GE Healthcare

MAC™ 7 Resting ECG Analysis System

Version 1.00

Regulatory and Safety Manual

2109599-003 A

MAC™ 7 Resting ECG Analysis System
Version 1.00
English

Publication Information

This document describes version 1.00 of MAC™ 7 Resting ECG Analysis System, also referred to as the “product” or "system" or "device". It does not apply to earlier product versions. Due to continuing product innovation, specifications in this document are subject to change without notice.

The MAC ™7 Resting ECG Analysis System is intended to be used, under the direct supervision of a licensed healthcare practitioner by trained operators in a hospital or facility providing patient care.

This document provides information required for the proper use of the system. Familiarize yourself with this information and read and understand all instructions before attempting to use this system.

NOTE:

Illustrations in this document are provided as examples only. Depending on system configuration, screens in the document may differ from the screens on your system. Patient names and data are fictitious. Any similarity to actual persons is coincidental.

The document part number and revision are on each page of the document. The revision identifies the document’s update level. The revision history of this document is summarized in the following table.

Revision	*Date*	*Comment*
A	15 August 2018	Initial Release

To access other GE Healthcare Diagnostic Cardiology documents, go to the Common Documentation Library (CDL), located at *http://apps.gehealthcare.com/servlet/ClientServlet?REQ=Enter+Documentation+Library*, and click **Cardiology**.

To access Original Equipment Manufacturer (OEM) documents, go to the device manufacturer's website.

Support

GE Healthcare maintains a trained staff of application and technical experts to answer questions and to respond to issues and problems that may arise during the installation, maintenance, and use of this product.

If you require additional assistance, contact your GE Healthcare representative or GE Healthcare support at one of the following numbers:

- North America: 1-800-558-7044
- Europe: +49 761 45 43 -0
- Asia: +86 21 3877 7888

Training

This document is intended as a supplement to, not a substitute for, thorough product training. If you have not received training on the use of the product, you should request training assistance from GE Healthcare.

To see available training, go to the GE Healthcare training website (*www.gehealthcare.com/training*). Select **Education** > **Product Education-Technical** > **Diagnostic Cardiology**. For more self-paced course offerings, tools, and reference guides you may find useful, please visit the GE Healthcare Education Store at *www.gehealthcare.com/educationstore*.

Table of Contents

1

Regulatory Information

Familiarize yourself with this information before attempting to use this system. Keep this manual with your Operator Manual and equipment at all times, and periodically review it.

This section provides information about the regulatory compliance of this system. The system software is considered medical software. As such, it was designed and manufactured to the appropriate medical regulations and controls.

Intended Use

The system is intended to acquire, analyze, display, and record electrocardiographic information from adult, pediatric or neonatal populations. Basic system delivers 3,6, or 12 lead ECG's and interpretive analysis. Transmission and reception of ECG data and other clinical data to and from a central clinical information system is optional.

The system is intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital or medical professional's facility.

Indications for Use

This device is a non-invasive prescription device.

The device is indicated for use:

- To acquire, analyze, display and print electrocardiograms.
- To provide interpretation of the data for consideration by a physician.
- In a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis. The interpretations of ECG offered by the device are only significant when used in conjunction with a physician over-read as well as consideration of all other relevant patient data.
- On adult and pediatric (birth through 21 years of age) populations.

Contraindications

This system is not intended for use in the following manner:

- During patient transport
- With high-frequency surgical units
- As an intra-cardiac application
- As a sole means of diagnosis
- As a vital signs physiological monitor

Prescription Device Statement

CAUTION:

United States federal law restricts this device to sale by or on the order of a physician.

Classification of Medical Device

The device is classified as follows according to IEC 60601-1.

Table 1: Medical Device Classifications

Category	*Classification*
Type of protection against electrical shock	Class I, internally powered
Degree of protection against electrical shock	Type CF defibrillation-proof applied part
Degree of protection against harmful ingress of solids and liquids	The Ingress Protection (IP) code for this device is IP 20.
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or with nitrous oxide	Equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or with nitrous oxide
Method(s) of sterilization or disinfection recommended by the manufacturer	Not applicable
Mode of operation	Continuous operation

Recording ECGs during Defibrillation

This equipment is protected against the effects of cardiac defibrillator discharge to ensure recovery, as required by test standards. The patient signal input of the acquisition module is defibrillation-proof. It is not necessary to remove the ECG electrodes prior to defibrillation.

When using stainless steel or silver electrodes, a defibrillator discharge current may cause the electrodes to retain a residual charge causing a polarization or DC offset voltage. This electrode polarization blocks acquisition of the ECG signal. To avoid this condition, if there is a situation where a defibrillation procedure is necessary, use non-polarizing electrodes such as silver/silver-chloride types, which do not form a DC offset voltage when subjected to a DC current.

If you use polarizing electrodes, GE Healthcare recommends disconnecting the leadwires from the patient before delivering the shock.

Electrode defibrillation recovery is the ability of the electrode to allow the ECG trace to return after defibrillation. GE Healthcare recommends using non-polarizing disposable electrodes with defibrillation recovery rating as specified in AAMI EC12.5.2.2.4. AAMI EC12 requires that the polarization potential of an electrode pair does not exceed 100 mV 5 seconds after a defibrillation discharge.

