Med-Fit

Premier TENS Stimulator

Pain Relief TENS Machine

EM6100A

med-fit

Patient Instruction & User Manual

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

Thank you for purchasing a Premier Range Stimulator. These devices are manufactured to the highest of medical standards using the latest and most advanced technology. Each unit is fully tested in final assembly and inspection ensuring you receive the highest quality and an extremely reliable device.

Important information
Please read the following instructions

The Premier range of stimulators use soft touch control technology.
When increasing the intensity control, please press the button in single "light touch" actions. Each press increases the intensity by
1mA (max 99mA). This is a safety feature which ensures that you stimulate at a pleasant comfortable rate.

Contents:
1 x Premier TENS Unit
1 x Charger and USB Cable
4 x Packs of Self-Adhesive Electrodes (4 electrodes per pack)
1 x Pair of Patient Cables
1 x User Manual

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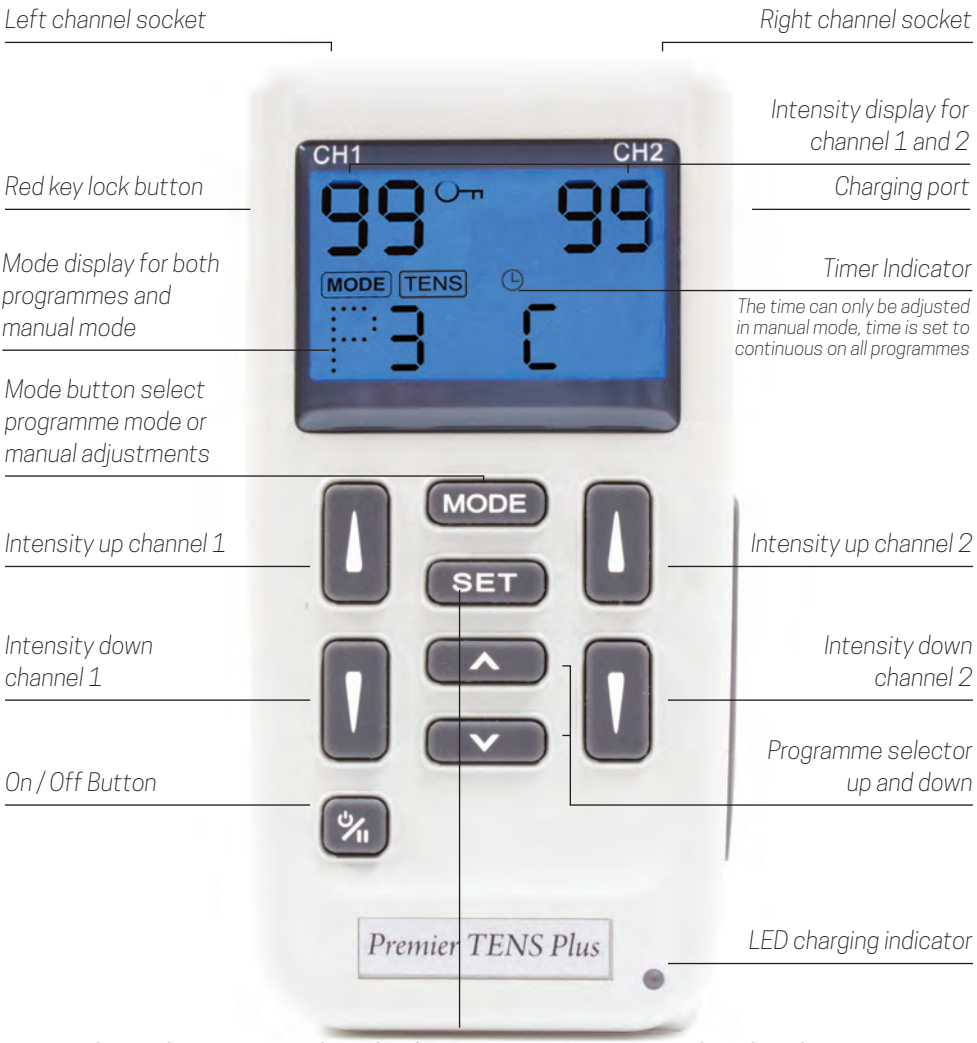
CONTROLS AND FUNCTIONS



The set button is to select the desire parameters in manual mode only it has no function when using the pre-set programmes.

STEP BY STEP GUIDE

STEP 1 Before using your premier TENS for the first time, please fully charge the battery see page 7.

