



# OMNISTIM®FX<sup>2</sup> CYCLE / WALK

## Portable Muscle Stimulator

### Professional User Manual

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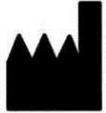





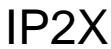






## OMNISTIM® FX<sup>2</sup> CYCLE / WALK

### *Portable Muscle Stimulator*

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		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 Omnistim Cycle/Walk 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

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

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

### 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 Cycle/Walk 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® FX<sup>2</sup> CYCLE / WALK

### Delivery of the OMNISTIM® FX<sup>2</sup> CYCLE / WALK



Upon receipt of your **OMNISTIM® FX<sup>2</sup> CYCLE / WALK**, 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.

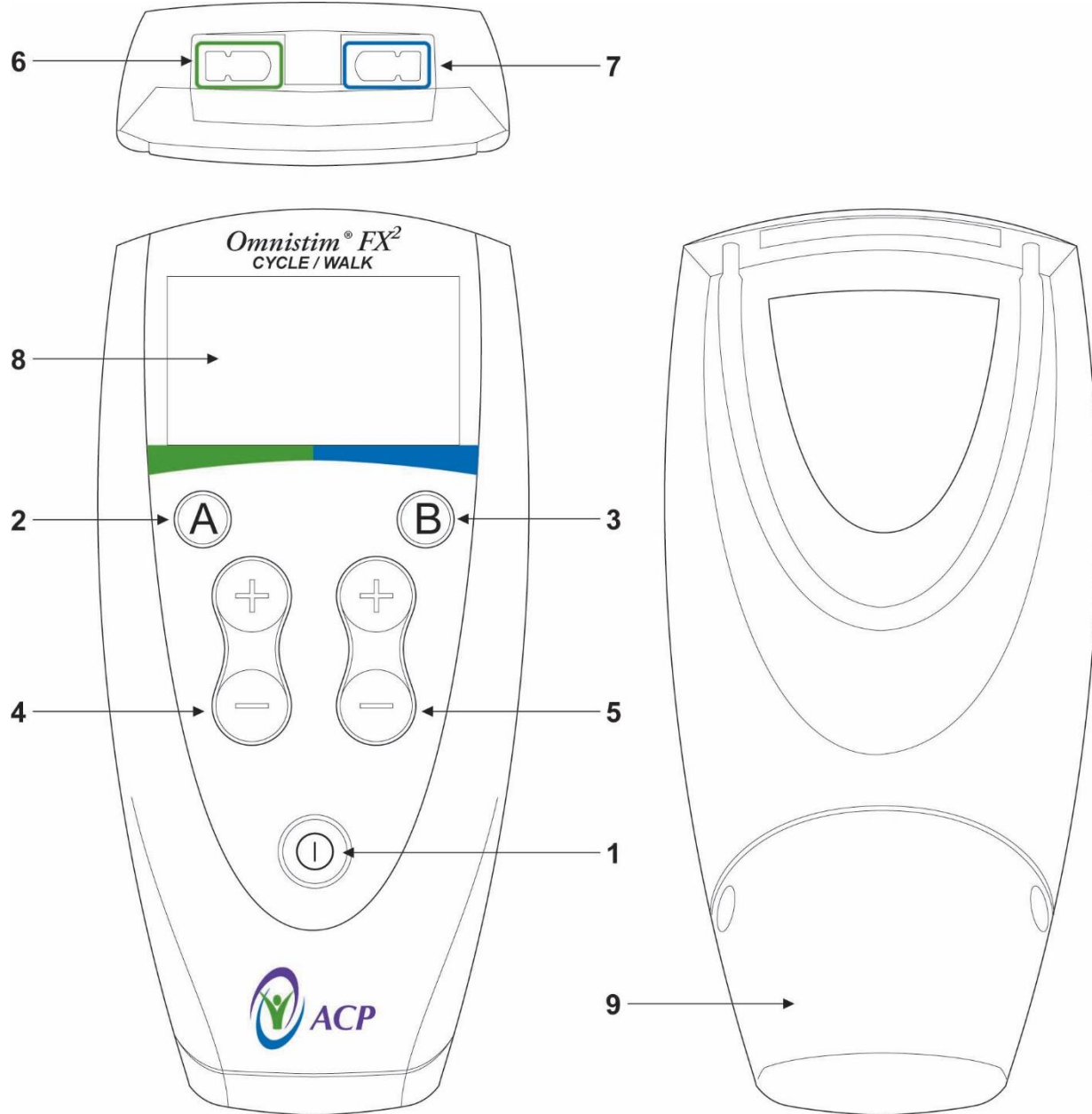
#### **Note:**

The purpose of this manual is to acquaint you with the Omnistim operating features and functionality. Please read the manual carefully before attempting to operate the Omnistim. 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® FX<sup>2</sup> CYCLE / WALK** 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 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



- (1) Main Power Switch – is used to turn the device on and/or off.
- (2) Program Button A – is used to select the first program prescribed.
- (3) Program Button B – is used to select the second program prescribed.
- (4) Output Adjustment Channel A – is used to adjust the intensity level of channel A.
- (5) Output Adjustment Channel B – is used to adjust the intensity level of channel B.
- (6) Channel A Connection – plug the green marked lead into the green channel which corresponds to the Program Button “A” being used.
- (7) Channel B Connection – plug the blue marked lead into the blue channel which corresponds to the Program Button “B” being used.
- (8) Display – displays program information and intensity readings. The A and B at the top of the display mark the channels.
- (9) Battery Compartment – this is where the 9-volt battery is located.

