M-Wave

User's Manual

M-Wave

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Zynex Medical

Contact Information

CUSTOMER SERVICE	800-495-6670
Supplies:	To order more electrodes or other accessories
Technical Support:	Questions or problems with using your device
Device Return:	Order a postage paid return envelope to return your device at no charge
MAIN OFFICE	800-495-6670
Billing Questions:	Questions regarding insurance benefits and covered benefits for Durable Medical Equipment (DME) or questions about an Explanation of Benefits form you received in the mail
FAX NUMBER	800-495-6695 855-845-5941
MAILING ADDRESS	Zynex Medical, Inc. 9655 Maroon Circle Englewood, CO 80112 USA
EMAIL	info@zynex.com
WEBSITE	www.zynex.com

About the M-Wave

The M-Wave is an easy-to-use NeuroMuscular Electrical Stimulator (NMES) designed to accurately deliver the desired intensity and frequency of electrical current using modern state-of-the-art technology. M-Wave is one of the safest stimulators in the world with safety features such as an electrode alarm, level locking, and a guaranteed constant current. It is a fully programmable, compact, battery or plug-in powered device with a digital on-screen display, an adjustable treatment timer and compliance meter, and biphasic or monophasic waveforms (AC or DC).

Neuromuscular Electrical Stimulation (NMES)

NMES delivers electrical impulses to muscle motor points at a frequency of 4 to 100Hz. The stimulation is set by the user at a level to cause muscle contraction. There are three different settings buttons to choose from and each has default settings.

Factory Setting Values

Home “HOME”	Intensity: 0 mA
Mode “MODE”	Simultaneous (SIM)/Alternate (ALT): SIM Alternating Current (AC)/Direct Current (DC): AC
Parameter “PARA”	Pulse Width (PW): 200µS Frequency (FREQ): 30Hz On Time: 6 sec. “Active Period” (stimulation) Off Time: 6 sec. “Rest Period” (no stimulation) Ramp On Time: 1 sec. Ramp Off Time: 1 sec.

Caution: Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the state in which he/she practices to use or order the use (Adult or age-limited pediatric per licensed practitioner) of the device.

Safety Information

Equipment Classification

As per the International Electrotechnical Commission standard IEC 60601-1, and the European standard EN 60601-1, Medical Electrical Equipment, General Requirements for Basic Safety and Essential Performance, the M-Wave is classified as follows:

- **Type BF Equipment**
  A Type BF piece of equipment is one that provides a particular degree of protection against electric shock, particularly regarding allowable leakage current. Type BF applied part is one that is floating above ground and is isolated from all other parts of the equipment such as device case, lead wires, and electrode accessories.
- **Internally Powered Equipment**
  When the M-Wave is powered by the internal, 9 VDC, MN1604, battery it is classified as Internally Powered Equipment.
- **Class II Medical Equipment**
  When powered by the external, 12 VDC, medical grade, power supply, the M-Wave is classified as Class II Medical Electrical (ME) Equipment. Note: When the external power supply is connected to the M-Wave device, the power supply is considered part of the ME equipment.
- **Electromagnetic Compatibility**
  Conforms to IEC 60601-1-2.
  For full EMC testing information refer to test specifications pg.30
- **Temperature**
  Operating temperature range: 0° - 40° C (32° - 104° F)
- **Relative Humidity**
  Relative humidity range: 30 - 90% RH
- **Atmospheric pressure**
  Atmospheric pressure range: 70 - 106 kPa
- **Ingress Protection Code IP22**
  Device protected against solid foreign objects of 50mm Ø and greater.
  Device protected against vertically falling water drops when enclosure tilted up to 15°.
- **Flammable Anesthetics**
  This device is not suitable for use in the presence of a flammable anesthetic mixture with air, or in the presence of a flammable anesthetic mixture with oxygen or nitrous oxide.
- **Mode of Operation**
  This device is suitable for continuous operation.

Safety Information

Symbols

Safety symbols shown on this device above are defined below.

On/Off. This symbol indicates that the labeled switch electronically cycles the DC power on and off for part of the equipment. Note: To disconnect the external power supply, unplug the power cord of the supplied AC adapter from the AC main outlet.

General Warning Sign. Follow warnings stated in the instruction manual to prevent potential hazards.

Refer to Instruction Manual/Booklet. The operator must read, understand, and follow all instructions in the accompanying document including all warnings, cautions, and precautions before using this medical device.

Type BF Equipment. This symbol indicates that the patient applied parts (electrodes, lead wires, and device case) are Type BF (floating from ground) offering the user a specific level of safety.

Waste Electrical and Electronic Equipment (WEEE). This product may contain substances known to be hazardous to the environment or to human health. It should be disposed of properly (for example, at your local waste collection administration or recycling plant) and in accordance with local ordinances.

