Direct Supply® Direct Choice™ Digital TENS Device

Model #DSDC2CD

Owner's Manual

Thank you for purchasing a Direct Supply® Direct Choice™ Digital TENS Device from Direct Supply Equipment & Furnishings®. Please read this entire guide carefully and keep it for future reference. This guide will provide you with instructions, warnings, warranty information and other important information about your Direct Supply Direct Choice Digital TENS device. Share this information with your housekeeping, nursing and maintenance staff to help ensure the Digital TENS device is used and cared for properly.

Please keep and refer to this Owner's Manual.

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Introduction & Definitions and Symbols

Introduction

Thank you for purchasing this Direct Supply Direct Choice Digital TENS Device from Direct Supply Equipment & Furnishings, a division of Direct Supply, Inc. In this owner's manual, you'll find important information that you should read before using this product. Please keep this manual available for future reference. Should you have any questions, please contact your Direct Supply Equipment & Furnishings account manager.

Transcutaneous Electrical Nerve Stimulation (TENS) is a non-invasive, drug free method of helping to control pain. TENS uses tiny electrical impulses sent through the skin to nerves to modify pain perception. TENS does not cure any physiological problem; it only helps control the pain. TENS does not work for everyone. However, in most residents it is effective in helping to reduce or eliminate the pain, which may allow an individual to return to normal activity.

Definitions and Symbols

NOTE: Indicates a tip.

⚠ Attention. Read the instructions.

WARNING: Calls attention to a potential danger that requires correct procedures or practices in order to prevent personal injury.

CAUTION: Indicates correct operating or maintenance procedures in order to prevent damage to or destruction of the equipment or other property

DEVICE: Your Direct Supply Direct Choice Digital TENS Device

YOU and YOUR: The facility, community or other entity that has purchased the device.

WE, US and OUR: Direct Supply Manufacturing, Inc.

: Degree of Electrical Protection BF

: Timer

: Low battery indicator

: Increase

: Decrease

Safety Notices – Warnings and Cautions

Check your Direct Supply Direct Choice Digital TENS Device each week based on the following checklist:

1. Check the device for external damage, such as deformation of the housing and damaged or defective output sockets.
2. Check the device for defective operating elements, such as the switches or knobs. Check the legibility of labels.
3. Check that the LCD is displaying information when a channel is turned on.
4. Check the usability of accessories. Check that the cables and electrodes are not damaged. If the device seems to be damaged in any way, do not use the device and contact Direct Supply Equipment & Furnishings for troubleshooting assistance.

⚠ WARNINGS

Read and follow all directions and warnings before using this device. Do not operate this device without first reading and understanding this user manual. Damage, injury or even death may result from improper use of this device or not following directions and warnings. This device is intended for use by trained and licensed healthcare or senior care providers in normal, indoor conditions.

- Caution should be used in applying TENS to residents suspected of having heart disease. Further clinical data is needed to show there are no adverse results.
- TENS devices have no AP/APG protection. Do not use them in the presence of explosive atmosphere and flammable mixture.
- The safety of TENS devices for use during pregnancy or birth has not been established. Do not use TENS during pregnancy.
- TENS is not effective for pain of central origin. (This includes headache.)

- TENS devices have no curative value.
- TENS is a symptomatic treatment and as such suppresses the sensation of pain which would otherwise serve as a protective mechanism.
- Electronic monitoring equipment (such as EGG monitors and EGG alarms) may not operate properly when TENS stimulation is in use.
- There should be a prominently placed statement warning that stimulus delivered by this device may be sufficient to cause electrocution. Electrical current of this magnitude must not flow through the thorax because it may cause a cardiac arrhythmia.
- Do not place electrodes on the front of the throat as spasm of the laryngeal and pharyngeal muscle may occur.
- Care should be taken so that when operating potentially dangerous machinery the stimulator controls are not changed abruptly.
- Keep this device out of the reach of children and individuals with cognitive impairment.
- Never use in environments with high humidity such as in the bathroom or when having a bath or shower.
- Electrodes should never be placed over the eyes, in the mouth, near the genitals or internally.
- Do not use while sleeping.
- Skin irritation and electrode burns are possible adverse reactions. If either occurs, discontinue use and consult your physician.
- Residents with an implanted electronic device (for example, a pacemaker) should not undergo TENS treatment without first consulting a doctor. The same applies to patients with any metallic implants.

