



Medtronic

ENPULSE™

E2DR00/20/30 Series

E2D00 Series

E2VDD00 Series

E2SR00 Series

Vision® Programmer Software Model 9991

Pacemaker Programming Guide

2003



EnPulse Pacemaker Programming Guide

*A guide to using the 9790/C and
2090 programmers with EnPulse
pacemakers*

*Refer to the EnPulse Pacemaker
Reference Guide for information on the
pacemakers.*

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How to use this guide

Information is contained in two guides

Product information about EnPulse software and pacemakers is presented in two separate guides.

The Pacemaker Programming Guide (PPG) accompanies EnPulse software and contains instructions on how to use the programmer and the programming software.

The Pacemaker Reference Guide (PRG) provides detailed information on EnPulse pacemakers.

About the Pacemaker Programming Guide

The Pacemaker Programming Guide presents the following information to use the 9790/C and 2090 programmers.

- How to setup and configure the programmer and access on-line help.
- How to start a patient session, use the various follow-up features during the session, and properly end the session.
- How to use checklist to streamline a follow-up session.
- How to view and print the patient's ECG and EGM waveform traces.
- How to configure the pacemaker to collect diagnostic data and how to retrieve and view this information.
- How to measure stimulation thresholds and sensing levels.
- How to program parameter values and verify rate response parameters settings.
- How to run EP Studies.

About the Pacemaker Reference Guide

The Pacemaker Reference Guide describes in detail, how the pacemaker operates and specifies the capabilities of each model.

- Describes the pacing modes, rate response options, special therapy features, telemetry types, and data collection options. In some cases, guidelines are given on how to configure the pacemaker operation.
- Contains troubleshooting information for electrical and hemodynamic problems.
- Specifies parameter and data collection capabilities, longevity projections, and mechanical and electrical specifications.
- Provides general warning and cautions, potential interference sources, and general indications for pacing.
- Contains a glossary of terms.

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Setting up the programmer

1

This chapter provides an overview of setting up the programmer and covers information you should be familiar with before you begin a patient session.

This chapter briefly explains the components associated with the 9790/C and 2090 programmers. This chapter also includes information on connecting an external printer, connecting peripheral devices, and using the display screen.

For more detailed information on setting up your programmer, refer to your programmer manual.

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Operating differences between the 9790/C and 2090 programmers

Medtronic pacemakers (IPGs) can be programmed with either the Model 9790/C programmer or Medtronic CareLink programmer (Model 2090). There are operating differences between the Model 9790/C and Model 2090 programmers.

The major operating differences between the Model 9790/C and the 2090 programmers include:

- display screen changes
- calibration button
- built-in keyboard

Display screen changes

- A task bar has been added at the top of the screen on the Model 2090 programmer. It includes two new indicators:
 - Position Head Light Array
 - Remote View icon

Refer to the *Medtronic CareLink Programmer Reference Guide* for complete information on these features.

- Additional waveform display. (This display screen change applies only to Vision software applications.)

All screens display an additional waveform. For example, if a screen displays two waveform on the Model 9790/C programmer, this screen displays three waveforms on the Model 2090 programmer.

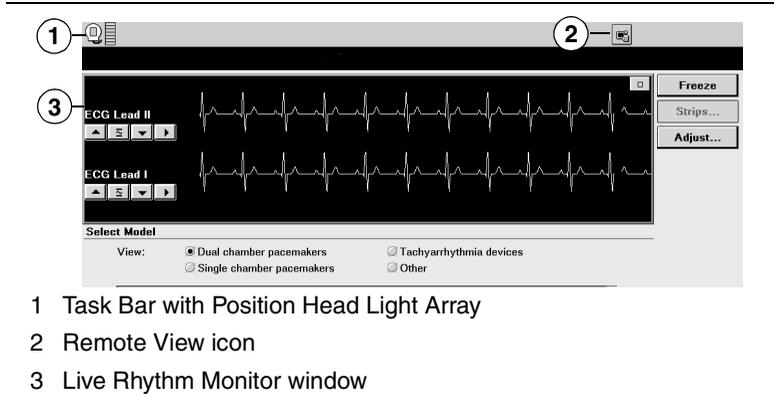


Figure 1-1. Additional display screen features of the Model 2090 programmer

Select Model screen

For pacemaker applications, the [Nominals...] button is inactive for Vision software.

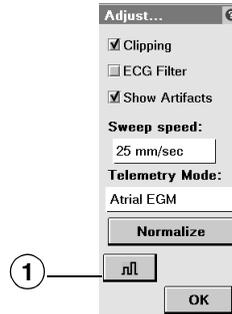
Calibrate button

The Calibrate button¹ is located on the Adjust button menu (when this menu is available) on the Model 2090 programmer. To add a reference signal to the waveform, place the touch pen on the Calibrate button (see Figure 1-2).

¹ For Vision software applications.

Setting up the programmer

Operating differences between the 9790/C and 2090 programmers



1 The Calibrate button is located on the Adjust... menu.

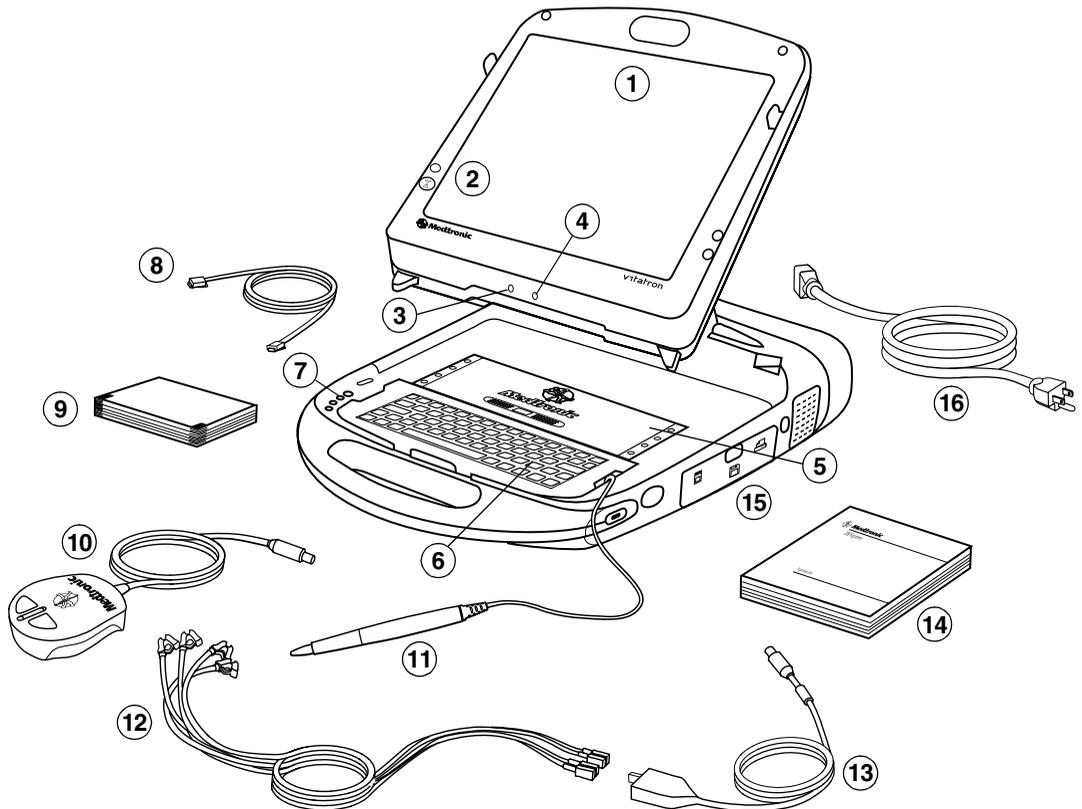
Figure 1-2. Calibrate button

Built-in keyboard operation

The Model 2090 programmer includes a built-in keyboard which is active only when the on-screen keyboard is displayed.

Tap the touch pen outside the area of the keyboard to inactivate the on-screen keyboard. When the soft keyboard is inactive, the hard keyboard is also inactive.

The 2090 programmer system components



- | | |
|------------------------|----------------------------|
| 1 Display screen | 9 Printer paper |
| 2 Emergency VVI button | 10 Programming head |
| 3 Microphone jack | 11 Touch pen |
| 4 Headphone jack | 12 Electrode leads |
| 5 Keyboard cover | 13 ECG Cable with Plug |
| 6 Keyboard | 14 Reference guide |
| 7 Printer controls | 15 Disk drive, Modem cover |
| 8 Telephone cord | 16 Power cord |

Figure 1-3. Programmer components - front view

Note: Only accessories approved by the manufacturer should be used.

Setting up the programmer

The 2090 programmer system components

Display screen – The display can be positioned smoothly from closed to nearly horizontal. Programming options are selected on the screen with the touch pen.

Emergency VVI button – Used to deliver bradycardia VVI operation.

Microphone jack – Intended for future use.

Headphone jack – Intended for future use.

Keyboard cover – Slides forward to protect the keyboard.

Keyboard – Used to enter information.

Printer controls – Selects paper speeds of 12.5, 25, or 50 mm/s. Push a button once to select printing speed. Push it again to stop printing. The Paper Advance button allows the user to properly align the paper.

Telephone cord – Connects the programmer's modem to a telephone jack. The telephone cord must be 26 wire gauge, minimum.

Printer paper – Paper for the internal printer.

Programming head – Provides the communication link between the programmer and the patient's implantable device. The programming head contains a strong permanent magnet, radio-frequency (RF) transmitter and receiver, and light array. It must be held over the implantable device during a program or interrogate operation.

Touch pen – Used to select options on the display screen. Predetermined options are selected by applying the pen to the screen.

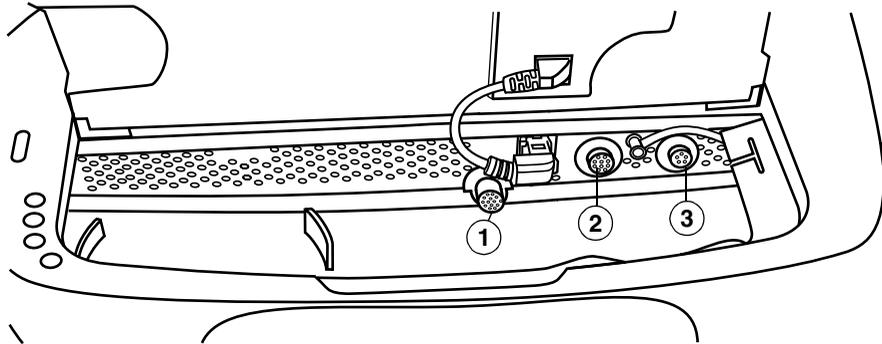
Electrode leads / ECG cable – Connects the programmer to skin electrodes on the patient for ECG and measurement functions requiring surface detection of cardiac and implantable device signals. Five color-coded lead wires connect the cable to standard, disposable skin electrodes applied to the patient.

Note: If you received a five-lead cable with a plug, the plug can be removed for five-lead ECG applications.

Reference guide – The 2090 Programmer Reference Guide provides information about setting up the programmer and between session features.

Disk drive, Modem cover – Provides access to the disk drive, modem, and parallel connector

Power cord – Connects the programmer to an AC power outlet.



- 1 Programming head port (yellow marker)
- 2 Analog input/output port (green marker)
- 3 ECG cable port (black marker)

Figure 1-4. Front connectors (keyboard turned up)

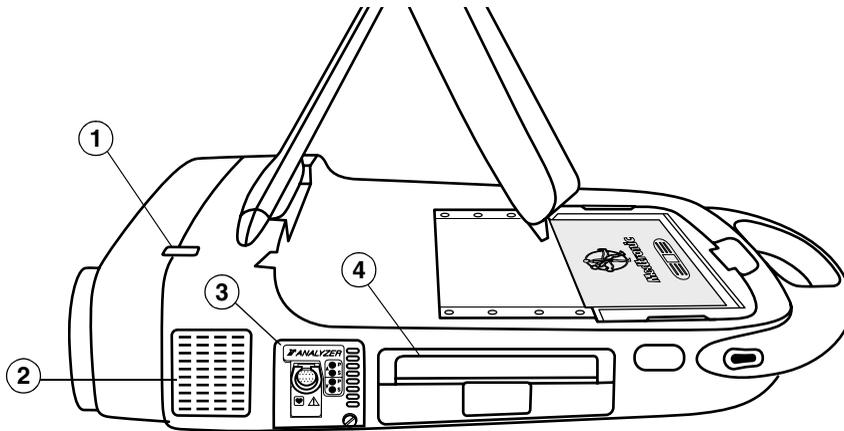
Programming head port – Programming head connector. This connector has a yellow marker.

Analog input/output port – Allows an external monitor or recorder to be connected to the programmer. This connector has a green marker.

ECG cable port – Connects the ECG Cable to the programmer. This connector has a black marker.

Setting up the programmer

The 2090 programmer system components



- 1 ON/OFF switch
- 2 Cooling fan
- 3 Expansion slot
- 4 Printer

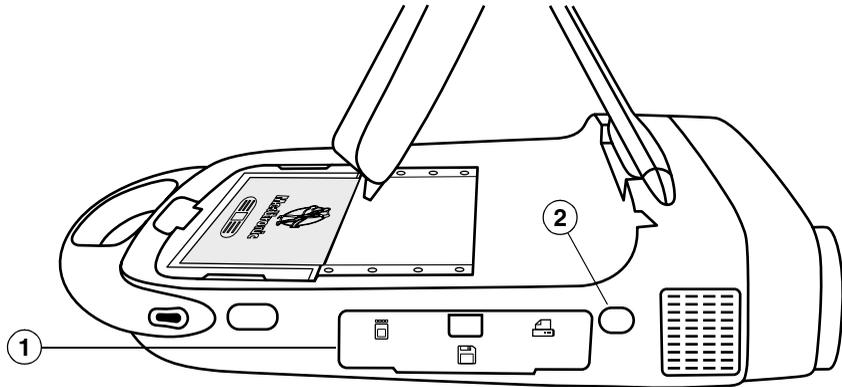
Figure 1-5. Left view

ON/OFF switch – Controls power (AC) to the programmer. Once the programmer is turned off, wait two seconds before turning it on again.

Cooling fan – Internal fan provides continuous airflow to prevent the internal circuitry from overheating.

Expansion slot – Allows for additional features to be added, such as the 2290 analyzer that is available as an option.

Printer – Integral thermal printer with text and graphic output capabilities. According to the selected function, the printer provides data reports, or it prints out a continuous ECG with accompanying Marker Channel telemetry, EGM, or both when available.

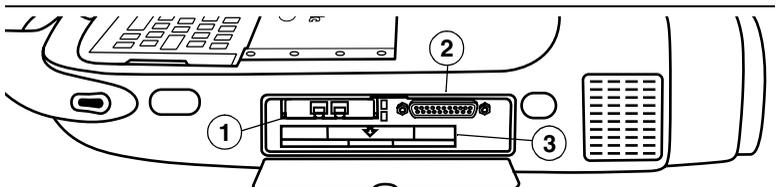


- 1 Disk drive, Modem cover
- 2 Infrared window

Figure 1-6. Right view

Disk drive, Modem cover – Provides access to the disk drive, modem, and parallel connector.

Infrared window – Intended for future use.



- 1 Modem
- 2 Parallel connector
- 3 Floppy disk drive

Figure 1-7. Disk drive, Modem cover open

Modem – Intended for software updates and linking the programmer to a consultant's computer.



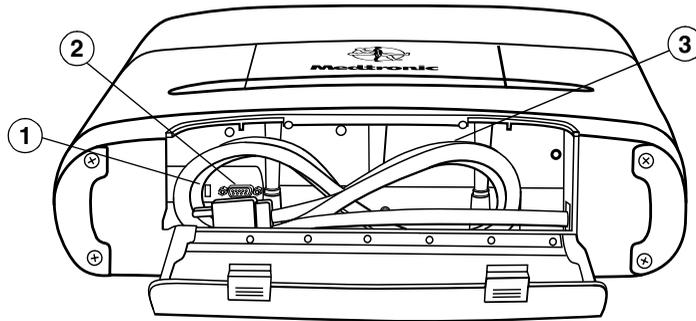
Warning: It is the responsibility of the user to ensure that the telecom voltage does not exceed 125 V.

Parallel connector – Allows a printer or CD ROM drive to be connected to the programmer.

Setting up the programmer

The 2090 programmer system components

Floppy disk drive – 3.5 inch formatted diskette that is IBM-compatible. It can have a capacity of either 720 Kb (DS, DD) or 1.44 Mb (DS, HD).



- 1 USB port
 - 2 VGA Output port
 - 3 Power cord
-

Figure 1-8. Back view (power cord door open)

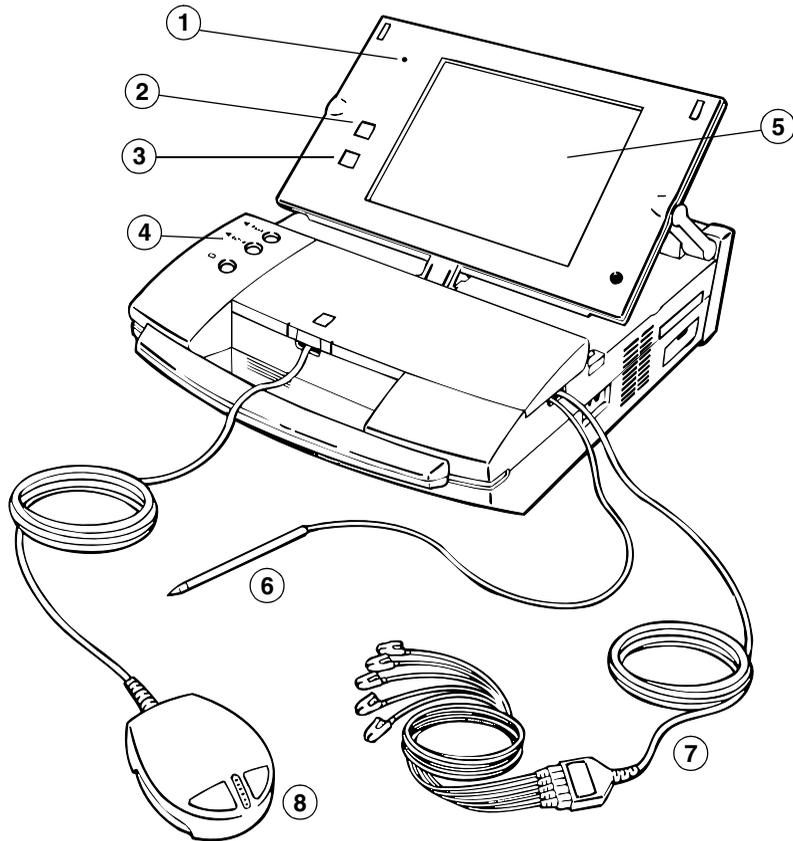
USB port – Intended for future use.

VGA Output port – On some models of programmer the VGA port can be used in porting the screen image of the programmer to an external VGA monitor or for conversion of the output signal to NTSC/PAL format for presentation on a television monitor. Please contact Medtronic for technical guidance.

Caution: To protect against interference or surge/leak currents, the use of a secondary VGA monitor that meets an applicable safety standard such as UL 60950 or IEC 60950 is strongly recommended.

Power cord – Cord connects the programmer to line (AC) power.

The 9790/C programmer system components



- 1 Position head light
- 2 Emergency button
- 3 Deliver button
- 4 Printer controls
- 5 Display panel
- 6 Touch pen
- 7 ECG cable
- 8 Programming head

Figure 1-9. External components - front view

Setting up the programmer

The 9790/C programmer system components

Programming head – Provides the communication link between the programmer and the patient's implantable device. The programming head contains a strong permanent magnet, radio-frequency (RF) transmitter and receiver, and Light Array. It must be held over the implantable device during a program or interrogate operation.

ECG cable – Connects the programmer to skin electrodes on the patient for ECG and measurement functions requiring surface detection of cardiac and implantable device signals. Five color-coded lead wires connect the cable to standard, disposable skin electrodes applied to the patient.

Touch pen – Used to select programming options on the display screen. Options are selected by applying the pen to the screen.

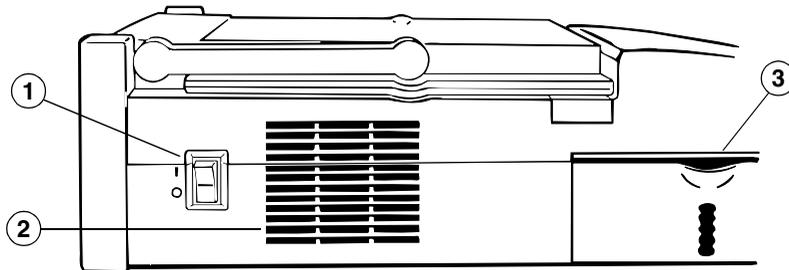
Display panel – Flat panel display with nine adjustable positions ranging from nearly horizontal (15°) to vertical (90°). Programming options are selected on the screen with the touch pen.

Position head light – Dual color (amber/green) light works with the programming head to indicate when a valid communication link to the implantable device exists. An amber colored light indicates no link. When the light goes off, or green, the programming head is positioned and can transmit and receive data. Use of the programming head Light Array is described on page 2-15.

Emergency button – Used to deliver bradycardia VVI operation, or with the Deliver Button, to deliver a tachycardia therapy.

Deliver button – Used with the Emergency Button to deliver tachycardia therapies, which include a defibrillation shock.

Printer controls – Select paper speeds of 12.5 or 25 mm/s. Push a button once to select printing speed. Push it again to stop printing. The Paper Advance button allows you to properly align the paper.



- 1 On/Off switch
- 2 Cooling fan
- 3 Printer

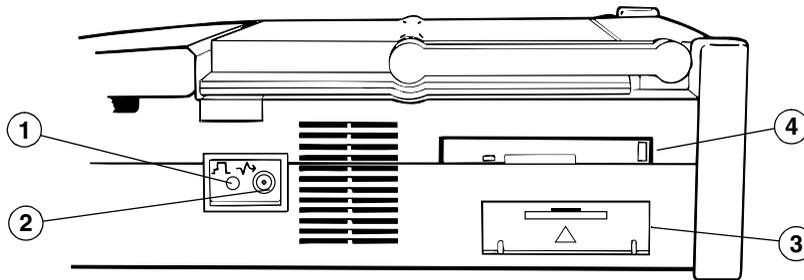
Figure 1-10. External components - left view

Printer – Integral thermal printer with text and graphic output capabilities. Depending upon the selected function, the printer provides data reports, or it prints a continuous ECG with accompanying Marker Channel telemetry or EGM.

On/Off (1/0) switch – Controls power (AC) to the programmer. Once the programmer is turned off, five seconds should pass before turning it on again.

Cooling fans – Internal fans provide continuous airflow to prevent the internal circuitry from overheating. Air is taken in from the front and right side and expelled out the left side.

Setting up the programmer
The 9790/C programmer system components



- 1 Calibration button
- 2 Analog Output
- 3 PCMCIA access
- 4 Disk drive

Figure 1-11. External components - right view

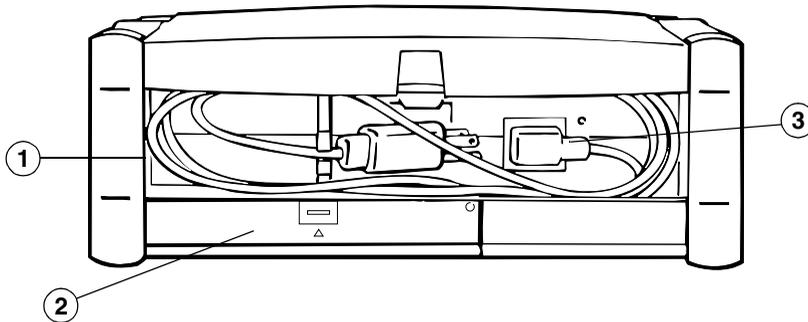
Disk drive – Used to install the software that operates the programmer. The disk drive accepts 3.5 inch diskettes. Once installed, software is permanently stored on an internal hard disk drive. Also used for save-to-disk and DMR-to-disk operations.



PCMCIA access – Personal Computer Memory Card International Association compartment containing two ports for future use.

Analog Output – Provides four analog signals: ECG, Marker Channel telemetry, EGM, and software application specific waveforms.

Calibration button – Used to calibrate the external device connected to the Analog Output.



- 1 Power cord
- 2 Input/Output ports
- 3 AC Power Input

Figure 1-12. External components - back view (power cord door removed)

AC Power Input – Receptacle for connecting the power cord.

Power cord – Cord connects the programmer to line power.



Input/Output ports: Keyboard, Parallel, Serial, and VGA – Currently, the input/output ports are for Medtronic use only. When customer applications for these ports are implemented, specific instructions will be provided in the software manuals.

Connecting an external printer

Connecting a compatible printer to the programmer allows you to print full, page-size reports of session data when available (see the reference guide for the implanted device). This section describes how to connect a printer to your programmer.



Warning: Peripheral equipment connected to the programmer must be certified according to the applicable IEC standards (IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). The system formed by connecting peripheral equipment to the programmer must comply with IEC 60601-1-1 for medical electrical systems. It is the responsibility of the person who connects the peripheral equipment to comply with IEC standards. It is the responsibility of the user to keep peripheral equipment that is certified to IEC 60950 at least two meters away from the patient. Contact the peripheral equipment manufacturer for information about IEC certification.

Printers listed by this software are certified to IEC 60950 (based on information provided by the manufacturers) except the Canon BJC-1000, OKI Okipage 10ex, Samsung QwikLaser 6050, and the Xerox DocuPrint P8ex. Only printers listed by this software may be connected to the programmer.

Printer compatibility

The programmer supports a number of printers as indicated by the printer options accessible on two software screens:

- Session Preferences (see “To set up printing preferences” on page 3-13)
- Print Queue screen (see Figure 1-13)

Note: The print queue during a session lists print jobs for that session only. See “Printing reports held in the Print Queue” on page 3-35 for more information.

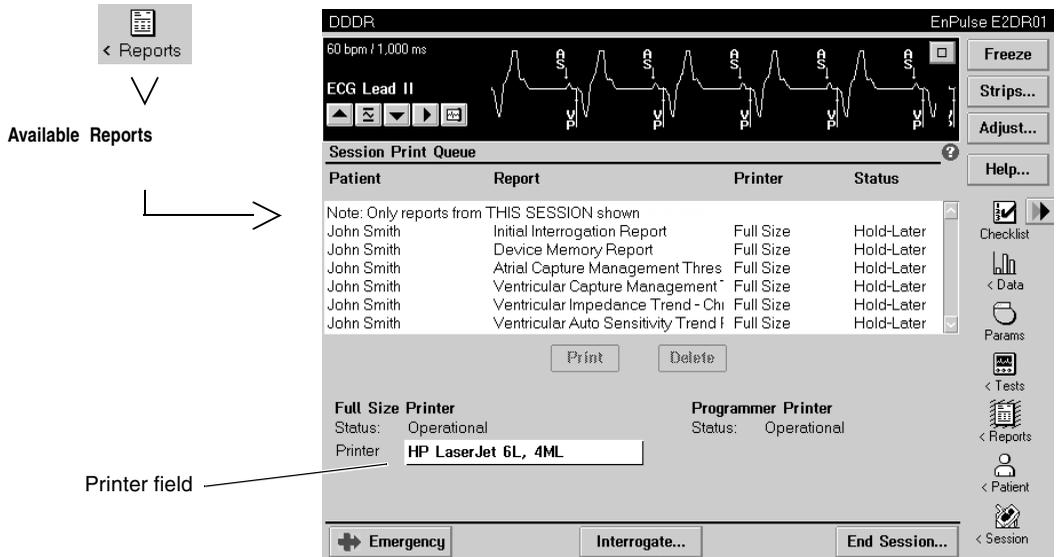


Figure 1-13. Session Print Queue screen

If you are not conducting a patient session, select the Print Queue icon.



The printer that you connect to the programmer must be compatible with one of the printer drivers listed. If your printer is not listed, refer to the manual you received with your printer to see if it emulates (uses the same “driver”) as one of those listed.

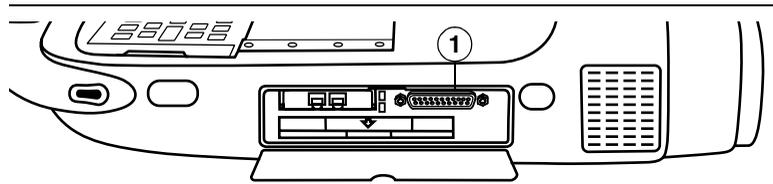
Materials you will need

To connect a printer to the programmer, you will need a Parallel Interface printer cable. One end of the cable must fit the parallel interface port on your printer. The other end of the cable must be a standard 25-pin male D connector. To connect a printer to the 9790/C programmer, you will also need a small Phillips screwdriver to open the parallel port access panel on the back of the programmer.

Connecting the printer

Before connecting a printer to your programmer, you should exit the patient session and turn the programmer off.

To connect a printer to your 2090 programmer



- 1 Parallel connector

Figure 1-14. Parallel connector

Procedure

1. Locate the Modem, Disk drive cover on the right side of the programmer. Open the cover by pushing down on the small latch at the top center of the panel.
2. Connect the printer cable to the parallel connector on the programmer.
3. Connect the other end of the cable to the printer. Connect the printer power cord to an outlet and turn the printer on. Make sure that there is paper in the printer.

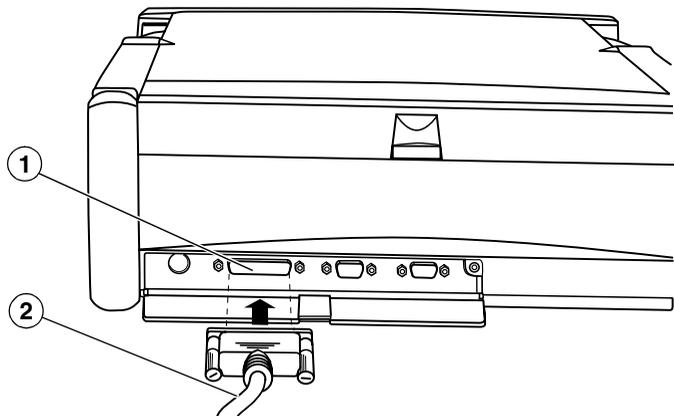
Note: Refer to the technical information provided with your printer for information about connecting and operating the printer.

4. Turn the programmer on, and select the Print Queue icon.

Note: Be sure to select the correct printer driver from the options listed when you select the Printer field on the Print Queue window. You are now ready to use your programmer with the connected printer.

To connect a printer to your 9790/C programmer

1. Locate the parallel port access panel on the back of the programmer.
2. Remove the small Phillips head screw in the upper right corner of the access panel.
3. Open the access panel by pushing downward on the small latch at the top center of the panel.
4. Connect the printer cable to the parallel port on the programmer.



- 1 Parallel port
- 2 Printer cable

Figure 1-15. Connect the printer to the programmer

5. Connect the other end of the cable (if it is not already connected) to the printer. Connect the printer power cord to an appropriate power outlet, and turn the printer on. Make sure that the printer has been loaded with paper.

Note: Refer to the technical information provided with your printer for information about connecting and operating the printer.

6. Turn the programmer on, and select the Print Queue icon.

Setting up the programmer
Connecting peripheral devices

From the Print Queue window, be sure to select the correct printer driver from the options listed when you select the Printer field. You are now ready to use your programmer with the connected printer. Refer to “Printing reports” on page 3-33 for instructions on printing session reports.

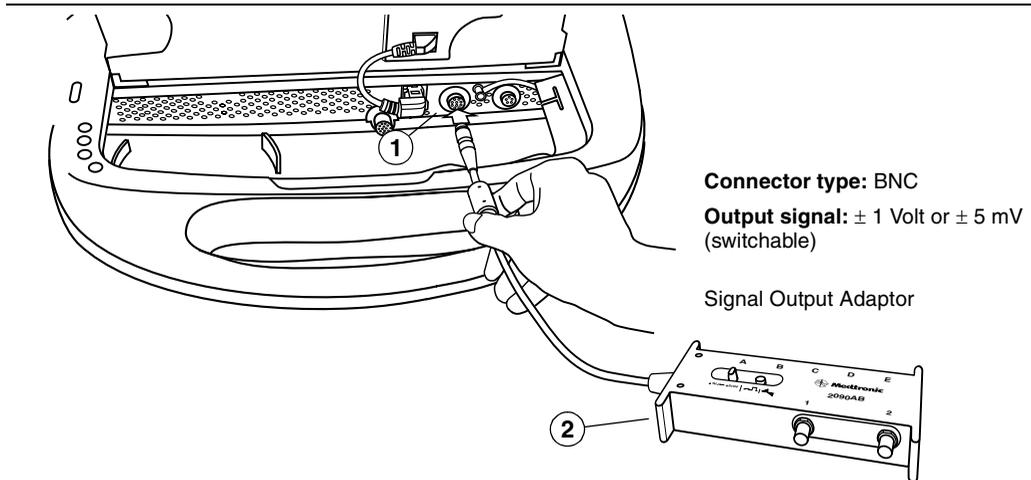
Connecting peripheral devices

An analog input/output connector allows the use of a peripheral isolated medical grade recorder or monitor. A special adapter accessory (not included with the programmer) is needed to use the input/output connector. For a 9790/C series programmer, use a 9790AB analog input/output cable, and for a 2090 programmer, use a 2090AB analog input/output cable. Contact your Medtronic representative for more information. The signals present at the output depend on the software application but may include the following:

- ECG
- Marker Channel telemetry
- EGM
- Software specific waveforms

All electronic devices that are connected to the programmer must meet the electrical safety requirements of IEC-60950.

Locating the peripheral device connector on a 2090 programmer



Connector type: BNC

Output signal: ± 1 Volt or ± 5 mV
(switchable)

Signal Output Adaptor

Adaptor output signals (after model selection):

- A** - Patient's ECG (uppermost ECG on display)
- B** - Telemetered EGM (uppermost EGM on display)
- C** - Telemetered EGM (other EGM if programmed)
- D** - Marker Channel Telemetry
- E** - Intended for future use

Adaptor input signals (after model selection):

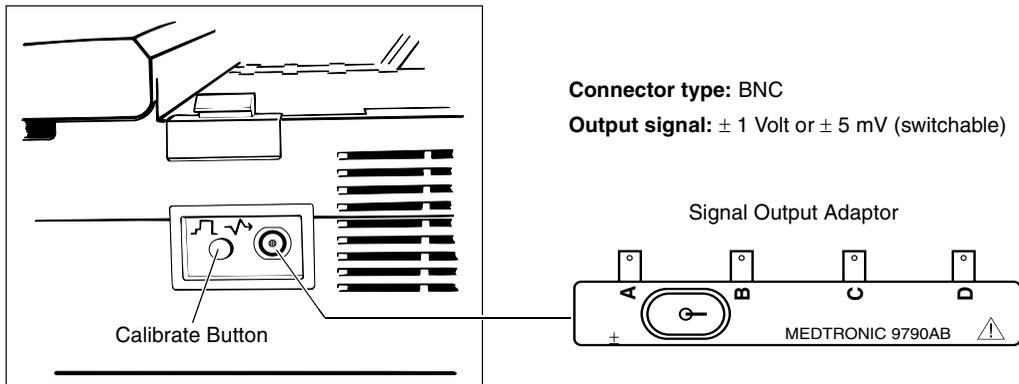
- 1** - Intended for future use
- 2** - Intended for future use

1 Analog Input/Output connector with green marker (under the keyboard)

2 Model 2090AB Analog Input/Output adaptor

Figure 1-16. Analog Input/Output connector

Locating the peripheral device connector on a 9790/C programmer



Connecting the Optional Adaptor to the Analog Output Port on the Programmer.

Adaptor output signals (after model selection):

- A** - Patient's ECG (uppermost ECG on display)
- B** - Telemetered EGM (uppermost EGM on display)
- C** - Telemetered EGM (other EGM if programmed)
- D** - Marker Channel Telemetry

Figure 1-17. Connecting the optional external adaptor

Using the Calibrate button

Selecting the Calibrate button located next to the analog output port adds a reference signal (as shown in Figure 1-18 and Figure 1-19) to the trace of Marker Channel and EGM telemetry.

The Marker Channel signal shows the relative marker amplitudes, which are not annotated with character codes on an external device. The EGM calibration signal acts as a voltage reference for the displayed EGM.

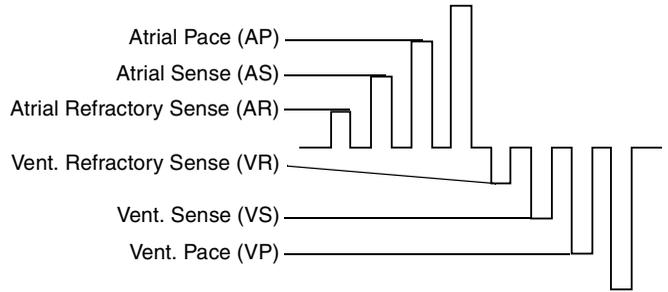


Figure 1-18. Marker Channel signals

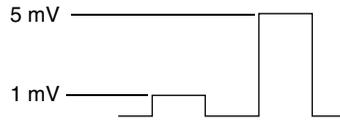


Figure 1-19. EGM calibration signals

The display screen

The programmer display screen is an interactive device that not only displays information in the form of both text and graphics but also functions as a control panel by displaying buttons and menu options that you can select using the stylus.

Features and conventions of the display screen

This section describes the features and conventions of the display screen. The Therapy Parameters screen below shows the main elements of the typical screen.

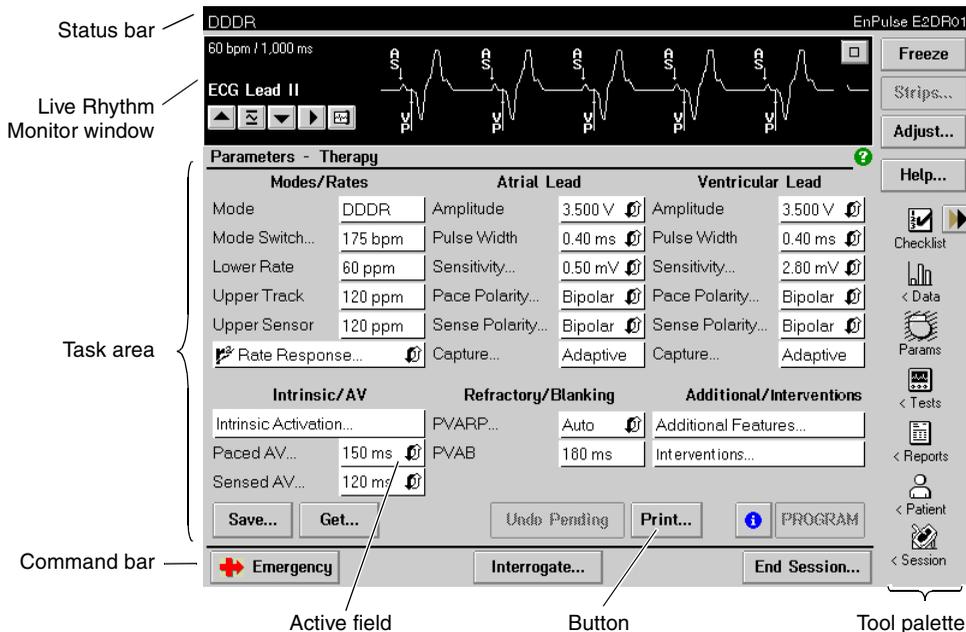


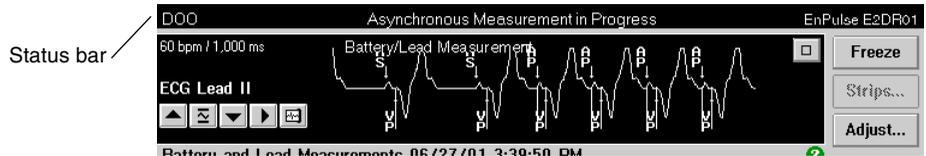
Figure 1-20. Main elements of a display screen

Note: For information on changing the language in the screens (for example, from English to German), see “Changing the language setting” on page 2-4.

The status bar

The status bar at the top of the screen shows this information:

- The present pacing mode
- When any one of a number of test conditions is occurring
- The pacemaker model

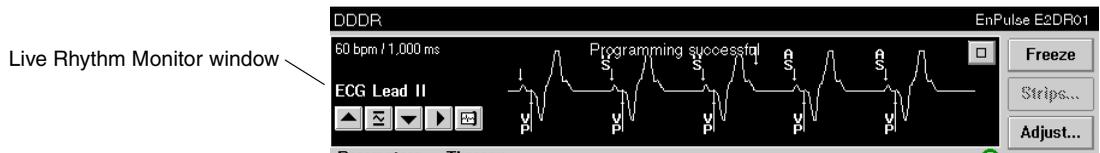


Status bar

The Live Rhythm Monitor window

This window is a partial view of the full-screen display of ECG, Marker Channel, and telemetered EGM waveform traces. You can expand this window to its full size by selecting the small square button in the upper-right corner of the window or by selecting the [Adjust...] button.

- Heart rate and rate interval show if the programming head is positioned over the pacemaker.
- Annotations above the waveform trace show the point of programmed parameter changes.



Live Rhythm Monitor window

The waveform trace or traces that show in this window depend on the selected task screen and how traces have been arranged in the full-screen view. Refer to “Viewing the patient’s ECG and EGM traces” on page 4-1 for information about the live rhythm monitor.

The task area

The portion of screen between the live rhythm monitor window at the top and the command bar at the bottom changes according to the task or function you select. The example in Figure 1-20 shows the Therapy Parameters screen for programming pacemaker parameter settings. This task area would appear much different if you selected, for example, the Threshold Test Setup screen.

The command bar

The bar at the bottom of the screen always shows the command buttons for programming emergency parameters settings, interrogating the pacemaker, and ending the patient session.

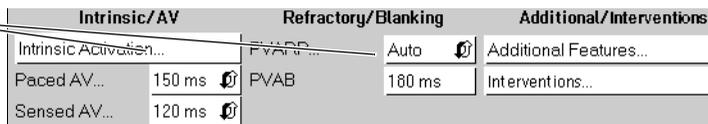


For complete information on these functions, see “Programming Emergency parameters” on page 2-19, “Interrogating the pacemaker” on page 3-16, and “Ending a patient session” on page 3-38.

Active fields

Unshaded areas, or boxes, that appear in the task area are active fields that respond to the stylus.

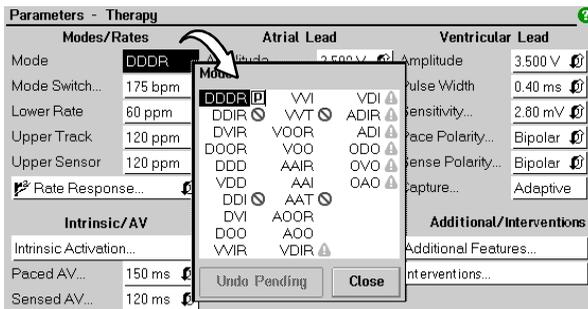
Active fields show as unshaded areas on the screen.



Selecting a value, word, name, or phrase that appears in an active field opens a menu or window of alternative options for whatever is represented in that field.

For example, touching the mode value “DDDR” in the Mode field with the tip of the stylus opens a window of mode options. Selecting any one of these options replaces the original DDDR value with the selected one, which becomes a pending value.

Selecting an active field opens a menu or window of alternative options or, in some cases, an on-screen keyboard.



Selecting some fields (those with terms ending in an ellipsis, such as “Rate Response...”) opens a window displaying additional fields. Some fields that require entry of information, such as patient data, open an on-screen keyboard. How to use this keyboard is described later in this section.

Buttons

Buttons like those shown below allow you to operate the programmer using the stylus. You can “press” a button by touching it with the tip of the stylus.

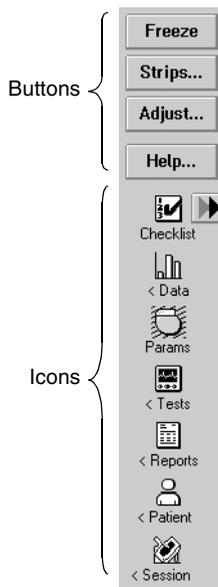
Buttons having a less distinct shaded label are not presently active.



Buttons may directly execute a command, such as the [**Program**] button, or they may open a window that prompts another action. Usually such buttons have a label ending with an ellipsis, such as the [**Save...**] or [**Get...**] buttons shown above.

A procedure may instruct you to “press and hold” a button. In such cases you should touch the tip of the stylus to the button and continue to maintain pressure against the button until it is time to “release” the button.

The tool palette



The collection of buttons and icons along the edge of the screen is referred to as the tool palette. These are the controls you use to choose the task or function screen you want displayed. Once you have started a patient session, the tool palette is always displayed, making it quick and easy to move to the desired task or function.

Each of the icons acts like a button. To select an icon, touch the icon with the stylus. The “<” symbol adjacent to some of the icons indicates that selecting one of these icons opens a menu of related options. The icons without the “<” symbol directly open a task screen.

Refer to Table 3-1 on page 3-6 for a brief explanation of the purpose of each button and icon in the tool palette.

Note: If the programmer is operating in the Demo mode, the Session icon is replaced with the Demo icon.

Using the on-screen keyboard

Certain fields on the screen allow you to enter data, such as the patient's name or chart number. Selecting such a field automatically displays the on-screen keyboard shown below. By touching the letter or character buttons with the stylus, you can use this display feature like an actual keyboard.

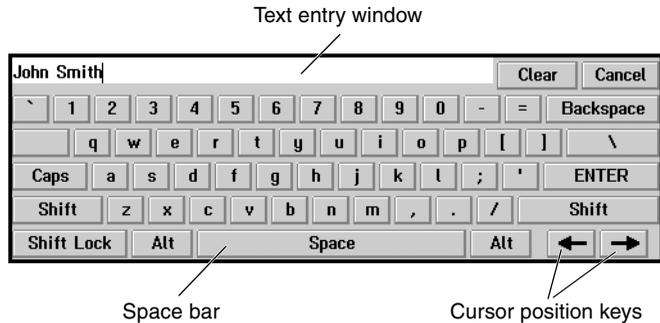


Figure 1-21. Keyboard screen

The function of the on-screen keyboard buttons are very similar to the keys on a computer keyboard or typewriter (see "Keyboard buttons" on page 1-30).

Note: The Model 2090 programmer includes a built-in keyboard, which is active only when the on-screen keyboard is displayed.

Setting up the programmer
The display screen

Table 1-1. Keyboard buttons

Button or feature	Function
Text entry window (See Figure 1-21)	Shows the text as you enter it using the keyboard. You can enter only as many characters as can fit in the selected field.
	Clears all characters from the text entry window.
	Closes the keyboard screen without changing the selected field.
	Deletes the character to the left of the cursor in the text entry window.
	Not intended for use.
	Locks all characters into upper case until the [Caps] key is selected again. While the [Caps] key is down, the [Shift] and [Shift Lock] keys operate as described below except that characters will shift to lower case.
	Shifts all of the characters into upper case and replaces the top row of numbers with commonly used symbols. This shift cancels automatically after you select a character or symbol.
	Locks all of the characters into upper case and replaces the top row of numbers with commonly used symbols. Press this key again to return to number keys and lower case.
	Shifts the keyboard to a limited set of characters. Selecting a character or symbol cancels [Alt] key.
Space Bar (See Figure 1-21)	Inserts a blank space.
 	Moves the cursor one space to the left or the right.
	Closes the keyboard screen and enters the text in the text entry window into the selected field.

Using the programmer

2

This chapter guides you through setting your programmer preferences, connecting the programmer to skin electrodes, using the programming head, programming emergency parameters, recording an ECG strip, and using the on-line help feature.

This chapter also describes how you can use the Checklist feature to streamline a standardized follow-up routine or protocol.

Setting programmer preferences 2-2

About the Checklist feature 2-7

Using Checklist 2-8

Creating a custom checklist 2-9

Connecting the programmer to skin electrodes 2-13

Positioning and using the programming head 2-14

Programming Emergency parameters 2-19

Recording an ECG strip 2-21

Using the On-line Help feature 2-24

Setting programmer preferences

Adjusting programmer time and date

If the time or date displayed and printed by the programmer is incorrect, use the following procedure to enter the correct settings.

◆ **To adjust the Time and Date**

1. Select **Programmer > Time and Date**.

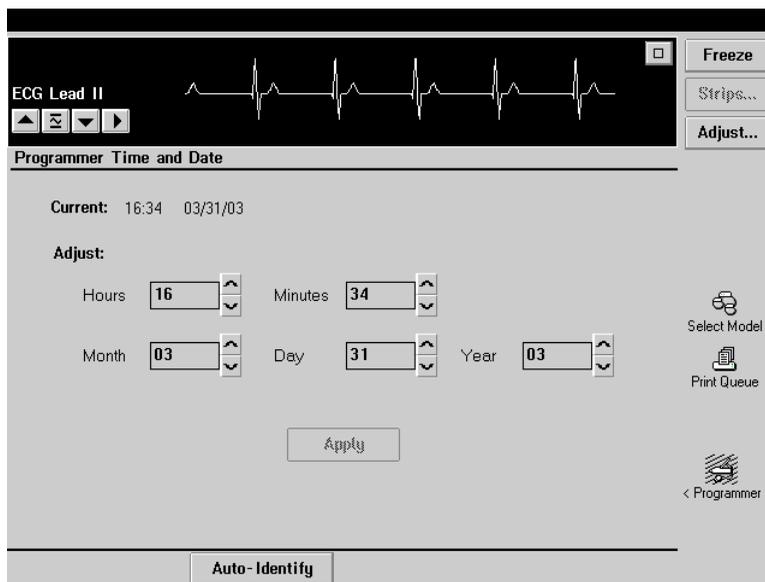
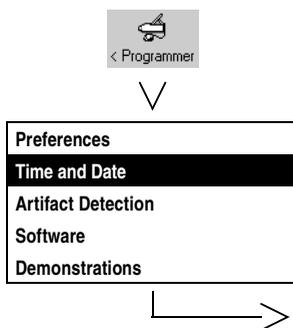


Figure 2-1. Programmer time and date adjustment

2. From the Programmer Time and Date screen, select the or button to increase or decrease the value for the unit of time you want to change. Press and release the button for single unit changes, or press and hold the button to effect greater changes.

Note: Time must be entered on the basis of a 24-hour clock, with 00:00 being midnight and 12:00 being noon.

3. When all fields show the correct time and date, press the **[Apply]** button. Select another tool palette icon to close the Programmer Time and Date window.

Using audible tones

Certain events in the operation of the programmer result in an audible signal. The following tones alert the user to the success or failure of an action.

- A two-tone beep (low-to-high) indicates confirmation of an Interrogate or a Program command.
- A single low-tone beep indicates that an Interrogate, Program, or Emergency command was **not** confirmed. It may also indicate that the selected command cannot be executed.
- A single, short beep coincides with pressing the Interrogate or the Program button. It also occurs upon automatic identification of the pacemaker.

◆ **To turn the audible tones on or off**

1. Select **Programmer > Preferences**.
2. From the Preferences screen, select the [**Audio ON**] or [**Audio OFF**] button as desired.

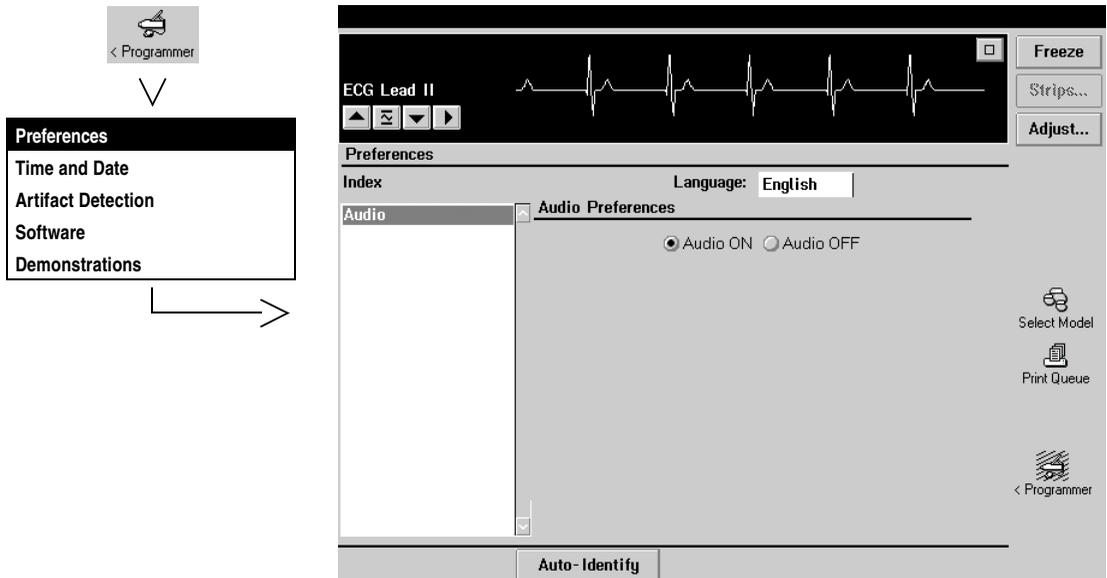


Figure 2-2. Preferences screen

Changing the language setting

The software is translated into several languages. Use the following procedure to determine which languages are available.

To change the language setting

1. Select **Programmer > Preferences**.
2. From the Preferences screen, select the Language field for the desired language.

Checking the software version

If you need to know what version of software is currently loaded on the programmer for any of the pacemaker models, use the following procedure.

◆ To check the software version number

- Select **Programmer > Software**.

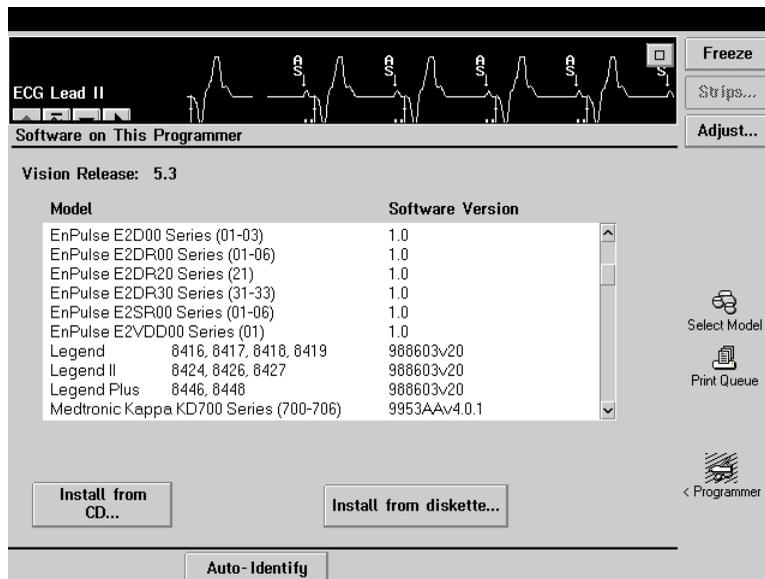
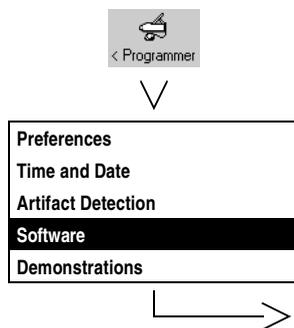


Figure 2-3. Software on This Programmer screen

For each pacemaker model with software loaded on the programmer, the screen displays the software version number next to the model number.

Note: If the model that interests you is not displayed, the software to support that model is not currently loaded on the programmer.

Starting the Demonstrations option

The Demonstrations option allows you to run a demonstration program on the programmer.



To start a Demonstration program

1. Select **Programmer > Demonstrations**.

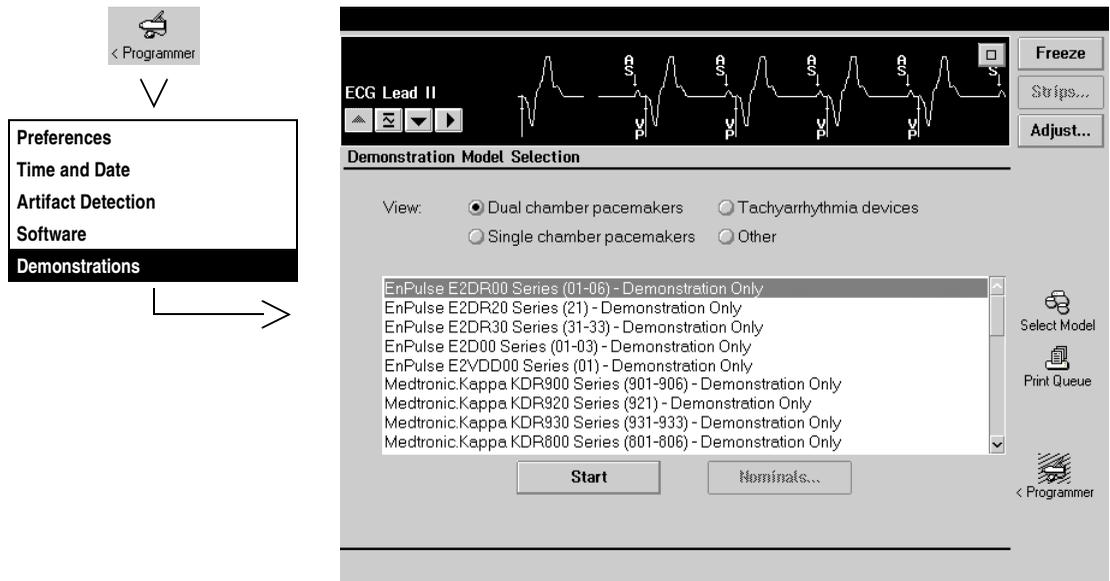


Figure 2-4. *Demonstrations Model Selection screen*

2. Insert the demonstration diskette into the disk drive.
3. From the Demonstration Model Selection screen, select the desired View option to list the available demonstration programs.
4. Select the desired demonstration program, and press the [**Start**] button.

Note: The [**Nominals**] button accesses nominal parameter values for pacemaker models that are not available for Vision software.

Improving the detection of pacing artifacts

Enabling the Artifact Detection function improves the detection of pacing artifacts when interference causes false artifacts to appear on the patient's ECG. Pacing artifacts are displayed on the patient's ECG when the artifact enhancement option (Show Artifacts) has been enabled as described in "Enabling or disabling artifact enhancement" on page 4-13.

◆ **To access the Artifact Detection function setup screen**

For information on using the Artifact Detection function on the 9790 programmer, refer to the Programming Guide Supplement supplied with the 9886 or 9891 software previously installed in your programmer. For information on using the Artifact Detection function on the 2090 programmer, refer to the *CareLink 2090 Programmer Reference Guide*. To access the Artifact Setup screen, use the procedure described above rather than the access instructions provided in the Programming Guide Supplement.



Preferences
Time and Date
Artifact Detection
Software
Demonstrations

About the Checklist feature

Checklist lets you use a predefined list of tasks to select each of the programmer functions you use as you progress through a patient follow-up protocol or device implantation procedure. Selecting a single “go-to” button at the end of each task starts the function you will use for your next task.

You can use the Master Checklist or create and save a task list that follows your specific follow-up protocol or implantation procedure. The Checklist screen tracks which tasks on the list have been completed by placing a checkmark next to the task.

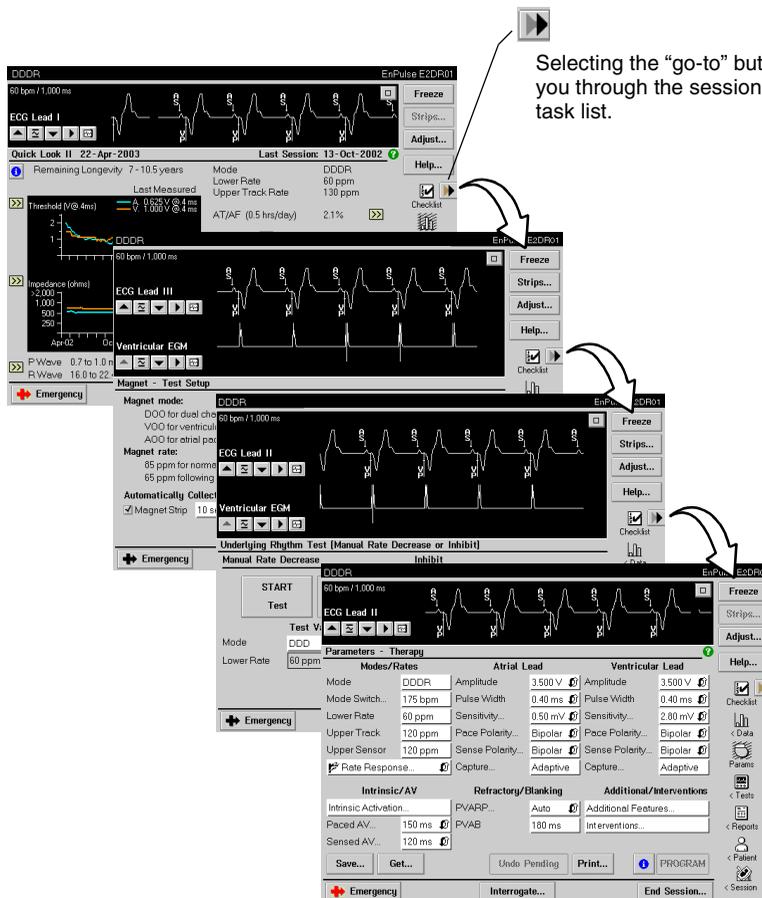


Figure 2-5. The Checklist feature

Using Checklist

The following procedure describes how to use checklist to step through the tasks in a follow-up session or implant.

◆ To use the Checklist feature



1. Select the Checklist icon to open the Checklist screen
2. If the desired task list is not displayed, select the Checklist field and then the desired option. Refer to “Creating a custom checklist” on page 2-9 if you need to create a new task list.

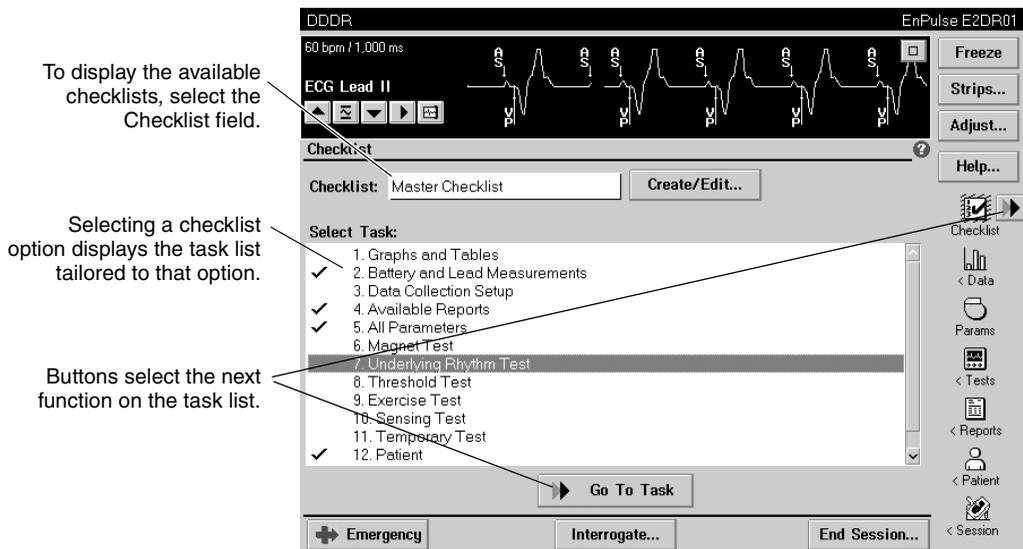


Figure 2-6. The Checklist screen

3. To begin the session with the first task, select the [Go To Task] button or the [>>] button next to the Checklist icon.
4. At the completion of each task, select the [>>] button next to the Checklist icon to start the next task function.

At any time during a session, you can manually select any function you wish to use and then return to using Checklist.

To perform a task out of order in the tasklist, open the Checklist screen, select the desired task, and then select the [Go To Task] button or the [>>] button next to the checklist icon.

To review the tasks that have been completed, select the Checklist icon. A checkmark appears by the completed tasks.

Creating a custom checklist

You can create your own checklist to show the specific tasks and the order in which you perform them during a follow-up session. A maximum of five checklists may be saved for use with EnPulse pacemakers. The following sections describe the procedure for creating a custom checklist:

- Selecting the Create/Edit... window.
- Choosing a checklist as a source for copying tasks.
- Building the custom checklist by copying the desired tasks.
- Saving the custom checklist.

Selecting the Create/Edit... window

To start the procedure for creating a custom checklist, select the **[Create/Edit...]** button on the Checklist screen to open the Create/Edit... window.

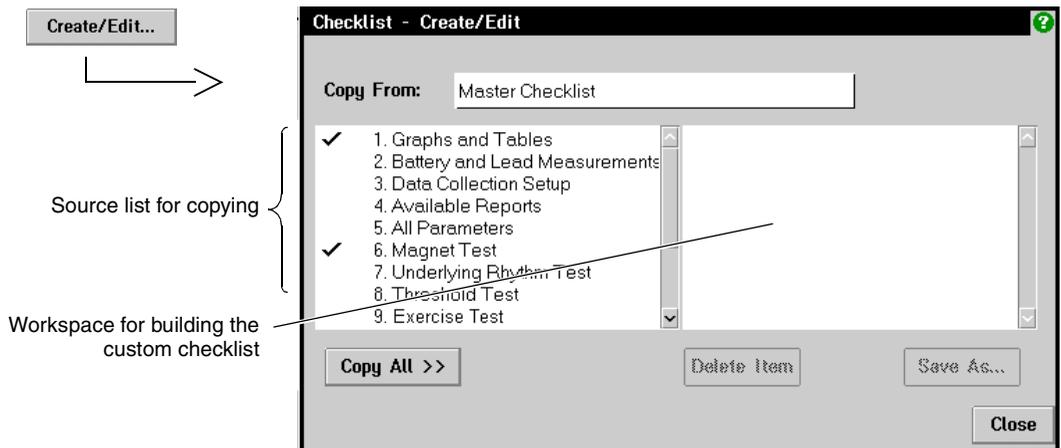


Figure 2-7. The Create/Edit... window

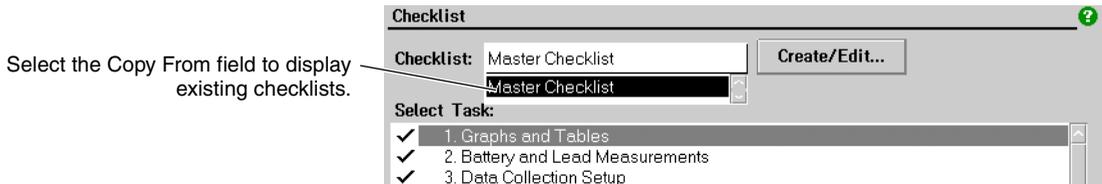
This window allows you to build a checklist by copying tasks from the list on the left (source) to the empty field (workspace) on the right. Use the procedures described on the following pages to create a completely new checklist that conforms to your follow-up protocol or to make changes to refine an existing checklist.

