MED-FIT

4 CHANNEL MULTI STIM PLUS TENS & EMS

37 PROGRAMMES AND FULLY ADJUSTABLE IN MANUAL MODE

PATIENT INSTRUCTION & USER MANUAL

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

EV906B

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.

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IMPORTANT SAFETY INFORMATION

Read instruction manual before operation. Be sure to com-ply with all “CAUTIONS” and “WARNINGS” in the manual. Failure to follow instructions can cause harm to user or device.

SIDE EFFECTS

TENS

Transcutaneous Electrical Nerve Stimulation (TENS) is a therapy that uses low voltage electrical currents to relieve pain. TENS treatment is generally considered safe and rarely causes any side effects. However, some people may experience the following side effects:

- Skin irritation: Some people may experience skin irritation at the site of the electrodes.
- Muscle twitching: In some cases, TENS treatment may cause muscle twitching.
- Nausea: Some people may experience nausea during TENS treatment.

Overall, TENS therapy is generally safe and well-tolerated. However, it is important to use it properly and under the guidance of a healthcare professional to minimize the risk of side effects.

EMS

Electrical Muscle Stimulation (EMS) is a therapy that uses electrical impulses to stimulate muscle contractions. It is commonly used to improve muscle strength, increase range of motion. While EMS is generally safe and well-tolerated, there are some potential side effects to be aware of:

- Skin irritation: Some people may experience skin irritation at the site of the electrodes.
- Muscle soreness: After EMS therapy, some people may experience muscle soreness.
- Muscle spasms: In rare cases, EMS therapy may cause muscle spasms or cramps. This can usually be prevented by adjusting the intensity of the device or by changing the placement of the electrodes.

Overall, EMS therapy is generally safe and well-tolerated. However, it is important to use it properly and under the guidance of a healthcare professional to minimize the risk of side effects.

GENERAL DESCRIPTION

The EV906 Digital TENS/EMS is a battery operated pulse generator that sends electrical impulses electrodes to the body and reach the nerves and underlying muscle group. This unit is a combination stimulator of TENS and EMS which can be used for muscle stimulation and pain relief. The device is provided with four controllable output channels, each independent of each other. 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.

There is nothing "magic" about Transcutaneous Electrical Nerve Stimulation (TENS). TENS is intended to be used to relieve pain. The TENS unit sends comfortable impulses through the skin that stimulate the nerve (or nerves) in the treatment area. In many cases, this stimulation will greatly reduce or eliminate the pain sensation the patient feels. Pain relief varies by individual patient, mode selected for therapy, and the type of pain. In many patients, the reduction or elimination of pain lasts longer than the actual period of stimulation (sometimes as much as three to four times longer). In others, pain is only modified while stimulation actually occurs. You may discuss this with your physician or therapist.

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INTRODUCTION TO EMS

EXPLANATION OF EMS

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

It is a product derived from the square waveform, originally invented by John Faraday in 1831. Through the square wave pattern it is able to work directly on muscle motor neurons. The EMS has low frequency and this in conjunction with the square wave pattern allows direct work on muscle groupings. This is being widely used in hospitals and sports clinics for the treatment of muscular injuries and for the re-education of paralysed muscles, to prevent atrophy in affected muscles and improving muscle tone and blood circulation.

HOW EMS WORKS

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

The EMS units send comfortable impulses through the skin that stimulate the nerves in the treatment area. When the muscle receives this signal it contracts as if the brain has sent the signal itself. As the signal strength increases, the muscle flexes as in physical exercise. Then when the pulse ceases, the muscle relaxes and the cycle starts over again, (Stimulation, Contraction and Relaxation.) Powered muscle stimulators should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

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WARNINGS AND PRECAUTIONS

PLEASE NOTE:

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

WARNING! PATIENTS WITH PACEMAKERS MAY NOT BE TREATED WITH TENS

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

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

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

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

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.

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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.

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.

CAUTIONS

CONFORMITY TO SAFETY STANDARDS

The EV906B Digital TENS/EMS 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.

MALFUNCTIONS

Should any malfunctions occur while using the EV906B Digital TENS/EMS, check:
- whether the parameters are 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 LCD reveals the menu. If necessary, insert 4 new AA batteries.
- for possible damage to the cable. Change the cable if any damage is detected.

SAFETY-TECHNICAL CONTROLS

For safety reasons, review the following checklist before using your EV906B Digital TENS/EMS:
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.
- Batteries are not corroded

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FUNCTIONS AND CONTROLS

To access the controls, open the front cover (open from the left hand side see below) for control functions.

1. Output sockets.
2. Intensity up.
3. Intensity down.
4. Programme buttons.
5. Set button.
6. Mode button.
7. On/Off button.

FUNCTIONS AND CONTROLS

A low battery indicator will be displayed on the screen when the batteries need to be replaced. Remove the batteries if the device is not likely to be used for some time.

