AccuRelief™

Single Channel TENS

Natural, drug-free pain relief

Target-specific pain relief.

SAFE AND EFFECTIVE
Clinically Proven
PAIN RELIEF

User Manual

Model ACRL-2000

This manual is valid for the AccuRelief™ Single Channel TENS Pain Reliever ACRL-2000.

This instruction manual is published by Carex Health Brands.

Carex 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.

Conformity to safety standards

Carex 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

TABLE OF CONTENTS

INTRODUCTION

Thank you for purchasing the AccuRelief™ Single Channel TENS unit (Model ACRL-2000) for your pain relief solution.

In order to use the stimulator safely, read the complete manual carefully before using the device for the first time.

Keep this instruction manual in a convenient place, or store with the device for future reference.

The AccuRelief™ Single Channel TENS unit is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. It should be applied to normal, healthy, clean and dry skin of adult patients.

Standard Parts

The package contains the following components:

No.	DESCRIPTION	QUANTITY
A	Single Channel TENS Stimulator ACRL-2000	1PC
B	Electrode pads (2 in. × 2 in.)	4PCS
C	Lead wire	1PC
D	Instruction manual	1PC
E	Quick start guide	1PC
F	Electrode placement guide	1PC
G	AAA Batteries	2PC

IMPORTANT SAFETY PRECAUTIONS AND WARNINGS

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 damage to the device.

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.

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, active 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.
- 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.

WARNINGS AND PRECAUTIONS REGARDING THE PADS

- Apply pads 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 on that area of the skin.

NEVER APPLY THE PADS TO:

- The head or any area of the face.
- 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.

CAUTION

WARNINGS AND PRECAUTIONS REGARDING THE PADS

- Do not bend or fold because the pad may not function properly. Place the pads onto the plastic film and then store in the sealed package when not in use.
- Do not apply ointment or any solvent to the pads or to your skin because it will keep the pads from functioning properly.
- The pads are already pre-gelled and will adhere to your skin.
- To avoid damage to the adhesive surface of the pads, put the pads only on the skin or on the plastic film provided.
- Place pads at least 2 inches apart on your skin. The pads should never touch each other.
- Always place clean pads in accordance with the illustrations provided (Refer to pages 18 and 19 for electrode placement).
- Make sure the components are connected well and the pads are fixed on the part of the body you wish to treat or the therapy may not be effective.

DO NOT USE YOUR PADS THIS WAY:

- Pads should not touch each other when placed onto your skin.
- Do not place on your spine or backbone.
- Pads should not touch any metal object, such as a belt buckle, necklace or other jewelry made from metal.
- Pads should not be placed simultaneously on the soles of both feet.
- Pads should not be placed simultaneously on the calves of both legs.
- Do not share pads with another person. This may cause a skin irritation or infection. Pads are intended for use by one person.
- Do not place or relocate the pads while the device is on.

- Always turn the power off before removing or changing the pad location.
- Do not leave pads attached to the skin after treatment.

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 jack on the main TENS 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 TENS unit to malfunction.
- Do not bend or pull the end of the cord.
- When removing the cord from the device, hold the plug and pull.
- Replace the cord when broken or damaged.
- The size, shape and type of pads may affect the safety and effectiveness of electrical stimulation.
- The electrical performance characteristics of the pads may affect the safety and effectiveness of electrical stimulation.
- Using pads that are too small or incorrectly applied, could result in discomfort or skin burns.
- Do not throw the batteries into a fire. The batteries may explode.
- Dispose of the device, batteries, and components according to applicable legal regulations. Unlawful disposal may cause environmental pollution.

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 disease 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.
- 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.

- For best results use this device with the AccuRelief™ brand electrodes and lead wires.

- Keep unit out of the reach of young children. The electrode cord can cause strangulation.

POSSIBLE ADVERSE REACTIONS

- Do not use device to treat one region for extended periods of time (more than 30 minutes a session, up to 3 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.

HOW TENS WORKS FOR PAIN RELIEF

What is it?

The Single Channel TENS ACRL-2000 is a single output channel TENS machine and is highly effective in relieving pain. TENS is now regularly recommended by doctors, physiotherapists and pharmacists throughout the world.

