Tens 3000

INSTRUCTION MANUAL

Richmar®

This manual is valid for the

TENS 3000 Stimulator

This user manual is published by Richmar.

United States Federal Law restricts this device to sale by or on the order of a physician or licensed practitioner

Conformity to safety standards

Richmar declares that the device complies with following normative documents:

IEC60601-1, IEC60601-1-2, IEC60601-2- 10, IEC60601-1-4, ISO10993-5, ISO10993-10, ISO10993-1

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1. GENERAL INFORMATION

1.1 General Description

The TENS 3000 is a battery operated pulse generator that sends electrical impulses electrodes to the body and reach the nerves causing pain. The device is provided with two controllable output channels, each independent of each other.
The electronics of the TENS 3000 create electrical impulses whose Intensity, duration, number per second and modulation may be altered with the controls or switches. Dial controls are very easy to use and the slide cover prevents accidental changes in the setting.

1.2 Medical Background

EXPLANATION OF PAIN

Pain is a warning system and the body's method of telling us that something is wrong. Pain is important; without it abnormal conditions may go undetected, causing damage or injury to vital parts of our bodies. Even though pain is a necessary warning signal of trauma or malfunction in the body, nature may have gone too far in its design.

Aside from its value in diagnosis, long-lasting persistent pain serves no useful purpose. Pain does not begin until the coded message travels to the brain where it is decoded, analyzed, and then reacted to. The pain message travels from the injured area along the small nerves leading to the spinal cord. Here the message is switched to different nerves that travel up the spinal cord to the brain. The pain message is then interpreted, referred back and the pain is felt.

EXPLANATION OF TENS

Transcutaneous Electrical Nerve Stimulation (TENS) is a non-invasive, drug free method of controlling pain. TENS uses tiny electrical impulses sent through the skin to nerves to modify your pain perception. TENS does not cure any physiological problem; it only helps control the pain. TENS does not work for everyone; however, in most patients it is effective in reducing or eliminating the pain, allowing for a return to normal activity.

HOW TENS WORKS

There is nothing "magic" about Transcutaneous Electrical Nerve Stimulations (TENS). TENS is intended to be used to relieve pain. The TENS unit sends comfortable impulses through the skin that stimulate the nerve (or nerves) in the treatment area. In many cases, this stimulation will greatly reduce or eliminate the pain sensation the patient feels. Pain relief varies by individual patient, mode selected for therapy, and the type of pain. In many patients, the reduction or elimination of pain lasts longer than the actual period of stimulation (sometimes as much as three to four times longer). In others, pain is only modified while stimulation actually occurs. You may wish to discuss this method of pain management treatment with your physician or therapist.

1.3 Indication For Use

TENS 3000 Stimulator may be used for the following conditions:

TENS:

1. Symptomatic relief of chronic intractable pain.
2. Acute post-traumatic pain.
3. Acute post-surgical pain.

2. SAFETY INFORMATION

Read instruction manual before operating. Be sure to comply with all "Contraindications", Warnings", "Cautions" and "Adverse reactions" in the manual. Failure to follow instructions may cause harm to user or device.

Safety Symbols Used in this Manual	
⚠ WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in serious injury and equipment damage.
⚠ CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the device or other property.

2.1 Contraindications

1. This device should not be used for symptomatic local pain relief unless etiology is established or unless a pain syndrome has been diagnosed.
2. This device should not be used when cancerous lesions are present in the treatment area.
3. Stimulation should not be applied over swollen, infected, inflamed areas or skin eruptions (e.g. phlebitis, thrombophlebitis, varicose veins, etc.).
4. Electrodes must not be applied to sites that might cause current/stimulation to flow through the carotid sinus region (anterior neck) or trans-cerebrally (through the head).
5. **DO NOT** use this device if the patient has a demand-type cardiac pacemaker or any implanted defibrillator.
6. This device should not be used over poorly enervated areas.
7. This device should not be used on patients with epilepsy.
8. This device should not be used on patients with serious arterial circulatory problems in the lower limbs.
9. This device should not be used on patients with abdominal or inguinal hernia.
10. **DO NOT** use this device if you have heart disease without consulting your physician.

