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ELI 380

RESTING ELECTROCARDIOGRAPH
USER MANUAL



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



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



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1. GENERAL STATEMENTS

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2. 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.

This manual must be kept in a safe place to prevent its deterioration and/or alteration. The user and Mortara Instrument, Inc. authorized personnel must have access to this manual at any time.

The user of this device must periodically check the accessories, their functionality and integrity.

Equipment Identification

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

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Other Important Information

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3. WARRANTY INFORMATION

Your Mortara Warranty

MORTARA INSTRUMENT, INC. (hereafter referred to as “Mortara”) warrants that components within Mortara products (hereafter referred to as “Product/s”) will be free from defects in workmanship and materials for the number of years specified on documentation accompanying the product, or previously agreed to by the purchaser and Mortara, or if not otherwise noted, for a period of twenty-four (24) months from the date of shipment.

Consumable, disposable or single use products such as, but not limited to, PAPER or ELECTRODES are warranted to be free from defects in workmanship and materials for a period of 90 days from the date of shipment or the date of first use, whichever is sooner.

Reusable product such as, but not limited to, BATTERIES, BLOOD PRESSURE CUFFS, BLOOD PRESSURE HOSES, TRANSDUCER CABLES, Y-CABLES, PATIENT CABLES, LEAD WIRES, MAGNETIC STORAGE MEDIUMS, CARRY CASES or MOUNTS, are warranted to be free from defects in workmanship and materials for a period of 90 days. 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.

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.

4. 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.

NOTE: *This manual may contain screen shots and pictures. Any screen shots and pictures are provided for reference only. Consult the actual screen in the host language for specific wording.*



Warnings

1. 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.
2. 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.
3. Users are expected to be licensed clinical professionals knowledgeable about medical procedures and patient care, and adequately trained in the use of this device. Before attempting to use this device for clinical applications, the operator must read and understand the contents of the user manual and other accompanying documents. Inadequate knowledge or training could result in increased risk of harm to users, patients and bystanders, or damage to the device. Contact Mortara service for additional training options.
4. To ensure that electrical safety is maintained during operation from AC (~) power, the device must be plugged into a hospital-grade outlet.
5. Only use parts and accessories supplied with the device and/or are available through Mortara Instrument, Inc.
6. Mortara acquisition modules intended for use with the device include series resistance (9 Kohm minimum) in each lead for defibrillation protection. Acquisition modules should be checked for cracks or breakage prior to use.
7. The ELI 380 uses lithium-ion batteries. The following precautions should be taken regarding the batteries:
 - o Do not immerse the device in water.
 - o Do not heat or throw the device in fire.
 - o Do not leave the device in conditions over 60 °C or in a heated car.
 - o Do not attempt to crush or drop the device.
 - o Only use the approved Mortara battery pack with the ELI 380.
 - o Follow the disposal instructions in the ELI 380 Service Manual when the device is taken out of service.
8. The ELI 380 battery/batteries must be initially fully charged prior to use. Ideally, the battery/batteries must be fully charged and fully discharged several times to allow for optimal performance.
9. Portions of the device are constructed from glass. If the machine is dropped, or otherwise impacted this glass can shatter. Broken glass can cause injurious cuts.

10. The movable touchscreen display can pinch fingers when closing. Use caution when closing and opening the display.
11. Conductive parts of the acquisition module(s), electrodes, and associated connections of type CF applied parts, including the neutral conductor of the acquisition module(s) and electrodes, should not come into contact with other conductive parts including earth ground.
12. ECG electrodes could cause skin irritation; patients should be examined for signs of irritation or inflammation.
13. To avoid the possibility of serious injury or death during patient defibrillation, do not come into contact with the device or acquisition module(s). Additionally, proper placement of defibrillator paddles in relation to the electrodes is required to minimize harm to the patient.
14. This device does not automatically switch between direct or wireless acquisition modules. Clinician must choose the type of acquisition module before ECG acquisition. If your device is equipped with a receiver for a wireless acquisition module, always make sure that you are receiving data from the expected module.
15. 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.
16. 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.
17. A possible explosion hazard exists. Do not use the device in the presence of a flammable anesthetic mixture.
18. Where the integrity of external protective earth conductor arrangement is in doubt, the device shall be operated from its internal electrical power source.
19. Medical devices have been designed to have a higher degree of protection against electric shock than, for instance, information technology equipment because patients often are connected to multiple devices and also may be more prone to the adverse effect of electric currents than healthy persons. All equipment that is connected to the patient, can be touched by the patient, or can be touched by another person while that person touches the patient at the same time, should have the same level of protection against electric shock as medical equipment. The ELI 380 is a medical device that has been designed to be connected to other devices for the purpose of receiving and transmitting data. Certain measures must be taken to prevent the risk of excessive electric current flow through the operator or patient when connected:
 - All electrical equipment that is **not medical electrical equipment** must be placed outside of the “patient environment,” defined by applicable safety standards to be at least 1.5 meters (5 feet) from the patient. Alternatively, non-medical equipment may be provided with additional protection such as an additional protective earth connection.
 - All **medical electrical equipment** that has a physical connection to the ELI 380 or the patient, or is in the patient environment must comply with applicable safety standards for medical electrical devices.
 - All electrical equipment that is **not medical electrical equipment** and has a physical connection to the ELI 380 must comply with applicable safety standards, such as IEC 60950 for information technology equipment. This includes information network equipment connected through the LAN connector.
 - Conductive (metal) parts that can be touched by the operator in normal use and that are connected to **non-medical equipment** should not be brought into the patient environment. Examples are connectors for shielded Ethernet or USB cables.

- If **multiple devices** are connected to each other or to the patient, device chassis and patient leakage currents may be increased, and should be measured for compliance with applicable standards for medical electrical systems.
 - Avoid the use of **portable multiple socket outlets**. If used and not compliant with medical electrical device standards, an additional protective earth connection is required.
 - 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.
20. 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.
 21. When the 40 Hz filter is used, the frequency response requirement for diagnostic ECG equipment cannot be met. The 40 Hz filter significantly reduces high-frequency components of the ECG and pacemaker spike amplitudes, and is recommended only if high-frequency noise cannot be reduced by proper procedures.
 22. Other medical equipment, including but not limited to defibrillators and ultrasound machines, may cause interference with the ECG signals recorded by the device.
 23. 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.
 24. Unauthorized connection to IT networks could result in previously unidentified risks to patients, operators, or third parties. The manufacturer is not liable for these additional risks, as the identification, analysis, evaluation, and control should be conducted by the responsible organization. Changes to the IT network could also introduce new risks that require additional analysis. This includes changes in network configuration, connection of additional items, disconnection of items, update of equipment, and upgrade of equipment.
 25. Some Mortara electrocardiographs can be equipped with a wireless LAN (WLAN) module for transmitting ECG records. Device labeling 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 WLNN-AN-MR551
(model subject to change without notice)
 26. Use of the 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.
 27. 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 and the head and body of the user and any nearby persons at all times.
 28. The WLAN module complies 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



Cautions

1. Do not attempt to clean the device or acquisition module by submersing into a liquid, autoclaving, or steam cleaning as this may damage equipment or reduce its usable life. 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.
2. 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/repared by qualified service personnel prior to continued use.
3. The rechargeable internal battery is a sealed lithium-ion type. If the battery appears to become defective, refer to Mortara Technical Support.
4. Do not pull or stretch the acquisition module lead wires and cable as this could result in mechanical and/or electrical failures.
5. Proper functioning backup items such as spare lead wires, front-end device, and other equipment are recommended on hand to prevent delayed treatment due to an inoperable device.
6. The WAM will only work with receiving devices that are equipped with the appropriate option.
7. No user-serviceable parts are inside the WAM. Damaged or suspected inoperative equipment must be immediately removed from use and must be checked/repared by qualified service personnel prior to continued use.
8. This WAM is not recommended for use in the presence of imaging equipment such as Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) devices, etc.
9. The following equipment may cause interference with the WAM RF channel: microwave ovens, diathermy units with LANs (spread spectrum), amateur radios, and government radar.
10. When necessary, dispose of the device, its components and accessories (e.g., batteries, cables, electrodes), and/or packing materials in accordance with local regulations.
11. AA batteries are known to leak their contents when stored in unused equipment. Remove battery from WAM when not used for an extended period of time.
12. Be careful to insert the connector block into the appropriate input connector by matching the lead wire labels to the WAM or AMxx label. (AMxx refers to USB equipped acquisition modules. Examples of AMxx acquisition modules include AM15E, AM12M, and AM12.)

FCC Compliance Statement for the WAM

In the United States use of this device is regulated by the Federal Communications Commission (FCC). The WAM with its antenna complies with FCC's RF exposure limits for general population/uncontrolled exposure.

FCC Warning (Part 15.21): Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the device.

WAM FCC ID: HJR-WAM2500
UTK FCC ID: HJR-UTK2500

These devices comply with Part 15 of the FCC rules. Operation is subject to the following conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

Industry Canada Compliance Statement

These devices comply with RSS-210 of the Industry Canada rules. Operation is subject to the following two conditions:

1. This device may not cause interference, and
2. This device must accept any interference, including interference that may cause undesired operation of the device.

WAM IC: 3758B-WAM2500
UTK IC: 3758B-UTK2500

The term "IC:" before the certification/registration number only signifies that the Industry Canada technical specifications were met.

Notes

1. Patient movement may generate excessive noise that may affect the quality of the ECG traces and the proper analysis performed by the device.
2. Proper patient preparation is important to proper application of ECG electrodes and operation of the device.
3. The algorithm detecting electrode reversal is based on normal physiology and ECG lead order, and tries to identify the most likely switch; however, it is advisable to check the other electrode positions in the same group (limb or chest).
4. 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.
5. The WAM LEDs will automatically start flashing if the batteries have been discharged below 1.0 volts.
6. During normal WAM/AMxx operation, the green LED will display continuously.
7. If the WAM battery cover is opened during transmission, the device will stop transmitting. The battery must be reinserted and the cover must be applied to resume operation.
8. The WAM will automatically turn off (LEDs off) if the battery has been severely discharged.
9. The WAM will automatically turn off when the electrocardiograph is powered down.
10. The WAM will automatically turn off after being disconnected from the patient. This will happen regardless of ELI 380 battery/AC power state.
11. The display of absent waveform while using the WAM wireless acquisition module could be due to the WAM being turned off or having no battery, or the WAM being out of range or experiencing a calibration error. Review the LED indicator on the WAM to ensure the unit is turned on and has proper battery level. Ensure the WAM is paired correctly and is within recommended proximity of the electrocardiograph, and/or power cycle the WAM to re-calibrate.
12. The display of absent waveform display while using the AMxx acquisition module could be due to an improper auto-calibration. Reconnect the AMxx or power cycle the electrocardiograph.
13. Square waves on the display and rhythm printout could be due to the WAM or the AMxx lead wires not being connected to the patient.
14. 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.

15. 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

16. The device will automatically turn off (blank screen) if the batteries have been severely discharged and the AC mains is disconnected from the device.
17. 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.
18. When using the WAM, it must be paired to electrocardiograph before operation.
19. The device is UL classified:



WITH RESPECT TO ELECTRIC SHOCK,
 FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH
 AAMI ES 60601-1(2012), CAN/CSA C22.2 No. 60601-1(2014), IEC
 60601-1(2012), AND IEC 60601-2-25(2011)

20. The WAM 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, IEC60601-2-25,

Wireless Data Transmission

21. ELI 380 electrocardiographs are equipped with a wireless data transmission module (WLAN). This technology uses 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 WLAN signals may propagate better to allow successful transmissions.

WLAN

22. Wireless options transmit in the 2.4 GHz or 5 GHz range. Other nearby wireless devices in the same frequency range may cause interference. If possible, move or turn off other devices to minimize potential interference.
23. The Wireless LAN module used is compliant with the IEEE 802.11 a, b, g and n standards.





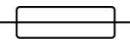
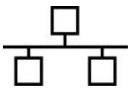







24. Access Points used should respect IEEE 802.11 standards as well as local Radio Frequency regulations. The device will scan the available channels and connect to the Access Point on the channel where the SSID that is configured on the device is available.
25. The following table shows the radio channels allocated in different geographic areas in the world. For bands 802.11b and g, only channels 1, 6, 11 and 14 (Japan only) are non-overlapping; for band 802-11 a, channels shown represent non-overlapping channel numbers.

Band	Typical Power	Region	Frequency Range (GHz)	No. of channels	Channel numbers
802.11b	15 dBm / 32 mW	USA/Canada	2.401 - 2.473	11	1 – 11
		Europe	2.401 - 2.483	13	1 – 13
		Japan	2.401 - 2.495	14	1 – 14
802.11g	13 dBm / 18 mW	USA/Canada	2.401 - 2.473	11	1 – 11
		Europe	2.401 - 2.483	13	1 – 13
		Japan	2.401 - 2.483	13	1 – 13
802.11a	17 dBm / 50 mW	USA/Canada	5.15 - 5.35, 5.725 - 5.825	13	36,40,44,48,52,56,60,64,149,153,157,161,165
		Europe	5.15 - 5.35, 5.47 - 5.725	19	36,40,44,48,52,56,60,64,100,104,108,112,116,120,124,128,132,136,140
		Japan	4.91 – 4.99, 5.15 - 5.35, 5.47 - 5.725	23	36,40,44,48,52,56,60,64,100,104,108,112,116,120,124,128,132,136,140,184,188,192,196
		China	5.725 - 5.825	5	149,153,157,161,165

26. 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.
- 27.
28. 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 where the WLAN frequencies are available.

5. EQUIPMENT SYMBOLS AND MARKINGS

Symbol Delineation

	Caution
	Consult accompanying documents
	Alternating current
	Protective earth symbol (appears on inside of unit)
	Fuse symbol (appears on inside of unit)
	Network (LAN)
	Universal Serial Bus (USB)
	Defibrillator-proof type CF applied part
	Patient Cable Input
	ON/OFF (Standby/power)
	Shift key (to enter upper case text on keyboard)
	Do not dispose as unsorted municipal waste. Per European Union Directive 2002/96, requires separate handling for waste disposal according to national requirements
	Indicates compliance to applicable European Union directives

Display Icons and Keyboard Buttons



Patient Information



ECG Acquisition



Rhythm Print



Synchronize



Configuration



Home



Full disclosure page up



ECG Acquisition from full disclosure selection



Full disclosure page down

6. GENERAL CARE

Precautions

- Power 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 Lead Wires and Cables, Patient Acquisition Device and Electrocardiograph

1. Remove cables and lead wires from device before cleaning. Disconnect the power source.
2. For general cleaning of device, display, 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 device, 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, or a 3% hydrogen peroxide solution.
4. For disinfecting the cables and lead wires, wipe exterior with a soft, lint-free cloth using the same solutions as for the device, or use highly concentrated (> 70%) isopropanol or ethanol.
5. Use caution with excess liquid as contact with metal parts may cause corrosion.
6. Do not immerse cable ends or lead wires; immersion can cause metal corrosion.
7. Do not use excessive drying techniques such as forced heat.



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



WARNING: Use of unspecified cleaning/disinfecting agents or failure to follow recommended procedures could result in increased risk of harm to users, patients and bystanders, or damage to the device.

NOTE: Mortara does not endorse any specific off-the-shelf wipes or liquids. However, products that only contain the disinfecting agents mentioned above are likely to be compatible with the device. Some products contain a mixture of agents and may have a detrimental effect if used intensively and frequently. Check the Material Safety Data Sheet of the product used for the list of ingredients

7. 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 the appropriate EMC table for recommended separation distances between the radio equipment and the device.

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

Guidance and Manufacturer's Declaration: Electromagnetic Emissions

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

Emissions Test	Compliance	Electromagnetic Environment: Guidance
RF Emissions CISPR 11	Group 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	
Harmonic Emissions IEC 61000-3-2	Complies	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

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.

Immunity Test	Compliance	Compliance Level	Electromagnetic Environment: Guidance
Electrostatic discharge (ESD) EN 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 EN 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.

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.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment: Guidance
Conducted RF EN 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	<p>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.</p> <p>Recommended separation distance</p> $d = \left[\frac{3.5}{3\sqrt{V_{rms}}} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = \left[\frac{3.5}{3\sqrt{V/m}} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{3\sqrt{V/m}} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>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).</p> <p>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.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

- 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.

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.

8. INTRODUCTION

Manual Purpose

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

- Using and understanding the ELI™ 380 electrocardiograph, and the function control icons.
- Preparing the ELI 380 for use.
- Acquiring, printing, and storing an ECG.
- Connectivity and transmitting ECGs.
- Managing the ECG directory, MWL Orders, and the Patient List.
- Configuration settings.
- Maintenance and troubleshooting.

NOTE: This manual may contain screen shots. Any screen shots are provided for reference only and are not intended to convey actual operating techniques. Consult the actual screen in the host language for specific wording.

Audience

This manual is written for clinical professionals with a working knowledge of medical procedures and terminology as required for monitoring cardiac patients.

Indications For Use

- Device is indicated for use to acquire, analyze, display, and print electrocardiograms.
- Device is indicated for use to provide interpretation of the data for consideration by a physician.
- 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.
- 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 380 is a 12-lead and 15-lead resting ECG diagnostic electrocardiograph with a bright, 17" LCD color display capable of acquiring, viewing, transmitting, printing, and storing resting ECG test data. The device is equipped with Mortara Instrument's VERITAS™ resting ECG interpretation algorithm using gender specific and adult and pediatric criteria. 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 VERITAS with Adult and Pediatric Resting ECG Interpretation* (see Accessories).