Refer to the supplies and accessories guide for this system for a list of approved electrodes.

Modulating Effects in Digital Systems

This section describes the modulating effects that may occur in digital systems of the product.

This device uses digital sampling techniques that may produce some variation in amplitudes of Q, R, and/or S waves from one heart beat to the next, which may be particularly noticeable in pediatric recordings. If you observe this phenomenon, be aware that the origin of amplitude variations is not entirely physiological. For measuring voltages of Q, R, and S waves, GE Healthcare advises using the QRS complexes with the largest deflection of the particular waves.

Biocompatibility

The parts of the system described in this manual that come into contact with the patient during the intended use, including all accessories, fulfill the biocompatibility requirements of the applicable standards. If you have questions in this matter contact your GE Healthcare representative.

Legal Notice

GE Healthcare software contains several fields that can be populated before performing an ECG. Some of these fields are required, others are optional and left to the user to assess whether they are needed to perform the exam. The field **Race** is one of these optional fields. Race has been acknowledged by the medical profession as useful to analyze some pathologies. You should be aware that, in some jurisdictions, the processing of data revealing an individual's racial origin is subject to legal requirements, such as obtaining the patient's prior consent. If you elect to

collect this type of data, it is your responsibility to ensure that you comply with all applicable legal requirements.

Responsibility of the Manufacturer

This section describes the responsibility of GE Healthcare as the manufacturer of your product.

GE Healthcare is responsible for the safety, reliability, and performance of hardware supplied by GE Healthcare only if the following conditions are met:

- Assembly operations, extensions, readjustments, modifications, or repairs are performed by persons authorized by GE Healthcare.
- The electrical installation of the room where the device is used complies with the requirements of the appropriate local, state, and other government regulations.
- The equipment is used in accordance with the instructions for use.

Responsibility of the Purchaser/Customer

The customer is responsible for providing appropriate desks, chairs, electrical wall outlets, network connections, and analog phone lines, and for locating any of the system components described in the manuals in compliance with all local, state, and national codes.

Lack of data security may compromise patient privacy. GE Healthcare recommends that you take appropriate steps to secure the privacy of communication on your network when using this product.

Warranty Information

This device is considered GE Healthcare-supplied hardware. Only authorized GE Healthcare service personnel should service the device. Any unauthorized attempt to repair equipment under warranty voids that warranty. It is the user's responsibility to report the need for service to GE Healthcare or to one of their authorized agents.

2

Safety Information

Safety Conventions

This section describes the safety conventions used in the documentation for the product.

A Hazard is a source of potential injury to a person, property, or the system.

The manuals for this system use the terms DANGER, WARNING, CAUTION, and NOTICE to point out hazards and to designate a degree or level of seriousness. Familiarize yourself with the following definitions and their significance.

Table 2: Definitions of Safety Conventions

Safety Convention	*Description*
DANGER	Indicates an imminent hazard, which, if not avoided will result in death or serious injury.
WARNING	Indicates a potential hazard of unsafe practice, which, if not avoided, could result in death or serious injury.
CAUTION	Indicates a potential hazard or unsafe practice, which, if not avoided, could result in moderate or minor injury.
NOTICE	Indicates a potential hazard or unsafe practice, which, if not avoided, could result in the loss or destruction of property or data

Safety Hazards

The following safety messages alert you to potentially hazardous conditions that could arise during the normal use of this product and recommend steps that can be taken to avoid those conditions. Safety messages pertaining to hazardous conditions that may arise during specific actions may also be provided during the discussion of those actions in this or other manuals for this product.

WARNING:

EQUIPMENT MALFUNCTION - Any attempt by unauthorized personnel to service the device could result in equipment malfunction and void the warranty. This

equipment contains no user-serviceable parts. Refer servicing to authorized service personnel.

CAUTION:

EQUIPMENT COMPATIBILITY

Compatibility is critical to safe and effective use of this device. Please contact your local sales or service representative prior to installation to verify equipment compatibility.

WARNING:

PERSONAL INJURY-STUMBLING HAZARD - Patients can become entangled in the cables and leadwires connected to the device, which could cause the patient to stumble or trip.

Route cables and leadwires in a way to avoid creating a stumbling hazard: keep them off the floor, and route leadwires away from the patient's legs and the healthcare provider's work area.

WARNING:

MAGNETIC AND ELECTRICAL INTERFERENCE - Magnetic and electric fields can interfere with the acquisition of ECG readings.

Make sure that all peripheral components operated in the vicinity of the device comply with the relevant EMC requirements. X-ray equipment, MRI devices, radio systems (cellular phones) and so forth, are possible sources of interference because they may emit higher levels of electromagnetic radiation. Verify the performance of the system before use.

WARNING:

EXPLOSION HAZARD - Using this device in the presence of anesthetic vapors or liquids can cause explosions.

Do not use this device in the presence of anesthetic vapors or liquids. Only persons with adequate training in the correct use of this device may use this device.

