

NeuroMove[®]

PATHWAY TO RECOVERY



NeuroMove[®] NM900

PROGRAMMING GUIDELINES

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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**

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

• **Medical Device Directive (MDD) Classification**

The NeuroMove® is a Class IIb medical device per the European Medical Device Directive.

• **Internally Powered Equipment**

The NeuroMove® is classified as an internally powered device. Note: 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)

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.



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/cm² which may require special attention of the operator.

Do not exceed 2 watts/cm² with recommended electrodes, assuming a load of 1000 Ω.

- 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 KΩ load). The maximum peak current that the NeuroMove® can produce is 100 mA (1 KΩ load). The maximum output power that the NeuroMove® can produce is 1.28 W (1 KΩ load).

- Maximum peak output voltage (1 KΩ load) = 100 V
- Maximum peak output current (1 KΩ 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 KΩ load) = 100 V
- Maximum peak output current (2 KΩ load) = 50 mA
- Pulse width range: 50 - 400 μs
- Pulse frequency range: 2 - 160 Hz
- Maximum RMS voltage (1 KΩ load) = 35.78 V
- Maximum RMS current (1 KΩ load) = 35.78 mA
- Maximum output power (1 KΩ 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 KΩ load) = 35.78 V
- Maximum RMS current (2 KΩ load) = 17.89 mA
- Maximum output power (2 KΩ 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) should not be subjected to stimulation unless specialist medical opinion has first been obtained.

Stimulation should 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 1 m) 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 should 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 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.

Simultaneous connection of a patient to high frequency surgical equipment may result in burns at the stimulator electrodes and possible damage to the stimulator.

Operations within close proximity (with one meter) of shortwave or microwave therapy equipment may produce instability in the stimulation output.

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.
- Biofeedback and relaxation.

Contraindications

Receptive or global aphasia to the degree that the patient can not understand the process involved in using the NeuroMove®.

Powered muscle stimulators should not be used on patients with cardiac demand pacemakers.

Powered muscle stimulators should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

Powered muscle stimulators should not be used on carotid sinus (neck) region or transcerebrally (through the head).

Powered muscle stimulators should 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 should be used only with the leads and electrodes recommended for use by the manufacturer.

This device 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 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.

Programming the NeuroMove®

Settings normally do not need to be adjusted. See below on how to change from the default Stroke Rehab mode to the more sensitive Spinal Cord Injury (SCI) mode.

The unit is programmed by stepping through the various programming functions. Each programming function is described in sequence below. To program a particular function, press the Program button in sequence until the desired function is displayed. Pressing the Program button in consecutive fashion will skip over any programming functions that are not desired. To exit the programming mode, consecutively press the Program button until the programming mode is exited.

Note: The unit will automatically exit the programming mode after 20 seconds if a key press is not detected.

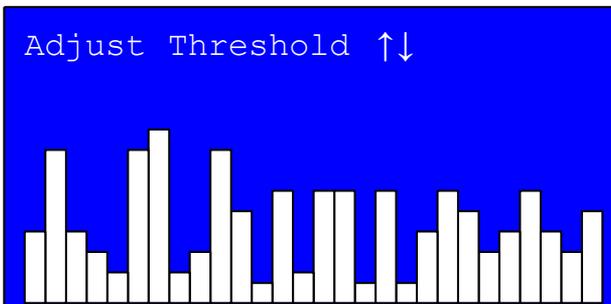
Adjust Threshold

To change the threshold, press the program button once.

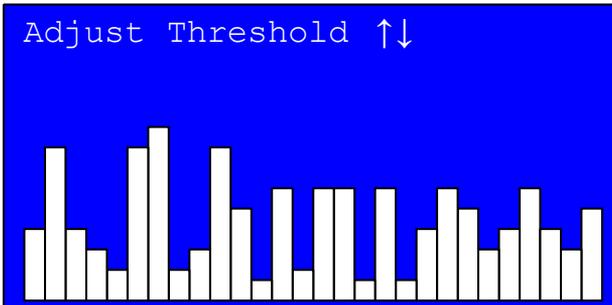
The threshold is the signal level at which stimulation is triggered. If the patient is able to produce enough signal strength to meet or exceed this threshold, an electrical muscle stimulation signal will be fed to the electrodes in order to produce a contraction.

