

OMNIVERSA® Ultrasound / Electrotherapy System User Manual

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OMNIVERSA® Ultrasound / Electrotherapy System

ACP manufactures a premier line of rehabilitation technologies to assist health care professionals with improved outcomes and quality-of-life for Patients. The ACP product line includes Pain Control Systems, Muscle Stimulators, Interferential Therapy, Therapeutic Ultrasound, Pulsed Shortwave Diathermy devices, and advanced Therapeutic Exercise Systems. Our MEGAPULSE®, NEUROPROBE, OMNISTIM®, OMNISOUND®, OMNICYCLE®, OMNIVR®, OMNISTAND®, OMNIVERSA®, OMNISWD® and SYNCHRONY represent the most recent worldwide advances available for therapeutic application of electromedical devices and other rehabilitation technology.

ACP is internationally recognized for its contribution to research in the development of medical applications for therapeutic rehabilitation. The Company sponsors and conducts research at leading health care institutions and major universities throughout the world.

SYMBOLS ON THE PRODUCT

Symbol	Used for	Symbol	Used for
SN	Serial number	†	Type BF medical device per: IEC 60601
M	Date of manufacture		Manufacturer
\triangle	Caution, consult accompanying documents	A	Caution, electrical precautions
×	Remote Control connection	C € ₀₁₉₇	CE mark of confidence compliant to MDD (93/42/EEC)
P	Connection Electrode Cable	IP2X	Classification against intrusion of water, dust, accidental contact of a body part.
	Proper disposal required. Do not dispose of with regular household waste. Follow state and/or local regulations.	\sim	Alternating current device.
(ii)	Observe the user manual		Consult instructions for use
*	Protect the product from humidity	(1)	ON / OFF push button

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ELECTROTHERAPY INDICATIONS & CONTRAINDICATIONS

CAUTION: Federal law restricts this device for sale or use by or on the order of a Practitioner licensed by the laws of the state in which he/she practices to use or order the use of the device.

Please notice that Accelerated Care Plus cannot provide medical advice. If you have specific medical questions, please contact your healthcare professional.

Indications

The OmniVersa is indicated for:

- Relaxation of muscle spasms
- Re-education of muscle
- Prevention or retardation of disuse atrophy
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
- Increase local circulation
- Maintaining or increasing range of motion
- Symptomatic relief and management of chronic intractable pain and as an adjunctive treatment in the management of acute pain, post-surgical pain and pain associated with post-traumatic injury.

Electrical muscle stimulator devices should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

Contraindications

• Do not use this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device because this may cause electric shock, burns, electrical interference, or death.

Note:

There is no contraindication to the application of Transcutaneous Electrical Stimulation or Powered Muscle Stimulation over metal implants.

• Never connect lead wires to the power line or high frequency electro-surgery equipment. Simultaneous connection of a patient to a high frequency surgical or medical equipment and the stimulator may result in burns and possible damage to the stimulator. Use only the lead wires recommended or approved by the manufacturer

Adverse Reactions

- Skin irritation and burns, beneath the electrodes, have been reported with the use of powered muscle stimulators. Patients may experience skin irritation and burns beneath the stimulation electrodes applied to the skin.
- Patients may experience headache and other painful sensations during or following the application of electrical stimulation near the eyes and to the head and face.
- Patients should stop using the device and should consult with their physicians if they experience adverse reactions from the device.

ELECTROTHERAPY WARNINGS & PRECAUTIONS

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Please note that Accelerated Care Plus cannot provide medical advice. If you have specific medical questions, please contact your healthcare professional.

Warnings

- The long-term effects of electrical stimulation are unknown;
- Do not apply stimulation over the patient's neck because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure
- Do not apply stimulation across the patient's chest because the introduction of electrical current into the chest may cause rhythm disturbances to the patient's heart, which could be lethal. Stimulation should not be applied transthoracically in the vicinity of the heart, as introduction of electrical current into the heart may cause or increase risk of cardiac arrhythmias (e.g. fibrillation)
- Do not apply stimulation when the patient is in the bath or shower
- Do not apply stimulation while the patient is sleeping; andDo not apply stimulation while the patient is driving, operating machinery, or during any activity in which electrical stimulation can put the patient at risk of injury.
- Consult with the patient's physician before using this device because the device may cause lethal rhythm disturbances to the heart in susceptible individuals
- Apply stimulation only to normal, intact, clean, healthy skin. Make sure electrodes are not covering the mouth.
- Do not operate this device until the User Manual, including all Indications for Use, Contraindications, Warnings and Precautions, have been carefully read and understood.
- Operation of this device or placement of lead wires, probes, pads and electrodes in close proximity (less than 5 feet) to an operating shortwave or microwave diathermy unit may produce instability in the device output or burns at the treatment site. Lead wires and device can pick up the magnetic field output of the diathermy and through induction convert it into an electrical field, transmit the energy into the patient increasing the current density at the electrodes of applicators. Since the patient may not feel the 27 MHz frequency, they lack the protective sensation and tissue burns could result. Short-wave field could potentially damage or reset medical devices in close proximity to the drum applicator.
- Treatment should not be applied over the carotid sinus nerves, (located in the anterior neck triangle), including, stellate ganglion, vagus nerve, or laryngeal or pharyngeal muscle. Particular care should be taken for patients with a known sensitivity to the carotid sinus reflex, as carotid sinus stimulation may alter blood pressure and cardiac contractility.
- Do not apply treatment over testes, heart or eyes. Electrical stimulation may affect organ function.
- Do not apply over or in close proximity to active cancer (except in terminal / palliative / hospice care), as therapy may increase blood flow to the tumor.
- Treatment should not be applied when high fever is present over swollen, severe infection (osteomyelitis, sepsis, tuberculosis, etc.) or inflamed areas/skin eruptions (phlebitis, thrombophlebitis, varicose veins, etc.).
- Do not apply over the lumbar or abdominal region, or over the uterus during pregnancy (to prevent uterine contraction), or during menstruation as therapy may temporarily increase menstrual flow. Treatment should not be applied transcranially. Since the effects of stimulation of the brain are unknown, stimulation should not be applied across the head, and electrodes should not be placed on opposite sides of the head;
- Stimulation should not be applied to patients connected to patient monitoring equipment, as the stimulation may have an effect on the proper operation of the monitoring equipment.
- Stimulation should not be applied directly over external stimulator systems with lead wires
- Neuromuscular electrical stimulation (NMES) should not be applied directly over or in close proximity to Deep Vein Thrombosis (DVT), as it activates the muscle and causes muscle contractions. This should be avoided in tissue following an acute DVT when the thrombosis is not completely resolved. Therapists should follow the guidelines provided by the referring physician on recommended activity level and modality use. If the patient is not permitted exercise, NMES therapy should be avoided. Generally, NMES over a DVT of six weeks or less should be avoided altogether.

Precautions

- The safety of electrical stimulation during pregnancy has not been established;
- 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 alternate conductive medium, or alternate electrode placement.
- Application site and settings should be based on the guidance of the prescribing practitioner.
- All equipment and accessories should be kept out of the reach of children or unqualified persons.
- Do not connect this device to any wall outlet that has not been properly grounded, or to any electrically non-isolated medical device Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer. Use this device only with the leads, electrodes, and accessories recommended by the manufacturer. Use only ACP specified accessories and/or supplies with ACP devices. Do not use any power cords, or power supplies, other than the ones provided or specified for this device. Use of any other power supply could seriously damage the device and will void the warranty.
- The use of conductive mediums other than specifically approved pre-gelled or self-adhering electrodes such as ultrasound gel or lotion, hand or body lotion, electrolyte spray mist, paper towels, non-approved reusable or disposable pre-gelled or self-adhering electrodes—are contraindicated for use with OmniVersa, Omnistim Systems.
- When cleaning the device, never immerse them or wash them with water. See the infection control section in this manual for cleaning instructions. Devices should not be submerged in water or other liquids.
- Failure to follow the manufacturer's prescribed maintenance for this device may lead to device failure and transient or unreliable performance. State and federal survey and JCAHO require all equipment to be maintained and calibrated according to the manufacturer recommended schedules.
- A potential electric shock hazard exists once the device outer casing has been in part, or fully, removed. Only
 qualified service personnel should perform Service and repairs. Warranty will be voided if the outer casing has
 been removed or tampered with.
- Use caution when the patient has a tendency to bleed internally, such as following an injury or fracture. Do not apply over areas of hemorrhage or active bleeding.
- Inspect and cleanse the skin prior to application. Following treatment check the skin for evidence of irritation or burns, and if present, treat as appropriate. If the patient has, or complains of, skin irritation following treatment; shorten the treatment time on the next treatment session, or use an alternative type of therapy or electrode placement.
- Gradually increase the output intensity/power to required dose or patient tolerance while monitoring the device display.
- Caution should be taken with patient exhibiting psychological or physical hypersensitivity to the therapeutic
 treatment. Several attempts should be made to place them at ease so that their confidence and cooperation can be
 gained during the treatment.
- The treatment area should be checked from time to time, and if there is evidence of, or if the patient complains of, pain during treatment, adjust the output downward until it is tolerated by the patient. If the patient continues to complain of pain, discontinue the treatment and shorten the treatment time on the next treatment session, or use an alternative type of therapy or electrode placement.
- Do not apply treatment directly over/under hot or cold packs. Caution is recommended when treatment follows the application of hot or cold therapy, which may alter the patient's sensation. Application of thermal agents over areas of impaired circulation should be performed with caution as the circulation may be insufficient to heat or cool the tissue, altering the patient's perception of warmth and pain, and burns or tissue necrosis may result from subsequent treatment.
- Caution is recommended when treatment follows the application of medicated patches, salves, or creams which may alter the patient's sensation. If there is a medical necessity to perform such treatments, these patients should be monitored diligently during application. The effect of electrical stimulation may be altered by the presence of these materials on the patient's skin.

- Caution should be used over areas of body where circulation is impaired, or which lack normal sensation. Absent
 or diminished sensation should be avoided or, if unavoidable, treated with caution. Establishment of acceptable
 intensity levels for desensitized areas may be related to the intensity levels tolerated on normal skin in opposite
 or related body parts.
- Caution should be used in the presence of recent surgical procedures, fractures or healing bone and soft tissue when muscle contraction may disrupt the healing process.
- Caution should be used for patients with suspected or diagnosed epilepsy. Patients with suspected or diagnosed epilepsy should follow precautions recommended by their physicians.
- Electrodes should not be placed in direct contact or in close proximity (one inch or less) of each other during treatment. Electrodes placed in contact or in close proximity can lead to high energy density and skin burns under or between the electrodes.
- Care should be used when removing electrodes after treatment, in order to minimize the potential for skin tearing. Skin should be inspected after removal of electrodes for any signs of tearing or irritation.
- Do not connect the stimulator to any electrical equipment for combination therapy except the Omnisound® family
 of ultrasounds.

THE OMNIVERSA Delivery of the OmniVersa

Upon receipt of your OmniVersa, inspect the shipping container and contents for any obvious or concealed damage. All ACP products are packaged carefully, for rapid safe delivery. We guarantee delivery in perfect condition to the postal or delivery services. However, any damage or loss incurred during transportation or delivery is the postal or delivery company responsibility. If damage or loss to the product and/or container is obvious or suspected, appropriate notation must be made on the signed freight bill at the time of delivery. All damage claims should be promptly filed with the delivering carrier and must be initiated by the addressee where the package was to be delivered. Retain the original shipping container and inserts for validation of damage claim or use at a later date.

Unpack and check all accessories. A list of enclosed accessories is provided with each unit to assist you in identification of the type and number of accessories.

Note:

The purpose of this manual is to acquaint you with the OmniVersa operating features and functionality. Please read the manual carefully before attempting to operate the OmniVersa. If questions remain unanswered, contact your ACP sales representative or call 800-350-1100. Outside the USA call 1-775-685-4000.

Introduction

The OmniVersa is a Multi-Modality therapy system that integrates electrotherapy, ultrasound and combination therapy into one system. The electrotherapy is equipped with two identical electrotherapy channels. The electrotherapy channels can be used in combination (linked) or independent. A comprehensive set of current waveforms is available, targeting both pain management and muscle stimulation applications. Protocol driven operation is available, providing both factory and/or user defined sequences of treatment steps. Protocols can run on linked or independent channels. With independent channels two different protocols can be performed simultaneously.

The OmniVersa ultrasound therapy section provides two positions for attachment of an ultrasound applicator. Depending on the device configuration ordered, the Omnisound® Professional comes with an applicator with a large contact area, an applicator with a small contact area or with both applicators. The applicators can operate in continuous or pulsed mode at an ultrasound frequency of 1 MHz or 3 MHz and are suitable for underwater treatments.

The OmniVersa can be operated as a combination device, combining the functions of the OmniVersa and the Omnisound Pro in a single device when the Omnisound transducers are added to the system. With the OmniVersa the simultaneous application of ultrasound and electrotherapy (combination therapy) is also possible. The remaining electrotherapy channel can then be used independently.

The OmniVersa is designed to provide Interferential Current Therapy (IFC), Medium Frequency Alternating Currents (MFAC), Low Voltage Pulsed Current (LVPC), High Voltage Pulsed Current Therapy (HVPC), and Patterned Electrical Neuromuscular Stimulation (PENS), which is a form of stimulation that replicates the correct firing patterns of muscles (agonist and antagonist or reciprocal muscle pairs) in Triphasic (ballistic), biphasic (reciprocal), or functional patterns.

In Interferential and MFAC modes two separate generators produce medium frequency (2000, to 10,000 Hz) alternating current in continuous or burst modulated modes. Two isolated output circuits with independent intensity controls are provided. The output of each circuit is easily determined in milliamps through the display screen. The digital timer allows the operator to select the length of the total treatment time and to monitor the time remaining in minutes.

The OmniVersa offers Full Field (Premodulated) Interferential Current Therapy. An interferential vector scanning mode can be turned off or on for stationary or continuous movement of the interferential field.

The OmniVersa provides MFAC and LVPC modes with fully adjustable ON and OFF Times and ON and OFF Ramps provides a wide variety of uses for neuro-muscular re-education, treatment of muscle disuse atrophy and muscle spasm reduction programs for innervated muscle.

The OmniVersa provides High Voltage Pulsed Current (HVPC) on two channels. Continuous or surged operation with fully adjustable ON and OFF times and ramps allow applications of HVPC therapy. Increasing circulation, pain control and neuro-muscular re-education can be set up in this mode.

The OmniVersa provides Patterned Electrical Neuromuscular Stimulation (PENS) EMG based function patterns adjustable timing and ramps allow applications of PENS therapy neuro-muscular re-education, treatment of muscle disuse atrophy and muscle spasm reduction programs for innervated muscle.



A - MAIN TOUCHSCREEN DISPLAY: **E - OUTPUT CHANNEL B:** Electrotherapy channel Choose between Electrotherapy, Ultrasound Therapy, or Combination Therapy The Electrotherapy menu provides access to ways to F - OUTPUT CHANNEL C: navigate. Options include Indications, Manual mode Multifunction connection used for Ultrasound Applicators or Favorites. The Indications menu provides a listing of Clinical **G - OUTPUT CHANNEL D:** Indications and grouping of protocols to select from. Multifunction connection used for Ultrasound Applicators The Manual Mode menu provides a listing of all the clinical waveforms found within the OmniVersa. **H - POWER LED INDICATOR:** The Favorites menu is a provides access to custom protocols Green: Device plugged in and battery is charging programmed by the therapist Orange: Device is operating on battery **B - MAIN POWER SWITCH: (backside of unit)** I - Therapist Remote Control Mains power supply ON and OFF switch. Multifunction remote for use in hand control protocols **C - ROTARY SELECTOR DIAL:** J - 0.8cm² Transducer This is used to increase or decrease outputs, move between Optional transducer for use with the OmniVersa systems selection menus, and maneuver within the graphic user **D - OUTPUT CHANNEL A:** K - 5cm² Transducer Electrotherapy channel Standard transducer for use with the OmniVersa systems

OmniVersa Controls and Functions (cont.)



I - POWER CORD INLET:

Connect power cord here

J - MAIN POWER SWITCH:

Used to power unit ON-and-OFF

K - LCD DISPLAY POWER SWITCH (Orange push button):

Used to turn on and off the LCD touchscreen display

L - USB PORT:

This connection has two functions:

- Attach authorized remote controls only. There are two authorized types of remote controls, the OmniVersa Patient Safety Switch and the OmniVersa Clinician Hand Control.
- Attachment of a USB-stick used for backing up and restoring Favorite programs and by ACP employees for software updates

! CAUTION:

the safety of the patient

WARNING:

The supply current of this connection is limited to 100 mA. Do not connect USB mass storage devices such as USB powered hard disks, as this might result in data loss. Only authorized remote controls and USB-sticks are allowed.

Do not connect externally powered USB devices or other information technology equipment as this can adversely affect



Main Power Switch ON and Off Position

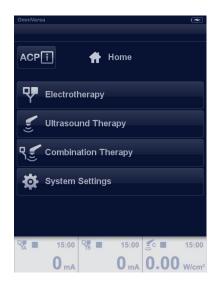
- ON Position In this position and the unit plugged into an outlet the Power LED is GREEN and the OmniVersa is operating on mains power. The OmniVersa Main Power Switch should always be in the ON position as it will keep the internal battery at an optimum level of charge.
- OFF Position In this position even if the unit is plugged into an outlet the Power LED is ORANGE and the OmniVersa is operating on battery power.
- NOTE: If the Main Power Switch is turned to the OFF position during a therapy session the system will continue to operate under battery power. The current will continue to flow through the patient and potentially through the therapist should they try to remove the electrodes.

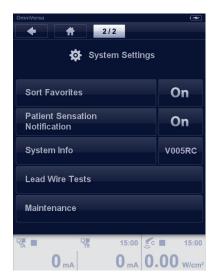
Factory Settings

The OmniVersa comes with the following factory settings:

Screen Brightness	100%
Speaker Volume	100%
Sleep Mode	3 min.
End of Treatment Tone	5
End of Treatment – Duration	5

These default settings are generally suitable for most clinicians. To adjust these default settings, proceed as follows:





- 1. From the Home screen select "System Settings" using the touch screen. You will then be able to adjust the factory settings.
- 2. Settings can be changed by selecting the current value and use the dial to scroll through the available choices. Select another setting using the touch screen to lock in the selected value.
- 3. The new settings will be saved as long as the battery is charged.

Note:

The above settings cannot be accessed during operation and are only available following the startup screen.





The OmniVersa Boot-up Check

Upon power up the OmniVersa checks the integrity of Internal storage, Graphic display, Electrotherapy module and internal Temperature to be sure all items are running optimally. If any of these items are not within calibration an Error Code would appear.

Note: The clicking sound heard at system boot-up is the software checking the internal relays of the electrotherapy waveforms.

Installation

Connection to mains supply

• Insert the mains power cable into socket and connect it to a wall socket

CAUTION: Do not place the device in a location where the power cord could be tripped over or pulled out during treatment. Do not connect this device to any wall outlet that has not been properly grounded, or to any electrically non-isolated medical device.

Use only ACP specified accessories and/or supplies with ACP devices. Do not use any power cords, or power supplies, other than the ones provided or specified for this device. Use of any other power supply could seriously damage the device and will void the warranty.

- Turn on the power line switch located above the power cord inlet.
- Power LED indicator is lit green indicating that the device is connected to the mains supply.
- Turn on the device with the orange push button located at the top of the unit next to the USB port.
- The device will initialize and perform a self-test. Allow the device a minute or so to start up.
- At the end of the self-test the device enters the Home menu and is ready for use.

Disconnection from mains supply

- Turn off the device with orange push button located at the top of the device next to the USB port.
- Power indicator LED is still lit green, indicating that the device is still connected to the mains supply and that the battery is being charged.
- Set power line switch located above the power cord to "OFF" to stop charging and to disconnect the unit from the mains supply.

Installing/Replacing the battery

- Remove the power cable from the power line inlet.
- Turn the device upside down and on a soft surface.
- Remove the two screws from the battery cover using the supplied screwdriver.
- Slide and lift the battery cover.
- Align the battery on the bottom of the main unit with the polarity of battery terminals in the correct position. The polarity is marked at the bottom of the battery compartment.
- Locate the black wire and attach it to the terminal of the battery.

CAUTION: Do not interchange the black and red wires as this will damage your device. The battery contains material that is noxious to the environment. Observe the local regulations when disposing of the battery.

- Locate the red wire and attach it to the + terminal of the battery.
- Slide the battery upside down into the battery compartment taking care that the wires do not get jammed.
- Place and slide the battery cover back into position.
- Secure the battery cover with the two screws using the supplied screwdriver.
- Place the device back on its feet.
- Reconnect the mains cable to the power line connector.

Operation from battery

- Charging: Plug in power cord. Turn ON the Power Switch (back of unit). Power LED indicator will turn green while charging. Turning orange push button ON or OFF does not affect charging.
- **Operation:** Push orange button to turn ON display.
- **ON/OFF:** To turn the device OFF in between therapy sessions, push orange button to turn OFF.
- Battery Life: Battery charge status is indicated in the top right corner of the display.

Recommendation: Keep device in charging mode when possible. This will increase the service life of the battery.

Low battery warning alerts:

Warning	Description of each Warning
Potentially insufficient power to complete an Ultrasound treatment - Recommend using Power Cord	The estimated battery power may not be sufficient to complete the selected ultrasound treatment.
Low Battery - Use Power Cord	There is insufficient battery power to complete the selected electrotherapy treatment. Suggest you connect the system to mains power to continue.
Battery Empty - Use Power Cord	When this message is displayed the battery level is critically low and the system is locked. You should connect the system to mains power and then restart.

Navigation Icons

Button	Meaning
•	Back, return to previous screen.
#	Home, return to Home screen.
i	The information button which provided access to the embedded clinical libraries.
# / n	Page number / number of pages in multi-page menu screens
	Store therapy settings or a programmed sequential protocol in a favorite.
Î	Delete Favorite.
ОК	Accept the selected protocol.
/	Accept the selected option.
	Emergency Stop. Stop treatment on all channels simultaneously.
Y _A	Run
YA II	Pause
A B	Stop
ACP	ACP Contact Information

Operational Flow

[A] DEVICE name

[B] NAVIGATION Level – On some screens a white box will display the page number and total pages of an area i.e. 1/4.

