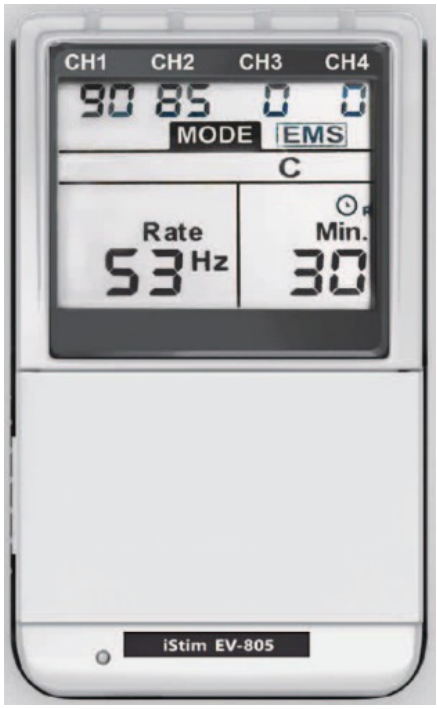
istm EV-805 Channel Rechargeable Combo Machine Instruction Manual

Channel Rechargeable Combo Machine
INSTRUCTION MANUAL
EV-805



Contents

Indication for Use

1. Everyway TENS/EMS combination stimulator is just combing the individual TENS function and individual EMS function in one device. The device only can be operated in TENS function mode or EMS function mode at the same time, it cannot be operated by both TENS and EMS function modes simultaneously.
2. TENS is intended for temporary relief of pain associated with sore and aching muscles in the low back as well as upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities. (Choose TENS Modes B/N/M/S1/S2 adjustable mode)
3. EMS is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. (Choose EMS Modes C/S/A adjustable mode)

Safety Instructions

Key Guidelines:

1. Read instruction manual before operation. Be sure to comply with all “CAUTIONS” and “WARNINGS” in the manual. Failure to follow instructions can cause harm to user or device.
2. Please read the following information carefully before using the EV-805 TENS/EMS combination stimulator.
3. This device is only to be used on adults aged 18 and over only.
4. Patients do not need special training or particular qualifications to use the device.
5. The risk associated with the potential use of the device is an excess current exceeding 10mA or an excess of current densities for any electrodes to exceed 2mA/cm2.
6. Any serious incident that has occurred in relation to the device should be reported to Everyway(manufacturer) and the competent authority of the Member State in which the user and/ or patient is established.
7. The device is a medical device, since it is a device to be used in combination with TENS/EMS for the treatment or alleviation of disease and /or injury.
8. The TENS/EMS device users are adults from the general public, i.e. lay users with no specific health literacy or medical training. They however likely have experience with a TENS/EMS device and some knowledge of the TENS/EMS (muscle stimulation, unit, etc.).

9. This TENS/EMS is suitable for use by all healthy adults; however, as with other forms of exercise, some care is needed when using it. Always follow the guidelines below and read the instruction manual before use. The unit can deliver a strong signal to your skin, so although it may be used by all healthy adults, it should only be used on healthy, uninjured skin.

Contraindications:
• Do not use this device if any of the following conditions are present:

1. Do not use this device if you have a cardiac pacemaker, implanted defibrillators or any other implanted metallic or electronic device.
2. Do not use this device if you have undiagnosed chronic pain.
3. Portable powered muscle stimulators should not be used while driving, operating machinery, or during any activity in which involuntary muscle contraindications may put the user at undue risk of injury.

Warnings for proper use and safety

1. Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
2. Stimulation should not be applied transcerebrally.
3. The device should be used only with the leads and electrodes recommended for use by the manufacturer.
4. If you are under the care of a Physician, consult with your Physician before using this device.
5. The long-term effects of this device are not known.
6. Do not place electrodes on or close to your heart.
7. Do not place electrodes around or close to your neck. Do not apply stimulation over the neck.
8. Severe spasms of the muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing. Stimulation over the neck could also affect hearing or blood pressure.
9. Do not apply stimulation across the chest because the introduction of electrical current into the chest may cause rhythm disturbances to the heart.
10. Do not place electrodes on or around your head. The effects of stimulation of the brain are unknown.
11. Do not use if you feel numbness.
12. Do not use these devices in or close to water.
13. Use this patch only on normal, healthy, clean, and dry skin. Do not use it on open wounds or rashes, or over swollen, red, infected, or inflamed skin.
14. If you have ever had back surgery, consult your Physician before using this device.
15. Do not apply stimulation over, or in proximity to, cancerous lesions.
16. Do not use the device on children if it has not been evaluated for pediatric use.
17. Consult with your physician before using this device, because the device may cause lethal rhythm disturbances to the heart in susceptible individuals.
18. No modification of this equipment is allowed.
19. Please dispose of it according to the local rule of the disposition of electronic devices/accessories.
20. Stimulation connection of a PATIENT to a high-frequency surgical medical device may result in burns at the site of the STIMULATOR electrodes and possible damage to the STIMULATOR.
21. Operation in proximity (e.g., 1m) to a shortwave or microwave therapy medical device may produce instability in the STIMULATOR output.

22. Do not apply stimulation on the eyes and mouth.
23. Do not servicing and maintenance of the equipment while in use.
24. Do not connect the device or electrode probe directly to a battery charger or any other device connected to an electrical outlet (i.e., mainspoweredequipment).
25. Do not use a Ni-Cd rechargeable battery or Lithium battery in the device.

Precautions for the Safe Use of EV-805 TENS/EMS Combination Stimulator.

1. TENS/EMS stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.
2. Read this User Manual before using this device for the first time.
3. Keep this manual available whenever you use this device.
4. This device is intended for individual person use only.
5. This device is not effective for pain associated with Central Pain,Syndromes, such as headaches.
6. This device is for pain caused by muscle soreness, and should be placed only around muscles where pain originates.
7. The pain may indicate that you have some other health problem.
8. You should know the reason and source of your pain before using these devices. Do not solely rely on the treatment of this device for pain.
9. The safety of using this device during pregnancy or birth has not been established.
10. The effectiveness of this device depends greatly on a person's individual physical condition. It may not always be effective for every user.
11. If you have had medical or physical treatment for your muscle pain, consult with your treatment provider before using this device. You should contact your physician prior to using this device following recent surgical procedures. Stimulation may disrupt the healing process.
12. Remove the battery if the equipment is not likely to be used for some time.
13. Please recycle the used battery in accordance with domestic regulations.
14. Do not throw the used battery into the fire.

⚠ Use Caution and consult your Physician before using EV-805 TENS/EMS combination stimulator if any of the following conditions apply to you:

1. If you have suspected or diagnosed heart problem.
2. If you have suspected or diagnosed epilepsy.
3. If you have a tendency to bleed internally following an injury.
4. If you recently had surgery, or have ever had surgery on your back.
5. If areas of skin lack normal sensations, such as skin that tingles or is numb.
6. During menstruation or during pregnancy.
7. Some people may feel skin irritation or experience a very sensitive feeling in the skin due to electrical stimulation. If this occurs, stop using these devices and consult your Physician.
8. If skin under the pad feels irritated after using the stimulator for a long period of time, use the stimulator for a shorter period of time.
9. Minor redness at stimulation placement is a normal skin reaction.
10. It is not considered a skin irritation, and it will normally disappear within 30 minutes after the electrodes are

removed. If the redness does not disappear after 30 minutes from the removal of electrodes, do not use the stimulator again until after the excessive redness has disappeared.

