

FLUKE®

Biomedical

PS410

ECG Simulator

Users Manual

PN 2631795
April 2006

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Warranty and Product Support

Fluke Biomedical warrants this instrument against defects in materials and workmanship for one full year from the date of original purchase. During the warranty period, we will repair or, at our option, replace at no charge a product that proves to be defective, provided you return the product, shipping prepaid, to Fluke Biomedical. This warranty does not apply if the product has been damaged by accident or misuse or as the result of service or modification by other than Fluke Biomedical. IN NO EVENT SHALL FLUKE BIOMEDICAL BE LIABLE FOR CONSEQUENTIAL DAMAGES.

Only serialized products and their accessory items (those products and items bearing a distinct serial number tag) are covered under this one-year warranty. PHYSICAL DAMAGE CAUSED BY MISUSE OR PHYSICAL ABUSE IS NOT COVERED UNDER THE WARRANTY. Items such as cables and nonserialized modules are not covered under this warranty.

Recalibration of instruments is not covered under the warranty.

This warranty gives you specific legal rights, and you may also have other rights which vary from state to state, province to province, or country to country. This warranty is limited to repairing the instrument to Fluke Biomedical's specifications.

Warranty Disclaimer

Should you elect to have your instrument serviced and/or calibrated by someone other than Fluke Biomedical, please be advised that the original warranty covering your product becomes void when the tamper-resistant Quality Seal is removed or broken without proper factory authorization. We strongly recommend, therefore, that you send your instrument to Fluke Biomedical for factory service and calibration, especially during the original warranty period.

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Unpacking and Inspection

Follow standard receiving practices upon receipt of the instrument. Check the shipping carton for damage. If damage is found, stop unpacking the instrument. Notify the carrier and ask for an agent to be present while the instrument is unpacked. There are no special unpacking instructions, but be careful not to damage the instrument when unpacking it. Inspect the instrument for physical damage such as bent or broken parts, dents, or scratches.

Technical Support

For application support or answers to technical questions, either email techservices@flukebiomedical.com or call 1-800- 648-7942 or 1-425-446-6945.

Claims

Our routine method of shipment is via common carrier, FOB origin. Upon delivery, if physical damage is found, retain all packing materials in their original condition and contact the carrier immediately to file a claim. If the instrument is delivered in good physical condition but does not operate within specifications, or if there are any other problems not caused by shipping damage, please contact Fluke Biomedical or your local sales representative.

Standard Terms and Conditions

Refunds and Credits

Please note that only serialized products and their accessory items (i.e., products and items bearing a distinct serial number tag) are eligible for partial refund and/or credit. Nonserialized parts and accessory items (e.g., cables, carrying cases, auxiliary modules, etc.) are not eligible for return or refund. Only products returned within 90 days from the date of original purchase are eligible for refund/credit. In order to receive a partial refund/credit of a product purchase price on a serialized product, the product must not have been damaged by the customer or by the carrier chosen by the customer to return the goods, and the product must be returned complete (meaning with all manuals, cables, accessories, etc.) and in “as new” and resalable condition. Products not returned within 90 days of purchase, or products which are not in “as new” and resalable condition, are not eligible for credit return and will be returned to the customer. The Return Procedure (see below) must be followed to assure prompt refund/credit.

Restocking Charges

Products returned within 30 days of original purchase are subject to a minimum restocking fee of 15 %. Products returned in excess of 30 days after purchase, but prior to 90 days, are subject to a minimum restocking fee of 20 %. Additional charges for damage and/or missing parts and accessories will be applied to all returns.

Return Procedure

All items being returned (including all warranty-claim shipments) must be sent freight-prepaid to our factory location. When you return an instrument to Fluke Biomedical, we recommend using United Parcel Service, Federal Express, or Air Parcel Post. We also recommend that you insure your shipment for its actual replacement cost. Fluke Biomedical will not be responsible for lost shipments or instruments that are received in damaged condition due to improper packaging or handling.