The device includes bidirectional LAN support and can also be configured with WLAN connectivity and DICOM® Modality Work List with synchronization of orders and date and time as well as encrypted transmission of ECGs. A query of patient demographics can also be performed utilizing the Patient List feature.

The device can operate on a single lithium-ion battery or AC line power. An optional second lithium-ion battery can be added for extended operating time.

A capacitive-touch glass keyboard with navigational touchpad provides the user-interface. A swivel touchscreen is available. A USB bar code reader for demographic text entry and navigation is optional.

12-lead ECGs can be printed in standard and Cabrera 1-page 3+1, 6+6, 3+3, and 12 channel layouts as well as a 2-page 6 channel layout. 15-lead ECGs can be printed in standard and Cabrera 1-page 3+1 and 3+3 layouts. Rhythm prints can be in 3, 6, 8, or 12-channel layouts. The ECG and rhythm strip can be initiated at the ELI 380 as well as with a button-press on the acquisition module at the patient.

A Best 10 feature that captures a 10-second ECG with the lowest noise content in the collected ECG is included. The clinician may choose between automatic Best 10 or Last 10 (seconds) ECG selection from accumulated full disclosure ECG. Best 10 is taken from the last 5 minutes of the full disclosure. Additionally, the clinician can select any 10-second period from up to 20-minutes of accumulated full disclosure ECG for viewing, printing, transmitting, and storing.

Alternate 12-lead placement of the precordial leads, V1 to V6, with user-defined labeling is supported for pediatric, posterior, right-sided, and other user-preferred chest lead positions. In these cases, interpretation is disabled. The 3 additional leads for 15-lead placement can also be moved to user-preferred locations.

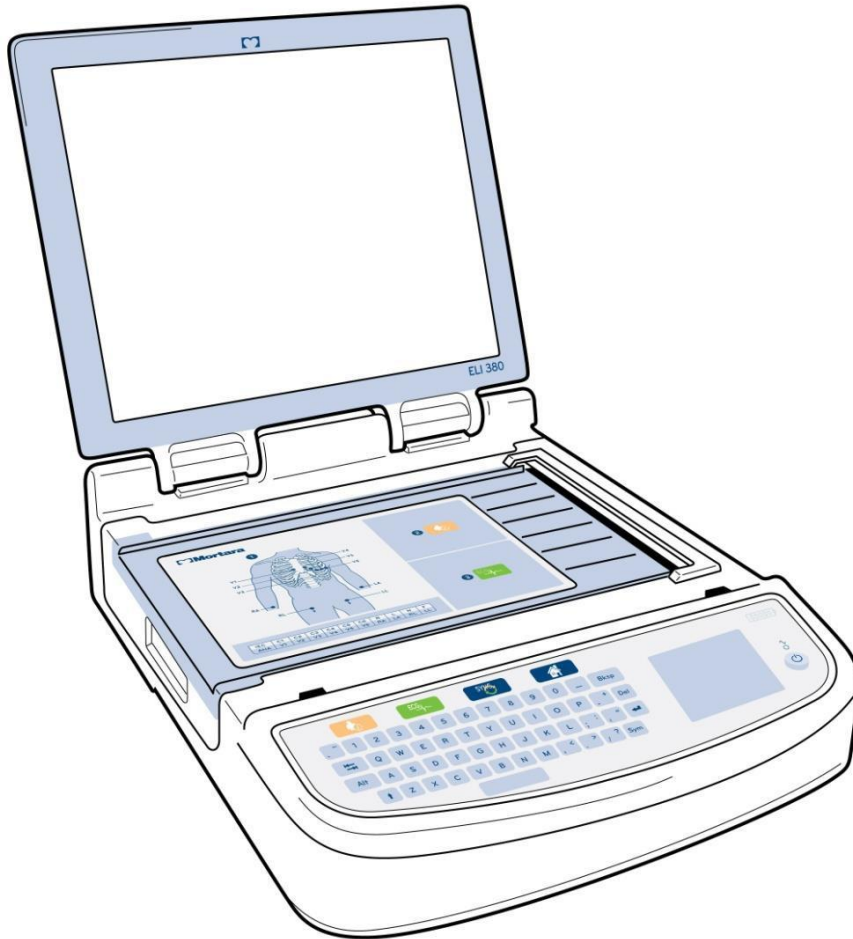
A total of approximately 500 ECGs can be stored in the device and are available for retrieval from the directory, for printing, and/or for transmission to a central repository.

The ELI 380 includes:

- WAM™, AM12™, AM12M or AM15E acquisition module with banana lead wire set
- Hospital-grade power cord
- 1 pack thermal paper
- Physician's Guide to VERITAS with Adult and Pediatric Resting ECG Interpretation
- User manual CD

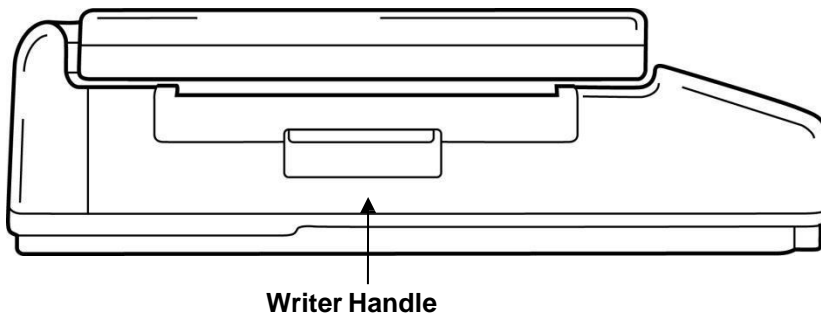
System Illustration

Figure 1 ELI 380 Front



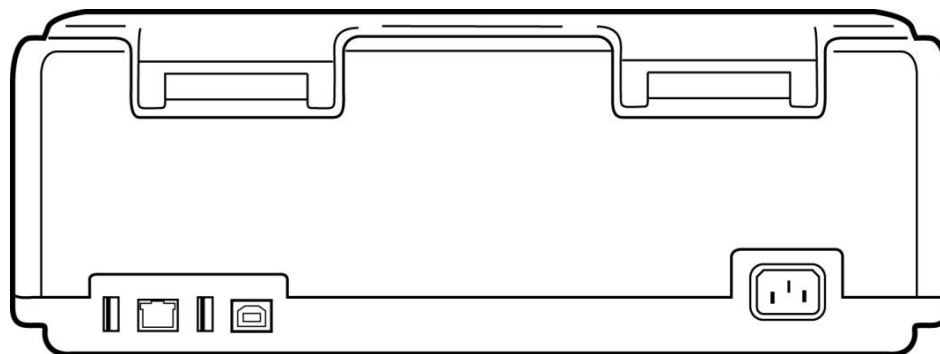
Side View

Figure 2 ELI 380 Side with Writer Handle



Rear View

Figure 3 ELI 380 Rear with Connector Ports



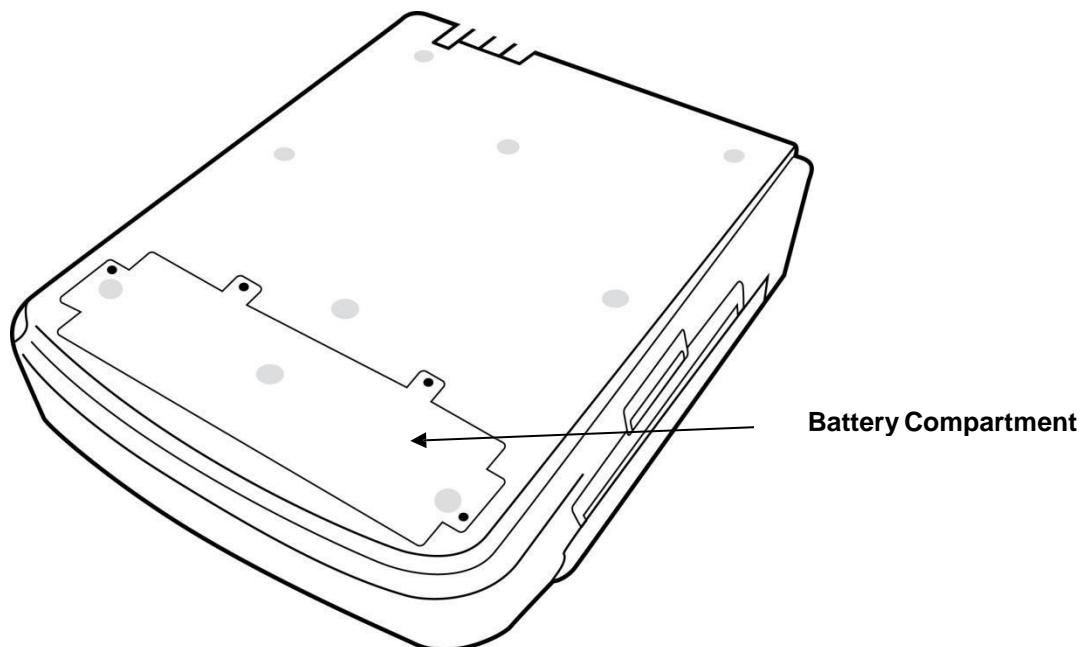
1 2 3 4

5

- 1 AMxx ECG connector port
- 2 RJ45 LAN connector port
- 3 USB connector port
- 4 USB Device Port
- 5 100 – 240V power

Base View

Figure 4 ELI 380 Base with Battery Compartment



Battery Compartment

Swivel Touchscreen Model

The ELI 380 is available in a model that has a special touchscreen that swivels, side-to-side.

Note: An on-screen keyboard is available mainly for languages other than English (Special characters). Users in English speaking markets should generally avoid using this feature. In other languages, press the ALT key twice to start the on-screen keyboard.

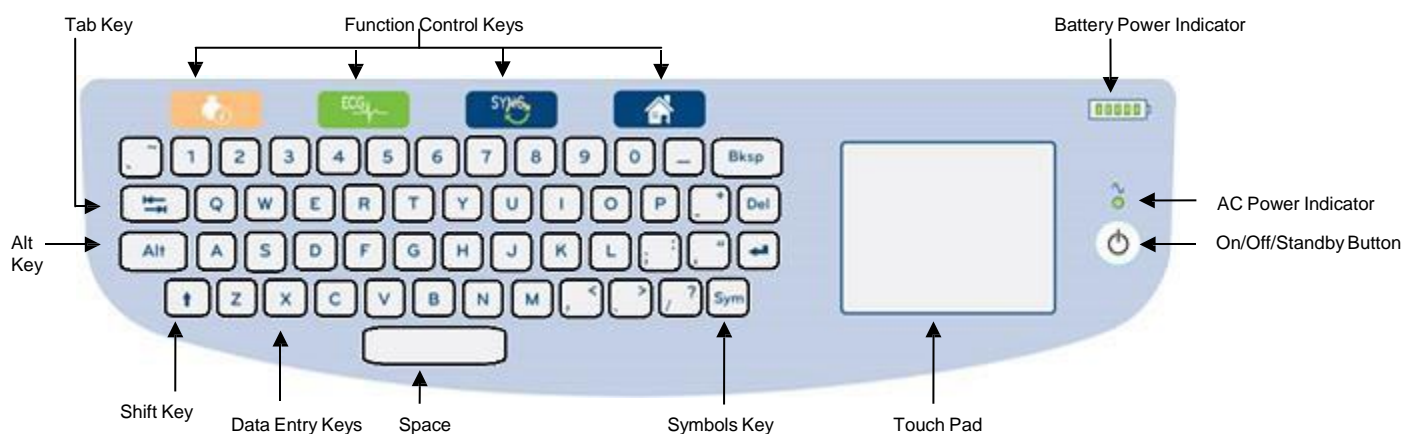


Caution:

Avoid breaking the hinge on swivel touchscreen models. Close the display **only** in the home position (facing forward).



ELI 380 Capacitive-touch Glass Keyboard with Touchpad

Figure 5 ELI 380 Keyboard



The capacitive touchscreen is functional even when wearing gloves.

Cleaning Mode

To clean the touchscreen or keyboard, place the device into sleep mode. Press the power On/Off  button on the keyboard once for less than 7 seconds. The display goes black and cleaning will not affect changes. After cleaning, press the On/Off  button again to restore operation.

Navigation Overview

Navigation of the user interface is achieved with either the touchpad point-and-tap interface or the function control keys. Use of the touchpad requires navigating the mouse arrow over the desired action and tapping. The **TAB** key allows movement from one field to another in some menus.

Power Status

A battery power indicator is displayed in the upper right keyboard area with five bars to indicate the battery charge level. See [Power Status](#) for explanation of battery indications.

The AC power indicator is lit and green when the device is connected to AC power. This indicator is not lit when the unit is running on battery power or powered off. The On/Off/Standby button is used to power on the device initially, enable/disable standby mode, and shutdown the device. During normal operation, the ELI 380 will be in standby when the display cover is closed and will quickly power up when the display is opened. See [Power Status](#) for explanation of power management.

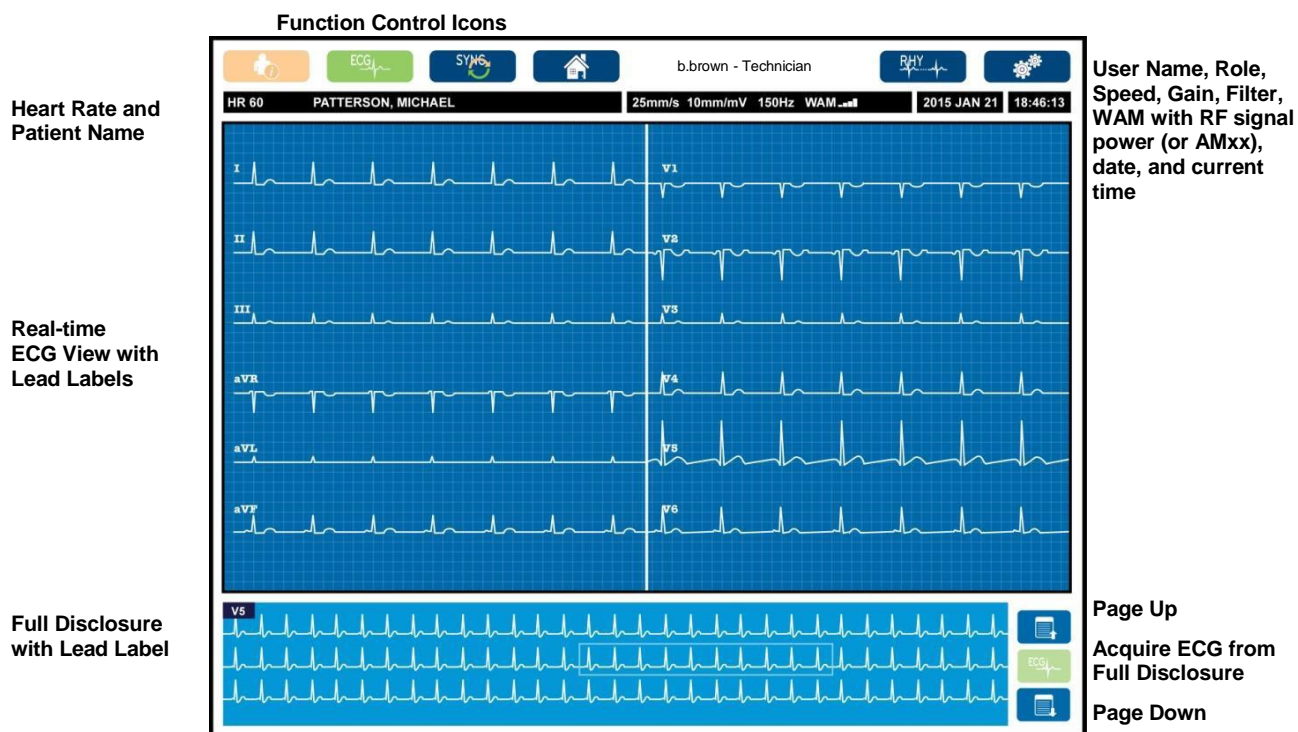
Symbols Entry

When symbols or special characters are required, selection of the **Sym** (symbols) key will open a keyboard menu allowing entry. The **Alt** key will alternate display of different keyboard character selection groups.

Display Overview

The ELI 380 features a 17” diagonal, bright LCD color display to preview the ECG waveform and other parameters as explained below. During ECG connection and acquisition, notification messages may appear on the display. (See [Record an ECG.](#))

Figure 6 ELI 380 Home Display with Full Disclosure



Settings for the display may be altered by a touchpad click in the real-time ECG view. A menu allowing for format, speed, gain, filter, full disclosure, lead placement, and lead mode changes will display. Highlight the desired options and then select **OK** to save changes and exit the menu, or **Cancel** to exit without saving.

***NOTE:** When settings are changed in this menu, ELI 380 will return to configured (default) settings for the next test.*

Display Format	Display Speed	Display Gain	Display Filter	Full Disclosure	Lead Placement	Lead Mode
12x1	5mm/s	5mm/mV	40Hz	On	Standard	12
4x2	10mm/s	10mm/mV	150Hz	Off	Pediatric	15
6x2	25mm/s	20mm/mV	300Hz		Posterior	
II-V1-V5	50mm/s				Right Sided	
		OK		Cancel		

Display Parameters

Heart Rate (HR): HR displays in real time in the upper left corner when a patient is connected to the device. The heart rate in beats per minute is calculated and updated continuously during real-time ECG.

