motion INFORMATICS

Stimel-03 & SSMD:

BioRhythmIQ™ Technology

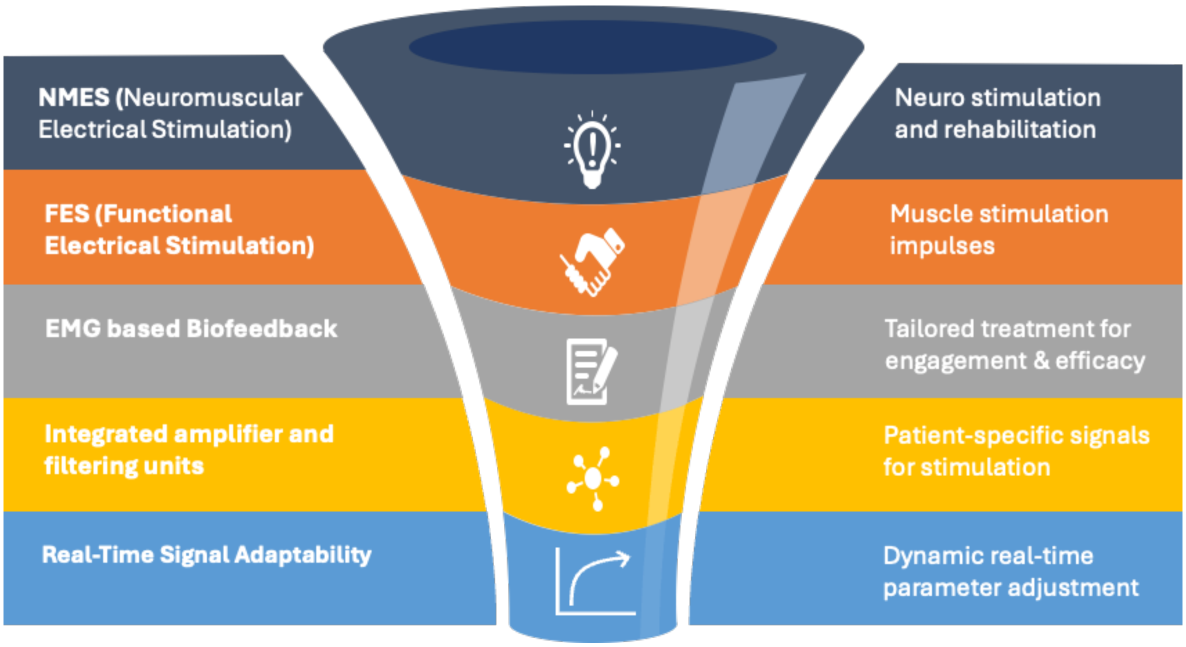
FDA CLEARED

A Breakthrough in Stroke Rehabilitation by Motion Informatics

Motion Informatics has engineered the Stimel-03 and SSMD, devices offering personalized electrical stimulation for stroke rehabilitation. Far from being limited to stroke victims, they also aid in the recovery of car accident survivors, sports-injury patients, and others with neurological or muscular impairments. The **BioRhythmIQ Technology** enables targeted re-mapping of motor areas in the brain to facilitate the relearning of movement. The technology harnesses the brain's neuroplasticity to reteach movement, a concept well-established in neurophysiological literature (mirror-neurons and the plasticity of the brain), but seldom implemented in real-world rehabilitation.

The BioRhythmIQ™ Technology

The **BioRhythmIQ Technology** introduces three layers of personalization to enhance therapeutic precision and clinical efficacy.



The first layer leverages **EMG-based biofeedback**, using **real-time muscle activity** to guide the timing and delivery of electrical stimulation. By incorporating customized threshold values, this layer tailors stimulation onset to the patient's neuromuscular profile, optimizing motor unit recruitment while minimizing fatigue and discomfort, thereby improving patient engagement and adherence.

The second layer of personalization integrates **patient-specific EMG signal characteristics** into the stimulation protocol, mimicking the brain's recognition of natural muscle activation patterns. By replicating this neurophysiological process, the therapy aligns with the patient's intrinsic neuromuscular responses, promoting more effective motor relearning and rehabilitation.

The third is **real-time signal adaptability**, which continuously adjusts stimulation parameters based on EMG readings during the session. This ensures the treatment dynamically reflects the patient's clinical status and movement attempts in real time.

