

# **User Manual**

# **Dual Channel TENS**

Prescription Strength Pain Relief

- Quick and Easy Set-Up
- 20 Minute Treatment Timer
- 12 Preset Modes
- 100 Intensity Levels
- Treatment Record Log
- Auto Shut-Off



This manual is valid for the InTENSity at Home™ Dual Channel TENS E200-6R.

This instruction manual is published by Compass Health Brands Corp.

Compass Health Brands reserves the right to improve and amend this manual at any time without prior notice. Amendments may however be published in new editions of this manual.

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#### Please Note:

Compass Health Brands recommends consulting a physician before using a TENS unit to verify any possible contraindications.

Conformity to safety standards.

Compass Health Brands declares that the device complies with the following normative documents:

IEC60601-1, IEC60601-1-2, I EC60601-2-10, IEC62366, IEC60601-1-11, ISO10993-5, ISO10993-10, ISO10993-1, ISO7010

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#### INTRODUCTION

Thank you for purchasing the InTENSity at Home™ Dual Channel TENS (Model E200-6R) for your pain relief solution.

Please read the complete manual carefully before using the device for the first time, and keep this instruction manual in a convenient place or store with the device for future reference.

#### What is TENS?

TENS stands for Transcutaneous Electrical Nerve Stimulation. It is a noninvasive, drug-free method of controlling pain. TENS uses tiny electrical impulses sent through the skin to the 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 patients, it is effective in reducing or eliminating the pain, allowing for a return to normal activity.

#### How does TENS work?

Scientific theory suggests that electrical stimulation therapy may work in several ways:

- The gentle electrical pulses move through the skin to nerves nearby the source of pain, shutting out the pain message from ever reaching the brain.
- The gentle electrical pulses increase the production of endorphins, the body's natural pain killer.

# **INTRODUCTION (CONT'D)**

### What conditions can TENS help relieve?

TENS provides pain relief for a number of different pain conditions associated with exercise, normal work and household activities. This product is designed for temporary relief of pain associated with sore and aching muscles in the:

- Neck
- Shoulders
- Waist
- Upper Extremities (arms)

Back

Lower Extremities (legs)



The InTENSity at Home™ Dual Channel TENS should be applied to normal, healthy, clean and dry skin of adult patients.

#### What can I treat?

The InTENSity at Home™ Dual Channel TENS can treat many different types of pain. Refer to diagrams on pages 26 – 28 for the ideal locations to place the electrodes to treat the most common forms of pain. For other areas of pain, place the electrodes on

either side of the pain area. **PLEASE NOTE**: Never place the electrodes on the head, throat, face, heart, chest area, eyes, oral cavity, sexual organs or over the spine or bony premises.

## How long can I use the TENS unit?

You may use the TENS unit no more than 20 minutes a session, up to 2 times per day for each area of your body, or muscles in that region may become exhausted and sore.

**PLEASE NOTE:** The electrodes are designed for temporary use for approximately 10 treatments.

#### Package Contents:

1 x TENS Device

• 4 x "AAA" Batteries

4 x Electrodes

• 2 x Lead Wires

1 x User Manual



It is important that you read all the warning and precautions included in this manual because they are intended to keep you safe, prevent injury and avoid a situation that could result in serious injury and equipment damage.

# SAFETY SYMBOLS USED IN THIS MANUAL



Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.



Indicates a potentially hazardous situation which, if not avoided, could result in serious injury and equipment damage.



Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user, or damage to the device or other property.

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#### DANGER

This stimulator must not be used in combination with the following medical devices:

- Internally transplanted electronic medical devices, such as pacemakers.
- Electronic life-support equipment, such as respirators.
- Electronic medical devices attached to the body, such as electrocardiographs.

Using this stimulator with other electronic medical devices may cause erroneous operation of those devices.



#### WARNING

Consult with your physician before using this device, because the device may cause lethal rhythm disturbances in certain susceptible individuals.

