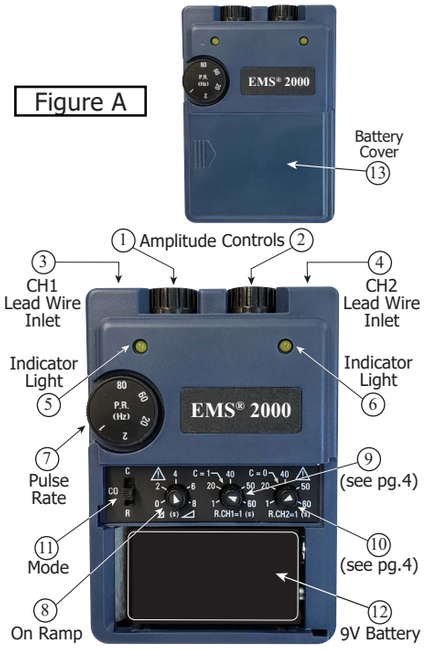
Figure A



Included Accessories

2 BMLS® touch proof lead wires
4 BioStim® electrodes
1 9V Battery
1 Carrying pouch

Optional Approved Accessories

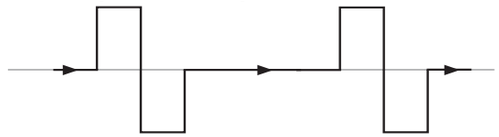
- BMLS approved rechargable 9V NiNH battery
- BMLS approved battery charger for 9V NiNH battery
- Assorted Biostim® electrodes

Specifications

Size	3.9" x 2.75" x 1"
Weight	4.6 oz.
Power Source	9V Battery, E-block, type 6F22
Channels	Dual (2)
Waveform	Symmetrical biphasic square
Pulse Rate	1 - 80 Hz adjustable
Pulse Width	300 (µs) microseconds fixed
Intensity	0 - 98 mA adjustable
Output	Constant current
Modes	Cycled, Constant, and Reciprocation
On Ramp	0 - 8 seconds
On Time	0 - 8 seconds
Off Ramp	0 - 8 seconds
Off Time	0 - 8 seconds

Intensity	0 - 98 mA adjustable
Voltage	0 - 49V
Electrodes	2 pair
Lead Wires	4 electrodes
Tolerances	+/- 10%

Symmetrical Biphasic Waveform



Graphic Symbol Definitions


Refer to operating instructions


Electronic waste should be disposed in the proper manner in accordance with local regulations.

Patient Safety Information

Caution:
• Powered muscle stimulators should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

Indications for Use:
• Relaxation of muscle spasms.

• Prevention or retardation of disuse atrophy.

• Increasing local blood circulation.

• Muscle re-education.

• Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

• Maintaining or increasing range of motion.

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

• EMS devices should not be applied to malignant tumors.

Warnings:
• The long-term effects of chronic electrical stimulation are unknown.

• Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.

• 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.

• Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.

• Stimulation should not be applied transcerebrally.

• Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.

• Stimulation should not be applied over, or in proximity to, cancerous lesions.

Precautions:
• Safety of powered muscle stimulators for use during pregnancy has not been established.

• Caution should be used for patients with suspected or diagnosed heart problems.

• Caution should be used for patients with suspected or diagnosed epilepsy.

• 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 disrupt the healing process.

c. Over the menstruating or pregnant uterus.

d. Over areas of the skin which lack normal sensation.

• 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.

• Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.

• Powered muscle stimulators should be kept out of the reach of children.

• Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.

• [FOR PORTABLE DEVICES ONLY]: Portable powered muscle stimulators should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

Adverse Reactions:

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

General Operating Instructions

Battery/Control Cover (13)
Slide the battery cover (13) to reveal of the controls and battery compartment of the EMS® 2000. Simply press the cover slightly and slide it sideways to the right.

Battery Compartment (12)
Place a battery in the direction as indicated by the diagram located in the rear of the battery compartment, with the positive/negative raised electrode poles against the right end of the compartment, then push down over the metal plate to secure. (DO NOT place battery under the metal plate) To remove the battery, push the battery to the left and lift battery up from the right side.