Together, these three layers of personalization create an individualized therapy framework that incorporates patient-specific data to optimize neuromuscular re-education, enhance therapeutic engagement, and prevent over- or under-stimulation. This approach represents a significant advancement in neuromuscular rehabilitation, offering clinicians a sophisticated tool for delivering highly tailored and effective treatments.

Versatile Usage: Clinic and Home Settings

In a clinical setting, the Stimel-03 and SSMD and the BioRhythmIQ Technology seamlessly integrate into existing operations – no need for additional staff or space. Clinic staff can easily operate the devices, allowing for simultaneous treatment of multiple patients and increasing patient throughput. For home-based rehabilitation, **the Stimel-03 and SSMD** offer user-friendly operation, requiring only a prescription (RX) in the United States to get started. They are designed for simplicity, enabling patients to take charge of their own rehabilitation.

FDA Cleared[1] and Proven with a Patented Technology[2]

The BioRhythmIQ Technology has not only proven its efficacy in comprehensive clinical trials with hundreds of stroke survivors but also earned clearance from the Food and Drug Administration (FDA). Hundreds of scientific publications reinforce the credibility of the different sub-technologies we use (FES, NMES, biofeedback). Furthermore, we hold an exclusive U.S. patent, underscoring our position as industry pioneers.

Patient-Centric Rehabilitation (Biofeedback)

Stimel-03 and SSMD stands apart by actively incorporating the patient as an integral part of the rehabilitation process (with the use of biofeedback). By utilizing three electrodes attached to the hand or leg, the device captures and stores faint neural signals emitted by the stroke-afflicted brain.

[1] 510k - K130424
[2] Patent No.: US 7,221,980 B2

EMG: The Underlying Diagnostic Procedure

Electromyography (EMG), an essential diagnostic tool, measures the condition of muscles and the motor neurons that control them. It begins when a patient tries to engage their arm or leg muscles, creating a biofeedback loop. This feedback is visually represented on the device's screen as a moving line approaching a stationary reference line, indicating the level of muscle activation.

EMG is conducted with an instrument known as an electromyograph, which produces a record called an electromyogram. The electromyograph captures the electrical potential generated by muscle cells when they are electrically or neurologically stimulated.

Surface EMG, a non-invasive method, is employed by professionals such as physiotherapists and neurologists to evaluate muscle activation**Error! Reference source not found.**. It is useful both for functional diagnosis and during instrumental motion analysis. Surface EMG measures electrical signals within the muscles by recording activity from electrodes placed on the skin above the muscles. During the neuro-motor process, neural signal from the brain induces an electrical signal within the muscles, which then, if strong enough, causes muscle contraction (see Figure 1). Surface EMG captures this electrical signal within the muscles that may potentially lead to contraction, by recording activity from electrodes placed on the skin above the muscles, even when the muscles are not contracted. In practice, a surface EMG signal represents the linear transformation of motor neuron discharge times by the compound action potentials of the innervated muscle fibers and is used as a source of information about neural activation of muscle**Error! Reference source not found.**.

