

Technical Report



NeMus 2 - 600
Illustrative image

NEMUS LINE

The extremely versatile multimodal capture unit for ENG/EMG/EP acquisition

FOCUS ON

NeMus 2 - 600 version

1. Acquisition unit with 22 inputs
Integrated stimulators
2. Medical trolley with safety closure
3. Highly flexible and intuitive
4. External interface for data interconnection and archive retrieval

CND: Z121002 / RDM: 10879

GENERAL DESCRIPTION

NeMus2 - 600 is an extremely versatile multimodal system, consisting of a NeMus 2 acquisition module and GALILEO management software, which allows the execution of electromyography, electroneurography, evoked potential examinations and optional electroencephalography also with synchronized video recording (EEG video).

It is therefore a diagnostic electromedical system, dedicated to the recording of EMG/EP/EEG/VEEG signals, equipped with both electromyographic/polygraphic and monopolar EEG/EP input channels. NeMus2- 600 is a polyvalent instrument of the latest generation, with fully digital technology, capable of integrating perfectly into any laboratory of neurophysiology. Very high sampling rates and sophisticated filtering algorithms, allow recordings with quality standards typical of high-cost systems.

HARDWARE MODULARITY

NeMus2 offers a section of specific channels for electromyography and polygraphy (bipolar channels) and one dedicated to evoked potentials and, optionally, electroencephalography. It is also equipped with electrical, acoustic and visual stimulator, programmable in different modes.

The system is equipped with 22 channels, of which 20 monopolar with touchproof inputs (that can be coupled into bipolar) and 2 bipolar channels with triple input (DIN 6-pole tuchel, 3-pole touchproof and touchproof). There are 2 additional reference and 2 ground inputs.

There is an impedance control feature, with analog (bar graph) and numeric display of the measured value.

The acquisition head, equipped with IN and OUT triggers, offers connections for external stimulators/actuators (e.g. pattern reversal monitor, pre-calibrated headset, magnetic stimulator, etc.) that can be programmed and separated from the machine body.

Possible stimulation types are:

- Electrical stimuli
- Acoustic stimuli
- Visual stimuli (Pattern, Flash and Google)

The protection degree against direct and indirect electrical contacts related to EMG patient inputs and stimulator output is BF type.

It is possible to define different types of stimuli morphology according to the examination to be performed as, for example, the electrical stimulator that can deliver positive/negative polarity, biphasic stimuli or the acoustic stimulator that can generate both clicks and tones.

The connection with the control station is via Ethernet with TCP/IP network protocol. System and Hardware are also electrically shielded from external interference.



TRANSPORT TROLLEY

NeMus2- 600 is based on a medical trolley of small size and easy maneuverability, with small size and weight, rear door for the protection of wiring, interference shielding, isolation transformer, pantograph head support arm, designed to be easily used in any situation.

The trolley is specially designed to accommodate on multiple shelves (which can be positioned at will) all the components of the system with all possible options, such as PC latest generation high performance, high-resolution 22-inch color LCD monitor that can simultaneously manage all the tracks acquired according to the protocol in use, keyboard and mouse, high-performance laser printer for printing reports in A4 format and high-fidelity powered speakers for perfect sound reproduction related to the EMG signal.

The acquisition head and the LED Flash stimulator (optional on request), can be housed either on the right or on the left side.

The trolley, built in a robust manner, has 4 non-marking wheels, two of which are equipped with parking brake and is designed to accommodate any future expansions/options.

On the bottom is housed an isolation transformer with fuse and ground socket, which supplies all parts of the system making it compliant with the regulations in force. Automatic switching on and off the isolation unit from the PC switch to facilitate ready-to-use operations.

The features described above contribute to creating an ergonomic system that is easy to use and operate.

