Mortara

www.mortara.com

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ELI 350

RESTING ELECTROCARDIOGRAPH

USER MANUAL

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

CE 0459

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

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Biomedical Training Classes
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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.

Copyright and Trademark Notices

Other Important Information

The information in this document is subject to change without notice.

Mortara Instrument, Inc. makes no warranty of any kind with regard to this material including, but not limited to, implied warranties of merchantability and fitness for a particular purpose. Mortara Instrument, Inc. assumes no responsibility for any errors or omissions that may appear in this document. Mortara Instrument, Inc. makes no commitment to update or to keep current the information contained in this document.

WARRANTY INFORMATION

Your Mortara Warranty

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 twelve (12) 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.

THE REMEDY UNDER THIS WARRANTY IS LIMITED TO THE REPAIR OR REPLACEMENT WITHOUT CHARGE FOR LABOR OR MATERIALS, OR ANY PRODUCT/S FOUND UPON EXAMINATION BY MORTARA TO HAVE BEEN DEFECTIVE. This remedy shall be conditioned upon receipt of notice by Mortara of any alleged defects promptly after discovery thereof within the warranty period. Mortara's obligations under the foregoing warranty will further be conditioned upon the assumption by the purchaser of the Product/s (i) of all carrier charges with respect to any Product/s returned to Mortara's principal place or any other place as specifically designated by Mortara or an authorized distributor or representative of Mortara, and (ii) all risk of loss in transit. It is expressly agreed that the liability of Mortara is limited and that Mortara does not function as an insurer. A purchaser of a Product/s, by its acceptance and purchase thereof, acknowledges and agrees that Mortara is not liable for loss, harm, or damage due directly or indirectly to an occurrence or consequence therefrom relating to the Product/s. If Mortara should be found liable to anyone under any theory (except the expressed warranty set forth herein) for loss, harm, or damage, the liability of Mortara shall be limited to the lesser of the actual loss, harm, or damage, or the original purchase price of the Product/s when sold.

EXCLUDED FROM THE LIMITED WARRANTY SET FORTH ABOVE ARE CONSUMABLE ITEMS SUCH AS PAPER, BATTERIES, ELECTRODES, PATIENT CABLES, LEAD WIRES, AND MAGNETIC STORAGE MEDIUMS.

EXCEPT AS SET FORTH HEREIN WITH RESPECT TO REIMBURSEMENT OF LABOR CHARGES, A PURCHASER'S SOLE EXCLUSIVE REMEDY AGAINST MORTARA FOR CLAIMS RELATING TO THE PRODUCT/S FOR ANY AND ALL LOSSES AND DAMAGES RESULTING FROM ANY CAUSE SHALL BE THE REPAIR OR REPLACEMENT OF DEFECTIVE PRODUCT/S TO THE EXTENT THAT THE DEFECT IS NOTICED AND MORTARA IS NOTIFIED WITHIN THE WARRANTY PERIOD. IN NO EVENT, INCLUDING THE CLAIM FOR NEGLIGENCE, SHALL MORTARA BE LIABLE FOR INCIDENTAL, SPECIAL, OR CONSEQUENTIAL DAMAGES, OR FOR ANY OTHER LOSS, DAMAGE, OR EXPENSE OF ANY KIND, INCLUDING LOSS OF PROFITS, WHETHER UNDER TORT, NEGLIGENCE OR STRICT LIABILITY THEORIES OF LAW, OR OTHERWISE. THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO THE IMPLIED WARRANTY OF MERCHANTABILITY AND THE WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE.

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.
- 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 (7 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 electrodes, 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 does not automatically switch between direct or wireless patient cables. Clinician must choose patient cable before ECG acquisition.

- 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.

- To improve immunity to potential interfering electromagnetic signals, shielded cabling is recommended when connecting the device to a network.

- To maintain operator and patient safety, equipment connected to the same network as the device must meet the requirements of IEC 60950 or IEC 60601-1.

- To prevent electric shock due to unequal ground potentials that may exist between points of a distributed network system or fault conditions in external network connected equipment, network cable shielding (where used) must be connected to protective earth ground appropriate to the area where the device is used.

- 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. Do not connect a telephone line cable to the LAN connector.

- This device may contain a GSM/GPRS (cellular modem) or wireless LAN (WLAN) module for transmitting ECG records. Device labeling and the presence of an antenna port will indicate if your device is equipped with such a module. If so equipped, the following notices apply:

    - The WLAN identification can be found on a label on the bottom of the device.
        - Quatech, Inc. Model WLNG-AN-DP101: 2400 MHz
          (model subject to change without notice)

- Use of the GSM/GPRS or WLAN module may interfere with other equipment operating in the vicinity. Check with local authorities or spectrum management officials in your facility to determine if restrictions apply to the use of this feature in your area.

- Do not transmit via the GSM/GPRS or WLAN module with a missing or damaged antenna. Replace a damaged antenna immediately.

- Use only the antenna supplied for use with this device. Unauthorized antennas, modifications, or attachments could damage the GSM module and may contravene local RF emission regulations or invalidate type approval.

- To ensure compliance with current regulations limiting both maximum RF output power and human exposure to radio frequency radiation, a separation distance of at least 20 cm must be maintained between the device's antenna and the head and body of the user and any nearby persons at all times. To help prevent degradation of RF signal and to avoid excess RF energy absorption, do not touch the antenna during data transmission.

- The GSM/GPRS and WLAN modules comply with applicable RF safety standards including standards and recommendations for the protection of public exposure to RF electromagnetic energy that have been established by governmental bodies and other qualified organizations, such as the following:
    - Federal Communications Commission (FCC)
    - Directives of the European Community
    - Directorate General V in Matters of Radio Frequency Electromagnetic Energy

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 electrode is not properly connected to the patient, or one or more of the patient cable lead wires is damaged, 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

- The device will automatically turn off (blank screen) if the batteries have been severely discharged and the AC mains is disconnected from the device.
- 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.
- WAM (wireless acquisition module) must be paired to electrocardiograph before operation.
- The device must be configured at the factory for use with the WAM.
- 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

Wireless Data Transmission

- The device can be equipped with an optional wireless data transmission module (WLAN or GSM). Both these technologies use radios to transmit data to a Mortara receiving application. Due to the nature of radio transmissions, it's possible that, due to the characteristics of the environment where the device is located, some other RF sources may interfere with the transmission generated by the device. Mortara Instrument has tested the coexistence of the device with other devices that can interfere such as devices using WLAN, Bluetooth radio, and/or cell phones. Although the current technology allows a very successful rate of transmission, it's possible that in some rare occurrences, the system may not perform at its best resulting in a "failed transmission". When this occurs, patient data will not be erased from the device nor stored in the receiving application, ensuring that partial or corrupted data are not made available to the receiving station. If the failure mode persists the user should move to a position where the RF signals may propagate better and allow successful transmissions.

WLAN Option

- Wireless options transmit at 2.4 GHz. Other nearby wireless devices may cause interference. If possible, move or turn off other devices to minimize potential interference.

- The following table shows the channels allocated in different geographic areas in the world. Please consult with your IT personnel in order to set the device on the proper channels.

Specification	Description
Technology	IEEE 802.11 b/g DSSS, WiFi compliant
Frequency	2.400 – 2.4835 GHz (U.S./CAN/Japan/Europe) 2.471 – 2.497 GHz (Japan)
Channels	U.S.A./CANADA: 11 channels (1-11) Europe: 13 Channels (1-13) Japan: 14 Channels (1-14) France: 4 Channels (10-13)
RF Power	+15dBm (typical) approx. 32 mW

- The following table lists the frequency allocated for each channel used by the WLAN option.

Channel	Center Frequency	Frequency Spread
1	2412 MHz	2399.5 MHz - 2424.5 MHz
2	2417 MHz	2404.5 MHz - 2429.5 MHz
3	2422 MHz	2409.5 MHz - 2434.5 MHz
4	2427 MHz	2414.5 MHz - 2439.5 MHz
5	2432 MHz	2419.5 MHz - 2444.5 MHz
6	2437 MHz	2424.5 MHz - 2449.5 MHz
7	2442 MHz	2429.5 MHz - 2454.5 MHz
8	2447 MHz	2434.5 MHz - 2459.5 MHz
9	2452 MHz	2439.5 MHz - 2464.5 MHz
10	2457 MHz	2444.5 MHz - 2469.5 MHz
11	2462 MHz	2449.5 MHz - 2474.5 MHz
12	2467 MHz	2454.5 MHz - 2479.5 MHz
13	2472 MHz	2459.5 MHz - 2484.5 MHz
14	2484 MHz	2471.5 MHz – 2496.5 MHz

- In order to achieve the best transmission rate, it is necessary that the facility where the device is operated can provide good area coverage. Please consult the IT personnel of the facility to verify the proper WLAN availability in the area where the device will be used.

- RF wave propagation may be blocked or reduced by the environment where the device is used. Most common areas where this may occur are: shielded rooms, elevators, underground rooms. In all such situations it is recommended to move the device to a proper location and verify with the IT personnel of the facility the areas where the WLAN signals are available.

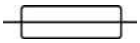
EQUIPMENT SYMBOLS AND MARKINGS

Symbol Delineation

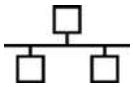

Attention, consult accompanying documents


Alternating current


Protective earth


Fuse


Telephone line (modem)


Network (LAN)


Universal Serial Bus (USB)


Defibrillator-proof type CF applied part


Output/Transmit


Input


ON/OFF (power)


Stop (of action)


Shift key (to enter upper case text)


Space key

	Enter key (accept data/return)
AUTO	Initiate acquisition of ECG
RHY	Initiate printing of continuous rhythm strip
XMT	Initiate transmission of records
STOP	Stop rhythm print out
	Do not dispose as unsorted municipal waste. Per EC Directive 2002/96, requires separate handling for waste disposal according to national requirements
	Antenna
	Indicates compliance to applicable EEC 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**: Do not attempt to clean/disinfect the device or patient cables by submerging into a liquid, autoclaving, or steam cleaning. Never expose cables to strong ultra-violet radiation.*

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.

Sterilization

EtO sterilization is not recommended but may be required for cables and lead wires. Frequent sterilization will reduce the useful life of cables and lead wires. If required, sterilize with ethylene oxide gas (EtO) at a maximum temperature of 50°C/122°F. After EtO sterilization, follow the recommendations from the sterilizer manufacturer for required aeration.

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 and cables other than those specified below, may result in increased emissions or decreased immunity of the device.

Part Number	Description
9293-032-50	PAT CBL 10WIRE AHA BANANA JSCREW
9293-032-51	PAT CBL 10WIRE IEC BANANA JSCREW
9293-033-50	PAT CBL 10WIRE AHA SNAP JSCREW
9293-033-51	PAT CBL 10WIRE IEC SNAP JSCREW
9293-039-50	ECG CABLE RDS TRUNK/YOKE 10 WIRE
9293-040-50	ECG CABLE RDS 10 WIRE BANANA AHA
9293-040-51	ECG CABLE RDS 10 WIRE BANANA IEC
9293-041-50	RPLCMNT LEAD SET RDS 10 WIRE BANANA AHA
9293-041-51	RPLCMNT LEAD SET RDS 10 WIRE BANANA IEC
9293-041-60	REPLACEMENT RDS V3R V4R V7 AHA BANANA
9293-041-61	REPLACEMENT RDS C3R C4R C7 IEC BANANA
9293-041-62	REPLACEMENT LEAD SET V7, V8, V9 LEADS AHA BANANA
9293-041-63	REPLACEMENT LEAD SET C7, C8, C9 LEADS IEC BANANA
9293-042-50	ECG CABLE RDS 10 WIRE CLIPS AHA
9293-042-51	ECG CABLE RDS 10 WIRE CLIPS IEC
9293-043-50	RPLCMNT LEAD SET RDS 10 WIRE CLIPS AHA
9293-043-51	RPLCMNT LEAD SET RDS 10 WIRE CLIPS IEC
9293-043-52	REPLACEMENT RDS LIMBS AHA CLIPS
9293-043-53	REPLACEMENT RDS LIMBS IEC CLIPS
9293-043-54	REPLACEMENT RDS V1-V3 AHA CLIPS
9293-043-55	REPLACEMENT RDS C1-C3 IEC CLIPS
9293-043-56	REPLACEMENT RDS V4-V6 AHA CLIPS
9293-043-57	REPLACEMENT RDS C4-C6 IEC CLIPS
9281-002-50	ADAPTER 4mm BAN PLG TO SNAP LDWIRE PK/10
3181-008	POWER CORD HOSPITAL GRADE 8FT DOM
3181-002	POWER CORD INTERNATIONAL

Table X-1 Guidance and Manufacturer's Declaration: Electromagentic 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 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
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.

<table>
<tr><th>Emissions Test</th><th>IEC 60601 Test Level</th><th>Compliance Level</th><th>Electromagentic Environment: Guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
150 kHz to
80 MHz</td><td>3 Vrms
150 kHz to
80 MHz</td><td rowspan="2">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

$d = \left[\frac{3.5}{3Vrms}\right]\sqrt{P}$

$d = \left[\frac{3.5}{3V/m}\right]\sqrt{P}$ 80 MHz to 800 MHz

$d = \left[\frac{7}{3V/m}\right]\sqrt{P}$ 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:

  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to
2.5 GHz</td><td>3 V/m
80 MHz to
2.5 GHz</td></tr>
</table>

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.

