Anexa 32

Specificație tehnică completată

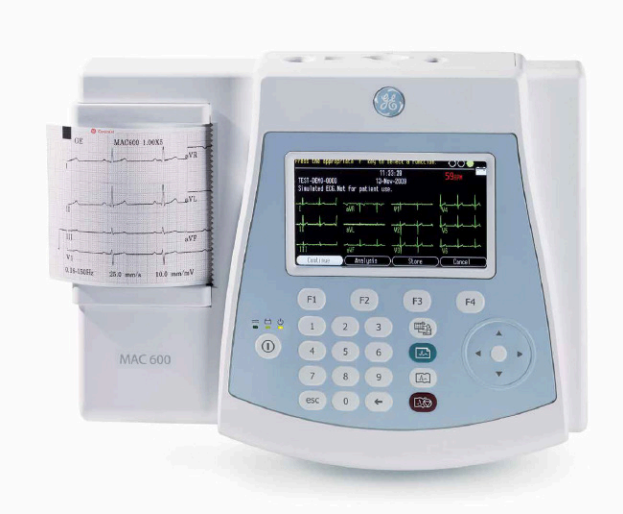
Model: MAC 600, Producător: GE Medical Systems, GE Healthcare, Tara: USA/SUA

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină completată de către autoritatea ofertantă
Electrocardiograf 3 canale, caracteristici avansate cu troleu pe rotile	Electrocardiograf cu 3 canale, caracteristici avansate **DA**
Cod 260211	Cod 260211
Descriere Electrocardiograf cu 3 canale, care înregistrează, printează şi/sau interpretează ECG de la o singură sau mai multe derivații simultan cu display color.	Descriere Electrocardiograf cu 3 canale, care înregistrează, printează şi/sau interpretează ECG de la o singură sau mai multe derivații simultan cu display color. **DA**
Parametrul Specificația	Parametrul Specificația
Tip pacient adult, pediatric	Tip pacient adult, pediatric **DA pagina 1 din Resting ECG**
Numărul de canale de procesare 3	Numărul de canale de procesare 3 **DA**
Configurația Portabil da	Configurația Portabil **DA dimensiuni mici 81x263x208 mm, greutea tot cu acumulator 1,2 kg**
Derivațiile Tip înregistrare auto și manual	Derivațiile Tip înregistrare auto și manual **DA**
Sensivitatea 2.5, 5, 10, 20 mm/mv	Sensivitatea 2.5, 5, 10, 20 10/5(folosit in calibrare divizata) mm/mv **DA**
Semnal de calibrare 1 mV, ± 3%	Semnal de calibrare 1 mV, ± 3% **DA**
Gama de frecvență	Gama de frecvență
De diagnostic 0.05-150 Hz	De diagnostic 0.01-150 Hz **DA**
Filtru muscular 25, 35Hz	Filtru muscular 25, 35Hz **DA**
Filtru frecvență joasă 0.05, 0.16, 0.25, 0.32, 0.5, 0.67Hz	Filtru frecvență joasă 0.01, 0.02, 0.16, 0.32 Hz **DA**
Filtru frecvență înaltă 20, 40, 100, 150Hz	Filtru frecvență înaltă 20, 40, 100, 150Hz **DA**
Filtru de rețea 50 Hz	Filtru de rețea 50 Hz **si de 60 Hz DA**
Impendanța de intrare ≥ 10 M Ohm	Impendanța de intrare ≥ 10 M Ohm **DA**
Gama de rejecție a modului comun la 50 Hz > 110 dB	Gama de rejecție a modului comun la 50 Hz > 100 dB **DA**
Convertor analog-digital ≥ 16 bit	Convertor analog-digital ≥ 16 bit **DA**
Scurgeri spre pacient prin electrozi ≤10 μA	Scurgeri spre pacient prin electrozi ≤10 μA **DA**
Detector de pacemaker da	Detector de pacemaker **DA**
Indicator deconectare electrod acustic sau vizual da	Indicator deconectare electrod acustic sau vizual **DA**
Imprimantă Termică încorporată	Imprimantă Termică încorporată **DA**
Mărimea hîrtiei ≥ 60 mm	Mărimea hîrtiei **80 mm DA**
Să se indice numele derivației printate da	Să se indice numele derivației printate **DA**
Viteza de înscriere 5, 10, 12.5, 25, 50 mm/s	Viteza de înscriere 5, 12.5, 25 si 50 mm/s **DA**
Densitatea imprimarii 8 dpi/mm (rezoluție verticală) și 40 dpi/mm (rezoluție orizontală) la viteza de 25 mm/s	Densitatea imprimarii 8 dpi/mm (rezoluție verticală) și 40 dpi/mm (rezoluție orizontală) la viteza de 25 mm/s **DA**
Derivațiile înscrise minim 12	Derivațiile înscrise minim 12 **DA**
Numărul de derivații înscrise simultan 3	Numărul de derivații înscrise simultan 3 **DA**
Hîrtia termică să fie compatibilă și de la alți producători de hîrtie cu dispozitivul ECG da	Hîrtia termică să fie compatibilă și de la alți producători de hîrtie cu dispozitivul ECG **DA**
Display Grafic, LCD TFT color da	Display Grafic, LCD TFT color **DA**
Monitorizarea pe display:	Monitorizarea pe display

Anexa 32

data, ora, sensibilitatea, viteza de înscriere, filtru, derivațiile da Marime ecran ≥ 3 inch Rezoluția ≥ 320x240 pix Numărul de derivații afișate simultan ≥ 6 Posibilitatea transmiterii datelor la un sistem de management al datelor ECG prin fir (să se indice interfața de transmitere) 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 ≥ 3 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 Troleu pe rotile troleu pe rotile da, (indicati modelul) ≥ 4 roți da ≥ 2 roți cu frînă da mîner pentru transportarea standului da coș pentru accesorii da braț articulat pentru electrozi ECG da suport pentru gel de contact da sistem de fixare dispozitivului de suport da	data, ora, sensibilitatea, viteza de înscriere, filtru, derivațiile da **DA** Marime ecran **- 4.3 inch DA** Rezoluția – **480 x 272 pix DA** Numărul de derivații afișate simultan – **12** DA Posibilitatea transmiterii datelor la un sistem de management al datelor ECG prin fir (**Serial, SD-Card sau Wifi**) **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 ± 5 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 **-7,5 h de monitoring continu fara printrare.** 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** Troleu pe rotile troleu pe rotile **DA**, (Versa X – fabricat la comanda) ≥ 4 roți **DA** ≥ 2 roți cu frînă **DA** mîner pentru transportarea standului **DA** coș pentru accesorii **DA** braț articulat pentru electrozi ECG **DA** suport pentru gel de contact **DA** sistem de fixare dispozitivului de suport **DA**

