schwa-medico
HOLISTIC HEALTH

TENS eco 2

2-channel muscle stimulator for transcutaneous nerve and muscle stimulation

EN Instructions for use REF 10001774 Version 07 Last updated: 2023-05-09

1. Contents

1. General information

1.1 Intended purpose

The **TENS eco 2** is used for transcutaneous electrical nerve and muscle stimulation on humans to relieve acute and chronic pain, to improve blood circulation and to strengthen muscles.

Pain treatment with the **TENS eco 2** 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 **TENS eco 2** is needed.

Muscle stimulation with the **TENS eco 2** 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 skin electrodes. Indications that treatment with a **TENS eco 2** is needed are situations where muscle inactivity, such as illness, pain or immobilisation, threatens to cause or has caused a breakdown of the muscles and muscle appendages.

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

Treatment with a **TENS eco 2** can be carried out several times a day.

The **TENS eco 2** 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 user instructions, in particular the chapters "Contraindications", "TENS (low-frequency electrostimulation) contraindications in pregnant women" and "Safety instructions/warnings" 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 it is used for the first time.

Pain can indicate serious disorders in the body and must be clarified by a doctor. Even if applying the **TENS eco 2** has good success and leads to distinct pain relief, this is not to be equated with curing the cause of the pain.

1.2 Indications

- Acute and chronic nociceptive pain
- Acute and chronic neuropathic pain
- Blood circulation improvement
- Muscle-related pain
- Muscle relaxations
- Atrophy prophylaxis

1.3 Safety instructions/warnings

Please read the instructions for use carefully prior to using the device. Keep for future reference!

1. **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 and repairs are only to be carried out by authorised specialists** to ensure safety and maintain the guarantee (you can find the addresses listed in the appendix).
   Caution: If the product is modified, suitable inspections and tests must be carried out to ensure the further safe use of the device. Otherwise, all guarantee and warranty claims are void.
2. **Caution: Only use after prior consultation with a physician** Electrical stimulation therapy should never 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 when using electrode surfaces placed on the chest and upper back or crossing the heart.

   Warning: Attaching the electrode surfaces near the thorax might increase the risk of atrial fibrillation. 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.
3. **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!
4. **Keep water and other liquids away from the product**, because otherwise uncontrolled current flows may occur, electric shocks are possible, and the product would be damaged.
5. **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.
6. **Caution:** Simultaneous connection of the patient to an ME (medical electrical) device for high-frequency (HF) surgery can cause burns below the electrode surfaces of the product and result in damage to the electrostimulation device.
7. **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 output levels, resulting in painful effects.
8. **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 **TENS eco 2** (including its accessories). Non-compliance may lead to inferior device performance or faulty operation.
9. **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 previously described is nevertheless necessary, this device and the other devices should be monitored to establish that they are working properly.
10. **Affixing the electrodes:**
    a. The product should only be connected to one patient at a time.
    b. lean the skin surface where the electrodes will be affixed before attaching the electrodes. Otherwise, faulty operation cannot be ruled out.

c. 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.

d. Tattoo inks can contain metallic pigments which, under the influence of current, can 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.

e. Current densities above 2 mA/cm^2 on all electrode surfaces require increased operator attention or painful effects may occur.

f. **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.

g. 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.

11. **Do not drop the product or handle it improperly.**
    Apply only at temperatures of 10°C - 40°C, a relative air humidity of 30% - 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.
    Warning: Do not operate the device in the vicinity of potentially explosive and/or flammable substances or fumes.
    Caution: If this device is exposed to sudden temperature changes from cold to hot, do not turn on the device until it reaches the same temperature as the environment in which it will be used and wait for at least 30 minutes. Otherwise, condensation formed inside the device might cause electric shocks, fire, damage to this device and/or personal injury.
12. Careful supervision is recommended if the product is used on or in the vicinity of children. Keep the product and its packaging so that is **inaccessible to children**. **Risk of strangulation** from the cables and wires of this device and its accessories.
13. Store the product in its original packaging to protect it from damage and soiling.
14. 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 carrying out technical safety checks on the product every 24 months. Please observe the legal requirements that apply in your country.

1.4 Contraindications

Who is not allowed to use the TENS eco 2 or only after consulting the doctor in charge?

- Patients with electronic implants such as pacemakers or pumps
- Patients with cardiac arrhythmias
- 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 at increased risk of bleeding as a result of illness or medications or with fresh bleeding in the stimulation area

1.5 TENS (low-frequency electrostimulation) contraindications in pregnant women

The following applies in addition to the general contraindications:

- The use of TENS during pregnancy must 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 3 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.

1.6 Side effects

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, especially during the first treatments, and not for longer than 30 minutes or less if necessary.

Skin intolerances: Skin intolerance can occur as a reaction to the electrodes, the electrode gel or the current pulses themselves. In the event of prolonged redness, burning, itching or skin blisters under the electrodes or around the electrode site following stimulation, you must consult the doctor before further stimulation. A slight, non-persistent reddening of the skin following stimulation in the area of the electrodes is normal, as blood circulation is improved by the stimulation.

Muscle pain: Muscle pain in the sense of 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.

1.7 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 a 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 ("Measures for avoiding physical overload reactions"). 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 discomfort, 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 occurs 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.

1.8 Instructions for avoiding physical overload reactions due to muscle stimulation

1.8.1 Before each treatment

- The patient and the user must have read and understood the contraindications, safety instructions, side effects and the instructions for avoiding physical overload reactions.
- 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 adjusts the stimulation intensity to a comfortable level and readjusts it themself if necessary. The aim is to trigger non-painful muscle tension in the area of the current flow. 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 treatment.
- **Before/during treatment drink 2 glasses**, e.g. of water to support kidney function.
- **Do not undergo stimulation on an empty stomach**. Instead, have a small meal 1-2 hours before treatment to avoid any drop in blood sugar.