Safety Notices – Warnings and Cautions (cont.)

- 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 of injury.
- Federal law restricts this device to sale by or on the order of a physician. This device is intended for use under the order of a healthcare practitioner licensed by your state.

⚠ CAUTIONS

- Isolated cases of skin irritation may occur at the site of electrode placement following long-term application. Effectiveness is highly dependent upon resident selection by a person qualified in the management of pain patients. This device should be used under the supervision of a licensed healthcare professional.
- Possible allergic reaction to gel, skin irritation and electrode burn are potential adverse reactions.
- If TENS therapy becomes ineffective or unpleasant, stimulation should be discontinued until its use is reevaluated by a licensed healthcare professional.
- Turn the device off before applying or removing electrodes.

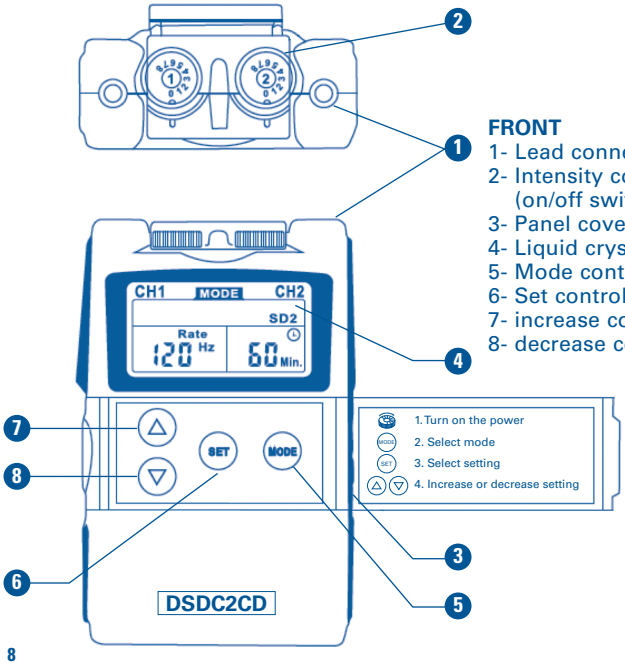
Contraindications

- This device should not be used for symptomatic local pain relief unless etiology is established or unless a pain syndrome has been diagnosed.
- TENS is not recommended for patients with known heart disease without physical evaluation of risk.
- This device should not be used when cancerous lesions are present in the treatment area.
- Stimulation should not be applied over swollen, infected, inflamed areas or skin eruptions (e.g. phlebitis, thrombophlebitis, varicose veins, etc.).
- Electrodes must not be applied to sites that might cause current/stimulation to flow through the carotid sinus region (anterior neck) or transcerebrally (through the head).
- Do not use this device if the resident has a demand-type cardiac pacemaker or any implanted defibrillator.
- This device should not be used over poorly enervated areas.
- Epilepsy.
- Serious arterial circulatory problems in the lower limbs.
- Abdominal or inguinal hernia.

Device Description

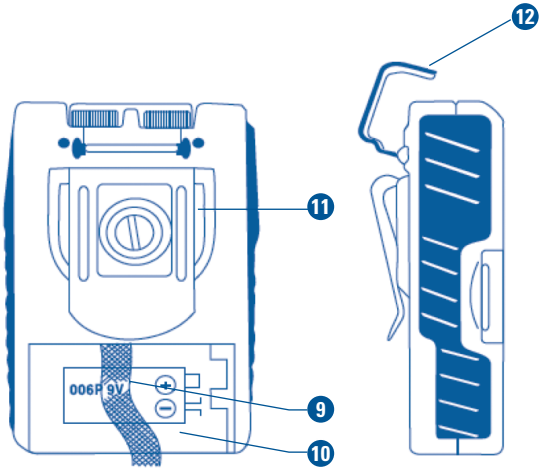
The Direct Supply Direct Choice Digital TENS Device is a battery-operated pulse generator that sends electrical impulse electrodes to the body and reaches the nerves that are causing pain. The device is provided with two controllable output channels, each independent of the other. An electrode pair can be connected to each output channel.

