PATHWAY STM-10 OPERATOR'S GUIDE
- FOR THE PATIENT -

In this Operator's Guide:

FOR ASSISTANCE CONTACT YOUR LOCAL SALES REPRESENTATIVE, DISTRIBUTOR, OR THE PROMETHEUS GROUP AT 800-442-2325 IN THE US AND CANADA OR AT 603-749-0733. FOR TECHNICAL ASSISTANCE, CALL THE PROMETHEUS GROUP TECH SUPPORT LINE AT 800-272-8492 IN THE US AND CANADA OR AT 603-742-6053.

Indications for use:

- Urinary Incontinence: Stress, Urge, and Mixed Incontinence
- Neuromuscular Reeducation

Contra-indications:

- Active Infection or Genital Disease
- Severe Pelvic Pain
- Pregnancy
- Postpartum or Post Surgical (6 weeks)
- Inflammation of the vaginal canal
- Pain caused by sexual activity (female)
- Menstrual Period
- Pacemaker or Irregular heartbeat
- Presence of Any Known Malignancy
- History of Severe Urine Retention
- Protrusion of the pelvic organs into our outside of the vaginal or rectal canal
- Diminished sensory perception

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Warnings:

- Be sure to read this operator's guide before using this device.
- Do not put this device underwater or get device wet. It could damage the device.
- Do not connect any preamp, lead wire, or electrode to a wall outlet.
- Do not leave electrodes attached when device is not in use.
- Do not use while sleeping.
- Do not use during intercourse.
- Do not use with any other object in vagina or rectum.
- Do not keep electrode in vagina or rectum for extended periods.
- Never operate machinery including automobiles during stimulation.
- Discontinue use if bleeding develops.

Precautions:

- STM-10 should only be used with Pathway Vaginal or Rectal EMG/Stim Sensors.
- Always turn off the device before removing a Pathway Vaginal or Rectal EMG/Stim Sensor.

Adverse Effects:

- Skin irritation beneath or around the electrode sites may develop.

Connecting to Your Pathway STM-10 Device

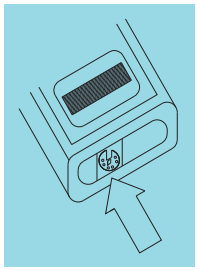

Figure 1

Plug the Pathway Vaginal or Rectal EMG/Stim Sensor into the connector at the top end of the device as shown above in Figure 1.

Using Your Pathway STM-10 Device: The Interface

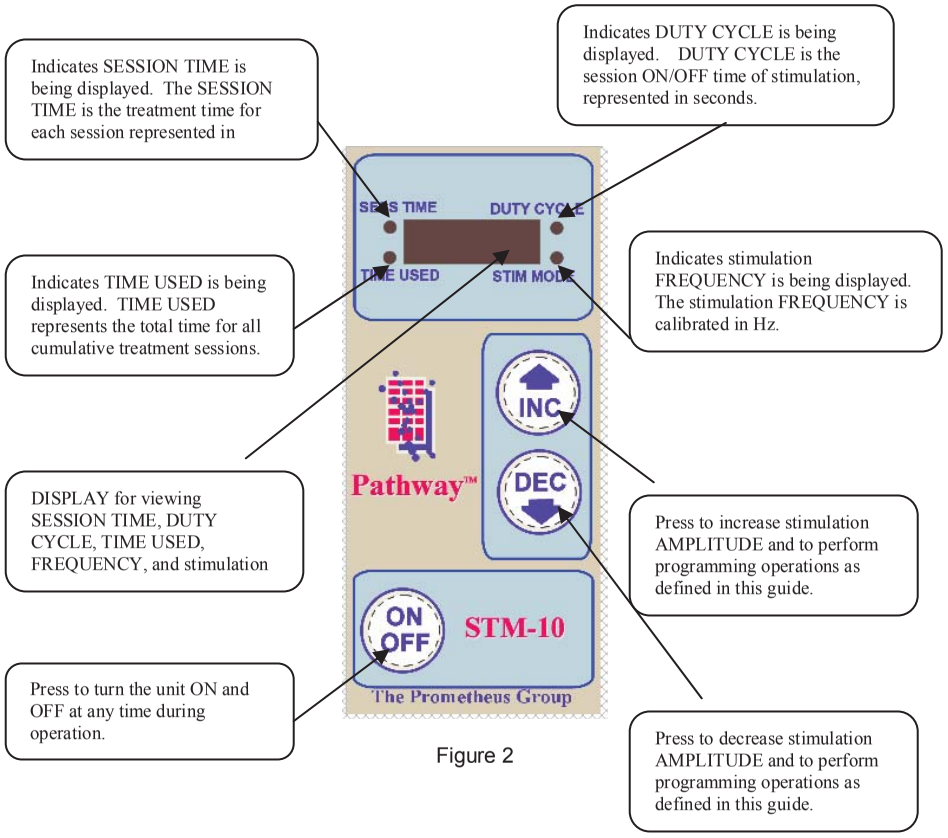

Figure 2

Using Your Pathway STM-10 Device: General Instructions

1. Connect the Pathway Vaginal or Rectal EMG/Stim Sensor to the Pathway STM-10 device as described in the section *Connecting to Your Pathway STM-10 Device*.

