

AccuRelief™

Wireless 3-in-1 Pain Relief Device



User Manual

Model ACRL-9100

This manual is valid for the Wireless 3-in-1 Pain Relief Device ACRL-9100

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

The device complies with all the standards relating to Class II electrical medical devices and
to devices which use electrical stimulation for use at home.

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Conformity to safety standards

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

IEC60601-1, IEC60601-1-2, IEC60601-2-10, IEC62366, IEC60601-1-11
ISO10993-5, ISO10993-10, ISO10993-1, ISO14971

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INTRODUCTION

Thank you for purchasing the Wireless 3-in-1 Pain Relief Device ACRL-9100 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.

Indications for use:

n TENS: The device 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.

n EMS: The device is designed to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.

It should be applied to normal, healthy, dry and clean skin of adult patients. It is design to be used at home.

The package contains the following components:

Standard Parts:		
No.	DESCRIPTION	QUANTITY
A	ACRL-9100	1PC
B	Electrode pad (2 in. x 2 in)	4PCS
C	Instruction manual	1PC
D	Micro-USB cable	1PC
E	Remote control	1PC

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



DANGER

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



WARNING

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



CAUTION

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



DANGER

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

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





WARNING
DO NOT USE THIS DEVICE UNDER
THESE CONDITIONS:

- n Consult with your physician before using this device, because the device may cause lethal rhythm disturbances in certain susceptible individuals.
- n On open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins); or on top of, or in proximity to, cancerous lesions.
- n Over areas of skin that lack normal sensation.
- n Stimulation should not take place while the user is connected to high-frequency surgical equipment, it may cause burn injuries on the skin under the electrodes, as well as problems with the stimulator.
- n Do not use the stimulator in the vicinity of shortwave or microwave therapy equipment, since this may affect the output power of the stimulator.

DO NOT USE ON THESE INDIVIDUALS

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

DO NOT USE THIS DEVICE DURING
THESE ACTIVITIES

- n When in the bath or shower;
- n While sleeping;
- n While driving, operating machinery, or during any activity in which electrical stimulation can put you at risk for injury.



WARNING **PAIN MANAGEMENT WARNINGS**

- n If you have had medical or physical treatment for your pain, consult with your physician before using this device.
- n 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.
- n 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 Stimulator.

WARNINGS AND PRECAUTIONS **REGARDING THE PADS**

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

- n Pads should not touch each other when placed onto your skin.
- n Pads must be placed at least 2 in apart.



DANGER **NEVER APPLY THE PADS TO**

- n The head or any area of the face.
- n Never apply the pads to the side of the neck (on the carotid sinus) or any area of the throat (front of the neck) because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- n Both sides of the thorax simultaneously or across your chest because the introduction of electrical current may cause rhythm disturbances which could be lethal.



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.

Consult your physician if you have a tendency to bleed internally, such as following an injury or fracture.

This stimulation should not be applied over the menstruating or pregnant uterus.



CAUTION

- n Do not bend or fold because the pad may not function properly. Place the pads onto the plastic film and then store into the sealed package when not in use.
- n Do not apply ointment or any solvent to the pads or to your skin because it will disrupt the pads from functioning properly.

- n The pads are already pre-gelled and will adhere to your skin.
- n To avoid damage to the adhesive surface of the pads, put the pads only on the skin or on the plastic film provided.
- n Always place the electrodes in accordance with illustrations provided (Refer to the Pad Placement illustrations).
- n 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.



WARNING

DO NOT USE YOUR PADS THIS WAY

Pads should not touch each other when placed onto your skin. Pads should be at least 2 in apart.
Do not place on your spine or backbone.

Pad should not touch any metal object, such as a belt buckle or necklace.

Do not share pads with another person. This may cause a skin irritation or infection. Pads are intended for use by one person.

Always turn the power off before removing or changing the pad location.

Do not leave pads attached to the skin after treatment.



