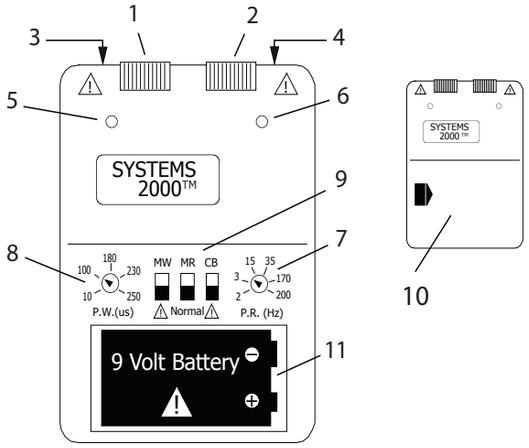


ACCESSORIES:

2 Leadwires with electrodes
1 Instruction Booklet
1 Battery
1 Carry Pouch

Optional Accessories: 1 recharger kit comprising recharger with matching battery type. Only use accessories, electrodes, leadwires and batteries approved by BioMedical Life Systems, Inc.

SPECIFICATIONS:

Size:	99 mm x 70 mm x 25 mm
Weight:	132 g
Channels:	2
Waveform:	asymmetrical, biphasic square-wave
Output:	constant current
Intensity:	continuously adjustable from 0 - 100 mA peak
Frequency:	2 - 200 Hz
Impulse Width:	10 - 250 µs adjustable
Constant:	constant stimulation
Modulation Width:	decrease of set Width of 50% over a 5-second period
Modulation Rate:	decrease of set Rate of 50% over a 5-second period
Modulation of Rate and Width:	decrease of set Rate and increase of set Width followed by increase of set Rate and decrease of set Width over a 5-second period
Cycled Burst:	2.5 seconds On and 2.5 seconds Off of set Rate

Power Supply:	9V Battery, E-block, type 6F22

Electrical data is recorded across a 500 OHM resistance.

Graphic Symbol Definitions

Refer to operating instructions

An IEC 601-1 safety standard (type BF)

CE 0086

We herewith declare that the above mentioned product meets the provisions of the Medical Device Directive

Patient Safety Information

Caution
Federal law (USA) 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 adversely 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 undiagnosed pain syndromes until etiology is established. Do not place electrodes in a manner that causes current to flow transcerebrally (through the head).
Warnings
This device should be used only under the continued supervision of a physician, or outside the USA, by a qualified pain management specialist. 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.
Electronic equipment such as ECG monitors and ECG alarms may not operate properly when TENS is in use. The user must keep the device out of the reach of children. TENS is for external use only.
Precautions
Avoid adjusting controls while operating machinery or vehicles. Turn the stimulator off before applying or removing electrodes. Isolated cases of skin irritation may occur at the site of electrode placement following long-term application. Use only for the specific pain

problem as prescribed by the physician, or outside the USA, by a qualified pain management specialist. Effectiveness is dependent upon patient selection by a qualified pain specialist. EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE
Adverse Reaction
Possible allergic reaction to tape or gel. Possible skin irritation or electrode burn.

Figure 2
Constant

Figure 3
Cycled Burst

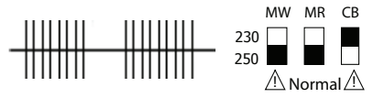
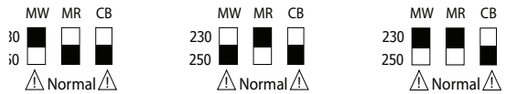