Tabel 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.*

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MAINTENANCE AND TROUBLESHOOTING APPENDIX A

INTRODUCTION

Manual Purpose

This manual is intended to provide the user with information about:

- Using and understanding the ELI™ 350 electrocardiograph, the function and feature keys, the display screen, and navigating the user interface.
- Preparing the ELI 350 for use. (Section 2)
- Acquiring, printing, and storing an ECG. (Section 3)
- Connectivity and transmitting ECGs. (Section 4)
- Maintaining the ECG directory. (Section 5)
- System settings. (Section 6)
- 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

- The device is indicated for use to acquire, analyze, display, and print electrocardiograms.
- The device is indicated for use to provide interpretation of the data for consideration by a physician.
- The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed 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 a physician over-read as well as consideration of all other relevant patient data.
- The device is indicated for use on adult and pediatric populations.
- The device is not intended to be used as a vital signs physiological monitor.

System Description

The ELI 350 is a multi-lead diagnostic electrocardiograph capable of acquiring, viewing, transmitting, printing, and storing 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 6) 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 to ECG Interpretation* (see Accessories).

The ELI 350 can also be configured with expanded memory including full-disclosure data capture, bi-directional connectivity, and DICOM® protocol support. The device can operate on battery or line power, and offers two different user-interface options: touchpad or click knob.

Supported print formats include: 3, 3+1, 6 channel, 3+3, 12 channel, 6+6 channel, 15 channel, Cabrera 3+1, Cabrera 6, Cabrera 3+3, Cabrera 6+6, or Cabrera 12 lead.

The ELI 350 includes:

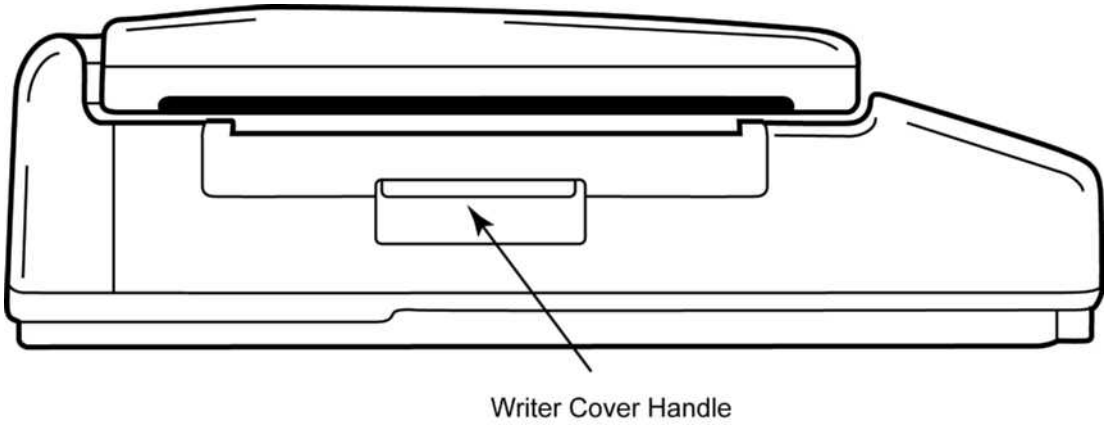
- Patient cable with lead wire set
- Hospital-grade power cord
- Cart/trolley with storage bins (not available in all configurations)
- Antenna (with WLAN option)
- 1 pack paper (standard or A4)
- Physicians Guide to ECG Interpretation (with interpretation feature)
- User's manual
- Accessory starter kit

ELI 350, System Illustration

Figure 1-1

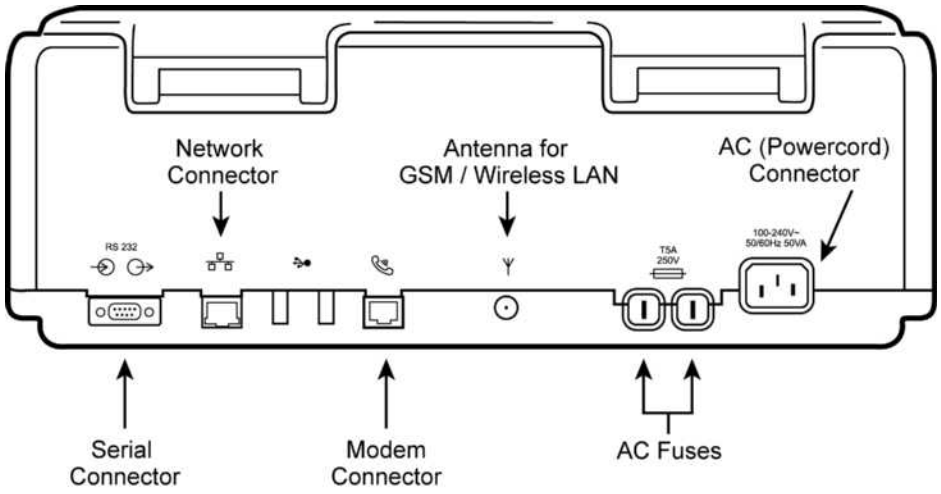
ELI 350, Side View

Figure 1-2



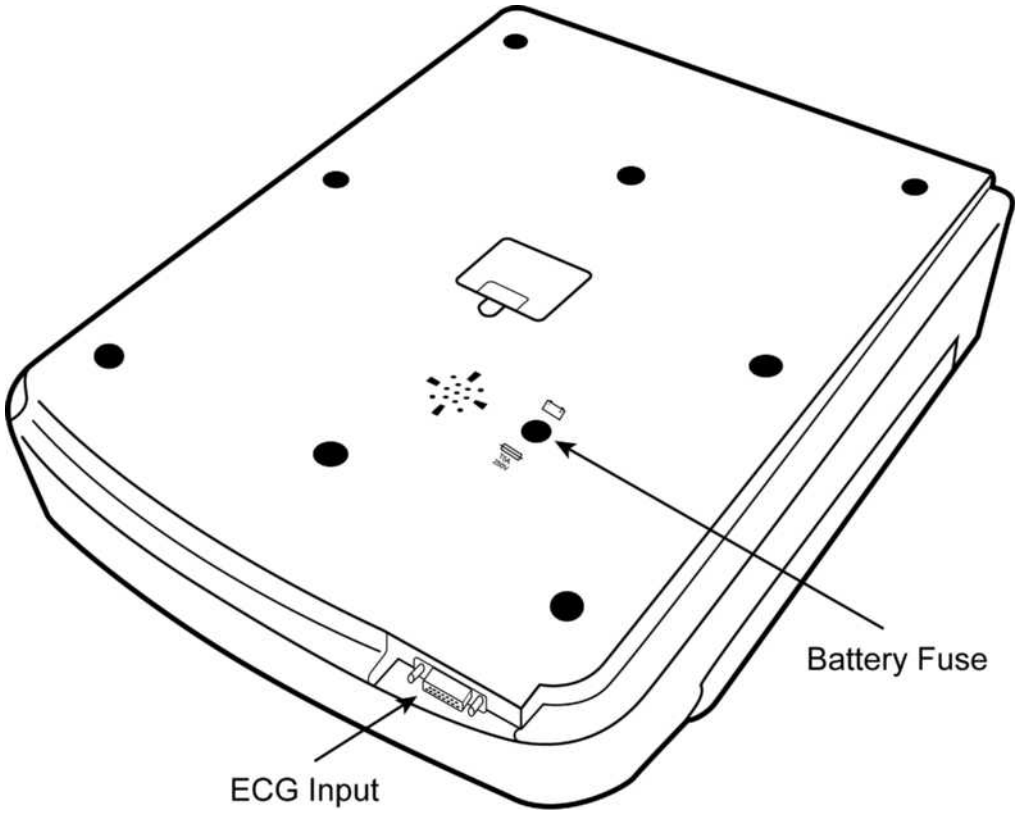
ELI 350, Rear View

Figure 1-3



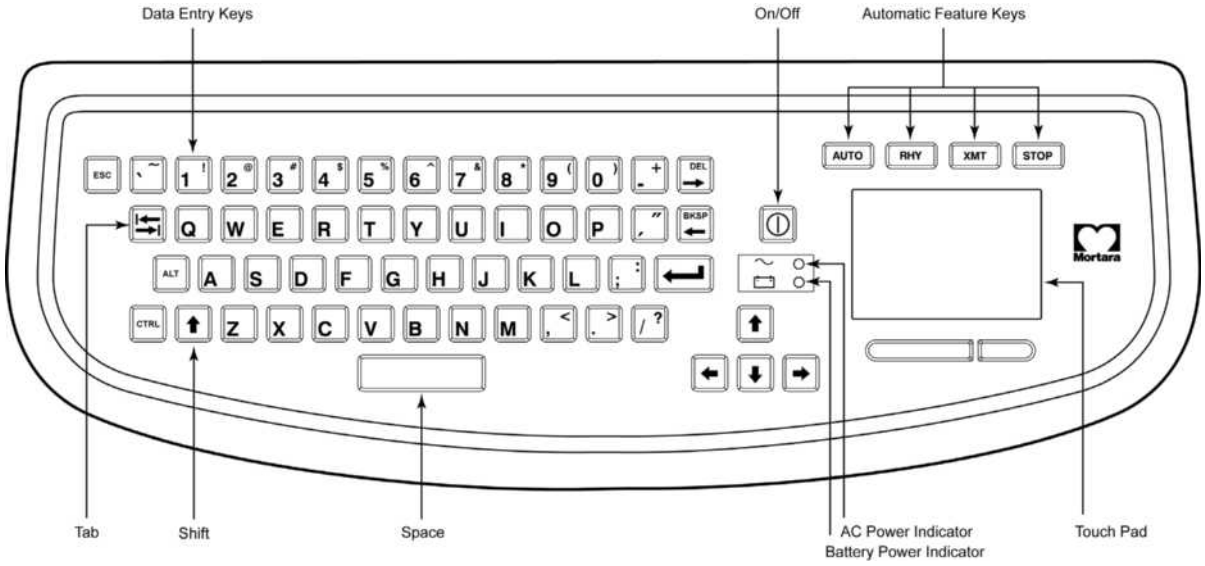
ELI 350, Base View

Figure 1-4



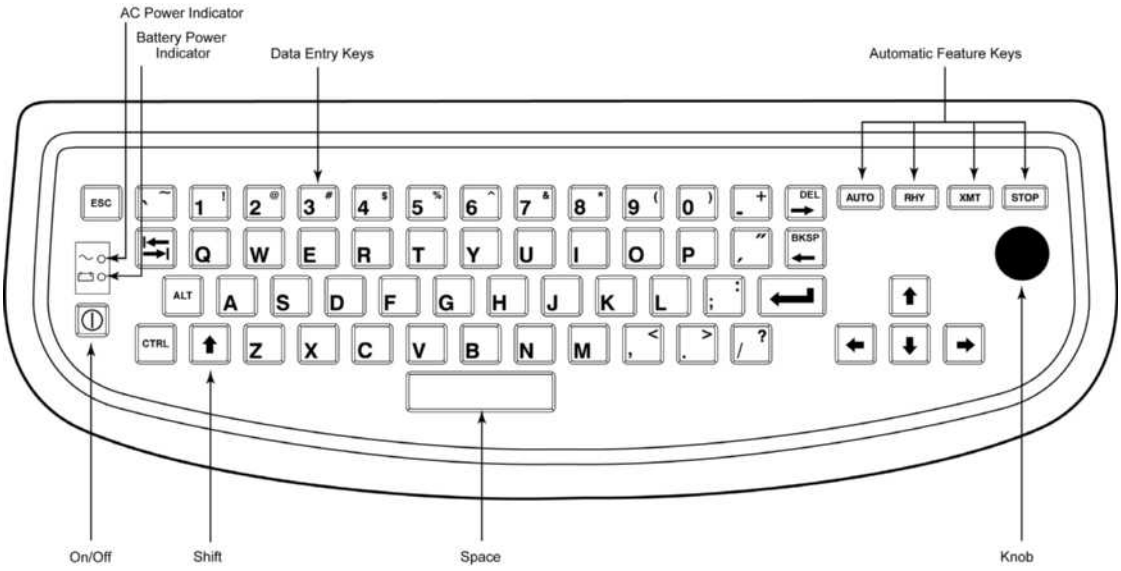
ELI 350, Keyboard Touchpad

Figure 1-5



ELI 350, Keyboard Click Knob

Figure 1-6



Automatic Feature Keys

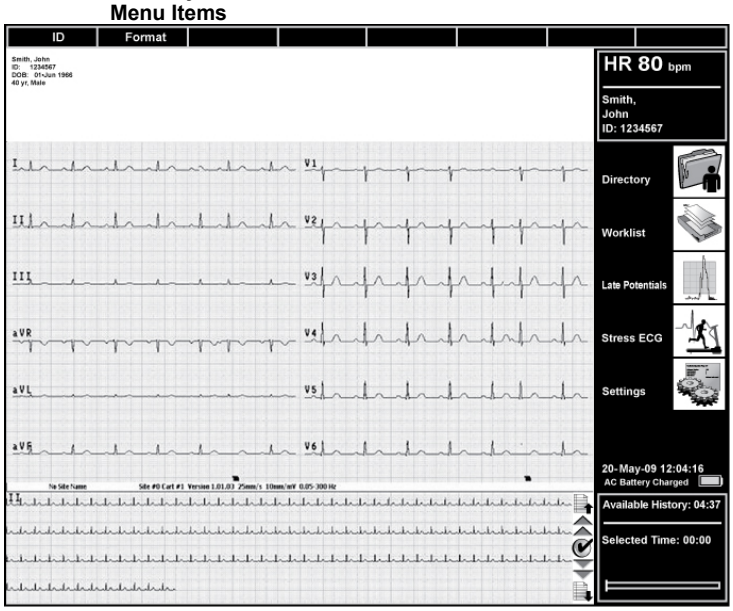
Automatic feature keys are used as a one-touch operation for:

AUTO	ECG Acquisition
RHY	Rhythm Printing
XMT	Transmitting
STOP	Stop

Display Overview

The ELI 350 features a 17" 1280 x 1024 LCD display for valuable preview of ECG waveform and other parameters as explained below.