The threshold is shown by a horizontal line on the display. In Stroke Rehab and SCI modes the threshold is automatically adjusted upward or downward every 15 seconds in order to track the patient's progress. In Manual mode the threshold remains at a fixed level. See Operational Modes setting below.

To increase the threshold, press the Up button. The threshold will increase as shown below.



To decrease the threshold, press the Down button. The threshold will decrease as shown below.

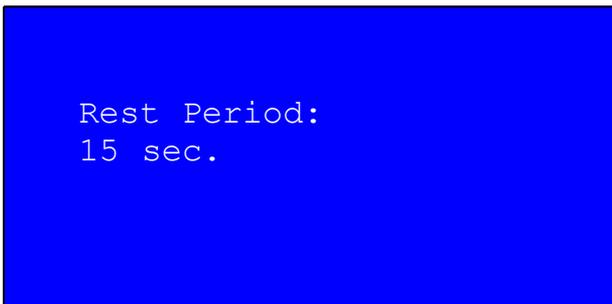


When in Stroke Rehab or SCI mode, the threshold will adjust automatically during the next sampling period (15 seconds). In Manual mode the threshold will remain as set. See Operational Mode settings below.

Rest Period

To change the rest period, press the program button once again.

The rest period is the time after stimulation ends during which the patient is encouraged to relax as much as possible. The rest period can be adjusted in the range from 0.1 - 60 seconds. The default is 15 seconds. Note: the word "Relax" flashes in the upper right corner of the display during the rest period.



To increase the rest period, press the Up button. To decrease, press the Down button.

Operational Modes

To change the operational mode, press the program button once again.

The NeuroMove® has four different operational modes.

Stroke Rehabilitation

This is the normal mode for the NeuroMove®. It has good low-level sensitivity and a wide dynamic range. The range is 1.25-1000 microvolts (58 decibels). It is intended primarily for stroke rehabilitation.

SCI (Spinal Cord Injury)

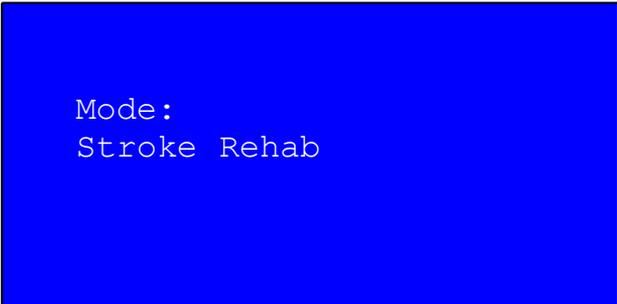
This mode is similar to Stroke Rehabilitation but has more low-level sensitivity and less range. It is intended primarily for spinal cord injury rehabilitation. There are two sensitivity ranges available: 0.25-25 microvolts (40 decibels) and 0.50-50 microvolts (40 decibels). See Change Parameters programming below for range selection procedure.

Manual

This mode is similar to Stroke Rehabilitation, but requires manual setting of the threshold.

Stim Only

In this mode, the unit acts like a stimulator only. See “Operational Modes Descriptions” below.

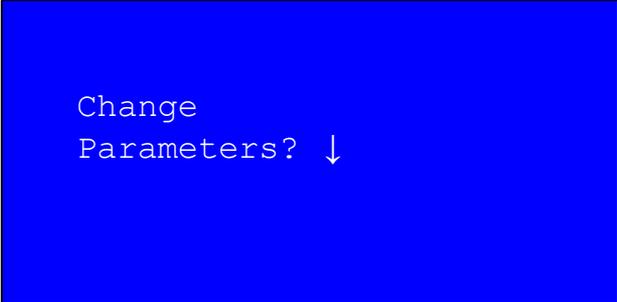


Mode:
Stroke Rehab

Use Up and Down buttons to select the desired mode.

