

Instruction Manual



Duet™ PMD-2000 Interferential Stimulator

Duet™ PMD-2000 Specifications

Therapy Output Channels:	2 Therapy Channels
Therapy Output Modes:	True Interferential and Conventional Muscle Stimulation
Waveform:	Symmetrical biphasic square wave with zero net DC component
Carrier Frequency:	4000 Hz
Interference Frequency (IF):	4001 Hz to 4150 Hz adjustable in 1 Hz increments
Net Interferential Frequency:	1 to 150 Hz– verifiable
Output Voltage:	22.5 volts peak / 0-45 volts peak-to-peak, adjustable in 1/10th volt increments
Output Current:	0-45 milliamps, adjustable
Pulse Width:	125 micro seconds
Power System:	2 AA batteries OR EAZE™ AC adapter
Wall Adapter:	EAZE™ UL approved AC wall adapter (included)
Dimensions:	3.2" W x 4.8" L x 1.1" Th. (81mm W x 122mm L x 27mm Th.)
Weight:	6.0 oz. (167 Grams) including batteries
Preset Therapy Protocols:	15 (11 Interferential Stimulation, 4 Muscle Stimulation)

Precautionary Notices



This device is ONLY to be used by and for the benefit of the person to whom it was prescribed. Use by any other person is prohibited and could result in injury.



CAUTION: Federal Law (USA) restricts this device to sale by, or on the order of, a practitioner licensed by the State in which he or she practices to use or order the use of the device.



PLEASE READ THIS ENTIRE MANUAL BEFORE USE

Prior to use, please read and understand the contraindications, warnings, precautions and adverse effects relating to this device



KEEP THIS DEVICE OUT OF THE REACH OF CHILDREN



Follow your physician's or therapist's instructions as to which therapy presets to use, electrode placement and suggested amplitude levels

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Package Contents

Qty. (1) Duet™ PMD-2000 Stimulator

Qty. (1) EAZE™ Lead wire assembly

Qty. (1) Instruction manual

Qty. (1) EAZE™ AC wall adapter

Qty. (1) Carrying and storage case

Qty. (2) Duracell™ AA batteries

Warning – Only use the supplied UL approved AC wall adapter. Use of any other type or brand of wall adapter may cause damage to the device.

Note: The PMD-2000 is not supplied with electrodes.



Please read this Manual carefully to become familiar with the features, benefits, and operation of the Duet™ PMD-2000 Interferential Stimulator before using it.

Introduction to Electrotherapy

True Interferential Stimulation produces a different stimulation frequency through each of two channels – a “carrier” frequency that is fixed or doesn’t change and an “interference” frequency that does change depending on the therapy protocol. When these two stimulation frequencies cross and “interfere” with each other within the body, the two frequencies subtract resulting in a third frequency, which is the therapeutic frequency “seen” by the targeted injury site. This phenomenon of subtracting two frequencies to create a third frequency is called “beating”.

Duet™ uses a carrier frequency of 4000 Hz (hertz or cycles per second). At this frequency the skin impedance, or resistance to the stimulation, is at a minimum, so that the stimulation is allowed to penetrate deeply without significant discomfort for the patient. Interferential Stimulation is used to treat chronic and traumatic pain.

Depending on the Pre-Set Therapy Protocol selected, the interference frequency utilized by Duet may vary between 4001 to 4150 Hz. The sophisticated, advanced digital electronic engineering utilized in the construction of Duet produces a very precise and repeatable interference frequency. This results in accurate therapeutic frequencies at the targeted injury site.

Neuromuscular Stimulation uses low frequencies to stimulate the contraction of muscles. This low frequency electrical current is similar to the electrical impulses produced by the brain to perform a contraction of muscles. Neuromuscular Stimulation uses an electrical pulse generator (Duet™), lead wires and electrodes to bring the electrical current to an individual muscle or muscle group. A contraction and relaxation rhythm is created in the muscle which helps to relieve muscle spasms, re-educates muscles, advances range of motion and resumption of motor control, helps prevent or retard muscle atrophy from disuse and increase local blood circulation. The treatment is safe and after the initial newness of the tingling sensation from the electrical current, can even become relaxing for the patient. The length of contraction and relaxation periods is a matter for discussion with your physician or therapist. The amplitude or intensity of the treatment is patient controllable.

