OMNISTIM® FX² PRO

Electrotherapy System

User Manual

Revised 01.22.2018
Part No. 290FX2C Rev 5

OMNISTIM® FX² 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 **MEGAPULSE®**, **NEUROPROBE®**, **OMNISTIM®**, **OMNISOUND®**, **OMNIBAND®**, **OMNITEST®, OMNICYCLE®,** and **OMNIVR®** represent the most recent world wide 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. This new medical frontier holds great promise and opportunity, which will result in substantial advancements in the health care industry and for ACP.

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 0197	CE mark of confidence compliant to MDD (93/42/EEC)
	Connection Electrode Cable	IP2X	Classification against intrusion of water, dust, accidental contact of a body part.
	Proper disposal required. Do not dispose of with regular household waste. Follow state and/or local regulations.		Alternating current device.
	Observe the user manual		Consult instructions for use
	Protect the product from humidity		ON / OFF push button

TABLE OF CONTENTS

ELECTROTHERAPY INDICATIONS & CONTRAINDICATIONS

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

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

Indications

The Omnistim FX2 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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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 not advised 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® FX² PRO

Delivery of the Omnistim® FX² Pro

Upon receipt of your Omnistim® FX² 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 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® FX² Pro operating features and functionality. Please read the manual carefully before attempting to operate the Omnistim® FX² Pro. If questions remain unanswered, contact your ACP sales representative or call 800-350-1100. Outside the USA call 1-775-685-4000.*

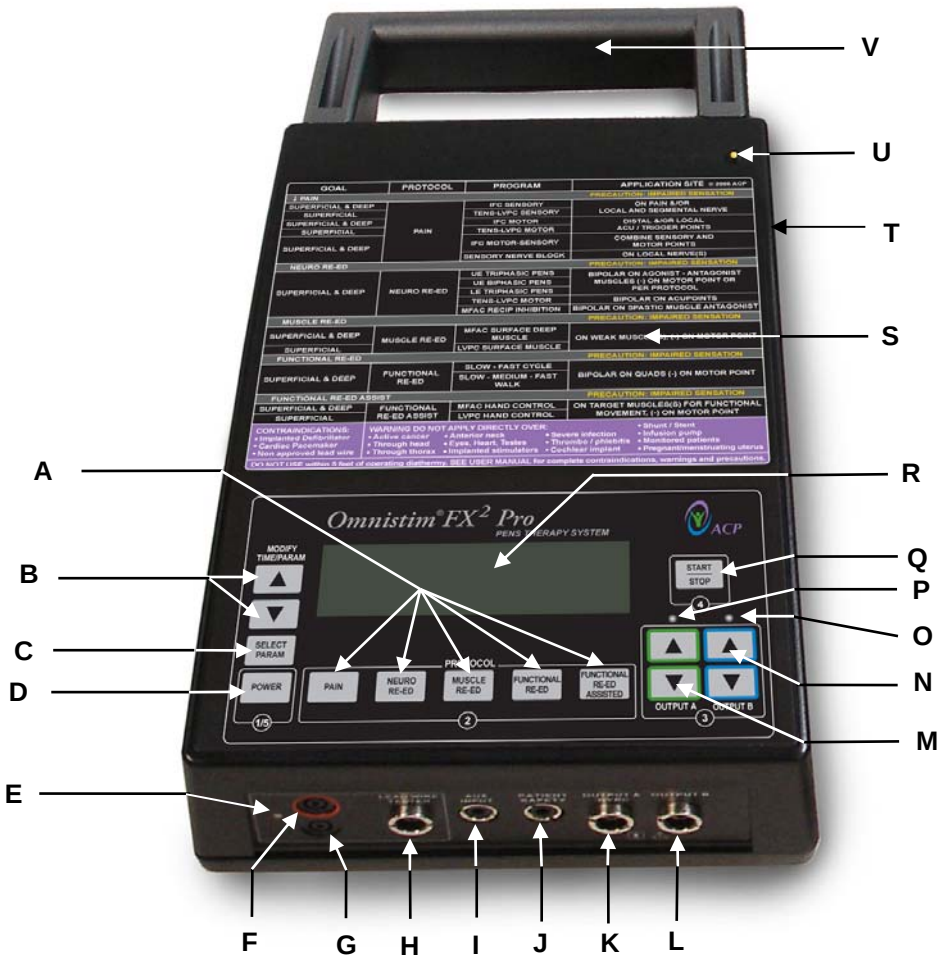
Introduction

The Omnistim® FX² Pro provides Patterned Electrical Neuromuscular Stimulation (PENS), which is a form of stimulation that replicates the correct firing patterns of muscles (agonist and antagonist or reciprocal muscle pairs) in triphasic (ballistic), biphasic (reciprocal), or functional patterns. This approach to neuro re-ed provides a high intensity, precisely timed sensory input, which duplicates the firing activity of sensory neurons and muscle stretch receptors during voluntary activity.

The Omnistim® FX² Pro is designed to provide Medium Frequency Alternating Currents (MFAC) and Low Voltage Pulsed Current (LVPC). Its two separate generators produce medium frequency (2000, 2500, 4000, 5000 or 10,000 Hz) alternating current in continuous or modulated modes or asymmetric biphasic pulsed current. 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® FX² 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 programs for innervated muscle.

Controls and Functions



A. Press button corresponding to the desired functional PROTOCOL group. Chose between PAIN, NEURO RE-ED, MUSCLE RE-ED, FUNCTIONAL RE-ED, or FUNCTIONAL RE-ED ASSISTED.

B. MODIFY TIME/PARAMETER UP or DOWN buttons are used to increase/decrease treatment time or changes parameters in SET mode.

C. 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.

D. Main power switch. Press for power ON, press again for power OFF. The display illuminates with default display: SELECT PROTOCOL / TREATMENT OFF.

E. 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.

F. 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.

G. 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.

H. Connector for the device end of the lead wire when testing lead wire in the LEAD WIRE TESTER.

I. AUX INPUT used to connect cable for remote hand control operation.

J. PATIENT SAFETY input switch connector.

K. Output for CHANNEL A.

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® FX² Pro comes with the following factory settings:

Button Speed, A & B Output	87
Audio	ON

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

1. When the main screen comes up and displays "SELECT PROTOCOL / TREATMENT OFF" push the SELECT PARAMETER button. You will then be able to adjust the factory settings. The new settings will be saved for use as long as you do not remove the batteries or allow a full discharge of the unit.
2. 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 (85 - 95) so as not to startle the patient.
3. AUDIO on or off disables or enables the audio system, which beeps at the end of the treatment and during the NMES programs.

