Mortara

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ELI 230

12-LEAD RESTING ELECTROCARDIOGRAPH

USER MANUAL

$C\,\epsilon$
0459

Manufactured by Mortara Instrument, Inc., Milwaukee, Wisconsin U.S.A.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Mortara

TECHNICAL SUPPORT AND SERVICE

Headquarters

Mortara Instrument, Inc.
7865 North 86th Street
Milwaukee, WI 53224
U.S.A.
Tel: 414.354.1600
Tel: 800.231.7437
Fax: 414.354.4760
Internet: http://www.mortara.com

European Union Representative

Mortara Rangoni Europe, Srl
(European Headquarters)
Via Cimarosa 103/105
40033 Casalecchio di Reno (BO)
Italy
Tel: +39.051.298.7811
Fax: +39.051.613.3582

Service/Technical Support Group

Mortara Instrument, Inc.
7865 North 86th Street
Milwaukee, WI 53224
U.S.A.
Tel: 414.354.1600
Service: 888.MORTARA
            (888.667.8272)
Fax: 414.354.4760
E-mail: techsupport@mortara.com

24-hour Technical Support
Same-day Shipment of Replacement Parts
Biomedical Training Classes
Extended Warranties/Service Contracts

Sales Support/ Supplies & Accessories

Mortara Instrument, Inc.
7865 North 86th Street
Milwaukee, WI 53224
U.S.A.
Tel: 414.354.1600
Fax: 414.354.4760
E-mail: sales@mortara.com

Mortara Instrument Germany
Kaninenberghöhe 50
45136 Essen
Germany
Tel: +49.201.18 55 69 70
Fax: +49.201.18 55 69 77

Mortara Instrument Netherlands
Postbus 324
5680 AH Best
Industrieweg 160b
5683 CG Best
Netherlands
Tel: +31.499.377310
Fax: +31.499.377908

Mortara Instrument Australia
PO Box 7568
Baulkham Hills NSW 2153
Unit 28, 9 Hoyle Avenue
Castle Hill NSW 2154
Australia
Tel: +61 2 8070 9303
Fax: +61 2 9899 9478

NOTICES

Manufacturer's Responsibility

Mortara Instrument, Inc. is responsible for the effects on safety and performance only if:

- Assembly operations, extensions, readjustments, modifications, or repairs are carried out only by persons authorized by Mortara Instrument, Inc.

- The device is used in accordance with the instructions for use.

Responsibility of the Customer

The user of this device is responsible for ensuring the implementation of a satisfactory maintenance schedule. Failure to do so may cause undue failure and possible health hazards.

Equipment Identification

Mortara Instrument, Inc. equipment is identified by a serial and reference number on the back of the device. Care should be taken so that these numbers are not defaced.

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MORTARA INSTRUMENT, INC. (hereinafter referred to as "Mortara") hereby warrants that Mortara products (hereinafter referred to as "Product/s") shall be free from defects in material and workmanship under normal use, service, and maintenance for the warranty period of such Product/s from Mortara or an authorized distributor or representative of Mortara. The warranty period is defined as twenty-four (24) months following the date of shipment from Mortara. Normal use, service, and maintenance means operation and maintenance in accordance with appropriate instructions and/or information guides. This warranty does not apply to damage to the Product/s caused by any or all of the following circumstances or conditions:

a) Freight damage;

b) Parts and/or accessories of the Product/s not obtained from or approved by Mortara;

c) Misapplication, misuse, abuse, and/or failure to follow the Product/s instruction sheets and/or information guides;

d) Accident; a disaster affecting the Product/s;

e) Alterations and/or modifications to the Product/s not authorized by Mortara;

f) Other events outside of Mortara's reasonable control or not arising under normal operating conditions.

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USER SAFETY INFORMATION

⚠ **Warning:** Means there is the possibility of personal injury to you or others.

⚠ **Caution:** Means there is the possibility of damage to the device.

Note: Provides information to further assist in the use of the device.

⚠ **Warning(s)**

- This manual gives important information about the use and safety of this device. Deviating from operating procedures, misuse or misapplication of the device, or ignoring specifications and recommendations could result in increased risk of harm to users, patients and bystanders, or damage to the device.

- Device captures and presents data reflecting a patient's physiological condition that when reviewed by a trained physician or clinician can be useful in determining a diagnosis; however, the data should not be used as a sole means for determining a patient's diagnosis.

- Users are expected to be licensed clinical professionals knowledgeable about medical procedures and patient care, and adequately trained in the use of this device. Before attempting to use this device for clinical applications, the operator must read and understand the contents of the user manual and other accompanying documents. Inadequate knowledge or training could result in increased risk of harm to users, patients and bystanders, or damage to the device. Contact Mortara service for additional training options.

- To ensure that electrical safety is maintained during operation from AC (~) power, the device must be plugged into a hospital-grade outlet.

- To maintain designed operator and patient safety, peripheral equipment and accessories used that can come in direct patient contact must be in compliance with UL 60601-1, IEC 60601-1, and IEC 60601-2-25. Only use parts and accessories supplied with the device and available through Mortara Instrument, Inc.

- Patient cables intended for use with the device include series resistance (9 Kohm minimum) in each lead for defibrillation protection. Patient cables should be checked for cracks or breakage prior to use.

- Conductive parts of the patient cable, electrodes, and associated connections of type CF applied parts, including the neutral conductor of the patient cable and electrode, should not come into contact with other conductive parts including earth ground.

- ECG electrodes could cause skin irritation; patients should be examined for signs of irritation or inflammation.

- To avoid the possibility of serious injury or death during patient defibrillation, do not come into contact with device or patient cables. Additionally, proper placement of defibrillator paddles in relation to the electrodes is required to minimize harm to the patient.

- This device was designed to use the electrodes specified in this manual. Proper clinical procedure must be employed to prep the electrode sites and to monitor the patient for excessive skin irritation, inflammation, or other adverse reactions. Electrodes are intended for short-term use and should be removed from the patient promptly following testing.

- To avoid potential for spread of disease or infection, single-use disposable components (e.g., electrodes) must not be reused. To maintain safety and effectiveness, electrodes must not be used beyond their expiration date.

- To ensure the safety of both the patient and the device, 1.5 meters (5') of open area should surround the patient.

- A possible explosion hazard exists. Do not use the device in the presence of a flammable anesthetic mixture.

- Where the integrity of external protective earth conductor arrangement is in doubt, the device shall be operated from its internal electrical power source.

- All signal input and output (I/O) connectors are intended for connection of only those devices complying with IEC 60601-1, or other IEC standards (e.g., IEC 60950) as appropriate to the device. Connecting additional devices to the device may increase chassis and/or patient leakage currents. To maintain operator and patient safety, consideration should be given to the requirements of IEC 60601-1-1, and leakage currents should be measured to confirm no electric shock hazard exists.

- The device has not been designed for use with high-frequency (HF) surgical equipment and does not provide a protective means against hazards to the patient.

- The quality of the signal produced by the device may be adversely affected by the use of other medical equipment, including but not limited to defibrillators and ultrasound machines.

- For proper operation and the safety of users or patients and bystanders, equipment and accessories must be connected only as described in this manual.

⚠ Caution(s)

- To prevent possible damage to the keyboard, do not use sharp or hard objects to depress keys, only use fingertips.

- Do not attempt to clean the device or patient cables by submersing into a liquid, autoclaving, or steam cleaning as this may damage equipment or reduce its usable life. Wipe the exterior surfaces with a warm water and mild detergent solution and then dry with a clean cloth. Use of unspecified cleaning/disinfecting agents, failure to follow recommended procedures, or contact with unspecified materials could result in increased risk of harm to users, patients and bystanders, or damage to the device.

- No user-serviceable parts inside. Screw removal by qualified service personnel only. Damaged or suspected inoperative equipment must be immediately removed from use and must be checked/repaired by qualified service personnel prior to continued use.

- The rechargeable internal battery is a sealed lead-acid type and it is totally maintenance free. If the battery appears to become defective, refer to Mortara Instrument Service Department.

- Do not pull or stretch patient cables as this could result in mechanical and/or electrical failures. Patient cables should be stored after forming them into a loose loop.

