Medica Corporation
5 Oak Park Drive
Bedford, Massachusetts 01730
Tel 781 275 4892
Fax 781 275 2731
www.medicacorp.com

Declaration of Conformity CE

Product Name:	Model/Type:
EasyLyte and accessories per attachment	EasyLyte Na/K, Na/K/Cl, Na/K/Li, Na/K/Cl/Li, Na/K/Ca/pH, Na/K/Cl/Ca/Li
EasyElectrolytes and accessories per attachment	EasyElectrolytes Na/K/Cl, Na/K/Li

Manufacturer

Medica Corporation
5 Oak Park Drive, Bedford, Massachusetts, 01730, USA

Representative

EC REP Emergo Europe, Prinsessegracht 20,
2514 AP The Hague, The Netherlands
Tel: +31 70 345 8570
Fax: +31 70 346 7299

Means of Conformity

Medica Corporation declares that the products listed are covered by Annex III of Directive 98/79/EC. These products are self-certified since they are for professional use only and are not listed on Annex II, List A or Annex II, List B of Directive 98/79/EC. In addition, they are in conformity with the Annex I, "Essential Requirements" and provisions of council Directive 98/79/EC for In Vitro Diagnostic Medical Devices, Directive 2011/65/EU Restriction of Hazardous Substance in Electrical and Electronic Equipment, and the corresponding national laws of the Member States.

Place and Date: Bedford, Massachusetts, USA, September 27, 2018

Signature:

Digitally signed by Ceaicovschi Tudor
Date: 2021.03.17 17:41:55 EET
Reason: MoldSign Signature
Location: Moldova

Name: Photios Makris, Ph.D.
Title: VP, Regulatory Affairs

EasyLyte Accessories

Catalog No.	Accessory	EDMA Code
2004	EasyLyte Na/K Analyzer	21 07 11 02
2014	EasyLyte Plus Na/K/Cl Analyzer	21 07 11 02
2015	EasyLyte Lithium Na/K/Li Analyzer	21 07 11 02
2016	EasyLyte Calcium Na/K/Ca/pH Analyzer	21 07 11 02
2021	EasyLyte Na/K/Cl/Li Analyzer	21 07 11 02
2030	EasyLyte EXPAND Analyzer, Na/K/Cl/Ca-Li	21 07 11 02
2070	EasyLyte EasySampler	21 07 11 02
2101	EasyLyte K+ Electrode	11 04 01 06
2102	EasyLyte Na+ Electrode	11 04 01 07
2113	EasyLyte Cl- Electrode	11 04 01 03
2106	EasyLyte Li+ Electrode	11 04 01 04
2150	EasyLyte Ca++ Electrode	11 04 01 02
2151	EasyLyte pH Electrode	11 70 31 02
2152	EasyLyte Disposable Reference Electrode	11 04 04 01
2103	EasyLyte Reference Electrode	11 04 04 01
2258	EasyLyte Membrane Assembly	21 07 11 02
2120	EasyLyte Na/K 800 ml Solutions Pack	11 04 04 02
2121	EasyLyte Na/K/Cl 800mL Solutions Pack	11 04 04 02
2122	EasyLyte Na/K/Li 800mL Solutions Pack	11 04 04 02
2123	EasyLyte Na/K/Ca/pH 800mL Solutions Pack	11 04 04 02
2028	EasyLyte Na/K/Cl/Li 400mL Solution Pack	11 04 04 02
2109	EasyLyte Na/K 400mL Solutions Pack	11 04 04 02
2112	EasyLyte Na/K/Cl 400mL Solutions Pack	11 04 04 02
2115	EasyLyte Na/K/Li 400mL Solutions Pack	11 04 04 02
2114	EasyLyte Na/K/Ca/pH 400mL Solutions Pack	11 04 04 02
2026	EasyLyte Na/K/Cl/Li 800mL Solution Pack	11 04 04 02
2124	EasyLyte Na/K/Cl/Ca-Li 800ml Solutions Pack	11 04 04 02
2814	EasyQC Bi-Level Quality Control Kit	11 50 02 04
2815	EasyQC Tri-Level Quality Control Kit	11 50 02 04
2843	EasyLyte Quality Control Sample Cups (60)	21 07 11 02
2118	Daily Cleaning Solution Kit	11 01 01 27
2598	EasyLyte Daily Cleaner Cup	21 07 11 02
2108	EasyLyte Solutions Valve	21 07 11 02
2107	EasyLyte Sample Probe	21 07 11 02
2257	EasyLyte Sample Detector	21 07 11 02

