NORAV medical

ECG Excellence

Norav User Guide

ECGUSB1D-EX / ECGUSB1D-EXR

NV-54/ECG-USB1

Norav User Guide

For Models: ECGUSB1D-EX, ECGUSB1D-EXR

Document Number: NV-54/ECG-USB1 Revision 07

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Standards Compliance

Caution

US Federal Law restricts this device to sale by, or on the order of, a physician.

The ECG-USB1 has been tested and certified for compliance with the following standards (including device features regulated by these standards):

IEC60601-1:	International
IEC 60601-2-27:	International
Protection type and class:	II CF
Defibrillation protection:	Built in

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 system.

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 your local supplier or Norav Medical.

Table of Contents

Document Conventions

Notes and Cautions

Pay particular attention at 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 system or signify an important step or procedure that requires special attention.

Equipment Symbols

Symbol	Description
	Type CF equipment, defibrillator proof
	Class II equipment
	Complies with the Medical Device Directive of the European Union
	Date of Manufacture
	Waste electrical and electronic equipment (WEEE)

MD	Medical device

Indications for Use of the ECG-USB1

ECG Intended Use

The ECG-USB1 device provides a single channel ECG for host systems that require an external unit in order to add ECG\Respiration capabilities in an easy and fast way to their platform. The host owner should write its own software application that communicates with the device via USB port using the Norav USB driver and SDK.

Contraindications for Use and Adverse Effects

The device has no contraindications or adverse effects.

Safety

WARNING

Connect the ECG-USB1 only to a system that is isolated from the electric power supply.

It is also sensitive to electrical interference.

To prevent possible injury, read this page carefully prior to installing the device.

- The ECG-USB1 is designed to work only with medical devices that comply with the IEC60601-1 standard.
- Connect the ECG-USB1 only to a system isolated from the mains supply.
- Connect via USB using a compatible cable only. Use only the original USB cable.
- 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.
- Defibrillation protection is built in the device and ECG cable.
- Use only ECG Cables that are supplied by Norav Medical.

Operation

> **!**
>
> **Caution**
>
> Cautions refer to practices necessary to protect against potential damage or loss to equipment.

1. Connect the standard A-type plug of the USB cable (Figure 2, detail 1) to the USB connector of the host.
2. Connect the Mini-B type USB plug of the USB cable (Figure 2, detail 2) to the input of the ECG-USB1 acquisition device (Figure 1, detail 1).
3. Connect plug of detachable patient cable (Figure 4, detail 3) to the round connector on ECG-USB1 (Figure 1, detail 2)
4. Apply the leads to the patient (Right Arm, Left Arm and Right Leg) according to their markings (R(RA), L(LA) and N(RL) respectively).

   Apply the leads to the patient (Right Arm, Left Arm and Left Leg) according to their markings (R(RA), L(LA) and F(LL) respectively).
   If use –EXR model.
   If need connect external ECG auxiliary output to the device (-EX,EXR models only) :
   Connect plug of BNC cable (Figure 3, detail 2) to the input of the ECG-USB1 acquisition device (Figure 1, detail 1). Connect BNC connector to the auxiliary output.
5. Operate through the host system.

