OMNISTIM® Sport Elite

Electrotherapy System

User Manual

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OMNISTIM® Sport Elite
Electrotherapy System

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

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

SYMBOLS ON THE PRODUCT

Symbol	Used for	Symbol	Used for
	Serial number		Type BF medical device per: IEC 60601
	Date of manufacture		Manufacturer
	Caution, consult accompanying documents		Caution, electrical precautions
	Remote Control connection		CE mark of confidence compliant to MDD (93/42/EEC)
	Connection Electrode Cable	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

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ELECTROTHERAPY INDICATIONS & CONTRAINDICATIONS

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

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

Indications

The OmniVersa is indicated for:

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

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

Contraindications

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

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

- Never connect lead wires to the power line or 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 contraindicated for use with OmniVersa, Omnistim Systems.
- When cleaning the device, never immerse them or wash them with water. See the infection control section in this manual for cleaning instructions. Devices should not be submerged in water or other liquids.
- Failure to follow the manufacturer's prescribed maintenance for this device may lead to device failure and transient or unreliable performance. State and federal survey and JCAHO require all equipment to be maintained and calibrated according to the manufacturer recommended schedules.
- A potential electric shock hazard exists once the device outer casing has been in part, or fully, removed. Only qualified service personnel should perform Service and repairs. Warranty will be voided if the outer casing has been removed or tampered with.
- Use caution when the patient has a tendency to bleed internally, such as following an injury or fracture. Do not apply over areas of hemorrhage or active bleeding.
- Inspect and cleanse the skin prior to application. Following treatment check the skin for evidence of irritation or burns, and if present, treat as appropriate. If the patient has, or complains of, skin irritation following treatment; shorten the treatment time on the next treatment session, or use an alternative type of therapy or electrode placement.
- Gradually increase the output intensity/power to required dose or patient tolerance while monitoring the device display.
- Caution should be taken with patient exhibiting psychological or physical hypersensitivity to the therapeutic treatment. Several attempts should be made to place them at ease so that their confidence and cooperation can be gained during the treatment.
- The treatment area should be checked from time to time, and if there is evidence of, or if the patient complains of, pain during treatment, adjust the output downward until it is tolerated by the patient. If the patient continues to complain of pain, discontinue the treatment and shorten the treatment time on the next treatment session, or use an alternative type of therapy or electrode placement.
- Do not apply treatment directly over/under hot or cold packs. Caution is recommended when treatment follows the application of hot or cold therapy, which may alter the patient's sensation. Application of thermal agents over areas of impaired circulation should be performed with caution as the circulation may be insufficient to heat or cool the tissue, altering the patient's perception of warmth and pain, and burns or tissue necrosis may result from subsequent treatment.
- Caution is recommended when treatment follows the application of medicated patches, salves, or creams which may alter the patient's sensation. If there is a medical necessity to perform such treatments, these patients

should be monitored diligently during application. The effect of electrical stimulation may be altered by the presence of these materials on the patient's skin.

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

THE OMNISTIM® Sport Elite

Delivery of the OMNISTIM® Sport Elite

Upon receipt of your **OMNISTIM**® Sport Elite, 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.

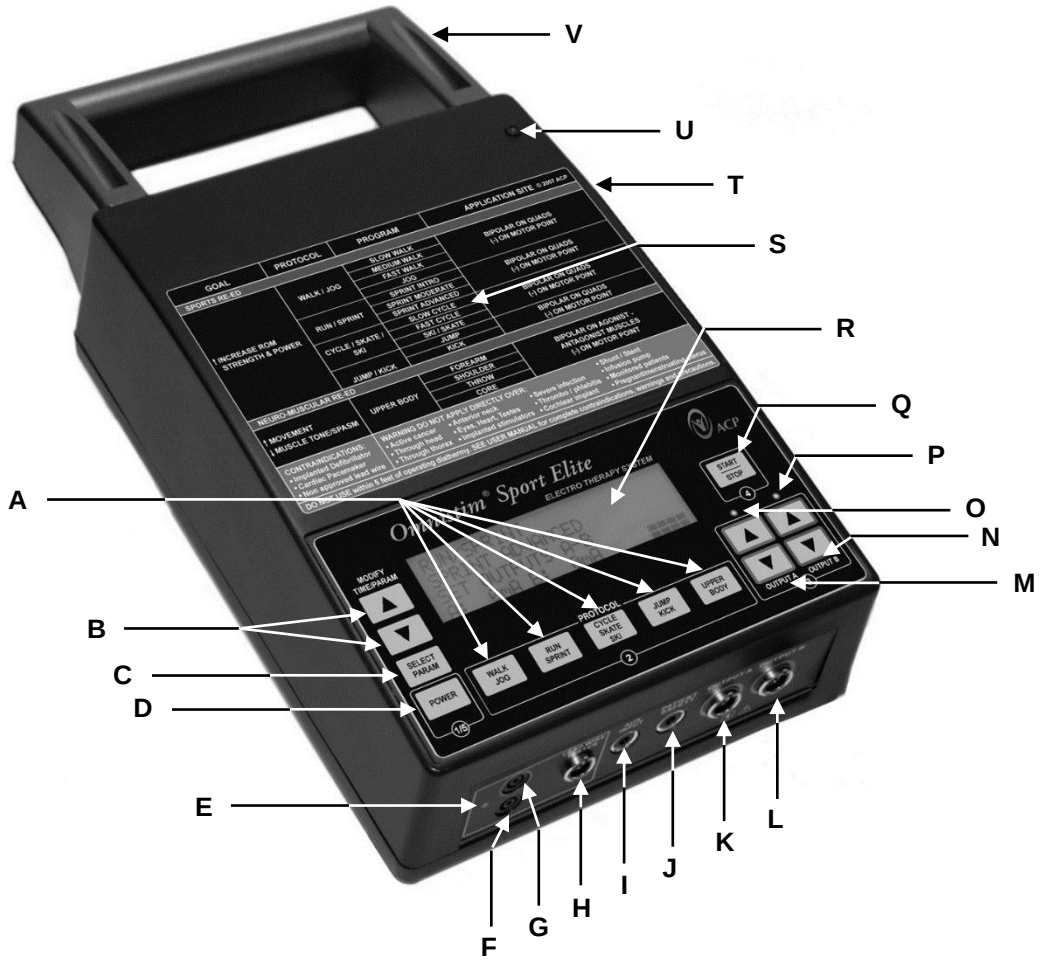
Unpack and check all accessories. A list of enclosed accessories is provided with each unit to assist you in identification of the type and number of accessories.