Use the original carton and packaging material for shipment. If they are not available, we recommend the following guide for repackaging:

- Use a double-walled carton of sufficient strength for the weight being shipped.
- Use heavy paper or cardboard to protect all instrument surfaces. Use nonabrasive material around all projecting parts.
- Use at least four inches of tightly packed, industry-approved, shock-absorbent material around the instrument.

Returns for partial refund/credit:

Every product returned for refund/credit must be accompanied by a Return Material Authorization (RMA) number, obtained from our Order Entry Group at 1-800-648-7952 or 1-425-446-6945.

Repair and calibration:

To find the nearest service center, goto www.flukebiomedical.com/service or

In the U.S.A.:

Cleveland Calibration Lab

Tel: 1-800-850-4606

Email: globalcal@flukebiomedical.com

Everett Calibration Lab

Tel: 1-800-850-4606

Email: service.status@fluke.com

In Europe, Middle East, and Africa:

Eindhoven Calibration Lab

Tel: +31-402-675300

Email: ServiceDesk@fluke.com

In Asia:

Everett Calibration Lab

Tel: +425-446-6945

Email: service.international@fluke.com

Certification

This instrument was thoroughly tested and inspected. It was found to meet Fluke Biomedical's manufacturing specifications when it was shipped from the factory. Calibration measurements are traceable to the National Institute of Standards and Technology (NIST). Devices for which there are no NIST calibration standards are measured against in-house performance standards using accepted test procedures.

WARNING

Unauthorized user modifications or application beyond the published specifications may result in electrical shock hazards or improper operation. Fluke Biomedical will not be responsible for any injuries sustained due to unauthorized equipment modifications.

Restrictions and Liabilities

Information in this document is subject to change and does not represent a commitment by Fluke Biomedical. Changes made to the information in this document will be incorporated in new editions of the publication. No responsibility is assumed by Fluke Biomedical for the use or reliability of software or equipment that is not supplied by Fluke Biomedical, or by its affiliated dealers.

Manufacturing Location

The PS410 ECG Simulator is manufactured in Norway for Fluke Biomedical, 6920 Seaway Blvd., Everett, WA, U.S.A.

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PS410 ECG Simulator

Introduction

The PS410 ECG Simulator (hereafter called the Simulator) is a compact, lightweight, high-performance simulator for use by trained service technicians for patient monitor testing. The Simulator replicates various electrocardiogram conditions based on settings you select.

Upon receipt, inspect the outer box for damage. Carefully unpack all items from the box and check that you have the following items:

- PS410 ECG Simulator (PN 2631276)
- Users Manual (PN 2631795)
- CD-ROM (PN 2631742)
- Battery Eliminator (PN 2647372)

If you are missing any of these items, or if you find a damaged item, follow the procedures found under Unpacking and Inspection in the front of this manual.

Safety

Warning

Read before using the Simulator.

To avoid personal injury, follow these guidelines:






- **Do not use the Simulator in any manner not specified in the Users Manual. Otherwise, the protection provided by this product may be impaired.**
- **Always press power off on the Simulator and unplug the Battery Eliminator before cleaning the outer surface.**

- **Inspect the product. If the Simulator appears damaged or appears to operate in a manner not specified in the manual, DO NOT CONTINUE USE. Return the product for service.**
- **Avoid spilling liquids on the Simulator; fluid seepage into internal components creates corrosion and a potential shock hazard. Do not operate the instrument if internal components are exposed to fluid.**
- **Do not open this product. There are no user replaceable parts.**

Caution

Calibrate the Simulator annually. Only qualified technical personnel should perform troubleshooting and service procedures on the Simulator.

Do not expose the Simulator to temperature extremes. Ambient operating temperatures should remain between 15 and 35 °C. Simulator performance may degrade if temperatures fluctuate above or below this range.

Symbol	Description
	See Users Manual.
	Caution risk of electric shock
	Manufacturer's declaration of product compliance with applicable EU directives
	Battery Eliminator Port
	Do not mix with solid waste stream. Dispose of using a qualified recycler or hazardous material handler.

