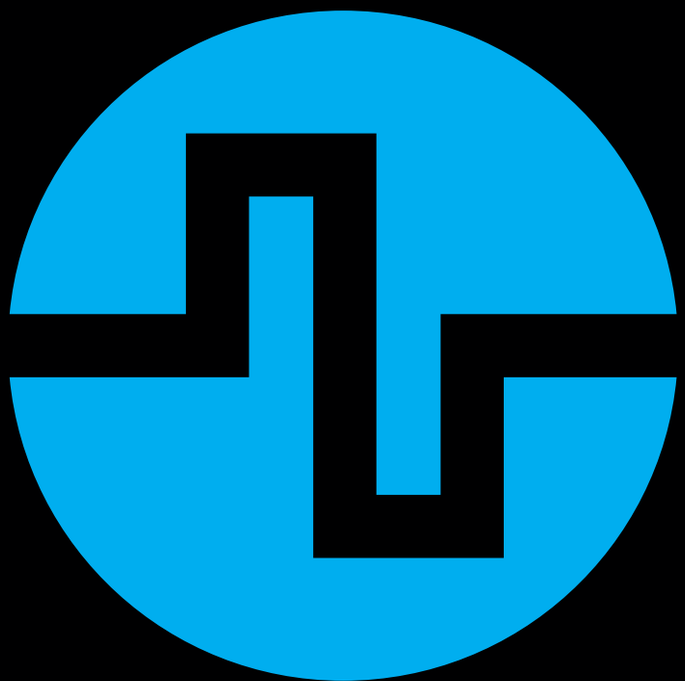


Compex | TENS / HEAT

TRAIN STRONGER
RECOVER FASTER

TABLE OF CONTENTS

INTRODUCTION

Compex Tens / Heat delivers electric pulses and heat to the user's body areas such as knee and back through the conductive silver pads. The portable and compact device has multiple modes of different pulse frequencies, covering Transcutaneous Electrical Nerve Stimulation (TENS) and Electrical Muscle Stimulation (EMS). It includes operating elements of ON/OFF button, intensity increase button, intensity decrease button, mode button, timer button, and heat/temperature button, and can be attached and detached to a wrap with conductive silver pads through magnetic connectors.

INDICATIONS FOR USE

To be used for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities.

It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

To stimulate healthy muscles in order to improve and facilitate muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the arms, abdomen, legs, and buttocks. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

It is also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities.

SAFETY WARNING

CONTRAINDICATIONS

» Do not use this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device, because this may cause electric shock, burns, electrical interference, or death.

» Do not use this device on patients whose pain syndromes are undiagnosed.

WARNINGS

» WARNING: Use carefully. May cause serious burns. Do not use over sensitive skin areas or in the presence of poor circulation. The unattended use of this device by children or incapacitated persons may be dangerous. To reduce the risk of buns, electric shock, and fire, this device must be used in accordance with the instructions.

» Do not crush the device and the wrap and avoid sharp folds.

» Carefully examine the device and the wrap, and do not use if they show any sign of deterioration.

» Do not tamper with this device and the wrap in any way. There are no user serviceable parts. If for any reason they do not function satisfactorily, return to the authorized service center at address given.

» The long-term effects of chronic electrical stimulation are unknown.

» Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.

» Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.

» Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.

» Stimulation should not be applied transcerebrally.

» Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.

» Stimulation should not be applied over, or in proximity to, cancerous lesions.

PRECAUTIONS

» Safety of stimulation use during pregnancy has not been established.

» Caution should be used for patients with suspected or diagnosed heart problems.

» Caution should be used for patients with suspected or diagnosed epilepsy.

» Caution should be used if you have any of the following:

- if you have a tendency to bleed internally following an injury;
- if you recently had surgery, or have ever had surgery on your back;
- if areas of skin lack normal sensations, such as skin that is numb.

» Consult with your physician before use over the menstrual uterus.

» Caution should be used in the presence of the following:

- When there is a tendency to hemorrhage following acute trauma or fracture;
- Following recent surgical procedures when muscle contraction may disrupt the healing process;
- Over the menstruating or pregnant uterus; and
- Over areas of the skin which lack normal sensation.

» You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.

» Do not use this device while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

» Keep this device out of reach of children.

