NORAV medical

ECG Excellence

PC-ECG 1200T

INSTRUCTIONS FOR USE

IFU VERSION: 14

DATE: 30.06.2025

General Information

Norav PC-ECG 1200 Series: PC-ECG 1200T. Instructions for Use.

For device model: PC-ECG 1200T3, PC-ECG 1200TUSB

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Copyright Information

The most recent version of this document can be downloaded from our website:
https://www.noravmedical.com/support-center/

Manufacturer and Contact Information

Manufactured by:
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Compliance Information

The PC-ECG 1200T device conforms to the MDD 93/42/EEC and EN 60601-1-3.

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

The PC-ECG 1200 T is a derived device and is part of the Norav PC-ECG 1200 Series. The Norav PC-ECG 1200 Series is tested and certified for the following standards:

EN60601-1:	International
Protection type and class:	II BF
Defibrillation protection:	Built-in

Disclaimer

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

Important Usage Notice

Like in all medical (including, but not limited to ECG) data processing systems, noise or artifacts may produce false-positive events. Therefore, patient data must be reviewed and edited only by a qualified technician or physician who has received appropriate training. Norav Medical and its staff shall not be held liable for patient data reviewed or edited by an unqualified person, or by a qualified person acting outside the scope of appropriate medical judgment.

Norav Medical Limited Warranty

Norav Medical products are warranted to be free from manufacturing and material defects for a period of one (1) year from the date of shipment by Norav Medical or an authorized dealer to the original purchaser. Expendable supply items, including but not limited to electrodes, lead wires, and patient cables, are excluded from this warranty. This warranty does not apply to any product that Norav Medical determines has been modified or damaged by the customer.

Except for the express warranties stated above, Norav Medical 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 Medical for any damages, including but not limited to special, incidental, indirect, or consequential damages, arising out of or in connection with the use or performance of Norav Medical products.

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

For service or technical support, please contact your local supplier or Norav Medical.

Contents

CHAPTER 1: INTRODUCTION

Document Organization

These Instructions for Use (IFU) explain in detail how to install and use the PC-ECG 1200T device.

Document Conventions

Symbols Used in This Manual

Pay particular attention to specific points in a procedure when one of the following messages appears:

WARNING

Warnings call attention to possible hazards involving potential damage or injury to persons.

Caution

Cautions refer to practices necessary to protect against potential damage or loss to equipment. Pay careful attention to instructions.

Note

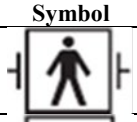
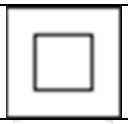
Notes provide pertinent information to help obtain optimum performance from the device or signify an important step or procedure that requires special attention.

Abbreviations and Acronyms

Abbreviation	Meaning
ECG	Electrocardiogram
CT	Computerized tomography
P/N	Part number

Equipment Symbols Glossary

This section provides descriptions of the symbols and markings that may appear on devices and related accessories referenced in these Instructions for Use. Use this section as a reference to understand the symbols and markings, ensuring compliance with international standards and proper device usage.

Symbol	Title	Description
	Defibrillation-proof type BF applied part	To identify a defibrillation-proof type BF applied part complying with IEC 60601-1.
	Defibrillation-proof type CF applied part	To identify a defibrillation-proof type CF applied part complying with IEC 60601-1
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	General warning	Indicates that caution is required, and users must consult accompanying documentation for critical safety-related information or specific instructions that cannot be fully conveyed on the device or accessory itself (ISO 15223-1:2021).
	Follow instructions for use or electronic instructions for use	Indicates that the instruction manual/booklet must be read.
	CE marking	It indicates that the product is in compliance with European legislation for medical devices.
	CE Marking with Notified Body number	It indicates that the product is in compliance with European legislation for medical devices. The four-digit number (in this case, 2797) that is displayed next to the CE mark on the medical device is the Notified Body (BSI) number.
	Manufacturer	Indicates the medical device manufacturer
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Reference number / Catalogue number	Indicates the manufacturer's reference (catalogue) number so that the medical device can be identified.
	Date of manufacture	Indicates the date when the medical device was manufactured.
	Recycle: Electronic Equipment	Disposal of the device in accordance with the EU Directive 2002/96/EC (WEEE). Separate collection for electrical and electronic equipment. Do not dispose of this product in unsorted waste stream.
	Class II equipment	To identify equipment meeting the safety requirements specified for Class II equipment according to IEC 61140.
	Direct current	Indicates that the equipment is suitable for direct-current (DC) supply only and identifies the relevant DC terminals.

