



1200W

User Manual

NV-54/1200W3 Revision 1

NV-54/1200W3
Revision 1
US English

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Disclaimer

This system is intended as a decision support system for persons who have received appropriate medical training and should not be used as a sole basis for making clinical decisions pertaining to patient diagnosis, care, or management. Any application of medical information from the program, other than the original design or intended use thereof, is not advised and considered a misuse of the software product.

Norav Limited Warranty

Norav products are warranted to be free from manufacturing and material defects for a period of one (1) year from the date of shipment from Norav or the dealer to the original purchaser.

Excluded from this warranty are expendable supply items including, but not limited to, electrodes, lead wires, patient cables, and batteries. This warranty does not apply to any product that Norav determines that it has been modified or damaged by the customer.

Except for the express warranties stated above, Norav disclaims all warranties including implied warranties of merchantability and fitness. The stated express warranties are in lieu of all obligations or liabilities on the part of Norav for damages, including but not limited to, special, indirect, or consequential, arising out of or in connection with the use or performance of Norav products.

Any action for breach of warranty shall be commenced within one (1) year of said breach or be forever barred. Any repairs made to the product that are not covered by the warranty shall be billed to the customer.

For service or technical support contact GE Healthcare or its authorized distributor.



Caution

Federal Law restricts this device to sale by or on the order of a licensed physician or healthcare provider

NOTE: The information in this manual only applies to the product 1200W. Due to continuing product innovation, specifications in this manual are subject to change without notice.

Document History

Revision	Date	Updates
1	20-May-2025	Initial document

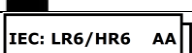
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Symbols

Symbol	Definition
	Warnings call attention to possible hazards involving potential damage or injury to persons.
	Cautions refer to practices necessary to protect against potential damage or loss to equipment. Pay careful attention to instructions.
	Notes provide pertinent information to help obtain optimum performance from the device or signify an important step or procedure that requires special attention.

Device Labels

Symbols	Definition
	Defibrillation-proof type CF Applied part.
	Caution
	Refer to operation manual NOTE On ME EQUIPMENT "Follow instructions for use"
	CE marking
	Manufacturer Name and Address
	Device Serial Number
	Device Reference Number
	Date of manufacture
FCC ID:	Contains FCC certified RF module
IC:	Contains ISED certified RF module
	Contains RCM certified RF module
	Disposal of the device in accordance with the EU Directive 2002/96/EC (WEEE).
	Use this battery/accumulator rating

Warning and Precautions

 WARNING	• ELECTROSURGERY - There is a risk of burns and injury to the patient. If an electro surgery device is used, disconnect the ECG leadwires from the patient. • LEADWIRES - ECG Leadwires present a possible strangulation hazard. To avoid possible strangulation, route all ECG Leadwires away from patient's throat. • CONDUCTIVITY - Electric shock or device malfunction may occur if electrodes contact conductive materials. Keep the conductive parts of lead electrodes and associated parts away from other conductive parts, including earth. Also make sure that no contact to other conductive parts is possible if the electrodes loosen during recording. • GENERAL DANGER TO THE PATIENT - Instructions listed in this manual in no way supersede established medical practices concerning patient care. Perform the established medical practices under all circumstances. • EXPLOSION HAZARD-Do not use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide. • DEFIBRILLATION - Device is defibrillation protected when the original Norav Medical patient cable is used. However, as a safety precaution when possible, remove the electrodes before defibrillation. • GENERAL DANGER TO THE PATIENT - The device is not designed for direct cardiac application. • INFECTION RISK - Reuse of disposable parts that come into contact with patients pose a risk of infecting patients. Do not reuse disposable parts that have had direct contact with the patient, such as ECG electrodes. • INTERPRETATION HAZARD - Computerized interpretation is only significant when used in conjunction with clinical findings. A qualified physician must over read all computer-generated tracings. • MAGNETIC AND ELECTRICAL INTERFERENCE - Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason, make sure that all external devices operated in the vicinity of the device comply with the relevant EMC requirements. X-ray equipment or MRI devices are possible sources of interference as they may emit higher levels of electromagnetic radiation. Ensure that there are no X-ray arrays, MRI or high-performance transformers are near the device. • OPERATOR - Medical technical equipment such as this system must only be used by qualified and trained personnel. Operate the unit only at clinics and hospitals. Do not use at home. • OPERATION WITH OTHER DEVICES ▪ Other devices which are part of the system must meet the requirements of the Standard for Information Technology Equipment (IEC/EN 60950-1) and the Standard for Electrical Medical Devices (IEC/EN 60601-1). ▪ The personal computer should be approved to the appropriate safety standard for non-medical electrical equipment (IEC/EN 60950-1, or its national variants). ▪ Accessory equipment connected to the analogue and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950-1 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore, all configurations shall comply with the valid version of the standard IEC/EN 60601-1. Therefore anybody, who connects additional equipment to the signal input or output connector to configure a medical system, must make sure that it complies with the standard. ▪ When using 1200W in combination with any other equipment, refer to a qualified service technician for correct handling. ▪ 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 1200W, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. • MIXING UP RECORDINGS -To ensure that a recording is not assigned to the wrong patient DO NOT use more than one identical marked RF ID pair of 1200W at the same wireless environment.
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Warning and Precautions

