schwa-medico
HOLISTIC HEALTH

TENStem eco basic

transcutaneous 2-channel
nerve and muscle stimulation

EN Instructions for use REF 10001787 Version 13 Last updated: 2023-05-30

Contents

1. General information

1.1 Terms

In these instructions for use, "patient" means a person (male, female or diverse) on whom the **TENStem eco basic** is used. The term also applies if the device is operated by a person other than the patient themself and regardless of whether the use of the **TENStem eco basic** in the specific case is medically necessary or is used with a medical purpose.

The term "user" means the person operating the device (doctor or any other person operating the device while the electrodes are attached to the patient). If the product is used independently, "patient" and "user" are one and the same person. The device is designed for use by the patient.

The term "therapy" refers to the repeated use of the product over a lengthy (defined) period.

The term "treatment" or "session" describes the individual use/stimulation (for example, 10/20 minutes).

1.2 Intended purpose

The **TENStem eco basic** is used for transcutaneous electrical nerve and muscle stimulation on humans to relieve acute and chronic pain, to improve blood circulation and strengthen muscles.

Pain treatment with the **TENStem eco basic** is carried out by stimulating sensory and peripheral motor nerves using skin electrodes. This irritation activates the body's own pain-relieving processes. Pain of any kind is an indication that treatment with a **TENStem eco basic** is needed.

Muscle stimulation with the **TENStem eco basic** acts to maintain and build up the skeletal muscles and their appendages such as tendons, ligaments and joints. This is done by stimulating peripheral motor nerves that can be reached using electrodes.

Indications that treatment with a **TENStem eco basic** is needed are situations where muscle inactivity, such as illness, pain or immobilisation, threatens to cause or has caused a breakdown of the muscles.

Muscle stimulation also promotes blood circulation and metabolism in the stimulated areas.

Treatment with a **TENStem eco basic** can be carried out several times a day.

The **TENStem eco basic** can be used to treat anyone who is mentally and physically capable of positioning the electrodes and adjusting the current strength, taking into account the contraindications, or who is capable of expressing pain or a desire to modify or end treatment in the event of non-independent treatment.

The product can also be used by people without medical training. However, they must have

read and understood the instructions for use, in particular the chapters 1.3 "Safety instructions/warnings" and 1.4 "TENS (low-frequency electrostimulation) contraindications in pregnant women" before they use the device for the first time. If anything is unclear, it is essential to consult a healthcare professional (or the manufacturer). If the product is prescribed by a doctor's prescription, the user/patient must be given instruction before their first use.

Caution: Pain can indicate serious disorders in the body and must be clarified by a doctor. Even if applying the **TENStem eco basic** has good success and leads to distinct pain relief, this is not to be equated with curing the cause of the pain.

1.3 Safety instructions

Please read the instructions for use carefully prior to using the product! It is recommended to keep this for future reference!

1.3.1 General safety instructions

Caution: Never use the product if it is not working properly or if it has been damaged.

If malfunctions or errors unexpectedly occur, please contact our service technicians. Service (e.g. battery replacement) and repairs may only be performed by authorised specialists to ensure safety and maintain the warranty (you can find the addresses of specialists on the last page of the instructions for use).

Caution: If the product is modified, suitable inspections and tests must be carried out to ensure the further safe use of the device.

Do not drop the product or handle it improperly.

Apply only at temperatures between 10 and 40°C, a relative air humidity of between 30% and 75% and air pressure between 70 kPa and 106 kPa. Therefore the product should not be used in a bathroom or in a similarly humid environment.

Store the product in its original packaging to protect it from damage and soiling.

Caution: Careful supervision is recommended if the product is used in the vicinity of children. Keep the product and its packaging so that is inaccessible to children. There is a risk of strangulation from the cables and wires of this device and its accessories!

The product may only be used with its original accessories. The use of other accessories (especially electrodes with an electrode surface area smaller than 2 cm^2) can lead to improper operation. The electrodes in the scope of delivery can be used without any problems.

Caution: Keep water and other liquids away from the product, because otherwise uncontrolled current flows may occur, electric shocks are possible, and the device would be damaged.

Caution: If you expose this device to sudden temperature changes from cold to warm, do not switch the device on until it has reached the same temperature as its environment that

it is to be used in. Wait for at least 30 minutes. Otherwise, condensation that forms inside the device may result in electrical shock, fire, damage to the device and/or personal injury.

For commercial use in Germany, the operator is required, as per Section 11 of the Ordinance on Operators of Medical Devices (MPBetreibV), to conduct technical safety controls for the product in regular and appropriate intervals. The manufacturer recommends running technical safety checks on the product every 24 months. Please observe the legal requirements that apply in your country.

1.3.2 Application-related safety instructions

Affixing the electrodes:

1. The device may only be connected to one patient at a time.
2. Clean the skin surface where the electrodes will be affixed before attaching the electrodes. Otherwise, faulty operation cannot be ruled out.
3. **Caution:** Make sure that no metallic objects such as jewellery or piercings come into contact with the electrodes during stimulation, as this may result in localised burns.
4. **Caution:** Tattoo inks can contain metallic pigments which, under the influence of current, could in rare cases cause high current densities and skin damage. Wherever possible, stimulation in areas of the body with tattoos should be avoided. If it is not possible, stimulation in these areas of the body should be observed with closer attention and ended immediately in the event of an emergency.
5. **Caution:** Place the electrodes on the skin so that the electrode surface makes full and even contact with the skin. Make sure additionally that the distance between the electrodes is at least 2 cm. Otherwise, too high current densities can occur and painful skin lesions might appear on the skin.
6. **Caution:** In patients with metal implants who have sensory disorders in the area of the metal, special caution should be taken when stimulating and placing electrodes in this area. The sensory disorder might tempt users to increase the stimulation intensity setting and lead to skin irritation with reddening of the skin or pain in the area around the metal. In this case, it will be necessary to stop the stimulation.
7. **Caution:** Please also observe the instructions for use of the electrodes you use, especially the safety instructions they include.
8. **Caution:** Electrical stimulation therapy should only be applied over or through the head, directly to the eyes, with the mouth covered, at the front of the neck (particularly the carotid sinus) or using electrodes placed on the chest and upper back or crossing the heart after prior consultation with a physician.

Warning: Attaching the electrodes next to the thorax might increase the risk of cardiac arrhythmia. In the case of electrode systems being used in the chest area, intensive high-frequency stimulation (from approx. 15 Hz) can lead to disturbed breathing activity during stimulation.

Warning: The product must not be used when operating machinery or during activities that require a high degree of attention. This applies especially in traffic!

Warning: Stimulation in the facial area (trigeminal stimulation) can cause drowsiness, so you can only resume the stated activities if you no longer feel sleepy. For optimum safety, you should only carry out stimulation in the facial area when sitting or lying down.

Warning: Do not operate the device in the vicinity of potentially explosive and/or flammable substances or fumes.

1.3.3 Special safety instructions

Caution: Simultaneous connection of the patient to a medical electrical (ME) device for high-frequency (HF) surgery can cause burns below the electrodes of the product and result in damage to the electro-stimulation device.

Caution: Operation immediately next to (e.g. 1 m from) an ME device for short-wave or microwave therapy may cause fluctuations in the product's current pulses (output levels), which may have painful effects.

Caution: Portable HF telecommunication devices (radio equipment, mobile telephones) (including their accessories such as antenna cables and external antennas) should not be used within a distance of less than 30 cm (12 inches) to the **TENStem eco basic** (including its accessories). Non-compliance may lead to inferior device performance or faulty operation.

