

NeuroMove®

PATHWAY TO RECOVERY



• USER'S MANUAL

NeuroMove® NM900

ZYNEX
NeuroDiagnostics

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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 Safety, the NeuroMove® is classified as follows:

· **Type BF Equipment**

Protection against electric shock, particularly regarding allowable leakage current. A BF-Type applied part is one that is floating above ground and is isolated from all other parts of the equipment. A Type BF piece of equipment is one that provides a particular degree of protection.

- **Internally Powered Equipment**

The NeuroMove® is classified as an internally powered device. Use only with supplied battery charger. Input range: 100-240 VAC, 50-60 Hz. Output: 12 VDC, 500 mA.

- **Electromagnetic Compatibility**

Conforms to IEC 60601-1-2.

- **Temperature**

Operating temperature range: 0° - 50° C (32° - 122° F).

Transport & storage temperature range: -20° - 70° C (-4° - 158° F).

- **Humidity**

Operating relative humidity range: 0 – 95%, non condensing.

Transport and storage relative humidity range: 0 – 95%, non condensing.

- **Pressure**

Operating pressure range: 500 – 1060 hPa.

Transport and storage pressure range: 500 – 1060 hPa.

- **Water Ingress**

Ordinary equipment. This device has protection against Ingress of water.

- **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.

- **Disinfection**

The enclosure and patient cable may be disinfected and cleaned with a 70% isopropyl alcohol solution.

The NeuroMove 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 surface clean. Rinse off the soap. 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.



· Symbols

Symbols marked on the device are defined below.



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



Attention, consult accompanying documents. The operator must read, understand, and follow all instructions in the accompanying documents including all warnings, cautions, and precautions before using the medical device.



Standby/On. 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 charger input, unplug the power cord of the supplied AC adapter from the AC mains receptacle.



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.



Refer to Instruction Manual/ Programming Guidelines

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

Warnings

- The device does not function as a medical device when external battery charger is plugged in and battery is being recharged.
- The device does not incorporate a power switch to isolate the system from the AC mains. Unplug the power cord of the AC battery charger from the AC mains outlet in order to positively disconnect from the AC mains.
- The 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 2 watts/cm^2 with recommended electrodes, assuming a $1 \text{ K}\Omega$ load.
 - 1" round: Maximum stimulation setting = 28 mA
 - 2" round: Maximum stimulation setting = 100 mA
 - 2" square: Maximum stimulation setting = 100 mA
- Output waveform/power information

When delivering stimulation energy, the NeuroMove® is a constant current output device. Therefore its output voltage, current, and power is dependent upon the load as well as the pulse width and frequency of the output waveform. The maximum peak voltage that the NeuroMove® can produce is 100 V (1 K Ω load). The maximum peak current that the NeuroMove® can produce is 100 mA (1 K Ω load). The maximum output power that the NeuroMove® can produce is 1.28 W (1 K Ω load).

 - Maximum peak output voltage (1 K Ω load) = 100 V
 - Maximum peak output current (1 K Ω load) = 100 mA
 - Maximum peak output voltage (500 Ω load) = 50 V
 - Maximum peak output current (500 Ω load) = 100 mA
 - Maximum peak output voltage (2 K Ω load) = 100 V

- Maximum peak output current (2 K Ω load) = 50 mA
 - Pulse width range: 50 - 400 μ s
 - Pulse frequency range: 2 - 160 Hz
 - Maximum RMS voltage (1 K Ω load) = 35.78 V
 - Maximum RMS current (1 K Ω load) = 35.78 mA
 - Maximum output power (1 K Ω load) = 1.28 W
 - Maximum RMS voltage (500 Ω load) = 17.89 V
 - Maximum RMS current (500 Ω load) = 35.78 mA
 - Maximum output power (500 Ω load) = 0.64 W
 - Maximum RMS voltage (2 K Ω load) = 35.78 V
 - Maximum RMS current (2 K Ω load) = 17.89 mA
 - Maximum output power (2 K Ω load) = 0.64 W
-
- The device is capable of generating currents and voltages in excess of 10 mA RMS and 10 V RMS, respectively, into a 1000 Ω load as shown above. A yellow LED indicator is provided on the front panel to show that the unit is delivering energy for any non-zero value of stimulation output (1-100 mA).