MAC™ 600
Resting ECG



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 samples/second (sps)
Digital sampling rate	2,000 samples/second/channel
ECG on-screen preview	On-screen preview of acquired 10 second ECG waveform and optional 12SL measurement and interpretation
Acquisition mode	Pre-acquisition or post-acquisition, provide 10 seconds of instantaneous ECG acquisition
Dynamic range	AC Differential ± 5mV DC offset ±300 mV
Resolution	4.88 µV/LSB at 500 sps
Frequency response	-3 dB at 0.01 to 150 Hz
Low cut-off frequency	0.01 Hz, 0.02 Hz, 0.16 Hz or 0.32 Hz (-3 dB limits)
High cut-off frequency	Configurable at 20 Hz, 40 Hz, 100 Hz or 150 Hz
Adaptive AC filter	47 Hz to 53 Hz when set to 50Hz 57 Hz to 63 Hz when set to 60 Hz
Common mode rejection	>100 dB (with AC filter switched on)
Input impedance	>10MW at 10 Hz, defibrillator protected
Patient leakage	<10 µA
Special acquisition functions	Disconnected lead detection except RL, excessive AC noise, baseline wander and muscle tremor messages
Heart rate meter	30 to 300 BPM ±10% or ±5 BPM, whichever is greater. Heart rates outside this range will not be displayed
Start-up time	Less than 7 seconds

Patient information

Supported patient information	Patient ID, Secondary ID, Age, Date of Birth, Gender Alphanumeric entry in T9 type for patient ID and secondary ID

Display

Display type	4.3 inch (110 mm) diagonal, TFT LCD with LED graphics backlit (color optional)
Display resolution	480 X 272 pixels with scrolling waveform
Display data	Heart rate, patient ID, clock, battery power indicator, waveforms, lead labels, speed, gain and filter settings, warning messages, information messages, prompts. 12 leads standard display.

Writer

Writer technology	Thermal dot array
Writer speed	5, 12.5, 25, & 50 mm/s

Number of traces	3 leads + 1 Rhythm or 3 leads; user selectable
Writer sensitivity/gain	2.5, 5, 10, 20, 10/5 (split calibration) mm/mV
Writer speed accuracy	±5%
Writer amplitude accuracy	±5%
Writer resolution	Horizontal 40 dots/mm at 25 mm/s, 8 dots/mm vertical
Paper type	Thermal. Z-fold perforated, 80 mm width, 280 sheets/pack. Roll paper 15.7 m

Keyboard

Type	Type Membrane keyboard with tactile feedback

Software standard

Resting ECG mode	Records and prints 12-lead resting ECGs with 10 seconds duration as a standard feature
Hookup Advisor™	Provides visual indication of signal quality
Multi-language support	Supports 16 languages

Software options

Measurement	Supports measurement with Marquette 12SL ECG Analysis Program
Measurement and interpretation	Supports measurement and interpretation with Marquette 12SL ECG Analysis Program
Color	Color display
External Storage	200 ECGs in external memory (SD card)
Transmission	ECG data transmission via serial cable
XML Format	ECG Storage in XML format
PDF format[1]	ECG Storage in PDF format

Communication (optional)

MUSE™ Cardiology Information System compatible

Serial cable	ECG Transmission to MUSE™ Cardiology Information System
Serial cable	ECG transmission in XML format
SD card interface	Compatible with MUSE V7 or later

Cardiosoft™ interface

SD card interface	Compatible with Cardiosoft V6.51 or later
Serial cable	ECG transmission over serial line to CardioSoft V6.61 or above

MobileLink RC WiFi Interface

MobileLink RC	ECG wireless transmission through a communicator module attached to the device

Storage (optional)

ECG Storage Format	GE™ storage format for MUSE and Cardiosoft XML storage format PDF storage format
PDF File name format	User configurable file name, which includes patient ID, secondary ID, Date of Birth, ECG recording date and time

Report formats

Thermal printer report formats	4 by 2.5s 4 by 2.5s + 1 rhythm lead 4 by 3s 4 by 10s Autorhythm (10 second ECG data for 3 leads) Printing of 4 by 10s or Autorhythm for abnormal ECG Continuous 3 channel rhythm
PDF report format (A4 format)	4 by 2.5s 4 by 2.5s + 1 rhythm lead 2 by 5s 2 by 5s + 1 rhythm ld 2 by 5s at 50mm/s 4 by 10s Autorhythm (12 lead)

Accessories

IEC/AHA lead-wire and electrode adaptor sets (user selectable)

10-lead patient cable (user selectable replaceable leads or fixed lead cables)

Electrodes (disposable or reusable, user selectable)

Country-specific power cords

Z-fold and Roll paper

Electrode cream 250ml/tube

Electrical

Power Supply	External ACDC adaptor or battery operation

External adaptor specifications

Input voltage	100 to 240 VAC ±10 %
Input current	Maximum 0.6A at 90 VAC, 0.3A at 240 VAC
Input frequency	50 to 60 Hz ±3Hz
Output voltage	12V ± 5%

Battery specifications

Battery type	Replaceable and rechargeable, Lithium Ion
Battery capacity	7.2V typical, 3.35 AH ±10% 450 minutes of continuous operation without recording or 350 ECGs in 2.5 X 4 format at 25 mm/S and 10 mm/mV or 150 minutes continuous rhythm print at 25 mm/S and 10 mm/mV
Battery charge time	Approximately 4 hours from total discharge (with display off)

