

Viking™ On Nicolet™ EDX

Specifications



System Overview

The Nicolet EDX System with Viking Software (Viking EDX) is intended for the acquisition, display, analysis, reporting, and management of electrophysiological information from the human nervous and muscular system during routine clinical electromyography (EMG) and evoked potential (EP) testing. The Viking EDX can also be used in the Operating Room (OR), Emergency Room (ER) and Intensive Care Unit (ICU) for monitoring of the nervous and muscular system. The Viking EDX can be portable or cart-based.

General Description

The Viking EDX consists of a base unit, an amplifier, a control panel, an electrical stimulator probe, a computer, and Viking Software. The base unit contains an integrated speaker, the electrical and auditory stimulators, and all the connectors for stimulators and other peripheral devices. Two amplifier types are available: 2 channel (AT2) with two (2) non-switched amplifier channels and an 8 channel (AT2+6) with two (2) non-switched and six (6) switched amplifier channels. Both amplifiers include a connector for temperature measurement. Two types of electrical stimulator probes are available: Comfort Probe (RS10) and the Comfort Probe Plus (WR50). In addition to delivering the stimuli, the Comfort Probe Plus allows direct control of stimulus parameters as well as the examination workflow. The 8 channel (AT2+6) amplifier can be used with an optional head box (HB-6). The computer can either be a laptop or desktop computer and a cart is available.

The Nicolet EDX Base Unit

Integrated Stimulators

Two electrical stimulators, one auditory stimulator and one visual LED stimulator are integrated in the base unit.

Stimulator Switching

Up to 12 switchable output sites plus 1 low-level independent output for each electrical stimulator.

Audio Speaker

Built-in audio speaker available for output of both live signals as well as playback of recorded data (line-out, line-in, and speaker-out connections). Audio Speaker Notch filter adjustable to 50 Hz, 60 Hz, or off.

Computer Interface

The base unit is connected through a single USB (2.0) connection to the computer. The base unit also contains an USB hub with two additional USB ports.

Trigger Input/Output

The base unit has two trigger inputs and two trigger outputs for connection to external devices.

Additional Devices

The base unit also has connections for a patient response unit, footswitch (single or triple footswitch), control panel, LED goggles, audio transducers (headphones, bone conductors, ear inserts, etc.), and reflex hammer.

Integration with external acquisition system

All eight channels are available to external acquisition equipment for on-line analysis through the Analog Out connector.

Disconnect/Reconnect

A built-in safety feature will stop any stimulation after a few seconds of lost communication between the base unit and the computer. Restoring the USB communication will automatically bring the system back to running condition without any need for additional user intervention. The same recovery procedure will apply when power is restored after an unintentional power loss.

Digital Signal Processing

A powerfully built-in Digital Signal Processor (DSP) provides advanced signal processing functionality such as signal filtering, sound optimization, analog output, etc. The base unit firmware and DSP software can easily be field upgraded to incorporate most recent enhancements and updated functionality.

Computer

The Viking EDX operates with either a laptop or desktop computer. Please see your Nicolet representative for the latest computer specifications that are shipped with the system. Below are minimum specifications.

Processor Core 2 Duo with minimum speed of 1.6 GHz (laptop) or 2.0 GHz (desktop).

Hard Drive Minimum of 80 GB

RAM Minimum of 2 GB

Display Resolution Minimum of 1024 x 768 pixels

Operating System Microsoft® Windows® 7 32-bit or Windows XP® (SP3)

Amplifiers

Amplifier Types

The Viking EDX system comes with two different amplifiers. The 2 channel (AT2) has two (2) non-switched amplifier channels and the 8 channel amplifier (AT2+6) has two (2) non-switched and six (6) switched channels that can be used in any combination. The 8 channel amplifier can be configured from 3 to 8 simultaneously active channels. The six switched channels can be configured to use any of the 22 input connectors available on the amplifier or on the optional head box (HB-6).

Analog to Digital Converter

The amplifier utilizes a 24 bit Analog to Digital Converter (ADC) with 48 kHz sampling rate per channel.

