Med-Fit

Med-Fit 1 TENS Machine

Pain Relief
TENS Machine

CE 2460

med-fit

Patient Instructions & User Manual

Tel: 0161 429 7330 email sales@med-fit.co.uk

Med-Fit 1

Introduction to TENS

Preparing your TENS

Warnings & Precautions

How to use Electrodes

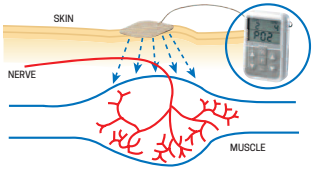
Technical Specifications

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 a connection of a lead wire and self adhesive conductive electrode.

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 60 to 90 minutes. 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, endorphins. Place the electrodes on a muscle in the painful area so that a visible contraction occurs. You can use low-frequency TENS three times a day, but it can lead to sore muscles.

How to use your TENS?

Two channel (four electrode) machines are more flexible especially if the pain is large or widespread. Start with conventional TENS with a continuous pulse settings.

- Use middle pulse frequency (approx 80-100 per second) and pulse duration (100-200 μs).
- Increase the intensity until the sensation is strong and a little uncomfortable, then turn it down slightly, until comfortable.
- You may need to experiment with the settings as there is no sure way of telling which combination will suit you without trial and error.
- Put the electrodes on normal healthy skin. Check to make sure you don't have any cuts or other breaks in the skin which could be very uncomfortable and react badly.
- Take time to find the best electrodes placements - this may be tricky.

How long to use your TENS and what dose

Conventional or high frequency settings is performed when the Pulse Rate is set to 60 pulses per second or more. The sensation produced will be a steady buzzing or tingling feeling between the electrodes. Because the TENS signal is perceived as stronger than the pain signal being produced by the body, it effectively blocks the pain signal from travelling along nerves to the brain. Treatment duration - 60 - 90 minutes, or continuous if required. Low-frequency or burst type of treatment is produced when the Pulse Rate setting on the TENS unit is set manually below 10 pulses per second (or as with some units, at automatic burst mode). Low-frequency treatments produce visible muscle twitching often described as a tapping or pulsating sensation.

In reaction to this type of stimulation the body releases endorphins (pain-killing chemicals produced naturally in the body). These endorphins act as a chemical nerve block to reduce pain by interrupting the pain signals along the nerves to the brain. Often this type of treatment can take longer to be effective but the results last longer.

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
- Bruising
- Calf Strain
- Dead Leg
- Fibrositis Finger Pain
- Headaches Migraines
- Knee Pain
- Lumbago Muscle Stress
- Neck Pain
- Neuralgia
- Osteo-arthritis
- Period Pains
- Post Herpatic Neuralgia
- Pregnancy/ Labour Pains
- Rheumatism
- Sciatica
- Shoulder Pain
- Sleeplessness
- Spondylosis
- Sports Injuries
- Tennis Elbow
- Tenosynovitis
- Wrist Pain

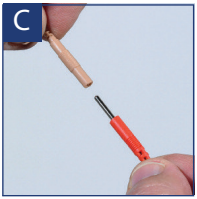
Preparing your TENS

So Lets Get Started

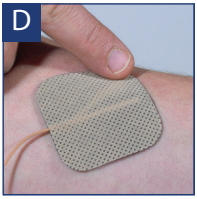
As with many Instruction and User Manuals there is a lot to digest prior to using a device. This Patient's Practical Guide does not replace the Instruction Manual provided, however it helps you to understand the basic controls and features of your TENS device.

Remove the front cover, insert the battery and replace the cover.

Fit the electrode lead into the TENS device as shown.



Connect the lead wires to the self-adhesive electrodes as shown.

