



MAC VU360™ v1.02

Resting ECG workstation



General

Instrument type	Microprocessor augmented automatic electrocardiograph; 14-leadwire acquisition with programmable lead configuration
ECG interpretation	Marquette™ 12SL™ ECG Analysis Program for Adults and Pediatrics
Computerized measurements	15-lead analysis includes measurements of user-selectable additional 3 leads
Heart rate meter	30 to 300 BPM ±10% or 5 BPM, whichever is greater. Heart rates outside this range will not be displayed
ECG data formats	GE HealthCare Hi-Fidelity ECG, XML
External archiving	USB removable media SFTP (Secure File Transfer Protocol) Shared Drive
Pre-acquisition	Provides 10 seconds of instantaneous ECG acquisition
Digital rhythm	Up to 5 minutes of continuous rhythm storage (exportable as a PDF)
Full disclosure	Select, review acquire, print and/or transmit any 10 second ECG segment from the continuous 12 or 15 lead ECG data in internal memory (optional)
Storage	1000 records consisting of 10 second Resting ECG records and Digital Rhythm records on the device internal memory
Dynamic range	AC Differential ±5mV, DC offset ±300 mV
Common mode rejection	>130 dB (>100 dB with AC filter disabled)
Input impedance	>10MΩ @ 10 Hz
Defibrillation protection	Per IEC 60601-2-25:2011
Patient leakage	<10 μA
Log Aggregation	Event log entries can be sent directly to a networked Log Aggregator via syslog protocol

Specifications for digital acquisition and analysis of waveforms

Analog to digital conversion	24-bit analog to digital conversion resolution; Bandwidth: DC to 500 Hz; Digital over sampling rate: 512 ksps
Down sampled ECG waveform	Bandwidth: 0.04 to 150 Hz; Sample rate: 2 ksps; Resolution: 1.22 μV
Input to 12SL	Bandwidth: 0.04, 0.56 ZPD to 150 Hz; Sample rate: 1 ksps; Resolution: 4.88 μV
Additional report filters	20 Hz, 40 Hz, 100 Hz, or 150 Hz

Specification for stored/transmitted waveforms

Digital rhythm waveform	Bandwidth: 0.04, 0.56 ZPD to 150 Hz; Sample rate: 1000 sps; Resolution: 4.88 μV
12-lead ECG waveform	Bandwidth: 0.04, 0.56 ZPD to 150 Hz; Sample rate: 500 & 1000 sps; Resolution: 4.88 μV
Representative (median) complex	Sample rate: 500 & 1000 sps; Resolution: 4.88 μV

Pace detection

Pacemaker waveform	Bandwidth: 23.5 Hz to 10.5 kHz; Sample rate: 75 ksps; Resolution: 11.8 μV
Pace detection	Duration: 0.2 ms to 2.1 ms Amplitude: 2 mV to 700 mV Separation: 1 ms or greater
Pace annotation	Dedicated pace channel on display and printed reports

Communications

ECG management systems connectivity	MUSE™ Cardiology Information System Compatible (v8 or later) with bi-directional orders and ADT support Transmit Resting ECG records to CardioSoft via removable media (v6.73 or later) or via network (v7 or later)
DICOM	Modality Worklist/Orders: Supported via GE HealthCare MUSE (v9 or higher) and DICOM Gateway with bi-directional orders support
EMR connectivity	Via MUSE Cardiology Information System (v8 or later) and via EMR Gateway with bi-directional ADT support
Web	HTML/web capable for access to pre-configured web applications (optional)
Data export	Export of Resting ECG (in PDF or XML format), Digital Rhythm and Full Disclosure reports (in PDF format) over Secures File Transfer Protocol (SFTP) or to a Shared folder
Wireless	Wireless 802.11 a/b/g/n wireless connectivity (2.4GHz/5GHz) IPv4 DHCP, hostname and static IP options for configuring device IP/network address WEP and Enhanced Security WPA-PSK, WPA2-PSK, WPA/WPA2 enterprise protocols TLS, PEAP-MSCHAPV2, PEAP-GTC, TTLS-MSCHAPV2, TTLS-GTC. (PEAP requires network evaluation/ approval prior to purchase) Ultra-high security 4096 bit encryption/long certificate support SHA1 and SHA2 support
Network connectivity	802.3 Ethernet interface via RJ45 connector Compatible to 10Base-T, 100Base-T and 1000Base-T LAN IPv4 DHCP, hostname and static IP options for configuring device IP/network address
Network clock	Network time synchronization (NTP)

Display

Display & resolution	15.6" diagonal, LED backlit, Full HD (1920 × 1080 pixels)
Touch screen type	Projected Capacitive (PCAP) multipoint touch input that works while wearing medical exam gloves
Display data	Heart rate, patient name, patient ID, date, clock, battery power indicator, scrolling waveforms, lead labels, speed, gain and filter settings, warning messages, prompts, hookup advisor and help messages
Sensors	Accelerometer for putting unit in standby when display is closed