Disconnect / Reconnect

Due to the advanced system design it is possible to disconnect and reconnect the amplifier without powering off the base unit. Restoring the connection to the amplifier will automatically bring the system back to running condition without any need for additional user intervention.

Stimulus Artifact Suppression

The amplifiers contain new and patented stimuli artifact rejection hardware. This technology prevents the stimuli artifact from saturating the amplifier resulting in a quicker baseline recovery making it easier to detect and measure small responses.

Electrode Impedance Measurement

The amplifier has built-in impedance measurement capability measuring the impedance at 20 Hz with a range from 500 Ω to 450 k Ω .

Calibration

The amplifier has a built-in rectangular calibration pulse selectable between 2, 20, 200, 2,000, 20,000 μ V.

Sensitivity Hardware gain can be adjusted from 1 μ V/division to 10 mV/division in 13 steps.

Amplifiers continued on next page

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Amplifiers (continued)

Filters

Fixed input channel low filter settings:

0.2, 0.3, 0.5, 1, 2, 3, 5, 10, 20, 30, 50, 100, 150, 200, 250, 300, 500 Hz, 1 kHz, 2 kHz, 5 kHz; selectable at 6 or 12 dB/octave slope (above 0.5 Hz).

Switched input channel low filter settings:

0.05, 0.1, 0.2, 0.3, 0.5, 1, 2, 3, 5, 10, 20, 30, 50, 100, 150, 200, 250, 300, 500 Hz, 1 kHz, 2 kHz, 5 kHz; selectable at 6 or 12 dB/octave slope (above 0.2 Hz).

Fixed input channel high filter settings:

30, 50, 100, 200, 250, 300, 500, 1K, 1.5K, 2K, 3K, 5K, 10K, 20K Hz; fixed 12 dB/octave slope.

Switched input channel high filter settings:

30, 50, 100, 200, 250, 300, 500, 1K, 1.5K, 2K, 3K, 5K, 10K Hz; fixed 12 dB/octave slope.

Notch Filter

Notch (line) filter can be set to 50 Hz, 60 Hz, or Off.

Common Mode Input Impedance (CMII)

> 1000 M Ω (fixed channels).

> 100 M Ω (switched channels).

Common Mode Rejection Ratio (CMRR)

> 110 dB (316,277:1) at 50 to 60 Hz. Typical values: fixed input channels = 115 dB, switched input channels = 112 dB.

> 80 dB (100,000:1) at 10 kHz.

Noise

Fixed input channels < 0.6 μ V RMS from 2 Hz to 10 kHz with inputs shorted.

Switched input channels < 0.7 μ V RMS from 2 Hz to 10 kHz with inputs shorted.

Temperature Measurement

An optional temperature probe can be connected to the amplifier providing automatic temperature measurement synchronized with the recording.

Safety Isolation

Type BF.

Amplifier Holder and Arm

A universal amplifier holder is supplied with the amplifier that fits both the AT2 (2 channel) and AT2+6 (8 channel) amplifier. A holder for both the Comfort Probe and Comfort Probe Plus can be attached to either side of the amplifier holder.

A needle holder can also be attached to either side of the amplifier or amplifier holder. The holder is attached to an arm that can be inserted into either side of the cart or can be inserted into a holder attached to an optional desk clamp.

Head Box (Optional)

The optional clinical head box (HB-6) is intended for clinical use for instance Evoked Potential studies. The head box is connected to the amplifier by a cable available in different lengths, 1.8 m (6 Foot) and 4.5 m (15 Foot). The head box has 22 electrode inputs configured according to the 1020 EEG electrode layout. User can re-label each electrode input using a writable overlay.

Electrical Stimulator

Electrical stimulator options and functionality may vary between different test types.

Electrical stimulators

Two independent electrical stimulators are available. The stimulator outputs are isolated (transformer coupled).