Change Parameters

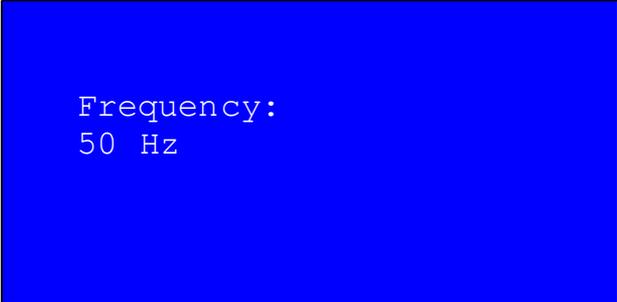
To change parameters, press the program button once again. Then press the Down button.



Change
Parameters? ↓

Frequency

The frequency is the rate at which stimulation pulses are sent. For example, for a 50 Hz frequency, pulses are sent at a rate of 50 per second or one every 0.020 seconds. The frequency can be selected in the range of 2 - 160 Hz. The default is 50 Hz.



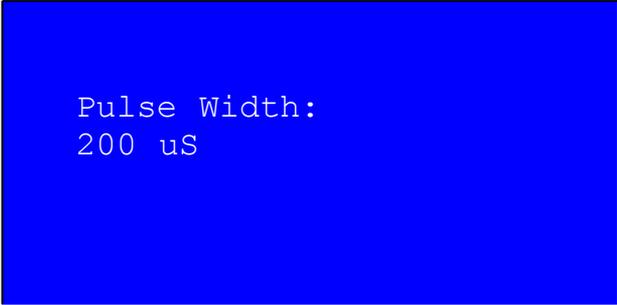
Frequency:
50 Hz

To increase the frequency, press the Up button. To decrease, press the Down button. This parameter normally does not need to be changed by the user.

Pulse Width

To change the stimulation pulse width, press the program button once again.

The pulse width can be selected in the range from 50 - 400 μs (microseconds) in 5 microsecond increments. The default is 200 microseconds. This parameter normally does not need to be changed by the user.



```
Pulse Width:  
200 uS
```

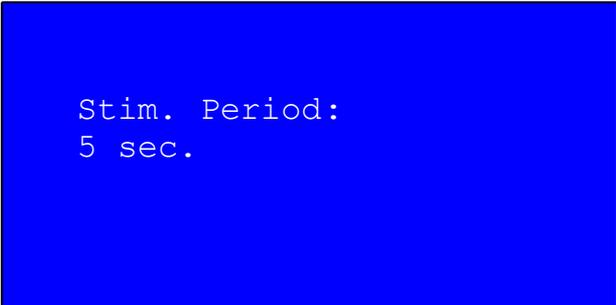
To increase the pulse width, press the Up button. To decrease, press the Down button.

Stimulation Period

To change the stimulation period, press the program button once again.

The stimulation period is the time during which unit delivers electrical energy to the patient to create a muscle contraction. The stimulation time can be selected in the range from 0.5 - 30 seconds. The default is 5 seconds.

Note: the word "Stim" along with the intensity appears in the upper left corner of the display during the stimulation period.



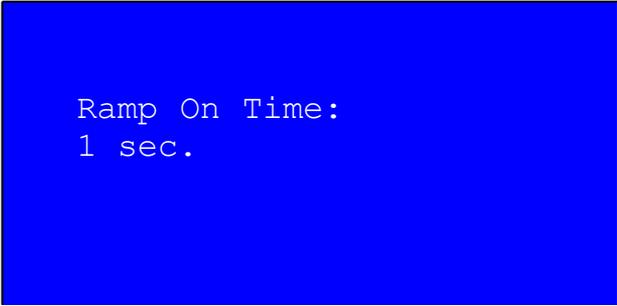
```
Stim. Period:  
5 sec.
```

To increase the stimulation period, press the Up button. To decrease, press the Down button.

