

Adhesive pre-gelled pads for defibrillation

Desfi-Dormo

> Product description

Pack of two adhesive pre-gelled pads for manual defibrillation for adult patients.



> Product characteristics

- This product does not contain natural latex, phthalates or compounds of animal or biologic origin.
- This product is in compliance with RoHS standard.
- Maximum permanence time recommended for contact with patient skin is 24 h.
- Resists up to 15 consecutive defibrillation loads at 360 J.
- Product intended for adult patient. Minimum weight 25 kg.

> Technical specifications

> Materials

- Backing material: Waterproof flexible white PE foam ring, closed cell, with biocompatible acrylic adhesive.
- Conductive area: Tin foil with conductive acrylic based hydrogel, biocompatible.
- Release liner: PET.
- Packaging: PET / aluminum / PE film.

> Physical and dimensional properties

- Active area (each pad): 135 cm².
- Electrode pad measurements: 165 mm x 132 mm.
- Active area size: 134 mm x 101 mm.

> Electrical properties

- AC Impedance 10 Hz specification: <math><3000\Omega</math>
- AC Impedance 30 kHz specification: <math><5\Omega</math>
- AC large signal impedance specification: <math><3\Omega</math>
- Defibrillation overload recovery:
 - ΔV after 4s specification: <math><500\text{ mV}</math>
 - ΔV after 60s specification: <math><400\text{ mV}</math>
- DC offset voltage specification: <math><100\text{ mV}</math>
- Combined offset instability and internal noise specification: <math><100\ \mu\text{V}</math>
- Bias current tolerance 8 h specification: <math><100\text{ mV}</math>

Conclusion: Requirements established by electrical safety standards IEC 60601-2-4 and ANSI/AAMI DF-80 are met.

> Biocompatibility

- ISO 10993-5: No cytotoxic.
- ISO 10993-10: No sensitizing.
- ISO 10993-10: Negative intracutaneous irritation test.

Conclusion: The product is biocompatible.

> Sterilization and expiry date

- Non-sterile product.
- Shelf life: 2 years upon the manufacturing date.

> Storage and maintenance

- Keep protected from direct sunlight / the outside.
- Keep in a dry place.
- Temperature limitation: 5-35°C.
- Single use product. No maintenance required.

> Packaging

#	Ref	Packaging
TOOXX	ED-1010	Primary packaging containing a set of 2 defibrillation pads. Service boxes of 50 units.

> Instructions for use

- Clean and dry application site. Avoid contact with alcohol or other disinfectants.
- To minimize adhesion or burn problems, shave the application area, whenever possible.
- Open package and remove electrodes.
- Remove protective film from pads.
- Place pads on patient at clinically indicated site, making sure that all adhesive area is stuck to the skin. Be careful not to trap any pockets of air between hydrogel and patient's skin.
- Place defibrillator paddles on the metallic surface of the pads.
- Apply firm and uniform pressure on each of the paddles when carrying out the electrical discharge.

Date: October 2023

Specification N°: ETP/001/19

> Regulatory information

TELIC, S.A.U. guarantees that this product is in conformity with **MDD 92/43/EEC** 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 IX of MDD 93/42/EEC, rule 1.

- GMDN code: 11130 – Electrode, defibrillation.