Caution: Using this device directly next to other devices or stacked on top of them should be avoided because it may result in malfunctions. If the use as described is nevertheless necessary, this device and the other devices should be monitored to establish that they are working properly.

Special instructions for the product's muscle stimulation programmes

Enzymes (e.g. creatine kinase) and proteins (e.g. myoglobulin) are released during every muscle strain. In the case of severe muscle strain, but also due to one's constitutional predisposition or in conjunction with certain medications or drugs, certain individuals may experience more severe muscle breakdown (rhabdomyolysis). In rare cases (especially with overtrained muscles or pre-existing conditions), the amount of enzymes and proteins released as well as electrolyte imbalances can also damage internal organs such as the kidneys, liver and heart. This risk also exists in the case of electrical muscle stimulation, as it may constitute intensive muscle training. This risk is generally very rare and, in most cases, is avoided by observing the information in the following chapter ("Instructions for avoiding physical overload reactions due to muscle stimulation"). No such harm has occurred to date with our products.

The muscles can quickly reach their stress limit, especially during the first training sessions. This is associated with the risk of muscular overload, which can also occur in healthy and trained users. Muscular overload may already manifest itself during training through dis-

comfort, circulatory reactions, muscle pain and other complaints. The most frequent consequence of overload is pain in the muscles after the training. Pain and irritation of tissues connected to the muscles - such as ligaments, tendons, joints and bones - are also possible. Muscle overload due to electrical muscle stimulation can occur particularly during the first training units. Over the course of regular training, the muscles usually adjust to the demand placed on them and there is a significant decrease in the release of muscle enzymes and muscle proteins.

Special instructions for avoiding physical overload reactions due to muscle stimulation

Before every muscle stimulation

Only undergo stimulation if you are feeling rested and fit.

Do not undergo stimulation if you have a fever or any other symptoms that impair your physical performance capacity. If you have chronic, long-term conditions, seek medical advice and approval of the treatment before starting any training.

The patient and the user must have read and understood the contraindications, safety instructions, side effects and the instructions for avoiding physical overload reactions.

If possible, drink two glasses, e.g. of water, before/during the stimulation to stimulate metabolic activity.

Do not undergo stimulation on an empty stomach. Instead, have a small meal one to two hours before treatment to avoid any drop in blood sugar.

The user adjusts the stimulation intensity to a comfortable amount and readjusts it themselves where required. The aim is to trigger non-painful muscle tension in the area of the stimulated muscle.

The intensity of the current is perceived differently by individuals and depending on the situation and may vary from treatment to treatment.

The stimulation and treatment must never be painful.

Only medically necessary medications should be taken prior to training.

After every muscle stimulation

Severe muscle pain after treatment is a sign of overload and should result in a reduction in the intensity and frequency of treatment. Persistent or especially severe muscle pain and muscle weakness following treatment can also indicate muscle breakdown (rhabdomyolysis). In these cases, medical advice must be sought. In the event of doubt (e.g. in the case of discomfort or similar symptoms), medical advice should always be sought.

To support kidney function, after treatment one to two glasses, e.g. of water should be drunk.

Application in the familiarisation phase for muscle stimulation (first to seventh treatment)

As the training begins, the muscles must be given sufficient time to get used to the strain. This also applies to trained muscles. Particularly during the first two sessions, only light stimulation with short periods of muscle tension may be carried out, without full muscular strain. In addition, during the first two sessions the stimulation must not be applied for more than ten minutes at a time. The device's longer programmes should be stopped after this time. Programmes with lower frequencies and longer pause times are preferable.

There should be at least four days between the first two sessions.

In the next five training units, the intensity of the training can be slowly increased until the desired level of strain is reached and a training duration of 20 minutes each is achieved. The interval between the training sessions can be gradually shortened.

Training after the familiarisation phase for muscle stimulation

The training duration for muscle stimulation should not be longer than 20 minutes per training unit.

Muscle pain should not occur during the training session; constant muscle tension must be avoided.

1.4 Contraindications

1.4.1 General contraindications

When am I not allowed to use the **TENStem eco basic** or use it only after consulting the doctor in charge?

- Patients with electronic implants such as pacemakers or pumps
- Patients with cardiac arrhythmia
- Patients with seizure disorders (epilepsy)
- Patients with skin disorders (such as wounds, eczema, radiation damage) in the area where the electrodes would be used
- Patients with malignant disorders in the stimulation area
- Patients with pathogenic infections (e.g. tuberculosis, osteomyelitis) in the stimulation area
- Patients with phlebitis and blood clots (thrombophlebitis and thrombosis) in the stimulation area
- Patients with an increased risk of bleeding as a result of illness or medications or with fresh bleeding in the stimulation area

1.4.2 Special contraindications for low-frequency electrostimulation with TENS in pregnant women

The following applies in addition to the general contraindications for TENS:

- The use of TENS during pregnancy should always be agreed with the attending doctor and the midwife, taking into account the benefits and risks.
- TENS should not be used during pregnancy in patients who have experienced a miscarriage or a premature birth.
- TENS should not be used on patients in early labour.
- TENS should generally not be used or only used after careful consideration of the risks during the first three months of pregnancy. In particular, stimulation near the womb should be avoided.
- From the 4th month of pregnancy TENS should never be used near the womb. This concerns all placement of the electrodes in the abdomen, pelvis and lower back.
- TENS may be used during birth.

1.4.3 Special contraindications for muscle stimulation

The product should not be used or only used after consulting the responsible doctor in the following cases:

- Persons in whom muscle stimulation leads to a high release of muscle enzymes and proteins (e.g. creatine kinase, myoglobulin). This release can also be caused by the simultaneous taking of medications, e.g. cholesterol-lowering drugs (e.g. statins), and requires medical supervision.
- With muscle disease (myopathies)
- Following drug use (e.g. alcohol) or those taking medications (e.g. lipid-lowering agents, muscle relaxants, cortisone) that lead to the increased release of muscle enzymes and muscle proteins in the blood serum
- For Diseases, such as of the kidneys or the liver as well as heart diseases, which are associated with a reduced compensation of increased values of muscle enzymes, muscle proteins and electrolyte imbalances

1.5 Side effects

1.5.1 Special side effects for nerve stimulation

- Pain intensification: Excessive and prolonged use might cause an increase in pain. In order to avoid an increase in pain, treatment should be carried out using a rather weak current intensity (intensity control), especially during the first treatments, and not for longer than 30 minutes.
- Skin intolerances: These can occur as a reaction to the electrodes, to the electrode gel when using rubber electrodes or if the pulses of current are too high.

- A slight, non-persistent reddening of the skin following stimulation in the area of the electrodes is normal, as blood circulation is stimulated by the TENS application.
- If prolonged redness, burning, itching or skin blisters should occur under the electrodes or around the electrode site following stimulation, you must consult the doctor before further TENS application.

1.5.2 Possible side effects of muscle stimulation

- Muscle pain: Muscle pain similar to muscle soreness can occur if muscle stimulation is too intense and extensive. Avoid this by using shorter and less intense stimulation, especially during the first treatments.
- Muscle cramps with possible damage to the muscle and neighbouring muscle structures such as connective tissue, ligaments, tendons and bones
- Muscular overload reactions with
  - Muscle pain that may last for several days
  - Muscle weakness that may last for several days
  - The release of muscle enzymes and muscle proteins as well as electrolyte imbalances due to muscle strain and muscle breakdown (rhabdomyolysis) can in very rare cases (especially with undetected pre-existing conditions/overtraining) result in strain and damage to internal organs such as the kidneys, liver and heart.
- The consequences of long-term electrical muscle stimulation (for more than six weeks at a time) are not known, so negative long-term effects cannot be ruled out. We are not aware of any such cases when using our products.

