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*Together in Motion™*



## VitalStim Therapy | 2013



## INTRODUCTION



Chattanooga is the world's largest manufacturer of rehabilitation equipment for treating musculoskeletal, neurological and soft tissue disorders. For over six decades, Chattanooga has set a benchmark for leadership, reliability and excellence. Our products contribute to better treatment outcomes in hospitals, clinics and home settings worldwide. We lead the physiotherapy industry by example and, through continuous innovation, provide real world solutions for clinicians and their patients.

As the world's leading brand in rehabilitation, Chattanooga is sold in over 80 countries worldwide. Chattanooga is directly represented in our key markets but also has long lasting relationships with dedicated distributors in the USA, Canada, Latin America, EMEA and Asia Pacific. Our Chattanooga distributors and customers are supported for order placement, training, product delivery and after sales service by a dedicated team of highly skilled DJO employees based all over the world.

Chattanooga is a brand of DJO Incorporated. DJO is a leading global developer, manufacturer and distributor of high-quality medical devices that provide solutions for musculoskeletal health, vascular health and pain management. The company's brands address the continuum of patient care from injury prevention to rehabilitation after surgery, injury or degenerative disease.



AIRCRAFT

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Empi

PROCARE

## 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 the patients to swallow. Successful VitalStim Therapy is getting patients off PEG tubes or thickened liquids and back to the joys of eating. Some patients have been able to leave the hospital eating food and drinking liquids after as little as five VitalStim therapy sessions.



## VITALSTIM THERAPY - FREQUENTLY ASKED QUESTIONS



### 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.

### How does a clinician get certified to perform VitalStim Therapy?

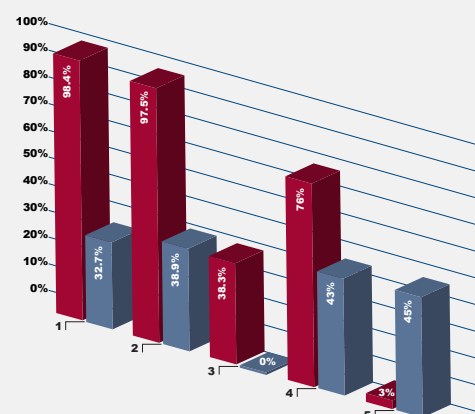
A good knowledge base of dysphagia, head and neck physiology, and VitalStim protocol is key to obtaining successful treatment outcomes with VitalStim Therapy.

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.

### 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



## ORDERING INFORMATION

| Part Number                 | Description                                      |
|-----------------------------|--|
| 5951                        | Intellect VitalStim Therapy System               |
| <b>Standard Accessories</b> |  |
| 1264                        | Nylatex Wrap (3x)                                |
| 27469                       | Patient Interrupt Switch Ch 1/2                  |
| 27465                       | Patient Data Card (1x)                           |
| 59050                       | Lead Wire Ch 1                                   |
| 59054                       | Lead Wire Ch 2                                   |
| 27508                       | Operator Remote Ch 1/2                           |
| 59000                       | VitalStim Electrodes Large (12x Single Use Kits) |
| 59085                       | User Manual on CD                                |
| <b>Optional Accessories</b> |  |
| 2775                        | Therapy Cart                                     |
| 5921                        | VitalStim Education Suite                        |
| 27470                       | Patient Interrupt Switch Ch 3/4                  |
| 59055                       | Lead Wire Ch 3                                   |
| 59056                       | Lead Wire Ch 4                                   |
| 27079                       | Operator Remote Ch 3/4                           |
| 2771                        | EMG Module                                       |
| 59057                       | EMG Lead Wire Ch 1                               |
| 59058                       | EMG Lead Wire Ch 2                               |
| 59101                       | STIM Module (Channel 3 & 4)                      |
| 27167                       | EMG Card   |
| 59000                       | VitalStim Electrodes Large (12x Single Use Kits) |
| 59005                       | VitalStim Electrodes Small (12x Single Use Kits) |
| 59042                       | VitalStim Electrodes Large (30 Bulk Pack)        |
| 59043                       | VitalStim Electrodes Large (50 Bulk Pack)        |
| 59044                       | Vital Stim Electrodes (100 Bulk Pack)            |

## INTELECT® VITALSTIM®



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

Intellect 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 Intellect VitalStim.

Intellect 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.

Intellect 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 Intellect VitalStim device prompts the clinician to input all relevant data.



