FLUKE®
Biomedical

PS400
Patient Simulator

Operators Manual

PN 2572345
March 2006

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 non-serialized 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.

Notices

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- 648-7952 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: 1-888-99 FLUKE (1-888-993-5853)
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 PS400 Patient Simulator is manufactured in Everett, WA, U.S.A.

Table of Contents

Title	Page
Introduction	1
Safety Information	1
General Specifications	2
Instrument Specifications	2
Accessories	3
Instrument Familiarity	4
Preparation for Use	5
Operating the Simulator	6
Power-Up	6
Selection Waveforms	7
Menu 1 Selections	7
Menu 2 Selections	8
Amplitude Selection	9
Waveform Examples	9
Menu 1 Waveforms	9
Menu 2 Waveforms	14

List of Tables

Table	Title	Page
1.	Menu 1 Selections	7
2.	Menu 2 Selections	8

List of Figures

Figure	Title	Page
1.	PS400 Controls and Indicators	4
2.	Installing the Battery	6

PS400 Patient Simulator

Introduction

The PS400 Patient Simulator (herafter “the Simulator”) is a high–performance ECG/arrhythmia simulator that generates all the waveforms necessary to check the frequency response, linearity, amplitude accuracy, and beats–per–minute measurement accuracy of an electrocardiograph. In addition, the Simulator generates arrhythmias.

The Simulator has a complete 12–lead output and a single high–level output.

The Simulator is for biomedical equipment technicians or service representatives to test the basic operation of physiological monitoring and diagnostic equipment. These tests are typically conducted during routine or scheduled preventive maintenance inspections.

This instrument can also verify calibration to the precision stated in Simulator Instrument Specifications. For the recommended inspection protocol and the required level of precision, refer to the calibration manual for the actual equipment under test. The Simulator is not intended to be used as the primary signal source for the initial validation of patient–related equipment.

Safety Information

In this manual, a ⚠⚠**Warning** identifies conditions and actions that pose hazards to the user. A ⚠**Caution** identifues conditions and actions that may damage the Simulator or the equipment under test. Do not proceed beyond a warning or caution until the indicated conditions are fully understood and met.

To ensure safe operation of the Simulator, observe all instructions and warnings contained in this manual.

General Specifications

Power Requirements

- **Battery** ..... 9 V Alkaline
- **Battery Life** ..... 200 hours
- **Line Power** ..... Battery Eliminator (115 or 230 V to 7.7 Vdc @ 100 mA unregulated
  Connector: 2.5 mm center (+)

Temperature Performance

- **Operating** ..... 15 °C to 35 °C (59 °F to 95 °F)
- **Storage** ..... 0 °C to 55 °C (32 °F to 131 °F)

Weight ..... 0.41 kg (0.9 lb)

Size ..... 3.56 cm H x 13.21 cm L x 9.91 cm W
(1.4" H x 5.2" L x 3.9" W)

Instrument Specifications

Waveforms:

- **ECG waveforms** ..... 30, 60, 120, 180, and 240 BPM
- **Square wave** ..... 2 Hz
- **Sinewave** ..... 10, 40, 50, 60, and 100 Hz

Arrhythmias:

Atrial fibrillation
Second degree A–V block, type 1
Right bundle branch block
Premature atrial contraction
Premature ventricular contraction, early
Premature ventricular contraction, RonT
Multifocal PVCs
Bigeminy
Run of 5 PVCs
Ventricular tachycardia
Ventricular fibrillation
Paced

Automated sequence:

- **Pulse** ..... 4 seconds
- **Sine wave** ..... 10, 40, 60, and 100 Hz
- **Triangle wave** ..... 2 Hz

Rate accuracy: ..... ± 0.5%

Amplitudes:

- **Lead I** ..... 0.5, 1.0, 1.5, 2.0 mV
- **High level output** ..... 0.25, 0.50, 0.75, & 1.00 V
- **Accuracy** ..... ±2 %

2Hz square wave at 2 mV (all leads)