Specifications

Size	Height: 11.2 cm (4.4 in); Width: 10.0 cm (3.9 in); Depth: 3.4 cm (1.4 in)
Weight	0.4 kg (0.9 lb)
Environmental	Indoor use
Temperature, Operating	15 to 35 °C (59 to 95 °F)
Temperature, Storage	0 to 50 °C (32 to 122 °F)
Maximum Humidity, Operating	80 % relative humidity up to 31 °C (88 °F), decreasing linearly to 50 % relative humidity at 40 °C (104 °F).
Maximum Humidity, Storage	95 %
Altitude	Up to 2000m
Battery Power Supply	
Voltage	9 VDC
Power Consumption	< 70 mA
Battery Life	> 7 hours
External Power Supply	
Output Voltage	12 to 15 V
Output Current	1.2 A
Display	15 x 30 mm (0.58 x 1.15 in.) window displaying up to two lines of text
Controls	Six control keys and ON/OFF power switch.
Interface	RS232 bi-directional interface. Baud rate: 9600.
ECG Output Connectors	10 AHA/IEC color-coded connectors accepting ECG snaps and pins
Case	High impact plastic
Part Number	PS410 ECG Simulator (PN 2631276)

Standard AccessoriesUsers Manual (printed) (PN 2631795)
 Users Manual CD-ROM (PN 2631742)
 Battery Eliminator (PN 2647372)

ECG

12 Leads with Independent Outputs Referenced to RL

Output Impedance.....940 ohms between leads
 High Level Output.....1000x Lead II
 Rates30, 40, 60, 80, 100, 120, 140, 160, 180, 200, 220, 240, 260, 280, and 300 BPM
 Default Rate80 BPM
 Rate Accuracy..... $\pm 1\%$ of selection

Adult or Pediatric Waveforms

ECG Amplitudes.....0.5, 1.0, 1.5, and 2.0 mV
 Amplitude Accuracy..... $\pm 2\%$ (Lead II).
 Superimposed Artifact.....50 and 60 Hz, muscle, baseline wander, and respiration.

ECG Performance, Lead II

Square Wave.....0.125 and 2.0 Hz.
 Pulse30, 60, and 120 BPM; 60 ms pulse width.
 Sine Waves0.5, 5, 10, 40, 50, and 60 Hz (1 mV amplitude).
 Triangle Wave2.0 Hz.

ST Segment Analysis

Elevated or Depressed.....- 0.2 mV to + 0.6 mV in 0.2 mV steps

Pacemaker Selections

Pacemaker Rhythm	Demand Occasional Sinus
Pacemaker Non-Function	Demand Frequent Sinus
Pacemaker Non-Capture	A-V Sequential

Arrhythmia Selections

Base Rate of 80 BPM			
PVC1 Left Ventricular Focus *	PVC2 Early, RV Focus *	Ventricular Fibrillation Coarse/Fine	Atrial Fibrillation Coarse/Fine
PVC1 Early, LV Focus *	PVC2 R on T, RV Focus *	Supraventricular Tachycardia	Atrial Tachycardia
PVC1 R on T, LV Focus *	Bigeminy	Premature Atrial Contraction *	Conduction Defects
Pair PVCs *	Trigeminy	Premature Nodal Contraction *	First Degree
Run 5 PVCs *	PVCs 6 / minute	Asystole	Second Degree
Run 11 PVCs *	PVCs 12 / minute	Missed Beat *	Third Degree
Multifocal PVCs *	PVCs 24 / minute	Nodal Rhythm	Right Bundle Branch Block
Frequent Multifocal PVCs *	Ventricular Tachycardia	Irregular Rhythm	Left Bundle Branch Block
PVC2 Right Ventricular Focus *		Atrial Flutter	

* The symbol * indicates that the event occurs once. To repeat the event, enter the selection again.

Controls and Terminals

Refer to Figure 1 and Table 1 for descriptions of Simulator controls and terminals.