2. Operation

2.1 Simple quick guide for the self-application of TENS

Check and, if necessary, clean areas of skin for electrode placement In general, keep the corresponding areas of skin dry, especially free from oil and cream.

Connect electrode cables to the electrodes. Red and white plugs have no significance for you, only for therapists and special applications.

Affix electrodes to the desired areas. Ensure there is full contact with the skin. The placement suggestions (chapter 4 “Overview of electrode placement”) show you where you should position the electrodes.

Affix the electrodes around the pain, “where it hurts”.

Insert the plugs of the electrode cables into the TENS device. The plugs can only be inserted in one direction.

Switch device on with the ⊙ button. Select programme with the **P** button until the desired programme number appears on the display. Please use programme 1 at the beginning.

Now start the application by pressing the left ∧ button and then the right ∧ button. You can press up until you feel a clearly perceptible and pleasant tingling sensation. This tingling may become so clearly noticeable that you no longer perceive your actual pain so clearly in this moment. Once the tingling becomes unpleasant and if your pain increases, make a slight adjustment with the ∨ button.

The treatment now runs automatically for 30 minutes. You can see on the display at any time how long the stimulation will continue. The application then stops by itself.

Press the ⊙ button to stop the stimulation yourself. The device then stops the stimulation immediately.

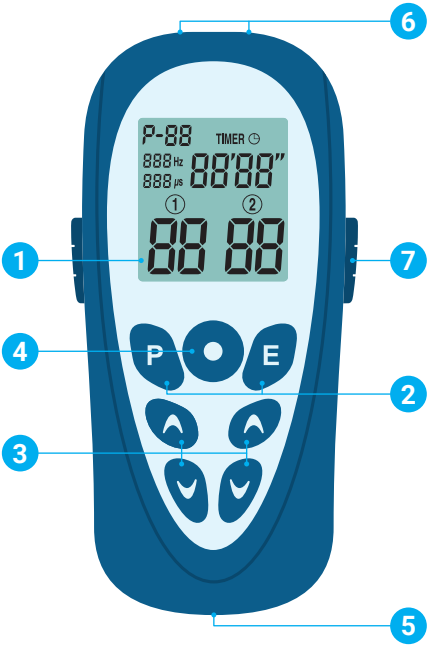
If you want to change the electrode placement, interrupt the stimulation and change the position of the electrodes. Then restart the process by pressing the ∧ button, as before, until you once again feel a clearly perceptible tingling.

When the stimulation ends as programmed, you can restart it if you wish. If you want to stop, turn the device off with the ⊙ button. Afterwards, you can remove the electrodes and affix them to the film again. Remove the plugs from the device and the electrodes and store everything in the box provided.

2.2 Operation of the control unit (“device”)

2.2.1 Controls

The **TENStem eco basic** was designed for the stimulation of nerves and muscles in humans. All settings can be made using the buttons. The LCD display shows the different operating states.



1. **LCD display**
2. **Menu buttons**
3. **Modification buttons**
4. **On/off button**
5. **Battery compartment**
6. **Output sockets for electrode cables**
7. **Belt clip (back)**

2.2.2 Keypad

The **TENStem eco basic** has seven buttons:

⏻ to switch the **TENStem eco basic** on and off

P to select the programme

E "Edit" mode

∧ to increase the intensity (left for channel 1, right for channel 2)

∨ to reduce the intensity (left for channel 1, right for channel 2)

Note: It is not possible to increase the intensity of both channels at the same time.

2.3 Preparation for stimulation

2.3.1 Insert batteries

Before putting the **TENStem eco basic** into service, the batteries supplied are to be inserted into the battery compartment (see also section "Changing the batteries"). Please ensure the correct polarity when inserting the batteries.

2.3.2 Connecting the cables and electrodes

The **TENStem eco basic** has two channels, the intensity of which you can set independently of one another. You can also choose to use only one of the two channels. First, connect one of the supplied cables to two electrodes per channel. It does not matter to which electrode (pad) you connect the red or white plugs. Plug the other end of the cable into one of the two output sockets at the top of the **TENStem eco basic**.

Now position the electrodes on the skin. In the chapter "Electrode placement", you can find illustrations as examples of where the electrodes can be positioned on the skin. The electrodes are usually attached in the immediate vicinity of the painful area.

The **TENStem eco basic** automatically detects when the electrodes are not correctly affixed to the skin and then cannot be set to a high intensity for safety reasons; it automatically switches off above an intensity of 10 mA. Always ensure that you only switch the device on when you have correctly positioned the electrodes!

2.3.3 Positioning of electrodes

The self-adhesive electrodes included in the scope of delivery meet the quality requirements according to the register of assistive products PG 09.99.01. The electrodes are intended for multiple use. With normal use, the electrodes have a working life of at least 30 days. They lose their adhesion over time and should be replaced.

Tip: Clean away any sweat, moisture or soiling in the area of skin to which the electrodes should adhere and do not apply any ointments or creams before treatment.

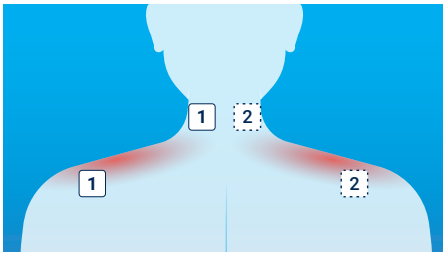
Important: Do not affix the electrodes to irritated or diseased areas of skin.

Important: If you want to change the position of an electrode, you must switch off the device briefly before doing so.

Any residue left on the skin from the self-adhesive electrodes can be easily removed using soap and water.

Important:

In the illustrations, the electrodes are labelled with 1 for channel 1 or with 2 for channel 2.



2.3.4 Switching the control unit (“device”) on and off

To switch the device on, please press the ⊙ button. An audio signal will sound, the **TENStem eco basic** is in “Ready” mode. Pressing the ⊙ button again in “Ready” or “Stimulation” mode: A single audio signal will sound, the **TENStem eco basic** switches off. The device automatically switches off if no button has been pressed for two minutes and no stimulation has been started.

2.3.5 Starting the application in “Ready” mode

The selected programme, therapy time, frequency, pulse width and intensity are shown on the LCD display of the device.

8. Press the **P** button to select a programme.
9. Pressing one of the two ∧ buttons starts the stimulation. You will perceive a slight tingling from around 10 mA.
10. Pressing the left ∧ button: Channel 1 of the **TENStem eco basic** enters “Stimulation” mode and the intensity for channel 1 increases by 1 mA per increment. The intensity increases by 1 mA with each press of the button, until the maximum intensity of 60 mA is reached and is shown on the LCD display. If necessary, press the ∨ button to reduce the intensity in the same way to reach the range that feels pleasant and right for you.
11. Pressing the right ∧ button: Channel 2 of the **TENStem eco basic** enters “Stimulation” mode and the intensity for channel 2 increases in the same way as the left channel (see 3).