## Factory Settings

The OMNISTIM® FX<sup>2</sup> CYCLE / WALK comes with the factory settings defaulted to the CYCLE program. This is generally suitable for most patients using the Omnicycle® or Omnicycle® Elite. The following chart shows the available channel configurations.

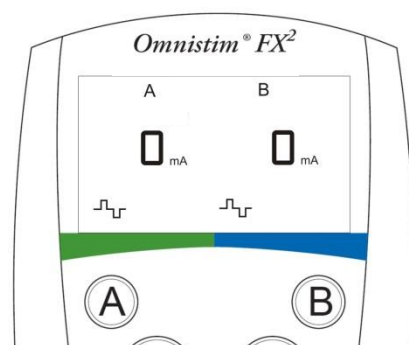
PROGRAM	PROTOCOL	USER ADJUSTABLE PARAMETERS		
		RPM	PHASE DURATION	TREATMENT TIME
CYCLE	Variable	Range = 1 to 75 rpm	Range = 50 -120 µs	Range = 1 to 30 min
WALK	Variable			

DEFAULT	PROGRAM	DEFAULT		
		RPM	PHASE DURATION	TREATMENT TIME
PROGRAM BUTTON A	CYCLE	45 rpm	100 µs	15 min
PROGRAM BUTTON B	WALK	60 rpm		

## Professional Programming Sequence

1. Press the on/off button (1) to power on the device.
2. At power on, the display will default to the factory loaded CYCLE program. This is a two channel program requiring output adjustment of both channel A (4) and channel B (5). It may be necessary to change the default parameters and/or settings to meet the patient's specific needs.
3. To change programmable settings for the CYCLE program, press and hold the Program Button A (2) for 5 seconds to enter the programming mode. In the programming mode, the program setting for RPM will flash. Use the (+) (-) buttons (4) to increment or decrement the adjustable setting. When set, press the Program Button A (2) once to proceed to the next programmable setting.
4. To set the device for the WALK program, press the Program Button B (3) once to select WALK then press and hold for 5 seconds to enter the programming mode. In the programming mode, the program setting for RPM will flash. Use the (+) (-) buttons (5) to increment or decrement the adjustable setting. When set, press the Program Button B (3) once to proceed to the next programmable setting.
5. Once complete, press the on/off button (1) to power down the device. The new settings will be saved as the new "default program" that starts the next time the device is powered on. **Note:** The settings will not be saved unless the unit is powered down following programming.



**NOTE:** The above settings cannot be accessed during operation and are only available following the start up screen. All changed settings will be saved for the next use. To reset to factory settings, press and hold both Program Buttons A + B for 5 seconds.