[C] BATTERY INDICATOR – Displayed as either charging or a traditional battery icon

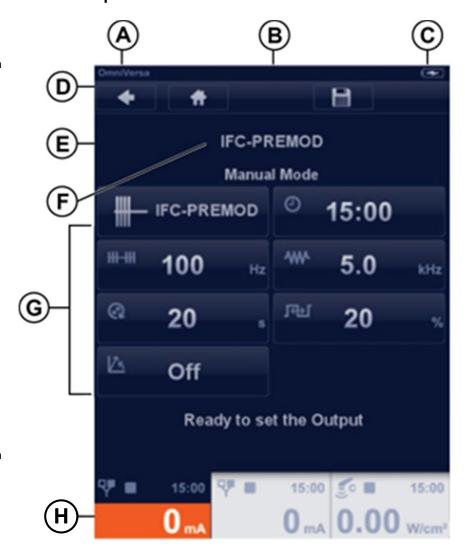
[D] NAVIGATION BAR -Provides screen dependent buttons for several functions

[E] SCREEN HEADER – Displays the name of the selected program i.e. IFC-Premed Sensory or the name of the selected electrotherapy waveform

[F] PARAMETERS - Are indicated with icons. When a parameter is selected its name appears here

[G] SCREEN BODY – Displays the parameters of a selected channel or, when no channels are selected, the menu buttons

[H] CHANNEL TAB - Used to select a channel and to display and adjust the output amplitude of that channel



The visual display is organized as a series of menus that provide access to groups of parameters for each channel. The output channels are located on the front of the unit labeled as A, B, C, and D. The menu can be selected by touching its channel tab. The channel tab [H] shows information such as the output amplitude and the remaining treatment time.

When you turn on the unit, you will first enter the Home menu. The Home menu provides access to all therapies available within the unit. To select a therapy, touch its button and navigate to its main menu. You can navigate back to the previous screen by touching the back arrow at the top of the screen. Anywhere in the navigation, you can jump back to the Home menu, by touching the home button

Electrotherapy Menu Navigation

Electrotherapy

Home

The Home menu gives access to all of the systems therapeutic modalities. Select the desired modality by touching its button.

Select "Electrotherapy" and the Electrotherapy menu appears.

Electrotherapy – Indications Operation

The Electrotherapy menu provides access to the ways you can navigate and the Electrotherapy Contraindications library.

- Indications
- Manual Mode
- Favorites
- Contraindications

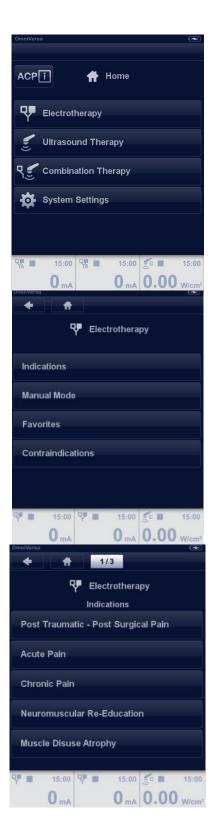
Select "Indications" by touching the button and the Electrotherapy Indications menu appears.

Electrotherapy Indications Menu

Use the Rotary Selector Dial to scroll through the list and select the indication by touching the button. The number of pages in a menu is displayed in the navigation bar i.e. 1/3.

Indications list includes the following

- Post Traumatic Post Surgical Pain
- Acute Pain
- Chronic Pain
- Neuromuscular Re-education
- Muscle Disuse Atrophy
- Functional Re-Education Upper Extremity
- Functional Re-Education Lower Extremity
- Functional Re-Education Sports
- Increase Local Circulation
- Decrease Muscle Tone Spasm
- Maintain-Increase Muscle Tone



Electrotherapy Indications Protocol List

Select the desired protocol by touching the button.

Each protocol has an embedded clinical library of reference material and a library of electrode placement illustrations accessed by touching the information button.



Electrotherapy Protocol Information

The embedded clinical library includes protocol and setup information with example electrode placement illustrations.

Use the Rotary Selector Dial to scroll through the pages.

Touch the OK button in the navigation bar to proceed to channel selection or the parameter menu.

Note:

Preset 2-channel programs will proceed to the parameter menu.

Electrotherapy Protocol Electrode Placement Illustrations

Use the Rotary Selector Dial to scroll through the illustration pages.

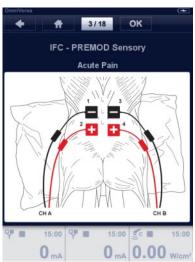
Touch the OK button in the navigation bar to proceed to channel selection or the parameter menu.

The embedded pictures have squares to represent 2" x 2" electrodes and rectangles to represent 2" x 4" electrodes, large rectangles to represent 3" x 5" electrodes.

Note:

Preset 2-channel programs (e.g. PENS) will proceed to the parameters menu.





Channel Selection

After a protocol is chosen select the channel(s) for use. When Ch. A is selected, Ch. B is still available for another therapy.

When Ch. A+B are selected both channels have the same parameters and only the intensity can be set differently.

When both channels are already activated, additional protocol parameter screens can not be selected; attempting to do so will result in a beep sound. If two different protocols have been selected one channel may still be running. Always check that the channel output on the display is zero prior to removing electrodes.

Note:

PENS will default automatically to two channel mode (A+B).



Electrotherapy Parameter Adjustment – Changing parameters

All parameter settings are changed by the same two-step process.

- 1. Select/touch the parameter which will then illuminate bright white. The example shown is Treatment Time
- 2. Changes are made using the Rotary Selector Dial. Within 12 seconds of making the change the highlighted setting will fade back to blue.

Repeat this process for all other parameters.

Note:

- To access the embedded clinical library, press the information button.
- All parameters can be changed before starting a treatment.
- Some parameters may not be changed during active treatment; attempting to do so will result in a beep sound.
- A complete list of all program settings and ranges can be found in the OmniVersa Program section of the operations manual



Setting Output Intensity

Output intensity can only be set when the selected channel tab(s) are illuminated orange. Screen text saying "Ready to set the output" appears during initial setup. As soon as intensity is increased the START start and STOP buttons appear.

Note:

- If a 2-channel application is selected to simultaneously increase the intensity of both channels, press and hold both channel tabs with your fingers until both channel tabs illuminate orange.
- Within 12 seconds after setting the desired output intensity the orange illuminated channel tab(s) fades to blue.
- If additional output adjustment is needed prior to selecting START Start, press the channel tab with your finger and it will illuminate orange.

Setting Output Intensity Simultaneously: 2 Channel Program

If a 2-channel application is selected to simultaneously increase the intensity of both channels, press and hold both channel tabs with your fingers until both channel tabs illuminate orange.





Channel A The maximum intensity for AC waveforms per electrode: size: dose: -2"x2" = 40mA -3"x5" = 100mA Please confirm you read this information. Start Stop 15:00 MA O mA

Maximum Intensity Guidelines Per Electrode Size

The maximum intensity levels for the Alternating Current (AC) waveforms including MFAC and IFC/Premod and the Low Volt Pulsed Current (LVPC) waveforms including PENS and TENS per the size of electrode used are presented at specific threshold levels as the intensity is raised.

AC current maximum intensities per electrode size:

- 2" x 2" size The recommended maximum intensity level is 40mA
- 2" x 4" size The recommended maximum intensity level is 80mA
- 3" x 5" size The recommended maximum intensity level is 100mA

LVPC current maximum intensities per electrode size:

- 2" x 2" size The recommended maximum intensity level is 80mA
- 2" x 4" size The recommended maximum intensity level is 140mA

• 3" x 5" size – The recommended maximum intensity level is 140mA

Note:

- Press the green checkmark to acknowledge the waveform dosage guideline.
- If electrode sizes other than those listed are being used, please contact ACP at 1-800-350-1110 ext. 2.

Starting and Stopping a Treatment

As soon as output intensity is increased the START and STOP buttons appear.

- To start a treatment, touch the START button. A green RUN triangle icon will appear at the top of the channel tab
- To end the treatment, touch the STOP button

Note:

- As soon as the Start button is pressed the Pause and Stop buttons appear.
- The treatment can also be stopped by pressing the emergency stop icon located on the top right of the display.

 Pressing this button stops the output on all channels in use.

Pausing a Treatment

As soon as the Start button is pressed the PAUSE and STOP buttons appear. To pause a treatment, touch the PAUSE button.

- When PAUSE Pause is selected output intensity ramps down to 0 and the START Start and STOP buttons reappear.
- A two-bar orange pause Icon will appear at the top of in the channel tab
- To resume the paused treatment, press the START button, touch the channel tab(s) to illuminate orange and reset the output intensity.
- After pressing PAUSE Pause do not remove electrodes for 3 seconds to allow any remaining capacitance to dissipate.

Note:

- To end the treatment, touch the STOP button
- The treatment can also be stopped by pressing the emergency stop icon located on the top right of the display.

 Pressing this button stops the output on all channels in use.





END OF TREATMENT: QR CODE

At the end of a treatment, a pop-up window containing a QR code with embedded device information can be scanned using the ACPlus application.

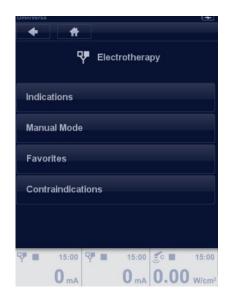


Electrotherapy – Manual Mode Operation

The Electrotherapy menu provides access to the ways you can navigate and the Electrotherapy Contraindications library.

- Indications
- Manual Mode
- Favorites
- Contraindications

Select "Manual Mode" by touching the button and the Electrotherapy Manual Mode menu appears.

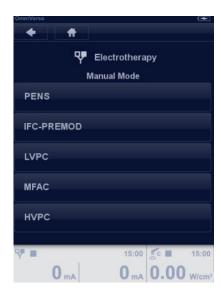


Electrotherapy Manual Mode Menu

Select the desired waveform by touching the button from the waveform list.

Note:

PENS and LVPC have a submenu of waveform programs or waveforms from which selections are made.



Channel Selection

After a waveform is chosen select the channel for use. When Ch. A is selected; Ch. B is still available for another therapy protocol.

When Ch. A+B is selected both channels have the same parameters and only the intensity can be set differently.

Note:

All PENS-programs will default automatically to two channel mode (A+B).



Electrotherapy Parameter Adjustment Changing Parameters

All parameter settings are changed by the same two-step process.

- 1. Select/touch the parameter which will then illuminate bright white. (The example shown is Treatment Time)
- 2. Changes are made using the Rotary Selector Dial. Within 12 seconds of making the change the highlighted setting will fade back to blue.

Repeat this process for all other parameters.

Note:

- All parameters can be changed before starting a treatment.
- Some parameters may not be changed during active treatment.
- A complete list of all program settings and ranges can be found in the OmniVersa Program section of the operations manual.



Setting Output Intensity

Output intensity can only be set when the selected channel tab(s) are illuminated orange.

Screen text saying "Ready to set the output" appears during initial setup.

As soon as intensity is increased the START and STOP buttons appear.

Note:

- If a 2-channel application is selected to simultaneously increase the intensity of both channels, press and hold both channel tabs with your fingers until both channel tabs illuminate orange.
- Within 12 seconds after setting the desired output intensity the orange illuminated channel tab(s) fades too blue.
- If additional output adjustment is needed prior to selecting START, press the channel tab with your finger and it will illuminate orange.

Setting Output Intensity Simultaneously: 2 Channel Program

If a 2-channel application is selected to simultaneously increase the intensity of both channels, press and hold both channel tabs with your fingers until both channel tabs illuminate orange.





Maximum Intensity Guidelines Per Electrode Size

The maximum intensity levels for the Alternating Current (AC) waveforms including MFAC and IFC/Premod and the Low Volt Pulsed Current (LVPC) waveforms including PENS and TENS per the size of electrode used are presented at specific threshold levels as the intensity is raised.

AC current maximum intensities per electrode size:

- 2" x 2" size The recommended maximum intensity level is 40mA
- 2" x 4" size The recommended maximum intensity level is 80mA
- 3" x 5" size The recommended maximum intensity level is 100mA

LVPC current maximum intensities per electrode size:



- 2" x 2" size The recommended maximum intensity level is 80mA
- 2" x 4" size The recommended maximum intensity level is 140mA
- 3" x 5" size The recommended maximum intensity level is 140mA

Note:

- Press the green checkmark to acknowledge the waveform dosage guideline.
- If electrode sizes other than those listed are being used, please contact ACP at 1-800-350-1110 ext. 2.

Starting and Stopping a Treatment

As soon as output intensity is increased the START and STOP buttons appear.

- To start a treatment, touch the START button. A green RUN triangle Icon will appear at the top of the channel tab
- To end the treatment, touch the STOP button.

Note:

- As soon as the Start button is pressed the Pause and Stop buttons appear.
- The treatment can also be stopped by pressing the emergency stop icon located on the top right of the display.

 Pressing this button stops the output on all channels in use.

Pausing a Treatment

As soon as the Start button is pressed the PAUSE pause and STOP button appear. To pause a treatment, touch the PAUSE pause button. A two-bar orange PAUSE Icon will appear at the top of in the channel tab.

- When PAUSE Pause is selected output intensity ramps down to 0 and the START Start and STOP buttons reappear.
- To resume the paused treatment, press the START button, touch the channel tab(s) to illuminate orange and reset the output intensity.
- After pressing PAUSE Pause do not remove electrodes for 3 seconds to allow any remaining capacitance to dissipate.

Note:

- To end the treatment, touch the STOP button. A red square STOP Icon will appear at the top of the channel tab.
- The treatment can also be stopped by pressing the emergency stop icon located on the top right of the display.

 Pressing this button stops the output on all channels in use.





END OF TREATMENT: QR CODE

At the end of a treatment, a pop-up window containing a QR code with embedded device information can be scanned using the ACPlus application.



Three ways to switch off the output of current flow

It is recommended that the user stop the output of current flow in one of three ways:

- 1. Pressing the Stop button on the lower right side of the display
- 2. Pressing the Emergency Stop icon on the upper right corner of the display
- 3. Pressing the orange LCD Display Power Switch on the top rear of the system.



All three ways will cause the unit to immediately switch off the output power and drain any remaining capacitance. Doing this will therefore make it impossible for the therapist to feel a shock from remaining output power.

NOTE: – If the Main Power Switch is turned to the OFF position during a therapy session the system will continue to operate under battery power. The current will continue to flow through the patient and potentially through the therapist should they try to remove the electrodes.



ULTRASOUND INDICATIONS & CONTRAINDICATIONS

CAUTION: Federal law restricts this device for sale or use by, or on the order of, a Practitioner licensed by the laws of the state in which he/she practices to use or order the use of the device.

Please notice that Accelerated Care Plus cannot provide medical advice. If you have specific medical questions, please contact your healthcare professional.

Indications

The Omnisound is indicated for:

- Relieving pain
- Decreases joint stiffness and contractures
- Reduction of muscle spasm
- Increases local circulation
- Relief of pain, muscle spasms, and joint contractures that may be associated with: adhesive capsulitis, bursitis with slight calcification, myositis, soft tissue injuries, shortened tendons due to past injuries and scar tissues
- Relief of sub-chronic, chronic pain and joint contractures resulting from: capsular tightness, capsular scaring

Contraindications

- Patients with an implanted medical device other than a pacemaker.
- Near brain, cervical ganglia, spine, laminectomy sites (can cause spinal-cord heating)
- Near the reproductive organs
- Total hip arthroplasties with methylmethacrylate or high density polyethylene
- Arthroplasties—the effect on bony ingrowth arthroplasties is not well defined; for this reason the most prudent course is avoiding ultrasonic therapy over these areas
 Note:

There is no contraindication to the application of Ultrasound over metal implants.

- Over or near bone growth centers until bone growth is complete
- Over the thoracic area if the patient is using a cardiac pacemaker
- In an area of the body where a malignancy is known to be present
- In an area of the body where infectious disease is present
- Blood vessels in poor condition should not be treated as the vessel walls may rupture as a result of the exposure
- Patients suffering from cardiac disease should not receive treatment over the cervical ganglia, the stellate
 ganglion, the thorax in the region of the heart, or the vagus nerve, as a reflex coronary vasospasm might
 result. Only low intensities and short treatment times should be used if these patients are treated in other
 areas since the stimulation of practically any afferent autonomic nerve (especially the vagus nerve) in the
 body may cause a change in cardiac rate
- Patients with thrombophlebitis or other potentially thromboembolic diseases (such as DVT) should not be treated since a partially disintegrated clot could result in an obstruction of the arterial supply to the brain, heart or lungs
- Over a healing fracture
- Over the eye
- Over the pregnant uterus
- Over ischemic tissues in individuals with vascular disease where the blood supply would be unable to follow the increase in metabolic demand
- Over areas of recent bleeding or hemorrhage
- Over areas of active tuberculosis

ULTRASOUND WARNINGS & PRECAUTIONS

CAUTION: Federal law restricts this device for sale or use by, or on the order of, a Practitioner licensed by the laws of the state in which he/she practices to use or order the use of the device.

Please notice that Accelerated Care Plus cannot provide medical advice. If you have specific medical questions, please contact your healthcare professional.

Warnings

- Do not operate this device until the User Manual, including all Indications for Use, Contraindications, Warnings
 and Precautions, have been carefully read and understood.
- Operation of this device or placement of lead wires, probes, pads and electrodes in close proximity (less than 5 feet) to an operating shortwave or microwave diathermy unit may produce instability in the device output or burns at the treatment site. Since the patient may not feel the 27 MHz frequency, they lack the protective sensation and tissue burns could result. Short-wave field could potentially damage or reset medical devices in close proximity to the drum applicator.
- Treatment should not be applied over the carotid sinus nerves, (located in the anterior neck triangle), including, stellate ganglion, vagus nerve, or laryngeal or pharyngeal muscle. Particular care should be taken for patients with a known sensitivity to the carotid sinus reflex, as carotid sinus stimulation may alter blood pressure and cardiac contractility.
- Do not apply treatment over heart. Thermal/sub-thermal treatment may affect organ function.
- Treatment should not be applied when high fever is present.
- Do not apply over the lumbar or abdominal region, or over the uterus during menstruation as therapy may temporarily increase menstrual flow.
- Treatment should not be applied directly over external stimulator systems.
- The treatment head should be moved continuously during treatment to avoid discomfort and burns.
- An appropriate coupling medium should be employed in order to ensure energy transmission to the tissue.

Precautions

- Application site and settings should be based on the guidance of the prescribing practitioner.
- All equipment and accessories should be kept out of the reach of children or unqualified persons.
- Do not connect this device to any wall outlet that has not been properly grounded, or to any electrically nonisolated medical device.
- Use only ACP specified accessories and/or supplies with ACP devices. Do not use any power cords, or power supplies, other than the ones provided or specified for this device. Use of any other power supply could seriously damage the device and will void the warranty.
- When cleaning the device, never immerse them or wash them with water. See the infection control section in this manual for cleaning instructions. Devices should not be submerged in water or other liquids.
- Failure to follow the manufacturer's prescribed maintenance for this device may lead to device failure and transient or unreliable performance. State and federal survey and JCAHO require all equipment to be maintained and calibrated according to the manufacturer recommended schedules.
- A potential electric shock hazard exists once the device outer casing has been in part, or fully, removed. Only qualified service personnel should perform Service and repairs. Warranty will be voided if the outer casing has been removed or tampered with. Inspect and cleanse the skin prior to application. Following treatment check the skin for evidence of irritation or burns, and if present, treat as appropriate. If the patient has, or complains of, skin irritation following treatment; shorten the treatment time on the next treatment session, or use an alternative type of therapy or applicator placement.
- Gradually increase the output intensity/power to required dose or patient tolerance while monitoring the device display.
- Caution should be taken with patient exhibiting psychological or physical hypersensitivity to the therapeutic
 treatment. Several attempts should be made to place them at ease so that their confidence and cooperation can be
 gained during the treatment.
- The treatment area should be checked from time to time, and if there is evidence of, or if the patient complains of, pain or overheating during treatment, adjust the output downward until it is tolerated by the patient. If the patient continues to complain of pain or overheating, discontinue the treatment and shorten the treatment time on the next treatment session, or use an alternative type of therapy or applicator placement.
- Do not apply treatment directly over/under hot or cold packs. Caution is recommended when treatment follows
 the application of hot or cold therapy, which may alter the patient's sensation. Application of thermal agents over
 areas of impaired circulation should be performed with caution as the circulation may be insufficient to heat or
 cool the tissue, altering the patient's perception of warmth and pain, and burns or tissue necrosis may result from
 subsequent treatment.
- Treatment should not follow the application of medicated patches, salves, or creams. The presence of electrical stimulation may be altered by the presence of these materials on the patient's skin. Some medications can alter the patient's sensation. Heat can also increase the absorption of medication and may be contraindicated. If there is a medical necessity to perform such treatments, these patients should be monitored diligently during application.
- Caution should be used when applying thermal ultrasound over areas of body where circulation is impaired, or
 which lack normal sensation. Absent or diminished sensation should be avoided or, if unavoidable, treated with
 caution. Establishment of acceptable intensity levels for desensitized areas may be related to the intensity levels
 tolerated on normal skin in opposite or related body parts.
- Do not connect this device to any electro medical equipment for combination therapy except the Omnistim® family of electro stimulators.
- Do not immerse any part of the operator's body into the water bath during underwater techniques since the long-term biophysical effects of ultrasonic energy exposure have not been evaluated.
- Over acute skin conditions such as eczema, dermatitis, etc.

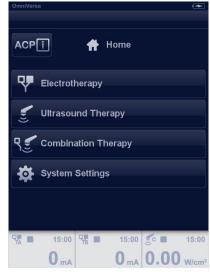
Ultrasound Menu Navigation

Ultrasound Therapy

Home

The Home menu gives access to all of the systems therapeutic modalities. Select the desired modality by touching its button.

Select "Ultrasound Therapy" and the Ultrasound Therapy menu appears.

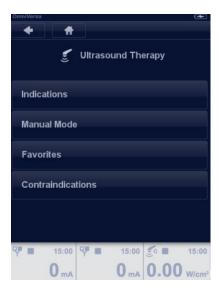


Ultrasound Home Page - Indications Operation

The Ultrasound Therapy menu provides access to the ways you can navigate and the Ultrasound Contraindications library.

- Indications
- Manual Mode
- Favorites
- Contraindications

Select "Indications" by touching the button and the Ultrasound Therapy Indications menu appears.



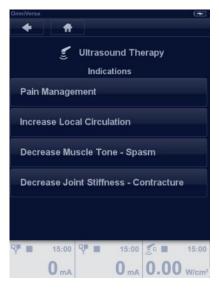
Ultrasound Indications Menu

Select the Ultrasound Therapy Indication by touching its button.

Indications include

- Pain Management
- Increase Local Circulation
- Decrease Muscle Tone Spasm
- Decrease Joint Stiffness Contracture

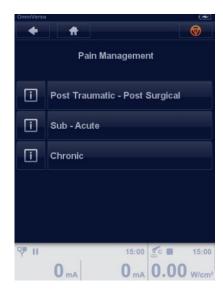
Select "Pain Management" and the Pain Management Protocol menu appears.



Ultrasound Indication Protocols Menu

All Ultrasound Indications have menu of Protocols that allow the selection of severity, Post Traumatic – Post Surgical, Sub-Acute and Chronic. Select by touching the desired button.

Each protocol has an embedded clinical library of reference material and application illustrations that are accessed by touching the information button.



Ultrasound Protocol Information

The embedded clinical library includes protocol and setup information with and example application illustrations.

Use the Rotary Selector Dial to scroll through the pages.

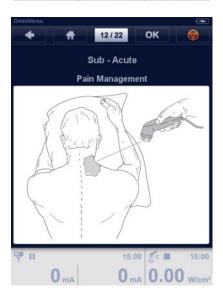
Touch the OK button in the navigation bar to proceed to the ultrasound parameters menu.

