ThoughtTech

PRESSURE SENSOR
HARDWARE MANUAL

FOR USE WITH

MYONYX

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Product Name: Pressure Sensor for MyOnyx

REF SA9003

Manual Number/Rev: SA9012 Rev 1 (October 2020)

Labeling Symbols

Refer to the instruction manual.

Caution. Consult accompanying documents

Type BF Applied Parts

Do not dispose with general household waste. Dispose according to local recycling initiatives.

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Product Overview

The pressure sensor is designed for use with the MyOnyx device in the treatment of incontinence. It is intended for use in a medical or physiotherapy clinic.

Specifications

- **Range**: 0-200 mm Hg
- **Resolution**: 0.1 mm Hg
- **Sample Rate**: 2048 samples/sec
- **Pressure**: Auto-set 55 mm Hg
- **Power consumption when pump is operating**: 140 mA @ 5VDC (700 mW)
- **Power consumption when pump is not operating**: 50 mA @ 5VDC (250 mW)

Safety Information

Before using the pressure sensor, ensure that you have read all warnings and precautions in this manual and in the *MyOnyx User Guide*.

Indications for Use

- Biofeedback, relaxation, and muscle re-education
- Relaxation of muscle spasms
- Treatment of stress, urge, or mixed urinary incontinence, acute and ongoing, where the inhibition of the detrusor muscle, through reflexive mechanisms, may improve urinary control.
- Assessing activity of the pelvic floor and accessory muscles such as the abdominal or gluteal muscles in incontinence treatment

- The Pressure Sensor and MyOnyx device are to be used only under medical supervision in adjunctive therapy for the treatment of medical diseases and conditions.

RxOnly **Caution:** US Federal Law restricts this device to sale by or on order of a licensed health-care practitioner.

Patient Population

- Young women with urinary incontinence (UI) and pelvic organ prolapse (POP), sexual dysfunctions, and pelvic pain, the elderly with fecal/urinary incontinence, post-partum women, and males post prostatectomy.

Contraindications

- The device is not designed or intended for diagnostic purposes or life support.
- Do not use on a patient undergoing MRI, electrosurgery, or defibrillation.

Intended Use Environment and Operator Profile

- The device is intended for use under medical supervision in a health-care facility.

Note: It is advisable to continuously monitor the patient's physiological signals while the device is being used. The clinician must have the necessary education to assess and monitor the

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effectiveness of training programs and be able to make necessary adjustments.

Warnings and Precautions

Read and follow all the warnings and cautions provided in this section.

Warnings

- Stop using the device immediately if the patient shows any sign of distress or discomfort.

- Do not use the Pressure Sensor in conjunction with electrical stimulation. When using the Pressure Sensor, do not touch it for more than 10 seconds as it may become hot to the touch.

- Do not use the pressure probe for six weeks following childbirth or pelvic surgery as this may interfere with healing.

- The vaginal pressure probe is sold only in sealed packages. Do not accept or use the device if the seal was not intact upon delivery. Contact Technical Support at Thought Technology Ltd. or your local authorized distributor for a replacement.

- It is recommended to use the MyOnyx device and Pressure Sensor on a hard surface such as a desk or a cart.

- Do not attempt to service or modify the device. It has no user-serviceable parts.

- If a device appears damaged, do not use it. Contact Technical Support at Thought Technology Ltd. or your local authorized distributor for a replacement.

- Do not expose the device to extreme environmental conditions. Do not allow contact with water or other liquids.

- Do not use the device in the presence of a flammable anesthetic mixture with air or with Oxygen or Nitrous Oxide.

- Always transport, store, and use the device within the specified temperature and humidity ranges only. Otherwise, it might not meet the performance specifications.

- MyOnyx is isolated from line power (110 or 220 VAC) due to battery operation or use of the Class 2 power adapter. Use only the power adapter/charger provided with the device by Thought Technology.

- Electrical safety codes for healthcare facilities require that computers, printers, and other equipment used with medical devices be electrically isolated from line voltage to UL, CSA or other recognized consensus medical safety standards.

- Ensure that the PC used with the MyOnyx device is placed outside the patient/client environment (more than 10 feet or 3 meters) or that the PC system complies with IEC/EN 60601-1 (medical electrical equipment safety standard).

- Use cables and electrodes provided by Thought Technology only.

- Use of accessories and cables other than those specified or provided by Thought Technology could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

- To diminish the risk of spreading communicable diseases, always use good hygiene practices. In all cases, refer to your facility’s infection control procedure.

