med▸fit

Painless TENS Machine

Med-Fit Solo

- Fully Rechargeable
- Very Simple to Operate
- Completely Wireless

med▸fit

Telephone: 0161 429 7330

www.tensmachineuk.com

Technical Specification:

Channel: x 1
Amplitude: 0~100mA Peak (500 ohm load)
Power Supply: 3.7V/480m A Lithium Polymer Battery
Size: ø60(W) x 19.5(H)mm
Weight: 38.6g (battery included)
Wave form: Symmetrical Rectangular Biphasic Pulse
Output Type: TENS
Treatment Mode: TENS Preset
(2 programmes repeat automatically until the battery runs out.)
P1 -15 minutes (Convential TENS - Frequency: 80Hz / Pulse Width: 70-180µs
P2 -15 minutes (Modulation TENS - Frequency: 80Hz / Pulse Width: 70-180µs
Low Battery Sign: A low battery Logo will flash when the battery is low

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Company registration number 08758741 Vat registration number 308286105

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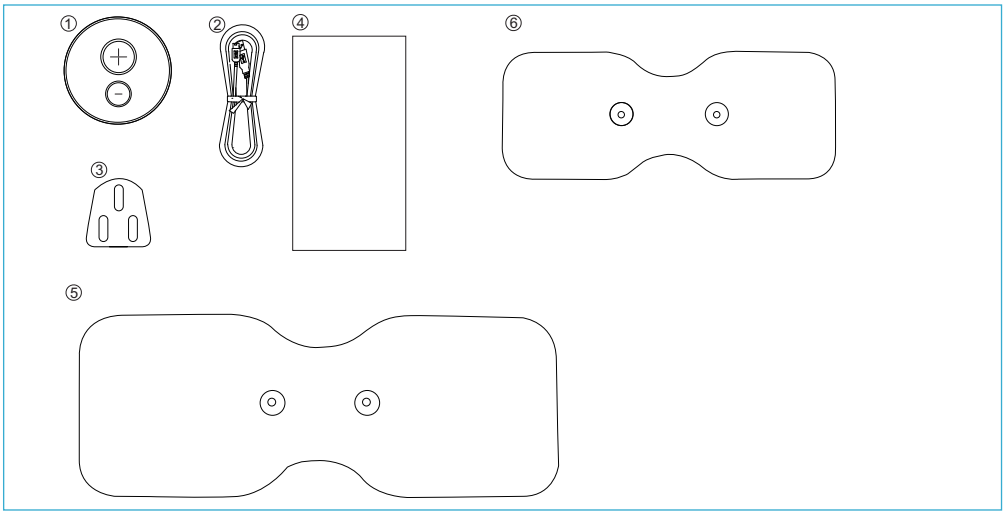
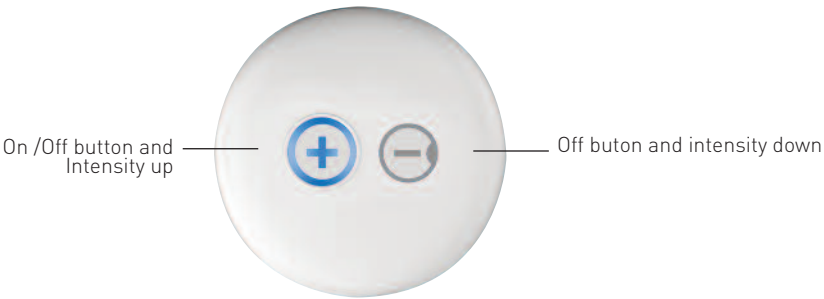


CONTENTS & GENERAL INFORMATION

Please check carefully the contents of the
Med-Fit Solo Wireless TENS

1. Wireless TENS Module
2. USB and AC Adaptor Charging Lead
3. AC adaptor
4. Instruction & User Manual
5. Self adhesive Large Electrode 21cm x 8cm
6. Self adhesive Medium Electrodes 14cm x 5.5cm

CONTROLS



CHARGING YOUR DEVICE

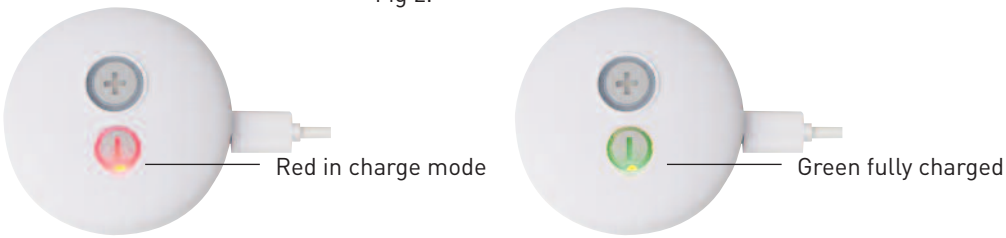
To charge your TENS please use the charger and USB cable provided, connect the large end of the USB cable to the charger and the small end fits into the TENS module as shown in Fig 1.