2. The Pathway Vaginal or Rectal EMG/Stim Sensor should be cleaned and prepared with a water-based lubricating jelly and inserted into the vagina or rectum as shown to you by your clinician. If you have any questions or concerns, contact the clinician who prescribed and fitted you with the Pathway Vaginal or Rectal EMG/Stim Sensor.

   Be sure to read the **Instructions for Use** provided with each sensor for additional information on using and fitting the Pathway Vaginal or Rectal EMG/Stim Sensors.

3. Turn the Pathway STM-10 device ON by pressing the ON/OFF button.

Note: The treatment session is defined by those treatment options saved during the last programming activity of the device by your clinician.

Warning: Do not begin stimulation until after the sensor is properly connected to the Pathway STM-10 device and inserted into the vagina or rectum.

4. The stimulation amplitude is presently displayed at 0 ma. Begin stimulation by pressing the UP ARROW button. This button increases the amplitude of the stimulation. Continue to increase the amplitude of the stimulation by continually pressing the UP ARROW button. Adjust the stimulation amplitude to the desired amplitude as described to you by your clinician.

Note: When stimulation is active ON is displayed.

Note: Pressing the UP ARROW increases the stimulation amplitude in 1 mA increments. Pressing and holding down the UP ARROW button will allow the amplitude to be adjusted more quickly in 1mA increments.

Decrease the amplitude of the stimulator by pressing the DOWN ARROW button.

Note: Pressing the DOWN ARROW decreases the stimulation amplitude in 1 mA increments. Pressing and holding down the DOWN ARROW will allow the amplitude to be adjusted more quickly in 1 mA increments.

Note: During stimulation amplitude adjustment, constant stimulation is delivered.

Caution: Always exercise caution when increasing the amplitude setting. Adjust to strong contractions, however stimulation should not be uncomfortable.

5. If the UP ARROW or DOWN ARROW button is not pressed for 7 seconds, the treatment session will begin at the last selected amplitude.

Note: During the treatment session, the ON TIME of the cycle is counted down on the display. During the OFF TIME of the cycle, the OFF TIME is counted down on the display. When stimulation is active ON is displayed. If stimulation has been chosen to be Continuous, during the treatment session "ON C" is displayed, and there is no count down.

6. Pressing the UP ARROW or DOWN ARROW button at any time during the treatment will revert the device to constant stimulation, displaying the present stimulation amplitude, and allowing stimulation amplitude adjustment. Pressing the UP ARROW or DOWN ARROW button a second time to change the stimulation amplitude as described above.

7. When the prescribed treatment time is over, the stimulation will automatically end and the STM-10 device will turn OFF.

Note: If you are in the 12.5Hz session of a linked 12:50 treatment, the stimulation will automatically end and the STM-10 device will be at 0ma amplitude, awaiting the adjustment of stimulation for the 50Hz treatment. At the end of the 50Hz session the STM-10 device will automatically turn OFF.

8. Press the ON/OFF button to turn OFF the STM-10 at any time during use.

Note: If you are in the 12.5Hz session of a linked 12:50 treatment, pressing the ON/OFF button will end the stimulation at 12.5Hz and the STM-10 device will be at 0ma amplitude, awaiting the adjustment of stimulation for the 50Hz treatment. Press the ON/OFF button at any time during the 50Hz session and the STM-10 device will turn OFF.

Warning: Always turn the stimulator OFF before removing the sensor.

Using Your STM-10 Device: Treatment Protocols and Guidelines

It is suggested that all patients keep both a treatment (exercise) and voiding log during the program.

It is generally recommended that follow-up visits take place at least every four weeks to evaluate progress, adjust the parameters and solve any patient problems.

It is important that there is proper patient selections and compliance with the treatment programs. Assessment by a digital vaginal or rectal examination should be conducted and the patient's ability to hold a contraction should be measured.

Care and Maintenance: Changing the Battery in your STM-10 Device

When the battery is low and needs to be replaced your STM-10 Device will FLASH *LO BATT* and then proceed to automatically turn OFF. This feature disables the ability to use the device with low battery power.