**CAUTION:
CAUTION WHILE USING THE STIMULATOR**

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

Do not use for any other purpose except for what it is intended for.

Do not use the device while wearing electronic devices such as watches as this may damage the device.

Dispose of the device, batteries, and components according to applicable legal regulations. Unlawful disposal may cause environmental pollution.

The size, shape and type of pads may affect the safety and effectiveness of electrical stimulation.

The electrical performance characteristics of 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.



**CAUTION:
GENERAL PRECAUTIONS**

The user is the intended operator.

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.



CAUTION:

You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).

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 areas of skin that lack normal sensation.



- n Keep unit away from young children. The unit contains small pieces that may be swallowed. Contact your physician immediately if ingested.
- n Use this device only with the electrodes and Micro-USB cable recommended by the manufacturer.
- n Keep unit out of the reach of young children. The cable can cause strangulation.
- n Do not use the device if it is closer than 12 inches (30.5cm) to wireless communication equipment, such as wireless home network routers, cell phones, cordless phones and their base stations, and walkie-talkies. The electromagnetic interference of this wireless communication equipment may prevent the device from operating properly.
- n If you have any problems with this device, such as setting up, maintaining or using, please contact Carex Health Brands.



CAUTION:
Possible Adverse Reactions

- n Do not use 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.
- n You may experience skin irritation and burns beneath the stimulation electrodes applied to your skin.
- n You should stop using the device and consult with your physician if you experience adverse reactions from the device.

HOW TENS WORKS FOR PAIN RELIEF

What is it?

The Wireless 3-in-1 Pain Relief Device ACRL-9100 is a single output channel TENS machine and highly effective in temporarily relieving pain. TENS therapy 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 nerves to modify your pain perception. TENS does not cure any physiological problem; it only helps control the pain. TENS does not work for everyone; however, in most patients it is effective in temporarily 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:

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

HOW EMS WORKS FOR MUSCLE STIMULATION

What is it?

EMS works by sending electronic pulses to the muscle needing treatment; this causes the muscle to exercise passively. It is a product derived from the square waveform (ladder - shaped). Through the square wave pattern it is able to work directly on muscle motor neurons. This device has low frequency and this in conjunction with the square wave pattern allows direct work on muscle groupings.

How EMS works?

The EMS units send comfortable impulses through the skin that stimulate the nerves in the treatment area. When the muscle receives this signal it contracts as if the brain has sent the signal itself. As the signal strength increases, the muscle flexes as in physical exercise. Then when the pulse ceases, the muscle relaxes and the cycle is repeated.

The goal of electrical muscle stimulation is to achieve contractions or vibrations in the muscles. Normal muscular activity is controlled by the central and peripheral nervous systems, which transmit electrical signals to the muscles. EMS works similarly but uses an external source (the stimulator) with electrodes attached to the skin for transmitting electrical impulses into the body. The impulses stimulate the nerves to send signals to a specifically targeted muscle, which reacts by contracting, just as it does with normal muscular activity.

How MASSAGE works?

The massage stimulation program is a type of low level EMS used to loosen tight muscles. Its main function is to mimic manual massage to promote relaxation and reduce muscle tension.

PACKAGE CONTENTS



ACRL-9100 Unit



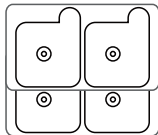
Remote Controller



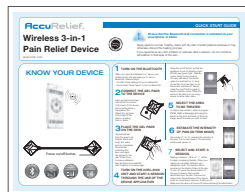
AAA batteries



Micro-USB cable



Electrode Pads (2 in. x 2 in.)