1.8.2 After each treatment

» 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 1-2 glasses e.g. of water**, should be drunk.

1.8.3 Treatment in the familiarisation phase (first to seventh treatment)

» As the therapy 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 10 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 4 days between the first two sessions**.

» In the next 5 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 treatments can be gradually shortened.

1.8.4 Training after the familiarisation phase

» The training duration 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.

1.9 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 training 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.
- Muscle disease (myopathies)
- Use of drugs (e.g. alcohol) or 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
- 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

1.10 Side effects of muscle stimulation

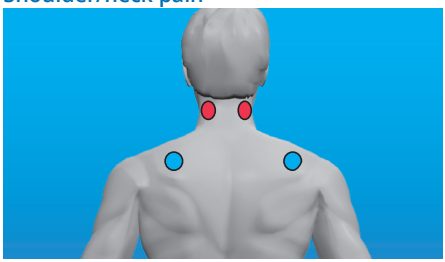
- Muscle cramps with possible damage to the muscle and neighbouring muscle structures such as connective tissue, ligaments, tendons and bones
- Muscular overload reactions with
- Muscle pain that may last for several days
- Muscle weakness that may last for several days
- The release of muscle enzymes 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 6 weeks at a time) are not known, so negative long-term effects cannot be ruled out.

1.11 Examples of electrode placement

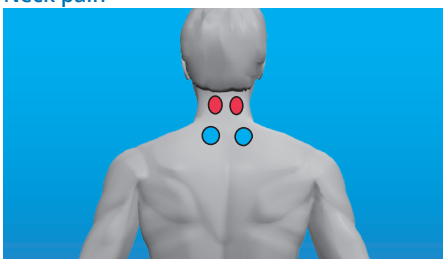
Now place the electrodes. The self-adhesive electrodes are to be affixed to the skin at the application points shown in the following illustrations. The current that flows out of a channel consists of the positive pole, the anode, and the negative pole, the cathode. The red cable connector that connects the TENS device to the electrode represents the anode. The blue cable connector represents the cathode.

Anode: red cable connector Cathode: blue cable connector

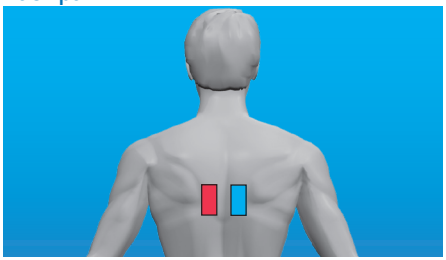
Shoulder/neck pain

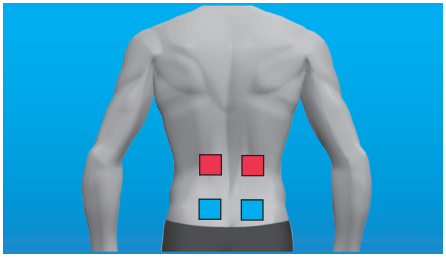


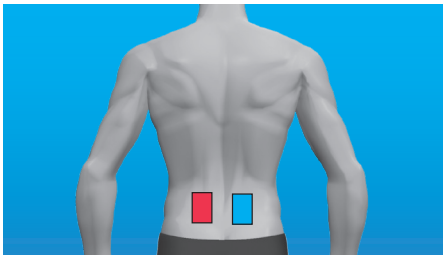
Neck pain



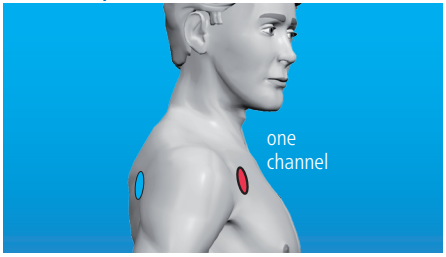
Back pain

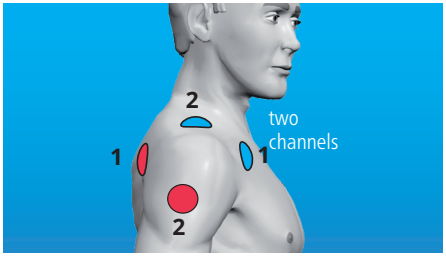




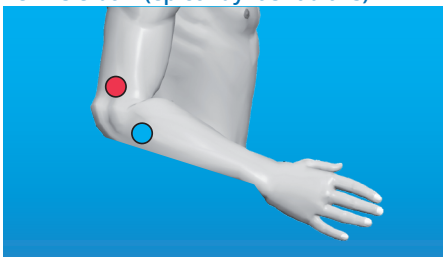


Shoulder pain

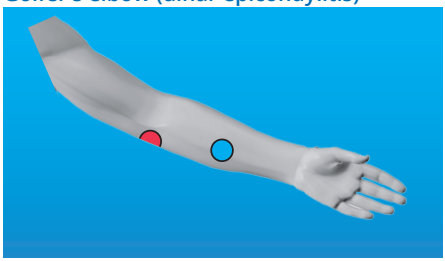




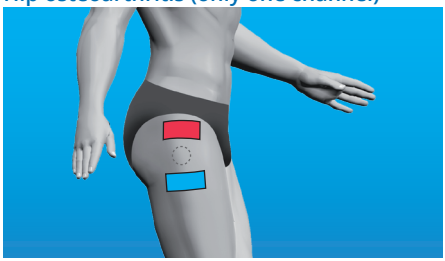
Tennis elbow (epicondylitis radialis)