## Program Counters

1. The OMNISTIM® FX<sup>2</sup> CYCLE / WALK is equipment with imbedded counters to tell you how many times the patient has used the device.
2. Press the on/off button (1) and hold for 5 seconds to enter the counter readings.
3. The unit will default to the CYCLE program first, and will display a 3 digit number to represent the number of times that the program has been used.
4. Use the (+) (-) buttons (4) or (5) to toggle to the WALK counter. It will be displayed in the same 3 digit number as described above.
5. To clear the counters and reset to zero (0), press and hold both Program Buttons A + B for 5 seconds.

**NOTE:** When you reset the counters, this will also reset the unit to factory settings. You will need to reprogram any patient specific programming necessary for the patient's treatment plan.

## Operational Sequence

Follow the sequence below. The number in parenthesis references the location of the button from the control section on the previous page.

1. Install battery in compartment located on the back of the unit (9)
2. Connect lead wires to corresponding bar code under the display window (green lead wire in the left input (6), blue lead in the right input (7)).
3. Wash the skin with water, (use soap if dirty)
4. Connect black unit lead wires to white electrode wires.
5. Press the power on/off button (1) to power on the device.
6. At power on, the display (8) will default to the pre-set program selected for your condition.
  - a. If a second program has been ordered by your physician, press Program Button B (3) to access the additional program.
  - b. To return to the first program, press Program Button A (2)
7. Apply electrodes to treatment area paying attention to the lead wire polarity (red and black tip pins)
8. Adjust stimulation intensity to a gentle muscle action causing a minor contraction of the muscle. This will sequence back and forth between the channels. This may be increased over time as the patient adapts to the current to provide a stronger contraction. Note: It is not necessary to cause contraction intensities that create passive movement during cycling or walking. The stimulation is intended to provide sensory input and comfortable motor activation to re-educate muscle movement or treat disuse atrophy of the muscles.
  - a. Increase / decrease (4) Output A. Press (+) button to increase intensity in channel A. Press the (-) button to decrease intensity in channel A.
  - b. Increase / decrease (5) Output B. Press (+) button to increase intensity in channel B. Press the (-) button to decrease intensity in channel B.

**NOTE:** If electrodes are worn or not connected to the device, the highest output you will be able to obtain is 5mA. If this occurs, check the electrodes and wires. You may need to re-wet or replace the electrodes if they are too dry.

Shortly after reaching the desired intensity setting, the unit will lock the setting preventing an accidental increase in the intensity. A lock icon will be indicated on the display. To unlock, you must first press the (-) button to decrease the intensity, and then press the (+) button to increase the intensity to the new desired level.



9. The treatment timer will automatically end the treatment in the time prescribed. Treatment ends when bars show up on the display (8)
10. Turn the unit off by pressing the Power Button (1)
11. Remove the stimulation electrodes. Repack the re-useable electrodes into their foil pouch electrodes and follow the directions on the label for electrode care and storage.

**NOTE:** If you are using single use electrodes, discard after each use.
12. Clean unit with ACP Germicidal Wipes.
13. Store unit in carrying case
14. Record treatment activity and settings on form provided at the end of this manual.



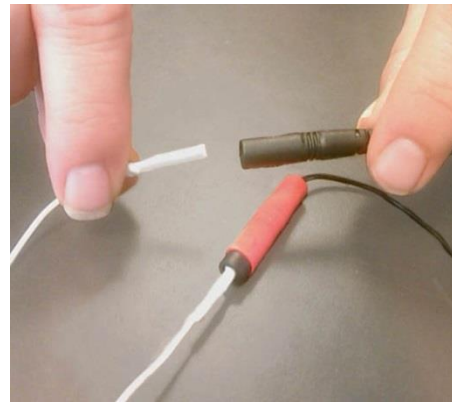
1). Install battery in compartment located on the back of the unit.



2). Connect lead wires to corresponding bar code under the display window (green lead wire in the left input, blue lead in the right input).



3). Wash the skin with water (use soap if dirty).



4). Connect black unit lead wires to white electrode wires.



5). Press the power on/off button to power on the device.