Physical specification

Height	81 mm
Width	263 mm
Depth	208 mm
Weight	1.2 kg including battery, without paper

Environmental specification

Temperature

Operating	5°C to 40°C
Transport/storage	-15°C to 50°C

Humidity

Operating	25% to 95% RH non-condensing
Transport/storage	25% to 95% RH non-condensing

Pressure

Operating	700 to 1060 hPA
Transport/storage	500 to 1060 hPA

Certification

Class I, type CF defibrillator proof

UL 60601-1 Medical Electrical Equipment, part 1:General Requirements for Safety

CAN/CSA C22.2 No. 601.1 General Requirements for Safety

CE marking for Council Directive 93/42/EEC concerning medical devices

IEC 60601-1 General Requirements for Safety

IEC 60601-1-1 General Requirements for Safety Medical Electrical systems

IEC 60601-2-25 Particular Requirements for the Safety of Electrocardiographs

IEC 60601-2-51 Particular requirements for safety, including essential performance, of recording and analyzing single channel and multi channel electrocardiographs

IEC 60601-1-2 General Requirements for Safety Electromagnetic Compatibility

IEC 60601-1-4 General Requirements for Safety – Programmable electrical medical systems

IEC 60601-1-6 General Requirements for basic safety and essential performance – Collateral Standard: Usability – Edition 2.0

Meets applicable AAMI EC-11 requirements and AAMI EC 13 (Clause 4.2.7 only)

[1]ECG storage in PDF format is not supported in Russian language.

MAC 600 Resting ECG
DOC0444964 rev6

14 June 2022

MAC 600 ECG Analysis System

Reaching more people with digital ECG

Reaching more people with digital ECG

Introducing the MAC™ 600 ECG Analysis System

The 3-channel ECG system for cost-sensitive clinics as well as practices who want portability, ease-of-use, high quality and communication possibilities.

