Intelect® NMES

INSTRUCTION MANUAL

Please read the instruction manual before use

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

Contents

1. GENERAL INFORMATION

1.1 What is a Neuromuscular Stimulator?

Neuromuscular Stimulation is achieved by sending small electrical impulses through the skin to the underlying motor units (nerves and muscles) to create an involuntary muscle contraction.

Neuromuscular stimulation has many uses beyond its traditional application to prevent disuse atrophy, including:

- An increased range of motion: As a substitute for passive stretching exercise performed by the patient or therapist.
- Muscle re-education: for example, teaching patients how to set their quads.

1.2 How does a Neuromuscular Stimulator work?

Because the transdermal stimulation of nerves and muscles may be accomplished by electrical pulses, this modality can help prevent disuse atrophy. Accordingly, incapacitated patients can receive therapeutic treatment to create involuntary muscle contractions thereby improving and maintaining muscle tone without actual physical activity.

1.3 The Instrument:

The Neuromuscular Stimulator is an easy to use system. A marvel of miniaturized electronics, the lightweight power unit transmits electrical pulses through the skin surface and stimulates motor units (nerve and muscles). The electrical impulses are "ramped" so they closely emulate natural muscle contractions.

2. *SAFETY*

2.1 Caution:
Federal law (USA) restricts this device to sale by or on the order of practitioners licensed by the State in which they practice to use or order the use of the device.

2.2 Indications:
This NMES is intended to be used in:
1. Relaxation of muscle spasm.
2. Prevention or retardation of disuse atrophy.
3. Increase 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.

2.3 Warnings:
- The long-term effects of chronic electrical stimulation are unknown.
- Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
- 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 transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
- Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, (e.g., phlebitis, thrombophlebitis, varicose veins, etc).
- Stimulation should not be applied over, or in proximity to, cancerous lesions.
- Keep electrodes separate during treatment. Electrodes in contact with each other could result in improper stimulation or skin burns.

2.4 Precautions:

- 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:
  a. When there is a tendency to hemorrhage following acute trauma or fracture
  b. Following recent surgical procedures when muscle contraction may disrupt the healing process
  c. Over the menstruating or pregnant uterus
  d. Over areas of the skin which lack normal sensation.
- 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.

- Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
- Stimulators should be kept out of the reach of children.
- Stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.
- Machinery Operation: Patient should never operate potentially dangerous machinery such as power saws, automobiles, etc. during stimulation.

2.5 Adverse Reactions:

- Possible skin irritation or electrode burn under the electrodes may occur.
- Possible allergic skin reaction to tape or gel may occur.
- If the stimulation levels are uncomfortable or become uncomfortable, reduce the stimulation amplitude to a comfortable level and contact your physician if problems persist.

3. TECHNICAL SPECIFICATIONS

Channel	Dual channels, isolated between channels
Pulse Amplitude	0 ~ 80 mA = 0 ~ 40 volts, adjustable (at 500 ohm load)
Pulse Frequency (Hz)	5, 30, 100
Pulse Width (μs)	250, fixed
Contraction (On) Time (sec)	1 ~ 30, adjustable
Relaxation (Off) Time (sec)	1 ~ 45, adjustable
Waveform	Asymmetric biphasic square pulse.
Timer Control (mins)	No
Stimulation Mode	One
Power Supply	9V DC square shape battery
Size (D x W x H)	1.0" x 2.5" x 3.6" (26 mm x 62 mm x 91 mm)
Weight (including battery)	4.4 oz (126 g)
Safety standard	EN 60601-1, EN 60601-1-2, IEC 60601-2-10
Operation Ambient Temperature Range	50 ~ 95°F (10 ~ 35°C)
Operation Ambient Humidity Range	20 ~ 90% RH
Storage & Transportation Temperature Range	32 ~ 158°F (0 ~ 70°C)
Storage & Transportation Humidity Range	20 ~ 90% RH

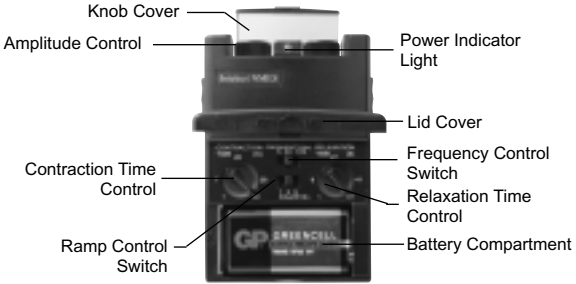
All values have ±10% tolerance.

4. CONTROLS AND INDICATORS

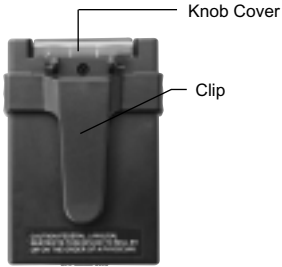
2.1 Front and Rear panel:

Top View

Front View



Back View



Knob Cover:
An acrylic knob cover protects amplitude controls from accidental user touch when the unit is being used. After adjusting the output, remember to have the cover closed.

