


DYSPHAGIA THERAPY STIM UNIT

MODEL: 9950



USER MANUAL

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FORWARD

Thank you for your purchase from eSwallow!

The eSwallow Dysphagia Treatment Device is a prescription device intended for use by or on the order of a physician or other licensed professional, certified in eSwallow or NMES Dysphagia Therapy.

This equipment is to be used only by a licensed practitioner certified in the use of the eSwallow Dysphagia Therapy System. Federal Law restricts this device to be used by a physician or licensed practitioner.

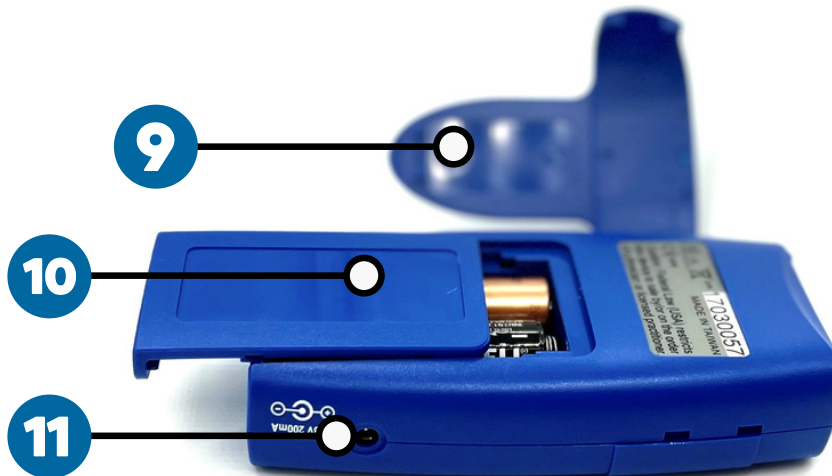
The eSwallow Dysphagia Unit is to be used in accordance with the eSwallow Dysphagia Therapy's approved procedures. Any other use may result in death, injury, or undesirable results.

For best results, it is recommended that eSwallow electrodes and accessories be used with the eSwallow Dysphagia Therapy Unit. Use of other accessories and or techniques not approved under the eSwallow certification training may result in death, injury, or adverse effects to patient or undesirable results.

FEATURES

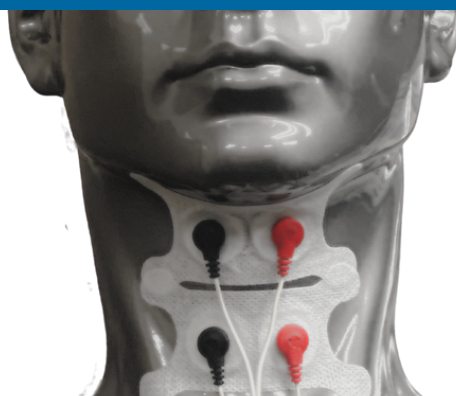


- 1** Channel 1: leadwire port
- 2** Channel 2: leadwire port
- 3** Therapy session timer indicator
- 4** Channel 1: amplitude indicator
- 5** Channel 2: amplitude indicator
- 6** Channel 1: Intensity adjuster (by 0.5 milliamp)
- 7** Channel 2: Intensity adjuster (by 0.5 milliamp)
- 8** Power on/off button
- 9** Belt clip
- 10** Battery door: requires two AA batteries
- 11** External power input



PREPARATION

- 1** Install two AA batteries in the backside compartment.
- 2** Prior to turning the device “ON,” carefully connect one lead wire set to each lead wire port on the unit.
- 3** Attach electrodes to leadwires and place the electrodes on the patient as indicated in the eSwallow training manual or approved NMES protocol.
- 4** Turn on the eSwallow stimulation unit by depressing the power button.
- 5** Set the program sequence and power level for each channel as described in the eSwallow training manual.
- 6** The “amplitude” safety feature will automatically engage after approximately 30 seconds with no user input. To disable “amplitude lock,” press the “down” arrow on either channel. The amplitude may now be adjusted as desired.



