

Draft Literature/Labeling Review

**Project: ZOOM LATITUDE operator's manual
US**

Draft Review

Monday, July 26

Date due: Tuesday, July 27

Return to:

Mail Stop:

You are being asked to review product literature/labeling because of your particular expertise. To minimize the number of review cycles, please review the attached draft thoroughly and provide any comments, changes, or concerns at this time.

- Please provide any comments on the attached draft by the due date indicated above.
- A non-response will be taken to mean that you accept the draft content "as is."
- Use the grid on the reverse side of this form to help focus your review efforts.
- Your signature is not required.

Note: After receiving comments and making any revisions that are required, Technical Communications will use Windchill to route a final version of this literature/labeling to obtain required electronic signatures.

We appreciate your efforts and value your feedback. Thank you!

Department	Mail Stop	Reviewers	For Tech Comm Use Only				FYI Reviewers (Return not necessary)	Mail Stop
			Rec'd	OK	Chgs	Trans		
Engineering		Scott Freeberg						
Regulatory		Karen Alsop						
Tech Comm		Nathan Quanbeck						

Reason for review / Writer's comments: Please review the operator's manual carefully. Pay particular attention to any content that should not appear in the US manual (OUS manual will be routed later). Note: there is at least one outstanding issue having to do with the On/Off button and its description. Thanks. WWS

Instructions For Review

The table below was designed to help streamline the literature review process, to reduce the number of reviews per piece of literature, to reduce the amount of time you need to spend reviewing each piece, and to help you focus your attention while reviewing literature.

Suggested Areas of Focus	Clinicals	Tech Comm	Design Engineer	Legal	Marketing	Package Design	Project Manager	Reg	FCE
Verify against clinical protocol	X				X			X	
Product description, product handling (sterilization, shipping, storage)			X		X				
Product specifications, units of measure (in tables and throughout text)			X		X				
Product features—appropriate features highlighted? described correctly? any features overlooked?	X		X	X	X			X	X
Illustrations appropriate to corresponding text and labeled correctly?	X	X	X		X				X
Tables and text relating to parameters, tolerances, product functions correct?	X		X		X				
Review cautions and notes—appropriate? necessary? any missing?	X		X	X	X			X	X
Implant procedures correct?	X				X				X
Equipment hook-up procedures, lead-to-PG connections, etc.	X		X		X				X
Are references to other Guidant products still correct and relevant?	X		X		X		X	X	
Is info in this literature consistent with other related literature (leads, pg)?	X	X	X		X			X	X
References to other products affect other submissions?	X	X			X			X	
Liability issues based on claims made in literature	X			X				X	
Warranty information correct?				X	X				
Has any information that should be included been overlooked (features, specs, government requirements, legal requirements)?	X	X	X	X	X	X	X	X	X
List of items packaged with product (is the list correct? anything missing?)			X		X	X			
Does the piece of literature match the documentation specs? correct size?		X			X	X			
Verify part number of literature. Labels: appropriate mfg codes, ACNs, etc.		X				X			
Verify copyright and trademark notations		X		X	X				
Adherence to literature/communications standards		X							
Punctuation, consistency in treatment of product names, parameter, etc.		X							
Guidant address, phone numbers, warranty layout formats correct?		X							

Operator's Manual

ZOOM® LATITUDE™

**Programming
System**

MODEL 3120 PRM

RESTRICTED DEVICE: Federal law (USA) restricts
the sale, distribution, or use of this device to, by, or
on the lawful order of a physician.

GUIDANT

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DESCRIPTION AND USE

The ZOOM® LATITUDE™ Programming System, which includes the Model 3120 Programmer/Recorder/Monitor (PRM), is a portable cardiac rhythm management system designed to be used with Guidant implantable pulse generators.

For programming instructions, refer to the System Guide for the Guidant pulse generator being interrogated.

Intended Use

The Model 3120 PRM is intended to be used as a complete system to communicate with Guidant implantable pulse generators.

The software in use controls all communication functions for the pulse generator. For detailed software application instructions, refer to the System Guide for the Guidant pulse generator being interrogated.

Contraindications

For contraindications for use, refer to the System Guide for the Guidant pulse generator being interrogated.

The Model 3120 PRM is contraindicated for use with any pulse generator other than a Guidant device.

Precautions

General

- Use the appropriate Guidant programmers equipped with the appropriate software to program Guidant pulse generators.
- The Model 3120 PRM is designed to be used only with the Model 6577 Sterilizable Telemetry Wand. Do not use the Model 6575 Telemetry Wand with the Model 3120 PRM.
- Use only the supplied stylus with the Model 3120 PRM; the use of any other object could damage the touchscreen.

NOTE: *Use of the stylus is recommended for accuracy; however, touching an item on the screen with your finger will also activate a selection.*

Preparation for Use

- Remove the telemetry wand from all packaging material before sterilizing it.
- Avoid establishing telemetry communication between the PRM and the pulse generator when the PRM is in close proximity to monitors, high-frequency electrosurgical equipment, and strong magnetic fields, such as magnetic resonance imaging (MRI) devices. The telemetry link may be impaired and, in the case of MRI, may interfere with the PRM.

Maintenance and Handling

- Do not use an abrasive cloth or volatile solvents to clean any portion of the PRM.

- Keep disks away from magnets and magnetized objects, including telephones, power-supply adapters, and monitors.
- Do not place a magnet on the PRM.
- The PRM is not water-proof or explosion-proof. It should not be used in the presence of flammable gas mixtures including anesthetic mixture with air, oxygen, or nitrous oxide.

Adverse Effects

None known.

SYSTEM FEATURES

The PRM communicates with Guidant pulse generators via telemetry using the Guidant Model 6577 Sterilizable Telemetry Wand to perform the following functions:

- Interrogates the programmable pulse generator.
- Programs detection and therapy parameters for an implantable Guidant pulse generator.
- Displays, records, and stores patient data and allows the physician to evaluate alternative prescription modes.
- Stores patient data that can be recalled later in the patient session for analysis. (For certain applications only)
- Stores patient data on a disk that can be accessed at later sessions.
- Generates printed reports that detail pulse generator functions, stored patient data, and test results.
- Allows the physician to perform tests in an electrophysiology (EP) laboratory, in an operating room, in an emergency room, or at a patient's bedside.

In addition, the PRM has the following capabilities:

- Provides a direct interface between an external stimulator and an implanted Guidant pulse generator for programmed electrical stimulation (PES) during EP studies.
- Provides use without device telemetry as an electrocardiogram (ECG) display and recorder for patient diagnosis.
- Simultaneously prints real-time surface ECG and telemetered signals (intracardiac electrograms and event markers) via the internal printer/recorder.