The electronics of the Digital TENS Device 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.



FRONT

1- Lead connector
2- Intensity control (on/off switch)
3- Panel cover
4- Liquid crystal display
5- Mode control
6- Set control
7- increase control
8- decrease control



BACK
9- Battery strip
10- Battery case
11- Belt clip

SIDE
12- Protective cover

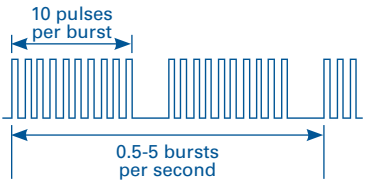
Technical Specifications

Specification	Technical Description
Channels	Dual, isolated between channels.
Pulse Amplitude	Adjustable, 0-100 mA peak into 500 ohm load each channel.
Pulse Rate	Adjustable from 2 to 150 Hz.
Pulse Width	Adjustable from 50 to 300 µs.
Modes	B(Burst), N(Normal), M(Modulation), SD1(Strength Duration), SD2
Normal Mode	The pulse rate and pulse width are adjustable. It generates continuous stimulation based on the setting value.
Burst Mode	Burst rate: Adjustable, 0.5-5 Hz Pulse width: Adjustable, 50-300 µs Frequency: Fixed at 100 Hz
Modulation Mode	Modulation mode is a combination of pulse rate and pulse width modulation. The pulse rate and width are automatically varied in a cycle pattern. The pulse width is decreased by 50% from its original setting in 0.5 seconds, and then the pulse rate is decreased by 50% from its original setting in 0.5 seconds. Total cycle time is 1 second. In this mode, pulse rate (2-150Hz) and pulse width (50-300 µs) are fully adjustable.
SD1 Mode	The SD1 (Strength-Duration) mode consists of automatic modulation intensity and pulse in a 40% range. The intensity is always increasing while the pulse width is decreasing and vice versa. The intensity is decreased by 40% while the pulse width is increased by 40% in 5 seconds. In the next 5 seconds, the intensity is increased by 40% while the pulse width is increased by 40%. Total cycle time is 10 seconds. Pulse rate (2-150Hz) and pulse width (50-300 µs) are fully adjustable.

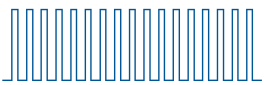
Specification	Technical Description
SD2 Mode	The SD2 (Strength-Duration) mode consists of automatic modulation intensity and pulse in a 70% range. The intensity is always increasing while the pulse width is decreasing and vice versa. The intensity is decreased by 70% while the pulse width is increased by 70% in 5 seconds. In the next 5 seconds, the intensity is increased by 70% while the pulse width is increased by 70%. Total cycle time is 10 seconds. Pulse rate (2-150Hz) and pulse width (50-300 µs) are fully adjustable.
Waveform	Asymmetrical bi-phasic square pulse.
Timer	Continuous or adjustable from 1 to 60 minutes (in 1-minute increments from 1-15 and in 5-minute increments from 15 to 60 minutes).
Record Storage	This device can store 60 sets of operation records. Total recorded time is 999 hours.
Voltage	0 to 50V (Load: 500 ohms)
Power Supply	One 9V battery
Battery Life	Approximately 50 hours
Operating Conditions	Temperature: 32°F - 104°F Relative Humidity: 30% - 75% Atmospheric Pressure: 525 mmHg - 795 mmHg
Size	3.98"L x 2.40"W x 0.96"H
Weight	5.29 oz. (battery included)

Waveforms

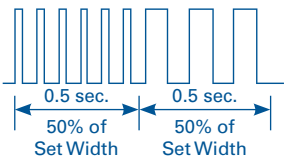
Burst



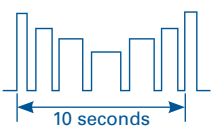
Normal



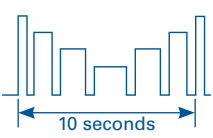
Modulation



SD1 (Strength-Duration)



