# Welch Allyn®

# ELI® 230

12-LEAD RESTING ELECTROCARDIOGRAPH

**SERVICE MANUAL**

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

CE 0459

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

*For patent information, please visit www.welchallyn.com/patents*

*For information about any Welch Allyn product, visit: https://www.welchallyn.com/en/about-us/locations.html*

*Customer Service and Technical Support: https://www.welchallyn.com/en/other/contact-us.html*

*1.888.667.8272, mor_tech.support@hillrom.com*

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# 901130 ELECTROCARDIOGRAPH

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EC REP EU IMPORTER

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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.

## Equipment Identification

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

## Copyright and Trademark Notices



## Other Important Information

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

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

## 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.

# Warranty Information

## Your Welch Allyn Warranty

WELCH ALLYN, INC. (hereinafter referred to as “Mortara”) hereby warrants that Welch Allyn products (hereinafter referred to as “Product/s”) shall be free from defects in material and workmanship under normal use, service, and maintenance for the warranty period of such Product/s from Welch Allyn or an authorized distributor or representative of Welch Allyn. The warranty period is defined as twelve (12) months following the date of shipment from Welch Allyn. Normal use, service, and maintenance means operation and maintenance in accordance with appropriate instructions and/or information guides. This warranty does not apply to damage to the Product/s caused by any or all of the following circumstances or conditions:

a) Freight damage;

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

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

EXCEPT AS SET FORTH HEREIN WITH RESPECT TO REIMBURSEMENT OF LABOR CHARGES, A PURCHASER’S SOLE EXCLUSIVE REMEDY AGAINST 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

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

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

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

## WARNING(S)

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

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

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

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

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

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

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

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

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

10. This device was designed to use the electrodes specified in this manual. Proper clinical procedure must be employed to prepare 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.

11. 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.

12. To ensure the safety of both the patient and the device, 1.5 meters (5') of open area should surround the patient.
13. A possible explosion hazard exists. Do not use the device in the presence of a flammable anesthetic mixture.

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

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

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

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

18. 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.

19. 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.

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

21. 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.

## Caution(s)

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

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

3. 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.

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

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

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

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

## Notes

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

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

3. 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.

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

5. 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.

6. 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

7. The device will automatically turn off (blank screen) if the batteries have been severely discharged and the AC power cord is disconnected from the device.

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

# Equipment Symbols and Markings

## Symbol Delineation

CAUTION The caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property, or loss of data.

WARNING The warning statements in this manual identify conditions or practices that could lead to illness, injury, or death. In addition, when used on a patient applied part, this symbol indicates defibrillation protection is in the cables. Warning symbols will appear with a grey background in a black and white document.

Alternating current

Protective earth

Defibrillator-proof type CF applied part

Input

ON/OFF (power)

Stop (of action)

Do not dispose as unsorted municipal waste. Requires separate handling for waste disposal according to local requirements


Indicates compliance to applicable EEC directives


Follow instructions/directions for use (DFU) – mandatory action. A copy of the DFU is available on the website. A printed copy of the DFU can be ordered from Welch Allyn for delivery within 7 calendar days.

| | |
|---|---|
|  | Non-ionizing electromagnetic radiation |
|  | Medical Device |
|  | Model Number |
|  | Reorder Number |

# Electromagnetic Compatibility (EMC)

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

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

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

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

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

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

| Emissions Test | Compliance | Electromagnetic Environment: Guidance |
|---|---|---|
| RF Emissions CISPR 11 | Group 1 | The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment. |
| RF Emissions CISPR 11 | Class A | The equipment is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic Emissions IEC 61000-3-2 | Complies | |
| Voltage Fluctuations/Flicker Emissions IEC 61000-3-3 | Complies | |

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

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

| Emissions Test | Compliance | Compliance Level | Electromagnetic Environment: Guidance |
|---|---|---|---|
| Electrostatic discharge (ESD) IEC 61000-4-2 | +/- 6 kV contact<br>+/- 8 kV air | +/- 6 kV contact<br>+/- 8 kV air | Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst IEC 61000-4-4 | +/- 2 kV for power supply lines<br>+/- 1 kV for input/output lines | +/- 2 kV for power supply lines<br>+/- 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<br>+/- 2 kV common mode | +/- 1 kV differential mode<br>+/- 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<br>40% UT (60% dip in UT) for 5 cycles | <5% UT (>95% dip in UT) for 0.5 cycle<br>40% UT (60% dip in UT) for 5 cycles | Mains power quality should be that of a typical commercial or hospital environment. |
| Power frequency (50/60 Hz) magnetic field | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |

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

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

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

| Emissions Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment: Guidance |
|---|---|---|---|
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | 3 Vrms 150 kHz to 80 MHz | Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>**Recommended separation distance**<br><br>$d = \left[\frac{3.5}{3Vrms}\right]\sqrt{P}$ |
| Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m 80 MHz to 2.5 GHz | $d = \left[\frac{3.5}{3V/m}\right]\sqrt{P}$ 80 MHz to 800 MHz<br><br>$d = \left[\frac{7}{3V/m}\right]\sqrt{P}$ 800 MHz to 2.5 GHz<br><br>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).<br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b].<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br><br>  |

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

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

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

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

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

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

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

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

# General Information

## Service Manual Purpose

The purpose of this manual is to supply information to authorized service personnel so they can properly maintain the ELI 230 product. This manual is intended to function as the primary guide to preventive maintenance and electrical repairs considered field repairable for the ELI 230 product.

## 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 as defined in this manual. Failure to do so may cause undue failure and possible health hazards.

## Serial and Part Number Location

For questions and service information, have serial number and part number available when contacting Welch Allyn. The model type, serial number (SN) and part number (REF) are found on the back label of the unit similar to the one pictured below.


Care should be taken so that these numbers are not defaced.

## Warranty Tracking by Serial Number

Welch Allyn tracks products by serial number for the purposes of warranty, device configuration, and software version. The device serial number will be required for all warranty claims made to Welch Allyn, Inc.