Choosing a source for copying

Before you build a new custom checklist, select an existing checklist to act as source for the tasks you want to copy (or use the checklist presently displayed if it meets your needs).

◆ **To copy from a checklist source**

1. Select the Copy From field to display the existing checklists.

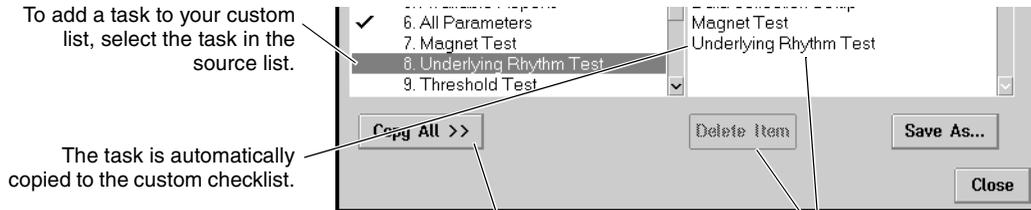


2. From this list, select the Checklist you want to use as a source for creating your custom checklist.
 - If you want to make changes to an existing checklist, select that checklist.
 - If you want to use an existing checklist as a template for building a new one, select that checklist.
 - Select the Master Checklist if you want access to all available follow-up tasks to build a completely new checklist.

Note: The EP Studies test function is not available from the Master Checklist.

Building the custom checklist

From the list that appears on the left in the Create/Edit window, you can build a custom checklist by using the create and edit options described below.



To add a task to your custom list, select the task in the source list.

The task is automatically copied to the custom checklist.

To copy all tasks from the left list to your custom list, select the **[Copy All >>]** button.

To delete a task from your custom list, select the task and then select the **[Delete Item]** button.

- To copy all the tasks listed on the left to your custom list on the right, select the **[Copy All >>]** button.
- To build your custom checklist one task at a time, select each desired task from the source field on the left. Select the tasks in the order you want them to appear in the custom checklist.
- To insert a task in the middle of your custom checklist, highlight (select) the task that is just above where you want the new task to appear in the custom checklist. Then select the desired task from the source list on the left.
- To eliminate a task that you do not want in your custom list, select the task in the custom checklist and then select the **[Delete Item]** button.

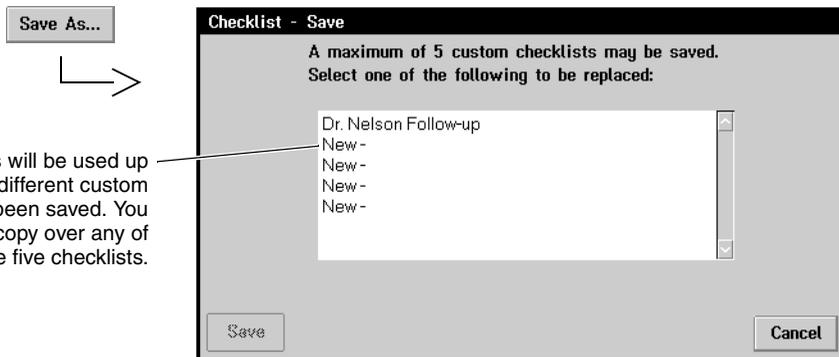
Note: You can select a different checklist (source) at any time while you are building your custom checklist.

Saving the custom checklist

To save your custom checklist, complete the following procedure.

◆ To save a custom checklist

1. Select the [Save As...] button to open the Save window.



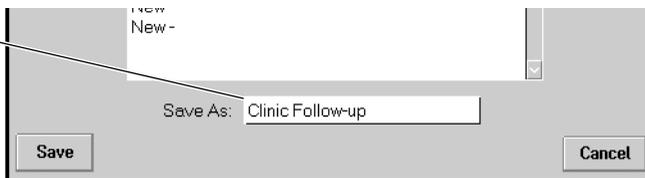
The “New” options will be used up once five different custom checklists have been saved. You can revise or copy over any of these five checklists.

2. Select “New” from the field of options, or select an existing checklist if you want to overwrite it with the new checklist.

The Save As field shows the name that will be used to identify the new checklist.

3. If you want to change the name, select the Save As field to open the on-screen keyboard; otherwise, skip to step 5. Do not change the name if you are replacing or updating an existing checklist.

Selecting the Save As field opens the on-screen keyboard, which allows you to enter your own checklist name.



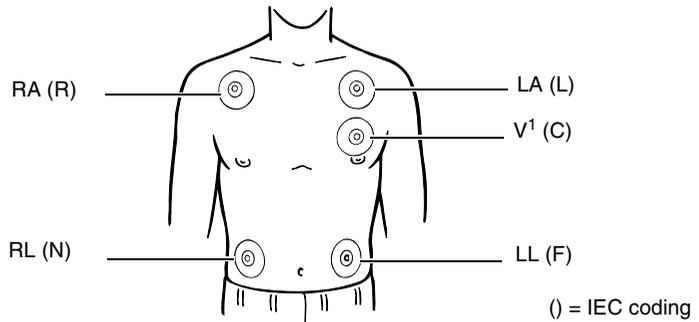
4. To change the name, clear the original name ([Clear] button), and enter the desired name using the on-screen keyboard. Then press the keyboard [ENTER] button.
5. To save the custom checklist, select the [Save] button. Then select the [Close] button to complete this procedure, and return to the Checklist window.

The new custom checklist will be available as a Checklist option until it is replaced by a new custom checklist.

Connecting the programmer to skin electrodes

At the start of a patient session, the programmer must be connected to skin electrodes on the patient. The ECG display and measurement functions will not operate without detection of the surface ECG signal.

Use an electrode lead to connect each skin electrode to the appropriate port on the ECG cable. Typical electrode placement is shown below. Use standard procedures for attaching disposable skin electrodes to the patient.



¹ Labeled C on some cables

Figure 2-8. *Connecting the programmer to skin electrodes*

Refer to your programmer manual for more details on this procedure.

Positioning and using the programming head

In many of the procedures described in the following chapters, you will be directed to position the programming head over the patient's implanted device.

When to position the programming head

During a patient session, properly position the programming head over the implanted device before any of the following actions:

- Selection of any command that initiates a programming transmission. The programming head must be held in position until completion of the transmission, which is usually indicated by a confirmation message.
- Selection of any command that initiates data transmission from the implantable device. The programming head should be held steady until data reception is complete, which is usually indicated by a confirmation message.
- Selection of a measurement function that requires the implantable device to be operating asynchronously as a result of the programming head magnet.

For any temporarily programmed state or function or for reception of continuous data such as Marker Channel telemetry or EGM waveforms, the programming head must be held in place over the implantable device for the duration of the function or until termination is desired. Lifting the programming head cancels a temporary program and terminates continuous telemetry. The implantable device reverts to permanently programmed values.

Caution: Do not position the programming head over an implanted pacemaker during electrocautery or defibrillation procedures.

◆ ***To position the programming head***

The programming head must be properly positioned as described below. An incorrectly positioned programming head can result in the failure of a transmitted command and the loss of telemetry.

1. Hold the programming head directly against the patient's skin with the face of the programming head parallel to the implanted device.

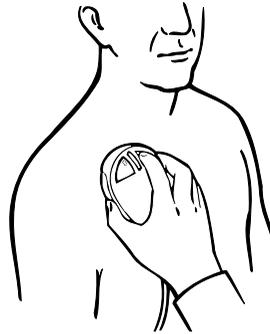


Figure 2-9. Positioning the programming head

2. Position the programming head so that the amber light in the light array goes out and one or more of the green lights come on. Move the head a little in each direction to find the position that lights the greatest number of green lights. This is the optimum position.

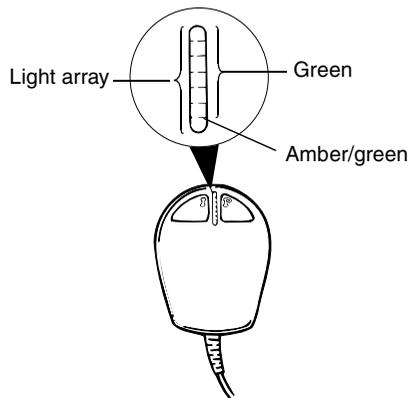


Figure 2-10. Light array indicator

Using the programmer

Positioning and using the programming head

Effect of the programming head on pacemaker operation

If model selection and application (software) loading are complete, positioning the programming head over an EnPulse pacemaker does *not* put the pacemaker in the magnet mode of operation. The programmer automatically sends a Cancel Magnet command to the pacemaker, which causes it to continue to operate as programmed.

An exception to this operation can occur if the programming head does not establish a telemetry link with the pacemaker (because of strong electrical interference or because the programming head is improperly positioned). In such cases, positioning the programming head would result in magnet mode operation until a telemetry link is established. You can easily verify the present pacing mode by observing the Status Line at the top of the screen.

The present pacing mode shows in the status bar at the top of the screen.



Pacemaker operation returns to its programmed state about two seconds after you remove the programming head from its position over the pacemaker.

Observing magnet mode operation

To observe magnet mode operation during a patient session, you must conduct the Magnet test described on page 3-28. Initiating the Magnet test results in a Threshold Margin Test (TMT) and causes the pacemaker to operate in the magnet mode.

Note: Before you select the pacemaker model, positioning the programming head over an EnPulse pacemaker results in magnet mode operation.

Alternative PROGRAM and INTERROGATE buttons

To initiate the Program and Interrogate commands, you have the option to use the on-screen **[Program]** and **[Interrogate]** buttons or the Program **[P]** and Interrogate **[I]** buttons on the programming head.

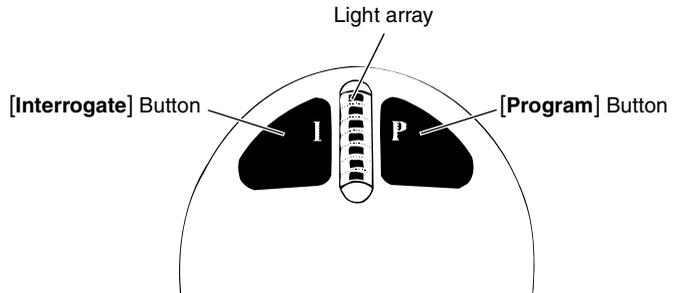


Figure 2-11. Alternative Program and Interrogate programming head buttons

Note: The **[P]** or **[I]** button on the programming head is active only when its counterpart is displayed as an active button on the display screen.

Using the programmer

Positioning and using the programming head

Automatic interrogation at the start of a session

At the start of a session when you select **[Start]** or **[Auto Identify]**, the programmer automatically interrogates the patient's pacemaker for most of the data stored in the pacemaker. For this process, you must position the programming head and hold it steady in place until the interrogation is complete.

At the bottom center of the screen you will see an indicator showing the progress of the interrogation. Because this interrogation retrieves most of the data stored in the pacemaker, the process may take about a minute.



Programming Emergency parameters

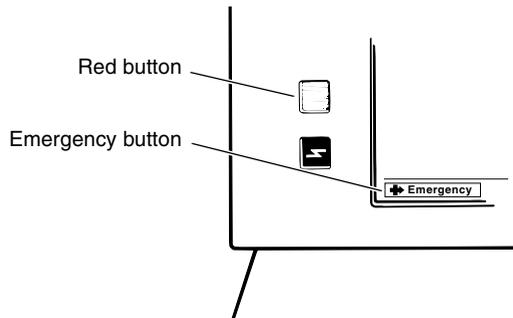
The Emergency programming command is a safety feature that overrides all other functions and immediately programs the pacemaker to preset emergency values intended to provide pacing support under a variety of conditions. This programming cancels any temporary function in effect and restores Magnet mode operation.

Note: Use of the Emergency command clears the Ventricular Chronic Lead Trend and Capture Management Trend diagnostic data collected by the pacemaker. If “Collected Data” has been interrogated previously during the session, this data will be available for viewing and printing until the session ends. Collection of new trend data starts after you end the session.

◆ To program Emergency parameters with the 9790/C programmer

1. Position the programming head over the pacemaker.
2. Take either of the following actions:
 - Press the square red button on the left side of the display panel.
 - Or select the on-screen [Emergency] button in the lower left corner of the screen.

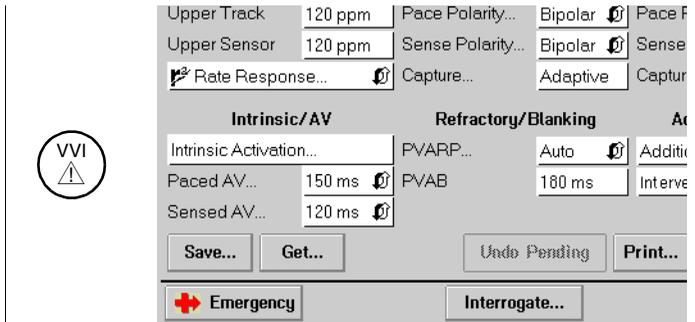
Emergency values are programmed settings that provide higher-than-normal energy output. **It is not intended that the pacemaker be left at these settings.** Refer to the *EnPulse Pacemaker Reference Guide* for a list of Emergency parameters settings for EnPulse pacemakers.



3. Hold the programming head steady until a confirmation message appears. If programming is not confirmed, verify that the programming head is properly positioned, and then reselect the [Emergency] button or the square red button.

◆ **To program Emergency parameters with the 2090 programmer**

1. Position the programming head over the pacemaker.
2. Take either of the following actions:
 - Press the Emergency VVI hard key on the left side of the programmer display panel.
 - Or select the on-screen [Emergency] button in the lower left corner of the screen.



3. Hold the programming head steady until a confirmation message appears. If programming is not confirmed, verify that the programming head is properly positioned, and then reselect the [Emergency] button or the Emergency VVI hard key.

Recording an ECG strip

At any time during a patient session, you can initiate a continuous, real-time ECG recording as described below.

◆ **To start an ECG recording**

- Press the desired paper speed button.

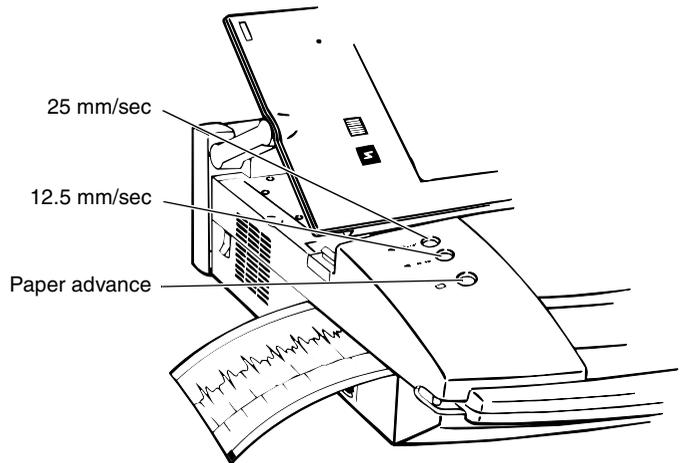


Figure 2-12. ECG chart recorder control buttons on 9790/C programmer

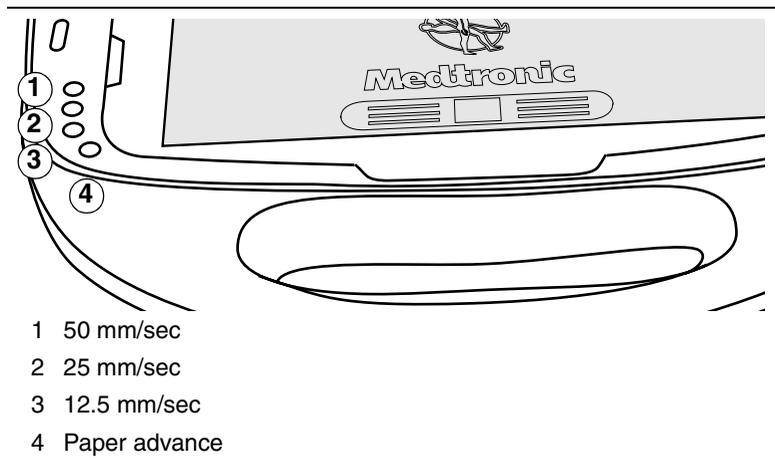


Figure 2-13. Printer buttons on 2090 programmer

Using the programmer

Recording an ECG strip

50, 25, or 12.5 mm/s – Three buttons allow for selection of a desired paper speed for ECG, Marker Channel telemetry, and EGM recording. Pressing a button selects the printer speed and turns on the adjacent indicator light. Pressing a lit button stops the printout. The selected paper speed is printed once along the top edge of the chart recording. Paper speed for text printing is not affected by these buttons.

PAPER ADVANCE – Pressing PAPER ADVANCE advances the printer paper to its next perforation for tearing off.

◆ **To stop the recording**

- Press the same paper speed button again.

Before you tear off the ECG strip, press the [**Paper Advance**] button to advance the strip to a perforation.

About the ECG recording

Because the printed recording provides a higher resolution, it may show artifacts and events that do not appear on the display.

Annotation of executed commands – Information on the ECG printout includes an indication of when certain commands to the pacemaker occurred. When confirmation of the command is received, the command name is printed at the appropriate point in the margin above the waveform grid. A recording made during the use of the following test functions shows the programmed test values as they are programmed: Magnet, Underlying Rhythm, Threshold, Sensing, EP Studies, and Temporary.

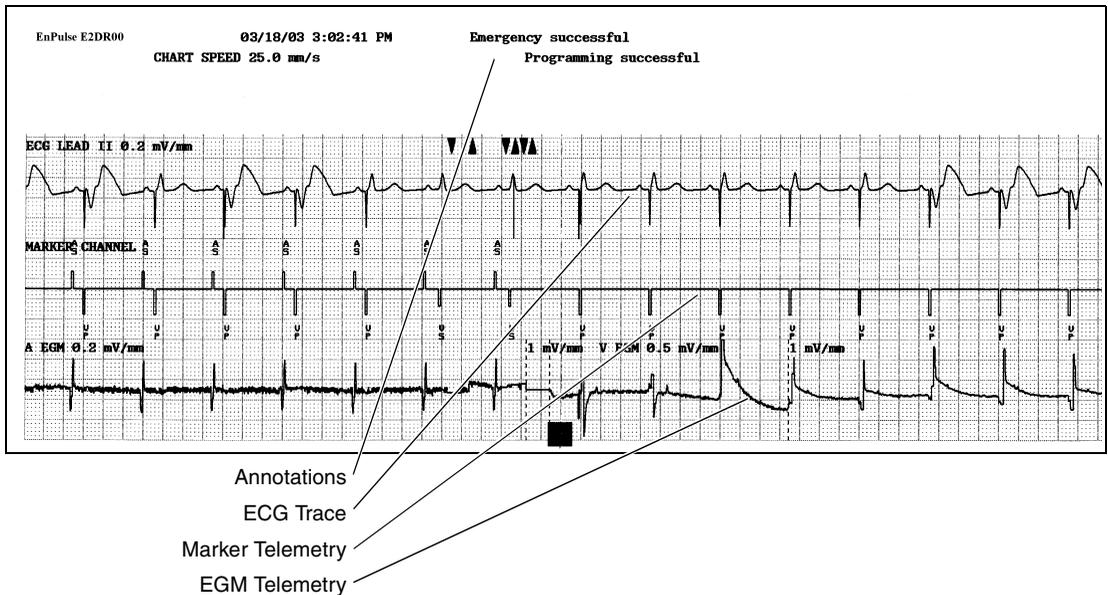


Figure 2-14. Example ECG printout with Marker and EGM telemetry

Marker Channel and EGM telemetry – If the programming head is positioned over the patient’s pacemaker, the recording includes a trace and traces of the telemetry being received from the pacemaker. In this example, the patient’s ECG is accompanied by Marker and EGM telemetry.

ECG and EGM trace adjustment – The ECG and EGM are recorded according to control settings accessible from the live rhythm monitor window on the programmer screen (see “Adjusting and arranging the waveform traces” on page 4-7). The ECG source (Lead I, II, or III) and the EGM source are each selected using the button bars appearing with each waveform trace.

Missing markers – A programming command or interrogation momentarily interrupts the transmission of Marker Channel telemetry. This interruption may result in missing markers. The point at which the command occurred is marked above the ECG trace by a “down” or “up” arrow. The down arrow (▼) indicates a transmitted command from the programmer; the up arrow (▲) indicates a telemetry response from the pacemaker.

Using the On-line Help feature

The On-line Help system provides on-screen information about many of the features and operations of the programmer. When you request help, a Help window opens, temporarily covering much of the workspace. If the initial Help window does not have the information you are seeking, you can find another one that does by using the buttons and icons listed in Table 2-1.

When you are ready to leave the On-line Help system, simply close the Help window. You will return to the workspace that was in view before you requested help.

Table 2-1. Getting around in the Help system

Button or icon	What It does
	Specific Help — If this icon is displayed within a screen or window, select it to get specific help related to that screen or window. This icon is displayed only if specific help is available.
	General Help — Select this button at any time to enter Help, starting with a topics list.
	Displays the Help window last viewed or closes the Help window first opened.
	Closes the Help window.
	Displays a list of terms discussed in Help. From this list, you can select a help topic to learn about one of the terms.
	Displays a list of all available help topics. From this list you can select any topic.
	Link icon — Indicates that more help is available. Select this symbol to jump to a related topic. Some pictures may have links also.
<u>(underlined phrase)</u>	Definition available — Select the phrase to see a pop-up window that defines the phrase. Select [Previous] to close the pop-up window or tap the stylus outside the pop-up window to close the window.
Scroll bar	Use this if a help topic extends beyond the window size.

Entering the Help system

Figure 2-15 shows ways to enter the Help system:



- If the [?] icon is present, select it for specific help about the screen or window in which it appears. This icon appears near the window's title bar when specific help is available.
- Select the [Help...] button, which is always present. This leads you directly to a topics list so that you can search for information. You can also search by using a Help index.

Once you have entered the Help system, you can use the built-in links to jump from the current Help window to other related Help windows.

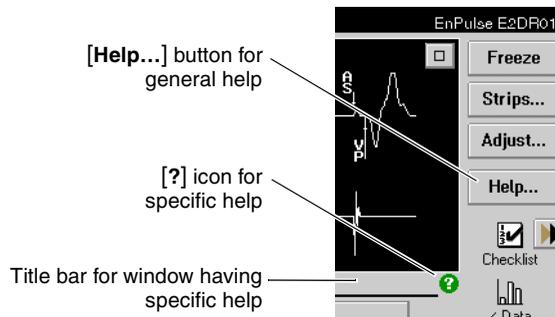


Figure 2-15. Entering On-line Help

Using the links in Help

Figure 2-16 shows the links that allow you to see additional Help windows:



- The basic link, whose icon indicates that more help is available. Select it to jump to a related topic.
- The definition link, whose symbol is an underlined phrase, indicates that there is a pop-up window to define the phrase. Select the phrase to open the pop-up window. Select outside the pop-up window (or select [**P**revious]) to close it.

Note: Some pictures may have links also. Each of these pictures has instructions on how to select the links and where they lead.

If you have viewed a series of topics and wish to return to a topic viewed earlier in that series, you can use the [**P**revious] button to go backward through the series of topics one at a time.

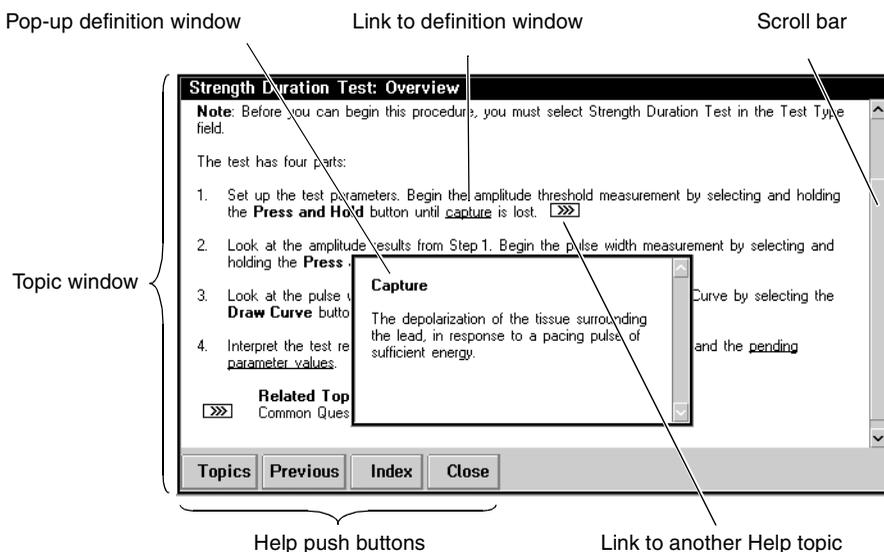


Figure 2-16. Typical Help windows (topic and definition)

Exiting the Help system

When you are ready to leave Help and return to the programmer workspace, select the **[Close]** button. The Help window closes, and the programmer screen displays the same information that it did when you entered Help.

Note: Except for the **[Emergency]** button, no other functions on the programmer screen are usable when Help is open. To use other programmer functions, you must first exit the Help system.

Searching for information in Help

If you do not find the information you were looking for in the current Help screen, there are several methods for searching for it:

- **Topics List** — Select the **[Topics]** push button to open a window having two columns. The column on the left lists categories of help topics. One of these categories is always selected, and the topics for that category are listed in the right-hand column. You can view
 - any of the topics listed (on the right) by selecting the link icon next to its name
 - another category by selecting its name (on the left)

Figure 2-17 shows what happens when you select a different category. In this example, the category “Initial Help” is selected first. The right-hand column lists topics included in this category. Suppose that you are searching for Help on one of the pacing therapies. If you select “Pacemaker Features” as a new category, notice that the right-hand column changes. You can then select a link icon for the specific topic you would like to view.

- **Help Index** — Select the **[Index]** button to open a window that lists indexed terms in alphabetical order. Like a book index, the terms are not limited to titles in Help. You can go to a Help window that explains any of the indexed terms by selecting the link icon next to that term.

Figure 2-18 shows some typical index entries.

Using the programmer
Using the On-line Help feature

To expand a new Help category, select its name

Expanded Help category (list of available topics)

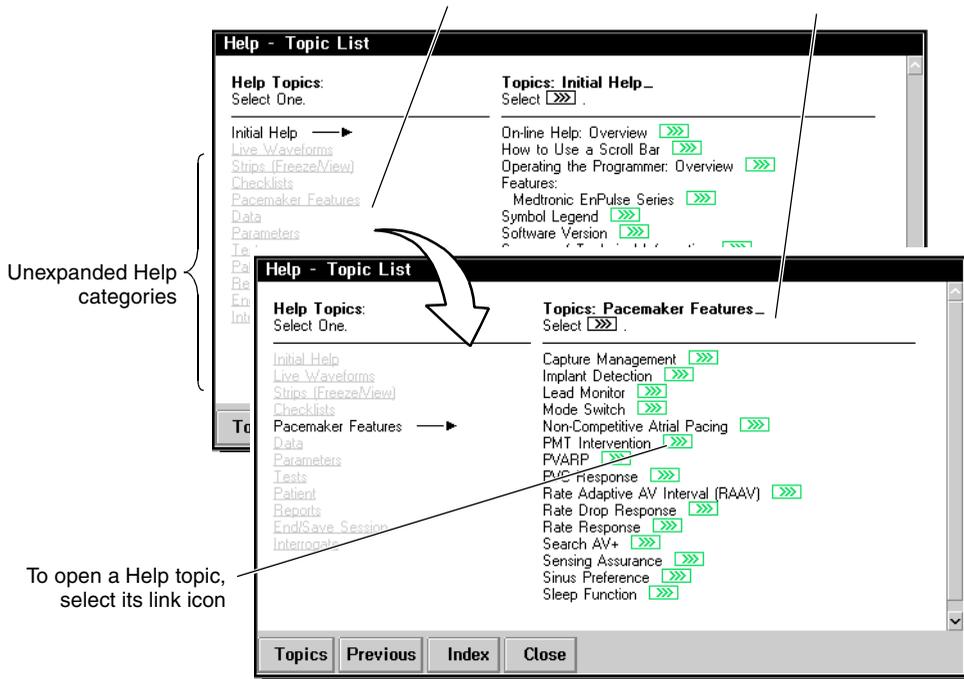


Figure 2-17. Topics List for Help

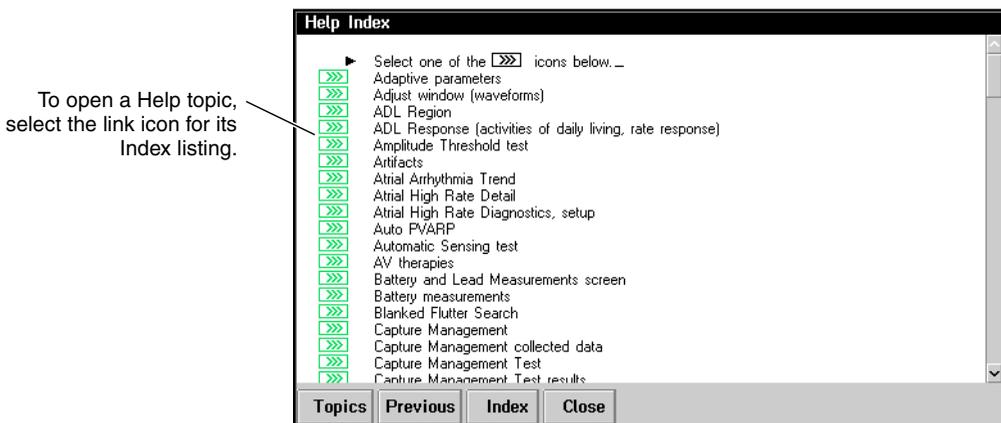


Figure 2-18. Help Index

Conducting a patient session

3

This chapter describes how to begin a patient session and how to execute some of the typical tasks you might use to evaluate operation of the patient's pacing system.

Included is information about printing, saving, and transferring the data accumulated during the session. This chapter concludes with a description of how to properly end a patient session.

Programmer features 3-2

Automatically adapting parameters 3-2

Starting a patient session 3-4

Proceeding with session tasks 3-11

Interrogating the pacemaker 3-16

Taking a quick look at pacemaker operation 3-17

Viewing Battery and Lead Measurements 3-22

Checking the present parameter settings 3-25

Viewing and programming patient information stored in the pacemaker 3-26

Recording an ECG Strip of magnet operation 3-27

Checking the patient's Underlying Rhythm 3-30

Printing reports 3-33

Saving session data on a diskette 3-36

Ending a patient session 3-38

Programmer features

Auto cancel magnet – Cancels the magnet automatically when you place the programmer head over the pacemaker. With Magnet Test, you can view and record magnet operation.

Auto-interrogation – Occurs automatically at the start of a session. The programmer automatically prints a report of the interrogated information unless this feature is turned off.

Checklist feature – You can advance quickly to the next task to be done in a patient session. Clinicians can create custom checklists that streamline task selection in follow-up and implant sessions.

Full page-size reports – You can choose to connect an external printer for printing full page-size reports.

Live rhythm waveform display – You can quickly tailor a multiple-trace display of the patient's ECG, atrial and ventricular EGMs, and Marker Channel signals.

Saved session data – You can save data from a session on a diskette, which allows you to import session data into a data base or review it using Read From Disk in Demo mode.

Automatically adapting parameters

This section lists some of the automatically adapting parameters:

- Rate Profile Optimization
- Automatic Implant Detection
- Capture Management
- Sensing Assurance
- Lead Monitor
- Search AV+
- Automatic PVARP

Rate Profile Optimization

When Rate Profile Optimization is programmed On, the pacemaker can adapt submaximal and maximal rate response levels once each day by comparing the patient's current sensor rate profiles against a nominal or clinician prescribed target rate profile. This feature is intended to provide automatic and independent monitoring of rate response at both submaximal rates for daily patient activities, such as walking and daily chores, and at maximal rates for vigorous patient activities.

Automatic Implant Detection

The Automatic Implant Detection feature:

- Determines that the pacemaker has been implanted and that its leads are stable and sets lead polarities.
- At implant initializes Sensing Assurance, Capture Management, rate response, and diagnostic data collection.

Capture Management

The Atrial Capture Management and Ventricular Capture Management features check the patient's pacing thresholds at regular intervals. Using these threshold measurements, the pacemaker can determine whether pacing pulses in that chamber are capturing the heart. Optionally, it makes adjustments to the amplitude and pulse width parameters based on these measurements.

Sensing Assurance

The Sensing Assurance feature, when active for a specific chamber, allows the pacemaker to change the sensitivity threshold for that chamber to track changes in the sensed amplitude.

Lead Monitor

This feature monitors lead integrity by measuring and recording lead impedance. Optionally, it can switch either lead (or both leads) from bipolar to unipolar polarity if lead impedance is out of range.

Conducting a patient session

Starting a patient session

Search AV+

The Search AV+ feature is intended to promote intrinsic ventricular activation in patients with intact or intermittent AV conduction and prevent inappropriate therapy in patients without conduction. Search AV+ is available in the DDDR, DDD, DDIR, DDI, DVIR, DVI, and VDD modes for dual chamber EnPulse pacemakers. The pacemaker searches for the patient's intrinsic AV conduction time and adjusts the SAV and PAV intervals either longer or shorter to promote intrinsic activation of the ventricles. When Rate Adaptive AV is active, the pacemaker also adjusts the SAV and PAV intervals relative to the rate adaptive values. If the pacemaker does not observe intrinsic ventricular activation during its periodic searches over the course of a week, it turns off the Search AV+ feature.

Automatic PVARP

When automatic PVARP is programmed, the pacemaker determines a value for the PVARP based on the mean atrial rate (which is an average of all A-A intervals except those starting with an atrial sense or atrial refractory sense and ending with an atrial pace). In the DDDR, DDD, and VDD modes, automatic PVARP is intended to provide a higher 2:1 block rate by shortening the PVARP and SAV (if necessary) at higher tracking rates and protect against PMTs at lower rates by providing a longer PVARP.

Starting a patient session

Because the programmer collects and stores data on a session-by-session basis, it is important to correctly start and end each session. This section describes how to start a patient session. To end a session, refer to "Ending a patient session" on page 3-38.

The starting point of a patient session

A patient session always begins at the Select Model screen. See "Procedure for starting a patient session" on page 3-9. If you are between patient sessions, you can access other screens by using the icons and buttons described in Table 3-1 on page 3-6.

The Select Model screen appears:

- Upon completion of the self test when you turn the programmer on.
- After you end a patient session.

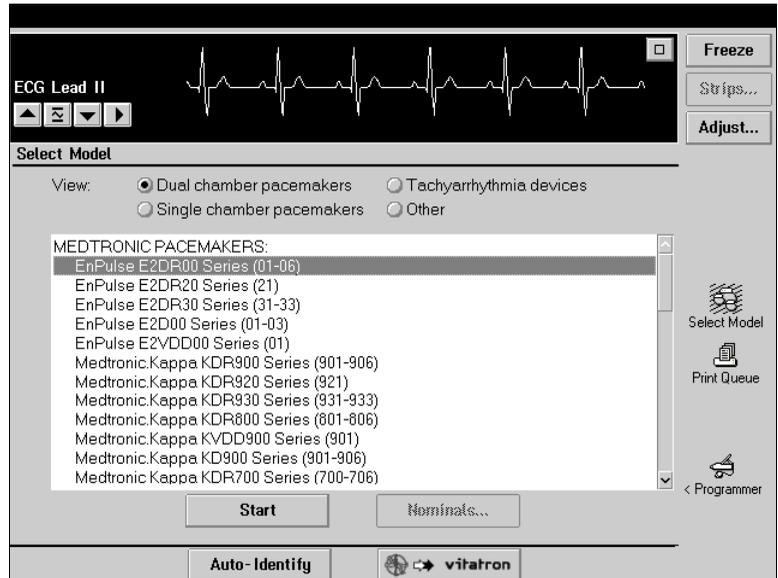


Figure 3-1. Select Model screen

Notes:

- If the Select Model screen does not look like this example and you see a  button, select the button to display this screen.
- The **[Nominals]** button does not apply to EnPulse pacemakers. This button allows you to set up Site Nominals if you select a pacemaker with this feature.

Conducting a patient session

Starting a patient session

The tool palette between sessions

Table 3-1. Tool palette between patient sessions

Tool palette	Tool	Selecting the tool (button or icon)...	Reference
		Freezes a segment of the live rhythm display. Note: A frozen strip can be viewed and printed (but not saved) between patient sessions. Markers and EGM traces are not present between patient sessions.	page 4-16
		Accesses the rhythm strips saved during a patient session. Note: No saved strips are available between patient sessions.	page 4-23
		Opens a window of options for adjusting the live rhythm display. Note: Additional adjustment options are present during a patient session.	page 4-7
		Displays the screen for selecting a pacemaker model and starting a patient session.	page 3-4
		Displays a queue of print requests from previous sessions as well as frozen waveform reports requested between sessions.	page 3-35
		Displays the programmer setup options.	
		Preferences	page 2-2
		Time and Date	page 2-2
		Artifact Detection	page 2-6
		Software	page 2-4
	Demonstrations	page 2-5	
	Programmer Profile (2090 programmer only)^a		

^a For more information on the Programmer Profile feature, refer to the *2090 CareLink Programmer Reference Guide*.

Note: When some functions are active on the display, selecting a tool button or icon will have no effect. Closing the active window restores operation of the tool palette.

About automatic interrogation

At the start of a patient session when you select the **[Auto-Identify]** button or the **[Start]** button (see “Procedure for starting a patient session” on page 3-9), the programmer automatically attempts to interrogate the patient’s pacemaker to retrieve most of the data that might be needed during the session.

Note: To take advantage of this automatic interrogation, you must position the programming head over the pacemaker and continue to hold it in place until the interrogation is complete.

Clinician-selected diagnostic data is not included in the initial interrogation. The programmer interrogates that data when you choose to view the clinician-selected data on-screen or when you select the **[Interrogate...]** button.

The interrogation time may take about a minute because of the amount of information stored in the pacemaker. A status gauge at the bottom of the screen shows progress of the interrogation. The **[Stop]** button lets you cancel the interrogation once it has started.



Note: Except for use of the **[Emergency]** button or the **[Stop]** button, you cannot proceed with session activities until the interrogation is 100% complete.

You can choose to stop interrogation and continue with other activities (not using the automatic interrogation feature). To do this, select the **[Stop]** button or lift the programming head before the process is complete. In this case, when data is needed, the programmer will display a message prompting you to interrogate the pacemaker.

You also can manually interrogate the pacemaker at any time during the patient session (see “Interrogating the pacemaker” on page 3-16).

Warning messages – As a result of an interrogation, a warning message box may be displayed. Examples of these include:

- ERI (Elective Replacement Indicator)
- POR (Power On Reset) or Full Electrical Reset
- Interrogation interrupted or unsuccessful
- Lead warnings

Conducting a patient session

Starting a patient session

You must acknowledge the message before proceeding with other activities. For an ERI, POR, or lead message, you can attempt to clear them by following the instructions in the message. Otherwise, you can close the message box and clear the condition later. See “Resetting ERI or electrical reset” on page 7-12.

Initial Interrogation Report

Following a successful interrogation, a report based on this interrogation is printed automatically. Session preferences allow you to turn this function on or off (see “Verifying or changing session preferences” on page 3-13). If the function is on, the same preferences allow you to choose whether or not to include the Arrhythmia Summary and Permanent Parameters sections in the report. Depending on the programmed status of the implanted pacemaker, this report can include the following:

- Patient/Pacemaker Information
- Pacemaker Status
- Last Measured Threshold
- P and R-Wave Measurements
- Threshold Trend
- Impedance Trend
- Parameter Summary
- Clinical Status
- Long Term Heart Rate Histograms
- Pacing % counters
- Event counters
- High Rate Episodes Summaries
- Arrhythmia Summary, including:
 - High Rate Episodes Summaries
 - V. Rate During Atrial Arrhythmias
 - Atrial Arrhythmia Durations
 - Atrial Arrhythmia Trend
- All Permanent Parameters

Procedure for starting a patient session

From the Select Model screen, you can start a patient session by either of two methods:

- By selecting the **[Auto-Identify]** button, which automatically identifies and selects the patient's pacemaker model.
- By selecting the appropriate pacemaker model and then the **[Start]** button yourself.

Note: To review software screens without interrogating the pacemaker, use the demonstrations option (See "Starting the Demonstrations option" on page 2-5). Starting a session without an interrogation provides only a limited number of screens for review.

◆ *To start a session using Auto-Identify*

1. Display the Select Model screen:

- If the programmer is not operating, turn it on. The power switch is on the left side and near the back. The Select Model screen appears after a short, self-test sequence. (Select the  button if it appears on the screen.)
- If the programmer is operating, but the Select Model screen is not displayed, choose the Select Model icon from the tool palette at the side of the screen.
- If the Select Model icon is not in the tool palette, the steps to properly end the previous patient session have not been executed. Refer to "Ending a patient session" on page 3-38.



2. Position the programming head over the patient's pacemaker and continue to hold it steady.

3. Select the **[Auto-Identify]** button at the bottom of the screen.

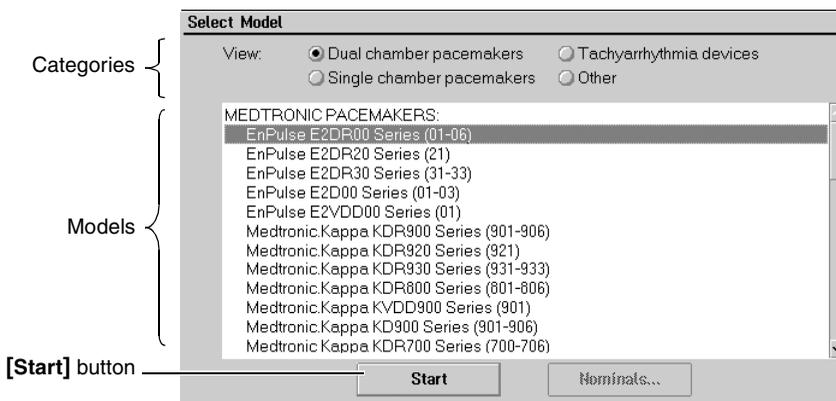
After 40 to 50 seconds of internal software loading, the programmer displays the first task screen. Continue to hold the programming head in place until the initial interrogation process is 100% complete.



Refer to "Proceeding with session tasks" on page 3-11 for information on selecting the functions or tasks you have planned for the session.

◆ **To start a session by selecting the pacemaker model**

1. Display the Select Model screen. (Refer to the previous procedure.)
2. Select the appropriate category to view pacemaker models.



3. Select the desired pacemaker model from the list of models. (During the patient session, the specific model number will appear on the status bar at the top of the display screen.)
4. If you want the programmer to automatically interrogate the patient's pacemaker, position the programming head.
5. Select the **[Start]** button.
6. After loading the internal software, the programmer displays the first task screen. Continue to hold the programming head in place until the initial interrogation process is 100% complete.

Refer to the next topic for information on selecting the functions or tasks you have planned for the session.

Proceeding with session tasks

After you select the [**Auto-Identify**] or [**Start**] button to begin a patient session, a short period of internal software loading occurs before the first task screen appears.

The first task screen

The first task screen to appear is the Quick Look II screen. Refer to “Taking a quick look at pacemaker operation” on page 3-17 for information about the Quick Look II screen.

Selecting another task or function

To proceed with the session, select the desired task or function from the button and icon options grouped along the edge of the screen (see Table 3-2 on page 3-12). This group of buttons and icons is referred to as the “tool palette.” It is always available (except during the execution of certain functions) so that you can quickly and easily display a desired task or function screen.

Note: When some functions are active on the display, selecting a tool button or icon will have no effect. Closing the active window restores operation of the tool palette.

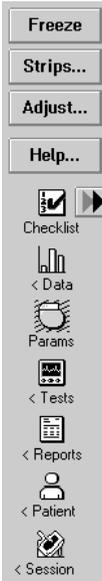
Consider using Checklist

During a follow-up session, you can use the tool palette to select tasks or functions in any order as you proceed through the session. However, if you use a particular follow-up routine or protocol, you can configure and use the Checklist feature to streamline the session. For more information, see “Using Checklist” on page 2-8.

With Checklist, you can advance quickly to each successive task in a follow-up session. You also can create custom checklists that can be used for task selection during an implant procedure.

Conducting a patient session
Proceeding with session tasks

Table 3-2. Tool palette during a patient session

Tool palette	Tool	Selecting the tool (button or icon)...	Reference
		Freezes a segment of the live rhythm display.	page 4-16
		Accesses the rhythm strips saved since the start of the session.	page 4-23
		Opens a window of options for adjusting the live rhythm display.	page 4-7
		Accesses the available Help topics	page 2-24
		Selecting the icon displays a screen for setting up and viewing the Checklist function. Selecting the [>>] button starts the next function on the follow-up task list.	page 2-7
		Displays the options for retrieving information about the patient's pacemaker and its operation and for setting up or clearing the data collection functions.	<p>Quick Look II - Initial Interrogation page 3-17 Graphs and Tables page 5-8 Battery and Lead Measurements page 3-22 Data Collection Setup/Clear page 5-45</p>
		Displays the parameter programming screen.	page 7-2
		Displays the pacing system test options.	<p>Magnet page 3-27 Underlying Rhythm page 3-30 Threshold page 6-2 Exercise page 8-2 Sensing page 6-21 Temporary page 6-29 EP Studies page 9-9</p>
		Displays the following session report options:	<p>Available Reports page 3-34 Print Queue page 3-35</p>
		Displays patient information:	<p>Patient Information page 3-26 Key Parameter History page 7-18</p>
		Displays options for setting session preferences and saving session data to a diskette.	<p>Preferences page 3-13 Save To Disk... page 3-39</p>
		This icon is replaced by the Demo icon during the Demo mode.	
		Displays case study options in the Demo mode (use of a demonstration diskette). This icon otherwise is not displayed.	page 2-5

Verifying or changing session preferences



At the start of a patient session, or anytime during the session, you can select the Session icon to access preference settings that apply to printing reports and viewing waveform traces during test procedures. Preference settings are saved and will not be canceled when the session ends.

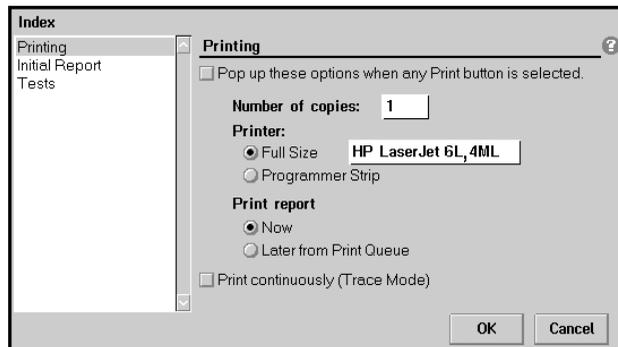
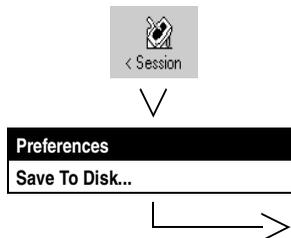
Printing preferences

Printing preferences let you set up how reports are printed when you select the **[Print...]** button. You can choose to have the setup window show each time you select the **[Print...]** button or have the **[Print...]** button immediately print the report or send it to the print queue. You can also enable or disable the printer Trace Mode. With the Trace Mode enabled, the programmer prints programmed variables and their values.



To set up printing preferences

1. Select **Session > Preferences**.



2. Select the check box for “Pop up these options when any Print button is selected” as follows:
 - If a check mark (✓) appears, the print setup window will appear each time you select the **[Print...]** button.
 - If there is no check mark, the **[Print...]** button immediately prints the report or transfers it to the print queue.
3. Select the **Number of copies** field to change the number of report copies to be printed. Options are 1 to 4 copies.

Conducting a patient session
Proceeding with session tasks

4. Select the desired **Printer** (Full Size or Programmer Strip).
 - *Full Size* requires that a compatible, external printer be connected to the programmer (see “Connecting an external printer” on page 1-16).

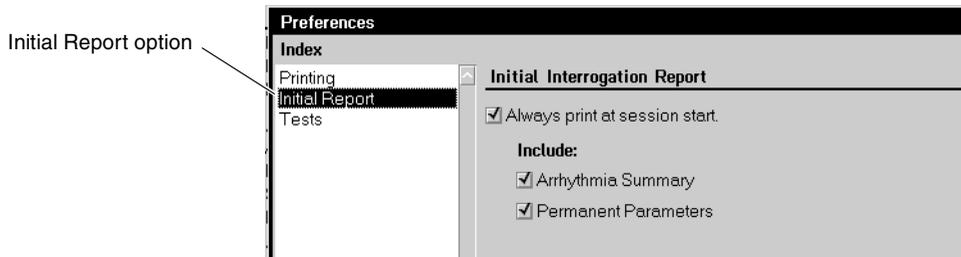
Important: Select the printer field and choose the appropriate printer. The selected printer type must be compatible with the input requirements of the connected printer.
 - *Programmer Strip* prints reports on the programmer’s strip chart printer.
5. Select the desired **Print report** option (Now or Later from Print Queue).
 - *Now:* The report prints immediately when you select the [Print...] button.
 - *Later from Print Queue:* Selecting the [**Print...**] button sends the report to the print queue. See “Printing reports held in the Print Queue” on page 3-35.
6. Select the check box for “Print continuously (Trace Mode)” as follows:
 - If a check mark (✓) appears, the programmer prints programmed variables and their values. The data in this case is not printed in a report format.
 - If there is no check mark, the programmer does not print automatically.

Initial report preference

The Initial Report preference lets you choose whether or not an initial interrogation report is automatically printed at the start of each patient session following a successful interrogation.

◆ **To select your initial report preference**

1. Select the Initial Report option in the Preferences window.



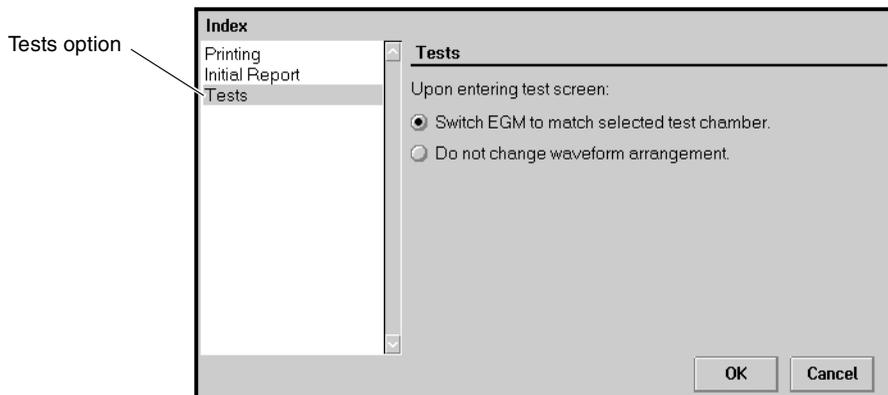
2. Select the check box for “Always print at session start” as follows:
 - If a check mark (✓) appears, the programmer automatically prints the initial interrogation report.
 - If there is no check mark, the programmer does not automatically print the initial interrogation report.
3. Use the additional check boxes to select whether the initial report will include an Arrhythmia Summary or Permanent Parameters or both.

Tests preference

The Tests preference lets you choose how waveform traces are displayed during a selected follow-up test. You can choose whether the live rhythm display automatically displays the EGM for the heart chamber being tested (atrium or ventricle) or does not change the arrangement of the rhythm traces.

◆ **To select your preference for the trace display**

1. Select the Tests option in the Preferences window.



2. Choose the desired option (“Switch EGM to match selected test chamber” or “Do not change waveform arrangement”).

Interrogating the pacemaker

At the start of the patient session (as described in “Procedure for starting a patient session” on page 3-9) the programmer performs an automatic interrogation to retrieve most of the information stored in the pacemaker.

You can also manually interrogate the pacemaker at any time during the patient session. In some cases, a pop-up window may request that you do so.

◆ **To interrogate the pacemaker**



1. Select the **[Interrogate]** button at the bottom center of the screen or press the Interrogate **[I]** button on the programming head.
2. From the window of options, select the type of information you want to retrieve. You can select more than one option.

Collected data can be interrogated only once during a patient session.

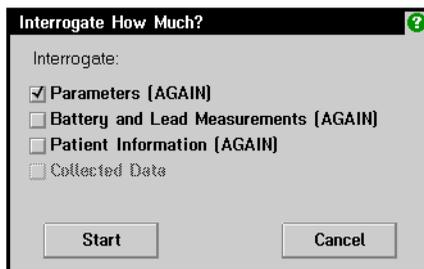


Figure 3-2. *Interrogate How Much? screen*

The word “(AGAIN)” indicates that a previous interrogation has already retrieved this data.

3. Position the programming head and select the **[Start]** button or press the programming head Interrogate **[I]** button.

Hold the programming head steady until the interrogation is 100% complete as shown by the status gauge at the bottom of the screen. The **[Stop]** button lets you cancel the interrogation.



Taking a quick look at pacemaker operation

Quick Look II provides a summary or overview of pacemaker operation by displaying the essential information on one screen. This data was retrieved during the initial interrogation of the session.

The Quick Look II screen

The Quick Look II screen appears automatically when you start a patient session or when you choose to display it.

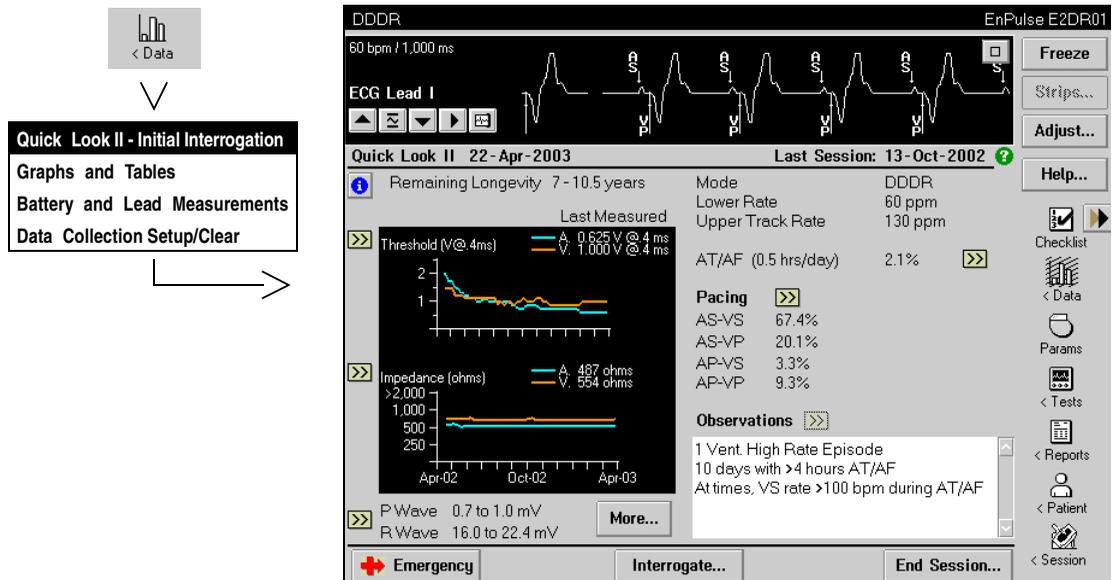


Figure 3-3. Pacemaker information on the Quick Look II screen

Note: Each QuickLink [>>] button on the screen provides a direct link to diagnostic data related to information displayed next to the button.

Viewing data on the Quick Look II screen

The Quick Look II screen displays the following information and information access options.

Remaining Longevity – This is an estimate of the time in years or months remaining until pacemaker replacement is required. This estimate is based on the programmed parameter settings and events recorded by the pacemaker since the last patient session. Note the following explanation of the longevity estimates, which you can view by selecting the **i** symbol after the “Remaining Longevity” heading.

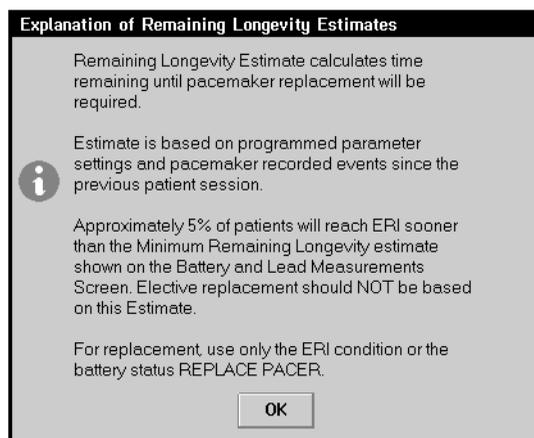


Figure 3-4. Remaining Longevity screen

Threshold Trend – The graph shows the average weekly atrial and ventricular pacing thresholds over the last year. If Capture Management is enabled, the last measured threshold is shown in the box to the right of the graph (see Figure 3-5 on page 3-19). To view detailed Automatic Capture Management data, select the QuickLink [**>>**] button. Refer to “Capture Management Trend” on page 5-25 for more information.

Impedance Trend – The graph shows the average weekly atrial and ventricular measured impedances over the last year. The lead impedances measured during initial interrogation are shown in the box to the right of the graph (see Figure 3-5 on page 3-19). To view detailed Lead Impedance Data, select the QuickLink [**>>**] button. Refer to “Lead Impedance” on page 5-29 for more information.

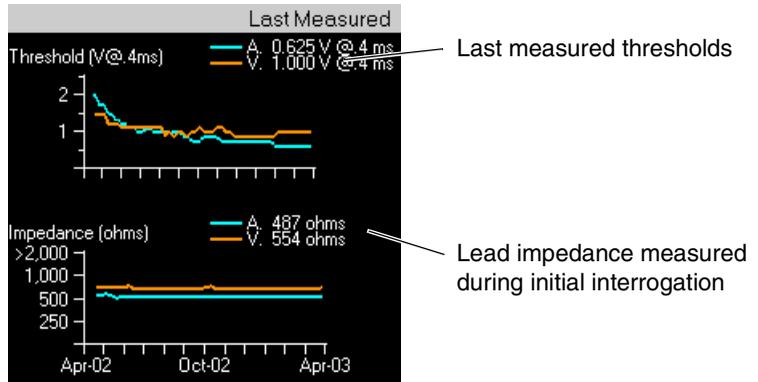


Figure 3-5. Last measured values

P Wave – If Atrial Sensing Assurance is on, this shows the current P Wave amplitude range measured by the pacemaker within the last week. To view detailed P Wave Amplitude trend data, select the QuickLink [[>>](#)] button. Refer to “Sensitivity Trend” on page 5-27 for more information.

R Wave – This shows the current R Wave amplitude range if Ventricular Sensing Assurance is on. To view detailed R Wave Amplitude trend data, select the QuickLink [[>>](#)] button. Refer to “Sensitivity Trend” on page 5-27 for more information.

Mode – This shows the currently programmed mode.

Lower Rate – This is the slowest rate at which pacing occurs during a mode’s basic operation. In rate responsive modes, in the absence of sensor-detected activity, the sensor-indicated rate is equal to the programmed Lower Rate.

Upper Track Rate – This is the maximum rate at which the ventricle may be paced in response to sensed atrial events in the DDDR, DDD, and VDD modes.

AT/AF – This shows the average number of hours each day in which atrial arrhythmia episodes are occurring and the total percentage of patient time that is spent in atrial arrhythmias. To view the Atrial Arrhythmia Trend, select the QuickLink [[>>](#)] button. Refer to “Atrial Arrhythmia Trend” on page 5-22 for more information.

AT/AF (0.5 hrs/day) 1.9% [[>>](#)]

Conducting a patient session

Taking a quick look at pacemaker operation

Pacing – Listed under this heading are the pacing and sensing event sequences applicable to the programmed pacing mode (see Table 3-3 on page 3-20). Shown is the percent of the total number of heart beats (recorded since the last patient session) that occurred in each category.

To view a recorded heart rate histogram, select the QuickLink [>>] button. Refer to “Heart Rate Histograms” on page 5-11 for information about the histogram displays.

Pacing	>>
AS-VS	99.4%
AS-VP	0.6%
AP-VS	0.0%
AP-VP	< 0.1%

Note: The data under the Pacing and the Observations headings show data collected by the pacemaker since the last patient session. This data is automatically cleared from pacemaker memory after the session has ended. After the data is cleared, it cannot be recalled.

Observations – The information displayed in the field under this heading summarizes the results of diagnostic data collection since the last patient session. This field lists the number of significant events recorded by the various diagnostic monitoring functions (see Table 3-4 on page 3-21).

Observations	>>
High A. Threshold: 03/25/03 12:56 PM	

To view a graph or table showing the details associated with an observation, select the event and then select the QuickLink [>>] button. Refer to “Viewing the collected data” on page 5-8 for information about viewing the data recorded by the various monitoring functions.

Table 3-3. Event sequence categories

Dual chamber pacing modes (and ADI, ADIR, VDI, VDIR, VDD)	
AS-VS	Atrial Sense - Ventricular Sense
AS-VP	Atrial Sense - Ventricular Pace
AP-VS	Atrial Pace - Ventricular Sense
AP-VP	Atrial Pace - Ventricular Pace

Table 3-3. Event sequence categories

Single chamber pacing modes	
Paced	Atrial or Ventricular Pace
Sensed	Atrial or Ventricular Sense

Table 3-4. Observation monitoring functions

Functions and criteria used for observation reporting	
Atrial Lead Monitor	Lead impedance outside Min/Max settings.
Vent. Lead Monitor	Lead impedance outside Min/Max settings.
Atrial High Rate Episodes	One or more episodes detected.
Ventricular High Rate Episodes	One or more episodes detected.
Rate Drop Response Episodes	One or more episodes detected.
Remote Assistant Monitor	Symptom or exercise data collected.
ERI Monitor	Occurrence of ERI conditions.
Electrical Reset Monitor	Occurrence of reset conditions.
Capture Management	High ventricular or atrial threshold measurement. Abort threshold searches prior to ERI. Capture Management unable to run.

Viewing Battery and Lead Measurements

By selecting the Battery and Lead Measurements screen, you can view information about the pacemaker battery and the lead system based on real-time measurements and calculations made at the time of pacemaker interrogation.

Battery and Lead Measurements screen

The information on this screen provides a detailed status of the pacemaker battery and the output conditions pertaining to the pacing lead system.

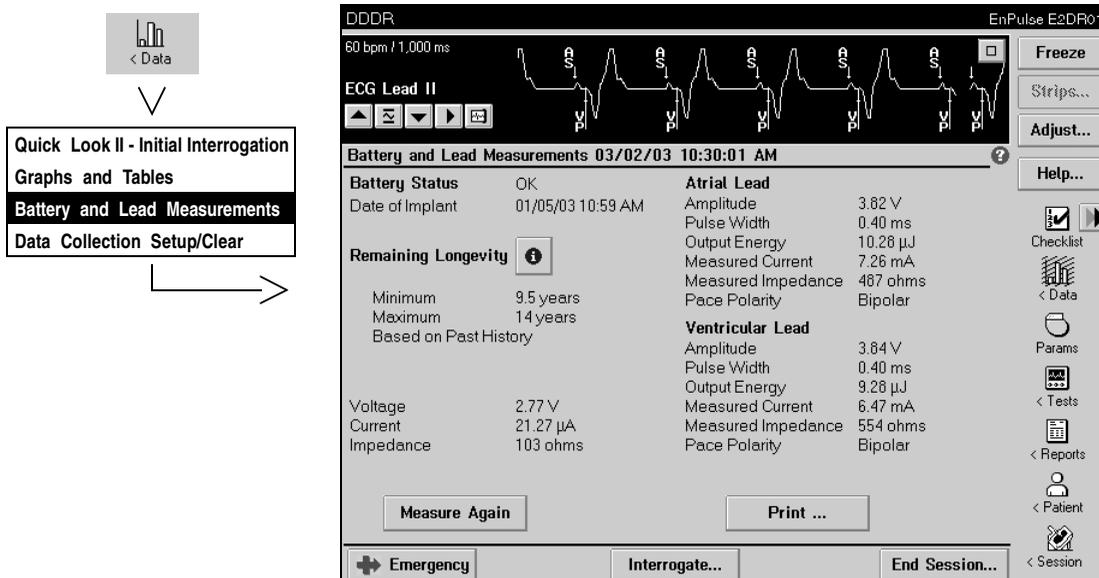


Figure 3-6. The Battery and Lead Measurements screen

Note: The values measured for the pacemaker battery and the lead system can change from one measurement to the next.

Pacemaker Battery and Lead Measurements

The Battery and Lead Measurements screen displays the following information.

Battery Status – Displays an “OK” or “Replace Pacer” message based on battery voltage and internal impedance measurements. Included below the battery status message is the date of pacemaker implantation, which is based on the most recent operation of the Implant Detect function.

Remaining Longevity – This is a calculated estimate of the time remaining until pacemaker replacement will be required. This calculated estimate is based on the programmed parameter settings and event data accumulated by the pacemaker since the previous patient session.

Remaining Longevity 

For an on-screen explanation of the longevity estimates, select the information () button appearing after the “Remaining Longevity” heading.

Explanation of Remaining Longevity Estimates

Remaining Longevity Estimate calculates time remaining until pacemaker replacement will be required.

 Estimate is based on programmed parameter settings and pacemaker recorded events since the previous patient session.

Approximately 5% of patients will reach ERI sooner than the Minimum Remaining Longevity estimate shown on the Battery and Lead Measurements Screen. Elective replacement should NOT be based on this Estimate.

For replacement, use only the ERI condition or the battery status REPLACE PACER.

