Anexa 117 Specificație tehnică completată

Model: MAC 2000, Producător: GE Medical Systems, GE Healthcare, Tara: USA/SUA

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină completată de către autoritatea ofertantă
"Electrocardiograf cu 12 canale, caracteristici de baza Cod 260230 Descriere Electrocardiograf cu 12 canale, care înregistrează, printează şi/sau interpretează ECG de la o singură sau mai multe derivații simultan, cu display color. Parametrul Specificația Tip pacient adult, pediatric Numărul de canale de procesare 12 Configurația Portabil da Derivațiile Tip înregistrare auto și manual Sensivitatea 2.5, 5, 10, 20 mm/mv Semnal de calibrare 1 mV, ± 2% Gama de frecvență De diagnostic 0.05-150 Hz Filtru muscular 25, 35Hz Filtru frecvență joasă 0.05, 0.16, 0.25, 0.32, 0.5, 0.67Hz Filtru frecvență înaltă 20, 40, 100, 150Hz Filtru de rețea 50 Hz Impendanța de intrare ≥ 50 M Ohm Gama de rejecție a modului comun la 50 Hz > 100 dB Convertor analog-digital ≥ 16 bit Scurgeri spre pacient prin electrozi ≤10 μA Detector de pacemaker da Indicator deconectare electrod acustic sau vizual da Imprimantă Termică încorporată Mărimea hîrtiei ≥ 110 mm Să se indice numele derivației printate da Viteza de înscriere 5, 10, 25, 50 mm/s Densitatea imprimarii 8 dpi/mm (rezoluție verticală) și 40 dpi/mm (rezoluție orizontală) la viteza de 25 mm/s Acuratețea ± 5% (axa x), ± 5% (axa y) Derivațiile înscrise minim 12 Numărul de derivații înscrise simultan 3, 6, 12 Hîrtia termică să fie compatibilă și de la alți producători de hîrtie cu dispozitivul ECG da Display Grafic, LCD TFT color da ""Monitorizarea pe display: data, ora, sensibilitatea, viteza de înscriere, filtru, derivațiile"" da Marime ecran ≥ 7 inch Rezoluția ≥ 800x480 pix	Electrocardiograf cu 12 canale, caracteristici de baza **DA** Cod 260230 Descriere Electrocardiograf cu 12 canale, care înregistrează, printează şi/sau interpretează ECG de la o singură sau mai multe derivații simultan, cu display color. **DA** Parametrul Specificația Tip pacient adult, pediatric **DA** Numărul de canale de procesare 12 **DA** Configurația Portabil **DA** Derivațiile Tip înregistrare auto și manual **DA** Sensivitatea 2.5, 5, 10, 20 mm/mv **DA** Semnal de calibrare 1 mV, ± 2% **DA** Gama de frecvență De diagnostic 0.05-150 Hz **DA** Filtru muscular 25, 35Hz **DA** Filtru frecvență joasă 0.05, 0.16, 0.25, 0.32, 0.5, 0.67Hz **DA** Filtru frecvență îna ltă 20, 40, 100, 150Hz **DA** Filtru de rețea 50 Hz **DA** Impendanța de intrare ≥ 50 M Ohm **DA** Gama de rejecție a modului comun la 50 Hz > 100 dB **DA** Convertor analog-digital ≥ 16 bit **DA** Scurgeri spre pacient prin electrozi ≤10 μA **DA** Detector de pacemaker **DA** Indicator deconectare electrod acustic sau vizual **DA** Imprimantă Termică încorporată **DA** Mărimea hîrtiei ≥ 110 mm **DA** Să se indice numele derivației printate **DA** Viteza de înscriere 5, 10, 25, 50 mm/s **DA** Densitatea imprimarii 8 dpi/mm (rezoluție verticală) și 40 dpi/mm (rezoluție orizontală) la viteza de 25 mm/s **DA** Acuratețea ± 5% (axa x), ± 5% (axa y) **DA** Derivațiile înscrise minim 12 **DA** Numărul de derivații înscrise simultan 3, 6, 12 **DA** Hîrtia termică să fie compatibilă și de la alți producători de hîrtie cu dispozitivul ECG **DA** Display Grafic, LCD TFT color **DA** ""Monitorizarea pe display: data, ora, sensibilitatea, viteza de înscriere, filtru, derivațiile"" **DA** Marime ecran ≥ 7 inch **DA**

Anexa 117

Numărul de derivații afișate simultan 12 Posibilitatea transmiterii datelor la un sistem de management al datelor ECG Ethernet / USB / SD card da Format date ECG ""BMP / JPG / GIF / PDF / XML / DICOM"" da Memorie ≥ 200 inregistrari ECG da Soft specializat pentru analiza rezultatelor ECG la calculator da Posibilitatea introducerii rapide a datelor pacientului Nume, ID, vîrsta, sex, greutate, înălțimea Ajustarea automată a izoliniei da Identificarea aritmiei da Ritmului cardiac Diapazon 30 - 300 BPM Acuratețea ± 1 BPM Interpretarea Sistem de interpretare a datelor ECG da Măsurări PR, QT, QTC, P, QRS, T, HR; Timpul interpretării minim 10 s Alimentarea 220 V, 50 Hz Baterie internă reîncărcabilă da Timp operare autonomă ≥ 2 h Protecție defibrilator ≥ 400 J Indicatori vizuali contact slab sau lipsă de contact da status sistem da deconectare alimentare rețea da baterie descărcată da Accesorii Cablu pacient cu set de electrozi pectorali de tip pară (6 buc.) și membranari de tip clește (4 buc.) 2 set. Hîrtie termică 30 buc. Gel de contact 1 litru "	Rezoluția ≥ 800x480 pix **DA** Numărul de derivații afișate simultan 12 **DA** Posibilitatea transmiterii datelor la un sistem de management al datelor ECG Ethernet / USB / SD card **DA** Format date ECG ""BMP / JPG / GIF / PDF / XML / DICOM"" **DA** Memorie ≥ 200 inregistrari ECG **DA** Soft specializat pentru analiza rezultatelor ECG la calculator **DA** Posibilitatea introducerii rapide a datelor pacientului Nume, ID, vîrsta, sex, greutate, înălțimea **DA** Ajustarea automată a izoliniei **DA** Identificarea aritmiei **DA** Ritmului cardiac Diapazon 30 - 300 BPM **DA** Acuratețea ± 1 BPM **DA** Interpretarea Sistem de interpretare a datelor ECG **DA** Măsurări PR, QT, QTC, P, QRS, T, HR; **DA** Timpul interpretării minim 10 s **DA** Alimentarea 220 V, 50 Hz **DA** Baterie internă reîncărcabilă **DA** Timp operare autonomă ≥ 2 h **DA** Protecție defibrilator ≥ 400 J **DA** Indicatori vizuali contact slab sau lipsă de contact **DA** status sistem **DA** deconectare alimentare rețea **DA** baterie descărcată **DA** Accesorii Cablu pacient cu set de electrozi pectorali de tip pară (6 buc.) și membranari de tip clește (4 buc.) 2 set. **DA** Hîrtie termică 30 buc. **DA** Gel de contact 1 litru **DA** "

SIMPLE IS **SMART**

MAC 2000 ECG Analysis System
Streamlined for your healthcare facility

gehealthcare.com

Simple is **smart**

Complex healthcare environments demand simple solutions. Equipment that simply works, every time. Technology that delivers clear, accurate data in simple ways. Intuitive tools that are simple to use. And support you can count on without question. ***Simple.***

The MAC™ 2000 from GE Healthcare helps the physician make a fast and accurate diagnosis with the power of the Marquette™ 12SL analysis program. It's the proven† diagnostic support you need, in an ECG system that's intuitive and easy to use.

Really, really smart.

†*Marquette 12SL ECG Analysis Program Physician's Guide*. 2036070-006 Revision A. 2010. GE Healthcare: Milwaukee, WI.

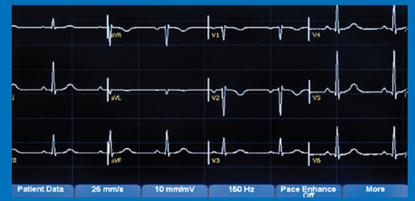
Simple is **productive**

Easy capture of 10-second ECGs with one-touch operation

On-screen preview of 12-lead waveforms and ECG results helps streamline review and diagnosis

Multiple connectivity and export options for easy data access, transfer and storage

Marquette 12SL ECG analysis program with reason statement for clinical decision support



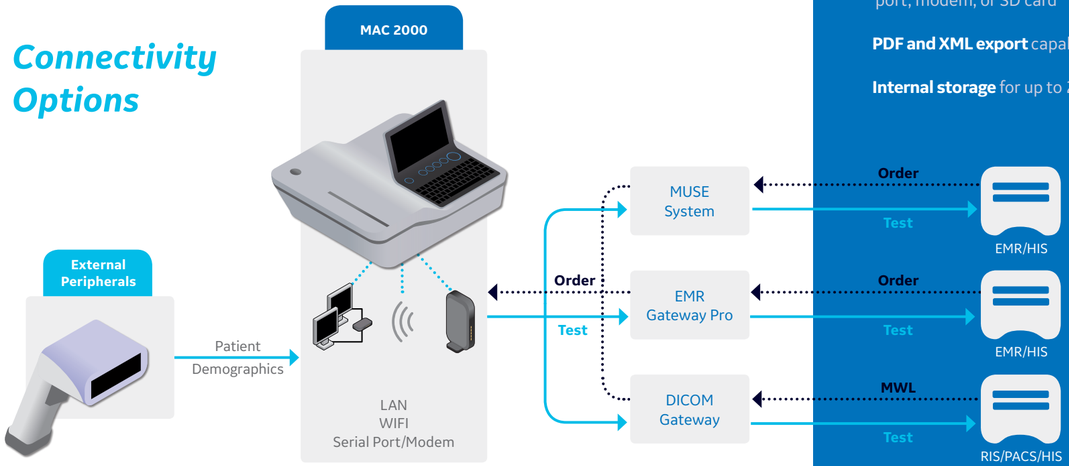
The MAC 2000 helps ECG Professionals be productive from the first ECG. Available tools such as HookUp Advisor™ assist in identification of a quality signal before acquisition, helping avoid costly repeat ECGs. It's all part of a smarter, simpler workflow that lets you do more in less time.

Simple is **connected**

Streamlined data connectivity

The MAC 2000 connects seamlessly with your existing environment, immediately making it easier to acquire, print, store, and transmit ECG data. It's your link to productivity, however you need to connect.