## Copyright and Trademark Notices



## Other Important Information

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

## 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.

# System Overview

The ELI 230 is a 12-lead diagnostic electrocardiograph intended for recording, viewing and printing ECGs of adult patients who are suspected of having abnormal heart rhythms. The ELI 230 is capable of storing one ECG and is not capable of transmitting ECG records. The ELI 230 receives patient data via either the Welch Allyn Wireless Patient Cable or a wired USB patient cable.

The ELI 230 is optionally equipped with Welch Allyn's VERITAS™ resting ECG interpretation algorithm which considers both age and gender specific criteria. If this option is enabled the VERITAS algorithm can provide an over-reading physician with a silent second opinion through diagnostic statements output on the ECG report.

# Maintenance & Cleaning

 **Warning**:

- Remove AC power and turn off the device before maintenance or cleaning operations are performed.
- Do not immerse the device in water or any other fluid.

## Maintenance Schedule

| Maintenance Type | Recommended Period | Notes |
|---|---|---|
| | | |
| Device Cleaning | 6 Months | Refer to cleaning instructions below |
| Print head Cleaning | 80 hours of use | Refer to cleaning instructions below |
| Battery Replacement | 2 – 5 years | Highly dependent upon usage and charging frequency |
| Safety Testing | - | As required by facility or regulatory requirements |

## Cleaning the Device

 **Caution:** *Use care and proper procedure whenever cleaning or maintaining the device. Improper cleaning products and processes can damage the device, produce brittle lead wires and cables, corrode the metal, and void the warranty. Use of excessive liquid may result in fluid entering the device which may cause corrosion or damage to internal circuitry. 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.*

- Disconnect the AC 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.

## Recommended Supplies

- Clean lint free cloth
- Mild detergent
- Isopropyl Alcohol (80-99%)
- 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 Thermal Print Head

Dampen a clean lint-free cloth with 80-99% isopropyl alcohol and wipe the thermal print head surface until clean. Allow to air dry.

## Cleaning the Patient Cable

For disinfecting the cables and lead wires, wipe exterior with a soft, lint-free cloth using a solution of Sodium Hypochlorite (10% household bleach and water solution) minimum 1:500 dilution (minimum 100 ppm free chlorine) and maximum 1:10 dilution as recommended by the APIC Guidelines for Selection and Use of Disinfectants.

## Sterilization

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

# Unit Disassembly / Reassembly

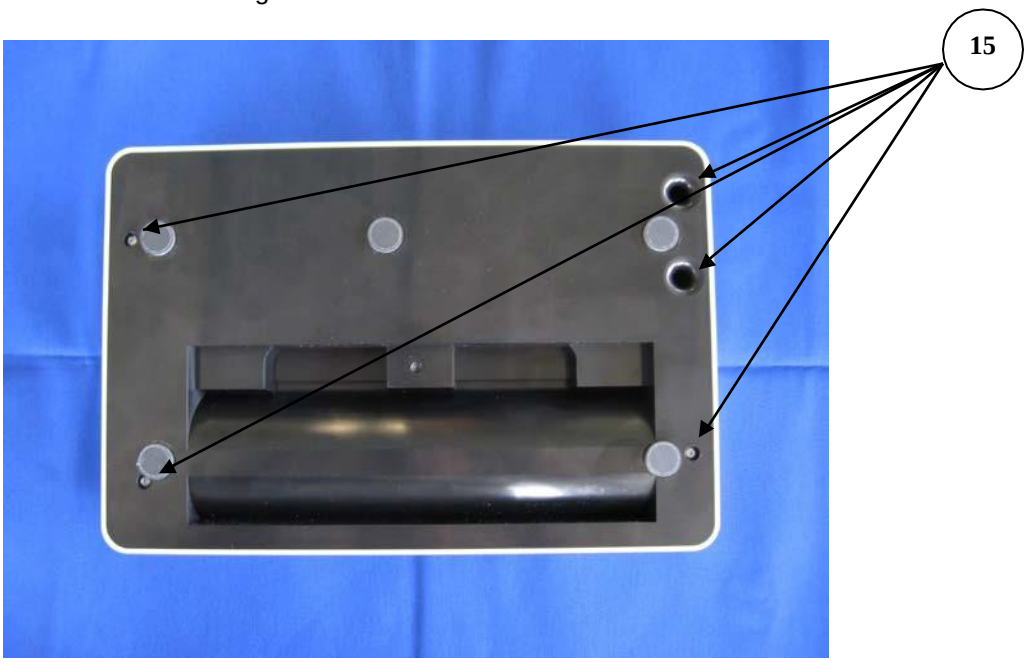
**Refer to the item listing at the end of this section for Welch Allyn part numbers**.

Pictures are for Reference Only.

1. Open the writer door and remove the paper roll (if installed)

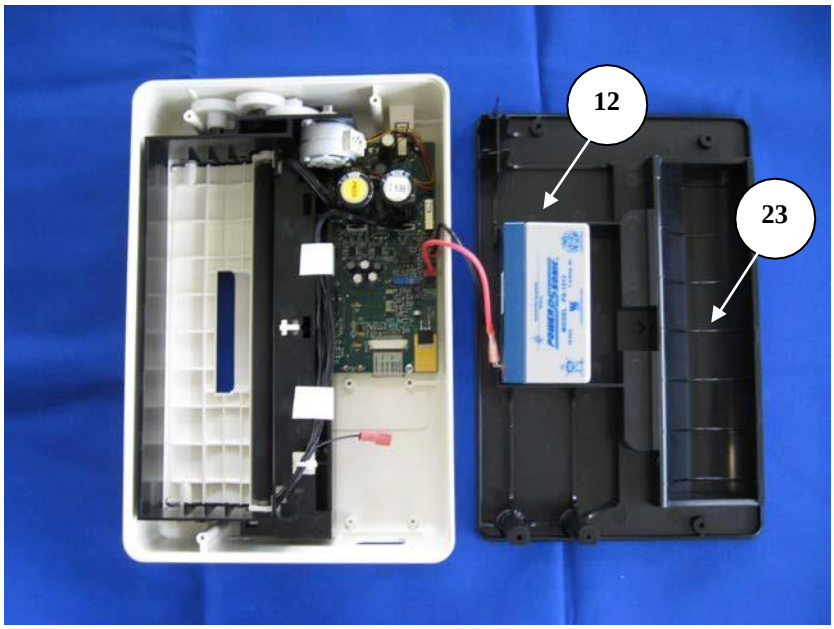
2. Close the writer door.