Quick Start Guide



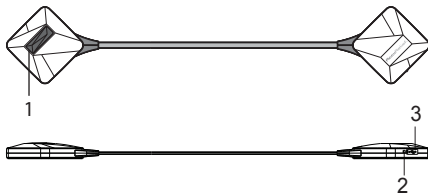
Instruction Manual

KNOW YOUR DEVICE

Features

- n Channels: One channel
- n Treatment modes TENS: 6 programs
EMS: 5 programs
MASSAGE: 3 programs
- n Output Amplitude: 0-60mA (1000 Ω Load)
- n Waveform type: Symmetrical Biphasic square pulse
- n Control platform APP control (ios or Android) and Remote control

Front and Rear Panel



1. On/off button []: Press this button to turn on the device or turn off the device.

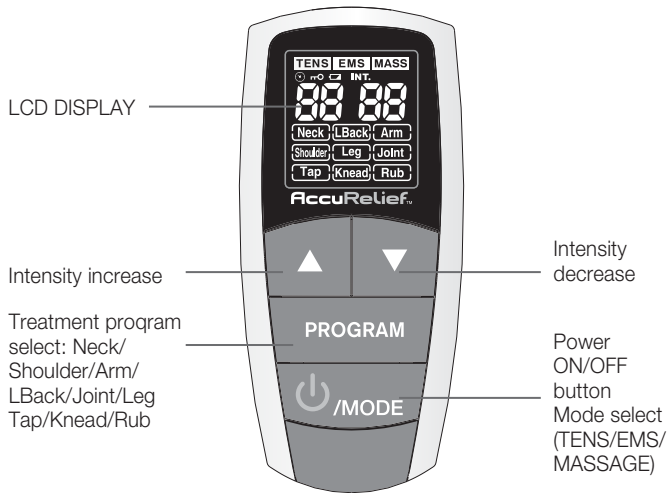
- n Green Flashing indicator light: The device hasn't connected with APP or the Remote Controller;
- n Continuous green: The device is in standby mode;
- n Continuous Orange: The device is in treatment mode;
- n Orange flashing: The device is in paused mode;

2. Indicator light when charging:

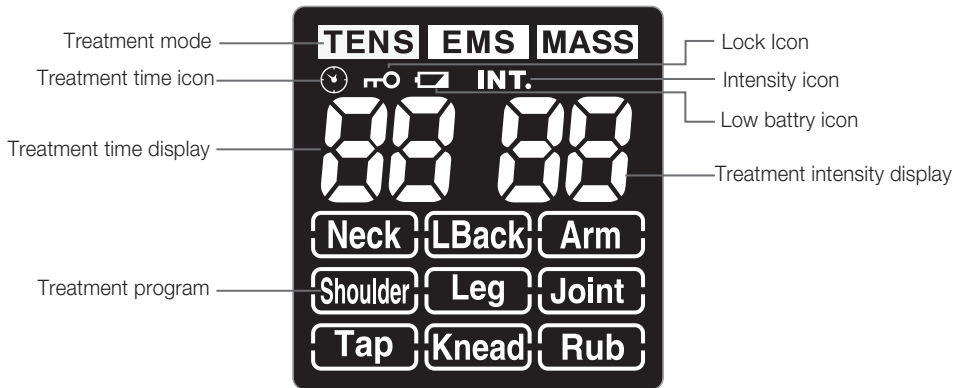
- n Continuous orange: The battery is charging;
- n Continuous green: The battery is fully charged.

3. Device charging port:

- n Connect the Micro-USB cable and the adaptor to the device port to charge;

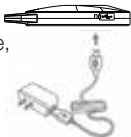


LCD Display



CHARGING

Insert the Micro-USB plug of the Micro-USB cable into the Micro-USB charging port of the ACRL-9100 device, and then connect to the Standard USB plug of the Micro-USB cable to the appropriate power supply device which could output 5V d.c. , 300mA. When the battery light goes from continuous orange (which means that the battery is being charged) to a continuous green (the battery is full), remove the micro-USB plug from the micro-USB socket of the device.