NOTE: *The above 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® FX² Pro battery charger/power supply:

- Verify that rechargeable batteries are installed within the Omnistim® FX² Pro battery compartment.
- 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® FX² Pro comes on. 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:*

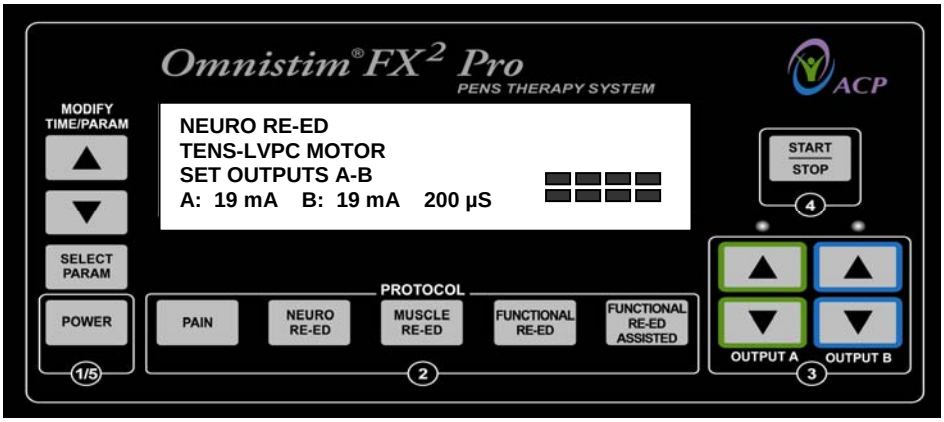
1. *Do not use the charger.*
2. *Make sure that the rechargeable/non-rechargeable selector switch in the bottom of the battery compartment is in the non-rechargeable position.*

Life expectancies of batteries under nominal (40mA MFAC) load conditions:

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

Operational Sequence

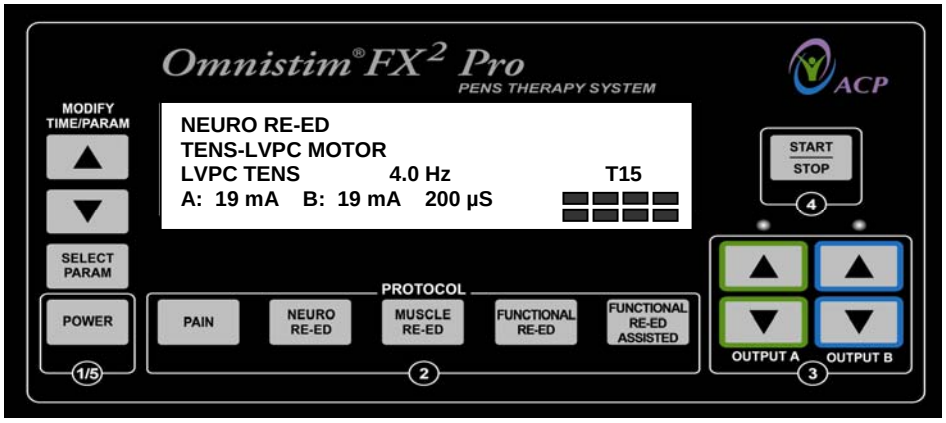
1. Press the POWER button (1/5) to turn on the power. The display panel will illuminate. There will be no stimulation current and the unit will be in the SELECT PROTOCOL / TREATMENT OFF mode.
2. At this time select the treatment protocol desired and the appropriate treatment program by using the PROTOCOL buttons (2) to select PAIN, NEURO RE-ED, MUSCLE RE-ED, FUNCTIONAL RE-ED, or FUNCTIONAL RE-ED ASSISTED.
3. Press the SELECT PARAM button to modify any settings. Press the MODIFY TIME/PARAM UP of 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/PARAM UP or DOWN arrow 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. 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. Note that the treatment time is pre-set for each program but may be adjusted at will during 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 UP or DOWN buttons (3), to deliver appropriate output based on patient sensation. The screen will display the following (in this example, TENS-LVPC MOTOR was selected from the NEURO RE-ED 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 the output intensity by pressing the up/down arrow 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.
8. Turn the unit off by pressing the POWER button (1/5).

TREATMENT GUIDELINES

Introduction to Medium Frequency Currents

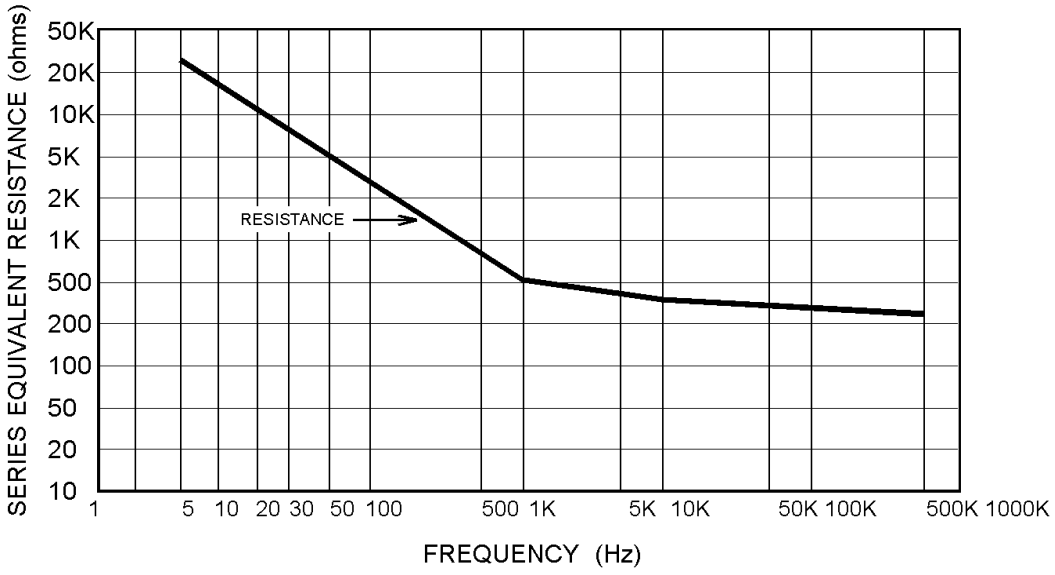
Medium frequency (MF) currents may be described as electrical currents applied to the body for therapeutic purposes, which fall in the range of 1000 to 10,000 cycles per second (Hz). This is in contrast to low frequency currents (0.1 to 1000 Hz) such as LVPC and high frequency currents (1 million Hz 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 1000 or 5000 Hz provide markedly lower resistance to penetration than low frequency electrical stimulation commonly used in Transcutaneous Electrical Nerve Stimulation (TENS) and LVPC 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 (0.1 to 1000 Hz) stimulators, which are capable of only stimulus synchronous neural activation.

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

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



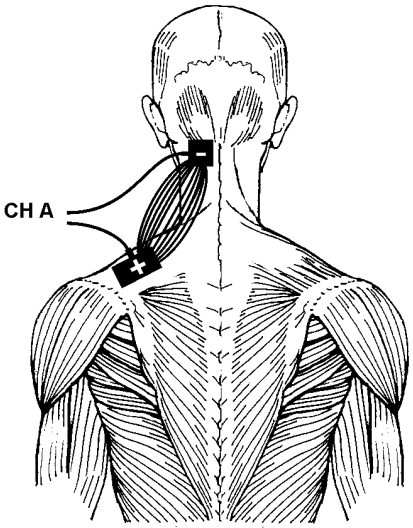
PLOT OF IMPEDANCE AS A FUNCTION OF FREQUENCY USING EPIDUCTIVE SYSTEMS

Electrode Application Techniques

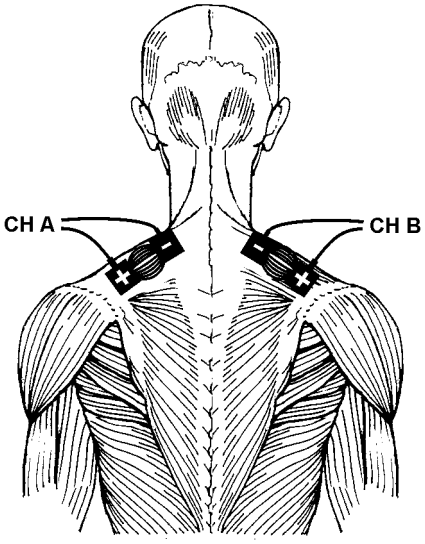
The following electrode placement diagrams are a theoretical representation of treatment set-ups using the Omnistim® FX² Pro. Monopolar, bipolar and quadripolar techniques are illustrated. Electrode placement is dependent on the etiology of the condition.