Sub - Acute Pain Management Indication: Pain Management Protocol: Sub-Acute Thermal therapeutic ultrasound maybe used to 1) heat the myoneural junction causing muscle relaxation thereby reducing muscle spasm and 2) cause vasodilation to increase local circulation and decrease pain. Ultrasound Default: 3 MHz (superficial) and 1 Delta T for mild heating and will increase tissue temperature by approximately 1 degree Celsius.

Ultrasound Protocol information – illustrations

Use the Rotary Selector Dial to scroll through the illustration pages.

Touch the OK button in the navigation bar and the ultrasound parameters menu appears.



Ultrasound Parameter Adjustment – Changing parameters

All ultrasound parameter settings are changed by the same two-step process.

- 1. Select/touch the parameter which will then illuminate bright white. (The example shown is Megahertz MHz)
- 2. Changes are made using the Rotary Selector Dial.

Repeat this process for all other parameters

Note:

- Within 12 seconds of making a parameter change the highlighted setting will fade back to blue.
- All parameters can always be changed before starting a treatment.
- Some parameters may not be changed during active treatment, attempting to do so will result in a beep.
- A complete list of all program settings and ranges can be found in the OmniVersa Program section of the operations manual.

Setting Output Intensity

Output intensity can only be set when the Ultrasound channel tab is illuminated orange.

Screen text saying "Ready to set the output" appears during initial setup.

As soon as intensity is increased the START and STOP buttons appear, and the red Stop square at the top of in the channel tab becomes the two-bar orange PAUSE Icon.

Note:

- Within 12 seconds after setting the desired output intensity the orange illuminated channel tab fades to blue.
- If additional output adjustment is needed prior to selecting START , press the channel tab with your finger and it will illuminate orange.

Starting and Stopping a Treatment

As soon as output intensity is increased, the START start and stop buttons appear.

- To start a treatment, touch the START button. A green RUN
 Triangle Icon will appear at the top of the channel tab
- To end the treatment, touch the STOP button. A red square STOP Icon will appear at the top of the channel tab.

Note:

• The treatment can also be stopped by pressing the emergency stop icon located on the top right of the display.

Pressing this button stops the output on all channels in use.







End of Treatment: QR Code

At the end of a treatment, a pop-up window containing a QR code with embedded device information can be scanned using the ACPlus application.

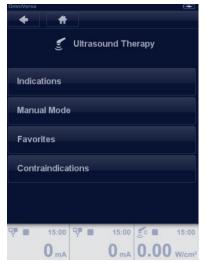


Ultrasound Home Page – Manual Mode Operation

The Ultrasound Therapy menu provides access to the ways you can navigate and the Ultrasound Contraindications library.

- Indications
- Manual Mode
- Favorites
- Contraindications

Select "Manual Mode" by touching the button and the Ultrasound Manual Mode menu appears.



Ultrasound Manual Mode Menu

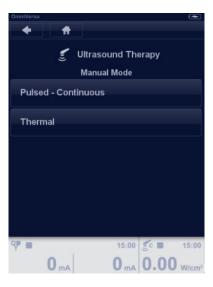
The Ultrasound Manual Mode menu gives access to the following modes of operation.

- Pulsed Continuous
- Thermal

Select "Pulsed-Continuous" by touching the button and the Ultrasound Pulsed-Continuous parameters menu appears.

Note:

- Pulsed Ultrasound Duty factor: 5, 10, 20, 25, 33 or 50% Pulsed duration is fixed at 2 msec.
- Thermal Delta T modes: 1ΔT, 2ΔT, 4ΔT
 - Delta T technology only available on the 5cm² sound head only



Ultrasound Parameter Adjustment – Changing parameters

All ultrasound parameter settings are changed by the same two-step process.

- 1. Select/touch the parameter which will then illuminate bright white. (The example shown is Megahertz MHz)
- 2. Changes are made using the Rotary Selector Dial.

Repeat this process for all other parameters

Note:

- Within 12 seconds of making a parameter change the highlighted setting will fade back to blue.
- All parameters can always be changed before starting a treatment.
- Some parameters may not be changed during active treatment.
- A complete list of all program settings and ranges can be found in the OmniVersa Program section of the user manual

Setting Output Intensity

Output intensity can only be set when the Ultrasound channel tab is illuminated orange.

Screen text saying "Ready to set the output" appears during initial setup.

As soon as intensity is increased the START and STOP buttons appear, and the red Stop square at the top of the channel tab becomes the two-bar orange PAUSE III Icon

Note:

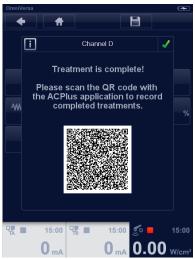
- Within 12 seconds after setting the desired output intensity the orange illuminated channel tab fades to blue.
- If additional output adjustment is needed prior to selecting START start, press the channel tab with your finger and it will illuminate orange.





End of Treatment: QR Code

At the end of a treatment, a pop-up window containing a QR code with embedded device information can be scanned using the ACPlus application.



Combination Therapy Menu Navigation

Combination Therapy

Home

Combination Therapy combines ultrasound and electrotherapy. The Home menu gives access to all of the systems therapeutic modalities. Select the desired modality by touching its button.

Select in "Combination Therapy" and the Combination Therapy menu appears.

Note:

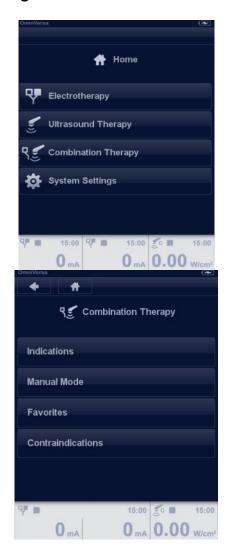
Combination Therapy is a combination of contraindications, warnings, and precautions for both electrotherapy and ultrasound.

Combination Therapy – Indications Operation

The Combination Therapy menu provides access to the ways you can navigate and the Combination Therapy Contraindications library.

- Indications
- Manual Operation
- Favorites
- Contraindication

Select "Indications" by touching the button and the Combination therapy indications menu appears.



Combination Therapy Indications Menu

Select the specific Indication by touching the button on the screen.

Indications include

- Pain Management
- Increase Local Circulation
- Decrease Muscle Tone-Spasm

Select "Pain Management" and the Pain Management Protocol menu appears.

Ref Combination Therapy Indications Pain Management Increase Local Circulation Decrease Muscle Tone - Spasm 15:00 © 15:00 O mA 0.00 W/cm²

Combination Therapy Indication Protocols Menu

All Combination Therapy Indications have a menu of Protocols that allow the selection of severity, Post Traumatic – Post Surgical, Sub-Acute and Chronic.

Select by touching the button.

Each protocol has an embedded clinical library of reference material and application illustrations that are accessed by touching the information button.

Combination Therapy Protocol Information

The embedded clinical library includes protocol and setup information and with example application illustrations.

Use the Rotary Selector Dial to scroll through the pages.

Touch the OK button in the navigation bar to proceed to the protocol parameters menu.



Indication Information - illustration

Use the Rotary Selector Dial to scroll through the illustration pages.

Touch the OK button in the navigation bar and the Combination Therapy parameter menu appears.

Combination Therapy Menus – Ultrasound and Electrotherapy

Ultrasound

Ultrasound output intensity is set first, use the Rotary Selector Dial to set output intensity.

Screen text saying "Ready to set the output" appears during initial setup.

As soon as intensity is increased the START and STOP buttons appear, and the red Stop square at the top of the channel tab becomes the two-bar orange PAUSE 11 Icon.

To access the electrotherapy therapy parameters, touch the electrotherapy button .

Note:

The Ultrasound section provides detailed ultrasound setup information.

Electrotherapy

Use Channel B for electrotherapy.

Output intensity can be set using the Rotary Selector Dial only when the selected channel tab is illuminated orange.

After setting the electrotherapy output intensity press START to begin the treatment.

Note:

- Detailed Combination Ultrasound-Electrotherapy setup guidelines can be found on page 62.
- To return to the ultrasound parameters menu press the ultrasound button





Maximum Intensity Guidelines Per Electrode Size

The maximum intensity levels for the Alternating Current (AC) waveforms including MFAC and IFC/Premod and the Low Volt Pulsed Current (LVPC) waveforms including PENS and TENS per the size of electrode used are presented at specific threshold levels as the intensity is raised.

AC current maximum intensities per electrode size:

- 2" x 2" size The recommended maximum intensity level is 40mA
- 2" x 4" size The recommended maximum intensity level is 80mA
- 3" x 5" size The recommended maximum intensity level is 100mA

LVPC current maximum intensities per electrode size:

- 2" x 2" size The recommended maximum intensity level is 80mA
- 2" x 4" size The recommended maximum intensity level is 140mA
- 3" x 5" size The recommended maximum intensity level is 140mA

Note:

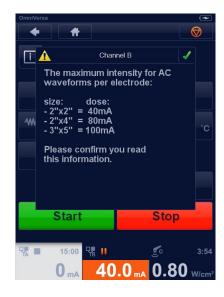
- Press the green checkmark to acknowledge the waveform dosage guideline.
- If electrode sizes other than those listed are being used, please contact ACP at 1-800-350-1110 ext. 2.

Stopping a Combination Therapy Treatment

After the treatment is started to stop the treatment press the STOP button.

Note:

• The treatment can also be stopped by pressing the emergency stop icon located on the top right of the display. Pressing this button stops the output on all channels in use





End of Treatment: QR Code

At the end of a treatment, a pop-up window containing a QR code with embedded device information can be scanned using the ACPlus application.



Combination Therapy - Manual Mode Operation

The Combination Therapy menu provides access to the ways you can navigate and the Combination Therapy Contraindications library.

- Indications
- Manual Operation
- Favorites
- Contraindications

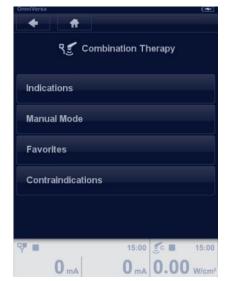
Select "Manual Operation" by touching the button and the Combination Therapy Manual Mode menu.

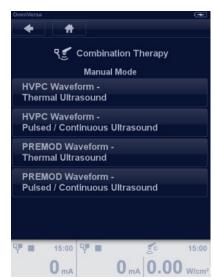
Note:

• Detailed Combination Ultrasound-Electrotherapy setup guidelines can be found on page 62.

Combination Therapy Manual Mode Menu

The manual mode menu provides access to the common Combination Therapy modes of use. Press the box of the desired mode to advance to the ultrasound parameter menu.





Combination Therapy - Ultrasound Menu

Ultrasound

In this screen the user can adjust the intensity or change the ultrasound parameters by touching the button and changing the value with the Rotary Selector Dial.

To access the electrotherapy parameters, touch the electrotherapy button at the bottom left of the screen.

Note:

• Detailed Combination Ultrasound-Electrotherapy setup guidelines can be found on page 62.

Combination Therapy - Electrotherapy Menu

Electrotherapy

In this menu the user can adjust the intensity or change the electrotherapy parameters by touching the button and changing the value with the Rotary Selector Dial.

To return to the ultrasound parameters touch the ultrasound button at the bottom left of the screen.

Note:

• Detailed Combination Ultrasound-Electrotherapy setup guidelines can be found on page 62.

Maximum Intensity Guidelines Per Electrode Size

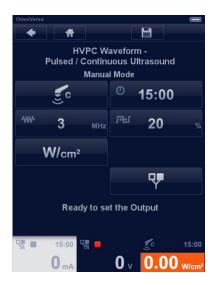
The maximum intensity levels for the Alternating Current (AC) waveforms including MFAC and IFC/Premod and the Low Volt Pulsed Current (LVPC) waveforms including PENS and TENS per the size of electrode used are presented at specific threshold levels as the intensity is raised.

AC current maximum intensities per electrode size:

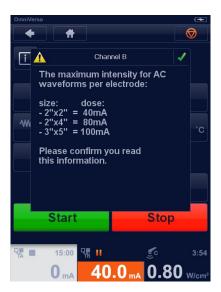
- 2" x 2" size The recommended maximum intensity level is 40mA
- 2" x 4" size The recommended maximum intensity level is 80mA
- 3" x 5" size The recommended maximum intensity level is 100mA

LVPC current maximum intensities per electrode size:

- 2" x 2" size The recommended maximum intensity level is 80mA
- 2" x 4" size The recommended maximum intensity level is 140mA







• 3" x 5" size – The recommended maximum intensity level is 140mA

Note:

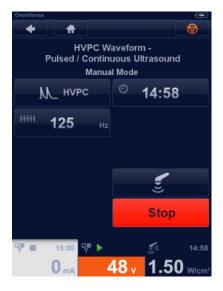
- High Volt Pulsed Current Due to its low current density, no maximum intensity exists for high volt pulsed current (HVPC) waveform
- Press the green checkmark to acknowledge the waveform dosage guideline.
- If electrode sizes other than those listed are being used, please contact ACP at 1-800-350-1110 ext. 2.

Stopping a Combination Therapy Treatment

After the treatment is started to stop the treatment press the STOP button.

Note:

The treatment can also be stopped by pressing the emergency stop icon . Pressing this button stops the output on all channels in use.



End of Treatment: QR Code

At the end of a treatment, a pop-up window containing a QR code with embedded device information can be scanned using the ACPlus application.



Creating, Saving and Deleting Favorite Programs

Creating a Favorite Program

Any treatment program can be saved as a "Favorite" by pressing the Save button [1] for later use.



Saving a Favorite Program

After you have selected the Save icon, the process to save and store in the Favorites library is as follows.

- Enter the name of the favorite using the keyboard.
- Touch the OK button to store your favorite under the name just entered.

Note:

 Once saved, favorites can be retrieved from the Electrotherapy, Ultrasound Therapy and Combination Therapy menus. Dual Channel treatments are automatically saved and loaded as a dual channel treatment.



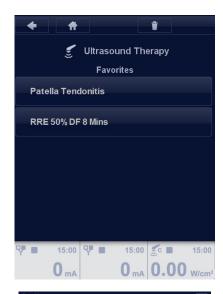
Deleting a Favorite Program

To Delete a Favorite Program, follow these few steps

- Enter into the selected modality Favorites menu (electrotherapy, ultrasound or combination therapy)
- Touch the trashcan icon which will illuminate to white



- Touch the Favorite Program you wish to delete and it will be deleted.
- Confirm deletion of this favorite by selecting the green checkmark or red X to cancel.



Note:

An activated Favorite Program i.e. a program just selected or completed cannot be deleted until a new program is selected for use.

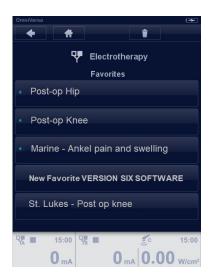


Converting Favorites to V006 Software Format

When updating OmniVersa software to V006 all current Favorites will be marked with an asterisk (*).

In order for these saved Favorites to be recognized in the new QR code format and scanned using the ACPlus application they need to be deleted and remade using the V006 software.

All saved Favorites made using the V006 OmniVersa software will not have an asterisk.



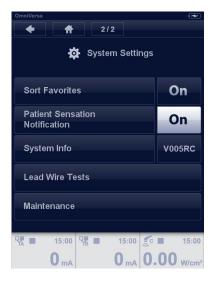
Patient Sensation Change Warnings

At the beginning of the Motor-Sensory, Sensory-Motor and Sequential protocols a Pop-up will apear instructing the therapist to inform the patient they will perceive different sensations as the frequency changes during these treatments. Press the green check mark to confirm and clear the message.

In addition, an auditory tone notification or "beep" prior to the frequency change occurs during the Sensory-Motor and Motor-Sensory treatment. Sequential does not have the auditory tone, due to repetitive frequency change (every 15 secs).

Note:

The patient sensation warning Pop-up feature can be turned "On" or "Off" on the second page of the Systems Setting section.



REMOTE CONTROL OPERATION

The OmniVersa includes two handheld Remote Controls, one single button Patient Saftey Switch intended for patient use during a treatment and one five button Clinician Hand Control intended for clinician during treatment.

Patient Safety Switch



Clinician Hand Control

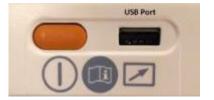


Connecting the Remote Control

Insert the end of the remote control (Patient Safety Switch or Clinician Hand Control) lead wire into the USB Port.

Note:

Only one Remote can be used at a time.



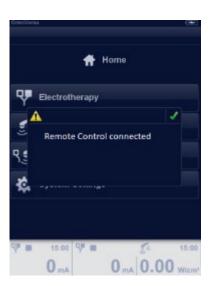
Remote Control Connected Conformation

When the Remote Control is connected to the OmniVersa a visual confirmation will appear saying "Remote Control connected".

To confirm and clear this message press the green check mark.

Note:

When the Remote Control is removed a similar confirmation message will appear saying "Remote Control disconnected". Press the green check mark to confirm and clear the message.



Patient Safety Switch Function

The Patient Safety Switch has only 1 function, to Stop the treatment session. Press the STOP button to stop output and end a treatment session.



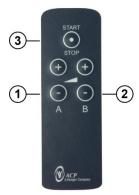
Clinician Hand Control Function

The Clinician Hand Control has three primary functions

- 1. Setting Channel A output intensity up or down
- 2. Setting Channel B output intensity up or down
- 3. START ESTIM and STOP ESTIM control.

Note:

The OmniVersa is designed to allow all Clinician Hand Control functionality accessible on the Main Touchscreen Display.

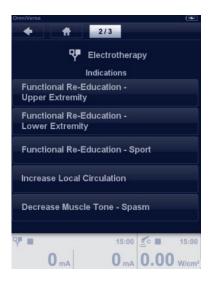


Clinician Hand Control Operation

The Clinician Hand Control can only be used when navigating in two of the Electrotherapy section Indications.

The two indications are

- Functional Re-Education Upper Extremity
- Functional Re-Education Lower Extremity



Clinician Hand Control – Functional Re-Education Upper Extremity Protocols Submenu

There are three protocols to select from

- LVPC Small Muscle Asymmetrical Biphasic Hand Control
- LVPC Medium Muscle Asymmetrical Biphasic Hand Control
- MFAC Hand Control

Select the desired protocol from the options to proceed to the channel selection menu.

Note:

Use of the hand control protocols do not require the Clinician Hand Control but can be performed using touch screen as well. The following example of use can be applied to all of the Hand Control Protocols.

Channel Selection

After the Clinical Hand Control selection is made select the channel for use. When Ch. A is selected; Ch. B is still available for another therapy.

When Ch. A+B is selected both channels have the same parameters and only the intensity can be set differently.

Channel Selection A B A+B

Electrotherapy Parameter Adjustment – Clinician Hand Control Modes of Use

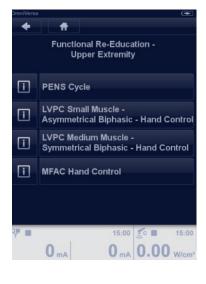
The Hand Control Protocols provide the clinician with additional control over the following.

- Output intensity can be set using either the Clinician Hand Control or the Rotary Selector Dial
- Electrical stimulation ON (Start Estim) and Off (Stop Estim) times can be activated using either the Clinician Hand Control or buttons on the screen.

Select "Channel Timing" to view Channel Timings and Remote Modes of use.

Note:

 As soon as output intensity is set either from the Clinician Hand Control or the Rotary Selector Dial the Start Estim and Stop buttons appear.





• The Electrotherapy section provides detailed electrotherapy setup information.

Channel Timing Menu - Channel Interactions

The Clinician Hand Control Channel Interaction is defaulted to the Manual mode of use. The options available will depend if you have selected a Single Chanel use (i.e. Ch. A or B only) or a Two Channel use (i.e. Ch. A and B together).

Select "Manual" to enter the Channel Interactions submenu for a Two Channel setup

Note:

The Channel Timing menu also provides access to electrotherapy Ramp up and Ramp down time and the option to have audible tones heard when stimulation is activated On or Off.

Channel Interactions – Two Channel Operation

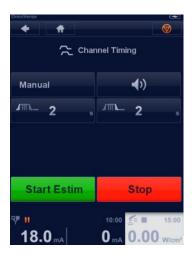
When a two channel setup (Ch. A+B) is selected Channel Interaction options are as follows.

- Manual: Ch. A+B Ramp Up and Ramp Down Times are
 preset and the same for both channels. Stimulation On time
 (Start Estim) and Off time (Stop Estim) are controlled by the
 clinician using either the Clinician Hand Control or
 commands on the Main Touchscreen Display.
- Sequential Simultaneous: Ch. A+B Ramp Up Time, Stimulation On Time and Ramp Down Time are the same for both channels. Output stimulation from Ch. A+B occurs Simultaneously.
- Sequential Alternating: Ch. A+B Ramp Up Time, Stimulation On Time and Ramp Down Time are the same for both channels. Output stimulation from Ch. A+B alternates first Ch. A then Ch. B.
- **Sequential Delayed**: Ch. A+B Ramp Up Time, Stimulation On Time and Ramp Down Time are the same for both channels. Output stimulation from Ch. A+B occurs Simultaneously, but Ch. B has a Delayed start.

Channel Interactions – Single Channel Operation

When a single channel setup (Ch. A or B only) is selected the Channel Interactions are as follows.

- Manual: Ch. A Ramp Up and Ramp Down Time are preset to 2-seconds. Stimulation On time (Start Estim) and Off time (Stop Estim) are controlled by the clinician using either the Clinician Hand Control or commands on the Main Display.
- Sequential Simultaneous: Ch. A Ramp Up and Ramp Down Time preset to 2-seconds. Stimulation On Time (Start Estim) is preset to 10-seconds. Stimulation off time controlled by the clinician using either the Clinician Hand Control or commands on the Main Touchscreen Display.







TREATMENT GUIDELINES

Introduction to Medium Frequency Currents

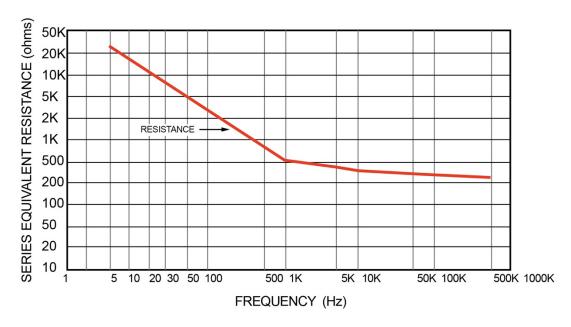
Medium frequency (MF) currents may be described as electrical currents applied to the body for therapeutic purposes, which fall in the range of 1000 to 10,000 cycles per second (Hz). This is in contrast to low frequency currents (0.1 to 1000 Hz) such as LVPC and high frequency currents (1 million Hz and beyond), which include ultrasound, shortwave and microwave diathermy. Medium frequency and short duration low frequency currents are very advantageous for clinical use due to their ease of skin penetration at lower intensities.

Normal human skin reacts differently to different frequencies of current. Specifically, there is an inverse relationship between the frequency of the applied current and the skin's resistance to it. Medium frequency alternating currents in the range of 1000 or 5000 Hz or biphasic waveforms with pulse durations less than 200 usec provide markedly lower tissue resistance.

