MAC™ 5 A4 data sheet

GENERAL

Instrument type	Microprocessor augmented automatic electrocardiograph; 10-lead wire acquisition with programmable lead configuration
ECG interpretation	Marquette™ 12SL™ ECG analysis program for adults and pediatrics
Computerized measurements	12-lead analysis includes measurements
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 Hi-Fidelity ECG, XML
External archiving	USB removable media
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	Review up to 5 minutes of 12 Lead ECG, abiliy to selet 10 second Resting ECG records, ability to generate 5 minute single lead full disclosure report
Storage	300 records consisting of 10 second Resting ECG and rhythm records
	200 minutes Digital Rhythm or Full Disclosure records
Dynamic range	AC differential ± 10 mV DC offset ±600 mV
Common mode rejection	>125 dB (>100 dB with AC filter disabled)
Input impedance	>50MΩ @ 10 Hz

Defibrillation protection	Per IEC 60601-2-25:2011
Patient leakage	<10 μA

Specifications for digital acquisition and analysis of waveforms

Analog to digital conversion	24-bit analog to digital conversion resolution
	Over sampled rate: 512 ksps
Down sampled ECG waveform	Bandwidth: 0.04 to 300 Hz* Sample rate: 2 ksps Resolution: 1.22 μV
Input to 12SL	Bandwidth: 0.04, 0.56 ZPD to 300 Hz* Sample rate: 1 ksps Resolution: 4.88 μV
Additional report filters	20 Hz, 40 Hz, 100 Hz, 150 Hz or 300 Hz*

Specification for stored / transmitted waveforms

Digital rhythm waveform	Bandwidth: 0.04, 0.56 ZPD to 300 Hz* Sample rate: 1000 sps Resolution: 4.88 μV
12-lead ECG waveform	Bandwidth: 0.04, 0.56 ZPD to 300 Hz* Sample rate: 500 and 1000 sps Resolution: 4.88 μV
Representative (median) complex	Sample rate: 500 and 1000 sps Resolution: 4.88 μV

Pace detection

Pacemaker waveform	Sample rate: 75 ksps
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 (configurable)

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 MUSE (v8 or higher) and DICOM Gateway with bi-directional orders support
EMR connectivity	Via MUSE cardiology information system (v8 or later) with EMR Gateway
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 connectivity	Wireless 802.11 a/b/g/n wireless (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 LAN
	IPV4
	DHCP, hostname and static IP options for configuring device IP/network address
Network clock	Network time synchronization (NTP)

DISPLAY

Display and resolution	8.9" diagonal, LED backlit, 892 x 558 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

WRITER

Writer technology	Integrated thermal dot array
Number of traces	3, 6, 12 user selectable
Writer speeds	5, 12.5, 25, and 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 at 25 mm/s Vertical: 8 dots/mm
Paper type	Thermal, Z-fold, perforated, fan fold, 150 sheets/pack
Paper size	Modified Letter: 8.43 in x 11 in (214.2 mm x 279.4 mm)
	A4: 8.27 in x 11.7 in (210 mm x 297.5 mm)
Network printer	Support printing to network printer

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	Minimum 180 minutes with acquiring and printing a single page ECG report every 15 mins (with five minutes auto standby enabled and all accessories connected, except KISS)
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 (STAT mode)	This user can access the device without providing 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

PHYSICAL SPECIFICATIONS

Weight and dimensions

Max weight	5 kg
Max height	125 mm
Max width	325 mm
Max length	370 mm

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	Touch keyboard
Touchscreen	8.9", 892 x 558 pixels projected Capacitive (PCAP) multipoint touch input that works while wearing medical exam gloves
Barcode	External barcode scanner (optional)
Mouse	Supported but not included

External USB barcode 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 60601-1:2006/A1:2013 EN 60601-1-2:2007 +AC 2010 EN 60601-1-2:2015 EN 60601-2-25:2015 IEC 62366-1:2015 EN 62304:2006+A1:2015
Pharma mode*	Support 21CFR Part 11 clauses for the control of electronic records in closed systems when Phrama mode option is activated. No support for electronic signature

ORDERING INFORMATION

Available user interface languages	Chinese, Danish, Dutch, English, French, Finnish, German, Italian, Norwegian, Swedish, Korean, Japanese, Russian, Spanish, Portuguese, Brazilian Portuguese, Polish