

Baxter

Welch Allyn

ELI 150c

Resting Electrocardiograph

Software version 2.2.X



Instructions for use

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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

Baxter 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.

The **ELI** 150c product label is applied showing the unique identification numbers along with other important information printed on the label.

Serial number format: YYYWWSSSSSS

Format	Description
YYY	First Y is always 1 followed by two-digit Year of manufacture
WW	Week of manufacture
SSSSSS	Sequence number of manufacture

The UDI label (when applicable) is placed below the product label. If the unit is configured for a modem, this label is placed to the right of the product label. If the unit is configured for WLAN, this label is placed to the right of the product label.

AM12 module identification

The wired Acquisition Module is identified with a product label on the back of the device and will have its own unique serial number and UDI label applied.

Wireless module identification

The Wireless Acquisition Module (**WAM**) is identified with a product label on the back of the device and has its own unique serial number and UDI label applied. When the **ELI** 150c is configured for the **WAM**, the **UTK** label is placed to the right of the product label and below the Modem or WLAN labels when present.

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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.

User safety information

About warnings and cautions



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.

Warnings



WARNING 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.

WARNING 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.

WARNING 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 Baxter service for additional training options.



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



WARNING Only use parts and accessories supplied with the device and/or are available through Baxter.



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



WARNING 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.



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



WARNING 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.



WARNING 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.



WARNING 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.



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



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



WARNING 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 150c** 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 150c** 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 150c** 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.
- After defibrillation pulse, electrocardiograph has a maximum recovery time of 5 seconds.
- 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.



WARNING 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.

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

WARNING 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.

WARNING 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.

 **WARNING** Some Baxter electrocardiographs can be equipped with a wireless LAN (WLAN) module for transmitting ECG records. Device labeling and the presence of an antenna port will indicate if your device is equipped with such a module. If so equipped, the following notices apply:

- The WLAN identification can be found on a label on the bottom of the device.
- **Advantech:** radio module WLNNNA-AN-MR551 (model subject to change without notice).

 **WARNING** 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.

 **WARNING** Do not transmit via the WLAN module with a missing or damaged antenna. Replace a damaged antenna immediately.

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

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

 **WARNING** 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

 **WARNING** This product complies with relevant electro-magnetic interference, mechanical safety, performance, and biocompatibility standards. However, the product cannot completely eliminate potential patient or user harm from the following:

- Harm or device damage associated with electro-magnetic hazards,
- Harm from mechanical hazards,
- Harm from device, function, or parameter unavailability,
- Harm from misuse error, such as inadequate cleaning, and/or

 **WARNING** The device and IT Network the device is connected to should be securely configured and maintained per the IEC 80001 standard, or an equivalent network security standard or practice.

Cautions

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

 **CAUTION** 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.

-  **CAUTION** No user-serviceable parts inside. Screw removal by qualified service personnel only. Damaged or suspected inoperative equipment must be immediately removed from use and must be checked/repared by qualified service personnel prior to continued use.
-  **CAUTION** 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 Baxter Service Department.
-  **CAUTION** 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.
-  **CAUTION** No calibration or special equipment is needed for the proper operation or maintenance of the device.
-  **CAUTION** When necessary, dispose of the device, its components and accessories (e.g., batteries, cables, electrodes), and/or packing materials in accordance with local regulations.
-  **CAUTION** Use only No. 26 AWG or larger telecommunication line cord.
-  **CAUTION** Proper functioning backup items such as a spare patient cable, front-end device, display monitor, and other equipment are recommended on hand to prevent delayed treatment due to an inoperative device.

Notes

-  **NOTE** Patient movements may generate excessive noise that may affect the quality of the ECG traces and the proper analysis performed by the device.
-  **NOTE** Proper patient preparation is important to proper application of ECG electrodes and operation of the device.
-  **NOTE** The algorithm detecting electrode misplacements is based on normal physiology and ECG lead order, and tries to identify the most likely switch; however, it is advisable to check the other electrode positions in the same group (limb or chest).
-  **NOTE** 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.
-  **NOTE** A square wave presentation on the display while using the **WAM** may be due to the **WAM** being turned off, having no battery, not being paired correctly, operating out of range, or due to a calibration error. Review the LED indicator on the **WAM** to ensure the unit is turned on, has proper battery level, is paired correctly, and is within recommended proximity of the electrocardiograph, or power cycle the **WAM** to re-calibrate. Review the **WAM** user manual for details.
-  **NOTE** A square wave presentation on the display while using the **AM12** may be due to improper auto-calibration. Power cycle the **AM12** or the electrocardiograph.
-  **NOTE** If electrode is not properly connected to the patient, or one or more of the patient cable lead wires is damaged, display will indicate a lead fault for the lead(s) where the condition is present and if the signal is being printed, the respective lead(s) will print out as a square wave.
-  **NOTE** 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.

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.



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



NOTE WAM must be paired to electrocardiograph before operation.



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



NOTE 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.



NOTE The device is UL classified.



WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005 + C1:09 + A1:2012 + A2:10), IEC 60601-1:2005+A1:2012, CAN/CSA C22.2 No. 60601-1:14, CAN/CSA-C22.2 No. 60601-2-25:12, AND IEC 60601-2-25:2011/60601-1:2005+A1:2012+A2:2020, CAN/CSA C22.2 No. 60601-1 AND IEC 60601-2-25:2011



NOTE The device is a member of the **ELI** 1xx Series 2 electrocardiograph family.

Wireless data transmission

Some Baxter electrocardiographs can be equipped with an optional wireless data transmission module (WLAN). This technology uses a radio to transmit data to a Baxter 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. Baxter has tested the coexistence of the device with other devices that can interfere such as devices using WLAN, **Bluetooth**® radio, and/or cell phones. Although the current technology allows a very successful rate of transmission, it's possible that in some rare occurrences, the system may not perform at its best resulting in a "failed transmission." When this occurs, patient data will not be erased from the device nor stored in the receiving application, ensuring that partial or corrupted data are not made available to the receiving station. If the failure mode persists the user should move to a position where the RF signals may propagate better and allow successful transmissions.

WLAN option

- Wireless options transmit in the 2.4 GHz or 5 GHz range. Other nearby wireless devices 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.

User safety information

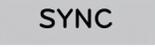
- The following table shows the channels allocated in different geographic areas in the world. For bands 802.11 b, g, and n, only channels 1, 6, and 11 are non-overlapping, channel count denotes number of non-overlapping channels, and channels shown represent non-overlapping channel numbers.

Band	Typical Power (dB)	Region	Frequency Range (GHz)	No. of Channels	Channel Numbers
802.11b	17±1.5	USA/Canada	2.401 - 2.473	11	1 - 11
		Europe	2.401 - 2.483	13	1 – 13
802.11g	16±1.5	USA/Canada	2.401 - 2.473	11	1 - 11
		Europe	2.401 - 2.483	13	1 – 13
802.11g	16±1.5 (BW20)	USA/Canada	2.401 - 2.473	11	1 - 11
	14±1.5 (BW40)	Europe	2.401 - 2.483	13	1 – 13
802.11a/n	13±2 (11a)	USA/Canada	5.15 - 5.35	11	36, 40, 44, 48, 52, 56, 60, 64, 149, 153, 157
			5.470-5.725	8	100, 104, 108, 112, 116, 132, 136, 140
			5.725 - 5.825	2	161, 165
	13±2 (11n, BW20)	Europe	5.15 - 5.35,	19	36, 40, 44, 48, 52, 56, 60, 64, 100, 104, 108, 112, 116, 120, 124, 128, 132, 136, 140
			5.47 - 5.725		
12±2 (11n, BW40)					

- 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 signals are available.

Symbols and definitions

Symbol information

	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 gray background in a black and white document.
	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.
	Alternating current
	Protective Earth
	Telephone line (modem)
	Network (LAN)
	Defibrillator-proof type CF applied part
	Universal Serial Bus (USB) port
	Input
	On / Off (power)
	Stop (of action)
	Shift key (to enter uppercase text)
	Enter key (accept data/return)
	Initiate printing of 12-lead ECG
	Initiate printing of continuous rhythm strip
	Transmit, receive and time sync operation depending upon configuration settings

Symbols and definitions

	Do not dispose as unsorted municipal waste. Requires separate handling for waste disposal according to local requirements as per 2012/19/EU WEEE.
	Antenna
	Indicates compliance to applicable European Union directives.
	CE symbol
	UL approved mark
	Do not re-use, Single use device
	Refer to instruction manual / booklet.
	Medical Device
	Reorder Number
	Model Identifier
	Non-ionizing electromagnetic radiation.
	Version 2 UTK indicator (next to ECG input)
	Manufacturer
	Authorized representative in the European Community
	Serial Number
	Global Trade Item Number
	Lot Number

	Importer
	Use by date
R_x ONLY	Prescription only or "For use by or on the order of a licensed medical professional"
	Telecommunication Regulation Commission symbol for Jordan
EAC	Eurasia Certification

Package symbol information

	Keep away from sunlight
	This way up
	Fragile
	Keep dry
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Contains non-spillable battery

Introduction

Manual purpose

This manual is intended to provide information about:

- Using and understanding the **ELI 150c** electrocardiograph, the function and feature keys, and the display screen.
- Preparing the device for use.
- Acquiring, printing, and storing an ECG.
- System settings.
- Connectivity and transmitting ECGs.
- Maintenance and troubleshooting.



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

Audience

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

System description

The device is a 12-lead diagnostic electrocardiograph used for acquiring, viewing, and printing adult and pediatric 12-lead ECG data. The device is optionally equipped with the Baxter **VERITAS** resting ECG interpretation algorithm with 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. For additional information on the **VERITAS** algorithm, please refer to the *Physician's Guide Adult and Pediatric user manual*.

The device can be configured with expanded memory, bidirectional connectivity, and **DICOM** protocol support, and operates on battery or line power.

Supported print formats for the **ELI 150c** include: standard or Cabrera 3, 3+1, 3+3, or 6 channel in automatic mode; 3 or 6 channel rhythm strip printing.

With either model, during rhythm strip printing the user can toggle between the various channels (default leads, limb and chest leads, etc.) to print by selecting F2 (Leads). To suspend a rhythm strip print, press **F6** (Stby); press **F6** (Cont) to resume. Press **STOP** at any time to end rhythm strip printing.

The device includes:

- Acquisition module with lead wire set
- Hospital-grade power cord
- Antenna (with WLAN)
- 1 pack paper
- Physicians Guide to **VERITAS** with Adult & Pediatric Resting ECG Interpretation
- User manual web direct card
- Accessory starter kit

Intended use (Functional purpose)

The **ELI 150c** is intended to be a high-performance, 12-lead, multifunctional electrocardiograph. Once the data is acquired, it can be reviewed and/or stored, and/or printed. It will be a device primarily intended for use in hospitals but may be used in medical clinics and offices of any size.

Indications for use

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

System illustrations

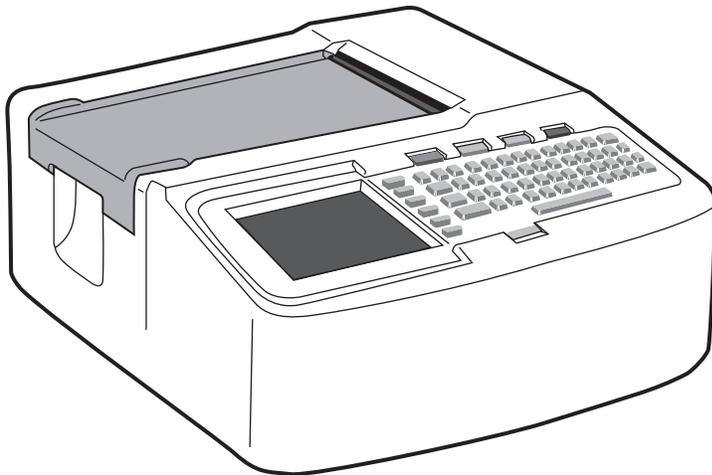


Figure 1: Top view

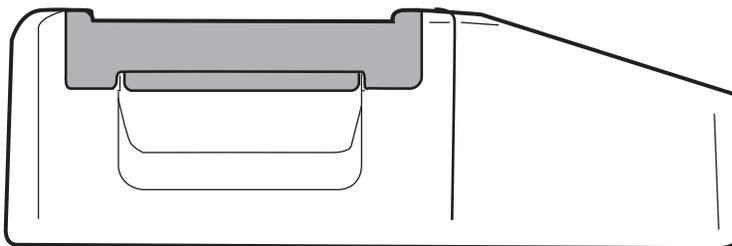


Figure 2: Left side

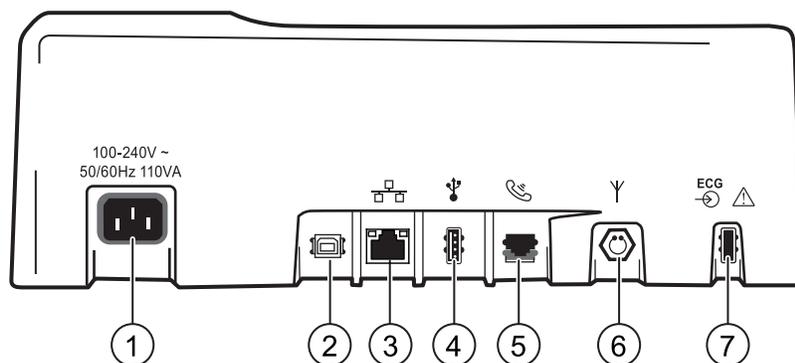


Figure 3: Rear

No.	Description
1	100-240V power
2	USB device port
3	RJ45 LAN connector port
4	USB connector port
5	Modem Port
6	WLAN antenna connector
7	AM12 ECG connector port