NOTES:

- n Only use the Micro-USB cable which is provided by the manufacturer.
- n Device must be charged prior to first use. Typically it takes 2 hours to charge the device. A full charge allows a battery life of about 4 hours continuously when functioning in normal (ambient temperature) conditions.

- n Please charge the device fully before beginning each session. If the charge is not complete at the beginning of a program, the battery may become depleted before the end of the session. You cannot use the device while it is charging.



WARNING:

- n If batteries leak and come into contact with the skin or eyes, wash immediately with copious amounts of water.
- n Dispose of the used batteries safely according to the local regulations.
- n The life of a rechargeable battery depends on the number of recharging/rundown cycles it undergoes and how these cycles are performed. The service life of rechargeable battery is more than 300 recharging/rundown cycles. We provide the following suggestions to extend the life of the battery:
- n Whenever the device is not used frequently, we recommend recharging the battery once a month.

EASY STEPS TO GET STARTED WITH YOUR THERAPY WITH ELECTRODE PADS

Using the APP to control main device:

Step 1 Downloading the APP

Download the application to your smart phone :

- n By the Appstore or Google Play
- n Then search 'ACRL-9100', and click the Smart Pain Reliever ACRL-9100 icon.

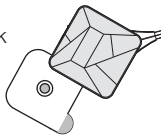
The app operates on ios and Android platforms
(At least ios 8.0, Android 5.0)

Step 2- Cleaning of skin

Clip excess hair from the treatment area and remove any jewelry that may come in contact with the stimulation of the device. Wash area with soap and water, and dry completely.

Step 3- Preparation of the ACRL-9100 unit

Each gel pad is pre-fixed with a male snap to connect to the back of the device, and is protected by a transparent film. Press the male snap of the gel pad to the female snap of the device as shown in the picture on the right:



Step 4-Placing the gel pads

Place electrodes on clean, dry and healthy skin at least 2 in. apart and do not let them touch. Make sure there is a linear path between the two electrodes. (See the pages 22-23).

Note: Replace the electrodes when they are damaged or dirty, when they have lost their adhesive power or when stimulation becomes uncomfortable, i.e. when you experience an unpleasant stinging or biting sensation.



WARNING:

Note: Always connect the device before you place the electrodes on the skin.

Note: DO NOT place the electrodes on top of each other or so close to each other that they touch each other.

Note: It is possible that you may need external assistance for placing the electrodes in certain areas.

Replace the electrodes if:

- n they are damaged or torn.
- n they are past the use-by date indicated on the re-sealable bag.
- n they have lost their adhesive power. Never use plaster or tape to attach them to your skin.
- n stimulation feels less strong.
- n when stimulation is uncomfortable, i.e. when you experience an unpleasant stinging or biting sensation.

Note: Always replace the electrodes with electrodes recommended for this device by the manufacturer.



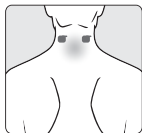
WARNING: Make sure the device is turned off before applying electrodes.



WARNING: Place the electrode pads according to the electrode Pad placement illustrations, on pages 22-23.

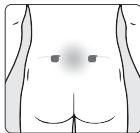
Pad Placement illustrations

Position of the electrodes-TENS programs:



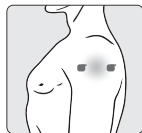
NECK / CERVICAL PAIN

Attach both pads on the neck.
(DO NOT place on the back of the carotid artery, throat or the front of the neck.)



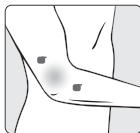
LOWER BACK

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



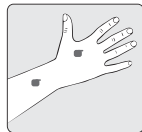
SHOULDER PAIN

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



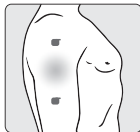
ELBOW PAIN

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



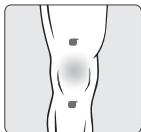
CARPAL TUNNEL / HAND PAIN

Attach both pads on the hand where you feel pain.



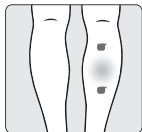
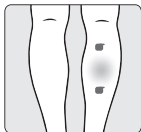
UPPER ARM PAIN

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



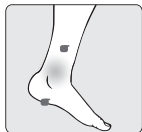
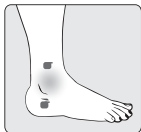
KNEE / JOINT PAIN

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.**

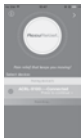


ANKLE / FOOT PAIN

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. Treat one at a time.**

Step 5–Starting a session through the use of the device application

- n Ensure that the Bluetooth (4.0) connection is activated on your smartphone or tablet. Turn on the APP.
- n Press the on/off button on the device so that the device is in standby mode (Continuous green light : Standby mode, ready for the session). The App detects the device which is switched on. In case of inactivity for more than 5 min, the device switches off. Press the on/off button again to begin a session.



Step 6–Select the area to be treated

In the case of a new session, it is essential to select a treatment area and a program.



Step 7–Estimate the intensity of pain you are currently experiencing in the area to be treated (in TENS mode)

On a scale of 1 to 10, evaluate the intensity of the pain. For no pain press 0, for extremely intense pain press 10.



Step 8–Select and start a session

- n Starting a session : Click“+” button to begin treatment
- n After session is complete, estimate your satisfaction level, the session is then recorded in the history



Step 9 - Following completion of session

- n To turn off the device, press the “On/Off” button.
- n Remove the electrodes from the skin. Detach from the edges.
- n Remove the device from the electrodes. If you forget the device for more than 5 minutes, it turns off. If the device is frequently used during the day, it is advisable to charge it before starting a new session.

Using the Remote control to control the main device:

Step1–inserting batteries

1. Remove the battery cover on the back of the device
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 .

Notes:

- Please use 2xAAA batteries in this remote control.

- 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.
- Remove exhausted batteries from the remote control.



CAUTION:

- Batteries must be handled by an adult. Keep batteries out of the reach of children.



Step 2– Cleaning of skin

Please refer to pg.19

Step 3– Preparation of the ACRL-9100 unit

Please refer to pg.19

Step 4–Placing the gel pads

Please refer to pg.19

STEP 5-Operating the remote controlled device.

NOTE: You cannot turn the ACRL-9100 unit on by pressing the remote control. You must do so by pressing the on/off button on the device itself.

- n A steady green light indicator light will turn on to let you know the unit is on.
- n Using the remote control press the Mode button to switch treatment mode in standby mode.
- n Using the remote control press the Program button to select treatment part in standby mode.
- n Using the remote control when the unit is press the ▲ button to increase or the ▼ button to decrease the intensity.

NOTE: There are 60 levels of intensity.

STEP 6 - Turn off the device

You can turn device off in the following ways:

- The device will turn off automatically after 30 minutes treatment time.
- Press the power button continuously until the LED light turns off.
- Turn the remote controlled device off by pressing the On/Off button on the remote control

Step 7 - Following completion of session

- n To turn off the device, press the “On/Off” button.
- n Remove the electrodes from the skin. Detach from the edges.
- n Remove the device from the electrodes. If you forget the device for more than 5 minutes, it turns off. If the device is frequently used during the day, it is advisable to charge it before starting a new session.

CLEANING AND STORAGE

Cleaning the main device and the remote control

- 1) Turn unit off. Remove USB if device has been charging.
- 2) Clean the device after use with a soft, slightly moistened cloth and wipe gently.
 - n Do not use chemicals (like thinner, benzene).
 - n Do not let water get into the internal area.

Note:

- n This device and accessories does not require sterilization.

Cleaning the electrode pads

- 1) Turn the power off
- 2) Remove pads from device.
- 3) Wash the pads when the adhesive surface becomes dirty and/or the pads are difficult to attach.
 - n 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 adhesive side, do not use detergents, chemicals or soap).

- 4) Dry the pads and let the adhesive surface air-dry completely (do not wipe with a tissue paper or cloth).



