Технические характеристики на беспроводные устройства медицинской электростимуляции TGS 440 компании DITTMANN

- Radio TENS device for nerve stimulation with the aid of stimulation current
- 2-channel device (TENS stimulators A and B)
- Comfortable control of the TENS stimulators using the remote control or directly on the stimulators
- TENS stimulators A and B can be used and controlled individually or simultaneously
- Pre-programmed application sequence with therapy duration of 30 minutes
- 20 levels for output intensity
- Frequency range from 5 to 125 Hz
- Pulse duration of 130/250 µs
- Warranty: 24 months
- Contains: 2x TENS stimulators (A and B), 1x remote control, 2x adhesive electrode pads, 1x instruction manual, 6x 1.5 V AAA batteries

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Dear purchaser,
Congratulations on your purchase of a new radio TENS device TGS 440 and thank you for your trust. In order to ensure optimal functionality and operation of your radio TENS device, please read the instruction manual before using the device for the first time. This guarantees a long useful life of this product.

1.0 Definition of symbols

The safety symbols shown in this instruction manual contain information concerning the correct use of the radio TENS device and your safety.

The symbols refer to the following content:

Read and follow the instruction manual!

Warning / danger: If not used correctly, there might be the risk of serious injury, damage and mortal danger!

These instructions must be followed under all circumstances!

Warning / danger: The device must not be used by persons with a pacemaker!

2.0 Basic information

2.1 Characteristics of a TENS device

The **radio TENS device TGS 440** is an electro-stimulation device. To this end, an electric current is transmitted through the skin to the nerves.
"TENS" means "transcutaneous electric nerve stimulation". Using this convenient and comfortable radio TENS device, certain parts of the body are stimulated in a targeted manner with the effect that pain and symptoms can be relieved significantly.

2.2 Information concerning the TENS therapy

The device uses low-frequency electric currents for therapeutic purposes. The induced electric pulses, their intensity, frequency and frequency width are controlled by the respective application programme. By means of adhesive electrode pads applied on the skin, the electric pulses are transmitted to the nervous system and the muscles.

The current flows from the positive **(+)** adhesive electrode to the negative **(-)** adhesive electrode. For the purpose of pain treatment, the delivery of pain to the central nervous system is influenced during the application of a TENS therapy. The user does no longer perceive the pain at all or perceives the pain to a limited extent only. The two TENS stimulators A and B (correspond to channels 1 and 2) can be used independently of one another on two different parts of the body. Thus, you are able to treat two areas of pain at the same time. Using the remote control, the intensity of the TENS stimulators A and B can be comfortably set either individually for each of the two TENS stimulators or simultaneously for both TENS stimulators. As an alternative, the intensity can also be set separately on each of the two TENS stimulators A and B. The TENS therapy activates the body's own pain suppressing sequences in the central nervous system, inhibiting the transmission of pain impulses to the brain.

The TENS therapy with low frequency and high intensity (muscle twitches occur in the area of the electrodes) activates the body's own pain regulating systems in the brain. As a result, the body's own messengers (e.g. endorphins) which suppress the pain and can cause a general improvement of the blood circulation are increasingly released.

3.0 Safety instructions

3.1 General safety instructions

3.1.1 In case of a defect, the radio TENS device must no longer be used and must not be repaired or modified (changed) by the users themselves. If used incorrectly, the stimulation current may cause pain, injuries and burns.

3.1.2 If skin alterations, pain, swelling, discomfort or other irregularities occur during the use of the radio TENS device, you must stop the therapy immediately and seek medical advice.

3.1.3 Please remove all metallic objects such as jewellery, belts, watches and other utensils from your body, before starting the therapy in such a manner that they do not come into contact with the radio TENS device or the adhesive electrode pads.

3.1.4 Do not perform any other activities while using the radio TENS device. Do not use the radio TENS device especially while driving!

3.1.5 If you have any doubts concerning the therapy with the radio TENS device, please seek medical advice in advance.

3.1.6 Only use the radio TENS device on parts which give inexplicable pain, on swollen muscles or after a serious muscle injury after having sought prior medical advice. The therapy sessions using the radio TENS device are not a substitution for a medical diagnosis and treatment!

3.1.7 Please store this instruction manual during the service life of the radio TENS device for later reference and also hand it over if you pass it on to third parties. Please make the instruction manual also available to third parties. The instruction manual is an integral part of the radio TENS device.

3.1.8 Any misuse and use not in conformity with the application must be avoided.

3.1.9 Accessories from other devices must not be used.

3.2.0 If irregularities occur while using the device, the therapy must be stopped immediately.

3.2.1 The adhesive electrode pads must not be bent sharply or folded.

3.2.2 Do not place any heavy or sharp-edged objects on the radio TENS device, the remote control or the adhesive electrode pads.

3.2.3 Prior to any therapy session, check the device, the remote control and the adhesive electrode pads for errors and defects. In the event of an error or defect, the device, the remote control and the adhesive electrode pads must not be used.

3.2.4 While using the radio TENS device, do not wear any body jewellery or tattoo stickers / tattoos in the stimulation area.

3.3 Usage / environment for which the radio TENS device is suited

3.3.1 Only use the radio TENS device for the intended purposes, i.e. for an external low-frequency therapy (electric pulses in a range up to max. 125 Hz and max. 120 mA) on the human body.

3.3.2 The radio TENS device is only intended for external application (skin application) on humans for electric nerve stimulation.

3.3.3 As part of a TENS therapy, the device can be used for the treatment of acute pain, arthrosis, rheumatic complaints and other chronic pain conditions.

3.3.4 Unless instructed otherwise by your doctor, we recommend an average therapy duration of 30 minutes up to three times a day.

3.3.5 The sense of intensity may actually depend on the user's respective daily constitution. Therefore, the user may adjust the intensity to his/her personal individual needs using the intensity control of the radio TENS device.

3.4 Usage / environment for which the radio TENS device is not suited

3.4.1 The radio TENS device must not be used at the same time with other medical and electric devices of any type.

3.4.2 Do not use the radio TENS device while showering, while swimming, in the sauna, while taking a bath or in any other environment with high air humidity. Keep away any liquids during the therapy. Injuries may occur or your health may be impacted adversely by an increased stimulation or a short circuit. **Attention!** Mortal danger!

3.4.3 Do not use the radio TENS device in bed and/or while sleeping.

3.4.4 Do not use the radio TENS device near highly flammable substances or gases or near explosives.

3.4.5 While using the radio TENS device, it may interfere with other electric devices or may be impaired by other electric devices. Therefore, do not use the radio TENS device near other electric devices.

3.4.6 Keep a distance of at least 1.5 metres to short wave or microwave devices and/or high-frequency surgical devices when using the radio TENS device; otherwise, there is a risk of skin irritations or burns being caused to the skin below the electrodes. Do not use the radio TENS device on mountains higher than 3,000 metres.

3.4.7 Please note that portable and mobile HF (high-frequency) communication equipment (e.g. mobile phones) may influence other medical electrical devices.

3.4.8 Medical electrical devices are subject to special precautions regarding EMC (electromagnetic compatibility). Therefore, please observe the EMC instructions (page 24-27) on the installation and commissioning of the device provided in this instruction manual.

3.5 Application for which the radio TENS device is suited

3.5.1 Pain relief therapies with the radio TENS device are purely of a symptomatic nature. They can effect pain relief and, under certain circumstances, cure. Please seek medical advice if you have any therapy-related questions.