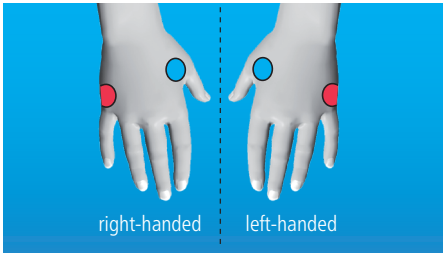
Golfer's elbow (ulnar epicondylitis)



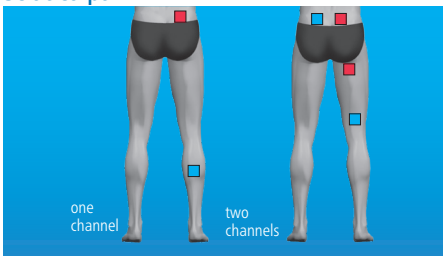
Hip osteoarthritis (only one channel)



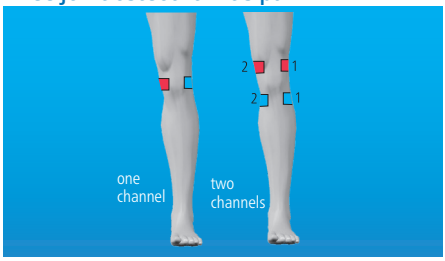
Kaada stimulation



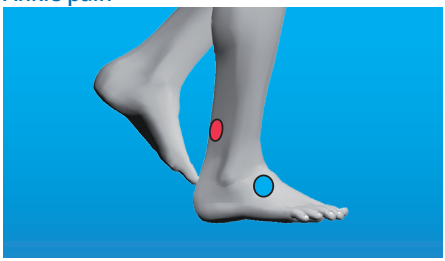
Sciatica pain



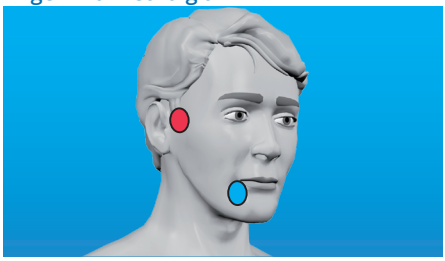
Knee joint osteoarthritis pain

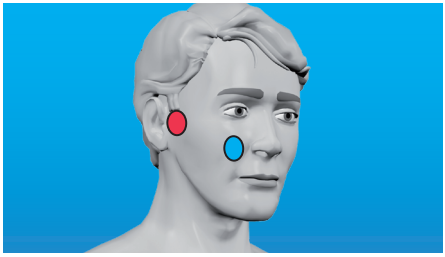


Ankle pain

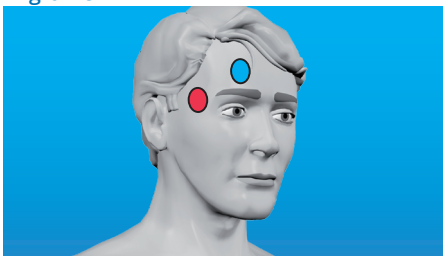


Trigeminal neuralgia

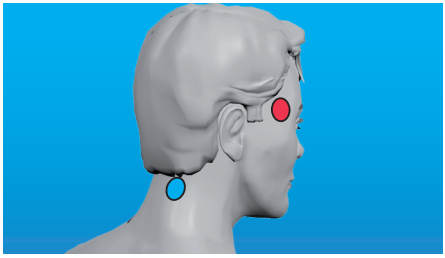




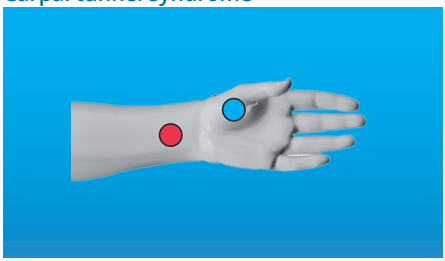
Migraine



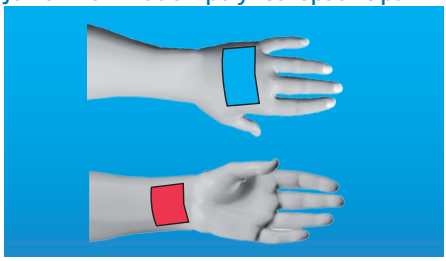
Tension headache



Carpal tunnel syndrome

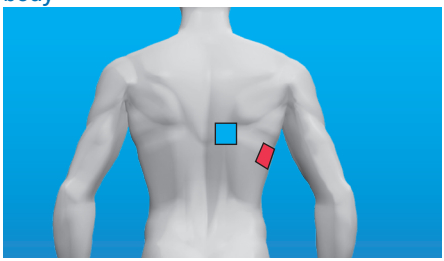


Joint inflammation/polyneuropathic pain



Achilles tendon pain

Postherpetic neuralgia, affix electrodes in mirror image to the unaffected half of the body

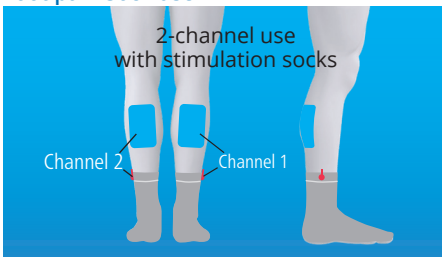


Polyneuropathic pain

Hand pain Glove use

Caution: Use only one channel at a time for one side. e.g.: Connect the self-adhesive electrode and glove on the right arm to channel 1 and the self-adhesive electrode and glove on the left arm to channel 2.