Reaching more people with digital ECG

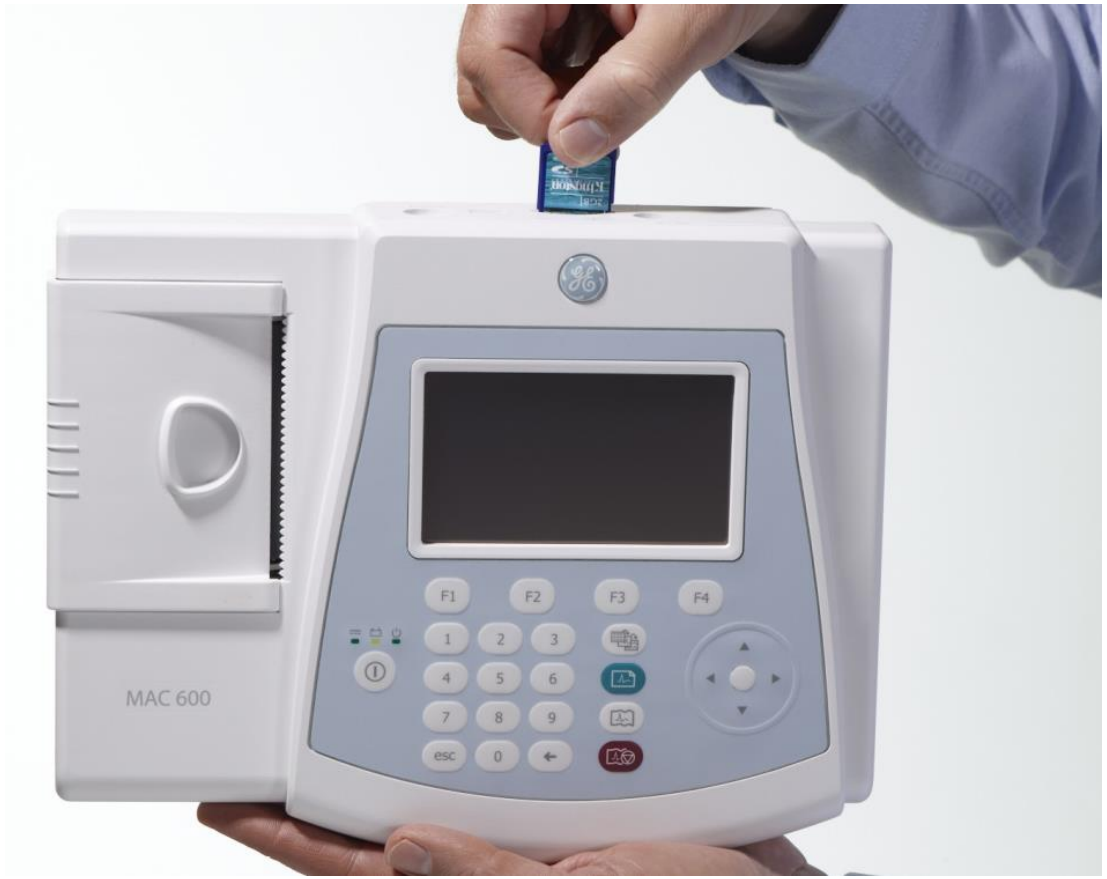
Portable

Advanced Technology

Connected

Portable

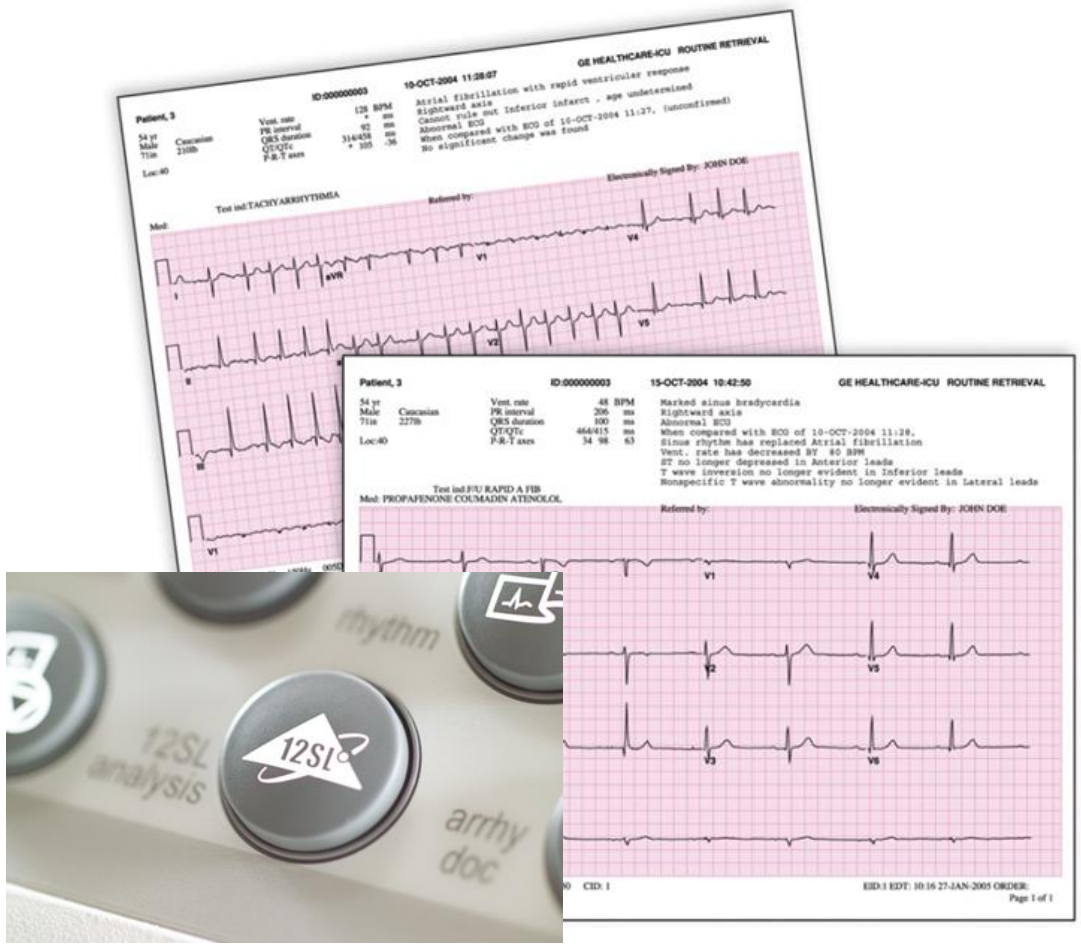
Portable



- Compact and easy to carry
- Very light weight of 1.1 kg
- Battery allows 250 single pages of continuous operation
- Easy cleaning
- 3 channel and one rhythm print out
- Storage of up to 200 ECGs on SD card
- Easy to use buttons

Advanced Technology

Marquette™ 12SL™



MAC 600 I Reaching more people with digital ECG

- 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]

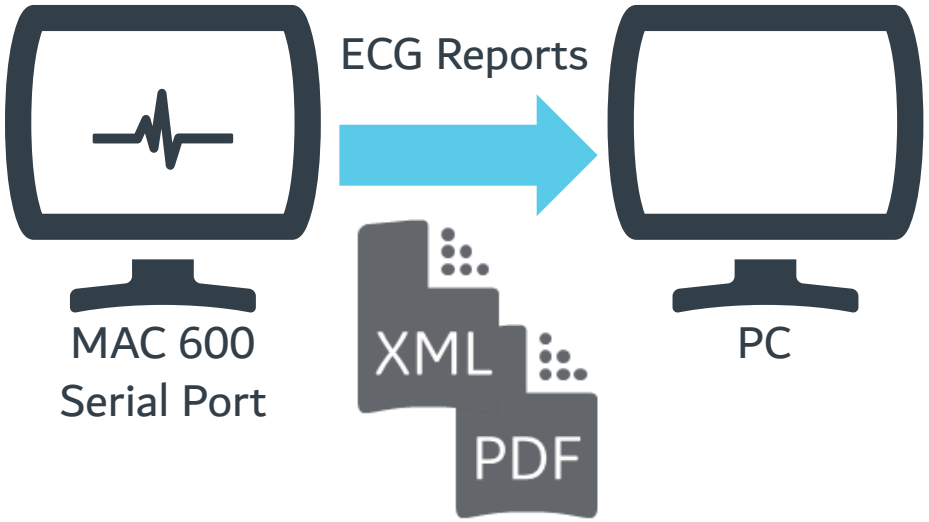
[1]for more details please refer to the GE 12SL statement of validation and accuracy
[2]Xue, J. et al. “A New Method to Incorporate Age and Gender into the Criteria for the Detection of Acute Inferior Myocardial Infarction.” J Electrocardiol. 34(4) (Part 2) (Oct 2001):229-234

