INSTRUCTION MANUAL

STIM-PRO I-2000

axion GmbH

Mollenbachstr. 13

71229 Leonberg

Germany

CE 2460

INTRODUCTION

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The STIM-PRO I-2000 is a medical device. The primary purpose is to stimulate muscles and nerves of the human body electrically through skin (transcutaneous) and mucous membranes (transmucosal) in order to strengthen the immune system and to alleviate incontinence problems.

What is incontinence?

Incontinence is defined as the involuntary loss of urine, faeces or both.

Causes and forms of incontinence

Stress incontinence – This is the most common type of incontinence that usually affects women. At first, it only occurs during physical exertion and then later at rest, causing a drop-wise or radiant loss of urine. Often the pelvic floor muscles relax. This results in a lowering of the organs of the small pelvis. The resulting increased internal abdominal pressure can no longer reach the urethra as a closing pressure, but it can still reach the bladder at full strength.

Stress incontinence is divided into three degrees of severity:

Involuntary urination

1st degree: in case of sudden, heavy stress, e. g. coughing, laughing or sneezing

2nd degree: for light physical strain, e. g. when walking, climbing stairs or lifting things

3rd degree: in the case of unstressed movements, standing or lastly lying down

Urge incontinence (overactive bladder) - An overactive bladder is a sudden, unsuppressable urge to urinate, which forces the person affected to immediately go to a toilet.

Mixed incontinence - This is a mixture of urgency and stress incontinence.

Anal incontinence - Anal incontinence can be caused by an impairment of the sphincter muscle. It occurs after surgeries of the sphincter muscle, such as haemorrhodial disease or births with perineal rupture, etc. The trigger can also be an age-related muscle decline.

Anal incontinence is also classified into 3 severity levels:

Involuntary loss of

1st degree: flatulence

2nd degree: flatulence and/or liquid faeces

3rd degree: solid faeces

The treatment of incontinence with stimulation current

Stimulation current therapy is suitable for the treatment of stress incontinence, overactive bladder or urge incontinence as well as its hybrid forms and muscular forms of anal incontinence. With this type of therapy, the nerves and muscles in the pelvic floor area are stimulated by a light current. The current is usually applied via a vaginal or rectal probe.

GENERAL DESCRIPTION

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The device is a battery-operated pulse generator that gives electrical impulses to the body via electrodes and thus stimulates the nerves and muscles. The microprocessor of the STIM-PRO I-2000 generates electrical pulses whose pulse duration and frequency are preset.

SAFETY INFORMATION

- Read the instructions carefully before using the device.
- Keep this device out of the reach of children.
- Do not place electrodes in the area of the carotid arteries!
- Do not place electrodes on the front of the throat!
- Be careful with stimulation over metal implants.
- Do not place electrodes above your heart.
- Do not use electrodes on open wounds / injuries.
- Do not use if you have fever.
- Do not use if you have arrhythmia.
- Do not use if you have epilepsy.
- Never use the device when you are operating machines.
- Never use near explosive or flammable gases.
- Always TURN OFF the device before placing / removing electrodes.
- Do not use on overflow incontinence
- Do not use for cervical cancer
- Do not use if there are metal implants in the area of application
- Do not use in case of severe local inflammation

- Do not use when using a metal containing Intrauterine pessary (contraceptive device)
- Do not use in case of severe sensory disturbances in the area of application.
- Do not use for higher level haemorrhoid disease (when using a rectal probe)
- For users of pacemakers and during pregnancy, the device must only be used under medical supervision (!).
- In case of overflow incontinence, the unit should not be used.
- The device must not be used in case of cervical cancer, fistulas, fistulas, or the inversion of uterus / vagina.
- The device must not be used in case of infections in the vaginal or rectal area.
- For hygiene reasons, the probe may only be used by one person.
- The unit must not be used if the pelvic floor is completely denervated.

SCOPE OF DELIVERY

Each STIM-PRO I-2000 is fully equipped with the following standard equipment:

- **1 piece** **EMS pelvic floor trainer**
- **1 piece** **Electrode connecting cable**
- **1 piece** **Storage case**
- **2 pieces** **AA batteries 1.5V**
- **1 piece** **Instructions manual**

Depending on the variant

- **1 piece** **Vaginal or rectal probe or**
- **4 pieces** **self-adhesive TENS machine pads**

STARTING THE STIMULATION

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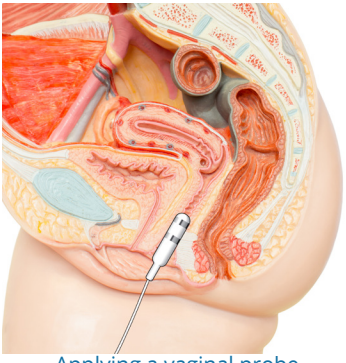
The pelvic floor can be stimulated with either a rectal or vaginal probe, or with externally attached self-adhesive electrodes. Both applications lead to the desired effect. However, application with probes is more efficient and is therefore recommended.