Accessories

Standard	**Fluke Part#**
Operators Manual	2572345
Battery, 9 V Alkaline	614487
Battery Eliminator (90-264 Vac, 9V, IEC – 320/C6 inlet)	2183983
Power Cord (IEC – 320/C5 connector)	See Note
Carrying Case (Vinyl)	2248424

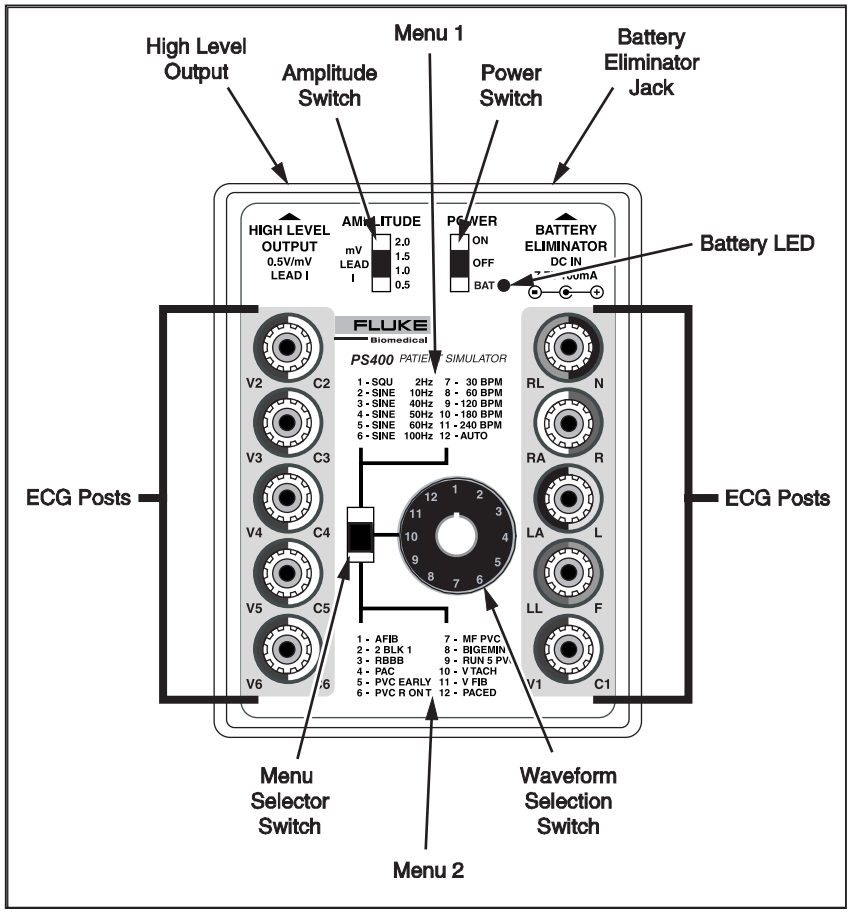
Optional

Cable, High Level ECG (3.5 mm phone to BNC)	2200116
Calibration Manual	2577801

Note: Refer to the current Fluke Biomedical Price List for availability, part number and price.

Instrument Familiarity

Figure 1 identifies the controls and connectors of the Simulator.



ehd1.eps

Figure 1. PS400 Controls and Indicators

Preparation for Use

Use the 9 volt battery supplied by Fluke Biomedical or use the optional Battery Eliminator.

To install or replace the battery, locate the Battery Compartment at the bottom of the instrument case. (See the illustration on the next page.) Press down on the arrow and slide the Battery Compartment Cover off. Connect the 9–volt alkaline* battery (Duracell MN1604 or equivalent) as illustrated in Figure 2. Make sure not to pinch the Battery Connector wires. Replace the cover.

Note

Use only alkaline batteries.

To check the battery, set the Power Switch to "BAT". If the Battery LED lights, the battery is good. If not, the battery is dead.

Note

Refer to the Instrument Familiarity section for the location of controls and indicators

Note

No special cables are required for using the ECG Posts.

