IVY BIOMEDICAL

Innovation in Cardiac Monitoring

Model 7600/7800

OPERATION MANUAL

Cardiac Trigger Monitor

Model 7800 shown

REF: 3232-00-16 Rev.20 EN

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1.0 USER RESPONSIBILITY

This product will perform in conformity with the description contained in this Operation Manual and accompanying labels and/or inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. This product must be checked periodically. A defective Product should not be used. Parts that are broken, missing, plainly worn, distorted or contaminated should be replaced immediately. Should such repair or replacement become necessary, Ivy Biomedical Systems, Inc. recommends that a telephone call or written request for service advice be made to Ivy Biomedical Systems, Inc.'s Service Department. This product or any of its parts should not be repaired other than in accordance with instructions provided by Ivy Biomedical Systems, Inc.'s trained personnel. The product must not be altered without the prior written approval of Ivy Biomedical Systems, Inc.'s Quality Assurance Department. The user of this Product shall have the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage or alteration by anyone other than Ivy Biomedical Systems, Inc.

⚠ **CAUTION:** US Federal law restricts this device to sale by or on the order of a licensed medical practitioner.

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Multi-language translations of this Operation Manual may be found on the Ivy Biomedical website:
www.ivybiomedical.com

2.0 MANUAL REVISION HISTORY

Revision	Date	Description
00	August 11, 2011	Initial Release of Model 7600 Operation Manual
01	March 13, 2012	Changed title to Model 7600/7800 Operation Manual. Added model 7800 description, specifications etc. to Operation Manual.
02	May 7, 2012	Revised Operation Manual to comply with IEC 60601-1 3rd edition.
03	June 4, 2012	Added Patient Population and Contraindications statements to Monitor Description section of the Operation Manual.
04	June 5, 2012	Revised Power/Standby symbol and added IPX1 statement.
05	September 28, 2012	Added warning statement regarding reducing the possibility of a tripping hazard to the Monitor Setup section of the Operation Manual.
06	January 31, 2013	Increased Operating Environment and Storage Environment Temperature Range.
07	November 20, 2013	Updated China RoHS table and Warning and Caution symbols.
08	December 9, 2013	Corrected typographical errors in sections 7.3 and 7.4.
09	March 9, 2015	Updated EMC Guidance and Manufacturer's Declaration on pages 8, 9 and 10. Added EAC symbol to User Responsibility section on page 1. Updated all references to WEEE Directive to 2012/19/EU. Revised all references to fuse rating and type to T .5A, 250V.
10	September 2, 2015	Revised all references to fuse rating and type to T 0.5AL, 250V.
11	June 8, 2016	Revised sections 6.10 and 6.12.
12	March 1, 2017	Revised section 19.0 to include additional regulatory standards.
13	March 15, 2017	Revised section 5.0 as per new requirements for IEC 60601-1-2:2014.
14	June 15, 2018	Revised section 19.0 to include additional regulatory standards.
15	February 19, 2019	Revised section 19.0 to update regulatory standards.
16	October 14, 2019	Revised section 5.6.
17	March 26, 2020	Updated to comply with the EU-MDR.
18	May 4, 2020	Added "Consult Instructions for Use" symbol with eIFU indicator to section 5.14.
19	June 1, 2020	Updated image in section 6.5.
20	September 21, 2020	Updated accessories in section 17.4. Updated section 9.3.

3.0 WARRANTY

All products manufactured by Ivy Biomedical Systems, Inc. under normal use, are warranted to be free from defects in material and workmanship and to operate within published specifications, for a period of 13 months from date of original shipment.

All accessories such as ECG trunk cables and lead wires, supplied by Ivy Biomedical Systems, Inc. under normal use, are warranted to be free from defects in material and workmanship and to operate within published specifications, for a period of 90 days from date of original shipment.

If an examination by Ivy Biomedical Systems, Inc. discloses such product(s) or component part(s) to have been defective, then Ivy's obligation is limited at Ivy's option, to repair or replacement.

When a product or products need to be returned to the manufacturer for repair or examination, contact service personnel at Ivy Biomedical Systems to obtain a Return Material Authorization number (RMA #) and the correct packing instructions:

Service / Tech Support:
Telephone: +1 203.481.4183 or +1 800.247.4614
Fax: +1 203.481.8734
E-mail: service@ivybiomedical.com

All products being returned for warranty repair shall be shipped prepaid to:

Ivy Biomedical Systems, Inc
Attn: Service Department
11 Business Park Drive
Branford, CT 06405 USA

Ivy will send the shipment of the repaired or replacement product to customer at Ivy's expense.

4.0 INTRODUCTION

This manual provides information on the correct use of the Model 7600/7800 Cardiac Trigger monitor. It is up to the user to ensure that any applicable regulations regarding the installation and operation of the monitor are observed.

The Model 7600/7800 is ME EQUIPMENT (Medical Electrical Equipment) that is intended to monitor patients under medical supervision. The Model 7600/7800 monitor must be operated by trained and qualified medical personnel only.

Using This Manual

We recommend that you read this manual before operating the equipment. This manual is written to include all options. If your monitor does not include all options, menu selections and display data for those options will not appear on your monitor.

Use the Monitor Description section for general descriptions of controls and displays. For details on the use of each option, refer to the section of the manual dealing with the appropriate option.

Boldface type is used in text to refer to the labeling on user controls. Brackets [ ] surround menu selections used with the programmable touch keys.

Manufacturer's Responsibility

The manufacturer of this equipment is responsible for the effects on safety, reliability, and performance of the equipment only if:

- Assembly operations, extensions, re-adjustments, or repairs are carried out by persons authorized by the manufacturer
- The electrical installation complies with all applicable regulations
- The equipment is used in accordance with the instructions in this manual

Incorrect operation or failure of the user to maintain the monitor in accordance with proper maintenance procedures relieves the manufacturer or his agent from all responsibility for consequent non-compliance, damage, or injury.

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This manual explains how to set up and use the Model 7600/7800. Important safety information is located throughout the manual where appropriate. READ THE ENTIRE SAFETY INFORMATION SECTION BEFORE YOU OPERATE THE MONITOR.

5.0 SAFETY

5.1 Essential Performance

List of Essential Performance functions (defined in the IEC 60601-1 Test Report):

- To monitor and display the patient's heart rate accurately (within limits of 60601-2-27).
- To monitor and display the patient's ECG waveform accurately (within limits of 60601-2-27).
- To produce an R-Wave gating output pulse to provide proper, accurate, reliable triggering.
- To produce an alarm signal when operator intervention is required.

5.2 Electrical

This product is intended to be operated from a mains power source of 100-120V~ or 200-230V~, 50/60 Hz and a maximum ac power consumption of 45VA.

WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth. Connect the monitor only to a three-wire, grounded, hospital grade receptacle. The three-conductor plug must be inserted into a properly wired three-wire receptacle; if a three-wire receptacle is not available, a qualified electrician must install one in accordance with the governing electric code.

WARNING: Do not under any circumstances remove grounding conductor from the power plug.

WARNING: The power cable supplied with this equipment provides for this protection. Do not attempt to defeat this protection by modifying the cable or by using ungrounded adapters or extension cables. The power cord and plug must be intact and undamaged. To disconnect the equipment from the mains power; unplug the power cord.

WARNING: Do not connect to an electrical outlet controlled by a wall switch or dimmer.

WARNING: If there is any doubt about the integrity of the protective ground conductor arrangement, do not operate the monitor until the ac power source protective conductor is fully functional.

WARNING: For power interruptions exceeding 30 seconds, the monitor must be turned on manually by pressing the **Power On/Standby** switch. When monitor power is restored, the monitor will return to manufacturer's DEFAULT settings. (An option is available which will allow monitor to use the last used or STORED settings.)

WARNING: To avoid unacceptable RISK caused by power interruptions, connect the monitor to an appropriate medical-grade uninterruptable power source (UPS).

WARNING: Do not place the monitor in any position that may cause it to fall on the patient. Do not lift the monitor by the power supply cord or ECG trunk cable.

WARNING: Carefully route monitor cables (ECG trunk cables, power cords, etc.) to reduce the possibility of a tripping hazard.

WARNING: Do not position the monitor in a way that would cause difficulty to the operator to disconnect it from the power source.

WARNING: Electric shock hazard! Do not remove covers or panels. Refer service to trained and qualified service personnel.

WARNING: Disconnect the monitor from its power source when serviced. Refer service to trained and qualified service personnel.

WARNING: All replaceable parts should be replaced by trained and qualified service personnel.

WARNING: To avoid electrical shock, disconnect the monitor from its power source before changing fuses. Replace fuse only with same rating and type: T 0.5AL, 250V.

WARNING: Do not clean monitor while it is plugged into a power source.

WARNING: If unit is accidentally wet, immediately disconnect the monitor from its power source. Discontinue use until dry and then test unit for proper operation before reuse on a patient.

WARNING: This unit uses a common isolation path for the ECG leads and Electrodes. Do not allow the ECG leads and/or Electrodes to come in contact with other conductive parts including earth ground. Do not connect any non-isolated accessories to the ECG input when connected to a patient, as this may compromise the safety of the unit. When attached to other devices, ensure that the total chassis leakage currents of all units do not exceed 300 µA.

WARNING: The synchronized output pulse is not designed to synchronize a defibrillator discharge or a cardioversion procedure.

WARNING: To ensure proper monitor ventilation, do not use the monitor without the bottom cover feet or the optional bottom cover mounting plate.

WARNING: Do not modify this equipment without authorization of the manufacturer.

5.3 Explosion

WARNING: Explosion hazard! Do not use this equipment in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environment or nitrous oxide.

5.4 Patient Connections

WARNING: Carefully route ECG trunk cables to reduce the possibility of patient entanglement or strangulation.

Patient connections are electrically isolated. For all connections use isolated probes. Don't let patient connections contact other conductive parts, including earth ground. See instructions for patient connections in this manual.

Leakage current is limited internally by this monitor to less than 10 μA. However, always consider cumulative leakage current that can be caused by other equipment used on the patient at the same time as this monitor.

To ensure that the leakage current protection remains within the specifications, use only the ECG trunk cables specified in this manual. This monitor is supplied with protected lead wires. *Do not use* cables and leads with unprotected lead wires having exposed conductors at the cable end. Unprotected lead wires and cables may pose an unreasonable risk of adverse health consequences or death.

Line isolation monitor transients may resemble actual cardiac waveforms and thus inhibit heart rate alarms. To minimize this problem, ensure proper electrode placement and cable arrangement.

If an alarm condition occurs while the alarms are set to off, neither visual nor audio alarms will be present.

5.5 MRI

WARNING: MR-unsafe! Do not expose the Model 7600 and Model 7800 to a magnetic resonance (MR) environment. The Model 7600 and Model 7800 may present a risk of projectile injury due to the presence of ferromagnetic materials which can be attracted by the MR magnet core.

WARNING: Thermal injury and burns may occur due to the metal components of the device which can heat during MR scanning.

WARNING: The device may generate artifacts in the MR image.

WARNING: The device may not function properly due to the strong magnetic and radiofrequency fields generated by the MR scanner.

5.6 Pacemakers

WARNING – PACEMAKER PATIENTS: Rate meters might continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely on rate meter ALARM SIGNALS. Keep pacemaker PATIENTS under close surveillance. See the SPECIFICATIONS section in this manual for disclosure of the pacemaker pulse rejection capabilities of this instrument. AV sequential and dual chamber pacemaker pulse rejection have not been evaluated; do not rely on pacemaker rejection with patients with dual chamber pacemakers.

5.7 Electrosurgery Protection

This equipment has been tested in accordance with EN 60601-2-27.
This equipment is protected against electrosurgery potentials. To avoid the potential of electrosurgery burns at monitoring sites, ensure proper connection of the electrosurgery return circuit as described by the manufacturer's instructions. If improperly connected, some electrosurgery units might allow energy to return through the ECG electrodes. This equipment returns to normal operation in less than 10 seconds.

5.8 Defibrillation Protection

This equipment is protected up to 360 J defibrillator discharge. The monitor is internally protected to limit current through the electrodes to prevent injury to the patient and damage to the equipment as long as the defibrillator is used in conformance with the manufacturer's instructions. Use only Ivy specified accessories (see Accessories).

5.9 Signal Amplitude

WARNING: The minimum patient physiological "R-wave" signal amplitude is 0.5 mV.
The use of the Model 7600/7800, below the above amplitude value, may cause inaccurate results.

5.10 EMC

This equipment has been certified to be protected to emissions and immunity according to IEC-60601-1-2:2014 for use in hospital and small clinic.

CAUTION: Medical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Operation Manual.

CAUTION: Portable and mobile RF communications equipment can affect medical electrical equipment.

WARNING: This device has not been tested for use in the presence of various potential EMC/EMI sources such as diathermy, radio frequency identification (RFID), electromagnetic security systems (e.g. metal detectors), etc. Caution should be used if operating this device in the presence of such devices.

WARNING: The Model 7600/7800 should not be used adjacent to or stacked with other equipment. However, if adjacent or stacked use is necessary, the Model 7600/7800 should be observed to verify normal operation in the configuration in which it will used.