6). Select Program Button A or Program Button B



7). Apply electrodes to treatment area



8). Adjust stimulation intensity to the appropriate level for comfortable Sensory and motor activation



NOTE: To re-adjust stimulation intensity, remove the lock by pressing (-) Button and then (+) Button to preferred level.



9). Treatment is completed when bars appear in the Display Window.



10). Remove the stimulation electrodes. Repack the re-useable electrodes into their foil pouch electrodes and follow the directions on the label for electrode care and storage. (note if you are using single use electrodes, discard after each use.



11). Turn the unit off by pressing the Power Button.





12). Clean unit with ACP Germicidal Wipes.



13). Store the device in carry case.



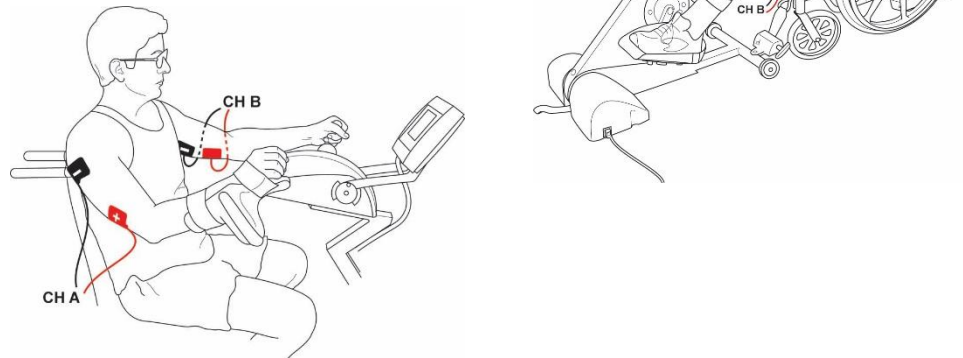
14). Record treatment activity and setting on form provided.

## Electrode Application Techniques

The following electrode placement diagrams are a general representation of treatment set-ups using the **OMNISTIM® FX<sup>2</sup> CYCLE / WALK** (bipolar techniques are illustrated). Electrode placement is dependent on the etiology of the condition.

### CYCLE PROGRAM

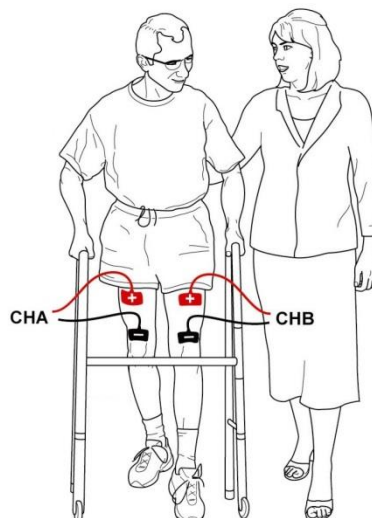
Apply electrodes on the Triceps or Quadriceps as shown, paying particular attention to the channel and lead wire placement. Ideally, the patient should be actively participating in alternating reciprocal movements of the extremities during **OMNICYCLE®** exercise programs. Start the **OMNICYCLE®** or **OMNICYCLE® ELITE** with a resistance free load. Start the **OMNISTIM® FX<sup>2</sup> CYCLE / WALK** with a low RPM setting (typically 20-30 RPM) and progress to higher resistive RPM cycling over the course of treatments. (i.e. You may choose to use 30 RPM for the first treatment, 45 RPM for the next treatment etc.) If sitting balance is poor, have the patient supported during cycling. If joint pathology is present, establish the correct joint range of motion by altering the seat to pedal (L.E.) or shoulder to pedal (U.E.) distance. Maximum assist to non-weight bearing patients can safely practice pre-gait reciprocal L.E. patterns while eliminating the demands of standing balance.



### WALK PROGRAM

**OMNISTIM® FX<sup>2</sup> CYCLE / WALK** programs can be used to improve weight shift and gait initiation, increase gait speed and distance, improve step symmetry, minimize shuffling or “freezing gait”. Apply electrodes on the Triceps or Quadriceps as shown, paying particular attention to the channel and lead wire placement. Ideally, the patient should be actively participating in standing weight shift or gait training (with or without assistive devices) or with **OMNIVR®** exercise programs; using the Walk program. Start with a low RPM parameter setting on the **OMNISTIM® FX<sup>2</sup> CYCLE / WALK** and progress to a higher RPM setting during the course of treatment.