Connectivity Options



Supports paperless workflow with options for bi-directional communication, including Orders and ADT query features

Seamless connectivity with your **Electronic Medical Record** via EMR Gateway Pro

Seamless connectivity to **RIS/PACS systems** using DICOM Gateway

Seamless connectivity with **the MUSE™ cardiology information system or the CardioSoft™ program** - or send reports to a shared directory on a PC

Send report to remote locations using FTPS

Connectivity with LAN, Wi-Fi, serial port, modem, or SD card

PDF and XML export capabilities

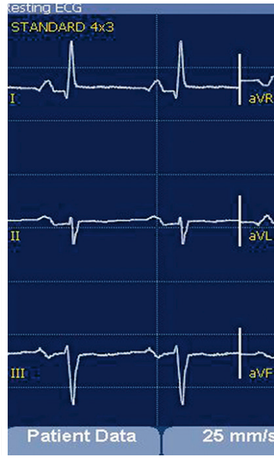
Internal storage for up to 200 ECGs

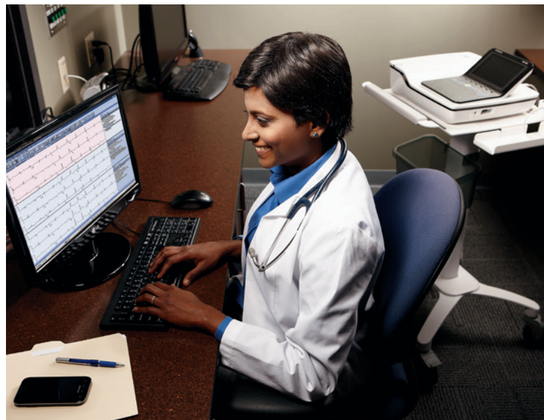
Simple is **reliable**

- **Marquette 12SL ECG analysis program** with measurement and interpretation
- **Arrhythmia detection** helps maximize rhythm capabilities and minimize paper consumption
- **ACI-TIPI algorithm** for acute cardiac ischemia
- **Gender-specific interpretation** provides improved sensitivity to Acute Myocardial Infarction in women
- **RR analysis** for detection of patterns in heart rate variability†
- **Full disclosure** to store up to 5 minutes of a single lead in PDF format†

The MAC 2000 delivers the diagnostic insights physicians need. Empowered with the Marquette 12SL analysis program, the system provides a complete set of analysis tools you can trust, because they've been rigorously validated against clinically correlated databases with multiple patient populations. It's clinical decision support made simple.

†RR analysis and full-disclosure are not available in all regions. Please contact your local GE Healthcare representative for more information.





Simple is **supported**

The MAC 2000 makes it simple the moment you open the box. Easy installation won't disrupt your hospital operations.

The familiar, intuitive interface with full keyboard means physicians and ECG Professional won't need days of training — more like minutes.

And because we know training needs can change with your team, we offer convenient computer-based training tools for on-demand learning.

Expert GE Healthcare service and support are always just a click or call away — our extensive network of trained service professionals are ready so you don't have to wait for help. It's another way the MAC 2000 embraces simplicity to give you a hassle-free experience.

Simple is **here**

To learn more about the MAC 2000 ECG, contact your GE Healthcare representative or visit **www.gehealthcare.com.**

GE Healthcare provides transformational medical technologies and services to meet the demand for increased access, enhanced quality and more affordable healthcare around the world. GE (NYSE: GE) works on things that matter – great people and technologies taking on tough challenges.

From medical imaging, software & IT, patient monitoring and diagnostics to drug discovery, biopharmaceutical manufacturing technologies and performance improvement solutions, GE Healthcare helps medical professionals deliver great healthcare to their patients.

Imagination at work

GE Healthcare, a division of General Electric Company

MAC 2000 1.1 SP6
JB50049XX(1)

MAC™ 2000

Specification Sheet

Instrument type

Microprocessor augmented automatic electrocardiograph; 10-leadwire, 12-lead simultaneous acquisition with programmable lead configuration.

.Processing

ECG Interpretation	Marquette™ 12SL™ ECG Analysis Program for Adults and Pediatrics
Computerized measurements	12-lead analysis
ECG analysis frequency	500 or 1000 samples/second/channel
Digital sampling rate	16000 samples/second/channel for normal data acquisition
Pace sampling rate	75K samples/second/channel
ECG on-screen preview	On-screen preview of acquired 10 second ECG waveform
Acquisition mode	Provides 10 seconds of instantaneous ECG acquisition
Dynamic range	AC Differential ±5 mV, DC offset ±300 mV
Resolution	4.88 µV +/-1% per LSB @ 500 SPS
Frequency range	0.04 to 150 Hz
Low cut off frequency	0.04 Hz (ADS off), 0.56 Hz (ADS On)
High cut off frequency	Configurable at 20 Hz, 40 Hz, 100 Hz or 150 Hz
Common mode rejection	>135 dB (with 50/60 Hz filter ON)
Input impedance	>10MΩ @ 10 Hz
Patient leakage	<10µA (Normal Condition), <50µA (Single Fault Condition)
Lead detection	All disconnected lead detection except RL and RA
Heart rate meter	30 to 300 BPM
Operating system	Microsoft® Windows® Embedded Compact 7
Start-up time	Less than 30 seconds

Patient information

Supported patient information	Patient ID, secondary patient ID, visit ID, last name, first name, height, weight, gender, race, pacemaker patient, systolic BP, diastolic BP, location number, room, order number, phone number, medication, ordering physician, referring physician, attending physician, technician, test indication

Display

Display type	7 in. color TFT display with support of minimum 32K colors
Display resolution	WVGA resolution – 800 x 480
Display data	Heart rate, patient ID, clock, battery power indicator, waveforms, lead lables, speed, gain and filter settings, warning messages, prompts, help messages, and 12-lead display

Writer

Writer technology	Thermal dot array
Writer speed`	5, 12.5, 25, and 50 mm/s
Number of traces	Up to 12 ECG traces
Writer sensitivity/gain	2.5, 5, 10, 20, 40 mm/mV
Writer speed accuracy	5, 12.5 mm/s @ ±5% and 25, 50 mm/s @ ±2%
Writer amplitude accuracy	+/-5%

Writer resolution	Horizontal 40 dots/mm @ 25 mm/s, 8 dots/mm vertical
Paper type	Z-fold Thermal Paper with pre-printed grid and perforation with Queue mark or Queue hole
Paper size	8.46 in x 11 in (215 mm × 280 mm) Letter 8.27 in × 11.69 in (10 mm x 295 mm) A4 8.43 in x 11 in (214.2 mm x 279.4 mm) Modified Letter

Keyboard

Type	Membrane keyboard with tactile feedback – Soft function keys, alphanumeric keys (Qwerty key set), writer controls and Trim Pad cursor controls

Operating modes and additional features

Resting ECG mode	Records and prints 12-lead resting ECGs with 10 seconds duration as a standard feature
Arrhythmia mode	Continuously monitors ECG and prints report when arrhythmia events of the user-selected class occur
Exercise mode	Exercise mode for exercise stress testing
RR Analysis mode*	RR analysis for RR intervals analysis
Full Disclosure mode	Store upto 5 minutes of 1 lead data in PDF format
Hookup advisor	Provides visual indication of signal quality
Multi-language support	Supports 19 languages in User Interface and 31 languages in User Manual
Order manager	Provides an interface for managing orders
ADT and Order Query	Provides an interface for querying patient demographics and orders
File manager	Provides an interface for managing ECG Records
System setup	Provides an interface for managing Device Configuration

Stress/Pharma application options

Stress testing application	Ergometers supported include: eBike Treadmills supported include: T2100, T2000 Master's Step device without interface (acoustic signal only) *Note: Ergometer, Master Step, and Treadmill sold separately*
Pharma application options	• Date & Time Prompt upon log in • Auto Save and export to SD Card of Patient test record after acquisition • Audit trail export • CT Data Guard™ • High security login protection

External peripherals

Keyboard	Standard USB English Keyboard
Barcode reader	Jadak-1799
Barcode Symbologies	Code 39, Code 39EX, Code 128, PDF-417, Interleaved Code 2 of 5, Data Matrix
Special Characters	In Italian, French, German, English and Spanish Languages

Communication

- Secured Digital card, Serial, LAN, and WIFI communicates outbound to MUSE™ and CardioSoft™
- LAN, and WIFI communicates inbound to MUSE
- MUSE Cardiology Information System and CardioSoft* compatible
- Bi-directional communication enabled with integration capabilities to MUSE, EMR, DICOM and DICOM modality work list systems workflow

RS232 serial cable Protocol	ECG Transmission with A5 and CSI
Supported MUSE/CardioSoft	Compatible with MUSE V 7.1.1, v8.0.1, v9.0.0 and NX CardioSoft/CS V6.51, V6.61, V6.71, V6.73 and V7
RJ45 Wired LAN	ECG Transmission with CSI, DCP Protocol, FTPS and Shared Directory‡
Wireless LAN (WIFI)	ECG Transmission with CSI, DCP Protocol, FTPS and Shared Directory‡

WiFi Authentication Protocols

Wireless Bridge Option:	Open, Shared, WPA2 with pre-shared key, WPA/WPA2 Mixed Mode with pre-shared key, WPA2 with PEAP, WPA/WPA2 Mixed Mode with PEAP, WPA2 with EAP-TLS, WPA/WPA2 Mixed Mode with EAP-TLS, WPA2 with EAP-TTLS, WPA/WPA2 Mixed Mode with EAP-TTLS, WPA2 with EAP-FAST, WPA/WPA2 Mixed Mode with EAP-FAST, WPA2 with LEAP, WPA/WPA2 Mixed Mode with LEAP
Embedded Wireless Module:	• Open • Shared • WPA – PSK* • WPA2-PSK* • WPA/WPA2 with PEAP • WPA/WPA2 with TLS • WPA/WPA2 with TTLS

Certain network settings are required for WIFI authentication. To determine whether your network is compatible, please refer to the MAC2000 site survey document DOC2368090.

*Not available in some countries.