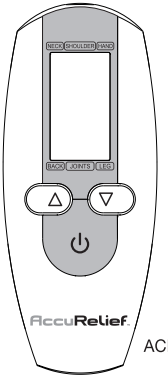
Transcutaneous Electrical Nerve Stimulation (TENS) is a noninvasive, drug-free method of controlling pain. TENS uses tiny electrical impulses sent through the skin to the nerves to modify pain perception. TENS does not cure any physiological problem. It only helps control the pain. TENS does not work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

How TENS works?

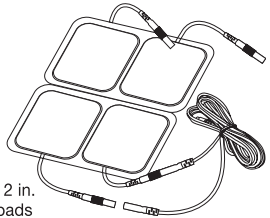
Scientific theory suggests that electrical stimulation therapy may work in several ways:

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

PACKAGE CONTENTS



ACRL-2000 unit

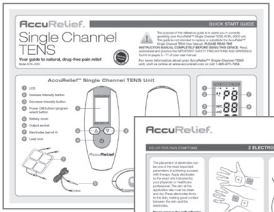


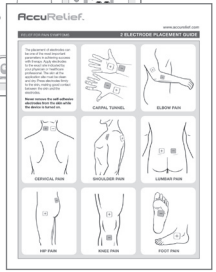
Lead wire
and 2 in. x 2 in.
electrode pads

AAA batteries

Instruction manual

Quick start guide





Electrode placement guide

AccuRelief™

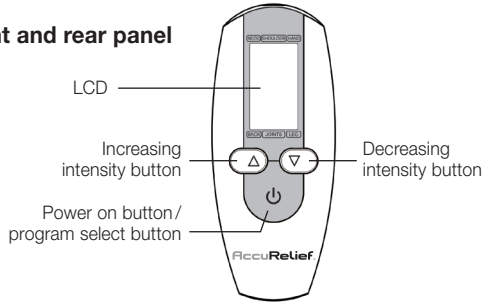
Single Channel TENS

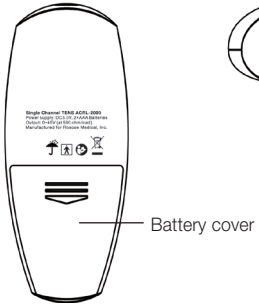
KNOW YOUR DEVICE

Features

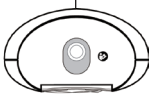
- One output channel TENS stimulator.
- ACRL-2000 offers P1~P6 programs that are suitable for different parts of the body and pain. [Neck, shoulder, hand (hand and wrist), back, joints (elbows and knees) and leg (thigh, calf, ankle and foot).]
- 25 intensity levels of therapy, one (1) low intensity to 25 high intensity.

Front and rear panel



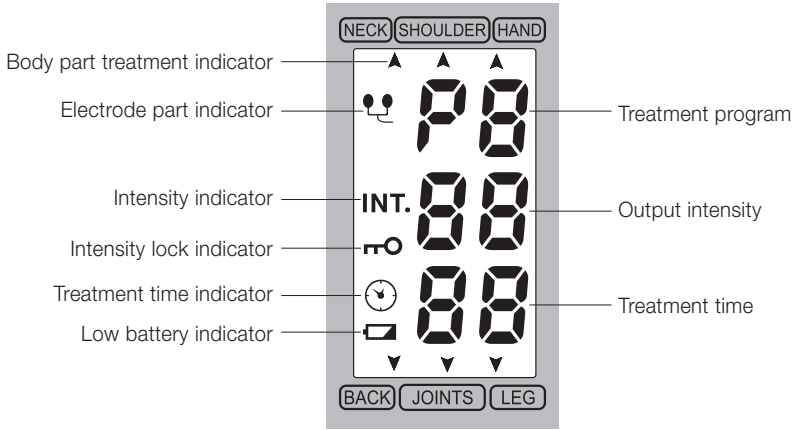


Output socket



Top View

LCD Display

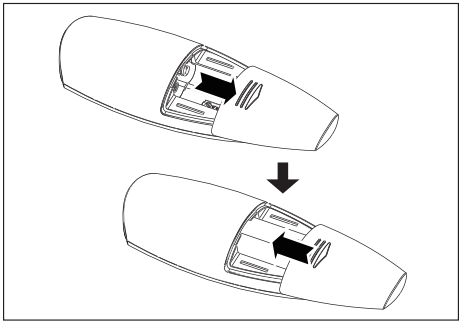

NECK
SHOULDER
HAND
Body part treatment indicator
Electrode part indicator
P 8
Treatment program
Intensity indicator
INT.
8 8
Output intensity
Intensity lock indicator
Treatment time indicator
8 8
Treatment time
Low battery indicator
BACK
JOINTS
LEG

INSERTING BATTERIES

1. Remove the battery cover on the back of the device as shown by the graphic to the right.
2. Insert 2xAAA batteries. Make sure the positive **+** and negative **–** signs correspond with the markings in the device when inserting batteries. Reinstall the battery cover as shown by the graphic to the right.

Notes:

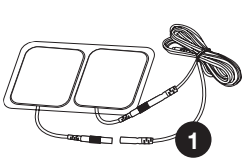
- Please use 2×AAA batteries in this TENS unit.
- Remove the batteries if the device is not in use for long periods of time.
- Do not mix old and new batteries or different types of batteries.
- Warning: If batteries leak and come into contact with the skin or eyes, wash immediately with large amounts of water.



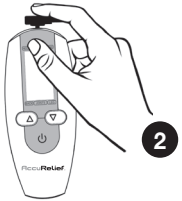
- Batteries must be handled by an adult. Keep batteries out of the reach of children.
- Remove exhausted batteries from the unit.
- Dispose the used batteries safely according to local regulations.

EASY STEPS TO GET STARTED WITH YOUR THERAPY WITH ELECTRODE PADS

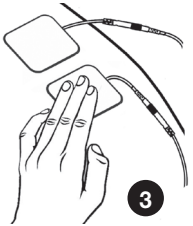
STEP 1
Attach pads to the lead wire
Take the pads out of the sealed package. Insert the lead wire connector into the electrode connector. Make sure there are no bare metal pins exposed.



STEP 2
Insert lead wire into the TENS unit
Hold the lead wire plug and insert it into the socket on the top of the stimulator as shown by the graphic on the right.

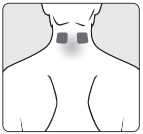


STEP 3
Pad placement
Remove the clear plastic film from the back of the pads. Place pads on clean, dry and healthy skin, near or surrounding the area with pain at least 2 inches apart, and do not let them touch. Make sure there is a linear path between the two pads. (See Pad Placement Guide or refer to the following illustrations on pages 18 and 19).



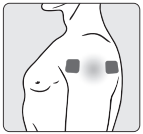
WARNING: Make sure the device is turned off or the intensities are set to zero (0) levels before placing pads on skin.

Never remove the self-adhesive electrodes from the skin while the device is turned on.



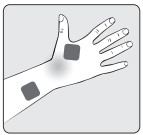
NECK / CERVICAL PAIN

Attach both pads on the neck. (Do not place on the carotid artery or throat.)



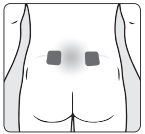
SHOULDER PAIN

Attach one pad in front and one in back of the muscle.



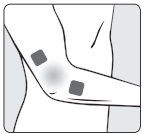
CARPAL TUNNEL / HAND PAIN

Attach both pads on the hand where you feel pain.



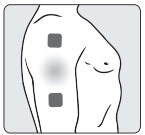
LOWER BACK

Attach both pads on the lower back with the backbone in the center. **Do not place on the backbone or spine.**



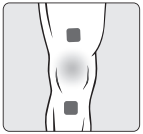
ELBOW PAIN

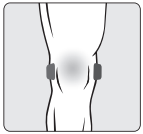
Attach both pads on either side of the joint with the pain.



UPPER ARM PAIN

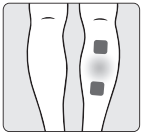
Attach both pads on either side of the region where you feel pain.

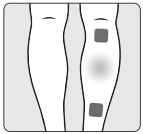




KNEE / JOINT PAIN

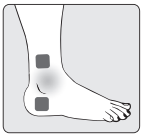
Attach both pads above the knee or above and below the joint with pain.