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

Introduction

The **OMNISTIM**® Sport Elite 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 Upper and Lower Extremity Triphasic (ballistic), or Upper Extremity Biphasic (reciprocal) patterns. This approach to neuro Re-Ed provides a comfortable, precisely timed sensory input, which duplicates the firing activity of sensory nerves and muscles during voluntary activity.

Controls and Functions



A. Press button corresponding to the desired functional PROTOCOL group. Choose between WALK/JOG, RUN/SPRINT, CYCLE/SKATE/SKI, JUMP/KICK, or UPPER BODY.

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

C. SELECT PARAMETER button provides adjustment of stimulation parameters, audio on/off and button speed. Press to enter SET mode.

D. Main power switch. Press for power ON, press again for power OFF. The display default display is: 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 black lead wire into black 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 red lead wire into red 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 dark yellow/orange when output is being applied thru channel A.

P. LED which lights-up dark yellow/orange when output is being applied thru channel B.

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:

S. PROTOCOL LABEL to assist therapist in quick operation and treatment selection.

T. Power Supply input jack.

U. Battery charging operation indicator LED. This light is on when the batteries are being charged. The LED is on/off intermittently when the batteries are fully charged. When the LED is turning on/off at a very fast rate, this indicates that there may be problems with the batteries (i.e. batteries not in compartment, or depleted batteries not being able to be recharged).

V. Solid carrying handle for easy transport of the unit.

Factory Settings

The **OMNISTIM**® Sport Elite comes with the following factory settings:

Button Speed, A & B Output	91
Audio	ON

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

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 provides various warning or notification signals.

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**® Sport Elite battery charger/power supply:

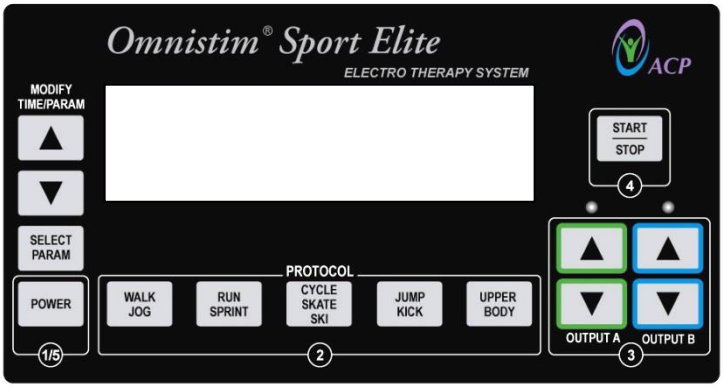
- Verify that rechargeable batteries are installed within the **OMNISTIM**® Sport Elite battery compartment.
- Check to see that the battery type selector switch located inside the battery compartment has been switched to the rechargeable position.

If you plug in the power supply, after two seconds, the charge LED on the **OMNISTIM**® Sport Elite comes on showing that the rechargeable batteries are now being charged. After the batteries are fully charged, the LED blinks at regular intervals. If the LED blinks at a very fast rate, this is an indication that there are some possible problems with the battery charging, such as no batteries in the battery compartment or incorrect/bad batteries.

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 - 40 Hours

Operational Sequence



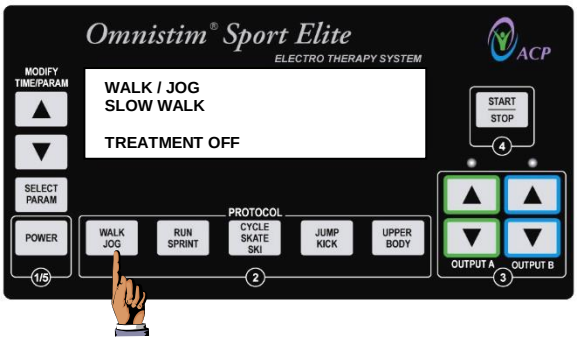
1. Press the POWER button (1/5) to turn on the power. The display panel will illuminate. There will be no stimulation current and the unit will be in the SELECT PROTOCOL / TREATMENT OFF mode.
2. At this time select the treatment protocol desired and the appropriate treatment program by using the PROTOCOL buttons (2) to select WALK/JOG, RUN/SPRINT, CYCLE/SKATE/SKI, JUMP/KICK, or UPPER BODY.

   Press the SELECT PARAM button to modify any settings. Press the MODIFY TIME/PARAM UP or DOWN buttons to adjust the desired treatment time, or other settings if you wish to change from the default settings. Set the timer for the desired treatment time. Pressing MODIFY TIME/PARAM UP or DOWN arrow buttons increases or decreases the duration from a minimum of 0 to a maximum of 99 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 20 - 60 seconds. Note that the treatment time is pre-set for each program but may be adjusted at will during treatment.
3. Prepare the treatment site
4. Attach the electrodes to the lead wires.
5. Now, position the electrodes on the patient.
6. Adjust the output by pressing the OUTPUT A and OUTPUT B UP or DOWN buttons (3), to deliver appropriate output based on patient sensation. A bar graph on the lower right of the display will show the relative output of the two channels with respect to channel output setting. The numeric display on the lower left will shows the output intensities into a 500-ohm load. The patient safety switch can be used by the patient to stop the treatment.