» Do not use this device while sleeping.

» Do not use this device in high humidity areas such as a bathroom.

» Stop using this device at once if you feel discomfort, dizziness or nausea, and consult your physician.

» Do not attempt to move the conductive silver pads while the device is operating.
» Do not apply stimulation of this device in the following conditions:
  - across the chest because the introduction of electrical current into the chest may cause rhythm disturbances to the heart, which could be lethal;
  - over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins);
  - in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms);
  - on children or incapacitated persons.
» Be aware of the following.
  - consult with your physician before using this device;
  - this device is not effective for pain associated with Central Pain Syndromes, such as headaches;
  - the device is not a substitute for pain medications and other pain management therapies;
  - the device is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism;
  - stop using the device if the device does not provide pain relief; and,
  - use this device only with the conductive silver pads, and accessories recommended for use by the manufacturer
» Keep the device away from high-temperature and direct-sunlight place.
» Do not share the use of the conductive silver pads with others.
» Do not use the device while it's charging.
» The device contains the lithium battery. If overheating of the device occurred during the charging, stop the charging or operation immediately and report to the seller.
» Dispose of the battery-containing device according to the local, state, or federal laws.
» Skin burns may occur, and check the skin under the conductive silver pads periodically.

ADVERSE REACTIONS

» You may experience skin irritation and burns beneath the conductive silver pads applied to the skin;

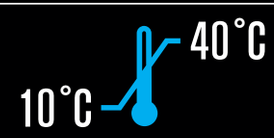
» You should stop using the device and should consult with your physicians if you experience adverse reactions from the device.

SYMBOL AND TITLE

Information essential for proper use shall be indicated by using the corresponding symbols. The following symbols may be seen on the device and labeling.

	*Consult instructions for use*		*Manufacturer*
	*Caution, consult accompanying documents*		*Temperature limitation*
	*Use by date*		*Humidity limitation*
	*Date of manufacture*		*Non-sterile*
	*Batch code*		*Fragile, handle with care*
	*Catalogue number*		*Keep away from rain*
	*Serial number*		*Product packaging is able to be recycled*
	*Type BF applied Part*		

ENVIRONMENTAL CONDITION FOR TRANSPORT AND STORAGE

 TEMPERATURE LIMITATION	*Normal working ambient temperature: 10~40°C (50~104°F)*
	*Normal working ambient humidity: 30~85%*
 TEMPERATURE LIMITATION	*Store and transport ambient temperature: -10 ~50°C (14~122°F)*
	*Store and transport ambient humidity: 30~90%*
	*Fragile; handle with care*
	*Keep away from rain*
	*Non-sterile*
	*Product packaging is able to be recycled*

ELECTROMAGNETIC COMPATIBILITY

1. This product needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided. This unit can be affected by portable and mobile radio frequency (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. Caution: 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 device is intended for use in the electromagnetic environment specified below. The customer of the user of the device should assure that it is used in such an environment.

EMISSION 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 emission CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	The device is suitable for use in all establishments, including domestic establish public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

GUIDANCE AND MANUFACTURE'S DECLARATION – ELECTROMAGNETIC EMISSION

The device is intended for use in the electromagnetic environment specified below. The customer of the user of the device 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	±6 kV contact ±8 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	±2kV for power supply lines	Main 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	Main 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	Main power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power nterruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Main power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.

NOTE UT is the a.c. mains voltage prior to application of the test level.

GUIDANCE AND MANUFACTURE'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should not be used near any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	**3 Vrms** **150 kHz to 80 MHz**	**3 Vrms**	$d = 1{,}2\sqrt{P}$
Radiated RF IEC 61000-4-3	**3 V/m** **80 MHz to 2.5 GHz**	**3 V/m**	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 80 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 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: 

NOTE 1 At 80 MHz and 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.

observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting 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 device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device 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	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
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, w and people.

