Welch Allyn[®] ELI[®] 380 RESTING ELECTROCARDIOGRAPH SERVICE MANUAL

Manufactured by Welch Allyn, Inc., Skaneateles Falls, NY U.S.A.



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

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9516-189-50-ENG Rev M Revision Date: 2020-08



901133 ELECTROCARDIOGRAPH



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NOTICES

Manufacturer's Responsibility

Welch Allyn, 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 Welch Allyn, 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 Welch Allyn, 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

Welch Allyn, 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

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

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Notice to EU Users and/or Patients:

Any serious incident that has occurred in relation to the device, should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established

Your Welch Allyn Warranty

WELCH ALLYN, INC. (hereafter referred to as "Welch Allyn") warrants that components within Welch Allyn 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 Welch Allyn, 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 Welch Allyn;
- 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 Welch Allyn;
- f) Other events outside of Welch Allyn'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 WELCH ALLYN TO HAVE BEEN DEFECTIVE. This remedy shall be conditioned upon receipt of notice by Welch Allyn of any alleged defects promptly after discovery thereof within the warranty period. Welch Allyn'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 Welch Allyn's principal place or any other place as specifically designated by Welch Allyn or an authorized distributor or representative of Welch Allyn, and (ii) all risk of loss in transit. It is expressly agreed that the liability of Welch Allyn is limited and that Welch Allyn does not function as an insurer. A purchaser of a Product/s, by its acceptance and purchase thereof, acknowledges and agrees that Welch Allyn is not liable for loss, harm, or damage due directly or indirectly to an occurrence or consequence therefrom relating to the Product/s. If Welch Allyn should be found liable to anyone under any theory (except the expressed warranty set forth herein) for loss, harm, or damage, the liability of Welch Allyn 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 WELCH ALLYN 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 WELCH ALLYN IS NOTIFIED WITHIN THE WARRANTY PERIOD. IN NO EVENT, INCLUDING THE CLAIM FOR NEGLIGENCE, SHALL WELCH ALLYN BE LIABLE FOR INCIDENTAL, SPECIAL, OR CONSEQUENTIAL DAMAGES, OR FOR ANY OTHER LOSS, DAMAGE, OR EXPENSE OF ANY KIND, INCLUDING LOSS OF PROFITS, WHETHER UNDER TORT, NEGLIGENCE OR STRICT LIABILITY THEORIES OF LAW, OR OTHERWISE. THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO THE IMPLIED WARRANTY OF MERCHANTABILITY AND THE WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE.

USER SAFETY INFORMATION



NOTE: This manual may contain screen shots and pictures. Any screen shots and pictures 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.

WARNING(S)

- This manual gives important information about the use and safety of this device. Deviating from operating procedures, misuse or misapplication of the device, or ignoring specifications and recommendations could result in increased risk of harm to users, patients and bystanders, or damage to the device.
- Device captures and presents data reflecting a patient's physiological condition that when reviewed by a trained physician or clinician can be useful in determining a diagnosis; however, the data should not be used as a sole means for determining a patient's diagnosis.
- Users are expected to be licensed clinical professionals knowledgeable about medical procedures and patient care, and adequately trained in the use of this device. Before attempting to use this device for clinical applications, the operator must read and understand the contents of the user manual and other accompanying documents. Inadequate knowledge or training could result in increased risk of harm to users, patients and bystanders, or damage to the device. Contact Welch Allyn service for additional training options.
- To ensure that electrical safety is maintained during operation from AC (~) power, the device must be plugged into a hospital-grade outlet.
- Only use parts and accessories supplied with the device and/or are available through Welch Allyn, Inc.
- Welch Allyn 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.
- The ELI 380 uses lithium-ion batteries. The following precautions should be taken regarding the batteries:
 - Do not immerse the device in water.
 - Do not heat or throw the device in fire.
 - \circ Do not leave the device in conditions over 60 °C or in a heated car.
 - Do not attempt to crush or drop the device.
 - Only use the approved Welch Allyn battery pack with the ELI 380.
 - Follow the disposal instructions in the ELI 380 Service Manual when the device is taken out of service.
- 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.

- 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.
- ECG electrodes could cause skin irritation; patients should be examined for signs of irritation or inflammation.
- To avoid the possibility of serious injury or death during patient defibrillation, do not come into contact with 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.
- 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.
- This device was designed to use the electrodes specified in the user manual. Proper clinical procedure must be employed to prep the electrode sites and to monitor the patient for excessive skin irritation, inflammation, or other adverse reactions. Electrodes are intended for short-term use and should be removed from the patient promptly following testing.
- To avoid potential for spread of disease or infection, single-use disposable components (e.g., electrodes) must not be reused. To maintain safety and effectiveness, electrodes must not be used beyond their expiration date.
- A possible explosion hazard exists. Do not use the device in the presence of a flammable anesthetic mixture.
- Where the integrity of external protective earth conductor arrangement is in doubt, the device shall be operated from its internal electrical power source.
- 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.
- 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.
- 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.
- Other medical equipment, including but not limited to defibrillators and ultrasound machines, may cause interference with the ECG signals recorded by the device.
- 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.
- Some Welch Allyn 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. The following WLAN manufacturers and models may be present depending on the date of manufacture of the device.
 - Laird WB45NBT
 - B&B Electronics WLNN-SP-MR551
 - Quatech, Inc. Model WLNN-AN-MR551 (model subject to change without notice)
- 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.
- 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.
- 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

- 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.
- No user-serviceable parts inside. Screw removal by qualified service personnel only. Damaged or suspected inoperative equipment must be immediately removed from use and must be checked/repaired by qualified service personnel prior to continued use.
- The rechargeable internal battery is a sealed lithium-ion type. If the battery appears to become defective, refer to Welch Allyn Technical Support.
- Do not pull or stretch the acquisition module lead wires and cable as this could result in mechanical and/or electrical failures.
- 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.
- The WAM will only work with receiving devices that are equipped with the appropriate option.
- No user-serviceable parts are inside the WAM. Damaged or suspected inoperative equipment must be immediately removed from use and must be checked/repaired by qualified service personnel prior to continued use.
- 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.
- The following equipment may cause interference with the WAM RF channel: microwave ovens, diathermy units with LANs (spread spectrum), amateur radios, and government radar.
- When necessary, dispose of the device, its components and accessories (e.g., batteries, cables, electrodes), and/or packing materials in accordance with local regulations.
- 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.
- Be careful to insert the connector block into the appropriate input connector by matching the lead wire labels to the WAM, AM12 or AM15E label.

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

- Patient movement may generate excessive noise that may affect the quality of the ECG traces and the proper analysis performed by the device.
- Proper patient preparation is important to proper application of ECG electrodes and operation of the device.
- 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).
- 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.
- The WAM LEDs will automatically start flashing if the batteries have been discharged below 1.0 volts.
- During normal WAM/AM12/AM15E operation, the green LED will display continuously.

- 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.
- The WAM will automatically turn off (LEDs off) if the battery has been severely discharged.
- The WAM will automatically turn off when the electrocardiograph is powered down.
- 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.
- The display of absent waveform display while using the AM12 or AM15E acquisition module could be due to an improper auto-calibration. Reconnect the AM12/AM15E or power cycle the electrocardiograph.
- Square waves on the display and rhythm printout could be due to the WAM or the AM12/AM15E lead wires not being connected to the patient.
- As defined by IEC 60601-1 and IEC 60601-2-25, the device is classified as follows:
 - Class I equipment or internally powered.
 - Type CF defibrillation-proof applied parts.
 - Ordinary equipment.
 - Equipment not suitable for use in the presence of a flammable anesthetic mixture.
 - Continuous operation.

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

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

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

- The device will automatically turn off (blank screen) if the batteries have been severely discharged and the AC mains is disconnected from the device.
- After operating the device using battery power, always reconnect the power cord. This ensures that the batteries will be automatically recharged for the next time you use the device. A light next to the on/off switch will illuminate indicating that the device is charging.

- When using the WAM, it must be paired to electrocardiograph before operation.
- The device is UL classified:



WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH AAMI ES 60601-1(2005), CAN/CSA C22.2 No. 60601-1(2008), IEC 60601-1(2005), AND IEC 60601-2-25(2011)

• The WAM is UL classified:



WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH IEC60601-1, CAN/CSA CC22.2 No. 60601-1, IEC60601-2-25,

Wireless Data Transmission

• ELI 380 electrocardiographs are equipped with a wireless data transmission module (WLAN). This technology uses radios to transmit data to a Welch Allyn 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. Welch Allyn 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

- 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.
- The Wireless LAN module used is compliant with the IEEE 802.11 a, b, g and n standards.
- 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.
- In order to achieve the best transmission rate, it is necessary that the facility where the device is operated can provide good area coverage. Please consult the IT personnel of the facility to verify the proper WLAN availability in the area where the device will be used.
- RF wave propagation may be blocked or reduced by the environment where the device is used. Most common areas where this may occur are: shielded rooms, elevators, underground rooms. In all such situations it is recommended to move the device to a proper location where the WLAN frequencies are available.

EQUIPMENT SYMBOLS AND MARKINGS

Symbol Delineation





Non-ionizing electromagnetic radiation

Reorder Number

Model Identifier



Medical Device

Display Icons and Keyboard Buttons



Patient information

ECG Acquisition

Rhythm Print

Synchronize

Configuration

Home

Full disclosure page up

Full disclosure ECG Acquisition

Full disclosure page down

GENERAL CARE

Precautions

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

Inspection

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

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

Cleaning 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: Welch Allyn 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.

Disposal

This product and its accessories must be disposed of according to local laws and regulations. Do not dispose of this product as unsorted municipal waste. For more specific disposal information see www.welchallyn.com/weee.

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 Welch Allyn 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	The equipment is suitable for use in all establishments other than domestic and those directly connected to the public low- voltage power supply network that supplies buildings used for
Harmonic Emissions IEC 61000-3-2	Complies	domestic purposes.
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
			Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF EN 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	$d = \left[\frac{3.5}{3Vrms}\right] P$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = \begin{bmatrix} 3.5 \\ 3V/m \end{bmatrix} \sqrt{P} 80 \text{ MHz to } 800 \text{ MHz}$
			$d = \begin{bmatrix} 7 \\ 3V / m \end{bmatrix} \sqrt{P}$ 800 MHz to 2.5 GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
			Field strengths from fixed RF transmitters, as
			be less than the compliance level in each frequency range ^b .
			Interference may occur in the vicinity of equipment marked with the following symbol:
			((()))

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

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

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

PREVENTIVE MAINTENANCE

Preventive Maintenance Schedule

Maintenance to be Performed	RECOMMENDED FREQUENCY	NOTES
Device Cleaning	As Needed	Refer to the device cleaning portion of this section.
Preventive Maintenance Procedure	12 Months	Refer to procedure defined below.
Battery Replacement	24 Months	Replacement period varies based on frequency and duration of use; refer to the Battery Health value displayed in the device special functions for specific information regarding battery capacity.

WARNING: Preventive maintenance is to be performed by Welch Allyn authorized service personnel only.