Figure 4
Modulation



Operating Instructions

General Description
This device is a Transcutaneous Electrical Nerve Stimulator. One pair of electrodes can be connected to each output channel using the leadwires supplied. Stimulation pulses are transferred from the device through the leadwires to the electrodes. The intensity, duration, and number of pulses per second can be adjusted.
Device Description / Operation / Display (See figure 1)
For safety reasons, the setting controls 7, 8, and 9 are located under the battery compartment cover.
On/Off Switch and Amplitude Control (1, 2)
If both Amplitude controls are in the "0" position (arrow markings on the housing), the device is switched off.
By turning the Amplitude controls clockwise, the appropriate channel is switched on and the Impulse Display Lamp (5, 6) will illuminate and begin to pulse according to the frequency set.
The intensity of the stimulation, transmitted through the electrodes, increases as the Amplitude control is turned clockwise.
To reduce the intensity of stimulation and/or switch the device off, turn the Amplitude control counterclockwise until it stops.
Connector sockets for the electrode cables (3,

4)
Connection of the electrodes is made with these two sockets. The device must be switched off before connecting the cables (both Amplitude Intensity controls (1, 2) must be at the "0" position).
Impulse Display Lamp (5, 6)
Each of these lamps illuminates whenever the device is "On." The human eye is limited to recognizing the frequency of the yellow LED only below 30 pps or Hertz; at settings in excess of 30 pps (Hertz) the light will appear to be constant.
Frequency Control Dial (7)
By turning this dial, the number of impulses per second (Hz) for both channels can be continually adjusted between 2 - 200 Hz.
Impulse Width Dial (8)
This dial allows the continuous adjustment of the impulse width between 10 µs and 250 µs. If no instructions regarding the impulse width are given in therapy, set the control dial midway, at 180 µs.
Operating Mode Switches (9)
There are five positions: MW for Modulation of Width, MR for Modulation of Rate, MW and MR for Modulation of Rate and Width, CB for Cycled Burst and Normal for Continuous Stimulation.

- Modulation of Width: In this position the set width is slowly switched on and off within a 5-second period. MW in upper position and MR, CB in lower position (see figure 4a).
- Modulation of Rate: In this position the set Rate is slowly switched on and off within a 5-second period. MR in upper position and MW, CB in lower position (see figure 4b).
- Modulation of Rate and Width: In these positions the Rate is slowly switched on, the Width is slowly switched off, and as the Rate is slowly switched off the Width is slowly switched on over a 5-second period. MW and MR in upper position, CB in lower position (see figure 4c).
- Cycled Burst: In this position the set Rate is given for 2.5 seconds with a 2.5 second pause in between. MW and MR in lower position, CB in upper position (see figure 3).
- Continuous Stimulation: The set therapy current remains constant for the duration of the therapy session. MW, MR and CB in lower position (see figure 2).

Battery

In order to maintain the functional operation of the SYSTEMS 2000TM, the batteries will have to be changed periodically. The device is supplied with a 9 volt Eveready Alkaline or special rechargeable battery, e.g., Nickel Cadmium (Ni-Cad). All rechargeable batteries are initially sent out without any charge. Allow 16 hours for charging. Warning: Do not recharge disposable batteries.
To change batteries:

- Before opening the battery compartment, check to make sure that the device is switched off—both Amplitude controls (1, 2) must be at the "O" position.
- Slide the battery compartment cover (10) in the direc-tion of the arrow and remove.
- Remove the battery (11) from the compartment by gently pushing the battery toward the left side of the compartment and lifting it out. Gently insert the new battery by matching the +/– end of the battery with the +/– symbol found inside the battery compartment and push the opposite end firmly in, securing the battery in place.
- Replace the battery compartment cover and slide to close.
- Remove the battery if you do not plan to use the device for long periods of time. Otherwise leakage and damage to the device can occur.
- Dispose of batteries in a proper manner.

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.

Electrode Placement for Typical Conditions

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 2 Hz has been shown to produce effective stimulation.

The Amplitude and Width settings should be set as high as possible without causing discomfort. 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, is 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 100 - 150 Hz. The pulse width

settings are generally set between 50 - 100 µs. However, the wide range of settings on this device allows the treatment to be customized to achieve optimal results for the patient.

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.
- 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!

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.