Note

The High Level Output uses a 3.5–mm 2–conductor phone plug. Refer to Accessories, Optional *in the Accessories section.*

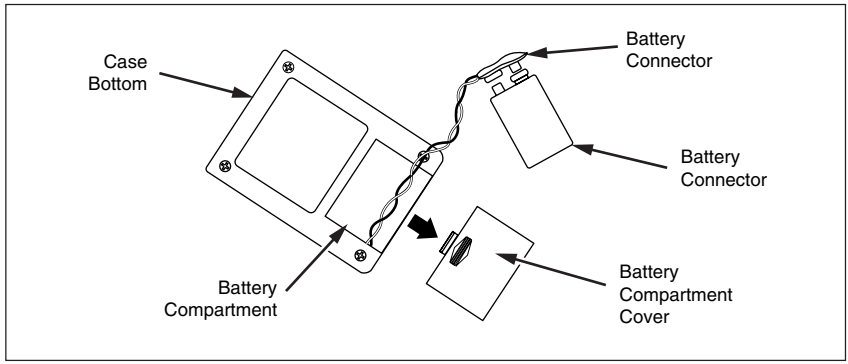


Figure 2. Installing the Battery

Operating the Simulator

The following sections cover powering-Up the Simulator and how to select the various waveforms used in testing.

Power-Up

Confirm that the battery is installed (see the Preparation for Use section) or that the Battery Eliminator is firmly connected to the Battery Eliminator Jack, which is located on the top of the instrument.

Note

For locations of PS400 controls and indicators, see the Instrument Familiarity section.

The Power Switch has three positions: “ON”, “OFF”, and “BAT”.

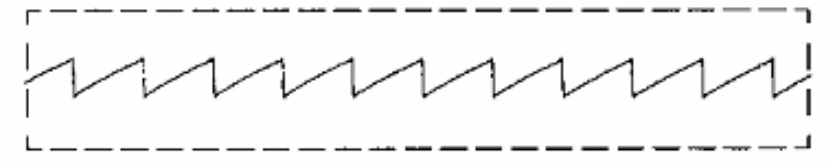
To power up the Simulator, push the Power Switch to the “ON” position.

Note

The Simulator does not have a continuous power–on indicator (extending battery life). ***Turn the instrument off when not using it.***

To check the battery’s status, hold the Power Switch in the “BAT” position. The Battery LED illuminates if the battery is good. If the Battery LED does not light, replace the battery.

If the battery is low but not dead, the Simulator output waveform is a sawtooth, such as illustrated below, regardless of the waveform selected. Amplitude of the sawtooth waveform varies depending on how low the battery is.



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Selection Waveforms

The Simulator is able to produce 24 different waveforms.

To select a waveform, select one of the two menus using the Menu Selector Switch, and turn the 12–position rotary Waveform Selector Switch to the number that corresponds to the desired waveform.

The waveforms are available on both the ECG Posts and the High Level Output.

Menu 1 Selections

Setting the Menu Selector Switch to the *upper* position enables the following selections from Menu 1 as described in Table 1.

Table 1. Menu 1 Selections

Switch Position	Simulation
1 – SQU 2 Hz	Square waveform at 2 Hz
2 – Sine10 Hz	Square waveform at 10 Hz
3 – Sine40 Hz	Square waveform at 40 Hz
4 – Sine50 Hz	Square waveform at 50 Hz
5 – Sine60 Hz	Square waveform at 60 Hz
6 – Sine100 Hz	Square waveform at 100 Hz
7 – 30 BPM	ECG waveform at 30 BPM
8 – 60 BPM	ECG waveform at 60 BPM
9 – 120 BPM	ECG waveform at 120 BPM
10 – 180 BPM	ECG waveform at 180 BPM
11 – 240 BPM	ECG waveform at 240 BPM
12 – Auto	Automated sequence: each segment runs for 4 seconds in this order, a 4-second pulse, sine waves 10, 40, 60, and 100 Hz, and a 2-Hz triangle wavefrom.

Menu 2 Selections

Setting the Menu Selection switch to the lower position enables the following selections from Menu 2 as described in Table 2.

