cefar®

Direct TENS™

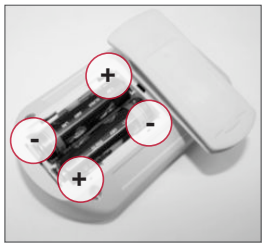
Transcutaneous Electrical Nerve Stimulator for Pain Treatment

USER GUIDE

CONTENTS

QUICK START GUIDE

1. Insert batteries



2. Attach belt clip and close battery compartment

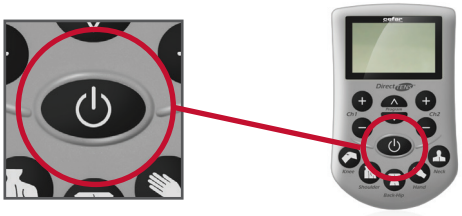
3. Connect the electrodes to the leadwire

4. Apply the electrodes.
The electrode placement depends on the indication, see also chapter 2.2 / page 13

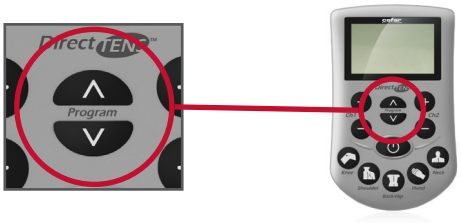
5. Connect the electrode leadwire to the device

QUICK START GUIDE

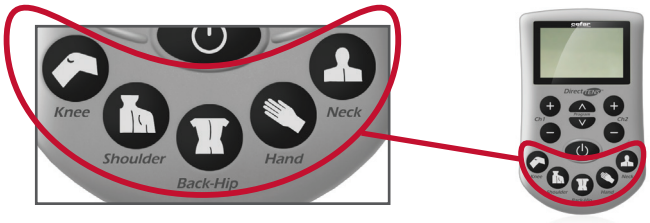
6. Switch the therapy unit on



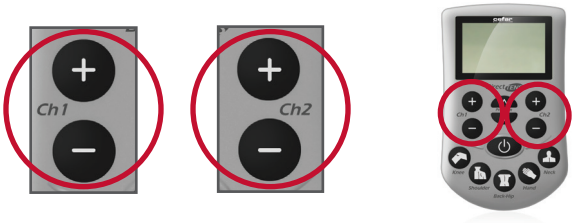
7. Select a program (only possible when intensity = 0)
The program depends on the indication to treat, see also chapter 2.2 / page 13



OR



8. Set intensity for selected channel



9. After approx. 10 seconds the keys are automatically locked to prevent the treatment parameters from being changed inadvertently. To unlock the keys, press either key (channel 1 or 2).

10. To terminate the treatment simply turn off the device with the ON/OFF key. When the therapy timer is activated, the stimulator switches automatically off at the end of the programmed interval.

Note: The Belt Clip can be attached or removed as required. You can find the procedure to attach/remove the belt clip on page 16, chapter 3.1.

GENERAL INFORMATION

- The product Direct TENS™ bears the CE marking CE-0473 (Notified Body: AMTAC Certification Services Limited) showing that it complies with the Council Directive 93/42/EEC as amended concerning medical devices and fulfils the essential requirements of Annex I of this directive. It has an internal power source and is classified as IIa equipment (MDD).
- The device has a type BF applied part.
- The device fulfils the requirements of the standard EN 60601-1 "Medical electrical equipment, Part 1: General requirements for safety" as well as the immunity requirements of the standard EN 60601-1-2 "Electromagnetic compatibility - medical electrical equipment".
- This manual is an integral part of the device and should be kept near the device at all times. Close observance of the information given in this manual is a prerequisite for using the device as intended and for correct operation to ensure user's safety. **Please note that information pertinent to several chapters is given only once. Therefore, carefully read the manual once in its entirety.**
- Using the device for purposes other than those described in this manual is not permitted.
- The safety information given in this manual is classified as follows:

Warning

Indicates a hazard. If not avoided, the hazard can result in death or serious injury.

Caution

Indicates a potential hazard. If not avoided, the hazard may result in minor injury and/or product/property damage.

- No part of this manual may be reproduced without written permission from DJO.
- Key to symbols used on the equipment

KEY TO THE SYMBOLS

Reference number, part number

Follow instruction for uses

Type BF applied parts

Council Directive 2012/19/EU concerning Waste Electrical and Electronic Equipment (WEEE) requires not to dispose of WEEE as municipal waste. Contact your local distributor for information of the unit and accessories

Keep the device dry

Minimum and maximum temperature indications to respect

This equipment complies with all requirements of the Medical Device Directive (93/42/EEC)

Manufacturer name and address, manufacturing year

Power/Pause

1. POINTS TO NOTE BEFORE USE

Intended Use

Direct TENS™ (882700) is a transcutaneous electrical nerve stimulator. Transcutaneous electrical nerve stimulation (TENS) uses electrical pulses that are delivered through the skin to the cutaneous (outer) and afferent (deeper) nerves to alleviate pain. Contrary to medication and cream used on the skin, there are no known side effects resulting from TENS therapy.
Use Direct TENS™ only as described in this manual. Other uses of the stimulator are not permitted.

Intended User

The user of both the TensMed P82 and S82 can be a Health Care Professional or a patient. The device should be used indoors and may be used in a healthcare facility setting or in a home environment.