3. Remove the 5 housing screws from the bottom of the unit.



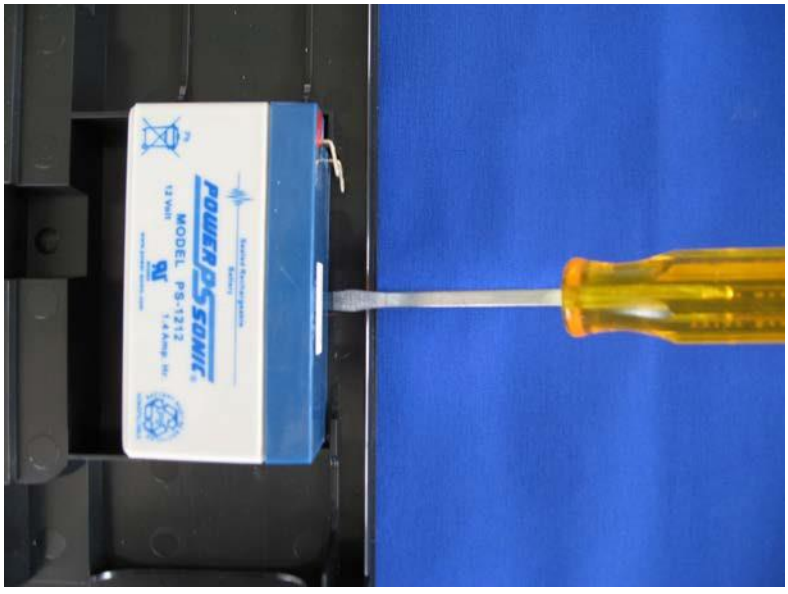
For re-assembly, use the 7lb-in torque driver and T-10 bit to install three (3) *1/2" Screws* in the three shallow wells. Use the 5lb-in torque driver and T-10 bit to install two ½" *Screws* in two deep wells.

4. Disconnect the positive and negative battery terminals from the sealed rechargeable battery.



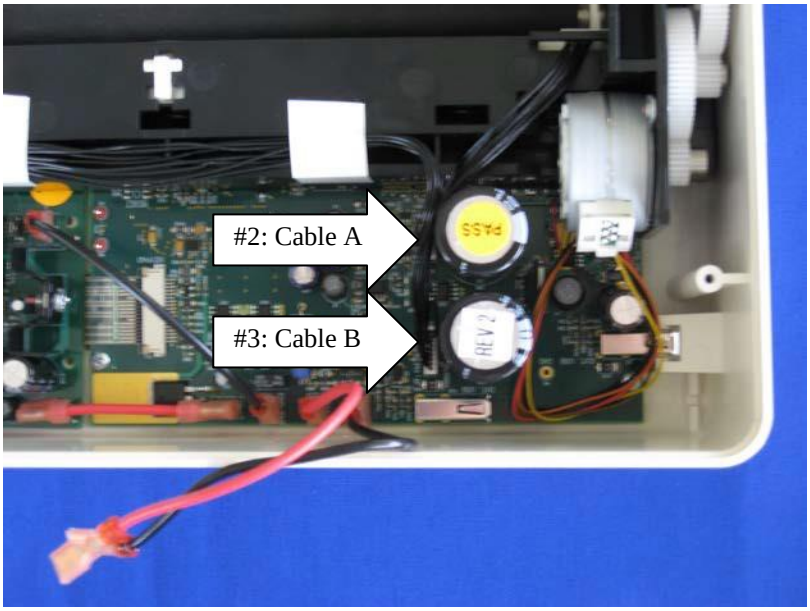

5. Remove Battery (Item #12) by detaching it from the double stick foam tape (Item # 19) adhering it to the lower housing.

   (The foam tape will need to be replaced to reinstall a battery)

