the PSA wand can be used with the Model 3510 programming system as a standard telemetry wand for programming devices and performing device-based testing.
- a PSA wand adapter
The Model 3615 adapter connects the PSA wand to the Merlin PCS.
- a patient-cable adapter
The patient-cable adapter connects the PSA wand to sterile patient cables that attach to the implanted lead connectors.

Note

Only persons properly trained to operate the PSA system should do so.

The Model 3150 PSA wand can only be used as a telemetry wand with the Model 3510 programming system and pulse generators that do not require the use of a magnet with the wand for programming. The PSA wand does not function as a telemetry wand when used with the Merlin PCS. Refer to the appropriate user's manual or reference manual for magnet use information.

For information on the Model 3510 programming system, refer to the St. Jude Medical Programmer Hardware Manual. For information on the Merlin PCS, refer to the Merlin PCS User's Manual. For technical data and other information on the PSA wand and accessories, refer to Appendix A.

Intended Use

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

Contraindications

There are no known 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 PSA system is not intended for use as a temporary pacemaker.

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 pulse generator and leads as possible.

Rapid Atrial Stimulation. Use of high rates in the atrium could result in high-rate conduction to the ventricle. Accidental high rate stimulation of the ventricles may result in ventricular tachycardia or fibrillation. Defibrillation equipment should be readily available during non-invasive programmed stimulation.

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 PSA system in the DDD or VDD pacing mode with only the ventricular pacing lead connected. Interference detected at the unconnected atrial input of the PSA wand 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 PSA system may inhibit completely or revert to asynchronous operation, pacing at the Base Rate. The Model 3510 programmer or Merlin PCS could potentially cause interference with the PSA wand. Additional sources of strong EMI that can temporarily affect the operation of the PSA wand include the following:

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

Move the PSA wand as far from potential sources of EMI as possible.

Threshold Tests. During threshold tests, 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 PSA system as a temporary pacemaker. It is a diagnostic device and 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 PSA wand continues to pace in the selected mode and at the selected base rate. However, the PSA system should not continually be used as an external temporary pacemaker and the patient should be connected to an external temporary pacemaker as soon as possible.

High Output and Maximum Sensitivity. In the presence of large ventricular depolarization potentials or large output pulses, use of high atrial sensitivity (low numerical settings) may allow ventricular potentials to inappropriately inhibit (or trigger) the atrial output. Similarly, use of high sensitivity in the ventricle may result in inappropriate inhibition of the ventricular output due to T-wave or myopotential sensing.

Connecting the Lead System. Connect the PSA wand to the programmer and launch the PSA application. Then connect the patient-cable adapter, and the sterile patient cable(s), to the PSA wand before connecting the lead(s) 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, the leads, or the PSA wand.

Whenever possible, disconnect the patient-cable adapter from the PSA wand before moving the PSA wand or cables. Failure to do so may result in damage to the PSA wand.

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 end the PSA session.

Defibrillation/Cardioversion. The PSA wand may be damaged by defibrillation shocks when it is connected to an implanted lead system. Test the PSA wand after it has been exposed to such charges by launching the PSA application and verify that the LED on the wand is on. Whenever possible, for the safety of the patient, disconnect the PSA wand from the lead system before defibrillation or cardioversion.

Environmental Precautions. The PSA wand 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 PSA wand to extreme temperatures and/or humidity as that may result in inaccurate measurements
- do not expose the PSA wand to mechanical shock as it may damage the wand and result in unreliable measurements
- do not store the PSA wand 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 PSA system.

Sterilization. Do not sterilize the PSA wand or damage will result.

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

Fundamentals of PSA Operation

Setting Up the PSA System

Note

When connecting the PSA wand to the implanted lead(s), make sure that all connections are secure.

Connecting the PSA Wand to the Model 3510 Programmer

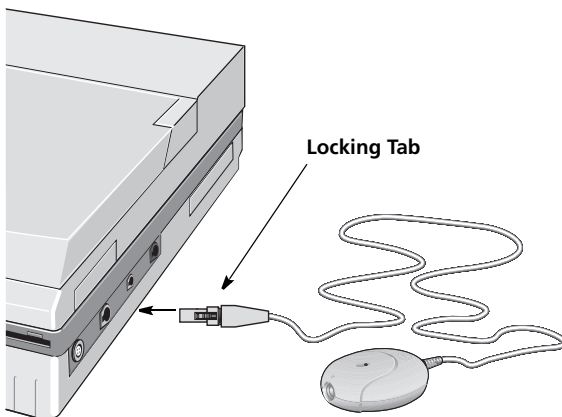


Figure 2-1. Connecting the PSA wand to the Model 3510 Programmer

To set up the PSA system with the Model 3510 programmer:

1. Plug the PSA wand into the “Telemetry Wand” port on the right side of the programmer. The PSA wand plug has a locking tab to prevent accidental disconnection resulting in loss of communication (Figure 2-1).

To use the PSA wand as a standard telemetry wand inside the sterile field (Model 3510 programming system only), place it into a sterile bag or glove. The PSA wand can not be sterilized. For information on cleaning the PSA wand, see “Cleaning” on page A-3.

Note

To disconnect the PSA wand from the programmer, depress the locking tab and pull the connector out of the port.

2. Turn the programmer On.

The programmer powers up and the Start-Up screen appears, prompting you to go to the Main Menu, Interrogate the pulse generator, or access the Pacing System Analyzer application.

For information on the Main Menu or Interrogating the pulse generator, refer to the Model 3510 Programmer Hardware Manual or appropriate reference manual.

3. Press the Pacing System Analyzer button on the Start-Up screen to launch the PSA application.

Note

If the programmer is already On, launch the PSA application before connecting to an implanted lead. The ECG/EGM display and parameter settings used during the previous PSA session are retained until the PSA application is fully launched. These settings may not be desirable for the next patient. Verify the settings prior to connecting to an implanted lead.

Connecting the PSA Wand to the Merlin PCS

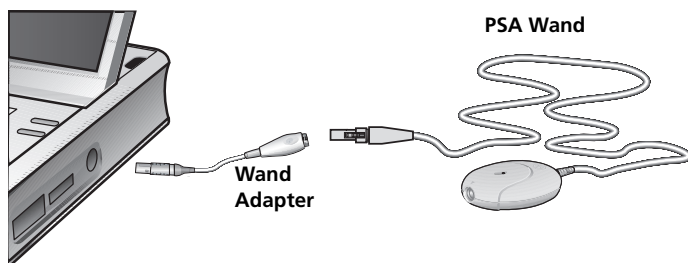


Figure 2-2. Connect the wand adapter to the Merlin PCS and PSA wand

To set up the PSA system with the Merlin PCS:

1. Plug the Merlin wand adapter (Model 3615) into the “PSA” port on the right side of the programmer (Figure 2-2). The Merlin wand adapter plug has a locking mechanism to prevent accidental disconnection resulting in loss of communication.

Note

To disconnect the wand adapter from the programmer, pull back on the locking mechanism and pull the connector out of the port.

2. Plug the PSA wand into the Merlin wand adapter (Figure 2-2). The PSA wand plug has a locking tab to prevent accidental disconnection resulting in loss of communication. The PSA wand and adapter can not be sterilized. For information on cleaning the PSA wand and adapter, see “Cleaning” on page A-3.

Note

To disconnect the PSA wand from the wand adapter, depress the locking tab and pull the connector out of the wand adapter.

3. Turn the programmer On.
The Merlin PCS powers up and the Start-Up screen appears.
4. Select Tools > PSA from the Start-Up screen to launch the PSA application.

Note

If the programmer is already On, launch the PSA application before connecting to an implanted lead. The ECG/EGM display and parameter settings used during the previous PSA session are retained until the PSA application is fully launched. These settings may not be desirable for the next patient. Verify the settings prior to connecting to an implanted lead.

Connecting Cables to the PSA Wand

1. Connect either the St. Jude Medical patient-cable adapter or the Biotronik™-style patient-cable adapter to the PSA wand (Figure 2-3).
Select the adapter that is appropriate for the desired patient cable. For a list of accessories approved for use with the PSA system, see page A-7.