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



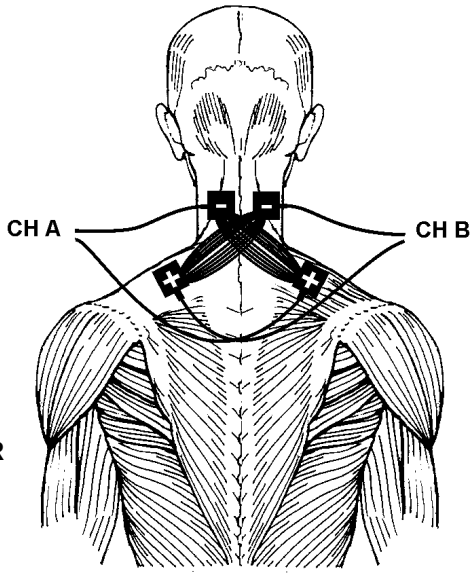
Bipolar (Bi-Polar) Technique

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 and interferential pattern.



CERVICAL QUADRIPOLAR PLACEMENT OF ELECTRODES

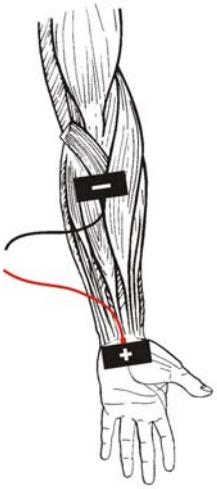
PENS Neuro Re-Education Techniques

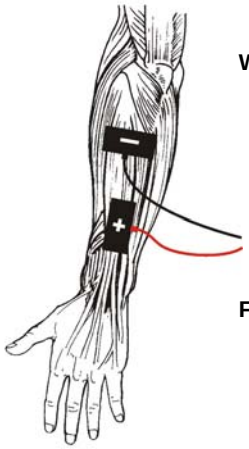
WRIST AND FINGER FLEXION AND EXTENSION

WRIST
- **FLEXOR CARPI**
- **RADIALIS & ULNARIS**

CH A

FINGERS
- **FLEXOR DIGITORUM**
- **SUPERFICIALIS & PROFUNDUS**





WRIST
- **EXTENSOR CARPI ULNARIS**
- **EXTENSOR CARPI**
- **RADIALIS LONGUS & BREVIS**

CH B

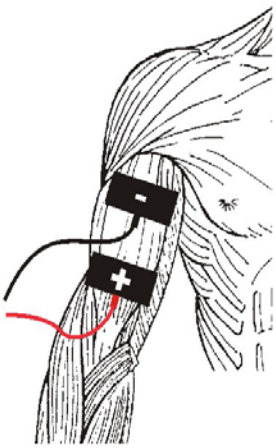
FINGERS
- **EXTENSOR DIGITORUM**
- **EXTENSOR DIGITI MINIMI**

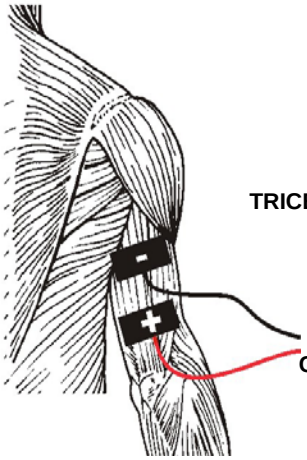
- **PATIENT IS PASSIVE DURING STIMULATION**

ELBOW FLEXION AND EXTENSION

BICEPS BRACHII

CH A





TRICEPS BRACHII

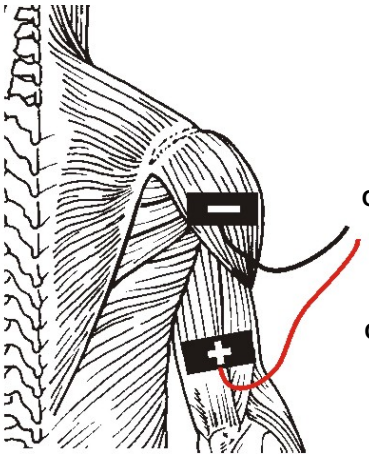
CH B

- **PATIENT IS PASSIVE DURING STIMULATION**

SHOULDER FLEXION AND EXTENSION

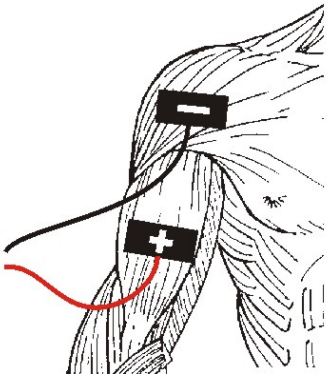
MID POSTERIOR DELTOID

MID TRICEPS BRACHII



CH B

CH A



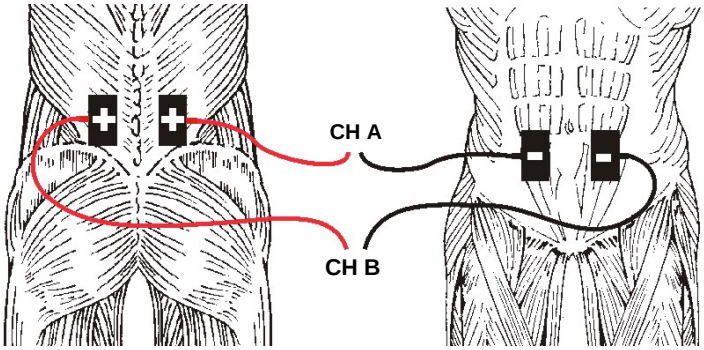
MID ANTERIOR DELTOID

MID BICEPS BRACHII

- PATIENT IS PASSIVE DURING STIMULATION

LUMBAR STABILIZATION

BILATERAL PARASPINALLY OVER MULTIFIDUS MUSCLE



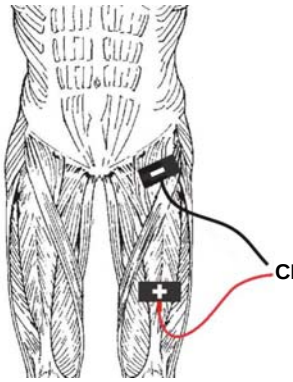
CH A

CH B

LEVEL OF UMBILICUS ½ WAY BETWEEN THE ASIS AND THE ANTERIOR MIDLINE, OVER THE TRANSVERSE ABDOMINAL MUSCLE

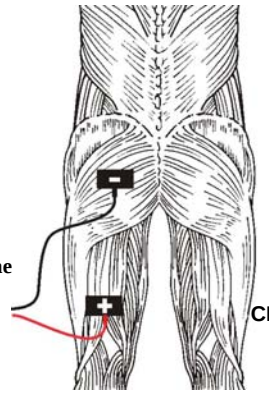
- PATIENT IS PASSIVE DURING STIMULATION
- FOR UNILATERAL INVOLVEMENT, APPLY CH A TO THE MOST INVOLVED SIDE

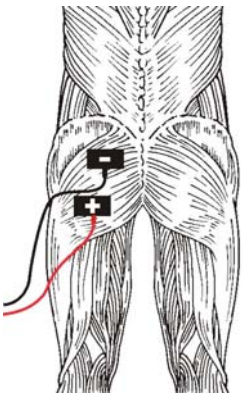
HIP FLEXION AND EXTENSION



\+ Over the iliopsoas, just distal to the inguinal ligament, medial and proximal to the sartourius, and the lateral femoral artery.