Caution: Elective replacement should **not** be based on the estimated remaining longevity. For this decision, use only the elective replacement indicators or the “Replace Pacer” battery status message.

Battery Voltage/Current/Impedance – These values show the measured pacemaker battery voltage, the present current drain on the pacemaker battery averaged over a pacing cycle, and the battery’s impedance.

Conducting a patient session

Viewing Battery and Lead Measurements

Atrial and Ventricular Leads – Lead information includes the following:

Amplitude	The measured amplitude of a pacing pulse
Pulse Width	Present programmed pulse width setting
Output Energy	Output energy contained in a single pacing pulse
Measured Current	The measured current in the pacing lead during delivery of a pacing pulse
Measured Impedance	The measured electrical impedance presented by the pacing lead and electrode/tissue interface
Pace Polarity	The present lead electrode configuration (unipolar or bipolar) used for pacing

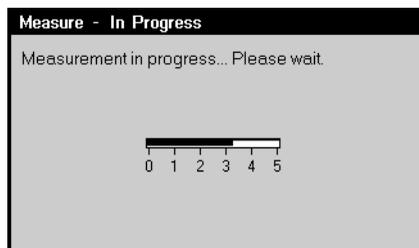
Updating the displayed data

You can update the data shown on the screen by the following interrogation procedure.

◆ **To update the pacemaker Battery and Lead Data**

1. Position the programming head and hold it in place.
2. Select the **[Measure Again]** button.

As indicated by the pop-up window, the interrogation and measurement process takes a few seconds.



Checking the present parameter settings

The first step to viewing the parameter settings to which the patient's pacemaker is presently programmed is to display the Therapy Parameters screen shown below.

The Therapy Parameters screen

This screen is used to view permanent parameters or to program them to the desired settings.

Params

DDDR EnPulse E2DR01
60 bpm / 1,000 ms

ECG Lead II

Parameters - Therapy

Modes/Rates		Atrial Lead		Ventricular Lead	
Mode	DDDR	Amplitude	3.500 V	Amplitude	3.500 V
Mode Switch...	175 bpm	Pulse Width	0.40 ms	Pulse Width	0.40 ms
Lower Rate	60 ppm	Sensitivity...	0.50 mV	Sensitivity...	2.80 mV
Upper Track	120 ppm	Pace Polarity...	Bipolar	Pace Polarity...	Bipolar
Upper Sensor	120 ppm	Sense Polarity...	Bipolar	Sense Polarity...	Bipolar
Rate Response...		Capture...	Adaptive	Capture...	Adaptive

Intrinsic/AV		Refractory/Blanking		Additional/Interventions	
Intrinsic Activation...		PVARP...	Auto	Additional Features...	
Paced AV...	150 ms	PVAB	180 ms	Interventions...	
Sensed AV...	120 ms				

Save... Get... Undo Pending Print... PROGRAM

Emergency Interrogate... End Session...

An ellipsis (...) appearing after an option indicates that selecting that option will display additional parameters.

Figure 3-7. The Therapy Parameters screen

The parameter values displayed on this screen are the parameter settings to which the patient's pacemaker is presently programmed. If the field for a parameter or option displays an ellipsis (e.g., Rate Response...), there are subordinate parameters that are not displayed on this screen.

For more information, see "Programming parameters" on page 7-2. Table 7-1 on page 7-10 lists subordinate therapy parameters.

Conducting a patient session

Viewing and programming patient information stored in the pacemaker

Viewing and programming patient information stored in the pacemaker

The EnPulse pacemakers can store patient related information that you can view and print during a patient session. This information typically is programmed into the pacemaker at the time of implantation, but it can be revised at any time.

The screenshot shows the 'Patient Information' screen on an EnPulse E2DR01 pacemaker. At the top, it displays 'DDDR' and '60 bpm / 1,000 ms'. Below this is an ECG trace labeled 'ECG Lead II'. The main section is titled 'Patient Information' and contains several data entry fields:

- Patient Identification:** Name (John Smith), Year of Birth (1945), ID Number (1234-5678), Chart Number (js1234).
- Leads Implanted:** Atrial Lead... (Medtronic), Ventricular Lead... (Medtronic).
- Devices Implanted:** Serial Number (123456), Implant Date (01/05/03 6:29 PM), Implanted Defibrillator? (No).
- Indications for Implant:** Dependency (Yes), Symptoms (Unspecified), Indications (A. Flutter/Fib. + bradycardia), Etiology (Ablation).
- Physician Information:** Name (Dr. Dent), Phone No. (555-1234).

Navigation buttons at the bottom include 'Emergency', 'Interrogate...', and 'End Session...'. A vertical menu on the right side includes 'Freeze', 'Strips...', 'Adjust...', 'Help...', 'Checklist', 'Data', 'Params', 'Tests', 'Reports', 'Patient', and 'Session'.

Figure 3-8. Viewing the Patient Information screen

◆ To program patient information

1. On the Patient Information screen, select the data field in which you want to enter or change the data.

This action displays selectable options or the on-screen keyboard for entering data. Refer to “Using the on-screen keyboard” on page 1-29 for information about entering data using this keyboard.

2. Select the desired information option, or type the desired information, and then select the [Enter] button on the on-screen keyboard.
3. Repeat steps 1 and 2 for any field to which you want to add, delete, or change the data.

4. When you have finished, position the programming head and press the **[PROGRAM]** button.

This action programs into the pacemaker all the data as it is presently displayed on the Patient Information screen.

Recording an ECG Strip of magnet operation

With the EnPulse pacemakers, positioning the programming head does *not* cause the pacemaker to operate in its magnet mode. To record or view magnet operation for EnPulse models, you must use the Magnet test.

The Magnet Test Setup screen

From the Magnet Test Setup screen, you can start and stop magnet operation in the pacemaker. Options let you collect an ECG strip of magnet operation and, if desired, non-magnet operation.

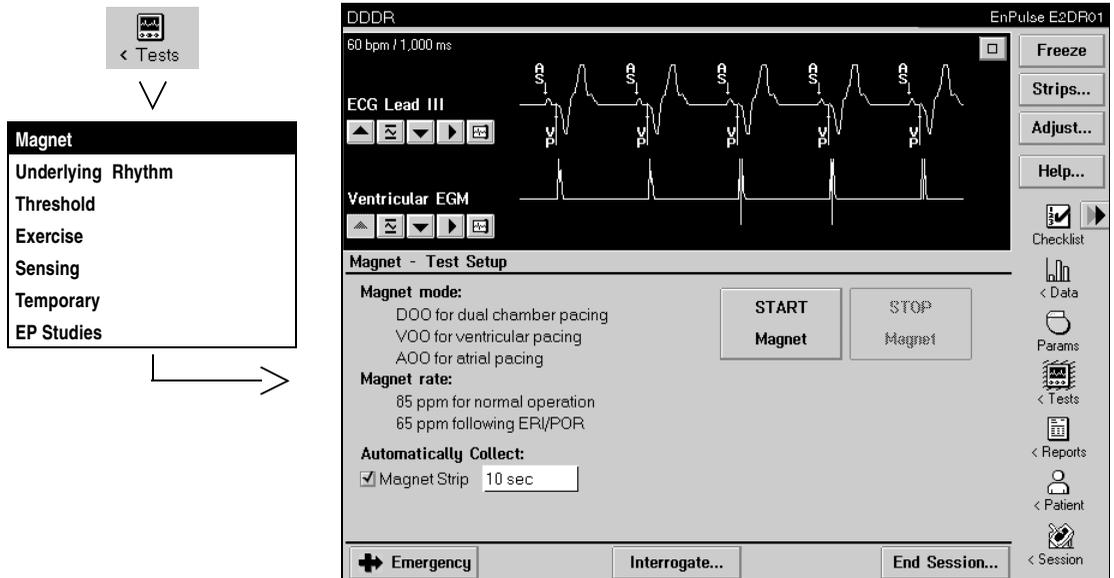


Figure 3-9. Magnet Test Setup screen

Conducting a patient session

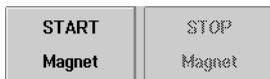
Recording an ECG Strip of magnet operation

Note: At any time during a Magnet test, lifting the programming head from over the patient's pacemaker for at least 2 seconds restores operation of the pacemaker to its permanent status. This action should be taken in the event of programmer malfunction, loss of power, or the absence of an appropriate command confirmation.

Procedure for conducting a Magnet Test

◆ To conduct a Magnet Test

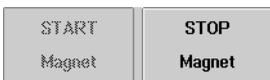
1. Display the Magnet Test Setup screen (see Figure 3-9 on page 3-27).
2. To start magnet operation, position the programming head and select the **[START Magnet]** button.



Observe that the live rhythm display shows the point at which magnet operation begins (“DOO, 85 min⁻¹” for example). At this point, the pacemaker performs a Threshold Margin Test.

If you have chosen to collect an ECG strip (see “Collecting an ECG strip” on page 3-29), a pop-up window shows progress during the collection process. Select the **[Stop Collection]** button if you want to stop the ECG collection before it completes. Selecting this button does not stop magnet operation.

3. To stop magnet operation, select the **[STOP Magnet]** button.



A pop-up window gives you the option to collect an ECG strip of non-magnet operation. Select **[Yes]** to collect a non-magnet strip or select **[No]** to close the window.

Collecting an ECG strip

The programmer automatically collects an ECG strip during the Magnet test unless you cancel this option.

- A check mark (✓) appearing in the Magnet Strip check box indicates that a strip will be collected. This is the default status when you open the screen.



- To change the length of the strip, select the time field and choose the collection time you desire.
- If you do not want automatic strip collection, select the Magnet Strip check box to clear the check mark.

About the collected ECG strips

If you have chosen to collect a Magnet strip or both a Magnet and Non-Magnet strip, the strips are stored by the programmer for viewing and printing. A Magnet Strip (and Non-Magnet Strip) icon appears at the bottom of the screen to indicate when strips are available for viewing and printing.

◆ **To view a collected ECG strip**

- Select the Magnet Strip or the Non-Magnet Strip icon near the bottom of the screen. Refer to “Recalling and viewing waveform strips” on page 4-23 for information about using the strip viewing feature.



◆ **To print a Magnet Test report**

- Select the [Print...] button and then choose the desired printing options. Refer to “Printing the frozen strip” on page 4-19 for information about printing waveform strips and reports.

Checking the patient's Underlying Rhythm

To evaluate a patient's underlying rhythm or determine the patient's intrinsic heart rate, use the Underlying Rhythm test.

Caution: The use of this test function is intended for diagnostic and test purposes. It should be used only under conditions of careful patient monitoring and control.

The Underlying Rhythm Test screen

The Underlying Rhythm Test screen provides two means for evaluating the patient's underlying rhythm: 1) the Inhibit test and 2) the Manual Rate Decrease test.

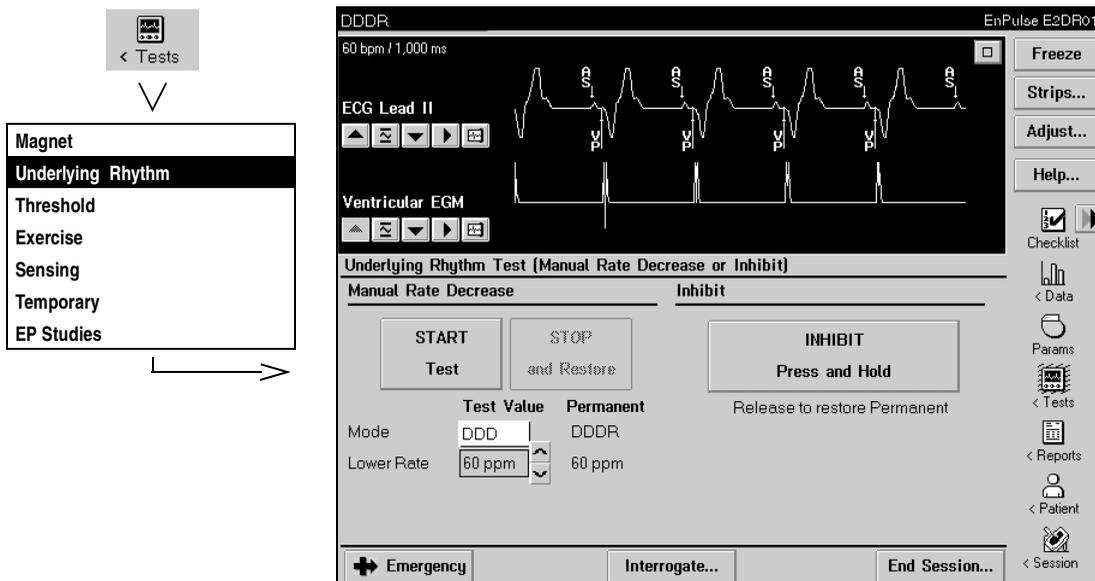


Figure 3-10. Underlying Rhythm Test screen

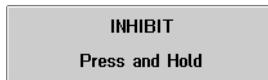
Note: At any point during use of the Underlying Rhythm test, lifting the programming head away from the site of the patient's pacemaker for at least two seconds will restore normal pacemaker operation. In the event of a programmer malfunction or loss of power, lift the programming head immediately.

Procedure for checking the patient's Underlying Rhythm

Note: The Inhibit mode shuts off pacemaker output for the test duration.

◆ **To check Underlying Rhythm using Inhibit**

1. Display the Underlying Rhythm Test screen (see Figure 3-10 on page 3-30).
2. To stop the output of pacing stimuli:
 - a. Position the programming head.
 - b. Press and hold the **[INHIBIT Press and Hold]** button.



Pacemaker blanking periods are shortened during this test to increase the period during which cardiac events can be sensed.

3. To restore pacing, release the **[INHIBIT Press and Hold]** button.

◆ **To check Underlying Rhythm using manual rate decrease**

1. Display the Underlying Rhythm Test screen (see Figure 3-10 on page 3-30).
2. Choose the desired test pacing mode and the starting value for Lower Rate:
 - a. Select the Mode field to display the test mode options.
 - b. Select the test pacing mode from the options displayed.
 - c. Select the or button to adjust the Test Value for Lower Rate to a setting close to the patient's present pacing rate.

	Test Value	Permanent
Mode	DDD	DDDR
Lower Rate	50 ppm	50 ppm

3. Select the **[START Test]** button to engage the test mode and rate.
4. Select the button to gradually decrease Lower Rate until the patient's underlying rhythm emerges. (Select the button to increase Lower Rate as desired.)
5. To end the test, select the **[STOP and Restore]** button.

Collected ECG strips

During either type of Underlying Rhythm test, the programmer automatically collects and saves a 10-second ECG strip. A Test Strip icon appears near the bottom of the screen (after the test has ended) to indicate its availability.

◆ **To view a collected ECG strip**



- Select the Test Strip icon near the bottom of the screen. Refer to “Recalling and viewing waveform strips” on page 4-23 for information about using the strip viewing feature.

◆ **To print an Underlying Rhythm Test report**



- Select the [Print...] button and then choose the desired printing options. Refer to “Printing the frozen strip” on page 4-19 for information about printing waveform strips and reports.

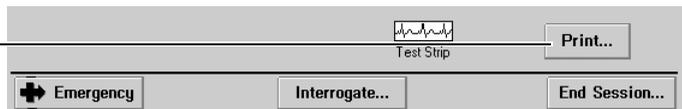
Printing reports

You can print the data generated during a patient session using the **[Print...]** button or by opening the Available Reports window. You can also print reports that are being held in the print queue.

Using the Print button

On most task screens, the **[Print...]** button appears or becomes active as soon as the execution of a task or function generates the data needed for a report. Selecting the **[Print...]** button allows you to print a formatted data report associated with the current task. The **[Print...]** button appears near the bottom of the task screen.

[Print...] button appears or becomes active when task-related data has been generated.



Depending on the Session preference settings (see “Verifying or changing session preferences” on page 3-13), selecting the **[Print...]** button does one of the following:

- Immediately initiates printing of the associated report.
- Sends the report to the print queue to be printed later.
- Opens the Print Options window shown below.

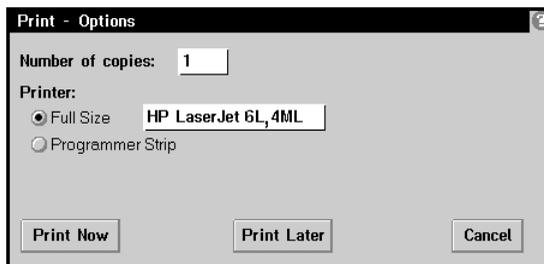


Figure 3-11. Print Options window

Refer to “Verifying or changing session preferences” on page 3-13 for information about choosing print options.

Printing from the Available Reports window

During a patient session, the programmer automatically generates and saves the following reports:

- The Initial Interrogation report
- The Final report
- Reports generated by the use of the Tests functions.

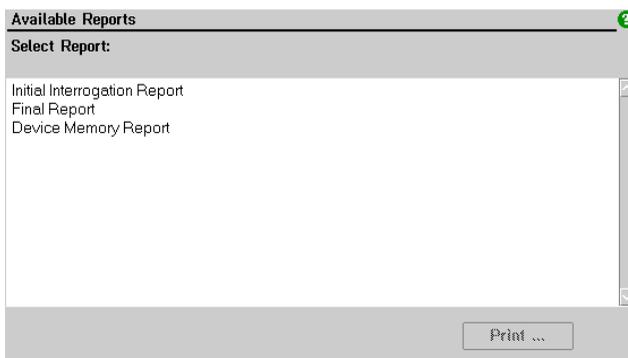
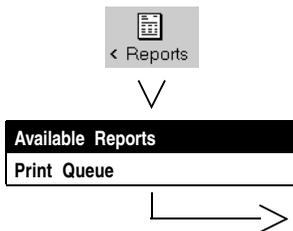
Note: If a test function is used more than once, a report for only the most recent use is available.

- Device Memory report (This is a special report intended for use only by Medtronic technical support personnel.)

At any time during the session, you can view the list of reports that are available for printing and select the ones you want to print immediately or save in the print queue for printing later in the session or after the session has ended.

◆ **To print from the list of Available Reports**

1. Select **Reports > Available Reports**.



2. From the displayed list of available reports, select the report you want to print.
3. Select the [**Print...**] button (refer to “Using the Print button” on page 3-33).

Printing reports held in the Print Queue

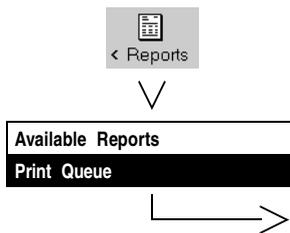
Whenever you request a report by selecting the **[Print...]** button, control of the print job is passed on to the print queue.

By displaying the Print Queue window, you can check the status of any print job and either print or delete those print jobs that are being held. All print jobs held for printing are displayed and up to 25 print jobs already printed are reported.

Note: When you end a patient session, the print queue is still available. It lists any reports held from that session and other previous sessions.

◆ To print or delete reports from the Print Queue

1. Select **Reports > Print Queue**.



The screenshot shows the EnPulse E2DR01 software interface. At the top, it displays 'DDR' and 'EnPulse E2DR01'. Below that, it shows '60 bpm / 1,000 ms' and 'ECG Lead II' with a corresponding ECG waveform. The main section is titled 'Session Print Queue' and contains a table of reports. Below the table are 'Print' and 'Delete' buttons. At the bottom, there are buttons for 'Emergency', 'Interrogate...', and 'End Session...'. On the right side, there are various control buttons like 'Freeze', 'Strips...', 'Adjust...', 'Help...', 'Checklist', 'Data', 'Params', 'Tests', 'Reports', 'Patient', and 'Session'.

Patient	Report	Printer	Status
Note: Only reports from THIS SESSION shown			
John Smith	Initial Interrogation Report	Full Size	Hold-Later
John Smith	Device Memory Report	Full Size	Hold-Later
John Smith	Atrial Capture Management Thres	Full Size	Hold-Later
John Smith	Ventricular Capture Management *	Full Size	Hold-Later
John Smith	Ventricular Impedance Trend - Chr	Full Size	Hold-Later
John Smith	Ventricular Auto Sensitivity Trend I	Full Size	Hold-Later

2. From the list of reports, select the report you want to print or delete.

Caution: Once deleted, a report cannot be recovered.

3. Select the button for the desired action:
 - Select **[Print]** to print the report.
 - Select **[Delete]** to delete the report from the print queue Report list.

Saving session data on a diskette

Any time during a patient session, you can save data from the session on a diskette. Table 3-5 on page 3-36 lists the data saved. Data is saved as a text file that can be imported into a word processing or data base program.

Table 3-5. Saved session data

Feature name	Information exported
Therapy Parameters	Initial interrogated values Last programmed values
Patient Information	Last programmed values
Battery and Lead Measurements	Last measured values
Threshold Tests ^a	Last results for each test type conducted (for each chamber tested)
Sensing Tests ^a	Last results for each test type conducted (for each chamber tested)
Exercise Test	Results for the last test conducted
Automatic Diagnostics	Event Counters Atrial High Rate Episodes Ventricular High Rate Episodes Mode Switch Episodes Rate Drop Response Episodes
Device Memory	Retrieved from interrogation performed only for saving session data.

^a Manual test results are saved only if the user has saved the results.

◆ **To save session data on a diskette**

1. Select **Session > Save To Disk...** to display the Save To Disk window.



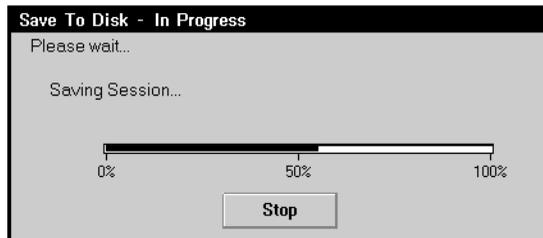
Note: A similar procedure on page 3-39 allows you to save session data, but it requires that you end the session immediately after doing that.

2. Insert a 3.5-inch computer diskette into the disk drive on the right side of the programmer.

Use a formatted diskette that is IBM-compatible. It can have a capacity of either 720 Kb (DS, DD) or 1.44 Mb (DS, HD).

3. Position the programming head and select the **[Start]** button from the Save To Disk window.

This initiates an interrogation and then starts the transfer of data to the diskette. The programming head must be held in position until the interrogation is complete. Depending on the amount of session data being saved, this process may take several minutes. A gauge on the screen indicates the progress of the data transfer to the diskette.



Note: If the diskette is full, the programmer will notify you that you need to insert a different diskette.

4. When the transfer of data is complete, remove the diskette from the programmer.

The programmer automatically assigns a unique file name so that it cannot overwrite any existing session file. To determine which file was saved for a particular session, use an IBM-compatible computer to view the diskette file directory. The directory lists the date and time each file was created.

Optionally, you can continue with the patient session after saving the data.

Ending a patient session

Note: The pacemaker will be unresponsive to the application of a magnet for one hour following the use of a programmer unless the session is ended with the command option to immediately clear data collected in the pacemaker. The default command for ending a session allows the pacemaker to retain collected data for one hour, during which use of a magnet has no effect. See “Clearing pacemaker data” on page 3-41.

Because the programmer collects and stores data on a session-by-session basis, it is important to correctly end a session when you finish. You should not begin using the programmer with a different patient until you have completed the procedure described in this section.

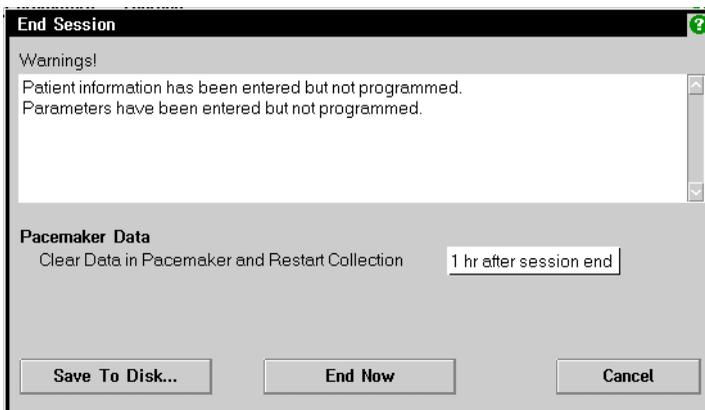
Note: If the programmer detects a serial number that is different from the one acquired during the initial interrogation, it will automatically end the current session.

Once you end a session, you can still access the Print Queue window to print reports from the session. Prior to ending the session, you have the options to:

- Save the session data on a diskette.
- Change the way the pacemaker clears collected data.

◆ **To end a patient session**

1. Select the **[End Session...]** button in the command bar at the bottom of the screen.



2. Note the “Warnings!” field at the top of the End Session window. It informs you of any action you should take or any information you should know before you end the session. To return to the session, select the **[Cancel]** button.
3. Before ending the session, consider the options available from the End Session window.
 - To save the session data on a diskette, see “Saving a session on diskette” below.
 - To change the settings for how collected data is cleared from the pacemaker when you end the session, see “Clearing pacemaker data” on page 3-41.

To accomplish either of these tasks, proceed to its appropriate procedure. *Do not* select the **[End Now]** button in step 4.
4. To end the session now and return to the Select Model screen, select the **[End Now]** button.

Saving a session on diskette

Before you end a patient session, you can save data from the session on a diskette. Refer to Table 3-5 on page 3-36 for a list of the data saved. Data is saved as a text file that can be imported into a word processing or data base program.

◆ To save session data on a diskette

Note: When using this procedure, you must end the patient session after saving session data on a diskette. If you choose to initiate the save by selecting the Session icon, you can continue the session (see page 3-36).

1. Insert a 3.5-inch computer diskette into the disk drive on the right side of the programmer.

Use a formatted diskette that is IBM-compatible. It can have a capacity of either 720 Kb (DS, DD) or 1.44 Mb (DS, HD).
2. From the End Session window (see step 1 on page 3-38), select the **[Save To Disk...]** button.

Conducting a patient session

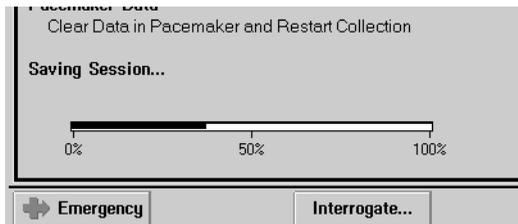
Ending a patient session



Note: If the diskette is full, the programmer will notify you that you need to insert a different diskette.

3. Position the programming head and select the [Start] button from the Save To Disk window.

This initiates an interrogation and then starts the transfer of data to the diskette. The programming head must be held in position until the interrogation is complete. Depending on the amount of session data being saved, this process may take several minutes. A gauge on the screen indicates the progress of the data transfer to the diskette.



Note: After session data has been saved, you can change the options for clearing data (see “Clearing pacemaker data” below). However, you cannot cancel the End Session sequence and return to the session.

4. When the transfer of data is complete, select the [End Now] button to end the patient session. Remove the diskette from the programmer.

Note: The programmer automatically assigns a unique file name so that it cannot overwrite any existing session file. To determine which file was saved for a particular session, use an IBM-compatible computer to view the diskette file directory. The directory lists the date and time each file was created.

Clearing pacemaker data

The diagnostic data collected in the implanted pacemaker is cleared one hour after you end a patient session. Collection of new data then starts. You can restart a session within one hour of ending it and still retrieve the collected data. For further information see “Clearing data from the pacemaker” on page 5-47.

Viewing the patient's ECG and EGM traces

4

This chapter describes how to use the features of the live rhythm window to view the patient's cardiac signals and monitor pacemaker operation. Also covered is the waveform Freeze feature, which lets you freeze a 15-second strip of the patient's rhythm signals.

For instructions on using the programmer's ECG chart printer, refer to "Recording an ECG strip" on page 2-21.

Viewing the ECG and other rhythm waveforms 4-2

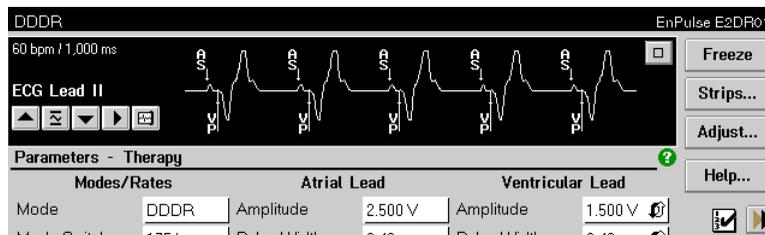
Adjusting and arranging the waveform traces 4-7

Freezing and analyzing a waveform strip 4-16

Recalling and viewing waveform strips 4-23

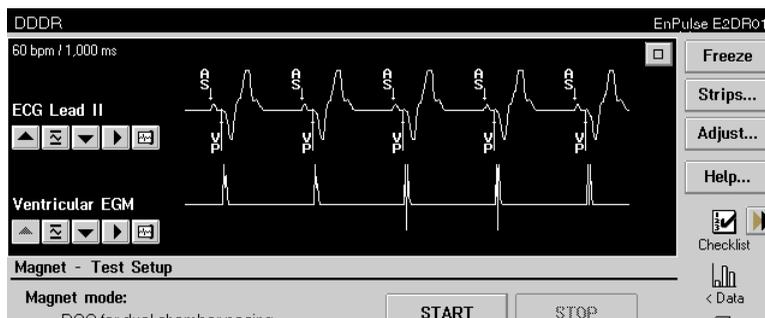
Viewing the ECG and other rhythm waveforms

During a patient session, the programmer continuously displays the patient's ECG (or other selected waveform trace) in the live rhythm monitor window at the top of the screen.



On the 9790 programmer, the size of the window automatically changes between the single-trace size shown above and the dual-trace size shown below, depending on the selected task screen. The dual-trace window is displayed for test functions, in which case, the traces displayed are the patient's ECG and the EGM in the chamber being tested.

On the 2090 programmer, the size of the window automatically changes between a dual-trace size and a triple-trace size.



The instructions on the following pages describe how you can:

- Expand the monitor window to its full-screen size.
- Adjust the size, position, and color (programmers with color display panels) of the waveform traces.
- Choose a different sweep speed, display pacing artifacts or turn them off, engage an interference filter.
- Program pacemaker telemetry to a different EGM mode.

Expanding the Live Rhythm Monitor window

To view all of the available waveform traces, you can expand the ECG window to its full size with the touch of a button. The expanded screen covers the task area of the current screen.



To expand the Monitor Window to its full size



- Select the square button in the upper-right corner of the partial-view window.

This action expands the live rhythm monitor window to its maximum size.

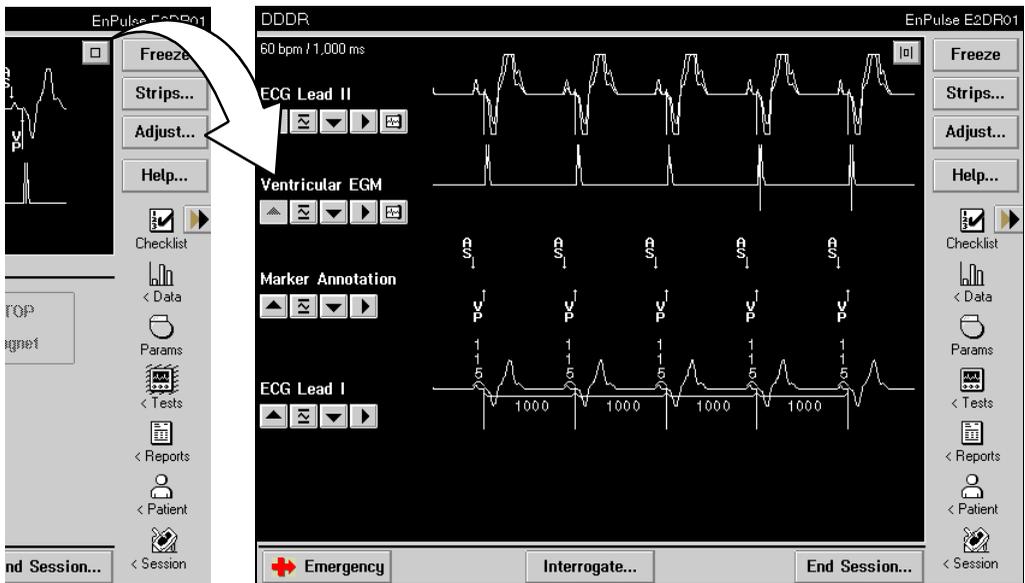


Figure 4-1. Live Rhythm Monitor window - expanded view

Viewing the patient's ECG and EGM traces

Viewing the ECG and other rhythm waveforms

◆ To return to the partial-view window



- Select the minimize button in the upper-right corner of the full-view window.

This action collapses the monitor window to its previous size and displays the task screen as it was prior to expanding the monitor window.

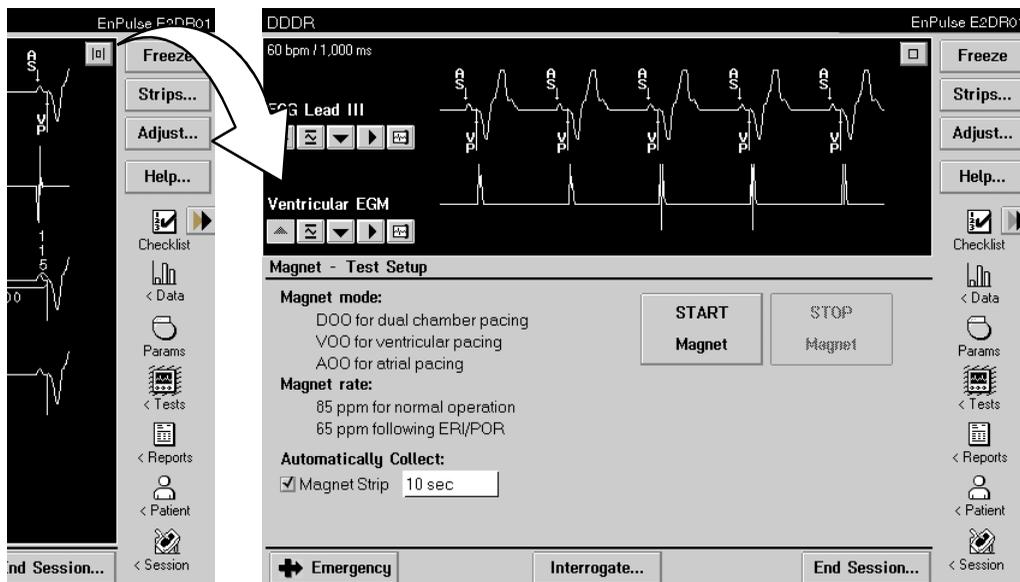


Figure 4-2. Live Rhythm Monitor window - partial view

About the waveform traces

The programmer can display traces from up to six signal sources. The ECG Leads (I, II, and III) are always available if the ECG leads are connected. Marker Annotation and Marker Intervals are displayed if the programming head is positioned over the pacemaker. These signal sources are labeled 1 - 5 in Figure 4-3.

The source of the sixth trace, also shown in Figure 4-3 as Ventricular EGM, is programmable to any one of the different telemetry options. (See "Programming a different telemetry mode" on page 4-14.)

Viewing the patient's ECG and EGM traces
Viewing the ECG and other rhythm waveforms

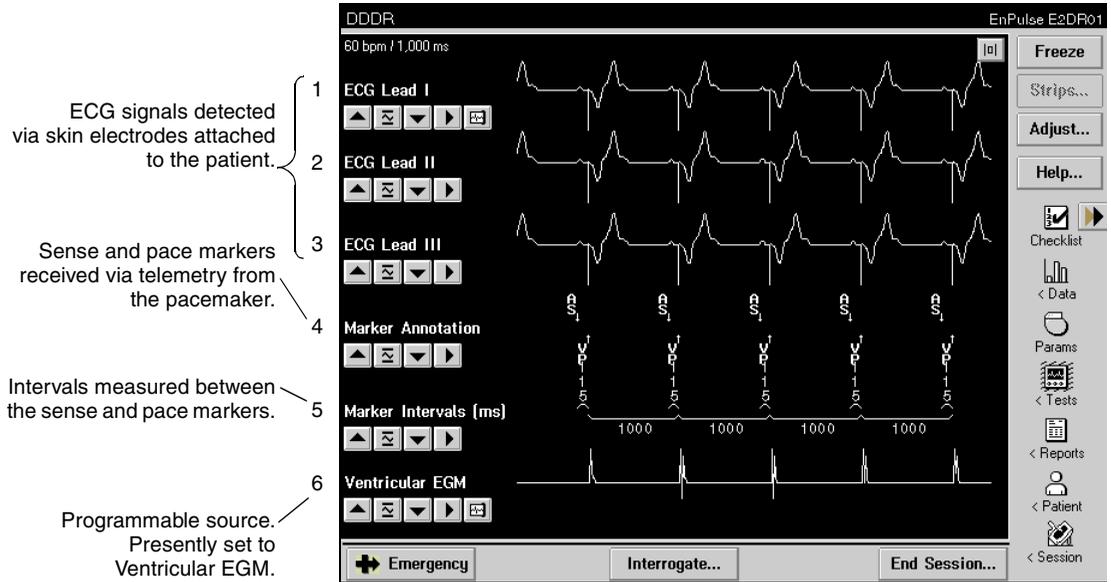


Figure 4-3. Waveform trace breakdown

The traces in Figure 4-3 are shown in a separated fashion for the purpose of explanation. Typically, the Marker Annotation and Marker Intervals traces are superimposed on an ECG or EGM trace to facilitate interpretation. Instructions on how to arrange the traces are covered on page 4-8 and page 4-15.

Note: A programming command or interrogation momentarily interrupts the transmission of marker annotations. This interruption can result in missing markers on the trace display.

Viewing the patient's ECG and EGM traces

Viewing the ECG and other rhythm waveforms

Table 4-1. Waveform trace information

Trace	Description														
ECG Lead I ECG Lead II ECG Lead III	ECG signals are detected via skin electrodes attached to the patient. The programmer must be connected to these electrodes with the ECG cable as described in "Connecting the programmer to skin electrodes" on page 2-13.														
Marker Annotation^a	<p>Marker annotations depict pacemaker operation by showing events as they occur within the pacemaker. These annotations, which are coded as shown below, are intended to facilitate ECG interpretation. The typical position of the Marker Annotation trace is superimposed on an ECG trace.</p> <table border="0" data-bbox="387 510 1126 713"> <thead> <tr> <th data-bbox="387 510 612 531">Dual Chamber Models</th> <th data-bbox="852 510 1096 531">Single Chamber Models</th> </tr> </thead> <tbody> <tr> <td data-bbox="387 539 534 560">AP - Atrial pace</td> <td data-bbox="852 539 935 560">P - Pace</td> </tr> <tr> <td data-bbox="387 569 548 590">AS - Atrial sense</td> <td data-bbox="852 569 948 590">S - Sense</td> </tr> <tr> <td data-bbox="387 598 709 619">AR - Atrial sense during refractory</td> <td data-bbox="852 598 1126 619">SR - Sense during refractory</td> </tr> <tr> <td data-bbox="387 628 588 649">VP - Ventricular pace</td> <td></td> </tr> <tr> <td data-bbox="387 657 599 678">VS - Ventricular sense</td> <td></td> </tr> <tr> <td data-bbox="387 687 760 708">VR - Ventricular sense during refractory</td> <td></td> </tr> </tbody> </table> <p>Other Markers</p> <p>TP - Triggered pace (AAT or VVT pacing mode)</p> <p>MS - Mode Switch episode (marks the beginning and end)</p> <p>ER - Error marker (indicates a marker signal that could not be decoded)</p>	Dual Chamber Models	Single Chamber Models	AP - Atrial pace	P - Pace	AS - Atrial sense	S - Sense	AR - Atrial sense during refractory	SR - Sense during refractory	VP - Ventricular pace		VS - Ventricular sense		VR - Ventricular sense during refractory	
Dual Chamber Models	Single Chamber Models														
AP - Atrial pace	P - Pace														
AS - Atrial sense	S - Sense														
AR - Atrial sense during refractory	SR - Sense during refractory														
VP - Ventricular pace															
VS - Ventricular sense															
VR - Ventricular sense during refractory															
Marker Intervals^a	<p>The programmer automatically measures the interval between pace and sense markers and displays these intervals (in milliseconds) as one of the traces. For dual chamber and ADI, ADIR, VDI, VDIR modes, the trace displays the A–V interval and the V–V interval. For single chamber modes, the trace displays the A–A or V–V interval depending on the chamber being paced.</p>														
Programmable Trace (Telemetry Mode)^a	<p>The Telemetry Mode feature described on page 4-14 lets you program the pacemaker to transmit any one of four types of EGM signals to be displayed in the live rhythm monitor window. Refer to the instructions on page 4-14 for a description of each of these EGM options.</p> <ul style="list-style-type: none"> - Atrial EGM - Ventricular EGM - Dual EGM - Summed EGM <p>Note: The Telemetry Mode feature is not available when the pacemaker is at elective replacement indicator. Also, the Telemetry Mode feature can be programmed Off.</p>														

^a Since these traces depend on telemetry received from the pacemaker, they are not displayed unless the programming head is positioned over the pacemaker.

Adjusting and arranging the waveform traces

A button bar associated with each waveform trace (Figure 4-4) and the viewing options displayed when you select the [Adjust...] button (Figure 4-5) provide the controls for tailoring the live rhythm display.

Changing trace size, source, and print status

The button bar appearing below the source title of each waveform trace provides controls for adjusting the waveform size, selecting the trace source, and choosing whether or not the trace will appear on the printed chart recording.

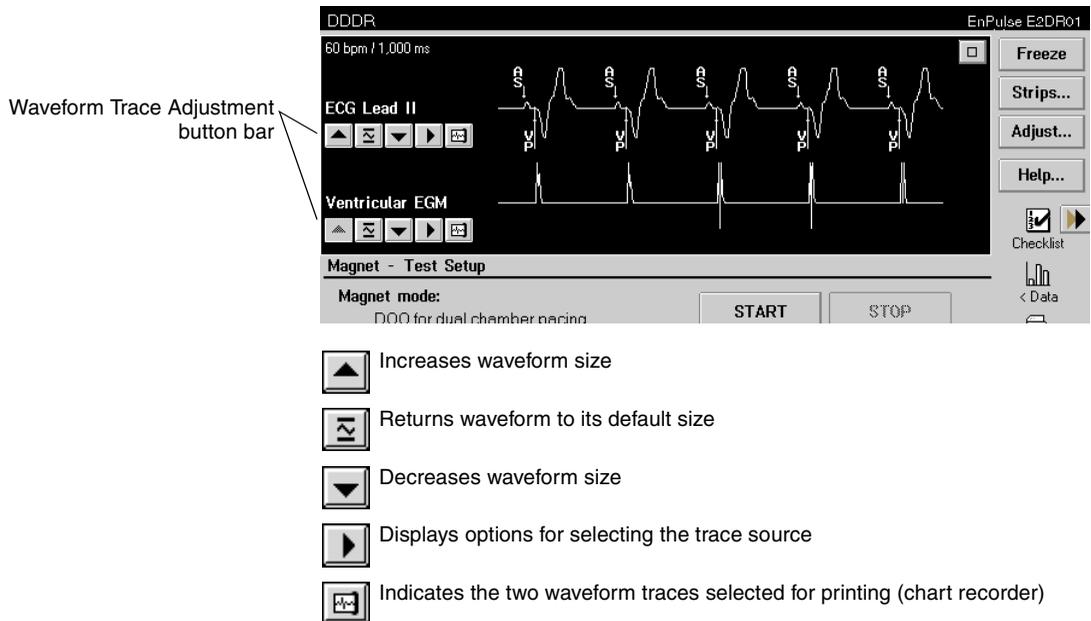


Figure 4-4. Waveform trace adjustment buttons

Adjusting trace size (amplitude)

- To increase or decrease the size (or amplitude) of the trace waveforms, select  or  on the associated button bar. ECG and EGM traces can be adjusted by a maximum of four steps.
- To return the waveform trace to its default size, press the  button.

Changing the trace source

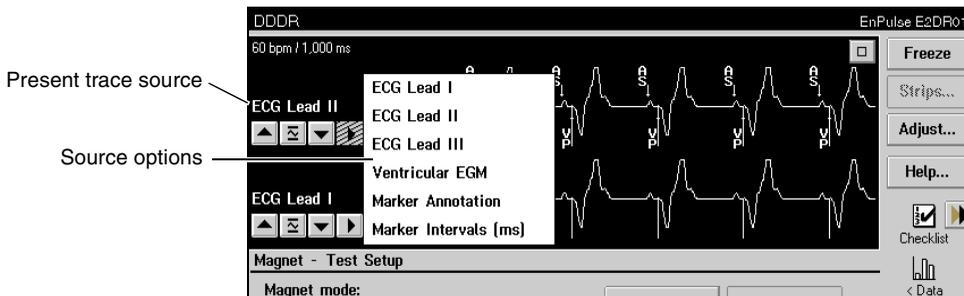
You can change the order in which traces appear in the monitor window. One method is by changing the “source” of one or more of the traces as described below. You also can use the stylus to “drag” a trace to the desired location as described on page 4-15.

◆ **To change the source of a displayed trace**

1. Select the  button from the associated button bar.

Note: Traces may be superimposed on one another. For example as shown below, both ECG Lead II and Marker Annotation sources make up a single composite trace. The name of only one source appears at the left edge of the screen.

To display the name of the other source, “tap” the trace name at the left edge of the screen. It will change to show the source of the other trace. The source name of the trace you want to change must be displayed.



2. Select the desired source from the drop-down menu of Source options.

The trace for the newly selected source now appears in place of the previously displayed trace. If the monitor window is fully expanded, you will see that the original trace and the selected trace have switched positions on the screen.

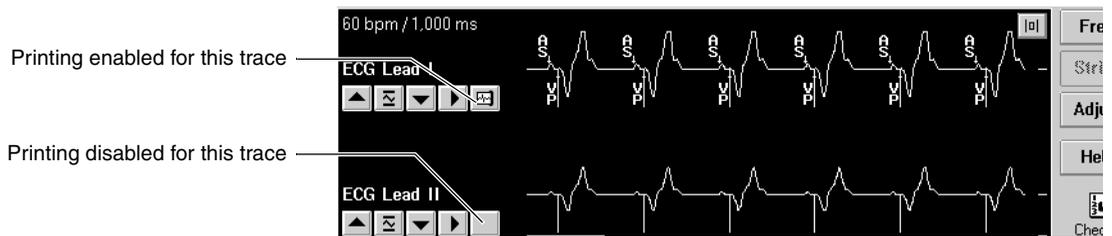
Note: You can also rearrange the trace positions on screen by dragging the traces with the stylus. Refer to “Arranging waveform traces using the stylus” on page 4-15.

Selecting traces to be printed by the chart recorder

Initiating a continuous trace recording on the programmer chart recorder (see Chapter 1) results in a printout of Marker Channel telemetry and two waveform traces based on selections made as described below. Only ECG and EGM traces can be selected for printing.

◆ **To select an ECG or EGM trace to print**

1. Select  (printing enabled button) next to the print-enabled trace that you **do not** want to print. This disables printing for that trace.



2. Select  (printing disabled button) next to the trace you want to print.

The button changes from  to  indicating that the trace is now enabled for printing.

Displaying additional adjustment options

The Adjust window contains additional controls that let you tailor the live rhythm display to your specific needs. Once certain display attributes have been adjusted, the programmer will maintain these settings from one patient session to another.

To open the Adjust window, select the **[Adjust]** button near the top of the tool palette. This action:

- Expands the live rhythm display window (if it is not already expanded)
- Displays options for changing the trace color coding
- Opens the Adjust window (see Table 4-2).

Viewing the patient's ECG and EGM traces
 Adjusting and arranging the waveform traces

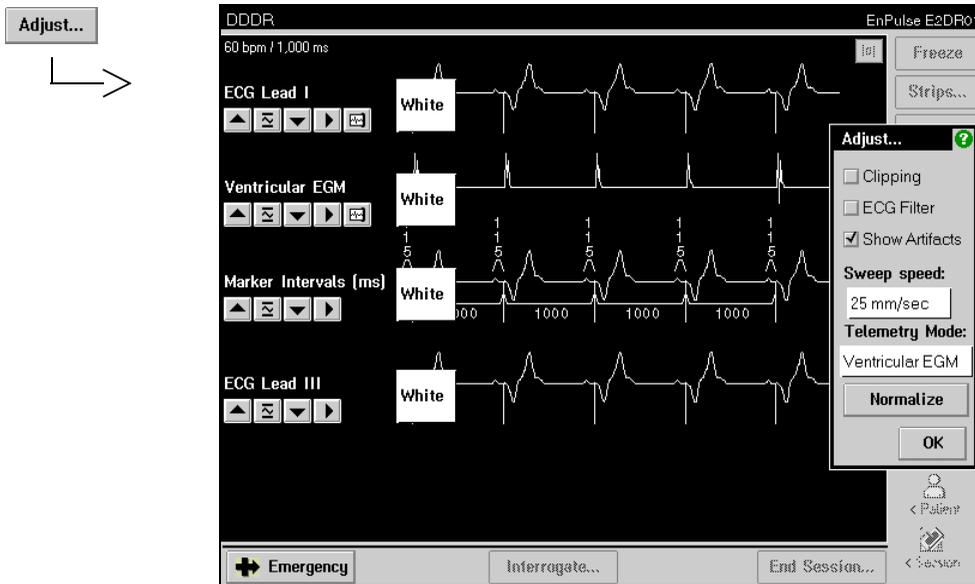
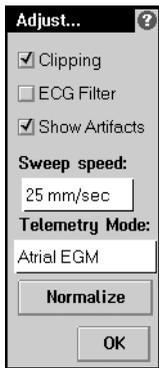


Figure 4-5. Live Rhythm Display and Adjust window

Instructions in the following sections describe using the trace color options and each of the options in the Adjust window.

Table 4-2. The Adjust window options



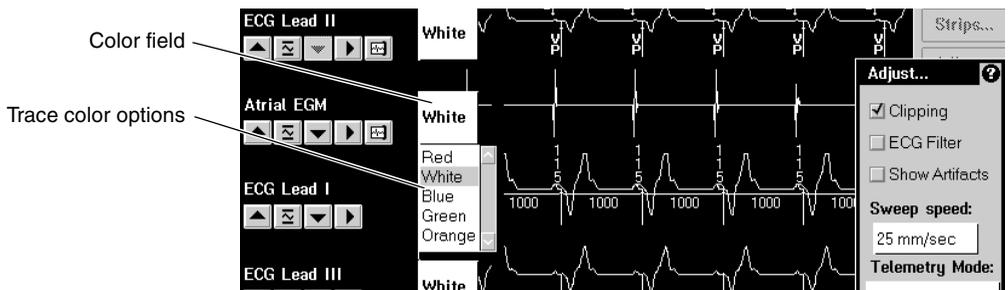
Clipping	Select this checkbox to truncate the tops and bottoms of waveform traces at a 22 mm boundary (see page 4-12). A checkmark (✓) indicates that this option is selected.
ECG Filter	Select this checkbox to turn the ECG filter on or off. A checkmark (✓) indicates that the filter is on (see page 4-12).
Show Artifacts	Select this checkbox to enable or disable the pacing artifact enhancement function. A checkmark (✓) indicates that the function is enabled (see page 4-13).
Sweep speed	Select the Sweep speed field to display options for changing the sweep speed (see page 4-13). Sweep speed options are 12.5, 25, 50, and 100 mm/sec.
Telemetry Mode	Select the Telemetry Mode field to display options for programming the type of waveform telemetry transmitted by the device (see page 4-14).
Normalize	Select this button to equalize the trace spacing and to adjust the size of each trace to the default setting.
OK	Select this button to close the Adjust window.

Color coding the waveform traces

The live rhythm display with the adjust window open provides options for color coding the displayed traces as described below. This procedure applies only to programmers that have a color display.

◆ **To change the color of a trace**

1. Select [**Adjust...**] to open the rhythm monitor adjustment window.
2. Select the color field for the trace you want to change.



3. Select the desired color from the drop-down menu of color options.

Enabling or disabling waveform clipping

The Clipping option in the Adjust window allows you to limit the vertical space that a trace can occupy on the screen and on the chart recording. With the Clipping option selected, the vertical space allotted to each trace is 22 mm on the screen and 25 mm on the printout. Waveforms that exceed this limit will be "clipped" as shown below.

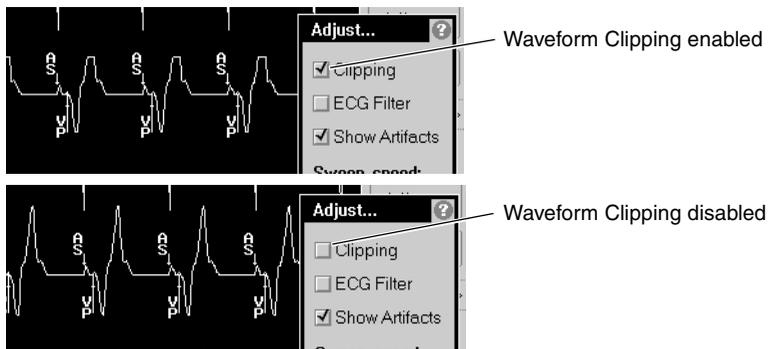
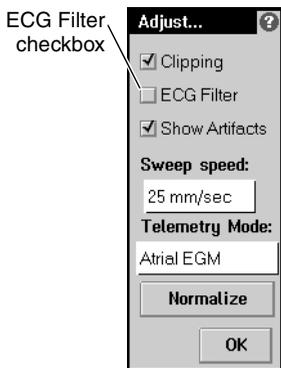


Figure 4-6. Waveform Clipping option

◆ To enable or disable waveform clipping

- Select the Clipping checkbox in the Adjust window. A checkmark (✓) indicates that the clipping option is enabled.

Using the ECG Filter option



In the presence of interference, the ECG filter may improve clarity of both the displayed and printed ECG. The filter affects the ECG detection frequency bandwidth as follows:

- Filter Off (no checkmark) – Bandwidth = 0.05 to 100 Hz
- Filter On (checkmark) – Bandwidth = 0.5 to 40 Hz

To turn the ECG filter on or off

- Select the ECG Filter checkbox in the Adjust window. A checkmark (✓) indicates that the filter is turned on.

Enabling or disabling artifact enhancement

The Show Artifacts option allows you to enable or disable the artifact enhancement function, which shows the position of each pacing stimulus on the ECG traces. The two illustrations in Figure 4-7 show how an ECG trace appears with and without this feature enabled.

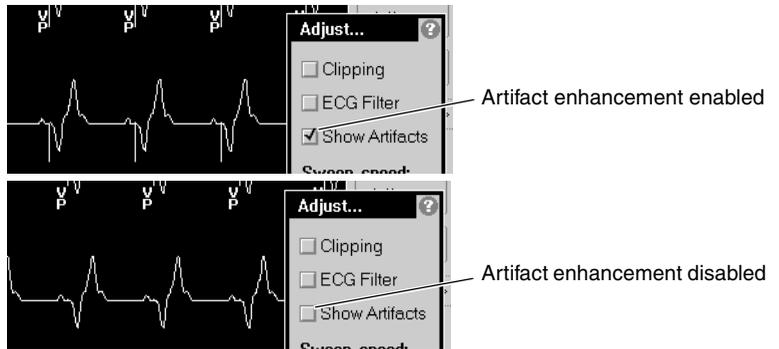


Figure 4-7. Examples of Artifact Enhancement

◆ **To enable or disable the Show Artifacts option**

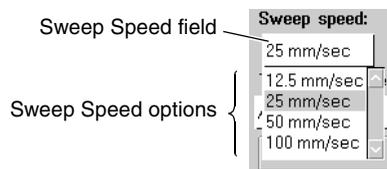
- Select the Show Artifacts checkbox in the Adjust window. A checkmark (✓) indicates that this function is enabled.

Selecting a different sweep speed

From the Adjust window, you can set the trace sweep speed to one of four settings: 12.5, 25, 50, and 100 mm/sec. These sweep speeds apply only to the rhythm monitor display. The default setting is 25 mm/sec.

◆ **To change the display sweep speed**

1. Select the Sweep Speed field in the Adjust window.



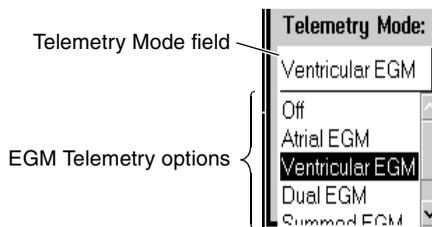
2. From the drop-down menu of options, select the desired sweep speed.

Programming a different telemetry mode

In contrast to the traces that automatically appear in the live rhythm monitor window (the ECG, Marker Annotation, and Marker Intervals traces), the EGM trace can be programmed to any one of the Telemetry Mode options (see Table 4-3).

◆ **To program a different EGM telemetry mode**

1. Position the programming head over the patient's implanted device. Observe that marker annotations are appearing on the screen.
2. Select the Telemetry Mode field in the Adjust window.



3. From the drop-down menu of options, select the desired EGM telemetry (see Table 4-3).

Table 4-3. Programmable telemetry modes

Atrial EGM	The intracardiac signal detected in the atria by the atrial pacing lead.
Ventricular EGM	The intracardiac signal detected in the ventricle by the ventricular pacing lead.
Dual EGM	Display of both the atrial and ventricular EGM traces. Since the device transmits both EGMs over a single telemetry channel in a “time sharing” fashion, resolution of the EGM signals in this case is reduced.
Summed EGM	The atrial and ventricular EGM signals combined (added together) into a single trace.
Off	No EGM trace is displayed.

Note: For single-chamber models, the mode choices are EGM or Off.

Arranging waveform traces using the stylus

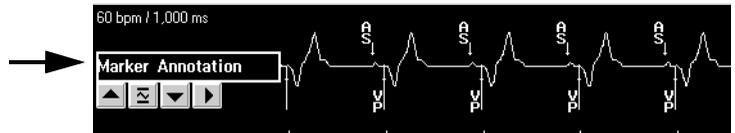
In addition to arranging waveform traces by selecting the source as described on page 4-8, you can use the stylus to “drag” a trace to the desired position. The procedure in the example below shows how to move the Marker Annotation trace from its position over the ECG Lead II trace to a position over the Ventricular EGM trace.

◆ **To move a trace using the stylus**

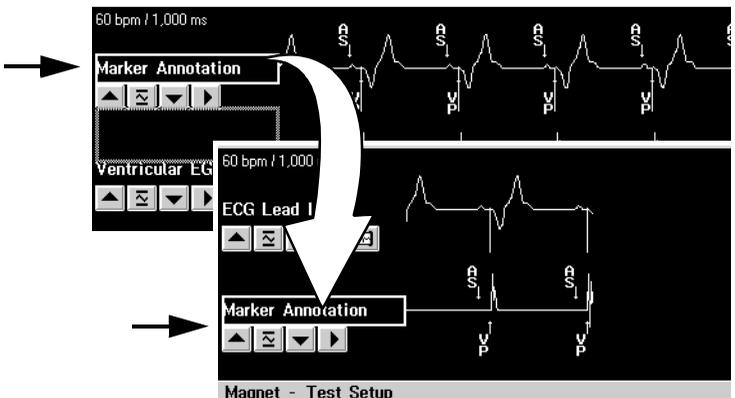
1. First decide which trace you want to move. If the trace name is not displayed (Marker Annotation in this case), tap the name of the superimposed trace to display the hidden name.



2. Press and hold the stylus against the name of the trace you want to move.



3. Without lifting the stylus, drag the box now appearing around the trace name to the desired location.



Viewing the patient's ECG and EGM traces

Freezing and analyzing a waveform strip

4. When you have the box positioned where you want the trace to appear, lift the stylus. If you are positioning the trace over another, the trace will “snap” into position.
5. To equalize the spacing between the traces in the new arrangement, select the **[Normalize]** button in the Adjust window.

Freezing and analyzing a waveform strip

The Freeze feature enables you to “freeze” the last 15 seconds of all waveform traces that show in the expanded monitor window. Selecting the **[Freeze]** button at the top of the tool palette captures the previous 15 seconds of the trace signals and opens the frozen trace viewing window shown below.

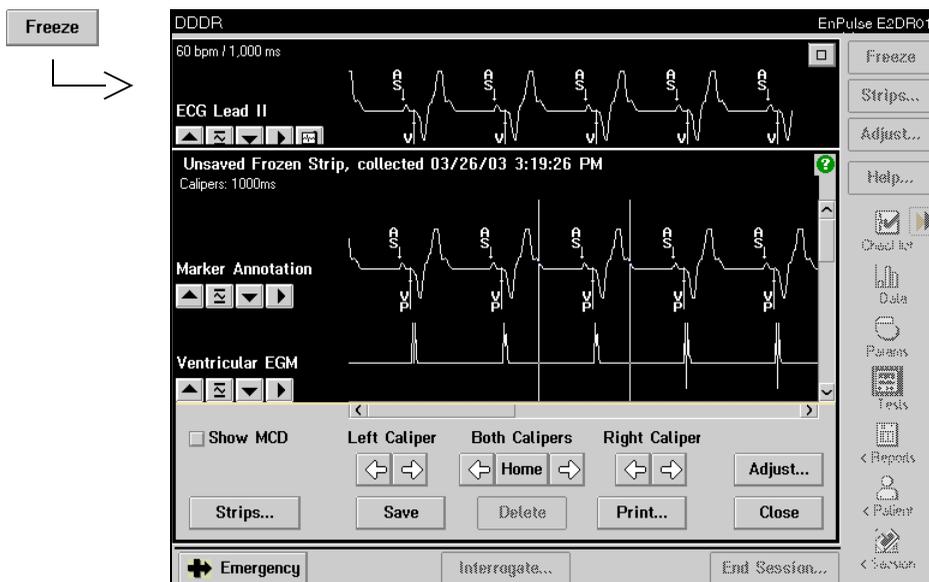


Figure 4-8. Freezing and analyzing a waveform strip

Viewing the patient's ECG and EGM traces Freezing and analyzing a waveform strip

Controls below the viewing window include the caliper controls described on the next page and the following buttons:

Adjust...	Select to open a window of waveform adjustment controls (see page 4-18).
Strips...	Select to view a list of other frozen waveform strips (see page 4-23).
Save	Select to save the waveform strip presently displayed (see page 4-19).
Delete	Select to delete a saved waveform strip. This button is active only if you are viewing a saved waveform strip.
Print...	Select to print the waveform strip presently displayed (see page 4-19).
Close	Select to close the frozen waveform viewing window. If you have not saved the trace, a pop-up window will remind you to save or delete the trace.

Using the on-screen calipers

The control buttons shown below control the frozen trace viewing window by letting you move each of the two vertical cursors appearing in the window to any desired position. The cursors thus act as calipers allowing you to measure the time interval between events. The caliper measurement is displayed in milliseconds in the upper-left corner of the window.

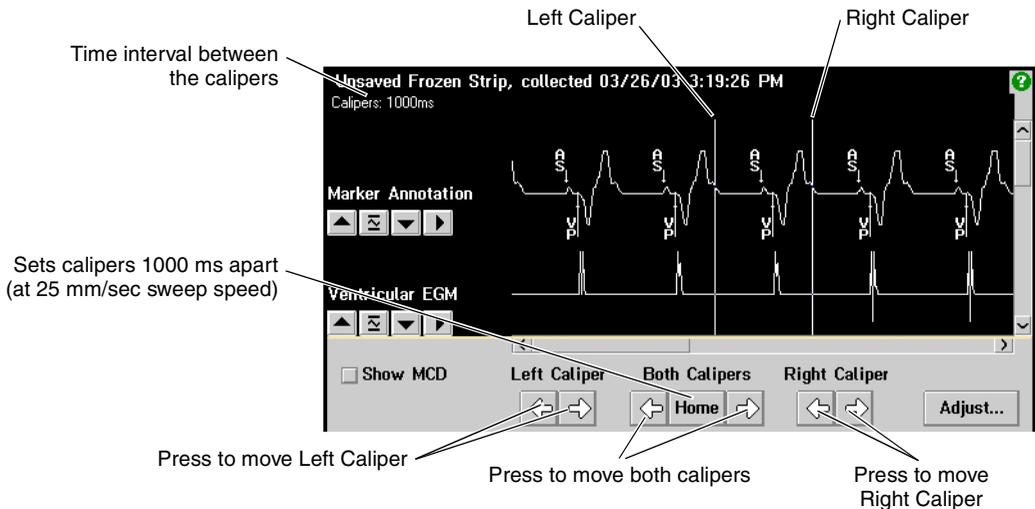


Figure 4-9. The On-Screen calipers

Viewing the patient's ECG and EGM traces
Freezing and analyzing a waveform strip

◆ **To use the caliper positioning buttons**

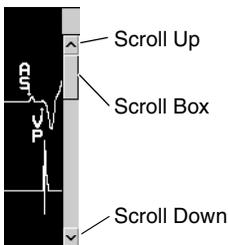
- Alternately press and release the appropriate button to make small movements, or press and hold the button to make larger movements.

◆ **To view other portions of the frozen waveform display**

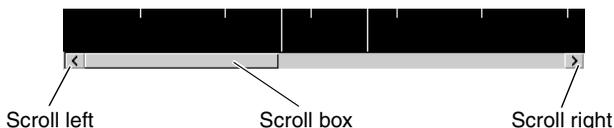
1. Use the vertical scroll bar to scroll the display up or down to view other waveform traces.

Tap the scroll up arrow (^) or scroll down arrow (v) to scroll the traces up or down in small increments.

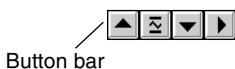
The scroll box shows the relative position of the window with respect to the total height of the strip. Touch and drag the box to scroll the strip up or down.



2. Use the horizontal scroll bar, which operates like the vertical scroll bar, to move the display to the right or left to see other portions of the 15-second strip.



Adjusting the frozen traces



The button bar next to the trace source name provides options for adjusting the trace size and selecting a different trace source. Selecting the [Adjust...] button opens the Adjust window, which provides additional control options. In both cases, these are some of the same controls available for the live rhythm monitor window. For information about using the button bar and the Adjust controls, refer to these pages:

- Using the button bar to adjust trace size or select a trace source page 4-7
- Using the waveform Clipping option page 4-12
- Selecting a Sweep Speed^a page 4-13
- Using the [Normalize] button page 4-10

^a Sweep Speed options for frozen traces are 12.5, 25, 50, 100, and 200 mm/sec.

