chattanooga™

VitalStim® Plus

Four Channel Electrotherapy System User Manual

Operator and Installation Instructions

Rx only

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FOREWORD

This manual is intended for users of VitalStim® Plus Electrotherapy System. It contains general information on operation, precautionary practices, and maintenance. In order to maximize use, efficiency, and the life of the system, please read this manual thoroughly and become familiar with the controls, as well as the accessories before operating the system.

Specifications put forth in this manual were in effect at the time of publication. However, owing to DJO's policy of continual improvement, changes to these specifications may be made at any time without notification on the part of DJO.

Before administering any treatment to a patient, the users of this equipment should read, understand and follow the information contained in this manual for each mode of treatment available, as well as the indications, contraindications, warnings and precautions. Consult other resources for additional information regarding the application of electrotherapy.

PRECAUTIONARY INSTRUCTIONS

The precautionary instructions found in this section and throughout this manual are indicated by specific symbols. Understand these symbols and their definitions before operating this equipment. The definitions of these symbols are as follows:

⚠ CAUTION

Text with a "CAUTION" indicator explains possible safety infractions that have potential to cause minor or moderate injury or damage to the equipment.

⚠ WARNING

Text with a "WARNING" indicator explains possible safety infractions that will potentially cause serious injury and equipment damage.

⚠ DANGER

Text with a "DANGER" indicator will explain possible safety infractions that are imminently hazardous situations that would result in death or serious injury.

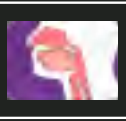
NOTE: Throughout this manual, "NOTE" indicators provide helpful information regarding the particular area of function being described.

GENERAL TERMINOLOGY

The following are definitions for the terminology used throughout this manual. Study these terms to become familiar with them for ease of system operation and control functionality of the VitalStim® Plus Electrotherapy System.

SYSTEM SOFTWARE SYMBOLS

	Back Arrow/Previous Screen
	Forward Arrow/ Next Screen
	Increase/Decrease Parameter
	Scroll Up or Down in a text box
	Select
	Customize
	Micro SD Card indicator
	Hand switch indicator
	Battery voltage level indicator
	Bluetooth connection indicator

	VitalStim
	VMS
	sEMG
	sEMG+VMS
	Electrode Placement
	Modality Description
	Custom Protocols
	Patient Data
	Anatomical Library
	Utilities

DESCRIPTION OF DEVICE MARKINGS

The markings on the unit are assurance of its conformity to the highest applicable standards of medical equipment safety and electromagnetic compatibility. One or more of the following markings may appear on the device:

Refer to Instructional Manual Booklet 

Neuromuscular Stimulation (STIM) and sEMG +Stimulation should not be used by Patients fitted with demand style cardiac pacemakers 

Testing Agency 

Electrical Type BF 

ON/OFF 

Remote Switch Jack

sEMG Reference Jack REF

Output channel Jack Ch

Back

Resource Library 

Home 

Manufacturer's Catalog Number for the Device REF

Manufacturer's LOT/Batch Number LOT

Manufacturer's Serial Number of the Unit SN

Name and address of Manufacturer 

Date of Manufacture 

Keep Dry 

Protection against ingress of solid foreign objects of 12.5mm and greater IP20

Do not dispose in normal dustbin (see page 35 for instructions) 

ELECTROTHERAPY, sEMG+VMS INDICATIONS

Indications

For VMS™ - VitalStim Waveforms and sEMG Triggered Stimulation.

- Muscle re-education by application of external stimulation to the muscles necessary for pharyngeal contraction.

Intended Uses- VMS™ Waveform

VMS waveform is a square symmetrical biphasic waveform with the application for use on the musculature of the face.

The intended uses are:

Optional application of sEMG biofeedback with Muscle Stimulation VMS™ waveform for prevention or retardation of disuse atrophy, for muscle re-education, and for relaxation of muscle spasms in the treatment of swallowing musculature dysfunction in post-traumatic conditions or after neurological insult with impaired neuromuscular function.

Intended Uses- VitalStim Waveform

VitalStim waveform is a square symmetrical biphasic waveform with interphase interval pulse with the application for use on the swallowing musculature in the anterior portion of the neck.

The intended uses are:

The VitalStim waveform intended uses are muscle re-education of the swallowing musculature in the treatment of dysphagia (swallowing problems) from any etiology except mechanical causes that would need surgical intervention (for instance, obstructing tumors). Non-mechanical causes of dysphagia include: neurological and muscle disorders; cardiovascular accidents; respiratory disorders with swallowing complications; latrogenic conditions (conditions caused by surgery); fibrosis/ stenosis arising from radiation; disuse due to stroke, intubation, or birth-related anoxic injuries; and trauma to the head and neck. This device is a prescription device intended for use by or on the order of a physician or other licensed health professional.

Intended Uses- Surface EMG

sEMG is surface biofeedback for use on the swallowing musculature of the face and/or anterior portion of the neck. The intended uses are:

The sEMG intended uses are surface electromyography biofeedback for relaxation training and muscle re-education.

Contraindications

The VitalStim® Plus Electrotherapy System should NOT be used under the following conditions:

- This device should not be used when cancerous lesions are present in the treatment area.
- Stimulation should not be applied over swollen, infected, inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
- This device should be used with caution on patients with cardiac demand pacemakers or other implanted electronic devices.
- Stimulation should not be applied over the carotid sinus nerve particularly in patients with a known sensitivity to the carotid sinus reflex.
- Other contraindications are patients with the following:
  - who are severely demented and exhibit non-stop verbalization. Constant verbalization could result in aspiration during trials of oral intake.
  - with significant reflux due to use of a feeding tube. Such patients are prone to repeated cases of aspiration pneumonia, and the device has not been studied in this population.
  - with dysphagia due to drug toxicity. Patients suffering from drug toxicity could aspirate during trials of oral intake.
  - undiagnosed syndromes or until etiology is established.
  - carrying serious infectious disease and/or disease where it is advisable, for general medical purposes, to suppress heat or fevers.
- Safety has not been established for the use of therapeutic electrical stimulation during pregnancy.

Additional Precautions

- Caution should be used for patients with suspected or diagnosed epilepsy
- Caution should be used for patients with suspected or diagnosed heart problems
- Caution should be used in the presence of the following:
  - When there is a tendency to hemorrhage following acute trauma or fracture
  - Following recent surgical procedures when muscle contraction may disrupt the healing process
  - Over areas of the skin that lack normal sensation
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternative conductive medium or an alternative electrode placement.
- Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner
- Powered muscle stimulators should be used only with the lead wires and electrodes recommended for use by the manufacturer
- Isolated cases of skin irritation may occur at the site of electrode placement following long term application
- The effective management of dysphagia by NMES waveforms is highly dependent upon patient selection by a person qualified in the management of dysphagia

Adverse Effects

- Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators

PRODUCT DESCRIPTION

The VitalStim® Plus Electrotherapy System is a 2 Channel sEMG and 4 Channel electrotherapy system used in treating patients with oral-pharyngeal dysfunctions (dysphagia) and disorders of the head and neck, with Bluetooth connection to PC software.

To maximize functionality and life of VitalStim® Plus Electrotherapy System, be sure to:

- Stay current with the latest clinical developments in the field of electrotherapy, sEMG (Surface Electromyography), sEMG + Stim (Surface Electromyography with Triggered Stimulation) and VitalStim therapy.
- Observe all applicable precautionary measures for treatment.

NOTE: This equipment is to be used only under the prescription and supervision of a licensed medical practitioner.

OPERATOR INTERFACE

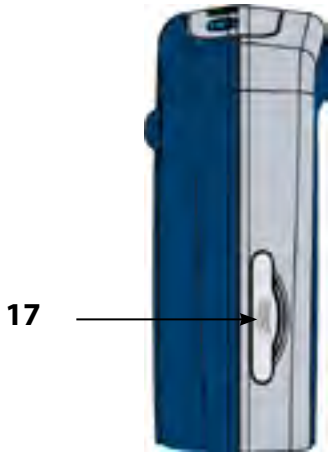
VitalStim® Plus Electrotherapy System Operator Interface contains all the functions and controls necessary for operator access to all operator utilities, modalities, and parameters for modification and system set up.

