Leadwires and Trunk cables Instruction for Use

Product Name : Leadwires and Trunk cables

Description

Designed to comply with the performance of standard ANSI/AAMI EC53.

Intended Use

ECG leadwire and trunk cable assemblies provide connection between ECG surface, electrodes and various electrocardiograph to transmit electrical signal for diagnostic purposes. Use is limited by the indications for use of the connected diagnostic equipment.

Products are intended to be used by trained operators in a medical professional's environment or under the direction of a trained medical professional. ECG leadwire and trunk cable assemblies are reusable, which is intended to be used on a patient who requires ECG/EKG monitoring.

Clinical Benefit

Enables ECG monitoring with monitoring equipment.

Structure

These products consist of the plug, trunk cable, connector, lead wires, connector for the lead wire, etc.

Purpose of Document

This document contains the instructions necessary to use, clean and store the Leadwires and Trunk cables. Always refer to the Instructions for use of the cable and device for additional instructions.

Hazards

⚠ WARNING - Contradiction-Do not use the product during magnetic resonance imaging(MRI) or in an MRI environment.

⚠ WARNING - ECG WAVEFORM CORRUPTION-Do not use product exhibiting sign of wear or damage, such as cracking or degradation of the connectors of cable insulation. This could result in the corruption of ECG waveforms during acquisition.

⚠ WARNING - Trace each individual leadwire from its colored identification connector back to the acquisition module label or trunk cable to make sure that it is matched to the correct location. Follow hospital protocol for proper attachment to patient. Improper connection will cause inaccuracies in the ECG

⚠ WARNING - STRANGULATION- To avoid possible strangulation, route all cables away from the patient's throat.

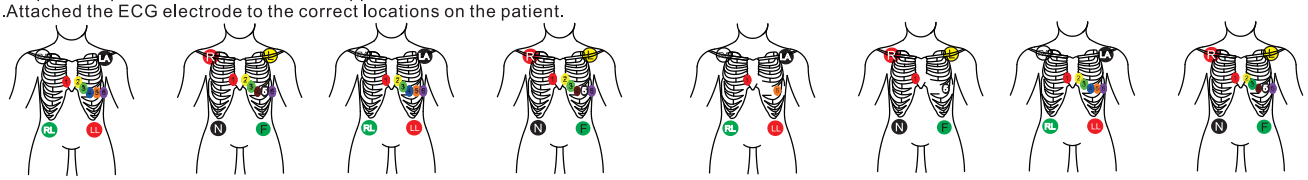
⚠ WARNING - TRIPPING HAZARD- Cables present a potential trip hazard. Route the cables to avoid tripping or stumbling.

⚠ CAUTION – Follow cleaning instructions exactly. Failure to follow instructions, or to use cleaning solution other than those recommended, my cause damage or corrosion; affect signal quality, product discoloration, metal part corrosion, brittle wires, brittle and breaking connectors, reduced life, and unit malfunction; and void the warranty

⚠ CAUTION – PRODUCT DISPOSAL – The accessories described in this document must be disposed of in compliance with local, state, or federal guidelines regulating the disposal of such products.

Instructions for Use

1.Check the product for the compatibility, performance, and appearance before use. Do not use if any damage is found;
2.Plug the ECG Cable into the ECG Monitor（electrocardiograph);
3.Connect the lead wire with the Electrodes;
4.Prepare the patient's skin for electrode application.
5.Attached the ECG electrode to the correct locations on the patient.



Instructions for Cleaning

Observe the following guidelines while cleaning the device.

- Follow cleaning instructions and observe hazards exactly as listed in this document.
- Avoid exposure to hypochlorite solutions and solutions containing iodine or high chlorine content, as these will promote corrosion.
- Avoid exposure to highly alkaline conditions (pH > 11), as this can damage the product (for example, aluminum parts).
- Never use conductive solutions or solutions that contain wax or wax compounds to clean the equipment.
- Do not immerse the device in any liquid as this may corrode metal contacts and affect signal quality.
- Do not allow fluid to pool around connection pins. If this happens, blot dry with a soft, lint-free cloth.
- Never autoclave or steam-clean the device.
- Pull the plug out of the monitor (electrocardiograph).
- Wipe and clean the cable with a soft cloth dampened with recommended clean agents.
- Remove the residual solution from the cable with soft cloth dampened with clean water.
- A soft cloth or small brush may be used.
- Do not use until thoroughly dry.

Recommended cleaning Agents

The following products are compatible with the device and may be used for cleaning.

- 2% glutaraldehyde solution;
- 10% sodium hypochlorite solution;
- 70% ethanol (ethyl alcohol);
- 70% isopropyl alcohol;
- Green soap
- Water;

Storage and Working Recommendations

- Storage environment: Temperature：-20℃~55℃, relative humidity:0%~95%，Atmospheric Pressure：70kPa~106kPa
- Working Environment: Temperature：5℃~40℃, relative humidity: 0%~95%，Atmospheric Pressure：70kPa~106kPa
- Vertically hang cables and leadwires.
- Do not coil leadwires or cables tightly around any medical device.
- Avoid Kinking.

Expected Service Life

Expected service life is the time period during which the cable is expected to remain safe for use. The following criteria can be used to determine the end of the expected service life.

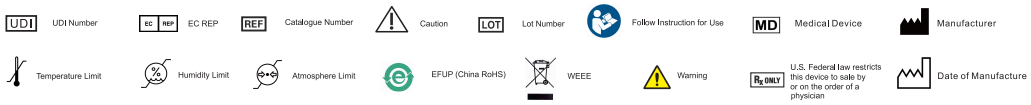
-The cable shows signs of physical damage.
-The cable is malfunctioning or the monitor shows unusual data.
-The medical device has an expected lifetime of 2 years.

Troubleshooting

See the device manual for troubleshooting information.

Notice

Any serious incident that has occurred in relation to the device should be reported to the manufactured and the competent authority of the Member state in which user and/or patient is established.



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A Class I medical device according to 2017/745, Medical Device Regulation for Europe.

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