# DO NOT USE THIS DEVICE UNDER THESE CONDITIONS:

- If you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.
- Together with a life-supporting medical electronic device such as an artificial heart, lung or respirator.
- 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.
- If there are any underlying skin conditions (i.e. erythema, psoriasis, eczema, etc.)

- On open wounds or rashes, over swollen, red, infected, inflamed areas, or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins); or on top of, or in proximity to, cancerous lesions.
- Over areas of skin that lack normal sensation.
- On the opposite sides of your head since the effects of stimulation of the brain are unknown.

#### DO NOT USE ON THESE INDIVIDUALS:

- Pregnant women, because the safety of electrical stimulation during pregnancy has not been established.
- Children or infants, because the device has not been evaluated for pediatric use.
- Persons incapable of expressing their thoughts or intentions.

# DO NOT USE THIS DEVICE DURING THESE ACTIVITIES:

- Bathing or showering
- Sleeping
- Driving, operating machinery or any activity in which electrical stimulation can put you at risk for injury.



#### PAIN MANAGEMENT WARNINGS

- If you have had medical or physical treatment for your pain, consult with your physician before using this device.
- If your pain does not improve, becomes seriously chronic or severe, or continues for more than five days, stop using the device and consult with your physician.
- The mere existence of pain functions as a very important warning telling us that something is wrong. Therefore, if you suffer from any serious

illness, consult your physician in order to confirm that it is advisable for you to use this TENS unit.

 Consult a physician if you are on any pain medications as they may decrease your normal level of sensation, causing possible adverse reactions not to be felt.



#### WARNING AND PRECAUTIONS REGARDING THE ELECTRODES

- Apply electrodes to normal, healthy, clean, dry skin (of adult patients) because it may otherwise disrupt the healing process.
- If you experience any skin irritation or redness after a session, do not continue stimulation in that area of the skin.



#### NEVER APPLY THE ELECTRODES TO:

The head or any area of the face.



- The neck or any area of the throat because this can cause severe muscle spasms resulting in closure of the airway, difficulty breathing, or adverse effects on heart rhythm or blood pressure.
- Both sides of the thorax simultaneously (lateral or front and back), or across your chest because the introduction of electrical current may cause rhythm disturbances, which could be lethal.



# WARNING AND PRECAUTIONS REGARDING THE ELECTRODE

- Do not bend or fold because the electrode may not function properly. Place the electrode onto the plastic film and then store in the sealed container when not in use.
- Do not apply ointment or any solvent to the electrodes or to your skin because it will keep the electrode from functioning properly.

- The electrode is already pre-gelled and will adhere to your skin.
- To avoid damage to the adhesive surface of the electrode, put the electrodes only on the skin or on the plastic film provided.
- Place electrodes anywhere from 2"-6" apart from each other on your skin.
- Always place clean electrodes in accordance with the illustrations provided (Refer to pages 26 – 28 for electrode placement).

#### DO NOT USE YOUR ELECTRODES THIS WAY:

- Do not place on your spine or backbone.
- Electrodes should not touch any metal object, such as a belt buckle, necklace or other jewelry made from metal.

#### DO NOT USE YOUR ELECTRODES THIS WAY (CONT'D)

- Do not share electrodes with another person. This may cause a skin irritation or infection. Electrodes are intended for use by one person.
- Do not place or relocate the electrodes while the device is on.
- Always turn the power off before removing or changing the electrode location.
- Do not leave electrodes attached to the skin after treatment.
- Electrodes should not be placed on the soles of both feet at the same time.
- Electrodes should not be placed on the calves of both legs at the same time.

# 1 CAUTION WHILE USING THE TENS UNIT

• If the TENS unit is not functioning properly or you feel discomfort, immediately stop using the device.

- Do not use for any other purpose except as described in this manual.
- Do not insert the electrode plug into any place other than the output socket on the main unit.
- Do not mix Alkaline and Manganese batteries as this will shorten the battery life.
- Do not pull on the electrode cord during treatment.
- Do not use the TENS device while wearing electronic devices such as watches as this may damage the device.
- Do not use near a cell phone as this may cause the stimulator to malfunction.
- Do not bend or pull the end of the cord.
- When pulling out the cord from the device, hold the plug and pull.
- Replace the cord when broken or damaged.

