

ELI® 150c Technical System Requirements

Overview

The ELI 150c is a 12-lead resting ECG diagnostic electrocardiograph with an LCD display capable of acquiring, viewing, transmitting, printing, and storing adult and pediatric resting ECG test data. The device is optionally equipped with the Welch Allyn VERITAS™ resting ECG interpretation algorithm using gender and age specific criteria. The VERITAS algorithm can provide an over-reading physician with a silent second opinion through diagnostic statements output on the ECG report.

The device includes bidirectional LAN support and can also be configured with WLAN connectivity and DICOM® Modality Work List with synchronization of orders, date, and time as well as encrypted transmission of ECGs.

The device can operate on a single sealed lead-acid battery or AC line power.

The ELI 150c system can transmit acquired ECG records to ELI Link via LAN or WLAN. Before transmitting ECGs, certain configuration settings must be defined depending upon the type of transmission and type of electronic storage used.



Device Specifications

Instrument Type	Multi-lead resting electrocardiograph						
Input Channels	Simultaneous acquisition of all 12 leads						
Standard Leads Acquired	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6						
Display	Backlit, 1/4 VGA color LCD (320 x 240); 3, 4+4, or 6+6 lead presentation						
Digital Sampling Rate	<ul style="list-style-type: none"> ▪ 40,000 samples/s/channel used for pacemaker spike detection ▪ 1,000 samples/s/channel used for recording and analysis 						
Keyboard	Alphanumeric elastomer keyboard features: <ul style="list-style-type: none"> • Dedicated one-touch buttons for ECG acquisition, rhythm printing, and ECG transmission/order retrieval • Soft-key menus • Dedicated function keys 						
Filters	<ul style="list-style-type: none"> ▪ 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	<ul style="list-style-type: none"> ▪ Internal storage up to 40 ECGs ▪ Optional expansion up to 200 ECGs 						
# of Active Orders	Up to 256 (<i>dependent on query & information management system settings</i>)						
Information Exchange	Requires ELI Link software version 4.2.0 or greater						
Power Requirements	<ul style="list-style-type: none"> ▪ Universal AC power supply (100-240 VAC at 50/60 Hz) ▪ Internal, rechargeable sealed lead-acid battery ▪ Battery Charge times from minimum level, 10.6V to: <table style="margin-left: 20px; border: none;"> <tr> <td style="padding-right: 20px;">85%</td> <td>~4 hours</td> </tr> <tr> <td>90%</td> <td>~7 hours</td> </tr> <tr> <td>100%</td> <td>7+ hours</td> </tr> </table> ▪ Battery shelf-life*: ~6 months without charging <p><i>*Note: When the battery charge is depleted to its lowest level (10.6V), the device will automatically power down. If battery has been stored for a long period in a discharged state, it may not regain its capacity even if recharged.</i></p>	85%	~4 hours	90%	~7 hours	100%	7+ hours
85%	~4 hours						
90%	~7 hours						
100%	7+ hours						
Input Impedance Input Dynamic Range Electrode Offset Tolerance Common Mode Rejection Frequency Response	<ul style="list-style-type: none"> ▪ Meets or exceeds requirements of IEC 60601-2-25 						
Patient Leakage Current Chassis Leakage Current	<ul style="list-style-type: none"> ▪ Meets or exceeds the requirements of IEC 60601-1 						
Additional Clinical Features	<ul style="list-style-type: none"> ▪ Best 10: automatic capture of the 10 seconds of data with the least amount of noise from the last 5 minutes of full disclosure ▪ 5-minute running acquisition buffer 						
Optional Functions	<ul style="list-style-type: none"> ▪ Connectivity with bidirectional communication ▪ Optional multi-study support for managing up to three studies on one machine 						

	<ul style="list-style-type: none"> ▪ Populate demographic data by entering subject's ID number or from memory ▪ Download demographic data fields for each study protocol
Optional Audit Trail	<ul style="list-style-type: none"> ▪ Encrypted while stored on ELI 150c ▪ Exportable to external USB in text file format (requires Site Administrator access) ▪ Audit Trail logs the following: <ul style="list-style-type: none"> ○ Username ○ Date/time ○ The following events: <ul style="list-style-type: none"> ▪ Power Up/Down ▪ Log In/Out ▪ Login Failure ▪ Guest access ▪ Role elevation via password entry ▪ View/Create/Edit/ Delete ECG(s) ▪ Create Patient ▪ ECG Print ▪ Rhythm Strip Print ▪ ECG Transmission ▪ View/Create/Edit/Delete locally stored users ▪ View/Select/Download Order(s) ▪ Edit Settings ▪ Change Date/Time ▪ Export Audit Trail ▪ Software Upgrade

