EM-5200 Wireless

TENS & EMS Unit

Please read this user manual before using your device

EVERYWAY

ISO9001/ISO13485

Telephone : 02-2662-0038 www.everyway-medical.com

Comes Complete with:

2 x Wireless TENS & EMS Unit
1 x Wireless TENS & EMS Remote Controller
1 x Large Back Electrode 22cm x 10cm
2 x 10x5cm Electrodes
2 x USB Charging Leads
1 x User Manual

EVERYWAY
ISO9001/ISO13485

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Telephone: 02-2662-0038

INTRODUCTION

Thank you for purchasing the Wireless TENS & EMS Unit
It is the most advanced Wireless Stimulator and is manufactured to the highest of medical standards which fully comply to the Medical Device Directive (M.D.D).

GENERAL DESCRIPTION

The Wireless TENS & EMS Unit device is a rechargeable battery operated Stimulator which sends electrical impulses from the remote control to the module through a bluetooth signal. The electrodes are attached to the module using snap connectors, which are then placed over the painful site. This stimulates what are the nerves causing the pain, which in turn blocks the pain signals to the brain.

SKIN PATCH TEST

It is recommended that you carry out a patch test before applying your first treatment, To do this remove one electrode from the packaging and place on a part of your body which is both visible and easy to inspect. After 30 minutes, remove the electrode and inspect the area for any redness or irritations. If no change is noticed, proceed with your first TENS treatment following the User Guide and instructions provided. If skin irritation has been noticed we recommended the use of sensitive gel electrodes.

WARNINGS & PRECAUTIONS

PLEASE NOTE:

It is imperative that patients read and understand the warnings and precautions before using this device. Do not allow your machine or electrodes to be used by anyone else, as they are designed for single patient's use only. It is recommended that proper medical advice on the use of TENS is sought from a Qualified Practitioner (Physiotherapist, Doctor or Nurse) prior to use, in order to ensure safe and effective treatment. If you are taking any medication please carry on as normal but seek advice from your Doctor/Healthcare Professional before using the device.

WARNING! PATIENTS WITH PACEMAKERS MAY NOT BE TREATED WITH TENS

- Do Not use during pregnancy except during labour (under medical supervision)
- Do Not place electrodes over the Carotid Sinus
- Do Not use on broken or damaged skin
- Do Not place electrodes close to the eyes or in the mouth.
- Do Not use TENS whilst driving or operating machinery.

TENS is unsuitable and should not be used in the following situations.

- Persons suffering from conditions where the circulation is impaired.
- Epilepsy, Heart Condition or any form of Malignancy.
- Patients with poor skin sensation and non-compliant patients who are emotionally disturbed or have dementia.
- Over metal implants or in conjunction with sleep apnea or heart monitors.

You should be aware that TENS units provide symptomatic relief only and are not considered curative.

INTRODUCTION TO TENS

What is TENS?

Transcutaneous electrical nerve stimulation is a pain control treatment. It is often called TENS for short.

A TENS unit is a portable, pocket-sized, battery-powered device.

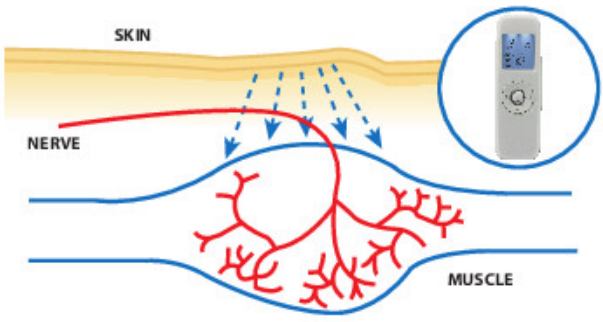
The TENS unit uses mild, safe electrical signals to help control pain and delivers the electrical signal to the body through self-adhesive conductive electrodes.

How does TENS work?

The most common TENS programmes use high-frequency stimulation, which is the first choice for both acute and chronic pain.

High-frequency stimulation sends impulses to the nervous system's own pain-inhibiting mechanisms, which block the pain.You can use it as often and as long as you like, but each treatment should last at least 1 hour.

Another type of TENS is low-frequency stimulation. Low-frequency TENS treatment can alleviate pain by stimulating muscles to release the body's own morphine-like substances, called endorphins.