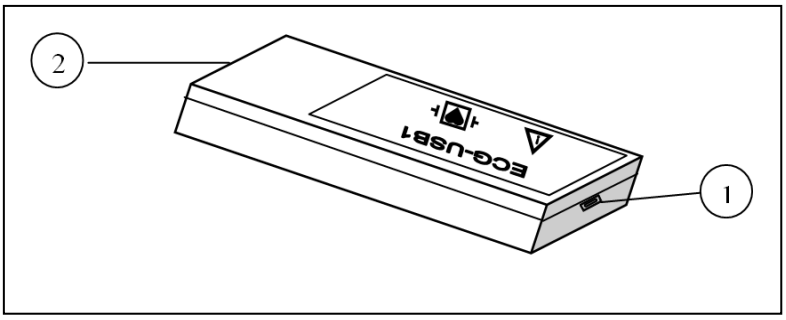


Figure 1: ECG-USB1 Device

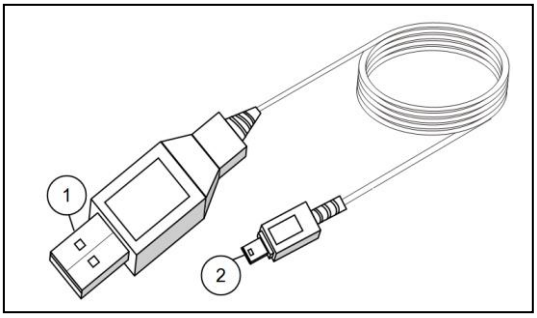


Figure 2: USB Cable

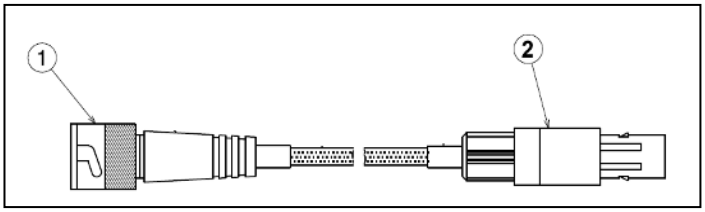


Figure 3: BNC Cable

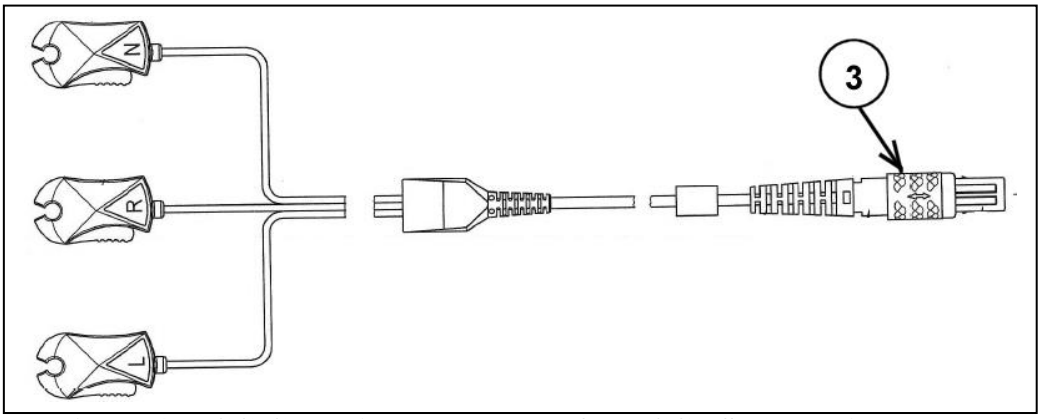


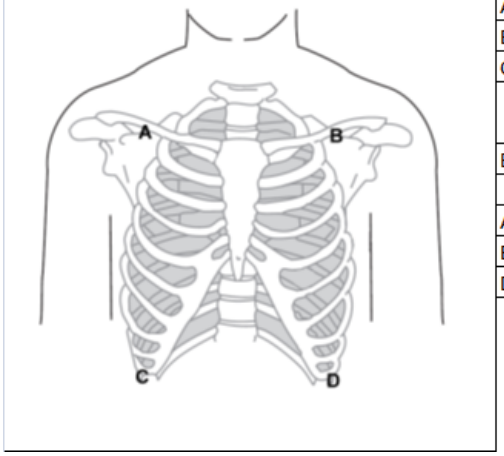
Figure 4: ECG Cable (relates to cable for ECGUSB1D-EX)

Patient preparation

The ECG traces quality depends very much on the stability and conductivity of the electrodes during the test, especially during high stages when the patient movements can cause artifacts. Here are some basic rules to ensure good electrical contact:

- ◊ Shave hair at the electrode contact points
- ◊ Use high quality liquid gel electrodes
- ◊ Make sure that the lead wires do not swing

Attach the leads as shown in Figure 5. Use the detachable ECG 3-lead cable, each lead 100 cm long, with clip connectors at the patient end, designed for use with disposable ECG electrodes.