Figure 1-7



- **Softkey Menu Items.** Display across the top of the screen. These menu items change depending on which screen is displayed.
- **Patient Demographics.** Any entered patient demographics will display in the upper right-hand corner.
- **12-lead Real-time ECG View.** A 6+6 lead format displays all 12 leads. Lead groups are simultaneous and each lead is 5 seconds in duration. If the 15-lead option is enabled, the augmented leads (aVR, aVL, aVF) are replaced by leads V3R, V4R, V7; V7, V8, V9; or E1, E2, E3 depending on system settings (see Section 6).
- **Full-disclosure ECG Buffer.** Up to 2 minutes accumulated ECG data displays at the bottom. Although only a single lead is visible, accumulated data is stored for all 12 or 15 leads along with up to 20 minutes of full-disclosure data which can also be reviewed.
- **Patient Heart Rate (HR).** When a patient is connected to the ELI 350, 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, an indicator flashes in this location.*

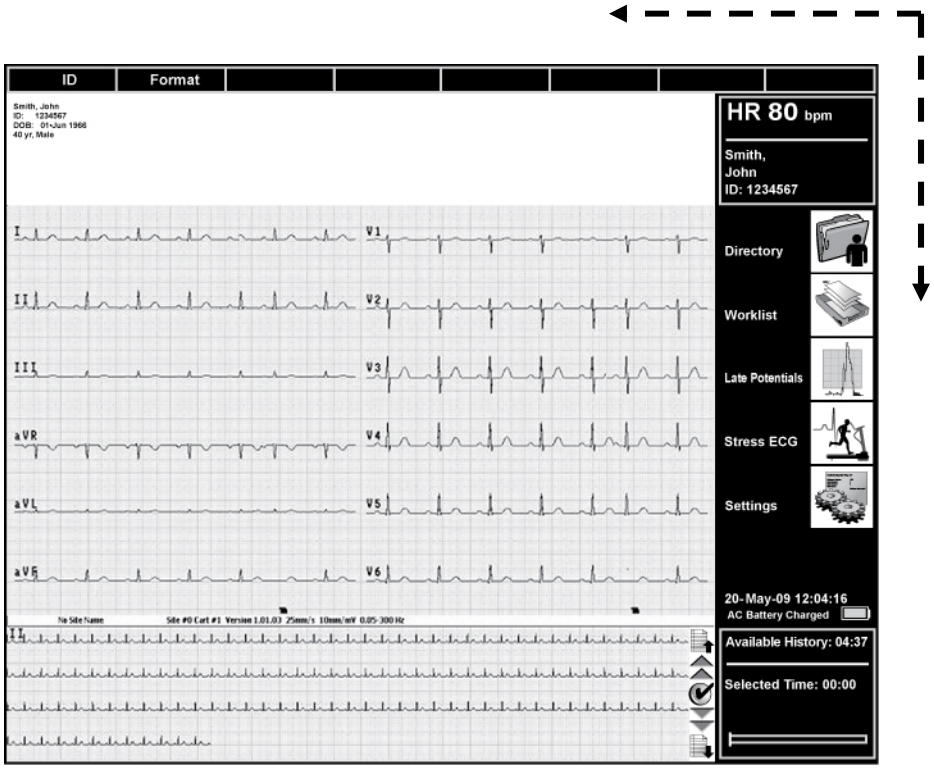
- **Date/Time and Battery Status.** Current date/time and battery status display in the lower right-hand side. See Section 2 for explanation of battery indications.
- **ID and Format Menus.** Allows user input of patient demographics as well as setting of display and print formats for acquiring a resting ECG.

Navigation Overview

Navigation of the user interface is achieved with either a touchpad point-and-click interface, or with a click knob rotary select and click interface. Use of the touchpad requires navigating the mouse arrow over the desired action and clicking. Use of the click knob requires turning the knob to the desired action and pressing the knob. When using the click knob, the keyboard up/down arrows permit navigation within a drop-down menu. The **TAB** key moves from one field to another.

Navigation with Click Knob

Figure 1-8



Rotary Selection Clockwise or Counter Clockwise Through "Softkey" and Button Menu Items

***NOTE**: Some features may require purchase of additional options.*

ELI 350 Specifications

Feature	Specifications
Instrument Type	12 or 15-lead resting electrocardiograph
Input Channels	Simultaneous acquisition of all 12 or 15 leads
Standard Leads Acquired	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 optional V3R, V4R, V7; V7, V8, V9; or E1, E2, E3
Waveform Display	Backlit, 17 ” SXGA color LCD display
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 the requirements of ANSI/AAMI ES1
Digital Sampling Rate	10,000 s/sec/channel used for pacemaker spike detection; 1000 s/sec/channel used for recording and analysis
Special Functions	Optional Mortara VERITAS resting ECG interpretation with age and gender specific algorithm; connectivity options for bi-directional communication; Exercise Stress option with report generation; Late Potential
Paper Type	Full-size (8.5 x 11” or A4), Z-fold thermal paper; 250 sheets stored in paper tray
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: 3+1, 3+3, 6, or 12 channel
Rhythm Print Formats	3, 6, or 12 channel with configurable lead groups
Keyboard Type	Elastomer keypad with complete alphanumeric keys, soft-key menu, and dedicated function keys. Click knob or touchpad option
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
A/D Conversion	20 bits (1.17 microvolt LSB)
Device Classification	Class I, Type CF defibrillation-proof applied parts
ECG Storage	Internal storage up to 200 ECGs; optional expanded up to 500 or 2,000 ECGs
Weight	27.9 lbs. (12.68 kg) including battery (without paper)
Dimensions	15.5 x 17 x 6” (39.4 x 43.2 x 15.2 cm)
Power Requirements	Universal AC power supply (100-240 VAC at 50/60 Hz) 150 VA; internally rechargeable battery

Accessories

PART NUMBER	DESCRIPTION
9300-032-50	ECG MONITORING ELECTRODES CASE 300
9300-036	ELECTRODES RESTING 24mm SUCTION PK/6
9300-037	ELECTRODE RESTING CLAMP IEC PK/4 IEC
9300-033-51	ELECTRODE RESTING TAB BOX/500
9300-033-52	ELECTRODE RESTING TAB CASE/5000
9100-026-50	PAPER ELI 250 HDR US CASE/12/250 ZFOLD
9100-026-51	PAPER ELI 250 HDR A4 CASE/12/250 ZFOLD
9903-026-50	STAND BAR CODE SCANNER THRU-HOLE MOUNT
9911-013-63	CABLE ARM/ADAPTER FOR ELI CART
25000-027-61	CABLE ASSY 9 POS CPU TO ELI 250
9042-057-02	LABELING LEAD-WIRE V3R, V4R, V7 AAMI/IEC
9042-057-03	LABELING LEAD-WIRES V7, V8, V9 AAMI/IEC
9293-032-50	PAT CBL 10WIRE AHA BANANA JSCREW
9293-032-51	PAT CBL 10WIRE IEC BANANA JSCREW
9293-033-50	PAT CBL 10WIRE AHA SNAP JSCREW
9293-033-51	PAT CBL 10WIRE IEC SNAP JSCREW
9293-039-50	ECG CABLE RDS TRUNK/YOKE 10 WIRE
9293-040-50	ECG CABLE RDS 10 WIRE BANANA AHA
9293-040-51	ECG CABLE RDS 10 WIRE BANANA IEC
9293-040-60	ECG CABLE RDS 13 WIRE BANANA AHA
9293-040-61	ECG CABLE RDS 13 WIRE BANANA IEC
9293-041-50	RPLCMNT LEAD SET RDS 10 WIRE BANANA AHA
9293-041-51	RPLCMNT LEAD SET RDS 10 WIRE BANANA IEC
9293-041-52	REPLACEMENT RDS LIMBS AHA BANANA
9293-041-53	REPLACEMENT RDS LIMBS IEC BANANA
9293-041-54	REPLACEMENT RDS V1-V3 AHA BANANA
9293-041-55	REPLACEMENT RDS C1-C3 IEC BANANA
9293-041-56	REPLACEMENT RDS V4-V6 AHA BANANA
9293-041-57	REPLACEMENT RDS C4-C6 IEC BANANA
9293-041-60	REPLACEMENT RDS V3R V4R V7 AHA BANANA
9293-041-61	REPLACEMENT RDS C3R C4R C7 IEC BANANA
9293-041-62	REPLACEMENT RDS V7-V9 AHA BANANA
9293-041-63	REPLACEMENT RDS C7-C9 IEC BANANA
9293-042-50	ECG CABLE RDS 10 WIRE CLIPS AHA

PART NUMBER	DESCRIPTION
9293-042-51	ECG CABLE RDS 10 WIRE CLIPS IEC
9293-043-50	RPLCMNT LEAD SET RDS 10 WIRE CLIPS AHA
9293-043-51	RPLCMNT LEAD SET RDS 10 WIRE CLIPS IEC
9293-043-52	REPLACEMENT RDS LIMBS AHA CLIPS
9293-043-53	REPLACEMENT RDS LIMBS IEC CLIPS
9293-043-54	REPLACEMENT RDS V1-V3 AHA CLIPS
9293-043-55	REPLACEMENT RDS C1-C3 IEC CLIPS
9293-043-56	REPLACEMENT RDS V4-V6 AHA CLIPS
9293-043-57	REPLACEMENT RDS C4-C6 IEC CLIPS
9281-002-50	ADAPTER 4mm BAN PLG TO SNAP LDWIRE PK/10
9325-001-50	ADAPTER 4mm ALLIGATOR CLIP PK/10
9515-001-50-ENG	PHYSICIAN'S GUIDE ADULT & PEDIATRIC USER MANUAL
9515-166-50-GER	ELI LINK USER MANUAL GERMAN
9515-166-50-ITA	ELI LINK USER MANUAL ITALIAN
9515-166-50-ENG	ELI LINK USER MANUAL ENGLISH
9293-039-60	ECG CABLE RDS TRUNK/YOKE 13/14 WIRE
9515-171-50-CD	ELI 350 USER MANUALS
9516-171-50-ENG	ELI 350 SERVICE MANUAL
9903-029	CABLE BAR CODE SCANNER USB
9911-014-51	CART ELI 350 W/2 LARGE BINS
9911-014-53	CART ELI 350 2F/2S W/2 LARGE BINS
9911-013-61	STORAGE BIN FRONT CART ASSY ELI XXX
9911-013-62	STORAGE BIN REAR CART ELI XXX
9903-021-52	BAR CODE SCANNER HAND-HELD FOR USB
30012-019-50	WIRELESS ACQUISITION MODULE

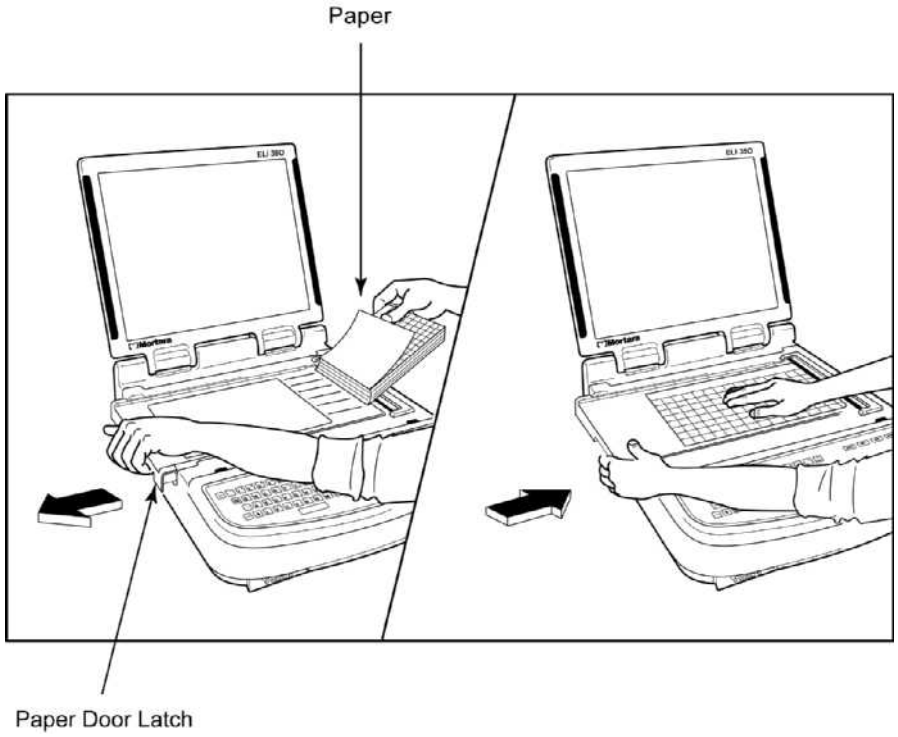
Connecting the Patient Cable

Connect patient cable to the patient-cable connector on the front left side of the device.