STEP 2 Press the button to switch on the TENS. This is located at the bottom left hand corner of the TENS device. Please push and hold down the button for 2 seconds to turn the unit on.

STEP 3 Pressing the MODE button will allow you to change from programme mode to manual mode. Before using manual mode, we recommend starting with a pre-set programme (P1-P12).

STEP 4 To change the programmes please use the arrow keys directly below the set button this will allow you to choose the required programme.

STEP 5 Please refer to the programme information supplied (please see pages 13 to 14 for programme details).

STEP 6 The recommended programme to use for the first time TENS treatment is programme P1. This is a gentle TENS treatment with a good pain-blocking effect and is an introduction to TENS stimulation.

STEP 7 You are now ready to use the TENS for the first time. (see step 8).

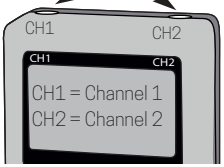
STEP BY STEP GUIDE

STEP 8

Connect one of the TENS lead cables supplied to the top of your TENS machine. As shown in Fig1.

Now connect the other end of the TENS cable to the self-adhesive electrodes supplied. As shown in Fig2.

Fig1



Next place the self-adhesive electrodes on to the painful site or as recommended by your healthcare professional. You are now ready to turn up the intensity on your TENS machine.

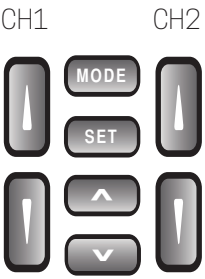
You must use two self adhesive pads connected to one cable for the TENS to work. Please keep a 2.5cm gap between the pads.

Fig2

When connecting the leads, ensure they are inserted straight not at an angle.

STEP 9

The intensity keys on your TENS are marked CH1 and CH2. To increase the intensity press the up arrow key, each press increases the intensity by 1mA and is displayed in the screen. It is recommended that you increase the intensity to a sensation which is comfortable and not too strong. As you use the TENS for longer periods it may be necessary to increase the intensity to higher levels. To control your pain more effectively.
It is recommended the first treatment should be a minimum of 1 hour to $1^{1}/_{2}$ hours to give the best possible results.



CHARGING INSTRUCTIONS

Important information The USB charging cable connects to the TENS charging port as shown in fig 1 (Please ensure you connect the cable the right way round).

Before using your Premier TENS Stimulator please charge the unit, as follows:

Charging your TENS device.

Connect the USB cable to the AC adaptor or USB port as shown in figure 1.

Now connect the USB cable directly into the USB socket, which is located on the right hand side of your Premier TENS.

A red indicating light will be seen in the bottom right hand corner of your TENS device. We recommend you charge the device for approximately 2 hours. Once fully charged the unit will be ready for use and the LED charging light will turn to green, this indicates the unit is fully charged. Remove the USB charging lead from your TENS device and disconnect from the mains supply or USB port. Please store your adaptor and cable in the carry case provided when not in use.

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WARNINGS & PRECAUTIONS

PLEASE NOTE:

Patients must 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) before use, 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.

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GENERAL DESCRIPTION

The EM6100A Digital TENS is a battery operated pulse generator that sends electrical impulses electrodes to the body.

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.

An electrode pair can be connected to each output channel. The intensity level is controlled by press buttons.

INTRODUCTION TO TENS

EXPLANATION OF PAIN

Pain is a warning system and the body 's method of telling us that something is wrong. Pain is important; without it abnormal conditions may go undetected, causing damage or injury to vital parts of our bodies.

Even though pain is a necessary warning signal of trauma or malfunction in the body, nature may have gone too far in its design. Aside from its value in diagnosis, long-lasting persistent pain serves no useful purpose. Pain does not begin until coded message travels to the brain where it is decoded, analysed, and then reacted to. The pain message travels from the injured area along the small nerves leading to the spinal cord. Here the message is switched to different nerves that travel up the spinal cord to the brain. The pain message is then interpreted, referred back and the pain is felt.

EXPLANATION OF TENS

Transcutaneous Electrical Nerve Stimulation is a non-invasive, drug-free method of controlling pain. TENS uses tiny electrical impulses sent through the skin to nerves to modify your pain perception. TENS does not cure any physiological problem; it only helps control the pain. TENS does not work for everyone; however, in most patients it is effective in reducing or eliminating the pain, allowing for a return to normal activity.

INTRODUCTION TO TENS

How to use your TENS?