## FEATURES

- **2 Channel Neuromuscular Electrical Stimulation (NMES) device**
- **Optional 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
- **Optional 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



## TECHNICAL SPECIFICATIONS

|                          |                            |
|--------------------------|----------------------------|
| Mains Power:             | 100-240 VAC, 50-60 Hz      |
| Weight:                  | 3.2 kg                     |
| Dimensions*:             | 33 x 24 x 29 cm            |
| Electrical Safety Class: | Class I, Type BF           |
| Safety Tests:            | IEC 60601-1, IEC 60601-1-2 |

\* Dimensions are listed as L x W x H

## ORDERING INFORMATION

| Part Number | Description                                      |
|-------------|--|
| 59000       | VitalStim Electrodes Large (12x Single Use Kits) |
| 59005       | VitalStim Electrodes Small (12x Single Use Kits) |
| 59042       | VitalStim Electrodes Large (30 Bulk Pack)        |
| 59043       | VitalStim Electrodes Large (50 Bulk Pack)        |
| 59044       | VitalStim Electrodes Large (100 Bulk Pack)       |

## VITALSTIM® ELECTRODES



## HOW IS IT DIFFERENT?

It's more efficient and more reliable than ever before.

Based on feedback from our customers, we have redesigned our electrode to meet the unique demands of dysphagia treatment:

**A challenging therapy requires a different electrode.**

The VitalStim electrode has been custom engineered to deal with the challenging treatment conditions of dysphagia therapy using NMES.

## FEATURES

- Unique construction to safely transmit the high current load and current density of the VitalStim Therapy protocol (which results in a much higher load on the electrode than a typical NMES application in physical medicine and rehabilitation).
- VitalStim electrodes have a low impedance measurement and are specifically designed to deliver one-hour VitalStim Therapy treatment sessions while maintaining high quality performance
- Unique design and material that stretches and molds to the irregular surface of the anterior neck.
- Demonstrated effectiveness in multiple clinical trials.

- Unique material that stretches and moves with the patient without gapping
- Material tears without scissors for quick application
- Constructed to provide reliable conductivity with no internal electrode separation
- Excellent adhesion and gentle removal for delicate skin

The new VitalStim Therapy electrode is easy to use and gives you the confidence that you are delivering electrical current consistently and effectively.





## FEATURES

- Two independent channel stimulation providing the ability to apply 4 electrodes
- Large digital display for better treatment control
- 0,5 mA step for amplitude settings allows for a very precise stimulation level
- Constant current generator for better comfort

The VitalStim Therapy System is an adjunctive modality to traditional exercise that unites the power of electrical stimulation of the motor nerve with the benefits of swallowing exercises. Combined therapy allows you to accelerate strengthening, restore function, and help the brain remap the swallow. Research has demonstrated that combined therapy results in better outcomes than using either one alone.



## ORDERING INFORMATION

| Part Number                               | Description                                      |
|---|--|
| <b>VitalStim Dysphagia Therapy System</b> |  |
| 5900                                      | VitalStim Portable with Large Electrodes         |
| 5905                                      | VitalStim Portable with Small Electrodes         |
| <b>Standard Accessories</b>               |  |
| 59004                                     | VitalStim Unit W/Battery                         |
| 59000                                     | Electrode VitalStim Large 12PK                   |
| 59006                                     | VitalStim Lead Wire Set                          |
| 59007                                     | VitalStim bag                                    |
| 59010                                     | Neoprene Bag                                     |
| 59001                                     | Instruction User Manual                          |
| <b>Optional Accessories</b>               |  |
| 5921                                      | VitalStim Education Suite                        |
| 59000                                     | VitalStim Electrodes Large (12x Single Use Kits) |
| 59005                                     | VitalStim Electrodes Small (12x Single Use Kits) |
| 59042                                     | VitalStim Electrodes Large (30 Bulk Pack)        |
| 59043                                     | VitalStim Electrodes Large (50 Bulk Pack)        |
| 59044                                     | VitalStim Electrodes Large (100 Bulk Pack)       |

## TECHNICAL SPECIFICATIONS

|                       |  |
|-----------------------|--|
| Waveform              | Biphasic pulsed with interphase interval (VMS)   |
| Frequency             | 80 Hz  |
| Phase duration        | 300 microseconds   |
| Duty cycle            | 57 seconds ON, 1 second RAMP DOWN, 1 second OFF, 1 second RAMP UP  |
| Treatment duration    | 60 minutes (per patient tolerance)   |
| Intensity             | Increase to a submaximal motor recruitments level, not to exceed 25 milliamperes   |
| Electrode placements  | One of several possible combinations on the anterior neck and face based on the muscle groups that are targeted  |
| Treatment progression | Skilled dysphagia therapists perform swallowing therapy based on standard exercise therapy criteria with the electrical stimulation running continuously during the entire treatment session |