

## 1. Important instructions - please read before use!

### *Intended purpose*

#### **Use and indications**

The UROstim 2 is a medical device. It is used for transcutaneous (transcutaneous: through the skin by means of skin electrodes) and transmucosal (transmucosal: through the mucous membrane, by means of vaginal electrodes and rectal electrodes) electrical stimulation of the muscles and nerves in humans. The UROstim 2 is designed to relieve symptoms associated with overactive bladder and various forms of urinary incontinence such as stress incontinence, urge incontinence, mixed incontinence and faecal incontinence. In addition, acute and chronic pain of all kinds can be treated with the use of a pain programme.

Treatment with the UROstim 2 can be carried out in a clinical or home environment by users (doctors, therapists, nurses, etc.) and/or patients after instruction. Treatment can be administered several times a day and as long-term therapy.

#### **Target group**

##### 3.1.1. URO Stim 2 tinkamas naudoti visiems asmenims

The UROstim 2 can be used to treat all persons who are mentally and physically capable of placing the electrodes and adjusting the current strength, taking into account the contraindications, or who are capable of expressing pain or a desire to modify or end treatment in the case of non-independent treatment.

The use of the vaginal and rectal electrode accessories is only approved for adolescent and adult patients.

The product can also be used by laypeople.

They must have read and understood the instructions for use, especially the chapters "Contraindications" and "Safety instructions / warnings", before using the product for the first time. If anything is unclear, it is essential to consult a healthcare professional (or the manufacturer).

Detailed medical questions, especially regarding contraindications, may only be clarified by the attending physician or family doctor. If the product is prescribed by a doctor's prescription, the user/patient must be given instruction before their first use.

**Attention:** Incontinence or pain can indicate serious disorders in the body and must be clarified by a doctor. Even if the use of UROstim 2 is successful, this does not necessarily mean that the cause of the condition has been cured. Please also pay particular attention to the contraindications for the vaginal and rectal electrodes.

### 3. Function of the UROstim 2

#### Control elements

All settings can be made using the buttons. The display visualises the different operating states.

- 1 Display (see A-F)
- 2 Menu buttons
- 3 Modification keys
- 3A Intensity channel 1
- 3B Intensity channel 2

The 3A and 3B buttons can be used in Edit mode to change various parameters.

- 4 On/off button
- 5 Accumulator slot (rear)
- 6 Output sockets
- 7 Socket for charging cable
- 8 ON/OFF slide switch



## 6. Technical specifications and general information

### **Technical data** 3.1.2. 2-kanalų nervų stimulatorius su nepriklausomais išėjimais

2-channel nerve stimulator with separate outputs, constant current characteristic, output short-circuit circuit (AKS), 8 integrated programmes (URO standard programmes U1 through U8) and 8 freely editable user programmes (P1 through P8).

Output current	100 mA (at 1 k $\Omega$ real) 3.1.4. Išėjimo srovė 100 mA
Pulse shape	positive rectangle with negative component
Frequency range	1–120 Hz 3.1.6. Impulso dažnio ribos 1-120 Hz
Pulse width	50-600 $\mu$ s 3.1.5. Impulso plotis 50-600 $\mu$ s
Current consumption	3 mA (no-load)
Power supply	4.8 volt NiMH rechargeable battery pack (rechargeable)
Dimensions	approx. 115 mm x 65 mm x 28 mm
Weight	approx. 145 g (without accessories)
Working/operating conditions	10-40°C, 30-75% rel. humidity, 70-106 kPa air pressure
Transport/storage conditions	-10 to +55° C, 10-90% rel. humidity, 50-106 kPa air pressure

### **Classification**

The product UROstim 2 is classified as class IIa according to Annex IX of Directive 93/42/EEC or according to the Medical Devices Regulation (EU) 2017/745 on medical devices.

### **Warranty**

The legal warranty rights as per BGB apply.

### **Warranty**

The manufacturer grants a warranty of 12 months on the UROstim 2 device from the date of acceptance by the end customer.

The guarantee does not apply:

- » to wear parts and consumables such as electrodes, batteries and connection cables
- » in the event of damage resulting from improper operation
- » for defects that were already known to the customer
- » in the event of the customer's own fault

### **Description of the symbols**



Attention! The product has some non-apparent risks. Please comply with the safety precautions contained in the instructions for use!



Attention! Following the instructions for use is necessary for the safe use of the product.



Type BF application component Galvanically isolated application component with higher level of protection against an electric shock to the body, **but not directly to the heart!**



Manufacturer



Date of production



Order reference



Serial number



**Environmental protection** Do not dispose of the product in normal domestic waste. Take it to an authorised collection site for recycling. By doing this, you can help protect the environment.

**IP 22** The device provides protection against the ingress of solid foreign material with a diameter  $\geq 12.5$  mm and protection against vertically dripping water (when the device is tilted by up to  $15^\circ$ ).

**CE0482** The manufacturer affixes the CE marking to declare that the product fulfils all suitable requirements of the relevant EC directives and that a conformity assessment procedure stipulated for the same product has been successfully completed. The CE marking must be followed by the identification number of the notified body responsible for conducting the conformity assessment procedure.



Protect from moisture / keep dry

### Care and cleaning

No special care or cleaning products are required for the UROstim 2. Clean the UROstim 2 and the electrode cables as needed with a soft, lint-free cloth. Make sure that no moisture enters the inside of the device. If moisture nevertheless enters the device, it must be subjected to a technical safety control before reuse.

The vaginal/rectal electrodes can be lightly moistened with water or ultrasound gel for easier insertion.

### Scope of delivery 3.1.8.

Item	Quantity	Art. no.
UROstim 2	1 piece	101454
Cable type 5.15	2 pieces	106351
Self-adhesive electrodes 50 mm round	1 pack	282000
4.8 volt NiMH battery pack	1 piece	450781-0025
Plug-in charger	1 piece	104776
Instruction for use	1 piece	10006805
Incontinence leaflet	1 piece	451730-0051