Stimulus Intensity

Stimulus output can be set either to constant-voltage or constant-current mode delivering, 0 – 400V / 0 – 100 mA stimulus into a 4 k Ω load. The stimulus intensity is continuously adjustable with a user definable maximum level. The stimulus intensity can be adjusted with a resolution of 0.01 mA. The stimulus intensity can be adjusted either from the control panel or directly from the Comfort Probe Plus stimulator probe. The stimulus intensity is stored for each trace.

Stimulus Intensity Monitoring

Delivered stimulus is monitored and "Short-circuit" and "Open-circuit" conditions are indicated. Additionally in constant-current mode a deviation between requested and delivered stimulus intensity, due to high electrode impedance, is indicated using color codes.

Stimulus Duration The stimulus duration can be adjusted within 0.01 – 1 ms.

Stimulus Modes

The stimulus can be set to either monophasic or biphasic stimulation using single, pair, pair dual level, or train stimulation.

Stimulus Rate

The stimulus can be set to non-recurrent or recurrent stimulation. The stimulus rate can be varied between: 0.1 – 100 stimuli per second (Hz).



L to R: Nicolet 2+6 Channel Amplifier, 2 Channel Amplifier, HB-6 Head Box

Safety Isolation The electrical stimulator outputs are Type BF.

Electrical Stimulus Pods

The Electrical Stimulus Pod 1 can be connected to any of the two Electrical Stimulator (IES-1 or IES-2) switched output connectors located on the front of the EDX Base Unit. The Pod 1 can switch the electrical stimuli delivered by the IES-1 or IES-2 between 6 separate connector pairs and 1 low level (LL) connector pair limited to a maximal output of 5 mA. The Pod 1 contains also a 7 pin DIN connector providing a way to connect a stimulator probe to the Pod.

The second Electrical Stimulus Pod 2 can be connected to the Pod 1 in a daisy chain fashion adding an additional 6 separate connector pairs totalling 12 high level and 1 low level output pairs for each of the two Electrical Stimulators.

Electrical Stimulator Probes (Optional)

The Comfort Probe and Comfort Probe Plus stimulator probes are small and light weight and designed for maximal comfort. Ergonomically designed handles allows for a comfortable grip even when examining difficult to reach sites. Both Comfort probes can be used with any of the five available probe heads. The probe cable is partially coiled to allow an extended reach while preventing the cable from touching the floor.

Comfort Probe (RS10)

The Comfort Probe's ergonomic design makes it very small and comfortable to use. It is intended to be used together with the control panel.

Comfort Probe Plus (WR50)

The Comfort Probe Plus allows for direct control of stimuli parameters as well as of the examination workflow using an integrated wheel and buttons. Users can customize the functionality of the probe and modify what functions the different buttons do. The following can be adjusted directly from the Comfort Probe Plus per default: stimulus intensity, start/stop, duration, polarity, and move to next trace.

Probe Heads

The probe heads are available as two (2) large probes (0.8" (2 cm) between prongs) and two (2) small probes (0.4" (1.1 cm) between prongs) both in a straight and an angled (45°) version. The probe heads are rounded to optimize contact while minimizing discomfort. There is also a probe head available with touch proof connectors to be used with external electrodes.



Electrical Stimulus Pods

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Auditory Stimulator (Optional)

Auditory stimulator options and functionality may vary between different test types.

Stimulus Type

The stimulus type can be selected between Click, Tone Pip, and Tone Burst.

Stimulus Intensity

The stimulus intensity can be set between 0 to 139 dB pSPL or -31 to 109 dB nHL, depending on stimulus type, stimulus frequency, and transducer type. The stimulus increment steps can be selected between 1 to 30 dB. Stimulus intensity can also be set relative to the examined patient's hearing threshold.

Stimulus Polarity

The stimulus polarity can be set to: condensation, rarefaction, or alternating.

Click Stimuli

The Click duration can be set to 0.05, 0.1, 0.2, 0.5, and 1.0 ms.