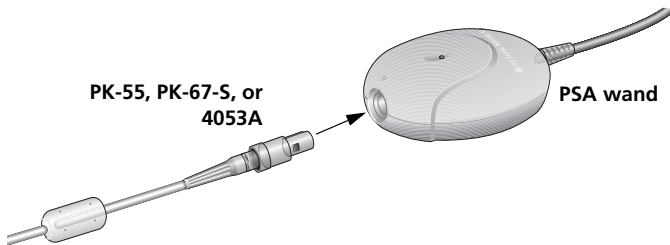


Figure 2-3. Connect the Patient-Cable Adapter to the PSA wand

Note

Place the PSA wand on a stable surface. A mechanical shock, such as a fall to the floor, may damage the PSA wand. If the PSA wand receives a mechanical shock, contact St. Jude Medical.

Avoid winding extra length of cord around the PSA wand as it may shorten its lifetime.

2. Connect the sterile patient cable to the patient-cable adapter (Figure 2-4).

Note

For DF4¹ leads, it is recommended that you use a sterile patient cable with a plunger clip (such as Models 4160 or 4161) as the alligator clips on other patient cables are too large to connect to a single lead electrode on a DF4 lead tip.

Avoid squeezing or compressing the sterile patient cable as it may cause interference on the corresponding channel.

1. SJ4-LLHH is equivalent to DF4-LLHH. SJ4 and DF4 connectors comply with ISO27186:2010(E).

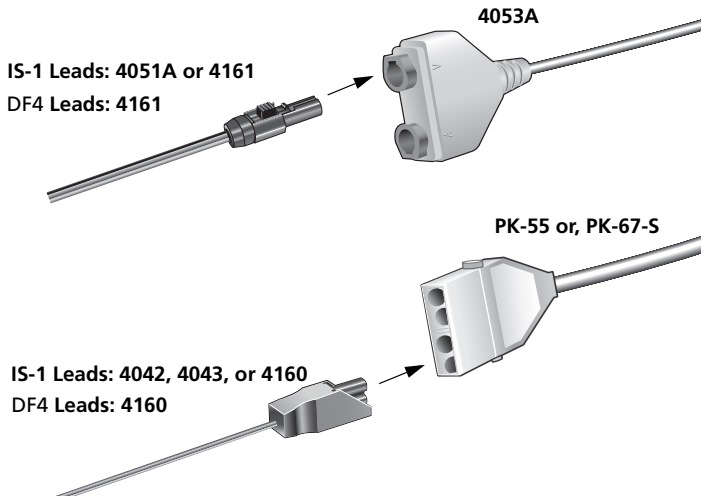


Figure 2-4. Connect the single-use Patient Cable to the Patient-Cable Adapter

3. Connect the sterile patient cable to the tip of the implanted lead.

For appropriate measurements, connect the (+) and (-) patient-cable to the appropriate connection on the lead. For DF4 leads, connect the black plunger clip on the patient cable to the lead pin and the red plunger clip to the first ring from the tip. Refer to the appropriate lead manual for information on the lead configuration.

CAUTION

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

IS-1 Cables: Whether using a single cable with dual connectors for atrial and ventricular channels or using a single connector cable per channel, make sure the atrial lead is connected to the atrial channel and that the ventricular lead is connected to the ventricular channel. Inadvertently reversing the atrial and ventricular connections could result in inappropriate or harmful stimulation as well as inaccurate intrinsic signal and slew rate measurements.

Ensure that the plunger clips on the cables are in contact with the metal portion of the lead tip, as the clip can deform the plastic material and compromise the lead.

Note

Use care when connecting the sterile patient cable to the lead. Avoid contamination of or damage to the sterile connectors or leads.

Whenever possible, disconnect the patient-cable adapter from the PSA wand before moving the PSA wand or cables. Failure to do so may result in damage to the PSA wand.

4. Select the implantable device type on the Lead Tests screen.
Specifying the implantable device type (Pacemaker or ICD) ensures the most accurate test results.
5. You are now ready to begin a PSA session.

User Interface

The PSA system's user interface has three components:

- Touch screen - See the following section, Navigating the Screen Display
- Console buttons
 - Model 3510 programmer - The console buttons are located just above the keyboard. For information on [PRINT MENU] and [PRINT], see page 6-1; [HELP], see page B-1; [EMERGENCY VVI], see page 7-1; and [INITIAL VALUES], see page A-1.
 - Merlin PCS - The console buttons are located on the touch screen. For information on [PRINT], see page 6-1; and [VVI], see page 7-1.
- Keyboard¹ - See "Printing a Report" on page 6-1.

For more information refer to the Programmer Hardware Manual or Merlin PCS User's Manual.

1. For the Merlin PCS, the keyboard is available on-screen.

Navigating the Screen Display

The PSA screens offer various options for selecting parameter values and viewing the EGMs and surface ECG. This section describes some of the features common to the programmer screens.

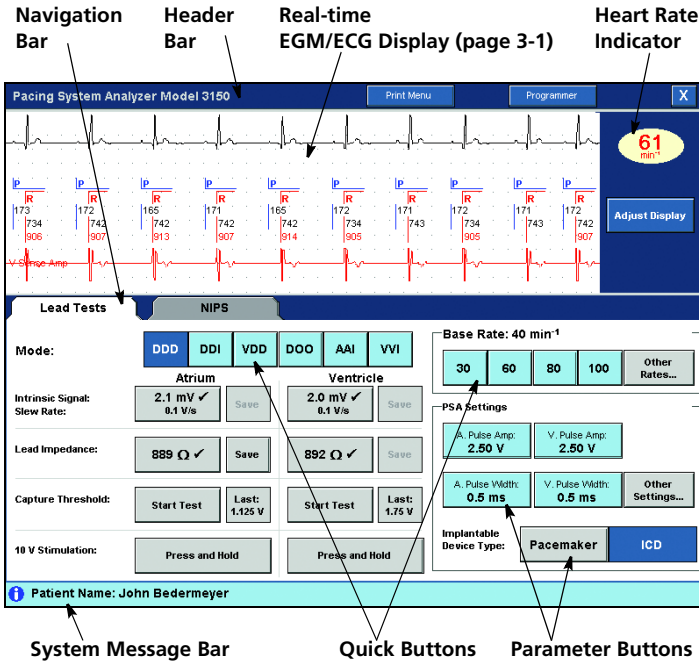


Figure 2-5. Common features of the screen display

Header Bar

The header bar displays the name of the application and provides access to the print menu (“Printing” on page 6-1), programmer applications (“Moving Between PSA and Programming Sessions” on page 2-10) and “X” button (“Ending a Session” on page 2-11).

Heart Rate Indicator

The heart rate indicator oval shows the patient’s sensed intrinsic or paced ventricular heart rate. It is displayed when there is communication between the programmer and the PSA wand.

Navigation Bar

The navigation bar provides access to the primary PSA application functions:

- Lead Tests - see “Assessing the Lead” on page 4-1
- NIPS - see “Using NIPS” on page 5-1.

Buttons

To select a button, press anywhere on its surface.

- **Parameter buttons**

A parameter button displays the parameter name and selected value within the button. Some parameter buttons have up/down arrow buttons adjacent to the parameter button. Pressing the up or down arrow button increments or decrements the selected parameter value. The complete range of values can also be accessed by pressing the parameter button.

- **Quick buttons**

Quick buttons are sets of buttons that allow immediate access to parameter values. Press one of the quick buttons to program the corresponding value.

System Message Bar

The PSA system displays three types of messages:

- **Information**

Information messages report general information. These messages have a blue circle with a white “i” in the center. Examples of conditions that result in an information message are: the patient’s name is entered and stored, or temporary programming is in effect.

- **Work in Progress**

Work in progress messages provide information about an operation which is being completed. These messages display an hourglass. Examples of conditions that result in an in-progress message are: test measurements are being retrieved, or test results are being recorded.

- **Alert**

Alert messages provide information about system conditions and may suggest further action. These messages display a red triangle with a white exclamation point in the center. Examples of conditions that result in an alert message are: printer is out of paper, or emergency VVI settings in effect.

The PSA Session

Beginning a Session

At the beginning of a PSA session, nominal parameter values are loaded. For a list of the nominal parameter values, see “PSA System Parameters” on page A-5.

- To launch a PSA session from the Start-Up screen, press the Pacing System Analyzer button (Model 3510 programmer), or select Tools > PSA (Merlin PCS).
- To begin a new PSA session from within the PSA application, press the “X” button in the header bar to end the current PSA session.