- No calibration or special equipments are needed for the proper operation or maintenance of the device.

- When necessary, dispose of the device, its components and accessories (e.g., batteries, cables, electrodes), and/or packing materials in accordance with local regulations.

Note(s)

- Patient movements may generate excessive noise that may affect the quality of the ECG traces and the proper analysis performed by the device.

- Proper patient preparation is important to proper application of ECG electrodes and operation of the device.

- There is no known safety hazard if other equipment, such as pacemakers or other stimulators, is used simultaneously with the device; however, disturbance to the signal may occur.

- If an electrode is not connected properly to the patient, or one or more of the patient cable lead wires are damaged, the display will indicate a lead fault for the lead(s) where the condition is present and if the signal is being printed, the respective lead(s) will print out as a square wave.

- As defined by IEC 60601-1 and IEC 60601-2-25, the device is classified as follows:
  - Class I equipment or internally powered.
  - Type CF defibrillation-proof applied parts.
  - Ordinary equipment.
  - Equipment not suitable for use in the presence of a flammable anesthetic mixture.
  - Continuous operation.

  NOTE: From a safety perspective, per IEC 60601-1 and derivative standards/norms, this device is declared to be "Class I" and uses a three-prong inlet to ensure an earth connection is made along with mains. The ground terminal on the mains inlet is the only protective earth point in the device. Exposed metal accessible during normal operation is double insulated from mains. Internal connections to earth ground are functional earth.

- This device is intended to be used in a hospital or doctor's office setting, and should be used and stored according to the environmental conditions specified below:

Operating temperature:	+10° to +40° C (+50° to +104° F)
Operating humidity:	10% to 95% RH, non-condensing
Storage temperature:	-40° to +70° C (-40° to +158° F)
Storage humidity:	10% to 95% RH, non-condensing
Atmospheric pressure:	500 hPa to 1060 hPa

- WAM™ (wireless acquisition module) must be paired to electrocardiograph before operation.

- Device must be configured at the factory for use with the WAM.

- After operating the device using battery power, always reconnect the power cord. This ensures that the batteries will be automatically recharged for the next time you use the device. A light next to the on/off switch will illuminate indicating that the device is charging. This light will turn off when the battery is fully charged.

- The power supply cord and appliance inlet serve as the means to disconnect the unit from the mains power supply. To remove mains power from the unit, disconnect the power supply cord from the appliance inlet.

- The device is UL classified:

WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL2601-1, IEC60601-1, CAN/CSA CC22.2 No. 601.1, AND IEC60601-2-25

EQUIPMENT SYMBOLS AND MARKINGS

Symbol Delineation

⚠	Attention, consult accompanying documents
∿	Alternating current
⏚	Protective earth
♥	Defibrillator-proof type CF applied part
⏻	ON/OFF (power)
♻	Do not dispose as unsorted municipal waste. Per European Union Directive 2002/96, requires separate handling for waste disposal according to national requirements
Ψ	Antenna
CE 0459	Indicates compliance to applicable European Union directives

GENERAL CARE

Precautions

- Turn off the device before inspecting or cleaning.
- Do not immerse the device in water.
- Do not use organic solvents, ammonia-based solutions, or abrasive cleaning agents which may damage equipment surfaces.

Inspection

Inspect your equipment daily prior to operation. If you notice anything that requires repair, contact an authorized service person to make the repairs.

- Verify that all cords and connectors are securely seated.
- Check the case and chassis for any visible damage.
- Inspect cords and connectors for any visible damage.
- Inspect keys and controls for proper function and appearance.

Cleaning Exterior Surfaces and Patient Cable

1. Remove cables and lead wires from device before cleaning.
2. For general cleaning of cables and lead wires, use a soft, lint-free cloth lightly moistened with a mild soap and water solution. Wipe and air dry.
3. For disinfecting the cables and lead wires, wipe exterior with a soft, lint-free cloth using a solution of Sodium Hypochlorite (10% household bleach and water solution) minimum 1:500 dilution (minimum 100 ppm free chlorine) and maximum 1:10 dilution as recommended by the APIC Guidelines for Selection and Use of Disinfectants.
4. Use caution with excess liquid as contact with metal parts may cause corrosion.
5. Do not immerse cable ends or lead wires; immersion can cause metal corrosion.
6. Do not use excessive drying techniques such as forced heat.

   WARNING: Prevent liquid from penetrating the device and do not attempt to clean/disinfect the device or lead wires by submerging into a liquid, autoclaving, or steam cleaning. Never expose lead wires to strong ultra-violet radiation. Do not sterilize the device or ECG lead wires with Ethylene Oxide (EtO) gas..

Cleaning the Device

Disconnect the power source. Clean the exterior surface of the device with a damp, soft, lint-free cloth using a solution of mild detergent diluted in water. After washing, thoroughly dry off the device with a clean, soft cloth or paper towel.

Cautions

Improper cleaning products and processes can damage the device, produce brittle lead wires and cables, corrode the metal, and void the warranty. Use care and proper procedure whenever cleaning or maintaining the device.

ELECTROMAGNETIC COMPATIBILITY (EMC)

Electromagnetic compatibility with surrounding devices should be assessed when using the device.

An electronic device can either generate or receive electromagnetic interference. Testing for electromagnetic compatibility (EMC) has been performed on the device according to the international standard for EMC for medical devices (IEC 60601-1-2). This IEC standard has been adopted in Europe as the European Norm (EN 60601-1-2).

The device should not be used adjacent to, or stacked on top of other equipment. If the device must be used adjacent to or stacked on top of other equipment, verify that the device operates in an acceptable manner in the configuration in which it will be used.

Fixed, portable, and mobile radio frequency communications equipment can affect the performance of medical equipment. See Table X-4 for recommended separation distances between the radio equipment and the device.

The use of accessories, transducers, and cables other than those specified by Mortara Instrument may result in increased emissions or decreased immunity of the equipment.

Table X-1 Guidance and Manufacturer's Declaration: Electromagnetic Emissions

The equipment is intended for use in the electromagnetic environment specified in the table below. The customer or the user of the equipment should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment: Guidance
RF Emissions CISPR 11	Group 2	The equipment must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class A	The equipment 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	Complies	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

Table X-2 Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The equipment is intended for use in the electromagnetic environment specified in the table below. The customer or the user of the equipment should ensure that it is used in such an environment.

Emissions Test	Compliance	Compliance Level	Electromagnetic Environment: Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 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	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	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 kV differential mode +/- 2 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 IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: UT is the AC Mains voltage prior to application of the test level.

Table X-3 Guidance and Manufacturer's Declaration: Electromagnetic Immunity

The equipment is intended for use in the electromagnetic environment specified in the table below. The customer or the user of the equipment should ensure that it is used in such an environment.

Emissions Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\dfrac{3.5}{3Vrms}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = \left[\dfrac{3.5}{3V/m}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\dfrac{7}{3V/m}\right]\sqrt{P}$ 800 MHz to 2.5 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 equipment marked with the following symbol:

a. Field strengths 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 equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m.

Table X-4 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Equipment

The equipment is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the equipment can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the equipment as recommended in the table below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter (m)	
	150 KHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.1 m	0.2 m
0.1	0.4 m	0.7 m
1	1.2 m	2.3 m
10	4.0 m	7.0 m
100	12.0 m	23.0 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

> **NOTE 1:** At 800 MHz, the separation distance for the higher frequency range applies.

> **NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection from structures, objects, and people.

TABLE OF CONTENTS

INTRODUCTION SECTION 1

EQUIPMENT PREPARATION SECTION 2

RECORD AN ECG SECTION 3

SYSTEM SETTINGS SECTION 4

MAINTENANCE AND TROUBLESHOOTING APPENDIX A

INTRODUCTION

Manual Purpose

This manual is intended to provide the user with information about:
- Using and understanding the ELI™ 230 electrocardiograph, the function keys, and the display screen.
- Preparing the ELI 230 for use. (Section 2)
- Acquiring, printing, and storing an ECG. (Section 3)
- System settings. (Section 4)
- Maintenance and troubleshooting. (Appendix A)

Audience

This manual is written for clinical professionals. They are expected to have working knowledge of medical procedures and terminology as required for monitoring cardiac patients.