***NOTE:** If a lead fail occurs, an indicator flashes in the center of the display and the HR number displays dashes until the lead failure is corrected.*

Patient Name: The patient's last and first name are presented in the upper left corner of the display.

User Name and Role: When user authentication is enabled, the user's name and role are displayed in the orange box at the top.

Speed, Gain, and Filter: The current settings for sweep speed, ECG gain, and ECG filter display along the top center of the display.

WAM, AM12, AM12M or AM15E: The acquisition module currently in use is presented in the upper right corner of the display. When WAM is in use, RF signal strength is displayed with bars.



WARNING: *If your device is equipped with a receiver for a Wireless Acquisition Module (WAM), always make sure that you are receiving data from the expected module.*

Current Date: The current date appears on top right.

Current Time: The digital clock located in the upper right corner displays hour, minutes and seconds. The time appearing on the ECG printout is the time the ECG was acquired.

Real-time ECG: Lead groups are simultaneous and 7-seconds in duration when 6x2 or 4x2 display format is selected. 12x1 and 3-channel format displays a total of 14-seconds simultaneously.

Full Disclosure ECG: Up to 90-seconds of the most recent accumulated ECG is shown at the bottom of the display when full disclosure is enabled. Although only a single lead is visible, accumulated data is stored for all leads. Page back and page forward selections allow navigation through up to 20-minutes of stored ECG. Full disclosure ECG can be selected for acquisition using the icon to the right of the full disclosure display.

Function Control Icons

Use the keyboard Function Control icons and the touchpad to select and complete patient information and ECG functions. The Configuration menu is also accessible in this manner.



Patient Information

Select this icon to either manually enter patient demographics or pick from the modality work list (MWL), patient list, or ELI 380 directory to find and download patient demographics.



ECG Acquisition

Select this icon to display the ECG in one of several formats: 3+1, 6, 3+3, 12, or 6+6 channel for 12-lead ECGs, or 3+1 or 3+3 channel for 15-lead ECGs. The on-screen ECG report displays patient name, date and time, Last 10 or Best 10, and the filter setting.

Settings for display and printout may be altered in this screen by a touchpad tap in the waveform. A menu allowing for layout, speed, gain, filter, pacer channel, and Best 10/Last 10 changes will display. Select **OK** to save changes and exit the menu, or **Cancel** to exit without saving.

***NOTE:** When settings are changed in this menu, ELI 380 will return to configured (default) settings for the next test.*

Print Layout	Print Speed	Print Gain	Print Filter	Pacer Channel	Best10
3+1 Channel	25mm/s	5mm/mV	40Hz	Off	Best10
6 Channel	50mm/s	10mm/mV	150Hz	On	Last10
3+3 Channel		20mm/mV	300Hz		
12 Channel					
6+6 Channel					
		OK		Cancel	

Select the **Print**, **Transmit**, or **Erase** button to manually perform these actions while the ECG is displayed. You will be prompted “Erase ECG?” when Erase is selected. Selecting **Yes** will return you to the real-time ECG display.



Rhythm Print

Select this icon to begin rhythm printing. Select **Done** to stop rhythm printing and return to the real-time ECG display (Home).

**SYNChronize**

Select this icon or keyboard function key to retrieve orders, transmit unsent ECGs, synchronize directories, and update the time/date between ELI 380 and an information management system. The ELI 380 will synchronize with specific versions of ELI Link.

***NOTE:** This device supports automatic time synchronization with a remote server. Inaccurate time/date settings can result in ECGs marked with inaccurate time stamps. Confirm the accuracy of the synchronized time prior to acquiring ECGs.*

**Configuration Menu (Settings)**

Selection of this icon allows any user to view the About menu, download a custom ID, set the time/date, switch between WAM and AMxx front-ends, test the WLAN connection, and print the system configuration. Access to advanced settings requires an administrative password to configure the system's display and ECG acquisition format along with other settings. These configuration settings become the default setting at power up and for each ECG test.

**Home**

Select this icon or keyboard function key to return to the real-time ECG acquisition display.

**Full Disclosure Page Up**

Select this icon in the bottom right area of the display when full disclosure is on to move back through the stored ECG.

**Full Disclosure ECG Acquisition**

Select this icon to save and display a 10-second ECG surrounded with a green frame within the full disclosure. The ECG is then stored and will display on the main ECG panel with further selections for printing, transmission, or erasure.

**Full Disclosure Page Down**

Select this icon in the bottom right area of the display when full disclosure is on to move forward through the stored ECG.

Specifications

Feature	Specifications
Instrument Type	Multi-lead resting electrocardiograph
Input Channels	Simultaneous acquisition of all leads
Standard 12 Leads Acquired	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Standard 15 Leads Acquired	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6, V7, V8, V9
12-lead Alternate Lead Groups	Up to three additional groups can be labeled using any combination of 6 precordial leads with V1, V2, V3, V4, V5, V6, V7, V8, V9, V3R, V4R, V5R, V6R, and V7R lead labels
15-lead Alternate Lead Groups	Up to two additional groups can be labeled using any combination of 3 leads with V1, V2, V3, V4, V5, V6, V7, V8, V9, V3R, V4R, V5R, V6R, and V7R lead labels
Waveform Display	Backlit, 17" color LCD with 1280 x 1024 resolution
Input Impedance Input Dynamic Range Electrode Offset Tolerance Common Mode Rejection	Meets or exceeds the requirements of ANSI/AAMI/IEC 60601-2-25
Patient Leakage Current Chassis Leakage Current	Meets or exceeds the requirements of ANSI/AAMI ES 60601-1
Digital Sampling Rate	40,000 samples/s/channel used for pacemaker spike detection; 1,000 samples/s/channel used for recording and analysis
Miscellaneous Features	Best 10 automatic capture of the best-quality 10-second ECG from the last 5 minutes of full disclosure; Any 10-second period from up to 20-minutes of accumulated full disclosure is available for viewing, printing, transmitting, and storing. Alternate lead placement selection with default for pediatric, right-sided, posterior and any combination of user-defined precordial lead labeling
Optional Functions	Connectivity with bidirectional communication Security including user authentication and encryption of stored memory
Paper	Smart (210 x 280 mm) perforated Z-fold thermal cued paper with full grid, 250 sheets stored in paper tray
Thermal Printer	Computer-controlled dot array; 1 dot/ms horizontal, 8 dots/mm vertical
Thermal Printer Speeds	5, 10, 25, or 50 mm/s
Gain Settings	5, 10, or 20 mm/mV
Report Print Formats	12-lead Standard or Cabrera: 3+1, 3+3, 6, 6+6, or 12 channel 15-lead Standard or Cabrera: 3+1 or 3+3 channel
Rhythm Print Formats	3, 6, 8 or 12 channel with configurable lead groups
Keyboard	Glass keyboard with alphanumeric keys, soft-key menu, dedicated function keys, and touchpad pointing device
Mouse	Supports USB mouse.
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 500 ECGs
Weight (Standard Display Model)	22 lbs. (10 kg) including battery (without paper)
Weight (Swivel Display Model)	27 lbs. (12.5 kg) including battery (without paper)
Closed Dimensions (Standard Display Model)	15.5 x 20 x 5.5 in (39 x 51 x 14 cm)
Closed Dimensions (Swivel Display Model)	15.5 x 20 x 7 in (39 x 51 x 17.8 cm)
Touchscreen Range of Motion (Swivel Model Only)	120° from center (180° total swivel)
Power Requirements	Universal AC power supply (100-240 VAC at 50/60 Hz) 110 VA; internal rechargeable lithium-ion battery with support for a second optional battery

Accessories

Replacement Lead Sets and Accessories

Part Number	Description
9293-046-07	COMBINER WAM/AM12
9293-046-60	LEAD SET WAM 10 WIRE BANANA AHA GRAY
9293-046-61	LEAD SET WAM 10 WIRE BANANA IEC GRAY
9293-046-62	RPLCE LD SET WAM/AM12 LIMBS BANA AHA GRY
9293-046-63	RPLCE LD SET WAM/AM12 LIMBS BANA IEC GRY
9293-046-64	RPLCE LD SET WAM/AM12 V1-V3 BANA AHA GRY
9293-046-65	RPLCE LD SET WAM/AM12 C1-C3 BANA IEC GRY
9293-046-66	RPLCE LD SET WAM/AM12 V4-V6 BANA AHA GRY
9293-046-67	RPLCE LD SET WAM/AM12 C4-C6 BANA IEC GRY
9293-046-80	LEAD SET AM15E 13-WIRE BANANA AHA GRAY
9293-046-81	LEAD SET AM15E 13-WIRE BANANA IEC GRAY
9293-046-82	RPLCE LEAD SET AM15E E2-E4 BANANA AHA GR
9293-046-83	RPLCE LEAD SET AM15E E2-E4 BANANA IEC GR
9293-047-60	LEAD SET WAM 10 WIRE CLIPS AHA GRAY
9293-047-61	LEAD SET WAM 10 WIRE CLIPS IEC GRAY
9293-047-62	RPLCE LD SET WAM/AM12 LIMBS CLIP AHA GRY
9293-047-63	RPLCE LD SET WAM/AM12 LIMBS CLIP IEC GRY
9293-047-64	RPLCE LD SET WAM/AM12 V1-V3 CLIP AHA GRY
9293-047-65	RPLCE LD SET WAM/AM12 C1-C3 CLIP IEC GRY
9293-047-66	RPLCE LD SET WAM/AM12 V4-V6 CLIP AHA GRY
9293-047-67	RPLCE LD SET WAM/AM12 C4-C6 CLIP IEC GRY

Paper

Part Number	Description
9100-026-52	SMART PAPER
9100-026-55	ARCHIVAL SMART PAPER (25 year life)

Electrodes

Part Number	Description
9300-032-50	ECG MONITORING ELECTRODES CASE 300
9300-033-51	ELECTRODE RESTING TAB BOX/500
9300-033-52	ELECTRODE RESTING TAB CASE/5000
047029	ULTRA II RESTING TAB ELECTRODES
015-0630-00	BLUE MAX RESTING TAB ELECTRODES

Acquisition Modules

Part Number	Description
9293-048-54	WIRED PATIENT CABLE (AM12) W/O LEAD WIRES
9293-065-50	WIRED PATIENT CABLE (AM12M) W/O LEAD WIRES
9293-063-50	WIRED PATIENT CABLE (AM15E) W/O LEAD WIRES
30012-019-54	WIRELESS ACQUISITION MODULE (WAM) W/O LEAD WIRES

Power Cords

Part Number	Description
3181-008	POWER CORD US/CAN HOSPITAL 5-15P+320-C13
3181-012-01	POWER CORD AUSTRALIA AS3112+IEC320-C13
3181-015-01	POWER CORD UK BS1363+IEC320-C13
3181-002	POWER CORD INTN'L CEE7/7+IEC320-C13
3181-016-01	POWER CORD BRAZIL

Manuals

Part Number	Description
9515-001-51-CD	PHYSICIAN'S GUIDE ADULT & PEDIATRIC V7 UM
9515-166-50-CD	ELI LINK USER MANUALS
9515-189-50-CD	ELI 380 USER MANUALS
9516-189-50-ENG	ELI 380 SERVICE MANUAL

Miscellaneous

Part Number	Description
9903-029	CBL BARCODE SCANNER USB
9903-021-52	BARCODE SCANNER HAND HELD FOR USB
4800-017	ELI 380 LITHIUM-ION BATTERY

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

9. EQUIPMENT PREPARATION

Initial Startup

When powering the ELI 380 on for the first time, the device requires the user to set certain configurations prior to obtaining an ECG:

1. Custom ID (if applicable). Refer to the ELI Link user manual for instructions on how to set and change the Custom ID.
2. Date and time, including daylight savings start and end time selection.
3. Configure the acquisition module.
4. Advanced ECG and system settings. Refer to [Configuration Settings](#) for instructions.

NOTE: The WAM, AM12, AM12M, and AM15E acquisition modules can be used with the ELI 380; however, only one acquisition module can be used per ECG acquisition. To switch from one acquisition module to the other prior to ECG acquisition, see the configuring instructions below.

NOTE: When using a Wireless Acquisition Module (WAM) care must be taken to ensure that the expected WAM module is paired with the cardiograph. It is recommended to use visual identifying indicators (like color coded or matching labels) on the WAM and Cardiograph to avoid mismatch between units.

Configuring the AMxx Acquisition Module

Connect the AMxx to the ECG connector at the rear of the device and configure it at the ELI 380 before operation.


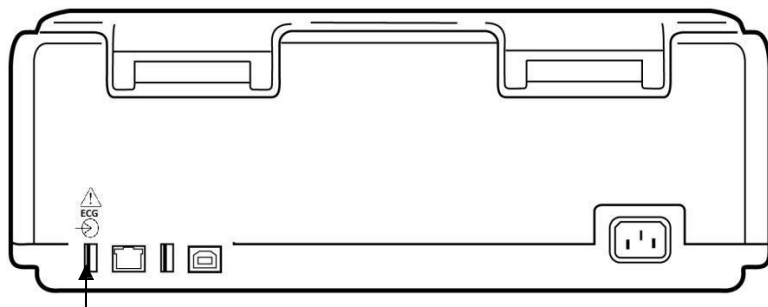
At the ELI 380 select  followed by **WAM/AM-XX**. Dependent on last saved setting, either AM12, AM15E, or WAM is displayed with FPGA and UTK Firmware versions. Select **Switch to AM-XX** and then select **Done** to return to the Configuration screen.


Figure 7 ELI 380 AMxx Connection




AMxx USB Connection Port

Configuring the WAM Wireless Acquisition Module

When using the WAM for ECG acquisition, no physical connection is required. WAM must be selected and paired to the ELI 380 before operation. Only one WAM can be configured to one ELI 380. The same WAM will remain paired with the electrocardiograph for future use. A different WAM must be paired to the ELI 380 before use.

At the ELI 380 select  followed by **WAM/AM-XX**. Dependent on last saved setting, either AM12, AM15E, or WAM is displayed with FPGA and UTK Firmware versions. Select **Switch to WAM** followed by **WAM Pairing**. Follow the on-screen instructions. Once the WAM is paired, a Successfully Paired message will display. Select **Done** to return to the Configuration screen.

ELI 380 Configuration for All Users

Select  to enter the configuration menu. The following selections are available to all users. For more detail, refer to [Configuration Settings](#).

About: Upon selection of the Configuration function icon, information is initially displayed for the ELI 380 serial number, software version, DICOM enabled, WLAN enabled, LAN and WLAN MAC addresses.

Custom ID: Selection of this function will initiate download of the Custom ID. The user is notified about success of the download. Select **Done** to save changes and exit the menu, or **Cancel** prior to completion of download to exit without saving.

Date/Time: Use this function icon to manually enter date and time. The time zone can be set to your region as well as daylight saving start and end times and dates. Date and time can also be synchronized with an available time server. Select **Done** to save changes and exit the menu, or **Cancel** to exit without saving.

NOTE: If the system goes through a hard reboot, the set Date/Time screen will appear at start-up so the settings can be reset.

WAM/AM-XX: Select to display the device version and to switch between use of AMxx or WAM. When **Switch To WAM** function is selected, an additional **WAM Pairing** function becomes available and must be selected. Select **Done** to save changes and exit the menu.

NOTE: The WAM must be paired to ELI 380 before operation. Refer to [Configuring the WAM Wireless Acquisition Module](#) for instructions.

Network: Select to evaluate network communication. WLAN or LAN information such as MAC Address, module and radio firmware version, connection status, IP address and current signal strength is displayed. Select **Test WLAN** or **Test LAN** to initiate a test with status information. Select **Done**, or **Cancel** during the WLAN or LAN test to exit the menu.


Print: Select to generate a printout of all ELI 380 configuration settings.

Options Code: Select to present a field for options code entry. The code is obtained from Mortara Service personnel to enable specific features. After the code is entered, select **Done** to save changes and exit the menu, or **Cancel** to exit without saving.

