

P R O D U C T   S P E C I F I C A T I O N S

**OMNISTIM<sup>®</sup> FX<sup>2</sup> PRO**

**Multi-Modality Electrical Stimulation System with EMG Patterned Electrical Neuromuscular Stimulation**

**PRODUCT HIGHLIGHTS**

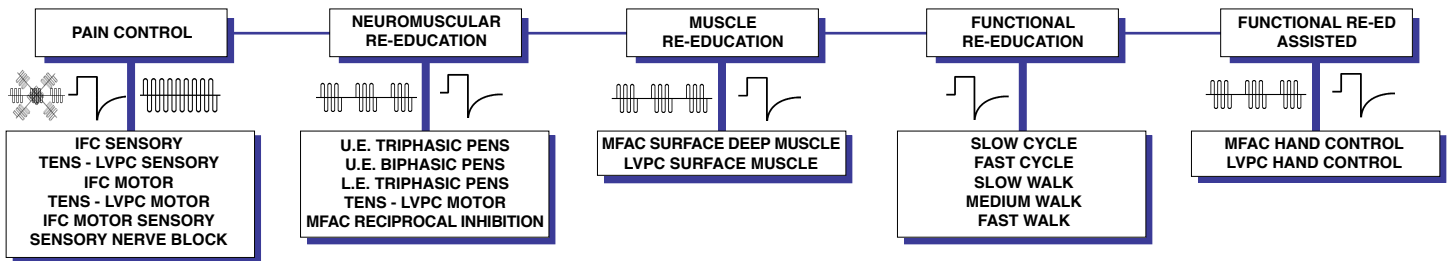
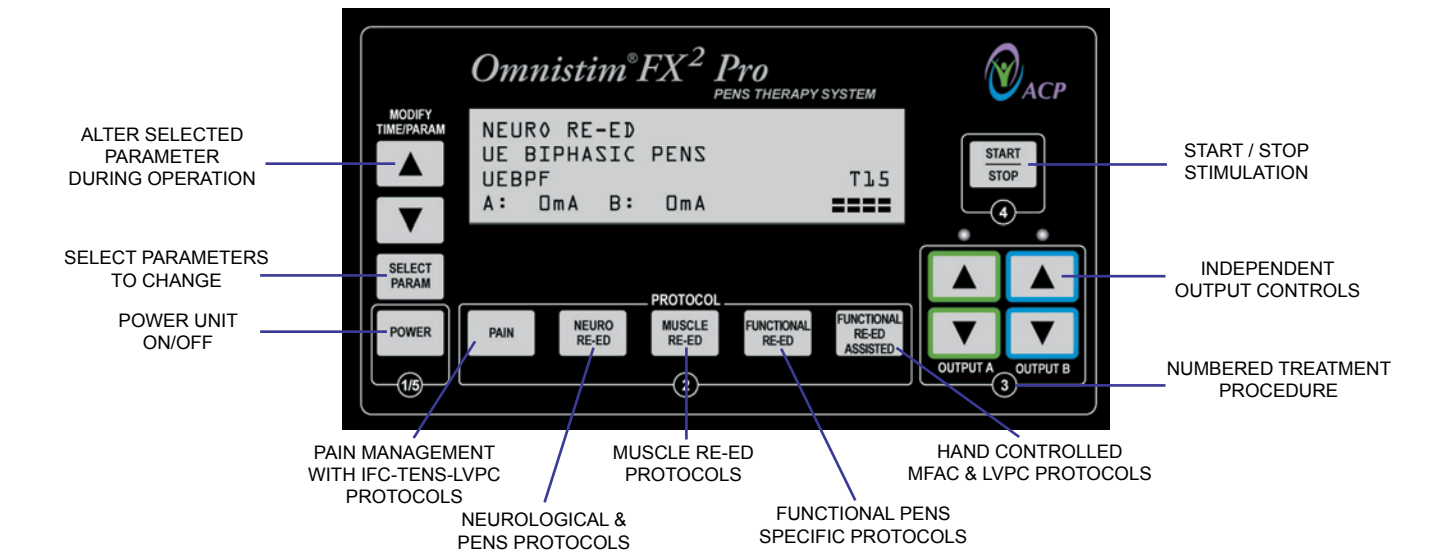
The Pro is the latest generation in ACP's widely recognized Omnistim<sup>®</sup> FX<sup>2</sup> line of electrical stimulation systems. With multi-modality capabilities, including the revolutionary Patterned Electrical Neuromuscular Stimulation (PENS) Waveform, this patented workstation offers unmatched capabilities serving a broad range of patient conditions. With new condition-specific protocols, the FX<sup>2</sup> is easier to use than ever, offering faster therapist set-up and greater treatment flexibility.

