Product Manual

Transcutaneous Electrical Nerve Stimulator Accessory (Stimulation Electrode)

Model：KTR-2601L

@Thank you for choosing and using this product, and please read this manual completely!

Shenzhen Kentro Medical Electronics Co., Ltd

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1.Product Intended use

The Transcutaneous Electrical Nerve Stimulator Accessory (Stimulation Electrode) is used in conjunction with pelvic floor electrical stimulation and/or electromyographic biofeedback devices，for delivering electrical stimulation signals and transmit pelvic floor electromyographic signals. It is intended for the treatment of symptoms of stress, urge, and mixed urinary incontinence as well as fecal incontinence.

2.Contraindication

Do not use the proposed Electrodes if you have the following conditions:

- Patients with cardiac demand pacemakers.
- During pregnancy
- During Menstrual period
- Abnormalities in dermis or skin tactile sensation
- Open wounds or rashes
- Epilepsy patients
- Bladder, vaginal or rectal infection, or recent surgical scar - Probe insertion may aggravate infection
- With a history of carcinoma at the site of stimulation -Laboratory tests show that electrical stimulation may enhance cell division.

3.Size

108.5mm (length) X 32mm (diameter) (excluding the wire).

4. Performance requirements

The conduction resistance is less than 10Ω;

The insulation resistance is greater than 10MΩ;

Dielectric strength: Apply an AV 1500V, 50Hz voltage between the two conductive sheets for 1 minute. There should be no flashover and breakdown.

Shelf life: 3 years, use life is 6 months.

5. Structural composition

It is mainly composed of a plastic shell, conductive sheets and connecting wires.

6. Usage method

1) After unpacking the electrical stimulation electrode, check that the appearance of the product is intact;

2) This product is provided in a non-sterile state and must be disinfected before use. The disinfection method should be carried out as recommended in section 7;

3) Insert the disinfected electrical stimulation electrode until the limit handle adheres to the

opening;

Note: Lubricate the mental electrode surfaces and probe tip with a CE marked water-based lubricant to aid insertion and provide good electrode conductivity.

4) Connect it to the main unit through the connecting wire, and then operate according to the instructions of the main unit;

Notes: Please use the electrode with the main unit Transcutaneous Electrical Nerve Stimulator (model KTR-2702) which is manufactured by Shenzhen Kentro Medical Electronics CO.,LTD. or other CE marked stimulator whose connecting wire could be cable to match with 1.5 mm pins of the electrode.

5) After the treatment, disconnect the connection, pull out the electrical stimulation electrode, and clean and disinfect as required in section 7;

6) For the scrapping of the electrical stimulation electrode, please handle it properly in accordance with local laws and regulations.

7. Cleaning and disinfection

Soak it in 75% medical alcohol for 30 minutes before use, rinse it with clean water and dry it with a dry cloth.

After use, rinse it with clean water first, wipe it with 75% medical alcohol and dry it with a dry cloth.

Note:

1. If the device is not visually clean at the end of the cleaning, you should repeat the cleaning step.
2. The electrode is for use by the same person only.

8. Disposal

The product out of shelf life or use life should not be thrown randomly.

To dispose of packing materials, take appropriate actions in accordance with the rules and regulations in force in your area to prevent adverse ecological effects.

The expected shelf life is 3 years..

The use life of the probe is 6 months, the longest time is not more than 6 months.

9. Precautions

1) If it is found that the packaging bag is damaged before use, do not use it;

2) Avoid water contact at the tail socket of the electrical stimulation electrode;

3) The probe should avoid contacting wounds and scars during the equipment operation;

4) The electrical stimulation electrode should be in close and uniform contact with mucosa when in use;

5) Do not insert or pull out the electrical stimulation electrode when the main unit is working;

6) The electrical stimulation electrode is only for use by the same person. Do not share with other people.

7) If you have active cancer, consult with your clinician before use due to concerns for stimulation potentially spreading cancerous cells.

8) If you have any contraindications or experience any discomfort during use, please consult a doctor.

9) Caution should be used if you have suspected or diagnosed heart problems because stimulation devices can affect heart rhythm in certain circumstances.

10) Do not touch the two metal electrodes of the probe after turning the device on except for normal operation.

11) Do not use the probes with non-compatible stimulators or EMG biofeedback devices.

12) Replace the electrodes when the product deteriorates, breaks or becomes electrical.

13) When connecting and disconnecting a wire, grasp it by the molded end and gently pull. Do not pull on the wire itself.

14) If you need a manual in electronic form, please refer to the official website of Shenzhen Kentro Medical Electronics CO.,LTD..

10. Product Environmental Requirement

a) Operation environment requirements:

Environment temperature: +5℃-+40℃;

Environment humidity: 15%-93%RH;

Atmospheric environment conditions: 700hPa-1060hPa.

b) Storage and transport environment requirements:

Environment temperature: -25℃-+70℃;

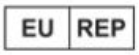
Environment humidity: 0-93%RH;

Atmospheric environment conditions: 700hPa-1060hPa.

After use, please place the clean probe in the original box for storage. Keep away from direct sunlight and keep out of the reach of children.

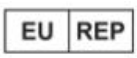
11. Symbols

	Batch code
	Manufacturer

	Date of manufacture
	Type BF applied part
	Caution
	Follow instructions for use
	Indicates the item is a medical device.
	Authorized representative
	Symbol for CE Mark.
	Unique device identifier
	"WEEE (Waste Electrical and Electronic Equipment)". The waste products should be handled legally.

12. Contact information

Shenzhen Kentro Medical Electronics CO.,LTD.
2nd Floor, No. 11, Shanzhuang Road, Xikeng Village, Yuanshan Street, Longgang District, Shenzhen City, Guangdon Province, China
[Tel]: +86(755)33825998, [Fax]: +86(755)33825996



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Am Schulzentrum 12, 41564 Kaarst, Germany