SPECIFICATIONS

- Adapter Input: 120 VAC, 60 Hz, 2W; Output: 3V DC, 200mA
- Channels: Dual, isolated between channels
- Output Waveform: symmetric waveform
- Intensity Control: 0~25mA/0~4000 ohms. Each push increases or decreases power on channels by 0.5mA. Tolerance $\pm 20\%$
- Pulse Rate: Fixed 80Hz. Tolerance $\pm 10\%$
- Pulse Width: Fixed 300 μ s. Tolerance $\pm 10\%$
- Low Batter: A battery symbol will show on LCD display while supply voltage is under 1.8 volts.
- Timer: Tolerance $\pm 10\%$
 - Session: 60 minutes
 - Countdown by 1 minute
 - Beep 4 times when count down to 30 minutes. Beep 8 times when countdown to 0 minutes then the unit will turn off automatically.
- Rest Period: Each 60 seconds of operation, the unit will reduce power down to zero for a period of half a second. The power ramps down to zero and back up to the present power over a total time of 5 seconds.
- Lock-on Design: The unit will lock on increasing intensity on either channel after 30 seconds of no adjustment, users have to decrease intensity first then increase intensity will be active. When Lock-On is active, there will be symbol shown on LCD display.

DEVICE HANDLING PRECATIONS

- Device to be cleaned with soap and water, only.
- Use only fingers to operate button controls on control panel. Use of tools or other objects such as pens will result in damage to the unit.
- DO NOT connect the eSwallow Dysphagia Therapy Unit to any other equipment.
- Care must be taken when operating this equipment in close proximity with other electrical equipment. Potential electromagnetic or other interference could occur to this or the other equipment. Minimize this interference by not using other equipment with it.
- The eSwallow Dysphagia Unit should NOT be used while driving, operating machinery or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.
- Men's necks should be clean shaven prior to use of this device.
- Turn unit OFF before positioning electrodes on a patient, removing electrodes from a patient, or replacing batteries.

DEVICE HANDLING PRECATIONS

cont.

BATTERY

- When the low-battery indicator appears on the LCD panel, replace the battery in the device's backside compartment.
- Dispose of all used accessories and spent batteries according to local, state, and federal codes and regulations.

STORAGE

- To properly store the device for an extended period of time, remove the batteries from the unit. Put the unit and accessories in the carrying case and store in a cool, dry location.
- Keep unit secured from unauthorized users, including children.

PATIENT USE WARNINGS

- Safe use of electrotherapy during pregnancy has not been established.
- The long-term effects of chronic electrical stimulation are unknown.
- Caution should be used for patients with suspected or diagnosed heart problems.
- Caution should be used for patients with suspected or diagnosed epilepsy.
- Caution should be used in the presence of a tendency to hemorrhage following acute trauma or fracture, following recent surgical procedures when muscle contraction may disrupt the healing process and over areas of skin which lack normal sensation.
- This device should be used with caution on patients with cardiac demand pacemakers.
- Use of this device is contraindicated in patients who are severely demented and exhibit non-stop verbalization. Constant verbalization could result in aspiration during trials of oral intake.
- Use of this device is contraindicated in patients with dysphagia due to drug toxicity. Patients suffering from drug toxicity could aspirate during trials of oral intake.
- Use of this device is contraindicated for treating dysphagia for etiologies of mechanical causes requiring surgery.

PATIENT USE WARNINGS cont.

- Some patients may experience skin irritation or hypersensitivity due to electrical stimulation or electrical conductive medium. The irritation can usually be reduced using an alternate conductive medium or electrode placement.
- Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators. Follow the eSwallow Electrode Instruction Card contained within the eSwallow electrode packet for recommended use.
- Stimulation should not be applied over or in proximity to cancerous lesions.
- Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
- Stimulation should not be applied over the carotid sinus nerve as death or serious injury is likely to occur.
- Explosion hazard if used in the presence of flammable anesthetics.
- To ensure the utmost safety and effectiveness, it is crucial to restrict the utilization of eswallow electrodes and stimulation units exclusively to the placements and techniques taught within the eswallow certification course. Engaging in alternative uses can lead to unfavorable outcomes, including ineffective results, potential injury, or even loss of life.

TROUBLESHOOTING

If the unit stops operating during therapy and the display becomes blank, use the “power on” switch to re-start the unit.

