



OMNISTIM[®] 500 PRO

Electrotherapy System

User Manual

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OMNISTIM® 500 PRO

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 OMNISWD®, MEGAPULSE®, OMNIVERSA®, NEUROPROBE®, OMNISTIM®, OMNISOUND®, OMNICYCLE®, OMNISTAND®, OMNIVR®, and SYNCHRONY DYSPHAGIA SOLUTIONS by ACP® 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










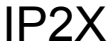






Symbol	Used for	Symbol	Used for
	Serial number		Type BF medical device per: IEC 60601
	Date of manufacture		Manufacturer
	Caution, consult accompanying documents		Caution, electrical precautions
	Remote Control connection		CE mark of confidence compliant to MDD (93/42/EEC)
	Connection Electrode Cable		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.		Alternating current device.
	Observe the user manual		Consult instructions for use
	Protect the product from humidity		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 note that Accelerated Care Plus cannot provide medical advice. If you have specific medical questions, please contact your healthcare professional.

Indications

The Omnistim® 500 Pro 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 electro-surgery equipment. 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 cardiac arrhythmias.
- Do not apply stimulation when the patient is in the bath or shower
- Do not apply stimulation while the patient is sleeping; and
- Do 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.
- 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 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 OMNISTIM® 500 PRO

Delivery of the Omnistim® 500 Pro

Upon receipt of your Omnistim® 500 Pro 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's 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 Omnistim® 500 Pro's operating features and functionality. Please read the manual carefully before attempting to operate the Omnistim® 500 Pro. If questions remain unanswered, contact your ACP sales representative or call 1-800-350-1100. Outside the USA call 1-775-685-4000.*

Introduction

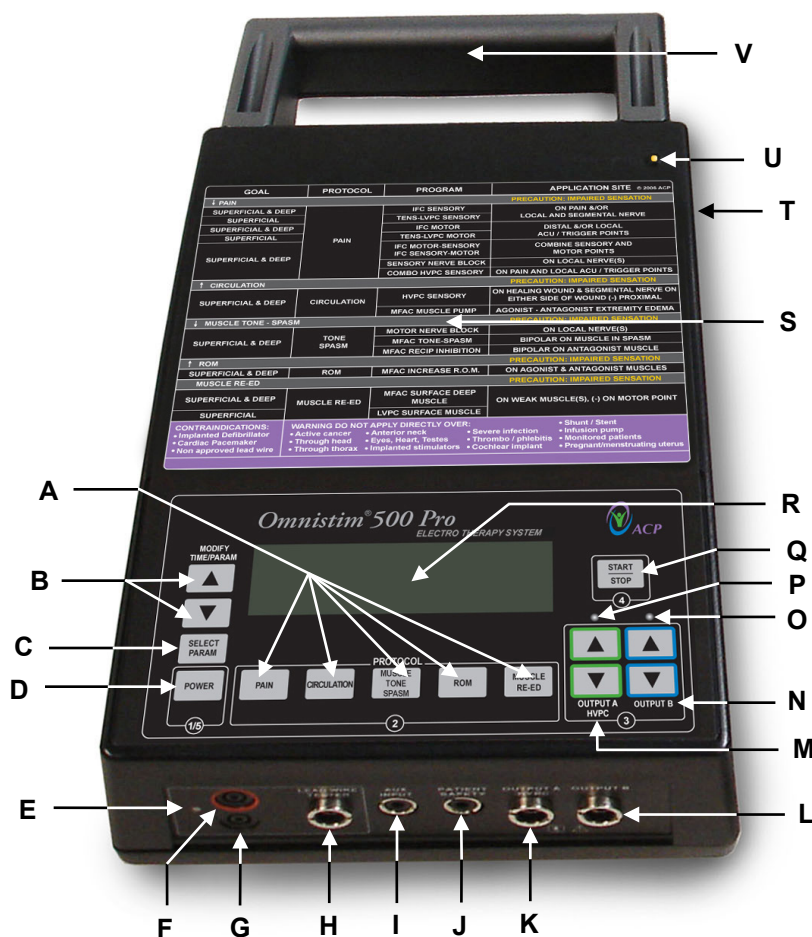
The Omnistim® 500 Pro is designed to provide Interferential Current Therapy (IFC), Medium Frequency Alternating Currents (MFAC), Low Voltage Pulsed Current (LVPC) and High Voltage Pulsed Current Therapy (HVPC). Its two separate generators produce medium frequency (2000, 2500, 4000 or 5000 Hz) alternating current in continuous or 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 Omnistim® 500 Pro offers Frequency Difference (FD) and Full Field (FF) Interferential Current Therapy. An interferential vector scanning mode can be turned off or on for stationary or continuous movement of the interferential field.

The Omnistim® 500 Pro MFAC and LVPC modes with fully adjustable ON and OFF times and ON and OFF ramps provides a wide variety of uses for muscle re-education and muscle spasm reduction protocols for innervated muscle.

The Omnistim® 500 Pro provides High Voltage Pulsed Current (HVPC) on one channel. Continuous or surged operation with fully adjustable ON and OFF times and ramps allow applications of HVPC therapy. Increasing circulation, pain control and muscle re-ed can be set up in this mode.

Controls and Functions



- Press button corresponding to the desired functional PROTOCOL group. Chose between PAIN, CIRCULATION, MUSCLE TONE SPASM, ROM, or MUSCLE RE-ED.
- MODIFY TIME/PARAMETER UP or DOWN buttons are used to increase/decrease treatment time or changes parameters in SET mode.
- SELECT PARAMETER button provides adjustment of stimulation parameters, audio on/off and button speed. Press to enter SET mode. It is possible to adjust most stimulation parameters at any time during treatment.
- Main power switch. Press for power ON, press again for power OFF. The display illuminates with default display: SELECT PROTOCOL / TREATMENT OFF.
- LEAD WIRE TESTER indicator LED. When lead wires are properly connected to the LEAD WIRE TESTER, the LED will display green if lead wires function properly, and it will be red if lead wires are faulty or are not connected to the LEAD WIRE TESTER properly.
- Connector for the distal (patient end) of the lead wire when testing lead wire in the LEAD WIRE TESTER. Observe proper polarity, and connect red lead wire into red connector.
- Connector for the distal (patient end) of the lead wire when testing lead wire in the LEAD WIRE TESTER. Observe proper polarity, and connect black lead wire into black connector.
- Connector for the device end of the lead wire when testing lead wire in the LEAD WIRE TESTER.
- AUX INPUT used to connect cable for remote hand control operation.
- PATIENT SAFETY input switch connector.

- K. Output for CHANNEL A and HVPC protocols.
- L. Output for CHANNEL B.
- M. Increase / decrease OUTPUT A. Press UP arrow button to increase intensity in channel A. Press the DOWN arrow button to decrease intensity in channel A.
- N. Increase / decrease OUTPUT B. Press UP arrow button to increase intensity in channel B. Press the DOWN arrow button to decrease intensity in channel B.
- O. LED which lights-up red when output is being applied thru channel B.
- P. LED which lights-up red when output is being applied thru channel A.
- Q. START/STOP button. Having selected the type of treatment and protocol, press to start or stop the treatment.
- R. LCD graphics screen for all functions and parameters. The graphics screen displays:
 - Protocol selected
 - Program selected
 - Time remaining
 - Carrier Frequency
 - Bar graph for Vector and detection modes
 - Button speeds
 - Vector selection
 - Output current
 - Sweep rate and modulation selection
- S. PROTOCOL LABEL to assist therapist in quick operation and treatment selection.
- T. Power Supply input jack.
- U. Power Supply operation indicator LED. This light is on when the power supply is plugged in and power is supplied to the unit.
- V. Solid carrying handle for easy transport of the unit.

Factory Settings

The Omnistim® 500 Pro comes with the following factory settings:

Button Speed, A & B Output	91
Audio	ON

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

- When the main screen comes up and states “SELECT PROTOCOL / TREATMENT OFF” push the SELECT PARAMETERS button repeatedly to display the factory settings. You will then be able to adjust the selected factory settings by pressing the MODIFY TIME/PARAMETER UP / DOWN arrow button. The new settings will be saved from use to use as long as you do not remove the batteries or allow a full discharge of the unit.
- The BUTTON SPEED for output A & B sets the speed at which output will increase and decrease when you push the buttons. This should generally be set at a slower speed (80 - 90) so as not to startle the patient.
- AUDIO on or off disables or enables the audio system that beeps at the end of the treatment and during the NMES programs.

NOTE: The factory settings cannot be accessed during operation and are only available following the start up screen. The settings will reset to their initial default parameters if the batteries are removed or the unit is fully discharged. To restore the new settings follow the procedure in Appendix I.

Battery Charger / Power Supply Operation

Before using the Omnistim® 500 Pro battery charger/power supply:

1. Verify that rechargeable batteries are installed within the Omnistim® 500 Pro battery compartment.
2. Check to see that the battery type selector switch located inside the battery compartment has been switched to the rechargeable position.

If you plug in the charger, after two seconds, the charge LED on the Omnistim® 500 Pro is illuminated. After the batteries are fully charged, the LED blinks. If you plug in the charger during treatment or when the unit is ON the LED turns off. (The charging continues but at a trickle and does not cause the LED to glow.) When you turn OFF the unit after two seconds the LED comes on to announce charging.

NOTE: *If non-rechargeable batteries are used:*

1. *Do not use the charger.*
2. *Make sure that the rechargeable/non-rechargeable selector switch in the bottom of the battery compartment is in the non-rechargeable position.*

Life expectancies of batteries under nominal (20 mA IFC, 40 mA MFAC, 100v HVPC) load conditions:

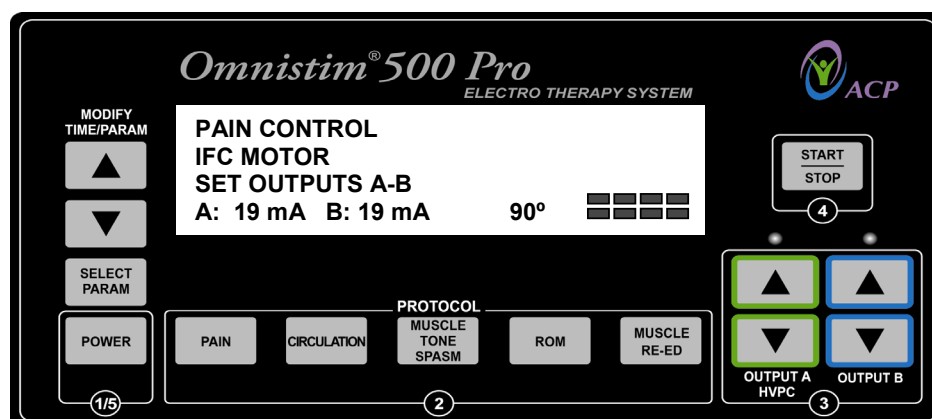
- 4.4Ah NiCad rechargeable batteries - 10 Hours.
- Alkaline non-rechargeable batteries - 100 Hours.