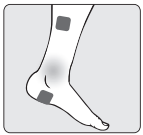




CALF PAIN

Attach both pads on the calf/leg where you feel pain. **Do not place electrode pads simultaneously to the calves of both legs.**

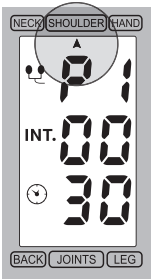




ANKLE / FOOT PAIN

Attach pads per the illustration on the left for pain on the outside of your ankle/foot. Attach the pads per the illustration on the right for pain on the inside of your ankle/foot. Do not place electrode pads simultaneously to the soles of both feet.

STEP 4
Turn on the device
Press the ⏻ button to turn on the device. The following screen will appear:

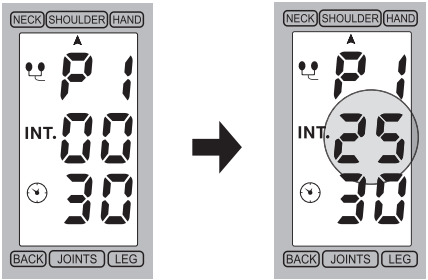


STEP 5
Select the therapy program
The AccuRelief™ Single Channel TENS device offers P1~P6 programs for you to select. Different programs suit different parts of the body. Please refer to page 22 for detailed program information and to page 26 for specific applications (Practical recommendations).

Press the ⏻ button cycle to select program P1~ P6. The ▲ indicator will point to the corresponding body part treatment.

STEP 6
Start treatment and adjust intensity
Press ▲ button to start treatment.

Press ▲ or ▼ button to adjust the output intensity. The stimulator will start to work. The maximum output intensity level is 25.



Note: If you switch programs during treatment, the device automatically resets the intensity to zero (0) and the treatment time to 30 minutes.

CAUTION:

- If the electrodes are not placed firmly on skin, or the device has not connected with the electrodes, and the output intensity level is over 5, 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.
- If your pain does not improve and you become sore from over-use, refrain from treating those areas for two (2) days. If this issue reoccurs, reduce the treatment time and intensity settings for future treatment.
- If you feel pain, dizziness, discomfort or nausea, call your physician or medical practitioner.
- Caution should be used when working with maximum intensities, (i.e., always at the limit of what you can support.) Do not exceed your comfort level.

STEP 7
Turn off the device

Press the ⏻ button and hold for five (5) seconds to turn off the device. If there is no operation in the panel for two (2) minutes in the waiting state, the device will turn off automatically.

OTHER IMPORTANT FUNCTIONS IN THIS STIMULATOR

Safety Lock Feature

The lock function automatically activates after there is no operation in the panel for 30 seconds, and will be indicated by the display on the LCD. This is a safety feature to prevent accidental changes to your settings and to prevent accidental increases the output intensity level. Press ▼ button to unlock.

Low battery indicator

When the low power indicator flashes on LCD, you should replace the batteries as soon as possible. The device will continue to operate for several more hours.

PROGRAM LIST

Program	Waveform description	Treatment location	Treatment duration
P1	Modulation	Shoulder	30 min
P2	Burst	Hand / wrist	30 min
P3	Continuous + burst	Lower back / waist	30 min
P4	Deep TENS	Joint - knee / elbow	30 min
P5	Modulation	Leg - thigh / calf / ankle / foot	30 min
P6	Modulation	Neck	30 min

SPECIFICATIONS

- Power sources: 3.0V DC, 2xAAA batteries
- Frequency: 2Hz~150Hz
- Pulse width: 50μs~300μs
- Output voltage: 0~90mA
- Output intensity level: 0~25 levels
- Treatment time: about 30 minutes
- Operating Conditions: 41°F~104°F (5°C~40°C); 30%RH~75%RH
- Storage Conditions and Transportation: 14°F~131° F (-10°C~55°C); 10%RH~90%RH
- Size: 115mm x 48mm x 22mm
- Weight: about 75.5g (without batteries)
- Service life of the device: 3 years
- Service life of the battery: With new super heavy duty batteries, approx. 15 days when used for 30 min/day in P02 program at 13 level intensity.

HOW TO CONTROL AND REDUCE YOUR PAIN

When should the device be used?