ECGUSB1D , -EX models				
	AAMI	Color	IEC	Color
A	RA	White	R	Red
B	LA	Black	L	Yellow
C	RL	Green	N	Black

ECGUSB1D-EXR model				
	AAMI	Color	IEC	Color
A	RA	White	R	Red
B	LA	Black	L	Yellow
D	LL	Red	F	Green

Figure 5: Electrode Placement

! Caution	Refer to Appendix B for examples of improper patient preparation results.

Maintenance

! Caution	The device is not waterproof. Do not expose the device to water or any kind of liquid. Maintain in a dry place.

The exterior of the Recorder may be wiped clean with a soft cloth. Do not use harsh cleaning agents to clean the unit. Do not immerse the unit in any liquid.

Clean the cables with a hospital approved cleaning procedure such as those recommended by AAMI or AORN. Wiping the cables with a solution of soap and water followed by a rinse with water is a simple yet effective method to clean the cables. Do not immerse the cables in water.

Worn or damaged patient cables are the most common cause of poor recordings. Successive poor ECG tracings may indicate the patient cable needs to be replaced.

Store the device in a dry place.

Always protect the recorder from coming into contact with moisture. In rain or snow conditions, protect the recorder from bad weather elements by wearing the recorder inside a coat.

Calibration

The device does not need any calibration.

APPENDIX A: TECHNICAL SPECIFICATIONS

	ECGUSB1D-EX	***ECGUSB1D-EXR***
Protection		
Defibrillator Protection	Yes, Recovery 5s	Yes, Recovery 5s
Patient Leakage current	<10 uA	<10 uA
Ground Isolation	4 kV rms	4 kV rms
ECG		
Patient Cable	3 leads AHA/IEC	3 leads AHA/IEC
Input Range (ac)	10 mV p-p	10 mV p-p
Input Range (dc)	± 0.3V	± 2.4V
Bandwidth (-3db)	0.5 –150 Hz	0.05 –150 Hz
Lead Fault Indicator	no	Yes
External ECG		
Input Range (ac)	8.2v p-p	10v p-p
Bandwidth (-3db)	0.05 – 150 Hz	0.55 – 150 Hz
Lead Fault Indicator	no	yes
A2D converter		
A2D resolution	12 bit ‚2'comp.	12 bit ‚2'comp.
Sample Rate	1000	1000,500,250
USB		
USB 2.0 compliant	Yes, USB1.1 FS device	Yes, USB1.1 FS device
Power Input	USB 5v DC, 80 mA ± 5%	USB 5v DC, 60 mA ± 5%
Mechanical		
Weight	80 g.	80 g.
Size [mm]	85x45x22 mm	85x45x22 mm
Environmental		
Operating Temperature Range	10°C to 40°C	10°C to 40°C
Operating Atmospheric Pressure	860-1060 hPa	860-1060 hPa
Operating Humidity	10%-95%	10%-95%
Storage Temperature Range	0°C to 40°C	0°C to 40°C
Storage Atmospheric Pressure	860-1060 hPa	860-1060 hPa
Storage Humidity	5%-95%	5%-95%
Regulatory		
Safety Standards	IEC60601-1	IEC60601-1
Device Classification	Type CF	Type CF
RoHS and WEEE compliance	yes	yes
DEHP and BPA compliance	yes	yes
UL94 V-0 compliance	yes	yes

APPENDIX B: TROUBLESHOOTING

Noisy ECG Signal

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

Some common causes of noisy ECG signals include:
- Poor skin prep.
- Dried electrode gel.
- Muscle artifact caused by shivering, movement or tremors.
- Baseline wander caused by excessive chest movement, or the electrical differences between two brands of electrodes.
- Respiration artifact caused by thoracic or abdominal movement of both spontaneous and ventilated breathing patterns.
- Nearby electrical equipment.

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, on-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 equipments near patient.