Figure 2-1

Loading Paper

Figure 2-2



1. Remove packaging and cardboard backing from the paper stack.

2. Facing the front of the device, use the release latch on the left side and slide the paper tray cover to the left.

3. Place the stack of thermal paper into the paper tray such that the grid side of the paper is up when it is pulled over the paper tray cover. The paper cue mark (a small black rectangle) should be in the lower left corner.

4. Manually advance one page of paper beyond the closure point. Make sure the paper lays on the black roller evenly within the channel of the paper door. If paper is not manually advanced evenly, risk of jamming or queue faults increases.

5. Slide paper tray cover to the right until the cover latches in a locked position. You will hear a sharp click when the cover is properly latched.

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

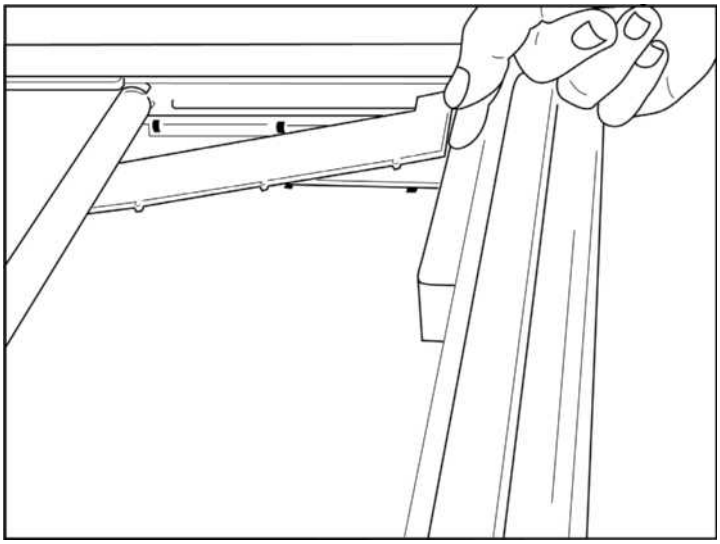
NOTE: *For proper performance of thermal printer, be certain to use Mortara recommended thermal paper.*

A4 Paper Users

If the device was ordered with A4 paper, the paper tray spacer will be inserted in the paper tray and the configuration option to use A4 paper will be set to YES. A paper tray spacer will not be provided if the device was purchased with standard paper.

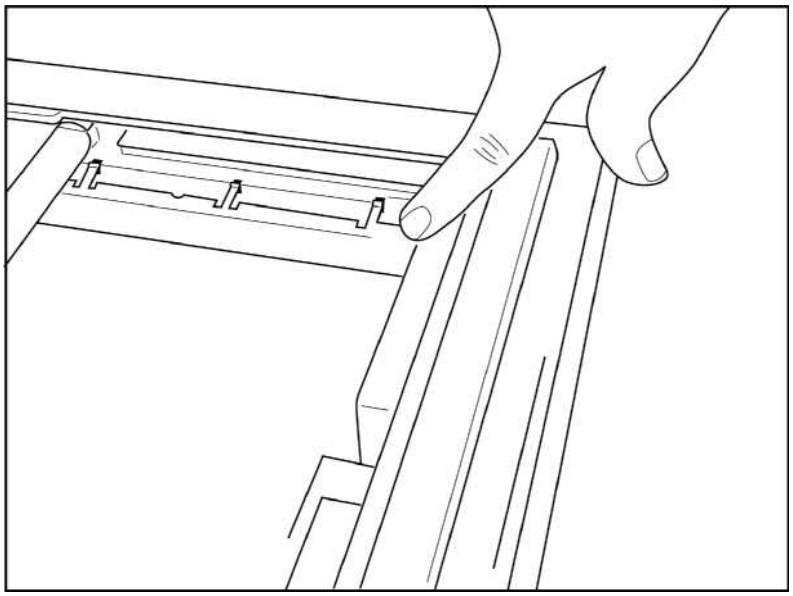
To insert the paper tray spacer:

Figure 2-3



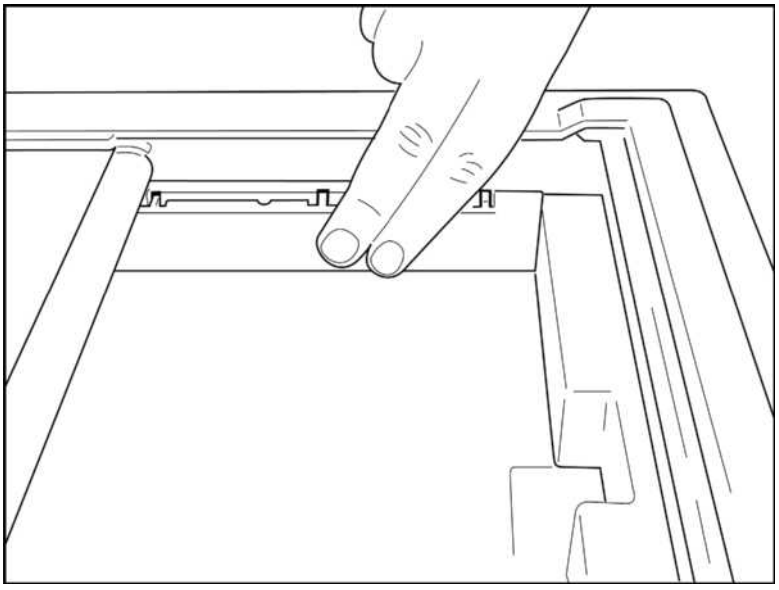
1. Slide paper tray spacer towards rear wall of paper tray. Align the bottom four plastic arms with the four openings in the base of the paper tray. Similarly, align the top 3 plastic arms with the three openings on the rear wall of the paper tray.

Figure 2-4



2. The paper tray spacer should be parallel with the rear wall of the paper tray.

Figure 2-5



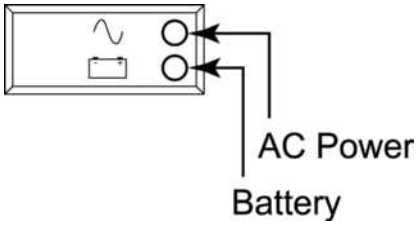
3. Gently press paper tray spacer in place.
4. Set configuration option to use A4 paper. (See Section 6.)
5. Gently press on the top three plastic arms to remove the paper tray spacer.

Applying Power

1. Plug the power cord into an AC wall outlet and into the back of the ELI 350. (Reference Figure 1-3.)

2. Press the power ON/OFF button ⏻ on the keyboard.

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 is used to indicate the following conditions:
  - ON indicates battery is charging.
  - Initial FLASHING on power up indicates system boot-up has begun; no buttons should be pushed until boot up is complete, approximately 30 seconds.
  - FLASHING while in use indicates battery is critically low and device must be attached to AC power.
  - OFF indicates battery is fully charged.

When device is operating on battery power, the battery icon in the lower right-hand corner of the display indicates battery status:

- WHITE indicates charging and device is plugged into an AC power source.
- GREEN indicates battery is between 100 and 35% charge.
- YELLOW indicates battery is between 35 and 20% charge.
- RED indicates battery is between 20 and 0% charge. Device will automatically power down.

Immediately plug the ELI 350 into AC power if the battery indicator turns red.

The ELI 350 should be connected to AC power for recharging when not in use.

NOTE: *Two AC line fuses and one battery fuse are installed on your ELI 350.*

NOTE: *There are configurable features on the ELI 350 that can be used to help prolong battery life (see Section 6). Proper battery care and maintenance will also help prolong battery life.*

NOTE: *When the battery charge is depleted to its lowest level (10.6V), the device will automatically power down. To recharge a battery from its lowest level to 85%, 4 hours of recharging may be necessary. To reach 90%, 7 hours of recharging may be necessary. It may take longer to reach 100%. The device can be used with AC power while simultaneously charging.*

Power Management

The ELI 350 has three distinct power states: On, Standby, and Shutdown.

While On, the ELI 350 performs all of its functions including display, acquisition, printing, and transmission of ECGs. With a fully charged battery the ELI 350 is expected to operate continuously up to 8 hours depending upon display brightness, settings, and printing operation. Place the ELI 350 in Standby mode by pressing and releasing the ON/OFF button or closing the display cover.

In Standby mode, the ELI 350 is in a low power "sleep" mode. From a fully charged battery the ELI 350 can remain in sleep mode for up to 3 days before entering the Shutdown state. Standby allows the ELI 350 to conserve power while not in use, but provide "instant on" with startup. To turn the ELI 350 on from Standby, press and release the ON/OFF button with the display open or open the closed display to an upright position. The system display will power-up and be ready for use within approximately 3 seconds.

In Shutdown mode the system is completely off. Normal operation of the ELI 350 should not have the device enter a Shutdown mode unless the system is left for prolonged periods of time in Standby with no recharging of the battery. To turn the ELI 350 on from Shutdown, press and release the ON/OFF button. The Battery LED will initially flash as the system begins its boot-up process. The system display will power-up and be ready for use within approximately 30 seconds.

Setting Date and Time

1. Select **SETTINGS** from the main display.
2. Select **DATE/TIME**.
3. Position cursor over TIME using the click knob; cursor highlights sequentially the hours, minutes, and seconds. With the desired parameter highlighted, use the keyboard to type the new value and move the cursor to the next parameter. When done use the click knob to move to the next area.
4. Repeat the same operation to set DATE, TIME ZONE, and date format.
5. Highlight **OK** to save and exit.

> ***NOTE:*** *If using the touchpad, simply click over the parameter and adjust it using the keyboard or up/down arrows.*

Installing the WLAN Antenna

The ELI 350 with optional WLAN module is shipped with the antenna not installed: the antenna can be found in the accessory box.

1. Remove the antenna from the accessory box.
2. Locate the antenna connector on the back of the device.
3. Mount the antenna on the connector by rotating the antenna clockwise. The antenna must be finger tight to its connector.
4. Locate the built-in hinge and fold the antenna (it will now be at a 90° angle); continue to rotate the antenna clockwise until it is placed vertically. This will guarantee the best signal for the WLAN module.

> ***NOTE:*** *For more information about the use of the WLAN option, refer to Appendix A.*

Using the WAM Acquisition Module

ECG acquisition and rhythm strip printing can also be performed at the WAM (wireless acquisition module). To use the WAM with the ELI 350, refer to the WAM user manual.

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

> ***NOTE****: The ELI 350 must be configured at the factory for use with the WAM.*

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 *(*do not use alcohol).
- Dry skin vigorously with an abrasive pad such as 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.

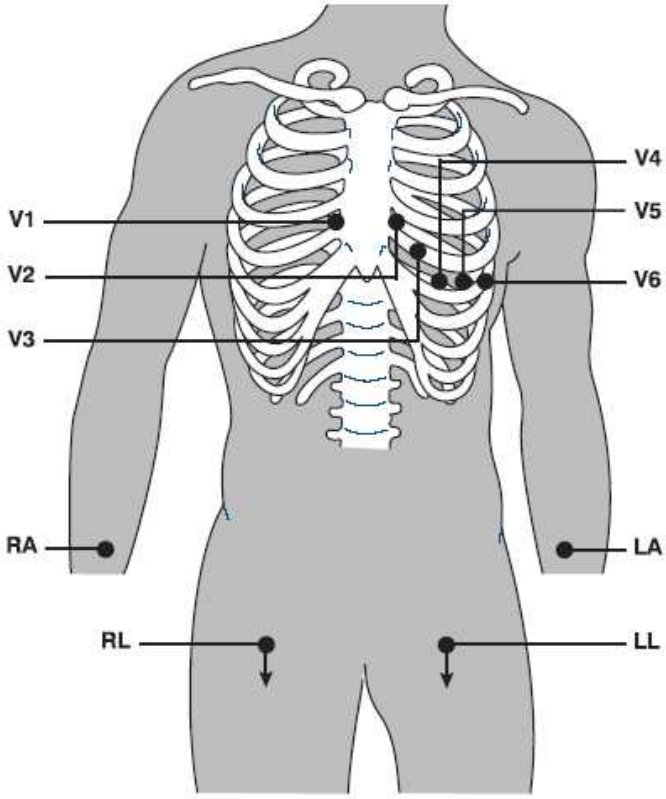
> ***TIP**: Electrodes should be stored in an air-tight container. Electrodes will dry out if not stored properly which will cause loss of adhesion and conductivity.*

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. Place the electrodes on the inside of each arm (between the wrist and elbow).
4. Place the electrodes on the inside of each calf (between the ankle and knee).
5. Place the electrodes at equal distance from the heart and at the same position on each limb.
6. If a limb site is not available, place the electrodes at an equal distance from the torso, and at an equal distance on a perfused area of the stump.
7. 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.