3.5.2 Using the radio TENS device, acute and chronic pain can be treated.

3.6 Application for which the radio TENS device is not suited

3.6.1 You must not use the radio TENS device under the following circumstances: a. heart diseases and cardiac arrhythmias (may lead to cardiac arrest), b. directly on wounds, c. on the eyes, d. for patients with pacemakers, e. parts of the body that are poorly supplied with blood, f. for patients with psychological and/or emotional problems, g. for patients with diagnosed dementia (deterioration of mental faculties), h. for patients with a low IQ (intelligence quotient) who do not understand the functioning and dangers of the device.

3.6.2 Please consult your doctor before using the radio TENS device under the following circumstances: a. acute diseases, b. tumours, c. infectious diseases, d. fever, e. blood pressure problems, f. skin diseases, g. after an accident, h. nausea or dizziness, i. onset of illnesses, j. if anomalies occur, k. pain of indefinable cause, l. diabetes, m. seizures, n. during menstruation, o. if pain is not experienced in some parts of the body, p. people with metals in the body, q. pregnancy.

3.6.3 With indefinable pain, such as indefinable headaches, a therapy with the radio TENS device is not effective.

3.6.4 Do not use the radio TENS device if you could hurt yourself in any way due to a sudden fright.

3.6.5 The adhesive electrode pads of the radio TENS device must not be used on open wounds, on areas where the skin is sensitive and on fresh scars.

3.6.6 The following people should not use the radio TENS device: children, helpless people, allergy sufferers (e.g. people reacting in an allergic manner to the application of the electrode pads or the like), people with immunodeficiency, people with deficits (e.g. epilepsy), people with indefinable pain, diabetes or circulatory insufficiencies, people with circulatory disorders of the exterior arteries and tissues or serious cardiovascular diseases. If in doubt, seek medical advice!

3.6.7 If a person is not able to perceive the electric stimulation current correctly, a therapy using the radio TENS device must not be performed. Children are more sensitive to stimulation current! People of frail health and handicapped people might not be able to attract attention to themselves if too high an intensity of the stimulation current device has been reached.

3.7 Usage by children and adolescents

3.7.1 Children may only be treated using this radio TENS device if supervised by adults.

3.7.2 The radio TENS device and its accessories must be stored out of the reach of children and adolescents younger than 18 years.

3.7.3 Keep the radio TENS device out of the reach of children! Small parts could be swallowed by children who might then choke! Children could hurt themselves when using the device.

3.8 Usage of the radio TENS device

3.8.1 For the radio TENS device TGS 440, only use the adhesive electrode pads developed especially for this device.

3.8.2 The adhesive electrode pads included in the scope of delivery may only be connected to the **radio TENS device TGS 440**. Please ensure that the TENS stimulators are always switched off when applying or removing the adhesive electrode pads.

3.8.3 If you wish to reposition the adhesive electrode pads during the therapy, make sure that you switch off the TENS stimulators first.

3.8.4 Using the radio TENS device may result in skin irritations. If skin irritations such as redness, blisters or itching occur, you should no longer use the radio TENS device and seek medical advice! Do not apply the adhesive electrode pads permanently on the same part of the body, as this can lead to skin irritations.

3.8.5 Before using the adhesive electrode pads, the areas of the skin on which you wish to apply them must be thoroughly cleaned and dried. These areas of the skin should be greaseless and clean.

3.8.6 Only connect the adhesive electrode pads to the TENS stimulators if they have been switched off!

3.8.7 Carefully remove the adhesive electrode pads from the TENS stimulators in order to prevent them from being damaged.

3.8.8 The adhesive electrode pads can also be connected to the TENS stimulators or disconnected from them using the press stud connection.

3.8.9 Each person reacts differently to an electric nerve stimulation. If the therapy is not successful, please seek medical advice.

3.9.0 Please remove the protective foil before applying the adhesive electrode pads on the skin. The adhesive strength of the electrode pads depends on the condition of the skin, storage and number of therapy sessions. If the adhesive electrode pads do no longer stick completely on the skin surface, they must be replaced by new adhesive electrode pads. The adhesive electrode pads must lie completely flat against the skin in order to avoid locally high current densities which might result in skin burns. After the application has been completed, stick the adhesive electrode pads back on the protective foil and keep them in a protected environment to ensure that they cannot dry out. Thus, their adhesive strength can be maintained for a longer period of time.

3.9.2 Avoid any contact with the adhesive electrode pads during the therapy. Under certain circumstances, touching the electrodes results in a short circuit involving an excessive current density. This excessive current density might cause burns and injuries!

4.0 Areas where the adhesive electrode pads are applied

4.0.1 Each person reacts differently to an electric nerve stimulation. The positioning of the adhesive electrode pads might thus deviate from the standard positions. If the therapies are not successful, please consult your doctor as to which positioning techniques are most suitable for you.

4.0.2 In order to position the adhesive electrode pads correctly, use the information as well as the figures on page 20 and 21 for TENS therapies intended as application examples as guidance.

4.0.3 Do not use any adhesive electrode pads of an electrode size smaller than 90x57 mm; otherwise, too high a current density can flow and injuries may be caused. Smaller electrodes falling below a minimum size of 90x57 mm may only be used if approved by the doctor in charge. In this respect, it is absolutely necessary to observe the safety instructions of the manufacturer of the respective adhesive electrodes.

4.0.4 The adhesive electrode pads must not be resized, e.g. by cutting off parts.

4.0.5 The adhesive electrode pad consists of two individual electrodes (+ (positive) and - (negative) pole) which are separated by a white strip in the middle. The distance between the electrodes has already been defined by the design and, thus, cannot be changed.

4.0.6 Do not pull the TENS stimulators if you wish to remove the adhesive electrode pads from the skin! To this end, lift the adhesive electrode pad in the area of the arrow with the "**PULL**" imprint and remove it carefully from the skin. Please make sure that you do not touch the adhesive surfaces with your fingers. Afterwards, stick the adhesive electrode pads back onto the protective foil and store them in a cool and dry place.

4.0.7 Please ensure that the painful part of the body is enclosed by the positions of the electrodes during a TENS therapy. For an aching group of muscles, you should apply the electrodes in such a manner that the affected muscles are also enclosed by the electrodes.

4.1 Areas where the adhesive electrode pads must not be applied

4.1.1 The adhesive electrode pads must not be applied on parts of the body with skin inflammations or open and fresh wounds or fresh scars.

4.1.2 Do not apply the adhesive electrode pads on the following parts of the body: a. on and in the mouth, b. eyelids, c. front neck area, d. larynx, e. throat area, f. carotid artery, g. heart region, h. genitalia (genital organs: penis, testicles, ...), i. fingers, j. pacemakers.

4.1.3 The adhesive electrode pads must not be applied in such a manner that the current can directly flow through the brain, e.g. on both templates.

4.1.4 The adhesive electrode pads must not be applied directly on the heart region or positioned directly next to the heart region in order to prevent current flowing through the heart region.

4.2 Storage / maintenance of the radio TENS device

4.2.1 The radio TENS device is maintenance-free.
4.2.2 Do not dismantle or repair the radio TENS device; otherwise, technical or physical accidents may occur. Warning: Mortal danger!
4.2.3 If the device is not operated for a longer period of time, remove the batteries from the device.
4.2.4 If the radio TENS device TGS 440 is subject to trade or commercial usage, a safety inspection must be performed every two years in accordance with § 6 MPBetreibV [German Medical Devices Operator Ordinance]. The safety inspections must be carried out by a company specialised in medical devices. Further information may be obtained from our service centre (see page 29).