SOFTWARE MODULARITY

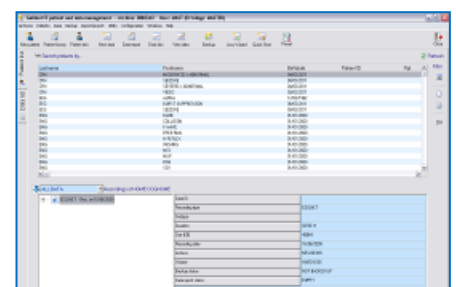
NeMus2- 600 is equipped with an efficient database developed in Borland environment, which performs the task of storing, organizing, and managing all patient data and examinations performed. Its strengths lie in the absolute guarantee of security in terms of privacy, in the simplicity of use guaranteed by its easy-to-understand user interface and in the speed of search within even large databases.

The Galileo application, manager of the NeMus 2 acquisition module, allows to meet the needs of all the methods listed below through a single database, in which the different examinations performed are grouped for each patient.

PATIENT/EXAM DATABASE

The SQL patient/exam database, oriented to network connections (multiple and distributed archives) guarantees flexibility and security.

Each User is identified by a Name and can access the system by providing his own access password.



At the moment of his registration in the authorized users list, he receives an "access level or privilege" according to which he will be allowed or prevented certain operations.

There are four levels of access available for database, exam and patient management: Reader, Writer, Master or Service.

Service: *is typically an EB Neuro technician who is delegated the installation of the system and its specifically technical maintenance.*

Master: *is the highest level among the non-technical users of the system, typically the medical manager. A user with this level of access can perform any acquisition, replay, reporting operation, can delete traces and/or patients from the archive, can insert new users in the authorized user list and can assign them an access level.*

Writer: *this is typically the level of the technician in charge of acquiring traces. This level allows: the insertion of new patients and/or traces in the database, to perform data acquisition, to open and write patient and/or trace reports. This level, however, does not allow the user to declare a track as closed and therefore to modify the data and the relative reports once it has been "closed".*

Reader: *basically, a user with this level can only read and print the information present in the system.*

The organization of the information allows to quickly search, even on multiple archives, patients, exams, medical history, reports, backup archives based on name, age, pathology, type of exam and date. A powerful statistical analysis, according to various levels of attribution of codes and values to data and patients, allows to extract useful and always updated information in a few steps, thanks also to the management of ISTAT Codes of Cities and Countries.

The editing system (PDF) of the patient's history and report is completely integrated in the Database, with the possibility to use predefined templates or to create and customize new ones according to the needs of the medical/technical staff.

The database is predisposed for interfacing between different Galileo acquisition stations through dedicated software and offers the possibility to create shared databases and workflows, as well as to read the exams on other PCs in the service network.

