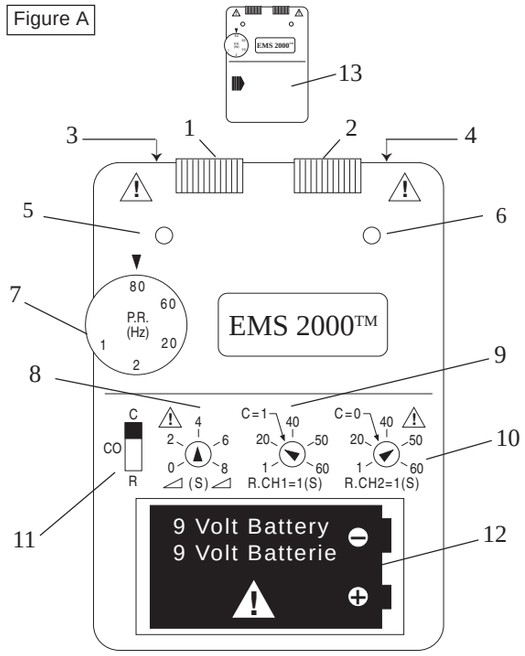
Figure A



Accessories:

2 Lead Wires
with electrodes
1 Instruction Booklet
1 Battery
1 Carry Pouch

Optional Accessories: Only use accessories, electrodes, leadwires and batteries approved by BioMedical Life Systems, Inc.

Technical Data

Size	3.9" x 2.75" x 1" (9.90 cm x 6.98 cm x 2.54 cm)
Weight	4.6 oz (132 grams)
Channels	Dual
Waveform	Symmetrical biphasic square
Pulse Rate (adj.)	1 to 80 Hz
Pulse Width	300 µs
Stimulation Modes	Cycled, constant and reciprocation
On Ramp	0 - 8 seconds
Off Ramp	2 seconds (preset)
On Time	1 - 60 seconds
Off Time	1 - 60 seconds
Output Voltage	0 - 49V
Output Current	
Intensity (adj.)	0 - 98 mA
Battery	9V Battery, E-block, type 6F22
Number of Electrodes	2 pair
Number of Lead Wires	2 pair
Tolerances	±10%

Output parameters are across a 500 ohm resistance.

■ Graphic Symbol Definitions

Refer to operating instructions

An IEC 601-1 safety standard (reference type BF)

CE 0086 We herewith declare that the above-mentioned product meets the provisions of the Medical Device Directive 93/42/EEC.

Patient Safety Information

PRECAUTIONS should be exercised when stimulation is used:

- -After recent surgical procedure where muscle contraction may disrupt the healing process.
- -After an acute trauma or fracture where there is a tendency to hemorrhage;
- -Over the menstruating uterus;
- -Where the sensory nerve damage has caused the loss of normal skin sensation

Caution:

EMS Devices should only be used under medical supervision for adjunctive therapy in the treatment of medical diseases and conditions.
Dependent upon government regulation, this device may or may not require a medical prescription.
Federal law (USA) restricts the sale by, or on the order of, a physician so licensed by the State. Keep out of reach of children.

Adverse Reactions:

Improper use of stimulation may result in skin irritation and burns beneath the electrodes.

Indications:

External electrical neuromuscular stimulation using bi-phasic output is indicated as therapeutic adjunct forprevention or retardation of muscle spasm; muscle reeducation; maintaining and increasing the range of motion; increasing local blood circulation and as an immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

Contraindications:

Use of electrical stimulation may be hazardous for patients with certain demand-type cardiac pacemakers. EMS devices should not be applied to malignant tumors.

Warning:

Stimulation should not be applied over the carotid sinus. Severe spasm of the laryngeal and/or pharyngeal muscles may occur when electrodes are placed over the neck or mouth. (These contractions may be strong enough to close the airway or cause difficulty in breathing.) Stimulation should not be applied transcerebrally. Adequate precaution should be taken with patients with suspected heart problems or epilepsy. Caution should be exercised in the transthoracic application of EMS devices so that the introduction of electrical current into the heart does not cause arrhythmias. The safety of electrical stimulation for use during pregnancy has not been established. The long-term effects of chronic electrical stimulation are unknown. EMS devices should be kept out of the reach of children. Persistent use of stimulation in the presence of skin irritation may be injurious.
Simultaneous connection to RF surgery equipment can cause a burn. Operation near (e.g. 1m) short wave or micro wave therapy equipment can change the output values of the stimulator.