Amplitude (Intensity) Adjustment (1, 2)
Turn the device on by rotating the Amplitude (Intensity) control (1, 2) in a clockwise direction. The yellow channel indicator light (5, 6) comes on when the device is turned on. Continue to rotate the Amplitude control clockwise until a setting is reached which produces the appropriate muscle contraction.

Pulse Rate (7)
Turn the pulse rate control (7) to the lowest setting that maintains muscle tetany yet remains comfortable for the user.

Mode Switch (11)
This switch has 3 mode selections:

• "CO" CONSTANT: This mode delivers a "Constant" Pulse Rate (Hz) and 300 (µs) Pulse Width. In this mode, there are no timing options. In this mode, the device will function similar to a TENS unit.

• "C" CYCLED: This mode delivers the set Pulse Rate (Hz) and 300 (µs) Pulse Width in repeating cycles in order to elicit repeated muscle contractions and rest periods. In this mode both Channel 1 and Channel 2 outputs cycle simultaneously.

• "R" RECIPROCAL: This mode delivers the set Pulse Rate (Hz) and 300 (µs) Pulse Width in repeating cycles in order to elicit repeated muscle contractions and rest periods. In this mode Channel 1 and Channel 2 outputs alternate through set timing cycles.

CYCLED and RECIPROCAL Timing Controls (8, 9, 10)
• CYCLED mode: In this mode control dial (8) adjusts "ON RAMP", (9) adjusts "ON TIME", and (10) adjusts "OFF TIME" for both CH1 & CH2.

• RECIPROCAL mode: In this mode control dial (8) adjusts "ON RAMP", (9) adjust "ON TIME" for CH1 and (10) adjusts "ON TIME" for CH2. "OFF TIME" adjusts are not needed when using a reciprocating mode.

Cycle Term Definitions
• ON RAMP: This is the amount of seconds the device ramps up to the adjusted intensity level before "ON TIME".

• OFF RAMP: In the EMS® 2000, a default of 2 seconds has

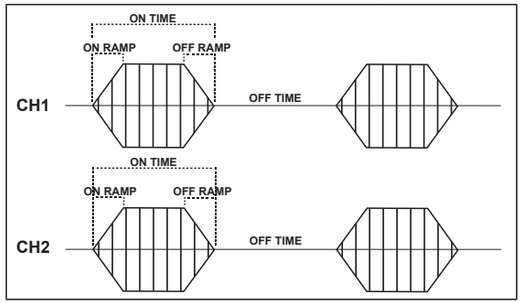
Definitions (continued)

...been incorporated to give a soft decrease of the electrical stimulation at the end of each cycle.

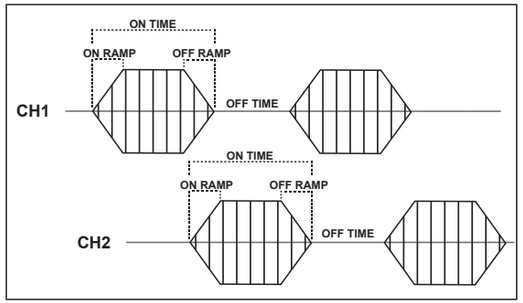
• ON TIME: This is the total amount of seconds in each cycle that the device intensity is "ON", including the ramp times. Each cycle includes an "ON RAMP", "ON TIME", "OFF RAMP".

• OFF TIME: This is the amount of seconds after each cycle of no electrical stimulation.

CYCLED Stimulation Pattern
channels work simultaneously



RECIPROCATING Stimulation Pattern
channels alternate stimulation between CH1 & CH2



Electrode Placement Guidelines

• Clean your skin thoroughly prior to placement of electrodes.

• Place electrodes on muscle groups as directed by your physician.

• As a rule, place the electrodes on the muscle group that you would like to strengthen so that the two electrodes are alongside of the muscle.