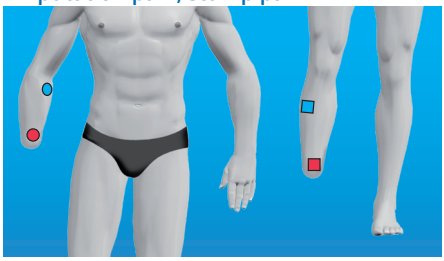
Foot pain Sock use



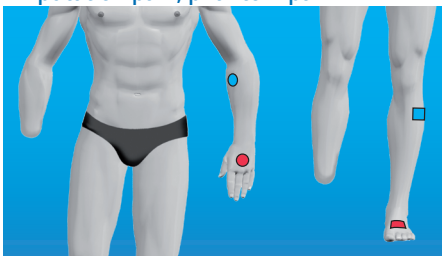
Caution: Use only one channel at a time for one side. e.g. Connect the self-adhesive electrode and sock on the right leg to channel 1, the self-adhesive electrode and sock on the left leg to channel 2.

Attention! Stimulation socks and gloves must be moistened well!

Amputation pain, stump pain



Amputation pain, phantom pain



2. Using the TENS eco 2

2.1 Controls

1 Display

2 Programme selection

3 Edit button for changing the settings

4 Modification keys intensity channels 1 and 2 These buttons can be used in Edit mode to change various parameters.

5 On/off button

6 Cable output sockets for the electrodes

7 Charging cable connection

8 ON/OFF slide switch (ON/OFF)

2.2 Connecting the cables and electrodes

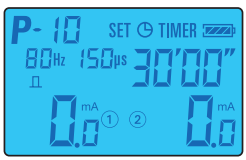
Connect the cables to the electrodes (2 per cable). Plug the other end of the cable into one of the output sockets at the top of the device. Position the electrodes on the skin.

2.3 Starting

Turn the device on using the ● button. The **TENS eco 2** will start with the programme number that was last used. If the lock is activated, a key will be displayed on the top left of the display.

2.4 Selecting a programme

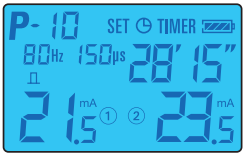
Press the P button to switch to the next programme. However, this is only possible if the device is unlocked. Programmes 1 - 12 marked with a "P" are called up first. Then come user programmes 1 - 12 marked with a "U". Once the last programme has been reached, the next press of the button will switch back to programme 1 (P1).



2.5 Starting stimulation

First position the electrodes on the desired parts of the body and then connect the electrode cables to the electrodes and the device. After the desired programme has been selected via the P button or the locked device has been started directly with the desired programme, stimulation can be started by pressing the two buttons.

2.6 Setting the intensity



You can use the modification buttons to readjust the intensity of the relevant channel to a comfortable value at any time. It can be set anywhere in the range between 0 - 100 mA.

ATTENTION: Safety switch

The device locks automatically after the last setting if it is not operated within 5 seconds to prevent the intensity level from changing unintentionally. Unlock the device by pressing the button, then all of the settings can be adjusted when they are unlocked.

If the electrodes are not correctly connected to the device or placed on the skin, the current intensity will be reset to zero from 10mA.

Important: You can adjust the intensity more quickly by holding down the or buttons. Now adjustment will be much faster.

2.7 Stopping the stimulation

Stimulation can be stopped at any time by pressing (for 1 second) the P button or the button. Stimulation will stop automatically after the programme's total running time has elapsed.

2.8 Locking the device

Select the desired programme for the patient using the P button (see chapter Programme description). Pressing the button for the right-hand channel for 3 seconds and simultaneously pressing the P button will lock the device with the preset programme. A key will now be displayed on the right of the programme number. The patient can only use this one programme. To unlock, repeat the procedure and press the buttons and P again.

2.9 Timer setting

You can use the device with or without the timer function. To deactivate the timer (preset to 30 minutes), press the E and buttons for the left-hand channel simultaneously for a period of 3 seconds. The display will now change to TIMER.

Press the E button again to switch to "TIMER OFF" mode. The symbol "---" symbol will be displayed. Now press the button to accept your timer modification.

2.10 Programme overview

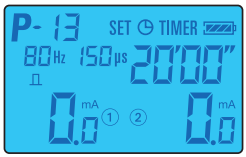
Progr. No.	Name	Indications	Description of the programmes	Frequency/ Hz	Pulse width/µs	Time/ min.
1	Gate control 1	Acute nociceptive pain, acute and chronic neuropathic pain	Both channels the same	100	200	30
2	Gate control 2	Alternative to programme 1	Both channels the same	80	150	30
3	Low frequency	Chronic nociceptive pain, blood circulation improvement, for the Kaada system	Both channels the same	2	250	30
4	Gate control + Low frequency	Combined high and low frequency stimulation via special contact points	Channel 1: 100 Hz Channel 2: 2 Hz	100 2	200	30
5	Adjustment	Muscle-related pain	First 10 minutes at 100 Hz, then 20 minutes at 2 Hz	100/2	150/ 200	10/ 20
6	HAN	Ideal for almost all pain indications	100 Hz for 3 seconds, then 2 Hz for 3 seconds	100/2	150/ 200	30
7	Burst	Alternative to programme 3 (more pleasant)	0.25 seconds long at 100 Hz, then 0.25 seconds pause (=> 2 Hz)	100	150	30
8	Modulation	Alternative to the other programmes in case of therapy resistance	Automatic frequency response: 2 -> 80 -> 2 Hz in 15 seconds	2-80-2	200- 100	30
9	Muscle training	Atrophy prophylaxis	Rising time 2 seconds, working time 5 seconds, falling time 1 second, pause time 12 seconds; automatic intensity adjustment	50	250	30
10	Gate control dynamic 1	Relaxation of the musculature	Intensity set to maximum in 1 second, then to zero in 1 second. Both channels in alternating operation.	80	150	30
11	Gate control dynamic 2	Relaxation of the musculature	Intensity set to maximum in 0.25 seconds, then to zero in 0.25 seconds. Both channels in alternating operation.	80	150	30
12	Deep TENS	Muscle-related pain, deep-seated causes of pain	Pulse blocks with 4 pulses, the specific pulses at intervals of 200 µs	100	75	30

