

Vaginal probe with 4 electrodes
for perineal re-education,
by electrical stimulation
and EMG biofeedback

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Description and intended use

Personal vaginal probe with 4 electrodes (2 lower + 2 lateral), for the treatment of urinary incontinence by perineal electrostimulation or EMG biofeedback. It may be used either, by the professional dealing with incontinence re-education, or directly by the patient for home care.

For perineal electrostimulation

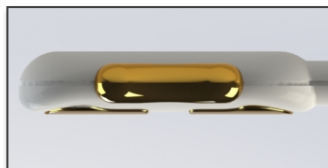
It must be used as an applied part of a certified electromedical equipment, supplying symmetrical biphasic pulses (zero mean value). It is characterised by a double circuit formed by two large flat electrodes (lower side) for the global stimulation of the pelvic floor and two "saddle-shaped" side electrodes for the undifferentiated stimulation of both the right and the left branches of the pubococcygeal muscle. For optimal utilisation, all four electrodes, with a dual-channel electrostimulator, should be used by supplying symmetrical biphasic pulses through the lower electrodes and alternated biphasic pulses through lateral electrodes. However if the operator is accustomed using probes only equipped with side electrodes and has or wants to use only one stimulation channel, they can connect the equipment to the white connectors only.

For perineal biofeedback

As an alternative to electrical stimulation, it can be used for perineal biofeedback, if connected to an electro-medical device suitable for detecting and displaying surface EMG signals (sEMG). Through the lower electrodes, it allows to detect the global EMG (Electro-Mio-Graphic) signal of the pelvic floor. Since the electromyographic detection requires a reference electrode, it is necessary to apply a trans-cutaneous adhesive electrode on the outer surface of the skin, preferably at a bony prominence (eg: iliac crest).

Patient position for use

It is suitable to treat a patient in laying position and the special design, in addition to ensuring a perfect anatomical fit with the vaginal walls, allows for easy insertion and comfortable retention by the patient.



Technical features:

- **Code:** RU-PSPH-U
- **Materials in contact with the patient:** ABS/PC + gold. Nickel-free plating technique. Latex-free.
- **Invasiveness:** vaginal orifice for a period up to 1 hour.
- **Dimensions:** insertable body 30x15 mm, Insertable body length 60 mm. Total length 120 mm.,
- **Weight:** 23g.
- **Surface of electrodes:** Lateral 3,5 cm² - Lower 4,7 cm²
- **Available colours:** White.
- **Packaging:** Supplied individually (non-sterile) with warranty label and instructions for use.
- **Cleaning and disinfection:** with water and mild soap. If required, disinfect with alcohol to and rinse with water before use. DO NOT sterilise.
- **Personal use:** It can be used for 60 sessions by the same patient (it can not be used by multiple patients)
- **Combined use:** it Must be used with any electromedical pulse generator (with CE marking) equipped with a 2 mm plug ending wires, provided that it is capable of delivering biphasic pulses at zero mean value.
- **Production quality control:** In ISO9001 - ISO13485-certified system.
- **Use and storage environment:** +5 °C to + 35 °C with R.H. between 20% and 80%.
- **CE marking:** MD class IIa according to rule 5 Annex IX 93/42/EEC - CE marking CE0051, released by IMQ, according to Annex II Directive 93/42/EEC.
- **Registration to the Repertory of Medical Devices** of the Italian Ministry of Health **1023966**, CND: U070399.



CONTRAINDICATIONS

- Vaginal or vesical infections,
- Colo-rectal or genito-urinary cancer,
- Pregnancy,
- Cardiac pace-maker holders (consult the doctor who prescribed the pace-maker),
- vesico-ureteral reflux
- hypotonic bladder