WARNING:

EQUIPMENT FAILURE - Polarizing electrodes (stainless steel or silver constructed) may cause the electrodes to retain a residual charge after defibrillation. A residual charge blocks acquisition of the ECG signal.

Whenever patient defibrillation is a possibility, use non-polarizing electrodes (silver-silver chloride construction) for ECG monitoring.

CAUTION:

EQUIPMENT DAMAGE

Devices intended for emergency application must not be exposed to low temperatures during storage and transport to avoid moisture condensation at the application site. Wait until all moisture has vaporized before using the device.

WARNING:

PERSONAL INJURY - Contact with patients during defibrillation can cause serious injury or death.

Do not contact patients during defibrillation. Patient signal inputs labeled with the CF symbols with paddles are protected against damage resulting from defibrillation voltages. To ensure proper defibrillator protection, use only GE Healthcare recommended cables and leadwires. Proper placement of defibrillator paddles in relation to the electrodes is required to ensure successful defibrillation.

CAUTION:

EXPLOSION HAZARD

Do NOT use in the presence of flammable anesthetics vapors or liquids.

WARNING:

INTERPRETATION HAZARD - Results of the automated QT analysis are not considered a diagnosis.

A qualified physician or cardiologist must review and confirm the measurements and waveforms recorded by the system. It should be used only as an adjunct to the clinical history, symptoms, and results of other tests.

WARNING:

INTERPRETATION HAZARD - Computerized interpretation is only significant when used in conjunction with clinical findings.

A qualified physician must overread all computer-generated tracings.

WARNING:

IMPROPER USE - This is a prescriptive device.

This equipment is intended for use by or under the direct supervision of a licensed healthcare practitioner.

WARNING:

BATTERY EXPLOSION HAZARD - Batteries may explode in fires.

Do not dispose of the battery by fire or burning. Follow local environmental guidelines concerning disposal and recycling.

WARNING:

ELECTRIC SHOCK HAZARD/SYSTEM MALFUNCTION - Liquids inside a device can cause electric shock or system malfunction.

Do not allow liquids to enter the device. If liquids enter the device, turn it off and inform your service technician. Do not use the device until it is checked by a service technician.

WARNING:

ELECTRIC SHOCK - Improper connection of this equipment may cause electric shock.

To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

WARNING:

EQUIPMENT MALFUNCTION/INTERFERENCE - Use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation.

Do not use portable phones or other electronic equipment that may emit radio frequency (RF) near this system.

WARNING:

EQUIPMENT MALFUNCTION/INTERFERENCE - Do not use the equipment or system adjacent to, or stacked with, other equipment.

If adjacent or stacked use is necessary, test the equipment or system to verify normal operation in the configuration in which you are using it.

WARNING:

ACCESSORIES/COMPONENTS - Adding accessories or components, or modifying the medical device or system, may result in increased EMISSIONS or decreased IMMUNITY of the device or system.

CAUTION:

ACCESSORIES/COMPONENTS - Ensure that all cables are less than 3 meters long. Cable lengths greater than 3 meters may result in decreased IMMUNITY of the device or system.

CAUTION:

ACCESSORIES (SUPPLIES)

To ensure patient safety, use only parts and accessories manufactured or recommended by GE Medical Systems Information Technologies. Parts and accessories used must meet the requirements of the applicable IEC 60601 series safety standards and essential performance standards, and/or the system configuration must meet the requirements of the IEC 60601-1-1 medical electrical systems standard.

CAUTION:

ACCESSORIES (EQUIPMENT)

The use of ACCESSORY equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include: Use of the accessory in the PATIENT VICINITY; and Evidence that the safety certification of the ACCESSORY has been performed in accordance to the appropriate IEC 60601-1 and/or IEC 60601-1-1 harmonized national standard.

WARNING:

DATA LOSS - Formatting the device's internal flash drive erases all the data in memory and returns the device to its factory settings.

If possible, back up or record any data that you do not want to lose before performing the following procedure.

WARNING:

EQUIPMENT FAILURE AND HEALTH HAZARDS - Failure on the part of all responsible individuals, hospitals or institutions, employing the use of this system, to implement the recommended maintenance schedule, may cause equipment failure and possible health hazards. The sole responsibility rests with the individuals, hospitals, or institutions utilizing the system. The manufacturer does not, in any manner, assume the responsibility for performing the recommended maintenance schedule, unless an Equipment Maintenance Agreement exists.

CAUTION:

DISPOSAL HAZARD

Disposable devices are intended for single use only. They should not be reused as performance may degrade or contamination could occur.

CAUTION:

DISPOSAL HAZARD - At the end of its service life, the product described in this manual, as well as its accessories, must be disposed of in compliance with local, state, or federal guidelines regulating the disposal of such products.

If you have questions concerning disposal of the product, please contact GE or its representatives.

CAUTION:

INTERCONNECTED DEVICES - When several items of medical equipment are interconnected, summation of leakage current must meet the leakage current as per IEC 60601-1.

Connect the device only to the GE approved supplies and accessories.

CAUTION:

ISOLATION FROM SUPPLY MAINS

Do not position the device so that it is difficult to operate the disconnection of the AC power supply of the device.