Indications

- Direct TENS™ can be used to alleviate different types of acute and chronic pain such as
- Joint pain (e.g. knee, hip arthrosis)
- Chronic pain originating in the spine
- Degenerative diseases of the musculoskeletal system
- Tension headache
- Radiating pain (e.g. back pain, cervicobrachial syndrome)
- Amputation stump/phantom limb pain
- Pain from rheumatic diseases

Contraindications

Do not use Direct TENS™ in the following situations:

- If you have an implanted demand pacemaker, intracardiac defibrillator or other active implants
- Undiagnosed pain until the cause has been ascertained
- Epilepsy
- During pregnancy (unless approved by your referring gynaecologist)

Treatment should never be applied near the area of an implant, such as cochlear, pacemakers, skeletal or electrical.

Do not apply stimulation in the vicinity of metal. Remove jewellery, body piercings, buckles or any other removable metallic product or device in the area of stimulation.

Do not attempt to place electrodes on any part of the body not directly visible without assistance.

Do not stimulate at the front or side of the neck to avoid a drop in blood pressure. Furthermore it is not permitted to attach electrodes to the head.

This device should not be used for symptomatic local pain relief unless diagnosis is established or unless a pain syndrome has been diagnosed.

Biocompatibility

Those parts of the Direct TENS™ that come into contact with the user when the device is used as intended, are designed to fulfil the biocompatibility requirements of the applicable standards.

PRECAUTIONARY MEASURES

Contraindications

- Implanted electronic devices. Do not use the device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted electronic device, because this may cause electric shock, burns, electrical interference, or death.
- TENS for Undiagnosed Pain. Do not use the device as a TENS device on patients whose pain syndromes are undiagnosed.

Warnings

- Consult with physician. Consult with the patient's physician before using the device, because the device may cause lethal rhythm disturbances to the heart in susceptible individuals.
- Skin condition. Apply stimulation only to normal, intact, clean, healthy skin.
- Long term effects. The long-term effects of chronic electrical stimulation are unknown.
- Stimulation location. Stimulation over Neck or Mouth. Do not apply stimulation over the patient's neck (especially the carotid sinus) or the patient's mouth, because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- Stimulation across Chest. Do not apply stimulation across the patient's chest, because the introduction of electrical current into the chest may cause rhythm disturbances to the patient's heart, which could be lethal.
- Across the head. Since the effects of stimulation of the brain are unknown, stimulation should not be applied across the head, and electrodes should not be placed on opposite sides of the head.
- Stimulation over compromised skin. Do not apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins).
- Stimulation near cancerous lesions. Do not apply stimulation over, or in proximity to, cancerous lesions.
- Stimulation over eyes. Do not apply stimulation directly on the eyes.
- Environment. Electronic monitoring equipment. Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use.
- Bath or Shower. Do not apply stimulation when the patient is in the bath or shower. Do not apply stimulation in humid atmosphere exceeding 75% of relative humidity.
- Sleeping. Do not apply stimulation while the patient is sleeping.
- Driving or operating machinery. Do not apply stimulation while the patient is driving, operating machinery, or during any activity in which electrical stimulation or involuntary muscle contraction can put the patient at risk of injury.
- Electrosurgical equipment or defibrillators. Disconnect the stimulation electrodes before using electrosurgical equipment or defibrillators. Otherwise skin burns may be caused below the electrodes and the device might be destroyed.
- Magnetic Resonance Imaging. Do not wear electrode or the device during Magnetic Resonance Imaging (MRI) scans as this may result in metal overheating and causing skin burns in the area of the electrode.
- Flammable or explosive environment. Do not use the device in areas where there is a risk of fire or explosion, such as oxygen-rich environments, in the vicinity of flammable anaesthetics, etc.
- Power supply. Never connect stimulation cables to an external power supply as there is a risk of electric shock.
- Near other equipment. Do not use the device beside or stacked on top of any other equipment. If you must use it side by side or on top of another system, you should check that the device works properly in the chosen configuration.
- Miscellaneous. Electrodes for Single Patient. Do not share electrodes with other persons. All users should have individual set of electrodes to prevent undesirable skin reactions or disease transmission.

- Accessories. Use this device only with the leads, electrodes, and accessories recommended by the manufacturer. Use of other accessories may adversely affect the performance of the device or may result in stronger electromagnetic emissions or reduce the electromagnetic immunity of the device.
- No Modification. No modification of the equipment is allowed.

Precautions

- Supervision. Use this device only under the continued supervision of a licensed practitioner. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
- Manufacturer. The manufacturer does not take any responsibility for any electrode placements other than recommended.
- Pregnancy. The safety of electrical stimulation during pregnancy has not been established.
- Skin irritation. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel). The irritation may be reduced by using an alternate conductive medium or alternate electrode placement. Some patients may experience redness under the electrodes after a session. This redness usually disappears within a few hours. Advise the patient to consult the clinician if the skin redness does not disappear after a few hours. Do not start another stimulation session in the same area if the redness is still visible. Don't scratch the redness area.
- Heart Disease. Patients with suspected or diagnosed heart disease should follow precautions recommended by their physicians.
- Epilepsy. Patients with suspected or diagnosed epilepsy should follow precautions recommended by their physicians.
- Internal Bleeding. Use caution when the patient has a tendency to bleed internally, such as following an injury or fracture.
- After Surgery. Use caution following recent surgical procedures when stimulation may disrupt the patient's healing process.
- Over uterus. Do not place electrodes directly over the uterus or connect pairs of electrodes across the abdomen if you are pregnant. The reason is that, theoretically, the current could affect the foetus's heart (although there are no reports of it being harmful).
- Lack of sensation. Use caution if stimulation is applied over areas of skin that lack normal sensation. Don't apply stimulation on patient unable to express themselves.
- Stimulation. The stimulator should only be used with skin electrodes intended for nerve and muscle stimulation. Muscle soreness may occur after stimulation but usually disappears within a week.
- Hot casing or batteries. Under extreme use conditions, some parts of the casing might reach up to 109 °F (43 °C). Use caution when manipulating the batteries right after device use or when holding the device. There is no particular health risk associated with this temperature besides your comfort.
- Children. Keep this device out of the reach of children.
- Electrode Size. Do not use electrodes with an active area less than 16 cm2, as there will be a risk of suffering a burn injury. Caution should always be exercised with current densities more than 2mA/cm2.
- Strangulation. Do not wrap leadwires around your neck, and keep them out of the reach of children. Strangulation may result from entanglement in the leadwires.
- Tripping. Care should be used to avoid tripping on lead wires.
- Damaged Device or Accessories. Never use the device or any of its accessories if it is damaged (case, cables, etc.) or if the battery compartment is open as there is a risk of electric shock. Carefully inspect the lead wires and connectors prior to each use.
- Inspect Electrodes. Inspect electrodes before each use. Replace electrodes when they begin to deteriorate or lose adhesion. Poor contact between the electrodes and the patient's skin increases the risk of skin irritation or burns. Electrodes will last longer if used and stored according to instructions on electrode packaging. Attach the electrodes in such a way that their entire surface is in contact with the skin.
- Foreign bodies. Do not allow any foreign bodies (soil, water, metal, etc.) to penetrate the device and the battery compartment.

