ELI® 150c Technical System Requirements

Overview

The ELI 150c is a 12-lead resting ECG diagnostic electrocardiograph with a LCD display capable of acquiring, viewing, transmitting, printing, and storing adult and pediatric resting ECG test data. The device is equipped with Mortara Instrument's optional 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 and 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	• 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 dedicated "one-touch" buttons for ECG acquisition, rhythm printing and ECG transmission/order retrieval. Soft-key menus and dedicated function keys
Filters	• High-performance baseline filter • AC interference filter 50/60 Hz • Low-pass filters: 40 Hz, 150 Hz, or 300 Hz
A/D Conversion	20 bits (1.17 microvolt LSB)
Device Classification	Class I, Type CF defibrillation-proof applied parts
ECG Storage	• Internal storage up to 40 ECGs • *Optional* expansion up to 200 ECGs
# of Active Orders	Up to 256 *(dependent on query & information management system settings)*
Information Exchange	Requires ELI Link software version 4.2.0 or greater

Power Requirements	• 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:
	  85% ~4 hours
	  90% ~7 hours
	  100% 7+ hours
	• **Battery shelf-life*:** ~6 months without charging
	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!

Input Impedance **Input Dynamic Range** **Electrode Offset Tolerance** **Common Mode Rejection** **Frequency Response**	• Meets or exceeds requirements of IEC 60601-2-25
Patient Leakage Current **Chassis Leakage Current**	• Meets or exceeds the requirements of IEC 60601-1
Additional Clinical Features	• **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**	• Connectivity with bidirectional communication. • Optional multi-study support for managing up to three studies on one machine • Populate demographic data by entering subject's ID number or from memory • Download demographic data fields for each study protocol

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***Optional* Audit Trail**	▪ Encrypted while stored on ELI 150c
	▪ Exportable to external USB in text file format (requires Site Administrator access)
	▪ Audit Trail logs the following:
	o Username
	o Date/time
	o The following events:
	▪ 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 *(Option)*	▪ Internal	
	Wired Network	▪ IEEE 802.3 LAN, 10/100 Mbps or faster	
Wireless Network *(option)*	**Wireless Protocols** **Country dependent*	▪ IEEE 802.11 b/g *(2.4 GHz)* ▪ **Channels:** Up to 14* (3 non-overlapping) @ 2.4 GHz	
	Data Rates **802.11g** (OFDM)	▪ 6, 9, 12, 18, 24, 36, 48, 54 Mbps	
	802.11b (DSSS, CCK)	▪ 1, 2, 5.5, 11 Mbps	
	Standards	▪ None ▪ WEP ▪ WEP 64/128 *(Wireless Equivalent Privacy)* ▪ WPA-PSK 64/128 *(Wi-Fi Protected Access)* ▪ WPA-LEAP *(Lightweight Extensible Authentication Protocol)* ▪ WPA-LEAP 64/128 *(Lightweight Extensible Authentication Protocol)* ▪ WPA2-PSK *(Wi-Fi Protected Access II)* ▪ WPA2-PEAP *(Protected Extensible Authentication Protocol)*	

Encryption	▪ AES 256-bit ▪ WEP, RC4 ▪ TKIP, RC4
Direct Connection	▪ USB communication directly to PC or storage media
User Authentication	▪ Local login using password account ▪ Configurable local user account based authentication

Password Based Roles	▪ Able to create three generic roles – Technician, Site Administrator, Administrator – via case sensitive passwords
	▪ Configurable *local* Technician password:
	    o Access/change directory of stored ECGs and ECG Orders
	▪ Configurable *local* Site Administrator password to access:
	    ▪ All Technician functions ▪ Device configuration
	    ▪ Assign/change passwords ▪ Audit trail export
	▪ Configurable *local* Administrator password to access:
	    ▪ All Site Administrator functions ▪ All additional functionality
	▪ Non-configured guests only able to acquire, print, and transmit ad hoc ECGs

Local User Accounts	▪ Device can store up to 30 users
	▪ Each user account created by adding the following:
	    o Username (30 characters)
	    o Password (30 characters)
	    o Sites (up to 3)
	    o Role (up to 1):
	        ▪ Guest
	        ▪ Technician
	        ▪ Site Administrator
	        ▪ Administrator

Printer

Paper	▪ Perforated double Z-fold thermal paper; 108 mm (4") wide, 200 sheets ▪ Up to 200 sheets stored in paper tray
Thermal Printer	▪ Computer-controlled dot array ▪ 1 dot/ms horizontal, 8 dots/mm vertical
Thermal Printer Speeds	5*, 10*, 25, or 50 mm/s *(*Rhythm prints only)*
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	Supports external orders in the following formats: ▪ **XML** *(via ELI Link)* o Mortara XML o Accepts orders via XML files saved by external system in a shared folder ▪ **DICOM® Modality Worklist** *(via ELI Link)* o Able to retrieve Resting test orders from a DICOM® Service Class Provider (SCP) by performing a DICOM® Modality Worklist query ▪ **HL7** *(by adding ELI Link and optional Mortara® HL7 Gateway)* *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.*
Export Formats	Supports exporting data in the following formats: ▪ **XML** **Via ELI Link:** ▪ **PDF** ▪ **DICOM®** encapsulated PDF ▪ **DICOM®** 12-Lead ▪ **HL7** *(by adding optional Mortara®HL7 Gateway)*

Associated Software

- ▪ ***Optional:*** ELI Link v4.00 *and later* – **or** – EScribe v9.0 *and later*
    *Note: Information Exchange requires **ELI Link v4.2.0** or later*
    Note: There were 2 issues discovered during EScribe 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). These issues are both related to EScribe and will be corrected in a future EScribe software release.

- ▪ ***Optional:*** Pyramis®, HeartCentrix®
- ▪ ***Optional:*** ECG Safe™ Cloud Service
- ▪ ***Optional***: Mortara® 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	▪ Optional ECG Cart Configurations ▪ Table top

Physical Characteristics

Weight *(without paper)*	**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 (***Pressure***)**: 500 hPa to 1060 hPa

Supporting Documentation

Manuals	**IFU:** 9515-177-50-xxx **DICOM Conformance Statement:** M0356-001 **Physician's Guide:** 9515-001-50-xxx **MDS2:** 9710-177-xx-ENG **21 CFR 11 Checklist:** 80027662 **WAM IFU**: 9515-174-50-xxx **AM12 IFU**: *(see ELI 150c/250c IFU above)*

*xxx represents language specific extension (e.g. XXX = ENG, is the English manual)
** xx represents a number that increments for each version release

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)