- Patients with an implanted electronic device (for example a cardiac pacemaker) shall not be subjected to stimulation unless specialist medical opinion has first been obtained.
- Stimulation shall not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
- 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.
- The safety of this device for use during pregnancy or birth has not been established.
- This device shall only be used under the continued supervision of a trained physician.

- This device does not have a curative value.
- 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 shall not be applied over swollen, infected or inflamed areas of skin, eruptions, e.g. phlebitis, thrombophlebitis, varicose veins, etc.
- Stimulation shall not be applied over, or in proximity to, cancerous lesions.
- **STRANGULATION HAZARD.** The lead wire included with this product presents a potential strangulation hazard. Keep this cord out of the reach of children.

Indications for Use

- Maintaining or increasing range of motion for stroke rehabilitation by muscle re-education.
- Relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, edema reduction.
- Biofeedback and relaxation.

Contraindications

- Receptive or global aphasia to the degree that the patient cannot understand the process involved in using the NeuroMove®.
- Powered muscle stimulators shall not be used on patients with cardiac demand pacemakers.
- Powered muscle stimulators shall only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.
- Powered muscle stimulators shall not be used on carotid sinus (neck) region or transcerebrally (through the head).
- Powered muscle stimulators shall not be used whenever pain syndromes are undiagnosed until etiology is established.

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 have been reported with the use of powered muscle stimulators.

Maintenance and Calibration

- Do not remove the cover. There are no user serviceable parts. Refer all service to authorized Zynex® Medical personnel.
- No preventative inspections are required. Factory testing ensures equipment accuracy and response.

Introduction

The NeuroMove® has been developed to combine the beneficial effects of both biofeedback and muscle stimulation in assisting patients to regain a measure of control of affected limbs after the occurrence of a stroke.

Electrodes are attached to the muscles to be treated and connected to the NeuroMove®. The electrodes pick up the electrical signals (EMG) which the patient's brain sends to the muscle with the intent of carrying out a particular movement. If this signal is not of sufficient strength to innervate the muscle, very little movement will occur. The purpose of the NeuroMove® is to detect this low level signal and reward the patient with a movement that provides a visual muscle contraction as well as sensory feedback.

The NeuroMove® also prompts the patient to relax after each successful attempt. The effect of relaxing the muscle on demand is not only reduced tone, but also an additional voluntary control.

This method of relearning muscle control has been shown to motivate the patient to even greater performance and to significantly speed the rehabilitation process of increasing control and range of motion.

The NeuroMove® has been designed to operate with a three electrode format. Both stimulation and biofeedback are performed through the same two electrodes. The third electrode acts as a reference point for the monitoring of the EMG.

The NeuroMove® automatically senses the natural EMG activity of the patient when attempting to contract a muscle and will set this level as the threshold at which the electrical stimulation will be introduced to reinforce the contraction. Each improved “attempt” results in a gradual increase in the threshold level at which the “reward” of stimulation occurs. The NeuroMove® will also sense when the patient tires and will adjust the threshold level downward accordingly.

Patient Requirements

Patients should be motivated for treatment, cognitively intact, and be able to follow instructions.

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.

The NeuroMove® is intended to be used with re-usable, self-adhesive electrodes. Extended numbers of uses can be obtained by adding water to the adhesive surface immediately after each use and placing them on the plastic pad. They will retain their conductivity and adhesiveness as compared to leaving them dry.

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

Follow directions of the prescribing physician.

WARNING

The NeuroMove® is **PRESET** with defaults.
(Settings generally applicable to most patients).

DO NOT CHANGE SETTINGS without first consulting
the separate **Programming Manual**.