‡Shared Directory require WINS

WiFi Encryption

Wireless Bridge Options:	Disabled (for Open authentication), WEP (for Shared and Open authentications) TKIP (for WPA/WPA2 Mixed Mode authentications), AES (for WPA & WPA2 authentications)
Embedded Wireless Module:	• Disabled (For Open authentication) • WEP (For Shared and Open authentications) • TKIP (for WPA-PSK1, WPA2-PSK1, WPA2 authentications) • AES (for WPA-PSK1, WPA2-PSK1, WPA2 & WPA22 authentications)

Storage

ECG Storage Format	XML format, Hilltop format, PDF storage format
Storage Capacity	Internal storage of 100 or 200 ECGs

Accessories

ECG Cables/Leadwires	IEC/AHA Value 10LD Patient Cable/Leadwire 10-lead IEC/AHA Patient trunk cable IEC/AHA Leadwire set (ECG 10-L w/resist, Banana) IEC/AHA Set of leadwires (4mm connector, 10 leads, defibrillator proof)
ECG Adapter	IEC/AHA Kit Adapter, 10 set Banana Electrode Prep Pads, CLIP Universal GE 10/Pkg
Electrodes	ECG Electrode Clamp (Large, 4/set) ECG Electrode Bulb (6/set) Baby MAC electrodes Silver Mactrode Plus 1000/CASE Electrode Application System KISS 10-lead
Other accessories	Country specific power cords Z-fold Thermal Paper with pre-printed grid and perforation with Queue mark or Queue hole of size: • 8.46 in x 11 in (215 mm × 280 mm) Letter • 8.27 in × 11.69 in (210 mm x 295 mm) A4 • 8.43 in x 11 in (214.2 mm x 279.4 mm) Modified Letter • 150 sheets/pack, 1500 sheets/case USB data matrix barcode scanner Secure Digital High Capacity Card – 2GB/4GB/8GB/16GB/32GB

Electrical

Power supply	Internal AC/DC or battery operation

AC/DC operation specifications

Input voltage:	100 to 240 VAC ±10%
Input current:	Maximum 1.5A in voltage range 115 V to 230 V AC
Input frequency:	47 to 63 Hz

Battery specifications

Battery type:	Replaceable and rechargeable, Lithium Ion
Battery capacity:	14.54V nominal voltage @ 3.5 AH – 10% 150 single page resting ECG recordings or 6 Hours (typical) of continuous monitoring without printing, at a minimum.
Battery charge time:	Approximately 3.5 hours after low battery shut down (with device off) to 90% full capacity

Physical specification

Height	7.87 inches (200 mm)
Width	15.35 inches (390 mm)
Depth	Depth 12.99 inches (330 mm)
Weight	Approx. 11.02 lbs (5 kg) including battery, without paper

Environmental specification

Temperature	Operating: 50°F to 104°F (10°C to 40°C) Transport/storage: -104°F to 158°F (-40°C to 70°C)
Humidity	Operating: 20% to 95% RH non-condensing Transport/storage: 15% to 95% RH non-condensing
Pressure	Operating: 700 to 1060 hPA (Altitude range: 3010.9 to -381.9 meters Transport/storage: 500 to 1060 hPA (Altitude range: 5570 to -380 meters)

Safety and regulatory

- CE marking for Council Directive 93/42/EEC concerning medical devices
- EN 60601-1 (IEC 60601-1) Medical electrical equipment – Part 1: General Requirements for Safety
- IEC 60601-1-2 General Requirements for Safety Electromagnetic Compatibility
- IEC 60601-2-25 Safety of Electrocardiographs
- UL 60601-1: 2006 UL Standard for Safety Medical Electrical Equipment, Part 1: General Requirements for Safety
- CAN/CSA C22.2 No. 601.1 M90
- IEC 60601-1-6 General Requirements for Safety – Usability

[1] WPA-PSK and WPA2-PSK are personal authentication frameworks.

[2] WPA and WPA2 are enterprise authentication frameworks.

GE Healthcare
9900 Innovation Drive
Wauwatosa, WI 53226
U.S.A.

www.gehealthcare.com

MAC 2000 V1.1 SP7 onwards
DOC1303761 Rev 9

14 June 2022

MAC 2000 ECG Analysis System

Simple is better

Simple is Smart

Introducing the MAC™ 2000 ECG Analysis System

The support you want in a connected system that's intuitive and easy to use.

Really, really smart.

Simple is Smart

Introducing the MAC™ 2000 ECG Analysis System

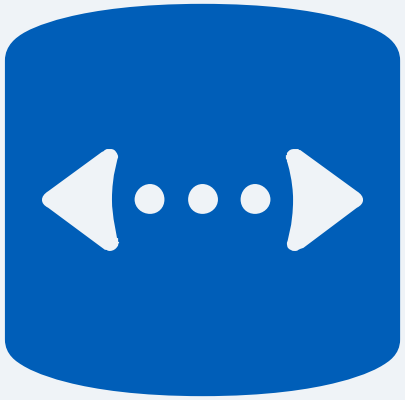
The support you want in a connected system that’s intuitive and easy to use.

Really, really smart.

Simple is Smart

Simple

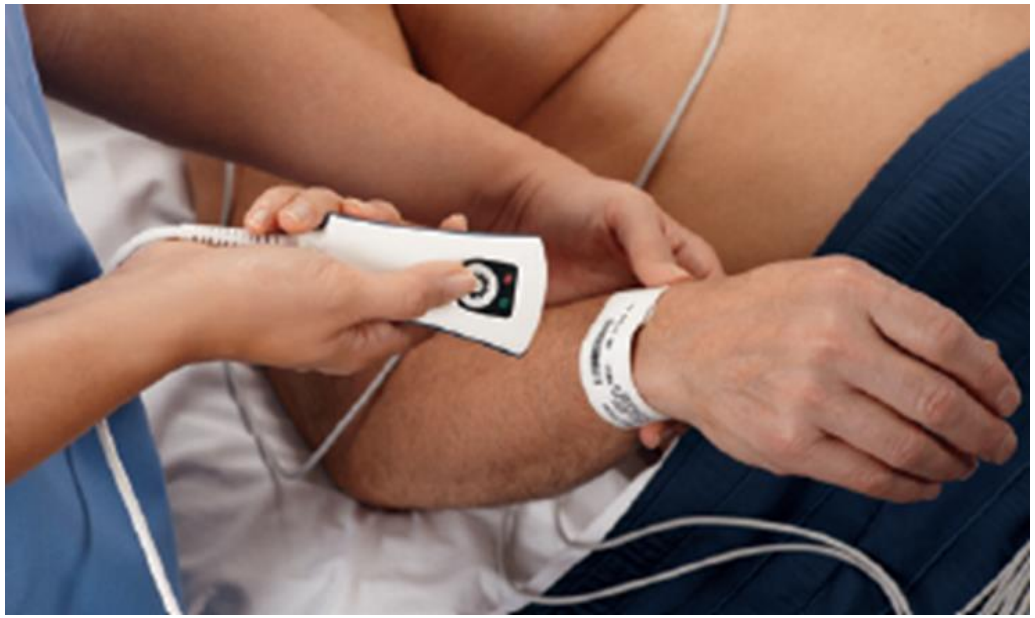
Connected



Advanced Technology

Simple

Simple is Productive



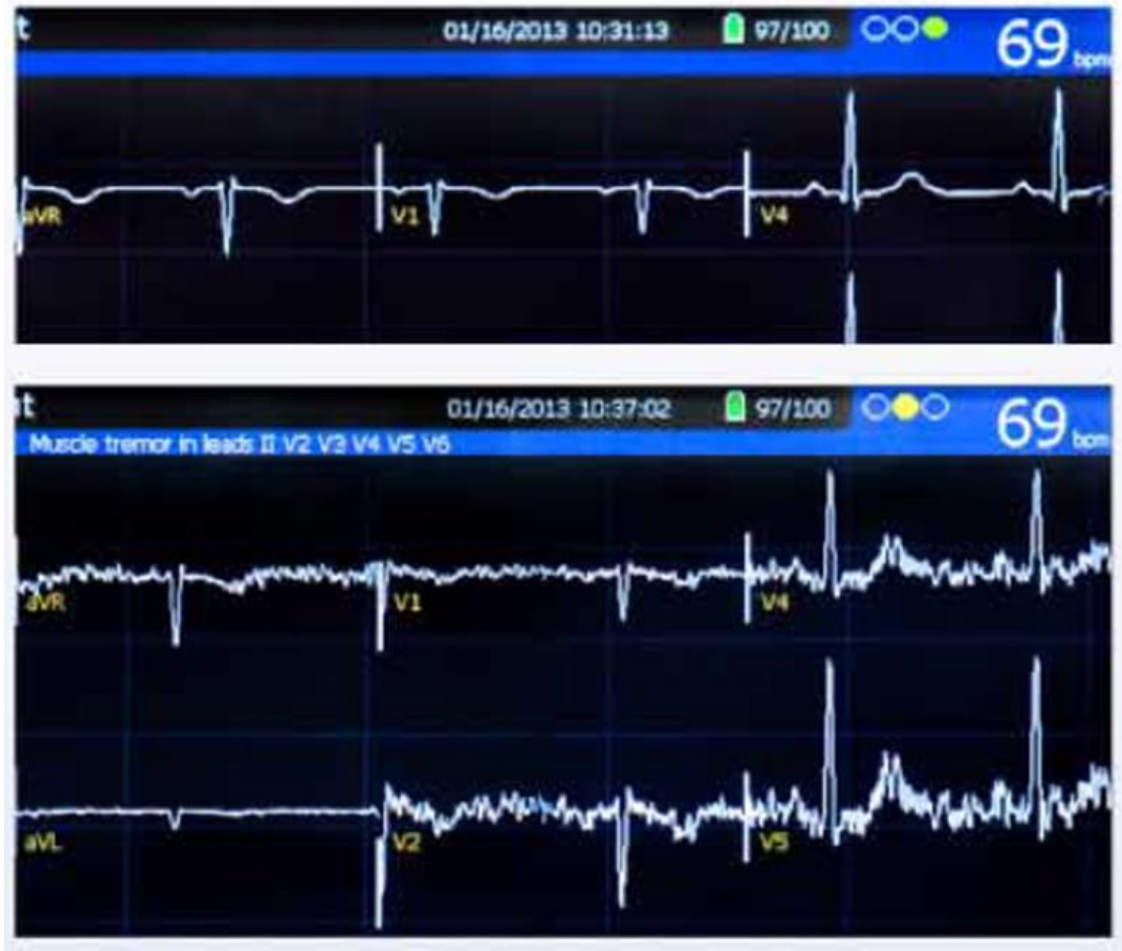
Tools to simplify your ECG workflow

- Hookup Advisor™ program helps clinicians identify a quality signal prior to acquisition
- On-screen 12 lead results help streamline ECG review and analysis
- Convenient computer-based training tools to bring your team up to speed quickly
- Available in exercise testing configuration