SD2 (Strength-Duration)



Replacement Parts & Accessories

Please contact your Direct Supply Equipment & Furnishings account manager to order replacement parts or accessories for your Digital TENS Device. Only Direct Supply Direct Choice accessories are intended for use with this device. Available accessories may include:

- Electrode lead wires
- Electrodes
- Belt clip
- Battery case cover
- Lead connector
- Main PCB
- Intensity control cover
- Intensity knob
- LCD cover
- Owner's manual
- Carrying case

Functions and Use

Pulse Duration:
Wider pulse duration settings will deliver stronger stimulation for any given intensity setting. As mentioned in the Controls section, by using a combination of intensity and pulse duration, various pulse widths may stimulate different groups of nerve fibers. The choice of which pulse duration to use is partially dependent upon the Treatment Mode selected (refer to the appropriate section).

Pulse Rate:
The Pulse Rate (hertz or pulses per second) chosen depends greatly upon the type of electrode placement given to the resident. When using contiguous and dermatome electrode placements (i.e. stimulating directly through the area of pain or localized enervation), a quick pulse rate (setting greater than 80 Hz on the Pulse Rate Control) is typically desired. The resident should not perceive individual pulses but rather have the sensation of steady continuous stimulation. Despite any general recommendations, individual residents may require slight variations in the device settings, according to the nature of their condition.

Treatment Mode:
Normal mode offers the practitioners complete control over all the various treatment parameters of the instrument. Burst Mode is analogous to the Low Rate TENS technique except the low frequency individual pulses are replaced by individual "bursts" of 7-10 individual pulses. It is thus a combination of Conventional TENS and Low Rate TENS. In Burst Mode, the treatment frequency is fixed by the instrument and is not adjustable with the Frequency Rate control. Modulated Mode attempts to prevent nerve accommodation by continuously cycling the treatment intensity. When using Modulated Mode increase the intensity only when the unit is at the maximum intensity of the modulation cycle. If the intensity

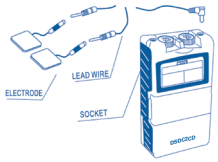
is increased during a low intensity period of the modulation cycle, the patient should increase the intensity slowly until the modulation cycle reaches the maximum to insure a true maximum intensity output. Strength-Duration Modulation {SD1 & SD2} consists of alternating modulated amplitude and width so that one parameter is always decreasing while the other is increasing and vice versa. The amplitude decreases from the amplitude control setting and returns to that setting. The width decreases from the width control setting and returns to that setting.

Time Duration:

The onset of pain relief should occur shortly after the intensity setting has been determined. However, in some cases, pain relief may take as long as 30 minutes to achieve. TENS units are typically operated for long periods of time, with a minimum of 20- 30 minutes and in some post-operation protocols, as long as 36 hours. In general, pain relief will diminish within 30 minutes of the cessation of stimulation.

Attachment of Electrode Lead Wires:

The wires provided with the device insert into the jack sockets located on top of the device. Holding the insulated portion of the connector, push the plug end of the wire into one of the jacks (see drawing); one or two sets of wires may be used.



After connecting the wires to the stimulator, attach each wire to an electrode. Use care when you plug and unplug the wires. Jerking the wire instead of holding the insulated connector body may cause wire breakage.

Functions and Use (cont.)

⚠ **WARNING**: Do not insert the plug of the resident lead wire into any AC power supply socket.

Electrode Options

The electrodes are disposable and should be routinely replaced when they start to lose their adhesive nature. If you are unsure of your electrode adhesive properties, discard the existing electrodes and order replacement electrodes. Replacement electrodes should be re-ordered through or on the advice of your physician to ensure proper quality. Follow application procedures outlined in electrode packing to maintain optimal stimulation and to prevent skin irritation.