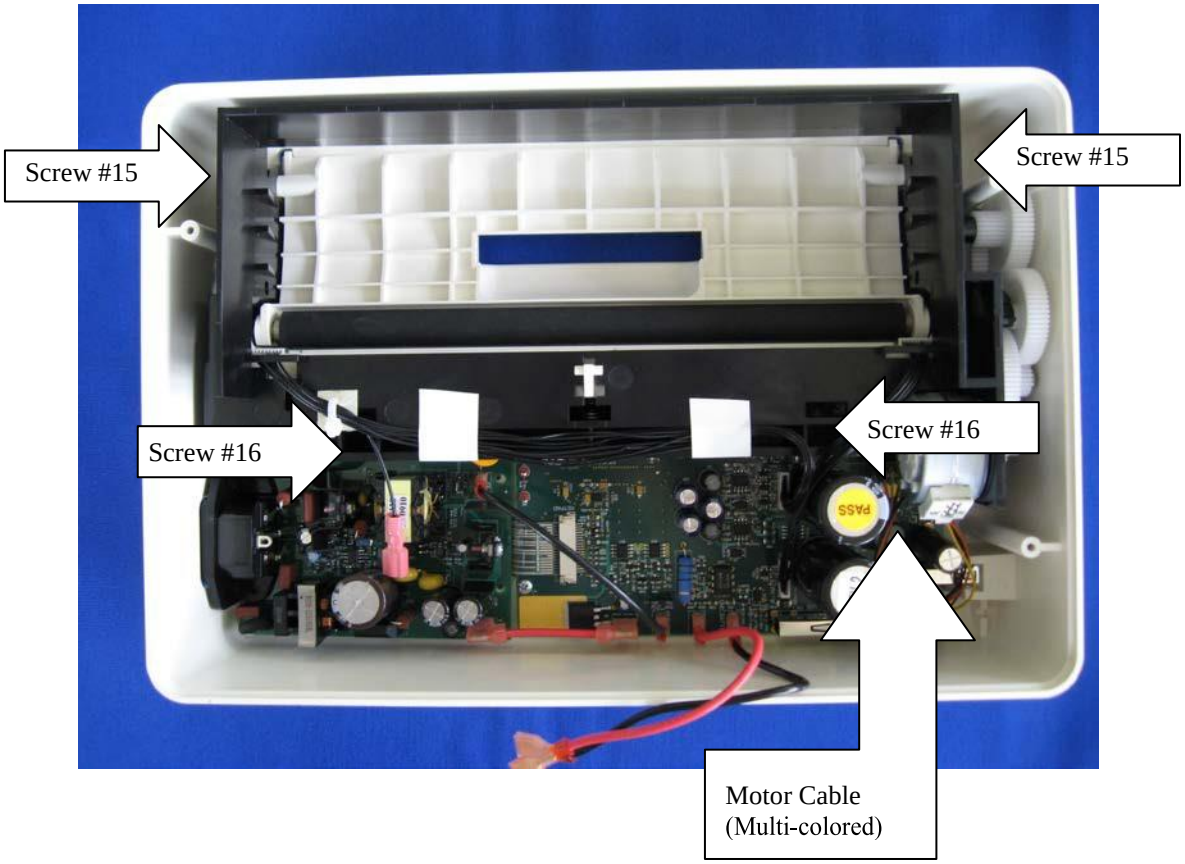



6. Disconnect the Printhead Cable A (Item #2) from the Digital Circuit Board.

7. Disconnect the Printhead Cable B (Item #3) from the Digital Circuit Board.



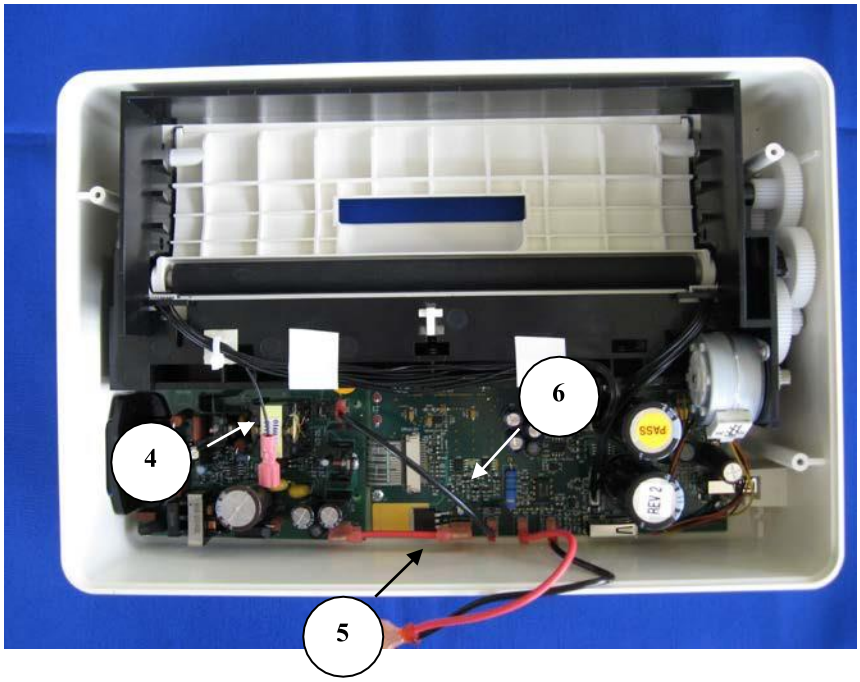

8. Remove the 4 writer mounting screws; two of item #15, and two of item #16 from the upper housing. For re-assembly, use the 5lb-in torque driver and T10 bit to install the 4 writer mounting screws.



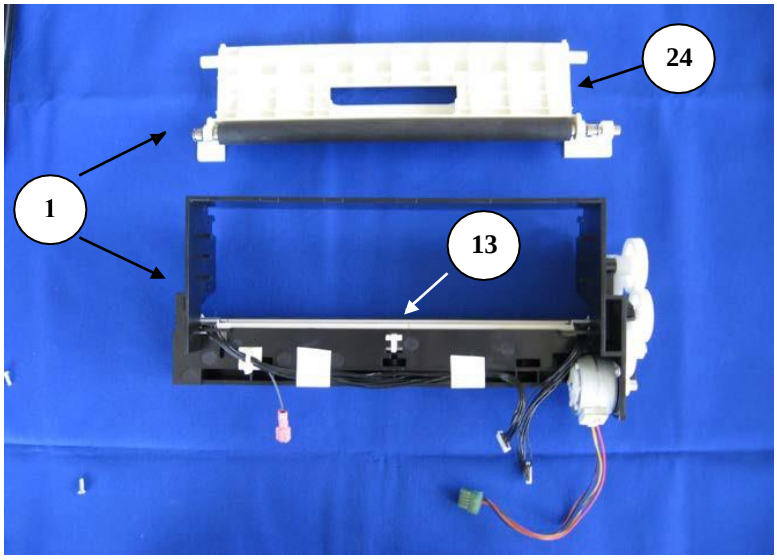

9. Remove the motor cable for the Digital Circuit Board.

10. Disconnect the Positive (red) wire (Item #5) that goes from the AC supply to the Digital PCB terminal P12, then disconnect the Negative (black) wire (Item #6) that goes from the AC supply to the Digital PCB terminal P14.