1. Color Display
2. BACK button
3. HOME button
4. Clinical Resource Library button
5. ON/OFF button
6. STOP button
7. START/PAUSE button
8. Ch1,Ch2,Ch3,Ch4 intensity buttons
9. Ch3 Lead Wire Connector (STIM)
10. Ch4 Lead Wire Connector (STIM)
11. Operator Remote Switch Connector
12. Ch2 Lead Wire Connector (sEMG or STIM)
13. Ch1 Lead Wire Connector (sEMG or STIM)
14. sEMG Reference Lead Wire Connector
15. Concealed button
16. Battery Compartment (Cover Removed)
17. Micro SD Card Slot

Front Controls

Front Panel and Battery Compartment

Micro SD card slot



⚠ CAUTION

- Read, understand, and practice the precautionary and operating instructions. Know the limitations and hazards associated with using any electrical stimulation. Observe the precautionary and operational decals placed on the unit.
- DO NOT operate this unit when connected to any accessories other than DJO accessories specifically described in user or service manuals.
- DO NOT use sharp objects such as a pencil point or ballpoint pen to operate the buttons on the keypad.
- DO NOT disassemble, modify, or remodel the unit or accessories. This may cause unit damage, malfunction, electrical shock, or personal injury.
- DO NOT permit foreign materials, liquids or cleaning agents to enter the unit, including, but not limited to, inflammables, water, and metallic objects from entering the unit, to prevent unit damage, malfunction, electrical shock, fire, or personal injury.
- DO NOT operate the VitalStim Plus Electrotherapy System within the vicinity or environment as any therapeutic microwave or RF shortwave diathermy system in operation.
- Device is designed to comply with electromagnetic safety standards. However, there is no guarantee that interference will not occur in a particular installation. Harmful interference to other devices can be determined by turning this equipment on and off.
- Inspect cables, lead wires and associated connectors before each use.
- This unit should be operated at 5°C to 40°C and 15% to 93% Relative Humidity. The unit should be transported and stored at -25°C to 70°C and 0% to 90% Relative Humidity.
- Place the patient in a comfortable position during VitalStim therapy session.
- Failure to use and maintain the VitalStim® Plus Electrotherapy System, and its accessories in accordance with the instructions outlined in this manual will invalidate the warranty.
- If you have difficulty operating the unit after carefully reviewing this user manual, contact DJO or authorized DJO distributor for assistance.
- Use of parts or materials other than DJO's can degrade minimum safety.
- Safe use of electrotherapy during pregnancy has not been established.
- 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.
- Some patients may experience skin irritation or hypersensitivity due to electrical stimulation or electrical conductive medium. The irritation can usually be reduced by moistening the skin, using an alternative conductive medium or electrode placement.
-

⚠ CAUTION

- Inspect lead wires and associated connectors for signs of damage before each use. Replace damaged lead wires immediately with new before any treatment is applied.
- Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner or other licensed health professional.
- Portable powered muscle stimulators 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.
- Always check the stimulation controls before treating a patient. The stimulation amplitude/intensity should always be adjusted gradually.

⚠ WARNING

- U.S.A. Federal Law restricts these devices to sale by, or on the order of, a physician or licensed practitioner. This device should be used only under the continued supervision of a physician or licensed practitioner.
- Be sure to read all instructions for operation before treating patient.
- Care must be taken when operating this equipment around other equipment. Potential electromagnetic or other interference could occur to this or to the other equipment. Try to minimize this interference by not using other equipment in conjunction with it.
- Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when electrical stimulation is in use.
- Do not drop the unit on hard surfaces or submerge in water. These actions will damage the unit. Damage resulting from these conditions is not covered under the warranty.
- This device should be kept out of the reach of children.
- Use only cables and accessories that are specially designed for the VitalStim® Plus unit. Do not use accessories manufactured by other companies on the VitalStim® Plus unit. DJO is not responsible for any consequence resulting from using products manufactured by other companies. The use of other accessories or cables may result in increased emissions or decreased immunity of the VitalStim® Plus unit.
- Contaminated electrodes, lead wires, and gel can lead to infection.
- Use of electrode with degraded hydrogel can result in burn to the skin.
- DO NOT operate this unit in an environment where other devices are being used that intentionally radiate electromagnetic energy in an unshielded manner.
- Use of electrode on multiple patients can lead to infection.
- Stop treatment immediately if patient experiences discomfort or pain.
- Long term effects of chronic electrical stimulation are unknown.
- Stimulation should not be applied transcerebrally.
- Stimulation should not be applied over swollen, infected, and inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
- Stimulation should not be applied over, or in proximity to, cancerous lesions.
- Using the supplied stimulation electrodes, the current density will not exceed 2mA/cm2. Using smaller electrodes or needle electrodes may lead to current density greater than 2mA/cm2. In such cases, special caution is to be exercised when adjusting the current level as too high values may cause skin irritation or possibly burns. Consult the Electrode Current Density table in Appendix 3.
- The VitalStim® Plus Electrotherapy System optional accessories are designed for use only with the VitalStim® Plus Electrotherapy System.
- Medical electrical equipment needs special precautions regarding EMC. Portable and mobile RF communication equipment can be affected by other medical electrical devices. If you believe interference is occurring, please consult page 38, Electromagnetic Compatibility, to assist in removing the interference.
- Common RF emitting devices (e.g., RFID) and electromagnetic security systems (e.g., metal detectors) may interfere with the operation of the VitalStim® Plus Electrotherapy System. The VitalStim® Plus Electrotherapy System has been tested in the presence of these types of devices and while no adverse event occurred, the device should not be operated within the vicinity or environment as another RF emitting device.

⚠ WARNING

- Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.
- Before administering any treatment to a patient you should become acquainted with the operating procedures for each mode of treatment available, as well as the indications, contraindications, warnings and precautions. Consult other resources for additional information regarding the application of each mode of treatment.
- Simultaneous connection of a patient to high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
- Keep electrodes separated during treatment. Electrodes in contact with each other could result in improper stimulation or skin burns.
- Electrodes should be inspected before each use for resistance. (i.e. hydration level, tack, discoloration and impurities) Follow the manufacturing guidelines on electrode packaging.
- Long term effects of chronic electrical stimulation are unknown.
- Any patient may be treated with the VitalStim® Plus Electrotherapy System. Extra care should be taken when this unit is used with children.

⚠ DANGER

- Stimulation should not be applied over the carotid sinus particularly in patients with a known sensitivity to the carotid sinus reflex.
- Use only electrodes and accessories designed specifically for use with the VitalStim® Plus Electrotherapy System. Use of other accessories and/or techniques not approved under the VitalStim® Plus certification training may result in death, injury, or adverse effects to patient or undesirable and ineffective results.

COMPONENTS

The components of the VitalStim® Plus Electrotherapy System are shown below.

Stand

Rubber Sleeve

Lead wires

The available lead wires are shown below. Package includes:

Blue Channel 1 lead wire
Green Channel 2 lead wire,
Orange Channel 3 lead wire
Cranberry Channel 4 lead wire
White sEMG reference Channel lead wire

Lead wire Clips (attached to lead wire)

Operator Remote Switch

JACK PANEL

1. Channel 1 (sEMG or Stimulation)

2. Channel 2 (sEMG or Stimulation)

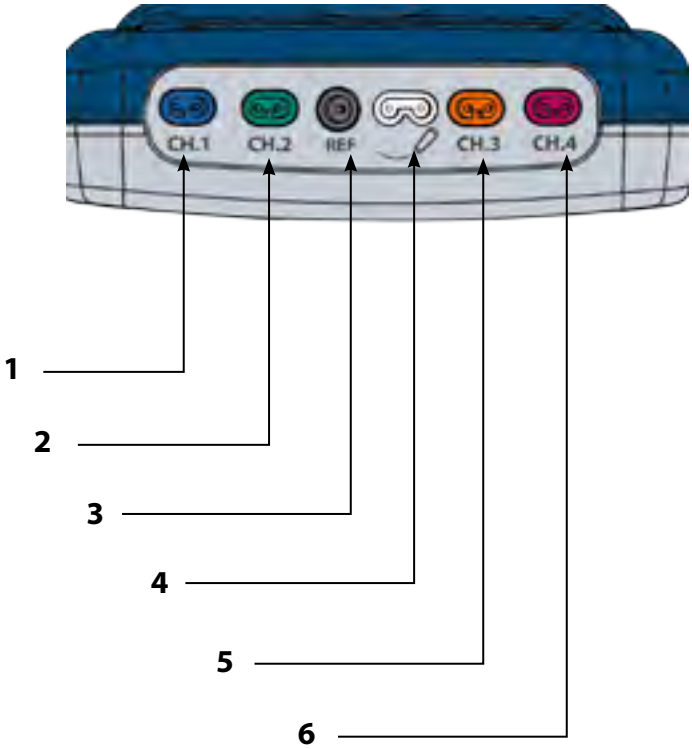
3. sEMG Reference Channel

NOTE: Always use Reference wire (REF) with electrode attached to body for precise sEMG measurement!