Operational Sequence

1. Press the POWER button (1/5) to turn on the power. The display panel will illuminate. There will be no stimulation current and the unit will be in the SELECT PROTOCOL mode.
2. At this time select the appropriate treatment protocol by pressing one of the protocol buttons (2) to select PAIN, CIRCULATION, MUSCLE TONE SPASM, ROM or MUSCLE RE-ED protocols.
3. Press the SELECT PARAM button to modify any settings. Press the MODIFY TIME/PARAM UP or DOWN buttons to adjust the desired treatment time, or other settings, if you wish to change from the default settings. Set the timer for the desired treatment time. Pressing MODIFY TIME/PARAMETER up or down buttons, increases or decreases the duration from a minimum of 1 minute to a maximum of 60 minutes. The timer will count down to zero during treatment; when zero is reached a warning tone is emitted from the unit, the treatment current is switched off and TREATMENT OFF is displayed.

NOTE: *The treatment time is preset for each program but may be adjusted at will during the treatment.*

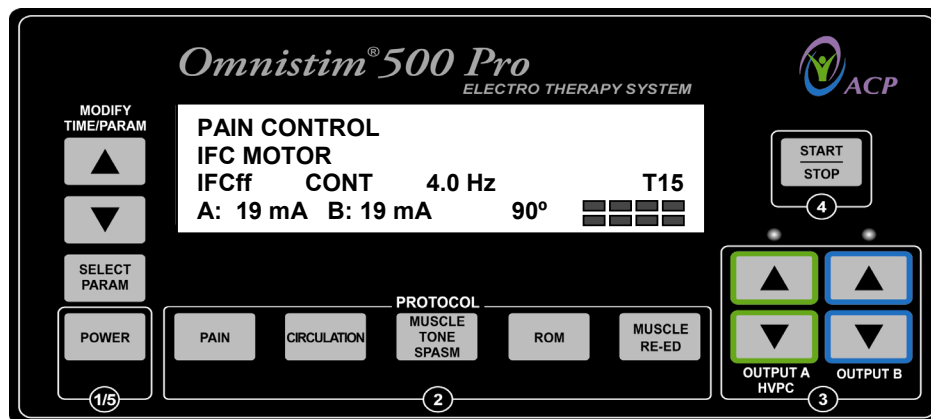
4. Now position the electrodes on the patient and connect the electrode plug(s). Adjust the output by pressing the OUTPUT A and OUTPUT B buttons (3), to deliver appropriate output based on patient sensation. The screen will display the following (in this example, IFC MOTOR was selected from the PAIN protocol functional group):



The bar graph on the lower right of the display shows the relative outputs of the two channels primarily with respect to Time On and Time Off and Vector operation. The numeric displays on the lower left show the output intensities into a 500-ohm load. Each time a treatment is commenced, the output current level is reset to zero; this ensures that your patient cannot receive an initial shock due to the current output, inadvertently, being left at a high setting from a previous treatment. The patient safety switch is a remote duplicate of the START/STOP switch and therefore resets the outputs to zero.

NOTE: *In some protocols using alternate or delayed modes, the system will allow set up of output A followed by set up of output B.*

5. Adjust output by pressing the up/down buttons (3) for channel A and channel B. When the desired output is obtained, press the START/STOP button (4) to begin treatment. The following screen will be displayed:



At this time, the timer display on right side of the screen will display the selected treatment time, and will continuously display time remaining during treatment.

6. During operation most of the parameters may be altered within the program at will by selecting the set mode. See set mode operation and adjustable parameters for each modality.
7. Once the treatment is completed, remove the electrodes from the patient and disconnect the lead wires from the electrodes. Pressing the START/STOP button (4) will shut off the warning tone. If the unit is left unattended, the warning tone is emitted for ten seconds before power is automatically switched off.
8. Turn the unit off by pressing the POWER button (1/5).

TREATMENT GUIDELINES

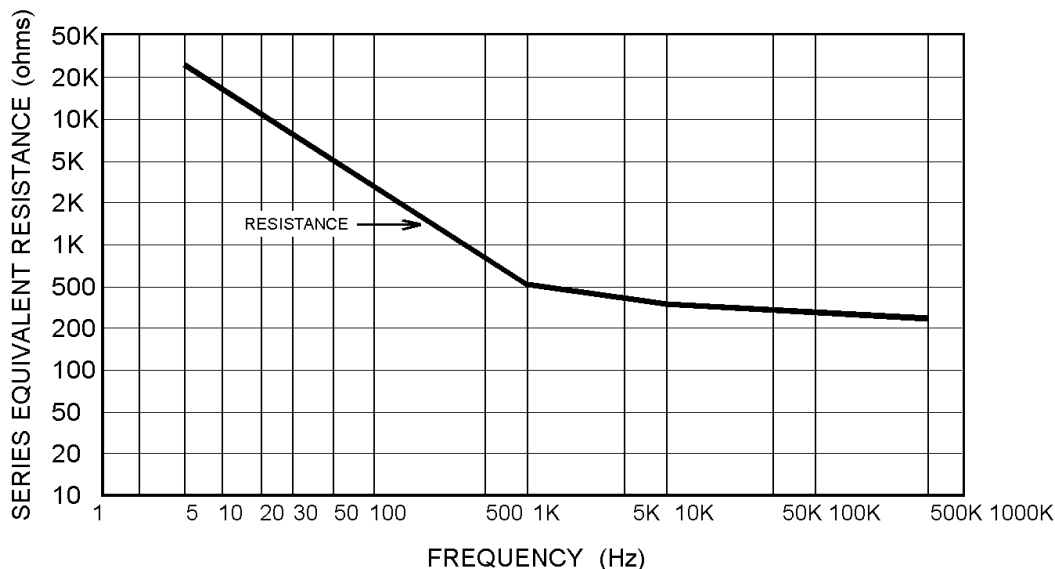
Introduction to Medium Frequency Currents

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, HVPC, and high frequency currents (1 million Hz and beyond), which include ultrasound, shortwave and microwave diathermy. Medium 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 2000 or 5000 Hz provide markedly lower resistance to penetration than low frequency electrical stimulation commonly used in TENS, LVPC, and HVPC stimulation. Medium frequency currents can be used in Bipolar or in Quadripolar Interferential mode for patient treatment.

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 stimulators (0.1 to 1000Hz), 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, (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 IMPEDANCE AS A FUNCTION OF FREQUENCY USING EPIDUCTIVE SYSTEMS

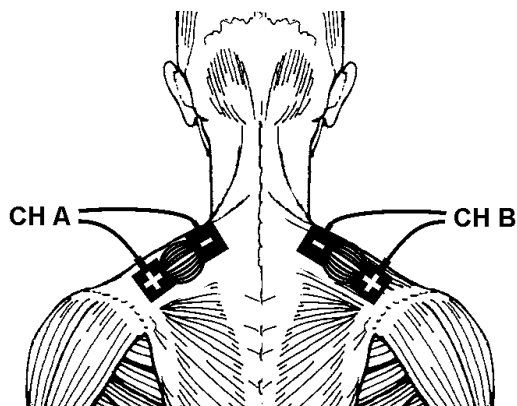
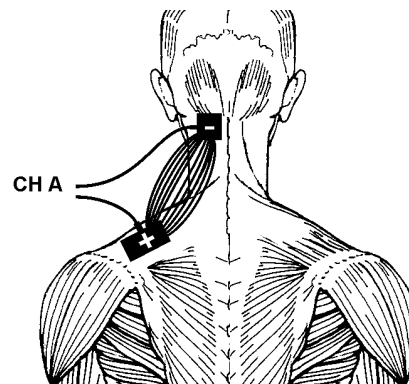
Electrode Application Techniques

The following electrode placement diagrams are a theoretical representation of treatment set-ups using the Omnistim® 500 Pro. 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

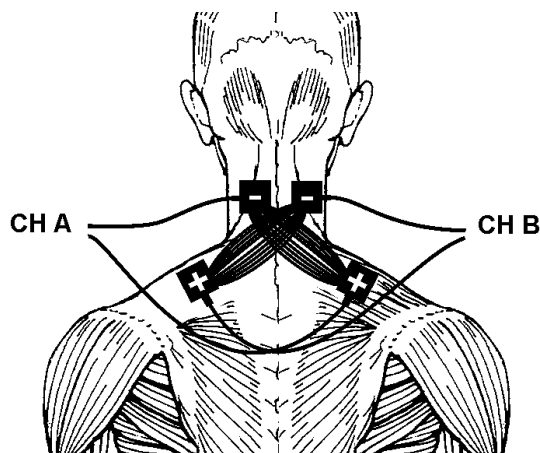
This is the most commonly used technique for muscle stimulation. This technique utilizes two electrodes but not exclusively of the same size. One electrode should be applied over the motor point and the other electrode over the belly of the muscle as far away from the motor point as possible. This technique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

CERVICAL BIPOLAR PLACEMENT OF ELECTRODES

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 an interferential pattern.

CERVICAL QUADRIPOLEAR PLACEMENT OF ELECTRODES



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; 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.

NOTE: *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 Omnistim® Systems.*

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 stereo jack plug and tip pins. Insert the stereo plug completely. Allow the lead wires to hang freely with no excessive strain on the stereo plug insulator.

Periodically check the lead wires by using the lead wire tester in the front of the Omnistim® unit.

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 bloodborne 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 Omnistim® 500 Pro

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

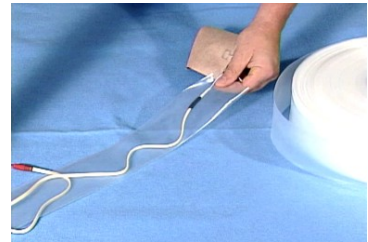
This method is recommended to keep the equipment clean and free of contaminants when used between patients for treatment of non-intact skin or incontinence management, where there is an increased risk of patient cross-contamination. The following are the recommended practices.

- 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 Omnistim® 500 Pro 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 Omnistim® 500 Pro unit prior to the next treatment application.