EasyLyte Accessories, continued

Catalog No.	Accessory	EDMA Code
2104	EasyLyte Tubing Kit	21 07 11 02
2100	EasyLyte Calcium Tubing Kit	21 07 11 02
2492	EasyLyte Internal Filling Solution (125mL)	11 04 04 90
2309	EasyLyte Wash Solution (50mL)	11 04 04 90
2111	EasyLyte Urine Diluent (500mL)	11 04 04 90
2577	EasyLyte Standard Solution, Urine (50mL)	11 04 04 90
2323	EasyLyte Probe Wipers (6)	21 07 11 02
2541	EasyLyte Printer Paper (3 rolls)	21 07 11 02
2595	EasyLyte EasySampler Sample Cups, 500uL (500)	21 07 11 02
2596	EasyLyte Sample Cups 2.0mL (500)	21 07 11 02
10745	Anti-Evaporation Caps (500)	21 07 11 02
2293	EasyLyte Capillary Tubes	21 07 11 02
2590	EasyLyte Capillary Adaptor Kit	21 07 11 02
2292	EasyLyte Capillary Adaptor Cleaning Kit	21 07 11 02
2578	EasyLyte Red Dye Test Solution (50mL)	11 30 01 11
2572	EasyLyte Troubleshooting Kit	21 07 11 02
2571	EasyLyte Troubleshooting Kit (Na/K/Ca/pH and Na/K/Cl/Li)	21 07 11 02
2105	EasyLyte Quarterly Operating Kit	21 07 11 02
2095	EasyLyte Maintenace Kit	21 07 11 02
2076	EasyLyte Sample Tray	21 07 11 02
2074	EasyLyte Sample Cup Retainer Ring	21 07 11 02
7118	Daily Rinse/Cleaning Solution Kit	11 01 01 27
2544	EasyLyte C Series Printer Paper (5 rolls)	21 07 11 02
2934	EasyLyte Barcode Reader Kit	21 07 11 02

EasyElectrolytes Accessories

Catalog No.	Accessory	EDMA Code
4002	EasyElectrolyte Na/K/Cl Analyzer	21 07 11 02
4003	EasyElectrolyte Na/K/Li Analyzer	21 07 11 02
4102	Reagent Module, Na/K/Cl	11 04 04 02
4103	Reagent Module, Na/K/Li	11 04 04 02
7205	EasyElectrolyte/EasyStat Na+ Electrode	11 04 01 07
7206	EasyElectrolyte/EasyStat K+ Electrode	11 04 01 06
4203	EasyElectrolyte Cl- Electrode	11 04 01 03
4204	EasyElectrolyte Li+ Electrode	11 04 01 04
6204	EasyElectrolyte/EasyStat/EasyBloodGas Reference Electrode	11 04 04 01
4207	EasyElectrolyte Spacer Electrode	11 04 01 90
4301	EasyElectrolyte Troubleshooting Kit	21 07 11 02
2118	Daily Cleaning Solution Kit	11 01 01 27
4402	EasyStat/EasyBloodGas/EasyElectrolyte Red Test Dye Solution	11 30 01 11
4403	EasyElectrolyte Urine Diluent	11 04 04 90
2814	Bi-Level Quality Control Kit	11 50 02 04
2815	Tri-Level Quality Control Kit	11 50 02 04
4405	EasyElectrolyte Na/K/Cl Demonstration Kit	21 07 11 02
4406	EasyElectrolyte Na/K/Li Demonstration Kit	21 07 11 02
4404	EasyElectrolyte Capillary Tube Kit	21 07 11 02
4306	EasyElectrolyte Sampler	21 07 11 02
6504	EasyBloodGas/EasyElectrolyte Pump Tube	21 07 11 02
6505	EasyStat/EasyBloodGas/EasyElectrolyte Printer Paper	21 07 11 02
4506	EasyElectrolyte Sensor Module	21 07 11 02
4507	EasyElectrolyte Valve Module	21 07 11 02
4508	EasyStat/EasyBloodGas/EasyElectrolyte Compression Plate	21 07 11 02
7302	Probe Wipers	21 07 11 02
4522	EasyElectrolyte Daily Cleaner Sample Cups	21 07 11 02
4539	EasyElectrolyte Sensor Module, Li+	21 07 11 02
6537	EasyElectrolyte/EasyStat/EasyBloodGas Serial Cable, 9-pin	21 07 11 02
6520	EasyElectrolyte/EasyStat/EasyBloodGas Barcode Reader Kit	21 07 11 02

intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the quality management system of:

Medica Corporation

Main Site: 5 Oak Park Drive

Bedford, Massachusetts 01730 United States

has been assessed by Intertek as conforming to the requirements of:

ISO 13485:2016

The quality management system is applicable to:

The Design, Development, Manufacture, Service, Distribution of in-vitro diagnostic medical devices, in-vitro diagnostic test kits, in-vitro diagnostic reagents, in-vitro diagnostic analyzers/software used in the diagnosis and management of cancer, immune status, disease status, autoimmune status, cardiac markers, protein metabolism, endocrine disorders, blood analytes, urinalysis, blood gases.

Certificate Number:
0082581-01

Initial Certification Date:
2009-04-17

Certificate Issue Date:
2019-01-01

Certificate Expiry Date:
2021-04-16

SCC Accredited CB-MS
OCSM
Accrédité CCN

Calin Moldovean
President

Intertek Testing Services NA Ltd.,
1829, 32nd avenue, Lachine, QC, H8T 3J1,
Canada

Declaration of Conformity

According to the Medical Devices Directive 93/42/EEC

Holder： Kveina Technology Group Limited

Address: 4/F,Building A,Zhongcheng Industrial Zone,Industry East, Load,Longhua Town,Shenzhen,Guangdong, China.

Manufacturer Name: Kveina Technology Group Limited

Manufacturer Address: 4/F,Building A,Zhongcheng Industrial Zone,Industry East, Load,Longhua Town,Shenzhen,Guangdong, China.

Authorized representative： CKMedical International

Laan van cattenbroeck 10,Zeist ,The Netherlands, postcode 3703BM.