If settings are accidentally changed, please call
Patient Care at **800-495-6670**

Using Your NeuroMove®

1. Plug the lead wire into the mating connector on the back of the unit. Connect the black electrode to the black pin of the EMG cable. Connect the two red electrodes to the two red pins of the EMG cable.
2. Remove the plastic pads from the back of each electrode.
3. Place the two, red electrodes one inch apart over the muscle to be exercised, while the black is placed near but not touching the other two electrodes.
4. Turn the unit on with the standby/on button.
5. Using the ↑ button, increase the stimulation to the point where a visible yet comfortable contraction of the muscle occurs. **It is important to set a level that makes a visible contraction.** The unit will prompt the user to increase the stimulation to at least 10 mA. **Note: A yellow LED on the front panel illuminates whenever the stimulation level is greater than 0 mA.**
6. **RELAX** and attempt to drive the signal level bars in the display down lower until the display changes to **READY**.

7. **CONCENTRATE** and think about moving the muscle. **IMAGINE** that it actually happens. **WATCH** the signal level columns in the display window increase towards the threshold. Initiate as much movement as possible. The threshold will automatically adjust to a level that is not too difficult to attain.
8. If a signal level is produced by the patient that is equal to or greater than the threshold level, the NeuroMove® will respond by outputting electrical stimulation to produce a muscle contraction (reward).
9. Repeat steps 6-8 for 20-30 minutes.

While exercising, you should be in a quiet, comfortable environment without distractions.

Please call 1-800-495-6670 and a Patient Care Representative will help you get started with your first session.

Battery Maintenance

The NeuroMove® has a built-in, rechargeable battery. The battery comes pre-charged from the factory. The unit can be operated for about 50 hours before recharging is required.

To recharge the battery, plug the AC adapter into a wall socket then connect the small cylindrical plug to the mating jack on the back of the NeuroMove.

Recharging takes four to nine hours depending upon the extent of discharge. It is recommended that the battery be recharged overnight once every 2-3 weeks.

Note: For safety reasons, the unit cannot be operated while the battery is charging.

Please dispose of used batteries properly.

Treatment Time, Frequency, and Duration

- Treatment Time: 15-30 minutes.
- Treatment Frequency: Once a day building to 2 times per day.
- Overall Treatment: 4-8 months or until the patient reaches a plateau.

The frequency of treatments is not limited and can improve outcome. For example, 3-4 times per day at 15-30 minutes.

However, each treatment should **not** exceed 30 minutes.

When using the NeuroMove®, the muscle contraction (reward) must be set first!

This is done by pressing the Up button a number of times, typically to a level above 9 mA. See display for level. A strong, visible, yet comfortable, contraction of the muscle must be present.

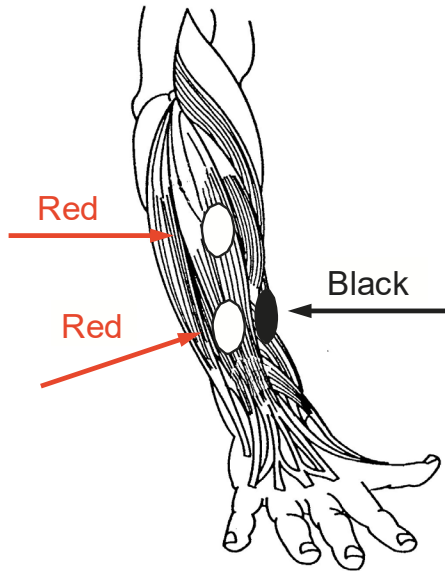
Stimulation Parameter Changes:

Please call our support hot-line at (800) 495-6670 if it's desirable to change parameters.