- Make sure the power is off.
- Open the battery compartment (push the cover downwards)
- Remove the batteries or insert the 4 non-rechargeable AA batteries supplied
- Insert the new batteries. Please check that the polarity is correct!
- Close the battery compartment
- Rechargeable batteries may be used in this device

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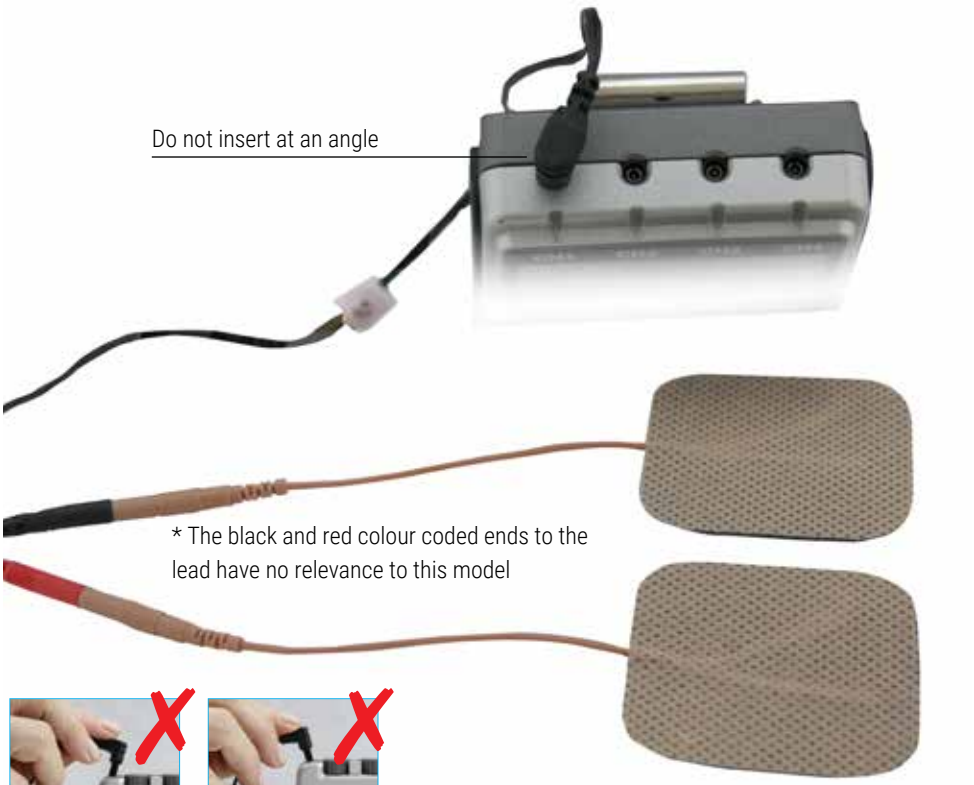
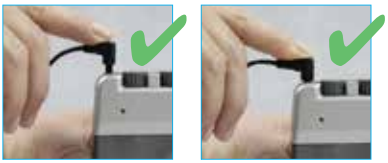
INSTRUCTIONS FOR USE

Connecting patient leads to your device

Please note: you can use all four channels simultaneously each lead must have two self-adhesive pads connected to the patient lad as shown below





When connecting the Patient leads, please ensure they are inserted completely straight and not at an angle. Pushing at an angle may bend the pins.

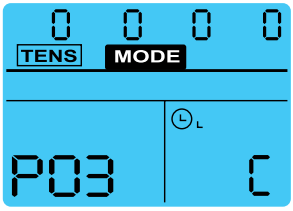
INSTRUCTIONS FOR USE
SELECTING A PROGRAMME

Select programme mode by pressing the mode button. (MODE)
In program mode you have a choice of 37 different programs for various areas of application. These are pre-set programmes simply set the intensity for the connected channel and start the treatment.

Please Note: The program starts immediately when you set the intensity

Most programs run in continuous mode, indicated by a "C" shown in the lower right corner of the display. Some programs also have a pre-set duration. The device ends the application automatically when the time expires.

To set a program, press the "MODE" button until you reach P mode, indicated by a P shown in the bottom-left corner of the display.
Press (▲) or (▼) to select the desired programs (P1 – P37). You find an overview over all available programs in this manual.
When you have chosen the right program, please set the intensity for the connected channels (1-4).



Increase intensity (△)

Decrease intensity (▽)

In P mode, the parameters are pre-set and can not be changed!

TENS programmes are P1 to P16

EMS programmes are P17 to P32

Pelvic floor stimulation programmes P33 to P37

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TENS – STIMULATION

The programmes have proven to be helpful in may cases for the suggested applications. However, they might be used for the treatment of other injuries or discomforts as well. Every patient responds individually to each programme.

