Med-Fit

Premier TENS & EMS

Pain Relief - TENS Machine - Muscle Stimulation.
Alivio del dolor - Máquina TENS - Estimulación muscular.
Schmerzlinderung - TENS Machine - Muskelstimulation.
Soulagement de la douleur - Machine TENS - Stimulation musculaire.

EM6300A

CE 2460

med-fit

Patient Instructions & User Manual

Instrucciones para el paciente y manual del usuario
Patientenanweisungen & Benutzerhandbuch
Instructions pour le patient et manuel d'utilisation

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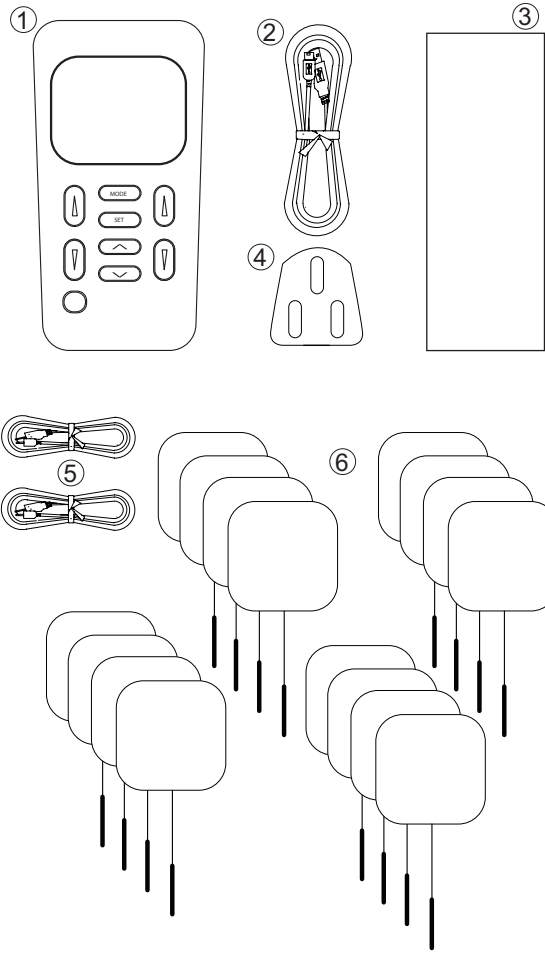
Skin Patch Test

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.

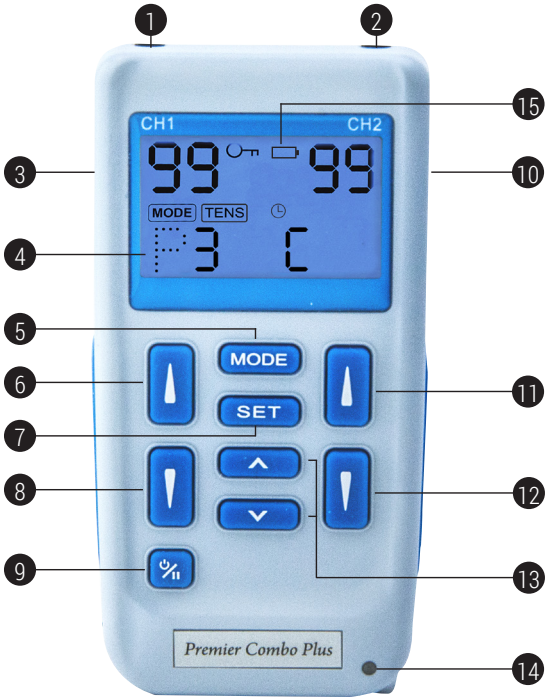
After 30 minutes, remove the electrode and inspect the area for any redness or irritations. If no change is noticed, proceed with your first TENS treatment following the User Guide and Instructions provided. If skin irritation has been noticed, we recommended the use of sensitive gel electrodes.

What's in the box?