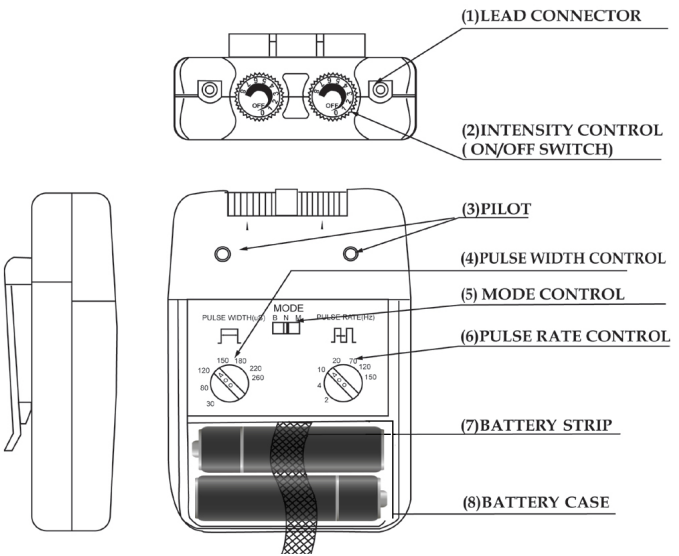


Clean the skin. Remove the plastic cover from the electrodes before attaching it to the skin.

Choose your programme settings as instructed by your clinician.

Adjust the stimulation level by turning the control.

Controls



Accessories

The MED-FIT 1 comes completed with the following accessories:

2 x Packs of SA10 5 x 5 cm electrodes 8 in total.

2 x Patient lead wires.

2 x AA Batteries.

1 x Instruction manual and the Patients Guide to TENS.

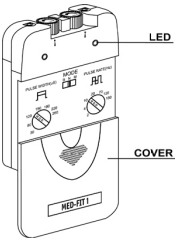
Label

The label attached to the back of the unit contains important information this model, serial number, supply voltage, the name of manufacturer, CE number and classification. Please do not remove.

Adjusting the controls

1. Slide Cover:

A sliding panel covers the controls for Pulse Width, Pulse Rate, Mode Selector and Modulation Selector. Take advice from your clinician regarding the settings and then leave the cover in place.

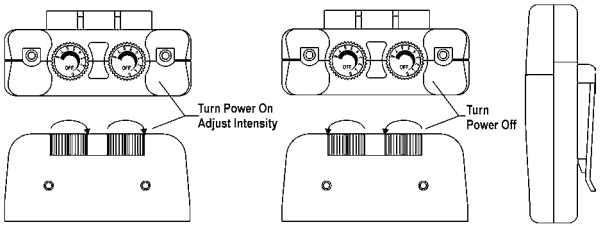


2. Display LED lights:

The LED corresponding to the appropriate channel will light whenever that channel is activated. At low frequencies each individual pulse may be observed but at frequencies above 30 Hz the LED will appear to be constantly illuminated.

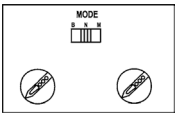
3. On/Off Switch and Intensity Control:

The unit is switched on by turning the appropriate channel control clockwise. The LED will illuminate as described above. The output intensity increases as the control is turned further clockwise. To reduce the output intensity and/or switch off the unit the control is turned anti-clockwise.



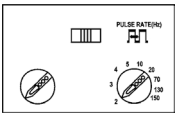
5. Mode Control:

Expose the controls by sliding front cover down. This switch has 3 positions: B for Burst stimulation, N for Constant stimulation, and M for modulated stimulation. Push the Mode Selector to the desired position.



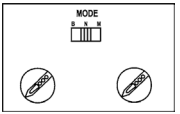
6. Pulse Rate Control:

This control determines the frequency (pulses per second). This dial controls the frequency to both channels. Unless otherwise instructed set the pulse rate to between 70 - 120 Hz.



7. Pulse Width Control:

This control adjusts the length of each electrical impulse. By increasing the pulse width the strength and sensation of the stimulus will be increased. By reducing the pulse width the strength and sensation will be reduced. Unless otherwise instructed set the control to between 70 - 120 μs.



8. Check/Replace the Battery:

Over time, in order to ensure the functional safety of TENS, changing the battery is necessary.

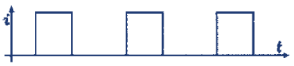
1. Make sure that both intensity controls are in the off position.
2. Slide the battery compartment cover and remove.
3. Remove the battery from the compartment.
4. Insert the battery into the compartment. Note the polarity indicated on the battery and in the compartment.
5. Replace the battery compartment cover and slide to close.

Battey Information

1. Remove battery if equipment is not likely to be used for some time.
2. Please recycle the used battery in accordance with domestic regulation.
3. Do not throw the used battery into fire.