5.11 Accessories

WARNING: The use of accessories other than those specified in the Accessories Section of this manual may result in increased emissions or decreased immunity of the equipment.

5.12 Guidance and Manufacturer's Declaration-Electromagnetic Emissions

Guidance and manufacturer's declaration – Electromagnetic emissions		
The Model 7600/7800 monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 7600/7800 should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11 Radiated	Group 1 Class B	The Model 7600/7800 uses RF energy only for its internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11 Conducted	Class B	The Model 7600/7800 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Class A	

5.13 Guidance and Manufacturer's Declaration-Electromagnetic Immunity

Guidance and manufacturer's declaration – Electromagnetic immunity			
The Model 7600/7800 monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 7600/7800 should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±9 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines 100 kHz repetition frequency	±3 kV for power supply lines ±1.5 kV for input/output lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1.5 kV differential mode ±3 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC61000-4-11	0 % U_T: 0.5 cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees. 0 % U_T: 1 cycle and 70% U_T; 25/30 cycles. Single phase: at 0 degrees 0 % U_T; 250/300 cycles.	0 % U_T: 0.5 cycle at 0, 45, 90, 135, 180, 225, 270 and 315 degrees. 0 % U_T: 1 cycle and 70% U_T; 25/30 cycles. Single phase: at 0 degrees 0 % U_T; 250/300 cycles.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Model 7600/7800 requires continued operation during power mains interruptions, it is recommended that the Model 7600/7800 be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz and 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

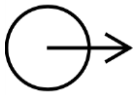
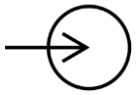
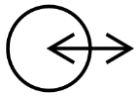
Guidance and manufacturer's declaration – Electromagnetic immunity			
The Model 7600/7800 monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 7600/7800 should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3, including Clause 8.10, Table 9, for proximity to wireless devices.	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz 80% AM @ 2 Hz 3 V/m 80 MHz to 2.7 GHz 80% AM @ 2 Hz Including Clause 8.10, Table 9, for proximity to wireless devices	5 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz 80% AM @ 2 Hz 10 V/m 80 MHz to 2.7 GHz 80% AM @ 2 Hz Including Clause 8.10, Table 9, for proximity to wireless devices	Portable and mobile RF communications equipment should be used no closer to any part of the Model 7600/7800, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{p}$ $d = 1.2\sqrt{p}$ 80 MHz to 800 MHz $d = 2.3\sqrt{p}$ 800 MHz to 2.7 GHz Where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b] Interference may occur in the vicinity of the equipment marked with the following symbol: 
NOTE 1 – At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 – These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
[a] Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Model 7600/7800 is used exceeds the applicable RF compliance level above, the Model 7600/7800 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model 7600/7800. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

5.14 Symbols Glossary

Standard Reference Number and Title

- ISO 15223-1 references 5.1.1, 5.1.2, 5.1.3, 5.1.6, 5.4.3 and 5.4.4: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied-Part 1: General requirements
- ISO 7010 reference W001: Graphical symbols - Safety colours and safety signs - Registered safety signs
- IEC 60417 references 5009, 5016, 5017, 5021, 5032, 5034, 5035, 5036, 5336 and 5448: Graphical symbols for Use on Equipment
- ISO 7000 reference 5576: Graphical symbols for use on equipment-Registered Symbols
- IEC 62570 reference 7.3.3: Standard practice for marking medical devices and other items for safety in the magnetic resonance environment

Symbol	Title	Explanatory Text	Standard Reference Number
  eIFU Indicator	Consult instructions for use	Indicates the need for the user to consult the instructions for use When used to indicate an instruction to consult electronic instructions for use (eIFU), this symbol is accompanied by an eIFU indicator (eIFU website) and is placed adjacent to the symbol.	ISO 15223-1 reference 5.4.3
	General Warning Sign	To signify a general warning	ISO 7010 reference W001
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot for a variety of reasons, be present on the medical device itself	ISO 15223-1 reference 5.4.4
	Defibrillator-proof type CF Applied Part	To identify a defibrillator proof type CF applied part complying with IEC 60601-1	IEC 60417 reference 5336

Symbol	Title	Explanatory Text	Standard Reference Number
	Equipotential (Ground) connector	To identify the terminals which, when connected together, bring the various part of an equipment or of a system to the same potential, not necessarily being the earth (ground) potential	IEC 60417 reference 5021
	Earth (Ground)	To identify an earth (ground) terminal in cases where neither the symbol 5018 nor 5019 is explicitly required	IEC 60417 reference 5017
	Fuse type / rating	To identify fuse boxes or their location	IEC 60417 reference 5016
	Output Signal	To identify an output terminal when it is necessary to distinguish between inputs and outputs	IEC 60417 reference 5035
	Input Signal	To identify an input terminal when it is necessary to distinguish between inputs and outputs	IEC 60417 reference 5034
	Input / Output Signal	To identify a combined input/output connector or mode	IEC 60417 reference 5448
	Alternating Current	Indicate on the rating plate that the equipment is suitable for alternating current only	IEC 60417 reference 5032
	Power On/Standby	To identify the switch position by means of which part of the equipment is switched on in order to bring it into the standby condition	IEC 60417 reference 5009
	Alarm Mute	To identify the control whereby a bell may be switched off or to indicate the operating status of the bell	ISO 7000 reference 5576

Symbol	Title	Explanatory Text	Standard Reference Number
	Catalog or Number	Indicates the manufacturer's catalog number so that the medical device can be identified	ISO 15223-1 reference 5.1.6
	Manufacturer	Indicates the medical device manufacturer, as defined in EU directives 90/385/EEC, 93/42/EEC and 98/79/EC.	ISO 15223-1 reference 5.1.1
	Date of Manufacture	Indicates the date when the medical device was manufactured.	ISO 15223-1 reference 5.1.3
	CE Mark	Indicates that the device complies with applicable European regulations	MDD 93/42/EEC Annex XII
	Authorized Representative in the European Community	Indicates the authorized representative in the European Community	ISO 15223-1 reference 5.1.2
	Medical Device	Indicates the item is a medical device.	Not applicable
	RoHS	RoHS Compliance	RoHS Directive 2011/65/EU
	MR Unsafe	To identify an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment	IEC 62570 reference 7.3.3
	WEEE Compliant	Indicates compliance with the Waste from Electrical and Electronic Equipment Directive	WEEE Directive 2012/19/EU
	Dangerous Voltage	To indicate hazards arising from dangerous voltage	IEC 60417 reference 5036

6.0 MONITOR DESCRIPTION

The Model 7600/7800 is an easy-to-use Cardiac Trigger Monitor that features a bright color touch screen LCD display. The Model 7600/7800 displays two simultaneous ECG vectors and the patient's heart rate. The Trigger ECG vector (top ECG waveform) can be selected from Leads I, II III or Auto. The Second ECG vector (bottom ECG waveform) can be selected from Leads I, II or III. In addition, high and low heart rate alarm limits can be adjusted to bracket the patient's heart rate so that a violation of these limits produces an audible and visual indication of the violation. The Model 7600/7800 color display includes dual ECG traces, large heart rate numbers and alphanumeric characters for other data, alarm messages, menus and user information.

- The Model 7600/7800 monitor is intended primarily for use on patients in applications requiring precision R-wave synchronization such as timed imaging studies.

- The Model 7600/7800 includes an AUTO lead select feature (Trigger lead only). When selected, this feature will determine which lead (I, II or III) provides the best quality ECG signal and, thus, a more reliable cardiac trigger.

- The Model 7600/7800 has an electrically isolated RS-232 micro-D connector that provides two-way communications between the monitor and the external console for the transfer of ECG data.

- The Model 7600/7800 is available with different options; not all options are included in all monitors. An optional integral recorder is available. Set up of recorder functions is made through the monitor touch screen menus.

- The Model 7600/7800 is suitable for use in presence of electrosurgery.

- The Model 7600/7800 is not intended for use with any other physiological monitoring unit.

- The Model 7600/7800 is restricted to use on one patient at a time.

Model 7800 Only:

- The Model 7800 has special hardware and software that allows for the measurement of skin to electrode impedance.

- The Model 7800 provides two Ethernet channels from a single RJ45 connector. The first channel provides two-way communications between the monitor and the CT console for the transfer of ECG data, trigger timing data and the receipt of patient identification information. The second channel provides ECG data to the CT Gantry display. These functions will only operate when the Model 7800 is electrically connected to a CT console and CT gantry capable of displaying ECG data.

- The Model 7800 has a USB drive that allows the operator to store and retrieve ECG data on a USB memory stick device.

- The Model 7800 has an Auxiliary 9-pin D-subminiature connector that provides a customized interface for specific installations.

6.1 Intended Use

The Ivy Biomedical Model 7000 Series Cardiac Trigger Monitors are simple-to-use instruments for monitoring ECG and Heart Rate. They are designed for use in the ICU, CCU and operating room conditions. They can sound an alarm when HR falls outside of preset limits. They provide an output pulse, synchronized to the R-wave for use in applications requiring precision R-wave synchronization.

6.2 Patient Population

The Model 7000 Series Cardiac Trigger Monitor is intended to perform ECG monitoring and R-wave pulse detection on adult, pediatric and neonatal patients. R-Wave synchronization is typically used for gating nuclear scanners, CT scanners, or other imaging devices.

6.3 Contraindications

The Model 7000 Series is limited to use by trained and qualified medical professionals. This device is not intended for use as life support equipment or for performing cardiac diagnostics. The product is not intended for use in home care monitoring or for use in an MRI environment.

6.4 Classification (in accordance with ANSI/AAMI ES60601-1)

Protection against electric shock:	Class 1.
Degree of protection against electric shock:	Type CF applied part. Defibrillator proof: ECG
Degree of protection against harmful ingress of water:	Ordinary Equipment IPX1 per IEC-60529
Methods of Maintenance and Cleaning:	See Maintenance and Cleaning section of this manual
Degree of safety of application in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide:	Equipment not suitable for use in the presence of a flammable anesthetic mixture
Mode of operation:	Continuous

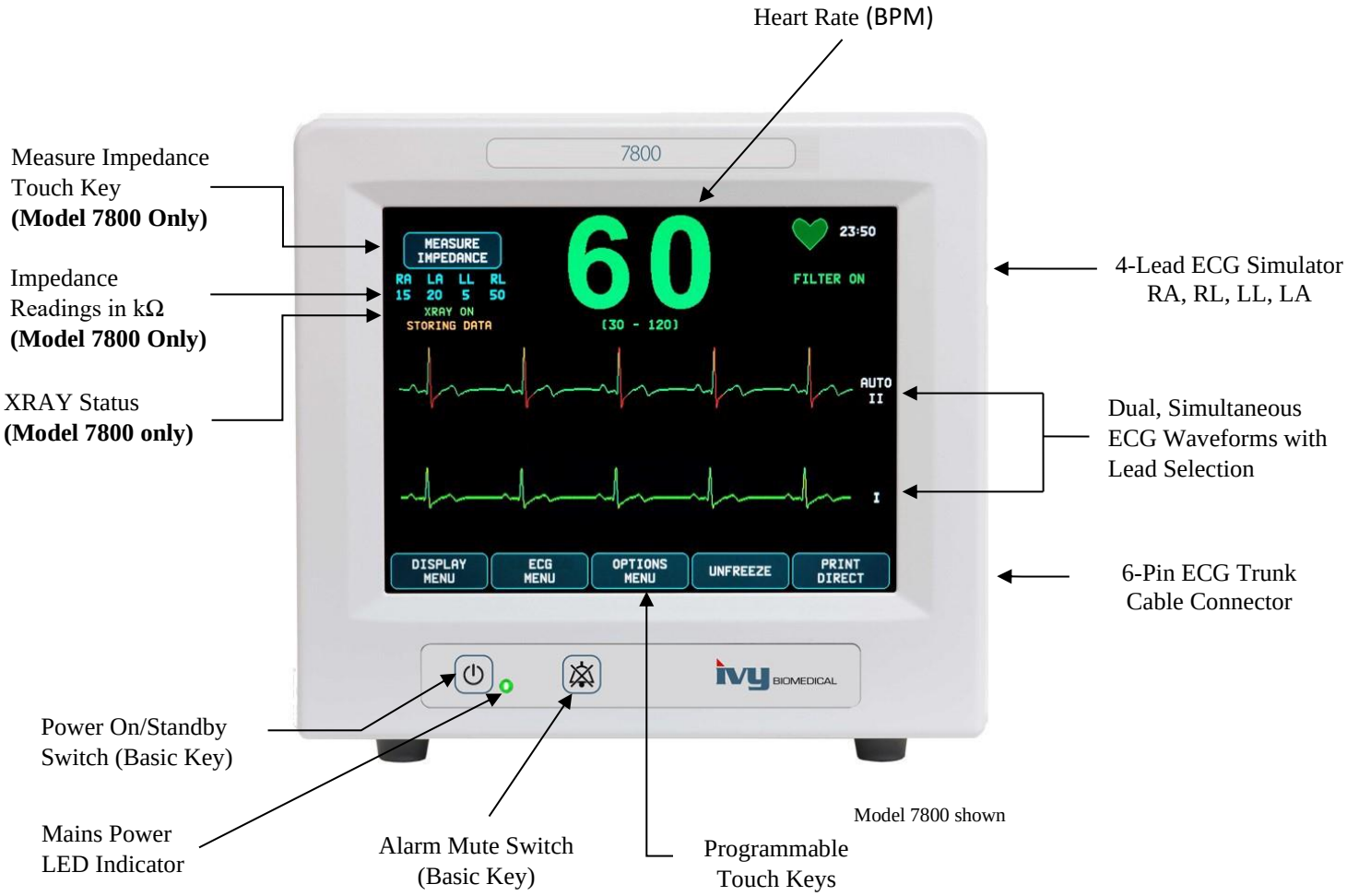
6.5 Controls and Indicators

Basic Keys

When the monitor is plugged into an ac power source, the **Power On/Standby** switch, when pressed, provides power to the monitor's electronic circuits. Press this key again to disconnect power from the monitor's electronic circuits.