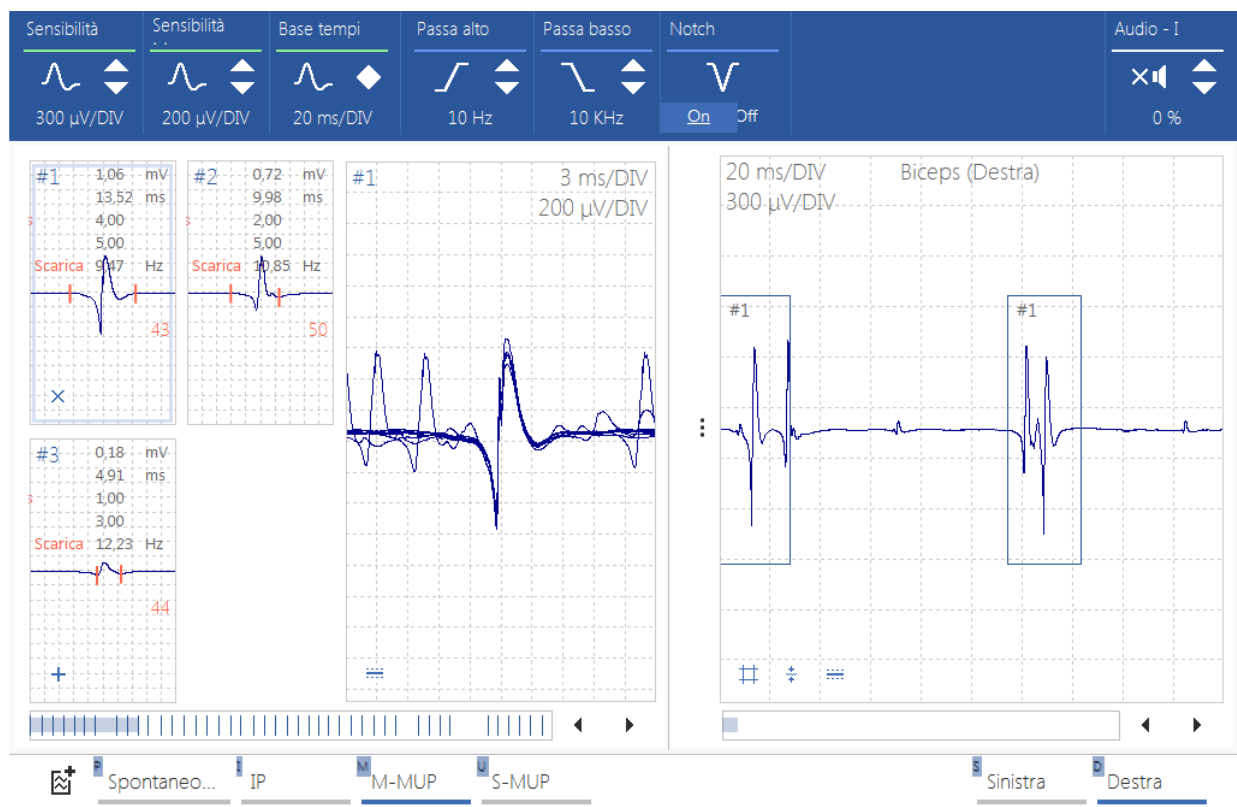
System predisposed also for HL7 interfacing with SIO and CUP.

STORAGE/ARCHIVE

The functional archiving is dedicated to the management and the safe execution of the backup operations of all the acquired data (patient data, traces, reports and anamnesis), with the possibility to store the data on centralized archives resident on company servers and/or on optical supports by means of an integrated CD/DVD/external Hard Disk/Blue Ray burner (optional Drive on request).

There is also a special "Data Browser" feature, which allows the storage on CD/DVD/USB Key of tracks that can be read on any computer, without the need to install a specific application. This feature actually creates a stand-alone re-reading tool, fully compliant with the directives of the "Regulation containing the modalities for the ascertainment and certification of death" (Law of 29 December 1993, n. 578 - Ministerial Decree of 22 August 1994, n. 582 - updated by Decree of the Ministry of Health of 11 April 2008).

SW MODULE – NEXt



The software application NEXt of the Galileo line is specifically designed and developed to perform in the most complete way electromyography, nerve conduction and evoked potentials examinations.

Working in combination with the NeMus2 system, it allows to perform, through dedicated EMG channels, all electromyography activities, both needle and surface, and evoked potentials.

Each setting can be managed by the user according to his needs and preferences, both in general and specific way, acting quickly from various locations (mouse, dedicated keyboard, shortcuts associated to the PC keyboard, controls integrated in

the handpiece, controls integrated in the head). Some values can be selected or freely edited by clicking on the parameter of interest.

In addition to the main editable parameters, such as amplifiers and stimulators, you can select the type of measurement you want the machine to calculate, with the help of intuitive images.

In order to want to program the sequence of the value both routine and non-routine, you can quickly create specific protocols that streamline the execution time and the complexity of the diagnostic procedure, thus responding to both the increasingly concentrated outpatient time and the emotional impact of patients.

Thanks to an advanced Work List, temporary work lists can be created, even on the fly and during acquisition. If needed, work lists can be saved as definitive protocols. From the Work List you can also access the list of available and previously acquired tests.