Programme 1

Conventional TENS	Frequency	Pulse Width
Can be applied in most existing types of pain (acute and chronic). Gate-Control-Effect.	80Hz	180µs

Programme 2

Low Frequency Burst TENS	Frequency	Pulse Width
Endorphins release application for example in case of radiating pain on arms/legs/feet, muscular and deeper-lying pain.	2Hz	180µs

Programme 3

Modulated TENS (massage effect)	Frequency	Pulse Width
Applied for longer periods. Can be applied for most types of pain (acute and chronic).	80Hz	70-180µs

Programme 4

Mixed Frequencies 15/2Hz	Frequency	Pulse Width
Application for example in case of stiff joints, neck pains, lumbago and menstrual problems.	15Hz/2Hz	180µs

Programme 5

Mixed Frequencies 80/2Hz	Frequency	Pulse Width
Perfect for a variety of different pain conditions.	80Hz/2Hz	180µs

Programme 6

Nausea, feeling of sickness or travel sickness	Frequency	Pulse Width
The electrodes should be placed above the acupuncture point C6.	10Hz	180µs

TENS – STIMULATION

Programme 7

Migraine and Headaches	Frequency	Pulse Width
Applications are to be specifically used in cases of tension headache, face pain, neck pain, herpes zoster, and migraine. Apply the smaller round electrodes supplied for this treatment.	80Hz	180µs

Programme 8

Chronic Pain Relief	Frequency	Pulse Width
Application in case of pains in the neck, hip, shoulders, elbows, rheumatic pains, back and lumbar pain, menstrual problems, and knee arthritis.	10Hz	200µs

Programme 9

Rheumatic Pain Relief	Frequency	Pulse Width
Pains due to rheumatoid arthritis, radiating pain on arms/legs/feet, through modulation suitable for long-term use.	50Hz	250µs

Programme 10

Frequency TENS	Frequency	Pulse Width
In cases of therapy-resistant complaints, stimulation both on sensory and motor basis, against habituation effect.	80-7Hz	260µs

Programme 11

Frequency Modulation TENS and pulse duration modulation	Frequency	Pulse Width
Applicable for most types of acute and chronic pain. With anti-habituation effect.	2-100Hz	260-150µs

Programme 12

Frequency Modulation TENS and pulse duration modulation	Frequency	Pulse Width
Application in case of pain in the back, knee, shoulders, legs, elbows, neck, and rheumatic pains.	80<->7Hz	260µs

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TENS – STIMULATION

Programme 13

Modulated TENS	Frequency	Pulse Width
Muscular spasms	100-2Hz	200-300µs

Programme 14

High-Frequent TENS	Frequency	Pulse Width
Acute pains, tensions, Gate-Control-Effect.	100Hz	250µs

Programme 15

Combination TENS	Frequency	Pulse Width
Programmes of TENS. In cases of long-term pain. Consists of high and low frequency TENS as well as frequency/pulse duration/intensity modulation. Duration: 40 minutes	3-100Hz	150-300µs

Programme 16

Wrist Pain TENS	Frequency	Pulse Width
Pains in the wrist and fingers, long-term application. Duration: 40 minutes.	5-125Hz	120µs

EMS – STIMULATION

Large muscle groups

Thigh
Buttock
Abdominal
Back
Chest

Small muscle groups

Calf
Biceps
Shoulder
Forearms
Fingers and toes

EMS – STIMULATION

These programmes cover warm-up, rehabilitation, strengthening, recovery, and massage. Programmes 17-28 contain a warm-up phase of one minute. Followed by the stimulation programme.

Programme 17

	Section Time	Rate	Width	Ramp Up	Ramp Down	On Time	Off Time
Muscle Training	1	10	150				
small muscle groups	3	30	200	3	3	4	10
	6	40	250	2	2	4	10
	C	50	300	1	1	6	10

Programme 18

	Section Time	Rate	Width	Ramp Up	Ramp Down	On Time	Off Time
Muscle Training	1	10	150				
large muscle groups	3	30	200	3	3	4	10
	6	40	250	2	2	4	10
	C	50	300	1	1	6	10

Programme 19

	Section Time	Rate	Width	Ramp Up	Ramp Down	On Time	Off Time
Muscle strength	1	10	150				
training	3	35	200	3	3	4	10
small muscle groups	6	50	250	2	2	4	10
	C	70	300	1	1	6	10

Programme 20

	Section Time	Rate	Width	Ramp Up	Ramp Down	On Time	Off Time
Muscle strength	1	10	150				
training	3	30	200	3	3	9	15
large muscle groups	6	40	250	2	2	11	15
	C	50	300	1	1	13	15

Programme 21

	Section Time	Rate	Width	Ramp Up	Ramp Down	On Time	Off Time
Muscle strength	1	10	150				
training re-education	3	30	200	3	3	9	15
small muscle groups	6	40	250	2	2	11	15
	C	50	300	1	1	13	15

EMS – STIMULATION

Programme 22

	Section Time	Rate	Width	Ramp Up	Ramp Down	On Time	Off Time	Timer
Muscle strength	1	10	150					C
training re-education	3	30	250	3	3	9	15	
large muscle groups	6	40	300	2	2	11	15	
	C	50	350	1	1	13	15	