\- Over the distal part of the rectus femoris



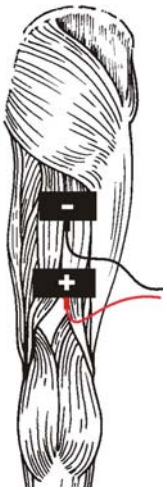


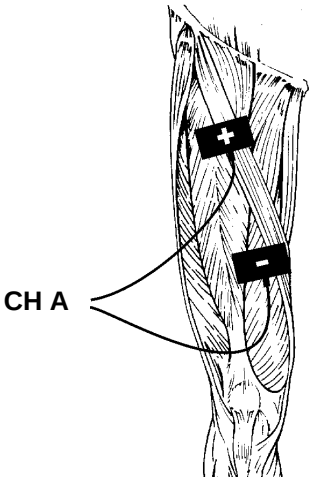
GLUTEUS MAXIMUS OR GLUTEUS & HAMSTRINGS

- PATIENT IS PASSIVE DURING STIMULATION
- PATIENT NEEDS TO BE SUPINE WITH HIPS EXTENDED

KNEE FLEXION AND EXTENSION

BICEPS FEMORIS
SEMIMEMBRANOSUS
SEMITENDINOSUS





RECTUS FEMORIS
VASTUS INTERMEDIALIS
VASTUS LATERALIS

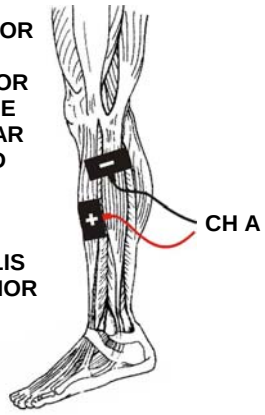
VASTUS MEDIALIS (VMO)

PATIENT IS PASSIVE DURING STIMULATION

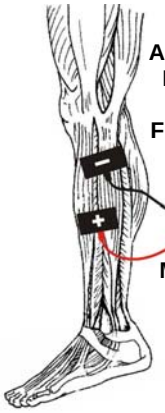
ANKLE DORSIFLEXION

ANTERIOR AND INFERIOR TO THE FIBULAR HEAD

MID TIBIALIS ANTERIOR



ANKLE DORSIFLEXION AND EVERSION

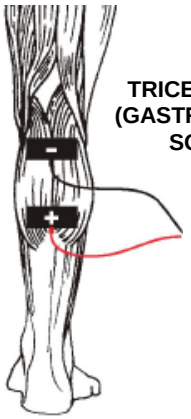


ANTERIOR AND INFERIOR TO THE FIBULAR HEAD

CH A

MID TIBIALIS ANTERIOR PERONEUS LONGUS & BREVIS

PLANTAR FLEXION



TRICEPS SURAE (GASTROCNEMIUS SOLEUS)

CH B

- PATIENT IS PASSIVE DURING STIMULATION IN A RELAXED TOE DOWN POSITION
- TO ACCOMPLISH A TOE DOWN POSITION WHILE SEATED: PLACE A TOWEL ROLL UNDER HEEL, PLACE A PILLOW UNDER THIGH, RAISE SEAT HEIGHT

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

Cleaning / Disinfecting of the Omnistim® FX² 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

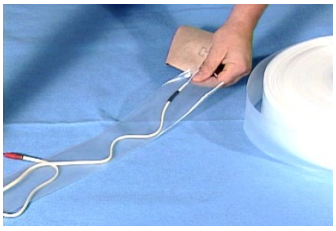
This method is recommended to keep the equipment clean and free of contaminants when used between patients for treatment of non-intact skin or incontinence management, where there is an increased risk of patient cross-contamination. The following are the recommended practices.

- 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® FX² 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® FX² 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.	• 5000Hz – 80/120 BPS Continuous • Vector Fast 90º • 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.	• 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.	• 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.	• 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.	• 2500Hz – 2/6 BPS Continuous • Vector Fast 90º • 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.	• 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.	• 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.	• 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.	• 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.	• 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.
SENSORY NERVE BLOCK Symptomatic relief of superficial and deep pain from localized dermal or segmental origin.	• 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.	• 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.

Neuro Re-Education

PROTOCOL / CLINICAL INDICATION	STIMULATION PARAMETERS	MECHANISM OF ACTION	APPLICATION TECHNIQUE	OPERATIONAL SEQUENCE
UE TRIPHASIC PENS Neuro-re-education FX² before Therex	• 70 µS phase duration • Triphasic EMG Pattern • Treatment time of 15 minutes	Patterned Electrical Neuromuscular Stimulation (PENS) is a precise reproduction of EMG firing patterns of muscle agonist and antagonist pairs. The stimulation helps to re-establish proper firing sequence in the spinal and supraspinal central pattern generators, re-educating neuromuscular function. PENS helps re-boot the sense position system and neuromuscular junction to improve recruitment and muscle function. It should be used prior to Therex to improve recruitment and motor performance. It's also used to decrease spasticity and muscle tone.	This program is used to re-educate U.E. agonist and antagonist muscle pairs where fine motor control and positioning is required. Place the (+) and (-) electrodes as indicated in the clinical treatment charts over the agonist and antagonist muscle pair to be treated. In patients with severe disuse atrophy, decreased sensation or inflammation use a sensory level of stimulation for the first two weeks of treatment. This can be increased to a moderate muscle twitch during the next 4-6 weeks of treatment.	• Press NEURO RE-ED button until screen reads "UE TRIPHASIC PENS". • 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.
UE BIPHASIC PENS Neuro-re-education FX² before Therex	• 70 µS phase duration • Biphasic EMG pattern • Cycle time of 0.75 seconds • Treatment time of 15 minutes		This program is used to re-educate U.E. agonist - antagonist muscle pairs for reciprocal movement such as pursing the lips, chewing, and for the treatment of torticollis. Place the (+) and (-) electrodes as indicated in the treatment clinical charts over the agonist and antagonist muscle pair to be treated. In patients with severe disuse atrophy, decreased sensation or inflammation use a sensory level of stimulation for the first two weeks of treatment. This can be followed increased to a moderate muscle twitch during the next 4-6 weeks of treatment.	• Press NEURO RE-ED button until screen reads "UE BIPHASIC PENS". • 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.
LE TRIPHASIC PENS Neuro-re-education FX² before Therex	• 70 µS phase duration • L.E. Triphasic EMG Pattern • Treatment time of 15 minutes		This program is used to re-educate L.E. agonist and antagonist muscle pairs where fine motor control and positioning is required. Place the (+) and (-) electrodes as indicated in the clinical treatment charts over the agonist and antagonist muscle pair to be treated. In patients with severe disuse atrophy, decreased sensation or inflammation use a sensory level of stimulation for the first two weeks of treatment. This can then be increased to a moderate muscle twitch during the next 4-6 weeks of treatment.	• Press NEURO RE-ED button until screen reads "LE TRIPHASIC PENS". • 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 Neuro-re-education Post stroke.	• 4Hz - 200uSec PD Continuous • Treatment time of 15 minutes.	Motor level stimulation activates recovery of function in post ischemic stroke patients based on clinical trial evidence.	Target tissue-superficial. Bipolar placement over local and distal acu points. Set intensity to elicit a moderate muscle twitch.	• Press NEURO RE-ED 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.
MFAC RECIPROCAL INHIBITION Reduces muscle tone (spasm) of spastic muscle	• 50 BPS - 2500 Hz • 12Sec "ON" and 18Sec "OFF" time • Channels fire simultaneously • Ramps are 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.	• Press NEURO RE-ED 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.