11. Remove the writer ground cable (item #4) from the Power Supply PCB terminal P3.



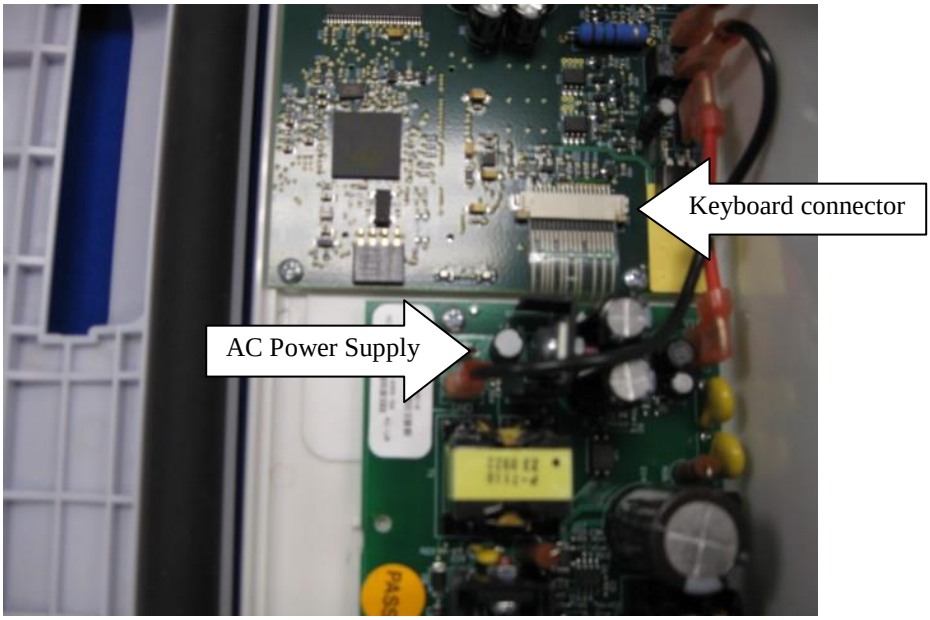

12. Remove the Writer Assembly (Item #1) from the Upper Housing.



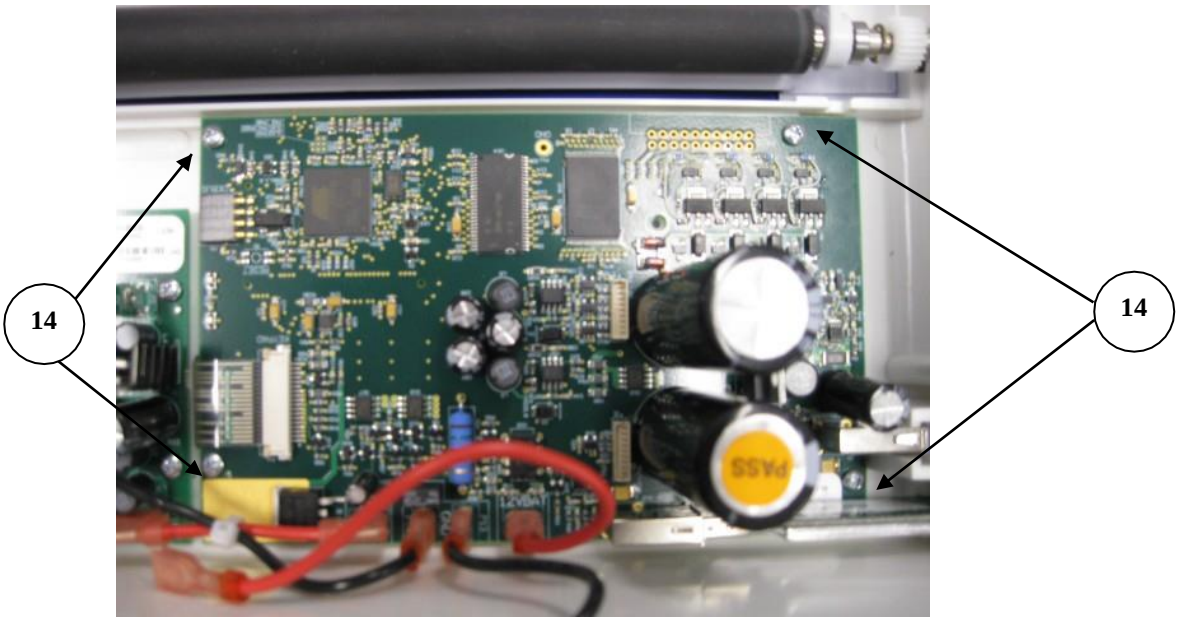

13. Remove the Writer Door Assembly (Item #24) from the Upper Housing.

14. Remove the 2 screws (Item #14) from the AC Power Supply PCB

For re-assembly, use the 5 lb-in torque driver and T10 bit to install these 2 screws.




15. Remove the AC Power Supply from the Upper Housing.
16. Remove the Keyboard Connector from the Main Circuit Board.

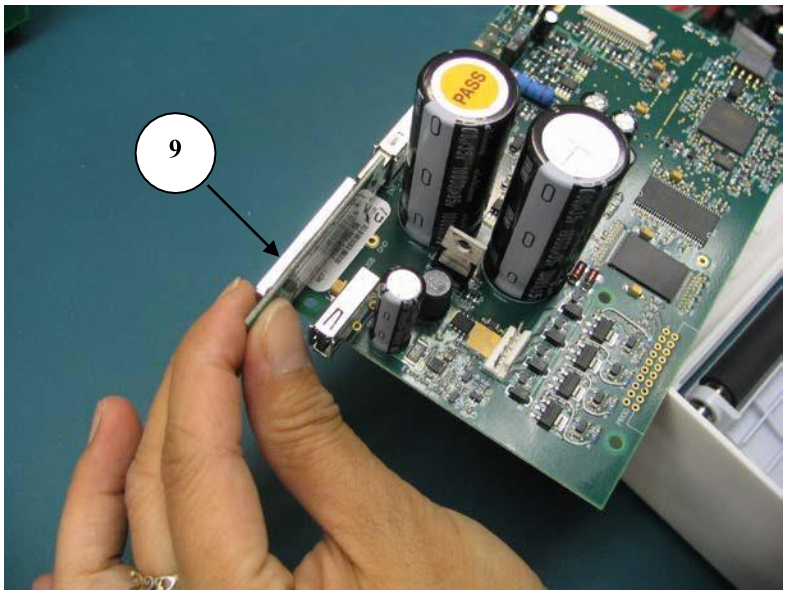



17. Remove the 4 circuit board mounting screws (Item #14) from the Upper Housing. For re-assembly, use the 5 lb-in torque driver and T10 bit to install these 4 screws.

