chattanooga®

VitalStim®Plus

Four Channel Electrotherapy System

QuickStart Guide

Rx only

DESCRIPTION OF THE STIMULATOR

Note: You are strongly advised to carefully read the safety precautions and contraindications described in this Quick Start Guide prior to using your VitalStim Plus Electrotherapy System.

VitalStim Plus users are advised to review the User Manual, which is available on the provided USB stick and at

http://www.djoglobal.com/vitalstim

To order a hardcopy of the User Manual at no charge, please contact:

Customer Service

Toll Free: 1-866-512-2764
Part number: 13-0892

⚠ 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.

⚠ 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.

⚠ CAUTION

- 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 of 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.

⚠ CAUTION

- 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.
- 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.

⚠ WARNING

- 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.

- 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

- 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.
- 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.

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 

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 

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

Do not dispose in normal dustbin 

ELECTROTHERAPY, sEMG+VMS 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; iatrogenic 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

Cautions and Contraindications

- 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

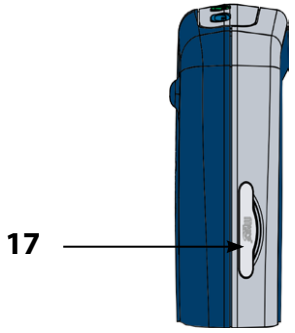
Adverse Effects

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

OPERATOR INTERFACE

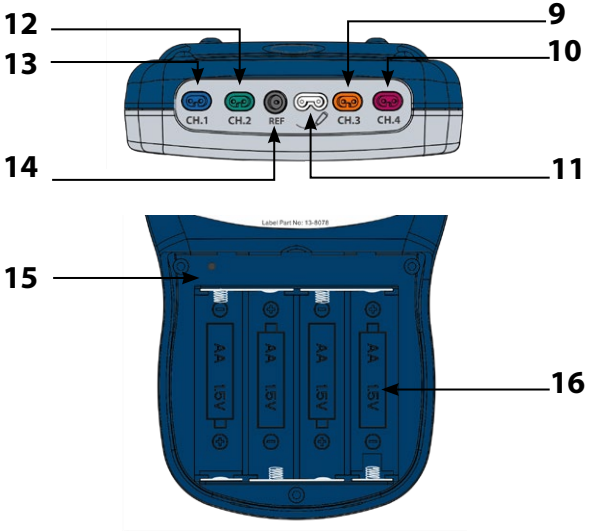
1. Color Display
2. BACK button
3. HOME button
4. Clinical Resource Library button
5. ON/OFF button
6. STOP button
7. START/PAUSE button
8. Ch1, Ch2, Ch3, Ch4 intensity buttons
9. Ch3 Lead Wire Connector (STIM)
10. Ch4 Lead Wire Connector (STIM)
11. Operator Remote Switch Connector
12. Ch2 Lead Wire 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

Micro SD card slot



Front Controls

Front Panel and Battery Compartment



COMPONENTS

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

Stand

Rubber Sleeve

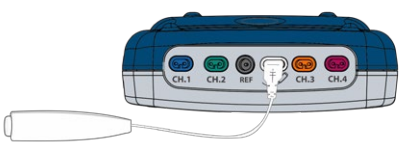
Lead wires

Lead wire Clips (attached to lead wire)

Operator Remote Switch

OPERATOR REMOTE SWITCH

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



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.

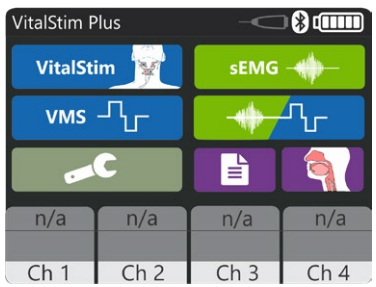
⚠ CAUTION

- 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, place back the cover.
2. Press the ON/OFF button located on the front of the device:
3. Select desired function on the Home Screen (shown below).



SCREEN DESCRIPTION

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

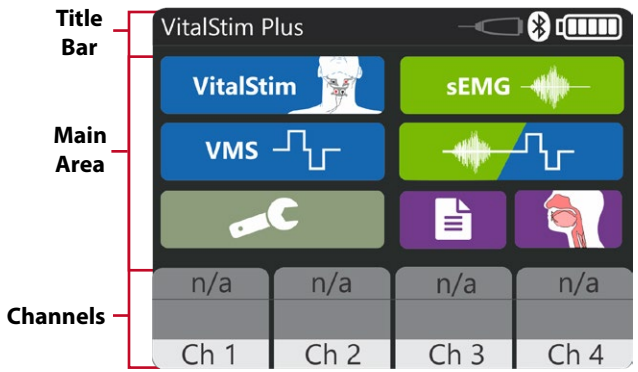
Available: Indicates the channel is available for use