With medium frequency currents, the energy of each individual pulse is low providing for stimulation of only one or two neurons. Since the pulses are coming in very rapid succession, stimulation of surrounding neurons occurs prior to completion of the previous neurons refractory period. This allows for asynchronous activation of individual sensory neurons, mimicking the natural physiologic process of the intact nervous system. This is not the case with low frequency (0.1 to 1000 Hz) stimulators, which are capable of only stimulus synchronous neural activation.

Medium frequency currents provide rapid analgesic effects. This occurs due to rapid depolarization of non-myelinated pain-transmitting fibers, which block pain transmission, further contributing to high muscle contraction capabilities.

Additionally, medium frequency currents have been shown to alter the vascular dynamics affecting local and possibly systemic blood flow to the muscle(s) being stimulated. The unique characteristics of medium frequency currents, (i.e., higher percent duty cycle, higher average current intensity, and wider pulse widths), can significantly increase blood flow by altering the metabolic activity of muscles.



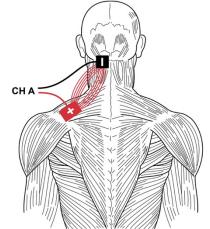
PLOT OF IMPEDANCE AS A FUNCTION OF FREQUENCY USING EPIDUCTIVE SYSTEMS

Electrode Application Techniques

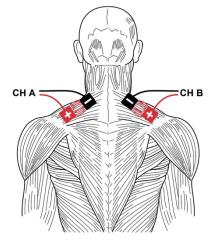
The following electrode placement diagrams are a theoretical representation of treatment set-ups using the Omnistim[®] FX² Professional. Monopolar, Bipolar and Quadripolar techniques are illustrated. Electrode placement is dependent on the etiology of the condition.

Monopolar (Mono-Polar) Technique

This technique may use two electrodes of different sizes. The smaller or "active" electrode can be positioned over the segmental innervation or peripheral nerve path of the involved tissue, or over a distal location overlying any muscle that is not an antagonist to the muscle being stimulated.



CERVICAL MONOPOLAR PLACEMENT OF ELECTRODES



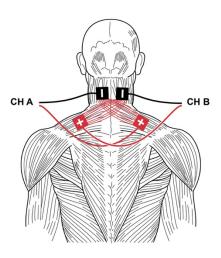
Bipolar (Bi-Polar) Technique

This is the most commonly used technique for muscle stimulation. This technique utilizes two electrodes but not exclusively of the same size. One electrode should be applied over the motor point and the other electrode over the belly of the muscle as far away from the motor point as possible. This technique allows for more effective muscle and nerve fiber recruitment since the entire neural innervation of the muscle is furnished with current.

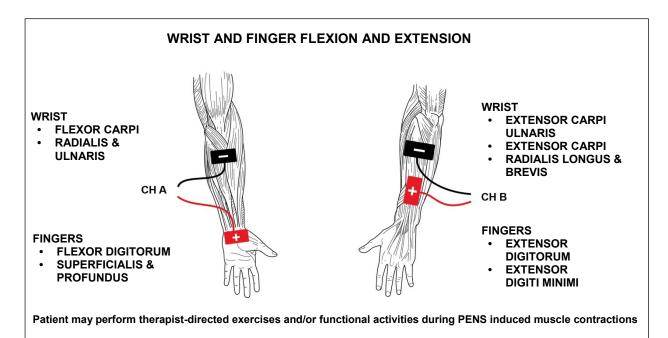
Quadripolar (Quadri-Polar) Technique

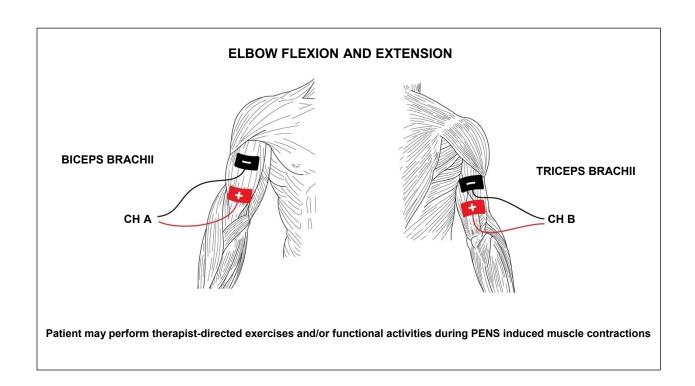
This technique requires the use of two output channels and four electrodes usually, but not exclusively of the same size. The two electrodes from one channel are usually placed diagonally across the tissue area or joint to be treated with the second channel electrodes placed on the opposite diagonal. This ensures that the current will intersect and thus provide and interferential pattern.

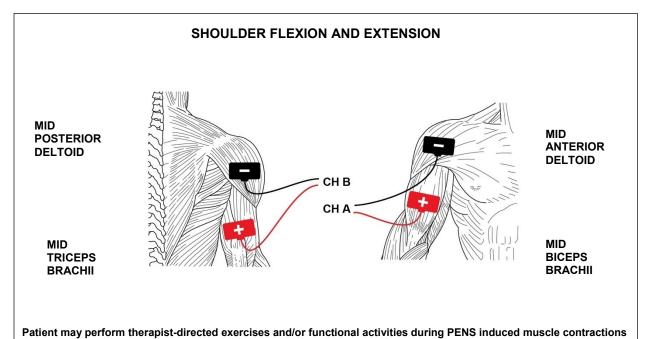




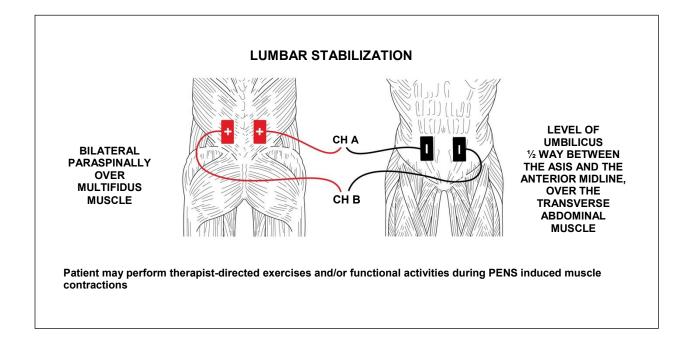
PENS Neuro Re-Education Techniques - Electrode Placement

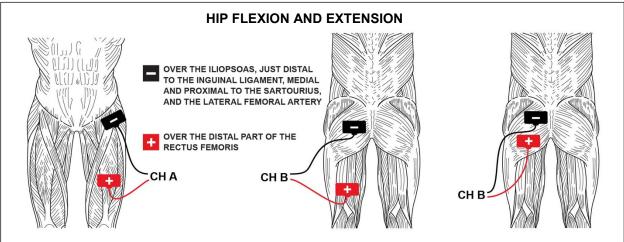






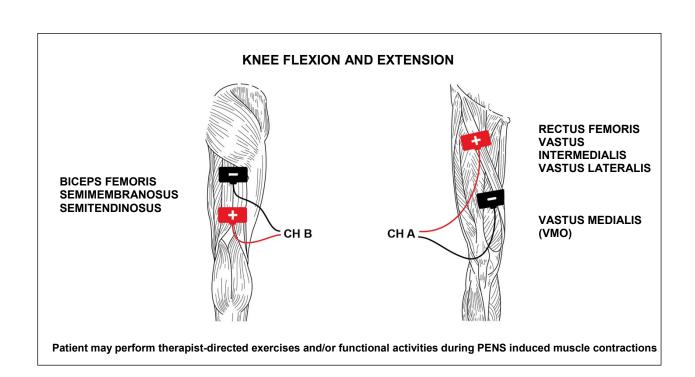


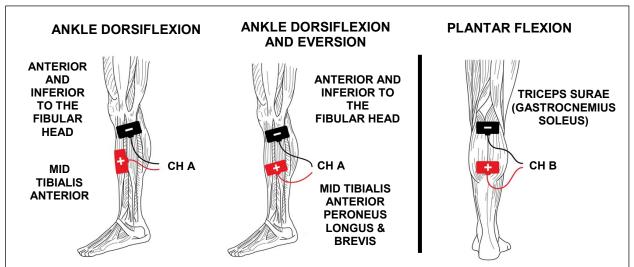




GLUTEUS MAXIMUS OR GLUTEUS & HAMSTRINGS

- Patient may perform therapist-directed exercises and/or functional activities during PENS induced muscle contractions
- · Patient needs to be supine with hip extended





- Patient may perform therapist-directed exercises in a relaxed toe down position and/or functional activities during PENS induced muscle contractions
- TO ACCOMPLISH A TOE DOWN POSITION WHILE SEATED: PLACE A TOWEL ROLL UNDER HEEL,
 PLACE A PILLOW UNDER THIGH, RAISE SEAT HEIGHT

• ELECTRODES ARE FOR INDIVIDUAL PATIENT USE ONLY!

- Do not turn power on, or power-off the Stimulator while electrodes are applied and the patient is connected to the unit.
- Use a quality, high conductivity electrode specified by the manufacturer (ACP).
- If decreased sensation is suspected, test prior to application of stimulation. Treatment areas with absent or diminished sensation should be avoided or treated with caution.
- For maximum comfort, use the largest electrodes possible without causing overflow to non-targeted areas.
- Place electrodes a minimum of 1" apart. Extend the distance between electrodes to achieve deeper current flow and/or stimulation of larger areas or multiple muscles. Do not place electrodes under hot or cold packs.
- Do not use small electrodes (less than 2"x2") when treating with medium frequency currents (MFAC or IFC).

Treatment Preparation

Skin Inspection

Thoroughly cleanse the treated area with soap and water to remove oils, creams, dirt, and sweat; this will ensure uniform current conduction across the skin. After cleansing, inspect and evaluate the skin's integrity and sensation prior to treatment. Avoid absent or diminished sensation; if unavoidable, treat with caution. Establishment of acceptable intensity levels for desensitized areas may be related to the intensity levels tolerated on normal skin in opposite or related body parts. Frequently monitor the intensity level and skin response during all treatments.

Stinging, burning or other painful sensation under the electrodes on normal or desensitized areas is an indication of increased current density under part or the entire electrode surface. In this case, slowly but immediately reduce the current intensity to zero; Make sure that the channel output on the display is zero, and then remove the electrodes to inspect the surface skin. Recheck your application techniques.

Immediately after treatment, clean and thoroughly inspect the skin under the electrode. Peripheral vasodilatation along with systemic vasomotor responses can lead to redness (hyperemia) directly under both electrodes. Inform the patient of this normal after effect and that the redness will disappear within an hour or two. Apply topical agents to the reddened area under the electrodes if needed to decrease post-treatment irritation. Persistent skin irritation could be due to repeated stimulation of the same electrode site or a possible allergic reaction to the conductive mediums, tapes, elastic wraps, and/or cleaning and disinfectant solutions. Therefore, use additional electrode stimulation sites to decrease or eliminate skin irritation on electrically sensitive patients. If skin irritation persists with alternate site applications, decrease the treatment times and lower the intensities; if necessary, discontinue treatment. If an allergic reaction is suspected, attempt to identify and change the allergic substance(s). If skin irritation persists, discontinue treatment until the source of irritation is determined.

By far the most common error with reported faulty machines is inadequate or improper conductive medium interface or lead wire breakage. Because of the increased current density available with pulsed or continuous medium frequency currents, a proportionally greater degree of conductive medium interface problems exists and should be monitored by the clinician.

ACP Reusable Electrodes

Remove the electrodes from their foil packaging. Cleanse the skin, and then apply the electrodes over the treatment site points according to the electrode placements techniques described in this manual. Various sizes of electrodes are available dependent upon muscle size of the area to be treated. Follow the enclosed infection control procedures. Review the warnings and application directions on the electrode packaging.

<u>CAUTION:</u> Connection of accessories other than the ones specified by the manufacturer can adversely affect the safety of the patient and correct functioning of the equipment, and is therefore not permitted.

WARNING: The use of conductive mediums other than specifically approved pre-gelled or self-adhering electrodes such as ultrasound gel or lotion, hand or body lotion, electrolyte spray mist, paper towels, non-approved reusable or disposable pre-gelled or self-adhering electrodes—are contraindicated for use with OmniVersa and Omnistim Systems. Any electrodes that have current densities exceeding 2 mA/cm2 may require special attention of the operator.

Lead Wires

Inspect the full length of the lead wires for signs of frayed or cut wires and loose connections where the lead wires join the tip pins. Insert the sheathed tip pins into the plug completely. Allow the lead wires to hang freely with no excessive strain on the connectors and plug insulator.

ULTRASOUND THERAPY INTRODUCTION

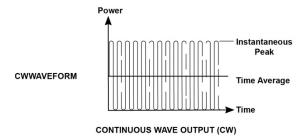
Welcome to the Omnisound Pro, the system that redefines therapeutic ultrasound. While conceiving and designing the Omnisound Pro, ACP set out to overcome the limitations of ordinary ultrasound devices. Here are just a few of the functions we developed that make the Omnisound Pro truly the future of ultrasound therapy:

- □ Controlled Depth of Penetration The Omnisound Pro enables you to treat soft tissue injuries, superficially with 3 MHz and instantly at the push of a button, treats deeper injuries with 1 MHz without switching transducers.
- □ **Two Transducer Sizes** Our 0.8cm² and 5cm² heads offer optimum flexibility in treatment and are automatically enabled as you change from one to the other.
- Continuous and Pulsed Modes Variable duty factors offer a choice between 5, 10, 20, 25, 33, 50 and 100% (continuous) applications for optimum flexibility in all phases of treatment.
- □ **Delta T Temperature Mode** Automatic dose control system helps to assure consistent tissue heating. This mode is available only on the 5cm² transducer.
- ☐ **Combination Therapy** Internal connection allows for combination therapy.
- □ Excellent BNR and ERA Our superior BNR and ERA makes for highly uniform and comfortable applications.
- Automatic Self-Test with Problem Identification Allows accurate evaluation and documentation of unit functionality before you begin treatment.

Ultrasound therapy devices generally consist of a generator and a transducer. The generator produces the electrical drive output to the transducer and provides measurement of its ultrasonic output. The transducer converts the electrical energy from the generator into mechanical vibrations, known as ultrasonic vibrations. These vibrations are then coupled to the patient's tissue via a coupling medium such as ultrasonic gel, water or mineral oil.

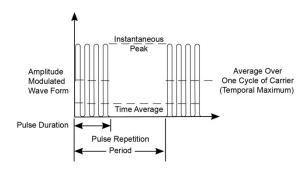
The frequency of the ultrasonic wave will determine the absorption by the tissue and thus the penetration of the beam in the tissue. Output intensities of 0.1 - 3 watts/cm² are typically applied for therapeutic purposes in pulsed or continuous wave modes.

Ultrasonic output may be produced on a continuous basis or may be pulsed.



Continuous Wave Output

In continuous wave mode (CW) the time average power is defined as the temporal average power and is 50 percent of the peak instantaneous power. When the ultrasound unit is calibrated with a power measurement device, it is generally measured in the continuous wave mode.



PULSED OUTPUT WAVEFORM

Pulsed Wave Output

Ultrasound devices may also produce pulsed waveforms. These outputs are generally square wave in shape as is the case with the Omnisound. The output of pulsed ultrasound is defined as the average output over one cycle of the carrier, rather than the average over time (time average). Duty factor is the ratio of on time to total time for pulsed waveforms. Decreasing duty factor will reduce the average ultrasonic power, which will lower the thermal effect of the beam on the tissue.

Beam Characteristics, Power, and Intensity Measurement

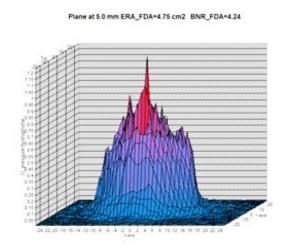
Intensity is a quantity used to establish exposure level to the ultrasound beam. Ultrasonic output power or intensity can be measured in watts or watts per square centimeter. Watts are a measure of the total power emitted in the form of ultrasonic radiation by the applicator, averaged over each cycle of the ultrasonic radiation carrier wave. However, ultrasound applicators do not generally produce beams of perfectly uniform intensity over the surface of the transducer. When the power is expressed in watts/cm², it provides the output in watts for each square centimeter of effective radiating area on the transducer surface. The effective radiating area (ERA) is a measurement of the surface area of the transducer, which produces more than 5 percent of the maximum intensity in the near ultrasound field measured at 5mm from the transducer surface. It should be noted that the effective radiating area does not generally cover the entire surface area of the transducer (effective radiating surface) and varies with the crystal frequency when operated at different crystal harmonics. Thus the measurement represents an average for the effective radiating surface area.

Beam Non-Uniformity Ratio (BNR)

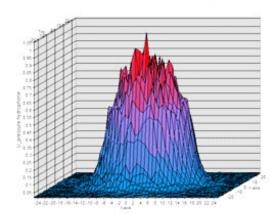
Ultrasound has an excellent ability to penetrate deeply, primarily due to its small beam divergence (Schwan, 1958). A typical beam scan of an applicator is presented below.

Model Number: Omnisound® Pro Serial Number: 11.529

Frequency: 1 & 3 MHz
Test Date: 11/19/2015
ERA: 5.0 cm²
BNR: < 5:1







Beam non-uniformity ratio is defined as the ratio of temporal - average spatial - maximum intensity to the temporal average effective intensity as measured at 5mm from the transducer surface. The typical range for most commercially obtainable transducers is between 3 to 1 and 10 to 1. BNR can be useful in comparing one unit to another for field uniformity. One should keep in mind that the spatial maximum intensity in watts/cm² is equal to the calibrated intensity on the output display multiplied by the BNR, i.e.: if 1 W/cm² was registering on the output display and the BNR was 7:1 the maximum intensity in the tissue would equal 7 W/cm² at certain portions of the field. This should be kept in mind when determining output dosage.

Note:

It is also important to maintain continuous movement of the head for these reasons.

Output Power and Exposure Time

The total power for a given amount of treatment time determines the total energy transferred to the tissue. One should note that if one uses different ultrasonic generators with differing effective radiating areas, one should use the total power measurement not the intensity measurement in order to correlate the settings on the units. Times must also be accurate in order to assure proper treatment dosage.

Note:

Care should be taken when applying therapy to move the head continuously over the treatment area.

Monitoring of Delivered Power or Intensity

The power meter displays the ultrasonic power level to be delivered to the patient under proper coupling conditions. First apply an ultrasound coupling to the treatment area. The output control (up power arrow) should then be increased to the desired power or intensity level. Power should be reduced prior to decoupling to avoid overheating of the transducer when used. If little coupling is occurring in the treatment area due to the size of the area, underwater application technique may be indicated. It is poor practice to allow continuous overheating of the transducer.

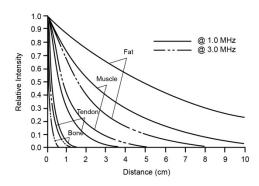
Ultrasound Transmission and Absorption

When ultrasonic energy is applied to the tissue, it is absorbed in varying degrees. This absorption of energy can increase tissue kinetic energy leading to increased temperature or the formation of cavitation or acoustic micro streaming.

It is known that different tissue types absorb ultrasound differently and for this reason, the modality has the ability to selectively treat certain tissues due to their greater energy absorption. The absorption coefficient describes the degree of absorption by the tissue and is approximately equal to the frequency in the 1-4MHz range. For this reason, ACP uses both 1.0 and 3.0MHz ultrasonic outputs through its treatment transducer. The use of these two frequencies allows

greater or less attenuation of the beam, for example, 1.0MHz penetrates approximately 3 times more than 3.0MHz. This may be helpful in selecting intensity and time for ultrasonic therapy applications. Due to this reason, the patient will generally experience much faster heating with 3MHz ultrasound and dosage or treatment time may have to be reduced to avoid overheating of the tissue.

Temperature Mode of Operation / ΔT Mode



In order to achieve repeatable thermal effects of ultrasound in tissue the dosage of the ultrasound beam must be carefully controlled. This involves accurate determination of the treatment area, coupling to be used, frequency of operation, BNR and the desired temperature increase required to achieve appropriate therapeutic effects in the tissue.

Lehman and other investigators have categorized the effects of ultrasound on tissue as being of a mild or 1°C increase, moderate or 2°C increase or vigorous or 2-4°C heating effect above the baseline tissue temperature of 37.5°C. Typically, vigorous heating is used to treat connective tissue contracture and scar tissue while moderate and mild heating are used in pain control, sub-acute and chronic inflammatory conditions and for muscle spasm reduction.

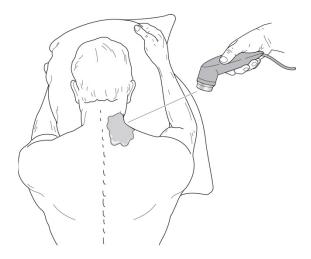
Note:

The 5cm transducer is the only transducer capable of operating in the ΔT mode. The 0.8cm head will default to 20% duty factor and can only be used in pulsed or continuous modes.

Thermal Mode Availability			
Transducer Size	1MHz	3MHz	
5 cm ²	1∆T or 2∆T	$1\Delta T$, $2\Delta T$, or $4\Delta T$	
0.8 cm ²	N/A	N/A	

ULTRASOUND APPLICATION TECHNIQUES

The following guidelines should be followed when applying ultrasound for therapeutic treatment.



Note:

Make sure that the output is switched OFF when the transducer is not in use. Temperature will rise rapidly if the output is switched ON and the transducer is not in contact with the skin.

- Prior to starting treatment, cleanse and inspect the US Transducer applicator head for cracks, which may allow
 the ingress of conductive fluid; Inspect the treatment head cables and associated connectors; The user should
 handle the US transducer applicator head with care at all times, since rough handling may adversely affect its
 characteristics
- 2. Thorough cleansing of the treated area for removal of oils, creams, dirt, and sweat will ensure more uniform delivery of ultrasonic energy across the skin. After cleansing, an inspection and evaluation of the skin's integrity and sensation should be done prior to treatment.
- 3. Test the patient's skin in the desired treatment area for sensory response prior to the application of ultrasound therapy. If areas of anesthesia or lack of temperature sensitivity are found, use caution and low doses (subthermal). Care should be exercised with these patients, as they may not detect damaging thermal effects.
- 4. Use the minimum effective dosage (including power and exposure time). If more therapy is required, a longer time at a lower output is recommended. Avoid using maximum power levels. For example, a typical comfortable output should be 0.5 1.5 W/cm².
- 5. Use a slow (approximately 1cm per second) linear or circular motion with the transducer. The treatment area should be restricted to two of the transducer sizes, which approximates 2 effective radiating areas (ERA). This is absolutely mandatory if the correct relationships in the calculation equations are to be met.
- 6.. Apply coupling medium plentifully to the area to be treated. As the superficial skin temperature increases, more gel may be added to cool the skin while performing the treatment.
- 7.. ACP applicators are fully waterproof and may be used with underwater technique for the smaller joints where effective coupling is not possible. The water temperature should be slightly warmer than the target tissue temperature. It is recommended that the handle is held by the operator without direct contact to the water, to avoid exposure. If this is not possible, it is recommended that the operator wear gloves to avoid direct contract with treatment area.

