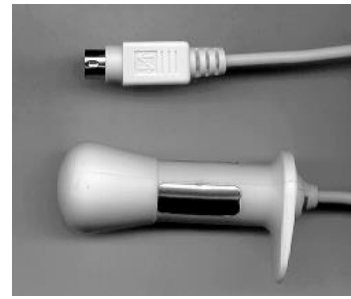


Lot#

The Prometheus Group
1 Washington Street, Suite 3171
Dover, NH 03820
603.749.0733/800.442.2325 (US & Canada)
603.749.0511 (fax)/E-Mail: info@theprogrp.com
Web Site: http://www.theprogrp.com

SENSOR
PLUG
→

SENSOR
TIP
→



←
SENSOR
TAB

Order #: 6330 Item: Pathway Vaginal
EMG/Stimulation Sensor

CAUTION:

(USA) Federal Law restricts this device to sale by or on the order of a physician or licensed healthcare practitioner. **This sensor is restricted for use to a single person only.** Use by another person is strictly prohibited by Federal Regulations. If irritation or discomfort develops discontinue use and notify your physician or healthcare practitioner immediately. This sensor is sold in a sealed package; if seal is broken do not accept or use the sensor.

Read these instructions before using

This *single-user* perineometer sensor is designed to provide accurate detection and biofeedback of the electromyographic (EMG) activity OR the neuromuscular stimulation of the pelvic musculature for the purpose of rehabilitation of weak pelvic muscles and/or restoration of neuromuscular control. This sensor should be utilized with FDA registered EMG devices and compatible stimulators only and FDA regulations require that a physician or licensed healthcare practitioner provide ongoing supervision of this Class II device.

Cleaning

This sensor should be **cleaned before the first use and immediately after each subsequent use.** Wash and lather your hands with soap and flowing luke-warm water in the sink, then apply the same lather to the sensor and wash it thoroughly. Completely rinse hands and sensor of all soap residue and then wipe the sensor dry with a clean cloth or paper towel. **Allow the sensor to air-dry and when you are sure it is completely dry, store the sensor in the original bag.** Do not use abrasive cleaners on the sensor. Do not expose the sensor to high temperatures. Do not submerge or use sensor in water. Do not get sensor plug or cable wet. Do not attempt to sterilize the sensor by any method.

Note

- 1) Never wrap the sensor cable around the unit or the sensor. This could damage the sensor and void your warranty.
- 2) It is suggested that when the sensor is not in use, it should be disconnected from the unit.
- 3) After use, once the sensor is ensured to be completely dry; lightly coil sensor cable and place sensor in original plastic bag for storage between uses. Store sensor in cool dry place.
- 4) Please retain this insert as proof of warranty.

Indications and Contraindications

Indications For Use

- * **Urinary Incontinence :**
 Stress, Urge and Mixed Incontinence
- * **Neuromuscular Reeducation**
- * **Fecal Incontinence (EMG use only)**

Contraindications for Use

- * **Active Infection**
- * **Severe Pelvic Pain**
- * **Pregnancy**
- * **Postpartum or Post Surgical (6 weeks)**
- * **Atrophic Vaginitis**
- * **Dyspareunia**
- * **Menstrual Period**
- * **Pacemaker**

Directions for Use

1. Clean the sensor as described in the *Cleaning* section.
2. If necessary, empty your bladder and bowels before your training session to avoid later interruption.
3. If required for ease of insertion, lubricate the tip of the sensor lightly. Place a 1/2 inch dab of lubricant on a paper towel and touch the tip of the sensor to the lubricant. Do not use too much lubricant as this may coat the sensing surfaces and cause inaccurate measurements or cause the sensor to unseat itself upon contraction. Use a water-soluble lubricant such as K-Y® jelly which is available at any pharmacy. Avoid petroleum-based lubricants such as Vaseline®.

4. Use the tab located at the base of the sensor to orient and guide the insertion and removal process. Grasp the tab with your thumb and forefinger and insert the sensor until the tab and sensor rim come in contact with the body (the sensor is now fully inserted). The tab and rim of the sensor act as a stop and insure proper insertion depth. The tab should be pointing towards the pubis (the front of the body).

5. Connect the sensor plug to the input of the EMG or stimulator device. Be sure the stimulation level of the unit to be used is turned OFF. The sensor is compatible with any high-impedance input surface EMG device and plugs directly into any device which has a 6 pin mini din connector input. Adapters are available for devices with other input connectors. If you require an adapter, call The Prometheus Group with the manufacturer and model of the device used. When used for stimulation, the sensor is compatible with the Hollister InCare stimulator, the Empi

stimulator, the Utah Medical Liberty stimulator, the BMR Neurotech stimulator, the Femex stimulator, and the Pathway CTS 2000 and STM-10.

6. The sensor is now ready for use.

7. Refer to stimulator manual for recommended stimulation parameters and therapy regimen.

8. When the training session is complete, remove the sensor using the tab. Clean the sensor as described in the **Cleaning** section. After air-drying, store the sensor in a safe, clean, dry place in the bag provided.

9. This sensor is a potential bio-hazard. Dispose in a manner consistent with bio-hazard requirements for your area.

K-Y is a registered trademark of Advanced Care Products,
Vaseline is a registered trademark of Chesebrough-Pond's Inc.

The Prometheus Group 90 Day Limited Product Warranty

The Prometheus Group warrants the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of ***90 days from the date of purchase***. The liability of The Prometheus Group under this limited product warranty will be limited to repair or replacement of the defective product, in The Prometheus Group's sole discretion or refunding your net price paid in the event repairing is impractical and replacing is impossible.

If you believe this product is defective, you should immediately contact your local distributor or The Prometheus Group at **800-442-2325** or write to the address listed. The Prometheus Group will then evaluate this product and determine whether it may be repaired in the field, or should be returned to The Prometheus Group for repair, replacement or refund. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES RESPECTING THIS PRODUCT, WHETHER EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL THE PROMETHEUS GROUP BE LIABLE TO YOU FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Disassembly of the sensors will invalidate this warranty.