Tone Stimuli

The tone stimuli type can be set to either Pip or Burst. The tone frequency can be set to 250, 500, 750, 1K, 1.5K, 2K, 3K, 4K, 6K, 8K (Hz). The pip total cycles can be set to between 2 to 20 cycles. The burst ramp cycles can be set to between 1 to 10 cycles and the burst plateau can be set to between 1 to 400 cycles. The tone envelope can be set to Linear, Gaussian, Hanning, or Blackman.

Noise

Noise intensity range from -15 to 125 dB SPL or from -1 to 103 dB nHL, depending on transducer type, and can be set relative to the stimulation intensity.

Transducers

Following transducers can be used: 300Ω TDH-39 Headphones (non-shielded or shielded), TIP 300 Insert Phones, Bone Vibrator.

2015 Visual Stimulator (Optional)

The external 2015 visual stimulator is connected to the Nicolet EDX base unit via the Trigger In/Out connectors.

Pattern

It is possible to choose pattern stimulus color (foreground and background) and pattern intensity. The pattern type can be selected from checks, bars, or gratings. The pattern can be full-field or partial-field (hemi, quadrants, eighths, and sixteenths) with possibility to select the partial-field position. The stimulator calculates changes in check size, distance, and visual angle.

Fixation Target

It is possible to choose the target size, position, color, and choose between a static or a pulsating target.

LED Goggles (Optional)

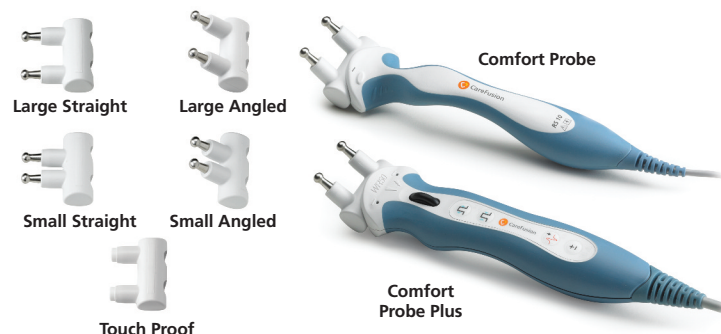
Optional LED goggles are connected with a single 15 foot (4.6 m) cable to the dedicated LED goggle connector located on the back of the Nicolet EDX base unit.

LED Stimulus

The goggles consist of high efficiency red LEDs (635 nm) in 3 x 5 array in each eyepiece. The flash rate can be set between 0.1 – 100 per second (Hz) with a duration between 1 – 50 ms.

Triple Footswitch (optional)

The optional Triple Footswitch is connected to the USB connector on the computer or the EDX Base Unit and allows extensive control of the application using a foot. User can customize the Triple Footswitch and modify what functions the different switches do. The Footswitch is rated IP68 for dust and water immersion.



Software

Software options and functionality may vary between different test types.

Operating System

The Viking EDX ships on Microsoft® Windows® 7 32-bit (also Windows XP® (SP3) compatible).

Reporting

Utilizes Microsoft Word® 2010 (also Microsoft Word® 2007 compatible).

Clinical Tests

The Viking EDX operates with Viking System Software Version 20 or higher and is available in English, French, German, Italian, and Spanish. Choice of Viking software packages includes (but are not limited to): Motor Nerve Conduction (MNC), Sensory Nerve Conduction (SNC), Additional Nerve Studies (ANS), Inching Studies, Reference Help, F-Wave, HReflex, Blink Reflex, Repetitive Nerve Stimulation, Needle EMG, Macro EMG, Volitional and Stimulated Single Fiber EMG, AEP, SEP, VEP, P300, ERG/EOG, Multi-Modality, Conduction Velocity Distribution (CVD), Bereitschafts Potentials, R-R Interval, Sympathetic Skin Response (SSR)/Galvanic Skin Response (GSR), Spike Triggered Averaging, and Intraoperative Monitoring - IOM.

Additional Clinical Tests

Tests available outside the U.S. include Tremor and Triple Stimulation.

