

# Resting electrodes

## Dormo-tab

### > Product description

Dormo® -TAB 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

- Non-polarisable Ag/AgCl conductive support.
- Safe, smooth and comfortable adhesion.
- Conforms to body shape.
- Resting test electrodes for adult and pediatric use.
- Radiotransparent electrodes.
- Suitable for Nuclear Magnetic Resonance (NMR).

### > Technical specifications

#### > Materials

- Supporting materials: paper-PET coated with conductive carbon – Ag/AgCl
- Adhesive-Conductive Gel: Acrylic hydrogel, biocompatible
- Protector: Siliconized paper
- Pouch: PET/aluminium/PE film

#### > Main dimensional properties

- Conductive electrode thickness: 0,61-0,65 mm
- Contact surface: 26,4 x 22,5 mm
- Total electrode measurements: 35 x 22,5 mm

**> Electrical properties ANSI/AAMI EC12**

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

*Conclusion: safety electrical requirements are met*

**> 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: 2 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. No maintenance required.

**> Packaging**

#	Ref	Packaging
TEL01	T-2226	100 units per pouch. Primary box containing 25 pouches, 2500 units. Service box with 5000 units.

## > Instructions for use

1. If necessary, clean the skin with appropriate preparation material. Always ensure the application site is dry prior to application of the electrodes
2. Connect the lead wires to the electrodes and peel the plastic liner.
3. Place the electrodes on the skin. Smooth the backing surface with the fingers as necessary
4. Turn the equipment on and perform the ECG procedure.
5. After monitoring, lift the tab to gently remove the electrode from the skin.

**Date:** April 2023

**Specification N°:** ETP/056/11

## > 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).