Fuji System

INSTRUCTION MANUAL FOR PATIENT & PROFESSIONAL

- TENS - Transcutaneous Electrical Nerve Stimulator

Fuji System Models:
- TENS 2K
- 804S and 804SI II
- 804M

CAUTION: Federal law restricts this device to sale by, or on the order of, a licensed professional
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TENS - Transcutaneous Electrical Nerve Stimulator

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- 804S & 804SIII
- 804M
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<td>The TENS system is designed for the treatment of pain -- chronic, acute or post-operative pain.</td>
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instrument should not be used, and safety precautions that must be taken by all who use it.

The manual provides complete operating instructions, an operations checklist, and care and maintenance steps.

**Patient**

The instructions in this booklet are designed to cover most operational issues. However, if you have questions about your situation, or if unusual problems arise, contact your physician or therapist.

**Professional**

Please instruct all patients to read this booklet thoroughly.
HOW THE TENS AFFECTS PAIN

What is pain?

There are different types of pain.

One type of pain is a warning system. The body uses pain to alert us that something may be wrong. For example, an abnormal condition such as an ulcer might go undetected if it were not for the sensation of pain.

However, other types of pain do not appear to serve any known purpose. For example, long-lasting, persistent pain that does not warn us about any particular condition serves no apparent purpose.
How pain messages are transmitted

We don't feel pain until a coded "message" travels to the brain where it is decoded, analyzed and then responded to. The pain message travels from the affected area along small nerves leading into the spinal cord. Here the message is relayed to different nerves that travel up the spinal cord to the brain.

To stop pain

There are several ways to stop pain. Sometimes you can stop pain by simply moving away from the pain-causing situation. You stop pain this way when you let go of a hot utensil, for example.

Medications are used to relieve some types of pain. Surgery can also remove some pain-causing conditions.
Electrical stimulation

Another method of pain relief is electrical stimulation -- the kind provided by your TENS.

Scientific research supporting use of TENS

In 1965, researchers Melsack and Wall presented their concept of a "gate" mechanism for the control of pain.

They theorized that a "T" cell transmits to the dorsal horn (in the spinal column), and that the stimulation of large nerve fibers may block pain transmission.

Recently, investigators have proposed that multiple gates exist in the peripheral and/or central nervous system.
They suggest that electrical nerve stimulation passing through the skin -- the kind provided by the TENS -- activates one or more of the pain gates. When this happens, peripheral pain signals are prevented from reaching the brain. In other words, part of the pain "message" is blocked. As a result, an individual may be relieved of much of their pain.

Your TENS instrument may replace your pain with a buzzing or tingling feeling that spreads throughout the painful area. This is normal and may be present whenever pain relief is occurring.

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WARNINGS AND PRECAUTIONS - TO patient and professional

- **Use only under medical supervision**

  TENS devices should only be used under the continued supervision of a physician, or a licensed medical practitioner to whom you have been referred by your physician.

- **Not for use with undiagnosed pain syndromes**

  Use TENS devices only when pain syndromes have been diagnosed.

- **A note about chronic pain**

  In chronic pain situations, it is necessary to try stimulation extensively before deciding whether a particular patient can be treated further by long-term stimulations.
• **Pacemaker wearers**

The TENS stimulator could affect the operation of certain types of cardiac pacemakers. It is not recommended for use by pacemaker patients.

• **Heart patients**

Take adequate precautions before stimulating patients who may have heart disease. At this time, clinical data is not sufficient to prove the safety of TENS use for these patients.

• **Monitoring equipment**

Avoid use of TENS in post-operative recovery rooms when the patient is on a heart monitor. Other electronic monitoring equipment such as EKG monitors and EKG alarms may not operate properly when TENS is in use.
- **Pregnancy**

  The safety of TENS use during pregnancy or delivery has not been established.

- **Skin conditions**

  Continued use of electrical stimulation in the presence of skin irritation may be harmful.

  If skin rash or other unusual symptoms develop while using the system, turn the stimulator off, remove the electrodes from your skin, and notify your professional.

  Discontinue stimulation until the source of irritation is determined. Moving the
electrodes to an adjacent position may allow continued stimulation, and should be done routinely if the device is being used chronically.