- Do not throw the batteries into a fire. The batteries may explode.
- Dispose of the device and components according to applicable legal regulations. Unlawful disposal may cause environmental pollution.
- Using electrodes that are too small or incorrectly applied, could result in discomfort or skin burns.
- Always use electrodes that are legally marked and sold in the United States for over-the-counter (OTC) use only (InTENSity at Home™ Electrodes – E201-6R).

#### **GENERAL PRECAUTIONS**

- The long-term effects of electrical stimulation are unknown.
- Apply stimulation to only normal, intact, clean, dry, and healthy skin.
- TENS is not effective in treating the original source or cause of the pain, including headache.

- TENS is not a substitute for pain medications and other pain management therapies.
- TENS devices do not cure diseases or injuries.
- TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
- Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients.
- You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel) on the electrodes.
- If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician.
- If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your physician.

## **GENERAL PRECAUTIONS (CONT'D)**

- Use caution if you have a tendency to bleed internally, such as following an injury or fracture.
- Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process.
- This stimulation should not be applied over the menstruating or pregnant uterus.
- This stimulation should not be applied over areas of skin that lack normal sensation.
- Keep unit away from young children.
  The unit contains small pieces that may
  be swallowed. Contact your physician
  immediately if ingested.
- Use this device only with the InTENSity at Home<sup>™</sup> brand electrodes (E201-6R).

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### POSSIBLE ADVERSE REACTIONS

- Do not use the device to treat one region for extended periods of time (more than 20 minutes a session, up to 2 times/day) or muscles in that region may become exhausted and sore.
- You may experience skin irritation and burns beneath the stimulation electrodes applied to your skin.
- You should stop using the device and consult with your physician if you experience adverse reactions from using the device.

### **PACKAGE CONTENTS**



E200-6R Unit



(2) Lead Wires



(4) "AAA" Batteries

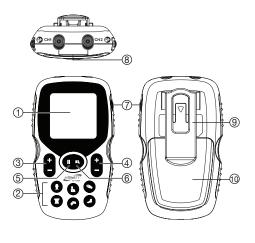


Instruction Manual



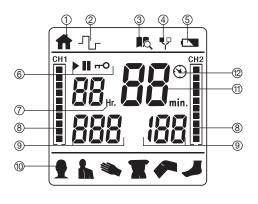
(4) 2" x 2" Electrodes

#### **KNOW YOUR DEVICE**



- 1. LCD Display: Operating state of the device
- **2. Program Buttons:** Select body part and treatment program.
- 3. CH 1 Output Intensity: Increase or decrease channel 1 intensity.
- **4. CH 2 Output Intensity:** Increase or decrease channel 2 intensity.
- 5. Pause Button: Pause/resumes treatment.
- Treatment Records: To check treatment records and usage history.
- 7. Power: Press to turn on the device. Press and hold for 3 seconds to turn off the device.
- 8. Output Sockets: Lead wire output sockets
- 9. Belt Clip
- 10. Battery Cover

# **KNOW YOUR DEVICE (CONT'D)**

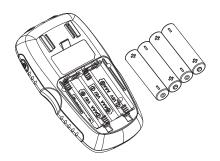


- 1. Home
- 2. Treatment Mode
- 3. Treatment Records
- Electrode Load Indicator: Alerts user of a bad connection between the lead wires, electrodes and skin.
- 5. Low-Battery Indicator
- 6. Output Display: Start, pause or lock
- 7. Hour Indicator: For treatment records only
- 8. Channel Intensity: Graphic display (CH1 & CH2)
- 9. Channel Intensity: Numeric display (CH1 & CH2)
- 10. Therapeutic Body Part: Displays selection
- Treatment Time: Displays time remaining for selected treatment.
- <u>Timer Indicator:</u> Will blink while treatment is in progress and stay solid when paused or stopped.