1. TENS unit
2. USB charging lead
3. User manual
4. AC adaptor.
5. Patient leads.
6. 16 5x5 self-adhesive electrodes.

Controls and Functions



1. Left channel socket.
2. Right channel socket.
3. Red key lock button. - Pressing the Red Key Lock Button locks all parameters including the intensity level. This is ideal once you have set the device which removes accidental movement of the setting.
4. Mode display.
5. Mode select button to change from TENS to EMS.
6. Intensity up channel 1.
7. The set button is to select the desire parameters in manual mode only it has no function when using the pre-set programmes.
8. Intensity down channel 1.
9. On / Off Pause Button. - When your device is on you can pause the treatment by pressing and holding down the on-off button for approximately 2 seconds.
10. Charging port.
11. Intensity up channel 2.
12. Intensity down channel 2.
13. Programme selector up and down.
14. LED charging indicator.
15. Low Battery Indicator - When the battery level reaches 10% capacity a battery symbol will appear on the screen indicating a charge will be required.

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 

button will allow you to change from TENS to EMS Mode (we always recommend to start with a TENS 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 charts supplied in this guide for details on each programme available, please remember that P1-P12 are TENS programmes and P13-P24 are EMS programmes.

Step 6

The recommended programme to use for a 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

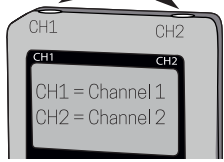
You are now ready to use the TENS for the first time. (see step 8).

Step by Step Guide

Step 8

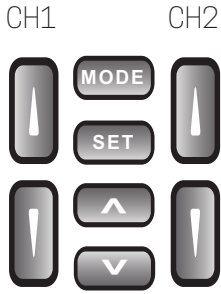
Connect one of the TENS lead cables supplied to the top of your TENS machine. As shown in Fig1. Now connect the other end of the TENS cable to the self-adhesive electrodes supplied. As shown in Fig2. Next place the self-adhesive electrodes on to the painful site or as recommended by your healthcare professional. You are now ready to turn up the intensity on your TENS machine.

Fig1



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 2 hours to give the best possible results.



Charging Instructions

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

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.

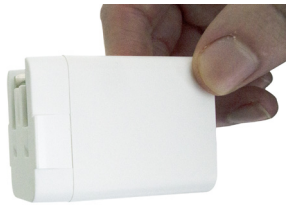
A red indicating light will be seen in the bottom right hand corner of your TENS device. We recommend you charge the device for approximately 2 hours. Once fully charged the unit will be ready for use and the LED charging light will turn to green, this indicates the unit is fully charged. Remove the 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.

Place the small USB connector in the charging port.

The charging light will turn red.

Fit the plug to the other USB connector

Make sure the the connectors face up see fig 1



Place the plug over the connectors see fig 2

Slide down until it clicks into place see fig 3

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 while 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.

Malfunctions

Should any malfunctions occur while using the EM6300A Digital TENS/EMS, check - check the cable is correctly connected to the device. The cables should be inserted completely into the sockets.

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.
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.

Safety-Technical Controls

For safety reasons, review the following checklist before using your EM6300A 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.

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

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.

Conformity to Safety Standards

The EM6300A 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.

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. 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 Recommended treatment time 90 minutes or until the pain subsides.

Programme 4

Knee Pain

This programme is ideal for treating knee injuries both acute and chronic including osteoarthritis rheumatoid arthritis and joint pain.

Programme 5

Shoulder Pain

Treating shoulder pain relief from heavy or repetitive lifting, arthritis, and tendinopathy.

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).

TENS Programmes

Programme 7

Migraine/Headaches

Reduced pulse width ideal for treating nerve rich areas.
Suitable Conditions: Tension Type Headache, Facial Pain, Neck Pain, Postherpetic Neuralgia.

Programme 8

Cervical (Neck) Pain

Cervical pain relief due to poor ergonomic work positions.

Programme 9

Epicondylitis - (Elbow)

Pain relief for epicondylitis resulting from repetitive gripping of objects.

Programme 10

Foot & Ankle Pain

This programme is most suited for foot and ankle pain and increases circulation.

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

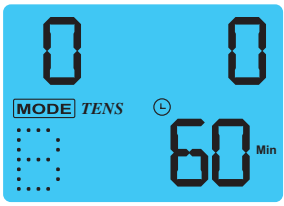
Joint Pain & Fracture Pain

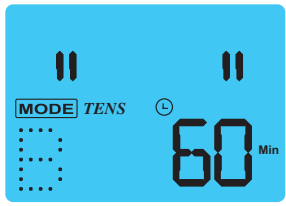
This programme is ideal for all common areas of joint pain, with this treatment we recommend that the stimulation is increased to a stronger level than the pain itself.

