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Room Hall C-Area B

Design and Development of a New Electromyographic Neuromuscular Monitor

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Background. Careful management of neuromuscular blockade in the operating room reduces the risk of residual neuromuscular blockade. Qualitative neuromuscular monitoring devices (peripheral nerve stimulators) are utilized in clinical practice, but their responses (i.e., presence or absence of fade) are subjective and inaccurate. Quantitative devices that measure evoked responses and display results numerically are preferred because they distinguish clinically important degrees of block and recovery.

We describe the design and development of a quantitative monitor prototype. The proof-of-concept work included design of the battery-operated prototype to ensure safety of testing in humans, IRB approval for testing in volunteers, and development of the monitoring unit separately from the stimulating unit.

Device Description. The T4-EMG is a dedicated neuromuscular stimulator & recorder that evokes, records, and analyzes muscle potentials during surgery (Fig 1). The prototype consists of 2 components. The stimulator/recorder (S/R) is contained in one box, galvanically separated, with separate battery power supplies for each function. The controller/display (C/D) is contained in a battery-powered laptop computer connected to the S/R by isolated USB cable. Standard commercial surface electrodes connect the isolated stimulating and recording circuits to the patient.

Stimulator consists of a battery-operated (9V) pulse generator that produces square-wave electrical pulses of 200 μsec duration and 0-80 mA constant-current amplitude. The pulse generator operates in Manual Mode (patterns of stimulation delivered on-demand), or in Continuous Mode (patterns delivered sequentially at pre-determined intervals, eg, q 12 sec). The stimulation patterns include 1 Hz Single Twitch (ST), Train-of-Four (TOF), and Tetanic (Tet) protocols.

Recorder consists of a single-channel physiological amplifier with high-impedance differential input leads. The inputs are electrically isolated with overload protection. Signal acquisition parameters record signals from -25 to 25 mV amplitude, 50 μV resolution; frequency response is 1 Hz-250 Hz. Analog signals are digitized at 1000 Hz and relayed to the C/D unit for data storage and display at a 10-bit resolution of 0.05 mV (Fig 2).

The C/D operates as a simple state-sequence controller, executing a series of protocol steps. In setup, the operator can deliver single stimuli and adjust stimulus strength (pulse width, current amplitude) interactively, while observing the evoked EMG signal on the display. In recording, the operator can trigger delivery of ST, TOF or Tet stimulus set. The horizontal (time) and vertical (voltage) scales are adjustable. Recordings are stored to non-volatile memory. Additional controls record time of day, subject identifiers, and free-text annotations during data collection. Baseline noise levels of less than 0.1 mV RMS were achieved, stimulus artifact was below 0.2 mV at supramaximal stimulating current of 30 mA, and clear reproducible EMG signals were collected.

The prototype was used successfully in an IRB-approved human volunteers protocol, and testing of intraoperative clinical use in patients is underway.

Figure 1

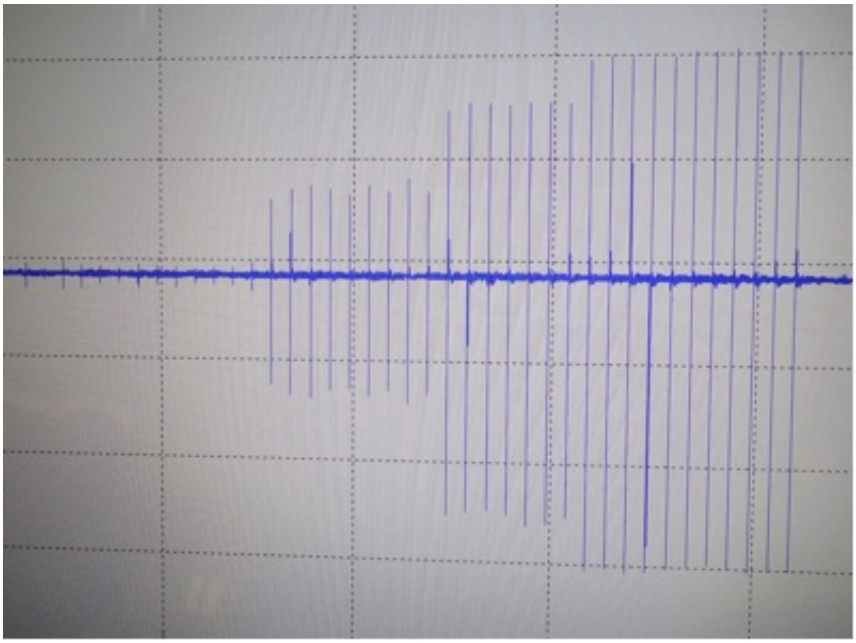

Figure 2