It is useful for you to have a pain assessment before you start TENS. This will identify what kind of pain you have and exactly where it is. If you have numb areas on your skin, for example, these will need to be avoided as TENS needs an intact nerve pathway to work.

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

- Use middle pulse frequency(approx 80-100 per second) and pulse duration (100-200 microseconds).
- 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.

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. Put lotion on your skin where the electrodes were placed. The electrodes should be put in a new place for each new treatment. This will help prevent the skin from becoming red or sore.

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WHICH PROGRAMME SHOULD I USE?

We always recommend you start with programme 1, as already mentioned in your step-by-step guide. The premier TENS has 12 programmes P1 to P12, 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 12 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.

MED-FIT PREMIER TENS PROGRAMMES

P1-P12 - 12 Clinically validated TENS programmes for drug-free pain relief. (All programmes run on a continuous time indicated by the letter [C] on your display.

Programme 1

Conventional TENS

Ideal for your first TENS treatment, for both acute, chronic and long-term use.

Suitable Conditions
Neck Pain - Shoulder Pain - Knee Pain - Lower Back Pain - Sciatica - Arthritic Pain

Programme 2

Sciatica - Pain Relief

Effective pain relief for irradiation of pain along the path of the sciatic nerve, for electrode placement please refer to page 23. Recommended treatment time 2 + hours or until pain alleviates.

Programme 3

Lower back Pain

Programme 3 is most effective for lower back pain and increased blood circulation. This programme alleviates the pain by stimulating muscles to release the body's own morphine-like substances for electrode placement please refer to page 23. Recommended treatment time 90 minutes or until the pain subsides.

MED-FIT PREMIER TENS PROGRAMMES

Programme 4

Knee Pain

This programme is ideal for treating knee injuries both acute and chronic including osteoarthritis rheumatoid arthritis and joint pain. for examples of electrode placement please refer to pages 23 and 24.

Programme 5

Shoulder Pain

Treating shoulder pain relief from heavy or repetitive lifting, arthritis, and tendinopathy. Please refer to page 22 for electrode placement.

Programme 6

Muscle Pain

This programme is pre-set for all types of muscle pain relief ideal for muscle tension in the neck, shoulder and lower back (lumbar spasms). Please refer to pages 22 to 25 for electrode placement.

Programme 7

Migraine/Headaches

Reduced pulse width ideal for treating nerve rich areas.

Suitable Conditions
Tension Type Headache, Facial Pain, Neck Pain, Postherpetic Neuralgia.

MED-FIT PREMIER TENS PROGRAMMES

Programme 8

Cervical (Neck) Pain

Cervical pain relief due to poor ergonomic work positions. Please see the electrode placement page 21 for more details.

Programme 9

Epicondylitis - (Elbow)

Pain relief for epicondylitis resulting from repetitive gripping and objects. Please see the electrode placement page 20 for more details.

Programme 10

Foot & Ankle Pain

This programme is most suited for foot and ankle pain and increases circulation. Please see the electrode placement page 21 for more details.

Programme 11

Arthritic Pain

This programme is ideal for arthritic pain as it can be used for long periods of time with little or no accommodation which offers superior pain relief on most areas of the body.

Programme 12

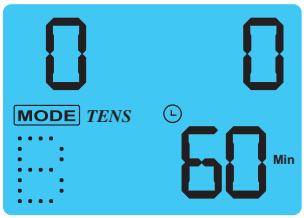
Joint Pain & Fracture Pain

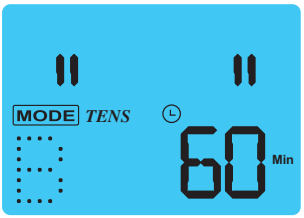
This programme is ideal for all common areas of joint pain, with this treatment we recommend that the stimulation is increased to a stronger level than the pain itself.

ADJUSTING THE CONTROLS USING THE MANUAL ADJUSTMENT

1. Power On/Off/Pause Button 

The power of unit can be turned on by pressing the On/Off/Pause button. You may start to adjust the settings when the liquid crystal display is on. Press and hold for 2 seconds to switch off. To pause stimulation press the button once. To resume stimulation press the button again and stimulation will be restored in 2 seconds.

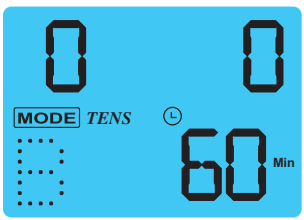




If the unit is not used (buttons not pressed or output level at 0) for 5 minutes, the power will be shut off automatically.