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User/Patient Protocols

Wrist and Finger Extension



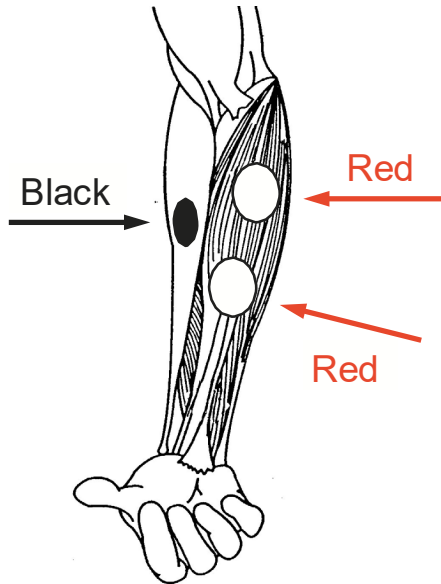
Patient Position:

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 red electrode on the top of the forearm (extensor group), one inch from the elbow crease.
- Place the other red electrode one inch below the first red electrode.
- Place the black electrode near, but not touching, the other electrodes.
- **Exact electrode placement may require some trial and error using low level stimulation.**

Wrist and Finger Flexion



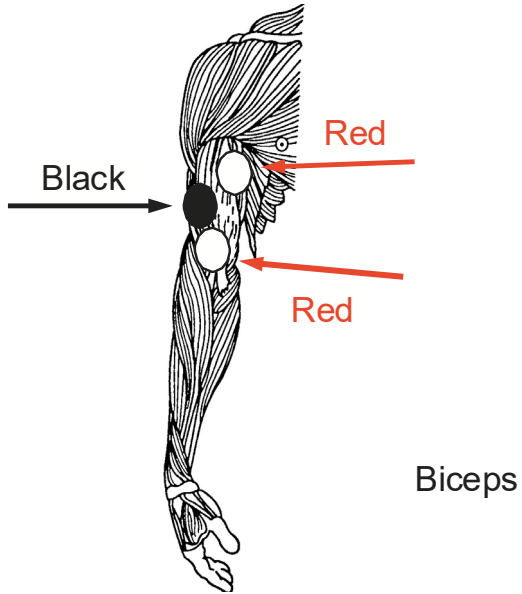
Patient Position:

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 red electrode on the bottom of the forearm (flexor group), one inch from the elbow crease.
- Place the other red electrode one inch below the first red electrode.
- Place the black electrode near, but not touching, the other electrodes.
- **Exact electrode placement may require some trial and error using low level stimulation.**

Elbow Flexion - Front



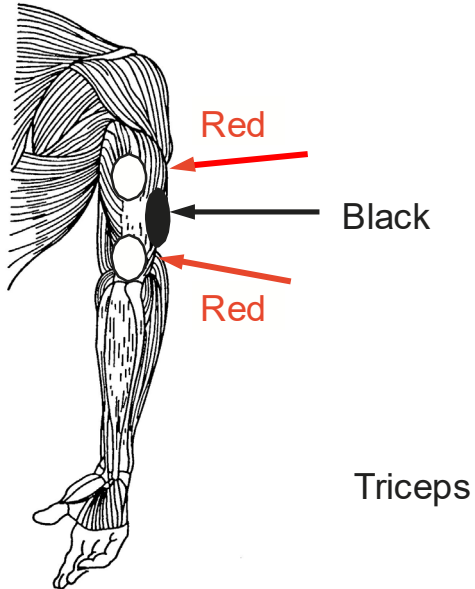
Patient Position:

Standing or sitting with the affected arm draped off to the side of the chair.