- Batteries. Do not carry batteries in a pocket, purse, or any other place where the terminals could become short-circuited (e.g. by way of paper clip). Intense heat could be generated and injury may result. Never open the battery cover during stimulation in order to avoid electrical shock. Remove the batteries from the device if you do not intend to use it for a prolonged period of time (more than 3 months). Extended storage of the batteries in the device might lead to batteries and device damage.
- Cable. The cable is best preserved if left attached to the stimulator between sessions. Do not jerk the cable or connection.
- Heat and Cold products. The use of heat or cold producing devices (e.g. electric heating blankets, heating pads or ice packs) may impair performance of the electrode or alter the patient's circulation/sensitivity and increase the risk of injury to the patient.
- Pulled muscles. Do not apply electrodes over pulled muscles. Using the stimulator on a previously extended muscle might further pull such muscle. The higher the stimulation intensity, the higher the risk to further overextends such muscle.
- Additional Precautions for TENS
  - TENS is not effective for pain of central origin, including headache.
  - TENS is not a substitute for pain medications and other pain management therapies.
  - TENS devices have no curative value.
  - TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
- Effectiveness of TENS is highly dependent upon patient selection by a practitioner qualified in the management of pain patients.

Dangers

- Electrodes. Any Electrode with a minimum active area of 16 cm^2 may be used with this device. Use of an electrode with an area less than 16 cm^2 can cause burns when the unit is used at higher intensities. Consult your clinician prior to using any electrode less than 16 cm^2.

Adverse Reactions

- Patients may experience skin irritation and burns beneath the stimulation electrodes applied to the skin.
- Patients may experience headache and other painful sensations during or following the application of electrical stimulation near the eyes and to the head and face.
- Patients should stop using the device and should consult with their physicians if they experience adverse reactions from the device.
- Precaution: Do not disconnect any stimulation cables during a session while the stimulator is switched on. Switch the stimulator off first. Always turn off the stimulator before moving or removing any electrodes during a session.
- Precaution: Do not use electrodes with an active area less than 16 cm2, as there will be a risk of suffering a burn injury. Caution should always be exercised with current densities more than 2mA/cm2.
- Precaution: Do not apply stimulation in the vicinity of metal. Remove jewelry, body piercings, buckles or any other removable metallic product or device in the area of stimulation. Never use the electrodes contra-laterally, i.e. do not use two pins connected to the same channel on opposite segments of the body.
- Precaution: Never carry out an initial stimulation session on a person who is standing. The first five minutes of stimulation must always be performed on a person who is sitting or lying down. In rare instances, people of a nervous disposition may experience a vasovagal reaction. This reaction is connected with fear of the muscle stimulation as well as surprise at seeing one of their muscles contract without having intentionally contracted it themselves. A vasovagal reaction causes heart to slow down and blood pressure to drop, which can make you feel weak and faint. If this does occur, stop the stimulation and lie down with the legs raised until the feeling of weakness disappears (5 to 10 minutes).
- Precaution: Sudden temperature changes can cause condensation to build up inside the stimulator. To prevent this, allow it to reach room temperature before use.

2. HOW DOES THE DIRECT TENS™ DEVICE FUNCTION

Via electrodes attached to the skin, Direct TENS™ sends electrical pulses to the nerves. This will block the pain impulses.
Four electrodes – two for each channel – can be connected to the device. Pain relief is most efficient during stimulation, but the effect can last after the treatment. Additionally, the TENS treatment increases the blood circulation. You can use Direct TENS™ at any time for pain relief and muscle relaxation. Each therapy session should last 30 minutes minimum and can be continued for several hours.

This is where you connect the electrode lead wires.

This key are used to increase the current and thus the intensity of stimulation: Increase the intensity very carefully!

These keys are used to select one of the 13 programs.

This key are used to decrease the intensity and to unlock the locked keys during operation.

This button is used to switch the stimulator on and off. If no stimulation is started for approximately 5 minutes, the stimulator automatically switches off to save batteries.

These are the quick select keys for choosing an indication-related program.

2.1. TENS Therapy Principle

Two pain theories play an important role in the application and parameter settings of the Direct TENS™ device:

- The **Gate Control Theory** by WALL and MELZACK (1965)
- The **Endorphine Theory** by ERIKSON and SJÖLUND (1979)

According to the Gate Control Theory, **weak** TENS impulses block the pain impulses travelling to the brain (sensor stimulation).
ERIKSON and SJÖLUND found that **strong** TENS impulses increase the release of internal substances (e.g. endorphins) that also alleviate pain (motor stimulation).