INTRODUCTION TO TENS

During the TENS treatment

If your muscles start to twitch, this may mean that the TENS signals are too strong or too fast. If you cannot feel any tingling at all, this may mean that the signal is too weak or too slow.

The electrodes should be removed at least once a day if the TENS treatment is used around the clock. The skin under the electrodes must be checked to see if it is red or tender. The skin should also be cleaned and dried while the electrodes are off. Apply lotion to your skin where the electrodes were placed. The electrodes should be applied to a different area for each new treatment. This will help prevent the skin from becoming red or sore.

TENS can be used for

TENS can be used to treat most types of pain where the cause has been determined including:

- Arthritis
- Back Pain Post Herpatic
- Bruising Neuralgia
- Calf Strain
- Dead Leg
- Fibrositis Finger Pain
- Rheumatism
- Sciatica
- Headaches
- Migraines
- Shoulder Pain
- Sleeplessness
- Knee Pain
- Lumbago Muscle
- Stress
- Sports Injuries
- Tennis Elbow
- Neck Pain
- Neuralgia
- Osteoarthritis

INTRODUCTION TO EMS

This EMS unit is used for muscle stimulation. The device is provided with controllable output channels, each independent of the other. A pair of electrodes can be connected to each output channel. An independent switch controls the intensity level and settings.

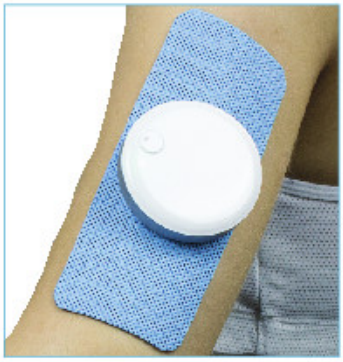
EXPLANATION OF EMS

Electrical Muscle Stimulation is an accepted and proven way of treating muscular injuries. It works by sending electronic pulses to the muscle injuries. It works by sending electronic pulses to the muscle needing treatment: this causes the muscle to contract.

It is derived from the square waveform, originally invented by John Faraday in 1831. It works by directly stimulating motor neurons which cause muscle contraction. It is widely used in hospitals and sports clinics for the treatment of muscular injuries and for the re-education of paralyzed muscles, to prevent atrophy in affected muscles and improve muscle tone and blood circulation.

IMPORTANT SAFETY INFORMATION

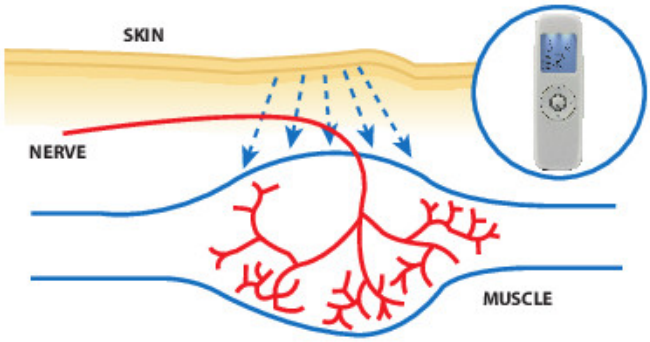
Read Instruction Manual before operation. Be sure to comply with all "CAUTIONS" and "WARNINGS" in the manual. Failure to follow instructions can cause harm to user or device.



HOW EMS WORKS

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Muscle re-education
5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
6. Maintaining or increasing range of motion

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 the signal strength increases, the muscle contracts as in physical exercise. When the pulse ceases the muscle relaxes and the cycle starts over again, (Stimulation, Contraction and Relaxation). Powered muscle stimulators should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.