MODES OF OPERATON: Protocol Reference Sheets Pain Control

PROTOCOL / CLINICAL INDICATION	STIMULATION PARAMETERS	MECHANISM OF ACTION	APPLICATION TECHNIQUE	OPERATIONAL SEQUENCE
IFC SENSORY Symptomatic relief of superficial and deep pain from localized dermatome or segmental origin.	<ul style="list-style-type: none"> 5000Hz – 80/120 BPS Continuous Vector Fast 90° Treatment time of 15 minutes 	Sensory stimulation activates A-beta fibers causing the release of spinal Enkephalin and Dynorphin to block pain at the segmental level (Gate Control). Duration of relief is typically from 30 min to 2 hrs. Fast onset of relief usually within 15-20 minutes.	Target tissue - superficial and deep. Bilateral, bipolar or quadripolar through the painful area or over the involved spinal segments. Apply parallel to incision line for post op pain management. Set intensity to elicit a pleasant tingling sensation, just below muscle contraction.	<ul style="list-style-type: none"> Press PAIN button until screen reads "IFC SENSORY". Set Outputs A and B until the patient feels the desired sensation. Press START / STOP and T15 will display in upper right corner. Adjust treatment time if necessary using the TIME/PARAMETER button. The treatment will end at the end of the preset time or if the patient safety switch is pressed.
TENS-LVPC SENSORY Symptomatic relief of superficial pain from localized dermatome or segmental origin.	<ul style="list-style-type: none"> 100Hz - 80uSec PD, Continuous Treatment time of 15 minutes. 	Sensory stimulation activates A-beta fibers causing the release of spinal Enkephalin and Dynorphin to block pain at the segmental level (Gate Control) Duration of relief is typically from 30 min to 2 hrs Fast onset of relief usually within 15-20 minutes.	Target tissue-superficial. Bilateral bipolar through the painful area or over the involved spinal segments. Apply parallel to incision line for post-op pain management. Set intensity to elicit a pleasant tingling sensation, just below muscle contraction.	<ul style="list-style-type: none"> Press PAIN button until screen reads "TENS-LVPC SENSORY". Set Outputs A and B until the patient feels the desired sensation. Press START / STOP and T15 will display in upper right corner. Adjust treatment time if necessary using the TIME/PARAMETER button. The treatment will end at the end of the preset time or if the patient safety switch is pressed.
IFC MOTOR Symptomatic relief of superficial and deep pain with inflammation, and pain of generalized or multi-segmental nature.	<ul style="list-style-type: none"> 2500Hz – 2/6 BPS Continuous Vector Fast 90° Treatment time of 15 minutes 	Motor level stimulation activates motor and A-delta fibers causing the release of Bendorphin systemically. Duration of relief is typically from 2-6 hours. Slow Onset of relief usually within 15 minutes to 1 hour	Target tissue - superficial and deep. Bipolar placement over local and distal acu / trigger points; quadripolar placement over area of local pain; or quadripolar placement at spinal segment. Set intensity to elicit a moderate muscle twitch.	<ul style="list-style-type: none"> Press PAIN button until screen reads "IFC MOTOR". Set Outputs A and B until the patient feels the desired sensation. Press START / STOP and T15 will display in upper right corner. Adjust treatment time if necessary using the TIME/PARAMETER button. The treatment will end at the end of the preset time or if the patient safety switch is pressed.
TENS-LVPC MOTOR Symptomatic relief of superficial pain with inflammation, or pain of a generalized or multi-segmental nature.	<ul style="list-style-type: none"> 4Hz - 200uSec PD, Continuous. Treatment time of 15 minutes. 	Motor level stimulation activates motor and A-delta fibers causing the release of Bendorphin systemically Duration of relief is typically from 2-6 hours Slow Onset of relief usually within 15 minutes to 1 hour.	Target tissue-superficial. Bipolar placement over local and distal acu / trigger point or at spinal segmental level. Set intensity to elicit a moderate muscle twitch.	<ul style="list-style-type: none"> Press PAIN button until screen reads "TENS-LVPC MOTOR". Set Outputs A and B until the patient feels the desired sensation. Press START / STOP and T15 will display in upper right corner. Adjust treatment time if necessary using the TIME/PARAMETER button. The treatment will end at the end of the preset time or if the patient safety switch is pressed.
IFC MOTOR SENSORY Symptomatic relief of superficial and deep pain with inflammation, and pain of local, generalized single or multi-segmental nature.	<ul style="list-style-type: none"> 5000Hz – 15/2/100 BPS Vector OFF Treatment time of 30 minutes 	Combines motor and sensory stimulation. Starts with motor and ends with sensory. More aggressive protocol. Duration of relief is typically from 2-6 hours. Slower onset of relief usually within 15-30 minutes.	Target tissue - superficial and deep. Bipolar placement over local and distal acu / trigger points; quadripolar placement over area of local pain; or quadripolar placement at spinal segment. Set intensity to elicit a moderate muscle twitch.	<ul style="list-style-type: none"> Press PAIN button until screen reads "IFC MOTOR SENSORY". Set Outputs A and B until the patient feels the desired sensation. Press START / STOP and T30 will display in upper right corner. Adjust treatment time if necessary using the TIME/PARAMETER button. The treatment will end at the end of the preset time or if the patient safety switch is pressed.

Pain Control (cont.)

PROTOCOL / CLINICAL INDICATION	STIMULATION PARAMETERS	MECHANISM OF ACTION	APPLICATION TECHNIQUE	OPERATIONAL SEQUENCE
IFC SENSORY MOTOR Symptomatic relief of superficial and pain with inflammation, pain of local, generalized single or multi-segmental nature.	<ul style="list-style-type: none"> 5000Hz – 100/2 BPS Continuous Vector OFF Treatment time of 30 minutes 	Combines sensory and motor stimulation. Starts with sensory and ends with motor. Less aggressive protocol. Duration of relief is typically from 2-6 hours. Faster onset of relief usually within 15-20 minutes.	Target tissue - superficial and deep. Bipolar placement over local and distal acu / trigger points; quadripolar placement over area of local pain; or quadripolar placement at spinal segment. Set intensity to elicit a strong tingling sensation just under muscle contraction.	<ul style="list-style-type: none"> Press PAIN button until screen reads "IFC SENSORY MOTOR". Set Outputs A and B until the patient feels the desired sensation. Press START / STOP and T30 will display in upper right corner. Adjust treatment time if necessary using the TIME/PARAMETER button. The treatment will end at the end of the preset time or if the patient safety switch is pressed.
SENSORY NERVE BLOCK Symptomatic relief of superficial and deep pain from localized dermal or segmental origin.	<ul style="list-style-type: none"> 10,000Hz Continuous Vector OFF Treatment time of 15 minutes 	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 1-2 hours. Faster onset of relief usually within 5-10 minutes.	Target tissue - superficial and deep. Bipolar placement over local nerve; quadripolar placement over area of local pain; quadripolar placement at spinal segment. Set intensity to a numb-gripping sensation just under muscle contraction.	<ul style="list-style-type: none"> Press PAIN button until screen reads "SENSORY NERVE BLOCK". Set Outputs A and B until the patient feels the desired sensation. Press START / STOP and T15 will display in upper right corner. Adjust treatment time if necessary using the TIME/PARAMETER button. The treatment will end at the end of the preset time or if the patient safety switch is pressed.
COMBO HVPC SENSORY Symptomatic relief of superficial and deep pain from localized dermatome or segmental origin.	<ul style="list-style-type: none"> 125Hz - 100uSec IPI Continuous Treatment time of 15 minutes 	Sensory stimulation activates A-beta fibers causing the release of spinal Enkephalin and Dynorphin to block pain at the segmental level (Gate Control). Duration of relief is typically from 30 min to 2 hrs. Fast onset of relief usually within 15-20 minutes.	Target tissue - superficial and deep. Bipolar through the ultrasound transducer at the painful area and over the involved spinal segments or trigger points. Set intensity to elicit a pleasant tingling sensation, just below muscle contraction. The patient will feel a higher intensity at trigger points, motor points or over painful areas as the transducer is moved over the treatment site, which may illicit a muscle contraction.	<ul style="list-style-type: none"> Press PAIN button until screen reads "COMBO HVPC SENSORY". Connect the Negative (Black) CHA lead wire to the Ultrasound input port. Set US output parameters, and apply gel to the treatment area Place the Red CHA electrode on an appropriate location in the treatment area (Spinal nerve root, TP) Contact the transducer to the gel and set Output A until the patient feels the desired sensation. Press START / STOP and T15 will display in upper right corner. Adjust treatment time if necessary using the TIME/PARAMETER button The treatment will end at the end of the preset time or if the patient safety switch is pressed.

Circulation

PROTOCOL / CLINICAL INDICATION	STIMULATION PARAMETERS	MECHANISM OF ACTION	APPLICATION TECHNIQUE	OPERATIONAL SEQUENCE
HVPC SENSORY Symptomatic relief of pain from localized dermatome or segmental origin. Increase circulation.	<ul style="list-style-type: none"> 125Hz - 100uSec IPI Continuous Treatment time of 45 minutes 	Sensory stimulation reduces pain through segmental release of Enkephalin and Dynorphin (Gate Control). It also activates local vasodilation increasing local circulation. Application of negative polarity over the edematous site has been demonstrated to reduce post-traumatic edema in clinical trials.	Target tissue - superficial and deep. Monopolar or bipolar through the painful, edematous or tissue area where circulation is to be increased and/or over the involved nerves. Set intensity to elicit a pleasant tingling sensation, just below muscle contraction.	<ul style="list-style-type: none"> Press CIRCULATION button until screen reads "HVPC SENSORY". Set Outputs A and B until the patient feels the desired sensation. Press START / STOP and T45 will display in upper right corner. Adjust treatment time if necessary using the TIME/PARAMETER button. The treatment will end at the end of the preset time or if the patient safety switch is pressed.
MFAC MUSCLE PUMP Increase circulation, venous and lymphatic return through muscle pump.	<ul style="list-style-type: none"> 5000Hz - 35 BPS 10Sec "ON" time and 20Sec "OFF" time Reciprocal (alternating) timing pattern Ramps 2Sec "ON/OFF" Treatment time of 15 minutes 	Activation of the agonist and antagonist muscle pair. The muscle pump action compresses fluids into the venous and lymphatic return, while improving blood flow to the edematous tissue.	Target tissue - superficial and deep muscle groups and large joints. Bipolar set-up over agonist and antagonist muscles for target joint. Set intensity to elicit muscle contraction causing pain free joint movement typically a grade 3-4 muscle contraction. Reduce treatment time based on muscle fatigue.	<ul style="list-style-type: none"> Press CIRCULATION button until screen reads "MFAC MUSCLE PUMP". Set Outputs A and B until the patient feels the desired sensation. Press START / STOP and T15 will display in upper right corner. Adjust treatment time if necessary using the TIME/PARAMETER button. The treatment will end at the end of the preset time or if the patient safety switch is pressed.