Programme 23

	Section Time	Rate	Width	Ramp Up	Ramp Down	On Time	Off Time	Timer
Muscle re-education	1	10	150					C
training re-education	3	35	250	3	3	9	15	
small muscle groups	9	50	300	2	2	11	12	
	C	65	350	1	1	13	10	

Programme 24

	Section Time	Rate	Width	Ramp Up	Ramp Down	On Time	Off Time	Timer
Muscle re-education	1	10	200					C
training re-education	3	35	300	3	3	9	15	
large muscle groups	9	50	350	2	2	11	12	
	C	65	400	1	1	13	10	

Programme 25

	Section Time	Rate	Width	Ramp Up	Ramp Down	On Time	Off Time	Timer
Endurance training	1	18	150					C
training re-education	3	15	200	2	2	6	3	
small muscle groups	3	10	250	2	2	6	2	
	C	6	300	1	1	6	1	

Programme 26

	Section Time	Rate	Width	Ramp Up	Ramp Down	On Time	Off Time	Timer
Endurance training	1	18	150					C
training re-education	3	15	200	2	2	6	3	
large muscle groups	3	10	250	2	2	6	2	
	C	6	350	1	1	6	1	

EMS – STIMULATION

Programme 27

	Section	Time	Rate	Width	Ramp Up	Ramp Down	On Time	Off Time	Timer
Endurance training	1		15	150					C
training re-education	3		12	200	2	2	6	3	
small muscle groups	3		10	300	2	2	6	2	
	C		6	350	1	1	6	1	

Programme 28

	Section	Time	Rate	Width	Ramp Up	Ramp Down	On Time	Off Time	Timer
Endurance training	1		15	150					C
training re-education	3		12	250	2	2	6	3	
large muscle groups	3		10	320	2	2	6	2	
	C		6	400	1	1	6	1	

Programme 29

	Section	Time	Rate	Width	Ramp Up	Ramp Down	On Time	Off Time	Timer
Intermittent stimulation	1		100	150					C
for relax & warm down	C		100	250	0	0	1	1	

Programme 30

	Section	Time	Rate	Width	Ramp Up	Ramp Down	On Time	Off Time	Timer
Intermittent stimulation	1		80	200					C
for relax & warm down	C		100	300	0	0	1	1	

Programme 31

	Section	Time	Rate	Width	Ramp Up	Ramp Down	On Time	Off Time	Timer
Massage & toning	8		80-2	180			6		C
small muscle groups	8		2-35	50-300			10		
	C		100	70-180			8		

Programme 32

	Section	Time	Rate	Width	Ramp Up	Ramp Down	On Time	Off Time	Timer
Massage & toning	5		20	300-400			8		C
large muscle groups	5		6-30	250			8		
	C		5-45	75-220			10		

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STIMULATION OF THE PELVIC FLOOR MUSCLES

Programme 33

	Section Time	Rate	Width	Ramp Up	Ramp Down	On Time	Off Time	Timer
Pelvic floor Stress incontinence	C	35	250	1	1	4	8	C

Programme 34

	Section Time	Rate	Width	Ramp Up	Ramp Down	On Time	Off Time	Timer
Pelvic floor Stress incontinence	C	40	200	1	1	6	15	C

Programme 35

	Section Time	Rate	Width	Ramp Up	Ramp Down	On Time	Off Time	Timer
Pelvic floor Urge incontinence	C	10	250	1	1	5	3	C

Programme 36

	Section Time	Rate	Width	Ramp Up	Ramp Down	On Time	Off Time	Timer
Maintenance	4	7	150	1	1	4	4	C
of the pelvic floor	4	8	150	1	1	4	4	
	4	9	150	1	1	4	4	
	4	10	150	1	1	4	4	
	4	11	150	1	1	4	4	
	4	12	150	1	1	4	4	
	4	13	150	1	1	4	4	
	4	14	150	1	1	4	4	
	4	15	150	1	1	4	4	
	4	16	150	1	1	4	4	
	4	12	150	1	1	4	4	
	4	7	150	1	1	4	4	

Programme 37

	Section Time	Rate	Width	Ramp Up	Ramp Down	On Time	Off Time	Timer
Enduring building	C	20	250	1	1	5	5	C

Programme 37 is a warm-down programme to be used after programmes P33 -P36.

STIMULATION OF THE PELVIC FLOOR MUSCLES

Tightens & Tones the pelvic floor muscles, and restores pelvic health.

Programmes P33-36 are medically approved to strengthen, tighten and tone the pelvic floor muscles and restore pelvic health.

THESE PROGRAMMES ARE SPECIFICALLY RECOMMENDED FOR THE FOLLOWING.

A. Weak pelvic floor muscles.
B. Bladder weakness.
C. All urinary incontinence.
D. Tighten, tone and improve pelvic muscles.
E. Stress incontinence.
F. Urge incontinence.