Theory	Gate Control Theory	Endorphin Theory
Principle	Via sensory nerves	Via motor nerves
Intensity	Low, light tingling	High, just bearable
Impulse Width[1]	Short, e.g. 100 µs	Long, e.g. 250 µs
Frequency[1]	100 Hz	2-10Hz
Muscle Contraction	No	Yes
Onset Pain Relief	Quickly	Slowly (20-60 minutes)
Duration of Pain Relief	Short (5-15 minutes)	Long (30 minutes-12 hours or longer)
Treatment Duration	Permanent	30-60 minutes, 3-5 times/day

[1] *For easier operation, intensity and pulse width are combined in Direct TENS™.*
(low intensity = short pulse width, high intensity = long pulse width)

2.2. Description of the programs and the corresponding indications

Program	Stimulation	Frequency (Hz)	General Indications	Advantages
1	1 impulse every 2 seconds	0.5	Kaada TENS (similar to acupuncture)	Ideal for sensitive people Supports acupuncture treatment
2	Double pulse at 20 Hz (pulse separation 3 ms) 	20	Cervical spine syndrome Tense muscles	Muscle relaxation by double pulses
3	High frequency, 1000 Hz 	1000	Acute, strong back pain (lumbar spine)	Strong analgesia Brief, very intensive TENS treatment
4	Bi-modal	Channel 1 = 100Hz Channel 2 = 4Hz	Tension headache Neck / back pain Radiating pain	Simultaneous treatment with high and low frequency In 2-channel mode, channel 1 stimulation is superimposed on the low frequency stimulation in channel 2
5	Burst with alternating work and rest phases of 3 and 2 seconds respectively	Work = 100Hz Rest = 0Hz	Tense muscles Amputation stump /phantom limp pain Herpes zoster Reflex sympathetic dystrophy (RSD)	Easily tolerable stimulation for chronic pain conditions Sensory as well as motor stimulation
6	Similar to program 5, but channels 1 and 2 alternating and longer work/rest times, 6 seconds respectively 	Work = 100Hz Rest = 0Hz	See program 5	Similar to program 5, but channels 1 and 2 alternating
7	Intensity decreases 40% in 0.5 second intervals 	100	Lumbar back pain Joint pain	Similar to massage Effects both on the sensory and on the motor level Avoids habituation

Program	Stimulation	Frequency (Hz)	General Indications	Advantages
8	Random modulation of intensity and frequency (down to 50% of set intensity and frequency modulation between 8 different frequencies, 2-150 Hz)	Random modulation	Chronic pain resisting therapy	Avoids habituation Sensory as well as motor stimulation
9	Continuous 	2 – 150	Standard TENS	Fast pain relief in acute pain conditions Fast acceptance of therapy Different programmable frequencies, e.g. 100 Hz = Standard 2 Hz = Similar to acupuncture
10	Burst with alternating work and rest phases of 2 seconds each	Work = 2 - 150 Hz Rest = 0 Hz	Long-term treatment	Classic burst Pleasant form of stimulation Reduces muscle fatigue Prolongs battery life
11	Mixed frequency	Phase 1 = 2 - 150 Hz Phase 2 = 50% of work freq	Strong pain	Pleasant stimulation also at higher intensities Permanent stimulation of the deep afferent nerve fibers with modulated muscle activation
12	Multi modulation	2 – 150	Chronic pain	Avoids habituation Simultaneous sensory and motor stimulation Fixed modulation pattern for intensity and frequency
13	Simple modulated pulse (SMP), intensity modulation diametrically opposite to frequency modulation according to a fixed 12-second cycle	2 – 150	Chronic pain	Avoids habituation Simultaneous sensory and motor stimulation Intensity and frequency modulation according to fixed pattern, but diametrically opposed, i.e., when the intensity increases, the frequency decreases and vice versa.

Frequency Selection for Programs 9 to 13

2 – 60 Hz	60 – 150 Hz
Preferred in the treatment of **chronic** pain	Preferred in the treatment of **acute** pain

With the standard TENS programs 9 to 13, the frequency can be adapted manually.
Possible settings: 2, 10, 20, 40, 60, 100, 125, 150 Hz
Factory defaults for programs 9 to 12 is 100 Hz and 125 Hz for program 13.

Changing the frequency:

1. Turn on the device and select one of the programs 9 to 13

2. **Simultaneously** press the program selection keys 

and release them.

3. Using the intensity keys 

, choose the set frequency.

4. Press the two program selection keys again or switch the device off to save the settings.

3. PREPARATION

3.1. Inserting Batteries

- Adjust the belt clip until it points to the right at a 90° angle. (Figure 3-1)
- Push the battery cover down and lift. (Figure 3-2)
- Insert the batteries as shown in the illustration. Observe the correct polarity, see label in battery compartment. (Figure 3-3)
- Reinstall the battery cover and close the compartment.

Notes:
- Use only new AA type batteries.
- You may or may not use the belt clip, as preferred. Open the battery compartment. If you wish to remove the clip, pull it out towards the left. If you wish to attach the clip, push it into the holder from the left. When you close the battery compartment, the belt clip is automatically secured onto the device. (Figure 3-4)
- Dispose of the worn out batteries in accordance with local and national regulations

Figure 3-1
Turning the belt clip

Figure 3-2
Opening the battery compartment

Figure 3-3
Inserting the batteries

Figure 3-4
Removing/attaching the belt clip

3.2. Applying Electrodes, Connecting Leadwires

- First connect the electrode leadwires to the electrodes (Figure 3-5). (The colour of the electrode connectors is irrelevant.)
- Peel the electrodes off their protective paper. Keep the protective paper and the bag, because the electrodes will be reattached to the protective paper after use and stored in the bag (see also 3.3.2 "Care of the Electrodes").
- Carefully apply the electrodes on the skin (see also 3.3.3 "Electrode Placement").
- Connect the electrode leadwire(s) to the Direct TENS™ device (Figure 3-6).