2.11 Programming options

Progr. No.	Name	Indications	Description of the programmes	Frequency/Hz	Pulse width/µs	Time/ min.
U1	Gate control 1	Acute nociceptive pain, acute and chronic neuropathic pain	Both channels the same	1-120	50-400	1-99
U2	Gate control 2	Alternative to pProgramme 1	Both channels the same	1-120	50-400	1-99
U3	Low frequency	Chronic nociceptive pain, blood circulation improvement, for the Kaada system	Both channels the same	1-120	50-400	1-99
U4	Gate control + Low frequency	Combined high and low frequency stimulation via special contact points	Channel 1: 100 Hz Channel 2: 2 Hz	Channel 1: 4-120 Channel 2: 2	50-400	1-99
U5	Adjustment	Muscle-related pain	First 1/3, then 2/3 of the set time 2 Hz fixed	1-120	50-400	1-99
U6	HAN	Ideal for almost all pain indications	2 Hz fixed	1-120	50-400	1-99
U7	Burst	Alternative to programme 3 (more pleasant)	0.25 seconds long at 100 Hz, then 0.25 seconds pause (=> 2 Hz)	50-120	50-400	1-99
U8	Modulation	Alternative to the other programmes in case of therapy resistance	Frequency response: between set value and 80 Hz	1-50	100-400	1-99
U9	Muscle training	Atrophy prophylaxis	Rising time 2 seconds, working time 5 seconds, falling time 1 second, pause time 12 seconds; automatic intensity adjustment	1-120	50-400	1-99
U10	Gate control dynamic 1	Relaxation of the musculature	Intensity set to maximum in 1 second, then to zero in 1 second. Both channels in alternating operation.	10-120	50-400	1-99
U11	Gate control dynamic 2	Relaxation of the musculature	Intensity set to maximum in 0.25 seconds, then to zero in 0.25 seconds. Both channels in alternating operation.	50-120	50-400	1-99
U12	Deep TENS	Muscle-related pain, deep-seated causes of pain	Pulse blocks with 4 pulses, the specific pulses at intervals of 200 µs	1-120	50-400	1-99

2.12 Programming user programmes 1-12

By repeatedly pressing the E button you can call up the specific parameters for the relevant programme. Flashing indicates which parameter you can change at the moment using the ∨ or ∧ buttons. Changeable parameters are the frequency, the pulse width and the time. Only the time can be changed in the P1 - P12 programmes.



2.13 Switching the tone off and on

Simultaneously press the P button and the left-hand ∨ button. The tone's current status will be displayed after five seconds. "BEEP ON" means the tone is switched on. "BEEP OFF" indicates that the tone is switched off. Use the E button to switch the tone off and on alternately. Press the ⊙ button to save the new setting. You will then be returned to "Ready" mode.

2.14 Switching off the device

You can switch off the device at any time by pressing the ⏻ button.

It will switch off automatically if the battery voltage is insufficient (flat) or the device has not been operated for more than 2 minutes.

2.15 Recharging the integrated battery

The battery's voltage status is displayed at the top right of the screen as a battery with 4 segments. The device will switch off and can no longer be operated if the voltage drops into the critical range (1 segment or less).

You now have to recharge the battery:

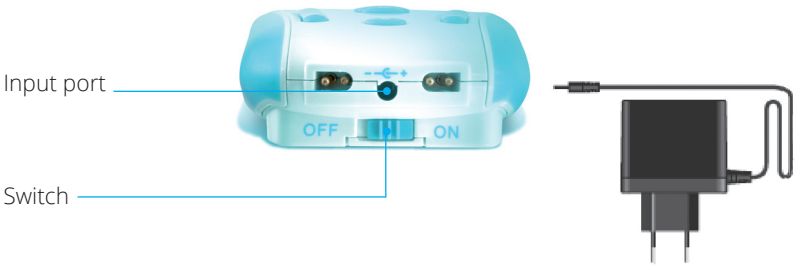
» Set the slide switch to the OFF position.

» Connect the charger to a power socket. The diode on the charger lights up red (charging).

» Recharge the **TENS eco 2** until the diode on the charger switches from red to green. The green diode indicates that recharging is complete.

» Important! Now disconnect the charger from the socket and then disconnect the charger from the **TENS eco 2**. Do not recharge the **TENS eco 2** for longer than 4 hours.

Attention! Do not forget to set the slide switch back to the ON position after recharging to make the device operational again.



2.16 Stimulation and setting the intensity

Do not try to set the intensity higher and higher (in mA). Choose an intensity that makes you feel comfortable, regardless of which programme group you want to use (recovery, pain management, muscle training). Set the intensity to a slight pain threshold and then reduce the intensity step by step down to a comfortable level. You will notice that the comfortable level may change over time, even if you stimulate in the same place as before. This is a normal effect, as various factors affect the current tolerance and its level:

Skin resistance: Dry skin conducts less current than damp skin (effect of sweat). Skin resistance also differs depending on the body region. Skin resistance is two times greater on hard skin than in the hollow of the knee. Innervation is also dependent on the stimulation area, which also explains differences in sensitivity.

Muscle mass volume: The greater the muscle mass, the higher the intensity should be set using the same parameters.

Muscle fatigue: The more fatigued the muscle, the less intensity it will tolerate.

Condition of the electrodes being used: Self-adhesive electrodes have a limited life span. The resistance of the electrodes increases and their conductivity decreases with age. Remember to replace the electrodes regularly.