PROGRAMME INDICATIONS

For A, B & C use Programme P33,34.
For F use Programme P35.
For D use Programme P36.
For E use Programme P33,34.

Performing pelvic floor exercises

Connecting the wires

Unpack the vaginal/rectal probe, clean it under running water, and dry it. Connect one of your patient lead to the device and attach it to the probe.

Inserting of the probe

Begin by emptying your bladder. The exercises should be carried out whilst lying down with your knees slightly bent. Apply gel to the probe and insert slowly and carefully.

Program selection, performing the stimulation

Turn on the device. Select the desired program (P33 - P36) and start the stimulation by increasing the intensity by pressing the buttons △▽.

Please note: This device is not supplied with an internal probe as standard.
Please visit www.tensmachineuk.com for the range of probes available.

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STIMULATION OF THE PELVIC FLOOR MUSCLES

Medical Background

Incontinence

Urinary incontinence, involuntary loss of urine from the bladder, is a problem for many people. There are two main types of urinary incontinence; stress incontinence and urge incontinence. Faecal incontinence, the involuntary passage of faeces, is not often discussed, but still a common problem. Electrical stimulation through a vaginal/anal probe, or in some cases surface electrodes, is a well-tolerated treatment for urge stress, mixed and faecal incontinence and has shown positive results in improving bladder and bowel control.

Stress incontinence

Stress incontinence is urine leakage caused by increased abdominal pressure on the bladder, such as coughing, sneezing, laughing, exercising, or lifting something heavy. Stress incontinence is the most common type of incontinence and is primarily affecting women. It usually occurs when the perineal and pelvic floor muscles are weakened, for example by pregnancy, childbirth, or menopause.

Urge incontinence

Urge incontinence means a sudden, strong urge to urinate followed by an immediate bladder contraction resulting in an involuntary leakage of urine. Both men and women can be affected, particularly the elderly. One reason for this condition can be a disruption in the part of the nervous system that controls the bladder.

Mixed incontinence

Mixed incontinence is a combination of stress and urge incontinence.

Faecal incontinence

Faecal incontinence, also called anal or bowel incontinence, is the impaired ability to control passage of gas or stool. There are many possible causes of faecal incontinence, the most common is injury to the anal sphincter (ring-like muscle), for instance during childbirth or surgery, or damage to the nerves that control the anal sphincters. The condition usually becomes worse as people age.

STIMULATION OF THE PELVIC FLOOR MUSCLES

Incontinence treatment

Electrical stimulation via the pelvic nerves is a recognised treatment alternative for urinary incontinence. It is also proposed as a treatment method for faecal incontinence due to pelvic floor dysfunction or a poorly functioning anal sphincter.

When treating stress incontinence, the aim of the electrical stimulation is to mirror a voluntary muscle contraction and improve the function of the pelvic floor muscles. For urge incontinence, the aim is to inhibit involuntary bladder contractions by stimulating the nerves in the pelvic floor. When treating mixed incontinence, a stimulation appropriate for both urge incontinence and stress incontinence is used.

For faecal incontinence, the aim is to improve bowel control by strengthening and toning pelvic floor muscles.

Contraindications and Precautions

Incontinence may be due to a number of different causes. The incontinence stimulator should never be used unless a medical practitioner has diagnosed the causes and source of incontinence.

Precautions

1. Read the instruction manual before use.
2. Patients with an implanted electronic device (for example, a pace maker or other device) must not undergo incontinence stimulation treatment without first consulting their doctor.
3. If incontinence therapy becomes ineffective or unpleasant stimulation should be discontinued until its use is re-evaluated by the physician or therapist.
4. Do not use an incontinence stimulator while operating machinery or vehicles.
5. Turn the device off before applying or removing the electrodes.
6. The Med-Fit Total Tone incontinence stimulator device has no AP/APG protection. Do not use it in the presence of explosive atmosphere and flammable mixtures.

Contraindications

1. Do not use incontinence stimulator if you suffer from any muscle disorders
2. Do not use incontinence stimulator if a bladder or vaginal infection is present.
3. Do not use incontinence stimulator if you have been diagnosed or treated for cervical cancer.
4. Do not use incontinence stimulator if you have, or have had epilepsy.

ADJUSTING THE CONTROLS AND SETTINGS IN MANUAL MODE

Power On/Off button and intensity control

The device can be switched on and off by pressing the On/Off button. The intensity can be reduced or increased by pressing the intensity buttons. The intensity can be adjusted for each channel from 0 to 99mA in steps of 1mA.

There are 4 LED lights at the top of the device which are indicated in yellow to show activity of the corresponding channel.

Mode control

There are 5 TENS modes available (N, B, M, SD1, SD2) and 3 EMS modes (C, S, A) as well as the P mode (programs 1-37). The modes can be selected by pressing the "MODE" button. If a TENS mode is selected, the LCD display shows "TENS". If an EMS mode is selected, "EMS" is displayed.