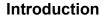
- 8.. When using ultrasound, a moving head technique is recommended to avoid the buildup of "Hot Spots" or standing waves which might lead to tissue damage.
- 9.. To start the treatment, supply adequate coupling, apply the transducer to the patient and increase the power. Adjust the output intensity typically to a range of 0.5W/cm² to 1.5W/cm² based on patient comfort. The treatment time will automatically adjust based on the power setting chosen to provide the correct dosage. As the power is increased, the time decreases and vice versa. If the patient experiences any discomfort, decrease the power by a small amount (0.1 .2W/cm²) and note if the pain is reduced. If so, continue the treatment.

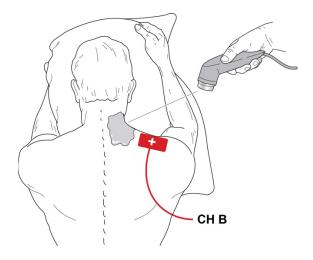
Note:

The Delta T mode of operation is calibrated for muscle not in proximity of bone. If the ultrasound application at 3MHz is within 1 cm of bone the 2-Delta T mode will heat at a rate of 4 °C, or the 1-Delta T mode will heat at 2 °C. Within .5cm proximal to bone, the 1-Delta T mode will heat at 4 °C due to the reflection of the ultrasound field from the bone back into the overlying tissue.

- 10. Reduce the output power if the patient complains of pricking sensations, "pins and needles" or painful temperature changes. Induced pain is also a good indication that the dosage level is too high. This sensation may indicate periosteal heating and should be avoided as significant tissue damage may occur under prolonged treatment application.
- 11. Proper personnel training on use of ultrasound and the equipment is essential in order to ensure high standards of therapy.
- 12. Avoid operator exposure to the ultrasonic field.

COMBINATION ULTRASOUND - ELECTROTHERAPY





Combination therapy with Ultrasound and Electrotherapy has been used for the treatment of pain, muscle spasm and to increase local circulation. The treatment of trigger points with a combination of electrotherapy and sub-thermal or thermal ultrasound is an effective technique in acute and chronic pain management, which simultaneously relieves muscle spasm. For POST TRAUMATIC - POST SURGICAL, ACUTE pain and INCREASE LOCAL CIRCULATION, it is generally applied as a combination of sub-thermal ultrasound with HVPC currents or PREMOD sensory. For more chronic pain conditions or muscle spasms, it is generally applied as thermal US with PREMOD motor stimulation.

Combination Therapy Application Technique

The OmniVersa system has built in protocols for the combination of ultrasound and electrotherapy.

- Prior to starting treatment, cleanse and inspect the US Transducer applicator head for cracks, which may allow the ingress of conductive fluid; Inspect the treatment head cables and associated connectors; The user should handle the US transducer applicator head with care at all times, since rough handling may adversely affect its characteristics
- 2. Determine the appropriate indication or electrotherapy waveform (Manual mode) best suited to treat the patient's specific condition.
- 3. Select size of electrode, making certain that the electrode chosen is larger than the transducer head size. Attach the self-adhesive electrode to the patient's body.
- 4. Using the positive wire on Channel B of the OmniVersa connect the Combination Therapy single lead wire positive (red) tip pin into the unit and the other end into the electrode. This will allow the ultrasound applicator to remain as the active electrode.
- 5. From the user interface "Home screen", choose Combination Therapy and select either Manual Operation or the appropriate Indication or Favorites protocol.
- 6. Select desired electrotherapy protocol or waveform (either PREMOD or HVPC).
- 7. Apply a liberal amount of conductive gel to the patient's body and place the transducer on the target tissue and keep the sound head in motion.
- 8. From the ultrasound screen set the appropriate treatment parameters and intensity level.

- 9. Next, press the electrotherapy icon. At the electrotherapy screen set the appropriate parameters and intensity settings.
- 10. Press Start.
- 11. Repeat treatment in adjacent areas to fully treat involved tissue, as needed.

The total treatment time is based upon the dosage selected and the ultrasound intensity. Provide the treatment until the end time is reached and the energy outputs cease.

During Combination Therapy, observe both electrotherapy and ultrasound contraindications, warnings and precautions.

INFECTION CONTROL EQUIPMENT AND PRINCIPLES OF USE

Definitions

- **Barrier Film** One-time use, disposable plastic film for use over touch/operator surfaces of equipment to reduce risks of cross-contamination and need for high level disinfection of equipment between patients.
- **Germicidal Disposable Wipe** Low level and/or intermediate level disposable germicidal disinfectant wipe for use on electrotherapeutic devices and accessories.
- Plastic Lead Wire Sleeve Barrier to be used on electrical stimulation lead wires, covering the junction of lead wire and electrode wire.

Universal Precautions – Body Substance Isolation

Universal Precautions (UP) must be implemented in the care of all patients to protect employees from occupational exposure to blood borne pathogens. Personal protective equipment (gloves, masks, gowns) should be available and worn by staff when occupational exposure to blood, body fluids containing blood, semen and vaginal secretions is likely to occur. Health care workers with exudating lesions or weeping dermatitis should refrain from all direct patient care and from handling patient care equipment until the condition resolves. Equipment must be cleaned/disinfected and protective barriers used when appropriate.

Cleaning / Disinfecting of the OmniVersa

Modality equipment shall be cleaned/disinfected per facility infection control policy. ACP recommends the following guidelines:

Cleaning and Low Level Disinfection

This is a recommended daily housekeeping practice to keep the equipment clean and free of contaminants which could contribute to transmission of infection. The following practices are recommended for use when treating intact skin without the presence of physiologic fluids such as blood and urine.

- Clean equipment daily with ACP germicidal wipes. At the end of the day, wipe common contact surfaces, such as control panel and lead wires, with germicidal disposable wipe and allow to air dry. This technique will inactivate M. tuberculosis as well as most bacteria and viruses. This will also facilitate removal of organic material contaminants from equipment.
- Disposable/reusable electrodes are for individual patient use only and should not be used on multiple patients.

Intermediate Level Disinfection and Barriers

This method is recommended to keep the equipment clean and free of contaminants when used between patients for treatment of non-intact skin or incontinence management, where there is an increased risk of patient cross-contamination. The following are the recommended practices.

- After each use, clean common contact surfaces, such as control panel and lead wires with ACP germicidal wipes.
- With a second ACP germicidal cloth, wipe again leaving surfaces wet for at least 5 minutes. Allow the surface to air dry before patient use.
- Barriers should also be used on the equipment for treatment of non-intact skin or incontinence management. This technique will inactivate *M. tuberculosis* as well as most bacteria and viruses.

Use of Barriers - Intermediate Level Disinfection

The use of an all-purpose barrier film provides surface protection from cross-contamination resulting from a variety of applications. This precaution should be used whenever dealing with non-intact skin or the chance of coming in contact with bodily fluids. Barrier film is designed to cover any surface that may be touched during a patient treatment, in order to help prevent cross-contamination. Barrier film is for single-use only. The film is discarded after each patient treatment. The procedure for use is as follows:

- 1. Wash hands.
- 2. Apply Intermediate Level Disinfection prior to barrier application.
- 3. Select, tear or cut with clean scissors a length of barrier film to fit over the operator surfaces of the OmniVersa unit.
- 4. Select and cut with clean scissors a 2-foot length of plastic sleeve and fit over the lead wire and the electrode cabling.
- 5. Prepare any items which may become in contact with the therapist during treatment, such as ultrasound gel, pens, assessment tools, cart handles, etc.
- 6. Set up the patient per guidelines for the procedure.
- 7. Provide treatment as appropriate.
- 8. Discard all disposables.
- 9. With clean gloves, remove the plastic film from the unit and discard.
- 10. Remove the plastic sleeve from the lead wire by sliding it toward the electrode. Remove the electrode and discard with the sleeve.
- 11. Intermediate disinfect the OmniVersa unit prior to the next treatment application.



OMNIVERSA PROGRAM MENU - ELECTROTHERAPY

ELECTROTHERAPY INDICATION PROTOCOLS

Post Traumatic -Post Surgical Pain **Neuromuscular Re-Education HVPC SENSORY** PENS UE BIPHASIC HEAD & NECK SENSORY NERVE BLOCK 2 PENS UE TRIPHASIC UPPER EXTREMITY & THORACIC **Acute Pain** PENS LE TRIPHASIC LOWER EXTREMITY & TRUNK IFC - PREMOD SENSORY PENS LE TRIPHASIC - PELVIC FLOOR 4 2 TENS - LVPC SENSORY 5 TENS - LVPC MOTOR 3 IFC - PREMOD SENSORY - MOTOR **Muscle Disuse Atrophy** SENSORY NERVE BLOCK 4 LVPC SMALL MUSCLE - ASYMMETRICAL BIPHASIC **Chronic Pain** 2 LVPC MEDIUM MUSCLE - SYMMETRICAL BIPHASIC IFC - PREMOD SEQUENTIAL 3 MFAC LARGE MUSCLE 2 IFC - PREMOD MOTOR 4 MFAC LARGE MUSCLE - PELVIC FLOOR 3 TENS - LVPC MOTOR Functional Re-Education - Sport **IFC - PREMOD MOTOR SENSORY** 4 1 PENS CYCLE SENSORY NERVE BLOCK 2 5 PENS WALK to RUN PENS SPRINT **Increase Local Circulation** 3 **HVPC SENSORY** PENS SKATE MFAC MUSCLE PUMP 2 5 PENS JUMP PENS MUSCLE PUMP PENS THROW 3 6 PENS KICK Decrease Muscle Tone - Spasm 7 PENS UE BIPHASIC HEAD & NECK Maintain - Increase ROM PENS UE TRIPHASIC UPPER EXTREMITY & 2 MEAC INCREASE ROM 1 THORACIC PENS LE TRIPHASIC LOWER EXTREMITY & 3 **TRUNK** MOTOR NERVE BLOCK MFAC TONE-SPASM 5 MFAC RECIPROCAL INHIBITION Functional Re-Education - Upper Extremity

- 1 PENS CYCLE
- 2 LVPC SMALL MUSCLE ASYMMETRICAL BIPHASIC HAND CONTROL
- 3 LVPC MEDIUM MUSCLE SYMMETRICAL BIPHASIC HAND CONTROL
- 4 MFAC HAND CONTROL

Functional Re-Education - Lower Extremity

- 1 PENS CYCLE
- 2 LVPC SMALL MUSCLE ASYMMETRICAL BIPHASIC HAND CONTROL
- 3 LVPC MEDIUM MUSCLE SYMMETRICAL BIPHASIC HAND CONTROL
- 4 MFAC HAND CONTROL

	MANUAL MODE WAVEFORMS				
1	PENS UE BIPHASIC	9	PENS Throw		
2	PENS UE TRIPHASIC	10	PENS KICK		
3	PENS LE TRIPHASIC	11	IFC-PREMOD		
4	PENS CYCLE	12	LVPC ASYMMETRICAL BIPHASIC		
5	PENS WALK to RUN	13	LVPC SYMMETRICAL BIPHASIC		
6	PENS SPRINT	14	MFAC		
7	PENS SKATE	15	HVPC		
8	PENS Jump				

Pain Control

HVPC Sensory

Stimulates segmental pain modulation and vasodilation, increasing local circulation. Application of negative polarity over the edematous site has been demonstrated to reduce post-traumatic edema in clinical trials.

Intensity: Set amplitude to as high as comfortably tolerated. Increase amplitude during the treatment in response to accommodation to the electrical stimulation, when and as needed.

Adjustable Parameter (Y/N)	Parameter Name	Range (unit)	Default (unit)
Υ	PULSE RATE	1200 (Hz)	100 (Hz)
Υ	TREATMENT TIME	060 (min)	15 (min)

IFC - PREMOD Sensory

This program is used for symptomatic relief of superficial and deep pain from localized dermatome or segmental origin. Duration of relief is typically several hours. Fast onset of relief usually happens within 15-20 minutes. Target tissue is superficial and deep. Bilateral, Bipolar, or Quadripolar application; through the painful area; or over the involved spinal segments. Apply parallel to incision line for post-operative pain management. The intensity should be set to elicit a pleasant tingling sensation, just below a muscle contraction.

User Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
Y	CARRIER FREQ	210 KHz	5.0 (kHz)
N	BURST FREQUENCY		100 (Hz)
N	BURST RATE SCAN		20 (%)
N	RATE SCAN		ON
N	RATE SCAN TIME		20 (s)
Y	VECTOR	Slow 45, Fast 45, Slow 90, Fast 90, OFF	OFF
Υ	TREATMENT TIME	060 (min)	15 (min)

TENS-LVPC Sensory

This program is used for symptomatic relief of superficial pain from localized dermatome or segmental origin. Duration of relief is typically several hours. Fast onset of relief usually within 15-20 minutes. Target tissue is superficial. Bilateral bipolar application through the painful area or over the involved spinal segments. Apply parallel to incision line for post-operative pain management. The intensity should be set to elicit a pleasant tingling sensation, just below a muscle contraction.

User Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
Y	PHASE DURATION	40400 (μs)	80 (µs)
Y	PULSE RATE	0.0200 (Hz)	100 (Hz)
N	PHASE DURATION MOD	0-50 (%)	20 (%)
N	MODULATION		ON
N	RATE SCAN TIME	0-20 (s)	4 (s)
Y	TREATMENT TIME	060 (min)	15 (min)

IFC - PREMOD Sensory Motor

Provides symptomatic relief of superficial and deep pain and pain of local, generalized single or multi-segmental nature. Combines sensory and motor stimulation. Starts with sensory and ends with motor. Duration of relief is typically from 2 to 6 hours. Slower onset of relief usually within 15 to 30 minutes. Target tissue is superficial and deep. Bipolar placement over local and distal trigger points. Quadripolar placement over area of local pain, or at involved spinal segment. The intensity should be set to elicit a moderate muscle twitch. This protocol is comprised of two sub-programs, as follows:

User Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
N	CARRIER FREQ	5.0 (kHz)	5.0 (kHz)
N	BURST FREQ	0.0200 (Hz)	100
N	MODULATION	ON, OFF	ON
N	RATE SCAN	ON, OFF	ON
N	RATE SCAN TIME	020 (s)	15
N	RATE SCAN %	0-50 (%)	20 (%)
Y	VECTOR	(0)OFF (1)Slow 45, (2)Fast 45, (3)Slow 90, (4)Fast 90,	OFF
Y	TREATMENT TIME	060 (min)	10 (min)

IFC - PREMOD Sensory Motor (Cont.)

User Adjustable Parameter (Y/N)	Parameter Name	Range (unit)	Default (unit)
N	CARRIER FREQ	5.0 (kHz)	5.0 (kHz)
N	BURST FREQ	0.0200 (Hz)	2
N	MODULATION	ON, OFF	ON
N	RATE SCAN	ON, OFF	ON
N	RATE SCAN TIME	020 (s)	15
N	RATE SCAN %	0-50 (%)	50 (%)
Υ	VECTOR	(0)OFF (1)Slow 45, (2)Fast 45, (3)Slow 90, (4)Fast 90,	OFF
Y	TREATMENT TIME	060 (min)	20(min)

IFC - PREMOD Motor

Provides symptomatic relief of superficial and deep pain and pain of generalized or multi-segmental nature. Duration of relief is typically from 2 to 8 hours. Slow onset of relief usually within 15 minutes to 1 hour. Target tissue is superficial and deep. Bipolar placement over local and distal trigger points. Quadripolar placement over area of local pain, or at involved spinal segment. The intensity should be set to elicit a moderate muscle twitch.

User Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
Y	CARRIER FREQ	2.010.0 (kHz)	2.5 (kHz)
Υ	BURST FREQUENCY	0.0200 (Hz)	4.0 (Hz)
N	BURST RATE SCAN		50 (%)
N	RATE SCAN		ON
N	RATE SCAN TIME		20 (s)
Υ	VECTOR	Slow 45, Fast 45, Slow 90, Fast 90, OFF	OFF
Y	TREATMENT TIME	060 (min)	15 (min)

TENS-LVPC Motor

Application of this program will provide symptomatic relief of superficial pain with inflammation, or pain of a generalized or multi-segmental nature. Duration of relief is typically from 2 to 8 hours. Slow onset of relief is usually within 15 minutes to 1 hour. Target tissue is superficial. Bipolar placement over local and distal trigger points or a spinal segmental level. Intensity should be set to elicit a moderate muscle twitch.

User Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
Y	PHASE DURATION	40400 (µs)	200 (μs)
Y	PULSE RATE	0.0200 (Hz)	4.0 (Hz)
N	PHASE DURATION MOD		20 (%)
N	MODULATION		OFF
N	RATE SCAN TIME		4 (s)
Y	TREATMENT TIME	060 (min)	15 (min)

IFC - PREMOD Motor Sensory

Provides symptomatic relief of superficial and deep pain and pain of local, generalized single or multi-segmental nature. Combines motor and sensory stimulation. Starts with motor and ends with sensory. Duration of relief is typically from 2 to 8 hours. Slower onset of relief usually within 15 to 30 minutes. Target tissue is superficial and deep. Bipolar placement over local and distal trigger points. Quadripolar placement over area of local pain, or at involved spinal segment. The intensity should be set to elicit a moderate muscle twitch. This protocol is comprised of three sub-programs, as follows:

IFC - PREMOD Motor Sensory, Subprogram 1

User Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
N	CARRIER FREQ		5.0 (kHz)
N	BURST FREQUENCY		15.0 (Hz)
N	BURST RATE SCAN		50 (%)
N	RATE SCAN		ON
N	RATE SCAN TIME		15 (s)
Υ	VECTOR	Slow 45, Fast 45, Slow 90, Fast 90, OFF	OFF
Y	TREATMENT TIME	060 (min)	5 (min)

IFC - PREMOD Motor Sensory, Subprogram 2

User Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
N	CARRIER FREQ		5.0 (kHz)
N	BURST FREQUENCY		2.0 (Hz)
N	BURST RATE SCAN		50 (%)
N	RATE SCAN		ON
N	RATE SCAN TIME		15 (s)
Υ	VECTOR	Slow 45, Fast 45, Slow 90, Fast 90, OFF	OFF
Υ	TREATMENT TIME	060 (min)	15 (min)

IFC Motor Sensory, Subprogram 3

User Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
N	CARRIER FREQ		5.0 (kHz)
N	BURST FREQUENCY		100.0 (Hz)
N	BURST RATE SCAN		20 (%)
N	RATE SCAN		ON
N	RATE SCAN TIME		15 (s)
Y	VECTOR	Slow 45, Fast 45, Slow 90, Fast 90, OFF	OFF
Y	TREATMENT TIME	060 (min)	10 (min)

IFC - PREMOD Sequential

This protocol provides symptomatic relief of superficial and deep pain and pain of local, generalized single or multi-segmental nature. Combines sensory and motor stimulation in 3 sequences of 4 Hz, 15 Hz and 100 Hz repeated every 15 seconds. Duration of relief is typically from 2 to 6 hours. Rapid onset of relief usually within 5-15 minutes. Target tissue is superficial and deep. Bipolar placement over local and distal trigger points. Quadripolar placement over area of local pain, or at involved spinal segment. The intensity should be set to elicit a moderate muscle twitch. The protocol consists of three sequences. This sequence is repeated throughout the program until the time runs out. The amplitude does not change when the sequence shifts in the protocol.

Adjustable Parameters

Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
Υ	VECTOR	Off, Slow 45, Fast 45, Slow 90, Fast 90,	Off
Υ	TREATMENT TIME	060 (min)	15 (min)

Note:

Total treatment time on the timer is set at 15 minutes. At the end of treatment timer, the output shuts off regardless of sequence completion.

IFC - PREMOD Sequential, First Sequence

Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
N	CARRIER FREQ		5.0 (kHz)
N	BURST FREQ		4
N	RATE SCAN TIME		15
N	RATE SCAN %		50 (%)
Y	VECTOR	Off, Slow 45, Fast 45, Slow 90, Fast 90	Off
N	TREATMENT TIME (SEQ)		15 (sec)

IFC - PREMOD Sequential, Second Sequence

Adjustable Parameter Parameter Name (Y/N)			
N	CARRIER FREQ		5.0 (kHz)
N	BURST FREQ		15
N	RATE SCAN TIME		15
N	RATE SCAN %		50 (%)
Υ	VECTOR	Off, Slow 45, Fast 45, Slow 90, Fast 90	Off
N	TREATMENT TIME		15 (sec)

IFC - PREMOD Sequential Third Sequence

Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
N	CARRIER FREQ		5.0 (kHz)
N	BURST FREQ		100
N	RATE SCAN TIME		15
N	RATE SCAN		20 (%)
Υ	VECTOR	Off, Slow 45, Fast 45, Slow 90, Fast 90	Off
N	TREATMENT TIME		15 (sec)

SENSORY NERVE BLOCK

Provides symptomatic relief of superficial and deep pain from localized dermal or segmental origin. Blocks pain by causing a temporary nerve block through reactive depolarization (Conduction block) of the pain signal on its way to the spinal input. Also known as Wedensky inhibition. Duration of relief is typically from 1 to 2 hours. Faster onset of relief usually within 5 to 10 minutes. Target tissue is superficial and deep. Bipolar placement over local nerve. Quadripolar placement over area of local pain, or at involved spinal segment. The intensity should be set to elicit a numb-gripping sensation just under muscle contraction.

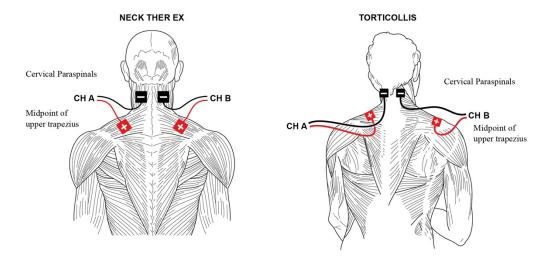
User Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
N	CARRIER FREQ		10.0 (kHz)
Υ	TREATMENT TIME	060 (min)	15 (min)

Neuro Muscular Re-Education

UE BIPHASIC PENS

This program is used to re-educate upper extremity agonist - antagonist muscle pairs to enhance reciprocal and fast movement. It is called biphasic because the agonist fires first followed by the antagonist. Due to reciprocating action of the muscle groups there is no third phase. Functional task simulation is reciprocal movement such as typing, boxing, piano playing, swimming, upper extremity positioning speed walking, rowing, etc. Patterned Electrical Neuromuscular Stimulation (PENS) is a precise reproduction of EMG firing patterns of muscle agonist and antagonist pairs. PENS should be used prior to Therex to improve recruitment and motor performance. It's also used to decrease spasticity and muscle tone.

