

# UROstim

Transcutaneous Muscle And Nerve Stimulator



Instruction Manual

Art. no. 101472

# Contents

1	Introduction .....	3
	Incontinence – what is it? .....	3
	Most frequent types and causes of urinary incontinence.....	3
	Most frequent types and causes of defecatory incontinence.....	3
	Incontinence treatment .....	4
	Electric current stimulation.....	4
2	Purpose and safety .....	4
	Purpose for use .....	4
	Safe use of the instrument.....	4
	Contra-indication.....	4
	Possible side effects .....	5
	Warning .....	5
3	Description of the UROstim unit.....	5
4	Overview of programs .....	6
5	Operating the device .....	7
	Power mode / changing battery .....	7
	Using vaginal or anal probes .....	7
	Using self-adhesive or rubber electrodes .....	7
	Switching ON the UROstim .....	8
	Selecting a program.....	8
	Editing the parameters.....	8
	Setting the intensity .....	8
	Stopping the stimulation .....	9
	Locking the key pad.....	9
	Switching OFF the device.....	9
6	Creating a user program (own settings).....	9
7	Parameters checking mode .....	10
8	Delivery content .....	10
9	General information.....	11
	Description of the symbols.....	11
	Technical Specifications .....	11
	Settings, modifications and repairs.....	12
	Guarantee.....	12
	Maintenance and cleaning.....	12
	Classification of the device .....	12
	Technical check .....	13
10	Accessories.....	13
	Stimex self-adhesive electrodes .....	13
	Stimex FLOWER POWER self-adhesive electrodes .....	13
	Silicone electrodes (to be used with contact gel).....	14
	Contact gel for silicone electrodes.....	14
	Vaginal and anal probes .....	14

## 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 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 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 is only to be used for stimulation purposes on one patient at one time.
- Only use the UROstim with original accessories. The size of the electrodes should be not less than 2 cm<sup>2</sup>.
- The electrodes should be positioned in such ways that the current flow will not cross through the heart.
- Keep the UROstim away from water or other liquids. Do not drop the UROstim, 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 if it is not working properly or if it has been damaged in any way.
- Be careful when using the UROstim near or on children. Keep the unit away from children.
- Always store the UROstim in its case to protect it from damage and dust.
- To avoid reciprocal interference, the UROstim 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 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

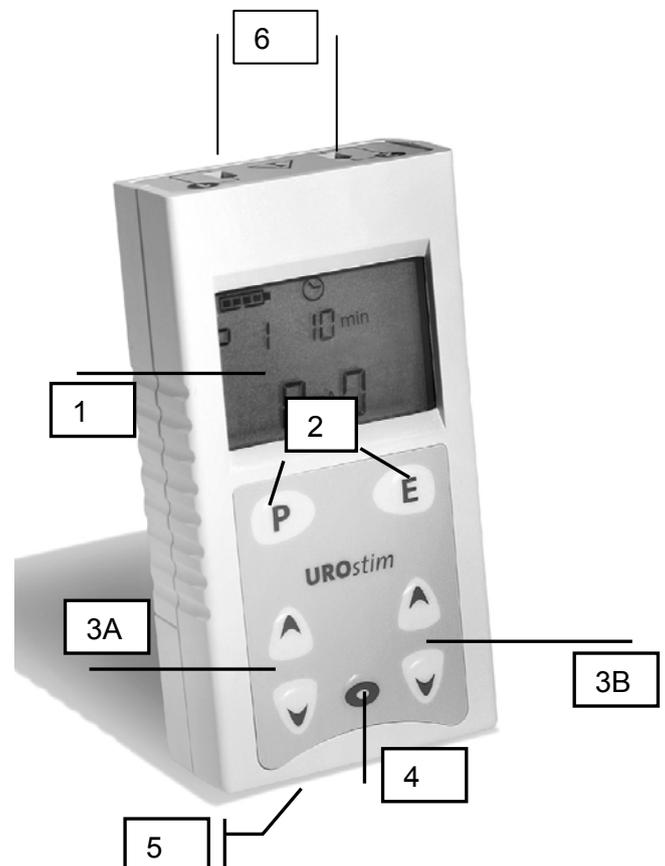
- Pain caused by the stimulation: The stimulation can be perceived as uncomfortable/painful if the electric current is too intensive or if the electrodes have been positioned unfavorably. Unpleasant side effects can be avoided by adjusting the intensity, using the sensitivity program and the possible 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

