CMYK

INSTRUCTION MANUAL

FOR THE

EMS 5.0

Distributed by:

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Chapter 1 : 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

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.

Chapter 2 : 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 for patients with suspected or diagnosed epilepsy.
4. Caution should be used in the presence of the following:
   a. When there is a tendency to hemorrhage following acute trauma or fracture;
   b. Following recent surgical procedures when muscle contraction may dis rupt the healing process;
   c. Over the menstruating or pregnant uterus; and
   d. Over areas of the skin which lack normal sensation.
5. 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.
6. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
7. Powered muscle stimulators should be kept out of the reach of children.
8. Powered muscle stimulators should be used only with the leads and elec trodes recommended for use by the manufacturer.

9. Portable powered muscle stimulators should not be used while driving, operating machinery, or during any activity in which involuntary muscle con tractions may put the user at undue risk of injury.

Chapter 3 : WARNINGS

1. The long-term effects of chronic electrical stimulation are unknown.
2. Stimulation should not be applied over the carotid sinus nerves, particuarly 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, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
7. Stimulation should not be applied over, or in proximity to, cancerous lesions.

Chapter 4: CONTRAINDICATION

Powered muscle stimulators should not be used on patients with cardiac demand pacemakers.

Chapter 5: ADVERSE REACTIONS

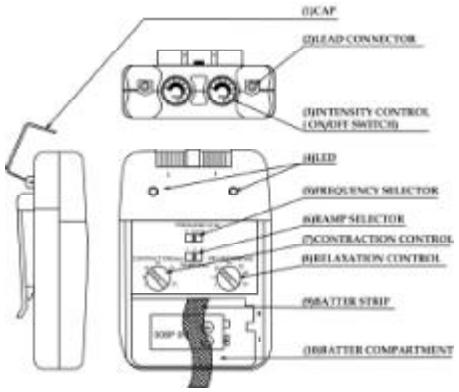
Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators.

Chapter 6 : 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.

Chapter 7 : CONSTRUCTION



‘Chapter 8 : TECHNICAL SPECIFICATION

The technical specification details of EMS 5.0 are as follows

	MECHANISM	TECHICAL DESCRIPTION
01	Channel	Dual, isolated between channels
02	Pulse Amplitude	Adjustable, 0-80mA Max output 80mA(peak to peak) into 500ohm load each channel.
03	Voltage	Adjustable, 0-40V Max output 40V(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	Fixed at 250uS
10	Contraction Time	Adjustable, 1~30 seconds
11	Relaxation Time	Adjustable, 1~45 seconds
12	Ramp Time	1, 3 or 5 seconds
13	Operating	Temperature : 0°~40°C Condition Relative Humidity : 30%~75%Atmosphere Pressure : 700Hpa~1060Hpa 14 Remark There may be up to a +/- 20% tolerance of all parameters.

Chapter 9 : REPLACABLE PARTS

The replaceable parts and accessories of EMS devices are as given below –Except leads, electrodes and battery, battery cover, please do not try to replace the other parts of a device.

	PARTS
01	ELECTRODES LEADS
02	ELECTRODES
03	BATTERY 006P 9V
04	BELT CLIP
05	BATTERY CASE COVER
06	LEAD CONNECTOR
07	MAIN PCB
08	INTENSITY KNOB
09	CONTRACTION KNOB
10	RELAXATION KNOB
12	PULSE RATE KNOB
13	RAMP KNOB

Chapter 10 : ACCESSORIES

Each set N605 EMS are completed with standard accessories as given below

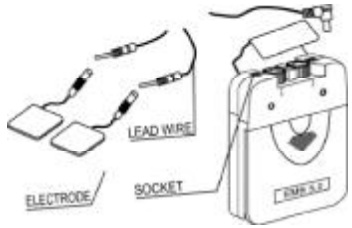
	REF. NO.	PRODUCT	Q’TY
1.	KS4040	40 X 40 MM Adhesive Electrodes	4 pieces
2.	KE-24	Electrodes Leads	2 pieces
3.	GC-01	9 V Battery, type 6F22	1 piece
4.		Instruction Manual	1 piece
5.		Carrying Case x 1 EA	1 piece

Chapter 11 : GRAPHIC SYMBOLS

1. Note Operating Instructions
2. Degree of Electrical Protection BF
3. Do not insert the plug into AC power supply socket
4. Direct Current (DC power source)

Chapter 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. Jerking 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.

Chapter 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.