User Adjustable Parameter (Y/N)		Adjustable Range (unit)	Default (unit)
Y	PHASE DURATION	40100 (μs)	70 (µs)
N	PULSE RATE		50 (Hz)
Y	TREATMENT TIME	060 (min)	15 (min)
Υ	CYCLE TIME	2.5; 1.5; .75; .6; .5 (sec)	.75 (sec)
N	PATTERN		Bi Phasic



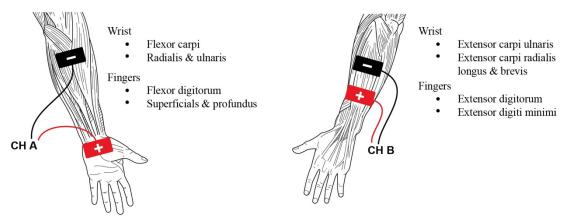
- For unilateral involvement, apply CH A to the most involved side
- For Torticollis, place CH A on the side that the head is tilted toward

UE TRIPHASIC PENS

This program is used to re-educate upper extremity agonist - antagonist muscle pairs where fine motor control and positioning is required. It is called Triphasic because the agonist fires first, followed by the antagonist followed by a small burst of agonist muscle to slow down the antagonist and position the joint. Patterned Electrical Neuromuscular Stimulation (PENS) is a precise reproduction of EMG firing patterns of muscle agonist and antagonist pairs. PENS should be used prior to Therex to improve recruitment and motor performance. It's also used to decrease spasticity and muscle tone.

User Adjustable Parameter (Y/N)		Adjustable Range (unit)	Default (unit)
Υ	PHASE DURATION	40100 (μs)	70 (µs)
N	PULSE RATE		50 (Hz)
Y	TREATMENT TIME	060 (min)	15 (min)
N	PATTERN		Tri Phasic

WRIST AND FINGER FLEXION AND EXTENSION



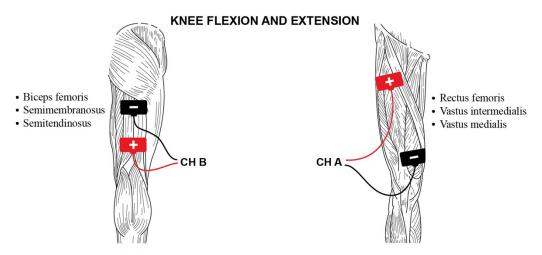
Note:

Apply Channel A to the agonist and B to its antagonist.

LE TRIPHASIC PENS

This program is used to re-educate lower extremity agonist - antagonist muscle pairs where fine motor control and positioning is required. It is called Triphasic because the agonist fires first, followed by the antagonist followed by a small burst of agonist muscle to slow down the antagonist and position the joint. Patterned Electrical Neuromuscular Stimulation (PENS) is a precise reproduction of EMG firing patterns of muscle agonist and antagonist pairs. PENS should be used prior to Therex to improve recruitment and motor performance. It's also used to decrease spasticity and muscle tone.

User Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
Υ	PHASE DURATION	40100 (μs)	70 (µs)
N	PULSE RATE		50 (Hz)
Y	TREATMENT TIME	060 (min)	15 (min)
N	PATTERN		Tri Phasic



TENS-LVPC MOTOR

This program motor level stimulation provides neuromuscular stimulation to begin treatment of disuse muscle atrophy. Target tissue is superficial. Bipolar placement over local and distal trigger points. The intensity should be set to elicit a moderate muscle twitch.

User Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
Υ	PHASE DURATION	40400 (µs)	200 (μs)
Y	PULSE RATE	0.0200 (Hz)	4.0 (Hz)
N	PHASE DURATION MOD		20 (%)
N	MODULATION		OFF
N	RATE SCAN TIME		4 (s)
Y	TREATMENT TIME	060 (min)	15 (min)

Treatment of Muscle Disuse Atrophy

MFAC LARGE MUSCLE

Program used for muscle re-education and treatment of muscle disuse atrophy. Activation of muscle with electrical stimulation at a high intensity for a short time with long "ON/OFF" ramps reduces atrophy. The patient should participate to the extent possible by contracting during the stimulation "ON" time. Target tissues are superficial and deep muscle groups. Bipolar set-up over agonist and antagonist muscles for target muscle. The intensity should be set to elicit a grade 2 to 4 muscle contraction. Treatment time should be reduced based on muscle fatigue. The affected joint movement should be restricted by holding manually, or using weights or exercise bands.

User Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
Y	CARRIER FREQ	2.010.0 (kHz)	2.5 (kHz)
Y	BURST FREQUENCY	0.0200 (Hz)	75 (Hz)
N	BURST RATE SCAN		20 (%)
N	RATE SCAN		ON
N	RATE SCAN TIME		4 (s)
Y	TREATMENT TIME	060 (min)	10 (min)
Y 2	B OUTPUT DELAY	0.09.9 (s)	0.0 (s)
Y	RAMP UP	0.09.9 (s)	2.0 (s)
Y	RAMP DOWN	0.09.9 (s)	2.0 (s)
Y	T-ON	060 (s)	10 (s) ¹
Y	T-OFF	0120 (s)	50 (s) ¹
Y	CHANNEL MODE	A/B SIMULTANEOUS, A/B ALTERNATE, B DELAYED	A/B SIM.

When T-OFF = 0, T-ON = CONTINUOUS.

² B OUTPUT DELAY parameter is shown only when the Channel Mode is set to B DELAYED.

LVPC Small Muscle Asymmetric Biphasic or Medium Muscle - Symmetric Biphasic

Program used for strength development and treatment of muscle disuse atrophy. Activation of muscle with electrical stimulation at a high intensity for a short time with long "ON/OFF" ramps reduces atrophy. The patient should participate to the extent possible by contracting during the stimulation "ON" time. Target tissues are smaller superficial muscle groups. Bipolar set-up over agonist and antagonist muscles for target muscle. The intensity should be set to elicit a grade 2 to 4 muscle contraction. Treatment time should be reduced based on muscle fatigue. The affected joint movement should be restricted by holding manually, or using weights or exercise bands.

User Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
Υ	PHASE DURATION	40400 (μs)	70 (µs)
Y	PULSE RATE	0.0200 (Hz)	50.0 (Hz)
N	MODULATION		OFF
N	RATE SCAN TIME		0 (s)
Y	TREATMENT TIME	060 (min)	10 (min)
Y 2	B OUTPUT DELAY	0.09.9 (s)	0.0 (s)
Υ	RAMP UP	0.09.9 (s)	2.0 (s)
Υ	RAMP DOWN	0.09.9 (s)	2.0 (s)
Y	T-ON	060 (s)	10 (s) ¹
Y	T-OFF	0120 (s)	50 (s) 1
Y	CHANNEL MODE	A/B SIMULTANEOUS, A/B ALTERNATE, B DELAYED	A/B SIM.

¹ When T-OFF = 0, T-ON = CONTINUOUS.

Functional Re-Education (FES)

PENS CYCLE

Program simulates cycling, from 10-120 rpm, and can be used to retrain reciprocal movement of the U.E. or L.E. with or without resistance. Use an upper or lower extremity ergometer or pedal exerciser in combination with stimulation at mild to moderate contraction intensity for closed chain functional training. Increase resistance as patient progresses in the rehab program.

User Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
Υ	PHASE DURATION	40100 (μs)	70 (µs)
N	CYCLE TIME	10-120 rpm	60 rpm
N	PULSE RATE		50 (Hz)
Υ	TREATMENT TIME	060 (min)	15 (min)

² B OUTPUT DELAY parameter is shown only when the Channel Mode is set to B DELAYED.

PENS WALK to RUN

This protocol simulates muscle activation in reciprocal patterns (ie. walking, jogging, and running). Strides or revolutions per minute (RPMs) range from 10 to 120.

Walk Speed: Approximately 40 (Slow) to 88 (Fast) represent various walking speeds.

Jog - Run Speed: At higher RPMs, this protocol simulates running and is used for rehabilitation or sports-specific training.

Position Progression: sitting, weight shifting in standing, marching in place, ambulating, running in place. Intensity: Muscle Twitch with active contraction. Adjust amplitude during the treatment in response to the electrical stimulation, when and as needed.

User Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
Y	PHASE DURATION	40100 (μs)	70 (µs)
N	CYCLE TIME	10120 Rpm	60 RPM
N	PULSE RATE		50 (Hz)
Υ	TREATMENT TIME	060 (min)	15 (min)

PENS SPRINT

This protocol simulates sprinting via muscle activation in reciprocal patterns for neuromuscular rehabilitation or sports-specific training. It stimulates 3 short sprint starts, followed by a series of 10 simulated 100-meter sprints (approximately), with 30 seconds of rest between sprints.

Intensity: progress from muscle twitch to full intensity simulating sprint practice. Adjust amplitude during the treatment in response to the electrical stimulation, when and as needed.

Positioning - Early rehab: Have athlete lie on training table with hips and knees flexed, or legs over table.

Positioning – Late rehab: 30 degrees hip-knee flexion. Instruct the athlete to weight shift or run in place in synchrony with the electrical stimulation.

User Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
	PHASE DURATION	40100 (μs)	70 (µs)
N	CYCLE TIME		0.68 (s)
N	PULSE RATE		50 (Hz)
Y	TREATMENT TIME	060 (min)	15 (min)
Y*	REPEATE CYCLES	0100	12

^{*} Repeat Cycles are adjustable on Indications mode only

PENS Skate, PENS Jump PENS Kick, and PENS Throw are sports specific function protocols designed to reeducate function following injury and during the later phases of a rehab program. They simulate the activities with the correct EMG firing pattern.

PENS SKATE

This protocol simulates skating and can be used for lower extremity neuromuscular re-education in a lateral (side to side) movement pattern.

Positioning – Early rehab: Have athlete lie on training table with hips and knees flexed, or legs over table.

Positioning – Mid to Late Rehab: Have athlete stand on a slide board with hip and knees slightly bent while they wt, shift, or mimic skating motion across slide board with stim.

Positioning – Mid rehab: Have athlete stand on a slide board with hip and knees slightly bent weight shift with stim.

Intensity: Moderate to strong muscle twitch with active muscle contraction. Adjust amplitude during the treatment in response to the electrical stimulation, when and as needed

User Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
Y	PHASE DURATION	40100 (μs)	70 (µs)
Y	CYCLE TIME	.5 – 6 sec	1.3(s)
N	PULSE RATE	100-50 Hz	50 (Hz)
Υ	TREATMENT TIME	060 (min)	15 (min)

PENS JUMP

This protocol simulates jumping and provides aggressive neuromuscular re-education of the lower extremities. Positioning: Standing with both knees slightly flexed. Instruct the athlete to actively jump when they hear the tone, in synchrony with the start of the electrically stimulated muscle contractions.

Intensity: Moderate to strong muscle twitch with active muscle contraction. Adjust amplitude during the treatment in response to the electrical stimulation, when and as needed.

User Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
Y	PHASE DURATION	40100 (μs)	70 (µs)
N	CYCLE TIME	15 (s)	15 (s)
N	PULSE RATE	10-100 Hz	50 (Hz)
Y*	REPEAT CYCLE	099	12
N	TREATMENT TIME	060 (min)	15 (min)
N	T-ON	030 (s)	1 (s) ¹
N	T-OFF	0199 (s)	14 (s) ¹

^{*} Repeat Cycles are adjustable on Indications mode only

PENS KICK

Kick (step – plant – kick ball) - This protocol simulates ball kicking and is an aggressive late rehab or sports specific protocol for neuromuscular re-education.

Positioning: Have athlete stand upright in kicking position, shift weight to one leg, flex then extend kicking leg. Instruct athlete to perform the kick sequence in time with the electrical stimulation.

Intensity: Moderate to strong muscle twitch with active muscle contraction. Adjust amplitude during the treatment in response to the electrical stimulation, when and as needed.

User Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
Y	PHASE DURATION	40100 (μs)	70 (µs)
Υ	CYCLE TIME	09.9 (s)	6 (s)
N	PULSE RATE	10-100 Hz	50 (Hz)
Υ	TREATMENT TIME	060 (min)	15 (min)

PENS THROW

Simulates the mid portion of throwing and includes both the acceleration and deceleration phases of throwing, providing late activation of the triceps and infraspinatus to stabilize the shoulder during follow through. Used for late-stage rehabilitation or sport-specific training. Intensity: Moderate to strong muscle twitch with active contraction. Adjust amplitude during the treatment in response to the electrical stimulation, when and as needed Baseball patient position: Place the patient in sitting with the arm supported in 90 degrees of abduction, 90 degrees of elbow flexion and 45 degrees of external rotation. Have patient hold a baseball or 1-lb weight for light resistance. The resistance, and muscle contraction, can be progressively increased over subsequent treatments, as tolerated.

Football patient position: The arm should be supported at 90 degrees' abduction and slightly flexed with the elbow at 90 degrees and the palm slightly pronated in a throwing position. A football or 1-lb weight can be held in the hand for light resistance. The resistance, and muscle contraction, can be progressively increased over subsequent treatments, as tolerated. Regardless of sport, follow the PENS Throw protocol with PENS UE Triphasic to the Wrist and Finger Flexors and Extensors.

User Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
Υ	PHASE DURATION	40100 (μs)	70 (µs)
N	CYCLE TIME		2.5 (s)
N	PULSE RATE		50 (Hz)
N	CHA stop pulse index cycle		10
N	CHB Start pulse index cycle		6
N	CHB Start pulse index cycle		15
Υ	TREATMENT TIME	060 (min)	15 (min)

MFAC - LVPC HAND CONTROL MANUAL

Program provides for active assisted treatment to develop functional movement of superficial and deep muscle. Activation of muscle with electrical stimulation occurs during functional movement when the therapist presses and holds the start button. The patient should participate to the extent possible with the functional movement by contracting during the stimulation "ON" time. Target tissue is superficial and deep muscle groups. Bipolar set-up over agonist and antagonist muscles for target muscle. Set intensity to elicit a grade 3-5 muscle contraction. Reduce treatment time based on muscle fatigue.

User Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
Υ	CARRIER FREQ	2.0, 2.5, 4.0, 5.0, 10.0 (kHz)	2.5 (kHz)
Υ	BURST FREQUENCY	0.0250 (Hz)	50 (Hz)
N	BURST RATE SCAN		20 (%)
N	RATE SCAN		ON
N	RATE SCAN TIME		4 (s)
Υ	TREATMENT TIME	060 (min)	15 (min)
N	CHANNEL MODE		A/B SIM.

MFAC-LVPC HAND CONTROL SEQUENCED

Program provides for active assisted treatment to develop functional movement of superficial muscle. Activation of muscle with electrical stimulation during functional movement. The patient should participate to the extent possible with the functional movement by contracting during the stimulation "ON" time. Target tissue is smaller superficial muscle groups. Bipolar set-up over agonist and antagonist muscles for target muscle. Set intensity to elicit a grade 3-5 muscle contraction. Reduce treatment time based on muscle fatigue.

User Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
Υ	PHASE DURATION	40400 (μs)	70 (µs)
Υ	PULSE RATE	0.0250 (Hz)	50.0 (Hz)
Υ	Ron, Roff, Ton		1,1,5
N	MODULATION		OFF
N	RATE SCAN TIME		4 (s)
Y	TREATMENT TIME	099 (min)	15 (min)
N	CHANNEL MODE	AB SImulAlterating Delayed	A/B SIM.

INCREASE LOCAL CIRCULATION

HVPC Sensory

Increases local circulation by stimulating vasodilation. Application of negative polarity over the edematous site has been demonstrated to reduce post-traumatic edema in clinical trials. In addition, if pain is present, can reduce it via segmental pain modulation mechanisms. Set amplitude to as high as comfortably tolerated. Increase amplitude during the treatment in response to accommodation to the electrical stimulation, when and as needed. Bipolar either side of trauma or black (negative) electrode over edematous tissue, red (positive) adjacent.

Adjustable Parameter (Y/N)		Range (unit)	Default (unit)
Υ	PULSE RATE	1200 (Hz)	125 (Hz)
Υ	TREATMENT TIME	060 (min)	45 (min)

PENS Muscle Pump

This protocol provides gentle high repetition muscle contractions of stimulated muscle thereby increasing local circulation. Apply channels and lead wire polarities to the electrodes on the largest muscle groups in the targeted body area, Channel A on the agonist and Channel B on the antagonist. Set for moderate comfortable muscle contractions. Adjust amplitude during the treatment in response to the electrical stimulation, when and as needed.

Adjustable Parameter (Y/N)		Range (unit)	Default units
Υ	PHASE DURATION	40…100 (μs)	70 (µs)
Υ	RPM	10-120 rpm	30 (rpm)
N	PULSE RATE		50 (Hz)
Y	TREATMENT TIME	060 (min)	15(min)

MFAC Muscle Pump

Increases venous and lymphatic circulation via electrical stimulation-induced muscle contractions, which act as a 'pump' and compress fluids into the venous and lymphatic systems. The "Off Time" default is 4 secs. Change the "On Time" from 4 secs to 12 secs with 2 sec ramp-up and ramp-down times by selecting Channel Timing and highlighting the "On time", "ramp-up time" and "ramp-down time" icons and turning the rotatory dial to 12 sec, 2 sec and 2 sec respectively. Moderate muscle contraction. Increase amplitude during the treatment in response to accommodation to the electrical stimulation, when and as needed. Bipolar over muscles in target tissue area. If using 2 Channels, treat the agonist and the antagonist.

Adjustable Parameter (Y/N)	Parameter Name	Range (unit)	Default (unit)
N	CARRIER FREQ		5.0 (kHz)
Υ	BURST FREQUENCY	0.2200 (Hz)	35 (Hz)
Y	TREATMENT TIME	060 (min)	15 (min)
Y	CHANNEL MODE TIMING: (S)Simultaneous, (A)Alternating (D)Delayed,	S,A,D	А
Υ	B OUTPUT DELAY	069 (s)	0 (s)
Υ	RAMP UP	09 (s)	1 (s)
Υ	RAMP DOWN	09 (s)	1 (s)
Υ	T-ON	060 (s)	4(s)
Υ	T-OFF	0120 (s)	4 (s)

REDUCE MUSCLE SPASM

Motor Nerve Block

This protocol provides symptomatic relief of superficial and deep muscle spasm and hypertonicity. It blocks motor nerves by causing a temporary nerve block through reactive depolarization (Conduction block) of the motor signal on its way to the muscle. Also known as Wedensky inhibition. Duration of relief is typically from 1 to 2 hours. Faster onset of relief usually within 5 to 10 minutes. Target tissue is superficial and deep. Bipolar or quadripolar electrode placement over local muscle and nerve supply. The intensity should be set to elicit a numb-gripping sensation just under muscle contraction. This current is more aggressive than Sensory nerve block as the carrier frequency is set to 5000 Hz instead of 10,000 Hz. As the current adapts over time, the intensity should be adjusted upwards during treatment.

Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
N	CARRIER FREQ		5.0 (kHz)
Υ	VECTOR	Off, Slow 45, Fast 45, Slow 90, Fast 90	Off
Υ	TREATMENT TIME	060 (min)	15 (min)

MFAC RECIPROCAL INHIBITION

This program provides for stimulation of the spastic muscle's antagonists. It activates reciprocal inhibition of the spastic muscle reducing tone. Slow ramps decrease the potential to trigger spasticity of the agonist. A single channel (A or B) is used over the spastic muscle's antagonist. Intensity should be set to elicit a grade 2 to 3 muscle contraction. Intensity should not be too high to induce overflow activation of the spastic muscle. Treatment time can be reduced based on muscle fatigue and inhibition of spasticity.

User Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
Υ	CARRIER FREQ	2.0, 10.0 (kHz)	2.5 (kHz)
Υ	BURST FREQUENCY	0.0250 (Hz)	50 (Hz)
N	BURST RATE SCAN		20 (%)
N	RATE SCAN		ON
N	RATE SCAN TIME		4 (s)
Υ	TREATMENT TIME	060 (min)	15 (min)
Y 2	B OUTPUT DELAY	0.09.9 (s)	0.0 (s)
Υ	RAMP UP	0.09.9 (s)	6.0 (s)
Υ	RAMP DOWN	0.09.9 (s)	4.0 (s)
Υ	T-ON	060 (s)	12 (s) 1
Υ	T-OFF	0120 (s)	18 (s) 1
Y	CHANNEL MODE	A/B SIMULTANEOUS, A/B ALTERNATE, B DELAYED	A/B SIM.

When T-OFF = 0, T-ON = CONTINUOUS.

² B OUTPUT DELAY parameter is shown only when the Channel Mode is set to B DELAYED.

MFAC Tone - Spasm

This program provides for stimulation of the spastic muscle. The short rest time exhausts the muscle metabolism reducing spasm- tone. Slow ramps decrease the potential to trigger spasm. Intensity should be set to elicit a grade 2 to 3 muscle contraction Treatment time can be reduced based on muscle fatigue and inhibition of spasticity.

User Adjustable Parameter (Y/N)	Parameter Name	Adjustable Range (unit)	Default (unit)
Y	CARRIER FREQ	2, 2.5,3,3.5,4, 5, 6, 7, 8, 9, 10 kHz	5.0 (kHz)
Υ	BURST FREQUENCY	1100 (Hz)	90 (Hz)
Υ	BURST RATE SCAN	050 (%)	20 (%)
Υ	RATE SCAN	ON, OFF	ON
Υ	RATE SCAN TIME	020 (s)	4 (s)
Υ	TREATMENT TIME	060 (min)	15 (min)
Υ	B OUTPUT DELAY	0.080 (s)	0.0 (s)
Υ	RAMP UP	0.09 (s)	2.0 (s)
Υ	RAMP DOWN	0.09 (s)	2.0 (s)
Υ	T-ON	060 (s)	10 (s)
Υ	T-OFF	0120 (s)	10 (s)

Increase Range of Motion (ROM)

MFAC INCREASE ROM

Program used for stimulation of range of motion through muscle activation of the agonist or agonist-antagonist muscle pairs. Activation of muscle with electrical stimulation at a moderate intensity for a longer time (Endurance protocol) with longer "ON/OFF" ramps improves range of motion. The patient should participate to the extent possible by contracting during the stimulation "ON" time. Bipolar set-up over agonist and antagonist muscles for target muscle. The intensity should be set to elicit a grade 2 to 3 muscle contraction. Treatment time should be reduced based on muscle fatigue.

Adjustable Parameter (Y/N)	Parameter Name	Range (unit)	Default (unit)
Υ	CARRIER FREQ	2, 2.5,3,3.5,4, 5, 6, 7, 8, 9, 10 kHz	2.5 (kHz)
Υ	BURST FREQUENCY	1100 (Hz)	35 (Hz)
Υ	BURST RATE SCAN	050 (%)	20 (%)
Υ	RATE SCAN	ON, OFF	ON
Υ	RATE SCAN TIME	020 (s)	4 (s)
Υ	TREATMENT TIME	060 (min)	15 (min)
Υ	B OUTPUT DELAY	0.080 (s)	0.0 (s)
Υ	RAMP UP	0.09 (s)	2.0 (s)
Υ	RAMP DOWN	0.09 (s)	2.0 (s)
Υ	T-ON	060 (s)	4 (s)
Υ	T-OFF	0120 (s)	12 (s)

STIMULATION THERAPY MODES

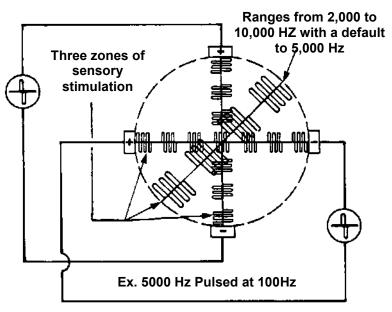
Interferential Current Therapy (IFC)

The new Webster Encyclopedia Dictionary of the English Language defines interference as "the mutual action waves of any kind (water, sound, heat or light) upon each other, by which the vibrations and their effects are increased, diminished or neutralized."