There is also a risk of skin burns if the metal electrode pin is not fully inserted into the electrode or if it lies directly against the skin. (Full instructions for electrode placement are provided in this booklet.)

- New persistent pain

The TENS system should not be used in cases of new persistent pain without first consulting your doctor. New persistent pain is often an early warning of conditions which may require medical treatment.
• **Machinery operation**

Avoid abrupt changes of the TENS stimulator controls while operating potentially dangerous machinery such as power saws, vehicles, etc.

• **Leadwires**

Do not connect leadwires to electric power cords or AC outlets.

• **Placement of electrodes**

Always turn the TENS stimulator off before attaching or moving electrodes, or before reversing electrode polarity.
Some DON'Ts about electrode placement:

- Do not place electrodes over mouth or neck. Severe muscle spasms may occur which can block airways if electrodes are placed across the neck or in the mouth.

- Do not place electrodes over carotid sinus nerves, also located in the neck. Consult your professional for safe electrode location.

- Do not place electrodes so that current will flow across the head.

(See "How to place electrodes" for more information.)
• Care of the system

Your TENS system is a precision electronic device and may be damaged if dropped or mishandled. Read thoroughly the section in this booklet entitled "IMPORTANT INSTRUCTIONS FOR ALL SYSTEMS" for operation and maintenance steps.

• Patient aversion

Some people find the sensation of electrical stimulation extremely unpleasant. These patients should probably be excluded from use of the TENS.
More about transcutaneous electrical nerve stimulation.

- Given present understanding, this type of stimulation treats symptoms. As such, it may suppress the progress of pain which would otherwise serve as a protective influence on the outcome of a disease process.

- The potential for physical and/or psychological dependence upon transcutaneous nerve stimulation as a means of relieving pain has not yet been determined.

- Transcutaneous nerve stimulation is not effective for pain of central origin, as compared to pain of peripheral origin.
- Transcutaneous nerve stimulation is of no known curative value.

- Treatment outcome will be influenced by the patient's psychological state and use of drugs.

- The use and effectiveness of this system is directly related to patient selection.

- Keep the system out of the reach of children.
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- The use and effectiveness of this system is directly related to patient selection.

- Keep the system out of the reach of children.
USING YOUR TENS SYSTEM FOR PAIN RELIEF

Talk to Your health professional first

Your physician or therapist will instruct you on using your system. The TENS is relatively easy to operate and maintain. The most common problems arise from failure to:

- Change the battery as required.
- Wear the electrodes as directed.
- Experiment with electrode positions to find the most successful contact points.

The material in this section will help you use your TENS system effectively. You'll be able to carry out your professional's instructions and help relieve your pain.
Pain relief needs vary

The pain relief routine varies from patient to patient. Some people experience pain relief by stimulating for only minutes a day. Others may have to use their stimulators all the time. Sometimes complete pain relief is not achieved. Often, pain relief will improve with time.

IMPORTANT: Your physician or therapist can discuss these matters with you. He or she is an excellent resource for answering all of your questions.
SYSTEM PARTS - ALL TENS Systems

Your TENS system includes:

- **Stimulator:**

  The stimulator contains the power source and electronics of the system. The stimulating signal is transferred from the stimulator through the skin by means of leadwires and electrodes.

- Electrical leadwires
- Electrodes (black "rubber" pads)
- A tube of gel to use with the electrodes
- Adhesive patches to place over the electrodes and hold them in place
HOW TO OPERATE YOUR TENS - MODELS TENS 2K, 804S & 804SIII

Models 804S and 804SIII - For each model, the stimulator is contained in a high-impact case. It has four control dials, with two leadwire jacks on the top.

The 804SIII stimulator also includes "Burst" and "Modulation" outputs (in addition to the standard TENS output -- "Constant"). The stimulation Model Selector Switch is located on the top of Model 804SIII, between the channel indicator lights. (See diagram)

Each stimulator operates on a 9-volt battery.
Controls and Functions - Model TENS 2K, 804S III

MODE SELECTION SWITCH:
B=Burst
C=Constant
M=Modulation

OUTPUT JACK:
Leadwire plug is inserted here.

AMPLITUDE CONTROLS:
Controls power on and off and amplitude (output) for Channel 2 (on the right).

AMPLITUDE CONTROL:
Controls power on and off and amplitude (output) for Channel 1 (on the left).