CAUTIONS

1. Safety of powered muscle stimulators for use during pregnancy has not been established.
2. Caution should be used for patients with suspected or diagnosed heart problems.
3. Caution should be used in the presence of the following:
   a. When there is a tendency to haemorrhage following acute trauma or fracture;
   b. Following recent surgical procedures when muscle contraction may disrupt the healing process;
   c. Over the menstruating or pregnant uterus; and
   d. Over areas of the skin which lack normal sensation.
4. Some patients may experience skin irritation or hypersensitivity due to electrical stimulation or electrical conductive medium. Using an alternate conductive medium, or alternate electrode placement can usually reduce the irritation.
5. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
6. Powered muscle stimulators should be kept out of the reach of children.
7. Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.
8. Portable powered muscle stimulators should not be used while driving, operating machinery or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

WARNINGS

1. The long term effects of chronic electrical stimulation are unknown.
2. Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
3. 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.
4. Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
5. Stimulation should not be applied transcerebrally
6. Stimulation should not be applied over swollen, infected, inflamed areas or skin eruptions, eg, phlebitis, thrombophlebitis, varicose veins etc.
7. Stimulation should not be applied over or in proximity to cancerous lesions.

Contraindication

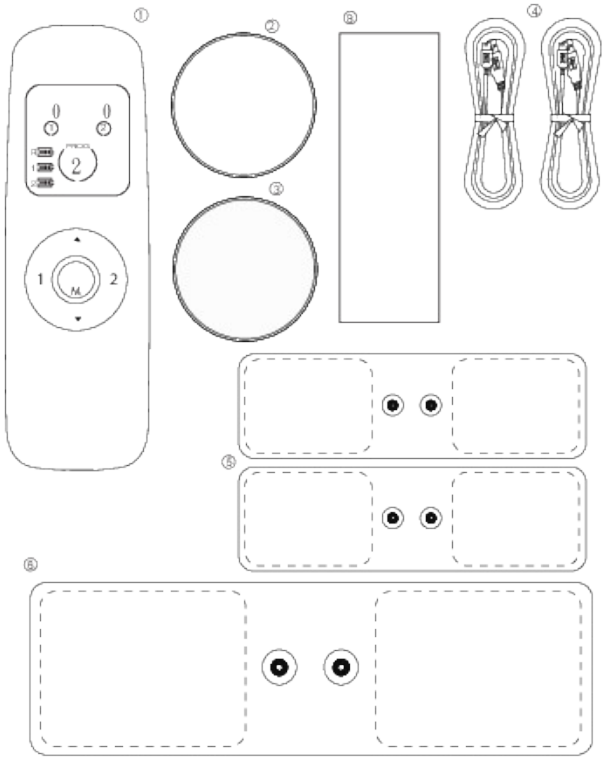
Electrical stimulators should not be used on patients with cardiac demand pacemakers.

Adverse Reactions

On rare occasions skin irritation and burns beneath the electrodes have been reported with the use of electrical stimulators. If irritation occurs, discontinue use and consult your Healthcare Professional.

CONTENTS & GENERAL INFORMATION

Please check carefully the contents of the Wireless TENS & EMS Unit



1. Remote Control Unit
2. TENS & EMS Unit Module 1
3. TENS & EMS Unit Module 2
4. USB Charging Leads x2
5. Self Adhesive Electrodes 10cm x 5cm x2
6. Self Adhesive Electrode 22cm x 10cm (Lumbar)
7. Instruction & User Manual

CHARGING THE REMOTE CONTROL AND MODULE

Please fully charge the remote control and both module before using the device

USB Charging Port

USB Charging Port

The USB cable only fits one way please do not force into the sockets as this will damage the device.

CHARGING THE REMOTE USING THE AC ADAPTOR

Fig 1

Connect the small end of the USB cable to the remote and the larger end to the USB power port (as shown in Fig 1)

During charging, the letter R will flash on the display. Three bars in the battery symbol indicate a fully charged battery.

*Charging time from a flat state approx. 90 minutes.

CHARGING THE TENS MODULE

Connect the USB, as already described, to the module See Fig 3.

Fig 3

In charge mode

Fully charged

A red light indicates the module are in charge mode. Once fully charged the light will turn green. (the module charge time from a fully discharged state is approx. 90 minutes).