2. Mode Control 

There are 5 TENS modes (B, N, M, S1, S2) available. The mode is selected by pressing the “Mode” button.



B = Burst Mode
N = Normal or constant mode
M = Modulation Mode
S1 = Modulation Mode Advanced
S2 = Modulation Mode Advanced

ADJUSTING THE CONTROLS USING THE MANUAL ADJUSTMENT

3. Set Control 

By pressing the "Set" control you select the setting you intend to adjust. The value is set by pressing the "Increment" or "Decrement" controls when the "Set" value is flashing.

4. Increment Control 

This button controls the increase of settings.

5. Decrement Control 

This button controls the decrease of settings.

6. Intensity Increase Control

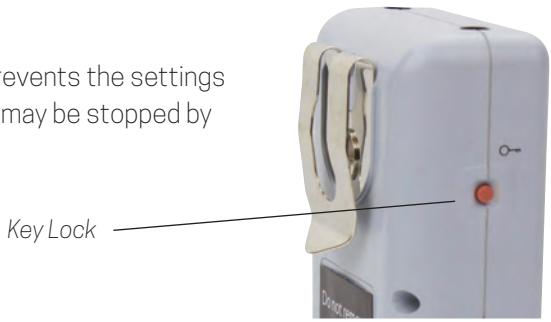
There are 99 steps of intensity adjustment control.
Press the button until the desired intensity level is reached.

7. Intensity Decrease Control

There are 99 steps of intensity adjustment control.
Press the button until the desired intensity level is reached.

8. Key Lock Facility

Pressing the "Lock" buttons prevents the settings being changed but the output may be stopped by pressing the "On/Off/Pause".



ADJUSTING THE CONTROLS USING THE MANUAL ADJUSTMENT

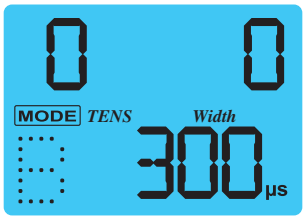
9. Steps to Set a TENS Program

The settings can be adjusted according to the following steps.

a. Turn on the Power

b. Select a Mode

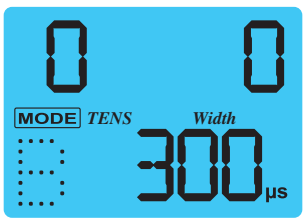
Select a mode by pressing the "Mode" control. The mode you selected will show up on the top of liquid crystal display. There are 5 modes of your option including - B(Burst), M(Normal), M(Modulation), S1, S2 and P. When a TENS mode is selected, it shows "TENS" on the liquid crystal display.



After a mode is selected, always press "Set" to enter next setting, and press " ^ " or " v " to adjust its value.

c. Set Pulse Width

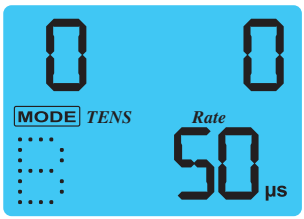
Pulse Width is adjustable from 50 µs to 300 µs. Press "SET" control to enter this menu, then press " ^ " or " v " to adjust the setting. If no instructions regarding the pulse width are given in therapy, set the control to the suggested 70-120 µs setting.



ADJUSTING THE CONTROLS USING THE MANUAL ADJUSTMENT

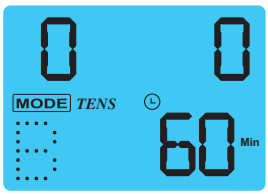
d. Set Pulse Rate

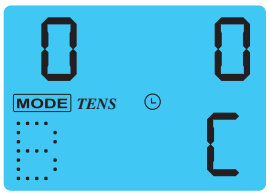
Pulse rate is adjustable from 2Hz to 150 Hz . Press "SET" control to enter this menu, then press " ^ " or " v " to adjust the setting. Unless otherwise instructed, set the pulse rate l to the 70-120 Hz range.

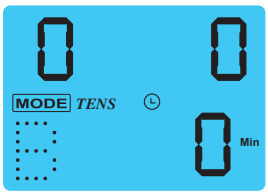


e. Set Timer

The treatment time is adjustable between 5 - 60 minutes and Continue(C). Press "SET" control to enter this menu, then press " ^ " or " v " to adjust the setting. The liquid crystal will show the balance treatment time after the stimulation is started. Output will be terminated when time is up. Turn off the unit when the output is off.