Saving a frozen waveform strip

Save

You can save the frozen waveform strip you are viewing by pressing the [**Save**] button. You may then recall the saved strip for viewing or printing later (see page 4-23).

Printing the frozen strip

Print...

To print a frozen strip, select the [**Print...**] button near the bottom of the Frozen Strip window. Depending on the Session preference settings (see “Verifying or changing session preferences” on page 3-13), selecting the [**Print...**] button does one of the following:

- Immediately initiates printing of the selected strip.
- Sends the strip to the print queue to be printed later.
- Opens a window of print options.

Displaying a Marker Channel Diagram

If the pacemaker was operating in a dual chamber or VDD mode during the 15 seconds of the frozen strip, you can choose to include a Marker Channel Diagram (MCD) as one of the displayed traces.

Note: You can display a Marker Channel Diagram only if the pacing mode is dual chamber or VDD and the display includes marker annotations.

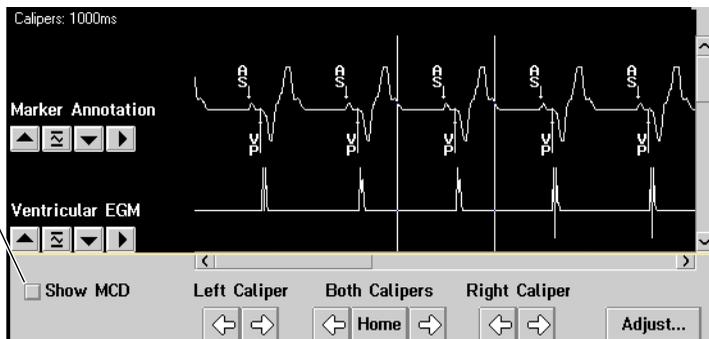
Displaying a Marker Channel Diagram

To display a Marker Channel Diagram, select the Show MCD checkbox near the lower left corner of the frozen trace viewing window. A checkmark (✓) indicates that the MCD is selected.

Viewing the patient's ECG and EGM traces

Freezing and analyzing a waveform strip

Selecting the Show MCD checkbox displays a Marker Channel Diagram as the second trace in the viewing window.



To eliminate the Marker Channel Diagram, select the checkbox again.

About the Marker Channel Diagram

The Marker Channel Diagram shows more details of pacemaker operation by depicting the various timing intervals, including blanking and refractory periods. The diagram is intended to further clarify operation of the pacemaker and simplify analysis of the patient's ECG, see Figure 4-10.

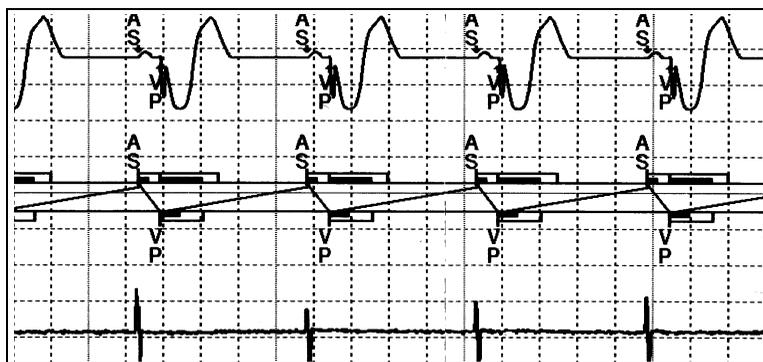
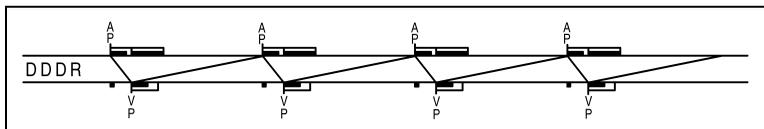


Figure 4-10. Example of a Marker Channel Diagram

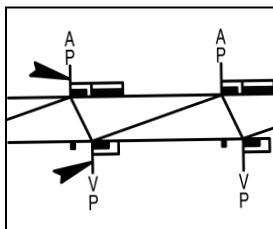
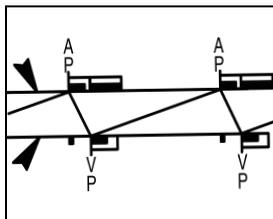
Note: If events portrayed on the diagram occur in very rapid succession, the Pace and Sense marker annotations (P, S, R) may not appear, and the supplemental labels (**Sensor**, **Safe**, **PVC**, and **NCAP**) that define certain events may overlap. Overlapping characters or labels displayed on the screen may not appear exactly the same on the printout.

Interpreting the diagram

Each Marker Channel Diagram is formed by a series of lines and symbols that depict pacemaker operation. The pacing mode in effect is printed at the start of the diagram (between the two horizontal lines).

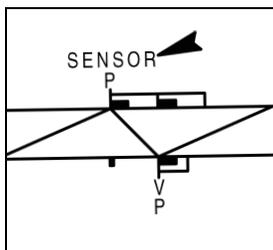


Atrial and Ventricular Baselines – The diagram is formed along two parallel baselines. Symbols depicting atrial activity appear along the top side of the upper baseline; symbols depicting ventricular activity appear along the bottom side of the lower baseline. Sloped lines appearing between the two baselines depict the timing relationship between atrial and ventricular events.



Pace and Sense Markers – Short vertical lines extending upward from baseline A and downward from baseline V are the event markers received via Marker Channel telemetry. Each marker is labeled according to the event it represents.

- AP, VP** (Pace) Output of a pacing stimulus.
- AS, VS** (Sense) A sensed event.
- AR, VR** (Refractory Sense) An event sensed within the refractory period.
- ER** (Error) A marker that could not be decoded because of interference or interrupted telemetry.

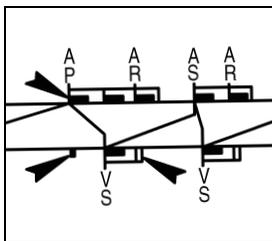


Supplemental Marker Labels – Supplemental labels indicate when a marker is the result of one of the following conditions:

- Sensor** A sensor-driven pace.
- Safe** A ventricular safety pace.
- PVC** A pacemaker-defined premature ventricular contraction.
- NCAP** A non-competitive atrial pace.

Viewing the patient's ECG and EGM traces

Freezing and analyzing a waveform strip

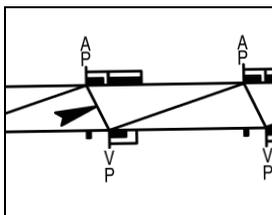


Blanking and Refractory Periods – Rectangles on the A and V baselines depict atrial and ventricular blanking and refractory periods.

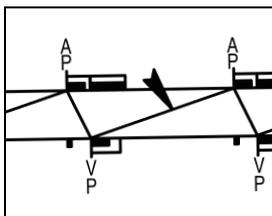
Solid Rectangles – Depict blanking periods.

Open Rectangles – Depict refractory periods. Vertical lines appearing within the rectangle mark the timing of sense or pace events occurring in the opposite chamber. Such lines may indicate the start of a new refractory (and blanking) period.

Timing Lines – The sloped, horizontal, and vertical lines appearing *between* the A and V baselines depict the timing relationship between the atrial and ventricular events.

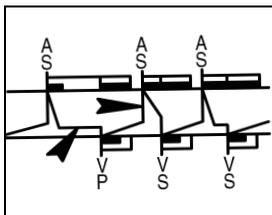


Downward Sloping Lines – Depict A–V timing (based on the pacemaker's operating AV interval) initiated by an atrial pace or sense event. The course of this line results in a ventricular pace, unless it is interrupted by a ventricular sense.



Upward Sloping Lines – Depict V–A timing (based on the pacemaker's operating pacing rate) initiated by a ventricular pace or sense event. Except as stated below, the course of this line results in an atrial pace unless it is interrupted by an atrial sense or a PVC.

In the VDD pacing mode, a ventricular pace (not an atrial pace) occurs if V–V timing completes before an atrial sense occurs.



Horizontal Lines – Depict any extension in the timing required to maintain a proper pace schedule. In this example, the upper tracking rate results in an extension of A–V timing. Another example is non-competitive atrial pacing, which shows as an extension of V–A timing.

Timing extensions are common in diagrams of the DDIR and DDI modes because of the absence of atrial tracking.

Vertical Lines – Depict interruption of a timing interval by a sense or the conclusion of a timing extension, which results in a pace.

Error conditions

Under certain conditions, the programmer may not be able to properly determine pacemaker operation from the data available. Most such conditions result in the appearance of an error message on the diagram.

If an error message appears, you should reposition the programming head and freeze another 15-second trace segment to obtain a new Marker Channel Diagram.

Note: A Marker Channel Diagram cannot be displayed if an interrogation or programming transmission occurred during the 15-second interval of the frozen trace.

Below is an explanation of the messages that indicate an error condition.

“Missing Event” – This message appears if an event did not occur when it was expected based on the interrogated data registered in programmer memory. This situation can occur in the presence of interference that interrupts telemetry.

“Diagram Error” – This message indicates that a particular sequence of events portrayed by the Marker trace cannot be processed and properly displayed by the Marker Channel Diagram.

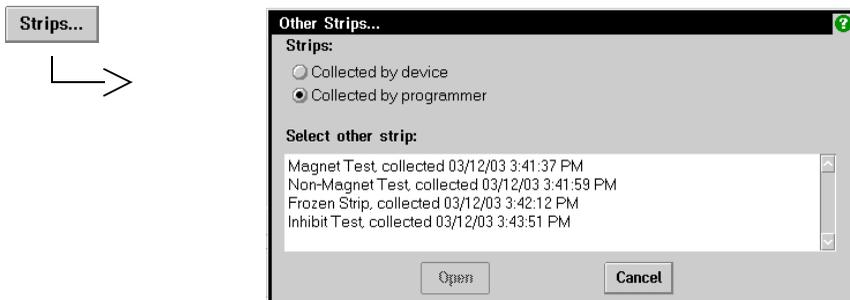
“Bad Data” – This message indicates that the programmer has not received the information it requires to complete the Marker Channel Diagram. This can occur when there is an interruption or fault in the telemetry being received - possibly due to interference or movement of the programming head.

Recalling and viewing waveform strips

Prior to ending the patient session, you can recall and view any waveform strip collected and saved during the session. Such strips may be strips saved during a test such as the Magnet test, Threshold test, or Underlying Rhythm test, or a strip saved during use of the Freeze feature.

◆ **To view a previously collected strip**

1. Select the **[Strips...]** button that appear near the top of the tool palette or the **[Strips...]** button in the lower-left corner of the Frozen Strip viewing window.



Viewing the patient's ECG and EGM traces

Recalling and viewing waveform strips

2. From the Other Strips window now displayed, select the Collected by programmer option.
3. From the list of strips in the selection field, select the strip you want to view.

It may be necessary to use the scroll bar at the right side of the field if there are more than five strips available.

4. Select the **[Open]** button.

For instructions on using the Frozen Strip viewing window, refer to the information starting on page 4-16.

Collecting diagnostic data

5

This chapter describes the diagnostic information collected automatically by the pacemaker. This information includes procedures for viewing the collected data and programming certain data collection options.

***About diagnostic data
collection 5-2***

Viewing the collected data 5-8

***The automatically collected data
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***Clinician-selected detailed data
displays 5-30***

***Programming data collection
options 5-45***

***Clearing data from
the pacemaker 5-47***

About diagnostic data collection

To aid in the evaluation of pacemaker operation and delivery of pacing therapy, the pacemaker records several types of information pertaining to the patient's heart rate and certain device operations. This recording process occurs automatically and continuously during the period between patient sessions.

Automatic data collection

Once implanted, the pacemaker automatically records information for several types of data displays, depending on the programmed pacing mode and the pacemaker model.

- Patient's Heart Rate (histogram and data format)
- Patient's AV Conduction Status (histogram and data format)
- Search AV+ Histogram (histogram and date format)
- Sensor Indicated Rate Profile
- High Rate Episodes
- Rate Drop Response Episodes
- Atrial Arrhythmia Trend
- Atrial Arrhythmia Durations (printed only, Initial Interrogation Report)
- Ventricular Rate During Atrial Arrhythmias (histogram and data format)
- Capture Management Trends
- Sensitivity Trends
- Lead Impedance (Chronic Trends and Impedance Data)
- Key Parameter History

Clinician-selected data collection

In addition to the automatically collected data, the clinician can choose to have the pacemaker collect additional data by programming one option from the following list of options:

- Custom Rate Trend
- Atrial Capture Management Detail
- Ventricular Capture Management Detail
- High Rate Detail
- Rate Drop Response Detail
- Remote Assistant - Patient activated data collection for recording data during symptoms or a specific exercise activity.

Data collection availability

With the programmer, you can retrieve the recorded information and view it in a graphic format. You can print the information in its graphic format, with or without a tabular summary of the numerical data.

Table 5-1 shows the types of diagnostic data that can be collected for each series of pacemakers. Each model series represents the following model numbers:

E2DR00 Series	→	Models E2DR01, E2DR03, E2DR06, E2DR21, E2DR31, E2DR33
E2D00 Series	→	Models E2D01, E2D03
E2VDD00 Series	→	Models E2VDD01
E2SR00 Series	→	Models E2SR01, E2SR03, E2SR06

Collecting diagnostic data
About diagnostic data collection

Table 5-1. Diagnostic data collection availability

Automatic diagnostics	Pacemaker series
Heart Rate Histograms	All ^a
AV Conduction Histograms	All except E2SR00
Search AV+ Histogram	All except E2SR00
Sensor Indicated Rate Profile	All
High Rate Episodes	All ^b
Rate Drop Response Episodes	E2DR00
Atrial Arrhythmia Trend	All ^c
Atrial Arrhythmia Durations	All ^c
Ventricular Rate During Atrial Arrhythmias	All except E2SR00
Capture Management Trends	
Ventricular Capture Management	All
Atrial Capture Management	E2DR00, E2D00
Sensitivity Trends	All
Chronic Lead Impedance Trends	All
Key Parameter History	All
Clinician-Selected diagnostics	Pacemaker series
Custom Rate Trend	All
Atrial Capture Management Detail	E2DR00, E2D00
Ventricular Capture Management Detail	All
High Rate Detail	All ^d
Rate Drop Response Detail	E2DR00
Remote Assistant (Exercise or Symptoms)	All

^a For single chamber models (E2SR00 Series), Heart Rate Histograms are available for the paced chamber. For all models, Heart Rate Histograms can be programmed to include or exclude refractory sensed events.

^b For single chamber models (E2SR00 Series), High Rate Episodes are available for the paced chamber.

^c For single chamber models (E2SR00 Series), atrial mode must be selected.

^d For single chamber models (E2SR00 Series), High Rate Detail is available for the paced chamber.

Important points about using the data function

Data collection is automatic

Data collection starts automatically at the time of device implantation when the device detects the presence of an acceptable lead impedance. Thereafter, data collection is automatic throughout the life of the device. If Implant Detection is restarted, data collection is suspended until implant detection is complete or programmed off.

Programmable setup options

The data types listed below have programmable options that allow you to make some adjustments to the automatic data collection process. Refer to “Programming data collection options” on page 5-45.

Time and date notations

The time and date information that appears on the display or printout of the diagnostic data is based on current settings of the programmer’s clock/calendar function. You can verify that the programmer time and date are set correctly by selecting the [**Freeze**] button. The current settings appear at the top of the strip viewing window. Refer to “Adjusting programmer time and date” on page 2-2 for instructions on setting the clock/calendar function.

Effects of the programming head or a magnet

Data collection is suspended while the programming head or a magnet is positioned over the implanted device. If data collection is suspended during an episode, the word “Suspended” appears in the data listed for that episode. If a patient session has been initiated, data collection is suspended until one hour after the patient session has ended. At this time histogram and episode data are automatically cleared, and new data collection begins.

For trend data, a dashed vertical line indicates that data collection was suspended at that time.

Automatically cleared diagnostics.

The following diagnostics are always cleared automatically following each patient session: histograms, episode data, sensitivity trend, and clinician-selected diagnostics. By default, the data are cleared one hour after the end of the patient session, at which time collection of new data begins. You can choose to start new data collection immediately upon ending the session (see “Clearing data from the pacemaker” on page 5-47).

Note: The minimum action that constitutes a patient session is interrogation of the device.

Note: Sensor Indicated Rate Profile data are cleared only when programming certain rate response parameters or another rate responsive mode.

Manually cleared trend data

Certain types of trend data are not cleared automatically. Unless you choose to manually clear these specific trends, collection occurs continuously as follows:

- Chronic lead trend data are collected for the most recent 14 months and typically should not be cleared unless the lead is replaced. Clearing the lead trend data for a particular chamber (atrial or ventricular), clears both the Lead Impedance and Capture Management Trend data for that chamber.
- The Atrial Arrhythmia Trend can show up to the most recent 6 months of collected data.

See “Clearing data from the pacemaker” on page 5-47 for information about clearing trend data.

Effects of ERI status

Data collection stops when the device reaches ERI status. Accumulated data can still be retrieved for viewing and printing. If the ERI condition is reset, diagnostic data is cleared and data collection automatically resumes one hour after the end of the programming session (or immediately, if programmed). If the device is at ERI status, the data collection setup options cannot be programmed.

Effect of an electrical reset

In the event of an electrical reset, all diagnostic data recorded before the electrical reset are lost.

Sense events not included in data collection

Data collected for the Rate Histogram, AV Conduction Histogram, High Rate Episodes, Search AV+ Histogram, and Ventricular Rate Histogram During Atrial High Rate include ventricular paces triggered by the Ventricular Safety Pacing feature. However, the ventricular sense events that trigger these outputs are not included in the collected data. In the view of an episode marker strip, for example, the triggering sense (VS) event is not shown, but the resulting triggered pace is shown.

Using the Exercise Test and EP Studies functions

The use of these functions disables and clears data collected for the clinician-selected diagnostic. You should interrogate the diagnostic data before using these functions. Once interrogated, the collected data are available on the programmer throughout the patient session but are lost when you end the session. You should view and print the collected data before ending the session (see “Viewing the collected data” on page 5-8).

- The procedure for using the Exercise Test includes a step that automatically restores the data collection settings. If this step is not completed or is not successful, you must reprogram the clinician-selected diagnostic on the Data Collection Setup screen (see “Programming data collection options” on page 5-45).
- Conducting an Exercise test clears both automatic and clinician-selected diagnostic data immediately from pacemaker memory.
- Using the EP Studies function clears clinician-selected diagnostic EGM data immediately from pacemaker memory. The EGM type is set to Off after using the EP Studies function.

Viewing the collected data

To display the options for viewing each of the automatically collected types of data, select the Data icon and then the Graphs and Tables menu option as shown below.

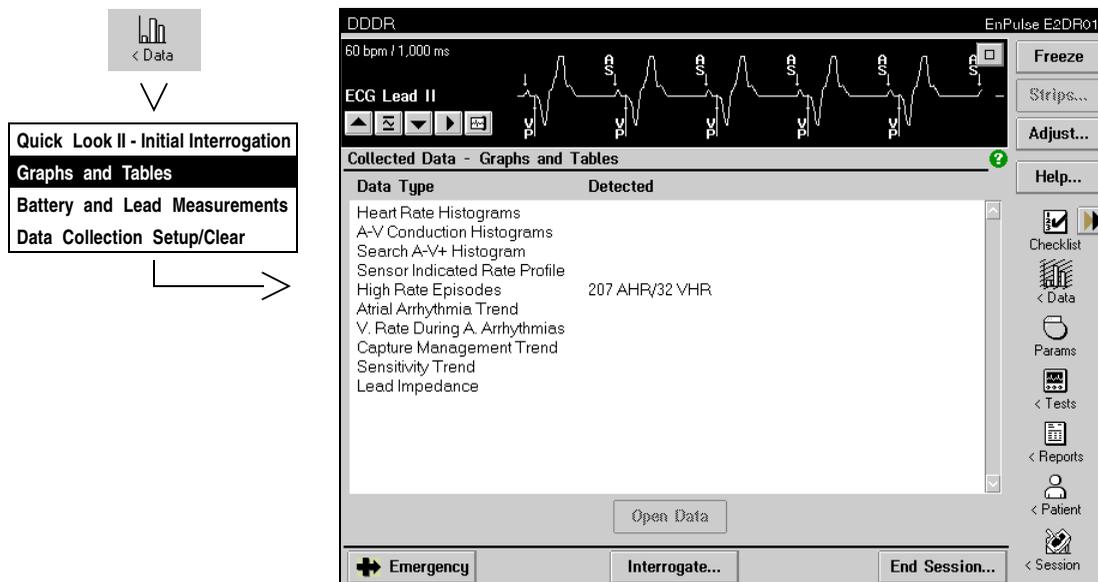


Figure 5-1. Graphs and Tables screen

Figure 5-1 shows an example of the Collected Data Graphs and Tables screen. The range of data types that can be selected for viewing from this screen depends on the pacemaker model, the programmed pacing mode, and the programmed option for Clinician Selected data collection. See “The automatically collected data displays” on page 5-11 for a description of each data display.

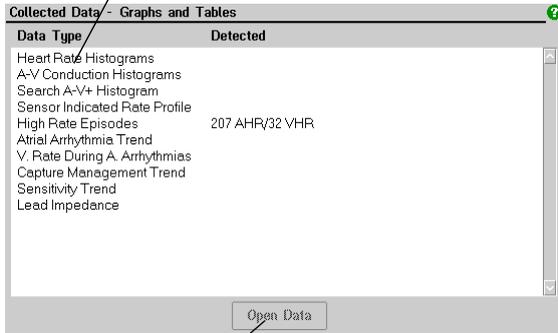
Viewing procedure

From the Graphs and Tables screen, you can select the data you wish to view as follows (see Figure 5-2):

1. Select the desired option from the list of Data Types.
2. Select the [Open Data] button.

Collecting diagnostic data
Viewing the collected data

To view a diagnostic data display, select the desired option from the list of data types.

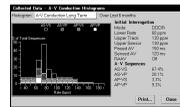


Select the [**Open Data**] button to view a display of the selected data type.

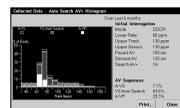
Some of these data displays have additional options that allow you to view certain data in more detail. Refer to the display descriptions.



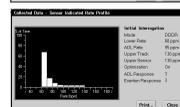
Heart Rate Histograms. See page 5-11.



AV Conduction Histogram. See page 5-14.



Search AV+ Histogram. See page 5-15.



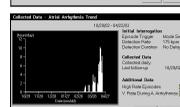
Sensor Indicated Rate Profile. See page 5-16.

Serial	Start/End	Duration	Max Rate	Avg Rate	Additional
1444	10/20/11 10:00 AM - 10/20/11 10:05 AM	5:00	180	150	None
1445	10/20/11 10:05 AM - 10/20/11 10:10 AM	5:00	180	150	None
1446	10/20/11 10:10 AM - 10/20/11 10:15 AM	5:00	180	150	None
1447	10/20/11 10:15 AM - 10/20/11 10:20 AM	5:00	180	150	None
1448	10/20/11 10:20 AM - 10/20/11 10:25 AM	5:00	180	150	None
1449	10/20/11 10:25 AM - 10/20/11 10:30 AM	5:00	180	150	None
1450	10/20/11 10:30 AM - 10/20/11 10:35 AM	5:00	180	150	None
1451	10/20/11 10:35 AM - 10/20/11 10:40 AM	5:00	180	150	None
1452	10/20/11 10:40 AM - 10/20/11 10:45 AM	5:00	180	150	None
1453	10/20/11 10:45 AM - 10/20/11 10:50 AM	5:00	180	150	None
1454	10/20/11 10:50 AM - 10/20/11 10:55 AM	5:00	180	150	None
1455	10/20/11 10:55 AM - 10/20/11 11:00 AM	5:00	180	150	None

High Rate Episodes. See page 5-17.

Serial	Start/End	Rate	Additional
1444	10/20/11 10:00 AM - 10/20/11 10:05 AM	None	None
1445	10/20/11 10:05 AM - 10/20/11 10:10 AM	None	None
1446	10/20/11 10:10 AM - 10/20/11 10:15 AM	None	None
1447	10/20/11 10:15 AM - 10/20/11 10:20 AM	None	None
1448	10/20/11 10:20 AM - 10/20/11 10:25 AM	None	None
1449	10/20/11 10:25 AM - 10/20/11 10:30 AM	None	None
1450	10/20/11 10:30 AM - 10/20/11 10:35 AM	None	None
1451	10/20/11 10:35 AM - 10/20/11 10:40 AM	None	None
1452	10/20/11 10:40 AM - 10/20/11 10:45 AM	None	None
1453	10/20/11 10:45 AM - 10/20/11 10:50 AM	None	None
1454	10/20/11 10:50 AM - 10/20/11 10:55 AM	None	None
1455	10/20/11 10:55 AM - 10/20/11 11:00 AM	None	None

Rate Drop Response Episodes. See page 5-20.



Atrial Arrhythmia Trend. See page 5-22.



Ventricular Rate During Atrial Arrhythmias. See page 5-24.



Capture Management Trend. See page 5-25.



Sensitivity Trend. See page 5-27.



Lead Impedance. See page 5-29.

Figure 5-2. Viewing the collected data

Viewing tools

Some data displays allow you to “zoom in” on a selected segment of the plotted data to show more detailed information.

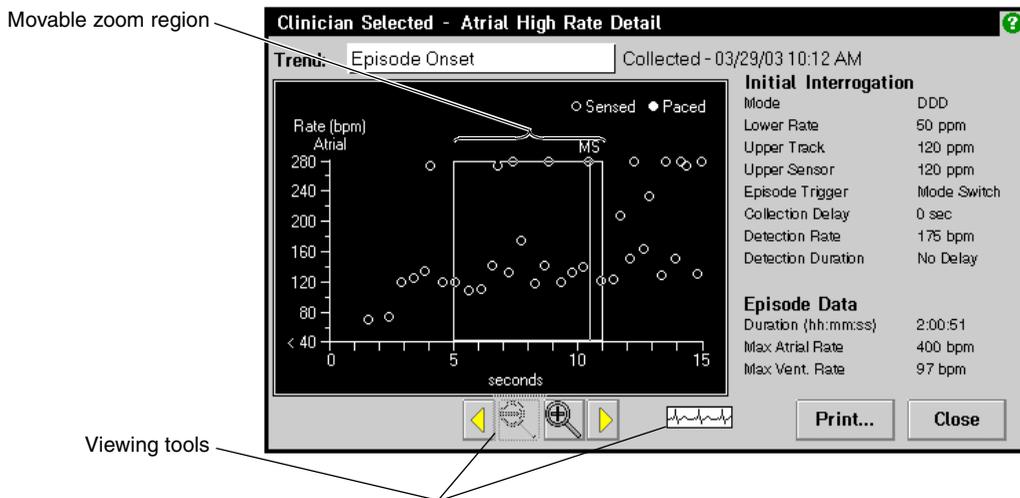


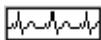
Figure 5-3. Viewing tools



Use these buttons to position the zoom region over the data that you want to see in more detail. These buttons also scroll the data if there is more data than can be displayed at one time.



Select the Zoom In (+) icon to display details of the zoom region. Select the Zoom Out (-) icon to return to the full data display screen. For some data displays, the details of the zoom region are in the form of a recorded strip of event markers. On some screens, selecting the Zoom In (+) icon has the same effect as selecting the Strip icon (see below).



If applicable, select the Strip icon to display the collected EGM or strip of event markers.

The automatically collected data displays

Automatic data collection

- Patient's Heart Rate (histogram and data format)
- Patient's AV Conduction Status (histogram and data format)
- Search AV+ Histogram (histogram and data format)
- Sensor Indicated Rate Profile
- High Rate Episodes
- Rate Drop Response Episodes
- Atrial Arrhythmia Trend
- Atrial Arrhythmia Durations (printed only, Initial Interrogation Report)
- Ventricular Rate During Atrial Arrhythmias (histogram and data format)
- Capture Management Trends
- Sensitivity Trends
- Lead Impedance (Chronic Trends and Impedance Data)
- Key Parameter History

Heart Rate Histograms

Description

The Heart Rate Histogram shows at a glance the range of the patient's heart rate (to a resolution of 10 min^{-1}) recorded since the last patient session and how the number of heart beats counted during this period are distributed over that rate range. This histogram is intended as an aid for evaluating rate response parameter settings and chronotropic incompetence.

Collecting diagnostic data
The automatically collected data displays

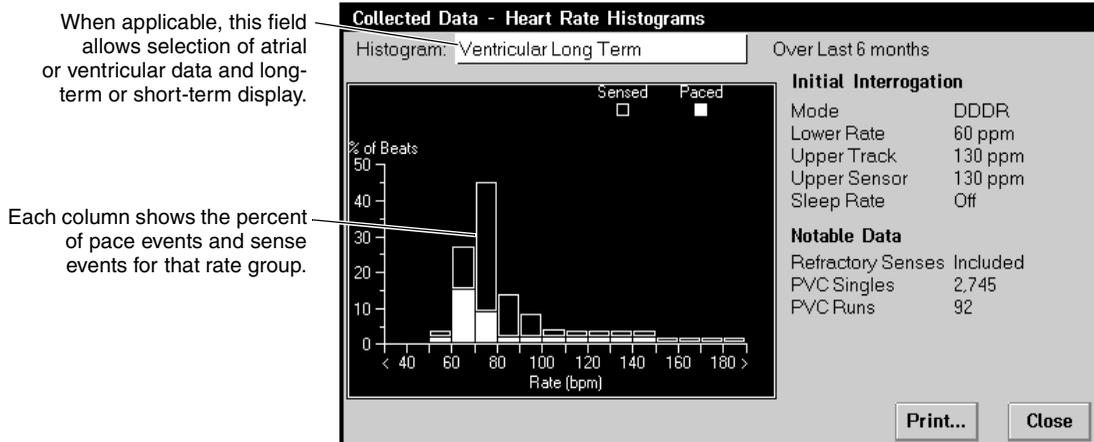


Figure 5-4. Ventricular Heart Rate Histogram

Data collection and presentation

The Heart Rate Histograms can be displayed for two intervals of data collection:

- Short-term heart rate histograms represent data collected over the last 3 to 6 days.
- Long-term heart rate histograms represent data collected since the last follow-up.

Heart Rate Histograms indicate the percentage of rate events counted during the monitoring period that fall into 10 min⁻¹ segment in the range from 40 min⁻¹ to 180 min⁻¹ (the “< 40” min⁻¹ group also includes events occurring below 40 min⁻¹; the “180 >” min⁻¹ group also includes events occurring above 180 min⁻¹). Each 10 min⁻¹ event group is coded to show the percentage of paced events and the percentage of sensed events. See Figure 5-4 and Figure 5-5.

Both atrial and ventricular histograms display the pertinent programmed parameter settings. Ventricular histograms also display the recorded number of single PVCs and PVC runs. Atrial histograms display the number of PAC runs.

Atrial and ventricular histograms

If data were collected during device operation in a dual chamber mode (including ADIR, ADI, VDIR, VDI, and VDD modes), both atrial and ventricular histograms can be viewed by selecting the Histogram field at the top of the display (Figure 5-5).

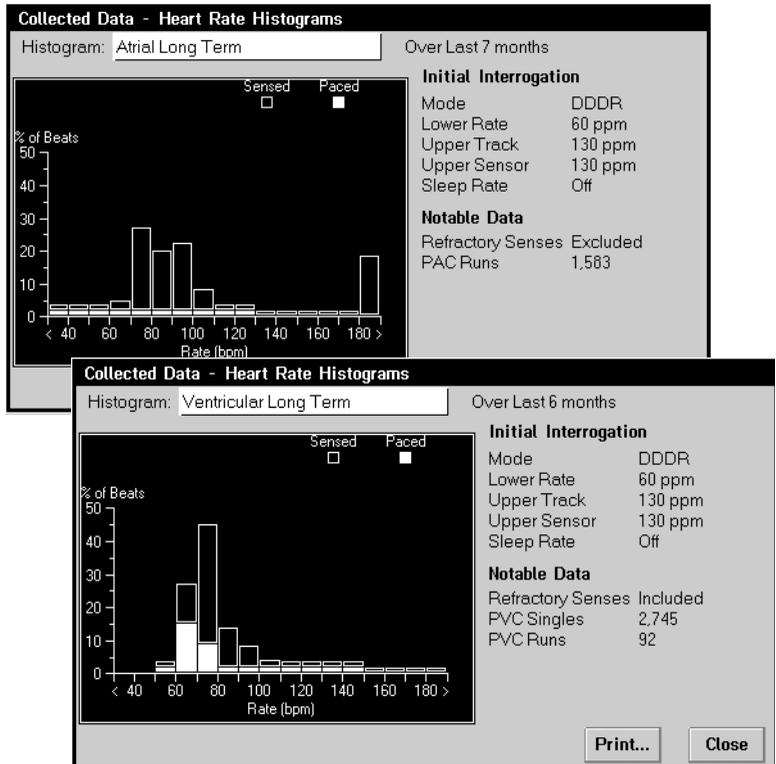


Figure 5-5. Atrial and ventricular Heart Rate Histograms

Setup options

Data collection can be set to include or exclude refractory senses (events sensed during the refractory period). See “Programming data collection options” on page 5-45.

Refer to the *EnPulse Pacemaker Reference Guide* for additional information about collecting Atrial and Ventricular Rate Histogram data.

AV Conduction Histograms

Description

Like the Rate Histogram, the AV Conduction Histogram indicates the percentage of the total number of heart beats counted since the last patient session occurred in each of the displayed 10 min⁻¹ rate groups. The AV Conduction Histogram is available only if a dual chamber mode (including ADIR, ADI, VDIR, VDI, and VDD modes) has been programmed.

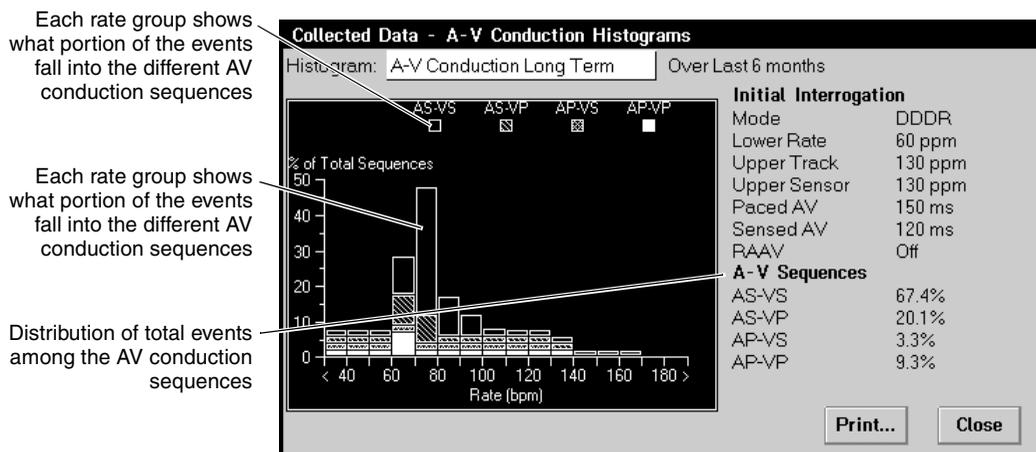


Figure 5-6. AV Conduction Histogram

AV conduction sequence categories

Each 10 min⁻¹rate group is coded to show the portion of the events in that group that fall into the different AV conduction sequence categories. The AV conduction sequence categories are as follows:

- AS - VS** Atrial Sense - Ventricular Sense
- AS - VP** Atrial Sense - Ventricular Pace^a
- AP - VS** Atrial Pace - Ventricular Sense^b
- AP - VP** Atrial Pace - Ventricular Pace^{a, b}

^a Sequences AS-VP and AP-VP do not apply to the ADIR and ADI modes.

^b Sequences AP-VS and AP-VP do not apply to the VDD, VDI, and VDIR modes.

A rate group on the histogram that represents less than 5 percent of the counted events may be coded to the AV sequence with the highest percentage of events.

Short-term AV conduction histograms represent data collected over the last 3 to 6 days.

Long-term AV conduction histograms represent data collected since the last follow-up.

Refer to the *EnPulse Pacemaker Reference Guide* for additional information about collecting AV Conduction Histogram data.

Search AV+ Histogram

The Search AV+ Histogram data is automatically collected when Search AV+ is programmed On. A Search AV+ Histogram shows the percentage of the following intervals versus rate in every rate range:

- A-VS: AV sequences ending in a ventricular sense within the programmed paced AV or sensed AV interval.
- VS from Search: AV sequences ending in a ventricular sense due to the extension of the AV interval by Search AV+.
- A-VP: AV sequences ending in a ventricular pace.

Search AV+ Histogram data can be displayed from the Graphs and Tables screen.

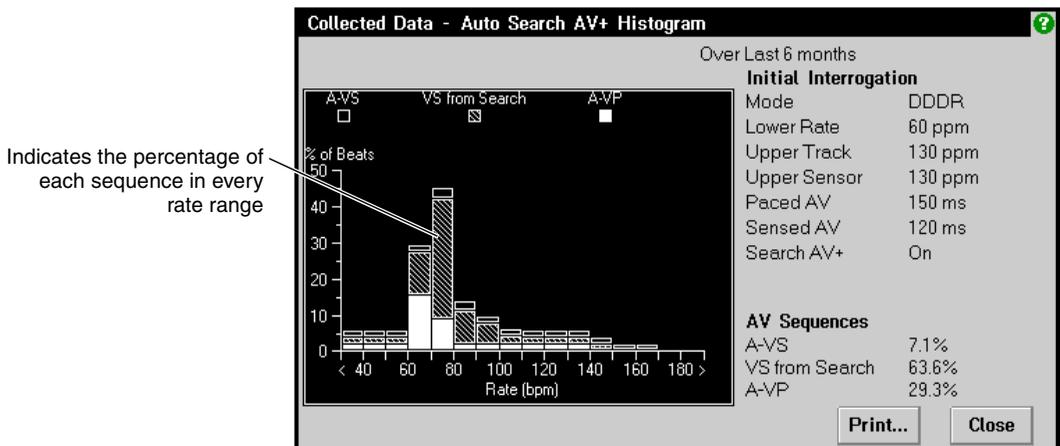


Figure 5-7. Search AV+ Histogram

Collecting diagnostic data
The automatically collected data displays

Refer to the *EnPulse Pacemaker Reference Guide* for additional information about collecting Search AV+ Histogram data.

Sensor Indicated Rate Profile

Sensor Indicated Rate Profile records the rate that is derived from activity sensor operation. Because this diagnostic shows the measured sensor rate profile, it aids in evaluating the Rate Profile Optimization feature.

Rates are recorded in 10 min⁻¹ ranges from 40 min⁻¹ to 180 min⁻¹. Rates outside this range are recorded in two additional ranges. Rates below 40 min⁻¹ are counted in the lowest range. Rates above 180 min⁻¹ are counted in the highest range.

The Sensor Indicated Rate Profile can be accessed from the Graphs and Tables screen.

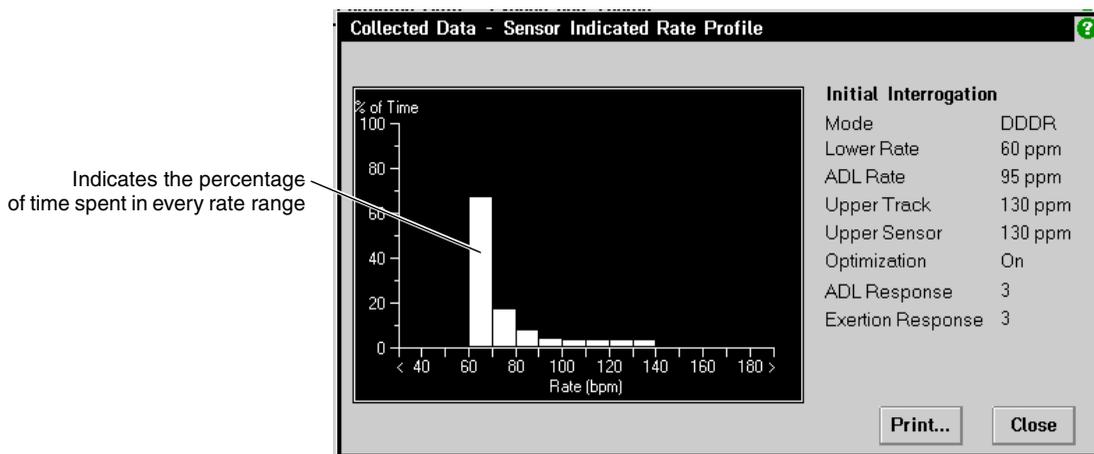


Figure 5-8. Sensor Indicated Rate Profile screen

Note: Sensor Indicated Rate Profile data is cleared only when programming certain rate response parameters or another rate responsive mode.

Refer to the *EnPulse Pacemaker Reference Guide* for additional information about collecting Sensor Indicated Rate Profile data.

High Rate Episodes

High Rate Episodes data include the date and time, the maximum rate in both chambers, the average ventricular rate, and the duration of episodes. On printed reports, the High Rate Episodes data will also include the sensor rate at the time the episode was detected.

The programmed Collection Method determines whether episode data are updated or data stops when the limit is reached. The options are listed below:

- Rolling: Data for the first, fastest, longest, and the most recent 13 episodes are collected until the pacemaker is interrogated.
- Frozen: Data are collected for the first 16 episodes that occur after the device is programmed. Data collection stops after 16 episodes; however, the Episodes Detected count continues.

Episodes are defined by the programmed collected data setup options. See Table 5-4 on page 5-46 for more information about programming setup options.

The maximum number of high rate episodes the pacemaker will count is 16,777,215 for atrial episodes and the same count for ventricular episodes. Once a limit is reached, the count is frozen.

High Rate Episodes data (shown in Figure 5-9) can be accessed from the Graphs and Tables screen. This screen has check boxes that allow you to view atrial data, ventricular data, or both types.

If Mode Switch is programmed on, the atrial data collected will be based on Mode Switch episodes. If Mode Switch is programmed off, the atrial data collected will be based on independent Atrial High Rate detection criteria.

Collecting diagnostic data
 The automatically collected data displays

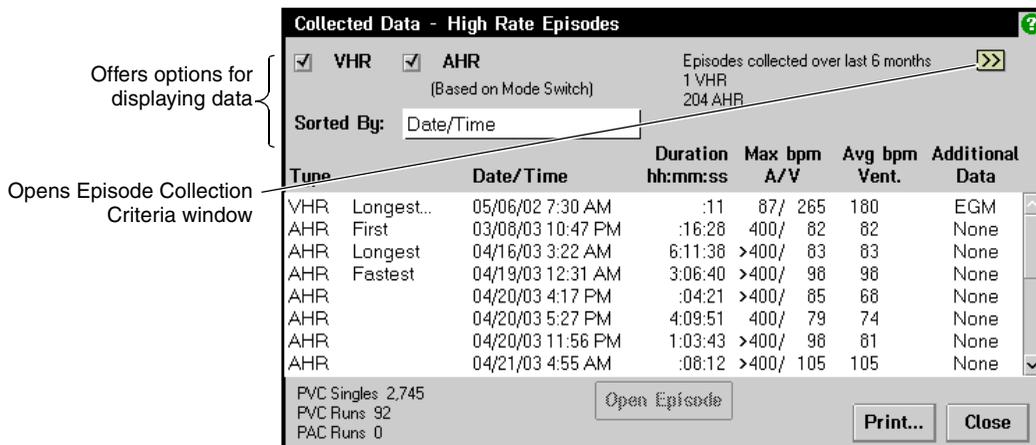


Figure 5-9. High Rate Episodes screen

Figure 5-9 lists only automatic High Rate Episodes. When the clinician-selected data is High Rate Detail, the screen lists those episodes also, indicated as having EGM and/or Trend data (see Figure 5-28 on page 5-40). To view the additional data, select the episode and then select the **[Open Episode]** button.

Note: When Mode Switch is programmed On, the diagnostic parameter Collection Delay sets up a minimum length that mode switching episodes must satisfy to be included in High Rate data collection. (Collection Delay does not affect Mode Switch therapy, but it allows the user to filter out short episodes from the high rate episode collection.)

If you select the QuickLink [**>>**] button, a second window opens that lists the criteria for collection of atrial and ventricular episodes (see Figure 5-10).

Collecting diagnostic data
The automatically collected data displays

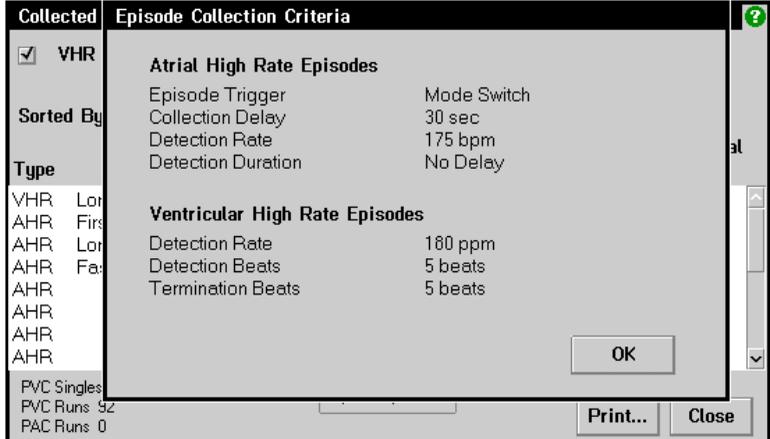


Figure 5-10. Collection Criteria for High Rate Episodes

Refer to the *EnPulse Pacemaker Reference Guide* for additional information about collecting High Rate Episodes data.

Clinician-selected data collection option

High Rate Detail is an optional clinician-selected diagnostic. For more information, see page 5-37.

Collecting diagnostic data

The automatically collected data displays

Rate Drop Response Episodes

Rate Drop Response Episodes records the operation of the Rate Drop Response function (no data will be collected if Rate Drop Response function is Off). Depending on the programmed settings for Rate Drop Response, it will record the number of Low Rate Episodes, Rate Drop Episodes, or both. Low Rate and Rate Drop Episodes are defined as follows:

- *Low Rate Episode:* When a programmed number of lower rate paced events occurs with no intervening non-refractory sensed events.
- *Rate Drop Episode:* Defined by programmed values for Drop Rate and Drop Size.
 - Drop Rate: Intrinsic ventricular rate must decrease to, or falls below, this rate.
 - Drop Size: Number of beats per minute the ventricular intrinsic rate must decrease within the detection window time.
 - Detection Window: Maximum allowable time for the rate drop criteria to be met.

If more than 255 Rate Drop Response episodes occur, the Rate Drop Response count stops recording.

The date/time, type, and intrinsic detection rate of the initial and the nine most recent episodes can be accessed from the Graphs and Tables screen (Figure 5-11).

To view the Additional Data, select the episode, and then select the **[Open Episode]** button. Trend data is collected only when the clinician-selected data is Rate Drop Response Detail.

Collecting diagnostic data
The automatically collected data displays

Lists the options for displaying data

Displays the selected detailed data listed in the Additional Data column

Date/Time	Type	Rate (bpm)	Additional Data
03/20/03 7:54 AM	Rate	58	Trend
03/20/03 6:00 AM	Rate	58	Trend

Figure 5-11. Rate Drop Response Episodes screen

Refer to the *EnPulse Pacemaker Reference Guide* for additional information about collecting Rate Drop Response Episodes data.

Clinician-selected data collection option

Rate Drop Response Detail is an optional clinician-selected diagnostic. For more information, see page 5-41.

Atrial Arrhythmia Trend

Description

The Atrial Arrhythmia Trend shows a log of how much time each day that the patient spends in atrial arrhythmias. Collected over a period of weeks or months, this information indicates when there is an upward or downward trend in this type of cardiac activity.

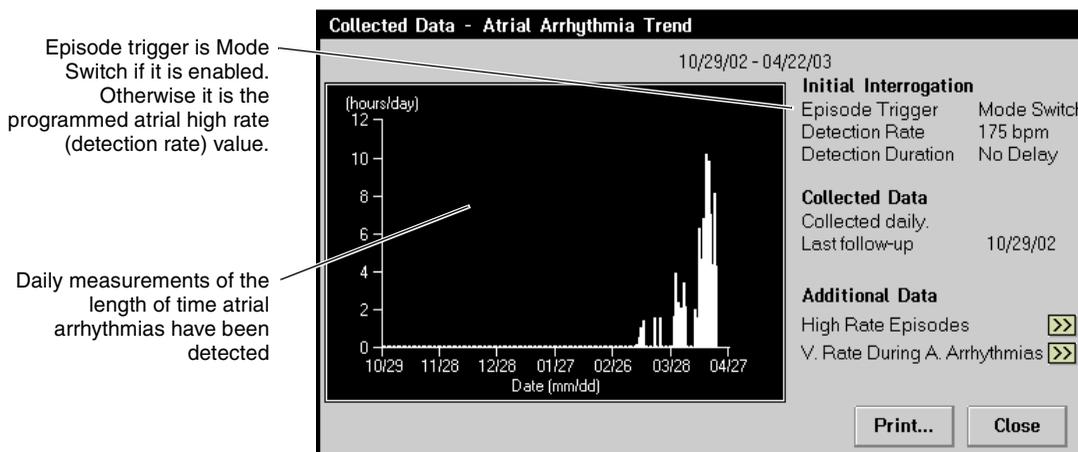


Figure 5-12. Atrial Arrhythmia Trend

Data collection and presentation

This display is a graph of daily measurements of the length of time that the implanted device detects atrial arrhythmias. Included with the trend display is the time period covered by the accumulated data, the pertinent programmed parameter settings, and the date of the last patient follow-up session.

The Atrial Arrhythmia Trend can show up to six months of collected data, and it is a rolling trend that updates continuously. An option allows you to clear the accumulated data if desired (see “Clearing data from the pacemaker” on page 5-47).

If you select the QuickLink [$>>$] button next to High Rate Episodes, the diagnostic window opens. See page 5-37 for more details.

If you select the QuickLink [$>>$] button next to V. Rate During A. Arrhythmias, the diagnostic window opens. See page 5-24 for more details.

Atrial Arrhythmia Durations

This diagnostic data appears only in the Initial Interrogation Report under Arrhythmia Summary. Each atrial arrhythmia episode is counted under one of these eight ranges of episode duration:

- ≥ 72 hr
- 24 hr to <72 hr
- 12 hr to <24 hr
- 4 hr to <12 hr
- 1 hr to <4 hr
- 10 min to <1 hr
- 1 min to <10 min
- <1 min

Ventricular Rate During Atrial Arrhythmias

Description

This histogram shows a profile of ventricular rate recorded during the atrial arrhythmias that have been recorded since the last patient session. This information can show how well ventricular rate is being controlled during atrial arrhythmias.

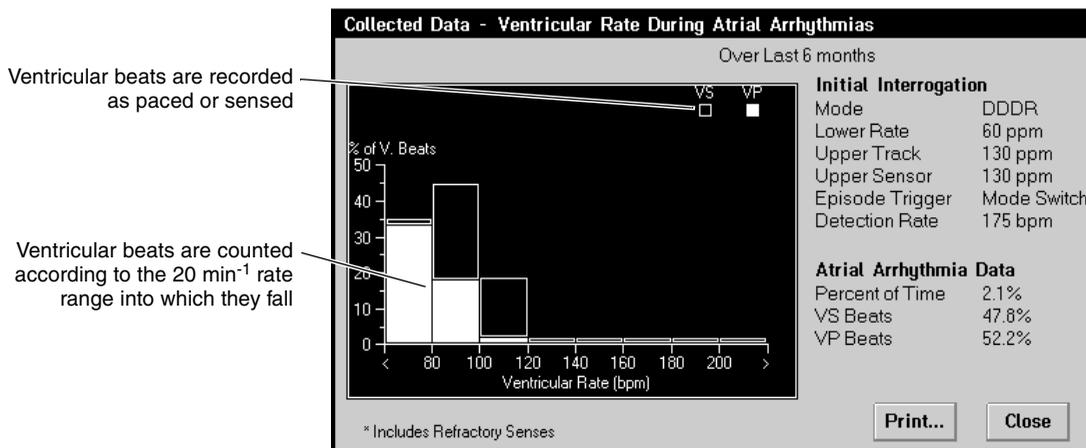


Figure 5-13. Ventricular Rate Histogram During Atrial Arrhythmias

Data collection and presentation

During each atrial arrhythmia, the implanted device collects ventricular rate data in addition to atrial data. This histogram shows the percentage of the total number of ventricular beats counted during these arrhythmias that falls into each of eight 20 min⁻¹ rate groups in the measured rate range. The beats within each rate group are coded to show the proportion of paced and sensed beats.

Information included with the histogram lists the pertinent programmed parameter settings and summary information about the recorded atrial arrhythmias during which the ventricular rate information was recorded.

Setup options

Data collection can be set to include or exclude refractory senses (events sensed during the refractory period). See “Programming data collection options” on page 5-45.

Capture Management Trend

Capture Management Trend data are collected automatically when Capture Management is programmed On. This trend records pacing threshold history for the most recent 14 months. When VCM and ACM are enabled, the pacemaker collects the following data every 7 days:

- Maximum Threshold
- Average Threshold
- Max Adapted Amplitude
- Capture Management Setting (Adaptive or Monitor Only)

When Capture Management Trend is selected from the link on the Quick Look II screen or from the Graphs and Tables screen, the Capture Management Trend window opens (see Figure 5-14).

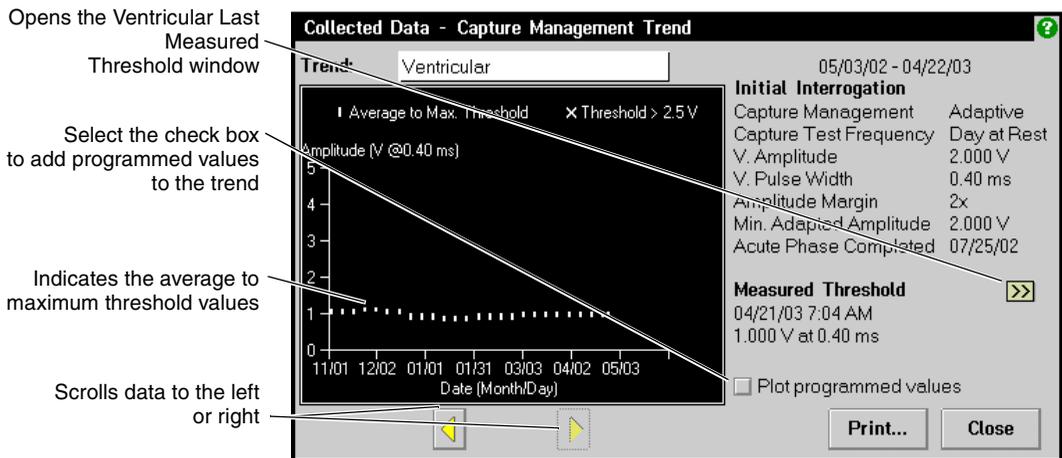


Figure 5-14. Ventricular Capture Management Trend

If you select the QuickLink [$>>$] button, the Last Measured Threshold window opens (see Figure 5-16). It presents the results of the most recent ambulatory ventricular pacing threshold search. This includes the measured strength duration curve and the curve corresponding to a 2X Amplitude Margin.

Note: The QuickLink [$>>$] button is not available when viewing the Atrial Capture Management Trend window.

Collecting diagnostic data
 The automatically collected data displays

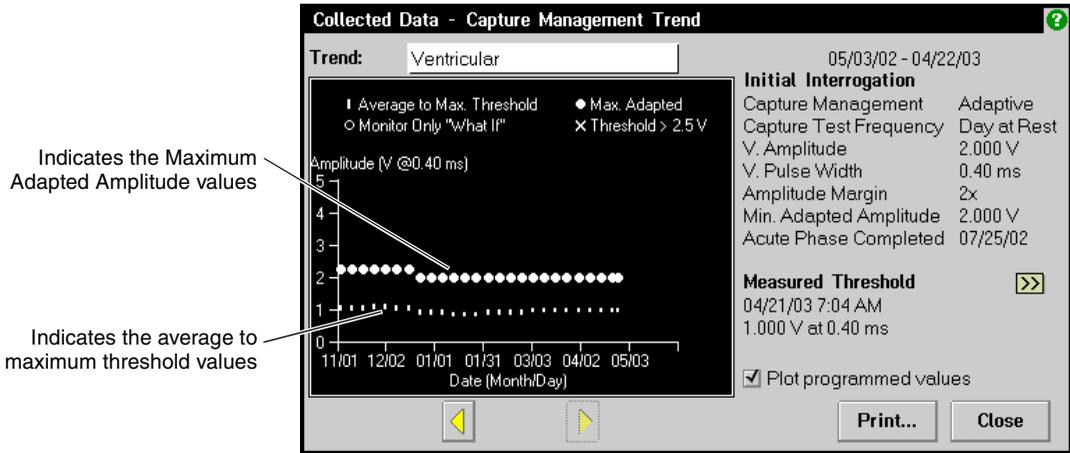


Figure 5-15. Same trend showing programmed values

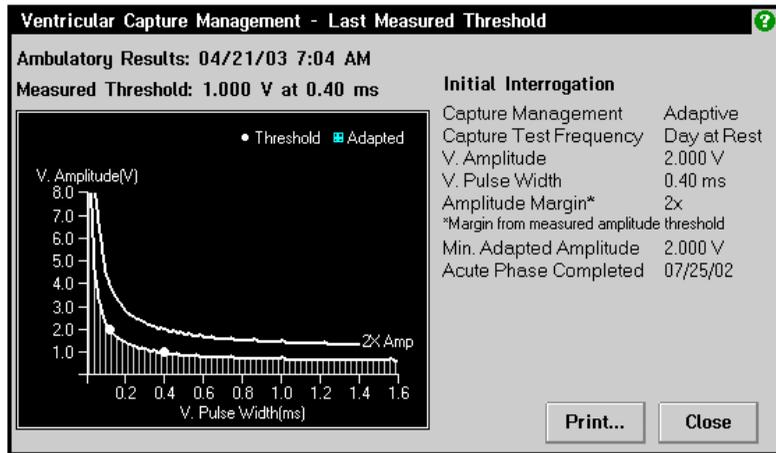


Figure 5-16. Last Measured Threshold window

Refer to the *EnPulse Pacemaker Reference Guide* for additional information about collecting Capture Management Trend data.

Clinician-selected data collection option

Atrial and Ventricular Capture Management Detail are optional clinician-selected diagnostics. For more information, see page 5-35.

Sensitivity Trend

Sensitivity Trend data is collected automatically when Sensing Assurance is programmed On. The pacemaker records the following information for both chambers every seven days:

- Minimum Sensitivity
- Maximum Sensitivity
- Whether sensitivity adjustments reached the lower limit (most sensitive)

Sensitivity Trend data can be displayed from the Graphs and Tables screen.

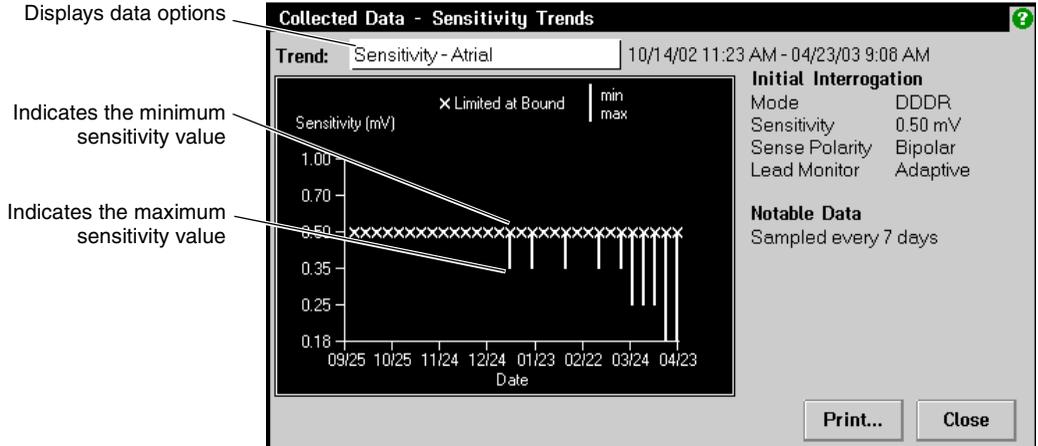


Figure 5-17. Sensitivity Trend

By changing the Trend: setting, you can view a P-Wave Amplitude Trend or an R-Wave Amplitude Trend (see Figure 5-18).

Collecting diagnostic data
The automatically collected data displays

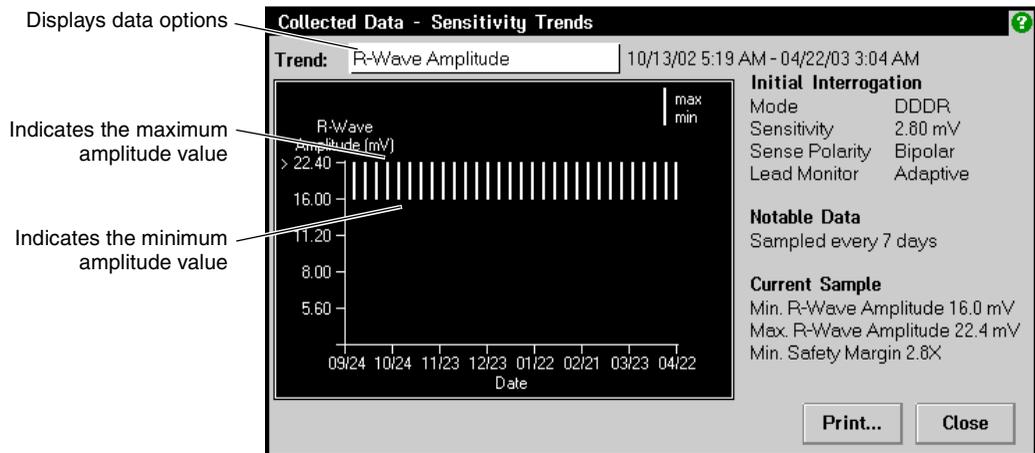


Figure 5-18. R-Wave Amplitude Trend

Refer to the *EnPulse Pacemaker Reference Guide* for additional information about collecting Sensitivity Trend data.

Lead Impedance

Selecting Lead Impedance on the Graphs and Tables screen displays lead impedance trend and polarity switch data that is automatically collected for the last 14 months. Data includes high impedance paces and low impedance paces from the Lead Monitor function.

Measurements are taken every three hours in each chamber that is being paced. The maximum, minimum, and average lead impedance are recorded every seven days. For each paced chamber, two display options can be selected:

- Chronic Lead Impedance Trend (see Figure 5-19).
- Lead Impedance Data (Figure 5-20).

The lead impedance may be programmed On or Off via the data collection set up screen.

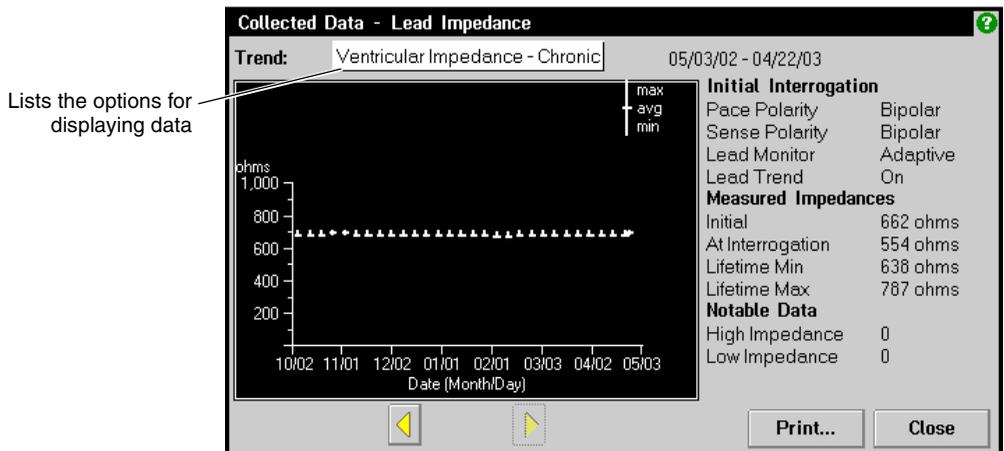


Figure 5-19. Chronic Lead Impedance Trend screen

Collecting diagnostic data
Clinician-selected detailed data displays

Lists the options for displaying data

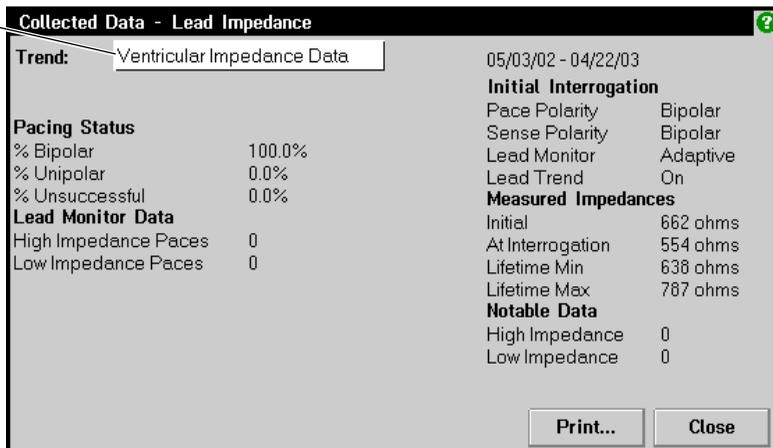


Figure 5-20. Lead Impedance Data screen

Refer to the *EnPulse Pacemaker Reference Guide* for additional information about collecting lead impedance data.

Clinician-selected detailed data displays

Only one type of clinician-selected data can be programmed On at one time. The options for clinician-selected data that are accessed from the Data Collection - Setup screen are listed:

- Custom Rate Trend
- Atrial Capture Management Detail
- Ventricular Capture Management Detail
- High Rate Detail
- Rate Drop Response Detail
- Remote Assistant

Note: Refer to Table 5-1 (page 5-4) for information about which clinician-selected diagnostics are available for each series of pacemakers.

Custom Rate Trend (rate versus time)

The pacemaker can be set to record the patient's heart rate for a beat-to-beat, 1-hour, or 24-hour monitoring period, depending on the programmed "duration."

- *Beat-to-Beat duration:* Records beat-to-beat data for several minutes depending on the mode, rate, and number of refractory events. Shows the maximum, mean, and minimum rates.
- *1-hour duration:* The pacemaker records the patient's heart rate every 2 seconds and accumulates one hour of data.
- *24-hour duration:* The pacemaker measures heart rate every 60 seconds.