WARNING: To disconnect the monitor from mains power, unplug the ac power cord.

The **Alarm Mute** switch disables the audible alarms. Press this key again to return the alarms to normal function.



Model 7800 shown

6.6 Display

HEART RATE: Displayed in large numerals in beats per minute (BPM) on the upper part of the screen.

ECG: Dual simultaneous ECG waveforms are displayed across the screen moving from left to right. The trigger ECG trace is displayed on the top and the second ECG trace is displayed on the bottom.

SETUP: Selections are made through the touch screen menus. Lead selects are displayed to the right of their respective traces. Filter ON/OFF is displayed on the upper right-hand corner of the display. Alarm limits are displayed directly under the heart rate.

Impedance Measurement (Model 7800 Only): Displays the measured value of the impedance between the patient's skin and each individual ECG electrode (RA, LA, LL, RL). Impedance measurements are located at the upper left-hand corner of the display.

XRAY Status (Model 7800 Only): Displays the status of the CT Scanner X-ray. The XRAY status message is located in the upper left-hand corner of the display. Displayed messages are either: XRAY OFF, XRAY ON, or XRAY DISCONNECT.

6.7 Alarm Messages

ALARM MUTE:	A REMINDER SIGNAL indicating that the audible alarms have been turned off. Note: ALARM MUTE is equivalent to AUDIO OFF.

The following alarm indications are displayed in reverse video. Alarm indications appear on the center of the screen and flash once per second.

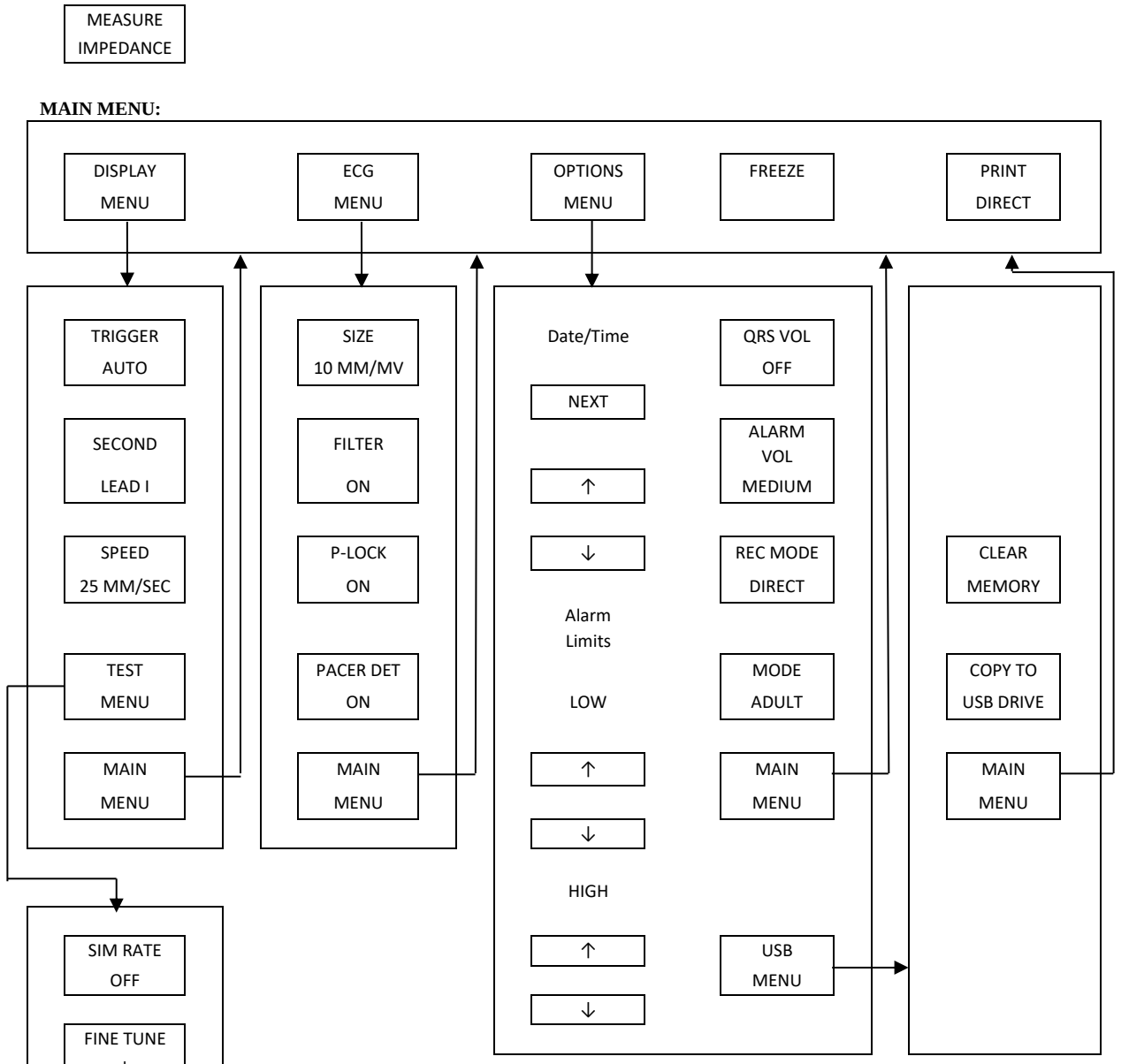
LEAD OFF:	A TECHNICAL ALARM indicating that a lead has become detached. The LEAD OFF alarm message will appear within 1 second of detection.
CHECK LEAD:	A TECHNICAL ALARM indicating that an imbalance between leads has been detected. The CHECK LEAD alarm message will appear within 1 second of detection.
HR HIGH:	A PATIENT ALARM indicating that the high heart rate limit has been exceeded for three seconds.
HR LOW:	A PATIENT ALARM indicating that the low heart rate limit has been exceeded for three seconds.
ASYSTOLE:	A PATIENT ALARM indicating that the interval between heartbeats has exceeded six seconds.

 **WARNING:** The monitor powers on with audible alarms paused for 30 seconds. Other configuration options are available upon request.

6.8 Programmable Touch Keys

Pressing a programmable touch key will display other menu levels or activate an appropriate function. Menu functions are described in the Menu Structure.

6.9 Menu Structure



KEY SELECTIONS

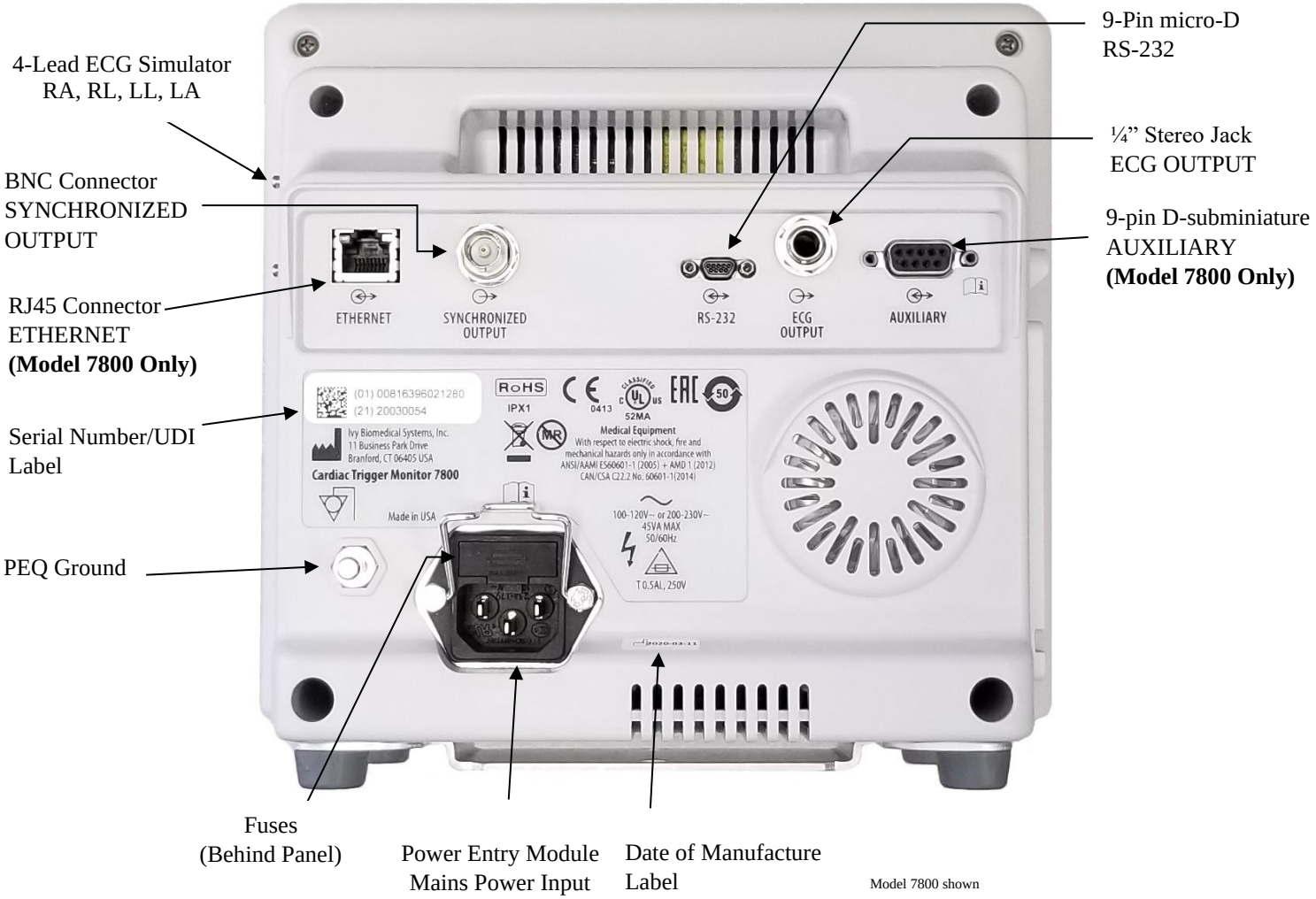
DISPLAY MENU
Trigger: Lead I – II – III – AUTO
Second: Lead I – II – III
Speed: 25mm/s and 50mm/s

ECG MENU
Size: 5, 10, 20, 40mm/mV
Filter: On, Off
P-Lock: On, Off
Pacer Detect: On, Off

OPTIONS MENU
QRS Volume: Off, Low, High
Alarm Volume: Low, Medium, High
Recorder Mode: Direct, Timed, Delay
Mode: Adult, Ped/Neo

Model 7800 Only Selections:
Measure Impedance
USB Menu

6.10 Rear Panel



Model 7800 shown

6.11 Fuse Ratings

The fuses are located behind the cover of the power entry module. To replace the fuses, unplug the ac power cord. Remove the power entry module cover and replace the fuse(s) only with same rating and type: T 0.5AL, 250V.

6.12 Rear Panel Description

The following are located on the rear panel.

MAINS POWER INPUT: A receptacle for a standard ac power cord.

⚠ **CAUTION:** When the monitor is connected to another piece of equipment, always make sure that each piece of connected equipment has its own separate ground connection.

Do not attempt to connect cables to these connectors without contacting your Biomedical Engineering Department. This is to ensure the connection complies with leakage current requirements of one of the following applicable standards: ANSI/AAMI ES60601-1:2005, CAN/CSA-C22.2 No.60601-1:08, and CE-MDD 93/42/EEC. The maximum non-destructive voltage that may be applied to these connectors is 5V.

SYNCHRONIZED OUTPUT: A BNC type connector with a pulse output synchronized with the peak of the R-wave. The synch pulse amplitude is factory configurable: 0 to +5V, +5V to 0V, -10V to +10V, or +10V to -10V. Available synch pulse widths: 1ms, 50ms, 100ms and 150ms.

PEQ GROUND: Potential Equalization - A ground connection that can be used to ensure that no potential differences can develop between this equipment and other electrical equipment.

FUSE: Replace only with the same type and rating of fuse as indicated on the fuse rating label: T 0.5AL, 250V.

ECG OUTPUT: This is a ¼ inch stereo jack with an ECG analog waveform output on the tip, synchronized pulse output on the ring, and common on the sleeve. Limit to 100Hz bandwidth.