Muscle Tone Spasm

PROTOCOL / CLINICAL INDICATION	STIMULATION PARAMETERS	MECHANISM OF ACTION	APPLICATION TECHNIQUE	OPERATIONAL SEQUENCE
MOTOR NERVE BLOCK Reduces muscle tone (spasm) of spastic muscle.	<ul style="list-style-type: none"> 5000Hz Continuous Treatment time of 15 minutes 	Blocks muscle tone by causing a temporary block of the motor nerve for the muscle in spasm. Also known as Wedensky Inhibition. Duration of relief is typically from 1-2 hours. Fast reduction of muscle tone-spasm usually within 5-10 minutes.	Target tissue - superficial and deep. Bipolar placement over local nerve and spastic muscle; quadripolar placement over area of local spasm. Set intensity to a numb-gripping sensation just below muscle contraction.	<ul style="list-style-type: none"> Press MUSCLE TONE SPASM button until screen reads "MOTOR NERVE BLOCK". Set Outputs A and B until the patient feels the desired sensation. Press START / STOP and T15 will display in upper right corner. Adjust treatment time if necessary using the TIME/PARAMETER button. The treatment will end at the end of the preset time or if the patient safety switch is pressed.
MFAC TONE- SPASM Relaxation of muscle spasm.	<ul style="list-style-type: none"> 5000Hz - 90 BPS 10Sec "ON" and 10Sec "OFF" time Channels fire simultaneously Ramps are for 2 Sec "ON/OFF" Treatment time of 15 minutes 	Activation of muscle with electrical stimulation with a 1:1 ratio of "ON/OFF" times causes muscle fatigue reducing muscle spasm. Sensory stimulation of the muscles also reduces pain and thus reflex muscle spasm.	Target tissue - superficial and deep muscle groups. Bipolar set-up over agonist and antagonist muscles for target muscle. Set intensity to elicit a grade 2-3 muscle contraction.	<ul style="list-style-type: none"> Press MUSCLE TONE SPASM button until screen reads "MFAC TONE SPASM". Set Outputs A and B until the desired contraction level is obtained. Press START / STOP and T15 will display in upper right corner. Adjust treatment time if necessary using the TIME/PARAMETER button. The treatment will end at the end of the preset time or if the patient safety switch is pressed.
MFAC RECIPROCAL INHIBITION Reduces muscle tone (spasm) of spastic muscle	<ul style="list-style-type: none"> 2500Hz - 50 BPS 12Sec "ON" and 18Sec "OFF" time Channels fire simultaneously Ramps 6Sec "ON" and 4Sec "OFF" Treatment time of 15 minutes 	Stimulation of the spastic muscle's antagonists 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. Set intensity to elicit a grade 2-3 muscle contraction. Ensure the intensity is not too high to induce overflow activation of the spastic muscle. Reduce treatment time based on muscle fatigue and inhibition of spasticity.	<ul style="list-style-type: none"> Press MUSCLE TONE SPASM button until screen reads "MFAC RECIPROCAL INHIBITION". Set Outputs A and B until the desired contraction level is obtained. Press START / STOP and T15 will display in upper right corner. Adjust treatment time if necessary using the TIME/PARAMETER button. The treatment will end at the end of the preset time or if the patient safety switch is pressed.

Range of Motion (ROM)

PROTOCOL / CLINICAL INDICATION	STIMULATION PARAMETERS	MECHANISM OF ACTION	APPLICATION TECHNIQUE	OPERATIONAL SEQUENCE
MFAC INCREASE ROM To provide e-stim assisted passive or active assisted R.O.M. at a joint.	<ul style="list-style-type: none"> 2500Hz - 35 BPS 4Sec "ON" and 12Sec "OFF" time Channels fire alternately. Ramps are for 2Sec "ON/OFF" Treatment time of 15 minutes 	Activation of muscle causing contraction of the agonist and antagonist to move the joint and improve the R.O.M.	Target tissue – superficial and or deep muscle groups. Bipolar set-up over agonist/antagonist muscles for targeted joint. Set intensity to elicit muscle contraction causing pain free joint movement typically a grade 3-4 muscle contraction.	<ul style="list-style-type: none"> Press ROM button until screen reads "MFAC INCREASE ROM". Set Outputs A and B until the desired contraction level is obtained. Press START / STOP and T15 will display in upper right corner. Adjust treatment time if necessary using the TIME/PARAMETER button. The treatment will end at the end of the preset time or if the patient safety switch is pressed.

Muscle Re-Education

PROTOCOL / CLINICAL INDICATION	STIMULATION PARAMETERS	MECHANISM OF ACTION	APPLICATION TECHNIQUE	OPERATIONAL SEQUENCE
MFAC SURFACE DEEP MUSCLE Treatment of muscle disuse atrophy for strength development	<ul style="list-style-type: none"> 2500Hz - 75 BPS 10Sec "ON" and 50Sec "OFF" time Channels fire simultaneously Ramps are 2Sec "ON/OFF" Treatment time of 10 minutes 	Activation of muscle with electrical stimulation at a high intensity for a short time with long "ON/OFF" ramps reduces atrophy and improves strength. The patient should participate to the extent possible by contracting during the stimulation "ON" time.	Target tissue - superficial and deep muscle groups. Bipolar set-up over agonist and antagonist muscles for target muscle. Set intensity to elicit a grade 2-4 muscle contraction. Reduce treatment time based on muscle fatigue. Restrict joint movement by holding manually, or using weights or exercise bands.	<ul style="list-style-type: none"> Press MUSCLE RE-ED button until screen reads "MFAC SURFACE DEEP MUSCLE". Set Outputs A and B until the desired contraction level is obtained. Press START / STOP and T10 will display in upper right corner. Adjust treatment time if necessary using the TIME/PARAMETER button. The treatment will end at the end of the preset time or if the patient safety switch is pressed.
LVPC SURFACE MUSCLE Treatment of muscle disuse atrophy for strength development	<ul style="list-style-type: none"> 50Hz - 70uSec PD 10Sec "ON" and 50Sec "OFF" time Channels fire simultaneously Ramps are 2Sec "ON/OFF" Treatment time of 10 minutes 	Activation of muscle with electrical stimulation at a high intensity for a short time with long "ON/OFF" ramps reduces atrophy and improves strength. The patient should participate to the extent possible by contracting during the stimulation "ON" time.	Target tissue - smaller superficial muscle groups. Bipolar set-up over agonist and antagonist muscles for target muscle. Set intensity to elicit a grade 2-4 muscle contraction. Reduce treatment time based on muscle fatigue. Restrict joint movement by holding manually, or using weights or exercise bands.	<ul style="list-style-type: none"> Press MUSCLE RE-ED button until screen reads "LVPC SURFACE MUSCLE". Set Outputs A and B until the desired contraction level is obtained. Press START / STOP and T10 will display in upper right corner. Adjust treatment time if necessary using the TIME/PARAMETER button. The treatment will end at the end of the preset time or if the patient safety switch is pressed.

OMNISTIM® 500 PRO PROGRAM MENU

Pain Control

The following protocols are found by pressing the PAIN protocol button. The first protocol displayed is IFC SENSORY. Other protocols follow, in the sequence presented below, by continuously pressing the PAIN button.

A. IFC SENSORY:

Provides symptomatic relief of superficial and deep pain from localized dermatome or segmental origin. Bilateral, bipolar or quadripolar application through the painful area or over the involved spinal segments. Apply parallel to incision line for post op pain management. Set intensity to illicit a pleasant tingling sensation, just below muscle contraction. Sensory stimulation activates A-beta fibers causing the release of spinal Enkephalin and Dynorphin to block pain at the segmental level (Gate Control). Duration of relief is typically from 30 minutes to 2 hours. Fast onset of relief is usually within 15-20 minutes.

USER ADJUSTABLE PARAMETER (Y/N)	ORDER IN PARAMETER SET LOOP	PARAMETER NAME	ADJUSTABLE RANGE (UNIT)	DEFAULT (UNIT)
N		CARRIER FREQ		5.0 (kHz)
N		BURST FREQUENCY		100 (Hz)
N		BURST RATE SCAN		20 (%)
N		RATE SCAN		ON
N		RATE SCAN TIME		20 (s)
Y	2	VECTOR	Slow 45, Fast 45, Slow 90, Fast 90, OFF	Fast 90
Y	1	TREATMENT TIME	0...99 (min)	15 (min)

B. TENS-LVPC SENSORY:

This program provides symptomatic relief of superficial pain from localized dermatome or segmental origin. Bilateral, bipolar application through the painful area or over the involved spinal segments. Apply parallel to incision line for post op pain management. Set intensity to illicit a pleasant tingling sensation, just below muscle contraction. Sensory stimulation activates A-beta fibers causing the release of spinal Enkephalin and Dynorphin to block pain at the segmental level (Gate Control). Duration of relief is typically from 30 minutes to 2 hours. Fast onset of relief is usually within 15-20 minutes.

USER ADJUSTABLE PARAMETER (Y/N)	ORDER IN PARAMETER SET LOOP	PARAMETER NAME	ADJUSTABLE RANGE (UNIT)	DEFAULT (UNIT)
Y	2	PHASE DURATION	40...300 (µs)	80 (µs)
Y	3	PULSE RATE	0.0...250 (Hz)	100 (Hz)
N		PHASE DURATION MOD		20 (%)
N		MODULATION		OFF
N		RATE SCAN TIME		4 (s)
Y	1	TREATMENT TIME	0...99 (min)	15 (min)
N		CHANNEL MODE		A/B SIM.

C. IFC MOTOR:

This program is used to provide symptomatic relief of superficial and deep pain with inflammation, and pain of generalized or multi-segmental nature. Bilateral placement over local and distal acu trigger point. Quadripolar placement over area of local pain, or at spinal segment. The intensity should be set to elicit a moderate muscle twitch. Motor level stimulation activates motor and A-delta fibers causing the release of Bendrophen systematically. Duration of relief is typically from 2-6 hours. Slow onset of relief usually within 15 minutes to 1 hour.

USER ADJUSTABLE PARAMETER (Y/N)	ORDER IN PARAMETER SET LOOP	PARAMETER NAME	ADJUSTABLE RANGE (UNIT)	DEFAULT (UNIT)
Y	3	CARRIER FREQ	2.0. 2.5. 4.0. 5.0. 10.0 (kHz)	2.5 (kHz)
Y	4	BURST FREQUENCY	0.0...250 (Hz)	4.0 (Hz)
N		BURST RATE SCAN		50 (%)
N		RATE SCAN		ON
N		RATE SCAN TIME		20 (s)
Y	2	VECTOR	Slow 45, Fast 45, Slow 90, Fast 90, OFF	Fast 90
Y	1	TREATMENT TIME	0...99 (min)	15 (min)

D. TENS-LVPC MOTOR:

Symptomatic relief of superficial pain with inflammation, or pain of a generalized or multi-segmental nature. Bilateral placement over local and distal acu trigger points, or at spinal segmental level. The intensity should be set to elicit a moderate muscle twitch. Motor level stimulation activates motor and A-delta fibers causing the release of Bendrophen systematically. Duration of relief is typically from 2-6 hours. Slow onset of relief usually within 15 minutes to 1 hour.

USER ADJUSTABLE PARAMETER (Y/N)	ORDER IN PARAMETER SET LOOP	PARAMETER NAME	ADJUSTABLE RANGE (UNIT)	DEFAULT (UNIT)
Y	2	PHASE DURATION	40...300 (us)	200 (us)
Y	3	PULSE RATE	0.0...250 (Hz)	4.0 (Hz)
N		PHASE DURATION MOD		20 (%)
N		MODULATION		OFF
N		RATE SCAN TIME		4 (s)
Y	1	TREATMENT TIME	0...99 (min)	15 (min)
N		CHANNEL MODE		A/B SIM.

E. IFC MOTOR SENSORY:

Symptomatic relief of superficial pain and deep pain with inflammation, and pain of local, generalized, single or multi-segmental nature. Bipolar placement over local and distal acu trigger points; quadripolar placement over area of local pain, or at spinal segment. The intensity should be set to elicit a moderate muscle twitch. Combines motor and sensory stimulation, starting with motor and ending with sensory. This is a more aggressive protocol. Duration of relief is typically from 2-6 hours. Slow onset of relief usually within 15-30 minutes.

This protocol is comprised of three sub-programs, as follows:

IFC Motor Sensory, Subprogram 1

USER ADJUSTABLE PARAMETER (Y/N)	ORDER IN PARAMETER SET LOOP	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)
Y	2	VECTOR	Slow 45, Fast 45, Slow 90, Fast 90, OFF	OFF
Y	1	TREATMENT TIME	0...99 (min)	5 (min)

IFC Motor Sensory, Subprogram 2

USER ADJUSTABLE PARAMETER (Y/N)	ORDER IN PARAMETER SET LOOP	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)
Y	2	VECTOR	Slow 45, Fast 45, Slow 90, Fast 90, OFF	OFF
Y	1	TREATMENT TIME	0...99 (min)	15 (min)

IFC Motor Sensory, Subprogram 3

USER ADJUSTABLE PARAMETER (Y/N)	ORDER IN PARAMETER SET LOOP	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	2	VECTOR	Slow 45, Fast 45, Slow 90, Fast 90, OFF	OFF
Y	1	TREATMENT TIME	0...99 (min)	10 (min)

F. IFC SENSORY MOTOR:

Symptomatic relief of superficial pain and pain with inflammation, pain of local generalized single or multi-segmental nature. Bipolar placement over local and distal acu trigger points; quadripolar placement over area of local pain, or at spinal segment. The intensity should be set to elicit a strong tingling sensation just below muscle contraction. Combines sensory and motor stimulation, starting with sensory and ending with motor. This is a less aggressive protocol. Duration of relief is typically from 2-6 hours. Slow onset of relief usually within 15-20 minutes.

This protocol is comprised of three sub-programs, as follows:

IFC Sensory Motor, Subprogram 0

USER ADJUSTABLE PARAMETER (Y/N)	ORDER IN PARAMETER SET LOOP	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	2	VECTOR	Slow 45, Fast 45, Slow 90, Fast 90, OFF	OFF
Y	1	TREATMENT TIME	0...99 (min)	10 (min)

IFC Sensory Motor, Subprogram 1

USER ADJUSTABLE PARAMETER (Y/N)	ORDER IN PARAMETER SET LOOP	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)
Y	2	VECTOR	Slow 45, Fast 45, Slow 90, Fast 90, OFF	Fast 90
Y	1	TREATMENT TIME	0...99 (min)	20 (min)

G. SENSORY NERVE BLOCK:

Symptomatic relief of superficial and deep pain from localized dermal or segmental origin. Bipolar placement over local nerve; quadripolar placement over area of local pain, or at spinal segment. The intensity should be set to numb-gripping sensation just under muscle contraction. 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 1-2 hours. Faster onset of relief usually within 5-10 minutes.

USER ADJUSTABLE PARAMETER (Y/N)	ORDER IN PARAMETER SET LOOP	PARAMETER NAME	ADJUSTABLE RANGE (UNIT)	DEFAULT (UNIT)
N		CARRIER FREQ		10.0 (kHz)
Y	1	TREATMENT TIME	0...99 (min)	15 (min)

H. COMBO HVPC SENSORY:

Symptomatic relief of superficial and deep pain from localized dermatome or segmental origin. Bipolar application through the ultrasound transducer at the painful area and over the involved spinal segments or trigger points. The intensity should be set to elicit a pleasant tingling sensation just below muscle contraction. The patient will feel a higher intensity at trigger points, motor points or over painful areas as the transducer is moved over the treatment site, which may illicit a muscle contraction. Sensory stimulation activates A-beta fibers causing the release of spinal Enkephalin and Dynorphin to block pain at the segmental level (Gate Control). Duration of relief is typically from 30 minutes to 2 hours. Fast onset of relief is usually within 15-20 minutes.

USER ADJUSTABLE PARAMETER (Y/N)	ORDER IN PARAMETER SET LOOP	PARAMETER NAME	ADJUSTABLE RANGE (UNIT)	DEFAULT (UNIT)
Y	3	IP INTERVAL	10...250 (µs)	100 (µs)
Y	2	PULSE RATE	0.0...125 (Hz)	125 (Hz)
Y	1	TREATMENT TIME	0...99 (min)	15 (min)

Circulation

The following protocols are found by pressing the CIRCULATION protocol button. The first protocol displayed is HVPC SENSORY. Other protocols follow, in the sequence presented below, by continuously pressing the CIRCULATION button.

A. HVPC SENSORY:

Symptomatic relief of pain from localized dermatome or segmental origin, as well as increased circulation. Monopolar or bipolar application through the painful, edematous or tissue area where circulation is to be increased, an/or over the involved nerves. Set intensity to illicit a pleasant tingling sensation, just below muscle contraction. Sensory stimulation reduces pain through segmental release of Enkephalin and Dynorphin (Gate Control). It also activates local vasodilation increasing local circulation. Application of negative polarity over the edematous site has been demonstrated to reduce post-traumatic edema in clinical trials.

USER ADJUSTABLE PARAMETER (Y/N)	ORDER IN PARAMETER SET LOOP	PARAMETER NAME	ADJUSTABLE RANGE (UNIT)	DEFAULT (UNIT)
Y	3	IP INTERVAL	10...250 (µs)	100 (µs)
Y	2	PULSE RATE	0.0...125 (Hz)	125 (Hz)
Y	1	TREATMENT TIME	0...99 (min)	45 (min)
Y	6	RAMP UP	0.0...9.9 (s)	2.0 (s)
Y	7	RAMP DOWN	0.0...9.9 (s)	2.0 (s)
Y	4	T-ON	0...30 (s)	Cont ¹
Y	5	T-OFF	0...199 (s)	0 ¹

¹ When T-OFF = 0, T-ON = CONTINUOUS.

B. MFAC MUSCLE PUMP:

Increase circulation, venous and lymphatic return through muscle pump. This program targets superficial and deep muscle groups and large joints. Bilateral set-up over agonist and antagonist muscles for target joint. Set intensity to illicit muscle contraction (typically grade 3-4 muscle contraction), causing pain free joint movement. Reduce treatment time based on muscle fatigue. Activation of the agonist and antagonist muscle pair. The muscle pump action compresses fluids into the venous and lymphatic return, while improving blood flow to the edematous tissue.

USER ADJUSTABLE PARAMETER (Y/N)	ORDER IN PARAMETER SET LOOP	PARAMETER NAME	ADJUSTABLE RANGE (UNIT)	DEFAULT (UNIT)
N		CARRIER FREQ		5.0 (kHz)
Y	2	BURST FREQUENCY	0.0...250 (Hz)	35 (Hz)
N		BURST RATE SCAN		20 (%)
N		RATE SCAN		ON
N		RATE SCAN TIME		4 (s)
Y	1	TREATMENT TIME	0...99 (min)	15 (min)
Y ²	8 ²	B OUTPUT DELAY	0.0...9.9 (s)	0.0 (s)
Y	5	RAMP UP	0.0...9.9 (s)	2.0 (s)
Y	6	RAMP DOWN	0.0...9.9 (s)	2.0 (s)
Y	3	T-ON	0...30 (s)	10 (s) ¹
Y	4	T-OFF	0...199 (s)	20 (s) ¹
Y	7	Channel Mode	A/B SIMULTANEOUS, A/B ALTERNATE, B DELAYED	A/B ALT.

¹ When T-OFF = 0, T-ON = CONTINUOUS.

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

Muscle Tone Spasm

The following protocols are found by pressing the MUSCLE TONE SPASM protocol button. The first protocol displayed is MOTOR NERVE BLOCK. Other protocols follow, in the sequence presented below, by continuously pressing the MUSCLE TONE SPASM button.

A. MOTOR NERVE BLOCK:

Reduces muscle tone (spasm) of spastic muscle. Target is superficial and deep tissue. Bipolar placement over local nerve and spastic muscle. Quadripolar placement over area of local spasm. Intensity should be set to a numb-gripping sensation just below muscle contraction. Blocks muscle tone by causing a temporary block of the motor nerve for the muscle in spasm. Also known as Wedensky Inhibition. Duration of relief is typically from 1-2 hours. Fast reduction of muscle tone-spasm usually within 5-10 minutes.

USER ADJUSTABLE PARAMETER (Y/N)	ORDER IN PARAMETER SET LOOP	PARAMETER NAME	ADJUSTABLE RANGE (UNIT)	DEFAULT (UNIT)
N		CARRIER FREQ		5.0 (kHz)
Y	1	TREATMENT TIME	0...99 (min)	15 (min)

B. MFAC TONE-SPASM:

Relaxation of muscle spasm. Target is superficial and deep muscle groups. Bipolar set-up over agonist and antagonist muscles for target muscle. Intensity should be set to elicit a grade 2-3 muscle contraction. Activation of muscle with electrical stimulation with a 1:1 ratio of “ON/OFF” times causes muscle fatigue reducing muscle spasm. Sensory stimulation of the muscles also reduces pain and thus reflex muscle spasm.

USER ADJUSTABLE PARAMETER (Y/N)	ORDER IN PARAMETER SET LOOP	PARAMETER NAME	ADJUSTABLE RANGE (UNIT)	DEFAULT (UNIT)
Y	9	CARRIER FREQ	2.0, 2.5, 4.0, 5.0, 10.0 (kHz)	5.0 (kHz)
Y	6	BURST FREQUENCY	0.0...250 (Hz)	90 (Hz)
N		BURST RATE SCAN		20 (%)
N		RATE SCAN		ON
N		RATE SCAN TIME		4 (s)
Y	1	TREATMENT TIME	0...99 (min)	15 (min)
Y ²	8 ²	B OUTPUT DELAY	0.0...9.9 (s)	0.0 (s)
Y	4	RAMP UP	0.0...9.9 (s)	2.0 (s)
Y	5	RAMP DOWN	0.0...9.9 (s)	2.0 (s)
Y	2	T-ON	0...30 (s)	10 (s) ¹
Y	3	T-OFF	0...199 (s)	10 (s) ¹
Y	7	(93h) Channel Mode	A/B SIMULTANEOUS, A/B ALTERNATE, B DELAYED	A/B SIM.

¹ When T-OFF = 0, T-ON = CONTINUOUS.

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

C. MFAC RECIPROCAL INHIBITION:

Reduces muscle tone (spasm) of spastic muscle. A single channel (A or B) is used over the spastic muscle's antagonist. Set intensity to elicit a grade 2-3 muscle contraction. Ensure the intensity is not too high to induce overflow activation of the spastic muscle. Reduce treatment time based on muscle fatigue and inhibition of spasticity. Stimulation of the spastic muscle's antagonists activates reciprocal inhibition of the spastic muscle reducing tone. Slow ramps decrease the potential to trigger spasticity of the agonist.

USER ADJUSTABLE PARAMETER (Y/N)	ORDER IN PARAMETER SET LOOP	PARAMETER NAME	ADJUSTABLE RANGE (UNIT)	DEFAULT (UNIT)
Y	2	CARRIER FREQ	2.0, 2.5, 4.0, 5.0, 10.0 (kHz)	2.5 (kHz)
Y	3	BURST FREQUENCY	0.0...250 (Hz)	50 (Hz)
N		BURST RATE SCAN		20 (%)
N		RATE SCAN		ON
N		RATE SCAN TIME		4 (s)
Y	1	TREATMENT TIME	0...99 (min)	15 (min)
Y ²	9 ²	B OUTPUT DELAY	0.0...9.9 (s)	0.0 (s)
Y	6	RAMP UP	0.0...9.9 (s)	6.0 (s)
Y	7	RAMP DOWN	0.0...9.9 (s)	4.0 (s)
Y	4	T-ON	0...30 (s)	12 (s) ¹
Y	5	T-OFF	0...199 (s)	18 (s) ¹
Y	8	Channel Mode	A/B SIMULTANEOUS, A/B	A/B SIM.

¹ When T-OFF = 0, T-ON = CONTINUOUS.

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

Range of Motion (ROM)

The following protocol is found by pressing the ROM protocol button. The protocol displayed is MFAC INCREASE ROM.

A. MFAC INCREASE ROM:

Provides e-stim-assisted passive or active assisted ROM at a joint. Target tissue is the superficial and/or deep muscle groups. Bipolar set-up over agonist/antagonist muscles for targeted joint. Intensity should be set to elicit muscle contraction causing pain-free joint movement (typically a grade 3-4 muscle contraction). Activation of muscle causing contraction of the agonist and antagonist causes joint movement and improved R.O.M.

USER ADJUSTABLE PARAMETER (Y/N)	ORDER IN PARAMETER SET LOOP	PARAMETER NAME	ADJUSTABLE RANGE (UNIT)	DEFAULT (UNIT)
Y	9	CARRIER FREQ	2.0, 2.5, 4.0, 5.0, 10.0 (kHz)	2.5 (kHz)
Y	6	BURST FREQUENCY	0.0...250 (Hz)	35 (Hz)
N		BURST RATE SCAN		20 (%)
N		RATE SCAN		ON
N		RATE SCAN TIME		4 (s)
Y	1	TREATMENT TIME	0...99 (min)	15 (min)
Y ²	8 ²	B OUTPUT DELAY	0.0...9.9 (s)	0
Y	4	RAMP UP	0.0...9.9 (s)	2.0 (s)
Y	5	RAMP DOWN	0.0...9.9 (s)	2.0 (s)
Y	2	T-ON	0...30 (s)	4 (s) ¹
Y	3	T-OFF	0...199 (s)	12 (s) ¹
Y	7	Channel Mode	A/B SIMULTANEOUS, A/B ALTERNATE, B DELAYED	A/B ALT.

¹ When T-OFF = 0, T-ON = CONTINUOUS.

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

Muscle Re-Education

The following protocols are found by pressing the MUSCLE RE-ED protocol button. The first protocol displayed is MFAC SURFACE DEEP MUSCLE. Other protocols follow, in the sequence presented below, by continuously pressing the MUSCLE RE-ED button.

A. MFAC SURFACE DEEP MUSCLE:

Treatment of muscle disuse atrophy for strength development, targeting superficial and deep muscle groups. Bipolar set-up over agonist and antagonist muscles for target muscle. Intensity should be set to elicit a grade 2-4 muscle contraction. Treatment times can be reduced based on muscle fatigue. Joint movement should be restricted by holding manually, or using weights or exercise bands. Activation of muscle with electrical stimulation at a high intensity for a short time with long “ON/OFF” ramps reduces atrophy and improves strength. The patient should participate to the extent possible by contracting during the stimulation “ON” time.

USER ADJUSTABLE PARAMETER (Y/N)	ORDER IN PARAMETER SET LOOP	PARAMETER NAME	ADJUSTABLE RANGE (UNIT)	DEFAULT (UNIT)
Y	9	CARRIER FREQ	2.0, 2.5, 4.0, 5.0, 10.0 (kHz)	2.5 (kHz)
Y	6	BURST FREQUENCY	0.0...250 (Hz)	75 (Hz)
N		BURST RATE SCAN		20 (%)
N		RATE SCAN		ON
N		RATE SCAN TIME		4 (s)
Y	1	TREATMENT TIME	0...99 (min)	10 (min)
Y ²	8 ²	B OUTPUT DELAY	0.0...9.9 (s)	0.0 (s)
Y	4	RAMP UP	0.0...9.9 (s)	2.0 (s)
Y	5	RAMP DOWN	0.0...9.9 (s)	2.0 (s)
Y	2	T-ON	0...30 (s)	10 (s) ¹
Y	3	T-OFF	0...199 (s)	50 (s) ¹
Y	7	Channel Mode	A/B SIMULTANEOUS, A/B ALTERNATE, B DELAYED	A/B SIM.

¹ When T-OFF = 0, T-ON = CONTINUOUS.

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

B. LVPC SURFACE MUSCLE:

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

USER ADJUSTABLE PARAMETER (Y/N)	ORDER IN PARAMETER SET LOOP	PARAMETER NAME	ADJUSTABLE RANGE (UNIT)	DEFAULT (UNIT)
Y	6	PHASE DURATION	40...300 (μs)	70 (μs)
Y	7	PULSE RATE	0.0...250 (Hz)	50.0 (Hz)
Y	1	TREATMENT TIME	0...99 (min)	10 (min)
Y ²	9 ²	B OUTPUT DELAY	0.0...9.9 (s)	0.0 (s)
Y	4	RAMP UP	0.0...9.9 (s)	2.0 (s)
Y	5	RAMP DOWN	0.0...9.9 (s)	2.0 (s)
Y	2	T-ON	0...30 (s)	10 (s) ¹
Y	3	T-OFF	0...199 (s)	50 (s) ¹
Y	8	Channel Mode	A/B SIMULTANEOUS, A/B ALTERNATE, B DELAYED	A/B SIM.

¹ When T-OFF = 0, T-ON = CONTINUOUS.

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

STIMULATION THERAPY MODES

Interferential Current Therapy (IFC)

The new Webster Encyclopedia Dictionary of the English Language defines interference as “the mutual action of 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.

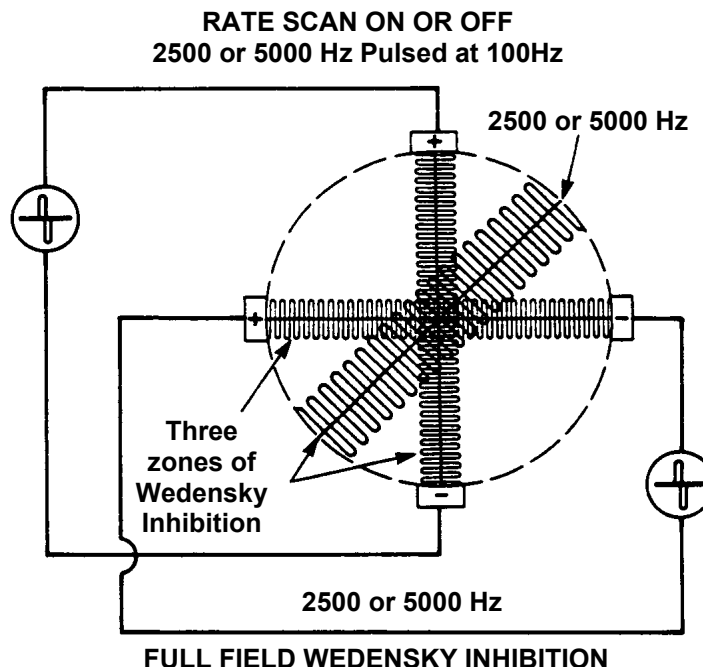
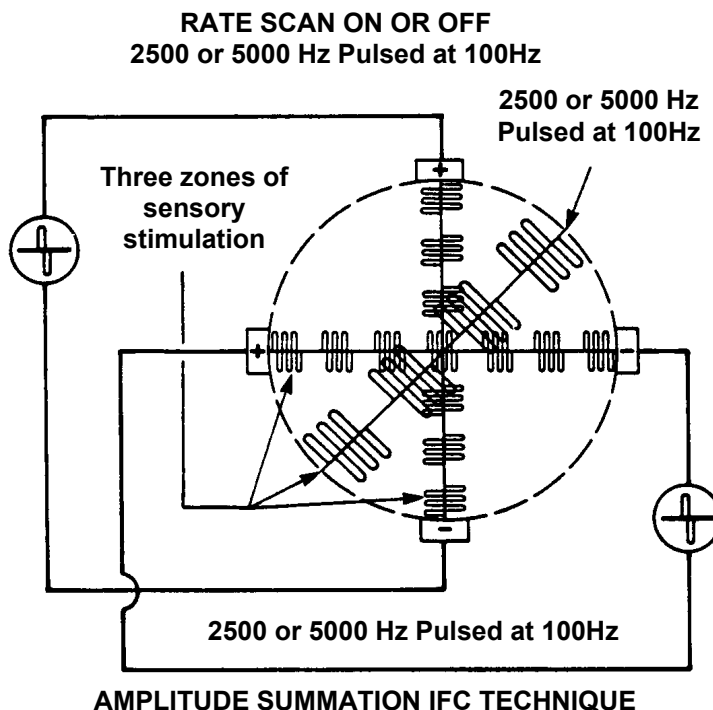
The purpose of interferential current therapy is to provide deep tissue treatment, which is not generally obtainable with conventional electrotherapy approaches. Its primary application is in the reduction of pain and in the stimulation of increased blood flow in the deeper tissues and muscles.