Indications for Use

- Device is indicated for use by a licensed healthcare practitioner in a hospital or clinical setting. Personnel must be experienced in cardiovascular problematic situations, and emergency procedures or pathologies related to cardiac involvements.
- Device is indicated for use to acquire, analyze, display, and print electrocardiograms.
- Device is indicated for use for patients of any age
- Device is indicated for use to provide interpretation of the data for consideration by a physician. It is not intended as a sole means of diagnosis.
- The interpretations of ECG offered by the device are only significant when used in conjunction with physician over read as well as consideration of all other relevant patient data.
- The device is not intended to be used as a vital signs physiological monitor.
- The cardiac data and analysis provided is reviewed, confirmed, and used by trained medical personnel in the diagnosis of patients with various rhythm patterns.
- The device is not designed for use in highly invasive environments, such as an operating theatre.

System Description

The ELI 230 is a 12-lead diagnostic electrocardiograph used for acquiring, viewing, and printing of adult and pediatric 12-lead ECG data. The device is optionally equipped with Mortara Instrument's VERITAS™ resting ECG interpretation algorithm with age and gender specific criteria. If this option is enabled (see Section 4) the VERITAS algorithm can provide an over-reading physician with a silent second opinion through diagnostic statements output on the ECG report. For additional information on the VERITAS algorithm, please refer to the *Physician's Guide Adult and Pediatric user manual.* (See Accessories.)

Supported print formats include: standard 3+1, 6, or 12 channel, or Cabrera 3+1, 6, or 12 channel in automatic mode, and 3, 6, or 12 channel rhythm strip printing. During rhythm strip printing user can toggle between the various 3 or 6 channels to print. The device can operate on battery or line power.

The ELI 230 includes:
- Acquisition module
- Hospital-grade power cord
- 1 pack paper (210mm roll paper)
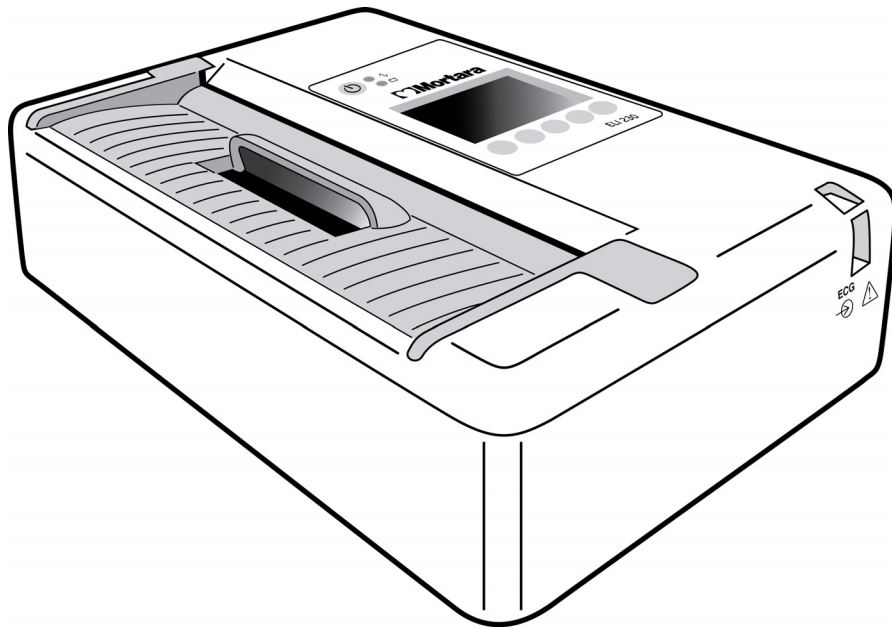- User manual CD
- Accessory starter kit