Product Name: ECG cable, Spo2 adapter cable,IBP cable

MDD-Classification: Class I

Product Part Number： As Appendix II

Person responsible for making this declaration：

Name : Jerry Liu　　Position/Title: Sales Manager

We Hereby Declares that the Medical device as indicated above conforms with the essential requirement listed in the Annex V of the European Medical Device Directive 93/42/EEC。

CE

Jan. 18th. 2013

Date of issue

signature

Lampen | Bulbs

FÜR KaWe-PRODUKTE | FOR KaWe PRODUCTS

2,5 V

für | for
KaWe EUROLIGHT® C +
VET C30 + VET C30 OP,
KaWe COMBILIGHT® C,
KaWe PICCOLIGHT® C

VE = 6 St. | PU = 6 items

VL **REF 12.75111.013**

2,5 V

für | for
KaWe EUROLIGHT® E30,
KaWe PICCOLIGHT® E50, E55 + D

VE = 6 St. | PU = 6 items

VL **REF 12.75112.003**

2,5 V

für | for
KaWe EUROLIGHT® E15 + E16

VE = 6 St. | PU = 6 items

VL **REF 12.75113.003**

2,5 V

für | for
KaWe EUROLIGHT® E10

VE = 6 St. | PU = 6 items

VL **REF 12.75114.003**

2,5 V

für | for
WL Mehrweg-Laryngoskop-Spatel,
kompatibel für Spatelgröße 00 - 1
WL reusable laryngoscope blades,
compatible with blade sizes 00 - 1

VE = 6 St. | PU = 6 items

VL **REF 12.75126.003**

2,5 V

für | for
WL Mehrweg-Laryngoskop-Spatel,
kompatibel für Spatelgröße 2 - 5
WL reusable laryngoscope blades,
compatible with blade sizes 2 - 5

VE = 6 St. | PU = 6 items

VL **REF 12.75127.003**

2,5 V

für | for
KaWe EUROLIGHT® E36+D30,
KaWe PICCOLIGHT® E56

VE = 6 St. | PU = 6 items

XH **REF 12.75132.003**

2,5 V

passend zu allen Fiber Optik,
Laryngoskop-Batterie-
und Ladegriffen
suitable for all fibre-optic,
laryngoscope battery
and charging handles

VE = 6 St. | PU = 6 items

XL **REF 12.75141.003**

2,5 V

passend zu allen Fiber Optik,
XL-Otoskopen 2,5 V
suitable for all fibre-optic,
XL-otoscopes 2.5V

VE = 6 St. | PU = 6 items

XL **REF 12.75144.013**

VL Vakuum-Lampe / vacuum bulb
XL Xenon-Lampe / xenon bulb

GE Healthcare

EC Declaration of Conformity

EG Konformitätserklärung

Document No. DOC0711295

Manufacturer/ Hersteller:
GE Medical Systems Information Technologies
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Authorized EU Representative/ EU Repräsentant:
GE Medical Systems Information Technologies GmbH
Munzingerstrasse 5
79111 Freiburg, Germany

We herewith declare that the product/ *Wir erklären hiermit, dass das Produkt*

MAC 600
(including system components and accessorie/*einschließlich Systemkomponenten und Zubehör)*
UMDNS-Code: 11411; GMDN-Code: 11-411

fulfills the requirements of the following directives, standards and normative documents:
mit den folgenden Richtlinien, Normen und normativen Dokumenten übereinstimmt:

1. *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices*
2. *EN 60601-1:1990, A1:1993, A2:1995; Medical Electrical Equipment – Part 1: General Requirements for basic safety and essential performance*
3. *EN 60601-1-1:2001; Medical Electrical Equipment - Part 1-1: General Requirments for Safety - Collateral Standard: Safety Requirements for Medical Electrical Systems*
4. *EN 60601-1-2:2001, A1:2006 (IEC 60601-1-2:2004); Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests*
5. *EN 60601-2-25: 1995, A1:1999; Medical Electrical Equipment – Part 2-25: Particular Requirements for the safety of electrocardiographs*
6. *EN 60601-1-4:1996, A1:1999 (IEC 60601-1-4:2000); Medical Electrical Equipment – Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems*
7. *EN 60601-2-51: 2003: Medical Electrical Equipment – Part 2-51; Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs*
8. *EN 60601-1-6; 2007; Medical Electrical Equipment – Part 1-6: General Requirements for Safety – Collateral Standard Usability*

Compliance of the designated product with the Directive 93/42/EEC has been certified by:
Die Übereinstimmung des bezeichneten Produktes mit der Richtlinie 93/42/EWG wird bescheinigt durch:

GE Medical Systems Information Technologies
8200 West Tower Avenue
Milwaukee, WI 53223 USA
Technical Dossier CE-A-005

The medical device has been assigned to class <**IIa**> as specified in the Directive 93/42/EEC. It bears the mark

GE Healthcare

Das Medizinprodukt ist eingestuft in die Klasse <**IIa**> *gemäss der Richtlinie 93/42/EWG, es trägt die Kennzeichnung*

CE
0459

The designated product has been designed and manufactured under a quality management system according to EN ISO 13485: 2003 and Annex II of Directive 93/42/EEC concerning medical devices. The conformity of the quality management system has been certified by:
Das bezeichnete Produkt wurde unter Anwendung des Qualitätsmanagementsystems gemäss ISO 13485:2003 und Anhang II der Richtlinie 93/42/EWG über Medizinprodukte entwickelt, hergestellt und geprüft. Die Konformität des Qualitätsmanagementsystems wird bescheinigt durch:

G-MED France

Jan 15, 2010
Dave Wahlig *Date*
Director, Regulatory Affairs
Wauwatosa, Wisconsin

Jan. 15, 2010
Joe Lucas *Date*
Regulatory Leader
Wauwatosa, Wisconsin

The technical documentation is filed at Research Park, Wauwatosa, WI
Die technische Doukmentation ist archiviert bei Research Park, Wauwatosa, WI

EasyLyte EasyBloodGas EasyStat

Training Certificate

This is to certify that

Soracovici Sergiu

Of Global Biomarketing Group

has completed training for the operation and service of the EasyLyte, EasyBloodGas, and EasyStat analyzers.