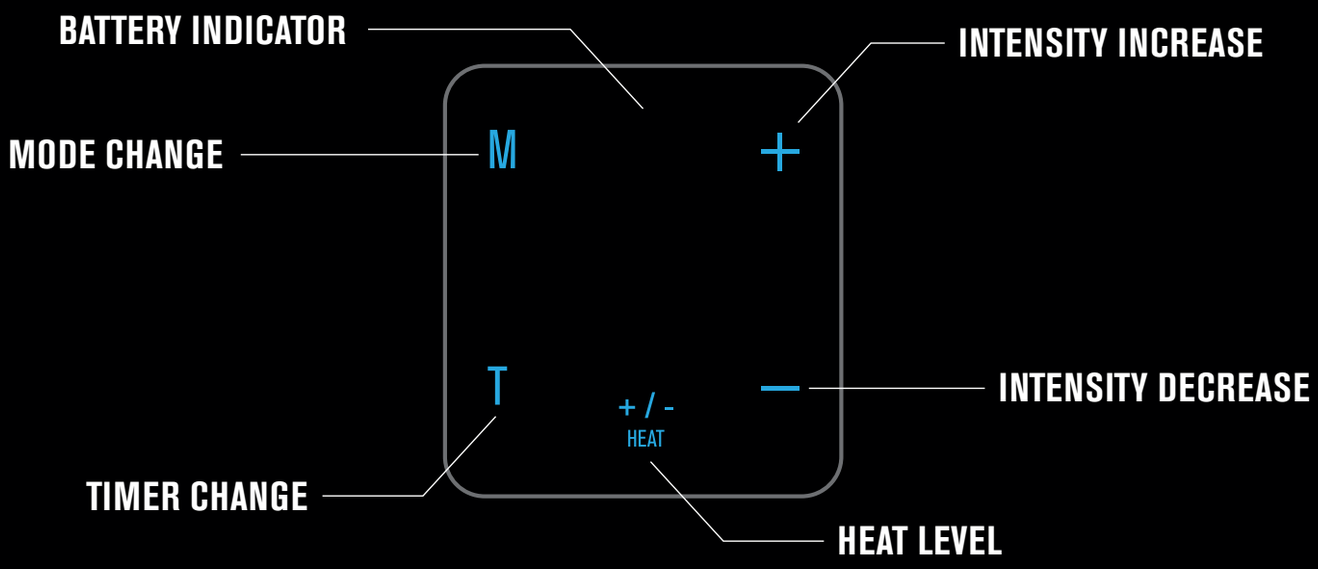
HOW THE DEVICE WORKS

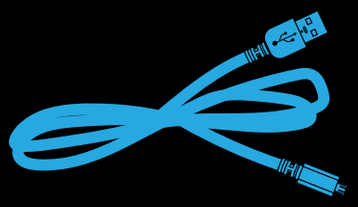
The device has multiple modes, covering TENS and EMS. If you are using the device for the first time, it is recommended that you start with the default Mode 1, which combines different pulse frequencies. Some modes are particularly effective for certain users, but you may need to select the mode that is best for you. You may need to try a few modes before finding the one that suits you the best. The best choice of modes may vary from one user to another, in spite of having the same type of symptom.

	PULSE FREQUENCY (HZ)	MODE DESCRIPTION	INTENDED USE
Mode 1	Combination of Mode 2-8	Combination of below	Pain relief and muscle stimulation with combined pulse rates
Mode 2	69 Hz	Pulse on for 3.4 second and off for 1.6 second	Pain relief with a pulse rate of 69 Hz
Mode 3	12.5-55.5 Hz	Pulse on for 20 second and off for 1 second	Muscle stimulation with variable pulse rate
Mode 4	1.2 Hz	Pulse on every 0.85 second	Pain relief with a pulse rate of 1.2 Hz
Mode 5	100 Hz	Pulse on for 10 second and off for 2.5 second	Pain relief with a pulse rate of 100 Hz
Mode 6	100 Hz	Pulse on for 20 second and off for 1 second	Pain relief with a pulse rate of 100 Hz and longer on time
Mode 7	20 Hz	Pulse on for 5 second and off for 1 second	Muscle stimulation with a fixed pulse rate of 20 Hz
Mode 8	160 Hz	Pulse on for 10 second and off for 2 second	Pain relief with a pulse rate of 160 Hz

DEVICE DESCRIPTION

Remove the device and accessories from the packaging. The accessories include a USB cable used for charging, and a wrap with conductive silver pads.