Electrode Placement

The placement of electrodes can be one of the most important parameters in achieving success with TENS therapy. Of utmost importance is the willingness of the clinician to try the various styles of electrode placement to find which method best fits the needs of the individual resident. Contiguous placement is the most common placement technique. It involves placing the electrodes alongside the area of localized pain, in such a way as to direct the flow of current through or around the area of pain. In a single-channel application, this would involve placing each pad on either side of the pain site if the pain is localized on a limb and deep within the tissue. Pad placement on the posterior and anterior aspects of the affected limb will typically allow the current to flow completely through the limb and thus through the endogenous pain site. With a two-channel application, the clinician may either direct the current flow to cross through the pain site or, in what is called the “bracket” method, allow the current flow on either side of the painful area, generally through the nerve branches that feed into the pain site.

Application of Adhesive Electrodes

Application:

- Clean and dry the skin at the prescribed area thoroughly with soap and water prior to application of electrodes.
- Insert the lead wire into the pin connector on the pre-wired electrodes.
- Remove the electrodes from the protective liner and apply the electrodes firmly to the treatment site.

Removal:

- Lift at the edge of electrodes and peel; do not pull on the lead wires because it may damage the electrodes.
- Place the electrodes on the liner and remove the lead wire by twisting and pulling at the same time.

Care and Storage:

- Between uses, store the electrodes in the resealed bag in a cool dry place.
- It may be helpful to improve repeated application by spreading a few drops of cold water over the adhesive and turning the surface up to air dry. CAUTION: Over-saturation with water will reduce the adhesive properties.

⚠ **WARNING:**

- Only use the device with electrodes provided by the manufacturer.
- Do not apply electrodes to broken skin.
- The electrodes should be discarded when they no longer adhere to the skin.
- The electrodes are intended for single resident use only.
- If irritation occurs, discontinue use and consult your clinician or other licensed healthcare professional.

- Read the instructions for use of self-adhering electrodes before application.

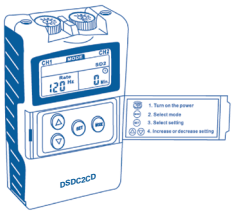
Tips for Resident Skin Care

To avoid skin irritation, especially if the resident has sensitive skin, follow these suggestions:

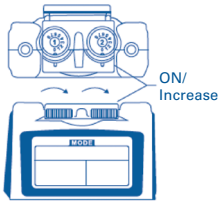
- Wash the area of skin where you will be placing the electrodes, using mild soap and water before applying electrodes, and after taking them off. Be sure to rinse soap off thoroughly and dry skin well.
- Excess hair may be clipped with scissors; do not shave stimulation area.
- Wipe the area with the skin preparation your clinician has recommended. Let this dry. Apply electrodes as directed.
- 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.
- To minimize "pulling stress", tape extra lengths of lead wires to the skin in a loop to prevent tugging on electrodes.
- When removing electrodes, always remove by pulling in the direction of hair growth.
- It may be helpful to rub skin lotion on electrode placement area when not wearing electrodes.
- Never apply electrodes over irritated or broken skin.

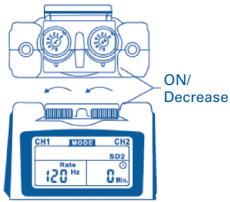
Adjusting the Controls on the Digital TENS Device:

- Panel Cover: A lid covers the controls for selecting mode and adjusting settings. A licensed healthcare professional may wish to set these controls for you and request that you leave the cover in place.



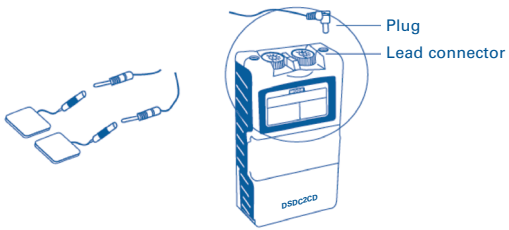
- On/Off Switch and Intensity Control: If both controls are in the off-position, the device is switched off. By turning the controls clockwise, the appropriate channel is switched on and the indicator of power (CH1 or CH2) will reveal on the LCD. The current strength of the impulses transmitted to the electrodes increases further when the control is turned clockwise. To reduce the current strength or switch the device off, turn the controls counter clockwise to the required setting or off position. The controls are protected by a cap to avoid unintentional changes.