The PRM is equipped with the following features:

- PRM function keys, including PROGRAM, STAT PACE, STAT SHOCK, DIVERT THERAPY, and INTERROGATE.
- Printer/recorder function keys, including paper speed, calibrate, zero to baseline, and paper feed.
- Touchscreen with tethered stylus.

- Color display screen.
- One floppy disk drive.
- Internal hard drive.
- High-speed four-inch (110 cm) thermal printer/recorder.
- Connections for slaved stimulation via an external signal source.
- Connection for recording data on an external FM tape recorder or strip chart recorder or both.
- Connection for an optional external printer.
- USB port for software installation by Guidant personnel.

System Accessories

The ZOOM LATITUDE programming system consists of the Model 3120 PRM and the following accessories:

- Model 2902 AC Power Cord
- Model 6577 Sterilizable Telemetry Wand
- Model 6627 Patient Data Disks (10)
- Model 6750 Surface ECG Patient Cable
- Model 6979 Printer Paper (4)
- Antenna

Other accessories for use with the PRM that can be ordered from Guidant include the following:

- Model 6809 Accessory Kit
- Model 6892 Controller-Stimulator Cable
- Model 6750 Surface ECG Patient Cable
- Model 6924 External Recorder Cable
- Model 6629 ECG-BNC Slave Cable
- Model 6930 Stimulation Input Cable Adapters
- Model 6934 Phono-BNC Adapters
- Model 6977 VGA Extension Cable

Optional External Printer

The use of an external printer is optional. Only compatible external printers that have been tested and qualified for use should be used with the Model 3120 PRM. Contact your Guidant sales representative to determine which printer(s) can be used.

CAUTION: Although the external printer meets leakage-current requirements for commercial products, it may not meet the reduced leakage requirements for medical products. Consequently, the external printer must be kept outside the patient environment (at least 1.5 meters away from the patient).

Optional External Monitor

The use of an external monitor is optional. Contact your Guidant sales representative to determine which monitor(s) can be used.

CAUTION: Although the external monitor meets leakage-current requirements for commercial products, it may not meet the reduced leakage requirements for medical products. Consequently, the external monitor must be kept outside the patient environment (at least 1.5 meters away from the patient).

PREPARING THE PRM FOR USE

Prepare the Telemetry Wand

1. If the telemetry wand is to be used in a sterile field when using the PRM, it **first must be sterilized** with ethylene oxide or steam. To sterilize it, follow the instructions in the product literature for the wand.

CAUTION: Remove the telemetry wand from all packaging material before sterilizing it.

2. Plug the telemetry wand into the connector on the right side of the PRM (Figure 1).

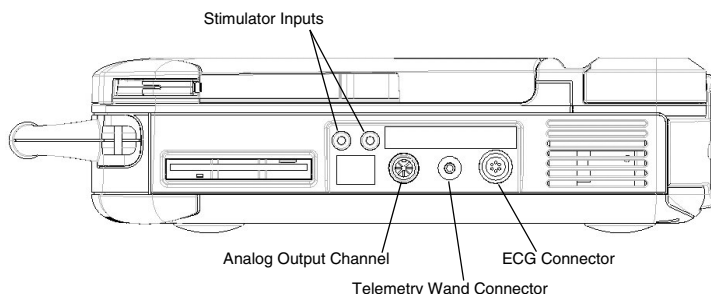


Figure 1. Right side panel of the PRM.

CAUTION: Avoid establishing telemetry communication between the PRM and the pulse generator when the PRM is in close proximity to monitors, high-frequency electrosurgical equipment, and strong magnetic fields, such as MRI devices. The telemetry link may be impaired and, in the case of MRI, may interfere with the PRM.

This device complies with Part 15 of the Federal Communications Commission (FCC) rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

CAUTION: Changes or modifications not expressly approved by Guidant could void the user's authority to operate the equipment.

Make External Cable Connections

1. Connect the Model 6750 Surface ECG Patient Cable to the ECG connector on the right side of the PRM (Figure 1). This patient connection is electrically isolated. Attach the surface electrodes to the patient in a standard three-wire or five-wire configuration.

NOTES:

- If the PRM is in close proximity to high-frequency electrosurgical equipment, the surface ECG traces may exhibit noise interference. Refer to the troubleshooting section for corrective action.
 - The ECG subsystem may be sensitive to ambient noise when the ECG inputs are not terminated.
2. Connect the Model 6924 External Recorder Cable to the analog output channel on the right side of the PRM (Figure 1). Connect the other end to the multichannel recorder or external strip chart recorder. The Model 3120 PRM has high-level analog outputs.
 3. Connect the Model 6892 Controller-Stimulator Cable to the pacing stimulation source connector marked "Stimulator Input" on the right side of the PRM (Figure 1) and then into the corresponding terminal on the electrical stimulation source.
 4. (Optional) Connect the external printer to the PRM using the parallel cable provided with the printer (Figure 2). The external printer must be connected and activated to allow external reports to be printed.
 5. (Optional) Connect the external monitor to the PRM using a standard VGA cable (Figure 2). The Model 6977 VGA Extension Cable is available from Guidant as an accessory.

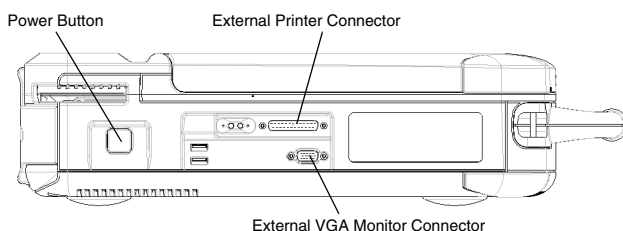


Figure 2. Left side panel of the PRM.

Start the PRM

Perform the following steps to start the PRM:

1. Connect the power cord into the AC connector on the rear panel (Figure 3).
2. Plug the power cord into the appropriate AC outlet.

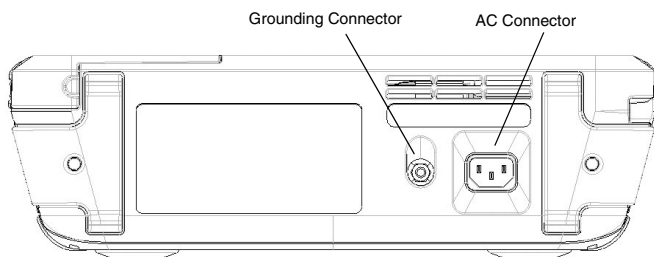


Figure 3. Rear panel of the PRM.