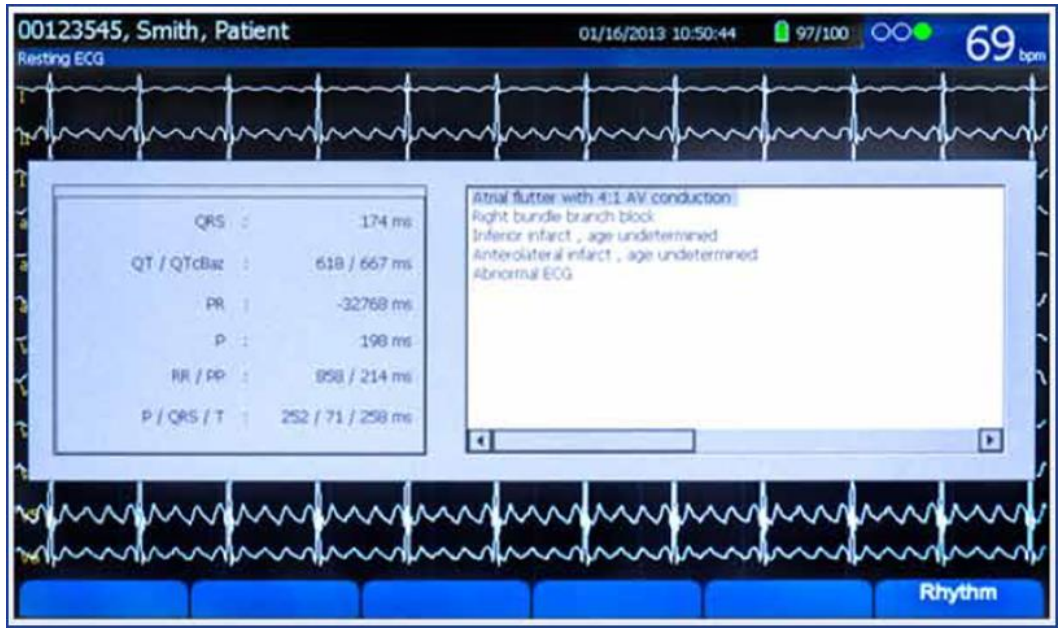
Simple is Productive

Hookup Advisor program

- Hookup Advisor program helps clinicians identify a quality signal prior to acquisition
- Identifies the type of noise & leads affected
- Helps clinicians avoid costly repeat ECGs



Simple is Productive



On-screen 12-lead results

- Help to streamline ECG review and analysis
- 12-lead waveforms, measurements, and computerized Marquette™ 12SL™ interpretation available as soon as ECG is recorded

Simple is Productive

Computer-based training

- Provides a thorough look at the features and functionality of the MAC 2000 system
- Modular design of the training encourages user interaction
- Move through basic system overview, acquiring an ECG, acquiring an arrhythmia report, completing a stress ECG test, and managing patient data
- Facilitates on-demand initial and refresher training

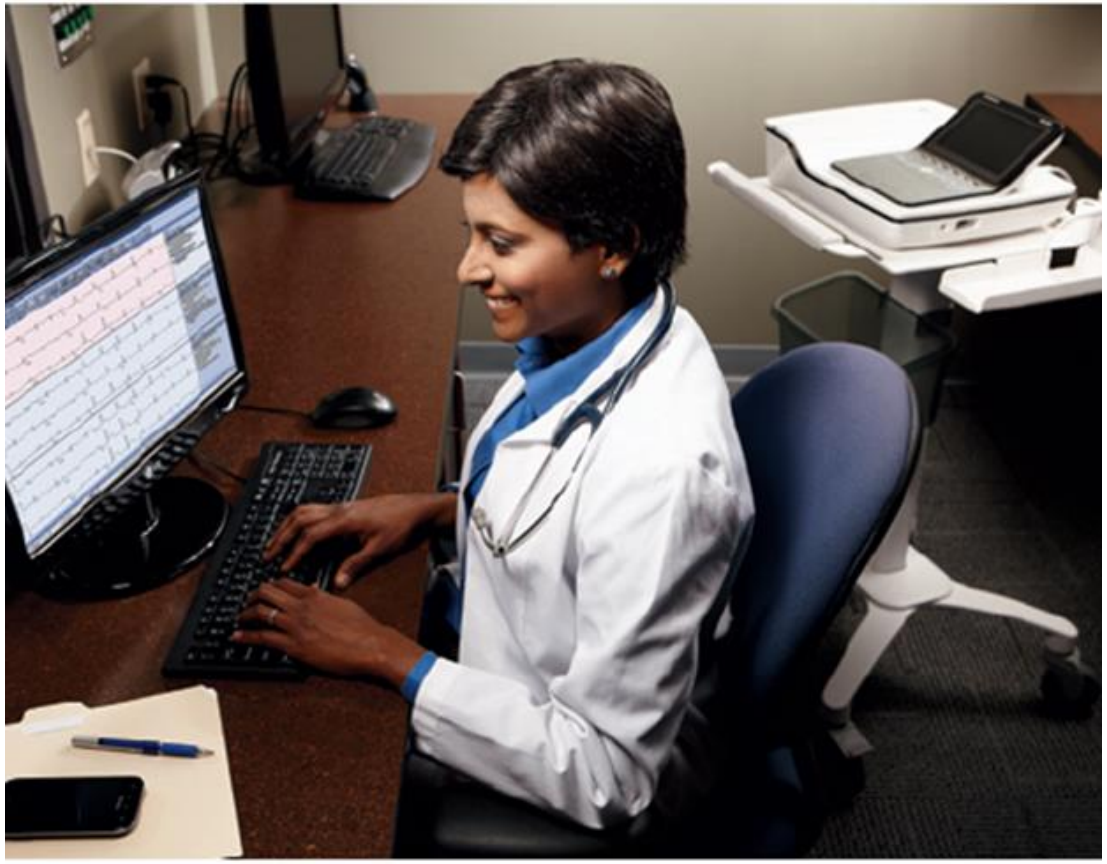
Simple is Productive

Stress testing configuration

- Expanded capability to help you make the most of your device investment
- Available for use with GE brand ergometers and treadmills

Connected

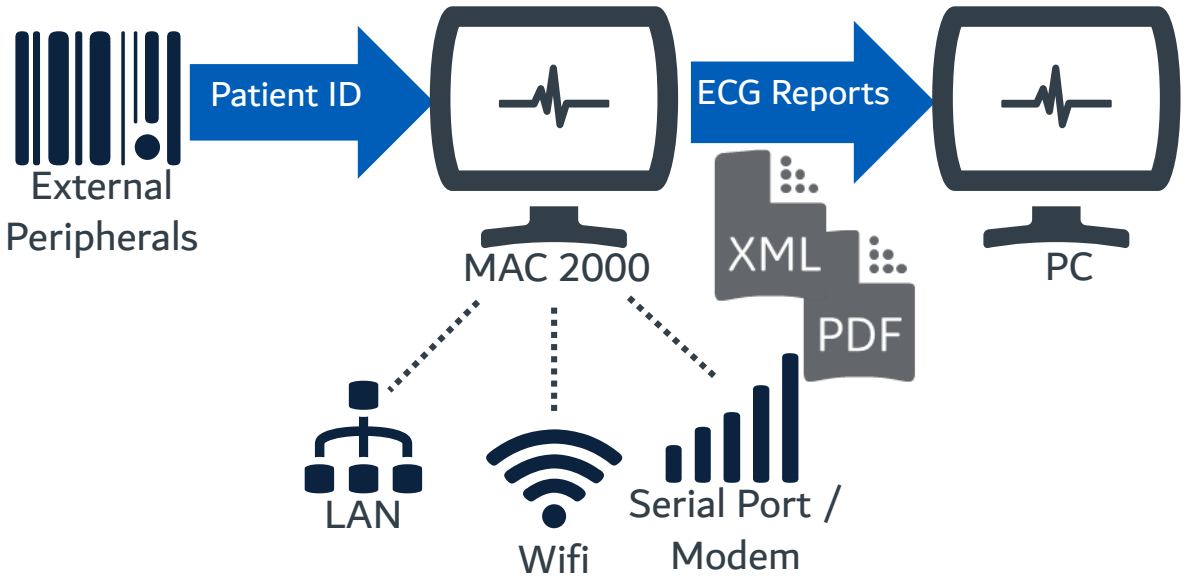
Simple is connected



Your link to ECG data connectivity

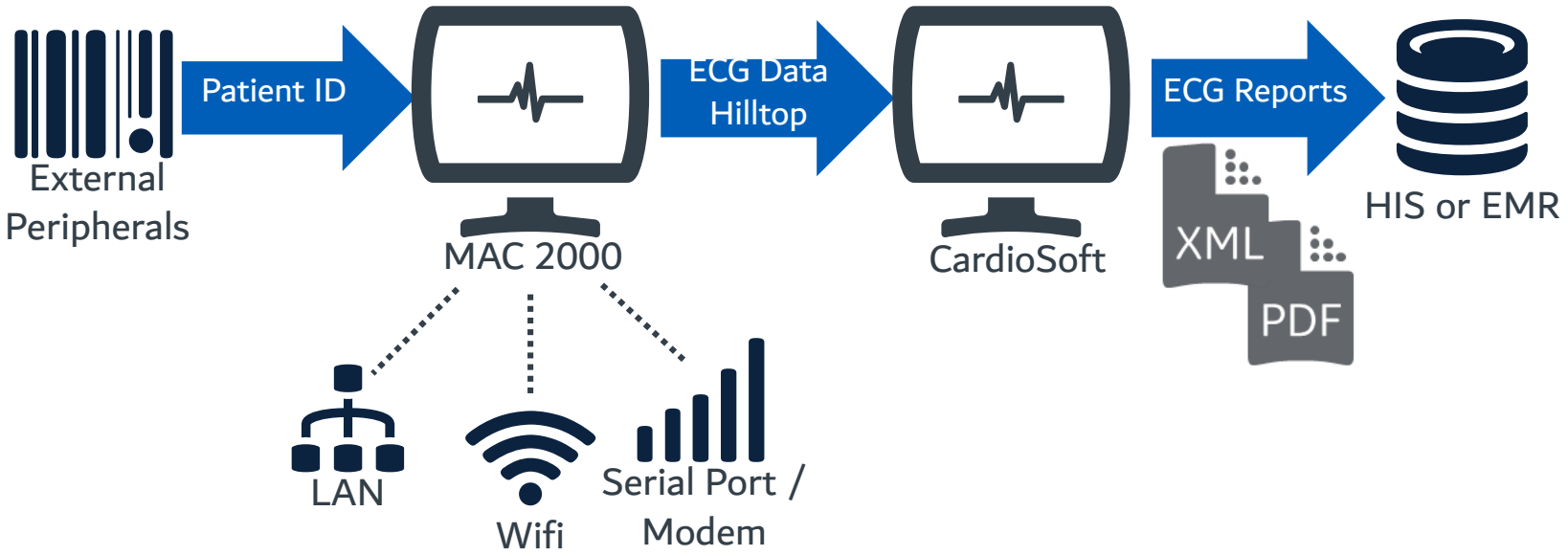
- Seamless connectivity with the MUSE™ cardiology system and the CardioSoft™ program
- Transfer data via Wi-Fi, LAN, SD cards, modem, and serial ports
- PDF and XML export capabilities

