

Synergy On Nicolet EDX

Specifications



Intended Use

The CareFusion Nicolet EDX Systems with Synergy Software (Synergy 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 Synergy 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 Synergy EDX can be portable or cart-based.

General Description

The Synergy EDX consists of a base unit, an amplifier, a control panel, an electrical stimulator probe, a computer, and Synergy 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.

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 a 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, 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 Synergy EDX operates with either a laptop or desktop computer. Please see your CareFusion 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 or Windows XP® (SP3) 32-bit

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Amplifiers

Amplifier Types

The Synergy 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 10 nV to 100 mV/division in 22 steps.

Low Frequency (-6 dB/octave High Pass) Hz: 0.2, 1, 2, 5, 10, 20, 30, 50, 100, 150, 200, 250, 300, 500, 1K, 2K, 5K.

Fixed input channels also support 0.5 Hz and 3 Hz.

Switched input channels also support 0.05 Hz.

High Frequency (-12 dB/octave Low Pass) Hz: 30, 50, 100, 200, 250, 300, 500, 1K, 1.5K, 2K, 3K, 5K, 10K.

Fixed input channels also support 20 kHz.

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 < 0.7 μ V RMS.

Switched input channels < 0.7 μ V RMS.

Temperature Measurement

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

Safety Isolation Type BF.



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

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)

An optional head box (HB-6) can be connected to the 8 channel amplifier (AT2+6) using a 6 foot (1.8 m) cable. 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. 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 0.1 V or 0.03 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 0.02 – 1 ms.

Stimulus Modes

The stimulus can be set to either monophasic or biphasic stimulation using Single, Refractory, Collision, Double, or Train.

Stimulus Rate

The stimulus can be set to non-recurrent or recurrent stimulation. The stimulus rate can be varied between: 0.06 – 200 stimuli per second (Hz).

Safety Isolation The electrical stimulator outputs are Type BF.

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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 or getting trapped under the wheels of the UB4 cart.

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. The following can be adjusted directly from the Comfort Probe Plus: stimulus intensity, start/stop, duration, polarity, and move to next trace.

Probe Heads

The probe heads are available as two (2) adult probes (0.8" (2 cm) between prongs) and two (2) pediatric 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.

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 130 dBnHL pSPL or -31 to 109 dB SPL 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, rarefraction, or alternating.

Click Stimuli

The Click duration can be set to 0.05, 0.1, 0.2, 0.50, 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, 4K, 6K, 8K (Hz). The tone envelope can be set to Linear, Gaussian, Hanning, or Blackman.

Pips/Tone Bursts Intensity 0 to 130 dBnHL, 0 - 130 dB SPL, 1 dB increments.

Plateau (Pips) 0 - 500 cycles in steps of 1 cycle

Rise/Fall (Pips) 1 - 40 cycles in steps of 1 cycle

Plateau (Bursts) 4 - 2,000 ms in steps of 1 ms

Rise/Fall (Bursts) 4 - 100 ms in steps of 1 ms

Masking White Noise, HP Noise, Notched Noise

Intensity + 10 dB to - 50 dB relative to stimulus

Presentation: Binaural, Ipsilateral, Contralateral

Transducers

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

2015 Visual Stimulator (Optional)

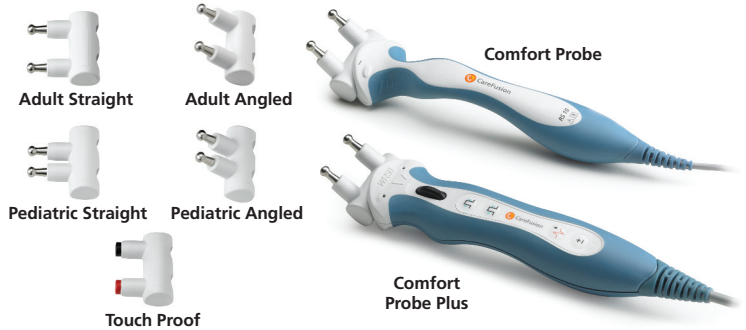
The external 2015 visual stimulator is connected to the Nicolet EDX base unit via the Trigger In/Out connectors.

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 - 500 ms.

Software

Software options and functionality may vary between different test types.

Operating System

The Synergy 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 Synergy EDX operates with Synergy System Software Version 20 or higher and is available in English, French, German, Italian, Spanish, and Japanese. Choice of Synergy software packages includes (but are not limited to): Motor Nerve Conduction (MNC), Sensory Nerve Conduction (SNC), Combined Sensory Index, Combined Motor and Sensory Nerve Conduction, Inching Studies, Reference Help, F-Wave, H-Reflex, Blink Reflex, Repetitive Nerve Stimulation, Needle EMG, Multi-MUP Analysis, Single Fiber EMG, Macro EMG, Turns and Amplitude, AEP, SEP, VEP, P300/CNV, IOM, Tremor, R-R Interval, and Sympathetic Skin Response (SSR)/Galvanic Skin Response (GSR).

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, and timebase for optimal review of results. Data can be displayed as free run or triggered with a delay ranging from -9.9 to +9.9 divisions.

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 960 seconds for 2 channels or 360 seconds for 8 channels. Stored data can be reanalyzed, digitally filtered, smoothed, inverted, summed, replayed, displayed as trends, in plots, frequency analysis, etc. 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 Synergy offers a number of averaging techniques to optimize the averaging results such as mean, exponential, median, rectified, and weighted mean. 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 0.01 µV/division to 100 mV/division in 22 steps.

Roll Back, Roll Forward and 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.

Software continued on next page

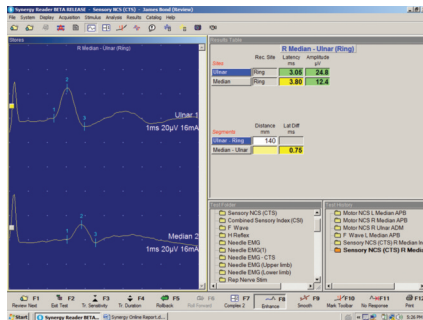
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Software (continued)

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 Synergy is optimized to support different types of clinical workflow. Multiple exams can be organized into test folders ensuring simple and consistent examination even with the most complex diagnostic procedures or research setups.

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 and generate a summary of findings. Reports are very flexible and can be setup by the user according to specific needs utilizing Microsoft Word® 2010 (also Microsoft Word® 2007 compatible).

Image and Video Capturing

The integrated Producer functionality makes it easy to capture the Synergy 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 Synergy 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 Synergy 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.

Support Software

Utilizes Remote Support Software to allow CareFusion Nicolet Technical Support to view and remotely diagnose and service the system optimizing response time.

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.

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 by CareFusion NeuroCare 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:

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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