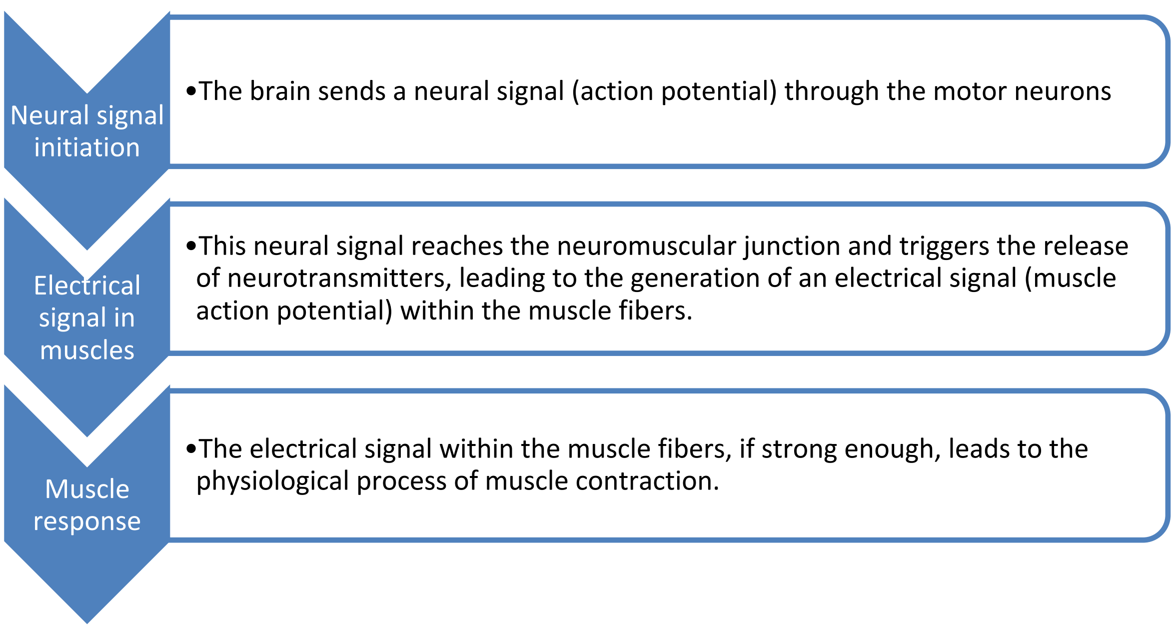


Figure 1: Schematic representation of the neuro-motor process

In clinical settings such as physiotherapy, muscle activation is monitored using surface EMG. Patients receive either auditory or visual feedback, helping them understand when they are effectively activating their muscles.

EMG signal decomposition

EMG signals consist primarily of overlapping motor unit action potentials (MUAPs) from multiple motor units. For detailed analysis, these EMG signals can be broken down into their individual MUAPs. MUAPs originating from different motor units usually exhibit distinct characteristic shapes. In contrast, MUAPs captured by the same electrode from the same motor unit generally appear similar. It is important to note that the size and shape of MUAPs are influenced by the electrode's placement relative to the muscle fibers; thus, any movement of the electrode can alter how these signals appear. Decomposing EMG signals is a complex process, and numerous methods for this task have been developed.

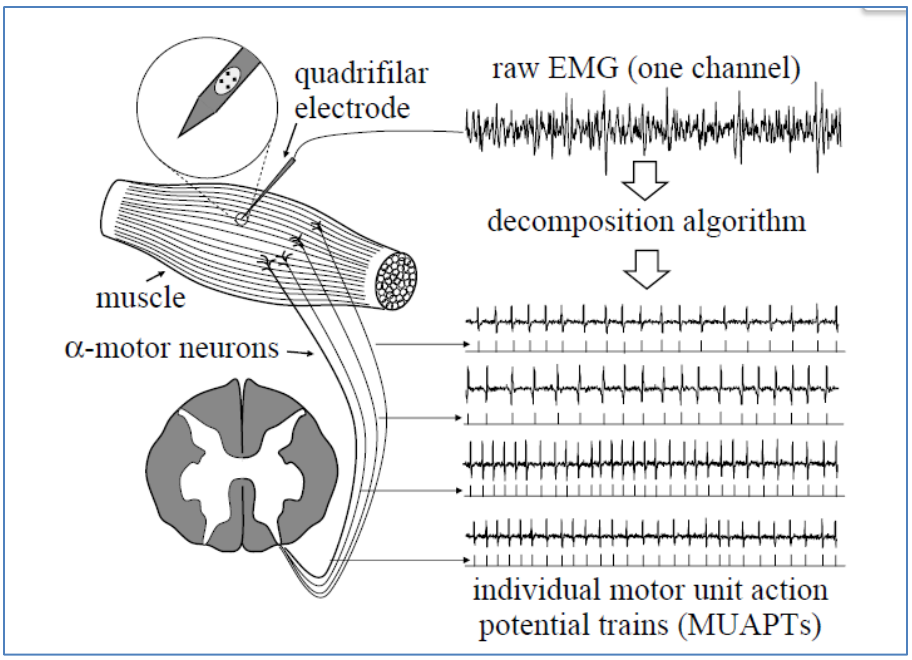


Figure 2: A schematic representation of the detection and standard decomposition of intramuscular EMG signals (adopted from Merletti and Farina, 2008**Error! Reference source not found.**).