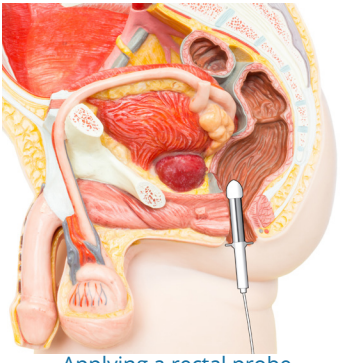
a) with a probe

Connecting the cable
Remove the probe from its packaging and clean it under running water. Connect the cable to the device and the vaginal / rectal probe.

Insert the probe
If necessary, go to the toilet before use. The application should be done lying down with the knees slightly tightened. **Always apply contact gel to the probe before insertion** to ensure optimum transmission of impulses. Insert the probe slowly and gently into the vagina or anus.

Against stress incontinence, women can use both a vaginal and a rectal probe. A vaginal probe is recommended for the treatment of overactive bladder and urge incontinence.


Applying a vaginal probe


Applying a rectal probe

b) with self-adhesive TENS machine pads

Connecting the cable

Take the electrodes out of the packaging and clean the skin before applying to remove grease, sweat or cream residue. Connect the connecting cable to the device and to the electrodes.

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Attaching the electrodes

Place the electrode with the red connecting cable above the pubic bone. Place the electrode with the black connection cable either above the buttocks (see fig. 1 & 2) or alternatively on the perineum (see fig. 3).

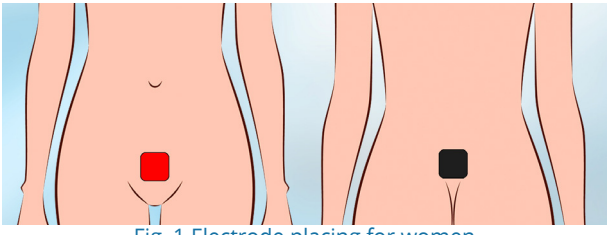

Fig. 1 Electrode placing for women

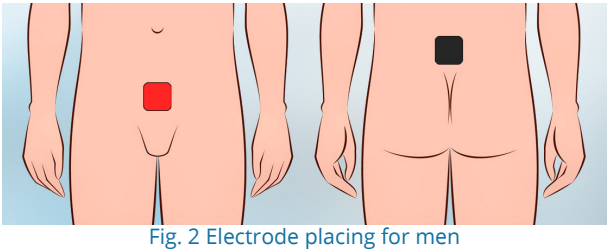

Fig. 2 Electrode placing for men

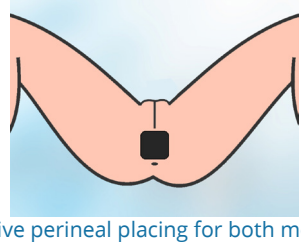

Fig. 3 Alternative perineal placing for both men and women

OPERATING THE DEVICE

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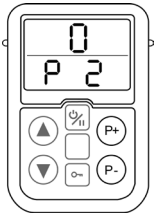
Turn on the device.

Press and hold the On/Off button for a long time to turn the device on. During the application, you can pause and restart the application by briefly pressing this key.

Program selection, start of stimulation
In program mode you can choose between 5 different programs. These are fully programmed - just set the current intensity and start the treatment.

The program starts immediately when the intensity is set!

The programs run in continuous operation, recognizable by the "C" in the display. Press the buttons P- or P+ to select a program (P1 – P5).



TIP: For optimal treatment success, use the programs P1 to P5 alternately on a daily basis. Thus, the pelvic floor is stimulated optimally and there is no habituation effect.

After you have selected the desired program, please adjust the intensity from 0-99 until a noticeable muscle contraction occurs.

Increase intensity

Decrease intensity

If there is no noticeable muscle reaction, use **more contact gel** for probes or **check the placement** of the adhesive electrodes.

If you have not received any prescription from your therapist or doctor, the recommended duration of treatment is **20 minutes at one session per day.**

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Ending the stimulation
Turn off the unit by pressing and holding the power button. Remove the adhesive electrodes and stick them back on the protective foil, then remove the connection cables.

If you are using a probe, slowly pull it out of the vagina or anus. **Attention: To avoid cable breakage, the probe must always be pulled out at the shaft!** Clean the probe with warm water and soap, rinse and store in a dry plastic bag.

Key lock

The control elements are locked by pressing the key lock and cannot be inadvertently adjusted during treatment. The key lock can be deactivated by pressing the key again.