4.3 Cleaning and care of the radio TENS device

4.3.1 The radio TENS device and the remote control must not be exposed to direct sunlight. Do not place them on hot surfaces.
4.3.2 During cleaning and care, the radio TENS device must be switched off and must not be connected to the adhesive electrodes.
4.3.3 Clean the surfaces of the radio TENS device and remote control carefully with a soft, damp cloth. Please make sure that, in the area of the function keys in particular, no moisture enters the device and the remote control. If the device or the remote control are very dirty, a mild detergent can be added. The radio TENS device must be switched off during cleaning. To this end, remove the batteries from the device and remote control before cleaning them. Afterwards, let the radio TENS device dry completely. Do not use any chemical detergents or cleaners to clean the radio TENS device, the remote control or the adhesive electrode pads.
4.3.4 For hygienic reasons, every user should use his/her own adhesive electrode pads.
4.3.5 A suitable, commercially available disinfectant may be used in order to disinfect the device. Afterwards, let the radio TENS device dry completely.
4.3.6 Do not immerse the radio TENS device into water or other liquids.

5.0 Scope of delivery / contents

C

B

A


RADIO TENS DEVICE TGS 440

INSTRUCTION MANUAL

CE 0123 TGS 440

1x instruction manual

Radio TENS device TGS 440:
A: TENS stimulator A (channel 1)
B: TENS stimulator B (channel 2)
C: Remote control

6x 1.5 V AAA batteries

2x adhesive electrodes
with press stud connection

6.0 Disposal of the radio TENS device

6.1 If the radio TENS device **TGS 440** is to be recycled, observe the legal regulations concerning disposal. Contact your municipality or a waste disposal company for further information. Dispose of the radio TENS device in accordance with the Waste of Electrical and Electronic Equipment Directive 2002/96/EC (WEEE Directive).

7.0 Inserting the batteries / battery change

7.1 Remote control: Battery change

Insert two 1.5 V batteries (type AAA) observing the correct polarity (+ (positive) and - (negative) pole) in the remote control.

Battery types: For the **remote control** of the radio TENS device, two alkaline batteries of the type AAA are required. Do not use any rechargeable batteries!

Rear side of the remote control

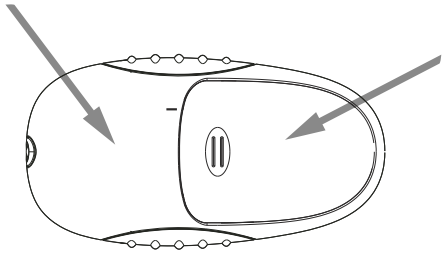

Figure 1

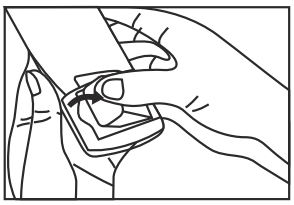

Figure 2

Cover of the battery compartment:
In order to open the cover lock, press on the shaded area of the battery compartment and push it outwards away from the housing of the remote control (**Figure 1**). Remove the used batteries and insert two new 1.5 V alkaline batteries (type AAA) (**Figure 2**). When inserting the batteries, observe the correct polarity (see marking / embossing (+) / (-) in the battery compartment). Afterwards, re-insert the cover of the battery compartment on the housing of the remote control and push it backwards until it has engaged firmly. The remote control is now ready for operation.

7.2 TENS stimulators A and B: Battery change

Insert two 1.5 V batteries (type AAA) according to the description on the following page (page 14) observing the correct polarity (+ (positive) and - (negative) pole) in the **TENS** stimulator A and **TENS stimulator B**.

Battery types: For the TENS stimulators, two alkaline batteries of the type AAA are required for each TENS stimulator. Do not use any rechargeable batteries!

PLEASE NOTE: The batteries can only be changed if no adhesive electrodes are connected to the TENS stimulators!

BATTERY CHANGE

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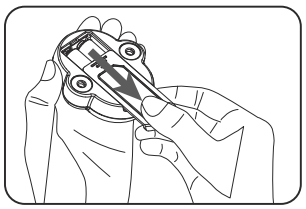


Figure 3

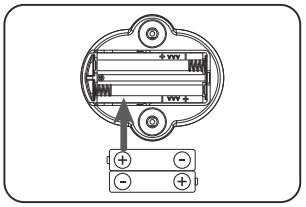


Figure 4

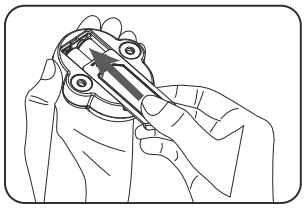


Figure 5

In order to open the cover lock, press on the shaded triangular area of the battery compartment of the TENS stimulator and push it outwards away from the housing of the device (**Figure** 3). Remove the used batteries and insert two new 1.5 V alkaline batteries (type AAA) in the battery compartment of the TENS stimulator. When inserting the batteries, observe the correct polarity: each of the negative poles (-) of the batteries must lie flat against the two springs in the battery compartment (in this respect, please see **Figure 4**). Afterwards, re-insert the cover of the battery compartment on the housing of the TENS stimulator and push it backwards until it has engaged firmly by clicking into place (see **Figure 5**). If you connect the adhesive electrode pads to the press studs on the TENS stimulator, the device is now ready for operation.

PLEASE NOTE: Remove the batteries from the device if they are empty or if you do not use the product for a longer period of time. Thus, you can avoid any damage which may be caused by leaking or corroding batteries.

7.3 Information concerning batteries

Pb, Hg, Cd

7.3 Disposal of the batteries: Used batteries must not be disposed of as household waste! Dispose of the batteries via your specialist dealer for electronic equipment or your public collection point for recyclable materials. As a consumer, you are legally obliged to return used batteries.

7.4 These chemical symbols indicate a battery containing harmful substances: **Pb** = contains lead, **Hg** = contains mercury, **Cd** = contains cadmium.

7.5 Batteries may be fatal if swallowed. Therefore, store batteries and products out of the reach of infants. If a battery was swallowed, seek medical advice immediately.

7.6 If a battery has leaked, avoid any contact with the skin, the eyes and the mucous membranes. Immediately rinse the affected parts with plenty of clear water and instantly consult a doctor or seek medical advice.

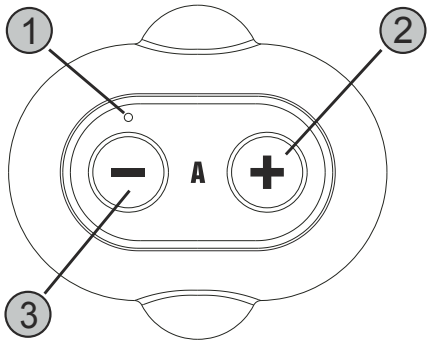
7.7 Batteries must not be charged (except for rechargeable batteries), taken apart, thrown into fire or short-circuited.

7.8 Protect the batteries from excessive heat. Remove the batteries from the device if they are empty or if you do not use the product for a longer period of time. Thus, you can avoid any damage which may be caused by leaking batteries.

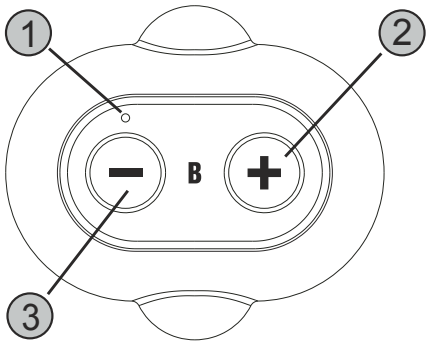
7.9 Always replace all batteries of a device. Do not use any different battery types, accumulators (rechargeable batteries) or batteries with different capacities.