RS-232: An electrically isolated RS-232 micro-D connector for device communication. The RS-232 connector provides 6V and -6Vwith a maximum current of 20mA.

AUXILIARY (Model 7800 only): A 9-pin D-subminiature connector that provides a customized interface for specific installations. The auxiliary output provides +5V and -12V with a maximum current of 12mA.

ETHERNET (Model 7800 Only): This is a two-channel Ethernet output that provides an Ethernet protocol (10Base-T, IEEE 802.3) from a single RJ45 connector. The first channel connects the Model 7800 and the CT scanner console to share data and control options. A second Ethernet channel from the same connector provides ECG data to the CT gantry display.

SERIAL NUMBER/UDI LABEL: The Serial Number/UDI label provides a unique identifier and serial number for the product in both human and machine-readable (barcode) form.

DATE OF MANUFACTURE LABEL: The date of manufacture label indicates the date that the monitor was manufactured. The date of manufacture is encoded using the YYYY-MM-DD format.

⚠ **WARNING:** The use of ACCESSORY equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice of accessories shall include:

- Use of the accessory in the PATIENT VICINITY
- Evidence that the safety certification of the ACCESSORY has been performed in accordance with the appropriate IEC 60601-1 and/or IEC 60601-1-1 harmonized national standard

7.0 MONITOR SETUP

7.1 Monitor Installation

⚠ **CAUTION: Underwriters Laboratory (UL) has not tested/approved the Model 7600/7800 with Roll Stand (Ivy REF: 590441) as a system.**

1. Assemble the Roll Stand (Ivy REF: 590441) by following the GCX Light Duty Roll Stand Assembly Instructions (DU-RS-0025-02).
2. Align the monitor and its adapter plate with the roll stand mounting adapter (Fig.1).

Fig. 1

Fig. 2

3. Pull down the safety pin and slide the monitor onto the roll stand mounting adapter (Fig. 2). Release the safety pin and make sure the safety pin is engaged in the monitor's adapter plate. (The adapter plate has a hole to allow the safety pin to secure the monitor.)
4. Tighten the two nylon screws in the roll stand mounting adapter by turning them clockwise.

7.2 To Set Up the Instrument for Operation

1. Plug in the supplied detachable hospital grade power cord into the monitor. Plug the other end into an ac power source (100-120V~ or 200-230V~).

⚠ **CAUTION**: Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "Hospital Grade".

2. Press the **Power On/Standby** switch at the left side of the front panel to turn power on.
3. Connect the ECG trunk cable to the ECG connector on the side panel.

⚠ **WARNING:** Carefully route monitor cables (ECG trunk cables, power cords, etc.) to reduce the possibility of a tripping hazard.

7.3 Setting the Date and Time

Use the following procedure to set the date and time. The time is indicated in the upper right-hand corner of the display.

1. Press the [OPTIONS MENU] touch key in the main menu.
2. Press the ⇧ and ⇩ touch keys under DATE/TIME to select the MONTH.
3. Press [NEXT -- >] to move to the DAY setting. Use the ⇧ and ⇩ touch keys to increase or decrease the day setting.
4. Press [NEXT -- >] to move to the YEAR setting. Use the ⇧ and ⇩ touch keys to increase or decrease the year setting.
5. Press [NEXT - - >] to move to the HOUR setting. Use the ⇧ and ⇩ touch keys to increase or decrease the hour setting.
6. Press [NEXT -- >] to move to the MINUTE setting. Use the ⇧ and ⇩ keys to increase or decrease the minute setting.

7.4 Setting the QRS and Alarm Volume

Use the following procedure to set the QRS and Alarm volume.

1. Press the [OPTIONS MENU] touch key in the main menu.
2. Press the [QRS VOL] touch key to select QRS Volume. Selections are OFF, LOW, or HIGH.
3. Press the [ALARM VOL] touch key to select Alarm Volume. Selections are: LOW, MEDIUM, or HIGH.

When all date, clock and audio settings are correct, press [**MAIN MENU**] to return to the main monitoring screen.

7.5 Setting the Alarm Limits

1. Press the [OPTIONS MENU] touch key in the main menu.
2. Press the HR LOW ⇧ and ⇩ touch keys under ALARM LIMITS to select HR LOW limits. Selections are from 10 BPM to 245 BPM in 5 BPM increments.
3. Press the HR HIGH ⇧ and ⇩ touch keys under ALARM LIMITS to select HR HIGH limits. Selections are from 15 BPM to 250 BPM in 5 BPM increments.

7.6 Setting the Trace Speed

1. Press the [DISPLAY MENU] touch key in the main menu.
2. Press the [SPEED] touch key to select the trace speed. Selections are 25 and 50 mm/s.

⚠ **CAUTION:** The [SPEED] touch key also changes the speed of the recorder.

7.7 Default Settings

To reset the monitor to the default settings, turn the monitor off by pressing the **Power On/Standby** switch; then turn the monitor back on by again pressing the **Power On/Standby** switch.

Setting	Initial Default
Language Setting	English (Configuration Dependent)
ECG Size	10mm/mV
Trigger Lead	II or Auto (Configuration Dependent)
Second Lead	I
Filter	ON
Impedance Threshold	50kΩ (Configuration Dependent)
Heart Rate Low Limit	30
Heart Rate High Limit	120
Trace Speed	25mm/sec
Recorder	Direct
QRS Volume	Off
Alarm Volume	Medium
Internal Test	Off
Simulator Rate	Off
Alarms	30 Seconds or Off (Configuration Dependent)
Trigger Polarity	Positive or Negative (Configuration Dependent)
P-Lock	On or Off (Configuration Dependent)
Pacer Detection	On or Off (Configuration Dependent)

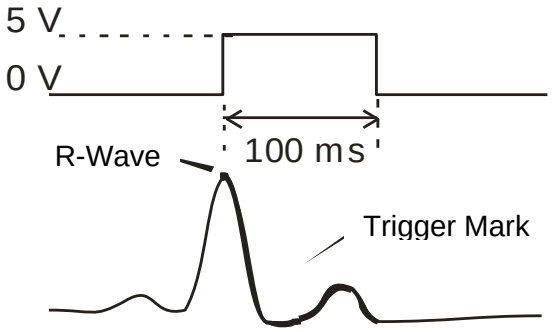
Default/Stored settings may be customized (password required) by a Responsible Organization. For information on how to activate this feature, contact Ivy Biomedical Systems at +1 203.481.4183.

8.0 SYNCHRONIZED OUTPUT (Trigger)

8.1 The Synch Pulse

The ECG Synchronized Output produces a trigger pulse starting at the peak of each R-wave, which is available on the **SYNCHRONIZED OUTPUT** BNC connector and on the **ECG OUTPUT** (ring on the ¼" stereo jack) connector on the rear panel of the monitor. Connect the Synchronized Output from the monitor to the device being synchronized.

The following shows the timing of the trigger pulse compared to the ECG waveform.



8.2 Trigger Mark

The Synchronized trigger output is always active. A portion of the ECG waveform corresponding to the timing of the synch pulse is highlighted in red.

If the trigger function appears to be erratic verify the following:

- Select lead with the highest amplitude, typically Lead II or select AUTO.
- The proper placement of the ECG electrodes. The ECG electrodes may need to be repositioned.
- The ECG electrodes still have moist conductive gel.

8.3 Polarity Lock (P-LOCK)

With some patients' ECGs the shape of a tall T wave or deep S wave sometimes matches the criteria used to detect the R wave. When this situation occurs the monitor correctly detects the R wave and then falsely detects the T wave or S wave causing double triggering. The polarity control algorithm (P-Lock) reduces the number of false triggers when tall T waves or deep S waves occur. The P-Lock algorithm allows the Model 7600/7800 to detect and trigger only at the peak of the R wave, rejecting most of the tall T waves and deep S waves that might have caused false triggers.

To turn P-Lock ON / OFF follow the next steps:

1. Press the [ECG MENU] touch key in the main menu.
2. Press the [P-LOCK] touch key to select P-LOCK. Selections are ON and OFF.

9.0 ECG MONITORING

Dual simultaneous ECG waveforms move across the display from left to right. The top waveform (Trigger) is used for cardiac triggering. The bottom trace (Second) is used for display only. Lead selections are displayed to the right of their respective waveforms. The heart rate and heart rate alarm limits are displayed on the upper part of the screen. Alarm indications appear on the center of the screen and flash once per second. Also, a heart symbol flashes each time a heartbeat is detected.

9.1 Safety Considerations

WARNING: This monitor is supplied with protected lead wires. Do not use cables and leads with unprotected lead wires having exposed conductors at the cable end. Unprotected lead wires and cables may pose an unreasonable risk of adverse health consequences or death.

CAUTION: ECG Electrodes are intended for single-use only. Do not attempt to reuse.

CAUTION: ECG Patient connections are electrically isolated **Type CF**  For ECG connections use insulated probes. Don't let patient connections contact other conductive parts, including earth. See instructions for patient connections in this manual.

CAUTION: Leakage current is limited internally by this monitor to less than 10 μA. However, always consider cumulative leakage current that can be caused by other equipment used on the patient at the same time as this monitor.

CAUTION: The Model 7600/7800 is compatible with HF electrosurgical devices. When used with HF electrosurgical devices, applied parts of the equipment are provided with protection against burning of the patient. To avoid the potential of electrosurgery burns at ECG monitoring sites, ensure proper connection of the electrosurgery return circuit as described by manufacturer's instructions. If improperly connected, some electrosurgery units might allow energy to return through the electrodes.

CAUTION: Line isolation monitor transients may resemble actual cardiac waveforms and thus inhibit heart rate alarms. To minimize this problem, ensure proper electrode placement and cable arrangement.

9.2 Patient Connections

To ensure compliance with safety and performance specifications, use the ECG trunk cables supplied by Ivy Biomedical Systems (see Accessories). Other cables might not produce reliable results.

Use only high-quality silver/silver-chloride ECG Electrodes or equivalent. For best ECG performance, use ECG Electrodes supplied by Ivy Biomedical Systems (see Accessories).

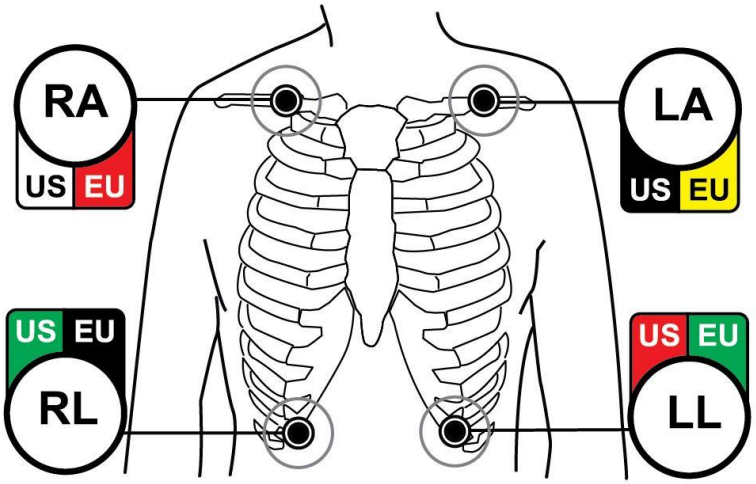
Use the following procedure for ECG monitoring:

1. Prepare each electrode site and apply the electrodes.
2. Connect a 4-lead ECG trunk cable to the monitor's **ECG** input.
3. Connect the leads to the ECG trunk cable.
4. Attach the leads to the electrodes as shown below.

Color code comparison table for patient leads:

Lead Type	US (AHA) Color Code	EU (IEC) Color Code
RA – Right Arm	White	Red
RL – Right Leg	Green	Black
LL – Left Leg	Red	Green
LA – Left Arm	Black	Yellow

Recommended Lead Placement:



5. Use the procedures described in the following sections for alarm limit settings, lead selection, amplitude adjustment and enabling or disabling the filter.

9.3 ECG Electrodes

ECG electrodes vary in both construction and quality among the different manufacturers. However, typically there are two main groups: long term monitoring electrodes and short-term monitoring electrodes. Ivy recommends the use of short-term monitoring electrodes which stabilize faster due to their higher chloride content. Please see the Accessories section of this manual for Ivy-recommended ECG electrodes.