4. Remote Switch Connection

5. Channel 3 (Stimulation)

6. Channel 4 (Stimulation)



OPERATOR REMOTE SWITCH

To operate the Patient Remote Switch, plug the remote into the device on the Jack Panel, as shown below:

Once the switch is plugged into the device the switch icon visible in the title line will turn from gray (not connected) to white (connected)

After connecting the electrodes and setting up VitalStim or VMS, complete the following steps to activate Operator Remote Switch (activated switch indicated by blue icon):

1. Connect Remote Control
2. Select the stimulation channel and adjust intensity to desired level
3. Press and Release Remote Control button to activate Manual Mode. Intensity will decrease to 0 mA
4. To start stimulation, press and hold the Remote Control button
5. To stop stimulation, release the button
6. To adjust intensity level, press and hold the remote control button while increasing or decreasing intensity.

⚠ CAUTION

- Operator Remote Switch to be used under supervision of a physician or certified VitalStim user only.

THERAPY SYSTEM START-UP

Complete the following steps for initial setup of the VitalStim® Plus Electrotherapy System:

1. Remove battery cover, insert batteries following mode of insertion defined inside the compartment, place back the cover.

   NOTE: Battery cover should be closed prior to turning the device ON.

2. Press the ON/OFF button located on the front of the device:

3. Select desired function on the Home Screen (shown below).

SYSTEM SPECIFICATIONS AND DIMENSIONS

Width..... 3.8″(9.6 cm)
Depth..... 1.4″(3.6 cm)
Height ..... 6.2″(16 cm)
Weight..... 0.75 lb (0.34kg)

POWER

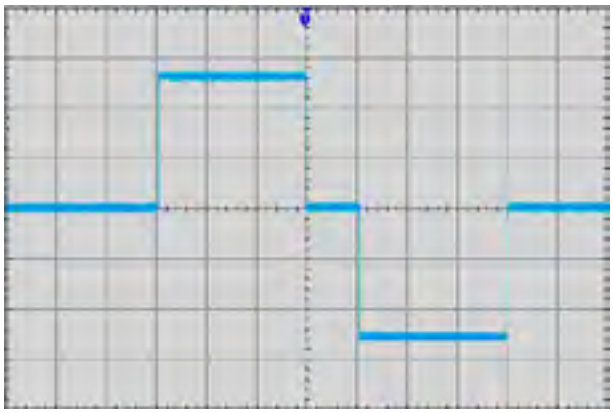
Input ..... 6V (4x1.5V AA battery cells)
Max. Output Voltage(Patient) ..... 70V (+0/-5V)
Mode of Operation..... Continuous

Output Intensity

The is theoretical standard measurement output current across purely resistive loads at maximum intensity setting. Pulse Width and current measured as shown across 2.8 kOhm loads. This measurements is also valid on a 500 Ohm load, as the VitalStim® Plus is current controlled device. Any load between 500 Ohms and 2.8 kOhm will not affect the output measurements. Your output may vary depending on parameter settings.

VitalStim® Waveform

Maximum Intensity: 25mA
Zero net DC component
Maximum charge per pulse: 7.5 µC



Electrical Type (Degree of Protection)

Electrotherapy & sEMG .....TYPE BF

NOTE: VMS™, VitalStim waveform output intensities are measured, specified, and listed to peak, not peak to peak.

GENERAL SYSTEM OPERATING AND STORAGE TEMPERATURE

Operating conditions

The device will meet its requirement under the following conditions:
Temperature: ..... 5° C to 40° C
Relative Humidity: .....15% to 95%
Atmospheric Pressure: ..... 700hPa to 1060hPa

Transport and storage conditions

The device will remain in proper condition under the following conditions:
Temperature: .....-25° C to 70° C
Relative Humidity: ..... max 90%
Atmospheric Pressure: ..... 700hPa to 1060hPa

WAVEFORMS

VMS™

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.

Output Mode ..... Electrodes
Output Intensity ..... 0-25 mA (Constant Current)
Channel Mode ..... Continuous, Reciprocal, Co-Contract
Phase Duration ..... 60-300 µsec (10 % accuracy)
Set Intensity ..... Individual Channel Intensity Setting
Cycle Time ..... User Defined (ON time/OFF time 1-99s)
Frequency ..... 1-80 pps (5 % accuracy)
Ramp Up/Ramp Down ..... 0-3 sec
Treatment Time ..... 1-240 min
Available on Channels ..... 1, 2, 3, or 4

VitalStim™

VitalStim is a symmetrical square biphasic waveform with a 100 µs interphase interval pulse with the application for use on the swallowing musculature in the anterior portion of the neck.

Output Mode ..... Electrodes
Output Intensity ..... 0-25 mA (Constant Current)
Channel Mode ..... Co-Contract
Phase Duration ..... 300 µsec (10 % accuracy)
Set Intensity ..... Individual Channel Intensity Setting
Cycle Time ..... ON time 57s , OFF time 1s
Frequency ..... 80 pps (5 % accuracy)
Ramp Up/Ramp Down ..... 2 sec
Treatment Time ..... 60 min
Available on Channels ..... 1, 2, 3, or 4

sEMG

sEMG

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.

sEMG Range ..... 0.2 to 2000 µV RMS (continuous)

Sensitivity ..... 0.1 µV RMS

Accuracy ..... 6% of µV reading +/- 0.3 µV

Selectable Bandpass filter (3db Bandwidth)

Heart Beat Filter OFF

Reading below 235 µV ..... 18 Hz +/- 4 Hz to 370 Hz +/- 10%
Reading above 235 µV ..... 10 Hz +/- 3 Hz to 370 Hz +/- 10%

Heart Beat Filter On ..... 100 Hz +/- 5 Hz to 370 Hz +/- 10%

Notch Filter ..... 50 Hz - 33 dbs (0. 1% accuracy)

Common Mode Rejection Ratio ..... 130 dbs Minimum at 50 Hz

Available on Channels ..... 1 or 1 and 2

ELECTRODE PLACEMENT GENERAL

- Examine the skin for any wounds and clean the skin
- Apply the electrodes to the treatment area
- Ensure the electrodes are applied securely to the skin
- Ensure good contact between each electrode and the skin
- Check the electrode contact regularly during the treatment
- Examine the skin again after the treatment
- View the Electrode Placement recommendations in the Treatment Review screen as a reference point only prior to administering treatment
- Follow electrode manufacturer instructions

VitalStim® ELECTRODES

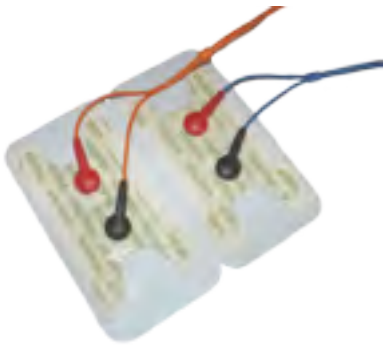
VitalStim® Electrodes are a self adhesive, disposable , electrodes designed specifically for use with VitalStim® Plus Electrotherapy System.

For reordering of the electrodes , refer to page 33.