ELI 230, System Illustration

Figure 1-1
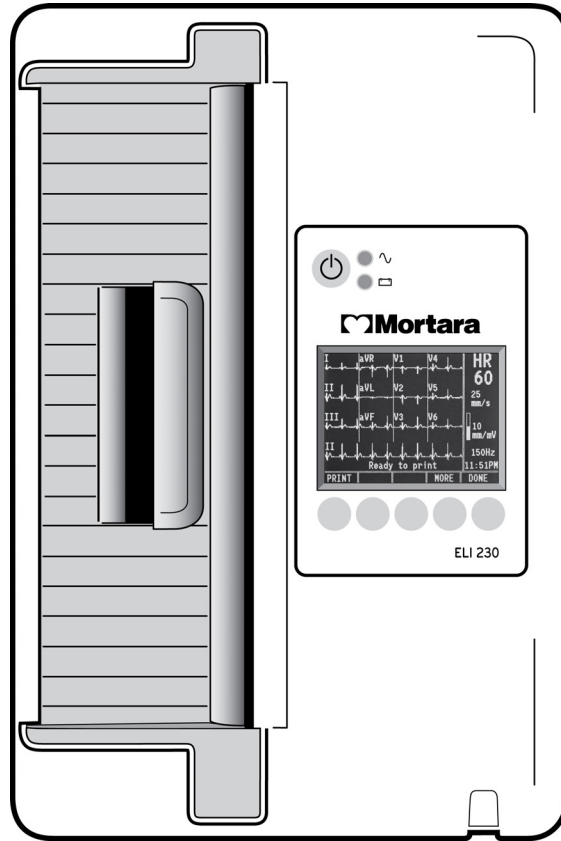
ELI 230, Left Side

Figure 1-2

ELI 230, Rear

Figure 1-3

100-240V ~
50/60Hz 110VA
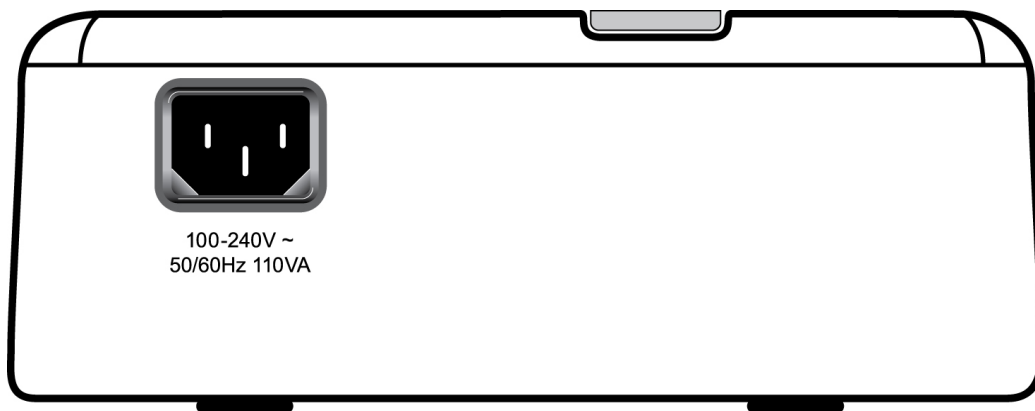
ELI 230, Base

Figure 1-4

ELI 230, Display Overview

Figure 1-5

Heart Rate

Speed

Best 10
Gain

Filter
Clock

Function Key Labels
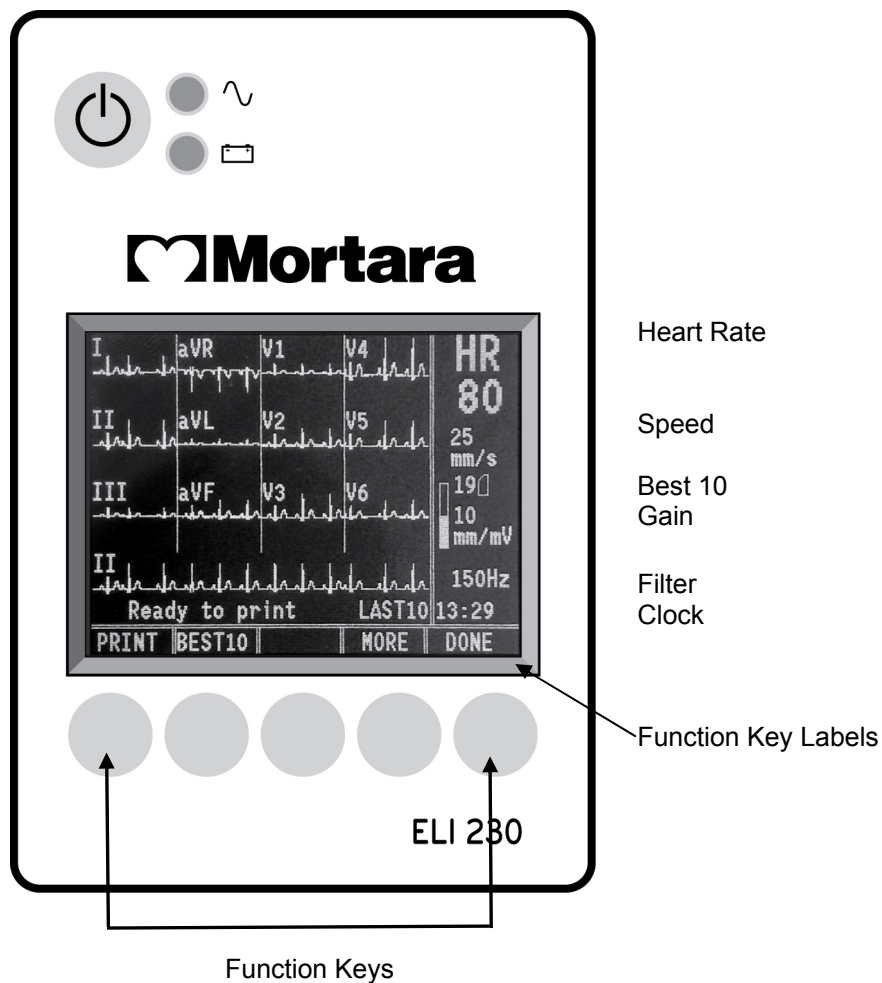
Function Keys

Function Keys

Function keys activate the liquid crystal display (LCD) label above each function key. LCD labels/functions change depending upon the screen displayed. If the label is blank, the function key is not active.

The ELI 230 features a ¼ VGA 320 x 240 pixel LCD color display for valuable preview of ECG waveform, function key labels, and other parameters as explained below:

Heart Rate (HR):

When a patient is connected to the electrocardiograph, his/her HR is displayed in real time. The HR is the average ventricular rate measured over an average of the patient's last five beats.

> *NOTE: If a lead fail occurs, a yellow indicator flashes in the middle of the display signifying which lead has the problem.*

ECG:

Use **ECG** to acquire an ECG.

Rhythm:

Use **RHY** to start a rhythm print. Use **RHY** again to switch to alternate leads.

Speed:

Use **MORE** followed by **SPEED** to select display speed or rhythm printout speed: 5 mm/s, 10 mm/s, 25 mm/s, or 50mm/s. Paper speed is printed at the bottom right corner of the ECG printout.

> *NOTE: ECG paper speed is configured in page one of the Configuration menus.*

Gain:

Use **GAIN** to select waveform amplitude for display and printout: 5 mm/mV, 10 mm/mV, or 20 mm/mV. Gain is printed at the bottom right corner of the ECG printout.

Filter:

Use **FILT** to select the low-pass filter options: 40 Hz, 150 Hz, or 300 Hz for ECG printouts. Filter is printed at the bottom right corner of the ECG printout.

Clock:

Time display with hour, minutes, and seconds resolution. (See Section 2 for setting a new time and date.) When the ECG is acquired, the time displayed is the printed ECG acquisition time.

Specifications

Feature	Specification
Instrument Type	12-lead electrocardiograph
Input Channels	Simultaneous acquisition of all 12 leads
Standard Leads Acquired	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Waveform Display	Backlit, ¼ VGA 320 x 240 LCD color display 4+4 or 6+6 lead presentation
Input Impedance Input Dynamic Range Electrode Offset Tolerance Common Mode Rejection	Meets or exceeds the requirements of ANSI/AAMI EC11
Patient Leakage Current Chassis Leakage Current	Meets or exceeds requirements of ANSI/AAMI ES1
Digital Sampling Rate	40,000 s/sec/channel used for pacemaker spike detection; 1000 s/sec/channel used for recording and analysis
Resolution	1.875 microvolt LSB
A/D Conversion	20 bits
Frequency Response	0.05 to 300 Hz
Filters	High-performance baseline filter; AC interference filter 50/60 Hz; low-pass filters 40 Hz, 150 Hz, or 300 Hz
Optional Functions	Optional Mortara VERITAS resting ECG interpretation with age and gender specific algorithm
Paper	Thermal roll paper; 210 mm (8.25") wide
Thermal Printer	Computer-controlled dot array; 8 dots/mm
Thermal Printer Speeds	5, 10, 25, or 50 mm/s
Gain Settings	5, 10, or 20 mm/mV
Report Print Formats	Standard or Cabrera; 12, 6, or 3+1 channel
Rhythm Print Formats	12, 6, or 3 channel with configurable lead groups
Device Classification	Class I, Type CF defibrillation-proof applied parts
ECG Storage	Internal storage up to 20 ECG records; external storage to USB memory stick
Weight	5.8 lbs. (2.63 kg) including battery (without paper)
Dimensions	11.25 x 7.5 x 2.75" (28.58 x 19 x 7 cm)
Power Requirements	Universal AC power supply (100-240 VAC at 50/60 Hz) 110 VA; internally rechargeable battery

Accessories

| Part Numbers	Description
9100-029-50	PAPER CASE ELI 230 ROLL W/ HEADER 210mm
9293-048-50	AM12 PATIENT CABLE ASSEMBLY
30012-019-50	WIRELESS ACQUISITION MODULE (WAM)
9300-036	ELECTRODES RESTING 24mm SUCTION PK/6
9300-037	ELECTRODE RESTING CLAMP IEC PK/4 IEC
9325-001-50	ELECTRODE CLIP 4mm SET OF 10
9515-175-50-CD	ELI 230 USER MANUALS
9516-175-50-ENG	ELI 230 SERVICE MANUAL
9515-001-51-ENG	PHYSICIAN'S GUIDE ADULT & PEDIATRIC UM

Contact your dealer or go to **www.mortara.com** for more information.

EQUIPMENT PREPARATION

Connecting the Acquisition Module

Connect the AM12™ to the USB port on the front end of the device. The ELI 230 will automatically convert to the AM12 acquisition module.