Supplies and Accessories

This section is in regard to the supplies and accessories you may purchase for your product.

You should use only supplies and accessories recommended by GE Healthcare. For a list of recommendations, refer to the supplies and accessories guide for this system.

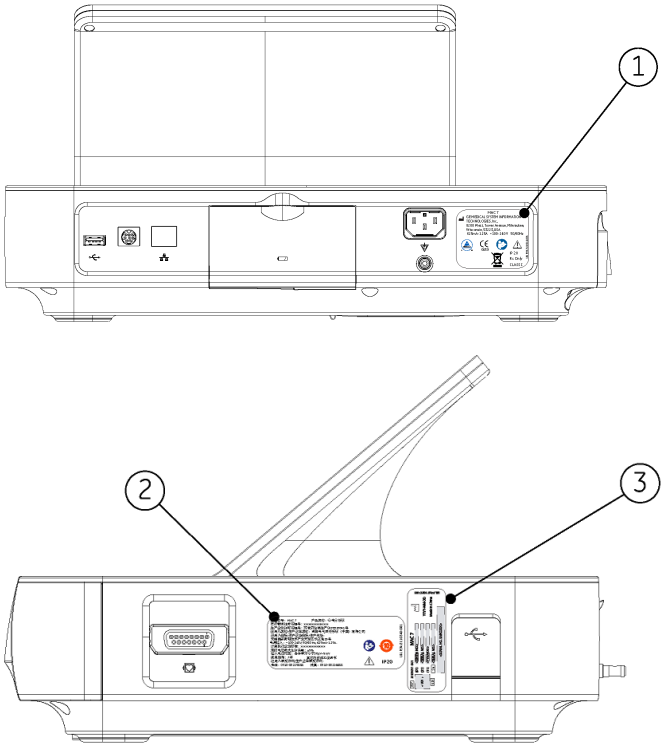
Contact GE Healthcare before using anything that is not recommended for this system.

3

Product and Packaging Information

Hardware Label Locations

The following illustrations and table describe the labels and their location on your device and its packaging.



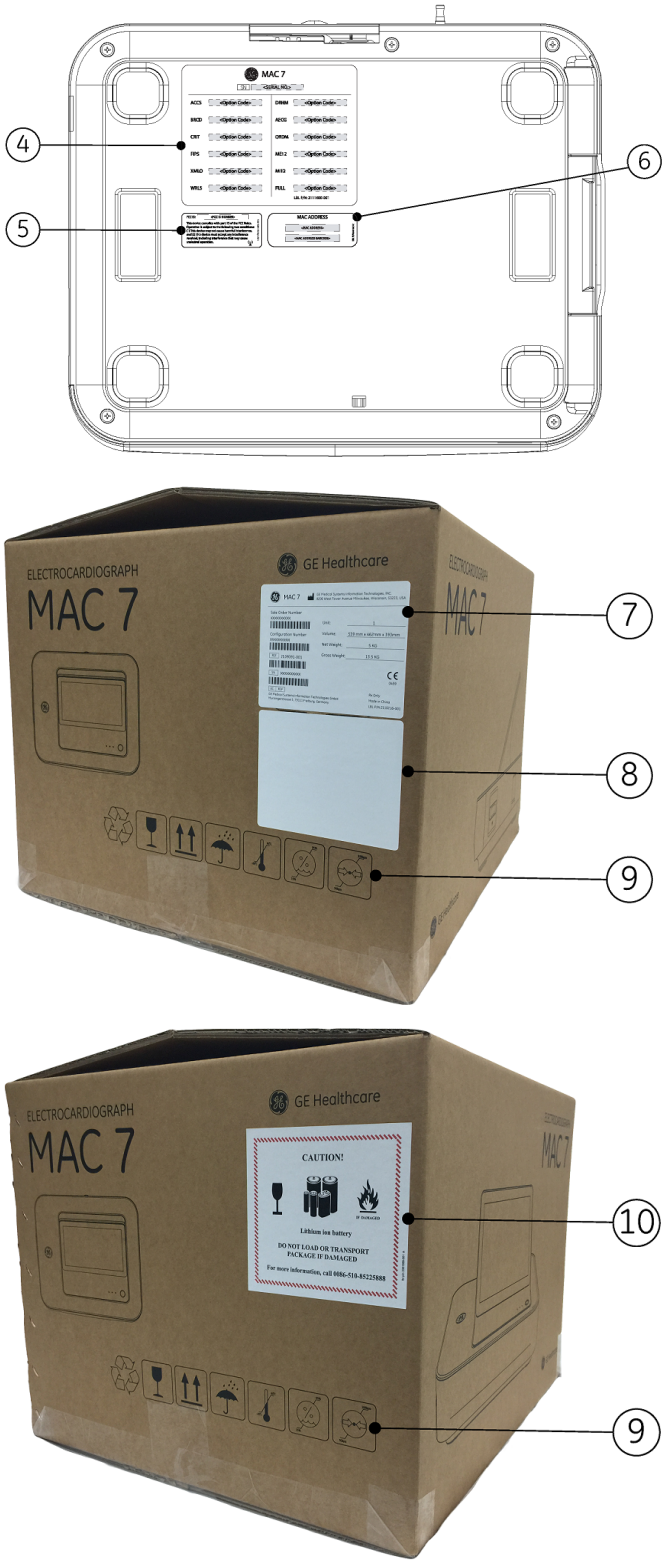
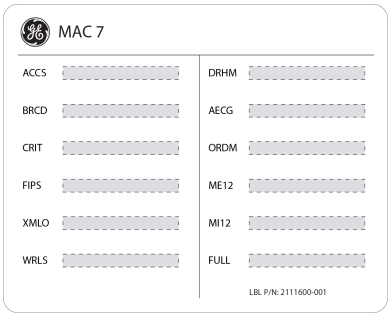
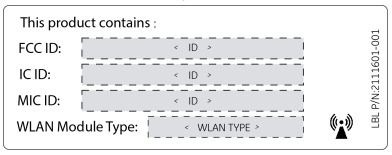
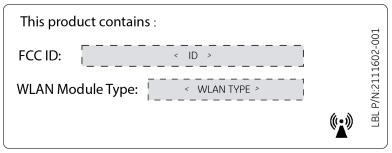
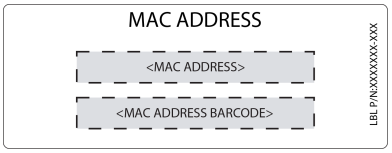
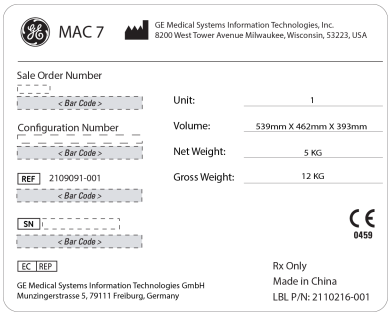
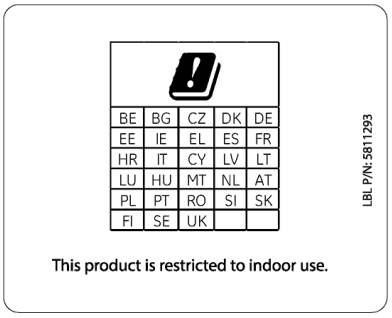