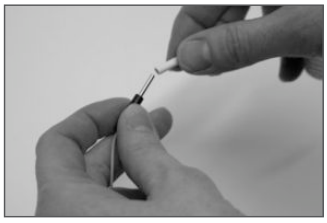


Figure 3-5
Connecting the electrode leadwire to the electrodes

Figure 3-6
Connecting the electrode leadwire to the device

3.3. Selection, Care and Placement of the Electrodes

3.3.1. Electrode Selection

Use large electrodes (e.g. 50 x 90 mm, to be purchased separately) for large body areas (e.g. back, leg) and for general conditions of pain.
Use small electrodes (e.g. 50 x 50 mm) for small body areas (e.g. face, hand) and for deep, local pain.

3.3.2. Care of the Electrodes

When properly handled and maintained, the supplied electrodes can be used 20 times or more.

Important for a long service life:

- Clean the skin application sites with mild soap water before attaching the electrodes. After cleaning,
  thoroughly rinse with water and dry the skin carefully.
- Dry electrodes with poor adhesion can be reconditioned as follows: apply a small quantity of water to the adhesive surface with your finger tip.
- If you face bad contact with the skin or repeated open lead detection, change the electrodes.
- Remove electrodes by pulling on their edges. Do not pull on the leadwire.
- After use, reattach the electrodes to their protective paper. Store the electrodes in their bags.
- Store the electrodes in a refrigerator, if possible. Do not store them in warm rooms.
- We recommend shaving skin sites where electrodes will be applied, if very hairy. Shaving irritates the skin. Therefore wait 24 hours after shaving before you attach the electrodes. Then you may start therapy.
- Do not leave the electrodes attached to your skin for a prolonged period of time. Remove the electrodes after each use. Apply the electrodes on different sites to avoid skin irritations. For the same reason clean the skin thoroughly after treatment. If you observe skin irritations, consult your physician and suspend therapy until clarification.

3.3.3. Electrode Placement

If your physician showed you the best application points, we recommend that you use them. Otherwise figures 3-7 to 3-11 show possible electrode configurations.
Figures 3-12 to 3-21 show electrode configurations for different indications. However, check that the configuration is appropriate and adapt, if necessary. Depending on the site and cause of the pain, electrodes may be placed on acupuncture points or in specific dermatomic areas.
In other situations we recommend applying the electrodes around the center of the pain at a distance of 3 to 5 cm (where you feel the pain).

Caution
Failed stimulation, skin irritation, malfunction -
- Use only the original electrodes supplied with the system and replacement electrodes provided by DJO.
- Attach the electrodes on intact skin only, avoid skin areas with reduced sensitivity.
- Ensure that good contact is achieved between electrode and skin. Although the stimulator switches off when the electrode-skin contact resistance is too high, poor electrode techniques may cause skin irritations under the electrodes.

Notes:

- Concerning the choice of indication-specific **programs**, please refer to the Notes in section **2.2**.
- Before applying the electrodes, observe the care instructions in section 3.3.2.
- If appropriate, you can also use only two electrodes (one channel).

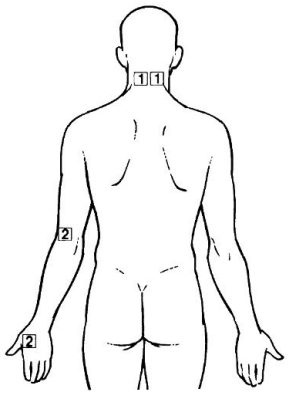


Figure 3-7 Bilateral placement (e.g. cervical dysfunction)

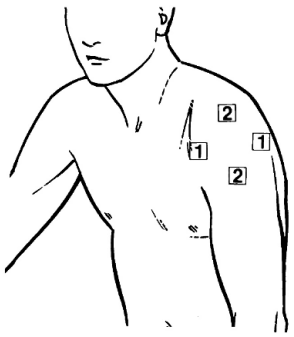


Figure 3-8 Diagonal placement (e.g. shoulder or knee)

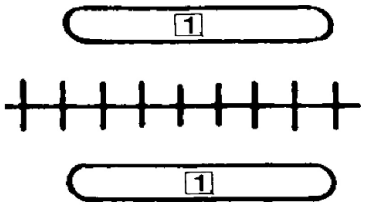


Figure 3-9 Parallel placement (e.g. on scarred tissue)

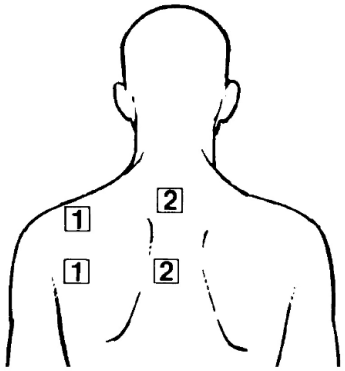


Figure 3-10 Bracket position

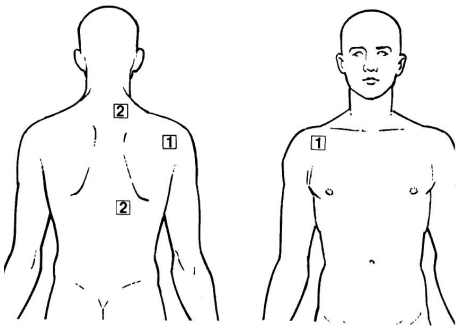


Figure 3-11 Electrode application in pain conditions involving the shoulder and shoulder blade