 Caution	• DAMAGE TO THE DEVICE THROUGH BATTERY LEAKAGE - Batteries may leak if left in an unused device for prolonged periods. If you intend to store the device for longer than one week, remove the battery from it. • LEADWIRE DAMAGE - Bending or wrapping the ECG Leadwire can damage it. When attaching and affixing the ECG leadwire, make sure not to bend it excessively. Avoid coiling the ECG leadwire around the device, as this can damage the leadwire. • DAMAGE TO THE DEVICE - You may only open the battery compartment of the patient unit. Do not use force when handling the recorder. • SAFETY ONLY WITH APPROVED ACCESSORIES - Safe and reliable operation of the device is only possible when using the supplied and approved accessories. 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. • DIFFICULTIES FINDING CAUSES FOR MALFUNCTIONS - To find and repair a malfunction, both device and ECG leadwires are needed. Remember to include the ECG leadwire when returning the device for service or repair. (Avoid wrapping the ECG leadwires around the device, as this can damage the leadwires.) Always use the same ECG leadwires sets with a device. If an institution has several devices and ECG leadwires sets, try to ensure that each device is matched with a specific ECG leadwires set. In this way, leadwire or recorder failures can be isolated and eliminated faster. In the event of apparent changes in the performance of the device, discontinue use immediately. Do not resume use until the device is approved by the manufacturer or by a representative of the manufacturer. • DAMAGE TO DEVICE AND ACCESSORIES - Unauthorized personnel do not have the proper training to repair the device. Repairs carried out by unauthorized personnel could result in damage to the device or accessories. Send the device for inspection to an authorized facility if you find or even suspect a malfunction. Please add a detailed description of the observed malfunction. • DAMAGE TO THE DEVICE - Take care to prevent chemicals\liquids from entering the connectors or internal part of the device. • PACEMAKER - It is recommended that a minimum separation of 15 cm (6 inches) be maintained between the wireless patient unit 1200W and a pacemaker to avoid potential interference with pacemaker. Some studies have shown that wireless devices might interfere with implanted cardiac pacemakers if used within eight inches of the pacemaker. Pacemaker users may want to avoid placing or using a wireless device this close to their pacemaker. If you have any reason to suspect that interference is taking place, turn off the ECG immediately.
 Caution	Use only while patient unit 1200W is worn on patient with its strap. Use only with battery compartment of patient unit 1200W is closed.
 NOTE	FCC/ISED Regulatory notices: • Modification statement - Norav Medical Ltd has not approved any changes or modifications to this device by the user. Any changes or modifications could void the user's authority to operate the equipment. Norav Medical Ltd. n'approuve aucune modification apportée à l'appareil par l'utilisateur, quelle qu'en soit la nature. Tout changement ou modification peuvent annuler le droit d'utilisation de l'appareil par l'utilisateur. • Interference statement - This device complies with Part 15 of the FCC Rules and with Industry Canada licence-exempt RSS standard(s). 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. • Wireless notice - This device complies with FCC/ISED radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines and RSS-102 of the ISED radio frequency (RF) Exposure rules. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter. • CAN ICES-3 (B) / NMB-3 (B) This Class B digital apparatus complies with Canadian ICES-003 Cet appareil numérique de classe B est conforme à la norme canadienne ICES-003. • FCC Class B digital device notice - 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:

Controls and Indicators

	- Reorient or relocate the receiving antenna. - Increase the separation between the equipment and receiver. - Consult the dealer or an experienced radio/TV technician for help.
 NOTE	NO OPTIMUM WIRELESS PERFORMANCE Note that the complete data transfer cannot be guaranteed under all circumstances when using Norav proprietary RF technology and that range loss can occur if this technology and other RF Devices (Bluetooth, WLAN.) are used near each other. Also, other devices could interfere with the equipment, even if the other devices comply with CISPR emission requirements In case of interruptions with the Norav proprietary RF technology: • Remove any objects from the line of sight between patient acquisition unit 1200W and Receiver unit • Remove any possible RF interfering devices from the vicinity of 1200W and 1200WR Receiver. • Do not position the devices closer than 50cm to each other or more than 10m from each other.
 NOTE	The 1200W recording system is intended for use on adult and pediatric patients in professional healthcare facility environment (such as physician offices, clinics, hospitals etc.) by trained personnel under the supervision of a licensed healthcare practitioner. It is designed to acquire 12 lead ECG data during periods of physiological stress, induced through exercise or pharmacological means or during resting ECG testing. The device may interface with external devices, including a non-invasive blood pressure equipment, and computer communications equipment.

Controls and Indicators



Element	Description
1	Patient unit 1200W – Power ON/OFF Button
2	Patient unit 1200W – Low Battery indicator
3	Patient unit 1200W – Power ON/OFF indicator. Transmit/Standby indicator
4	Patient unit 1200W – Detachable ECG Leadwires
5	Patient unit 1200W – Leadwires guides. Strap Holders.
6	Patient unit 1200W – Battery compartment door
7	Receiver unit 1200WR – Detachable RF Antenna
8	Receiver unit 1200WR – Power ON/OFF indicator, BNC (#1,2,3) outputs ON/OFF indicator.
9	Receiver unit 1200WR – Detachable USB Cable
10	Receiver unit 1200WR – Auxiliary BNC (#1,2,3) Cable outputs

Battery Assembly

- (1) Open Battery cover. Note battery polarity direction label.



- (2) Insert the battery and push it to the right and down with the same movement.



- (3) Attach the battery cover by pushing it at leftward angle, so that the two tabs snap into place.



- (4) Push battery cover down until get click.



Caution

- Do not leave battery in the recorder for extended periods (more than two weeks) when the recorder is not in use.
- If you use rechargeable batteries, the battery recharger should be kept out of the patient environment and hook-up area.
- Dispose of used batteries carefully, using environmentally friendly methods wherever possible following the state's recycling laws or your facility's recycling policy
- Use only the recommended battery type as instructed in the technical specifications to operate the 1200W device (AA size Alkaline or NiMH rechargeable batteries).
- Do not use batteries with expired dates.

Belt Strap Assembly

1. Take the end of the strap (ensuring there are no twists present), thread the strap via strap holders of the 1200W.



2. Take the end of the strap and the end of the buckle with center bar and then thread the strap from the bottom side of the buckle up between the main body of the buckle and the innermost side of the center bar.



3. Pass the strap over the top side of the bar, and thread it back down between the inner bar and the outermost bar. This is the end of the buckle that allows you to adjust the length of the strap if needed.



Electrode Application

 NOTE	Many ECG adhesive electrodes are suitable for use. As ECG electrodes from different manufacturers have different electrical properties, the choice of ECG electrodes can considerably affect the measurement results and quality. Ensure that only high-quality electrodes are used. Wet gel electrodes are recommended. Always refer to the ANSI/AAMI EC12:2000 Standard for safety, performance, and labeling requirements for the disposable electrodes, and guidelines for reliable patient connections.
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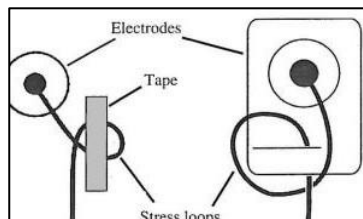
Prepare the patient's skin prior to applying the electrodes. Skin is a poor conductor of electricity, so skin preparation is important in achieving good electrode-to-skin contact.

- If necessary, clip hair at the electrode sites (or shave sites, if needed).
- Clean and abrade the skin at the electrode sites to remove oil and dead skin.
- Wash the skin thoroughly with soap and water.
- Dry the electrode placement sites.

Attaching the Electrodes

- Attach the leads to the electrodes before placing them on the patient.
- Apply the electrodes by peeling them, one at a time, from the protective backing and sticking them firmly to the patient's skin.
- The electrodes should be placed over bone at each of the sites.
- The offset connector tab should be positioned in the same direction as the lead wires, towards the equipment.
- Place the electrode on the skin by gently pressing around the edge. For wet gel always avoid pressing down the centre of the electrode. If in doubt refer to the directions on the reverse of the pouch.