MEDICA

November 25, 2004

Date

MEDICA CORPORATION CORPORATE SEAL MASSACHUSETTS 1965

Randall Rollins

Signed: Randall Rollins
Technical Service Manager

MED CERT®

Certification. Medical Only.

Certificate

The Certification Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith confirms that the company

Kommanditgesellschaft Behnk Elektronik GmbH & Co.
Hans-Böckler-Ring 27
22851 Norderstedt
Germany

has introduced, applies and maintains a Quality Management System in the area of:

Development, manufacture, final inspection, distribution and service of laboratory measurement instruments for in-vitro-diagnostics

The compliance of the Quality Management System with the requirements of the below mentioned standard was verified by an audit:

EN ISO EN ISO 13485:2016

The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 12 November 2021

Report No.: 2500PS19F
Process No.: QS – 2500
Certificate No.: 2500GB445190617

Hamburg, 17 June 2019

MEDCERT Certification Body
(Markus Bianchi)

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00

MAC™ 600 Resting ECG Analysis System

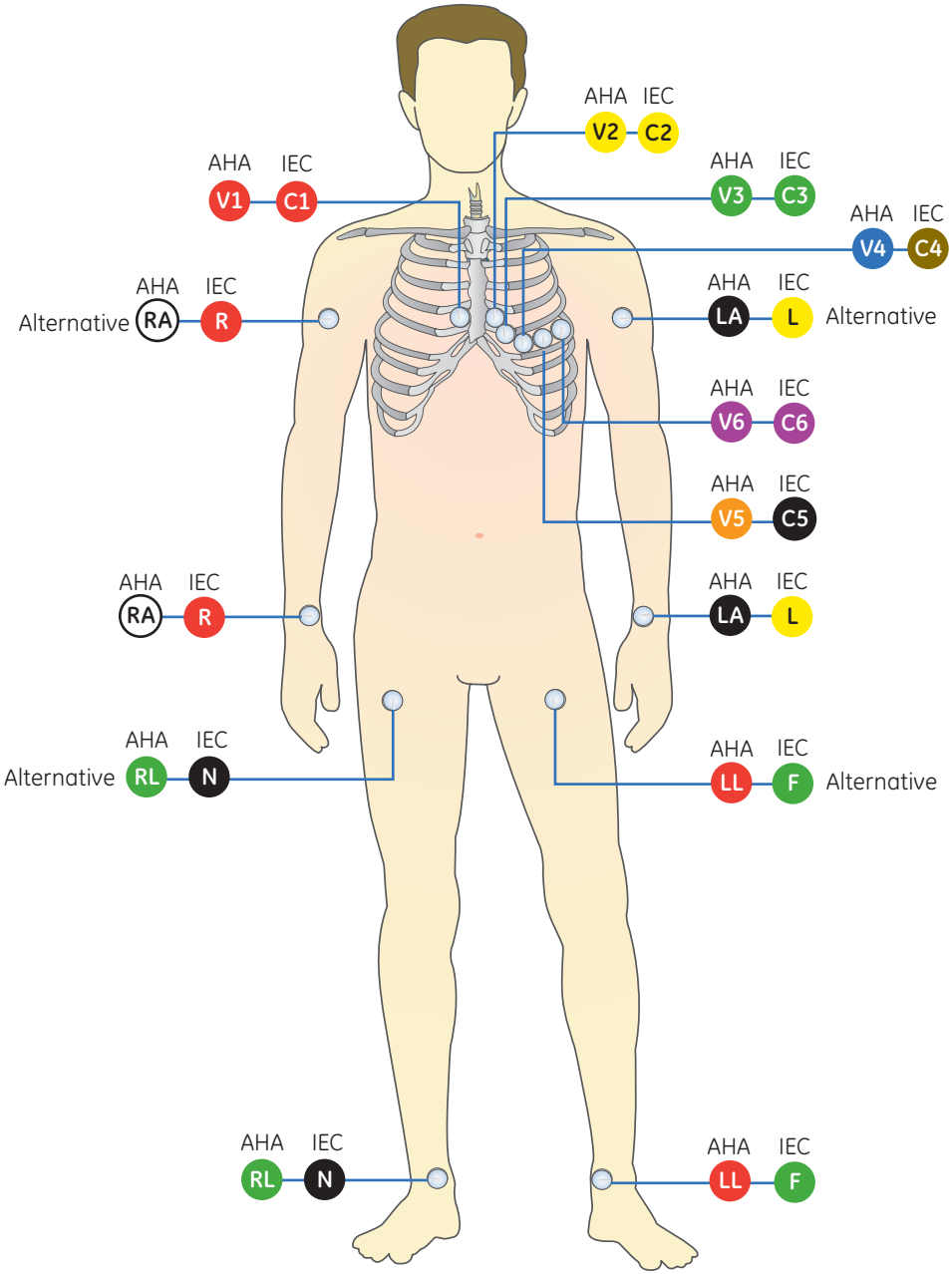
Quick Reference Guide

Education Services
Clinical Development

Notice

The materials contained in this document are intended for educational purposes only. This document does not establish specifications, operating procedures or maintenance methods for any of the products referenced. Always refer to the official written materials (labeling) provided with the product for specifications, operating procedures and maintenance requirements.