When using the WAM™ (wireless acquisition module) for ECG acquisition, the connector is not required. Refer to the WAM user manual for pairing instructions to the ELI 230.
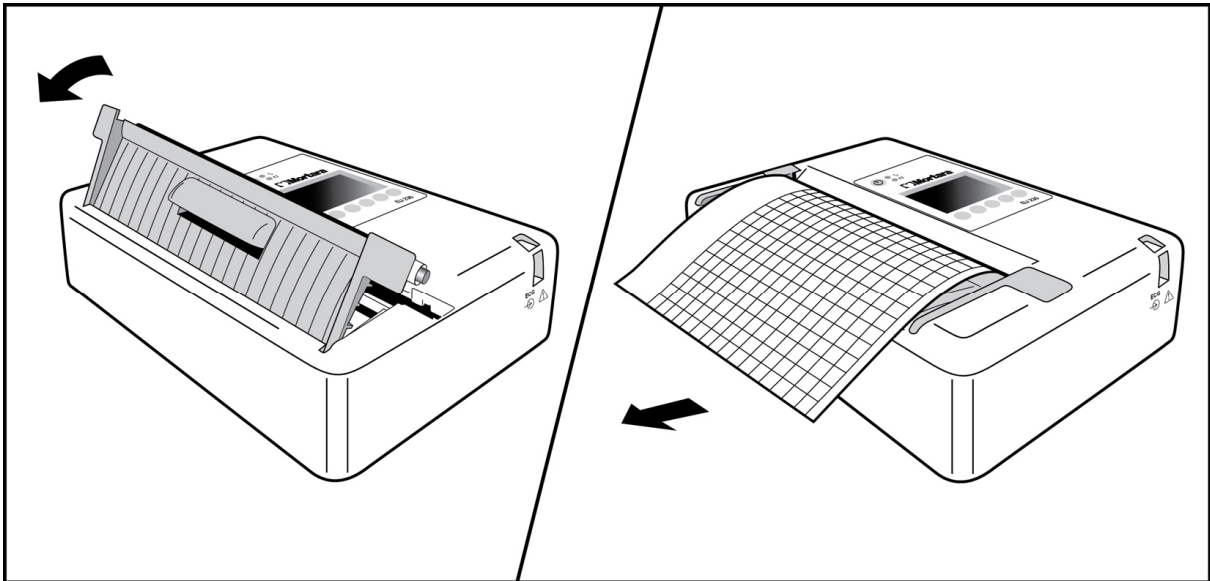
Figure 2-1
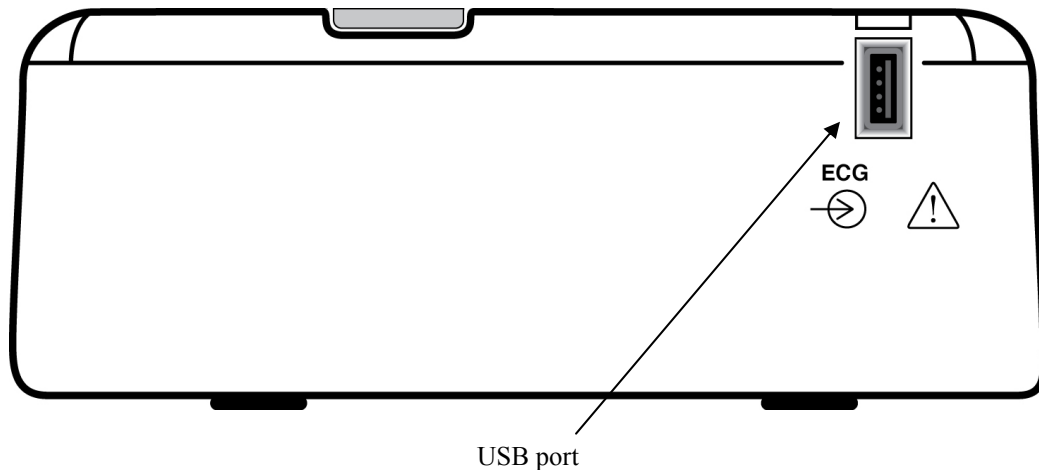
USB port

> *NOTE*: *The ELI 230 must be configured at the factory for use with the WAM. Select* **MORE***, followed by* **CONFIG** *to determine the device's setting. "Wireless Option Available" will display if the ELI 230 is configured to work with the WAM.*

> *NOTE*: *WAM must be paired to electrocardiograph before operation.*

Loading Paper

Figure 2-2

1. Remove the outer packaging from the paper roll.

2. Facing the front of the device, use the release latch on the top side to pull the paper tray cover slightly to the right and lift up to open. Note: cover does not come completely off. Remove any empty paper rolls.

3. Place the roll of thermal paper into the paper tray such that the grid side of the paper is up and paper roll edge faces to the left.

4. Pull paper roll edge up and to the right to allow the paper tray cover to close with paper roll edge extended out of the device. Use the release latch to pull the paper tray cover slightly to the right and down until the cover latches in a locked position. You will hear a sharp click when the cover is latched properly; this may require pressing down firmly on the top and bottom tabs of the paper tray cover with your thumbs.

WARNING: Risk of injury to fingers in paper tray door or platen drive mechanisms.

NOTE: For proper performance of thermal writer, be certain to use Mortara recommended thermal paper.

Applying Power

1. Plug the power cord into an AC wall outlet and into the back of the ELI 230. (Reference Figure 1-3.)
   Device powers on automatically and cannot be turned off when AC is connected (device can be put
   into standby mode).

2. If using battery power, press the power ON/OFF button ⏻ located on the face panel of the device.
   (Reference Figure 1-5.)

Indicators on the keyboard will illuminate as follows:
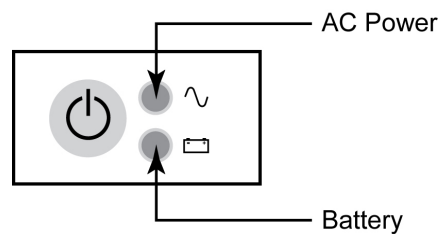
- The AC power LED indicator illuminates when device is connected to mains (AC power).

- The battery LED indicator illuminates when charging and flashes when battery is low; it will turn off when
  the battery is fully charged.

The ELI 230 should be connected to AC power for recharging when not in use.

> **TIP:** *Check battery voltage by selecting* **MORE** *followed by* **CONFIG**.

> **NOTE:** *For typical usage, battery charging time should be approximately 6 hours or less.*

> **NOTE:** *There are configurable features on the ELI 230 that can be used to help prolong battery life (see Section 4). Proper battery care and maintenance will also help prolong battery life.*

Low Battery Conditions

To prevent permanent damage to the internal lead-acid battery, the device will automatically power down when the battery has been depleted to its lowest allowable level. When the device detects that the battery voltage has been depleted to this level, it will display the messages "*Battery Low – Charge Unit*" for 10 seconds before shutting down. Plugging in the AC cord during this time will cause the unit to return to the main acquisition screen.

If the device is in the ECG acquisition mode when the battery voltage is detected at its lowest allowable level, the unit will display the message "*Battery Low – Charge Unit*", but will **not** automatically shutdown until the user exits the ECG acquisition mode. This allows the user to complete an ECG already in progress.

13

Setting Date and Time

1. Select **MORE** from real-time ECG view.

2. Select **CONFIG**.

3. Select **3 Set Time/Date**.

4. The preprogrammed date and time is displayed. To make changes to the date and time values (using a 24-hour clock) in the same format as displayed, use ▲ and ▼ to move back and forth through each row.

5. Use ► to select the year, month, day, hour, or minute.

6. Use **+10** or **-10** along with **+1** or **-1** to advance year, month, day, hour, or minute.

7. Select **DONE** to save changes.

8. Select **DONE** to return to the Configuration menu and **DONE** again to return to real-time ECG view.

Using the WAM or AM12 Acquisition Modules

ECG acquisition and rhythm strip printing can also be performed at the WAM or the AM12 acquisition module. To use the WAM, refer to the WAM user manual. To use the AM12, refer to the AM12 short-form instruction card.

NOTE: The ELI 230 must be configured at the factory for use with the WAM. Select **MORE***, followed by* **CONFIG** *to determine the device's setting. "Wireless Option Available" will display if the ELI 230 is configured to work with the WAM.*

NOTE: WAM must be paired to electrocardiograph before operation.

RECORD AN ECG

Patient Preparation

Before attaching the electrodes, assure the patient fully understands the procedure and what to expect.
- Privacy is very important in assuring the patient is relaxed.
- Reassure the patient that the procedure is painless and that the electrodes on their skin are all that they will feel.
- Make sure the patient is lying down and is comfortable. If the table is narrow, tuck the patient's hands under his/her buttocks to ensure their muscles are relaxed.
- Once all the electrodes are attached, ask the patient to lie still and to not talk. Explain this will assist you in acquiring a good ECG.

Preparing Patient Skin

Thorough skin preparation is very important. There is natural resistance on the skin surface from various sources such as hair, oil, and dry, dead skin. Skin preparation is intended to minimize these effects and maximize the quality of the ECG signal.

To prepare the skin:
- Shave hair from electrode sites if necessary.
- Wash area with warm, soapy water.
- Dry skin vigorously with a pad such as a 2 x 2 or 4 x 4 gauze to remove dead skin cells and oil, and to increase capillary blood flow.

> *NOTE: With elderly or frail patients take care to not abrade the skin causing discomfort or bruising. Clinical discretion should always be used in patient preparation.*

Patient Hookup

Correct electrode placement is important for acquiring a successful ECG.

A good minimum-impedance pathway will provide superior noise-free waveforms. Good quality silver-silver chloride (Ag/AgCl) electrodes should be used.

