

ECG Cable

User Manual

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Declaration

The intellectual property rights of these products and this user manual belong to Shenzhen Creative Industry Co., Ltd (hereinafter referred to as “Creative”). No individual is allowed to copy, revise and translate this user manual without the prior written approval of Creative.

This cable meets the requirements of the standard, ECG TRUNK CABLES and PATIENT LEADWIRES (ANSI/AAMI EC53). This cable is intended for MULTI-PATIENT USE.

This user manual details the purpose, function and operation of these products. Before use, please read it carefully and understand all information contained in it to ensure your correct use of these products, the safety of patients and the operator.

Provided that all the following conditions are conformed to, Creative will be responsible for the safety, reliability and performance of these products if the products are:

- Used as per this user manual and;
- Damaged due to non-human factors, human factors mean careless drop, deliberate damage, etc.

Instructions for Safe Operation

- Choose an appropriate ECG trunk cable and lead wire according to the connector type of the patient monitor.
- Check the ECG trunk cable and lead wire, in case of damage or material degeneration, never apply them for patient monitoring.

Warnings

- The cable shall be properly arranged to avoid tangling or suffocating the patient.
- Never use the ECG trunk cable for MRI to reduce the burning risk.
- Minimize patient movement during patient measurement.
- Do not use the non-defibrillation trunk cables to perform defibrillation on a patient.
- When HF electrosurgical equipment is used, the ECG trunk cable and lead wire should be away from the surgical operation site and other devices.
- ECG cables with ESU-proof capability have additional circuits, which can protect the patient in operation from being burnt and can lower the electrical interference.
- Never use this product to measure respiration.
- When connecting the electrode or trunk cable, ensure that all ECG electrodes are connected onto the patient and that the connector does not contact other conductive parts and grounded surface.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

1 About the Products

Product Name: ECG Cable
Model: See product label
Serial Number/Manufacturing Date: See product label
Service life: 3 years
Scope of Application:
The reusable ECG trunk cable and lead wire are used to connect human body (via ECG electrodes) and ECG devices to acquire and transfer ECG signals.
The ECG trunk cable and lead wire should be used with the monitoring device (including accessories) specified by us. The user has the liability to read the user manual of the device (including accessories) or contact and consult us before use in order to confirm the compatibility of the accessories with the device (including accessories). The products must be used by trained clinical professionals.
Structure:
These products consist of the plug, trunk cable and lead wires.

2 How to Use

- Before use, ensure that you have understood all notices listed here.
- Refer to Figure 1 to place the electrodes to all correct positions on the patient.
 - Plug the trunk cable into the device’s ECG connector.
 - Connect the corresponding lead wires to the electrodes stuck onto the patient before patient monitoring.

- Note:**
- Improper placement of the electrodes may affect the accuracy of measurements.

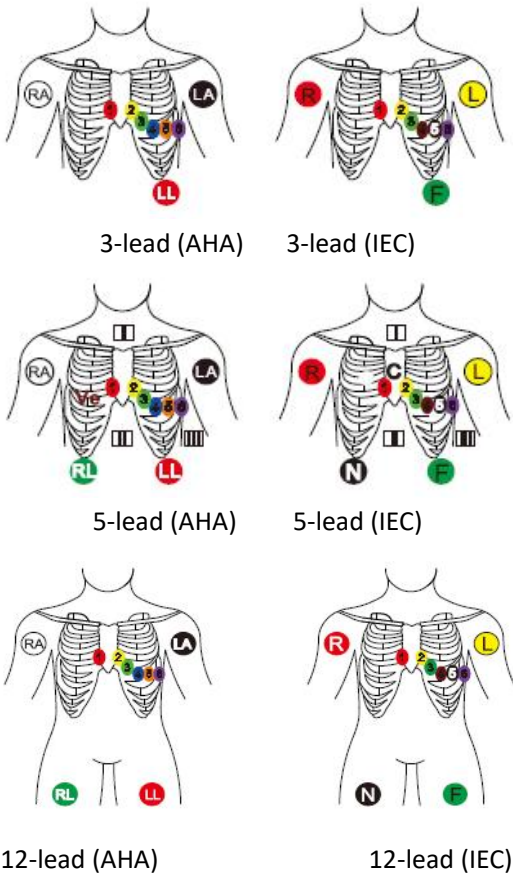


Figure 1 Electrode placement

IEC Standard		AHA Standard	
Identifier	Color Code	Identifier	Color Code
R	Red	RA	White
L	Yellow	LA	Black
N or RF	Black	RL	Green
F	Green	LL	Red
C1	White/Red	V1	Brown/Red
C2	White/Yellow	V2	Brown/Yellow
C3	White/Green	V3	Brown/Green
C4	White/Brown	V4	Brown/Blue
C5	White/Black	V5	Brown/Orange
C6	White/Violet	V6	Brown/Violet

Table 1 Identifiers and Colors

3 Symbols

MD	Medical device	SN	Serial number
	Type CF applied part, Defibrillation-Proof	LOT	Batch code
CE	CE mark	EC REP	Authorised representative in the European Community
	Storage temperature		Storage humidity
	Storage atmospheric pressure		Follow WEEE regulations for disposal
	Manufacturer		Country of manufacture (CN stands for Made in China) and Date of manufacture
	Refer to User Manual (Background: blue; Symbol: white)		General warning sign (Background: yellow; Symbol and line: black)

4 Cleaning and Disinfection

- Cleaning:**
- 2% glutaraldehyde solution;
 - 10% sodium hypochlorite solution;
 - Wipe the cable surface with a clean cloth dampened in the above cleansers and clear water, to dry the surface.
- Disinfection:**
The following disinfectants are recommended:
70% ethanol, 70% isopropanol and 2% glutaraldehyde solution.
- Before disinfection, clean the cable;
 - Wipe and clean the cable module with a cotton ball or soft cloth dampened with disinfectant solution;
 - Remove the disinfectant residual solution on the cable with soft cloth dampened with clean water;
 - Air-dry the cable in a cool, dry place.
- Cautions:**
- Do not immerse the cable module into water or disinfectant.
 - Never allow any liquid to enter the cable connector.
 - Only disinfect the cable according to the hospital regulations where necessary as frequent disinfections may result in cable damage.
 - Always use the cleanser and disinfectant specified in this instructions for use.

5 Working and Storage Environment Requirements

Working Environment:
Temperature: 5℃- 40℃
Relative Humidity: ≤80%
Atmospheric Pressure: 70kPa-106kPa
Storage Environment:
Temperature: -20℃-55℃
Relative Humidity: ≤93%
Atmospheric Pressure: 70kPa-106kPa

6 Replacement and Disposing

- Replacement:**
In case of broken or discontinuity, a new ECG cable shall be used to replace the damaged one.
- Disposing:**
Follow the local or hospital laws and regulations to properly dispose of this product.

7 Packing List

ECG cable	1 set
User manual	1 copy