Attention! If the electrodes are not correctly connected to the **TENStem eco basic** and placed on the skin, the intensity will be reset to zero from a current of 9 to 10mA. Please then first position the electrodes correctly and restart the application by pressing the intensity controls for the left and right channels ∧.

2.4 Adjustments during the application in “Stimulation” mode

The programme, remaining therapy time, frequency, pulse width and intensity are shown on the LCD display during stimulation.

1. Pressing the ⊙ button stops the therapy and the **TENStem eco basic** goes back into “Ready” mode.
2. Press the left ∧ button and left ∨ button to set the individual intensity of channel 1 (from 0 to 60 mA).
3. Press the right ∧ button and right ∨ button to set the individual intensity of channel 2 (from 0 to 60 mA).
4. Once the therapy time has ended, the stimulation is automatically stopped and the **TENStem eco basic** goes back into “Ready” mode.

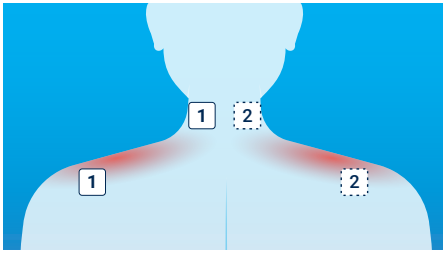
3. Programme overview

Pro-gramme	Name	Area of application	Type	Timer (min)
1	Standard	Acute nociceptive pain, acute and chronic neuropathic pain	For novice users	30
2	Standard (weak-ened)	Like Novice 1, just a little gentler	For novice users	30
3	Intensive	Introductory programme for permanent, severe pain	For advanced users	30
4	Standard + Intensive (var. 1)	Special pain therapy via special contact points, instructions for self-application required from therapist	For advanced users	30
5	Standard + Intensive (var. 2)	Alternative to Standard + Intensive 1	For advanced users	30
6	Special (according to Han)	Good alternative for therapy resistance	For advanced users	30
7	Intensive (weakened)	Gentle introductory programme for permanent, severe pain	For advanced users	30
8	Modulation	Anti-habituation programme	For advanced users	30
9 Muscle	Muscle stimu-lation 1	Introductory programme before and immediately after operations, preparation for procedures, building up basic musculature	Special muscle stimulation	30
10 Muscle	Massage 1	Novice programme for muscle massage for relaxation	Special muscle stimulation	30
11 Muscle	Massage 2	Advanced programme for muscle massage for relaxation	Special muscle stimulation	30
12	Deep TENS	Pain in deeper layers of muscle	For advanced users	30
Modifiable programmes from series C (editable values) / Special programmes for therapists, modifiable (from series C)				
13	Therapist 1	Stimulation parameters can be set individually by therapists according to the desired effect for pain therapy	For therapists	10–90
14 Muscle	Therapist 2	Stimulation parameters can be set individually by therapists according to the desired effect for muscle stimulation	For therapists	10–90
15 Muscle	Therapist 3	Stimulation parameters can be set individually by therapists according to the desired effect for muscle stimulation	For therapists	10–90
Modifiable programme from series E (editable values) / Special programme for therapists, modifiable (from series E)				
16	Mono 1	Stimulation parameters can be set individually by therapists for monophasic application (not recommended for self-applica-tion)	For therapists	20

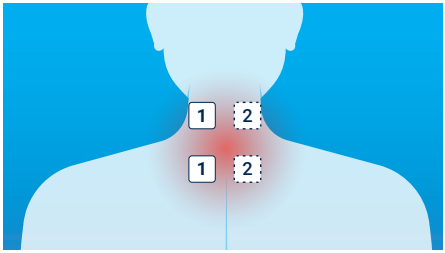
Frequency in Hz	Pulse width in µs	Description
100	200	Both channels are operated with the same frequency and pulse width.
80	150	Both channels are operated with the same frequency and pulse width.
2	250	Both channels are operated with the same frequency and pulse width.
Channel 1: 100 Channel 2: 2	200	Channel 1 operates at 100 Hz and 200 µs. Channel 2 operates at 2 Hz and 200 µs.
100/2	150/200	Phase 1: Both channels operate for 10 min at 100 Hz and 150 µs. Phase 2: Both channels operate for 20 min at 2 Hz and 200 µs. Phase 1 switches automatically to phase 2 If the therapy time is changed, the times of phase 1 and 2 change in the ratio 2/8 to 5/8.
100/2	150/200	Channel 1 and channel 2 operate for 3 s at 100 Hz (150 µs) and 3 s at 2 Hz (200 µs), continuously alternating.
100	150	Pulse packs (bursts) at 100 Hz (150 µs) are emitted for 0.25 seconds. The pause time between the pulse packs is 0.25 s.
2–80	100–200	The frequency changes continuously between 2 and 80 Hz within 7.5 s.
50	250	Trapezoidal pulse with 50 Hz frequency and 250 µs pulse width and 2 s increase, 5 s working time, 1 s decrease and 12 s rest. The intensity changes continuously according to the parameters.
80	150	The intensity increases to its maximum within 1 s and decreases to 50% within 1 s. The intensity changes continuously according to the specified parameters, with the two channels alternating with each other (massage).
80	150	The intensity increases to its maximum within 0.25 s and decreases to 50% within 0.25 s. The intensity changes continuously according to the specified parameters, with the two channels alternating with each other (massage).
100	75	P12 works like P1. However, instead of one pulse, there are four short pulses at 100 Hz
1–120	75–300	Both channels are operated with the same frequency and pulse width.
1–120	75–300	Trapezoidal pulse with 2 s increase, 5 s working time, 1 s decrease and 12 s rest. The intensity changes continuously according to the parameters.
1–120	75–300	The intensity increases to its maximum within 1 s and decreases to 50% within 1 s. The intensity changes continuously according to the specified parameters, with the two channels alternating with each other (massage).
1–120	75–300	Both channels operate with positive right pulses. P16 is used for iontophoresis or Jenkner nerve blocking

4. Overview of electrode placement

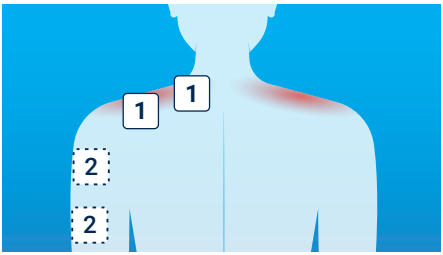
Shoulder/neck pain I



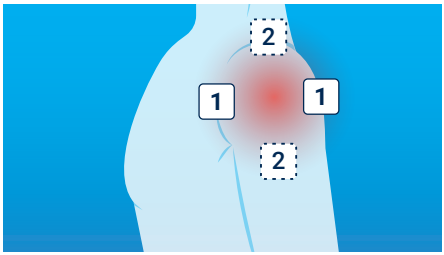
Neck pain I | 2-channel use



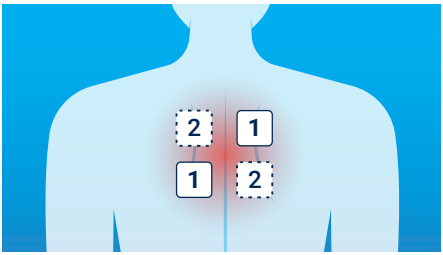
Cervicobrachialgia (shoulder-arm syndrome)