Settings

Conventional:



Suitable for pain relief. The Therapy consists of short electrical pulses where the stimulation may never be so strong that any muscle contractions occur. Electrodes are usually placed on the nerve paths around the pain site. TENS stimulation can be used for pain therapy for the following: Muscle pain, Arthralgia, Tennis elbow, Arthritis Osteoarthritis, Gout , Fibromyalgie, Tenosynovitis, Carpal tunnel, Hip and back pain Muscle tension (myalgia), Sinusitis, Neuritis etc.

Modulation:

Stimulation pulses vary for both pulse width and stimulation current. The variation is random and built up as: pulse width multiplied by stimulation current being constant. This modulated TENS prevents any habituation to a set pulse width and has the following variables: frequency, pulse width and treatment time. Modulated TENS stimulation can be used for pain therapy as mentioned for conventional mode.However, for chronic conditions where long term treatment is required modulated TENS is recommendable.

Burst:

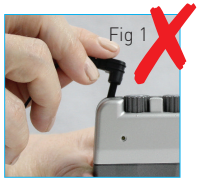
Stimulation form consisting of short series of pulses with high frequency that are repeated with low frequency. BURST stimulation is used for general pain relief and stimulation must be so strong that muscle contraction is perceived. In general terms the electrode is placed on a large muscle near the pain location. BURST has the following variables: frequency, pulse width and treatment time.
A long-cycle pain relief is given with BURST stimulation due to the fact that the body increases its own production of natural painkillers, the endorphins. BURST stimulation can be used for: Sciatic pain, Scleroses, Back pain, Circulatory disturbances,Tinnitus, Whiplash etc.

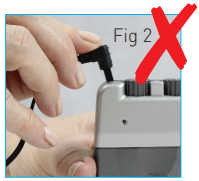
Important Information

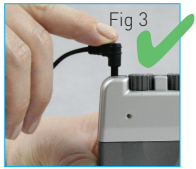
Connecting your patient leads to your TENS device

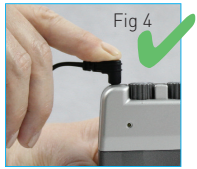
When connecting the Patient leads, please ensure they are inserted completely straight and not at an angle that may bend the pins, see Fig 1 & 2.

To insert the Patient lead correctly into the socket on your TENS device, push down gently making sure that you keep the lead straight, do not force it, it is also recommended to slightly rotate the lead, as the sockets in the TENS device may be tight when the machine is new.









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 that is comfortable and always perceptible, never turn up to a level that 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 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 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 have a detrimental effect on your results.

Warnings & Precautions

Please Note!

Patients must read and understand the warnings and precautions before using the unit. It is recommended that proper medical advice on the use of TENS is sought from a Qualified Practitioner before use, to ensure safe and effective treatment. If you are taking any medication please carry on as normal but seek advice from your clinician before using the device.

WARNING!

PATIENTS WITH PACEMAKER NOT TO BE TREATED WITH TENS THERAPY

- Do not use during pregnancy except during labour.
- 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 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.

The degree of pain relief declines in some cases with time, TENS may have less effect after extended use. To reduce the risk of development of tolerance, the following measures may be taken:

- Frequent follow-ups.
- Teach the patient to use burst, modulated, and conventional stimulation.
- Vary electrode placement.
- Vary the frequency

If none of the above are successful discontinue TENS for up to 2 weeks and then resume.

As with pain-killing medicines, TENS provides temporary pain relief, which often lasts up to four hours after treatment. Treatment usually lasts 60-90 minutes, 2-4 times daily.

The time taken to achieve pain relief varies from an immediate effect up to about an hour. Some patients prefer continuous stimulation while others prefer intermittent stimulation. Remove the electrodes and discontinue stimulation if you experience skin irritation or discomfort.

Maintenance, transportation and storage

1. Non-flammable cleaning solution is suitable for cleaning the device. Note: Do not smoke or work with open lights (for example, candles, etc.) when working with flammable liquids.
2. Stains and spots can be removed with a cleaning agent.
3. Do not submerge the device in liquids or expose it to large amounts of water.
4. Return the device to the carrying box with sponge foam to ensure that the unit is well-protected before transportation.
5. If the device is not to be used for a long period of time, remove the batteries from the battery compartment (acid may leak from used batteries and damage the device). Put the device and accesso ries in carrying box and keep it in cool dry place.
6. The packed EMS device should be stored and transported under the temperature range of -20°C ~ + 60°C, relative humidity 20% ~ 95%, Atmosphere pressure 500hPa ~ 1060hPa.

