

ECG Electrodes

Instructions for use

These instructions for use are intended for the following
Ambu ECG electrodes: L, M, N, P, Q, QR, R, SP, SU, T, VL and VLC.

Instructions for use

Инструкции за употреба

Návod k použití

Brugervejledning

Bedienungsanleitung

Οδηγίες χρήσης

Instrucciones de uso

Kasutusjuhend

Käyttöohjeet

Mode d'emploi

Upute za upotrebu

Használati útmutató

Istruzioni per l'uso

使用説明書

Naudojimo instrukcija

Lietošanas pamācība

Gebruiksaanwijzing

Bruksanvisning

Instrukcja užycia

Instruções de utilização

Instruçiuni de utilizare

Инструкция по применению

Návod na použití

Navodila za uporabo

Bruksanvisning

Kullanım talimatları

使用说明

Instructions for use

ECG electrodes

1.0 Intended Use

The electrode is applied to the surface of the body to transmit the electrical signal at the body surface to a recording and monitoring device that produces an electrocardiogram or vectorcardiogram.

1.1 Contra Indications

None known.

1.2 Warnings and Cautions

Warnings

1. Surface electrodes should be applied only to intact, clean skin (e.g., not over open wounds, lesions, infected, or inflamed areas).
2. For single use only. Reuse of the product may cause contamination, leading to infections.
3. After removal of electrodes from the protective liner, the protective liner should be disposed of in assigned waste bin.
4. Except for SU-00-C Remove the electrode from the patient when performing MRI scan as this may cause skin burn on the patient.

Cautions

1. During surgical procedures electrodes should be placed as far as possible from the electro-surgical area to minimize unwanted RF current flow which could lead to skin burns.
2. Electrodes should only be used by or in consultation with a health care provider familiar with their proper placement and use.
3. Do not soak, rinse, or sterilize the electrodes as these procedures may leave harmful residues or cause malfunction of the electrodes.
4. To minimize the risk of skin irritation, when replacing electrodes find a new area of skin on which to place them.
5. Electrodes may damage the skin if removed carelessly.
6. US Federal laws restricts these devices for sale only by, or on the order of, a physician.
7. Electrodes with no lead wire attached should only be used with lead wires in compliance with IEC 60601-1.
8. For SU-00-C only: During MRI scan the electrodes shall only be used with MRI compliant lead wires.










1.3 Potential Adverse Events

Potential adverse events in relation to the use of surface electrodes are skin reactions such as skin burn, skin redness, skin itching and small blisters.

1.4 General Notes

If, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority.

2.0 Explanation of Symbols Used

Symbols for the Ambu ECG electrodes	Indication	Symbols for the Ambu ECG electrodes	Indication	Symbols for the Ambu ECG electrodes	Indication
	Medical Device		Foam		Micropore
	Country of manufacturer		Wet gel		Polymer
	Radioactive		Electrical Safety Type BF Applied Part		
	Magnetic Resonance Conditional. Static magnetic field of 1.5 Tesla and 3 Tesla, with maximum spatial field gradient of 12,900 G/cm or 129 T/m. Maximum whole body averaged (WBA) specific absorption rate (SAR) of 2 W/kg (Max temp. increase 2.2 °C (1.5 Tesla) and 1.2 °C (3 Tesla)) or 4 W/kg (Max temp. increase 4.4 °C (1.5 Tesla) and 3.1 °C (3 Tesla)) for 15 minutes of scanning.				

3.0 Directions for Use

- If needed, clean application areas with a mild soap and water and dry thoroughly.
- For adults only: Clip off hair on excessively hairy areas if necessary. Only gently abrade if skin impedance is too high.
- The correct placement of electrodes is typically determined by the hospital/physician and/or local protocol/procedures.
- Protective liners may have sharp corners, and care should be taken when removing electrodes from the pouch. Peel the electrode away from the protective liner and place it on the skin. Dispose of the protective liner immediately after removal of electrodes.
- When using electrodes with connectors or pre-attached leadwire, the connector or the pre-attached leadwire should be positioned in the direction so that leadwires run in the same direction towards the equipment.
- Place the electrode on the skin by gently pressing around the adhesive edge with a circular smooth and firm motion.
- Connect the leadwire from the ECG monitoring device to the electrode. If the electrode is supplied with a pre-attached leadwire it may be connected directly to the ECG monitoring device.
- Electrode Removal: Gently lift the tab or the edge of the electrode, maintaining a low profile, and slowly pull off the electrode from the skin, holding and supporting down the newly exposed skin as the electrode is removed. Keep the electrode close to the skin surface when pulling back over itself. Avoid removing the electrode at 45-degree angle, to reduce the risk of mechanical trauma.
- Self-adhesive electrodes should be replaced if they no longer stick firmly to the skin.
- Gel residue can be removed using paper towels or water.
- Electrodes in an opened pouch may dry out, therefore do not open pouch until necessary.
- The electrodes are disposable and must be disposed of according to local hospital procedures.

4.0 Duration of application (time in hours)

Item number	Gel System	Adhesive System	Sensor Material	Patient indication	Duration of application
L	Wet Gel	Acrylic	Ag/AgCl	Adult	72
M	Wet Gel	Acrylic	Ag/AgCl	Adult	24
N	Wet Gel	Acrylic	Ag/AgCl	Pediatric	24
P	Wet Gel	Acrylic	Ag/AgCl	Pediatric	24
Q	Wet Gel	Acrylic	Ag/AgCl	Adult	24
QR	Wet Gel	Acrylic	Ag/AgCl	Adult	24
R	Wet Gel	Acrylic	Ag/AgCl	Adult	24
SP	Wet Gel	Acrylic	Ag/AgCl	Adult	24
SU	Wet Gel	Acrylic	Ag/AgCl	Adult	24
T	Wet Gel	Acrylic	Ag/AgCl	Adult	24
VL	Wet Gel	Acrylic	Ag/AgCl	Adult	72
VLC	Wet Gel	Acrylic	Ag/AgCl	Adult	72