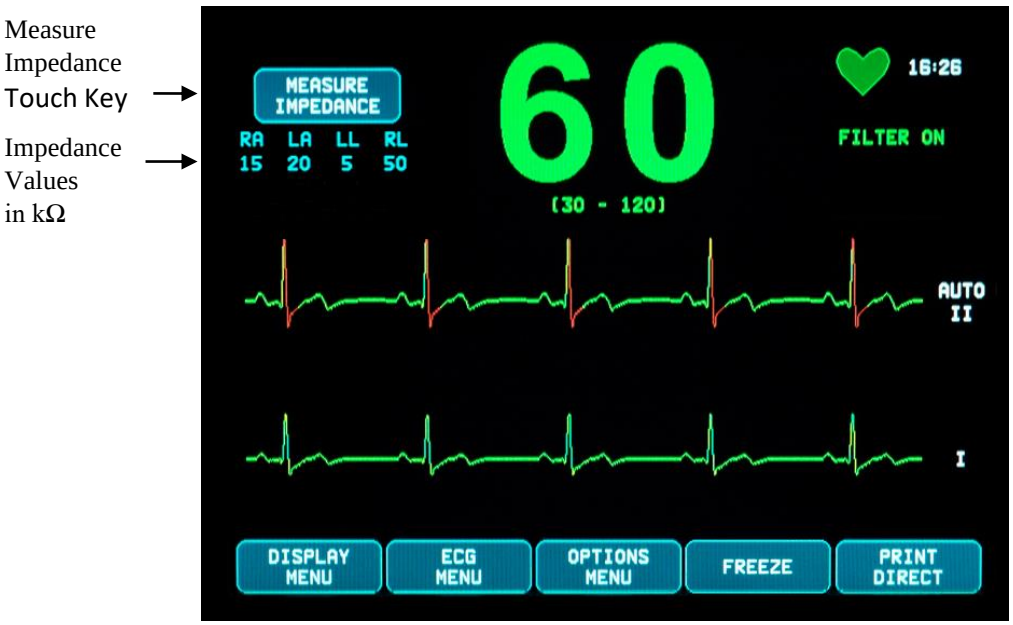
Prior to applying the ECG electrodes to the patient's skin, Ivy recommends preparing the electrode location by rubbing the skin with a dry gauze pad or a skin prep gel such as Nuprep gel (Ivy REF: 590291). Alternatively, it may be necessary to remove cream or powder from the patient's skin using warm soapy water.

9.4 Impedance Measurement (Model 7800 Only)

The Model 7800 has unique hardware and software which allows the measurement and identification of the impedance value between the patient's skin and each individual ECG electrode (RA, LA, LL and RL).

The purpose of the impedance measurement is to verify proper skin preparation and proper ECG electrode application and to assure a good ECG signal and therefore a reliable trigger pulse. Ivy recommends that the impedance value of each ECG connection be less than 50,000Ω (50kΩ). The use of the wrong type of ECG electrodes, improper application or poor skin preparation can increase the electrode impedance value, causing an imbalance between the leads which can allow noise to be induced into the ECG signal which can cause inaccurate trigger pulses.

- The impedance value of each ECG electrode can be measured by pressing the **Measure Impedance** touch key on the screen. Note: ECG is not monitored during impedance measurements. ECG recovers within 8 seconds after pressing the **Measure Impedance** touch key.
- The impedance value is displayed in the top left-hand portion of the display.
- Impedance values of less than 50kΩ are displayed in blue.
- Should any electrode impedance value be over 50kΩ, the appropriate lead(s) will flash the value in red indicating that the value is outside the recommended range.
- If the measurements are in red, remove the ECG electrodes and clean the skin with a gauze pad or a skin prep gel such as Nuprep gel (Ivy REF: 590291) before re-applying a fresh ECG electrode.
- For proper skin preparation follow the instructions indicated on the ECG electrode packaging.
- Re-measure skin impedance after 1-2 minutes of repositioning electrodes on the patient's skin.



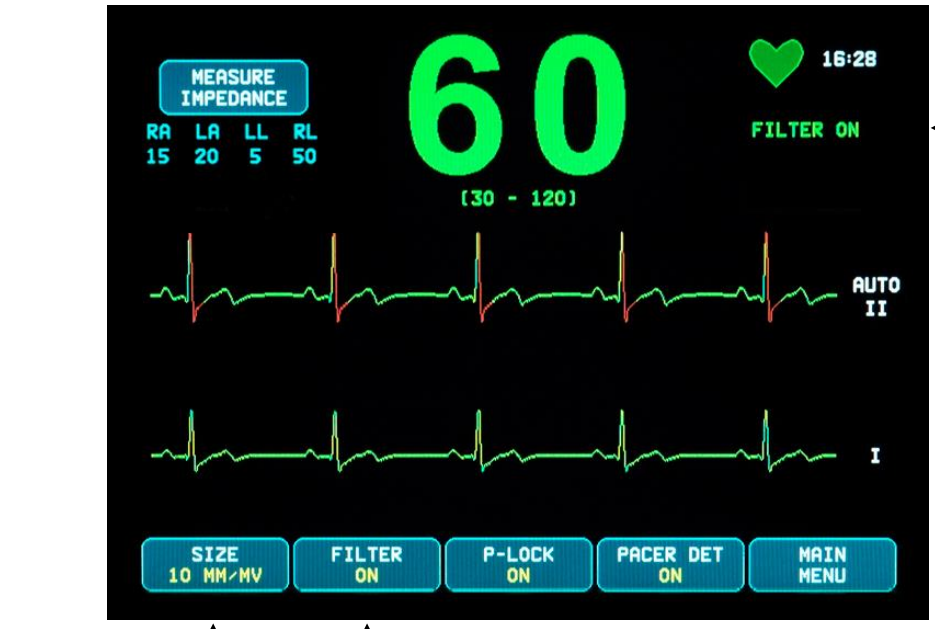
9.5 ECG Waveform Amplitude (Size)

Use the following procedure to adjust the amplitude (size) of the displayed ECG waveforms.

1. Press the [ECG MENU] touch key from the main menu. The following menu appears.

2. Press the first programmable touch key [SIZE] to adjust the ECG waveform amplitude. Selections are: 5, 10, 20, and 40mm/mV.

3. Press [MAIN MENU] to return to the main menu.



ECG Notch Filter Status

ECG SIZE Touch Key

ECG NOTCH FILTER Touch Key

9.6 ECG Notch Filter

Use the following procedure to activate the ECG Notch Filter:

1. Press the [ECG MENU] touch key from the main menu. The above menu appears.

2. Press the second programmable touch key [FILTER] to change the ECG NOTCH FILTER selection. Select between FILTER ON and FILTER OFF. The FILTER status indicator is shown in the upper right-hand portion of the display. The FILTER sets the frequency response of the displayed waveform as follows:

    a. Filtered: 1.5 to 40 Hz or 3.0 to 25 Hz (Configuration Dependent)
    b. Unfiltered: 0.67 to 100 Hz

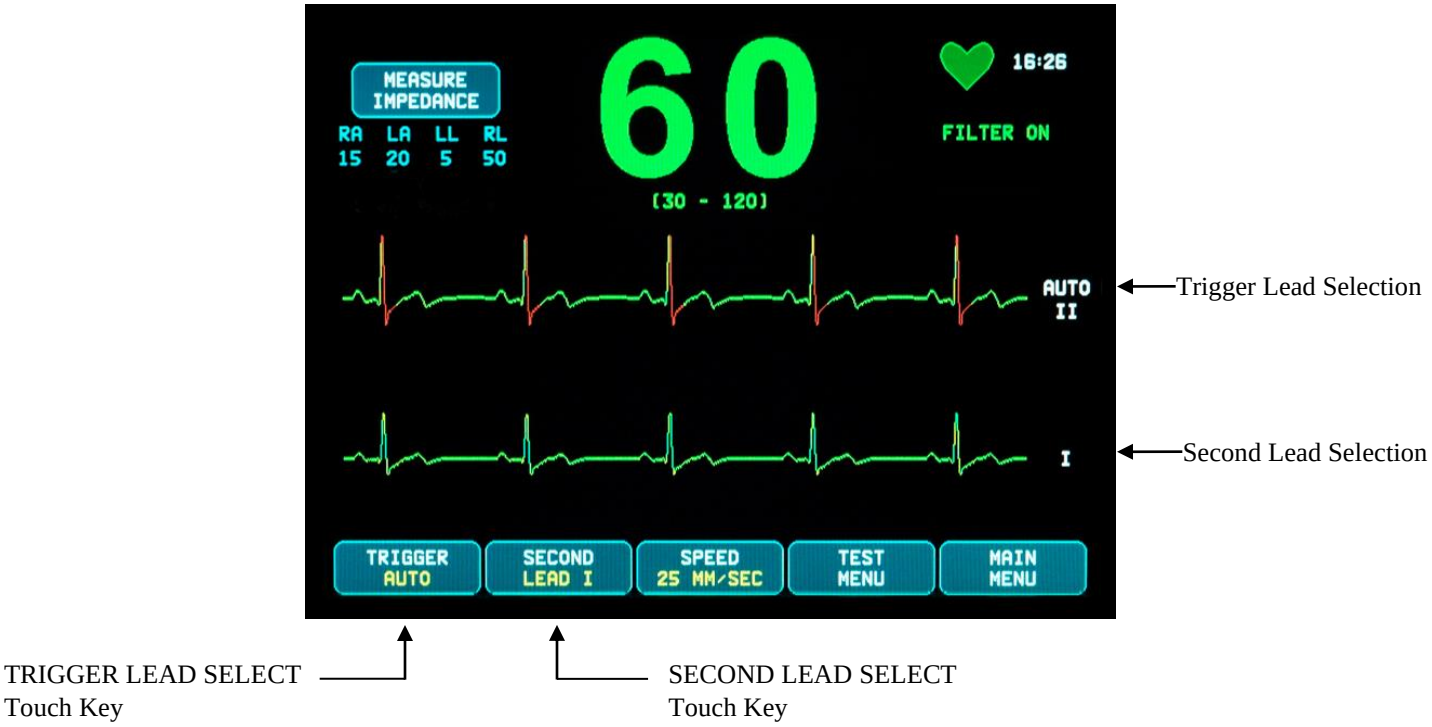
3. Press [MAIN MENU] to return to the main menu.

9.7 Lead Selection

The Model 7600/7800 includes an AUTO lead select feature (Trigger lead only). When selected, this feature will determine which lead (I, II or III) provides the best quality ECG signal and thus a more reliable cardiac trigger.

Use the following procedure to change the lead selection of the Trigger ECG vector (top ECG waveform) and the Second ECG vector (bottom ECG waveform).

1. Press the [DISPLAY MENU] touch key from the main menu. The following menu appears.



2. Press the first programmable touch key [TRIGGER] to select the desired ECG lead for the top ECG waveform. Selections are: Lead I, Lead II, Lead III, and AUTO. The selected lead will appear to the right of the top ECG waveform.

3. Press the second programmable touch key [SECOND] to select the desired ECG lead. Selections are: Lead I, Lead II, and Lead III. The selected lead will appear to the right of the bottom ECG waveform.

4. Press [MAIN MENU] to return to the main menu.

9.8 Low Signal Message

If the amplitude of the ECG signal is between 300µV and 500µV (3-5mm of amplitude at size 10mm/mV) for a period of eight seconds a LOW SIGNAL message will be displayed in yellow.

If the trigger function appears to be erratic while the message is displayed, verify the following:

- Select the TRIGGER lead with the highest amplitude, typically Lead II or AUTO.
- The proper placement of the ECG electrodes. The ECG electrodes may need to be repositioned.
- The ECG electrodes still have moist conductive gel.

9.9 Pacemaker

Use the following procedure to activate or deactivate the pacemaker detection function:

1. Press the [ECG MENU] touch key from the main menu.

2. Press the [PACER DET] touch key to toggle between pacer detection ON and OFF.

    - When a pacemaker has been detected, a **P** will start flashing in the heart symbol.

    - The message PACER DETECT OFF will appear in red if the pacer detection circuit is not active.

 **WARNING – PACEMAKER PATIENTS:** Rate meters might continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely on rate meter ALARM SIGNALS. Keep pacemaker PATIENTS under close surveillance. See the SPECIFICATIONS section in this manual for disclosure of the pacemaker pulse rejection capabilities of this instrument. AV sequential pacemaker pulse rejection has not been evaluated; do not rely on pacemaker rejection with patients with dual chamber pacemakers.

9.10 Alarm Limits

1. Press the [OPTIONS MENU] touch key from the main menu. The menu shown below appears.

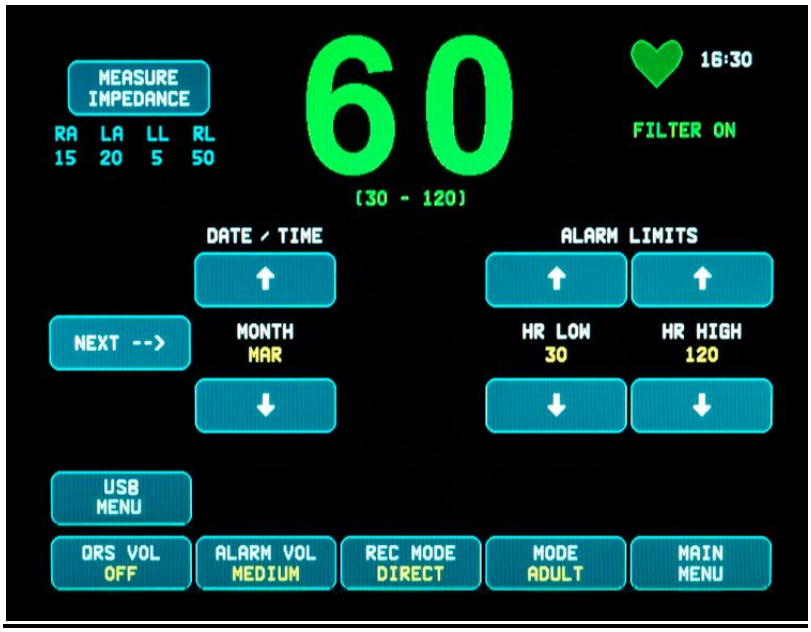
2. Use the programmable up/down arrow touch keys to set the high and low heart rate limits.