8.0 Designations and functionality of the TENS stimulators

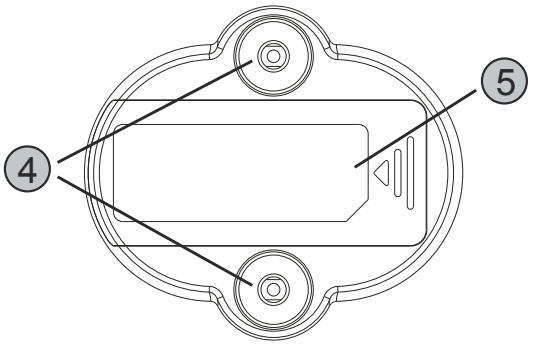
TENS stimulator A



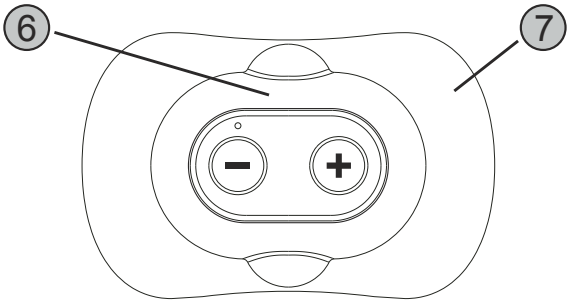
TENS stimulator B



Rear side of the TENS stimulator

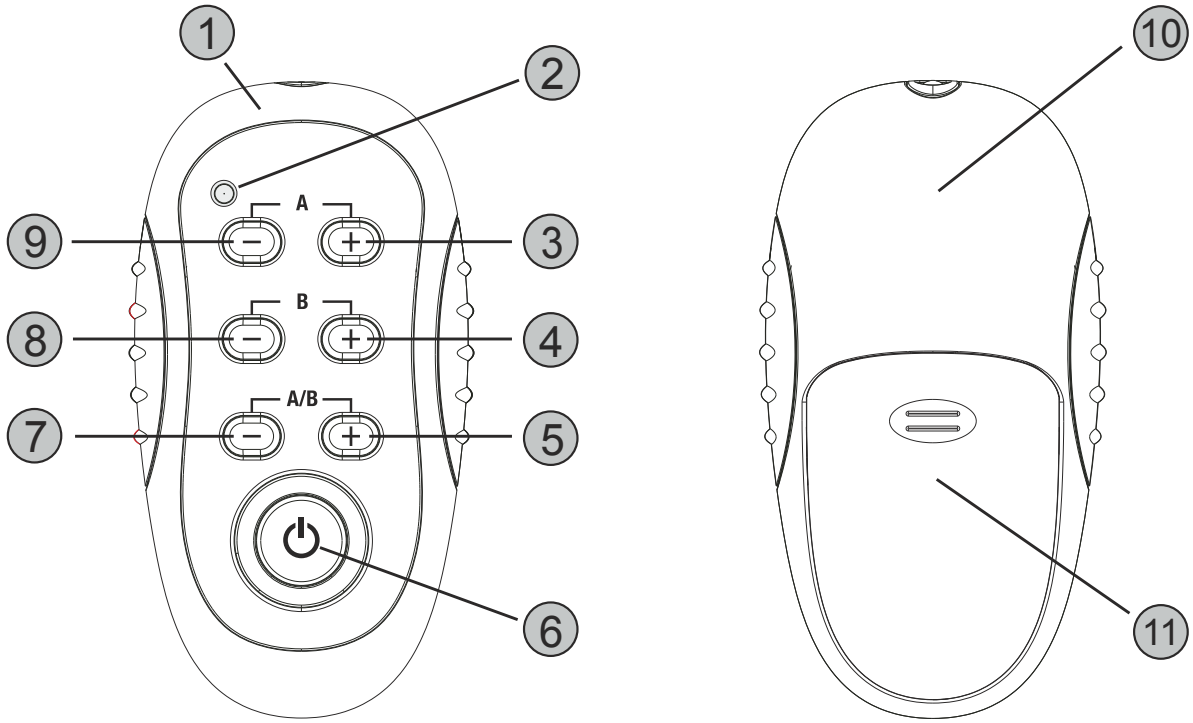


TENS stimulator with an adhesive electrode



1. Green LED indicator light
2. **(+)** key for **increasing the intensity** setting of the TENS stimulator
3. **(-)** key for **reducing the intensity** setting of the TENS stimulator
4. 2 press stud connections to connect the adhesive electrode pad
5. Cover of the battery compartment on the rear side of the TENS stimulator
6. TENS stimulator
7. Adhesive electrode pad connected to the TENS stimulator

8.0 Designations and functionality of the remote control



1. Remote control (front side)
2. Green LED indicator light
3. **A (+)** key for increasing the intensity setting for TENS stimulator A
4. **B (+)** key for increasing the intensity setting for TENS stimulator B
5. **A/B (+)** key for increasing the intensity setting simultaneously (both at the same time) for both TENS stimulators A and B
6. **ON/OFF** key ⏻
7. **A/B (-)** key for reducing the intensity setting simultaneously (both at the same time) for both **TENS stimulators A and B**
8. **B (-)** key for reducing the intensity setting for **TENS stimulator B**
9. **A (-)** key for reducing the intensity setting for **TENS stimulator A**
10. Remote control (rear side)
11. Cover of the battery compartment

9.0 Commissioning of the radio TENS device

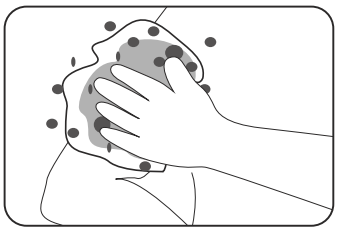


Figure 6

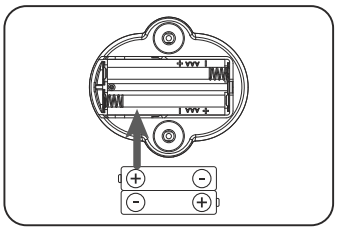


Figure 7

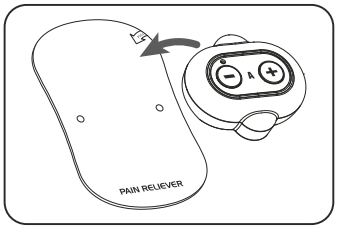


Figure 8

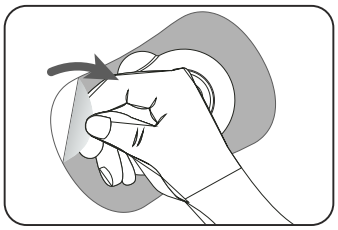


Figure 9

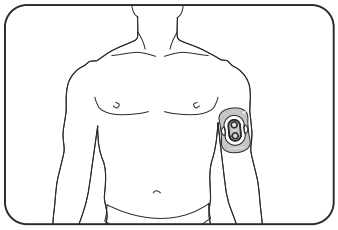


Figure 10

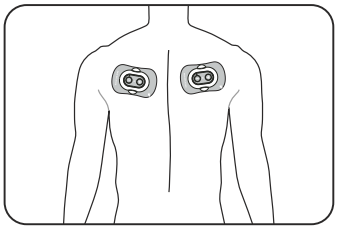


Figure 11

Step 1
Prior to starting a therapy session, carefully clean the skin areas in the application area using water and soap and dry it well afterwards (see **Figure 6**).

Step 2
Insert two 1.5 V batteries (type AAA) observing the correct polarity (+ (positive) and - (negative) pole) in the remote control and in the TENS stimulators (see **Figure 7** and description in **Chap. 7.0** on page 13-14).

Step 3
Using the two press stud connections, fasten an adhesive electrode pad to the TENS stimulator **A** and fasten another adhesive electrode pad to the TENS stimulator **B** if you wish to use both TENS stimulators at the same time. In this respect, make sure that the adhesive electrode pads are securely connected to the TENS stimulators by means of the two press stud connections (see **Figure 8**).
Attention! At this point, the TENS stimulators must not have been switched on yet! Please ensure that you do not press unintentionally on the (+) key of the TENS stimulators when connecting the adhesive electrode pads!