Chapter 14 : ELECTRODE OPTIONS

You should use the same size and type of electrodes that was supplied with your EMS device, unless your clinician instructs you to use a different electrode. Follow application procedures outlined in electrode packing, to maintain stimulation and prevent skin irritation. Use the legally marketed EMS electrode is recommended. The device is completed with standard carbon film adhesive electrodes in size 4x4cm.

Chapter 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. Once an acceptable placement has been achieved, mark down the electrodes

sites and the settings on the patient's Reference sheet of this manual, so the patient can easily continue treatment at home.

Chapter 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. Excess hair may be clipped with scissors; do not shave stimulation area.
3. Wipe the area with the skin preparation your clinician has recommended. Let this dry. Apply electrodes as directed.
4. Many skin problems arise from the "pulling stress" from adhesive patches that are excessively stretched across the skin during application. To prvent this, apply electrodes from center outward; avoid stretching over the skin.
5. To minimize "pulling stress", tape extra lengths of lead wires to the skin in a loop to prevent tugging on electrodes.
6. When removing electrodes, always remove by pulling in the direction of hair growth.
7. It may be helpful to rub skin lotion on electrode placement area when not wearing electrodes.
8. Never apply electrodes over irritated or broken skin.

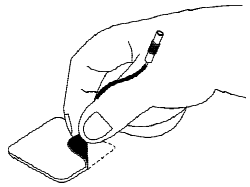
Chapter 17APPLICATION OF RE-USABLE SELF ADHESIVE ELECTRODES

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 n 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 be cause 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. It may be helpful to improve repeated application by spreading a few drops of cold water over the adhesive and turn the surface up to air dry. Over Saturation with water will reduce the adhesive properties.

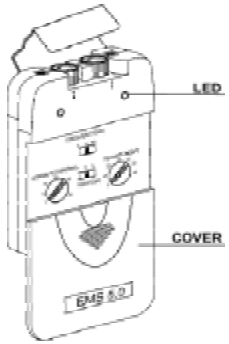
Important

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 instruction for use of self-adhesive electrodes before application.

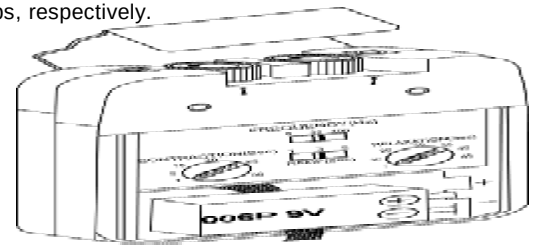
Chapter 18 : ADJUSTING THE CONTROLS

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 profes sional may wish to set these controllers for you and request that you leave the cover in place.

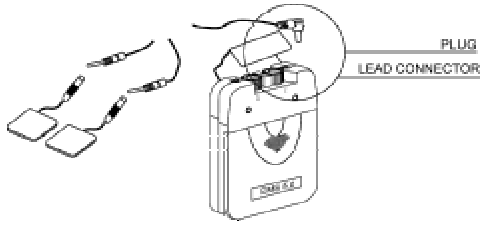
2. Display Led
   Each of these leds illuminates whenever the electronics of the device create a current impulse at contraction time and does not illuminate when the stimulation is ceased at relaxation time. Due to the capacity of the human eye, the illumination of the lamp can only be recognized up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



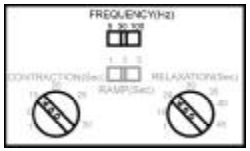
3. On/Off Switch and Intensity Controls:
   If both controllers are in the off-position (white markings on the housing), the device is switched off.
   By turning the controls clockwise, the appropriate channel is switched on and the impulse display led will illuminate and begin to pulse according to the frequency set.
   The current strength of the impulses transmitted to the electrodes in creases 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.



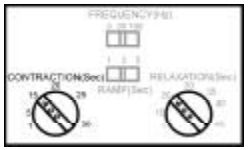
4. Lead Connector
   Connection of the electrodes is made with two-lead connector. The device must be switched off before connecting the cables. Both intensity controls must be at the Off position. Electrodes must be pressed firmly on the skin.



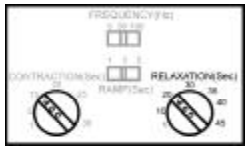
5. Pulse Rate Control:
   This dial determines how many electrical impulses are applied through the skin each second. By turning these controls, the number of current im pulses per second (Hz) for both channels has 3 options 5, 30 and 100 Hz. Push this dial to select the position desired.



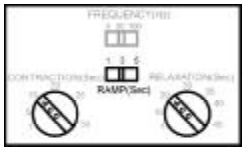
6. Contraction Time Control
   The contraction time control adjusts the time of stimulation. By turning this control, the contraction time can be pre-set. The range is adjustable from 1 second to 30 seconds. The contraction time of EMS device can be changed by turning this dial.



7. Relaxation Time Control
   This dial determines the time of relaxation. The stimulation ceases at set ting relaxation time and then re-start in a cycle pattern. The relaxation time of both channels is changed by turning this dial. The range of it is adjustable from 1 second to 45 seconds.



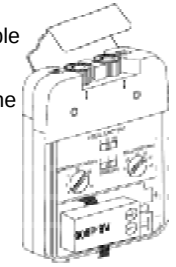
8. Ramp Time Control
   This dial controls the time intensity of current output that increases from 0 to the setting level. When the ramp time is set, each contraction may be ramped in order that signals come on gradually and smoothly. There are 3 choices of ramp time - 1,3,5 seconds.



9. Check/Replace the Battery:
   Over time, in order to ensure the functional safety of EMS, changing the batteries is necessary.
   1. Make sure that both intensity controls are switched to off position.
   2. Slide the battery compartment cover and remove.
   3.Remove the battery from the compartment.
   4.Insert the batteries into the compartment. Note the polarity indicated on the batteries and in the compartment.
   5. Replace the battery compartment cover and slide to close.

Chapter 19 : BATTERY INFORMATION

The EMS 5.0 can be used with 6F22 rechargeable battery when necessary.
If you use rechargeable battery, please follow the following indication.



RECHARGEABLE BATTERIES:

Prior to the use of a new unit, the rechargeable battery should be charged according to the battery manufacturer's instructions. Before using the battery charger, read all instructions and cautionary markings on the battery and in this instruction manual.

After being stored for 60 days or more, the batteries may lose their charge. After long periods of storage, batteries should be charged prior to use.

BATTERY CHARGING

(1) Plug the charger into any working 110 or 220/240v mains electrical outlet. The use of any attachment not supplied with the charger may result in the risk of fire, electric shock, or injury to persons.
(2) Follow the battery manufacturer's instructions forcharging time.
(3) After the battery manufacturer's recommended charging time has been completed, unplug the charger and remove the battery.
(4) Batteries should always be stored in a fully charged state.To ensure optimum battery performance, follow these guidelines:
   (a) Although overcharging the batteries for up to 24 hours will not damage them, repeated overcharging may decrease useful battery life.
   (b) Always store batteries in their charged condition. After a battery has been discharged, recharge it as soon as possible. If the battery isstored more than 60 days, it may need to be recharged.
   (c) Do not short the terminals of the battery. This will cause the battery to get hot and can cause permanent damage. Avoid storing the batteries in your pocket or purse where the terminals may accidentally come into contact with coins, keys or any metal objects.

(d) WARNINGS:
   1. Do not attempt to charge any other types of batteries in your charger, other than the nickel-cadmium rechargeable batteries. Other types of batteries may leak or burst.
   2. Do not incinerate the rechargeable battery as it may explode!

Chapter 20: MAINTENANCE, TRANSPORATION AND STORAGE OF EMS DEVICE

1. Alcohol is suitable for cleaning the device.
   Note: Do not smoke or work with open lights (for example, candles, etc.)
   when working with flammable liquids.
2. Stains and spots can be removed with a cleaning agent.
3. Do not submerge the device in liquids or expose it to large amounts of water.
4. Return the device to the carrying box with sponge foam to ensure that the unit is well-protected before transportation.
5. If the device is not to be used for a long period of time, remove the batteries from the battery compartment (acid may leak from used batteries and damage the device). Put the device and accessories in carrying box and keep it in cool dry place.
6. The packed EMS device could be stored and transported under the temperature range of -20℃ – 60℃

Chapter 21: SAFETY-TECHNICAL CONTROLS

For safety reason, 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.

Please consult your distributor if there is any problem on device and accessories.

Chapter 22 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.

Chapter 23Conformity to Safety Standard

The EMS 5.0 devices are in compliance with the EN60 601-1: 1990+A1:1993+A2:1995.

Chapter 24 : WARRANTY

All EMS 5.0 models carry a warranty of one year 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 failure to follow the operating instructions, accidents, abuse, alteration or disassembly by unauthorized personnel.