Introduction to Muscle Stimulation

Electrical Muscle Stimulation (EMS) or NeuroMuscular Stimulation (NMS) is the use of electrical stimulation on muscle groups to contract and reeducate muscles. Some of the uses of EMS are as follows:

1. The Prevention or Retardation of Muscle Disuse Atrophy:
Muscle disuse atrophy is a reduction in muscle contraction and size due to prolonged impairment or joint immobility from surgery, injury or disease. The use of electrical stimulation to contract the muscles builds and strengthens the muscles, assisting in prevention of disuse atrophy.

2. Relaxation of Muscle Spasms:
Muscle spasms and cramping often occur in areas of localized pain and tenderness. Stimulation is used to fatigue the “spastic” muscle.

3. Muscle Reeducation:
Evidence has shown that a combination of both exercise and electrical stimulation is far superior in strengthening atrophied muscles.

4. Maintaining and Increasing Range of Motion:
In conditions where the reduction of physiological range of motion is due to or the result of fractures with consequent immobilization, operative intervention, or arthroscopy, in shoulders, knees, and backs.

5. Increasing Local Blood Circulation
Rhythmic muscle contraction helps improve blood circulation, thereby aiding in the reduction of localized swelling and tenderness.

6. Immediate Post-surgical Stimulation of Calf Muscles to Prevent Venous Thrombosis
The use of EMS to increase blood circulation assists in the prevention of venous thrombosis.

General Operating Instructions

Front Cover

(13)- A slide-on panel covers the controls of the EMS 2000™. To remove the cover, simply press the cover slightly and slide it sideways to the right.

Battery

To insert a battery into the 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 the other end (left side) of battery to secure. To remove the battery, push the battery clip and pull the battery up from the right side. The battery will lift out.

Constant Stimulation

If the EMS 2000™ device is set on Cycled Stimulation, each time you turn the device on, it will deliver a period of constant, uncycled stimulation. This occurs automatically without you having to slide the Stimulation Switch **(11)** to Constant. The Constant Stimulation period lasts about twice the adjusted "On Time," after which the device resumes its adjusted On/Off Cycling. Use this Constant Stimulation period to adjust the Intensity control gradually until you achieve the strength of muscle contraction prescribed by your health professional. Whenever you need additional Constant Stimulation time, slide the Stimulation Switch **(11)** to the Constant position. The device will deliver Constant Stimulation for as long as the switch is in this uncycled Constant Position.

After the initial period of Constant Stimulation has ended, your device will begin to operate according to the On/Off or Reciprocating Cycle selected. The yellow indicator light **(5,6)** glows during the stimulation period of each Cycle and turns off during the period of no stimulation.

Adjust Cycle Timing

Turn the "On Ramp" control **(8)** to the desired time setting (seconds). This will allow gradual delivery of electrical stimulation to its maximum intensity. This control provides a "soft turn-on" of electrical stimulation, making the therapy more comfortable for the user. Two seconds of "On Ramp" time is a typical comfortable setting. An Off Ramp time of 2 seconds has been incorporated into the device to give a "soft turn-off" of the electrical stimulation.

Note: The "On Ramp and Off Ramp" period is part of the adjusted "On Time" period. Therefore, the "On Time" setting you choose will be the total of a. the desired "On Ramp" time; b. the preset "Off Ramp" time of 2 seconds; and c. the desired time of maximum stimulation

Turn the "On Time" control **(9)** to the desired period required for stimulation.intensity required to sustain muscle contraction. For example, if you desire an "On Ramp" time of 4 seconds, followed by 6 seconds of maximum stimulation and 2 seconds of "Off Ramp" time, then adjust your "On Time" control to 12 seconds. The "On Time" must be equal to or greater than your selected "On Ramp" time and the preset "Off Ramp" time.

Turn the "Off Time" control **(10)** to the desired "off" time period.

Adjust the Stimulation

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.

Instruct the user to adjust the stimulation to the Amplitude prescribed. The Amplitude should consistently produce the prescribed strength of muscle contraction. To obtain a consistent length of muscle contraction, the patient may need to make slight upward Amplitude adjustments.

Adjust the Rate

Turn the Rate control **(7)** to the lowest setting that maintains muscle tetany yet remains comfortable for the user. The range of comfortable muscle tetany for most users lies between approximately 20 and 45 pps (Hz). Instruct the user not to change the Rate setting from that which is selected by the health professional.

