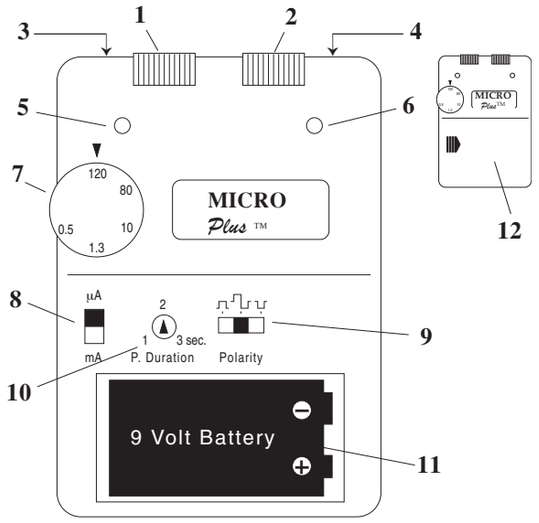


Technical Data

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)
Carrier Freq.	14,000 cycles
Waveform	Square
Polarity	Positive, negative, or bipolar with 1, 2, or 3 second adjustment within each range
Output Current	0 - 5 mA adjustable 0 - 1000 µA adjustable Intensity dial corresponds numerically
Output Voltage	0 - 2.5 Volts
Pulse Rate	.5 - 120 Hz adjustable
Power Source	9 Volt Battery, E-Block, type 6F22
Number of Electrodes	2 pair
Number of Lead Wires	2 pair
Tolerances	±10%

Output parameters are across a 15,000 ohm resistance. Current must not exceed 5 mA peak.

WARNING:

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

Your MICRO *Plus*™ comes with (1) 9 volt battery, (2) lead-wires, (4) electrodes and an instruction manual. Please contact your clinician for appropriate replacement parts/accessories.

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

Caution
In the USA Federal law restricts this device to sale by or on the order of a physician so licensed by the State.

Indications
Transcutaneous Electrical Nerve Stimulation (TENS) devices are used for the symptomatic relief and management of chronic (long-term) intractable pain and as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain problems.

Contraindications
TENS devices can affect the operation of demand-type cardiac pacemakers. TENS is not recommended for patients with known heart disease without a physician's evaluation of risk. Do not stimulate over the eyes or carotid sinus nerves. Do not apply TENS for 1. undiagnosed pain syndromes until etiology is established, 2. electrode placement that causes current to flow transcerebrally (through the head).

Warnings
This device should be used only under the continued supervision of a physician. TENS is ineffective for pain of central origin, (i.e. appendicitis, hepatitis). TENS is of no curative value; it is a symptomatic treatment which suppresses pain sensation which would otherwise serve as a protective mechanism on the outcome of the clinical process. Safety of TENS devices for use during pregnancy or delivery has not been established.
For external use only. Electronic equipment such as EKG monitors and EKG alarms may not operate properly when TENS is in use. The user must keep the device out of the reach of children.

Precautions
Avoid adjusting controls while operating machinery or vehicles. Turn the stimulator off before applying or removing electrodes. Long-term stimulation at the same electrode site may cause skin irritation. Use only for the specific pain problem prescribed by the physician. Effectiveness is dependent upon patient selection.

Adverse Reactions
Possible allergic reaction to tape or gel. Possible skin irritation or electrode burn under electrode.

Operating Instructions for the Transcutaneous Nerve Stimulator MICRO *Plus*™

You have been prescribed the BioMedical MICRO *Plus*™. Your MICRO *Plus*™ produces safe electrical pulses that pass along two lead wires and are delivered through the skin by means of two external electrodes.

Using Your MICRO *Plus*™:

1. Make sure that the Amplitude control **(1, 2)** is turned fully counterclockwise to the "O" (Off) position.
2. Insert one 9-volt battery into the battery compartment **(11)**. (See #13 for instructions to insert battery.)
3. Attach the electrodes to the lead wires.
4. Prepare the electrodes for use according to the instructions of your health professional and/or the electrode manufacturer's directions. Make sure that the skin areas where the electrodes will be placed are clean and dry before applying the electrodes.

Caution: Improper use of electrodes may cause burns. Care should be exercised to use only electrodes specified by BioMedical Life Systems, Inc.

5. Attach the electrodes to the skin areas indicated to you by your health professional.
6. Insert the plug ends of the lead wires into the output jacks of your device. You may insert the lead wires into either jack **(3, 4)**.
7. Turn on your device by rotating the Amplitude control **(1 or 2)** in a clockwise direction. The amber indicator lights on the front of your device come on whenever you turn the device on **(5 or 6)**.
8. Rotate the Amplitude control clockwise until you reach the setting recommended by your health professional **(1 or 2)**.
9. Mode selectors **(8, 9, 10)**: Your health professional may have already adjusted the controls to the appropriate setting. Do not re-adjust these controls.
10. After each stimulation session turn off your MICRO *Plus*™ by rotating the Amplitude controls fully counterclockwise to the "O" (Off) position **(1 or 2)**
11. Failure of the amber indicator light **(5, 6)** to come on when you turn your device on means that the 9-volt battery needs to be replaced with a fresh battery or recently charged Ni-Cad battery. Always turn your device off before changing batteries. (See #14 on how to remove battery.)
12. Front Cover—A slide-on panel covers the controls (12). Your health professional may wish to set these controls for you and request that you leave the cover in place, except to change the battery. However, to remove the cover, simply press cover slightly and slide it sideways to the right.

