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Document Number: 80025284 Ver A

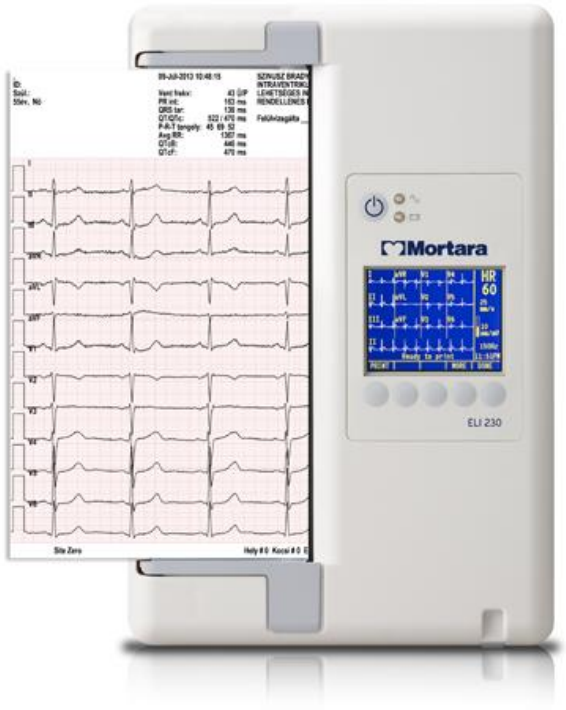
ELI 230 Technical System Requirements

Overview

The ELI 230 is a 12-lead resting ECG diagnostic electrocardiograph capable of acquiring, printing, and storing adult and pediatric resting ECG test data. The device is equipped with Mortara Instrument's VERITAS™ resting ECG interpretation algorithm using age and gender specific criteria. The VERITAS algorithm can provide an over-reading physician with a silent second opinion through diagnostic statements output on the ECG report.

Once exams are acquired, they can be downloaded to a USB storage device and transferred to a PC. With a site installation of ELI Link, those ECGs can then be transmitted with encryption in various formats from the PC.

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



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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, ¼ VGA 320 x 240 LCD color display with 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	5-button, soft-key menus
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 (1.875 microvolt LSB)
Device Classification	Class I, Type CF defibrillation-proof applied parts
ECG Storage	▪ *Internal* storage up to 20 ECGs ▪ *External* storage to **USB**
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% ~6 hours 100% Varies by how battery is maintained ▪ **Battery shelf-life*:** ~6 months without charging **Note: 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** **Pacemaker Pulse Display** **Frequency Response**	▪ Meets or exceeds the 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 1 minute of full disclosure. ▪ 1-minute running acquisition buffer

Network Specifications

N/A

Printer

Paper	▪ Thermal roll paper ▪ 210 mm (8.25”) wide
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, 6, 12 channel
Rhythm Print Formats	3, 6, or 12 channel with configurable lead groups

Connectivity Interfaces

Orders	▪ N/A
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 v3.00 *and later* – **or** – EScribe v8.10 *and later*
- ***Optional:*** ECG Safe
- ***Optional***: Mortara® VERITAS™ Resting ECG interpretation algorithm v7.20.1 w/ age & gender specific criteria

Hardware Interfaces

Barcode Reader	N/A
Mounting	▪ Optional ECG Cart Configurations ▪ Table top

Physical Characteristics

Weight	5.8 lbs. (2.63 kg) including battery (without paper)
Dimensions	11.25 x 7.5 x 2.75” (28.58 x 19 x 7 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**: 10% to 95%, non-condensing **Storage Humidity**: 10% to 95%, non-condensing **Altitude (*Pressure*)**: 3,000 meters

Supporting Documentation

Manuals	**IFU:** 9515-175-50-xxx **Physician’s Guide:** 9515-001-51-xxx **WAM IFU**: 9515-174-50-xxx **AM12 IFU**: *(see ELI 230 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
- Swedish
- Turkish
- Chinese
- Italian
- Finnish
- Dutch
- Hungarian
- Croatian
- Japanese
- Spanish
- French
- Polish
- Czech
- Romanian
- Russian

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*

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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)