Press New Session on the confirmation screen.

Moving Between PSA and Programming Sessions

You can launch a programming session directly from a PSA session. Data and settings from the current PSA session are retained and can be restored after ending a programming session and launching a new PSA session from the Start-Up screen (Model 3510 programmer) or Tools menu (Merlin PCS), as long as the programmer has not been powered off.

To access a programming session from the PSA application:

1. Press the Programmer button in the header bar.

A message asks you to confirm that you want to launch a programming session.

2. Press Continue to launch a programming session.

- Model 3510 programming system: Place the PSA wand over the pulse generator. The programmer automatically interrogates the pulse generator.
- Merlin PCS: Place the programmer inductive telemetry wand over the pulse generator. The programmer automatically interrogates the pulse generator.

For devices with RF telemetry capability, the programmer communicates with the device through the FRF antenna.

3. Press Cancel to remain in the PSA session, or for the Model 3510 programmer, press the Interrogate button.

A PSA session can be launched only from the Start-Up screen (Model 3510 programmer) or Tools menu (Merlin PCS). If you are in a programming session you must first end the programming session.

Ending a Session

Press the "X" button in the header bar to end the current PSA session. You can either remain in the PSA application to begin a new PSA session or exit the PSA application and return to the Start-Up screen.

The PSA parameter settings are retained until a new PSA session is fully launched, but test results from the previous PSA session are not retained. Launching a new PSA session resets all settings to nominal parameter values. For a list of the nominal parameter values, see "PSA System Parameters" on page A-5.

Note

For the Model 3510 programmer, you can also exit the PSA application by pressing the [SYSTEM RESET] console button.

3. ECG/EGM Display

This chapter describes the real-time ECG/EGM data display. For information on printing surface ECGs and real-time EGMs, see “Continuous ECG/EGM Printing” on page 6-2.

Viewing Surface ECGs and Real-Time EGMs

Surface ECG and electrogram data can be viewed in real-time at the top of the PSA screen. Up to two channels of EGM data with associated markers and one surface ECG tracing can be displayed.

Ventricular sense/pace and atrial sense/pace EGMs reflect the actual sensed signal amplitudes. The markers may be affected by noise (EMI). The markers displayed are defined in Table 3-1.

Marker	Description
A	Atrial Paced Event
V	Ventricular Paced Event
P	Atrial Sensed Event (P-wave)
R	Ventricular Sensed Event (R-wave)
P	Atrial Sensed Event Inside the Relative Refractory Period (P-wave)
R	Ventricular Sensed Event Inside the Relative Refractory Period (R-wave)

Table 3-1. ECG/EGM display markers

Note

ECG/EGM signals are not always displayed while test measurements are retrieved. Continuously monitor the patient’s intrinsic or paced rhythm during testing using an external monitoring system.

For information on using the ECG connection on the programmer, refer to the Programmer Hardware Manual or Merlin™ PCS User’s Manual.

Adjusting the ECG/EGM Display

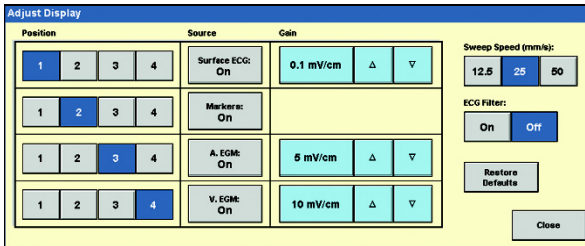


Figure 3-2. An example of the Adjust Display screen

To adjust the display characteristics of the surface ECG and real-time EGM display window:

1. **Press the Adjust Display button.**

This opens the Adjust Display window (Figure 3-2), which allows you to choose the display characteristics of surface ECGs, real-time EGMs, and markers.

2. **Select the desired display characteristics.**

Changes take effect immediately. Press Close to close the Adjust Display window. The ECG/EGM display characteristics are retained from one PSA session to the next.

Surface ECG Vector Selection

For the Merlin PCS, when all five surface ECG electrodes are attached to the patient, you can view any one of seven ECG vectors in the real-time ECG/EGM display. After a PSA session is launched, the programmer displays the ECG vector selection buttons above the real-time ECG/EGM display. The default is vector II.

To change the surface ECG vector, select one of the vector buttons. The surface ECG vector characteristics are retained from one PSA session to the next.

ECG/EGM Display Parameters

Each ECG/EGM channel can be turned On or Off and has an independently adjustable gain. The sweep speed at which the real-time data is displayed is adjustable (12.5, 25, or 50 mm/s). The ECG Filter can be turned On or Off. When the ECG Filter is On, a digital filter attenuates noise in the surface ECG channel. The marker channel can also be turned On or Off.

All ECG/EGM display parameters are retained when the programmer is turned off.

You can adjust the gain of each individual waveform by manually selecting a gain value or by pressing the up and down arrows to increase or decrease the gain by one step each time they are pressed.

To restore the default ECG/EGM display options, press the Restore Defaults button. The default settings are:

- Position 1: Surface ECG On, Gain 0.25 mV/cm
- Position 2: Markers On
- Position 3: A. EGM On, Gain 2.5 mV/cm
- Position 4: V. EGM On, Gain 2.5 mV/cm
- Sweep Speed: 25 mm/s
- ECG Filter: On.

4. Assessing the Lead

This chapter describes the lead assessment features of the PSA system, and instructions for:

- Retrieving and saving intrinsic signal amplitude, slew rate, and lead impedance measurements
- Performing a capture threshold test and a diaphragmatic stimulation check.

Note

Test results from the PSA system should be used as a guideline.

Also described in this chapter are adjusting the mode, base rate, and other PSA settings, along with selecting the implantable device type. All of these controls can be accessed from the Lead Test screen shown in Figure 4-1.

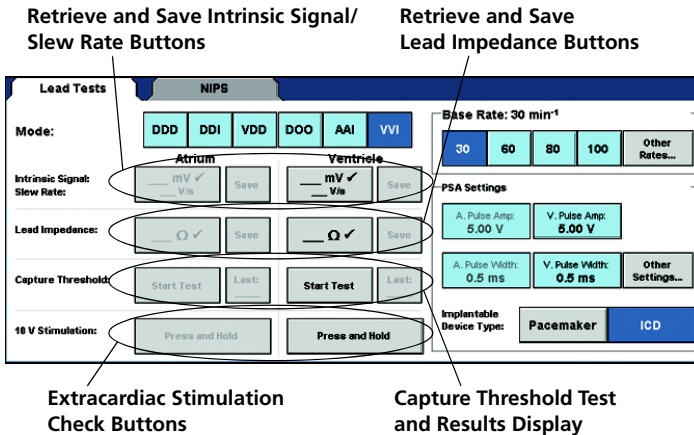


Figure 4-1. An example of the Lead Tests screen

Retrieving Lead Measurements

After the lead is implanted and the PSA system is connected to the implanted lead, you can retrieve intrinsic signal amplitude, slew rate, and lead impedance measurements.

The intrinsic signal amplitudes, slew rates, and lead impedance measurements can each be retrieved as many times as desired. Retrieved measurements must be saved to be available in the printed summary report. Only the three most recent measurement results will be recorded and printed in the summary report. After the third storage of a single measurement, the newest measurement overwrites the oldest measurement stored.

Intrinsic Signal Amplitude and Slew Rate Measurements

CAUTION

Whether using a single cable with dual connectors for atrial and ventricular channels or using a single connector cable per channel, make sure the atrial lead is connected to the atrial channel and that the ventricular lead is connected to the ventricular channel. Inadvertently reversing the atrial and ventricular connections could result in inappropriate or harmful stimulation as well as inaccurate intrinsic signal and slew rate measurements.

To retrieve an intrinsic signal amplitude and slew rate measurement:

1. **Confirm that the patient has intrinsic activity.**
2. **Press the ✓ button for the desired chamber.**

Before any measurements are retrieved, “__” is displayed within the button. If a measurement is unavailable or invalid, “---” is displayed within the button. A valid measurement is displayed within the button.

Three intrinsic wave amplitude and slew rate measurements for the corresponding chamber are retrieved and displayed within the button each time the ✓ button is pressed. Only the third measurement is displayed at the end of the test. As each of the measurements are retrieved, they are displayed within the button and in the real-time ECG/EGM display alongside the corresponding beat. If the three measurements retrieved during a single test are significantly different, this may suggest a PAC, PVC or other undesirable measurement. Perform the test again to reassess the measurements.