PULSE CONTROL:
Controls the number of pulses per second for Channel 1 (on the left.)

PULSE CONTROL:
Controls the number of pulses per second for Channel 2 (on the right.)

Transcutaneous Electrical Nerve Stimulator
Model 804S  same as 804SIII except for top:

- Channel 1 Indicator light.
- Channel 1 Output jack.
- Channel 2 Indicator light.
- Channel 2 Output jack.
HOW TO OPERATE YOUR TENS - MODELS TENS 2K, 804S & 804SIII

PREPARATION

1. Become familiar with the controls.

Amplitude Controls

The Amplitude Controls are the upper two dials. There is one on each side of the stimulator, with numbers marked 1 - 5. The amplitude dial on the right controls the output of the channel (jack) on the right. The dial on the left controls output of the channel on the left.

Increase output

Turning these dials clockwise turns them ON and increases amplitude (output).
HOW TO OPERATE YOUR TENS - MODELS TENS 2K, 804S & 804SIII

Decrease output

Turning them counterclockwise turns them OFF and decreases amplitude.

Pulse Controls

The Pulse Controls are the lower two controls on either side of the stimulator. They each have settings marked from 1 - 120. These dials control the number of pulses generated per second, or the output rate for the corresponding channel.

Increase pulses

To increase the number of pulses per second turn these dials clockwise.

Decrease pulses

To decrease rate of output, turn the Pulse Control dial counterclockwise.
HOW TO OPERATE YOUR TENS - MODELS TENS 2K, 804S & 804SIII

2. Set the controls on the stimulator to OFF or minimum settings first.

Set both Amplitude Controls at "off":
Turn the Amplitude Control dials counterclockwise until they "click" into OFF position.

Set Pulse Controls (dials with settings from 1 - 120) at "1." Turn each dial as far to the left, or counterclockwise, as possible.
HOW TO OPERATE YOUR TENS - MODELS TENS 2K, 804S & 804SII

Move the stimulation Mode Selector Switch at the top of the stimulator to "C" for Constant -- the standard TENS position.

Channel 1 Indicator light.
Channel 2 Indicator light.
Channel 1 Output jack.
Channel 2 Output jack.
Stimulation mode selector switch
B = Burst mode
C = Constant mode (Standard TENS)
M = Modulation mode
HOW TO OPERATE YOUR TENS - MODELS TENS 2K, 804S & 804SIII

Move the stimulation Mode Selector Switch at the top of the stimulator to "C" for Constant -- the standard TENS position.

Diagram:

- Channel 1: Indicator light, Output jack.
- Channel 2: Indicator light, Output jack.
- Stimulation mode selector switch:
  - B = Burst mode
  - C = Constant mode (Standard TENS)
  - M = Modulation mode
OPERATION OF CONTROLS - MODELS TENS 2K, 804S & 804SIII

IMPORTANT: See "How to place electrodes" on page 42 before you begin.

Step 1 With electrodes in place, turn on the Amplitude Controls.

Step 2 Slowly increase output by turning the dials clockwise until you can feel the electrical stimulation -- a tingling or buzzing feeling. Continue to increase output until the sensation is strong, but not uncomfortable.

Step 3 Next, turn the Pulse Control dials clockwise. If the sensation becomes too strong as you adjust the rate, then: Turn Amplitude Controls counterclockwise to decrease output on the numbered dials.
**Step 4**

Move through the rate range until you find the setting that is most comfortable for you.

Most patients find that one particular setting gives them the best pain relief. Others find that changing the rate often is more comfortable.

As you become familiar with your TENS you'll find setting combinations that are the most comfortable to you and effective for controlling your pain.

**NOTE:** To achieve optimal results, vary electrode placement as needed until you find the spot that works best for you.
USING THE BURST OR MODULATION MODE ON THE TENS 2K & 804SI II

CAUTION: Failure to follow this procedure could cause discomfort.

Step 1  Turn the Amplitude Controls to OFF position.

Step 2  Set the Mode Selector Switch at "C" for Constant.

Step 3  Turn on the Amplitude Controls and adjust them by turning the dials clockwise until you reach a comfortable intensity.