The USB cable only fits one-way round, please do not force the cable into the USB socket. You may also charge your TENS from any USB port (typically found on computers).

Fig 1.

The (-) button will glow red when charging, once fully charged the button will turn green, ready for use.

Fig 2.



A flashing LED indicated your TENS requires charging.

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FITTING THE ELECTRODES

There is a choice of two types of which snap connect onto the TENS as shown in Fig 3 and Fig 4.

Fig 3.

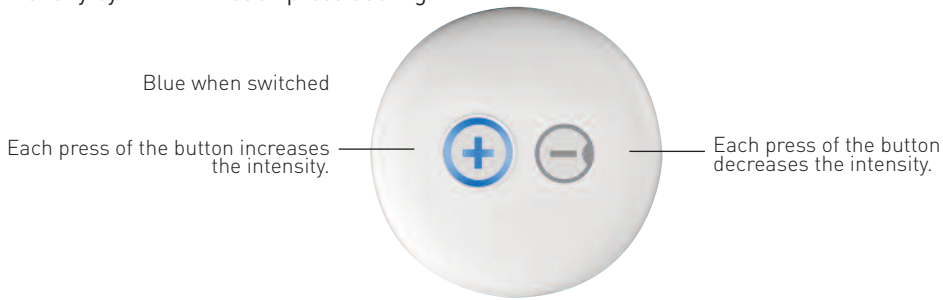
Fig 4.

INSTRUCTIONS FOR USE

Turning on your TENS

To turn on your TENS hold the ⊕ button down for 2 seconds the button will now glow blue, indicating the TENS is turned on.

The TENS device will automatically turn off after 2 minutes when not in use. Prior to turning off, you will hear a series of beeps indicating that the TENS is switching off. Place the TENS over the painful area and switch on. You can turn up the intensity by pressing the ⊕ button. Each press increases the intensity by 1mA. The ⊖ button will decrease the intensity by 1mA with each press see Fig 4.



Please turn off by pressing and holding the ⊕ or ⊖ button for 2 seconds before removing from the treatment area.

TREATMENT TIMES AND INTENSITY SETTINGS

Recent research has shown TENS to be most effective when used for longer periods typically $1^1/_2$ - 2 hours at a lower intensity (a level which is just above the sensory level and pleasant in sensation).

Your TENS, therefore, runs on a continuous program or until it is switched off. A full charge will typically give 10 hours continuous use.

INTRODUCTION

Thank you for purchasing the Med-Fit Solo Wireless TENS.

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).

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.

FAQS

Question: The sensation is not as strong as when I first received my TENS.
Answer: Apply a small amount of water to the gel area as described on page ? of this guide.

Question: I need to increase the intensity a little higher each day.
Answer: Applying TENS to the same area each day can dry out your skin. It is important to wipe the treatment area with warm water before applying your electrodes

SKIN PREPARATION BEFORE APPLYING YOUR ELECTRODES

It is important that your skin is clean and free from any oils gels or creams before applying your adhesive pads to the skin.

We recommend however to rub the area to be treated with warm water before applying the electrodes as this will give the most comfortable stimulation and decrease your skin resistance.

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. Grasping a tiny edge of the electrode, peel and remove electrode from the protective plastic liner. Save liner for electrode storage.
4. 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.
5. 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. If the 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. .
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 of your neck.
5. Keep electrodes separated during treatment
6. Using stimulation electrodes that are small or incorrectly applied could result in discomfort or skin burns.

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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 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.

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.

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.

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.

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 Herpetic
- 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

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.

LIMITED WARRANTY

Med-Fit 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 one year from the initial date of purchase from Med-Fit ("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
Med-Fit sole obligation in the case of any breach of its warranties set forth in the paragraph above, shall be, at Med-Fit 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 Med-Fit 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.

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 electromagnetic 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	(>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s 3 A/m	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <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		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.			

COMFORMITY TO SAFETY STANDARDS

The devices are in compliance with the following standards:

- EN 60601-1:2006 Medical electrical equipment -Part 1: General requirements for basic safety and essential performance
- EN 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

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.

CE 2460 Comply with MDD 93/42/EEC requirements as amended by 2007/47/EC. Notify body Det Norske Veritas (DNV)

Class II equipment (Double insulation)

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

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