Accustomisation of the nervous system to the current: During the first 5 minutes of stimulation, the user will often find that sensitivity to the current changes. Even though the amount of current remains constant, many users will find that they feel less current. The nervous system has simply become accustomed to the current. This occurs less when using dynamic programmes. Do not hesitate to increase the intensity afterwards while maintaining a comfortable level despite this.

Different parameters: The frequencies and pulse widths used in the programmes are diverse. This also explains why different intensities are chosen for the same stimulation area. For example, the following rules of thumb apply: the higher the frequency, the lower the intensity. The greater the pulse width, the lower the intensity.

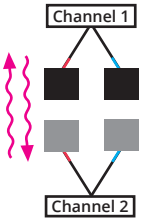
2.17 Dynamic stimulation

The principle of dynamic stimulation is that stimulation is not applied to all channels simultaneously. Dynamic stimulation creates a wave motion for the stimulation pulse, which moves back and forth between the electrode pairs to better simulate a massage effect. The user will feel dynamic stimulation as being a more pleasant process than classic neuromuscular stimulation. Distributing the current through the 2 channels alternately enables good results to be realised for both pain-relieving treatment and low-frequency muscle relaxation. Using dynamic stimulation during lymph drainage will emphasise the effect of wave-like muscle contraction.

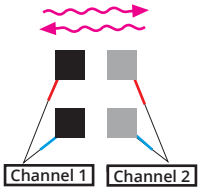
2.18 Electrode placement for dynamic stimulation programmes

2.18.1 Dynamic stimulation progress diagram

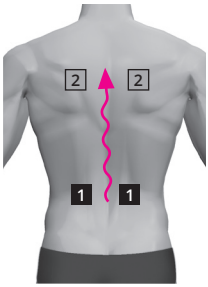
Up or down movement for back or legs



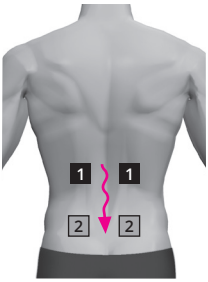
Lateral movement for gluteal or abdominal muscle



Upward movement



Downward movement



We recommend that you use 5 x 9 cm electrodes for stimulating the lower extremities. Attach one electrode from both channels to each leg.

For paravertebral stimulation you should attach one electrode from both channels on the right and left of the spine.

3. Technical information

3.1 Symbols

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.

Attention!

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

Application part of the BF model

Galvanically isolated application part with a higher level of protection against an electric shock to the body but **not directly to the heart!**

REF Article number

SN Serial number

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

Date of production

Manufacturer

Distribution

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

Store in a dry place

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°)

MD Medical device

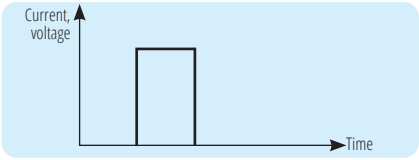
3.2 Technical data

2 channel nerve stimulator with galvanically isolated outputs, constant current characteristic, integrated device for skin-friendly long-term application, 12 integrated programmes, 12 modifiable programmes.

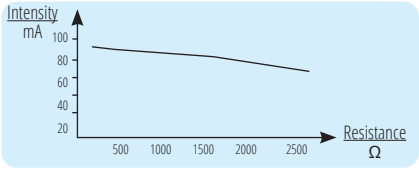
Output current	100 mA (at 1 kΩ real)
Frequency range	1-120 Hz
Pulse width	50 – 400 µs
Pulse shape	positive rectangle with negative component
Power consumption	approx. 3 mA at min. load, approx. 130 mA at max. load
Voltage supply	rechargeable NiMH 4.8V battery (approx. 3 hours running time depending on intensity levels)
Dimensions	11.4 x 6.5 x 2.7 cm
Weight	Approx. 150 g
Working conditions	Temperature range: 10°C to 40°C, Relative humidity: 30% to 75%, Air pressure: 70 - 106 kPa
Storage and transporting conditions	Temperature range: - 10°C to 55°C, Relative humidity: 10% to 90%, Air pressure: 50 - 106 kPa

3.3 Pulse shape

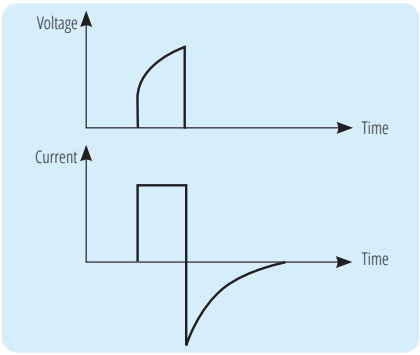
On load 1 kΩ real



Output current change
as a function of load resistance



On load ANSI/AAMI standard



3.4 Care, cleaning and disinfecting

No special care or cleaning products are needed for the **TENS eco 2**. If the device and/or the cables are soiled, clean them using a soft, lint-free cloth. See "Accessories" for electrode care.

3.5 Warranty/guarantee

The statutory warranty rights apply.

The manufacturer grants a guarantee of 12 months for the **TENS eco 2** device from the date of acceptance by the end customer. The guarantee does not apply:

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

3.6 Classification

The **TENS eco 2** is classified as Class IIa according to Annex IX of Directive 93/42/EEC or according to the Medical Devices Regulation (EU) 2017/745.

3.7 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 is established.

3.8 Combining

The **TENS eco 2** may **only** be combined with the articles listed in the scope of delivery and under "Accessories".

3.9 Maintenance/safety controls

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
   - of 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.

3.10 Disposal

3.10.1 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 include rechargeable batteries, we are legally obliged in accordance with § 18 subs. 1 of the German Battery Act (BattG) to inform you of the following: The dustbin symbol () indicates batteries containing harmful substances and the fact **that batteries must 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 percent by weight of mercury

Battery contains more than 0.004 percent lead by weight of lead

3.10.2 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, 35360 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 5 other electrical appliances, which each do not exceed 25 cm in height, width and length, free of charge in its sales area (address: Dreieiche 7, 35360 Ehringshausen).