Ramp-On Time

To change the ramp on time, press the program button once again.

When stimulation is initially delivered to the patient, the output pulse level increases from zero to full intensity during a specified period of time. This effect provides a more comfortable transition for the patient rather than delivering full output from the beginning. For example, if the ramp on time is one second, it takes one second for the output pulse level to increase from zero intensity to full intensity. The ramp-on time is adjustable in the range from 0.1- 6 seconds. The default is one second. This parameter normally does not need to be changed by the user.



```
Ramp On Time:  
1 sec.
```

To increase the ramp on time, press the Up button. To decrease, press the Down button.

Ramp-Off Time

To change the ramp off time, press the program button once again.

Similar to ramp on time, when the stimulation period is over, the unit gradually turns off the intensity from full intensity to zero during a specified period of time. For example, if the ramp off time is one second, it takes one second for the output pulse level to decrease from full intensity to zero intensity. Again, this effect provides a more comfortable transition for the patient rather than abruptly removing the stimulation. The ramp-off time is adjustable in the range from 0.1 - 6 seconds. The default is one second. This parameter normally does not need to be changed by the user.



Ramp Off Time:
1 sec.

To increase the ramp off time, press the Up button. To decrease, press the Down button.

Sensitivity Range

To change the sensitivity range, press the program button once again.

The sensitivity range describes the range of signal levels from the patient that the NeuroMove® can detect.

When in Stroke Rehab operational mode there is only one range, 1.25 – 1000 μV (microvolts). Switch to SCI operational mode if Stroke Rehab is not sensitive enough (displayed signal levels are at a very low level or bottomed out).

In SCI mode, two ranges are selectable: 0.25 - 25 μV and 0.50 - 50 μV . Use the latter if the former is too sensitive (levels are reaching maximum).



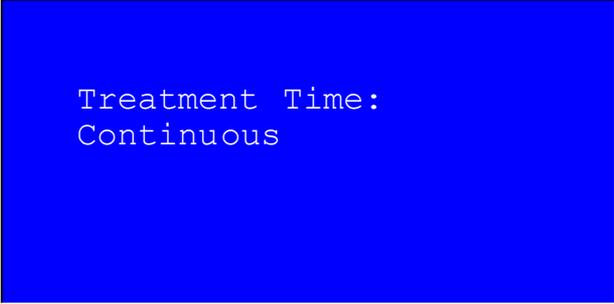
Sensitivity:
1.25-1000 μV

Press the Up or Down key to select the desired range.

Treatment Timer

To change the treatment time, press the program button once again.

The NeuroMove® can time therapy sessions. The selectable treatment times are from 10 - 90 minutes, in ten-minute increments. The default time is continuous. The unit will automatically shut off after the selected amount of time. In continuous mode, the unit never turns off.



Treatment Time:
Continuous

To increase the treatment time, press the Up button. To decrease, press the Down button.

Set Defaults

To set the factory defaults, press the program button once again.

If any of the parameters are mistakenly set, the NeuroMove® provides a way to return to factory default conditions.



Set Defaults? ↓

To set defaults press the Down button. The display will show “DefaultsSet”.

Press the programming button again to exit the Change Parameters subfunction.

Battery Charge Status

The charge state of the built-in, rechargeable, 7.4 V, 2000 mAh, lithium-ion battery is provided during charging or discharging. The battery is charging when the AC adapter is plugged in. The battery is discharging when the AC adapter is not plugged in. The value provided indicates percentage of full charge. 100% means that the battery is fully charged. It is recommended to charge the battery at least once every 2-3 weeks.