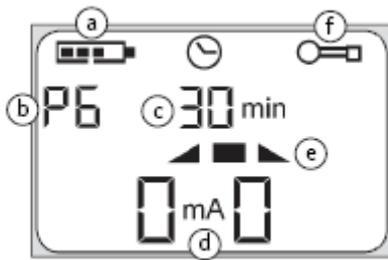
- A medical examination and a diagnosis are necessary before treatment begins.
- Please also consider the contra-indications of vaginal and anal probes.

### 3 Description of the UROstim unit

1. Display
2. Menu key
3. Keys to adjust the intensities of all channels
  - ▲ Increasing intensity
  - ▼ Decreasing intensity
  - 3 A to set the intensity of channel 1
  - 3 B to set the intensity of channel 2
4. ON/OFF key
5. Battery compartment
6. Output sockets for the cables



## Description of the display:



- a. Battery level
- b. Program in use
- c. Stimulation time
- d. Intensity level
- e. Electrical current form
- f. Key symbol for locked unit

Display of electrical current form:

- Pause
- ▲ Rising ramp
- Work phase
- ▼ Falling ramp

## 4 Overview of programs

<p>Program 1 <b>Urge Incontinence</b></p>	<p>Frequency: 10 Hz Pulse width: 220 <math>\mu</math>s Time: 10 min</p>
<p>Program 2 <b>Stress Incontinence</b></p>	<p>Frequency: 50 Hz Pulse width: 220 <math>\mu</math>s Muscle stimulation: 2 s ramp up, 5 s work phase, 1 s ramp down, 15 s pause Time: 15 min</p>
<p>Program 3 <b>Mixed Incontinence</b></p>	<p>Frequency: 20 Hz Pulse width: 250 <math>\mu</math>s Muscle Stimulation: 2 s ramp up, 5 s work, 1 s ramp down, 15 s pause Time: 12 min</p>
<p>Program 4 <b>Anal Incontinence</b></p>	<p>Frequency: 20 Hz Pulse width: 220 <math>\mu</math>s Muscle Stimulation: 2 s ramp up, 5 s work, 1 s ramp down, 15 s pause Time: 12 min</p>
<p>Program 5 <b>Sensitive program for anal and urinary incontinence</b></p>	<p>Frequency: 25 Hz Pulse width: 130 <math>\mu</math>s Muscle Stimulation: 3 s ramp up, 5 s work, 1 s ramp down, 15 s pause Time: 12 min</p>

Program 6  
**Pain program**      Frequency: 100 Hz  
Pulse width: 180 µs  
Time: 30 min

Program 7  
**Acupuncture type stimulation**      Frequency: 8 Hz  
Pulse width: 200 µs  
Time: 30 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 µs to 300 µs  
Time: 1 Min to 99 Min or timer OFF

P2, P3, P4, P5      Frequency: 10 Hz to 120 Hz  
Pulse width: 60 µs to 300 µs  
Time: 1 Min to 99 Min or timer OFF

## 5 Operating the device

### Power mode / changing battery

Open the battery compartment, place the 9V battery in the compartment (check polarity) and close the compartment. The battery symbol displays battery level. A completely charged battery shows all bars in the symbol . The fewer the bar symbols, the lower the battery charge level.

This symbol  indicates the need to change batteries.  
The device is ready for battery mode operations.

**Important!** If you are using rechargeable batteries the mains circuit adapter will not recharge the rechargeable batteries. If you are not using UROstim for a longer period please remove the batteries from the device.