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	• 2500Hz - 75 BPS • 10 Sec "ON" time and 50 Sec "OFF" time • Channels fire simultaneously • Ramps are 2Sec "ON/OFF" • Treatment time 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.	• 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	• 50 Hz - 70 uSec PD • 10Sec "ON" time and 50Sec "OFF" time • Channels fire simultaneously • Ramps are 2Sec "ON/OFF" • Treatment time 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.	• 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.

Functional Re-Education

PROTOCOL / CLINICAL INDICATION	STIMULATION PARAMETERS	MECHANISM OF ACTION	APPLICATION TECHNIQUE	OPERATIONAL SEQUENCE
SLOW CYCLE FAST CYCLE	• 70 µS PD • EMG based cycle pattern • 42 or 60 RPM • Treatment time 15 minutes	Functional re-education of synchronized muscle movement for simulating cycling.	This program simulates cycling and can be used to retrain reciprocal movement of the L.E. with or without resistance. Electrodes are applied to both quads while sitting with hips and knees flexed. Use a lower extremity ergometer or pedal exerciser in combination with stimulation at mild to moderate contraction intensity for closed chain functional training. Increase resistance as the patient progresses in the rehab program.	• Press FUNCTIONAL RE-ED button until screen reads "SLOW CYCLE" or "FAST CYCLE". • 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.
SLOW WALK MEDIUM WALK FAST WALK	• 70 µS PD • EMG based walk pattern • 42, 60 or 88 strides/min • Treatment time 15 minutes	Functional re-education of synchronized muscle movement for simulating walking.	This program simulates walking at a speed of 1-1.5 strides/sec. The program is used to re-educate gait function. Electrodes are applied to both quads while sitting with hips and knees flexed. A light resistance using weight cuffs or exercise band can be applied. The stimulation should cause a light to moderate contraction. Transition to standing, with weight shifting activities then to walking in place in later rehab.	• Press FUNCTIONAL RE-ED button until screen reads "SLOW WALK" or "MEDIUM WALK" or "FAST WALK". • 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.

Functional Re-Ed Assisted

PROTOCOL / CLINICAL INDICATION	STIMULATION PARAMETERS	MECHANISM OF ACTION	APPLICATION TECHNIQUE	OPERATIONAL SEQUENCE
MFAC HAND CONTROL Active assisted treatment to develop functional movement of superficial and deep muscle.	• 2500Hz - 50 BPS • Channels fire simultaneously • Treatment time 15 minutes	Activation of muscle with electrical stimulation during functional movement. The patient should participate to the extent possible with the functional movement by contracting during the stimulation "ON" time.	Target tissue - superficial and deep muscle groups. Bipolar set-up over agonist and antagonist muscles for target muscle. Set intensity to elicit a grade 3-5 muscle contraction. Reduce treatment time based on muscle fatigue. The patient should participate in active functional movement.	• Press FUNCTIONAL RE-ED ASSIST button until screen reads "MFAC HAND CONTROL". • 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.
LVPC HAND CONTROL Active assisted treatment to develop functional movement of superficial and deep muscle.	• 50 Hz - 70 uSec PD • Channels fire simultaneously • Treatment time 15 minutes	Activation of muscle with electrical stimulation during functional movement. The patient should participate to the extent possible with the functional movement by contracting during the stimulation "ON" time.	Target tissue - smaller superficial muscle groups. Bipolar set-up over agonist and antagonist muscles. Set intensity to elicit a grade 3-5 muscle contraction. Reduce treatment time based on muscle fatigue. The patient should participate in active functional movement.	• Press FUNCTIONAL RE-ED ASSIST button until screen reads "LVPC HAND CONTROL". • 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.

OMNISTIM® FX² PRO PROGRAM MENU

Pain Control

A. IFC SENSORY

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

User Adjustable Parameter (Y/N)	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 is used for symptomatic relief of superficial pain from localized dermatome or segmental origin. 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 usually within 15-20 minutes. Target tissue is superficial. Bilateral bipolar application through the painful area or over the involved spinal segments. Apply parallel to incision line for post operative pain management. The intensity should be set to elicit a pleasant tingling sensation, just below a muscle contraction.

User Adjustable Parameter (Y/N)	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

Provides symptomatic relief of superficial and deep pain with inflammation, and pain of generalized or multi-segmental nature. Motor level stimulation activates motor and A-delta fibers causing the release of Bendorphin systemically. Duration of relief is typically from 2 to 6 hours. Slow onset of relief usually within 15 minutes to 1 hour. Target tissue is superficial and deep. Bipolar placement over local and distal acu / trigger points. Quadripolar placement over area of local pain, or at involved spine segment. The intensity should be set to elicit a moderate muscle twitch.

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

Application of this program will provide symptomatic relief of superficial pain with inflammation, or pain of a generalized or multi-segmental nature. Motor level stimulation activates motor and A-delta fibers causing the release of Bendorphin systemically. Duration of relief is typically from 2 to 6 hours. Slow onset of relief is usually within 15 minutes to 1 hour. Target tissue is superficial. Bipolar placement over local and distal acu / trigger point or a spinal segmental level. Intensity should be set to elicit a moderate muscle twitch.

User Adjustable Parameter (Y/N)	Order in Parameter Set Loop	Parameter Name	Adjustable Range (unit)	Default (unit)
Y	2	PHASE DURATION	40…300 (μs)	200 (μs)
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

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

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. SENSORY NERVE BLOCK

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

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)

Neuro Re-Ed

A. UE TRIPHASIC PENS

This program is used to re-educate upper extremity agonist - antagonist muscle pairs where fine motor control and positioning is required. It is called triphasic because the agonist fires first, followed by the antagonist followed by a small burst of agonist muscle to slow down the antagonist and position the joint. Patterned Electrical Neuromuscular Stimulation (PENS) is a precise reproduction of EMG firing patterns of muscle agonist and antagonist pairs. The stimulation helps to re-establish proper firing sequence in the spinal and supraspinal central pattern generators, re-educating neuromuscular function. PENS helps re-boot the sense position system and neuromuscular junction to improve recruitment and muscle function. It should be used prior to Therex to improve recruitment and motor performance. It's also used to decrease spasticity and muscle tone.

User Adjustable Parameter (Y/N)	Order in Parameter Set Loop	Parameter Name	Adjustable Range (unit)	Default (unit)
Y	2	PHASE DURATION	40…100 (µs)	70 (µs)
N		PULSE RATE		50 (Hz)
Y	1	TREATMENT TIME	0…99 (min)	15 (min)
N		CHANNEL MODE		Tri Phasic

B. UE BIPHASIC PENS

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

User Adjustable Parameter (Y/N)	Order in Parameter Set Loop	Parameter Name	Adjustable Range (unit)	Default (unit)
Y	2	PHASE DURATION	40…100 (µs)	70 (µs)
N		PULSE RATE		50 (Hz)
Y	1	TREATMENT TIME	0…99 (min)	15 (min)
Y	3	CYCLE TIME	2.5; 1.5; .75; .6; .5 (sec)	.75 (sec)
N		CHANNEL MODE		Bi Phasic

C. LE TRIPHASIC PENS

This program is used to re-educate lower extremity agonist - antagonist muscle pairs where fine motor control and positioning is required. It is called triphasic because the agonist fires first, followed by the antagonist followed by a small burst of agonist muscle to slow down the antagonist and position the joint. Patterned Electrical Neuromuscular Stimulation (PENS) is a precise reproduction of EMG firing patterns of muscle agonist and antagonist pairs. The stimulation helps to re-establish proper firing sequence in the spinal and supraspinal central pattern generators, re-educating neuromuscular function. PENS helps re-boot the sense position system and neuromuscular junction to improve recruitment and muscle function. It should be used prior to Therex to improve recruitment and motor performance. It's also used to decrease spasticity and muscle tone.