Service and Calibration

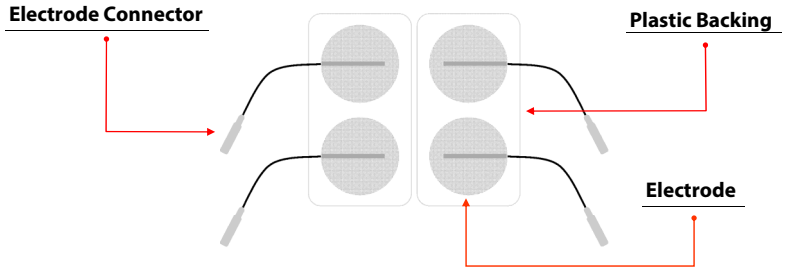
- Do not remove the cover. There are no user serviceable parts. Refer all service requests to authorized personnel. No modification of the equipment is allowed.
- No preventative inspections are required. Factory testing and calibration ensure equipment accuracy and response.

M-Wave

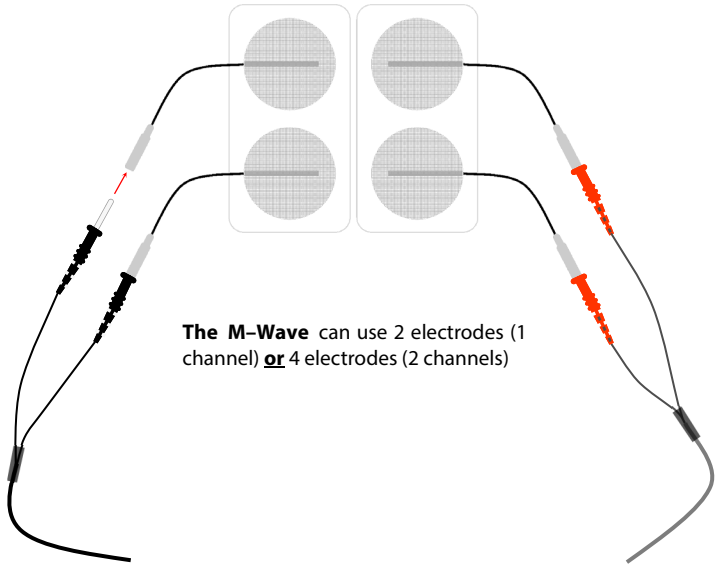
Electrode and Lead Wire Setup

Step 1 Open electrode package and remove electrodes from package. Keep electrodes on plastic backing.

Note: Zynex Medical electrodes are recommended for use with the M-Wave. See additional accessories on page 43.



Step 2 Insert lead wire pin connectors into electrode connectors as shown below. **RED** lead wire connectors on one side and **BLACK** lead wire connectors on the other side.



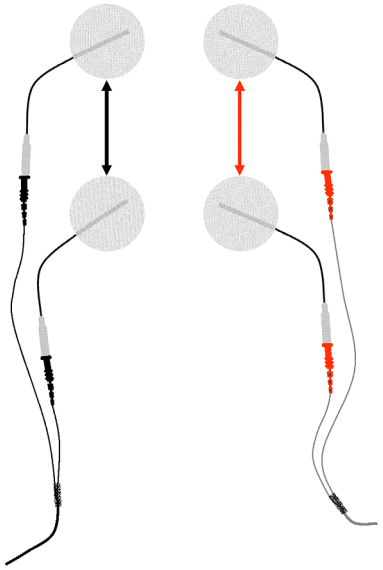
Electrode and Lead Wire Setup (continued)

Step 3 Remove each electrode from the plastic backing and place on the treatment site according to the type of modality selected.

Electrode Arrangement

NMES: *Using both channels is optional.*

NMES Example
Up and Down Pattern



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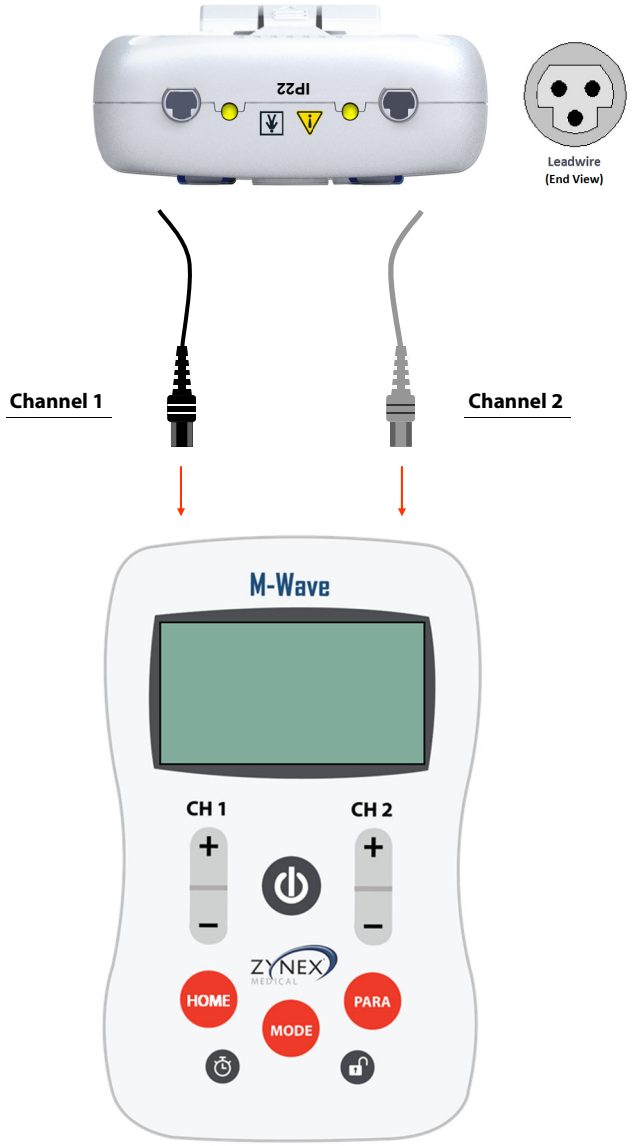
Electrode and Lead Wire Setup (continued)