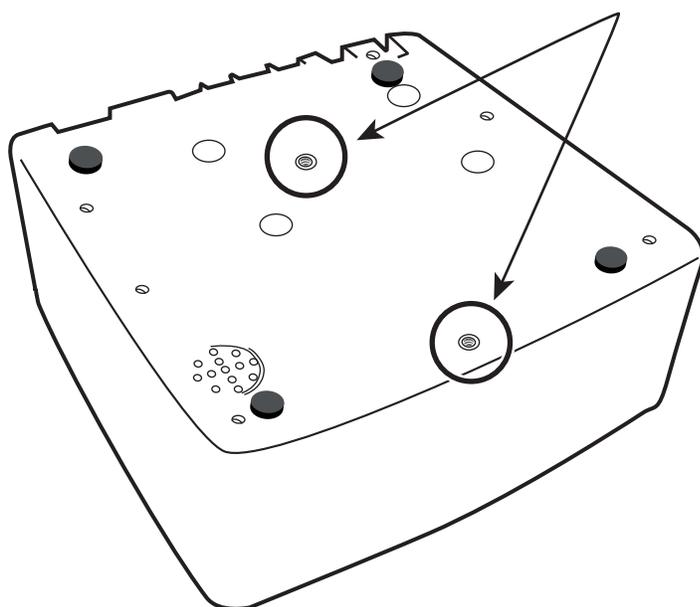


Figure 4: Base / Cart mounting

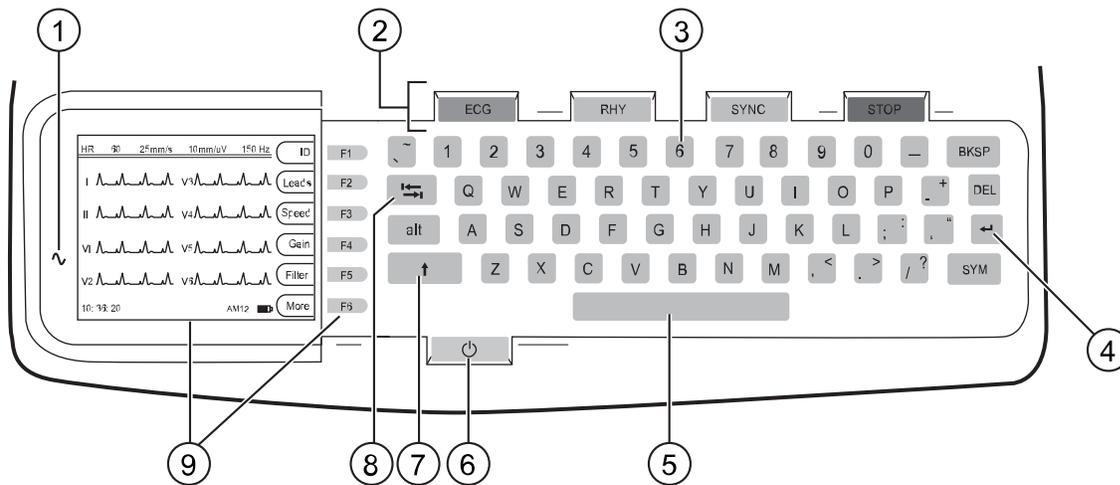


Figure 5: Display and keyboard

No.	Description
1	AC Power Indicator
2	Automatic Feature Keys
3	Data Entry Keys
4	Enter
5	Space
6	On / Off
7	Shift
8	Tab
9	LCD* and Function Keys

*Real Time ECG view is pictured.

Automatic feature keys

Automatic feature keys are used as a one-touch operation.

ECG	ECG Acquisition
RHY	Rhythm Printing
SYNC	Transmit and/or Download Order List; Time
STOP	Sync Stop

Display overview

The device features a ¼ VGA 320 x 240 pixels LCD color display for valuable preview of ECG waveform, function key labels, and other parameters as explained below. During ECG acquisition, notification messages will also appear on the display.

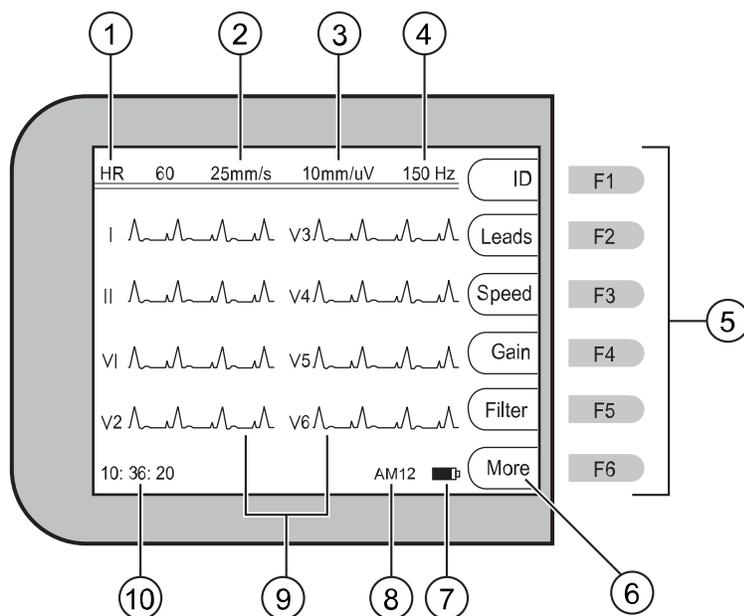


Figure 6: Display

No.	Description
1	Heart Rate (or Lead Fail indicator)
2	Speed
3	Gain
4	Filter
5	Function Keys
6	Function Key Labels
7	Battery Indicator
8	Acquisition Module
9	Waveform Display
10	Clock

Display parameters

Patient Heart Rate [HR]

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

Speed

Use F3 (Speed) to select display speed or rhythm printout speed: 5 mm/s, 10 mm/s, 25 mm/s, or 50mm/s. Paper speed is printed at the bottom right corner of the ECG printout.

Gain

Use F4 (Gain) to select waveform amplitude for display and printout: 5 mm/mV, 10 mm/mV, or 20 mm/mV. Gain is printed at the bottom right corner of the ECG printout.

Filter

Use F5 (Filt) to select the low-pass filter options: 40 Hz, 150 Hz, or 300 Hz for ECG printouts. Filter is printed at the bottom right corner of the ECG printout.



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

Function keys

Function keys activate the LCD label adjacent to each function key. LCD labels/functions change depending upon the screen displayed. If the label is blank, the function key is not active.

Battery indicator

Indicates available battery power.

Acquisition module

Displays type of acquisition module being used.

Clock

Time display with hour, minutes, and seconds resolution. When the ECG is acquired, the time displayed is the printed ECG acquisition time.

Display parameters

Equipment preparation

Initial startup

With initial use, the device requires certain configurations be set prior to obtaining ECGs. See "System settings" to set language, AC filter frequency, and height/weight units of measure.

- Date and time (including daylight savings time selection)
- Language (not editable)
- AC filter frequency (not editable)
- Height/weight units of measure (not editable)
- **WAM** pairing (if used)

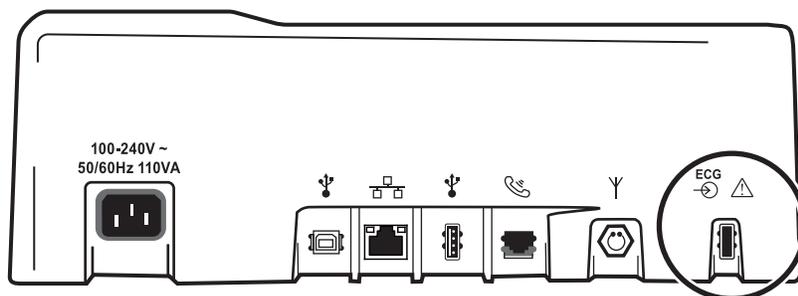


NOTE Refer to the **WAM** user manual for detailed pairing instructions to the device.

Connecting the acquisition module

Connect the **AM12** to the ECG connector at the rear of the device. When using the optional **WAM** for ECG acquisition, this connector is not required.

Figure 7: Connect the AM12 to the ECG



NOTE The device must be configured at the factory for use with the **WAM**. Select **F6** (More) followed by **F6** (More) to determine the device's setting. "WAM Option Not Available" will display if the device is not configured to work with the **WAM**.



NOTE **WAM** must be paired to electrocardiograph before operation. Please see the **WAM** user manual for instructions.



NOTE To use the **AM12** in a **WAM**-configured device, turn the **AM12** on, select **WAM** in the Configuration Screen, and press **AM12 On**.

Load paper

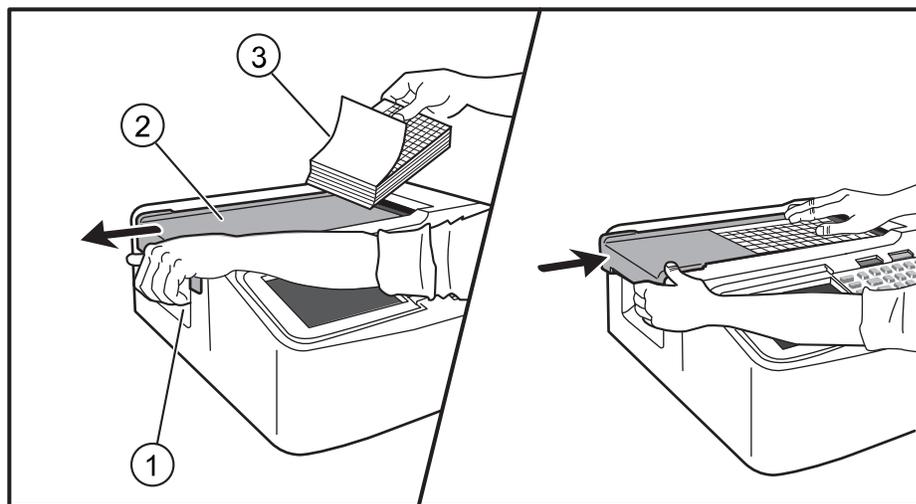


Figure 8: Load paper

No.	Description
1	Paper door latch
2	Paper tray cover
3	Paper

1. Remove all packaging including cardboard backing from the paper stack.
2. Facing the front of the device, use the release latch on the left side and slide the paper tray cover to the left.
3. Place the stack of thermal paper into the paper tray such that the grid side of the paper is up when it is pulled over the paper tray cover. The paper cue mark (a small black rectangle) should be in the lower left corner.
4. Manually advance one page of paper beyond the closure point of the writer. Make sure the paper lays on the black roller evenly within the channel of the paper door. If paper is not manually advanced evenly, risk of jamming or queue faults increases.
5. Slide paper tray cover to the right until the cover latches in a locked position. You will hear a sharp click when the door is properly latched.



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



NOTE For proper printing performance, be certain to use Baxter recommended thermal paper.

Powering the ELI 150c

1. Plug the power cord into an AC wall outlet and into the back of the device.
Refer to "Figure 3: Rear".
2. Press the power **ON/OFF** button located on the face panel of the device.
Refer to "Figure 5: Display and keyboard".

When using battery power, the battery indicator illuminates in green with a 35% to 100% charge and in yellow with a 20% to 35% charge. The battery indicator will turn to red when the battery charge is 20% or less.

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

Battery voltage is displayed at the bottom of the Time/Date screen.



NOTE There are configurable features on the device that can be used to help prolong battery life. Proper battery care and maintenance will also help prolong battery life.



CAUTION The device can be operated on AC line voltage in the absence of a battery or in the event of an otherwise fully depleted battery. When line voltage is removed the system immediately and automatically continues on battery power. When the battery voltage is below 10.5V the device will automatically power down. Once the battery voltage rises above 10.5V the device may be operated on battery power. It may require up to 30 hours on AC line voltage to recharge the battery from its lowest level. Routinely discharging a battery to the lowest level will severely shorten the life of the battery.



NOTE When the On/Off button is depressed for longer than approximately 10 seconds, the electrocardiograph will do a "hard reboot" and reset the internal clock to default date and time (1-1-2010) and advise the user to "Set date/time." When turned on, the user will need to re-enter the date and time. This requirement may be bypassed if desired and an ECG can be acquired by selecting **F6** (Exit) or **F5** (Save), but this ECG will have the date of 1-1-2010. With the next patient the electrocardiograph will request the operator to enter the proper time and date again.

Low battery conditions

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

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

Log-in screen

When the Log-In Authentication mode is enabled (see "System settings"), and the device is powered on or comes out of standby mode, a username/password prompt will display. If the Log-In Authentication is not enabled (default setting), the device will proceed to the real-time ECG view.

To log-in, enter a username and password that match credentials found in the device's user list ("Configuration settings" for details on configuring the user list and default password settings). Successful log-in grants access based on role, which is set in the users list. Log off occurs after 10 minutes of inactivity.

Selecting Guest on the log-in screen bypasses the username and password entry. This allows quick access to the ECG functionality and gives the ability to configure the user list.

Username

- Letters are converted to upper case.
- Pressing a letter enters an uppercase letter.
- Holding the SHIFT key while simultaneously pressing a letter, enters an uppercase letter.
- Holding the ALT key while simultaneously pressing a letter, enters a lowercase letter.

Password

- Letters are not converted to upper case.
- Pressing a letter enters a lowercase letter.
- Holding the SHIFT key while simultaneously pressing a letter, enters an uppercase letter.
- Holding the ALT key while simultaneously pressing a letter, enters a lowercase letter.

Set time and date

1. From real-time ECG view, press **F6** (More) followed by **F5** (Set Time/Date).
2. Use Enter, Tab, F1 (▲), or F2 (▼) to move through each row. Use the keyboard to type in desired values for the date and time (using a 24-hour clock).



NOTE To set time immediately via auto synchronization press **F3** (Sync).

3. Use F3 (▶) to move through the selections for setting Time Zone and Daylight Savings. To use Daylight Savings, select **Yes**. Use F2 (▼) to scroll to, or F4 (Page) to move to the begin/end settings page. Enter the month, day, and time to begin Daylight Savings and the month, day, and time to end Daylight Savings. Use F1 (▲), F2 (▼), or F4 (Page) to return to the previous screen. If the time zone selected does not support Daylight Savings, customize a begin and end time by selecting Custom. The Custom setting can also be used to override the current Daylight Savings settings.