If you use lead lock or clip lock electrodes, be sure to use the lock or clip to relieve stress on each lead wire. Otherwise, tape each lead wire into a stress loop to help prevent movement of the electrode.



 WARNING	As you attach electrodes, be careful to not let any unattached electrode come in contact with other conductive objects, including ground. Leave 1.5 meters (5 feet) of open area around the patient during recorder hookup and removal. Do not connect external devices to the recorder. Connect patient lead wires only to the patient electrodes. Keep the recorder and patient cable clean, especially the components that touch patients. Do not use electrodes for adults on children. Before each recording and before attaching sensors or electrodes to the patient, check the casing and the ECG patient leadwires for damage which may have occurred, for example, due to mechanical overload, falling from a great height or wear and tear (chafed patches on the cable). Do not use the instrument or the leadwires if you detect cracks, melted areas or any other signs of damage to the leadwires or housing.
 Caution	Verify that dates on applicable accessories have not expired. ECG electrodes can cause skin irritation. Examine the skin for signs of irritation or inflammation and avoid placement of the electrode in those areas. If skin irritation occurs during the procedure advise the patient to remove the electrodes and contact the health service provider as soon as possible.

Patient Leadwires Assembly

This Leadwires set is intended to be used for the hook-up of a patient to an electromedical device with the purpose of sensing electrocardiography signals from the human skin using appropriate disposable or reusable ECG electrodes. The application must be performed by a skilled medical professional. Use the patient cable only as it is intended.

Insert the Patient ECG leadwire connector into ECG leadwire connector slot of the 1200W unit, as shown on the picture. Make sure that marking of leadwires are the same as marking on the slot connector

 Caution	Be careful not to connect the Patient ECG leadwire connector upside down or at an angle into the ECG leadwire slot on the 1200W unit. This may result in damage to both the Leadwire connector and the ECG leadwire input slot of the unit. During recording, make sure that the lead wires are not caught by the moving parts of a machine or sport equipment. This could lead to damage or injury (e.g. if loops are formed in the lead wires). NEVER pull on the leadwire itself because this can easily break the wire inside the insulation. Pulling on the cable also can cause a noisy and intermittent ECG recording.
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Maintenance and Cleaning

Remove the battery before cleaning the 1200W recorder.

 Caution	Take care to prevent chemicals\liquids from entering the connectors or internal part of the recorder. The battery contacts should not come in contact with soap or water. Do not polish the housing with abrasive or chemical cleanser. Use of alcohol, acetone, Alkyl Dimethyl Benzyl ammonium chlorides or a methyl ammonium chloride is NOT recommended to clean the recorder unit and holster. Use of alcohol or acetone on lead wires could cause the lead wires to stiffen and the insulating plastic to crack. Use of a methyl ammonium chloride (commonly found in many consumer wipes) on the recorder unit and holster could cause the plastic to deteriorate. The recorder and patient leadwires must not be autoclaved or sterilized with steam.
 NOTE	If liquid penetrates the device, i.e., during cleaning or recording, this may interfere with correct functioning. Switch the recorder OFF and remove the battery. Leave the recorder in a warm, dry room with the battery door open for 48 hours. If the functioning is still affected, contact the contact customer support.

Manual Cleaning Procedure:

1. Wear disposable gloves.
2. Use a soft non-abrasive damp cloth with tap water, wipe the device for at least 30 sec., repeat as necessary or until there is no residues of soil and dirt on the device.
3. Prepare a neutral/mild pH enzymatic detergent, according to manufacturer's instructions (in the lowest recommended concentrations). Effective cleaning can be achieved by using Deconex Power Zyme, prepared using concentration of 1% (20 ml per 2 liters of water) with tap water.
4. Immerse the soft non-abrasive damp cloth with the prepared detergent, then wipe the device for at least 30 sec., Repeat as necessary or until there is no residues of soil and dirt on the device.
5. Finally, use an Isopropanol 70% wipes to clean the device for at least three (3) minutes.
6. Dry for ten minutes.

Low level Disinfection Procedure:

After the cleaning procedure completes, perform the disinfection procedures as following:

1. Use an Isopropanol 70% wipes to disinfect the device for at least three (3) minutes. Repeat as necessary.
2. Dry for ten minutes.