2.2 Warnings, Cautions and Adverse Reactions

⚠ WARNINGS:

1. This device should be used only under the continued supervision of a licensed physician or practitioner.
2. The long-term effects of chronic electrical stimulation are unknown. Electrical stimulation devices **DO NOT** have any curative value.
3. TENS is a symptomatic treatment and, as such, suppresses the sensation of pain, which would otherwise serve as a protective mechanism.
4. Safety has not been established for the use of therapeutic electrical stimulation during pregnancy. **DO NOT** use during pregnancy unless directed by your physician.
5. Electrical stimulation is not effective for pain of central origin, such as a headache.
6. Electrical monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when electrical stimulation is in use.
7. Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
8. Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contraction may be strong enough to close the airway or cause difficulty in breathing.
9. Stimulation should not be applied transthoracically. Introduction of electrical current into the heart may cause cardiac arrhythmias.
10. Stimulation should not take place while the user is connected to high-frequency surgical equipment, it may cause burn injuries on the skin under the electrodes, as well as problems with the stimulator.
11. **DO NOT** use the stimulator in the vicinity of shortwave or microwave therapy equipment, since this may affect the output power of the stimulator.
12. **NEVER** use in environments with high humidity such as in the bathroom or when having a bath or shower.
13. Caution should be used in applying electrical stimulation to patients suspected of having heart disease. Further clinical data is needed to show there are no adverse results.
14. **NEVER** use near the heart. Stimulation electrodes should **NEVER** be placed anywhere on the front of the thorax (marked by ribs and breastbone), take extreme caution not to place near or on the two large pectoral muscles. Here it can increase the risk of ventricular fibrillation and lead to cardiac arrest.
15. Electrodes should not be placed over the eyes, in the mouth, near the genitals or internally.

16. **NEVER** use on the areas of the skin which lack normal sensation.
17. Apply the electrodes to clean, dry, and unbroken skin only.
18. Keep electrodes separate during treatment, electrodes in contact with each other could result in improper stimulation or skin burns.
19. Keep the stimulator out of reach of children.
20. Consult your doctor if you have any questions or concerns before using this device.

⚠ CAUTIONS:

1. Federal law (USA) restricts this device to sale by or on the order of a physician.
2. This device is for single patient use only.
3. Keep yourself informed of the contraindications.
4. This device is not intended for use on an unattended patient who is non-compliant, emotionally disturbed, has dementia, or low IQ.
5. Read, understand, and practice the warnings, cautions and operating instructions. Know the limitations and hazards associated with using this device. Observe the cautionary and operational decals placed on the unit. Always follow the operating instructions prescribed by your healthcare practitioner.
6. The instruction of use was listed; any improper use may be dangerous.
7. Do no use this device for undiagnosed pain syndromes until consulting a physician.
8. Patients with an implanted electronic device, such as a cardiac pacemaker, implanted defibrillator, or any other metallic or electronic device should not use this device without first consulting a doctor.
9. Stimulation delivered by this device may be sufficient to cause electrocution. Electrical current of this magnitude must not flow through the thorax or across the chest because it may cause cardiac arrhythmia.
10. **DO NOT** place electrodes on the front of the throat as Laryngeal and Pharyngeal muscle spasms may occur. Stimulation over the carotid sinus (neck region) may close the airways, make breathing difficult, and may have adverse effects on the heart rhythm or blood pressure.
11. **DO NOT** place electrodes on your head or at any sites that may cause the electrical current to flow transcerebrally (through the head).
12. Patients with heart disease, epilepsy, cancer or any other health condition should not use this device without first consulting a physician.
13. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or silicone rubber. If rash develops or pain persists, discontinue use and consult a doctor.
14. Electrode placement and stimulation settings should be based on the guidance of prescribing practitioner.