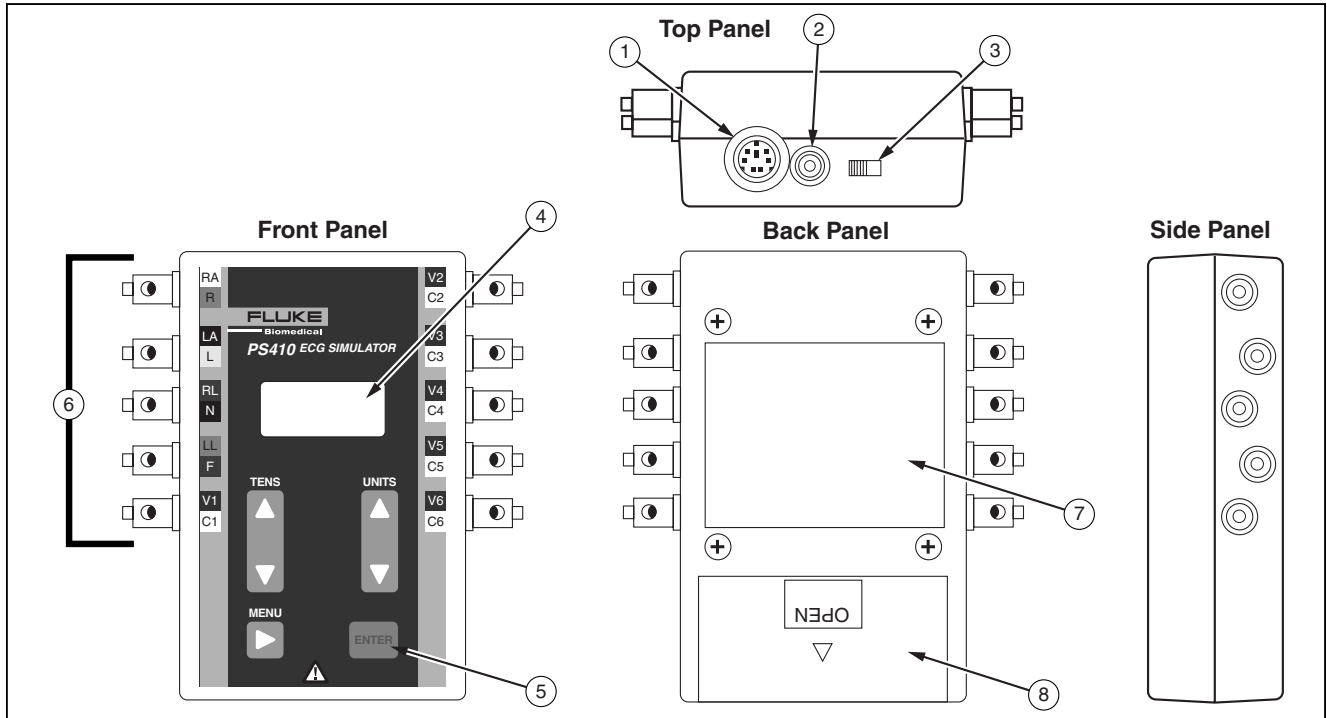


Figure 1. Controls and Terminals

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Table 1. Controls and Terminals

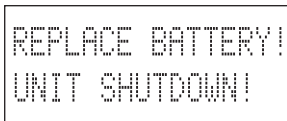
Item	Name	Description
①	RS-232	8-pin mini-DIN plug for connecting an RS232 cable.
②	Battery Eliminator	<p>For use in operating the Simulator from any standard electrical outlet. To ensure safe operation, use only the Fluke Biomedical Battery Eliminator (PN 2647372).</p> <p style="text-align: center;">⚠⚠Warning</p> <p style="text-align: center;">Caution risk of electric shock. Use only the Battery Eliminator specified in this manual or the protection provided may be impaired.</p>
③	Power Switch	Switches the power on and off.
④	LCD Display	15 mm x 30 mm (.58 in. x 1.15 in.) window displaying up to two lines of text.
⑤	Control Keys	
	TENS	These up/down arrow keys (▲ ▼) allow you to increment or decrement the code line presets by 10. The up TENS arrow key (▲) increases the preset codes by 10, while the down TENS arrow key (▼) decreases the presets by 10.
	UNITS	These up/down arrow keys (▲ ▼) allow you to increment or decrement the code line presets by 1. The up UNITS arrow key (▲) increases the preset codes by 1, while the down UNITS arrow key (▼) decreases the presets by 1.