Step 4 Plug lead wires into the top of the M-Wave while carefully observing their orientation. NMES modality requires one or both lead wires (channel 1 & 2).

Step 5 Proceed to page 16 to start treatment or page 12 to program device.

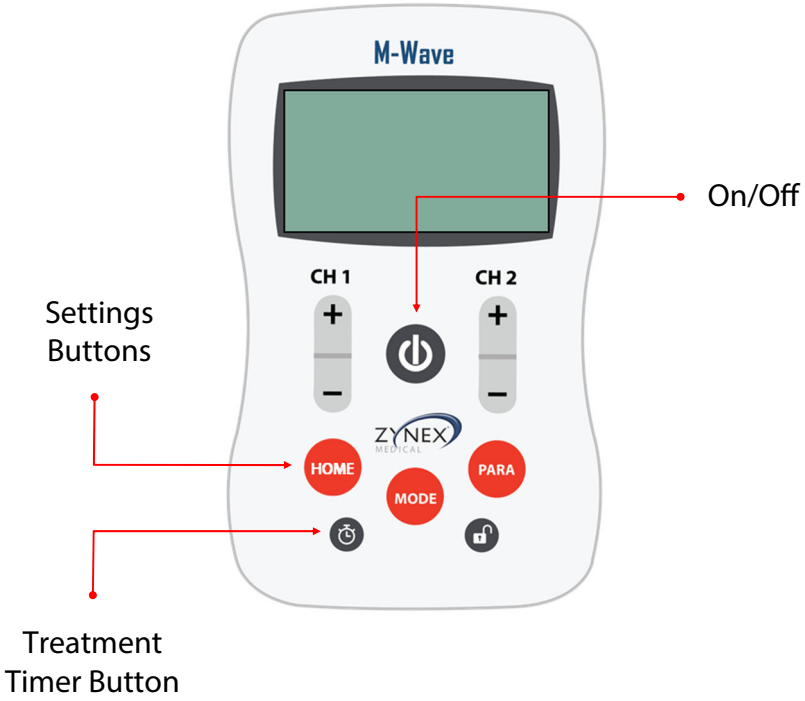


M-Wave

Device Programming Instructions

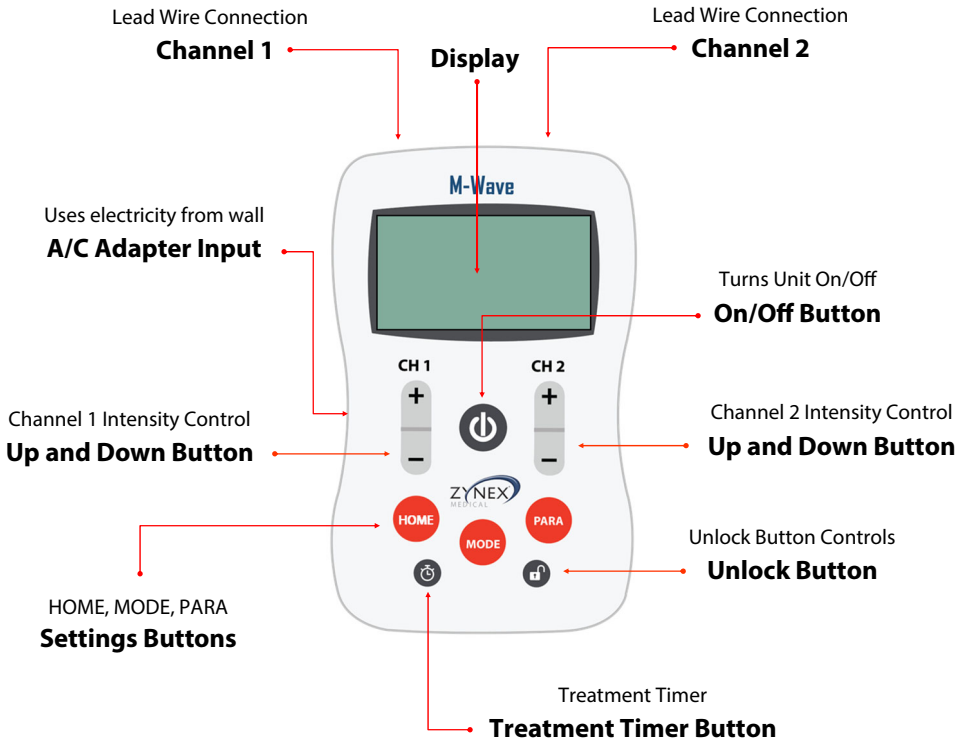
1. Place electrodes on the skin prior to turning on this device.
2. Turn device on by pressing the black On/Off button
3. Select desired settings by pressing the “HOME”, “MODE”, or “PARA” button once.
4. Continue to press the selected settings button until desired program is displayed.
5. Press Treatment Timer button until desired treatment time is set on screen.

