

TECHNICAL DATA SHEET

# Disposable ECG electrodes

## > Product description

The DENA ECG electrodes Ag/AgCl range consist of an electrode family designed to detect and amplify the small electrical pulses on the skin generated by the activity of the heart muscles during each heartbeat.

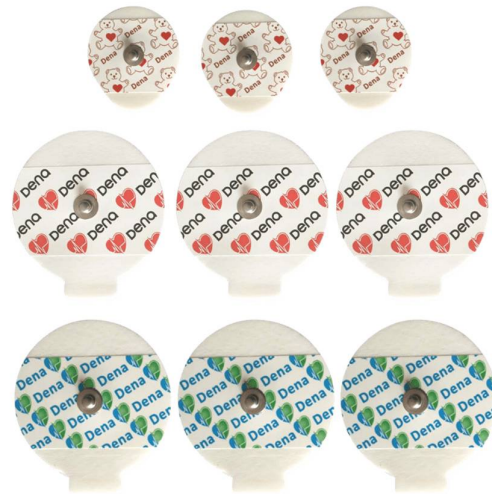


## > Product characteristics

### ▣ Electric properties ANSI/AAMI EC12

- Offset DC voltage: <100mV
- AC 10Hz impedance: <2000Ω
- Defibrillation overload recovery:
  - <100mV
  - <1mV/s
- Combined offset instability and internal noise <150μV
- Bias current tolerance in 8h: <100mV

**Conclusion: safety electrical requirements are met**






## > Technical specifications

### ▣ Materials

- Supporting materials: PE foam.
- Adhesive: Acrylic.
- Sensor: Stainless steel / Ag-AgCl.
- Cover: PET.
- Label: PET/PP Film.
- Pouch: Aluminium / PE film.

### > Main dimensional properties

Shape	Reference	Diameter	Type
	DEE-AS	50mm ± 1 mm	Liquid Gel / Solid Gel
	DEE-AL	50mm ± 1 mm	Liquid Gel / Solid Gel
	DEE-NS	40 x 36mm ± 1mm	Solid Gel

### > Biocompatibility

- ISO 10993-5: no cytotoxic.
- ISO 10993-10: no sensitizing.
- ISO 10993-10: negative intracutaneous irritation test.

**Conclusion: product is biocompatible.**

### > Sterility and expiry date

- Non sterile.
- Expiry date: 2 years upon manufacturing date.

### Storage and maintenance

- Keep protected from direct sunlight / the outside.
- Keep in a dry place.
- Temperature range: 5-35°C.
- Single use product. Disposable.
- Latex free.

## ➤ Packaging

Code #	Ref	Description	Packaging
120001	DEE-AS	Adult , Foam, Solid gel	50 units per pouch. 50 pouches per service box, 2500 units
120002	DEE-NS	Pediatric , Foam, Solid gel	50 units per pouch. 50 pouches per service box, 2500 units
120045	DEE-AL	Pediatric , Foam, Solid gel	50 units per pouch. 40 pouches per service box, 2000 units

## ➤ Instructions for use

- Open the pouch along the indicated line.
- Determine the positioning points. Remove any excess hair and calluses and ensure that the skin is clear of any oils, creams, fluids, dirt or other impediments to good electrical contact.
- If necessary, clean the skin with appropriate preparation material. Always ensure the positioning point is dry prior to placement of the electrodes.
- Connect the lead wires to the electrodes and peel the plastic cover.
- Place the electrodes on the skin. Smooth the backing surface with the fingers as necessary.
- Turn the unit on and carry out the ECG procedure. After the check, lift the tab to gently remove the electrode from the skin.
- Remove any gel residue with a paper towel or water.

## ➤ Regulatory information

D.G.DENA guarantees that this product is in conformity with **Regulation (UE)2017/745** and that it has been manufactured following the directives of the Quality Assurance System certified as **ISO 13485**.

This product is classified as:

- **Class I** product according to Annex VIII of Regulation (UE) 2017/745, **rule 1**.
- GMDN code: 35035 Electrocardiographic electrode, single-use.

**Date:** Jan. 2025