#### **BATTERY INFORMATION**

#### Check/Replace the battery

- Remove the belt clip and battery cover
- Insert 4 "AAA" batteries, as shown.
- · Replace the battery cover and belt clip.





#### **DISPOSAL OF BATTERIES**

Depleted batteries do not belong in the household waste. Dispose of the batteries according to your federal, state and local regulations. As a consumer, you are obligated by law to properly dispose depleted batteries.





### ?\ CAUTION

- Keep the batteries and TENS unit out of the reach of children.
- Do not dismantle, throw into fire or short-circuit batteries.
- Do not expose the batteries to excess heat.
- Remove the batteries from the TENS unit if it is not going to be used for a long period of time.
- Always replace with the same type of battery.

#### TREATMENT SETUP

## Step 1 Cleaning the Skin

Olip excess hair from the treatment area. Wash area with soap and water, and dry completely.

# Step 2 Connect Electrodes to Lead Wires

Take the electrodes out of the sealed package and insert the pin end of the lead wire into each pigtail connection of the electrodes you plan to use. Make sure there is no bare metal exposed from the pins.



**NOTE:** You must use at least 2 electrode pads.

# Step 3 Connect Lead Wires to the Device

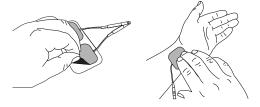
- 1. Make sure the device is turned OFF.
- Holding the insulated portion, push the plug end of the lead wire into CH1 output socket. If using all 4 electrodes, repeat for CH2.



**NOTE:** This device has two output sockets called channels. You may use one or both channels with a pair of lead wires on each. Using both channels gives you the advantage of stimulating two different areas at the same time. If using just one channel, only connect to CH1 and leave CH2 empty.

#### Step 4 Electrode Placement

- Ensure skin is clean and thoroughly dry before applying the electrodes.
- Remove the electrodes from the plastic film and position them on your body — pressing firmly to ensure good contact.





#### WARNING

Before using the device for the first time, you are strongly advised to take careful note of the contraindications and safety measures detailed on pages 6-12 of this manual. This is a powerful piece of equipment and is neither a toy nor a gadget!

**Note:** Electrode placement suggestions can be found on pages 26 –28.

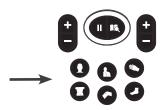
#### Step 5 Turn the Power On

- 1. Press the "🔥" button on the top right side to turn the unit on. This will be indicated by the LED screen lighting up blue and an audible quick chirp sound.
- 2. The device will not start treatment until a channel intensity is increased.



# Step 6 Select the Therapeutic Body Part and Program

- There are 6 therapeutic body part buttons available: neck, shoulder, hand, low back, knee and foot.
- Each therapeutic body part has 2 programs (12 total programs) — P1 and P2. You can toggle between them by pressing the body part button repeatedly.
- 3. P1 is for acute pain and P2 is for chronic pain.



Body Part	Program	Treatment Time	Frequency	Pulse Width	Cycle Time
	P1	20 Min.	80 – 100Hz	100 – 150μs	10 Sec
Neck	P2	20 Min.	4Hz	150 – 200µs	20 Sec
2	P1	20 Min.	80 – 100Hz	100μs	10 Sec
Shoulder	P2	20 Min.	10Hz	220 – 260µs	20 Sec
***	P1	20 Min.	100Hz	100µs	Fixed
Hand	P2	20 Min.	1 – 10Hz	150µs	20 Sec

Body Part	Program	Treatment Time	Frequency	Pulse Width	Cycle Time
	P1	20 Min.	80 – 100Hz	120µs	10 Sec
Low back	P2	20 Min.	4Hz	200 – 260µs	20 Sec
	P1	20 Min.	120Hz	100 - 120μs	10 Sec
Knee	P2	20 Min.	1 – 10Hz	150 – 200µs	20 Sec
	P1	20 Min.	80 – 120Hz	100 – 120µs	10 Sec
Foot	P2	20 Min.	1 – 10Hz	200µs	20 Sec

# **Step 7 Adjust Intensity and Start Treatment**

- 1. To start treatment, press [CH1+] or [CH2+].
- The intensity output will start at 1. Repeatedly press the [CH1+] or [CH2+] buttons to increase the output intensity to the desired level.
- Press [CH1-] or [CH2-] to decrease the output intensity.



