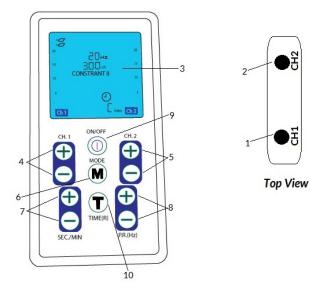


Criterion Med NMS Operating Instructions

General Description

This device is a Neuromuscular Electrical Stimulator (NMS). One pair of electrodes can be connected to each output channel using the leadwires supplied. Stimulation pulses are transferred from the device through the leadwires to the electrodes. The intensity, duration, and number of pulses per second can be adjusted.



- 1) Channel 1 Leadwire Port
- 2) Channel 2 Leadwire Port
- 3) Display
- 4) Channel 1 Intensity Control
- 5) Channel 2 Intensity Control
- 6) Mode Control
- 7) Timer Control
- 8) Pulse Rate Control
- 9) Power Button
- 10) Timer

Instructions for Use

- 1. Attach leadwires to Channel 1 and Channel 2.
- 2. Attach electrodes to leadwires, following instructions on electrode packaging.
- 3. Place electrodes on body as directed by your clinician.
- 4. Turn on Device (Ensure Power Slider on the bottom of the unit is set to the right before hitting the Power Button.
- 5. Select desired mode.

- 6. Set Pulse Rate as directed by clinician.
- 7. Increase or decrease intensity to a strong but comfortable level, as directed by clinician.
- 8. (Optional) Set an automatic timer for your treatment. By default your unit will read C, for Constant, next to the Minute Counter. To adjust this, hit the Timer Button until the C is blinking, and then use the SEC / MIN buttons to raise or lower the time in increments of 10 to between 10 and 50 minutes.

Technical Considerations

Pulse Rate (Hz)

The Pulse Rate indicates the number of pulses or cycles per second; affects the quality of contraction and can create muscle fatigue at higher rates. Increase or decrease the P.R. (Hz) by using the corresponding + and – buttons. The P.R. (Hz) is adjustable from 20 – 110 Hz in 5 Hz increments.

Timer Settings

The Timer can be used to set the duration of your treatment session, On Time and Off Time of each cycle, and the Ramp Settings.

Duration – Set a time after which your unit will automatically turn off. Can be set to between 10 and 50 minutes, in increments of 10.

On/Off Time – The "On Time" in a cycle, is the time that the unit spends at the maximum set intensity to contract the muscle. The "Off Time" is the resting part of the cycle, that lets the muscles rest between cycles.

Ramp Up/Down – Set a length of time over which the current will "Ramp Up" to maximum intensity, and conversely "Ramp Down" to a resting state. This setting helps control for comfort, as well as prevent accommodation.

Programming a Stimulation Pattern

Select the desired stimulation pattern by pushing the Mode Button until the desired stimulation pattern is displayed on the screen. The patterns will appear in the following order:

CONSTANT I & II – Constant: Default Setting. Base pulse is 20 Hz and 100 µs. Constant II base pulse is 20 Hz and 300 µs. Both feature adjustable Pulse Rate.

CYCLE I & II – Helps prevent accommodation by having the pulse "Ramp Up" to a certain intensity, before "ramping down" to a more comfortable, lower intensity. Contains two adjustable presets for treatments, based on Ramp Up/Down times and On/Off times.

RECIPROCAL – Similar to the "Cycle" presets, this mode prevents accommodation by having the pulse "Ramp Up" to a certain intensity, before "ramping down" to a more comfortable, lower intensity. The primary difference between "Cycle" and "Reciprocal" is that in "Reciprocal" mode the two channels fire one after another, rather than at the same time. This may result in a greater level of patient comfort. Contains three adjustable presets for treatments, based on Ramp Up/Down times and On/Off times.

Operational Notes

- If a new mode is selected during treatment, the intensity will automatically drop to o.
- Ensure the power slider is set to off once you are done using the unit, to prevent any loss of power.
- When adjusting timer settings, all other buttons (Mode, Pulse Rate, Intensity) are disabled.
- When the unit detects an incomplete circuit due to improper attachment or placement of electrodes, an

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indicator, , will be displayed at the top of the relevant channel's intensity settings.

- While charging, the unit is not capable of output.
- When the unit's battery indicator displays the unit is fully charged
- The unit will automatically shutdown if it detects no output within 1 minute.
- Treatment settings are preserved after unit shutdown; treatment time, if applicable, must be manually input during each session.
- The unit backlight will turn off after 10 seconds without any input, unless the unit is charging.

Unit Technical Data

Channels = 2

Waveform = Symmetrical Bi-Phasic rectangular waveform

Output = Constant, Cycle, Reciprocal

Intensity = Continuous, Adjustable from o - 62 mA Peak

Frequency (Hz) = 20 - 110 Hz, Adjustable

Pulse Width (μ s) = 100 or 300 Microseconds (μ s), Adjustable

Power Supply = 600 mA Rechargeable Battery

Dimensions = 3.9" x 2.5" x 1.1"

Weight = 3.25 oz (92g)

Accessories

Set (2) of Leadwires

"Fitting" Electrodes of various sizes and shapes

Portable Charger for NMS Unit (1)

Instruction Booklet (1)

Carry Pouch (1)

Patient Safety Information

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician licensed by the State.

Indications

Neuromuscular Electrical Stimulation (NMS) devices provide muscle rehabilitation post injury, surgery, or disease by exciting targeted motor nerves and thereby producing muscle contractions.

Contraindications

Can affect the operation of demand type cardiac pacemakers.

Not recommended for patients with known heart disease without physical evaluation of risk.

Do NOT apply over the anterior aspect of the neck or carotid sinus.

Do not apply TENS for undiagnosed pain syndromes until etiology is established.

<u>Warnings</u>

Electrodes should not be placed over the eyes.

Avoid active epiphyseal regions in children.

Use of abdominal electrodes during labor may interfere with fetal monitoring equipment.

Turn the stimulator off before applying or removing electrodes.

Electrotherapy may cause skin irritation beneath the electrodes.

Use of Electrodes and Accessories

Do not use electrodes smaller than $\frac{3}{4}$ " in diameter. Please note, the smaller the electrode, the greater the intensity of the stimulation

Only Criterion, Inc authorized electrodes and accessories are to be used with this device.

Replace electrodes after 2-4 applications or when conductivity and the adhesion of gel decreases significantly.

<u>Contact</u>

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All Criterion units come with a limited lifetime warranty. The NMS Criterion Medical Device has a limited lifetime warranty to be free from manufacturing defects or workmanship for the original patient prescribed this unit. Should the stimulator fail due to manufacturing defects or workmanship during the warranty period, Criterion, Inc. may, at its option, replace any defective unit with a new or rebuilt stimulator. Criterion's liability shall be limited only to repair or replacement of the stimulator as described. The limited warranty is made only and expressly to the initial purchaser of the stimulator and is not transferable. No warranty is made with respect to any accessories including electrodes, lead wires, batteries, or any other accessory. Please direct all questions regarding the NMS device, accessories, electrodes, etc. to Criterion, Inc.