Waveform Acquisition and Display

Parallel processing allows simultaneous waveform acquisition, display, plotting and real-time signal analysis. The data and results can be displayed in many different ways according to the clinical need or user preference. Data can be repositioned, superimposed, or shown in a rastered mode. The same data can simultaneously be displayed with different filters, sensitivity (1 nV/div - 10 mV/div), and timebase (0.1 ms/div - 5 s/div) for optimal review of results. Data can be displayed as free run or triggered with a delay ranging from -3,000 to +500 ms.

Data Storage and Analysis

Extensive data storage is implemented and available to maximize the extraction of clinical information from the recorded data. Free run EMG data and sound can be recorded for up to 120 seconds. Stored data can be reanalyzed, digitally filtered, smoothed, inversed, summed, replayed, displayed as trends, in plots, frequency analysis, etc. Up to 8 channels of live data can be streamed continuously to disk, limited only by the disk space available. The data are stored in the standard WAV format making it simple to export to other research or analysis programs.

Averager Capabilities

Averaging functionality is frequently necessary when recording small signals buried in large background activity. The Viking offers a number of averaging techniques to optimize the averaging results like odd and even averaging, weighted average, and back averaging. The Artifact Reject function will automatically exclude artifacts that exceed a user definable amplitude threshold but it is also possible to manually include or exclude data on a trace per trace basis. The averager display sensitivity can be set from 0.001 µV/division to 10 mV/division in 22 steps.

Roll Back, Roll Forward & Replication

The Roll Back and Roll Forward features will automatically store previous responses ensuring that the best response is available eliminating unnecessary stimulations. Up to four replications are available allowing the user to quickly verify a small pathological biological response with an easy way of selecting what result to report.

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Software (continued)

Signal Enhancer

The Signal Enhancer highlights clinically relevant data to simplify analysis and measurements. In SNC, it reduces stimulus artifacts to yield a better baseline. In F-waves it will hide the M-portion during the time of the F-response making it easier to identify the response and place markers. This feature can be turned on or off by the user.

Clinical Workflow

The Viking is optimized to support different types of clinical workflow. Multiple exams can be organized into a single Study ensuring simple and consistent examination even with the most complex diagnostic procedures or research setups. Additionally the Quick Access Bar gives one click access to examine the opposite side, a new anatomy, or another exam type.

Reporting

On-line result views give a compact clinical overview with links back to the raw data. The report can highlight results that are outside of reference values. Reports are very flexible and can be setup by the user according to specific needs utilizing Microsoft Word® 2010 (also Microsoft Word® 2007 compatible). Multiple report templates can be created.

Image and Video Capturing

The integrated Producer functionality makes it easy to capture the Viking screen both as a picture or as a movie that can be incorporated into reports, training material, publications, presentations, and much more.

Patient Administration

The Viking has an integrated data base with user defined patient demographics and visit information. Optional NicVue software is available to manage multi-modality patient data and hospital information system integration (optional V-Link module).

Networking

The Viking EDX supports full networking functionality with multiple acquisition stations storing to a central server. The data are available for review from any acquisition or review station.

Hardware Diagnostic Tool

Diagnostic software is available that validates the integrity of the system and reports detailed system information regarding amplifier, base unit firmware, etc. to simplify and speed up service.

Component Dimensions and Weight

Approximate dimensions and weights.

Nicolet EDX base unit

14" L x 13.5" W x 3.4" H (35.6 x 34.3 x 8.6 cm), 8 pounds (3.5 kg).

2 Channel Amplifier

6.5" L x 6" W x 1" H (16.5 x 15.2 x 2.5 cm), 1 pound (0.5 kg).

2+6 Channel Amplifier

10.3" L x 8" W x 1.5" H (26 x 20.3 x 4 cm), 1.6 pound (0.7 kg).

Control Panel 8" L x 5" W x 2" H (20 x 13 x 5 cm), 1.25 pounds (0.6 kg).

Comfort Probe (RS10)

7" L x 1.5" W x 1.25" H (18 x 4 x 3.2 cm), 0.25 pounds (0.11 kg).