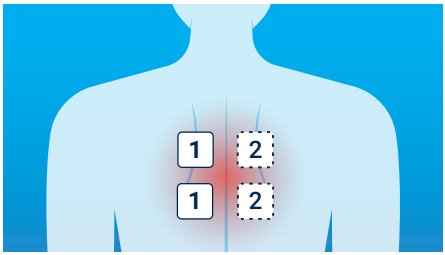
Shoulder pain



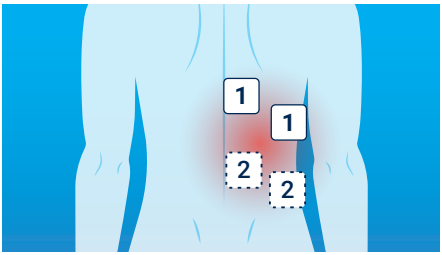
Thoracic spine | Crossed positioning



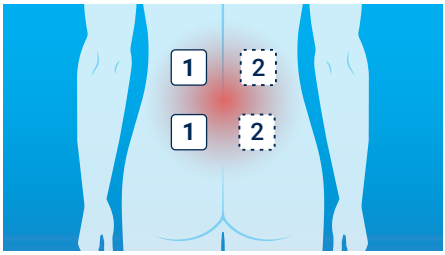
Thoracic spine



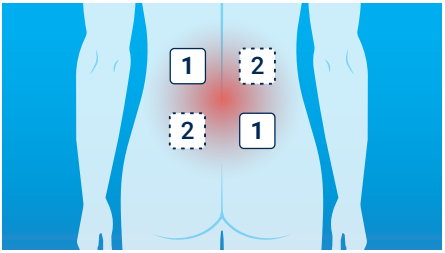
Radiculopathy (lower back)



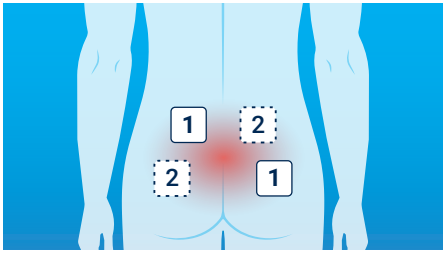
Lumbar spine I



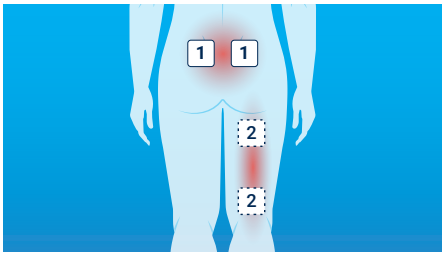
Lumbar spine II | Crossed positioning



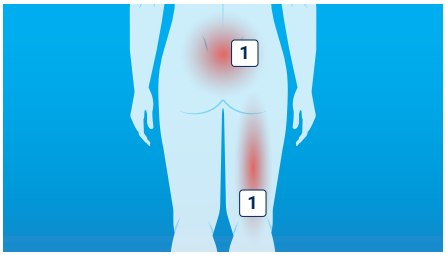
SI joint | Crossed positioning



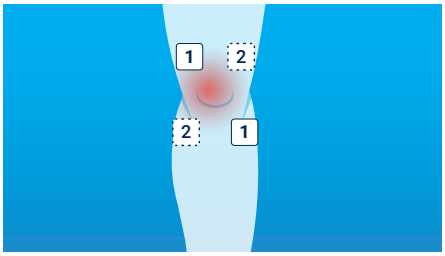
Sciatic pain



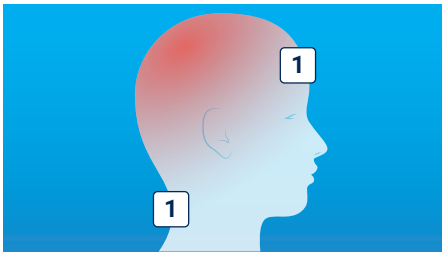
Sciatic pain II



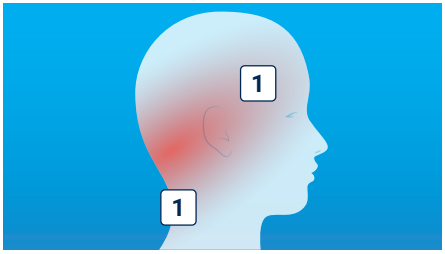
Knee joint osteoarthritis pain | Crossed positioning