Device is now ready to use.



M-Wave

Device Controls



Device Controls

- **Turn Unit On and Off** : Press the power button. The display will light up. Press the power button again to turn the unit off. If no controls have been touched for five minuets with a stimulation level lower than 3 mA the device will automatically turn off.

- **Setting Stimulation Level** : Press the HOME button until "INTENSITY" appears. Use the up and down button to increase or decrease intensity for the desired channel. After 20 seconds of inactivity the stimulation level is electronically locked as a safety feature to prevent the patient from unintentionally increasing stimulation. To unlock button functions, just press the Unlock button. Afterwards you will have 20 seconds to adjust the intensity level.

- **Setting Pulse Width** : Press the PARA button until "PULSE WIDTH" appears. Use the up and down buttons for either channel to increase or decrease the pulse width

- **Setting Frequency** : Press the PARA settings button until "Frequency" appears. Use the up and down buttons for either channel to increase or decrease the Frequency.

- **Setting the Treatment Time** : Press the Treatment Timer button to increase the treatment time in 10 minute increments. Press the timer button until the timer display disappears in order to activate constant stimulation.

- **Setting the On-Time** : Press the PARA button until "ON TIME" appears. Use the up and down buttons for either channel to increase or decrease the On-Time.

- **Setting the Off-Time** : Press the PARA button until "OFF TIME" appears. Use the up and down buttons for either channel to increase or decrease the Off-Time.

- **Setting the Ramp-Up** : Press the PARA button until "RAMP ON TIME" appears. Use the up and down buttons for either channel to increase or decrease the Ramp on time.

- **Setting the Ramp Down** : Press the PARA button until "RAMP OFF TIME" appears. Use the up and down buttons for either channel to increase or decrease the Ramp off time.

- **Setting Waveform Mode** : Press the MODE settings button until "WAVEFORM" appears. Use the up and down buttons for either channel to select either Biphasic (AC) or Monophasic (DC) waveforms.

- **Setting Stimulation Output Mode** : Press the MODE settings button until "OUTPUT" appears. Use the up and down buttons for either channel to select either Alternating (ALT) or Simultaneous (SIM) stimulation between the two output channels.

- **Compliance Data** : Press the HOME settings button until "COMPLIANCE METER" appears. Use the up and down buttons for either channel to view compliance meter data. While compliance meter data is displayed use the up and down buttons for either channel to reset compliance meter data.

- **Lock Desired Parameters** : Press the lock button so that the lock icon appears in order to lock all current parameters while being able to cycle through menus. Either press the Unlock button until the lock icon disappears or turn the device off and on again to unlock parameter selection.

- **Return to Factory Default Settings** : Press the HOME settings button until "DEFAULT" appears. Use the up and down buttons for either channel to reset the device to factory settings.

Start Treatment:

Before starting treatment electrodes must be placed on the treatment site and lead wires and electrodes connected to this device. See pages 9-11 and 17-31 for examples.

1. Turn M-Wave on by pressing On/Off button once.

2. Increase intensity by pressing Channel 1 *Up button* until a strong but comfortable stimulation level is felt. Repeat for Channel 2 if both lead wires are attached.

3. Once desired level of stimulation is set, the unit will automatically shut off at the preset treatment time shown on the display. If Treatment Timer has been set to "No Timer" then this device will need to be shut off manually. *Refer to Programming Instructions on page 12 to adjust Treatment Timer.*

4. To turn off device manually, press the On/Off button. Turn the device off before removing electrodes from the skin.

During Treatment:

IMPORTANT: *Button controls lock after 20 seconds of inactivity. To unlock button controls, press Unlock button.*

Increase Intensity:
To increase intensity, press the Up Intensity button for the desired channel until the preferred level of stimulation is felt.

Decrease Intensity:
To decrease intensity, press the Down Intensity button for the desired channel until the preferred level of stimulation is felt.

Display Alerts:
Check Connections: Lead wire(s) and/or electrode(s) may not be attached properly. Check all connections and try again (see page 42). If problem persists, call Technical Support (see page 4).

Low Battery: Replace battery immediately or connect the A/C adapter.

Locked: Stimulation level and mode cannot be changed until Unlock button is pressed.

IMPORTANT NOTES:

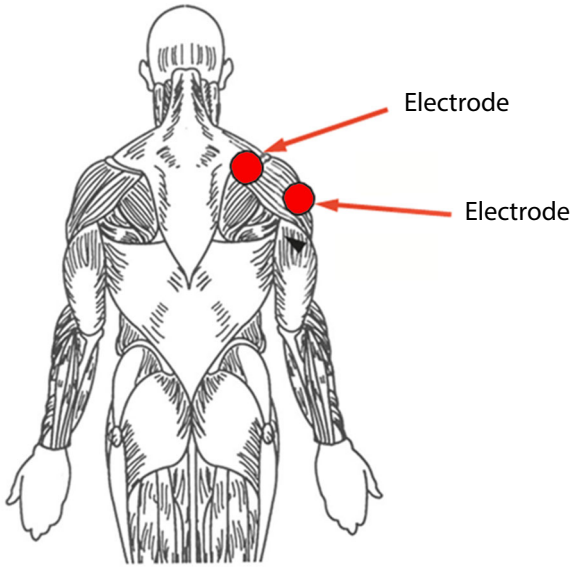
Consult with a physician for treatment and electrode placement.