*NOTE: Selecting **Done** with improper code entry will cause an Invalid Code notification. Select **Cancel** to exit.*

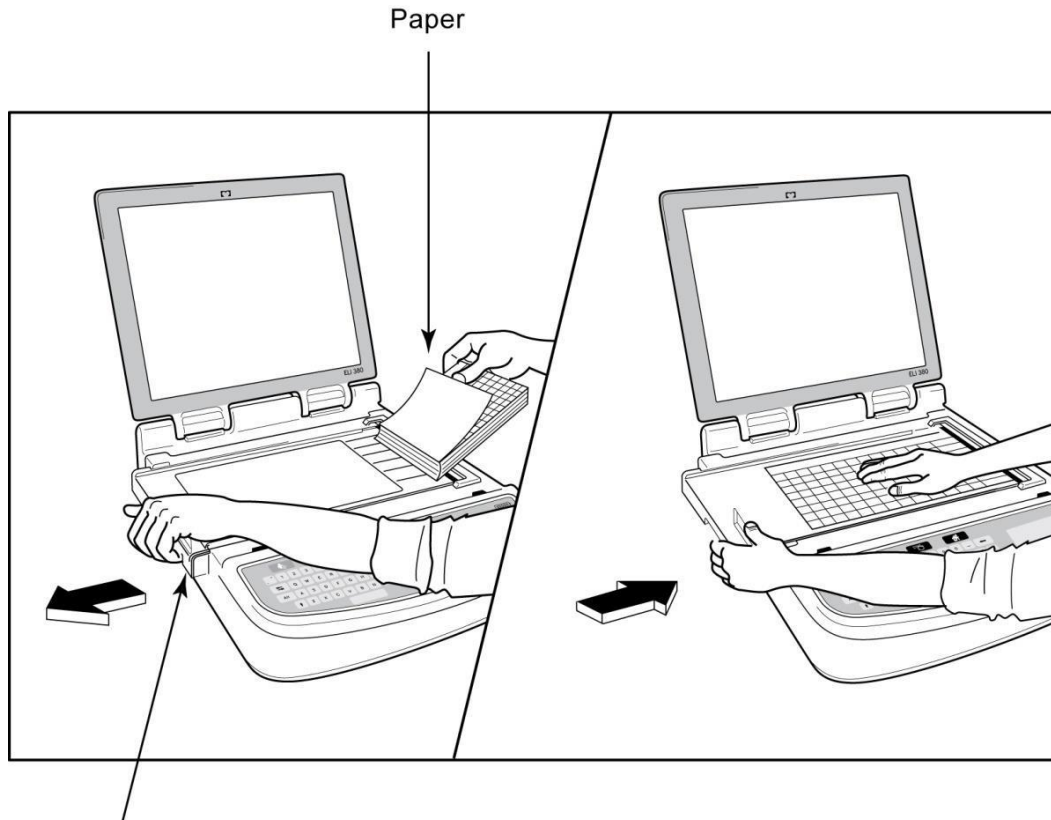
Advanced: Selection requires an administrative password and is explained in [Configuration Settings](#). Select **Cancel** to exit the menu.

Log On/Off: When user authentication is enabled, select **Log On** to log on as a technician or administrator. Select **Log Off** when done using the device or to use the device with a different account.

Select  at any time to return to the real-time ECG display.

Loading Paper

Figure 8 ELI 380 Paper Loading



Paper Door Latch

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 lies 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 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, use Mortara recommended thermal paper.

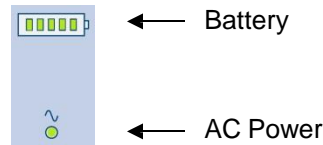
Powering the ELI 380

ELI 380 is an AC powered and battery operated device that can simultaneously charge the internal battery/batteries while connected to AC power. The device can be operated on AC line voltage in the absence of a battery, or in the event of a depleted battery. When AC power is removed, the device immediately switches to battery power.

Operating on AC Power

Plug the power cord into an AC wall outlet and into the back of the ELI 380. (See [Figure 3.](#)) ELI 380 is automatically powered on when connected to AC power and will not power off.


Indicators on the keyboard will illuminate as follows:



- The AC power LED indicator illuminates when device is connected to mains (AC power).
- The battery indicator represents the battery charge level from zero to five illuminated bars.

NOTE: In the event of complete power loss due to battery removal or a hard reboot (depressing the On/Off button for greater than 7 seconds) the system will require a time/date reset.

Battery Operation

Press the power On/Off  button on the keyboard. ELI 380 is automatically powered off after a fifteen-minute period of no patient connection.

With a new, fully charged lithium-ion battery, the ELI 380 is typically capable of acquiring more than 30 resting ECGs with 1 performed every 10 minutes before a recharge is necessary. When two lithium-ion batteries are used, more than 60 resting ECGs may be acquired with 1 performed every 10 minutes before a recharge is necessary.

When operating on battery power, the battery indicator on the keyboard reflects battery status:

Five green LED bars	=	90 – 100% charge
Four green LED bars	=	75 – 89% charge
Three green LED bars	=	55 – 74% charge
Two green LED bars	=	35 – 54% charge
One green LED bar	=	15 – 34% charge
One amber LED bar	=	Less than 14% charge*
No LED bars illuminated	=	Depleted battery/batteries

*30 minutes after the amber LED is displayed and when the ELI 380 battery has less than 10 seconds of power remaining, the message, **“Battery Low! Charge Unit!”** will display. The device will then automatically power down. Connecting to AC power while the *Battery Low! Charge Unit!* message is displayed (10 seconds), will prevent the automatic shutdown.

If *Battery Low! Charge Unit!* is displayed during ECG acquisition, the device will continue normal operation until the user exits the ECG acquisition mode. The device will then automatically power down.

For optimal performance, connect the ELI 380 to AC power whenever it is not in use. The device can be used with AC power while simultaneously recharging the battery/batteries.

Power Status

The ELI 380 has three distinct power states: Power On, Standby, and Off. While powered on, the ELI 380 performs all of its functions including display, acquisition, printing and transmission of ECGs.

Powered by AC

Power is automatically turned on when the device is connected to AC power.

When a patient is connected, ECG is displayed and the On/Off/Standby button is not operational.

When no patient is connected, a quick press of the On/Off/Standby button as well as closing the display cover will place the ELI 380 in standby mode. After a five-minute period, the device will automatically enter standby. As soon as the next patient is connected, the device will change from standby to On status.

When powered by AC, the ELI 380 will never power off.

Powered by Battery

The On/Off/Standby button is used to power on when the device is battery powered.

When a patient is connected, ECG is displayed and the On/Off/Standby button is not operational.

When no patient is connected, a quick press of the On/Off/Standby button as well as closing the display cover will place the ELI 380 in standby mode. After a five-minute period, the device will automatically enter standby. After a fifteen-minute period, the device will automatically power off.

If a new patient is connected in less than fifteen minutes, the device will change from standby to On.

Standby

When in standby, the ELI 380 is in a low power “sleep” mode. Standby allows the ELI 380 to conserve power while not in use, but provide “instant on” with startup. To turn the ELI 380 on from standby, open the display cover or depress the On/Off/Standby button. The device is ready to use instantly.

Reboot

Depressing the On/Off button for a period longer than 15 seconds causes the ELI 380 to execute a hard reboot. This will reset the internal clock to the default time and date.

***NOTE:** During normal use, it is not necessary to use this reboot function.*

Power Off

To power off the device manually:

1. Disconnect AC power from the device.
2. Disconnect any patient or simulator.
3. Close the lid
4. Press the On/Off/Standby button once.

10. RECORD AN ECG

Patient Preparation

Before attaching the electrodes, ensure the patient fully understands the procedure and what to expect.

- Privacy is very important in ensuring 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 not talk. Conditions such as jerking, shivering, or muscle tremors can interfere with ECG results. Explaining the process to the patient may help relax them further and assist 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 or clip hair from electrode sites if necessary.
- Wash area with warm, soapy water.
- Dry skin vigorously with a 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. High quality silver-silver chloride (Ag/AgCl) electrodes similar to those provided by Mortara are recommended.

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

To Attach the Electrodes

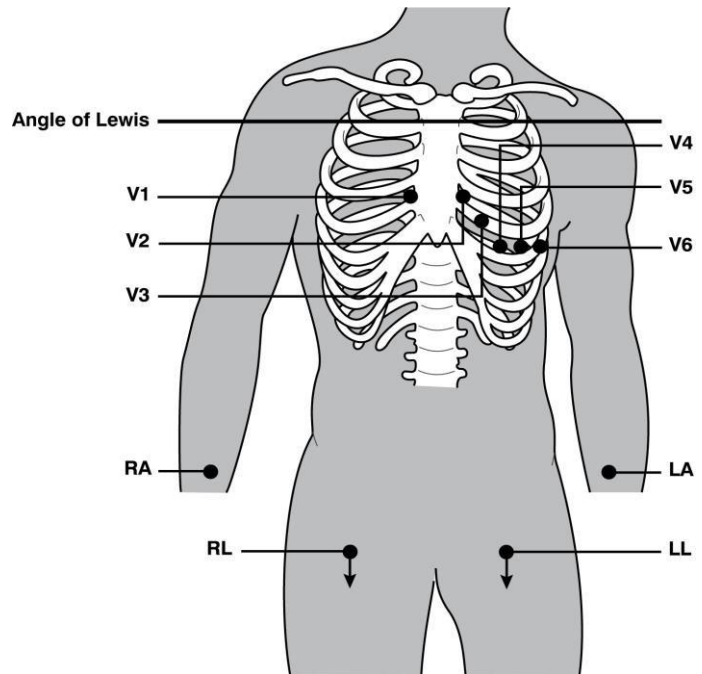
1. Expose the arms and legs of the patient to attach the limb leads.
2. Place the electrodes on flat, fleshy parts of the arms and legs.
3. If a limb site is not available, place the electrodes on a perfused area of the stump.
4. Attach the electrodes to the skin. A good test for firm electrode contact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

TIP: Check the display for any notification messages indicating lead problems.

For accurate precordial (V or C) 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 located, and the space just below it is the 2nd intercostal space. Palpate and count down the chest until you locate the 4th intercostal space.

Patient Hookup Summary Table

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



Alternate 12-Lead Placement

ELI 380 supports combinations of alternate lead placement. The following three are defined as default selections.

1. Pediatric utilizes V3R where the V3 lead should be positioned as shown in the diagram below.
2. Posterior leads are V7, V8, and V9 where V1, V2, and V3 should be positioned as below.
3. Right-sided leads are V3R, V4R, V5R, V6R, and V7R where leads V3 through V6 should be positioned as below.

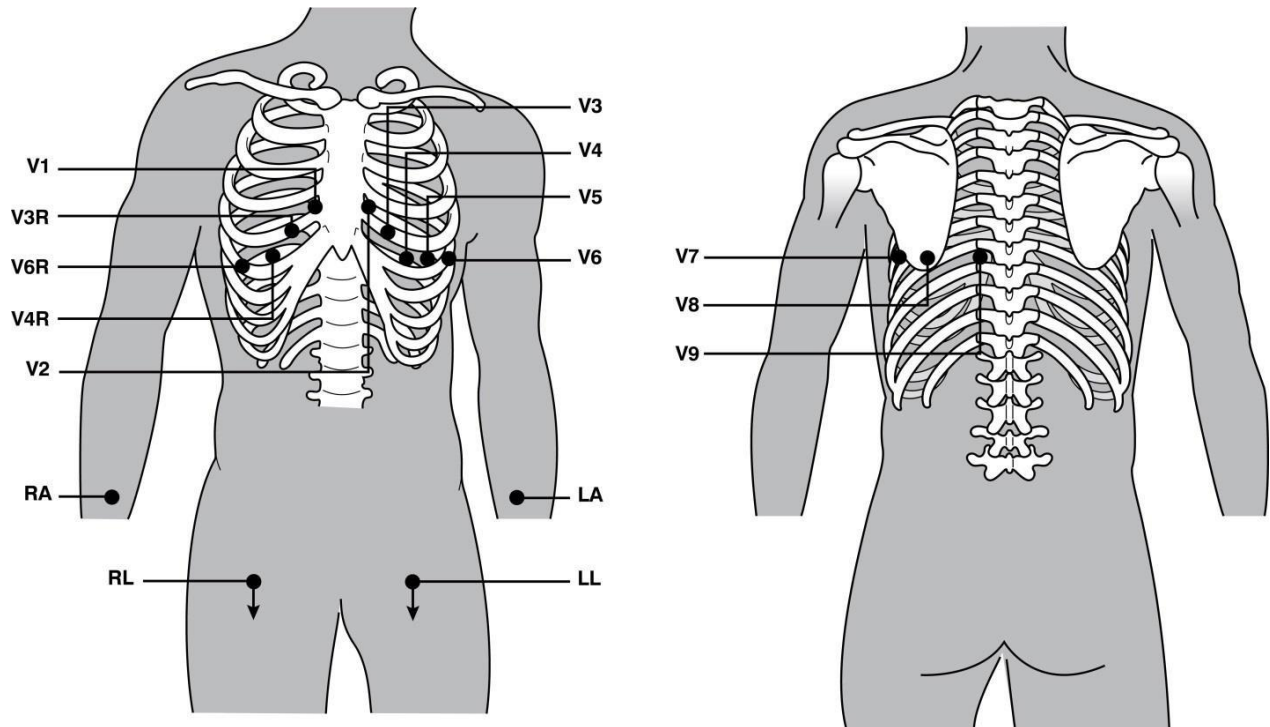
Alternate leads may be user-defined utilizing any order and combinations of user-defined leads or the leads above.

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.
- V5R: midway between V4R and V6R.
- V6R: on the right midaxillary line, horizontal with V4R electrode.
- V7R: right posterior axillary line, horizontal with V6R electrode.

For posterior leads:

- V7: left posterior axillary line, horizontal with V6.
- V8: left midscapular line, horizontal with V7.
- V9: left paraspinal line, horizontal with V8.



NOTE: Resting ECG interpretation is suppressed when non-standard lead placement is selected.

NOTE: When an alternate placement set is selected, the full disclosure buffer is cleared and restarted.

15-lead placement

In a 15-lead configuration, three combinations of additional lead wires are available. The following are the factory-default lead sets:

1. Pediatric: uses the right precordial leads V3R and V4R, and the posterior lead V7
2. Posterior: uses the posterior leads V7, V8, and V9
3. Right-sided: uses the right-sided leads V3R, V4R, and V6R

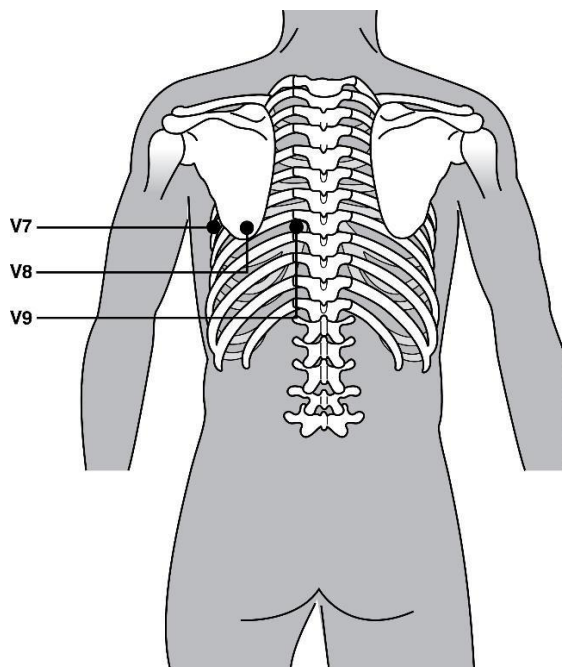
NOTE: Attached to each 15 lead wire is a plug to be inserted into the AM15E. Each plug has a single label. The label is either E2, E3 or E4. Insert each plug into the corresponding AM15E socket labeled E2, E3 and E4. The E1 socket on the AM15E is not used. All 15 lead wire sets ordered from Mortara include a spacer. The spacer prevents insertion of a lead wire plug into a socket. Please put the spacer into the E1 socket on the AM15E to prevent insertion of a lead wire plug.

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

The factory-default Posterior and Right-sided lead sets can be renamed and redefined. The three leads can be defined to be any of the following: V1, V2, V3, V4, V5, V6, V7, V8, V9, V3R, V4R, V5R, V6R, and V7R. The lead sets are defined by selecting the **15 Leads Alt. Placement** button on the advanced settings page.

For posterior leads:


- V7: left posterior axillary line, horizontal with V6.
- V8: left midscapular line, horizontal with V7.
- V9: left paraspinal line, horizontal with V8.



Patient Demographic Entry

Patient demographic information can be entered before acquisition. The entered patient ID fields will remain populated until the ECG signal is detected. The ELI 380 will prompt you with “Patient Hookup Is Required” before proceeding.

To access the patient demographic data entry menu, select  from the real-time display.


NOTE: Select  at any time to go to the real-time display.

Patient Demographic Formats

The patient demographic labels available are determined by the ID format selected from the configuration settings. In addition to short or long patient ID formats, the ELI 380 also supports a custom ID format. The custom ID format designed in ELI Link can be downloaded to the ELI 380. Additional information about custom ID can be found in [ECG Directory, MWL, and the Patient List](#) or in the ELI Link user manual.

Manually Entering Patient Demographics

Patient demographics can be completed manually. Manually entered patient demographics are saved after completing the entries and selecting **Next**.

1. Select  from the real-time display.
2. Select any of the demographic fields to enter patient information.
3. Once a demographic field is selected, the field is highlighted orange.
4. Use the keyboard to complete the demographic field entry. Once completed, press the tab key or use the touchpad to navigate to the next demographic field. Repeat this process until all the demographic fields have been completed.

NOTE: Do not press **Next** until the data entry for all required fields is complete. Pressing **Next** prior to completion will display the real-time ECG. Select **Patient Information** to display the Patient Demographic screen and complete the data entry. Select **Next** to return to the real-time ECG display.

TIP: Select **X** to erase if you wish to cancel all manual demographic data entries.

5. Several fields (e.g., Sex, Race, etc.) will provide a dropdown list when selected. Choose from the list or enter the first letter of an item for quick selection.
6. When finished, select **Next** to save and return to the real-time display. Skipped fields appear as a blank data entry field on the header of the ECG printout.


NOTE: If no age is entered, the interpretation will default to a 40-year old. The statement “INTERPRETATION BASED ON A DEFAULT AGE OF 40 YEARS” will be in the interpretation text.