Step 4
The adhesive electrode pads should only be applied on clean, greaseless and dry areas of the skin. Grasp the adhesive electrode pad in the area of the arrow with the "PULL" imprint and remove it carefully from the protective foil. Please make sure that you do not touch the adhesive surfaces with your fingers (see **Figure 9**).
Attention - Observe the safety instructions! After the therapy session has been completed, stick the electrode pads back onto the protective foil.

Step 5
Now, apply the adhesive electrode pad (**Figure 10** - Example) or both adhesive electrode pads (**Figure 11** - Example) with the TENS stimulator connected on the skin. In this respect, please ensure that each adhesive electrode pad is fully applied onto the skin area to be treated so as to make sure that the entire surface of the electrode is in proper contact with the skin. Whenever possible, apply the adhesive electrode pads on flat and not on uneven or rounded areas of the skin in order to ensure that full contact with the skin is ensured. Application examples on the correct positioning of the adhesive electrode pads can be found on page 21 and 22.
Attention! The device must not have been switched on while the adhesive electrode pads are applied!

9.0 Commissioning of the radio TENS device

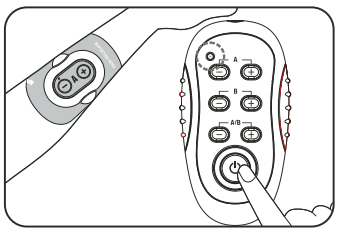


Figure 12

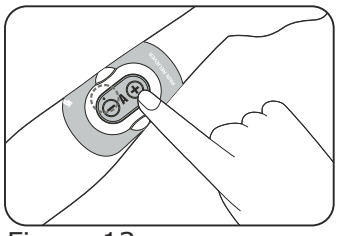


Figure 13

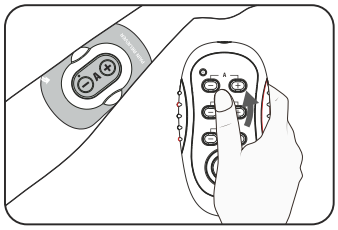


Figure 14

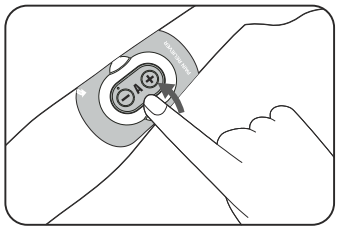


Figure 15

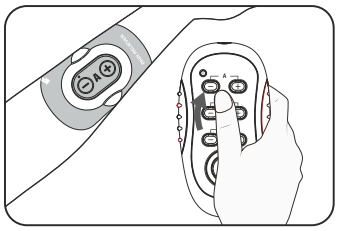


Figure 16

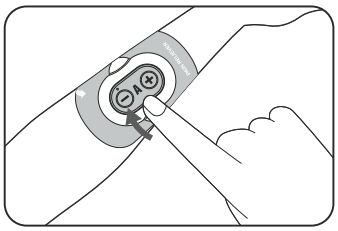


Figure 17

Step 6

Now, press the **ON/OFF** key ⏻ on the remote control first in order to switch it on (see **Figure 12**). The green LED flashes briefly for confirmation and goes out again. Now, switch on the TENS stimulator **A** or **B** (or both TENS stimulators) by pressing once on the **(+)** key of the respective TENS stimulator. The green LED on the TENS stimulator lights up (see **Figure 13**).

Step 7

Increase the output intensity by pressing the **A (+)** or **B (+)** keys on the remote control (see **Figure 14**) or on the TENS stimulator **A or B** (see **Figure 15**) according to your individual needs. Every time you press one of the **(+)** keys, the output intensity of the respective TENS stimulator is increased by one level. If both TENS stimulators are used, you can increase the intensity setting for both TENS stimulators **A and B** simultaneously (both at the same time) by pressing the **A/B** (+) key on the remote control.
By using the **A (-)** or **B (-)** keys on the remote control (see **Figure 16**) or on the TENS stimulator **A or B** (see **Figure 17**), you can **reduce** the intensity of the TENS stimulators. Every time you press one of the **(-)** keys, the output intensity of the respective TENS stimulator is reduced by one level. If both TENS stimulators are used, you can reduce the intensity setting for both TENS stimulators A and B simultaneously (both at the same time) by pressing the **A/B (-)** key on the remote control.

Step 8

The programme sequence and the application time of **30 minutes** are permanently set and cannot be changed. After the application time has expired, the TENS stimulators are switched off automatically and the green LEDs go out. If you wish to stop the therapy session before the application time has expired, you can press the **ON/OFF** key ⏻ on the remote control. The current therapy session is then stopped immediately and the TENS stimulators are switched off. Afterwards, carefully remove the adhesive electrode pads from the skin. To this end, lift the adhesive electrode pad in the area of the arrow with the "**PULL**" imprint and remove it carefully from the skin. Please make sure that you do not touch the adhesive surfaces with your fingers. Afterwards, stick the adhesive electrode pads back onto the protective foil and store them in a suitable place under cool and dry conditions.
Attention! Never remove the adhesive electrode pads from the skin while the device is still switched on!

9.0 Functions of the radio TENS device

Functions of the green LEDs of the TENS stimulators

LED lights up:	**Standby mode** / The device is ready for operation
LED flashes:	**Operating mode** / The adhesive electrodes have been applied and the device is in operation
LED flashes quickly:	**Receive mode** / The device receives the pulses from the remote control
LED out:	**"OFF" mode /** The device has been switched off

Setting the output intensity of the TENS stimulators

In order to **increase the output** intensity, the **(+)** keys on the TENS stimulators as well as the **(+)** keys on the remote control are used, where the output intensity of the TENS stimulators can be increased individually using the **A (+)** or **B (+)** keys or simultaneously using the **A/B (+)** key.
In order to **reduce the output** intensity, the **(-)** keys on the TENS stimulators as well as the (-) keys on the remote control are used, where the output intensity of the TENS stimulators can be reduced individually using the **A (-)** or **B (-)** keys or simultaneously using the **A/B (-)** key.

PLEASE NOTE:
During operation, the green LEDs of the TENS stimulators flash slowly; however, every time one of the **(+)** or **(-)** keys of the remote control is pressed, they flash rapidly. Rapid flashing indicates that the device receives a control pulse from the remote control. Every time a key is pressed on the remote control, the green remote control LED flashes in addition to this. If you press one of the **(+)** keys on one of the TENS stimulators during the therapy session, the output intensity is increased by one level. If you press one of the **(-)** keys on one of the TENS stimulators during the therapy session, the output intensity is reduced by one level. Every time one of the **(+)** or **(-)** keys on one of the TENS stimulators A or B are pressed, the green LEDs of the TENS stimulators flash slowly.

PLEASE NOTE: If the green LED on a TENS stimulator does no longer flash during the therapy session, please check if the adhesive electrode pad has full contact with the skin.

Switching off the TENS stimulators

The permanently set application time is 30 minutes. The TENS stimulators are switched off automatically after this time has expired. However, you can also switch off the TENS stimulators manually at any time as follows:

1. In the standby mode (green LED lights up constantly), you can switch off the TENS stimulators by pressing the **(-)** key on the TENS stimulator.

2. Press the **ON/OFF** key ⏻ on the remote control. The green LED of the remote control flashes and the TENS stimulators are switched off immediately.