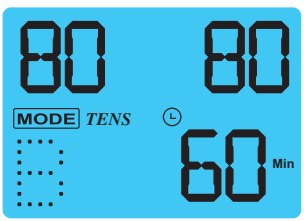






f. Adjust Intensity

There are 99 steps within the intensity range. Set the desired level by pressing the " " or " " controls. Press the "Lock" button to prevent accidental changes.



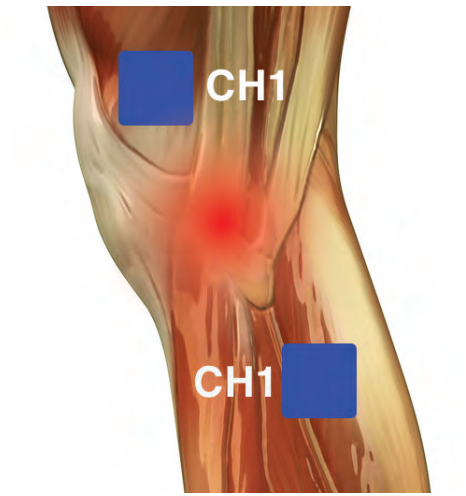
HELPFUL TIPS FOR SUCCESSFUL TENS TREATMENT

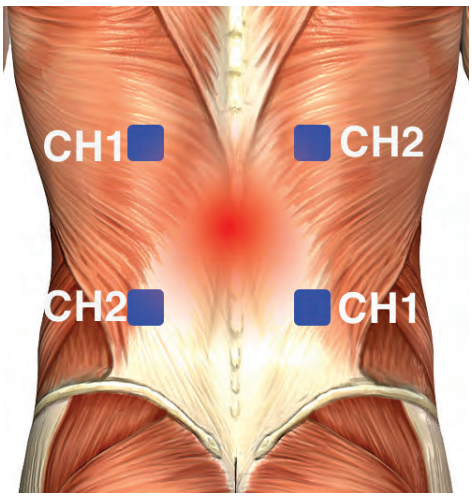
Once you have familiarised yourself with the controls and features of your TENS device, it is important to place the TENS electrodes in a position which gives the most pain relief. This may take 3 or 4 attempts to find the most suitable position, for maximum pain relief.

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.

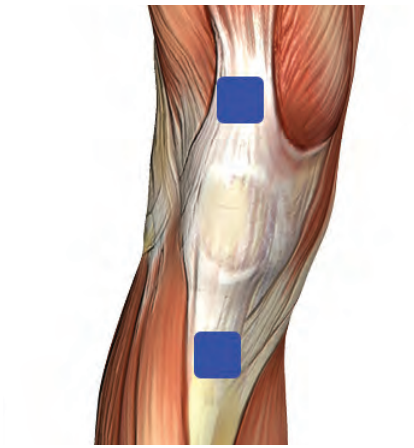
The complete area between the electrodes will now be treated when positioning the electrodes as shown.



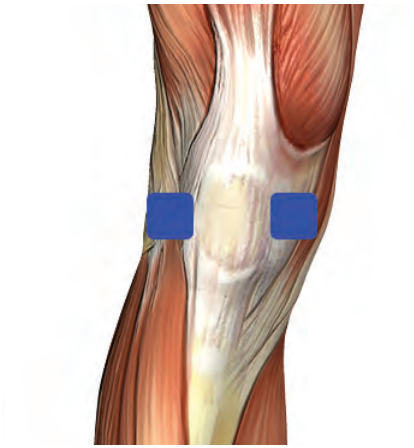


EXAMPLES OF ELECTRODE PLACEMENT

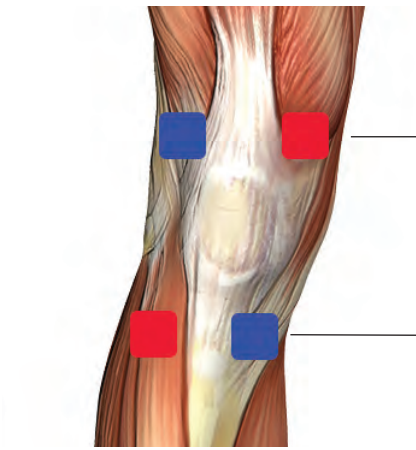
Here are three examples of electrode placement for knee pain. For best results, we recommend you try all variations as shown.