3. Raise the screen to a comfortable viewing angle.
4. Press the Power button (Figure 2).
5. Wait for the Guidant startup screen (Figure 4) to appear.

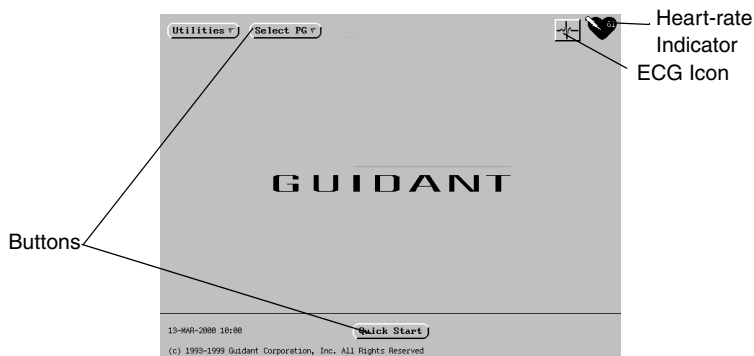


Figure 4. The startup screen is displayed when the programmer is powered On.

USING THE PRM

Startup Screen

The startup screen (Figure 4) displays the following information:

- The Utilities button allows access to programmer information and set-up functions prior to accessing the application software.

- The Select PG button allows the desired application to be chosen and started.
- The ECG icon changes the screen display to an ECG display available for patient diagnosis.
- The heart-rate indicator displays the intrinsic ventricular rate of the patient.
- The Quick Start® button is an automated method for starting the appropriate application.
- The bottom left corner of the screen displays the date, time, and programmer information.

Touchscreen

The Model 3120 PRM has a touchscreen. You can select a button or icon on the touchscreen by touching the desired item with the stylus attached to the PRM and lifting the stylus from the screen. Only one button or icon may be selected at a time. Menu and parameter selection buttons will activate when selected; the buttons in the parameter value palettes will activate when the stylus is lifted from the screen. To move from one screen to another, select the navigation buttons at the bottom of the screen.

CAUTION: Use the supplied stylus with the Model 3120 PRM; the use of any other object could damage the touchscreen.

NOTE: Use of the stylus is recommended for accuracy; however, touching an item on the screen with your finger will also select that item.

Indicator lights

The Model 3120 PRM has three indicator lights on the upper left corner, above the screen:

Symbol	Indicator light	Function
	For future use.	For future use.
	Inductive telemetry	Lit when inductive, wandless telemetry has been established and interrogation or programming is occurring
	On	Lit when the PRM is On.

NOTE: ZIP telemetry is a wandless, two-way radio frequency (RF) communication option that allows the PRM system to communicate with the pulse generator.

ECG Display

To display surface ECG signals on the PRM without device interrogation, select the ECG icon on the startup screen (Figure 5). Connect the patient leads; for instructions on proper patient cable connections, refer to “EXTERNAL CABLE CONNECTIONS” on page 22. The PRM can display three surface traces of up to six limb leads or one chest lead. The top displayed lead will be annotated with the pacing spike marker if that feature is selected. To display the pacing spike markers correctly, the Lead II electrodes must be connected to the patient regardless of which lead is displayed. The heart-rate indicator in the upper-right corner of the startup screen will display the intrinsic ventricular rate as the trace runs.

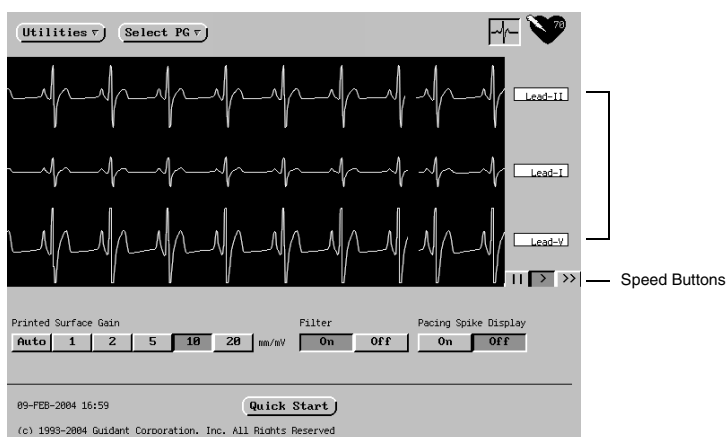


Figure 5. The ECG screen, as accessed from the startup screen.

The following screen buttons can be used to change the values and appearance of the traces:

- **Lead Selection Buttons**—Select the lead traces to be displayed.
- **Speed Buttons**—Select the desired speed button on the ECG display: Pause (II) (to freeze the trace), Play (>), or Fast-Forward (>>).
- **Printed Surface Gain**—Select the appropriate value to adjust the surface gain of the traces that are captured on printouts.
- **Filter**—Select On to minimize noise on the surface ECG.
- **Pacing Spike Display**—Select On to show detected pacing spikes, annotated by a marker on the top waveform.

NOTE: The values as set up on the startup screen will be the defaults used for the application traces. The corresponding values can be changed from the Trace Selections screen while in the application. For detailed application programming instructions, refer to the System Guide for the Guidant pulse generator being interrogated.

Keys

For specific instructions on how to operate the PRM keys and use the telemetry wand, refer to the System Guide for the Guidant pulse generator being interrogated. General key functions are summarized below. The key pad on the right side of the PRM is shown in Figure 6.

Table 1 Key Functions

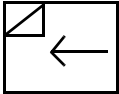
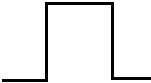
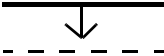
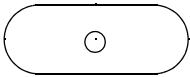
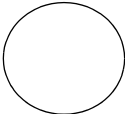
<i>Left side of key pad:</i>	
0 (stop), 10, 25, 50, and 100 mm/sec (paper-speed keys)	Press the speed keys to specify the paper speed for the internal printer/recorder. The printout will show the date and time, lead(s) being printed, gain setting, chart speed, and filter setting. To stop the printer/recorder, press the speed key labeled "0" (zero).
	Press the paper-feed key to scroll the printer paper on the internal printer/recorder.
	Press this key to cause the internal printer/recorder to print a one-mV calibration pulse.
	Press this key to force the trace back to the baseline after a defibrillation shock.
<i>Right side of key pad</i>	
 STAT PACE	Press STAT PACE when in telemetry communication with the pulse generator to program predetermined parameters for emergency bradycardia pacing
 DIVERT THERAPY	Press DIVERT THERAPY when in telemetry communication with the pulse generator to divert tachycardia therapy delivery.