9.0 Commissioning of the radio TENS device

PLEASE NOTE:
There are 20 output intensity levels for the TENS stimulators. Every time one of the **(+)** keys on the remote control or on one of the TENS stimulators is pressed the output intensity is increased by one level. For safety reasons, a fast forward by pressing the key and keeping it pressed is not possible; thus, increasing the output intensity too fast can be avoided. If you increase the output intensity on one of the **(+)** keys on the remote control, the increase by one level is indicated with the green LEDs on the TENS stimulators flashing fast. If this fast flashing of the LEDs of the TENS stimulators no longer occurs despite pressing one of the **(+)** keys on the remote control, the highest output intensity has already been reached.

Every time one of the **(-)** keys on the remote control or on one of the TENS stimulators is pressed the output intensity is reduced by one level. A fast rewind by pressing the key and keeping it pressed is not possible. If you reduce the output intensity on one of the **(-)** keys on the remote control, the reduction by one level is indicated with the green LEDs on the TENS stimulators flashing fast. If this fast flashing of the LEDs of the TENS stimulators no longer occurs despite pressing one of the **(-)** keys on the remote control and the LEDs light up constantly, the lowest output intensity has already been reached. If you then press the **(-)** key on one of the TENS stimulators, this TENS stimulator is switched off and the green LED goes out.

PLEASE NOTE: If the green LED on a TENS stimulator does no longer flash during the therapy session, please check if the adhesive electrode pad has full contact with the skin.

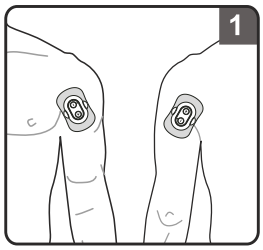
10.0 Remote control

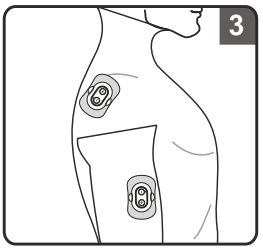
4.4.1 The radio TENS device TGS 440 can be controlled comfortably using the remote control included in the scope of delivery. Using this remote control, the output intensity of the TENS stimulators **A** and **B** can be increased and reduced both separately (individually) and simultaneously (both at the same time) and the stimulators can also be switched off by pressing a single key.

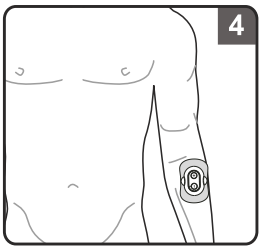
4.4.2 However, switching on and off as well as increasing and reducing the output intensity can also be carried out by directly pressing the **(+)** and **(-)** keys on the TENS stimulators (**channel 1 = TENS stimulator A, channel 2 = TENS stimulator B**).

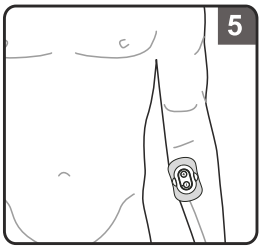
POSITIONING OF THE ELECTRODES

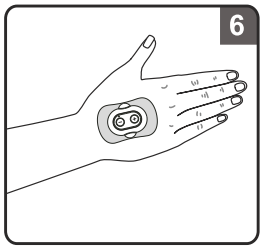
11.0 Examples of the correct position of the adhesive electrode pads

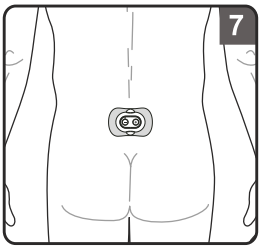


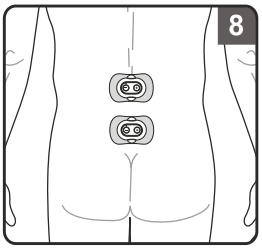


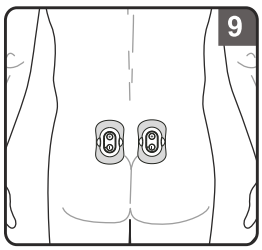


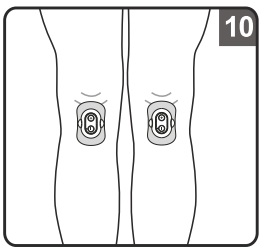


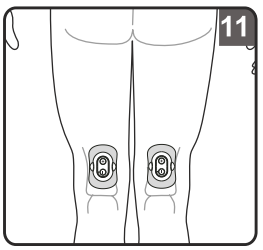


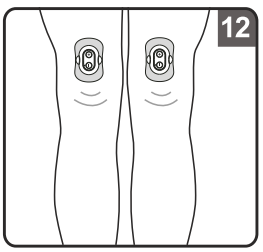


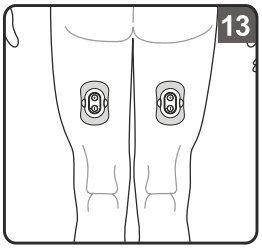


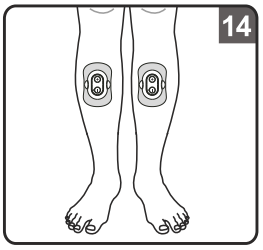


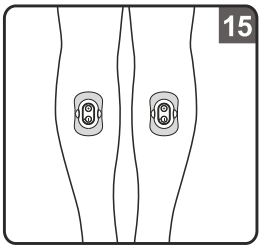


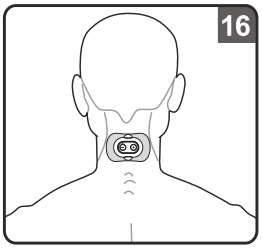


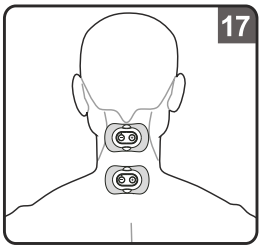












POSITIONING OF THE ELECTRODES

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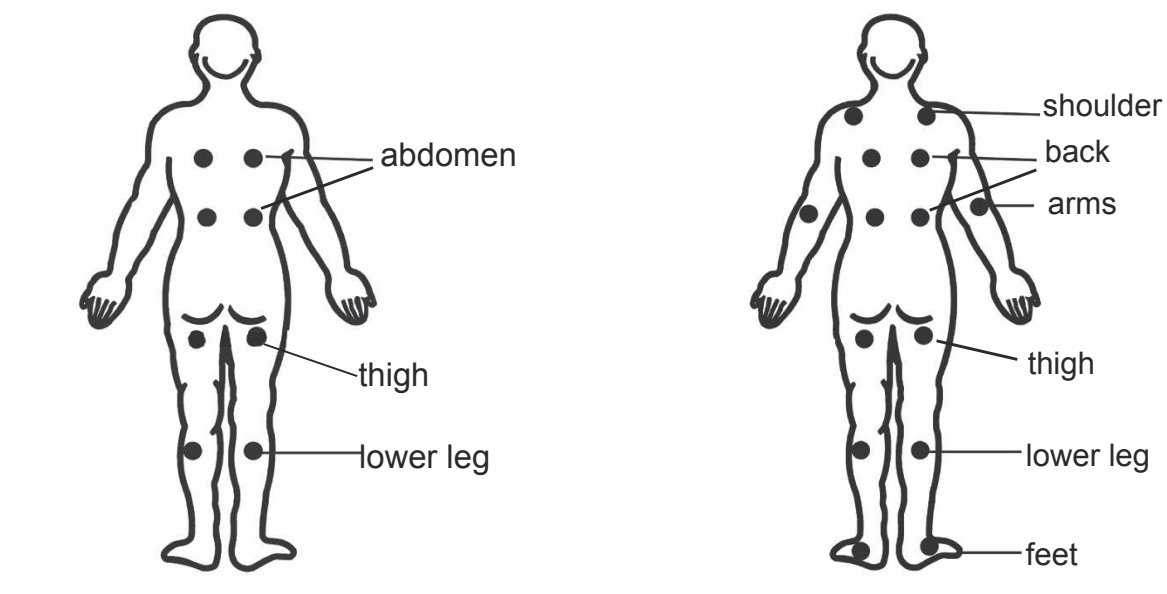
11.0 Examples of the correct position of the adhesive electrode pads



Information concerning the positioning of the electrodes

The following application examples show standard positions for the positioning of the adhesive electrode pads. As each user reacts differently to electric nerve stimulation, it is very important that the correct positions of the adhesive electrode pads are determined in collaboration and upon consultation with your doctor in order to ensure a successful pain relief therapy or stimulation of the groups of muscles.