MAC 2000 workflow with shared directory/PC workstation



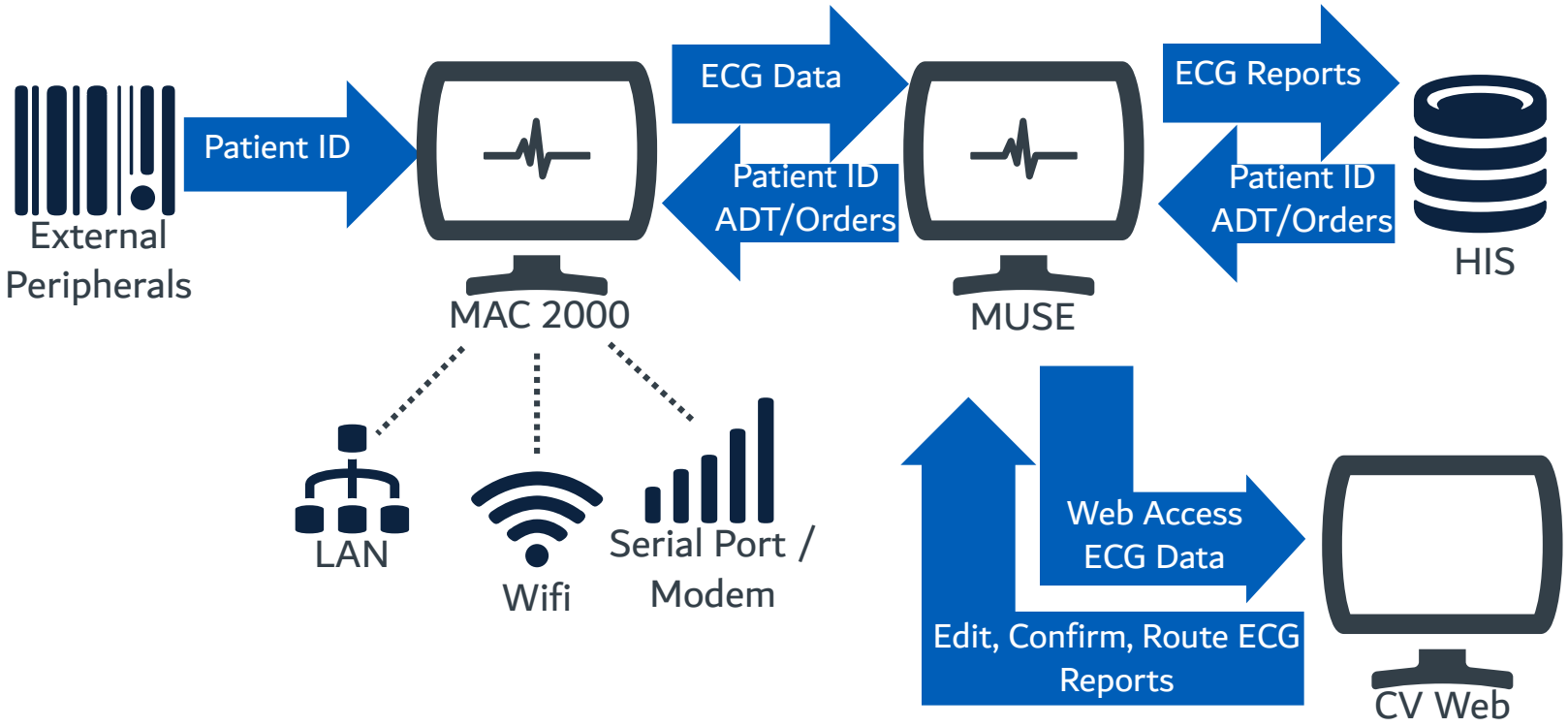
- Paperless workflow
- PDF out
- Wi-Fi connection
- Built-in storage of up to 200 ECGs

MAC 2000 workflow with CardioSoft Diagnostic Program



- Paperless workflow
- ECG measurement and editing
- PDF out
- Wi-Fi connection
- Built-in storage of up to 200 ECGs

MAC 2000 workflow with MUSE Cardiology Information System

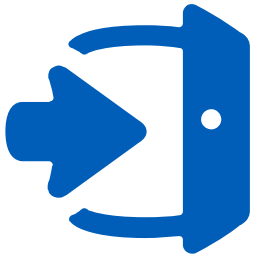


- Bi-directional communication with HIS system
- Orders and ADT query capabilities
- Web-enabled ECG report access and editing possible with CV Web 3.0
- Fast communication with DCP protocol
- Optional barcode reader functionality

Secure

Simple is Secure

Patient data encryption



Automatic, time configurable log-off

Username and password authentication

Site and location support

Audit trail, activity log

Automatic patient data deletion after transmission

Just a few ways this approach is manifested in MAC 2000

We encrypt all patient information stored on the MAC 2000 using 128 bit encryption software.

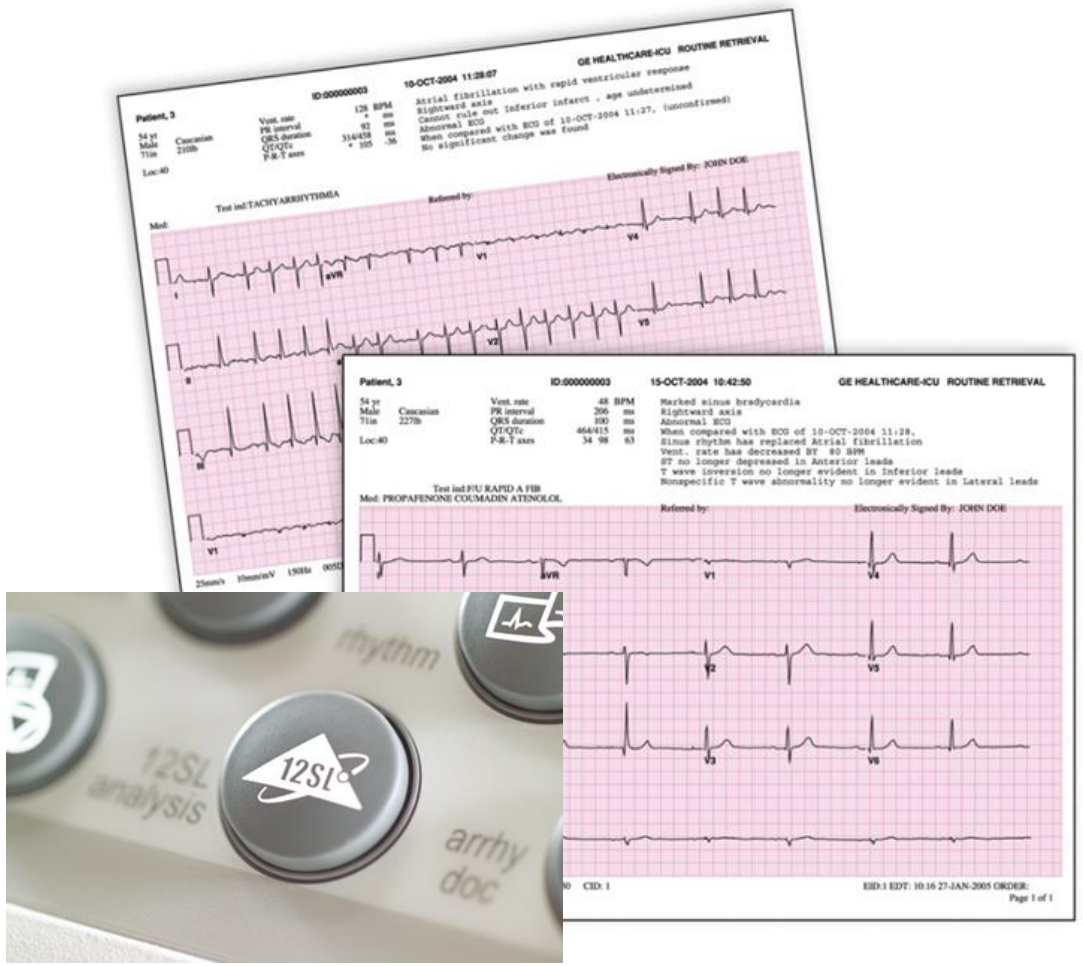
As an added layer of security, the MAC 2000 offers the option to create usernames and passwords.

To keep the system safe MAC 2000 can only receive inbound traffic from GE's MUSE, Gateways and FTP servers with a designated port.

The MAC 2000 can monitor and record security-related activities, such as logins and network connections, for audit.

Advanced Technology

Marquette™ 12SL™



- Over 30 years of innovation and development
- Over 150 scientific references[1]
- Validated against clinically-correlated databases for accuracy[1]
- ACI-TIPI option calculates probability of the presence of Acute Cardiac Ischemia
- Gender-specific interpretation has been shown to provide a 25% relative improvement in detection of Acute Inferior MI in women under 60 years of age[2]

[1]for more details please refer to the GE 12SL statement of validation and accuracy
[2]Xue, J. et al. "A New Method to Incorporate Age and Gender into the Criteria for the Detection of Acute Inferior Myocardial Infarction." J Electrocardiol. 34(4) (Part 2) (Oct 2001):229-234

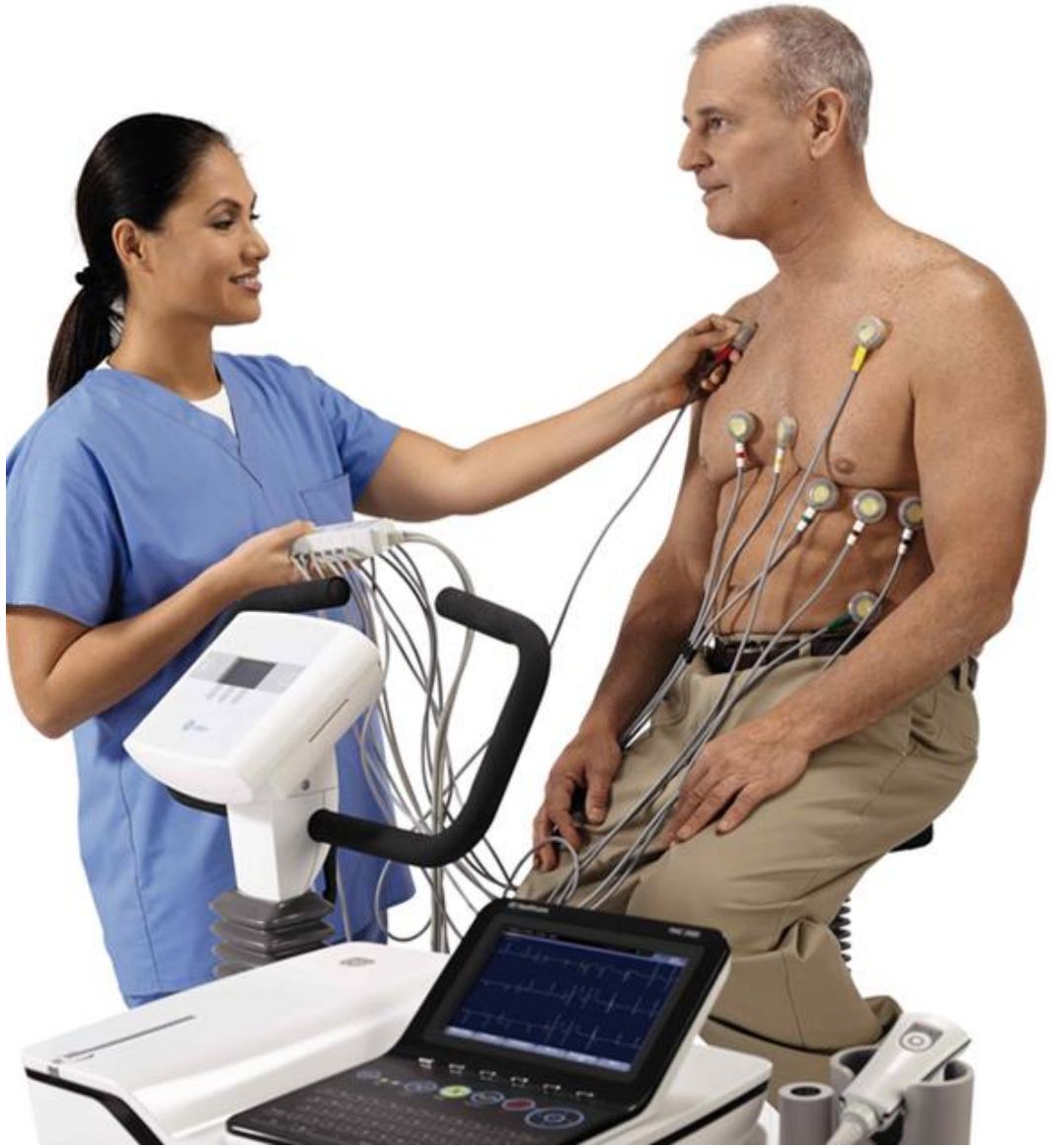
MAC 2000 Solution for Pharma Clinical Trials

