

UROstim 2

Transcutaneous Muscle And Nerve Stimulator
For the treatment of incontinence and for uro-genital use



Instruction Manual

Art. no. 101500



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1 Introduction

Incontinence – what is it?

Incontinence is regarded as the involuntary release of either urine or faeces or both. Millions of people suffer from this disorder.

Most frequent types and causes of urinary incontinence

Where the incontinence is stress related, body activity (and subsequently also at rest) causes the release of droplets or jets of urine; it is women who are mostly affected.

Urinary incontinence is divided into three categories according to severity:

- I: Involuntary urine release caused by sudden body activities such as coughing, laughing and sneezing.
- II: Involuntary urine release caused by moderate exercise such as walking, climbing stairs or lifting activities.
- III: Involuntary urine release in the standing position without any change of pressure in the stomach area, ultimately also when lying.

Stress related incontinence is caused by a disorder in the closure system, for the most part by untrained or over-elongated pelvic floor muscles, for example as a result of difficult child-berths. For women, an age related lack of hormones can be a contributory factor.

Urge incontinence is involved, the urge to pass water often occurs when only minimal amounts of urine are present in the bladder; this can lead to premature release. The cause of urge incontinence is an over-active bladder musculature, usually triggered by the nervous system.

A mix of stress and urge incontinence occurs frequently.

Another form of urinary incontinence is the **overflow incontinence**, whereby a constriction in the bladder prevents free discharge. The reason can be, for example, an enlargement of the prostate.

Lastly, there is the **reflex incontinence**, which is the uncontrolled discharge of the bladder. It occurs, inter alia, where spinal marrow injuries are involved.

Most frequent types and causes of defecatory incontinence

Defecatory incontinence is also divided into three categories according to severity:

- Category 1: Uncontrolled flatulence
- Category 2: Uncontrolled flatulence and watery faeces
- Category 3: Uncontrolled release – also with solid faeces

Defecatory incontinence can be caused by a disorder in the muscular closure system, and can occur after childbirth, perineal lacerations or other injuries, for example after operations on the pelvic floor/closing muscles. Age-related muscular degeneration can occur.

A malfunctioning sensory system with an accompanying lack of information concerning the filling and solidity status can lead to incontinence. The reasons, inter alia, are operations for hemorrhoid disorders or nerve injuries.

Incontinence treatment

The type of treatment for incontinence depends on the causes of the condition. Treatment can involve medication, physiotherapy such as pelvic floor training or electro-stimulation or surgery. A medical examination and a diagnosis are necessary before treatment begins in all cases.

Electric current stimulation

In this type of treatment the nerves and muscles in the pelvic floor region are stimulated by means of a low level electric current. The current is applied via electrodes affixed to the skin or via probes which are positioned in the vagina or the rectum. Various types of urinary and defecatory incontinence can be treated gently and successfully. The treatment can be carried out in conjunction with other types of therapy such as pelvic floor training, medication or .

The easy to operate unit has been designed to be used in the home and the function will be explained to the patient by the physician or physiotherapist.

Electric current stimulation is also an effective aid to relieve pain and the UROstim 2 provides specific programs for the treatment of pain in the region of the lower part of the abdomen.

2 Purpose and safety

Purpose for use

The UROstim 2 is a medical product. It serves for the transcutaneous and transmucosal electric stimulation of muscles and nerves in order to reduce discomfort and pain associated with incontinence.

Safe use of the instrument

Please read carefully the operating instructions before using the device.

- The UROstim 2 is only to be used for stimulation purposes on one patient at one time.
- Only use the UROstim 2 with original accessories. The size of the electrodes should to be not less than 2 cm².
- The electrodes should be positioned in such ways that the current flow will not cross through the heart.
- Keep the UROstim 2 away from water or other liquids. Do not drop the UROstim 2, do not use it inappropriately or expose it to extreme temperatures or high levels of humidity (not less than 10 °C or more than 40 °C or a relative humidity of more than 90 %). Do not use the UROstim 2 if it is not working properly or if it has been damaged in any way.
- Be careful when using the UROstim 2 near or on children. Keep the unit away from children.
- Always store the UROstim 2 in its case to protect it from damage and dust.
- To avoid reciprocal interference, the UROstim 2 should not be operated in the vicinity of other electronic devices. If this is not possible, the various unit functions should be closely monitored during operation so that proper use in accordance with the regulations is ensured.
- The simultaneous connection to the patient of a high frequency surgical unit can lead to burning under the electrodes or around the probe. Operating close (for example 1m) to short wave and microwave units or mobile telephone systems can cause fluctuations in the output values of the electric current stimulation unit.
- Do not use the machine during the simultaneous operation of other machines, when driving or when asleep.