With the Snapshot and Data Browser functions, you can capture screenshots with one click or export the entire exam with all elements of the exam, so that they can be used with other programs.

During acquisition, exams performed on the patient in previous visits can be opened in re-reading for comparison.

These features take configuration flexibility and speed of exam execution to the highest levels, both in routine and research.

NExT features the following application modules for the neurography/myography portion:

1. Nervous, Motor, Sensory and Mixed Conduction
2. Motor and Sensory Inching
3. F-wave
4. H reflex
5. Blink Reflex
6. Repetitive Nerve Stimulation
7. SSR sympathetic response
8. Neurovegetative testing (RR Interval, Valsalva, Deep Breathing, Tilt test)
9. Free-run and triggered needle EMG
10. S-MUP analysis
11. Quantitative PAH analysis (optional on request)
12. M-MUP analysis (optional on request)
13. Macro EMG (optional on request)
14. EMG of single fiber stimulated and non-stimulated (optional upon request)
15. Collision testing (optional upon request).

General Features:

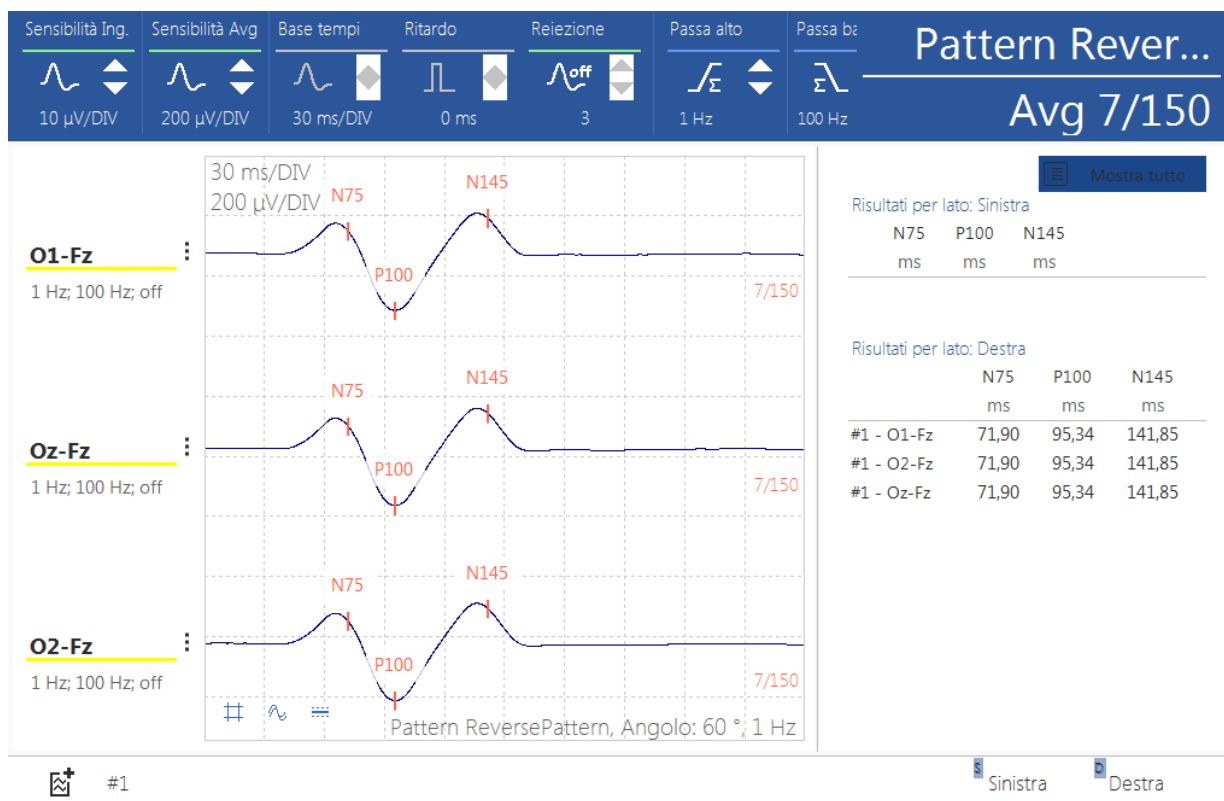
- **dynamic layout, easy and fast to use**, which can be managed at will by adding or deleting, enlarging or moving, the settings, calculation tables, notes, trend graphs,