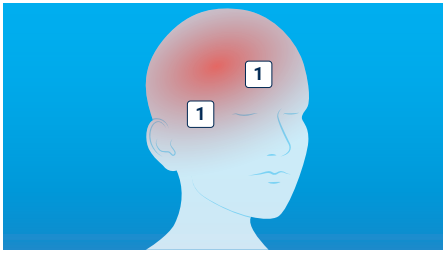
Tension headaches I



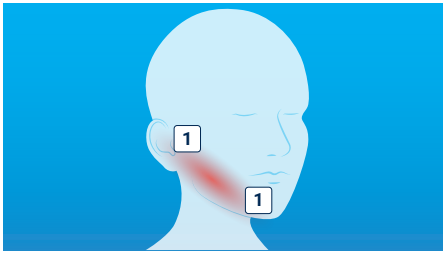
Tension headaches II



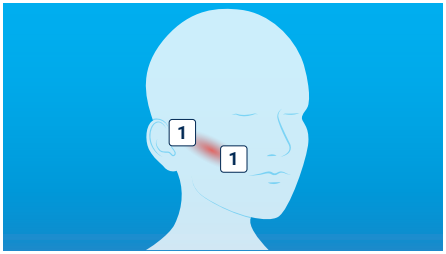
Migraine



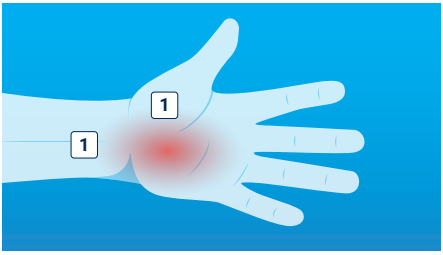
Trigeminal neuralgia mandibular nerve



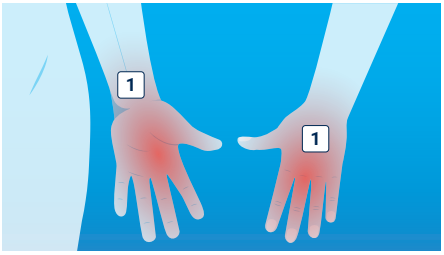
Trigeminal neuralgia maxillary nerve



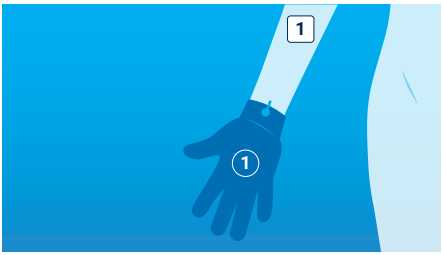
Carpal tunnel syndrome



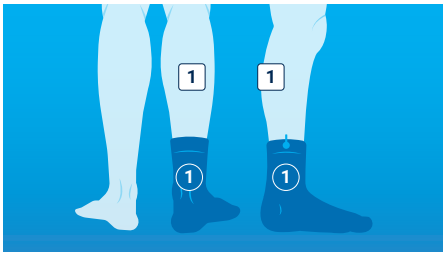
Hand pain



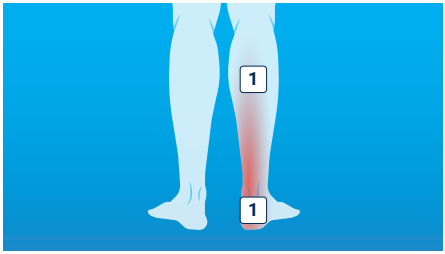
Hand pain Glove use 1-channel placement



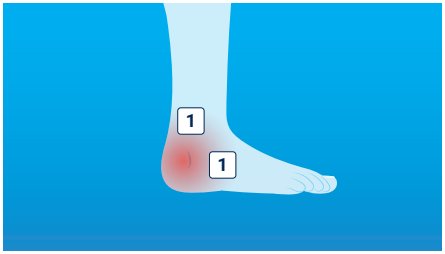
Foot pain | Sock use



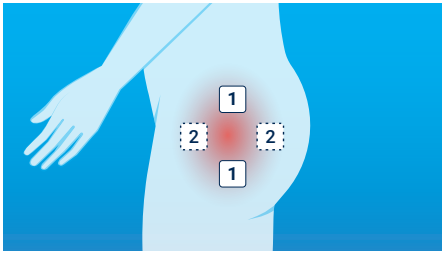
Achilles tendon pain



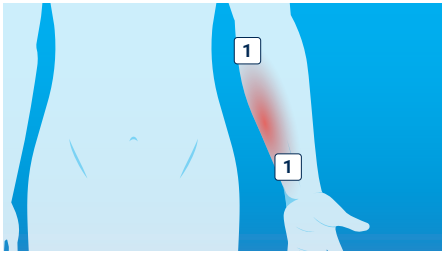
Ankle pain



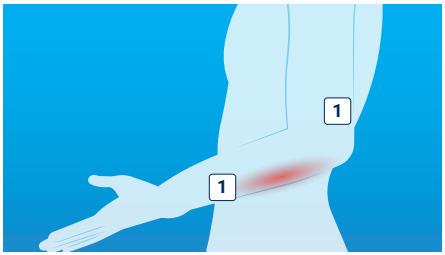
Hip pain | 2-channel use



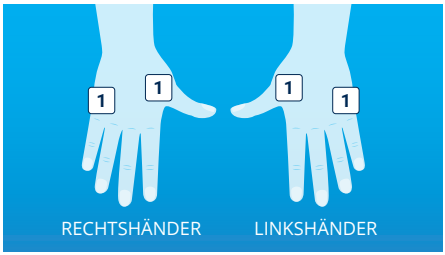
Golfer's elbow (ulnar epicondylitis)



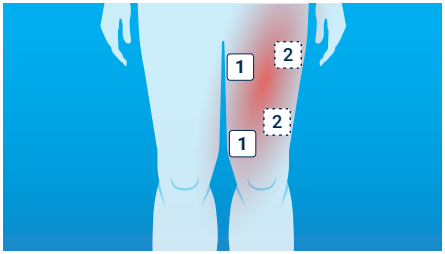
Tennis elbow (epicondylitis lateralis)



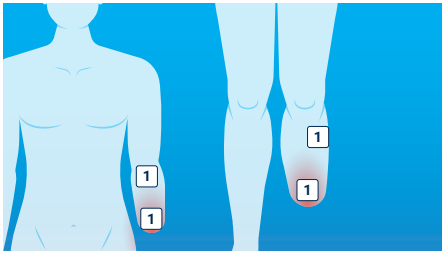
Kaada stimulation



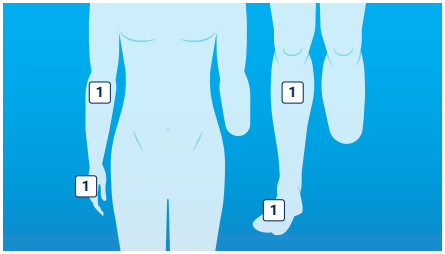
Placement for muscle stimulation of the quadriceps musculature



Amputation pain | stump pain



Amputation pain | phantom pain



5. Special functions and possibility of editing programmes

5.1 Locking the programme selection

Press and hold the left ∨ button and the **P** button at the same time for three seconds (two seconds for devices from series A and B): The programme selection function of the **P** button and the editing function for programme parameters are locked.

The lock symbol ⚿ appears on the display. This function prevents a device setting chosen for an application from being changed accidentally. Pressing the left ∨ button and the **P** button again for three seconds releases the programme selection function of the **P** button and the editing function for programme parameters.

5.2 Locking and unlocking

After locking or unlocking the device, the programme must first be started via a ∧ button. Only then is the locking or unlocking saved and also retained after switching the device off and on.

5.3 Switching the signal generator off and on

Simultaneously press the **E** button and the right ∨ button. The signal generator's current status will be displayed after 3 seconds. "BEEP ON" means the signal generator is switched on. "BEEP OFF" indicates that the signal generator is off. Use the **E** button to switch the signal generator off and on alternately. Press the ⊙ button to save the new setting. You will then be returned to "Ready" mode.

5.4 Special functions for devices from series A and B

Press and hold the left ∨ button and the **E** button at the same time for three seconds: Display of the total stimulation duration. Pressing the **E** button again takes you back into “Ready” mode.

5.5 Special functions for devices from series C

Pressing the **E** button takes you into “Edit” mode (see also section “‘Edit’ mode”). Press and hold the **E** button for three seconds to enter “Date/time” mode (see also section “‘Date/time’ mode”).

5.6 Special functions for devices from series D

Reset all editable parameters: Press and hold the ⊙ button for three seconds to reset all editable parameters on the device to the default settings. The device confirms the execution

of the function with a long signal tone. This sets the therapy time for all programmes (except 16/20-minute programmes) to 30 minutes. The parameters frequency and pulse width in the user programmes are assigned the following default values:

Programme	Frequency	Pulse width in µs	Timer in min
13	100	150	30
14	80	100	30
15	50	200	30
16	35	200	20

5.7 "Edit" mode for therapists

Only for devices from series C:

The programme, frequency, pulse width and intensity are shown on the LCD display. The therapy time flashes. Pressing the left or right ∧ button increases the therapy time by five minutes (max. 90 minutes). Pressing the left or right ∨ button decreases the therapy time by five minutes (min. ten minutes). Pressing the **E** or ⊙ button in programmes 1-12 saves the set time and exits "Edit" mode.

In programmes 13–15 (and programme 16 from series E), pressing the **E** button takes you into the setting mode for the therapy frequency. The therapy frequency flashes. Pressing the left ∧ button increases the therapy frequency by one hertz (max. 120 Hz). Pressing the left ∨ button decreases the therapy frequency by one hertz (min. 1 Hz). Pressing the **E** button again takes you into the setting mode for the pulse width. The pulse width flashes. Pressing the left ∧ button increases the pulse width by five microseconds (max. 300 µs). Pressing the left ∨ button decreases the pulse width by five microseconds (min. 75 µs). Pressing the **E** or ⊙ button saves the set parameters and exits "Edit" mode.

The **TENStem eco basic** automatically switches off if no button has been pressed for two minutes. No changes are saved in this case.

5.8 "Date/time" mode

Two numbers are shown on the LCD display. The left number stands for the date, the right number for the time. Pressing the left ∧ button increases the date by one day (max. 30). Pressing the left ∨ button decreases the date by one day (min. 1). Pressing the right ∧ button increases the time by one hour (max. 23). Pressing the right ∨ button decreases the time by one hour (min. 0). Pressing the ⊙ button saves the set parameters and exits the "date/time" mode. The date and time are counted continuously.