Table 1. Controls and Terminals (cont.)

Item	Name	Description	
⑤	MENU	Pressing this key causes the code line preset to increase. Each time you press the key, the code line preset increases by 1 unit.	
	ENTER	Pressing this key executes the selected simulation.	
⑥	ECG Connectors	Ten snap and multi-banana connectors for ECG output, allowing for connection to any twelve-lead ECG. Labels for these terminals appear on the front panel. The labels are AHA/IEC color-coded to aid in matching them to corresponding patient leads. Labels and their definitions are as follows:	
		Label	Description
		RA / R	Right Arm
		LA / L	Left Arm
		RL / N	Right Leg (Reference or grounded)
		LL / F	Left Leg
V1 / C1 to V6 / C6	V leads (US and Canada). Also referred to as pericardial, precordial or unipolar chest leads, and chest leads (IEC)		
⑦	Menu Selection	This lists all code line values that you can execute in the Simulator.	
⑧	Battery Compartment	Compartment for holding a 9-V alkaline battery.	

Powering the Simulator

The Simulator uses a 9-V alkaline battery. It uses as much of the battery as possible. When it detects less than about 5.6 volts, it goes into a shutdown mode, sounds a continuous tone alarm, and displays the following message:



REPLACE BATTERY!
UNIT SHUTDOWN!

The battery resides in the base of the instrument. Use a 9-volt alkaline battery (Duracell® MN1604 or equivalent). Do not use mercury, air, or carbon-zinc batteries.

⚠ Warning

The 9-volt alkaline battery provided with the Simulator may explode or leak if recharged, inserted improperly, disposed of in a fire, or mixed with different battery types. Dispose of the battery in accordance with any applicable state or local regulations.

As an alternative to a battery, you can power the Simulator with a battery eliminator. Use only the Fluke Biomedical Battery Eliminator (PN 2647372) to ensure safe operation.

⚠⚠ Warning

Caution risk of electric shock. Use only the Battery Eliminator specified in this manual or the protection provided may be impaired.

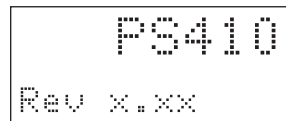
Note

Remove the battery and disconnect the Battery Eliminator if you do not intend to use the Simulator for an extended period.

Operating the Simulator

Connect the Simulator to the device under test. Use the Simulator keypad to enter the code presets. The Simulator then transmits the selected preset simulation to the device.

1. Switch the Simulator **ON**. The LCD window displays the program version for about two seconds.



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The window then displays the default code display.



2. Press the **TENS** and **UNITS** keys to enter the required preset code.
 - a. Use the up/down **TENS** arrow keys (**▲ ▼**) to increment or decrement the code line presets by 10. The up **TENS** arrow key (**▲**) increases the preset codes by 10, while the down **TENS** arrow key (**▼**) decreases the presets by 10.
 - b. Use the up/down **UNITS** arrow keys (**▲ ▼**) to increment or decrement the code line presets by 1. The up **UNITS** arrow key (**▲**) increases the preset code by 1, while the down **UNITS** arrow key (**▼**) decreases the preset code by 1.
3. After reaching the required preset, press **ENTER** to transmit the selected simulation to the device under test.

Simulating Functions

This section describes Simulator simulation procedures by function. If you are unfamiliar with basic Simulator operation, refer to “Operating the Simulator.”

ECG/Arrhythmia

The Simulator replicates several different types of arrhythmias, from inconsequential types of PNCs to asystole. In addition, the Simulator can send waveforms to test any electrocardiograph, and can accommodate twelve-lead configurations with independent outputs for each signal lead referenced to the right leg (RL).

ECG Waveform

The Simulator replicates three ECG waveform amplitudes, with a $\pm 2\%$ accuracy of selection (Lead II). The Simulator uses these as references only during arrhythmia simulations. They are set through direct code entry, as follows. To change the amplitude, use the **UNITS** keys (**▲ ▼**) to scroll to the available presets. This setting remains in effect until you change it or switch the Simulator off.