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

3.11 Scope of delivery

Art. No.	REF	Article	Quantity
10005474	104062	**TENS eco 2**	1 pc.
10005273	283400	STIMEX, 50 x 50 mm (PU= 4 pcs.) or on prescription	4 pcs.
10002245	106351	Electrode cable type 5.15	2 pcs.
10005057	104776	Charger 3PN0508S	1 pc.
10001774	101446	Instructions for use	1 pc.

4. Accessories

4.1 Self-adhesive electrodes

Self-adhesive electrodes are affixed directly to the specified skin areas.

Do not affix to unclean, greasy or diseased skin, or wounds!

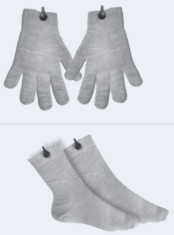
Important: If you want to change the position of an electrode, you must switch off the device briefly before doing so. Any residue left on the skin from the self-adhesive electrodes can be easily removed using soap and water. The electrodes should only be used on one patient for hygienic reasons. Please 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.

Art. No.	REF	Article	Quantity
10005269	281000	STIMEX, round 32 mm Ø	4 pieces
10005272	282000	STIMEX, round 50 mm Ø	4 pieces
10005273	283400	STIMEX, 50 x 50 mm	4 pieces
10005275	283600	STIMEX, 50 x 90 mm	2 pieces
10006160	283000	STIMEX, 50 x 130 mm	2 pieces
10005277	283100	STIMEX, 80 x 130 mm	2 pieces
10005278	281060	STIMEX, 100 x 170 mm	1 piece
10005274	281027	STIMEX sensitive, 50 x 50 mm	4 pieces

4.2 Fabric electrodes

The glove and sock electrodes used in combination with the **TENS eco 2** 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 user instructions for the glove/socket electrodes (Art. No. 451600-0438; 451600-0439) for more safety information and detailed cleaning instructions.

Art. No.	REF	Article	Size	Quantity
10005382	107014	Stimulation gloves	S	1 pair
10005381	107021	Stimulation gloves	M	1 pair
10005380	107022	Stimulation gloves	L	1 pair
10005360	107023	Stimulation socks	M	1 pair
10005359	107024	Stimulation socks	L	1 pair
10005361	107067	Stimulation socks	XL	1 pair



4.3 Other accessories

Art. No.	REF	Article	Quantity
10002245	106351	Electrode cable type 5.15	2 pcs.
10005057	104776	Charger 3PN0508S	1 pc.

5. 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 battery is low or flat.	» Recharge the battery.
The device suddenly switches off.	» The battery is low or flat.	» Recharge the battery. » Replace the battery if recharging is unsuccessful. » Use a new charger if replacing the battery is also unsuccessful.
The intensity cannot be increased above 10 mA.	» 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 intensity suddenly drops 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 the electrodes if necessary.
The stimulation is barely noticeable.	» The electrodes do not affix correctly to the skin.	» Check the electrodes and affix them firmly. Replace the electrodes 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 battery is too weak.	» Recharge the battery.

6. Manufacturer's declaration on electromagnetic compatibility

Recommended protective distances between portable and mobile HF telecommunication devices and the TENS eco 2

The **TENS eco 2** is intended for operation in an electromagnetic environment in which RF disturbances are controlled. The customer or the user of the **TENS eco 2** can help to avoid electromagnetic interference by maintaining the minimum distance between portable and mobile RF telecommunication devices (transmitters) and the **TENS eco 2** - depending on the output power of the communication device, as indicated below.

Rated power of the Transmitter W	**Protective distance depending on the transmission frequency m**		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters whose maximum power rating is not specified in the above table, the recommended separation distance d in metres (m) can be determined using the equation associated with each column, where P is the maximum power rating of the transmitter in watts (W) as specified by the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not be applicable in all cases. The propagation of electromagnetic quantities is affected by absorptions and reflections of buildings, objects and people

Guidelines and manufacturer's declaration - Electromagnetic emission

The **TENS eco 2** unit is intended for operation in an environment as specified below. The customer or the user of the **TENS eco 2** should ensure that it is operated in such an environment.

Störaussendungsmessung	**Übereinstimmung**	**Elektromagnetische Umgebung - Leitfaden**
HF emissions according to CISPR 11	Group 1	The **TENS eco 2** must emit electromagnetic energy to ensure its intended function. Neighbouring electronic devices can be influenced.
HF emissions according to CISPR 11	Class B	The **TENS eco 2** is suitable for use in all facilities including those in residential areas and those directly connected to a public supply network that also supplies buildings used for residential purposes.
Emission of harmonics according to IEC 61000-3-2	not applicable	
Emission of voltage fluctuations/ flicker according to IEC 61000-3-3	not applicable	

Guidelines and manufacturer's declaration - Electromagnetic immunity			
The **TENS eco 2** is intended for use in the electromagnetic environment specified below. The customer or the user of the **TENS eco 2** should ensure that it is used in such an environment.			
Immunity tests	**IEC 60601 test level**	**Agreement level**	**Electromagnetic environment - Guidelines**
Static electricity discharge (ESD) according to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be made of wood or concrete or have ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30 %.
Fast transient electrical disturbances/ bursts according to IEC 61000-4-4	± 2 kV for mains lines ± 1 kV for input and output lines	not applicable	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Surges according to IEC 61000-4-5	± 1 kV Gegentaktspannung ± 2 kV Gleichtaktspannung	not applicable	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Voltage dips, short-term interruptions and fluctuations of the supply voltage according to IEC 61000-4-11	5 % U_T (> 95 % UT dip) for ½ period 40 % U_T (60 % UT collapse) for 5 periods 70 % U_T (30 % UT collapse) for 25 periods < 5 % U_T (> 95 % dip of UT) for 5 s	not applicable	The quality of the supply voltage should correspond to that of a typical business or hospital environment. If the user of the TENS eco 2 requires continued function even when power supply interruptions occur, it is recommended that the TENS eco 2 be powered from an uninterruptible power supply or a battery.
Magnetic field at the supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	not applicable	Magnetic fields at the mains frequency should correspond to typical values found in business and hospital environments.
NOTE	U_T is the AC mains voltage before the application of the test levels		