How to use Electrodes

Position of the Electrodes

Best results are achieved by placing the electrodes directly over the pain site. With dual machines, additional electrodes can be positioned to surround the site. Electrodes can also be used to stimulate traditional acupressure points if required.

How do I know it's time to replace my Electrodes?

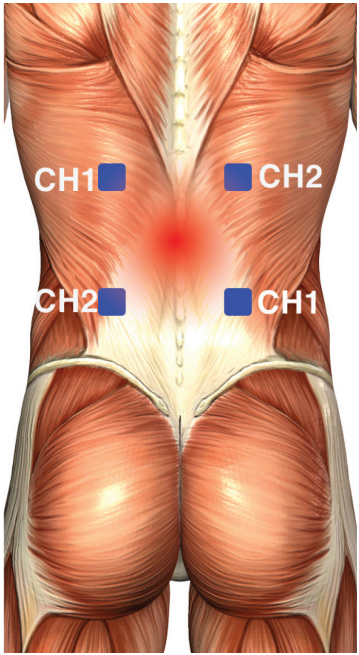
It is very important that the self-adhesive electrodes (pads) be replaced when they no longer stick or if you begin to feel a "stinging" sensation. The usual life-span is approximately 3-6 weeks, depending on skin type and weather conditions, humidity will effect how long they last. Most of the pre-gelled reusable electrodes are considered hypoallergenic, in some cases people with sensitive skin may develop an allergy to a particular type of electrode, just like some people who are allergic to certain band-aids or tapes. One solution is to change the electrode and there are also products available to help act as a skin "barrier" in these situations.

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.

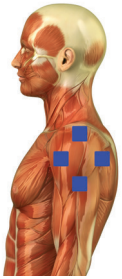
If you are using two electrodes, place the electrodes directly onto the painful area at a position where you feel the pain starts and where it finishes. You may now position the electrodes around the painful area to locate the most suitable position for maximum pain relief.

The alternative method is to use four electrodes surrounding the painful area see examples below The complete area between the electrodes will now be treated when positioning the electrodes as shown.



TENS Electrode Placement

Frozen Shoulder



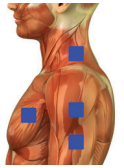
Primary Placement

Setting
Mode: Continuous or Modulation
Mode
Pulse Width: 160 - 200µs
Pulse Mode: 80 - 100Hz
Output: Adjust to the most comfortable and perceptible intensity level

Treatment Time

60 minutes, twice daily thereafter

Shoulder Pain

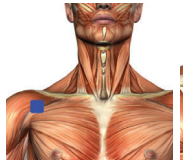


Primary Placement

Setting
Mode: Modulation
Mode
Pulse Width: 260µs
Pulse Mode: 80 - 100Hz
Output: Adjust to the most comfortable and perceptible intensity level

Treatment Time

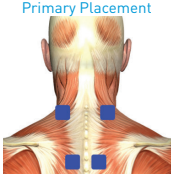
60-90 minutes, 3 times daily thereafter



Alternative Placement

Degenerative Arthritis: Cervical and Lumbar

Primary Placement



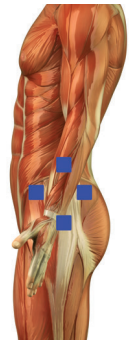
Alternative Placement

Setting
Mode: Continuous
Mode
Pulse Width: 100µs
Pulse Mode: 100Hz
Output: Adjust to the mos comfortable and perceptible intensity level

Treatment Time

90 minutes, 3 times daily thereafter

Chronic Hip Pain



Primary Placement

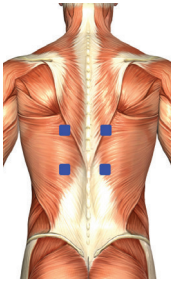
Setting
Mode: Modulation
Mode
Pulse Width: 200µs
Pulse Mode: 100Hz
Output: Adjust to the most comfortable and perceptible intensity level