MICRO USB TO USB CHARGER

OPERATING INSTRUCTION

The following steps are used to guide the device operation, and the details about each step are listed in the following table.

01 Charge control unit before first use

02 Lightly dampen conductive silver pads with water

03 Apply brace to body part

NOTE: Skin should be clean. Remove sweat and lotions prior to use

04 Connect control unit to brace

05 Turn control unit on (Hold 2 sec.)

06 Select program

07 Change simulation time

08 Adjust stimulation intensity

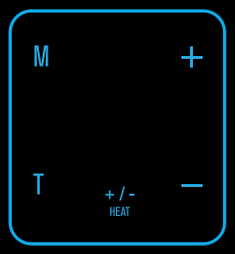
09 Adjust heat level

10 Turn control unit off when done

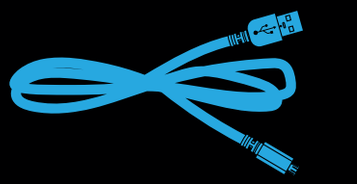
NOTE: Intensity + button only works when device is attached to wrap and wrap is in contact with skin.

1ST STEP – Charge control unit before first use

The control unit comes with a built-in rechargeable battery, and can be used as received. If the battery icon on the turned-on control unit keeps flashing, it means the battery is running out. Charge the control unit with the enclosed USB cable. The battery icon flashes during charging, and becomes solid when the control unit is charged fully.



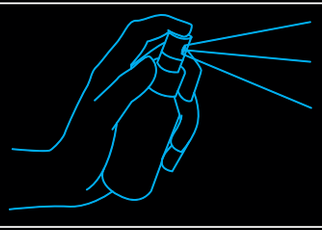
CONTROLL UNIT



USB CABLE

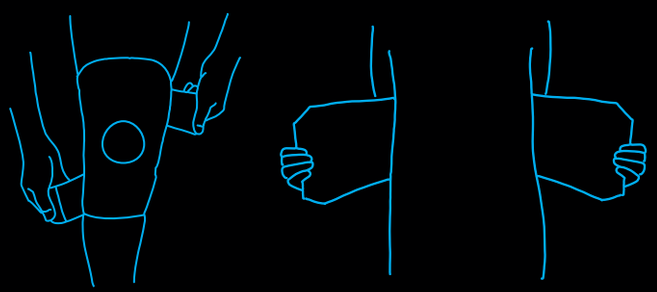
2ND STEP - Dampen wrap pads for best results

Lightly dampen conductive silver pads with clean water



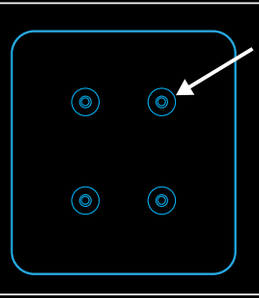
3RD STEP - Apply to the body part

Apply wrap to the body part using velcro strap/s to secure in place



4TH STEP - Connect control unit to the brace

Apply control unit to brace using magnets to secure connectors. Connect gold magnets to gold connectors, and silver magnets to silver connectors. The screen should be right reading from the user looking down.

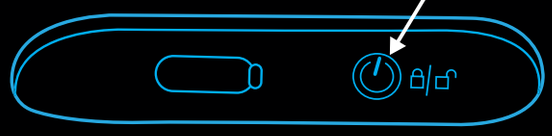


MAGNETS

5TH STEP - Turn control unit on

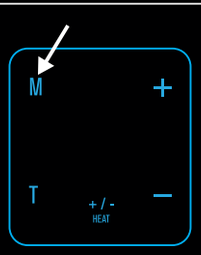
Hold On/Off button for 2 seconds to turn on device. Front display panel will light-up, indicating the device is on. Press the On/Off button once to lock/unlock the screen buttons. When buttons are locked, no adjustments can be made. Hold On/Off button for 2 seconds to turn off the device.

ON/OFF BUTTON



6TH STEP - Select program

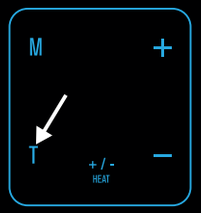
There are eight stimulation modes. Press the “M” button to select a desired pulse mode. The mode selected will be shown on the display.