Set control

By pressing the set button, you may enter the setting you intend to adjust. You may start to set the value by pressing the or controls when the value is flashing.

Increment control

When pressing this button, the parameter will increase. This button controls the increase of settings.

Decrement control

When pressing this button, the parameter will decrease. This button controls the decrease of parameter.

Dual timer

The unit has a timer of 1-60 minutes and Continuous mode. It can be adjusted by pressing the "SET" button and the or controls. The application will end when the time is up. Displaying time (L) for channels 1+2 / (R) for channels 3+4

Low battery indicator

If this symbol is shown, the battery is low and the batteries need to be replaced immediately.

MANUALLY ADJUSTING THE CONTROLS FOR TENS

The settings can be adjusted according to the following steps.

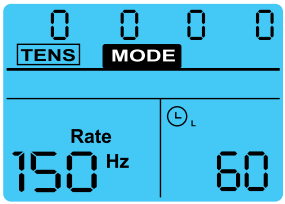
1. Turn on the device

After the electrodes are placed firmly on skin and the lead wires are plugged in the socket of device, press the on button.

2. Select mode

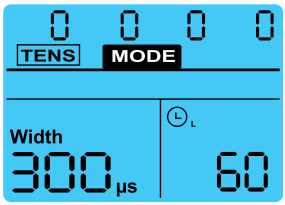
Select a mode by pressing the "MODE" control. The mode you select will be shown on the display. There are 5 modes available: **(B) Burst, (N) Normal, (M) Modulation, SD1 and SD2.**

When a TENS-mode is selected, the LCD-Display will show "TENS". After a mode is selected, press control to enter next setting. Then press the ▲ or ▼ control to change the settings. The settings are stored in the unit as soon as selected.



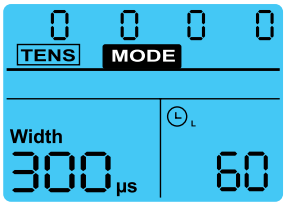
3. Set pulse width

The pulse width can be set from 30µs to 400µs. Press "SET" control to enter this setting. Then press the ▲ or ▼ control to change the settings. If no instructions regarding the pulse width are given in therapy, set the control to 70 – 120 µs.



4. Set pulse rate

The pulse rate is adjustable from 2Hz to 150Hz. Press "SET" control to enter this setting. Then press the "Increment" or "Decrement" control to change the settings. If no instructions regarding the pulse width are given in therapy, set the control to 70 – 120µs.



MANUALLY ADJUSTING THE CONTROLS FOR TENS

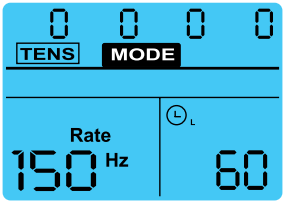
5. Set timer

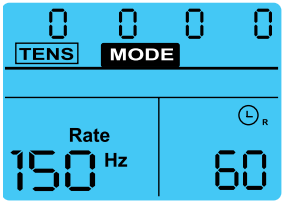
There are two adjustable timers available.

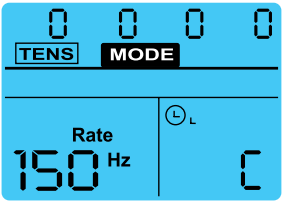
controls the application duration for the channels CH 1&2

controls the application duration for the channels CH 3&4

The settings are adjustable from 1 to 60 minutes. With the setting (C) the machine runs in continuous mode. Press “SET” control to enter the settings. Press ▲ or ▼ control to adjust the setting. Press the ▲ control when the Timer shows 60 minutes to set the timer to continuous stimulation. Both Timers can be adjusted in the same way.







6. Adjusting the intensity

The intensity can be adjusted from 0 – 100. Press ▲ or ▼ control to adjust the setting of the respective channels 1-4.

MANUALLY ADJUSTING THE CONTROLS FOR EMS

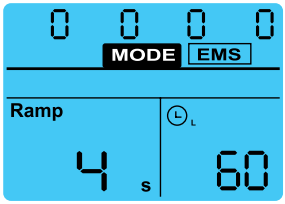
The settings can be adjusted according to the following steps.

1. Turn on the device

After the electrodes are placed firmly on skin and the lead wires are plugged in the socket of device, press the on button.

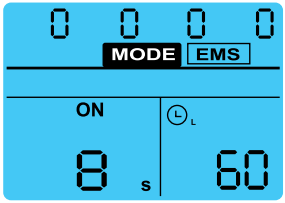
2. Select mode

Select a mode by pressing the "Mode" control.
The mode you selected will show up on the top of liquid crystal display. There are 3 modes available: **C (Constant), S (Synchronous) and A (Asynchronous).** When an EMS mode is selected, the LCD display will show "EMS". After a mode is selected, press "SET" control to enter next setting. Then press the ▲ or ▼ control to change the settings. The settings are set as soon as they are selected.