Introduction to the Duet™ PMD-2000 Stimulator

The Duet™ PMD-2000 is a high quality, advanced technology medical device designed to be used as a combination Interferential and Muscle Stimulator. Duet is battery powered or power can be supplied with the included AC wall adapter. Current is generated and controlled by Duet’s circuitry using the latest Texas Instruments Microprocessor chips. These chips provide Duet with the greatest degree of control and intelligence on the market today. Duet was designed for the home health care market and many of Duet’s features are a result of countless discussions with patients, physicians and therapists as to what they want and need in a clinic and home use electrotherapy device. Duet has been approved for sale by the FDA and Phoenix Medical Devices, the manufacturer of Duet has received very high marks for the Quality of its products and the Quality controls in place at its manufacturing facility.

Indications

Interferential Stimulation: The PMD-2000 Stimulator may be used, with a physician's prescription for a variety of reasons. They include:

Symptomatic relief and management of chronic pain and/or as an adjunctive treatment for the management of post surgical and post traumatic pain.

Neuro-muscular Stimulation: The PMD-2000 Stimulator may be used, with a physician's prescription for a variety of reasons. They include:

1. Relaxation of muscle spasms, **2.** Prevention of retardation of disuse atrophy, **3.** Increasing local blood circulation, **4.** Muscle re-education, **5.** Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, **6.** Maintaining or increasing range of motion.

NOTE: The PMD-2000 should only be used under the medical supervision of a qualified practitioner for adjunctive therapy for the treatment of medical disease and conditions.

Contraindications

Cancer patients and anyone with a demand type cardiac pacemaker should not use the PMD-2000 Stimulator.

Warnings

1. The long term effects of chronic electrical stimulation are unknown.
2. Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
3. Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing
4. Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
5. Stimulation should not be applied transcerebrally.
6. Stimulation should not be applied over swollen, infected, or inflamed areas of skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
7. Stimulation should not be applied over, or in proximity to cancerous lesions.
8. Stimulation should not be used whenever pain syndromes are undiagnosed until etiology is established.

Precautions

1. The safety of electrical stimulation during pregnancy or delivery has not yet been established.
2. Caution should be used for patients with suspected or diagnosed heart problems or epilepsy.
3. KEEP THIS DEVICE OUT OF THE REACH OF CHILDREN.
4. Electrode placement and stimulation settings should be based on the guidance of a prescribing practitioner.
5. Precautions should be observed in the presence of the following:
 - a. When there is a tendency to hemorrhage following acute trauma or fracture,
 - b. Following surgical procedures when muscle contraction may disrupt the healing process,
 - c. Over the menstruating or pregnant uterus,
 - d. Where sensory nerve damage is present by a loss of normal skin sensation.
6. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. This irritation can usually be reduced by use of an alternate conductive gel.
7. Interferential stimulation is not effective on pain of central origin. This includes headache.
8. Interferential stimulation devices should only be used under the continued supervision of a physician.
9. Interferential stimulation devices have no curative value.
10. Interferential current therapy is a symptomatic treatment and as such suppresses the sensation of pain, which would otherwise serve as a protective mechanism.
11. Electronic monitoring equipment (such as ECG monitors and alarms) may not operate properly when interferential stimulation is in use.
12. Stimulus delivered by this device may be sufficient to cause electrocution. Electrical current of this magnitude must not flow through the thorax.
13. Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain patients.
14. The PMD-2000 Stimulator should only be used with the lead wires provided with the device or original manufacturer replacement lead wires.
15. The PMD-2000 Stimulator should not be used while driving, operating machinery or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

Adverse Effects

1. Skin irritation and burns beneath the electrodes have been reported with the use of electrical stimulators.
2. Unusually high sensitivity to electrical stimulation may result in skin irritation and burns beneath the electrodes. If this occurs, discontinue use until the source has been determined and corrected.

Additional Features

Auto Shut-Off

To control the maximum treatment given to a patient, an automatic shut-off feature is incorporated into the PMD-2000. There are 20, and 30 minute time limits (depending on the selected Pre-set) that any particular therapy session will last. After the session timer reaches zero, the output amplitude of both channels is reduced to zero and the unit remains in an idle state. After 5 minutes in an idle state, the unit automatically shuts-off to conserve battery power and prevent inadvertent operation.

Pause / Resume

The PMD-2000 has a Pause and Resume feature that allows the user to suspend or "Pause" treatment to allow for the readjustment of electrodes or any external interruption such as a phone call. If the user wishes to Pause treatment, simply press the Red button once. The screen will display "Paused". When the user is ready to resume therapy, press the Green button once and the previous therapy will resume where it left off with the exception that the amplitude (intensity) setting has been reset to zero for safety reasons. Increase the amplitude to the desired amplitude setting.