- V1 on the 4th intercostal space at the right sternal border.
- V2 on the 4th intercostal space at the left sternal border.
- V3 midway between V2 and V4 electrodes.
- V4 on the 5th intercostal space at the left midclavicular line.
- V5 on the left anterior axillary line, horizontal with V4 electrode.
- V6 on the left midaxillary line, horizontal with V4 electrode.
- RA on the right deltoid, forearm, or wrist.
- LA on the left deltoid, forearm, or wrist.
- RL on the right thigh or ankle.
- LL on the left thigh or ankle.



15-lead placement

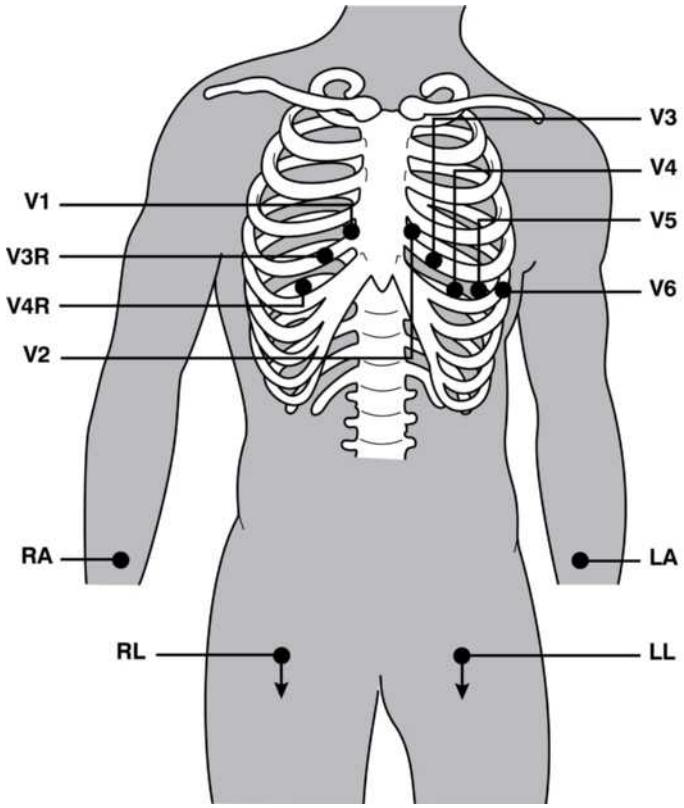
In a 15-lead configuration, three combinations of additional lead wires are available:

1. Right precordial leads V3R, V4R and posterior lead V7, or
2. Posterior leads V7, V8, V9, or
3. Physician preference lead placement E1, E2, E3.

For limb leads and precordial leads V1 thru V6, follow the instructions for a standard 12-lead hookup as described previously.

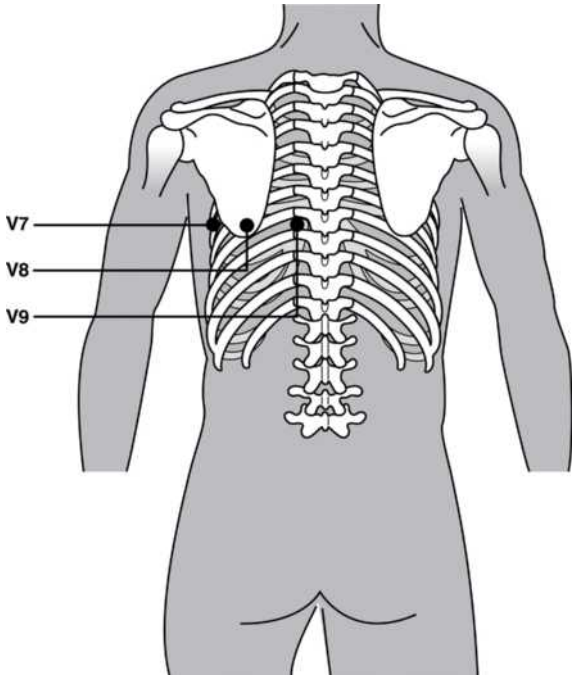
For right precordial leads, use positions symmetrical to left precordial leads:

- V3R: symmetrical to V3 position on the right side of the chest.
- V4R: on the 5th intercostal space at the right midclavicular line.



For posterior leads:

- V7: left posterior axillary line, straight line from V6.
- V8: left midscapular line, straight line from V7.
- V9: left paraspinal line, straight line from V8.



Lead Identification and Color Coding

AAMI-Color Scheme	
Lead Label	**Lead ID Color**
RA	White
LA	Black
LL	Red
RL	Green
V1	Red
V2	Yellow
V3	Green
V4	Blue
V5	Orange
V6	Violet
3R	White
4R	White
V7	White

IEC-Color Scheme	
Lead Label	**Lead ID Color**
R	Red
L	Yellow
F	Green
N	Black
C1	Red
C2	Yellow
C3	Green
C4	Brown
C5	Black
C6	Violet
3R	White
4R	White
C7	White

Patient Demographic Entry

Patient demographic information can be entered before acquisition. The entered patient ID fields will remain populated until you acquire the ECG; however, if you turn off the electrocardiograph or select cancel the patient information will be cleared. If you attempt to acquire an ECG before patient hookup, the ELI 350 will prompt you to complete patient hookup before proceeding.

To access the patient demographic data entry menu, select **ID** from the main display. The patient demographic labels available are determined by the ID format selected in the configuration settings. In addition to short, standard, or long patient ID formats, the ELI 350 also supports a custom ID format. The custom format, designed in ELI LINK or an E-Scribe™ data management system, can be downloaded to the ELI 350. Additional information about the custom ID can be found in Section 4, or in the ELI LINK and E-Scribe user manuals.

Patient demographic entry can be completed manually or automatically using an existing patient record in the directory. To manually enter the patient demographics, use **Enter, Tab,** the click knob, or touchpad to move to each data entry field. Skipped fields will appear as a blank field on the header of the ECG printout.

> ***TIP:*** *Type* **F** *from the keyboard to change the gender to female; type* **M** *to change the gender to male.*

To automatically populate the demographics using an existing patient record, select **Directory** from the ID screen**.** Use the click knob or touchpad to navigate through the ECG directory list. To quickly select a patient name, use the keyboard to enter the first few letters of the last name and move to the general location of the desired patient record, or continue typing the patient name to obtain a closer proximity. Press either the **Enter** key or the click knob and the patient ID screen will return with all demographic fields populated. Select **OK** to return to the main display.

> ***TIP:*** *Automatically populating demographic fields via the directory is only possible when the ID formats are the same between records.*

> ***TIP:*** *Entry of a lower case letter in the last or first name will automatically be capitalized.*

> ***NOTE:*** *The ELI 350 must have ECG input for the unit to retain patient demographics.*

Optional Bar Code Scanner

By connecting the optional bar code scanner to the ELI 350's USB port, portions of acquiring an ECG are automated for speed and accuracy of alphanumeric entry, functions, and feature processes. (Bar Code scanner capability is either 39 or 128.)

Please reference the Bar Code Scanner user manual for instructions on setup and use.

ECG Acquisition, Printing, Storage

ECG acquisition and rhythm strip printing can also be performed at the WAM (wireless acquisition module). To use the WAM with the ELI 350, refer to the WAM user manual.

Acquisition

Once the patient is connected, the ELI 350 continuously collects and displays ECG data; therefore, before you press **AUTO** 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.

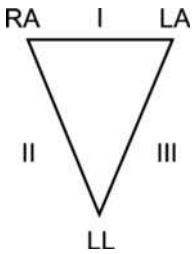
With optional 15 lead, clinicians can use the Settings sub menu ECG SETTINGS to preset the ELI 350 for:

- 12 & 15 lead (V3R, V4R, V7)
- 12 & 15 lead (V7, V8, V9)
- 12& 15 lead (E1, E2, E3)
- 15 & 12 lead (V3R, V4R, V7)
- 15 & 12 lead (V7, V8, V9)
- 15& 12 lead (E1, E2, E3)

Alternate between 12-lead and 15-lead presentation and recordings by selecting **FORMAT** on the main display followed by **ECG Acq. Mode**. This setting will only affect the monitoring and printing of the current patient; setting will revert back to the default setting when a new ECG is acquired.

To acquire an emergency (STAT) or unidentified ECG for a new patient, press AUTO. The patient ID menu will appear in the upper left-hand corner of the display. Select **AUTO** again and the ECG is acquired. "Collecting 10 seconds of data" is displayed on the top of the LCD and "captured, analyzed, formatted" is displayed on the bottom of the LCD. The real-time ECG view is then replaced with the acquired ECG view. To add patient demographics, select **Edit ID**.

Examine the display for artifact or baseline drift. Re-prep and replace electrodes if necessary to obtain satisfactory waveforms. (See *Patient Preparation*.) If a lead fault occurs, square waves appear on the display for that lead and the lead(s) in fault will display in the upper left corner of the screen one at a time. 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
Lead I and II artifact	Poor RA electrode
Lead I and III artifact	Poor LA electrode
V Leads	Re-prep site & replace electrode

If physician over-read option is enabled, choose **Edit Interp** to update or modify the VERITAS interpretation. Selecting this requires an optional password to be entered.

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

NOTE: *Button functions are not available during acquisition.*

ECG Selection from Full-disclosure ECG Buffer (Optional)

In acquired ECG view, the bottom of the screen displays a single lead of the 12-lead or optional 15-lead full-disclosure buffer. A rectangular box in the full-disclosure pane indicates the ECG signal corresponding to the current acquired ECG. Use the navigation arrows in the full-disclosure pane to select different periods of time stored in the memory buffer; the rectangular box will move with the navigation arrows. Pausing over any section of time will automatically provide a preview of the ECG on the main ECG pane. Process the interpretation of the new ECG by clicking on the check box in the full-disclosure pane.

Best 10 Seconds Selection

The ELI 350 automatically selects the best 10 seconds from within the available 20-minute buffer. The user can use the suggested 10 seconds or navigate to a different ECG strip.

If the BEST 10 mode is enabled in the configuration, the footer of the ECG screen (in both real time and preview) displays BEST 10 MODE. (This message disappears if the default is set to LAST 10.)

If the BEST 10 mode is set as the default, a VIEW LAST 10 option is available in the preview display. Selecting this option replaces the ECG on screen with the last 10-second ECG available in the buffer. The option label changes to VIEW BEST 10 allowing the user to switch between the two.

If the LAST 10 mode is set as the default, the function above is reversed

> ***NOTE:*** *When the ECG is acquired and the preview screen is displayed, the highlight (focus) must be positioned on the BEST 10/LAST 10 label.*

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 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 (regardless of the plot format configuration setting) of the acquired ECG, select **Format**. To make an ECG printout of the new plot format, select **Print**.

Storage

The ELI 350 manages storage in one of two ways – automatically or manually. When the Auto-Save configuration option is enabled, ECGs are automatically saved to the directory upon acquisition, printing, transmitting, or any combination of the three. When the Auto-Save configuration option is disabled, the user is prompted to save the ECG after acquisition. At that time, the user can also choose to delete the record and it will not be added to the directory.

> ***NOTE:*** *If Auto-Save is enabled but the ECG is not printed, the user is prompted to save.*

> ***TIP****: Manual save is possible by selecting* **Save** *in the acquired ECG view.*

Acquiring Rhythm Strips

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

Begin routine rhythm strips by connecting the patient to the ELI 350 and entering the patient identification information. After the last data entry field from the ID menu is completed, select **OK** 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 ID.

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

> ***NOTE:*** *Rhythm acquisitions are only printed and not stored in the ELI 350.*

In addition to manipulating Speed, Gain, and Filter, the user can toggle different lead groups. When the default rhythm format is set to either 3-channel or 6-channel, the user can change lead groups during printing by selecting **RHY**.

To stop the rhythm printing, press STOP and the writer will automatically form-feed in preparation for a new patient's rhythm recording or ECG.

CONNECTIVITY AND ECG TRANSMISSION

ECG Transmission

You may transmit ECGs to another Mortara Instrument electrocardiograph, to an E-Scribe system, to ELI LINK, or to a third party EMR using a direct connection, optional factory installed internal modem, LAN, WLAN, UNIPRO, UNIPRO 32, DICOM, or DICOM 32 connection.

Before transmitting ECGs, certain configuration options must be set in system settings depending upon the transmission media used and the electronic storage media you are transmitting to (see Section 6).