free-run tracks

- each program is equipped with a control panel in which are available the buttons of the main parameters of acquisition, stimulation and filtering distinct through **color coding** (each track can also be managed separately thanks to its own menu)
- with the **Atlas** function, i.e. a 3D anatomical model, it is possible to select a nerve, follow its course and identify its stimulation points;
- the measured values can be compared with **normative data** (from the collection of Joe Jabre and Byron Salzsieder, available on the website www.mynorms.com), and be automatically highlighted in the report if they deviate from the normal range;
- the Recording function allows to record an indefinite number of EMG tracks and to review them later in **live mode** (including audio playback), thus making possible revisions after the acquisition phase;
- The Recording function allows you to record an indefinite number of EMG tracks and then review and analyze them in post-acquisition **live mode** (including audio playback), thus allowing review and analysis after the acquisition phase; The EMG can be viewed simultaneously on two free run windows with different display parameters and at least two screens of analysis / saving;
- **other minor functions but of great impact in daily practice are**, for example, the possibility of acquiring for each track an unlimited number of repetitions that are automatically saved and that will form a **History**, so you can later select those of greatest interest (and possibly remedy them); | the possibility of adding infinite sites during acquisition (without exiting the test) with the possibility of renaming them with a single click; a **Change side/nerve** function that, in case of error, allows you to swap the right side with the left, and vice versa, (or select the right nerve to study), without the need to rename the label or, worse, to repeat the stimulations; two modes of **Comparison** between the two sides, a passive one for simple viewing and an advanced one to make any changes; the possibility of adding measurements during the examination, selecting them with the help of explanatory images and filtering them by type;
- it is possible to create an unlimited number of **report templates** to be used and it is possible to select, even in the registration phase, the graphs and tables to be inserted or discarded, by means of the Work List window in which there is a list of the completed examinations;
- through the Dictionary you can access the **expression editor** screen that allows you to create, and automatically insert into the report, predefined phrases.

NEXT presents the following application modules for the Evoked Potentials part:

1. Somatosensory
2. Auditory
3. Visual (Pattern, Goggles and Flash)
4. Engines
5. Cognitive (optional on request)



General Features .

- management of examination **protocols** created by the user
- possibility to quickly set and modify values such as filters, mounts, stimulation parameters, sensitivity, etc.
- automatic positioning of **markers** with the possibility of freely adding new ones to the traces, with a simple click of the mouse, and renaming them in the measurement table without interrupting the acquisition;
- possibility of inserting automatic algebraic measures (including peak-to-peak amplitudes), of showing/hiding the average granularity, of modifying the style of the traces and of performing smoothing operations;
- management of **fast measurements** (also available in latency, amplitude, differential), even in acquisition without any interruption;
- possibility of comparing and acquiring in a single screen examinations

- performed in the contralateral hemisphere;
- presence of the History also for EP exams in order to quickly discard a noisy trace from the average;
- possibility to use an **advanced filtering** that acts on the raw data regenerating completely the potential;
- possibility of performing multiple MEP acquisitions on the same site and averaging them without losing the raw data.

NExT presents itself as an innovative software that readily succeeds in adapting to the most straightforward outpatient reality and at the same time satisfies the complex needs of diagnostic investigation and research.

NExT works in combination with NeMus, NeMus 2 and BePlusPro systems to meet any kind of requirement.