CHAPTER 2: OVERVIEW

Description

PC-ECG 1200T is a single-channel ECG device with a synchronized R-wave trigger pulse output. It uses a standard 3-lead cable to acquire an ECG signal. The ECG channel can be selected from the three available channels: LI, LII, or LIII (channel selection is available on both 1200T3 and 1200TUSB models).

The device performs digital signal processing to detect ECG R-waves and generates a trigger pulse starting at the peak of each R-wave.

- In 1200T3, the trigger pulse is available through the DB9 connector output. Optionally, the digitized ECG signal and trigger pulse data can be read by the host via isolated RS-232 communication and displayed on the host display. An additional output (optional) is the analog signal of the amplified (×1000) ECG waveform.
- In 1200TUSB, the trigger pulse is available through the BNC connector output. Optionally, the digitized ECG signal and trigger pulse data can be read by the host via isolated USB-to-UART communication and displayed on the host display. An additional BNC connector outputs the analog signal of the amplified (×1000) ECG waveform.

Indications for Use

The PC-ECG 1200T device is intended for use on adult and pediatric patients in a clinical setting by trained personnel under the supervision of a licensed healthcare practitioner.

The PC-ECG 1200T provides ECG and R-wave pulse for display and triggering applications. R-wave synchronization is typically used for gating nuclear scanners, CT scanners, or other imaging devices.

Contraindications and Adverse Effects

There are no known contraindications or adverse effects for using the PC-ECG 1200T devices.

Warnings and Precautions

WARNING

- **ELECTROSURGERY** - There is a risk of burns and injury to the patient. If an electrosurgical device is used, disconnect the ECG lead wires from the patient.
- **LEAD WIRES** - ECG lead wires present a possible strangulation hazard. To avoid possible strangulation, route all ECG lead wires away from the 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 ground. Also make sure that no contact with 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 the patient poses 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 overread 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.
- **OPERATOR -** Medical technical equipment such as this system must only be used by qualified and trained personnel.
- **PACEMAKER PATIENTS** – Indication of the heart rate may be adversely affected by cardiac pacemaker pulses or by cardiac arrhythmias. Do not rely entirely upon heart rate meter alarms. Keep pacemaker patients under close surveillance.

WARNING

- **OPERATION WITH OTHER DEVICES**

- Other devices that 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 according to the appropriate safety standard for non-medical electrical equipment (IEC/EN 60950-1, or its national variants).
- Accessory equipment connected to the analog 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 the PC-ECG 1200T in combination with any other equipment, refer to a qualified service technician for correct handling.
- All electrical equipment that is not medical electrical equipment must be placed outside of the "patient environment," defined by applicable safety standards to be at least 1.5 meters (5 feet) from the patient, unless the non-medical peripherals receive power from an isolation transformer that meets medical safety standards.
- Conductive (metal) parts that can be touched by the operator in normal use and that are connected to non-medical equipment should not be brought into the patient environment. Examples are connectors for shielded BNC, RS232, or USB cables.

Caution

- **LEAD WIRE DAMAGE** - Bending or wrapping the ECG lead wire / cable can damage it. When attaching and affixing the ECG lead wire, make sure not to bend it excessively. Avoid coiling the ECG lead wire / cable around the device, as this can damage the lead wire / cable.
- **SAFETY ONLY WITH APPROVED ACCESSORIES** - Safe and reliable operation of the device is only possible when using the supplied and approved accessories.
- **DIFFICULTIES FINDING CAUSES FOR MALFUNCTIONS** - To find and repair a malfunction, both the device and ECG cable are needed. Remember to include the ECG cable when returning the device for service or repair. (Avoid wrapping the ECG cable around the device, as this can damage the cable.) Always use the same ECG cable with the device. If an institution has several devices and ECG cables, try to ensure that each device is matched with a specific ECG cable. In this way, ECG cable or device 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 parts of the device.

Residual Risks

After thorough risk assessment and implementation of all necessary risk control measures, no residual risks have been identified for this device. Users can operate the device with confidence, following the provided instructions and guidelines.