Table 2. Menu 2 Selections

Switch Postion	Simulation
AFIB	Atrial Fibrillation.
2° BLK 1	Second degree A–V block, type 1, Wenckebach.
RBBB	Right bundle branch block.
PAC	Premature atrial contraction.
PVC	Premature ventricular contraction, early.
PVC R ON T	Premature ventricular contraction, R on T.
MF PVC	Multifocal PVCs.
BIGEMINY	Bigeminy
RUN 5 PVC	Run of 5 PVCs.
V TACH	Ventricular tachycardia.
V FIB	Ventricular fibrillation.
PACED	Paced

Amplitude Selection

Use the 4-position Amplitude Switch to make the following selections (on Lead I):

0.5 mV
1.0 mV
1.5 mV
2.0 mV

Waveform Examples

The Simulator waveform selections and their purposes are listed in this section.

The waveform examples illustrated were plotted using an ECG strip chart recorder set at 1 mV/cm sensitivity and 25 mm/s chart speed in the Lead I

configuration. The frequency response was set in the monitoring quality mode (–3 dB @ 30 Hz).

Because of inherent differences in frequency response, signal acquisition, and filtering techniques, the responses of the ECG equipment under test may vary from the waveforms illustrated.

The major differences are noticed between instruments intended for either monitoring or diagnostic applications. For example, the high–end frequency response (–3 dB) can range from 30 Hz for a bedside monitor to over 100 Hz for a 12–lead diagnostic recorder. Additionally, to attenuate noise on the ECG signal during recording, narrow “band reject” filters, common to many instruments, eliminate any response at the power system line frequencies of either 50 or 60 Hz.

Not all waveform selections are illustrated because of the wide range of responses possible.

Menu 1 Waveforms

The following waveform selections are selectable through the Waveform Selection Switch when the Menu Selection switch is in the Menu 1 position.

SQU 2 Hz

Waveform Selection Switch Position: 1

Purpose: Test amplitude accuracy (gain/damping).

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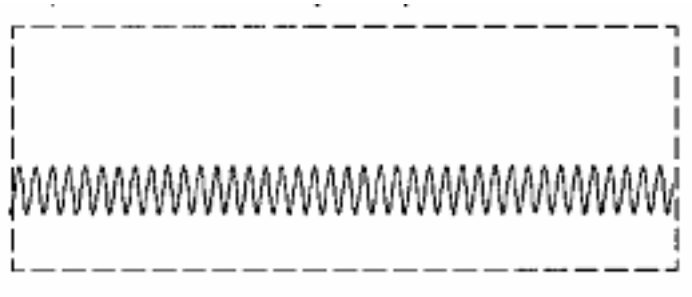
Sine 10 Hz

Waveform Selection Switch Position: 2

Purpose: Test bandpass response.



ehd5.bmp

Sine 40 Hz

Waveform Selection Switch Position: 3

Purpose: Test low frequency response. (monitor –3 dB point).

Note

Waveform example not shown because of wide range of responses possible.

Sine 50 Hz

Waveform Selection Switch Position: 4

Purpose: Test 50–Hz rejection (notch filter).

Note

Waveform example not shown because of wide range of responses possible.

Sine 60 Hz

Waveform Selection Switch Position: 5

Purpose: Test 60–Hz rejection (notch filter).

Note

Waveform example not shown because of wide range of responses possible.

Sine 100 Hz

Waveform Selection Switch Position: 6

Purpose: Test high–end frequency roll–off (diagnostic –3 dB point).

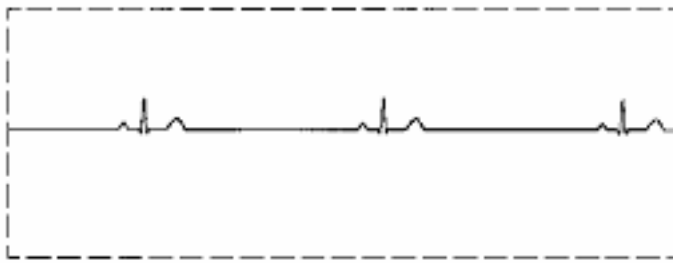
Note

Waveform example not shown because of wide range of responses possible.