Preventive Maintenance / Conformance Testing Recommended Equipment

- Multi-Meter
- ECG Simulator
- AM12 Patient Input Module (9293-048-5X)
- WAM Patient Input Module (30012-019-5X)
- WAM/AM12 Lead Wire Set (9293-046-70)
- AM15E Patient Input Module (9293-063-50)
- LEAD SET AM15 (9293-046-80)
- Patient Cable Snap Adapter Set (9281-002-50)
- 10 Lead Shorting Block (or equivalent)
- Lead Test Failure Box (or equivalent)
- PC with ELI-Link v3.10 or later
- USB Cable Type A to B (6400-012)
- PC with NIC and ELI-Link v4.5 or later
- Wireless Router 802.11 (a, b, g, n)
- FAT 32 USB Memory Device
- Electrical Safety Analyzer
- Ruler (mm)
- Smart Thermal Paper

Preventive Maintenance Procedure

Print the device configuration (attach to the Preventative Maintenance Data Record / PMR).

Remove the unit cover per Unit Disassembly section of this manual, and perform a visual inspection of the following items:

- **Enclosure/Housing** Look for damage or cracks in the external housing or enclosure that could possibly 0 expose the device to the introduction of foreign objects or fluids. Attention should also be paid to areas that could expose an operator or patient to internal circuitry of the device.
- **Contamination** Look for any contamination that may have occurred over time that could not be 0 seen with the housing in place.
- Markings and Labeling Verify all labels and device markings are clearly visible and legible to the 0 device user and have not been worn off or rendered unreadable through the use of harsh cleaning agents.
 - Fluid damage (perhaps caused during device cleaning)
 - Debris on or behind display shield
 - Battery leakage (main battery(s))
- Internal Cabling Look for cracked, pinched or partially disconnected cable connections. 0
- Integrity of Mechanical Parts Verify the following items are properly secured to the device and 0 have not become loose or damaged through usage over time.
 - AC Inlet
 - **USB** Connectors
 - Communication ports and antenna
 - Writer mechanics/latching mechanism
 - LCD Assembly

Reinstall the unit cover per Unit Disassembly section of this manual.

Note battery age!

The ELITM 380 may have 1 or 2 batteries installed at time of servicing.

Turn the unit over and remove the battery plate and battery(s) (see Unit Disassembly section, Battery Removal).

Battery 2 0

The battery date code is stamped on the side of the battery pack (first 6 digits of string, see picture). Date code for this battery is 131126 (format = YYMMDD).

- Document battery date code(s).
- Reinstall battery(s) and battery plate, turn unit over.



Power Testing

Ensure there is no power connected to the ELI 380 AC inlet until test states to run on AC Power.

Access Settings

- 1. Select the Settings icon in the upper right corner of the main screen
- 2. Select **Advanced** in upper right.
- 3. Type **admin** when prompted for password.
- 4. Select **Service**.
- 5. Select **Battery Info**.

Battery Voltage

Document the battery voltage as shown in battery information.

State of Charge

Document the present state of charge of the battery given in percent form.

Charge Cycles

Document the amount of charge cycles the battery has been charged.

Charging

Document the message displayed (Yes, No, or Fault).

Avg. Current ("On" current)

Document the average current as shown in battery information.

Battery Health

Document the health of the battery in percent form. (Recommend replacement when under 70%; the ELI 380 will notify user when lower than 70%.)

Running on DC & AC power (connect AC power cord)

- Verify AC power LED indicator illuminates (located above powerbutton). Record Results on PMR
- Verify AVG Current value gradually changes from negative to positive (the value will remain at 0 if the battery is fully charged). Record Results on PMR
- Verify Charging is Yes (if current is flowing to battery). Record Results on PMR

Battery Performance Information

- 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.
- 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.

Functional Testing

MAIN SCREEN:

- The MAIN SCREEN is displayed when the unit is first turned on.
- The LCD will timeout and go dark in 5 minutes if there is no ECG or user input. Touch the touchpad to reactivate.

SERVICE SCREEN:

- To access the SERVICE SCREEN begin at the MAIN SCREEN.
- Press
- Press **ADVANCED**, then enter the Admin password.
- Press SERVICE.

CONFIGURATION SCREEN:

- To access the CONFIGURATION SCREEN begin at the MAIN SCREEN.
- Press
- Press **ADVANCED**, then enter the Admin password.

Display and Standby Mode

- Press the ON button and verify the text on display is clear and legible and there are no flickering or missing lines/pixels. Record Results on PMR
- Close (tilt) the LCD Display towards the writer. After a few seconds verify the LCD backlight turns off. Open the LCD Display and verify the unit comes out of the standby mode returning to the MAIN SCREEN. Record Results on PMR
- The following procedure applies to the ERGO variant:
 - 1. Rotate the screen 90 degrees away from the front user face to the right and verify that the LCD backlight is on with no flickering or missing lines/pixels. Record Results on PMR
 - 2. Rotate the screen 90 degrees away from the front user face to the left and verify that the LCD backlight is on with no flickering or missing lines/pixels. Record Results on PMR
 - 3. Tilt the display out until a mechanical stop is reached. Verify the stop is reached at 120 degrees. Record Results on PMR

Auto Test

• From the Service Screen, select Auto Test. Verify the auto test completes one cycle without an error.

The Auto Test function tests the ELI 380's ability to read and write an ECG file to the flash memory in the unit. Record Results on PMR

Writer Test

- Open and close the writer door to verify smooth operation. Verify that the door unlatches without sticking and that it latches completely.
- From the Service Screen, select **Writer Test**. Verify that a test page is printed and the writer stops on the cue mark. The perforation of the paper should line up with the tear edge on the writer. Assure there are no gaps in the printing and the print darkness is uniform across the entire page (see example).
- Verify the writer gears do not skip and paper is tracking properly (you may need to print multiple pages to observe this).
- Record Results on PMR



ECG Test

- Connect an ECG simulator to the AM12[™], AM15E or WAM[™] patient interface. Set the simulator to a known heart rate and amplitude; preferably to a setting that you have a "known good" printout for comparison.
- From the Main Screen, select the patient info icon
- Enter "TESTECG" into the last name field and select the next icon.
- From the Main Screen, select **ECG**.
- Review results and then select **PRINT**.
- Verify that 12 or 15 ECG traces print with clarity and assess the overall printout quality. Ensure uniform darkness across entire printout.
- Record Results on PMR

ECG Noise Test

- Connect a Shorting Block (TF-0063) and adapter or equivalent to the AM12, AM15E or WAM patient interface.
- Set the ECG gain on the unit to 20mm/mV.
- Print a rhythm strip (approx. 1 page). Verify that no channels have more than 0.5mm of noise.
- Record Results on PMR

Communication Options Testing (as applicable)

The receiving station for modem, LAN and WLAN transmissions should be running Welch Allyn ELI-Link software. Refer to the ELI-Link user manual for proper configuration.

Verify successful transmission of all applicable communication options by acquiring ECG records that include the transmission method in the "Patient Name" field (such as Last Name = USBD) then subsequently transmitting the ECG record stored to a compatible receiving device. Consult the product user manual if needed to properly configure the communication settings for each option present on the unit under test.

Successful transmission of the test records can be verified by viewing the ECG records in the unit directory after transmission and confirming they are marked as "transmitted" (as defined in the product user manual). Record Results on the PMR

- USB host (USB memory device needed)
- LAN
- WLAN

Cleaning Exterior Surfaces and Patient Acquisition Device

WARNING: Do not spray cleaner directly onto the exterior surface. Spray the cleaner onto a lintfree cloth and then wipe the surface.

Cautions

- Improper cleaning products and processes can damage the device, produce brittle lead wires and cables, corrode the metal, and void the warranty.
- For disinfecting the device, cables, and lead wires, wipe exterior with a soft, lint-free cloth using a solution of Sodium Hypochlorite (10% household bleach and water solution) minimum 1:500 dilution (minimum 100 ppm free chlorine) and maximum 1:10 dilution as recommended by the APIC Guidelines for Selection and Use of Disinfectants.
- Use caution with excess liquid as contact with metal parts may cause corrosion.
- Do not immerse cable ends or lead wires; immersion can cause metal corrosion.
- 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.

Caution: Disinfecting or cleaning agents that contain **Quaternary Ammonium** (including ammonium chloride) have been identified as having negative effects if used to disinfect the product. Use of such agents may result in discoloration, cracking, and deterioration of the external housing of the device.

Device Cleaning / Consumables:

- Clean lint free cloth
- Mild detergent
- Isopropyl Alcohol (80-99%)
- Disinfectant Clorox Healthcare[®] Bleach Germicidal Wipes (use according to instructions on product label), or 10% Household bleach and water solution (Sodium Hypochlorite solution consisting of a minimum 1:500 dilution and maximum of 1:10 dilution for disinfecting use only)

Cleaning the Device

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

For general cleaning of cables and lead wires, use a soft, lint-free cloth lightly moistened with a mild soap and water solution. Wipe and air dry.

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.

Safety Testing

If the cardiograph housing was opened for repair or inspection work, the following safety tests should be performed in accordance with the IEC 60601-1 or IEC 62353 methods and limits.

The ELI380 is considered a Class 1 Type CF device, intended to only be utilized with the Welch Allyn AM12 or WAM patient input modules. Defibrillation isolation from the patient is provided by the patient input modules, which are tested separately as part of the manufacturing process (they are considered non-serviceable devices), therefore Hi-pot testing is not required for the ELI380 cardiograph.

- Earth Leakage
- Enclosure Leakage

Non-conductive (fully insulated) chassis testing should be performed utilizing 200 cm2 conductive foil or equivalent, earth ground on AC input is utilized for functional earth (not safety grounding).

- Patient Leakage Applied part – patient input (utilize Mortara AM12 patient cable)
- Patient Auxiliary Current

Applied part – patient input (utilize Mortara AM12 patient cable)

ELI 380 Preventive Maintenance Record

Unit Serial #:

Print device configuration (attach to this report).

Perform Visual Inspection of:

- Enclosure/Housing
- Contamination
- Markings and Labeling
- Cabling
- Integrity of Mechanical Parts

The ELI 380 may have 1 or 2 batteries installed at time of servicing.

