DJO GLOBAL

AUSTRALIA: T: +1300 66 77 30 F: +1300 66 77 40 E: customerservice.au@DJOglobal.com

CHINA:

SOUTH AFRICA:

UK & IRELAND:

T: (8621) 6031 9989 **F:** (8621) 6031 9709 **E:** information_china@DJOglobal.com

BENELUX

T: Belgium 0800 18 246 T: Netherlands 0800 0229442 T: Luxemburg 8002 27 42 E: benelux.orders@DJOglobal.com

DENMARK, FINLAND

NORWAY & SWEDEN: T: Sweden 040 39 40 00 T: Norway 8006 1052 T: Finland 0800 114 582 T: Denmark +46 40 39 40 00 E: info.nordic@DJOglobal.com

ITALY: T: +39 02 484 63386 F: +39 02 484 09217 E: vendite@DJOglobal.com

SPAIN: T: +34 934 803 202 **F:** +34 934 733 667 **E:** ventas@DJOglobal.com

UNITED STATES: T: +1 800 336 6569

F: +1 800 936 6569 E: customercare@DJOglobal.com

DJO GLOBAL, EXPORT CENTRES

ASIA-PACIFIC: DJO Asia-Pacific Limited Unit 1905, 19/F, Tower II Grand Central Plaza 138 Shatin Rural Committee Road Shatin HONG KONG T: +852 3105 2237 F: +852 3105 1444 E: info.asia@DJOglobal.com

EUROPE, MIDDLE EAST & AFRICA:

DJO Benelux Welvaartstraat 8 2200 Herentals BELGIUM **T:** +32 (0) 14248350 **F:** +32 (0) 14248099 **E:** info.emea@DJOglobal.com

LATIN AMERICA

DJO Global, Inc 1430 Decision Street Vista CA 92081-8553 U.S.A. **T:** 1 800 336 6569 **F:** 1 800 936 6569 **E:** info.latam@DJOglobal.cor



FRANCE:

T: +33 (0)5 59 52 86 90 **F:** +33 (0)5 59 52 86 91 **E:** sce.cial@DJOglobal.com

INDIA: T: +91 44 66915127 E: customercare.india@DJOglobal.com

SWITZERLAND:

F: +41 (0) 21 695 2360 **F:** +41 (0) 21 695 2361 **E:** info@compex.ch



MOTION IS MEDICINE









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 Global Inc. DJO Global provides solutions for musculoskeletal health, vascular health and pain management. Our products help prevent injuries or rehabilitate after surgery, injury or from degenerative disease, enabling patients to regain or maintain their natural motion.

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VitalStim Therapy







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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, and Cerebral Palsy.

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. However, management strategies aiming to limit the risk for aspiration perpetuate and often reinforce the underlying impairments. The more the patient compensates, the less he moves normally. Treatment interventions that produce exercise and facilitation will address the 'weakness' and have the potential to break the vicious circle and to restore functional 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. Stimulation can also be applied at the sensory level, promoting cortical reorganisation. 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.

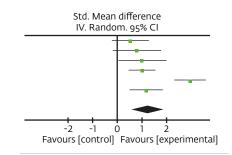
How does a clinician get qualified to perform VitalStim Therapy?

A good knowledge base of dysphagia, head and neck physiology, and electrode placement is key to obtaining successful treatment outcomes with VitalStim Therapy. Because the education component is such an important factor, therapists are educated in multiple aspects of VitalStim therapy through a two-day on site training course complemented with online learning modules.

Scientific evidence – NMES in Stroke

The effects of surface neuromuscular electrical stimulation on post-stroke dysphagia: a systemic review and meta-analysis. Chen et al. Clin Rehabil. 2016 Jan;30(1):24-35.

- 8 randomised controlled trials, 329 stroke patients
- 5 studies compared traditional swallow therapy with concurrent NMES versus traditional therapy alone
- 3 compared NMES alone versus traditional swallow therapy alone
- Results of the meta-analysis: traditional swallow therapy + NMES was more effective than traditional swallow therapy alone.
- Key message: adding NMES to traditional swallow therapy significantly increases the effectiveness of the treatment.



Forest plot comparison of the effectiveness between swallow treatment with NMES and swallow treatment without NMES.

Ordering Information

| Part Number | Description |
|-------------|-------------|
|-------------|-------------|

Intelect VitalStim Therapy

5951 Intelect VitalStim Therapy System

Standard Accessories

| 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 |

Optional Accessories

| 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 |
| 12-6030 | 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 Intelect

Intelect VitalStim 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.

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.

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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

| ordering mornation | | |
|--------------------|---------------------------------------|--|
| Part Number | Description | |
| | | |
| VitalStim Plus | | |
| 5923-3 | Vitalstim Plus Electrotherapy System | |
| | | |
| Standard Accessor | ies | |
| 25-8080 | Vitalstim Plus Snap Lead Wires | |
| 13-8083 | Vitalstim Plus Reference Emg Lead Wir | |
| 13-8085 | Vitalstim Plus Hand Switch | |
| 13-8088 | Vitalstim Plus Stand | |
| 13-8089 | Vitalstim Plus Stylus | |
| 13-8090 | Vitalstim Plus Rubber Sleeve | |
| | | |
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Optional Accessories

| 13-8082 | Vitalstim Plus Reference Emg Electrode |
|---------|--|
| 59000 | Vitalstim Adult Electrodes, 12 Pack |
| 59042 | Vitalstim Adult Electrodes, 30 Pack |
| 59043 | Vitalstim Adult Electrodes, 50 Pack |
| 59044 | Vitalstim Adult Electrodes, 100 Pack |
| 13-8075 | VitalStim Plus Battery Door |
| | |

VitalStim[®] Plus





VitalStim Plus neuromuscular electrical stimulation helps recruit and re-educate muscles in the process of swallowing. Under the guidance of a clinician, patients partner in an interactive therapy that aids muscle strengthening to rehabilitate swallowing. Preset or customized programs allow the provider to truly customize treatments while biofeedback and visuals create a patient focused experience that encourages engagement and achievement of goals.

