

# E.C.G. electrodes Ag/AgCl solid gel Dormo

## > Product description

The Dormo® ECG electrodes Ag/AgCl consist of an electrode family designed to detect and amplify the small electric pulses on the skin produced by the heart muscle depolarization during each heartbeat.



## > Product characteristics

### > Electrical 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*

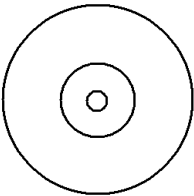
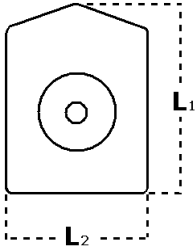
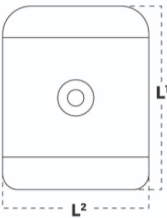
## > Technical specifications

### > Materials

- Supporting material:
  - SX-50, SX-36, SF-36, SX-30: flexible PE foam (impermeable).
  - SP-50: non-woven breathable tissue.
  - SF-40: flexible PE foam (impermeable).
- Adhesive: Acrylic (Biocompatible, ISO 10993)
- Sensor: Stainless steel / Ag-AgCl coated plastic rivet
- Cover: PET
- Label: Film PET/PP (only references SX-30, SF-36 y SP-50)
- Solid gel: Acrylic based, hydrosoluble polymer
- Pouch: Cellulose / Aluminium / PE film



➤ **Main dimensional properties**

|   | Reference      |  | Diameter (mm)       |                     |
|------------------------------------------------------------------------------------|----------------|--|---------------------|---------------------|
|                                                                                    | SX-50<br>SP-50 |  | 50 ± 1              |                     |
|                                                                                    | SX-30          |  | 30 ± 1              |                     |
|   | Reference      |  | L <sub>1</sub> (mm) | L <sub>2</sub> (mm) |
|                                                                                    | SF-36          |  | 42 ± 1              | 36 ± 1              |
|                                                                                    | SX-36          |  | 50 ± 1              | 36 ± 1              |
|  | Reference      |  | L <sub>1</sub> (mm) | L <sub>2</sub> (mm) |
|                                                                                    | SF-40          |  | 42 ± 1              | 32 ± 1              |

➤ **Biocompatibility**

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

*Conclusion: product is biocompatible*

➤ **Sterilization and expiry date**

- Non-sterile product.
- Shelf life: 3 years after the manufacturing date.

➤ **Storage and maintenance**

- Keep protected from direct sunlight / the outside.
- Keep in a dry place.
- Temperature limitation: 5-40°C.
- Single use product. Disposable.
- Latex free

**> Packaging**

| #     | Ref   | Packaging                                                    |
|-------|-------|--------------------------------------------------------------|
| TEA09 | SX-50 | 50 units per pouch. 20 pouches per service box, 1000 units.  |
| TEA08 | SX-36 | 50 units per pouch. 20 pouches per service box, 1000 units.  |
| TEA07 | SF-36 | 50 units per pouch. 20 pouches per service box, 1000 units.  |
| TEM01 | SF-30 | 50 units per pouch. 20 pouches per service box, 1000 units.  |
| TEI10 | SP-50 | 50 units per pouch. 20 pouches per service box, 1000 units.  |
| TEA12 | SF-40 | 100 units per pouch. 25 pouches per service box, 2500 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.

**Date:** March 2023**Specification N°:** ETP/060/13**> Regulatory information**

TELIC, S.A.U. 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