Note Battery 1 Date Code	(YYMMDD) or enter N/A if no battery
Note Battery 2 Date Code	(YYMMDD) or enter N/A if no battery
(Recommend replacement every 2 y	years.)
Power Testing	
Battery 1 – Installed? 🗌 Yes 🗌 No	o (if No, skip Battery 1 section)
Running on DC power only (disc	connect AC power cord)
Battery Voltage	V
State Of Charge	%
Charge Cycles	
Verify Charging is No	Pass / Fail (Circle One)
On Current (Displayed as (Negative reading when on DC)	Avg. Current)A (max draw = 1.6A)
Battery Health	% (Recommend replacement when under 70%.)
Running on DC & AC power (co	nnect AC power cord)

- Verify AC power LED indicator illuminates (located above power button). Pass / Fail (Circle One)
- Verify AVG Current value gradually changes from negative to positive (the value will remain at 0 if the battery is fully charged). Pass / Fail (Circle One)
- Verify Charging is Yes (if current is flowing to battery). Pass / Fail (Circle One)

Battery 2 – Installed? Yes No (if No, skip Battery 2 section)

Running on DC power only (disconnect AC power cord)

	Battery Voltage		V	
	State Of Charge		%	
	Charge Cycles			
Veri	fy Charging is No		Pass / F	ail (Circle One)
	On Current (Displayed as Avg. Current)A (max draw = 1.6A) (Negative reading when on DC)			
	Battery Health		%	(Recommend replacement when under 70%.)
Running on DC & AC power (connect AC power cord)				
 Verify AC power LED indicator illuminates (located above power button). Pass / One) 				minates (located above powerbutton). Pass / Fail (Circle

- Verify AVG Current value gradually changes from negative to positive (the value will remain • at 0 if the battery is fully charged). Pass / Fail (Circle One)
- Verify Charging is Yes (if current is flowing to battery). Pass / Fail (Circle One)

Functional Testing

- **Display Functionality** Pass / Fail (Circle One) .
- **Tilt Switch Operation** Pass / Fail (Circle One) •
- Ergo Variant Test 1. Pass / Fail / NA (Circle One) •
- Ergo Variant Test 2. Pass / Fail / NA (Circle One) •
- Ergo Variant Test 3. Pass / Fail / NA (Circle One) •
- Pass / Fail (Circle One) Auto Test
- Writer Test Pass / Fail (Circle One)
- ECG Test Pass / Fail (Circle One)
- ECG Noise Test Pass / Fail (Circle One) •
- Communication Option(s) •
 - - o USB host Pass / Fail / NA (Circle One) o LAN
 - Pass / Fail / NA (Circle One)
 - o WLAN Pass / Fail / NA (Circle One)

Safety Testing **PASS** FAIL (check one)

- Earth Leakage
- Enclosure Leakage •
- Patient Leakage
- Patient Auxiliary Current

Performed by:

UNIT DISASSEMBLY

This section describes the methods used to disassemble and repair the ELI 380 and the tools required to perform the defined steps.

Cautions and Special Instructions



CAUTION: Risk of Explosion.

DO NOT SHORT battery terminals. Leave the protective covers on the battery terminals until assembly into the base unit.



CAUTION: Risk of Shock.

Line voltage may be present on the power supply of the device. Use caution when the device housing is removed and AC power is applied.



ATTENTION: PCB assembly contains ESD sensitive devices. Use appropriate precaution when handling electronic assemblies.



ATTENTION: PCB assembly contains mechanically sensitive electrical devices. Handle with extreme care to reduce the stress on solder connections.



ATTENTION: Before applying all adhesive backed materials, clean surface with alcohol to make sure it is clean and oil free.

Tools Required

- Phillips Screwdriver
- Torque Driver Phillips #1 Bit (3.5 in/lbs)
- Torque Driver Phillips #2 Bit (18 in/lbs)
- T10 Torx Bit
- Nut Driver Socket 9/32
- 1/4" Extension Bit
- M4 Allen wrench
- M2 Allen wrench
- HX1.3 Driver Bit
- Needle Nose Pliers
- Tweezers
- Side Cutters

Battery Removal

CAUTION: Risk of Explosion - DO NOT SHORT battery terminals.

Turn the unit over and remove the (4) screws (Item 38) and remove the battery cover plate. Labels must be installed on new lower housings if replaced.





Remove the battery (Item 4). The device may have dual batteries installed when opened. The device should be shipped with only one battery installed per regulations.



Upper Housing Removal

Remove the 11 housing screws (Item 38) from the recessed areas identified by the arrows molded into the lower housing.



Designation Arrow



Remove the 4 writer screws (Item 26) from the recessed areas.



Carefully turn the unit over while holding the display against the lower housing. Place the unit on a flat surface and flip up the display assembly. Open the paper door of the writer assembly (Item 35, Table 2) approximately three quarters of full travel. Lift the upper housing assembly (Item 41) and tilt it as shown



Disconnect keypad cable (Item 18) from the bottom side of the upper housing by squeezing the plastic portion of the connector (do NOT attempt to pull the connector loose by pulling on the wires)




With the keypad cable removed, tilt the lower housing up and slide the upper housing over the extended writer door.

Remove the upper housing assembly and close the writer door.



Thermal Writer Removal



Lift the writer assembly from the left side enough to remove the motor cable from connector J11 (as shown).





Continue to lift the writer assembly and remove the remaining cable assemblies from the PCBA.



- Longer BLACK Print head cable from J7
- Cue sensor cable from J9
- Shorter BLACK Print head cable from J8
- Ground (single wire) to GND terminal

Hinge Cover Removal

Remove the housing hinge cover (Item 28) by pulling the cover towards the front of the ELI 380.

Care must be used when removing the hinge cover to prevent damage to the plastic retainer pieces on the rear cover covered in the next step.



Rear Cover Removal

Fold down the display prior to rear cover removal.

Care must be taken to ensure the display does not slip causing damage to the installed PCBAs. The thermal writer is no longer installed to provide support for the display.



Remove plug (Item 32) from center retaining screw hole then remove screw (Item 38).





Pull the housing rear cover (Item 29) straight out from the back of the device.



Display Removal

Remove all display cable connections from the Motherboard and WLAN Module (as shown).

All of the connectors should be removed via the plastic portion of the connector, do NOT attempt to pull them loose from the wires).



Connector ID Table



P5 – LCD Left front

- P6 LCD Right front
- J5 LCD Data Cable (colored wires)

CH2 WLAN Module – Antenna (circled)

Remove WLAN antenna (Item 13a shown) from the display bracket if replacing the display assembly.



Cut the tie wrap securing the cabling from the display bracket.

Gently pull straight up on the antenna assembly to remove it from the bracket.

The antenna shown to the left (item 13a) is for the B&B WLAN module, refer to the following page for units using the Laird WLAN module.

Adhesive kit (Item 31) will be needed during reassembly if the antenna assembly is removed. Note: Refer to the WLAN label on the bottom of the unit to identify the WLAN module installed.

Wireless LAN Module: B&B Electronics Model: WLNN-SP-MR551 FCC ID: F4AWLNN551 IC: 3913A-WLNN551

This device complies with part 15 of the FCC rules. Operation is subject to the following two 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. Wireless LAN Module: Laird Technologies Model: WB45NBT FCC ID: SQG-WB45NBT IC: 3147A-WB45NBT

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions: 1) This device may not cause harmful interference, and 2) This device may accept any interference received including interference that may cause undesired operation.

ELI380 units using the Laird WLAN module (item 20b) are configured as shown below. The antenna is mounted to the display bracket via a foam pad with double sided adhesive (item 61). If the antenna is removed from the foam mount, a new adhesive mounting pad should be used to ensure the antenna is properly secured. The antenna cable (item 60) uses a snap tight vertical plug/unplug connector.



Laird Antenna (item 13b/c) mounted to foam pad (item 61)



Antenna connection to WLAN module connect as shown.



One of two different Laird antenna configurations will be present (item 13b or 13c). The earlier version b antenna has 2 antenna connectors as shown above, the newer version c has only 1 antenna connection.

Remove the 4 screws (Item 15) which hold the display bracket to the lower housing as indicated by the square (monitor) symbols molded into the lower housing (as shown).



Care must be taken to ensure the display does not fall from the lower housing during disassembly.



Lift the display assembly (Item 10) up to remove it from the lower housing.

Ensure proper handling of removed display to prevent accidental damage.

If the LCD assembly being removed has ferrite cores (item 63) on the white and black ELI380 Cable Assy as shown in the right-hand picture below, and the new assembly does not have the cores present, remove the ferrite cores from the old LCD assembly, by utilizing the snap connector latches on the core housings, and snapping them onto the new assembly as shown. If the cores were not present on the original assembly, they do not need to be added.





Depending on the age of the unit, it may have 2 display insulators (item 62) as shown below. The insulators were introduced on units built from mid-2019 forward to comply with 4th Edition EMC standards. If present, inspect the insulators for signs of wear or damage, and replace if necessary. If the unit did not have the insulators installed, they do not need to be added retrospectively.



Mother Board Removal

Remove the cables connected to the mother board (as shown).



Remove the UTK (Item 35) prior to PCBA removal to avoid damaging the connector.

Refer to the Item Identification Table for the correct item, as there are two versions of WAM/UTK pairs that must match (v1 to v1 or v2 to v2) for the wireless interface to operate properly. Units utilizing the v2 UTK will have a round "2" label (item #65) near the ECG input connector on the housing.



Remove screws (Item 37) from the 7 locations identified.

IMPORTANT:

When replacing a motherboard the following items will need to be accounted for:

Software Version - If the software version on the new motherboard does not match the software version being used by the customer, refer to MIS-18-189-01 for instructions on software compatibility and upgrading.

Optional Features: If any of the following optional features (WLAN, DICOM/Enterprise, Security, Late Potential, PDQ) need to be enabled on the unit contact Technical Support with the device serial number to receive an "Option Code" to enable the features. Refer to MIS-18-189-01 for instructions on using the option file to enable features.

Unit Serial Number – The replacement motherboard will be shipped from the factory with a "generic" service serial number, which can be changed to the correct serial number by utilizing the service tool located in the Advanced Menu, Service Settings feature set.

Cue Sensor Calibration – The cue sensor will need to be recalibrated when replacing a motherboard. The automatic cue sensor calibration utility is located in the Advanced Menu, Service Settings feature set.

Power Supply Board Removal

Remove the power cable connected to the power supply board.



Remove the AC inlet bracket (Item 34) by removing the 2 screws (Item 33) from the lower housing with an M2 Allen wrench





Remove the 2 longer screws (Item 26) from the power supply board. Remove the remaining 3 screws (Item 37) from the PCBA.



Battery Connector Board and Retainer Removal

Remove the battery cable screws (Item 6) from the battery connector PCBA.





Remove the 3 screws (Item 14) from the battery connector PCBA (as shown), then remove the battery connector retainer (Item 7) by pulling it straight up from the housing.

Remove the battery connector board (Item 8) by pulling it straight up from the lower housing.



Speaker and Battery Wire Removal

Cut the cable tie (Item 16) from the cable tie mount (Item 40) and gently pry the speaker from the lower housing.

Adhesive kit (Item 31) will be needed during reassembly if the speaker assembly is removed.



Item Identification, Table 1

The items listed in Item Identification, Table 1 identify the serviceable level of the device. Subcomponents of assemblies listed are not available as individual service items from Welch Allyn. The assembly level item must be used for servicing purposes.