Treatment Time

90 minutes, three times daily thereafter

TENS Electrode Placement

Lower Back Pain



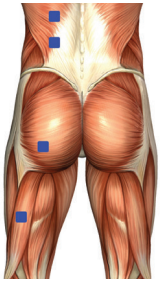
Primary Placement

Setting
Mode: Continuous or Modulation
Mode
Pulse Width: 200 - 250µs
Pulse Mode: 50 - 80Hz
Output: Adjust to the most comfortable and perceptible intensity level

Treatment Time

90 minutes minimum twice or three times daily thereafter

Hip Neuralgia



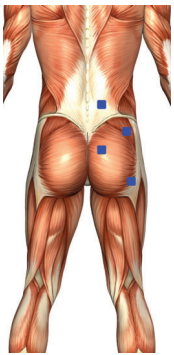
Primary Placement

Setting
Mode: Modulation
Mode
Pulse Width: 150 - 220µs
Pulse Mode: 80 - 120Hz
Output: Adjust to the most comfortable and perceptible intensity level

Treatment Time

60 - 90 minutes minimum for the first 4 days 4 hours per day thereafter

Phantom Limb, Lower Extremity



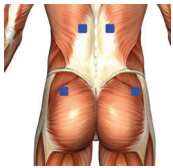
Primary Placement

Setting
Mode: Continuous or Modulation
Mode
Pulse Width: 200 - 260µs
Pulse Mode: 50 - 100Hz
Output: Adjust to the most comfortable and perceptible intensity level

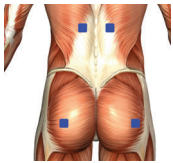
Treatment Time

60 minutes minimum, three times daily thereafter

Sciatica



Primary Placement



Alternative Placement

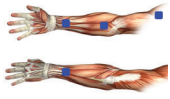
Setting
Mode: Modulation
Mode
Pulse Width: 260µs
Pulse Mode: 150Hz
Output: Adjust to the most comfortable and perceptible intensity level

Treatment Time

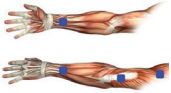
60 minutes minimum, 2 or 3 times daily thereafter

TENS Electrode Placement

Wrist Pain



Primary Placement



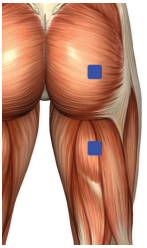
Alternative Placement

Setting
Mode: Continuous Mode
Pulse Width: 200µs
Pulse Mode: 30 - 50Hz
Output: Adjust to the most comfortable and perceptible intensity level

Treatment Time

60 minutes minimum, twice daily thereafter

Low Extremity Pain



Primary Placement

Setting
Mode: Continuous or Modulation Mode
Pulse Width: 120 - 150µs
Pulse Mode: 50 - 80Hz
Output: Adjust to the most comfortable and perceptible intensity level

Treatment Time

90 minutes minimum, twice daily thereafter

Degenerative Arthritis - Knee Pain

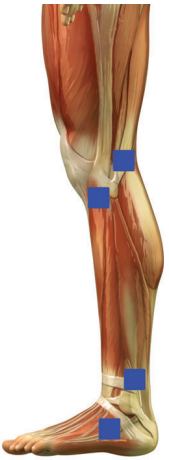
Primary Placement

Setting
Mode: Continuous Mode
Pulse Width: 200µs
Pulse Mode: 80Hz
Output: Adjust to the most comfortable and perceptible intensity level

Treatment Time

60 - 90 minutes, twice daily thereafter

Primary Placement



Alternative Placement

TENS Electrode Placement

Lower Leg Pain

Primary Placement

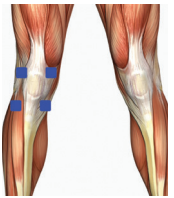
Alternative Placement

Setting
Mode: Modulation Mode
Pulse Width: 100 - 160µs
Pulse Mode: 80 - 100Hz
Output: Adjust to the most comfortable and perceptible intensity level

Treatment Time
60 - 90 minutes, twice daily thereafter

Knee Pain - Post-Op

Primary Placement



Alternative Placement

Setting
Mode: Modulation Mode
Pulse Width: 100 - 150µs
Pulse Mode: 120Hz
Output: Adjust to the most comfortable and perceptible intensity level