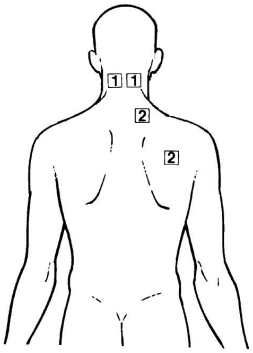


Figure 3-12 Electrode application on the shoulder blade
Indications:
e.g. General pain in the shoulder accompanied by headache

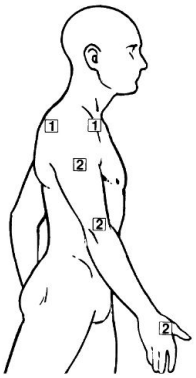


Figure 3-13 Electrode application on the shoulder joint
Indications:
e.g. General pain in the shoulder, bursitis

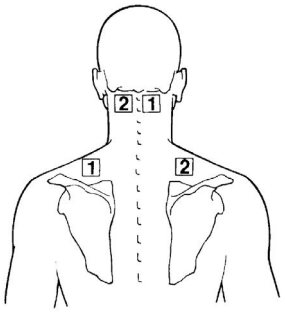


Figure 3-14 Electrode application on the cervical spine
Indications:
e.g. pain caused by intervertebral disk or vertebral arch joint problems , cervical spine syndrome, cervical syndrome, tension headache, migraine
Recommended electrode placement:
Diagonal

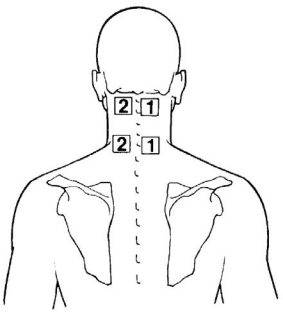


Figure 3-15 Electrode application on the cervical spine Picture to be replaced
Indications:
e.g. for conditions of pain in the muscles or soft parts, see also Figure 3-15
Recommended electrode placement:
Parallel

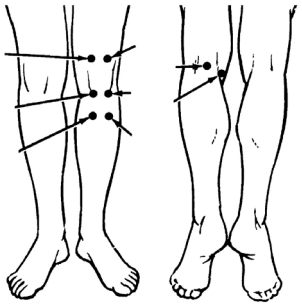


Figure 3-16 Electrode application on the knee joint
Indications:
e.g. arthrosis of the knee joint (gonarthrosis), generalized pain in the knee, TEP
Recommended electrode placement:
Attach electrodes above superficial skin nerves or acupuncture points around the knee joint. The electrode configuration may be parallel, medial, lateral or crosswise above or below the knee.

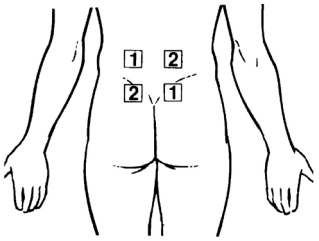


Figure 3-17 Electrode application on the back
Indications:
e.g. lumbar spine syndrome, lumboischialgia, pseudoradicular back pain
Recommended electrode placement:
paraspinal, proximal and distal to the pain area. Channels 1 and 2 diagonal

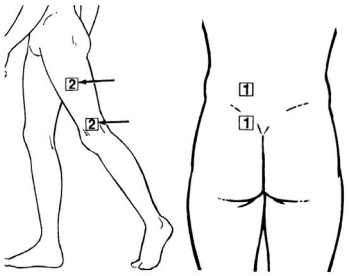


Figure 3-18 Electrode application on the back
Indications:
Radicular (radiating) pain
Recommended electrode placement:
Channel 1 proximal and distal to the pain area, channel 2 above the nerve.

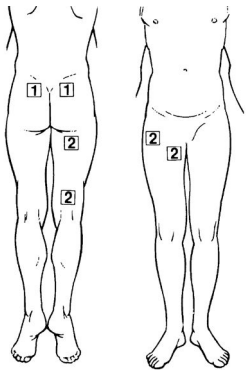


Figure 3-19 Electrode application on the back
Indications:
Radicular (radiating) pain (alternative)
Recommended electrode placement:
Channel 1 proximal and distal to the pain area, channel 2 above the nerve.

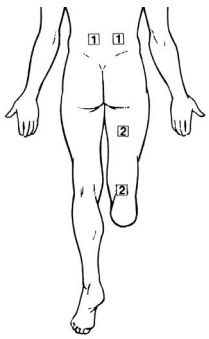


Figure 3-20 Electrode application for phantom limb pain, version 1

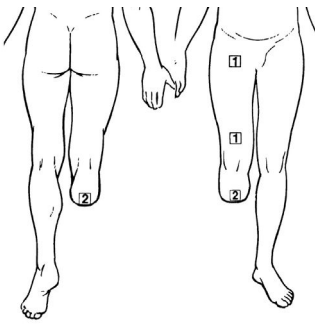


Figure 3-21 Electrode application for phantom limb pain, version 2

4. TREATMENT

Figure 4-1 Switching the stimulator on

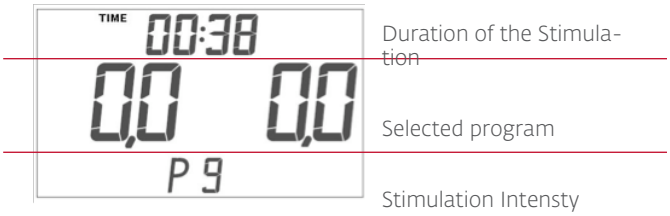


Figure 4-2 Initial screen

4.1. Starting Therapy

• Switch the stimulator on.