Item #	General Description	Part Number	Picture
1a	LOWER HOUSING (Black)	8365-002-50	
1b	LOWER HOUSING (Cool Gray)	8365-002-70	
2	FOOT	6320-003	
	LCD BUMPER ELI 350	8351-029-50	
3	LABEL ELI 380 NAMEPLATE	9050-094-01	CONSISTENT INSTRUMENT MIGHAE RUNA LABO ELGADO ELG
	LABEL ELI 380 NAMEPLATE INMETRO	9050-094-02	Image: State Stat
4	BATTERY	4800-017	
5a	BATTERY DOOR (Black)	8365-007-50	
5b	BATTERY DOOR (Cool Gray)	8365-007-70	

Item #	General Description	Part Number	Picture
6	CABLE ASSEMBLY BATTERY CONNECTOR TO MOTHERBOARD	25020-080-50	
7	BATTERY PCBA RETAINER	8365-008-50	
8	BATTERY CONNECTOR PCBA	26025-128-150	
9	FOLLOW INSTRUCTIONS FOR USE LABEL	9042-084-01	63
10a	STANDARD DISPLAY ASSEMBLY (ELI380-Axxxx model only) Recommended Service Replacement	8365-024-50	
10b	ERGO DISPLAY ASSEMBLY (Touchscreen) (ELI380-Dxxxx model only) Recommended Service Replacement	8365-051-70	
11	BRACKET ASSEMBLY MONITOR MOUNT - FOR STANDARD DISPLAY (ELI380-Axxxx model only)	8351-019-60	
12a	CABLE ASSEMBLY ELI 380 LCD TO MOTHERBOARD Previously used on models ELI380 Axxxx	25018-042-60 (No longer used, consolidated materials to use only item # 25018-042-70 shown below as 12b)	
12b	CABLE ASSEMBLY ELI 380 ERGO LCD TO MOTHERBOARD	25018-042-70	

13a	DUAL BAND ANTENNA	3600-015	
13b	Laird WLAN Antenna (2 connectors)	411590	
13c	Laird WLAN Antenna (1 connector)	413214	
14	SCREW THD-FORM PANHEAD TORX 3/8"	6020-062	

Item #	General Description	Part Number	Picture
15	SCREW M4x0.7x8MM PHILLIPS PANHEAD	6020-006-02	
16	CABLE TIE 3.9"	7495-001	
17	CABLE ASSEMBLY AC CONNECTOR TO MOTHERBOARD	25020-081-50	
18	CABLE ASSEMBLY KEYBOARD TO MOTHERBOARD	25020-082-60	
19a	ELI380 ERGO MOTHERBOARD PCB ASSEMBLY	SERV 26025-126-152	
19b	ELI380 ERGO MOTHERBOARD ASSY W/B&B WIRELESS LAN	S26025-126-152-WLA (top picture)	
19c	ELI 380 STS MOTHRBOARD W/Laird WIRELSS LAN 4th	S26025-126-410-WLA (bottom picture)	
20a	MODULE B&B-N AIRBORNE SPI WLAN RED Model: WLNN-SPMR551	9910-023-06	
20b	WLAN MODULE – LAIRD Model: WB45NBT (RADIO CARD,NEWMAR, 380 PROVISIONED)	413243	

21	POWER SUPPLY PCB ASSEMBLY	26025-123-151	
22a	LABEL, WLAN B&B Electronics	9050-059-12	B&B 9373 E E R-C-BVT-9373 E FCC ID: F4AWLNN551 E IC ID: 3913A-WLNN551 CNC ID: C-22663
22b	LABEL, WLAN LAIRD	413242	LAIRD WB45NBT FCC ID: SOGWB45NBT IC ID: 3147A-WB45NBT CNC ID: C-21740
23	WRITER ASSEMBLY ELI280/ELI380 - NO LABEL	22500-280-50	E Contraction of the second se

Item #	General Description	Part Number	Picture
24	WRITER LABEL	9042-078-01	
25	A4/Smart PAPER SPACER	8342-007-02	
26	SCREW PANHEAD TORX M3 X 8	6020-835-02	annun an
28	HOUSING HINGE COVER	8351-003-51	
29	HOUSING REAR COVER	8365-004-50	
31	 ADHESIVE KIT ELI380 Must be ordered when replacing the display, speaker or antenna. 	8365-011-50	
32	PLUG ELASTOMERIC REAR COVER	8351-023-51	
33	SCREW FLAT HEAD ALLEN M3x10	6020-010-02	3
34	AC INLET BRACKET	8365-017-50	
35a	UTK w/Software v1.x	26025-092-151	
35b	UTK w/Software v2.x	26025-092-404	

Item #	General Description	Part Number	Picture
36	LABEL, UTK	9050-059-07	Internal Radio Model: UTK FCC ID: HJR-UTK2500 IC: 37598-UTK2500 This device camples with part 16 of the FCC rules. Operation is subject to the following two candities: 1) This device may not cause harmful interformese, and 2) This device most accept any Interformere received including interference that may cause undesired operation.
37	SCREW PANHEAD TORX M3x6	6020-430-03	
38	SCREW PHILLIPS PANHEAD M3x10	6020-930	(PD)
39	SPEAKER ASSEMBLY	25020-053-50	
40	CABLE TIE MOUNT	7495-008	
41	UPPER HOUSING ASSEMBLY ENGLISH ELI380	8365-001-50	
41	UPPER HOUSING ASSEMBLY RUSSIAN ELI380	8365-001-60	*Not actual item, for reference only
60	Laird WLAN Antenna Cable	728306	

61	Foam pad with dual adhesive (Laird WLAN Antenna mount)	728803	0.500 REF
			1.500
62	INSULATOR BRACKET MONITOR MOUNT	729157	
63	FERRITE CORE SNAP ON	1420-019	
64	SCREW, M2 X 6 INTERNAL TOOTH SEMS PHP	721455	
65	v2 UTK Label for Cardiographs	728940	2
66	WRAP CABLE BRAIDED SPLIT 1/2 DIA WT	4175-022-01	
67	HEAT SHRINK TUBING	729248	

NOTE: Items 42 – 59 are only compatible with the STS Touchscreen, model ELI380-Dxxxx				
Item #	General Description	Part Number	Picture	
42	INSULATOR LVDS FORMEX ELI 380 ERGO	8365-030-70	P.	
43	COVER HINGE PLATE BASE ELI 380 ERGO	8365-031-70	0	
44	COVER SET HINGE FRONT ELI 380 ERGO	8365-032-70		
45	COVER SCREW ELI 380 ERGO	8365-033-70	000	
46	COVER LCD HINGE ELI 380 ERGO	8365-042-70		
47	COVER REAR ELI 380 ERGO	8365-043-70		
48	COVER REAR CENTER ELI 380 ERGO	8365-044-70	-	
49	COVER HINGE ELI 380 ERGO	8365-045-70		

Item #	General Description	Part Number	Picture
50	COVER HINGE SHUTTER ELI 380 ERGO	8365-046-70	
51	PIVOT BLOCK RIGHT ELI 380 ERGO	8365-047-70	60
52	PIVOT BLOCK LEFT ELI 380 ERGO	8365-048-70	
53	PIVOT HORIZONTAL ELI 380 ERGO	8365-049-70	
54	PIVOT AXLE ELI 380 ERGO	8365-050-70	
55	Monitor hinge mount	8365-019-70	
56	M4x8 SCREW FLAT HD PHIL BLK OXIDE COATED	6020-732-01	and a statement
57	Hinge	6422-010	
58	M4 x 70 PAN HD PHILLIPS	6020-070-01	
59	M3 X 30 PAN HD PHIL	6020-045-01	

Thermal Writer Disassembly





Special Instructions

- This assembly procedure describes the use of Vibra-Tite on some threaded parts. The Vibra-Tite must dry for a minimum of 10 minutes before assembly. The Vibra-Tite may be applied to the threaded pieces ahead of time and allowed to dry. This way the parts will be available for assembly when needed. If the parts already have Vibra-Tite, this process can be skipped.
- Before applying all adhesive backed materials, clean surface with alcohol to make sure it is clean and oil free.
- Torque specifications for all fastening devices shall be 3.5-4.0 lbs-in, unless otherwise noted.

NOTE: Item numbers in this section refer to the parts in Table 2 unless stated differently.

NOTE: The writer assembly can be obtained as a complete assembly for service purposes, or a specific part or subassembly can be obtained to repair a specific writer related issue. The entire writer door (Item 23, Table 1) with the platen roller, latch assembly, and instruction label attached is available as an assembly; and the thermal print head, print head mount, anti-static brush, and associated cables are also available as an assembly (see Table 2).

To remove the writer door assembly, both the door latch assembly and print head assembly must be removed to allow the writer door full travel to reach the insertion/removal slots provided.

To remove the latch assembly, open the writer door, then turn the writer over and remove the 4 screws (17) shown. There are 2 Pivot Bar Restraining Plates (22) under the screws.



Remove the Latch Release (20), Pivot Bar (19), and the spring (21).





The picture shows the writer assembly with the latch removed.



On the other end of the writer assembly, the print head assembly must be removed from its installed position. This is done by removing the O-Ring that holds the assembly in place (underside of area circled) and unlatching the spring bar retaining clips as shown below.



Once the print head assembly is removed from its installed position, the writer door assembly can be removed by sliding it past the "closed" position until the removal/install slots are aligned. The door assembly is then lifted in an upward direction.



To remove the platen from the cover, loosen set screw (Item 9) from the pinion (Item 10).



Remove the E-Ring (Item 7) as shown.



Remove the following items from the platen.

- 1. Ball bearing (Item 3)
- 2. Small spacer (Item 4)
- 3. Ball bearing (Item 3)
- 4. Wave washer (Item 5)
- 5. Large spacer (Item 6)



Remove the E-Ring (Item 7) as shown.



Remove the following from the shorter side of the platen.

- 1. Ball bearing (Item 3)
- 2. Small spacer (Item 4)
- 3. Ball bearing (Item 3)
- 4. Small spacer (Item 4)



Gearbox and Motor



Turn the paper tray over and remove the 3 screws (18) to release the gearbox assembly.

Remove the stepper motor from the gearbox (Item 16) by removing 2 screws (17).



Remove the set screw (9), to remove the stepper motor (15).



Cue Sensor Replacement

14

Remove the cue sensor cable (Item 14) from the cue sensor PCB (11) located on the paper tray.

Two of the 4 plastic posts (A) that hold the cue sensor onto the paper tray (12) have a cyanoacrylate adhesive applied to hold it in place. Use a side cutter to flush cut the two posts with the adhesive to remove the cue sensor PCB (11) from the paper tray (use the two remaining posts to fasten the replacement item).



Print Head Replacement

Remove the print head cables (25 & 26).



To remove the print head from the print head mount (Item 27 above) remove the two shoulder screws (Item 28) and coated screw (Item 18). Remove ground wire (Item 29) with bare screw (Item 30) as shown.



When reinstalling the print head assembly, create a loop with the ground wire to allow it to move freely within the provided slot.



ELI 380 Writer A4/Smart paper Spacer

If A4/Smart paper spacer is part of configuration, install A4/Smart paper spacer (Item 25, Table 1) into paper tray as shown. Snap into place.


Item Identification, Table 2

Items highlighted in grey listed in the Item Identification, Table 2 identify the serviceable level of the device. Subcomponents of assemblies listed are not available as individual service items from Welch Allyn. The assembly level item must be used for servicing purposes.

	Thermal Writer			
Item #	General Description	Part Number	Picture	
1	Platen	6570-842-02		
2	Paper Tray Cover	8342-003-51		
3	Ball Bearing	6520-003	00	
4	Small Spacer	6125-017	00	
5	Wave Washer	6100-004	0	
6	Large Spacer	6125-004	0 4	

	Thermal Writer			
Item #	General Description	Part Number	Picture	
7	E-Ring	6140-003	C.	
8	Vibra-Tite	7403-001		
9	Setscrew M2.5 x 4mm	6030-025		
10	Pinion (Spur w/ Hub)	8342-009-01	The second second	
11	Cue Sensor PCB	26025-045-151		
12	Paper Tray	8342-005-51		

	Thermal Writer				
Item #	General Description	Part Number	Picture		
13	Cyanoacrylate Adhesive	9326-002			
14	Cable Assembly for Cue Sensor	25020-066-50			
15	Stepper Motor	6545-008-01	A Contraction of the second seco		
16	Gear Box Assembly	8342-004-53			
17	Screw Flathead Torx	6020-735-02			
18	Panhead Torx Screw Coated	6020-835-02	and the second sec		
19	Release Pivot Bar	8342-018-01			

	Thermal Writer			
Item #	General Description	Part Number	Picture	
20	Release Latch	8342-008-02		
21	Spring, Compression	8342-019-01	000000	
22	Pivot Bar Plate	8342-020-01		
23	Printhead	5450-004		
24	Anti-Static Brush	7480-090		
25	Cable Assembly Black, print head to PCB	25018-041-50		
26	Cable Assembly Black, print head to PCB	25018-034-50		
27	Printhead Mount	8342-006-03		
28	Shoulder Screw	6001-002-01	S	
29	Ground Wire	25020-058-50		

	Thermal Writer			
Item #	General Description	Part Number	Picture	
30	Panhead Screw Bare Metal Torx	6020-835		
31	O-Ring	<u>6141-003</u>	0	
32	Retention Clip	8342-025-50	60	
33	Spring Bar	8342-017-01		
34	User Instruction Label	9042-078-01		
35	8" WRITER LID ASSEMBLY - ELI280/380 NO LABEL	SERV-ASSY-181- 02		
36	ELI 280/350/380 PRINTHEAD ASSY BLACK	41000-028-54		
37	A4/Smart paper spacer	8342-007-02		

ERGO VERSION Display Disassembly

This section describes the methods used to disassemble and repair the ELI 380 ERGO display and the tools required to perform the defined steps.

Cautions and Special Instructions



CAUTION: Risk of Explosion.

DO NOT SHORT battery terminals. Leave the protective covers on the battery terminals until assembly into the base unit.



CAUTION: Risk of Shock.

Line voltage may be present on the power supply of the device. Use caution when the device housing is removed and AC power is applied.



ATTENTION: PCB assembly contains ESD sensitive devices. Use appropriate precaution when handling electronic assemblies.



ATTENTION: PCB assembly contains mechanically sensitive electrical devices. Handle with extreme care to reduce the stress on solder connections.



ATTENTION: Before applying all adhesive backed materials, clean surface with alcohol to make sure it is clean and oil free.

Tools Required

- Phillips Screwdriver
- Needle Nose Pliers
- Tweezers
- Side Cutters
- Scraper

Display Disassembly

Note: Depending on the age of the ELI380 unit, the LCD cables may utilize either a braided cable wrap (item 66) or heat shrink tubing (item 67) to protect the LCD cables as they pass through the LCD bracket and hinge assembly. The heat shrink tubing was added at a later date to achieve 4th edition compliance for the device.

Remove the 4 screw covers from the hinge and axels.



Remove the 2 screws from the LCD hinge.



Remove the hinge axel and hinge cover screws from each side of the display as shown below.



Remove the LCD hinge cover.





Remove the hinge shutter as shown right.



Remove the rear hinge cover vertically.



Remove the M4x70 screw from the pivot blocks, then remove the pivot blocks (one from each side).

Rotate the screen 90 degrees from user side to remove hinge base sticker. Repeat for other side.





Remove Silicon Plug from the Rear Housing location.



Remove the screw from the center rear cover.



Remove the screw used as the horizontal hinge stop



Rotate the screen so that it is facing away from the user side, then remove the rear cover.



Cable Removal

ATTENTION: Routing and retention of the cabling is required to ensure proper function and electrical safety of the device.

Remove the cable tie from the cable mount on the side of the bracket.



Disconnect all 4 cables from the mainboard. All of the connectors should be removed via the plastic portion of the connector, do NOT attempt to pull them loose from the wires.



ATTENTION: The monitor must be supported as it is being removed from the base.

Remove the 4 screws from the hinge, removing it from the metal bracket.



Unthread the cables back through the bracket and hinge.





Once the cables are out of the way. Remove the 4 screws from the hinge and hinge cover set.

LCD Cable Replacement

If the LCD cables require replacement, remove the LCD back housing by removing the screw hole caps, and screws as shown below.



Once the housing screws are removed, clip the cable ties holding the white cables and the LVDS cable as needed.





Remove the Acrylic tape (7401-005) holding the cables to the LCD assembly if replacing the associated cable.

 Backlight Cable – 25020-079-70
 Touch Controller Cable – 25020-088-70

 LCD Data Cable – 25018-042-70
 Tilt Switch Cable – 25020-083-70

Braided Loom Process – Item 66 (refer to following Heat Shrink Process if the unit utilized item 67)

Reassemble in reverse order, covering the combined cables with the 6.5" piece of braided loom, which must be bundled smoothly to fir back through the hinge bracket.



Thread the white display cables through first, and then thread the LVDS cable. You may have to twist the loom to fit it through hinge. If you do, straighten it out before continuing. The loom should be tight inside the hinge and should not move easily.



Pull the braided loom past the hinge screws as shown below.



Close the screen, press the cables to make sure it touches the back of the LCD screen. This ensures it has enough slack to open/close the LCD screen.

Also, ensure it is tight enough to limit the lateral movement of the cables, as shown in the following two pictures.





Lateral movement Check



Once verified correct, tighten two cable ties (item #7495-001) to the braided loom in opposite direction to limit its vertical movement.



Heat Shrink Process – Item 67 (refer to Braided Loom Process if the unit utilized item 66)

Bundle the cables together and thread them through the Heat Shrink Tubing (item 67)

NOTE: If needed, fold the LVDS and white display cable's plug and tie them together using ESD tape.

Push the Heat Shrink Tubing upward until it is touching the LCD back cover as shown.

Using a heat shrink gun, apply heat on the heat shrink tubing to snugly wrap the cables.

NOTE: Ensure the heat is not directly applied to the cables and the LCD back cover.

Verify the heat shrink tubing is shrunk adequately round and there is no damage to the cables and LCD back cover due to heat.

As shown, thread the Heat Shrink Tubing with cables through the hinge.

Close the screen, press the Heat Shrink Tubing with cables to make sure it touches the back of the LCD screen. This ensures it has enough slack to open/close the LCD screen.

Tighten two cable ties on the Heat Shrink Tubing in opposite direction with a cable tie tool to limit its vertical movement.

WLAN Antenna Removal

Remove the cable tie mount from the side of the bracket.

Remove the formex insulator, be sure to clean any residue left over by the formex insulator.

Disconnect the WLAN antenna from ANT2 on the WLAN module. Then remove the WLAN antenna from the metal bracket. Lastly, remove the adhesive kit from the metal bracket (pictures show the B&B WLAN antenna, use similar removal process for the Laird WLAN antenna, items 13b and 61).

Conformance Testing

Conformance testing is to be performed by Authorized Welch Allyn Service Representatives to verify the device is functioning correctly after repair operations have been performed. Testing results should be documented on the test data record (TDR) at the end of this section of the manual. Include the following

printouts: Configuration page, Writer Test, ECG, and Noise Test.

Power Testing

Ensure there is no power connected to the ELI 380 AC inlet until test states to run on AC Power.

Access Settings

- 6. Select the Settings icon in the upper right corner of the main screen
- 7. Select **Advanced** in upper right.
- 8. Type **admin** when prompted for password.
- 9. Select Service.
- 10. Select Battery Info.

Battery Voltage

Document the battery voltage as shown in battery information.

State of Charge

Document the present state of charge of the battery given in percent form.

Charge Cycles

Document the amount of charge cycles the battery has been charged.

Charging

Document the message displayed (Yes, No, or Fault).

Avg. Current ("On" current)

Document the average current as shown in battery information.

Battery Health

Document the health of the battery in percent form. (Recommend replacement when under 70%; the ELI 380 will notify user when lower than 70%.)

Running on DC & AC power (connect AC power cord)

- Verify AC power LED indicator illuminates (located above power button). Record Results on the TDR
- Verify AVG Current value gradually changes from negative to positive (the value will remain at 0 if the battery is fully charged). Record Results on the TDR
- Verify Charging is Yes (if current is flowing to battery). Record Results on the TDR

Repeat Power Testing for Battery #2 if installed.

Battery Performance Information

- 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.
- 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.

Functional Testing

MAIN SCREEN:

- The MAIN SCREEN is displayed when the unit is first turned on.
- The LCD will timeout and go dark if there is no ECG or user input. Touch the touchpad to re-activate.

SERVICE SCREEN:

- To access the SERVICE SCREEN begin at the MAIN SCREEN.
- Press
- Press **ADVANCED**, then enter the Admin password.
- Press SERVICE.

CONFIGURATION SCREEN:

- To access the CONFIGURATION SCREEN begin at the MAIN SCREEN.
- Press
- Press **ADVANCED**, then enter Admin password.

Display and Standby Mode

- Press the ON button and verify the text on display is clear and legible and there are no flickering or missing lines/pixels. Record Results on the TDR
- Close (tilt) the LCD Display towards the writer. After a few seconds verify the LCD backlight turns off. Open the LCD Display and verify the unit comes out of the standby mode returning to the MAIN SCREEN. Record Results on the TDR
- The following procedure applies to the ERGO variant:
 - 1. Rotate the screen 90 degrees away from the front user face to the right and verify that the LCD backlight is on with no flickering or missing lines/pixels. Record Results on the TDR
 - 2. Rotate the screen 90 degrees away from the front user face to the left and verify that the LCD backlight is on with no flickering or missing lines/pixels. Record the Results on the TDR
 - 3. Tilt the display out until a mechanical stop is reached. Verify the stop is reached at 120 degrees. Record Results on the TDR

Auto Test

• From the Service Screen, select **Auto Test**. Verify the auto test completes one cycle without an error. The Auto Test function tests the ELI 380's ability to read and write an ECG file to the flash memory in the unit. Record Results on the TDR

Writer Test

- Open and close the writer door to verify smooth operation. Verify that the door unlatches without sticking and that it latches completely.
- From the Service Screen, select **Writer Test**. Verify that a test page is printed and the writer stops on the cue mark. The perforation of the paper should line up with the tear edge on the writer. Assure there are no gaps in the printing and the print darkness is uniform across the entire page (see example).
- Verify the writer gears do not skip and paper is tracking properly (you may need to print multiple pages to observe this).
- Record Results on the TDR

ECG Test

- Connect an ECG simulator to the AM12, AM15E or WAM patient interface. Set the simulator to a known heart rate and amplitude; preferably to a setting that you have a "known good" printout for comparison.
- From the Main Screen, select the patient info icon
- Enter "TESTECG" into the last name field and select the next icon.
- From the Main Screen, select **ECG**.
- Review results and then select **PRINT**.
- Verify that 12 or 15 ECG traces print with clarity and assess the overall printout quality. Ensure uniform darkness across entire printout.
- Record Results on the TDR

ECG Noise Test

- Connect a Shorting Block (TF-00629) and adapter or equivalent to the AM12, AM15E or WAM patient interface.
- Set the ECG gain on the unit to 20mm/mV.
- Print a rhythm strip (approx. 1 page). Verify that no channels have more than 0.5mm of noise as measured by using Welch Allyn thermal paper. (Smallest grid line = 1mm)
- Record Results on the TDR

Communication Options Testing (as applicable)

The receiving station for modem, LAN and WLAN transmissions should be running Welch Allyn ELI-Link software. Refer to the ELI-Link user manual for proper configuration.