CHAPTER 3: HARDWARE INSTALLATION

1200T3 Controls and Indicators

Table 1: 1200T3 controls and indicators

Element	Description
1	DB9 connector (Power input, RS232 communication, and Trigger/Analog ECG out)
2	ON/OFF switch
3	Indicator LEDs (Green for Power ON, Orange for Trigger)
4	ECG Patient Cable Receptacle

Table 2: DB9 connector – pin description

DB9 Connector pin out:

Pin Number	Description
1	GND
2	RXD (RS232 input)
3	TXD (RS232 output)
4	GND
5	GND
6	Auxiliary output (R-wave Trigger)
7	Auxiliary output (High-Level ECG)
8	Not connected (reserved)
9	VCC (Power input 5V)

Installing 1200T3 Unit

To Install the Trigger Unit

1. Connect the ECG trigger unit to the power supply module using the **DB9 connector** (see **Tables 1 and 2** above).
2. Connect the patient cable to the ECG trigger unit using the **ECG Patient Cable Receptacle**.
3. Verify that the **Power ON** green indicator LED is illuminated.

1200TUSB Controls and Indicators

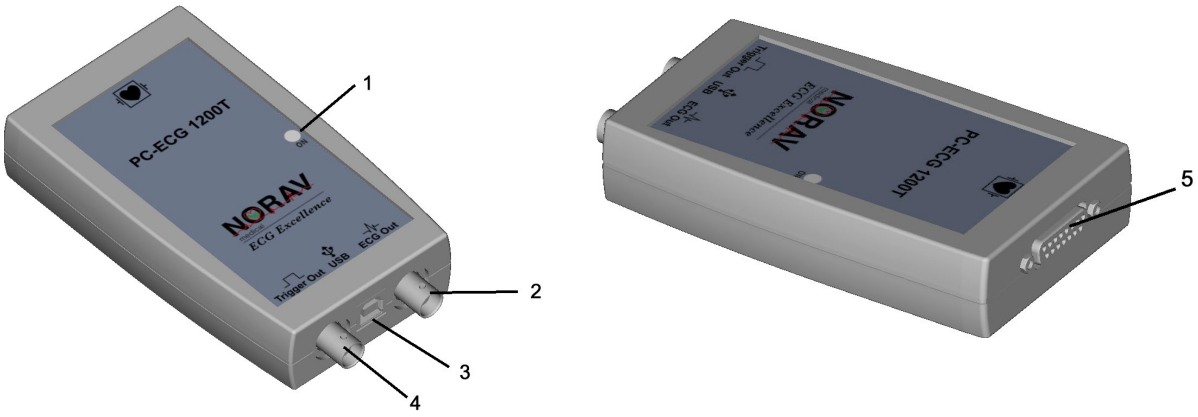


Table 3: 1200TUSB controls and indicators

Element	Description
1	Led Power ON/OFF indicator.
2	BNC connector of ECG out signal.
3	USB type B connector for Power supply and USB data.
4	BNC connector of ECG trigger out signal.
5	ECG Patient Cable Receptacle.

Installing 1200TUSB Unit

To Install the Trigger Unit

1. Connect the ECG trigger unit to the host PC using the **USB type B connector** (see **Table 3** above).
2. Connect the patient cable to the ECG trigger unit using the **ECG Patient Cable Receptacle**.
3. Verify that the **Power ON** green indicator LED is illuminated.

CHAPTER 4: PATIENT PREPARATION

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 disposable electrodes, and guidelines for reliable patient connections.

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 center of the electrode. If in doubt, refer to the directions on the reverse of the pouch.

WARNING

- As you attach electrodes, be careful not to 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 device hookup and removal.
- Connect patient lead wires only to the patient's electrodes.
- Keep the device and patient cable clean, especially the components that touch the patient.
- 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 lead wires 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 lead wires if you detect cracks, melted areas, or any other signs of damage to the lead wires or housing.

Caution

- Verify that the 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.