User Adjustable Parameter (Y/N)	Order in Parameter Set Loop	Parameter Name	Adjustable Range (unit)	Default (unit)
Y	2	PHASE DURATION	40…100 (µs)	70 (µs)
N		PULSE RATE		50 (Hz)
Y	1	TREATMENT TIME	0…99 (min)	15 (min)
N		CHANNEL MODE		Tri Phasic

D. TENS-LVPC MOTOR

This program motor level stimulation activates recovery of function in post ischemic stroke patients. Target tissue is superficial. Bipolar placement over local and distal acu points. The intensity should be set to elicit a moderate muscle twitch.

User Adjustable Parameter (Y/N)	Order in Parameter Set Loop	Parameter Name	Adjustable Range (unit)	Default (unit)
Y	2	PHASE DURATION	40…300 (µs)	200 (µs)
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. MFAC RECIPROCAL INHIBITION

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

User Adjustable Parameter (Y/N)	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 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.

Muscle Re-Ed

A. MFAC SURFACE DEEP MUSCLE

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

User Adjustable Parameter (Y/N)	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

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

User Adjustable Parameter (Y/N)	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)
N		PHASE DURATION MOD		0
N		MODULATION		OFF
N		RATE SCAN TIME		0 (s)
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.

Functional Re-Ed

A. SLOW CYCLE

Program simulates slow cycling, at 42 rpm, and can be used to retrain reciprocal movement of the L.E. with or without resistance. Electrodes are applied to both quads while sitting with hips and knees flexed. Use a lower extremity ergometer or pedal exerciser in combination with stimulation at mild to moderate contraction intensity for closed chain functional training. Increase resistance as patient progresses in the rehab program.

User Adjustable Parameter (Y/N)	Order in Parameter Set Loop	Parameter Name	Adjustable Range (unit)	Default (unit)
Y	2	PHASE DURATION	40…100 (µs)	70 (µs)
N		CYCLE TIME		1.40 (s)
N		PULSE RATE		50 (Hz)
Y	1	TREATMENT TIME	0…99 (min)	15 (min)

B. FAST CYCLE

Program simulates fast cycling, at 60 rpm, and can be used to retrain reciprocal movement of the L.E. with or without resistance. Electrodes are applied to both quads while sitting with hips and knees flexed. Use a lower extremity ergometer or pedal exerciser in combination with stimulation at mild to moderate contraction intensity for closed chain functional training. Increase resistance as the patient progresses in the rehab program.

User Adjustable Parameter (Y/N)	Order in Parameter Set Loop	Parameter Name	Adjustable Range (unit)	Default (unit)
Y	2	PHASE DURATION	40…100 (µs)	70 (µs)
N		CYCLE TIME		1.0 (s)
N		PULSE RATE		50 (Hz)
Y	1	TREATMENT TIME	0…99 (min)	15 (min)

C. SLOW WALK

Program simulates slow walking at a speed of 42 strides/minute. The program is used to re-educate gait function. Electrodes are applied to both quads while sitting with hips and knees flexed. A light resistance using weight cuffs or exercise band can be applied. The stimulation should cause a light to moderate contraction. Transition to standing, with weight shifting activities then to walking in place in later rehab.

User Adjustable Parameter (Y/N)	Order in Parameter Set Loop	Parameter Name	Adjustable Range (unit)	Default (unit)
Y	2	PHASE DURATION	40…100 (µs)	70 (µs)
N		CYCLE TIME		1.40 (s)
N		PULSE RATE		50 (Hz)
Y	1	TREATMENT TIME	0…99 (min)	15 (min)

D. MEDIUM WALK

Program simulates medium-speed walking at a rate of 60 strides/minute. The program is used to re-educate gait function. Electrodes are applied to both quads while sitting with hips and knees flexed. A light resistance using weight cuffs or exercise band can be applied. The stimulation should cause a light to moderate contraction. Transition to standing, with weight shifting activities then to walking in place in later rehab.

User Adjustable Parameter (Y/N)	Order in Parameter Set Loop	Parameter Name	Adjustable Range (unit)	Default (unit)
Y	2	PHASE DURATION	40…100 (µs)	70 (µs)
N		CYCLE TIME		1.0 (s)
N		PULSE RATE		50 (Hz)
Y	1	TREATMENT TIME	0…99 (min)	15 (min)

E. FAST WALK

Program simulates fast walking speed at a rate of 88 strides/minute. The program is used to re-educate gait function. Electrodes are applied to both quads while sitting with hips and knees flexed. A light resistance using weight cuffs or exercise band can be applied. The stimulation should cause a light to moderate contraction. Transition to standing, with weight shifting activities then to walking in place in later rehab.

User Adjustable Parameter (Y/N)	Order in Parameter Set Loop	Parameter Name	Adjustable Range (unit)	Default (unit)
Y	2	PHASE DURATION	40…100 (µs)	70 (µs)
N		CYCLE TIME		0.68 (s)
N		PULSE RATE		50 (Hz)
Y	1	TREATMENT TIME	0…99 (min)	15 (min)

Functional Re-Ed Assisted

A. MFAC HAND CONTROL

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

User Adjustable Parameter (Y/N)	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	2	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)
N		CHANNEL MODE		A/B SIM.

B. LVPC HAND CONTROL

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

User Adjustable Parameter (Y/N)	Order in Parameter Set Loop	Parameter Name	Adjustable Range (unit)	Default (unit)
Y	2	PHASE DURATION	40…300 (µs)	70 (µs)
Y	3	PULSE RATE	0.0…250 (Hz)	50.0 (Hz)
N		PHASE DURATION MOD		50 (%)
N		MODULATION		OFF
N		RATE SCAN TIME		4 (s)
Y	1	TREATMENT TIME	0…99 (min)	15 (min)
N		CHANNEL MODE		A/B SIM.

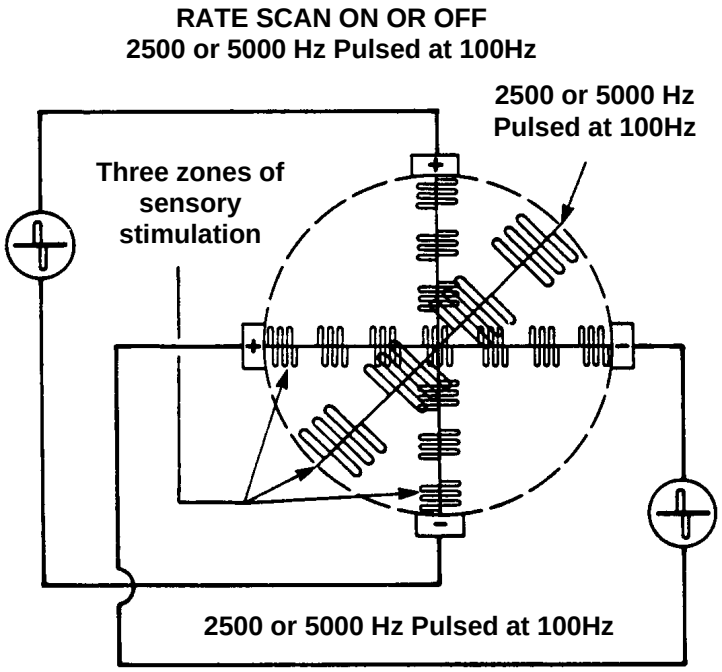
STIMULATION THERAPY MODES

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.