11. Turn off your device if the stimulation feels unpleasant or does not provide pain relief.
12. Keep this device out of the reach of children.
13. Use this device only with the pads and accessories recommended by the manufacturer.
14. Do not use this device when driving, operating machinery or when swimming.
15. Before removing these electrodes, be sure to turn it OFF, avoiding unpleasant stimulation.
16. If your pain does not improve, (!) or if it continues for four to six days, stop using this device and consult your Physician.
17. TENS function is not a substitute for pain medications and other pain management therapies.
18. TENS function have no curative value.
19. TENS function is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
20. EMS function is not intended for medical use, for the treatment of any medical condition, or for any permanent physical changes.

Adverse Reactions

1. Skin irritation and burns under the pads have been reported by some people who have applied electronic stimulators to their skin.
2. Only very rare occasions, first time users of EMS have reported feeling light-headed or faint.
3. We recommend that You use the product while seated until you become accustomed to the sensation.
4. You should stop using the device and should consult with your physician if you experience adverse reactions from the device.

Hydrogel Pads Precautions

1. To reposition hydrogel pads during a session, always pause the program currently running, reposition the hydrogel pads as directed “HYDROGEL PADS PLACEMENT” and then restart the program again.
2. Only use hydrogel pads supplied by the manufacturer with the TENS/ EMS. Any others may not be compatible with your unit and could degrade the minimum safety levels.
3. The hydrogel pads are for single person use only.
4. Do not plunge the hydrogel pads into water.
5. Do not apply solvents of any kind to the Hydrogel pads.
6. Always ensure the unit is OFF before removing the hydrogel pads.
7. Apply the whole surface of the hydrogel pads firmly to the skin.
8. Do not use hydrogel pads which do not adhere properly to the skin. You can purchase new hydrogel pads from the distributor.
9. If your skin is red under the hydrogel pads after a session, do not start another session on the same area until the redness has completely disappeared.

Note: If you are in doubt about using your TENS/EMS stimulator for any reason, please consult your doctor before use.

Accessories

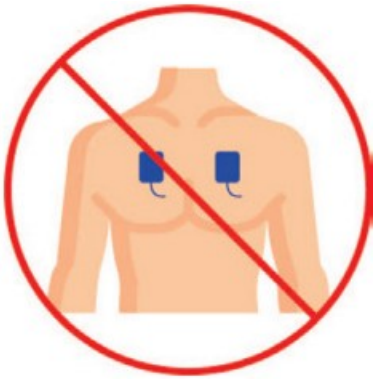
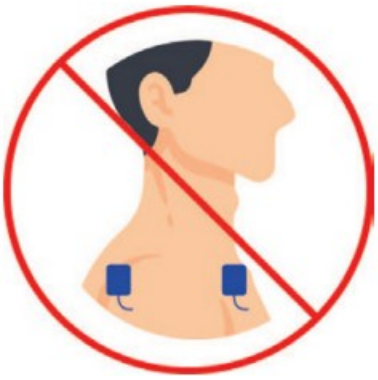
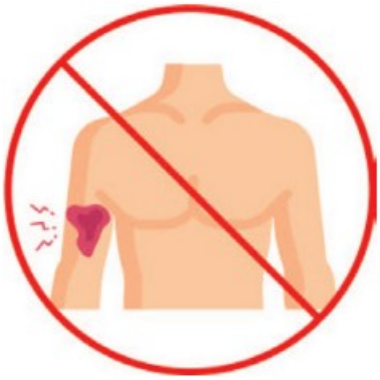
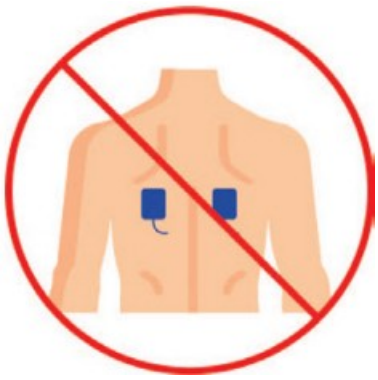
Each unit comes complete with standard accessories and the standard labels as given below:

1. Accessories:

Device	X 1 piece
Adhesive Electrodes	X 8 pieces (50X50mm)
Adhesive Electrodes	X 8 pieces (50X100mm)
Lead Wires	X 4 pieces
Instruction Manual	X 1 piece
1.5V (AA type) Battery	X 4 pieces
Paper case	X 1 piece

2. Label:
   The label attached to the back of the device contains important information about this device – model name, serial number, supply voltage, name of the manufacturer, and safety symbols.
   Please do not remove it.
3. UDI Serial Number(YYMMDDXXXX)
   The serial number of the device is put on the back of the unit. There are 10 digits in the number. The first 2 digits represent the year the unit is produced. For example, “16” means 2016. The second 2 digits means the month number. The third 2 digits means the Day number. The last digits means the serial number of unit produced in that week. Please always tell your distributor the serial number of the device if you have any question about the device

Where Never to Place the Hydrogel Pads
DO NOT apply hydrogel pads and use on the follow conditions.

	
On the head or face chest	On the neck
	
On both sides of the simultaneously	On the front and back of the thorax simultaneous
	
Over skin abrasions broken or inflamed skin	Never place the hydrogel pads with one half either side of

Caution When Using Hydrogel Pads

	Hydrogel pads are for single person use only
	Wash skin thoroughly before use
	Ensure skin is dry before applying the hydrogel pads

Introduction of TENS/EMS Device

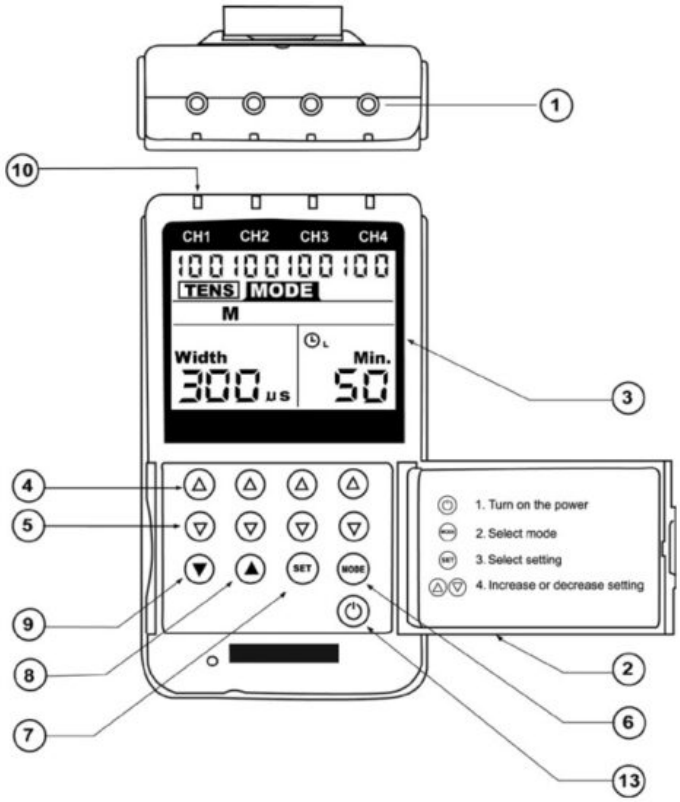
The TENS/EMS combination device, model EV-805 is a four channels TENS/ EMS stimulator used for pain relief and muscle training by applying an electrical current to electrodes, which are attached on the user's skin.
The TENS/EMS combination stimulator, model EV-805, consist mainly of two parts: the stimulus generator, electrode. The stimulus generator generates the output current specified as the input of controller. The output port transmits the output current to the electrode, which is attached to the user's skin so as to transmit this stimulus current for pain relief or muscle training.