Table 1 Key Functions

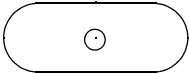
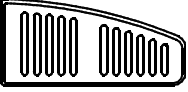
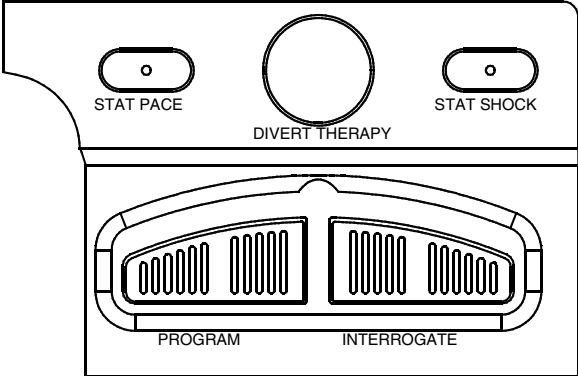
 STAT SHOCK	Press STAT SHOCK when in telemetry communication with the pulse generator to program predetermined high-energy parameters for emergency shock delivery.
 PROGRAM	Press PROGRAM when in telemetry communication with the pulse generator to transmit new parameter values to the pulse generator.
 INTERROGATE	Press INTERROGATE when in telemetry communication with the pulse generator to obtain information stored in the pulse generator's memory.
	

Figure 6. Model 3120 PRM right-side keypad.

Monitoring/Recording Functions

Surface ECG

Pressing any speed key will run a surface ECG if the surface ECG patient cable is connected to the PRM and electrodes are attached to the patient (unless a report is being printed). For detailed instructions, refer to “ECG Display” on page 10.

Intracardiac Electrogram

Intracardiac electrograms may be printed or displayed and event markers may be printed by the PRM. For detailed instructions, refer to the System Guide for the Guidant pulse generator being interrogated.

Using an External Recorder

To view the surface ECG traces on an external recorder, press the desired speed key on the external printer/recorder while the traces are displayed on the PRM screen. See “EXTERNAL CABLE CONNECTIONS” on page 22 for instructions on connecting the PRM to the external recorder. Refer to the external recorder manual for instructions specific to its operation.

Using an External Printer

If supported by the software application currently running, an optional external printer can be used. To print reports to an external printer, first connect the printer to the Model 3120 PRM using the parallel cable. The cable connects the external printer to the PRM via the external printer connector (Figure 2). The external printer must be connected and activated to allow external reports to be printed. For more information, see “Optional External Printer” on page 5.

Equipment connected to the external connections must comply with the respective IEC standards (e.g. IEC 950 for data processing equipment and IEC 601-1 for medical equipment). Furthermore all configurations shall comply with the system standard IEC 601-1-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the system standard IEC 601-1-1. If in doubt, Guidant Technical Services department or your local Guidant Representative.

Quick Start

The Quick Start button is used to automatically identify and interrogate the implanted pulse generator. Place the telemetry wand over the pulse generator, and select the Quick Start button. A message window will appear, indicating one of the following conditions, based on the implanted device:

- **Application Startup in Progress**—If the software for the implanted device is installed on the PRM, the PRM will identify the device, open the correct application, and automatically interrogate the pulse generator.
- **Software not installed**—If the software application for the implanted device is available for the PRM but not installed on it, a message window will appear, identifying the device and stating that the software is not installed on the PRM.
- **Software not available on PRM**—If an older model of Guidant device is identified, a message window will appear, informing the user that he or she must use a Model 2035 or 2901 programmer to interrogate and/

or program the device. The model number of the software module or application will also be identified.

- **PG not identified**—If a non-Guidant or one of certain older models of Guidant pulse generators is implanted, a message window will appear, notifying the user that the wand is out of range, telemetry noise is present, or the device is not identified.

To access the demonstration (DEMO) mode (or the Read Disk feature, which is available in some applications), use the Select PG button at the top of the screen to choose the pulse generator family instead of using the Quick Start button.

The Utilities Menu on the Startup Screen

If desired, before accessing the pulse generator software application, the version numbers of the system software and software applications can be displayed, the programmer clock can be modified, the institution name can be changed, and data disks can be copied and formatted. (To access the startup screen from within a software application, select the Quit option from the Utilities button to exit the software application and return to the startup screen.)

1. On the startup screen, select the Utilities button.
2. Select the About option to view the version numbers of the system software and application software residing on the programmer.
3. Select the Set Programmer Clock option to change the programmer date and time (24-hour clock), which is displayed in the lower left corner of the startup screen. The Set Date and Time window will appear (Figure 7).
 - a. Change the values by selecting an up or down arrow.
 - b. To reset the seconds display to zero, select the box containing two digits (shown as 00 in Figure 7).



Figure 7 The Set Date and Time window.

- c. When the desired values are displayed, select the Set Programmer Clock button to confirm the new date and time. (To cancel any changes prior to confirming the new values, select the Cancel button; the window will close without changing the values.)

NOTE: The programmer and pulse generator clocks may be synchronized once the application is accessed. Refer to the “Set Clock” section in the System Guide for the Guidant pulse generator being interrogated.

4. Select the About option to update the institution name. If the programmer has been moved to a different institution, the name of the institution as it appears on the startup screen can be changed. For instructions on entering new data, refer to “Changing Parameter Values” on page 16.

NOTE: The institution name also is displayed in the heading of printed reports.

5. Select the Format Disk option to erase all data from a Model 6627 Patient Data Disk and reformat it so new data can be saved on the disk. Follow the directions displayed in the message windows.
6. Select the Copy Disk option to copy patient data from one disk (the source disk) to another (the destination disk). Do not use a destination disk that contains patient data, because the existing data will be lost. Follow the directions displayed in the message windows. (This function performs in the same manner as the Copy Disk function of the software application; refer to the “Utilities Button on the Main Application Screen” section of the System Guide for the Guidant device being interrogated.

The Select PG Option on the Startup Screen

This option allows the software application to be selected manually. Use this option to access the DEMO mode (or the Read Disk feature, which is available in some applications). (You can also use this option to interrogate a pulse generator, but you may find it more convenient to use the Quick Start feature described earlier in this manual.)