TENS using one channel vertical pad placement



TENS using one channel horizontal pad placement



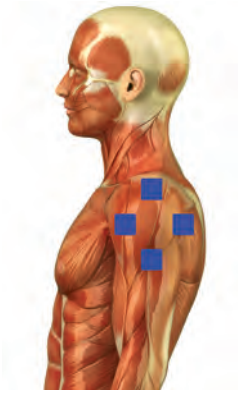
Red squares represents placement of electrode Channel 1

Blue squares represents Placement of electrode Channel 2

TENS using both channels

TENS ELECTRODE PLACEMENT

Frozen Shoulder

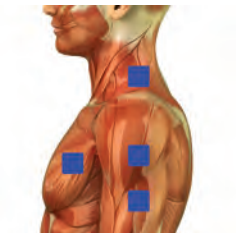


Primary Placement

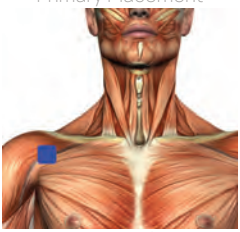
Suggested Programmes

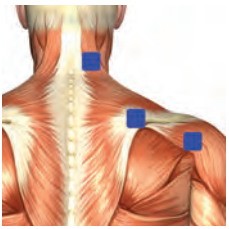
P1, P5, P12

Shoulder Pain



Primary Placement



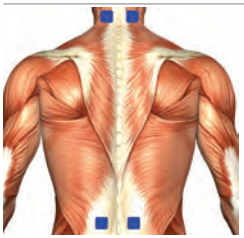


Alternative Placement

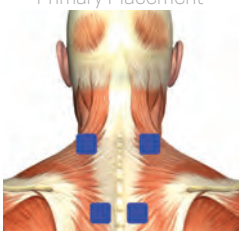
Suggested Programmes

P1, P5, P12

Degenerative Arthritis: Cervical and Lumbar



Primary Placement

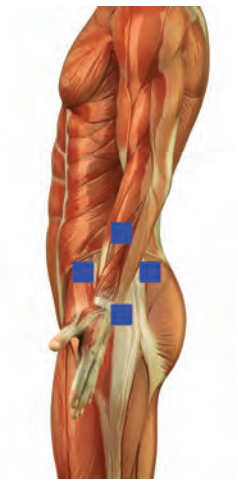


Alternative Placement

Suggested Programmes

P1, P3, P8, P11

Chronic Hip Pain



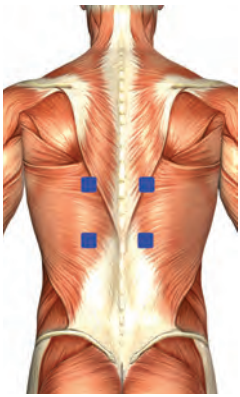
Primary Placement

Suggested Programmes

P1, P11, P12

TENS ELECTRODE PLACEMENT

Lower Back Pain

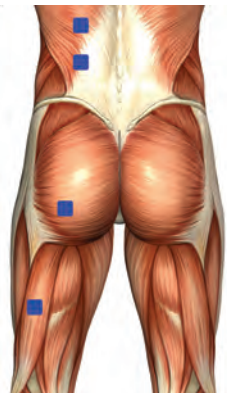


Primary Placement

Suggested Programmes

P1, P3

Hip Neuralgia

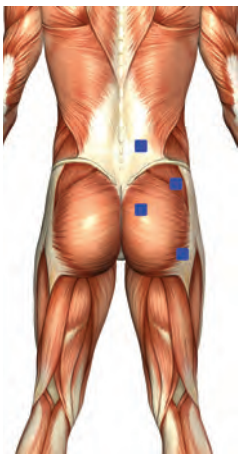


Primary Placement

Suggested Programmes

P12,P11

Phantom Limb, Lower Extremity

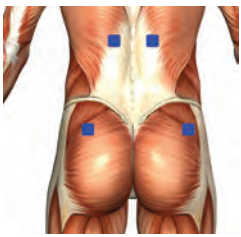


Primary Placement

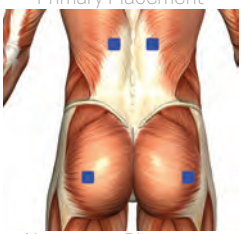
Suggested Programmes

P12

Sciatica



Primary Placement



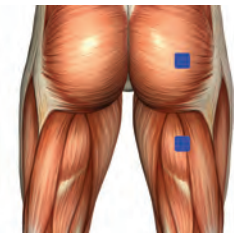
Alternative Placement

Suggested Programmes

P1, P2, P3

TENS ELECTRODE PLACEMENT

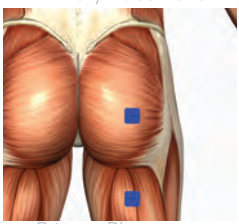
Low Extremity Pain



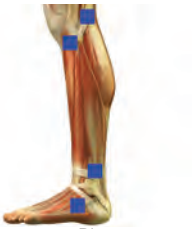
Suggested Programmes

P6, P12

Primary Placement

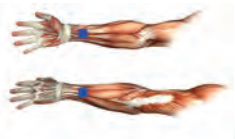


Primary Placement



Alternative Placement

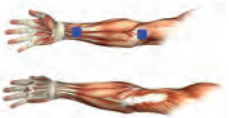
Carpal Tunnel Syndrome