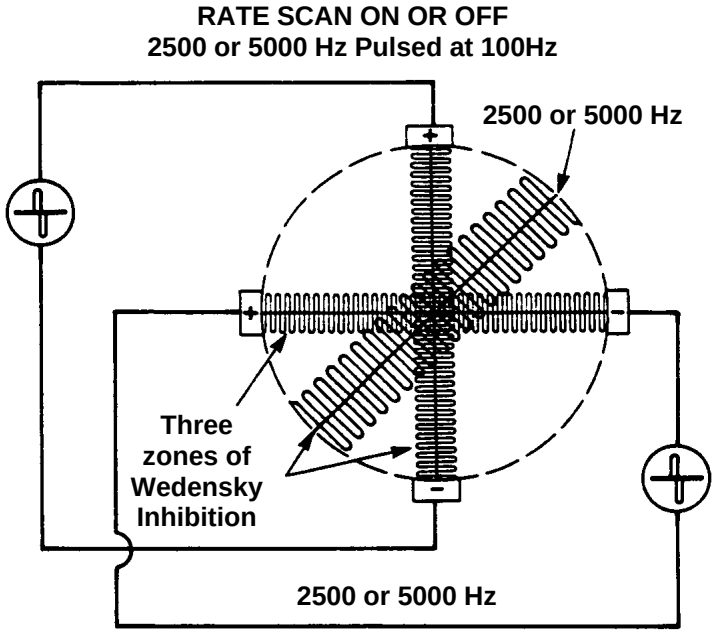
AMPLITUDE SUMMATION IFC TECHNIQUE

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® FX² Pro Sport when in the full field mode of operation.



FULL FIELD WEDENSKY INHIBITION

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.

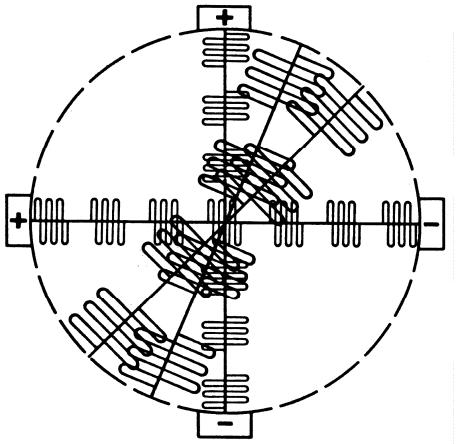
The effects of full field interferential current therapy may be described as follows:

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 mid point of the range of motion where the muscle can generate maximum torque.

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

Procedure:

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

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.

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

Procedures:

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

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.

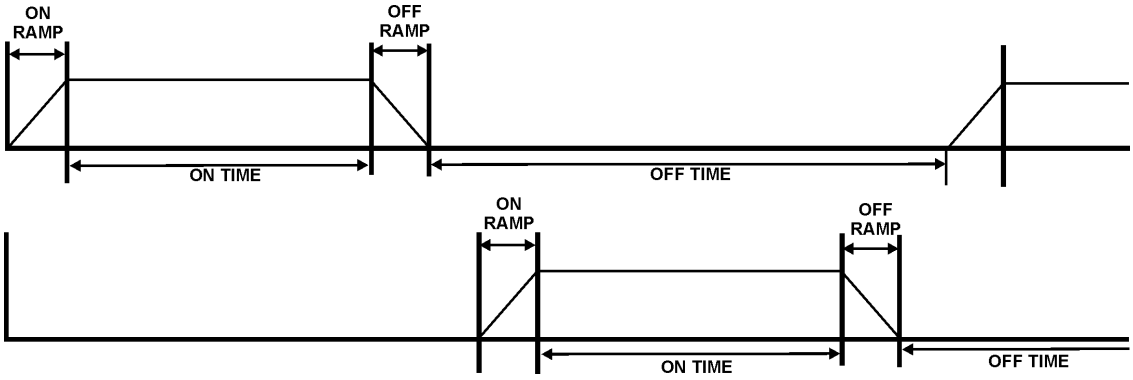
Blood Flow	
Mode	NMES Simultaneous
Time ON	15 Sec
Time OFF	50 Sec
ON Ramp	2 Sec
OFF Ramp	2 Sec
Pulse Rate	50Hz

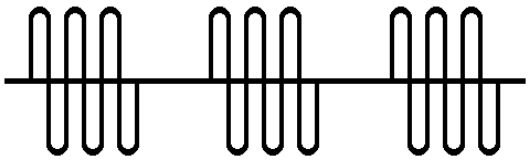
Muscle Pump Edema Reduction	
Mode	NMES Alternate
Time ON	4 Sec
Time OFF	4 Sec
ON Ramp	2 Sec
OFF Ramp	2 Sec
Pulse Rate	35Hz

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.

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.

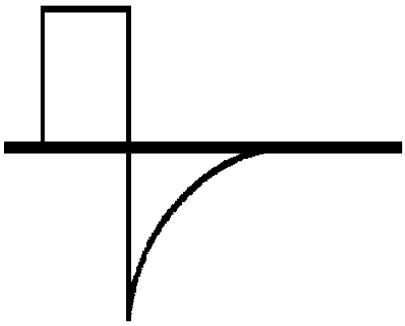




MFAC WAVEFORM

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.



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)	• No batteries • Low batteries	• 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)	• Power Supply not plugged in to the unit of AC outlet • Power Supply not operational	• Verify if the Power Supply is connected as appropriate • Verify 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	• Battery charge is too low	• Recharge batteries for future use
Unit will not start	• No program selected	• Select PROTOCOL
Cannot set carrier frequency	• Treatment in progress	• Stop treatment, adjust, and restart
Patient feels surging or spiking sensation	• Absent, inadequate, or improper conductive medium interface • Lead wire(s): short or breakage • Non-conductive or poorly conductive electrodes	• 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	• Failure of lead wire(s), electrode(s), or conductive medium interface • Failure of the Omnistim® FX² Pro	• 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.

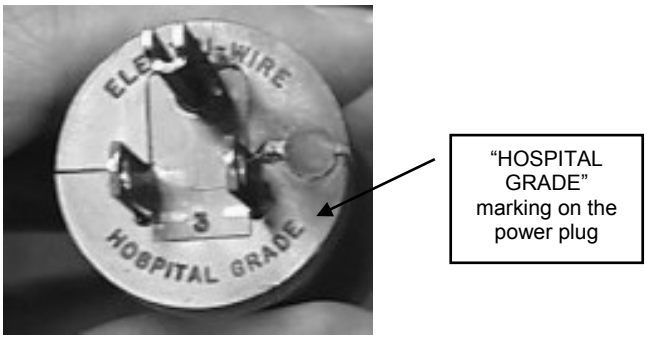


Figure 1

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).

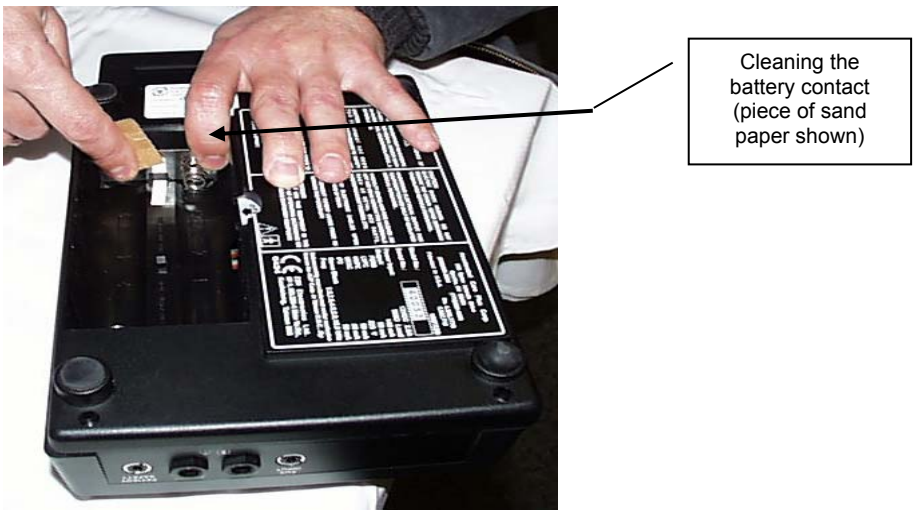


Figure 3

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).