For TENS programs:
Pain Relief TENS is intended for temporary relief of pain associated with sore and aching muscles in the low back as well as upper and lower extremities (armand/or leg) due to strain from exercise or normal household and work activities. There are 5 type modes (B, N, M, SD1, SD2) of TENS function. Whenusing any of the 5 modes function for pain relief always start with the lowest intensity and gradually increase the level of intensity until you feel a "tingling" sensation. All modes are different and therefore feel differently. You may tryall modes function in the beginning and choose one that feels pleasant. Never increase the intensity to a level so that it hurts, always stay under the point of discomfort. Start with short sessions of 5 or 10 minutes until your body gets used to the stimulation.

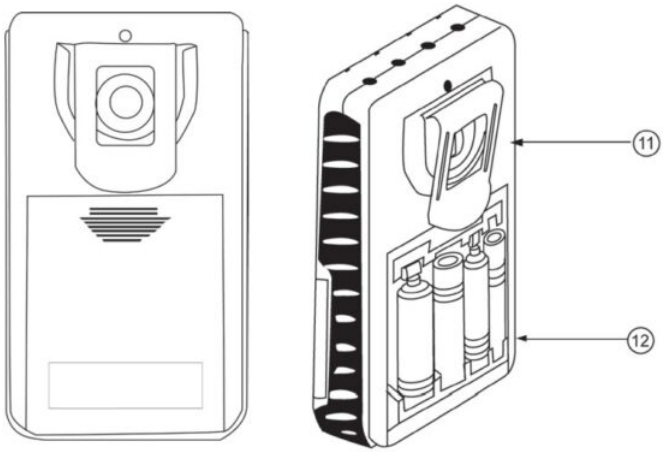
For EMS programs:
EMS is intended to stimulate healthy muscles in order to improve or facilitate muscle performance.
There are 3 type modes (C, S, A) of EMS function. When using the device for muscle stimulation (EMS) any of the 3 modes function may be used. The intent is to cause a muscle to contract, and then release. All modes will achieve contraction and vary mainly by the rate and duration of the contractions. As with any exercise regiment, start out slowly with low intensity levels for a warm-up (5~10min). You may increase intensity level and treatment time as you progress with your muscle performance. Use the device regularly over a longer period of time as to maintain the benefit you may have gained during "exercise".

For the hydrogel pads:
Included in this submission, we use the following of our EU Regulation 2017/745 (MDR) legally marketed predicate electrodes: DE/CA09/00183049 , "Self Adhesive Electrode", model no. #KF5050 , square size 50x50mm, pigtail connector.

Components and Functional Parts of the Unit

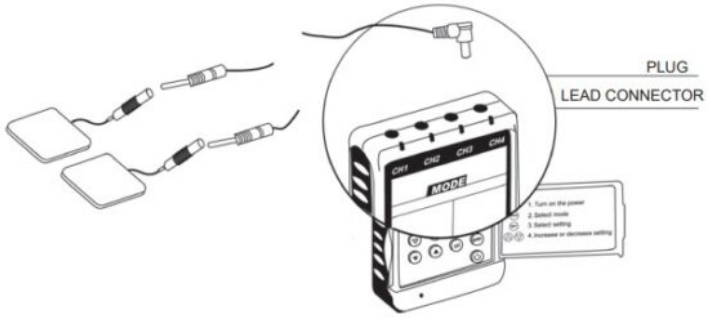


(1) Lead connector (2) Panel cover (3) LCD: Display related information of indications. (4) Intensity increase control (5) Intensity decrease control (6) Mode select	(7) Setting key (8) Setting increment (9) Setting decrement (10) LED (13) Power On/Off

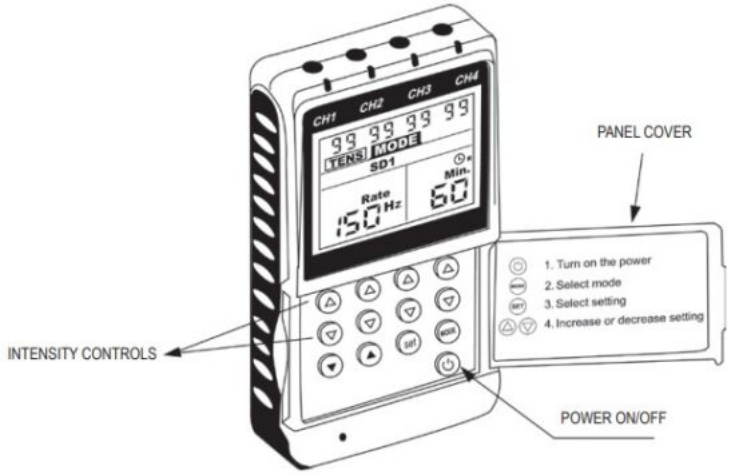


(11) Belt Clip
(12) Battery Compartment

① Lead connector
Connection of the electrodes is made with the two-lead connector (lead wires). The device must be switched off before connecting the cables. Electrodes must be pressed firmly on the skin.



② Panel cover
A lid covers the press buttons for turning ON/OFF the unit, selecting mode, adjusting settings and selecting intensity level.
Your medical professional may wish to set these controls for you and request that you leave the cover in place after intensity level is selected.



③ LCD: Display related information of indications.

④ Intensity increase control (△)
Push button for increasing the output power strength by individual 4 channels. Intensity level can be adjusted in 100 steps linearly.

⑤ Intensity decrease control (▽)
Push button for decreasing the output power strength by individual 4 channels. Intensity level can be adjusted in 100 steps linearly.

⑥ Mode select (MODE)
Pressing the “MODE” key sequentially for selecting 5 TENS modes (B, N, M,SD1, SD2) function, 3 EMS modes (C,S,A) function
Note: During in TENS modes, the LCD shows “TENS” and Mode name on the top.
During in EMS modes, the LCD shows “EMS” and Mode name on the top.

⑦ Setting key (SET)

Pressing the “SET” key sequentially then together with the “Setting increment” key (▲) and “Setting decrement” key (▼) for adjusting as:
– Pulse rate: 2~150Hz, 1Hz/step
– Pulse width: 50~300μs, 10μs/step
– Ramp time: 1~8 sec., 1sec./step (Only for EMS modes)
– On time: 2~90 sec., 1sec./step (Only for EMS modes)

– Offtime:0~90sec.,1sec./step(OnlyforEMSmodes)
– Timer: 1 to 60 min or Continuous, 1 min./step, and LCD will shows

⑧ Setting increment 

For setting to increase the value of Pulse rate, Pulse width, Timer, On time,Offtime,Ramptime.

⑨ Setting decrement 

For setting to decrease the value of Pulse rate, Pulse width, Timer, On time, Off time, Ramp time.