PATIENT PREPARATION

Install VitalStim® Electrodes

1. Connect lead wires to VitalStim® Electrodes.

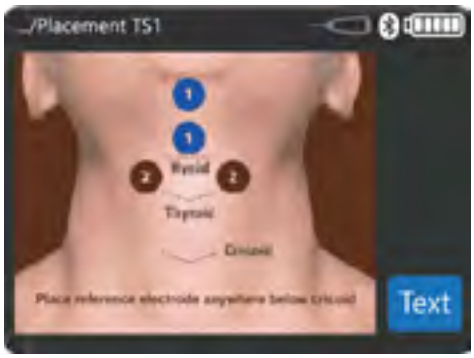


2. Leave protective backing on electrodes until treatment area has been prepared.

Electrode Placement Guidance (as needed)

1. From the Home Screen, select desired modality
   - VitalStim (Ch 1, 2, 3 and/or 4)
   - VMS (Ch 1, 2, 3 and/or 4)
   - sEMG (Ch 1 and /or 2)
   - sEMG + Stim VMS (sEMG in Ch 1 and/or 2; Stim in Ch 1, 2, 3 and/or 4)

2. Select Electrode Placement icon



Connect the Lead wires.

1. Connect the lead wire(s) to the appropriate port(s) on the device.
2. Press the "Back Arrow" button/icon to return to desired screen.
3. Examine the skin for any wounds.

PATIENT PREPARATION (CONTINUED)

4. Thoroughly cleanse the skin treating area. Open the packet of electrodes and remove the Clean-Cote® skin wipe. Apply the wipe to the skin area where the electrodes will be positioned and allow approximately 30 seconds for the area to dry. Discard the wipe after use.

NOTE: Thorough cleaning of the treatment area to remove any topical medication and cream film as well as loose skin particles from the treatment area is essential to obtain good skin contact and ensure good conductivity during sEMG and sEMG + Stim therapy.

Electrode Placement

1. Apply the electrode to the appropriate skin area or as instructed at your VitalStim therapy certification program.

2. Attach the lead wire strain relief clips to the patient's clothing in a position that allows ease of movement and adequate strain relief for the lead wire.

For sEMG and sEMG + Electrical Stimulation OPERATION, refer to page 24-28.

⚠ CAUTION

- Do not apply to broken skin
- Single patient use only

SCREEN DESCRIPTION

Each screen contains the following areas:

Title Bar
Located at the top of each screen and lists the current screen and previous screens back to the Home screen. It also contains a SD card in Icon, Patient Remote Switch status icon, Bluetooth connectivity and battery level icon.

Main Area
Located under the Title Bar, this area displays icons unique to the current screen.

Channel Area
Located at the bottom of each screen, this screen displays the following status information about each channel:

n/a: Indicates the channel is not (yet) available to be selected

Available: Indicates the channel is available for use

Running: Indicates a treatment for the channel is currently running

Paused: Indicates a treatment is currently paused

No contact: indicates open circuit which could be caused due to poor electrode contact or fault with lead wires being damaged or not connected properly

The image below shows the Home screen with modality and resource icons.

HOME SCREEN

The VitalStim® Plus Electrotherapy System Home screen provides access to all of the system modalities and functions. The Home screen has the following information:

Modality Icons:

1) Utilities
2) VMS
3) VitalStim
4) sEMG
5) sEMG+VMS
6) Patient Data
7) Anatomical Library

UTILITIES AND OPTIONS

The Utilities icon on the Home screen offers users the opportunity to set the following preferences:

1. **Clinic Name**
   Select the <**Clinic Name**> icon to enter the name of your clinic. The clinic displays on the Home Screen and on the patient Treatment Summary reports saved to the SD card.

2. **LCD Brightness**
   Select the <Brightness> icon to set the brightness of the LCD screen. The brightness ranges from 10% (dimmest) to 100% (brightest) in 10% increments. The default setting is 80%.

3. **Volume**
   Select the <Volume >icon to set desired audio volume. The volume range is 0% (off) to 100% (loudest) and is adjusted in 10% increments. The default setting is 60%.

4. **Date and Time**
   Select the <Date and Time>icon to set the date and press the right arrow button to set the time on the unit.

5. **Language**
   Select the <Language> icon to set unit interface language.

6. **Patient Weight Units**
   Select the <Pat. Weight Units> icon to set desired unit of measure for weight .

7. **Bluetooth**
   Press the right arrow button and press the <Bluetooth> button to toggle between ON and OFF, setting will be automatically saved. The default setting is ON.

8 **Display Unit Version Information**
   Select the <**Firmware Version Info**> icon to view installed version.

9. **Restore Default Unit Settings**
   Select the <**Restore Default Unit Settings**> Unit Settings icon to reset all of the following settings back to their factory defaults:

   - Volume
   - LCD Brightness
   - Clinic Name
   - Date and Time
   - Language
   - Patient Weight Unit
   - Bluetooth Connectivity

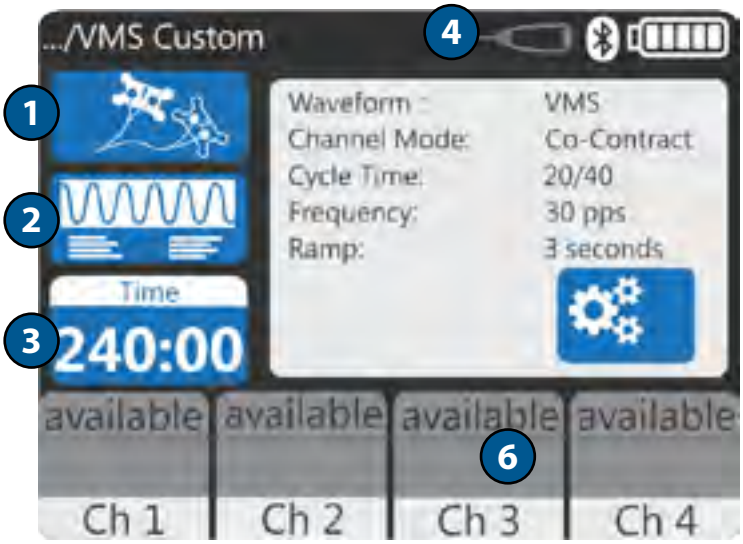
10. **Restore Default Protocols**
    Select the <Restore Default Protocols> icon to reset all protocols (factory custom,) to their factory defaults.

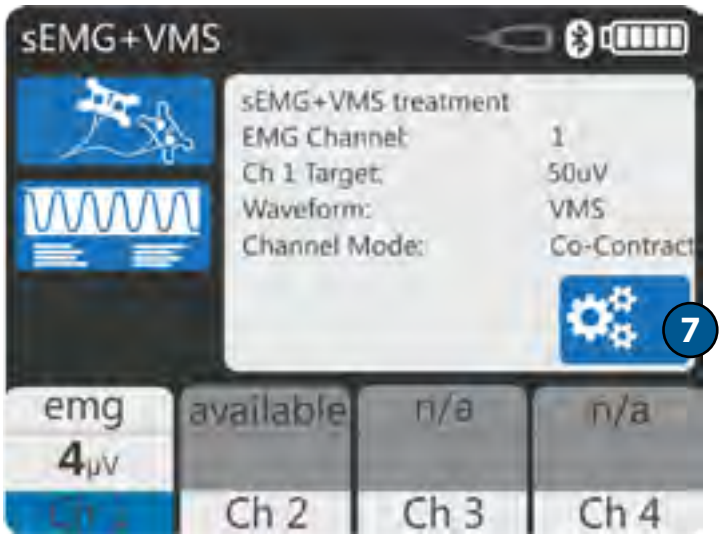
11. **Patient Data Erase**
    Select the <Patient Data Erase> to erase entire Patient Data from Mico SD Card inserted.

12. **Heart Beat Filter**
    Heart Beat Filter eliminates heart beat signal that can affect sEMG signal. Select OFF if you want to disable the filter. The default setting is ON.

TREATMENT SCREENS

The VitalStim® Plus Electrotherapy System Treatment screens for Electrotherapy and sEMG, include the following information:





1. **Electrode Placement Icon**
   Press the Electrode Placement Icon to view suggested electrode placements for the Clinical Protocol selected.
2. **Modality Description Icon**
   Press the Modality Description Icon to view the text explaining the rationale for the modality associated with the specific Clinical Protocol selected.
3. **Time Icon**
   Press the Time icon to adjust therapy time/duration.
4. **Remote Icon**
   Changes color to white when Remote Control is inserted and to blue when Remote button is pressed and current is being delivered.
5. **Therapy Information Window**
   View selected Therapy information such as Waveform, Cycle Time, Frequency, in the Therapy Information Window.
6. **4 Channel Icons**
   This icon shows the modalities in use.
7. **Customize Icon**
   Press the "Customize" icon to edit the therapy information.