1. To access the desired software application without using the Quick Start feature, select the Select PG button.
2. The names of the available software applications will appear. Select the applicable software application. Each application communicates with its pulse-generator family.
3. A screen will appear with options to interrogate the pulse generator or use the DEMO mode. (Some applications will also display the option to read a patient data disk).
4. To become familiar with the software without interrogating a pulse generator, select the DEMO button; the main application screen will be displayed and the DEMO logo will appear at the top of the screen. The screens displayed during the DEMO mode reflect the software application family's device features and programmable values.

NOTE: STAT PACE, STAT SHOCK, and DIVERT THERAPY commands are functional in DEMO mode only if the telemetry wand is positioned over the pulse generator.

5. To exit the DEMO mode, depending on which application you are using, select the New Patient or Quit options from either the Utilities button or the Exit button. For more information about these options, refer to the System Guide for the Guidant pulse generator being interrogated.
6. To proceed with an interrogation session or read data from a patient data disk (which is a feature that is available in some applications), refer to the System Guide for the Guidant pulse generator being interrogated.

Changing Parameter Values

The screens for many of the features contain parameter information, including parameter names, values for the present parameter settings, value boxes to accommodate value changes, and buttons to cancel changes. Many screens display two columns next to the parameter names: the Present column and the Change column. The Present column displays the currently programmed value for each parameter, and the Change column displays value boxes that allow the clinician to make changes to the parameters. If a particular parameter is not applicable in the current mode, dashes will be displayed in the Present column. If a particular parameter is not applicable to the mode in the Change column, that parameter's value box is not displayed.

Palette Window: To change the parameter values, first select the appropriate parameter's value box in the Change column. A palette window will appear (as shown in Figure 8). Select a value from the palette window (by touching the desired value and lifting the stylus from the screen). Touching the screen outside a window will close it without making a selection. When changes have been made to parameter values, the data appear in the Change box until programmed into the pulse generator.

0.05	1.00
0.10	1.10
0.20	1.20
0.30	1.30
0.40	1.40
0.50	1.50
0.60	1.60
0.70	1.70
0.80	1.80
0.90	1.90

Palette Window

Patient's First Name

1 2 3 4 5 6 7 8 9 0 % ↵

Q W E R T Y U I O P

A S D F G H J K L

Z X C V B N M

< > = Space . , + -

Cancel Changes Clear Close

Keyboard Window

Figure 8 Types of windows enabling value changes.

In some screens (e.g., Patient Data screens), data are not displayed in Present and Change columns. These screens display value boxes that require unique data to be entered. Typically, the data are entered from a keyboard window (as shown in Figure 8). The values entered will remain in the value boxes when programmed; they will not move from a Change column to a Present column.

Keyboard Window: Touch the first character of the new value; it will appear in the data-entry box in the graphic keyboard. Continue until the entire new entry appears in the box. To delete one character at a time, starting with the last character, select the left arrow key on the graphic keyboard. Each time the left arrow key is selected, a character will be deleted in the box. To cancel any deletions or additions just made, select the Cancel Changes button. When all the appropriate characters have been selected, select the Close button on the graphic keyboard.

NOTE: *If, when the graphic keyboard initially appears, it contains data in the value box, select the Clear button to delete all the characters in the value box.*

Copy button: On screens that contain a Copy button, you can simply copy parameter values from one screen to another. Select the Copy button. A window will appear with a Copy From column and a Copy To column, with buttons below the columns. Select the desired buttons in both columns, and then select the Copy button.

To program the device, follow the instructions in the System Guide for the Guidant pulse generator being interrogated.

NOTE: *If additional parameters require reprogramming, repeat these steps. **Multiple parameter changes can be programmed at one time (batch programming).***

MAINTENANCE AND HANDLING

Loading the Paper

The internal printer/recorder uses four-inch wide (110 mm) thermosensitive printing paper. Model 6979 Printer Paper refills can be ordered from Guidant.

Use the following procedure to load paper into the internal printer/recorder:

1. Open the printer door.
2. If any sheets from the previous pack remain but did not feed, remove them and rotate the roller with clean fingertips to remove any small pieces of paper still under the printhead.
3. Unfold one sheet of paper and orient the pack such that the sensitive side is up and the pagination mark is at the bottom of the paper. Insert the pack into the printer/recorder.

NOTE: *You must use paper with pagination markings. Paper will not paginate properly if paper does not have markings.*

4. Allow the unfolded sheet to lay straight between the guides on the right side of the printer/recorder.
5. Close the printer door completely. The printer/recorder will automatically begin the paper-loading sequence and will stop at the first pagination mark after paper is detected. If the paper's edges are wrinkled, wait for four or five pages to feed through the printer. The printer will self-align the paper to its proper position.

The printer/recorder is now ready to resume printing.

For information regarding loading paper into the optional external printer, refer to the user manual for the printer.

Thermal Paper Storage

Store the heat-sensitive paper for the internal printer/recorder in a cool, dark environment. Do not attempt to erase the printer/recorder paper. Printed paper will last approximately 30 days under direct fluorescent light. To ensure the permanence of a patient's record, **store the printed paper away from direct sunlight, heat, or fumes from organic compounds**. Storage temperatures above 65°C, sustained exposure to direct sunlight, or exposure to high humidity, acetone, ammonia, alcohols, or other organic compounds may cause the paper to discolor.

NOTES:

- *If printed reports are to be kept for prolonged periods, you must make a photocopy of the thermosensitive paper as this paper is not intended for long-term retention and will lose legibility over time.*
- *Some brands of adhesive tape applied to a printed report will fade the printing after 30 days.*

Cleaning the PRM

Clean the housing and touchscreen of the PRM with a soft cloth lightly dampened with water.

Clean the printer/recorder with a dry, soft brush to eliminate dust and particles that may accumulate during printing and storage.

CAUTION: Do not use an abrasive cloth or volatile solvents to clean any portion of the PRM.

The cables used with the PRM are **not** sterile when packaged. When necessary, clean the cables with a soft cloth dampened with a mild cleaning solution (e.g., Liqui-nox for the sterilizable telemetry wand; Borax or a 1:10 bleach solution for other cables). Using the same method, wipe them completely with sterile water and towel- or air-dry. **DO NOT use an ultrasonic cleaner NOR immerse the cables. Clean the sterilizable telemetry wand in the same manner, allowing no fluids to enter the wand cavity. See “Prepare the Telemetry Wand” on page 6 for sterilization instructions.**

Patient Data Disk

The Model 6627 Patient Data Disk must be inserted with the arrow on the top left side and pointing into the disk drive (Figure 9).