The following M-Wave NMES general electrode placements are for reference only. Exact electrode placement may require some trial and error using low level stimulation.

Shoulder Subluxation / Abduction

Patient Position:
Sitting or standing with the affected arm draped at the side.

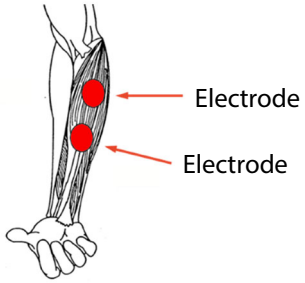
Electrode Placement:
Place one electrode above the shoulder blade (supraspinatus). Place the other electrode on the middle of your upper arm near the shoulder (middle deltoid).



Wrist and Finger Flexion

Patient Position:
The patient should be seated comfortably in a chair, leaning back, with the arm placed on the legs as comfortable as possible.

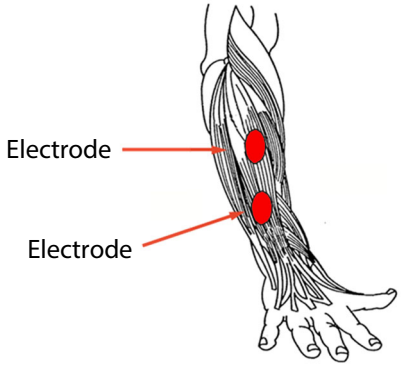
Electrode Placement:
With palm facing up, place one electrode on the bottom of the forearm (flexor group), one inch from the elbow crease. Place the other electrode one (1) inch below the first red electrode.



Wrist and Finger Extension

Patient Position:
The patient should be seated comfortably in a chair, leaning back, with the arm placed on the legs as comfortable as possible.

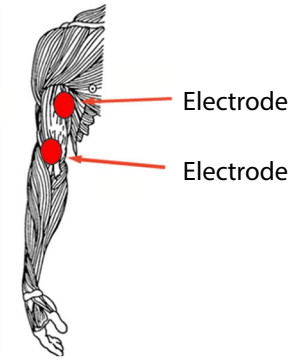
Electrode Placement:
With palm facing down, place one electrode on the top of the forearm (extensor group), one inch from the elbow crease. Place the other electrode one (1) inch below the first red electrode.



Elbow Flexion - Front

Patient Position:
Standing or sitting with the affected arm draped off the side of the chair.

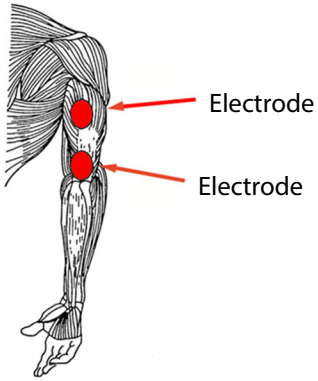
Electrode Placement:
Place one electrode high on the biceps muscle (front of upper arm). Place the other electrode two (2) inches above the elbow crease.



Elbow Extension - Back

Patient Position:
Standing or sitting with the affected arm draped off the side of the chair.

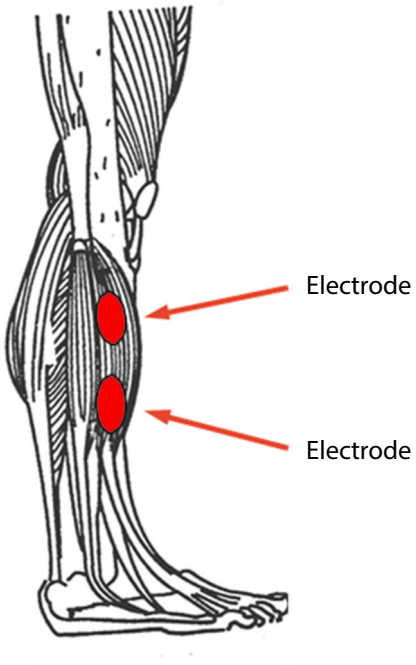
Electrode Placement:
Place one electrode high on the triceps muscle (top back, inner arm, but not armpit). Place the other electrode just above the elbow.



Ankle Dorsiflexion

Patient Position:
The patient should be in a seated position with the affected foot resting on the floor and the leg bent at a 90° angle.