> *TIP: Electrodes should be stored in an air-tight container. Electrodes will dry out if not stored properly which will cause loss of adhesion and conductivity.*

To Attach the Electrodes

1. Expose the arms and legs of the patient to attach the limb leads.
2. Place the electrodes on flat, fleshy parts of the arms and legs.
3. If a limb site is not available, place the electrodes on a perfused area of the stump.
4. Attach the electrodes to the skin. A good test for firm electrode contact is to slightly tug on the electrode to check adhesion. If the electrode moves freely, it needs to be changed. If the electrode does not move easily, a good connection has been obtained.

For accurate V-lead placement and monitoring, it is important to locate the 4th intercostal space. The 4th intercostal space is determined by first locating the 1st intercostal space. Because patients vary with respect to body shape, it is difficult to palpate the 1st intercostal space with accuracy. Thus, locate the 2nd intercostal space by first palpating the little bony prominence called the **Angle of Lewis**, where the body of the sternum joins the manubrium. This rise in the sternum identifies where the second rib is attached, and the space just below it is the 2nd intercostal space. Palpate and count down the chest until you locate the 4th intercostal space.

Patient Hookup Summary Table

AAMI Lead	IEC Lead	Electrode Position
V1 Red	C1 Red	On the 4th intercostal space at the right sternal border.
V2 Yellow	C2 Yellow	On the 4th intercostal space at the left sternal border.
V3 Green	C3 Green	Midway between V2/C2 and V4/C4 electrodes.
V4 Blue	C4 Brown	On the 5th intercostal space at the left midclavicular line.
V5 Orange	C5 Black	Midway between V4 and V6 electrodes.
V6 Violet	C6 Violet	On the left midaxillary line, horizontal with V4 electrode.
LA Black / RA White	L Yellow / R Red	On the deltoid, forearm, or wrist.
LL Red / RL Green	F Green / N Black	On the thigh or ankle.
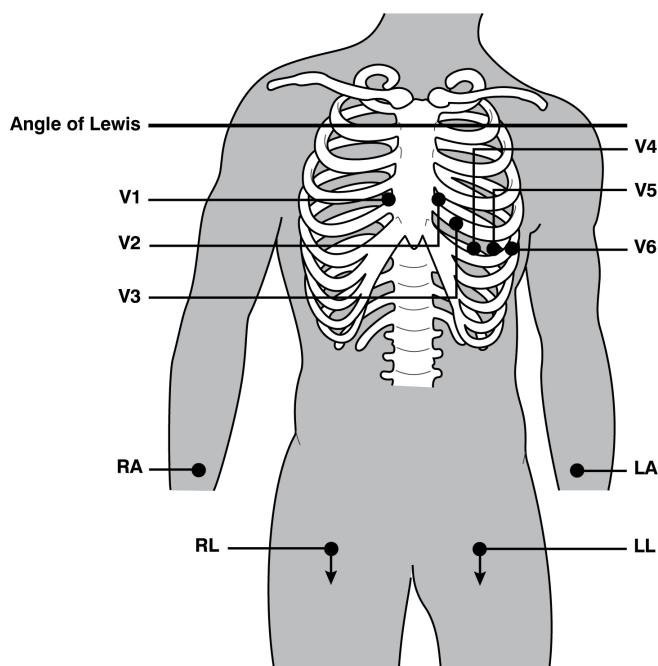
Patient Demographic Entry

Patient demographic information can be entered before acquisition only if the patient is connected to the ELI 230. The entered patient ID fields will remain populated until you acquire the ECG; however, if you disconnect the leads from the patient, turn off the electrocardiograph, or change a configuration setting before acquisition, the patient information will be cleared.

To access the patient demographic data entry menu, press **MORE** from real-time ECG view, followed by **ID.** The patient demographic labels available are determined by the ID format selected in the configuration settings. In addition to short, you may select None, Sex/Age, or Sex/DOB ID formats.

Use the arrow function keys to move through the available demographic fields. At the desired field, select **Edit**. When entering last name, first name, or ID, use the arrow function keys (►, ◄, ▲, ▼) to move the cursor to the right or left, or up and down through the alphanumeric character menu. Select the desired character and press **Enter**. Once all the characters have been selected, move the cursor to "DONE" and press **Enter** to return to the patient demographic data entry menu. When entering date of birth, the ▲ and ▼ function keys are used to increase or decrease selections for day, month, and year. Select **DONE** to return to the patient demographic data entry menu (age is automatically calculated). When selecting gender, use the "MALE" or "FEMALE" function key and select **DONE.** When finished with the data entry fields, select **DONE** to return to real-time ECG view. Skipped fields will appear as a blank field on the header of the ECG printout.

> *NOTE: If no age was calculated or entered before acquiring an ECG, the interpretation will default to a 40-year old male. The statement "INTERPRETATION BASED ON A DEFAULT AGE OF 40 YEARS" will be added to the interpretation text.*

> *NOTE: If an age of zero (0) is used, the interpretation will default to a 6-month old infant. The statement "INTERPRETATION BASED ON A DEFAULT AGE OF 6 MONTHS" will be added to the interpretation text.*

> *NOTE: Where global measurement values are not available (i.e., rate, interval, axis), text such as '‑ ‑'or '*' or similar will display/print for the unavailable value.*

> *NOTE: If ID Format is set for "None" in the configuration settings, the interpretation function will be turned off regardless of its setting. In order to maintain interpretive statements, the ID Format must be set to Short, Sex/Age or Sex/DOB (date of birth).*

ECG Acquisition, Printing, Storage

ECG acquisition and rhythm strip printing can also be performed at the WAM (wireless acquisition module) or the AM12 acquisition module. To use either acquisition module with the ELI 230, refer to the WAM user manual or the AM12 short-form instruction card.

Acquisition

Once the patient is connected, the device continuously collects and displays ECG data; therefore, before you press **ECG** or **RHY** you should instruct the patient to relax in a supine position to ensure that the ECG is free from artifact (noise) due to patient activity. If workflow permits patient demographic entry prior to acquisition, enter the patient identification information as explained in *Patient Demographics*. After you complete the last data entry field, select **DONE** to return to the real-time ECG view.

> *NOTE: A STAT ECG can be acquired using either the WAM or AM12 acquisition module as well as the electrocardiograph.*
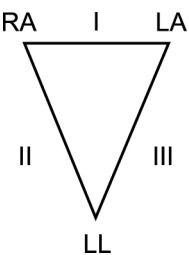
17

Examine the display for any of the following notification messages:

- **Leads Off** –displays when patient is not connected.
- **Lead Fault** –displays faulty lead(s). Re-prep and replace electrode(s) if necessary to obtain satisfactory waveform(s). (See *Patient Preparation*.)
- **Electrode Wrong Position** – displays one of the following when a lead is connected incorrectly or is in the wrong location. (See *Patient Preparation*.)
  - "Limb leads misplaced?"
  - "LA or LL misplaced?"
  - "RA or RL misplaced?"
  - "RA or LL misplaced?"
  - "RA or LA misplaced?"
  - "V1 or V2 misplaced?"
  - "V2 or V3 misplaced?"
  - "V3 or V4 misplaced?"
  - "V4 or V5 misplaced?"
  - "V5 or V6 misplaced?"

  NOTE: The algorithm detecting electrode misplacements is based on normal physiology and ECG lead order, and tries to identify the most likely switch; however, it is advisable to check the other electrode positions in the same group (limb or chest).

- **WAM Low Battery** – displays when a low battery signal for the WAM is detected.
- **Searching for WAM** – displays when the WAM is not detected. Occurs usually when the WAM is out of range or not powered on.

When the problem is corrected, the device waits for 10 seconds of good data before analyzing the ECG. Please refer to the following troubleshooting guide based on Einthoven's Triangle:

Artifact	Check Electrode
Lead II and III artifact	Poor LL electrode or left leg tremor
Lead I and II artifact	Poor RA electrode or right arm tremor
Lead I and III artifact	Poor LA electrode or left arm tremor
V Leads	Re-prep site & replace electrode

Press **ECG**. The real-time ECG view is then replaced with the acquired ECG view. The default real-time ECG view is not available in the acquired ECG view for navigation purposes.

  NOTE: New LCD label functions are available in the acquired ECG view.

  NOTE: Functions are not available during acquisition.