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

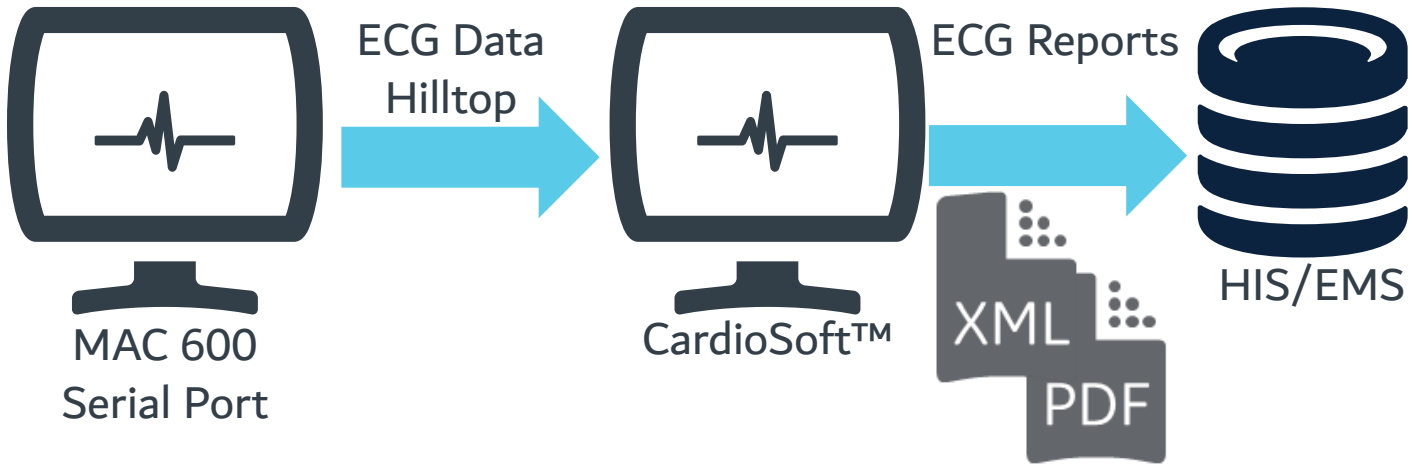
Connected

MAC 600 workflow with shared directory/PC workstation



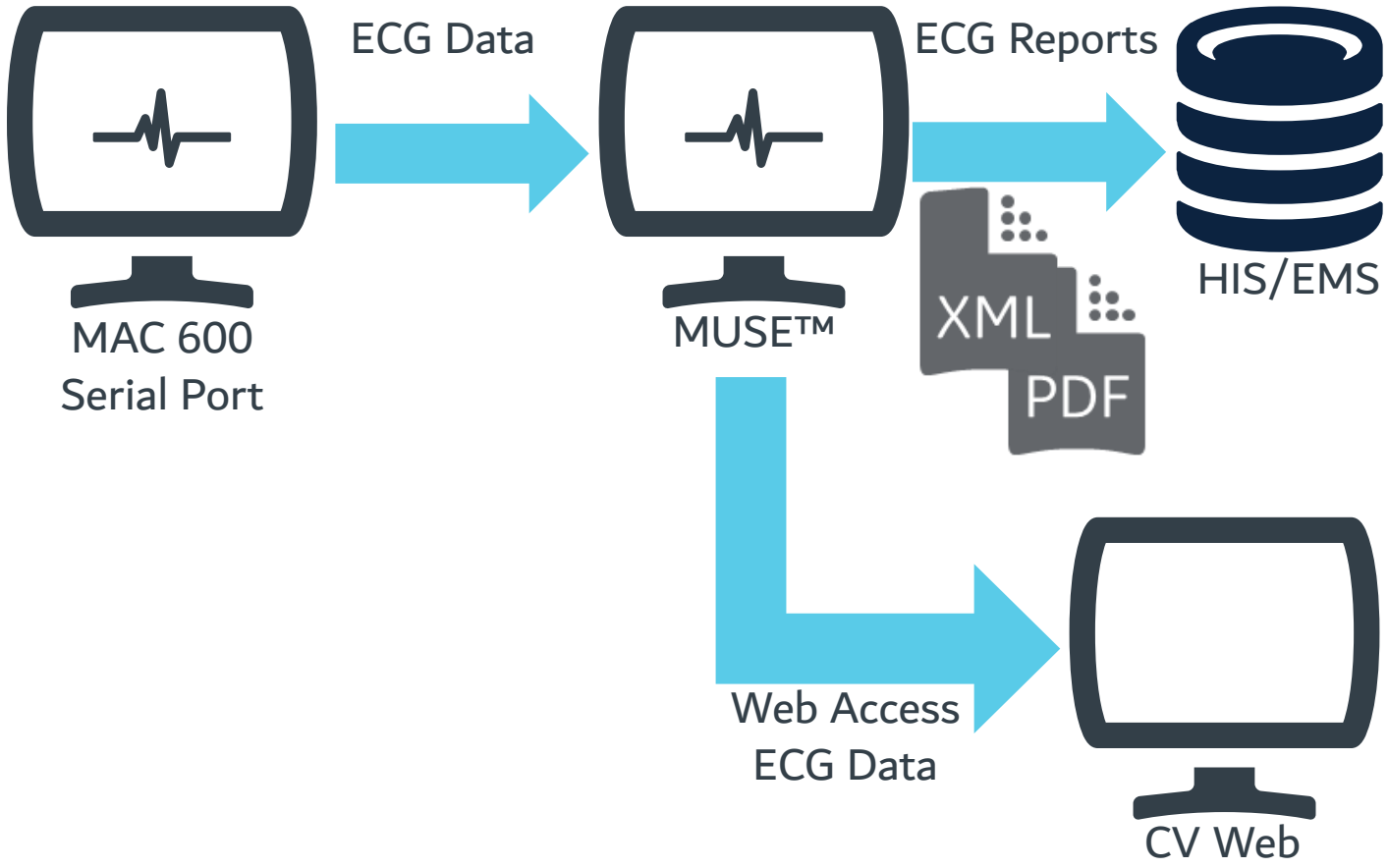
- Paperless workflow
- PDF out, selectable naming
- Built-in storage of up to 200 ECGs
- Serial port communication

MAC 600 workflow with CardioSoft Diagnostic Program



- Paperless workflow
- ECG measurement and editing
- PDF out
- Built-in storage of up to 200 ECGs
- Serial port communication