If both the atrial and ventricular waveforms are displayed in the real-time ECG/EGM display, only the waveform for the test chamber is displayed while the measurement is retrieved. The displayed waveform may be rescaled during the measurement.

3. **To store the measurement for reporting, press the corresponding Save button to save the value.**
4. **To confirm the values, repeat the steps above.**

Lead Impedance Measurement

Note

Lead impedance measurements with the PSA system are made using asynchronous pacing. Use caution with patients that need additional pacing support.

Performing a lead impedance measurement with the Base Rate at 80 min^{-1} or higher will result in optimal performance of the PSA system.

To retrieve a lead impedance measurement:

1. **Press the ✓ button for the desired chamber.**

The lead impedance at a pacing output of 4.5 V or greater is retrieved and displayed within the button.

If the programmed pulse amplitude is less than 4.5 V, it is automatically increased to 4.5 V for the duration of the lead impedance test. If it is 4.5 V or greater, it remains as programmed.

Before any measurements are retrieved, “—” is displayed within the button. If a measurement is unavailable or invalid, “---” is displayed within the button. A valid measurement is displayed within the button.

Intracardiac EGM waveforms are not displayed in the real-time ECG/EGM display while the measurement is retrieved. Also, only the waveform for the chamber being measured is displayed.

Note

ECG/EGM signals are not always displayed while test measurements are retrieved. Continuously monitor the patient’s intrinsic or paced rhythm during testing using an external monitoring system.

2. To store the measurement for reporting, press the corresponding Save button to save the value.
3. To confirm the value retrieved, repeat the steps above.

Performing a Capture Threshold Test

The PSA system allows you to perform a capture threshold test for pacing capture by delivering fixed-rate pulses on demand. A capture threshold test for each lead can be performed as many times as desired. One result for each lead can be stored.

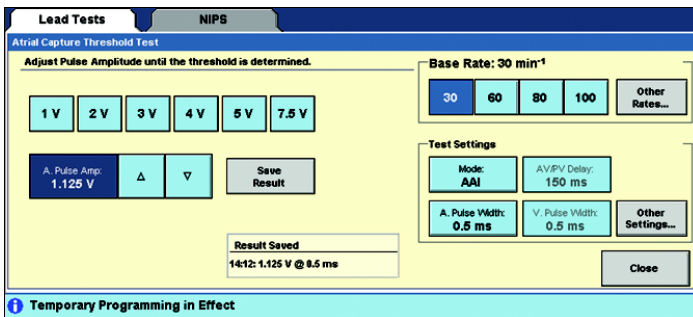


Figure 4-2. An example of the Capture Threshold Test screen

Note

Performing a capture threshold test with the Base Rate at 80 min⁻¹ or higher will result in optimal performance of the PSA system.

To perform a capture threshold test:

1. Press the Start Test button for the desired chamber.

This opens the Capture Threshold Test window. Select the desired PSA settings for the test. To begin the test, increase the base rate above the patient’s intrinsic rhythm. The initial pulse amplitude is displayed.

2. **To adjust the pulse amplitude, either:**

- select one of the quick buttons, or
- press the up or down arrows to increment or decrement from the pre-selected pulse amplitude in smaller steps. *Press and release* the arrows to adjust the pulse amplitude *manually* step by step, or *press and hold* the arrows to adjust the pulse amplitude *automatically* at one step per cycle.

Continue to adjust the pulse amplitude until the capture threshold is determined.

3. **Press Save Result to store the results from this test, or press Close (Cancel Test if no results are recorded) to exit the Capture Threshold Test window.**

The recorded test result is available for review on the Lead Tests screen and for printing on the summary report.

4. **To repeat the capture threshold test, repeat steps 2 and 3.**

5. **Press Close to end the test.**

Saved results are available for review on the Lead Tests screen and for printing in the summary report.

Selecting Capture-Threshold Test Settings

Capture-threshold test settings are selected on the Capture Threshold Test window. When a capture-threshold test begins, all parameters are set to the current PSA values.

Along with pacing mode, AV/PV delay, pulse width, and base rate, additional test settings can be selected by pressing the Other Settings button. This opens the Other Test Settings window. From here, you can adjust the atrial and ventricular sensitivity and refractory periods, and maximum tracking rate.

Any changes to test settings while on the Capture Threshold Test screen apply only during the Capture Threshold Test. All values revert to the PSA settings in effect prior to the test when the Capture Threshold Test screen is closed.

Performing a Stimulation Check

It may be desirable to perform a 10-volt stimulation check to ensure that there is no extracardiac stimulation due to lead placement.

You cannot change the settings associated with the 10-volt stimulation test.

When a 10-volt stimulation test begins, the pulse amplitude is set to 10 V. The pacing mode, pulse width, sensitivity, and refractory periods remain as programmed. If the PSA base rate is less than 80 min^{-1} , it is automatically increased to 80 min^{-1} for the duration of the 10-volt stimulation test. If it is 80 min^{-1} or greater, it remains as programmed. AV/PV delay is available only in dual-chamber modes, and is set to 100 ms. Pulse width, sensitivity, and refractory remain as programmed. All values revert to the PSA settings in effect prior to the test at the end of the 10 V stimulation check test.

Note

Performing a stimulation check with the Base Rate at 80 min^{-1} or higher will result in optimal performance of the PSA system.

To perform a stimulation check:

- **Press and hold the 10 V Stimulation Press and Hold button for the desired chamber.**
Observe the patient for extracardiac stimulation.

A message is displayed with instructions on how to end the 10 V stimulation.

Adjusting Lead Tests Parameters

The PSA pacing Mode, Base Rate, Pulse Width, Pulse Amplitude, Implantable Device Type, AV/PV Delay, Max Track Rate, Refractory period, and Sensitivity parameters can be accessed on the Lead Tests screen (Figure 4-1).

Mode

The pacing mode (Mode) selected determines the availability of measurement and testing controls as well as additional parameters.

To change the PSA pacing mode:

- **Select the desired Mode quick button.**

Base Rate

The current PSA Base Rate is displayed above the base rate quick buttons and is used during a lead assessment to provide pacing support through the lead system.

To change the PSA Base Rate:

- **Select the desired base rate quick button, or**
- **Press the Other Rates button and select the desired base rate from the Base Rate Options window.**

Pulse Amplitude and Pulse Width

The PSA Pulse Amplitude and Pulse Width determine the strength and duration of the pacing pulse during a lead assessment. The Pulse Amplitude and Pulse Width are independently programmable for the atrium and ventricle.

To change the PSA pulse amplitude or pulse width:

1. **Press the parameter selection button for the parameter you want to change.**

The parameter options window opens and displays the available values for that parameter.

2. **Select the desired value.**

This programs the new value and returns you to the Lead Tests window. The new value is displayed within the corresponding parameter selection button.

Implantable Device Type

Specifying the implantable device type ensures the most accurate test results for leads implanted with St. Jude Medical devices.

To change the Implantable Device Type:

- **Select the desired Implantable Device Type quick button.**

Other Settings

The PSA AV/PV Delay, Max Track Rate, Refractory, and Sensitivity can be accessed through the Other Settings button on the Lead Tests screen.

AV Delay is the interval between an atrial pulse and a ventricular pulse in the absence of an inhibiting R-wave. PV Delay is the interval between a sensed atrial event and a ventricular paced pulse in the absence of an inhibiting R-wave.

Max Track Rate is the upper limit of the ventricular stimulation rate in response to the patient's intrinsic atrial activity.

The refractory period is the time in which sensing is effectively disabled in the atrium (A. Refractory) or ventricle (V. Refractory). The atrial refractory period begins after a P-wave or atrial stimulus. The ventricular refractory period begins after an R-wave or ventricular stimulus.

Sensitivity determines the amplitude of signals to which the sense amplifier responds. The higher the mV value, the lower the sensitivity. The device detects any signal equal to or greater than the programmed sensitivity mV value. Sensitivity is independently programmable for the atrium (A. Sensitivity) and ventricle (V. Sensitivity).

To change the AV/PV delay, max track rate, refractory period, or sensitivity:

1. Press the Other Settings button.

The Other PSA Settings window opens and displays the parameter selection buttons available.