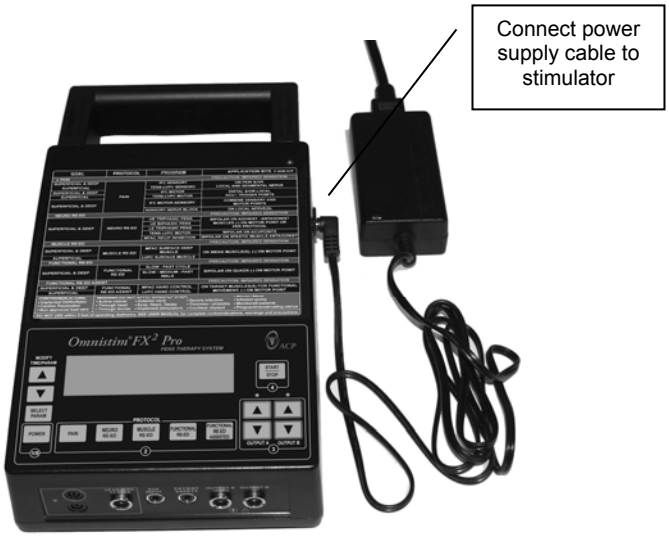


Figure 4

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

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

Press power supply switch ON

Figure 5a

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.

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.

Figure 6

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.

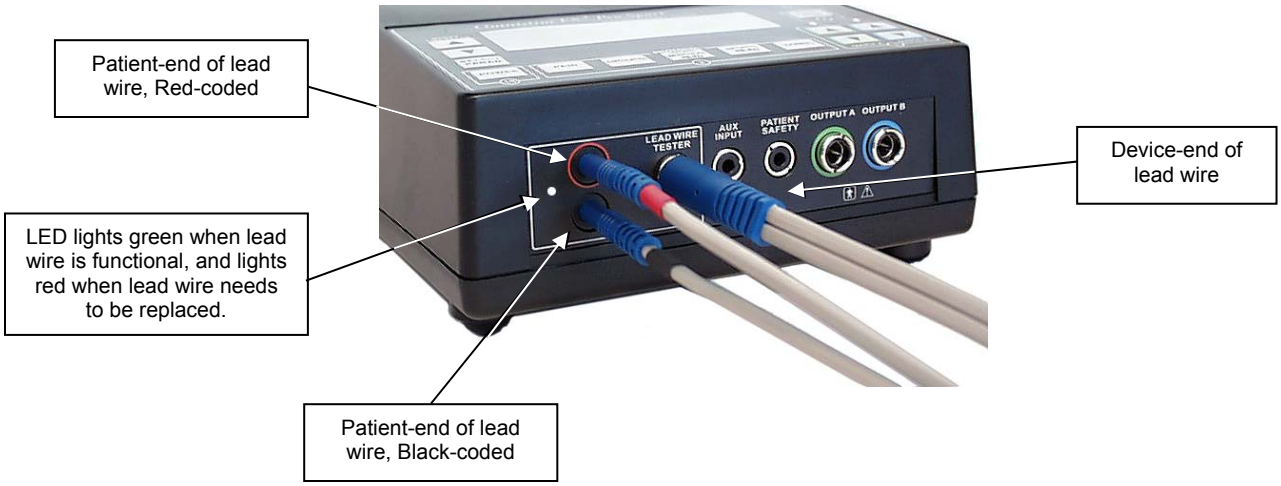
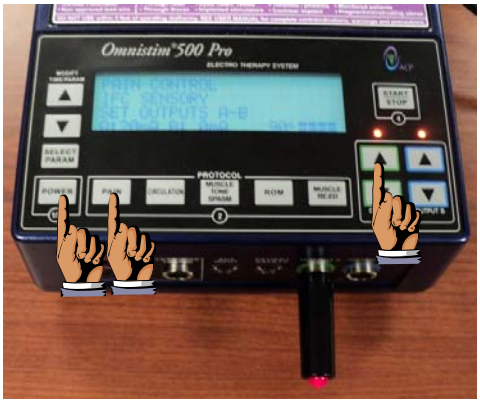


Figure 7

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" (30 cm) D x 6.5" (16.5cm) W x 3" (7.6cm) H
Weight (Including batteries):	3lbs. 14oz. (1.75kgs)
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 mono-phasic 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.
MFAC (MEDIUM FREQUENCY ALTERNATING CURRENT) MODE:	
Waveform:	Modified sine wave into physiologic load 2 KHz, 2.5 KHz, 4 KHz , 5 KHz AND 10 KHz carrier frequency.
Burst Rate:	Adjustable from 0.1 to 250bps, 50% duty factor
Rate Scan:	From 0-50%, from 0-20 seconds
LVPC (LOW VOLTAGE PULSED CURRENT) MODE:	
Waveform:	Asymmetrical biphasic square wave
Phase Duration:	10 - 300 μs
Pulse Rate:	0.1 – 250 pps
IFC (INTERFERENTIAL CURRENT) MODE:	
Frequency Difference Rate:	Output channel A, fixed at 2.0 KHz, 2.5, KHz, 4.0 KHz, or 5.0 KHz. Output channel B variable from channel A frequency + .0 to 250 Hz. Beat rate may be set during treatment.
Full Field Burst Rate:	.1 – 250 Hz
Rate Scan:	0-20 seconds, 0-50% modulation. Upper and lower frequencies are fully programmable and sweep time is adjustable in set mode.
Vector:	Scans amplitude of channel A relative to channel B which varies concurrently out of phase.
PENS (PATTERNED ELECTRICAL NEUROMUSCULAR STIMULATION) MODE:	
Waveform:	Asymmetric Biphasic
Phase Duration:	Variable from 40 μs to 100 μs
Pulse Rate:	Set at 50 Hz

HAND CONTROL:	
MFAC Hand Control:	• Modified Sine wave into physiologic load 2 KHz, 2.5 KHz, 4 KHz , 5 KHz AND 10 KHz 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 Hand Control:	• Asymmetrical biphasic square wave • Phase duration adjustable from 10 - 300 µs • Pulse rate adjustable from 0.1 – 250 pps
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 9.9 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® FX² PRO STANDARD AND OPTIONAL ACCESSORIES

ITEM	ITEM NO.	DESCRIPTION
	**100FX2C**	**OMNISTIM® FX² PRO** **MULTIMODALITY** **MICROPROCESSER CONTROLLED** **TREATMENT SYSTEM** Offers 2 channels of programmable stimulation with MFAC (Russian style NMES) and Low Volt Pulsed Current (LVPC). Shipping Weight: 5 lbs (2.3 kg)

ITEM	ITEM NO.	DESCRIPTION
	**48758**	Lead Wire – Standard Blue & Green (pair)
	***24248**	Lead Wire - Bifurcated 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)
	**75542**	Omnistim® FX2 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)

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 one (1) year 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 six (6) months 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

CE 2460

EC REP

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