To complete the system, it is possible to combine a dual foot control (optional on request) and/or the NExT R-KEY myographic keyboard dedicated to the execution of all ENG/EMG/EP examinations (optional on request).



General Description

NExT R-Key is the innovative myographic keyboard that allows to manage and control the entire neurophysiological diagnostic process, speeding up the outpatient routine and simplifying the procedures in critical environments and conditions. Thanks to the Bluetooth connection and to the integrated display that updates in real-time the stimulation parameters set, it is possible to control the examination even from a distance from the acquisition station.

NExT R-Key represents a valuable aid in the execution of neurophysiological examinations, accompanying the health professional throughout the examination, from the start of the acquisition to the reporting phase.

With its simple and intuitive design, the memorization of the functions is immediate and guarantees that even the most traditional user will immediately become familiar with the device and make it his own.

Combined with the Galileo NT Line software NExT version, you get a tool of the latest generation able to meet the needs and the most deeply rooted habits of the health professional but especially to accompany and improve the diagnostic path of the patient.

Main Features

NExT R-Key has been entirely conceived and realized to guarantee the user full control of the examination, even when it is not possible to follow it from the PC station. For this reason, the keyboard is equipped with a display, in which it is possible to visualize the



stimulation parameters in real time, and with luminous leds that light up in correspondence of the pressed buttons.

Key Features:

- **OK/ESC** buttons, turn the keyboard on and off and allow to save or cancel changes
- Backlit LCD **display** (with automatic switch-off after 10s of inactivity), shows the battery level, the name of the current exam and the stimulation parameters that are updated in real time (stimulator input channel, stimulus type, intensity, duration, frequency, acoustic threshold);
- **Function keys**, associated to the shortcuts of the PC keyboard allow to control each program, from the quick modification of the settings, to the start of the stimulation/acquisition, to the reporting phase;
- **Quick control keys**, associated with an encoder with button, allow to quickly start and modify stimulation parameters (intensity, frequency, duration, polarity), to move to the next track, to activate the averaging function and to change the stimulation side;
- **Track keys**, associated with a push-button encoder to quickly change sensitivity and time base, rejection/trigger level, and reposition markers without using the mouse;
- **Audio control**, associated with a push-button encoder to activate/deactivate the audio and control its intensity;
- **Luminous LEDs**, to know in every moment which function is being activated and on which side is being acquired/stimulated;
- Rear clamp, to securely fix the keyboard to the patient's bed;
- **USB** connection
- Bluetooth 4.0 connection, to achieve maximum independence from the acquisition system;
- Input for temperature probe.

The offered system is compliant with the General Data Protection Regulation (Application EU Regulation 2016/679) in force since May 25, 2018 (so-called GDPR):

The provided systems are equipped with Galileo NT Line software applications that meet the requirements of EU Regulation 2016/679 by implementing, for example, features of encryption of sensitive data (master data, reports, medical history), software access control, protection of exam CDs/DVDs, secure data storage (protection from deletion, corruption or theft), improved login management, timed password expiration, minimum password requirements, automatic logout for inactivity, logout/login on the fly, report versioning, disaster recovery, etc