> ***NOTE:*** *Telephone transmission is available with internal modem option only.*
>
> ***NOTE****: In order to properly connect to telephone lines, the ELI 350 internal modem needs to be set on the proper country code. This is an internal setting and should not be confused with International calling codes.*

The WLAN performance of the ELI 350 may vary due to changes in RF (radio frequency) properties at your site or to environmental conditions. If you are experiencing intermittent connectivity in certain areas of your facility, it may be necessary to re-initiate the transmission process. You can also consult your hospital IT department or your Mortara Instrument technical service representative regarding modification of your WLAN to improve system performance.

> ***NOTE****: Test your location's RF signal strength at the ELI 350 by selecting* **SETTINGS** *followed by* **Test WLAN**. *Signal strength will display as zero to six bars (zero being no RF signal strength; six being full signal strength). If an adequate signal is not being obtained, it is recommended that you move to a more suitable location before trying to transmit.*

To transmit records, use 

.

To transmit an ECG at the time of acquisition, use **XMT** while the ECG is still displayed.

To transmit an ECG from the ECG directory, use the arrow keys, touchpad, or click knob to choose a record. To quickly select a patient name, use the keyboard to enter the first few letters of the last name and move to the general location of the desired patient record, or continue typing the patient name to obtain a closer proximity. When the desired record is highlighted, use **XMT** to transmit the individual ECG.

To batch transmit all records in the directory, select **Batch**. In a batch transmission, only those records which have not been previously transmitted or marked for deletion will be transmitted.

Direct Connection (RS-232)

For a direct connection, set the XMT media to RS-232. Connect the ELI 350 to another Mortara Instrument electrocardiograph, to an E-Scribe, or to ELI LINK with a direct connect serial cable.

In the configuration setting, select matching baud rates for both units. Use 38400 bps for a direct connection to E-Scribe.

Modem Transmission

For a modem transmission, set the XMT media to modem. Connect the ELI 350 to a standard telephone jack with the provided phone line cable. Plug the cable into the telephone jack located on the back of the electrocardiograph and the other end into a telephone wall jack. Confirm telephone number in the configuration settings.

Modem Initialization

The modem initialization string is country specific. At the time of production, the modem initialization string is configured for the country of purchase; however, if the unit is relocated to a different country, the modem initialization string will need to be modified. Contact Mortara Instrument Customer Service to receive the procedure to change the code.

External Modem Country Code List

Country	Code	Country	Code
Afghanistan	34	Canary Islands	34
Albania	34	Cape Verde	34
Algeria	34	Cayman Islands	34
American Samoa	34	Central African Republic	34
Andorra	34	Chad	34
Angola	34	Chile	34
Anguilla	34	China	34
Antigua and Barbuda	34	Colombia	34
Argentina	34	Congo	34
Armenia	34	Congo, The Democratic Republic of the	34
Aruba	34	Cook Islands	34
Australia	1	Costa Rica	34
Austria	34	Côte D'Ivoire	34
Azerbaijan	34	Croatia	34
Bahamas	34	Cyprus	34
Bahrain	34	Czech Republic	25
Bangladesh	34	Denmark	34
Barbados	34	Djibouti	34
Belarus	34	Dominica	34
Belgium	34	Dominican Republic	34
Belize	34	East Timor	34
Benin	34	Ecuador	34
Bermuda	34	Egypt	34
Bhutan	34	El Salvador	34
Bolivia	34	Equatorial Guinea	34
Bosnia and Herzegovina	34	Estonia	34
Botswana	34	Ethiopia	34
Brazil	34	Faero Islands	34
Brunei Darussalam	34	Fiji	34
Bulgaria	34	Finland	34
Burkina Faso	34	France	34
Burundi	34	French Guiana	34

Country	Code	Country	Code
Cambodia	34	French Polynesia	34
Cameroon	34	Gabon	34
Canada	34	Gambia	34
Georgia	34	Korea, Republic of (South Korea)	30
Germany	34	Kyrgyzstan	34
Ghana	34	Lao People's Democratic Republic	34
Gibraltar	34	Latvia	34
Greece	34	Lebanon	34
Greenland	34	Liberia	34
Grenada	34	Libya	34
Guadeloupe	34	Liechtenstein	34
Guam	34	Lithuania	34
Guatemala	34	Luxembourg	34
Guernsey, C.I.	34	Macau	34
Guinea	34	Macedonia, The Former Yugoslav Republic	34
Guinea-Bissau	34	Madagascar	34
Guyana	34	Malawi	34
Haiti	34	Malaysia	30
Holy See (Vatican City State)	34	Maldives	34
Honduras	34	Mali	34
Hong Kong	30	Malta	34
Hungary	30	Martinique	34
Iceland	34	Mauritania	34
India	30	Mauritius	34
Indonesia	30	Mayotte	34
Iran	34	Mexico	34
Iraq	34	Moldova, Republic of	34
Ireland	34	Monaco	34
Isle of Man	34	Mongolia	34
Israel	30	Montserrat	34
Italy	34	Morocco	34
Jamaica	34	Mozambique	34
Japan	10	Namibia	34
Jersey C.I.	34	Nauru	34
Jordan	34	Nepal	34
Kazakhstan	34	Netherlands	34
Kenya	34	Netherlands Antilles	34
Kiribati	34	New Caledonia	34
Kuwait	34	New Zealand	9

Country	Code	Country	Code
Niger	34	Nicaragua	34
Nigeria	34	Swaziland	34
Norway	34	Sweden	34
Oman	34	Switzerland	34
Pakistan	34	Syrian Arab Republic	34
Palestine Territory, Occupied	34	Taiwan	34
Panama	34	Tajikistan	34
Papua New Guinea	34	Tanzania, United Republic of	34
Paraguay	34	Thailand	34
Peru	34	Thaiti	34
Philippines	30	Togo	34
Poland	30	Tonga	34
Portugal	34	Trinidad and Tobago	34
Puerto Rico	34	Tunisia	34
Qatar	34	Turkey	34
Reunion	34	Turkmenistan	34
Romania	34	Turks and Caicos Islands	34
Russian Federation	34	Uganda	34
Rwanda	34	Ukraine	34
Saint Kitts and Nevis	34	United Arab Emirates	34
Saint Lucia	34	United Kingdom	34
Saint Vincent and the Grenadines	34	Uruguay	34
Samoa	34	USA	34
Saudi Arabia	34	Uzbekistan	34
Senegal	34	Vanuatu	34
Seychelles	34	Venezuela	34
Sierra Leone	34	Viet Nam	30
Singapore	30	Virgin Islands, British	34
Slovakia	34	Virgin Islands, U.S.	34
Slovenia	30	Yemen	34
Solomon Islands	34	Yugoslavia	34
South Africa	35	Zambia	34
Spain	34	Zimbabwe	34
Sri Lanka	34		
Sudan	34		
Surinam	34		

LAN Transmission

For a LAN transmission, connect the ethernet cable to the LAN connection at the rear of the ELI 350 and set the XMT media to LAN in system settings. It is necessary that the IT Manager of your facility set the ELI 350 LAN configuration values.

> ***NOTE:*** *Addresses are always entered as 4 sets of 3 digits; therefore, an address of 192.168.0.7 must be entered on the ELI 350 as 192.168.000.007.*

> ***NOTE:*** *LAN/WLAN settings will be password protected when printing configuration. If the password is entered, users will be able to view these parameters on the screen; however, all printouts will print **** instead of the real parameters.*

> ***CAUTION:*** *Possible damage to the electrocardiograph may occur if telephone cable is connected to the LAN connector.*

Ethernet Status LEDs

At the external LAN interface connector, the user is presented with two LEDs (Light Emitting Diodes). The two status indicator LEDs provide signals for "link status" and "packet transmit/receive". As the external connector is viewed from the outside rear of the ELI 350, the left LED remains illuminated when the network link is detected. The ELI 350 LAN will support signaling rates of 10 and 100 MBPS. The right LED flashes when a transmit or receive packet occurs or any traffic on the network is detected. The electrocardiograph conserves power by only turning on the LAN module at time of transmission. Therefore, the link status LEDs remain OFF until you push the final button to transmit the record. At this point the module is powered on, configured, and begins to communicate to the network. It takes approximately 6 seconds from the final button push until you see the link status LEDs illuminate.

WLAN Transmission

For a WLAN transmission, set the XMT media to WLAN. It is necessary that the IT Manager of your facility configure the wireless access point(s) and E-Scribe workstation. It is also required that your IT Manager provide the ELI 350 WLAN configuration values. The ELI 350 can be configured for Dynamic Host Communication Protocol (DHCP) or static IP. Wireless security encryption options include WEP, WPA, and LEAP.

> ***NOTE:*** *Environmental conditions may affect the reliability of WLAN transmissions.*

If DHCP is set to NO, your wireless access point will have a static network setting and the following parameters must be configured in the device:
IP Address
Default Gateway
Sub Net Mask

If DHCP is set to YES, your wireless access point will have an automatic network setting and IP address; default gateway and sub net mask do not need to be configured.

In either DHCP setting, the following wireless network parameters must be provided by your IT Manager:
Host IP
Port Number
SSID
Channel Number

> ***NOTE:*** *Addresses are always entered as 4 sets of 3 digits; therefore, an address of 192.168.0.7 must be entered on the ELI 350 as 192.168.000.007.*

If WEP security is disabled on your access point, then set security (WEP) to NO. If WEP security is enabled on your access point, the following wireless network parameters must be configured in the device by the IT Manager:
Security: WEP
WEP Key
WEP Key ID

> ***NOTE:*** *The range for the WEP key is 0-3. If the range on your access point is 1-4, then 0 at the ELI 350 maps to 1 on the access point; 1 maps to 2 on the access point, etc.*

If your wireless security environment is WPA or WPA2 (Wi-fi Protected Access) then you will need to enter:
Security: WPA-PSK
Passphrase:

> ***NOTE:*** *The passphrase length is limited to 64 digital Hex Value characters or 63 ASCII characters.*

If your wireless security environment is LEAP then you will need to enter:
Security: LEAP
LEAP User Name
LEAP Password

> ***NOTE:*** *LEAP user name and password are limited to 63 characters.*

> ***NOTE:*** *When saving the WLAN configuration, the ELI 350 may require several seconds to complete the saving procedure.*

Receiving ECGs

To receive ECGs from another Mortara Instrument electrocardiograph, select **Receive** from the Settings menu. The ELI 350 only acts as a printer. Received ECGs will not be viewed on the display or stored in the receiving electrocardiograph's memory.

> ***NOTE**: The ELI 350 will receive records from Mortara model electrocardiographs ELI 350, ELI 250, ELI 150, and ELI 10.*

Retrieving ECGs

It is possible to retrieve ECGs from an E-Scribe system using any of the connectivity options. Before attempting to retrieve ECGs, configure the XMT media, the telephone number (if using modem transmission), and the site number. Select **Retrieve** from the Settings menu.

ECGs are retrieved by ID number. Enter the desired ID and select **OK**. E-Scribe transmits the most recent ECG with the specified ID number (or the configured number of ECGs retrieved – refer to Section 6). The ELI 350 prints the retrieved ECG(s); viewing and storing retrieved ECGs is not possible.

> ***NOTE**: The ID field defaults the last acquired ECG.*

Orders Download

> ***NOTE**: A custom ID must be downloaded before downloading the orders. Please reference the E-Scribe or ELI LINK user manuals, and Custom ID Download of this section.*

The ELI 350 can download and process an ECG order list from an E-Scribe or another compatible electronic information management system.

Order lists containing the demographic information of patients requiring an ECG are designed in ELI LINK or an E-Scribe system. The technician at the electrocardiograph selects the desired order code (e.g., a code specific to a department or floor) and the patients belonging to the order list. Once downloaded to the ELI 350, the ECG list for the selected order code is stored in the device as the order list (similar to the ECG directory). As with ECG data transmission, you can use any of the connectivity options to download the order list.

From the main display, select **Orders** to display the available order code(s). Use the arrow keys, touchpad, or click knob to scroll through the list; use **OK** to select the desired order code.

Once connected, the screen will indicate the number of orders (ECGs) received for the order code.

Custom ID Download

Custom ID formats are uniquely defined by your facility's needs. This customized ECG header information is designed in ELI LINK or an E-Scribe system and downloaded to the ELI 350.

Select **Custom ID Download** from the application menu. "Transmission Status" will remain visible for approximately 10 seconds followed by "Waiting for Response", "Connected", and "Custom ID downloaded". A return to the real-time ECG view indicates the custom ID download is complete. The custom ID remains the new header format for all future ECGs until you select a different ID format in the configuration settings. You may alter the ID format configuration to short, standard, long, or custom based on your patient demographic entry needs. The custom ID is only deleted upon downloading a new custom ID or on the rare occasion of downloading software – it will not be lost due to power loss or switching to a different ID format.

> ***TIP:*** *Upon custom ID download, the ID format will assume the group name as designed in ELI LINK or E-Scribe.*
>
> ***NOTE:*** *The site number must be configured in the electrocardiograph and recognized as an established, valid site number at the E-Scribe before downloading the custom ID.*
>
> ***TIP:*** *Confirm the baud rate in the configuration settings before downloading the custom ID from ELI LINK or E-Scribe.*

ECG Directory

The standard ECG directory saves up to 200 ECG individual records. The optional expanded memory permits up to either 500 or 2,000 ECGs.