ELECTROTHERAPY OPERATION (VITALSTIM, VMS)

All waveforms in the VitalStim® Plus Electrotherapy System are set up and edited in the same basic fashion. The VitalStim® Plus Electrotherapy System has the following Electrotherapy waveforms: VMS, VitalStim® .

Complete the following steps to begin Electrotherapy treatment:

1. Prepare patient and therapy system for Electrotherapy. Refer to the PATIENT PREPARATION section on page 17 for electrode selection, preparing the patient, and securing electrodes.
2. From the Home Screen, select desired Electrotherapy modality. Refer to the Specifications section of this manual for all waveform specifications for the VitalStim® Plus Electrotherapy System. The Treatment screen below will then appear (VitalStim mode example).

- To view information explaining the waveform, select the Modality Description icon. Press Up and Down arrows to scroll the text. Press the Back button to return to the previous screen or the Home button to return to the Home screen.
- To view the most commonly used electrode placement for the selected waveform, select the Electrode Placement Icon. Press the Text icon see additional description. Press the Back button to return to the previous screen or the Home button to return to the Home screen.
- To customize waveform settings (**available only for VMS and sEMG+VMS Modality**), select one of the custom protocols (up to six protocols can be defined), press the Customize icon located in the therapy information window, and the screen below will appear. Make the desired changes and press the Back button to return to the previous screen, the Home button to return to the home screen, new settings will be automatically saved.

3. If desired, connect optional Remote Control to device.
4. Select the appropriate channel and then use the intensity buttons +/- to start the stimulation and set therapy intensity for each channel.
5. Press the Start/Pause button to pause/restart the treatment, or the Stop button to terminate the treatment.

   NOTE: Customize icon is disabled during therapy. Only Intensity can be adjusted once treatment has started

6. When treatment has completed, the Treatment Summary screen will appear with the following options:
   - Save Summary - the data will be saved to the SD card (if inserted).
   - Repeat the treatment by pressing the Run This Treatment icon.
   - Export to PC (available if Bluetooth connection with designated PC software is established.

sEMG OPERATION

The VitalStim® Plus Electrotherapy System sEMG modality 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. These signals are accurately relayed to the VitalStim® Plus Electrotherapy System through VitalStim Electrodes. sEMG can be beneficial to muscle retraining therapy by setting target values and charting the patient progress in reaching those goals in a specific muscle or muscle group. Within this section, general set up procedures of the various parameters of sEMG are explained. The following options are available: sEMG (Channel 1), sEMG (Channel 2), sEMG (Channels 1 & 2),

NOTE: Do not place the VitalStim Plus device in close proximity with a wireless device such as a cell phone or wireless keyboard. Emissions from such devices may interfere with the VitalStim Plus device.

NOTE: Complete the following steps to begin sEMG treatment:

1. Prepare Patient and therapy system – Refer to the PATIENT PREPARATION section for electrode selection, preparing the patient, and securing electrodes on page 17.

   NOTE: Always connect a single reference electrode to the white reference lead wire in addition to the active recording electrodes. Always use at least channel 1 when using sEMG or sEMG+VMS (channel 2 cannot be used alone).

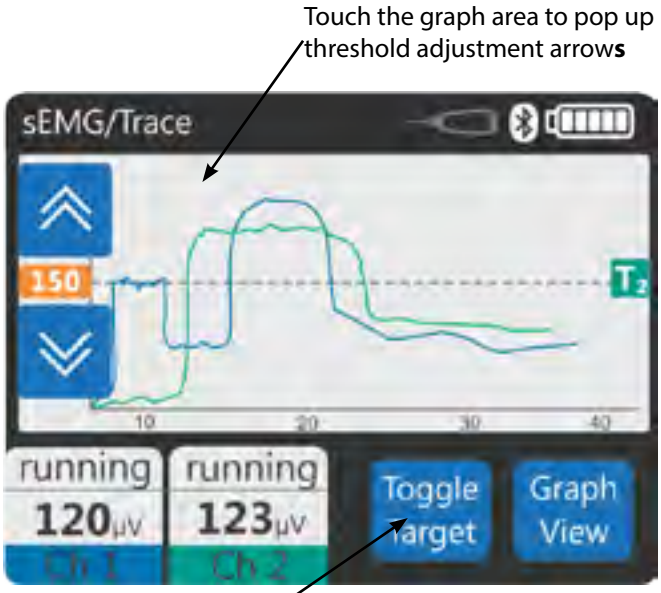
2. Select sEMG icon from the Home screen.
3. Press the prescribed channel icon to activate or deactivate it (see above for the available choices). The treatment screen will appear (image below illustrates the sEMG Channel 1 &2 selection).

Set-up Steps:

- To view information explaining the modality, select the Modality Description icon. Press Up and Down arrows to scroll the text. Press the Back button to return to the previous screen or the Home button to return to the Home screen.

- To view the most commonly used electrode placement for the selected modality select the Electrode Placement Icon. Press the Text icon see additional description. Press the Back button to return to the previous screen or the Home button to return to the Home screen.

- To view the Trace view, touch the Trace view Icon. Trace View displays a real time view of the current sEMG value as well as previous values. A horizontal trace graph will be displayed. Left Axis (Y): Value in µ Volts, bottom Axis (X): Time in seconds. The target value will be displayed as a dashed line on the graph. The numeric sEMG value will be displayed below the graph. Press the Back button to return to the previous screen or the Home button to return to the Home screen.



4. The following options are available in Graph View treatment screen:

- Volume - press the Volume button to adjust volume
- Target - press the Target button to select the method Target Acquisition:

  Max - Device captures the maximum effort from number of muscle contractions.
  Manual - Set Target manually.

- Swallow trials - Set a number of trials (0-90) to challenge the patient and set an optional minimum number of seconds to hold each contraction to count as a successful trial
- Capture (or Adjust)Target - start Target Acquisition

5. Setting Maximum Target

- Make certain Target "Max" is displayed in the Target icon. Press the Capture Target button. Select channel for which you want to set the threshold by touching channel bar. Begin contracting the muscle and press the Begin Capture button to start setting the target (Capture Target period indicated by flashing "Contract" icon and threshold bar).

NOTE: The capture may be stopped by pressing the End Capture Button. The System will then select the maximum contraction level achieved during the contraction period.

- Once the maximum target value is captured, the device switches to the screen which allows manual adjustment (up or down by a percentage of the value). Use the Up and Down Arrow buttons to adjust the Target percentage displayed at the bottom channel column.

- Press the Select button to set the Target.

- Once the target is set the sEMG Treatment Screen will be displayed with the new target value set.

6. Setting Manual Target

- Make certain Target "Manual" is displayed in the Target icon. Press the "adjust target" button to switch to manual adjustment screen .

- Use the Up and Down Arrow buttons to adjust the Target value displayed at the top of each channel column.

- Press the Select button to set the Target.

7. sEMG session

- To begin sEMG session press START/PAUSE button. Session data will be collected (indicated by sEMG value displayed in red and session time counter). Once STOP button is pressed a Treatment Summary screen will be displayed showing session data captured.

8. Swallow Trials

- Swallow Trials monitors and displays the number of successful swallows a patient has performed. Press the Swallow Trials button. Select the desired number of successful swallows during treatment. The number of swallow trials to select range from 1 to 90. Select the desired Hold time which is the time required for patient to hold above the threshold to score a successful trial. The Hold time can be selected in range from 0 to 10 seconds.

- The sEMG Trace View Screen will display, Contract , Hold and Relax prompts, trial the patient is currently performing as well as achievement towards target.

NOTE: Once the Swallow Trials modality has been started, the following sEMG options will not be available: Swallow Trials, sEMG Channel Selection, 8. Swallow Trials

- Once the number of trials has been successfully achieved, the treatment will end showing Flashing reward message (After 5 seconds display will change to Treatment summary screen).

NOTE: A successful swallow trial is when the patient starts below the set sEMG target value, exceeds the set sEMG target, holds it for set Hold time, and then drops below the set sEMG target value for at least 1 second.