Please dispose of the batteries separately at an appropriate collection point and not deposit in the normal domestic unsorted waste disposal. In the interests of environmental protection please observe those laws and regulations of your country.

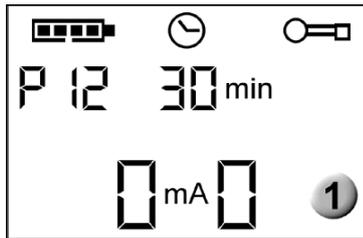
### Using vaginal or anal probes

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

### 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 on the socket on the upper side of the device.
- Place the electrodes on the desired area.
- Switch on the UROstim.

## Switching ON the UROstim



Press the ● key to start the device.  
The program shown on the display is the last program used.  
The device automatically switches off after 2 minutes of disuse.

## Selecting a program

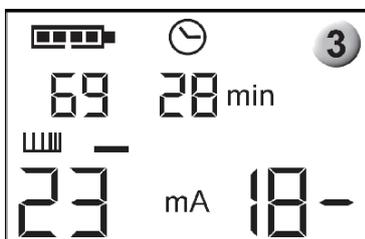


Select a program by pressing the **P** key. To scroll through the programs, press the **P** key as often as necessary until you have selected the program of your choice. The user programs U1 to U7 are displayed after P7. Once you have selected the last program you automatically get back to P1. If you have saved user programs into the UROstim you will find them after the last program (P7).

## Editing the parameters

You can check the parameters of each program by pressing the **E** key. The display first indicates the frequency. If you press the **E** key again the display indicates the pulse width. Press the **E** key one more time to exit this mode.

## Setting the intensity



Start the stimulation by increasing the intensity with the ▲ key of the connected channel(s).

▲ key to increase the intensity

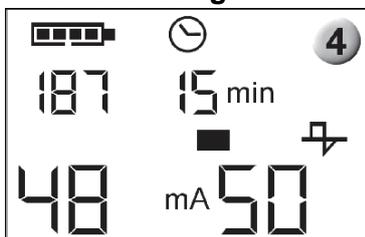
▼ key to decrease the intensity

The intensity can be set in steps of 0.5 mA. Each side bar indicates half a mA.

The intensity of each channel is displayed on the screen.

The intensity can be set between 0 and 60 mA.

## Electrode recognition for enhanced safety



The UROstim constantly monitors the correct connection of electrodes/probe and cables.

The UROstim automatically stops the stimulation if:

- an electrode detaches itself from the skin
- electrodes are not attached correctly in pairs
- electrodes are not conductive enough
- the probe is not inserted correctly
- the connection between the cables and the electrodes is interrupted
- the connection between cables of electrodes/probe and device is interrupted

The intensity cannot be set on more than 8 mA and then returns to 0. This is also indicated by a short acoustic signal.

### Intensity settings in fixed steps for enhanced safety

By keeping the intensity keys pressed, the intensity will increase/decrease more rapidly. UROstim indicates that you have reached 20 mA by an acoustic signal. For safety manner the UROstim will further stop to increase the intensity once you have reached 20 mA, 30 mA, 40 mA, 50 mA and 60 mA. You have to let go the intensity key and press it again if you want to set the intensity to a level higher than the one described above.

### Setting the intensity by using P2, P3, P4, P5

You have selected P2, P3, P4 or P5.

If you press the ▲ key while your program is running the ramp up or the pause phase UROstim will automatically skip the ramp up or the pause phase and switch to the work phase.

Only if you do not press any key for 4 seconds the stimulation will start normally.

If you press the ▼ key the program is not interrupted.

### Stopping the stimulation

You can stop the stimulation at any time by pressing the P key or the ● key. When the therapy time is completed, the stimulation stops automatically. The end of stimulation is indicated by a double acoustic signal.

### Locking the key pad

Choose the desired program by pressing the P key (see chapter Selecting a program).