Network Specifications

GPRS (Cellular) Modem <i>(Option)</i>		<ul style="list-style-type: none"> ▪ Internal
Wired Network		<ul style="list-style-type: none"> ▪ IEEE 802.3 LAN, 10/100 Mbps or faster
Wireless Protocols <i>*Country dependent</i>		<ul style="list-style-type: none"> ▪ IEEE 802.11 b/g (2.4 GHz) ▪ Channels: Up to 14* (3 non-overlapping) @ 2.4 GHz
Data Rates	802.11g (OFDM)	<ul style="list-style-type: none"> ▪ 6, 9, 12, 18, 24, 36, 48, 54 Mbps
	802.11b (DSSS, CCK)	<ul style="list-style-type: none"> ▪ 1, 2, 5.5, 11 Mbps
Standards		<ul style="list-style-type: none"> ▪ WPA2-PSK (<i>Wi-Fi Protected Access II</i>) ▪ WPA2-PEAP (<i>Protected Extensible Authentication Protocol</i>) ▪ WPA2-EAP-TLS ▪ WPA2-EAP-TLS (p12/pfx)
Encryption		<ul style="list-style-type: none"> ▪ AES 256-bit ▪ WEP, RC4

	<ul style="list-style-type: none"> ▪ TKIP, RC4 ▪ USB communication directly to PC or storage media
Direct Connection	
User Authentication	<ul style="list-style-type: none"> ▪ Local login using password account ▪ Configurable local user account-based authentication
Password Based Roles	<ul style="list-style-type: none"> ▪ Able to create three generic roles – Technician, Site Administrator, Administrator – via case sensitive passwords ▪ Configurable local Technician password: <ul style="list-style-type: none"> ○ Access/change directory of stored ECGs and ECG Orders ▪ Configurable local Site Administrator password to access: <ul style="list-style-type: none"> ▪ All Technician functions ▪ Assign/change passwords ▪ Device configuration ▪ Audit trail export ▪ Configurable local Administrator password to access: <ul style="list-style-type: none"> ▪ All Site Administrator functions ▪ All additional functionality ▪ Non-configured guests only able to acquire, print, and transmit ad hoc ECGs
Local User Accounts	<ul style="list-style-type: none"> ▪ Device can store up to 30 users ▪ Each user account created by adding the following: <ul style="list-style-type: none"> ○ Username (30 characters) ○ Password (30 characters) ○ Sites (up to 3) ○ Role (up to 1): <ul style="list-style-type: none"> ▪ Guest ▪ Technician ▪ Site Administrator ▪ Administrator

Printer

Paper	<ul style="list-style-type: none"> ▪ Perforated double Z-fold thermal paper; 108 mm (4") wide, 200 sheets ▪ Up to 200 sheets stored in paper tray
Thermal Printer	<ul style="list-style-type: none"> ▪ Computer-controlled dot array ▪ 1 dot/ms horizontal, 8 dots/mm vertical
Thermal Printer Speeds	5*, 10*, 25, or 50 mm/s (<i>*Rhythm prints only</i>)
Gain Settings	5, 10, or 20 mm/mV
Report Print Formats	Standard or Cabrera: 3+1, 3+3, 6, 6+6, or 12 channel
Rhythm Print Formats	3, 6, 8, or 12 channel with configurable lead groups

