STIMEL-03 Prescription & Letter of Medical Necessity

Patient Name: _____
Patient Address: _____
City, State ZIP: _____ Patient Phone: _____
Patient e-mail: _____

Physician's Name: _____ DEA or UPIN # _____
Physician Address: _____
City, State ZIP: _____ Physician Phone: _____
Physician Fax _____ Physician e-mail: _____
Please provide ICD9 Code for Patient's Condition: _____
Date of CVA/Stroke Event: _____

Physician Signature: _____ Date: _____

The STIMEL-03 is specifically designed for the rehabilitation of upper and/or lower limbs and is not intended for use on other parts of the body. For optimal results, it is most effective when treatment begins during the stabilized post-stroke phase and within the first 12 months following a stroke. However, significant benefits can still be achieved up to 7 years after a stroke. While prolonged disuse may cause muscle stiffness, recovery remains possible with consistent effort and dedication, leading to meaningful improvement over time.

The FDA has indicated in 510K number K-130424 summaries that STIMEL-03 can be used for:

1. Relaxation of muscle spasms.
2. Prevention or retardation of disuse atrophy.
3. Increasing Local Blood circulation.
4. Stroke Rehabilitation by Muscle Re-education.
5. Maintaining or increasing range of motion.
6. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

CONTRAINDICATIONS

Powered muscle stimulators (Like Stimel-03 medical device) should not be used on patients with active implantable medical devices including cardiac demand pacemakers, implantable pacemakers, implantable cardioverter defibrillators, implantable neuro-stimulators and body worn devices such as insulin pumps.

Please send the signed prescription by one of the following:

- E-mail: wecare@motioninformatics.ai
- WhatsApp: +972-54-9994034
- Fax: +1-407-5041298

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Dear Qualified Health Professional,

I would like to introduce the Stimel-03 device, an advanced neuromuscular rehabilitation system designed to overcome the limitations of standard Functional Electrical Stimulation (FES) systems.

Unlike traditional FES devices, the Stimel-03 incorporates EMG-driven biofeedback, enabling real-time adaptation to patient signals. Utilizing surface EMG, it detects voluntary muscle effort above an adjustable threshold and delivers stimulation accordingly. Furthermore, the stimulation parameters are dynamically modified throughout each session to reflect real-time muscle activity and activation patterns.

By aligning stimulation intensity with actual muscle effort, the Stimel-03's EMG-based biofeedback reduces muscle fatigue more effectively than other devices. Moreover, the visual biofeedback interface enhances patient motivation by providing instant insights into their muscle activity, thereby improving engagement and adherence to therapy.

Clinical studies have demonstrated the superior efficacy of the Stimel-03 compared to standard FES and control physical therapy. Significant improvements were observed across a number of parameters, such as limb range of motion and muscle strength, where standard FES devices fell short. In comparison with control physical therapy, the Stimel-03 showed statistically significant improvements and advancements in functional independence and stroke symptoms. Notably, the Stimel-03 achieved greater improvements in limb range of motion than conventional FES.

The Stimel-03 has FDA clearance for stroke rehabilitation and other neuromuscular conditions. It offers your patients a highly effective and personalized solution for meaningful recovery, enhancing their rehabilitation outcomes.
For further information or clarification, please contact me at wecare@motioninformatics.ai

Sincerely,

Gary Sagiv
CEO
Motion Informatics LTD.