Use as soon as your pain begins. Start with one session. The unit automatically turns off at 30 minutes. If you address your pain early, it may prevent the pain from becoming worse, or even chronic. It is better to get pain under control sooner so it does not reach such a high pain threshold that it limits your daily activities.

Setting the intensity

Intensity is based upon your level of comfort. Begin the first session with a low intensity and a short duration while learning how to operate the device. Therefore, caution should be used when working with maximum intensities. (i.e., always at the limit of what you can support.) Do not exceed your comfort level.

How long should you use the device?

Start with one 30-minute session. Always turn unit off with pads still adhered to skin. Rate your pain to check your progress, 1 low to 25 high. Intensity is based upon your level of comfort. Begin the first session with a low intensity and a short duration while learning how to operate.

Stop the therapy session if pain has reduced or stopped. If your pain does not improve and you become sore from over-use, refrain from treating those areas for 2 days. If this issue reoccurs, reduce the treatment time and intensity settings for future treatment.

Recommended treatment session:

1 session	Max session	Max times/day
30 minute session shut-off	2 sessions	3 sessions per day

When to stop using the device?

1) If you experience an adverse reaction — skin irritation / redness / burns, headache or other painful sensation — or if you feel any unusual discomfort.
2) If your pain does not improve, becomes seriously chronic and severe, or continues for more than five (5) days.

NOTE: If you feel pain, dizziness, discomfort or nausea, call your physician or medical practitioner.

What type of pain is the TENS Unit best for?

This therapy works best on acute pain because it is localized. Acute pain occurs in one area for less than three (3) months. If you have chronic pain, you may have pain in more than one area and for longer than six (6) months. Chronic pain may be compounded by other issues that this device cannot address.

Remember this device does not cure your pain or the original cause of the pain. It provides temporary relief or reduction of pain so that you can control your life and activities better.

Specific applications (Practical recommendations)

Specific applications	Cycle duration	Program	Remark
Muscular pain in the back of the neck	4 weeks, 2x/day, with a 10 minute break between the 2 sessions	P6	You are advised to consult your doctor if no improvement is observed after the first week of use.
Neuralgia of upper limb	1 week, 1x/day minimum, then adapt according to how the pain develops.	P2	According to requirements, the program can be repeated a number of times during the same day.
Muscular pain in the thoracic back region	4 weeks, 2x/day, with a 10 minute break between the 2 sessions	P3	You are advised to consult your doctor if no improvement is observed after the first week of use.
Muscular pain in the low back region	4 weeks, 2x/day, with a 10 minute break between the 2 sessions	P3	You are advised to consult your doctor if no improvement is observed after the first week of use.
Elbow pain	1 weeks, 2x/day, then adapt according to how the pain develops.	P4	According to requirements, the program can be repeated a number of times during the same day.
Localized contracture in external side of the calf	1 week, 1x/day	P5	Consult your doctor if no improvement is observed after the first week of use.

CLEANING AND STORAGE

Cleaning the unit

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

Note:

- This device and accessories do not require sterilization.

Cleaning the electrode pads

1. Turn the power off and remove the lead wires from the pads.
2. Wash the pads when the adhesive surface becomes dirty and/or the pads are difficult to attach.
   - Wash the pad softly with your fingertips under slow running cold water for several seconds (do not use a sponge/cloth/sharp object like a nail on the adhesive side. Do not use detergents, chemicals or soap).
3. Dry the pads and let the adhesive surface air-dry completely (do not wipe with a tissue paper or cloth).

CAUTION:

- The life of pads may vary by the frequency of washing, skin condition, and storage state.
- If the pads no longer sticks to your skin or the pads are broken, you should replace them with new pads.
- Before applying the self-adhesive electrodes, it is recommended to wash and degrease the skin, and 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 in. x 2 in.) as the electrodes provided with the device.
- 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 device may increase the chance of skin irritation or electrode burns occurring under the electrodes.
- Always use electrodes that have been cleared for marketing in the U.S. by the FDA.

Storing the electrode pads and lead wire

- Turn the device off and remove the lead wire from the unit.
- Remove the pads from your body and pull out lead wire from the pads.
- Place the pads on the plastic film and store in the sealed package.
- Wrap the lead wire and store in the sealed package.