Suggested Programmes

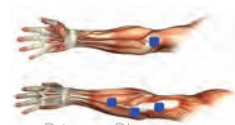
P6

Primary Placement



Alternative Placement

Elbow & Forearm Pain

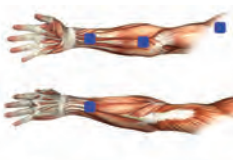


Suggested Programmes

P9, P6

Primary Placement

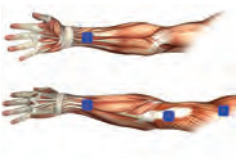
Wrist Pain



Suggested Programmes

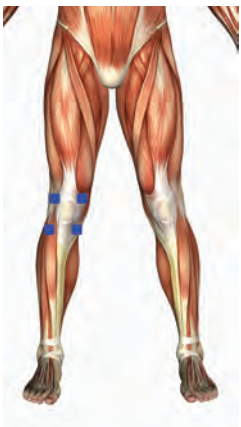
P1, P12

Primary Placement



Alternative Placement

Degenerative Arthritis - Knee Pain



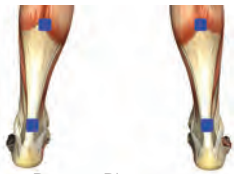
Suggested Programmes

P4, P12

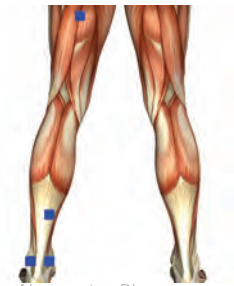
Primary Placement

TENS ELECTRODE PLACEMENT

Lower Leg Pain



Primary Placement

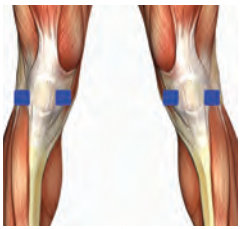


Alternative Placement

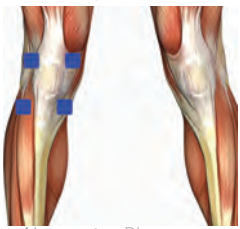
Suggested Programmes

P4, P6, P12

Knee Pain - Post-Op



Primary Placement

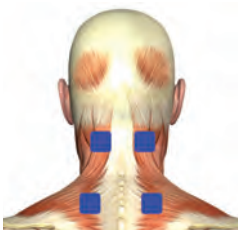


Alternative Placement

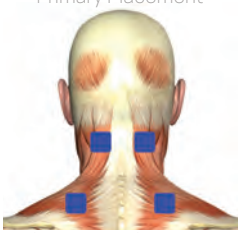
Suggested Programmes

P4, P6, P12

Cervical Placement



Primary Placement

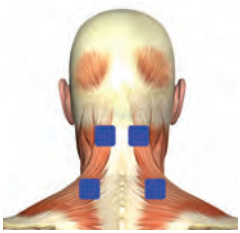


Alternative Placement

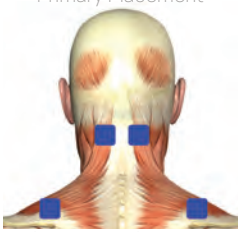
Suggested Programmes

P8

Chronic Cervical Strain



Primary Placement



Alternative Placement

Suggested Programmes

P8

LIMITED WARRANTY

Med-Fit UK Ltd 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 UK Ltd ("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 UK Ltd sole obligation in the case of any breach of its warranties set forth in the paragraph above, shall be, at Med-Fit UK Ltd 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 UK Ltd 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.

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.

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.

SAFETY-TECHNICAL CONTROLS

For safety reasons, review the following checklist before using your EM6100A Digital TENS.