CONSTRUCTION OF THE DEVICE

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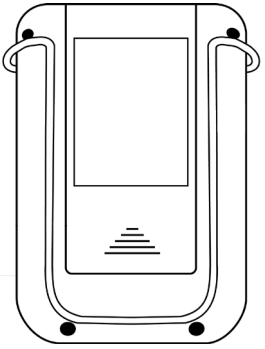
Front

Back



CHANGING BATTERIES

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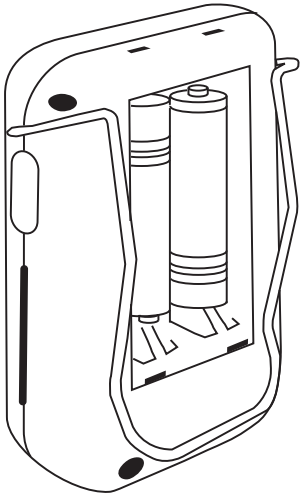
To ensure the function of the device, please change the batteries when the low battery indicator is shown.

- Make sure the power is off.
- Open the battery compartment on the back of the device.
- Remove the batteries.
- Insert the new batteries. Please check that the polarity is correct!
- Close the battery compartment.



MAINTENANCE, TRANSPORTATION AND STORAGE OF THE DEVICE

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- Non-flammable cleaning solution (containing 70% of alcohol) is suitable for cleaning the device.
- Stains and spots can be removed with a cleaning agent.
- Do not submerge the device in liquids or expose it to large amounts of water.
- Return the device to the carrying box with sponge foam to ensure that the unit is well-protected before transportation.
- If the device is not to be used for a long period of time, put it back into the carrying box and keep it in a cool, dry place.
- The packed TENS device should be stored and transported under the temperature range of -20°C ~+60°C, relative humidity 20% ~ 95%, atmosphere pressure 500 hPa ~ 1060 hPa.

SAFETY CHECKS

A For safety reasons, review the following checklist once a week.

- Check the device for deformation of the housing or damage to defective output sockets.
- Make sure that the descriptions and labels are not distorted.
- Check the LED when the device is turned on.
- Check the cables and electrodes for damage.

- The device must be subjected to safety checks and maintenance by authorized technicians before use and each re-use, but at least every 24 months.
- Please consult your distributor if there are any problems with device and accessories.
- The manual must always be carried with the device.

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MALFUNCTIONS

Should any malfunctions occur while using your device, check the following points. If none of these can solve the problem, please contact the customer service.

- Check whether the cables are correctly connected to the device.
- The display does not turn on? Change the battery.
- Check the cables for possible damage. The device may only be used when subjected to a load.
- There is no stimulation current? Check if the electrodes are connected to the same channel correctly and if the intensity is high enough.

CONFORMITY TO SAFETY STANDARDS

The STIM-PRO I-2000 device is in compliance with the EN 60601-1-2:2007 and 60601-1:2006 safety standards.

TECHNICAL DESCRIPTION

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01	Channel	1 channel
02	Intensity	Adjustable 0 - 80 mA with a load of 500 Ohm on each channel
03	Pulse amplitude	Asymmetrical, bi-phasic square pulse
04	Output Voltage	0 - 100 V
05	Power Source	2 pieces 1.5V AA batteries
06	Size	9.2cm(L) x 6.2cm(W) x 2.9cm(H)
07	Weight	123 g
08	Frequency	Pre-set, ranging from 1 - 100 Hz
09	Pulse width	Pre-set, possible values: 150µs, 200µs, 250µs
10	Modes	5 pre-defined programmes P1 - P5
11	Low battery indicator	Is shown when the batteries are empty. Replace batteries immediately.
12	Operating conditions	Temperature 0° C to 40° C Relative humiditiy 30 % - 75 % Air pressure 700 hPa - 1060 hPa
13	Note	All technical values include a tolerance of +/- 5 %

WARRANTY

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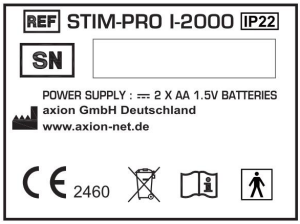
All TENS models carry a warranty of 24 months from the date of delivery. The warranty applies to the stimulator only and covers both parts and labor relating thereto. The warranty does not apply to damage resulting from improper handling, the failure to follow the operating instructions, loss or dropping.

Manufacturer:
axion GmbH
Mollenbachstr. 13
71229 Leonberg, Germany
www.tens-ems.com/en



1. Advice for operation
2. Degree of electrical protection
3. Do not insert the plug into the power supply socket of 230V
4. Timer
5. Low battery indicator
6. Increament
7. Decreament
8. Read the instruction manual
9. Direct current (DC)
10. Manufacturer
11. SN Serial number