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### CAUTION

- If the electrodes are not placed firmly on the skin or the device is not connected to the electrodes and the output intensity level is equal to 10mA or greater, the intensity will stop automatically.
- If the stimulation levels are uncomfortable or become uncomfortable, reduce the stimulation intensity to a comfortable level and contact your medical practitioner if problems persist.

# Step 8 Pause or Stop Treatment

- In case of an emergency or the need to stop treatment immediately, please press the [ II ] button to pause treatment, the "II" will display on the LCD screen.



# Step 9 Treatment Timer

- 1. All 12 presets are set to a 20 minute timer.
- When the timer counts all the way down to zero, the device will stop and return to the home screen.

## Step 10 Turn the Power Off

- 1. Press and hold the [b] button for 3 seconds.
- 2. When the screen turns off then the devise is off.



To conserve battery and prevent unexpected shock, the device will automatically power off when it is not in use for three (3) minutes (standby mode). The device will beep and shut off automatically.

#### PLEASE NOTE:

- Be sure not to move the electrode to another part of your body without turning off the power first.
- Keep the electrodes clean and do not expose to heat or direct sunlight.
- If the electrodes do not adhere to your body or are dirty, replace with a new electrode (item# E201-6R).
- Always use the electrodes with a CE mark, or which are legally marketed in the US under 510(K) procedure.
- Do not clean the electrode or adhesive gel with any chemical.
- Place the electrodes on intact skin only. Do not place on cuts or damaged skin.
- The InTENSity at Home<sup>™</sup> Dual Channel TENS is for single person use.
- Place the electrode on the protective transparent film when not in use.

## OTHER IMPORTANT FUNCTIONS

#### Safety Lock

 The lock function automatically activates after there is no operation for 20 seconds in treatment status, the indicator "→0" display on LCD. This is a safety feature to prevent accidental changes to your settings and to prevent accidental increases to the output intensity level. Press [CH1-] or [CH2-] button to unlock.







### Low Battery Indicator

 When the low power indicator "\sum" flashes on the LCD, you should replace all four (4) "AAA" batteries with new ones as soon as possible.

# OTHER IMPORTANT FUNCTIONS (CONT'D)

#### **Treatment Record Log**

- The treatment record log can store up to 60 treatments.
- The treatment record log can store up to 100 hours of total usage.

#### Check and Delete Individual Records

While on the home screen, press the [ ]
 button to enter the treatment record log. The LCD
 will show each of the records and corresponding
 treatment times. Press [ + ] and [ - ] buttons to
 cycle through each record.

#### **Check and Delete Accumulative Records**

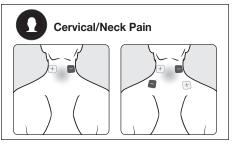
- While in the individual records menu, press the [ ] button to switch to accumulative records menu.

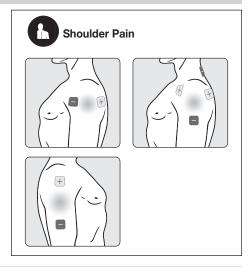
# **CAUTION**

The records will be permanently deleted and can not be restored if you complete the deletion process.

### **ELECTRODE PLACEMENT GUIDE**

- Apply electrodes around the pain site as indicated and keep them at least 2" but no more than 6" apart.
- · The skin must be clean and dry.
- Press on firmly, making good contact between the skin and the electrodes.
- Never remove electrodes from the skin while the device is turned on.





# **ELECTRODE PLACEMENT GUIDE (CONT'D)**

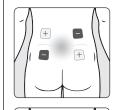


# Carpal Tunnel/ Wrist Pain





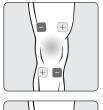








# **Knee/Elbow Pain**









# **ELECTRODE PLACEMENT GUIDE (CONT'D)**



# Foot/Calf Pain











Caution:
Do not stimulate both feet or calves simultaneously.