Use the BKSP key to erase entry errors.



NOTE F4 (Page) is only applicable to view read-only (Yes) or change (Custom) a Daylight Savings setting. F4 (Page) cannot be accessed from the Time Zone setting field.

4. Press **F5** (Save) to save changes before exiting.
5. Press **F6** (Exit) to return to real-time ECG view. If you did not save before selecting Exit, any changes made to the time or date will be lost.



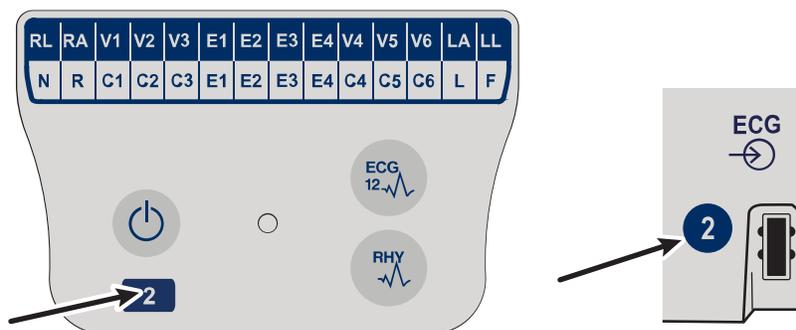
NOTE Date and time may be set to auto synchronization with the cardiology management system if available. See "System settings".



NOTE In the event of a hard reboot or the loss of battery power, the device will require the date and time to be re-entered. The device will present a message stating Set Date/Time. The user then by depressing any key (except alt, shift or power) will enter the date and time entry menu. You may bypass this by selecting **F6** (Exit) or **F5** (Save).

Important version information for the Wireless Acquisition Module (WAM)

There are two generations of **WAM** (Wireless Acquisition Module) and **UTK** (USB Transceiver Key). A legacy **WAM** and **UTK** and a newer version 2 **WAM** and **UTK**.



A number 2 located on the **WAM** label indicates a 30012-019-56 version 2 **WAM**.

If this number 2 label is not present it indicates a version 1 **WAM**.

A number 2 circular label on the back housing of the ELI electrocardiograph located next to the ECG input connector indicates the electrocardiograph internally contains a version 2 **UTK**.

If this circle 2 label is not present it indicates the electrocardiograph internally contains a version 1 **UTK**.

Important note regarding WAM connectivity

A version 1 **WAM** must be used with a version 1 **UTK**, and a version 2 **WAM** must be used with a version 2 **UTK**. If the version of **WAM** does not match the version of **UTK** that is within the ELI electrocardiograph, the **WAM** will not pair to the electrocardiograph and a **SEARCHING FOR WAM** message will continue to be displayed. When using the **WAM**, it must be successfully paired to the electrocardiograph before operation.

Using the **WAM** acquisition module

ECG acquisition and rhythm strip printing can be performed at the **WAM** acquisition module in addition to the **ELI** electrocardiograph. To use the **WAM**, refer to the **WAM** user manual.



NOTE The device must be configured at the factory for use with the **WAM**. Select **F6** (More) followed by **F6** (More) to determine the device's setting. **WAM Option Not Available** will display if the device is not configured to work with the **WAM**.



NOTE **WAM** must be paired to electrocardiograph before operation. Refer to the **WAM** operation manual for assistance in pairing the **WAM**.

Using the **AM12** acquisition module

ECG acquisition and rhythm strip printing can be performed at the **AM12** acquisition module after the patient is connected in addition to the **ELI** electrocardiograph. Refer to "Record an ECG" to prepare the patient.

1. Press  to acquire 12-lead ECG.
2. Press  for continuous rhythm print; press again to stop printing.

The LED indicates status of the connected leads:

- Not lit = Electrocardiograph is powered off or **AM12** is not connected.
- Green light = Power is on and all leads are connected.
- Yellow light = Lead fail.



Installing the WLAN antenna

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

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



NOTE For more information about the use of the WLAN option, refer to "Connectivity and ECG transmission".

Record an ECG

Patient preparation

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

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

Preparing patient skin

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

To prepare the skin:

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



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

Patient hookup

Correct electrode placement is important for acquiring a successful ECG.

A good minimum-impedance pathway will provide superior noise-free waveforms. High quality silver-silver chloride (Ag/AgCl) electrodes similar to those provided by Baxter are recommended to be used.



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

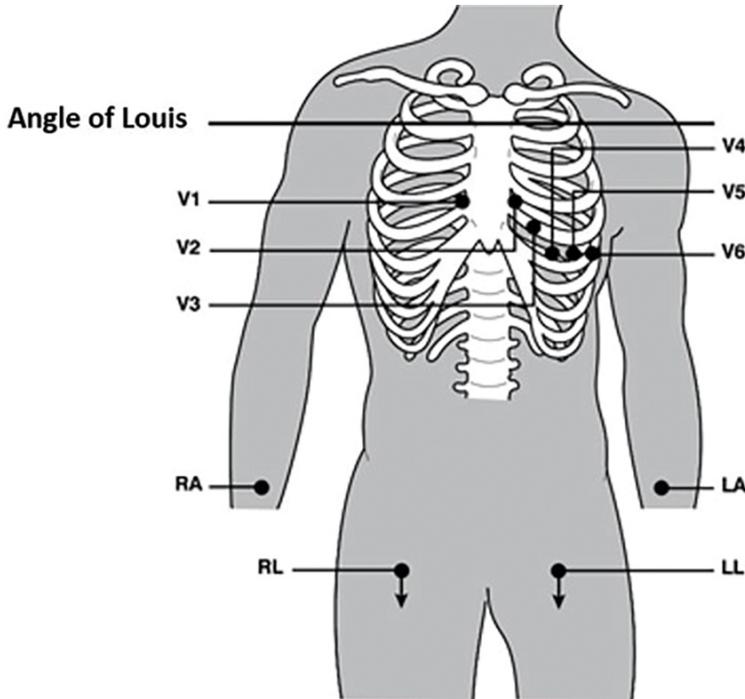
Attach the electrodes

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

For accurate V-lead placement and monitoring, it is important to locate the 4th intercostal space. The 4th intercostal space is determined by first locating the 1st intercostal space. Because patients vary with respect to body shape, it is difficult to palpate the 1st intercostal space with accuracy. Thus, locate the 2nd intercostal space by first palpating the little bony prominence called the Angle of Louis, where the body of the sternum joins the

manubrium. This rise in the sternum identifies where the second rib is attached, and the space just below it is the 2nd intercostal space. Palpate and count down the chest until you locate the 4th intercostal space.

Patient hookup summary table



AAMI Lead	IEC Lead	Electrode Position
V1 Red	C1 Red	On the 4 th intercostal space at the right sternal border.
V2 Yellow	C2 Yellow	On the 4 th intercostal space at the left sternal border.
V3 Green	C3 Green	Midway between V2/C2 and V4/C4 electrodes.
V4 Blue	C4 Brown	On the 5 th intercostal space at the left midclavicular line.
V5 Orange	C5 Black	Midway between V4 and V6 electrodes.

AAMI Lead	IEC Lead	Electrode Position
 Violet	 Violet	On the left midaxillary line, horizontal with V4 electrode.
 Black	 Yellow	On the deltoid, forearm, or wrist.
 White	 Red	
 Red	 Green	On the thigh or ankle.
 Green	 Black	

Patient demographic entry

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

To access the patient demographic data entry menu, press **F1** (ID) from real-time ECG view. Use the appropriate function key to select the desired study group. The patient demographic labels available are determined by the ID format selected in the configuration settings. In addition to short or long patient ID formats, the device also supports a custom ID format. The custom format, designed in **ELI Link** or an **E-Scribe** data management system, can be downloaded to the device. Additional information about the custom ID can be found in the Connectivity and ECG Transmission Section, or in the **ELI Link** and **E-Scribe** user manuals.

Patient demographic entry can be completed manually or automatically using an existing patient record in the directory.

- To manually enter the patient demographics, use **Enter**, **Tab**, **F1** (▲), or **F2** (▼) to move to each data entry field.
- To enter gender, use **F3** (►) to move through the options, or type **F** or **M** from the keyboard to change the gender to female or male.
- When done, select **F6** (Done). Skipped fields will appear as a blank field on the header of the ECG printout.
- To automatically populate the demographics using an existing patient record, select **F5** (Dir) from the ID screen.

The patient's date of birth should be entered whenever possible to ensure interpretation (if set in configuration settings) is as complete as possible.



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

Record an ECG



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



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



NOTE Where mandatory fields have been selected (i.e., Name, ID, or Tech Initials), the required field will be highlighted in red.

- Use **F1** (▼/▲) to navigate by line down the directory list; use **1'** (Shift), **F1** (▼/▲) to move up.
- Use **F2** (▼▼/▲▲) to page down the directory list; use **1'** (Shift), **F2** (▼▼/▲▲) to page up.
- To quickly select a patient name, use the keyboard to enter the first few letters of the last name. The letters will be displayed in the lower left corner of the display screen and the desired name will automatically be highlighted. Once the desired name is highlighted, press **F3** (Select) and the patient ID screen will return with all demographic fields populated.
- Return to real-time ECG view by selecting **F6** (Done).



NOTE Automatically populating demographic fields via the directory is only possible when the ID formats are the same between records.



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



NOTE A red ID label indicates there are no entries in the ID demographics, or a required field is missing from the selected patient demographics.



NOTE If Log-In Authentication mode is enabled, only the orders for the site(s) the logged in technician has access to will be available. Site Administrator and Administrator have access to orders for all sites.

Entering symbols

Punctuation characters, symbols, and/or accented alphanumeric characters (language dependent) can be entered using the SYM key on the keyboard. Selecting SYM will display 10 special characters at a time. Use **F1** (Prev) or **F2** (Next) to move to the previous/next set of special characters.

Each special character will have a numeric character located below it. Using the keyboard, press the desired numeric key to add the corresponding special character. Select **SYM** or **F6** (Done) to exit the symbol entry mode.

Auto-Fill ID

If Auto-Fill ID is enabled in the configuration, the system will automatically populate the demographic fields in the ID screen. When the patient ID field is manually populated and followed either by selecting **F6** (Done) or **F2** (▼), the system automatically scans the patient directory. If records with the exact patient ID are found, the existing data is used to fill some of the demographic fields. The auto-fill feature is designed to automatically populate last name, first name, date of birth, age, and gender only. If no matching records are found, a brief message is displayed and the user must manually enter the patient's demographics.



NOTE To avoid the use of incorrect data, the auto-fill feature is only possible when the ID formats are the same between records.

When time is of the essence or if patient demographics are not available, ID information can be added to the ECG after it has been acquired via the patient directory. Acquiring an emergency (STAT) or unidentified ECG is explained in "ECG Acquisition", "Printing", "Storage".

ECG acquisition

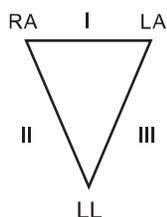
Once the patient is connected, the device continuously collects and displays ECG data; therefore, before you press ECG or RHY you should instruct the patient to relax in a supine position to ensure that the ECG is free from

artifact (noise) due to patient activity. If workflow permits patient demographic entry prior to acquisition, enter the patient identification information as explained in "Patient Demographics". After you complete the last data entry field, select **F6** (Done) to return to the real-time ECG view.

Examine the display for any of the following notification messages:

Message	Description
Leads Off	Displays when patient is not connected.
Lead Fault	Displays faulty lead(s). Re-prep and replace electrode(s) if necessary to obtain satisfactory waveform(s). See "Patient preparation".
Electrode Wrong Position	<p>Displays one of the following when a lead is connected incorrectly or is in the wrong location. See "Patient preparation".</p> <ul style="list-style-type: none"> • Limb leads misplaced? • LA or LL misplaced? • RA or RL misplaced? • RA or LL misplaced? • RA or LA misplaced? • V1 or V2 misplaced? • V2 or V3 misplaced? • V3 or V4 misplaced? • V4 or V5 misplaced? • V5 or V6 misplaced? <p> NOTE The algorithm detecting electrode misplacements is based on normal physiology and ECG lead order, and tries to identify the most likely switch; however, it is advisable to check the other electrode positions in the same group (limb or chest).</p>
WAM Low Battery	Displays when a low battery signal for the WAM is detected.
Searching for WAM	Displays when the WAM is not detected. Occurs usually when the WAM is out of range or not powered on.

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



Artifact	Check electrode
Lead II and III artifact	Poor LL electrode or left leg tremor
Lead I and II artifact	Poor RA electrode or right arm tremor
Lead I and III artifact	Poor LA electrode or left arm tremor

Artifact	Check electrode
V Leads	Re-prep site & replace electrode

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



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



NOTE Functions are not available during acquisition.



NOTE Change real-time display leads by selecting **F2** (Leads).

Acquire an emergency STAT or unidentified ECG

Acquire an emergency STAT or unidentified ECG from a new patient.

- Press the ECG key twice.
Collecting 10 seconds of data is displayed on the top of the LCD and captured, analyzed, formatted is displayed on the bottom of the LCD.
- To save the captured ECG, select **F1** (ID) to enter patient demographics.
- At the `New Patient?` prompt, select **No**.
The device will display the last patient record entered. (If “Yes”, is selected the ECG will not be saved and the user will return to the real-time ECG view.)
- Use the existing information, enter new demographics, or search the directory. Once completed, select **F6** (Done).
- Select **F3** (Print) to print or **F6** (Done) to exit.
- Choose to save or delete the ECG at the `Save ECG?` prompt.

Best 10 seconds selection

The **ELI 150c** incorporates a 5-minute memory buffer for collection of ECG data. When the **Best 10** feature is enabled, the device will automatically select the best 10 seconds of ECG from within the 5-minute buffer. The best 10 seconds is determined based upon measures of high and low-frequency noise found in the 10-second ECG segments. Should a single limb lead or two precordial lead fail conditions occur, the Best 10 feature is disabled until the limb lead fail or precordial lead fail condition is resolved. At resolution, the **Best 10** feature becomes available and the selection buffer continues.