As such, interferential current (IFC) therapy requires at least two signal sources, which "interfere" within the tissue to be treated. The resulting interference of the generators generates therapeutically useful stimulation of the area undergoing treatment. Interferential current therapy technique relies on amplitude differences between two or more isolated independent signals to produce fields of higher or lower intensity within the tissue.

The purpose of interferential current therapy is to provide deep tissue treatment, which is not generally obtainable with conventional electrotherapy approaches. Its primary application is in the reduction of pain and in the stimulation of increased blood flow in the deeper tissues and muscles.

RATE SCAN ON OR OFF 2500 or 5000 Hz Pulsed at 100Hz



AMPLITUDE SUMMATION IFC TECHNIQUE

RATE SCAN ON OR OFF

Simply stated, electric currents with frequencies in the range of 1000-10,000 Hz, known as medium frequency currents, are run through the tissue to be treated when applied continuously. These frequencies inhibit nerve conduction based on the fact that they cause temporary nerve membrane depolarization while present. This effect is known as Wedensky Inhibition or nerve block. Medium frequency currents have an inhibitory effect on pain transmission and sensation within the field of treatment. This effect is responsible for the decreased sensation under

the stimulation electrodes. Medium frequencies are also selected due to their excellent tissue penetration. This occurs as a result of the decreased tissue resistance at higher frequencies.

IFC - Full Field Pre-modulated Mode:

If the medium frequency is modulated the signal will stimulate the tissue and nerves at the modulation burst rate.

The well-known attributes of modulated medium frequency currents, i.e. deep tissue penetration, asynchronous neural stimulation, and low tissue resistance, allows the creation of an interferential therapy system capable of both deep and superficial stimulation with the goals of maximizing sensory inputs. This technique is referred to as full field interferential current therapy. Full field amplitude summation interferential current therapy relies on the addition and subtraction of two intersecting currents within the tissue. This effect is based on the relative phase differences between the currents at different

Range from 2,000 to 10,0000 with a default of 2500 or 5000 Hz Pulsed at 100Hz ex. 5000 Hz Three zones of Wedensky Inhibition Ex. 5000 Hz

FULL FIELD WEDENSKY INHIBITION

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positions in the field. The following technique is used in the Omnistim® when in the IFC mode of operation. The highest intensity field is obtained in the deep tissue at bisecting angles to the out-of-phase electrodes. This technique offers three stimulation fields.

IFC - Nerve Block Mode

Should the clinician desire rapid analgesia and maximum comfort in both the surface and deep tissues, continuous non-modulated MF currents may be used with the OmniVersa, which will produce strong nerve blocks (Wedensky Inhibition) throughout the entire treatment field. This is often useful in the mobilization of joints, prior to transverse friction massage, or for relieving acute pain. It should be noted that this technique would produce only transient relief of pain.

The effects of full field interferential current therapy may be described as follows:

- a. Stimulation of deep and surface tissues.
- b. May be used to produce deep and surface analgesia via nerve block (Wedensky Inhibition) when MF mode is used.

Vector Technique:

In order to move the position of the deep interferential fields, researchers developed systems to alter the relative amplitudes between stimulation channels in interferential stimulators. This alteration of relative amplitude changes the phase relationships and the position of the summated field in the tissue.

Advantages of Dynamic Vector:

- 1. When the patient expresses a poor pain location and cannot indicate whether or not the therapy feels the strongest at the subjectively perceived location of the problem.
- 2. When the target tissue area is extremely large.
- 3. When you wish to increase the amount of current density in the tissues to obtain a higher therapeutic dosage.
- 4. When your electrode placement sites are less than optimal.

Vector Options

The OmniVersa has 4 different dynamic vector options:

- Fast 90 degrees
- Slow 90 Degrees
- Fast 45 Degrees
- Slow 45 Degrees

Medium Frequency Alternating Current (MFAC)

Neuro-Muscular Stimulation

Since the mid-18th Century, neuromuscular electrical stimulation (NMES) has been used as an adjunctive therapy for various neuromuscular and musculoskeletal disorders. Clinicians and investigators have been successfully using NMES to facilitate muscle contraction, to re-educate muscle action, to aid in the prevention of atrophy and to overcome neuromuscular inhibition following injury or surgery.

• Isometric Muscle Stimulation

NMES during isometric exercise offers a reduced threat of over-stress and re-injury to the joint. NMES is clinically used at the mid-point of the range of motion where the muscle can generate maximum torque.

Mode	NMES
Time ON	10 Sec
Time OFF	50 Sec
ON Ramp	2 Sec
OFF Ramp	2 Sec
Pulse Rate	35-50Hz

Procedure:

Gradually increase intensity to maximum patient tolerance during each contraction. The intensity should be increased to produce at least 50 to 80% of Maximum Voluntary Contraction (MVC). Place ACP Reusable Electrodes in a Bipolar or Quadripolar pattern on the muscle(s) being stimulated. The treatment should be approximately 15 minutes duration 3 to 4 times a week.

Muscle Spasm Reduction

NMES can be utilized to induce fatigue of muscles in spasm. Researchers have found that the greatest fatigue of muscles occurs when the muscle contraction relaxation times are equivalent (1:1 ratio) and when higher frequencies (60-80 Hz) are used. Electrical stimulation of the motor neuron using medium frequency currents results in neuromuscular junction fatigue.

Mode	NMES
Time ON	10 Sec
Time OFF	10 Sec
ON Ramp	1-2 Sec
OFF Ramp	1-2 Sec
Pulse Rate	35-50Hz

Procedures:

Gradually increase intensity to maximum patient tolerance during each contraction. Place electrodes in a Monopolar, Bipolar or Quadripolar pattern on the muscles in spasm. The treatment time should be of approximately 20 minutes duration repeated 2 or 3 times per week.

Increased Blood Flow

Long and short-term electrical stimulation of muscle has been shown to alter the vascular dynamics affecting local muscle blood and lymph flow. It has been shown that blood-flow increased significantly during the first minute of electrical stimulation and remained elevated during and for ten minutes following stimulation. The immediacy of vasodilatation following electrical stimulation indicates that the vascular response is a functional, reflexive response. In addition, long-term electrical stimulation has been shown to increase the number of capillaries and thus improve the capillary blood-flow to the stimulated muscle. Not all types and parameters of electrical stimulation affect the blood-flow dynamics of the muscle being stimulated. Therefore, the following clinical parameters should be adhered to for optimal effectiveness.

Procedure:

Place one or two sets of electrodes in a Bipolar or Quadripolar technique over the selected muscle(s). Gradually increase intensity to 15 to 30% of maximum voluntary contractions. Continue the treatment for approximately 10 minutes.

Blood Flow		
Mode	NMES Simultaneous	
Time ON	15 Sec	
Time OFF	50 Sec	
ON Ramp	2 Sec	
OFF Ramp	2 Sec	
Pulse Rate	50Hz	

Muscle Pump		
Mode	NMES Alternate	
Time ON	4 Sec	
Time OFF	4 Sec	
ON Ramp	2 Sec	
OFF Ramp	2 Sec	
Pulse Rate	35Hz	

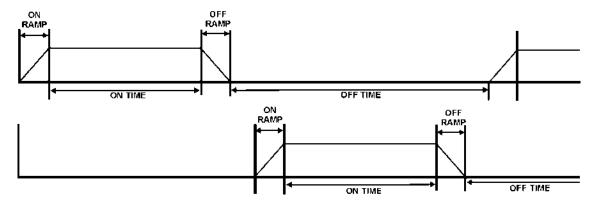
Timing Diagrams

ON - OFF TIME: On time adjustable from 0 - 30 seconds, off time adjustable from 0 - 199 seconds.

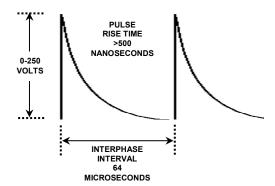
CHANNEL TIMING: Simultaneous, alternate or delayed channels.

DELAY MODE: Adjustable from 0-9.9 seconds.

AUTO INTENSITY: Adjusts the output during treatment automatically from 0 to 20% user programmable.



High Voltage Pulsed Current (HVPC)



This current type has a twin peak monophasic waveform with

a fixed duration of 64 µs between the two voltage peaks. The amplitude is adjusted in volts rather than in mA. The short rise time and short duration of each voltage peak (approximately 7 µs) is well suited to nerve stimulation and efficient discrimination between sensory, motor and pain responses. The very short pulse duration of high voltage creates a stimulation which is quite comfortable, and one which most patients can tolerate. The very short pulse duration followed by a very long interpulse interval eliminates the formation of any appreciable chemical or thermal effects in the tissue. High voltage Pulsed Current is used for stimulating nerves and muscles, causing muscle contractions. Examples for clinical use are to treat acute or chronic pain, and increase circulation. Muscle contraction or motor response of isolated muscle groups, superficial or deep, can be easily and comfortably stimulated. For patient comfort and to prevent accommodation, the Burst frequency can be can be varied through modulation.

Although not a continuous type of direct current (DC), HVPC is a pulsed unidirectional currents, which is unique in that it produces a polarity in the tissue. Therefore the end user has the ability to select a polarity of the electrode set up. The pulsing of the HVPC is done to reduce any chemical effects of the polarity in order to decrease skin irritation. Stop treatment immediately if patient complains of any pain, stinging or burning sensations under the electrodes

Parameters:

- Carrier Frequency, expressed in Hertz (Hz), is the sinusoidal frequency of the cycles with in the burst
- **Burst Frequency**, expressed in Hertz (Hz), the current is delivered in packages or "Burst" of sinusoidal waves, it is analogous to the pulse rate in the LVPC.
- **Burst Rate Scan**, expressed as a percentage, sets the burst frequency upper and lower limit range for Burst Rate Modulation.
- Rate Scan Time, refers to the time elapsed to cycle through the burst frequency modulation range

Low Voltage Pulsed Currents (Biphasic)

Asymmetrical, Symmetrical and Alternating Asymmetrical Biphasic

The biphasic pulsed current family of waveforms are often used in TENS (Transcutaneous Electrical Nerve Stimulation) and NMES applications. These waveforms are characterized by variable phase duration and variable pulse frequency. In an asymmetric biphasic waveform, the typical amplitude, duration, and rate of rise and decay are unequal for each phase with respect to the baseline, however the waveform is fully balanced, i.e. the phase charges of each phase are equal.

A variation to the standard biphasic asymmetrical pulsed current is the alternating one, in which the successive pulse phases alternate with respect to the baseline.

The symmetrical biphasic mode provides the same amplitude, duration, and rate of rise and decay for both the positive and negative phase of the waveform. This is often used to stimulate larger muscle as both phases have equal intensity.

To prevent accommodation to stimulation or to improve patient tolerance, the pulse duration can be varied through modulation.

Parameters:

- Phase Duration, expressed in μs, is the elapsed time from the beginning to the end of one phase of a pulse.
- Interphase interval, is the duration between two consecutive components of a pulse where no electrical activity occurs.
- Pulse duration, is the time from all the phases of a pulse and interphase interval (expressed in µsec)
- Interpulse interval the time between two successive pulses.
- Pulse Frequency, expressed in Hz or pps (pulses per second), defines the repetition rate of the biphasic pulses.
- **Phase Duration Modulation**, expressed in percentage, defines a variable phase duration range that can be swept between the upper and lower limit over a variable time.
- Rate Scan, expressed as a percentage sets the fluctuating Phase Duration range.
- Rate Scan Time, is the duration or how long it takes to cycle through the modulation upper and lower limit range during Phase Duration Modulation

Burst Symmetrical

The burst biphasic symmetrical pulsed current is a variation to its non-burst counterpart, in which the continuous train of pulses is interrupted by pulse pauses. A burst frequency can be set for motor stimulation, where the use of continuous stimulation with a low pulse frequency would be too painful. Each burst lasts for 100ms and the burst rate can separately be adjusted. With this milder LVPC waveform, it is easier to exceed the motor threshold stimulus.

PENS

PENS uses an asymmetric biphasic waveform. The typical amplitude, duration, and rate of rise and decay are unequal for each phase with respect to the baseline, however the waveform is fully balanced (i.e. the phase charges of each phase are equal). A narrow pulse duration is used (70 µsec) to avoid stimulating nociceptors. The two channels are timed and modulated to replicate basic EMG and functional EMG patterns for neuromuscular reeducation and treatment of muscle disuse atrophy.

OMNIVERSA PROGRAM MENU - ULTRASOUND

	ULTRASOUND THERAPY INDICATIONS
Pain	
1	POST TRAUMATIC - POST SURGICAL
2	SUB-ACUTE
3	CHRONIC
Increase Loc	al Circulation
1	POST TRAUMATIC - POST SURGICAL
2	SUB-ACUTE
3	CHRONIC
Decrease Mu	scle Tone -Spasm
1	ACUTE
2	CHRONIC
Decrease Joi	nt Stiffness - Contracture
1	DECREASE JOINT STIFFNESS-CONTRACTURE
Ultrasound T	herapy Manual Mode
1	Pulsed - Continuous
2	Thermal

PAIN MANAGEMENT - INCREASE LOCAL CIRCULATION- DECREASE TONE-SPASM

Sub-thermal and thermal ultrasound is used in protocols for pain management, increasing local circulation and decreasing muscle tone and spasm. The clinician starts with a low sub-thermal dose in high acuity cases and increases the dose as the inflammatory response moves from an acute to chronic condition.

Post Traumatic Post-Surgical Pain - Acute Muscle Tone Spasm

This sub-thermal protocol is used to reduce pain, increase circulation, and decrease muscle hypertonicity in the superficial tissues using 3 MHz or deeper tissues using 1 MHz. Apply the US over an area that is twice the Transducer size for five minutes. Three areas would provide a 15 minute treatment.

Adjustable Parameter (Y/N)	Parameter Name	Range (unit)	Default units
Y	ULTRASOUND FREQUENCY	1 or 3 MHz	3 (MHz)
Y	PULSED - CONTINUOUS	CW, 5,10, 20,25, 33, 50 (%)	20 (%)
Y	TRANSDUCER SIZE	5 cm ²	5 cm ²
Y	TREATMENT TIME	060 (min)	15 (min)

Sub-Acute Pain - Increase Local Circulation

This protocol uses a 1°C temperature increase to increase the metabolic rate and provide mild heating. It is used to decrease sub-acute pain, increase circulation and provide an acceleration of the inflammatory phase of healing.

Adjustable Parameter (Y/N)	Parameter Name	Range (unit)	Default units
Y	ULTRASOUND FREQUENCY	1 or 3 MHz	3 (MHz)
Y	DELTA T	1, 2, 4 °C	1 (°C)
N	TRANSDUCER SIZE	5 cm ²	5 cm ²
Y	TREATMENT TIME	060 (min)	Based on Delta T
			Selection

Decrease Chronic Pain and Muscle Tone-Spasm - Increase Local Circulation

This protocol uses a 2°C temperature increase to increase the tissue metabolic rate and provide moderate heating. It is used to increase circulation in chronic cases to provide absorption of chronic inflammatory components for pain management and chronic muscle tone and spasm. Temperature can be increased to 4°C for superficial tissue.

Adjustable Parameter (Y/N)	Parameter Name	Range (unit)	Default units
Y	ULTRASOUND FREQUENCY	1 or 3 MHz	3 (MHz)
Y	DELTA T	1, 2, 4 °C	2 (°C)
N	TRANSDUCER SIZE	5 cm ²	5 cm ²
Y	TREATMENT TIME	060 (min)	Based on Delta T Selection

Decrease Joint Stiffness-Contracture

Heating followed immediately by stretch has been demonstrated to create an increase in the elongation of collagen tissues. A 2-4°T change is capable of providing a temperature in tissue capable of reaching the viscoelastic temperature of collagen. It is important to note that the stretch window with ultrasound is approximately 5 minutes, so stretching must begin as the treatment starts. The patient should feel warmth from the US field.

Adjustable Parameter (Y/N)	Parameter Name	Range (unit)	Default units
Y	ULTRASOUND FREQUENCY	1 or 3 MHz	3 (MHz)
Y	DELTA T	1, 2, 4 °C	2 (°C)
N	TRANSDUCER SIZE	5 cm ²	5 cm ²
Y	TREATMENT TIME	060 (min)	Based on Delta T Selection

OMNIVERSA PROGRAM MENU - COMBINATION THERAPY

COMBINATION THERAPY INDICATIONS			
Pain			
1	POST TRAUMATIC - POST SURGICAL		
2	ACUTE		
3	CHRONIC		
Increase Local	Circulation		
1	HVPC SENSORY		
Decrease Muse	Decrease Muscle Tone - Spasm		
1	PREMOD MOTOR		
Combination T	herapy Manual Mode		
1	HVPC Waveform – Thermal Ultrasound		
2	HVPC Waveform – Pulsed/Continuous Ultrasound		
3	PREMOD Waveform – Thermal Ultrasound		
4	PREMOD Waveform – Pulsed/Continuous Ultrasound		

PAIN MANAGEMENT - INCREASE LOCAL CIRCULATION

COMBO: Post Traumatic - Post Surgical & Increase Local Circulation

HVPC Sensory

This protocol combines subthermal therapeutic ultrasound with high volt pulsed current (HVPC) electrical stimulation current at a sensory (100 Hz) frequency for 1) superficial pain reduction and 2) increase local circulation to targeted tissue area. Sensory current stimulates vasodilation, increasing local circulation. Application of negative polarity over the edematous site has been demonstrated to reduce post-traumatic edema in clinical trials. In addition, if pain is present, can reduce it via segmental pain modulation mechanisms. Therapeutic ultrasound can resolve post-traumatic edema, reduce pain and facilitate tissue healing.

Duration of relief is typically for several hours. Fast onset of relief usually happens within 15-20 minutes. Target tissue is superficial and deep. Application; Monopolar, using channel B, place the red (positive) electrode adjacent to the treatment area. The ultrasound transducer is the black (-) electrode. The intensity should be set to elicit a pleasant tingling sensation, just below a muscle contraction.

Adjustable Parameter (Y/N)	Parameter Name	Range (unit)	Default (unit)
Y	PULSE RATE	1200 (Hz)	125 (Hz)
Y	TREATMENT TIME	060 (min)	15 (min)

Adjustable Parameter (Y/N)	Parameter Name	Range (unit)	Default units
Y	ULTRASOUND FREQUENCY	1 or 3 MHz	3 (MHz)
Y	PULSED - CONTINUOUS	CW, 5,10, 20,25, 33, 50 (%)	20 (%)
Y	TRANSDUCER SIZE	$0.8~\mathrm{cm^2}$ or $5~\mathrm{cm^2}$	5 cm ²
Y	TREATMENT TIME	060 (min)	15 (min)

Combo: Acute Pain

Premod Sensory

This protocol combines subthermal therapeutic ultrasound with premodulated (PREMOD) current at a sensory (100 Hz) burst frequency for 1) pain reduction and 2) increase local circulation to targeted tissue area. Sensory stimulation stimulates segmental pain modulation and vasodilation, increasing local circulation. Application of negative polarity over the edematous site has been demonstrated to reduce post-traumatic edema in clinical trials. Therapeutic ultrasound can resolve post-traumatic edema, reduce pain and facilitate tissue healing.

This program is used for symptomatic relief of superficial and deep pain from localized dermatome or segmental origin. Duration of relief is typically for several hours. Fast onset of relief usually happens within 15-20 minutes. Target tissue is superficial and deep. Application; Monopolar, using Ch. B, place the red (positive) electrode adjacent to the treatment area. The intensity should be set to elicit a pleasant tingling sensation, just below a muscle contraction.

Adjustable Parameter (Y/N)	Parameter Name	Range (unit)	Default (unit)
Y	BURST RATE	1200 (Hz)	100 (Hz)
Y	TREATMENT TIME	060 (min)	15 (min)

Adjustable Parameter (Y/N)	Parameter Name	Range (unit)	Default units
Y	ULTRASOUND FREQUENCY	1 or 3 MHz	3 (MHz)
Y	PULSED - CONTINUOUS	CW, 5,10, 20,25, 33, 50 (%)	20 (%)
Y	TRANSDUCER SIZE	$0.8~\mathrm{cm^2}$ or $5~\mathrm{cm^2}$	5 cm ²
Y	TREATMENT TIME	060 (min)	15 (min)

Combo: Chronic Pain - Decrease Muscle Tone-Spasm

Premod Motor

This protocol combines therapeutic thermal ultrasound with premodulated (PREMOD) current at a motor (4 Hz) burst frequency, and may relieve pain for up to 8 hours via segmental and systemic pain modulation mechanisms. Thermal therapeutic ultrasound heats the myoneural junction causing muscle relaxation thereby reducing muscle spasm. Ultrasound Default: Frequency 3 MHz (superficial) and 2 Delta T for moderate heating and will increase tissue temperature by approximately 2 degrees Celsius.

This program is used for symptomatic relief of superficial and deep pain and pain of generalized or multi-segmental nature. Duration of relief is typically for up to 8 hours. Slow onset of relief usually within 15 minutes to 1 hour. Target tissue is superficial and deep. Application; Monopolar, using Ch. B, place the red (positive) electrode adjacent to the treatment area. The intensity should be set to elicit a muscle twitch. Combined with thermal ultrasound to heat the myoneural junction causing muscle relaxation thereby reducing muscle spasm.

Adjustable Parameter (Y/N)	Parameter Name	Range (unit)	Default (unit)
Y	PULSE RATE	1200 (Hz)	4 (Hz)
Y	TREATMENT TIME	060 (min)	15 (min)

Adjustable Parameter (Y/N)	Parameter Name	Range (unit)	Default units
Y	ULTRASOUND FREQUENCY	1 or 3 MHz	3 (MHz)
Y	DELTA T	1, 2, 4 °C	2 (°C)
N	TRANSDUCER SIZE	5 cm ²	5 cm ²
Y	TREATMENT TIME	060 (min)	Based on Delta T Selection

TROUBLESHOOTING

The following table lists machine problem symptoms and possible areas to check for the problem causes. If these suggested measures do not correct the machine malfunction, call your ACP Customer Support representative.