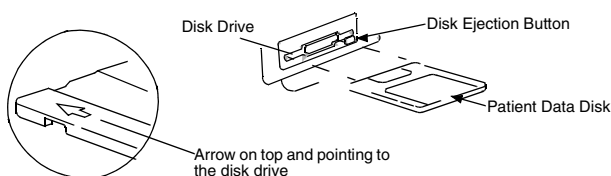


Figure 9. Disk drive on the right side of the PRM.

Be certain that the write-protect tab is closed on the disk (Figure 10). Insert a patient data disk firmly into the disk drive on the right side of the PRM until the disk ejection button protrudes.

NOTE: For complete instructions on using the patient data disk, refer to the *System Guide for the Guidant pulse generator being interrogated*.

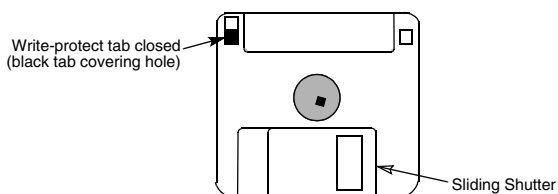


Figure 10. Floppy disk (3.5 inch) with write-protect tab closed.

Caring for Disks

Floppy disks can be damaged easily, making them unusable. To prevent damage to the disks:

- Write on labels before applying them to disks.

- Use only a felt-tipped pen to write on a label that is already applied to a disk.
- Keep food and beverages away from disks and away from the PRM.
- Keep disks away from heat or direct sunlight. Disks should be stored at temperatures between 5° and 60°C (41°–140°F).
- Keep disks dry and stored in a dry area (with a relative humidity between 8 percent and 80 percent).
- Do not bend disks.
- Do not attach paper clips, staples, or rubber bands to disks.
- Do not try to open the sliding shutter that covers the disks (Figure 10).
- Never touch the exposed disk area beneath the sliding shutter.

NOTE: *The write-protect tab must be closed in order to record data to the disk and to print reports. If data cannot be recorded to the disk, check to see that the tab is positioned to cover the hole (Figure 10).*

CAUTION: Keep disks away from magnets and magnetized objects, including telephones, power supply adapters, and monitors.

Operation and Storage Conditions

The Model 3120 PRM requires careful handling. The hard-disk drive and the floppy-disk drive must be protected from abusive handling. To protect the PRM from damage:

- Do not turn off the PRM while the drive is accessing data.
- Do not subject the PRM to abusive shocks or vibrations.
- When transporting the PRM from a cold environment to a warm environment, allow the PRM to warm to ambient temperature before use.
- Do not place heavy objects on the PRM surface when closed or when in operation.
- Do not place a magnet on the PRM.
- Do not pour or splash liquid into or onto the PRM.
- Do not strike, scratch, nick or otherwise abuse the touchscreen surface.
- Do not disassemble the PRM.
- Remove any disks from the drive prior to transporting the PRM.
- Turn off the PRM, close all covers and doors and put down the antenna prior to transporting the PRM.
- Unplug all external cables and cords prior to transporting the PRM.

Operate the PRM within a temperature range of 10° to 40°C and a humidity between 20 and 95 percent. Transport and store the PRM at temperatures between –40°C and 70°C, humidity of 5–95 percent, and pressure of 500–1,060 hPa. If the PRM has been stored in cold conditions (less than 10°C), turn it on and let the fan run for at least one hour before use.

Safety and EMC Compliance Standards

This equipment has been tested and found to comply with applicable safety portions of the following standards:

- EN60601-1:1990 + A1:1993 + A2:1995
- UL60601-1:2003
- CAN/CSA-C22.2 No. 601.1-M90

This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2: 2001 [or EN 60601-1-2: 2001 or Medical Device Directive 93/42/EEC]. This testing shows the device provides reasonable protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices or is negatively impacted by other devices, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the devices
- Increase the separation between the devices
- Connect the equipment to an outlet on a different circuit
- Consult the manufacturer or field service technician for help.

This equipment has been tested and found to comply with the following EMC standards:

FCC Part 15C

EN 300 330 -2 V 1.1

The PRM is capable of continuous operation and will not shut off automatically if it is unused for an extended time or if it runs out of paper. Keep the air intake and outlet free from obstruction.

CAUTION: The PRM is not water-proof or explosion-proof. It should not be used in the presence of flammable gas mixtures including anesthetic mixture with air, oxygen, or nitrous oxide.

PRM Storage

1. If using a patient data disk, remove disk from the disk drive by pressing the disk ejection button (Figure 9), and store the disk in a safe place.
2. Exit the current software application.
3. Press the Power button to turn the power off (Figure 2).

NOTE: Before unplugging the power cord to move the PRM, always exit the software application and press the Power button to turn off the PRM; otherwise, your system may lock up completely or have boot errors.

4. Unplug the power cord from the wall.
5. Unplug the cables from the back and side panels and other equipment.
6. Lower the screen until the front latch locks in place.

NOTE: *The programmer is not intended to be rested or stored in an up-right position (resting on rear panel with handle on top).*

EXTERNAL CABLE CONNECTIONS

The following cables are required for use with the Model 3120 Programmer/ Recorder/Monitor when using the configurations described in this section.

- Model 6924 External Recorder Cable: a six-channel DIN – six BNC cables (color-coded and numbered) for connection of the PRM analog output signals to another strip chart recorder or monitor.
- Model 6750 Surface ECG Patient Cable: a six-pin amphenol ECG cable for connecting the patient directly to the PRM.
- Model 6629 ECG-BNC Slave Cable: used for input of patient ECG signals to the PRM from an external monitor or recorder.
- Model 6577 Sterilizable Telemetry Wand.

The PRM also has two adapter kits that adapt cables with BNC connectors to fit other sockets:

- Model 6930: BNC–dual banana plug
BNC–pin tip
BNC–alligator clip adapters
- Model 6934: BNC–phono adapter

Refer to Figure 11 for cable connections.

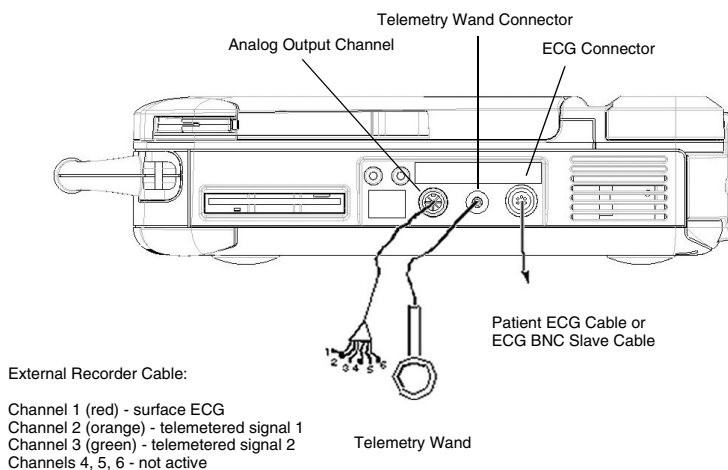


Figure 11. Cable connections for the Model 3120 PRM.