4
5
6
7
8
9
10
9
ELECTROCARDIOGRAPH
MAC 7
GE Healthcare
CAUTION!
Lithium ion battery
DO NOT LOAD OR TRANSPORT
PACKAGE IF DAMAGED

Table 3: Label Descriptions on the Device and Packaging

Item	*Label*	*Location*	*Description*
1	Device Address Label and Rating Plate	Back of the device	Provides regulatory and cautionary information. See *"Device Address Label and Rating Plate" on page 17* for an explanation of the label.
2	Country-specific Label	Back of the device	Contains registration information for China and Latin America.
3	Serial Number Label	Back of the device	Identifies this device. See *"Serial Number Label" on page 17* for a description of the label contents.
4	Option Code Label	Back of the device	Use the option codes to setup the purchased options in your system. 
5	Wireless Label	Back of the device	Depending on the customer's wireless option, the label will differ: Default wireless option:  FIPS wireless option: 
6	MAC Address Label	Back of the device	Indicates the MAC address of the device. 

Item	Label	Location	Description
7	Shipping Label	On the shipping package	Indicates the shipping address where the device is delivered. 
8	RED Lable	On the shipping package	Contains registration information of Radio Equipement Directive. 
9	Environmental Symbols		These symbols containing warning and caution indicators are required for shipping. For a full description of symbols, see *"Symbol Descriptions" on page 18*.
10	Battery Shipping Label	On the shipping package	FRAGILE—Lithium Ion batteries can cause fire if damaged. 

4

Equipment Identification

Serial Number Label

The serial number label is in the following format:

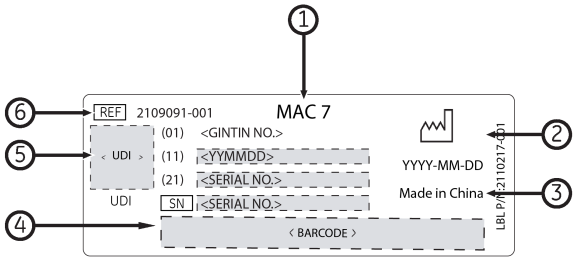


Table 4: Serial Number Label Format

Item	*Description*
1	Product Name
2	Date of Manufacture in YYYY-MM-DD Format
3	Country of Origin
4	Device Serial Number
5	UDI Barcode
6	Product Part Number

Device Address Label and Rating Plate

The device address label and rating plate is in the following format:

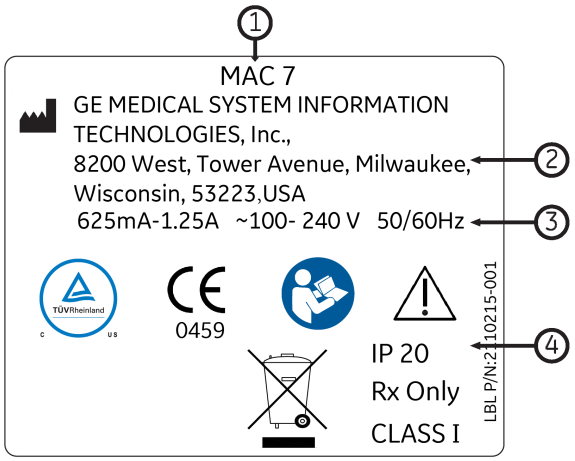


Table 5: Device Address Label and Rating Plate Format

Item	*Description*
1	Product name
2	Manufacturer name and address
3	Electrical rating of the device
4	Symbols See *"Symbol Descriptions" on page 18* for a description of the symbols used on this label.