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

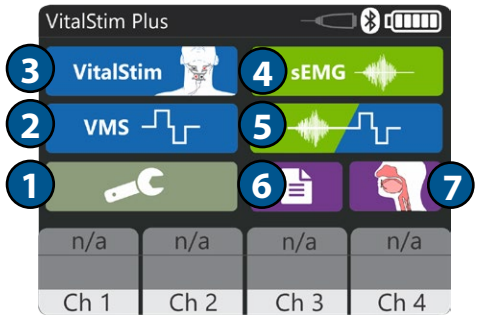
The image below shows the Home screen with modality and resource icons.



HOME SCREEN

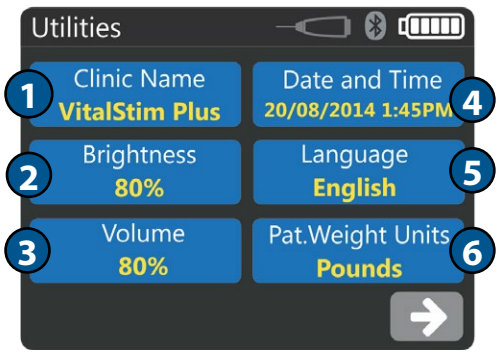
Modality Icons:

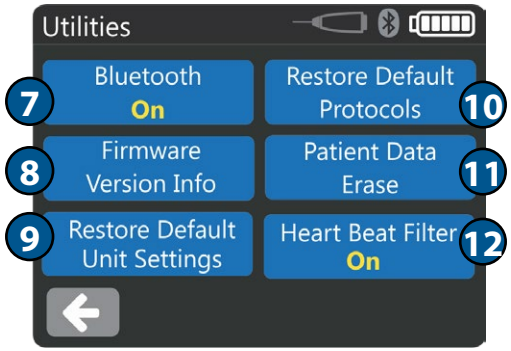
1) Utilities
2) VMS
3) VitalStim
4) sEMG
5) sEMG+VMS
6) Patient Data
7) Anatomical Library



UTILITIES AND OPTIONS

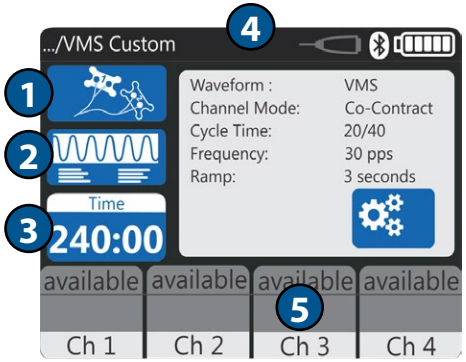
The Utilities icon on the Home screen offers users the opportunity to set the following preferences:

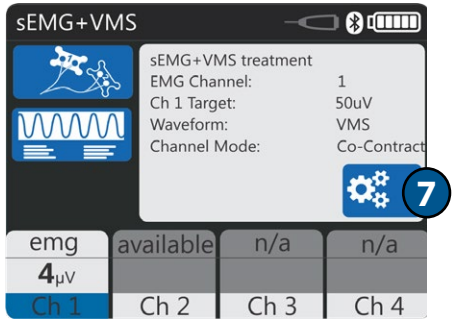


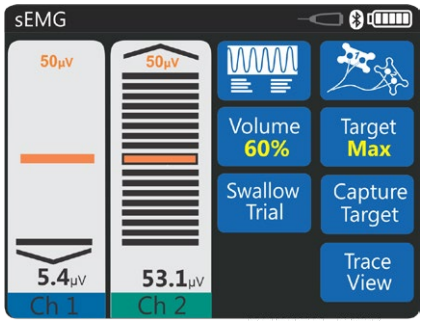


1. **Clinic Name**
   Select the <**Clinic Name**> icon to enter the name of your clinic.
2. **LCD Brightness**
3. **Volume**
4. **Date and Time**
5. **Language**
6. **Patient Weight Units**
7. **Bluetooth**
8. **Display Unit Version Information**
9. **Restore Default Unit Settings**
   Select the **<Restore Default Unit Settings>** icon to reset all the settings back to their factory defaults:
10. **Restore Default Protocols**
    Select the **<Restore Default Protocols>** icon to reset all protocols to their factory defaults.
11. **Patient Data Erase**
    Select the **<Patient Data Erase>** icon to erase entire Patient Data from Micro 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.

