

ECG DIAGNOSTIC ELECTRODE

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INSTRUCTIONS FOR USE ECG ELECTRODES

This document applies to the following ECG Electrode REF numbers: **0-4227-60** and **0-5235-60**

INTENDED USE

The electrode is intended to be 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 and vectorcardiogram.

PATIENT INDICATIONS

Adult & Pediatric.

APPLICATION

1. Open the pouch along the indicated line.
2. Determine application sites. Remove any excessive hair, calluses and ensure the skin is clear of any oils, creams, fluids, dirt, or other impediments to good electric contact.
3. If necessary, clean the skin with appropriate preparation material. Always ensure the application site is dry prior to application of electrode.
4. Remove electrodes from the liner care one at a time and place electrode on the skin by gently pressing around the adhesive edge with a circular smooth and firm motion.
5. After removal of all the electrodes, the liner card should be immediately disposed of in the assigned waste bin for disposal.
6. Place all electrodes on patient before any snap connectors are applied to the electrodes.
7. For electrodes with stainless steel stud, the offset tab should be positioned in the same direction as the lead wires and cable, towards the equipment.
8. Connect snap connectors to the bottom portion of the tab.
9. Always avoid pressing down on the center of the electrode.
 - Electrode removal: gently lift from 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 risk of mechanical trauma.
 - Remove gel residue, if any, with a paper towel or water.

DISPOSAL

- Dispose of as hospital contaminated waste, in accordance with regulations in force.
- Recycle package.

CAUTIONS, WARNINGS & SAFETY PRECAUTIONS

- Due to high adhesion strength of the adhesive material, this product is not suitable for use on patients with fragile skin. Not suitable for use on newborn or premature infants.
- Plastic cover should be immediately disposed of in the assigned waste bin for disposal after removal of electrodes.
- Gentle retrieval of electrodes from pouch to be ensured so as to prevent any injury to fingers as plastic cover is fine cut.
- ECG electrodes should only be used by or in consultation with a health care provider familiar with their proper placement and use. Any allergic or other skin reactions should be immediately evaluated by a physician.
- For use on intact, clean skin (do not use on open wounds, lesions, infected or inflamed areas).
- The product is not for internal use. In case of accidental ingestion of the electrode consult a physician immediately.
- For single use only. Use on other patients can cause cross contamination. Do not soak, rinse, or sterilize this device, as these products may leave harmful residues or cause malfunction of the device. The design and materials used are not compatible with conventional cleaning and sterilization procedures.
- Careless removal of the electrode may cause damage to the skin. Should the electrode be difficult to remove use water to dissolve the adhesive.
- DO NOT USE IF THE GEL IS DISCOLORED.
- Use: Rx only.

PRECAUTION

- Do not use the electrodes if the pouch is found damaged.
- In the even if use over the extended period, check for secure adhesion and absence of skin reaction on a daily basis.
- During surgical procedures electrodes should be placed as far as possible from the electro-surgical area to minimize unwanted RF current flow.
- For Radio Translucent electrodes only: it is important to be aware that the Radio Translucent marking applies only to the electrodes and not to any monitors, cables or leadwires, which may be attached to the electrode. Place the electrodes and electrode lead wires according to local safety guidelines for recording ECG in an MRI environment. The radio Translucent electrode shall only be used with lead wires compliant with use in an MRI environment.

POTENTIAL ADVERSE EFFECTS

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

DURATION OF USE

- ECG Electrodes may be used on patients for up to 48 hours.














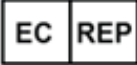

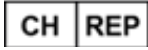



STORAGE

- Store in original package protected from the weather and within the indicated temperatures.
- Once the pouch is opened, use electrodes promptly. Protect remaining electrodes in original pouch from moisture loss by folding-over the top and securing.
- Remaining electrodes should be used within 30 days of opening the pouch.

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.

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EXPLANATION OF PACKAGING SYMBOLS

	Consult electronic instructions for use		Do not re-use
	Not made with natural rubber latex		Does not contain PVC
	Temperature limitations		Prescription only
	Keep dry		Keep away from sunlight
	Use by date		CE Marking of Conformity
	UKCA Marking of Conformity		Medical Device
	Manufacturer		Authorized Representative in the European Union
	Importer		Authorized Representative in Switzerland
	Catalog Number		Quantity
	Lot Number		