If the device does not function properly:

- ✔ Make sure the battery is properly installed. Be sure to observe proper polarity markings when replacing the battery. If the low-battery indicator appears when the unit is turned on, replace the battery and check again.
- ✔ If the intensity has been adjusted and there is no stimulation, check that the lead wires are properly connected to the electrode and the electrodes are properly positioned on the patient. If the unit appears to be functioning and no stimulation occurs, the lead wires or electrodes may need to be replaced.
- ✔ If the battery appears to be charged and the unit is not functioning, turn the unit off and contact eSwallow.

WARRANTY

I. WARNING

While in the opinion of eSwallow, the use of the eSwallow stimulation unit has met with some success in the treatment of dysphagia, eSwallow makes no warranties to the purchaser as to the effectiveness of the product.

II. WARRANTY

eSwallow warrants the eSwallow stimulation unit to be free from defects in workmanship and materials for two years. eSwallow will repair at its facility or replace any product found to be defective. This warranty does not apply to any product damaged by misuse, or repaired or altered by anyone other than eSwallow. This warranty is in lieu of any or all other warranties, expressed or implied. No person is authorized to bind eSwallow to any representation of warranty other than those specifically set forth herein. The warranty period begins with the date of purchase from eSwallow or an authorized reseller for one year. eSwallow shall not be held liable for any accident or injury resulting from the use of non-eSwallow electrodes or accessories.

III. Limitation of Liabilities and Disclaimer of Warranties

A. eSwallow's sole obligation in the case of any breach of its warranties set forth in paragraph I above, shall be, at eSwallow's option, to repair or replace the product with a new or factory reconditioned product without charge to the purchaser or to refund the purchase price of the product. In order to recover under this warranty, the purchaser must contact sales@eswallowusa.com within 30 days of discovery of the defect. Upon eSwallow's request and authorization, the purchaser shall return the product to eSwallow, freight and insurance prepaid for inspection. Notice and return shipment shall be sent to 8080 Graphic Dr NE, Belmont, MI 49306, United States. eSwallow will not be responsible for damage due to improper packaging or shipment. If eSwallow determines in its sole reasonable discretion that the product does not contain defective workmanship or materials, eSwallow will return the product to the purchaser, freight and insurance billed to the purchaser.

B. This warranty is voided immediately as to any product which has been repaired or modified by any person other than authorized employees or agents of eSwallow or which has been subjected to misuse, abuse, neglect, damage in transit, accident, or negligence.

C. Except as provided in paragraph II, the product is being sold on an "as is" basis, all accessories are sold "as is," and the entire risk as to the quality and performance of the product is with purchaser. The warranty provided in paragraph II is intended solely for the benefit of the initial purchaser and eSwallow disclaims all other warranties, expressed or implied, including, but not limited to, an implied warranty of merchantability and fitness for a particular purpose: provided, however, that notwithstanding the foregoing sentence. In the event an implied warranty is determined to exist, the period for performance shall be limited to the lifetime of the initial purchaser, no employee, representative or agent of eSwallow has any authority to bind eSwallow to any affirmation, representation or warranty except as stated in this written warranty policy. This warranty gives the purchaser specific legal rights and the purchaser may also have other rights which vary from state to state. Some states do not allow limitation of how an implied warranty lasts, so the above limitation may not apply to the purchaser.

D. eSwallow shall not be liable to any person for any direct, indirect, special, incidental, or consequential damages, lost profits or medical expenses caused by any defect, failure, malfunction or otherwise of the product, regardless of the form in which any legal or equitable action may be brought against eSwallow (e.g. contract, negligence, or otherwise) the remedy provided in paragraph II above shall constitute the purchaser's sole remedy. In no event shall eSwallow's liability under any cause of action relating to the product exceed the purchase price of the product. This warranty gives the purchaser specific legal rights and the purchaser may also have other rights which vary from state to state. Some states do not allow limitations of how an implied warranty lasts, so the above limitation may not apply to the purchaser.

THE ESWALLOW PROMISE

We stand behind all products we sell 100%

If you ever have a problem, we will send a replacement immediately. Should you need anything at all- contact us!

When the eSwallow stimulation unit requires service, contact eSwallow. All units returned for service must be accompanied by a written statement containing the following information: unit serial number, contact person with phone and email, billing address, shipping address, detailed description of problem.

CONTACT US!



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