30 BPM

Waveform Selection Switch Position: 7

Purpose: Test ECG rate accuracy.

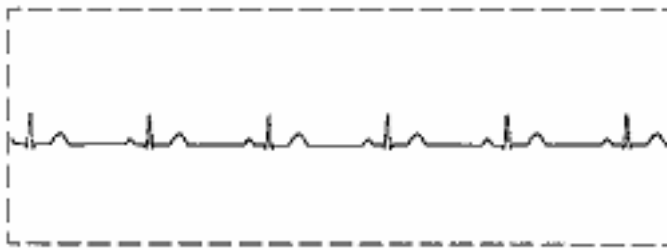


ehd6.bmp

60 BPM

Waveform Selection Switch Position: 8

Purpose: Test ECG rate accuracy.

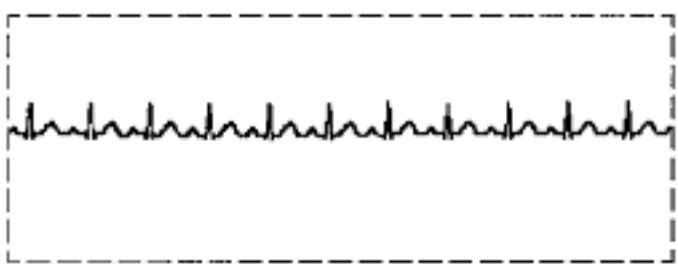


ehd7.bmp

120 BPM

Waveform Selection Switch Position: 9

Purpose: Test ECG rate accuracy.



ehd8.bmp

180 BPM

Waveform Selection Switch Position: 10

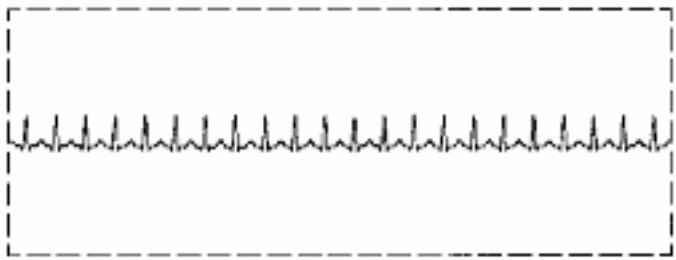
Purpose: Test ECG rate accuracy.

ehd9.bmp

240 BPM

Waveform Selection Switch Position: 11

Purpose: Test ECG rate accuracy.



ehd10.bmp

AUTO

Waveform Selection Switch Position: 12

Purpose: Test monitor performance (gain/damping) linearity and frequency response.

This selection is an automated sequence of six segments that run for 4 seconds each, in this order: a 4-second pulse; sine waveforms 10, 40, 60, and 100 Hz; and a 2-Hz triangle waveform; and then the sequence repeats.

Note

Waveform example not shown because of wide range of responses possible.

Menu 2 Waveforms

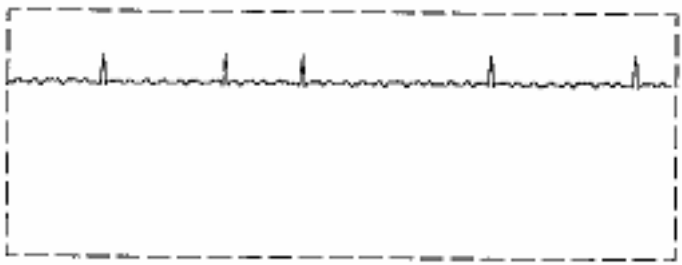
The following waveform selections are selectable through the Waveform Selection Switch when the Menu Selection switch is in the Menu 2 position.

AFIB

Waveform Selection Switch Position: 1

Description: Atrial fibrillation.

Purpose: Test the ECG monitor's ability to display a particular arrhythmia, and as a training aid for health–care personnel.