⇧ HR LOW	Increases HR LOW limit
⇩	Decreases HR LOW limit
⇧ HR HIGH	Increases HR HIGH limit
⇩	Decreases HR HIGH limit

Each time you press a key, the corresponding limit changes by 5 BPM. The current HR limits are shown in the upper portion of the display directly under the heart rate reading.

3. Press [MAIN MENU] to return to the main menu.

Alarm Type	Default Limit
Heart Rate Low	30
Heart Rate High	120



10.0 SYSTEM INTERLOCK OPERATION

10.1 X-RAY Status Messages (Model 7800 Only)

When the Model 7800 is interfaced via the rear panel AUXILIARY connector to a CT scanner, the monitor can store ECG data and transfer this data to a USB Memory Stick.

There are three X-RAY status messages:

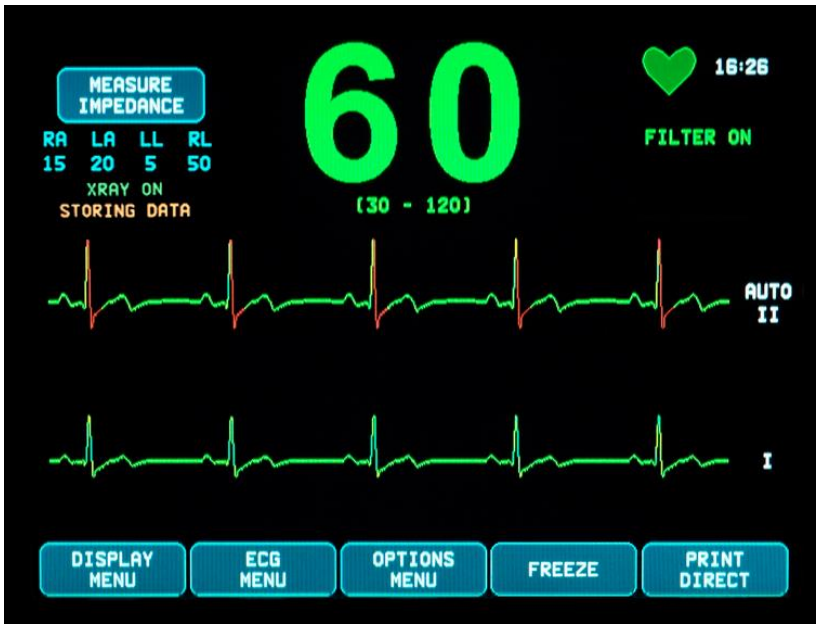
1. **XRAY ON**: The CT Scanner X-Ray is active or "ON". The Model 7800 will store ECG data during this time.

2. **XRAY OFF**: The CT Scanner X-Ray is "OFF".

3. **XRAY DISCONNECT**: The Model 7800 and the CT scanner are NOT interfaced correctly.

4. **STORING DATA**: ECG data is being stored.

X-RAY Status →
STORING DATA →



11.0 ECG DATA STORAGE AND TRANSFER

11.1 ECG Data Transfer Using the USB Port (Model 7800 Only)

The Model 7800 has a USB port that allows the user to connect a USB memory stick and retrieve up to 200 ECG events and measured impedance data stored in the monitor.

ECG data is stored in the monitor's memory when the X-RAY signal from the CT scanner becomes active. The ECG data storage stops 10 seconds after the X-RAY signal becomes inactive.

ECG Data Stored (1 event):

10 seconds prior to X-ray, during X-Ray, and 10 seconds after X-Ray

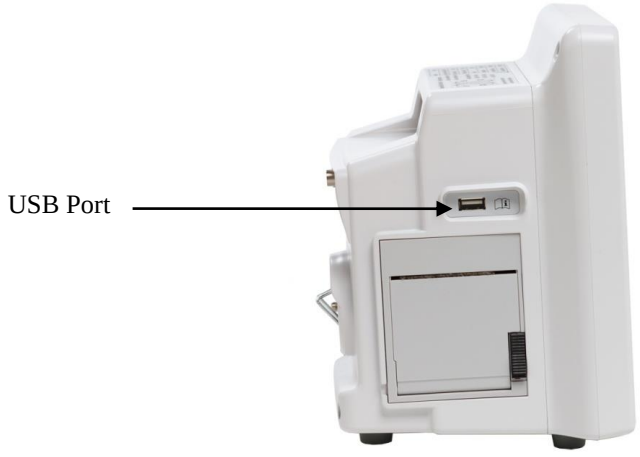
The ECG data can be downloaded to a memory stick device (1GB minimum) by following these steps:

1. Plug a USB memory stick into the USB port on the side of the monitor.
2. From the [OPTIONS MENU], press the [USB MENU] touch key.
3. Press [COPY TO USB DRIVE] touch key.
4. When all the data has been downloaded on to the memory stick, press [CLEAR MEMORY] to delete the ECG data from the monitor memory or press MAIN MENU to return to the main menu.

11.2 USB Port

⚠ **CAUTION:** The Model 7800 USB port is used only for the transfer of internal data to an external media using a standard USB type memory drive (memory stick). The connection of any other type of USB device to this port could result in damage to the monitor.

⚠ **WARNING:** The USB memory device used with this port **MUST NOT BE POWERED FROM AN EXTERNAL SOURCE.**

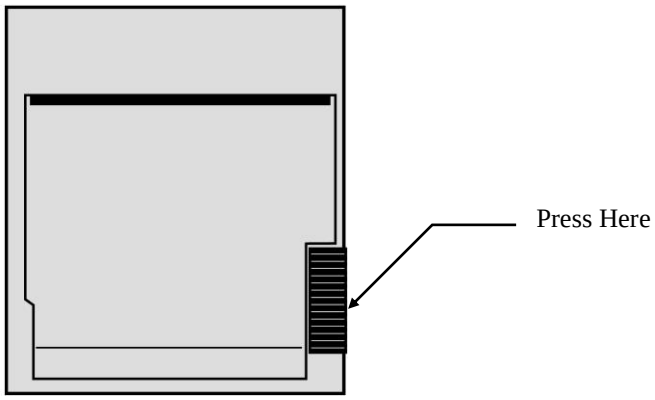


12.0 RECORDER OPERATION

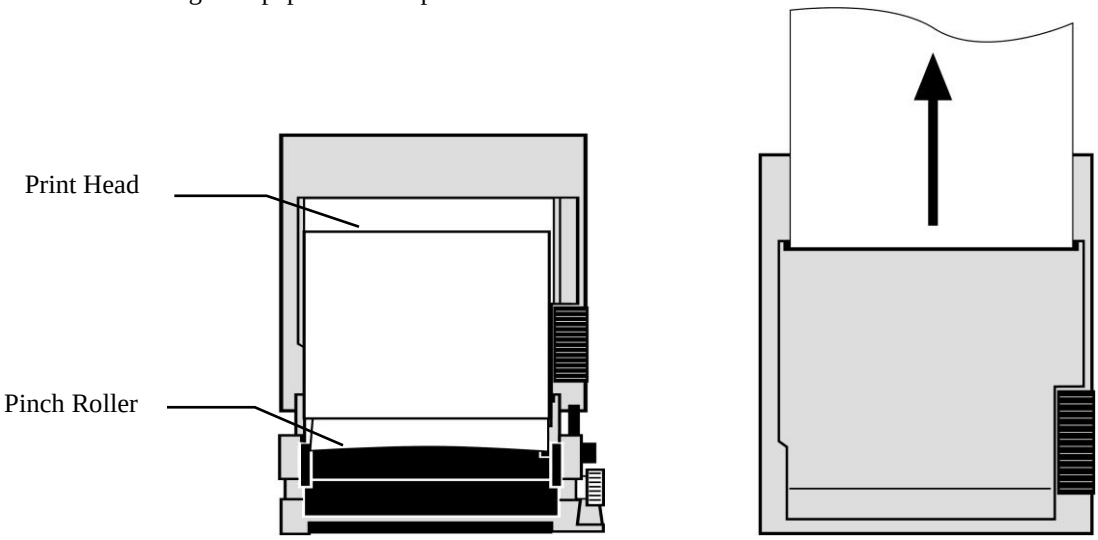
12.1 Changing Paper

Replace the roll of thermal paper as follows. (Recorder paper is Ivy REF: 590035)

1. Press the paper eject button to open the door at the front of the recorder. If the door does not open completely, pull it toward you until it is completely open.



2. Reach in and remove the spent paper core by pulling it gently toward you.
3. Place a new paper roll between the two round tabs of the paper holder.
4. Pull some paper from the roll. Make sure the sensitive (shiny) side of the paper faces the print head. The shiny side of the paper normally faces inside the roll.
5. Align the paper with the pinch roller on the door.



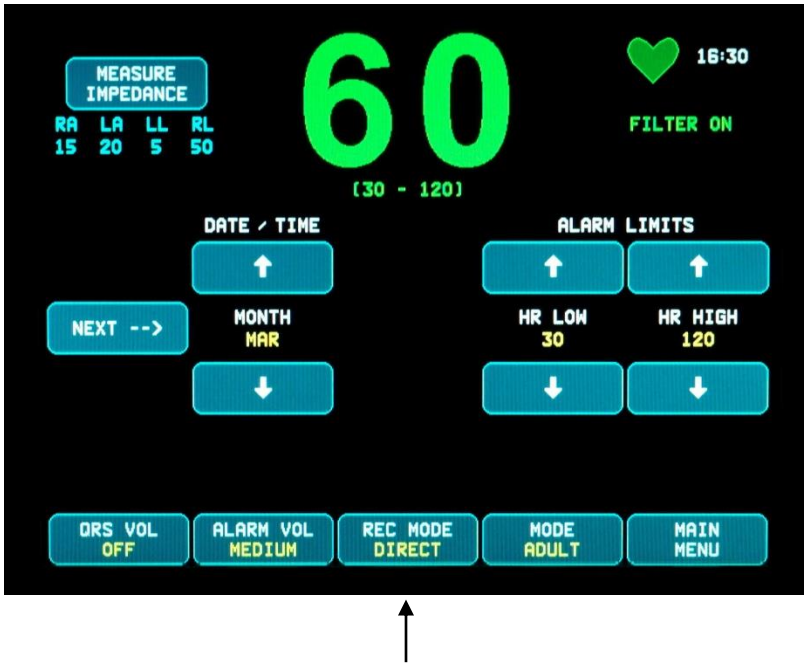
6. Hold the paper against the pinch roller and close the door.

12.2 Recorder Modes

Use the following procedure to select the recorder mode to be used. Selections are DIRECT, TIMED, DELAY, and XRAY.

1. Press the [OPTIONS MENU] touch key from the main menu.

2. Press the third programmable touch key [REC MODE] to select the recorder mode.



Recorder Mode Selection

All Recorder Modes - To print, press the [PRINT] key in the main menu. Press [PRINT] again to stop printing.

Direct - To print in DIRECT recorder mode, press the [PRINT] key in the main menu. Press [PRINT] again to stop printing.

The plot contains parameter settings and the time/date.

The speed of the plot and vertical resolution are the same as the display. The plot is labeled with the speed of the plot in mm/s, the recorder mode and the parameters.

Timed - TIMED mode starts by pressing PRINT and prints for 30 seconds.

Delay - Delay mode automatically prints 30 or 40 seconds of ECG waveform after the occurrence of an alarm condition depending on the speed selected:

15 seconds before and 15 seconds after at 50mm/s
20 seconds before and 20 seconds after at 25mm/s

XRAY (Model 7800 Only) - Xray mode automatically prints 20 seconds of ECG waveform after the occurrence of an X-ray:

10 seconds before and 10 seconds after the occurrence of an X-ray

12.3 Recorder Speed

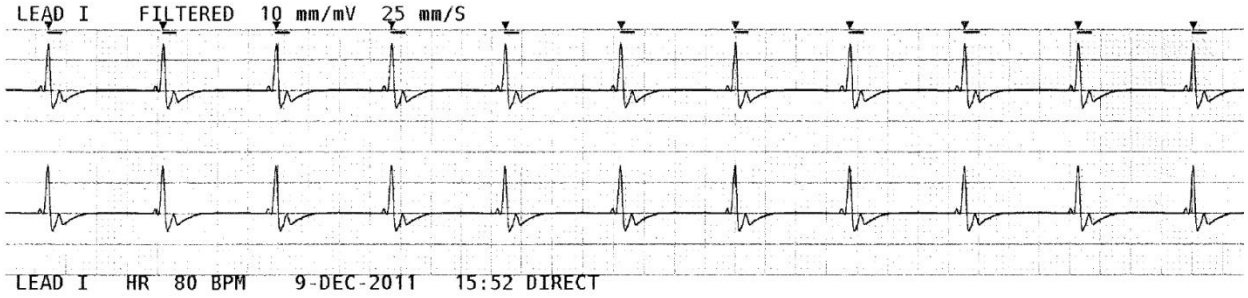
Use the following procedure to change the recorder speed.