- Do not clean the devices with alcohol or abrasive detergents. Follow manufacturer instructions to disinfect the reusable vaginal and rectal probes. Do not sterilize.

- The vaginal, rectal and pressure probes are to be used with the same patient only and cleaned thoroughly with water and mild soap before and after each use.

Precautions

- Read all precautions and instructions carefully before use. Follow operating and maintenance guidelines as described in this document.

- Keep the device out of the reach of children.

- Exercise caution when using the device,

- For patients with suspected or diagnosed heart problems
- For patients with suspected or diagnosed epilepsy
- Where there is a tendency to hemorrhage following acute trauma or fracture
- Following recent surgical procedures, when muscle contraction may disrupt the healing process
- Over the menstruating uterus
- Over areas of the skin which lack normal sensation.

- Before using the pressure probe, it is recommended that a proper evaluation of the patient be performed by a qualified medical practitioner. This would include, if

relevant, a proctologic, urologic, and/or gynecological evaluation. Determining whether to use pressure feedback is left to the discretion of the medical practitioner based upon his or her professional judgment.

- Use pressure biofeedback only after consulting a medical doctor, when patients are:
    - Pregnant, menstruating, or using contraceptives, such as diaphragms, cervical caps, or pessaries
    - Undergoing artificial insemination
    - Experiencing active symptoms of any pelvic disease, such as herpes, a sexually transmitted disease, vaginitis, or yeast infection as it may aggravate symptoms.

- Have inflammation, infection, or dilated veins in the area of the vagina, tumors, prolapsed uterus, or sustained hypertension of the pelvic floor.

- If the patient feels the pressure in the probe is so high that it feels uncomfortable, the patient should pull out the tube connector immediately. This will deflate the probe.

- There are no known adverse effects due to pressure biofeedback for urinary incontinence. If irritation occurs, notify the attending medical practitioner and discontinue its use.

- Avoid using this equipment adjacent to or stacked with other equipment. This could result in improper operation. If such use is

necessary, you must observe all equipment to verify normal operation.

- To avoid the risk of electrical shock, inspect the AC power adapter / charger and AC power cord on a regular basis. If you detect damage or excessive heating, remove from the wall outlet immediately and contact Technical Support at Thought Technology Ltd. or your local authorized distributor for replacement.

- Never position the AC power adapter / charger near combustible materials. Ensure that the charger is always accessible and that it can be easily disconnected from the wall outlet.

- The device may be susceptible to electrostatic discharges (ESD) and radiated radio frequency (RF) fields. Electrostatic discharge is common in conditions of low humidity. Discharge

yourself by touching a grounded bare metal surface before touching the unit.

- Do not operate active sensors within 10 feet (3 meters) of powerful radio interference producing sources such as arc welders, radio thermal treatment equipment, X-ray machines, or any other equipment that produces electrical sparks.

- Bluetooth operation may be interrupted by the presence of interfering devices in the 2.4 GHz ISM band.

- If anomalies are observed on acquired signals, and if you suspect a problem with electromagnetic interference, contact Thought Technology for a technical note on identification and remediation.

Maintenance and Care

- Discard the device following your local waste management legislation and guidelines.

- Discard disposable accessories following your local waste management legislation and guidelines.

- Wipe the hand-held MyOnyx device, pressure sensor and cables with a damp cloth after each use. Do not clean the devices with alcohol or abrasive detergents.

- Clean pressure probes thoroughly with water and mild soap before first use and immediately after each use.

- Never subject the probe to extreme temperatures or abrasive detergents.

Contact the manufacturer for instructions to disinfect the probes. Do not sterilize.

- Wash and lather your hands with soap in flowing lukewarm water and then liberally apply the same lather to the probe. Rinse all soap residue from the probe and your hands.

