



VITALSTIM[®]
THERAPY

for the treatment
of dysphagia

What is dysphagia?

Dysphagia, or difficulty in swallowing, is prevalent among the elderly, affecting as many as 20-40% of persons between 50-80 years of age. As many as 50% of stroke patients develop some degree of dysphagia. Symptoms can include coughing during or after swallowing, choking on food or liquid, the sensation of food getting stuck in the throat, pain during swallowing and shortness of breath while eating.

Dysphagia occurs when there is a problem with the swallowing process anywhere from the mouth to the stomach. It commonly occurs following stroke, radiation therapy for head and neck cancer, traumatic head or spinal cord injury, tracheotomy, burns and meningitis. It is also common in people with congenital or degenerative neurological diseases, such as Parkinson's disease, Multiple Sclerosis, Cerebral Palsy and Chronic Obstructive Pulmonary Disease.

What are the complications from dysphagia?

Dysphagia can have devastating complications such as aspiration pneumonia, which is caused by food or saliva going down the wind pipe and into the lungs. Aspiration pneumonia is a very serious condition and one of the leading causes of death among the elderly.

Dysphagia can also predispose patients to complications such as choking and bronchospasm as well as chronic malnutrition and life threatening dehydration, muscle wasting, physical debilitation, and asphyxia.

Dysphagia profoundly affects quality of life. Many patients with dysphagia end up with a feeding tube because they are not able to take in any kind of nutrition or fluids on their own. Patients with feeding tubes often experience personal discomfort and a drastic reduction in activity due to the inconvenience and pain. The loss of swallowing can also lead to severe depression due to interruption of patients' normal ways of life.

How is dysphagia diagnosed?

Physicians and speech-language pathologists who diagnose and treat swallowing disorders use a variety of tests that allow them to look at the different parts of the swallowing mechanism.



How is dysphagia successfully treated?

Until recently, dysphagia was treated with conventional speech therapy and oral exercises, thermal therapy, patient education, swallowing maneuvers and physiologic exercises. In many cases, a change of diet and food preparation was recommended to improve safety of swallowing.

A remarkable treatment for dysphagia is available called VitalStim Therapy.

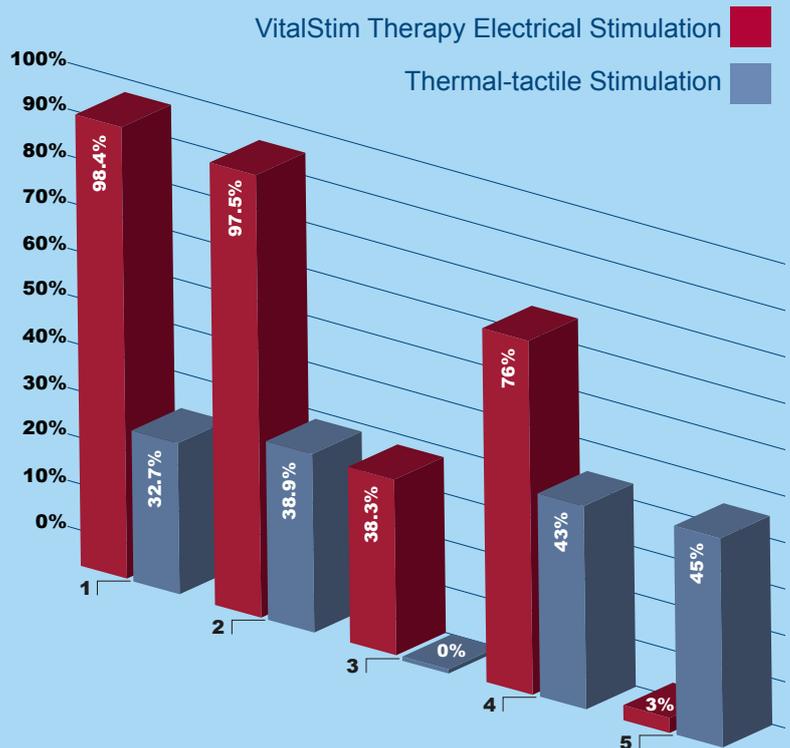
VitalStim Therapy is a specialized form of neuromuscular electrical stimulation (NMES) designed to treat dysphagia through muscle re-education. The small, carefully calibrated current is delivered by specially designed electrodes which are placed on the neck. The current stimulates motor nerves in the throat while the patient practices swallowing exercises that cause the swallowing muscles to contract. With repeated therapy, muscles are re-educated and the quality of the swallowing function improves. NMES has a long and proven track record in many areas of rehabilitation, and has been used for years by physical therapists to treat larger muscles, such as those in the legs, arms and shoulders.