- Hookup Advisor helps the clinician to identify a quality signal prior to acquisition. Less noise means reduced QT measurement variability[3]
- CT Data Guard helps in capturing clinical trial details, and records the same in the ECG report
- CFR Audit Trail supports 21 CFR Part 11 compliance requirements

[3] Farrell, R.M and Rowlandson, G.I., "The Effects of Noise on Computerized Electrocardiogram measurements." J Electrocardiol, 2006, 39(4 Suppl): p.S165-73.

KISS Suction Electrode Application System

- Provide consistent connection to patients
- Fast and easy electrode applications in the cardiology department
- Operates with a slight suction regulated by the electronically controlled suction pump via high sensitive sensors



MAC 2000 ECG Analysis System

Simple is here

Building a world that works

JB20046XE(4)

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 651490**

Issued To: **Micropace Pty Ltd**
41/159 Arthur Street
Homebush West
New South Wales
2140
Australia

In respect of:

Design and manufacture of Cardiac Stimulators for diagnostic electrical stimulation of the heart for initiation and termination of tachyarrhythmias, refractory measurements and measurements of electrical conduction.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2016-04-27** Date: **2020-03-04** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 651490

Issued To:

Micropace Pty Ltd
41/159 Arthur Street
Homebush West
New South Wales
2140
Australia

Class IIb		
GMDN	**Device or Generic Device Group**	**Intended purpose as per IFU**
35976	Stimulator, electrical, cardiac, diagnostic	The Micropace Cardiac Stimulator is intended to be used for diagnostic electrical stimulation of the heart for the purpose of initiation and termination of tachyarrhythmias, refractory measurements and measurements of electrical conduction.

First Issued: **2016-04-27** Date: **2020-03-04** Expiry Date: **2024-05-26**

...making excellence a habit.™

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 651490**
Date:	**2020-03-04**
Issued To:	**Micropace Pty Ltd** **41/159 Arthur Street** **Homebush West** **New South Wales** **2140** **Australia**

Subcontractor:	**Service(s) supplied**
Advena Ltd Tower Business Center 2nd Floor, Tower Street Swatar BKR 4013 Malta	**EU Representative**
Micropace EP Inc., 3205 West Warner Avenue Santa Ana California 92704 USA	**Manufacture**

...making excellence a habit.™

By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 651490**

Date: **2020-03-04**

Issued To: **Micropace Pty Ltd**
41/159 Arthur Street
Homebush West
New South Wales
2140
Australia

Date	Reference Number	Action
27 April 2016	8501818	Initial Issue. Transferred from another Notified Body.
09 June 2017	8676990	Change of manufacturer address from "Unit 7, 186-188 Canterbury Road, Canterbury, New South Wales, 2193, Australia" to 41/159 Arthur Street, Homebush West, New South Wales, 2140, Australia"
12 February 2019	8764551	Traceable to NB 0086.
28 March 2019	9717553	Certificate re-issue to change EU representative address from United Kingdom to Malta.
Current	9733043	Certificate renewal. Addition of product table.

ATTESTATION / *CERTIFICATE* **N° 7550 rev. 22**
Délivrée à Paris le 17 mai 2021
Issued in Paris on May 17th, 2021

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'Assurance Qualité */ Approval of full Quality Assurance System*
ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX II excluding section 4 DIRECTIVE 93/42/EEC concerning medical devices
Pour les dispositifs de classe III, un certificat CE de conception est requis
For class III devices, a EC design certificate is required

Fabricant / *Manufacturer*

GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC
8200 WEST TOWER AVENUE
MILWAUKEE, WISCONSIN 53223 UNITED STATES

Catégorie du(des) dispositif(s) */ Device(s) category*

Equipements de cardiologie et systèmes de surveillance de patients
Systèmes de surveillance clinique et systèmes de télémétrie médicale
Baie de cathétérisme et/ou d'électrophysiologie
Moniteurs cardiaques et leurs accessoires
Moniteurs de surveillance patient
Systèmes d'électrocardiographie et de surveillance de patients

Cardiology equipment and patient monitoring systems
Clinical Monitoring Systems and Medical Telemetry Systems
Catheterization and/or Electrophysiology lab System
Cardiology monitors and accessories
Patient monitors
Electrocardiographs and patient monitoring systems

Voir document complémentaire GMED */ See GMED additional document*
n° 38313

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P602818, P601202, le système d'assurance qualité – pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P602818, P601202, the quality system - for design, manufacturing and final inspection - of medical devices listed here aboved complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

La validité du présent certificat est soumise à une vérification périodique ou imprévue.
The validity of the certificate is subject to periodic or unexpected verification.

Début de validité / *Effective date :* **June 8th, 2021 (included)**
Valable jusqu'au / *Expiry date :* **May 26th, 2024 (included)**

DocuSigned by:
Lionel DREUX
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Lionel DREUX
Certification Director

GMED_b2p3_new2020-V0-04-

GMED – 7550 rev. 22
Renouvelle le certificat 7550-21

Ce document complémentaire GMED n° 38313 rev. 1 atteste de la validité du certificat CE N° 7550 rev. 22 au regard des informations listées ci-dessous.

This GMED additional document n° 38313 rev. 1 attests to the validity of EC certificate N° 7550 rev. 22 with regard to the information listed below.

Fabricant / *Manufacturer:*

GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC
8200 WEST TOWER AVENUE
MILWAUKEE, WISCONSIN 53223 UNITED STATES

Identification des dispositifs / *Identification of devices*

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	**Réf commerciale du dispositif ou code article** *Device commercial reference or article code*	**Classe du DM** *MD class*
Patient monitor, Central unit	**Central Station (CSCS)**	**IIb**
Patient monitor module, multiparameter	**Patient Data Module (PDM)**	**IIb**
Patient monitor, multiparameter	**B20**	**IIb**
Patient monitor, multiparameter	**B40**	**IIb**
Patient Monitor, multiparameter	**B105**	**IIb**
Patient Monitor, multiparameter	**B125**	**IIb**
Patient Monitor, multiparameter	**CARESCAPE ONE**	**IIb**
Transportable physiologic monitoring system	**V100**	**IIb**
Telemetry system, electrocardiograph	**ApexPro Telemetry System**	**IIb**
Clinical monitoring systems	**Unity Network ID**	**IIb**
Cardiac Catheterization monitoring system, Cardiac electrophysiology analysis system	**MacLab**	**IIb**
Cardiac Catheterization monitoring system, Cardiac electrophysiology analysis system	**CardioLab**	**IIb**
Cardiac Catheterization monitoring system, Cardiac electrophysiology analysis system	**ComboLab**	**IIb**

GMED 0459

GMED - 38313 rev. 1
Renouvelle le document n° 38313 rev. 0

GMED SAS GMED SAS GMED GROUPE LNE

DocuSigned by:
Lionel DREUX
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Lionel DREUX
Certification Director

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	**Réf commerciale du dispositif ou code article** *Device commercial reference or article code*	**Classe du DM** *MD class*
Electrocardiograph, Holter analyzer	**Mars**	**IIa**
Electrocardiograph, Holter analyzer	**Mars SP4**	**IIa**
Information system software, application program, cardiology	**MUSE – SW Only**	**IIa**
Information system software, application program, cardiology	**CV Web**	**IIa**
ECG Acquisition module	**CAM 14V2**	**IIa**
ECG Acquisition module	**CAM HD**	**IIa**
Interpretive multichannel electrocardiograph	**MAC 2000**	**IIa**
Interpretive multichannel electrocardiograph	**MAC 600**	**IIa**
Interpretive multichannel electrocardiograph	**MAC VU360**	**IIa**
Stress exercise monitoring system, cardiac	**Case**	**IIa**
Stress exercise monitoring system, cardiac	**Cardiosoft / CS**	**IIa**
Stress exercise monitoring system, cardiac	**Cardiosoft / CS WIN8**	**IIa**
Electrocardiograph, Electrodes	**KISS**	**IIa**

Site couvert et Activités / *Location and Activities*

Site / *Location*	**Activités** / *Activities*
GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC **8200 WEST TOWER AVENUE** **MILWAUKEE, WISCONSIN 53223 - USA**	**Siège social – responsable de la mise sur le marché** **Conception, fabrication et contrôle final** *Headquarters – legal manufacturer* *Design, manufacture and final control*

GMED	**0459**

GMED - 38313 rev. 1
Renouvelle le document n° 38313 rev. 0

GMED SAS GMED SAS
DocuSigned by:
Lionel DREUX
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Lionel DREUX
Certification Director

EC DECLARATION OF CONFORMITY

TF – DOC1430163 (CE-M-201)

Following the provisions of the medical devices directive 93/42/EEC, ROHS directive 2011/65/EU and Radio Equipment Directive 2014/53/EU

EG-KONFORMITÄTSERKLÄRUNG

Entspreched der Anforderung der Medizin Produkte Richtlinie 93/42/EEC, der Richtlinie 2011/65/EU und radio - richtlinie richtlinie 2014/53/EU