Manual Adjustment for TENS

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.

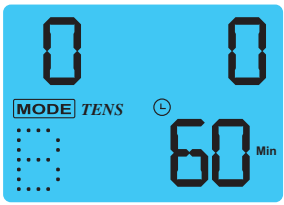




If the unit is not used (buttons not pressed or output level at 0) for 5 minutes, the power will be shut off automatically.

2. Mode Control MODE

There are 5 TENS modes(B, N, M, S1, S2) and 3 EMS modes (C, S, A) available. The mode is selected by pressing the “Mode” control. When a TENS mode is selected, the LCD shows “TENS”. When EMS mode is selected, the LCD shows “EMS”



3. Set Control SET

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.

Manual Adjustment for TENS

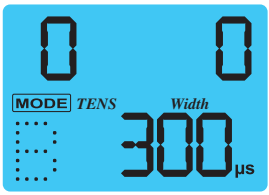
6. Intensity Increase Control
There are 99 steps of intensity adjustment control.
Press the button until the desired intensity level is reached.

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”.

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.

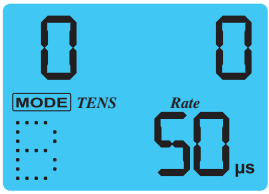
c. Set Pulse Width
Pulse Width is adjustable from 50 µs to 300 µs. Press “SET” control to enter this menu, then press “ ^ ” or “ v ” to adjust the setting. If no instructions regarding the pulse width are given in therapy, set the control to the suggested 70- 120 µs setting.



Manual Adjustment for TENS

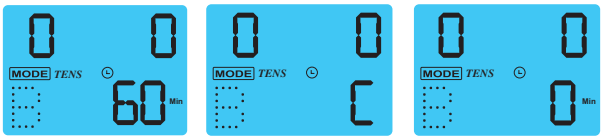
d. Set Pulse Rate

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



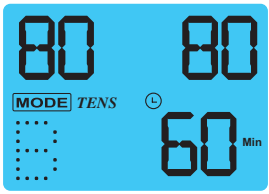
e. Set Timer

The treatment time is adjustable between 5 - 60 minutes and Continue(C). Press “SET” control to enter this menu, then press “ ” or “ ” 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.



Manual Adjustment for EMS

10. Steps to Set a EMS Program

The settings can be adjusted according to the following steps.

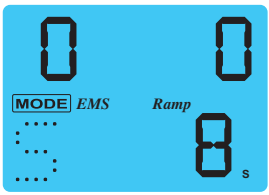
a. Turn on the Power

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 3 modes of your option including - C(Constant), S(Synchronous), A(Alternate). When an EMS mode is selected, it shows “EMS” 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. The settings will be stored immediately after selected.

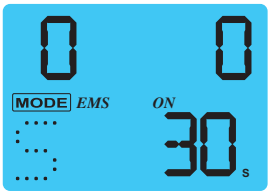
c. Set Ramp Time

The ramp time controls the time taken to reach maximum and the time taken to fall to zero I order to make the contraction more comfortable. The ramp time is adjustable between 1 - 8 seconds.



d. Set On Time

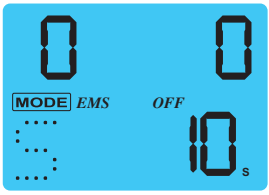
The On Time controls the length of stimulation. By pressing the “Set” control, the contraction time can be adjusted. Both channels’ stimulation is cycled on and off by the contraction and relaxation settings. The range is adjustable from 2 seconds to 90 seconds.The total “ON” time must be at least twice the “Ramp” time.



Manual Adjustment for EMS

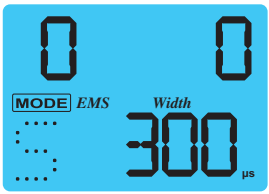
e. Set Off Time

The Off Time controls the length of relaxation. 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 2 seconds to 90 seconds. In Alternate mode, the OFF Time should be equal or more than the ON Time. (OFF TIME ON TIME).