Step 4  After you achieve a comfortable intensity, then move the Mode Selector Switch to either: "B" for Burst - or - "M" for Modulation.
To ensure proper operation of your TENS model TENS 2K, 804S or 804SIII, be sure also to read:

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DEVICE SPECIFICATIONS - Model TENS 2K, 804S and 804SIII

Channel : Dual
Waveform : Asymmetrical Bi-phasic rectangular
Output : Constant current
Intensity : Adjustable 0-95mA peak
Pulse rate : Adjustable 1-120 Hz
Pulse width : 150 microseconds
Burst (804SIII) : One burst consists of 1-160 pulses adjustable by pulse rate control.

Modulation (804SIII) : Pulse width is automatically varied in a cycle pattern in the range of 20-150 microseconds. Ramp up: 3 seconds Ramp down: 3 seconds
<table>
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<tr>
<th><strong>Maximum power density at</strong></th>
<th><strong>2,208 micro watts</strong></th>
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<tr>
<td>electrode</td>
<td>82 micro watts</td>
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<tr>
<td>Power divided on electrode</td>
<td>9-volt square type</td>
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<tr>
<td>Battery (power source)</td>
<td>At typical setting,</td>
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<tr>
<td>Effective battery life</td>
<td>approximately 40 hours</td>
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<td></td>
<td>with 9V zinc carbon</td>
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<td></td>
<td>battery; 50 hours</td>
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<td>with 9V hi-cad</td>
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<td>rechargeable</td>
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<td></td>
<td>battery (100mA h).</td>
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| Unit dimensions             | 10.1 x 6.6 x 2.3 cm   |
| Weight of the unit          | 85 g                  |
| Output jack                 | 3.5mm diameter jack   |

Electrical specifications are plus or minus 10% on 500 ohm load and subject to variation due to normal production tolerances.
HOW TO OPERATE YOUR TENS - MODEL 804M

MODEL 804M - The stimulator is contained in a high-impact case. It has four control dials, with two leadwire jacks on the top.

The 804M stimulator also includes "Burst" and "Modulation" outputs (in addition to the standard TENS output -- "Constant").

The stimulation Mode Selector Switch is located on the top of Model 804M, between the channel indicator lights.

The stimulator operates on a 9-volt battery.
Controls and Functions - Model 804M

MODE SELECTION SWITCH:
- B = Burst
- C = Constant
- M = Modulation

OUTPUT JACK:
Leadwire plug is inserted here.

OUTPUT JACK:
Leadwire plug is inserted here.

AMPLITUDE CONTROL:
Controls power on and off and amplitude (output) for Channel 2 (on the right).

AMPLITUDE CONTROL:
Controls power on and off and amplitude (output) for Channel 1 (on the left).

PULSE CONTROL:
Controls the number of pulses per second.

SUB-PULSE CONTROL:
Regulates the number of inner pulses contained in each principal pulse.
HOW TO OPERATE YUR TENS - MODEL 804M

PREPARATION

1. Become familiar with the controls.

Amplitude Controls

The Amplitude Controls are the upper two dials. There is one on each side of the stimulator, with numbers marked 1 - 5. The amplitude dial on the right controls the output of the channel (jack) on the right. The dial on the left controls output of the channel on the left.

To turn OFF or decrease

Turn each Amplitude Control dial counterclockwise to OFF position and to decrease amplitude.

To increase

Turn each dial clockwise to turn it on and increase amplitude.
HOW TO OPERATE YOUR TENS - MODEL 804M

Pulse rate control  The pulse rate control is located on the lower left on the stimulator. This dial is marked with numbers from 0.5-120.

Sub-pulse rate control  This dial is on lower right of the stimulator, with numbers from 1 - 5.

Increase  To increase activity for either of these lower two controls, turn the dial clockwise.

Decrease  To decrease activity, turn the dial counterclockwise.
OPERATION OF CONTROLS - MODEL 804M

IMPORTANT: Follow steps for "How to place electrodes" on page 42 before you begin.

CAUTION: Remember to make sure the Amplitude Controls are at OFF for both Channels 1 and 2. Failure to follow this procedure could cause discomfort.

Step 1 Select a stimulation mode on the Mode Selection Switch.

