

K952273

510(k) SUMMARY

**N.E.S.S. NEUROMUSCULAR ELECTRICAL STIMULATION  
SYSTEMS LTD.'S HANDMASTER NMS1 POWERED  
MUSCLE STIMULATOR**

**Submitter's Name, Address, Telephone Number, Contact Person  
and Date Prepared**

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## **Name of Device and Name/Address of Sponsor**

The HANDMASTER NMS1

N.E.S.S. Neuromuscular Electrical Stimulation Systems Ltd.  
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## **Common or Usual Name**

External Neuromuscular Stimulator

## **Classification Name**

Powered Muscle Stimulator

## **Predicate Devices**

- Dynatronics' DYNATRON 500 (K870947)
- Electro Med Supply, Inc.'s MS-189 Muscle Stimulator (K854801)
- Medtronic, Inc.'s RESPOND II Neuromuscular Stimulator (K813008)
- West Pac Labs, Inc.'s EMS 250 Electronic Muscle Stimulator (K850414)  
(Only for electrodes and intended use)

## **Intended Use**

The N.E.S.S. HANDMASTER NMS1 is intended to be used to exercise the lower arm and hand by activating the muscles thereof with electrical stimulation. As a powered muscle stimulator, the HANDMASTER NMS1 is intended to be used for the following indications: Maintenance or increase of range of motion, reduction of spasticity, prevention or retardation of disuse atrophy, facilitation and re-education of voluntary motor function, and influencing local blood circulation.

## **Technological Characteristics and Substantial Equivalence**

The HANDMASTER NMS1 is a portable, one-channel electrical neuromuscular stimulator for personal use in exercising the upper extremity. The stimulator serves five surface electrodes held on to the upper limb by a splint. The

control unit housing the stimulator may be worn using the shoulder strap provided, or it may be placed on any stable surface. The splint is worn on the hand and forearm. The splint is connected to the control unit by a light cable.

The HANDMASTER NMS1 is used for exercising the hand, conditioning selected muscles of the forearm and hand. It is intended for use by patients suffering from upper limb paralysis due to injury or disease of the central nervous system such as cervical spinal cord injuries or stroke.

A single channel of constant-voltage symmetrical biphasic Russian waveform stimulation is delivered to the muscles through five surface electrodes. Microprocessor-controlled switching of the stimulation between these five electrodes allows the muscles to be activated in combinations either cyclically or continuously. The stimulation is ramped up at the beginning and down at the end of each cycle.

The electrode locations allow the HANDMASTER NMS1 to give finger and thumb extension and flexion. The user can select from five stimulation programs by pressing the mode button on the control unit. The active mode is displayed by a light glowing next to the labeled mode. When the device is stimulating, the light flashes. The stimulation programs are supplied as microprocessor firmware. They comprise either cyclic or continuous activation of the finger and thumb extensors and flexors.

The user can increase or decrease the stimulation intensity in ten discrete levels by pressing on buttons labeled "+" or "-" on the control unit. This alters the duration of the stimulation pulse. The intensity is displayed as a number (0 to 9) on a seven-segment display.

During the initial system set-up, the clinician opens a clinical panel within the control unit. Adjustments are provided for limiting the maximum current to the extensor muscles and to the flexor muscles, along with a global timing factor which increases or decreases the duration of the stimulation cycles, effectively speeding or slowing the cyclic hand motion.

The user starts or stops the stimulation program by pressing a "trigger" button. If required, the user may also stop all stimulation immediately by switching OFF the device.

The HANDMASTER NMS1 splint is used to hold the wrist joint at a comfortable extension angle (20°), and also to hold the electrodes on the forearm and hand segments. It is constructed from fiber-reinforced plastic with soft polyurethane cushion sections to distribute stress over bony regions. The electrodes are made from metal foil coated with carbon-impregnated polymer. Replaceable water-soaked cloth pads are arranged over the electrodes to provide a conductive interface with the skin. A sponge-capped bottle is provided to facilitate wetting of the electrode pads.



Rechargeable nickel-cadmium batteries power the device. Battery status can be displayed both during device operation and while recharging the batteries. Both visual and audio battery-low warnings are provided. It is necessary to disconnect splint/electrodes in order to recharge the batteries, as the same socket is used for both.

The HANDMASTER NMS1 is substantially equivalent to the other currently marketed powered muscle stimulators referenced above. The HANDMASTER NMS1 and its predicate devices have the same intended use, which is to exercise the limb by activating the muscles with electrical stimulation. The HANDMASTER NMS1 and the predicate devices claim similar benefits from this use:

- Maintenance or increase of range-of-motion;
- Reduction of spasticity;
- Prevention or retardation of disuse atrophy;
- Facilitation and re-education of voluntary motor function; and
- Influencing local blood circulation.

Like the HANDMASTER NMS1, the predicate devices are capable of delivering electrical stimulation to surface electrodes positioned on the skin surface of the limb. In addition, the Medtronic RESPOND II claims to coordinate grasp and release. Both the HANDMASTER NMS1 and the predicate devices are operated either in flexion/extension cyclic mode or in a continuous mode.

