

Set of two multi-function electrodes. Adult.

DESFI-DORMO

> Product description

The product Desfi-Dormo® consists on a family of electrodes designed to transmit the energy, in the shape of electrical pulse, generated by the defibrillator to the patient, in order to obtain a cardiac defibrillation.



> Product characteristics

- Multifunction product, suitable for use in defibrillation, synchronized cardioversion and ECG monitoring.
- 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 24h.
- Resists up to 15 consecutive defibrillation loads at 360 J.
- Product intended for adult patient. Minimum weight 10 Kg.
- See annex I of the present technical data sheet for further details about connectors and their compatibilities.

> Technical specifications

> Materials

- Backing material: waterproof flexible white PE foam, closed cell, with biocompatible acrylic adhesive
- Conductive area: tin foil with conductive acrylic based hydrogel, biocompatible.
- Protective liner: PET
- Connection:
 - Cable: copper (65/0.127mm) with non-toxic PVC coating.
 - Plug mold: plastic material depending on the reference (PP,PVC...)
 - Terminals rings: Brass
 - Grommet: EVA/TPE
 - Socket: Plating brass
- Packaging: PET / aluminum / PE film.
 - Pouch Size: 16 cm x 21 cm.

> Physical and dimensional properties

- Active area (each pad): 76,94 cm²
- Electrode pad measurements: 105mm x 155mm
- Cable length: depending on the reference. Minimum 1,2m.
- See annex I for details about available connections.

> Electrical properties

- AC Impedance 10Hz : <3000Ω
- AC Impedance 30kHz: <10Ω
- AC large signal impedance: <5Ω
- Defibrillation overload recovery:
 - After 4s: <500mV
 - after 60s: <400mV
- DC offset voltage: <100mV
- Electrode active area: > 150 cm²

Conclusion: Requirements established by electrical safety standards IEC 60601-2-4 are met.

Note: These electrodes do not allow monitoring the quality of CPR.

> Biocompatibility

- ISO 10993-5: No cytotoxic
- ISO 10993-10: no sensitizing
- ISO 10993-10: Non- irritant

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

- EDC-10XX; EDC-20XX: Primary packaging containing a set of 2 defibrillation pads. Service boxes of 10 units.

> Instructions for use

- Clean and dry the application site. Avoid contact with alcohol or other disinfectants.
- To minimize adhesion or burn problems, shave the application area, whenever possible.
- Open the package and remove the electrodes.
- Remove protective film from electrodes.
- Place the electrodes on the 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 the hydrogel and patient's skin.
- Connect the electrodes to the defibrillator or multi-function cable.
- Follow the defibrillator instructions regarding the required function.

Date: March 2023

Specification N°: ETP/110/28

> Regulatory information

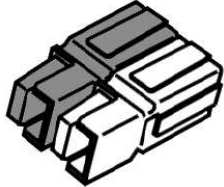
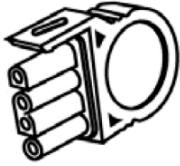


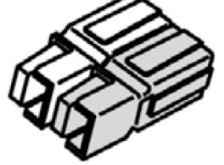
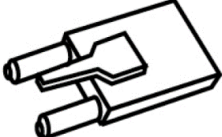

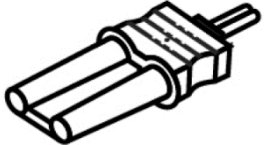
TELIC, S.A.U. guarantees that this product is in conformity with MDD of the **Directive 93/42/EEC on medical device** and that it has been manufactured following the directives of the Quality Assurance System certified as **ISO 13485**.


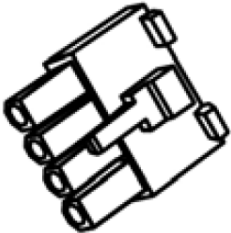

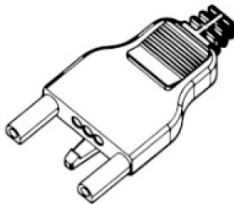
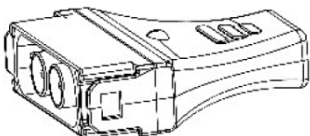
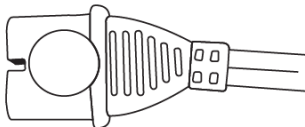
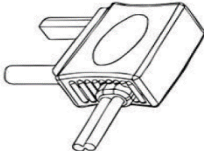
This product is classified as:

- **Class I** product according to According to Annex IX of the **Directive 93/42/EEC** , rule 1.
- GMDN code: 45806 – Multifunction cardiac electrode, adult.
- Emdn code: C020480 (Cardioversion and external desfibrillation Devices-accessories)

> ANNEX I

Conectors

Reference		Brand-Equipment-Model	Connector
Adult	Adult pre-connected		
EDC-1011	---	- Axion: DA-N-01, DA-N-02, DA-N-05, DKI-N-11	
EDC-1015	EDC-2015	Physio-Control/Medtronic: Lifepack 12, Lifepack 15, Lifepack 20e/20, Lifepack 1000 Mindray: Beneheart D3 Lecor: Cor-Res A6S	
EDC-1020	EDC-2020	- Agilent Philips: Heartstart XL, Heartstart FR2+	
EDC-1025	---	- Agilent: Heartstream XLT (cable M3507A)	
EDC-1030	---	- Progetti: Rescue Life, Rescue Sam - General electric: Responder AED	
EDC-1035	EDC-2035 EDC-2035L	- Zoll: Serie E, Serie R, Serie M - M&B: AED7000/MB7000	
EDC-1040	EDC-2040	- Nihon Kohden: Cardiolife Adapter cable JC-765V, Cardiolife Adapter cable JC-865V	
EDC-1045	EDC-2045	- Schiller: Defigard 4000, Fred Easy	

Reference		Brand-Equipment-Model	Connector
Adult	Adult pre-connected		
EDC-1050	---	- Cu Medical Systems: Paramedic CU-ER1	
EDC-1055	EDC-2055	- Nihon Kohden: Cardiolife, TEC-7731K Adapter cable JC-755V, ActiBiphasic Cardiolife TEC-5531K, ActiBiphasic Cardiolife TEK-5521K, Cardiolife Adapter cable JC-855V	
EDC-1060	EDC-2060	- HP/Philips: Heartstart XL - Agilent Philips: Heartstart FR2+	
---	EDC-2065	- Mediana: D500	
EDC-1070	EDC-2070	- Corpuls: Corpuls 3	
---	EDC-2080	- Schiller: Defigard touch 7, Fred PA-1	
---	EDC-2085	- Telefunken: HR1, FA1 - Heartreset: HR1, FA1	
EDC-1090	EDC-2090	Zoll: X Series	