About displaying Custom Rate Trends

Custom Rate Trends can be displayed from the Graphs and Tables screen. If data was collected during dual chamber pacing (including ADIR, ADI, VDIR, VDI, VDD, and ODO modes), atrial and ventricular graphs are recorded.

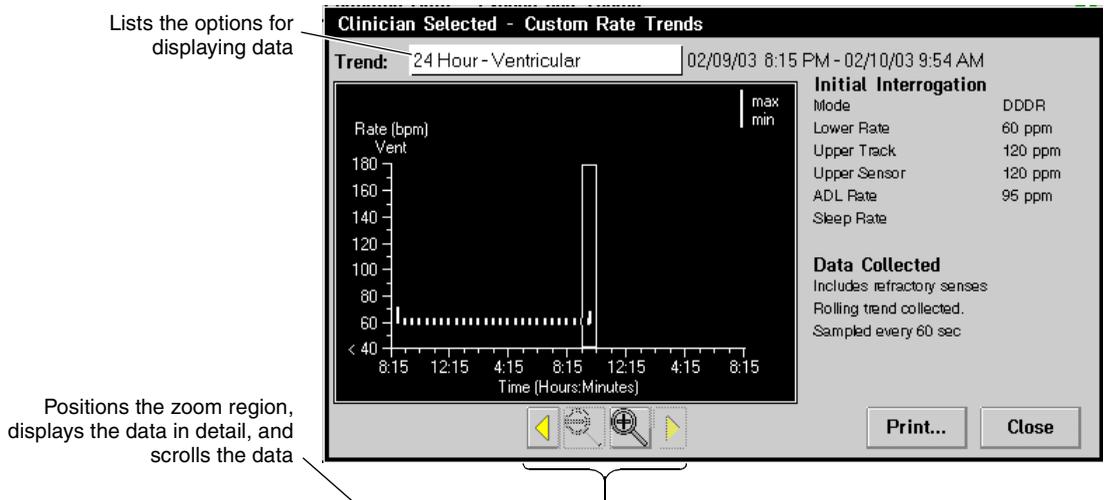


Figure 5-21. Example of a 24-hour rate vs. time display

Collecting diagnostic data
Clinician-selected detailed data displays

About Zoom-In

Zoom-In lets you view a segment of the Rate vs. Time graph in more detail. If the duration of recorded data is less than the zoom region, the zoom-in feature automatically is in effect when the data is displayed.

On the detailed display that shows a segment of the Rate vs. Time graph, the data samples are coded to indicate the percentage of the beats in each sample that are paced. In the Figure 5-22, the zoom-in feature was applied to the 24-hour Rate vs. Time data shown in Figure 5-21.

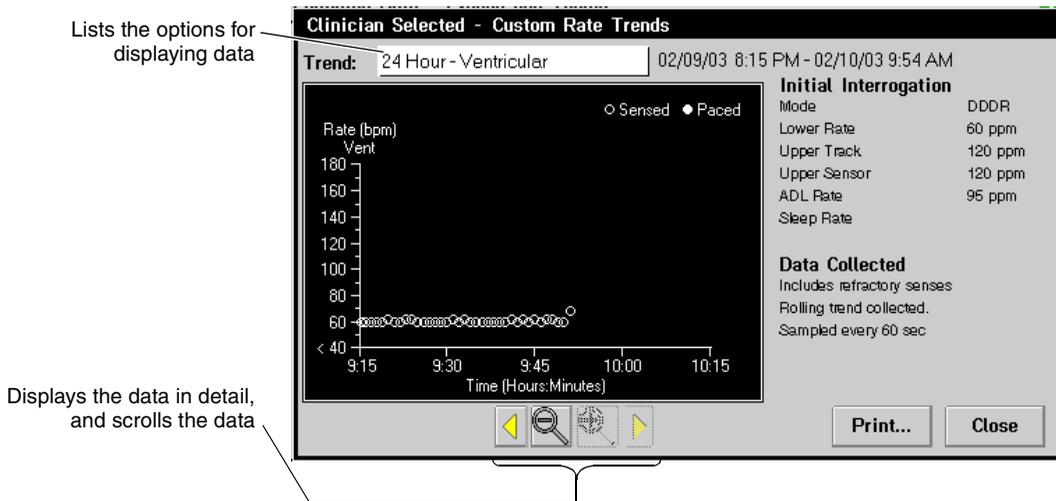


Figure 5-22. Example of detail (zoom) view of data

Refer to the *EnPulse Pacemaker Reference Guide* for additional information about collecting Custom Rate Trend data.

About Custom Rate Trend parameters

Choosing Rate Trend clinician-selected data involves programming the parameters shown in Table 5-2.

Table 5-2. *Clinician selected Rate Trend diagnostic parameters*

Parameter	Definition	Settings
Duration	This parameter programs the duration of data collection to beat-to-beat, 1 hour, or 24 hours.	Beat-to-Beat, 1 hr, 24 hr
Collection Method	“Rolling” programs the pacemaker to record continuously, so that new data overwrites the old data once memory capacity is reached. “Frozen” programs the pacemaker to record data until its memory capacity is reached. Recording then stops, and the collected data is frozen.	Rolling, Frozen
Include Refractory Senses ?	(Refractory Sensed Events) Programs the pacemaker to include or exclude events sensed within the refractory period when it counts heart rate events.	Exclude, Include

Atrial Capture Management Detail

Atrial Capture Management Detail data provides a record of the pacing threshold amplitude at a pulse width of 0.40 ms. The pacemaker records the following information for the most recent 359 atrial pacing threshold searches:

- Date and Time
- Amplitude Threshold
- Amplitude Margin
- Adapted or Monitor Only Amplitude

Atrial Capture Management Detail data can be displayed from the Graphs and Tables screen.

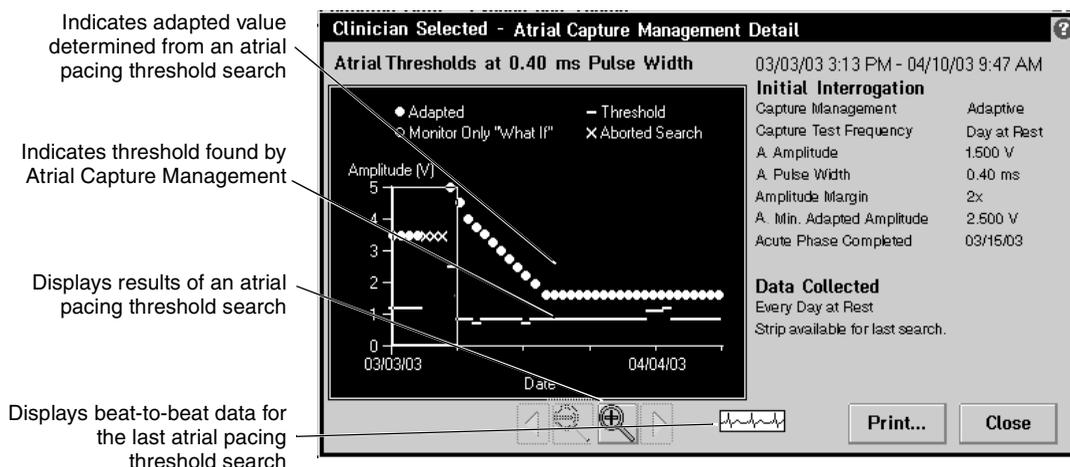


Figure 5-23. Atrial Capture Management Detail overview

A beat-to-beat trend for the most recent pacing threshold search is available. If you select the Strip icon, the trend shows the most recent 1000 events in the search.

The results of a pacing threshold search can be displayed by selecting the Zoom In icon. The pacing threshold search result can be selected from the list on the screen.

Clinicians have the option to record an EGM (atrial, ventricular, or summed EGM). No EGM is available if the last pacing threshold search was aborted.

Refer to the *EnPulse Pacemaker Reference Guide* for additional information about collecting Atrial Capture Management Detail data.

Ventricular Capture Management Detail

Ventricular Capture Management Detail data provide a record of the pacing threshold pulse width and amplitude. The pacemaker records the following information for the most recent 668 ventricular pacing threshold searches:

- Date and Time
- Amplitude Threshold
- Pulse Width Threshold
- Amplitude Margin
- Adapted or Monitor Only Amplitude

Ventricular Capture Management Detail data can be displayed from the Graphs and Tables screen.

Collecting diagnostic data
Clinician-selected detailed data displays

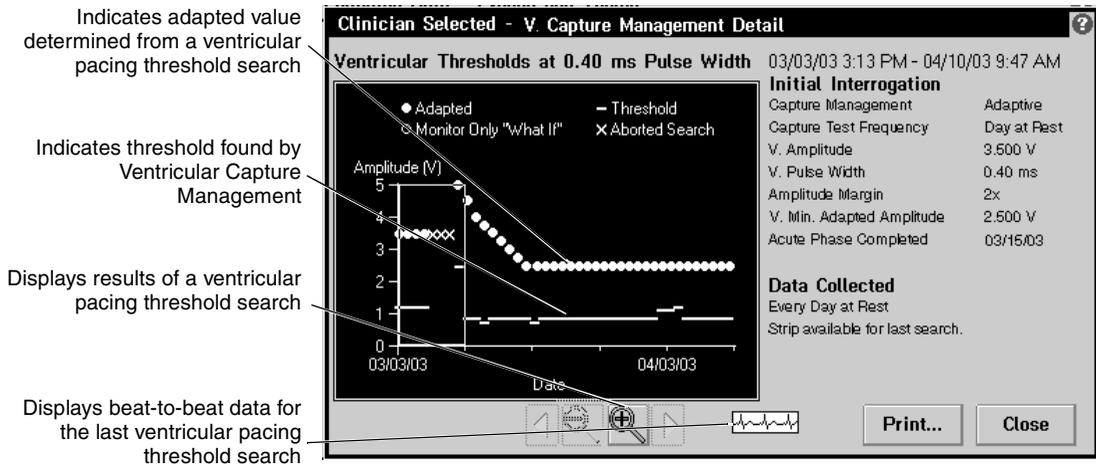


Figure 5-24. Ventricular Capture Management Detail overview

A beat-to-beat trend for the most recent pacing threshold search is available. If you select the Strip icon, the trend shows the most recent 1000 events in the search.

The results of a pacing threshold search can be displayed by selecting the Zoom In icon. The pacing threshold search result can be selected from the list on the screen.

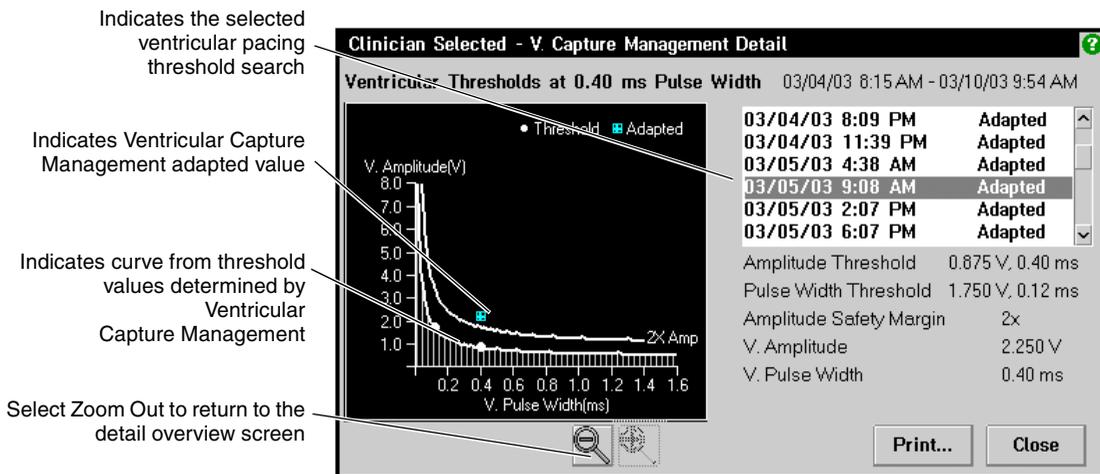


Figure 5-25. Ventricular Capture Management Detail search results

Clinicians have the option to record an EGM (atrial, ventricular, or summed EGM). No EGM is available if the last pacing threshold search aborted before finding the amplitude threshold.

Refer to the *EnPulse Pacemaker Reference Guide* for additional information about collecting Ventricular Capture Management Detail data.

High Rate Detail

The pacemaker collects a beat-to-beat trend at the onset and at the termination of selected episodes. Episode selection depends on the diagnostic parameters for automatic high rate episodes (see “High Rate Episodes” on page 5-17). The specific data collected for High Rate Detail is controlled by these diagnostic parameters:

- High Rate Type: AHR, VHR, or both
- EGM Type: AEGM, VEGM, Summed, or Off
- Allocation: how many episodes with EGM collection and how the EGM is aligned relative to the episode onset
- Pre-detection Timeout: the time limit in which pre-onset EGM can be collected

The total length of EGM collected is 48 seconds. As shown in Table 5-3, when Rolling data collection is used for pre-onset EGM, the total length of EGM collected ranges from 24 to 32 seconds.

Table 5-3. *Effect of allocation choices on EGM collection*

Alignment to onset	Number of episodes	Episode duration (seconds)	
		Rolling	Frozen
All pre-onset or	1	24	48
	2	16	24
Half pre-onset & Half post-onset	4	8	12
	8	4	6
All post-onset	1	48	48
	2	24	24
	4	12	12
	8	6	6

Collecting diagnostic data
Clinician-selected detailed data displays

Figure 5-26 and Figure 5-27 show two examples of the EGM Allocation window with the Collection Method set to Rolling. Each value in the window represents a number of episodes and the number of seconds of pre-onset and post-onset EGM to be collected for each episode. Each window offers choices corresponding to the episode durations in the Rolling column in Table 5-3.

Figure 5-26 shows the EGM Allocation window when High Rate Type is set to collect atrial data only.

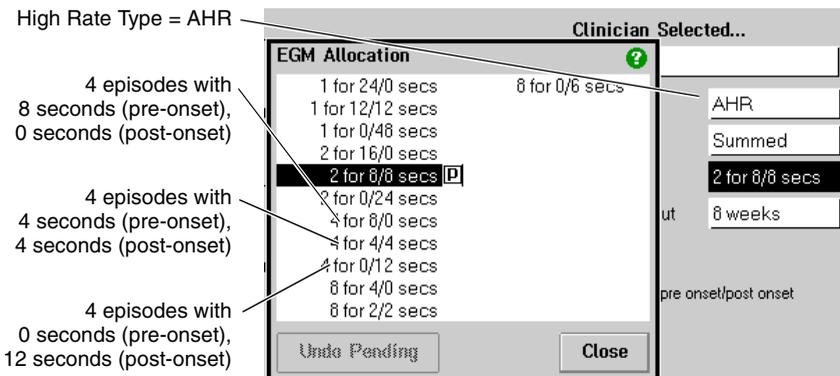


Figure 5-26. EGM Allocation window: atrial collection

Figure 5-27 shows the EGM Allocation window when High Rate Type is set to collect both atrial and ventricular data. In this table the number of episodes is split evenly between atrial episodes and ventricular episodes. For instance, if a “4 episode” value is selected, the pacemaker collects EGM for two AHR episodes and for two VHR episodes.

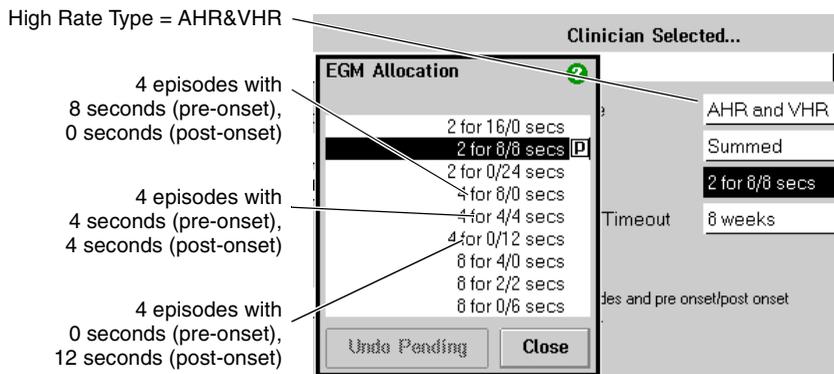


Figure 5-27. EGM Allocation window: atrial and ventricular collection

Trend data is collected whether or not EGM is collected. The number of episodes of trend data collected depends on Collection Method and High Rate Type:

- If High Rate Type is AHR or VHR, for Rolling collection, trend data is collected for the first episode and is updated for the most recent 13 episodes until the pacemaker is interrogated. For Frozen collection, trend data is collected for the first 16 episodes.
- If High Rate Type is AHR and VHR, Rolling trend data is collected for the most recent 8 AHR and 8 VHR episodes. Frozen trend data is collected for the first 8 AHR and 8 VHR episodes.

Note: If Rolling collection is programmed and several episodes of one type occur before episodes of the other type occur, EGM collection for the first type will use all allocated EGM storage until the other episode type occurs. For example, if an allocation of four EGM episodes is programmed and both AHR and VHR High Rate Types are selected, an occurrence of four consecutive VHR episodes results in EGM collection for all four VHR episodes. If any AHR episodes subsequently occur, EGM data for the first two AHR episodes replaces the EGM data of the oldest two VHR episodes. Thereafter, EGM data are allocated equally between the two triggers.

EGM can be collected with a programmable Pre-detection Timeout of 1 to 12 weeks, in 1-week increments, or of 14 to 24 weeks, in 2-week increments. If episodes occur before the programmable timeout, pre-onset and post-onset EGM can be collected. If episodes occur after the programmable timeout, only post-onset EGM can be collected.

◆ **To display a High Rate Detail screen**

1. Access the High Rate Episodes screen (Figure 5-28) from the Quick Look II screen or the Graphs and Tables screen.

Collecting diagnostic data
 Clinician-selected detailed data displays

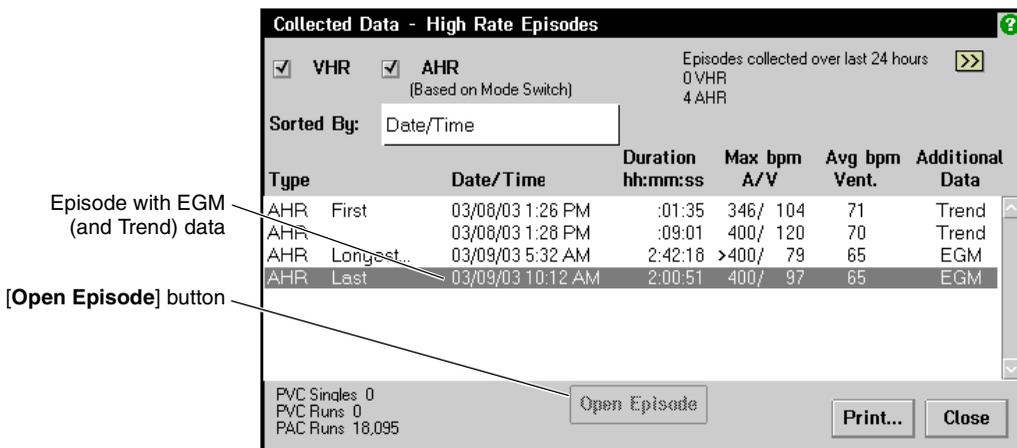


Figure 5-28. High Rate Episode screen

Note: Episodes with EGM data also have Trend data.

2. Select an episode with EGM and Trend data or an episode with Trend data only.
3. Select the **[Open Episode]** button. Figure 5-29 shows a High Rate Episode Detail screen for the selected episode in Figure 5-28.

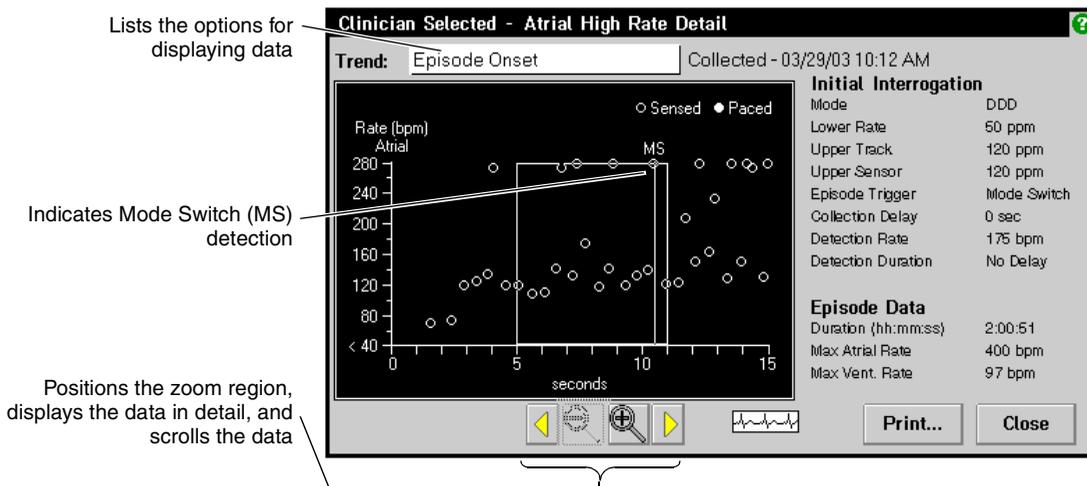


Figure 5-29. High Rate Detail episode

4. Select the Zoom In icon or the Strip icon from the Episode Onset screen to display episode onset data. Figure 5-30 shows the EGM data collected for the High Rate Episode in Figure 5-29.

Collecting diagnostic data
Clinician-selected detailed data displays

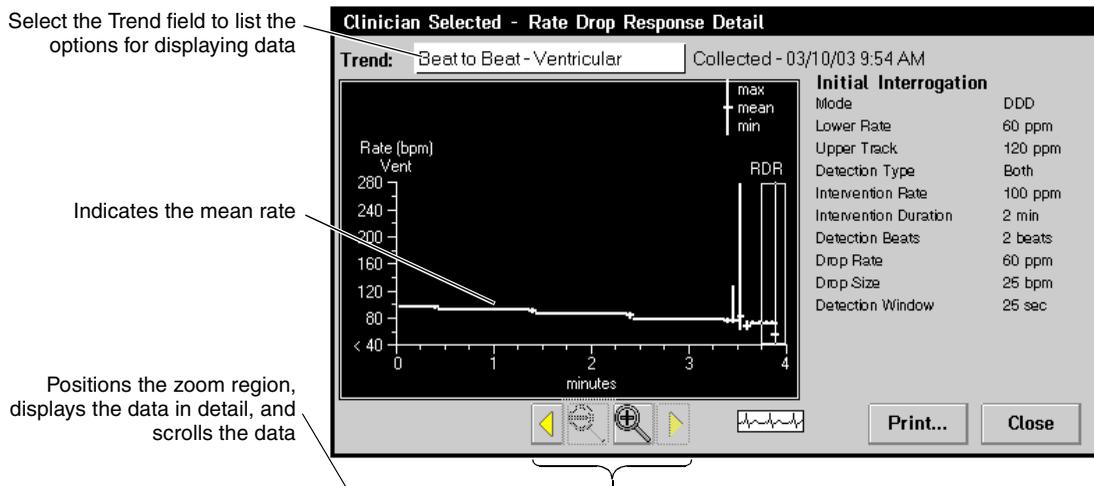


Figure 5-31. Rate Drop Response Detail episode

Refer to the *EnPulse Pacemaker Reference Guide* for additional information about collecting Rate Drop Response Detail data.

Remote Assistant

Programming the Remote Assistant diagnostic allows the patient to initiate a diagnostic data recording. Depending on the programmed Type option, the data recorded are cardiac events during an episode of perceived symptoms or of heart rate during a specific exercise activity.

Remote Assistant - Symptoms

Patients can record one episode when the Remote Assistant Symptoms is On by holding the Remote Assistant over the pacemaker and pressing the activation button. Only one episode can be recorded. Diagnostic parameters must be cleared before another episode can be recorded.

Episode information is collected as an approximate 4000 event beat-to-beat atrial or ventricular rate trend (3000 events predetection and 1000 events postdetection) and an EGM for events occurring approximately 16 seconds before activation.

An atrial, ventricular, or summed EGM may be collected. Rolling collection of EGM continues until an episode is recorded or a programmable EGM Timeout occurs.

About the Symptoms screens

Remote Assistant Symptoms screens may be displayed from the Graphs and Tables screen or from the Quick Look II screen.

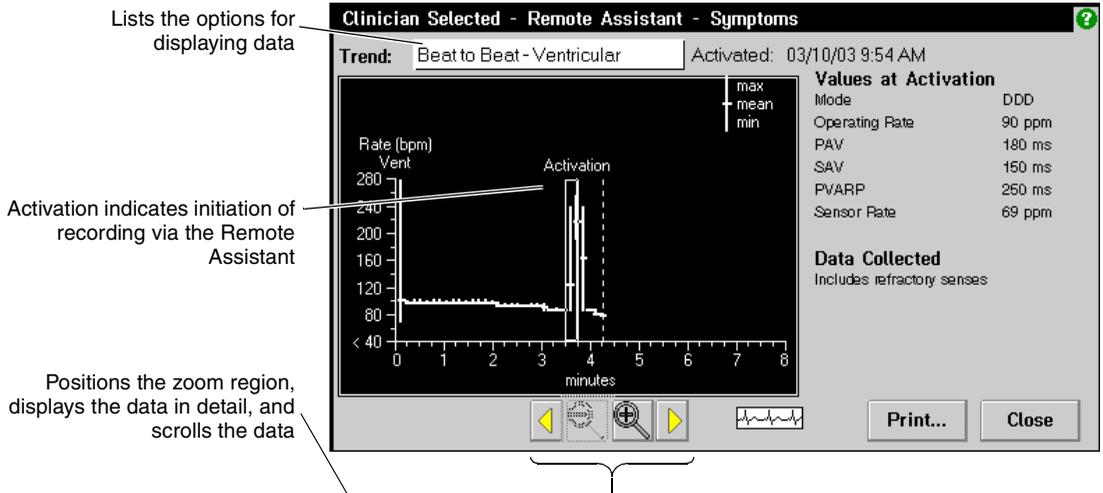


Figure 5-32. Remote Assistant Symptoms overview

Remote Assistant Confirmation Indicators

Green Light and 3 tones - Pacemaker is recording episode information.

Note: Selecting the Zoom In icon from the beat-to-beat screen displays an EGM collected before activation.

Remote Assistant – Exercise

When Remote Assistant is programmed to the Exercise option, the patient can activate a Remote Assistant recording any number of times, but only the last (most recent) recording is saved (only one heart rate trend can be recorded). The intent is to record heart rate data for a trend graph during a particular exercise activity.

Heart rate information is collected for approximately one hour. An EGM cannot be collected when Remote Assistant is programmed to Exercise.

About the Exercise screens

The Remote Assistant Exercise data may be selected for display from the Graphs and Tables screen or from the Quick Look II screen.

Select the “Clinician Selected” data type and then the **[Open Data]** button.

Collecting diagnostic data
 Clinician-selected detailed data displays

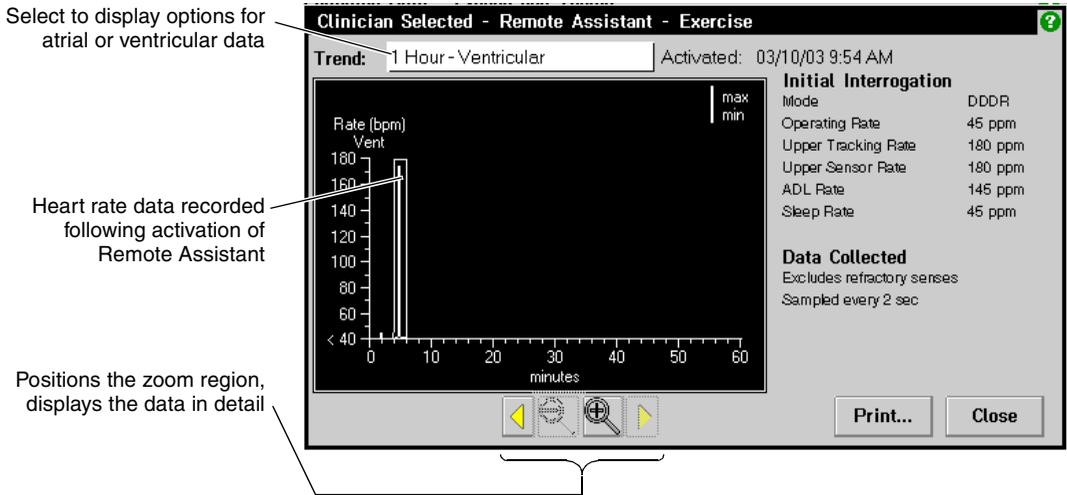


Figure 5-33. Remote Assistant Exercise overview screen

By positioning the zoom region rectangle over the desired interval of data and selecting the Zoom-In icon, you can view that data in detail.

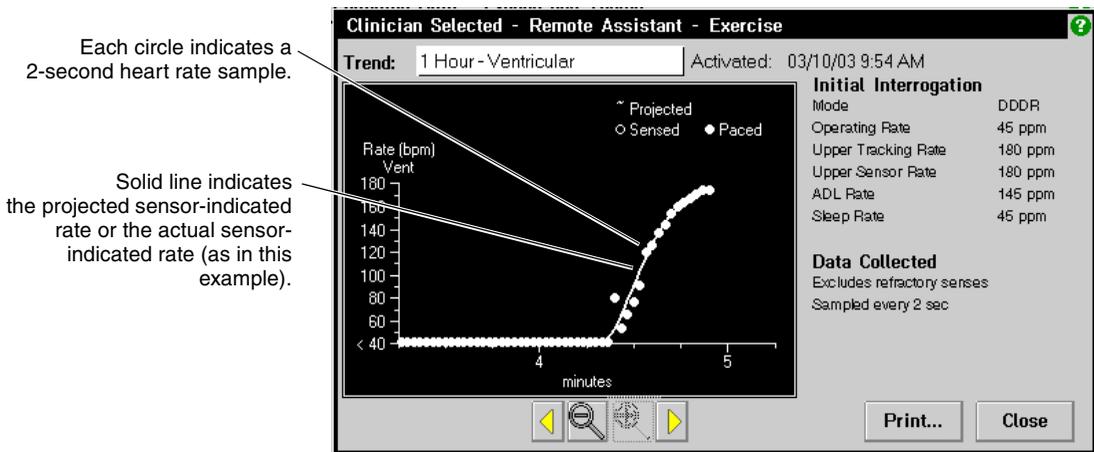


Figure 5-34. Exercise Trend detail view

Refer to the *EnPulse Pacemaker Reference Guide* for more information about the Remote Assistant diagnostic.

Programming data collection options

The Data Collection Setup screen displays the existing settings. To display this screen, select the Data icon, and then select Data Collection Setup/Clear from the menu.

Select the applicable field to display subordinate parameters or information about data collection.

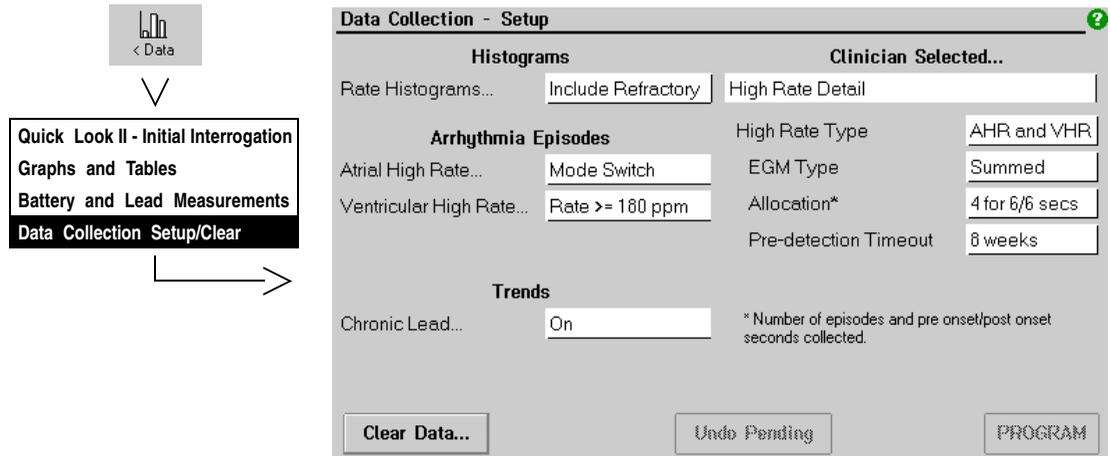


Figure 5-35. Programming data collection

Setup options for automatic data collection

Data is collected based on the programmed mode, parameter values, and setup options. Table 5-4 gives an overview of setup options necessary to collect certain types of data.

Table 5-4. *Data collection setup options*

Data type	Setup options	Parameters
Rate Histograms	Include or Exclude refractory sensed events from heart rate histograms.	Include Refractory Exclude Refractory
Atrial High Rate Episodes (Mode Switch Off)	Collect if: Atrial Rate \geq # ^a min ⁻¹ For more than # ^a seconds End Collection if: Atrial Rate $<$ # ^{a,b} min ⁻¹ for # ^a beats Frozen or Rolling Collection	Detection Rate Detection Duration Termination Rate (not programmable) Termination Beats Collection Method
Atrial High Rate Episodes (Mode Switch On)	Based on programmed Mode Switch therapy parameters (Mode Switch, Detect Rate, Detect Duration, and Blanked Flutter Search) Filter out short ModeSwitch episodes Frozen or Rolling Collection	Collection Delay after Mode Switch Collection Method
Ventricular High Rate Episodes	Collect if: Ventricular Rate \geq # ^a min ⁻¹ for # ^a beats End Collection if: Ventricular Rate $<$ # ^{a,b} min ⁻¹ for # ^a beats Filter out conducted SVT episodes Frozen or Rolling Collection	Ventricular Rate (for collection) for (X beats) Ventricular Rate (not programmable) for (Y beats) SVT Filter Collection Method
Clinician Selected	Select one of the following: Off Custom Rate Trend Atrial Capture Management Detail Ventricular Capture Management Detail High Rate Detail Rate Drop Response Detail Remote Assistant ^c	Duration, Collection Method, Refractory Senses (Include or Exclude) EGM Collection EGM Collection High Rate Type, EGM Type, Allocation, Predetection Timeout Refractory Senses (Include or Exclude) Type (Symptoms or Exercise), EGM Collection, EGM Timeout

^a # indicates a programmable parameter.

^b The Termination Rate has the same value as the programmable Detection Rate.

^c EGM collection is available only for Remote Assistant Symptoms.

Programming a clinician-selected data collection option

◆ *To program options for data collection*

1. Select **Data** > **Data Collection Setup/Clear**.
2. Verify the parameter settings.
3. (optional) Select the Clinician Selected... field and choose another option. Verify all of the parameter settings.
4. Select the **[Program]** button.

Clearing data from the pacemaker

Unless another setting is chosen, data is automatically cleared one hour after the end of the programming session. The End Session window provides access to options that let you make the following changes to the default settings:

- The following data are not automatically cleared, however, you can choose to have it cleared
 - Atrial Lead Trend (Lead Impedance and Pacing Threshold Trends)
 - Ventricular Lead Trend (Lead Impedance and Pacing Threshold Trends)
 - Atrial Arrhythmia Trend

Note: Chronic lead trend data typically should not be cleared unless the pacing lead has been replaced.

- You can choose to have data cleared immediately upon ending the session instead of the default setting of “1 hr after session end.”

Selecting the “Now” option causes the pacemaker to clear the collected data and start collection of new data immediately when you end the session. New data collection starts when you lift the programming head.

The Clear Data window (Figure 5-36) is accessed from the Data Collection Setup/Clear screen or the End Session window. Once the Clear Data window is open, the procedures and options for clearing data are identical. Refer to “Clearing pacemaker data” on page 3-41 for detailed information.

Collecting diagnostic data
Clearing data from the pacemaker

Chronic Ventricular Lead Trend data should be cleared only if the lead is replaced. Clearing Ventricular Chronic Lead data also clears automatic Ventricular Capture Management Trend data.

Note: Sensor Indicated Rate Profile data is cleared only when you program certain rate response parameters or another rate responsive mode.

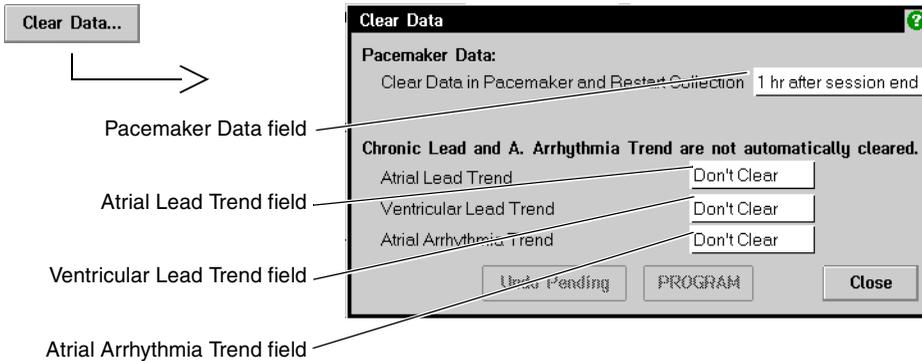


Figure 5-36. Clear Data window

Evaluating parameter settings

6

This chapter describes how to use the Test functions to determine appropriate settings for pulse amplitude (voltage), pulse width, and sensitivity.

The information also covers the Temporary test, which you can use to program certain parameters to temporary settings for test purposes.

Measuring stimulation thresholds 6-2

Determining a sensitivity setting 6-21

Using temporary programming to evaluate parameter settings 6-29

Measuring stimulation thresholds

The Threshold test function allows you to measure the patient’s stimulation thresholds to determine appropriate settings for amplitude and pulse width. To begin a threshold test, you must select the desired test type, heart chamber, and test parameter values from the Threshold Test Setup screen.

The Threshold Test setup screen

- ◆ **To display this screen**
- ▶ Select **Tests > Threshold**.

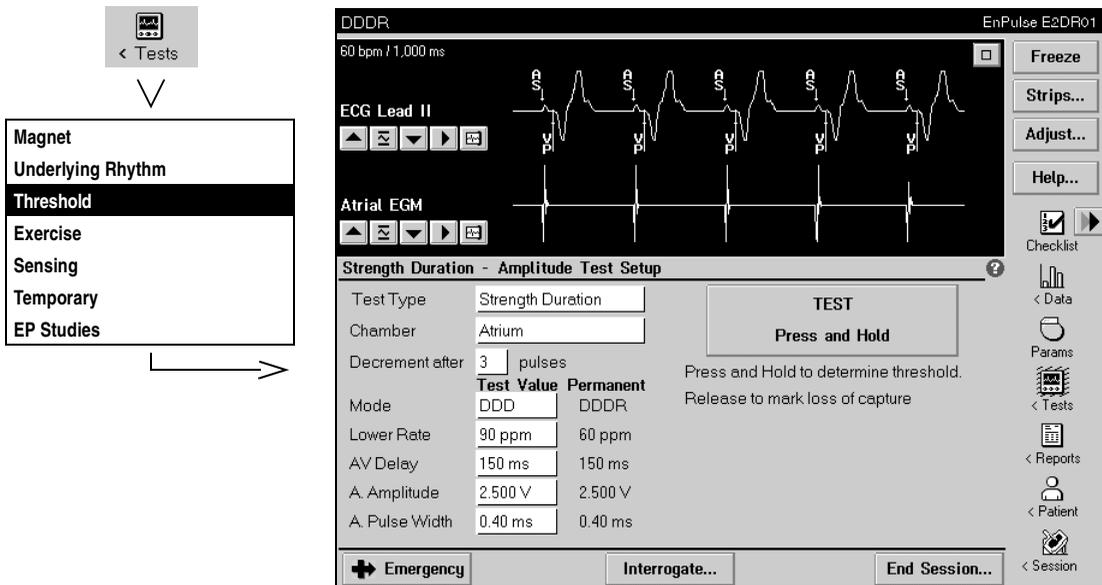


Figure 6-1. Threshold Test Setup screen

Note: During the execution of a threshold measurement, lifting the programming head from over the pacemaker for at least two seconds will return the pacemaker to its programmed state. This action should be taken in the event of a programmer malfunction, loss of power, or the absence of an appropriate command confirmation.

Setting up a threshold measurement test

Before you execute a threshold test, choose the test type and parameter options that will provide appropriate threshold information.

◆ **To set up a threshold test**

1. Display the Threshold Test Setup screen (see page 6-2).
2. Choose a setting for each of the three setup options (see the figure below). Note that not all setup options apply to every test and thus, are not displayed.

Select within the white field to display available settings

The screenshot shows a grey background with three white rectangular fields. The first field is labeled 'Test Type' and contains the text 'Strength Duration'. The second field is labeled 'Chamber' and contains the text 'Atrium'. The third field is labeled 'Decrement after' and contains the number '3' followed by the text 'pulses'. A white selection field is overlaid on the 'Strength Duration' option, and a line points from the text 'Select within the white field to display available settings' to this field.

3. Choose a test setting for each of the displayed parameters (see Table 6-1 on page 6-4).

Test Value	Permanent
DDD	DDDR
90 ppm	60 ppm
150 ms	150 ms
2,500 V	2,500 V
0.40 ms	0.40 ms

4. Turn to the procedure for executing the type of threshold test you selected in step 2 above:
 - Strength-Duration: See “Executing a Strength-Duration threshold test” on page 6-5.
 - Capture Management: See “Executing a Ventricular Capture Management threshold test” on page 6-11.
 - Amplitude - Auto Decrement: See page 6-17.
 - Pulse Width - Auto Decrement: See page 6-17.
 - Manual Amplitude & Pulse Width: See page 6-18.

Evaluating parameter settings
Measuring stimulation thresholds

Table 6-1. Threshold test parameters

Test parameter^a	Value selection
Mode	Select the pacing mode you want to be in effect during the threshold test. The available mode options depend on the programmed mode.
Lower rate	Select a lower rate value high enough to provide consistent pacing during the test. Loss of capture cannot be determined if the pacemaker is inhibited.
AV delay	If the selected test mode is DDD, DDI, or DOO, select an AV delay value short enough to provide a consistently paced ventricular rhythm. If the mode is DDD, the selected value applies to both Paced AV and Sensed AV intervals.
Amplitude	If the selected test type is Amplitude - Auto Decrement, Strength-Duration, or Manual, select the value at which you want the test to start. The value must be high enough to provide consistent capture. If the selected test type is Pulse Width - Auto Decrement, select the value you want to be in effect during measurement of the pulse width threshold.
Pulse width	If the selected test type is Pulse Width - Auto Decrement or Manual, select the value at which you want the test to start. The value must be high enough to provide consistent capture. If the selected test type is Amplitude - Auto Decrement or Strength-Duration, select the value you want to be in effect during measurement of the amplitude threshold. If the selected test type is Strength-Duration, pulse width cannot be less than 0.4 ms.

^a If the Ventricular Capture Management test type is chosen, the test parameters are fixed to pacemaker configured values.

Executing a Strength-Duration threshold test

If you completed the setup steps on page 6-3 and you selected Strength-Duration as the threshold test type, use this procedure to execute the test. The results of this test are graphically displayed as a strength-duration curve as described in Figure 6-2.

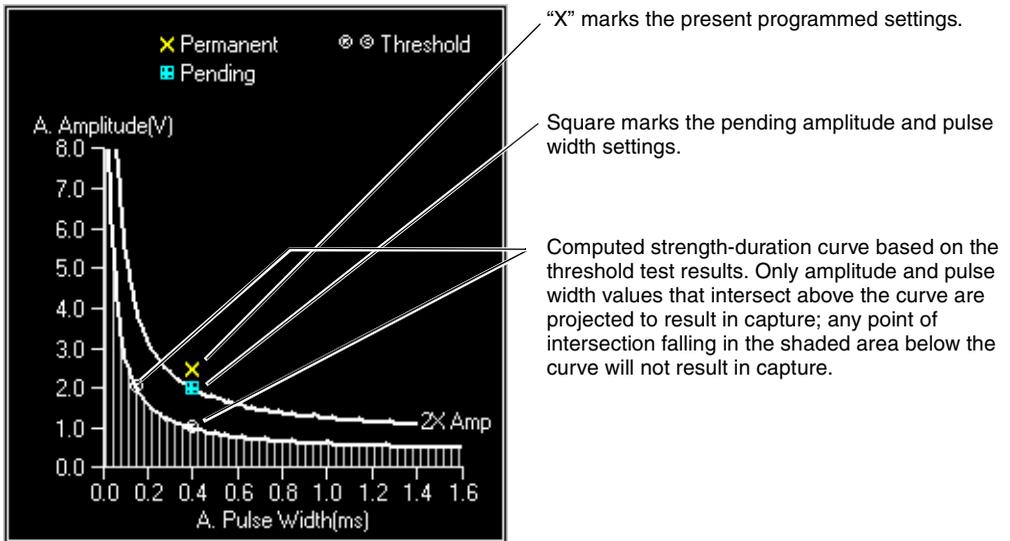


Figure 6-2. Graphic display of Strength-Duration Curve

Test restrictions

Any one of the following conditions will prevent or abort execution of the Strength-Duration threshold test. Selecting the [TEST Press and Hold] button results in a message window that informs you of the restricting condition.

- Implant detection is still operative.
- Elective Replacement Indicator (ERI) is set.

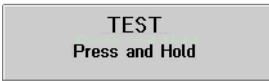
Test procedure

There are three parts to the Strength-Duration test. Complete all three parts in the order listed.

- Part I - Measuring the amplitude threshold
- Part II - Measuring the pulse width threshold
- Part III - Displaying the strength-duration curve

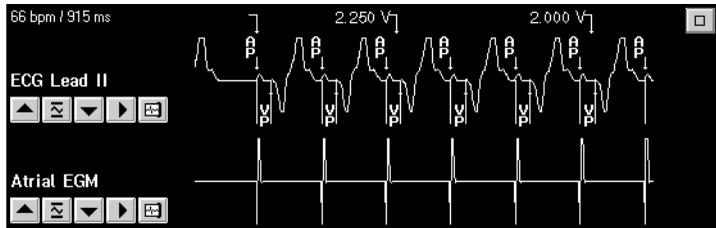
◆ **To measure the amplitude threshold (Part I)**

1. Position the programming head, and hold it steady for the duration of this procedure.
2. Select and hold the [TEST Press and Hold] button.



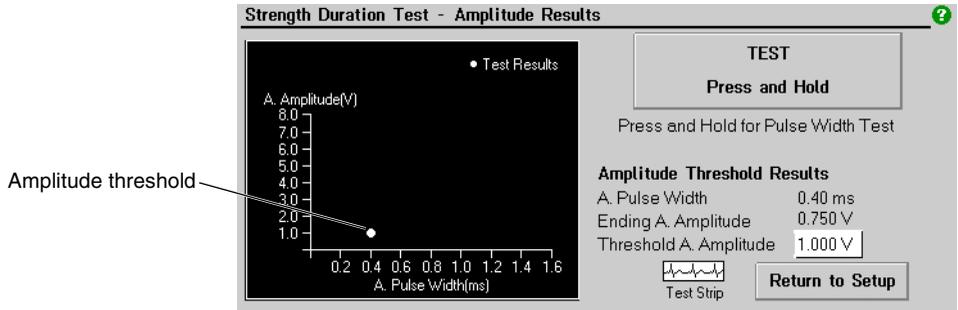
The programmer automatically reduces pulse amplitude one programmable value every 2 to 15 pacing pulses (as set during setup). The programmed value and the point at which it takes effect shows at the top of the live rhythm monitor.

In cases where pacing is inhibited, the test reduces pulse amplitude one value every eight seconds.



3. Carefully observe the patient's ECG for loss of capture.
4. At the moment you see loss of capture, release the [TEST Press and Hold] button.

The Strength-Duration test screen shows the results of the amplitude threshold measurement. The point at which capture is recovered is considered the amplitude threshold.

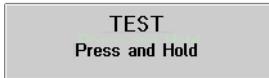


Select the Test Strip icon if you want to view or print a 10-second ECG strip starting 8 seconds before the test ended. If you want to restart the test, select the **[Return to Setup]** button.

Note: If the displayed threshold value is not the lowest programmed test value that maintained capture, select the Threshold Amplitude field to change the threshold value.



To measure the pulse width threshold (Part II)



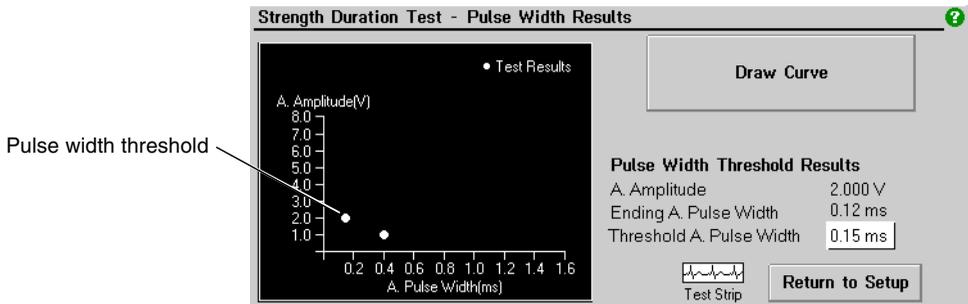
1. With the programming head in position, select and hold the **[TEST Press and Hold]** button.

The programmer automatically reduces pulse width one programmable value at a time. The amplitude setting in effect is twice the threshold value measured in Part I. The starting pulse width is approximately one-half the value used in Part I or 0.40 ms, whichever is greater.

2. Carefully observe the patient's ECG for loss of capture.
3. At the moment you see loss of capture, release the **[TEST Press and Hold]** button.

The screen now shows the results of both amplitude and pulse width threshold measurements. The point at which capture is recovered is considered the pulse width threshold.

Evaluating parameter settings
 Measuring stimulation thresholds



Select the Test Strip icon if you want to view or print a 10-second ECG strip starting 8 seconds before the end of the test.

Note: If the displayed threshold value is not the lowest programmed test value that maintained capture, select the Threshold Pulse Width field to change the threshold value.

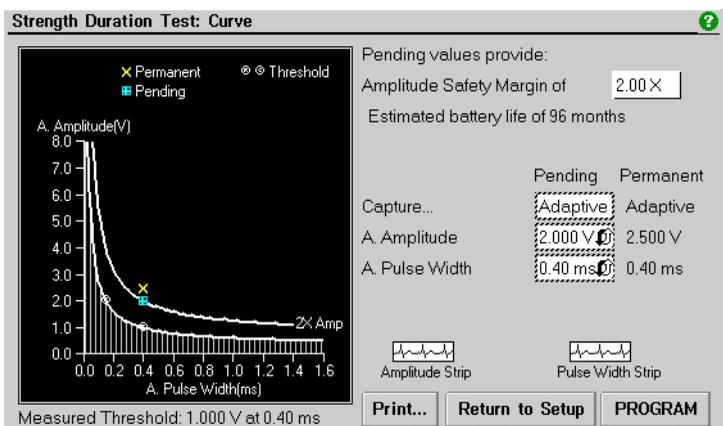
If you want to restart the test, select the [Return to Setup] button.

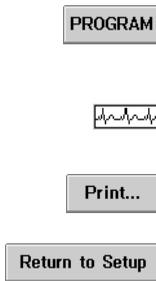
◆ **To display the strength-duration curve (Part III)**

- Select the [Draw Curve] button.

This action causes the programmer to calculate and draw the strength-duration curve based on the amplitude and pulse width threshold test results.

Note: For information about the strength-duration curve, see Figure 6-2 on page 6-5.





Options on this screen allow you to:

- Program amplitude and pulse width values (see page 6-10). After a Strength-Duration Test, you can program settings for ambulatory capture management operation also.
- View the 10-second ECG strip collected during either threshold measurement
- Print a Strength-Duration Threshold Test Report, which includes the ECG strips
- Return to the Test Setup screen, which clears this test data from the screen

Note: If certain pacing parameter values have changed during the session, the programmer may display a pop-up Warning window advising you that Battery and Lead parameters should be remeasured. This information is needed for the calculation of the estimated battery life appearing on the Test Results screen. Select the [Yes] button to allow the programmer to make these real-time measurements.

Selecting and programming amplitude and pulse width values

From the Strength-Duration Test Results screen, you can program the suggested amplitude and pulse width values or select different values, either by selecting a different amplitude safety margin or by directly selecting the desired parameter values.



To change the amplitude and pulse width values

- Select the amplitude safety margin or select the amplitude and pulse width values directly:

Safety Margin – Select the Amplitude Safety Margin field (see Figure 6-3) to display the safety margin options. Select the desired value. The programmer selects the nearest amplitude value that corresponds to the safety margin and displays the amplitude value under the pending column. Note that rounding to the nearest upper value may set a slightly higher safety margin.

Values – Select the Amplitude or Pulse Width field to display the programmable values. Select the desired value for pulse width or amplitude. Note that the programmer may recalculate the amplitude safety margin value to the nearest decimal value to approximate the selected amplitude value (for example, 3.20 X).

Evaluating parameter settings
Measuring stimulation thresholds

The programmer displays the pending threshold point on the strength-duration curve based on the pending amplitude safety margin value or output settings.

Safety Margin – Select this field to change the safety margin. Selecting an amplitude safety margin automatically displays the amplitude value that attains this safety margin at the lowest possible drain on the pacemaker battery.

Estimated Battery Life – A calculated estimate of the average time remaining until pacemaker replacement is required. This estimate is based on the amplitude and pulse width values selected for programming as well as data accumulated by the pacemaker since the previous patient session.

Pending Values – Select the A. Amplitude or A. Pulse Width fields if you want to choose amplitude or pulse width values other than what the safety margin provides. The safety margin and estimated battery life are recomputed. Select the Capture... field if you want to change Capture Management parameters.

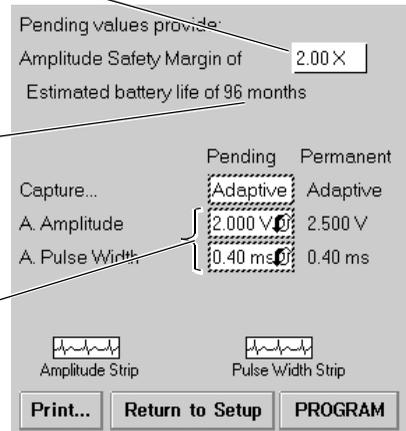


Figure 6-3. Strength-Duration Test Results programming options

◆ **To program the capture amplitude and pulse width values**

- Position the programming head, and select the [PROGRAM] button.

Note: The ambulatory capture management feature will discontinue ambulatory threshold measurements if amplitudes greater than 5.0 V or pulse widths greater than 1.0 ms are programmed.

Executing a Ventricular Capture Management threshold test

If you selected Ventricular Capture Management as the threshold test type, use this procedure to execute the test.

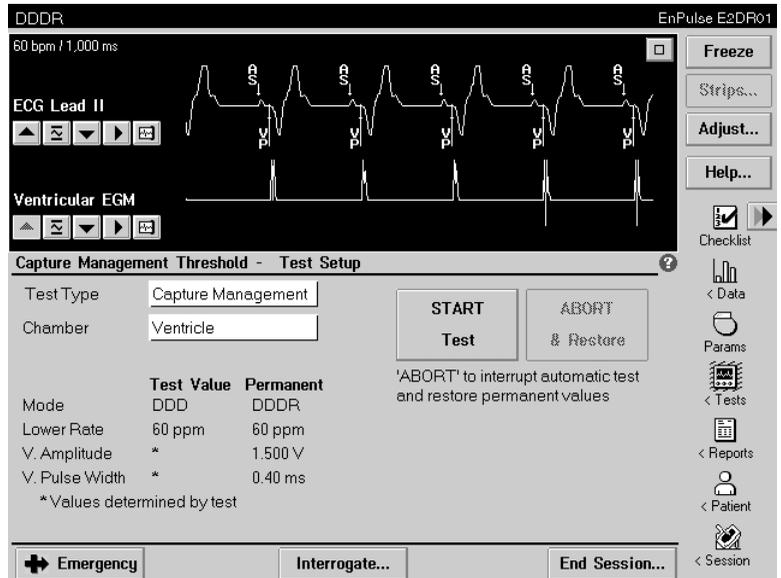


Figure 6-4. Ventricular Capture Management Threshold Test Setup screen

Test restrictions

Any one of the following conditions will prevent execution of the Ventricular Capture Management test. Selecting the Threshold test type from the Tests icon results in a message window that informs you of the restricting condition.

- Implant detection is still operative.
- Amplitude is set to a value greater than 5.0 V.
- Pulse width is set to a value greater than 1.0 ms.
- Pacing mode that does not support ventricular pacing and sensing (these include asynchronous modes, non-pacing modes, triggered modes, and atrial modes).
- Elective Replacement Indicator (ERI) is set.

Test procedure

The programmer will determine test values for mode and lower rate that are in effect before determining amplitude and pulse width thresholds.

Note: The patient should be at a resting rate before you execute this test. To verify a resting rate, the test performs an inactivity check to determine if pacing or sensing is at a low rate. If a high sensed or paced rate detected, the programmer will stop the test during the first stage of the test.

◆ **To execute a Ventricular Capture Management test**

1. Position the programming head and hold it steady for the duration of the test.
2. Select the [START Test] button to start the test sequence, which proceeds automatically (see “About the automatic test sequence”).



Note: To interrupt the test at any time during the automatic execution sequence, select the [ABORT & Restore] button. Previous parameter settings will be restored.

3. Upon successful completion, the test graphically displays the threshold measurement results as a strength-duration curve.

Refer to Figure 6-2 on page 6-5 for information about the strength-duration curve. Refer to Figure 6-6 and page 6-16 about using the screen options.

About the automatic test sequence

The following paragraphs describe each phase of the automatic test sequence, which starts when you select the [START Test] button in step 2 of the procedure.

The test applies a series of ventricular support cycles and test paces at each amplitude and pulse width value to determine if capture is present. Each series has one to three sets of support cycles, with each set followed by a test pace and a backup pace:

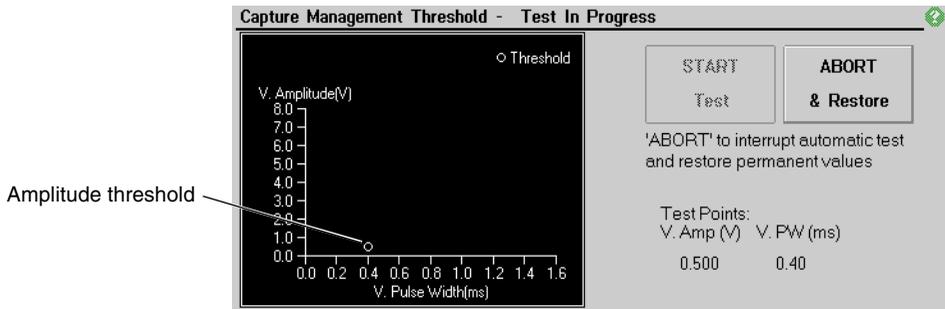
- The support cycles are at the currently programmed amplitude and pulse width (including ventricular safety paces and nonrefractory ventricular sensed events).
- The test pace is at a reduced amplitude or pulse width value, followed 110 ms later by a backup pace at the programmed amplitude and at a pulse width of 1.0 ms

During each phase of threshold measurements, the test annotates on the live rhythm window the test paces and whether each test pace maintained capture (CAP), lost capture (LOC), or capture could not be determined (Ignore).

Note: The programmer temporarily shortens AV intervals during the test so the pacemaker predominately paces the ventricle from conducted events.

How amplitude threshold is measured – The test first measures the stimulation threshold by reducing amplitude at a 0.4 ms pulse width. The test starts at the last ambulatory amplitude threshold measurement or at 0.75 V if the threshold has not been measured before.

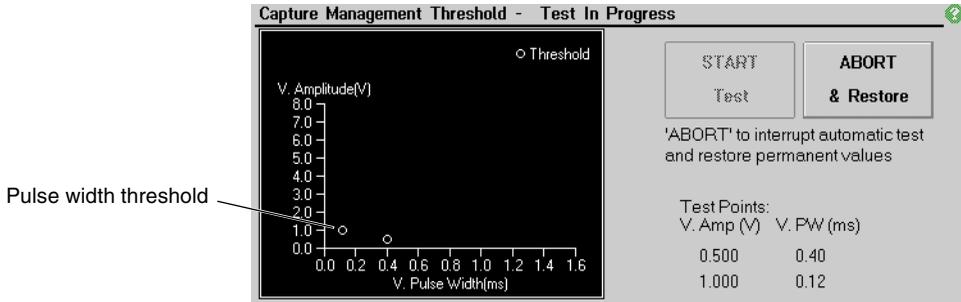
Amplitude values are automatically reduced by each programmable value until loss of capture occurs. Amplitude is then increased to regain capture. The point at which capture is recovered is considered the amplitude threshold. The programmer then plots this point on the strength-duration graph (see chart below).



How pulse width threshold is measured – The test next measures the stimulation threshold by reducing pulse width. The previously determined amplitude threshold value is doubled and the test starts at the last ambulatory pulse width threshold measurement. Alternately, the test will start at 0.21 ms if the threshold has not been measured before.

Pulse width values are automatically reduced by each programmable value until loss of capture occurs. Pulse width is then increased to regain capture. The point at which capture is recovered is considered the pulse width threshold. This point is plotted on the strength-duration graph (see chart below).

Evaluating parameter settings
 Measuring stimulation thresholds



How test results are displayed – The programmer now displays a strength-duration curve based on the measured amplitude and pulse width thresholds. The programmer also displays on the strength-duration curve the points where the capture threshold exists for current and pending output settings (amplitude and pulse width), see Figure 6-5.

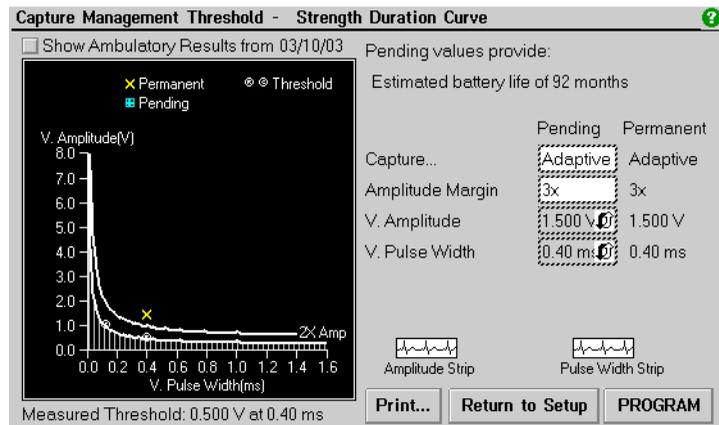
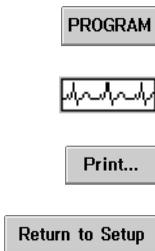


Figure 6-5. Ventricular Capture Management Threshold Test Results screen

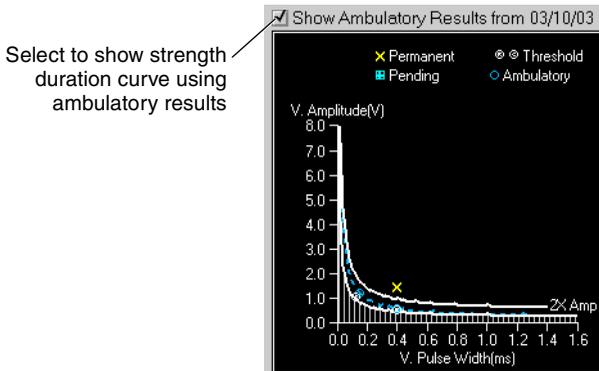
Options on this screen allow you to:



- Program settings for ambulatory capture management operation, particularly the amplitude margin value, see Figure 6-6 on page 6-16.
- View or print the 10-second ECG strip collected during either threshold measurement.
- Print a Ventricular Capture Management Threshold test report, which includes the ECG strips.
- Return to the Test Setup screen, which clears this test data from the screen.

Note: If certain pacing parameter values have changed during the session, the programmer may display a pop-up Warning window advising you that Battery and Lead parameters should be remeasured. This information is needed for the calculation of the estimated battery life appearing on the Test Results screen. Select the [Yes] button to allow the programmer to make these real-time measurements.

Displaying ambulatory test results – Optionally, the programmer can also display a second strength-duration curve based on the last successful threshold search measurement taken by the ambulatory capture management feature. This option can be used to compare the ambulatory threshold results against the in-office test results.



Selecting and programming the Amplitude Safety Margin

From the Test Results screen, you can program the amplitude safety margin value by selecting the Amplitude Margin field. You may also program the operation of the ambulatory Capture Management feature by selecting the Capture... field. The Capture Management window opens, which allows you to select several ambulatory Capture Management parameters. Refer to the *EnPulse Pacemaker Reference Guide* for more information on these options.

◆ **To change the Amplitude Safety Margin**

1. Select the Amplitude Margin field to display the safety margin options.
2. Select the desired value.

Note that the programmer displays the nearest amplitude value that corresponds to the selected safety margin and displays this value along with the pending value for pulse width under the pending column (see Figure 6-6).

The programmer also displays the pending threshold point on the strength-duration curve based on this pending safety margin.

Note: The ambulatory Capture Management feature will discontinue threshold measurements if amplitudes greater than 5.0 V or pulse widths greater than 1.0 ms are programmed.

Estimated Battery Life – A calculated estimate of the average time remaining until pacemaker replacement is required. This estimate is based on the amplitude and pulse width values selected for programming as well as data accumulated by the pacemaker since the previous patient session.

Ambulatory Capture Management – Select this field to change the operation of the ambulatory capture management feature.

Amplitude Margin – Select this field to change the safety margin. Selecting an amplitude safety margin automatically displays the amplitude value that attains this safety margin.