Press and hold for 3 seconds the left ▼ key and the P key to lock the UROstim on the chosen program. The UROstim can now only be used with the chosen program. A key symbol appears on the right side of the display. All keys except the intensity and the ON/OFF keys are locked into this mode. Use the same key combination to unlock the UROstim.

### Switching OFF the device

Press the ● key to switch off the device.

The device switches OFF automatically if:

- the power supply is too low (battery mode only)
- the device has not been used for 2 minutes.

This is indicated by an acoustic signal.

## 6 Creating a user program (own settings)

All pre-set programs (Px) can be changed with own settings parameters in user programs (Ux).

**P1, P6, P7**                      Frequency: 0,5 Hz to 120 Hz  
   Pulse width: 60 µs to 300 µs  
   Time: 1 Min to 99 Min or timer OFF

**P2, P3, P4, P5**                Frequency: 10 Hz to 120 Hz  
   Pulse width: 60 µs to 300 µs  
   Time: 1 Min to 99 Min or timer OFF

Please check that the key pad is not locked. Switch OFF the UROstim. Press and hold the E key and simultaneously turn ON the UROstim with the ● key to enter the user setting mode. The user mode is indicated by an E (for Editing) on the display. Press the P key to select the pre-set or USER program which you want to change (figure 6). Press the E key to get to the parameters to be changed. This is indicated by an E before the program number (figure 7). Press the ▲ and ▼ keys of any channel to change the frequency (figure 7). Press E again to go to the next parameter. Press the ▲ and ▼ keys of any channel to change the pulse width (figure 8). Press E again to go to the next parameter. Press the ▲ and ▼ keys of any channel to change the therapy

time (figure 9). Press **E** after changing the last parameter to save the changes in the user program. This is indicated by a U in front of the program number. The selected parameters are the same for both channels. Press **P** at any time if you want to abort the settings. The changed parameters up to that point are then not saved.

### Setting the timer OFF

If you want to set OFF the timer then press the ▼ key down to 0. This is indicated by the word “OFF” on the display (figure 10). If you set the timer OFF the display will first show “- -” and count the stimulation time from 1 to 99 once you have started the therapy session. In this case the stimulation is not ending at any time.

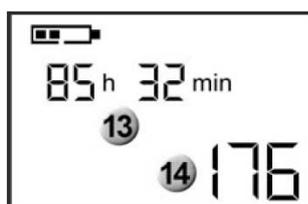
### Deleting all user programs

To delete all the user programs first switch the device OFF.

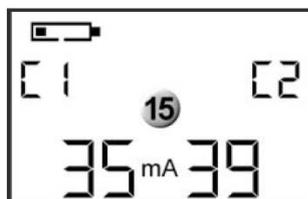
Simultaneously press the **P** key and the left ▼ key, hold them and turn ON the device. This is indicated by the word “Null” on the display.

## 7 Parameters checking mode

UROstim saves some information about the treatment: the total duration of stimulation (13) the number of ON/OFF switches (14), and the average intensity of each channel (15). Only intensity with more than 4 mA are registered for the statistics.



Simultaneously press the left ▼ key and the **E** key to enter the parameters checking mode. The display indicates the total duration of stimulation in hours and minutes on the upper part of the display and the number of ON/OFF switches on the lower part of the display. If you press the **E** key the display then indicates the average intensity of channel 1 on the left part of the display and the average intensity of channel 2 on the right part of the display.



### Deleting the stored parameters

To delete all the stored parameters first switch the device OFF.

Simultaneously press the **P** key and the left ▼ key, hold them and turn ON the device. This is indicated by the word “Null” on the display. Please note that all user programs are then also deleted.

## 8 Delivery content

Ref. no.	Article Description	Quantity
101453	UROstim	1
106351	Electrode cables 5.15	2
602000	9 V battery	1
283400	STIMEX self-adhesive electrodes 50x50 mm	1
	Video Box	1
	Instruction manual	1

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

## 9 General information

### 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.

REF

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

SN

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.

