

DESCRIPTION AND SPECIFICATIONS

FIAB Disposable electrodes for ECG have been designed for the surface recording of cardiac activity through the use of any kind of electrocardiographic monitoring device.

The description of each different model is specified on the electrode's pouch. FIAB electrodes can be classified on the basis of the following technical features:

- Connection to the patient cable: clip, plug, tab.
- Shape and dimensions: some models are available also in paediatric and neonatal versions.
- Gel status: solid, liquid.
- Pad's material: waterproof FOAM, transpiring nonwoven material.
- Magnetic resonance compatibility: some models are available also in radiotransparent version and are suitable for magnetic resonance.

For a general description of technical features please look on the pouch of each model.

Adhesiveness is guaranteed by a biocompatible medical grade adhesive.

The electrodes comply with the requirements of ANSI AAMI EC12 standard.

DIRECTIONS FOR USE

- Check that the package, the electrodes and the gel are intact; in case of any damage do not use the product.
- Select an area free of hair, cutaneous lesions or scars, folds of skin or bony protuberances.
- Shave (if necessary), clean and dry the application surface.
- Avoid the use of solvents; these can result in skin irritation and reduce electrode adhesion.
- If alcohol is used, make sure that this has evaporated or been completely removed before the application of the electrodes.
- If necessary, friction the skin gently to improve the adherence of the product.
- Connect the electrode to the patient cable before positioning it on the skin, in order to avoid the gel escaping from the sensor.
- Remove the protective support and immediately dispose off in the assigned waste bin for disposal. Then apply the electrode to the skin surface.
- When the recording is complete, disconnect the electrode and remove it gently from the skin, avoiding cutaneous irritation.
- Throw away the product after use (see "Waste and disposal").
- Close the bag carefully so that the remaining electrodes do not dry out.

WARNINGS

- Remove the electrode gently from the skin to avoid skin irritation.
- The electrodes must be replaced if they do not properly attach to the skin.
- Do not use the product if alterations in the gel are noted.
- The product is supplied not sterile.
- This is a single-use product, do not re-use it.
- The equipment and the connecting leads used with this device must comply with the regulations in force.
- For correct use of cables and equipment, follow the manufacturer's instructions.
- Do not use the product on patients with previous episodes of cutaneous irritation or contact allergies.
- The electrodes are in accordance with the biocompatibility ISO10993-1.
- Electrodes must be placed and connected by qualified staff.
- Protective support should be immediately disposed off in the assigned waste bin for disposal after removal of electrodes.
- Do not apply the electrodes to skin with abrasions, erythema or wounds.
- Once applied, do not change the position of electrodes.
- During electro-surgical procedures do not place the electrodes close to the neutral plates or to the operating field.
- As a general precept, replacement of the electrodes is recommended after 48 hours and mandatory after 72 hours.

STORAGE

The product must be stored in the original package at the environmental conditions (temperature and relative humidity) specified on the pouch's label. Putting external heavy weights on the package, the product could be damaged.

GUARANTEE – NOTICE

FIAB guarantees that the product complies with Directive 93/42/EEC and has been manufactured according to the procedures of FIAB Quality System certified ISO 13485. No responsibility may be ascribed to the producer who shall not be held liable for medical costs, direct or indirect damages due to lacking function or malfunction of the above products, when used differently

from the instructions for use. It is recommended to report opportunely any malfunction or defect of the product to FIAB Quality Assurance Service.

WASTE DISPOSAL

Waste coming from hospitals must be disposed of accordingly with regulations in force.

CAUTION:

U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN