EMS 5.0

INSTRUCTION MANUAL

DE5030

Richmar®

This manual is valid for the EMS 5.0 Stimulator

This user manual is published by Compass Health Brands.

Compass Health Brands does **NOT** guarantee its contents and reserves the right to improve and amend it at any time without prior notice. Amendments may however be published in new editions of this manual.
 DE5030_UM_B_250903

United States Federal Law restricts this device to sale by or on the order of a physician or licensed practitioner.

FCC SUPPLIER'S DECLARATION OF CONFORMITY

Product Name: EMS 5.0
Item Number: DE5030
Responsible Party: Compass Health Brands Corp.
6753 Engle Road, Middleburg Heights, OH 44130

FCC COMPLIANCE STATEMENT

This device complies with part 15 of the FCC Rules.
Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) This device must accept any interference received, including interference that may cause undesired operation.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Conformity to safety standards
Compass Health Brands declares that the device complies with following normative documents:
IEC60601-1, IEC60601-1-2, IEC60601-2- 10, ISO10993-5, ISO10993-10, ISO10993-1

TABLE OF CONTENTS

1. GLOSSARY OF SYMBOLS

WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in serious injury and equipment damage.
CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the device or other property.
LOT	Batch code
SN	Serial number
	This device complies with part 15 of the FCC Rules.
	Attention: Read the operating instruction before use! Equipment capable of delivering output values in excess of 10mA r.m.s. or 10V r.m.s. averaged over any period of 5s.
	Type BF Applied Part
	Do not insert the plug into AC power supply socket.
	Direct Current (DC power source)
	Refer to instruction manual.
CN	Made in China.
	DO NOT apply on the head or any area of the face.
	DO NOT apply to the neck or any area of the throat.
	DO NOT apply on both sides of the thorax simultaneously (lateral or front and back) or across the chest.
	Interference may occur in the vicinity of equipment.

2. SAFETY GUIDE

Who Should NOT use the Device

Check the following list of 14 questions:

Questions		Yes/No
1.	Are you equipped with a cardiac pacemaker, defibrillator, or other implanted metallic or electronic device?	
2.	Are you epileptic?	
3.	Have you recently been a victim of an acute trauma (less than 6 months)?	
4.	Have you recently been subject to a surgical procedure (less than 6 months)?	
5.	Do you have blood flow deficiency in your lower limbs?	
6.	Do you have an abdominal or inguinal hernia?	
7.	Do you suffer from cancer?	
8.	Are you pregnant?	
9.	Do you suffer from cardiac problems or diseases?	
10.	Do you have muscle spasms?	
11.	Do you have atrophied muscles?	
12.	Do you have skin that lacks normal sensation?	
13.	Do you need muscle reeducation?	
14.	Do you have any joint showing a decrease in its range of motion?	

If you answer “Yes”, or “Maybe”, or “I don’t know” to one or more questions, do not use the device and contact your physician or medical practitioner for more information.

3. INTRODUCTION

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. 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 paralyzed muscles, to prevent atrophy in affected muscles and improving muscle tone and blood circulation.

HOW EMS WORKS

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.

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.

INDICATIONS FOR USE

EMS 5.0 is an electrically powered muscle stimulator intended for use for medical purposes to repeatedly contract muscles by passing electrical currents through electrodes contacting the affected body area. In particular this device is indicated for use for:

- Relaxing muscle spasms
- Increasing blood circulation
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Muscle re-education
- Maintaining or increasing range of motion
- Preventing or retarding disuse atrophy

4. CONTRAINDICATION

Powered muscle stimulators **SHOULD NOT** be used on patients with cardiac demand pacemakers.

5. ⚠ CAUTIONS

1. **DO NOT** bend or fold electrodes, as they may not function properly. Place electrodes onto plastic film and store in the sealed package when not in use.
2. **DO NOT** apply ointment or any solvent o the electrodes or your skin, because it will disrupt the electrodes from functioning properly.
3. The electrodes are already pre-gelled and will adhere to your skin.
4. To avoid damage to the adhesive surface of the electrodes, put the electrodes only on the skin or on the plastic film provided.
5. Place the electrodes at least 2" apart, but no more than 6" apart per channel.
6. Make sure the components are connected well and the electrodes are fixed on the part of the body you wish to treat or the therapy may not be effective.
7. The life of the electrode is dependent on many factors including but not limited to cleanliness of treatment area, oiliness of skin, amount of hair, increased sweating, storage state, etc.

8. If the electrodes are lifting or no longer sticking to treatment area, they **MUST** be replaced to avoid sudden shock or possible burns on any of the applied electrodes, including the electrodes adhered correctly and completely.
9. Before applying self-adhesive electrodes, it is recommended to wash the area with mild soap and water, completely drying the treatment area before placing.
10. Ensure **NO** residual skin lotions or conductive gels are left on the skin prior to using the electrodes as this can result in burns due to inadequate adhesion.
11. **DO NOT** turn on the device without the electrodes being placed on the body.
12. **NEVER** remove the electrodes while the device is turned on.
13. It is recommended to use the same size electrodes that are supplied with the device, for replacement electrodes. Electrodes smaller than those provided many increase the chance of skin irritation or electrode burns. Electrodes larger than those provided may reduce the effect of the stimulation, which could result in a false need to increase the intensity resulting in electrode burn or shocks.
14. If replacement electrodes are necessary, use only electrodes that are the same size (2" x 2") as the electrodes provided with the EMS 5.0.
15. **ALWAYS** use electrodes that have been cleared for marketing in the USA by the FDA.
16. Electrodes should **NOT** touch each other when placed onto your skin.
17. **DO NOT** place electrodes on your spine or backbone.
18. Electrode pad should **NOT** touch any metal object, such as a belt buckle or necklace.
19. Electrodes should **NOT** be placed simultaneously on the soles of both feet.
20. Electrodes should **NOT** be placed simultaneously on the calves of both legs.
21. **DO NOT** share electrodes with another person. This many cause a skin irritation or infection. Electrodes are intended for use by one person.
22. **DO NOT** place or relocate the electrodes while the device is on.
23. **ALWAYS** turn the power off before removing or changing the pad location.

24. **DO NOT** leave electrodes attached to the skin after treatment.
25. If the stimulator is **NOT** functioning properly or you feel discomfort, **IMMEDIATELY** stop using the device. If any type of shock or burn should occur, stop using **IMMEDIATELY** and consider seeking medical attention if necessary.
26. **DO NOT** use for any other purpose except for what it is intended for.
27. **DO NOT** insert the electrode plug into any place other than the jack on the main device.
28. **DO NOT** pull on the electrode cord during treatment.
29. **DO NOT** use the device while wearing electronic devices such as watches, as this may damage the device.
30. **DO NOT** use near a cell phone as this may cause the stimulator to malfunction.
31. **DO NOT** bend or pull the end of the cord.
32. When pulling out the cord from the device, hold the plug and pull.
33. Replace the cord when broken or damaged.
34. **DO NOT** throw the batteries into a fire. The batteries may explode.
35. Dispose of the device, batteries and components according to applicable legal regulations. Unlawful disposal may cause environmental pollution.
36. The size, shape and type of electrodes may affect the safety and effectiveness of electrical simulation.
37. The electrical performance characteristics of electrodes may affect the safety and effectiveness of electrical stimulation.
38. Using electrodes that are too small or incorrectly applied, could result in discomfort or skin burns.
39. If an emergency occurs, rotate both knobs to 0 and the device will completely power **OFF** and stop all stimulation.
40. **DO NOT** remove electrodes from the treatment area until the device is turned off.
41. If the electrodes are not placed firmly on skin or the device has not connected with the electrodes and the output intensity level is over 5, the intensity will stop automatically.
42. If the stimulation levels are uncomfortable, or become uncomfortable, reduce the stimulation intensity to a comfortable level and contact your medical practitioner if the problems persist.
43. If your pain does not improve and becomes sore from over use, refrain from treating those areas for 2 days. If this issue reoccurs, reduce the treatment time and intensity settings for future treatment.

44. If you feel pain, dizziness, discomfort or nausea, call your physician or medical practitioner.
45. You should therefore take care to work with maximum intensities, i.e., always at the limit of what you can support. **DO NOT** exceed your comfort level.
46. Keep the battery and the product out of the range of children.
47. Battery may **NOT** be dismantled, thrown into fire or short circuited.
48. Protect the battery from excessive heat. Take the battery out of the product if the product is not in use for a long period of time.
49. **ALWAYS** replace with the same type of battery.
50. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
51. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
52. Caution should be used for patients with suspected or diagnosed epilepsy.

6. ⚠ WARNINGS

1. Consult with your physician before using this device. The device may cause lethal rhythm disturbances in certain susceptible individuals.
2. **DO NOT** use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.
3. **DO NOT** use this device together with a life-supporting medical electronic device, such as an artificial heart, lung or respirator.
4. **DO NOT** use in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms) which may not operate properly when the electrical stimulation device is in use.
5. **DO NOT** use on open wounds or rashes, or over swollen, red, infected or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins); or on top of or in proximity to cancerous lesions.
6. **DO NOT** use over areas of skin that lack normal sensation.
7. **DO NOT** use on opposite sides of your head since the effects of stimulation to the brain are unknown.

8. **DO NOT** use on pregnant women, because the safety of electrical stimulation during pregnancy has not been established.
9. **DO NOT** use on children or infants, because the device has not been evaluated for pediatric use.
10. **DO NOT** use on persons incapable of expressing their thoughts or intentions.
11. **DO NOT** use when in the bath or shower.
12. **DO NOT** use while sleeping.
13. **DO NOT** use while driving, operation machinery, or during any activity in which electrical stimulation can put you at risk for injury.
14. If you have had medical or physical treatment for your pain, consult with your physician before using the device.
15. If your pain does not improve, becomes seriously chronic or severe or continues for more than five days, stop using the device and consult with your physician.
16. The mere existence of pain functions as a very important warning telling us that something is up. Therefore, if you suffer from any serious illness, consult your physician in order to confirm that it is advisable for you to use this electrical stimulator.
17. Apply electrodes to normal, health, dry, clean skin (of adult patients) because it may otherwise disrupt the healing process.
18. If you experience any skin irritation or redness after a session **DO NOT** continue stimulation in that area of the skin.
19. Ensure **NO** residual skin lotions or conductive gels are left on the skin prior to using the electrodes, as this can result in burns due to inadequate adhesion.
20. **NEVER APPLY ELECTRODES TO:**

- The head or any area of the face
- The neck or any area of the throat because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects of heart rhythm or blood pressure.

- Both sides of the thorax simultaneously (lateral or front and back), or across your chest because the introduction of electrical current may cause rhythm disturbances which could be lethal.

7. ADVERSE REACTIONS

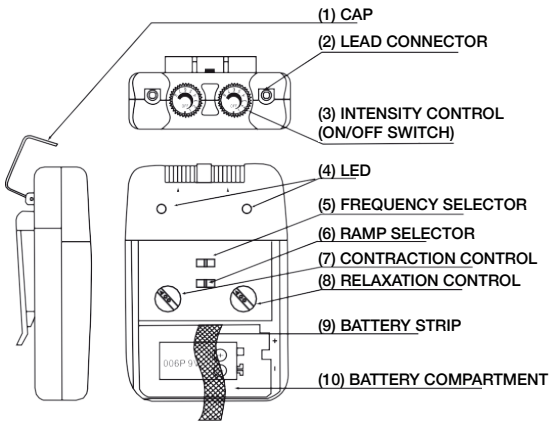
Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators.

8. GENERAL DESCRIPTION

The EMS 5.0 is a battery operated pulse generator that sends electrical impulses through electrodes to the body and reaches the underlying nerves or muscle group. The device is provided with two controllable output channels, each independent of each other. An electrode pair can be connected to each output channel.

The electronics of the EMS 5.0 create electrical impulses whose Intensity, Pulse Width, Pulse Rate, Contraction, Relaxation and Ramp may be altered with the switches. Dial controls are very easy to use and the slide cover prevents accidental changes in the setting.

9. CONSTRUCTION



10. TECHNICAL SPECIFICATION

The technical specification details of EMS 5.0 are as follows:

	MECHANISM	TECHNICAL DESCRIPTION
01	Channel	Dual, isolated between channels
02	Pulse Amplitude	Adjustable,0-100mA Max output 80mA(peak to peak) into 500ohm load each channel.
03	Voltage	Adjustable, 0-50V Max output 50V(peak to peak) into 500 ohm load each channel
04	Wave Form	Asymmetrical Bi-Phasic Square Pulse
05	Power supply	One 9 Volt Battery,type 6F22
06	Size	95(H)x 65(W) x 23.5(T)mm
07	Weight	115 grams (battery included)
08	Pulse Rate	5, 30, 100 Hz
09	Pulse Width	10μs~250μs
10	Contraction Time	Adjustable, 1~30 seconds
11	Relaxation Time	Adjustable,1~45 seconds
12	Ramp Time	1,3 or 5 seconds
13	Operating Condition	Temperature: 0°C~40°C Relative Humidity: 30%~75% Atmosphere Pressure: 700hPa~1060hPa
14	Remark	There may be up to a +/-20% tolerance of all parameters.

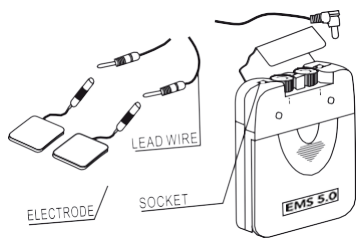
11. ACCESSORIES

The EMS 5.0 comes complete with the standard accessories below:

	ITEM	DESCRIPTION	QTY
1	EP2020WC2-INTM	2" x 2" InTENSity Self Adhesive Electrodes	1 Pack
2	WW3005	45" Lead Wires	2
3	BH9050	9V Heavy Duty Battery	1
5	CC3001	Carrying Case	1
4	Instruction Manual		1

12. ATTACHMENT OF ELECTRODE LEAD WIRES

The wires provided with the system insert into the jack sockets located on top of the device. Holding the insulated portion of the connector, push the plug end of the wire into one of the jacks (see drawing); one or two sets of wires may be used.



After connecting the wires to the stimulator, attach each wire to an electrode. Use care when you plug and unplug the wires.
Pulling the wire instead of holding the insulated connector body may cause wire breakage.

⚠ **CAUTION**
DO NOT insert the plug of lead wire into the AC power source.

13. LEAD WIRE MAINTENANCE

Clean the wires by wiping with a damp cloth. Coating them lightly with talcum powder will reduce tangling and prolong life.

14. ELECTRODE OPTIONS

The electrodes are disposable and should be routinely replaced when they start to lose their adhesive nature. If you are unsure of your electrode adhesive properties, order replacement electrodes. Replacement electrodes should be re-ordered through or on the advice of your physician to ensure proper quality. Follow application procedures outlined in electrode packing, to maintain optimal stimulation and to prevent skin irritation.

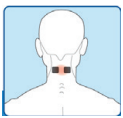
15. ELECTRODE PLACEMENT

The placement of electrodes can be one of the most important parameters in achieving success with EMS therapy. Of utmost importance is the willingness of the clinician to try the various styles of electrode placement to find which method best fits the needs of the individual patient.

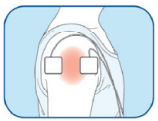
Every patient responds to electrical stimulation differently and their needs may vary from the conventional settings suggested here. If the initial results are not positive, feel free to experiment.

⚠ **WARNING:** Make sure the device is turned off or the intensities are in 0 levels before placing the electrodes.

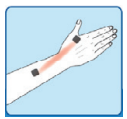
NEVER place electrodes on both legs, feet, arms or hands at the same time.
NEVER place electrodes on the front or sides of your neck, on any area of your head or directly over your heart.
NEVER place electrodes over the front of your chest and upper back at the same time.



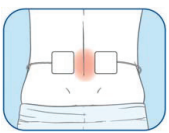
NECK
Attach both or four pads on the neck. **DO NOT** place on the carotid artery or throat.



SHOULDER
Attach one pad in the front and one in the back of the muscle.

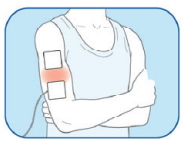


HAND
Attach both pads on the hand where you feel pain.

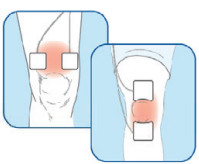


LOWER BACK
Attach both electrodes on the lower back with the backbone in the center. **DO NOT** place on the backbone or spine.

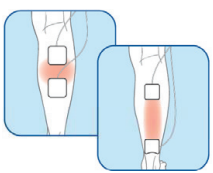
ELBOW
Attach both electrodes on either side of the joint with the pain.



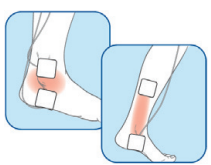
UPPER ARM
Attach both electrodes on either side of the region where you feel pain.



KNEE
Attach both electrodes above the knee or above and below the joint with pain.



CALF
Attach both electrodes on the calf/leg where you feel pain. **DO NOT** place electrodes simultaneously to the calves of both legs.



ANKLE/FOOT
Attach electrodes per the illustration, on the left for pain on the outside of your ankle/foot. Attach the electrodes per the illustration on the right for pain on the inside of your ankle/foot.

16. TIPS FOR SKIN CARE

To avoid skin irritation, especially if you have sensitive skin, follow these suggestions:

1. Wash the area of skin where you will be placing the electrodes, using mild soap and water before applying electrodes, and after taking them off. Be sure to rinse soap off thoroughly and dry skin well.
2. Ensure **NO** residual skin lotions or conductive gels are left on the skin prior to using the electrodes, as this can result in burns due to inadequate adhesion.
3. Excess hair may be clipped with scissors; **DO NOT** shave stimulation area.
4. Wipe the area with the skin preparation your clinician has recommended. Let this dry. Apply electrodes as directed.
5. Many skin problems arise from the “pulling stress” from adhesive patches that are excessively stretched across the skin during application. To prevent this, apply electrodes from center outward; avoid stretching over the skin.
6. To minimize “pulling stress”, tape extra lengths of lead wires to the skin in a loop to prevent tugging on electrodes.
7. When removing electrodes, always remove by pulling in the direction of hair growth.
8. It may be helpful to rub skin lotion on electrode placement area when not wearing electrodes.
9. Never apply electrodes over irritated or broken skin.

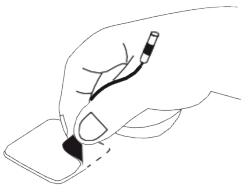
17. APPLICATION OF REUSABLE SELF ADHESIVE ELECTRODES

Application

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

Removal

1. Lift at the edge of electrodes and peel; **DO NOT** pull on the lead wires as it may damage the electrodes.
2. Place the electrodes on the liner and remove the lead wire by twisting and pulling at the same time.



Care and Storage

1. Between uses, store the electrodes in the resealed bag in a cool dry place.
2. To help improve adhesive surface and allow for multiple applications from electrodes, carefully sprinkle the adhesive side of the electrode with a few drops of cold water and let air dry. Be careful **NOT** to oversaturate with water, as that will reduce the adhesive properties.

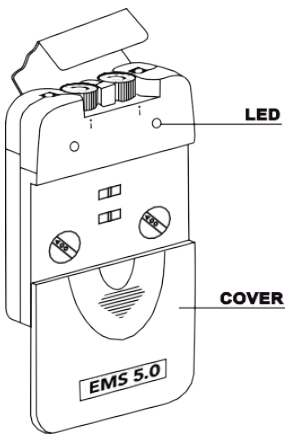
IMPORTANT

1. **DO NOT** apply to broken skin.
2. The electrodes should be discarded when they are no longer adhering.
3. The electrodes are intended for single patient use only.
4. If irritation occurs, discontinue use and consult your physician.
5. Read the instructions for use on the electrode packaging before application.

18. ADJUSTING THE CONTROLS

1. Panel Cover:
A slide-on panel cover covers the controls for Contraction Time, Relaxation Time, Ramp Time, Pulse Width, and Pulse Rate. Your medical professional may wish to set these controllers for you and request that you leave the cover in place.

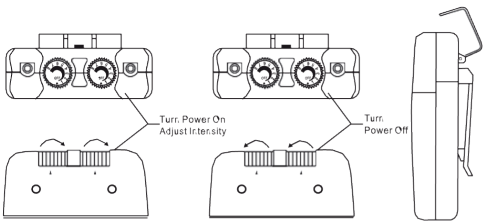
2. Display LED:
Each of these LEDs illuminates whenever the electronics of the device create a current impulse at Contraction Time and does not illuminate when the stimulation is ceased at Relaxation Time. Due to the capacity of the human eye, the illumination of the lamp can only be recognized up to a frequency of approximately 30Hz. At higher frequencies, the lamp will appear to be constantly illuminated.



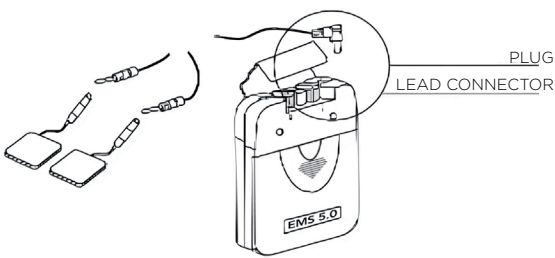
3. On/Off Switch and Intensity Controls:
If both controllers are in the off-position (white markings on the housing), the device is switched off.

By turning the controls clockwise, the appropriate channel is switched on and the impulse display LED will illuminate and begin to pulse according to the frequency set.

The current strength of the impulses transmitted to the electrodes increases the further the controller is turned clockwise.
To reduce the current strength an/or switch the device off, turn the controller counter clockwise or turn counter clockwise until it stops, respectively.

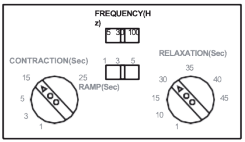


4. Lead Connector:
Connection of the electrodes is made with the two-lead connector. The device **MUST** be switched **OFF** before connecting the cables. Both intensity controls **MUST** be at the **OFF** position. Electrodes **MUST** be pressed firmly on the skin.



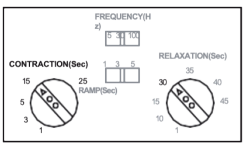
5. Pulse Rate Control:

This dial determines how many electrical impulses are applied through the skin each second. Turning these controls increases the number of current impulses per second (Hz) for both channels. There are three options - 5 Hz, 30 Hz, and 100Hz. Turn the dial to your desired position.



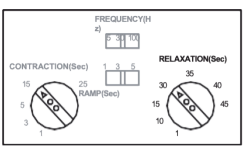
6. Contraction Time Control:

The contraction time control adjusts the time of stimulation. By turning this control, the contraction time can be pre-set. The range is adjustable from 1 second to 30 seconds. The contraction time of EMS device can be changed by turning this dial.



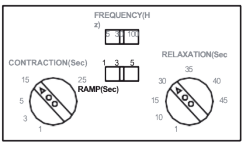
7. Relaxation Time Control:

This dial determines the amount of relaxation or rest time. The stimulation stops during the relaxation/rest time, and then restarts in a cycle pattern. The relaxation/rest time for both channels is adjusted by turning this dial. It is adjustable from 1 - 45 seconds.



8. Ramp Time Control

This dial controls the intensity of current output. When the ramp time is set, each contraction ramps up gradually at either one second, three seconds, or five seconds.



9. Check/Replace the Battery:

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

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

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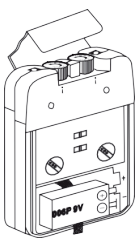

19. MAINTENANCE, CLEANING AND STORAGE

Cleaning the Unit

1. Turn unit off and disconnect the lead wires from the unit.
2. Clean the device after use with a soft slightly moistened cloth and wipe gently.
3. **DO NOT** use chemicals (like thinner, benzene).
4. **DO NOT** let water get into the internal area of the device.

Note: This device and accessories does not require sterilization.

Keeping Electrodes Clean

- Ensure the device is completely turned off when removing the electrodes from the treatment area.
- Disconnect the electrodes from each lead wire and place on protective liner supplied with the electrodes.
- If electrodes are difficult to attach to the skin or the protective liner, they may be able to be reconstituted for one more use prior to replacing with new electrodes.
- Place a small drop of water on your cleaned fingertip and rub the water across the entire gel part. Place the elctrode gel part, face up and let it air dry until the water is absorbed and reconstituted. This can only be done once and then the electrodes need to be replaced.
- **DO NOT** wipe with a tissue or cloth. If the electrodes are still not sticking completely to the treatment area without any lifting, they **MUST** be replaced with new electrodes.
- **DO NOT** use a sponge/cloth/sharp object like a nail on adhesive side, **DO NOT** use detergents, chemicals or soap.

⚠CAUTION

1. The life of electrodes is dependent on many factors including, but not limited to, cleanliness of treatment area, oiliness of skin, amount of hair, increased sweating, storage state, etc.
2. If the electrodes are lifting or no longer stick to the treatment area, they **MUST** be replaced to avoid sudden shock or possible burns on any of the applied electrodes, including the electrodes adhered correctly and completely.
3. Before applying self-adhesive electrodes, it is recommended to wash the area with mild soap and water, completely drying the treatment area before placement.
4. Ensure **NO** residual skin lotions or conductive gels are left on the skin prior to using the electrodes as this can result in burns due to inadequate adhesion**.**
5. **DO NOT** turn on the device without the electrodes being placed on the body.
6. **NEVER** remove the electrodes while the device is turned on.
7. It is recommended to use the same size electrodes that are supplied with the device for replacement electrodes. Electrodes smaller than those provided may increase the chance of skin irritation or electrode burns. Electrodes larger than those provided may reduce the effect of stimulation, which could result in a false need to increase the intensity resulting in electrode burns or shocks.
8. If replacement electrodes are necessary, use only electrodes that are the same size (2" x 2") as the electrodes provided with the EMS 7500.
9. **ALWAYS** use electrodes that have been cleared for marketing in the USA by the FDA.

Storing Device, Electrodes and Lead Wires

- After electrodes have been removed from treatment site and disconnected from lead wires, place electrodes on the plastic liner and store in a resealable package.
- Wrap lead wires and store in a resealable package.

- Place the device, electrodes and lead wires back into the carrying case. Store in a cool, dry place ranging from 14°F – 131°F (-10°C – 55°C) with a relative humidity of 10% – 90%. Protect it against heat, direct sunlight and moisture. **DO NOT** keep in places that can be easily reached by children.
- When not in use for a long period, remove the batteries before storage to avoid discharge from batteries.
- **NEVER** place any heavy objects on the device.

Safety-Technical Controls

For safety reasons, check your EMS 5.0 each week based on the following checklist.

1. Check the device for external damage.
   - deformation of the housing.
   - damaged or defective output sockets.
2. Check the device for defective operating elements.
   - legibility of inscriptions and labels.
   - make sure the inscriptions and labels are not distorted.
3. Check LED.
   - LED must be illuminated when switched on.
4. Check the usability of accessories.
   - patient cable undamaged.
   - electrodes undamaged.

If any of these conditions exist, discontinue use and contact your dealer.

Malfunctions

Should any malfunctions occur while using the EMS, check:

- whether the switch/control is set to the appropriate form of therapy. Adjust the control correctly.
- whether the cable is correctly connected to the device. The cables should be inserted completely into the sockets.
- whether the impulse display LED is illuminated. If necessary, insert a new battery.
- for possible damage to the cable. Change the cable if any damage is detected.
- If there is any other problem, please return the device to your distributor. **DO NOT** try to repair a defective device.

20. ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES

• This device should **NOT** be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, this device should be observed to verify normal operation in the configuration in which it will be used.
• Use of accessories other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
• Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
• When the operating environment is relatively dry, strong electromagnetic interference usually occurs. At this time, the device may be affected as follows:

- the device stops output;
- the device turns off;
- the device restarts;

• The above phenomenon does **NOT** affect the basic safety and essential performance of the device, and the user can use it according to the instruction. If you want to avoid the above phenomenon, please use it according to the environment specified in the manual.

TABLE 1		
declaration - electromagnetic emission		
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.		
Emissions test	Compliance	Electromagnetic environment - guidance.
RF emissions CISPR 11	Group 1	The device uses 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 emissions 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	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

TABLE 2			
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	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tie. If floors 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 ± 1 kV for input/ output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	Not applicable	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	0 % UT; 0.5 cycle At 0°,45°, 90°, 135°, 180°,225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	Not applicable	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 uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

TABLE 3

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	3V 0.15 MHz to 80MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of device, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ 150 KHz to 80 MHz $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 80 MHz to 2.7 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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] 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: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10V/m	

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 RF 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 device is used exceeds the applicable RF compliance level above, device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating device.

b Over the frequency range 0.15 MHz to 80 MHz, field strengths should be less than 3 V/m.

TABLE 4

Recommended separation distances between portable and mobile RF communications equipment and device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and 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)		
	0.15 MHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	80 MHz to 2.7 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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 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.

21. LIMITED WARRANTY

The EMS 5.0 carries a limited warranty of one year from the date of delivery. The limited warranty applies to the stimulator only and covers both parts and labor relating thereto. The limited warranty **DOES NOT** apply to damage resulting from failure to follow the operation instructions, accidents, abuse, alteration or disassembly by unauthorized personnel.

1. The limited warranty period for this device is one year from date of purchase. In case of a limited warranty claim, the date of purchase has to be proven by means of the sales receipt or invoice.
2. Repairs or replacement under the limited warranty **DO NOT** extend the limited warranty period either for the device or for the replacement parts.
3. The following is excluded under the limited warranty:
    - All damage which has arisen due to improper treatment, e.g. nonobservance of the user instructions.
    - All damage which is due to repairs or tampering by the customer or unauthorized third parties.
    - Damage which has arisen during transport from the manufacturer to the consumer or during transport to the service center.
    - Accessories included with the device.
4. Liability for direct or indirect consequential losses cause by the device is excluded even if the damage to the device is accepted as a limited warranty claim.

NOTES

Manufactured for:

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