Contra-indication

UROstim 2 should not be used without having checked with a physician if the following applies to you:

- Patients with electronic implants such as heart pacemakers, defibrillators or pumps,
- Patients with cardiac rhythm disorders,
- During pregnancy,
- Patients subject to seizures,
- Patients with skin disorders in the vicinity of the electrodes,
- Patients with malignant diseases in the region of application.

Possible side effects

- Pain caused by the stimulation: The stimulation can be perceived as uncomfortable/painful if the electric current is too intensive or if the electrodes have been positioned unfavorably. Unpleasant side effects can be avoided by adjusting the intensity, using the sensitivity program and the possible re-positioning of the electrodes.
- Too intensive treatment can cause an increase in the pain levels, the occurrence of which can be avoided by beginning treatment sessions with low level electric current and not exceeding a treatment period of 30 minutes.
- Skin intolerance which can result from the electrodes, the electrode gel or the electric current impulses. The physician should be consulted in cases of reddening, burning, itching or blistering under the electrodes or in the vicinity of the electrodes. Slight skin reddening of short duration in the area of the electrodes following stimulation is quite normal because blood circulation has been improved by the effects of the stimulation.

Warning

- A medical examination and a diagnosis are necessary before treatment begins.
- Please also consider the contra-indications of vaginal and anal probes.

3 Description of the UROstim 2 unit

1. Display
2. Menu keys (Program choice)
3. Keys to enter the programming mode
4. Modification keys to adjust parameters and to modify the intensity
5. ON/OFF key
6. Output sockets for the cables
7. Output socket for the battery charger
8. ON/OFF commutator



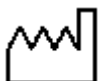
4 Description of the symbols



Please note: First read the operating instructions manual !



BF type application part. Protection against electric shocks.



The production year is followed by this symbol.



The article or order number of the product follows this symbol.



The serial number of the product follows this symbol.



This equipment is marked with the recycling symbol. It means that at the end of the working life of the equipment you must dispose of it separately at an appropriate collection point and not place it in the normal domestic unsorted waste disposal. In the interests of environmental protection please observe those laws and regulations of your country which relate to rechargeable battery disposal.



This equipment include a rechargeable battery. You must dispose of it separately at an appropriate collection point and not place it in the normal domestic unsorted waste disposal. In the interests of environmental protection please observe those laws and regulations of your country which relate to accumulator disposal.



Conformation with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

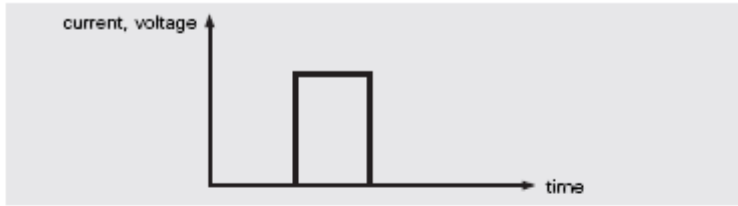
5 Technical Specification

Two-channel nerve and muscle stimulator with electrically insulated channels, constant current characteristic, output short circuit control element (AKS), 10 integrated pre-set programs (U1 – U10) and 10 user programs (P1 – P10).

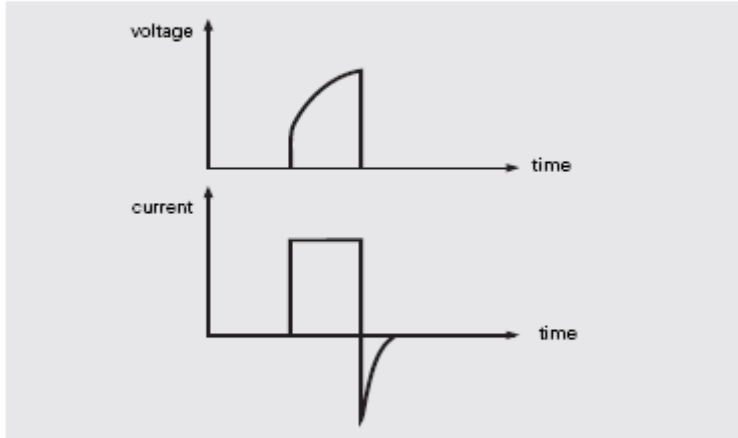
- Output current : 100mA (with an actual resistor of 1k Ω)
- Frequency range: 0.5-120 Hz
- Impulse width: 50-400 μ s
- Nominal current: 15 mA
- Power supply: integrated rechargeable accumulators Ni-mH 4.8 V
- Dimensions: 10.9 x 6 x 2.5 cm
- Weight approx. 150 g