#### **CLEANING AND STORAGE**

### Cleaning the Unit

- Turn unit off and disconnect the lead wires from the unit.
- 2. Clean the device after use with a soft, slightly moistened cloth and wipe gently.
  - Do not use chemicals (like thinner, benzene).
  - Do not let water get into the internal area.

**NOTE:** This device and accessories (including the electrodes) do not require sterilization.

### Cleaning the Electrode Pads

- Turn the power off and remove the lead wires from the electrodes.
- Wash the electrodes when the adhesive surface becomes dirty and/or the electrodes are difficult to attach to the skin.

#### Washing the Electrode Pads

 To "wash" the electrodes, place a small drop of water on your clean fingertip and rub the water across the entire gel surface. Place the gel adhesive face up and let it air dry until the water is absorbed and has been reconstituted. Do not wipe with a tissue paper or cloth. If the electrode still does not stick properly, replace them with new electrodes (E201-6R).

# **CLEANING AND STORAGE (CONT'D)**

# **!** CAUTION

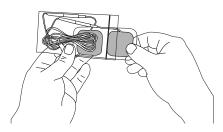
- The life of electrodes may vary by the frequency of washing, skin condition, and storage state.
- If the electrodes no longer stick to your skin or the electrodes are broken, you should replace with new electrodes.
- Before applying the self-adhesive electrodes, it is recommended to wash and degrease the skin, and then dry it.
- Do not turn on the device when the electrodes are not positioned on the body.
- Never remove the self-adhesive electrodes from the skin while the device is still turned on.

- If replacement electrodes are necessary, use only electrodes that are the same size (2" x 2") as the electrodes provided with the TENS.
- Use of electrodes that are larger, may reduce the effect of the stimulation. Use of electrodes that are much smaller than the electrodes provided with the TENS may increase the chance of skin irritation or burns occurring under the electrodes.
- Always use the electrodes with a CE mark, or which are legally marketed in the US under 510(K) procedure.

## **CLEANING AND STORAGE (CONT'D)**

#### Storing the Electrode Pads and Lead Wires

- Turn the device off and remove the lead wires from the unit.
- 2. Remove the electrodes from your body and disconnect the lead wires from the TENS unit.
- Place the electrodes onto the plastic film and then store them and the lead wires in the sealed package.



#### Storing the Unit

- Place the unit, electrodes, lead wires and manual back into the retail packaging. Store the box in a cool, dry place, 14°F ~ 122°F; 10% ~ 90% relative humidity.
- Do not store in places that can be easily reached by children.
- 3. When not in use for a long period of time, remove the batteries before storage.

#### **TECHNICAL INFORMATION**

Channel	Dual, isolated between channels	
Power Supply	(4) "AAA" Batteries	
Operating Conditions	10°C ~ 50°C (50°F to 122°F) Relative Humidity: 10% – 90% Atmospheric Pressure: 700 – 1060 Hpa	
Storage Conditions	-10°C ~ 50°C (14°F to 122°F) Relative Humidity: 10% – 90% Atmospheric Pressure: 700 – 1060 Hpa	
Dimensions	12.0×7.0×2.7cm (4.7"x2.8"x1.1") L*W*H	
Weight	100g (3.5 oz.) Without Battery	
Electrode Detection Function	The amplitude level will reset to 0mA when the amplitude level is 10mA or greater and an open circuit on either channel is detected.	