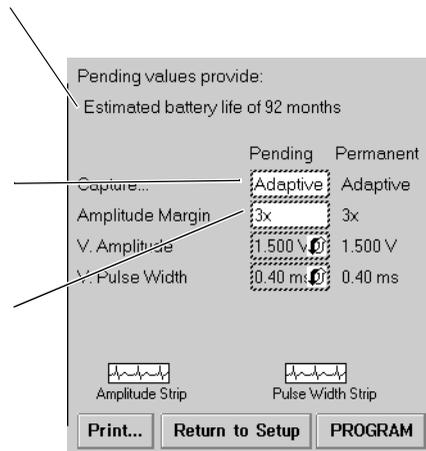


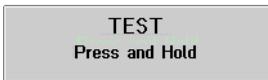
Figure 6-6. Capture Management threshold test options

Executing an Auto Decrement (Amplitude or Pulse Width) threshold test

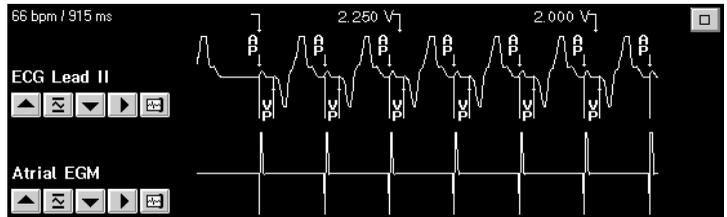
If you completed the setup steps on page 6-3 and you selected Amplitude - Auto Decrement or Pulse Width - Auto Decrement as the threshold Test Type, use this procedure to execute the test. The test results screen provides the option to program permanent values for amplitude and pulse width.

◆ *To execute an Auto Decrement threshold test*

1. Position the programming head and hold it steady in position for the duration of this procedure.
2. Select and hold the [TEST Press and Hold] button.



The programmer automatically reduces the test parameter (amplitude or pulse width) one programmable step every 2 to 15 pacing pulses (as set during setup). The programmed value and the point at which it takes effect shows at the top of the live rhythm display.



3. Carefully observe the patient's ECG for loss of capture.
4. At the moment you see loss of capture, release the [TEST Press and Hold] button.

The Test Results screen shows the results of the threshold measurement.

Amplitude Threshold - Atrial Test Results			
	Ending Value	Threshold	Permanent
Mode	DDD		DDDR
Lower Rate	90 ppm		60 ppm
AV Delay	150 ms		150 ms
A. Amplitude	1.000 V	1.500 V	3.500 V
A. Pulse Width	0.40 ms	0.40 ms	0.40 ms

 Test Strip
 Print...
Return to Setup
PROGRAM

Evaluating parameter settings
Measuring stimulation thresholds

Select the Test Strip icon if you want to view or print a 10-second ECG strip starting 8 seconds before the test ended.

Note: If the displayed threshold value is not the lowest programmed test value that maintained capture, select the Threshold field to change the threshold value.

Select the [Print...] button to print a Threshold Test Report. The Threshold Test Report includes the ECG strip.

If you want to restart the test, select the [Return to Setup] button.

◆ **To program Amplitude and Pulse Width values**

1. Select the Permanent value field for Amplitude and choose the desired setting from the values displayed.
2. Select the Permanent value field for Pulse Width and choose the desired setting from the values displayed.
3. Position the programming head and select the [PROGRAM] button.

Conducting a Manual Threshold test

If you completed the setup steps on page 6-3 and you selected Manual as the threshold test type, use this procedure to execute the test.

◆ **To execute a Manual Threshold test**

1. Position the programming head and hold it steady for the duration of this procedure.
2. Select the [START Test] button to program the selected test values.

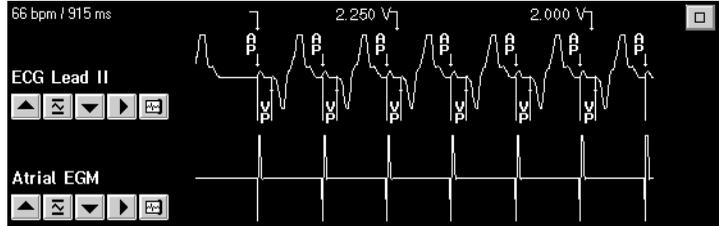
The screenshot shows the 'Manual Threshold - Test Setup' screen. It features a table of parameters with 'Test Value' and 'Permanent' columns, and two control buttons: 'START Test' and 'STOP and Restore'. The 'START Test' button is highlighted.

		Test Value	Permanent		
Test Type	Manual - Amplitude & F			START	STOP
Chamber	Atrium			Test	and Restore
Mode		DDD	DDDR	A. Amplitude	A. Pulse Width
Lower Rate		90 ppm	60 ppm	3.500V	0.40 ms
AV Delay		150 ms	150 ms		
A. Amplitude		3.500 V	3.500 V		
A. Pulse Width		0.40 ms	0.40 ms		



3. Select the or button to change the amplitude or pulse width setting.

The newly displayed value is automatically programmed. The value and the point at which it was programmed show at the top of the live rhythm display.



4. Observe the patient's ECG for loss of capture as you adjust the amplitude and pulse width settings.

By raising and lowering the parameter values, you can determine the lowest value or set of values that maintain capture.

5. To stop the test and return to permanent parameter settings, select the **[STOP and Restore]** button.



6. Select the **[Save/Print...]** button to display the Save/Print Test Values screen.



From the Save/Print Test Values screen, you can:

- View the sequence of all test values programmed during execution of the manual threshold test.
- View or print a 10-second ECG strip that starts 8 seconds prior to the test termination. (Select the "Stop" row from the field of tested values and then select the Test Strip icon.)

Save one or more of the programmed test values you want to include on the Manual Threshold Test report.

◆ **To save test values for the printed report**

1. Select each row to be saved.

Or, select the Select All check box to choose all test values.

If you do not want a selected value to be saved, select that row a second time.

2. Select the [Save] button.

The test values saved are marked in the right-most column.

Rows to be saved

Select All check box

[Save] button

Save/Print Test Values		
Select Values:		
Tested	at V	at ms
↓ Pulse Width	1.000	0.21
↑ Amplitude	1.250	0.21
↓ Pulse Width	1.250	0.15
↓ Pulse Width	1.250	0.12
↑ Pulse Width	1.250	0.15
STOP	1.250	0.15 - Strip Collected

Select All

Save Print... Close

- Print the Manual Threshold Test Report. Select the [Print...] button.

Note: Only those rows that are selected or saved are printed.

Determining a sensitivity setting

The Sensing (P/R wave amplitude) test lets you determine an appropriate setting for pacemaker sensitivity. You can select an automatic or a manual test method to determine the present level of P wave or R wave signals. A Sensing test begins at the Sensing Test Setup screen.

The Sensing Test setup screen

◆ **To display this screen**

- Select **Tests** > **Sensing**.

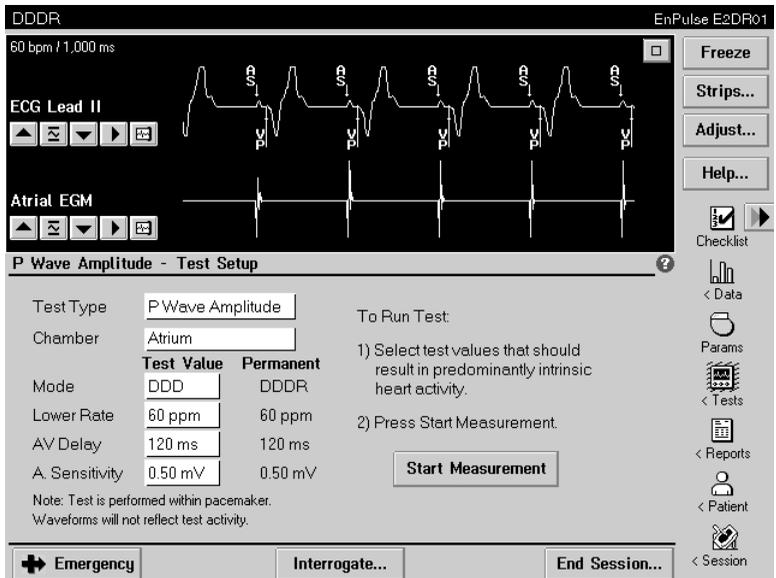
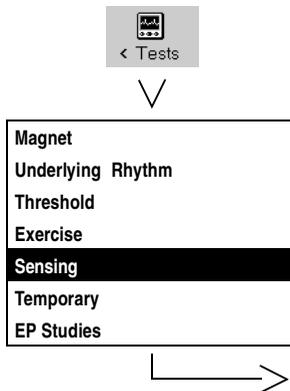


Figure 6-7. Sensing Test setup screen

Caution: The Sensing test requires that the pacemaker be programmed temporarily to a pacing rate that will result in predominantly intrinsic heart activity. This is necessary to allow sensing during execution of the test. For this reason, use of the Sensing test should be limited to patients having an intrinsic rhythm that will provide adequate support during execution of the test.

Evaluating parameter settings
Determining a sensitivity setting

Note: During the execution of a measurement, lifting the programming head from over the pacemaker for at least 2 seconds will return the pacemaker to its programmed state. This action should be taken in the event of a programmer malfunction, loss of power, or the absence of an appropriate command confirmation.

Checking the patient’s intrinsic rate

To properly conduct the Sensing test, it is helpful to first evaluate the patient’s intrinsic rhythm. Refer to “Checking the patient’s Underlying Rhythm” on page 3-30.

When you observe the patient’s intrinsic rhythm, note the rate and whether or not each intrinsic depolarization is accompanied by a Sense marker (AS or VS). If Sense markers do not appear, the present setting for pacemaker sensitivity may be too high. A test sensitivity value that provides consistent sensing is required to successfully run the Sensing test.

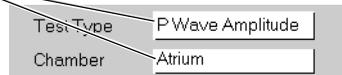
Executing an automatic Sensing test

This test automatically measures and reports the present level of R wave or P wave sensing and includes the option to program a sensitivity value based on the test results.

◆ **To execute the sensing measurement**

1. Display the Sensing Test Setup screen (see Figure 6-7 on page 6-21).
2. Choose P Wave Amplitude or R Wave Amplitude as the Test Type, or choose the desired Chamber (see Table 6-2 on page 6-24).

Select within the white field to display options



3. Choose a desired Test Value for each of the following test parameters (see Table 6-3 on page 6-24).

	Test Value	Permanent
Mode	DDD	DDDR
Lower Rate	60 ppm	60 ppm
AV Delay	120 ms	120 ms
A. Sensitivity	0.50 mV	0.50 mV

Note: Test is performed within pacemaker.
 Waveforms will not reflect test activity.

4. Position the programming head and press the [**Start Measurement**] button.

Continue to hold the programming head steady for the duration of the automatic testing process.

Caution: If the patient's condition indicates that pacing support is needed, select the [**Abort Test**] button or lift the programming head for at least 2 seconds to terminate the test.

5. Refer to "Automatic Sensing test results" on page 6-25 and read the test result examples in the message windows.

During execution of the Sensing test, the pacemaker determines whether or not sensing is lost as it steps sensitivity through a range of programmable settings above the selected test value. If sensing is lost when the sensitivity is stepped from 2.0 mV to 2.8 mV for example, the measured amplitude is stated to be between 2.0 and 2.8 mV

Note: Because a special test circuit in the pacemaker performs this test, pacemaker operating parameters do not vary from the selected test values, unless the intrinsic signal is significantly larger than the sensitivity test value. In such cases, the test value for sensitivity is automatically adjusted upward to 1.00 mV for atrial tests and 2.80 mV for ventricular tests. The ECG and Marker Channel traces will not show any changes in pacemaker operation during the test.

Evaluating parameter settings

Determining a sensitivity setting

Table 6-2. Sensing Test setup options

Setup option	Available settings
Test Type	Select Test Type to display the following options: P Wave Amplitude Select this test to determine the level of P wave sensing in the atrium. R Wave Amplitude Select this test to determine the level of R wave sensing in the ventricle. Manual Select this test to manually adjust sensitivity to determine the setting at which sensing is lost.
Chamber	Atrium, Ventricle You can select these options as an alternative to selecting P Wave Amplitude or R Wave Amplitude as the test type. For these automatic tests, the test type and chamber options are linked. If you selected Manual as the test type, select the chamber in which you want to conduct the test.

Table 6-3. Sensing Test parameters

Test parameter	Value selection
Mode	Select the pacing mode you want to be in effect during the Sensing test. The available options depend on the programmed pacing mode.
Lower Rate	Adjust rate to a value low enough to obtain consistent sensing. The Sensing test will not run unless the pacemaker is predominately inhibited.
AV Delay	If the test mode is DDD or VDD, adjust this interval to a value long enough to allow normal conduction. If the mode is DDD, the selected value applies to the paced AV interval and sensed AV interval during execution of the test.
Sensitivity	Select a sensitivity value that provides consistent sensing. This setting would typically be left to the same value as the present programmed value.

Automatic Sensing test results

Test Successful

Measured P Wave Amplitude between:
1.00 mV - 1.40 mV

The results of a successfully executed test displays the P wave or R wave amplitude as being between two sensitivity settings. You can use this information to determine an appropriate sensitivity setting.

Retest Required

Measured P wave Amplitude > 5.60 mV

For more precise measurement, select Return to Setup button and rerun at a higher sensitivity value.

This message indicates that the Test Value for Sensitivity is too low.

Loss of sensing did not occur within the range of values tested above the selected test value. In this case, you should select a higher test value for sensitivity and conduct the test again.

Measured P wave Amplitude between
1.00 mV – 1.40 mV

For more precise measurement, select Return to Setup button and rerun at a lower sensitivity value.

This message indicates that the Test Value for Sensitivity is too high.

If the test determines that sensing was lost at the next setting above the test value, the programmer displays this message. In this case, select a lower value for sensitivity and conduct the test again.

Test Aborted



No sense markers were received during the test. Please lower the test rate or increase the AV delay to allow patient intrinsic beats and rerun the test.

OK

This message indicates that Sense markers were not present.

Telemetered Sense markers (AS or VS) were not present to start the test. Verify on the live rhythm display that sensing of the patient's intrinsic rhythm is occurring. Adjustment of the lower rate or the Sensitivity test value may be required.

Executing a Manual Sensing test

Using this test, you can determine the level of P wave or R wave sensing by manually adjusting temporarily programmed values of atrial or ventricular sensitivity.

◆ To execute a Manual Sensing measurement

1. Display the Sensing Test Setup screen (see Figure 6-7 on page 6-21).
2. Choose Manual as the Test Type, then choose the desired Chamber.

Select within the white field to display options.

Test Type: Manual
 Chamber: Atrium

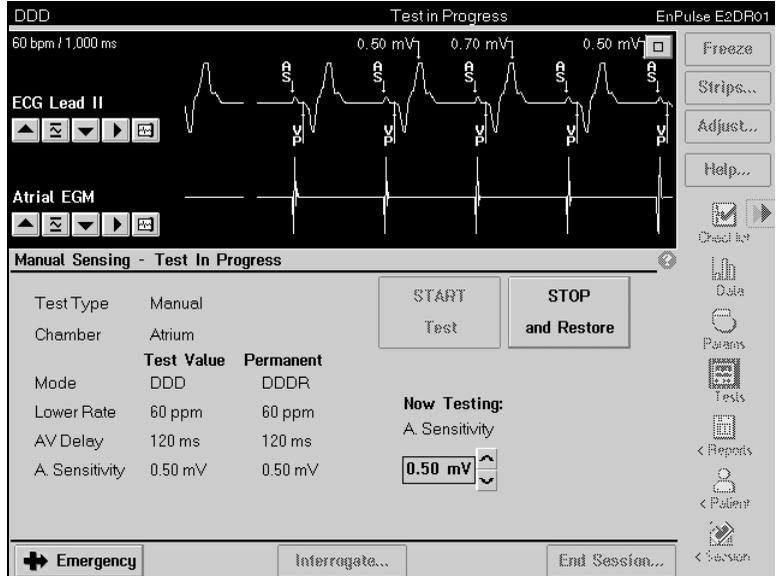
3. Choose a desired Test Value for each of the test parameters (see Table 6-3 on page 6-24).

Manual Sensing - Test Setup			
Test Type	Manual	<input type="button" value="START Test"/> <input type="button" value="STOP and Restore"/>	
Chamber	Atrium		
	Test Value	Permanent	
Mode	DDD	DDDR	
Lower Rate	60 ppm	60 ppm	
AV Delay	120 ms	120 ms	
A. Sensitivity	0.50 mV	0.50 mV	A. Sensitivity 0.50 mV <input type="button" value="▲"/> <input type="button" value="▼"/>

Now Testing:
 A. Sensitivity
 1.00 mV

4. Select the [START Test] button to program the selected test values.
5. Select the or button to change the sensitivity setting.

The newly displayed value is automatically programmed. The value and the point at which it was programmed shows at the top of the live rhythm display.



6. Observe the patient's ECG for loss of sensing as you adjust sensitivity. Loss of sensing is indicated by the loss of Sense markers in the chamber being tested.

By raising and lowering the sensitivity setting, you can determine the approximate sensed P wave or R wave amplitude, which is the range between the highest sensitivity setting that provided sensing and the one above it.

7. To stop the test and return to permanent parameter settings, select the [STOP and Restore] button.



8. Select the [Save/Print...] button to display the Save/Print Test Values screen.



From the Save/Print Test Values screen, you can:

- View the sequence of all values programmed during execution of the manual sensing test.
- View or print a 10-second ECG strip that starts 8 seconds prior to the test termination. (Select the "Stop" row from the field of tested values and then select the Test Strip icon.)
- Save one or more of the programmed test values you want to include on the Manual Sensing Test Report.

◆ **To save test values for the printed report**

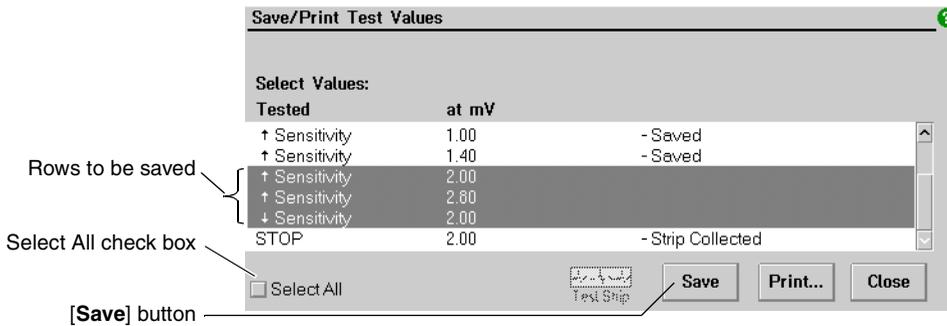
1. Select each row to be saved.

Or, select the Select All check box to choose all test values.

If you do not want a selected value to be saved, select that row a second time.

2. Select the [Save] button.

The test values saved are marked in the right-most column.



- Print the Manual Sensing test report. Select the [Print...] button.

Note: Only those rows that are selected or saved are printed.

Using temporary programming to evaluate parameter settings

The Temporary test lets you evaluate different parameter settings or use high-rate pacing while having the option to quickly and easily return to the original settings. The test settings remain in effect only while you press the [TEST Press and Hold] button.

The Temporary Test setup screen

◆ **To display this screen**

- Select **Tests** > **Temporary**.

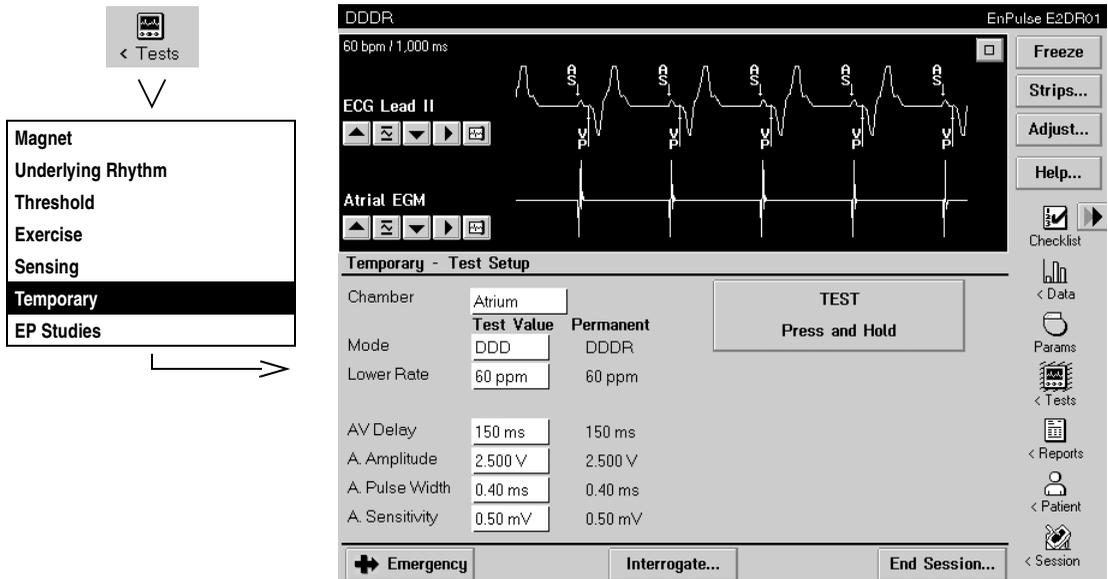


Figure 6-8. The Temporary Test setup screen



Warning: High-rate stimulation of the ventricles could result in ventricular tachycardia or fibrillation. Application of temporary high-rate pacing should be performed only under careful patient monitoring and control.

Evaluating parameter settings

Using temporary programming to evaluate parameter settings

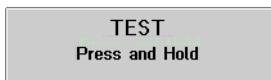
Procedure for conducting a Temporary Test

1. Display the Temporary Test Setup screen (see Figure 6-8 on page 6-29).
2. Select the desired test chamber and the parameter settings you want to test. Availability of temporary pacing mode options depend on the programmed mode setting.

Select within the white field to display options

Chamber	Atrium	
Mode	Test Value DDD	Permanent DDDR
Lower Rate	60 ppm	60 ppm
AV Delay	150 ms	150 ms
A. Amplitude	2.500 V	2.500 V
A. Pulse Width	0.40 ms	0.40 ms
A. Sensitivity	0.50 mV	0.50 mV

3. Position the programming head and continue to hold it in place for the duration of this test.
4. To initiate the test values, select and hold the [TEST Press and Hold] button.



60 bpm / 1,000 ms

DDD, 4.5 ppm

ECG Lead II

Atrial EGM

Temporary - Test In Progress

Chamber	Atrium		TEST Press and Hold
Mode	Test Value DDD	Permanent DDDR	
Lower Rate	60 ppm	60 ppm	

Release to restore Permanent

5. To end the test, release the [TEST Press and Hold] button.
6. Select the Test Strip icon to view or print a 10-second ECG strip starting 8 seconds before the temporary test ended.
7. Select the [Print...] button to print a Temporary Test Report, which includes the 10-second ECG strip.



Programming a high temporary pacing rate



Warning: High-rate stimulation of the ventricles could result in ventricular tachycardia or fibrillation. Application of temporary high-rate pacing should be performed only under careful patient monitoring and control.



To program a high temporary rate

1. From the Temporary Test Setup screen (see Figure 6-8 on page 6-29), select the desired test chamber and a single chamber test mode.

Chamber	Atrium	
	Test Value	Permanent
Mode	AAI	DDDR
Lower Rate	60 ppm	60 ppm

High pacing rates above 180 min^{-1} are available only if you select a single chamber pacing mode (AAI/VVI, AOO/VOO, AAT/VVT, ADI/VDI).

2. Select the Enable Rates > 180 min^{-1} check box so that a checkmark (✓) shows.

Chamber	Atrium		TEST Press and Hold
	Test Value	Permanent	
Mode	AAI	DDDR	
Lower Rate	60 ppm	60 ppm	
<input checked="" type="checkbox"/> Enable Rates > 180 ppm			

This action displays the High Rate Pacing Warning window; see below.

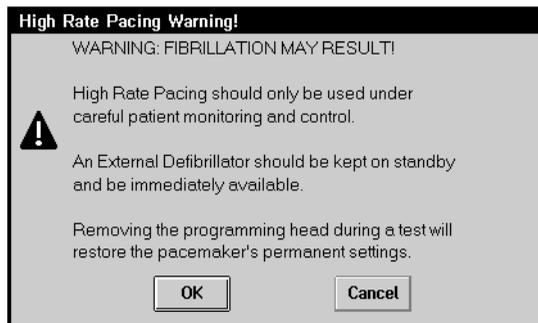
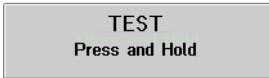


Figure 6-9. High Rate Pacing Warning window

3. Select [OK] to proceed or [Cancel] to discontinue this procedure.

Evaluating parameter settings

Using temporary programming to evaluate parameter settings



4. Selecting [**OK**] allows you access to pacing rates up to 400 min⁻¹. Select the desired rate and any other parameter setting you want to temporarily initiate.
5. Position the programming head and continue to hold it in place for the duration of this test.
6. To initiate the test values, select and hold the [**TEST Press and Hold**] button.
7. To end the test, release the [**TEST Press and Hold**] button.
8. Select the Test Strip icon to view or print a 10-second ECG strip starting 8 seconds before the temporary test ended.
9. Select the [**Print...**] button to print a Temporary Test Report, which includes the 10-second ECG strip.

Programming pacemaker parameters

7

This chapter provides instructions on how to program parameter settings and how to save or retrieve a custom or nominal parameter set.

Programming parameters 7-2

Saving/retrieving a set of parameter values 7-15

Retrieving Key Parameter History information 7-18

Programming parameters

Selecting the Therapy Parameters screen

To view the present parameter settings or to program changes, select the Params icon. This displays the Therapy Parameters screen (Figure 7-1). This screen allows you to select and program new parameter values applicable to the interrogated pacemaker model.

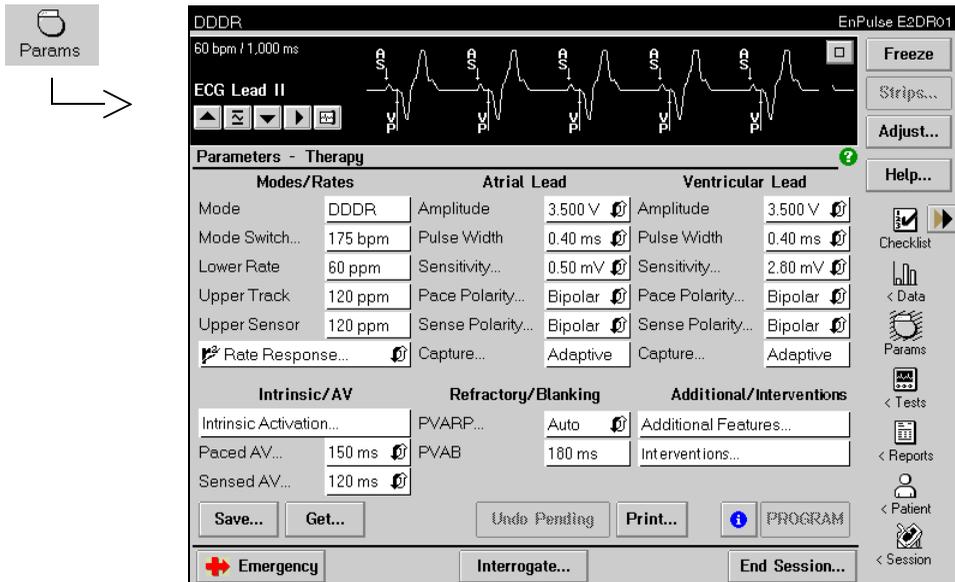


Figure 7-1. Therapy Parameters screen

Programming, printing, and clearing parameter values

Programming parameters – To program pending values for one or more parameters, select the **[PROGRAM]** button. This button is active only when one or more parameter values have been made pending and no parameter values are restricted (see “Parameter restrictions”).

Similarly, the Program key on the programming head will respond only when the **[PROGRAM]** button is active on the screen.

Printing parameters – To print the currently displayed parameter values, select the **[Print...]** button.

Clearing parameters – To clear all pending parameter values and restore the previously interrogated values on the screen, select the **[Undo Pending]** button. This button also appears on primary and subordinate parameter value windows.

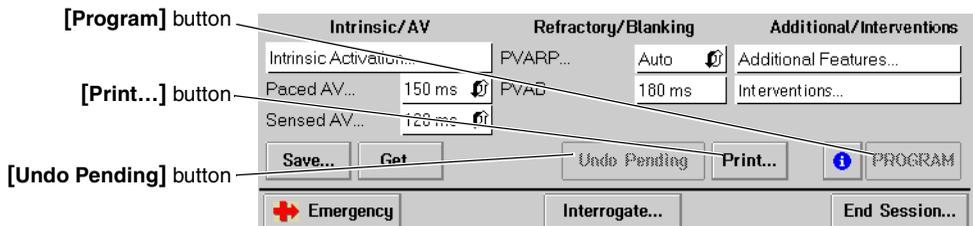


Figure 7-2. Parameter value buttons

Parameter restrictions

Certain combinations of parameter values are restricted because they are invalid or result in undesirable interactions. The programmer recognizes these combinations and may not allow programming until all parameter conflicts are resolved and all parameter selection requirements are met.

A symbol providing status on a parameter value appears next to that value in the value selection window. The symbol also appears on the Therapy Parameters screen if the value is pending.

120 
125 

Restricted parameter values – Any parameter value that conflicts with the setting of another present or pending parameter value has an interlock symbol next to it. You must select another value or resolve the conflicting parameter value before programming of the parameter is allowed.

180 
185 

Parameter warnings – When a parameter value appears with an exclamation point enclosed in a triangle next to it, a warning message appears regarding that value. Note that such parameter values can be programmed.

Adaptive parameter values

5.000 V 

The  symbol appearing next to a parameter value on the Therapy Parameters screen indicates that the programmed value can be changed automatically by the pacemaker. The symbol does not necessarily indicate that the parameter value has been adapted from a previously programmed value—only that it can be adapted.

For example, the  symbol appears next to the Ventricular Amplitude value, which is adaptive if Ventricular Capture Management is in the Adaptive mode. This is true whether the Adaptive mode is programmed or pending for Ventricular Capture Management.

5.000 V

If Ventricular Capture Management is in the Monitor Only mode (which is not adaptive), no  symbol appears next to the Ventricular Amplitude value.

Important information about pending values

Any time an undesirable parameter interaction is possible, a message access button appears next to the **[PROGRAM]** button.



- This button indicates that a parameter interlock exists. Programming is restricted until you resolve the conflict. Press this button for a message that describes the conflict.
- This button indicates that there is a warning associated with programming one or more of the pending parameter values. Press this button to view the warning message.
- This button indicates that there is an informational message regarding one or more of the pending parameter values. Press this button to see the message.

At times there may be two or more messages regarding the pending parameter values. The most significant message will determine the button symbol.

Other parameter value symbols

175

Medtronic Nominal parameter – The “n” symbol appears next to a parameter value if it is the Medtronic Nominal value.

140

Programmed parameter – The “P” symbol appears next to a parameter value if it is the programmed value.

Rate Response parameter – The “r²” symbol appears next to the Rate Response field as a logo for EnPulse rate responsive pacing.

How to program parameters

All pacing therapy parameters are changed by selecting the parameter value field (the white box containing the value).

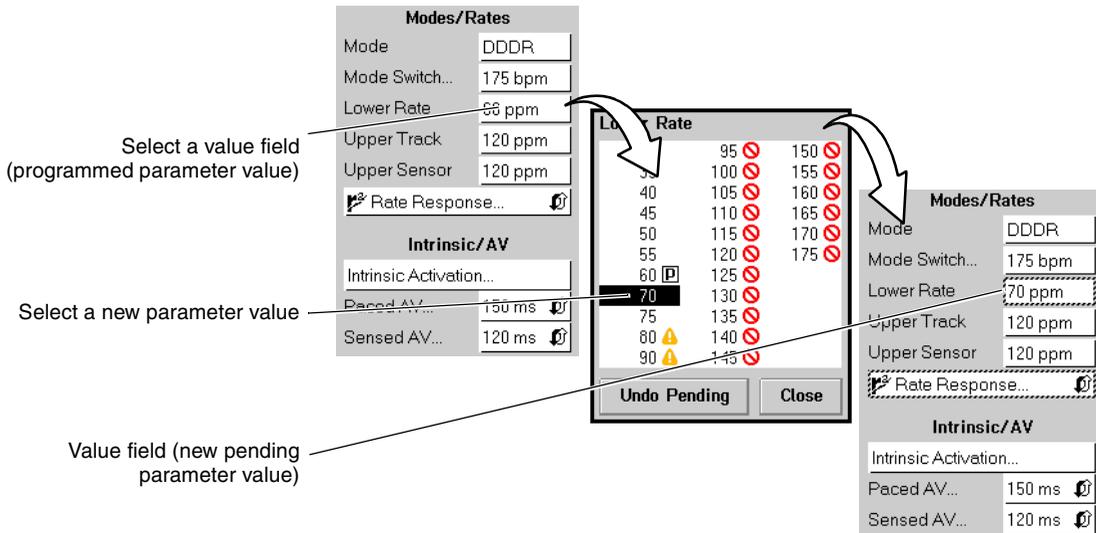


Figure 7-3. Programming pacing parameters

◆ To program parameter values

1. Select the desired parameter value from those displayed — for example, Lower Rate as shown in Figure 7-3.

Note: Select the pacing mode first if you intend to program a mode. Selecting a mode displays the parameters pertinent to that mode.

2. From the parameter value window, select the desired value.

If the value window displays subordinate parameters, refer to “How to program subordinate parameters” on page 7-8.

Selecting a value closes the window. The selected value appears in place of the present value and is denoted as “pending” by a dashed rectangle.

Note: To clear a pending value from the screen, select the value and then select the **[Undo Pending]** button. To close the value window without selecting a value, select the **[Close]** button or the **[OK]** button.

3. Repeat steps 1 and 2 to include other parameters you want to program.
4. Position the programming head and select **[PROGRAM]**, or press the program button on the programming head.

Select the **[PROGRAM]** button to program all pending parameter values. Hold the programming head over the pacemaker until the confirmation message appears in the displayed ECG strip.

Notes:

- If you end the patient session before programming the pending values, the End Session window displays a message stating that parameters have been selected but not programmed.
- If telemetry is interrupted, one or more of the parameters could remain unchanged and still show pending values. In such cases, programming is not confirmed, and a message to retry or cancel appears.
- If you want to clear all pending values associated with the Therapy Parameters screen, select the **[Undo Pending]** button near the bottom of the screen.

How to program subordinate parameters

Some pacing parameters have one or more subordinate parameters associated with the primary parameter. These subordinate parameters are displayed in two ways:

To Customize the Pacing Therapy – Parameters appear as additional parameters listed in the window under the primary parameter.

For Additional Customizing – Parameters are accessed from a name field ending with an ellipsis (e.g., Rate Response...). Selecting the field displays the additional parameters in a separate window.

◆ **To program subordinate parameters**

1. Select the desired subordinate parameter below the primary parameter or within the name field. For example, select ADL Response in the Rate Response window, as shown in Figure 7-4.

2. From the subordinate value window, select the desired value.

Selecting a value closes the window. The selected value appears in place of the present value and is denoted as “pending” by a dashed rectangle.

Note: To clear a pending value from the value window, select the **[Undo Pending]** button. Alternately, select the value from the params screen and then select the **[Undo Pending]** button. To close the value window without selecting a value, select the **[Close]** button.

3. Repeat steps 1 and 2 to include other subordinate parameters you want to program.
4. Select **[OK]** to close the subordinate parameter window. The primary parameter or its name field now has a dashed rectangle.
5. Position the programming head and select **[PROGRAM]**, or press the program button on the programming head.

Select the **[PROGRAM]** button to program all pending primary and subordinate parameter values. Hold the programming head over the pacemaker until the confirmation message appears in the displayed ECG strip.

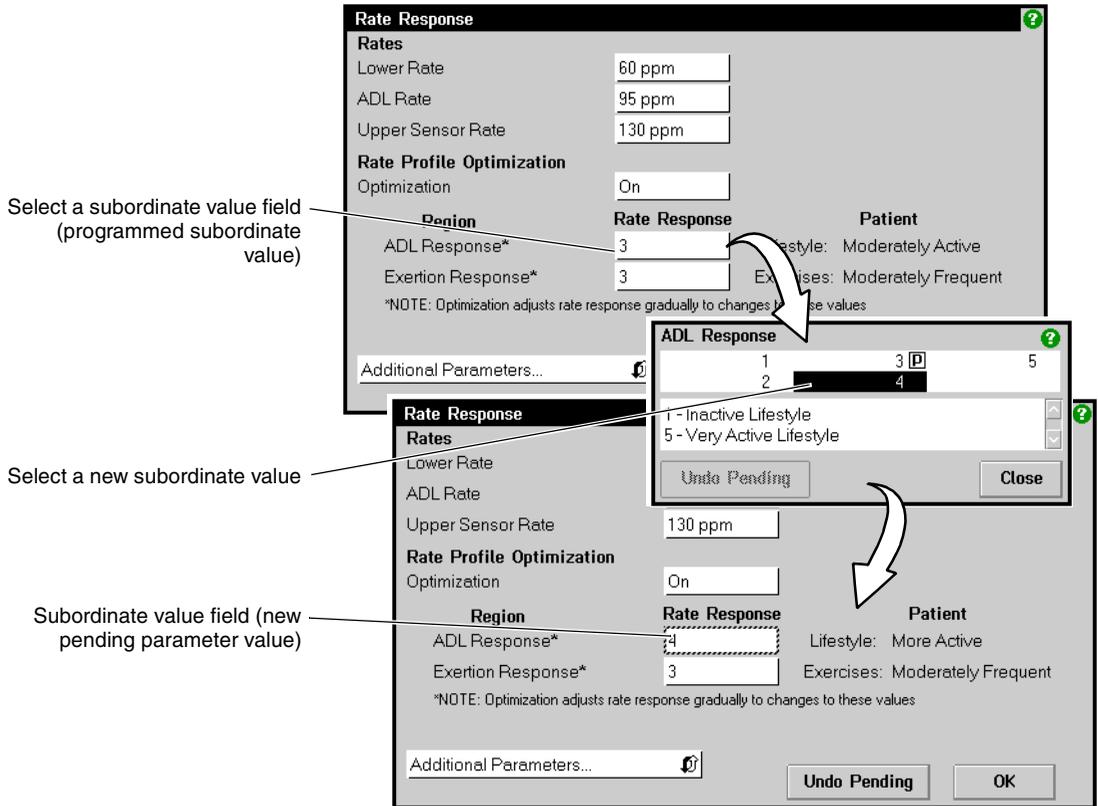


Figure 7-4. Programming subordinate parameter values

Refer to Table 7-1, which shows the primary parameters that have subordinate parameters and where the parameters are located on the Therapy Parameters screen (Params icon).

Refer to the *EnPulse Pacemaker Reference Guide* for detailed descriptions of the therapy features, definitions of the parameters, and tables of all the programmable parameter values.

Programming pacemaker parameters

Programming parameters

Table 7-1. Subordinate parameters for the therapy parameters screen

Primary parameters	1 st level subordinate	2 nd level subordinate
Mode Switch...	→ Mode Switch (On/Off) Detect Rate Detect Duration Blanked Flutter Search (On/Off)	
Rate Response...	→ Lower Rate ADL Rate Upper Sensor Rate Optimization (On/Off) ADL Response Exertion Response	
	Additional Parameters...	→ Activity Threshold Activity Acceleration Activity Deceleration
Sensitivity... (Atrial and Ventricular)	→ Sensitivity Sensing Assurance (On/Off)	
Polarity... ^a (Under Pace Polarity... and Sense Polarity...)	→ Pace Polarity Sense Polarity Lead Monitor (Options) Notify if < Notify if > Monitor Sensitivity Lead Status (Reset)	
Capture... (Atrial Capture Management, Ventricular Capture Management)	→ Capture Management (Options) Amplitude Amplitude Margin Minimum Adapted Amplitude Pulse Width Additional Parameters	
	Additional Parameters...	→ Capture Test Frequency Capture Test Time Acute Phase Days Remaining Acute Phase Completed Sensing During Search (VCM only)
Intrinsic Activation...	→ Paced AV Sensed AV	
	Rate Adaptive AV	→ Rate Adaptive AV (On/Off) Start Rate Stop Rate Maximum Offset
	Search AV+	→ Search AV+ (On/Off) Max Increase to AV
	Sinus Preference...	→ Sinus Preference (On/Off) Sinus Preference Zone Search Interval

Table 7-1. Subordinate parameters for the therapy parameters screen (Continued)

Primary parameters	1 st level subordinate	2 nd level subordinate
PVARP...	→ PVARP (Options) Minimum PVARP	
Interventions... (Arrhythmia)	→ Post Mode Switch (On/Off) Overdrive Period Overdrive Rate Ventricular Response Pacing (On/Off) Maximum Rate	
Additional Features...	→ Sleep...	→ Sleep (On/Off) Sleep Rate Bed Time Wake Time
	Non-Comp Atrial Pacing Single Chamber Hysteresis	
	Rate Drop Response...	→ Detection Type Intervention Rate Intervention Duration Detection Beats Drop Rate Drop Size Detection Window
	V. Refractory V. Blanking PMT Intervention PVC Response V. Safety Pacing	
	Telemetry Features...	→ Transtelephonic Monitor Extended Telemetry Extended Marker
	Implant Detection	
	ERI/POR Reset...	→ ERI/POR Reset ^b

^a Depending on Mode and model, all subordinate parameters are repeated for each chamber.

^b After a Power On Reset (POR), you will need the assistance of a Medtronic representative in setting other subparameters in the Factory Calibrations window.

Resetting ERI or electrical reset

If an ERI or electrical reset condition (POR) exists, you will see a Warning message at the time of interrogation. As described in “Warning messages” on page 3-7, each message box has a button you can select to attempt to reset the condition it warns you about. The procedures presented below give you the option to reset the condition later in a patient session.

◆ **To verify or clear an ERI status**

If you select the **[Close]** button (instead of the **[Clear]** button) in the Elective Replacement Indicated warning window, you can use the following procedure to attempt to clear the ERI condition later in the patient session.

1. Select the Additional Features name field from the Therapy Parameters screen.
2. From the Additional Features window, select the ERI/POR Reset field.
3. From the Factory Calibrations window, select the ERI/POR Reset field (see Figure 7-5).
4. Select the ERI/POR Reset option (this is the only option displayed).

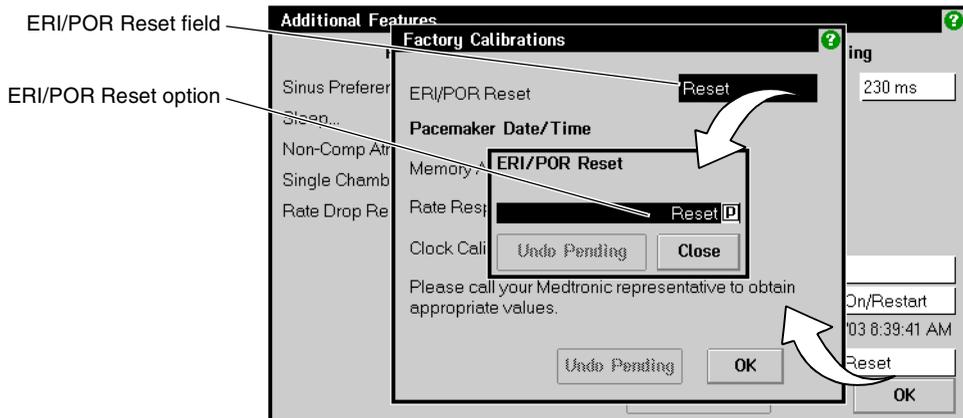


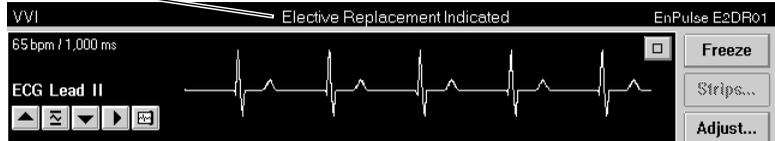
Figure 7-5. ERI/POR reset windows

5. Select the **[OK]** button twice to return to the Therapy Parameters screen.

6. Position the programming head and select [**PROGRAM**]. Continue to hold the programming head steady until you see the programming confirmation.

To verify whether the ERI condition has cleared, check that “Elective Replacement Indicated” no longer appears in the status line:

ERI message



Another way to verify whether or not the ERI condition has cleared is to interrogate the device for Battery and Lead Measurements (see “Interrogating the pacemaker” on page 3-16).

- If the ERI condition still exists, the Elective Replacement Indicated warning window will reappear following the interrogation.
- If battery voltage is above the ERI level, there will be no Elective Replacement warning, and you can proceed with reprogramming the device. To view the interrogated battery information, select the Battery and Lead Measurement screen (see “Viewing Battery and Lead Measurements” on page 3-22).

Note: During interrogation for battery and lead measurements, the device paces asynchronously at 100 min^{-1} (with an AV interval of 100 ms for dual chamber modes).

◆ **To clear a device electrical reset (POR)**

- Use the same procedure given for clearing an ERI condition (see previous two pages).

All parameters can now be reprogrammed to the desired settings. Refer to the *EnPulse Pacemaker Reference Guide* for information on device behavior and the specific parameter values that are in effect after an electrical reset.

Programming pacemaker parameters

Programming parameters

Note: If you attempt to clear an electrical reset and the programmer displays a message that the functionality of the device is limited due to an electrical reset, you will be unable to restore previous functionality. Contact your Medtronic representative for assistance to restore functionality. If the Memory Access Key option displays an active field (Figure 7-6), do not select this field without first contacting your Medtronic representative.

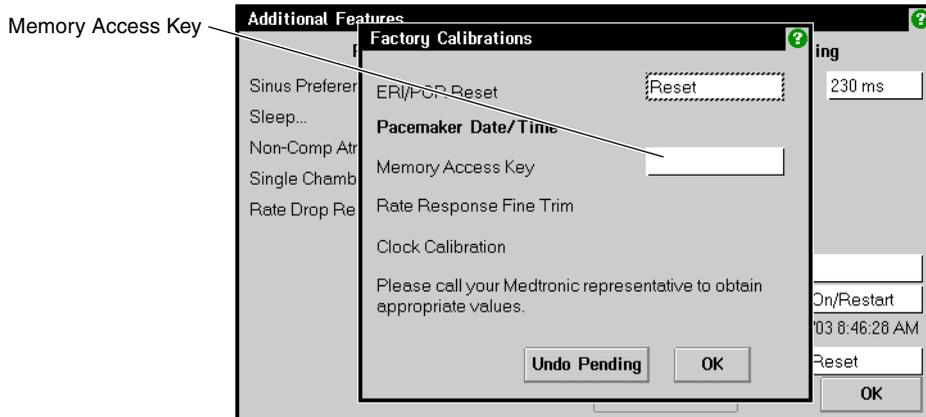


Figure 7-6. Clearing a full electrical reset

Saving/retrieving a set of parameter values

A complete custom set of parameter values can be saved in the programmer and retrieved at a later time. The **[Save...]** button opens the Save Parameters window to save a set of parameter values.

The **[Get...]** button opens the Get Saved/Nominal Parameters window to retrieve a saved parameter value set or a Medtronic Nominals parameter set.

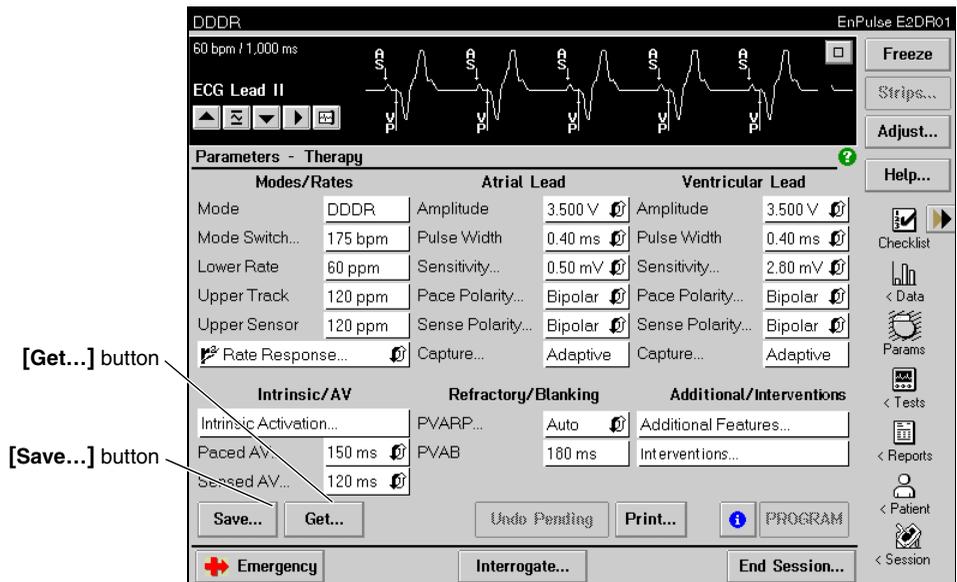


Figure 7-7. Save and Get buttons

Saving a set of parameter values

You can save the parameter values presently displayed by the Therapy Parameters screen. The values can be either present or pending.

◆ **To save a set of parameter values**

1. Select the **[Save...]** button to open the Save Parameters window (Figure 7-8).
2. Select New or an existing parameter set in the “Save to” field that you want to replace with the new parameter set.

Select Scratch Parameter Set if you want to temporarily save a parameter set for only the duration of the patient session.

3. Select the Name/Description field to display the on-screen keyboard. Type in a name for the parameter set, and select the **[Enter]** key. Skip this step if you selected Scratch Parameter Set.
4. Select the **[Save/Replace]** button. Once saved, the parameter set name with the current date and time will appear on the list.

Note: Up to five parameter sets for EnPulse models can be saved on the programmer.

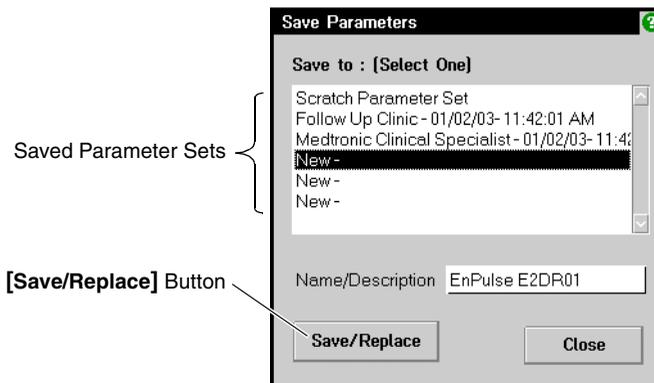


Figure 7-8. Save Parameters window

Retrieving a Saved or Nominal Set of parameter values

A saved set of parameter values is stored in the programmer memory.

◆ *To retrieve a set of parameter values*

1. Select the **[Get...]** button to open the Get Saved/Nominal Parameters window.
2. Select the parameter set you wish to retrieve (see description of options below).
3. Select the **[Copy to Params]** button.

The programmer copies all of the parameter values in the selected set to the Therapy Parameters screen as pending values.

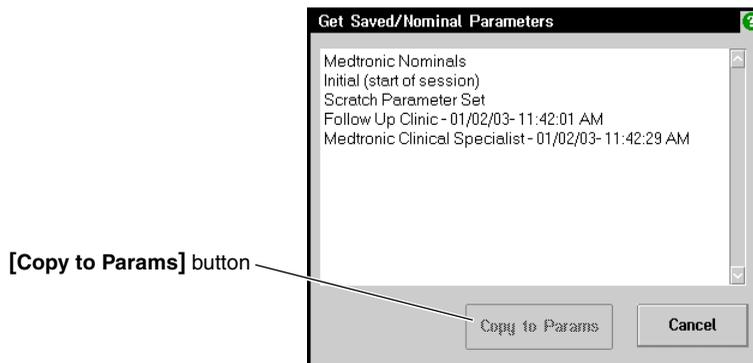


Figure 7-9. Get Saved/Nominal Parameters window

You can select these options from the Get Saved/Nominal Parameters field.

- **Initial:** The permanently programmed parameter values as determined by the first interrogation of the pacemaker during the programming session. This set of values cannot be changed.
- **Scratch Parameter Set:** Values saved only for the duration of the programming session. Ending the programming session clears the Scratch Parameter Set.
- **Medtronic Nominals:** Values chosen as nominal values for the pacemaker by Medtronic. This set of values cannot be changed.
- **Custom sets of values:** A maximum of five custom sets of values can be saved for each pacemaker model. A custom set of values may be overwritten at any time.

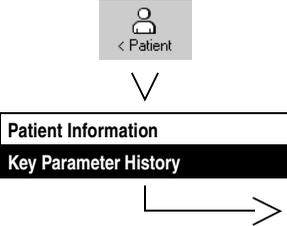
Retrieving Key Parameter History information

Key Parameter History information is collected automatically. Parameter values for the 8 most recent programming sessions are available.

Refer to the *EnPulse Pacemaker Reference Guide* for information about collecting Key Parameter History information.

◆ **To retrieve Key Parameter History information**

- Select **Patient > Key Parameter History.**



Parameter:	Present	04/14/03	03/27/03	03/01/03
Mode	DDDR	DDDR	DDDR	DDDR
Mode Switch	On	On	On	On
Lower Rate	60 ppm	60 ppm	60 ppm	60 ppm
ADL Rate	95 ppm	95 ppm	95 ppm	95 ppm
Upper Track	130 ppm	130 ppm	130 ppm	130 ppm
Upper Sensor	130 ppm	130 ppm	130 ppm	130 ppm
PAV	150 ms	150 ms	150 ms	150 ms
SAV	120 ms	120 ms	120 ms	120 ms
A. Amplitude	3.500 V	3.500 V	3.500 V	3.500 V
A. Pulse Width	0.40 ms	0.40 ms	0.40 ms	0.40 ms
A. Sensitivity	0.50 mV	0.50 mV	0.50 mV	0.50 mV
V. Amplitude	5.000 V	5.000 V	<< 3.500 V	3.500 V
V. Pulse Width	1.00 ms	1.00 ms	<< 0.40 ms	0.40 ms
V. Sensitivity	4.00 mV	4.00 mV	4.00 mV	<< 2.80 mV

Figure 7-10. Key Parameter History

Note: Left arrows (<<) indicate that a value has been changed. The ⚙ symbol indicates that the present programmed value has been changed automatically by the pacemaker.



Use the left page arrow to move data to the left.



Use the right page arrow to move data to the right.

Rate Response setup

8

This chapter provides instructions to set up and program rate response parameters using the Exercise test.

***Using Exercise test to verify
Rate Response 8-2***

Rate Response setup

Using Exercise test to verify Rate Response

Using Exercise test to verify Rate Response

Overview of the Exercise test

During patient follow-up sessions, use the Exercise test to evaluate the pacemaker's rate response operation and to program, if necessary, parameters that control rate response. The test uses heart rate and sensor rate trend data collected by the pacemaker while the patient exercises.

Note: Executing the Exercise test erases all pacemaker collected data from pacemaker memory (i.e., automatic and clinician-selected diagnostic data). This data will no longer be available once you have ended the test.

Selecting the Exercise test

◆ *To begin the Exercise test*

► Select **Tests** > **Exercise**.

The programmer automatically performs an interrogation of the pacemaker. The Test Setup screen opens and displays current test settings for mode, rates, and optimization.

Note: You can perform the Exercise test in a non-rate responsive mode for patients who are exercise competent. Using a pacing mode such as DDD allows you to view the patient's intrinsic rate response and the rate response that the pacemaker would have provided in a rate responsive mode during exercise.



Magnet
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Threshold
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EP Studies

Starting the Exercise test

Before starting the Exercise test, decide on an exercise that the patient should perform for at least two minutes (e.g., a typical hall walk).

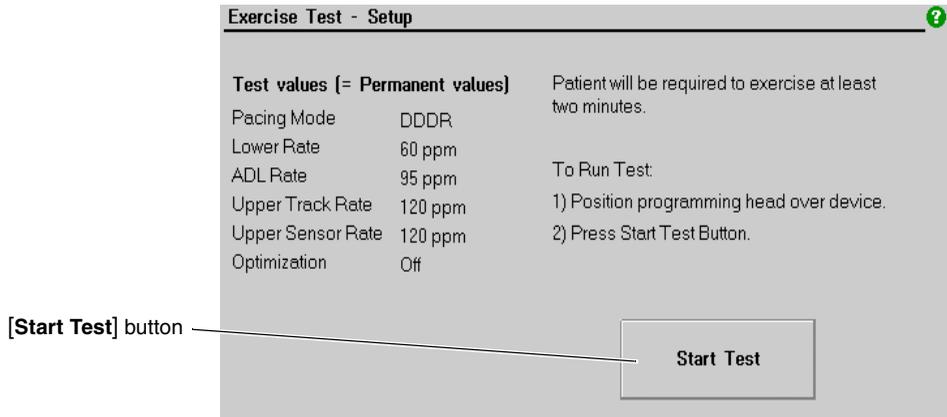


Figure 8-1. Starting the Exercise test

◆ **To start the Exercise test:**

1. Position the programming head over the pacemaker.
2. Select the **[Start Test]** button.
3. Remove the programming head and instruct the patient to begin exercising for at least two minutes, but no longer than 25 minutes. The programmer displays a two minute time progress bar.
4. Once the patient has finished exercising, reposition the programming head.
5. Select the **[Retrieve Data]** button (see Figure 8-2). After the programmer retrieves the data from the pacemaker, the programmer opens the Results screen.

Note: If you decide to stop the Exercise test, select the **[Abort Test]** button. A message instructs you to reposition the programming head and select the **[Restore Settings]** button to reconfigure the pacemaker's previous diagnostic data collection settings.

Rate Response setup

Using Exercise test to verify Rate Response

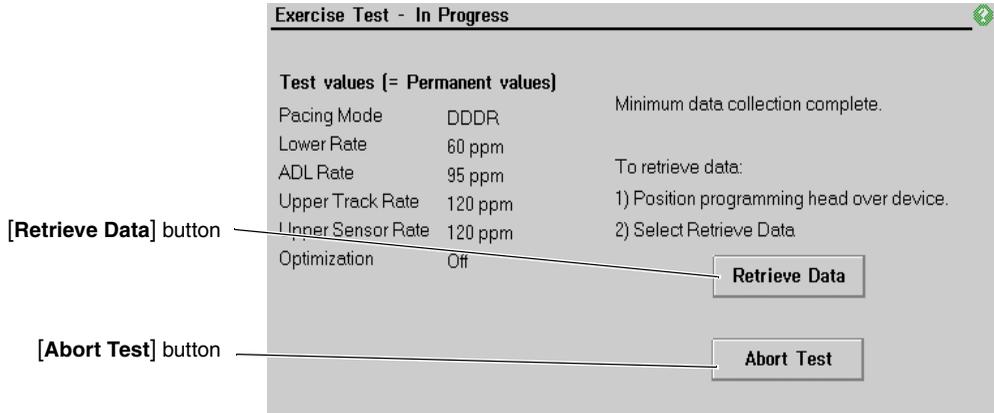


Figure 8-2. Retrieving Exercise Test data

Evaluating the results of the Exercise Test

The Results screen displays the test data results, represented by an atrial rate trend graph (or a ventricular rate trend for single chamber ventricular modes or the VDD mode). The graph displays the projected sensor rate and the actual heart rate (consisting of both sensed and paced events). The graph is based on the current rates and rate response parameter settings.

Select rates and optimization settings

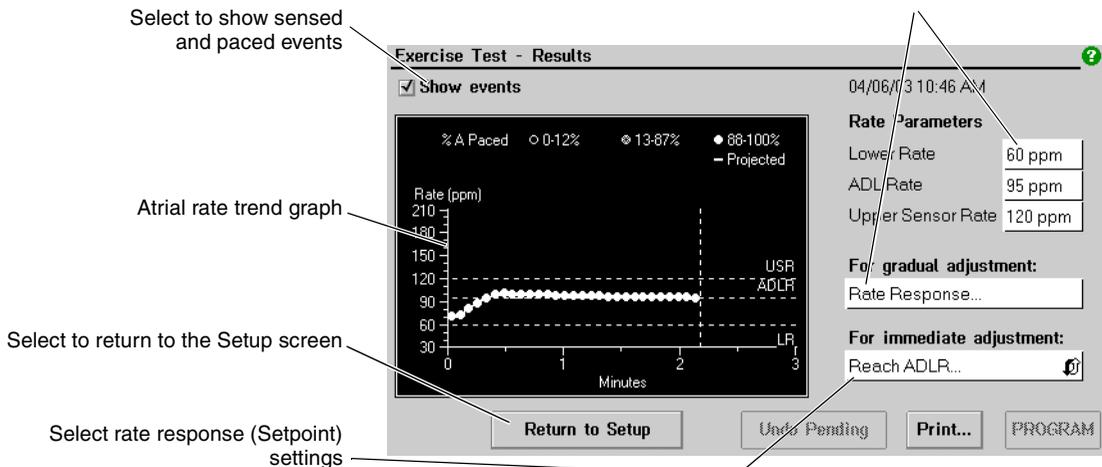


Figure 8-3. Evaluating Exercise Test results

If the evaluation of the heart rate trend and sensor rate trend indicate that a change to rate response is required, you can program the pacemaker to gradually adjust rate response (under the Rate Response... field) or program a change to rate response immediately (under the Reach ADLR... field).

Gradually adjusting Rate Response

In most cases, rate response can be adjusted by changing the rates or Rate Profile Optimization settings and allowing the pacemaker to gradually adjust rate response.

Note: Rate Profile Optimization must be On for the pacemaker to adjust rate response.

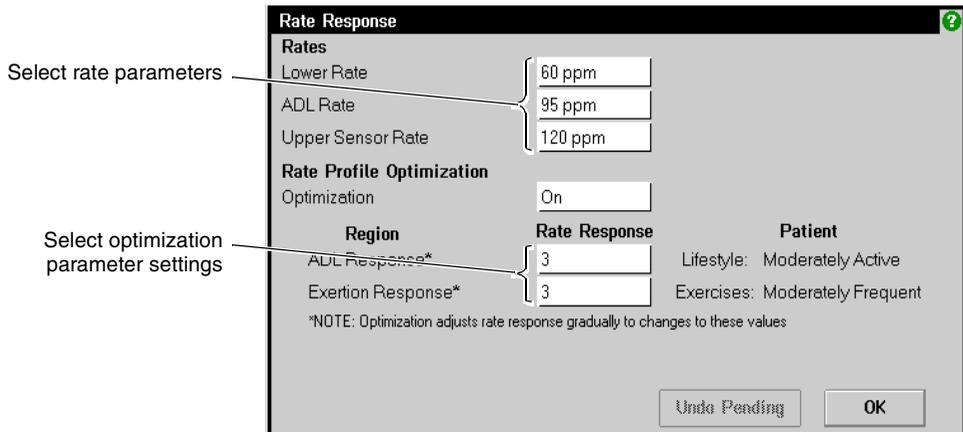


Figure 8-4. Selecting rates and optimization parameters

◆ To gradually adjust Rate Response

1. Select the Rate Response field on the Results screen. The Rate Response window will open.
2. From the Rate Response window, verify that the Lower Rate, ADL Rate, and Upper Sensor Rate values are appropriate.
 - a. If you change one or more of the rates, select the [OK] button and go to step 5. For your review, the programmer adjusts the sensor rate curve on the trend graph relative to the new rates.
 - b. If the rates are appropriate, go to step 3.

Rate Response setup

Using Exercise test to verify Rate Response

3. Select new settings for the ADL Response and Exertion Response parameters (see Table 8-1 for guidelines). The Patient column indicates the activity and exertion levels for the corresponding parameter setting.
4. When you are finished, select the [OK] button.
5. Select the [Program] button on the Results screen to invoke the new settings.

Note: Changes in the rates or Rate Profile Optimization settings do not result in immediate changes to rate response. Instead, the pacemaker gradually adjusts rate response to the new settings over the next few weeks.

Table 8-1. ADL Response and Exertion Response guidelines

Rate region		Select settings
		ADL Response
Submaximal or moderate rates	Rate response too aggressive	Lower number (less active)
	Rate response too low	Higher number (more active)
		Exertion Response
Maximal or high rates	Rate response too aggressive	Lower number (less frequent exertion)
	Rate response too low	Higher number (more frequent exertion) ^a

^a If a higher Exertion Response setting has not produced the desired rate response, increase the ADL Response setting.

Immediately adjusting Rate Response

If immediate adjustment to rate response is required, rate response can be changed by selecting the Reach ADLR field on the Results screen.

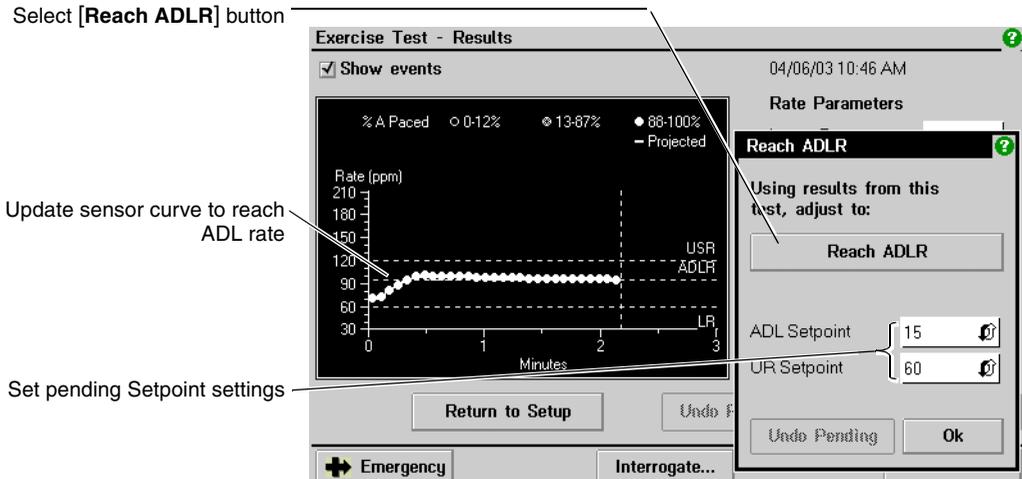


Figure 8-5. Selecting the Reach ADLR button



To immediately set Rate Response

1. Select the Reach ADLR field on the Results screen. The Reach ADLR window will open.
2. From the Reach ADLR window, select the **[Reach ADLR]** button.

The programmer chooses an ADL Setpoint setting that allows the rate to reach the ADL rate for the completed exercise activity. It also chooses a corresponding UR Setpoint setting for higher rates.

For your review, the programmer updates the sensor rate curve on the trend graph using the new setpoint settings and the current test data (Figure 8-5).