• One electrode should always be placed on the middle of the muscle belly.

• The electrodes should never touch and should be at least, 2" apart to be effective.

• When using EMS programs, a muscle contraction is the desired effect and should always occur. If no muscle contraction occurs in an EMS program, you have not placed the electrodes correctly or you have chosen an intensity level that is to low.

• If the muscle contractions feel uncomfortable, try varying the placement of the electrodes.

• As always, consult your physician for further questions.

Treatment Guidelines

Step 1

A. Insert battery and close battery cover (12, 13).

B. Adjust pulse rate (7) as recommended by your health professional. The range of comfortable muscle tetany for most users lies between approximately 20 and 45 (Hz).

C. Adjust cycle adjustments (8, 9, 10) as recommended by your healthcare professional.

D. Set mode (11) as recommended by your healthcare professional.

Step 2

Attach lead wires to electrodes, and place electrodes firmly to your body as you were shown by your healthcare professional.

Step 3

Insert lead wires into device outlet (3, 4).

Step 4

Slowly turn on the EMS® 2000 by turning the amplitude controls (1, 2) in a clockwise direction. Turn amplitude control until the appropriate muscle contraction produced as recommended by your healthcare professional.

Step 5 (End of treatment)

A. Turn off device.

B. Unplug lead wires.

C. Disconnect electrodes from lead wires.

D. Store electrodes according to the instructions on the electrode package.

Helpful Hints

• It may be useful to time the contractions and rest periods for a few cycles to allow slight adjustments of the control dials (9, 10).

• It may be helpful to adjust amplitude in "CONSTANT" mode first before switching to CYCLED or RECIPROCAL modes to ensure proper settings.

Device Maintenance

• Isopropyl alcohol is suitable for cleaning this device.

• Do not smoke or work with open flames when working with flammable liquids!

• Stains and spots can be removed with a cleaning agent.

• Do not submerge this device in any liquid or use excessive cleaning liquid when cleaning the surface area.

• Remove the batteries for long term storage.

• Damaged or leaking batteries should be disposed of in the proper manner in accordance with local regulations.

• Use only BioMedical Life Systems, Inc. approved accessories and electrodes. Non-approved accessories and electrodes may damage your device and affect your warranty.

Warranty

LIMITED TWO-YEAR WARRANTY

BioMedical Life Systems, Inc. promises to the original consumer-purchaser to repair or replace, at the option of BioMedical Life Systems, Inc., any neurostimulator which malfunctions or proves defective in materials or workmanship under normal use for a period of two years from the date of purchase. During the two years, BioMedical Life Systems, Inc. will provide all labor and parts necessary to correct such defects or malfunctions free of charge. It is the duty of the consumer-purchaser to deliver the unit to a service facility of the factory with a receipt of purchase. For further instructions, please call 800-726-8367.

EXCLUSIONS:

This warranty shall not apply to damage resulting from failure to follow the operating instructions in the user manual, accident, abuse, alteration, or disassembly by unauthorized personnel. This warranty does not extend to accessory items such as rechargeable batteries, electrodes, electrode and leads wires which are not an integral part of the stimulator. These items can be provided by your service representative, but costs for repair or replacement will be the responsibility of the consumer-purchaser. BioMedical Life Systems, Inc. shall not be liable for incidental or consequential damages resulting from the sale or use of the unit. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

WARNING:

Only use accessories, electrodes, lead wires and batteries approved by BioMedical Life Systems, Inc.

NO OTHER WARRANTIES:

This limited warranty is the only express warranty given by BioMedical Life Systems, Inc. Implied warranties, including, but not limited to, warranties of merchantability and fitness for a particular purpose are limited to the warranty period set forth above. Some states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you. This warranty gives you specific legal rights, and you may also have rights which vary from state to state.

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Manufactured for and Distributed by:

BioMedical Life Systems, Inc.

Transcutaneous Electrical Nerve Stimulator

EMS® 2000

Instructions

EMS® 2000 5/27/20 REV.L