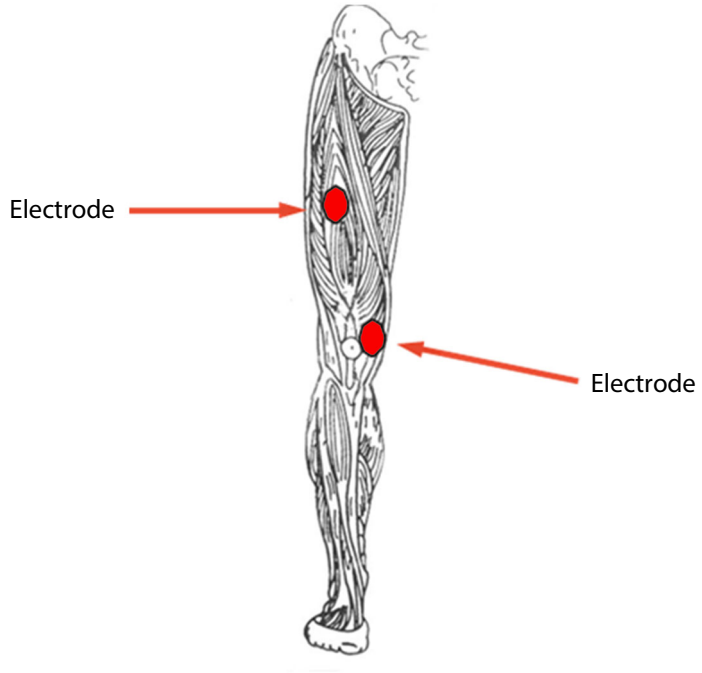
Electrode Placement:
Place one electrode high on the outside of lower leg 3-4 inches below the knee and one (1) inch away from the shinbone. Place the other electrode two (2) inches below the first red electrode.



Knee Extension - Front

Patient Position:
The patient should be in a seated position with the affected foot resting on the floor and the leg bent at a 90° angle.

Electrode Placement:
Place one electrode high on the mid-outer thigh. Place the other electrode on the inner thigh three inches above the knee.



M-Wave

Indications for Use

Neuromuscular Electrical Stimulation (NMES)

Indications

- Muscle re-education
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Maintaining or increasing range of motion
- Relaxation of muscle spasms

Contraindications

- This stimulator shall **not** be used on patients with a cardiac demand pacemaker.
- Electrodes shall **not** be placed so that current will be applied to the carotid sinus (neck) region or trans cerebrally (through the head).
- This stimulator shall **not** be used whenever pain syndromes are undiagnosed until etiology is established.

Warnings

- When using the separate external power supply, this medical electrical device does not incorporate a power switch to isolate the system from the AC mains. Unplug the power cord of the AC adapter from the AC mains outlet in order to positively disconnect from the AC mains. Ensure that the AC outlet is easily accessible.
- This device is capable of generating current densities for electrodes exceeding 2 mA rms/cm^2 which may require special attention of the operator.
- Do not exceed 0.5 W/cm^2 with recommended electrodes, assuming a load of 1000 Ω.
    - 1″ round: Maximum stimulation setting = 100 mA
    - 2″ round: Maximum stimulation setting = 100 mA
    - 2″ square: Maximum stimulation setting = 100 mA
- Output waveform/power information:
  When delivering stimulation energy, the M-Wave in NMES mode is a constant current output device. Therefore its output voltage, current, and power are dependent upon the load as well as the pulse width and frequency of the output waveform. The maximum peak voltage that the M-Wave can produce is 100 V (1000 Ω load).

Warnings (Continued)

Output voltage, current, and power are dependent upon the load as well as the pulse width and frequency of the output waveform. Therefore, the displayed mA value on the M-wave device is in reference to expected mA assuming a 1000 Ω load.
The maximum output power that the M-Wave can produce is 0.6 W per channel into a 1000 Ω load, 1.2W total.

- Maximum peak output voltage (500 Ω load) = 50 V
- Maximum peak output current (500 Ω load) = 100 mA
- Maximum peak output voltage (1 KΩ load) = 100 V
- Maximum peak output current (1 KΩ load) = 100 mA
- Maximum peak output voltage (2 KΩ load) = 100 V
- Maximum peak output current (2 KΩ load) = 50 mA
- Pulse width range biphasic: 100 - 600 µs
- Pulse width range monophasic: 50 - 300 µs
- Pulse frequency range: 4-100 Hz
- Maximum RMS voltage (500 Ω load) = 12.25 V
- Maximum RMS current (500 Ω load) = 24.49 mA
- Maximum output power (500 Ω load) = 0.3 W per channel
- Maximum RMS voltage (1 KΩ load) = 19.59 V
- Maximum RMS current (1 KΩ load) = 19.59 mA
- Maximum output power (1 KΩ load) = 0.4W per channel
- Maximum RMS voltage (2 KΩ load) = 12.96 V
- Maximum RMS current (2 KΩ load) = 6.48 mA
- Maximum output power (2 KΩ load) = 0.08W per channel

- The safety of NMES devices for use during pregnancy or birth has not been established.
- This device is not effective for pain of central origin (this includes headache).
- This device should only be used under the continued supervision of a physician.
- This device does not have curative value.
- This device offers symptomatic treatment such as suppressing the sensation of pain which would otherwise serve as a protective mechanism.
- The user must keep this device out of the reach of children.
- Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when this device is in use.
- The long-term effects of chronic electrical stimulation are unknown.
- Stimulation should not be applied over the carotid sinus nerves, particularly in patients with known sensitivity to the carotid sinus reflex.