Best 10 Seconds Selection

The ELI 230 incorporates a one-minute memory buffer for collection of ECG data. When the Best 10 feature is enabled, the device will automatically select the best 10 seconds of ECG from within the one-minute buffer. The best 10 seconds is determined based upon measures of high and low-frequency noise found in the 10-second ECG segments. Should a single limb lead or two precordial lead fail conditions occur, the Best 10 feature is disabled until the limb lead fail or precordial lead fail condition is resolved. At resolution, the Best 10 feature becomes available and the selection buffer continues.

Users can switch between BEST 10 or LAST 10 by selecting **BEST10 or LAST10**. Switching the view will automatically generate a second printout if auto print is selected. Otherwise the clinician will be required to select **PRINT**.

Pacemaker Spike Notification

Turn the pacemaker spike notification marker on or off by selecting Yes or No in the configuration menu. Selecting Yes will cause a spike location marker to display at the bottom of the printout.

Printing

If Auto-Print is enabled in the configuration, an ECG is printed following acquisition. To print a manual printout, select **PRINT**.

If the auto-print configuration is disabled, a 10-second preview will assist in ensuring a quality ECG acquisition prior to printing. When you acquire an ECG, the electrocardiograph captures a minimum of the last 10 seconds. The relationship between the display and the printout is the same – what is displayed in the ECG acquisition view is what will be printed.

In order to change the speed, gain, filter, or print format in the acquired ECG view, select **MORE**. To manipulate the print format of the acquired ECG regardless of the plot format configuration setting, select **FMT**. Continue to press **FMT** until the desired print format is displayed, then select **BACK**. The display will return to acquired ECG view. Select **PRINT** to make an ECG printout copy in the new plot format; select **DONE** to return to the real-time ECG view.

Storage

The ELI 230 will automatically store up to 20 ECGs in its internal memory; however, the ECG records must be transferred via USB memory stick to a PC running ELI Link to be reviewed. Starting with 20 and counting down to 0, the device will display the number of remaining storage slots available just below the display sweep speed on the right side of the display in acquired ECG view. Once the device has stored 18 records (2 storage slots remaining), a red box will appear around the countdown number. If set to Yes in the configuration menu, a storage warning message will appear in the center of the display on real-time ECG view to notify the user that maximum storage is about to be reached. Once maximum storage is reached, the device will automatically delete the oldest record to make room for the new record (first in, first out). The user can also enter the Service menu and delete all patient records at any time, or transfer all the ECG records to a USB memory stick. (See *Transfer to a USB Memory Stick.*)

19

Acquiring Rhythm Strips

Rhythm strips are printed in the format defined in the configuration (3, 6, or 12 channel). See Section 4 for instructions to configure rhythm leads.

Begin routine rhythm strips by connecting the patient to the ELI 230 and entering the patient data. Once completed, select **DONE** to return to the real-time ECG view. Select **RHY** to begin rhythm printing. You can also acquire a rhythm printout by selecting **RHY** without entering the patient data.

>   *NOTE: Rhythm printouts are only possible from the real-time ECG view.*

>   *NOTE: Rhythm acquisitions are only printed and not stored in the ELI 230.*

The rhythm activity screen appears as soon as the writer begins printing the rhythm strip. The waveform display format is similar to the real-time ECG view; however, new functions keys are available during rhythm printing.

In addition to manipulating **SPEED, GAIN,** and **FILTER**, the user can toggle different lead groups during printing by selecting **LEADS**. The change in lead groups is apparent on the printout whereas the waveform display will remain in the default display of 2.5 seconds of Leads I, II, and V1-V6.

During 3-channel rhythm printing, the available lead groups are:
1. Default (user-selected in configuration)
2. I-II-III
3. aVR, aVL, aVF
4. V1-V2-V3
5. V4-V5-V6

During 6-channel rhythm printing, the available lead groups are:
1. Default (user-selected in configuration)
2. I-II-III-aVR-aVL-aVF
3. V1-V2-V3-V4-V5-V6

During rhythm printing the user can place the writer in Standby mode by pressing **STOP**. To continue rhythm printing for the same patient without advancing to a new page, select **RHY**.

Transfer to a USB Memory Stick

The user can transfer all the ECG records from the ELI 230 to an external USB memory stick at any time. Using a PC, create a directory on the USB memory stick called "Records." When done, plug the USB memory stick into the USB port on the ELI 230 (same port as used for the AM12 acquisition module). Once the USB memory stick is connected, the device will automatically start transferring all existing records to the USB memory stick. The device will display the message "ECG TRANSFER IN PROGRESS". Upon completion another message will display confirming the number of records transferred, "TRANSFERRED: 20/20, DONE – remove USB stick". The device will automatically return to the real-time ECG display when the USB memory stick has been removed. All successfully transferred ECG records will have been cleared from the device.

> *NOTE*: *Not all USB memory sticks may fit the device's USB port.*

> *NOTE*: *If the device appears to be unresponsive, hold the Off key for 10 to 15 seconds to reboot.*

Deleting Records

To delete all existing patient records from the ELI 230:

- Select **MORE**, followed by **CONFIG**.
- Select application **4. Service** followed by **Yes**.
- Select application **3. Clear all ECG Records**. Once selected, a series of dots will start to appear on the display. This signals to the user that the records are being deleted. Once the deletion process is completed, the display will return to the main configuration screen.
- Select **DONE** to return to the real-time ECG display.

SYSTEM SETTINGS

Accessing Configuration Menus

The configuration pages define all operational conditions that do not change on a daily or patient-to-patient basis. Once you set these default conditions, you will rarely need to use the configuration screens again. To access the configuration menus:

1. Select **MORE** from real-time ECG view.

2. Select **CONFIG**.

3. Select **1** to print the configuration settings.

4. Select **2** to enter the Modify Configuration menu.

5. Use ▲ and ▼ to move back and forth through each row. Use ► to select the setting. Use **PAGE** to advance to the next page of settings.

6. Select **DONE** to save any changes and exit the Modify Configuration menu. Select **DONE** to return to real-time ECG view.

The following chart summarizes the configuration parameters and the available options for each field.

Summary of Configuration Menus

Configuration Parameter	Definition
Software Version	Displays software version on printout and in configuration menu
Language	Software language availability
Battery Timeout	10, 20, or 30 minutes
Time Mode	12 hour or 24-hour clock
ID Format	None, Short, Sex/Age, or Sex/DOB
AC Filter	None, 50, or 60Hz
Filter	40, 150, or 300Hz
Paper Speed	25 or 50mm/sec
Rhythm Paper Speed	5, 10, 25, or 50mm/sec
Interp	Yes or No
Reasons	Yes or No
Append	UNCONFIRMED REPORT or Reviewed by:
Number of copies	0 – 9
Auto print ECG	Yes or No
Display Format	4+4 or 6+6
Plot Format	Standard or Cabrera; 6, 12, or 3+1 channel
12 Rhythm leads	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
6 Rhythm Leads (1 thru 6)	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 in any combination
3 Rhythm Leads (1 thru 3)	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 in any combination
Avg RR:	Yes or No
QTc B	Yes or No
QTc F	Yes or No
Pace Spike Channel	Yes or No
ECG Capture	Last10 or Best10
Storage Warning	Yes or No

Configuration Settings

Software Version

Identifies the software version of your electrocardiograph.

Language

There are several languages available on the ELI 230 electrocardiograph.

> **CAUTION:** *Function labels are immediately translated upon selecting a new language and exiting the configuration menu.*

If an unknown language is visible, use the following steps to revert to the language of your country:

1. From real-time ECG view, select **MORE**.
2. Select **CONFIG**.
3. Select **2 Modify Configuration**.
4. Use ▲ or ▼ to select Language.
5. Press ► until the desired language appears.
6. Press **DONE** to return to the Configuration menu.
7. Press **DONE** to return to real-time ECG view.

Battery Time Out

Determines when the electrocardiograph will switch off in order to conserve the battery life of the device. The battery time out will only occur if the keyboard has not been depressed for the time specified. The battery time out setting is ignored if an active ECG signal is detected during transmission or while rhythm printing.