Verify successful transmission of all applicable communication options by acquiring ECG records that include the transmission method in the "Patient Name" field (such as Last Name = USBD) then subsequently transmitting the ECG record stored to a compatible receiving device. Consult the product user manual if needed to properly configure the communication settings for each option present on the unit under test.

Successful transmission of the test records can be verified by viewing the ECG records in the unit directory after transmission and confirming they are marked as "transmitted" (as defined in the product user manual). Record Results on the TDR

- USB host (USB memory device needed)
- LAN
- WLAN

Safety Testing

If the cardiograph housing was opened for repair or inspection work, the following safety tests should be performed in accordance with the IEC 60601-1 or IEC 62353 methods and limits.

The ELI380 is considered a Class 1 Type CF device, intended to only be utilized with the Welch Allyn AM12 or WAM patient input modules. Defibrillation isolation from the patient is provided by the patient input modules, which are tested separately as part of the manufacturing process (they are considered non-serviceable devices), therefore Hi-pot testing is not required for the ELI380 cardiograph.

- Earth Leakage
- Enclosure Leakage

Non-conductive (fully insulated) chassis testing should be performed utilizing 200 cm2 conductive foil or equivalent, earth ground on AC input is utilized for functional earth (not safety grounding).

- Patient Leakage Applied part – patient input (utilize Mortara AM12 patient cable)
- Patient Auxiliary Current Applied part – patient input (utilize Mortara AM12 patient cable)

ELI 380 Conformance Test Data Record

Unit Serial #:

Power Testing

Battery 1 – Installed?
Yes No (if No, skip Battery 1 section)

Running on DC power only (disconnect AC power cord)

Battery Voltage	V			
State Of Charge	%			
Charge Cycles				
Verify Charging is No				
On Current (Displayed a (Negative reading when on DC	as Avg. Current	t)A (max draw = 1.6A)		
Battery Health	%	(Recommend replacement when under 70%.)		
Running on DC & AC power (o	connect AC por	wer cord)		
 Verify AC power LED One) Verify AVG Current v at 0 if the battery is fu Verify Charging is Ye 	 Verify AC power LED indicator illuminates (located above power button). Pass / Fail (Circl One) Verify AVG Current value gradually changes from negative to positive (the value will rema at 0 if the battery is fully charged). Pass / Fail (Circle One) Verify Charging is Yes (if current is flowing to battery). Pass / Fail (Circle One) 			
Battery 2 – Installed?	No (if No, skip	Battery 2 section)		
Running on DC power only (di	sconnect AC p	ower cord)		
Battery Voltage	V			
State Of Charge	%			
Charge Cycles				
Verify Charging is No				
On Current (Displayed a (Negative reading when on DO	as Avg. Current C)	t)A (max draw = 1.6A)		
Battery Health	%	(Recommend replacement when under 70%.)		

Running on DC & AC power (connect AC power cord)

- Verify AC power LED indicator illuminates (located above power button). Pass / Fail (Circle One)
- Verify AVG Current value gradually changes from negative to positive (the value will remain at 0 if the battery is fully charged). Pass / Fail (Circle One)
- Verify Charging is Yes (if current is flowing to battery). Pass / Fail (Circle One)

Functional Testing

- Display Functionality Pass / Fail (Circle One)
- Tilt Switch Operation Pass / Fail (Circle One)
- Ergo Variant Test 1. Pass / Fail / NA (Circle One)
- Ergo Variant Test 2. Pass / Fail / NA (Circle One)
- Ergo Variant Test 3. Pass / Fail / NA (Circle One)
- Auto Test
 Pass / Fail (Circle One)
- Writer Test
 Pass / Fail (Circle One)
- ECG Test
 Pass / Fail (Circle One)
- ECG Noise Test
 Pass / Fail (Circle One)
- Communication Option(s)
 - USB host Pass / Fail / NA (Circle One)
 - LAN Pass / Fail / NA (Circle One)
 - WLAN Pass / Fail / NA (Circle One)

Safety Testing PASS FAIL (check one)

- Earth Leakage
- Enclosure Leakage
- Patient Leakage
- Patient Auxiliary Current

Performed by:

Date:

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 AM12, AM15E 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 30 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;	Lead fail.	Ensure lead and electrode connection is secure.
SQUARE WAVES ON DISPLAY.		Replace faulty electrode patches or lead wires if necessary. Consider patient prep steps.
"LEADS OFF" OR "SEARCHING FOR WAM" MESSAGE	WAM, AM12 or AM15E 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. Replace the battery.
		AM12/AM15E: Reconnect the module or power cycle the ELI 380.
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.
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.
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
All	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). Remove all portable electronic devices from the vicinity of the patient / ELI380.
		implanted muscle stimulator.
		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.
	Directory is full	Erase records. Check Delete rule.

Transmission Troubleshooting Chart

LCD Message	Problem	Correction
TRANSMIT FAILED	Unable to transmit ECG.	Ensure site number is valid. Retry. Verify ELI Link service is running.
		Obtain network log files via service utility "Dump Log Files" to diagnose network transmission issue.
ERROR-DICOM Not Enabled	A DICOM communication was attempted, but the unit is not configured for DICOM.	Configure the unit to DICOM and reboot.
UNABLE TO SAVE ECG	No available memory.	Transmit or erase records in the directory.
	ECG data too noisy to store.	Correct noise and try acquisition/storage again.
DHCP FAILURE	The WLAN module failed to get an address from DHCP.	Contact your Networking/IT to see if MAC authentication is required. Verify the request is getting to the DHCP server.
		Contact Welch Allyn Technical Service.
DPAC FAILURE	WLAN failed to initialize.	Contact Welch Allyn Technical Service.
CAN'T CONNECT TO ACCESS POINT	A link to the access point could not be established.	Ensure the IP address, security type, SSID and password are correct.
		If problem persists, contact Welch Allyn Technical Service.

		TROUBLESHOOTING
LCD Message	Problem	Correction
CAN'T CONNECT TO REMOTE LINK	A link to the access point was established, but the link to the destination failed.	Ensure the Sync IP address and port number are correct. Verify ELI Link service is running.
		If problem persists, contact Welch Allyn Technical Service.
TIME SYNC FAULT	Possible incorrect version of ELI Link	Install latest version. Verify ELI Link is running.
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.
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. Reset queue sensor in the Service
		menu.
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 or switch vs. crossover cable.
Disabled	Pressing SYNC key	Enable SYNC MODE and/or set SYNC MEDIA in configuration

Signal Strength Indicator

The signal strength indicator presentation was changed in software v2.4.2 and later, the signal strength table below defines the signal strength actual values.

Note: During any communication to the ELI Link server, the signal strength indicator does not get updated. It will resume regular updates once the communication has completed. This behavior is consistent with all ELI380 software versions (v2.4.2 and prior).

	Prior to v2.4.2	v2.4.2 and Later	
5 bars	-50 or higher	-65 or higher	
4 bars	-50 to -60	-65 to -70	
3 bars	-60 to -70	-70 to -75	
2 bars -70 to -80		-75 to -80	
1 bar < -80 < -80			
Values are in dBm			

Grayed out bars with a line through them signifies the device could not authenticate with an access point.

No image on the display indicates the WLAN module is not responding to commands.

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.	Ensure that AC power cord is not damaged and is firmly connected to AC power connector on rear of electrocardiograph. The green LED next to the power button is lit when AC is correctly connected. Ensure that electrocardiograph is plugged into grounded electrical outlet. 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 Welch Allyn Technical Support.
	Electrocardiograph is in Standby Mode	Press the On/Standby button to return to active use.
	Electrocardiograph will not power on.	Disconnect the AC power cable from the wall outlet and depress the On/Off button for >30 seconds. Plug AC power cord into wall outlet and follow the instructions on the display. If problem persists, contact Welch Allyn Technical Support.
	The screen does not turn on when the lid is lifted.	Press the power button once. If the Welch Allyn logo does not come on within 10 seconds, press and hold the power button for >30 seconds.

Printer Troubleshooting Chart

The paper will have part number 9100-026-52 or 9100-026-55 and Welch Allyn at the bottom of each page.

Printer problems can come from using incorrect paper, using old paper or not storing paper in a humidity controlled room. Stacking the paper too high can compress the bottom packages causing the pages to stick together.

With any printer problem, first take the paper out of the tray and fan it to see if the pages are sticking together. Replace the paper and test.

LCD message	Problem	Correction
Paper Queue Fault	Paper does not advance	Verify it is the correct paper. Verify paper is properly loaded with the cueing mark in the lower left corner.
		Open the paper door, remove the paper and make sure there are no sheets of cardboard under the paper.
		Pull ½ sheet of paper out and securely close the door. You should hear a loud click. Press RHY and press Done after a couple seconds. Paper should advance to the end of the page and stop.
	Paper advances less than one inch or more than one page and stops.	Open the paper door and bring ½ sheet of paper out and close the door. From the main screen press the gears icon then Advanced, enter password, the default is admin. Press Service, press Calibrate Cue. Press Done, press Home, press RHY and press stop after a couple seconds. Paper should advance to the end of the page and stop.
LCD message	Problem	Correction
----------------	--	--
Grinding noise	Paper does not advance and there is a grinding noise	Make sure you are using the correct Welch Allyn paper.
		Open the paper door and remove the paper to make sure there is no cardboard at the bottom of the paper.
		Inspect the paper tray to see if there is any broken plastic.
		Bring out ½ sheet of paper and close the door completely. Go into the Service menu and press Writer Test. If the paper does not advance and it is grinding, press on the lower right corner of the paper door. If the noise goes away, there is broken plastic someplace of the gearbox is out of alignment.
	Paper comes out crooked or has lines missing	Verify correct Welch Allyn paper.
		Clean the print head with an alcohol wipe and let dry before testing.

Patient Cable Troubleshooting Chart

Testing patient cable	Problem	Correction
	Excess artifact	Verify they are using Welch Allyn electrodes
		Pull the clips off the end of all lead wires, visually inspect the banana plug for corrosion, push the clips back on the lead wires. Inspect the metal part of the clip that comes in contact with the electrode for contamination or corrosion. Clean or replace if needed.
		Inspect the lead wires for cracks in the wires.
		Unplug the lead wires from the AM12/AM15E/WAM and push them back in again.
		Attach a simulator and view waveforms on the screen for artifact. If artifact is present, test the unit using another AM12/AM15E/WAM. If artifact is still present, contact Welch Allyn Technical Support.
		If no artifact on the simulator, turn off the simulator and gently bend all wires

Testing patient cable	Problem	Correction		
		while watching the screen for artifact. If you see artifact, replace one or all of the lead wires.		
AM12/AM15E	The sweep square is not going across the screen but the time is advancing.	Plug the AM12/AM15E into socket marked ECG.		
	No tracings on screen or gaps in the tracings. Screen shows Leads Off	The cable between the AM12/AM15E module and the ELI 380 may have a broken wire. Move the wire around starting at the AM12/AM15E module all the way to the plug going into the ELI 380. If tracing appear the cable is bad. This cable is a user replaceable part.		
		Contact Welch Allyn Technical Support to verify warranty status, part number and procedure to replace the		
	Screen shows Searching for WAM	Change setting to use the AM-XX. Select the gears icon , select WAM/AM-XX, Select Switch To AM- XX, select Done, press home.		
WAM	No tracings – screen displays Searching for WAM	Make sure you are within range of the WAM.		
		Inspect the battery cap for signs of damage.		
		Press the power button on the WAM.		
		Change the battery checking the battery compartment for signs of corrosion.		
		Make sure you have the correct WAM for the unit.		
		Pair the WAM. Press the gears icon, Select WAM/AM-XX, select WAM Pairing and follow the prompts.		
	LCD displays WAM low battery	Change the AA battery in the WAM.		