2. Press the parameter selection button for the parameter you want to change.

The parameter options window opens and displays the available values for that parameter.

3. Select the desired value.

This programs the new value and returns you to the Other PSA Settings window. The new value is stored and displayed within the corresponding parameter button.

4. Press Close to return to the Lead Tests window.

5. Using NIPS

Noninvasive Programmed Stimulation (NIPS) provides the ability to reproduce and/or terminate a patient's clinical arrhythmia.

NIPS parameters can be selected from the NIPS screen (Figure 5-1).

WARNING

NIPS should be performed only by physicians trained in tachycardia induction and reversion protocols.

Cardiac resuscitation equipment should be available when performing NIPS.

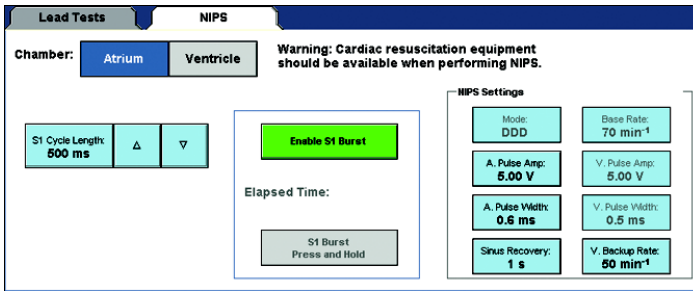


Figure 5-1. An example of the NIPS screen

To deliver NIPS:

1. **Select the desired chamber.**
Chamber selection may be restricted due to the selected mode.
2. **Select the S1 Cycle Length.**
Either:
 - press the S1 Cycle Length button to select a new cycle length, or
 - press the up/down arrows to increment/decrement from the pre-selected cycle length.
3. **Press the green Enable S1 Burst button.**
This activates the S1 Burst, Press and Hold button.
4. **To deliver the burst sequence, press and hold the green S1 Burst, Press and Hold button.**
S1 Burst allows you to deliver continuous stimuli at the selected S1 cycle length for as long as the S1 Burst, Press and Hold button remains depressed.
Release the button to end the burst sequence.
A timer begins with delivery of the first S1 stimuli. The elapsed time is recorded until the button is released. The elapsed time remains displayed until another S1 Burst sequence is initiated.

To change any of the other NIPS settings:

1. **Press the parameter selection button for the parameter you want to change.**
The parameter options window opens and displays the available values for that parameter.

2. Select the desired value.

NIPS Selectable Parameters

Chamber. Depending upon the selected PSA pacing mode, chamber allows the choice of either atrial or ventricular NIPS stimulation. Simultaneous atrial and ventricular NIPS cannot be performed. When the stimulation chamber chosen is the atrium, the Ventricular Backup Rate parameter becomes available to provide VOO support pacing.

Pulse Amplitude. The pulse amplitude is used during delivery of NIPS. It is independent of the currently selected PSA setting for pulse amplitude and applies only to the NIPS protocol in the chosen chamber.

Pulse Width. The pulse width is in effect during delivery of NIPS. It is independent of the currently selected PSA setting for pulse width and applies only to the NIPS protocol in the chosen chamber.

Sinus Recovery. Sinus recovery is the time allowed between the final atrial NIPS pulse and the resumption of atrial pacing. This delay provides a period with no external stimulation to allow time for the sinus node to recover from the stimuli.

Ventricular Backup Rate. During the delivery of atrial NIPS, VOO support pacing is available to reduce the risk of ventricular asystole. You can choose the pacing rate at which ventricular support is delivered. All other parameters remain at their currently selected PSA settings.

6. Printing

This chapter describes printing a summary report, selecting a print source (Merlin™ PCS only), as well as printing continuous real-time ECG/EGM waveforms.

Printing a Report

You have two choices for printing a summary report:

- Press the [PRINT MENU] console button or the Print Menu button located within the header bar. Select the check boxes next to the report details to be printed. You can choose as many or as few of the report details as you want for printing.
To enter a patient's name or implant information, use the keyboard to enter the desired information. Use the Tab key on the keyboard or press the desired field with your finger to navigate between these two fields.
Press the green Print button to print the summary report.
- Press the [PRINT] console button.
A summary report with currently programmed settings is printed.

Printing is interrupted if continuous real-time print is started, and resumes once the real-time print is stopped. Pressing print several times adds summary reports to the print queue, and will be printed when the printer is available.

To cancel the printing of all summary reports in the print queue:

- Press the [PRINT MENU] console button or the Print Menu button located within the header bar. Press Cancel Print Jobs to delete all summary reports in the print queue.

Printer Preferences (Merlin™ PCS only)

When using the Merlin™ PCS, you can print reports to three different printing sources, described below. To select the source, select the Tools Menu, then select Preferences and Printer Preferences.

This window contains two panels:

- **Selected Printer.** You have three choices:
 - PDF Only (Paperless). Sends reports to the programmer's hard disk as a PDF (paperless printing) with no paper documents. See "PDFs" on page 6-2.
 - Internal & PDF. Sends the report to the programmer's internal printer and simultaneously creates a PDF on the hard disk.
 - External & PDF. Sends the report to an external USB printer and simultaneously creates a PDF on the hard disk. Before reports can be sent to an external printer, you must first connect the external printer to any one of the USB ports on the programmer. For more information on connecting an external printer, see the Merlin PCS User's Manual.
- **Number of Paper Copies.** This selects how many reports are printed by the internal or external printer whenever a Print button is selected.

Note

Supported Printers. The Merlin PCS can print to many laser jet printers. For a list of compatible printers, contact your St. Jude Medical Representative or Technical Assistance (page 1-1).

PDFs

Every time you select any Print button to create a report, the Merlin PCS programmer saves the report as a PDF (portable document file).¹ This file can be exported to a flash drive connected to one of the programmer's USB ports. You must install Adobe™ Acrobat™ Reader or Adobe Reader™ on your PC to view the PDF.²

From the PDFs window, you can:

- Check the number of PDFs stored on the programmer's hard disk that have not been exported
- Export all the stored PDFs.
- Export the Most Recent PDFs (created in the last actual session or demo session, including your current session).
- Delete all PDFs.

When you select one of the Export buttons, the Export Data screen appears.

The file naming and storing of the PDFs are as follows:

All PDFs are stored in a folder entitled "PDFs."

Subfolder Name: "Date of PDF creation"

Sub-subfolder Name: "Patient Name_Model Number_Device Serial Number" (read from the Patient Data)

File Name: "Device name_Device Model Number_Device Serial Number_Reportname.pdf"

Example: In the PDF folder is a subfolder called "2008-03-22." In this subfolder is a sub-subfolder called "John Smith_PromoteRF_3207-36_201399." Inside the sub-subfolder is the PDF titled: "PromoteRF_3207-36_201399_TestResults.pdf" containing the test results for John Smith on 3/22/2008.

The Merlin PCS can store a total of 30 "Date of PDF creation" subfolders containing PDFs. When 30 subfolders are stored on the programmer, the oldest subfolder is erased when a newer subfolder is created.

Continuous ECG/EGM Printing

The programmer can print the currently displayed ECG/EGM waveform and marker data in continuous, real-time. For the Model 3510 programming system, select the yellow and blue keys on the programmer keyboard (located near the function keys). For the Merlin PCS, select the real-time print keys (12.5 mm/s, 25 mm/s, and 50 mm/s) on the programmer. While continuous printing is taking place testing can continue simultaneously.

The format and content of the real-time ECG/EGM printout are determined by the settings of the real-time ECG/EGM display (page 3-1). Each segment on the printout represents 5 mm.

-
1. The programmer does not create a PDF for Freezes printed from the Start-Up screen, the Print Screen function, real-time printing, or on-screen Help.
 2. Adobe, Acrobat, and Adobe Reader are trademarks of Adobe Systems Incorporated.

For the Model 3510 programmer, to begin and end continuous printing, press the yellow on/off key on the keyboard at any time. The default printing speed is 25 mm/s, but the programmer resumes printing at the last selected speed. Alternatively, you can select one of the blue sweep speed keys to begin printing. The sweep speed can be changed while the programmer is printing by selecting the appropriate blue sweep speed key (12.5 mm/s, 25 mm/s, and 50 mm/s) on the keyboard.