15. Effectiveness is highly dependent upon the patient and the selection of therapy by a person qualified in the management of pain.
16. Isolated cases of skin irritation have occurred at the site of the electrode placement following long-term application. If this occurs, discontinue use and consult your physician.
17. The electrodes are only to be placed on healthy skin. Avoid skin irritation by ensuring that good contact is achieved between electrodes and skin.
18. If the stimulation levels are uncomfortable or become uncomfortable, reduce the stimulation intensity to a comfortable level and contact your physician if problems persist.
19. This device should not be used while driving, operating machinery, close to water or during any activity in which involuntary muscle contractions may put the user at undue risk for injury.
20. **NEVER** use the device in rooms where aerosols (sprays) are used or pure oxygen is being administered.
21. **DO NOT** use it near any highly flammable substances, gases or explosives.
22. **DO NOT** use this device at the same time as other equipment which sends electrical pulses to your body.
23. **DO NOT** confuse the electrode cables and contacts with your headphones or other devices, and **DO NOT** connect the electrodes to other devices.
24. **DO NOT** use sharp objects such as pencil point or ballpoint pen to operate the buttons on the control panel.
25. Inspect applicator cables and associated connectors before each use.
26. Turn the device off before applying or removing the electrodes.
27. Electrical stimulator should be used only with the leads and electrodes recommended for use by the manufacturer.
28. This device has no AP/APG protection. **DO NOT** use it in the presence of explosive atmosphere of flammable mixture.
29. **DO NOT** pull on the electrode wire as that may damage the wire and electrode.
30. **DO NOT** apply to broken skin.
31. The electrodes should be discarded when they are no longer adhering to the skin.
32. The electrodes are intended for single patient use only.
33. If irritation occurs, discontinue use and consult your clinician.
34. Read the instructions for use of self-adhesive electrodes before application.
35. Always use the electrodes with the requirements of the IEC/EN60601-1, ISO10993-1/-5/-10 and IEC/EN60601-1-2, such as with CE mark, or are legally marketed in the U.S. under 510(K) procedures.

ADVERSE REACTIONS:

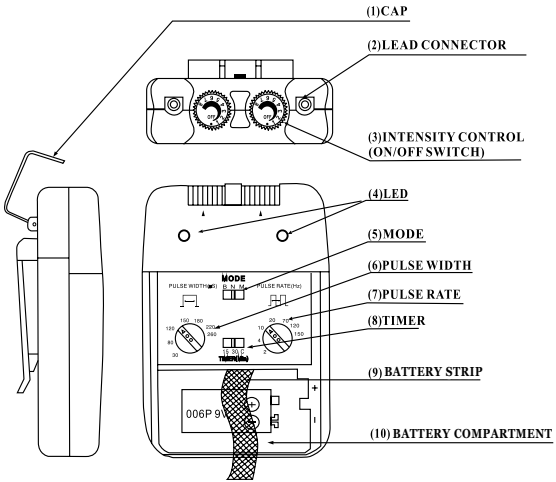
1. Skin irritation from the electrode gel and electrode burns are potential adverse reactions. If skin irritation occurs, discontinue use and consult your physician.

Note: Always use electrodes that are legally marketed and sold in the United States under 510K guidelines.

2. If the stimulation levels are uncomfortable, reduce the stimulation intensity to a comfortable level and contact your physician if any problems persist.