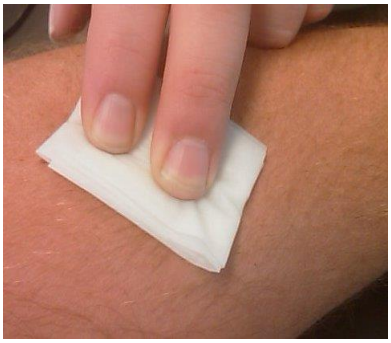
   Note:
   In some protocols using alternate or delayed modes, the system will allow set up of output A followed by set up of output B.
7. When the desired output the timer will start to begin timed treatment mode. At this time, the timer display on the right side of the screen will display the selected treatment time, and will continuously display time remaining, in minutes, during treatment. During operation some of the parameters may be altered within the program by pressing the SELECT PARAM button. See set mode operation and adjustable parameters for each modality. Certain parameters can only be changed before treatment is started and output initiated.
8. Once the treatment is completed, remove the electrodes from the patient and disconnect the lead wires from the electrodes. Turn the unit off by pressing the POWER button (1/5).

Operational Sequence

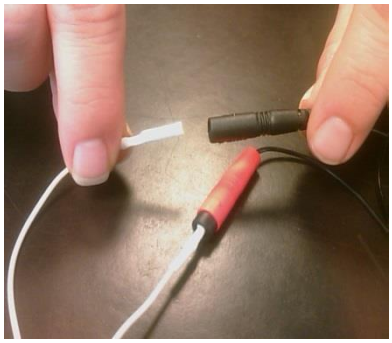
1). Press the POWER button (1/5) to turn on the power. The display panel will illuminate. There will be no stimulation current and the unit will be in the SELECT PROTOCOL / TREATMENT OFF mode.



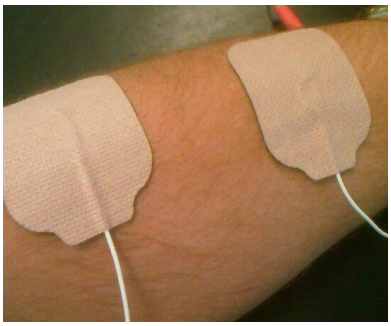
2). At this time select the treatment protocol desired and the appropriate treatment program by using the PROTOCOL buttons (2) to select WALK/JOG, RUN/SPRINT, CYCLE/SKATE/SKI, JUMP/KICK, or UPPER BODY.



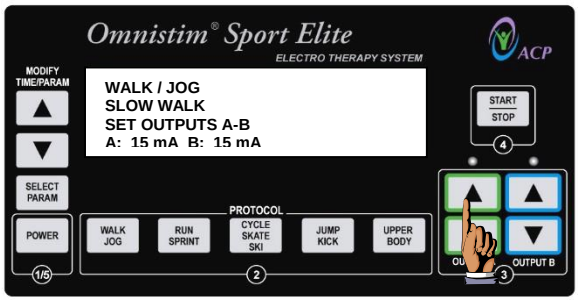
3). Prep the skin



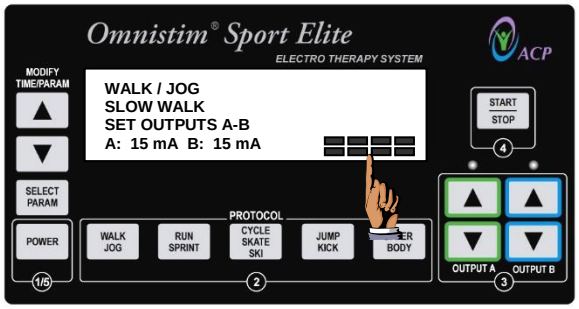
4). Attach electrodes



5). Now, position the electrodes on the patient and connect the electrode plug(s).



6). Adjust the output by pressing the OUTPUT A and OUTPUT B UP or DOWN buttons (3), to deliver appropriate output based on patient sensation.



7). When the desired output the timer will start to begin timed treatment mode. At this time, the timer display on the right side of the screen will display the selected treatment time, and will continuously display time remaining, in minutes, during treatment.

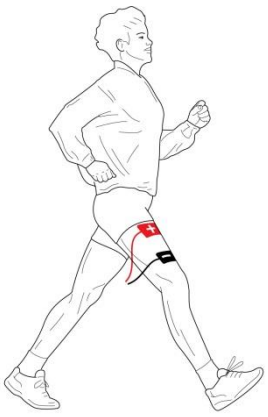
8). Once the treatment is completed, remove the electrodes from the patient and disconnect the lead wires from the electrodes. Turn the unit off by pressing the POWER button (1/5)

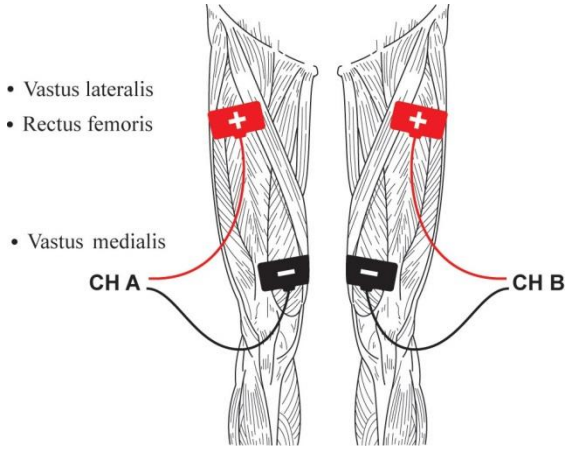
Electrode Application Techniques

WALK / JOG

This group of programs simulates walking at speeds of 42 to 88 strides per minute. The program is used to re-educate walking 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 position with weight shifting activities, then transition to walking, or jogging in place.