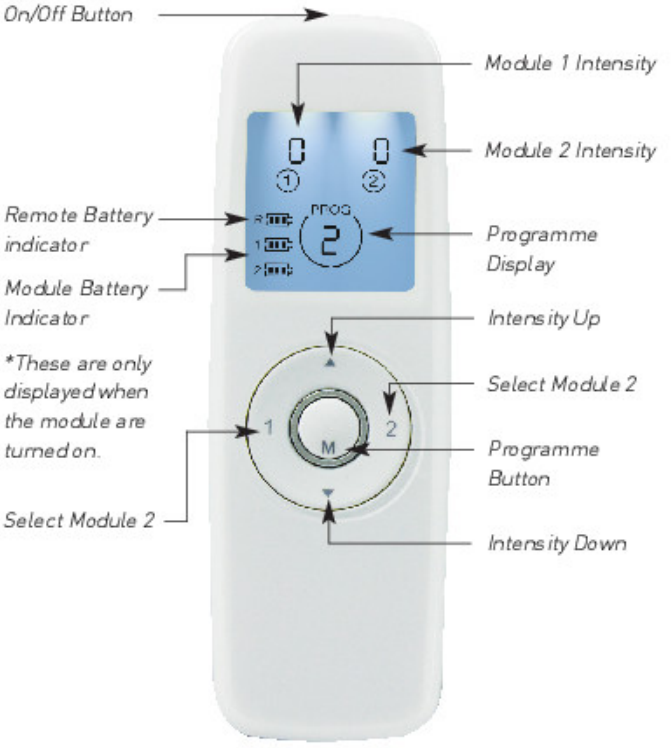
CHARGING YOUR DEVICES VIA A COMPUTER USB PORT

You may charge your TENS remote and TENS module through a computer by using the USB port (See Fig 2).

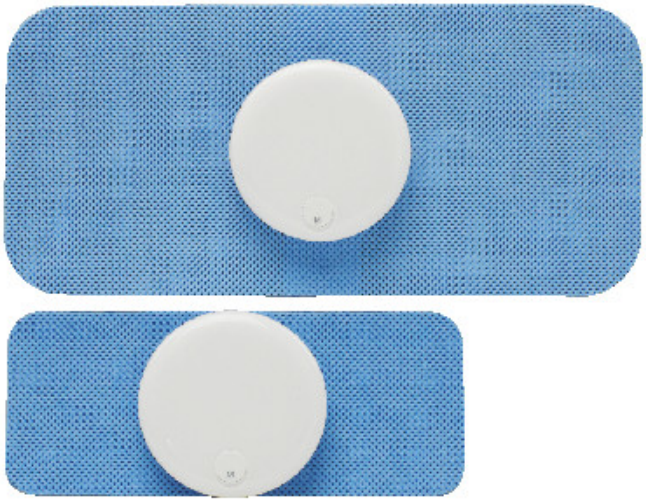
Please note your computer must be switched on to perform this function.

REMOTE CONTROL FUNCTIONS

The remote control and functions are very simple to operate. We have illustrated this in Fig A below.



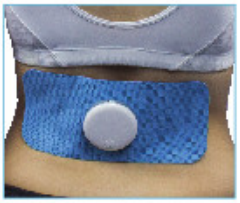
CONNECTING THE SELF-ADHESIVE ELECTRODES

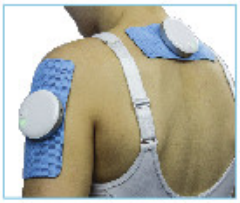


The Wireless TENS & EMS Unit is supplied with

2 x 5cm x 10cm electrodes

1 x 10cm x 22cm Large Back Electrode





To connect the module simply press the module on to the snap connectors on your electrodes. Remove the plastic film from the electrode and place directly to the area of the body to be treated.

After each treatment please place your electrodes back on to the plastic film provided.

ELECTRODE INSTRUCTIONS

Turn Stimulator OFF before applying or removing electrodes

Application

1. Skin site must be very clean and dry. Dirty, flaky or oily skin will prevent electrodes from adhering to the skin. If necessary, trim excess hair with scissors. If skin is oily wipe down with an alcohol or electrode skin prep prior to application. Be sure to wash hands before handling electrodes.
2. Remove electrodes from bag and reseal bag to protect remaining electrodes.
3. Insert lead wire pin from the stimulator into the wire connector of the electrode, making sure that no bare metal shows.
4. Grasping a tiny edge of the electrode, peel and remove electrode from the protective plastic liner. Do not remove by pulling on the wire connector. Save liner for electrode storage.
5. Place electrode onto skin treatment site (as recommended by your clinician) by firmly applying from the centre of the electrode to the outer edges. Adhesion improves when electrodes reach skin temperature.
6. If gel appears oversaturated with excessive moisture or perspiration, allow the electrode to air-dry in a refrigerator with the gel side facing up until the gel regains its tack. Ifthe gel appears dry, try adding a few drops of water to the gel and allow to rest in a dust-free environment until the gel regains its tack.