9. When treatment has completed, the Treatment Summary screen will appear with the following options:
   - Save Summary - the data will be saved to the SD card (if inserted).
   - Repeat the treatment by pressing the Run This Treatment icon.
   - Export to PC (available if Bluetooth connection with designated PC software is established.

sEMG+VMS OPERATION

The VitalStim® Plus Electrotherapy System sEMG+VMS modality utilizes sEMG biofeedback activity coupled with triggered electrical muscle stimulation using selected electrotherapy waveform for the maximum benefit in muscle retraining. The following options are available: sEMG+VMS (sEMG: Ch 1 and/or 2; Stim: Ch 1, 2, 3 and/or 4)

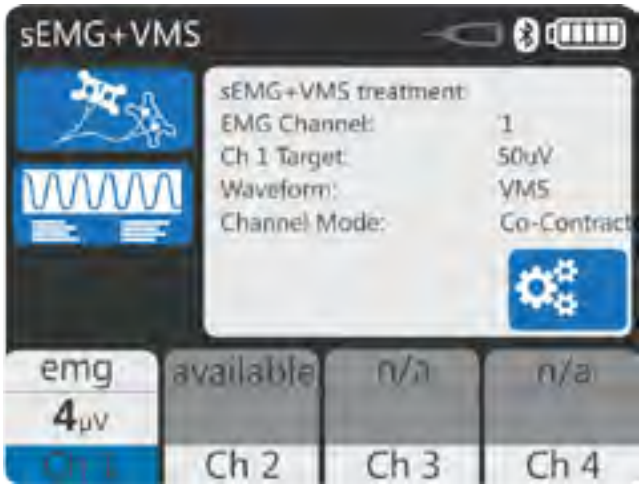
Stimulation is triggered by Channel 1 sEMG reading and can be delivered to any of 4 Channels

The Electrical Muscle Stimulation is triggered when the muscle contraction (sEMG portion of the therapy) reaches the target, sEMG stops, and the muscle is then electrically stimulated for the pre-set period. After stimulation, the patient is given a Rest period and then repeats the muscle contraction, attempting to reach the target to again trigger the electrical stimulation. This is repeated throughout the therapy session.

The sEMG portion of sEMG+VMS modality is used to force the patient to contract the muscle to a prescribed target.

NOTE: Complete the following steps to begin sEMG treatment:

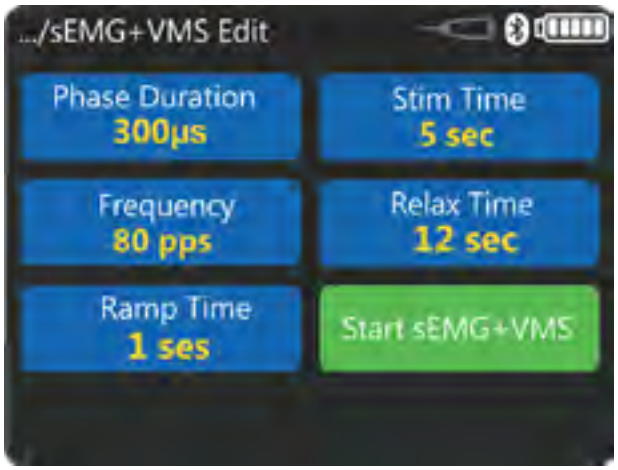
1. Prepare Patient and therapy system – Refer to the PATIENT PREPARATION section for electrode selection, preparing the patient, and securing electrodes on page 17.
2. From the Home Screen select sEMG+VMS icon. The screen below will then appear



- To view information explaining the modality, select the Modality Description icon. Press Up and Down arrows to scroll the text. Press the Back button to return to the previous screen or the Home button to return to the Home screen.
- To view the most commonly used electrode placement for the selected modality select the Electrode Placement Icon. Press the Text icon see additional description. Press the Back button to return to the previous screen or the Home button to return to the Home screen.

3. Press the prescribed channel icon to activate or deactivate sEMG Ch2 (sEMG Ch1 as a triggering channel has to be active). The treatment screen will appear (image below illustrates the sEMG+VMS Channel 1 selection).
4. The following options are available under the Customize treatment screen and accessed by pressing the Customize icon:

- Volume - press Volume button to adjust the volume
- Target (refer to description in sEMG section, Adjustable only for Channel 1)
- Capture (or Adjust) target (refer to description in sEMG section)
- Edit sEMG+VMS - press the Edit sEMG+VMS to view or customize waveform settings (**available only for VMS and sEMG+VMS Modality**), the screen below will appear. Make the desired changes and press the Back button to return to the previous screen, the Home button to return to the home screen, new settings will be automatically saved.



5. Press Start/Pause button (or Start sEMG+VMS icon in Edit sEMG+VMS menu) to begin therapy.

- Session starts with prompt to activate and adjust mA level of the Stimulation channels which will be used during the session. Once intensity is increased to desired level press START/Pause button to begin the session. (Initial "Relax" prompt).

- "Contract" - Instructs the patient to attempt to reach the Target Threshold. "Contract" appears on the screen, indicating the patient should attempt to contract the selected muscle(s). "Contract" remains on the screen until the patient's sEMG output reaches the Target Threshold, at which time Electrical Stimulation is delivered.

- "Hold (Stim time)" - when the Target Threshold is reached, the "Hold" prompt appears, instructing the patient to continue to contract the selected muscle(s) until the pre-set time for the Stimulation ends.

- "Relax (Rest time)" - Instructs the patient to Relax. "Relax" appears, indicating the patient should relax, stopping the contraction. Relax continues for the pre-set time. The cycle repeats when "Contract" re-appears again, indicating that the patient should attempt to contract the selected muscle(s).

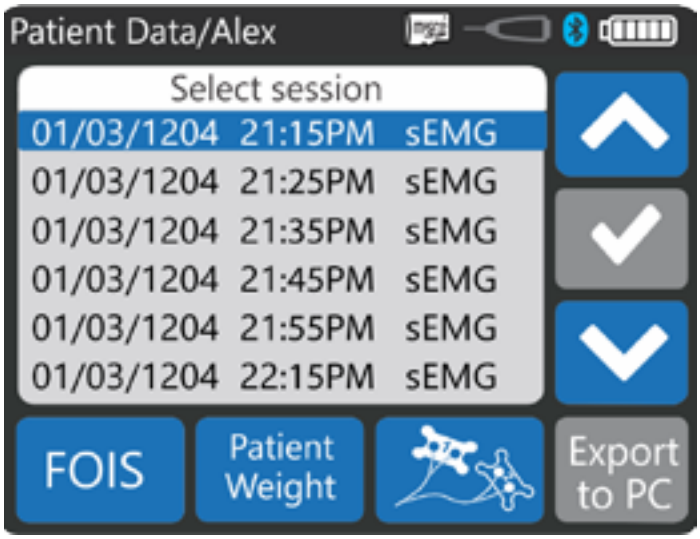
6. Press the Start /Pause button to pause treatment, or the Stop button to terminate the treatment.
7. When treatment has completed, the Treatment Summary screen will be displayed

PATIENT DATA

Patient treatment data can be saved to the Micro SD Card for retrieving for later reference, sending and viewing/ printing on a PC software .
Complete the following steps to view and **access patient data:**

1. Press the Patient Data icon in the Home screen. The screen will display a list box of all previously saved patient data accounts and sessions.

2. Select the patient ID from the list box by using the Up and Down arrows. Select the patient ID you wish to view and access by pressing the "√" symbol.



Choose one of the following options from the Patient Account screen:

- View the intake information by selecting the FOIS icon (Functional Oral Intake Scale).
- View the patient weight by selecting Patient Weight icon.
- View electrode placement by selecting Electrode Placement icon .

3. By using the Up and Down arrows select the treatment date of desired session you wish to view and access by pressing the "√" symbol.

4. The Treatment Summary list box will appear with detailed information about the specific treatment (below example for sEMG treatment).

5. Choose one of the following options from the Treatment Summary screen:

- Delete the treatment summary by pressing the Delete summary icon.

  A confirmation prompt will appear asking, "Are you sure you want to delete summary". Press the Yes icon to delete.
  Return to Home Screen by pressing the Home button, or press the Back arrow button to scroll back one screen at a time.