Code	Display	Selects ECG amplitude of:
00	SEN .5mV	0.5 mV
01	SEN 1mV	1.0 mV
02	SEN 2mV	2.0 mV

NSR

The Simulator replicates fifteen normal sinus rhythms, or NSRs. These NSRs are set through direct code entry, as follows. After selecting the preset, press **ENTER**. To change the NSR use the **UNITS** keys (**▲ ▼**) to scroll to the available presets.

Code	Display	Selects NSR rate of:
03	30 BPM	30 BPM
04	40 BPM	40 BPM
05	60 BPM	60 BPM
06	80 BPM	80 BPM
07	100 BPM	100 BPM
08	120 BPM	120 BPM

Code	Display	Selects NSR rate of:
09	140 BPM	140 BPM
10	160 BPM	160 BPM
11	180 BPM	180 BPM
12	200 BPM	200 BPM
13	220 BPM	220 BPM
14	240 BPM	240 BPM
15	260 BPM	260 BPM
16	280 BPM	280 BPM
17	300 BPM	300 BPM

Adult and Pediatric NSR QRS

You can set an adult NSR with a QRS width of 80 ms or a pediatric NSR with a QRS width of 40 ms. These will remain in effect throughout ECG and arrhythmia selections until changed by reentering the following codes and pressing **ENTER**.

Code	Display	Selects:
20	NSR PED	Pediatric NSR with QRS width of 40 ms.
21	NSR ADLT	Adult NSR with QRS width of 80 ms.

Arrhythmias: Premature Beats

Code	Display	Selects:
28	PVC1 *	PVC with left ventricle focus. The Simulator then assumes NSR at 80 BPM.
29	PVC1 EAR *	Early PVC with left ventricle focus. The Simulator then assumes NSR at 80 BPM.
30	PVC1 ROT *	R on T PVC with left ventricle focus. The Simulator then assumes NSR at 80 BPM.
34	MULTIFOC *	Multifocal PVCs. The Simulator then assumes NSR at 80 BPM.

Code	Display	Selects:
36	PVC2 *	PVC with right ventricle focus. The Simulator then assumes NSR at 80 BPM.
37	PVC2 EAR *	Early PVC with right ventricle focus. The Simulator then assumes NSR at 80 BPM.
38	PVC2 ROT *	R on T PVC with right ventricle focus. The Simulator then assumes NSR at 80 BPM.

* The simulation event occurs only once. To repeat the event, enter the selection again.

Arrhythmias: Ventricular

Code	Display	Selects:
31	PVCs (2) *	Pair of PVCs. The Simulator then assumes NSR at 80 BPM.
32	RUN 5 *	Run of 5 PVCs. The Simulator then assumes NSR at 80 BPM.

Code	Display	Selects:
33	RUN 11 *	Run of 11 PVCs. The Simulator then assumes NSR at 80 BPM.
35	FREQ MUL	Frequent multifocal rhythm.
39	BIGEMINY	Bigeminy rhythm.
40	TRIGEMIN	Trigeminy rhythm.
41	PVC 6/M	6 PVCs per minute.
42	PVC 12/M	12 PVCs per minute.
43	PVC 24/M	24 PVCs per minute.
44	VENT TAC	Ventricular tachycardia.
45	VENT FIB	Ventricular fibrillation.
46	V FIB #2	Ventricular fibrillation at 1/2.
47	SUPRA VE	Supraventricular tachycardia.
50	ASYSTOLE	Asystole. No ECG.
* The simulation event occurs only once. To repeat the event, enter the selection again.		