Connectivity Interfaces

Orders	<p>Supports external orders in the following formats:</p> <ul style="list-style-type: none"> ▪ XML (<i>via ELI Link</i>) <ul style="list-style-type: none"> ○ Mortara XML ○ Accepts orders via XML files saved by external system in a shared folder ▪ DICOM Modality Worklist (<i>via ELI Link</i>) <ul style="list-style-type: none"> ○ Able to retrieve Resting test orders from a DICOM Service Class Provider (SCP) by performing a DICOM Modality Worklist query ▪ HL7® (<i>by adding ELI Link and optional Mortara HL7 Gateway</i>) <p>Note: Request codes can be downloaded or entered on the keyboard. Request codes are passed to ELI Link or MWL to filter the orders. If configuration parameter "Comm. Protocol" is set to "UNIPRO" or "DICOM", any request code will be up to 23 (valid) characters long.</p>
Export Formats	<p>Supports exporting data in the following formats:</p> <ul style="list-style-type: none"> ▪ XML <p>Via ELI Link:</p> <ul style="list-style-type: none"> ▪ PDF ▪ DICOM encapsulated PDF ▪ DICOM 12-Lead ▪ HL7 (<i>by adding optional Mortara HL7 Gateway</i>)

Associated Software

- Optional: ELI Link v4.00 and later – or – E-Scribe® v9.0 and later

Note: Information Exchange requires ELI Link v4.2.0 or later

Note: There were 2 issues discovered during E-Scribe testing where the custom ID response does not contain site name information (ARTS B104635) as well as the custom ID field overlapping with UNIPRO 64 carts (ARTS B104692).

- HeartCentrix®
- Optional: Welch Allyn VERITAS Resting ECG interpretation algorithm v7.2.3 w/ age & gender specific criteria

Hardware Interfaces

Barcode Reader	Supports barcode scanners with 39, 128, and 2D capabilities.
Mounting	<ul style="list-style-type: none"> Optional ECG Cart Configurations Table top

Physical Characteristics

Weight <i>(without paper)</i>	ELI 150c: 7.2 lbs. (3.3 kg) including battery
Dimensions	ELI 150c: 11.25 x 11.5 x 3.75" (29.2 x 30.5 x 10.2 cm)
Operating Environment	Operating Temperature: +10 to +40 deg. C (+50 to +104 deg. F) Storage Temperature: -40 to +70 deg. C (-40 to +158 deg. F) Operating Humidity: 25% to 95%, non-condensing Storage Humidity: 10% to 95%, non-condensing Altitude (<i>Pressure</i>): 500 hPa to 1060 hPa

Supported Languages

- English
 - German
 - Portuguese (European)
 - Polish
 - Czech
 - Latvian
 - Danish
 - Russian
 - Italian
 - Finnish
 - Portuguese (Brazilian)
 - Swedish
 - Croatian
 - Romanian
 - Chinese
 - Spanish
 - French
 - Dutch
 - Hungarian
 - Turkish
 - Norwegian
 - Japanese
-

Resting ECG Acquisition Modules

WAM – Wireless Acquisition Module



Instrument Type	12-lead wireless acquisition module for resting ECG
Input Channels	12-lead signal acquisition and transmission
ECG Leads Transmitted	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, and V6
WAM Transmission Protocol	Bidirectional and frequency hopping; beacon and response method links a single acquisition module to a single electrocardiograph
Frequency Range	2400.96 MHz to 2482.56 MHz
WAM and Receiver Distance	Approximately 10 feet (3 meters)
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	1.875 microvolt LSB
User Interface	Two-button operation: ON/OFF and 12-lead ECG acquisition; Rhythm button is non-functional
Defibrillator Protection	Complies with IEC 60601-2-25
Special Functions	LED indication of power status, operating mode, lead fail, and remaining battery charge
Device Classification	Type CF, battery operated
Weight	6.7 oz. (190 g) with battery
Dimensions	4.45 x 4.25 x 1.1" (11.3 x 10.8 x 2.79 cm)
Battery	1 AA alkaline battery (typically powers WAM for 250 acquisitions)

See 80025243 for additional details on the *Wireless Acquisition Module*

AM12 – Wired Acquisition Module



Instrument Type	12-lead wired acquisition module for resting ECG
Input Channels	12-lead signal acquisition and transmission
ECG Leads Transmitted	I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, and V6
Device Connection Type	USB 2.0 type-A
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
User Interface	Two-button interface to issue commands to start a 10-second ECG, rhythm strip, or enter special operating modes
Defibrillator Protection	Complies with IEC 60601-2-25
Special Functions	LED indication of power status, operating mode, lead fail, and remaining battery charge
Device Classification	Type CF, USB Powered
Dimensions	4.7 x 4.3 x 1" (12cm x 11cm x 2.5cm)