SLOW WALK - MEDIUM WALK - FAST WALK – JOG

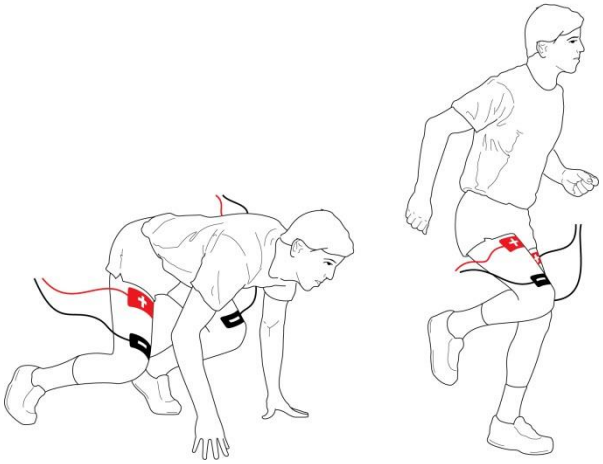




RUN / SPRINT

This program group simulates running and sprinting and is used in late rehab or sports specific programs. The output reciprocates between right to left side quads. Positioning: Start in middle rehab with sitting, low to moderate stimulation, place 0-5 lb weight on ankle cuff. In later rehab, go to standing shifting weight with the stimulation timing. The advanced program simulates three starts followed by a 100-meter sprint. A rest time of 30 seconds follows and the cycle is repeated. This is an aggressive program for late rehab and sports enhancement. Position: 30 degrees hip - knee flexion. Athlete should time shift weight or run in place in time with stimulation. Return to sport late rehab, enhancing 10-20 sequences repeats; full intensity simulating sprint practice 10 - 20 all out sprints, 3-5 times a week.

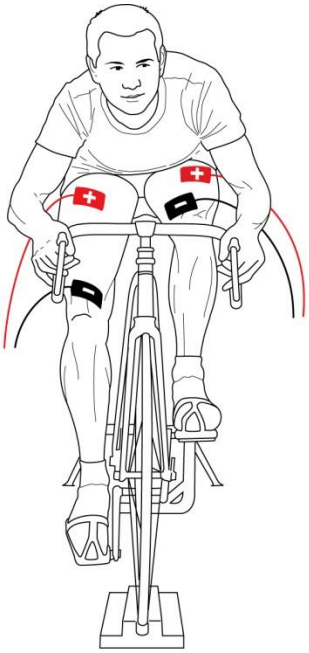
SPRINT INTRO - SPRINT MODERATE - SPRINT ADVANCED

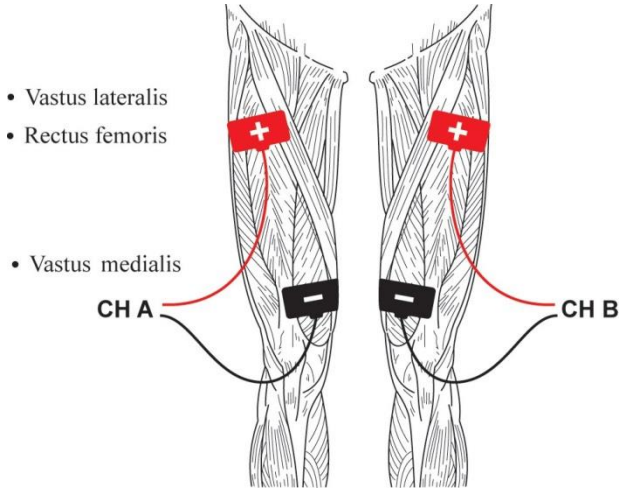


CYCLE

This program group simulates cycling, at 42 to 60 rpms, 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.