⑩ LED

Forindicatingthepoweroutputworkingbyflashing.

Belt Clip

Battery Compartment

Insert four new 1.5V batteries (AA type) into the BATTERY COMPARTMENT matching the “+” and “-” terminals.

Power On/Off 

Power of the unit can be turned on by pressing the power control button and can be turned off by pressing the button over 3 seconds when the device is on.

Program Modes and Specification

TENS: 5 modes

TENS Mode	Five TENS Modes: B(Burst), N(Normal), M(Modulation), SD1(Strength Duration), SD2(Strength Duration)
B: Burst Mode	Burst rate: Adjustable, 0.5-5Hz Pulse width adjustable, 50-300 ps Frequency fixed = 100 Hz
N: Normal Mode	Pulse rate: Adjustable, from 2 to 150 Hz, 1 Hz/step Pulse width: Adjustable, from 50 to 300 ps,10 ps/step The pulse rate and pulse width are adjustable. It generates continuous stimulation based on the setting value.
M: Modulation Mode	Pulse rate: Adjustable, from 2 to 150 Hz, 1 Hz/step Pulse width: Adjustable, from 50 to 300 ps,10 ps/step Modulation mode is a combination of pulse rate and pulse width modulation. The pulse rate and width are automatically varied in a cycle pattern. The pulse width is decreased by 50% from its original setting in 0.5 second, then the pulse rate is decreased by 50% from its original setting in 0.5 second. Total cycle time is 1 second. In this mode, pulse rate (2-150Hz) and pulse width (50-300ps) are fully adjustable.
SD1 Mode	Pulse rate: Adjustable, from 2 to 150 Hz, 1 Hz/step Pulse width: Adjustable, from 50 to 300 ps,10 ps/step The SD1(Strength-Duration) mode consists of automatic modulation intensity and pulse width in 40% range. The intensity is always increasing while the pulse width is decreasing and vice-versa. The intensity is decreased by 40% while the pulse width is increased by 40% in 5 seconds. In the next 5 seconds, the intensity is increased by 40% while the pulse width is decreased by 40%. Total cycle time is 10 seconds. Pulse rate(from 2-150Hz) and pulse width (from 50-300ps) are fully adjustable.
SD2 Mode	Pulse rate: Adjustable, from 2 to 150 Hz, 1 Hz/step Pulse width: Adjustable, from 50 to 300 ps,10 ps/step The SD2(Strength-Duration) mode consists of automatic modulation intensity and pulse width in 70% range. The intensity is always increasing while the pulse width is decreasing and vice-versa. The intensity is decreased by 70% while the pulse width is increased by 70% in 5 seconds. In the next 5 seconds, the intensity is increased by 70% while the pulse width is decreased by 70%. Total cycle time is 10 seconds. Pulse rate(from 2-150Hz) and pulse width (from 50-300ps) are fully adjustable.

EMS: 3 modes

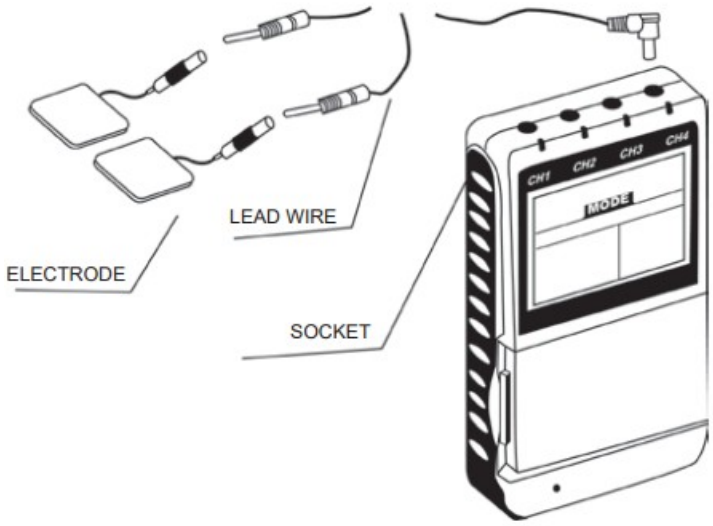
EMS Mode	Three EMS Modes: C (Constant), S (Synchronous), A (Alternate)
C: Constant Mode	Pulse width adjustable, 50-300ps Pulse rate adjustable, 2-150 Hz
S: Synchronous Mode	Pulse rate: Adjustable, from 2 to 150 Hz, 1 Hz/step Pulse width: Adjustable, from 50 to 300 psi 0 ps/step Stimulation of both channels occurs synchronously. The “ON” time including “Ramp Up” and “Ramp Down” time. Therefore, the setting of ON Time should be no less than two times of the “Ramp” time in this mode. ON TIME > Ramp up + Ramp down
A: Alternate Mode	Pulse rate Adjustable, from 2 to 150 Hz, 1 Hz/step Pulse width: Adjustable, from 50 to 300 ps,10 ps/step The stimulation of the CH2 will occur after the 1st contraction of CH1 is completed. In this mode, the setting of ON Time should be no less than two times of the “Ramp” time. The OFF Time should be equal or more than the ON Time. ON TIME > Ramp up + Ramp down OFF TIME > ON TIME

Interconnects with other components or accessories.

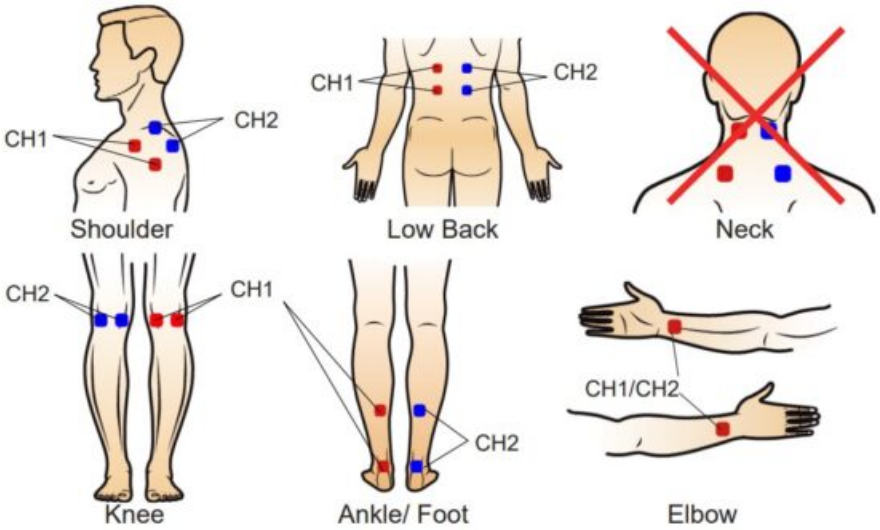
A. Attach lead wires to the device: The wires provided with the system insert into the jack sockets located on top of the device.