Removal and storage

1. Lift a corner of the electrode and slowly peel the electrode off the skin, touching the adhesive gel as little as possible.
2. Place the electrodes back onto the saved protective plastic liner.
3. While grasping the electrodes connector with one hand, use the other hand to gently twist and disconnect the lead wire pin from the electrode connector. Do not pull on the electrode wire connector as this may damage the electrode.
4. Return the electrodes back into the storage bag and reseal tightly to prevent dry-out.
5. Store at room or cool temperature and keep out of direct sunlight.
6. The life of the electrode varies depending on skin conditions, amount of use, storage and climate. Electrode life may be extended by carefully following the application, removal, and storage instructions.

Caution

1. DO NOT place electrodes on broken skin. If skin irritation develops discontinue use. Consult physician. Replace electrodes when they do not adhere or when treatment becomes uncomfortable.
2. DO NOT use unit while driving or operating machinery
3. DO NOT wear electrodes when showering, bathing or swimming
4. DO NOT apply electrodes across the head or across the heart or on the front neck.
5. Keep electrodes separated during treatment
6. DO NOT remove electrode by pulling on the lead wire.
7. DO NOT exceed 0.1 watts/cm2
8. Using stimulation electrodes that are small or incorrectly applied could result in discomfort or skin burns.
9. Latex Free

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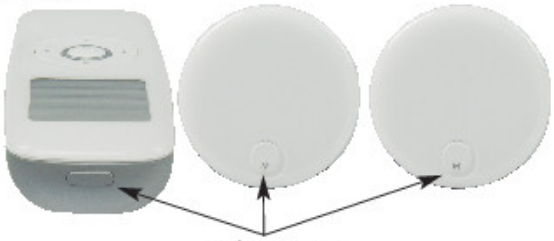
INSTRUCTIONS FOR USE
A STEP BY STEP GUIDE

STEP 1

Fully charge the batteries as described on pages 14 & 15

STEP 2

Switch on both the remote control and both module as Fig 4.

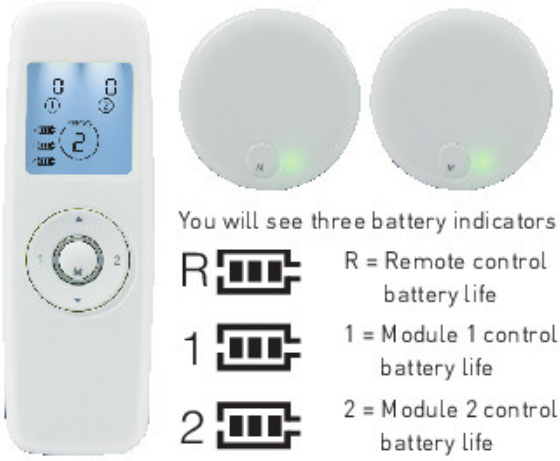


On/Off Buttons

Please note

When the units are not in use, all devices will automatically shut down after two minutes.

Once the remote and module are switched on the displays will be as shown in Fig 5.



You will see three battery indicators

R R = Remote control battery life

1 1 = Module 1 control battery life

2 2 = Module 2 control battery life

This indicates the module and remote controls are functioning and are ready for use.

INSTRUCTIONS FOR USE
A STEP BY STEP GUIDE

STEP 3

Choosing the programmes

The Wireless TENS & EMS Unit device has 15 clinically validated programmes to choose from.

9 TENS programmes (1-9).

6 Muscle stimulation programmes (A-F).

To change programmes simply press the M button in the centre of the remote control.

Each press of the button will change the programme to the next programme.

STEP 4

We always recommend that you start with programme 1. This is a gentle TENS treatment and excellent pain block effects and is a good introduction to TENS stimulation.

STEP 5

You are now ready to use your device for the first time.