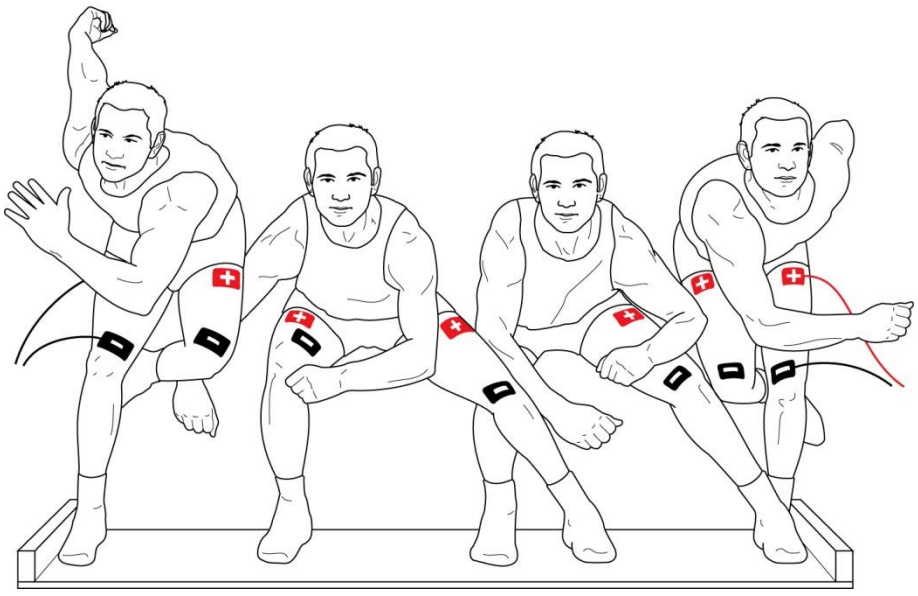
SLOW CYCLE – FAST CYCLE





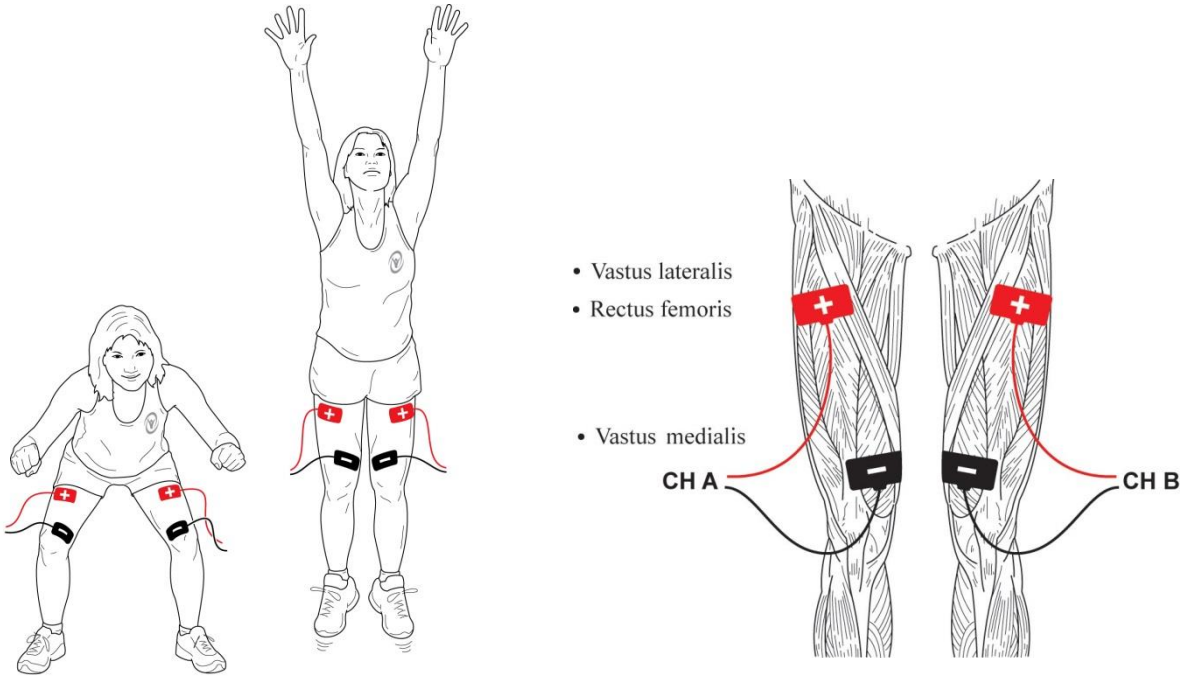
SKI – SKATE

This program simulates cycling and skating and is used for sports specific training. Positioning: Sitting with hips and knees flexed, or standing with slightly bent with weight shift. Rehab: lie on training table with hips and knees flexed or legs over table with weights up to 5 lbs. Intensity moderate to strong.



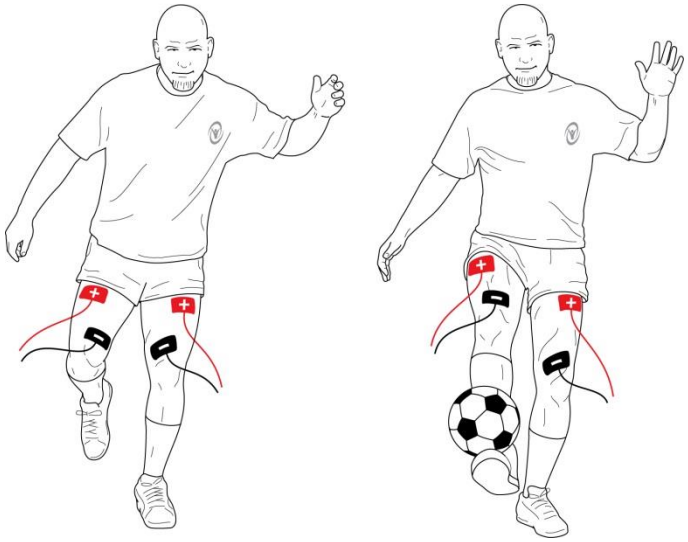
JUMP

This program simulates jumping and is an aggressive sports specific program. Positioning: Standing with both knees slightly flexed. Weight bearing: at sound get ready and spring up with stim.



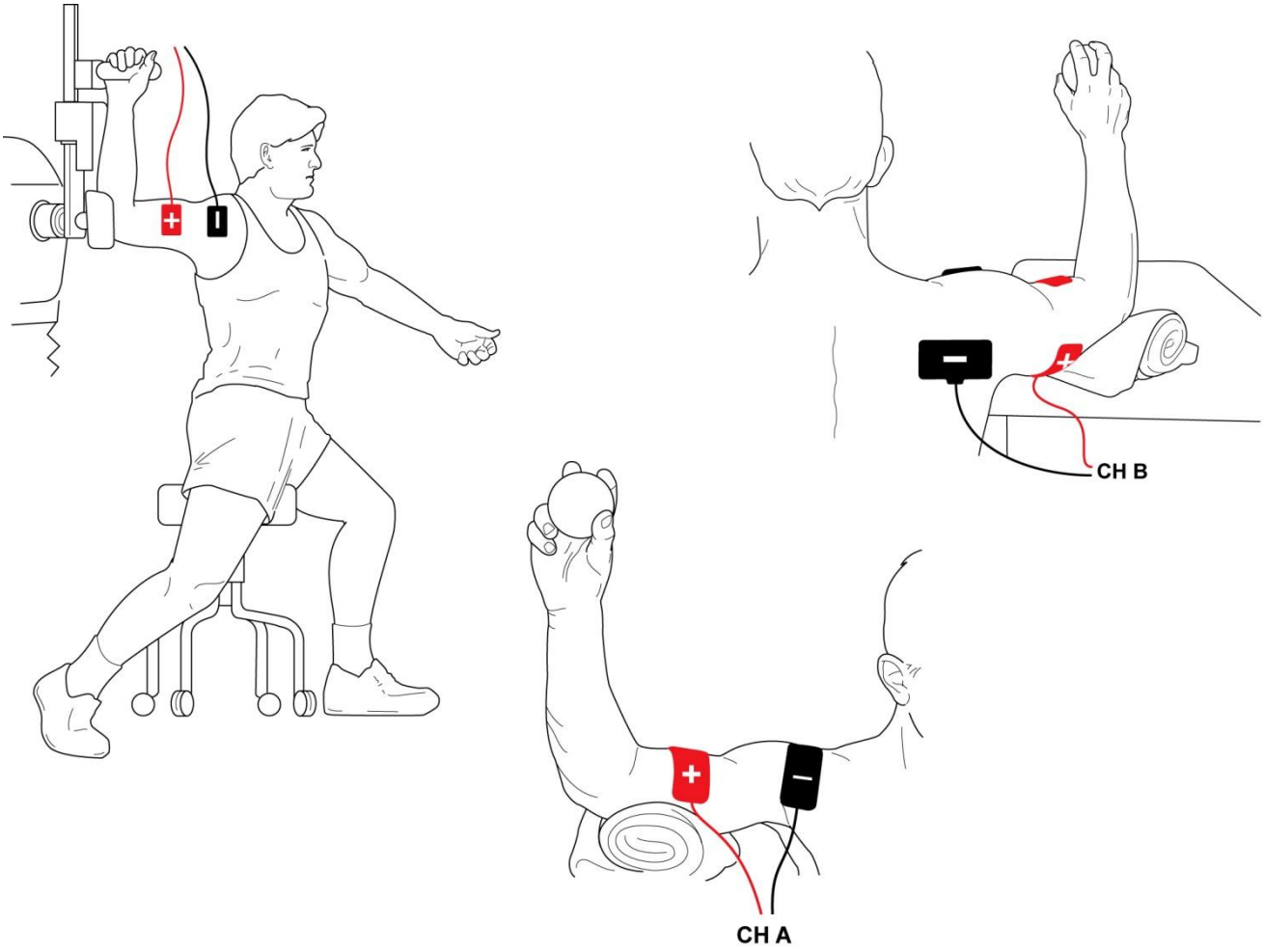
KICK (step – plant - kick ball)