**OMNISTIM® FX<sup>2</sup> CYCLE / WALK** Program can also be used in combination with **OmniVR™ Gait Training stroll exercise program** using the electrode placement described above.





## 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 Reusable Pre-gelled Surface Electrodes

Remove the electrodes from their foil packaging. Connect the electrodes to the device. 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 jack plug and tip pins. Insert the plug completely. Allow the lead wires to hang freely with no excessive strain on the connector.

**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.*

## 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® FX<sup>2</sup> CYCLE / WALK

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® FX<sup>2</sup> CYCLE / WALK** 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® FX<sup>2</sup> CYCLE / WALK** unit prior to the next treatment application.



## 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 service representative.

PROBLEM	CAUSE	REMEDY
Unit will not power on	<ul style="list-style-type: none"><li>• No batteries</li><li>• Low batteries</li></ul>	<ul style="list-style-type: none"><li>• Install batteries</li><li>• Replace batteries</li><li>• Verify type of batteries</li><li>• Inspect battery contacts</li></ul>
Display shows low battery symbol	<ul style="list-style-type: none"><li>• Battery voltage is too low</li></ul>	<ul style="list-style-type: none"><li>• Replace batteries for future use</li></ul>
Patient feels surging or spiking sensation	<ul style="list-style-type: none"><li>• You may not be using enough gel</li><li>• Lead wire(s) breakage</li></ul>	<ul style="list-style-type: none"><li>• Replace with correct and adequate conductive medium</li><li>• Remove electrode(s) and replace if necessary</li></ul>
Patient cannot detect output	<ul style="list-style-type: none"><li>• Failure of lead wire(s), electrode(s)</li><li>• You may not be using enough gel or the gel is dried out</li><li>• Device failure</li></ul>	<ul style="list-style-type: none"><li>• Replace with correct and adequate amount of gel</li><li>• Remove electrode(s) and replace if necessary</li><li>• Contact your physician</li></ul>

### Inspect Battery Contacts

1. Remove batteries if they are installed.
2. Inspect the battery contacts for any corrosion or discoloration. If corrosion or discoloration is found, clean the contact with emery cloth or fine grit sandpaper to remove the corrosion
3. Verify the battery door closes correctly. The door should lock into place when closed.

### 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 7:00am 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:	1.5" (38mm) D x 2.5" (65mm) W x 5.4" (137mm) H
Weight (Including batteries):	0.35lbs. (0.16kgs)
Operating Power:	9V alkaline
Battery Life:	New alkaline batteries operate the system for 40 hours at full output and over 100 hours at normal settings. Battery voltage emblem is displayed when battery low voltage is indicated.
Display System:	LCD Display
Push Buttons:	Polyester embossed overlay for tactile feel and infection control.
System Memory:	The system remembers all prior custom settings from treatment to treatment in non-volatile memory.
System Architecture:	CMOS integrated micro-controller with on board memory and instruction set.
PENS (PATTERNED ELECTRICAL NEUROMUSCULAR STIMULATION) PROGRAMS:	
Waveform:	Asymmetric Biphasic Pulsed Current 0-80mA average single pulse peak current into a 500 ohm load.
Phase Duration:	Set at 100 $\mu$ s; Variable from 50 $\mu$ s to 120 $\mu$ s
Pulse Rate:	Set at 50 Hz
RPM:	Channels alternate in a reciprocal fashion between channel A and B. The setting can be adjusted from 1-75 RPM
TIMER FUNCTIONS:	
Treatment Timer:	Set to 15 minutes by default; Adjustable for 1-30 minutes in one minute increments.