Storing the unit

- Place the unit, electrodes, lead wire and manual back into retail box. Store the box in a cool, dry place, 14°F~131°F (-10°C~55°C); 10%~90% relative humidity.
- Do not store in places that can be easily reached by children.
- When not in use for a long period, remove the batteries before storage to avoid liquid discharge from batteries.

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. You are under legal obligation to dispose of batteries correctly.

Please dispose of the device in accordance with local regulations.

TROUBLESHOOTING

If the unit does not operate after taking these measures, contact Carex Health Brands.

PROBLEM	POSSIBLE CAUSES	POSSIBLE SOLUTION
The unit cannot power on	Are the batteries exhausted?	Replace the batteries.
	Are the batteries installed correctly?	Insert the batteries observing polarity.
Stimulation weak or cannot feel any stimulation	Electrodes are dried out or dirty.	Replace with new electrodes.
	Electrodes do not stick to skin well.	Replace with new electrodes.
	Lead wire is old, worn, or damaged.	Replace with new lead wire.
Stimulation is uncomfortable	Intensity is too high	Decrease intensity.
	Electrodes are too close together.	Reposition electrodes to be at least 2 inches apart.
	Electrode active area size is too small.	Replace electrodes with ones that have an active area no less than 4 in^2 (2 in x 2 in).
	Is the device being operated according to the manual?	Please check the manual before use.

PROBLEM	POSSIBLE CAUSES	POSSIBLE SOLUTION
Intermittent output	Lead wire	Verify connection is secure. Insert wire firmly.
		Turn down the intensity. Rotate lead wire in socket 90°. If still intermittent, replace lead wire.
		If still intermittent after replacing lead wire, a component may have failed. Call the repair department.
Stimulation is ineffective.	Improper electrode placement.	Reposition electrode.
	Unknown	Contact clinician.
The skin becomes red and/or you feel a stabbing pain	Using electrodes on the same site every time.	Reposition the electrodes. If at any time you feel pain or discomfort, stop use immediately.
	Electrodes are not adhered to the skin properly.	Ensure the electrodes are securely adhered to the skin.
	The electrodes are dirty.	Clean the electrodes according to description in this manual or replace with new electrodes.
	The surface of the electrode is scratched.	Replace with new electrodes.
Output current stops during therapy	The electrodes come off the skin.	Turn off the device and place the electrodes on again, or replace with new electrodes.
	The lead wire is disconnected.	Turn off the device and connect the lead wire.
	The batteries' power has been exhausted.	Replace with new batteries.

GLOSSARY OF SYMBOLS

Electrical devices are recyclable material and should not be disposed of with household waste after their useful life. Help us protect the environment and save resources and by taking this device to the appropriate collection point. Please contact the organization which is responsible for waste disposal in your area if you have any questions.

Caution

Type BF Applied Part

Refer to instruction manual because of the higher levels of output.

Keep Dry

IMPORTANT INFORMATION REGARDING ELECTROMAGNETIC COMPATIBILITY (EMC)

With the increased number of electronic devices such as PC's 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 (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the IEC 60601-1-2 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 Carex Health Brands conform to this IEC 60601-1-2:2007 standard for both immunity and emissions.

Nevertheless, special precautions need to be observed:

- The use of accessories and cables other than those specified by Carex Health Brands, with the exception of cables sold by Carex Health Brands as replacement parts for internal components, 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		
AccuRelief™ 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 CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

TABLE 2:

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
AccuRelief™ 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 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			
AccuRelief™ 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	3 V/m	**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 √*P* d = 1.2 √*P* 80 MHz to 800 MHz d = 2.3 √*P* 800 MHz to 2.5 GHz Where **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in 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] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz		

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.

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE DEVICE			
The TENS device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the TENS 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 watts	**Separation distance according to frequency of transmitter in meters**		
	150 kHz to 80 MHz $d = 1.2 \sqrt{}$	**80 MHz to 800 MHz** $d = 1.2 \sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters 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.

