Ambu
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ECG Electrodes

Instructions for use

These instructions for use are intended for the following Ambu White Sensor electrodes:
WS, WS/RT, WSP25, WSP30, 0215M, 0415M, 0715M, 2742*, 2742/RT*, 2837*, 3245D/RT*, 3351/RT*, 3552*, 3552/RT*, 3552JOU/AL/RT*, 4200, 4300, 4242, 4440, 4500M, 4500M-H, 4530, 4535M, 4540, 4560M, 4570M, 4831Q, 4841P, 5050, 6060, 7841P, CMM/1.
Ambu Blue Sensor electrodes: BS-TAB-2300.

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Instructions for use

EN

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.

1.2 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.

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 professional who has been trained in electrode placement.
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 lead wires attached should only be used with lead wires in compliance with IEC 60601-1.
8. For MR Conditional Electrodes: During MRI scan the electrodes shall be used with MR compliant lead wires.

1.1 Contra Indications
None known.

1.3 Potential Adverse Events
Potential adverse reaction 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
3. After removal of electrodes from the protective liner, the protective liner should be disposed of in assigned waste bin.
4. Except for MR Conditional Electrodes: Remove the electrode from the patient when performing MRI scan as this may cause skin burn on the patient.

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 used for the Ambu White/ Blue Sensor electrodes	Indication	Symbols for the Ambu White/ Blue Sensor electrodes	Indication	Symbols for the Ambu White/ Blue Sensor electrodes	Indication
MD	Medical Device		Wet gel		Cloth
	Radiolucent		Polymer		Foam
	Solid gel		Electrical Safety Type BF Applied Part		
	Magnetic Resonance Conditional. Static magnetic field of 1.5 Tesla and 3 Tesla only. Maximum spatial gradient field of 25,000 Gauss/cm or 250 Tesla/m. Maximum whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning. * The Maximum Spatial Gradient Field of 12,900 Gauss/cm or 129 Tesla/m.				

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 application and the lead wire configuration.
- 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, the connector should be placed so that the direction of the 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.
- 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 until the electrode is removed. Keep the electrode close to the skin surface when pulling back over itself. Remove the electrode at a 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.
- Unused electrodes remaining in 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	Options - Application of use	Duration of application (hours)
BS-TAB-2300	Solid Gel	Solid Gel	Ag/AgCl	Adult	Resting	1/2
WS	Solid Gel	Acrylic	Ag/AgCl	Adult	Short term	24
WS/RT	Solid Gel	Acrylic	Ag/AgCl	Adult	Short term	24
WSP25	Solid Gel	Acrylic	Ag/AgCl	Pediatric	Resting/Long term	48
WSP30	Solid Gel	Acrylic	Ag/AgCl	Adult/Pediatric	Resting/Long term	48
0215M	Solid Gel	Solid Gel	Ag/AgCl	Pediatric	Resting	1/2
0315M	Solid Gel	Solid Gel	Ag/AgCl	Adult	Resting	1/2
0415M	Solid Gel	Solid Gel	Ag/AgCl	Adult	Resting	1/2
0715M	Solid Gel	Solid Gel	Ag/AgCl	Adult	Resting	1/2
2742	Wet gel	Acrylic	Ag/AgCl	Adult/ Pediatric	Resting	24
2742/RT					Long term**	48
2837	Wet gel	Acrylic	Ag/AgCl	Adult	Resting	1/2
3245D/RT	Wet gel	Acrylic	Ag/AgCl	Adult	Resting/Long term	48
3351/RT	Solid Gel	Acrylic	Ag/AgCl	Adult	Stress/Resting/Monitoring	48
3552	Wet gel	Acrylic	Ag/AgCl	Adult	Resting	24
3552/RT					Long term**	48
3552JOU/AL/RT					Resting/Long term	48
4200	Solid Gel	Acrylic	Ag/AgCl	Adult	Short term	24
4300	Solid Gel	Acrylic	Ag/AgCl	Adult	Short term	24
4242	Wet gel	Acrylic	Ag/AgCl	Adult	Stress/Long term	48
4440	Wet gel	Acrylic	Ag/AgCl	Adult	Long term	48
4500M	Wet gel	Acrylic	Ag/AgCl	Adult	Short term	24
4500M-H	Wet gel	Acrylic	Ag/AgCl	Adult	Short term	24
4530	Wet gel	Acrylic	Ag/AgCl	Adult	Resting	24
4535M	Wet gel	Acrylic	Ag/AgCl	Adult	Short term	24
4540	Wet gel	Acrylic	Ag/AgCl	Adult	Resting	24
4560M	Wet gel	Acrylic	Ag/AgCl	Adult	Stress test	24
4570M	Wet gel	Acrylic	Ag/AgCl	Pediatric	Short term	24
4831Q	Solid Gel	Acrylic	Ag/AgCl	Adult/Pediatric	Short term	24
4841P	Solid Gel	Acrylic	Ag/AgCl	Adult	Short term	24
5050	Wet gel	Acrylic	Ag/AgCl	Adult	Stress/Long term	48
6060	Wet gel	Acrylic	Ag/AgCl	Adult	Stress/Long term	48
7841P	Solid Gel	Acrylic	Ag/AgCl	Adult	Short term	24
CMM/1	Solid Gel	Acrylic	Ag/AgCl	Adult	Long term	48

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