Amplitude Lockout

To prevent an accidental increase or decrease of the treatment amplitude (intensity), the PMD-2000 has an intratherapy "amplitude lock" feature. 60 seconds after the last increase or decrease of the amplitude, the device will go into "amplitude lock" mode. If the device is in "lockout" mode and the user accidentally pushes the "+" or "-" buttons (increase or decrease amplitude) the LCD screen will display a message indicating the amplitude is locked. If the device is in "lockout" mode and the user wishes to increase or decrease the amplitude, they can press the green "On" button to remove the amplitude lock and then increase or decrease the amplitude as desired.

Quick Start

If the PMD-2000 Stimulator is placed into Therapy Protocol Lockout mode the Quick Start feature will be activated. The Quick Start feature is the fastest and easiest way to start a therapy. Ask your healthcare professional to place the stimulator into Therapy Protocol lockout mode.

Multilingual

The PMD-2000 Stimulator's User Interface (the information shown on the display) is available in three common languages; English, Spanish and French. To change the language (with the device on) hold down the "ON" button and at the same time press the "+" button. Scroll through the languages and press enter when the desired language is flashing.

Pre-Set Therapy Protocols

Pre-set#	Function	Treatment Timer (in minutes)	Base Freq. (in Hz)	High Freq. (in Hz)	Sweep or Dwell Time (in seconds)
Pre-set 1	Abrupt 2/2	30 minutes	1 Hz	10 Hz	2 seconds
Pre-set 2	Abrupt 6/6	30 minutes	1 Hz	20 Hz	6 seconds
Pre-set 3	Abrupt 9/9	30 minutes	1 Hz	30 Hz	9 seconds
Pre-set 4	Ramp 6 sec. "low"	30 minutes	1 Hz	30 Hz	6 seconds
Pre-set 5	Ramp 12 sec. "high"	30 minutes	80 Hz	150 Hz	12 seconds
Pre-set 6	Full Sweep 6 sec.	30 minutes	1 Hz	150 Hz	6 seconds
Pre-set 7	Full Sweep 15 sec.	30 minutes	1 Hz	150 Hz	15 seconds
Pre-set 8	Dual LOW: Abrupt Ramp 15 min ea.	Total Time 30 minutes	1 Hz 80 Hz	6 Hz 150 Hz	6 seconds 6 seconds
Pre-set 9	Dual MED: Abrupt Ramp 15 min ea.	Total Time 30 minutes	1 Hz 80 Hz	10 Hz 150 Hz	6 seconds 6 seconds
Pre-set 10	Dual HIGH: Abrupt Ramp 15 min ea.	Total Time 30 minutes	10 Hz 100 Hz	20 Hz 150 Hz	6 seconds 6 seconds
Pre-set 11	Muscle Stimulation	20 minutes	50 Hz	50 Hz	3 sec ON / 3 sec OFF
Pre-set 12	Muscle Stimulation	20 minutes	50 Hz	50 Hz	3 sec ON / 6 sec OFF
Pre-set 13	Muscle Stimulation	20 minutes	50 Hz	50 Hz	6 sec ON / 6 sec OFF
Pre-set 14	Muscle Stimulation	20 minutes	50 Hz	50 Hz	5 sec ON / 10 sec OFF
Pre-set 15	Continuous	30 minutes	Operator Variable	N/A	N/A

Pre-Set Therapy Protocols do not have variable or adjustable parameters (except Pre-set 15) other than treatment amplitude (intensity). All functions are subject to treatment time.