STEP 6

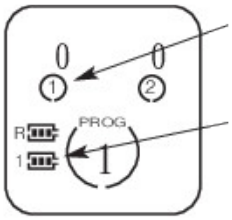
Connect Module 1 to one of the electrodes as previously described and turn on Module 1, Now apply to the painful site to be treated.

Please note you will feel no sensation until you increase the intensity which is described in step 8.

INSTRUCTIONS FOR USE
A STEP BY STEP GUIDE

STEP 7

The display on your remote will be as shown in Fig 7.

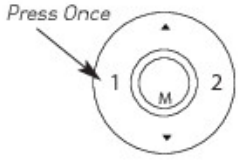


Circle around 1 indicates the module is connected and ready for use.

Battery indicator for Module 1 is displayed when the module is switched on.

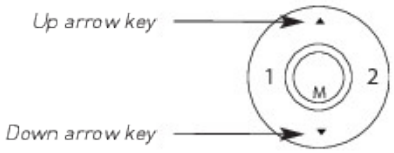
STEP 8

Press the 1 on the remote control as shown below.



The No1 will flash inside the circle. You can now increase the intensity by pressing the up arrow key. It is only possible to increase or decrease the intensity whilst the number is flashing within the circle on your remote control. This prevents accidental increase in the intensity.

Each press of this key will increase the output by 1. It is recommended that you increase the intensity to a level which is pleasant but not uncomfortable. The sensation you feel should be a mild sensation and not strong.

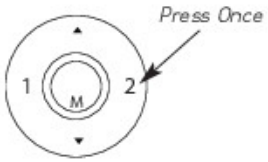


INSTRUCTIONS FOR USE
A STEP BY STEP GUIDE

STEP 9

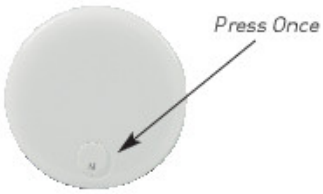
With many conditions you may need to use both module 1 and module2, simultaneously. To do this simply follow the procedure as described for module 1, and repeat the process by pressing the number 2 as shown below in Fig G.

Fig G



Press once to turn on Module 2

You will need to turn on Module 2 before proceeding..



STEP 10

Ending your treatment

All TENS programmes run on a continuous timer, to meet the requirements of the clinically approved programmes

WHICH PROGRAMME SHOULD I USE?

We always recommend you start with programme 3, as already mentioned in your step-by-step guide. The Wireless TENS & EMS Unit has 9 p rogrammes P1 to P9, Each programme has been shown to reduce and block pain in a wide range of conditions. It is very difficult to know which programme is best for you. It is therefore recommended that over a period of time you try all 9 programmes. To help get you started, we have included some common conditions with suggested electrode placements including treatment times and recommended programmes you may wish to try.

HOW HIGH SHOULD I TURN THE INTENSITY?

Everybody reacts differently to TENS Stimulation so it is important that you increase the intensity (sensation feeling) to the correct level.

Increase the intensity to a sensation which is comfortable and always perceptible; never turn up to a level which is strong and uncomfortable.

You may use TENS if required for long periods of time to combat long term chronic pain; however, please remember to place the electrodes in slightly different areas around the painful site, as this will help reduce skin irritation.

HOW LONG SHOULD A TYPICAL TREATMENT TIME LAST

The most up to date research in TENS treatment times indicates that a minimum of 1 hour to $1^{1}/_{2}$ hours is required for effective pain relief. Your TENS may be used for much longer periods and you may find treatment times of 3 to 4 hours may work best for you.

Please remember that the intensity level is always kept at a pleasant sensation, never increase the intensity to uncomfortable levels as this can possibly have a detrimental effect on your results.

