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SA9038

Product Name: Rectal Pressure Probe

**Insert Number/
Revision** IS9038 rev 0
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The Rectal Pressure Probe (Product No. SA9038) is designed for the Thought Technology's Pressure Sensor for MyOnyx (Product No. SA9003) and the MyOnyx device (Product No. SA9020). It is not designed for other products.

Intended Purpose

This probe is intended for rectal use only in clinical settings by trained professionals. It is used for biofeedback applications in the assessment and treatment of pelvic floor and anal sphincter muscles, including muscle re-education, relaxation, and neuromuscular control. It may be used either by:

- Inserting into the anal canal (approx. 2–3 cm), or
- Applying externally against the rectal region for pressure measurement.

Specifications



Dimensions

Size: 33*105 mm

Classification

Weight: 35 g

Environmental Conditions

Type BF equipment

Temperature: 5°C – 40°C,

Humidity: 80% or lower

Air pressure: 86 kPa – 106 kPa

Storage Conditions

Temperature: -20°C – 55°C

Humidity: 93% or lower

Air pressure: 70 kPa – 106 kPa

Altitude

2000m or lower

Caution

- RxOnly – US Federal law restricts this device to sale by or on the order of a physician
- Rectal use only – internal and external applications
- Single User Only
- Do not sterilize
- Do not use this device in conjunction with electrical stimulators
- If irritation or discomfort persists, discontinue use and notify your doctor or health care professional immediately.

Medical Precautions and Contraindications

Before using the pressure probe, a qualified medical practitioner should evaluate the patient. Use only after consulting a medical doctor when patients are:

- Pregnant
- Experiencing symptoms of rectal disease such as infection, hemorrhoids, or bleeding
- Have had recent rectal surgery (less than 6 weeks)

- Have suspected or known rectal malignancy or trauma

Contraindications:

- Severe anal stenosis
- Active infection or inflammation in the rectal area

Warnings / Precautions

- Do not use the Rectal Pressure probe for six weeks following childbirth or pelvic surgery as this may interfere with healing.
- To diminish the risk of spreading communicable diseases, always use good hygiene practices. In all cases, refer to your facility's infection control procedure.
- If the patient feels the pressure in the probe is so high that they feel uncomfortable, they should pull out the tube connector immediately. This will deflate the probe.

Adverse Reactions

There are no known adverse effects in using pressure biofeedback. If irritation persists, discontinue use and notify your clinician immediately.

Maintenance and Care Instructions

Clean the Rectal Pressure probe before using it for the first time and immediately after every use. Wash and lather your hands with soap in flowing lukewarm water and then liberally apply the same lather to the sensor. Rinse all soap residue from the sensor and your hands. Dry the pressure probe with a clean cloth or paper towel, allow it to completely air dry and store it in a plastic bag. Never subject the probe to extreme temperatures or abrasive detergents. Do not boil or autoclave the probe. Store at room temperature. Handle and dispose of the probe in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

Instructions for Use**A. Internal Rectal Use:**

1. Ask the patient to empty their bowels if needed.
2. Lubricate the tip lightly with water-soluble gel.
3. Gently insert the probe approximately 2–3 cm into the rectum, ensuring the inflatable section rests at the anal sphincter.
4. Inflate the probe to no more than 50 mmHg.
5. Begin the biofeedback session as described in the connected pressure sensor manual.

B. External Perianal Use:

1. Ask the patient to lie in a comfortable position.
2. Using a gloved hand, press the probe gently but firmly against the anal area.
3. Inflate the probe to the recommended pressure.
4. Proceed with pressure recording as the patient engages pelvic floor muscles.

Notes: Do not disassemble the Rectal Pressure probe as this will invalidate this warranty.

Do not alter or modify any cables or connectors. Doing so could affect the product safety and will invalidate the warranty.

The pressure probe is designed for single patient use. It is recommended to replace it after six weeks of regular use.

Important: This product is sold only in sealed packages. Do not accept or use the device if the seal was not intact upon delivery. Additional pressure probes are available from Thought Technology Ltd. by calling (514) 489-8251.

Thought Technology 90 Day Limited Product Warranty

Thought Technology Ltd. warrants to you, 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 your date of purchase. The liability of Thought Technology Ltd. under

this limited product warranty will be limited to repair or replacement of the defective product, in Thought Technology's Ltd. sole discretion or refunding your net price paid in the event repairing is impractical and replacing is impossible.

If you believe this product is so defective, you should immediately contact your local Thought Technology Ltd. sales representative. If you do not know who that representative is, please call Thought Technology's Customer Service Department at (514) 489-8251 or (800) 361-3651 (inside North America). Thought Technology will determine whether it may be repaired in the field, or if it should be returned to Thought Technology for repair, replacement, or refund. Wear and tear from normal use or defects resulting from misuse of this product is not covered by this limited warranty.

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