Note that you can also select specific ADL Setpoint and UR Setpoint settings.

3. When you are finished, select the **[OK]** button.
4. With Rate Profile Optimization On, a pop-up window warns you that the setpoint parameters may be modified automatically by the pacemaker. To continue, select the **[OK]** button.

Rate Response setup

Using Exercise test to verify Rate Response

5. Select the [**PROGRAM**] button on the Results screen to invoke the new settings. Rate response will immediately begin operating at these new response levels.

Note: Under certain clinical situations, it may be necessary to select new ADL Response and Exertion Response settings to prevent Rate Profile Optimization from dramatically changing the new setpoint settings. Refer to Table 8-1 for guidelines to change the ADL Response and Exertion Response settings.

Refer to the *EnPulse Pacemaker Reference Guide* for further information on the operation of rate response and Rate Profile Optimization.

Using the EP Studies function

9

This chapter describes the EP Studies test function and provides instructions for using each of the three stimulation protocols, PES, Burst, and VOO Burst.

About the EP Studies function 9-2

Starting the EP Studies function 9-9

Setting up and executing a PES protocol 9-16

Setting up and executing a Burst protocol 9-21

Setting up and executing a VOO Burst 9-25

PES parameter definitions and values 9-27

Burst parameter definitions and values 9-30

About the EP Studies function

EP (Electrophysiologic) Studies is a special function of the Medtronic 9790/C series and 2090 programmers that allows you to use the patient's implanted pacemaker to noninvasively deliver high-rate cardiac stimulation. Programmable mode, interval, and delay parameters allow you to set up protocols for delivering either programmed electrical stimulation (PES) or burst stimulation.

Intended use

The EP Studies function is intended for use in measuring or assessing conduction properties of the heart and inducing or terminating tachyarrhythmias. The EP Studies function covered in this chapter applies only to EnPulse pacemakers.

General Warning

The EP Studies function is intended for use only by those trained in electrophysiologic studies. The stimulation options of this function should be applied only under conditions of careful patient monitoring and control. High-rate stimulation of the ventricles can result in ventricular fibrillation. An external defibrillator should be placed on standby and be kept immediately available during the use of the EP Studies function.

Precautions and considerations

The following precautions and important considerations apply to using the EP Studies function.

Loss of clinician-selected diagnostic data

Starting EP Studies disables and clears EGM data collected for the clinician-selected diagnostic. You should interrogate the diagnostic data before using EP Studies. Once interrogated, the collected data are available on the programmer throughout the patient session, but are lost when you end the session.

EGM collection remains off until it is reprogrammed to the desired type (see "Ending the patient session" on page 9-4). Using EP Studies does not affect automatic (non-selectable) diagnostic data collection functions.

Using VOO Backup ventricular pacing

The VOO Backup option delivers *asynchronous* pacing to the ventricles during atrial stimulation. These pacing stimuli may compete with intrinsic ventricular activity. Refer to page 9-8 for information about using the VOO Backup pacing option.

Pacemaker battery condition

At reduced pacemaker battery capacity, execution of a PES or burst protocol can result in a significant temporary decrease in pacemaker battery voltage. See “Viewing information about achievable stimulus amplitudes” on page 9-14.

Selecting an appropriate amplitude setting

Selecting an amplitude setting of 7.5 volts for high-rate stimulation is not recommended. While this setting can provide the maximum available output, its use can result in a significant temporary decline in output voltage. An output setting of 6.0 volts or less, as shown in the Achievable Amplitudes window (page 9-14), will reduce battery drain and can provide a more constant output during protocol delivery.

Pulse amplitude information based on battery and lead measurements interrogated from the pacemaker can be displayed by selecting the  button labeled “Amplitudes” on the protocol setup screen. The chart listing achievable amplitudes versus rate is intended as a guide for selecting stimulus amplitude settings (see “Viewing information about achievable stimulus amplitudes” on page 9-14).

Positioning the programming head

During delivery of a PES protocol or burst stimulation, the programming head must be held steady in its proper position over the patient’s pacemaker. Movement of the programming head can result in abrupt termination of the stimulation sequence. Lifting the programming head at any time during the use of an EP Studies function causes the pacemaker to return to its permanently programmed state.

Interruption of marker telemetry

The communication between the programmer and pacemaker momentarily interrupts the transmission of marker telemetry. This interruption can result in missing markers on the trace display and the chart recording.

Using the EP Studies function
About the EP Studies function

Symbols appearing on the recording above the ECG trace indicate the point at which communication occurred.

▼ = Programming or interrogation command to the pacemaker.

▲ = Telemetry response from the pacemaker.

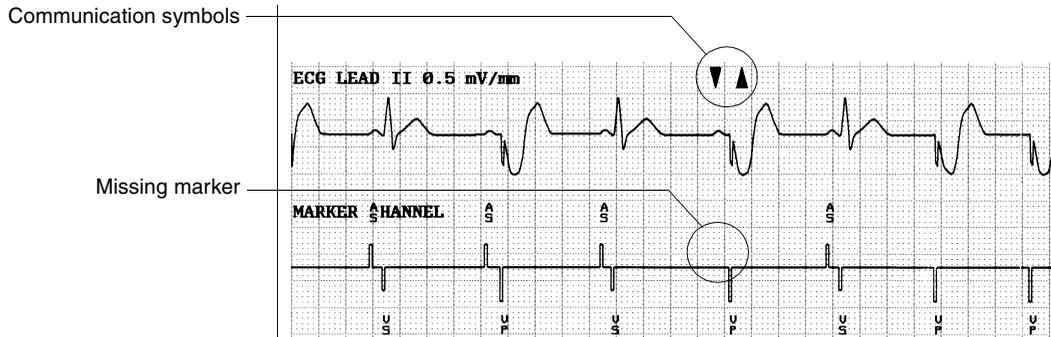


Figure 9-1. ECG recording example showing a missing marker

Ending the patient session

Reprogramming the pacing mode – If you programmed the pacemaker from a rate responsive mode as required to access the EP Studies function, reprogram the pacemaker to the desired mode and parameter settings prior to ending the session.

Reprogramming diagnostic data collection – As previously stated, using EP Studies disables *clinician-selected* diagnostic EGM collection, if programmed on (see “Loss of clinician-selected diagnostic data” on page 9-2). EGM collection will remain off unless you reprogram the desired EGM collection type option. Reprogram this option *after* you finish using EP Studies, but *before* you end the patient session.

Protocol options

The EP Studies function provides three protocol options for delivering cardiac stimulation.



Sections on the following pages describe each of these protocols. For a complete list of the programmable parameters and value options, refer to:

- “PES parameter definitions and values” on page 9-27
- “Burst parameter definitions and values” on page 9-30

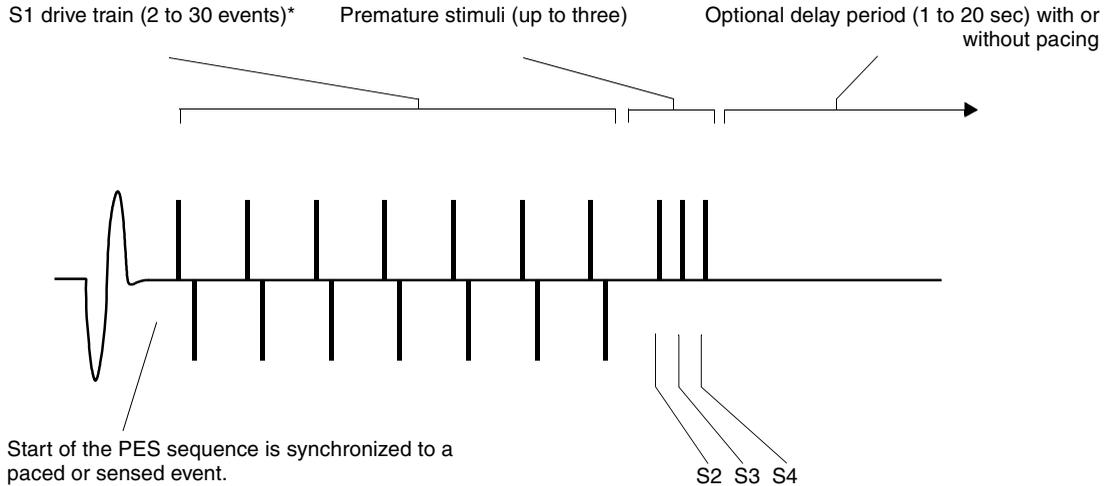
The PES protocol

Selecting the PES protocol displays parameter options for setting up a programmed stimulation sequence that includes:

- A drive train of up to 30 stimuli (S1).
- Up to three premature stimuli (S2, S3, and S4).
- An optional delay period with or without pacing stimuli.
- A “Scan” option that causes the PES sequence (and delay period) to automatically repeat. You can set the interval of the last premature stimulus to decrease with each repetition.
- Optional asynchronous backup ventricular pacing during atrial stimulation (dual chamber models)¹.

¹ Backup ventricular pacing is not available for VDD models.

Using the EP Studies function
About the EP Studies function



* In this example, the S1 drive train is delivered in a dual chamber mode.

Figure 9-2. Elements of the PES protocol

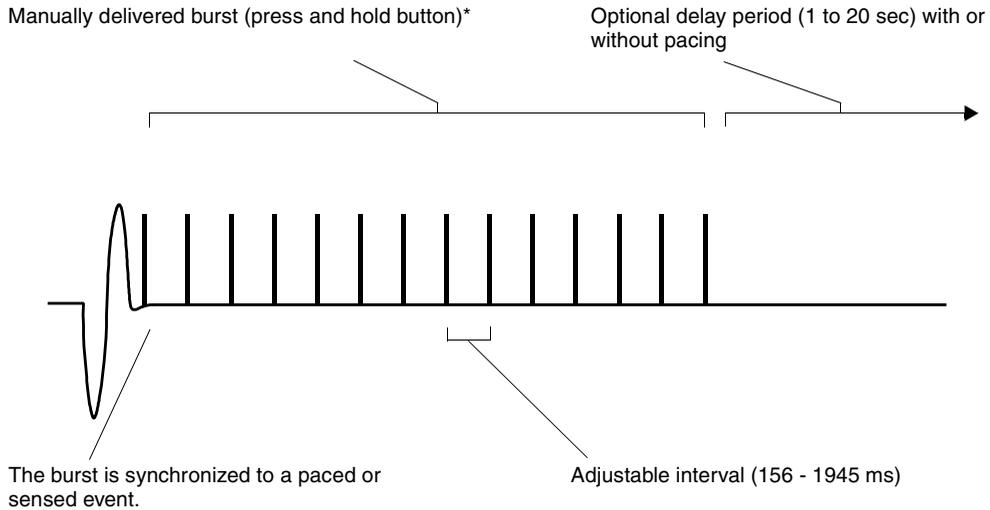
The Burst protocol

Selecting the Burst protocol displays options for setting up a manually-delivered asynchronous burst. Options include:

- An adjustable burst interval of 156 to 1945 ms (30 to 384 min⁻¹).
- Chamber selection (AOO¹ or VOO mode) for dual chamber models.
- An optional delay period with or without pacing stimuli.
- Optional asynchronous backup ventricular pacing during atrial stimulation (dual chamber models)².

¹ AOO is not available for VDD models.

² This does not apply to VDD models.



* With dual chamber models, stimuli can be delivered to the atrial chamber or the ventricular chamber.

Figure 9-3. Elements of the Burst protocol

The VOO Burst protocol

The VOO Burst option applies only to dual chamber models¹ and provides for quick setup of a basic stimulation protocol for the ventricles.

- The burst interval is adjustable from 156 to 1945 ms (30 to 384 min⁻¹).
- No chamber selection. The burst mode is fixed as VOO.
- The option to select a delay period does not apply.

¹ This does not apply to VDD models.

Using the EP Studies function

About the EP Studies function

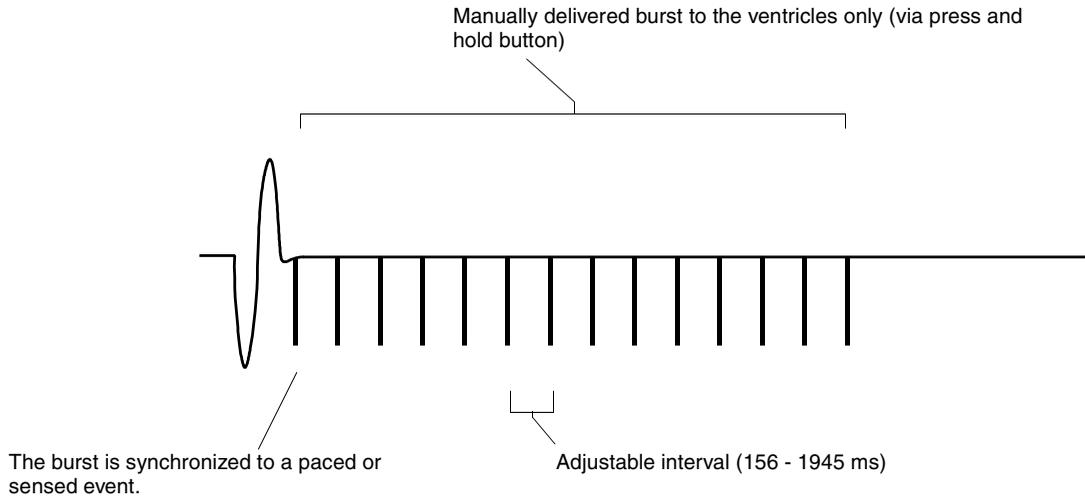


Figure 9-4. Elements of the VOO Burst protocol

Using VOO Backup pacing

Caution: The VOO Backup option delivers *asynchronous* pacing to the ventricles (during atrial stimulation). These pacing stimuli may compete with intrinsic ventricular activity.

Note: Setting the VOO Backup option to On restricts the S1 Mode, S2S3S4 Mode, and Burst Mode to AOO. Selecting VOO Backup for a PES protocol also enables it for the burst protocols.

What VOO Backup pacing does

VOO Backup pacing applies only to dual chamber pacemakers¹. Its purpose is to provide ventricular pacing support during atrial stimulation. Ventricular pacing otherwise is disabled during the execution of atrial stimulation and the inhibited delay period, if selected.

During atrial stimulation – During atrial stimulation (PES or burst), each ventricular pacing pulse is synchronized to an atrial stimulus with an intervening AV interval of 50 ms. To ensure that the backup pacing rate does not exceed 105 min⁻¹, the pacemaker automatically selects a ratio between the ventricular and atrial outputs to keep pacing rate within the range shown in Table 9-1.

¹ This does not apply to VDD models.

Table 9-1. VOO Backup Ventricular Pacing Rate

A-to-A Interval (ms)	Ratio (A-to-V Rate)	Vent. Rate (min ⁻¹)
≥ 570	1:1	30 - 105
313 - 563	2:1	53 - 96
211 - 305	3:1	66 - 95
156 - 203	4:1	74 - 96

During an inhibited delay – Pacemaker output is turned off during an inhibited delay period unless VOO Backup is enabled. If VOO Backup is enabled, the atrial output remains inhibited, but the ventricles are paced synchronously in the VDI mode at the programmed lower rate.

Starting the EP Studies function

Note the following requirements and restrictions before you begin the EP Studies start-up procedure.

Pacing mode restrictions

Access to the EP Studies protocols is not permitted if the present pacing mode is a *rate responsive* mode (DDDR, DDIR, DVIR, DOOR, VVIR, VDIR, VOOR, AAIR, ADIR, AOOOR) or a *non-pacing* mode (ODO, OVO, OAO).

If one of these modes is presently programmed, you must reprogram the pacemaker to another mode prior to selecting the EP Studies option.

Pacemaker operating-status restrictions

Any of the following operating conditions also prevents access to the EP Studies protocols.

- **ERI (Elective Replacement Indicator)** — If the pacemaker is at ERI status, you cannot access the EP Studies protocols unless you can clear this condition (ERI/POR Reset parameter).
- **Electrical Reset (POR)** — If an electrical reset has occurred, you must clear this condition (ERI/POR Reset parameter) before you select the EP Studies function.

Using the EP Studies function
Starting the EP Studies function

- **Implant Detection** — You cannot access the EP Studies protocols during the 30-minute Implant Detection period that begins with lead connection during pacemaker implantation.

Positioning the programming head

During the start-up procedure, the programmer must perform an interrogation and transfer, or “download,” a set of instructions to the pacemaker. This process (called “initialization”) can take up to 30 seconds, during which you must hold the programming head steady over the patient’s pacemaker.

Start-up procedure

To start the EP Studies function, complete the following steps.

1. Position the programming head and continue to hold it steady for the remainder of this procedure.
2. Select **Tests > EP Studies**.

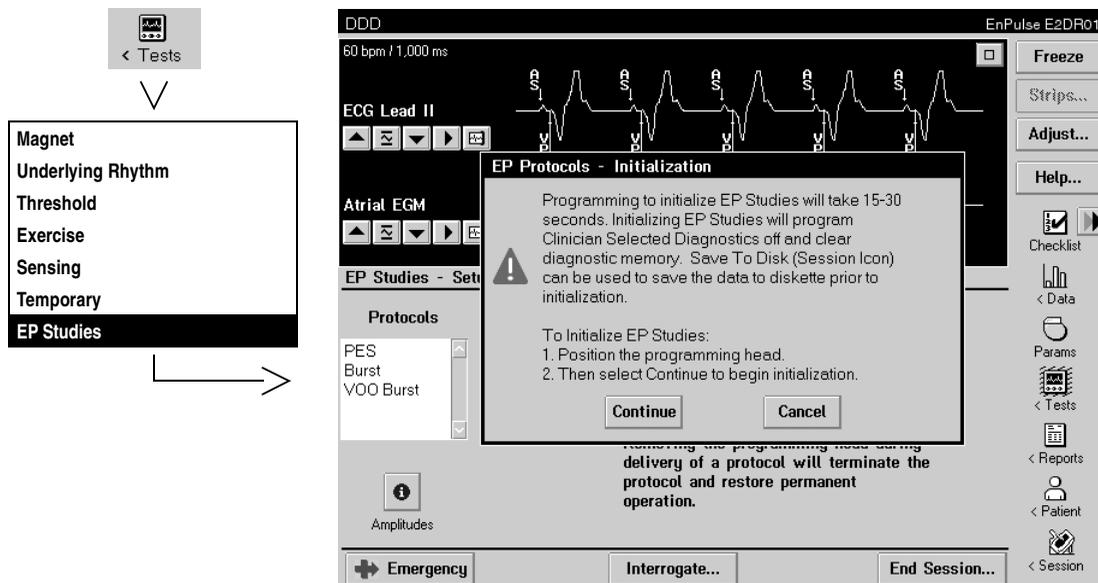


Figure 9-5. EP Studies setup screen

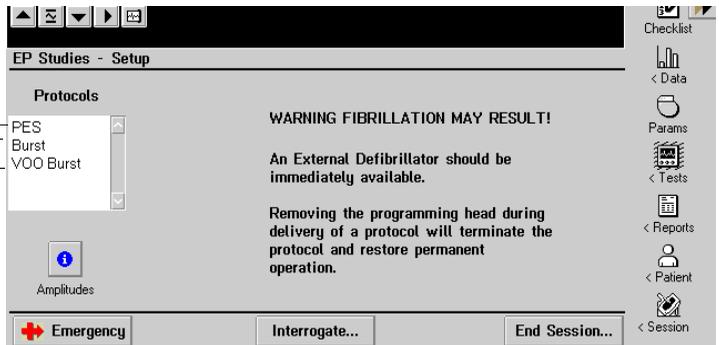
3. When you see the Initialization message window shown in Figure 9-5, select [**Continue**] to proceed with EP Studies. (Select [**Cancel**] if you wish to exit this procedure.) If you see another message, refer to “Explanation of start-up messages” on page 9-12.

Continue to hold the programming head steady until the “initializing” process is complete as indicated on the screen.

To set up a PES protocol, see page 9-16.

To set up a burst protocol, see page 9-21.

For parameter definitions and value options, see “PES parameter definitions and values” on page 9-27 and “Burst parameter definitions and values” on page 9-30.



Note: If you successfully started the EP Studies function previously during the patient session, the PES or Burst protocol screen will be set up as you left it. The screen shown above is displayed only the first time you select the EP Studies function during a session.

This completes the start-up procedure. Refer to “Before you proceed” on page 9-13 before setting up a PES or burst protocol.

Table 9-2. Explanation of start-up messages

1. EP Protocols - Initialization Restricted

Operation of the EP Studies function is restricted by any of the following situations:

- The pacemaker is programmed to rate responsive mode or a non-pacing mode.
- The pacemaker operating status is ERI or Electrical Reset (POR).
- The 30-minute Implant Detection period has not ended.

Action: As indicated in the text of the respective message, you must program the pacing mode temporarily to a different setting or program the ERI/POR Reset command. If Implant Detection is operating, you must wait until the 30-minute period has ended or program the following values: Lead Monitor (Atrial and Ventricular) to Monitor Only or Adaptive and Implant Detection to Off/Complete.

The ERI/POR Reset command is located under “Additional Features” on the Therapy Parameters screen. Lead Monitor is located under Pace/Sense Lead Polarity (Atrial and Ventricular) on the Therapy Parameters screen.

2. Interrogation - Not Complete

An interrogation for diagnostic data collected by the pacemaker has not occurred. If a clinician-selected diagnostic data option with EGM collection has been programmed, the collected EGM is cleared when you start EP Studies.

Action: You must select [**Cancel**] and perform an interrogation for Collected Data before you continue, otherwise the collected EGM will be lost before you have a chance to view or print it.

3. EP Protocols - Cannot be Initialized

The EP Studies initialization process was not successful, perhaps due to interruption of the programming process by interference or movement of the programming head.

Action: Assure that the programming head is properly positioned, then select the [**Retry**] button.

Before you proceed

Note the following information before you proceed to set up and execute a PES or burst protocol.

Protocol timing limitations

Delivery of a PES or burst protocol requires a coordinated series of automatic programming commands, telemetry responses, and processing factors that result in a certain amount of elapse time.

Start of the protocol – A second or two can elapse between selection of the [START PES] button and the start of the stimulation sequence. This time lag accommodates the protocol programming command (as indicated by the ▼ and ▲ symbols above the ECG trace) and synchronization of the first protocol stimulus.

Delay period accuracy – The delay period can be from one second shorter to two permanent pacing intervals longer than the selected time.

Burst count – One or two additional pulses will occur before a burst stops upon release of the [BURST Press & Hold] button.

VOO backup pacing – If VOO Backup is enabled, the mode transition that occurs following delivery of the last stimulus in a PES or Burst sequence can extend that ventricular pacing interval up to 1000 ms longer than the permanent lower rate interval.

Viewing information about achievable stimulus amplitudes

To view the window shown below, which presents achievable stimulus amplitudes versus rate, select the  (information) button labeled “Amplitudes” in the lower left corner of the setup screen.

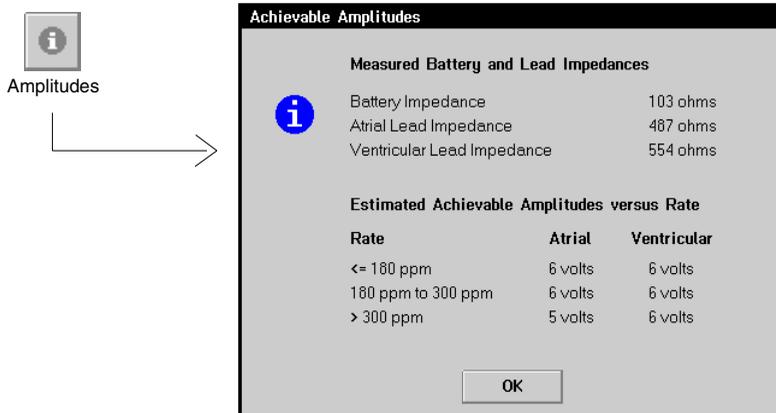


Figure 9-6. Achievable Amplitudes screen

Note: The message “Warning - Old Data” indicates that recent pacing parameter changes may have changed the Achievable Amplitudes information since it was last viewed. Select the [Yes] button if you want the programmer to update the Achievable Amplitude data. Select [No] if you are not using this information.

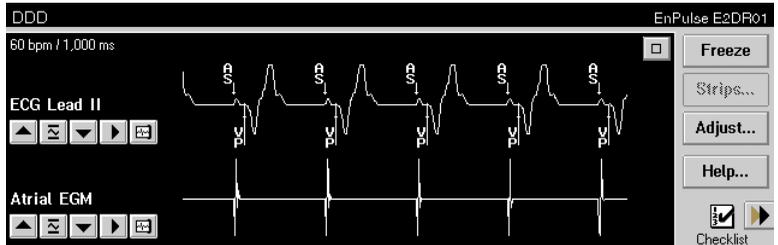
The projected achievable amplitudes are based on the following:

- Measured battery impedance (an indicator of battery condition) and lead impedance.
- The use of single chamber pacing at a pulse width of 1.0 ms (without VOO Backup Pacing) during protocol execution.

This information is intended as a guide for selecting protocol stimulus amplitude settings that should not significantly reduce pacemaker battery output which could abort the protocol execution.

Adjusting the live rhythm display

Prior to executing a protocol, verify that the live rhythm display at the top of the screen shows the desired traces. For information about displaying different traces, see “Changing the trace source” on page 4-8.

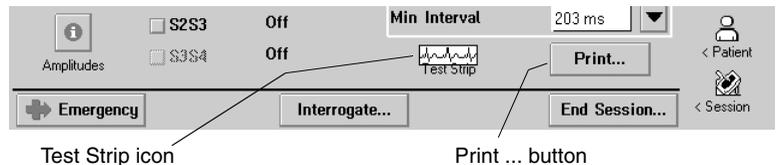


Note: Each time you select the EP Studies function or a different protocol, the live rhythm display adjusts to the following default settings unless the preferences have been set to maintain the current waveform arrangement:

- ECG trace with Markers
- Atrial EGM if the S1 Mode or Burst Mode is an atrial mode or Ventricular EGM if the mode is ventricular and dual chamber.

Protocol ECG strip and printed report

During execution of a PES or burst protocol, the programmer automatically collects and saves a 10-second ECG strip and the protocol parameter test values.



- To view the saved ECG strip, select the Test Strip icon (or the [Strips] button in the Tool Palette). The Test Strip icon appears only when a strip is available for viewing.
- To view options for printing a protocol report, select the [Print...] button. The report includes the protocol parameter test values and an ECG strip. The programmer saves only the most recent use of the PES, Burst, and VOO Burst protocols.

Setting up and executing a PES protocol

Setting up a PES protocol

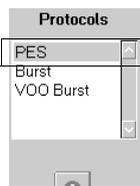
This procedure begins at the EP Studies - PES - Setup screen.

- Refer to “Starting the EP Studies function” on page 9-9 if you have not yet selected the EP Studies function.
- Refer to “PES parameter definitions and values” on page 9-27 for information on the protocol parameters.

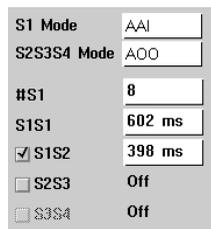
Procedure overview

This procedure is divided into the tasks illustrated in Figure 9-7.

1. Select **PES** from the Protocols list to display the PES setup options.



2. Select the desired values to set up the stimulation sequence.



3.. Select the desired settings in the Additional Test Values box.

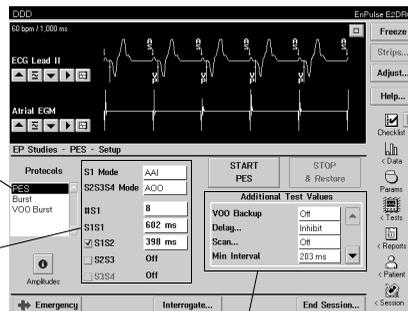
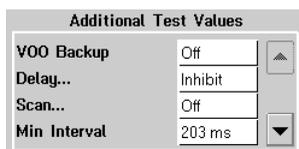


Figure 9-7. The basic tasks for setting up a PES protocol

PES protocol setup procedure

1. If the PES - Setup screen is not displayed (see Figure 9-7), select [PES] from the Protocols list.

The settings you select on this screen will remain selected if you choose to exit the EP Studies function or select another protocol option.

2. Set up the stimulation sequence by selecting a value for each of the parameters in steps **a** through **g** below.
 - a. **S1 Mode** — Select the desired mode for delivery of the S1 drive train.

S1 Mode	AAI
S2S3S4 Mode	A00
#S1	8
S1S1	602 ms
<input checked="" type="checkbox"/> S1S2	398 ms
<input type="checkbox"/> S2S3	Off
<input type="checkbox"/> S3S4	Off

In steps **a** and **b**, select the mode fields to display the mode options.

In steps **c** and **d**, select the parameter field to activate the change buttons. Select the up (^) or down (v) button to increase or decrease the value.

- b. **S2S3S4 Mode** — Select the desired mode for delivery of the premature stimuli.
 - c. **#S1** — Set the number of S1 events in the S1 drive train.
 - d. **S1S1** — Select a value for the S1S1 interval.
- Note:** It may be necessary to adjust the Min Interval setting (Additional Test Values) before you do steps **d**, **e**, **f**, and **g**.
- e. **S1S2** — Enable S2 if desired and set a value for the S1 to S2 interval.

S1 Mode	AAI
S2S3S4 Mode	A00
#S1	8
S1S1	602 ms
<input checked="" type="checkbox"/> S1S2	398 ms
<input checked="" type="checkbox"/> S2S3	398 ms
<input type="checkbox"/> S3S4	Off

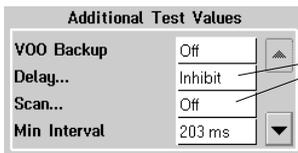
In steps **e**, **f**, and **g**, select the check-box to enable or disable the respective stimulus.

Select the value field of the enabled stimulus to activate the change buttons.

- f. **S2S3** — Enable S3 if desired and set a value for the S2 to S3 interval.
 - g. **S3S4** — Enable S4 if desired and set a value for the S3 to S4 interval.

Using the EP Studies function
Setting up and executing a PES protocol

3. Select a value for each of the parameters displayed in the Additional Test Values box:



Select the parameter value field to display its value options.

- a. **VOO Backup** (dual chamber models) ¹— Selecting the On option forces S1 Mode and S2S3S4 Mode to AOO. You cannot change these mode settings without first changing VOO Backup to Off.

The selected setting also applies to the Burst protocol.

- b. **Delay... (Type and Period)** — Select [**Delay...**] to open a window that lets you select the Delay Type (Off, Pace, or Inhibit) and the Delay Period (1 to 20 sec.).

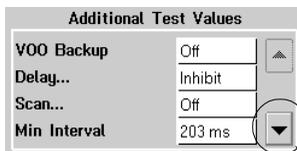
Choose the desired Type and Period by selecting the respective value field.

- c. **Scan...** (and **Scan Decrement**) — Select [**Scan...**] to open a window that lets you select the Scan option (Off or On) and the decrement value (0 to 48 ms).

Choose the desired Scan and Scan Decrement options by selecting the respective value field.

- d. **Min Interval** — Changing this value may affect the present settings for S1S1, S1S2, S2S3, and S3S4.

4. Select the page down arrow to display additional parameters.



¹ This does not apply to VDD models.

5. Select the desired values for Amplitude and Pulse Width. The selected values also apply to the burst protocols.

Caution: Condition of the pacemaker battery should be considered in the selection of a test amplitude. If the stimulus amplitude during execution of the protocol is not within 90 percent of the selected test value, the protocol will stop. A pop-up window will state that the protocol has been aborted because the test amplitude is not being achieved.

Selecting the **[Disable Check]** button in the pop-up window disables the amplitude check for any additional PES or Burst tests conducted during the present EP Studies session.

To view information about achievable amplitudes based on battery and lead impedance measurements, select the  button labeled "Amplitudes."

This completes the setup procedure. Refer to the next section for information on executing the protocol.

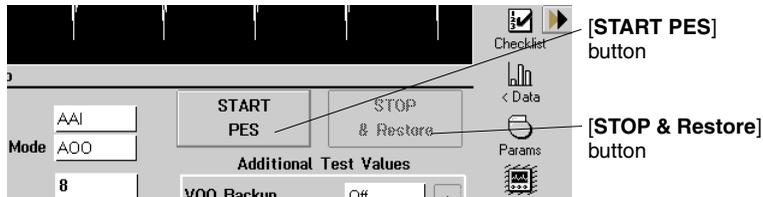
Executing the PES protocol

After you have completed the protocol setup procedure, use the following steps when you want to execute the protocol.

1. Position the programming head and observe that the live rhythm display shows the patient's ECG, markers, and the desired EGM trace.

Caution: Continue to hold the programming head steady in position for the duration of the protocol. The loss or interruption of telemetry during execution of the protocol will abruptly terminate the protocol without warning.

2. To initiate the protocol, select the **[START PES]** button.



The sequence begins with synchronization of the first S1 stimuli to a paced or sensed event. The status bar at the top of the screen indicates whether the protocol is “stimulating” or “delaying” and shows a countdown of the seconds remaining in the delay.

Note: You can adjust the S1 count (#S1) and stimulus intervals during the protocol delivery. The new settings take effect on the next automatic or manual execution of the protocol.

If you selected Scan, the protocol will continue to repeat until you select the **[STOP & Restore]** button.

3. To stop the protocol, select the **[STOP & Restore]** button.

Lifting the programming head also stops the protocol and returns the pacemaker to its permanently programmed state.

Setting up and executing a Burst protocol

Setting up a Burst protocol

This procedure begins at the EP Studies - Burst - Setup screen.

- Refer to “Starting the EP Studies function” on page 9-9 if you have not yet selected the EP Studies function.
- Refer to “Burst parameter definitions and values” on page 9-30 for information on the protocol parameters.

Procedure overview

This procedure is divided into the tasks illustrated in Figure 9-8.

1. Select **Burst** from the Protocols list to display the burst setup options.

2. Select the burst mode (if applicable) and the burst stimulus interval.

3. - 5. Select the desired settings in the Additional Test Values box.

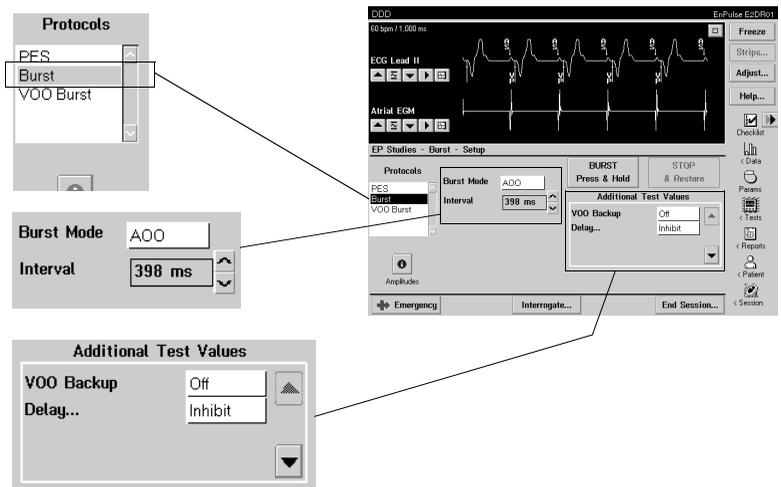


Figure 9-8. The basic tasks for setting up a Burst protocol

Burst Protocol setup procedure

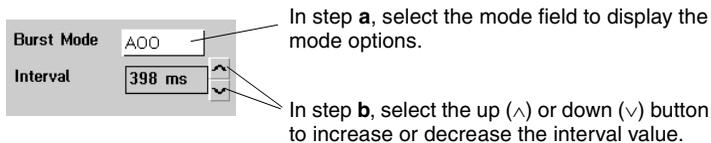
1. If the Burst - Setup screen is not displayed (see Figure 9-8), select **Burst** from the Protocols list.

The settings you select on this screen will remain selected if you choose to exit the EP Studies function or select another protocol option.

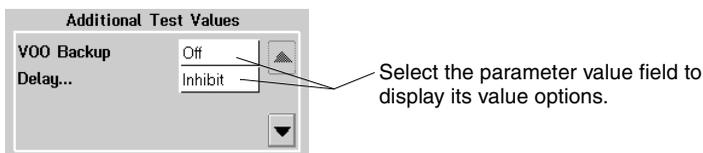
Using the EP Studies function

Setting up and executing a Burst protocol

2. Choose the desired burst setting(s).
 - a. **Burst Mode** — If the pacemaker is a dual chamber model, select the desired setting for Burst Mode¹.



- b. **Interval** — Select the desired interval for the burst stimuli.
3. Select a value for each of the parameters displayed in the Additional Test Values box:

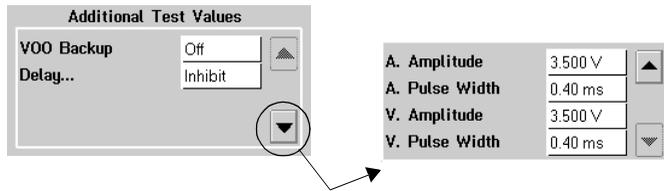


- a. **VOO Backup** (dual chamber models)¹ — Selecting the On option forces Burst Mode to AOO. You cannot change this mode setting without first changing VOO Backup to Off.
The selected setting also applies to PES protocol.
 - b. **Delay...** (Type and Period) — Select [**Delay...**] to open a window that lets you choose the Delay Type (Off, Pace, or Inhibit) and the Delay Period (1 to 20 sec.).
Choose the desired Type and Period by selecting the respective value field.

¹ This does not apply to VDD models.

Using the EP Studies function
Setting up and executing a Burst protocol

4. Select the page down arrow to display additional parameters.



5. Select the desired values for Amplitude and Pulse Width. The selected values also apply to the PES and VOO Burst protocols.

Caution: Condition of the pacemaker battery should be considered in the selection of a test amplitude. If the stimulus amplitude during execution of the protocol is not within 90 percent of the selected test value, the protocol will stop. A pop-up window will state that the protocol has been aborted because the test amplitude is not being achieved.

Selecting the **[Disable Check]** button in the pop-up window disables the amplitude check for any additional PES or Burst tests conducted during the present EP Studies session.

To view information about achievable amplitudes based on battery and lead impedance measurements, select the  button labeled "Amplitudes."

This completes the setup procedure. Refer to the next section for information on executing the protocol.

Executing the Burst protocol

After you have completed the protocol setup procedure, use the following steps when you want to execute the protocol.

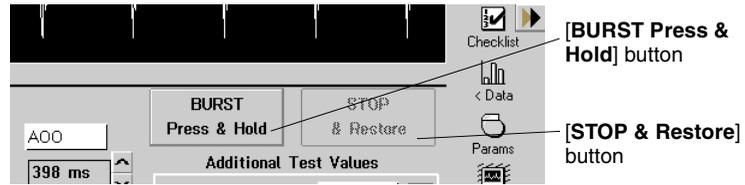
1. Position the programming head and observe that the live rhythm display shows the patient's ECG, markers, and the desired EGM trace.

Caution: Continue to hold the programming head steady in position for the duration of the protocol. The loss or interruption of telemetry during execution of the protocol will abruptly terminate the protocol without warning.

Using the EP Studies function

Setting up and executing a Burst protocol

2. To deliver the burst, select the **[BURST Press & Hold]** button and continue pressing for as long as you want the burst to continue.



The burst starts with synchronization of the first stimulus to a paced or sensed event. The status bar at the top of the screen indicates the burst stimulus count.

Note: In preparation for executing another burst at a different stimulus interval, you can adjust the interval setting during the delay period, if one has been selected.

3. To stop the burst, release the **[BURST Press & Hold]** button.

To interrupt the delay period, select the **[STOP & Restore]** button.

Lifting the programming head also stops the burst and returns the pacemaker to its permanently programmed state.

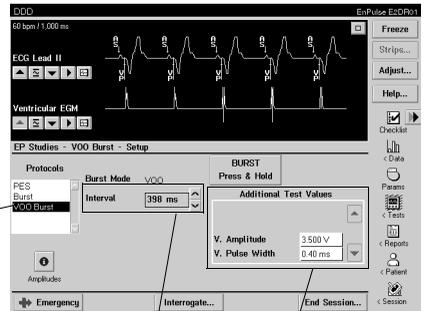
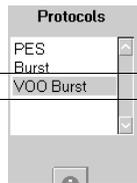
Setting up and executing a VOO Burst

VOO Burst is a simplified protocol that is quick and easy to set up. This protocol applies only to dual chamber models¹.

Setup procedure

To setup the VOO Burst protocol, complete the following three steps. For details about selecting parameter settings, refer to the applicable parts of the Burst setup procedure starting on page 9-21.

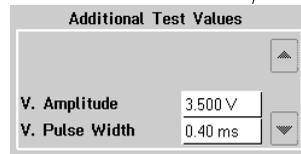
1. Select **VOO Burst** from the Protocols list to display the setup options.



2. Select the desired burst stimulus interval.



3. Select the desired settings for Amplitude and Pulse Width.



The interval setting you select on this screen will remain selected if you choose to exit the EP Studies function or select another protocol option. Since Amplitude and Pulse Width are common to all protocols, these parameters will be at their most recent settings.

¹ This does not apply to VDD models.

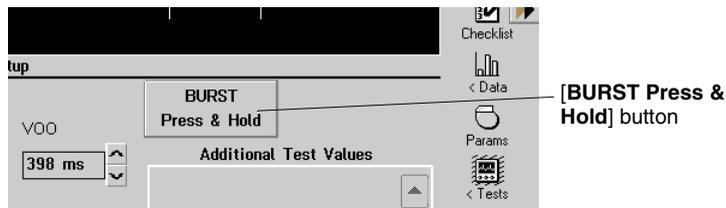
Executing a VOO Burst

After you have completed the protocol setup, use the following steps when you want to execute the protocol.

1. Position the programming head and observe that the live rhythm display shows the patient's ECG, markers, and the desired EGM trace.

Caution: Continue to hold the programming head steady in position for the duration of the protocol. The loss or interruption of telemetry during execution of the protocol will abruptly terminate the protocol without warning.

2. To deliver the burst, select the **[BURST Press & Hold]** button and continue pressing for as long as you want the burst to continue.



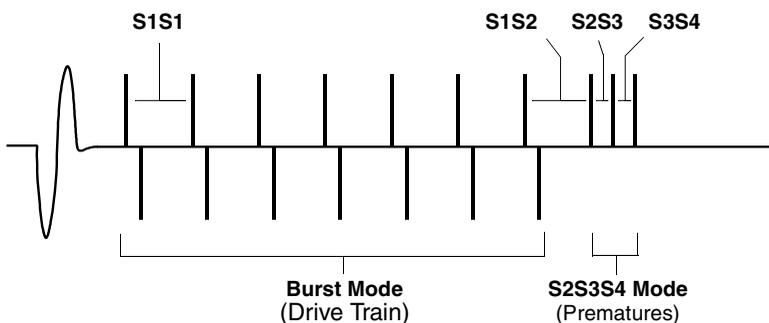
The burst starts with synchronization of the first stimulus to a paced or sensed event. The status bar at the top of the screen indicates the burst stimulus count.

3. To stop the burst, release the **[BURST Press & Hold]** button.

Lifting the programming head also stops the burst and returns the pacemaker to its permanently programmed state.

PES parameter definitions and values

PES parameter definitions



S1 Mode	The mode used for delivering the S1 drive train. The first S1 interval is synchronized to a sensed or paced event. If the permanent mode is a dual chamber mode, the first interval is synchronized to a ventricular event.
S2S3S4 Mode	For dual chamber pacemakers ^a , this mode (AOO or VOO) determines the chamber in which the S2, S3, and S4 premature stimuli are delivered.
#S1	The number of events in the S1 drive train. Both paced and sensed events are counted. Only events in the paced chamber are counted. If the S1 mode is a dual chamber mode, events are counted in the chamber specified by the S2S3S4 Mode.
S1S1	The interval at which S1 stimuli are delivered.
S1S2	The interval between the last event of the S1 drive train and delivery of the S2 stimulus.
S2S3	The interval between S2 and S3.
S3S4	The interval between S3 and S4.
VOO Backup	If the pacemaker is a dual chamber model (this does not apply to VDD models), this parameter provides for asynchronous backup ventricular pacing during the execution of atrial stimulation and the Inhibit delay period, if selected. The settings for S1 Mode and S2S3S4 Mode are forced to AOO. These settings cannot be changed while VOO Backup is enabled. During atrial stimulation, each ventricular pacing pulse is synchronized to an atrial stimulus with an intervening AV interval of 50 ms. The pacemaker automatically selects a ratio between the ventricular and atrial outputs to keep pacing rate within the range of 30 to 105 min ⁻¹ (see Table 9-1 on page 9-9). During an Inhibit delay period, ventricular pacing is delivered synchronously in the VDI mode at the programmed lower rate.

Using the EP Studies function
PES parameter definitions and values

Delay... Type	<p>Selects the type of delay period (Off, Pace, or Inhibit) that follows delivery of the stimulation sequence.</p> <p>Off — No delay period will occur.</p> <p>Pace — The pacemaker operates in the present permanent mode and rate during the delay period. Amplitude and pulse width are at the PES protocol settings.</p> <p>Inhibit — Pacemaker output is inhibited during the delay period, unless VOO Backup is enabled (see VOO Backup above).</p>
Delay... Period	<p>The number of seconds following the stimulation sequence during which the pacemaker operates according to the selected Delay Type of Pace or Inhibit. Delay period does not apply if Delay Type is Off.</p>
Scan	<p>Setting Scan to On causes the PES sequence including the delay period (if selected) to repeat automatically until the protocol is terminated.</p>
Scan... Decrement	<p>Applies only if Scan is set to On. Scan Decrement sets the amount by which the interval of the last premature stimulus in the sequence is reduced each time the sequence repeats. Scan Decrement does not apply to S1 interval.</p>
Min Interval	<p>As a safety feature, this parameter sets the minimum interval that can be used in the delivery of a PES protocol.</p> <p>Increasing this parameter value after you have selected intervals for the protocol stimuli will adjust any of these intervals if they do not comply with the new Min Interval setting.</p>
Amplitude (A and V)	<p>The pulse amplitude at which stimuli in a protocol are delivered. The selected value applies to all protocols (PES, Burst, and VOO Burst.)^b</p>
Pulse Width (A and V)	<p>The pulse width at which stimuli in a protocol are delivered. The selected value applies to all protocols (PES, Burst, and VOO Burst.)^b</p>

^a The mode is VOO for VDD models.

^b Atrial Amplitude and Atrial Pulse Width do not apply to the VOO Burst protocol.

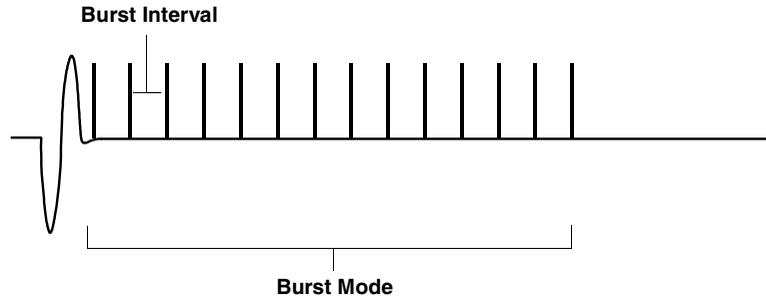
PES parameter values

S1 Mode	<p>Dual Chamber Models: AAI, AAT, AOO, ADI, VVI, VVT, VOO, VDI, <ul style="list-style-type: none"> • and DDD, DDI, DOO, VDD if the permanent mode is DDD • and DDI, DOO if the permanent mode is DDI • and DOO if the permanent mode is DOO </p> <p>VDD Models VVI, VVT, VOO, VDI <ul style="list-style-type: none"> • VDD if permanent mode is VDD </p> <p>Single Chamber Models: AAI, AAT, AOO, or VVI, VVT, VOO (based on programmed mode)</p>
S2S3S4 Mode	<p>Dual Chamber Models: AOO, VOO VDD Models: VOO Single Chamber Models: AOO or VOO (based on permanent mode)</p>
#S1	2 to 30
S1S1	156 to 1945 ms (in 7 or 8 ms steps)
S1S2	156 to 1945 ms (in 7 or 8 ms steps), Off
S2S3	156 to 1945 ms (in 7 or 8 ms steps), Off
S3S4	156 to 1945 ms (in 7 or 8 ms steps), Off
VOO Backup	Off, On (dual chamber models) ^a
Delay Type	Off, Pace, Inhibit
Delay Period	1 to 20 seconds
Scan	Off, On
Scan Decrement	0 to 48 ms (in 8 ms steps)
Min Interval	156 to 398 ms
Amplitude (A^a and V)	0.250, 0.500, 0.750, 1.000, 1.250, 1.500, 1.750, 2.000, 2.250, 2.500, 2.750, 3.000, 3.250, 3.500, 3.750, 4.000, 4.500, 5.000, 5.500, 6.000, 7.500 V
Pulse Width (A^a and V)	0.03, 0.06, 0.09, 0.12, 0.15, 0.21, 0.27, 0.34, 0.40, 0.46, 0.52, 0.64, 0.76, 1.0, 1.25, 1.5 ms

^a This does not apply to VDD models.

Burst parameter definitions and values

Burst parameter definitions



Note: Of the following parameters, only Interval, V Amplitude, and V Pulse Width apply to the VOO Burst protocol.

Burst Mode	The mode used for delivering the burst stimuli (not programmable in single chamber models). This mode applies to VDD models.
Interval	The interval at which the burst stimuli are delivered.
VOO Backup	<p>If the pacemaker is a dual chamber model^a, this parameter provides for backup ventricular pacing during atrial stimulation and the Inhibit delay period, if selected. The setting for Burst Mode is forced to AOO. This setting cannot be changed while VOO Backup is enabled.</p> <p>During atrial stimulation, each ventricular pacing pulse is synchronized to an atrial stimulus with an intervening AV interval of 50 ms. The pacemaker automatically selects a ratio between the ventricular and atrial outputs to keep pacing rate within the range of 30 to 105 min⁻¹ (see Table 9-1 on page 9-9). During an Inhibit delay period, ventricular pacing is delivered synchronously in the VDI mode at the programmed lower rate</p>
Delay... Type	<p>Selects the type of delay period (Off, Pace, or Inhibit) that follows delivery of the burst stimulation.</p> <p>Off — No delay period will occur.</p> <p>Pace — The pacemaker operates in the present permanent mode and rate during the delay period. Amplitude and pulse width are at the burst protocol settings.</p> <p>Inhibit — Pacemaker output is inhibited during the delay period, unless VOO Backup is enabled (see VOO Backup above).</p>
Delay... Period	The number of seconds following the stimulation sequence during which the pacemaker operates according to the selected Delay Type of Pace or Inhibit. Delay period does not apply if Delay Type is Off.

Amplitude (A^a and V)

The pulse amplitude at which stimuli in a protocol are delivered. The selected value applies to all protocols (PES, Burst, and VOO Burst).

Pulse Width (A^a and V)

The pulse width at which stimuli in a protocol are delivered. The selected value applies to all protocols (PES, Burst, and VOO Burst).

^a This does not apply to VDD models.

Burst parameter values

Note: Of the following parameters, only Interval, V Amplitude, and V Pulse Width apply to the VOO Burst protocol. VOO Burst does not apply to VDD models.

Burst Mode	Dual Chamber Models: AOO, VOO VDD Models: VOO Single Chamber Models: Fixed based on permanent mode (VOO, AOO)
Interval	156 to 1945 ms (in 7 or 8 ms steps)
VOO Backup^a	Off, On (dual chamber models)
Delay Type	Off, Pace, Inhibit
Delay Period	1 to 20 seconds
Amplitude (A^a and V)	0.250, 0.500, 0.750, 1.000, 1.250, 1.500, 1.750, 2.000, 2.250, 2.500, 2.750, 3.000, 3.250, 3.500, 3.750, 4.000, 4.500, 5.000, 5.500, 6.000, 7.500 V
Pulse Width (A^a and V)	0.03, 0.06, 0.09, 0.12, 0.15, 0.21, 0.27, 0.34, 0.40, 0.46, 0.52, 0.64, 0.76, 1.0, 1.25, 1.5 ms

^a This does not apply to VDD models.

Appendix: Parameter values and restrictions

A

This appendix provides programmable parameter and data collection capabilities for EnPulse pacemakers. In addition, it provides information on programming restrictions for pacemaker parameters.

Programmable modes and parameters A-2

Automatic and clinician-selectable diagnostics A-14

Programming restrictions A-19

Programmable modes and parameters

Parameter settings shown in Table A-1 through Table A-12 are listed by an EnPulse model series. Each model series represents the following model numbers:

- E2DR00 Series → Models E2DR01, E2DR03, E2DR06, E2DR21, E2DR31, E2DR33
- E2D00 Series → Models E2D01, E2D03
- E2VDD00 Series → Models E2VDD01
- E2SR00 Series → Models E2SR01, E2SR03, E2SR06

Caution: When programming Upper Tracking Rates of 190, 200, or 210 min⁻¹, be careful to ensure that these rates are appropriate for the patient. The Upper Tracking Rates of 190, 200, and 210 min⁻¹ are intended primarily for use in pediatric patients.

Table A-1. Mode and rates

Parameter	Series	Settings	Tolerances	Notes
Mode	E2DR00	DDDR, DDD, DDIR, DDI, DVIR, DVI, DOOR, DOO, VDD, VVIR, VDIR, VVI, VDI, VVT, VOOR, VOO, AAIR, ADIR, AAI, ADI, AAT, AOOR, AOO, ODO, OVO, OAO	None	
	E2D00	DDD, VDD, DDI, DVI, DOO, VVI, VDI, VVT, VOO, AAI, ADI, AAT, AOO, ODO, OVO, OAO, VVIR, VOOR, AAIR, AOOR, VDIR, ADIR	None	
	E2VDD00	VDD, VVIR, VDIR, VVI, VDI, VVT, VOOR, VOO, ODO, OVO, OAO	None	
	E2SR00	VVIR, VVI, VVT, VOOR, VOO, AAIR, AAI, AAT, AOOR, AOO, OVO, OAO	None	
Mode Switch	E2DR00, E2D00, E2VDD00	On, Off	None	DDDR, DDD, VDD modes
Detect Rate	E2DR00, E2D00, E2VDD00	120, 125, 130, ... 200, 210, 220 min ⁻¹	± 3 min ⁻¹	
Detect Duration	E2DR00, E2D00, E2VDD00	No Delay, 10, 20, ... 60 sec	None	
Blanked Flutter Search	E2DR00, E2D00, E2VDD00	On, Off	None	

Appendix: Parameter values and restrictions
Programmable modes and parameters

Table A-1. Mode and rates (Continued)

Parameter	Series	Settings	Tolerances	Notes
Post Mode Switch Pacing	E2DR00, E2D00	On, Off	None	DDDR and DDD modes
Overdrive Rate	E2DR00, E2D00	70, 75, 80, 90, 95, 100,... 120 min ⁻¹ , excluding 85 min ⁻¹ for magnet operation	None	DDDR and DDD modes
Overdrive Period	E2DR00, E2D00	0.5, 1, 2, 3, 5, 10, 20, 30, 60, 90, 120 min	None	DDDR and DDD modes
Ventricular Response Pacing (Regularizes V-V during AT/AF)	All	On, Off	None	Continuously in DDIR, VDIR or VVIR modes, or DDDR and DDD modes with mode switching
Maximum Rate		80, 85, 90, 95,... 130 min ⁻¹	± 2 min ⁻¹	
Lower Rate	All	30, 35, 40,... 120 min ⁻¹ 125, 130, 135,... 175 min ⁻¹ (except 65 and 85 min ⁻¹)	± 1 min ⁻¹ ± 2 min ⁻¹	
Upper Tracking Rate ^a	E2DR00, E2VDD00, E2D00	80, 90, 95, ... 180, 190, 200, 210 min ⁻¹ (except 85 min ⁻¹)	± 2 min ⁻¹	DDDR, DDD, VDD modes
Upper Sensor Rate	All	80, 90, 95, 100, ... 180 min ⁻¹ (except 85 min ⁻¹)	± 2 min ⁻¹	Rate responsive modes or DDD and VDD modes with mode switching

^a If the Upper Tracking Rate is set to 190 min⁻¹ or higher, the atrial and ventricular Rate Limit is 227 min⁻¹ (± 17 min⁻¹). Otherwise, the atrial and ventricular Rate Limit is 200 min⁻¹ (± 20 min⁻¹).

Appendix: Parameter values and restrictions
Programmable modes and parameters

Table A-2. Rate Response

Parameter	Series	Settings	Tolerances	Notes
ADL Rate	All	60, 65, 70, ... 120 min ⁻¹ 125, 130, 135, ... 180 min ⁻¹	± 1 min ⁻¹ ± 2 min ⁻¹	Rate responsive modes or DDD and VDD modes with mode switching
Rate Profile Optimization	All	On, Off	None	Rate responsive modes or DDD and VDD modes with mode switching
ADL Response	All	1–Inactive 2–Less Active 3–Mod. Active 4–More Active 5–Very Active	None	
Exertion Response	All	1–Infrequent 2–Less Frequent 3–Mod. Frequent 4–More Frequent 5–Very Frequent	None	
ADL Setpoint	All	5, 6, 7, ... 40, 42, 44, 46, ... 80	None	Programmable from the Exercise test only
UR Setpoint	All	15, 16, 17, ... 40, 42, 44, 46, ... 80, 85, 90, 95, ... 180	None	Programmable from the Exercise test only
Activity Threshold	All	Low, Medium Low, Medium High, High	None	
Acceleration	All	15 sec 30 sec 60 sec	+8, –2 sec +13, –3 sec +19, –3 sec	
Deceleration	All	2.5 min 5.0 min 10 min Exercise	+0.6, –0.2 min +1.1, –0.5 min +1.1, –1.0 min None	

Appendix: Parameter values and restrictions
Programmable modes and parameters

Table A-3. Atrial lead^a

Parameter	Series	Settings	Tolerances	Notes
Amplitude ^b	All except E2VDD00	0.5, 0.75, 1.0...4.0 V 4.5, 5.0, 5.5, 6.0 V 7.5 V	± 10% ± 10% +0/-20%	0.625, 0.875, 1.125, 1.375, 1.625, and 1.875 V can be set by Capture Management. Values are displayed but are not selectable.
Pulse Width	All except E2VDD00	0.12, 0.15 ms 0.21, 0.27, 0.34, 0.40, 0.46, 0.52, 0.64, 0.76, 1.00, 1.25, 1.50 ms	± 10 µs ± 25 µs	If Capture Management is programmed to Monitor or Adaptive, only settings of 0.40 or greater are available. Capture Management will not run at 1.25 and 1.5 ms.
Sensitivity	All	0.18 ^c , 0.25, 0.35 mV 0.5, 0.7, 1.0, 1.4, 2.0, 2.8, 4.0 mV	± 60% ± 40%	0.18, 0.25, 0.35 mV apply to bipolar atrial sensing only
Sensing Assurance		On, Off	None	
Pacing Polarity	All except E2VDD00	Bipolar, Unipolar ^d , Configure	None	Configure is displayed but is not selectable.
Sensing Polarity	E2DR00, E2D00, E2SR00 E2VDD00	Bipolar, Unipolar ^d , Configure Bipolar	None None	
Lead Monitor ^{e, f}	All except E2VDD00	Configure, Monitor Only, Adaptive, Off	None	
Notify if < (less than)		200 ohms	None	nonprogrammable

Appendix: Parameter values and restrictions
Programmable modes and parameters

Table A-3. Atrial lead^a

Parameter	Series	Settings	Tolerances	Notes
Notify if > (greater than)		1000, 2000, 3000, 4000 ohms	None	
Monitor Sensitivity		2, 3, 4, ... 16	None	

^a Applies to E2SR00 when set on atrial mode.

^b Tolerance for amplitudes from 0.5 V through 6.0 V is $\pm 10\%$, and for 7.5 V is $-20/+0\%$. Tolerances are based on 37°C and a 500-ohm load. Amplitude is determined 200 microseconds after the leading edge of the pace.

^c The atrial sensitivity value 0.18 mV does not apply to the E2SR00 models.

^d Unipolar only models (indicated by a "6" in the last digit of the model number).

^e For single chamber models (E2SR00 Series), Lead Monitor is available only for the paced chamber.

^f Unipolar only models (indicated by a "6" in the last digit of the model number) are set to a fixed value of Monitor Only.

Appendix: Parameter values and restrictions
Programmable modes and parameters

Table A-4. Ventricular lead^a

Parameter	Series	Settings	Tolerances	Notes
Amplitude ^b	All	0.5, 0.75, 1.0 ... 4.0 V 4.5, 5.0, 5.5, 6.0 V 7.5 V	± 10% ± 10% +0/-20%	0.625, 0.875, 1.125, 1.375, 1.625, and 1.875 V can be set by Ventricular Capture Management. Values are displayed but are not selectable.
Pulse Width	All	0.12, 0.15 ms 0.21, 0.27, 0.34, 0.40, 0.46, 0.52, 0.64, 0.76, 1.00, 1.25, 1.50 ms	± 10 µs ± 25 µs	If Ventricular Capture Management is programmed to Monitor or Adaptive, only settings of 0.40 or greater are available. Capture Management will not run at 1.25 and 1.5 ms.
Sensitivity	All	1.0, 1.4, 2.0, 2.8, 4.0, 5.6, 8.0, 11.2 mV	± 40%	
Sensing Assurance		On, Off	None	
Pacing Polarity	All	Bipolar, Unipolar ^c , Configure	None	Configure is displayed but is not selectable.
Sensing Polarity	All	Bipolar, Unipolar ^c , Configure	None	
Lead Monitor ^{d, e}	All	Configure, Monitor Only, Adaptive, Off		
Notify if < (less than)		200 ohms	None	non-programmable
Notify if > (greater than)		1000, 2000, 3000, 4000 ohms	None	
Monitor Sensitivity		2, 3, 4, ... 16	None	

^a Applies to E2SR00 when set on ventricular mode.

^b Tolerance for amplitudes from 0.5 V through 6.0 V is ± 10%, and for 7.5 V is -20/+0%. Tolerances are based on 37°C and a 500-ohm load. Amplitude is determined 200 microseconds after the leading edge of the pace.

^c Unipolar only models (indicated by a “6” in the last digit of the model number).

^d For single chamber models (E2SR00 Series), Lead Monitor is available only for the paced chamber.

^e Unipolar only models (indicated by a “6” in the last digit of the model number) are set to a fixed value of Monitor Only.

Appendix: Parameter values and restrictions
Programmable modes and parameters

Table A-5. Ventricular Capture Management

Parameter	Series	Settings	Tolerances	Notes
Ventricular Capture Management	All	Off, Monitor Only, Adaptive	None	
Amplitude Margin		1.5x, 2x, 2.5x, 3x, 4x (times)	None	
Minimum Adapted Amplitude		0.5, 0.75, 1.0 ... 3.5 V	None	
Capture Test Frequency		15, 30 minutes 1, 2, 4, 8, 12 hours, Day at Rest, Day at ..., 7 Days at...	None	For Day(s) at ..., next parameter specifies the time of day.
Capture Test Time		12:00 AM, 1:00 AM,... 11:00 PM	None	Applies only for Day(s) at ... parameter.
Acute Phase Days Remaining		Off, 7, 14, ... 84,112, 140, 168, 196, 224, 252 days	None	
V. Sensing during Search	All	Unipolar, Bipolar, Adaptive	None	

Table A-6. Atrial Capture Management

Parameter	Series	Settings	Tolerances	Notes
Atrial Capture Management	E2DR00, E2D00	Off, Monitor Only, Adaptive	None	
Amplitude Margin		1.5x, 2x, 2.5x, 3x, 4x (times)	None	
Minimum Adapted Amplitude		0.5, 0.75, 1.0 ... 3.5 V	None	
Capture Test Frequency		1, 2, 4, 8, 12 hours, Day at Rest, Day at ... , 7 Days at...	None	For Day(s) at ..., next parameter specifies the time of day.
Capture Test Time		12:00 AM, 1:00 AM, . . . 11:00 PM	None	Applies only for Day(s) at ... parameter.
Acute Phase Days Remaining		Off, 7, 14, ... 84,112, 140, 168, 196, 224, 252 days	None	

Appendix: Parameter values and restrictions
Programmable modes and parameters

Table A-7. Intrinsic Activation and AV Intervals

Parameter	Series	Settings	Tolerances	Notes
Paced AV (PAV)	E2DR00, E2D00	30, 40, 50, ... 350 ms	± 4 ms	Dual chamber modes, except VDD
Sensed AV (SAV)	E2DR00, E2D00, E2VDD00	30, 40, 50, ... 350 ms	+16/-4 ms	DDDR, DDD, VDD
RAAV	E2DR00, E2D00, E2VDD00	On, Off	None	DDDR, DDD, DDIR, DVIR, DOOR, VDD
Start Rate		50, 55, 60, ... 175 min ⁻¹	None	
Stop Rate		55, 60, 65, ... 180 min ⁻¹	None	
Maximum Offset		-10, -20, -30, ... -300 ms	None	
Search AV+	E2DR00, E2D00, E2VDD00	On, Off	None	Dual chamber modes except for DOOR and DOO
Max Increase to AV		10, 20, 30, ... 250 ms	None	
Sinus Preference	E2DR00	On, Off	None	DDDR
Sinus Preference Zone		3, 5, 10, 15, 20 min ⁻¹	None	
Search Interval		5, 10, 20, 30 minutes	None	

Appendix: Parameter values and restrictions
Programmable modes and parameters

Table A-8. Refractory / blanking

Parameter	Series	Settings	Tolerances	Notes
PVARP	E2DR00, E2D00, E2VDD00	Auto, Varied, 150, 160, 170, ... 500 ms	± 9 ms	DDDR, DDD, DDIR, DDI, VDD; Auto does not apply in DDIR and DDI; Varied does not apply in DDI
Minimum PVARP		150, 160, 170, ... 500 ms	± 9 ms	Auto PVARP only
PVAB	E2DR00, E2D00, E2VDD00	130, 140, 150, ... 350 ms	± 9 ms	Blanking for PVARP. Also applies to VDIR and VDI.
Ventricular Refractory Period	All	150, 160, 170, ... 500 ms	± 9 ms	Dual chamber and ventricular modes, except DOOR, DOO, VOOR, and VOO
Ventricular Blanking Period	E2DR00, E2D00	20, 28, 36, 44 ms	+0/-15 ms	After atrial pace
Ventricular Blanking Period	All	50 - 100 ms	None	Blanking for Ventricular Refractory Period; pacemaker- determined.
Atrial Refractory Period	E2DR00, E2D00, E2SR00	150, 160, 170, . . . 500 ms	± 9 ms	AAIR, AAI, AAT, ADIR, ADI
Atrial Blanking Period	E2DR00, E2D00, E2SR00	130, 140, 150, . . . 350 ms	± 9 ms	AAIR, AAI, AAT, ADIR, ADI
Atrial Blanking Period	E2DR00, E2D00, E2VDD00	50 - 100 ms	None	Blanking for Paced AV (PAV) and Sensed AV (SAV) intervals; pacemaker- determined.