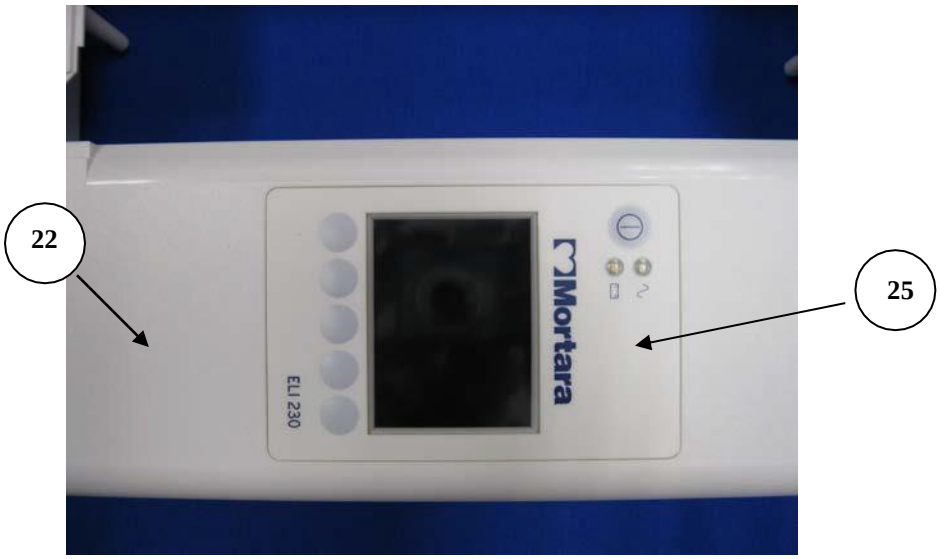
18. Remove the Digital PCB from the Upper Housing.

19. Remove the UTK (USB Transceiver Key) if the wireless patient interface option is installed.

    *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 # 29) near the ECG input connector on the housing.*

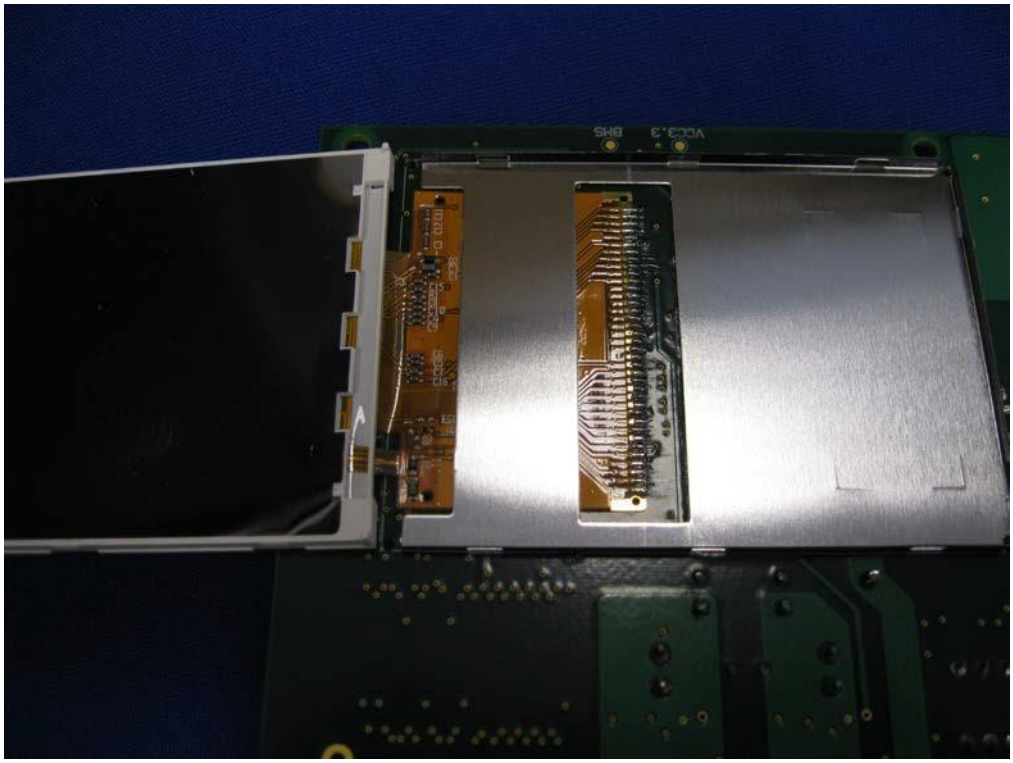



20. The keypad (Item #25) is attached via adhesive and can be removed from the Upper Housing (Item #22) by inserting a straight bladed scraping tool or small screwdriver to separate it from the Upper Housing.



The LCD connectors are factory soldered to the Digital PCB and fastened with double stick foam tape to hold it in place. The LCD panel can be removed by inserting a small prying tool underneath to separate the LCD from the Digital PCB and de-soldering the panel.

Note - Welch Allyn does not recommend this repair be performed in the field; replacement of the entire Digital PCB Assembly is recommended for field repairs.



* Care should be used in removal to ensure the PCB is not damaged by excessive force from the prying tool.

The items listed in the ELI 230 Item Listing table identify the serviceable level of the device. Subcomponents of assemblies listed are not available as individual service items. The assembly level item must be used for servicing purposes.

