

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 użycia Instruções de utilização Instrucțiuni de utilizare Инструкция по применению Návod na použitie Navodila za uporabo Bruksanvisning Kullanım talimatları 使用说明

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 l | ndications |
|--------------|------------|
| None known. | |
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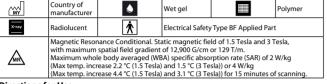
- 1.2 Warnings and Cautions
- Warnings
 Surface electrodes should be applied only to intact, clean skin (e.g., not over open wounds, lesions, infected, or inflamed areas).
 For single use only. Reuse of the product may cause contamination, leading to infections.
- Cautions

 1. During surgical procedures electrodes should be placed as far as possible from the electro-surgical area to minimize unwanted RF current flow which 5 could lead to skin burns.

 2. Electrodes should only be used by or in 6 consultation with a health care provider familiar with their proper placement and use.
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 3. Do not soak, rinse, or sterilize the electrodes as these procedures or may leave barroful residues or
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- these procedures may leave harmful residues or
- cause malfunction of the electrodes.To minimize the risk of skin irritation, when

| 0 Explanation of Symbols Used | | | | | | |
|--|-------------------|---|------------|---|--|--|
| ymbols for ne Ambu ECG lectrodes | Indication | Symbols for the Ambu ECG electrodes | Indication | Symbols for the Ambu ECC electrodes | | |
| MD | Medical Device | | Foam | WX | | |
| م مم | Country of | | Wat gol | | | |



- 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 |
| М | Wet Gel | Acrylic | Ag/AgCl | Adult | 24 |
| N | Wet Gel | Acrylic | Ag/AgCl | Pediatric | 24 |
| Р | 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 |
| Т | Wet Gel | Acrylic | Ag/AgCl | Adult | 24 |
| VL | Wet Gel | Acrylic | Ag/AgCl | Adult | 72 |
| VLC | Wet Gel | Acrylic | Ag/AgCl | Adult | 72 |



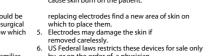
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After removal of electrodes from the protective liner, the protective liner should be disposed of in assigned waste bin.
 Except for SU-00-C: Remove the electrode from the patient when performing MRI scan as this may cause skin burn on the patient.



- by, or on the order of, a physician. Electrodes with no lead wire attached should only
- be used with lead wires in compliance with IEC 60601-1.
 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
 I.4 General Notes

Micropore

- - 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
- 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 to 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 maned place it on the skin. Disposit of the greattached leadwire, the connector or the pre-attached leadwire, should be positioned in the direction towards the equipment.
 Place the electrode with connectors or greattached leadwire should be positioned in the direction so that leadwires not in the same direction towards the equipment.
 Place the electrode in the shin. Disposationed in the direction towards the equipment.
 Place the electrode in the shin by gently pressing around the adhesive edge with a circular smooth and firm motion. 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.



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