Symbol Descriptions

The following table describes symbols or icons that are on the device or its packaging.

Any symbol on your device or packaging with markings in color indicates there may be a danger, warning, or mandatory action. Any symbol on your device or packaging that is in black and white provides additional information or may indicate a caution. Familiarity with these symbols assists in the proper use and disposal of the equipment.

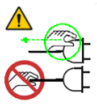
For equipment symbols not shown, refer to the original equipment manufacturer (OEM) manuals.

Table 6: Symbols, Icons, and Descriptions

Symbol	*Description*
REF	**Catalog or Orderable Part Number** Indicates the manufacturer's catalog or part number.
SN	**Serial Number** Indicates the manufacturer's serial number.

Symbol	*Description*
	**Batch Code or Lot Number** Indicates the manufacturer's batch code or lot number.
	**Date of Manufacture** (Year-Month-Date) Indicates the original manufacture date for this device.
	**Manufacturer** Indicates the name and address for the manufacturer of this device. It may also include the date it was manufactured.
Rx Only	**Rx Only** US Federal law restricts this device to sale by or on the order of a physician.
	**12SL** Indicates the device uses the Marquette™ 12SL ECG Analysis Program to analyze and interpret ECG readings.
IPxx	**IP Code (Ingress Protection Rating)** Classifies and rates the degree of protection provided against the intrusion of solid objects (such as body parts like hands and fingers, dust, accidental contact), and liquids. The first numeral (x) represents the degree of protection against the ingress of solid objects. The second numeral (x) represents the degree of protection against the ingress of liquids. For products with an IPxx rating, see the Classification of Medical Device in this chapter for a description of that rating. Not all products have an IPxx rating.
	**Regulatory Compliance Mark (RCM)** Indicates compliance with electrical safety, EMC, EME and telecommunications requirements, as applicable to the product. Required for Australia and New Zealand.
	**Wireless Communication** Indicates that that the equipment can be connected through wireless communication.
	**Waste Electrical and Electronic Equipment (WEEE)** Indicates this equipment contains electrical or electronic components that must not be disposed of as unsorted municipal waste but collected separately. Contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

Symbol	*Description*
	**Follow Instructions For Use** Read and understand the operator's manual before using the device or product. *As a mandatory action sign, this symbol is identified by a blue background and white symbol.*
	**This Way Up** Indicates the correct upright position of the package.
	**Keep Dry** Indicates that you need to keep the container away from rain and other sources of moisture.
	**Can Be Recycled** Indicates you may recycle this material or device. Recycle or dispose of in accordance with local, state, or country laws.
	**Temperature Limits** Indicates the upper and lower temperature limits for the transportation and handling of this package. They are indicated next to the upper and lower horizontal lines.
	**Humidity Limits** Indicates upper and lower humidity limits for the transportation and handling of this package. They are indicated next to the upper and lower horizontal lines.
	**Atmospheric Limits** Indicates the upper and lower barometric pressure limitations for the transportation and handling of this package. They are indicated next to the upper and lower horizontal lines.
	**Defibrillation-proof Type CF Applied Part** Identifies a defibrillation-proof type CF applied part on medical equipment that complies with IEC 60601–1. This device meets the requirements for protection against electric shock for an earth-free (floating) applied part (one intended for contact with patients) for cardiac application.
	**No User– or Field-serviceable Parts** Do not open or disassemble the device for any reason.
	**Protective Earth** (ground) Identifies the terminal of a protective earth (ground) electrode or any terminal that is intended for connection to an external conductor for protection against electric shock in case of a fault.

Symbol	*Description*
	**Do Not Stack** Indicates that you should not stack the container or place a load on the container.
	**CAUTION**: ELECTRIC SHOCK - Indicates the presence of hazardous energy circuits or electric shock hazards. To reduce the risk of electric shock hazards, do not open this enclosure. Refer servicing to qualified personnel.
	Equipotentiality Connect non-grounded peripheral devices to ensure equipotential.
	**Environmental Friendly Use Period (EFUP)** Per Chinese standard SJ/T11364–2014, indicates the number of years from the date of manufacture during which you can use the product before any restricted substances are likely to leak, causing a possible environmental or health hazard. **NOTE**: • If the device contains less than the maximum concentration of restricted substances, the symbol contains a lowercase ***e*** • This is also referred to as China RoHS.
	**Fragile** Indicates the contents are fragile. Handle with care.
	**CAUTION**: SAFETY GROUND PRECAUTION - Pulling on the cable can cause the cord to deteriorate resulting in electrical problems. Remove the power cord from the mains source by grasping the plug. DO NOT pull on the cable.
	**Contains <heavy metal chemical symbol>** Indicates this equipment contains heavy metal and must not be disposed of as unsorted municipal waste but collected separately. The example shows Lithium Ion.
	**Pushing Prohibited**