M = MODE CHANGE

7TH STEP - Change simulation time

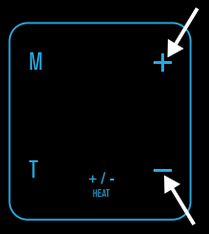
Default timer is set to 30 min. Press the “T” button to select a desired time (30, 40, 50, 60, 10 and 20 min) interval. The time selected will be shown on the display screen.



T = TIMER CHANGE

8TH STEP - Adjust stimulation intensity

Press and release the “+” button to increase the intensity, and the “-” button to decrease the intensity. The device will beep and the intensity level will flash with each change.
Note: With the increase of intensity (20 total levels), you may experience sensations like tingling, vibration, pain, etc. Therefore, gradually increase the intensity, and stop increasing when a comfortable level is reached.



+ = INTENSITY INCREASE
- = INTENSITY DECREASE

9TH STEP – Adjust heat level

Press the HEAT +/- button to select desired level of heat.

HEAT + / - =
HEAT OFF, LEVEL 1, LEVEL 2

10TH STEP - Turn control unit off when done.

When the countdown timer is up, the device will turn off automatically. The device can also be turned off by holding the On/Off button, indicated by the display light turning off.

OFF / ON

When using the device for the first time, we recommend starting from the default Mode 1, which combines the different frequencies. If you use one of the specific TENS or EMS modes, please refer to the following for details.

USE AS TENS

The control unit includes the following TENS frequencies, 69Hz (Mode 2), 1.2 Hz (Mode 4), 100Hz (Modes 5 and 6), and 160Hz (Mode 8). For treatment, place the wrap and conductive silver pads at the site of pain, and connect the device to the wrap.

For arthritis pain, inflammation of the joints, place the conductive silver pads on or near the area of the arthritis pain. The TENS mode of the device generates electrical pulses that are sent through the conductive silver pads for pain relief.

USE AS EMS

The control unit also includes the EMS frequencies, 13-56Hz (Mode 3) and 20Hz (Mode 7). For treatment, place the wrap and conductive silver pads where you desired muscle firming and strengthening, and connect the device to the wrap. Then select modes 3 or 7.

The EMS modes can also help temporarily increase local blood circulation in healthy muscles through the conductive silver pads, when they’re positioned on the extremity.

Recommended Practice for Both TENS and EMS:

- Start from the lowest intensity and gradually adjust the intensity to a comfortable level at a scale from from 1 to 20.
- Good skin care is important for a comfortable use of device. Be sure the treatment site is clean of dirt and body lotion.

CONDUCTIVE WRAP

The conductive wrap accessory is connected to the control unit through its magnentic connectors. The wrap accessory holds the conductive silver pad material that will be in contact with the skin. The electrical stimulation will be delivered to the body through these pads.

PERFORMANCE SPECIFICATIONS

Power Source	**3.7V Battery**
Number of Output Modes	**8 auto pulse modes**
Timer Range (minutes)	**10-60**
Dimensions (mm) [L x W x D]	**89 x 77 x 18 mm**
Waveform	**Biphasic**
Shape	**Rectangular**
Maximum Output Voltage	**64V@500Ω**
Maximum Output Current	**128mA@500Ω**
Pulse Duration	**100µSec**
Maximum Frequency	**160Hz**

CLEANING AND MAINTENANCE

Hand wash in warm water using mild soap, rinse thoroughly. Air dry.

TROUBLE SHOOTING

If your device is not operating properly, please check below for common problems and suggested solutions. If the recommended action does not solve the problem, please contact the seller.

STIMULATION IS WEAK OR NON-EXISTENT

- Be sure skin is clean and pads are firmly attached to skin.
- Be sure to lightly dampen the conductive silver pads for best results.
- Check if the battery is low and needs to be recharged.

DEVISE DOES NOT TURN ON

- Check if battery is low and needs to be charged.

SKIN TURNS RED

- Stop treatment.
- If problem persists, contact your physician.

CONTACT INFORMATION

Distributed by DJO, LLC

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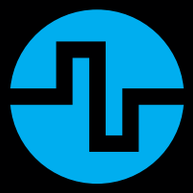

Compex

TRAIN STRONGER
RECOVER FASTER

PL-029K13 VERSION 1.0