13. To place battery into battery compartment **(11)**: Place battery in direction as indicated by diagram located in the rear of battery compartment, with the positive/negative raised electrode poles against right end of compartment, then push down on other end (left side) of battery to secure.
14. To remove battery: Push battery to left against clip and pull up battery from right side. Battery will lift out.

The battery should be removed if the device is not used for a prolonged period of time. The battery supplied is an Eveready Alkaline Model #522. This battery or something similar should always be used.

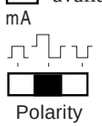
15. Your MICRO *Plus*™ may be clipped to clothing such as a belt, vest, shirtpocket or bra.

Mode Selectors

Mode Selectors within Battery Compartment (11)

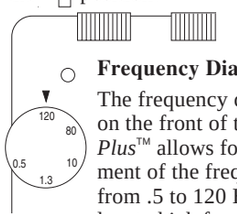
Your health professional may have already adjusted the controls to the appropriate setting. Do not re-adjust these controls if they have been set by your health professional.

Output Current Switch (8)
When the switch is in µA position, 0 - 1000 µA current is available. In the mA position 0 - 5 mA are available.



Polarity Switch (9)
When switch is on ⎍ MICRO *Plus*™ will be stimulating in the positive polarity. The ⎎ position allows for negative polarity stimulation. For positive then negative stimulation, move switch to the ⎍ position.

Polarity Duration Knob (10)
The duration of the polarity is adjustable from 1 - 3 seconds.



Frequency Dial (7)
The frequency dial found on the front of the MICRO *Plus*™ allows for adjustment of the frequency from .5 to 120 Hertz (from low to high frequency).

Recommendations for the Therapist

Tips for Skin Care
Skin should be cleaned prior to placement of the electrodes. If the electrodes do not contain gel, then gel should be applied directly to the skin prior to placement of the electrodes.

Electrode Placement Alternatives

- Place directly over the area from which the pain is emanating.
- Encircle the area of pain.
- Place proximally above the main nerve stem of the peripheral nerve responsible for the pain area.
- On specific points such as trigger points or acupuncture points.
- Place in the area of the pain site.

The treatment, when applied independently or in conjunction with medicinal therapy, should first be attempted with Low Frequency TENS treatment control settings.

A consistent application of approximately .5 - 1.3 Hz has been shown to produce effective stimulation.

The treatment period should be at least 20 - 30 minutes as the pain-inhibiting effect only commences after approximately 15 - 20 minutes. In the most favorable case, treatment lasting thirty minutes could contribute to a reduction in the need for analgesics. This will, however, be dependent upon the seriousness of the patient's condition.

Should Low Frequency TENS treatment not yield the desired result, High Frequency TENS treatment should be applied as follows:

(High Frequency TENS Treatment) Frequencies are found in the range of 120 - 150 Hz. The pain-inhibiting effect should commence within a few minutes. The treatment period should be between 20 - 30 minutes. In some cases, desensitizing must be carried out for several applications.

The correct level of stimulation should feel comfortable to the patient and should never be set at levels that cause discomfort.

Warning: Only electrodes and leadwires authorized by the device manufacturer should be used.

Safety and Technical Checks

Once a year, a maintenance check should be performed on the device as follows:

- Visually check the exterior case of the device for damage.
- Visually check the input and output sockets for damage.
- Visually check the device for clarity of reading instructions and indicator decals.
- Visually check that the illumination LED (lights) are operating correctly.
- Visually check the leadwires and electrodes for wear.

Maintenance and Care

- The case housing is made of insulated ABS plastic and can be cleaned with isopropyl alcohol.
- 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.
- *NOTE: Do not smoke or work with an open flame (for example, candles, etc.) when working with flammable liquids!*

Malfunctions

Should any malfunctions occur while using this device, check:

- whether the leadwires and electrodes are correctly connected to the device. The leadwires should be inserted firmly into the device sockets.
- whether the Impulse Display Light (LED) is illuminated. If not, insert a new battery.
- for possible damage to the leadwires. Change the leadwires if any damage is detected.

Do not attempt to repair a device yourself!

Opening the device case voids the warranty. Please contact the dealer from whom the device was purchased. If they are unable to assist you, please contact:

In the USA and Canada, BioMedical Life Systems, Inc., (760) 727-5600.

In Europe, BMLS BV, Alkmaar, The Netherlands.

This device MUST only be serviced by the manufacturer.

To reorder any accessories or supplies, contact your dealer.

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 neurostimulator 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."

BioMedical Life Systems, Inc.
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Vista, California 92081-7830, USA
Tel: (1) (760) 727-5600
FAX: (1) (760) 727-4220
BioMedical Life Systems, BV
Postbus 6
1800 AA Alkmaar,
Netherlands

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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.: 55611
Issued by BSI, Inc. Date: 05/06/03

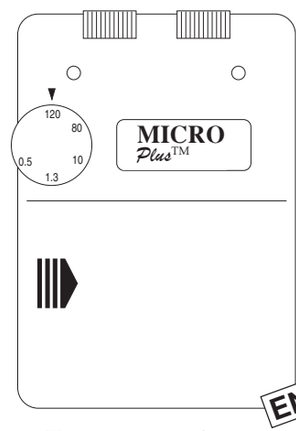
Signature: Hans W Reiss

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

BioMedical Life Systems, Inc.

Transcutaneous Electrical Nerve Stimulator

MICRO *Plus*™



Instructions