The **TENStem eco basic** automatically switches off if no button has been pressed for two minutes. No changes are saved in this case.

5.9 “Memory recall” mode

Only for devices from series C:

Press and hold the left ∨ button and the **E** button at the same time for three seconds to enter “Memory Recall” mode.

If there are no values in the **TENStem eco basic** memory, "ZERO" will appear on the LCD display for two seconds and the **TENStem eco basic** will return to "Ready" mode. Otherwise, the LCD display will show the parameters of the last therapy session.

Programme used:	P-01
Frequency:	100 Hz
Pulse width:	200 µs
Therapy duration:	0 min 44 s
Therapy day:	5
Therapy session	3

It is possible for you to save a total of 90 therapy sessions, the first three therapy sessions from 30 therapy days in each case.

Press the left ∨ button to access the parameters for the previous therapy day (up to the first day). Press the left ∧ button to access the parameters for the next therapy day (up to the current day). Press the right ∨ button to access the parameters for the previous therapy session (up to the first session of the respective day). Press the right ∧ button to access the operating parameters for the next therapy session (up to the last session of the respective day). Press and hold the **E** button for five seconds to clear the memory. “Clr” will appear for two seconds on the LCD display and the **TENStem eco basic** will return to "Ready" mode.

The **TENStem eco basic** automatically switches off if no button has been pressed for two minutes and it is not in stimulation mode.

6. Technical information

6.1 Symbols

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

Attention! The instructions for use must be followed in order to use the product safely.

Application part of the BF model
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

Distribution/dealer

Article number

Serial number

Store in a dry place

Environmental protection Do not dispose of the product at the end of its life cycle in normal domestic waste. Take it to an authorised collection site for recycling. By doing this, you will help to protect the environment.

CE 0482 The manufacturer affixes the CE marking to declare that the product fulfils all of the applicable 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.

IP22 The device provides protection against the ingress of solid foreign matter with a diameter ≥ 12.5 mm and protection against vertically dripping water (when the device is tilted up to 15°).

Medical device

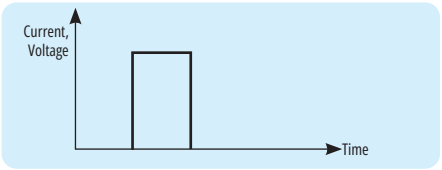
6.2 Technical data

2-channel electrostimulation device with separate outputs and twelve integrated programmes (three additional "user programmes" from series C and four additional "user programmes" from series E).

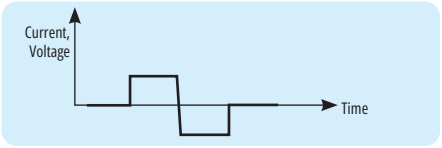
Voltage supply	6.0 V (4× 1.5 V battery AAA type Micro, e.g. LR03) or 4.8 V (4x1.2 V battery AAA), approximately 3 hours running time, depending on selected intensity
Power consumption	max. 100 mA (therapy); approx. 60 µA (power down)
Dimensions	approx. 140 mm × 64 mm × 28 mm
Weight	approx. 96 g (without batteries)
Output current	0–60 mA (on 1 kΩ load)
Pulse shape series A-K	positive rectangle with negative component
Pulse shape from series L	biphasic rectangular pulse
Pulse shape for P16	positive rectangular pulse
Frequency range	2-100 Hz or 1-120 Hz (from series C)
Pulse width	75–250 µs or 75–300 µs (from series C)
Working conditions	Temperature range: 10–40°C, relative humidity: 30-75%, air pressure: 70–106 kPa
Storage conditions	Temperature range: –10–55°C, relative humidity: 10-90%, air pressure: 50–106 kPa
Service life of the **TENStem eco basic**	5 years

6.3 Output pulses

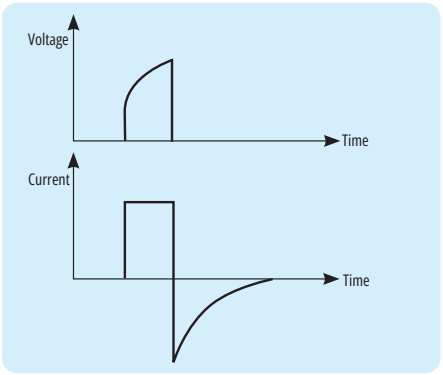
On load 1 kΩ real, series A–K



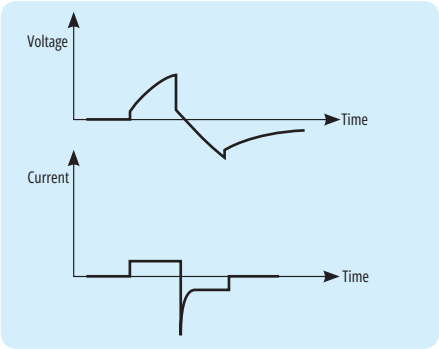
On load 1 kΩ real, from series L



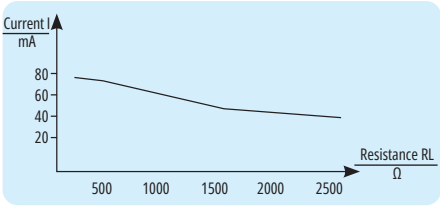
On load ANSI/AAMI standard, series A–K



On load ANSI/AAMI standard,
from series L



output current change
depending on the load resistance



6.4 Changing the batteries

The voltage of the batteries is monitored by the **TENStem eco basic**. If this falls below 3.7 V, the battery symbol appears on the LCD display. It is then necessary to insert four new 1.5 V batteries (AAA, e.g. LR03) into the device.

Switch the **TENStem eco basic** off. Open the battery compartment cover (back to the bottom) by sliding in the direction of the arrow. Remove the four flat batteries. Insert four new batteries into the battery compartment. Please note the marking in the battery compartment as a guide. Close the battery compartment again with the battery compartment cover.

ATTENTION! From series E devices: Please close the battery compartment cover firmly. The device will not switch on if the battery compartment cover is not closed!

Always remove the batteries if the device will not be used for a prolonged period.

If rechargeable batteries are used instead of disposable ones, the instructions for use of the charger are to be noted.

6.5 Disposal

6.5.1 Battery return and disposal

Caution: If the batteries are disposed of along with residual waste and later incinerated in a waste incineration plant, toxic pollutants (including mercury, cadmium and lead) can be released into the air. If the pollutants from the batteries find their way into the food chain, they can have serious health-endangering effects on humans! **Therefore, please note the following information:** In connection with the sale of products containing batteries, which also includes accumulators, we are legally obliged to inform you of the following pursuant to Section 18 (1) of the Battery Act (BattG): The dustbin symbol indicates batteries containing harmful substances and the fact that batteries may not be disposed of with household

waste, but must be disposed of properly. The chemical name of the pollutant is indicated under the dustbin symbol. You are legally obliged to return used batteries. You can return used batteries to a municipal collection point or to your local retailer. As a distributor of batteries, we are also obliged to take back used batteries, although our take-back obligation is limited to used batteries of the type that we carry or have carried in our range as new batteries. Used batteries of the above type can therefore either be returned to us with sufficient postage or handed in directly to our shipping warehouse free of charge at the following address: schwa-medico GmbH, Dreieiche 7, 35630 Ehringshausen.