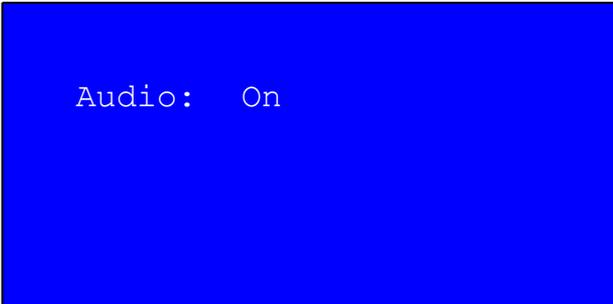
A screenshot of a blue screen with white text. The text reads "Battery" on the first line and "Charge: 100%" on the second line.

Battery
Charge: 100%

Audio Enable

To disable or enable audio prompts, press the program button once again.

The NeuroMove® provides audio prompts to help guide the user in the operation of the machine. See the “Audio Prompts” section for a detailed explanation of each audio prompt. Audio prompts are on by default.

A screenshot of a blue screen with white text. The text reads "Audio: On".

Audio: On

Press the Up or Down button to turn audio prompts on or off.

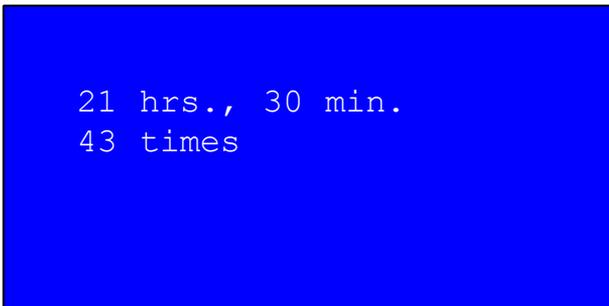
Compliance Data

To view the compliance data, press the program button once again.

The unit keeps track of the number of times and amount of time it's been used at stimulation level greater than 5 mA (milliamps).



Press the Down button to view the compliance data.



Press the Programming once again to exit the programming mode. The display will show "Restarting Ready Mode..."

Operational Mode Descriptions

The NeuroMove® has four operational modes. Three of the modes Stroke Rehab, SCI, and Manual are EMG triggered neuro-muscular stimulator modes. The fourth, Stim-Only, is a neuromuscular stimulator-only mode.

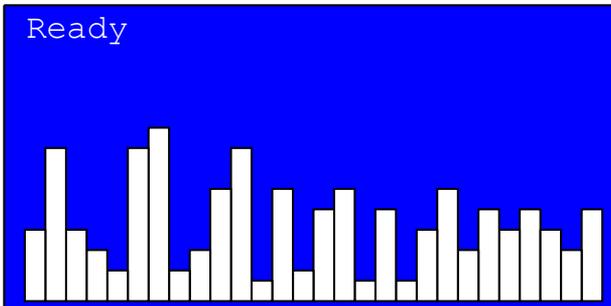
Stroke Rehabilitation Mode

Electrodes are attached to the target muscle group to be monitored and exercised. The electrodes detect minute electrical signals generated by the patient in an effort to move the limb controlled by the monitored muscle group. The signals are shown on the unit's graphic display in the form of vertical columns. The higher the column, the higher the signal level detected. A new column is added to the display every half second. The display is right-justified. I.e., new columns are added to the right-most column of the display after previous columns have been shifted to the left by one. Since the display is 120 columns wide, the display shows the last 60 seconds of history at any time.

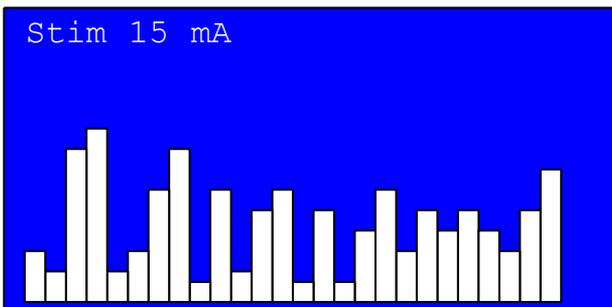
A horizontal "threshold" line is drawn across the display. This denotes the level at which the unit is "triggered" to deliver an electrical stimulation signal to the monitored muscle group. Triggered means that the detected signal level from the muscle group monitored is either equal to or greater than the signal level indicated by the horizontal threshold line. When triggered, one stimulation cycle is delivered by the unit.