Appendix: Parameter values and restrictions
Programmable modes and parameters

Table A-9. Additional features

Parameter	Series	Settings	Tolerances	Notes
Sleep Function	All	On, Off	None	All pacing modes
Sleep Rate		30, 35, 40, ... 90 min ⁻¹ (except 65 and 85 min ⁻¹)	± 1 min ⁻¹	
Bed Time		12:00 AM, 12:15 AM, 12:30 AM, ... 11:45 PM	± 10 min	
Wake Time		12:00 AM, 12:15 AM, 12:30 AM, ... 11:45 PM	± 10 min	
Non-Competitive Atrial Pacing	E2DR00, E2D00,	On, Off	None	DDDR, DDD
Single Chamber Hysteresis	All	40, 50, 60 min ⁻¹ , Off	± 1 min ⁻¹	VVI, VDI, VVT, AAI, ADI, and AAT modes
Rate Drop Response	E2DR00			DDD, DDI
Detection Type		Low Rate, Drop, Both, Off	None	
Intervention Rate		60, 70, 75, ... 120 min ⁻¹ 125, 130, 135,... 180 min ⁻¹ (except 65 and 85 min ⁻¹)	± 1 min ⁻¹ ± 2 min ⁻¹	
Intervention Duration		1, 2, 3, ... 15 minutes	None	
Detection Beats		1, 2, 3 beats	None	
Drop Rate		30, 40, 50, ... 100 min ⁻¹	± 1 min ⁻¹	
Drop Size		10, 15, 20, ... 50 min ⁻¹	± 2 min ⁻¹	
Detection Window		10, 15, 20, ... 30 seconds 1, 1.5, 2, 2.5 minutes	None	
PMT Intervention	E2DR00, E2D00, E2VDD00	On, Off	None	DDDR, DDD, VDD
PVC Response	E2DR00, E2D00, E2VDD00	On, Off	None	DDDR, DDD, DDIR, DDI, VDD
Ventricular Safety Pacing	E2DR00, E2D00	On, Off	None	DDDR, DDD, DDIR, DDI, DVIR, DVI
Implant Detection	All	On/Restart, Off/Complete ^a	None	All modes

^a If implant detection is completed, the time and date of completion are indicated below the Off/Complete setting.

Appendix: Parameter values and restrictions
Programmable modes and parameters

Table A-10. Telemetry features

Parameter	Series	Settings	Tolerances	Notes
Transtelephonic Monitor	All	On, Off	None	
Extended Telemetry	All	On, Off	None	
Extended Marker ^a	All	Standard, Therapy Trace	None	

^a Therapy Trace markers cannot be displayed or printed on the programmer.

The following parameters are programmable only when a specific type of Warning or Indicator status is set. You can check Observations on the Quick Look II screen to learn if a status type is set.

Table A-11. Status (reset) parameters

Parameter	Series	Settings	Notes
Atrial Lead Status	All	Reset Indicator	A subparameter of either Atrial Polarity
Ventricular Lead Status	All	Reset Indicator	A subparameter of either Vent. Polarity
ERI/POR Reset	All	Reset	Listed under Additional Features

Appendix: Parameter values and restrictions
Programmable modes and parameters

Table A-12. Temporary parameters

Parameter	Series	Settings	Tolerances	Notes
Chamber	All	Atrium, Ventricle	None	Setting determines available modes.
Pacing Mode	E2DR00, E2D00	DDD, DDI, DOO, VDD, VDI, VVI, VVT, VOO, AAI, ADI, AAT, AOO, ODO, OVO, OAO	None	Availability of modes is dependent on programmed mode.
	E2VDD00	VDD, VDI, VVI, VVT, VOO, ODO, OVO, OAO	None	
	E2SR00	VVI, VVT, VOO, AAI, AAT, AOO, OVO, OAO	None	
Pacing Rate	All	30, 35, 40, ... 120 min ⁻¹ (except 65 and 85 min ⁻¹), 125, 130, 135, ... 180 min ⁻¹ 190, 200, 210, ... 250 min ⁻¹ 260, 270, 280, 300, 310, 320, 330, 350, 370, 380, 400 min ⁻¹	± 1 min ⁻¹ ± 2 min ⁻¹ ± 3 min ⁻¹ ± 5 min ⁻¹	Rates above 180 min ⁻¹ are available by selecting the enable button.
Amplitude ^a	All	0.25, 0.375, ... 2.0 V 2.25, 2.50, 2.75, ... 4.0 V 4.5, 5.0, 5.5, 6.0 V 7.5 V	± 10% ± 10% ± 10% +0/-20%	
Pulse Width	All	0.03, 0.06, 0.09, ... 0.15 ms 0.21, 0.27, 0.34, 0.40, 0.46, 0.52, 0.64, 0.76, 1.00, 1.25, 1.50 ms	± 10 μsec ± 25 μsec	
Atrial Sensitivity	All	0.18 ^b , 0.25, 0.35 mV ^c 0.5, 0.7, 1.0, 1.4, 2.0, 2.8, 4.0 mV	± 60% ± 40%	
Ventricular Sensitivity	All	1.0, 1.4, 2.0, 2.8, 4.0, 5.6, 8.0, 11.2 mV	± 40%	
AV Intervals	E2DR00, E2D00	30, 40, 50, ... 350 ms	± 4 ms	Selection sets PAV and SAV if pertinent to mode. Not selectable in VDD mode.

^a The amplitude values in 0.125 V increments apply only to the Capture Management and Temporary tests.

^b The sensitivity value 0.18 mV does not apply to the E2SR00 models.

^c The values of 0.18, 0.25, and 0.35 mV are not available for unipolar-only models.

Automatic and clinician-selectable diagnostics

The automatic diagnostics listed in Table A-13 are automatically collected by the pacemaker. Note that some of the diagnostics have programmable parameters that are accessed by selecting Data Collection Setup under the Data icon. The clinician-selected diagnostics listed in Table A-14 are programmed by selecting Data Collection Setup under the Data icon.

Parameter settings are listed by an EnPulse model series. Each model series represents the following model numbers:

- E2DR00 Series → Models E2DR01, E2DR03, E2DR06, E2DR21, E2DR31, E2DR33
- E2D00 Series → Models E2D01, E2D03
- E2VDD00 Series → Models E2VDD01
- E2SR00 Series → Models E2SR01, E2SR03, E2SR06

Table A-13. Automatic diagnostics

Parameter	Series	Settings
Heart Rate Histograms (Short and Long Term, Atrial and Ventricular)	All ^a	
Include Refractory Senses		Include, Exclude
AV Conduction Histograms (Short and Long Term)	E2DR00, E2D00, E2VDD00	
Search AV+ Histogram	E2DR00, E2D00, E2VDD00	
Sensor Indicated Rate Profile	All	
Atrial High Rate Episodes (Mode Switch On)	E2DR00, E2D00, E2VDD00	
Collection Delay after Mode Switch		0, 1, 2,... 20, 25, 30,... 60 seconds
Collection Method		Frozen, Rolling

Appendix: Parameter values and restrictions
Automatic and clinician-selectable diagnostics

Table A-13. Automatic diagnostics (Continued)

Parameter	Series	Settings
Atrial High Rate Episodes (Mode Switch Off)	All ^b	
Detection Rate		80, 85, 90, ... 180, 200, 220, 240, ... 320, 330, 350, 370, 380, 400 min ⁻¹
Detection Duration ^c		1, 2, 3, ... 20, 25, 30... 50, 55, 60 sec
Termination Beats		5, 6, 7, ... 20 beats
Collection Method ^d		Frozen, Rolling
Ventricular High Rate Episodes	All ^b	
Detection Rate		80, 85, 90, ... 180, 200, 220, 240, ... 320, 330, 350, 370, 380, 400 min ⁻¹
Detection Duration ^c		2, 3, 4, ... 198, 199, 200 beats
Termination Beats		5, 6, 7, ... 20 beats
SVT Filter	E2DR00, E2D00, E2VDD00	Off, On
Collection Method ^d		Frozen, Rolling
Atrial Arrhythmia Trend	All	
Atrial Arrhythmia Durations	All	
Ventricular Rate During Atrial Arrhythmias	E2DR00, E2D00, E2VDD00	
Rate Drop Response Episodes	E2DR00	Based on programmed therapy
Chronic Lead Trends	All	
Lead Monitor Counters	All	
Sensitivity Trends	All	Monitors chambers with Sensing Assurance
Capture Management Trend		Based on use of Capture Management
Atrial Capture Management	E2D00, E2DR00	
Ventricular Capture Management	All	
Key Parameter History	All	

^a For single chamber models (E2SR00 Series), Heart Rate Histograms are available for the paced chamber. For all models, Heart Rate Histograms can be programmed to include or exclude refractory sensed events.

^b For single chamber models (E2SR00 Series), High Rate Episode is available for the paced chamber.

^c For E2SR00 models, Detection Duration is 2 to 200 beats.

^d Collection Method applies to Atrial High Rate Episodes and Ventricular High Rate Episodes.

Appendix: Parameter values and restrictions

Automatic and clinician-selectable diagnostics

Notes:

- The parameters settings for the automatic High Rate Episode diagnostics also apply to the corresponding clinician-selectable High Rate Detail diagnostics.
- For each clinician-selectable diagnostic with EGM collection, there is an automatic diagnostic that collects corresponding trend data.

Table A-14. *Clinician-selectable diagnostics*

Diagnostic and parameters	Series	Parameter settings
Custom Rate Trend	All	
Duration		Beat-to-Beat, 1 Hour, 24 hours
Collection Method		Frozen, Rolling
Include Refractory Senses?		Include, Exclude
Ventricular Capture Management Detail	All	
EGM Collection		Off, Atrial EGM, Ventricular EGM, Summed EGM ^a
Atrial Capture Management Detail	E2D00, E2DR00	
EGM Collection		Off, Atrial EGM, Ventricular EGM, Summed EGM

Appendix: Parameter values and restrictions
Automatic and clinician-selectable diagnostics

Table A-14. Clinician-selectable diagnostics

Diagnostic and parameters	Series	Parameter settings
High Rate Detail^b	All ^c	
High Rate Type ^d		AHR and VHR, AHR, VHR
EGM Type		Off, Atrial EGM, Ventricular EGM, Summed EGM ^e
Allocation (Collection Method ^f = Frozen, High Rate Type = AHR and VHR)		2 for 0/24, 2 for 24/0, 2 for 12/12, 4 for 0/12, 4 for 12/0, 4 for 6/6, 8 for 0/6, 8 for 6/0, 8 for 3/3 (number of episodes for pre-onset seconds/post onset seconds collected)
Allocation (Collection Method ^f = Frozen, High Rate Type = AHR only or VHR only)		1 for 0/48, 1 for 48/0, 1 for 24/24, 2 for 0/24, 2 for 24/0, 2 for 12/12, 4 for 0/12, 4 for 12/0, 4 for 6/6, 8 for 0/6, 8 for 6/0, 8 for 3/3 (number of episodes for pre-onset seconds/post onset seconds collected)
Allocation (Collection Method ^f = Rolling, High Rate Type = AHR and VHR)		2 for 16/0, 2 for 8/8, 2 for 0/24, 4 for 8/0, 4 for 4/4, 4 for 0/12, 8 for 4/0, 8 for 2/2, 8 for 0/6 (number of episodes for pre-onset seconds/post onset seconds collected)
Allocation (Collection Method ^f = Rolling, High Rate Type = AHR only or VHR only)		1 for 24/0, 1 for 12/12, 1 for 0/48, 2 for 16/0, 2 for 8/8, 2 for 0/24, 4 for 8/0, 4 for 4/4, 4 for 0/12, 8 for 4/0, 8 for 2/2, 8 for 0/6 (number of episodes for pre-onset seconds/post onset seconds collected)
Pre-detection Timeout		1, 2, 3,... 12, 14, 16,... 24 weeks
Rate Drop Response Detail	E2DR00	
Include Refractory Senses?		Include, Exclude
Remote Assistant	All	
Type		Symptoms, Exercise

Appendix: Parameter values and restrictions
Automatic and clinician-selectable diagnostics

Table A-14. Clinician-selectable diagnostics

Diagnostic and parameters	Series	Parameter settings
EGM Collection (applies to Symptoms only)		OFF, Atrial EGM, Ventricular EGM, Summed EGM ^a
EGM Timeout		1, 2, 3,... 12, 14, 16,... 24 weeks

^a For E2SR00 models, EGM Collection options are limited to OFF and EGM.

^b High rate detection rate, detection duration, and termination criteria are set by parameters for the automatic diagnostic (Atrial High Rate Episodes or Ventricular High Rate Episodes - see page A-14).

^c For single chamber models (E2SR00 Series), High Rate Detail is available for the paced chamber.

^d For E2SR00 models, High Rate Type is not displayed.

^e For E2SR00 models, EGM Collection options are limited to OFF and EGM.

^f Collection Method is set in the High Rate automatic diagnostic.

Programming restrictions

Table A-15 lists the programming restrictions for certain parameters for EnPulse pacemakers.

Table A-15. *Parameter programming restrictions*

Parameter	Restriction
PVARP	<p>For the E2SR00 Series pacemakers, PVARP is not available.</p> <p>When Rate Drop Response is programmed On in the DDD mode, Auto and Varied PVARP are not available.</p>
Capture Management	<p>When Capture Management is set to adaptive operation, the Amplitude setting must be less than or equal to 5.0 V, and the Pulse Width setting must be less than or equal to 1.0 ms.</p> <p>To use the Ventricular Capture Management feature, the pacemaker must be programmed to a mode that permits pacing and sensing in the ventricle. In order to use the Atrial Capture Management feature, the pacemaker must be programmed to a DDD or DDDR mode. Atrial Capture Management does not operate during mode switch episodes.</p> <p>Ventricular Safety Pacing (VSP) must be programmed On when Atrial Capture Management is set to adaptive or monitor. The pacemaker is shipped with VSP On.</p>
Mode Switch	<p>Detect Rate must be at least 10 min⁻¹ greater than the Upper Tracking Rate and the Upper Sensor Rate.</p> <p>Rate Drop Response is turned Off for DDD mode switching.</p> <p>PVAB period is limited to a maximum of 200 ms.</p> <p>It is recommended that Sensed AV and Paced AV intervals be set to a maximum of 320 ms.</p> <p>It is recommended that the Search AV+ Max Increase to AV parameter be set to a maximum of 320 ms minus the programmed Sensed AV value.</p> <p>Sensor-varied PVARP is not allowed for DDDR and DDD mode switching.</p> <p>For the E2SR00, and E2VDD00 Series pacemakers, Post Mode Switch Overdrive Pacing (PMOP) is not available.</p>

Appendix: Parameter values and restrictions
Programming restrictions

Table A-15. Parameter programming restrictions (Continued)

Parameter	Restriction
Rates	<p>It is recommended that the ADL Rate be at least 10 min⁻¹ less than the Upper Sensor Rate and at least 20 min⁻¹ greater than the Lower Rate. However, programming the ADL Rate above or below these limits is permitted.</p> <p>Programming a combination of high Upper Sensor Rate and Upper Tracking Rate and a long refractory period may result in a shorter “sensing window.” Loss of sensing in such cases could result in competitive pacing (unless Non-Competitive Atrial Pacing is programmed On).</p> <p>Programming the Upper Tracking Rate to a value greater than the Upper Sensor Rate permits the atrial rhythm to be tracked to a rate higher than the sensor-driven rate.</p> <p>The Upper Sensor Rate and/or Upper Tracking Rate must be greater than the Lower Rate. The Upper Sensor Rate must be greater than the ADL Rate.</p>
Rate Drop Response	<p>The Drop Rate cannot be less than the programmed Lower Rate. The Intervention Rate cannot be greater than the programmed Upper Tracking Rate and must be greater than the programmed Lower Rate.</p> <p>Mode Switch is unavailable when RDR is programmed On.</p> <p>Rate Adaptive AV, sensor-varied PVARP, and automatic PVARP are unavailable when RDR is programmed On.</p>
Sensing Assurance	<p>While Sensing Assurance is On, the clinician cannot manually program a lower or higher Sensitivity setting than those shown in the table below.</p> <p>Sensing Assurance will only adjust Sensitivity if the programmed mode allows both sensing and pacing in a chamber, with the exceptions that adjustments are allowed in the VDD mode and not allowed in the AAT/VVT modes.</p>
Search AV+	<p>Ventricular Safety Pacing (VSP) must be programmed On when Search AV+ is programmed On.. The pacemaker is shipped with VSP On.</p>
Ventricular Safety Pacing	<p>Ventricular Safety Pacing (VSP) must be programmed On for ventricular Sensing Assurance operation.^a Ventricular Safety Pacing is mode dependent. The pacemaker is shipped with VSP On.</p> <p>Ventricular Safety Pacing must programmed to On when ACM is at Adaptive or Monitor.</p> <p>Ventricular Safety Pacing must be programmed to On when Search AV+ is On.</p>

^a This does not apply to E2VDD00 or E2SR00 models.

Appendix: Parameter values and restrictions
Programming restrictions

Sensing type	Lower limit	Upper limit
Atrial		
Single Chamber Bipolar	0.18 mV ^a	0.5 mV
Dual Chamber Bipolar	0.18 mV	0.5 mV
VDD Mode	0.18 mV	0.35 mV
Unipolar	0.5 mV	1.4 mV
Ventricular		
Bipolar (Dual and Single Chamber)	2.0 mV	5.6 mV
Unipolar (Dual and Single Chamber)	2.0 mV	5.6 mV

^a For the E2SR00 Series, the lower limit is 0.25 mV.

Appendix: Implant information

B

The appendix covers warnings, device operation instructions, and device information for the EnPulse Series pacemakers. This appendix supplements the information provided in the four implant manuals for the Medtronic EnPulse Series.

Warnings B-2

Precautions B-5

Device operation B-11

Device information B-14

Warnings

Device operation

Rate responsive modes – Do not program rate responsive modes for patients who cannot tolerate rates above the programmed Lower Rate. Rate responsive modes may cause discomfort for those patients.

Single chamber atrial modes – Do not use program single chamber atrial modes for patients with impaired AV nodal conduction. Ventricular pacing will not occur.

Crosstalk – Crosstalk may cause the device to self-inhibit, which will result in no pacing. Program Ventricular Safety Pacing to On to prevent inhibition due to crosstalk.¹

Lead compatibility – Do not use another manufacturer's leads without demonstrated compatibility with Medtronic devices. If a lead is not compatible with a Medtronic device, the result may be undersensing of cardiac activity, failure to deliver necessary therapy, or a leaking or intermittent electrical connection.

Lead connection – Consider the following information when connecting the lead and the device:

- Cap abandoned leads to avoid transmitting electrical signals.
- Plug any unused lead ports to protect the device.
- Verify lead connections. Loose lead connections may result in inappropriate sensing and failure to deliver arrhythmia therapy.

Pacemaker dependent patients

Polarity override – Do not override the polarity verification prompt with bipolar polarity when a unipolar lead is connected. Overriding the polarity verification prompt results in no pacing output.

Threshold margin test (TMT) and loss of capture – Be aware that loss of capture during a TMT at a 20% reduction in amplitude indicates an inadequate stimulation safety margin.

¹ This applies to the following models: Bipolar/Unipolar Models E2DR01, E2DR03, E2DR21, E2DR31, E2DR33; Unipolar Model E2DR06; Bipolar/Unipolar Models E2D01, E2D03.

Inhibit function – Use caution when using the programmer to inhibit pacing. The patient is without pacing support when pacing is inhibited.

Pacemaker-dependent patients – Always program Ventricular Safety Pacing (VSP) to On for pacemaker-dependent patients.¹ Ventricular Safety Pacing prevents ventricular asystole due to inappropriate inhibition of ventricular pacing caused by oversensing.

Medical therapy hazards

Medical treatment influencing device operation – The electrophysiological characteristics of a patient's heart can change over time, especially if the patient's medications have changed. As a result of the changes, programmed therapies may become ineffective and possibly dangerous to the patient.

Diathermy – People with metal implants such as pacemakers, implantable cardioverter defibrillators, and accompanying leads should not receive diathermy treatment. The interaction between the implant and diathermy can cause tissue damage, fibrillation, or damage to the device components, which could result in serious injury, loss of therapy, and/or the need to reprogram or replace the device.

Electrosurgical cautery – Electrosurgical cautery may induce ventricular arrhythmias or may cause device malfunction or damage. If electrosurgical cautery cannot be avoided, observe the following precautions to minimize complications.

- Keep temporary pacing and defibrillation equipment available.
- Use a bipolar electrocautery system if possible.
- Use short, intermittent, and irregular bursts at the lowest clinically appropriate energy levels.
- Avoid direct contact with the implanted device or leads. If unipolar cautery is used, position the ground plate so the current pathway does not pass through or near the device and lead system. The current pathway should be a minimum of 15 cm away from the device and lead system.
- Program the device to the VOO/AOO² mode for pacemaker-dependent patients.

¹ This applies to the following models: Bipolar/Unipolar Models E2DR01, E2DR03, E2DR21, E2DR31, E2DR33; Unipolar Model E2DR06; Bipolar/Unipolar Models E2D01, E2D03.

² The Bipolar Model E2VDD01 should be programmed to the VOO mode.

Appendix: Implant information

Warnings

External defibrillation – External defibrillation may damage the implanted device. External defibrillation may also temporarily or permanently elevate pacing thresholds, or damage the myocardium at the electrode tissue interface. Current flow through the device and lead may be minimized by following these precautions.

- Use the lowest clinically appropriate defibrillation energy.
- Position the defibrillation patches or paddles a minimum of 15 cm away from the device.
- Position the defibrillation patches or paddles perpendicular to the device and lead.

If external defibrillation is delivered within 15 cm of the device, contact a Medtronic representative.

Hospital and medical environments

External defibrillation equipment – Keep external defibrillation equipment nearby for immediate use whenever arrhythmias are possible or intentionally induced during device testing, implant procedures, or post-implant testing.

Precautions

Storage and handling

Device storage – Store the device in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference. Exposing the device to magnets or electromagnetic interferences may damage the device.

Temperature limits – Store and transport the package between -18 °C and +55 °C. Electrical reset may occur at temperatures below -18 °C. Device longevity and performance may decrease at temperatures above +55 °C.

Inspecting the sterile package – Carefully inspect the package before opening it.

- If the seal or package is damaged, contact a Medtronic representative.
- Do not use the product after its expiration date.
- For instructions on opening the sterile package, see the diagram inside the lid of the shelf box.

Dropped device – Do not implant the device if it has been dropped on a hard surface from a height of 30 cm or more after it is removed from the package.

Device temperature – Allow the device to reach room temperature before it is programmed or implanted. Rapid temperature changes may affect initial device function.

Use by date (expiration date) – Do not implant the device after the use by date (expiration date) on the package label. Battery longevity may be reduced.

Ethylene oxide resterilization – The device was sterilized with ethylene oxide before shipment. If the integrity of the sterile package has been compromised before the expiration date, resterilize the device using ethylene oxide. Resterilization does not affect the expiration date. Avoid resterilization techniques that may damage the device.

- Do not use an autoclave, gamma radiation, organic cleaning agents, or ultrasonic cleaners to resterilize the device.
- Refer to the sterilizer product literature for operating instructions.

Appendix: Implant information

Precautions

- Do not exceed 55 °C or 103 kPa
- Use an acceptable method for determining sterilizer effectiveness, such as biological indicators
- After resterilization, allow the device to aerate ethylene oxide residues
- Do not resterilize more than twice

Explant and disposal – Explant the device post-mortem. In some countries, explanting battery-operated implantable devices is mandatory because of environmental concerns; please check the local regulations. In addition, if subjected to incineration or cremation temperatures, the device could explode. Medtronic implantable devices are intended for single use only. Do not resterilize and re-implant explanted devices. Return explanted devices to Medtronic for analysis and disposal.

Device operation

Atrial Capture Management – Atrial Capture Management does not program atrial outputs above 5.0 or 1.0 ms. If the patient needs a pacing output higher than 5.0 V or 1.0 ms, manually program the Amplitude and Pulse Width. If a lead dislodges partially or completely, Atrial Capture Management may not prevent loss of capture.

Ventricular Capture Management – Ventricular Capture Management does not program ventricular outputs above 5.0 or 1.0 ms. If the patient needs a pacing output higher than 5.0 V or 1.0 ms, manually program the Amplitude and Pulse Width. If a lead dislodges partially or completely, Ventricular Capture Management may not prevent loss of capture.

False bipolar pathway with unipolar lead – When implanting a unipolar device, ensure that the tip and ring setscrews are properly engaged and that all electrical contacts are sealed to prevent electrical leakage between the tip and ring contacts. Electrical leakage may cause the device to inappropriately identify a unipolar lead as bipolar, resulting in loss of output.

Device status indicators – If any of the device status indicators (examples include ERI and Electrical Reset) are displayed on the programmer after interrogating the device, inform a Medtronic representative immediately. If these device status indicators are displayed, therapies may not be available to the patient.

Accessories – Use this device only with accessories, parts subject to wear, and disposable items that have been tested to technical standards and found safe by an approved testing agency.

Hex wrench – Do not use a blue-handled or a right-angle hex wrench. These wrenches have torque capabilities greater than the lead connector can tolerate. The setscrews may be damaged by excessive torque.

Programmings – Use only Medtronic programmers and application software to communicate with the device. Programmings and software from other manufacturers are not compatible with Medtronic devices.

Epicardial leads – Epicardial leads have not been determined appropriate for use with the Ventricular Capture Management feature. Program Ventricular Capture Management to Off if implanting an epicardial lead.

Shipping values – Do not use shipping values or nominal values for pacing amplitude and sensitivity without verifying that the values provide adequate safety margins for the patient.

Electrical reset – Electrical reset can be caused by exposure to temperatures below -18 °C or strong electromagnetic fields. Advise patients to avoid strong electromagnetic fields. Observe temperature storage limits to avoid exposure of the device to cold temperatures. If a partial electrical reset occurs, pacing resumes in the programmed mode in many of the programmed settings. If a full electrical reset occurs, the device operates in VVI mode at 65 min⁻¹. Electrical reset is indicated by a programmer warning message displayed immediately upon interrogation. To restore the device to its previous operation, it must be reprogrammed. See the device implant manual for a complete list of preserved and changed partial and full reset parameters.

Slow retrograde conduction – Slow retrograde conduction may induce pacemaker-mediated tachycardia (PMT) when the conduction time is greater than 400 ms. Programming PMT intervention may help prevent PMT when the conduction time is less than 400 ms.

PMT intervention – Even with the feature turned to On, PMTs may still require clinical intervention such as pacemaker reprogramming, magnet application, drug therapy, or lead evaluation.

Extended Upper Tracking Rate – When programming Upper Tracking Rates of 190, 200, or 210 min⁻¹, be careful to ensure that these rates are appropriate for the patient. The Upper Tracking Rates of 190, 200, and 210 min⁻¹ are intended primarily for use in pediatric patients.

Appendix: Implant information

Precautions

Twiddler's syndrome – Twiddler's syndrome, i.e., patient manipulation of the device after implant, may cause the pacing rate to increase temporarily if the pacemaker is programmed to a rate responsive mode.

Muscle stimulation with unipolar pacing – Muscle stimulation (for example, due to high-output unipolar pacing) may result in pacing at rates up to the Upper Sensor rate in rate responsive modes.

Continuous myopotentials – Continuous myopotentials can cause reversion to asynchronous operation in unipolar pacing. Sensing of myopotentials is more likely to occur when sensitivity settings of 0.5 mV through 1.4 mV are programmed.

Pacing and sensing safety margins – Consider lead maturation when selecting pacing amplitudes, pacing pulse widths, and sensing levels. Loss of capture may occur if lead maturation is not considered when selecting settings.

Tip and ring contacts – When implanting a device, ensure that the tip and ring setscrews are properly engaged and all electrical contacts are sealed to prevent possible electrical leakage between the tip and ring contacts. Also, ensure that electrical contacts are sealed when using lead extenders or adaptors with bipolar models. Electrical leakage may cause a loss of output.

Pacemaker-dependent patients

Threshold margin test (TMT) and loss of capture – Be aware that loss of capture during a TMT at a 20% reduction in amplitude indicates an inadequate stimulation safety margin.

Diagnostic modes – Do not program diagnostic modes (ODO, OVO, and OAO) for pacemaker-dependent patients. Instead, use the programmer's inhibit function for brief interruption of outputs.

Medical therapy hazards

Magnetic resonance imaging (MRI) – Do not use magnetic resonance (MRI) on patients who have an implanted device. MRI may cause damage to the device.

If MRI must be performed, closely monitor patients treated with MRI and verify programmed device parameters upon cessation of MRI.

Therapeutic ultrasound – Do not expose the device to therapeutic ultrasound. Therapeutic ultrasound may permanently damage the device.

Radio frequency (RF) ablation – An RF ablation procedure may cause device malfunction or damage. Radio frequency ablation risks may be minimized by observing the following precautions.

- Keep temporary pacing and defibrillation equipment available.
- Avoid direct contact between the ablation catheter and the implanted system.
- Position the ground plate so the current pathway does not pass through or near the device and lead system. The current pathway should be a minimum of 15 cm away from the device and lead system.
- Program the device to the VOO/AOO mode for pacemaker-dependent patients.

Lithotripsy – Lithotripsy may permanently damage the device if the device is at the focal point of the lithotripsy beam. If lithotripsy must be used, take the following precautions.

- Keep the focal point of the lithotripter beam a minimum of 2.5 cm away from the implanted device.
- Program the implanted device to the VVI/AAI or VOO/AOO¹ mode before treatment for pacemaker-dependent patients.

High-energy radiation – Do not direct high-energy radiation sources such as cobalt 60 or gamma radiation at the device. High-energy radiation may damage the device. If a patient requires radiation therapy near the device, radiation exposure to the device should not exceed 500 rads. However, diagnostic x-ray and fluoroscopic radiation should not adversely affect the device.

Co-implantation with an implantable defibrillator – An ICD may be implanted at the same time as a bipolar pulse generator (IPG). Follow the implant instructions in the lead technical manual to place the lead. Observe the following precautions to avoid using pulse generator features that trigger unipolar polarity in patients with ICDs.

- Disable the IPG's Automatic Polarity Configuration feature, and manually program pacing lead polarities to bipolar configuration. Refer to the Pacemaker Reference Guide for complete instructions.

¹ The Bipolar Model E2VVD01 should be programmed to VVI or VOO.

Appendix: Implant information
Precautions

- Do not program the Lead Monitor to Adaptive because the monitor automatically reprograms the selected lead to unipolar polarity when an out-of-range lead impedance is detected.
- Do not program Transtelephonic Monitor to On because the pacing polarity is temporarily set to unipolar when the magnet is applied.
- If the programmer displays a message that an electrical reset has occurred, the IPG is operating in unipolar configuration. Contact Medtronic to program the IPG to bipolar polarity.
- If a full electrical reset occurs, the IPG resets to the Implant Detection feature.

Home and occupational environments

Static magnetic fields – Patients should avoid equipment or situations where they would be exposed to static magnetic fields greater than 10 gauss or 1 mT. Static magnet fields may cause the device to operate asynchronously. Sources of static magnetic fields include, but are not limited to, stereo speakers, bingo wands, extractor wands, magnetic badges, or magnetic therapy products.

Cellular phones – This device contains a filter that prevents most cellular phone transmissions from interacting with device operation. To further minimize the possibility of interaction, observe these cautions.

- Maintain a separation of 15 cm between the device and the cellular phone, even if the cellular phone is not on.
- Maintain a minimum separation of 30 cm between the device and any antenna transmitting above 3 W
- Hold the cellular phone to the ear farthest from the device.

This device has been tested to the frequency ranges used by common cellular phone transmission technologies. Based on this testing, the device should not be affected by the normal operation of cellular phones using such technologies.

Electromagnetic interference (EMI) – Instruct patients to avoid devices that generate strong EMI. Electromagnetic interference may cause device malfunction or damage such as prevention of programming, detection or therapy delivery. The patient should move away from the EMI source or turn off the source because this usually allows the device to return to its normal mode of operation. Electromagnetic interference may be emitted from these sources.

- High voltage power lines
- Communication equipment such as microwave transmitters, linear power amplifiers, or high-powered amateur transmitters
- Commercial electrical equipment such as arc welders, induction furnaces, or resistance welders.

Home appliances that are in good working order and properly grounded do not usually produce enough EMI to interfere with device operation. There are reports of temporary disturbances caused by electric hand tools or electric razors used directly over the implant site.

Electronic article surveillance (EAS) – Electronic article surveillance equipment, such as retail theft prevention systems, may interact with devices and result in inappropriate therapy delivery. Advise patients to walk through an EAS system and not to remain near an EAS system any longer than necessary.

Device operation

This section contains information about replacing an implanted pacemaker, magnet operation, and the elective replacement indicator. This information applies to all EnPulse Series pacemakers unless otherwise indicated.

Replace a device

Warning: Keep an external pacing instrument available for immediate use. When the lead is disconnected, pacemaker-dependent patients are without pacing support.

Replace a device by performing the following steps.

1. Program the device to a non-rate responsive mode to avoid potential rate increases while handling the device.

Appendix: Implant information

Device operation

2. Dissect the lead and the device free from the surgical pocket. Do not nick or breach the insulation.
3. Use a wrench to loosen the setscrews in the connector port.
4. Gently pull the lead out of the connector port.
5. Evaluate the condition of the lead. Replace the lead if electrical integrity is not acceptable or if the lead connector pin is pitted or corroded. Return the explanted lead to Medtronic for analysis and disposal.
6. Connect the lead to the replacement device.
Note: A lead adaptor may be needed to connect the lead to the replacement device. Contact a Medtronic representative for questions about lead adaptor compatibility.
7. Evaluate stimulation thresholds and sensing potentials. Use the replacement device or an implant support instrument.
8. After confirming acceptable electrical measurements, place the device in the pocket. Suture the pocket incision closed.
9. Return the explanted device to Medtronic for analysis and disposal.

For further information – For further information on implanting pacemakers, consult the implant manual packaged with each device. For information on available adaptor kits, consult the Pacemaker and ICD Encyclopedia (a Medtronic publication). Refer to “Connector dimensions” on page A-5 of the *EnPulse Pacemaker Reference Guide* for the different types of pacemaker connectors.

Magnet operation

Magnet operation may be initiated by performing one of the following actions:

- Placing a transtelephonic magnet over the IPG
- Performing a Magnet Test from the programmer

Note: The device does not respond to the application of a magnet for one hour after the use of a programmer unless the session is ended with a command option to immediately clear data collected in the device. The default command for ending a session allows the device to retain collected data for one hour.

The following responses occur automatically during magnet mode operation:

- The device performs a Threshold Margin Test (TMT) to allow a check for loss of capture. A TMT is performed at 100 min^{-1} with amplitude reduced by 20% on the third pulse.



Warning: Loss of capture during a TMT at a 20% reduction in amplitude indicates an inadequate safety margin. As soon as possible, perform a pacing threshold test and reprogram outputs to establish a 2:1 stimulation safety margin.

Note: When Transtelephonic Monitor is set to On, TMT is delayed for five seconds to enhance communication with Transtelephonic equipment.

- The magnet rate becomes 65 min^{-1} when the Elective Replacement Indicator (ERI) is set or when a full electrical reset has occurred.
- The magnet rate for normal operation switches to a rate of 85 min^{-1} and the appropriate asynchronous mode, see the following table for mode information.

Programmed mode	Magnet mode
Dual chamber	DOO
VDD	VOO
Single chamber	VOO/AOO

Elective Replacement Indicator

The Elective Replacement Indicator (ERI) warns when the device battery is nearing depletion. When the battery voltage has dropped below a defined limit, the device sets the ERI status and reverts to VVI operation at a rate of 65 min^{-1} . At most programmed settings, the majority of devices will function for a minimum of three months after ERI.

Appendix: Implant information

Device information

The device's elective replacement indicators are listed in the following table:

Table B-1. Elective Replacement Indicators

Operation	Indicator
Nonmagnet mode	VVI mode at 65 min ⁻¹
Magnet mode	VOO mode at 65 min ⁻¹
Telemetry	Replacement message on the programmer
Battery/Lead information	Replacement message and displayed battery voltage on programmer

Device information

This section contains a feature summary and information about emergency pacing and output waveforms.

Feature summary

The features described in this section are available with EnPulse Series pacemakers. Refer to the appropriate EnPulse Series pacemaker implant manual for a list of the features that are enabled at shipping. The features described in this section apply to all EnPulse Series pacemakers unless otherwise indicated.

Lead Monitor – This feature measures lead impedances during the life of the implanted device and controls automatic configuration of lead polarities at implant. If programmed to do so, this feature also allows the device to switch bipolar pacing and sensing to unipolar pacing and sensing if the integrity of a bipolar lead is compromised.

Rate Responsive Pacing – This feature varies the pacing rate in response to the patient's physical motion as detected by an activity sensor.

Rate Adaptive AV (RAAV) – This feature varies the Paced AV¹ and Sensed AV intervals to mimic the physiologic response of AV conduction times, shortening as the heart rate increases or lengthening as the heart rate decreases during dual chamber operation.²

¹ The Bipolar Model E2VDD01 does not vary the Paced AV (PAV) interval.

Mode Switch – This programmable feature prevents tracking of paroxysmal atrial tachycardias by switching from an atrial tracking mode to a non-atrial tracking mode when an atrial tachyarrhythmia is detected.²

Post Mode Switch Overdrive Pacing (PMOP) – This feature extends DDIR pacing for a programmed duration and rate following a mode switch episode.¹

Non-Competitive Atrial Pacing (NCAP) – This programmable feature is intended to prevent the triggering of atrial tachycardias by delaying atrial paced events scheduled to occur during the atrial relative refractory period.²

Pacemaker-Mediated Tachycardia (PMT) Intervention – This programmable feature provides automatic detection and interruption of PMTs by extending the PVARP for one interval.² This ensures that the next atrial event in the PVARP will be refractory.

Premature Ventricular Contraction (PVC) Response – This programmable feature prevents the tracking of retrograde P-waves by extending PVARP upon detection of a PVC.^{3,4} This ensures that the next atrial event in the PVARP will be refractory.

Ventricular Safety Pacing – This feature prevents ventricular asystole due to inappropriate inhibition of ventricular pacing caused by crosstalk of oversensing. A ventricular safety pace is delivered if a ventricular event is sensed during the VSP interval after an atrial pace.⁵

Sleep Function – This programmable feature suspends the programmed Lower Rate and replaces it with a Sleep Rate during a specified sleep period.

² This feature is found in the following models: Bipolar/Unipolar Models E2DR01, E2DR03, E2DR21, E2DR31, E2DR33; Unipolar Model E2DR06; Bipolar Model E2VDD01; Bipolar/Unipolar Models E2D01, E2D03.

¹ This feature applies to the E2DR00 and E2D00 devices.

² This feature is found in the following models: Bipolar/Unipolar Models E2DR01, E2DR03, E2DR21, E2DR31, E2DR33; Unipolar Model E2DR06; Bipolar/Unipolar Models E2D01, E2D03.

³ This feature is found in the following models: Bipolar/Unipolar Models E2DR01, E2DR03, E2DR21, E2DR31, E2DR33; Unipolar Model E2DR06; Bipolar/Unipolar Models E2D01, E2D03; Bipolar Model E2VDD01.

⁴ The Bipolar Model E2VDD01 does not have the inhibition of atrial pacing from retrograde P waves.

⁵ This feature applies to the E2DR00 and E2D00 devices.

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Device information

Single Chamber Hysteresis – This feature allows the device to track an intrinsic rhythm below the programmed Lower Rate. This feature prevents the device from overriding slow, but appropriate, intrinsic rhythms that may develop from extended periods of inactivity such as sleep.

Transtelephonic Monitor – This programmable feature is intended for use with remote monitoring services.¹ When Transtelephonic Monitor is programmed to On, the device delays the Threshold Margin Test (TMT) for five seconds when the magnet is applied. Delaying the TMT enhances communication with transtelephonic equipment.



Warning: Programming Transtelephonic Monitor to On is contraindicated for patients with an implanted defibrillator. When the feature is programmed to On, the pacing polarity is temporarily set to unipolar when the magnet is applied. Pacing in the unipolar configuration may cause the ICD to deliver inappropriate therapy or to withhold appropriate therapy.

Diagnostics – Diagnostics provide data for evaluating the patient's intrinsic rhythm and the implantable device's operation. Two categories of diagnostics are available: automatic and clinician-selected. Refer to the appropriate device reference manual for additional information on diagnostics.

Implant Detection – This feature starts a 30-minute period, beginning at lead connection, during which the device verifies lead connection by measuring lead impedance. When the Implant Detection period is completed, various automatic features and diagnostics are activated. Refer to the appropriate device reference manual for additional information on these features.

Automatic Polarity Confirmation – This feature uses Lead Monitor to automatically configure pacing and sensing polarities for bipolar devices during Implant Detection.

Sinus Preference – This programmable feature is intended to improve cardiac hemodynamics by giving preference to sinus activation of the heart over sensor-driven pacing.² The device searches for and then tracks an intrinsic sinus rate that is below the sensor-indicated rate in order to permit a slower intrinsic escape rate.

Atrial Capture Management – This feature provides automatic monitoring of atrial pacing thresholds and automatic adjustment of Amplitude and Pulse Width to maintain capture.³

¹ Use of the Transtelephonic Monitor is subject to local telecommunication regulations. The Transtelephonic Monitor may not be available in certain countries. Contact a Medtronic representative for more information.

² This feature applies to the E2DR00 devices

Ventricular Capture Management – This feature provides automatic monitoring of ventricular pacing thresholds and automatic adjustment of Amplitude and Pulse Width to maintain capture.

Rate Drop Response – This programmable feature provides backup pacing for patients who experience symptomatic episodes of a significant drop in heart rate. The device intervenes by elevating the pacing rate for a brief period.¹

Sensing Assurance – This feature automatically monitors the peak amplitude of sensed signals and adjusts atrial and ventricular sensitivities within defined limits to maintain adequate sensing margins. Sensing Assurance is enabled at the completion of Implant Detection.

Search AV+ – This programmable feature searches for the patient's intrinsic AV conduction time and adjusts the Sensed AV (SAV) and the Paced AV (PAV) intervals to promote intrinsic activation of the ventricles and to track fast atrial rates.¹

Ventricular Response Pacing – The feature regularizes the ventricular rhythm during AT/AF by modifying the pacing rate on a beat-by-beat basis to achieve pacing of just over 50% of ventricular events.

Rate Profile Optimization – This programmable feature monitors rate response at submaximal rates for activities such as walking and daily tasks and at maximal rates for activities such as vigorous exercise. Rate Profile Optimization compares the patient's daily and monthly sensor rate profiles to a nominal or programmed target rate profile, and adjusts rate response in the submaximal and maximal rate ranges to be more or less responsive.

Automatic PVARP – This feature protects against pacemaker-mediated tachycardia (PMT) and provides a higher 2:1 block rate, based on the mean atrial rate. Automatic PVARP enhances protection against PMT by lengthening PVARP at lower tracking rates and provides a higher 2:1 block rate by shortening PVARP and SAV (if necessary) at higher rates.¹

Sensor-varied PVARP – This programmable timing interval allows the device to automatically adjust the PVARP, based on the sensor-indicated rate. This protects against pacemaker-mediated tachycardia (PMT) and provides a higher 2:1 block rate.¹

³ This feature applies to the E2DR00 and E2D00 devices.

¹ This feature is found in the following models: Bipolar/Unipolar Models E2DR01, E2DR03, E2DR21, E2DR31, E2DR33; Unipolar Model E2DR06; Bipolar Model E2VDD01; Bipolar/Unipolar Models E2D01, E2D03.

Emergency pacing

Emergency pacing provides VVI pacing at high output settings in emergency situations for pacemaker-dependent patients. Table B-2 lists the emergency settings. The settings apply to all EnPulse Series pacemakers.

Table B-2. Emergency settings

Parameter	Setting
Mode	VVI
Pacing Rate	70 min ⁻¹
Ventricular	
Amplitude	7.5 V
Pulse Width	1.5 ms
Sensitivity	2.8 mV
Pacing Polarity	Unipolar
Sensing Polarity	Unipolar
Lead Monitor	Monitor Only
Ventricular Refractory Period	330 ms
Single Chamber Hysteresis	Off
Ventricular Capture Management	Off

Physical characteristics

Physical characteristics for the EnPulse Series pacemakers are provided in Table B-3 and connector block geometry information is provided in Table B-4.

Table B-3. Physical characteristics

Model	Dimensions: height X length X width (mm)	Mass (g)	Volume (cc ³)	Surface area (cm ²)	Materials in contact with human tissue	Radiopaque ID
E2DR01	44.7 x 47.9 x 7.5	27.1	12.1	30.7	For all E2DR models: Titanium, polyurethane, silicone rubber, parylene ^{a,b}	PNB
E2DR03	46.7 x 47.9 x 7.5	28.1	13.0	30.7		PNC
E2DR06	50.3 x 47.9 x 7.5	28.5	14.2	10.1 ^c		PNH
E2DR21	44.7 x 42.9 x 7.5	23.6	11.1	26.9		PMU
E2DR31	45.4 x 52.3 x 7.5	31.3	13.1	34.3		PNL
E2DR33	47.4 x 52.3 x 7.5	31.5	13.9	34.3		PNM
E2D01	44.7 x 47.9 x 7.5	27.1	12.1	30.7	For all E2D models: Titanium, polyurethane, silicone rubber	PNF
E2D03	46.7 x 47.9 x 7.5	28.1	13.0	30.7		PNG
E2SR01	40.2 X 42.9 x 7.5	21.5	9.7	26.9	For all E2SR models: Titanium, polyurethane, silicone rubber, parylene ^{a,b}	PMW
E2SR03	42.9 x 42.9 x 7.5	22.5	10.5	26.9		PMY
E2SR06	43.3 x 42.9 x 7.5	22.5	11.0	8.5 ^c		PNA
E2VDD01	44.7 x 42.9 x 7.5	23.6	11.1	26.9		Titanium, polyurethane, silicone rubber

^a Only the Models E2DR06 and E2SR06 have the parylene coating.

^b For Models E2DR21 and E2SR01, the parylene coating is optional.

^c This model is parylene coated. As a result, the exposed surface area is smaller than for a non-coated model.

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Table B-4. Connector block geometry

Models	Lead tip bore diameter	Overall bore depth
E2DR01, E2DR31, E2D01	1.93 mm	25.2 mm
E2DR03, E2DR33, E2D03	1.93 mm	25.6 mm
E2DR06	2.72 mm	26.4 mm
E2DR21, E2VDD01	1.93 mm	23.7 mm
E2SR01	1.93 mm	23.7 mm
E2SR03	1.93 mm	26.4 mm
E2SR06	2.72 mm	26.4 mm

Output waveform

The output waveform for the EnPulse Series pacemakers is provided in Figure B-1.

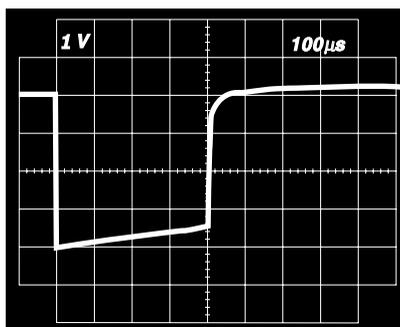


Figure B-1. Output waveform at nominal conditions (resistive load: 500 Ω)¹

¹ Amplitude and pulse width measured per prEN 45502-2-1 (1998), paragraph 6.1.1.

Batteries

Information about the batteries used in the EnPulse Series pacemakers is provided in Table B-5 through Table B-10.

Table B-5. Battery and power consumption for Models E2DR01, E2DR03, E2DR06

Parameter	Capability	Notes
Model	Sigma 263	
Type	Lithium-Iodine	
Manufacturer	Medtronic Energy and Component Center	
Voltage	2.8 V	
Usable capacity	1.3 Ah	Capacity available from BOL to EOL
Remaining capacity at ERI	0.12 Ah	Remaining capacity is measured at nominal settings, 500 Ω load in unipolar or bipolar polarity, 100% pacing
Current drain at 100% pacing		Current drain measured at nominal settings with a 500 Ω load
At implant in DDDR	21.8 μ A	
At implant in VVIR	16.2 μ A	
At ERI in VVI	15.0 μ A	
Current drain at 100% inhibited		Current drain measured at nominal settings with a 500 Ω load
At implant in DDDR	13.3 μ A	
At ERI in VVI	10.4 μ A	
Device input impedance	> 150 K Ω	Device input impedance is measured to CENELEC standard (prEN 45502-2-1)

Appendix: Implant information*Device information***Table B-6.** *Battery and power consumption for Models E2DR21*

Parameter	Capability	Notes
Model	Sigma 213	
Type	Lithium-Iodine	
Manufacturer	Medtronic Energy and Component Center	
Voltage	2.8 V	
Usable capacity	0.95 Ah	Capacity available from BOL to EOL
Remaining capacity at ERI	0.13 Ah	Remaining capacity is measured at nominal settings, 500 Ω load in unipolar or bipolar polarity, 100% pacing
Current drain at 100% pacing		Current drain measured at nominal settings with a 500 Ω load
At implant in DDDR	21.8 μ A	
At implant in VVIR	16.2 μ A	
At ERI in VVI	15.0 μ A	
Current drain at 100% inhibited		Current drain measured at nominal settings with a 500 Ω load
At implant in DDDR	13.3 μ A	
At ERI in VVI	10.4 μ A	
Device input impedance	> 150 K Ω	Device input impedance is measured to CENELEC standard (prEN 45502-2-1)

Table B-7. Battery and power consumption for Models E2DR31, E2DR33

Parameter	Capability	Notes
Model	Sigma 303	
Type	Lithium-Iodine	
Manufacturer	Medtronic Energy and Component Center	
Voltage	2.8 V	
Usable capacity	1.61 Ah	Capacity available from BOL to EOL
Remaining capacity at ERI	0.21 Ah	Remaining capacity is measured at nominal settings, 500 Ω load in unipolar or bipolar polarity, 100% pacing
Current drain at 100% pacing		Current drain measured at nominal settings with a 500 Ω load
At implant in DDDR	21.8 μ A	
At implant in VVIR	16.2 μ A	
At ERI in VVI	15.0 μ A	
Current drain at 100% inhibited		Current drain measured at nominal settings with a 500 Ω load
At implant in DDDR	13.3 μ A	
At ERI in VVI	10.4 μ A	
Device input impedance	> 150 K Ω	Device input impedance is measured to CENELEC standard (prEN 45502-2-1)

Appendix: Implant information*Device information***Table B-8.** *Battery and power consumption for Models E2SR01, E2SR03, E2SR06*

Parameter	Capability	Notes
Model	Sigma 213	
Type	Lithium-Iodine	
Manufacturer	Medtronic Energy and Component Center	
Voltage	2.8 V	
Usable capacity	0.94 Ah	Capacity available from BOL to EOL
Remaining capacity at ERI	0.10 Ah	Remaining capacity is measured at nominal settings, 500 Ω load in unipolar or bipolar polarity, 100% pacing
Current drain at 100% pacing		Current drain measured at nominal settings with a 500 Ω load
At implant in VVIR	15.2 μ A	
At ERI in VVI	14.6 μ A	
Current drain at 100% inhibited		Current drain measured at nominal settings with a 500 Ω load
At implant in VVIR	11.0 μ A	
At ERI in VVI	10.6 μ A	
Device input impedance	> 150 K Ω	Device input impedance is measured to CENELEC standard (prEN 45502-2-1)

Table B-9. Battery and power consumption for Models E2VDD01

Parameter	Capability	Notes
Model	Sigma 213	
Type	Lithium-Iodine	
Manufacturer	Medtronic Energy and Component Center	
Voltage	2.8 V	
Usable capacity	0.94 Ah	Capacity available from BOL to EOL
Remaining capacity at ERI	0.10 Ah	Remaining capacity is measured at nominal settings, 500 Ω load in unipolar or bipolar polarity, 100% pacing
Current drain at 100% pacing		Current drain measured at nominal settings with a 500 Ω load
At implant in VDD	17.5 μ A	
At ERI in VVI	15.2 μ A	
Current drain at 100% inhibited		Current drain measured at nominal settings with a 500 Ω load
At implant in VDD	13.3 μ A	
At ERI in VVI	11.0 μ A	
Device input impedance	> 150 K Ω	Device input impedance is measured to CENELEC standard (prEN 45502-2-1)

Appendix: Implant information*Device information***Table B-10.** *Battery and power consumption for Models E2D01, E2D03,*

Parameter	Capability	Notes
Model	Sigma 263	
Type	Lithium-Iodine	
Manufacturer	Medtronic Energy and Component Center	
Voltage	2.8 V	
Usable capacity	1.3 Ah	Capacity available from BOL to EOL
Remaining capacity at ERI	0.12 Ah	Remaining capacity is measured at nominal settings, 500 Ω load in unipolar or bipolar polarity, 100% pacing
Current drain at 100% pacing		Current drain measured at nominal settings with a 500 Ω load
At implant in DDD	21.8 μ A	
At implant in VVIR	16.2 μ A	
At ERI in VVI	15.0 μ A	
Current drain at 100% inhibited		Current drain measured at nominal settings with a 500 Ω load
At implant in DDD	13.3 μ A	
At ERI in VVI	10.4 μ A	
Device input impedance	> 150 K Ω	Device input impedance is measured to CENELEC standard (prEN 45502-2-1)

Longevity

Longevity projections from implant to ERI are listed in Table B-11 through Table B-16. The projections are based on operation in DDDR, SSIR, VDD mode at a programmed rate of 60 min⁻¹ and pulse widths of 0.4 ms. Additional longevity projections from implant to ERI are listed in Table B-17 through Table B-22. The projections are based on operation in DDDR, SSIR, VDD mode at a programmed rate of 70 min⁻¹ and pulse widths of 0.5 ms. These values should not be interpreted as precise numbers. Longevity for “worst case” settings is calculated at 100% pacing with 5-V amplitudes, 1 ms pulse width, a 500 Ω load, a 70 min⁻¹ (typical) or 100 min⁻¹ (pediatric) rate.

Appendix: Implant information

Device information

Table B-11. E2DR01/03/06 Longevity (years) (DDDR mode, 60 min⁻¹, 0.4 ms pulse width)

A amplitude, V amplitude	% Paced	Lead impedance (Ohms)			
		500	600	1000	1200
3.5 V, 3.5 V	100%	6.2	6.5	7.6	7.9
	75%	6.8	7.2	8.1	8.4
	50%	7.6	7.9	8.6	8.8
	25%	8.6	8.7	9.2	9.4
	0%	9.9	9.9	10.0	10.0
2.5 V, 2.5 V	100%	7.5	7.8	8.5	8.6
	75%	8.0	8.2	8.7	8.9
	50%	8.4	8.6	9.0	9.1
	25%	9.0	9.1	9.4	9.4
	0%	9.6	9.6	9.7	9.7
1.5 V, 2.5 V	100%	7.9	8.1	8.7	8.8
	75%	8.3	8.5	8.9	9.0
	50%	8.7	8.9	9.2	9.2
	25%	9.1	9.2	9.4	9.4
	0%	9.6	9.6	9.7	9.7
1.5 V, 1.5 V	100%	8.7	8.9	9.4	9.6
	75%	9.1	9.3	9.6	9.7
	50%	9.4	9.6	9.9	9.9
	25%	9.8	9.9	10.1	10.1
	0%	10.3	10.3	10.3	10.3

Longevity for "worst case" settings is 2.3 years (70 min⁻¹) and 1.6 years (100 min⁻¹)

Table B-12. E2DR21 Longevity (years) (DDDR mode, 60 min⁻¹, 0.4 ms pulse width)

A amplitude, V amplitude	% Paced	Lead impedance (Ohms)			
		500	600	1000	1200
3.5 V, 3.5 V	100%	4.3	4.6	5.4	5.6
	75%	4.8	5.0	5.7	5.9
	50%	5.3	5.5	6.1	6.3
	25%	6.0	6.2	6.6	6.7
	0%	7.0	7.0	7.1	7.1
2.5 V, 2.5 V	100%	5.4	5.6	6.0	6.1
	75%	5.7	5.9	6.2	6.3
	50%	6.0	6.2	6.4	6.5
	25%	6.4	6.5	6.7	6.7
	0%	6.8	6.9	6.9	6.9
1.5 V, 2.5 V	100%	5.7	5.8	6.2	6.3
	75%	5.9	6.1	6.4	6.5
	50%	6.2	6.3	6.5	6.6
	25%	6.5	6.6	6.7	6.8
	0%	6.9	6.9	6.9	6.9
1.5 V, 1.5 V	100%	6.2	6.4	6.8	6.9
	75%	6.5	6.6	6.9	7.0
	50%	6.8	6.8	7.1	7.2
	25%	7.0	7.1	7.2	7.3
	0%	7.4	7.4	7.4	7.4

Longevity for "worst case" settings is 1.5 years (70 min⁻¹) and 1.1 years (100 min⁻¹)

Appendix: Implant information

Device information

Table B-13. E2DR31/33 Longevity (years) (DDDR mode, 60 min⁻¹, 0.4 ms pulse width)

A amplitude, V amplitude	% Paced	Lead impedance (Ohms)			
		500	600	1000	1200
3.5 V, 3.5 V	100%	7.4	7.9	9.1	9.4
	75%	8.1	8.6	9.6	9.9
	50%	9.0	9.4	10.2	10.5
	25%	10.1	10.4	10.9	11.1
	0%	11.5	11.6	11.7	11.8
2.5 V, 2.5 V	100%	9.0	9.3	10.1	10.3
	75%	9.5	9.8	10.4	10.6
	50%	10.1	10.3	10.7	10.9
	25%	10.6	10.8	11.1	11.2
	0%	11.3	11.3	11.4	11.5
1.5 V, 2.5 V	100%	9.5	9.7	10.4	10.6
	75%	9.9	10.1	10.6	10.8
	50%	10.3	10.5	10.9	11.0
	25%	10.8	10.9	11.2	11.3
	0%	11.4	11.4	11.5	11.5
1.5 V, 1.5 V	100%	10.5	10.7	11.3	11.4
	75%	10.9	11.0	11.5	11.6
	50%	11.3	11.4	11.7	11.8
	25%	11.7	11.8	12.0	12.0
	0%	12.2	12.2	12.2	12.3

Longevity for "worst case" settings is 2.6 years (70 min⁻¹) and 1.9 years (100 min⁻¹).

Table B-14. E2VDD01 Longevity (years), (VDD mode, 60 min⁻¹, 0.4 ms pulse width)

Amplitude	% Paced	Lead impedance (Ohms)			
		500	600	1000	1200
3.5 V	100%	5.5	5.7	6.2	6.3
	75%	5.8	6.0	6.4	6.6
	50%	6.2	6.3	6.7	6.7
	25%	6.6	6.7	6.9	7.0
	0%	7.1	7.1	7.2	7.2
2.5 V	100%	6.1	6.2	6.5	6.6
	75%	6.3	6.4	6.6	6.7
	50%	6.5	6.5	6.7	6.8
	25%	6.7	6.7	6.9	6.9
	0%	6.9	6.9	6.9	6.9
1.5 V	100%	6.8	6.9	7.1	7.2
	75%	7.0	7.0	7.2	7.2
	50%	7.1	7.2	7.3	7.3
	25%	7.2	7.3	7.4	7.4
	0%	7.4	7.4	7.5	7.5

Longevity for “worst case” settings is 2.5 years (70 min⁻¹) and 1.8 years (100 min⁻¹).

Note: VDD longevity calculated with following conditions; Dual chamber device, DDD mode, 0.0 V amplitude in the atrium (atrium pacing disabled).

Appendix: Implant information

Device information

Table B-15. E2SR01/03/06 Longevity (years) (SSIR mode, 60 min⁻¹, 0.4 ms pulse width)

Amplitude	% Paced	Lead impedance (Ohms)			
		500	600	1000	1200
3.5 V	100%	6.3	6.6	7.3	7.5
	75%	6.7	7.0	7.6	7.8
	50%	7.2	7.5	7.9	8.1
	25%	7.9	8.0	8.3	8.4
	0%	8.5	8.6	8.7	8.7
2.5 V	100%	7.2	7.3	7.7	7.8
	75%	7.4	7.5	7.9	8.0
	50%	7.7	7.8	8.0	8.1
	25%	8.0	8.0	8.2	8.3
	0%	8.3	8.3	8.4	8.4
1.5 V	100%	8.1	8.3	8.5	8.6
	75%	8.3	8.4	8.6	8.7
	50%	8.5	8.6	8.8	8.8
	25%	8.7	8.8	8.9	8.9
	0%	9.0	9.0	9.0	9.0

Longevity for “worst case” settings is 2.7 years (70 min⁻¹) and 2.0 years (100 min⁻¹)

Table B-16. E2D01/03 Longevity (years) (DDD mode, 60 min⁻¹, 0.4 ms pulse width)

A amplitude, V amplitude	% Paced	Lead impedance (Ohms)			
		500	600	1000	1200
3.5 V, 3.5 V	100%	6.2	6.5	7.6	7.9
	75%	6.8	7.2	8.1	8.4
	50%	7.6	7.9	8.6	8.8
	25%	8.6	8.7	9.2	9.4
	0%	9.9	9.9	10.0	10.0
2.5 V, 2.5 V	100%	7.5	7.8	8.5	8.6
	75%	8.0	8.2	8.7	8.9
	50%	8.4	8.6	9.0	9.1
	25%	9.0	9.1	9.4	9.4
	0%	9.6	9.6	9.7	9.6
1.5 V, 2.5 V	100%	7.9	8.1	8.7	8.8
	75%	8.3	8.5	8.9	9.0
	50%	8.7	8.9	9.2	9.2
	25%	9.1	9.2	9.4	9.4
	0%	9.6	9.6	9.7	9.7
1.5 V, 1.5 V	100%	8.7	8.9	9.4	9.6
	75%	9.1	9.3	9.6	9.7
	50%	9.4	9.6	9.9	9.9
	25%	9.8	9.9	10.1	10.1
	0%	10.3	10.3	10.3	10.3

Longevity for "worst case" settings is 2.3 years (70 min⁻¹) and 1.6 years (100 min⁻¹)

Appendix: Implant information
 Device information

Table B-17. E2DR01/03/06 Longevity (DDDR mode, 70 min⁻¹, 0.5 ms pulse width)

A amplitude, V amplitude	% Paced	Lead Impedance (Ohms)
		500
2.5 V, 2.5 V	100%	6.7
	0%	9.2
5 V, 5 V	100%	3.4
	0%	9.0

Table B-18. E2DR21 Longevity (DDDR mode, 70 min⁻¹, 0.5 ms pulse width)

A amplitude, V amplitude	% Paced	Lead Impedance (Ohms)
		500
2.5 V, 2.5 V	100%	4.7
	0%	6.5
5 V, 5 V	100%	2.3
	0%	6.3

Table B-19. E2DR31/33 Longevity (DDDR mode, 70 min⁻¹, 0.5 ms pulse width)

A amplitude, V amplitude	% Paced	Lead Impedance (Ohms)
		500
2.5 V, 2.5 V	100%	8.0
	0%	10.9
5 V, 5 V	100%	4.0
	0%	9.5

Table B-20. E2VDD01 Longevity (VDD mode, 70 min⁻¹, 0.5 ms pulse width)

Amplitude	% Paced	Lead Impedance (Ohms)
		500
2.5 V	100%	5.6
	0%	6.7
5 V	100%	3.5
	0%	6.3

Appendix: Implant information
Device information

Table B-21. E2SR01/03/06 Longevity (SSIR mode, 70 min⁻¹, 0.5 ms pulse width)

Amplitude	% Paced	Lead Impedance (Ohms)
		500
2.5 V	100 %	6.6
	0%	8.0
5 V	100%	4.0
	0%	7.6

Table B-22. E2D01/03 Longevity (DDD mode, 70 min⁻¹, 0.5 ms pulse width)

A amplitude, V amplitude	% Paced	Lead Impedance (Ohms)
		500
2.5 V, 2.5 V	100%	6.7
	0%	9.2
5 V, 5 V	100%	3.4
	0%	9.0

Prolonged service period

Longevity projections from ERI to erratic pacing are provided in Table B-23. (See “Elective Replacement Indicator” on page B-13 for more information.) The projections are based on 100% pacing at a programmed rate of 60 min⁻¹, atrial and ventricular amplitudes of 3.5 V, pulse widths of 0.4 ms, and lead impedance of 500 Ω.

Table B-23. Prolonged service period

Previous Programmed Modes before ERI	Minimum projected longevity (months)	Average projected longevity (months) ^{a, b}
Models E2DR01, E2DR03, E2DR06		
DDDR	5.0	11.0
VVIR	4.2	8.8
Model E2DR21		
DDDR	4.7	11.8
VVIR	3.9	9.1
Model E2DR31, E2DR33		
DDDR	12.7	19.3
VVIR	10.6	16.0
Models E2SR01, E2SR03, E2SR06		
VVIR	3.8	8.8
VVI	3.8	8.8
Model E2VDD01		
VDD	4.1	9.8
VVIR	3.9	9.1
Model E2D01, E2D03		
DDD	5.0	11.0
VVIR	4.2	8.8

^a Programmed settings which lead to increased current demands in VVI 65 min⁻¹ operating conditions after ERI may slightly decrease average projections. Increased current demands post-ERI could be caused by an increase in pacing rate, an increase in amplitude, and an increase in pulse width.

^b Current data show that combinations of extreme pacing conditions (high output values ≥ 5.0 V) and high pulse widths and/or low impedance values [300 Ω] may decrease average projections in VVI modes.

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