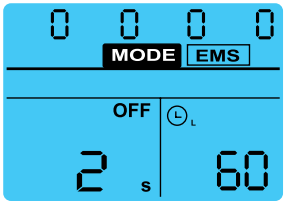
3. Set ramp time

The ramp time controls the time of output current that increase from 0 to the setting level, and from the setting value back to 0. The ramp time is adjustable from 1 to 8 seconds.



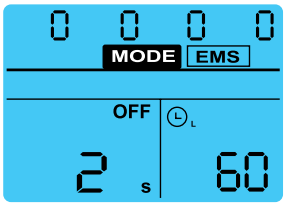
4. Set contraction time (ON-Time)

The ON time controls the contraction time. By pressing the "SET" control, the contraction time is adjustable from 0 – 90 seconds. This time includes the ramp time twice, once for the ramp up and once for the ramp down. **Example: 10s ON time & 3s ramp time = 3s ramp up, 4s full intensity, 3s ramp down.**



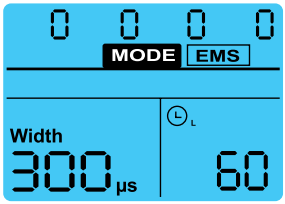
MANUALLY ADJUSTING THE CONTROLS FOR EMS

5. Set pause time (OFF-Time)



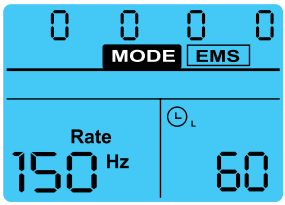
The Off Time controls the time of relaxation between two cycles. By pressing the "SET" control, the relaxation time can be adjusted. Both channels' stimulation is cycled on and off by the contraction and relaxation settings. The range is adjustable from 0 to 90 seconds. In Alternate mode, the OFF time should be equal or more than the ON time. (OFF TIME ≥ ON TIME).

6. Set pulse width



The pulse width is adjustable from 30 to 400µs. Press "SET" control to enter this setting. Then press the ▲ or ▼ control to change the settings. If no instructions regarding the pulse width are given in therapy, set the control to 70 – 120 µs.

7. Set Pulse Rate



The pulse rate is adjustable from 1Hz to 150Hz. Press "SET" control to enter this setting. Then press the ▲ or ▼ control to change the settings. If no instructions regarding the pulse rate are given in therapy, set the control to 70 – 120 Hz.

MANUALLY ADJUSTING THE CONTROLS FOR EMS

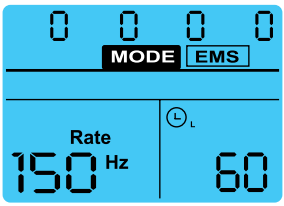
8. Set timer

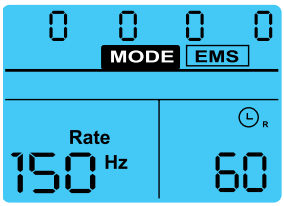
There are two adjustable timers available.

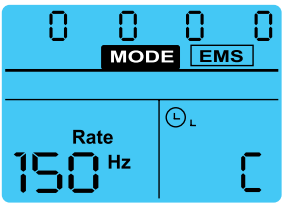
L controls the application duration for the channels CH 1&2

R controls the application duration for the channels CH 3&4

The settings are adjustable from 1 to 60 minutes. With the setting (C) the machine runs in continuous mode. Press “SET” control to enter the settings. Press ▲ or ▼ control to adjust the setting. Press the ▲ control when the Timer shows 60 minutes to set the timer to continuous stimulation. Both Timers can be adjusted in the same way.







9. Adjusting the intensity

The intensity can be adjusted from 0 – 100. Press ▲ or ▼ control to adjust the setting of the respective channels 1-4.

MAINTENANCE, TRANSPORTATION AND STORAGE

- Non-flammable cleaning solution (containing 70% of alcohol) is suitable for cleaning the device.
- Stains and spots can be removed with a cleaning agent.
- Do not submerge the device in liquids or expose it to large amounts of water.
- Return the device to the carrying box with sponge foam to ensure that the unit is well-protected before transportation.
- If the device is not to be used for a long period of time, remove the batteries and put it back into the carrying box and keep it in a cool, dry place.
- The packed TENS device should be stored and transported under the temperature range of -20°C ~+60°C, relative humidity 20% ~ 95%, atmosphere pressure 500 hPa ~ 1060 hPa.

SAFETY CHECKS

For safety reasons, review the following checklist once a week.

- Check the device for deformation of the housing or damage to the output sockets.
- Make sure that the descriptions and labels are not damaged.
- Check that the LED is on when the device is turned on.
- Check the cables and electrodes for damage.
- The device must be subjected to safety checks and maintenance by authorized technicians before use and each re-use, but at least every 24 months.
- Please consult your distributor if there are any problems with the device and accessories.
- The manual must always be carried with the device.

WARRANTY

All TENS models carry a warranty of 12 months from the date of delivery. The warranty applies to the stimulator only and covers both parts and labor relating thereto. The warranty does not apply to damage resulting from improper handling, the failure to follow the operating instructions.