Switch between **Best 10** or **LAST 10** by selecting **F5** (More) followed by **F5** (Last) or **F5** (Best) depending on the current view.

Printing

If Auto-Print is enabled in the configuration, an ECG is printed following acquisition. To print a manual printout, select **F3** (Print).

Toggle through the available waveform display formats (3, 8 or 12 lead) by selecting **F2** (Leads). A preview of the full 10-seconds of ECG waveform is available in the acquired ECG view. The first 5 seconds are shown on the initial view screen (page 1/2 is displayed in the upper right corner); the second 5 seconds is viewed by selecting **F2** (Leads) again (page 2/2 is displayed in the upper right corner).

If the auto-print configuration is disabled, a 10-second preview will assist in ensuring a quality ECG acquisition prior to printing. When you acquire an ECG, the electrocardiograph captures the last 10 seconds. The relationship

between the display and the printout is the same – what is displayed in the ECG acquisition view is what will be printed.

In order to change the speed, gain, filter, or printout format in the acquired ECG view, select **F5** (More). To manipulate the print format of the acquired ECG regardless of the plot format configuration setting, select **F4** (Fmt).

Select the function key corresponding to the desired print format. The acquired ECG view is then displayed and to make an ECG printout copy in the new plot format, select **F3** (Print). Select **F6** (Done) to return to the real-time ECG view.

Storage

The device stores and saves all acquired ECGs automatically.



NOTE Users may delete an acquired ECG from the acquired ECG screen. Once the delete selection has been made, a confirmation message will appear. Select **Yes** to permanently delete the record.

Acquiring rhythm strips

Rhythm strips are printed in the format defined in the configuration: 3 or 6 channel for the **ELI 150c**. See "Rhythm Leads" for instructions how to configure rhythm leads.

1. Begin routine rhythm strips by connecting the patient to the device and entering the patient identification information.
2. After the last data entry field from the ID menu is completed, select **F6** (Done) to return to the real-time ECG view.
3. Select **RHY** to begin rhythm printing. You can also acquire a rhythm printout by selecting RHY without entering the patient ID.



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



NOTE Rhythm acquisitions are only printed and not stored in the device.

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

In addition to manipulating Speed, Gain, and Filter, the user can toggle different lead groups: change lead groups during printing by selecting **F2** (Leads). The change in lead groups is apparent on the printout whereas the waveform display will remain in the default display of 2.5 seconds of Leads I, II, and V1-V6.

During 3-channel rhythm printing, the available lead groups are:

- Default (user-selected in configuration)
- I-II-III
- aVR, aVL, aVF
- V1-V2-V3
- V4-V5-V6

During 6-channel rhythm printing, the available lead groups are:

- Default (user-selected in configuration)
- I-II-III-aVR-aVL-aVF
- V1-V2-V3-V4-V5-V6

Record an ECG

During rhythm printing, place the printer in Standby mode by pressing **F6** (Stby). To continue rhythm printing for the same patient without advancing to a new page, select **F6** (Cont). To stop the rhythm printing, press **STOP** and the printer will automatically form feed in preparation for a new patient's rhythm recording or ECG.

Connectivity and ECG transmission

ECG transmission

ECGs can be transmitted to **ELI** Link, or to a third party EMR using an optional factory installed internal modem, LAN, or WLAN. All of the mentioned transmission modes can use the UNIPRO or **DICOM** communication protocol.



NOTE Units ship by default with Comm Protocol set to UNIPRO. The UNIPRO setting is not supported by **E-Scribe** versions prior to V8.10 or **ELI** Link versions prior to V3.10. For questions about compatibility of your device with **E-Scribe** or **ELI** Link and UNIPRO, contact Baxter Technical Support.

Before ECGs can be transmitted, specific system settings must be configured based on the transmission method and the type of electronic storage media being used. See "System Settings".



NOTE Telephone transmission is available with internal modem only.



NOTE In order to properly connect to telephone lines, the device's internal modem needs to be set on the proper country code. This is an internal setting and should not be confused with international calling codes.

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

Item	Description
Sync	Transmit records.
Stop	Stop transmission.
F2	Choose a record from the patient directory to transmit.
F1 (▼/▲)	Navigate by line down the directory list.
↑ (Shift), F1 (▼/▲)	Move up the list.
F2 (▼▼/▲▲)	Page down the directory list.
↑ (Shift), F2 (▼▼/▲▲)	Page up.
F3 (Sync)	Transmit the individual ECG.
F1 (Batch)	Transmits all records in the directory.

To quickly select a patient name, use the keyboard to enter the first few letters of the last name. The letters will be displayed in the lower left corner of the display screen and the desired name will automatically be highlighted.

When the desired record is highlighted, use **F3** (Sync) to transmit the individual ECG.

To batch transmit all records in the directory, select **F1** (Batch). In a batch transmission, only those records which have not been previously transmitted or marked for deletion will be transmitted. After the transmission of your record(s), the real-time ECG view is displayed.

Modem transmission

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



CAUTION Use only No. 26 AWG or larger telecommunication line cord.

Modem initialization

The modem initialization string is country specific. At the time of production, the modem initialization string is configured for the country of purchase; however, if the unit is relocated to a different country, the modem initialization string will need to be modified.

From the real time ECG view:

1. Power on the device.
2. Press **F6** (More).
3. Simultaneously press and hold **SHIFT+ALT+M**.
4. The country code will display on the bottom of the screen.
5. Verify the code is correct by using the table in this section. If the code is correct for your country, press **F6** (Exit).
6. If the code is incorrect for your country, press **F2** and enter "+CGI=", then enter the correct code for your country.
7. Press **F1** to send the new code to the modem.
8. After the code has been sent, the device will query the modem and display its current configuration.
9. Press **F6** (Exit) to end the procedure.

Modem country code list

Country	Code
Unless otherwise listed	34
Australia	1
Czech Republic	25
Korea, Republic of (South Korea)	30
Hong Kong	30
Hungary	30
India	30
Indonesia	30
Israel	30
Japan	10
Malaysia	30
New Zealand	9
Philippines	30
Poland	30

Country	Code
Singapore	30
Slovenia	30
Vietnam	30

LAN transmission

For a LAN transmission, connect the Ethernet cable to the LAN connection at the rear of the device and set the Sync media to LAN in the configuration. It is necessary that the IT Manager of your facility set the device's LAN configuration values.



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

Ethernet status LEDs

The device's LAN will support 10 and 100 mbps networks.

At the external LAN interface connector, the user is presented with two LEDs (Light Emitting Diodes). The two status indicator LEDs provide signals for "link status" and "packet transmit/receive". As the external connector is viewed from the outside rear of the device, the left LED remains illuminated when the network link is detected. The right LED flashes when a transmit or receive packet occurs or any traffic on the network is detected.

WLAN transmission

For a WLAN transmission, set the Sync media to WLAN. It is necessary that the IT Manager of your facility configure the wireless access point(s) and **ELI** Link or **E-Scribe** workstation. It is also required that your IT Manager provide the device's WLAN configuration values. The device can be configured for Dynamic Host Communication Protocol (DHCP) or static IP. Wireless security encryption options include WEP, WPA, WPA2, LEAP, and PEAP.



NOTE Environmental conditions may affect the reliability of WLAN transmissions.



NOTE When saving the WLAN configuration, the device may require several seconds to complete the saving procedure.

Network / Security protocol settings [LAN & WLAN]

Network / Security Protocol	Status	Network Setting	Parameters to Configure	Notes
DHCP	Disabled	Static	<ul style="list-style-type: none"> IP Address Default Gateway Subnet Mask 	
	Enabled	Automatic	<ul style="list-style-type: none"> Host IP Address Port Number SSID (WLAN only) Channel Number (WLAN only) 	
WEP	Disabled	N/A	<ul style="list-style-type: none"> WEP Security: "NO" 	The range for the WEP key is 0-3. If the range on your access point is 1-4, then 0 at the device maps to 1 on the access point; 1 maps to 2 on the access point, etc.
	Enabled	N/A	<ul style="list-style-type: none"> Security: WEP WEP Key WEP Key ID 	
WPA or WPA2	Enabled	N/A	<ul style="list-style-type: none"> Security: WPA-PSK or WPA2-PSK Passphrase 	WPA stands for Wi-Fi Protected Access Passphrase limited to 64 characters
LEAP	Enabled	N/A	<ul style="list-style-type: none"> Security: WPA-LEAP LEAP Username LEAP Password 	LEAP username and password limited to 32 characters
PEAP	Enabled	N/A	<ul style="list-style-type: none"> Security: WPA2-PEAP PEAP Username PEAP Password 	PEAP username and password limited to 63 characters



NOTE Addresses are always entered as 4 sets of 3 digits; therefore, an address of 192.168.0.7 must be entered on the device as 192.168.000.007.



NOTE All parameters related to network connection must be entered under the direction of the IT Manager of the facility where the device is installed. See the Connectivity and ECG Transmission Section for more information on device connectivity settings.



NOTE Network settings for LAN (first page of settings) and those for WLAN (second page of settings) are independent from each other.

SIM card installation

1. Power off the **ELI 150c**.
2. Open the printer cover and remove the pack of thermal paper.
3. Locate the small access panel on the floor of the paper tray. Remove the screw, and lift off the access panel.

- Using your finger, slide the SIM card socket towards the back of the unit (follow the arrow printed on the circuit board to the “open position”). Again, using your finger, lift the socket upright.
- To insert the SIM card, hold the SIM card so the gold contact is facing you and the key (angle-notched corner) is in the upper right. Slide the SIM card in between the two recessed notches of the socket. Lower the socket so the SIM card key appears in the lower right corner. Slide the socket towards the front of the unit (follow the arrow on the circuit board to the “lock position”).



NOTE Notched corner of SIM card must be located properly in socket. Do not force socket connector if SIM is not seated properly.

- Replace access panel, screw, and thermal paper. Power on the electrocardiograph.

If a wireless network carrier is not detected at the time of transmission (due to environmental conditions, i.e., poor signal), relocate or reposition the unit for a better signal and reattempt transmission.

In order to change a network carrier, you must scan the wireless network to determine what is detected and available for use. Select **F5** (Scan), a “scanning networks...” message will appear on the LCD. Once the scanning process is completed, the Select Networks screen is available. Highlight the desired network and press **F3** (Select).

Orders download



NOTE A custom ID must be downloaded before downloading the orders. Please reference the **ELI Link** user manuals, and Custom ID Download in this section.

The device can download and process an ECG order list from **ELI Link** or another compatible electronic information management system.

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

- From real-time ECG view, select **F6** (More) followed by **F3** (Orders Download). Use the appropriate function key to select the desired study group.
- Use **F1** (▲) and **F2** (▼) to scroll through the list; use **F3** (Select) to select the desired order code.
- Confirm or deny your download by selecting **F2** or **F4**.

“Transmission Status” will be displayed for approximately 10 seconds followed by “Dialing: telephone number”, “Waiting for Response”, and “Connected”. Once connected, the screen indicates the number of orders (ECGs) received for the order code. This only appears briefly before returning to the real-time ECG view.

- When the order list has been downloaded, you may select the patients who need ECGs. Select **F1** (ID) from the real-time ECG view.

Custom ID download

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

From real-time ECG view, select **F6** (More) followed by **F2** (Custom ID Download). “Transmission Status” will remain visible for approximately 10 seconds followed by “Waiting for Response”, “Connected”, and “Custom ID downloaded”. A return to the real-time ECG view indicates the custom ID download is complete. The custom ID remains the new header format for all future ECGs until you select a different ID format in the configuration settings. You may alter the ID format configuration to short, standard, long, or custom based on your patient demographic entry needs. The custom ID is only deleted upon downloading a new custom ID or on the rare occasion of downloading software – it will not be lost due to power loss or switching to a different ID format.



NOTE Upon custom ID download, the ID format will assume the group name as designed in **ELI Link** or **E-Scribe**.



NOTE The site number must be configured in the electrocardiograph and recognized as an established, valid site number at the **E-Scribe** before downloading the custom ID.



NOTE Confirm the baud rate in the configuration settings before downloading the custom ID from **ELI Link** or **E-Scribe** (applies to **ELI 150c** only).

USB memory

The **ELI 150c** comes equipped with a standard USB host port which can be used to transmit patient records from the device's internal memory to an external USB memory stick. In addition, either device can be equipped with an optional USB D (device) port. The optional USB D port can be used to directly connect the device to a PC running **ELI Link V3.10** or later.

Transmission using the USB host port to a USB memory stick

USB memory communication media permits storage of patient records to an external USB memory stick. The files will be saved in UNIPRO32 format for transfer to the **E-Scribe** or a compatible electronic information management system.



NOTE Device is compatible with FAT32 formatted USB memory sticks.



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



NOTE All communication options (MODEM, LAN, WLAN) including time sync and orders download are disabled when a USB memory stick is inserted in the device.



NOTE Upon successful transmission the device display will state "Transmission status transmit complete. Press any key to continue." The total number of patient records transmitted to the USB memory stick will also appear.



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

Transferring individual patient records to the USB memory stick

1. Place the USB memory stick into the USB host port on the back of the device.
2. Select **F6** (More) from real-time ECG view.
3. Select **F1** (Directory of Stored ECGs).
4. Select the patient record to be stored to the USB memory stick.
5. Select **SYNC**.

Transferring batch patient records to the USB memory stick

1. Place the USB memory stick into the USB host port on the back of the device.
2. Select **SYNC**.
3. Select **F1** (Batch).

Transmission using the optional USB D [device] port to a PC

The optional USB D port permits transmission of stored patient records to a PC using a direct USB cable. The patient records will be transmitted to an **ELI Link** application (requires V3.10 or later) and then exported and saved in various formats (see the **ELI Link** user manual).

