

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

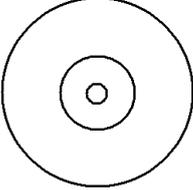
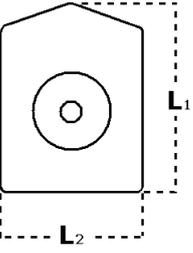
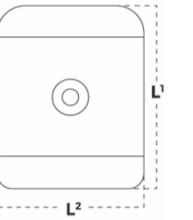
Conclusion: safety electrical requirements are met

> 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 SP-50	50 ± 1	
	SX-30	30 ± 1	
	Reference	L₁ (mm)	L₂ (mm)
	SF-36	42 ± 1	36 ± 1
	SX-36	50 ± 1	36 ± 1
	Reference	L₁ (mm)	L₂ (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