Serial Number Format

Each device has a serial number that uniquely identifies the device and provides important information about the device. The serial number format is shown in the following illustration:

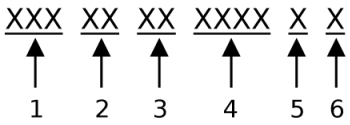


Table 7: Serial Number Format

Item	*Name*	*Description*
1	Product Code	A three-character code that uniquely identifies the product line.
2	Year Manufactured	A two-digit code identifying the year the device was manufactured. Values range from 00 to 99. For example: 00 = 2000, 04 = 2004, 17 = 2017 (and so on).
3	Fiscal Week Manufactured	A two-digit code identifying the week the device was manufactured. Values range from 01 to 52. GE Healthcare's fiscal weeks correspond to the calendar week. For example, 01 = the first week in January.
4	Product Sequence	A four-digit number identifying the order in which this device was manufactured. Values range from 0001 to 9999.
5	Manufacturing Site	A one-letter code identifying the site where the device was manufactured. For example, F = Milwaukee, N = Freiburg, P = Bangalore, W = Wuxi, H = Helsinki, S = Mexico
6	Miscellaneous Characteristic	A one-letter code identifying manufacturing status. For example, P = the device is a prototype, R = the device was refurbished, U = the device was upgraded to meet the specifications of another product code, A = device is in production.

Unique Device Identifier

Medical devices require a unique marking for identification—the Unique Device Identifier (UDI). In the event that you need the UDI for this product, check the product label on the back of the device.

5

Electromagnetic Compatibility (EMC)

Before installing or using the device or system, be aware of the proximity of known radio frequency (RF) sources, such as the following:

- Radio and TV stations
- Portable and mobile RF communication devices (cell phones, two-way radios)
- X-ray, CT, or MRI devices

  These devices are also possible sources of interference as they may emit higher levels of electromagnetic radiation.

WARNING:

EQUIPMENT MALFUNCTION

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING:

EQUIPMENT MALFUNCTION OR INTERFERENCE

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING:

PATIENT SAFETY/EQUIPMENT FAILURE

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Guidance and Manufacturer's Declaration—Electromagnetic Emissions

The system described in this document is intended for use in the following specified electromagnetic environment. It is the responsibility of the customer or user to ensure that this system is used in such an environment.

Table 8: EMC Emissions Test

Emissions Test	*Compliance*	*Electromagnetic Environment*
RF emissions (Radiated) EN 55011	Group 1 Class B	This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. Class B equipment is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions (Conducted) • EN 55011	Group 1 Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The system described in this document is intended for use in the following specified electromagnetic environment. It is the responsibility of the customer or user to ensure that this system is used in such an environment.

Table 9: EMC Immunity Test

Immunity Test	*EN60601 Test Level*	*Compliance Level*	*Electromagnetic Environment–Guidance*
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If the floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/burst (EFT) IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_t (> 95% dip in U_t) for 0.5 cycles < 40% U_t (> 60% dip in U_t) for 5 cycles < 70% U_t (> 30% dip in U_t) for 25 cycles < 5% U_t (> 95% dip in U_t) for 5 s	< 5% U_t (> 95% dip in U_t) for 0.5 cycles < 40% U_t (> 60% dip in U_t) for 5 cycles < 70% U_t (> 30% dip in U_t) for 25 cycles < 5% U_t (> 95% dip in U_t) for 5 s	Mains power should be that of a typical commercial or hospital environment. U_t is the AC mains voltage prior to application of the test level. If the user requires continued system operation during power mains interruptions, it is recommended that the system is powered from an applicably rated uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity Test	*EN60601 Test Level*	*Compliance Level*	*Electromagnetic Environment–Guidance*
Conducted RF IEC 61000-4-6	3 Vrms 0.15 MHz to 80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz	3 Vrms 0.15 MHz to 80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz	Recommended separation distance: $d = 12\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m at 80 to 2700 MHz, AM Modulation 9 to 28 V/m at 385 to 6000 MHz, FM or Digital Modulation	3 V/m at 80 to 2700 MHz, AM Modulation 9 to 28 V/m at 385 to 6000 MHz, FM or Digital Modulation	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz At 80 MHz and 800 MHz, the higher frequency range applies. Recommended separation distance: where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

Immunity Test	*EN60601 Test Level*	*Compliance Level*	*Electromagnetic Environment–Guidance*
NOTE: • Do not use portable or mobile RF communications equipment closer to any part of the system, including the cables, than the recommended separation distance calculated for the equation applicable to the frequency of the transmitter. • Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot, theoretically, be predicted with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, consider conducting an electromagnetic site survey. If the measured field strength in the location the system is used exceeds the applicable RF compliance level listed in this table, observe the system to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the system. • At 80 MHz and 800 MHz, the higher frequency range applies. • These guidelines may not apply in all situations. Electromagnetic propagation is affected by the reflection from structures, objects, and people.			