Treatment Time
60 - 90 minutes, twice daily thereafter

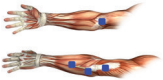
Carpal Tunnel Syndrome

Primary Placement

Setting
Mode: Continuous Mode
Pulse Width: 200µs
Pulse Mode: 100Hz
Output: Adjust to the most comfortable and perceptible intensity level

Treatment Time
60 - 90 minutes, twice daily thereafter

Elbow & Forearm Pain



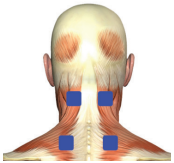
Primary Placement

Setting
Mode: Continuous Mode
Pulse Width: 100µs
Pulse Mode: 100Hz
Output: Adjust to the most comfortable and perceptible intensity level

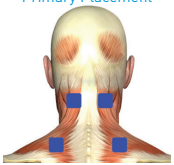
Treatment Time
60 - 90 minutes, twice daily thereafter

TENS Electrode Placement

Cervical Pain



Primary Placement



Alternative Placement

Setting
Mode: Continuous Mode
Pulse Width: 100 - 150µs
Pulse Mode: 60 - 100Hz
Output: Adjust to the most comfortable and perceptible intensity level

Treatment Time
60 - 90 minutes, 3 times daily thereafter

Chronic Cervical Strain

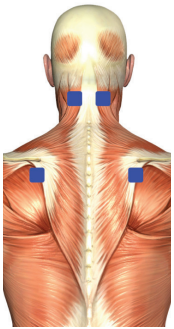
Primary Placement

Alternative Placement

Setting
Mode: Modulation Mode
Pulse Width: 160µs
Pulse Mode: 30Hz
Output: Adjust to the most comfortable and perceptible intensity level

Treatment Time
4 - 5 hours, 3 times daily thereafter

Chronic Cervical Strain



Primary Placement

Setting
Mode: Modulation Mode
Pulse Width: 200µs
Pulse Mode: 60 - 100Hz
Output: Adjust to the most comfortable and perceptible intensity level

Treatment Time
4 - 5 hours, 3 times daily thereafter

Application of reusable self-adhesive electrodes

Application:

1. Clean and dry the skin at the thoroughly with soap and water prior to application of electrodes.
2. Insert the lead wire into the pin connector on the pre-wired electrodes.
3. Remove the electrodes from the protective liner and apply the them firmly to the treatment site.

Removal:

1. Peel the electrodes from the skin; do not pull on the lead wires because it may damage the electrodes.
2. Place the electrodes on the liner and remove the lead wire by gently twisting and pulling.

Care and Storage:

1. Between uses, store the electrodes on their liner in the resealable bag in a cool dry place.
2. The adhesive properties of the electrodes may be improved by applying a few drops of cold water and allowing the electrode surface to dry. Do NOT soak the electrodes.

Important:

1. Do not apply to broken skin.
2. The electrodes should be discarded when they no longer adhere.
3. The electrodes are intended for single patient use only.
4. If irritation occurs, discontinue use and consult your clinician.
5. Read the instruction for use of self-adhesive electrodes before application.

Technical Specifications

The technical specification details of MED-FIT 1 are as follows:

	MECHANISM	TECHNICAL DESCRIPTION
01	Channel	Dual, isolated between channels
02	Pulse Amplitude	Adjustable 0-80mA, Max output 80mA peak to peak (15.8mA rms) into 500ohm load each channel.
03	Wave Form	Asymmetrical Bi-Phasic Square Pulse
04	Voltage	Adjustable 0-40V, Max output 40V peak to peak (7.9V rms) into 500ohm load each channel.
05	Power source	Two AA 1.5 Volt Batteries
06	Size	95(H) x 65(W) x 23.5(T) mm
07	Weight	115 grams (battery included)
08	Pulse Rate	Adjustable, from 2 Hz to 150 Hz
09	Pulse Width	Adjustable, from 30μs to 260μs
10	Burst Mode (B Mode)	Bursts occur twice per second. The pulse width is adjustable. The frequency is fixed at 100Hz
11	Modulation	Pulse rate is automatically varied in a cyclic pattern over a nominal 10 second interval (in max 150Hz). Pulse rate decreases linearly, over a period of 4 seconds, from the control setting valu to a value which is 40% less. The lower pulse rate will continue for 1 second and then the pulse rate increases linearly over a period of 4 seconds to the original value. This will continue for 1 second and the cycle is then repeated
12	Operating Condition	Temperature : 0°~40°C Relative Humidity : 30%~75% Atmosphere Pressure : 700Hpa~1060Hpa
13	Remark	There may be up to a +/- 5% tolerance of pulse width and pulse rate and +/- 20% tolerance of amplitude & voltage.