## **TECHNICAL SPECIFICATIONS**

Waveform	Symmetrical Biphasic
	Rectangular Wave
Pulse Amplitude	Adjustable, 0 ~ 100mA @ 1,000 ohm Load each channel, 1mA/Step.
Pulse Width	100μs ~ 260μs
Pulse Rate	1Hz ~ 120Hz
Treatment Time	20 Minutes

**NOTE:** If the unit does not operate after taking these measures, contact your nearest dealer.

### **TROUBLESHOOTING**

PROBLEM	POSSIBLE CAUSES	POSSIBLE SOLUTION
The Unit Cannot	Are the batteries depleted?	Recharge or replace the batteries.
Power On	Are the batteries installed correctly?	Insert the batteries observing the correct polarity.
	Electrodes are dried out or dirty.	Replace with new electrodes.
Stimulation Weak Or Cannot Feel Any Stimulation	Electrodes will not stick to skin.	Clean treatment area of dirt and/or oily substances (lotion).
,	Lead wires are old/worn/damaged	Replace with new lead wires.
	Intensity is too high.	Decrease intensity.
Stimulation Is	Electrodes are too close together	Reposition the electrodes to be a minimum of 1½" apart.
Uncomfortable	Electrode active area size is too small	Replace electrodes with ones that have an active area no less than 25.0cm² (5cm x 5cm).
	May not be operating the device according to the manual.	Please check the manual before use.

**NOTE:** If the unit does not operate after taking these measures, contact your nearest dealer.

# **CLEANING AND STORAGE (CONT'D)**

PROBLEM	POSSIBLE CAUSES	POSSIBLE SOLUTION
		Verify connection is secure.
		Turn down the intensity.
Intermittent Output	Lead Wires	Rotate lead wire in the socket 90°. If still intermittent, replace the lead wire.
		If still intermittent after replacing a lead wire, a component may have failed. Call tech support at 1-800-3-ROSCOE (376-7263).
Stimulation is	Improper electrode placement	Reposition electrodes.
Ineffective	Unknown	Contact tech support at 1-800-3-ROSCOE (376-7263)
Skin Becomes Red And/Or You	Using the electrode on the same site every time.	Re-position the electrode to another area. If at any time you feel pain or discomfort stop use immediately.
Feel A Stabbing Pain	The electrode is not sticking onto the skin properly.	Ensure the electrode is securely placed on the skin.

 $\ensuremath{\text{NOTE:}}$  If the unit does not operate after taking these measures, contact your nearest dealer. 34

# TROUBLESHOOTING (CONT'D)

PROBLEM	POSSIBLE CAUSES	POSSIBLE SOLUTION
Skin Becomes Red And/Or You	The electrode is dirty.	Clean the electrodes according to the description in this manual (page 29) or replace with new electrodes.
Feel A Stabbing Pain	The surface of the electrode is scratched.	Replace with a new electrode.
	If problems persist.	Contact your physician.
Output Current	The electrode came off the skin or the edges are lifting away from the skin.	Turn off the device and reapply the electrodes to your skin.
Stops During Therapy	The lead wires are disconnected.	Turn off the device and reconnect the lead wires.
	The batteries are depleted.	Charge or replace the batteries.

**NOTE:** If the unit does not operate after taking these measures, contact your nearest dealer.

#### DISPOSAL

Used fully discharged batteries must be disposed of in a specially labeled collection container, at toxic waste collection points or through an electrical retailer. You are under legal obligation to dispose of batteries correctly.

Please dispose of the device in accordance with the legal obligation.

### **GLOSSARY OF SYMBOLS**



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



Please refer to instruction manual because of the higher levels of output.

#### IMPORTANT INFORMATION REGARDING ELECTROMAGNETIC COMPATIBILITY (EMC)

With the increased number of electronic devices such as computers and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation. Medical devices should also not interfere with other devices.

In order to regulate the requirements for EMC (Electromagnetic Compatibility) with the aim to prevent unsafe product situations, the IEC60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.

Medical devices manufactured for Compass Health Brands conform to this IEC60601-1-2:2007 standard for both immunity and emissions. Nevertheless, special precautions need to be observed:

- The use of accessories and cables other than those specified by Compass Health Brands, with the exception of cables sold by Compass Health Brands as replacement parts, may result in increased emission or decreased immunity of the device.
- The medical devices should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the medical device should be observed to verify normal operation in the configuration in which it will be used.
- Refer to further guidance below regarding the EMC environment in which the device should be used.