3. PRESENTATION

3.1 Device Features



4. Specifications

4.1 Device Contents

NO	DESCRIPTION	QTY
1	TENS Device (Item: DT3002)	1 each
2	Pair of Lead wires (Item: WW3005)	2/pk
3	2" x 2" Self-Adhesive electrodes (Item: EP2020WC2-INTM)	4/pk
4	9V Battery, Type 6F22 (Item: TA9050-I)	1 each
5	Instruction manual	1 each
6	Carrying case (Item: CC3001)	1 each

4.2 Technical Information

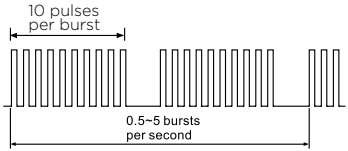
Channel	Dual, isolated between channels
Power supply	One 9 volt battery, (alkaline or nickel-cadmium rechargeable)
Operating Conditions	5°C to 40°C (41°F to 104°F) with a relative humidity of 30%-75%,atmospheric pressure from 700 to 1060 Hpa
Storage Conditions	-10°C to 50°C (14°F to 122°F) with a relative humidity of 10%-90%,atmospheric pressure from 700 to 1060 Hpa
Dimensions	3.75" x 2.60" x 1.0" (LxWxH
Weight	4 ounces.(With battery)
Tolerance	There may be a ±5% tolerance of all setting and ±10% tolerance of output of intensity.
Timer	15,30 minutes or continuous

Technical Specifications for Transcutaneous Electrical Nerve Stimulator (TENS) Mode

Waveform	Asymmetrical Biphasic Square Pulse
Pulse Amplitude	Adjustable, 0 ~ 80mA at 500 ohm Load each channel, 1mA/Step.
Pulse Width	Adjustable from 30-260μs
Pulse Rate	Adjustable from 2 to 150 Hz, 1 Hz/step
Burst	Burst occurs twice every second, Pulse width(adjustable) Frequency Fixed = 100 Hz
Modulation	The pulse width is automatically varied in a cyclic pattern over an interval of nominally 10 seconds, (in max 150Hz) Pulse rate decreases linearly over a period of 4 seconds from the control setting value to a value which is 40% less. The lower pulse rate will continue for 1 second. Then increase linearly over a 4 seconds period to its original value. The original pulse rate will continue for 1 second. The cycle is then repeated.
Normal	Normal stimulation based on setting value. Only pulse width, pulse rate and timer are adjustable in this mode.

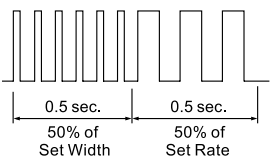
4.3 The Waveforms of the Stimulation Programs

Burst



Normal

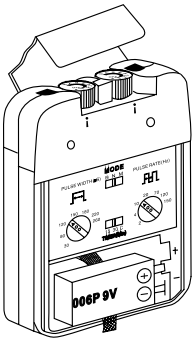
Modulation



5. INSTRUCTIONS FOR USE

5.1 Battery

5.1.1 Check/Replace the Battery



Over time, in order to ensure the functional safety of the device, changing the battery is necessary.

1. Slide the front battery cover down to open.
2. Insert the 9V battery into the battery compartment.
3. Make sure you are installing the battery properly. Be sure to match the positive and negative ends of the battery to the marking in the battery compartment of the device and placing the battery ribbon under the battery for easy removal later.
4. Press and push down battery snug into the compartment.
5. Slide battery cover back up to lock into place.
6. If battery requires replacement, slide the battery compartment cover to open. Pull up the battery out of the compartment by pulling on the battery ribbon to pop out easily and then insert a new 9V battery according to the above steps 2 to 5.

5.1.2 Disposal of Battery

Dispose of used batteries according to the current federal, state and local regulations. As a consumer, you are obligated by law to discard depleted batteries appropriately.