Contents

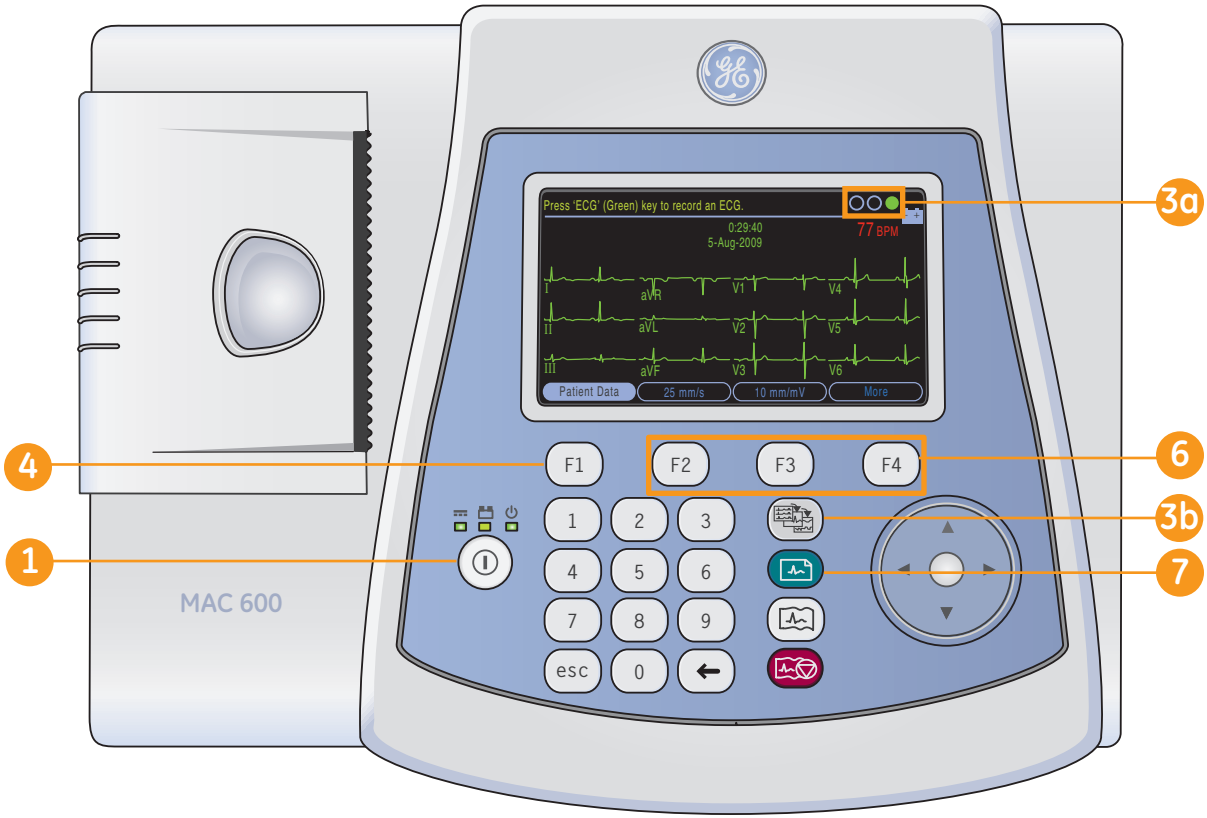


Skin Preparation and Lead Placement

1. Shave any hair from each electrode site and degrease each electrode site with alcohol.
2. Dry skin completely.
3. Apply the leads on the prepared area.
4. Verify the leads are connected and working properly.

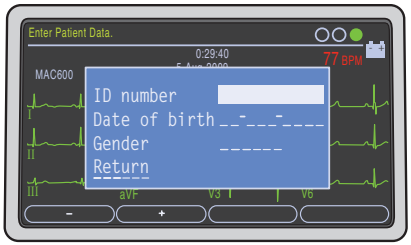
Table 1 **AHA and IEC Lead Placement**

AHA lead	IEC lead	Electrode Placement
V1 red	C1 red	Fourth intercostal space at the right sternal border.
V2 yellow	C2 yellow	Fourth intercostal space at the left sternal border.
V3 green	C3 green	Midway between C2/V2 and C4/V4.
V4 blue	C4 brown	Mid-clavicular line in the fifth intercostal space.
V5 orange	C5 black	Anterior auxiliary line on the same horizontal level as C4/V4.
V6 purple	C6 purple	Mid-auxiliary line on the same horizontal level as C4/V4 and C5/V5.
LA black	L yellow	Above left wrist (alternate placement: left deltoid).
LL red	F green	Above left ankle (alternate placement: upper leg close to torso).
RL green	N black	Above right ankle (alternate placement: upper leg close to torso).
RA white	R red	Above right wrist (alternate placement: right deltoid).