Once switched on, the display will briefly show the software version. A functional test where all display indicators appear for a short time is performed. The initial screen appears next (Figure 4-2).
When the initial screen is displayed, the device has successfully passed the functional test.
If the letter "E" is displayed instead of the initial screen, the stimulator is defective and must be replaced. Do not use this stimulator any more.

On the initial screen you will see:
- The remaining stimulation duration
- The intensity of the stimulation (indication of the selected intensity level, adjustable in steps of 0.5 from 0 to 60)
- The selected program

• Select the program either via the quick select keys or via the program selection keys.
• Increase the stimulation intensity for a channel (1 or 2) by pressing the corresponding  key.

Increase the intensity with great care and in small increments. Select a level which causes a pleasant sensation that is felt clearly.

Additionally, icons may appear on the screen

	The keys are locked (automatic function): To prevent inadvertent activation, the keys are automatically locked 10 seconds after the current intensity has been set. The keys can be unlocked with  or by switching the device off.
	The electric circuit is interrupted (see chapter 6 "What to do, if...)
	Batteries need to be replaced. When you see this icon, replace the batteries as soon as possible.

Operation Information

- You can interrupt therapy at any time with the ON/OFF switch.
- If the stimulator is not used, it switches off automatically after approx. 5 minutes.
- When the therapy timer is activated, the device switches automatically off at the end of the programmed interval. The remaining therapy time is always indicated on the display.
- The program can only be changed when the intensity in both channels is 0.

4.2. Ending Therapy

The default setting of the Direct TENS™ device is continuous operation. If you want to end the therapy, switch off the device with the ON/OFF switch.

When the therapy timer is activated, the device switches automatically off at the end of the programmed interval. The remaining time is indicated at the top of the display.

Check that the Direct TENS™ stimulator is switched off before you remove the electrodes.

- If the therapy timer is not activated, switch off the Direct TENS™ stimulator with the ON/OFF switch.
- Remove the electrodes very carefully. Do not pull on the leadwires, but on the electrode.
- Reattach the electrode to its protective paper. Be sure to attach the electrode to the side marked “on”, not to the side marked “no”.
- Disconnect the electrodes from the leadwire.
- Clean the skin with a mild soap solution.
- Electrodes no longer fit for use can be disposed of with the normal domestic waste.

5. SPECIAL DIRECT TENS™ FUNCTIONS

5.1. Therapy Timer

The Direct TENS™ stimulator comes with a therapy timer function. When the timer is activated, the remaining therapy time appears on the display. When this interval has elapsed, the device switches off automatically. You can set therapy times of:

- 1 to 59 minutes in 1-minute increments
- 1 to 24 hours in 30-minutes increments
- Continuous operation, displayed as **CONT.** (This is the **default setting.**) The timer is not activated.

Follow these steps to activate the timer:

- Press the quick select program key low back/hip  and hold it depressed.
- Then press the ON/OFF key  to switch the device on.
- The display indicates "Time" and the currently set therapy time (default setting: CONT.).
- Press the intensity control keys for channel 2 to set the therapy time. With  you select a longer time, with  , a shorter time. Go back to 00:00 to get the Continuous mode (CONT.).
- To save the timer settings, turn off the stimulator. When you turn the stimulator on again, the timer setting you saved is displayed.

5.2 Factory Defaults Settings

- Hold the program selection  key depressed.
- Then press the ON/OFF key  to switch the device on.
- The display shows DATA 000 000 flashing.
- Next press the two intensity decrease keys  simultaneously for channels 1 and 2 to reset the device to the factory defaults:
  - All stored data will be deleted.
  - The timer function is deactivated.
  - The program lock is deactivated.
  - The frequency for all programs is reset to the respective default value.
  - Program 9 is selected.
  - The initial screen is displayed.

6. WHAT TO DO, IF

...the stimulation feels unpleasant or different from previous sessions

- Check whether
  - The device settings were changed.
  - The electrodes are correctly placed and applied on the skin. Electrodes with poor adhesion must be replaced.
  - The skin is irritated.

...the stimulation is weak or not felt

- Check whether
  - The electrodes are properly applied to the skin. Electrodes with poor adhesion must be replaced.
  - The battery replacement symbol is displayed and the batteries need to be replaced (see the "Battery Replacement" section in chapter 7).
  - The "electric circuit interrupted" icon is displayed. This icon appears when the resistance between electrode and skin is too high. Reasons may be a poor electrode attachment or an interrupted electric circuit. When the electric circuit is interrupted, the intensity drops to 0. In this case check whether the electrode leadwire is correctly connected to the device and whether the electrodes are properly connected. If the problem persists, the electrode leadwire is probably broken and must be replaced.

...the letter "E" is displayed instead of the initial screen

In this case the device is defective and must not be used. Return the device to DJO for replacement.

...the device cannot be switched on

- Check whether
  - The batteries are inserted
  - The batteries are correctly inserted
  - The batteries are charged.