Connecting the **ELI 150c** to a PC

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

- Use a USB-D cable to connect the device to a PC.
- When properly connected, the PC will automatically detect the device and automatically install the drivers.

Transmit patient records to **ELI Link**

1. Create both an Input folder and Output folder on the PC.
2. Configure **ELI Link** to the individual Input and Output folders.
3. Connect the **ELI 150c** to the PC.
4. "USB Device ready" will appear on the device display; a "Removable Disk" message will display on the PC.
5. Using the PC mouse, select **Records** from the removable disk window displayed.
6. Select the patient record(s) to be copied.
7. Place the copied record(s) into the Input folder on the PC.
8. After a period of 5 seconds, select the copied record(s) to view on the PC or print via PDF from the Output folder.



NOTE Requires **ELI Link** V3.10 or later. See **ELI Link** user manual for further detail on settings.



NOTE Input and Output folders must be created for records to be stored or retrieved for use in **ELI Link**.



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



WARNING Do not change or modify any information existing in any of the **ELI 150c** folders that are visible on the PC in the removable disk file.



CAUTION To assure consistent operation and avoid confusion, connect only one **ELI 150c** using the USB device port to a PC at a time.

Network test

Network test sends a command to the server to verify there is a network connection. The status will display for the clinician to review. The test information is also placed into the Log File for review.

To view the log type select **F6** (More) from the real-time display, followed by **F4** (Network Test). When test is completed, select either **F3** (Log) to review the log files or **F6** (Exit).

Network log file

The **ELI x50c** will present a sync log file that contains troubleshooting information and status information from the previous SYNC operation. This file will have up to 3 sections (Time Sync, Transmit and Receive Requests), based on the SYNC Mode and Time Sync configuration settings. The contents of this file will be retained for viewing until the next SYNC or Network Test operation has been completed. The information available will contain status information that is currently shown on the screen during the sync operation as well as more detailed connection information and error codes.

System settings

Configuring users and roles

Options for configuring users and roles depends on whether Log-In Authentication is set to ON or OFF in Configuration Settings. If Log-In Authentication is OFF, three generic roles, Technician, Site Admin, and Admin, can be activated to manage access to specific device features. If Log-In Authentication is ON, up to 30 unique users can be configured for the device. The default device setting has Log-In Authentication set to OFF, and no active roles.

Configuring roles when Log-In Authentication is OFF

When Log-In Authentication is OFF, a user can access the basic ECG functionality of the **ELI 150c** without entering a password. If the user attempts to access features that require additional authorization, they will be prompted to input the password of an authorized role. The table below shows which features are accessible by which roles. The Admin role has access to all device features.



NOTE If the password for the Technician remains blank, a guest to the system will have the same access as described in the Technician column.

Configure the roles:

1. From real-time ECG view, select **F6** (More) followed by **F5** (Set Time/Date).
2. While holding down **↑** (SHIFT), depress **ALT** and **P** simultaneously.
3. If required, enter password. This will automatically advance you to the set passwords display.
4. Select which role you want to set the password for: Technician, Site Admin, or Admin.



NOTE The factory default password for the Admin is “admin” (lowercase, no quotation marks); the default for the Site Admin is “siteadmin”; the default for the Technician is a blank field. It is suggested that the password be changed after installation of the unit if utilizing role-based access features.

5. Enter a password for the selected role followed by a second entry to confirm.



NOTE Password is case sensitive and alphanumeric.

6. From this display, select **F6** (Exit) to return to real-time ECG view.

Patient Information

Feature	Guest	Tech	Site Admin
Type in Patient Information	X	X	X
Select Patient Information from Orders List		X	X
Select Patient Information from Patient List (Directory)		X	X

ECG Capture

Feature	Guest	Tech	Site Admin
Accept ECG	X	X	X
Reject ECG	X	X	X
Print ECG	X	X	X

System settings

Feature	Guest	Tech	Site Admin
Transmit ECG	X	X	X
Edit ECG	X	X	X

ECG Directory

Feature	Guest	Tech	Site Admin
View an ECG		X	X
Print an ECG		X	X
Transmit an ECG		X	X
Edit an ECG		X	X
Delete an ECG		X	X

Sync

Feature	Guest	Tech	Site Admin
Custom ID Download			X
Orders / MWL Download		X	X
Date & Time Sync		X	X
Real-Time Sync (Network)	X	X	X
Real-Time Sync (USB)		X	X

Settings

Feature	Guest	Tech	Site Admin
Settings Screens			X
Software Version			X
ECG Storage			X
Manage Passwords			X
Date/Time		X	X
Time Zone		X	X
Daylight Savings Mode and Settings		X	X
WLAN SSID, security, password			X
WLAN static or dynamic IP address			X
WLAN Default Gateway			X
WLAN Subnet Mask			X
LAN static or dynamic IP address			X

Feature	Guest	Tech	Site Admin
LAN Default Gateway			X
LAN Subnet Mask			X
Volume			X
AC Filter			X
Export Audit Trail to USB			X
Software Upload/Download Screen Access			X
Print Configuration	X	X	X

Configuring users when Log-In Authentication is ON

1. From real-time ECG view, select **F6** (More) followed by **F5** (Set Time/Date).
2. While holding down \uparrow (SHIFT), depress **ALT** and **P** simultaneously.
3. If required, enter the admin password. This will automatically advance you to the User List.



NOTE The factory default password is “admin” (lowercase, no quotation marks); it is suggested that the password be changed after installation of the unit.

The User List displays one user per page. Advancing to the next page by selecting **F4** (Page) will show the information for the next user. The device can hold up to 30 different users. If the User List is not full, the last page in the list will be blank and is used for creating new users. Selecting **F3** (Add) will advance to the last page to add a new user. When on a user’s page, selecting **F5** (Delete) will delete that user. Select **F6** (Save) to save changes and exit the User List.

Each new user will be assigned a username, password, role, and up to three site numbers. If a user attempts to create a new user by using a username which already exists, an error message will appear and prevent username duplication.



NOTE When assigning site numbers to a Guest or Technician user, the site number must match one of the site numbers defined in the cardiograph configuration. If an existing site is not assigned a `No Authorized Site Numbers` error message will occur.

When setting the role for the user, there are three options to choose from: Technician, Site Administrator, and Administrator. Each of these three roles, along with a guest role, are given permission to access different features of the device. The admin role has access to all device features while the other roles only have access to a subset of features as defined in the table below.

Patient Information

Feature	Guest	Tech	Site Admin
Type in Patient Information	X	X	X
Select Patient Information from Orders List		X	X
Select Patient Information from Patient List (Directory)		X	X

ECG Capture

Feature	Guest	Tech	Site Admin
Accept ECG	X	X	X

System settings

Feature	Guest	Tech	Site Admin
Reject ECG	X	X	X
Print ECG	X	X	X
Transmit ECG	X	X	X
Edit ECG	X	X	X

ECG Directory

Feature	Guest	Tech	Site Admin
View an ECG		X	X
Print an ECG		X	X
Transmit an ECG		X	X
Edit an ECG		X	X
Delete an ECG		X	X

Sync

Feature	Guest	Tech	Site Admin
Custom ID Download			X
Orders / MWL Download		X	X
Date & Time Sync		X	X
Real-Time Sync (Network)	X	X	X
(ECGs Only if Sync Mode: XMT+Orders / MWL)			
Real-Time Sync (USB)		X	X

Settings

Feature	Guest	Tech	Site Admin
Settings Screens			X
Software Version			X
ECG Storage			X
Manage Users List			X
Date/Time		X	X
Time Zone			X
Daylight Savings Mode and Settings			X
WLAN SSID, security, password			X
WLAN static or dynamic IP address			X

Feature	Guest	Tech	Site Admin
WLAN Default Gateway			X
WLAN Subnet Mask			X
LAN static or dynamic IP address			X
LAN Default Gateway			X
LAN Subnet Mask			X
Volume			X
AC Filter			X
Export Audit Trail to USB			X
Software Upload/Download Screen Access			X
Print Configuration	X	X	X

Configuration menus

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

1. From real-time ECG view, select **F6** (More) followed by **F5** (Set Time/Date).
2. While holding down **↑** (SHIFT), depress **ALT** and **C** simultaneously.
3. Using the keyboard, enter `admin` (lowercase, no quotation marks). The first configuration screen will appear. Notice the page indicator in the upper right-hand corner.

Navigate the configuration menus

Item	Description
F4 (Page)	Toggle through the configuration pages ; use ↑ (SHIFT), F4 (Page) to toggle in reverse.
F1 (▲) and F2 (▼)	Move back and forth through each configuration option.
F3 (►)	Toggle through pre-programmed available settings per configuration field.
F6 (Exit)	Return to real-time ECG view. Any changes you have made will be saved.
BKSP	Erase entry errors.

Print the device's configuration settings

1. Select **F6** (More) from real-time ECG view.
2. Select **F6** (More) again followed by **F1** (Print Configuration).

The configuration printout captures every configuration setting: the software version, the cart number of the device, and the date and time that the configuration printout occurred.

Summary of configuration menus

Configuration Parameter	Definition
Software Version	Displays software version on printout and display
Cart Number	Numeric field 0 to 65535
Site Number	Numeric field 0 to 8191
Site Name	Alphanumerical field (30 digits)
Telephone Number	Alphanumerical field (45 digits)
Language	Available software languages
Volume	Numerical field 0 to 8
Battery Timeout	10 min, 30 min, 60 min
ECG Storage	Normal or expanded (optional) — configured at time of purchase
ID Format	Short, Long, Custom
Auto-Fill ID	YES/NO
AC Filter	50 Hz, 60 Hz, None
Paper Speed	25 or 50 mm/sec
Filter	Frequency response for printouts: 40 Hz, 150 Hz, 300 Hz
Height Units	Inches or Centimeters
Weight Units	Pounds or Kilograms
Interpretation	YES/NO
Reasons	YES/NO
Append	Unconfirmed Report, Reviewed by
# of Copies	0 – 9
Copies with Interp.	YES/NO
Delete Rule	Post Plot, Post Transmit
Storage Resolution	Normal or High
Pace Spike Channel	YES/NO
ID Edit Disable	YES/NO
Cap Lock	YES/NO
Rhythm Format	3 or 6 channel
3 Rhythm Lead 1	V1-V6, I, II, III, aVR, aVL, aVF
3 Rhythm Lead 2	V1-V6, I, II, III, aVR, aVL, aVF
3 Rhythm Lead 3	V1-V6, I, II, III, aVR, aVL, aVF
6 Rhythm Lead 1	V1-V6, I, II, III, aVR, aVL, aVF
6 Rhythm Lead 2	V1-V6, I, II, III, aVR, aVL, aVF

Configuration Parameter	Definition
6 Rhythm Lead 3	V1-V6, I, II, III, aVR, aVL, aVF
6 Rhythm Lead 4	V1-V6, I, II, III, aVR, aVL, aVF
6 Rhythm Lead 5	V1-V6, I, II, III, aVR, aVL, aVF
6 Rhythm Lead 6	V1-V6, I, II, III, aVR, aVL, aVF
Plot Format	3, 3+1, 3+3, 6 channel; Cabrera or standard
3+1 Rhythm Lead	V1-V6, I, II, III, aVR, aVL, aVF
3+3 Rhythm Lead 1	V1-V6, I, II, III, aVR, aVL, aVF
3+3 Rhythm Lead 2	V1-V6, I, II, III, aVR, aVL, aVF
3+3 Rhythm Lead 3	V1-V6, I, II, III, aVR, aVL, aVF
Bar Code Scanner	YES/NO
Avg RR	YES/NO
QTcB	YES/NO
QTcF	YES/NO
ECG Capture	Last 10 or Best 10
Encryption Key	Up to 16 characters
DHCP (active for LAN or WLAN)	YES/NO
IP Address (active for LAN or WLAN)	XXX.XXX.XXX.XXX
Def Gateway (active for LAN or WLAN)	XXX.XXX.XXX.XXX
Sub Net Mask (active for LAN or WLAN)	XXX.XXX.XXX.XXX
Host IP (active for LAN or WLAN)	XXX.XXX.XXX.XXX
Port Number (active for LAN or WLAN)	Numeric field (9 digits)
Security	<p>Versions 2.2.0 and earlier: None, WEP128, WEP64, WPA-PSK, WPA-LEAP, WPA-PSK64, WPA-PSK128, WPA-LEAP 64, WPA-LEAP128, WPA2-PSK, WPA2-PEAP</p> <p>Version 2.2.1 and later: WPA2-PSK, WPA2-PEAP, WPA2-EAP-TLS</p> <p>Note: Following the software upgrade to 2.2.1 or higher, if the wireless is not connected, reconfigure the Wi-Fi to available secure protocols.</p>

Configuration Parameter	Definition
LAN MAC	XX XX XX XX XX XX
WLAN MAC	XXXXXXXXXXXX
SSID	Alphanumeric field (30 digits) (not on printout)
WEP Key	Numeric (1 digit) (not on printout); valid range 1-4 Only available in version 2.2.0 and earlier.
WEP Key ID	Alphanumeric field (26 digits) A-F, 0-9 (not on printout) Only available in version 2.2.0 and earlier.
PSK Passphrase	Alphanumeric field (64 digits) (not on printout)
LEAP Username	Alphanumeric field (32 digits) (not on printout) Only available in version 2.2.0 and earlier.
LEAP Password	Alphanumeric field (32 digits) (not on printout) Only available in version 2.2.0 and earlier.
PEAP Username	Alphanumeric field (63 digits) (not on printout)
PEAP Password	Alphanumeric field (63 digits) (not on printout)
Comm Protocol	UNIPRO or DICOM
Sync Mode	None, XMT, XMT+Orders (XMT+MWL if DICOM selected)
Sync Date/Time	YES/NO
XMT Mandatory Fields	None, Last Name, ID, and/or Tech ID
Audit Trails	YES/NO
File Encryption	YES/NO
File Encryption Key	Alphanumeric field (32 digits) (not on printout)
Log-In Authentication	YES/NO
WPA2-EAP-TLS Username	Alphanumeric field (63 characters)
WPA2-EAP-TLS Password	Alphanumeric field (63 characters)

Software version

Identifies the software version of your electrocardiograph.