Functions and Use (cont.)

- Lead Connector: Connection of the electrodes is made with a two-lead connector. The device must be switched off before connecting the cables. Both intensity controls must be at the off position. Electrodes must be pressed firmly on the skin.

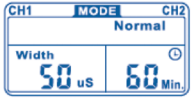


- Mode Control: There are five modes available: Burst, Normal, Modulation, SD1 and SD2. The mode can be selected by pressing the “MODE” control button.
- Set Control: By pressing the “SET” control button, you may enter the setting you intend to adjust. You may start to set the value by pressing the “Increase” and “Decrease” controls when the value is flashing.
- Increase Control: The upward-facing arrow button will increase the settings. When this button is pressed, the selected parameter will increase.
- Decrease Control: The downward-facing arrow button will decrease the settings. When this button is pressed, the selected parameter will decrease.
- Timer: This device has a timer of 1-60 minutes. The timer can be adjusted by pressing the “SET” and “Increase” or “Decrease” controls. The treatment time will countdown automatically by one minute. Its output will be shut off when time is up.

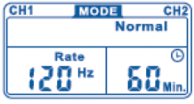
- Low Battery Indicator: A low battery indicator will show up on the liquid crystal display when the battery needs to be replaced as soon as possible. The unit may continue to operate for a few more hours depends on the setting intensity level. Immediately replace the battery when the low battery indicator appears and do not use the device if you suspect the battery is low.
- Steps to Set a New Program:

  The settings can be adjusted according to the following steps.

  - Turn on the Intensity: After the electrodes are placed firmly on skin and the lead wires are plugged into the socket of the device, turn the on/off control clockwise. The liquid crystal display will be lit up.
  - Select a Mode: Select a mode by pressing the “MODE” control. The mode you select will show up on the top of the liquid crystal display. There are five modes to choose from, including Burst, Normal, Modulation, SD1 and SD2.

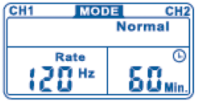


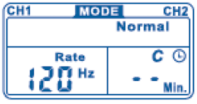
  - Set Pulse Rate: Pulse rate is adjustable from 2Hz to 150Hz. Press “SET” control to enter this menu, then press “Increase” or “Decrease’’ to adjust the setting. Unless otherwise instructed, adjust the pulse rate control to the 70-120 Hz setting.



Functions and Use (cont.)

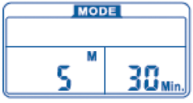
- Set Timer: Press “SET’ to enter this setting. The treatment time is adjustable from 1 to 60 minutes or Continuous. Press “Increase” or “Decrease” control to adjust setting. Your settings will be stored in this unit permanently unless they are adjusted again. You can set the timer to “Continuous” mode by pressing the “Increase” control when the display shows 60 minutes.



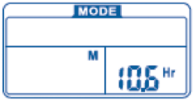


Continuous

- Resident Records: This unit can store 60 sets of operation records; total treatment time of up to 999 hours can be stored. To check and delete individual records, press “MODE” control and turn on the power simultaneously. The LCD will show the number of records and operation time. Press the “Increase” and “Decrease’’ buttons to check each record. To delete a record, press the “SET’ control for three seconds.



To check and delete accumulative records, press the “MODE” control button at the individual records menu to switch to accumulative record menu. Press the “SET” control first, then press the “MODE” control simultaneously for three seconds and all of the records will be deleted, followed by a beeping sound.



Battery Information

Check/Replace Battery

Over time, in order to ensure the functional safety of TENS, changing the battery is necessary. If you suspect the device is not functioning correctly due to a low battery, immediately discontinue use until the battery has been replaced.

1. Make sure that both intensity controls are switched to the off position.
2. Slide the battery compartment cover and open.
3. Remove the battery from the compartment.
4. Insert a new battery into the compartment. Note the polarity indicated on the battery and in the compartment.
5. Replace the battery compartment cover and slide to close
6. Discard the old battery in accordance with state and local regulations.