Lid Cover:
A panel covers the controls for Frequency, Ramp, Contraction Time & Relaxation Time. Your medical professional may ask to set these controls for you and request that you leave the cover in place.

Amplitude Controls:
It controls the "INTENSITY" level of stimulating pulses. These controls located at the top of the unit regulate the amplitude, or intensity, of the stimulation and are the ON/OFF CONTROL. The power indicator will light up with green color when the unit is working.

Caution: If the stimulation levels are uncomfortable or become uncomfortable, reduce the stimulation intensity to a comfortable level and contact your physician if problems persist.

Contraction Time Control
Adjust Contraction Time from 1s to 30s by turning the control knob.

Relaxation Time Control
Adjust Relaxation Time from 1s to 45s by turning the control knob

Frequency Control Switch
Select Frequency 5 Hz, 30 Hz, 100Hz by shifting the switch

Ramp Control Switch
Select Ramp Time 1s, 3s, 5s by shifting the switch

Battery compartment
9 Voltage battery- 1 pc

5. INSTRUCTIONS FOR USE

NOTE: Always read this instruction manual before use.

PREPARATION FOR USE

5.1 Check Battery:
Insert a fresh 9V alkaline or rechargeable battery into the battery compartment. Make sure you are installing the battery properly. The battery is inserted in the casing on the foot of the stimulator unit. **BE SURE TO MATCH THE POSITIVE AND NEGATIVE ENDS OF THE BATTERY TO THE MARKINGS IN THE BATTERY COMPARTMENT OF UNIT.**

CONNECTING THE STIMULATOR

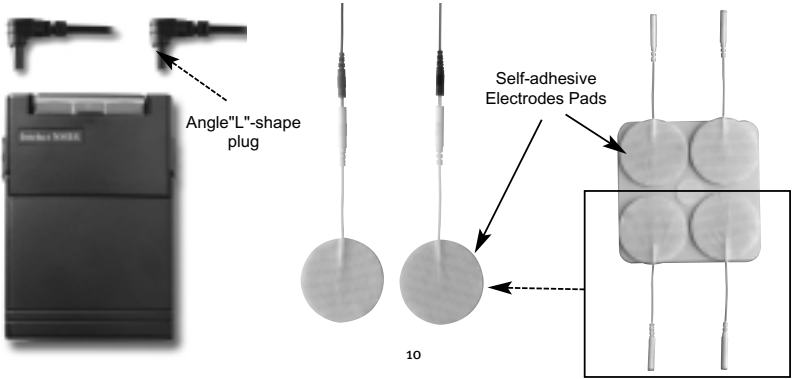
5.2 Connect electrodes to lead wires:
Insert the lead wire connector into electrodes connector (standard 0.08 inch female connection). **MAKE SURE THAT NO BARE METAL OF THE PINS IS EXPOSED.**

Caution: Always use the electrodes with the requirements of the EN60601-1 and EN60601-2, such as with CE mark, or which are legally marketed in the US under 510(K) procedure.

5.3 Connect lead wires to unit:

Before proceeding to this step, be sure the unit is completely turned OFF. Holding the insulated portion of the lead wire connector, insert the angled-"L" plug into the receptacle on the top of the main unit. Ensure the leads are inserted correctly.

The unit has two output receptacles controlled by Channel 1 and Channel 2 Amplitude Control knobs at the top of the unit. You may choose to use one channel with one pair of lead wires or both channels with two pairs of lead wires. Using both channels give the user the advantage of stimulating two different areas at the same time.



5.4 Place electrodes on skin:

Apply electrodes to the exact site indicated by your prescribing practitioner, following the instruction included with the electrodes labeling. Before applying electrodes, be sure the skin surface over which electrodes are placed is thoroughly cleaned and dried. Make sure the electrodes are placed firmly to the skin and make good contact between the skin and the electrodes. Place the electrodes over the skin; attach them properly, firmly, and evenly.

ADJUSTING THE CONTROLS

5.5 Adjust Contraction (ON) Time

The Contraction (ON) Time is adjustable 1~30 seconds.
Turn Contraction Time Control to adjust Contraction (ON) Time to the setting recommended by your medical professional.

5.6 Adjust Relaxation (OFF) Time

The Relaxation (OFF) Time is adjustable 1~45 seconds.
Turn Relaxation Time Control to adjust Relaxation (OFF) Time to the setting recommended by your medical professional. In order to prevent the spasticity, the Relaxation Time can't be adjusted less than the Contraction Time.

5.7 Select the Frequency:

The Frequency setting has three options: 5Hz, 30Hz & 100Hz

Shift "Frequency" switch to select the Frequency recommended by your physician or therapist.