Position the adhesive electrode pads above and below (or to the left and to the right) of the area of pain and avoid applying the electrodes directly on the pain centre. It is important that the stimulation current can flow through the area of pain!

Unless instructed otherwise by your doctor, we recommend an average therapy duration of 30 minutes up to three times a day.

The sense of intensity may actually depend on the user's respective daily constitution. Therefore, the user may adjust the intensity to his/her personal individual needs using the intensity control. Further application examples can be found in specialist books.

12.0 Malfunctions, troubleshooting

Malfunction	Cause	Solution
The batteries have been inserted, but the TENS stimulators and/or the remote control do not function properly.	The batteries of the devices are used or have not been inserted with the correct polarity. There might be foreign particles in the battery compartment.	Replace the used batteries by new batteries. Check if the batteries have been inserted observing the correct polarity. If there are any foreign particles, they must be removed from the battery compartment.
	There is a malfunction of the electronic system.	Remove the batteries and re-insert them after approx. 3 seconds.
The adhesive electrodes do not transfer any current pulses.	The TENS stimulators have not been assembled correct-ly onto the adhesive electro-de pads and do not have any contact.	Check if the TENS stimulators are assembled correctly onto the adhesive electrode pads.
On the device, an intensity level has been set; however, only little stimulation or no stimulation at all is felt on the adhesive electrode pads.	The batteries do no longer provide sufficient power.	Replace the batteries by full batteries. Observe the correct polarity!
	The skin surface or the adhesive surface of the pads is dirty.	Clean the skin surface and/or replace the adhesive electrode pads.
	The entire adhesive surface of the adhesive electrode pads does no longer have any adhesive effect and is worn out.	The adhesive electrode pads must be replaced by new adhesive electrode pads.
The intensity of the stimulation current increases, although a low intensity level has been set.	The adhesive electrode pads have not been applied completely on the skin surface.	Press the adhesive electrode pads firmly on the skin surface.
	The adhesive electrode pads stick only partially on the skin surface.	The adhesive electrode pads are worn out and must be replaced by new adhesive electrode pads.
The device stops while being used.	The battery does no longer provide sufficient power.	Replace the battery by a full battery. Observe the correct polarity!
	There is a malfunction of the electronic system.	Remove the battery and re-insert it after approx. 3 seconds.
The skin surface has changed or is reddened.	The changes to the skin might have been caused by the adhesive electrodes.	Immediately stop the application and consult your doctor.

12.0 Malfunctions, troubleshooting

Malfunction	Cause	Solution
The TENS stimulation is experienced as unpleasant and/or too intensive.	The intensity level of the TENS stimulators has been set to too high a level.	Reduce the output intensity of the TENS stimulators until the stimulation is no longer experienced as unpleasant.
	It might be possible that you do not use the device according to the instructions and information provided in the instruction manual.	Before using the device, please read and observe the instructions and information provided in the instruction manual.
	The adhesive electrode pads have not been applied completely on the skin surface or stick only partially on the skin surface.	Press the adhesive electrode pads firmly on the skin surface or replace the used adhesive electrode pads with new adhesive electrode pads.

13.0 Information on electromagnetic compatibility

Table 1 – Instruction and manufacturer's specifications – electromagnetic emissions – for all INSTALLATIONS and SYSTEMS (see 6.8.3.201 a) 3).		
Instruction and manufacturer's specifications – electromagnetic emissions		
The (INSTALLATION or the SYSTEM) is designed for the use in the electromagnetic environment described below. The customer or the user of the (INSTALLATION or the SYSTEM) should ensure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – instruction**
HF emissions CISPR 11	Group 2	The (INSTALLATION or the SYSTEM) only uses HF energy for its internal operation. Therefore, only very low HF emissions occur, which most probably do not cause any malfunctions in nearby electronic installations.

Guidelines and manufacturer's declaration – electromagnetic emissions		
The model TGS 440 is intended for use in an environment as specified below. The customer or the user of the model TGS 440 should ensure that it is used in such an environment.		
Electromagnetic interference measurements	**Compliance**	**Electromagnetic environment – guideline**
HF emissions according to CISPR 11	Group 2	The model TGS 440 only uses HF energy for its internal operation. Therefore, its HF emissions are very low, which most probably do not cause any malfunctions in nearby electronic installations.
HF emissions according to CISPR 11	Class B	The model TGS 440 is intended for use in all facilities, including residential environments and such environments that are directly connected to the public power supply, which also supplies buildings that are used for residential purposes.
Harmonic current emissions according to IEC 61000-3-2	Not applicable	
Emission of voltage fluctuations/flicker according to IEC 61000-3-3	Not applicable	

14.0 Information on electromagnetic compatibility

Guidelines and manufacturer's declaration – electromagnetic immunity			
The model TGS 440 is intended for operation in an electromagnetic environment as specified below. The customer or the user of the model TGS 440 should ensure that it is used in such an environment.			
Immunity tests	**IEC 60601 – test level**	**Conformity level**	**Electromagnetic environment – guidelines**
Electrostatic discharge immunity test according to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	Not applicable ± 8 kV air discharge	Floors should be made of wood or concrete or furnished with ceramic tiles. If the floor is furnished with synthetic material, the relative air humidity must be at least 30%.
Electrical fast transient/burst immunity according to IEC 61000-4-4	± 2 kV for power cables ± 1 kV for input and output cables	Not applicable	The quality of the supply voltage should correspond to the voltage of a typical commercial or hospital environment.
Surges according to IEC 61000-4-5	± 1 kV differential mode voltage ± 2 kV common mode voltage	Not applicable	The quality of the supply voltage should correspond to the voltage of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations according to IEC 61000-4-11	< 5% U_T (>95 % dip of U_T) during ½ period 40% U_T (60% dip of U_T) during 5 periods 70% U_T (30% dip of U_T) during 25 periods < 5% U_T (> 95% dip of U_T) during 5 s	Not applicable	The quality of the supply voltage should correspond to the voltage of a typical commercial or hospital environment. If the user of the model TGS 440 requires a continuous function also when interruptions in the energy supply occur, it is recommended to supply the model TGS 440 from an uninterruptible power source or a battery.
Magnetic fields at the power frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at the power frequency should correspond to typical values that can be found in a commercial or hospital environment.
NOTE U_T is the alternating mains voltage prior to application of test levels.			

15.0 Information on electromagnetic compatibility

Guidelines and manufacturer's declaration – electromagnetic immunity			
The model TGS 440 is intended for operation in an electromagnetic environment as specified below. The customer or the user of the model should ensure that it is used in such an environment.			
Immunity tests	**IEC 60601 – test level**	**Conformity level**	**Electromagnetic environment – guidelines**
			Portable and mobile radio devices should not be used in closer proximity to the [device or system] including the cables as the recommended protective distance calculated in accordance with the formula for the respective transmission frequency. **Recommended protective distance:**
Conducted HF disturbances according to IEC 61000-4-6	3 Vrms 150 kHz to 80 Mhz	3 Vrms	$d = 1.2\sqrt{P}$
Radiated HF disturbances according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 Ghz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
			$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
			Where P is the rated power of the transmitter in watt (W) according to the specification of the transmitter manufacturer and d is the recommended protective distance in metres (m). According to an on-site[a] investigation, the field strength of stationary radio transmitters is in all frequencies lower than the conformity level.[b] Disturbances are possible in the vicinity of devices carrying the following symbol. 
NOTE 1 For 80 MHz and 800 MHz, the higher value is applicable. **NOTE 2** These guidelines might not apply to all situations. The spreading of electromagnetic waves is influenced by absorptions and reflections of buildings, objects and people.			