- Export therapy information to PC by pressing export to PC icon.

PATIENT DATA (CONTINUED)

A new treatment summary may be saved at the Treatment summary (completed) screen.
Complete the following steps to save the Summary:

NOTE: Treatment Summary can be saved only if the Data Password has been set. If it was not done previously, the user will be prompted to set it in order to proceed with saving or exporting to PC.

1. Press the Save Summary icon Treatment Summary screen.

2. Select the patient ID from the list box by using the Up and Down arrows icons to locate the ID or by touching the name. Select the patient ID you wish to save the summary by pressing the "√" symbol.

If there is no Patient account created for the patient press "**New Patient**" icon and type in a patient ID name , a yellow text box will appear confirming the newly saved ID name.

Define other details from the "New Patient" screen:

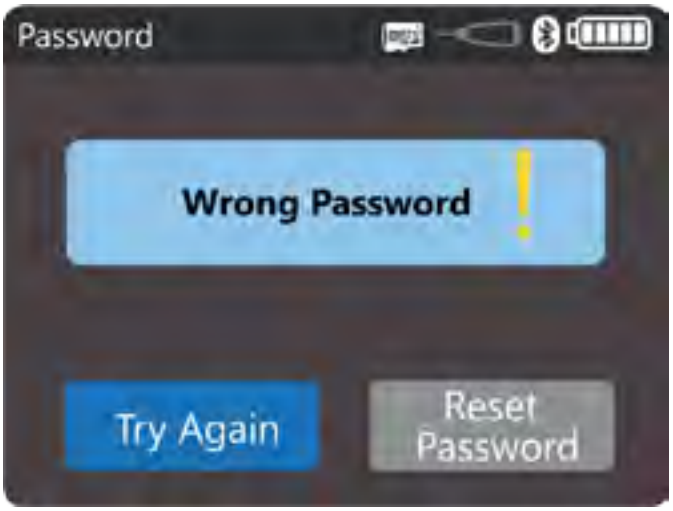
- Select level of Functional Oral Intake Scale by pressing "FOIS" icon.
- Define patient weight by pressing "patient weight "icon.
- Select specific electrode placement location by pressing "electrode placement " icon.

3. After saving the summary, you will return to Patient Data screen. Complete one of the following actions:

- Access patient data as described in previous section.
- Return to Home Screen by pressing the Home icon.

Device Password Reset

Complete the following steps to Reset your Password and access Patient Data (Note that once a password is reset, user names will change to Unknown#1, Unknown#2, Unknown#3. Original order of patient accounts will remain as-is).



1. Press the "Reset Password" button
2. Press keypad buttons in the following order: Home, STOP, Back, Ch2+, CH3-
3. Set Device Password and access Patient Data (patient names will be displayed as Unknown#1, Unknown#2, Unknown #3).

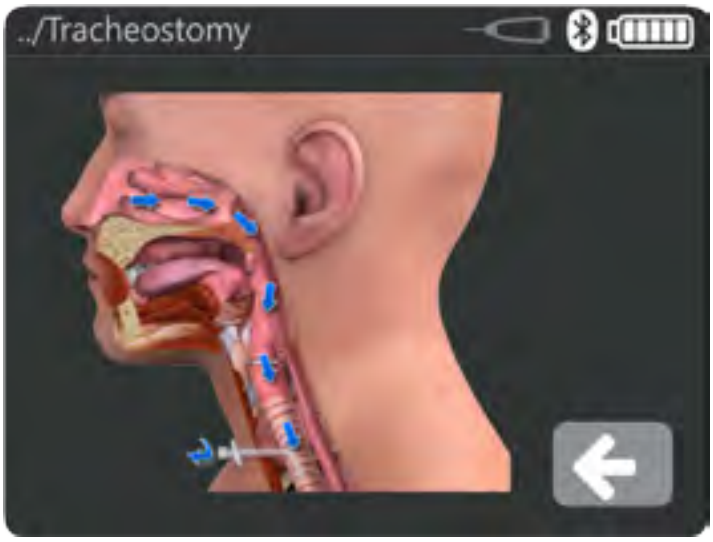
RESOURCE LIBRARY

The VitalStim® Plus Electrotherapy System contains a unique Resource Library (videos and pictures) designed to aid the operator in visually understanding and locating specific muscle groups and commonly found problems associated with pathological conditions as well as providing an educational tool for the clinician to use with the patient.

Complete the following steps to view the Anatomical Library:

1. Press the Resource Library icon on the Home screen.
2. Select Anatomical Library icon to access anatomical pictures.

- A list of related items to the body area will be displayed. Select particular item to view the graphics
- View the selected image
- Press Arrow to go back one screen



3. Select Videos icon to access tutorial videos.
4. Press the Back arrow button to scroll to the previous screen or Home button to return to the Home screen.

TROUBLESHOOTING

Problem	Probable Cause	Possible Remedies

REPLACEMENT ACCESSORIES

GENERAL ACCESSORIES	
Part Number	Description
5923-3	VITALSTIM PLUS ELECTROTHERAPY SYSTEM
25-8080	VITALSTIM PLUS SNAP LEAD WIRES
ADDITIONAL ACCESSORIES	
Model Number	Description
13-8083	VITALSTIM PLUS REFERENCE EMG LEAD WIRE
13-8085	VITALSTIM PLUS HAND SWITCH
13-8088	VITALSTIM PLUS STAND
13-8089	VITALSTIM PLUS STYLUS
13-8090	VITALSTIM PLUS RUBBER SLEEVE
13-8075	VITALSTIM PLUS BATTERY DOOR
ELECTRODES	
Model Number	Description
59000	VITALSTIM ADULT ELECTRODES, 12 PACK
59042	VITALSTIM ADULT ELECTRODES, 30 PACK
59043	VITALSTIM ADULT ELECTRODES, 50 PACK
59044	VITALSTIM ADULT ELECTRODES, 100 PACK
59005	VITALSTIM SMALL ELECTRODES, 12 PACK
13-8082	VITALSTIM PLUS REFERENCE EMG ELECTRODE

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CLEANING THE VITALSTIM® PLUS ELECTROTHERAPY SYSTEM

Clean the system with a clean, lint-free cloth moistened with water and mild antibacterial soap. If a more sterile cleaning is needed, use a cloth moistened with an antimicrobial cleaner.

Do not submerse the system in liquids. Should the unit accidentally become submersed, contact your DJO authorized distributor or DJO Service Department immediately. Do not attempt to use a system that has been wet inside until inspected and tested by a Trained Technician.

Cleaning the LCD Screen

Clean the Therapy System LCD screen with a clean, dry cloth, in the same way as cleaning the Computer Monitor Screen. Do not use abrasive materials or chemicals or liquids.

CALIBRATION REQUIREMENTS

No re-calibration or periodic maintenance is required for the unit. Its characteristic do not vary under normal conditions.

NOTE: The unit was calibrated during the manufacturing process and is ready to be placed into service upon delivery.

EXPECTED DEVICE LIVE AND DISPOSAL

The VitalStim® Plus Electrotherapy System is expected to provide at least five years of normal use.

Council Directive 2012/19/EU concerning Waste Electrical and Electronic Equipment (WEEE) requires not to dispose of WEEE as municipal waste. Contact your local distributor for information regarding disposal of the unit and accessories.

INSTRUCTION FOR SOFTWARE UPGRADE

1. Obtain a Micro SD card with upgrade file in root directory.

2. Insert the Micro SD card into the device SD port (card contacts facing upwards) and power On the unit. Allow the upgrade to complete.

3. Remove the card and restart the device while holding the concealed button in the battery compartment as shown on page 8.
   Allow the final stage upgrade to complete.

COPY OF MANUAL

To obtain a copy of the VitalStim Plus Electrotherapy System User Manual, Part Number: 13-0892 , contact VitalStim Customer Care at: 1-800-506-1130 Fax to: 1-800-896-1798

WARRANTY REPAIR/OUT-OF-WARRANTY REPAIR

SERVICE

When the VitalStim® Plus Electrotherapy System or any of the accessory modules require service, contact the selling dealer or DJO Service Department.