- Easy-to-use clinical protocol driven treatment menu for increased therapist comfort and efficiency
- Updated exterior design with integrated carrying handle for improved portability
- Lead wire tester for easy evaluation of lead wire integrity to avoid device returns
- Color coded output controls, lead wire connectors and lead wires eliminate confusion when setting up electrode placements and adjusting intensity
- Multi-modality system offers unparalleled treatment flexibility serving a variety of clinical applications:
  - Patterned Electrical Neuromuscular Stimulation (PENS) for neuromuscular re-education
  - Interferential Current (IFC) stimulation with full-field and varied frequency protocols for nerve block and pain management applications
  - Medium Frequency Alternating Current (MFAC or Russian Stimulation) for treatment of disuse atrophy, spasm reduction and muscle strengthening
  - Low Voltage Pulsed Current (LVPC or asymmetric biphasic) electrical stimulation for muscle re-education associated with innervated muscle
- Patented "PENS" technology (Patterned Electrical Neuromuscular Stimulation) extends traditional electrical stimulation capabilities by simulating normal muscle firing patterns for neuromuscular re-education:
  - Triphasic PENS protocols support early restoration of agonist / antagonist muscular timing patterns to enhance recovery of function following trauma or injury (neuromuscular re-education)
  - Biphasic PENS protocols enhance recovery of normal ballistic movement patterns at normal speeds and help eliminate abnormal gait patterns and upper extremity spasticity during the recovery process (muscle re-education)
  - Functional rehabilitation protocols for cycling, walking, and ADLs
  - Hand control feature for therapist and patient assisted ADLs



*Revolutionizing  
Rehabilitation*

# CONTROLS AND FUNCTIONS



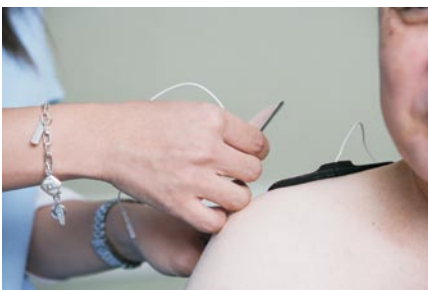
# CLINICAL APPLICATIONS

## Clinical Indications:

- Muscle Re-education
- Improve ROM
- Reduction of Disuse Atrophy
- Increase Local Blood Flow
- Reduce Spasm / Spasticity

## Patient Conditions:

- Incontinence
- Muscle Disuse Atrophy
- Spinal Cord Injury
- RSD / CRPS
- Post-Surgical Joint Rehabilitation
- Spasticity
- Torticollis
- Frozen Shoulder Syndrome / Adhesive Capsulitis
- Neuromuscular Diseases
- Lower Back Spasm
- Patello-Femoral Dysfunction
- Post-Stroke Rehabilitation



# TECHNOLOGY HIGHLIGHTS AND FEATURES

## Patterned Electrical Neuromuscular Stimulation (PENS)

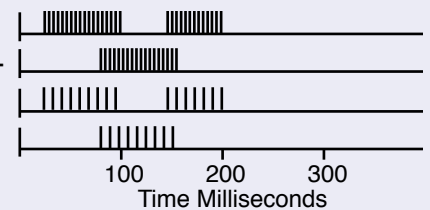
The Omnistim® FX<sup>2</sup> Pro's patented "Patterned Electrical Neuromuscular Stimulation" or "PENS" closely replicates the live-firing pattern of muscles as identified in EMG studies. This form of stimulation is applicable for nerve and muscle re-education following injury, surgery or muscle disuse atrophy. The system uses bi-phasic asymmetrical pulsed currents to induce contractions in the agonist

and antagonist muscles. By providing high intensity, precisely timed sensory input to these targeted muscles, the system is able to closely replicate the normal firing activity of sensory neurons and muscle stretch receptors during voluntary activity.