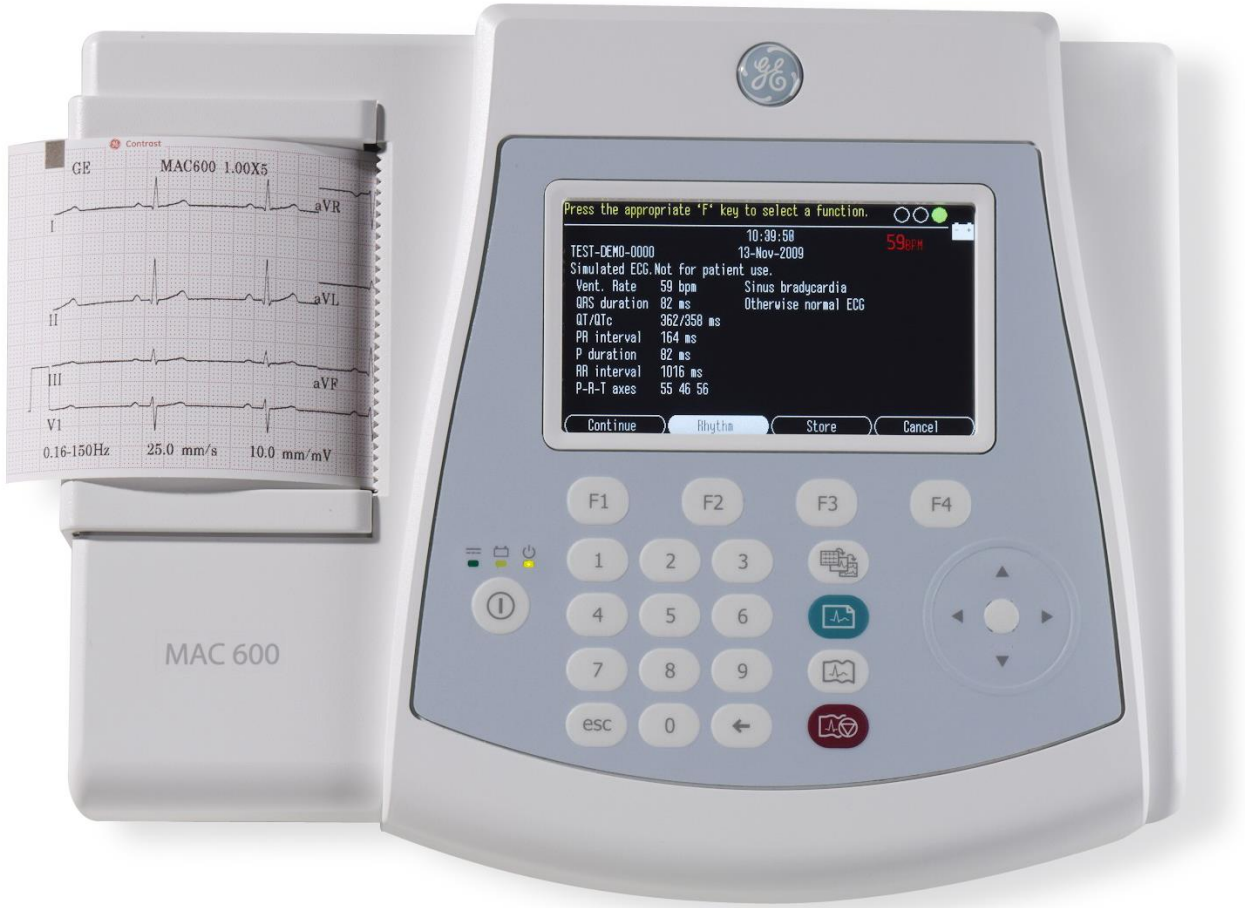
MAC 600 workflow with MUSE Cardiology Information System



- Send ECGs to HIS system
- Serial port communication
- Web-enabled ECG report access and editing possible with CV Web 3.0

MAC 600 ECG Analysis System

Reaching more people with digital ECG



Building a world that works

EC DECLARATION OF CONFORMITY

TF - DOC0681698 (CE-A-005)

Following the provisions of the medical devices directive 93/42/EEC, Annex VII and of the directive 2011/65/EU.

EG-KONFORMITÄTSERKLÄRUNG

Gemäß den Vorschriften der Richtlinie 93/42/EWG über Medizinprodukte, Anhang VII und der Richtlinie 2011/65/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
Kuortaneenkatu2
Helskinki, FIN-00510, Finland

GE Healthcare Critikon de Mexico
Calle Valle Del Cedro 1551
Ciudad Juarez, Chihuahua, Mexico, C.P. 32575

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

MAC 600

Interpretive Multichannel Electrocardiograph

Ref. : see addendum/ *oder siehe Anhang*

GMDN Code: 11407

UMDNS Code: 11411

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

Milwaukee, USA, 6-February-2015
Milwaukee, USA, 6.February.2015

Douglas Kentz
Regulatory Affairs Director

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) on 14-Jan-2013/ Certificate No. 7550.
- *EG-Zertifikat: Genehmigung des kompletten Qualitätssicherungssystems (Anhang II der Richtlinie 93/42/EWG über Medizinprodukte), ausgestellt von G-MED France,* NB #0459 *am* 14–Jan-2013 */ Zertifikat Nr.* 7550.
- List of harmonized standards applied for CE marking
  Liste der harmonisierten Normen, die für die CE-Kennzeichnung angewendet wurden

1. **EN 60601-1:1990, A1:1993, A2:1995**, Medical Electrical Equipment Part 1: General Requirements for Safety
2. **EN 60601-1-1:2001**, Medical Electrical Equipment Part 1-1: General Requirements for Safety Collateral Standard: Safety Requirements for Medical Electrical Systems
3. **EN 60601-1-2:2007, AC:2010**, Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
4. **IEC 60601-1-4:1996, A1:1999**, Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems
5. **EN 60601-2-25:1995, A1:1999**, Medical Electrical Equipment, Part 2: Particular Requirements for the Safety of Electrocardiographs
6. **EN 60601-2-51:2003**, Medical Electrical Equipment, Part 2-51: Particular Requirements for Safety, including Essential Performance, of Recording and Analysis Single Channel and Multichannel Electrocardiographs
7. **EN 60601-1-6:2010**, Medical Electrical Equipment, Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability
8. **EN 62366:2008**, Medical Devices – Application of Usability Engineering to Medical Devices
9. **EN 62304:2006, AC:2008**, Software Life-Cycle Processes
10. **EN 1041:2008, A1:2013**, Information Supplied by the Manufacturer of Medical Devices

Milwaukee, USA, 6-February-2015
Milwaukee, USA, 6.February.2015

Douglas Kentz
Regulatory Affairs Director

This EC declaration of conformity supersedes the previous declaration dated 6-February-2015
Diese EG-Konformitätserklärung ersetzt die vorherige Erklärung mit Datum vom 6-February-2015

ADDENDUM TO THE EC DECLARATION OF CONFORMITY dated 6-February-2015
ERGÄNZUNG ZUR KONFORMITÄTSERKLÄRUNG datiert 6.February.2015

