

# Disposable ECG electrodes semiliquid gel

## Dormo

### > Product description

The Dormo® ECG electrodes Ag/AgCl range 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

#### > 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*

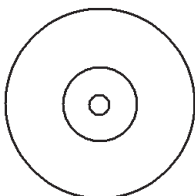
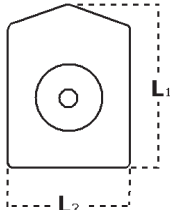
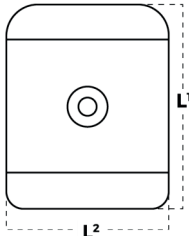
### > Technical specifications

#### > Materials

- Supporting materials
  - LF-50, LF-36, LEH-36: flexible PE foam (impermeable).
  - LP-50: non-woven breathable tissue.
  - LR-50: breathable twill.
  - LF-40: flexible PE foam (impermeable).
- Adhesive: Acrylic.
- Sensor: Stainless steel / Ag-AgCl coated plastic Rivet.
- Cover: PET.
- Label: PET/PP Film.
- Semiliquid gel: Hydrosoluble acrylic gel adsorbed on polyether foam.
- Pouch: Cellulose / Aluminium / PE film.



➤ **Main dimensional properties**

	Reference	Diameter (mm)	
	LF-50	50 ± 1	
	LP-50		
	LR-50		
	Reference	L <sub>1</sub> (mm)	L <sub>2</sub> (mm)
	LF-36	42 ± 1	36 ± 1
	LEH-36	50 ± 1	36 ± 1
		Reference	L <sub>1</sub> (mm)
LF-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.*

➤ **Sterility and expiry date**

- Non sterile producto.
- Expiry date: 3 years upon manufacturing date.

➤ **Storage and maintenance**

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

## > Packaging

#	Ref	Packaging
TEAS1	LF-50	50 units per pouch. 20 pouches per service box, 1000 units.
TEAL2	LF-36	50 units per pouch. 20 pouches per service box, 1000 units.
TEDS1	LEH-36	50 units per pouch. 20 pouches per service box, 1000 units.
TEALP	LP-50	50 units per pouch. 20 pouches per service box, 1000 units.
TESA1	LR-50	50 units per pouch. 20 pouches per service box, 1000 units.
TEAS2	LF-40	100 units per pouch 20 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.

**Date:** March 2023

**Specification N°:** ETP/090/19

## > 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.
- EMDN code: C020501 (ECG Electrodes).