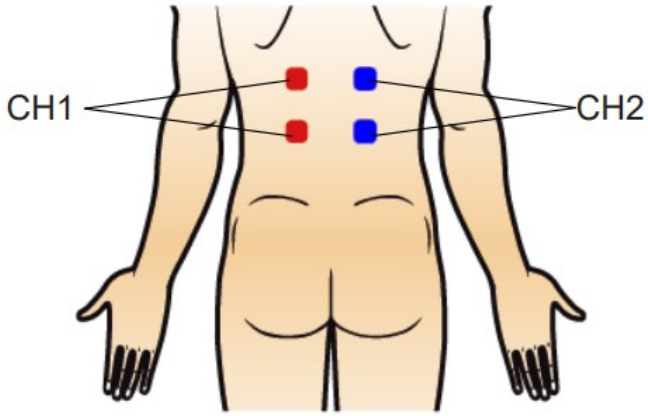
1. The device must be switched off before connecting the cables.
2. All intensity settings must be at the ZERO condition (No power output).
3. Holding the insulated portion of the connector, push the plug end of the wire into one of the jacks (see drawing); one or two sets of wires may be used.
4. Electrodes must be pressed firmly on the skin.

B. Placement of electrode The placement of electrodes can be one of the most important parameters in achieving success with TENS or EMS therapy.



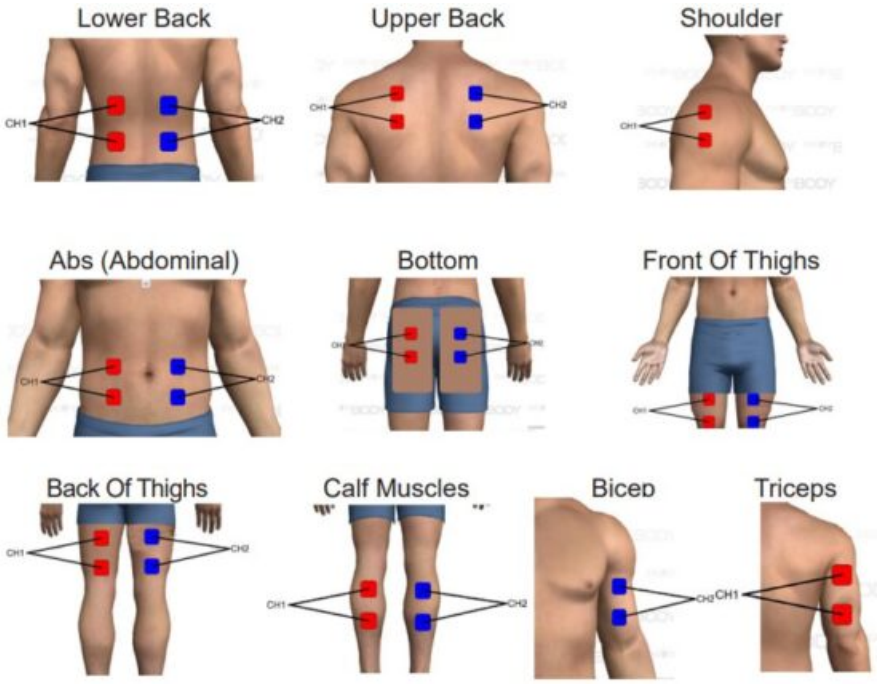
TENS
– For temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg)
– For temporary relief of pain associated with sore and aching muscles in the lower back





Note: You may need help to place the electrodes onto hard to reach areas.

EMS
– Place the hydrogel pads to exercise the muscles on one side of your body and that the two halves of the other lead are used on the other side of your body.
See the photos below for hydrogel pads positions:



Operation and Functions

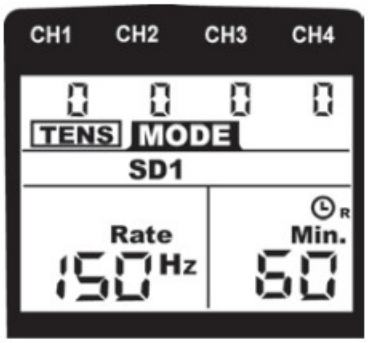
Steps to set TENS programs
a. Turn on the Power
After the electrodes are placed firmly on skin and the lead wires are plugged in the socket of device, push the "On/Off" key . The menu will reveal on LCD. Notice the indication of power and function on the LCD.

b. Select Mode

Select a mode by pressing the "MODE" key . The mode you selected will show up on the top of LCD. There are 5 modes of selection including:
B (Burst), N (Normal), M (Modulation), SD1 and SD2. When a TENS mode is selected, it shows TENS on the top of LCD.

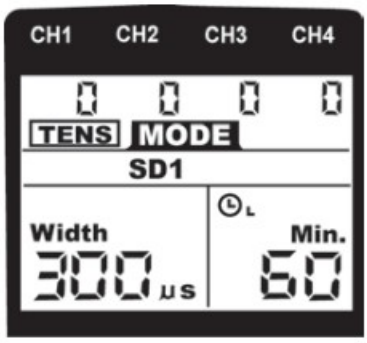
After a mode is selected, always press "SET" key to enter next setting, and press "Increment: key or

“Decrement” key ▼ to adjust the setting value when it is flashing.



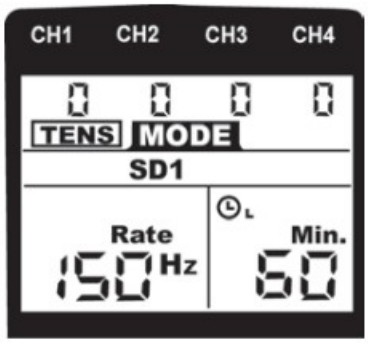
c. Set Pulse Width

Pulse Width is adjustable from 50μs to 300μs. Press “SET” key SET to enter this menu, then press “Increment” key ▲ or “Decrement” key ▼ to adjust the setting.



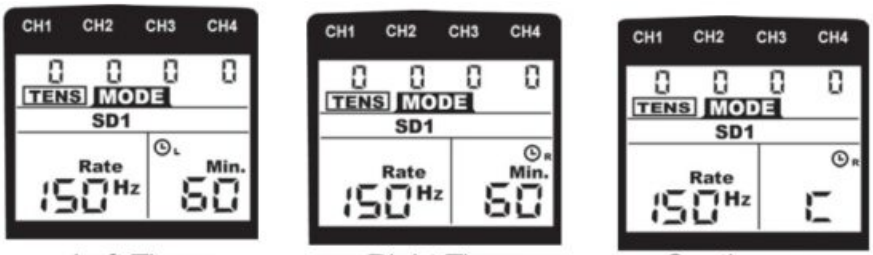
d. Set Pulse Rate

Pulse rate is adjustable from 2Hz to 150 Hz . Press “SET” key SET to enter this menu, then press “Increment” key ▲ or “Decrement” key ▼ to adjust the setting.



e. Set Timer

There are two adjustable timers available. The left timer controlling the treatment time of CH1 and CH2. The right timer controlling the treatment time of CH3 & CH4. The treatment time is adjustable from 1 to 60 minutes or C (Continuous). Press “SET” key SET to enter this menu, then press “Increment” key ▲ or “Decrement” key ▼ to adjust the setting. Press “Increment” key ▲ when the timer shows 60 minutes, it will be switched to continuous stimulation. Two timers can be set in the same way.