Surface ECG Connections

Three cable–electrode configurations frequently used to generate surface ECGs include the following:

- Patient to external recorder to PRM (Figure 12)
- Patient to PRM to external recorder (Figure 13)
- Simultaneous connections from patient to PRM and patient to external recorder (Figure 14)

NOTE: Annotated event markers cannot be sent to an external recorder.

Patient-Recorder-PRM Connection

To display a tracing on an external recorder and the PRM without using the patient ECG cable, set up equipment as shown in Figure 12.

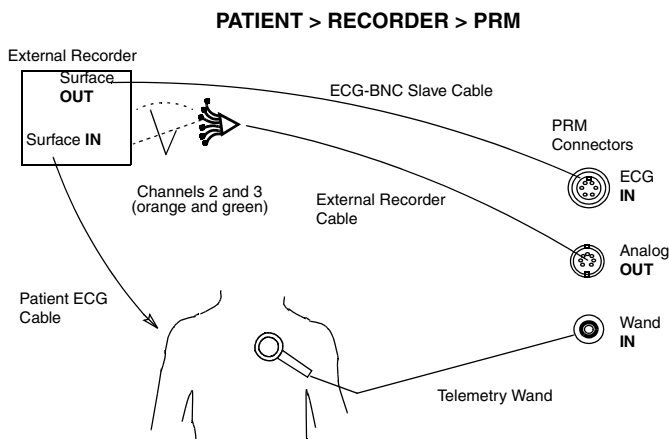


Figure 12. External recorder gets surface signal and sends it to the PRM. PRM sends electrograms to the external recorder.

1. Connect the external recorder's patient ECG leads to the appropriate electrodes.
2. Route the surface ECG channel to the PRM using the ECG-BNC slave cable. (Use the Model 6930 or 6934 adapter cables, if necessary.)
3. Connect the orange and green connectors of the external recorder cable to the external recorder for telemetered signals.
4. Adjust gain and filters on the external recorder.
5. Connect the telemetry wand and verify proper position. Make sure the wand cord does not cross other cables.

Setup is now complete.

Patient-PRM-Recorder Connection

To display a tracing on the PRM and an external strip chart recorder using the patient ECG cables, set up equipment as shown in Figure 13.

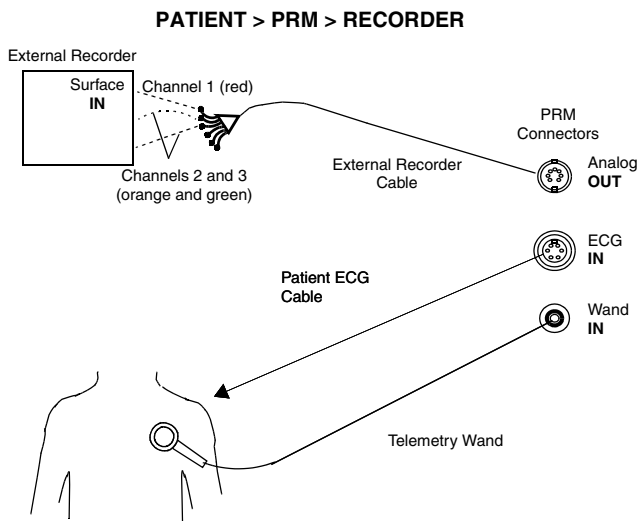


Figure 13. PRM receives surface signal via the patient cable and then sends surface and telemetered channels to the external strip chart recorder.

1. Connect the external recorder cable from the PRM to the external recorder input ports.
 - Channel 1 (red) for a surface trace
 - Channel 2 (orange) for telemetered signal 1
 - Channel 3 (green) for telemetered signal 2
2. Connect the patient ECG cable to the patient electrodes.
3. Verify proper telemetry wand position.

Setup is now complete.

Parallel Connection

To display traces on both PRM and ECG recorders using two different patient ECG leads, set up the equipment as shown in Figure 14.

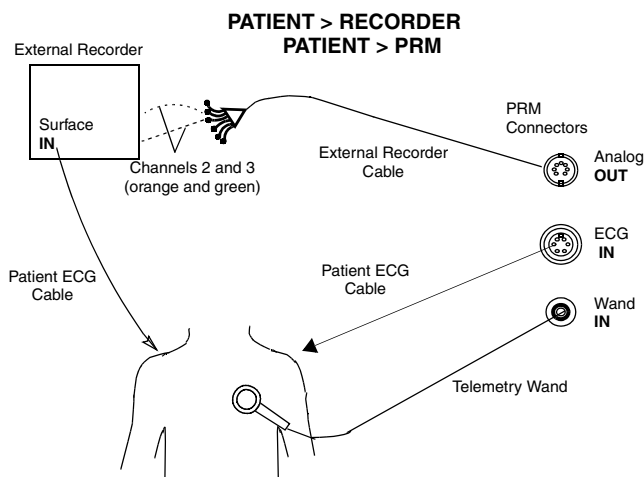


Figure 14. Parallel connection of PRM surface leads and external surface monitor.

1. Connect the external recorder patient ECG leads to the appropriate limb electrodes.
2. Connect the patient ECG cable to the patient electrode.
3. Connect the external recorder cable from the PRM to the external recorder.

NOTE: This configuration will add the most noise to the tracings of the two PRM–recorder configurations.

4. Adjust gain and filters on the external recorder.

Setup is now complete.

NOTE: The right leg electrode conductor on the patient ECG cable is a driven ground. When connecting the PRM and an external ECG monitor in parallel, the driven grounds for the two instruments must be connected to the same patient limb (e.g. right leg electrode); otherwise, noise problems will occur.

TROUBLESHOOTING

If the PRM does not operate properly, check that electrical cords and cables are securely connected and that cords and cables are in good working order (i.e., free of visible defects). Table 2 indicates possible causes and corrective actions for PRM problems. For external printer problems, refer to the manual for the external printer.