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.

1. IFC - Full Field Premodulated 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 positions in the field. The following technique is used in the Omnistim®



500 Pro Sport when in the full field 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.

2. 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 Omnistim®, 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:

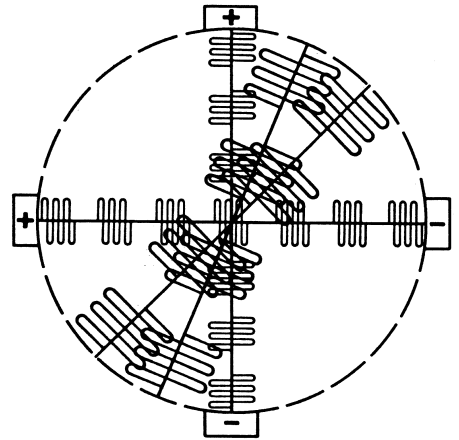
- a. Stimulation of deep and surface tissues.
- b. May be used to produce deep and surface analgesia via nerve block (Wedensky Inhibition) when MF mode is used.

3. 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.



Medium Frequency Alternating Current (MFAC)

1. Muscle 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.

a. 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 midpoint of the range of motion where the muscle can generate maximum torque.

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.

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

b. 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.

Procedure:

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.

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

c. Increased Blood Flow / Edema Reduction

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

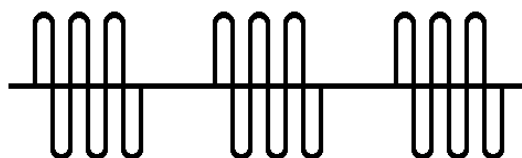
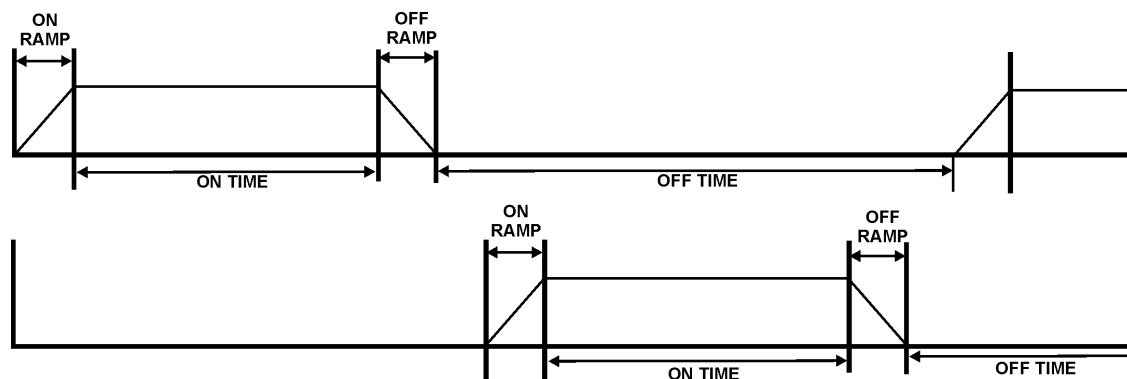
Muscle Pump Edema Reduction	
Mode	NMES Alternate
Time ON	4 Sec
Time OFF	4 Sec
ON Ramp	2 Sec
OFF Ramp	2 Sec
Pulse Rate	35Hz

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.

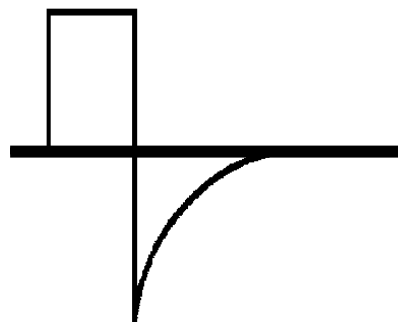


MFAC WAVEFORM

Low Voltage Pulsed Current (LVPC)

LOW VOLTAGE PULSED CURRENT WAVEFORM

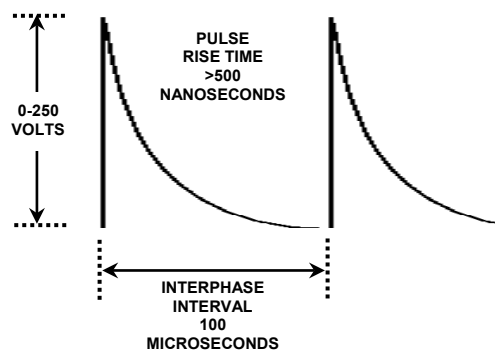
LVPC is generally used for surface and smaller muscle stimulation and pain control with TENS technique.



High Voltage Pulsed Current (HVPC)

HIGH VOLTAGE PULSED CURRENT WAVEFORM:

Continuous or surged operation with fully adjustable ON and OFF times and ramps allow applications of HVPC therapy. Reduction of edema, pain control, NMES and soft tissue management programs can be set up with the Omnistim® 500's high volt pulsed current mode.



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)	<ul style="list-style-type: none"> No batteries Low batteries 	<ul style="list-style-type: none"> Install batteries Charge or replace batteries Verify type and settings of batteries Inspect battery contacts and setting per procedure below
Unit will not power on (under line power use)	<ul style="list-style-type: none"> Power Supply not plugged in to the unit of AC outlet Power Supply not operational 	<ul style="list-style-type: none"> Verify if the Power Supply is connected as appropriate Verify if the AC outlet is functional Verify if the power plug used is appropriate and undamaged (see figure 1 below) Inspect Power Supply operation per procedure below
Display shows "LOW BATTERY" warning	<ul style="list-style-type: none"> Battery charge is too low 	<ul style="list-style-type: none"> Recharge batteries for future use
Unit will not start	<ul style="list-style-type: none"> No program selected 	<ul style="list-style-type: none"> Select PROTOCOL
Cannot set carrier frequency	<ul style="list-style-type: none"> Treatment in progress 	<ul style="list-style-type: none"> Stop treatment, adjust, and restart
Patient feels surging or spiking sensation	<ul style="list-style-type: none"> Absent, inadequate, or improper conductive medium interface Lead wire(s): short or breakage Non-conductive or poorly conductive electrodes 	<ul style="list-style-type: none"> Replace with correct and adequate conductive medium LEAD WIRE TESTER: Plug the distal (patient end) of the lead wire into the test connectors while observing polarity (red / black). Plug the device end of the lead wire into the receptacle labeled LEAD WIRE TESTER. When the POWER is on, green LED will turn on if the lead wire passes the test. LED will be red if the lead wires are faulty and need to be replaced. See Figure 7 below. Remove electrode(s) and replace if necessary
Patient cannot detect output	<ul style="list-style-type: none"> Failure of lead wire(s), electrode(s), or conductive medium interface Failure of the Omnistim® 500 Pro 	<ul style="list-style-type: none"> Use Omnistim® Output Tester to determine if unit has failed or is operating incorrectly. Plug the Output Tester into the Adapter. Turn on the Omnistim®. Increase output intensity. If LED illuminates properly, test lead wire(s). (see figure 2 below) If LED is not illuminated, contact ACP Service Center at (800) 350-1100. LEAD WIRE TESTER: Plug the distal (patient end) of the lead wire into the test connectors while observing polarity (red / black). Plug the device end of the lead wire into the receptacle labeled LEAD WIRE TESTER. When the POWER is on, green LED will turn on if the lead wire passes the test. LED will be red if the lead wires are faulty and need to be replaced. If Output Tester shows the unit to be functional, and the Lead Wire tester show the lead wires to be functional, examine the electrodes, or conductive medium interface for problems.



Figure 1

"HOSPITAL
GRADE"
marking on the
power plug



Figure 2

NOTE: When using the Omnistim® Output Tester, increase unit output intensity to 40 mA or higher in order to significantly illuminate the LED. Also, view the LED located at the end of the output tester directly. If viewed at an angle, the LED may be too dim to notice that it is illuminated.

INSPECT BATTERY CONTACTS / VERIFY BATTERY SWITCH SET TO RECHARGEABLE

1. Remove batteries if they are installed.
2. Inspect the battery contacts for any corrosion or discoloration. If corrosion or discoloration is found, perform the following steps to clean the metal contacts:
 - Remove the power cord from the stimulator unit.
 - Hold the metal contact plate in place with one finger.
 - Use a small piece of sand paper to clean the surface of the metal contact thoroughly as needed. (Figure 3).

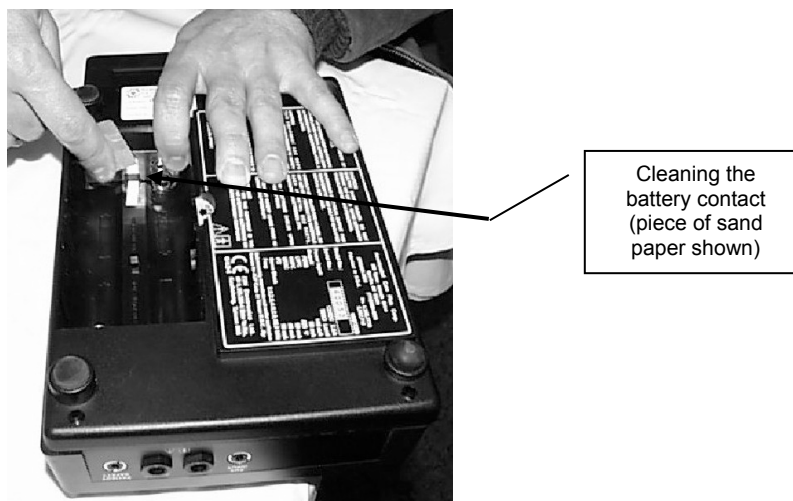


Figure 3

3. Verify the switch inside the battery compartment is set to the RECHARGEABLE BAT position (assuming rechargeable batteries are being used, which is recommended).
4. Install the rechargeable batteries into the unit.
5. Verify the battery door opens and closes correctly. The door should lock into place when closed.

INSPECT POWER SUPPLY OPERATION

1. Connect the power cord to the power supply and to a power outlet.
2. Connect the power supply cable to the stimulator unit (Figure 4).