16.0 Information on electromagnetic compatibility

a. Theoretically, the field strength of stationary transmitters, such as base stations of wireless telephones and land mobile services, amateur radio stations, AM and FM radio and television stations, cannot be predicted precisely. An investigation of the site is recommended to determine the electromagnetic environment due to stationary HF transmitters. If the determined on-site field strength of the model TGS 440 exceeds the conformity level specified above, the normal operation of the model TGS 440 must be observed at every application site. If unusual performance characteristics are observed, additional measures might have to be taken, such as reorientation or relocation of the model TGS 440. **b.** Not applicable above the frequency range from 150 kHz to 80 Mhz.

Recommended protective distances between portable and mobile HF telecommunication devices and the [DEVICE or the SYSTEM].

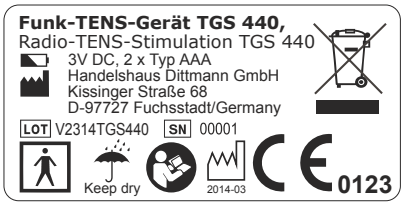
The model TGS 440 is intended for operation in an electromagnetic environment in which the HF disturbances are controlled. The customer or user of the model TGS 440 may contribute to the avoidance of electromagnetic disturbances by observing the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the model TGS 440, depending on the output rating of the communication device as specified below.

Rated power of the transmitter W	Protective distance depends 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 rated power is not specified in the table above, the distance can be caculated with the help of the formula of the respective column, with P being the rated power of the transmitter in watt (W) in accordance with the specification of the transmitter manufacturer.

NOTE 1 For the calculation of the recommended protective distance of transmitters in the frequency range from 80 MHz to 2.5 GHz, an additional factor of 10/3 was used to minimise the possibility that a mobile/portable communication device unintentionally brought into the patient area could lead to disturbances.
NOTE 2 These guidelines might not apply to all situations. The spreading of electromagnetic waves is influenced by absorptions and reflections of buildings, objects and people.

17.0 Technical specification, symbols, pictograms

Model type:	Radio TENS device TGS 440
Dimensions (L x W x H):	TENS stimulator A / B: approx. 60x53x18 mm Remote control: approx. 103x56x25 mm
Weight:	TENS stimulators A / B: approx. 21 g (without batteries) each Remote control: approx. 43 g (without batteries)
Surface of the adhesive electrodes:	approx. 90x57 mm per adhesive electrode pad
Material:	Plastics, metals
LOT	Lot designation: LOT V2314TGS440
SN	Serial number: SN 00001 (consecutive number)
2014-03	Date of manufacture: 2014-03 (year, month)
CE 0123	The radio TENS device TGS 440 is certified in accordance with the EU Council Directive 93/42 EEC for medical devices (Medical Devices Directive).
	Manufacturer: Handelshaus Dittmann GmbH, Kissinger Straße 68, D-97727 Fuchsstadt / Germany
	Protection against electric shock according to type BF (body floating). A therapy device of the type BF with a higher degree of protection against electric shock on the body, but not directly on the heart.
Type plate of the device:	

Electrical data:

Power supply:	3.0 V DC, 2x 1.5 V battery type AAA (V= volt, DC=direct current) each
Pulse voltage (V):	0-35 volt at a load of 500 ohm
Frequency (Hz):	5-125 Hz (Hz = vibrations per second)
Pulse width (duration):	130/250 µs (µs = microseconds))
Signal form:	Bipolar (symmetrical - two-phase) two-phase rectangular pulse wave
Output channels:	2 channels (TENS stimulators A and B), the intensity of which can be set separately

Application data:

Ambient temperature:	10 °C - 40 °C (degree Celsius)
Max. air humidity at normal operation:	30 % - 85 % (percent)
Atmospheric pressure:	700 hPa - 1060 hPa (hectopascal)

Storage / transport data:

50°C -10°C	Storage / transport temperature: -10 °C - 50 °C (degree Celsius)
95% 10%	Max. air humidity during storage / transport: 10 % - 95 % (percent)
Atmospheric pressure:	700 hPa - 1060 hPa (hectopascal)

18.0 Warranty

Your TGS 440 TENS device has been developed and manufactured with great care.

The statutory warranty period for defects in material and workmanship of the product is 24 months from date of purchase. Please keep the receipt in a safe place to furnish proof of purchasing the TGS 440 TENS device in case you must assert any warranty claim.

The following is not covered by the warranty:
- Damage resulting from improper use
- Defects that were already known to the customer at the time of purchase
- Wear parts
- Damage resulting from unauthorised manipulation and negligence of the customer

Upon expiry of the warranty period, you have the possibility of returning a defective device for repair to the address stated below. Repairs required after expiry of the warranty period are subject to a charge.

If you would like to contact us in case of technical problems, questions and warranty claims with regard to this device, please note the following:

NOTES: In case of a complaint with regard to the device, please contact the Service Centre first! If required, the Service Centre will initiate return of the device. Packages that are returned without the appropriate POSTAGE PAID shall not be accepted by the Service Centre!

Архангельск (8182)63-90-72
Астана (7172)727-132
Астрахань (8512)99-46-04
Барнаул (3852)73-04-60
Белгород (4722)40-23-64
Брянск (4832)59-03-52
Владивосток (423)249-28-31
Волгоград (844)278-03-48
Вологда (8172)26-41-59
Воронеж (473)204-51-73
Екатеринбург (343)384-55-89
Иваново (4932)77-34-06
Ижевск (3412)26-03-58
Иркутск (395)279-98-46
Казань (843)206-01-48
Калининград (4012)72-03-81
Калуга (4842)92-23-67
Кемерово (3842)65-04-62
Киров (8332)68-02-04
Краснодар (861)203-40-90
Красноярск (391)204-63-61
Курск (4712)77-13-04
Липецк (4742)52-20-81
Магнитогорск (3519)55-03-13
Москва (495)268-04-70
Мурманск (8152)59-64-93
Набережные Челны (8552)20-53-41
Нижний Новгород (831)429-08-12
Новокузнецк (3843)20-46-81
Новосибирск (383)227-86-73
Омск (3812)21-46-40
Орел (4862)44-53-42
Оренбург (3532)37-68-04
Пенза (8412)22-31-16
Пермь (342)205-81-47
Ростов-на-Дону (863)308-18-15
Рязань (4912)46-61-64
Самара (846)206-03-16
Санкт-Петербург (812)309-46-40
Саратов (845)249-38-78
Севастополь (8692)22-31-93
Симферополь (3652)67-13-56
Смоленск (4812)29-41-54
Сочи (862)225-72-31
Ставрополь (8652)20-65-13
Сургут (3462)77-98-35
Тверь (4822)63-31-35
Томск (3822)98-41-53
Тула (4872)74-02-29
Тюмень (3452)66-21-18
Ульяновск (8422)24-23-59
Уфа (347)229-48-12
Хабаровск (4212)92-98-04
Челябинск (351)202-03-61
Череповец (8202)49-02-64
Ярославль (4852)69-52-93

Киргизия (996)312-96-26-47
Россия (495)268-04-70
Казахстан (772)734-952-31

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