Before using the 1200W recorder, execute the check of the unit in accordance with the check procedure. In case that any rejected items are found as a result of the check, it will be totally judged as rejection. Take the corrective measures as the rejected items. Use the recorder after all the items become accepted.

Unit check shall be performed by each medical institution, or by Norav personnel, representative agent, or an authorized third party. For more details, do not hesitate to consult your dealer or Norav Medical personnel.

Details of the check	Check Method	Criteria
Operation manual	Check that the operation manual is kept in a predetermined place.	Should be kept in a predetermined place.
Cracks and distortion of the recorder enclosure	Visually check the recorder enclosure for cracks and distortion.	Must be free from cracks and distortion.
Cracks and distortion of the Leadwires	Visually check the ECG Leadwires for cracks and distortion.	Must be free from cracks and distortion.

Storage

Battery compartment	Check whether dirt or hair is not accumulated between the battery compartment and its door	Must be free from dirt or hair.
Keypad Power button	Check whether the keypad button have tactile feedback when pressed	Must get tactile feedback.
Battery contacts in the battery compartment	Visually check the battery contacts for strain, skew, and corrosion.	Must be free from strain, skew, and corrosion.

Storage

Before storage, make sure to remove the batteries from the 1200W recorder and close the battery compartment door tightly. Store the recorder in the provided storage carton case.

 Caution	• Store the 1200W recorder in an area free from water or humidity • Take care to avoid areas subject to high humidity, poor ventilation and direct sunlight; store the 1200W recorder in an area free from any adverse effects of surrounding air containing dust, sodium, and sulfur. • Do not store the 1200W recorder in an area where chemicals are kept, or which is exposed to chemical fumes or vapors.
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Service

If there is a problem with the 1200W recorder, review the Troubleshooting section for a listing of problems and solutions. If additional assistance is required, contact customer support via phone, fax or e-mail listed in this manual. Call customer support before returning a recorder to make shipping arrangements.

All repairs on products under warranty must be performed or approved by Norav Medical. Unauthorized repairs void the warranty. In addition, whether or not covered under warranty, any product repair shall exclusively be performed by Norav Medical certified service personnel.

When calling, please be prepared to provide:

- Product name and complete description of the problem.
- Serial number of your product.

In case a return cannot be avoided, the representative will record all necessary information and will provide a Return Material Authorization (RMA) number, as well as the appropriate return address. An RMA number must be obtained prior to any return.

If you have to return goods for service, follow these recommended packing instructions:

- Remove all cables, sensors, and ancillary products (as appropriate) before packing, unless you suspect they are associated with the problem.
- Wherever possible use the original shipping carton and packing materials.
- Include a packing list and the Norav Return Material Authorization (RMA) number.

It is recommended that all returned goods be insured. Claims for loss or damage to the product must be initiated by the sender.

Calibration

The device does not need any calibration.

Troubleshooting

Symptom	Solution
Recorder does not power on	• Ensure batteries are inserted with correct polarity. • Install a new AA battery.
Low battery indicator	• Install a new AA battery. • Inspect battery compartment, clean contacts if necessary.
Lead OFF (message on Host system)	• Ensure patient leadwire is connected to the recorder. • Check that the recorder sided connector is not damaged. • Check that the Leadwire connector pins are not broken or bent / damaged. • Ensure you have prepared the patient's skin according to the instructions. • Ensure the electrodes are properly applied to the patient. • Ensure the leads are making proper contact with the electrodes. • Replace the Patient ECG Leadwires.
Noise artifacts on ECG signal	• Ensure you have prepared the patient's skin according to the instructions. • Ensure the electrodes are properly applied to the patient. • Ensure the leads are making proper contact with the electrodes. • Replace the Patient ECG Leadwires.

ECG Cables and Accessories

Accessories	Part Number
Leadwires with Snaps IEC	L10-S-E-W-07 / L10-S-E-W-08
Leadwires with Snaps AHA	L10-S-U-W-07 / L10-S-U-W-08
Leadwires with Clips IEC	L10-C-E-W-07 / L10-C-E-W-08
Leadwires with Clips AHA	L10-C-U-W-07 / L10-C-U-W-08
Black belt strap for 1200W acquisition unit	1200W-BELT-01
USB cable 3m for 1200WR Receiver	C-USB-AB3
BNC cable 3m for 1200WR Receiver	C-BNC-3M
Detachable antenna for 1200WR Receiver	ANT-2.4-RPS-MAF94028-1