7. CARE, STORAGE, BATTERY REPLACEMENT, DISPOSAL

Taking care of and cleaning the Direct TensTM equipment is simple with the following instructions:

- Keep stimulator and accessories in the original case when they are not in use. It may, however, be practical to allow the electrodes to remain on the body between treatments. Carbon rubber electrodes can generally remain for 2-3 hours without the electrode gel drying out (does not apply to adhesive gel). They must then be taken off, washed, and dried before being applied again. This is especially important for persons with sensitive skin. In connection with stimulation, make sure that the electrodes are firmly in place.
- When using carbon rubber electrodes, use plenty of electrode gel and avoid drying out by applying tape around all the edges of the electrodes. Rinse the carbon rubber electrodes and the skin with water after use. Do not use detergent for the electrodes.
- Self-adhesive multi-use electrodes are re-moistened if necessary with a few drops of water and kept airtight (in a plastic bag) on protective paper when they are not in use.
- Never expose the stimulator to water. Wipe it off with a damp cloth if necessary.
- Do not jerk cables or connections.
- The cables are best preserved if left attached to the stimulator between sessions.
- No other maintenance of the device is required. Service life of the device can vary depending on usage conditions. Typical service life ifs 7 years.
- Never service the device while in use
- The device should be operated in temperatures between 10°C and 40°C, atmospheric pressures between 50 and 106 kPa, and relative humidity between 30% and 75%.
- The device should be transported and stored in temperatures between -40 °C and 70 °C, atmospheric pressures between 50 and 106 kPa and relative humidity between 10% and 90%.
- Contact manufacturer for assistance in setting up, using or maintaining the equipment or report events.

8. ORDERING INFORMATION, SPECIFICATIONS

Ordering Information

Electrodes used up?
Questions about the product?
We at DJO would be happy to help!

To avoid wrong deliveries, please indicate the part numbers when ordering products:

Part Number	Product
42190	Electrodes, Square 5x5 cm Durastick, Wire, pkg. of 4 electrodes
42191	Electrodes, Rectangular 5x9 cm Durastick, Wire, pkg. of 4 electrodes
193068-100	Lead wire, 100cm (40 inches)

To reorder, please contact:

DJO France
Centre Européen de Fret
64990 Mouguerre
France
Phone: +33 (0)5 59 52 86 90
Fax: +33 (0)5 59 52 86 91
E-mail: sce.cial@DJOglobal.com
Internet: www.DJOglobal.eu

Specifications

Number of channels	2
Constant Voltage	Up to a resistance of 1000 ohms (increased load can reduce the maximum current)
Output Intensity	0...60, adjustable in 0.5 steps
Maximum Output	40 mA @ 1000 ohms, 250 µs (charge maximum: 10µC)
Waveform	Asymmetrical biphasic square impulse
Frequency Range	0,5 – 1000 Hz
Impluse Duration	Determined by intensity setting, 0 – 250 µs
Power Supply	2 x 1.5 V AA disposable batteries ***or*** 2 x 1.2 V AA rechargeable batteries
Current consumption for 1 channel, 200 µs impulse duration, 100 Hz and 40 V	50 mA
Ambient conditions (operation)	Temperature 10°C to 40°C Relative humidity 30...75 %, no condensation Atmospheric pressure 700 to 1060 hPa
Ambient conditions (storage, transport)	Temperature 10°C to 40°C Relative humidity 30...75 %, no condensation Atmospheric pressure 500 to 1060 hPa
Dimensions (HxWxD)	110 x 70 x 30 mm
Weight	165 g (including batteries)

9. ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The Direct TENS™ Electrotherapy System is intended for use in the electromagnetic environment deified below. The customer or the user of the Direct TENS™ Electrotherapy System should assure that it is used in such an environment		
Emissions Tests	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The Direct TENS™ Electrotherapy System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Direct TENS™ Electrotherapy System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Not Applicable - Battery powered	
Voltage fluctuations IEC 61000-3-3	Not Applicable - Battery powered	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Direct TENS™ Electrotherapy System is intended for use in the electromagnetic environment specified below. The customer or the user of the Direct TENS™ Electrotherapy System should assure that it is used in such an environment			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Risk assessment on the Direct TENS™ Electrotherapy System indicates the compliance levels claimed are acceptable when ESD-precautionary measures are taken.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	Not Applicable - Battery powered Not Applicable - signal lines less then 3 meters	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+ 1kV differential mode (line to line) + 2kV common mode (line to ground)	Not Applicable - Battery powered	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Not Applicable - Battery powered	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Direct TENS™ Electrotherapy System requires continued operation during power mains interruptions, it is recommended that the Direct TENS™ Electrotherapy System be powered from an uninterrupted power supply.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The Direct TENS™ Electrotherapy System is intended for use in the electromagnetic environment deified below. The customer or the user of the Direct TENS™ Electrotherapy System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	[V_1] V, where V_1 = 3V	Portable and mobile RF communications equipment should be used no closer to any part of the Direct TENS™ Electrotherapy System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3.5}{V_1}]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	[E_1] V/m, where E_1 = 3V/m	$d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Direct TENS™ Electrotherapy System is used exceeds the applicable RF compliance level above, the Direct TENS™ Electrotherapy System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Direct TENS™ Electrotherapy System .

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Direct TENS™ Electrotherapy System			
The Direct TENS™ Electrotherapy System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Direct TENS™ Electrotherapy System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Direct TENS™ Electrotherapy System as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter P (W)	**Separation distance according to frequency of transmitter** d (m)		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$ (where $V_1 = 3V$)	**80 MHz to 800 MHz** $d = [\frac{3,5}{E_1}]\sqrt{P}$ (where $E_1 = 3V/m$)	**800 MHz to 2,5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$ (where $E_1 = 3V/m$)
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 rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

FCC REQUIREMENTS

Part 15 of the FCC Requirements	
This device complies with Part 15 of the FCC Rules. Operation is subject to the following 2 conditions:	• This device may not cause harmful interference • This device must accept any interference received, including the interference that may cause undesired operation.
FCC ID	T9J-RN42
Contains Transmitter Module IC	6514A-RN42

EC REP

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