Arrhythmias: Atrial

Code	Display	Selects:
48	PAC ATRI *	Premature atrial contraction. The Simulator then assumes NSR at 80 BPM.
49	PNC NODA *	Premature nodal contraction. The Simulator then assumes NSR at 80 BPM.
51	MISSED B *	Missed beat. The Simulator then assumes NSR at 80 BPM.
52	NODAL RY	Nodal rhythm.
53	IRREG RY	NSR with irregular rhythm.
54	A FLUTTE	Atrial flutter.
55	A FIBRIL	Atrial fibrillation.
56	A FIB #2	Atrial fibrillation 1/2 value.
57	A TACHYC	Atrial tachycardia.
* The simulation event occurs only once. To repeat the event, enter the selection again.		

Arrhythmias: Conduction Defects

Code	Display	Selects:
58	1ST DEGR	1st degree heart block rhythm.
59	2ND DEGR	2nd degree heart block rhythm.
60	3RD DEGR	3rd degree heart block rhythm.
61	RBBB	Right bundle branch block rhythm.
62	LBBB	Left bundle branch block rhythm.

ST Elevation and Depression Waves

These are set through direct code entry, as follows. After selecting the preset, press **ENTER**. To change the wave, use the **UNITS** keys (**▲ ▼**) to scroll to the available presets.

Code	Display	Selects ST elevation wave of:
80	ST+.6 mV	+0.6 mV
81	ST+.4 mV	+0.4 mV
82	ST+.2 mV	+0.2 mV
		Selects ST depression wave of:
83	ST-.2 mV	- 0.2 mV
84	ST-.4 mV	- 0.4 mV
85	ST-.6 mV	- 0.6 mV

Superimposed Artifacts

The Simulator replicates five different artifacts. Their purpose is to evaluate the effect of these artifacts on ECG accuracy. After selecting the artifact, press **ENTER** to transmit it to the ECG. The Simulator deactivates the artifact when you make another ECG or arrhythmia selection.

Code	Display	Selects:
75	50 Hz AR	50 Hz artifact (European lines).
76	60 Hz AR	60 Hz artifact (US lines).
77	MUSCLE	Muscle artifact.
78	BASE ART	Baseline wandering artifact.
79	RESP ART	Respiration artifact.

Pacemaker

The Simulator replicates six paced rhythms/signals. After selecting the required rhythm, press **ENTER**. After selecting the preset, press **ENTER**. To change the rhythm, use the **UNITS** keys (**▲ ▼**) to scroll to the available presets.

Code	Display	Selects:
63	PACER RH	Pacemaker rhythm.
64	PACER NC *	Noncapture event. The Simulator then assumes asynchronous pacemaker.
65	PACER NF	Non-function pacemaker rhythm.
66	DEMAND S	Pacemaker rhythm with occasional sinus beats.
67	DEMAND F	Pacemaker rhythm with frequent sinus beats.
68	SEQUENTA	Atrial-Ventricular sequential pacemaker rhythm.

* The simulation event occurs only once. To repeat the event, enter the selection again.

ECG Performance Testing

Square Wave

Code	Display	Sets:
22	2 Hz	2.0 Hz square waveform.
23	0.125 Hz	0.125 Hz square waveform.

Triangle Wave

Code	Display	Sets:
24	TRI 2 Hz	2.0 Hz triangle waveform.

Pulse Wave

Code	Display	Sets:
25	30 BPM P	Pulse of 30 BPM, width of 60 ms.
26	60 BPM P	Pulse of 60 BPM, width of 60 ms.
27	120BPM P	Pulse of 120 BPM, width of 60 ms.

Sine Wave

The Simulator fixes amplitude at 1.0 mV for sine waves.

Code	Display	Selects:
69	0.5 Hz SI	0.5 Hz sine wave.
70	5 Hz SI	5.0 Hz sine wave.
71	10 Hz SI	10.0 Hz sine wave.
72	40 Hz SI	40.0 Hz sine wave.
73	50 Hz SI	50.0 Hz sine wave.
74	60 Hz SI	60.0 Hz sine wave.

Cleaning

Clean only with a damp, lint-free cloth, using mild detergent, and wipe down gently.

⚠ Caution

Do not pour fluid onto the Simulator surface; fluid seepage into the electrical circuitry may cause Simulator failure.

⚠ Caution

Do not use spray cleaners on the Simulator; such action may force cleaning fluid into the Simulator and damage electronic components.