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

NOTE: A green highlighted field is shown where Mandatory Fields have been configured (i.e., last name, ID, or last name and ID). The user will be prompted to enter information into Mandatory Fields if left empty before acquiring an ECG.

Automatically Entering Patient Demographics from the ECG Directory

Patient demographics can be completed automatically by selecting an existing patient record in the directory. However, when user authentication is enabled, this option is only available when the user is logged in as a Technician or Administrator. If user authentication is disabled, the user will still be prompted to enter the device's Technician password if one has been configured.

1. Select  from the real-time display.
2. Select the **Directory** tab.
3. Use the double arrows (<< or >>) at the right center of the screen to move page by page through the list of acquired ECGs. The current/total number of pages is displayed between the double arrows. To select the desired patient, use the touchpad to move the cursor to the ECG record and select.
4. To search by patient name, select the **Search** field at the left side of the display and type the last name or ID number. This feature will update the listing as characters are entered.

TIP: Select **X** to clear the search field.

5. Select the patient record from the directory list. A menu is displayed.
6. Select **New ECG** to return to the patient ID screen with available demographic fields populated.
7. Press **Next** to go to the real-time ECG display.


NOTE: The ELI 380 must have ECG input to retain patient demographics. **Patient Hookup is Required** message will display and prevents a move to the real-time ECG display.

NOTE: 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 as the first letter in the last or first name will automatically be capitalized.


Automatically Entering Patient Demographics from the MWL (Modality Worklist)

Patient demographics can be completed automatically from Modality Worklist orders. However, when user authentication is enabled, this option is only available when the user is logged in as a Technician or Administrator. If user authentication is disabled, the user will still be prompted to enter the device's Technician password if one has been configured.

1. Select  from the real-time ECG display, and then tap the **MWL** tab if necessary.
2. Sort the MWL by **Name, ID, Location, Room,** or **Scheduled Date Last** by a tap on the column header. A second tap will sort the list in reverse order.
3. To search by Query Code, select the **Query Code** field from the dropdown list and then press **Download**.
4. The **Search** field can be used to locate downloaded orders by entering free text for name, ID, location, room, or scheduled date. The listing will refresh as characters are entered. Tap the **X** at the right of the search field to clear it.
5. Use the double arrows (<< or >>) at the right center of the screen to move page by page through the list of ECG orders. The current/total number of pages is displayed between the double arrows.
6. When an order is selected from the MWL, the available patient demographics are automatically filled and the scheduled order information appears in the upper area of the display.
7. Select the **Next** icon to proceed to the real-time ECG display.

Automatically Entering Patient Demographics from the Patient List

Patient demographics can be completed automatically by selecting patient information from the institution information system, or patient list. However, when user authentication is enabled, this option is only available when the user is logged in as a Technician or Administrator. If user authentication is disabled, the user will still be prompted to enter the device's Technician password if one has been configured.

1. Select  from the real-time display.
2. Select the **Patient List** tab.
3. Press **Download** to refresh the listing.
4. Sort the Patient List by **Name, ID, Location, Room, or DOB** by a tap on the column header. A second tap will sort the list in reverse order.
5. The **Search** field can be used to locate patients by entering free text for name, ID, location, room, or DOB. The listing will refresh as characters are entered. Tap the **X** at the right of the search field to clear it.
6. Use the double arrows (<< or >>) at the right center of the screen to move page by page through the list of patients. The current/total number of pages is displayed between the double arrows.
7. When a patient is selected, the available patient demographics are automatically filled in the upper area of the display.

***NOTE:** If you wish to cancel the patient selection, tap the **X** in the patient demographics panel.*

8. Select the **Next** icon to proceed to the real-time ECG display.

Automatically Entering Patient Demographics using the Optional Bar Code Scanner

ELI 380 supports bar code scanners with 39, 128 and 2D capabilities. When programmed for the institution's bar code, the optional bar code scanner is capable of downloading specific data from the patient's wristband bar code into the patient demographics fields.

Once in the real-time ECG display, the user can scan the patient's wristband barcode and the patient information screen is displayed with demographics automatically entered.

Specific download capability and utilization with the bar code scanner depends on the data available on the wristband bar code and the configuration of the ELI 380.

Refer to the bar code scanner user manual for instructions on setup and use.

ECG Display Setup—Individual ECG

The Display Setup screen allows you to set the following display configurations for an individual patient: display format, display speed, display (ECG) gain, display (ECG) filter, and full disclosure context view. Access these configuration choices by moving the cursor anywhere on the display's real-time ECG waveform and tap the touchpad. Once the appropriate selection has been made, select **OK**. The display setup will return to the configured (default) settings for the next patient.

Display Format	Display Speed	Display Gain	Display Filter	Full Disclosure	Lead Placement	Lead Mode
12x1	5mm/s	5mm/mV	40Hz	On	Standard	12
4x2	10mm/s	10mm/mV	150Hz	Off	Pediatric	15
6x2	25mm/s	20mm/mV	300Hz		Posterior	
II-V1-V5	50mm/s				Right Sided	
OK				Cancel		

Display Format: The real-time 12-lead ECG view can be set to any of the following formats by pressing the desired choice on the real-time display: 12x1; 4x2; 6x2; and any of three pre-selected leads (i.e., II-V1-V5).

Display Speed: The real-time display sweep speed and rhythm printout speed can be set to any of the following speeds by pressing the desired choice on the real-time display: 5 mm/s, 10 mm/s, 25 mm/s, or 50mm/s.

Display Gain: The real-time ECG gain can be set to any of the following amplifications by pressing the desired choice on the real-time display: 5 mm/mV, 10 mm/mV, or 20 mm/mV. The Gain setting is printed at the bottom right corner of the ECG printout. The Display Gain setting will also be used on the printed ECG, unless changed in the Acquired screen.

Display Filter: The ECG filter can be set to any of the following frequency limits by pressing the desired choice on the real-time display: 40 Hz, 150 Hz, or 300 Hz for ECG printouts. The Filter setting is printed at the bottom right corner of the ECG printout. The Display Filter setting will also be used on the printed ECG, unless changed in the Acquired screen.



WARNING: When the 40 Hz filter is used, the frequency response requirement for diagnostic ECG equipment cannot be met. The 40 Hz filter significantly reduces high-frequency components of the ECG and pacemaker spike amplitudes, and is recommended only if high-frequency noise cannot be reduced by proper procedures.

Full Disclosure: The Full Disclosure view can be set to On or Off. When On is selected, a window presenting the most current ECG data for up to 90 seconds will be presented on the real-time display. When Off is selected, the full disclosure view will not be available for review or selection.

Lead Placement: Lead Placement can be set as Standard or any one of three alternate user-defined positions. The factory definitions for alternate lead placements are Pediatric, Posterior, and Right Sided. Precordial leads V1 through V6 can be labeled and positioned according to patient condition.

NOTE: Resting ECG interpretation is suppressed when non-standard lead placement is selected.


ECG Acquisition and Printing with WAM or AMxx

Control buttons located on the WAM and AMxx are available to initiate ECG acquisition and start/stop rhythm strip printing. From the patient demographic screen, the ECG button on the acquisition module will cause the real-time display to appear when patients are connected. Refer to the WAM or the AMxx short-form instruction card for use.

ECG Acquisition

ECG data is collected immediately and continuously once the patient is connected to the acquisition module. For best results, instruct the patient to relax in the preferred supine position to ensure that the ECG is free from motion and muscle artifact (noise).

If workflow permits, enter patient information prior to acquisition as previously explained.

Select . The real-time ECG view is replaced with the acquired ECG view that includes patient information, the global measurements, and resting ECG interpretation.



WARNING: Always verify the accuracy of Patient demographics prior to printing and/or transmitting the ECG.

Print, **Transmit**, and **Erase** function icons are available for selection in the right corner of the display.

- Select **Print** to print the displayed ECG on the ELI 380 thermal printer.
- Select **Transmit** when the displayed ECG is of good quality and you wish to send it to the institution electronic medical records (EMR) system.
- Select **Erase** to immediately delete a poor quality ECG. You will be prompted “Erase ECG?” Select **Yes** to prevent ECG storage to the directory and return to the real-time ECG display.

Settings for display and printout may be altered in this screen. With a touchpad tap in the ECG waveform, a menu allowing layout, speed, gain, filter, pacer channel, and Best 10/Last 10 changes will become available. Select **OK** to save changes and exit the menu, or **Cancel** to exit without saving.

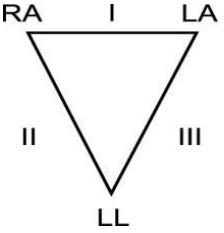
Print Layout	Print Speed	Print Gain	Print Filter	Pacer Channel	Best10
3+1 Channel	25mm/s	5mm/mV	40Hz	Off	Best10
6 Channel	50mm/s	10mm/mV	150Hz	On	Last10
3+3 Channel		20mm/mV	300Hz		
12 Channel					
6+6 Channel					
OK		Cancel			

NOTE: When settings are changed in this menu, the ELI 380 will return to configured (default) settings for the next test.

Select  to save the ECG to the directory and return to the real-time ECG display.

ECG Electrode Placement Troubleshooting

Please refer to the following troubleshooting guide based on Einthoven's Triangle:


	Artifact	Check Electrode	Possible Solutions
	Lead II and III artifact	Poor LL electrode or left leg tremor	Have patient relax tense muscles
	Lead I and II artifact	Poor RA electrode or right arm tremor	
	Lead I and III artifact	Poor LA electrode or left arm tremor	Ensure absence of tension on leadwires
	Any V lead artifact	Poor V electrode contact	Re-prep site(s) and replace electrode(s)

ECG Screen Notification Messages

The VERITAS interpretive algorithm detects Leads Off and Lead Fault conditions. It also detects electrode reversal based on normal physiology and ECG lead order and tries to identify the most likely switch. If the algorithm detects electrode leads are reversed, it's recommended that the user confirm the other electrode positions in the same group (limb or chest).

When the condition that triggered the notification message is addressed, the VERITAS analysis program collects 10 seconds of new data before analyzing the ECG.

Message	Description	Corrective Action
Any single or combination of leads off	No lead connection	Connect ECG lead(s) to patient.
Lead Fault	Faulty lead(s)	Re-prep and replace electrode(s) to obtain satisfactory waveform(s).
"Limb leads reversed?" "LA or LL reversed?" "RA or RL reversed?" "RA or LA reversed?" "V1 or V2 reversed?" "V2 or V3 reversed?" "V3 or V4 reversed?" "V4 or V5 reversed?" "V5 or V6 reversed?"	Electrode(s) misplaced	Check lead placement. Connect the lead(s) correctly to the patient or connect the lead(s) to the proper location.
Noise on Lead x	Noise detected on lead	Check lead connection, skin prep, electrode and connection quality.
WAM Low Battery	Low battery detected	Replace the AA battery in the WAM.
Searching for WAM	WAM not detected	Check WAM proximity to the ELI 380; replace WAM AA battery; ensure that the WAM is powered On; Pair the WAM with the ELI 380.

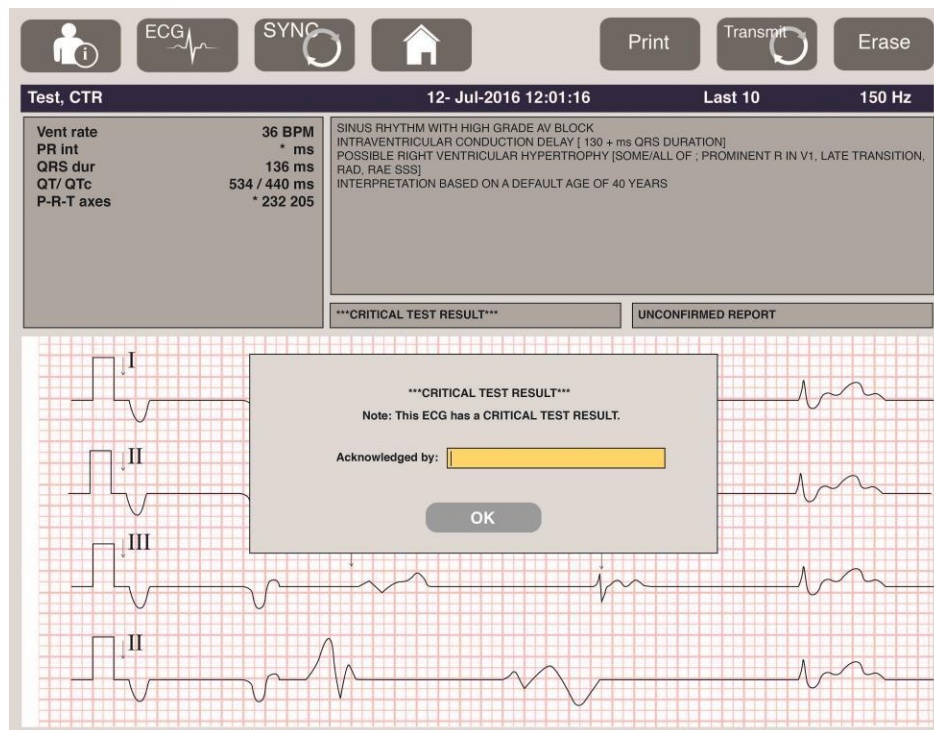
NOTE: In the event of a lead fault or leads reversed message, ECG acquisition may be forced by selecting  again.

Critical Test Result Notification

The Critical Test Results feature can be enabled to provide a specific message on the electrocardiograph when VERITAS finds criteria for an acute myocardial infarction or other critical ECG findings, signaling the user to alert a clinician for immediate attention. Critical test results are indicated by “***” in front and behind the conclusion statement that is displayed or printed on the acquired ECG above the waveforms and underneath the ECG interpretation text. For additional information on the Critical Test Result feature, please refer to the *Physician’s Guide to VERITAS with Adult and Pediatric Resting ECG Interpretation* (see Accessories).

If Critical Test Result is enabled, the ELI 380 will provide notifications to the user if an acquired ECG meets the CTR criteria:

- Audibly notify user – When the CTR dialog box is displayed the unit produces four audible beeps at high volume independent of the volume setting.
- Visually notify user – A dialog box is displayed indicating a CTR.
- User level acknowledgement – The OK button will not be active until the CTR is acknowledged by the technician (minimum of two characters) The “acknowledged by” field may be manually or automatically populated based on user log-on and/or Tech ID.




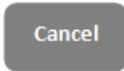

Post ECG acquisition, records with Critical Test Results are identified in multiple ways:

- As a Conclusion Statement [***ACUTE MI*** or ***CRITICAL TEST RESULT***] on-screen and on ECG printout (if CTR configuration setting is on or off).
- As part of the digital file (if CTR configuration setting is on or off).
- In the cardiograph directory with a marker beside the ECG or patient.

Printing a Rhythm Strip

Begin printing a rhythm strip by selecting . The Rhythm icon is replaced with a **Done** icon that will stop the rhythm strip printing and return you to the real-time ECG display. The  function icon is also available—its selection will also cause a return to the real-time ECG display.

Rhythm printout settings can be altered during the printout by a touchpad tap in the waveform. A menu allowing rhythm format, rhythm speed, rhythm gain, and rhythm filter changes as shown below will display. Select **OK** to save changes and exit the menu, or **Cancel** to exit without saving. **Stop** will stop rhythm printing.

Rhythm Format	Rhythm Speed	Rhythm Gain	Rhythm Filter
12 Channel	5mm/s	5mm/mV	40Hz
8 Channel	10mm/s	10mm/mV	150Hz
V1-V2-V3-V4-V5-V6	25mm/s	20mm/mV	300Hz
II-V1-V5	50mm/s		
  			



NOTE: When settings are changed in this menu, the ELI 380 will return to configured (default) settings the next time this menu is displayed.

NOTE: Printed rhythm strips are not stored in the ELI 380.



During a 6-lead or 3-lead rhythm print, selecting the **Leads** button in the top right corner of the screen will toggle rhythm printing between limb and chest leads.

Acquiring a STAT ECG

To acquire an emergency (STAT) ECG for an unidentified patient prior to entering patient demographics:

1. Select  from the display or the keyboard.
2. Select  a second time from the display or the keyboard. The ECG will be acquired.

NOTE: The message “Collecting 10 seconds of data” will appear in the top left area of the display if the patient was just connected.


3. Once completed, the acquired ECG with interpretation will display.
4. To enter patient information after the ECG has been acquired and displayed, select  to open the dialog and enter patient data. Select **Yes** to edit the current ECG patient information.
5. To return to the real-time ECG display without entering patient demographics, select . Additional ECG records prior to patient disconnection may be acquired and saved as needed.

NOTE: The ECG record is saved and can be found in the directory by acquisition date and time.



NOTE: When entering the patient information after a STAT ECG has been acquired, the ELI 380 will update the interpretation based on the correct age and patient information.

Editing Patient Demographics in a Stored ECG Record

Use the following steps to edit patient demographics on a completed ECG stored in the Patient Directory.


1. From the real-time ECG display, select  to access the directory tab.
2. In the Directory, locate the ECG record(s) by name, ID, or acquisition time/date and select from the list. Selection of a patient will display all ECG records for that patient in a list showing acquisition time as well as printed, transmitted, and deleted status.

NOTE: Tap on the column headers to sort the list by Name, ID, DOB, or Last Acquisition. A second tap on the column header will reverse the sort order.