Comfort Probe Plus (WR50)

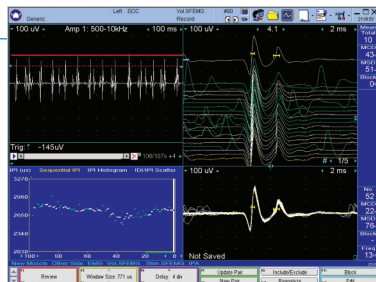
6.8" L x 1.5" W x 1.25" H (17 x 4 x 3.2 cm), 0.25 pounds (0.11 kg).

Clinical Head Box (HB-6)

6" L x 4.25" W x 0.9" H (15 x 11 x 2.3 cm), 0.6 pounds (0.3 kg).

Laptop System (Base Unit, 2 channel amplifier, laptop computer, and cables)

16 pounds (7.3 kg)



Desktop System (Base Unit, 2+6 channel amplifier, desktop computer, isolation transformer, 19" monitor, laser printer, and cart) 21" L x 32" W x 45" H (53 x 81 x 114 cm), 190 pounds (90 kg).

Power Requirements

Power Source

The EDX base unit can be powered by: 100 - 120 V, 220 - 240 V, 50/60 Hz.

Power Consumption

The power consumption varies between 140 - 600 W depending on computer, monitor, printer, and system configuration.

Cart (Optional)

The cart has two amplifier mounts on each side where the amplifier arm can be mounted. The cart has two (2) swivel and locking casters /wheels (in front) and two (2) swivel and tracking casters / wheels (in back). Four (4) hooks are available for hanging supplies and accessories, two (2) on each side.

Dimensions

Unibody cart approx. 47" H x 21" W x 30" D (119 x 53 x 76 cm)

Weight

Unibody cart approx. 150 lbs. (68kg) (depending on model of printer)

Retractable height-adjusted keyboard tray

Range of 6.25" (16 cm); 0.25" (0.6 cm) up and 6" (15.24 cm) high.

Tilt adjustment of ± 15 degrees.

Accommodates a full-featured keyboard or control panel.

Monitor Arm (Optional)

An optional monitor arm is available that gives 12" (30.5 cm) range of finger-tip height adjustment, 23" (58.4 cm) range of easy depth adjustment, 360 degree monitor rotation, and 60 degree range of lateral and vertical monitor tilt. The monitor arm supports monitors weighing between 5 and 20 pounds (2.3 and 9.1 kg).

Isolated Power Supply

The cart comes mounted with either an 115V or 230V isolation power supply with the following power ratings: 100-120 V or 220-240 V, 50 Hz / 60 Hz, 595 VA primary; 500 VA secondary.

Maximum computer dimensions to fit the standard configuration of the UB4 cart are approximately 16" L x 15" W x 4.3" H (40 x 38 x 11 cm).

Environmental Limits

Operating (in use)

Temperature: 60 to 90° F (15.6 to 32.2° C). Relative Humidity: 20-80%, non-condensing. Altitude: 0-10,000 ft (0-3 km).

Non-operating (in storage)

Temperature: 0 to 132° F (17.7 to 55° C). Relative Humidity: 10-90%, non-condensing. Altitude: 0-40,000 ft (0-12 km).

Quality Standards

Manufactured, designed, developed and marketed under ISO 13485 Certified Quality System.

Compliance/Regulatory Standards

Designed, tested, manufactured and certified to meet the following domestic (USA), Canadian, European and International Standards:

510(k) clearance

UL 60601-1 Medical Electrical Safety Standard (USA)

CAN/CSA-C22.2 no. 601.1-M90 Medical Electrical Safety Standard (Canada)

EN/IEC 60601-1 Medical Electrical Safety of Medical Equipment (International and Europe)

IEC 60601-2-40 Particular Safety of electromyography and evoked response equipment

EN 60601-1-2 Collateral safety standard for EMC

European Community (CE Mark)

Class 2B, Medical Device Directive (MDD) product



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