5.8 Select the Ramp Time:

The Ramp setting has three options: 1s, 3s & 5s

Shift "Ramp" switch to select the Ramp Time recommended by your physician or therapist. The special circuitry of the stimulator is designed so the electrical impulses gradually build to a peak. This "ramped" pulse produces a gradual muscle contraction emulating natural muscle movement. It can also prevent spastic patients from reacting adversely.

5.9 Adjust Channel Amplitude:

Turn Channel 1 or 2 clockwise. Slowly turn the channel control until you reach the setting recommended by your medical professional. Repeat for the other channel if both channels are to be used.

Caution: If the stimulation levels are uncomfortable or become uncomfortable, reduce the stimulation intensity to a comfortable level and contact your physician if problems persist.

5.10 Turn Unit Off:
Turn both Channel Amplitude controls to "OFF" . Unplug the electrode lead wires, grasping them by the plug, not the cord. If treatment will be resumed shortly the electrodes may be left on the skin. When the electrodes are removed, clean the skin thoroughly with mild soap and water. If there is skin irritation, consult your medical professional.

CARE AND MAINTENANCE

5.11 Portability:
Your unit is portable and may be clipped to a belt, shirt pocket, bra or other clothing.

5.12 Battery:
To replace battery, open the lid cover and extract the battery. Replace with a 9 V alkaline or similar rechargeable battery. Make sure you insert the battery correctly.

5.13 Care of Electrodes:

To avoid skin irritation and ensure good contact with your skin, clean silicone rubber electrodes with soap and water frequently. The electrodes must be dried completely before using.

❋ ***If you are using self-adhesive electrodes, disregard this procedure.***

❋ ***Always use the electrodes with the requirements of the EN60601-1 and EN60601-2, such as with CE mark, or are legally marketed in the US under 510(K) procedure.***

5.14 Care of Electrode cords:

Clean the electrode cords by wiping them with a damp cloth. Coating them lightly with talcum powder will reduce tangles and prolong the life.

6. DO'S AND DON'TS

A. DO:

1. DO place the electrodes only as your clinician recommends.
2. DO keep the stimulator clean.
3. DO see your clinician if you have any problems or questions regarding your system.
4. DO clean the cables only with water and mild soaps. DO NOT use rubbing alcohol or any other solvents.
5. DO remove the electrodes and discontinue stimulation if you experience skin irritation, until the source of that irritation is determined by your clinician.
6. DO turn both intensity knobs to "OFF" before replacing the battery.

B. DON'T:

1. DO NOT damage your stimulator by bumping, dropping, or rough use.
2. DO NOT engage in contact sports when using your stimulator.
3. DO NOT get the stimulator wet. However, a damp cloth may be used for cleaning the outside only.
4. DO NOT pull or kink the cables.
5. DO NOT clean the cables with alcohol or Freon.
6. DO NOT allow electrode gel to get into the connector holes of the electrodes. DO NOT allow the electrodes to touch each other during stimulation or improper stimulation and poor battery life will result.
7. DO NOT give the device to other individuals.
8. DO NOT store the unit at temperatures less than 32°F (0°C) or over 158°F (50°C).

7. HANDLING AND STORAGE

Keep this device in the carrying case and store at room temperature.

8. ACCESSORIES

Self-Adhesive Electrodes	4 PCS.
9 V Battery	1 PC.
Lead Wires	2 PCS.
Instruction Manual	1 PC.

9. TROUBLESHOOTING

If your unit does not seem to be operating correctly, refer to the chart below to determine what may be wrong. Should none of these measures correct the problem, the unit should be serviced.

• The power indicator lights up, but unit does not function properly.	• "On" and "Battery Light" are dim.	• None of indicators light up.
1. Check all control settings. Are they set to values prescribed by your medical professional? 2. Are electrodes in proper position? 3. Check lead wires. Be sure all connectors are firmly sealed. 4. Replace cord set with another to check for broken wires.	1. Replace battery with a new one.	1. Replace battery with a new one.

10. WARRANTY

* Unit: One year (12 months) from the date of the original consumer purchase.
* Accessories (consisting of lead wire, AC adapter, electrodes, carrying case, and belt clip): 90 days from the date of original consumer purchase.

To obtain service from Chattanooga Group or the selling dealer under this warranty, a written claim must be made within the warranty period to Chattanooga Group or the selling dealer.

Chattanooga Group shall not be held liable in any event for incidental or consequential damages. Some states do not allow exclusion or limitation of incidental or consequential damages so the above limitation or exclusion may not apply to you.

4717 Adams Road
Hixson, TN 37343 U.S.A.
1-800-592-7329 U.S.A.
1-800-361-6661 CANADA
+1-423-870-7200 Outside U.S.A.
+1-423-870-2046 Outside U.S.A. FAX
www.chattgroup.com

CE
0413

77391A

2003 Encore Medical