Press the [SPEED] touch key in the [DISPLAY MENU] select the recorder speed. Selections are 25, and 50 mm/s.

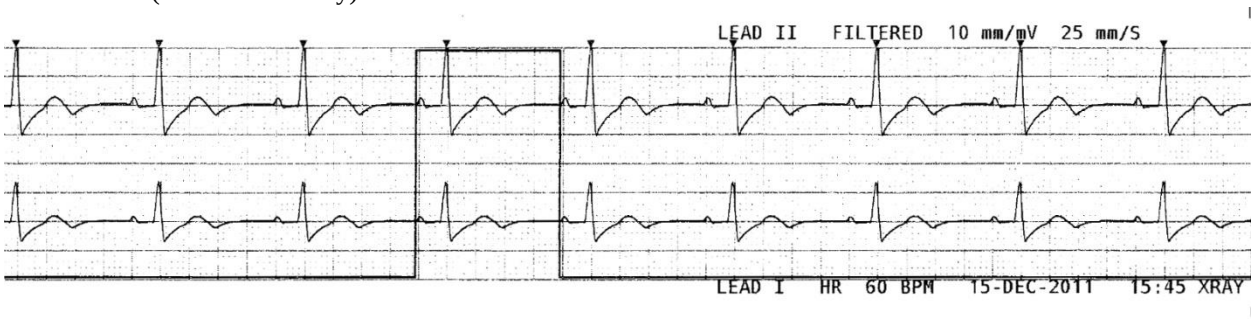
NOTE: The [SPEED] touch key also changes the speed of the ECG trace.

12.4 Sample Printouts

DIRECT Mode:



XRAY Mode (Model 7800 Only):



13.0 ALARM MESSAGES

13.1 Reminder Signals

WARNING: The monitor powers on with audible alarms paused for 30 seconds.
Note: Other options are available upon request.

The following messages are REMINDER SIGNALS that appear in the upper left-hand corner of the monitor's display. Reminder messages are displayed in white letters on a red background.

***PAUSE*:** Indicates time (seconds) before audible alarms are enabled.
ALARM MUTE: Audible alarms have been disabled.
Note: ALARM MUTE is equivalent to AUDIO OFF.

The Alarm Mute key allows the user to toggle between pausing audible alarms for 120 seconds and enabling audible alarms:

1. To pause audible alarms for 120 seconds, momentarily press the key once.
   Note: The ***PAUSE*** alarm message will appear in the upper left-hand corner of the display.

2. To re-enable audible alarms, momentarily press the key once.

The Alarm Mute key also allows the user to disable audible alarms:

1. To disable audible alarms, press and hold the key for three seconds.
   Note: The ***ALARM MUTE*** reminder signal will appear in the upper left-hand corner of the display.

2. To re-enable audible alarms, momentarily press the key once.

WARNING: All alarms are considered HIGH PRIORITY and require immediate attention.

13.2 Patient Alarms

The following messages are PATIENT ALARMS that appear directly below the heart rate on the monitor's display. White letters on a red background flash at a rate of once every second with an audio alarm tone.

HR HIGH: The high heart rate alarm limit has been exceeded for three seconds.

HR LOW: The low heart rate alarm limit has been exceeded for three seconds.

ASYSTOLE: The interval between heartbeats has exceeded six seconds.

13.3 Technical Alarms

The following messages are TECHNICAL ALARMS that appear directly below the heart rate on the monitor's display. White letters on a red back ground flash at a rate of once every second with an audio alarm tone.

LEAD OFF: A lead has become detached. The LEAD OFF alarm message will appear within 1 second of detection.

CHECK LEAD: An imbalance between leads has been detected. The CHECK LEAD alarm message will appear within 1 second of detection.

SYSTEM ERROR: A monitor malfunction has been detected. Contact qualified service personnel.

13.4 Informatory Messages

Low Signal Message
If the amplitude of the ECG signal is between 300µV and 500µV (3mm to 5mm at size 10mm/mv) for a period of eight seconds, a "LOW SIGNAL" message will be displayed in yellow below the ECG waveform (see ECG monitoring section).

Pacer Detect Message
The "PACER DETECT OFF" message will appear in red if the pacer detection circuit is turned OFF through the ECG menu.

Check Electrode Message (Model 7800 Only)
The "CHECK ELECTRODE" message will be displayed in yellow should any electrode impedance value be over 50kΩ. The appropriate lead(s) will flash the value in red indicating that the value is outside the recommended range.

14.0 MONITOR TESTING

⚠ **CAUTION:** Under normal operation, no internal adjustment or calibration is required. Safety tests should be done by qualified personnel only. Safety checks should be performed at regular intervals or in accordance with local or governmental regulations. In the event that service is necessary, contact qualified service personnel.

14.1 Internal Test

Turn on the monitor by pressing the front panel **Power On/Standby** key. Listen for three audio beeps. Press the DISPLAY MENU touch key from the main menu. Next, press the TEST MENU touch key. Press INTERNAL TEST touch key. Selections are OFF and ON. When turned ON, the INTERNAL TEST function generates a 1mV pulse at 70 BPM, causing a waveform and a 70 BPM indication on the display and a signal at the rear panel stereo jack and BNC connector. The INTERNAL TEST verifies the internal functions of the monitor. An INTERNAL TEST should be performed each time, prior to monitoring a patient. If the following indications are not present, contact qualified service personnel.

To test for visual and audio alarms:

If the alarms are paused or muted, press the  key to turn alarms on. Unplug the ECG trunk cable. Check that the LEAD OFF message is displayed and the audio alarm is on. With INTERNAL TEST ON, check for the following: 1) LEAD OFF message disappears, and 2) Monitor starts counting QRS.

14.2 ECG Simulator

The Model 7600/7800 has an integrated ECG simulator that is used to verify the integrity of the ECG trunk cable, lead wires and electronic circuits involved in the processing of the ECG signal.

⚠ **CAUTION:** The ECG trunk cable and lead wires are considered consumable items that periodically need to be replaced. To prevent disruptions with monitoring the patient, it is recommended that a spare set is always available.

⚠ **CAUTION:** The ECG simulator test should be performed each time prior to monitoring a patient. If the below indications are not present, contact qualified service personnel.

Turn on the monitor by pressing the front panel **Power On/Standby** key. Listen for three audio beeps. Plug in the ECG trunk cable. Attach the four lead wires to the simulator terminals that are located on the right-side panel of the monitor. The terminals have four color-coded labels for easy identification. The simulator generates an ECG waveform and heart rate range between 10-250 BPM (user selectable).

14.3 ECG Simulator Operation

To turn the simulator on and set the heart rate, follow the procedure below:

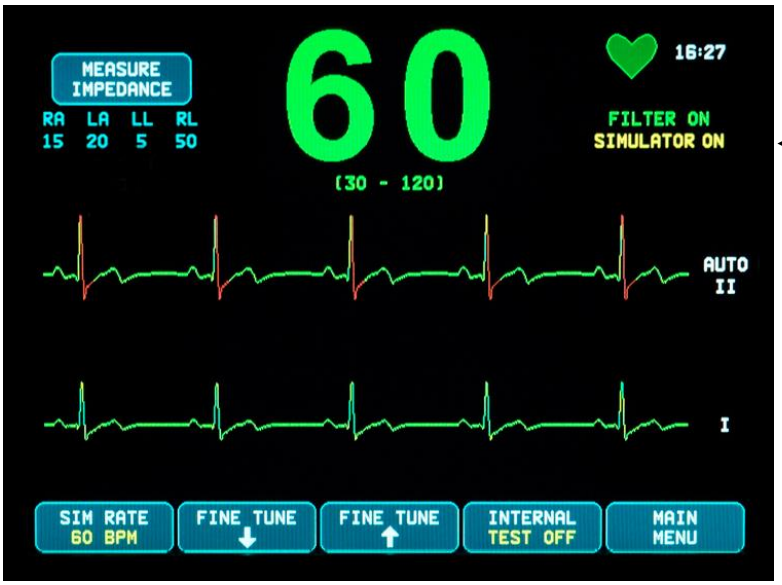
1. Press the DISPLAY MENU touch key from the main menu. Next, press the [TEST MENU] touch key.

2. Press the SIM RATE touch key to turn the simulator on and toggle through the heart rate options.

3. Press the keys ↑FINE TUNE↓ to change the heart rate in increments of one.

4. Check that the displayed heart rate is equivalent to the selected Simulator Rate. Check that two ECG traces are displayed.

NOTE: When the simulator is on, the SIMULATOR ON message is displayed in yellow on the screen.



SIMULATOR ON message

To test for visual and audio alarms:

If the alarms are paused or muted, press the key to turn alarms on.

1. Set the SIM RATE to OFF. Check that the ASYSTOLE alarm message is displayed and the audio alarm is present.
2. Unplug the ECG trunk cable. Check that the LEAD OFF message is displayed and the audio alarm is present.

15.0 TROUBLESHOOTING

Problem	Verify that:
• Unit does not turn on.	✓ Power cord is plugged into the monitor and the ac outlet. ✓ Fuses are not blown. ✓ The ON switch is pressed.
• Trigger pulse is not functional.	✓ ECG size is optimal (select Lead II or AUTO)
• Erratic ECG waveform. Heart Rate is not counting.	✓ ECG waveform has enough amplitude (Select Lead II or AUTO). ✓ Electrodes placement (see ECG section for proper placement diagram). ✓ ECG electrodes have enough conductive gel. ✓ Measured Impedance < 50kΩ. ✓ Perform ECG simulator test. ✓ Replace ECG trunk cable and/or leads as needed.
• No ECG.	✓ ECG trunk cable is plugged into ECG input on monitor. ✓ Leads are connected to ECG electrodes. ✓ Perform ECG simulator test. ✓ Replace ECG trunk cable and/or leads as needed.

16.0 MAINTENANCE AND CLEANING

16.1 The Monitor

When necessary, clean the exterior surfaces of the monitor with a cloth or swab dampened with water. Do not allow liquids to enter the interior of the instrument.

⚠ **CAUTION:**

- Do not autoclave, pressure sterilize, or gas sterilize the monitor.
- Do not soak or immerse in any liquid.
- Use cleaning solution sparingly. Excessive solution can flow into the monitor and cause damage to internal components.
- Do not touch, press or rub the display and covers with abrasive cleaning compounds, instruments, brushes, rough surface materials, or bring them into contact with anything that could scratch the display or the covers.
- Do not use petroleum based or acetone solutions or other harsh solvents to clean the monitor.

16.2 ECG Trunk Cables and Lead Wires

⚠ **CAUTION:** Do not autoclave ECG trunk cables or lead wires.

Wipe the cables using a cloth dampened with water. Never submerge the cables in any liquid or allow liquids to enter the electrical connections.

16.3 Preventive Maintenance

The Model 7600/7800 cardiac trigger monitor does not require any preventive maintenance. There are no serviceable items contained in the Model 7600/7800.

Check before connecting the monitor to a new patient that:

- ECG trunk cables and lead wires are clean and intact.
- The LEAD OFF message is displayed when the ECG trunk cable and/or the lead wires are not connected. Connecting the ECG trunk cable and the lead wires to the side simulator will make the LEAD OFF message disappear.

17.0 ACCESSORIES

17.1 ECG Trunk Cables

REF	DESCRIPTION
590432	ECG TRUNK CABLE, 4-LEAD, SHIELDED, AHA, 10 FT
590446	ECG TRUNK CABLE, 4-LEAD, SHIELDED, IEC, 10 FT
590479	ECG TRUNK CABLE, 4-LEAD, SHIELDED, AHA/IEC, 40 IN
590477	ECG TRUNK CABLE, 4-LEAD, SHIELDED, AHA/IEC, 5 FT
590478	ECG TRUNK CABLE, 4-LEAD, SHIELDED, AHA/IEC, 10 FT

17.2 Metallic ECG Lead Wires

REF	DESCRIPTION
590433	ECG LEAD WIRES, 4-LEAD SET, METALLIC, AHA, 24 IN
590447	ECG LEAD WIRES, 4-LEAD SET, METALLIC, IEC, 24 IN
590444	ECG LEAD WIRES, 4-LEAD SET, METALLIC, AHA, 30 IN
590448	ECG LEAD WIRES, 4-LEAD SET, METALLIC, IEC, 30 IN
590445	ECG LEAD WIRES, 4-LEAD SET, METALLIC, AHA, 36 IN
590449	ECG LEAD WIRES, 4-LEAD SET, METALLIC, IEC, 36 IN

17.3 Carbon ECG Lead Wires

REF	DESCRIPTION
590435	ECG LEAD WIRES, 4-LEAD SET, RT CARBON, AHA, 30 IN
590451	ECG LEAD WIRES, 4-LEAD SET, RT CARBON, IEC, 30 IN
590442	ECG LEAD WIRES, 4-LEAD SET, RT CARBON, AHA, 36 IN
590452	ECG LEAD WIRES, 4-LEAD SET, RT CARBON, IEC, 36 IN

AHA Colors: White, Green, Red, Black
IEC Colors: Red, Black, Green, Yellow

17.4 ECG Electrodes and Skin Prep

REF	DESCRIPTION
590436	ECG ELECTRODES, ADULT, 10x4/PKG, 10% KCl, BAG
590436-CS	ECG ELECTRODES, ADULT, 15 BAGS OF 40, 10% KCl, CASE
590494	ECG ELECTRODES, ADULT, 10x4/PKG, 10% KCl, BAG
590494-CS	ECG ELECTRODES, ADULT, 15 BAGS OF 40, 10% KCl, CASE
590291	NUPREP GEL, 4 OZ. TUBE

17.5 Mounting Solutions

REF	DESCRIPTION
590441	ROLLSTAND w/3” PLUNGER PLATE, 7000 SERIES
3302-00-15	ROLLSTAND ACC, 3” MOUNTING PLATE ASSY, 7000 SERIES

17.6 Miscellaneous Accessories

REF	DESCRIPTION
590035	RECORDER PAPER, 10 ROLLS/PKG
590368	RECORDER PAPER, 100 ROLLS/CASE
590386	USB MEMORY STICK WITH ECG VIEWER

To order accessories please contact customer service:

- Tel: +1 800.247.4614
- Tel: +1 203.481.4183
- Fax: +1 203.481.8734
- E-mail: sales@ivybiomedical.com

18.0 DISPOSAL

18.1 WEEE Directive 2012/19/EU

Disposal of devices or consumables must be done in accordance with local, state, and federal laws and regulations.