TREATMENT SCREENS



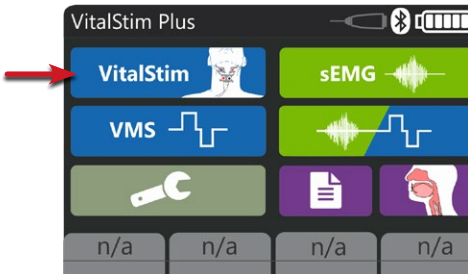




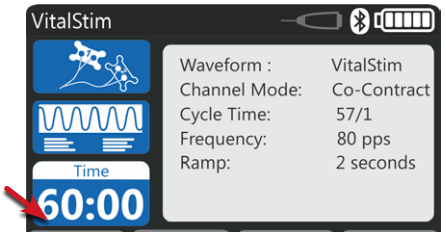
1. **Electrode Placement Icon**
2. **Modality Description Icon**
3. **Time Icon**
   Press the Time icon to adjust therapy time/duration.
4. **Remote Icon**
   Changes color to white when Remote Control is inserted and to blue when Remote button is pressed and current is being delivered.
5. **4 Channel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

VITALSTIM TREATMENT

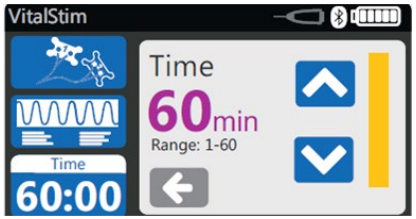
1) Insert leadwire connectors for Channel 1 (CH1) and/or Channel 2 (CH2), Channel (CH3) and Channel 4 (CH4)
2) After electrodes are placed on the patient, press the ON/OFF button once to turn on the device.
3) Select the VitalStim button from the Home Screen to access the VitalStim treatment.



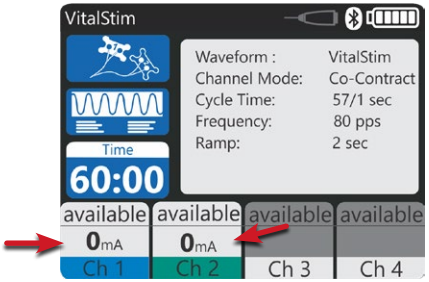
4) Press the Time button to select treatment time.



5) Increase or decrease the treatment time as prescribed and select the check mark button.



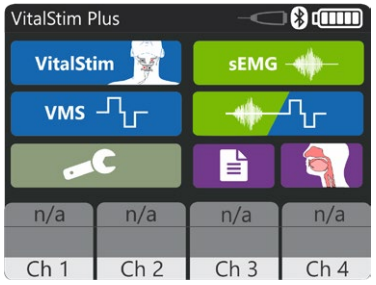
6) Press Channel (CH1), Channel 2 (CH2), Channel 3 (CH3) or Channel 4 (CH4) on the touch screen to activate desired channels.



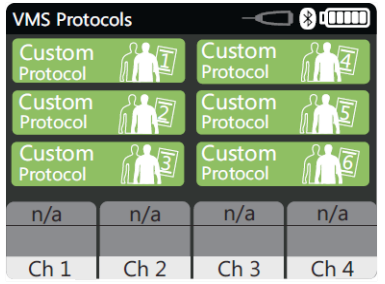
7) Set the appropriate level of intensity by using the (+) and (-) buttons for each channel and the treatment will start. Set the intensity level for each channel individually.

VMS TREATMENT

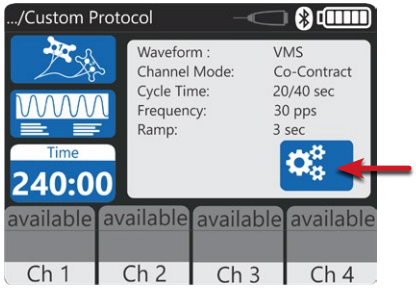
1) After electrodes are placed on the patient, press the VMS Button to access the VMS treatment



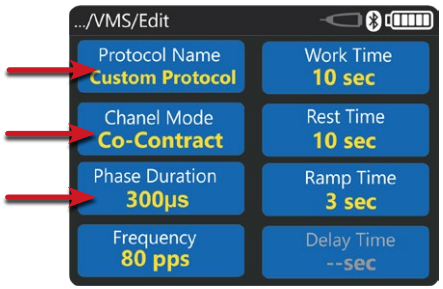
2) Select the Custom Protocol Button.



3) Select the Customize Parameters Button



4) Press each Button to adjust and customize parameters.