SPECIAL FUNCTIONS

To access the ELI 380 Configuration/Service functions, select **Advanced** for extended settings. Extended settings are password protected; the factory password is "admin". Select **Service** for extended settings and service functions.

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

Configuration Settings

Standard settings include: About, Custom ID, Date/Time, WAM/AM-XX, Network, Print, Options Code, and Advanced.

About

The About screen displays information about the ELI 380 including the serial number, software version, DICOM capabilities, WLAN capabilities, and LAN and WLAN MAC addresses.

Custom ID

Selecting Custom ID will start a Custom ID download. Simultaneously, the query codes will be downloaded. During the custom ID download process, the status will be displayed and updated. The custom ID downloaded will correlate with the custom IDs created in ELI Link. On the Custom ID screen, there is a *Cancel* button that will cause the ELI 380 to abort the custom ID download.

Date/Time

Date/Time screen displays the current date, time, time zone, daylight savings, daylight saving start, and daylight saving end settings. Any of these fields can be edited by selecting the item. The Sync Date/Time button will allow the ELI 380 to sync the date/time regardless of the Sync setting. The *Cancel* found on the Date/Time screen will discard any changes made and exit the Date/Time screen. The *Done* button will save any changes made and exit the Date/Time screen.

WAM/AM-XX

The WAM/AM-XX screen allows the selection of an acquisition device (WAM or AM12/AM15E). The WAM screen displays the FPGA version and UTK firmware version. When switching to WAM, there is a button to start the WAM pairing process. Instructions for WAM pairing are displayed on the screen as well as the status of the WAM pairing.

Network

The Network screen displays WLAN status, which includes the MAC address, Module F/W Version, Radio Firmware Version, Connection Status, IP Address, and Current Signal Strength. There is also a button for WLAN Test and LAN Test. Each button tests the ability to connect via LAN or WLAN. Custom ID will be downloaded during both of these tests.

Print

The Print button prints the current configuration settings.

Options Code

This button allows entry of an options code in order to modify certain options (DICOM, Security, WLAN, PDQ, or Late Potential). The serial number and LAN MAC address <u>cannot</u> be modified with an option code.

Advanced Settings

Select the **Advanced** button and enter admin password (if defined) to access advanced settings. Advanced settings include: System, ECG, Alternate Placement, LAN, WLAN, Passwords, and Service. Each of these setting screens will provide a *Cancel* button to discard any changes made and exit to the Settings screen. A *Done* button will also be provided to save any changes made and exit to the Settings screen.

All settings are explained in the user manual: 9515-189-50

System

The current system settings will be displayed and can be edited. All settings are outlined in the user manual. System settings include:

Language Volume ID Format Units for height Units for weight XMT Mandatory Fields - ID XMT Mandatory Fields - Last name XMT Mandatory Field - Tech ID Cart Number Site Number Site Name Transmitted ID Edit Disabled Communications Encryption Key File Encryption Key Auto-Sync Number of Barcode Prefix Digits Number of Barcode Postfix Digits Ignore Leading Barcode Zeros Sync XMT Sync Patients Sync MWL Sync Date/Time Patient List Comm. Protocol **ID** Edit Disable Full Disclosure Caps Lock Barcode Date Format. User Authentication Idle Log off Timeout (minutes)

ECG

The current ECG settings will be displayed and can be edited. ECG settings include:

AC Filter Filter Interp Interp Text Upper Case Reasons Critical Test Results Append Delete Rule Avg RR OTcB QTcF ECG Capture Pace Spike Channel Ecg Display Speed Ecg Print Speed # Copies Copies With Interp Cabrera Plot Format 3+1 rhythm lead 3+1 rhythm lead 1 3+1 rhythm lead 2 3+1 rhythm lead 3 Rhythm Format 3 Rhythm Lead 1 3 Rhythm Lead 2 3 Rhythm Lead 3 6 Rhythm Lead 1 6 Rhythm Lead 2 6 Rhythm Lead 3 6 Rhythm Lead 4 6 Rhythm Lead 5 6 Rhythm Lead 6 Rhythm Print Speed Delete Timeout (days) **Display Format**

Alternate Placement

The Alternate Placement screen displays the current lead placement names as well as the designated label for V1 through V6 for 3 lead sets. Any of these fields can be edited by selecting the item.

LAN

The current LAN settings will be displayed and can be edited. LAN settings include:

DHCP IP Address Def. Gateway Subnet Mask Sync IP Port Number LAN Option

WLAN

The current WLAN settings will be displayed and can be edited. WLAN settings include:

DHCP **IP** Address Subnet Mask SSID Security WEP Key (only visible for WEP64 and WEP128 Security) WEP Key ID (only visible for WEP64, WEP128 Security) PSK Passphrase (only visible for WPA-PSK and WPA2-PSK Security) FIPS (If FIPS hardware is detected the WPA-LEAP is disabled) LEAP UserName (only visible for WPA-LEAP Security) LEAP Password (only visible for WPA-LEAP Security) PEAP UserName (only visible for WPA-PEAP Security) PEAP Password (only visible for WPA-PEAP Security) TLS User Name (only visible for WPA2-EAP-TLS and WPA2-EAP-TLS (p12/pfx) Security) TLS Password (only visible for WPA2-EAP-TLS and WPA2-EAP-TLS (p12/pfx) Security) Sync IP RADIUS User Name (only visible for WPA2-EAP-TLS and WPA2-EAP-TLS (p12/pfx) Security) PEM User Name (only visible for WPA2-EAP-TLS Security) Certificates button (only visible for WPA2-EAP-TLS and WPA2-EAP-TLS (p12/pfx) Security) Import Password (only visible for WPA2-EAP-TLS (p12/pfx) Security) Port Number WLAN Option

The **Certificates** button uploads certificate files necessary for the WPA2-EAP-TLS security mode from a USB drive. This button is visible, but not functional on all other security selections.

Passwords

The Technician and Administrator password can be selected for editing by selecting the item. The password must be re-entered and must match in order for the password to change. When entering each password character, the character will be displayed and all previous characters will be displayed as an asterisk.

The administrator password grants access to Advance settings and Patient Information Screen lists. The technician password grants access only to the Patient Information Screen lists. The default administrator password for the English keyboard is **admin**. The default technician password is **blank**.

15 Leads Alt. Placement

The Alternate Placement screen displays the current lead placement names as well as the designated label for E2, E3 and E4. Any of these fields can be edited by selecting the item.

Service Settings Calibrate Cue

NOTE: Cue sensor calibration might be required when the cue sensor, writer assembly, or motherboard have been changed as a result of device servicing. Calibration is required if "Paper Queue Fault" message appears on the screen.

Important: Before selecting this function, verify that the cue mark on the paper and the cue sensor on the printer are offset. This can be done by making sure the paper is not stopped at the perforation line by opening the paper tray, pulling out ¹/₂ sheet and closing the paper tray.

Select Calibrate Cue. Select Done.

Auto Test

This button tests the ELI 380's ability to read and write an ECG file to the flash memory in the unit. The status of this test will be displayed on the Auto Test screen.

Firmware

This button searches a USB flash drive placed in the USB port on the back of the unit for ELI380.bin file and reprograms the firmware if found.

Config Files

This button searches a USB flash drive placed in the USB port on the back of the unit for ELI380Config.xml file, and replaces configuration file if found. It will also search for language files and writer font files and replace them if found.

Options File

This button searches a USB flash drive placed in the USB port on the back of the unit for the *.sno file, and replace the .sno file if found.

Dump Log Files

This button writes the following log files to a USB flash drive placed in the USB port on the back of the unit (X:\ELI380\LOG) in a .txt file format.

- LogBattery MMYYYY
- LogNetwork MMYYYY

Refer to the information at the end of this section of the manual for detailed information on the log file contents.

Dump Records

This button writes a copy of the ECG and order files on a USB flash drive placed in the USB port on the back of the unit.

SPECIAL FUNCTIONS

Erase Records

WARNING: This function will permanently erase all ECG records and orders from the device.

This button erases the ECG and order files from the ELI 380.

First Time Boot

WARNING: This function will reset the device to factory default settings. Contact Welch Allyn technical support before pressing this button.

This button enables the first time boot function. The ELI 380 is set to default configuration.

Writer Test

This button prints a test pattern on the thermal printer.

Test Config

WARNING: This function will reset the device to factory default settings. Recommend printing a configuration page before performing this test.

This button preloads a set of test configuration parameters for Operations use.

Clear Flags

WARNING: This function will remove the Print, Transmit and Delete flags (P T X) for all ECG records stored in the cardiograph.

This button clears all ECG record flags.

Fill Directory

WARNING: This function will copy and create ECG records with new names from existing ECG records in the cardiograph until the directory is full (requires at least one stored ECG to function).

This button fills the directory with records. The ELI 380 must have an ECG record in order to perform this function.

Battery Info

ELI 380 communicates with the Lithium Ion batteries' internal monitoring circuitry to acquire the batteries' status and display it on the Battery Info screen. Depending on the electrocardiograph, there can be 1 or 2 batteries in the ELI 380. The Battery Info screen displays:

Voltage

The battery's present stored voltage.

Avg Current

The amount of current flowing through the battery. When the battery is charging, the battery is drawing current from the charging source, which produces a positive value. When the battery is **<u>not</u>** charging, this value will be negative due to the unit drawing the current from the battery.

Relative State of Charge

The present state of charge of the battery given in percent form.

Battery Health

This value represents the ratio of full capacity (the amount of electrical charge capacity the battery holds at full charge) to design capacity (the amount of electrical charge capacity the battery is designed to hold). If below 70%, ELI 380 will notify user to replace battery.

Charge Cycles

The amount cycles the battery has been charged.

Charging

Message will display either Yes, No, or Fault. Yes: the battery is charging; No: the battery is not charging; Fault: there is a problem with the battery.

Enter Serial Number

This button allows the ability to modify the serial number. This screen is password protected.

USB Device

After connecting ELI 380 via a USB device to a computer, this button activates USB device mode, where user can access ELI 380 files on the computer.

Dump Config File

This button writes configuration file to a USB flash drive placed in the USB port on the back of the unit. These files can be used as a backup or used to configure another ELI380.

Network Log File Contents

The network log file contents can be used by service personnel to assist with identifying specific network connectivity issues that have been observed for a specific date/time point. The date and time of the occurrence will need to be known to locate the associated log file events recorded.