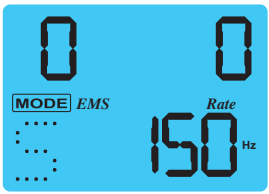
f. Set Pulse Width

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.



g. Set Pulse Width

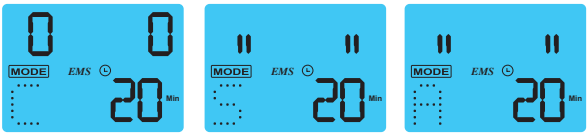
Pulse rate is adjustable from 2Hz to 150 Hz . Press "SET" control to enter this menu, then press " ^ " or " v " to adjust the setting. Unless otherwise instructed, set the pulse rate to the 70-120 Hz range.



Manual Adjustment for EMS

h. Set Timer

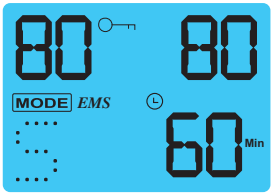
The treatment time is adjustable between 5 - 60 minutes and Continue(C). Press “SET” control to enter this menu, then press “ ” or “ ” to adjust the setting. The liquid crystal will show the balance treatment time after the stimulation is started. Output will be terminated when time is up. Turn off the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



i. 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.

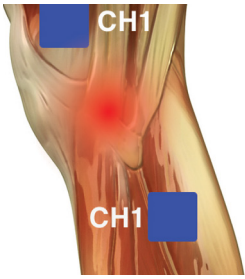


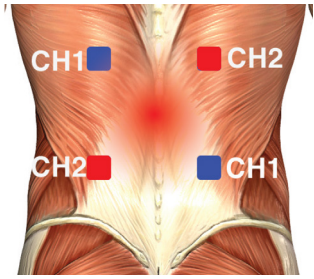
Helpful Tips

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.

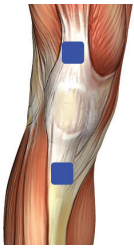
The alternative method is to use four electrodes surrounding the painful area see examples. The complete area between the electrodes will now be treated when positioning the electrodes as shown.



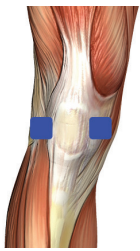


Examples of Electrode Placement

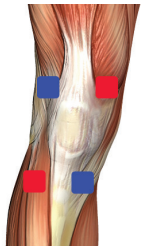
Here are three examples of electrode placement for knee pain. For best results, we recommend you try all variations as shown.



TENS using one channel vertical pad placement.



TENS using one channel horizontal pad placement.



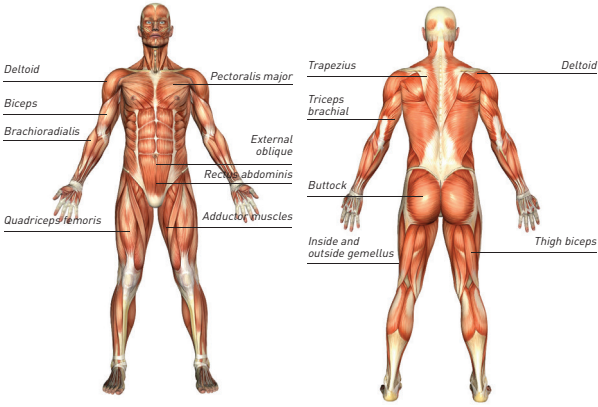
Red squares represents placement of electrode channel 1 blue channel 2.

EMS Programmes

These 12 individual electronic muscle stimulator (E.M.S) programmes P11 - P24 have been clinically proven for the treatment of:

1. Muscle Re-Education
2. Muscle Training
3. Muscle Strengthening
4. Muscle Toning & Massage

Please refer to the electrode placement charts provided for electrode placement guidelines.



Programmes P13, P16

Muscle Training & Muscle Re-Education Programmes

These programmes can be used for muscle training, prevention of muscle atrophy.

Programmes P17, P20

Muscle Strengthening & Muscle Re-Education Programmes

These programmes can be used for building stamina and strength. Muscle re-eduction.

Programmes P21-P24

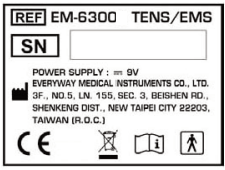
Muscle Toning & Massage Programmes

This programme stimulates the muscles with comfortable sensations which helps to tone and decrease any muscular tension.