TECHNICAL SPECIFICATIONS

HARDWARE

<i>Application head</i>	EMG/ENG/EP/EEG
<i>No. of channels</i>	22 channels
<i>Acquisition channels</i>	20 monopolar (configurable in bipolar) with touchproof inputs
	<ul style="list-style-type: none"> - 2 bipolar - With triple input (DIN 6-pole tuchel, 3-pole touchproof)
<i>Input Noise</i>	< 0.3 μ Vrms
<i>CMRR</i>	> 120 dB
<i>IMR</i>	> 150 dB
<i>Input Impedance</i>	> 10000 MOhm // 8 pF
<i>Input Dynamics</i>	250 mVpp
<i>Bandwidth</i>	Up to 20 kHz
<i>Filters</i>	Notch filter: 50Hz Adaptive notch filter function capable of detecting and cutting the actual network frequencies
<i>Isolation</i>	Class I Type BF for EMG channels Class I Type CF for EP channels
<i>Environmental Data</i>	Temperature: from +5°C to +40°C Relative Humidity: 30% to 75% RH Pressure: from 700hPA to 1060hPA Storage: max. 95% RH
<i>Keyboard</i>	PC keyboard with associated shortcut controls and dedicated NExT R-KEY keyboard (optional upon request).
TECHNOLOGICAL LEVEL	
<i>A/D Conversion</i>	1 A/D converter for each channel 24 bits Σ/Δ
<i>Sampling</i>	Resolution: 1/64 microV/bit
<i>Data storage</i>	32768 Hz
<i>Impedance control</i>	Floating Point, 32-bits Max DC Offset (AC mode): +_ 500 mV Continuous raw data storage
<i>Audio</i>	On all channels at 256 Hz
<i>Trigger</i>	LINE OUT for input to PC Audio Board.
<i>Impedance meter</i>	Audio on PC speakers + external high quality speakers integrated in the cart.

IN-HEAD STIMULATORS

<i>Single channel constant current electric</i>	<ul style="list-style-type: none"> ▪ Pulse Generator ▪ Power stage ▪ Various beacons ▪ Current sensor ▪ Overload detector ▪ 2 encoders: 1 to adjust and deliver single and continuous stimulus and 1 for audio and sensitivity control ▪ 5 inputs: 1 with DIN circular, touch proof bipolar and "key" PLASTIC ONE connector and 4 with PLASTIC ONE connector <u>Opzional</u> ❖ Stimulation handpiece 	<p><u>Stimulus characteristics</u></p> <ul style="list-style-type: none"> ▪ Positive, negative, biphasic output pulse ▪ Intensity 0-100mA (0.1mA step) ▪ Frequency 0.1-100Hz ▪ Duration 50µs-1ms (step 50µs) <p><u>Features Stimulation Handpiece</u></p> <ul style="list-style-type: none"> ▪ encoder with button to adjust the intensity and deliver the single or continuous pulse. ▪ 2 programmable and differentiable buttons for single program
<i>Acoustic</i>	<ul style="list-style-type: none"> ▪ acoustic stimulus generator (clicks and tones) <u>Opzional</u> ❖ Headset TDH 39 	<p><u>Stimulus characteristics</u></p> <ul style="list-style-type: none"> ▪ condensed, rarefied and alternating stimulation ▪ mono or biaural stimuli (and/or white noise) rental ▪ automatic subjective auditory threshold search
<i>Visual</i>	<ul style="list-style-type: none"> ▪ light stimulus generator <u>Opzional</u> ❖ PATTERN Monitor ❖ LED FLASH stimulator with support arm ❖ GOOGLE LED stimulator 	<p><u>Stimulus characteristics</u></p> <ul style="list-style-type: none"> ▪ 4 independent quadrants ▪ Quadrant content: uniform color, checkerboard, horizontal bars, vertical bars (with/without masking) ▪ Colors: selectable ▪ Contrast: between 0% and 100% ▪ Size: variable, with self-adjustment based on monitor-patient distance ▪ Customizable fixation point ▪ Visual angle expressed in ° or in no. of stimulation elements ▪ Stimulation mode: alternating or reverse ▪ Settable frequency ▪ Trigger: selectable on T or T/2 ▪ Integrated IN/OUT triggers to manage other types of stimulators ▪ These parameters are directly related and dependent on each other: the software automatically controls the value of each parameter and limits the range of permissible values according to the value set for the others.