Cart number

Indicates which electrocardiograph acquired or transmitted a particular ECG.

Site number

Identifies the site of your device. Site numbers designate the hospital, clinic, or institution for ECG records stored in an **E-Scribe** system and must be defined for transmitting and retrieving ECGs from that system. You can use up to four digits for the site number. Numbers from 0 – 8191 are supported.

Site name

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

Telephone number

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

You may need to dial a 9 to get an outside line. To wait for an additional dial tone, use the letter w. EXAMPLE:

9W14145554321

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

EXAMPLE:

P14145554321

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



NOTE To quickly delete or modify a phone number, use a shortcut. From the application screen, simultaneously press (**SHIFT**) + **ALT** + **P**. To edit an existing telephone number, use the **Tab** key.

Language

There are several languages available on the electrocardiograph.



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

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

1. **F6** (More) from real-time ECG view.
2. Select **F5** (Set Time/Date).
3. Simultaneously press ↑ (**SHIFT**) + **ALT** + **C**.
4. Enter password (admin)
5. Press **F2** (▼) four times.
6. Press **F3** (►) until the desired language appears.
7. **F6** (Exit) to return to real-time ECG view.

Alphabets of specific languages may require use of special characters in demographic fields. This is accomplished by using the SYM key on the keyboard.

Volume

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

Battery time out

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

ECG storage

Indicates ECG storage capacity. Normal indicates standard memory capacity of 40 patient records. Expanded indicates the optional expanded memory (200 patient records) has been installed.

ID format

Defines the format for the patient demographic information prompts. There are two standard formats: short or long. A custom ID format can be downloaded from **ELI** Link or an **E-Scribe** system. See the "Connectivity and ECG Transmission" section to download a custom ID.

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

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

Auto-fill ID

When enabled, the device will automatically populate last name, first name, date of birth, age, and gender in the ID screen if records with matching patient ID are found in the ECG directory.

AC filter

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

Paper speed

Configure to 25 mm/s or 50 mm/s for default ECG printouts. For rhythm printouts and display, speeds of 5 mm/s or 10 mm/s are also available. See "Display Parameters" section to change speeds for display or rhythm printing. Paper speed is printed at the bottom right corner of the ECG printout.

Filter

The ECG plot-frequency filter (or print filter) can be set to 0.05 to 40 Hz, 0.05 to 150 Hz, or 0.05 to 300 Hz. The plot-frequency filter does not filter the acquired digital record. A 40 Hz plot-filter setting will reduce the noise (40 Hz and higher frequencies) on the printed ECG, and a 150 Hz plot-filter setting will reduce the noise (150 Hz and higher frequencies) on the printout; a 300 Hz plot-filter setting will not filter the printed ECG. The filter setting is printed at the bottom right corner of the ECG printout.

Height and weight units

Defines the units of height (in./cm) and weight (lb/kg). Settings are selected independently of each other, allowing for metric or U.S. forms of measurement to be used simultaneously or separately.

Interpretation

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



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

Reasons

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

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

Where “Anteroseptal Infarct” is the interpretive statement, and “40+ ms Q WAVE IN V1-V4” is the reason statement or explanation as to why the interpretive statement was printed.

Append

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

Number of copies

Defines the number of printed copies when an ECG is taken. A zero (0) setting prints no ECG; one (1) prints the original; two (2) prints the original plus 1 copy, and so on. Up to 9 copies may be selected.

Copies with interpretation

Defines whether printed copies will include interpretation. The clinician may request the first ECG printout with the interpretation included. Additional copies may be printed with or without the interpretation.

Delete rule

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

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

Storage resolution

Dictates the resolution of all stored ECG records. The resolution setting is either **Normal** or **High**. If the value is set to **High**, the stored ECG will have a high resolution. As a result, the record size will be large and will reduce the storage capacity in the ECG directory.

Pace spike channel

Determines whether a pacemaker spike(s) notification marker(s) will display at the base of the ECG printout.

ID Edit disable

Selecting **YES** allows the ID to be edited at any time before the completion of the record or while still in the acquired screen. Once the acquired screen has been left and the record is stored in the directory, the ID demographics can no longer be edited at the electrocardiograph.

Caps lock

All character entry is translated to uppercase.

Rhythm formats

Defines the default values for rhythm printing. It is possible to set a 3 or 6-channel default rhythm format for the **ELI 150c**. Define rhythm leads one through three to customize a 3-channel rhythm printout or define rhythm leads one through six to customize the 6-channel rhythm printout.

Plot format

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

The ECG plot options are:

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

Rhythm leads

Displays continuous rhythm of selected ECG leads and permits printing of selected leads. User may toggle between selected leads, system set leads, or I, II, III, aVR, aVL, and aVF followed by V1, V2, V3, V4, V5, and V6.



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



NOTE See "Rhythm Acquisition" to acquire a rhythm printout.

Bar code scanner

Enabling this option will allow for the use of a Baxter approved USB bar code scanner.

Average RR

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

QTcB

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

QTcF

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

ECG capture

Up to 5 minutes accumulated ECG data can be acquired internally for use with the Best 10 feature. The device automatically selects the best 10 seconds from within the 5-minute buffer.

Users can switch between BEST 10 or LAST 10 by selecting **F5** (More) followed by **F5** (Last) or **F5** (Best) depending on the current view.

Encryption key

Encryption Key is a sequence of numbers used to encrypt or decrypt data and can consist of up to 16 alpha/numeric characters. All transmissions from x50c are sent using AES 256-bit encryption. The encryption key in the config menu allows the user to set a custom pre-shared key between the cart and **ELI** Link version 4.00 or later (all carts transmitting to one **ELI** Link must share the key) otherwise a default hidden key will be used.

Band mode

Use 850/1900 MHz (US) or 900/1800 MHz (EU). Applies to **ELI** 150c only.

DHCP

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



NOTE All parameters related to network connection must be entered under the direction of the IT Manager of the facility where the device is installed. See the "Connectivity and ECG Transmission" section for more information on device connectivity settings.



NOTE Network settings for LAN (first page of settings) and those for WLAN (second page of settings) are independent from each other.

IP Address

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



NOTE An IP address will be required for both LAN and WLAN applications.

Def Gateway

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

Sub Net Mask

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

Host IP

Enter the IP address of the host server.



NOTE Addresses are always entered as 4 sets of 3 digits; therefore, an address of 192 . 168 . 0 . 7 must be entered as 192 . 168 . 000 . 007.

Port Number

Enter the port number used by the host server.

LAN MAC

Shows the MAC address of the LAN.

Security [WEP]

Wired Equivalent Privacy (WEP) is an encrypted security protocol (part of the 802.11 standard). Access points can have multiple WEP keys stored. Each one of them is identified by a number (e.g., 1, 2, 3, 4).

WEP Key / ID

Enter the WEP key number.

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

WLAN MAC

Shows the MAC address of the device's wireless module for configuring access points.

SSID

Service Set Identifier (SSID) is the name of the wireless network. All **ELI** 150c electrocardiographs that will transmit to the same network must have the same SSID name. This field is case sensitive.

WPA-PSK/WPA2-PSK

Allows for implementation of the personal mode of WPA. This mode of encryption employs Temporal Key Integrity Protocol (TKIP) which dynamically changes keys as the system is used.

PSK Passphrase

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

WPA-LEAP

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

Username can be up to 32 characters in length.

LEAP password can contain up to 32 characters.

WPA2-PEAP

Enables use of the device with wireless networks employing the PEAP encryption protocol.

PEAP username can be up to 63 characters in length.

PEAP password can contain up to 63 characters.

Access Point Name / Username

Access Point Name can be up to 120 characters in length.

Access Point username can be up to 120 characters in length.

Access Point password can be up to 120 characters in length.

WPA2-EAP-TLS

Item	Description
Username	Alphanumerical field (63 characters).
Password	Alphanumerical field (63 characters).

Certificates

1. Select the mode where WLAN uses WPA2-EAP-TLS.
2. Insert a USB flash memory stick into the back of the **ELI 150c** device that contains the relevant certificates.
3. Touch the **Certificates** button.
4. Press **F5** to load the certificate files from the USB memory stick. The required files are Certificate Authority certificate, Client certificate, and Client Private Key.

Comm. Protocol

Select **UNIPRO** or **DICOM**. **DICOM** is only available if the **DICOM** option has been installed.



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



NOTE Units ship by default with Comm. Protocol set to **UNIPRO** or **DICOM**. The **UNIPRO** or **DICOM** setting is not supported by **E-Scribe** or **ELI Link** versions prior to V4.00. For questions about compatibility of your device with **ELI Link** and UNIPRO or **DICOM**, contact Baxter Technical Support.

Sync Mode

Select **None**, **XMT**, or **XMT+Orders** (**XMT+MWL** if **DICOM** enabled). **None** requires a manual transmission of reports and then a second manual request to receive orders from the cardiology management system. **XMT** will automatically transmit the report; **XMT+Orders** will both transmit the report and retrieve the orders.

Sync Date/Time

Select **Yes** or **No**. **Yes** will synchronize the date/time with the approved cardiology management system. With **No**, there will be no date/time synchronization. Date/time synchronization is done through **ELI Link** V4.00 or later.

XMT Mandatory Fields

Defines fields required for ECG transmission to the cardiology management system.

Item	Description
None	Allows data transmission without limitation.
Last Name	Requires the technician to enter a minimum of the Last Name.
ID	Requires the technician to enter a minimum of the patient's ID.
Tech ID	Requires the technician to enter a minimum of the technician's initials.



NOTE You may select each of these independently allowing for any multiple required selections.

Audit Trails

Enabling this option will create an audit log that records user actions and can be exported as a .TXT file via USB.

Managing audit logs

1. From real-time ECG view, select **F6** (More).
2. While holding down **↑** (SHIFT), depress **ALT** and **D** simultaneously.
3. Select **F4** (USB) to access the Software Upload/Download screen where the audit trails are managed.
 - Selecting **F4** in this screen will export the Audit Trails to a connected USB storage device.
 - Selecting **F5** in this screen will delete the Audit Trails stored on the **ELI 150c**.



NOTE Once maximum storage size is reached, the oldest audit trail file shall be deleted and a new one shall be created to continue logging user actions.

Each audit log file begins with a date and time of creation, software version, cart number, and the device serial number. Each entry in an audit trail file includes the date and time including time zone offset from UTC, username (if logged in), action name, what is affected by the action (if applicable) and associated data (if applicable).

Logged actions and associated data

Action	Action Effect	Associated Data
Startup		
Shutdown		
Audit Trail Cleared		
Log-in success	Username: <username>	
Log-in failure		
Log out	Username: <username>	
Unknown Guest Entered		
Password Entered	<Role> password entered	
Directory list viewing		
New ECG Patient Demographics Entry (Create ID)	<Pat ID> <Pat Name>	<field name> ADDED: <value>
ECG capture	<Pat ID> <Pat Name> <Acq Time>	
ECG Save	<Pat ID> <Pat Name> <Acq Time>	
ECG deletion	<Pat ID> <Pat Name> <Acq Time>	
ECG edit (patient demographics)	<Pat ID> <Pat Name> <Acq Time>	<Field name> Before: <value> After: <value>
ECG print	<Pat ID> <Pat Name> <Acq Time>	
ECG transmission	<Pat ID> <Pat Name> <Acq Time>	
Individual ECG viewing	<Pat ID> <Pat Name> <Acq Time>	
Orders list viewing		
Order selection	<Pat ID> <Pat Name>	
Orders download	<Quantity of Orders>	
Rhythm print	<Pat ID> <Pat Name>	
User list viewing		
User add	Username: <username>	
User delete	Username: <username>	
User edit	Username: <username>	<Field> Before: <value> After: <value>
Date/Time change		Before: <value > After: <value>
Other settings change		<Setting field name > Before: <value>After: <value>
Audit trail export		

Action	Action Effect	Associated Data
Software Update		Attempted filename: <value>
Software Update		Successful

File Encryption and Key

When the File Encryption is set to **ON**, all record and order files will be encrypted using the File Encryption Key. When the File Encryption is changed to **OFF**, all record and order files will be decrypted. The Audit Trail, configuration and User List files are always encrypted using the File Encryption Key independent of the File Encryption configuration setting.

The File Encryption key is editable by the administrator. If the File Encryption key is modified, all encrypted files are re-encrypted using the new key.

File Encryption Key can be used as the administrator password.

Log-In Authentication

Sets whether user authentication is required to access the device. See "Configuring Users and Roles" for further details.

Managing records

ECG directory

The standard ECG directory saves up to 40 individual ECG records. The optional expanded memory permits up to 200 individual ECG records.

To access the ECG directory, select **F6** (More) followed by **F1** (Directory of Stored ECGs) from the real-time ECG view.



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



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



NOTE Records marked for deletion will be maintained on the display.

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

- Use **F1** (▼/▲) to navigate by line down the ECG directory; use **1**' (Shift), **F1** (▼/▲) to move up.
- Use **F2** (▼▼/▲▲) to page down the ECG directory; use **1**' (Shift), **F2** (▼▼/▲▲) to page up.
- Select a patient name by using the keyboard to enter the first few letters of the last name. The letters will be displayed in the lower left corner of the display screen and the desired name will automatically be highlighted.

Delete status

An ECG may be stored in the directory but have a "delete status" (indicated by "X"). The directory saves records marked for deletion in the event that you may want to recover the ECG at a later time. Records are automatically marked for deletion based on the delete rule configuration (see "System Settings").

- To manually mark an ECG record for deletion, highlight a name from the ECG directory and select **F4** (Delete). An X will appear in the far right-hand column of the directory.
- To remove the delete status, re-highlight the name and select **F4** again. All stored ECGs will remain in the directory until it becomes full. When necessary to store a newly acquired ECG, only those records that have been marked for deletion will be removed.