Lead Placement

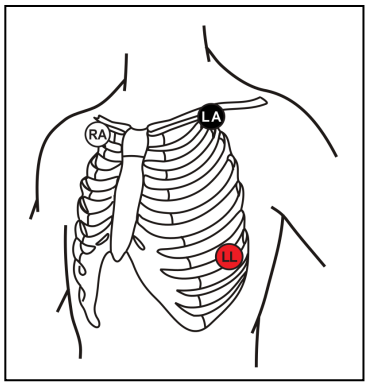
The ECG cable lead wires are intended to be used for the hook-up of a patient to an electromedical device for the purpose of sensing electrocardiography signals from the human skin using appropriate disposable or reusable ECG electrodes. The application must be performed by a skilled medical professional.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

The lead placement procedure that is utilized has a direct impact on the quality of the ECG waveform. The algorithm works best when a patient's R wave is significantly larger than the P or T waves to avoid difficulty in identifying the appropriate waves. On some patients, electrode patch placement and/or the ECG lead viewed may need to be adjusted to obtain a more prominent R wave.

Table 4 - Color code comparison for patient leads

Lead type	US(AHA) Color Code	EU(IEC) Color code
Right Arm	RA - White	R - Red
Right Leg	RL - Green	N - Black
Left Leg	LL - Red	F - Green

Standard Lead Placement

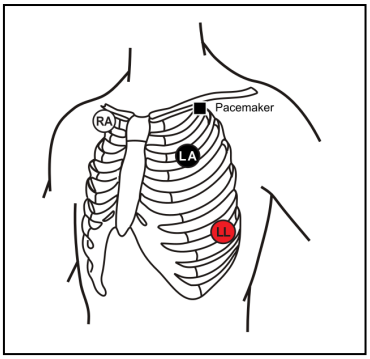


To monitor the patient's ECG, apply the electrodes as shown in the diagram.

Optimum sites may vary with the patient's individual physiological characteristics and condition. The best monitoring results will be obtained by placing the electrodes on the chest.

(AHA Color scheme shown)

Placement for Paced Patients



To monitor the paced patient's ECG, apply the electrodes as shown in the diagram.

Do not place an ECG electrode directly over the pacemaker generator. Place the electrode patches 7-12 cm away from the pacemaker generator area to avoid electrical interference. If the electrode patches are placed closer to pacemaker generator, the ECG will contain artifact, sometimes called "picket fence syndrome." For example, if the pacemaker generator is in the left subclavian area, relocate the Left Arm (black) electrode closer in towards the center of the chest.

(AHA Color scheme shown)

! **Caution**	• During recording, make sure that the lead wires are not caught by the moving parts of a machine or sports equipment. This could lead to damage or injury (e.g., if loops are formed in the lead wires). • NEVER pull on the lead wire itself, because this can easily break the wire inside the insulation. Pulling on the cable can also cause a noisy and intermittent ECG recording.

Maintenance and Cleaning

Disconnect the device from the power supply before cleaning it. To clean the device unit and ECG lead wires, wipe with dry cloth or a cloth soaked with regular household cleaner diluted with water.

Caution

- Take care to prevent chemicals / liquids from entering the connectors or internal parts of the device.
- Do not polish the housing with abrasive or chemical cleansers.
- Use of alcohol, acetone, Alkyl Dimethyl Benzyl ammonium chlorides or methyl ammonium chloride is NOT recommended to clean the device unit. Use of alcohol or acetone on lead wires could cause the lead wires to stiffen and the insulating plastic to crack. Use of methyl ammonium chloride (commonly found in many consumer wipes) on the device unit could cause the plastic to deteriorate.
- The device and patient lead wires 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. Disconnect the device from the power supply. Leave the device in a warm, dry room for 48 hours. If the functioning is still affected, contact customer support.

Manual Cleaning Procedure

1. Wear disposable gloves.
2. Use a soft non-abrasive damp cloth with tap water, and wipe the device for at least 30 seconds. Repeat as necessary or until there are 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 a 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 seconds. Repeat as necessary or until there are no residues of soil and dirt on the device.
5. Finally, use Isopropanol 70% wipes to clean the device for at least three (3) minutes .
6. Place the device on a clean cloth to avoid any contact between them, and allow it to dry for at least ten minutes before the next disinfection procedure .

Low level Disinfection Procedure

After the cleaning procedure is complete, perform the disinfection procedures as follows:

1. Use Isopropanol 70% wipes to disinfect the device for at least three (3) minutes. Repeat as necessary .
2. Place the device on a clean cloth to avoid any contact between them, and allow it to dry for at least ten minutes.