Please refer to the following illustration for the symbols used to identify batteries containing harmful substances:

Battery contains more than 0.002 percent by weight of cadmium

Battery contains more than 0.0005% mercury by weight

Battery contains more than 0.004 percent lead by weight

6.5.2 Device return and disposal

The following applies in the European Union: It is forbidden to dispose of the device together with household waste. You are obliged to take the device to a public collection point.

With regard to non-consumers, the manufacturer commits to take back the device at its premises (address: Dreieiche 7, 35630 Ehringshausen) and to dispose of it properly.

On delivery of this device to the end user, the distributor commits to accept an old device from the end user that is substantially identical in terms of function free of charge on request. This will apply only if the end user has notified the distributor of their request to hand over an old device prior to the date of delivery. In addition, the distributor will accept up to five other electrical appliances, which each do not exceed 25cm in height, width and length, free of charge in its sales area (address: Dreieiche 7, 35630 Ehringshausen).

Please also observe the legal requirements that apply in your country.

6.6 Classification

The **TENStem eco basic** is classified as class IIa according to Annex IX of Directive 93/42/EEC or according to Annex VIII of the Medical Devices Regulation (EU) 2017/745 on medical devices.

6.7 Reporting obligation

Any serious incident occurring in connection with this device is to be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

6.8 Warranty

The manufacturer grants a warranty of twelve months on the **TENStem eco basic** 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

6.9 Care and cleaning

No special care or cleaning products are required for the **TENStem eco basic**. If the device and/or the cables are soiled, clean them using a soft, lint-free cloth. See "Accessories" for electrode care.

6.10 Combining

The **TENStem eco basic** may only be combined with the articles listed in the scope of delivery and under "Accessories".

6.11 Technical safety controls (Section 11 MPBetreibV)

The technical safety controls include:

1. Inspection of accompanying documents for the presence of the instructions for use and the medical devices book
2. Check of equipment for completeness
3. Visual inspection
   - for mechanical damage
   - all cables and connectors for damage

4. Functional safety
   - Testing the output signals at a load resistance of 1 kΩ (current and voltage)
   - Testing the output signals at an ANSI load resistance (current and voltage)
   - Testing the frequency
   - Pulse width test

On request, we will gladly carry out technical safety controls for you for a fee.

7. Scope of delivery

REF	Article	Quantity
10005489	**TENStem eco basic**	1 piece
10005273	STIMEX, 50 x 50 mm (PU= 4 pcs.) or on prescription	4 pieces
10000610	1.5 V batteries LR03 Micro (AAA) (PU= 4 pcs.)	1 piece
10002263	Electrode cable type 7 (PU= 2 pcs.)	1 piece
10001787	Instructions for use	1 piece
10006539	Storage box	1 piece

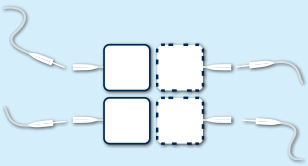
8. Accessories

8.1 Self-adhesive electrodes

The electrodes are affixed directly to the specified skin areas. Do not affix to unclean, greasy or diseased skin, or wounds!

Important: If you want to change the position of an electrode, you must switch off the device briefly before doing so. Any residue left on the skin from the self-adhesive electrodes can be easily removed using soap and water. The electrodes should only be used on one patient for hygienic reasons. Please reattach the electrodes back to the foil after each use and put them back in their original packaging. The electrodes will last longest if stored in a refrigerator. Read the "Self-adhesive electrodes (SAE)" (Art. No. 451600-0491) user instructions for more safety, cleaning, and maintenance instructions.

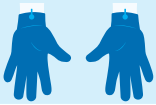
REF	Article	Quantity
10005269	STIMEX, round 32 mm Ø	4 pieces
10005272	STIMEX, round 50 mm Ø	4 pieces
10005273	STIMEX, 50 × 50 mm	4 pieces
10005275	STIMEX, 50 × 90 mm	2 pieces
10006160	STIMEX, 50 × 130 mm	2 pieces
10005277	STIMEX, 80 × 130 mm	2 pieces
10005278	STIMEX, 100 × 170 mm	1 piece
10005274	STIMEX sensitive, 50 × 50 mm	4 pieces



8.2 Fabric electrodes

The glove and sock electrodes used in combination with the **TENStem eco basic** stimulate the entire hand or foot/ankle. By using them, the sometimes problematic attaching of self-adhesive electrodes can be circumvented. Do not use the glove or sock electrodes on injured or diseased skin! Do not touch any metallic or electronic objects (e.g. mobile phone) during the treatment! Do not wear wrist watches or other metallic jewellery! Read the instructions for use for the glove/socket electrodes (Art. No. 10007110; 10007111) for more safety information and detailed cleaning instructions.

REF	Article	Size	Quantity
10005382	Stimulation gloves	S	1 pair
10005381	Stimulation gloves	M	1 pair
10005380	Stimulation gloves	L	1 pair



10005360	Stimulation socks	M	1 pair
10005359	Stimulation socks	L	1 pair
10005361	Stimulation socks	XL	1 pair

8.3 Rubber electrodes

Coat the flat side of the electrodes with electrode gel and fix them onto the skin with a piece of silk tape. **Caution:** When using silicone electrodes, care must be taken that the sufficient electrode gel is used to avoid irritation of the skin beneath the electrode. Do not affix to unclean, greasy or diseased skin, or wounds! The conductivity of the electrodes gradually decreases after approx. 50 hours of therapy. Replace them after approx. twelve months of intensive use at the latest. After each use, please clean the electrodes with soap and water or a disinfectant (such as 70% alcohol).

REF	Article	Quantity
10004084	48 × 100 mm	2 pieces
10004077	100 × 100 mm	2 pieces
10004085	48 × 48 mm	2 pieces
10004086	48 × 68 mm	2 pieces
10004079	100 × 200 mm	2 pieces
10004087	65 × 70 mm	2 pieces
10004081	20 mm, round	2 pieces
10001135	Electrode gel, tube	60 g

9. Troubleshooting

Please contact the manufacturer or the distributor if you need help starting, using or maintaining the device or if you have an unexpected operation or incident to report.

Problem	Possible cause	Proposed solution
The device will not switch on.	The batteries have not been inserted or have been inserted incorrectly.	Insert the batteries in the correct direction.
	The batteries are weak or flat.	Insert new batteries or charged rechargeable batteries.
The intensity cannot be increased above low intensity levels.	One or both electrodes do not affix properly to the skin.	Check that the electrodes are correctly seated and reattach them if necessary. Replace the electrodes if necessary.
	The cable is not properly connected to the device.	Plug the cable firmly into the output socket on the device.
	The cable is not properly connected to the electrodes.	Check that all of the electrodes being used are firmly connected to the cable.
	The cable is defective.	Replace the cable.
The device suddenly switches the intensity back to 0.	One or both electrodes have slipped or detached from the skin.	Check that the electrodes are correctly seated and reattach them if necessary. Replace them if necessary.
The device suddenly switches off.	The batteries are weak or flat.	Insert new batteries or charged rechargeable batteries. If charging the rechargeable batteries is unsuccessful, replace the batteries.
The stimulation is barely noticeable.	The electrodes do not affix correctly to the skin.	Check the electrodes and affix them firmly. Replace them if necessary.
	The electrodes are placed too close to each other or are touching.	Reposition the electrodes so that there is at least 2 cm of space between them.
	The set intensity is not high enough.	Increase the intensity using the ∧ button until you feel the stimulation clearly but not painfully.
	The batteries are too weak.	Insert new batteries or charged rechargeable batteries.

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