Timing Controls (8, 9, 10)

At your option, instruct the user in how to change "On" and "Off Times"; or instruct the patient to leave the "On Time," "Off Time" and "On Ramp" controls as you have initially set them. Follow-up sessions will enable you to assess the user's progress and to change the On/Off cycling, or other parameters, as required.

Maintence

12-Month Cycle Check-Up:

1. Visually check the exterior casing of the device for damage.
2. Visually check the input and output jacks (sockets) for damage.
3. Visually check the device for clarity of reading instruction and indicator decals.
4. Visually check the illumination LEDS (lights) are operating correctly
5. Visually check the lead wires (cables) and electrodes.
6. Measure the performance output using 500 OHM resistance. Current must not exceed 100 mA peak.

Malfunctions:

Should any malfunctions occur while using the EMS 2000™, check:

-Whether the Amplitude control is set to the appropriate form of therapy. Adjust the Amplitude control correctly.

-Whether the cable is correctly connected to the device. The cable(s) should be inserted completely into the sockets.

-Whether the Impulse Display Lamp is illuminated. If necessary, insert a new battery.

- For possible damage to the cable. Change the cable if any damage is detected.

Maintence and Care:

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!*

-Stubborn 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.
-If the device is not to be used for a long period of time, remove the battery from the battery compartment unless there is no risk of a SAFETY HAZARD arrising (acid can leak from old and used batteries and damage the device).

Warranty

LIMITED WARRANTY (USA only, unless otherwise noted)* BioMedical Life Systems, Inc. promises to the original consumer-purchaser to repair or, at the option of BioMedical Life Systems, Inc., to replace any muscle stimulator which malfunctions or proves defective in materials or workmanship under normal use during the period of the Warranty. During this time, BioMedical Life Systems, Inc. will provide all labor and parts necessary to correct such defects or malfunctions free of charge. If the product is no longer available, BioMedical Life Systems, Inc. reserves the right to substitute a comparable product. The consumer-purchaser is responsible for all shipping charges when returning the device to the manufacturer or designated service facility.

EXCLUSIONS

This warranty shall not apply to damage resulting from failure to follow these Instructions, accident, abuse, alteration, or disassembly by unauthorized personnel. This warranty does not extend to accessory items such as rechargeable batteries, electrodes, leadwires, and conductive gel. These items can be provided by your dealer, 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 device. In the USA, some states do not allow the exclusion or limitation of incidental or consequential damages, or do not allow limits on how long an implied warranty lasts, so the above limitation may not apply to you.

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 below. This warranty gives you specific legal rights, and you may also have rights which vary from state to state.

If the device case is opened or tampered with in any way, all warranty coverage is void.

* In the USA, unless otherwise indicated, the limited Warranty is five years.
Outside the USA, please check with your distributor to ascertain the "Limited Warranty Period."

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Postbus 6
1800 AA Alkmaar,
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EMS2000.ENG 08/22/03 REV.H

Declaration of Conformity

Manufacturer:	BioMedical Life Systems, Inc.
Address:	P.O. Box 1360 Vista, CA 92085, USA
Product Designations:	ElectroMedical Devices
Type, Model:	Stimulators: Transcutaneous Electrical Nerve, NeuroMuscular, High Volt Pulsed, Interferential, Microcurrent

We herewith declare that the above mentioned product(s) meet the provisions of the Medical Device Directive 93/42/EEC, Annex II

CE 0086

This Declaration is based on:
Certification of a Quality System
Certificate No.: 55661
Issued by BSI, Inc. Date: 05/06/03

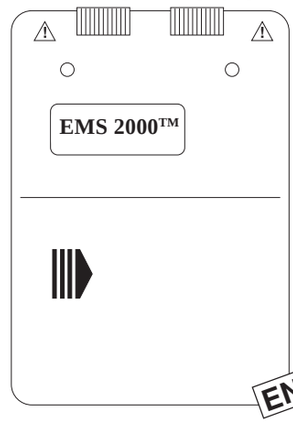
Signature: Hans W Reiss

Hans W. Reiss
Vice President
2448 Cades Way
Vista, CA 92081-7830, USA
06/09/03

BioMedical Life Systems, Inc.

NeuroMuscular Stimulator

EMS® 2000



ENGLISH

Instructions