The Direct Supply Direct Choice Digital TENS Device can be used with a rechargeable battery when necessary. If you use rechargeable batteries, please follow the instructions accompanying the batteries.

NOTE: Rechargeable batteries are not included.

Prior to the use of a new unit, the rechargeable battery should be charged according to the battery manufacturer's instructions. Before using the battery charger, read all instructions and cautionary markings on the battery and in this Owner's Manual. After being stored for 60 days or more, the batteries may lose their charge. After long periods of storage, batteries should be charged prior to use.

Care and Maintenance

Always verify the device is properly functioning before use. Use a non-flammable cleaning solution to clean the device. Stains and spots can be removed with a mild cleaning solution. When transporting the device, use the padded carrying case to keep the device protected. If the device is not to be used for a long period of time, remove the battery and place the device and accessories in the carrying case and store in a cool, dry place. The device should be stored or transported in a temperature range of 0°-140°F, relative humidity between 20% and 95%, and an atmospheric pressure range of 375-795 mmHg.

⚠ **WARNING**: Do not submerge the device in liquids or expose it to large amounts of water.

Troubleshooting & Conformity to Safety Standards

Troubleshooting

Should any malfunctions occur while using your Digital TENS Device, check the following:

1. Whether the switch/control is set to the appropriate form of therapy. Adjust the control correctly.
2. Whether the cable is correctly connected to the device. The cables should be inserted completely into the sockets.
3. Whether the LCD display is functioning. If necessary, insert a new battery.
4. For possible damage to the cables. Replace the cable if any damage is detected.

Should you have any issues with your Direct Supply Direct Choice Digital TENS Device, immediately discontinue use of the device and contact your Direct Supply Equipment & Furnishings account manager.

⚠ **WARNING**: Do not try to repair your device.

Conformity to Safety Standards

This Digital TENS Device is in compliance with the EN 60601-1-2:2007 and EN 60601-1:1990+A1:1993+A2:1995 safety standards.

Limited Warranty

We, Direct Supply Manufacturing, Inc. offer to you, as the original purchaser, a warranty for the Direct Supply Direct Choice Digital TENS Device. Our warranty applies for the limited warranty period stated below. If any device or device part listed below is defective in material or workmanship during the applicable limited warranty period, we will repair or replace it at our cost. Please note that the decision to repair or replace a device or device part will be at our discretion.

Our warranty applies only if the device is properly maintained by the original purchaser for normal, indoor use and does not cover normal wear and tear, modification of the product, or damage caused by abuse, improper use, failure to maintain, use which exceeds the published device limitations, or the combination of any device with another device. In addition, our warranty does not cover fading, colorfastness, stains, spills or exposure to chemicals, odors, heat or light. In certain cases, we may provide you repair or adjustment instructions and/or replacement parts, and ask you to perform a repair or adjustment or replace a defective part.

Our warranty gives you specific legal rights, and you may also have other rights, which vary, from state to state. Please note that our limited warranty period begins when we ship the product to you. The limited warranty period and our obligations under the warranty end once you transfer the product to someone else, or at the end of the applicable limited warranty period identified below, whichever is earlier.

	Warranty Period (Parts)	Anticipated Usable Device Life
Direct Supply Direct Choice Digital TENS Device	2 years	2 years
Accessories (cables, electrodes)	60 days	60 days

Anticipated Usable Device Life is based on normal use with proper maintenance, cleaning and storage. You should still inspect, monitor and care for the device as described in this guide, as the device may need to be replaced sooner than anticipated in particular situations.

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1-800-634-7328 ▪ directsupply.com

Customer Service

Our promise to you is that you will have a convenient and easy ordering experience, receive a quality Direct Supply Direct Choice Digital TENS Device and enjoy outrageous customer service. If you have any questions about the Digital TENS Device you have purchased or would like to request warranty service, please contact:

Direct Supply Equipment & Furnishings
at 1-800-634-7328, 6767 North Industrial Road, Milwaukee, WI 53223, deardirect@directsupply.net.

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