CAUTION:

- n The life of pads may vary by the frequency of washing, skin condition, and storage state.
- n If the pad no longer sticks to your skin or the pad is broken, immediately discontinue use and obtain replacement pads as recommended by the manufacturer.
- n Before applying the self-adhesive electrodes, it is recommended to wash and degrease the skin, and then dry it.
- n **DO NOT turn on the device when the electrodes are not positioned on the body.**
- n **Never remove the self-adhesive electrodes from the skin while the device is still turned on.**

- n If replacement electrodes are necessary, use only electrodes that are the same size (50*50mm) as the electrodes provided with the ACRL-9100.
- n 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 ACRL-9100 may increase the chance of skin irritation or electrode burns occurring under the electrodes.
- n Always use electrodes that have been cleared for marketing in the US by the FDA.
- n Always clean the electrodes after your treatment every time.

Storing the electrode pads

Place clean, dry pads on the plastic film and then store in the sealed package between uses.

Storing the unit

- n Place the unit, electrodes and manual back in package. Store the box in a dry place, 14°F~131°F (-10°C~55°C); 10% ~90% relative humidity.
- n **KEEP DEVICE AND ALL ACCESSORIES OUT OF REACH OF CHILDREN.**



CAUTION:

When not in use for a long period, remove the batteries before storage, to avoid liquid discharge from batteries.

SPECIFICATIONS

- n Power Sources: 3.7V Li-ion (remote control : DC 3.0V 2 x AAA Batteries)
- n Power Supply:5V DC, 300mA
- n Frequency: 2Hz~150Hz
- n Pulse Width: 50us~370us
- n Wave form: Biphasic square wave
- n Output Voltage: 0~60V (at 1000 ohm load)
- n Output Intensity Level: 0~60 levels
- n Operating Conditions: 5°C ~40°C ; 30%RH~75%RH; 700hPa ~1060hPa
- n Storage and transport conditions (main device): 14°F~131°F (-10°C~55°C); 10%RH~90%RH; 700hPa ~1060hPa
- n Size: 14.17''(L)x2.32''(W) x0.45''(H) (main device) 4.53''(L)x2.09''(W) x0.98''(H) (Remote control)
- n Weight: 36g (main device) 65g (Remote control)
- n Service life of the device: 2 years
- n Service life of electrode pads: 30 times
- n Applied part: Electrode
- n Size of electrode: 2 in. x 2 in.
- n IP classification system: IP22
- n Maximum separation distance: 10m (In the opened environment)
- n The recommended separation distance: 3m.

Description of the Wireless Functions and Technology:

n RF Frequency	2.4GHZ-2.48GHZ
n Channel Bandwidth	2 M H z (-20db)
n Operation Voltage	DC3.7V
n Types of spread spectrum	FHSS
n Modulation type	GFSK
n Number of channel	40
n Chanel spacing	2 MHz
n Channel frequency	0-39 Channel 2.402-2.480GHZ
n Dwell time (if FHSS)	400ms
n Hopping rate (if FHSS)	1600HZ
n Antenna gain	0dBi
n Bluetooth version	V1.0
n Maximum Output Powers	0dBm

The ACRL-9100 device uses the one-on-one connection of BLE4.0, and our device as a peripheral, responds to the APP's connection request passively, establishing a one-on-one connection with the APP. After the ACRL-9100 device connects to the APP, the device will not be connected to other wireless devices or controlled. After the APP connects to the peripheral device, the APP will send the command, and when the ACRL-9100 device ensures this command is right, it will open the control command, then you can control the ACRL-9100 device. Otherwise, the APP can't control the ACRL-9100 device.

HOW TO CONTROL AND REDUCE YOUR PAIN

When should the device be used?