The therapy cycle consists of three phases: Ready, Stimulation, and Rest. During the Ready phase the system is monitoring the target muscle group for electrical impulses indicating movement attempts. The signal levels detected are represented as vertical columns on the display. This phase represents what is known as biofeedback. The patient sees what he's accomplishing on the display and therefore can adjust his efforts in an attempt to exert harder and thus attain higher signal levels.

During the Ready phase, the threshold tracks the patient's progress. For example, the threshold will automatically drop if the patient's generated signal strength drops as shown below.



The Stimulation phase occurs when the patient has accomplished his goal. I.e., he has triggered the unit. He has produced a movement signal greater than or equal to the threshold and has thus initiated one stimulation cycle. At this point the unit will deliver a stimulation signal of programmed shape to the electrodes for a programmed period of time.

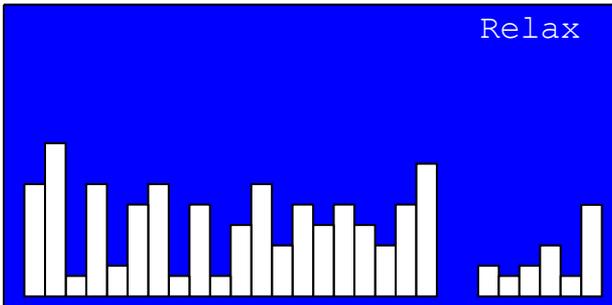


When the unit is triggered twice, the threshold is raised. Note that during automatic adjustment of the threshold, it can only be raised if the patient triggers the unit. During the Stimulation phase the threshold becomes dotted indicating that EMG monitoring has been disabled. Thus EMG levels are not displayed during this phase as shown above.

This phase represents a form of Pavlovian conditioning. I.e., assuming that the externally derived muscle contraction is the "reward", the patient will hopefully become conditioned to receiving the reward. He will become conditioned to making movements so that he can obtain a contraction. The goal is that, over time, the patient will become more and more proficient at creating his own movements rather than requiring the externally produced contraction.

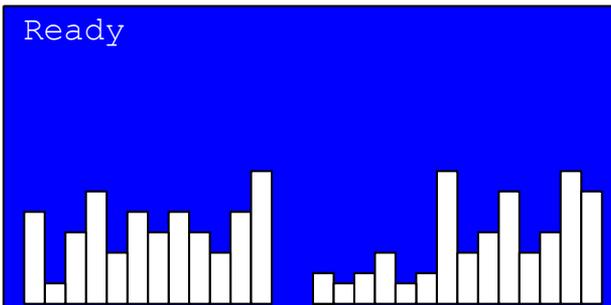
The Rest phase occurs after the cessation of the externally produced, muscle contracting, stimulation signal. During this phase, the patient is urged to do the opposite of what he was trying to do during the Ready phase.

I.e., relax to the point where the displayed signal levels are actually dropping. This phase will last for a programmed amount of time after which the unit will return to the Ready mode and cycle will begin all over again.



During the Rest phase the threshold remains dotted, but EMG levels are again displayed. As with the Ready phase, biofeedback principles are at work here. In this case, the patient again can see what he's accomplishing on the display in terms of driving down the signal and therefore can relax accordingly in order to lower the displayed signal levels.

When the Rest phase has completed, the system returns to the Ready phase and cycle begins all over again. The patient then returns to the mode where he is trying to "raise the bar". I.e., he again exerts and imagines movement as much as possible in order to retrigger the unit. Hopefully, retrigger can occur at a higher level than was previously attained.



SCI Mode

This mode is similar to Stroke Rehab mode except that the unit is more sensitive to input signals from the electrodes. The compromise is that the range is somewhat limited as compared to Stroke Rehab mode. In Stroke Rehab mode the detectable input signal range is 1.25 - 1000 microvolts. In SCI mode, two ranges are selectable: 0.25 - 25 microvolts and 0.50 - 50 microvolts. Most of the time, Stroke Rehab mode provides enough sensitivity. In those instances where more sensitivity is needed, SCI mode can be used.