Acquire an ECG

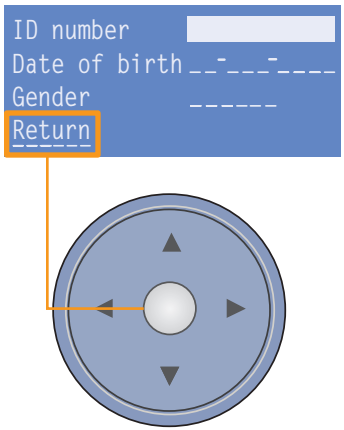
1. Power the system on.
2. Prepare the patient. Refer to section ***Skin Preparation and Lead Placement*** for details.
3. Verify waveform quality by:
   - 3a Checking ***Hook-up Advisor***. Green (always right most circle) indicates a good quality waveform.
   - 3b Press the ***Leads*** key to scroll through the leads.
4. Press ***F1*** to open the ***Patient Data window***. Enter the patient ***ID, DOB*** and ***gender*** using the numbered keyboard and arrow pad.
   - Press ***F1*** to insert a dash while entering the patient ID if needed.
   - Press ***F2*** to insert a **+** symbol while entering the patient ID if needed.



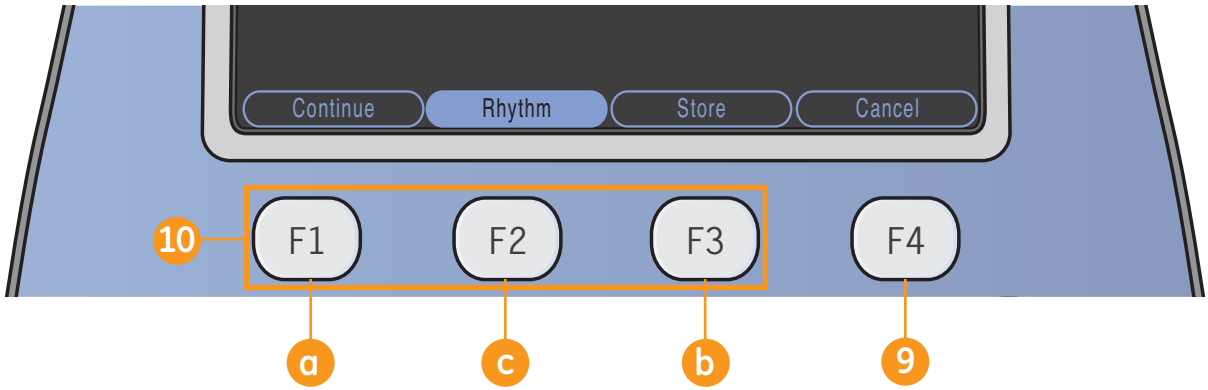
Color Display is a purchasable option.

Note! *Refer to the Operator's Manual for instruction on how to use Secondary ID, age and alfa-numeric input feature.*

5. Select ***Return,*** and press the center of the arrow pad to close the Patient Data window.



6. Use the ***F*** keys to make any necessary adjustments to:
   - Speed ***(F2)***
   - Gain ***(F3)***
   - ***More (F4)*** > ***Filter (F1***) to adjust Waveform Filter. Press ***More (F4***) to return ECG Screen.
7. Press the ***ECG*** key on the keypad to record an ECG.



8. Press ***Analysis (F2)*** to view the Measurement and Interpretation information. Once you have pressed Analysis you see the F keys as displayed in the above illustration.

Note! *Analysis and Measurement are purchasable options.*

9 If after reviewing the ECG and Analysis if you wish to stop and acquire another ECG, press ***Cancel (F4)*** and press the ***ECG*** key on the keypad to record another ECG. Otherwise continue with step 10.

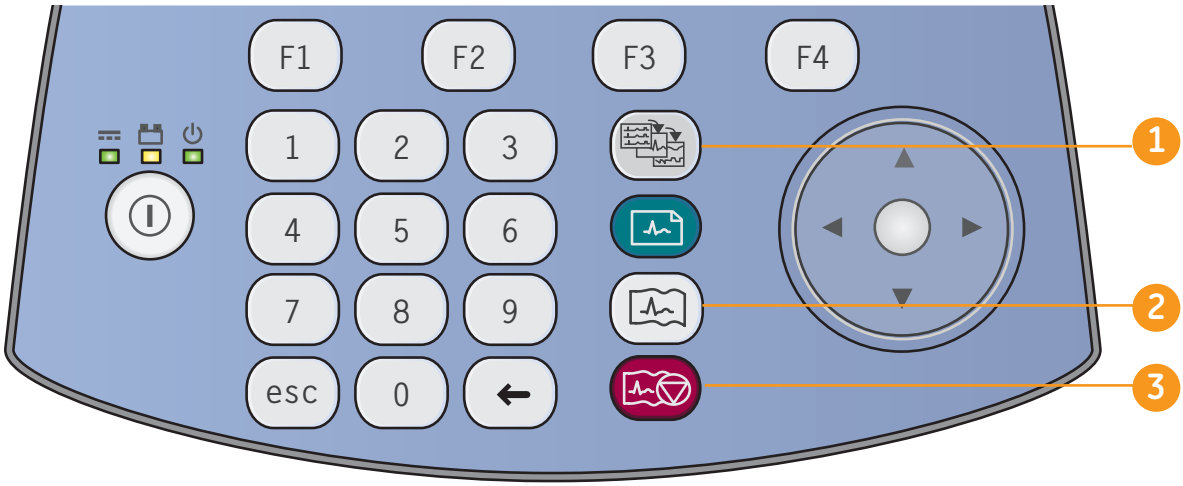
10 Other options from the Analysis window include:

a Press ***Continue (F1)*** to continue with the acquired 12 lead ECG.

b Press ***Store (F3)*** to store the ECG to the SD Card.