All Therapy Systems and accessory modules returned to the factory for service must include the following:

1. Written statement containing the following information:
    - RA Number – Obtain from DJO
    - Therapy System or Module Model Number
    - Therapy System or Module Serial Number
    - Contact Person with Phone and Fax Numbers
    - Billing Address (for out-of-warranty Repair)
    - Shipping Address (Where to Ship Unit after Repair)
    - Detailed Description of Problem or Symptoms

2. Copy of original invoice issued at purchase of the Therapy System or Module

3. Ship the unit to address specified by an authorized Service Technician

Service to these units should be performed only by a service technician certified by the Company.

Through the purchase of a Service Manual, DJO, LLC has made available circuit diagrams, component part lists, descriptors, or other information, which will assist authorized technical personnel to repair those parts of the equipment which are designated by DJO, LLC as repairable.

WARRANTY

DJO, LLC ("Company") warrants that the VitalStim® Plus Electrotherapy System is free of defects in material and workmanship. This warranty shall remain in effect for two years (24 months) from the date of original consumer purchase. If these Products fail to function during the two year warranty period due to a defect in material or workmanship, at the Company's option, Company or the selling dealer will repair or replace the respective Product without charge within a period of thirty (30) days from the date on which the Product is returned to the Company or the dealer.

All repairs to the Product must be performed by a service center authorized by the Company. Any modifications or repairs performed by unauthorized centers or groups will void this warranty.

To participate in warranty coverage, this Product's warranty registration card (included with Product) must be filled out and returned to the Company by the original owner within ten (10) business days of purchase.

This Warranty Does Not Cover:

- Replacement parts or labor furnished by anyone other than the Company, the selling dealer or a Company service technician
- Defects or damage caused by labor furnished by someone other than Company, the selling dealer or a Company service technician
- Any malfunction or failure in the Product caused by product misuse, including, but not limited to, the failure to provide reasonable and required maintenance or any use that is inconsistent with the Product User's Manual

COMPANY SHALL NOT BE LIABLE IN ANY EVENT FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES.

Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

To Obtain Service From Company or the selling dealer under this warranty:

1. A written claim must be made within the warranty period to the Company or the selling dealer. Written claims made to the Company should be sent to:

DJO, LLC
1430 Decision Street
Vista, CA 92081-8553 USA
T: 1-800-592-7329 USA
F: 1-760-734-5608

and

2. The Product must be returned to the Company or the selling dealer by the owner

This warranty gives you specific legal rights and you may also have other rights which vary from location to location.

The Company does not authorize any person or representative to create for it any other obligation or liability in connection with the sale of the Product.

Any representative or agreement not contained in the warranty shall be void and of no effect.

THE FOREGOING WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

ELECTROMAGNETIC COMPATIBILITY (EMC)

The VitalStim® Plus Electrotherapy System has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices to IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

The guidelines below are intended to help promote electromagnetic compatibility (EMC) in the identified use environment for the The VitalStim® Plus Electrotherapy System.

- **Make use of available resources** such as EMC professionals and publications and Internet web pages on the subject of medical device EMC;
- **Assess** the electromagnetic environment of the facility (e.g., identify radio transmitters in around the facility) and identify areas where critical medical devices are used;
- **Manage** the electromagnetic environment, RF transmitters and all electrical and electronic equipment, including medical devices, to reduce the risk of medical device electromagnetic interference (EMI) and achieve EMC;
- **Coordinate** the purchase, installation, service, and management of all electrical and electronic equipment used in the facility to achieve EMC;
- **Educate** healthcare facility staff, contractors, visitors, and patients about EMC and EMI and how they can recognize medical device EMI and help minimize associated risks;
- **Establish and implement written policies and procedures** that document the intentions and methods of the healthcare institution for reducing the risk of medical device EMI and achieving EMC;
- **Report** EMI problems to the US FDA MedWatch program and communicate EMI/EMC experiences to colleagues in open forums such as medical/technical publications and conferences.

More information is contained within a comprehensive guidance document for EMC in healthcare facilities, developed, with FDA participation, by the Association for the Advancement of Medical Instrumentation (AAMI): **Technical Information Report (TIR) 18, Guidance on Electromagnetic Compatibility of Medical Devices for Clinical/Biomedical Engineers. AAMI TIR 18-1997. Arlington, Virginia: Association for the Advancement of Medical Instrumentation; 1997**.

Caution:
Medical electrical equipment requires special precautions regarding EMC and must be installed and operated according to these instructions. It is possible that high levels of radiated or conducted radio-frequency electromagnetic interference (EMI) from portable and mobile RF communications equipment or other strong or nearby radio-frequency sources, could result in performance disruption of the EMG -too close to mobile phones or noisy computer chargers may result in higher EMG reading. If this occurs, survey the site of disruption, and take the following actions to eliminate the source(s).

- Turn equipment in the vicinity off and on to isolate disruptive equipment.
- Relocate or re-orient interfering equipment.
- Increase distance between interfering equipment and your VitalStim® Plus device.
- Remove devices that are highly susceptible to EMI.
- Lower power from internal sources within the facility control (such as paging systems).
- Label devices susceptible to EMI.
- Educate clinical staff to recognize potential EMI-related problems.
- Eliminate or reduce EMI with technical solutions (such as shielding).
- Restrict use of personal communicators (cell phones, computers) in areas with devices susceptible to EMI.
- Share relevant EMI information with others, particularly when evaluating new equipment purchases which may generate EMI.
- Purchase medical devices that comply with IEC 60601-1-2 EMC Standards (3V/meter EMI immunity, limit interference level to 0.0014 V/meter).

ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The VitalStim® Plus Electrotherapy System is intended for use in the electromagnetic environment deified below. The customer or the user of the VitalStim® Plus Electrotherapy System should assure that it is used in such an environment		
Emissions Tests	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The VitalStim® Plus Electrotherapy System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	VitalStim® Plus Electrotherapy System is suitable for use in all establishments , including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Not Applicable - Battery powered	
Voltage fluctuations IEC 61000-3-3	Not Applicable - Battery powered	

ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The VitalStim® Plus Electrotherapy System is intended for use in the electromagnetic environment specified below. The customer or the user of the VitalStim® Plus Electrotherapy System should assure that it is used in such an environment			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Risk assessment on the VitalStim® Plus Electrotherapy System indicates the compliance levels claimed are acceptable when ESD-precautionary measures are taken.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	Not Applicable - Battery powered Not Applicable - signal lines less then 3 meters	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+ 1kV differential mode (line to line) + 2kV common mode (line to ground)	Not Applicable - Battery powered	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Not Applicable - Battery powered	Mains power quality should be that of a typical commercial or hospital environment. If the user of the VitalStim® Plus Electrotherapy System requires continued operation during power mains interruptions, it is recommended that the VitalStim® Plus Electrotherapy System be powered from an uninterrupted power supply.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The VitalStim® Plus Electrotherapy System is intended for use in the electromagnetic environment deified below. The customer or the user of the VitalStim® Plus Electrotherapy System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	[V_1] V, where V_1 = 3V	Portable and mobile RF communications equipment should be used no closer to any part of the VitalStim® Plus Electrotherapy System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	[E_1] V/m, where E_1 = 3V/m	$d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the VitalStim® Plus Electrotherapy System is used exceeds the applicable RF compliance level above, the VitalStim® Plus Electrotherapy System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the VitalStim® Plus Electrotherapy System .

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.

ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES

Recommended separation distances between portable and mobile RF communications equipment and the VitalStim® Plus Electrotherapy System

The VitalStim® Plus Electrotherapy System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the VitalStim® Plus Electrotherapy System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VitalStim® Plus Electrotherapy System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter P **(W)**	**Separation distance according to frequency of transmitter** d (m)		
	150 kHz to 80 MHz $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ (where V_1 = 3V)	**80 MHz to 800 MHz** $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ (where E_1 = 3V/m)	**800 MHz to 2,5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ (where E_1 = 3V/m)
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

FCC REQUIREMENTS

Part 15 of the FCC Requirements	
This device complies with Part 15 of the FCC Rules. Operation is subject to the following 2 conditions:	• This device may not cause harmful interference • This device must accept any interference received, including the interference that may cause undesired operation.
FCC ID	T9J-RN42
Contains Transmitter Module IC	6514A-RN42

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User Manual
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