To replace the battery, remove the battery door at the back of the device and remove the low battery. Insert a new battery with respect to the labeling inside the battery compartment, making sure to place the positive terminal with the positive terminal labeling. After inserting the new battery, place the battery door back on the device.

Note: This unit must never be plugged into an electrical outlet or used with a 9-Volt adapter.

Care and Maintenance: Caring for Your Pathway STM-10 Device

The only maintenance necessary on your Pathway STM-10 is occasional cleaning.

Your Pathway STM-10 can be easily cleaned by wiping gently with a soft cloth or sponge dampened with water. This will remove the dust and dirt that naturally accumulates. A good quality rubbing alcohol may be used to remove stains or adhesives that stick to the case.

Do not use strong household cleaners, as they may damage the plastic parts.

Do not immerse the Pathway STM-10 in liquid. Excessive moisture may damage the internal electronic components.

Care and Maintenance: Pathway EMG/Stim Sensor Care Instructions

The Pathway Vaginal or Rectal EMG/Stim Sensors are single patient multi-use products. The electrode life expectancy depends upon use and care but should typically last several months.

The sensor should be washed with a pure mild soap and warm water. Then thoroughly rinse the sensor with warm water and air dry. The sensor should be kept in the original re-sealable bag between uses.

If the sensor becomes worn or develops an odor, immediately stop using and replace.

Be sure to read the **Instructions for Use** provided with each sensor for additional instructions regarding care and maintenance of your Pathway Vaginal or Rectal EMG/Stim Sensors.

Pathway STM-10 Technical Specifications

Stimulation

- Pulse amplitude (mA): 1 - 60
- Pulse Rate (Hz): 12.5/50/100/200
- Cycle (on/off) (S): 5/5, 5/10, 10/10, 10/20, Continuous (C)
- Ramp Up (S): 2 fixed
- Ramp Down (S): 1 fixed
- Pulse width (uS): 300
- Charge per pulse (uC): 17
- Power source: 9V alkaline battery
- Dimensions (in): 4.75 x 2.5 x 1
- Weight (oz): 4.2 (5.8 w/ 9V alkaline battery)

Compliance

- Compliance Use Timer: hours:minutes (99:59 max)

Electromagnetic Compatibility

This device has been tested in accordance to EN60601-1-2: 1993.

Warranty

The Prometheus Group warrants equipment of its own manufacture to be free from defects in material and workmanship as follows:

One year from the date of shipment to the original purchaser, subject to the terms, conditions, limitations, and exclusions specified herein.

1. Service: The Prometheus Group of New Hampshire, Ltd., hereafter "The Prometheus Group", shall provide, for the term of this warranty, repair of defective "Pathway" units. This warranty shall include all parts and labor charges. The purchaser must obtain a Return Authorization Number and must return the defective unit, at the purchaser's own expense to The Prometheus Group. The Prometheus Group may, at its option, repair and return the unit or provide a replacement unit. Should The Prometheus Group elect to provide a replacement unit, then this warranty is automatically transferred to the replacement unit. The Prometheus Group shall return, at The Prometheus Group's own expense, the repaired or replacement "Pathway" unit.

2. Exclusions: The following conditions are excluded from service under this warranty:

   A. Preventative maintenance. Preventative maintenance, defined as maintenance performed for the purpose of preventing a malfunction, is excluded from service under this warranty.
   B. Repair of damage or malfunction of "Pathway" equipment resulting from abuse, accident, modification, or other cause other than normal usage, including but not limited to operator error, failure of other user-supplied equipment, and equipment operation in excess of design specifications is excluded from service under this warranty.
   C. Loss due to fire, flood, robbery, burglary, theft, vandalism, radioactive contamination, or other natural disasters or Acts of God is excluded from service under this warranty
   D. Replacement of batteries, accessories and expendables such as electrodes, are excluded from service under this warranty.

3. Limitation of Remedy: The Prometheus Group shall not be liable for any damages caused by the delay in furnishing warranty services or other performance under this warranty. The service warranty expressed in paragraph 1 represents the sole and exclusive remedy for any warranty clams under expressed or implied warranties, including without limitation any warranty of merchantability or fitness. This warranty specifically limits the liability of The Prometheus Group, including liability for negligence claims by users and disclaiming any other claims of non-performance by The Prometheus Group. In no event shall The Prometheus Group be held liable for any incidental or consequential damages of any kind.

Assignment: This warranty shall not be assigned by the purchaser without prior written consent of The Prometheus Group. The warranty shall be binding upon all of the parties and their successors and assigns.