Safety-Technical controls

For safety reasons, check your MED-FIT 1 each week based on the following checklist.

1. Check the device for external damage.
- deformation of the housing.
- damaged or defective output sockets.

2. Check the device for defective operating elements.
- legibility of inscriptions and labels.
- make sure the inscriptions and labels are not distorted.

3. Check Led
- led must be illuminated when switched on.

4. Check the usability of accessories.
- patient cable undamaged.
- electrodes undamaged.

Please consult your distributor if there are any problems with the device and accessories.

Malfunctions

Should any malfunctions occur while using the TENS, check
- whether the switch/control is set to the appropriate form of therapy. Adjust the control correctly.
- whether the cable is correctly connected to the device. The cables should be inserted completely into the sockets.
- whether the impulse display led is illuminated. If necessary, insert a new battery.
- for possible damage to the cable. Change the cable if any damage is detected.

* If there is any other problem, please return the device to your distributor. Do not try to repair a defective device.

Conformity to safety standards

The MED-FIT 1 devices are in compliance with the
EN 60601-1-2:2001 and EN 60601-1:1990+A1:1993+A2:1995+A13:1996 safety standards.

Warranty

All MED-FIT 1 models carry a warranty of one year from the date of delivery. The warranty applies to the stimulator only and covers both parts and labour relating thereto.

The warranty does not apply to damage resulting from failure to follow the operating instructions, accidents, abuse, alteration or disassembly by unauthorised personnel.

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

Representative in the EU:
REHAB EUROPA SL
SANT GERVASI DE CASSOLES, 96 3o 4a
08022 BARCELONA, SPAIN.

Information for the distributor:
Please contact the above mentioned manufacturer for technical support and documentation when necessary.

IMPORTANT INFORMATION REGARDING ELECTRO MAGNETIC COMPATIBILITY (EMC)

This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.

1)* Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.

2) Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!

3) * Caution: this machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used。

4) Warning:

The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the MANUFACTURER of the DEVICE as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the ME EQUIPMENT or ME SYSTEM.

Guidance and manufacture's declaration – electromagnetic emission		
The DEVICE is intended for use in the electromagnetic environment specified below. The customer of the user of the DEVICE should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The DEVICE use RF energy only for its internal function.Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The DEVICE is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacture's declaration – electromagnetic immunity			
The DEVICE is intended for use in the electromagnetic environment specified below. The customer or the user of DEVICE should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2kV 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)	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles for 5 sec <5% U_T (>95% dip in U_T) for 0.5 cycle for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles for 5 sec <5% U_T (>95% dip in U_T) for 0.5 cycle for 5 sec	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 uninterruptable power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital IEC environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity

The DEVICE is intended for use in the electromagnetic environment specified below. The customer or the user of DEVICE 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	3 Vrms 150 kHz to 80 MHz	3 Vrms	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**
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.167\sqrt{P}$ $d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d = 2.333\sqrt{P}$ 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 metres (m).Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: (( ))

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

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

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the DEVICE is used exceeds the applicable RF compliance level above, the DEVICE should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the DEVICE.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the DEVICE .

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

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 KHz to 80 MHz $d = 2.333\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.167\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 1.167\sqrt{P}$
0.01	**0.117**	**0.117**	**0.233**
0.1	**0.369**	**0.369**	**0.738**
1	**1.167**	**1.167**	**2.333**
10	**3.689**	**3.689**	**7.379**
100	**11.667**	**11.667**	**23.333**

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

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

Med-Fit UK Ltd
Unit 8, Martel Court, S. Park Business Park
Hamilton Road, Stockport, SK1 2AF
Telephone: 0161 429 7330 Email: sales@med-fit.co.uk