Pulse forms

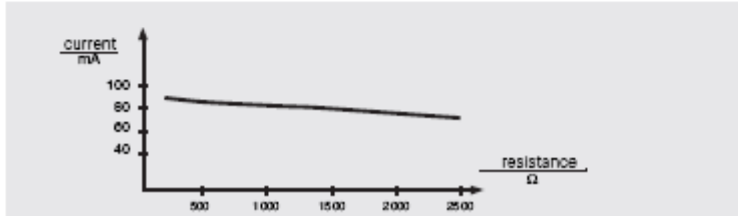
**Pulse form:
with 1kΩ load real**



**With ANSI/AAMI
standard load**



**Change in output current
depending on load**



6 Overview of programs

U1 Frequency: 15 Hz
Stimulation of Pulse width: 150 μs
nervous tibialis posterior Time: 20 min

U2 Frequency: 14 Hz
Stimulation of Pulse width: 210 μs
nervous tibialis posterior Time: 20 min

U3 Frequency: 10 Hz
Urinary and Anal Incontinence Pulse width: 200 μs
Stimulation of Time: 20 min
nervous tibialis posterior

U4 Frequency: 50 Hz
Stimulation of Pulse width: 200 μs
nervous tibialis posterior Time: 20 min

U5 Pain Program	Frequency: 80 Hz Pulse width: 200 μ s Time: 20 min
U 6 Vesical instability Treatment with a probe	Frequency: 10 Hz Pulse width: 300 μ s Time: 20 min
U 7 Stress Incontinence Treatment with a probe	Frequency: 60 Hz Pulse width: 250 μ s Rising ramp: 1 s, work phase: 7 s, Falling ramp: 1 s, pause: 14 s Time: 20 min
U 8 Mixed Incontinence Treatment with a probe	Frequency: 20 Hz Pulse width: 300 μ s Rising ramp: 1 s, work phase: 8 s, Falling ramp: 1 s, pause: 10 s Time: 20 min
U 9 Anal incontinence Parameters after ORALIA protocole	Frequency: 10 Hz Pulse width: 600 μ s Time: 20 min
U 10 Muscle Stimulation	Frequency: 50 Hz Pulse width: 300 μ s Rising ramp: 1 s, work phase: 4 s, Falling ramp: 1 s, pause: 6 s Time: 20 min

All programs offers the possibility to change the parameters for USER programs with own settings.

P1, P6, P7	Frequency: 0,5 Hz to 120 Hz Pulse width: 60 μ s to 300 μ s Time: 1 Min to 99 Min or timer OFF
P2, P3, P4, P5	Frequency: 10 Hz to 120 Hz Pulse width: 60 μ s to 300 μ s Time: 1 Min to 99 Min or timer OFF

7 Operating the UROstim 2

Using vaginal or anal probes

- Check if the intensity is set on 0.
- Connect the cable of the probe to the UROstim 2 on the socket on the upper side of the device.
- Insert the probe vaginal or rectal depending on the treatment.
- Switch on the UROstim 2.

Using self-adhesive or rubber electrodes

- Check if the intensity is set on 0.
- Connect the electrodes with the cable(s) (always 2 electrodes per cable).
- Connect the cables to the UROstim 2 on the socket on the upper side of the device.
- Place the electrodes on the desired area.
- Switch on the UROstim 2.

Connecting cables and electrodes/probe

Connect the electrodes or the probe with the cable(s) (always 2 electrodes per cable or one probe per cable). Connect the cable(s) to the UROstim 2 (no. 6). Place the electrodes on the desired area (see examples on chapter electrode placement) or introduce the probe into the vagina or anus.

Switching-ON the UROstim 2

Switch the commutator (no. 8) to the ON position. Switch on the TENS unit by pressing the ● key (no. 5). The program shown on the display is the last which was used during the previous session. If the display shows a key symbol on the upper left side, the UROstim 2 has previously interlocked a specific program (see chapter locking the key pad).