PROBLEM	CAUSE	REMEDY
Unit will not power on (under battery use)	LCD Power Display switch (orange power button) is off No battery or faulty battery Main power switch is Off preventing the battery to charge	Power on LCD display switch Place the Main Power Switch into the ON position and be sure the battery charging icon is displayed Verify type and settings of batteries Inspect battery contacts and setting per procedure below Charge or replace batteries
Unit will not power on (under battery use) Rotary Selector dial is blinking	Low battery power Main power switch is Off preventing the battery to charge	Connect to AC outlet, restart and charge battery Place the Main Power Switch into the ON position and be sure the battery charging icon is displayed
Unit will not power on (under line power use)	Power Supply not plugged in to the unit of AC outlet Power Supply not operational	 Verify if the Power Supply is connected as appropriate. Verify the LCD Power Display switch (Orange power button) is in the ON position. Verify if the AC outlet is functional Verify if the power plug used is appropriate and undamaged (see below) Inspect Power Supply operation per procedure below
Battery Warning Messages	Warning messages	Recharge batteries for future use Batteries should be charged 8 hours prior to use
Insufficient Power Warning	Potentially insufficient power to complete an Ultrasound treatment - Recommend using Power Cord	Connect to AC outlet Recharge batteries Place the Main Power Switch into the ON position and be sure the battery charging icon is displayed
Low Battery	▲ Low Battery - Use Power Cord	 There is insufficient battery power complete the selected treatment. Suggest you connect the system to AC outlet to continue. Place the Main Power Switch into the ON position and be sure the battery charging icon is displayed
Battery Empty	▲ ABattery Empty - Use Power Cord	 When this message is displayed the battery level is critically low and the system is locked. You should connect the system to AC outlet and then restart the display by turning off and on the LCD Display switch (orange power button). Place the Main Power Switch into the ON position and be sure the battery charging icon is displayed
Ultrasound displays a C or D-4008 Error "Device needs to cool down before you proceed. Please disconnect Ultrasound transducer"	Device needs to cool down before you can proceed. Please disconnect Ultrasound transducer.	The aluminum head of the ultrasound transducer has become too hot and needs to cool down prior to patient use.
Cannot change a parameter i.e. carrier frequency during a treatment session	Treatment in progress	Stop treatment, adjust, and restart Some electrotherapy parameters cannot be changed during a treatment session

TROUBLESHOOTING (cont.)

PROBLEM	CAUSE	REMEDY
Pain at the electrode site	Incorrectly placed electrodes too close together	Stop treatment Remove electrodes Reposition electrodes after increasing the distance between electrodes
Patient feels surging or spiking sensation during Combination Therapy	Lead wire(s): short or breakage Non-conductive or poorly conductive electrodes The current is still running during electrode removal	Replace with correct and adequate conductive medium Remove electrode(s) and replace if necessary Check that the channel output on the display is zero prior to removing electrodes After pressing PAUSE do not remove electrodes for 3 seconds to allow any remaining capacitance to dissipate
Patient cannot detect output	 Failure of lead wire(s), electrode(s) Non-conductive or poorly conductive electrodes Failure of the stimulator 	Test and Replace lead wires if required Remove electrode(s) and replace if necessary Perform auto tests on stimulator, if fault condition shown on the screen send unit to service center for replacement - repair

ACP Lead Wire Test

ACP lead wires can be tested to assure they are properly conducting current. The Lead Wire Test is found on page 2 of the of System Settings screen.



ACP Lead Wire Test Process

Single lead wire (2 electrodes)

- 1. Insert the lead wire in either channel A or B
- 2. Connect self-adhesive electrodes to ends of each lead wire and stick them together (i.e. gel-to-gel)
- 3. Press the START button and observe the PASS (green) / FAIL (red) response
- 4. Move the wires around paying special attention to the wire at the connection to the unit
- 5. Contact ACP Customer Support (800) 350-1100 to replace lead wires that FAIL

Note:

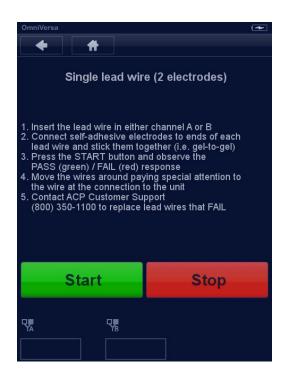
The START button must be pressed only after all the connections have been made. If the FAIL signal is illuminated, this will not change unless the STOP and START button are pressed again to start a new test sequence. A fail response will be present in any channel that is open and is not testing a lead wire.

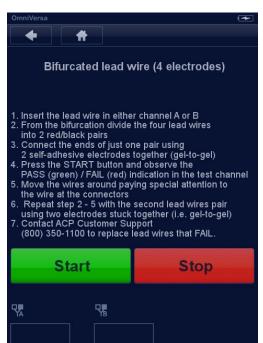
Bifurcated lead wire (4 electrodes)

- 1. Insert the lead wire in either channel A or B
- 2. From the bifurcation divide the four lead wires into 2 red/black pairs
- 3. Connect the ends of just one pair using 2 self-adhesive electrodes together (gel-to-gel)
- 4. Press the START button and observe the PASS (green) / FAIL (red) indication in the test channel
- 5. Move the wires around paying special attention to the wire at the connectors
- 6. Repeat step 2 -5 with the second lead wires pair using two electrodes stuck together (i.e. gel-to-gel) 7. Contact ACP Customer Support (800) 350-1100 to replace lead wires that FAIL

Note:

The START button must be pressed only after all the connections have been made. If the FAIL signal is illuminated, this will not change unless the STOP and START button are pressed again to start a new test sequence. A fail response will be present in any channel that is open and is not testing a lead wire.





Ultrasound Optimizer

The OmniVersa scans the resonance frequency of the crystal and re-sets the frequency of the units to calibrate with the frequency to the crystal.

This is done automatically by the system software when the transducer is put in and when turning on the unit.

If there is any question that the crystal isn't functioning properly (rare occurrence), a manual optimization option exists in the maintenance section of system settings.

Select "Optimize US Applicator C" or "Optimize US Applicator D", depending on into which channel the replacement transducer has been inserted, the Optimize US Applicator screen will appear. Pressing "Ok" at the top of the screen will initiate the optimization process, which only takes a few minutes.

While the optimization process is in progress, the screen will show an Orange bar indicating the percentage of completion. Upon full completion of the optimization process, the line will be Green and say 100% with a large green check mark. The US Applicator is now optimized



Back-up and Restore Favorites

When you have programmed and stored several Favorites, you might want to make a back-up on an external storage device.

To Back-up your favorites, proceed as follows:

- Attach a USB-stick to the remote control connection [3]. Read and obey the warnings and cautions mentioned on page 12.
- Go to Systems Settings -> Maintenance and select Back-up Favorites.
- If an error occurs during the back-up operation, i.e. USB-stick full, this will be displayed in a pop-up message.
- Touch the OK-button when the operation is complete.
- Detach the USB-stick

To restore your favorites:

- Attach the USB-stick containing your Favorites to the remote control connection [3]. Read and obey the warnings and cautions mentioned on page 12.
- Go to Systems Settings -> Maintenance and select Restore Favorites.
- If an error occurs during the restore operation, i.e. no favorites found, this will be displayed in a pop-up message.
- Touch the OK-button when the operation is complete.
- Detach the USB-stick

ACP SERVICE CENTER

For repair or service of ACP Products and accessories, please call (800) 350-1100 and follow the prompts. Normal hours of operation are 6:00am to 5:00pm Pacific Standard Time. After hours, please leave a message and a technician will return your call during the next scheduled workday.

ACP CONTACT INFORMATION

On the Home Screen is an ACP contact information Icon button that contains serial number, software version ACP Customer Support, ACP Clinical Question and Support phone number and email address, ACP website and physical mailing address.



TECHNICAL SPECIFICATIONS

GENERAL:		
Dimensions (W x H x D):	10" (24cm) x 5" (12cm) x 12.5" (32cm)	
Weight (including battery):	6lbs 10oz (3Kg)	
Operating Power:	100 - 240VAC; 50/60Hz; 100 VA	
System Memory:	The system remembers all prior custom settings from treatment to treatment as it is stored to memory.	
System Architecture:	CMOS integrated micro-controller with on board memory and instruction set.	
ENVIRONMENTAL CONDITIONS (STORAGE AND TRANSPORTATION):		
Temperature	-20° to +70° C	
Relative humidity	10 to 90 % (contained in original packaging)	
Atmospheric pressure	500 to 1060hPa	
ENVIRONMENTAL CONDITION	NS (NORMAL OPERATION):	
Temperature	10° to 40° C	
Relative humidity	10 to 90 % non-condensing	
Atmospheric pressure	500 to 1060hPa	

STIMULATION SYSTEM:			
Output:	Constant voltage (CV) above 1000 ohms, the system then operates in constant current with impedances less than 1000 ohms.		
Output/Waveform:	AC square wave into resistive load, IFC and MFAC modes, and biphasic asymmetrical or symmetrical square wave (LVPC) or mono-phasic pulsed current (HVPC mode). Output Amplitude: IFC 0 to 100 mA RMS current into a 500Ω , LVPC mode 140mA P-P, HVPC mode 225VDC peak into 500Ω loads.		
Channel Isolation:	Independent transformer isolation.		
Line Leakage:	<50 μA on line power		
MFAC (MEDIUM FREQUENCY	ALTERNATING CURRENT) MODE:		
Output/Waveform:	0 – 100 mA peak, 500 Ω load; square wave into resistive load 2 KHz, 2.5 KHz,3 KHz, 3.5 KHz, 4 KHz, 5 KHz, 7 KHz, 8 KHz, 9 KHz, and 10 KHz carrier frequency.		
Burst Rate:	Adjustable from 0.1 to 200 bps, 50% duty factor		
Rate Scan:	From 0-50%, from 0-20 seconds		
LVPC (LOW VOLTAGE PULSE	ED CURRENT) MODE:		
Output/Waveform:	0 – 140 mA peak, 500 Ω load; Asymmetrical biphasic square wave		
Phase Duration:	10 - 300 μs		
Pulse Rate:	1 – 200 Hz		
IFC (INTERFERENTIAL CURR	ENT) MODE:		
Output/Waveform:	0 – 100 mA peak, 500 Ω load; Full Field IFC (Premodulated)		
Frequency Difference Rate:	Output channel A, fixed at 2.0 KHz, 2.5, KHz, 3.0 KHz, 3.3 KHz, 4.0 KHz, or 5.0 KHz. Output channel B variable from channel A frequency + .0 to 250 Hz. Beat rate may be set during treatment.		
Full Field Burst Rate:	0.1 – 200 Hz		
Rate Scan:	0-20 seconds, 0-50% modulation. Upper and lower frequencies are fully programmable and sweep time is adjustable in set mode.		

TECHNICAL SPECIFICATIONS (cont.)

PENS (PATTERNED ELECTRICAL NEUROMUSCULAR STIMULATION) MODE:			
Output/Waveform:	0 – 100 mA peak, 500 Ω load; Asymmetric Biphasic – Based on EMG functional pattern		
Phase Duration:	Variable from 40 μs to 100 μs		
Pulse Rate:	Set at 50 Hz or 100 Hz		
HVPC (HIGH VOLTAGE PULS	ED CURRENT) MODE:		
Output/Waveform:	0 – 225V; Twin monophasic pulses each with 40 μs phase duration		
Phase Duration:	< 2 uSec		
Pulse Rate:	Adjustable 0 – 200 Hz		
Interphase Interval:	Preset at 65 µs		
HAND CONTROL:			
MFAC Hand Control:	 Modified Sine wave into physiologic load 2 KHz, 2.5 KHz, 3 KHz, 3.3 KHz, 4 KHz, 5 KHz, 6 KHz, 7 KHz, 8 KHz, 9 KHz, and 10 KHz carrier frequency. Burst rate adjustable from 0.1 to 100bps, 50% duty factor Rate scan from 0-50% programmable with scan time, programmable from 0-20 seconds 		
LVPC Hand Control:	 Asymmetrical biphasic square wave Phase duration adjustable from 10 - 300 µs Pulse rate adjustable from 0.1 – 200 pps 		
TIMER FUNCTIONS:			
Treatment Timer:	Adjustable for 0-60 minutes in one minute increments.		
Channel Timing:	In alternating mode channels follow each other sequentially. In simultaneous modes the output is simultaneous. In delayed mode channel B is delayed.		
TIMING SELECTIONS:			
Ramp Time:	Adjustable from 0 to 9 seconds in 1-second increments. Ramps overlap in NMES Alt mode or with channel delay.		
ON Time:	Adjustable from 1 to 60 seconds in 1-second increments		
OFF Time:	Adjustable from 0 (continuous) to 120 seconds in 1-second increments		
BATTERIES:			
Type:	Gel Cell rechargeable 12V /2AH		
Charge Time:	4-hour charge time is required for a full charge		
MISC.			
Useful Life	The device is deemed to have a useful life of 5 to 7 years. This is largely dependent on usage and maintenance (including cleaning after each use).		

CAUTION: Federal law restricts this device to sale by or on the order of a physician (or other health practitioner licensed by their State).

ACP reserves the right to change technical specifications and product availability without notice.

(EMC) Electromagnetic Compliance

Medical electrical devices series are subject to special precautions with regard to electromagnetic compatibility and must be installed and commissioned in accordance with the advice given in the instructions for use and accompanying documents. Portable and mobile RF communication systems (e.g. mobile phones) may interfere with medical devices. The OmniVersa

should only be operated with the original mains cable specified in the list of contents delivered. Operating the device with any other mains cable can lead to increased emissions or reduced interference immunity of the device.

Guidelines and manufacturer's declaration - Electromagnetic Interference

The OmniVersa is intended for operation in an electromagnetic environment as indicated below. The customer or user of the OmniVersa should ensure that it is operated in such an environment.

Interference tests	Conformity	Electromagnetic environment guideline
RF emissions according to CISPR 11	Group 1	The OmniVersa uses RF energy solely for its internal functioning. Its RF emission is therefore very low and it is unlikely that this will cause interference to neighbouring electronic 4-series.
RF emissions according to CISPR 11	ClassB	The OmniVersa is suitable for use in all installations including those in a residential environment and those which are directly connected to the
Harmonic emissions according to IEC 61000-3-2	Class B	public mains network which also supplies buildings which are used for
Voltage fluctuation emissions and flicker according to IEC 61000-3-3	Conforms	residential purposes.

The device should not be used when placed immediately next to or stacked on top of other devices. If operation is necessary when immediately next to or stacked on top of other devices, the device should be monitored to ensure it is operating as intended in this arrangement.

Guidance and manufacturer's declaration - Electromagnetic Immunity

The OmniVersa is intended for use in the electromagnetic environment specified below. The customer or the user of the OmniVersa TM should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) to IEC 61000-4-2	± 6 kV contact	± 6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity
` '	± 8 kV air	± 8 kV air	should be at least 30%.
Electrical fast transient / burst to IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
	± 1 kV for input / output lines	not applicable	
Surge IEC 6100-4-5	± 1 kV differential mode	± 1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
	± 2 kV common mode	± 2 kV common mode	-
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$ \begin{array}{l} <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 \\ seconds) \end{array} $	$ \begin{array}{l} <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 \\ seconds) \end{array} $	Mains power quality should be that of a typical commercial or hospital environment. If the use of the OmniVersa requires continued operation during mains power interruptions, it is recommended to install a battery.
Power frequency (50/60 Hz) magnetic field to 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 commerical or hospital environment.

Note: U_T is the AC mains voltage prior to application of the test level.

The main features of the device is as follows: interference-free delivery of shockwaves, interference-free control of all functions. Uninterrupted operation is not required with the use intended.

Guidelines and manufacturer's declaration – electromagnetic interference immunity

The OmniVersa is intended for operation in the electromagnetic environment specified below. The customer or user of the OmniVersaTM should ensure that it is used in such an environment.

Interference immunity tests	IEC 60601-test level	Compliance level	Electromagnetic environment - guidelines
Conducted RF disturbance variables according to IEC 61000-4-6 Radiated RF disturbance variables according to IEC 61000-4-3	3 Veffective value 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Veffective value 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Portable and mobile radios should not be used any closer to the OmniVersa, including cables, than the recommended separation distance calculated from the equation applicable to the transmission frequency. Recommended separation distance: d= 1.2 √P d= 0.35 √P for 80 MHz to 800 MHz d= 0,7 √P for 800 MHz to 2.5 GHz Where P is the rated power of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). According to an investigation in situ ^a , the field strength of stationary radio transmitters should be less than the compliance level at all frequencies. Interference may occur in the vicinity of OmniVersa™ which is marked with the following symbol:

NOTE: 1 At 80 MHz and 800 MHz the higher frequency range is applicable.

NOTE: 2 These guidelines may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended separation distances between portable and mobile RF telecommunications and the OmniVersa

The OmniVersa is intended for operation in an electromagnetic environment where RF disturbances are monitored. The customer or user of OmniVersa can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF telecommunications OmniVersaTM (transmitters) and the OmniVersa – according to the output power of the communications device, as indicated below.

^a Theoretically, it is not possible to exactly predict the field strengths of fixed transmitters such as base stations for radio telephones and land mobile radios, amateur radio stations, AM and FM radio and TV broadcasting. To determine the electromagnetic environment in relation to the fixed transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location where the OmniVersa is to be used exceeds the above compliance levels, the OmniVersa should be monitored in order to ensure that it is functioning as intended. If unusual features are noticed, additional measures may be necessary such as re-orienting or relocating the OmniVersa.

 $^{^{\}rm b}$ Above the frequency range from 150 kHz to 80 MHz the field strength should be less than 3 V/m.

Rated output of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz d= 1.2 √P	80 MHz to 800 MHz d= 0.35 √P	800 MHz to 2.5 GHz d= 0.7 √P
0.01	0.12	0.035	0.07
0.1	0.38	0.11	0.22
1	1.2	0.35	0.70
10	3.8	1.1	2.2
100	12	3.5	7

For transmitters rated at a maximum output which is not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the respective column, whereby P is the maximum rated output of the transmitter in Watts (W) according to the transmitter manufacturer.

NOTE: 1 At 80 MHz and 800 MHz the higher frequency range is applicable.

NOTE: 2 These guidelines may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

OMNIVERSA STANDARD AND OPTIONAL ACCESSORIES

ITEM	ITEM NO.	DESCRIPTION
	100FX2F-EQUIP	OMNIVERSA MULTI MODALITY THERAPY Offers 2 channels of programmable stimulation with MFAC (Russian style NMES), Low Volt Pulsed Current (LVPC), High Volt (HVPC),

Standard and/or Optional Accessories

ITEM	ITEM NO.	DESCRIPTION
	69631	Remote Control
© 22	19987	Remote Patient Stop
	19856	OmniVersa Power Cord, A/C, Hospital Grade
Appli, jumou	11486	OmniVersa FX2 Professional User Manual
Busin	*67652	OmniVersa Leatherette Soft Carry Case

^{*} This item is an optional accessory and is not included with the unit.

Lead Wires and Electrodes

ITEM	ITEM NO.	DESCRIPTION
	55405	Lead Wire – Standard Blue & Green (pair)
	10120	Lead Wire – Bifurcated Blue & Green (pair)
	MULTI-USE ELECTRODES	
	38155	2x2 Multi-use E-stim Electrodes (4ea/pkg., 10pkg/bx)
	61227	2x4 Multi-use E-stim Electrodes (4ea/pkg., 10pkg/bx)
	26854	3x5 Multi-use E-stim Electrode (2ea/pkg., 10pkg/bx)

Infection Control Supplies

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ITEM	ITEM NO.	DESCRIPTION	
	52479	Barrier Film for Surfaces, Infection Control, 4" x 6" perforated sheets – 1200 sheets/roll	
	66431	Barrier Film for Surfaces, Infection Control, 6" x 9" perforated Sheets – 1200 sheets/roll	
	50593	Barrier Film - for Surfaces, Infection Control, 12" x 14" perforated Sheets – 800 sheets/roll	
EHEATHES @ Angles	30355	Sheath® US Transducer covers 3" x 12" (25 ea./bx)	
V. Carlot	63574	Protective Barrier Tubing, 3" (1200ft/roll)	
CONTROL OF THE PROPERTY OF THE	55536	Super Sani-Cloth® Wipes, Single Use Packets (50 pkt./bx)	
	44425	Super Sani-Cloth® Wipes, Tub (160 wipes/tub)	
	96849	Sani-Cloth® Wipes w/ Bleach, Tub (75 wipes/tub)	

STANDARD LIMITED PRODUCT WARRANTY

The warranty information provided in this section is applicable only to products purchased from ACP, directly or through an authorized dealer. This section does <u>not</u> apply to leased products. The terms of maintenance and repair of any leased products are detailed in the separately executed agreement between the parties.

Warranty Coverage

This warranty provides coverage, for Equipment purchased, against manufacturer's defects in material and workmanship, and extends to the original owner of the product during the warranty period for that product. Only those items returned to the ACP Service Center within the warranty period, and also within thirty (30) days after notification to ACP of the defect, shall be eligible for repair under the Standard Limited Product Warranty. Buyer is responsible for shipping cost associated with sending the Equipment to the ACP Service Center. ACP shall ship Equipment to Buyer after repair at no cost to the Buyer provided repair is deemed to be under warranty. ACP may, at its discretion and only for valid warranty claim, repair or replace any part(s) that prove to be defective during the warranty period.

Warranty Exclusion

Any and all warranty coverage will be void if any of the following have occurred:

- 1. The product contains repairs or replacement parts not furnished by ACP.
- 2. The product is damaged resulting from misuse or negligence.
- 3. The product has been tampered with and/or altered, including serial number alteration.

Note: Use of the Equipment with accessories and/or supplies not approved by ACPL for use with the Equipment may void the warranty if such accessory or supply item caused damage to the Equipment.

Warranty Period

The following coverage is provided at no additional cost to the Buyer:

New Equipment / Product. Products purchased as new from ACP are warranted against manufacturer's defects in material and workmanship for a period of two (2) years from the date of purchase.

Refurbished Equipment / Product. Products purchased specifically as Refurbished Equipment are warranted against manufacturer's defects in material and workmanship for a period of one (1) year from the date of purchase.

Accessories. All accessories for ACP equipment / products are warranted against manufacturer's defects in material and workmanship for a period of three (3) months from the date of purchase.

Warranty Validation

The following information needs to be provided to the ACP Customer Support representative prior to the product being returned under warranty coverage:

- 1. Buyer name or account number as it appears under the "Bill TO" on the ACP or recognized ACP Dealer invoice.
- 2. Invoice Date and Number.
- 3. Model number, description, and serial number of equipment.
- 4. Detailed description of the problem.

Return of Defective Equipment

Any Equipment returned to the ACP Service Center under warranty coverage must have the Warranty coverage validated and must receive authorization from ACP Customer Support prior to being received at the Service Center.

Shipping charges, insurance, and any other costs incurred in sending product to ACP Service Center is the responsibility of the customer and will not be refunded. ACP shall cover the shipping charges and related costs to return the unit to the customer, provided repair is deemed to be under warranty.

ACP is not responsible for any loss or damage to the Equipment prior to receipt at the ACP Service Center. Equipment returned for warranty service must be shipped complete with all accessories (except for manuals), in its original packing or equivalent so as not to be damaged while in transit.

Note: Any Equipment sent to the ACP Service Center that is not covered by the ACP Limited Product Warranty is subject to a minimum service and handling fee.

IMPORTANT:

DO NOT SHIP THE EQUIPMENT TO ACP SERVICE CENTER WITHOUT FIRST SECURING AUTHORIZATION TO DO SO. EQUIPMENT SENT IN WITHOUT AUTHORIZATION FROM ACP CUSTOMER SUPPORT WILL NOT BE ACCEPTED.

Returned Materials Shipping Address:

Accelerated Care Plus Attn: ACP Service Center 4999 Aircenter Circle, Suite 103 Reno, NV 89502

Manufactured for ACP by:

Enraf-Nonius B.V. Vareseweg 127 3047 AT Rotterdam The Netherlands

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