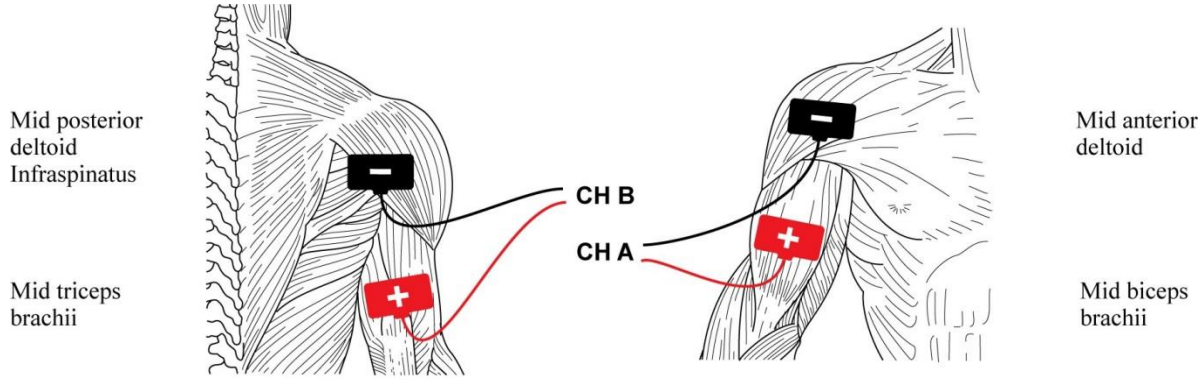
This program simulates ball kicking and is an aggressive late rehab or sports specific program. Positioning: Stand upright in kicking position, jump onto one foot at beep. (Start timing) Flex then extend kick leg. Go through timed kick cycle and simulate the movement pattern.



THROW

This program simulates throwing and is an aggressive late rehab or sports specific program. Positioning: The arm should be supported at 90 degrees palm forward in the throwing position.