Warnings (Continued)

- 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.
- Stimulation should not be applied trans thoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
- Stimulation should not be applied trans cerebrally.
- Stimulation should not be applied over swollen, infected, or inflamed areas of skin, eruptions, e.g. phlebitis, thrombophlebitis, varicose veins, etc.
- Stimulation should not be applied over, or in proximity to, cancerous lesions.
- This device is capable of generating currents and voltages in excess of 10 mA RMS and 10 V RMS, respectively. A yellow LED indicator is provided next to each lead wire connector to show that the unit is delivering energy for any non-zero value of stimulation output (1-100 mA).
- Simultaneous connection of a patient to high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
- Operations within close proximity (within one meter) of shortwave or microwave therapy equipment may produce instability in the stimulation output.
- Avoid using this device within 30 cm (12 inches) of Electromagnetic Emitters (EM) including but not limited to Radio –Frequency Identification Readers (RFID), Electronic Article Surveillance (EAS), Wireless Power Transfer (WPT), 5G Cellular Signals, or Magnetic Resonance Imaging (MRI)
- This device is suitable for residential, in-home, and personal proximity use.
- This device could become degraded or unresponsive in the presence of Electromagnetic disturbances. If the device were to become degraded or unresponsive, attempt to reset the device by pressing the ON/OFF button or unplugging and plugging back in the AC adapter connection or removing and then reinstalling the 9V battery. If none of the previous attempts to reset the device to a functional state once turned back on, return the device to the manufacturer.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Exposure to static discharge of greater than or equal to 8kV may result in disruption of the button pad resulting in channel 1 or 2 buttons to control stimulation of the opposite channel indicated by yellow led indicator and LCD display. In the event of this behavior refer to troubleshooting pg.26 .

Safety References

Zynex Medical, Inc. is only responsible for the safety, reliability, and function of this device when repairs and adjustments have been made by persons authorized by Zynex Medical, Inc., and this device is used in accordance with the user's manual. Repairs and technical safety tests shall only be performed by authorized personnel.

Precautions

- Isolated cases of skin irritation may occur at the site of the electrode placement following long-term application.
- Effectiveness is highly dependent upon patient selection by a person qualified in management of pain patients.
- Safety of powered muscle stimulators for use during pregnancy has not been established.
- Caution should be used for patients with suspected or diagnosed heart problems.
- Caution should be used for patients with suspected or diagnosed epilepsy.
- Caution should be used in the presence of the following:
  1. When there is a tendency to hemorrhage following acute trauma or fracture.
  2. Following recent surgical procedures when muscle contraction may disrupt the healing process.
  3. Over the menstruating or pregnant uterus
  4. Over the areas of the skin which lack normal sensation.
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrically conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
- Electrode placement and stimulation settings should be based on the guidance of the prescribing physician.
- This device should be kept out of reach of children.
- This device shall be used only with the leads and electrodes recommended for use by the manufacturer.
- This device shall 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 Reactions

- Skin irritation and burns beneath the electrodes are potential adverse reactions.

Troubleshooting

Troubleshooting	
Problem	**Solution**
Unit stays on even after treatment ends.	Press and release Off button to turn unit off. Otherwise unit will shut off automatically after 5 minutes of no stimulation. Alternatively you can start a new treatment session after the last one ends.
Cannot increase level from its current setting.	Press Unlock button until “Lock” icon disappears to unlock this safety feature. Then increase stimulation to the desired level/intensity. Intensity level is always locked after 20 seconds of key press inactivity.
Display shows “CHECK CH1!” or “CHECK CH2!” (electrode alarm).	Check electrode skin contact. Electrodes should be fresh and stick well. Use water if necessary to soften the gel for better contact. Verify that all four electrodes are connected to lead wires and that both lead wires are connected to the unit. Connect the bare metal pins together to short-circuit the outputs. If the electrode alarm ceases the problem is with the electrode connection integrity.
When the ON button is pressed, a “Lock” icon appears on the display and the M-Wave remains unresponsive.	Press UNLOCK button until the “Lock” icon on the display disappears.
Pressing the channel 1 button causes channel 2 lead to deliver stimulation or pressing the channel 2 button causes channel 1 lead to deliver stimulation as indicated by yellow led indicator and LCD display.	discontinue use of this device and return it to the manufacturer for replacement.

Neuromuscular Electrical Stimulation (NMES)

Amplitude:	0-100 mA
Frequency:	4-100 Hz,
Pulse Width:	50-300 µs
On-Time:	0.5 to 30 sec.,
Off-Time:	0.1 to 60 sec.,
Ramp Up:	0.1 to 6 sec.,
Ramp Down:	0.1 to 6 sec.,
Waveforms:	Symmetrical biphasic or monophasic.