Inside the clinical trial*

(1-5 corresponds to graph)

- 1) % of patients improved their swallow function score
- 2) % of patients with severe dysphagia regained swallow function past the point of PEG tube dependency
- 3) % of patients with severe dysphagia regained full normal swallow function
- 4) % of patients who retained swallow function at 3 year follow-up
- 5) % of patients who reported aspiration at 3-year follow-up



* Results reported based on FDA research submission data. Individual results may vary.

“That moment in 2003 when I tried VitalStim Therapy on myself was the moment I was more excited about swallowing therapy than I had been in 18 years.”¹



The impact of VitalStim Therapy

VitalStim Therapy is being used in rehabilitation hospitals, acute care facilities and freestanding clinics worldwide. In these facilities, it is helping speech-Language pathologists (SLP's) retrain a large percentage of patients to swallow. Successful VitalStim Therapy is getting patients off PEG tubes or thickened liquids and back to the joys of eating. When conventional dysphagia therapy is administered there is very little change over a period of several months. With VitalStim Therapy, results are seen in 10 to 12 sessions. Some patients have been able to leave the hospital eating food and drinking liquids after as little as five VitalStim Therapy sessions. With VitalStim Therapy, SLP's are witness to wonderful quality of life outcomes that would not have been possible otherwise. This has brought about a major change in the manner in which speech-Language pathologists treat swallowing disorders. SLP's now offer patients hope.

The VitalStim Therapy treatment program has been proven to be a safe application of electrical stimulation. To date, an estimated 1.5 million applications by over 7,000 SLP's and physicians have not resulted in any adverse effect.

The cost of the VitalStim Therapy equipment is small compared to the savings it can generate. Cost/benefit analysis reveals that VitalStim Therapy is a cost effective alternative to other forms of dysphagia therapies.

VitalStim Therapy has the potential to significantly impact healthcare costs. Patients who undergo VitalStim Therapy have moved from PEG-tube feeding to successful swallowing in an average of 14 one-hour sessions, thereby significantly reducing annual healthcare costs associated with PEG-tube feeding. Stroke victims especially benefit from VitalStim Therapy. It is usual for these patients to return to near normal or normal swallowing function before they progress to the point where they need a feeding tube. The cost expenditure of a stroke victim suffering with dysphagia may be increased by as much as \$20,000 annually. (According to Medicare Standard Analytic Results.)



How does a clinician get certified to perform VitalStim Therapy?

A good knowledge base of dysphagia, head and neck physiology, and VitalStim protocol is key to obtaining successful treatment outcomes with VitalStim Therapy. Because the education component is such an important factor, flexible learning opportunities are available through either a two day onsite training and certification course or through electronic courses on CD concluding with an on-line certification exam.

The VitalStim Education Suite and Passport to Certification is a multiple CD set designed to give the physician or SLP all required information to provide VitalStim Therapy to their patients.

1. **Primal Pictures Head and Neck** – 3D interactive anatomical resource of the head and neck.
2. **Anatomy and Physiology of the Head and Neck** – focuses specifically on the swallowing mechanism.
3. **MBS: The Clear Picture** – concentration on basic observational skills for the modified barium swallow study (MBSS).
4. **About Dysphagia** – compilation of documents that provide a greater understanding of this disorder.
5. **VitalStim Therapy** – background information on the use of neuromuscular electrical stimulation and video presentation of electrode placement and device usage.

Once proficient with the information found on the CD's, the clinician is ready to be certified. VitalStim certification is obtained via successful completion of the on-line examination. Certification allows the therapists to provide safe and effective treatments to their dysphagic patients.



The intelligence of VitalStim Therapy....housed in a clinical device aptly named Intelect

Intelect VitalStim by Chattanooga Group provides seven specific parameter sets to meet the needs of the physicians and SLP's who treat dysphagia. Each contains both a graphical and text explanation of the different electrode placements along with detailed descriptions about the VitalStim waveform. The device enables the clinician to edit certain parameters such as treatment time, intensity and phase duration to match the treatment needs of their dysphagic patients. With four channels of stimulation on board, the clinician can simultaneously provide therapy to both sides of the face and the anterior portion of the neck. Even difficult conditions such as scar tissue, patient frailty, and fatigue are now more easily treatable with Intelect VitalStim.