⚠ 5.1.3 CAUTION FOR BATTERIES:

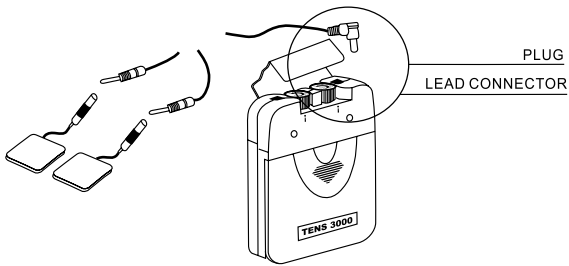
1. Swallowing a battery may be fatal. Keep the battery and the device out of the reach of children. If a battery is swallowed, consult a physician immediately.
2. If a battery has leaked, avoid contact with skin, eyes and mucus membranes. Rinse the affected areas with clear water immediately and contact a physician immediately.
3. Battery should not be charged, dismantled, thrown into fire or short-circuited.
4. Protect battery from excess heat.
5. Remove batteries from the unit if they are depleted or if you are not using the unit for prolonged periods of time. This prevents damage caused by leaking battery.
6. Always replace with the same type battery.

⚠ CAUTION:

Before using the device for the first time, you are strongly advised to take careful note of the contraindications and safety measures detailed at the beginning of this manual (on page 5-9 and throughout manual), as this powerful equipment is neither a toy nor a gadget!

5.2 Connect Lead Wires to Electrodes

Ensure the device is in the OFF position before proceeding to this step. Connection of the electrodes is made with two-lead connector. Both intensity controls must be at the Off position. Electrodes must be pressed firmly on the skin



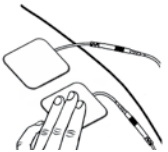
5.3 Electrode Options

Your clinician will decide which type of electrode is best for your condition. Follow application procedures outlined in electrode packing, to maintain stimulation and prevent skin irritation. Using the legally marketed TENS electrode is recommended.

⚠ CAUTION:

Always use the electrodes with CE mark, or which are legally marketed in the U.S. under 510(K) procedure.

5.3.1 Place Electrode on Skin



Apply electrodes to the exact site indicated by your physician or therapist. Before applying electrodes, be sure the skin surface over which electrodes are placed is thoroughly cleaned and dry.

Make sure the electrodes are pressed firmly to the skin and make good contact between the skin and the electrodes. Place the electrodes over the skin; attach them properly, firmly and evenly. Electrodes should be placed at least 2" but no more than 6" apart, per channel.

⚠ CAUTION:

1. Before applying the self-adhesive electrodes, it is recommended that you wash, degrease and dry the skin first.
2. **DO NOT** turn on the device when the self-adhesive electrodes are not positioned on the body.
3. **NEVER** remove the self-adhesive electrodes from the skin while the device is turned on. You will feel an uncomfortable electrical shock.
4. It is recommended that, at a minimum, 1.5" x 1.5" self-adhering, square electrodes are used at the treatment area.

5.3.2 Electrode Placement

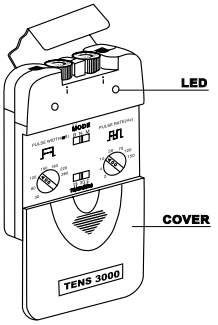
The placement of electrodes can be one of the most important parameters in achieving success with this therapy. Of utmost importance is the willingness of the physician to try the various styles of electrode placement to find which method best fits the needs of the individual patient.

Every patient responds to electrical stimulation differently and their needs may vary from the conventional settings suggested here. If the initial results are not positive, speak to your physician about alternative stimulation settings and/or electrode placements. Once an acceptable location has been achieved, mark down the electrode sites and the device settings, so the patient can easily continue treatment on their own.

5.4 Adjusting the Controls

5.4.1 Slide Cover:

A slide-on panel cover covers the controls for Pulse Width, Pulse Rate, Mode Selector and Modulation Selector. Your medical professional may wish to set these controls for you and request that you leave the cover in place.

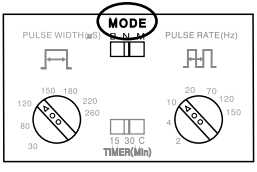


5.4.2 Display LED:

Each of the LEDs illuminates green whenever the electronics of the device create a current impulse. Due to the capacity of the human eye, the illumination of the lamp can only be recognized up to a frequency of approximately 30 Hz. At higher frequencies, the lamp will appear to be constantly illuminated.