Electrode Placement:

- Place one red electrode high on the biceps muscle (front of upper arm).
- Place the other red electrode two inches above the elbow crease.
- Place the black electrode near, but not touching, the other electrodes.
- **Exact electrode placement may require some trial and error using low level stimulation.**

Elbow Extension - Back



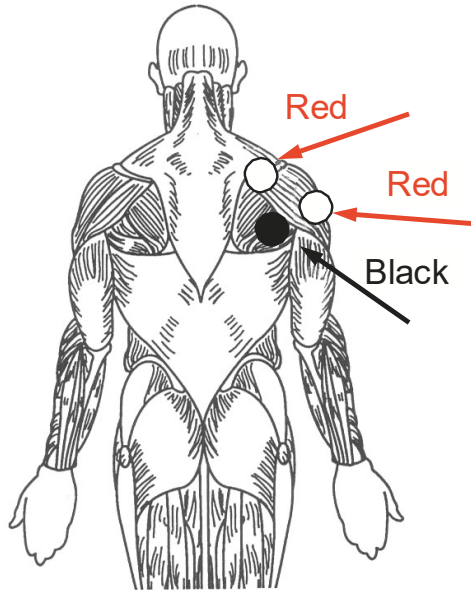
Patient Position:

Standing or sitting with the affected arm draped off to the side of your chair.

Electrode Placement:

- Place one red electrode high on the triceps muscle (top back, inner arm, but *not armpit*).
- Place the other red electrode just above the elbow.
- Place the black electrode near, but not touching, the other electrodes.
- **Exact electrode placement may require some trial and error using low level stimulation.**

Shoulder Subluxation / Abduction



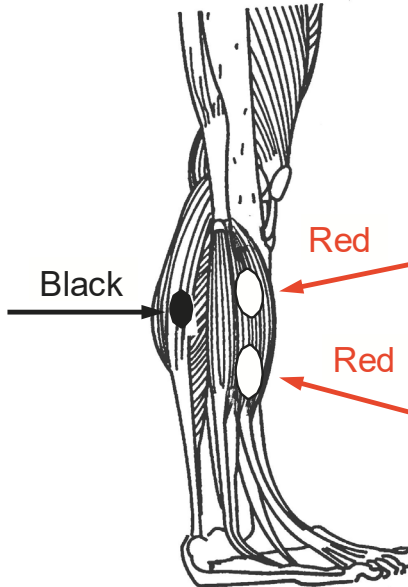
Patient Position:

Sitting or standing with the affected arm draped at the side.

Electrode Placement:

- Place one red electrode above the shoulder blade (supraspinatus).
- Place the other red electrode on the middle of your upper arm near the shoulder (middle deltoid).
- Place the black electrode near, but not touching, the other electrodes.
- **Exact electrode placement may require some trial and error using low level stimulation.**

Ankle Dorsiflexion (Drop Foot) / Flexion



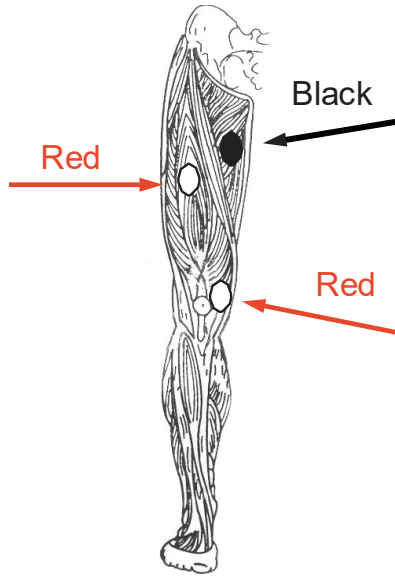
Patient Position:

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 red electrode high on the outside of lower leg 3-4 inches below the knee and 1 inch away from the shinbone.
- Place the other red electrode two inches below the first red electrode.
- Place the black electrode near, but not touching, the other electrodes.
- **Exact electrode placement may require some trial and error using low level stimulation.**

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 red electrode high on the mid-outer thigh.
- Place the other red electrode on the inner thigh three inches above the knee.
- Place the black electrode near, but not touching, the other electrodes.
- **Exact electrode placement may require some trial and error using low level stimulation.**

**To order
NeuroMove Electrodes please call Patient
Care at
1-800-495-6670 or
E-mail us at info@zynex.com**

NeuroMove®

PATHWAY TO RECOVERY

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Manufactured by Zynex Medical for



300420, Rev 6.0