Position Statement
American Association of Neuromuscular & Electrodiagnostic Medicine

ELECTRODIAGNOSTIC STUDY INSTRUMENT DESIGN REQUIREMENTS

INTRODUCTION

Electrodiagnostic (EDX) physicians rely upon quality nerve conduction studies (NCSs) and needle electromyography (EMG) instruments to diagnose neuromuscular disorders. Instrumentation has changed due to improved electronic technology and new research findings in EDX medicine. This statement is intended to define the requirements and specifications of a useful EDX instrument.

ELECTRICAL SAFETY

Safety standards are required for any electrical medical device. The EDX instruments should follow FDA standards for safety, including acceptable current leakage requirements.[1]

DATA INTEGRITY

An EDX instrument should provide password-controlled access to maintain patient record confidentiality.

EDX INSTRUMENT DESIGN

The purpose of an EDX instrument is to objectively record, amplify, display, and store low-amplitude neurophysiological signals in the presence of ambient noise, interference and stimulus artifacts. EDX instruments have three separate functional components: signal input, processing, and output.

I. Signal Input: Electrodes

Stimulating Electrode (Stimulator)

- cathode and anode clearly identified
- support for monopolar needle stimulation
- continuously adjustable intensity
- adjustable stimulus duration from 0.05 to 1 millisecond (ms)
- adjustable stimulation frequency from 0.1 to 50 Hertz (Hz)[2-4]

Recording Electrodes

- connections for three electrodes: active, reference, and ground
- connections being touch-proof for patient safety
- electrode design allowing for anatomical variation
- ability to use surface and needle recording electrodes for NCSs
- ability to use monopolar and concentric needle electrodes for needle EMG

Temperature indicator and temperature probe

- built in or an external temperature probe

II. Signal Processing

Differential amplifier

A differential amplifier magnifies the potential difference between the active and reference inputs to improve signal-to-noise ratio.

- high input impedance of the amplifier (>1,000M-Ohms)
- high common-mode rejection ratio (CMRR), e.g. >100 dB
- noise level with input shorted being less than 0.6 μVRMS
- channel selection mechanism if multiple channels are needed

Gain (Sensitivity)

- ability to acquire signals from 1 microvolt (μV) to 50 millivolts (mV) 2-4
- analog gain stages with minimum of 3 analog gains (digital amplification increases noise significantly and can mask the biological signal.)

Filters

All amplifiers use a band-pass filter to attenuate noise. The band-pass filter is characterized by adjustable low and high cut-off frequency settings.

- adjustable lower frequency (high pass filter) setting from 1 to 2,000 Hz
- adjustable high frequency (low pass filter) setting from 100 to 10,000 Hz 2-5
- notch filter for 50 Hz or 60 Hz for noise elimination (This is to attenuate the power line frequency but should not be active by default because of potential amplitude reduction and ringing.)

Analog-to-digital converter

- converts biological (analog) signals to digital waveforms
- ability of displaying and storing waveforms in a digital format
- adequate sampling frequency to prevent waveform distortion from aliasing
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III. Signal Output

Signal display

- sensitivity/gain control to determine the amplitude of potentials, with a range of 1 μV to 10 mV per division

- sweep speed adjustment, with a range of 0.1 to 500 ms per division
- trace area appearance of a rectangular grid, with the gain and sweep speed clearly labeled
- adequate vertical and horizontal resolution on monitor to enable visual analysis of waveforms
- automatic cursor placement at onset and peak of recognizable potentials, to measure latencies (onset and peak) and amplitudes (baseline-to-peak and peak-to-peak)
- manual adjustment of cursors for measurements during both NCSs and EMG testing
- automatic calculation of conduction velocity when distance values are entered
- free running and triggered modes

The free running mode updates signal display continuously, showing live electrophysiological signals as they are recorded. The triggered mode is necessary to record signals when a certain event (the trigger) occurs to assess signal variability and reproducibility. For triggered modes, the occurrence of the event (stimulus) should be synchronized to the acquisition of data point for accurate time zero calculation. For motor unit potential analysis, an adjustable level trigger should be available. A function of window triggering is optional. A function of delay line with adjustable delay time should be available to allow observation and analysis of signals preceding the trigger.

- capability of trace raster/superimpose
- square wave calibration signal to calibrate gain, sweep and other functions

Auditory Speaker
- high quality audio amplifier and loudspeakers for the production of characteristic sounds, for both potential recognition and criterion analysis
- volume adjustment

Data storage and report generation
- exports numerical data directly into the final report

Data are objective and based on real time measurement of biological signals without subjective input from the patient and are independent of psychophysical responses from patients.

- report editing
- lists normal reference values
- allows for inclusion of acquired waveforms

CONCLUSION

The EDX instrument should provide the original numerical NCS/EMG data delineated in the AANEM position statement "Reporting the Results of Needle EMG and Nerve Conduction Studies: An Educational Report." 7 The updated version includes an option to specify the EDX instrument manufacturer and model on the report.8

Finally, efficient usage of EDX instruments requires performance by or oversight of an appropriately trained EDX physician. The AANEM position statement "Who is Qualified to Practice Electrodiagnostic Medicine" defines recommended qualifications for an EDX physician.[9]

REFERENCES:

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7. AANEM Position Statement. "Reporting the Results of Needle EMG and Nerve Conduction Studies: An Educational Report." http://www.aanem.org/getmedia/670b50d3-bb67-4d22-85f5- 517b7221ca25/RptResultsEMGNCS.pdf.aspx. Updated and re-approved May 2014.
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