Selecting a program



Select a program by pressing the **P** key. To scroll through the programs, press the **P** key as often as necessary until you have selected the program of your choice. To return to the previous program, press one of the **▽** keys. Selecting a program is only possible if the keypad has not been locked on one specific program (see chapter locking the key pad).

Setting the intensity

Start the stimulation by increasing the intensity with the **▲** key of the channel(s) connected to the electrodes/probe.



- ▲ key to increase the intensity
- ▽ key to decrease the intensity

The intensity of each channel is displayed on the screen. The intensity can be set between 0 and 100 mA. By keeping the intensity keys pressed, the intensity will increase/decrease more rapidly.

Terminating the stimulation

You can terminate the stimulation at any time by pressing the **P** key. When the therapy time is completed the stimulation terminates automatically. If you press the ● key the stimulation stops and the UROstim 2 switches off.

Locking the key pad

Choose the desired program by pressing the **P** key (see chapter choosing a program). Press and hold for 3 seconds the **P** key and the right ▼ keys to lock the stimulator on the chosen program. The UROstim 2 can now only be used with the chosen program. A key symbol appears on the display adjacent to the program number. All keys except the intensity and the ON/OFF keys are locked into this mode. Use the same key combination to unlock the TENS unit.

Switching-OFF the timer

You can use the UROstim 2 with or without timer. All programs run for 20 minutes. Press and hold for 3 seconds the **E** key and the left ▼ key. The total therapy time appears on the display. Press the **E** key to switch off the timer. The symbol “---“ appears on the display. Press the “●“ key to save the changes.

Creating free programs (P1 – P10 only)



Choose one program between P1 and P10. Press the **E** key to access the programming mode. The parameters to be changed are flashing. You can modify them by pressing the ▲ and ▼ keys. Switch to the next parameter by pressing the **E** key. The frequency, the pulse width and the time can be modified in the free programs.

Switching-OFF the stimulator

Press the ● key to turn OFF the UROstim 2. If the battery level is too low or if the stimulator has not been used for the previous 2 minutes, it turns off automatically.

Charging the battery

The battery level is shown on the display with a battery symbol with 4 lines. If the battery level is too low, the stimulator switches off automatically and cannot be turned on again. The battery then needs to be re-charged.

- Switch the commutator to the OFF position (no. 8)
- Connect the charger with the UROstim 2 (socket no. 7)
- Connect the charger to the mains circuit. The diode on the charger illuminates in red.
- Charge the TENS unit until the diode on the charger illuminates in green.
- The battery is fully charged if the light on the charger appears in green.

Important! Do not forget to switch the commutator ON again after charging.
Do not charge the UROstim for more than 4 hours.

8 Delivery content

Ref. no.	Description
101453	UROstim 2
106351	2x cables type 5.15
283400	STIMEX self-adhesive electrodes 50x50 mm
	Instruction manual
	Transportation bag

The UROstim 2 may only be used together with accessories mentioned in the chapter „Accessories“



9 General information

Settings, modifications and repairs

The manufacturer is only responsible for the safety and performance of the UROstim 2 when settings, adjustments, alterations and repairs are carried out by authorized persons and when the UROstim 2 is used in accordance with the operating instructions.

Guarantee

We give a guarantee of 1 year from the date of purchase on the UROstim 2. This guarantee does not cover accessories such as cables, electrodes, battery, probes, etc.

Maintenance and cleaning

No special cleaning or care agents are required for the UROstim 2. Clean the unit with a soft, fluff-free cloth. Please ensure that no moisture permeates the unit. If moisture does permeate the unit, a technical check must be carried out before re-use.

Classification of the device

In accordance with the Law on Medical Devices, the UROstim 2 is classified as being a Class IIa medical device.

Technical check

We recommend a technical check on the UROstim 2 every 24 months. This includes:

1. Confirming that user instructions have been included in the accompanying documentation.
2. Checking the equipment for completeness.
3. Visual check:
 - for mechanical damage
 - for damage to all cables and sockets
4. Functional Safety:
 - Checking the output signals with a load resistance of 1 k Ω real current and voltage
 - Checking the frequency
 - Checking the pulse width

These technical checks may only be carried out by suitably qualified persons. The results must be documented with the date and name of the person carrying out the check.

10 Accessories

The UROstim 2 may only be used together with all accessories referred to in this chapter. The manufacturer cannot guarantee the safety of the UROstim 2 if it is not used with original accessories.