Time Mode

Determines if time displays in a standard 12 hour or 24-hour clock setting.

ID Format

Defines the format for the patient data prompts. There are four standard formats: None, Short, Sex/Age, and Sex/DOB.

> **NOTE:** *When ID format is set to "None" (no age/DOB and gender), interpretation setting is automatically set to Off. To turn the interpretation setting back On requires the user to make a manual change in the configuration setting.*

AC Filter

The ELI 230 removes 60 Hz or 50 Hz interference. The setting you select depends on the line frequency in your country. Always use the 60 Hz setting in the U.S. If AC interference is present, check to see that the proper AC filter is selected.

Filter

The ECG plot-frequency filter (or print filter) can be set to 40 Hz, 150 Hz, or 300 Hz. The plot-frequency filter does not filter the acquired digital record. A 40 Hz plot-filter setting will reduce the noise (40 Hz and higher frequencies) on the printed ECG, and a 150 Hz plot-filter setting will reduce the noise (150 Hz and higher frequencies) on the printout; a 300 Hz plot-filter setting will not filter the printed ECG. The filter setting is printed at the bottom right corner of the ECG printout.

Paper Speed

Configure to 25 mm/s or 50 mm/s for default ECG printouts.

Rhythm Paper Speed

Configure to 5 mm/s, 10 mm/s, 25 mm/s, or 50 mm/s.

Interpretation Option

The ELI 230 automatically analyzes ECGs and prints the optional interpretation on the ECG printout. This setting allows you to select or suppress the "interpretive" text on the ECG printout.

> *NOTE: The ECG interpretation offered by the device are only significant when used in conjunction with a physician over-read as well as consideration of all other relevant patient data.*

Reasons

The reasons statements indicate why a particular interpretive statement was printed. Reasons statements print enclosed in [square brackets] within the interpretive text if the interpretation option is turned on. Turning the reasons statement function on or off does not affect the measurements performed or the interpretive statements selected by the analysis program.

> **For Example:**
> Anteroseptal Infarct [40+ ms Q WAVE IN V1-V4]
> Where "Anteroseptal Infarct" is the interpretive statement,
> and "40+ ms Q WAVE IN V1-V4" is the reason statement or explanation as to why the interpretive statement was printed.

Append

A status or statement phrase can be appended to the ECG and printed under the interpretive text printout. Either "unconfirmed report" or "reviewed by" can be selected.

Number of Copies

Defines the number of printed copies when an ECG is taken. A zero (0) setting prints the original only; one (1) prints the original plus 1 copy; two (2) prints the original plus 2 copies, and so on. Up to 9 copies may be selected.

Auto-Print ECG

Defines whether or not the ELI 230 will automatically print the ECG after acquisition. If the selected configuration option is set to No, a manual printout is possible.

Display Format

Defines the default display format in either 4+4 or 6+6. Regardless of the display format selected, 10 seconds of 12 leads are always acquired.

> *NOTE: The ELI 230 cannot acquire more than the current ECG. Once* **DONE** *is selected the ELI 230 starts monitoring or acquiring new ECG data.*

26

Plot Format

Defines the default for one of the available plot formats in either standard or Cabrera presentation. Regardless of the plot format selected, 10 seconds of 12 leads are always stored.

ECG plot options are:

Format Option	ECG Data
3+1	2.5 seconds of standard 12 leads in a 3-channel format, plus 10-second rhythm strip of one user-selectable lead in a 1-channel format.
6	5 seconds of standard 12 leads in a 6-channel format.
12	10 seconds of standard 12 leads in a 12-channel format

Rhythm Leads

Identifies the 3 or 6 user-selectable, 10-second rhythm leads for the 3 and 6 channel ECG printout.

> *NOTE: Rhythm acquisition is not stored in memory, only printed.*

> *NOTE: See Section 3 to acquire a rhythm printout.*

Average RR

Enabling this option will display an averaged RR value to appear on the report.

QTcB

Enabling this option will display a Bazett's corrected QT value on the report along with the default linear QTc value.

QTcF

Enabling this option will display a Fridericia corrected QT value on the report along with the default linear QTc value.

Pace Spike Channel

Determines whether a pacemaker spike notification marker will display.

ECG Capture

Up to one minute accumulated ECG data can be acquired internally for use with the Best 10 feature. The device automatically selects the best 10 seconds from within the one-minute buffer.

Users can switch between BEST 10 or LAST 10 by selecting **BEST10** or **LAST10** from acquired ECG view.

Storage Warning

Determines whether a storage warning will display when the electrocardiograph is near the maximum storage level.

MAINTENANCE AND TROUBLESHOOTING

System Troubleshooting Chart

LCD Message	Problem	Correction
BATTERY LOW – CHARGE UNIT	Unable to acquire ECG or unable to print.	Charge the battery with AC power.
LEAD FAULT, NO ECG CAPTURE	Lead fail or noisy ECG data.	Correct faulty lead or noise.
USB MEMORY	USB memory stick not recognized or working	Ensure the USB memory stick contains a "Records" directory. Verify device displays real-time ECG view. USB memory stick must be formatted to FAT 32.

ECG Troubleshooting Chart

Affected Leads	Problem	Correction
LEADS OFF OR ONE OR MORE OF THE FOLLOWING: RA, LA, LL, V1, V2, V3, V4, V5, V6	Lead fail.	Indication of RL/RA/LA/LL/V1/V2/V3/V4/V5/V6. Check limb leads. Correct faulty lead(s).
Lead I	Missing/Noisy RA/LA.	Check patient prep; re-prep if necessary with new electrode.
Lead II	Missing/Noisy RA/LL.	Check patient prep; re-prep if necessary with new electrode.
Lead III	Missing/Noisy LA/LL.	Check patient prep; re-prep if necessary with new electrode.
All	High Freq. Noise.	Notch down filter from 300 Hz to 150 Hz; check proximity to power cables.

Test Operation

After cleaning and inspecting the ELI 230, proper operation of the unit may be confirmed by using an ECG simulator to acquire and print a standard 12-lead ECG of known amplitude. Printing should be dark and even across the page. There should be no evidence of print head dot failure (e.g., breaks in printing forming horizontal streaks). Paper motion should be smooth and consistent during printing. Waveforms should appear normal with proper amplitude and, without distortion or excessive noise.

Recommendations to Biomedical Staff

Following any service to the ELI 230 or when non-compliant operation is suspected, Mortara Instrument, Inc. recommends the following procedures:

- Confirm proper operation.
- Perform testing to ensure continued electrical safety of the device (use IEC 60601-1 or ANSI/AAMI ES1 methods and limits).
  - patient leakage current
  - chassis leakage current
  - earth leakage current
  - dielectric strength (mains and patient circuits)

Battery Maintenance

The ELI 230 houses an internal, sealed lead-acid battery. When installed, the battery has a shelf life of approximately six months without recharging. If the battery has been stored for a long period in a discharged state, it may not be able to regain its capacity even if it is recharged.

For information about replacing the battery, please refer to the ELI 230 service manual.

Mortara Instrument, Inc. recommends that the ELI 230 be plugged into AC power whenever possible to maximize battery life and for the user to develop a habit of recharging the battery before the unit indicates a "low battery" condition. (That is, reduced depth of discharge.) Battery life varies by how the battery is maintained and how much it is used. For improved battery life, keep the electrocardiograph plugged in when not in use.

The sealed lead-acid battery will provide optimum life when the unit is fully charged after each use. The ELI 230 will charge a depleted battery to 85% of its capacity in approximately 6 hours or less

Cleaning the Thermal Printer

To clean the printer

1. Disconnect the power source.

2. Clean the exterior surface of the unit with a damp cloth using a solution of mild dishwashing detergent diluted in water.

3. After washing, thoroughly dry off the unit with a clean, soft cloth or paper towel.

To clean the print head

NOTE: Do not let soap or water come into contact with the writer, plugs, jacks, or vents.

1. Open writer door.

2. Lightly rub print head with an alcohol pad.

3. Wipe with a clean cloth to remove alcohol residue.

4. Allow print head to air dry.

5. Clean the platen by using adhesive tape. Apply the tape and pull it off. Rotate roller and repeat until entire roller is clean.