#### TABLE 1:

#### **GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS**

InTENSity at Home™ electrical stimulators are intended for use in the electromagnetic environment specified below. The customer or the user of these electrical stimulators should assure that it is used in such 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 CISPR11	Class 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	
Harmonic emissions IEC 61000-3-2	Not applicable	buildings used for domestic purposes.	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable		

#### TABLE 2:

#### GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY

InTENSity at Home™ electrical stimulators are intended for use in the electromagnetic environment specified below. The customer or the user of these electrical stimulators should assure that it is used in such environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	Not applicable	Not applicable	Not applicable
Surge IEC 61000-4-5	Not applicable	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable	Not applicable
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.

#### TABLE 4:

#### GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY

InTENSity at Home™ electrical stimulators are intended for use in the electromagnetic environment specified below. The customer or the user of these electrical stimulators should assure that it is used in such environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	Not applicable		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
			d = 1.2 $\sqrt{P}$ d = 1.2 $\sqrt{P}$ 80 MHz to 800 MHz d = 2.3 $\sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3 3 V/m 80 MHz to 2.5 GHz 3 V/m	3 V/m	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.	
		Interference may occur in the vicinity of equipment marked with the following symbol:	

#### TABLE 4 (CONT'D):

NOTE I: At 80 MHz ends 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 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.

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

#### TABLE 6:

# 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) and as recommended below, according to the maximum output power of the communications equipment.

Output Power of Transmitter in Watt	Separation Distance According To Frequency Of Transmitter In Meter		
	150 kHz to 80 MHz d = 1.2 √P	80 MHz to 800 MHz d = 1.2 √P	800 MHz to 2.5 GHz d = 2.3 √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

#### TABLE 6 (CONT'D):

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (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 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.

NOTE: EMC tests conducted including attached electrode cord of 1.5 m length.

#### LIMITED ONE YEAR WARRANTY

Limited Consumer Product Warranty (United States)

This InTENSity at Home<sup>™</sup> Dual Channel TENS is warranted to the original consumer "the purchaser" to be free from defects in material and workmanship which are not commercially acceptable for the period of one year from the date of purchase. Warranty coverage terminates if you sell or otherwise transfer this product to another person. This warranty gives you specific legal rights and you may also have other rights, which vary by location.

COMPASS HEALTH BRANDS MAKES NO EXPRESS WARRANTY OF ANY KIND REGARDING THIS PRODUCT OTHER THAN THOSE WARRANTIES SET FORTH HEREIN. ANY IMPLIED WARRANTY, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE TO THE EXTENT PERMITTED BY LAW, SHALL BE LIMITED IN DURATION TO A PERIOD OF 120 DAYS FROM THE DATE OF PURCHASE BY THE ORIGINAL PURCHASER.

In the event that this product is found by Compass Health Brands to not meet the above limited warranty, as purchaser's sole and exclusive remedy, Compass Health Brands will repair or at the option of Compass Health Brands, replace this product without charge for such replacement parts or labor. The purchaser shall bear all expenses related to returning this product to Compass Health Brands

This warranty does not apply to any part of the product that has been subject to misuse, abuse, or alteration. Improper or incorrectly performed maintenance or repair voids this warranty. The warranty applies to the device only, accessories are not included in warranty.

TO THE EXTENT PERMITTED BY LAW, COMPASS HEALTH BRANDS SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES INCLUDING, BUT NOT LIMITED TO, REPLACEMENT COSTS RESULTING FROM THE BREACH OF ANY WRITTEN OR IMPLIED WARRANTY.

# LIMITED ONE YEAR WARRANTY (CONT'D)

If you wish to make a claim under this warranty, please contact your local DME dealer/retailer where you purchased the unit from. You will need the following information when making your claim:

- The entire original InTENSity at Home™ product and packaging
- · The original receipt showing date of purchase
- Detailed description of the problem
- Serial Number

TENSity at Home™ Model: _	
erial Number:	
ate of Purchase:	
istributor:	

Manufactured for:

# **C**(\*)**MPASS**HEALTH

Middleburg Heights, OH, 44130 800.376.7263

compass health brands.com

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