> ***NOTE:*** *With optional expanded memory of either 500 or 2,000 records, full-disclosure patient history is enabled.*

To access the ECG directory, select **Directory** from the main display.

> ***NOTE:*** *A password may be required in order to enter the ECG directory. Obtain the password from the department Administrator.*

> ***NOTE:*** *In the ECG directory list, "**P**" represents the record has been printed, "**X**" represents the record has a delete status, and "**T**" represents the record has been transmitted.*

> ***NOTE:*** *Records marked for deletion will be maintained on the display if requested by the user. Otherwise, selecting* **Show Deleted** *from the bottom of the directory window will display deleted records until the file is full. At that time the system will automatically remove the oldest and/or largest records marked for deletion.*

Management of the ECG record is performed within the directory of stored ECGs. The desired record must be highlighted in order to view, print, edit, add demographics, or to change delete status.

Use the click knob or touchpad to navigate through the ECG directory list. To quickly select a patient name, use the keyboard to enter the first few letters of the last name and move to the general location of the desired patient record, or continue typing the patient name to obtain a closer proximity. Alternatively, use the navigation device to move to the name or ID area.

An ECG may be stored in the directory but have a "deleted status" (indicated by "X"). The directory saves records marked for deletion in the event that you may want to recover the ECG at a later time. Records are automatically marked for deletion based on the delete rule configuration (see Section 6). To manually mark an ECG record for deletion, highlight a name from the ECG directory and select **Delete**. An "**X**" will appear in the directory. To remove the delete status, re-highlight the name and select **Delete** again. All stored ECGs will remain in the directory until it becomes full. When necessary to store a newly acquired ECG, only those records that have been marked for deletion will be removed.

To view a specific ECG record, highlight the desired name from the directory list and press **Select**. The selected ECG is presented in acquired ECG view. To access the patient demographic screen, select **Edit ID**. To make an additional copy of the ECG, select **Print**. To edit the interpretation, select **Edit Int**. To change the format of the displayed ECG, select **Format.** To return to the main screen, select **Exit**.

In order to change the speed, gain, filter, or print format (regardless of the plot format configuration setting) in the acquired ECG view, select **Format.** To make an ECG printout copy of the new plot format, select **Print**. Select **OK** to return to the acquired ECG view.

The directory is easily sorted either by name, ID, date of birth, or acquisition time. To sort the ECG records, select the appropriate field from the top of the ECG list:

- Select **Last Name** to sort the directory by patient last name
- Select **ID** to sort the directory by patient ID
- Select **DOB** to sort the directory by date of birth
- Select **Acq. Time** to sort the directory by time and date of ECG acquisition

> ***NOTE:*** *If the ID format used for the acquired ECG does not have DOB, entry will be listed as dd-mmm-yyyy.*

To make a printout of the ECG directory, select either **Print Directory** or **Print Page**. Print Directory generates a printout of the entire ECG directory (up to 2,000 records; 40 records per page). Print Page prints the currently displayed page.

Select **Cancel** to close the ECG directory.

Show Deleted/Hide Deleted

Allows for displaying or hiding ECGs marked as deleted. The ELI 350 displays only those records NOT marked as deleted by default.

ECG Orders

The ECG orders directory saves up to 256 ECG pending orders. Orders are displayed with last name, first name, ID, patient location, patient room number, and date and time of order.

From the Orders menu, you may Download orders, Print Orders, Delete orders, or Load an ID.

> ***NOTE:*** *Each time orders are downloaded, the ELI 350 will automatically refresh. ECGs that have been acquired, canceled, or deleted will be eliminated from the selection menu.*

Accessing the Format Menu

Access the Format drop-down menus by selecting **Format** from the main display.

- **ECG Rhythm Print Speed.** Select 5 mm/s, 10 mm/s, 25mm/s, or 50 mm/s.
- **ECG Print Speed.** Select 25mm/s or 50 mm/s.
- **ECG Display Speed.** Select 25 mm/s or 50 mm/s.
- **Gain**. Select waveform amplitude for display and printout: 2.5 mm/mV, 5 mm/mV, 10 mm/mV, or 20 mm/mV. Gain is printed at the bottom right corner of the ECG printout.
- **Format**. Select print format for ECG reports. Formats consist of 3+1, 6, 3+3, 12, 6+6, and Cabrera.
- **Filter**. Select low-pass filter option for ECG printouts: 40 Hz, 150 Hz, or 300 Hz. Filter settings are printed at the bottom right corner of the ECG printout. Note that the high-pass setting of 0.05 Hz for diagnostic ECG is not adjustable.
- **History Lead**. Select lead to be displayed in full-disclosure buffer on real-time screen. Note that selection of any given lead is for display only. All 12 or 15 leads are continuously stored.
- **ECG Acquisition Mode.** Select 12 lead or 15 lead for acquisition and display.

Accessing the Settings Menu

Access Settings and sub menus by selecting **Settings** from the main display.

- **System Settings** – Defines 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.
- **ECG Settings** – Defines all operational conditions that may change on a daily or patient-to patient basis. You can make changes through **Format** on the main display.
- **Custom ID** – Downloads a custom ID from an ELI LINK, E-Scribe system, or from another compatible information management system. See Appendix A.
- **Date/Time** – Sets the date and time of the ELI 350. See Section 2.
- **WAM** – Allows clinician to choose direct patient cable or pair with the WAM.
- **Test WLAN** – Tests RF signal strength to the wireless network of the hospital or facility in which you are working.
- **Receiving ECGs** - The ELI 350 will receive records from Mortara model electrocardiographs ELI 350, ELI 250, ELI 150, and ELI 10.
- **Retrieving ECGs -** The ELI 350 will retrieve records from Mortara's E-Scribe.
- **Password** – Can be used to limit access to the ELI 350 configuration menus, ECG directory, and/or orders/worklists.
- **Cancel** – Exits Settings menu.

Setting Passwords

The ELI 350 is delivered with a preset administrator password ("admin"); type this password in the Settings screen and select **ENTER** or press the click knob to display the Setup Passwords screen.

The top selection is dedicated to the administrator password; the lower selection is dedicated to the technician password. From this screen, the administrator can create a new password that will be required to access the Set Password function. The administrator can also create a technician-level password that will be required to access the ECG directory, and/or orders/worklists. Custom ID and date/time functions are always accessible without a password. During creation, each password will require retyping to ensure it has been entered correctly.

> ***NOTE:*** *Passwords are case sensitive.*
>
> ***NOTE:*** *It is strongly recommended that the administrator log these passwords in an area accessible during an emergency, or with the Biomedical Engineering department for immediate access if needed.*

Summary of Configuration Menus

Parameter	Options
Software version	Displays software version on printout and display
Cart Number	Numeric field 0 to 65535
Site Number	Numeric field 0 to 4095
Site Name	Alphanumerical field (30 digits)
Telephone number	Alphanumerical field (45 digits)
Language	English and any other languages available at time of release
Volume	Numerical field 0 to 8
Battery Time Out	10 min, 20 min, 30 min
Brightness AC	Auto, Low, Middle, or High
Brightness Battery	Auto, Low, Middle, or High
ID Format	Short, Standard, Long, or Custom
AC Filter	50 Hz, 60 Hz, or None
ECG Display Speed	25 or 50 mm/sec
ECG Print Speed	25 or 50 mm/sec
Rhythm Print Speed	5, 10, 25, or 50 mm/sec
Filter	Frequency response for printouts: 40 Hz,150 Hz, or 300 Hz
Ht/Wt Units	Lb/in or Kg/cm
Interp	YES/NO
Avg RR	YES/NO
QTcB	YES/NO
QTcF	YES/NO
Worklist Management	Standard or Refresh
XMT Button	Transmit the ECG or transmit the ECG and request an automatic download of the MWL.
Mandatory Demographic	None, Last Name, Patient ID, or Last Name and Patient ID
Serial Comp. Active	No/Text/Text + Waveforms
# ECG Comp.	1, 2, 3, 4
Append	Blank, UNCONFIRMED REPORT, Reviewed by
Reasons	YES/NO
# Copies	0 to 9
Copies with Interp	YES/NO
# ECGs Retrieved	0 to 7
Delete Rule	Post Plot, Post Transmit, Post Plot/Xmt
Storage Sensitivity	NORMAL or HIGH
Auto-save ECG	YES/NO
Auto-print ECG	YES/NO
ECG Capture	Best 10 or Last 10
Baud rate	9600, 19200, 38400, 57600, 115200

Summary of Configuration Menus (Continued)

Parameter	Options
Use A4 paper	YES/NO
Caps lock	YES/NO
Rhythm Format	3, 6, or 12 channels
3 Rhythm Lead 1	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 optional V3R, V4R, V7 or V7, V8, V9 or E1, E2, E3
3 Rhythm Lead 2	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 optional V3R, V4R, V7 or V7, V8, V9 or E1, E2, E3
3 Rhythm Lead 3	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 optional V3R, V4R, V7 or V7, V8, V9 or E1, E2, E3
6 Rhythm Lead 1	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 optional V3R, V4R, V7 or V7, V8, V9 or E1, E2, E3
6 Rhythm Lead 2	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 optional V3R, V4R, V7 or V7, V8, V9 or E1, E2, E3
6 Rhythm Lead 3	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 optional V3R, V4R, V7 or V7, V8, V9 or E1, E2, E3
6 Rhythm Lead 4	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 optional V3R, V4R, V7 or V7, V8, V9 or E1, E2, E3
6 Rhythm Lead 5	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 optional V3R, V4R, V7 or V7, V8, V9 or E1, E2, E3
6 Rhythm Lead 6	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 optional V3R, V4R, V7 or V7, V8, V9 or E1, E2, E3
History Lead	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 optional V3R, V4R, V7 or V7, V8, V9 or E1, E2, E3
ECG Mode	12 lead, 15 lead (V3R, V4R, V7), 15 lead (V7, V8, V9) 15 lead (E1, E2, E3)
Plot Format	3+1, 6, 3+3, 12, 6+6, and Cabrera
3+1 Rhythm lead	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 optional V3R, V4R, V7 or V7, V8, V9 or E1, E2, E3
3+3 Rhythm lead 1	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 optional V3R, V4R, V7 or V7, V8, V9 or E1, E2, E3
3+3 Rhythm lead 2	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 optional V3R, V4R, V7 or V7, V8, V9 or E1, E2, E3
3+3 Rhythm lead 3	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 optional V3R, V4R, V7 or V7, V8, V9 or E1, E2, E3
XMT Media	RS-232, Modem, LAN, WLANG
DHCP (active for LAN or WLANG)	YES/NO
IP Address (active for LAN or WLANG)	XXX.XXX.XXX.XXX
Def. Gateway (active for LAN or WLANG)	XXX.XXX.XXX.XXX
Sub Net Mask (active for LAN or WLANG)	XXX.XXX.XXX.XXX
Host IP (active for LAN or WLANG)	XXX.XXX.XXX.XXX
Port Number (active for LAN or WLANG)	XXXX
SSID (present for WLAN)	No SSID or SSID
Comm. Protocol	UNIPRO, UNIPRO 32, DICOM, or DICOM 32
WLAN Security	None, WEP128, WEP64, WPA-PSK, WPA-LEAP, WPA-PSK64, WPA-PSK128, WPA-LEAP64, WPA-LEAP128, WPA2-PSK, or WPA2-LEAP
WEP Key	Numeric (1 digit) (not on printout)

Summary of Configuration Menus (Continued)

Parameter	Options
WEP Key ID	Alphanumerical field (26 digits) A-F, 1-4 (not on printout)
LEAP Username	Alphanumeric field (32 digits) (not on printout)
LEAP Password	Alphanumeric field (32 digits) (not on printout)
PSK Passphrase	Alphanumeric field (64 digits) (not on printout)
WLAN MAC (only present for WLAN)	Display WLAN MAC Address (on printout)
LAN MAC (only present for LAN)	Display LAN MAC Address (only on printout)
ECG Storage	Low (History Disabled), Middle, or High (only on printout)
Comm. Socket	Modem or Wireless LAN B, Wireless LAN G (on printout)
Communications	Enabled Standard or Enabled DICOM (on printout)
Serial Comp. Active	No, Text Only, or Text + Waveform
# ECG Comp:	1, 2, 3, or 4
Rest Interpretation	Disabled, Enabled with Edit, or Enabled without Edit (only on printout)

Configuration Settings

Software Version

Identifies the software version of your electrocardiograph.

Cart Number

Indicates which electrocardiograph acquired or transmitted a particular ECG.

Site Number

Identifies the site of your ELI 350. Site numbers designate the hospital, clinic, or institution for ECG records stored in an E-Scribe data management system and must be defined for transmitting and retrieving ECGs from that system. You can use up to four digits for the site number. Numbers from 0 –4095 are supported.

Site Name

Defines your clinic, hospital, or office name. You can enter up to 30 alphanumeric characters. The site name prints at the bottom, left edge of the ECG printout.

Telephone Number

Specifies the telephone number for internal modem transmission to another unit or to an E-Scribe system. Enter up to 45 alphanumeric characters.