B = BURST mode (2 outputs per 1.2 seconds)
C = CONSTANT mode (constant output)
M = MODULATION mode (modulating output)

Constant mode is the recommended setting until you become familiar with the 804M.
OPERATION OF CONTROLS - MODEL 804M

Step 2  Adjust the pulse Rate Control (0.5-120) to the prescribed rate. If no rate has been prescribed, set the dial at "80." (Later you can adjust to the position where you feel most comfortable.)

Step 3  Adjust the Sub-Pulse Rate Control (1-5) to the prescribed rate. If no rate has been prescribed, set to "1." The number chosen indicates the number of inner pulses contained within each of the principal pulses.

When you increase the Sub-Pulse Rate, you'll feel an increase of sensation over the skin.

Step 4  Switch on the Amplitude Control. Turn this dial slowly in a clockwise direction until you feel an electrical stimulus.
Note: You may not feel any sensation, since the output current has been controlled in the level of microcurrent. However, stimulation is still occurring.

Step 5 Repeat Steps 1-4 for the other channel, if you are using both channels.

NOTE: To achieve optimal results, vary electrode placement as needed until you find the spot that works best for you.
Step 5

Repeat Steps 1-4 for the other channel, if you are using both channels.

NOTE: To achieve optimal results, vary electrode placement as needed until you find the spot that works best for you.
**IMPORTANT**

To ensure proper operation of your TENS model 804M, be sure also to read:

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DEVICE SPECIFICATIONS - MODEL 804M

Channel : Dual
Waveform : Mono- phasic rectangular
output voltage : 0-87 volts
Output current : 0-700 uA
Intensity : 0-87 volt adjustable
Carrier Frequency : 14,000 Hz
Number of Sub- pulses : 1-5 Sub- pulses per
Controlled pulse rate: controlled pulse
                        adjustable
Pulse width of the : 1-120 pulses per
frequency : second adjustable
Cycle on-time : 20 us
Output modes : 270 us
(stimulation modes) : Constant, Burst and
Modulation modes
| **Constant** | Constant output according to control settings |
| **Burst**     | 2 bursts per 1.2 seconds |
| **Modulation** | Numbers of the sub-pulses decrease gradually from 5 to 0 to 0.5 second, and return to 5 in another 0.5 second |

**Power source**

| 9-volt square type battery |

**Unit dimensions**

| 10.1 x 6.6 x 2.3 cm |

**Weight of the unit**

| 85 g |

**Output jack**

| 3.5mm diameter jack |

Electrical specifications are plus or minus 10% on 500 ohm load and subject to variation due to normal production tolerances.
HOW TO PLACE ELECTRODES - ALL SYSTEMS

Note: Your physician or therapist will have instructed you where to place the electrodes.

A KEY to successful use of your electrical stimulation system is finding the best placement for the electrodes. You may need to try several electrode locations before you find the best one to intercept your pain.

Step 1 Before placing the electrodes on your skin, gently wash the area with mild soap and water.

Washing removes skin oils and debris, and reduces resistance to the electrical current. Thoroughly rinse and dry the area.
Step 2  Locate the tape patch. Peel off the paper liner.

Step 3  Place the electrode onto the patch and press firmly.

Step 4  Insert pin end of leadwire into electrode, through the slit in the adhesive patch.

**IMPORTANT:** Do not connect the leadwire to electric power cords or AC outlets!

Step 5  Apply conductive gel evenly to the entire side of the electrode that will contact your skin. Use enough gel to completely cover the pad, but not so much that it won't make a good contact with your skin — like moistening a
Step 2 Locate the tape patch. Peel off the paper liner.

Step 3 Place the electrode onto the patch and press firmly.

Step 4 Insert pin end of leadwire into electrode, through the slit in the adhesive patch.

**IMPORTANT:** Do not connect the leadwire to electric power cords or AC outlets!

Step 5 Apply conductive gel evenly to the entire side of the electrode that will contact your skin. Use enough gel to completely cover the pad, but not so much that it won't make a good contact with your skin -- like moistening a
postage stamp. Take care not to get gel in the connector holes of the electrodes.

**Step 6**

Apply electrode to the treatment site.

**Step 7**

Insert the leadwire plug end into the output jack on the stimulator.
OPERATION CHECKLIST - ALL systems

✔ Is the stimulator turned on? Does your unit have more than one channel? If so, make sure the channel you're working with is turned on. Make sure you're using the dials for that particular channel.