Product Description ***Produktbezeichnung***	**Catalog Designation** ***Katalogbezeichnung***
MAC600 ECG SYSTEM WITHOUT 12SL FEATURE	2047228-001
MAC600 ECG SYSTEM 12SL WITH EXTERNAL MEMORY	2047228-002
MAC600 ECG SYSTEM 12SL WITH EXTERNAL MEMORY COMMUNICATION	2047228-003
Accessories: / Options: *Zubehör / Optionen:*	
VALUE STARTER KIT – IEC	2035819-001
VALUE STARTER KIT – AHA	2035819-002
DISP VALUE STARTER KIT – IEC	2040511-001
DISP VALUE STARTER KIT – AHA	2040514-001
DISP STARTER KIT – IEC	2040511-002
DISP STARTER KIT – AHA	2040514-002
CLAMP LIMB IEC VALUE 4/SET BOXED W/LBL	2029891-001
CLAMP LIMB AHA VALUE 4/SET BOXED W/LBL	2029894-001
REUSABLE BULB ELECTR 6/SET BOXED W/LBL	2029892-001

Milwaukee, USA, 6-February-2015
Milwaukee, USA, 6.February.2015

Douglas Kentz
Regulatory Affairs Director

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
A1D80E08C60D47A...

Lionel DREUX
Certification Director

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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

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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

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EC Certificate

EU Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.:	HZ 2214580-1
Manufacturer:	**GE Medical Systems Information Technologies, Inc.** 9900 Innovation Drive Wauwatosa, WI 53226 USA
EUDAMED Single Registration No.:	N/A
Products:	Class IIa- Z120503 ELECTROCARDIOGRAPHS Class IIb -Z120302 VITAL SIGNS MONITORING INSTRUMENTS
Authorised representative(s):	**GE Medical Systems SCS** 283 Rue de la Miniere, 78530 BUC France

Certificate history		
Revision:	Description:	Issue date:
0	Initial	2020-11-17

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.:	234158038-30
Effective date:	2020-11-17
Expiry date:	2025-10-30
Issue date:	2020-11-17

TÜV Rheinland Product Safety GmbH Zertifizierungsstelle TÜVRheinland®

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
BS-MDR-091

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

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

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

GE Healthcare

MAC® 600 Resting ECG

Connecting hearts and minds

Reaching more people with digital ECG

It's a new picture of global health

Around the world, improving health starts with improving access to healthcare technology. To meet this need, we must create both equipment and data that travels easily—connecting the hearts of patients to the minds of physicians seamlessly.

The MAC 600 enables physicians to bring advanced ECG analysis to patients they could never reach before. With leading clinical technology and an SD card that puts vital data right in your hands. With on-screen results that help save time, energy, and paper. And with the diagnostic confidence that comes from Marquette® 12SL™ analytical tools. All tucked inside an incredibly portable, easy-to-use ECG system.

Improving access. Meeting needs. The MAC 600 lets you picture a healthier future for people around the world. Starting today.

A clear view of cardiac health in just one click

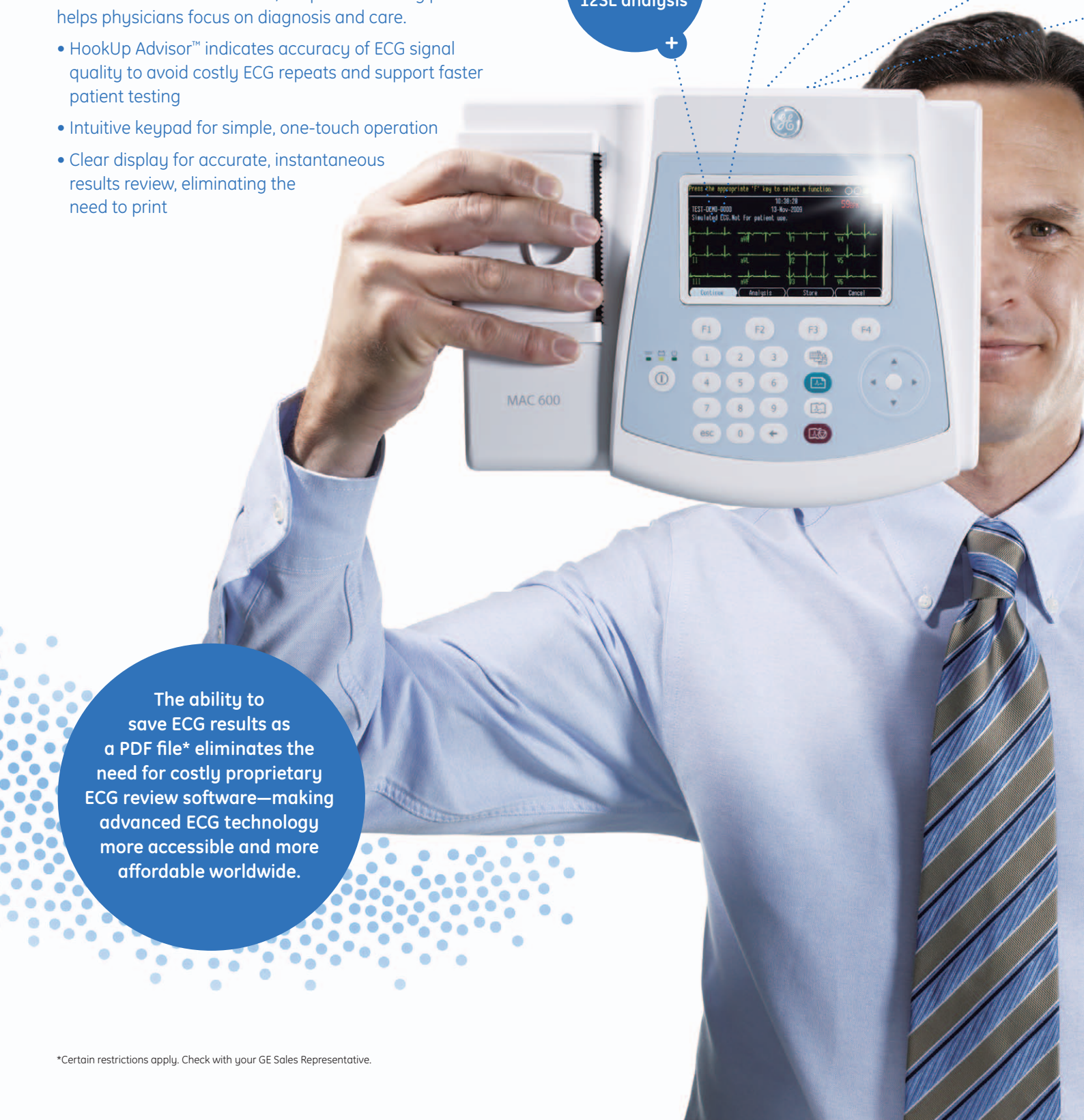
Easier-to-use ECG technology enables clinicians to test more patients in less time, increasing access to high-quality healthcare for everyone. That's why the MAC 600 is designed to be as easy as "connect and click," while ensuring the quality of ECG data. The result is a fast, simple ECG testing process that helps physicians focus on diagnosis and care.