THE MED-FIT 2 PREMIER WIRELESS TENS PROGRAMS P1 - P9

NO	PROGRAMME	FREQUENCY	PULSE WIDTH
1	**Covential TENS** Ideal for first applications of TENS for both acute and long term pain **CONDITIONS** Neck, Shoulder, Elbow Pain, Rheumatic Pain, Lumbago, Hip Pain, Osteoarthritic Pain in the knee	80Hz	180µs
2	**Burst TENS** Most effective for radiating pain if arms and legs and deep muscular pain **CONDITIONS** Osteoarthritic Pain in the Knee, Sciatica Central Pain	2Hz	180µs
3	**Modulated TENS** Pain relief with a massage effect **CONDITIONS** Neck, Shoulder, Elbow Pain, Rheumatic Pain, Lumbago, Menstrual Pain, Hip Pain, Osteoarthritic Pain in the knee	80Hz	70-180µs
4	**Mixed Frequency TENS** **CONDITIONS** Osteoarthritic Pain in the knee, Neck Pain, Shoulder Pain, Menstrual Pain, Central Pain Lumbago	15Hz/2Hz	180µs
5	**Fixed Frequency TENS** Effective programmes for long term use with reduced accommodation factor **CONDITIONS** Osteoarthritic Pain in the knee, Neck Pain, Shoulder Pain, Menstrual Pain, Central Pain Lumbago	80Hz/2Hz	180µs
6	**Nausea** Specifically for treatment of nausea, most successful placing electrodes over acupuncture point C6 **CONDITIONS** Nausea	10Hz	180µs
7	**Migraine/Headaches** Reduced pulse width ideal for treating nerve rich areas **CONDITIONS** Tension Type Headache, Facial Pain, Neck Pain, Postherpetic Neuralgia	80Hz	60µs
8	70% Rate Modulation over 10 seconds **CONDITIONS** Neck, Shoulder, Elbow Pain, Rheumatic Pain, Lumbago, Menstrual Pain, Hip Pain, Osteoarthritic Pain in the Knee	10Hz	200µs
9	90% Rate Modulation over 10 seconds **CONDITIONS** Neck, Shoulder, Elbow Pain, Rheumatic Pain, Lumbago, Menstrual Pain, hip Pain, Osteoarthritic Pain in the Knee	50Hz	250µs

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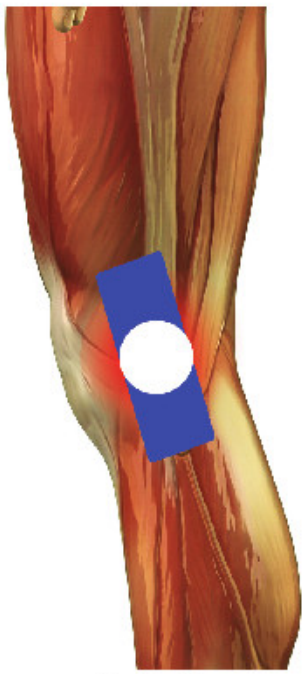
HELPFUL TIPS FOR SUCCESSFUL TENS TREATMENT

Once you have familiarised yourself with the controls and features of your TENS device, it is important to place the TENS electrodes in a position which gives the most pain relief. This may take 3 or 4 attempts to find the most suitable position for maximum pain relief.

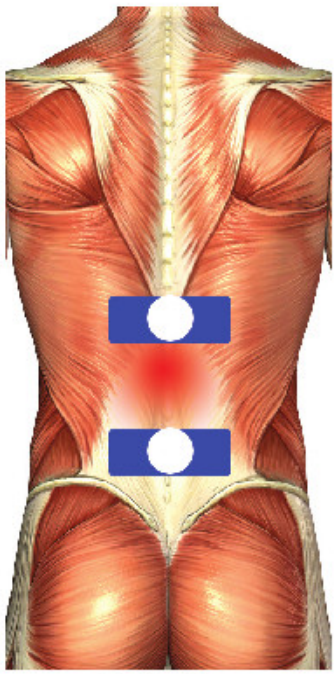
If you are using one module, place the electrode directly onto the painful area.

The alternative method is to use two module surrounding the painful area. See examples below.

The complete area between the electrodes will now be treated when positioning the electrodes as shown.



One Module



Two Module

MUSCLE STIMULATION

The Muscle stimulation programmes are programmes A, B, C, D, E and F.

Please see the chart below for more detailed information.

These 6 individual electronic muscle stimulator (E.M.S) programmes have been clinically proven for the treatment of

1. Muscle Re-Education
2. Muscle Training
3. Muscle Strengthening
4. Muscle Toning

When using the muscle stimulator programmes it is important to take professional advice wherever possible to achieve the best results.