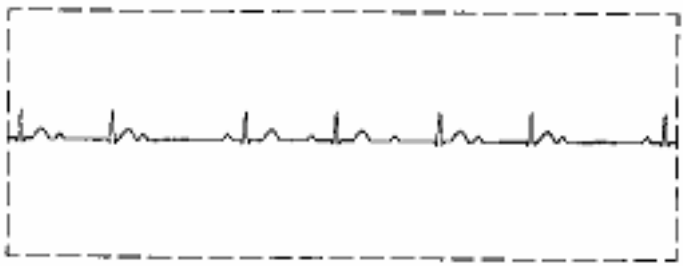


ehd11.bmp

2° BLK 1

Waveform Selection Switch Position: 2

Description: Second degree A-V block, type 1, Wenckebach.



ehd12.bmp

R B B B

Waveform Selection Switch Position: 3

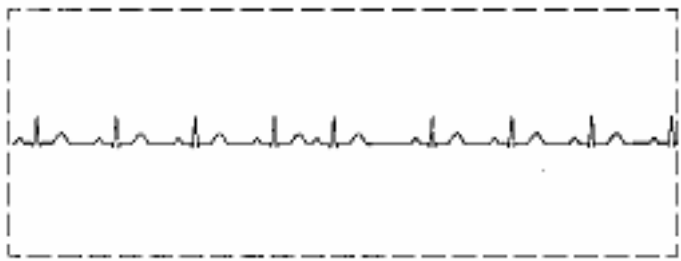
Description: Right bundle branch block.

ehd13.bmp

PAC

Waveform Selection Switch Position: 4

Description: Premature atrial contraction.

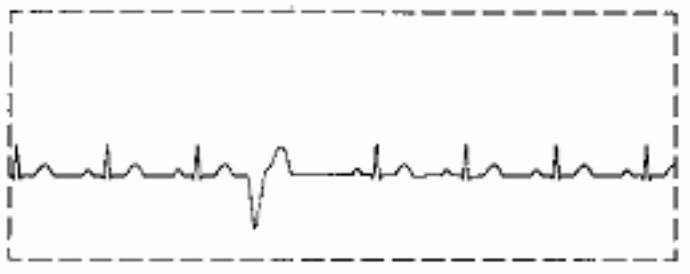


ehd14.bmp

PVC

Waveform Selection Switch Position: 5

Description: Premature ventricular contraction, early.

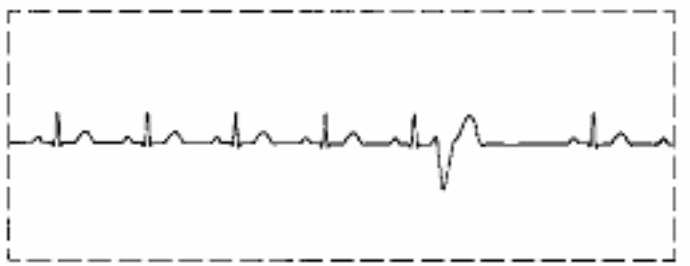


ehd15.bmp

PVC R ON T

Waveform Selection Switch Position: 6

Description: Premature ventricular contraction, R on T – 65% premature; 260 ms after previous normal R–wave peak.

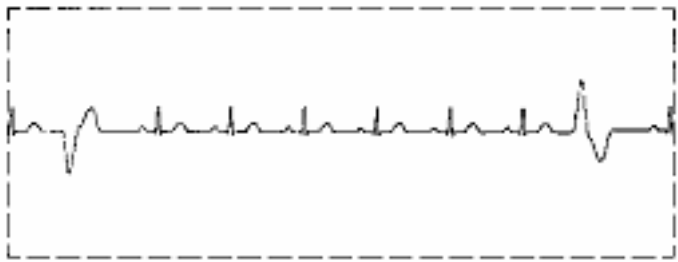


ehd16.bmp

MF PVC

Waveform Selection Switch Position: 7

Description: Multi-focal premature ventricular contractions.