The VitalStim Plus Electrotherapy and sEMG Biofeedback System projects live treatment progress onto a computer or tablet screen. The Screen Mirroring technology allows clinicians to guide patients through personalized, targeted swallowing exercises. sEMG biofeedback helps to increase effort and duration of swallowing attempts and to improve coordination. It also offers the potential for objective evaluation of swallowing function and patterns.

Waveforms



- VitalStim is a symmetrical square biphasic waveform with a 300 µs phase duration and a 100 µs interphase interval pulse for use on the swallowing musculature in the anterior portion of the neck.
- VMS is a symmetrical biphasic waveform with a 100 µsec interphase interval.
 Because the pulse is relatively short, the waveform has a low skin load, making it suitable for applications requiring high intensities, such as in muscle strengthening protocols.
- sEMG reads and records the sEMG biofeedback activity of a muscle or muscle group by sensing the electrical impulses generated during a voluntary muscle contraction and relax cycle.

VitalStim Treatment

The VitalStim waveform is delivered in Co-Contraction Mode. Up to four separate channels deliver stimulation concurrently and pause at the same time.

VMS Treatment

Customize your treatment protocol by adjusting the parameters of your choice, such as Phase Duration, Frequency, and Work and Rest Time. VMS treatment offers even more flexibility by allowing you to sequence the stimulation in the various channels to more closely match the natural swallowing sequence.



sEMG Treatment

Electrical signals in the muscle are measured and displayed on a screen and are amplified into sounds that the patient can hear. This feedback increases patient effort and participation, and provides the data and documentation required to measure patient outcomes and quantify progress.

sEMG + Triggered Stim

The patient initiates the swallowing exercise with the assistance of sEMG biofeedback. When the set threshold is reached, VitalStim Plus will switch to stimulation mode to increase the effort and exercise load.

Education Videos

VitalStim Plus includes videos that help demonstrate key therapeutic exercises, such as the Masako Exercise, the Mendelsohn Maneuver, the Supraglottic Maneuver, and images that show the various Electrode Placements Options.

Anatomical Library

VitalStim Plus includes a Dysphagia image library of Anatomy, Pathology and Therapeutic Treatment options to assist in educating your patient.

Bluetooth Technology

Screen mirroring technology projects your live treatment onto a computer or tablet screen. This allows you to guide therapeutic exercise activities and increase patient engagement.

VitalStim Plus Share Software

VitalStim Plus Share Software is included in the device kit, allowing the therapist real-time mirroring of the VitalStim Plus display on a Windows driven computer screen for better visibility and patient comfort.

VitalStim Plus Software

VitalStim Plus Software is included in the device kit. The advanced EMG biofeedback software includes patient database, session reports, graph analysis and biofeedback games.

| Technical Specifications | | |
|------------------------------|---------------------------------------|--|
| Dimensions | W= 96 mm D = 36 mm H = 160 mm | |
| Weight | 0.34 kg | |
| Input | 6V (4x1.5V AA) | |
| Maximum voltage (patient) | 70V (+0/-5V) | |
| Mode | Continuous | |
| Product characteristi | CS | |
| Temperature | 5º to 40º C | |
| Relative humidity | 15% to 95% | |
| Atmospheric pressure | 700hPa to 1060hPa | |
| Transport and storag | e conditions | |
| Temperature | -25ºC to 70ºC | |
| Relative humidity | max 90% | |
| Atmospheric pressure | 700hPa to 1060hPa | |
| 4-channel NMES | | |
| VMS™ Symmetrical b | iphasic | |
| Intensity | o-25 mA (Constant Current) | |
| Channel Mode | Continuous, Reciprocal, Co-Contract | |
| Phase Duration | 60-300 µsec (10 % accuracy) | |
| Frequency | 1-80 pps (5 % accuracy) | |
| Treatment Time | 1-240 min | |
| Interphase interval | 100 µѕес | |
| VitalStim™ | | |
| Intensity | o-25 mA (Constant Current) | |
| Channel Mode | Co-Contract | |
| Phase Duration | 300 µsec (10 % accuracy) | |
| Frequency | 80 pps (5 % accuracy) | |
| Treatment Time | 60 min | |
| Interphase interval | 100 µsec | |
| 2-channel EMG | | |
| sEMG | | |
| sEMG Range | 0.2 to 2000 μV RMS (continuous) | |
| Sensitivity | 0.1 μV RMS | |
| Accuracy | 6% of μV reading +/- 0.3 μV | |

Ordering Information

| Part Number | Description |
|-------------|-------------|
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| | |

VitalStim Dysphagia Therapy System

| 5900 | VitalStim Portable with Large Electrodes |
|------|--|
| 5905 | VitalStim Portable with Small Electrodes |

Standard Accessories

| 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 |

Optional Accessories

| 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 electrica stimulation running continuously during the entire treatment session |

VitalStim®





Features

- Two independant 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.

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VitalStim[®] Electrodes

Chattanooga



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.

| Part Number | Description |
|-------------|-------------|
| Part Number | Description |

| VitalStim Electrodes | | |
|----------------------|---|--|
| 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) | |

| 9 VitalStim Therapy | | |
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