GRAPHIC SYMBOLS

Degree of Electrical Protection BF

Timer

Increment

Decrement

Consult instructions for use

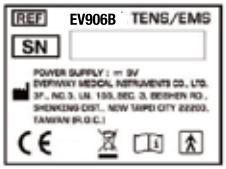
Manufacturer

SN Serial number

Low battery

Power

CE 2460 Comply with MDD 93/42/EEC requirement as amended by 2007/47/EC. Notified body det norske veritas (DNV)



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

TECHNICAL DESCRIPTION

The technical specification details of EV906B are as follows:

	MECHANISM	TECHNICAL DESCRIPTION
01	Channel	4 channels – with adjustable intensity
02	Intensity	Adjustable, 0 – 100 mA (in steps of 1 mA) with 500 ohm load on each channel
03	Pulse amplitude	Asymmetrical, Bi-phasic square pulse
04	Output voltage	0 – 50 V
05	Power source	4pcs 1.5V AA-batteries
06	Size	13.8cm (L) x 7.8cm (B) x 2.8cm (H)
07	Weight	276 grams (batteries included)
08	Pulse rate	Adjustable, from 1 – 150 Hz, 1 Hz/step
09	Pulse width	Adjustable, from 30 – 400 microseconds, 10 µ/step
10	ON time	Adjustable, from 2 – 90 seconds, 1 Sec./step
11	OFF time	Adjustable, from 0 – 90 seconds, 1 Sec./step
12	Ramp time	Adjustable, from 1 – 8 seconds, 1 Sec./step
13	Mode	5 TENS modes: B (Burst) N (Normal), M (Modulation), SD1 (40% modulation), SD2 (70% modulation) – 3 EMS modes: C (Constant), 5 (Synchronous), A (Alternate), P (Program-Mode) – 37 TENS programs (set by default)
14	TENS Burst mode B	Burst rate: Adjustable, 0.5 – 5 Hz – Pulse Width adjustable, 30 – 400 µs – Frequency fixed = 100 Hz
15	TENS Normal mode N	The pulse rate and pulse width are adjustable. It generates continuous stimulation based on the setting value
16	TENS Modulation mode M	Modulation mode is a combination of pulse rate and pulse width modulation. The pulse rate and width are automatically varied in a cycle pattern. The pulse width is decreased by 50% from its original setting in 0.5 second, then the pulse rate is decreased by 50% from its original setting in 0.5 second. Total cycle time is 1second. In this mode, pulse rate (1 – 150 Hz) and pulse width (30 – 400 µs) are fully adjustable.
17	TENS SD 1 mode	The SD1 (Strength-Duration) mode consists of automatic modulation intensity and pulse width in 40% range. The intensity is always increasing while the pulse width is decreasing and vice versa. The intensity is decreased by 40% while the pulse width is increased by 40% in 5 seconds. In the next 5 seconds, the intensity is increased by 40% while the pulse width is decreased by 40%. Total cycle time is 10 seconds. Pulse rate (1 – 150 Hz) and pulse width (30 – 400 µs) are fully adjustable.

TECHNICAL DESCRIPTION

	MECHANISM	TECHNICAL DESCRIPTION
18	TENS SD 2 mode	The SD2 (Strength Duration) mode consists of automatic modulation intensity and pulse width in 70% range. The intensity is always increasing while the pulse width is decreasing and vice versa. The intensity is decreased by 70% while the pulse width is increased by 70% in 4 seconds. In the next 4 seconds, the intensity is increased by70% while the pulse width is decreased by 70%. Total cycle time is 10 seconds. Pulse rate (1 – 150 Hz) and pulse width (30 – 400 µs) are fully adjustable.
19	EMS C Constant mode	Constant stimulation based on setting value. Only pulse width and pulse rate are adjustable in this mode.
20	EMS S Synchronous mode	Stimulation of all channels occurs synchronously. The "ON" time including "Ramp Up" and "Ramp Down" time. Therefore, the setting of ON Time should be no less than two times of the "Ramp" time in this mode.
21	EMS A Asynchronous mode	Alternating stimulation. Used for the training of both against and antagonist. First, channels 1&3 run simultaneously, then channels 2&4. The duration of one cycle is the duration of the ON time, including the ramp time. Please note that the ON time can not be shorter than twice the ramp time.
22	TENS/EMS P program mode	See section Program mode (P) – pages 42 – 46
23	Patient compliance meter	This unit can store 60 sets of operation records. The maximum recordable time is 999 hours.
24	Low battery indicator	A low battery indicator will show up on the LCD when the battery is low.
25	Operating condition	Temperature: 0°C - 40°C Relative humidity: 30 % - 75 % Air pressure: 700hPa - 1060hPa
26	Notice	All technical values include a tolerance of +/- 5%

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	

EMC INFORMATION

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.

EMC INFORMATION

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

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

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	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.