WARRANTY

Please contact Carex Health Brands or the device center in case of a claim under the warranty. If you have to send in the unit, enclose a copy of your receipt and clearly state the defect. The following warranty terms apply:

1) The warranty period for the 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 under warranty do not extend the warranty period for the device or for the replacement parts.
3) The following is excluded under the warranty:
   - All damage due to improper treatment, e.g. nonobservance of the user instruction.
   - All damage due to repairs or tampering by the customer or unauthorized third parties.
   - Damage during transport from the manufacturer to the consumer or during transport to the service center.
   - Accessories which are subject to normal wear and tear.
4) 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.

LIMITED ONE YEAR WARRANTY

Your AccuRelief™ device is warranted for a period of 1 year from the date of original purchase. Electrodes and lead wire are excluded from this warranty. Carex Health Brands sells its products with the intent that they are free of defects in manufacture and workmanship if used in accordance with the instructions provided. We will, at our option, repair or replace without charge any device covered by the above warranties. These warranties extend only to Consumers and do not extend to Retailers.

To obtain warranty service on your AccuRelief™ product, contact Customer Service by calling at 1-800-328-2935 for the repair center address and for the return shipping/handling fee. Enclose a letter with your name, address, phone number, model number, serial number, date of purchase, location of purchase and description of specific problem. Be sure to include your receipt as Proof of Purchase. Pack the product carefully to prevent damage in transit. Because of possible loss in transit, we recommend insuring the product with return receipt requested.

Carex Health Brands does not authorize anyone, including, but not limited to, Retailers, the subsequent consumer purchaser of the product from a Retailer or remote purchasers, to obligate Carex Health Brands in any way beyond the terms set forth herein. These warranties do not cover damage caused by misuse or abuse; accident; the attachment of any unauthorized accessory; alteration to the product; improper installation; unauthorized repairs or modifications; improper use of electrical/power supply; loss of power; dropped product; malfunction or damage of an operating part from failure to provide manufacturer's recommended maintenance and storage; transportation damage; theft; neglect; vandalism; or environmental conditions; loss of use during the period the product is at a repair facility or otherwise awaiting parts or repair; replacement batteries or any other conditions whatsoever that are beyond the control of Carex Health Brands. These warranties are effective only if the product is purchased and operated in the country in which the product is purchased. A product that requires modifications or adoption to enable it to operate in any other country than the country for which it was designed, manufactured, approved and/or authorized, or repair of products damaged by these modifications is not covered under this warranty.

THESE WARRANTIES PROVIDED HEREIN SHALL BE THE SOLE AND EXCLUSIVE WARRANTIES. THERE SHALL BE NO OTHER WARRANTIES EXPRESSED OR IMPLIED INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS OR ANY OTHER OBLIGATION ON THE PART OF THE COMPANY WITH RESPECT TO PRODUCTS COVERED BY THESE WARRANTIES. CAREX HEALTH BRANDS SHALL HAVE NO LIABILITY FOR ANY INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES. IN NO EVENT SHALL THESE WARRANTIES REQUIRE MORE THAN THE REPAIR OR REPLACEMENT OF ANY PART OR PARTS WHICH ARE FOUND TO BE DEFECTIVE WITHIN THE EFFECTIVE PERIOD OF THESE WARRANTIES. NO REFUNDS WILL BE GIVEN. IF REPLACEMENT PARTS FOR DEFECTIVE MATERIALS ARE NOT AVAILABLE, CAREX HEALTH BRANDS RESERVES THE RIGHT TO MAKE PRODUCT SUBSTITUTIONS IN LIEU OF REPAIR OR REPLACEMENT.

These warranties do not extend to the purchase of opened, used, repaired, repackaged and/or resealed products including but not limited to sale of such products on Internet auction sites and/or sales of such products by surplus or bulk resellers. Any and all warranties or guarantees shall immediately cease and terminate as to any products or parts thereof which are repaired, replaced, altered, or modified, without the prior express or written consent of Carex Health Brands.

These warranties provide you with specific legal rights. You may have additional rights which may vary from state to state. Because of individual state regulations, some of the above limitations and exclusions may not apply to you.

For more information regarding our product line in the USA, please visit:
www.accurelief.com

AccuRelief™ Model:_____

Serial Number: _____

Date of Purchase: _____

Distributor: _____

Manufactured for:
Carex Health Brands
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customerservice@carex.com