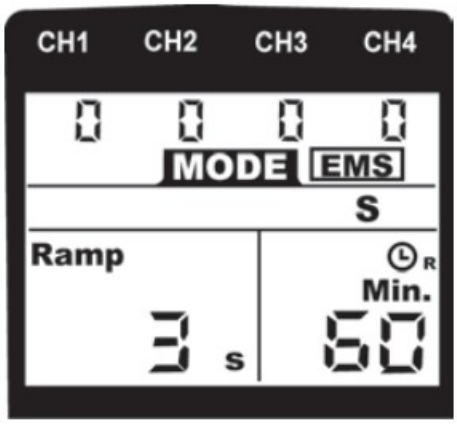
Steps to set EMS programs

a. Turn on the Power

After the electrodes are placed firmly on skin and the lead wires are plugged in the socket of device, push the "On/Off" key ⏻. The menu will reveal on LCD. Notice the indication of power and function on the LCD.

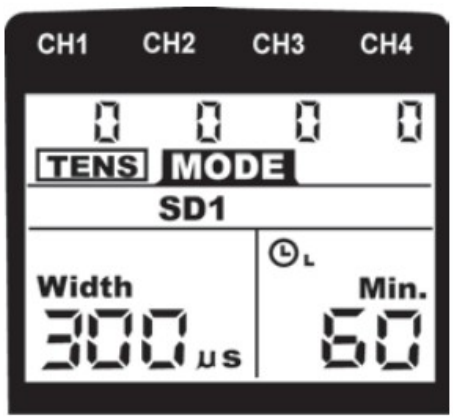
b. Select Mode

Select a mode by pressing the "MODE" key (MODE). The mode you selected will show up on the top of LCD. There are 3 modes of selection including: C (Constant) S (Synchronous) and A (Alternate). When a EMS mode is selected, it shows EMS on the top of LCD. After a mode is selected, press "SET" key (SET) to enter next setting, and press "Increment: key ▲ or "Decrement" key ▼ to adjust the setting value when it is flashing.



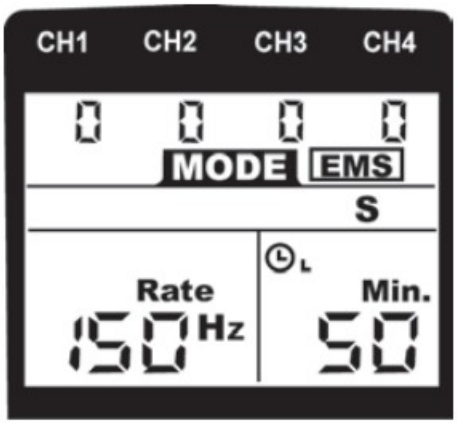
c. Set Pulse Width

Pulse Width is adjustable from 50 μs to 300 μs. Press "SET" key (SET) to enter this menu, then press "Increment" key ▲ or "Decrement" key ▼ to adjust the setting.



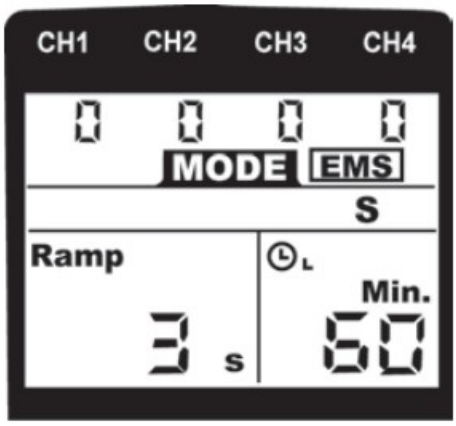
d. Set Pulse Rate

Pulse rate is adjustable from 2Hz to 150 Hz . Press “SET” key SET to enter this menu, then press “Increment” key ▲ or “Decrement” key ▼ to adjust the setting.



e. Set Ramp Time

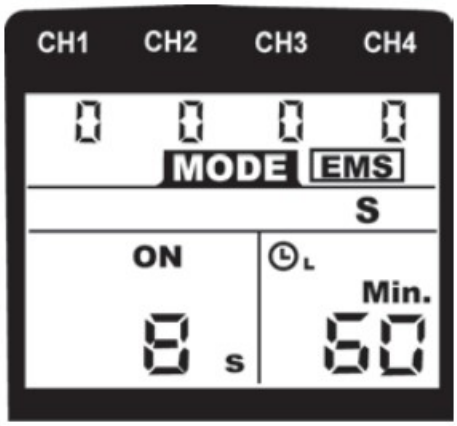
The Ramp time controls the time of output current that increase from 0 to the setting level, and from the setting value to 0. When the ramp time is set, each contraction may be ramped up and down in order that the signals come on and come off gradually and smoothly. The ramp time is adjustable from 1 to 8 seconds.



f. Set On Time

The On time controls the time of stimulation. By pressing the “SET” key SET, the contraction time can be adjusted. Both channels’ stimulation is cycled on and off by the contraction and relaxation settings. The range is adjustable from 2 Sec. to 90 Sec.

As the “ON” time including the Ramp up and Ramp down time, the setting of it should be no less than two times of the “Ramp” time. (ON time ≥Ramp up + Ramp down).

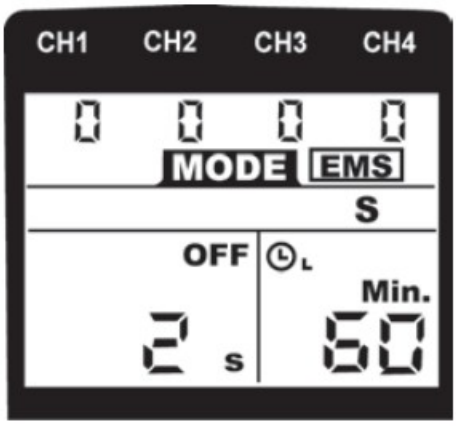


g. Set Off Time

The Off time controls the time of relaxation. By pressing the “SET” key SET, the relaxation time can be adjusted. Both channels’ stimulation is cycled on and off by the contraction and relaxation settings.

The range is adjustable from 0 second to 90 seconds. In Alternate mode, the “OFF” time should be equal or more

than the “ON” time. (OFF time ≥ON time).



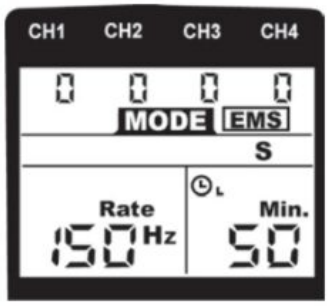
h. Set Timer

There are two adjustable timers available. The left timer controlling the treatment time of CH1 and CH2. The right timer controlling the treatment time of CH3 & CH4.

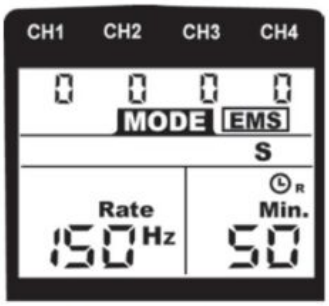
The treatment time is adjustable from 1 to 60 minutes or C (Continuous).

Press “SET” key (SET) to enter this menu, then press “Increment” key (▲) or “Decrement” key (▼) to adjust the setting.

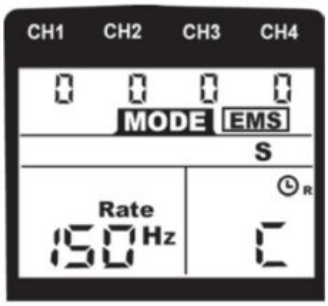
Press “Increment” key (▲) when the timer shows 60 minutes, it will be switched to continuous stimulation. Two timers can be set in the same way.