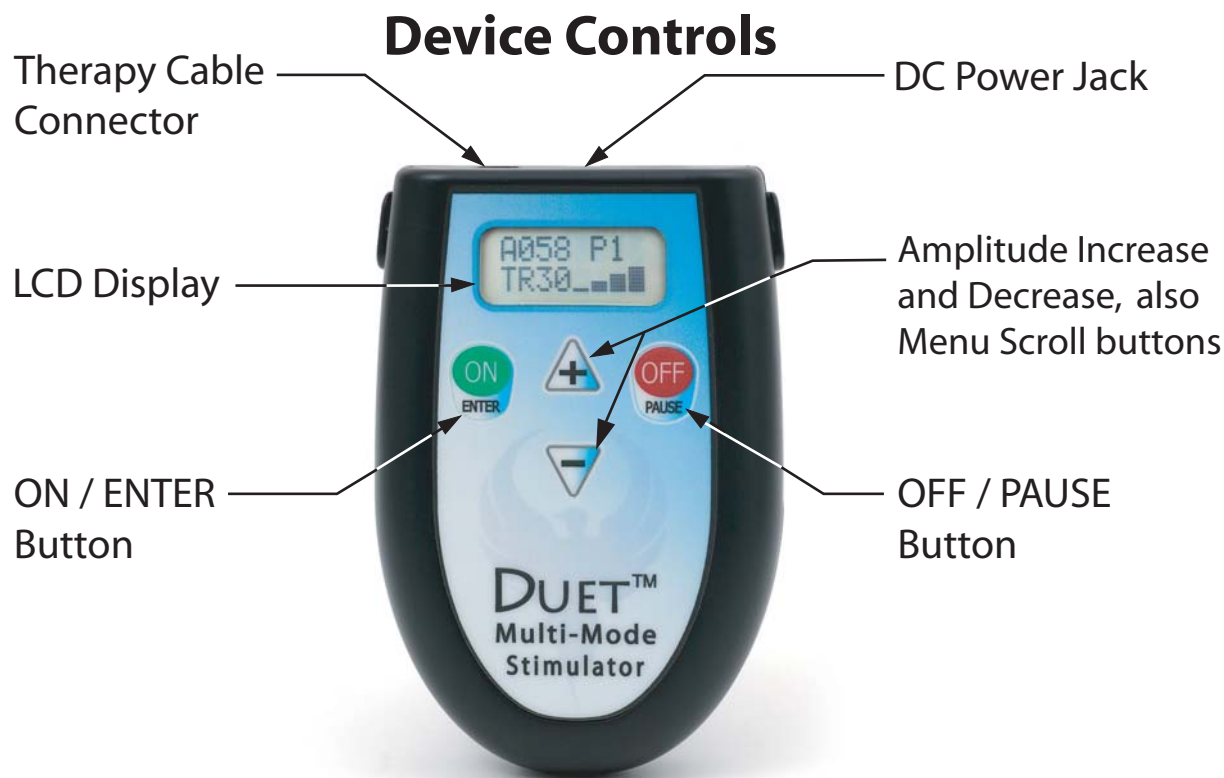
Dual Therapy – Output base frequency for set dwell time, then abrupt jump to high frequency for set dwell time, then repeat. After treatment time reaches ½ total treatment time, smooth ramp from 80 or 100Hz to 150 Hz over set sweep time, then back.

Ramp – Smooth ramp from base frequency to high frequency over set sweep time, then back.

Abrupt – Output base frequency for set dwell time, then abrupt jump to high frequency for set dwell time, then abrupt drop to base frequency, repeat.

Continuous – Outputs operator variable frequency continuously (no ramp, sweep, abrupt or dwell functions).

Relax and Contract Stimulation (muscle stimulation) – Relax = On for set dwell time at pre-set base frequency and zero Amplitude (intensity), then Contract = fast amplitude ramp to Amplitude (intensity) setting and maintain contraction for set dwell time at preset base frequency of 50Hz.



STOP! Do not use the PMD-2000 Stimulator until you have read the entire instruction Manual, especially the Warnings and Precautions on Page 4.

Standard Operation Instructions

1. Begin by placing the electrodes on your skin at the treatment location. Follow your healthcare professional's instructions as to the correct placement of the electrodes. A successful and beneficial therapy session is highly dependent on the proper placement and attachment of the electrodes. Use care at this important step.
2. Make sure the stimulator is turned OFF. Connect the lead wires to the electrodes and the opposite end to the therapy cable connector on the top of the device.
3. Turn the stimulator ON. In a few moments you will see a screen asking you to make a therapy selection. Using the "+" and "-" buttons scroll through the protocols until you locate the desired therapy.
4. Press enter to select the therapy protocol. The therapy has begun but the amplitude is set at zero. Increase the amplitude to the level recommended by your healthcare professional. Use the "+" or "-" buttons to adjust the amplitude to your desired level.

