Med-Fit

Fem-Ova

Relieve Menstrual Cramps: A Step-by-Step Guide to Pain Relief

CE 2460

Patient Instructions & User Manual

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

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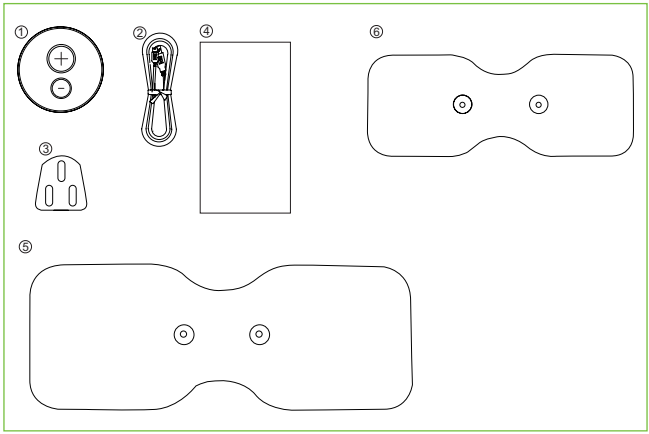
Thank you for purchasing the Med-Fit Fem-Ova Wireless TENS.

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).

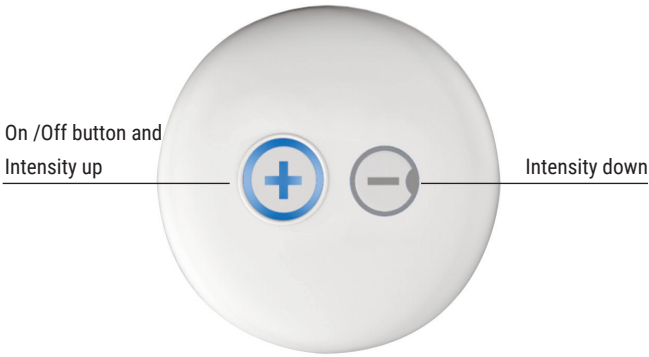
CONTENTS & GENERAL INFORMATION



Please check carefully the contents of the Med-Fit Fem-Ova 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).

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

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A flashing LED indicated your TENS requires charging.

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

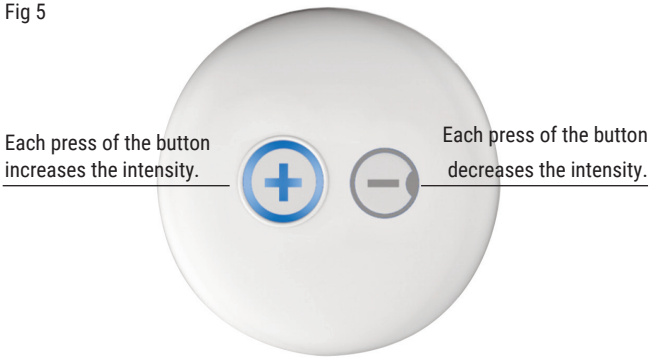
Turning on your TENS

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 5.

Fig 5



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

Prepare the Device

- Charge the device.
- Read the user manual to understand the settings and controls.

Position the Electrode Pads

- Clean and dry the skin on your lower abdomen or lower back where you'll place the pads.
- Attach the electrode pads to the skin. Common placements include:
- **Lower Abdomen**: Place the pads on either side of your belly button.
- **Lower Back**: Place the pads on either side of your spine, just above the hips.
- Ensure the pads are firmly attached and make good contact with the skin.

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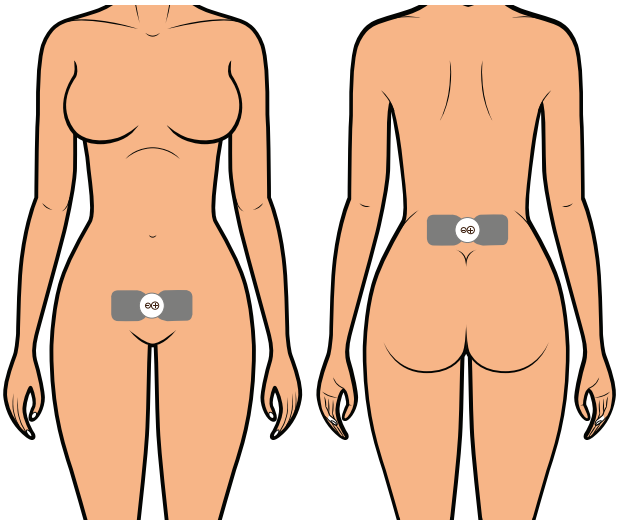

Adjust the Settings

- Turn on the TENS unit and start with the lowest intensity setting.
- Gradually increase the intensity until you feel a gentle tingling or buzzing sensation. It should not be painful or uncomfortable.

Use the Device

- Wear the TENS unit for 15-60 minutes as needed.
- You can use it several times a day but give your skin breaks to prevent irritation.

Remove the Pads and Clean Up

- Turn off the device and remove the electrode pads.
- Clean the skin where the pads were placed to remove any adhesive residue.
- Store the TENS unit and pads in a safe, dry place.

Tips for Best Results

- Use the TENS unit at the first sign of cramps for maximum effectiveness.
- Combine TENS therapy with other pain relief methods, such as heat packs, over-the-counter painkillers, or gentle exercise.
- Stay hydrated and maintain a healthy diet to help reduce cramping.
- We recommend 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.

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

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.

ELECTRODE INSTRUCTIONS

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.

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.
- Do not use the TENS unit if you are pregnant or have a pacemaker or other implanted medical device.

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

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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.

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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

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.			

EMC Information

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	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
	$d = 2.333\sqrt{P}$	$d = 1.167\sqrt{P}$	$d = 1.167\sqrt{P}$
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.

Everyway Medical Instruments Co., Ltd.
3Fl. & 8Fl., No. 5, Lane 155, Sec. 3, Beishen Rd.,
Shenkeng Dist., New Taipei City, 22203, Taiwan

EC REP

Luana Med. B.V.
Weena-Zuid 130, 3012NC Rotterdam, Netherlands

UK RP

MDSS-UK RP Ltd.
6 Wilmslow Road., Rusholme, Manchester M14 5TP United Kingdom

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 | www.med-fit.store
Company registration number 08758741 | Vat registration number 308286105