Left Timer



Right Timer



Continuous

After Use

1. The adhesiveness of Electrode is very high when first used and care should be taken when removing the complete unit, especially the first time.
2. Remove the electrodes from the skin by taking the electrodes at the edge and pulling carefully. Do not grasp at the wire. Replace the electrode pad onto the clear plastic shield.
3. Never remove the unit when it is switched on.
4. Remove the battery if the equipment is not likely to be used for some time.

● Notes for safety and care :

– Do not switch on the unit before the electrode pad is positioned on the body.
– Keep the electrodes from direct sunlight.
– Take care, that no water penetrates the unit.

Cleaning and Maintenance

Warning: The device was designed for single patient use. It is notrecommended to be used by any other than the person who owns the unit.

Device

1. The device does not require any special maintenance.
2. Never use aggressive cleaning products of stiff brushes.
3. Clean the device with a soft, possibly slightly moistened cloth (weekly for normal use condition).
   Step 1: Useaclean,dryandsoftclothtowipethedevicefirst.
   Step 2: Wet the cloth by tap water and wring it our as dry as possible, then clean it.
   Step 3: Clean the device again following Step 1.
4. Do not allow water to penetrate the device.
5. Do not use the device again until it is completely dry.
6. Do not expose the device to direct sunlight and protect it against dirt and moisture.

Battery

1. Only use 1.5 Volts (AA type x4)battery in the device.
2. Do not use rechargeable batteries in the device.
3. Replace the battery when the “LOW BATTERY INDICATOR” is flashing on the LCD screen of the device.
4. The device will not turn on if the battery voltage is below 1.3(+/- 0.1) Volts.If the “LOW BATTERY INDICATOR” is flashing, insert 4 new 1.5 Volts batteries.
5. Check the installed battery periodically and immediately remove the four 1.5 Volts batteries if there is any evidence of discharge.
6. If the device is not in use for an extended period of time (e.g. more than one week), remove the batteries completely.
7. Dispose of all batteries responsibly and in full compliance with all laws.

Electrodes and Lead Wire

1. For single person use only!
2. With the electrode pad on the protective plastic film, store the device in a cool, dry place.
3. Moisten the gel with a drop of water and allow it to dry briefly. Then stick the electrode back on the protective film.
4. The length of time the electrodes remain usable depends on their storage, skin type and use.
5. Replace electrodes when it is no longer stick or show cracks/ blemishes.
6. The electrodes are good for 5~10 times of use, 30 minutes each time.
7. User should periodically check the lead wire for damage.
8. Be sure to use only Everyway originally supplied of Self Adhesive Electrodes (EU Regulation 2017/745 (MDR)

: DE/CA09/00183049).

Replacement Parts
Contact your distributor to order replacement parts. Be sure to use only manufacturer's parts. You can check the Everyway website at **www.everyway-medical.com** for additional Product information.

TENS/EMS Combination Stimulator – Part # EV-805	Lead wires – Part # KE-26
	Self-Adhesive Pads – Part # KF5050 – 2mm diameter of pigtail connector – Electrode size: size 50x50mm
	AA Battery

Troubleshooting Guide

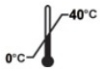
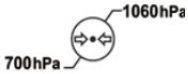
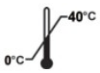
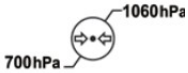
Problem	**Cause**	**Remedy**
LCD lights up weakly	-Battery low	-Changing battery
Low output from device	-Electrodes dirty -Device not applied p roperly	-Clean/replace electrode pad -Re-apply device
LCD function normal but no power output	-Battery low or near empty -Electrodes dirty or short- circuited	-Changing battery -Check electrode pads and replace if n ecessary
Device switches off prematurely	-Battery low or near empty -Electrodes worn out or dirty -Device not applied properly	-Changing battery -Check electrode pads and replace if n ecessary -Re- apply device

Product Information

Specifications
The relevant features and specifications of the device as below table:

	MECHANISM	**TECHICAL DESCRIPTION**
01	Channel	Four, isolated between channels
02	Pulse Amplitude	Adjustable 0-100mA, Max output 100mA peak to peak into 500ohm load each channel.
03	Voltage	Adjustable 0-50V, Max output 50V peak to peak into 500ohm load each channel.
04	Wave Form	Asymmetrical rectangular monophasic pulse
05	Power Supply	AA Battery x 4
06	Size	138(H) x 78(W)x28(D) mm
07	Weight	250 grams with battery
08	Pulse Rate	Adjustable, 2~150 Hz , 1Hz / step

09	Pulse Width	Adjustable, 50~300 μs , 10μs / step
10	On Time	Only for EMS mode: Adjustable, 2~90 seconds , 1 Sec./ step
11	Off Time	Only for EMS mode: Adjustable, 0~90 seconds , 1 Sec./ step
12	Ramp Time	Only for EMS mode: Adjustable, 1~8 seconds, 1 Sec./ step, The “On” time will increase and decrease in the setting value.
13	Timer	Adjustable timers, from 1 to 60 minutes or Continuous. Adjustable in 1 min./step
14	TENS Mode	Five TENS Modes: B(Burst), N(Normal), M(Modulation), SD1(Strength Duration), SD2(Strength Duration)
	B: Burst Mode	Burst rate: Adjustable, 0.5~5Hz Pulse width adjustable, 50~300μs Frequency fixed = 100 Hz
	N: Normal Mode	The pulse rate and pulse width are adjustable. It generates continuous stimulat ion based on the setting value.
	M: Modulation Mode	Modulation mode is a combination of pulse rate and pulse width modulation. T he pulse rate and width are automatically varied in a cycle pattern. The pulse width is decreased by 50% from its original setting in 0.5 second, then the puls e rate is decreased by 50% from its original setting in 0.5 second. Total cycle ti me is 1 second. In this mode, pulse rate (2~150Hz) and pulse width (50~300μs) are fully adjustable.
	SD1 Mode	The SD1 (Strength-Duration) mode consists of automatic modulation intensity and pulse width in 40% range. The intensity is always increasing while the puls e width is decreasing and vice-versa. The intensity is decreased by 40% while the pulse width is increased by 40% in 5 s econds. In the next 5 seconds, the intensity is increased by 40% while the puls e width is decreased by 40%. Total cycle time is 10 seconds. Pulse rate(from 2 ~150Hz) and pulse width (from 50~300μs) are fully adjustable.
	SD2 Mode	The SD2 (Strength-Duration) mode consists of automatic modulation intensity and pulse width in 70% range. The intensity is always increasing while the puls e width is decreasing and vice-versa. The intensity is decreased by 70% while the pulse width is increased by 70% in 5 s econds. In the next 5 seconds, the intensity is increased by 70% while the puls e width is decreased by 70%. Total cycle time is 10 seconds. Pulse rate (from 2 ~150Hz) and pulse width (from 50~300μs) are fully adjustable.
15	EMS Mode	Three EMS Modes: C (Constant), S (Synchronous), A (Alternate)
	C: Constant Mode	Pulse width adjustable, 50~300μs Pulse rate adjustable, 2~150 Hz
	S: Synchronous Mod e	Stimulation of both channels occurs synchronously. The “ON” time including “R amp Up” and “Ramp Down” time. Therefore, the setting of ON Time should be no less than two times of the “Ramp” time in this mode. ON TIME ≥ Ramp up + Ramp down
	A: Alternate Mode	The stimulation of the CH2 will occur after the 1st contraction of CH1 is comple ted. In this mode, the setting of ON Time should be no less than two times of th e “Ramp” time. The OFF Time should be equal or more than the ON Time. OFF TIME ≥ Ramp up + Ramp down ON TIME ≥ ON TIME