For the Merlin PCS, to begin continuous printing, select one of the real-time print keys on the programmer. The sweep speed can be changed while the programmer is printing by selecting the appropriate real-time print keys on the programmer. To end continuous printing, press the active sweep speed button.

There is a slight delay between the appearance of the marker on the screen and the printout.

The printout displays:

- ECG/EGM waveform data
- Marker data
- Wand model and serial numbers, and software release numbers
- ECG/EGM display settings
- Date and time.

7. Emergency Operation

Emergency VVI Pacing

Emergency VVI pacing can be delivered to the PSA connections using the programmer.

To begin emergency VVI pacing:

1. Launch the PSA application, if it is not already running
2. Press the red [EMERGENCY VVI] console button (Model 3510 programmer) or the red [VVI] hard key (Merlin™ PCS).

All other PSA system activities are terminated when Emergency VVI Pacing is in progress. A message in the System Notification bar at the bottom of the screen notifies you that Emergency VVI settings are in effect.

Emergency VVI pacing begins immediately, although there will be a slight delay before the System Notification bar message updates.

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

- Mode: VVI
- Base Rate: 70 min⁻¹
- V. Pulse Amplitude: 7.5 V
- V. Pulse Width: 1.5 ms
- V. Sensitivity: 2.0 mV
- V. Refractory: 400 ms.

Note

Pressing the [EMERGENCY VVI] console button (Model 3510 programmer) 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 PSA system, launch the PSA application, then press the [EMERGENCY VVI] console button (Model 3510 programmer) or the [VVI] hard key (Merlin PCS).

The PSA Wand only delivers Emergency VVI Pacing through the ventricular channel. EVVI pacing is not delivered through the atrial channel.

A. Technical Data

For information on the St. Jude Medical™ Model 3510 programmer, refer to the Programmer Hardware Manual. For information on the St. Jude Medical Merlin™ Patient Care System (PCS), refer to the Merlin PCS User's manual.

PSA Wand

Mechanical Specifications

Length	12.0 cm
Width	9.4 cm
Height	3.1 cm
Weight	0.350 kg
Materials	High impact plastic and silicone
Cable Length	3.5 m

LED

The following table lists the different states of the LED on the top surface of the PSA wand.

Type of Session	LED State	Activity
PSA (Merlin PCS & Model 3510 programmer)	On	Normal PSA function.
	Off	No PSA function available. Contact St. Jude Medical.
Programming (Model 3510 programmer only)	Blinking	Normal function. Attempt to communicate with a device.
	On	Normal function. Telemetry in process.
	Off	Normal function. No telemetry in process.

Table A-1. PSA Wand Operation

Electromagnetic Compatibility

The PSA wand 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 PSA wand 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 PSA wand.

The PSA wand complies with the requirements of the international EMC standard IEC 60601-1-2:2001 when used with the cables listed in Table A-5 on page A-7.

The PSA wand is intended for use in the electromagnetic environment specified in Table A-2 and Table A-3.

The PSA wand 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 PSA wand.

Test	Compliance	Electromagnetic Environment – Guidance
RF Emission CISPR 11	Group 2	The PSA wand must emit electromagnetic energy in order to perform its intended function. This is identified by the RF Transmitter symbol (page A-8). Nearby electronic equipment may be affected.
	Class B	The PSA wand can be used in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Table A-2. Guidance & manufacturer’s declaration – Electromagnetic Emissions

Test	IEC 60601 Test Level (Compliance Level)	Electromagnetic Environment – Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact (±6 kV contact) ±8 kV air (±8 kV air)	Pacing leads provide a low-impedance pathway to the heart. Discharge any static electricity prior to touching the patient, cables, leads, or PSA wand. Whenever possible, disconnect the patient-cable adapter from the PSA wand before moving the cables. Failure to do so may result in damage to the PSA wand. This is identified by the ESD sensitivity symbol (page A-8).
Electrical fast transient/burst IEC 61000-4-4	±1 kV for input/output lines (±1 kV for input/output lines)	None
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m (30 A/m)	None

Table A-3. Guidance & manufacturer’s declaration – Electromagnetic Immunity

Test	IEC 60601 Test Level (Compliance Level)	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms (10 Vrms) 150 kHz to 80 MHz	Interference may occur in the vicinity of equipment marked with the RF Transmitter symbol (page A-8).
Radiated RF IEC 61000-4-3	3 V/m (3 V/m) 80 MHz to 2.5 GHz	

Table A-3. Guidance & manufacturer’s declaration – Electromagnetic Immunity (continued)

RF Operating Frequencies

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

- RF Transmission – Carrier frequency below 100 kHz (magnetic field), 100% AM modulation. The effective radiated power is below the limits as specified in EN 300 330.
- RF Reception – Below 100 kHz (magnetic fields).

Maintenance

The PSA wand contains no user-serviceable parts. Contact St. Jude Medical for more information.

PSA Wand Battery

The PSA wand contains 4 batteries (CR2477 lithium/manganese) that are not replaceable. A message is displayed in the System Notification bar when the battery voltage is low. The current PSA session can be finalized. The accuracy of measurements retrieved after the low battery message is displayed is not guaranteed.

When the battery voltage reaches an even lower voltage, the PSA system function is halted. Only the Print Menu, Programmer, and “X” buttons, located in the header bar, and the [Print Menu]¹ and [EMERGENCY VVI] console button (Model 3510 programmer) or [VVI] hard key (Merlin PCS) are active. Even at this lower voltage, the PSA wand will still function as a standard telemetry wand when used with the Model 3510 programmer. For a replacement PSA wand, contact St. Jude Medical.

Cleaning

To clean the exterior of the PSA wand and wand adapter², wipe with a damp cloth moistened with a mild antimicrobial agent such as ethanol or hydrogen peroxide. The PSA wand can not be sterilized.

1. Available on the Model 3510 programmer only.

2. The PSA wand adapter is for use with the Merlin PCS only.

CAUTION

Do not immerse the PSA wand and wand adapter. A Patient-Cable Adapter must be attached to the PSA wand if the PSA wand is cleaned with running water. (See "PSA Accessories" on page A-6.)
Do not sterilize the PSA wand and wand adapter.

Note

The PSA wand is IP-classified to be splash-proof, IPX4, when a Patient-Cable Adapter is attached.
The PSA wand may be placed inside a sterile glove or bag during use.

Storage and Operating Conditions

Property/Parameter	Storage	Operating
Minimum Temperature	-20 C	10 C
Maximum Temperature	50 C	40 C
Minimum Humidity	10% (non-condensing)	10% (non-condensing)
Maximum Humidity	90% (non-condensing)	75% (non-condensing)

CAUTION

Allow the unit to warm to ambient temperature when transporting from a cold environment.

Disposal

Comply with your local regulations on handling of electronic waste.

The battery (4-CR2477 lithium/manganese) in the PSA wand must be disposed of according to local laws. Please recycle the battery whenever possible.

The plastic parts of the PSA wand are marked to ease recycling. Please recycle the plastic parts of the PSA wand whenever possible.

Contact St. Jude Medical for more information.

Initial Values

Press the [INITIAL VALUES] console button to reset all parameters to the values loaded when you turn the programmer On and launch a PSA session. These values are known as the nominal parameter values. The real-time ECG/EGM display settings remain as selected.

Refer to the following section, PSA System Parameters for the nominal parameter values.