View ECG records

To view a specific ECG record, highlight the desired name from the directory list and press **F3** (Select). The selected ECG is presented in acquired ECG view.

- Toggle through the available waveform formats by selecting **F2** (Leads).
- To make an additional copy of the ECG, select **F3** (Print).
- To view or change the patient demographics, select **F1** (ID).
- To return to the ECG directory, select **F6** (Done).

Change ECG format

- To change the speed, gain, filter, or printout format in the acquired ECG view, select **F5** (More) from the ECG directory.

Managing records

- To manipulate the print format of the acquired ECG regardless of the plot format configuration setting, select **F4** (Fmt).

Select the desired plot format setting and return to the acquired ECG view.

Sort ECG records

The directory is easily sorted either by name, ID, or date. To sort the ECG records, select **F5** (More) from the ECG directory.

- Select **F1** to sort the directory by patient name (patient ID and time/date are displayed in the top row).
- Select **F2** to sort the directory by patient ID (patient name is displayed in the top row).
- Select **F3** to sort the directory by acquisition date (patient name is displayed in the top row).

Print the ECG directory

1. Select **F4** (Print Directory). The directory lists stored ECGs based on how you have the directory sorted. The printout indicates if the ECGs have been printed, marked delete, or transmitted with an X in the appropriate column.
2. Select **F6** (Exit) to return to the ECG directory.

ECG order list

To display the ECG order list, select **F4** (Order) from the patient ID screen. The ECG order list is comparable to the ECG directory in looks and in practice; you can sort the list by name, ID, or date.

To sort the orders, select **F5** (More).

- Select **F1** to sort the orders by patient name (ID, time, and date are displayed in the top row).
- Select **F2** to sort the orders by patient ID (name is displayed in the top row).
- Select **F3** to sort the orders by acquisition date (name is displayed in the top row)

To make a printout of the orders list, select **F4** (Print Orders). Select **F6** (Exit) to return to the ECG order list.



NOTE A password may be required in order to enter the ECG Order List. Obtain the password from the department Administrator.

Cleaning and maintenance

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.

Disinfecting agents

The **ELI 150c** is compatible with the following disinfectants:

- Clorox Healthcare Bleach Germicidal Wipes (use according to instructions on product label), or
- a soft, lint-free cloth dampened with 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.



CAUTION Disinfecting or cleaning agents that contain Quaternary Ammonium Compounds (Ammonium Chlorides) 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.

Clean the **ELI 150c**

1. Disconnect the power source.
2. Remove cables and lead wires from device before cleaning.
3. Thoroughly wipe the surface of the **ELI 150c** with a clean, lint-free cloth dampened with a mild detergent and water for general cleaning or use one of the above recommended agents for disinfection.
4. Dry the device with a clean, soft, dry, lint-free cloth.



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.



WARNING Do not expose cables to strong ultra-violet radiation.



WARNING Do not sterilize the device or lead wires with Ethylene Oxide (EtO) gas.



WARNING Do not immerse cable ends or lead wires; immersion can cause metal corrosion. Use caution with excess liquid as contact with metal parts may cause corrosion.



WARNING Do not use excessive drying techniques such as forced heat.



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

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.

Clean the print head



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

1. Open writer door.
2. Lightly rub print head with an alcohol pad.
3. Wipe with a clean cloth to remove alcohol residue.
4. Allow print head to air dry.
5. Clean the platen by using adhesive tape. Apply the tape and pull it off. Rotate roller and repeat until entire roller is clean.
6. Clean cue sensor photo detector.

Power off the device

To completely shut down the device, disconnect the AC power cord then press the **ON/OFF** button. Such a shutdown should always be performed prior to authorized repair of the device.

Test operation

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

Recommendations to biomedical staff

Following any service to the device or when non-compliant operation is suspected, Baxter recommends the following procedures:

- Confirm proper operation
- Perform testing to ensure continued electrical safety of the device (use IEC 60601-1 or ANSI/AAMI ES 60601-1 methods and limits)
 - Patient leakage current
 - Chassis leakage current
 - Earth leakage current

- Dielectric strength (mains and patient circuits)

Battery maintenance

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

For information about replacing the battery, please refer to the device's service manual.

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

The sealed lead-acid battery will provide optimum life when the unit is fully charged after each use. When the battery charge is depleted to its lowest level (10.6V), the device will automatically power down. To recharge a battery from its lowest level to 85%, 4 hours of recharging may be necessary. To reach 90%, 7 hours of recharging may be necessary. It may take longer to reach 100%. The device can be used with AC power while simultaneously charging.

Disposal

Disposal must be in accordance with the following steps:

1. Follow cleaning and disinfection instructions in this user manual section.
2. Delete all existing data related to patients/hospital/clinic/doctor. Data backup may be performed prior to deletion.
3. Segregate material in preparation for the recycling process.
 - a. Components are to be disassembled and recycled based on type of material:
 - Plastic to be recycled as plastic waste
 - Metal to be recycled as metals
 - Includes loose components containing more than 90% metal by weight
 - Includes screws and fasteners
 - Electronic components, including the power cord, to be disassembled and recycled as Waste of Electrical and Electronic Equipment (WEEE)
 - Batteries to be dismantled from the device and recycled as per WEEE

Users must adhere to all federal, state, regional, and/or local laws and regulations as it pertains to the safe disposal of medical devices and accessories. If in doubt, the user of the device shall first contact Baxter Technical Support for guidance on safe disposal protocols.

Waste of Electrical and Electronic Equipment (WEEE)



Troubleshooting

System troubleshooting

Condition	Cause	Remedy
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.
NO ANSWER	Unable to transmit ECG.	Check for correct phone number. Ensure modem and E-Scribe are online.
Device is not responding.	Press and hold the On/Off button for 10 seconds.	Re-entry of date and time will be required after this function.
EXPORT & RESET AUDIT TRAIL. ##% FULL	Audit Trail is full or nearly full.	Export the audit trail and then clear the audit trails stored on the device.

ECG troubleshooting

Condition	Cause	Remedy
LEADS OFF OR ONE OR MORE OF THE FOLLOWING: RA, LA, LL, V1, V2, V3, V4, V5, V6	Lead fail. Indication of RL/RA/LA/LL/V1/V2/V3/V4/V5/V6.	Check limb leads. Correct faulty lead(s).
Lead I and Lead II	Poor RA electrode or right arm tremor.	Check patient prep; re-prepare with new electrode, if necessary.
Lead II and Lead III	Poor LL electrode or left leg tremor.	Check patient prep; re-prepare with new electrode, if necessary.
Lead I and Lead III	Poor LA electrode, or left arm tremor.	Check patient prep; re-prepare with new electrode, if necessary.
All	High Freq. Noise.	Adjust low pass filter setting; check proximity to power cables; check AC filter setting (50 Hz or 60 Hz).

Transmission troubleshooting

Condition	Cause	Remedy
TRANSMIT FAILED	Unable to transmit ECG.	Check phone line. Ensure site number is valid. Try again.
ERROR - DICOM Not Enabled	A DICOM communication was attempted, but the unit is not configured for DICOM .	Configure the system to DICOM and reboot.
UNABLE TO SAVE ECG	No available memory. ECG data too noisy to store.	Press stop to continue. Transmit or mark records for deletion in the directory. Correct noise and try acquisition/storage again.
DHCP FAILURE	The WLAN module failed to get an address from DHCP.	Contact Baxter Technical Service.
DPAC FAILURE	WLAN failed to initialize.	Contact Baxter Technical Service.
CAN'T CONNECT TO ACCESS POINT	A link to the access point could not be established.	Ensure the IP address is correct. If problem persists, contact Baxter Technical Service.
Log File	Any of the above information will be presented in the Log File.	Contact Baxter Technical Support.
CAN'T CONNECT TO REMOTE LINK	A link to the access point was established, but the link to the destination failed.	Ensure the IP address is correct. If problem persists, contact Baxter Technical Service.
TIME SYNC FAULT	Possible incorrect version of ELI Link or E-Scribe .	Install latest version.
UNABLE TO SAVE ORDER	Order storage failed.	Attempt to retransmit orders.
UNABLE TO SAVE WORK ITEM	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 and press STOP .
CONNECTION FAILED	Unable to transmit or receive ECGs.	Check for correct baud rate, phone number, and cable connections or site number.

Condition	Cause	Remedy
None	File not successfully transmitted via LAN.	Check share permissions on host device.
None	Unable to connect with LAN with crossover cable.	Implement hub vs. crossover cable.
Disabled	Pressing SYNC key.	Enable SYNC MODE and/or set SYNC MEDIA in configuration.

Specifications

Device specifications

Feature	Specification
Instrument Type	12-lead electrocardiograph
Input Channels	Simultaneous acquisition of all 12 leads
Standard Leads Acquired	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Waveform Display	Backlit, ¼ VGA color LCD (320 x 240); 3, 4+4, or 6+6 lead presentation
Input Impedance Input	Meets or exceeds requirements of ANSI/AAMI/IEC 60601-2-25
Dynamic Range	
Electrode Offset Tolerance	
Common Mode Rejection	
Pacemaker Pulse Display	
Patient Leakage Current	Meets or exceeds requirements of ANSI/AAMI ES 60601-1
Chassis Leakage Current	
Digital Sampling Rate	40,000 s/sec/channel used for pacemaker spike detection; 1000 s/sec/channel used for recording and analysis
Optional Functions	Baxter VERITAS resting ECG interpretation algorithm with age and gender specific criteria; connectivity with bidirectional communication
Paper	Perforated double Z-fold thermal paper; 108 mm (4 in.) wide, 200 sheets
Thermal Printer	Computer-controlled dot array; 8 dots/mm
Thermal Printer Speeds (mm/s)	5, 10, 25, or 50
Gain Settings (mm/mV)	5, 10, or 20
Report Print Formats	Standard or Cabrera; 3, 3+1, 3+3, or 6 channel
Rhythm Print Formats	3 or 6 channel with configurable lead groups
Keyboard	Elastomer keyboard with complete alphanumeric keys, soft-key menu, and dedicated function keys
Frequency Response	0.05 to 300 Hz
Filters	High-performance baseline filter; AC interference filter 50/60 Hz; low-pass filters 40 Hz, 150 Hz, or 300 Hz
A/D Conversion	20 bits (1.17 microvolt LSB)
Device Classification	Class I, Type CF defibrillation-proof applied parts
ECG Storage	v1.x software: Normal – 100 ECGs; Expanded – 200 ECGs v2.x software: Normal – 40 ECGs; Expanded – 200 ECGs

Specifications

Feature	Specification
Weight	7.2 lbs. (3.3 kg) including battery (without paper)
Dimensions	11.25 x 11.5 x 3.75 in. (29.2 x 30.5 x 10.2 cm)
Power Requirements	Universal AC power supply (100-240 VAC at 50/60 Hz) 110 VA; internal rechargeable battery
Battery	Rechargeable sealed lead-acid (SLA) 12V battery; rated 2.2 Watts/Cell at 20 hours; 6.97 in. x 1.34 in. x 2.6 in. (177 x 34 x 66 mm); weighs 1.76 lbs. (0.80 kg)

AM12 specifications

Feature	Specification
Instrument Type	12-lead ECG acquisition module
Input Channels	12-lead signal acquisition
ECG Leads Output	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, and V6
Trunk Cable Length	Approximately 10 feet (3 meters)
AM12 Lead Set	RA, LA, RL, LL, V1, V2, V3, V4, V5, and V6 (R, L, N, F, C1, C2, C3, C4, C5, and C6) with detachable lead wires
Sampling Rate	40,000 samples/second/channel acquisition; 1,000 samples/second/channel transmitted for analysis
Resolution	1.17 μ V reduced to 2.5 μ V for analysis
User Interface	12-lead ECG and rhythm strip buttons at acquisition module
Defibrillator Protection	Complies with AAMI standards and IEC 60601-2-25
Device Classification	Type CF, Defibrillator Proof
Weight	12 oz. (340 g)
Dimensions	4.72 x 4.3 x .98 in. (12 x 11 x 2.5 cm)
Power	Powered by USB connection to the ELI 150c



NOTE Specifications subject to change without notice.

WAM / UTK specifications

Radio specifications and certification information for the Wireless Acquisition Module (**WAM**) and USB Transceiver Key (**UTK**), can be found in the **WAM** user manual.

Regulatory radio compliance

Federal Communications Commission (FCC)

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

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

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions, it may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try and correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the distance between the equipment and the receiver
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

The user may find the following booklet prepared by the Federal Communications Commission helpful: The Interference Handbook This booklet is available from the U.S. Government Printing Office, Washington, D.C. 20402. Stock No. 004-000-0034504. Baxter is not responsible for any radio or television interference caused by unauthorized modification of the devices included with this Baxter product, or the substitution or attachment of connecting cables and equipment other than specified by Baxter. The correction of interference caused by such unauthorized modification, substitution, or attachment will be the responsibility of the user.

WLAN

Advantech: radio module WLNNA-AN-MR551

FCC ID: M82-BB-WLNNA

IC ID: 6100A-CM276NF

Industry Canada (IC) Emissions

RF radiation hazard warning

Using higher gain antennas and types of antennas not certified for use with this product is not allowed. The device shall not be co-located with another transmitter.

Cet avertissement de sécurité est conforme aux limites d'exposition définies per la norm CNR-102 at relative aux fréquences radio.

This device complies with RSS 210 of Industry Canada.

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 this device.

L'utilisation de ce dispositif est autorisée seulement aux conditions suivantes: (1) il ne doit pas produire de brouillage et (2) l'utilisateur du dispositif doit être prêt à accepter tout brouillage radioélectrique reçu, même si ce brouillage est susceptible de compromettre le fonctionnement du dispositif.

This Class B digital apparatus complies with Canadian ICES-003.

Cet appareil numérique de la classe B est conforme à la norme NMB-003 du Canada.