1. Check the device for external damage.
   - deformation of the housing.
   - damaged or defective output sockets.
3. Check the usability of accessories.
   - patient cable undamaged
   - electrodes undamaged.

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

MALFUNCTIONS

Should any malfunctions occur while using the EM6100A Digital TENS/EMS, check
- check the cable is correctly connected to the device. The cables should be inserted completely into the sockets.

CONFORMITY TO SAFETY STANDARDS

The EM6100A Digital TENS devices are in compliance with the following standards:

EN 60601-1-2: 2007 Medical electrical equipment -
Part 1-2: General requirements for basic safety and essential performance
-Collateral standard: Electromagnetic compatibility
-Requirements and tests

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

GRAPHIC SYMBOLS

	Degree of Electrical Protection BF
	Timer
	Increment
	Decrement
	Consult instructions for use
	Manufacturer
SN	Serial number
	Lock
	Low battery
	Pause
	DC current (DC Power source)
CE 2460	Comply with MDD 93/42/EEC requirement as amended by 2007/47/EC. Notify body det norske veritas (DNV)
	Power

The label attached to the back of device contains important information about this device model, supply voltage, CE number and caution. Please don not remove.

The Premier Plus TENS Programmes P1-P12

NO	PROGRAMME	FREQUENCY	PULSE WIDTH
1	**Conventional 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	**Conventional TENS** - Ideal for muscle pain for both acute and long term pain CONDITION S Neck, Shoulder, Elbow Pain, Rheumatic Pain, Lumbago, Hip Pain, Osteoarthritic Pain in the knee	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
10	Mixed Frequency long term use programme. Ideal for treating chronic pain over long periods example 5+ hours CONDITIONS Neck, Shoulder, Elbow Pain, Rheumatic Pain, Lumbago, Menstrual Pain, hip Pain, Osteoarthritic Pain in the Knee	5-125Hz	120µs
11	Modulation Rate & width over 6 seconds CONDITIONS Neck, Shoulder, Elbow Pain, Rheumatic Pain, Lumbago, Menstrual Pain, hip Pain, Osteoarthritic Pain in the Knee	2-100Hz	260-150µs
12	Modulation Rate over 6 seconds CONDITIONS Neck, Shoulder, Elbow Pain, Rheumatic Pain, Lumbago, Menstrual Pain, hip Pain, Osteoarthritic Pain in the Knee	80<->7Hz	260µs

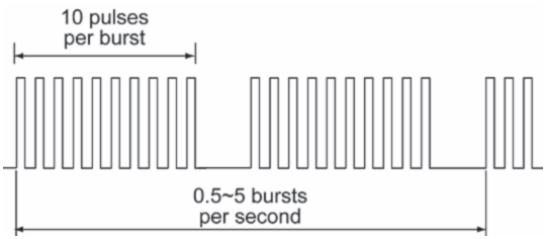
TECHNICAL SPECIFICATIONS

The technical specification details of EM6100A are as follows:

	MECHANISM	TECHNICAL DESCRIPTION
01	Channel	Dual, isolated between channels
02	Pulse Amplitude	Adjustable, 0-100 mA peak into 500 ohm load each channel.
03	Wave Form	Asymmetrical Bi-Phasic Square Pulse
04	Voltage	0 to 50V (Load: 500 ohm)
05	Power source	Lithium Battery
06	Size	11.8cm(L) x 6cm(W) x 3.1cm(H)
07	Weight	150 grams with battery.
08	Timer	Adjustable, from 1 to 60 minutes or Continuous. Adjustable in 1 minute each step from 1 to 15 minutes, and 5 minutes each step from 15 to 60 minutes. Treatment time countdown automatically.
09	Low Battery Indicator	A low battery indicator will show up when the battery is low.
10	Operating Condition	Temperature: °~°C Relative Humidity: 30%~75% Atmosphere Pressure: 700Hpa~1013Hpa
11	Remark	There may be up to a +/-5% tolerance of all parameters and +/-20% tolerance of output amplitude & voltage.

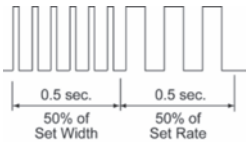
The waveforms of the TENS modes are as follows.

Burst

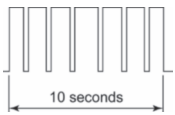


Normal

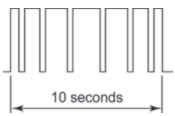
Modulation



S1 (Strength-Duration)



S2 (Strength-Duration)



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.

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