PSA System Parameters

Parameter ¹	Units	Range ²
P-wave Amplitude ³	mV	0.1 - 12.5, >12.5
R-wave Amplitude ³	mV	0.5 - 12.5, >12.5
Slew Rate	V/s	0 - 7.6 ⁴
Impedance ⁵	Ω	<200, 200, 201, ... 2500, >2500
A. & V. Pulse Amplitude ⁶	V	0.25, 0.5, ... 4.0, 4.5, 5.0 , ... 7.5, 10.0
A. & V. Pulse Width	ms	0.05, 0.1, 0.2, ... 0.4 ⁷ , 0.5 ⁷ , ... 1.5
Mode	n/a	AAI, VVI , VDD, DDI, DOO, DDD
Base Rate	min ⁻¹	30 ⁸ , 40, 45, ... 130, 140, ... 170
Implantable Device Type	n/a	Pacemaker , ICD
Max Track Rate	min ⁻¹	90, 95, ... 110 , 115, ... 130, 140, ... 180
A. Refractory	ms	125, 150, ... 275 , 300, ... 500
V. Refractory	ms	125, 150, ... 250 , 275, ... 500
AV/PV Delay	ms	25, 30, 40, ..., 150 , ... 200, 225, ... 300
A. Sensitivity	mV	0.1, 0.2, ... 0.5 , 0.75, ... 2.0, 2.5, ... 4.0, 5.0
V. Sensitivity	mV	0.5, 1.0, 1.5, 2.0 , ... 5.0, 6.0, ... 10.0, 12.5
Sinus Recovery Delay	s	Off, 1, 2, ... 5
ECG/EGM Display Source	n/a	Surface ECG, Markers, A. EGM, V. EGM
Gain, Surface ECG	mV/cm	0.025, 0.05, 0.1, 0.25, 0.5, 1, 2, 4, 8

Table A-4. PSA system parameters

Parameter ¹	Units	Range ²
Gain, A. & V. EGM	mV/cm	0.25, 0.5, 1, 2.5 , 5, 10, 20, 40
ECG Filter	n/a	On, Off

Table A-4. PSA system parameters (continued)

1. Sensitivity is with regard to a 20 ms haversine test signal. Input impedance is 25 k Ω . The definition of "pulse" in this manual does not conform to EN 50 061.
2. Nominal parameter values are listed in **bold**.
3. Labeled Intrinsic Wave on screen.
4. If the corresponding intrinsic wave (P-wave or R-wave) measurement is >12.5 mV, then the slew rate is displayed as > x, where x is the calculated value.
5. Impedance measured with fixed output (4.5 V).
6. Pulse Amplitude is measured 60 μ s from the leading edge of the pulse.
7. Nominal is 0.4 ms for Pacemaker and 0.5 ms for ICD.
8. VDD mode, 30 min⁻¹ is not available.

PSA Accessories

Note

The Model 3150 PSA wand is an accessory to the Model 3510 programmer and the Merlin PCS. While connected to the Model 3510 programmer or the Merlin PCS, the PSA system is a Class I system and complies with EN 60601-1:1988 and EN 60601-1-2:2001.

The Model 3150 PSA wand should only be used with accessories listed in Table A-5. The use of other accessories has not been tested and may affect patient safety.

Accessory Description	Model Number
Single-use patient cable, alligator clip (connects IS-1 lead to St. Jude Medical PSA Patient-Cable Adapter Model 4053A, 2.4 m)	4051A
Single-use patient cable, plunger clip (connects IS-1 or DF4 ¹ lead to St. Jude Medical PSA Patient-Cable Adapter Model 4053A), 2.4 m	4161
Single-use patient cable, alligator clip (connects IS-1 lead to Biotronik™ safety adapter (PK-55 or PK-67-S), 2.4 m)	4042, 4043
Single-use patient cable, plunger clip (connects IS-1 or DF4 lead to Biotronik™ safety adapter (PK-55 or PK-67-S), 2.4 m)	4160
PSA patient-cable adapter (connects PSA Wand to St. Jude Medical single-use Patient Cable Models 4051A or 4161), 0.2 m	4053A
PSA wand adapter (connects the PSA Wand Model 3150 to the Merlin PCS)	3615
PSA wand carrying case	50004265

Table A-5. Accessories for use with the PSA system

1. SJ4-LLHH is equivalent to DF4-LLHH. SJ4 and DF4 connectors comply with ISO27186:2010(E).

For specifications, cleaning, sterilization, or other instructions for the accessories listed in Table A-5, refer to the materials shipped with these accessories.

Cleaning












To clean the Patient-Cable Adapter, wipe with a damp cloth moistened with a mild antimicrobial agent such as ethanol or hydrogen peroxide. The patient-cable adapter can not be sterilized.








CAUTION

Do not sterilize the patient-cable adapter.

Symbols

Definitions of globally recognized hardware and packaging symbols used in the labeling of the PSA system required by regulatory authorities are described below.

Symbol	Description
	Type CF applied part Defibrillator-proof
	<p>Affixed to the Model 3150 PSA wand in accordance with European Council Directive 90/385/EEC and 1999/5/EC.</p> <p>Hereby, St. Jude Medical declares that the Model 3150 PSA wand is in compliance with the essential requirements and other relevant provisions of these Directives.</p>
 Programmer	<p>Affixed to the Model 3150 PSA wand in accordance with European Council Directive 1999/5/EC.</p> <p>Programmer connection</p>
 Patient	Patient connector
	RF transmitter
	<p>ETL Listed, US and Canada.</p> <p>Conforms to UL 60601-1. Certified to CAN/CSA C22.2 No.601.1-M90.</p>
	ESD sensitivity
	<p>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 St. Jude Medical at the end of its operating life.</p>
	Contents
	Authorized Representative in the European Community
	Method of sterilization using ethylene oxide

Symbol	Description
	Date of Manufacture
	Manufacturer
	Use By
	Temperature Limitation
LOT	Batch Code
	Do Not Reuse
	Consult instructions for use.
	Do not use if package is damaged.

B. Using On-Screen Help

Note

This chapter provides an overview of the On-Screen Help Function for the Model 3510 programming system. To access help for the Merlin™ PCS, select the ? button in the upper left corner of the screen.

You can view the contents of software reference manuals by selecting the [HELP] button on the programmer console. The Search feature, scroll bar, Index, and Table of Contents allow you to find specific information. Highlighted cross-references (hyperlinks) connect various topics.

Note

Before using On-Screen Help, select the On-Screen Help Language. Select [Main Menu] from the Start-Up screen, then select [System Options]. See the Programmer Hardware Manual for more information.

The On-Screen Help session may be interrupted or automatically terminated by a request from the programmer. Selecting [EMERGENCY VVI] automatically ends the On-Screen Help session.

Accessing On-Screen Help

From the Start-Up Screen

Press [HELP] to display the On-Screen Help Title Page (Figure B-1) which lists the device types for which help is available. Select the desired device type. The Home screen is displayed for that reference manual, which provides the option of seeing the Table of Contents or Index.

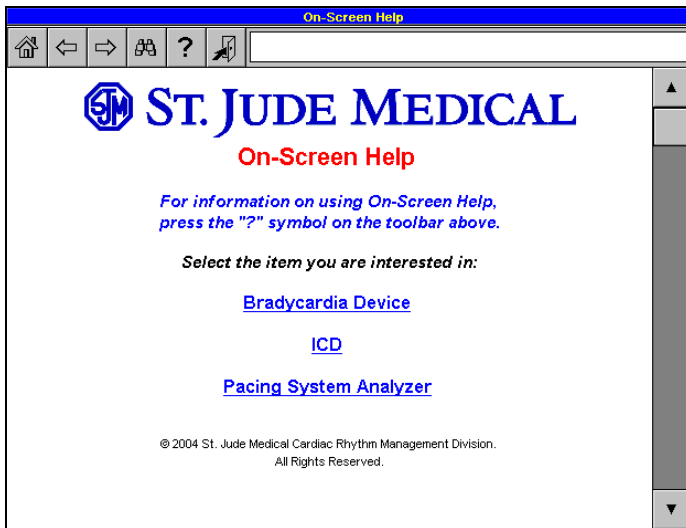


Figure B-1. On-Screen Help Table of Manuals

During a Session

To access the On-Screen Help function during a session, select [HELP]. The Home screen for that reference manual is displayed and provides the option of seeing the Table of Contents or Index.

Navigating On-Screen Help

You can navigate On-Screen Help in a number of ways.

Navigation Buttons

At the top of all On-Screen Help pages are navigation buttons that can speed you through the system.

- **Home Key.** Displays the Home screen (if [HELP] was selected during a session) or the Table of Manuals screen (Figure B-1) (if [HELP] was selected from the Start-Up screen)
- **Left Arrow.** Displays the previously viewed page (Back button)
- **Right Arrow.** Displays the previous page if navigated to by the Back button (Forward button)
- **Binoculars.** Displays the Search function (page B-3)
- **Question Mark.** Displays information on using On-Screen Help
- **Exit Door.** Leaves On-Screen Help and returns you to the session or the Start-Up screen.

Moving from Page to Page with the Scroll Bar

The Up and Down arrows on the scroll bar on the right of the screen move the document one page forward or backward.