Technical Specification

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. Notified body det norske veritas (DNV)
	Power



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 Specification

TENS Programmes specification P1 - P12:

No	Programme	Frequency	Pulse Width
1.	Conventional TENS Ideal for first applications of TENS	80Hz	180µs
2.	Burst TENS Most effective for radiating pain	2Hz	180µs
3.	Modulated TENS Pain relief with a massage effect	80Hz	70-180µs
4.	Mixed Frequency TENS	15Hz	180µs
5.	Fixed Frequency TENS Effective for long term use with reduced accommodation	80/2Hz	180µs
6.	Constant TENS Ideal for muscle pain	10Hz	180µs
7.	Modulated TENS Reduced pulse width ideal for treating nerve rich areas	80Hz	60µs
8.	Modulated TENS	10Hz	200µs
9.	Burst TENS 90% Rate Modulation over 10 seconds	50Hz	250µs
10	Mixed Frequency TENS	5-125Hz	120µs
11	Mixed Frequency TENS Modulation Rate & width over 6 seconds	2-100Hz	260-150µs
12.	Modulated TENS Modulation Rate over 6 seconds	80<->7Hz	260µs

Technical Specification

EMS Programmes specification P13 - P24:

No	Programme				SYN/ALT	
	Rate	Width	Ramp	On Time	Off Time	Timer
13	ACL repair/joint protection back muscle				SYNCHRONOUS	
	35 Hz	300 µs	3 sec	8 sec	24 sec	20 min
14	Spasm small muscle				SYNCHRONOUS	
	80 Hz	300 µs	3 sec	10 sec	5 sec	20 min
15	Spasm Postoperative				SYNCHRONOUS	
	80 Hz	250 µs	2 sec	8 sec	4 sec	20 min
16	Arthroscope				SYNCHRONOUS	
	25 Hz	200 µs	2 sec	6 sec	30 sec	15 min
17	Disuse atrophy				SYNCHRONOUS	
	35 Hz	300 µs	2 sec	5 sec	15 sec	30 min
18	Shoulder Subluxation				SYNCHRONOUS	
	50 Hz	300 µs	5 sec	15 sec	50 sec	15 min
19	Range of motion				SYNCHRONOUS	
	40 Hz	250 µs	3 sec	6 sec	21 sec	30 min
20	Muscle training / re-eduction				SYNCHRONOUS	
	50 Hz	250 µs	2 sec	10 sec	10 sec	20 min
21	Muscle training / re-eduction				SYNCHRONOUS	
	50 Hz	250 µs	2 sec	14 sec	14 sec	20 min
22	Muscle training / re-eduction				SYNCHRONOUS	
	35 Hz	400 µs	2 sec	10 sec	10 sec	20 min
23	Muscle training / re-eduction				ALTERNATE	
	50 Hz	250 µs	2 sec	10 sec	10 sec	20 min
24	Muscle training / re-eduction				ALTERNATE	
	50 Hz	250 µs	2 sec	14 sec	14 sec	20 min

Technical Specification

The Technical Specification Details of EM6300A are as follows:

	MECHANISM	TECHNICAL DESCRIPTION
1.	Channel	Dual, isolated between channels.
2.	Pulse Amplitude	Adjustable, 0-100 mA peak into 500 ohm load each channel.
3.	Wave Form	Asymmetrical Bi-Phasic Square Pulse.
4.	Voltage	0 to 50V (Load: 500 ohm).
5.	Power source	Lithium Battery.
6.	Size	11.8cm(L) x 6cm(W) x 3.1cm(H).
7.	Weight	150 grams with battery.
8.	Timer	60 minutes or Continuous. Treatment time countdown automatically.
9.	Low Battery Indicator	A low battery indicator will show up when the battery is low.
10	Operating Condition	Temperature:10°~40°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.

EMC Information

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

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

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

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

4) Warning:

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

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

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

EMC Information

Guidance and manufacture's declaration – electromagnetic immunity

The DEVICE is intended for use in the electromagnetic environment specified below. The customer or the user of DEVICE should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the DEVICE, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.167\sqrt{P}$ $d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d = 2.333\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol:

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

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

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

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

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

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 KHz to 80 MHz $d = 2.333\sqrt{P}$	**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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