Before using the PC-ECG 1200T device, perform a unit check in accordance with the specified check procedure. If any item is found to be non-compliant, the unit shall be classified as rejected. Apply corrective measures to resolve the non-compliant items. The device may only be used once all items meet the acceptance criteria. The unit check must be carried out by the medical institution, Norav Medical personnel, a representative agent, or an authorized third party. For further information, please contact your dealer or Norav Medical personnel.

Table 5 – Unit check requirements

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 device enclosure	Visually check the device enclosure for cracks and distortion.	Must be free from cracks and distortion.
Cracks and distortion of the ECG Lead wires\Cable	Visually check the ECG lead wires\Cable for cracks and distortion.	Must be free from cracks and distortion.

Storage

Before storage, disconnect the device from the power supply. Store the device in the provided storage carton or case.

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

Service

If there is a problem with the 1200T device, 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 device 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

Before any test begins, the ECG signal quality must be checked for electrical noise and for other inoperative (INOP) conditions.

Electrical Noise

"Noise" refers to any degradation of the ECG signal that makes it difficult to accurately detect and classify beats. Causes of noise, such as artifacts and electrical interference, should be avoided whenever possible.

Some common causes of noisy ECG signals include:

- Poor skin preparation
- Dried electrode gel
- Muscle artifact caused by shivering, movement, or tremors
- Baseline wander caused by excessive chest movement, or electrical differences between two brands of electrodes
- Respiration artifact caused by thoracic or abdominal movement from both spontaneous and ventilated breathing patterns
- Nearby electrical equipment

Prompt attention by the clinician to any ECG interference increases the accuracy of the algorithm and decreases the false detections. Types of noisy signals, their possible causes, and recommended corrective actions are shown in the table below.

INOP Conditions

INOP conditions are those where the signal is lost, such as:

- Detached electrodes
- Broken lead wires

A 'leads-off' condition, which results in the loss of ECG monitoring will also inhibit QRS detection until the condition is corrected and the lead has been restored.

You may need to select a different lead or change the electrodes or electrode position if there is excessive noise, unstable voltage, low amplitude QRS, or large P- or T-waves.

Table 6 – INOP conditions

Problem	Appearance	Cause	Corrective Action
Baseline Wander	Rhythmic Up-and-down movement of ECG baseline	• Movement of the Patient. • Improperly applied electrodes.	• Make sure patient is comfortable and still • Reapply electrodes
Irregular Baseline	Rough, jagged baseline	• Poor electrical contact. • Faulty or dry electrodes.	• Reapply electrodes, using proper technique. Check for loose connections on lead/cable • Apply new electrodes
Muscle Artifact	Fuzzy, irregular baseline	• Tense, uncomfortable patient. • Tremors, diaphoresis • Poor electrode placement	• Make sure patient is comfortable and still • Check that electrodes are applied on flat, non-muscular areas of the torso. • Reapply electrodes if necessary.
Poor Electrical Contact	Trace switching from high to low in steps and/or dashed trace	• Loose electrodes • Defective leads/cables	• Change all electrodes, using good skin prep. • Replace leads/cables.
Power Line Interference (50/ 60 Hz)	Regular saw-tooth baseline.	• Poor electrode placement. • Possible non-grounded instrument near patient.	• Reapply electrodes • Check grounding of equipment near patient.

Technical Specifications: 1200T3

Characteristic	Specification
Protection	
Defibrillator Protection	Protected against 360 J discharge
Patient Leakage current	<10 uA
Ground Isolation	4 kV rms
ECG	
Patient Cable	3 leads AHA coding.
Input Range (ac)	10 mV peak to peak
Input Range (dc)	Up to ± 300mV
Input Impedance	> 10 MOhm
CMRR	> 90 dB
Frequency Response Unfiltered	0.5 to 300 Hz
Lead fault indicator	yes
A2D resolution	2.44uV (One LSB)
ECG Data Transmission Rate	100 samples per second
Auxiliary output – ECG (Optional)	
Frequency Response	0.5 to 150 Hz
Amplification	1000 (1V/mV)
Output Range	± 4V
Auxiliary output – ECG Trigger	
Output level	0-5V (or 0-12V, Optional)
Trigger Pulse Width	1.2ms
Trigger Pulse Polarity	Negative
Trigger Pulse Delay	< 5 ms
Trigger Pulse Jitter	< 1.7 ms
Sensitivity	300 uV peak
Pulse rate	30-240 bpm
Pacemaker pulse rejection	Yes
RS232 & Power Input	
RS232 baud rate	115.2 kbps
Power Input	5V DC, 200 mA
Mechanical	
Weight [g]	200
Size [mm]	157x84x30 (excluding connectors)
Environmental	
Operating Temperature Range	10°C to 40°C
Storage Temperature Range	-20°C to 60°C
Humidity	10%-95% (non-condensing)
Regulatory	
Safety Standards	IEC60601-1
Device Classification	Class II, Type BF with defibrillation proof
Mode of Operation	Continuous
RoHS and WEEE compliance	Yes