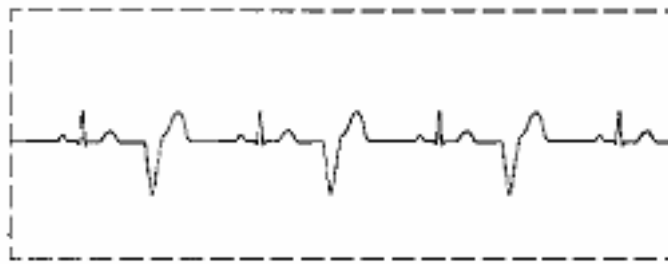


ehd17.bmp

BIGEMINY

Waveform Selection Switch Position: 8

Description: Normal beat followed by a PVC, repeated.

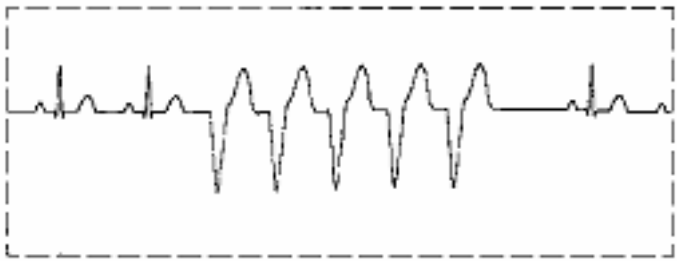


ehd18.bmp

RUN 5 PVC

Waveform Selection Switch Position: 9

Description: Run of 5 PVCs and 36 normal beats, repeated.

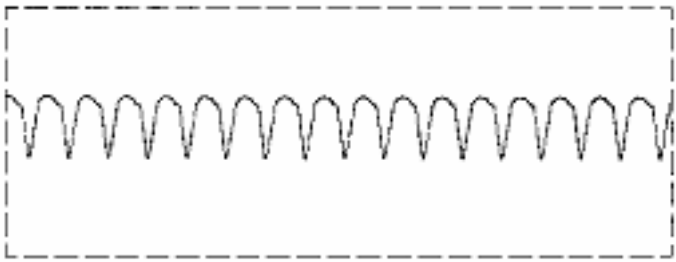


ehd19.bmp

V TACH

Waveform Selection Switch Position: 10

Description: Ventricular tachycardia.



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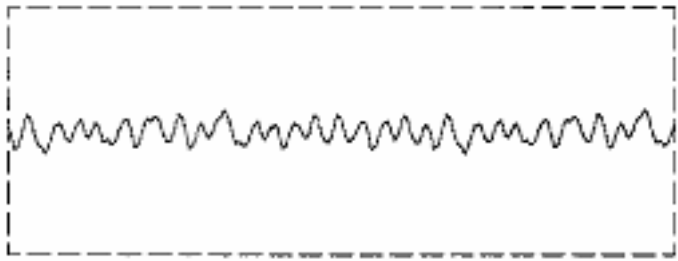
V FIB

Waveform Selection Switch Position: 11

Description: Ventricular fibrillation.

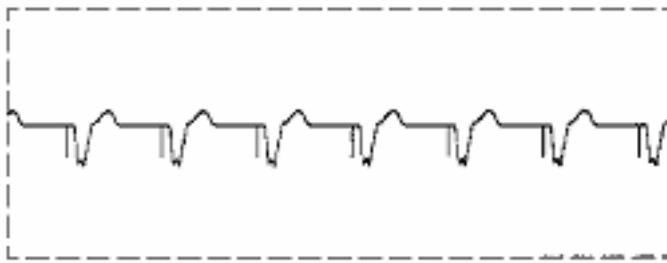


ehd21.bmp

PACED

Waveform Selection Switch Position: 12

Description: Paced.



ehd22.bmp

Note

The simulated pacer spike, preceding the ventricular response, may be filtered out by the instrument under test and replaced by an internally generated marker. Different instruments generate a wide range of markers to indicate that a spike has been sensed. Refer to the operation/service manual of the ECG equipment under test for specific information regarding the type of marker and pacer spike sensing level.