Recommended Separation Distances

The following table provides the recommended separation distances (in meters) between portable and mobile RF communication equipment and the system described in this manual, for equipment and systems that are not life-supporting.

The system is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining the following recommended minimum distance between portable and mobile RF communications equipment (transmitters) and the system, according to the maximum output power of the communications equipment.

Table 10: Recommended Separation Distances

Rated Maximum Output Power of Transmitter in Watts (W)	*Separation Distance (meters) According to Frequency of Transmitter*[1]					
	150 kHz to 80 MHz *d (meters) = 3.5/V1 x √ P* *d (meters) for V1 = 3 Vrms*		*80 MHz to 800 MHz*[2] *d = 3.5/E1 x √ P* *d for E1 = 3 V/m*		*800 MHz to 2.5 GHz* *d = 7/E1 x √ P* *d for E1 = 3 V/m*	
	Meters	*Feet*	*Meters*	*Feet*	*Meters*	*Feet*
0.01	0.117	0.383	0.117	0.383	0.233	0.766
0.1	0.369	1.210	0.369	1.210	0.738	2.421
1	1.167	3.828	1.167	3.828	2.333	7.655

Rated Maximum Output Power of Transmitter in Watts (W)	*Separation Distance (meters) According to Frequency of Transmitter*[1]					
	150 kHz to 80 MHz *d (meters) = 3.5/V1 x √ P* *d (meters) for V1 = 3 Vrms*		*80 MHz to 800 MHz*[2] *d = 3.5/E1 x √ P* *d for E1 = 3 V/m*		*800 MHz to 2.5 GHz* *d = 7/E1 x √ P* *d for E1 = 3 V/m*	
	Meters	*Feet*	*Meters*	*Feet*	*Meters*	*Feet*
10	3.689	12.104	3.689	12.104	7.379	24.208
100	11.667	38.276	11.667	38.276	23.333	76.552

NOTE:

[1] These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[2] At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

For transmitters rated at a maximum output power not listed above, estimate the recommended separation distance *d* in meters (m) using the equitation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (*W*) according to the transmitter manufacturer.

6

Wireless Regulations

The wireless and wired LAN functionality of the MAC 7 is used to retrieve ECG orders and send ECG reports to an ECG Management System. In addition, the wireless and wired LAN functionality can be used to interface to other hospital information systems to provide additional data to the care giver operating the electrocardiograph. These tasks are an adjunct to the device's intended use of acquiring, analyzing, displaying and printing an electrocardiogram. Because the wireless and wired LAN functionality is not required for the device to fulfill its intended use, network performance is not critical to the performance of the device. Furthermore, the MAC 7 does not transmit any real-time data or alarm information over the network. Network Quality of Service (QoS) parameters such as reliability of data transmission, latency, transfer rate, error rate, and priority levels are not critical to the MAC 7 functionality and are not specified.

FCC Compliance

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

CAUTION:

Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which

can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Limited by local law regulations, version for North America does not have region selection option.

To satisfy FCC RF exposure requirements, a separation distance of 20 cm or more should be maintained between the antenna of this device and persons during device operation.

To ensure compliance, operations at closer than this distance is not recommended.

IC Compliance

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

1. This device may not cause interference.
2. This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:

1. *L'appareil ne doit pas produire de brouillage;*
2. *L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement*.

This equipment complies with radio frequency exposure limits set forth by the Innovation, Science and Economic Development Canada for an uncontrolled environment.

This equipment should be installed and operated with a minimum distance of 20 cm between the device and the user or bystanders.

This device must not be co-located or operating in conjunction with any other antenna or transmitter.

Cet équipement est conforme aux limites d'exposition aux radiofréquences définies par la Innovation, Sciences et Développement économique Canada pour un environnement non contrôlé.

Cet équipement doit être installé et utilisé avec un minimum de 20 cm de distance entre le dispositif et l'utilisateur ou des tiers.

Ce dispositif ne doit pas être utilisé à proximité d'une autre antenne ou d'un autre émetteur.

The device for operation in the band 5150-5250 MHz is only for indoor use to reduce the potential for harmful interference to co-channel mobile satellite systems;

les dispositifs fonctionnant dans la bande de 5 150 à 5 250 MHz sont réservés uniquement pour une utilisation à l'intérieur afin de réduire les risques de brouillage préjudiciable aux systèmes de satellites mobiles utilisant les mêmes canaux;

RED Information

The MAC 7 embedded wireless module complies with CE RED 2014/53/EU.

BE	BG	CZ	DK	DE
EE	IE	EL	ES	FR
HR	IT	CY	LV	LT
LU	HU	MT	NL	AT
PL	PT	RO	SI	SK
FI	SE	UK		

This product is restricted to indoor use.

Frequency Range	2.4 GHz frequency bands: 2.4-2.483 GHz 5 GHz frequency bands: 5.15-5.35 GHz, 5.47-5.725 GHz
Maximum RF output power	20 dBm

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