16	Operation Ambient Condition	Temperature: 0°~40°C  Relative Humidty: 30%~75%  Atmosphere Pressure: 700hPa~1060hPa  
17	Storage Ambient Condition	Tem perature: -20°~60°C  Relative Humidty: 20%~95%  Atmosphere Pressure: 500hPa~1060hPa  
18	Remark	All parameters up to +/-5% tolerance Amplitude & Voltage up to +/-20% tolerance

Conformity to Standards

The TENS/EMS Combination stimulator is in compliance with:
– EN60601-1:2006/A1:2013 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
– EN60601-1-2:2015 Medical electrical equipment – Part 1-2:General requirements for basic safety and essential performance –CollateralStandard:

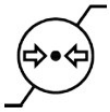
Warranty

Everyway provides a limited warranty to the original purchaser that this product will be free from defects in the material, components, and workmanship for a period of two (2) years from the date of purchase.
If Everyway is satisfied that the product is defective the purchaser may return the unit(s) to Everyway or to the appointed distributor for repair or replacement with a new unit. All returns must first be authorized by Everyway. The liability of Everyway under this limited product warranty does not extend to any extent to any misuse or abuse such as heating, cooling, freezing, tampering with or dismantling the device, commercial use, or normal wear and tear. Any evidence of abuse or tampering with the device will nullify this warranty.
The warranty does not apply to damage resulting from failure to follow operating instructions, accidents, abuse, alterations, or disassembly by unauthorized individuals
This warranty does not cover consumable items, including batteries, lead wire, and incontinence electrode probe.

Description of symbols

• There are several technical symbols on your unit explained as follows:

	Caution! (Electrical output).

	Consult instructions for use! Failure to do so could place the patient or operator at risk.
	Patient’s shock protection type: BF (Body Floated) Equipment. This equipment is not earthed but contains a battery within an insulated uni t.
	Manufacture information including the name and the address of the manufacturer (the person placing the device on the market).
	Importer
	Distributor
	Translation
	This symbol means “Temperature limit”, indicates the temperature limits to which the m edical device can be safely exposed.
	This symbol means “Humidity limitation”, indicates the range of humidity to which the medical device can be safely exposed.
	This symbol means ” Atmospheric pressure limitation”, indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	Keep away from sunlight or heat
	Keep dry or keep away from rain
	Medical device
	Indicates the Authorized Representative in the European Community.
	Notified Body Number of DNV Product Assurance AS
	Degrees of protection provided by enclosures (IP Code)
	Unique Device Identifier
	Waste Electrical and Electronic Equipment Directive 2012/19/EU

Electromagnetic Compatibility Information

1. The device complies with current specifications with regard to electromagnetic compatibility and is suitable for use in all premises, including those designated for private residential purposes. The radio frequency emissions of the device are extremely low and in all probability do not cause any interference with other devices in the proximity.
2. It is recommended that you do not place the device on top of or close to other electronic devices. Should you notice any interference with other electrical devices, move the device or connect it to a different socket.
3. Radio equipment may affect the operation of this device.

Table 1. Guidance and MANUFACTURER'S declaration—electromagnetic IMMUNITY—for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	"Not Applicable" No testing"	—	Portable and mobile RF communications equipment should be used no closer to any part of the Electrical Stimulator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 0.6\sqrt{P}$ $d = 0.35\sqrt{P}$ 80 MHz to 800 MHz $d = 0.7\sqrt{P}$ 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 equipmentmarked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	10 V/m [E1]	

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 Electrical Stimulator system is used exceeds the applicable RF compliance level above, the Electrical Stimulator system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Electrical Stimulator system.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 6 V/m.

Table 2. Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT or ME SYSTEM — for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

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

Rated maximum out put power of trans mitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz d= [3.5/V1] √P =0.6√P	80 MHz to 800 MHz d= [3.5/E1] √P =0.35√P	800 MHz to 2.5 GHz d= [7/E1] √P =0.7√P
0,01	0.06	0.04	0.07
0,1	0.19	0.11	0.22
1	0.60	0.35	0.7
10	1.90	1.11	2.21
100	6.0	3.50	7.0

Table 3. Guidance and MANUFACTURER.S declaration—electromagnetic IMMUNITY—for all ME EQUIPMENT and ME SYSTEMS
The unit is intended for use in the electromagnetic environment specified below.
The customer or the user of the unit should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic disc harge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic t ile. If floors are covered with synthetic materi al, the relative humidity should be at least 5%
Electrical fast tra nsient/burst IEC 61000-4-4	±2 kV for power supply l ines ±1 kV for input/ output li nes	Not Applicable No testing	Mains power quality should be that of a typic al commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not Applicable No testing	Mains power quality should be that of a typic al commercial or hospital environment.
Voltage dips, short interruption s and voltage va riations on power supply inp ut lines IEC 61000-4-11	0 % UT ; 0.5 cycle At 0o , 45o, 90o, 135o, 180o, 225o, 270o and 315o 0 % UT ; 1 cycle And 70 % UT ; 25/30 cycle Sing le phase: at 0o	Not Applicable No testing	Mains power quality should be that of a typic al commercial or hospital environment. If the user of the EQUIPMENT or SYSTEM require s continued operation during power mains int erruptions, it is recommended that the EQUI PMENT or SYSTEM be powered from an uni nterruptible power supply or a battery.
Power frequency (50/60 Hz) magn etic field IEC 610 00-4-8	30A/m	30 A/m	Power frequency magnetic fields should be a t levels characteristic of a typical location in a typical commercial or hospital environment The magnetic field from common appliances are not expected to affect the device.

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

Table 4. Declaration – electromagnetic EMISSIONS
The unit is intended for use in the electromagnetic environment specified below.
The customer or the user of the unit should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
CE emissions CISP R11	**Group 1**	The Electrical Stimulator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause an y interference in nearby electronic equipment.
RE emissions CISP R11	**Class B**	The Electrical Stimulator 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 f or domestic purposes.
Harmonic emis-sion s IEC 61000-3-2	**“Not Appli- c able, No testi ng”**	
Voltage fluctuations/ Flicker emissions IE C 61000-3-3	**“Not Appli- c able, No testi ng”**	

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Distributor Everyway4all EU B.V.

Translation Everyway4all EU B.V.

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Documents / Resources

	istm EV-805 Channel Rechargeable Combo Machine [pdf] Instruction Manual EV-805 Channel Rechargeable Combo Machine, EV-805, Channel Rechargeable Combo Machine, Rechargeable Combo Machine, Combo Machine, Machine

References

- fuego.si - This website is for sale! - fuego Resources and Information.
- EVERYWAY MEDICAL INSTRUMENTS CO., LTD. Rehabilitation Bed, Electric Rehabilitation Bed, Manual Therapy Bed, Rehabilitation Bed, Chiropractic Bed, Traction Bed, Medical Bed, Rehabilitation Three-piece Bed, Advanced Rehabilitation Bed, Standing Hospital Bed,
- User Manual