THE MED-FIT 2 PREMIER WIRELESS EMS PROGRAMS A - F

NO	PROGRAMME	SYN/ALT	Rate (Hz)	Width (µs)	Ramp (sec)	On Time (sec)	Off Time (sec)	Timer (min)
A	ACL repair/joint protection back muscle	SYNCHRONOUS	35	300	3	8	24	20
B	Spasm small muscle	SYNCHRONOUS	80	300	3	10	5	20
C	Muscle Strengthing/Re- Education	SYNCHRONOUS	80	250	2	8	4	20
D	Muscle Strengthing/Training	SYNCHRONOUS	25	200	2	6	30	15
E	Disuse atrophy	SYNCHRONOUS	35	300	2	5	15	30
F	Muscle Strengthing/Re- Education	SYNCHRONOUS	50	300	5	15	50	15

LIMITED WARRANTY

Everyway warrants to the initial Purchaser ("Purchaser") (and to no other person) that the product with the exclusion of accessories such as chargers, rechargeable batteries, electrodes, lead wires, self-adhesive electrodes and the component parts thereof, distributed or manufactured for three years from the initial date of purchase from Everyway ("the Warranty Period").

Accessories including, but not limited to chargers, rechargeable batteries, electrodes, lead wires and adhesive electrodes are excluded from the warranty and sold "AS IS" because their structure is such that they may be easily damaged before or during use.

Limited of Liabilities and Disclaimer of Warranties

Everyway sole obligation in the case of any breach of its warranties set forth in the paragraph above, shall be, at Everyway option, to repair or replace the Product without charge to Purchaser or to refund the purchase price of the Product. In order to recover under this Warranty, Purchaser must send Everyway written notice of the defect (setting forth the problem in reasonable detail) prior to expiration of the Warranty Period, and within 30 days of discovery of the defect.

GRAPHIC SYMBOLS

Refer to instruction manual/booklet

WEEE symbol: This symbol indicates that when the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling.

Comply with MDD 93/42/EEC requirements as amended by 2007/47/EC. Notify body Det Norske Veritas (DNV)

Manufacturer: Everyway Medical Instruments Co., Ltd. 3F., No.5, Ln. 155, Sec. 3, Beishen Rd., Shenkeng Dist., New Taipei City 22203, Taiwan

Caution: Read instructions, warnings and cautions

FCC-Approved Equipment Authorization Labels

COMFORMITY TO SAFETY STANDARDS

The devices are in compliance with the following standards:

- IEC 60601-1:2005 Medical electrical equipment -Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014 Medical electrical equipment -Part 1-2: Collateral standard: Electromagnetic compatibility - Requirements and tests
- R&TTE (Radio and Telecommunications Terminal Equipment Directive): 1999/5/EC
- Devices complied with regulations of FCC Part 15B and Part 15C.

EMC INFORMATION

The device complies with current EMC regulations.
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.It is recommended that you do not place the device on top of or close to other electronic devices.

Guidance and manufacturer's declaration electromagnetic emissions		
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.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The device must emit electromag netic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments other than domestic 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 C	
Voltage fluctuations / flicker emissions IEC 61000 3 3	Complies	

Guidance and manufacturer'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
Electrostatic discharge (ESD) IEC 61000 4 2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 % .
Electrical fast transient/burst IEC 61000 4 4	± 2 kV for power supply 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) and neutral	± 1 kV line(s) to line(s) and neutral	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 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cydes 70 % U_T (30 % dip in U_T) for 25 cydes <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cyde 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cydes <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000 4 8	3 A/m	Not applicable	Not applicable
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

EMC INFORMATION

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		
	150KHz bis 800MHz $d = 1,2\sqrt{P}$	80MHz bis 800MHz $d = 1,2\sqrt{P}$	80MHz bis 2.5GHz $d = 2,3\sqrt{P}$
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 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.			

EMC INFORMATION

Guidance and manufacturer'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 be used no closer to any part of the device , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2\sqrt{P}$
Conducted RF IEC 61000 4 6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1,2\sqrt{P}$ 80 MHz bis 800 MHz $d = 2,3\sqrt{P}$ 800 MHz bis 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. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000 4 3	3 V/m 80 MHz to 2,5 GHz	3 V/m	
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 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 device. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

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