WEEE Directive 2012/19/EU - Do not dispose of WEEE products in general waste. At the end of life of the product, contact Ivy Biomedical Systems, Inc.'s Customer Service for return instructions.

18.2 RoHS2 Directive 2011/65/EU

The Model 7600/7800 and its accessories are in compliance with the RoHS2 Directive 2011/65/EU.

18.3 Standard of the Electronics Industry of the People's Republic of China SJ/T11363-2006

Table of toxic or hazardous substances and elements for the Model 7600/7800

Part Name	**Toxic or Hazardous Substances and Elements**					
	Pb	**Hg**	**Cd**	**Cr (VI)**	**PBB**	**PBDE**
Model 7600/7800 Final Assembly	**X**	**O**	**O**	**O**	**O**	**O**
Packing Assembly	**O**	**O**	**O**	**O**	**O**	**O**
Accessory Option	**O**	**O**	**O**	**O**	**O**	**O**

O: Indicates that this toxic or hazardous substance contained in all of the homogeneous materials for this part is below the limit requirement in SJ/T11363-2006.
X: Indicates that this toxic or hazardous substance contained in at least one of the homogeneous materials used for this part is above the limit requirement in SJ/T11363-2006.
The data above represents best information available at the time of publication.

(EFUP) Environmentally Friendly Use Period - 50 Years
Some consumable or OEM items may have their own label with an EFUP value less than the system and may not be identified in the table. This symbol indicates the product contains hazardous materials in excess of the limits established by the Chinese standard SJ/T11363-2006. The number indicates the number of years the product can be used in normal conditions before the hazardous materials may cause serious harm to the environment or health of humans. This product must not be disposed of as unsorted municipal waste, and must be collected separately.

19.0 SPECIFICATIONS

ECG

Lead Selection:		
	Trigger Lead:	LI, LII, LIII, and AUTO - menu selectable.
	Second Lead:	LI, LII and LIII – menu selectable.
ECG Trunk Cable:		4-lead ECG trunk cable with 6-Pin AAMI standard connector.
Isolation:		Isolated from ground related circuits by >4 kV rms, 5.5 kV peak
CMRR:		≥90 dB with ECG trunk cable and 51 kΩ/47 nF imbalance
Input Impedance:		≥20 MΩ at 10 Hz with ECG trunk cable
Frequency Response		
LCD Display and Recorder:	Filtered:	1.5 to 40 Hz or 3.0 to 25 Hz (Configuration Dependent)
	Unfiltered:	0.67 to 100 Hz
Frequency Response		
ECG output:	Unfiltered:	0.67 to 100 Hz
Input Bias Current:		Each lead <100 nA dc maximum
Electrode Offset Potential:		±0.5 V DC
Lead Off sensing current:		56nA
Noise:		<20 μV peak-to-peak, referred to the input with all leads connected through a 51 kΩ/47 nF to ground
Defibrillator Protection:		Protected against 360 J discharge and electrosurgery potentials Recovery time < 5 seconds
Leakage Current:		<10 μA at normal condition
Electrosurgical Interference Protection:		Standard. Recovery time < 5 seconds
Notch Filter:		50/60 Hz (automatic).

Electrode Impedance Measurement (Model 7800 Only)

Measurement Technique:	10 Hz ac signal < 10 uA rms
Measurement Range:	200kΩ per lead
Measurement Accuracy:	±3% ±1kΩ
Measurement Leads:	RA, LA, LL, RL
Measurement Mode:	Manual
Measurement Time:	< 4 seconds; ECG recovery < 8 seconds
Minimum Recommended Electrode Impedance:	<50kΩ
Recommended Electrode:	10% Chloride sponge type (Ivy REF: 590436)

Cardiotach

Range:	10 to 350 BPM (Pediatric / Neonate) 10 to 300 BPM (Adult)
Accuracy:	±1% ±1 BPM
Resolution:	1 BPM
Sensitivity:	300 μV peak
Heart Rate Averaging:	Exponential averaging calculated once a second with a maximum response time of 8 seconds.
Response Time – Model 7600:	
– Change from 80 to 120 BPM:	8 seconds
– Change from 80 to 40 BPM:	8 seconds
Response Time – Model 7800:	
– Change from 80 to 120 BPM:	2 seconds
– Change from 80 to 40 BPM:	2 seconds
Response to irregular rhythm:	A1: 40 BPM, A2: 60 BPM, A3: 120 BPM, A4: 90 BPM (According to IEC specification 60601-2-27, 201.7.9.2.9.101-b-4)
Tall T Wave Rejection:	Rejects T waves ≤ 1.2 x R-wave

Pacer Pulse Rejection

Width:	0.1 to 2 ms at ±2 to ±700 mV
Overshoot:	Between 4 and 100ms and not greater than 2mV.
Fast ECG Signals:	1.73 V/s
Detector Disabling:	User selectable.

⚠ **CAUTION:** Pacemaker pulses are not present in any rear panel outputs.

Alarms

High Rate:	15 to 250 BPM in 5 BPM increments
Low Rate:	10 to 245 BPM in 5 BPM increments
Asystole:	R to R interval >6 seconds
Lead Off:	Detached lead
Check Lead:	Imbalance between leads > 0.5V
Time to alarm for Tachycardia:	
B1 and B2:	< 10 seconds Note: B1 Half Amplitude produces a LOW SIGNAL warning message in < 5 seconds (Not an alarm) (According to IEC specification 60601-2-27, 201.7.9.2.9.101-b-6)
Alarm Sound Pressure Level:	76 dBA (Alarm volume set to Low) to 88 dBA (Alarm volume set to High)
Alarm Tones:	Conforms to IEC 60601-1-8:2006 Table 3, High Priority Alarms

Test Mode

Internal:

ECG	1 mV/100 ms referred to input @ 70 BPM

Simulator:

ECG waveform amplitude:	1mV
Simulator Range:	10 – 250 BPM.
Simulator Rate:	In steps of 30, 60, 90, 120, 150, 180, 210 and 240 BPM. Adjustable in increments of 1 BPM.

SPECIFICATIONS

Display - Model 7600

Type:	Active Matrix TFT Color Touch Screen LCD (640x480)
Trace:	Dual simultaneous ECG traces with “freeze” function.
Screen Size:	13.25cm x 9.94cm, 16.5cm (6.5in) diagonal
Sweep Speed:	25, 50 mm/s

Display - Model 7800

Type:	Active Matrix TFT Color Touch Screen LCD (640x480)
Trace:	Dual simultaneous ECG traces with “freeze” function.
Screen Size:	17.09cm x 12.82cm, 21.36cm (8.4in) diagonal
Sweep Speed:	25, 50 mm/s

USB Port and Data Transfer (Model 7800 Only)

Type:	USB Flash Drive (memory stick
ECG storage:	200 most recent events

Ethernet Module (Model 7800 Only)

Network Interface:	RJ45 (10BASE-T)
Ethernet compatibility:	Version 2.0/IEEE 802.3
Protocol:	TCP/IP
Packet Rate:	250ms
ECG Data Rate:	240 samples/s
Default IP address:	10.44.22.21
Channels:	2
Standard Temperature:	32 to 158°F (0 to 70°C)
Size:	1.574 x 1.929 in (40mm x 49mm)

Mechanical – Model 7600

Size:	Height: 7.49in. (19.02cm)
	Width: 7.94in. (20.17cm)
	Depth: 5.18in. (13.16cm)
Weight:	3.9 lbs (1.80kg)

Mechanical – Model 7800

Size:	Height: 8.72in. (22.14cm)
	Width: 9.25in. (23.50cm)
	Depth: 6.10in. (15.49cm)
Weight:	5.6 lbs (2.54kg)

Recorder

Writing Method:	Direct Thermal
Number of Traces:	2
Modes:	Direct - Manual Recording Timed - Print button initiates a 30 second recording Delay - Records 20 seconds before and 20 seconds after the occurrence of an alarm at 25mm/s. Records 15 seconds before and 15 seconds after the occurrence of an alarm at 50mm/s. XRAY **(Model 7800 Only)** – Records 10 seconds before and 10 seconds after the occurrence of an X-ray
Paper Speeds:	25 and 50 mm/s
Resolution:	Vertical - 200 dots/in. Horizontal - 600 dots/in. at ≤25 mm/s 400 dots/in. at >25 mm/s
Frequency Response:	>100 Hz at 50 mm/s
Data Rate:	500 samples

Synchronized Output (Trigger)

Test input signal at ECG leads:	Conditions: ½ sine wave, 60ms width, 1mV amplitude, 1 pulse/second
Output Trigger Delay:	< 2 ms
R to R Trigger Accuracy:	±75 µs typical @ 1 mV input
Pulse width:	1ms, 50ms, 100ms or 150ms (Configuration Dependent)
Pulse amplitude:	0V to +5V or -10V to +10V (Configuration Dependent)
Pulse amplitude polarity:	Positive or Negative (Configuration Dependent)
Output Impedance:	<100 Ω
Sensitivity and Threshold Adjustment:	Fully Automatic

Real Time Clock

Resolution:	1 minute
Display:	24 hours
Power Requirement:	The real time clock keeps time whether the monitor has power or not. The real time clock is powered by a dedicated lithium battery whose life is a minimum 5 years at a temperature of 25ºC Note: The dedicated real time clock lithium battery is embedded in the SNAPHAT package (not a bare battery) and therefore is considered "contained in equipment".

Operating Environment

Temperature Range:	5°C to 40°C
Relative Humidity:	0% to 90% non-condensing
Altitude:	-100 meters to +3,600 meters
Atmospheric Pressure:	500-1060 mbar
Protection against ingress of fluids:	IPX1 – Protection against vertically falling drops of water

Storage Environment

Temperature Range:	-40°C to +70°C
Relative Humidity:	5% to 95%
Altitude:	-100 meters to +14,000 meters

Power Requirements

Voltage Input:	100-120V~; 200-230V~
Line Frequency:	50/60 Hz
Fuse Rating and Type:	T 0.5AL, 250V
Maximum ac Power Consumption:	45 VA
Power Recovery:	Automatic, if power is restored within 30 seconds

20.0 REGULATORY COMPLIANCE

Unit meets or exceeds the specifications for:

- ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
- IEC 60601-1 Edition 3.1 (2012)/EN 60601-1:2006 + A1:2013 + A12:2014
- IEC 60601-1-2 4th edition (2014)
- IEC 60601-1-6:2010 (Third Edition) + A1:2013; IEC 62366:2007 (First Edition) + A1:2014
- IEC 60601-1-8:2006 (Second Edition) + Am.1:2012
- IEC 60601-2-27 (2011)
- IEC 62304:2006
- CAN/CSA-C22.2 No. 60601-1:2014
- CAN/CSA-C22.2 No. 60601-1-2:2016
- MDD 93/42/EEC
- CE 0413
- ISO 13485:2016
- RoHS2 2011/65/EU
- WEEE 2012/19/EU
- FDA/CGMP
- MDSAP

Medical Equipment
With respect to electric-shock, fire and
mechanical hazards only in accordance with

ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012), CAN/CSA C22.2 No. 60601-1(2014),
IEC 60601-2-27 (2011), IEC 60601-1-6:2010 (Third Edition) + A1:2013, IEC 60601-1- 8: 2006 (Second Edition) + Am.1: 2012

Ivy Biomedical Systems, Inc. has declared that this product conforms with the European Council Directive 93/42/EEC Medical Device Directive when it's used in accordance with the instructions provided in the Operation and Service Manuals.

Eurasian Conformity (EAC): This product passed all conformity assessment (approval) procedures that correspond to the requirements of applicable technical regulations of the Customs Union.