## ELI 230 Item Listing

| Ref # | Item Number | Description |
|---|---|---|
| | | |
| 1 | 22500-230-50 | WRITER ASSEMBLY ELI 230 |
| 2 | 25018-034-50 | PRINTHEAD CABLE A |
| 3 | 25018-041-50 | PRINTHEAD CABLE B |
| 4 | 25020-067-50 | GROUND WIRE FOR ELI 230 PRINTHEAD |
| 5 | 25020-068-50 | CABLE ASSEMBLY POSITIVE SUPPLY ELI 230 |
| 6 | 25020-069-50 | CABLE ASSEMBLY NEGATIVE SUPPLY ELI 230 |
| 7 | 25020-070-50 | CABLE ASSEMBLY POSITIVE BATTERY ELI 230 |
| 8 | 25020-071-50 | CABLE ASSEMBLY NEGATIVE BATTERY ELI 230 |
| 9a | 26025-092-151 | USB TRANSCEIVER KEY (UTK) PCB ASSY v1.x |
| 9b | 26025-092-404 | UTK w/Software v2.x |
| 10 | 26025-098-401 | ELI230 DIGITAL BOARD 4TH ED |
| 11 | 26025-099-400 | AC POWER SUP 16VDC wUL_4THED |
| 12 | 4800-008 | BATTERY RECHARGEABLE SLA 12V 1.3/1.4Ah |
| 13 | 5450-004 | PRINTHEAD THERMAL 216mm 8.50" |
| 14 | 6020-060 | SCREW THD-FORM PAN HD TORX 4-20x1/4" |
| 15 | 6020-061 | SCREW THD-FORM PAN HD TORX 4-20x1/2" |
| 16 | 6020-062 | SCREW THD-FORM PAN HD TORX 4-20x3/8" |
| 17 | 6320-003 | FOOT BLACK .64 OD X .115 ADHESIVE |
| 18 | 6545-006-01 | WRITER MOTOR |
| 19 | 7401-003 | TAPE TWO-SIDED ADHESIVE 0.009THK x 0.25W |
| 20 | 7495-001 | CABLE TIE LOCKING 3.9 x .10 |
| 21 | 7500-006 | CLIP CABLE ADHESIVE BACKED .5 x .5 |
| 22 | 8357-001-50 | UPPER HOUSING ELI 230 |
| 23 | 8357-002-50 | LOWER HOUSING ELI 230 |
| 24 | SERV PART 175-01 | WRITER DOOR ASSEMBLY |
| 25 | 8357-006-50 | KEYPAD ELI 230 |
| 25 | 8357-006-70 | KEYPAD BURDICK BUR 230 |
| 26 | 8357-008-50 | LCD PROTECTOR ELI 230 |
| 27 | 421460<br>421480 | LABEL ELI 230 NAMEPLATE<br>LABEL ELI 230 INMETRO NAMEPLATE |
| 28 | 9205-076-50 | CARTON SHIPPING SET ELI 230 |
| 29 | 728940 | v2 UTK Label for Cardiographs |

# Troubleshooting / Testing

1. **Device will not power up:**

   - With AC Power Applied

     *Note - The ELI230 unit will operate under AC power even if there is no battery installed in the unit.*

     The following should occur when AC power is applied:

     - AC LED illuminates
     - Battery LED illuminates (if battery is being charged)
     - LCD powers up and displays active ECG input

     If none of these occur, verify the AC outlet and power cord by plugging it into another AC powered device.

     - If AC power is being applied by the AC cord, but none of the items above occur, verify there is DC power coming from the AC supply by measuring the voltage level between P12 and P14 on the Digital PCB (approximately 16VDC).
     - If the correct voltage is present, replace the Digital PCB Assembly.
     - If this voltage level is not present, check for the correct DC voltage on the Analog PCB between the GND and V16 test points.
     - If the correct voltage is present there is a problem with the power cabling between the two PCB assemblies.
     - If the voltage is not present, replace the Power Supply PCB.

     If the AC LED illuminates, but the LCD does not become active, there is either a problem with the LCD or the Digital PCB.

     - Replacement of the Digital PCB is recommended; LCD replacement should only be performed at an authorized Welch Allyn service center.

   - Battery Only

     Verify the internal battery is properly connected and has at least an 11v potential being applied to the main PCB at terminals P13 and P15.

     - If the voltage is less than 11VDC replace the battery.
     - If the voltage is acceptable, the main PCB will require replacement.

2. **Thermal printer problem**

   - Printer pushes paper but does not print at all or only a portion of the data.

- Verify thermal print head cables are not damaged and are properly connected between the print head and main PCB.

- If the cables are OK, the problem is either a defective print head or main PCB. Determine which item is the problem by replacing one of the two items and performing another printing operation.

- Printer pushes paper but prints light on the top or bottom of the page.

  **Is the manufacturer's paper being used?**

  **Print quality is only guaranteed when using the manufacturer's branded thermal paper.**

  This may be due to a mechanical writer assembly component, inspect the following items:

  - Proper spring tension on the print head assembly.
  - Writer platen not damaged.
  - Mechanical latching mechanism operating properly.

  If a problem exists in one of these areas the printer assembly should be replaced.

  **Printing a Test Page:**

  To test the Thermal Print head/printer, perform the following steps:

  1. Press "More"
  2. Press "Config"
  3. Press "4 Service"
  4. Press "Print"

  A Test page should then print out.

**3. ECG data has poor quality**

- Verify proper patient ECG hook-up per the user's manual.
- If another patient cable is available, replace the suspect cable and check to see if the ECG quality improves.

*If the problem cannot be identified, contact Welch Allyn Customer Care for assistance.*

## Conformance and Safety Test

1. Test Description
   This document describes the steps necessary to functionally test the ELI230 unit. The keyboard is checked for proper operation. The LEDs are verified to be functional. The printer is checked for proper operation.