Other Specifications

Treatment timer:	10 to 90 minutes, in 10 minute increments, with no timer setting
Compliance meter:	Records total usage time in minutes and number of times used
Dimensions:	2.9 x 4.6 x 1.0 in.
Weight:	5.8 oz. including battery
Warranty:	5 year manufacturer's warranty on materials and workmanship Accessories excluded

Accessories

Lead wires:	104203, lead wire, black, with black pins 104204, lead wire, gray, with red pins
Electrodes:	300027, electrodes, 2" diameter, round, pkg. of four
Power supply:	200109, power supply, medical grade, input 100-240 VAC, 50-60 Hz, 0.35 A ,output 12 VDC, 1 A, 12 W.
Battery:	130010, battery, 9 V, alkaline, MN1604

Electrodes and Skin Care

Proper skin care will help make the use of this device more comfortable and trouble-free. Prior to treatment, wash the areas where the electrodes will be placed with mild soap and water, rinse, and dry the skin thoroughly. If necessary, remove excess body hair.

Sterile electrodes may be required for some post-operative applications.

Follow directions of the prescribing physician.

Battery Power

One 9 V alkaline battery is used. The battery compartment on the back of this device opens by sliding the cover downwards. Rechargeable batteries are not recommended since they have only a short usage time and are not charged while in this device.

Replace battery when the battery icon appears on the display.

Insert the bottom of the battery into the battery compartment first, then press the contacts into position.

The M-Wave operates normally even if the 9 V battery is inserted with reverse polarity.

Remove battery if planning to store M-Wave.

Please dispose of used batteries properly.

AC Adapter

The M-Wave is supplied with an AC adapter that is plugged into the left side of this device and then into a 120 or 230 VAC electrical outlet. Note: The supplied AC adapter, Zynex P/N 200109, mains power requirement is 100-240 VAC, 50-60 Hz, 0.3A maximum. While plugged in, this device is powered from the electrical outlet and not the 9 V battery. The battery does not need to be removed while utilizing the AC adapter.

Device Cleaning

The M-Wave case and display window can be cleaned by lightly applying mild soap to a damp soft cloth or paper towel and using it to wipe the surfaces clean. Allow the unit to dry thoroughly before using. Do not spray cleaning solutions directly onto the unit, or immerse it in water or other liquids.

M-Wave

Warranty Information

The M-Wave device is warranted to be free from defects in material, workmanship, and structural integrity when subjected to normal domestic use and service for five years after the original purchase.

During that time, Zynex Medical, Inc. will replace, at its sole discretion, the M-Wave device that has been used in a standard manner. This warranty does not cover misuse or use contrary to the operating instructions supplied.

Warranty obligations are limited to replacement of defective parts and components, at the option of Zynex Medical, Inc. This warranty is only valid for the original purchaser of this product and will not be honored if the product ownership is transferred or is resold.

To obtain warranty service, please contact Technical Support at the number listed on page 4 of this manual.

Emissions and Immunity Test Specifications

Phenomenon	Basic EMC standard or test Method	
	Professional healthcare facility environment	Home healthcare environment
Emissions		
Radiated RF Emissions	CISPR 11	CISPR 11
Conducted RF Emissions	CISPR11	CISPR11
Harmonic Distortion	IEC 61000-3-2	IEC 61000-3-2
Voltage fluctuations and flicker	IEC 61000-3-3	IEC 61000-3-3

Phenomenon	Basic EMC standard or test Method	Immunity test levels	
		Professional healthcare facility environment	Home healthcare environment
Enclosure port			
Electrostatic discharge	IEC 61000-4-2	± 8kV contact ± 2kV, ± 4kV, ± 8kV, ± 15kV air	
Radiated RF EM fields	IEC 61000-4-3	3V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz
Proximity fields from wireless communica-tions equipment	IEC 61000-4-3	See Clause 8.10 of IEC 60601-1-2	
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50Hz or 60Hz	
Input AC power port			
Electrical fast transients/bursts	IEC 61000-4-4	± 2kV 100 kHz repetition frequency	
Surges line-to-line	IEC 61000-4-5	± 0.5kV, ± 1kV	
Surges line-to-ground	IEC 61000-4-5	± 0.5kV, ± 1kV, ± 2kV	
Conducted disturb-ances induced by RF fields	IEC 61000-4-6	3V 0,15 - 80 MHz 6V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3V 0,15 - 80 MHz 6V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Voltage dips	IEC 61000-4-11	0% U_Y;0,5 cycle, @ 0° ,45°,90°, 135°, 180°, 225°, 270°, and 315° 0% U_Y;1 cycle and 70%U_Y; 25/30 cycles, @ 0°	
Voltage interruptions	IEC 61000-4-11	0% U_Y; 250/300 cycle	

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Emissions and Immunity Test Specifications

Phenomenon	Basic EMC standard or test Method	Immunity test levels	
		Professional healthcare facility environment	Home healthcare environment
Patient coupling port			
Electrostatic discharge	IEC 61000-4-2	± 8kV contact ± 2kV, ± 4kV, ± 8kV, ± 15kV air	
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V 0,15 - 80 MHz 6V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3V 0,15 - 80 MHz 6V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Signal input/output parts port			
Electrostatic discharge	IEC 61000-4-2	± 8kV contact ± 2kV, ± 4kV, ± 8kV, ± 15kV air	
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V 0,15 -80 MHz 6V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3V 0,15 -80 MHz 6V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz

ZYNEX®
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Has A Story...

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