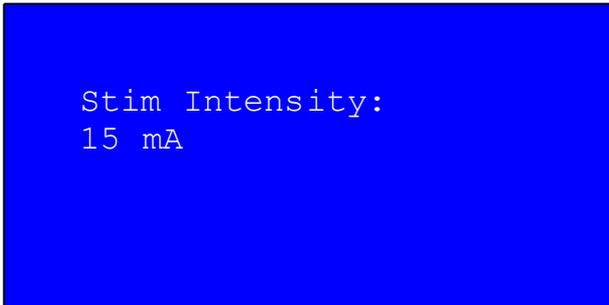
The Ready, Stimulation, and Rest phases are the same as Stroke Rehab mode. The only difference is that for a given signal level detected in the Ready or Rest modes, the vertical column will be higher in SCI mode as compared to Stroke Rehab mode.

Manual Mode

This mode is similar to Stroke Rehabilitation mode, but requires manual setting of the threshold. Set the threshold in the programming mode as described in the section “Programming the NeuroMove®” above. In Manual mode, the threshold does not automatically adjust up or down as in Stroke Rehab mode. The Ready, Stimulation, and Rest phases are the same as Stroke Rehab mode.

Stimulation-Only mode

In this mode, the unit acts as a neuro-muscular stimulator only. I.e., it does not need to be triggered to produce stimulation. In effect it continuously repeats the Stimulation and Rest phases of the normal therapy cycle. There is not a Ready phase since signal levels from the target muscle group are not monitored.



To increase the stimulation intensity, press the Up button. To decrease, press the Down button.

Audio Prompts

The NeuroMove® provides an array of audio prompts to assist the user in the operation of the machine. Audio prompts can be enabled or disabled in the programming mode. See Programming Section above.

- Set stimulation level. Upon turn-on, the unit will produce the prompt “set stim” and repeat it once.

- Increase stimulation level. If the stimulation level is set to 3 mA or above but less than or equal to 9 mA, the unit will produce the prompt “increase stim” and repeat it once. Stimulation levels below 10 mA are typically insufficient to produce muscle contractions and are therefore disallowed by the system.

- Rest (relax) mode. At the onset of the rest phase, the unit says the word “relax” once, prompting the patient to attempt to lower the EMG levels from the monitored muscle.

- Ready mode. At the onset of the ready mode, the unit says the word “ready” once prompting the patient to begin movement of the monitored muscle group.

- Triggered-stimulation mode. If the patient, through muscle exertion, is able to produce an EMG signal level equal to or greater than the threshold, the unit will trigger one stimulation cycle. At the onset of the triggered-stimulation mode, the unit says the word “good” once to inform the patient of his success and that an externally and electrically induced muscle contraction is about to take place.

- Electrode alarm. If during stimulation, the user hears the “check electrodes” prompt he should inspect the electrode placement and ensure that good contact exists between the electrode and skin surface. Refer to the **User’s Manual** for more information on proper electrode placement and maintenance. Note that this message can also indicate a cable fault.

Warranty

The NeuroMove® has a 5 years warranty against product and material defects from the date of delivery. The warranty does not apply to accessories. The warranty provides that the product is used in accordance with the protocol manual.

The warranty does not apply if the defect is due to improper use, changes, or repairs made without the consent of Zynex Medical, Inc.

NeuroMove®

PATHWAY TO RECOVERY

Zynex Medical, Inc.
9555 Maroon Circle
Englewood, CO 80112
USA

Phone:
800.845.1771
303.703.4906

Fax:
800.495.6695
303.347.9153

www.zynex.com

European Representative:
Zynex Europe
Fælledvej 1 Box 19 BDO
DK-5100 Odense C
DENMARK

Manufactured by Zynex
Medical, Inc. for