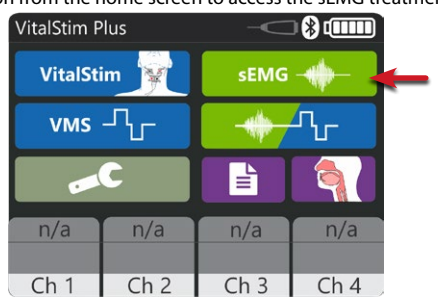
5) Press Channel (CH1), Channel 2 (CH2), Channel 3 (CH3) or Channel 4 (CH4) on the touch screen to activate desired channels.

6) Set the appropriate level of intensity by using the (+) and (-) buttons for each channel and the treatment will start. Set the intensity level for each channel individually.

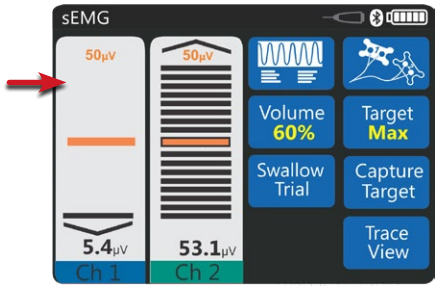
SURFACE EMG

1) Insert leadwire connectors for Channel 1 (CH1) or Channel 1(CH1) and Channel 2 (CH2) and the white reference lead wire into the top of the device
Note : Always use at least Channel 1 when using sEMG or sEMG+VMS (Channel 2 cannot be used alone).

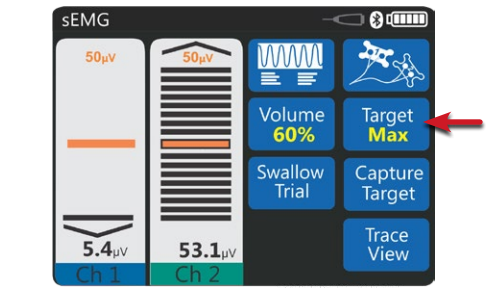
2) After electrodes are placed on the patient, select the sEMG button from the home screen to access the sEMG treatment.



3) Press the prescribed Channel 1 (CH1) or Channel 1 and 2 (CH1 and CH2) button on the touch screen to activate desired channels.

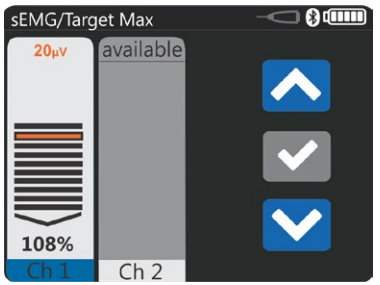


4) Select the Target Button to select the method of target acquisition (Max or Manual).



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).

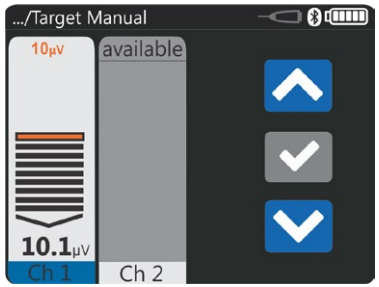
NOTE: The capture may be stopped by pressing the End Capture Button. Once the maximum target value is captured, the device switches to the screen which allows manual adjustment. Use the Up and Down Arrow buttons to adjust the Target percentage displayed at the bottom channel column. Press the Select button to set the Target.



5) Setting Manual Target

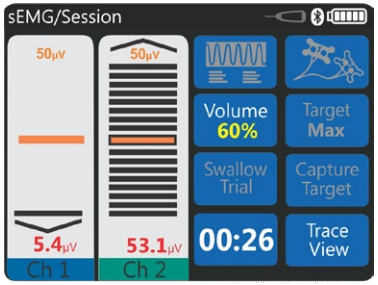
Make certain Target "Manual" is displayed in the Target icon. Press the "adjust target" button to switch to manual adjustment screen

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.



6) 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.



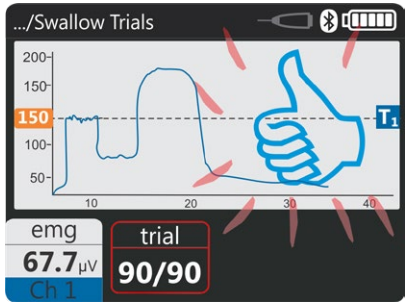
7) Swallow Trials monitors and displays the number of successful swallows a patient has performed. Press the Swallow Trials button. Select the desired number of successful swallows during treatment.

Select the desired Hold time which is the time required for patient to hold above the threshold to score a successful trial.

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.

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.