✔ Are the electrodes properly placed? Place electrodes as recommended by your physician or therapist. They must be properly located to achieve maximum benefit.

✔ Did you thoroughly clean and dry the electrode site on your skin before putting the electrodes in place?
✓ Have you applied conductive gel to the side of the electrode that contacts your skin? A good electrical contact can't be made with too much or too little gel.

✓ Is the battery fresh? Replace the stimulator battery whenever enough stimulation cannot be maintained. (As the battery wears down, turn the output controls up to maintain stimulation level.)

✓ Are the battery contacts properly clipped to the battery snap? Are battery connections clean?

✓ Are the leadwires firmly connected to the stimulator and electrodes? Make sure wires aren't tangled. Have leadwires been cleaned at pins and output jacked? (See MAINTENANCE) Are leadwires frayed? If so, replace.
Have you changed position? Sometimes the stimulation sensation will change when you change your posture. If necessary, adjust the output on the numbered dials when you change position.

If you still are receiving no pain relief, readjust the electrodes or reverse the leadwire pins in the stimulator jacks (for units with more than one jack). These adjustments may result in better pain relief.

**NOTE:** If you reverse or remove the electrodes, be sure to first turn the stimulator OFF.

Failure to turn the stimulator OFF may cause sudden unpleasant stimulation.
Have you changed position? Sometimes the stimulation sensation will change when you change your posture. If necessary, adjust the output on the numbered dials when you change position.

If you still are receiving no pain relief, readjust the electrodes or reverse the leadwire pins in the stimulator jacks (for units with more than one jack). These adjustments may result in better pain relief.

NOTE: If you reverse or remove the electrodes, be sure to first turn the stimulator OFF.

Failure to turn the stimulator OFF may cause sudden unpleasant stimulation.
TIPS FOR BEST PERFORMANCE - ALL SYSTEMS

Follow these guidelines to make sure your system functions optimally:

- Clean the black rubber electrodes and stimulator regularly.

- Change the battery regularly.

- Avoid damaging your stimulator by dropping or bumping it, or using it roughly.

- Don't engage in contact sports when using your TENS.

- Keep the stimulator and connector holes of the electrodes dry.
Do not pull the leadwire or allow it to become tangled or kinked. Grasp the jack itself to remove leadwires from the stimulator (rather than pull on it).

Use only mild soap solution to clean leadwires (NOT alcohol or freon).

Consult your physician or therapist if you have any questions or problems.

Be sure to read the MAINTENANCE section for how to care for and clean your system.
MAINTENANCE - ALL SYSTEMS

Your TENS requires no maintenance other than regular:

- Cleaning of the stimulator, leadwires and electrodes
- Battery replacement and contact cleaning
- Checking the equipment

CLEANING

Stimulator - IMPORTANT: Do not immerse stimulator in any cleaning solution or water.

The stimulator should be periodically wiped clean using a damp cloth and a solution of mild soap and water. Use of any other cleaning solution may damage the case.
- **Leadwires**

  Wipe the leadwires clean with a cloth dampened in a mild soap solution, then wipe them dry. (Do not use alcohol or freon to clean the leadwires.)

- **Electrodes**

  DO NOT use cleaning solvents on the "black rubber" type electrodes. You may use a soft damp cloth to wipe them clean. If necessary, the cloth may be dampened with mild soapy water -- but do not soak the electrodes.

**BATTERY MAINTENANCE**

- Your stimulator uses one standard 9-volt battery. This battery should be replaced
CHECKING THE EQUIPMENT

- If your stimulator does not seem to be operating properly, first change the battery.

- Most operational difficulties can be eliminated by replacing the old battery with a new one.

- Check also to be sure the battery contacts are properly clipped to the battery snap.

- Go through the OPERATIONS CHECKLIST to see if you've missed any steps.

- Finally, check to be sure that the leadwires are firmly connected to the stimulator and electrodes. (Replace leadwires if necessary.)
If none of these steps improves operation, then return the stimulator to your professional, who will return it to the manufacturer.

Note to professional: Return to -

Current Solutions, LLC
3814 Woodbury Drive
Austin, TX 78704
Tel: 800.871.7858
Fax: 512.600.7099
www.currentsolutionsnow.com