EMG signal processing

Rectification converts the raw EMG signal into a signal of a single polarity, typically positive. This process prevents the signal from averaging to zero by combining the positive and negative components of the EMG. There are two methods of rectification: full-wave and half-wave. Full-wave rectification combines the EMG components below and above the baseline into a uniformly positive signal. If the baseline is zero, this method is akin to taking the absolute value of the signal and is preferred for retaining all signal energy for analysis. Half-wave rectification, on the other hand, omits any part of the EMG signal that falls below the baseline, thus adjusting the data's average from zero for use in statistical analysis.

Our specialized EMG sensing circuit is capable of detecting extremely low-level EMG signals in the range of pico-volts, typical in cases of stroke-related injuries in the hands and legs. No other device on the market can measure, capture, and isolate these signals from environmental noise as effectively.

Signal Measurement Units

While a standard FES + biofeedback device will measure stimulation current in milliamperes (mA), such measurements may not accurately reflect real-life conditions in patients with stroke injuries, due to the variability in body resistance and response. To address this, the Stimel-03 and SSMD incorporate a measurement unit that operates on multiples of the threshold current required to perceive stimulation. This feature allows both patients and therapists to adjust the stimulation intensity, ranging up to 2.5 times the initial detection threshold based on individual preferences. By scaling the stimulation threshold current, the Stimel-03 and SSMD adhere to the principle of personalized treatment, enhancing rehabilitation outcomes for each patient.

Core Technology Components

- **Smart Sensors:** These facilitate intelligent capture and amplification of neural signals emanating from stroke-damaged areas.
- **Signal Analysis:** Advanced algorithms distill these signals into a unique movement "signature" for each patient, allowing for individualized biofeedback.

Functional Overview: How it Works

Electrodes equipped with sensors are strategically placed on the patient's affected limbs—be it hands, feet, or other areas—to capture faint electrical nerve signals. These captured signals undergo a sophisticated refinement process that consists of the following critical steps:

- Intensifying the signals without compromising their integrity.
- Filtering out surrounding "noise" to focus solely on the desired signals.
- Employing cutting-edge algorithms to discern the patient's unique movement signature, enabling the retransmission of signals that the brain perceives as natural actions.

Visual Biofeedback and Neural Relearning: The Rehab Process Explained:

Initially, the patient must attempt to engage their arm or leg muscles. The device's screen displays a mobile line (BAR) that moves from a zero position towards a predetermined target line (BAR). This target represents the patient's rehabilitation goal.

At this phase, the device captures faint neural signals from the patient's brain, measured in nanovolts. These signals represent the initial effort of the brain to communicate with the limbs post-stroke. The device amplifies these signals while preserving their unique characteristics, facilitating the neural relearning process. During this relearning, surrounding neurons adapt to perform the functions of the neurons lost due to the stroke.

Upon repeated efforts, as the brain-to-limb signal strengthens, the mobile line aligns with the target line. This triggers the device's recovery functionalities. It processes, amplifies, and reverses the neural signals, injecting them back into the targeted muscles via electrodes.

Consequently, the patient observes their hand or leg executing an action identical to what they could perform pre-stroke and pre-brain injury. This completes a loop of visual biofeedback, allowing mirror neurons in the brain to learn and memorize the movement, which they then teach to other motor neurons. The brain's learning centers reshape themselves based on this acquired knowledge, thanks to neural plasticity.

Over time, the brain's signal output not only strengthens but also morphs to resemble the original pre-stroke neural commands**Error! Reference source not found.**. In essence, an increasing number of neurons understand how to command limb movement, resulting in the progressive improvement and strengthening of limb activity. This constitutes the brain's relearning process.

Neurophysiology and Brain Plasticity: The Role of Mirror Neurons and Neuroplasticity in Rehabilitation:

Various types of neurons populate the human brain, including specialized ones known as mirror neurons. These neurons excel in mimicking visual movements. The closer the observed movement aligns with a patient's natural motor function, the more efficiently mirror neurons can learn and propagate these new commands to surrounding neurons, compensating for those lost during a stroke[0].

The brain's inherent plasticity[Error! Reference source not found.,Error! Reference source not found.] - the ability to rewire itself - comes into play here. Utilizing Stimel-03 and SSMD's advanced techniques, healthier brain regions are trained to assume the roles previously performed by areas damaged by stroke. At the conclusion of the rehabilitation process, new neural pathways are established, circumventing the defunct pathways in the impaired region.

References

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