8) sEMG Session

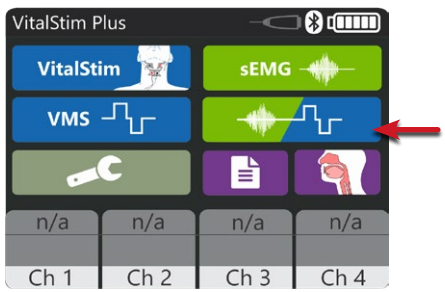
When treatment has completed, the Treatment Summary screen will appear with the following option: .

- Save Summary - the data will be saved to the SD card (If inserted)

sEMG+VMS

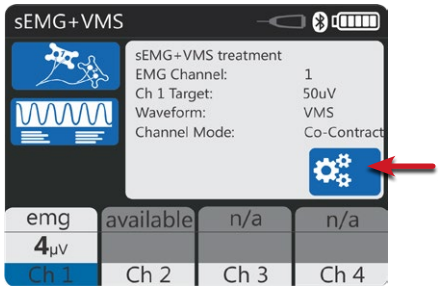
1) Insert leadwire connectors for Channel 1 (CH1), Channel 2 (CH2) and the white reference lead wire into the top of the device.

2) After electrodes are placed on the patient, select the sEMG + VMS button from the home screen to access the sEMG treatment.

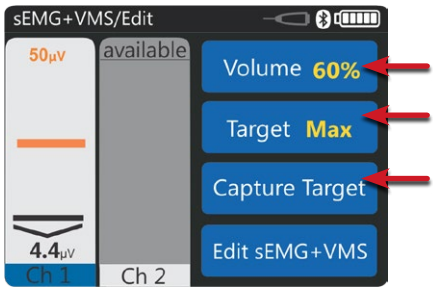


3) Press the prescribed channel icon to activate or deactivate sEMG Ch2 (sEMG Ch1 as a triggering channel has to be active).

Select the Customize icon.

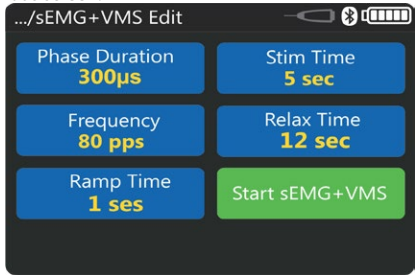


The following options are available under the Customize Treatment screen

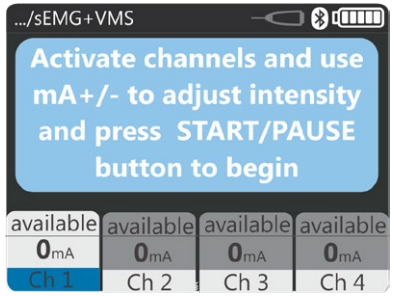


- Volume
- Target ,adjustable only for Channel 1
- Capture (or Adjust) target

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.

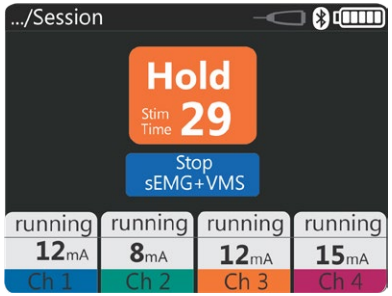


4) Press Start/Pause button (or Start sEMG+VMS icon in Edit sEMG+VMS menu) to begin therapy.
Session starts with prompt to activate and adjust mA level of the Stimulation channels

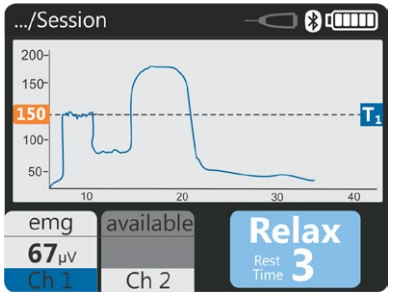


"Contract" - Instructs the patient to attempt to reach the Target Threshold. "Contract" remains on the screen until the patient's sEMG output reaches the Target Threshold, at which time Electrical Stimulation is delivered.

"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 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).



5) Press the Start /Pause button to pause treatment, or the Stop button to terminate the treatment.

VITALSTIM PLUS SHARE™

VitalStim Plus Share™ is a computer application that projects information shown in the device screen onto a computer screen via Bluetooth connection.

VitalStim Plus Share™ installation file is available for download at

http://www.djoglobal.com/vitalstim

After downloading the file open it, and follow instructions from the installer.

To use VitalStim Plus Share™ make sure your device has Bluetooth connection set to ON, located under the Utilities section of the device. Run the application and wait few seconds till Bluetooth connection between computer and the device is established.

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 sEMG 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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