Technical Specifications: 1200TUSB

Characteristic	Specification
Protection	
Defibrillator Protection	Protected against 360 J discharge
Patient Leakage current	<10 uA
Ground Isolation	4 kV rms
ECG	
Patient Cable	3 leads
Input Range (ac)	10 mV peak to peak
Input Range (dc)	Up to ± 300mV
Input Impedance	> 10 MOhm
CMRR	> 90 dB
Frequency Response Unfiltered	0.5 to 300 Hz
Frequency Response Filtered	0.5 to 15….40 Hz
Lead fault indicator	yes
Pacemaker pulse Indicator	yes
A2D resolution	2.44uV
ECG Data Transmission Rate	100,200,250,500 or 1000 samples per second
BNC output - ECG	
Frequency Response	0.5 to 150 Hz
Amplification	1000 (1V/mV)
Output impedance	100 Ohm
Output Range	± VUSB
BNC output – ECG Trigger	
Output level	0-5V or 0-12V
Output impedance	100 Ohm
Output current limit	28mA
Trigger Pulse Width	1….. 150ms
Trigger Pulse Polarity	Positive or Negative
Trigger Pulse Delay	< 5 ms
Trigger Pulse Jitter	< 2 ms
Sensitivity	300 uV peak
Pulse rate	30-300 bpm
Pacemaker pulse rejection	Yes
USB & Power Input	
USB-to-UART baud rate	115.2 kbps
USB compliance	USB 2.0 compliant; Full speed (12 Mbps)
USB Power Input (VUSB)	5V DC, 200 mA
Mechanical	
Weight [g]	142
Size [mm]	128x75x26 (excluding connectors)
Environmental	
Operating Temperature Range	10°C to 40°C
Storage Temperature Range	-20°C to 60°C
Humidity	10%-95% (non-condensing)
Regulatory	
Safety Standards	IEC60601-1
Device Classification	Class II, Type CF with defibrillation proof
Mode of Operation	Continuous
RoHS and WEEE compliance	Yes
UL94 V0 compliance	Yes

ECG Cables and Accessories: 1200T3

Item	Part Number
ECG Cables	
ECG 3L Cable, Clip, AHA, D15, 4m, RA+LA+LL	C3-C-U-LL-LA-D4R; C3-C-U-LL-LA-D4R-08
Accessories	
Power adapter 1200T&Trigger out,100-240V	1200T-PS-110-220-03

ECG Cables and Accessories: 1200TUSB

Item	Part Number
ECG Cables	
ECG 3L Cable, Clip, AHA, D15, 4m, RA+LA+LL	C3-C-U-LL-LA-D4R; C3-C-U-LL-LA-D4R-08
Accessories	
USB cable type-A to type-B, 3m	C-USB-AB3
BNC to BNC cable, 3m	C-BNC-3M

Electromagnetic Emissions and Immunity Information

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

Table 7: Electromagnetic emissions

Emissions Test	Compliance	Electromagnetic Environment—Guidance
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.*		
RF Emissions CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	This device is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Not applicable	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Not applicable	

Table 8: Electromagnetic immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
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.*			
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable	Mains power quality 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 cycle ±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 sec.	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage before application of the test level.			

Table 9: Guidance and Manufacturer's Declaration—Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance
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.			
Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	**Recommended Separation Distance** $d = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2.5 GHz 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[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m.

NOTES:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 10: Recommended separation distances

The following table details the recommended separation distances between portable and mobile RF communications equipment and 1200T device.

This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Users of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the device as recommended below, according to maximum output power of the communications equipment.			
	Separation Distance According to Frequency of Transmitter(m)		
Rated Maximum Output Power of Transmitter **W**	**150 kHz to 80 MHz** $d = 1.17\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.17\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation 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.

NOTES:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.