Both the HANDMASTER NMS1 and the DYNATRON 500 deliver a Russian waveform of electrical stimulation. This waveform is symmetrical, minimizing the possibility of a net current flow through the body. Furthermore, the relative maximum intensity of the various stimulation outputs of the HANDMASTER NMS1 and the predicate devices can best be compared directly by the Maximum Average Current, which takes into account the current amplitude, the pulse duration, and the pulse frequency. The maximum average current output of the HANDMASTER NMS1 lies between the maximum average current outputs of two of the predicate devices, being lower than that of the Electro Med Supply MS-189 but greater than the RESPOND II.

Both the HANDMASTER NMS1 and the DYNATRON 500 are basically constant voltage devices. This feature is particularly desirable for considerations of safety. In the constant voltage device, poor electrode contact results in reduced stimulation current flow. In the constant current device poor electrode contact results in an increase in the current density flowing through the skin resulting in so-called "hot spots".

Both the HANDMASTER NMS1 and the DYNATRON 500 include a firmware-programmed microprocessor. Additionally, both the HANDMASTER NMS1 and the DYNATRON 500 are supplied with carbon-impregnated electrodes.

The Electro Med Supply MS-189 is also supplied with similar graphite-impregnated rubber electrodes.

The HANDMASTER NMS1 can be used with an electrode gel or spray, as is recommended for the DYNATRON 500. However, cloth electrode covers are supplied with the HANDMASTER NMS1 which are soaked with tapwater. The predicate device EMS 250 Electronic Stimulator and the West Pac Labs EMS 250 are similarly equipped with cloth electrode covers which are soaked with tapwater. A further accessory supplied with the HANDMASTER NMS1 is a sponge applicator for wetting the cloth covers. A similar sponge applicator for wetting the cloth covers is also supplied with the EMS 250 Electronic Stimulator. Likewise, the Electro Med Supply MS-189 is also supplied with a sponge applicator for wetting the electrodes with tapwater.

One difference between the HANDMASTER NMS1 and its predicate devices is that the HANDMASTER NMS1 provides a plastic splint to hold the electrodes on to the patient's limb. On the other hand, the DYNATRON 500 uses either a vacuum unit or self-adhesive electrodes, whereas both the Electro Med Supply MS-189 and the West Pac Labs, Inc. EMS 250 supply straps to hold the electrodes to the limb. The use of the splint in the HANDMASTER NMS1 device increases its safety, as it limits the placement of the electrodes to the intended positioning on the forearm and hand, while the electrodes of the predicate devices can be positioned on any part of the body and rely on written warnings not to position the electrodes over potentially dangerous regions such as the carotid sinus.

Another technical difference between the HANDMASTER NMS1 and the predicate devices is that the HANDMASTER NMS1 delivers a single channel of stimulation which is switched between the flexion and the extension electrodes, whereas the predicate devices deliver four separate channels of stimulation, each dedicated to one electrode pair. The use of single-channel switching poses no new issues of safety or effectiveness and may marginally increase safety by eliminating the danger of crosstalk between channels. Thus, the HANDMASTER NMS1 raises no new issues of safety or effectiveness.

## **Performance Data**

Oscilloscope Tracing Specification tests have been carried out on the HANDMASTER NMS1 per Section 1 of the Draft FDA Guidance entitled "Technological Reporting for Powered Muscle Stimulators". This testing measured the stimulator output for the HANDMASTER NMS1 at various intensity levels, output loads and operating modes. The following is a summary of the tests:

The NESS HANDMASTER NMS1 device was connected to a HAMEG HM205-3 oscilloscope. The resulting graphs were passed through a HO79-3.0.2 printer interface to a chart printer.



Device stimulation output was measured at a pure resistive load of 10 K $\Omega$  (+/- 10%). In OPEN mode and with current limiter at zero, the stimulation carrier wave cycle had a duration of 80  $\mu$ S. At the zero intensity level, the stimulation enable signal from the microcontroller is stopped after 100  $\mu$ S, resulting in a tail to the pulse from 100  $\mu$ S to 270  $\mu$ S, where the net charge is balanced. *Note: At zero intensity level the stimulation is generally above the sensory threshold, but below the motor threshold, the device thus produces a slight tingling sensation with no muscle motor response.*

At stimulation intensity levels 0 to 5, the lengthening of the stimulation enable signal from the microcontroller results in the action of progressively more of the first cycle before it is chopped and the charge balancing tail dies away. At level 6, however, a second full cycle manifests. By level 9, five carrier wave cycles form the stimulation pulse.

Measurements were also performed at two other values of pure resistive load: 2 K $\Omega$  and 500  $\Omega$  (+/- 10%). The difference between the output at 2 K $\Omega$  and 10 K $\Omega$  is marginal; however at 500  $\Omega$ , a fall of approximately 30-40% in the voltage output is observed.

Measurements were also performed with a parallel resistor/capacitor as the output load (2 K $\Omega$  and 0.1  $\mu$ F). Again, the waveform remained similar, but a reduction of approximately 60% is observed in the voltage as compared to the pure resistive load of 2 K $\Omega$ .

The open circuit voltage output (200 V baseline to peak) was also measured at intensity level 9 (maximum). Finally, the stimulation output was measured on a far longer time scale for two modes demonstrating the two frequencies at which the HANDMASTER NMS1 operates. On this time scale the cyclic pulse appeared compressed to a single line. The pulse frequency of 36 Hz in the Exercise and Exercise-Open modes and that of 18 Hz in the Open, Grasp, and the Key modes was also visualized.

In all instances, the HANDMASTER NMS1 functioned as intended.