2. Definition of Terms

| | |
|---|---|
| CTR | Conformance Test Report |
| UUT | Unit Under Test |

3. Equipment needed
   - ECG Simulator (10 Lead)
   - AM12 Patient Input Module (9293-048-5x)
   - WAM Patient Input Module (30012-019-5x)
   - WAM/AM12 Lead Wire Set (9293-046-70)
   - Electrical Safety Analyzer

   3.1. Visual Inspection of final unit

   3.2. Complete a visual inspection of all sides of the unit. Verify no cosmetic issues observed. Verify proper labels are attached.

4. Functional Check

   4.1. Connect the UUT to an AC source. The unit should power ON automatically to the MAIN SCREEN.

   4.2. With the UUT plugged into AC, verify both LEDs above the LCD are illuminated.

   4.3. Install a roll of thermal paper into the writer tray. Connect an AM12 or WAM depending on the unit's configuration, with simulated ECG input to the UUT.

   4.4. Verify the five keypad buttons function as intended:

   4.4.1. Press the button corresponding to the **MORE** menu. Verify the menu changes to **BACK**. Press this button again to return to the **MORE** menu.

   4.4.2. Press the button corresponding to the **FILT** menu. Verify the value displayed for the filter on the LCD toggles between 40Hz, 150Hz and 300Hz each time the button is pressed.

   4.4.3. Press the button corresponding to the **MORE** menu. Next press the button corresponding to the **CONFIG** menu. With UUT not plugged into AC, verify the battery voltage is greater than 12.0. If it is less than 12.0, plug UUT into an AC source for 30 minutes, then unplug the unit from the AC source and verify voltage is greater than 12.0. If it is not, reject and replace the battery, and repeat these steps with the new battery.

   4.4.4. Press the button corresponding to the **GAIN** menu. Verify the value displayed for the filter on the LCD toggles between 5mm/mV, 10mm/mV and 20mm/mV each time the button is pressed.

4.4.5. Press the button corresponding to the **RHY** menu. Verify the UUT starts printing a rhythm strip. Press the **STOP** button to end the rhythm print.

4.4.6. Press the button corresponding to the **ECG** menu. Verify the LCD screen is cleared and the menu selections change. Press **STAT** and verify that the UUT acquires data and prints the ECG. Verify lines, waveforms, and text on the printout are consistent and legible.

4.5. Press the on/off button on the upper left corner of the user interface, with AC power on the unit will go into standby mode. With the unit running on the battery, the power will go off completely.

4.6. Safety Test

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 ELI230 is considered a Class 1 Type CF device, intended to only be utilized with the AM12 patient input module. 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 ELI230 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 AM12 patient cable)
- Patient Auxiliary Current
  Applied part – patient input (utilize AM12 patient cable)
- Complete DHR as required

# ELI230 Conformance Test Report

Unit Serial #: _____

| | | | |
|---|---|---|---|
| 3.1 | Visual Inspection | PASS / FAIL | (Circle One) |
| 4.1 | Unit Powers On | PASS / FAIL | (Circle One) |
| 4.2 | LEDs illuminated | PASS / FAIL | (Circle One) |
| 4.4 | Keypad Functions | | |
| 4.4.1 | "MORE" button | PASS / FAIL | (Circle One) |
| 4.4.2 | "FLT" button | PASS / FAIL | (Circle One) |
| 4.4.3 | "CONFIG" button | PASS / FAIL | (Circle One) |
| 4.4.4 | "GAIN" button | PASS / FAIL | (Circle One) |
| 4.4.5 | "RHY" Strip Test | PASS / FAIL | (Circle One) |
| 4.4.6 | "ECG" Acquire/Print Test | PASS / FAIL | (Circle One) |
| 4.5 | Unit Powers Off | PASS / FAIL | (Circle One) |

4.6 Safety Test PASS / FAIL (circle)

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

Performed By: _____ Date: _____

# ELI 230 Specifications

| Feature | Specifications |
|---|---|
| Instrument Type | 12-lead electrocardiograph |
| Input Channels | Simultaneous acquisition of all 12 leads |
| Standard Leads Acquired | I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 |
| Waveform Display | Backlit, ¼ VGA 320 x 240 LCD color display<br>4+4 or 6+6 lead presentation |
| Input Impedance<br>Input Dynamic Range<br>Electrode Offset Tolerance<br>Common Mode Rejection | Meets or exceeds the requirements of ANSI/AAMI EC11 |
| Patient Leakage Current<br>Chassis Leakage Current | Meets or exceeds requirements of ANSI/AAMI ES1 |
| Digital Sampling Rate | 40,000 s/sec/channel used for pacemaker spike detection; 1000 s/sec/channel used for recording and analysis |
| Resolution | 1.875 microvolt LSB |
| A/D Conversion | 20 bits |
| Frequency Response | 0.05 to 300 Hz |
| Filters | High-performance baseline filter; AC interference filter 50/60 Hz; low-pass filters 40 Hz, 150 Hz, or 300 Hz |
| Special Functions | Optional VERITAS resting ECG interpretation with age and gender specific algorithm |
| Paper Type | Thermal roll paper; 210 mm (8.25”) wide |
| Thermal Printer | Computer-controlled dot array; 8 dots/mm |
| Thermal Printer Speeds | 5, 10, 25, or 50 mm/s |
| Gain Settings | 5, 10, or 20 mm/mV |
| Report Print Formats | Standard or Cabrera; 12, 6, or 3+1 channel |
| Rhythm Print Formats | 12, 6, or 3 channel with configurable lead groups |
| Device Classification | Class I, Type CF defibrillation-proof applied parts |
| Weight | 8 lbs. (3.63 kg) including battery (without paper) |
| Dimensions | 11.25 x 8 x 3.75” (29.2 x 20.3 x 10.2 cm) |
| Power Requirements | Universal AC power supply (100-240 VAC at 50/60 Hz) 110 VA; internally rechargeable battery |