You may need to dial a **9** to get an outside line. To wait for an additional dial tone use the letter **W**.

EXAMPLE: 9**W**14145554321

To insert a pause use a comma (**,**).
To change tone dialing to pulse dialing, use the letter **P**.

EXAMPLE: **P**14145554321

(If necessary, you can use both the letter **W** and the letter **P** in the same phone number.)

NOTE: *It is not necessary to use alpha characters in the telephone number with GSM connectivity.*

Language

There are several languages available on the electrocardiograph.

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

1. Select **Settings**
2. Enter password (if required)
3. Select **Configuration**
4. Use the **Language** drop-down list to select appropriate language
5. Select **Save**
6. Power down the device completely and then restart

Alphabets of specific languages may require use of special characters in demographic fields. This is accomplished by selecting **ALT** + **the letter**. For example, ñ is entered by selecting **ALT + n**. Hold the ALT key and scroll the letter to view the available letter selections with diacritics.

Volume

Defines the keyboard and click knob loudness. Available settings range from 0 (off) to 8 (loud).

Battery Time Out

Determines when the electrocardiograph will enter Standby mode 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.

Brightness A/C

Determines screen brightness level when the ELI 350 is powered by A/C mains. The ELI 350 is also equipped with an ambient light sensor that can adjust the brightness automatically. Set this parameter to Auto to allow the device to automatically set itself according to the ambient light source throughout the room. Other settings include HIGH, MIDDLE, or LOW.

Brightness Battery

Determines screen brightness level when the ELI 350 is powered by the internal battery. The ELI 350 is also equipped with an ambient light sensor that can adjust the brightness automatically. Set this parameter to Auto to allow the device to automatically set itself according to the ambient light source throughout the room. Other settings include high, middle, or low. Proper use of this setting may help extend the battery-time operation of the ELI 350.

ID Format

Defines the format for the patient demographic information prompts. There are three standard formats: short, standard, or long. A custom ID format can be downloaded from an ELI LINK or E-Scribe system. See Section 4 to download a custom ID.

The short format includes the patient's last and first name, patient ID number, date of birth (automatically calculates the age), and gender.

The standard format includes the patient's last name, patient ID number, age, height, weight, gender, race, medication 1, medication 2, and a location field.

The long format is identical to the standard format except that it includes the patient's first name, room, and comment fields.

AC Filter

The ELI 350 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.

ECG Display Speed

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

ECG Print Speed

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

Rhythm Print Speed

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

Filter

The ECG plot-frequency filter (or print filter) can be set to 0.05 to 40 Hz, 0.05 to 150 Hz, or 0.05 to 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.

Height/Weight Units

Defines the units of weight and height to either pounds/inches (lb/in) or kilograms/centimeters (kg/cm).

Interpretation Option

The ELI 350 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 report.

> ***NOTE:*** *The ECG interpretations 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.*

Average RR

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

QTcB

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

QTcF

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

Worklist Management

The ELI 350 can download and process ECG order lists from the E-Scribe or another compatible information management system which identifies the ECGs (or ECG orders) needed for particular patients. Implementation of an order-based workflow can significantly reduce demographic data entry errors at the electrocardiograph. Orders are deleted from the list when the ordered ECG is acquired.

When set to Standard, new order lists are appended to the remaining list. When set to Refresh, each new order list will override the previously downloaded one.

XMT Button

The ELI 350 can transmit the ECG, or transmit the ECG and request an automatic download of the MWL.

Mandatory Demographic Fields

Requires the clinician to enter the patient last name, patient ID, or patient last name and patient ID before transmission to an electronic medical record system. Allow transmission of an ECG without requiring information by selecting none.

Serial Comparison

When enabled, the ELI 350 will print a comparison of up to 4 previous ECGs along with the most current ECG from the patient directory. The ELI 350 will only do a serial comparison of the ECGs currently residing on the ELI 350. The ECGs must have been acquired at least 30 minutes apart.

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; however, if you wish to have nothing appended to the ECG, "blank".

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.

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.

Copies With Interpretation

Defines the number of printed copies with interpretation when an ECG is taken. A zero (0) setting prints the first ECG with interpretation, and all consecutive ECGs up to 9 to be printed without interpretation. Settings from zero (0) to nine (9) assign interpretation to the appropriate number of selected ECG copies. Copies display patient demographics and measurements.

ECGs Retrieved

Defines the number of ECGs retrieved from an E-Scribe system. The ECGs are retrieved by ID number. A zero (0) setting retrieves the most current ECG for that ID number. Settings from one (1) to seven (7) retrieve the most current ECG plus "X" number of ECGs identified by the entered value. EXAMPLE: If you enter the number 5, you will retrieve the most current ECG plus the five preceding ECGs for that ID number. ECGs retrieved from the E-Scribe are only printed at the ELI 350 and not saved.

Delete Rule

Defines the rule to mark ECGs as deleted in the ECG directory. ECGs that are marked for deletion will be automatically removed or erased based on their acquisition date (a first-in/first-out philosophy) to make room for the new ECG record. ECGs are only erased from the directory when they are marked for deletion and if the directory becomes full. More than one ECG may be removed from the directory in order to make room for the new incoming record. The delete rule selections are:

Post Plot = ECG is automatically marked for deletion after printing
Post Transmit = ECG is automatically marked for deletion after transmission
Post Plot/Transmit = ECG is automatically marked for deletion after transmission and printing

Storage Sensitivity

Dictates the resolution of all stored ECG records. The sensitivity setting is either Normal or High. If the value is set to High, the stored ECG will have a high resolution. As a result, the record size will be large but will not affect the number of records that can be stored in the ELI 350.

Auto-Save ECG

Defines whether or not a newly acquired ECG will be automatically saved to the directory once it is acquired and printed. If the auto-save configuration is set to No and the record is printed, the ELI 350 will prompt you to "Save ECG?"

Auto-Print ECG

Defines whether or not the ELI 350 will automatically print the ECG after acquisition. If the selected configuration option is set to No, a manual printout is possible.

ECG Capture

Defines whether or not the ELI 350 will automatically display the Best 10 seconds of data acquired or the last 10 seconds of data acquired.

Baud Rate

Determines the serial port's data transmission rate in bits per second (bps). Set the baud rate to 9600, 19200, 38400, 57600, or 115200 bps for direct data transmission between the ELI 350 and another Mortara electrocardiograph; 38400 bps for a direct connection to an E-Scribe system.

Use A4 Paper

The ELI 350 accommodates use of Z-fold thermal paper in either letter size (8.5 x 11 inches; 216 x 279 mm) or A4 size (8.27 x 11.69 inches; 210 x 297 mm).

Caps Lock

All character entry is translated to upper case.

Rhythm Formats

Defines the default values for rhythm printing. It is possible to set a 3-channel, 6-channel, or 12-channel default rhythm format.

The 3-channel and 6-channel rhythm formats can be selected from a list of 12 leads, or 15 leads if this option is enabled. If the 15-lead option is enabled, the 12-channel rhythm format can be defined to include any 12 of the 15 leads available.

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 or optional 15 leads are always stored.

ECG plot options are:

Format Option		ECG Data
3+1	12-lead mode	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. Cabrera also available.
	15-lead mode	2 seconds of 15 leads in a 3-channel format, plus 10-second rhythm strip of one user-selectable lead in a 1-channel format. Cabrera also available.
6	12-lead mode	5 seconds of standard 12 leads in a 6-channel format. Cabrera also available.
3+3	12-lead mode	2.5 seconds of 12 leads in a 3-channel format, plus 10-second rhythm strip of user-selectable leads in a 3-channel format. Cabrera also available.
	15-lead mode	2 seconds of 15 leads in a 3-channel format, plus 10-second rhythm strip of user-selectable leads in a 3-channel format. Cabrera also available.
12	12-lead mode	10 seconds of standard 12 leads in a 12-channel format placing one lead over the other. Cabrera also available.
6+6	12-lead mode	10 seconds of standard 12 leads in a 6-channel format. Cabrera also available.

Rhythm Leads

Identifies the three user-selectable, 10-second rhythm leads for the 3+1 and 3+3 channel ECG printout.

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

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

XMT Media

Identifies the default transmission media; those connectivity options which have been optionally purchased and installed will be available for default selection.

DHCP

Defines whether the Dynamic Host Communication Protocol (DHCP) will be used to obtain an IP address. If DHCP is Yes, the network will automatically and dynamically assign an IP address. If DHCP is No, you must enter the IP address, def gateway, and sub net mask.

> ***NOTE****: All parameters related to network connection must be entered under the direction of the IT Manager of the facility where the device is installed.*

IP Address

Enter the fixed IP address for network transmission (if DHCP is not selected).

Def Gateway

Enter the address of the default gateway (if DHCP is not selected).

Sub Net Mask

Enter the sub net address (if DHCP is not selected).

Host IP

Enter the IP address of the host server.

> ***NOTE:*** *Addresses are always entered as 4 sets of 3 digits; therefore, an address of 192.168.0.7 must be entered as 192.168.000.007.*

Port Number

Enter the port number used by the host server.

SSID

Service Set Identifier (SSID) is the name of the wireless network. All ELI 350 electrocardiographs that will transmit to the same network must have the same SSID name. This field is case sensitive.

Communication Protocol

System may be set to UNIPRO, UNIPRO 32, DICOM, or DICOM 32.

> ***NOTE:*** *This parameter must be entered under the direction of the IT Manager of the facility where the device is installed.*

Security (WEP)

Wired Equivalent Privacy (WEP) is an encrypted security protocol (part of the 802.11 standard). Access points can have multiple WEP keys stored. Each one of them is identified by a number (e.g., 0, 1, 2, 3).

WEP Key

Enter the WEP key number.

WEP Key ID

Enter the 128-bit WEP Key ID value (26 digits in 13 sets of two digits).

WPA-PSK

WPA (Wi-Fi Protected Access) PSK (Pre-Shared Key) security allows for implementation of the "personal mode" of WPA. This mode of encryption employs Temporal Key Integrity Protocol (TKIP) which dynamically changes keys as the system is used.

PSK Passphrase

The passphrase may be from eight to 63 ASCII characters or 64 hexadecimal digits (256 bits).

WPA-LEAP

Cisco® LEAP (Light Extensible Authorization Protocol) enables use of the device with wireless networks employing the LEAP encryption protocol.

LEAP User Name

The LEAP user name can be up to 32 characters in length.

LEAP Password

The LEAP password can contain up to 32 characters.

ECG Storage

States purchased configuration of device regarding ECG storage.

Rest Interpretation

States purchased configuration of device regarding interpretation option.

MAINTENANCE AND TROUBLESHOOTING

System Troubleshooting Chart

LCD Message	Problem	Correction
BATTERY LOW, Battery LED flashing on the front panel	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.
NO ANSWER	Unable to transmit ECG.	Check for correct phone number. Ensure modems and E-Scribe are online.

ECG Troubleshooting Chart

LCD Message	Problem	Correction
LEADS OFF OR ONE OR MORE OF THE FOLLOWING: RA, LA, LL, V1, V2, V3, V4, V5, V6 IF 15 LEADS: V3R, V4R, V7 or V7, V8, V9, or E1, E2, E3	Lead fail.	Indication of RL/RA/LA/LL/V1/V2/V3/V4/V5/V6. Check limb leads. V3R,V4R,V7, V8,V9,E1, E2, E3. 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.

Transmission Troubleshooting Chart

LCD Message	Problem	Correction
TRANSMIT FAILED (MODEM)	Unable to transmit ECG.	Check phone line. Ensure site number is valid. Try again.
TRANSMIT FAILED (WLAN)	Unable to transmit ECG.	Select Settings followed by Test WLAN to verify that an adequate RF signal exists. If not, move to a location exhibiting a stronger RF signal.
UNABLE TO SAVE ECG	No available memory. ECG data too noisy to store.	Press stop to continue. Transmit or mark records for deletion in the directory. Correct noise and try acquisition/storage again.
PAPER QUEUE FAULT	Unable to print.	Add paper; manually advance page evenly past closure point of writer and close writer cover and press STOP.
CONNECTION FAILED	Unable to transmit or receive ECGs.	Check for correct baud rate, phone number, and cable connections or site number.
None	File not successfully transmitted via LAN.	Check share permissions on host device.
None	Unable to connect with LAN with crossover cable.	Implement hub vs. crossover cable.

Power Off the ELI 350

To shutdown the ELI 350, disconnect the AC power cord then press and hold the ON/OFF button for 4 seconds. Such a shutdown should always be performed prior to removal of fuses or authorized repair of the device.

Test Operation

After cleaning and inspecting the ELI 350, 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. Paper should stop with perforations near the tear-bar (indicating proper cue sensor operation).

Recommendations to Biomedical Staff

Following any service to the ELI 350 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 350 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 350 service manual.

Mortara Instrument, Inc. recommends that the ELI 350 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. When the battery charge is depleted to its lowest level (10.6V), the device will automatically power down. To recharge a battery from its lowest level to 85%, 4 hours of recharging may be necessary. To reach 90%, 7 hours of recharging may be necessary. It may take longer to reach 100%. The device can be used with AC power while simultaneously charging.

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.
6. Clean cue sensor photo detector.