Note! *Storing to SD card is a purchasable option.*

c Press ***Rhythm (F2)*** to view the waveform.

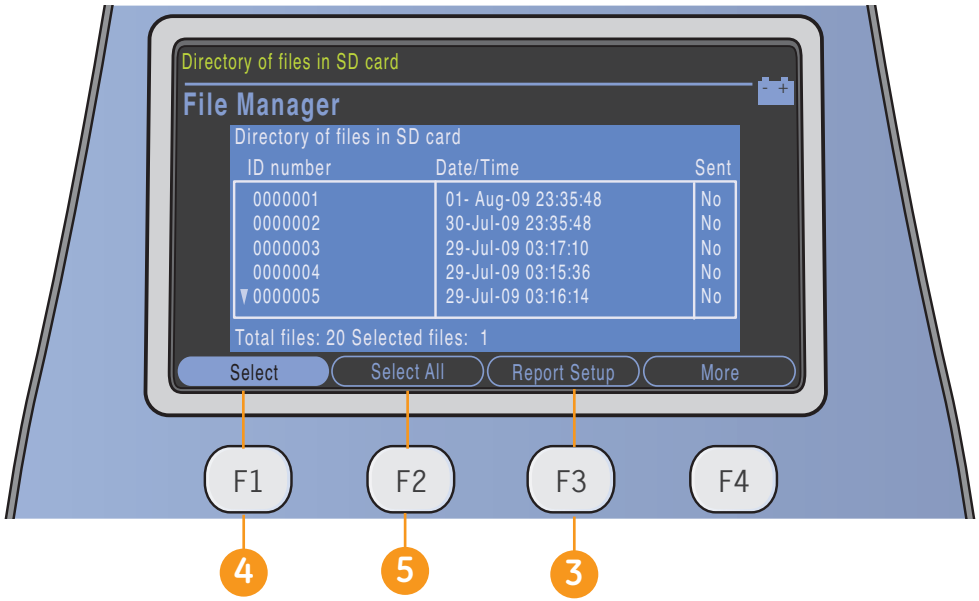


Print Continous Rhythm

1. Press the ***Leads*** key to select the desired 3-lead group for rhythm.
2. Press the ***Rhythm*** key on the Keypad to start the printing of continuous rhythm.

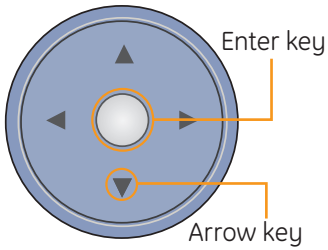
Note! If your display is showing the 12-lead or 6-lead presentation, pressing the ***Rhythm*** key will result in the display of 3 leads from the group configured as the autorhythm and will begin rhythm printing with those 3 leads.

3. Press the ***Stop Writer*** key on the keypad to stop the printing of the continuous rhythm.

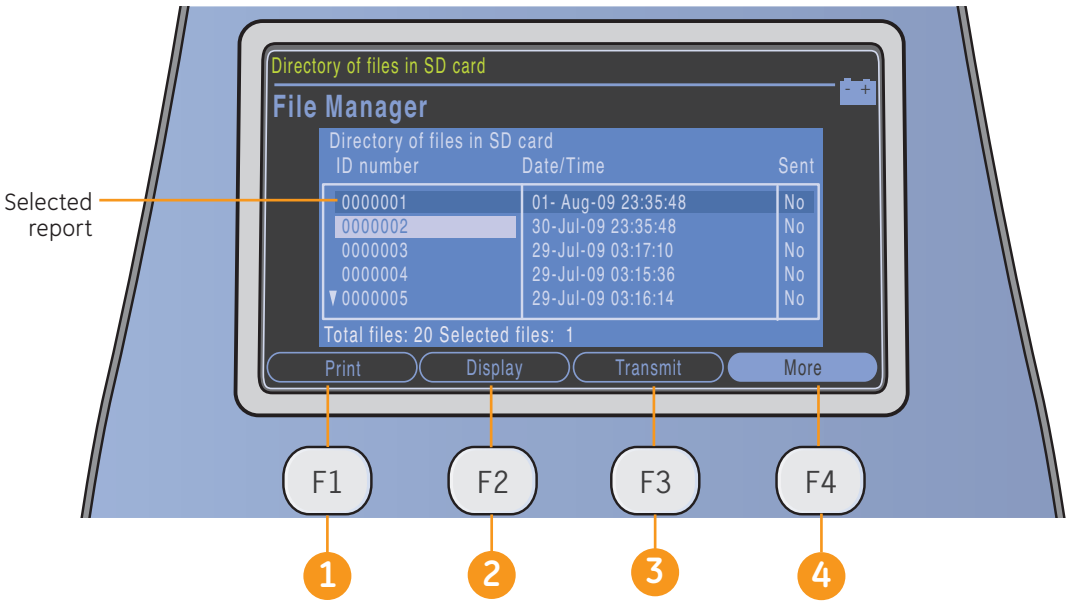


File Manager (Option)

1. From the startup screen press ***More (F4).***
2. Press ***File Manager (F3).***
3. Press ***Report Setup (F3)*** to select desired format for your printed reports.
   - **a.** Press ***Report Format (F1)*** to open the reports selection screen.
   - **b.** Use the arrow pad to go to the desired report.



