Product

DORMO® -TENS

Pre-gelled electrodes for electrical stimulation

References

Electrode	DT-30	Spare:	RT-30
	DT-50		RT-50
	DT-100		RT-100

Date

July 2022

Specification N.

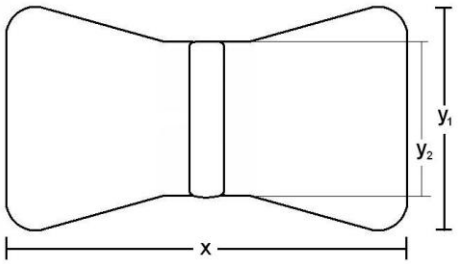
ETP/048/8

TECHNICAL SPECIFICATIONS

Materials

- Baking material:
  - DT references: conductive silicone
  - RT references: siliconized paper
- Adhesive conductive gel: Acrylic adhesive hydrogel, biocompa
- Release liner: PET
- Package: PE pouch with cardboard cover.

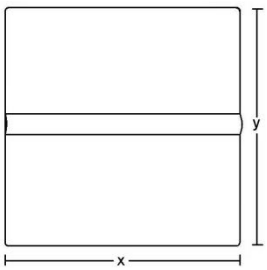
Main dimensional properties



DT-30

x = 50mm
y_1 = 29mm
y_2 = 19mm

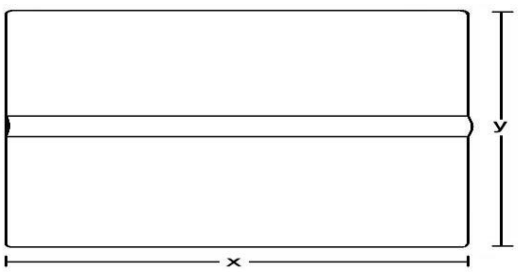
Spare:
RT-30



DT-50

x = 50mm
y = 50mm

Spare:
RT-50



DT-100

x = 100mm
y = 50mm

Spare:
RT-100

Biocompatibility

- No cytotoxic (ISO 10993-5)
- Negative intracutaneous irritation test (ISO 10993-10)
- No sensitizing (ISO 10993-10)

Conclusion: the product is biocompatible.

This product does not contain natural latex, phthalates or compounds of animal or biologic origin.

Electrical properties

- Hydrogel:
  - AC Impedance (10Hz): ≤ 2.000Ω
  - AC Impedance (100Hz): ≤ 2.000Ω
  - DC offset: ≤ 100mV
- Conductive silicon: 30-85Ω

Sterilization and expiry date

- Non sterile product.
  - Shelf life: -DT references: conductive silicone: 2 years after the manufacturing date
    - RT references: siliconized paper: 1 years after the manufacturing date

Storage and maintenance

- Keep protected from direct sunlight / the outside.
- Keep in a dry place.
- Temperature limitation: 5-40ºC.
- Single use product. No maintenance required.

Packaging

- DT-30: 6un in PE minigrip pouch. Spares 30un per pouch. Service box of 90 un.
- DT-50: 4un n PE minigrip pouch. Spares 20un per pouch. Service box of 80 un.
- DT-100 : 2un p n PE minigrip pouch. Spares 10un per pouch. Service box of 40 un.

INSTRUCTIONS FOR USE

- Verify that the package containing the electrodes or gel replacements is not damaged; in case of damages do not use the product. - Prepare the application area before use: it must always be clean, dry and free from hair. Lotions or oily skin will decrease the electrode adhesion. Avoid the use of solvents as these could cause skin irritation and reduce adherence of electrode. In case of using alcohol, make sure that this has completely dried up before applying the electrodes.
- Connect the electrodes to the electro-stimulator using adequate lead wires. Check that the leads and connections are not damaged, metal areas cannot be exposed.
- Carefully remove the electrode from protective liner by lifting a corner of electrode and slowly peel it away. Avoid touching the gel as much as possible. Do not peel the electrode by wire, pulling the wire might lead to damages in the connections.
- Stick the electrodes on the specified area: center first, then smooth down to electrode edges, press firmly. Electrodes must be placed following the instructions of the physician.
- Turn the stimulator on and adjust according to stimulator and physician's instructions for treatment. Refer to the user manual of the stimulator for further details.
- When the stimulation session is complete, turn the stimulator off and remove the electrodes.
- In case that the procedure is interrupted, check the functioning of the system again before restarting the session. Check that electrodes are conveniently adhered to the skin surface.
- Once treatment is completed, turn off the electrical stimulator.
- Lift at the edge of the electrode and carefully peel to remove electrode from the application area. A quick removal of the electrode could cause skin traumas. Do not remove electrodes by pulling the cable as damages might be produced in the product.
- Disconnect stimulator lead wires from the electrode connectors.
- Clean the electrodes after each use according to maintenance instructions. If electrodes begin to lose adhesion, replace with new electrodes
- Place the electrodes back on the protective liner and keep into the storage bag. Reseal tightly to prevent dry out.
- Disconnect the leads from the stimulation device.

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: 17191 Electrode, transcutaneous, electrical nerve stimulation.
- EMDN code: N010201 (Tens System Electrodes)