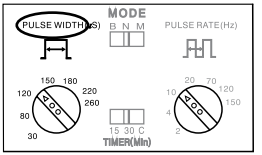
5.4.3 Mode Control

Expose the controls by sliding front cover down from top of unit. This switch has 3 positions: B for Burst stimulation, N for Constant stimulation, and M for modulation. Push the Mode Selector until engaged in position desired.



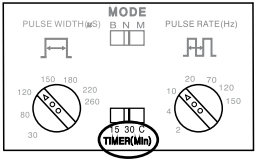
5.4.4 Pulse Width Control

This dial adjusts the length of time each electrical signal is applied through the skin, which controls the strength and sensation of the stimulation.



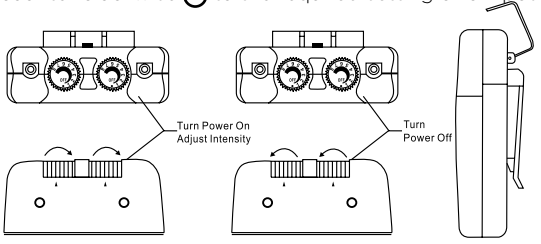
5.4.5 Timer Control

Treatment time of TENS can be preset with Timer Control. This switch has 3 positions, 15, 30 and C (Continue). Push the Timer Control until engaged in position desired.



5.5 Turn ON

If both controls are in the off-position (white markings on the housing match up with the OFF dot on each control), the device is switched off. By turning clockwise to hear/feel a click, and then stop, this means the appropriate channel is switched on and the impulse display led will illuminate and begin to pulse according to the frequency set.
To increase the current strength, slowly turn the dial clockwise, waiting about 2-3 seconds between each increase until you feel a strong but comfortable stimulation.
To reduce the current strength or switch the device off, turn the controls counter clockwise to the required setting or off-position.



6. CLEANING AND CARE

6.1 Tips for Skin Care

Follow these suggestions to avoid skin irritation, especially if you have sensitive skin:

1. Wash the area of skin you will be placing the electrodes on with soap. Rinse thoroughly and dry the area completely before and after placing electrodes.
2. Excess hair may be clipped with scissors; **DO NOT** shave stimulation area.
3. Wipe the area with the skin preparation your clinician has recommended. Let this dry. Apply electrodes as directed.
4. Many skin problems arise from the “pulling stress” from adhesive patches that are excessively stretched across the skin during application. To prevent this, apply electrodes from center outward; avoid stretching over the skin.
5. To minimize “pulling stress”, tape extra lengths of lead wires to the skin in a loop to prevent tugging on electrodes.
6. When removing electrodes, always remove by pulling in the direction of hair growth.
7. It may be helpful to rub skin lotion on electrode placement area during treatment down time when you are not wearing electrodes.
8. **NEVER** apply electrodes over irritated or broken skin.

6.2 Cleaning the Device

1. Remove the battery from the device before you clean the device.
2. Clean the device after use with a soft, slightly moistened cloth. For hard to clean situations, you can also moisten the cloth with mild soapy water.
3. **DO NOT** use any chemical cleaners or abrasive agents for cleaning.

6.3 Cleaning Electrodes

1. Electrodes cannot be cleaned as they are made with a self-adhesive gel. Electrodes can be re-used and number of uses vary from user to user.
2. If electrodes do not stick to the skin completely (including lifting edges) please replace with new electrodes. **DO NOT** use smaller electrodes than were provided by the manufacturer unless directed specifically by your physician.

TO REMOVE YOUR ELECTRODES:

1. Lift the corner of the electrode and gently remove it from the skin.
2. Between uses, place the electrodes back onto the protective sleeve and insert them into the resealable bag and store in a cool dry place.