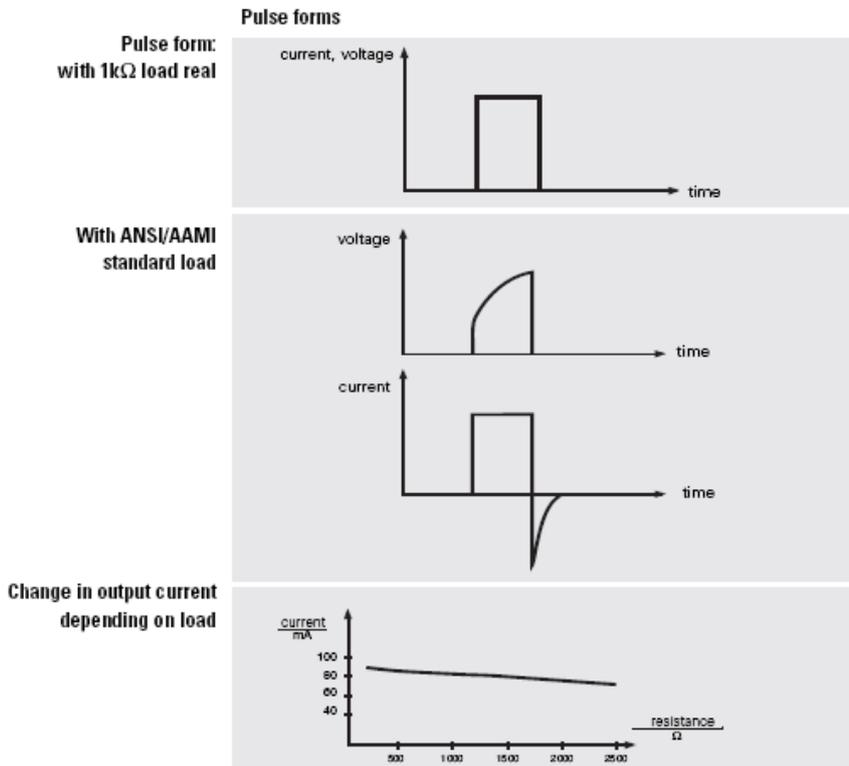
CE | 0197

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

### Technical Specifications

Two-channel nerve and muscle stimulator with electrically insulated channels, constant current characteristic, output short circuit control element (AKS), 7 integrated pre-set programs and 7 user programs.

Output current:	60mA (with an actual resistor of 1k $\Omega$ )
Frequency range:	0.5-120 Hz
Impulse width:	60-300 $\mu$ s
Power supply:	9 V battery
Dimensions:	11.5 x 6 x 3 cm
Weight:	approx. 130 g (without accessories)



## Settings, modifications and repairs

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

## Guarantee

We give a guarantee of 1 year from the date of purchase on the UROstim. 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. 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 is classified as being a Class IIa medical device.

## Technical check

We recommend a technical check on the UROstim 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 $\Omega$  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 may only be used together with all accessories referred to in this chapter. The manufacturer cannot guarantee the safety of the UROstim 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 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

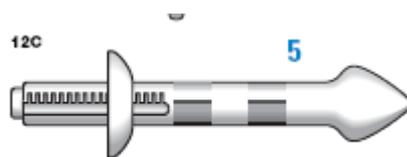


### Contact gel for silicone electrodes

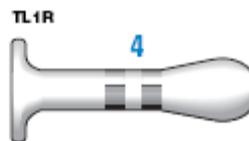
Item no. 108000) Tube, 60 g

### 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

Electrode placement

Manufacturer  
Pierenkemper GmbH  
Hoersheimer Eck 19  
35578 Wetzlar  
Germany

Distributor  
schwa-medico GmbH  
Wetzlarer Str. 41-43  
35630 Ehringshausen  
Germany  
Email: [export@schwa-medico.de](mailto:export@schwa-medico.de)  
[www.schwa-medico.com](http://www.schwa-medico.com)