*Magnetic
(optional on
request)*

Description

Powerful magnetic stimulator (available in 4 models) of new generation, wheeled with suitable arm to support the coils.
Through the wide color TFT display it is possible to control and set in a simple and intuitive way all the functions of the machine.
Control console with dedicated keys for direct functions and knob for setting the charge percentage and display functions.
Manual, automatic, double stimulation (optional) and repetitive stimulation operation.
Stimulus frequency up to 100 Hz (depending on model).
Trigger command on input and TTL output for connection to EMG devices.
Direct commands on the COIL for energy increase and stimulus activation, with energy setting visualization on display.
Two-channel MEP detection module (depending on model) connected to the USB port of the system that allows visualization and monitoring of the muscle response signal directly on the system display.

Technical Features

MONITOR TFT LCD Widescreen DELL

<i>Screen Size</i>	22"
<i>Screen Brightness</i>	250 cd/m ²
<i>Resolution</i>	1920 x 1080 Pixels
<i>USB hub version</i>	USB 2.0 e 3.0
<i>Product Color</i>	Nero
<i>VESA Mounting Interfaces</i>	100 x 100 mm
<i>AC Input Voltage</i>	100 - 240 V
<i>AC Input Frequency</i>	50/60 Hz
<i>Power Consumption (Max)</i>	37 W

PC

<i>Brand and Model</i>	Optiplex XE3
<i>Type</i>	Desktop compact
<i>Power</i>	100/240V-50/60 Hz
<i>Processor</i>	Intel® Core i5-8400
<i>Video Card</i>	Intel® UHD Graphics 630
<i>Ram</i>	8 GB espandibile a 16 GB
<i>Hard Disk</i>	1 TB + SSD 512 GB
<i>CD/DVD R/W</i>	8x DVD+/- RW Drive
<i>Operating System</i>	Microsoft® Windows® 10 Professional
<i>Keyboard and Mouse</i>	Inclusi
<i>Software License</i>	Microsoft Office 2016: MS Word, MS Excel, MS Power Point, MS Outlook e MS OneNote

PRINTER LASER B/N

<i>Processor</i>	600 MHz
<i>Memory (RAM)</i>	8 MB
<i>Interface (standard)</i>	USB 2.0 Hi-Speed
<i>Power Consumption</i>	380 W (Print) / 1,7 W (energy saving) / 0,5 W (stand-by)
<i>Noise</i>	6.5 dB
<i>Dimensions (WxDxH)</i>	332 x 215 x 178 mm
<i>Weight</i>	3,97 Kg
<i>Monthly Duty Cycle</i>	Max10000 pages
<i>Speed (B/W)</i>	Up to 23 ppm in A4
<i>Resolution</i>	1200 x 1200 dpi

Print languages	GDI	
ISOLATION TRANSFORMER		
Rated Voltage	220-240V/50Hz	115V/60Hz
Usage range	220-240V/±10%	115V±10%
Rated absorption	575VA	
Maximum output power	500VA	
Insulation voltage	Primary – secondary ≥ 4kV	
Surface distance	Primary - secondary ≥ 8mm	
Leakage current	≤ 100µA	
Frequency	50 Hz	
Short-circuit protection	Fuse 2xT5A, dim 5x20mm (for 220-240V/50Hz version) Fuse 2xT10A, 5x20mm (for 115V/60Hz version)	
Overload Protection	Thermal switch with 110°C trip temperature	
Inputs	N. 1 mains voltage input socket N. 1 input socket for remote control ON/OFF controlled auxiliary outputs N. 1 connection for equipotential terminal	
Outputs	N. 4 auxiliary isolated network output sockets controlled by an external ON/OFF signal N. 1 Master isolated output socket (not controlled ON/OFF by external signal)	
External dimensions and weight (Cart System)	Width: ~ 78 cm Height: ~ 125 cm Depth: ~ 90 cm Weight: ~ 35 Kg (Standard configuration)	

Consumer products are not exclusive. However, the products offered by EB Neuro have been optimized for the best function with the proposed equipment.

"Document containing parts to be considered secret for the purposes of disclosure in case of request for access to the acts" as provided for in Art. 53 of Legislative Decree no. 50 of 18/04/2016".

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