   - **c.** Enter ***1*** for each report you wish printed. You may enter a higher number if you wish more copies.
   - **d.** Select ***Return*** to save and exit screen.
   - **e.** Press ***More (F4).***
   - **f.** Press ***Return (F2)*** to get back to the main File Manager Screen.
4. Press ***Select (F1)*** to select individual reports. Use the arrow pad to navigate through the list and press the ***Enter*** key of the arrow pad to highlight the desired report. Use the same procedure to highlight multiple reports if desired.
5. If you wish to highlight all reports press ***Select All (F2)***.



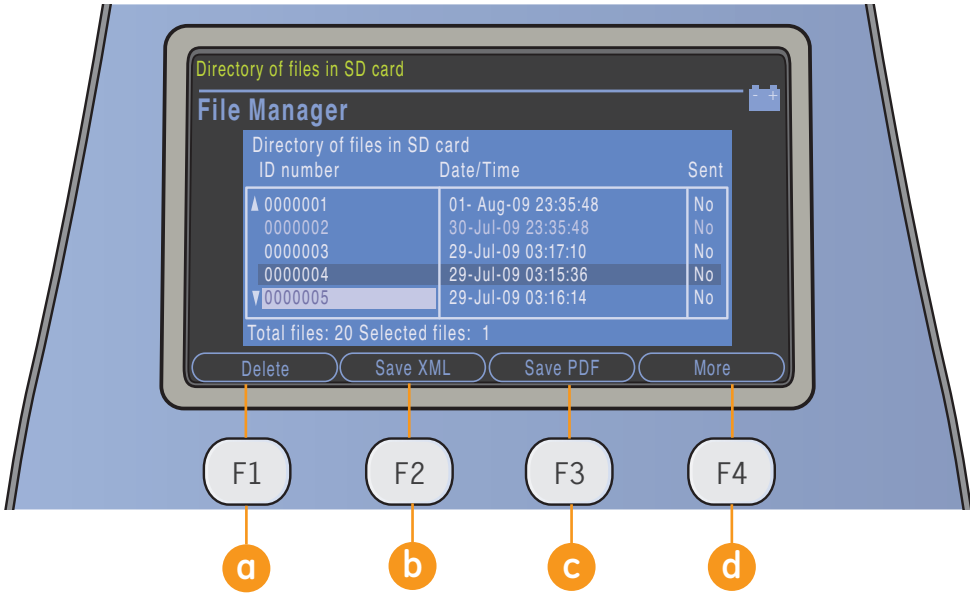
Note! *Your F key order may vary slightly from what is described based on your purchased options.*

Once you have selected a report(s) you have the following options:

1. **Print (F1):** prints the ECG of the selected report(s)
2. **Display (F2):** allows you to view the ***Medians (F1), Analysis (F2)*** or ***Print (F3)*** of the selected record(s).
3. **Transmit (F3):** allows you to transmit to a MUSE system or XML output via Serial Line.

Note! *Serial Transmission is a purchasable option.*

4. Select ***More (F4)*** then ***Return (F2***) to get back to File Manager main screen.



5. **More (F4):** Gives more selections including:

   a **Delete (F1):** press to delete record. User must enter password to delete record(s) from system

   b **Save XML (F2):** saves record to SD card in XML format

   Note! *Save to XML is purchasable option.*

   c **Save PDF (F3):** saves record to SD card in PDF format

   Note! *Save to PDF is purchasable option.*

   d **More (F4):** returns previous screen. Press ***Return (F1)*** to return to File Manager main screen.

6. From the main File Manager screen press **More (F4)** then press ***Resting ECG (F3)*** to return to the ***Resting ECG*** screen.





General Electric Company reserves the right to make changes in specifications and features shown herein, or discontinue the product described at any time without notice or obligation.

GE, GE Monogram, Marquette, 12SL, MAC and MUSE are trademarks of General Electric Company.

GE Medical Systems *Information Technology* Inc., a General Electric company, doing business as GE Healthcare.

Notice: The materials contained in this document are intended for educational purposes only. This document does not establish specifications, operating procedures or maintenance methods for any of the products referenced. Always refer to the official written materials (labeling) provided with the product for specifications, operating procedures and maintenance requirements.

GE Healthcare
9900 Innovation Drive
Wauwatosa, WI 53223
USA

www.gehealthcare.com

imagination at work

CE 0459

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GE Healthcare

MAC® 600 Resting ECG

Technical Specifications

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 @ 500 sps
Frequency response:	–3 dB @ 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
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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:	>10MΩ @ 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 @ 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-second 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
CardioSoft™ Interface	
SD card interface:	Compatible with Cardiosoft V6.51
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 lead 2 by 5s @ 50mm/s 4 by 10s Autorhythm (12-lead)
Accessories	
IEC/AHA leadwire and electrode adaptor sets (user-selectable) 10-lead patient cable (user-selectable replaceable leads or fixed leads cables) Electrodes (disposable or reusable, user-selectable) Country-specific power cords Z-fold and Roll paper Electrode cream 250 ml/tube	
Electrical	
Power supply:	External AC/DC adaptor or battery operation
External Adaptor Specifications	
Input voltage:	100 to 240 VAC ±10%
Input current:	Maximum 0.6A @ 90 VAC, 0.3A @ 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, 2.25 AH ±10% 360 minutes of continuous operation without recording or 250 ECGs in 2.5 X 4 format at 25 mm/S and 10 mm/mV or 100 minutes continuous rhythm print at 25 mm/S and 10 mm/mV.
Battery charge time:	Approximately 3 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

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

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 II, 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)	

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