Use as soon as your pain begins. Start with one session (unit automatically turns off at 30 minutes). If you get to your pain early, it may prevent the pain from becoming worse, or even chronic. It's better for you to get it under control sooner so that it does not reach a high pain threshold where 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. You should therefore take care to work 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 on.** Rate your pain to check your progress, 1 low to 60 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 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 as following:

You may use the device for 30 minutes a day. You may need to use it for longer (maximum 3 times per day and maximum 90 minutes in total) depending on the level of your pain.

**CAUTION:****When to stop using the device?**

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

NOTE:

If you feel pain, dizziness, discomfort or nausea, discontinue use of device and call your physician or medical practitioner.

What type of pain is it best for?

This therapy works best on acute pain because it is localized. Acute pain is pain in one area for less than 3 months. If you have chronic pain, you may have pain in more than one area and for longer than 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.

TROUBLESHOOTING

PROBLEM	POSSIBLE CAUSES	POSSIBLE SOLUTION
The unit will not 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.
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 no less than 2 in
	Is the device being operated according to the manual?	Please check the manual before use.

PROBLEM	POSSIBLE CAUSES	POSSIBLE SOLUTION
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 batteries' power has been exhausted.	Replace with new batteries.

PRODUCT/BATTERY 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



Refer to instruction manual

The first number 2: Protected against solid foreign objects of 12,5 mm Φ and greater. The second number: Protected against vertically falling water drops when enclosure tilted up to 15°. Vertically falling drops shall have no harmful effects when the enclosure is tilted at any angle up to 15° on either side of the vertical.

IP22

SN

Represent manufacture date and serial number.



This symbol means that this device emits non-ionizing radiation. All devices with RF transmitters or that use RF electromagnetic energy must have a label with this symbol.

IMPORTANT INFORMATION REGARDING ELECTROMAGNETIC COMPATIBILITY (EMC)

CAUTION:

- 1) This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.
- 2) Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
- 3) This unit has been thoroughly tested and inspected to assure proper performance and operation.
- 4) Caution: this machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacture's declaration – electromagnetic emission		
The ACRL-9100 is intended for use in the electromagnetic environment specified below. The user of the ACRL-9100 should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The ACRL-9100 use 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 emission CISPR 11	Class B	The ACRL-9100 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	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	


Guidance and manufacture's declaration – electromagnetic immunity			
The ACRL-9100 is intended for use in the electromagnetic environment specified below. The user of ACRL-9100 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.

Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ACRL-9100 requires continued operation during power mains interruptions, it is recommended that the ACRL-9100 be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_r is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity

The ACRL-9100 is intended for use in the electromagnetic environment specified below.
The user of the ACRL-9100 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.6 GHz</p>	<p>3 V RMS outside the ISM band, 6 V RMS in the ISM and amateur radio bands</p> <p>10 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the ACRL-9100, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance</p> $d = 1,2\sqrt{P}$ <hr/> $d = 1,2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ <hr/> $d = 2,3\sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$

			<p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol: </p>
<p>NOTE 1 NOTE 2</p>	<p>At 80 MHz and 800 MHz, the higher frequency range applies. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>		

- 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, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ACRL-9100
- 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 ACRL-9100

The ACRL-9100 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ACRL-9100 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ACRL-9100 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 KHz to 80 MHz $d = 1.2 \sqrt{P}$	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 metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

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

FCC Compliance information

Caution: The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- this device may not cause harmful interference,
- and
- this device must accept any interference received, including interference that may cause undesired operation.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.

- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected

- Consult the dealer or an experienced radio/TV technician for help.

FCC Radiation Exposure Statement:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be colocated or operating in conjunction with any other antenna or transmitter.

WARRANTY

Please contact Carex Health Brands 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:
 - n All damage due to improper treatment, e.g. nonobservance of the user instruction.
 - n All damage due to repairs or tampering by the customer or unauthorized third parties.
 - n Damage during transport from the manufacturer to the consumer or during transport to the retailer.
 - n 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.

Manufactured for:
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