To move from one screen to the next, press the Down Arrow at the bottom of the scroll bar. The Up Arrow at the top of the scroll bar moves the display to the previous page.

Touching and moving the scroll bar between the arrows moves the display to another part of the document.

Cross-References

Blue, underlined text represents a cross-reference (or hyperlink) that displays a different section of On-Screen Help. When you select a cross-reference, the page containing that information is displayed. All Table of Contents and Index listings function as cross-references.

To return to the previous page, press the Back button.

Table of Contents and Index

To display information on a topic, select the entry.

Search

You can search for a topic by selecting the Binoculars (Search) button and typing a word, part of a word, or a phrase.

To use the Search function:

1. Make sure you are not on the Home screen or the Table of Manuals screen (Figure B-1) by selecting a device type from the Table of Manuals screen and/or [Table of Contents] from the Home screen.
2. Select the Binoculars (Search) button.

The Search screen is displayed (Figure B-2).

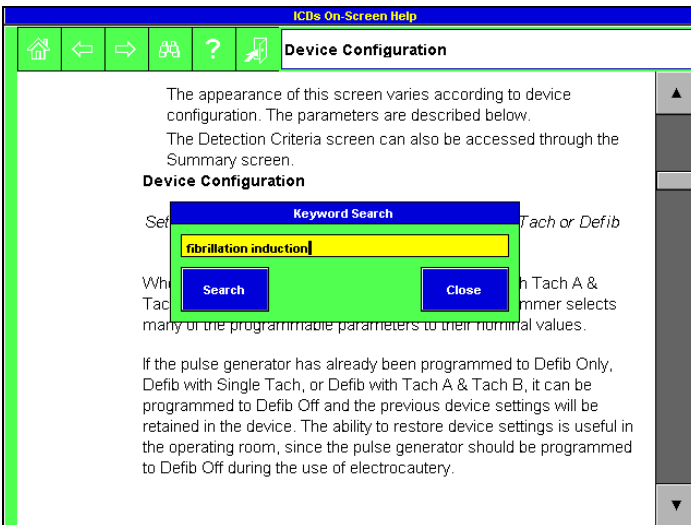


Figure B-2. On-Screen Help Search

3. Type your entry, either a word, part of a word, or a phrase.
4. Select the [Search] button. The programmer closes the search box and displays the first appearance of that word or phrase is displayed.
5. To search again for the same word or phrase, select the Binoculars (Search) button again, and select [Search].

Once you have found the page containing your keyword, close the Search screen by selecting [Close].

Printing On-Screen Help Pages

On-screen help cannot be printed from within the PSA application. To print, end the current PSA session, press [HELP] on the programmer console, locate the desired help page and select the [PRINT] console button.

The programmer prints only the page displayed, not the entire topic (if the topic exceeds a single page). Scroll up or down to print sequential pages.

For more information on printing, see page 6-1.

Index

A

- Accessories
 - cleaning A-7
 - sterilization A-7
- AV delay, lead tests 4-5

B

- Base rate
 - emergency VVI 7-1
 - lead tests 4-5
- Beginning a session 2-10
- Buttons
 - on-screen help B-2
 - parameter 2-10
 - quick 2-10
 - screen 2-10

C

- Cables
 - cleaning A-7
 - sterilization A-7
- Cancel printing 6-1
- Capture threshold test
 - parameters 4-4
 - performing 4-3
- Cautery, use of 2-2
- Chamber, NIPS 5-2
- Console buttons
 - description 2-8
 - print 6-1
 - print menu 6-1
- Continuous printing, ECG/EGM 6-2
- Contraindications 2-2

D

- Description, system 2-1
- Device type 4-5
- Displaying ECGs/EGMs 3-1

E

- ECG/EGM
 - continuous printing 6-2
 - display parameters 3-2

- displaying 3-1
- markers 3-1
- restore defaults 3-2
- viewing 3-1
- Electromagnetic compatibility A-1
- Electromagnetic interference 2-2
- Electrophysiologic Testing
 - Risks 5-1
- Electrostatic discharge 2-3
- Electrosurgical cautery 2-2
- EMC A-1
- EMI 2-2
- Ending a session 2-11
- ESD 2-3

H

- Header bar 2-9
- Heart rate indicator 2-9

I

- Impedance measurements, retrieving 4-2
- Implantable device type 4-5
- Intended use 2-2

K

- Keyboard 2-8

L

- Lead tests
 - AV delay 4-5
 - base rate 4-5
 - implantable device type 4-5
 - max track rate 4-6
 - mode 4-5
 - overview 4-1
 - pulse amplitude 4-5
 - pulse width 4-5
 - PV delay 4-5
 - refractory period 4-6
 - screen 4-1
 - sensitivity 4-6
- LED A-1

M

- Magnet, use of 2-1
- Markers, ECG/EGM 3-1
- Max track rate, lead tests 4-6
- Measurements
 - lead impedance 4-2
 - P-wave 4-2
 - R-wave 4-2
 - slew rate 4-2
- Message bar 2-10
- Messages
 - alert 2-10
 - information 2-10
 - work in progress 2-10
- Mode, lead tests 4-5
- Moving between PSA and programming session 2-10

N

- Navigation buttons, On-Screen Help B-2
- NIPS
 - chamber 5-2
 - delivering 5-1
 - overview 5-1
 - parameters 5-2
 - pulse amplitude 5-2
 - pulse width 5-2
 - screen 5-1
 - sinus recovery 5-2
 - ventricular backup rate 5-2
- Noninvasive pacing stimulation, see NIPS

O

- On-Screen Help
 - navigation buttons B-2
 - overview B-1
 - search B-3

P

- Parameter buttons 2-10
- Parameters
 - capture-threshold test 4-4
 - ECG/EGM display 3-2
 - lead tests 4-5
 - NIPS 5-2
- Patient-cable adapter, description 2-1
- PDFs 6-2
- Precautions 2-3

- Print menu
 - console button 6-1
 - screen button 6-1
- Print, console button 6-1
- Printing
 - cancel 6-1
 - ECG/EGM, continuous 6-2
 - reports 6-1
- PSA wand
 - cleaning A-3
 - description 2-1
 - EMC A-1
 - LED A-1
 - mechanical specifications A-1
 - RF operating frequencies A-3
 - sterilization A-3
- Pulse amplitude
 - lead tests 4-5
 - NIPS 5-2
- Pulse width
 - lead tests 4-5
 - NIPS 5-2
- PV delay, lead tests 4-5
- P-wave measurement, retrieving 4-2

Q

- Quick buttons 2-10

R

- Refractory period, lead tests 4-6
- Reports, printing 6-1
- Restore Defaults, ECG/EGM display 3-2
- Retrieving measurements, overview 4-1
- RF operating frequencies A-3
- R-wave measurement 4-2

S

- Screens
 - common features 2-9
 - lead tests 4-1
 - NIPS 5-1
- Search, On-Screen Help B-3
- Sensitivity, lead tests 4-6
- Sessions
 - beginning 2-10
 - ending 2-11
 - moving between PSA and programming 2-10
- Signal amplitude measurement, retrieving 4-2

- Sinus recovery, NIPS 5-2
- Slew rate measurement, retrieving 4-2
- Specifications
 - EMC A-1
 - mechanical A-1
 - RF operating frequencies A-3
- Static 2-3
- Sterilization
 - accessories A-7
 - cables A-7
 - PSA wand 2-4, A-3
- Stimulation check, performing 4-4
- Sweep speed, ECG/EGM continuous printing 6-3
- System
 - description 2-1
 - set-up 2-4

T

- Technical assistance 1-1
- Tests
 - 10 V stimulation 4-4
 - capture threshold 4-3
 - NIPS
- Touch screen 2-8
- Typographic conventions 1-1

V

- Ventricular backup rate, NIPS 5-2
- Viewing ECGs/EGMs 3-1

W

- Warnings 2-2

Cardiac Rhythm Management Division

Manufacturer:

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

**European Authorized
Representative:**

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

Australian Sponsor:

St. Jude Medical Australia Pty. Limited
17 Orion Road
Lane Cove NSW 2066
Australia

Manufacturing Site:

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

Manufacturing Site:

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

sjm.com



100034897



January 2014
Art 60028118/B



0123
2010