- HookUp Advisor™ indicates accuracy of ECG signal quality to avoid costly ECG repeats and support faster patient testing
- Intuitive keypad for simple, one-touch operation
- Clear display for accurate, instantaneous results review, eliminating the need to print

Review: On-screen 12SL analysis +

Acquisition: 12-lead ECG display +

Connect to MUSE® Cardiology Information System +

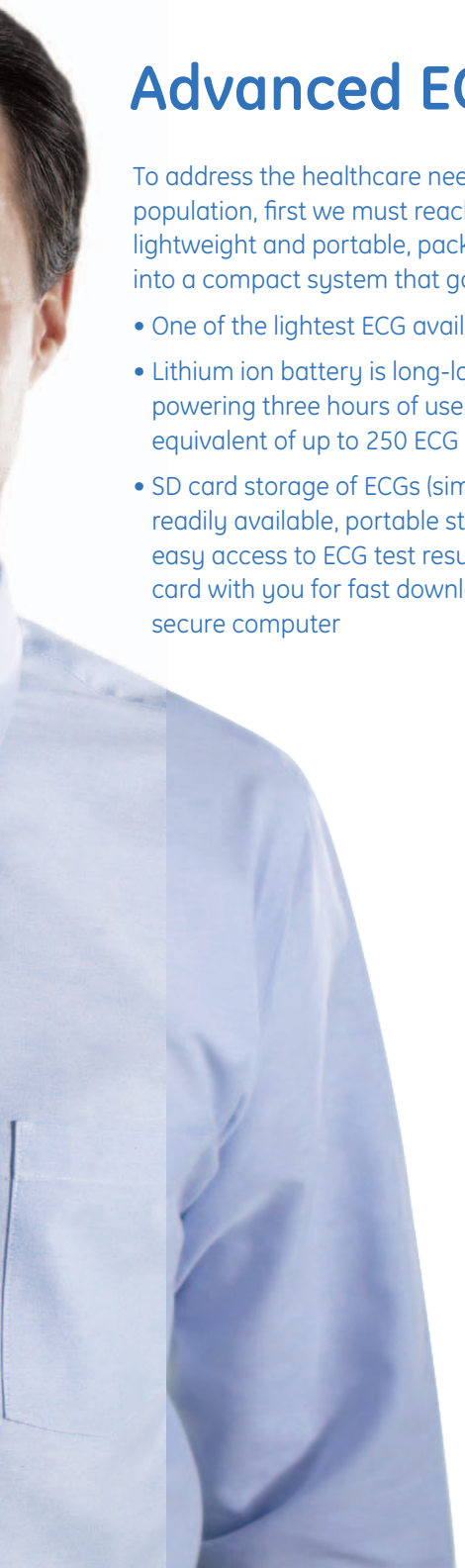


The ability to save ECG results as a PDF file* eliminates the need for costly proprietary ECG review software—making advanced ECG technology more accessible and more affordable worldwide.

*Certain restrictions apply. Check with your GE Sales Representative.

SD card for storage and transport +

Connect to CardioSoft ECG viewer +



Advanced ECG. Travel-sized.

To address the healthcare needs of a growing global population, first we must reach them. The MAC 600 is lightweight and portable, packing advanced ECG analysis into a compact system that goes where you do.

- One of the lightest ECG available—only 1,2 kg
- Lithium ion battery is long-lasting and energy-efficient, powering three hours of use on one charge, the equivalent of up to 250 ECG tests
- SD card storage of ECGs (similar to a digital camera) is a readily available, portable storage system that enables easy access to ECG test results—simply take your SD card with you for fast download and printing from a secure computer

Expanded abilities: scalable, searchable, incredibly capable

By connecting to the CardioSoft™ ECG Viewer, you can transform your MAC 600 into a complete ECG acquisition and storage system, with access to thousands of ECG tests, searchable by patient. CardioSoft is a completely scalable program, easily upgraded for expanded functionality and ECG workflow efficiencies.

More ECG technology in your hands. Less paper to carry around.

The MAC 600 puts advanced diagnostic tools at your fingertips, enabling physicians to deliver one of the world's best ECG analyses. And with on-screen ECG results, you have the completely digital workflow that can help you diagnose patients faster than ever before.

- On-screen preview of waveforms and 12SL interpretation enables digital ECG workflow for faster time to treatment
- Proven Marquette 12SL analysis helps support diagnostic confidence
- 12-lead color display provides clear results review without printing

By using the on-screen review feature, one MAC 600 used in an urban clinic has the potential to save the equivalent of one tree per year, or 59 kg of paper annually.

GE Healthcare, a division of General Electric Company

About GE Healthcare

GE Healthcare provides transformational medical technologies and services that are shaping a new age of patient care. Our broad expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, drug discovery, biopharmaceutical manufacturing technologies, performance improvement and performance solutions services helps our customers to deliver better care to more people around the world at a lower cost. In addition, we partner with healthcare leaders, striving to leverage the global policy change necessary to implement a successful shift to sustainable healthcare systems.

Our “healthymagination” vision for the future invites the world to join us on our journey as we continuously develop innovations focused on reducing costs, increasing access and improving quality and efficiency around the world.

GE Healthcare
Munzinger Straße 5
79111 Freiburg, Germany
Tel. +49 761 4543 0 • Fax +49 761 4543 233

www.gehealthcare.com

GE imagination at work

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