Table 2. Possible Causes and Corrective Actions for PRM Problems

Symptom	Possible Cause	Corrective Action
Internal printer/recorder does not function	No AC line voltage	Check that power cord is plugged securely into the rear panel of the PRM. Change to a different electrical outlet.
	Paper jam	Clear paper path of any obstruction.
Internal printer/recorder: paper-feed problems	Paper misaligned	Reload paper.
	Paper-feed obstruction	Clear obstruction from around the paper supply.
Internal printer/recorder: no print visible	Paper loaded upside down	Reload paper. (See "Loading the Paper" on page 17.)
No analog output	Using incorrect output port and/or connections	Recheck connection of the Model 6924 External Recorder Cable.
Patient data disk error	Using disk created for a previous model of PRM or unformatted floppy disk	Use only Guidant Model 6627 Patient Data Disks.
	Write-protect tab open	Close write-protect tab.
Noise problems: ECG	Improper patient connections	Recheck patient leads for adequate skin contact and correct limb lead placement.
	"Noisy" equipment	Check surrounding area for equipment with excessive radio frequency emissions. Move unneeded equipment away from patient and/or PRM, or turn off unneeded equipment. Consult ECG textbooks for additional ECG techniques.

Table 2. Possible Causes and Corrective Actions for PRM Problems

Symptom	Possible Cause	Corrective Action
Telemetry: no communication	Incorrect application software or incorrect PRM for pulse generator	Install proper application software for pulse generator in use.
	Incomplete telemetry communication	Reposition wand over the device; repeat interrogation.
Telemetry: intermittent communication	Incorrect telemetry wand	Use only the Guidant Model 6577 Sterilizable Telemetry Wand.
	“Noisy” equipment	Check surrounding area for equipment with excessive radio frequency emissions. Move unneeded equipment away from patient and/or PRM, or turn off unneeded equipment.
	Incomplete telemetry communication	Reposition wand over the device; repeat interrogation.
Displayed clock does not consistently keep time after setting	Low battery	Return to Guidant for replacement of clock battery.

LABEL SYMBOLS

Table 3 illustrates the symbols used on the Model 3120 PRM and includes an explanation of each symbol.

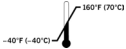
Table 3. Label Symbols and Their Meanings

Symbol	Meaning
 Need graphic.	Alternating current Power button: <<<DECISION PENDING WITH TUV>>>
	USB
	Parallel connector for printer
	VGA output for external monitor
	Analog output
	Telemetry wand input
	Indicates defibrillator-proof CF-type patient
	ECG cable connector
	Paper form feed
	Calibration pulse
	Bring trace to baseline
	Indicates the potential equalization conductor. This connection allows a common ground with other equipment in a clinical setting.

Table 3. Label Symbols and Their Meanings

Symbol	Meaning
	Mark for nationally recognized testing for safety standards.
	See instruction manual.
	Radio, Telecommunications and Terminal Equipment (RTTE) symbol. Indicates that device does not operate in a harmonized bandwidth.
	General warning.
	Dangerous voltage. Refer servicing to Guidant.
	Indicates the risk of electric shock; do not remove the cover (or back). Refer servicing to Guidant.
	Indicates separate collection for electrical and electronic equipment (i.e., do not throw this device in the trash).
	For future use.
	Inductive telemetry indicator light
	On indicator light
V	Voltage
S/N	Serial number

Table 3. Label Symbols and Their Meanings

Symbol	Meaning
A/N	Assembly number
	This side up
	Fragile, handle with care
	Keep dry
	Do not use hooks
	Temperature limitations
	Humidity limitations

WARRANTY INFORMATION

A limited one-year warranty and a warranty registration card for the Guidant PRM is packaged with the PRM. Unless otherwise agreed, the PRM remains the property of Guidant and Guidant must perform all necessary servicing and repair work.

ORDERING ACCESSORIES

To order accessories, contact the nearest Guidant sales representative or contact Guidant Corporation at the address or phone number on the back cover of this manual.

SERVICE

For questions regarding operation or repair of the PRM, call the nearest Guidant representative or call Guidant Technical Services at the phone number on the back cover of this manual. The PRM must be serviced by Guidant personnel only.

If the Guidant PRM malfunctions and requires repair, help to ensure efficient service by following these guidelines:

1. Leave the configuration of the instrument exactly as it was at the time of malfunction. Contact the nearest Guidant representative or call Guidant Technical Services at the phone number on the back cover of this manual.
2. Write a detailed description of the malfunction(s).
3. Save printouts or other materials that illustrate the problem.
4. If the PRM must be returned to Guidant for service, pack it in the shipping container in which it was received or in a shipping container provided by Guidant.
5. Send the PRM to Guidant at the address on the back cover of this manual.

For problems or questions that arise regarding operation or repair of the optional external printer, contact the printer manufacturer or agent.

PREVENTIVE MAINTENANCE

No preventive maintenance is needed by the user or service personnel.

ENVIRONMENTAL PROTECTION

Return the programmer to Guidant at the end of its useful life for appropriate disposal.

SPECIFICATIONS (Nominal)

Safety classification	Class I, Type CF, Defibrillation protected
Dimensions	19 in (48.3 cm) deep, 14.5 in (36.8 cm) wide, 4.75 in (12.1) cm high
Weight (approximate)	21.5 lb (9.8 kg)
Power rating	100–120/200–240 V and 50–60 Hz 3.8/1.9 A
Power cord	8 ft. 100–240 V. Reliable grounding is achieved only when equipment is connected to receptacle marked with “Hospital only” or “Hospital grade.”
Operating temperature	50–105°F (10–40°C)
Transport and storage temperature	–40 to 160°F (–40 to 70°C)
Relative humidity • Transport and storage • Operating	5–95% 20–95%
Atmospheric pressure	500–1,060 hPa
External printer support	DB 25 parallel port connector
External monitor support	DB 15 VGA port connector
Analog output	± 1 V output via seven-pin DIN connector
ECG performance • Lead selection • Intrinsic ventricular rate display • Input impedance • Electrode offset tolerance • Storage resolution • Filter settings • Gain settings	I, II, III, aVR, aVL, aVF, V 30–240 bpm ± 6 bpm > 2.5 M Ω 300 mV 800 samples/sec, 4.56 μV ON: 0.5–25 Hz, ± 0.2 dB; OFF: 0.05–100 Hz ± 0.2 dB 1, 2, 5, 10, 20 mm/mV ± 25%
Internal printer • Paper type • Paper width • Chart speed	Thermo-sensitive 4 in (110 mm) 10, 25, 50, 100 mm/sec
Battery type	DL 2450 or equivalent
Safety features • Leakage current • Defibrillator protection	< 10 μA (patient); < 100 μA (chassis) to 5,000 V, 400 J

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