### UPPER AND LOWER EXTREMITY FUNCTIONAL PROGRAMS:

- TRIPHASIC AND BIPHASIC AGONIST - ANTAGONIST EMG SIMULATED PATTERNS
- SIMULATED WALKING AND CYCLING BASED FUNCTIONAL PATTERNS

EMG AGONIST  
EMG ANTAGONIST  
OUTPUT A  
OUTPUT B



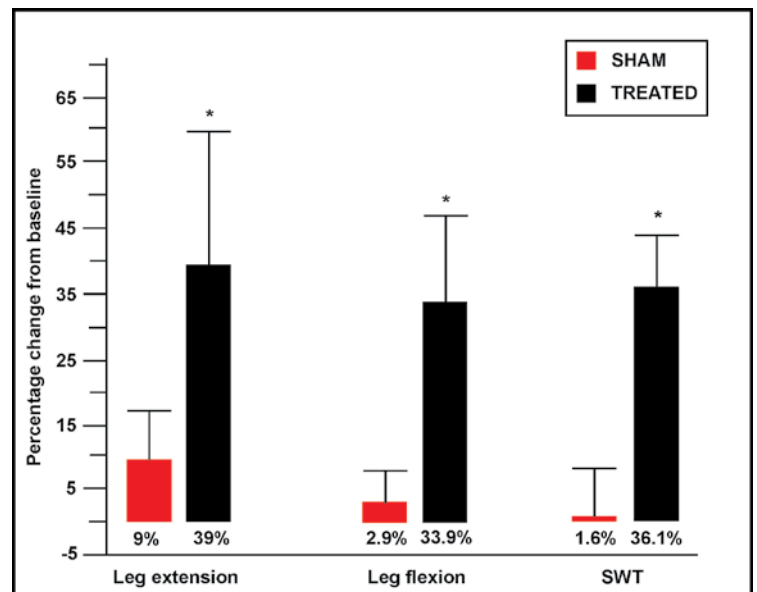
## Traditional Electrical Stimulation Currents

The Omnistim® FX<sup>2</sup> Pro's broad capabilities include Medium Frequency Alternating Currents (MFAC) and Low Voltage Pulsed Current (LVPC). Two separate generators produce medium frequency (2,000, 2,500, 4,000, 5,000 or 10,000 Hz) alternating current in continuous, modulated modes or asymmetric biphasic pulsed currents. In addition, two isolated output circuits with independent intensity controls are provided. The output of each circuit is easily determined in milliamps through the display screen. The digital timer allows the operator to select treatment times and monitor remaining treatment minutes.

- MFAC and LVPC modes offer fully adjustable ON/OFF times, as well as Ramps to support a wide variety of applications for muscle re-education and the reduction of muscle spasms associated with innervated muscle.
- Hand control feature for therapist and patient assisted ADLs

## Additional Technology and Features

- 20 pre-programmed upper and lower extremity treatment protocols provide easy-to-use muscle re-education applications for all patient types
- Evidence-based protocols are well researched and parameters are supported in refereed literature
- Easy to adjust parameters accommodate varied patient responses and individualized treatment needs
- Independent output controls with "Start," and "Stop" buttons provide easy adjustment of stimulation output
- Integrated numbering guide for quick set-up, simplicity-of-use and therapist efficiency
- Hand remote for expanded applications and greater therapist control over functional stimulation program
- Manufactured to meet or exceed CE, AAMI TES and FDA standards for maximum clinical efficacy and patient and operator safety
- Portable lightweight battery or AC line powered
- The Omnistim® FX<sup>2</sup> Pro's "Cycling" Protocol is easily integrated with ACP's Omnicycle™ Rehabilitation System for advanced neuromuscular re-education applications



Percentage change from baseline values in maximal leg extension and flexion and walking distance (SWT shuttle walking test) in treated and sham stimulated groups with Omnistim® FX<sup>2</sup>. \*Leg extension,  $p=0.046$ ; leg flexion,  $p=0.038$ ; SWT,  $p=0.007$ .