Technical Specifications

1200W (Acquisition unit)		
ECG	Lead system	Standard 12 Lead
	Patient Leads	Detachable 10 Lead wires conform to AAMI
	Defibrillation protection	Protected against 360J discharge
	Patient leakage current	< 10 uA
	Input impedance	> 10 MOhm
	CMMR	> 90dB
	Frequency range	0.05 – 150Hz
	Dynamic range	+/- 2.4V
	Resolution	24 bits (0.286 uV/LSB)
	Sample Rate Internal	8000
	Sample Rate Recording	500
	Lead OFF Detection	Yes
Communication	Proprietary Digital RF	2.4 GHz ISM Band
Power	Battery	Size AA x 1, Alkaline or NiMH
	Operation time	Up to 34 hours with Alkaline Batteries
Mechanical	Size	156 x 82 x 40 mm
	Weight	250g
Environmental	Operating Temp. Range	10 to 40 °C
	Storage Temp. Range	-20 to 60 °C
	Relative Humidity	10 to 95 % (non-condensing)
Regulatory	Safety Standards	IEC 60601-1, 60601-1-2, 60601-2-25
	Classification	Type CF with defibrillation proof. Internally powered
	Certification	CE, FDA
1200WR (Receiver)		
Auxiliary output	ECG Out Bandwidth (-3db)	0.5 to 150 Hz
	ECG Out Gain	1000
	ECG Out Sample Rate	500
	TTL Trigger width	16-128ms
	TTL Trigger delay	<11ms (delay from R-wave)
Communication	USB	USB2.0 Full Speed
	Proprietary Digital RF	2.4 GHz ISM Band
Power	USB 5V	100mA max at 5V input
Mechanical	Size	91 x 81 x 25 mm
	Weight	106g
Environmental	Operating Temp. Range	10 to 40 °C
	Storage Temp. Range	-20 to 60 °C
	Relative Humidity	10 to 95 % (non-condensing)

Electromagnetic Emissions and Immunity Information

Refer to the following tables for specific information regarding device compliance to IEC 60601-1-2.

Table 1: Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment—Guidance
<i>This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.</i>		
RF Emissions CISPR 11	Group 1	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.
RF Emissions CISPR 11	Class B	This device is intended for use in any professional healthcare environment.
Harmonic Emissions IEC 61000-3-2	Not applicable (battery powered equipment)	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Not applicable (battery powered equipment)	

Table 2: Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
<i>This device is intended for use in the electromagnetic environment specified below. The customer and/or user of this device should ensure that it is used in such an environment.</i>			
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 floors are covered with synthetic material, the relative humidity should be at least 5 %.
Electrical Fast Transient/Burst IEC 61000-4-4	2 kV for power supply lines 1 kV for SIP/SOP lines	Not applicable (battery powered equipment with SIP/SOP lines <1m)	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	1 kV line to line 2 kV line to earth	Not applicable (battery powered equipment)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips and interruptions on power supply input lines IEC 61000-4-11	0 % UT for 0,5 cycle 0 % UT for 1 cycle 70 % UT for 25/30 cycles 0 % UT for 250/300 cycles	Not applicable (battery powered equipment)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency 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.
NOTE: UT is the AC mains voltage before application of the test level.			

Electromagnetic Emissions and Immunity Information

Table 3: Guidance and Manufacturer's Declaration—Electromagnetic Immunity For Professional Healthcare Facility Environment

Immunity test	IEC 60601 level	Compliance level
IEC 61000-4-6 Conducted RF	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands (6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz)	[V] = 3 Vrms [V] = 6 Vrms
IEC 61000-4-3 Radiated RF	3 V/m 80 MHz to 2.7 GHz	[E] = 3 V/m
Proximity fields from RF wireless communications equipment	385 MHz	27 V/m
	450 MHz	28 V/m
	710 MHz	9 V/m
	745 MHz	
	780 MHz	
	810 MHz	28 V/m
	870 MHz	
	930 MHz	
	1720 MHz	28 V/m
	1845 MHz	
	1970 MHz	
	2450 MHz	28 V/m
	5240 MHz	9 V/m
	5500 MHz	
	5785 MHz	
IEC 61000-4-39 Immunity to magnetic fields in close proximity	65 A/m 134.2 kHz 7.5 A/m 13.56 MHz	65 A/m 134.2 kHz 7.5 A/m 13.56 MHz



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