WLAN

Advantech: radio module WLNNA-AN-MR551

FCC ID: M82-BB-WLNNA

IC ID: 6100A-CM276NF

Declaración de conformidad Mexico

La operación de este equipo está sujeta a las siguientes dos condiciones:

1. es posible que este equipo o dispositivo no cause interferencia perjudicial y
2. este equipo o dispositivo debe aceptar cualquier interferencia, incluyendo la que pueda causar su operación no deseada.

European Union

Czech	Baxter tímto prohlašuje, že tento WLAN device je ve shodě se základními požadavky a dalšími příslušnými ustanoveními směrnice 2014/53/ES.
Danish	Undertegnede Baxter erklærer herved, at følgende udstyr WLAN device overholder de væsentlige krav og øvrige relevante krav i direktiv 2014/53/EF
Dutch	Bij deze verklaart Baxter dat deze WLAN device voldoet aan de essentiële eisen en aan de overige relevante bepalingen van Richtlijn 2014/53/EC.
English	Hereby, Baxter, declares that this WLAN device is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EC.
Estonian	Käesolevaga kinnitab Baxter seadme WLAN device vastavust direktiivi 2014/53/EÜ põhinõuetele ja nimetatud direktiivist tulenevatele teistele asjakohastele sätetele.
Finnish	Baxter vakuuttaa täten että WLAN device tyyppinen laite on direktiivin 2014/53/EY oleellisten vaatimusten ja sitä koskevien direktiivin muiden ehtojen mukainen.
French	Par la présente, Baxter déclare que ce WLAN device est conforme aux exigences essentielles et aux autres dispositions de la directive 2014/53/CE qui lui sont applicables.
German	Hiermit erklärt Baxter die Übereinstimmung des Gerätes WLAN device mit den grundlegenden Anforderungen und den anderen relevanten Festlegungen der Richtlinie 2014/53/EG. (Wien)
Greek	ΜΕ ΤΗΝ ΠΑΡΟΥΣΑ Baxter ΔΗΛΩΝΕΙ ΟΤΙ WLAN device ΣΥΜΜΟΡΦΩΝΕΤΑΙ ΠΡΟΣ ΤΙΣ ΟΥΣΙΩΔΕΙΣ ΑΠΑΙΤΗΣΕΙΣ ΚΑΙ ΤΙΣ ΛΟΙΠΕΣ ΣΧΕΤΙΚΕΣ ΔΙΑΤΑΞΕΙΣ ΤΗΣ ΟΔΗΓΙΑΣ 2014/53/EK
Hungarian	Alulírott, Baxter nyilatkozom, hogy a WLAN device megfelel a vonatkozó alapvető követelményeknek és az 2014/53/EC irányelv egyéb előírásainak.
Italian	Con la presente Baxter dichiara che questo WLAN device è conforme ai requisiti essenziali ed alle altre disposizioni pertinenti stabilite dalla direttiva 2014/53/CE.
Latvian	Ar šo Baxter deklarē, ka WLAN device atbilst Direktīvas 2014/53/EK būtiskajām prasībām un citiem ar to saistītajiem noteikumiem.

Lithuanian	Šiuo Baxter deklaruoja, kad šis WLAN device atitinka esminius reikalavimus ir kitas 2014/53/EB Direktyvos nuostatas.
Malti	Hawnhekk, Baxter, jiddikjara li dan WLAN device jikkonforma mal-htigijiet essenzjali u ma provvedimenti ohrajn relevanti li hemm fid-Dirrettiva 2014/53/EC
Portuguese	Baxter declara que este WLAN device está conforme com os requisitos essenciais e outras disposições da Directiva 2014/53/CE.
Slovak	Baxter týmto vyhlasuje, ze WLAN device spĺňa základné požiadavky a všetky príslušné ustanovenia Smernice 2014/53/ES.
Slovene	Šiuo Baxter deklaruoja, kad šis WLAN device atitinka esminius reikalavimus ir kitas 2014/53/EB Direktyvos nuostatas.
Spanish	Por medio de la presente Baxter declara que el WLAN device cumple con los requisitos esenciales y cualesquiera otras disposiciones aplicables o exigibles de la Directiva 2014/53/CE
Swedish	Härmed intygar Baxter att denna WLAN device står i överensstämmelse med de väsentliga egenskapskrav och övriga relevanta bestämmelser som framgår av direktiv 2014/53/EG.

Electromagnetic Compatibility (EMC)

EMC compliance

Special precautions concerning electromagnetic compatibility (EMC) must be taken for all medical electrical equipment.

- All medical electrical equipment must be installed and put into service in accordance with the EMC information provided in this User Manual.
- Portable and mobile RF communications equipment can affect the behavior of medical electrical equipment.

The device complies with all applicable and required standards for electromagnetic interference.

- It does not normally affect nearby equipment and devices.
- It is not normally affected by nearby equipment and devices.
- It is not safe to operate the device in the presence of high-frequency surgical equipment.
- However, it is good practice to avoid using the device in extremely close proximity to other equipment.

 **WARNING** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

 **WARNING** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The **ELI 150c** electrocardiograph device complies to IEC 60601-1-2:2020 (EMC international standard, 4th Edition).

Refer to the proper Guidance and Manufacturer’s Declaration and Recommended Separation Distance tables based on which standard the device meets.

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 device 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.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Class A	<p>The device is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provide the following warning is heeded:</p> <p> WARNING This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the device or shielding the location.</p>
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

The device may contain a 2.4 GHz frequency hopping spread-spectrum / 5 GHz orthogonal frequency-division multiplexing transmitter for the purpose of wireless communication. The radio is operated according to the requirements of various agencies, including FCC 47 CFR 15.247 and EU Radio Emitting Device Directive. As the radio module complies with applicable national radio regulation, emission within its operating frequency bands do not require retesting to CISPR limit under IEC 60601-1-2. However, the device as a whole must still meet EMC requirement, including emissions outside the operating band and immunity testing. The radiated RF energy from wireless transmitter may cause electromagnetic interference with other equipment: refer to the recommended separation distances section for further detail.

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
Electrostatic Discharge (ESD) EN 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 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	+/- 0.5 kV, +/- 1 kV line(s) to line(s) +/- 0.5 kV, +/- 1 kV, +/- 2 kV line(s) to earth	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC 60601 Test Level	Compliance level	Electromagnetic environment - guidance
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles for 50 Hz and 60 Hz respectively Single phase: at 0° 0 % UT; 250/300 cycle for 50 Hz and 60 Hz respectively	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles for 50 Hz and 60 Hz respectively Single phase: at 0° 0 % UT; 250/300 cycle for 50 Hz and 60 Hz respectively	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency magnetic fields IEC 61000-4-8	30 A/m (50/60 Hz)	30 A/m (50/60 Hz)	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
			Recommended separation distance ¹
Conducted RF EN 61000-4-6	3 Vrms 0.15 MHz to 80 MHz 80% AM at 1 kHz 6 Vrms in ISM bands between 0.15 MHz to 80 MHz ² 80% AM at 1 kHz	3 Vrms 0.15 MHz to 80 MHz 6 Vrms in ISM bands between 0.15 MHz to 80 MHz ² 80% AM at 1 kHz	$d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ 150 kHz to 80 MHz where V ₁ is the compliance level in Vrms.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	$d = \left[\frac{3.5}{E1} \right] \sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E1} \right] \sqrt{P}$ 800 MHz to 2.7 GHz where E1 is the compliance level in V/m.
Proximity fields from RF wireless communications equipment IEC 61000-4-3	Reference Test Specifications for Enclosure Port Immunity to RF Wireless Communications Equipment.	Reference Test Specifications for Enclosure Port Immunity to RF Wireless Communications Equipment.	d = 0.3m

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey², should be less than the compliance level in each frequency range³.

Interference may occur in the vicinity of equipment marked with the following symbol:



NOTE At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.



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



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

¹ 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.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			<p>² The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.</p> <p>³ 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.</p>

Test specifications for Enclosure Port Immunity to RF wireless communications equipment

Test frequency (MHz)	Band (MHz) ¹	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380 - 390	TETRA 400	Pulse modulation ² 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM +/- 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 - 787	LTE band 13, 17	Pulse modulation ² 217 Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ² 18 Hz	2	0.3	28
870						
930						
1720	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 - 2570	Bluetooth , WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ² 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation ² 217 Hz	0.2	0.3	9
5500						
5785						

¹ For some services, only the uplink frequencies are included.

Test frequency (MHz)	Band (MHz) ¹	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
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² The carrier shall be modulated using a 50 % duty cycle square wave signal.

Test specifications for Enclosure Port Immunity to proximity magnetic fields

Test frequency	Modulation	Immunity test level (A/m)
134.2 kHz	Pulse modulation ¹ 2.1 kHz	65 ²
13.56 MHz	Pulse modulation ¹ 50 kHz	7.5 ²

¹ The carrier shall be modulated using a 50% duty cycle square wave signal.

² r.m.s. before modulation is applied

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 outside ISM bands $d = 1.2\sqrt{P}$	150 KHz to 80 MHz in ISM bands $d = 0.6\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.1 m	0.05 m	0.1 m	0.2 m
0.1	0.4 m	0.2 m	0.4 m	0.7 m
1	1.2 m	0.6 m	1.2 m	2.3 m
10	4.0 m	2.0 m	4.0 m	7.0 m
100	12.0 m	6.0 m	12.0 m	23.0 m



NOTE 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

Rated Maximum output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)			
	150 KHz to 800 MHz outside ISM bands	150 KHz to 80 MHz in ISM bands	80 MHz to 800 MHz	800 MHz to 2.7 GHz
	$d = 1.2\sqrt{P}$	$d = 0.6\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$

of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.



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



NOTE The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.



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

Appendix

Accessories

Replacement lead sets and accessories

Part number	Description
9293-046-07	COMBINER WAM LEADS 10 POS IEC & AHA GRAY
9293-046-60	LEAD SET WAM 10 WIRE BANANA AHA GRAY
9293-046-61	LEAD SET WAM 10 WIRE BANANA IEC GRAY
9293-046-62	RPLCE LD SET WAM/ AM12 LIMBS BANA AHA GRY
9293-046-63	RPLCE LD SET WAM/AM12 LIMBS BANA IEC GRY
9293-046-64	RPLCE LD SET WAM/AM12 V1-V3 BANA AHA GRY
9293-046-65	RPLCE LD SET WAM/AM12 C1-C3 BANA IEC GRY
9293-046-66	RPLCE LD SET WAM/AM12 V4-V6 BANA AHA GRY
9293-046-67	RPLCE LD SET WAM/ AM12 C4-C6 BANA IEC GRY
9293-047-60	LEAD SET WAM 10 WIRE CLIPS AHA GRAY
9293-047-61	LEAD SET WAM 10 WIRE CLIPS IEC GRAY
9293-047-62	RPLCE LD SET WAM/AM12 LIMBS CLIP AHA GRY
9293-047-63	RPLCE LD SET WAM/AM12 LIMBS CLIP IEC GRY
9293-047-64	RPLCE LD SET WAM/AM12 V1-V3 CLIP AHA GRY
9293-047-65	RPLCE LD SET WAM/AM12 C1-C3 CLIP IEC GRY
9293-047-66	RPLCE LD SET WAM/AM12 V4-V6 CLIP AHA GRY
9293-047-67	RPLCE LD SET WAM/AM12 C4-C6 CLIP IEC GRY
41000-032-50	AM12 acquisition module with 10 wire AHA lead set with banana plugs
41000-031-50	WAM wireless acquisition module with 10 wire AHA lead set with banana plugs
41000-031-52	WAM wireless acquisition module with 10 wire AHA lead set with clips
41000-032-52	AM12 acquisition module with AHA Clip Lead Set

Paper

Part number	Description
9100-028-50	PAPER ELI 150 US CASE/24/200 ZFOLD

Electrodes

Part number	Description
108070	ECG MONITORING ELECTRODES CASE 300
108071	ELECTRODE RESTING TAB CASE/5000

Acquisition modules

Part number	Description
9293-048-55	WIRED PATIENT CABLE (AM12) W/O LEADWIRES
30012-019-55	WIRELESS ACQUISITION MODULE (WAM) W/O LEAD WIRES Version 1
30012-019-56	WIRELESS ACQUISITION MODULE (WAM) W/O LEAD WIRES Version 2
41000-031-50	WAM wireless acquisition module with 10 wire AHA lead set with banana plugs
41000-031-51	WAM wireless acquisition module with 10 wire IEC lead set with banana plugs
41000-031-52	WAM wireless acquisition module with 10 wire AHA lead set with clips
41000-031-53	WAM wireless acquisition module with 10 wire IEC lead set with clips
41000-032-50	AM12 acquisition module with 10 wire AHA lead set with banana plugs
41000-032-51	AM12 acquisition module with 10 wire IEC lead set with banana plugs
41000-032-52	AM12 acquisition module with 10 wire AHA lead set with Clip Leads
41000-032-53	AM12 acquisition module with 10 wire IEC lead set with Clip Leads



NOTE Prior to ordering, refer to section: "Important version information for **WAM** (Wireless Acquisition Module)".

Power cords

Part number	Description
3181-008	POWER CORD US/CAN HOSPITAL 5-15P+320-C13
3181-012-01	POWER CORD AUSTRALIA AS3112+IEC320-C13
3181-015-01	POWER CORD UK BS1363+IEC320-C13
3181-002	POWER CORD INTN'L CEE7/7+IEC320-C13
3181-017-01	POWER CORD CHINESE

Contact your distributor or go to baxter.com for more information.

Warranty

WELCH ALLYN, INC., (hereinafter referred to as "Welch Allyn") 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 twenty-four (24) 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:

- Freight damage;
- Parts and/or accessories of the Product/s not obtained from or approved by Welch Allyn;
- Misapplication, misuse, abuse, and/or failure to follow the Product/s instruction sheets and/or information guides;
- Accident; a disaster affecting the Product/s;
- Alterations and/or modifications to the Product/s not authorized by Welch Allyn;
- 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, BLOOD PRESSURE CUFFS, BLOOD PRESSURE HOSES, 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.

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