# PRODUCT SPECIFICATIONS



## OMNISTIM® FX<sup>2</sup> PRO TECHNICAL SPECIFICATIONS

MODEL NUMBER: 100FX2C

### Stimulation System:

**Output:** Constant voltage up to preset current; the system then operates in constant current mode.

### Output Amplitude:

**IFC Mode:** FD 0-70 mA peak, FF 0-99 mA peak, 500 ohm load.

**MFAC Mode:** 0-99 mA peak to peak, 500 ohm load.

**LVPC Mode:** 0-99 mA peak into 500 ohm load.

**HVPC Mode:** 0-225 volts peak into 500 ohm load.

**Channel Isolation:** Independent channels transformer isolated.

**Line Leakage:** Less than 50 microamps.

### IFC (Interferential Therapy) Mode:

**Type:** Frequency Difference or Full Field IFC.

**Waveform:** Bipolar Square Wave at a 2,000, 2,500, 4,000, 5,000 and 10,000 Hz carrier frequency.

**Frequency Difference Modulation Rate:** 0 to 250 Hz.

**Beat - Sweep:** Presettable from lowest to highest frequency difference modulation rate.

**Full Field Burst Rate:** 0 - 250 Hz.

**Rate Scan Time:** Adjustable 0-20 seconds.

**Vector:** 45° or 90° fast or slow scan (7 or 74 sec).

### MFAC (Medium Frequency Alternating Current) Mode:

**Waveform:** Bipolar Square Wave at a 2,000, 2,500, 4,000, 5,000 and 10,000 Hz carrier frequency.

**Burst Frequency:** Adjustable from 0 to 250 Hz.

**Burst Rate Scan:** Sweeps from 0 to ± 50% of preset pulse rate.

**Rate Scan Time:** Adjustable 0-20 seconds.

### LVPC (Low Voltage Pulsed Current) Mode:

**Waveform:** Asymmetric Biphasic Square Wave.

**Pulse Rate:** 0 to 250 Hz.

**Phase Duration:** 40 to 300 µsec.

**Modulation:** Phase ± 20% in 8 seconds.

### PENS (Patterned Electrical Neuromuscular Stimulation) Modes:

**Waveform:** Asymmetric Biphasic Square Wave.

**Pulse Rate:** 50 or 100 Hz.

**Phase Duration:** 40 to 100 µsec.

**PENS Patterns:** Biphasic and Triphasic Upper Extremity, Triphasic Lower Extremity, Cycle and hand controlled Walk EMG patterns.

### Hand Control

**Activation:** Turns on stimulation when pressed and off when released.

**Waveforms:** LVPC or MFAC (see above sections for adjustable parameters).

### Time Functions:

**On/Time:** Adjustable from 0-30 seconds.

**Off/Time:** Adjustable from 0-199 seconds.

**On/Off Ramps:** Adjustable from 0-9.9 seconds independently.

**Channel Timing:** Alternate, Simultaneous or Channel B delayed 0-9.9 seconds.

**Treatment Timer:** Adjustable for 1-99 minutes in one minute increments.

### Patient Safety Systems:

**Activation:** Output levels are reset to zero at the start and completion of treatment. A patient safety hand control turns off the stimulation and sounds the buzzer if pushed.

### General:

**Dimensions:** 6.5" (16.5cm) W x 12" (30cm) D x 3.5" (9cm) H.

**Weight:** (Includes batteries) 4.5 lbs (2.03 kgs).

**Operating Power:** 100-240 volts AC 47-63 Hz 50 watts or 4 x 1.5 volt "D" cell alkaline or NiCd rechargeable batteries. Charge LED indicator lights when the unit is running on line power or charging. The indicator light flashes on charge completion. Rechargeable batteries run the system for 5-10 hours dependent on protocol used with full charge.

**Push Buttons:** Membrane switch label. Output controls feature LEDs above switches which light when stimulation is active on that channel.

**Lead Wire Tester:** Indicates a make or break in the lead wire by Green or Red LED, respectively.

**Lead Wire Color Coding:** Green and Blue coding for lead wires, output controls and channel identification.

**Audio Indicator:** Buzzes to signal treatment completion and start of On/Off timing cycles. May be turned on or off for timing cycle alert.

Subassembly manufactured under exclusive license for ACP in Taiwan, R.O.C. ACP reserves the right to change technical specifications and product availability without notice. Federal Law restricts this device to sale by or on the order of a physician or other health care practitioner.

Patented in U.S.A.: No. 5,562,718

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