3. Select the desired ECG and the ECG record is opened.
4. Once the ECG is displayed, select  and then select **Yes** to edit current ECG demographics.
5. Add new or edit existing information and then select **OK**.
6. **Back** may be used to return to that patient's ECG listing
7. Select **Done** to close the listing.
8. Select  to return to the real-time ECG display.

Erasing Stored ECG Records

Use the following steps to delete unwanted ECGs that have been saved in the Patient Directory.

1. From the real-time ECG display, select  and select the Directory tab.
2. In the Directory, locate the ECG record(s) by name, ID, or acquisition time/date and select from the list. Selection of a patient will display all ECG records for that patient in a list showing acquisition time as well as printed, transmitted, and deleted status.

NOTE: Tap on the column headers to sort the list by Name, ID, DOB, or Last Acquisition. A second tap on the column header will reverse the sort order.

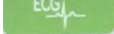
3. Select the desired ECG and the ECG record is opened.
4. Once the ECG is displayed, select **Erase** and then **Yes** to erase the ECG. The patient's ECG listing is then displayed.
5. Select **Erase All** to remove all listed ECGs. Then select **Yes** to erase all ECGs for this patient. You are returned to the directory listing.
6. Select  to return to the real-time ECG display.

Best 10 Second ECG

The ELI 380 incorporates a 20-minute memory buffer for collection of ECG data. When Best10 is enabled, the device will automatically select the best quality 10-second ECG from within the last 5-minutes of stored ECG. The best 10 second determination is based upon measurement of high and low-frequency noise found in the 10-second ECG segments.

When Last10 is selected the device will automatically capture the last ten seconds of ECG from the data stored in the memory buffer.

Changing Best 10 or Last 10

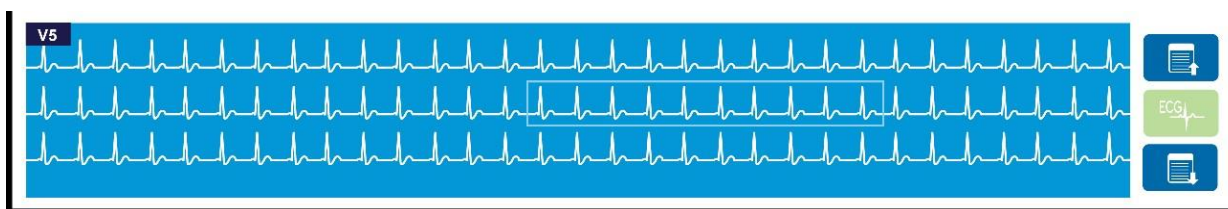
1. Select  from the real-time display to acquire an ECG.
2. From acquired ECG view, touch anywhere on the red grid ECG to open the configuration screen.
3. Select **Best10** or **Last10**.
4. Select **OK** to save the selection and reformat, print, and display the ECG, or **Cancel** to exit without any change.

NOTE: If a single limb lead or two precordial lead fail condition occurs, the Best 10 feature is disabled until the limb lead fail or precordial lead fail condition is resolved. Once the condition is corrected, the Best 10 feature automatically becomes available.

NOTE: Best10 function will automatically recognize signal dropout (e.g. with the WAM front end) and will not use dropout in creating the Best10 result.



ECG Selection from Full Disclosure


In the real-time ECG view, the bottom of the screen displays a single lead of the 12-lead context view.



At any time during the ECG acquisition you may move the cursor over an area of interest and select the ECG data for review and analysis.

Tap the lead label to display a menu allowing you to choose any other single lead.

Use  and  to page up or down through the full disclosure.


Tap  in this area of the window to provide a preview of the ECG on the main ECG panel for storage, printing, transmission, or erasure.

11. CONNECTIVITY AND ECG TRANSMISSION


ECG Transmission

The ELI 380 can transmit acquired ECG records to ELI Link via LAN or WLAN. Before transmitting ECGs, certain configuration settings must be defined depending upon the type of transmission and type of electronic storage to be used. Refer to [Configuration Settings](#) for details.

Transmitting Records to ELI Link

To transmit a record to ELI Link, select **Transmit** from the acquired ECG view. To transmit all saved records, select  from the real-time ECG display or the keyboard.

In both cases, dialog on the ELI 380 display shows syncing information during the transmission. To abort a transmission prior to completion select **Cancel**.

NOTE: Select  at any time to go to the real-time display.

If Auto-Sync is enabled, Sync/Transmit rules in System Configuration settings will automatically be followed every 5 minutes.

Transmission Using the USB Device Port to a PC

The USB Device port permits transmission of stored patient records to a PC using a direct USB cable. The patient records will be transmitted to ELI Link and are then exported and saved in various formats (refer to the ELI Link user manual).

USB Device Connection

The ELI 380 comes equipped with a USB Device port which can be used to directly connect the device to a PC running ELI Link.

Transmission Using the USB Host Port to a USB Memory Stick

USB memory communication media permits storage of patient records to an external USB memory stick. The files will be saved in UNIPRO format for manual transfer to a computer hosting ELI Link.

NOTE: ELI 380 is compatible with FAT32 formatted USB memory sticks.


NOTE: The USB memory stick must not contain any automatic features (e.g., SanDisk U3). Uninstall any features from the memory stick before connecting it to the device.

NOTE: Upon successful transmission, the ELI 380 will display the total number of ECGs transmitted to the USB memory stick.

NOTE: Patient records transmitted to a USB memory stick are marked as transmitted by the device.

NOTE: If Security option is enabled and either network or local authentication is used, only a user with administrative rights will be able to export patient records to an external USB memory stick.

Transferring Individual Patient Records to the USB Memory Stick

- Place the USB memory stick into the USB host port on the back of the device.
- Select  from the real-time ECG view or the keyboard.
- Select **Directory**.
- Select the patient record to be stored to the USB memory stick.
- Select **Transmit**.

Transferring Batch Patient Records to the USB Memory Stick

- Place the USB memory stick into the USB host port on the back of the device.
- Select **SYNC**.
- Select **Done** when transmission is complete.

Connecting the ELI 380 to a PC

When connecting the device to a PC for the first time, the proper USB driver will need to be installed prior to use.

- Use a USB cable to connect ELI 380 to a PC.
- When properly connected, the PC will detect the ELI 380 and automatically install the drivers.
- You will be required to power the ELI 380 on by pressing the On/Off button for a period of three seconds.

Transmitting Patient Records to ELI Link

- Create both an Input folder and Output folder on the PC.
- Configure ELI Link to the individual Input and Output folders.
- Connect the ELI 380 to the PC.
- “USB Device ready” appears on the device display; a “Removable Disk” message displays on the PC.
- Using the PC mouse, select **Records** from the removable disk window displayed in Windows Explorer.
- Select the patient record(s) to be copied.
- Paste the copied record(s) into the Input folder on the PC.
- After 5 seconds, select the copied record(s) to view on the PC or print via PDF from the Output folder.

***NOTE:** An Input and Output folder must be created for use with ELI Link.*

***NOTE:** Patient records transmitted to ELI Link are not marked as transmitted by the device.*



WARNING: Do not change or modify any information existing in any of the ELI 380 folders that are visible on the PC in the removable disk file.



CAUTION: To assure consistent operation and avoid confusion, connect only one ELI 380 using the USB device port to a PC at a time.

- Unplug the USB cable and power the ELI 380 On.

12. ECG REVIEW AND MANAGEMENT

Reviewing ECG Records

With the ECG subdirectory displayed, tap on the desired record to select and display the ECG.

Function icons for **Print**, **Transmit**, and **Erase** are available in the upper-right corner of the display.


1. To change the format of the acquired ECG touch the display and select the desired settings for Print Format, Print Speed, Print Gain, Print Filter and Pacer Channel.

Print Layout	Print Speed	Print Gain	Print Filter	Pacer Channel
3+1 Channel	25mm/s	5mm/mV	40Hz	Off
6 Channel	50mm/s	10mm/mV	150Hz	On
3+3 Channel		20mm/mV	300Hz	
12 Channel				
6+6 Channel				
<div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="background-color: #808080; color: white; padding: 5px 15px; border-radius: 5px;">OK</div> <div style="background-color: #808080; color: white; padding: 5px 15px; border-radius: 5px;">Cancel</div> </div>				

2. Select **OK** to save and return to ECG display, or **Cancel** to exit this menu without saving.
3. Select **Back** to return to the subdirectory.

DIRECTORY

The ECG directory saves up to 500 individual ECG records. Records are automatically deleted through a first-in, first-out process when the maximum number allowed has been reached.

To access the ECG directory, select  from the real-time display and then tap the **Directory** tab if not displayed. Access requires the user to be logged in as a Technician or Administrator, or to know the device's Technician password depending on the ELI 380 is configured.

Sort the directory by **Name**, **ID**, **DOB**, or **Last Acquisition** by a tap on the column header. A second tap will sort the list in reverse order.

The **Search** field can be used to locate patient records by entering free text for name, ID, DOB, or acquisition date. The listing will refresh as characters are entered. Tap the **X** at the right of the search field to clear it.

Use the double arrows (**<<** or **>>**) at the right center of the screen to move page by page through the list of acquired ECGs. The current/total number of pages is displayed between the double arrows.

An ECG with a Critical Test Result is flagged as such and easily identified in the Directory and Record lists (if CTR configuration setting is on).



When a patient is selected from the directory, a subdirectory is presented showing all ECG records stored for that patient with the acquisition date and time of each. Records that have been printed, transmitted, or deleted will be indicated by an **X** in the appropriate column.

Acquisition Time	Printed	Transmitted	Deleted
16-Jun-2014 12:04:28	X	X	
18-Jun-2014 07:22:34	X	X	
19-Jun-2014 08:35:56	X		

1/1

Erase All New ECG Done

Selection of **Erase All** will prompt the message, Erase All ECGs for this Patient? Select **Yes** to erase or **No** to cancel.

Selection of **New ECG** will populate the patient information fields. Choose **Next** to move to the real-time ECG display where a new ECG can be acquired.

Select **Done** to exit.


Erasing ECG Records from the Directory

Management of the ECG record is performed within the subdirectory of stored ECGs. The desired record must be selected in order to view, print, edit or add demographics, or erase the record.

An ECG may be stored in the directory but have a “deleted status” (indicated by **X** in the Deleted column). The directory saves records marked for deletion in the event that the record needs to be reviewed or printed at a later time. ECG records are automatically marked for deletion according to the ELI 380 configuration settings.

Stored ECGs will remain in the directory until the memory becomes full or the Delete Timeout (days) setting has been met. Only those records that have been marked for deletion will be removed to store a newly acquired ECG.

***NOTE:** If the number of records reaches 500 and no records are marked for deletion, ELI 380 will not store any new records and will display a “memory full” message*

1. Select  from the real-time display, and then tap the **Directory** tab if necessary.
2. Navigate to the desired patient record and select. All acquired ECGs for that patient are displayed.
3. Select **Erase All** to erase all of the ECGs in the subdirectory, or
4. Select the desired ECG from the subdirectory to display it and then select the **Erase** icon.
5. Select **Yes** when prompted to Erase ECG?

MODALITY WORKLIST (MWL)

The ELI 380 can download and process ECG orders from compatible information management systems that identify the ECG orders for particular patients. Implementation of an order-based workflow can significantly reduce demographic data-entry errors at the electrocardiograph. Orders are deleted from the MWL when the ordered ECG is acquired.

The Modality Worklist (MWL) directory saves up to 256 pending ECG orders. Orders are displayed with name, ID, patient location, patient room number, and scheduled date.

The MWL menu allows the user to synchronize or print orders, as well as query for a certain location within the facility. Sort, navigate and search ECG Orders in the same manner as the ECG Directory.

***NOTE:** Each time orders are synchronized, the orders list is automatically refreshed. Orders that have been executed, canceled or deleted are automatically eliminated.*

Synchronize Function

Select the  function icon to:

- Transmit an acquired ECG to a cardiology management system.
- Transmit and request a download of the MWL.
- Transmit, request a download of the MWL, and synchronize the date and time.


***NOTE:** ELI 380 supports automatic time synchronization with a remote server. Inaccurate time/date settings can result in ECGs marked with inaccurate time stamps. Confirm the accuracy of the synchronized time prior to acquiring ECGs.*

MWL Query Code Function

MWL query codes uniquely identify a location or department. Query codes may be assigned to a staff member or an electrocardiograph. Use the query code dropdown menu from the MWL directory to select orders specific to that query code or location.

Once a query code is selected, it will serve as the default query code for that particular ELI 380 until a different query code is selected.

Searching ECG Orders

1. Select  from the real-time ECG display, and then tap the **MWL** tab if necessary.
2. Sort the MWL by **Name, ID, DOB,** or **Last Acquisition** by a tap on the column header. A second tap will sort the list in reverse order.
3. To list orders by Query Code, select the **Query Code** field from the dropdown list and then press Download.

***NOTE:** ELI 380 will maintain the last queried location selected in the search process.*

4. The **Search** field can be used to locate orders by entering free text for name, ID, location, room, or scheduled date. The listing will refresh as characters are entered. Tap the **X** at the right of the search field to clear it.

5. Use the double arrows (<< or >>) at the right center of the screen to move page by page through the list of ECG orders. The current/total number of pages is displayed between the double arrows.
6. When an order is selected from the MWL, the available patient demographics are automatically filled and the scheduled order information appears in the upper area of the display.

*NOTE: If you wish to cancel the order selection, tap the **X** in the patient demographics panel.*

*NOTE: If you wish to acquire an unscheduled ECG using the patient information from the order, tap **X** under the Order information.*


7. Select **Next** to proceed to the real-time ECG display.

PATIENT LIST


The ELI 380 can download and maintain a list of patients with their associated demographic information. ELI 380 is synchronized with a remote server in support of those institutions that would like to perform unordered tests.

The Patient List directory saves up to 2,000 patients with ELI Link and an HL7 interface. Patients are displayed with name, ID, location, room number, and date of birth (DOB).

The Patient List menu allows the user to synchronize or print the patient list. Sort, navigate and search patients in the same manner as the ECG Directory.

Select the  function icon to synchronize the patient list with a remote server.

Searching the Patient List

1. Select  from the real-time ECG display, and then tap the **Patient List** tab if necessary.
2. The **Search** field can be used to locate patients by entering free text for name, ID, Admission ID, location, room, or DOB. The listing will refresh as characters are entered. Tap the **X** at the right of the search field to clear it.
3. Sort the Patient List by **Name, ID, Location, Room, or DOB** by a tap on the column header. A second tap will sort the list in reverse order.
4. Use the double arrows (<< or >>) at the right center of the screen to move page by page through the list of patients. The current/total number of pages is displayed between the double arrows.
5. When a patient is selected, the available patient demographics are automatically filled in the upper area of the display.

***NOTE:** If you wish to cancel the patient selection, tap the **X** in the patient demographics panel.*

6. Select the **Next** icon to proceed to the real-time ECG display.


PATIENT DEMOGRAPHIC QUERY (PDQ)

The ELI 380 can allow user to query EMR based on demographic criteria (ID, First Name, Last Name) to download a list of patients with their associated demographic information. The PDQ feature will search based on any combination of fields (i.e. broader search can be performed by filling out only one or two of the fields).

The ELI 380 is synchronized with a remote server in support of those institutions that would like to perform unordered tests.

Select the Download function icon to download the EMR query results.


Downloading PDQ Results

1. Select  from the real-time ECG display, and then tap the **PDQ** tab if necessary.
2. The ID, First, or Last fields can be used to query the server against patient demographics. Since this is a query, the query results will be downloaded. If new entries are made to server, search results will have to be redownloaded. Tap the **X** at the right of the search field to clear it.
3. Sort the results by **Name, ID, Location, Room, or DOB** by a tap on the column header. A second tap will sort the list in reverse order.
4. Use the double arrows (<< or >>) at the right center of the screen to move page by page through the list of patients. The current/total number of pages is displayed between the double arrows.
5. When a patient is selected, the available patient demographics are automatically filled in the upper area of the display.

***NOTE:** If you wish to cancel the patient selection, tap the **X** in the patient demographics panel.*


6. Select the **Next** icon to proceed to the real-time ECG display.

Printouts

On every tab, a print icon  at the right center of the display can be selected to generate a printout of results dependent on the current displayed screen. 40 items per page are printed.

13. CONFIGURATION SETTINGS

Menu Commands and Utilities

To access the ELI 380 configuration settings, select  from the real-time display. Select **Advanced** for extended settings. Extended settings are password protected; the factory password is “admin”. When user authentication is enabled, these settings are accessible when logged in as an Administrator.


NOTE: Select  at any time to return to the real-time ECG display.