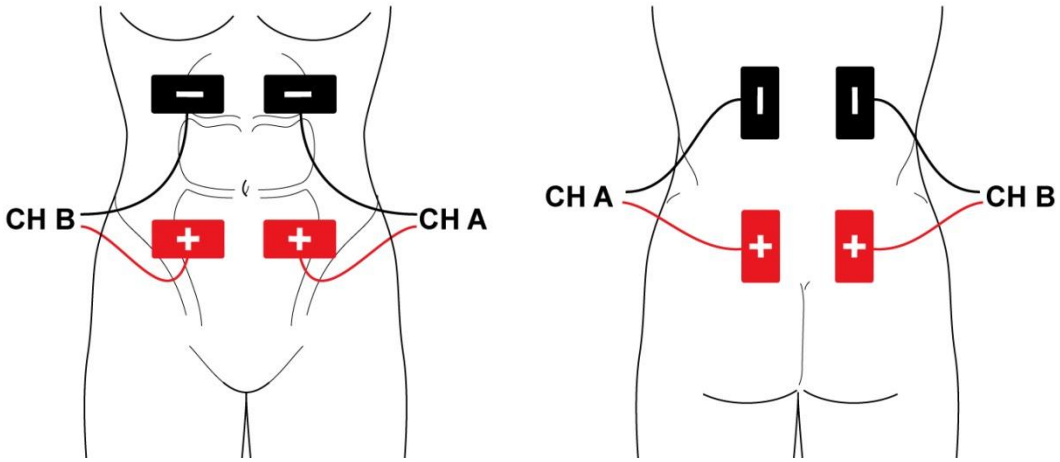


Ⓡ UPPER EXTREMITY

Note: Stimulation is used with exercise

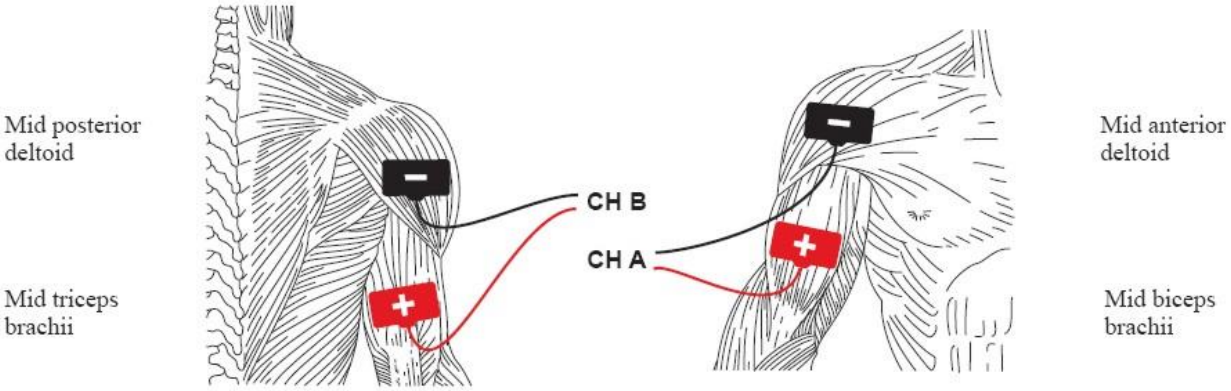
CORE STABILIZATION

This program is used to re-educate core stabilization through muscle pairs of the trunk and lumbar region.



SHOULDER TIMING

This program is used to re-educate upper extremity agonist - antagonist muscle pairs where fine motor control and positioning is required.



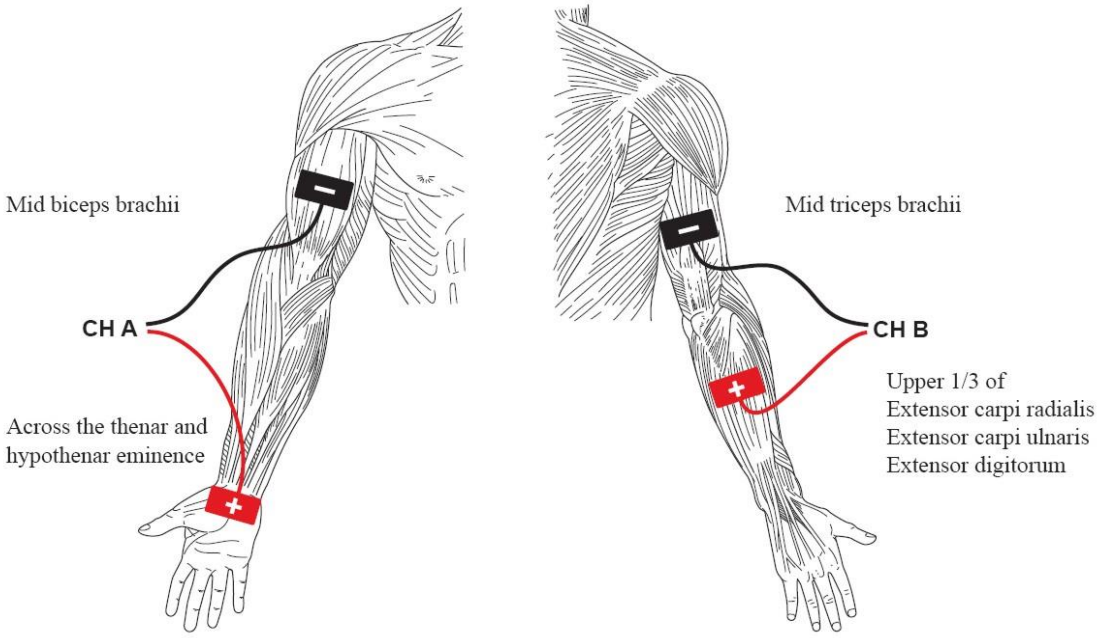
Ⓡ UPPER EXTREMITY

Note:

- Patient is passive during stimulation

FOREARM RECIPROCAL ACTIVITY

This program is used to re-educate upper extremity agonist - antagonist muscle pairs to enhance reciprocal and fast movement. Functional task simulation is reciprocal movement such as typing, boxing, piano playing, swimming, upper extremity positioning speed walking, rowing, etc.



Note:

- Patient is passive or active during stimulation

Treatment Preparation

Treatment Site / 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 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.

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.

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.*

CLEANING

Cleaning / Disinfecting of the OMNISTIM® Sport Elite

It is recommended to clean the device and lead wire attachments after each use to control the spread of infection.

- Clean the Omnistim® Sport Elite after each use with ACP germicidal wipes. Wipe common contact surfaces, such as control panel, lead wires, and probe tips with germicidal disposable wipes and allow to air dry. This technique will inactivate most bacteria and viruses. This will also facilitate removal of contaminants from the equipment and accessories.

- Disposable/reusable electrodes are for individual patient use only and should not be shared with others.

- All disposable electrodes should be discarded after each use. Do not attempt to clean and reuse disposable electrodes.

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 physician for assistance.

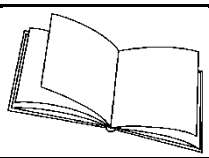
PROBLEM	CAUSE	REMEDY
Unit will not power on	• No batteries • Low batteries	• Install batteries • Replace batteries • Verify type of batteries • Inspect battery contacts
Display shows low battery symbol	• Battery voltage is too low	• Replace batteries for future use
Patient feels surging or spiking sensation	• The electrodes may be too dry or dried out. • Lead wire(s) breakage	• Replace electrodes • Remove electrode(s) and replace if necessary
Patient cannot detect output	• Failure of lead wire(s), electrode(s) • The electrodes may be too dry or dried out. • Device failure	• Replace electrodes • Remove electrode(s) and replace if necessary • Contact your physician

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 10 hours at full output and over 40 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:	Biphasic square wave PENS Waveform. Output Amplitude: 140 Ma Peak current into 500Ω load.
Channel Isolation:	Independent transformer isolation.
Line Leakage:	<50 µA when operated with the charger system.
PENS (PATTERNED ELECTRICAL NEUROMUSCULAR STIMULATION) MODE:	
Waveform:	Asymmetric Biphasic
Phase Duration:	Variable from 40 µs to 100 µs
Pulse Rate:	Set at 50 Hz
TIMER FUNCTIONS:	
Treatment Timer:	Adjustable for 0-99 minutes in one minute increments. Turns output to zero and sounds 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.
MISC.	
Activation:	Patient safety hand control shuts down output. Output modality may not be changed during operation.
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
Patents:	Protected under U.S. Patent No. 5,562,718, Additional patents pending.