We/ *Wir*

Manufacturer
Hersteller

GE Medical Systems
Information Technologies, Inc.
8200 West Tower Avenue
Milwaukee, WI 53223, USA

EU Authorized Representative
Autorisierter EU-Vertreter

GE Medical Systems
Information Technologies GmbH
Munzingerstrasse 5
79111 Freiburg, Germany

Manufacturing site (if different from manufacturer)
Fertigungsstätte (falls anders als Hersteller)

Wipro GE Healthcare Private Limited
No. 4, Kadugodi Industrial Area
Bangalore 560067, Karnataka, India

GE Healthcare Finland OY
Kuortaneenkatu 2
Helsinki, FIN-00510, Finland

Critikon de Mexico S. de R.L. de C.V.
Calle valle del cedro 1551 Juarez Mexico 32575

Declare under our sole responsibility that the class **IIa** medical device:
*Erklären unter alleiniger Verantwortung, dass das Medizinprodukt der Klasse **IIa**:*

MAC 2000 ECG Analysis System

Ref. : see addendum/ *oder siehe Anhang*

GMDN Code: 16231

UMDNS Code: 11411

Classification rule (93/42/EC Annex IX) / *Klassifizierungsregel (93/42/EG Anhang IX)*: **Rule 10**

March 15, 2021

Lee, Bush
Director, Regulatory Affairs, LCS MIC & DCAR

To which this declaration relates, is in conformity with the requirements of the medical devices directive 93/42/EEC which apply to it and with the requirements of the directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
Auf das sich diese Erklärung bezieht, den Anforderungen der Richtlinie 93/42/EWG über Medizinprodukte, die für das Produkt gelten, und den Anforderungen der Richtlinie 2011/65/EU zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten entspricht.

This medical device conformity is based on the following elements:
Diese Medizinprodukte Konformität basiert auf den folgenden Elementen:

- Information included in the documents:
  Technical Documentation/DHF Ref./ réf: **DOC0851945**, of the product to which this declaration relates.
  Informationen, die in den Dokumenten enthalten sind:
  Technische Dokumentation/DHF-Ref./réf: **DOC0851945** des Produkts, auf das sich diese Erklärung bezieht.
- EC certificate: approval of full quality assurance system (Annex II of the medical devices directive 93/42 EEC) delivered by LNE/G-MED France, (NB #0459) / Certificate No. 7550.

  The medical device bears the mark

CE
0459

- *EG-Zertifikat:* Genehmigung *des kompletten Qualitätssicherungssystems (Anhang II der Richtlinie 93/42/EWG über Medizinprodukte), ausgestellt von G-MED France,* NB #0459 */ Zertifikat Nr.* 7550.

- List of harmonized standards applied for CE marking as in Appendix 1
  Liste der harmonisierten Normen, die für die CE-Kennzeichnung angewendet wurden in anhang 1.

March 15, 2021

Lee, Bush
Director, Regulatory Affairs, LCS MIC & DCAR

DOC1430161

We, manufacturer, declare under our sole responsibility that:

Wir. Hersteller, Erklären unter unserer alleinigen Verantwortung

MAC 2000 embedded with MSD45N WLAN module

To which this declaration relates is in conformity with the requirements of the Radio Equipment Directive 2014/53/EU which applies to it.
die erklärung bezieht, in übereinstimmung mit den anforderungen der funkgeräte richtlinie 2014/53/EU

This conformity is based on the following elements:
Diese Konformität basiert auf den folgenden Elementen:

- The device conforms to the Directive 2014/53/EU through Annex II-Internal Production Control.
  das gerät mit der richtlinie 2014 / 53 / eu über anhang ii- interne fertigungskontrolle
- List of standards applied for CE marking as in Appendix 2.
  Liste der Normen, die für die CE-Kennzeichnung angewendet wurden in anhang 2.

March 15, 2021

Lee, Bush
Director, Regulatory Affairs, LCS MIC & DCAR

DOC1430161

Appendix 1/ *Anhang 1*

Relevant Standards*/ relevante normen*
EN 60601-1:2006/A1:2013 Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance
EN 60601-1-2:2015 Medical Electrical Equipment – Part 1-2: General Requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-2-25:2015 Medical Electrical Equipment - Part 2-25: Particular requirements for basic safety and essential performance of electrocardiographs
EN 60601-1-6:2010+A1:2015 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62366-1:2015 Medical devices - Application of usability engineering to medical devices
EN 62304:2006+A1:2015 Medical device software - Software life-cycle processes
EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN 1041:2008+A1:2013 Information supplied by the manufacturer with medical devices

March 15, 2021

Lee, Bush
Director, Regulatory Affairs, LCS MIC & DCAR

DOC1430161

Appendix 2/ *Anhang 2*

Relevant Standards/ *relevante normen*
EN 300 328 V2.2.2 Wideband transmission systems;Data transmission equipment operating in the 2.4GHz ISM band and using wideband modulation techniques;Harmonised Standaed covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 301 893 V2.1.1 5 GHz RLAN; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 301 489-1 V2.2.3 ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
EN 301 489-17 V3.2.2 ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
EN 62311:2008 Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz)
EN 60601-1-2:2007 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests
EN 60601-1:2006/A1:2013 Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance

This EC declaration of conformity supersedes the previous declaration dated 28 October 2020

Diese EG-Konformitätserklärung ersetzt die vorherige Erklärung mit Datum vom 28 October 2020

March 15, 2021

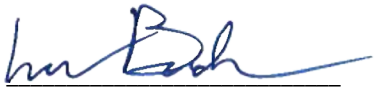
Lee, Bush
Director, Regulatory Affairs, LCS MIC & DCAR

DOC1430161

ADDENDUM TO THE EC DECLARATION OF CONFORMITY
ERGÄNZUNG ZUR KONFORMITÄTSERKLÄRUNG

Product Description ***Produktbezeichnung***	**Catalog Designation** ***Katalogbezeichnung***
MAC 2000	2063587-001
Unit Options	
MAC 2000 UNIT	2063587-017
MAC 2000 KISS UNIT	2063587-018
MAC 2000 ECG Pharma	2063587-171
MAC 2000 UNIT with embedded wifi	2063587-223
MAC 2000 STRESS OPTION	
MAC 2000 STRESS	2063587-140
STARTER KIT SELECTION	
MAC 2000 STARTER KIT AHA VALUE REUSABLE	2063587-500
MAC 2000 STARTERKIT AHA MULTILINK WITH ECG CLIP	2063587-501
MAC 2000 STARTER KIT AHA MULTILINK WITH ADAPTER	2063587-503
MAC 2000 STARTER KIT IEC VALUE REUSABLE	2063587-504
MAC 2000 STARTER KIT IEC MULTILINK REUSABLE	2063587-505
MAC 2000 STARTER KIT IEC MULTILINK WITH ECG CLIP	2063587-506
MAC 2000 STARTER KIT IEC MULTILINK WITH ADAPTER	2063587-508
MAC 2000 STARTER KIT IEC MULTILINK REUSABLE	2063587-509
MAC 2000 STARTER KIT AHA VALUE WITH CLIP	2063587-510
MAC 2000 STARTER KIT IEC VALUE WITH CLIP	2063587-511
Language Options	
MAC 2000 ENG LANGUAGE NON-STRESS	2063587-019
MAC 2000 GER LANGUAGE NON-STRESS	2063587-020
MAC 2000 FRE LANGUAGE NON-STRESS	2063587-021
MAC 2000 SPA LANGUAGE NON-STRESS	2063587-022
MAC 2000 ITA LANGUAGE NON-STRESS	2063587-023
MAC 2000 JAP LANGUAGE NON-STRESS	2063587-024
MAC 2000 SWE LANGUAGE NON-STRESS	2063587-025
MAC 2000 DUT LANGUAGE NON-STRESS	2063587-026
MAC 2000 HUN LANGUAGE NON-STRESS	2063587-027
MAC 2000 RUS LANGUAGE NON-STRESS	2063587-028
MAC 2000 FIN LANGUAGE NON-STRESS	2063587-029
MAC 2000 CHI LANGUAGE NON-STRESS	2063587-030
MAC 2000 CZECH LANGUAGE NON-STRESS	2063587-031

March 15, 2021



Lee, Bush
Director, Regulatory Affairs, LCS MIC & DCAR

DOC1430161

Product Description ***Produktbezeichnung***	**Catalog Designation** ***Katalogbezeichnung***
Language Options (Continued)	
MAC 2000 POL LANGUAGE NON-STRESS	2063587-032
MAC 2000 NOR LANGUAGE NON-STRESS	2063587-033
MAC 2000 SLO LANGUAGE NON-STRESS	2063587-034
MAC 2000 BRA POR LANGUAGE NON-STRESS	2063587-035
MAC 2000 DAN LANGUAGE NON-STRESS	2063587-036
MAC 2000 KOR LANGUAGE NON-STRESS	2063587-037
MAC 2000 EURO POR LANGUAGE NON-STRESS	2063587-038
MAC 2000 CRO LANGUAGE NON-STRESS	2063587-039
MAC 2000 GRE LANGUAGE NON-STRESS	2063587-040
MAC 2000 TUR LANGUAGE NON-STRESS	2063587-041
MAC 2000 EST LANGUAGE NON-STRESS	2063587-042
MAC 2000 LIT LANGUAGE NON-STRESS	2063587-043
MAC 2000 ROM LANGUAGE NON-STRESS	2063587-044
MAC 2000 BUL LANGUAGE NON-STRESS	2063587-045
MAC 2000 SER LANGUAGE NON-STRESS	2063587-046
MAC 2000 EGYPT LANGUAGE NON-STRESS	2063587-141
MAC 2000 VENEZUELA-SPA LANGUAGE NON-STRESS	2063587-142
MAC 2000 MEXICO-SPA LANGUAGE NON-STRESS	2063587-143
MAC 2000 INDONESIA LANGUAGE NON-STRESS	2063587-144
MAC 2000 ARG-SPA LANGUAGE NON-STRESS	2063587-166
MAC 2000 VIT LANGUAGE NON-STRESS	2063587-177
MAC 2000 LATVIAN LANGUAGE NON-STRESS	2063587-179
MAC 2000 KAZAKH LANGUAGE NON-STRESS	2063587-182
MAC 2000 TAIWAN LANGUAGE NON-STRESS	2063587-184
MAC 2000 MALAYSIA LANGUAGE NON-STRESS	2063587-190
MAC 2000 Pharma Japan	2063587-172
MAC 2000 ENG LANGUAGE W/STRESS	2063587-047
MAC 2000 GER LANGUAGE W/STRESS	2063587-048
MAC 2000 FRE LANGUAGE W/STRESS	2063587-049
MAC 2000 SPA LANGUAGE W/STRESS	2063587-050
MAC 2000 ITA LANGUAGE W/STRESS	2063587-051
MAC 2000 JAP LANGUAGE W/STRESS	2063587-052
MAC 2000 SWE LANGUAGE W/STRESS	2063587-053
MAC 2000 DUT LANGUAGE W/STRESS	2063587-054
MAC 2000 HUN LANGUAGE W/STRESS	2063587-055
MAC 2000 RUS LANGUAGE W/STRESS	2063587-056
MAC 2000 FIN LANGUAGE W/STRESS	2063587-057
MAC 2000 CHI LANGUAGE W/STRESS	2063587-058
MAC 2000 CZECH LANGUAGE W/STRESS	2063587-059
MAC 2000 POL LANGUAGE W/STRESS	2063587-060