6.4 Cleaning the Lead Wires

Clean the lead wires by wiping them with a damp cloth. Coating them lightly with talcum powder will reduce tangles and prolong their life.

6.5 Maintenance

1. Maintenance and all repairs should only be carried out by an authorized agency. The manufacturer will not be held responsible for the results of maintenance or repairs by unauthorized persons.
2. The user must not attempt any repairs to the device or accessories. Please contact the retailer for repair.
3. Opening of the equipment by unauthorized agencies is not allowed and will terminate any claim to warranty.
4. Check the unit before each use for signs of wear and/or damage. Replace worn items as required.

7. TROUBLESHOOTING

If your device does not seem to be operating correctly, refer to the chart below to determine what may be wrong. Should none of these measures correct the problem, the device should be serviced.

Problem	Possible Cause	Solution
Display fails to light up	Battery contact failure.	Try fresh batteries.
		Ensure batteries are inserted correctly
		Check contacts are in place.
		Check contacts are not broken.
Stimulation weak or cannot feel any stimulation	Electrodes are dried out or contaminated.	Replace and reconnect.
	Electrode placement.	
	Lead wires old/worn/ damaged.	Replace.
Stimulation is uncomfortable	Intensity is too high.	Decrease intensity.
	Electrodes are too close together.	Reposition the electrodes.
	Damaged or word electrodes or lead wires.	Replace.
	Electrode active area size is too small.	Replace electrode with ones that have an active area no less than 16.0cm² (4cm x 4cm).
	May not operate the device according to the manual.	Please check the manual before use.
Intermittent output	Lead wires.	Verify connection is secure and firmly seated and no metal pins are exposed
		Turn down the intensity. Rotate lead wires in socket 90°. If still intermittent, replace lead wire.
		If still intermittent after replacing the lead wire, a component may have failed. Call your distributor of the manufacturer

7 TROUBLESHOOTING CONT

Stimulation is ineffective	Improper electrode and applicator placement unknown.	Reposition electrode and applicator.
		Contact clinician.
The skin becomes red and/or you feel a stabbing pain	Using the electrodes on the same site every time.	Reposition the electrodes. If at any time you feel pain or discomfort stop use immediately.
	The electrodes are not sticking onto the skin properly.	Ensure the electrode is stuck securely on the skin.
	The electrodes are dirty.	Replace with new electrodes.
	The surface of the electrode was scratched.	Replace with new electrodes.
Output current stops during therapy	The electrode pads come off the skin.	Turn off the device and stick the electrode pad firmly to the skin. If that does not work, replace with new electrodes.
	The cable is disconnected.	Turn off the device and connect the cable.
	The power of the batteries has been exhausted.	Replace them with new batteries.

Malfunctions

Should any malfunctions occur while using the TENS, check:

- Whether the switch/control is set to the appropriate form of therapy, adjust the control correctly
- Whether the cable is correctly connected to the device. The cables should be inserted completely into the sockets
- Whether the LED is illuminated. If necessary, insert a new battery.
- For possible damage to the lead wire. Change the lead wire if any damage is detected.

8. STORAGE

1. For prolonged pauses in treatment, store the device in a cool dry room and protect it against heat, sunshine and moisture and remove the battery to avoid battery leaking.
2. Store the device in a cool, well-ventilated place.
3. **NEVER** place any heavy objects on the device.

9. DISPOSAL

Used fully discharged batteries must be disposed of in a specially labeled collection container, at a toxic waste collection point or through an electrical retailer. Please dispose of the device in accordance with the laws in your area.

10. ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES

Guidance and manufacturer's declaration - electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user assures that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device 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	Group B	The device is suitable for use in all establishments including domestic 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	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user 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	±6 kV contact	±6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
	±8 kV air	±8 kV air	
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply	Not applicable	Main power quality should be that of a commercial or hospital environment.
	±1 kV for input/ output lines		
Surge IEC 61000-4-5	±1 kV differential mode		
	±2 kV common mode		
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle		
	40% UT (60% dip in UT) for 5 Cycles		
	70% UT (30% dip in UT) for 25 Cycles		
	<5% UT (>95% dip in UT) for 5 sec		
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Immunity test	IEC 60501 test level	Compliance level	Electromagnetic environment guidance
			Portable and mobile RF Communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d=[\frac{3.5}{V1}]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m80 MHz to 2.5 GHz	3 V/m	$d=[\frac{3.5}{E1}]\sqrt{P}$ 80 MHz to 800 MHz $d=[\frac{7}{E1}]\sqrt{P}$ 800 MHz to 2.5 MHz
			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 meters (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. 

NOTE I. 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.

1. Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM 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 device is used exceeds the applicable RF compliance level above, should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
2. Over the frequency range 150 kHz to 80 MHz, field strength should be less than (Vi) W/m.

Recommended separation distances between portable and mobile RF communications equipment and the device.

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) as recommended below, according to the maximum output power of the communications equipment

Rate maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d=[\frac{3.5}{V1}]\sqrt{P}$	80 MHz to 800 MHz $d=[\frac{3.5}{V1}]\sqrt{P}$	800 MHz to 2,5 GHz $d=[\frac{3.5}{V1}]\sqrt{P}$
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 rated at a maximum output power not listed above, the recommended separation distance d in meters 9m0 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) accordable 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 propogation is affected by absorption and reflection from structures, objects and people.

11. GLOSSARY OF SYMBOLS

	Attention: Read the operating instruction before use! Equipment capable of delivering output values in excess of 10mA r.m.s. or 10V r.m.s. averaged over any period of 5s.
	Electrical devices are recyclable material and should not be disposed of with household waste after their useful life! Help us to protect the environment and save resources and take this device to the appropriate collection points. Please contact the organization which is responsible for waste disposal in your area if you have any questions.
	Type BF Applied Part
	**DO NOT** insert the plug into AC power supply socket
	Direct Current (DC power source)
	Refer to instruction manual

12. WARRANTY

Please contact your dealer in case of a claim under the warranty. If you have to send the unit back to your provider, enclose a copy of your receipt and state what the defect is.

The following warranty terms apply:

1. The warranty period for device is one year from date of purchase. In case of a warranty claim, the date of purchase has to be proven by means of the sales receipt or invoice.
2. Repairs or replacements under warranty **DO NOT** extend the warranty period either for the device or for the replacement parts.
3. The following is excluded under the warranty:

    - All damage which has arisen due to improper treatment, e.g. non-observance of the user instruction.
    - All damage which is due to repairs or tampering by the customer or unauthorized third parties.
    - Damage which has arisen during transport from the manufacturer to the consumer or during transport to the retailer.
    - Accessories which are subject to normal wear and tear.

Liability for direct or indirect consequential losses caused by the unit is excluded even if the damage to the unit is accepted as a warranty claim.

1. All products must be returned in original packaging and must contain all components, accessories and user manuals. If any components are missing, you will be responsible for the cost of the replacement component and the 25% restocking fee.
2. All returns must be approved with a Return Authorization Number. Please call our Customer Service Team at (800) 376-7263 to obtain a Return Authorization Number. Provide the following information when calling:
    - Item Number
    - Original Order Number
    - Product Serial Number/Lot Number
    - Reason for Return
3. The Return Authorization Number must be marked clearly on the returned carton and is valid for 10 business days from the date of issue.
4. Returned merchandise must be in the same unit of measure as originally purchased.

5. Return Labels or Call Tags can be issued by our customer service department to return merchandise.
6. Associated fees and return freight charges will apply. All returns of dropshipped items are subject to a restocking fee as well as inbound and outbound freight charges.
7. Returns will not be accepted on items that are:
    - Missing their serial number
    - Special order items
    - Returned more than 30 days after delivery
    - Returned without notification

Manufactured for:

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