Intelect VitalStim helps the patient and therapist work together to achieve the best possible treatment outcomes. The educational diagrams found in the device increase the patient and caregiver's understanding of dysphagia and the goals of the therapy. Building on this understanding, the patient is actually able to interact with the device's on-screen visual, auditory and sensory biofeedback during the treatment session. This exchange helps improve patient motivation, patient compliance, and patient performance. By working harder to reach their swallowing goal, the patient is "rewarded" with feedback and an increase in performance.

Likewise, the therapist benefits from the on-screen clinical resource library which provides information about anatomy and pathology and illustrates specific electrode placement as well as swallowing anatomy. The therapist can further use these screens as teaching tools to the patient as well, engaging them in their treatment protocol.

Intelect VitalStim's Patient Data Cards display useful information about previous treatment sessions such as: the number of successful swallows, average amplitude level, exact electrode placement and other patient specific functional data. Using this data, the therapist can provide a better continuity of therapy by "picking up where they left off."

The device records and reports information back to the therapist in a meaningful, objective, and industry accepted format. Evidenced-based tracking tools such as FOIS, weight, and VAS pain rating are utilized. Because proper documentation is necessary for the facility's regulatory compliance, the Intelect VitalStim device prompts the clinician to input all relevant data.



Ordering Information

Intelect® VitalStim® Features

- 4 Channel Neuromuscular Electrical Stimulation (NMES) device
- Clinical electrotherapy with integrated therapy cart
 - Generous amount of storage for supplies with pull out bins
 - Manage cords and lead wires with easily accessible, yet attractively hidden connections
- Surface Electromyography (sEMG) - reading and recording muscle activation
 - Visual and auditory biofeedback during swallowing for objective measurement of effortful swallows
 - Assists with muscle relaxation training
 - Determines the activation timing of muscles for re-education
- Surface Electromyography with Triggered stimulation (sEMG + Stim) - electrical muscle stimulation triggered when the muscle activation reaches a preset target
 - Provides biofeedback coupled with NMES treatment during swallowing therapy
 - Electrical stimulation to the target muscle group is activated by the patient's effort, creating a powerful reward-based biofeedback loop
- Clinical Resource Library - impressive full color graphical library of head and neck anatomy and pathologies
 - Facial muscles and nerves
 - Vocal cords, larynx, esophagus
 - Oral cavity
 - Neurology
 - Surgical techniques
- Patient Data Cards - record treatment session information on individual patient cards:
 - Successful swallows
 - Average amplitude level
 - Exact electrode placement
 - Patient specific functional data such as FOIS swallowing level, pain scale, and patient weight.



VitalStim Electrodes Bulk Pack



VitalStim Electrodes Single Use Kit



Operator Remotes



Lead Wires

5951 - Intelect VitalStim

Standard Accessories

- 2775 - Therapy Cart
- 1264 - Nylatex Wrap (2x)
- 27469 - Patient Interrupt Switch Ch 1/2
- 27470 - Patient Interrupt Switch Ch 3/4
- 27465 - Patient Data Cards (5x)
- 59050 - Lead Wire Ch 1
- 59054 - Lead Wire Ch 2
- 59055 - Lead Wire Ch 3
- 59056 - Lead Wire Ch 4
- 27508 - Operator Remote Ch 1/2
- 27079 - Operator Remote Ch 3/4
- 42061 - DuraStick II - 3 cm Round Electrode (4x)
- 59057 - EMG Lead Wire Ch 1
- 59058 - EMG Lead Wire Ch 2
- 59044 - Vital Stim Electrodes (100 Bulk Pack)
- 59085 - User Manual on CD

Optional Accessories

- 5921 - VitalStim Education Suite
- 59000 - VitalStim Electrodes Adult (12x Single Use Kits)
- 59005 - VitalStim Electrodes Pediatric (12x Single Use Kits)
- 59042 - VitalStim Electrodes Adult (30 Bulk Pack)
- 59043 - VitalStim Electrodes Adult (50 Bulk Pack)

VITALSTIM[®] THERAPY



ISO 13485 Certified

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