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

STANDARD AND OPTIONAL ACCESSORIES

ITEM	ITEM NO.	DESCRIPTION
	**100FX2E**	**OMNISTIM® Sport Elite** **MULTIMODALITY** **MICROPROCESSER CONTROLLED** **TREATMENT SYSTEM** Offers 2 channels of programmable stimulation with PENS. Shipping Weight: 5 lbs (2.3 kg)
	**WPC-259B** **WPC-259B**	Lead Wire – Blue or Green coded plug-in, 7' (214cm) .08 tip pin stereo plug
	*** WPC-238**	Lead Wire (single) - 7' (214cm) .080 tip pin stereo plug
	*** WPC-244**	Bifurcated Lead Wire
	**WHN01002**	Patient Safety Switch
	**LTF02702-G**	Charger / Line Power Supply 110v
	**WHN14401-G**	AC Line Cord – **OMNISTIM®**
	**OTH-04-02**	**OMNISTIM®** Output Tester
	***KCS00401**	**OMNISTIM®** Leatherette Soft Carry Case
	**KR-4400D**	Rechargeable Batteries (D size) 4400 mAh Heavy Duty Medical Grade Ni-Cd (Nickel Cadmium)
	**290FX2E**	**OMNISTIM®** Sport Elite Operator Manual

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

Electrodes

ITEM	ITEM NO.	DESCRIPTION
	**ERC2X2**	2x2 Silver Backed Reusable Electrode (4 per package)
	ERC2X4	2x4 Silver Backed Reusable Electrode (4 per package)
	ERC3X5	3x5 Silver Backed Reusable Electrode (2 per package)
	EDC4X4	4x4 Disposable Non-Gelled Carbon Electrode (for Wound Care) (25 per package)

Infection Control Supplies

ITEM	ITEM NO.	DESCRIPTION
	**1803C**	Protective Film for Surfaces, Infection Control, 4x6 Perforated sheets – 1,200 ft/Roll
	1866C	Protective Film for Surfaces, Infection Control, 6x9 Perforated Sheets– 800 ft/Roll
	1867C	Protective Film for Surfaces, Infection Control, 12x14 Perforated Sheets– 514 ft/Roll
	**1912B**	Barrier Tubing 3", 1,200'/roll
	**GDWP**	Germicidal Disposable Wipe - Single Use Packet (50 pk/bx)
	GDWT	Germicidal Disposable Wipe Tub (160/tub)

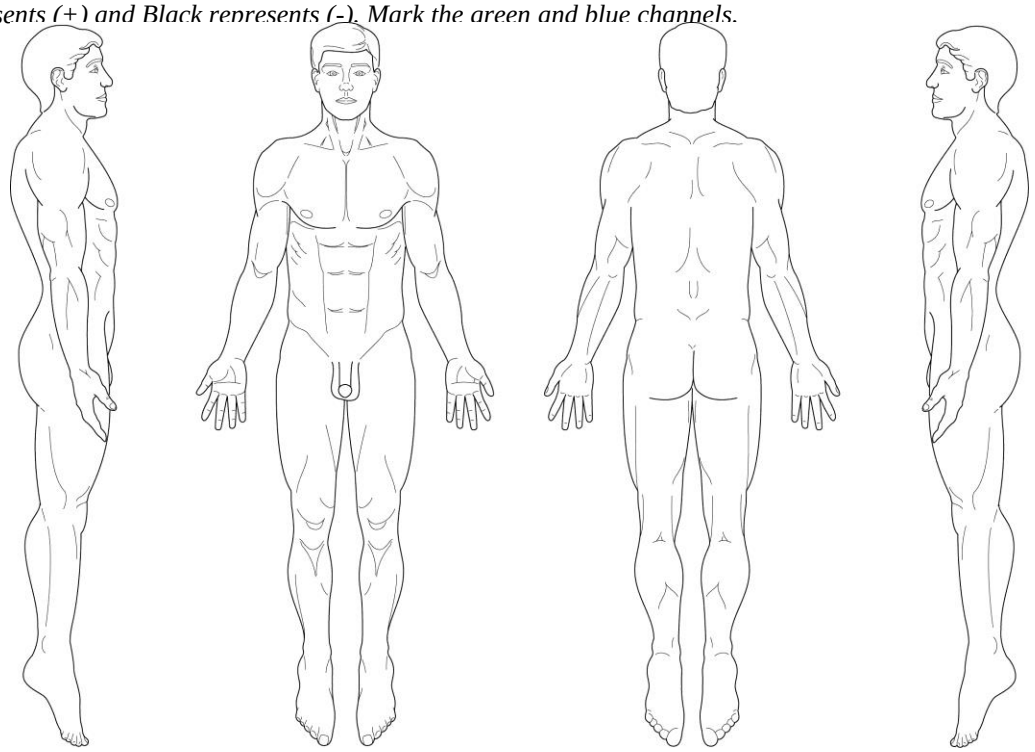
TREATMENT CHART

Mark the prescribed program, button, and intensity prescribed. Place date and time in the column provided, and comment on the intensity level.

DAY TIME	PROGRAM (Protocol Name)	BUTTON (A / B)	INTENSITY (1 to 140)	COMMENTS (Sensation)

ELECTRODE PLACEMENT GUIDE

Indicate the electrode placement for each treatment prescribed. Mark each electrode location with either + and – sign to indicate the polarity of the electrodes, or use red and black marker to identify the color code for each wire. Red represents (+) and Black represents (-). Mark the green and blue channels.



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. 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