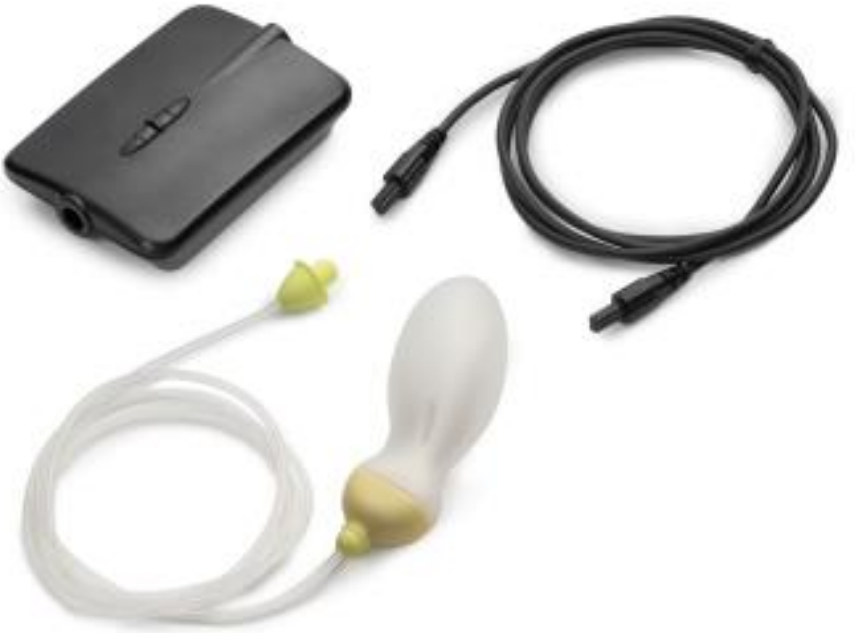
- Dry the probe with a clean cloth or paper towel, allow it to completely air dry and store it in a plastic bag. Store at room temperature.

- The probes are designed for single patient use. Follow manufacturer instructions for determining the useful life of the vaginal and rectal probes. It is recommended to replace the pressure probe after six weeks of regular use.

- When not in use, store the devices in accordance with the recommended

storage environmental conditions. Refer to the Transport and Storage Conditions in the MyOnyx User Guide.

Using the Pressure Sensor



To use the pressure sensor, you must connect it to the MyOnyx device. Then, connect the MyOnyx device, via Bluetooth, to a PC running the BioGraph Infiniti software or a tablet running the MyOnyx Mobile App.

The above diagram shows the pressure sensor with the pressure probe, and the 6-pin cable for connecting it to the MyOnyx device.

Refer to the *MyOnyx User Guide* for details on pairing the device to a PC or tablet and connecting to the software or mobile application.

Note: When in use, the pressure sensor must be placed on a hard surface, such as a desk or a cart, and not touched for longer than 10 seconds as it may become hot to the touch.

Preparing the Patient

1. Clean the probe, as described in the Maintenance and Care section of this manual. See page 15.

2. Instruct the patient to empty her bladder (and bowels, if necessary) before your

biofeedback session in order to avoid later interruption.

3. You may need to lightly lubricate the tip of the probe with a water-soluble lubricant. Do not use a petroleum-based lubricant.

   Place a dab of lubricant on a paper towel and touch the tip of the probe to the lubricant. Usually, you only need to lubricate the tip to facilitate insertion. Using too little lubricant may make insertion difficult. Using too much may impede proper measurement and cause the probe to pop out as soon as the patient contracts her muscles.

4. Instruct the patient to insert the probe gently into her vagina. She can adjust the depth and angle.

Running a Pressure Biofeedback training session

1. Turn on the MyOnyx device.
2. Connect one end of the 6-pin cable to the bottom port of the pressure sensor.
3. Connect the other end of the 6-pin cable to a biofeedback channel: A or B on the MyOnyx.
4. Start a biofeedback session using the MyOnyx Mobile App on a tablet or the BioGraph Infiniti software on a PC.
5. Connect the probe to the top port of the pressure sensor.
6. Press the top button of the pressure sensor once to inflate the probe. The pump stops when pressure reaches the resting state level. This is displayed as 0 on the MyOnyx.

Note: The pressure cannot increase enough for the patient to feel any discomfort or to damage the probe.

If the pressure sensor cannot read the pressure value for a predefined period of time, which is approximately eight seconds, it times out and the inflation pump stops working.

If the patient feels the pressure in the probe is so high that she feels uncomfortable, she should pull out the tube connector immediately. This will deflate the probe.

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7. Adjust the session settings if necessary.

8. At the end of the session, press and hold the lower button on the pressure sensor to

deflate the probe. It continues deflating until you release the button.

9. Instruct the patient to remove the probe.

Troubleshooting

Timeout

If the pressure sensor cannot read the pressure value for a predefined period of time, which is approximately eight seconds, it times out and the inflation pump stops working.

Note: The pressure cannot increase enough for the patient to feel any discomfort or to damage the probe.

Accessories

Refer to *the MyOnyx User Guide* for the list of approved accessories.