

ELI 280 Technical System Requirements

Overview

The ELI 280 is a 12-lead resting ECG diagnostic electrocardiograph with a 10.1" color LCD display capable of acquiring, viewing, transmitting, printing, and storing resting ECG test data. The device is equipped with Mortara Instrument's VERITAS™ resting ECG interpretation algorithm using gender specific and adult and pediatric 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. A query of patient demographics can also be performed utilizing the Patient Demographic Query (PDQ) feature.

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

The ELI 280 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, 10.1" high-resolution color LCD
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	Touchscreen keyboard with alphanumeric keys, soft-key menu and 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 <i>Optional</i> 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
SECUR-IT	Requires software v2.0.0 or greater <i>and</i> ELI Link software v4.4.0 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 <i>minimum level</i>, 10.6V to: <ul style="list-style-type: none"> 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 the 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. SECUR-it: <ul style="list-style-type: none"> User logging Automatic termination of sessions User Authentication Patient Demographic Query (PDQ) – allows for patient's demographic search via HL7® ADT



Network Specifications

Wireless Network (option)	Wired Network		<ul style="list-style-type: none"> IEEE 802.3 LAN, 100 Mbps or faster
	Wireless Protocols		<ul style="list-style-type: none"> IEEE 802.11 a/b/g/n (2.4 GHz or 5 GHz) Channels: Up to 14* (3 non-overlapping) @ 2.4 GHz Up to 23* non-overlapping @ 5 GHz
	Data Rates	802.11a/g (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
		802.11n (OFDM, HT20, MCS 0-7)	<ul style="list-style-type: none"> 6.5, 13, 19.5, 26, 39, 42, 58.5, 65 Mbps
	Standards		<ul style="list-style-type: none"> 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) WPA2-EAP-TLS (EAP Transport Layer Security)
	Encryption		<ul style="list-style-type: none"> AES 256-bit WEP, RC4 TKIP, RC4
	Direct Connection		<ul style="list-style-type: none"> Serial port communication directly to PC
	User Authentication		<ul style="list-style-type: none"> Local login or... LDAP or Active Directory service
	Admin Account		<ul style="list-style-type: none"> Configurable <i>local</i> administrator password or... LDAP/Active Directory authentication



Printer

Paper	<ul style="list-style-type: none"> Smart (210 x 280 mm), perforated Z-fold thermal cued paper w/ full grid A4 8.5" x 11" Up to 250 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	Supports external orders in the following formats: <ul style="list-style-type: none"> XML <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>)
Export Formats	Supports exporting data in the following formats: <ul style="list-style-type: none"> XML Via ELI Link: PDF DICOM® encapsulated PDF DICOM® 12-Lead HL7 (<i>by adding optional Mortara® HL7 Gateway</i>)

Associated Software

- Optional:** ELI Link v3.00 and later – or – EScribe v8.10 and later
Note: Information Exchange requires ELI Link v4.2.0 or later, SECUR-IT requires ELI Link v4.4.0 or later
- Optional:** ECG Safe
- Optional:** Mortara® VERITAS™ Resting ECG interpretation algorithm v7.2.6 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	13.9 lbs. (6.30 kg) including battery (without paper)
Dimensions	15.5 x 17 x 4" (39.4 x 43.2 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: 10% to 95%, non-condensing Storage Humidity: 10% to 95%, non-condensing Altitude (Pressure): 3,000 meters

Supporting Documentation

Manuals	IFU: 9515-181-50-xxx Physician's Guide: 9515-001-52-xxx MDS2: 9710-181-xx-ENG WAM IFU: 9515-174-50-xxx AM12 IFU: (see ELI 280 IFU above)
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*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

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

Resting ECG Acquisition Modules

WAM – Wireless Acquisition Module



Instrument Type	12-lead <i>wireless</i> 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 <i>wired</i> 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)