Table of Utility Descriptions and Access Requirement

UTILITY	DESCRIPTION	CHOICES	ACCESS
About	Utility settings of the ELI 380.	<ul style="list-style-type: none"> Serial Number Software version DICOM WLAN LAN MAC WLAN MAC 	No Password Required
Advanced	Gives access to the extended configuration menus.		ADVANCED Password Required
Custom ID	Downloads a Custom ID from a compatible information management system. See Configuration Menu: Custom ID .	<ul style="list-style-type: none"> ELI Link, V4.2.0 and later Compatible information management system 	No Password Required
Date/Time	Sets the date and time in the appropriate time zone.	<ul style="list-style-type: none"> Time zone Daylight savings Sync Date/Time 	No Password Required
WAM/AM-XX	Change between the AMxx and the WAM acquisition modules.	<ul style="list-style-type: none"> Switch to Amxx Switch to WAM WAM Pairing 	No Password Required
Network	Provides information and tests the communication between the ELI 380 and the institution network.	<ul style="list-style-type: none"> Test WLAN Test LAN 	No Password Required
Print	Prints ELI 380 configuration settings to the writer.		No Password Required
Options Code	Presents a field where the options code can be entered for update.		No Password Required
Done	Exits the utility and saves the setting.	Returns to the utility menu	No Password Required
Cancel	Exits the utility without saving changes.	Returns to the utility menu	No Password Required
Log On	Prompts for a user name and password when user authentication is enabled.	<ul style="list-style-type: none"> User Name Password 	
Log Off	Logs the user off when user authentication is enabled.		
Home icon	Exits the menu.	Returns to the real-time ECG display	No Password Required
System	Presents the system setting utilities.	<ul style="list-style-type: none"> Language Volume ID Format 	ADVANCED Password Required

UTILITY	DESCRIPTION	CHOICES	ACCESS
		<ul style="list-style-type: none"> • Units for height • Units for weight • XMT Mandatory Field – ID • XMT Mandatory Field – Last Name • XMT Mandatory Field – Tech ID • Cart Number • Site Number • Site Name • Encryption Key • Sync XMT • Sync Patients • Sync MWL • Sync Date/Time • Patient List • Comm. Protocol • ID Edit Disable • Full Disclosure • Caps Lock • Barcode Date Format • Display Format 	
ECG	Presents default settings for ECG-related parameters.	<ul style="list-style-type: none"> • AC Filter • Filter • Interp • Reasons • Append • Delete Rule • Avg RR • QTcB • QTcF • ECG Capture • Pace Spike Channel • ECG Display Speed • ECG Print Speed • # Copies • Copies With Interp. • Cabrera • Plot Format • Various rhythm lead selections • Rhythm format • Rhythm Print Speed • Delete Timeout (days) 	ADVANCED Password Required
Alternate Lead Placement	Presents default settings for 3 alternate lead selections.	<ul style="list-style-type: none"> • Lead Placement Name • Various Lead Labels 	ADVANCED Password Required
LAN	Set the parameters needed for the Local Area Network.	<ul style="list-style-type: none"> • Various parameter settings 	ADVANCED Password Required
WLAN	Set the parameters needed for the Wireless Local Area Network.	<ul style="list-style-type: none"> • Various parameter settings 	ADVANCED Password Required
Password	Administrator enters and changes passwords to limit access to the configuration menus, ECG directory, MWL, and Patient List.	<ul style="list-style-type: none"> • Technician Password • Confirm Technician Password • Administrator Password • Confirm Admin. Password 	ADVANCED Password Required

UTILITY	DESCRIPTION	CHOICES	ACCESS
Service	Allows qualified personnel access to Service utilities.	Refer to the ELI 380 Service Manual	ADVANCED Password Required

Configuration Menu: About

Serial Number: Indicates the serial number of the electrocardiograph.

Software Version: Indicates the software version of the electrocardiograph.

DICOM: Indicates if DICOM bidirectional communication is available (Yes) or not (No).

Security: Indicates if the user authentication and memory encryption feature is available (Yes) or not (No).

WLAN: Indicates if Wireless Local Access Networking is in use (Yes or No).

LAN MAC: Indicates the Local Access Network Mac address.

WLAN MAC: Indicates the Wireless Local Access Network Mac address.

Configuration Menu: Custom ID

Custom ID formats are uniquely defined by your facility's needs. This customized ECG header information is designed in ELI Link and downloaded to the ELI 380.

The Custom ID is retained for all future ECGs until a different ID format is downloaded, or Short or Long format is selected from the Settings menu located under System. The set Custom ID format will not be lost due to power loss or failure, or when switching to a different ID format.

Set the ID format configuration to short, long, or custom depending on the facility's patient demographic-entry needs.

NOTE: Custom ID must be configured in ELI Link. Refer to the ELI Link user manual.

TIP: Upon Custom ID download, the ID format will assume the demographic layout as designed in ELI Link.

NOTE: The site number must be configured in the electrocardiograph and recognized as an established, valid site number in ELI Link before downloading the Custom ID.

TIP: Communication configuration parameters must be set before downloading the Custom ID from ELI Link.

Configuration Menu: Date/Time

Year: Use the keyboard to enter the correct year in a four character format (i.e., 2014).

Month: Use the dropdown window to select the current month.

Day: Enter the current day.

Hour: Use the dropdown window to select the current hour. Use the up/down arrows to advance to more selections.

Minute: Use the dropdown window to select the current minute. Use the up/down arrows to advance to more selections.

Daylight Saving: Use the dropdown window to select **Yes** or **No** as observed within your region.

Time Zone: Use the dropdown window to select the regional time zone. Use the up/down arrows to advance to more selections.

Daylight Saving Start: Enter the month, week, day, hour, and minute that daylight savings will begin for your region.

Daylight Saving End: Enter the month, week, day, hour, and minute that daylight savings will end for your region.

Sync Date/Time: Allows for time synchronization to occur only when the ELI 380 is interfaced via ELI Link to a product that supports time synchronization. Select **Sync Date/Time** to synchronize with an available time server.

***NOTE:** This device supports automatic time synchronization with a remote server. Inaccurate time/date settings can result in ECGs marked with inaccurate time stamps. Confirm the accuracy of the synchronized time prior to acquiring ECGs.*

Select **Done** to save changes and exit this menu, or **Cancel** to exit without saving.

Configuration Menu: WAM/AMXX

Selecting **WAM/AMXX** allows the clinician to switch between WAM or AMxx patient interface cables. For pairing of the WAM with the ELI 380, refer to [Configuring the WAM Wireless Acquisition Module](#).

Configuration Menu: Network

Selecting **Network** establishes communication with your institution LAN or WLAN network and displays up to five bars of signal strength. Presentation of the MAC Address, Firmware module, Radio Firmware, and IP address connected to will also be presented. Refer to the [Connectivity and ECG Transmission](#) section for details.

Configuration Menu: Print

Selecting **Print** will generate a printout of all ELI 380 configuration settings.

Configuration Menu: Options Code

Select **Options Code** to present a field for options code entry. The code is obtained from Mortara Service personnel to enable specific features. After the code is entered, select **Done** to save changes and exit menu, or **Cancel** to exit without saving. Improper code entry will cause an **Invalid Code** notification.


Configuration Menu: System

Language: There are several languages available on the electrocardiograph.



CAUTION: Function labels are immediately translated upon selecting a new language and exiting the Configuration screen.

In the event that an unknown language has been defined, use the following steps to change the language:

1. Select  from the real-time ECG display.
2. Select **Advanced**. Enter your password and select **System**.
3. Touch the language field and use the dropdown list to select the appropriate language.
4. Select **Done** to save and return to the Configuration menu.

NOTE: The keyboard menu will allow symbol and character selections appropriate to the selected language. These are accessed through use of the Symbols and Alt keyboard keys.

Volume: This control sets the loudness when a key on the keyboard is pressed. Available settings are Off, Low and High.

ID Format: This selection allows definition of the format for the patient demographic information field prompts. There are three available formats: short, long and custom.

1. The short format contains the patient's last name, patient's first name, ID number, gender and date of birth. The system automatically calculates the patient age from the DOB.
2. The long format contains the patient's first name, patient's last name, ID number, age, height, weight, gender, race, medications, location, room, and comment fields.
3. A Custom ID format can be downloaded from ELI Link.

Units for Height: Selection to set the units of measure to inches (in) or centimeters (cm).

Units for Weight: Selection to set the units of measure to pounds (lb) or kilograms (kg).

XMT Mandatory Fields - ID: Set to **Yes** to require Patient ID before an ECG can be transmitted.

XMT Mandatory Fields – Last name: Set to **Yes** to require Patient Last Name before an ECG can be transmitted.

XMT Mandatory Fields – Tech ID: Set to **Yes** to require Technician ID before an ECG can be transmitted.

Cart Number: Allows assignment of an ELI 380 cart number from 0 to 65535 to identify which system acquired or transmitted particular ECGs.

Site Number: Allows assignment of an ELI 380 location using a site number. Site numbers designate the hospital, clinic, or institution for ECG records stored in a compatible cardiology management system for transmitting and retrieving ECGs from that system. Site numbers 0–8191 are supported. Up to three sites can be defined when multi-protocol is enabled.

Site Name: Allows entry of the clinic, hospital or office name. The site name is printed at the bottom, left edge of the ECG record. Up to 30 alphanumeric characters can be entered to create a specific site name. Up to three sites can be defined when multi-protocol is enabled.

Transmitted ID Edit Disable: Set to **Yes** to disable editing after an ECG has been transmitted to ELI Link.

Communications Encryption Key: Allows assignment of up to 32 alphanumeric characters for encryption of data. Leave blank to use the default encryption key.

Number Of Barcode Prefix Digits: The number of characters to strip from the beginning of barcodes.

Number Of Barcode Postfix Digits: The number of characters to strip from the end of barcodes.

Ignore Leading Barcode Zeros: Set to **Yes** if leading 0's should be stripped from barcodes.

Sync XMT: Set to **Yes** to allow automatic synchronization with the information system upon ECG transmission.

Sync Patients: Set to **Yes** to allow synchronization with the information system patient list.

Sync MWL: Set to **Yes** to allow synchronization with the information system MWL orders.

Sync Date/Time: Set to **Yes** to allow synchronization with the information system date/time server.

***NOTE:** ELI 380 supports automatic time synchronization with a remote server. Inaccurate time/date settings can result in ECGs marked with inaccurate time stamps. Confirm the accuracy of the synchronized time prior to acquiring an ECG.*

Patient List: Set to **Yes** to enable communication for the Patient List via ELI Link V4.2.0 and later.

Comm. Protocol: Allows IT personnel to set the communication protocol to UNIPRO or DICOM.

***NOTE:** This setting must be entered under the direction of the IT administrator at the facility where the device is installed.*

ID Edit Disable: **Yes** prevents the user from editing IDs on received orders.

Full Disclosure: **Yes** enables display of up to 20-minutes of full disclosure during ECG acquisition.

Caps Lock: **Yes** sets upper case letters as default for character entry.

Barcode Date Format: Selection to set the barcode date format to **MM/DD** or **DD.MM**.

User Authentication: Set to **Off** to disable user authentication and only use the device's technician and administrator passwords. Set to **Network** to authenticate users via Active Directory or other LDAP compatible service. The user's user name will auto-populate the Technician ID field. **Local** allows users to enter their own user names so they auto-populated the Technician ID field, but the device's technician or administrator password must be entered.

Idle Log Off Timeout (minutes): The number of minutes the ELI 380 can remain idle before the user is automatically logged off.

File Encryption Key: File Encryption Key can be set here by administrator. File Encryption key must match associated file encryption key in ELI Link – if these do not match, communication to ELI Link will fail. If File Encryption key is modified, all encrypted files are re-encrypted using new key.

Auto-Sync: Allows user to set Auto-Sync on ("Yes") or off ("No"). Default is "Yes." Auto-Sync will execute Sync rules set in System Configuration settings automatically.

Configuration Menu: ECG

AC Filter: Selection allows the user to remove 60 Hz or 50 Hz interference on the ECG trace. The setting selection depends on the line frequency in the host country. Always use the 60 Hz setting in the United States.

Filter: Selection allows the user to select the appropriate filtering for the desired trace results. The band-pass filter that is selected attenuates higher frequency noise and affects the fidelity of the electrocardiograph as viewed on the display and on the printed hard copy. The filter setting is printed at the bottom right corner of the ECG printout, and may also be viewed on the upper right-hand corner of the real-time display. Settings include:

1. The 40 Hz print-filter (0.05 to 40 Hz) setting reduces the noise from frequencies above 40 Hz.



WARNING: *When the 40 Hz filter is used, the frequency response requirement for diagnostic ECG equipment cannot be met. The 40 Hz filter significantly reduces high-frequency components of the ECG and pacemaker spike amplitudes, and is recommended only if high-frequency noise cannot be reduced by proper procedures.*

2. The 150 Hz print-filter (0.05 to 150 Hz) setting reduces the noise from frequencies above 150 Hz (default).
3. The 300 Hz print-filter (0.05 to 300 Hz) setting reduces the noise from frequencies above 300 Hz. This setting provides the least amount of filtering and the highest fidelity ECG signal to the printed and displayed ECG; this setting is recommended for pediatric ECG's.

NOTE: *The plot-frequency filter does not filter the digitized signal acquired for interpretation of the ECG.*

NOTE: *The Filter setting can also be changed for a single ECG by touching anywhere on the ECG waveform in the real-time or acquired view.*

Interp: Selection allows the clinician to turn the ECG interpretation statements On/Off for presentation on the display and/or printed report.

NOTE: *The ECG interpretations offered by the device are intended to be most relevant when used in conjunction with a physician over-read and with consideration of all other relevant patient data.*

Reasons: Selection allows the clinician to include additional information about the ECG interpretation on the printout. Reasons statements are specific details that indicate why a particular interpretive statement was chosen. Reasons statements print in brackets [] within the interpretive text. Reasons are only available if the interpretation statements option is enabled. Turning the reasons statement function ON or OFF does not affect the measurements criteria or the interpretive statement selected by the analysis program.

For Example:

Anteroseptal Infarct [40+ ms Q WAVE IN V1-V4]

“Anteroseptal Infarct” is the interpretive statement.

“40+ ms Q WAVE IN V1-V4” is the reason statement explaining the interpretive statement.

Critical Test Result (CTR): Yes for this option will enable the following:

The ELI 380 will provide notifications to the user if an acquired ECG meets the CTR criteria

The CTR feature will function even if ECG interpretation is disabled in the configuration menu.

If the option is disabled the user does not receive an audible or visual notification of CTR. ***CRITICAL TEST RESULT*** or ***ACUTE MI*** will still be presented as a conclusion statement on-screen and on ECG printout beneath interpretive text.

Append: Selection allows the user to choose a status message or statement phrase to the ECG that is printed under the interpretive text. The choices are “UNCONFIRMED REPORT” or “Reviewed by.”

Delete Rule: Allows the user to define how and when ECGs are automatically marked for deletion in the ECG directory. ECGs can be marked manually or marked for deletion per the Delete Rule. When the memory is full, ECGs that are marked for deletion will be automatically deleted based on their acquisition date and time (first-in/first-out) to make room for new ECG records. More than one ECG record may be removed from the directory to make room for the new incoming record.

The Delete Rule selections are:

1. Post Plot = ECG is automatically marked for deletion after printing
2. Post Transmit = ECG is automatically marked for deletion after transmission

*NOTE: A record may be permanently deleted by selecting the record, followed by selecting Erase from the left side of the display. A prompt will be presented as “Erase ECG?” If you select **Yes** the record will be permanently erased. If you select **No** the record will be maintained in the file.*

NOTE: Automatic deletion is also controlled by the Delete Timeout (days) feature. See below.

Average RR / QTcB / QTcF: **Yes** for these options will enable the following on the ECG:

- An averaged RR value.
- A Bazett’s corrected QT value along with the default linear QTc value.
- A Fridericia corrected QT value along with the default linear QTc value.

ECG Capture: Defines whether the ELI 380 will automatically display the Best 10 seconds of data acquired or the last 10 seconds of data acquired.

NOTE: The ECG Capture Mode can also be changed for a single ECG by touching anywhere on the ECG waveform in the acquired view.

Pace Spike Channel: This control allows the user to decide and set whether a pacemaker spike notification marker will display at the base of the ECG printout. A pacemaker spike notification marker coincides with each pacemaker event.

NOTE: The Pacemaker Spike Channel setting can also be toggled on or off for a single ECG by touching anywhere on the ECG waveform in the acquired view.

ECG Display Speed: This control allows the user to set the default display speed to 5 mm/s, 10 mm/s, 25 mm/s or 50 mm/s for ECG viewing.

NOTE: The Display Speed can also be changed for a single ECG by touching anywhere on the ECG waveform in the real time view.

ECG Print Speed: This control allows the user to set the paper speed to 25 mm/s or 50 mm/s for ECG printouts.

NOTE: The Print Speed can also be changed for a single ECG by touching anywhere on the ECG waveform in the acquired view.

Number of Copies: Allows selection for the number of printed copies that automatically print when an ECG is taken. A zero (0) setting prints no copies. Selecting one (1) prints the original copy, two (2) prints the original plus one copy, and so on up to 9 copies.

NOTE: No copies will automatically print when an ECG is selected from the Full Disclosure history.

Copies with Interp.: Allows selection for the number of printed copies containing interpretation when an ECG is taken. A zero (0) setting prints the first ECG with interpretation and all consecutive copies up to nine (9) printed without interpretation. Settings from one (1) to nine (9) contain an ECG interpretation on that number of selected printed copies. All copies display patient demographics and measurements.

Cabrera: Defines whether or not the ELI 380 will automatically display the ECG in the Cabrera format. The Cabrera format displays the limb leads in the order aVL, I, -aVR, II, aVF, III, instead of the standard I, II, III, aVR, aVL, aVF, allowing a different presentation of waveform progression in the vertical plane.

Plot Format: Allows the default to be set for one of the available print formats in either standard or Cabrera presentation. Regardless of the print format selected, 10 seconds of all 12 leads are always stored. ECG print options are:

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

NOTE: The Plot Format can also be changed for a single ECG by touching anywhere on the ECG waveform in the acquired view.