**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® FX<sup>2</sup> CYCLE / WALK STANDARD AND OPTIONAL ACCESSORIES

ITEM	ITEM NO.	DESCRIPTION
	<b>300400A</b>	<b>OMNISTIM® FX<sup>2</sup> CYCLE / WALK</b> Offers 2 channels of programmable stimulation with CYCLE and WALK programs.
	<b>28126</b>	<b>OMNISTIM® FX<sup>2</sup> CYCLE / WALK</b> Hard Carry Case
	<b>59762</b>	9V Alkaline battery
	<b>38155</b>	2x2 Reusable E-stim Electrodes (4ea/pkg)
	<b>61227</b>	2x4 Reusable E-stim Electrodes (4ea/pkg)
	<b>290POR4</b>	<b>OMNISTIM® FX<sup>2</sup> CYCLE / WALK</b> <i>Professional</i> User Manual

## Infection Control Supplies

ITEM	ITEM NO.	DESCRIPTION
	<b>55536</b>	Germicidal Disposable Wipe – Single-Use Packet (50 pkt/bx)
	<b>44425</b>	Germicidal Disposable Wipe - Tub (160/tub)
	<b>63574</b>	Barrier Tubing (3" x 1200'/roll)

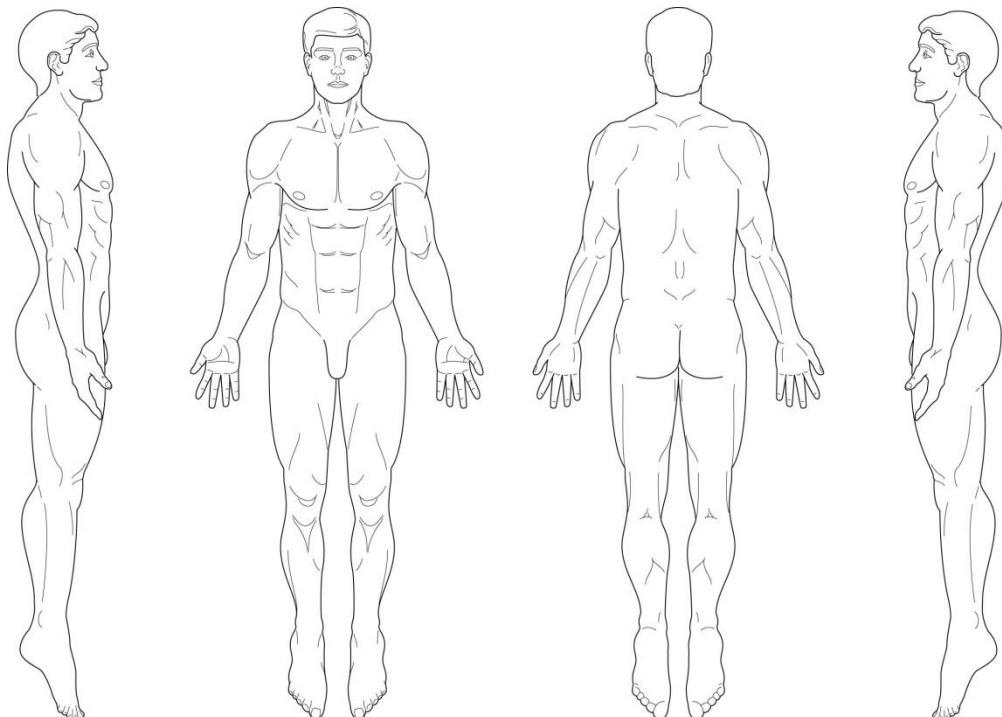
## TREATMENT CHART

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 (Cycle or Walk and RPM)	BUTTON ( A / B )	INTENSITY ( 1 to 100 )	COMMENTS ( TWITCH OR TINGLE )

## ELECTRODE PLACEMENT GUIDE

Provide the patient with the Patient Electrode Placement Guide and indicate the electrode placement for each treatment prescribed. Mark each electrode location with (+) or (−) 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 blue (B) and Green (A) channels.



## LIMITED PRODUCT WARRANTY

### 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 Service Representative prior to the product being returned under warranty coverage:

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 Products

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 89521**

Manufactured for ACP by:



Tic Medizintechnik  
Endelner Feld 9  
46286 Dorsten,  
GERMANY  
Tel: + 49-0-2369-2085-0  
Fax: + 49-0-2369-2085-720  
[www.tic-med.de](http://www.tic-med.de)