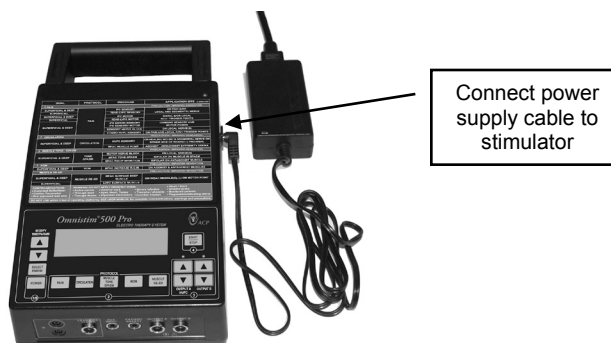


Figure 4

3. Press the power supply switch ON (if applicable, Figure 5a).

NOTE: Newer power supply model does not have an ON/OFF switch (Figure 5b).



Figure 5a

Press power
supply switch
ON



Figure 5b

4. Verify the CHARGE light is on or blinking (Figure 6).
5. Power on the stimulator and verify that you hear a click of the safety circuit relay energizing.



Figure 6

For reference only:

Charge light solid - charging in progress.

Charge light blinks slowly - charging completed.

Charge light flickers (blinks rapidly) - batteries not installed or are not charging properly.

LEAD WIRE TESTER OPERATION

Lead Wires should be inspected periodically, as well as any time there are output anomalies reported by the patient.

- Plug the distal (patient end) of the lead wire into the test connectors while observing polarity (red / black).
- Plug the device end of the lead wire into the receptacle labeled LEAD WIRE TESTER.
- When the POWER is on, green LED will turn on if the lead wire passes the test. LED will be red if the lead wires are faulty and need to be replaced.
- When lead wires pass the test, check for loose connections by holding the lead wire about 3 inches from plug-in connectors and slowly rotate the lead wire in a circular motion while the wires are plugged in. If the indicator LED is flickering between red to green, the lead wire should be replaced.

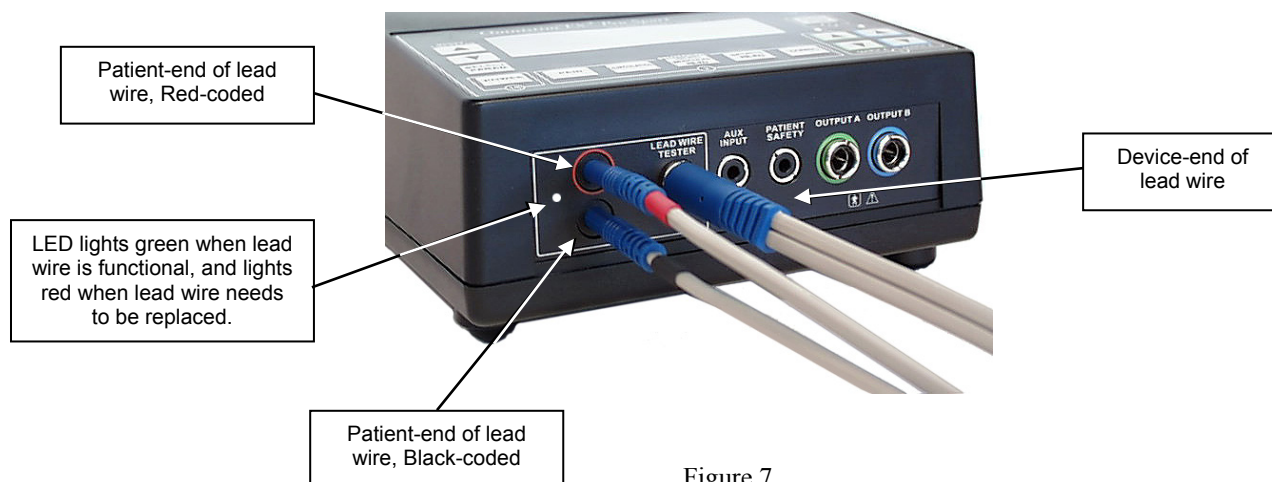


Figure 7

UNIT OUTPUT TEST

When testing a unit for output, the output tester should be used on a constant output protocol.

- Power unit ON.
- Insert output tester into channel A.
- Select Pain / IFC Sensory.
- Increase the output level to 20mA on channel A.
- Observe the output tester LED.
 - If the output tester has a solid, brightly lit LED, then there is sufficient output present on the selected channel.
- Change the output tester to channel B and follow the above process.



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.

TECHNICAL SPECIFICATIONS


GENERAL:	
Dimensions:	12" (30cm) D x 6.5" (16.5cm) W x 3" (7.6cm) H
Weight (including batteries):	3lbs. 14oz. (1.75 kgs)
Operating Power:	120/240VAC; 50/60Hz; 50W 4 x 1.5VDC "D" cell alkaline or rechargeable batteries.
Battery Life:	New alkaline batteries operate the system for 40 hours at full output and over 100 hours at normal settings. Battery voltage is displayed and monitored. With the 4.4Ah NiCad rechargeable cells the system will operate approximately 10 hours at normal settings.
Display System:	Super Twist LCD full character display with adjustable contrast /viewing angle.
Push Buttons:	Polyester embossed overlay for tactile feel and infection control. Speed and sensitivity are fully adjustable.
System Memory:	The system remembers all prior custom settings from treatment to treatment in active battery powered RAM memory. (Must be reset if the batteries are changed or discharged.)
System Architecture:	CMOS integrated micro-controller with on board memory and instruction set.
STIMULATION SYSTEM:	
Output:	Constant voltage up to maximum preset current limit
Output Waveform:	AC sine wave into physiologic load, IFC and MFAC modes, and biphasic square wave (LVPC) or monophasic pulsed current (HVPC mode). Output Amplitude: IFC FD and NMES modes-0 to 70 mA RMS current into a 500Ω, LVPC mode 75mA P-P, HVPC mode 250VDC peak into 500Ω loads.
Channel Isolation:	Independent transformer isolation.
Line Leakage:	<50 μA when operated with the charger system.
IFC MODES:	
Frequency Difference Rate:	Output channel A, fixed at 2KHz, 2.5KHz, 4KHz or 5KHz. Output channel B variable from channel A frequency + 0.0 to 250Hz. Beat rate may be set during treatment.
Full Field Burst Rate:	0.1 - 999Hz
Rate Scan:	0 - 20 seconds, 0 - 50% modulation, upper and lower frequencies are fully programmable and sweep time is adjustable in set mode.
Vector:	<i>Fast 90°</i> - Scans amplitude of channel A from 0 - maximum every 10 seconds relative to channel B, which varies concurrently out of phase. <i>Slow 90°</i> - Scans amplitude of channel A from 0 - maximum every 60 seconds relative to channel B, which varies concurrently out of phase. <i>Fast 45°</i> - Scans amplitude of channel A from 50% to maximum every 10 seconds relative to channel B, which varies concurrently out of phase. <i>Slow 45°</i> - Scans amplitude of channel A from 50% to maximum every 60 seconds relative to channel B, which varies concurrently out of phase.
MFAC MODE:	
Waveform:	Modified sine wave into physiologic load 2KHz, 2.5KHz, 4KHz or 5KHz carrier frequency.
Burst Rate:	Adjustable from 0.1 to 999bps, 50% duty factor
Rate Scan:	From 0-50% programmable with scan time, programmable from 0-20 seconds

LVPC (LOW VOLTAGE PULSED CURRENT) MODE:	
Waveform:	Biphasic square wave
Phase Duration:	10-500µs
Pulse Rate:	0.1 - 999pps
HVPC (HIGH VOLTAGE PULSED CURRENT) MODE:	
Waveform:	Twin monophasic pulses each with 40µs phase duration, with inter phase interval of 100µs
Pulse Rise Time:	<500 ns
Pulse Rate:	Adjustable from 1-125pps
Interphase Interval:	Adjustable from 10-250µs
TIMER FUNCTIONS:	
Treatment Timer:	Adjustable for 1-99 minutes in one minute increments. Turns output to zero and system off and sounds 10-second buzzer to indicate completion of treatment.
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 0.1 to 9 seconds in 0.1-second increments. Ramps overlap in NMES Alt mode or with channel delay
ON Time:	Adjustable from 1 to 30 seconds in 1-second increments
OFF Time:	Adjustable from 0 (continuous) to 199 seconds in 1-second increments
PATIENT SAFETY SYSTEMS:	
Activation:	Patient safety hand control shuts down output. Output modality may not be changed during operation. Output levels are reset to zero at the start and completion of treatment.
MISC.:	
Certificates and Approvals:	Devices are designed to meet or exceed all safety requirements of a medical device in its class per IEC 60601 and CSA C22.2 No. 601.1

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.

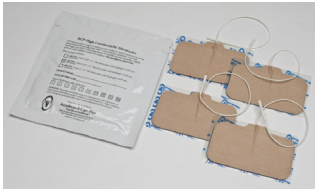

OMNISTIM® 500 PRO STANDARD AND OPTIONAL ACCESSORIES

ITEM	ITEM NO.	DESCRIPTION
	100500C	<p>OMNISTIM® 500 PRO MULTIMODALITY MICROPROCESSOR CONTROLLED TREATMENT SYSTEM</p> <p>2 channels of programmable stimulation with IFC Frequency Difference Interferential, MFAC (Russian style NMES), High Volt Pulsed Current (HVPC) and Low Volt Pulsed Current (LVPC).</p> <p>Shipping Weight: 5 lbs (2.3 kg)</p>




Accessories

ITEM	ITEM NO.	DESCRIPTION
	48758	Lead Wire – Standard Blue & Green (pair)
	39555	Patient Safety Switch
	51122	Omnistim® Power Supply, 110v
	19856	Omnistim® Power Cord, A/C, Hospital Grade
	13331	Omnistim® Output Tester
	*67652	Omnistim® Leatherette Soft Carry Case
	65662	Rechargeable Batteries (D size) 4400 mAh Heavy Duty Medical Grade Ni-Cd (Nickel Cadmium) (set of 4)
	29999	Omnistim® 500 Pro User Manual

Electrodes

ITEM	ITEM NO.	DESCRIPTION
	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)
	SINGLE-USE WOUND CARE ELECTRODE	
	40944	4x4 Single-use Non-Gelled Electrode (25ea/bx) (for Wound Care ONLY)

Infection Control Supplies

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
	63574	Protective Barrier Tubing, 3" (1200ft/roll)
	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)

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

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 not 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. PLEASE CALL CUSTOMER SERVICE AT (800)-350-1100 FOR AUTHORIZATION. 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



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