Stimex self-adhesive electrodes

Art. No.	Description	Quantity
281000	Stimex 32 mm round	4
282000	Stimex 50 mm round	4
283400	Stimex 50x50 mm	4
281032	Stimex 50x50 mm	20
283600	Stimex 50x90 mm	2
281007	Stimex 50x90 mm	4
283000	Stimex 50x130 mm	2
283100	Stimex 80x130 mm	2
281027	Stimex sensitive 50x50 mm	4

STIMEX



Stimex FLOWER POWER self-adhesive electrodes

Art. No.	Description	Quantity
281042	Flower Power 50 mm round	4
281035	Flower Power 50x50 mm	4
281040	Flower Power 50x90 mm	4



Silicone electrodes (to be used with contact gel)

Art. No.	Size	Quantity
107090	20 mm round	2
107060	25 mm round	2
107075	40x28 mm	2
107035	56x28 mm	2
107020	75x30 mm	2
107055	90x35 mm	2
107011	38x45 mm	2
107010	48x48 mm	2
107050	70x65 mm	2
107070	70x140 mm	2
108000	contact gel (tube, 60 g)	1



Contact gel for silicone electrodes

Item no. 108000 Tube, 60 g

Vaginal and anal probes

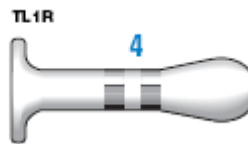
Art. Nr. 103045

Anal probe 12C



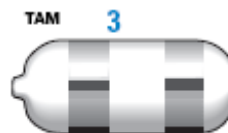
Art. Nr. 103044

Anal probe TL1R



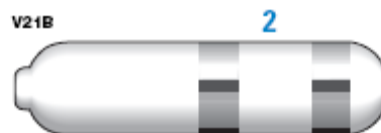
Art. Nr. 103043

Vaginal probe TAM



Art. Nr. 103046

Vaginal probe V21B



Art. Nr. 103042

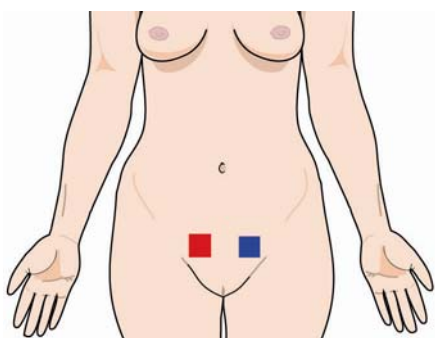
Vaginal probe VATT



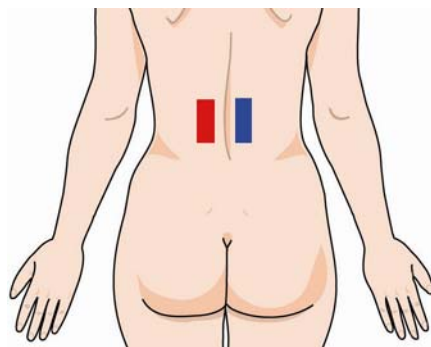
Contact gel for vaginal and anal probes electrodes (item no. 108030) Tube, 60 g

11 Examples of electrode positioning

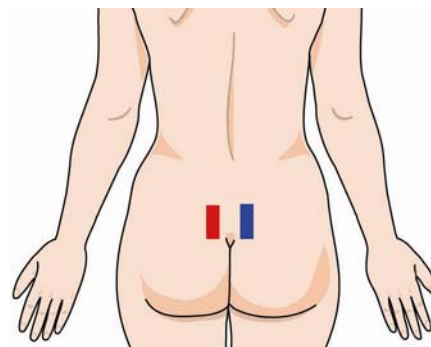
The presented electrode placement are examples only.



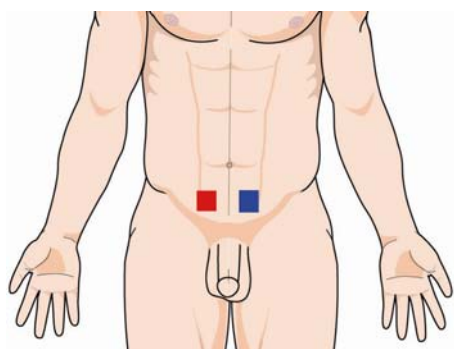
No 1 for women



No 2



No 3



No 1 for men

Premenstrual syndrome and dysmenorrhea:
Dysuria / Interstitial Cystitis:
Vestibulodynia:

No. 1 and 2
No. 1 and 2
No. 3

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