3 + 1 Rhythm Lead and 3 + 3 Rhythm Leads: Settings allow the user to select the lead configurations for the 10-second Rhythm Leads for the 3+1 channel and 3+3 channel ECG printout.

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

Rhythm Formats: Allows the user to set the default values for rhythm printing. Set the default rhythm format to 3, 6, 8 or 12-channel printing.

NOTE: The Rhythm Print Speed and Format can also be changed for a single ECG by touching anywhere on the ECG waveform in the real time view.

Rhythm Print Speed: Allows the user to set the default print speed to 5 mm/s, 10 mm/s, 25 mm/s, or 50 mm/sec.

Delete Timeout (days): Allows the user to define how many days to retain the stored ECG after it has been marked for deletion. ECGs that reach the number of days will be automatically deleted when ELI 380 goes into standby or when powering off.

Display Format: Allows user to set display format to 12x1, 4x2, 6x2, or II-V1-V5. Default is 12x1.

Interp Text Uppercase Allows the user to set interpretation statements to be displayed in all uppercase (“Yes”) or mixed-case (“No”). Default is Yes.

Configuration Menu: Alternate Placement

Alternate Lead Placement: Selection offers three alternate lead placements for V1 through V6 that can be assigned in this menu. ELI 380 is delivered with Pediatric, Posterior, and Right Sided lead sets as a default.

The user can reassign the Lead Placement Names with entry of up to 12 characters. Each set lists dropdown selections for each precordial lead, V1 to V6. Available labels are V1, V2, V3, V4, V5, V6, V7, V8, V9, V3R, V4R, V5R, V6R, and V7R. Labels will appear on both the display and on printouts. Refer to [Record An ECG](#) for further detail.

NOTE: Resting ECG interpretation is suppressed when non-standard lead placement is selected.

Select **Done** to save changes and exit the menu, or **Cancel** to exit without saving.

15 Leads Alt. Placement: Selection offers two alternate lead placements for E2, E3, and E4 that can be assigned in this menu. ELI 380 is delivered with Pediatric, Posterior, and Right Sided lead sets as a default.

The user can reassign the Lead Placement Names with entry of up to 12 characters. Each set lists dropdown selections for the E2, E3, and E4 leads. Available labels are V1, V2, V3, V4, V5, V6, V7, V8, V9, V3R, V4R, V5R, V6R, and V7R. Labels will appear on both the display and on printouts. Refer to [Record An ECG](#) for further detail.

Select **Done** to save changes and exit the menu, or **Cancel** to exit without saving.

Configuration Menu: Local Area Network (LAN) Connection and Setup

All parameters related to network connection must be entered under the direction of a qualified IT professional of the facility where the device is installed.


NOTE: LAN functionality can be confirmed by the presence of the LAN icon in the Settings menu.

The ELI 380 must be configured for LAN transmission by the facility Information Technology (IT) professional:

1. Connect the ethernet cable from the facility's local area network to the LAN connection at the rear of the ELI 380.



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

2. Select  from the real-time display, followed by **Advanced** and enter the password.
3. Select **LAN**.
4. Addresses are always entered as 4 sets of 3 digits; therefore, an address of 192.168.0.7 must be entered on the ELI 380 as 192.168.000.007.
 - a. LAN/WLAN settings may be password protected when printing the configuration. When the password is entered, users will be able to view these settings on the screen; however, all printouts will print “*****” instead of the actual values.
5. Select **Done** to save changes and exit the menu, or **Cancel** to exit the without saving.

Ethernet Transmission Status Indicator LEDs

The operator can monitor LAN interface connection and data transmission by observing the LEDs (Light Emitting Diodes) located at the system's external connector. The LEDs can be viewed from the outside (rear) of the ELI 380.

LED LOCATION	STATUS	INDICATES
Left LED	Dark	ELI 380 is in the Off state.
Left LED	Illuminated	Network link is detected; ELI 380 is On or in Stand-by.
Right LED	Flashing	When transmit or receive network traffic is detected.

NOTE: The ELI 380 LAN is compatible with 10 and 100 MBPS networks.

DHCP: Allows IT personnel to define 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, the IT professional must enter the IP address, def gateway, and subnet mask.

IP Address: Allows IT personnel to enter the fixed IP address for network transmission (if DHCP is not selected).

Def. Gateway: Allows IT personnel to enter the address of the default gateway (if DHCP is not selected).

Subnet Mask: Allows IT personnel to enter the sub net address (if DHCP is not selected).

Sync IP: Allows IT personnel to enter the IP address of the host server. The host server refers to the IP where ELI Link is installed.

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: Allows IT personnel to enter the port number used by the host server. The port number setting must match the ELI Link.

LAN Option: Allows IT personnel to enter the LAN option code; valid range is 0 to 10.


Select **Done** to save changes and exit the menu, or **Cancel** to exit without saving.

Configuration Menu: Wireless Local Area Network (WLAN) Connection and Setup

The facility Information Technology (IT) professional must:

- Configure the wireless access point(s).
- Configure the compatible electronic information management system.
- Provide the ELI 380 WLAN configuration values.

To set up the ELI 380 for WLAN transmission:

1. Select  from the real-time display, followed by **Advanced** and enter the password.
2. Select **WLAN**.
3. Configure the ELI 380 for Dynamic Host Communication Protocol (DHCP) or static IP. Wireless security encryption options are selected from a list and include:

- None
- WEP 128
- WEP 64
- WPA-PSK
- WPA-LEAP
- WPA2-PSK
- WPA2-PEAP
- WPA2-EAP-TLS

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. The 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 the IT professional:

- Host IP
- Port Number
- SSID
- Channel Number
- Password or passphrase

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 380 as 192.168.000.007.

If WEP wireless security is disabled on your access point, then set security (WEP) to **None**.

If WEP wireless security is enabled on your access point, the following wireless network parameters must be configured in the device by the IT professional:

- Security: WEP
- WEP Key
- WEP Key ID

NOTE: The range for the WEP key is 1-4. If the range on your access point is 0-3, then 1 at the ELI 380 maps to 0 on the access point; 2 maps to 1 on the access point, etc.

If your wireless security environment is WPA or WPA2 (Wi-Fi Protected Access) then enter the following:

- Security: WPA-PSK or WPA2-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 or PEAP then enter the following:

- Security: WPA-LEAP or WPA2-PEAP
- LEAP or PEAP User Name
- LEAP or PEAP Password

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

If your wireless security environment is WPA2 with EAP-TLS then enter the following:

- Security: WPA2-EAP-TLS
- TLS User Name
- TLS Password


EAP-TLS requires client 1024-bit TLS certificates to be installed in the system. A Certificates function icon is available with this security selection allowing you to load from storage (USB stick) to the WLAN module. Certificate files must have .cer for Root Certificate file extension and .p12 for Personal Information Exchange file extension. Select certificates from USB drive through drop down menu.

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

***NOTE:** Allow the ELI 380 several seconds to complete saving the WLAN configuration.*

In order to transmit ECGs, the WLAN signal must be strong enough to transmit. WLAN performance may vary due to changes in RF (radio frequency) properties at your site or to environmental conditions. Signal strength can be measured using utilities available in the ELI 380 configuration menu.

Testing RF Signal Strength

1. Select  from the real-time display, followed by **Network**.
2. Select **Test WLAN** to check your connection status.
3. Signal strength displays as zero to five bars with zero being no RF signal strength and five bars being full RF signal strength.
4. If an adequate signal is not being obtained, move to a location where more bars display before attempting to transmit.

***NOTE:** Intermittent connectivity in certain areas of your facility often indicates the need to restart the transmission process. Consult the IT department at your facility or your Mortara Field Service Engineer regarding modification of your WLAN to improve system performance.*

***NOTE:** Ensure ELI 380 has been configured to the area network before attempting a RF signal strength test.*

DHCP: Allows IT personnel to define 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, the IT professional must enter the IP address, def gateway, and subnet mask.

IP Address: Allows IT personnel to enter the fixed IP address for network transmission (if DHCP is not selected).

Def. Gateway: Allows IT personnel to enter the address of the default gateway (if DHCP is not selected).

Subnet Mask: Allows IT personnel to enter the sub net address (if DHCP is not selected).

Sync IP: Allows IT personnel to 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: Allows IT personnel to enter the port number used by the host server.

WLAN Option: Allows IT personnel to enter the WLAN option code; valid range is 0 to 10.

Security: Allows IT personnel to choose wireless security encryption options from a list. The following selections appear and are dependent on the enabled security type.

- **WEP64 or WEB128:** Allows IT personnel to enter the WEP key number; valid range is 1 to 4.
 - **WEP Key:** Allows IT personnel to enter the WEP key number; valid range is 1 to 4.
 - **WEP Key ID:** Allows IT personnel to enter the 128-bit WEP Key ID value (26 digits in 13 sets of two digits 00 to FF).
- **WPA-PSK or WPA2-PSK:** WPA (Wi-Fi Protected Access) PSK (Pre-Shared Key) security allows for implementation of the “personal mode” of WPA.
 - **PSK Passphrase:** The Passphrase can be up to 64 alphanumeric characters.
- **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 alphanumeric characters in length.
 - **LEAP Password:** The LEAP password can contain up to 32 alphanumeric characters in length.
- **WPA2-PEAP:** Cisco PEAP (Protected Extensible Authorization Protocol) enables use of the device with wireless networks employing the PEAP encryption protocol.
 - **PEAP User Name:** The PEAP user name can be up to 63 alphanumeric characters in length.
 - **PEAP Password:** The PEAP password can contain up to 63 alphanumeric characters in length.
- **WPA2-EAP-TLS:** Cisco WPA2 interface with EAP-TLS requires client TLS certificates for authentication.
 - **TLS User Name:** The TLS user name can be up to 64 alphanumeric characters in length.
 - **TLS Password:** The TLS password can contain up to 64 alphanumeric characters in length.
 - **Certificates:** This selection is available to load certificates from storage to the WLAN module.

Select **Done** to save changes and exit the menu, or **Cancel** to exit without saving.

Configuration Menu: Passwords


The Administrator password controls several functions and should be created and secured with care. Log the Administrator password in a location where it can be accessed during an emergency as well as in a backup location in case the primary location is compromised. The ELI 380 is preset with the case-sensitive Administrator password “admin.” To change the Administrator password, see [Setting Passwords](#).

The Administrator password enables:

- a. Access to the Configuration menu which controls all other passwords.
- b. Creation of a new password that is required to access the Password function.
- c. Creation of a technician-level password that is required to access the MWL, Patient List, or Directory tabs

Setting Passwords

To set or change the Administrator and Technician passwords:

1. Select  from the real-time display.
2. Select **Advanced** followed by **Passwords**. (A password is required to enter Advanced settings.)
3. Touch the appropriate password field and use the keyboard to enter the new password. Retype the new password in the appropriate Confirm field.
4. Select **Done** to save changes and exit the menu, or **Cancel** to exit without saving.

***NOTE:** Factory preset password for Advanced utility access is “admin”.*

***NOTE:** Passwords are case sensitive.*

***NOTE:** Creation of a technician password requires password entry to access the ECG Directory, MWL, and Patient List tabs.*

Configuration Settings: Service

Refer to the Service manual for definitions and assistance with the Service functions.


14. MAINTENANCE AND TROUBLESHOOTING

System Troubleshooting Chart

LCD Message	Problem	Correction
BATTERY LOW – CHARGE UNIT	Unable to acquire ECG or unable to print.	Charge the battery with AC power.
LEAD FAULT, NO ECG CAPTURE	Lead fail.	Correct faulty lead. Ensure that AMxx or WAM are properly configured. If using the WAM, ensure that the WAM is paired with the ELI 380.
None	Device is not responding	Press and hold the On/Off button for 10 seconds. Re-entry of date and time will be required after this function.

ECG Troubleshooting Chart

Affected Leads	Problem	Correction
LEADS OFF MESSAGE FOR ONE OR MORE OF THE FOLLOWING: RA, LA, LL, V1, V2, V3, V4, V5, V6; SQUARE WAVES ON DISPLAY.	Lead fail.	Ensure lead and electrode connection is secure. Replace faulty electrode patches or lead wires if necessary.
“LEADS OFF” OR “SEARCHING FOR WAM” MESSAGE	WAM or AMxx do not acquire ECG	Ensure that the correct module is configured in the ELI 380. WAM: Check to see that the WAM is in range and is powered on. Ensure the WAM is paired with the ELI 380. AMxx: Reconnect the AMxx or power cycle the ELI 380.
ARTIFACT / NOISE on Lead I and Lead II	Poor RA electrode or right arm tremor	Check patient prep; re-prep if necessary with new electrode. Ensure patient is relaxed and muscles are not tense.
ARTIFACT / NOISE on Lead II and Lead III	Poor LL electrode or left leg tremor	Check patient prep; re-prep if necessary with new electrode. Ensure patient is relaxed and muscles are not tense.
ARTIFACT / NOISE on Lead I and Lead III	Poor LA electrode, or left arm tremor	Check patient prep; re-prep if necessary with new electrode. Ensure patient is relaxed and muscles are not tense.

Affected Leads	Problem	Correction
ARTIFACT / NOISE on All Leads	High Freq. Noise.	Adjust low pass filter setting to 150 or 40 Hz (see warning); check proximity to power cables; check AC filter setting (50 Hz or 60 Hz). Ensure patient is relaxed and muscles are not tense.  WARNING: When the 40 Hz filter is used, the frequency response requirement for diagnostic ECG equipment cannot be met.
UNABLE TO SAVE ECG	ECG data too noisy to store.	Correct noise and try acquisition/storage again.
With WAM connected: <ul style="list-style-type: none"> Real-Time Screen or ECG Printouts have missing data (i.e. blank gap in waveform) AND/OR ECG can only be acquired by selecting ECG button twice (forced acquire) AND/OR Interpretation statements/measurements are not printed on report 	Unstable WAM connection preventing ELI 380 from recording data.	Reposition WAM for better wireless connection (see Notes under User Safety Information). If unable to secure better connection, use AM12 for wired connection instead. If problem persists, call Mortara Customer Service to search for possible radio interference sources.

Transmission Troubleshooting Chart

LCD Message	Problem	Correction
TRANSMIT FAILED	Unable to transmit ECG.	Ensure site number is valid. Retry.
ERROR-DICOM Not Enabled	A DICOM communication was attempted, but the unit is not configured for DICOM.	Configure the system to DICOM and reboot.
UNABLE TO SAVE ECG	No available memory. ECG data too noisy to store.	Transmit or mark records for deletion in the directory. Correct noise and try acquisition/storage again.
DHCP FAILURE	The WLAN module failed to get an address from DHCP.	Contact Mortara Technical Service.
DPAC FAILURE	WLAN failed to initialize.	Contact Mortara Technical Service.
CAN'T CONNECT TO ACCESS POINT	A link to the access point could not be established.	Ensure the IP address is correct. If problem persists, contact Mortara Technical Service.
CAN'T CONNECT TO REMOTE LINK	A link to the access point was established, but the link to the destination failed.	Ensure the IP address is correct. If problem persists, contact Mortara Technical Service.
TIME SYNC FAULT	Possible incorrect version of ELI Link	Install latest version.

UNABLE TO SAVE XML ORDER	Order storage failed.	Attempt to retransmit orders.
UNABLE TO SAVE MWL ORDER	DICOM order storage failed.	Directory full; mark records for deletion or delete records.
INCORRECT RESPONSE	Connection established, then failed.	Connection started but failed; attempt to reconnect.
NO CUSTOM ID	Received orders failed.	Previous Custom ID not compatible with current Custom ID, or no Custom ID.

LCD Message	Problem	Correction
PAPER QUEUE FAULT	Unable to print. Paper queue mark not detected as expected.	Add paper; manually advance page evenly past closure point of writer and close writer cover.
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.
Disabled	No response when pressing SYNC key	Enable SYNC MODE and/or set SYNC MEDIA in configuration

Display Troubleshooting Chart

LCD Message	Problem	Correction
Screen is dark	The AC power cord is not connected to a grounded electrical outlet or is damaged.	<p>Ensure that AC power cord is not damaged and is firmly connected to AC power connector on rear of electrocardiograph.</p> <p>Ensure that electrocardiograph is plugged into grounded electrical outlet.</p> <p>If AC power is being used and the AC power switch is set to the On position, but the AC power on indicator light does not illuminate and the display is still dark, contact Mortara Technical Support.</p>
	Electrocardiograph is in Standby Mode	Press the On/Standby button to return to active use.
	Electrocardiograph will not power on.	<p>Plug AC power cord into wall outlet and follow the instructions on the display.</p> <p>Do this only if correction above fails: Disconnect the AC power cable from the wall outlet and depress the On/Off button for >15 seconds.</p> <p>If problem persists, contact Mortara Technical Support.</p>

Reboot the Device

To completely shut down the device, disconnect the AC power cord then press and hold the On/Off button for approximately 15-seconds. Such a shutdown should only be performed when other attempts for correction have failed. This will reset the internal clock to the default time and date.



CAUTION: During normal use, the ELI 380 should not be operated in this manner.

Test Operation

After cleaning and inspecting the device, 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 device 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, ANSI/AAMI ES 60601-1, or IEC 62353 methods and limits).
 - patient leakage current
 - chassis leakage current
 - earth leakage current
 - dielectric strength or insulation resistance (mains and patient circuits, mains and signal input/output part (e.g., USB), mains and protective earth)

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 the 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.