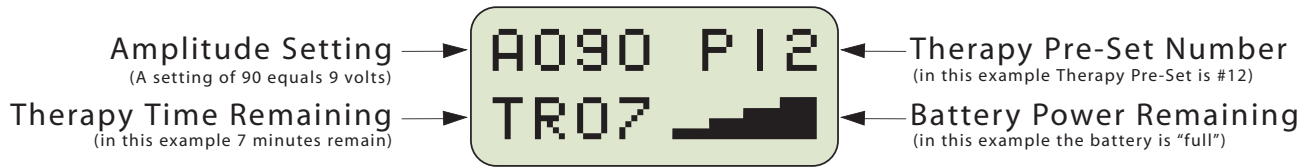
Quick Start Instructions

Note to user: your device must be placed in Therapy Lockout Mode by your healthcare professional before you can utilize the Quick Start feature. Begin by following steps 1 and 2 above.

To use the device in Quick Start mode simply turn the device on by pressing the green "ON" button.

You will now see the Therapy Status screen displayed. Your therapy protocol has been pre-selected for you. Your therapy has begun. Use the "+" or "-" buttons to adjust the amplitude to the level recommended by your healthcare professional.

Therapy Status Screen



Typical Display Screens

<p>SELECT PROTOCOL</p>	<p>When this screen is displayed, scroll through the 15 preset therapy protocols and press the enter button to select.</p>	<p>AMP.LOCK PRESS</p>	<p>This screen will appear when the amplitude is locked for safety reasons. Press enter to unlock the amplitude.</p>
<p>THERAPY COMPLETE</p>	<p>This screen will appear at the end of a therapy.</p>	<p>ENTER TO UNLOCK</p>	<p>When the amplitude is unlocked, it will be at the previous setting</p>
<p>SYSTEM FAILURE</p>	<p>This screen and the one below will both appear when the device operating system detects a fault.</p>	<p>*PAUSED* PRESS ON</p>	<p>When the device is in the paused state, the two screens to the left will be displayed alternately.</p>
<p>CONTACT DEALER</p>	<p>Do not use the device if this screen appears.</p>	<p>TO RESUME</p>	<p>Press the green button (ON/enter) to resume your therapy. When the therapy resumes the amplitude is set to zero for patient safety reasons.</p>
<p>REPLACE BATTERY</p>	<p>This screen will appear when the batteries need to be replaced. Insert fresh batteries.</p>		

Troubleshooting

Problem	Solution
Unit does not turn on	Insert fresh batteries. If problem persists, try powering up with AC wall adapter. If problem persists, stimulator is defective - please contact dealer
Device turns on but no stimulation is felt	<ul style="list-style-type: none"> a. Check all therapy cable connections - both at the stimulator and electrodes b. Remove and reattach electrodes c. At a low amplitude wiggle the lead wires - if intermittent stimulation is felt the lead wires are defective. Please contact dealer for replacement lead wires.
Stimulation felt but the unit is off	Unit is defective - do not use - please contact dealer for repair or replacement

Care and Maintenance

Duet is easy to maintain in top condition. Follow the simple practices below:

- Clean the unit by wiping gently with a damp cloth and mild soap,
- Do not use any abrasive cleaners,
- Do not immerse the unit in water or other liquids,
- Do not allow it to be splashed with water or other liquids,
- Do not drop the unit or treat it roughly,
- Store the unit in the provided carrying/storage case,
- Remove the batteries from the unit during storage.

Warranty Information:

Phoenix Medical Devices, LLC warrants the Duet™ PMD-2000 against any defect in materials and workmanship for a period of one year from the date the device is entered into service but no longer than 15 months from the date of sale.

Warranty does not cover accessories such as wall adapters or lead wires. Warranty does not cover batteries - these are considered consumables.

To obtain warranty service please go to our website, www.pmdirect.com and complete the Return Material Authorization (RMA) form and fax it to our office at the number listed below. You can also call our Customer Service department at the toll free number shown below and one of our service representatives will assist you.

Note: A complete listing of all warranty features and exclusions is included as part of your purchase invoice. Please refer to it for further details. You can also go to our website, www.pmdirect.com and download a full copy of the PMD-2000 warranty.

Customer Service:

Customer Service is easy to obtain by calling the toll free number below. Call this number for assistance with:

- Technical questions relating to the device,
- Assistance resetting the device,
- Answers to Frequently Asked Questions,

NOTE: For electrodes, wipes, & conductive gel, please contact your dealer

Manufactured by:

Phoenix Medical Devices, LLC

1672 Kaiser Ave.

Irvine, California 92614

Off: 949-955-3639 Fax: 949-266-5928

On the web at www.pmdirect.com



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1-800-689-9892