Writer

Writer technology	Integrated thermal dot array
Number of traces	3, 6, 12, or 15 user selectable
Writer speeds	5, 12.5, 25, & 50 mm/s
Writer sensitivity/gain	2.5, 5, 10, 20 mm/mV, and 10/5 mm/mV split gain
Writer speed accuracy	5, 12.5 mm/s @ +5% 25, 50 mm/s @ ±2%
Writer amplitude accuracy	±5%
Writer resolution	Horizontal: 40 dots/mm @ 25 mm/s Vertical: 8 dots/mm
Paper type	Thermal, Z-fold, perforated, fan fold, 300 sheets/pack
Paper size	8.5 in × 11 in (215mm × 280 mm) A4: 8.27 in × 11.7 in (210 mm × 297.5 mm)

Keyboard

Type	Sealed elastomer membrane keyboard with tactile feedback
Keys	Function keys, Alphanumeric keys, Writer controls, Trimpad cursor controls

Electrical

Power supply	AC mains or battery operation
Input voltage	100-240 VAC + 10%
Input frequency	50-60 Hz + 3 Hz
Battery type	Replaceable and rechargeable internal battery
Battery capacity	The system shall be able to continuously display scrolling waveforms without printing for a minimum of six hours (360 minutes) when the maximum total battery capacity is installed and the battery is fully charged.
Battery charge time	Approximately 240 minutes from total discharge when device is off or standby

Security and privacy

Encryption	All files containing PHI, local users and passwords
Login authentication	Network: LDAP/Active Directory Local: User database
User management	Customizable roles for limiting system access by user groups for Admin, Clinical, Service, Biomed, and user defined up to 10 customized roles
Audit trail	All user logins, logouts and login failures, file deletions, file changes, file views, file acquisitions, file transmissions, file printouts, system configuration changes
PHI access	Controlled by customizable roles with configurable advanced strict PHI access rules
PHI access logs	Detailed and exportable logs of all PHI viewing by users
Emergency access	This user can access the device without providing (STAT mode) login credentials to perform emergency tasks such as acquiring an ECG or rhythm while preventing access to any stored patient data, orders, ADT, or 3rd party applications
USB lockout	Software controls to disable USB ports/connections

Vectorcardiography

Report formats	Vector loops of main vector (QRS-STT)
Sensitivity	20, 40, 80, or 160 mm/mv
Time resolution	2 ms

Physical specifications

Weight	75.3 lbs max with adjustable height premium trolley and 1 battery
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System with fixed height value trolley

Handle height	36 in (91 cm)
Max height	57 in (145 cm)
Width	20.5 in (52 cm)
Depth	23.5 in (60 cm)

System with fixed height premium trolley

Handle height	35 in (89 cm) or 37 in (94 cm)
Max height	56 in (142 cm) to 58 in (147 cm)
Width	19 in (48 cm)
Depth	28 in (71 cm)

System with adjustable height premium trolley

Handle height	From 35 in (89 cm) to 41 in (104 cm)
Max height	From 56 in (142 cm) to 62 in (158 cm)
Width	19 in (48 cm)
Depth	28 in (71 cm)

Environmental specifications

Temperature

Operating	50° to 104° F (10° to 40° C)
Transport/storage	-4° to 140° F (-20° to 60° C)

Humidity

Operating	20% to 95% RH non-condensing
Transport/storage	15% to 95% RH non-condensing

Pressure

Operating	70 to 106 kPa
Transport/storage	50 to 106 kPa

Input devices

Keyboard	Sealed elastomer membrane keyboard with tactile feedback
Touchscreen	Full HD (1080p) projected Capacitive (PCAP) multipoint touch input that works while wearing medical exam gloves
Barcode	Integrated in CAM or external barcode scanner (both optional)
Mouse	Supported but not included

External USB barcode scanner

Types	External and internal integrated in the CC-14 acquisition unit (both optional)
Formats	Fixed and variable length
Symbologies	Code-128, PDF417, Code 39, Interleaved Code 2 of 5, and Data Matrix symbology for characters A-Z (upper case), a-z (lower case), and 0-9 for all supported languages

Acquisition unit

Quality Indicators	Real-time Hookup Advisor with LED lead quality indicators
Remote control	ECG acquisition button, rhythm acquisition button, stop button
Ingress Protection Level	IPx4
Integrated Input Device	Optional integrated bar code scanner
Types	Fixed and variable length
Symbologies	Code-128, PDF417, Code 39, Interleaved Code 2 of 5, and Data Matrix symbology for characters A-Z (upper case), a-z (lower case), and 0-9 for all supported languages

Cleaning

Approved cleaning agents	Soap and water solution Sodium Hypochlorite (NaOCl) 5% solution Ethanol (ethyl alcohol) 96% (v/v) Isopropyl alcohol 70% (m/m) Hydrogen Peroxide 20% (v/v) Phenol 2% (V/V)
FDA cleaning agent for efficacy	Super Sani-Cloths

Certification

Certification marks	cTUVus
Standards complied with	EN 60601-1:1990, A1:1993, A2:1995 EN 60601-1:2006/A1:2013 EN 60601-1-1:2001 EN 60601-1-2 : 2007 +AC 2010 EN 60601-1-2:2015 EN 60601-1-4:1996/A1:1999 EN 60601-1-6:2010 EN 60601-2-25:1995, +A1:1999 EN 60601-2-25:2011 EN 60601-2-51:2003 EN 62366:2008 EN 62304:2006

Language support

Available user interface languages	Danish, Dutch, English, French, Finnish, German, Italian, Norwegian, Swedish
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