The log files are created by use of the "Dump Log Files" special function located in the ADVANCED/ SERVICE menu. When this feature is used, the log files are created on a USB flash drive placed into the USB port on the back of the unit (X:\ELI380\LOG) in a .txt file format.

- LogBattery MMYYYY
- LogNetwork MMYYYY

A text editor (such as Notepad) can be used to search the log file contents for specific keywords listed in any of the message strings presented below, or other entries containing text of FAIL or ERROR.

System startup showing firmware version and IP

Batch processor startup showing SN and MAC:

BactchProcessorTask PowerOn++++ ELI380 SN: 120110000934 WLAN MAC: 00 17 23 EF 9F E6 2020-08-05 10:18:34 ****************

ELI380 Device shutdown showing SN and MAC:

Device Shut Down ELI380 SN: 120110000934 WLAN MAC: 00 17 23 EF 9F E6 2020-08-05 10:19:38 ********

Failure to communicate to Ethernet bridge

Laird/Newmar WLAN addition (v2.4.3 software and newer):

The following additional log file content was added in software v2.4.3 and newer to further assist with the diagnosis of WLAN related issues associated with the Laird WLAN module. The examples shown below list the log file event description, followed by an example log file entry.

Laird WLAN module becomes unresponsive and a reset of the module is triggered:

Association to the access point is lost for a given period of time and a reset of the module is triggered:

2020-08-05 11:09:22 ProcessGetWLANIORead TimeElapsed from last time communicating or authenticated: 125000 ms Resetting WLAN Module ************

System not associated to an Access Point

10:18:52 RSSI 0 NOT_ASSOCIATED

System is associated to an Access Point

11:09:37 RSSI -81 ASSOCIATED

System is authenticated to an Access Point

10:18:58 RSSI -58 AUTHENTICATED

Storing configuration

883: Storing Configuration to Newmar (SetIpInfo)
11575: Storing Configuration to Newmar (SetBasicSettings - WLAN_NONE)
11575: Storing Configuration to Newmar (SetBasicSettings - WLAN_WEP64)
11575: Storing Configuration to Newmar (SetBasicSettings - WLAN_WEP128)
11575: Storing Configuration to Newmar (SetBasicSettings - WLAN_WPAPSK)
11575: Storing Configuration to Newmar (SetBasicSettings - WLAN_WPA2PSK)
11575: Storing Configuration to Newmar (SetBasicSettings - WLAN_WPA2PSK)
11575: Storing Configuration to Newmar (SetBasicSettings - WLAN_WPA2PEAP)
11575: Storing Configuration to Newmar (SetWepSettings - WLAN_WEP64)
11575: Storing Configuration to Newmar (SetPskSettings - WLAN_WEP128)
11575: Storing Configuration to Newmar (SetPskSettings - WLAN_WPA2PSK)

Failed to read from Laird WLAN module

WLanGetIORead2 start time 11:09:11 Firmware Version V2.4.3.X 2020-08-05 11:09:11 WLanGetIORead2 ERROR WLanGetIORead2: failed to create/access newmar object WLanGetIORead2: WiFi Module communication error **********

Failure to communicate to Ethernet bridge

WLanGetIORead2 start time 11:09:11 Firmware Version V2.4.3.X 2020-08-05 11:09:11 936: WLanGetIORead2 ERROR 938: WLanGetIORead2: failed to connect to Ethernet bridge 941: WLanGetIORead2: WiFi Module communication error

Laird module failed to open socket to Wireless Bridge with error code.

WLanGetIORead2 start time 11:09:11 Firmware Version V2.4.3.X 2020-08-05 11:09:11 936: WLanGetIORead2 ERROR 938: WLanGetIORead2() Failed OpenWBM! – reason: XX 941: WLanGetIORead2: WiFi Module communication error

Laird module failed to get signal with error code

WLanGetIORead2 start time 11:09:11 Firmware Version V2.4.3.X 2020-08-05 11:09:11 936: WLanGetIORead2 ERROR 938: WLanGetIORead2: failed to get signal - reason: XX 941: WLanGetIORead2: WiFi Module communication error

Laird module failed to communicate to query IP address with error code

WLanGetIORead2 start time 11:09:11 Firmware Version V2.4.3.X 2020-08-05 11:09:11 936: WLanGetIORead2 ERROR 938: WLanGetIORead2: failed to query IP Address - reason: XX 941: WLanGetIORead2: WiFi Module communication error *************

Battery Log File Contents

This button writes the battery log files to a USB flash drive placed in the USB port on the back of the unit. The battery log file creates a new entry into the file every 15 minutes when the unit is in the ON state, the log is inactive when the unit is in STAND-BY mode, or in the OFF state.

The first entry is made 15 minutes after the unit enters the ON state.

Date and Time AC Charger Voltage(mV) Full Charge Capacity(mAh) Re	elative State Of Charge(%) ****	Charger	Voltage(mV)	Full Charge Capacity(mAh)	Relative State Of Charge(%)
4/1/2015 9:18 Off	****	Off	12144	8419	95
4/1/2015 9:33 Off	****	On	12049	8419	91
4/1/2015 9:48 Off	****	Un	11952	Battery Char	ner Flag
4/1/2015 10:03 Off	****	On	11830	(will charge if	AC is ON) 84
4/1/2015 10:18 Off Battony #2	****	On	11698	(init ondigo it)	80
4/1/2015 10:33 Off Dattery #2	****	On	11579	8419	76
4/1/2015 10:48 Off	ro ****	On	11475	8419	72
4/1/2015 11:03 Off	16 ****	On	11370	8419	68
4/1/2015 11:18 Off	****	On	11255	8419	64
4/1/2015 11:33 Off	****	On	11136	8419	60
4/1/2015 11:48 Off	****	On	11013	8419	56
4/1/2015 12:03 Off	****	On	10903	8419	51
4/1/2015 12:18 Off	****	On	10801	8419	47
4/1/2015 12:33 Off	****	On	10714	8419	43
4/1/2015 12:48 Off	****	On	10631	8419	39
4/1/2015 13:03 Off	****	On	10559	8419	35
4/1/2015 13:18 Off	****	On	10479	8419	30
4/1/2015 13:33 Off	****	On	10394	8419	26
4/1/2015 13:48 Off	****	On	10288	8419	22
4/1/2015 14:03 Off	****	On	10152	8419	18
4/1/2015 14:18 Off AC Power Applied	****	On	9970	8419	13
4/1/2015 14:33 Off	****	On	9783	8419	9
4/1/2015 14:48 Off	****	On	9444	8419	5
4/3/2015 9:54 On	****	On	10513	8534	7
4/3/2015 10:09 On	****	On	10708	8534	15
4/3/2015 10:24 On	****	On	10923	8534	23
4/3/2015 10:39 On	****	On	11065	8534	31
4/3/2015 10:54 On	****	On	11210	8534	39
4/3/2015 11:09 On	****	On	11386	8534	47
4/3/2015 11:24 On	****	On	11595	8534	55
4/3/2015 11:39 On	****	On	11813	8534	63
4/3/2015 11:54 On	****	On	12013	Battery Cha	rger Flag 71
4/3/2015 12:09 On	****	On	12226	(changes to tr	ickle charge) 78
4/3/2015 12:24 On	****	On	12415	-	85
4/3/2015 12:39 On	****	On	12477	8534	90
4/3/2015 12:54 On	****	On	12519	8534	94
4/3/2015 13:09 On	****	Off	12554	8534	96
4/3/2015 13:24 On	****	Off	12580	8534	97
4/3/2015 13:39 On	****	Off	12599	8534	98
4/3/2015 13:54 On	****	Off	12603	8534	100
4/3/2015 14:09 On	****	Off	12585	8534	100
4/3/2015 14:24 On	****	Off	12576	8534	100
4/3/2015 14:39 On	****	Off	12572	8534	100

Change ELI-Link Timeout

This function was added to software v2.4.2 in order to optimize the time delays that can occur when communicating to a facilities network. The default wait-time is 60 seconds, before the cardiograph will stop listening for a response from ELI-Link once a communication request is sent. This feature allows the wait-time to be adjusted to a different duration, depending on the typical response time of the particular network environment. The available options are 20, 40, 60, or 80 seconds.

The log files have also been modified (in v2.4.2 and later) to clearly show what the actual ELI-Link response time is for the network the cardiograph is connecting to, in order to determine the optimal setting for the timeout value. The log file example below shows how this information will appear. If using an ELI-Link version prior to v4.4 only one response time will be shown. When using ELI-Link v4.4 or newer, two response times will be shown (use the larger of the two for measurement purposes).

To change the TIMEOUT value, enter the service menu and click on the "Change ELI-Link Timeout" button. Each click of the button will change to the next optional setting (20,40,60,80).

Be sure the wait time selected is at least 5-10 seconds LONGER than the typical response times observed, as the response times will vary based on several factors, such as network traffic, size of orders table, etc. !

ELI 380 Configur	ation							
About	Custom ID	Date/ Time	WAM/ AM-XX	Network	Print	Options Code		
System	ECG	Alternate Placement	15 Leads Alt. Placement	LAN	WLAN	Passwords		
Calibrate Cue	Auto Test	Firmware	Config Files	Options File	Dump Log Files	Dump Records	Erase Records	
First Time Boot	Writer Test	Test Config	Clear Flags	Fill ECG Directory		Battery Info	Enter Serial Number	
USB Device	Dump Config File		Change ELI Link Timeout					
				About				
Seria	I Number:	11946000	0880		WLAN:	Yes		
Soft	ware version:	V2.4.2.22			LAN MAC:	00 OF	82 FF F5 F2	
DIC	OM:	Yes			WLAN MAC:	00 17	23 EF B5 F2	
Secu	urity:	Yes]		Late Potentials:	No		
PDQ	y:	Yes	י די					
ELI	Link time-out sett	ing (Newmar only	(): 40 Seconds					

COMMUNICATIONS OPTIONS

Communication Options

The following Communications Options are available on the ELI 380.

- Transmission to USB flash drive (USB Host Port)
- USBD Mount to Windows PC (USB Device option)
- LAN
- WLAN
- DICOM and Enterprise

Communication Option Installation/Upgrades

Transmission to USB Memory Device (USB Host Port)

Transmission of records to a USB flash drive is always enabled on the ELI 380.

USBD Mount to Windows PC (USB Device option)

The ability to allow the ELI 380 to be recognized by a computer as a USB memory device is always enabled on the ELI 380. This is only available through the Service menu.

LAN Option

The LAN option is always enabled on the ELI 380.

WLAN Option

The WLAN module is installed on all ELI 380 devices. Enabling of the option is done via a software file (.SNO) provided by Welch Allyn or an option code will be provided with the purchase of the option upgrade.

Note: The WLAN module <u>is not</u> included with PN: SERV 26025-126-152 (ELI 380 MOTHERBOARD ASSY) The WLAN module is included with PN: SERV 26025-126-152-WLA (ELI 380 MOTHERBOARD ASSY W/WIRELESS LAN)

DICOM and Enterprise option

An upgrade to DICOM and Enterprise is available via a software file (.SNO) provided by Welch Allyn or an option code will be provided with the purchase of the option upgrade.