March 15, 2021

Lee, Bush
Director, Regulatory Affairs, LCS MIC & DCAR

DOC1430161

Product Description ***Produktbezeichnung***	**Catalog Designation** ***Katalogbezeichnung***
Language Options (Continued)	
MAC 2000 NOR LANGUAGE W/STRESS	2063587-061
MAC 2000 SLO LANGUAGE W/STRESS	2063587-062
MAC 2000 BRA POR LANGUAGE W/STRESS	2063587-063
MAC 2000 DAN LANGUAGE W/STRESS	2063587-064
MAC 2000 KOR LANGUAGE W/STRESS	2063587-065
MAC 2000 EURO POR LANGUAGE W/STRESS	2063587-066
MAC 2000 CRO LANGUAGE W/STRESS	2063587-067
MAC 2000 GRE LANGUAGE W/STRESS	2063587-068
MAC 2000 TUR LANGUAGE W/STRESS	2063587-069
MAC 2000 EST LANGUAGE W/STRESS	2063587-070
MAC 2000 LIT LANGUAGE W/STRESS	2063587-071
MAC 2000 ROM LANGUAGE W/STRESS	2063587-072
MAC 2000 BUL LANGUAGE W/STRESS	2063587-073
MAC 2000 SER LANGUAGE W/STRESS	2063587-074
MAC 2000 EGYPT LANGUAGE W/STRESS	2063587-145
MAC 2000 VENEZUELA-SPA LANGUAGE W/STRESS	2063587-146
MAC 2000 MEXICO-SPA LANGUAGE W/STRESS	2063587-147
MAC 2000 INDONESIA LANGUAGE W/STRESS	2063587-148
MAC 2000 ARG-SPA LANGUAGE W/STRESS	2063587-167
MAC 2000 VIT LANGUAGE W/STRESS	2063587-176
MAC 2000 LATVIAN LANGUAGE W/STRESS	2063587-178
MAC 2000 KAZAKH LANGUAGE W/STRESS	2063587-181
MAC 2000 TAIWAN LANGUAGE W/STRESS	2063587-183
MAC 2000 MALAYSIA LANGUAGE W/STRESS	2063587-191
Power Cord Selection	
MAC 2000 N AMERICAN POWERCORD	2063587-085
MAC 2000 EURO POWERCORD	2063587-086
MAC 2000 BRITISH POWER CORD	2063587-087
MAC 2000 ITALIAN POWER CORD	2063587-088
MAC 2000 AUSTRALIAN POWER CORD	2063587-089
MAC 2000 ISRAELI POWER CORD	2063587-090
MAC 2000 SWISS POWER CORD	2063587-091
MAC 2000 INDIAN POWER CORD	2063587-092
MAC 2000 CHINESE POWER CORD	2063587-093
MAC 2000 JAPANESE POWER CORED	2063587-094
MAC 2000 BRAZIL POWER CORD	2063587-095

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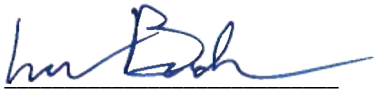

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Director, Regulatory Affairs, LCS MIC & DCAR

DOC1430161

Product Description ***Produktbezeichnung***	**Catalog Designation** ***Katalogbezeichnung***
Analysis Options	
MAC 2000 MEASUREMENT BY 12SL	2063587-096
MAC 2000 MEASUREMENT INTERPRETATION BY 12SL	2063587-097
MAC 2000 MEASUREMENT IINTERPRETATION ACITIPI BY 12SL	2063587-098
MAC 2000 MEASUREMENT BY HEART	2063587-099
MAC 2000 MEASUREMENT INTERP BY HEART	2063587-100
Storage And Export Options	
MAC 2000 INT STOR 100 – SDCD PDF/XML/HT	2063587-101
MAC 2000 INT STOR 200 – SDCD PDF/XML/HT	2063587-102
MAC 2000 INT STOR 100 – SDCD XML/HT	2063587-103
MAC 2000 INT STOR 200 – SDCD XML/HT	2063587-104
Workflow Executive Packages Options	
MAC2000 ADT – MUSE LAN SERL CONN – INT STOR 200 – SDCD PDF/XML/HT	2063587-150
MAC2000 ADT SIMP ORDRS – MUSE LAN SERL CONN – INT STOR 200 -SDCD PDF/XML/HT	2063587-151
MAC2000 ADT ADV ORDRS – MUSE LAN SERL CONN – INT STOR 200 – SDCD PDF/XML/HT	2063587-152
MAC2000 CARDIOSOFT LAN SERL CONN – INT STOR 200 – SDCD PDF/XML/HT	2063587-153
MAC2000 PC LAN CONN – INT STOR 200 – SDCD PDF/XML/HT	2063587-154
MAC2000 MUSE LAN SERL CONN – INT STOR 200 – SDCD PDF/XML/HT	2063587-155
MAC2000 ADT – NON-MUSE LAN CONN – INT STOR 200 – SDCD PDF/XML/HT	2063587-157
MAC2000 ADT SIMP ORDRS – NON-MUSE LAN CONN – INT STOR 200-SDCD PDF/XML/HT	2063587-158
MAC2000 ADT ADV ORDRS – NON-MUSE LAN CONN – INT STOR 200 – SDCD PDF/XML/HT	2063587-159
MAC2000 SIMP ORDRS - MUSE LAN SERL CONN - INT STOR 200-SDCD /XML/HT	2063587-160
MAC2000 SIMP ORDRS - MUSE LAN SERL CONN - INT STOR 100-SDCD /XML/HT	2063587-161
MAC2000 CARDIOSOFT LAN SERL CONN - INT STOR 200 - SDCD XML/HT	2063587-162
MAC2000 CARDIOSOFT LAN SERL CONN - INT STOR 100- SDCD XML/HT	2063587-163
MAC2000 MUSE LAN SERL CONN - INT STOR 200 - SDCD XML/HT	2063587-164
MAC2000 MUSE LAN SERL CONN - INT STOR 100- SDCD XML/HT	2063587-165
Pharma Workflow Option Pack	2063587-222
Pharma Workflow Option Pack 1 - Japan	2063587-221
WIFI CHNL 11 /Modem Option	
MAC 2000 WIFI BRIDGE CHANNEL 11	2063587-169

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Product Description ***Produktbezeichnung***	**Catalog Designation** ***Katalogbezeichnung***
WIFI CHNL 13 /Modem Option	
MAC 2000 MODEM	2063587-112
MAC 2000 WIFI BRIDGE CHANNEL 13	2063587-170
Pharma Options	
MAC 2000 AUDIT TRAIL EXPORT	2063587-122
MAC 2000 CT DATA GUARD	2063587-123
MAC 2000 PHARMA PKG	2063587-168
Barcode Options	
MAC 2000 ENG BARCODE	2063587-124
MAC 2000 GER BARCODE	2063587-125
MAC 2000 FRE BARCODE	2063587-126
MAC 2000 SPA BARCODE	2063587-127
MAC 2000 ITA BARCODE	2063587-128
MAC 2000 SWE BARCODE	2063587-129
MAC 2000 DUT BARCODE	2063587-130
MAC 2000 HUN BARCODE	2063587-131
MAC 2000 RUS BARCODE	2063587-132
MAC 2000 FIN BARCODE	2063587-133
MAC 2000 CZE BARCODE	2063587-134
MAC 2000 NOR BARCODE	2063587-135
MAC 2000 SLO BARCODE	2063587-136
MAC 2000 POR BARCODE	2063587-137
MAC 2000 DAN BARCODE	2063587-138
MAC 2000 BARCODE SW only	2063587-185
RR OPTION	
MAC 2000 RR ANALYSIS	2063587-106
FULL DISCLOSURE OPTION Optional	
MAC 2000 FULL DISCLOSURE	2063587-201
EMBEDDED WIRELESS OC	
MAC2000 EMBEDDED WIRELESS	2063587-174
MAC 2000 SW OPTION for EMBEDDED WIRELESS	2063587-224

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Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 60146867 0001

Organization:
GE Medical Systems
Information Technologies, Inc.
9900 Innovation Drive
Wauwatosa, WI 53226
USA

Scope: Design, Development, and Manufacture of Patient Monitoring Systems, Cardiology ECG Recording and Analysis Systems, Invasive Cardiology Equipment Systems and Medical Software

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 32090997.003

Effective date: 2020-08-12

Expiry date: 2023-03-11

Issue date: 2020-08-12

TÜV Rheinland LGA Products GmbH
TÜVRheinland®

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Balazs Bozsik
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60131555 0001

Report No.: 21198147 012

Manufacturer:

getemed Medizin- und
Informationstechnik AG
Oderstr. 77
14513 Teltow
Deutschland

Products:

Vital signs monitors, cardiac function diagnostic
and telemonitoring systems
(see attachment for products and sites included)

Replaces Approval, Registration No.: HD 60088821 0001

Expiry Date: 2023-10-03

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2018-10-04

Date: 2018-08-02

Notified Body

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60131555 0001
Report No.: 21198147 012

Manufacturer:
getemed Medizin- und Informationstechnik AG
Oderstr. 77
14513 Teltow
Deutschland

Products included:

Recorder, Long-term ECG portable
- CardioMem® and SEER

Long-term ECG evaluation system
- CardioDay®

Electrocardiograph, multi channel
- CardioLink®

Pulse oximeter, physiological monitoring system, neonatal
- VitaGuard® with VitaWin®

ECG-monitor, telemetric
- PhysioMem®

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2018-08-02

Dipl.-Ing. I. Munkler

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60131555 0001
Report No.: 21198147 012

Manufacturer: getemed Medizin- und Informationstechnik AG
Oderstr. 77
14513 Teltow
Deutschland

Sites included:

getemed Medizin- und Informationstechnik AG
Oderstr. 77, 14513 Teltow, Germany

getemed Medizin- und Informationstechnik AG
Otto-Schmerbach-Straße 19, 09117 Chemnitz, Germany

Date: 2018-08-02

Notified Body

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH TÜVRheinland® 1 Zertifizierungsstelle