Guidelines and manufacturer's declaration - Electromagnetic immunity			
The **TENS eco 2** is intended for use in the electromagnetic environment specified below. The customer or the user of the **TENS eco 2** should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Agreement level**	**Electromagnetic environment - Guidelines**
Conducted RF disturbances according to IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	not applicable	Portable and mobile radios should not be used at a distance from the **TENS eco 2**, including the lines, less than the recommended protective distance calculated according to the equation applicable to the transmission frequency. **Recommended protective distance:** $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ for 800 MHz to 2,5 GHz where P is the nominal power of the transmitter in watts as specified by the transmitter manufacturer and d is the recommended separation distance in metres [m]. The field strength of stationary radio transmitters should be less than the compliance level at all frequencies according to an on-site investigation [a, b]. Interference is possible in the vicinity of equipment bearing the following symbol.
Radiated RF disturbances according to IEC 61000-4-3	3 V/m 80 MHz bis 1000 MHz	3 V/m	

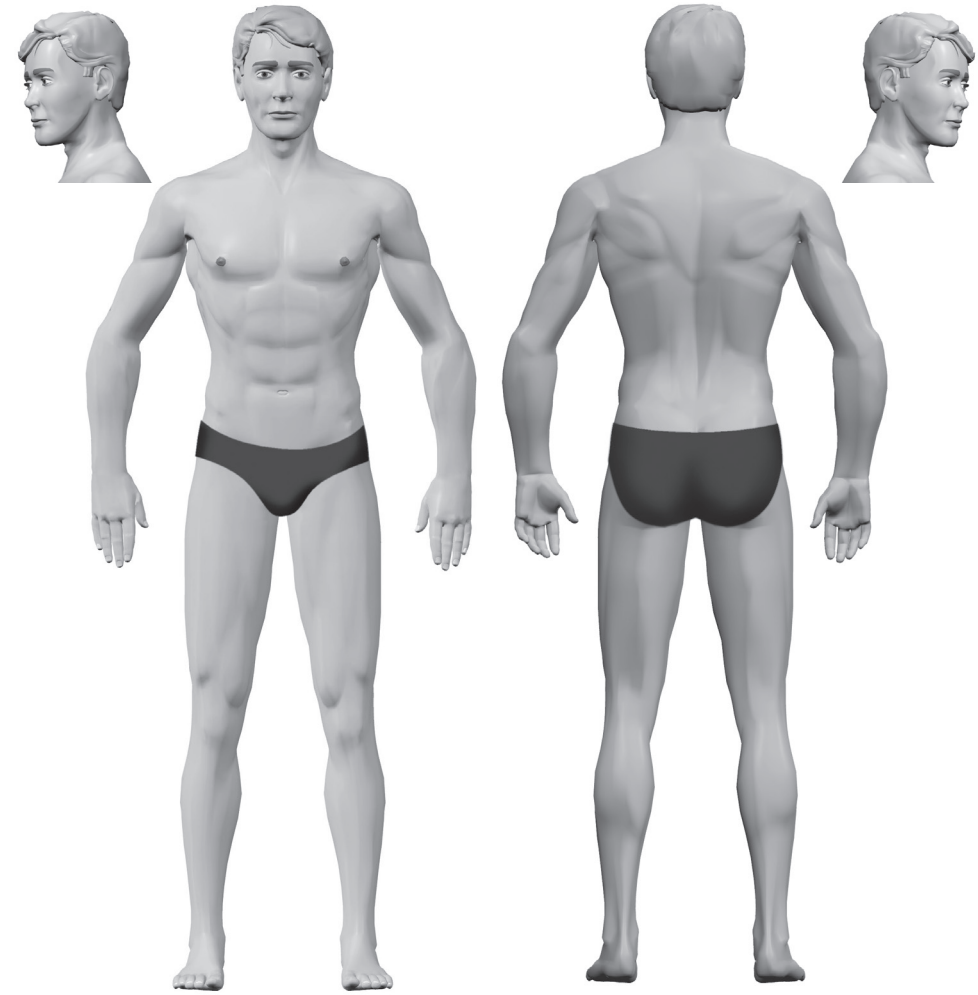
NOTE 1 For 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not be applicable in all cases. The propagation of electromagnetic quantities is affected by absorptions and reflections from buildings, objects and people

a The field strength of stationary transmitters, such as base stations of radiotelephones and land mobile radios, amateur radio stations, AM and FM radio and television transmitters, cannot theoretically be accurately predicted. To determine the electromagnetic environment with respect to stationary transmitters, a site study should be considered. If the measured field strength at the location where the **TENS eco 2** is used exceeds the above compliance levels, the **TENS eco 2** should be observed to demonstrate intended operation. If unusual performance characteristics are observed, additional measures may be required, such as changing the orientation or location of the **TENS eco 2**.

b Over the frequency range from 150 kHz to 80 MHz, the field strength should be less than 3 V/m.

7. Electrode placement



P1	U1	P5	U5	P9	U9		
P2	U2	P6	U6	P10	U10		
P3	U3	P7	U7	P11	U11		
P4	U4	P8	U8	P12	U12		

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