ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 049512 0022 Rev. 00

Manufacturer:

Shenzhen Delica Medical Equipment Co., Ltd.
18F, Building B, High-tech park
Guangqiao Road, Tianliao Community, Yutang Street
Guangming Distrct
518107 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

This Confirmation Statement is only valid in combination with the following EC Certificate (MDD):

G1 049512 0018 Rev. 02

This Confirmation Statement confirms the validity of the aforementioned EC Certificate MDD. It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2021 or later.
The conditions laid down in Article 120 (3) of Regulation (EU) 2017/745 on medical devices for placing devices on the market and putting into service apply.

Report No.: BJ21089703

Valid until: 2024-05-26

Issue Date: 2022-02-24

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Cârstocea Ioan-Răzvan
Date: 2022.06.17 15:45:00 EEST
Reason: MoldSign Signature
Location: Moldova

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Confirmation Statement on validity of EC Certificate (MDD)

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No. GCQ 049512 0022 Rev. 00

Product Category(ies): **Transcranial Doppler Ultrasound system, Neuro Monitor System, Multifunctional Vascular Ultrasound, Electroencephalograph (EEG), Cerebral-Somatic Oximetry System, Depth of Anesthesia Monitor.**

Description of Change: **Change of company address: "6F, Block 10, The Second Industrial Zone, Guanlong, Nanshan District, 518055 Shenzhen PEOPLE'S REPUBLIC OF CHINA" changed to "18F, Building B, High-tech park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming District, 518107 Shenzhen, P.R.China"**

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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 049512 0018 Rev. 02

Manufacturer:

Shenzhen Delica Medical Equipment Co., Ltd.
6/F, Block10, The Second Industrial Zone
Guanlong
Nanshan District
518055 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Transcranial Doppler Ultrasound system, Neuro Monitor System, Multifunctional Vascular Ultrasound, Electroencephalograph (EEG), Cerebral-Somatic Oximetry System, Depth of Anesthesia Monitor.**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 049512 0018 Rev. 02

Report No.: BJ20089702

Valid from: 2021-04-23
Valid until: 2024-05-26

Date, 2021-04-23

Christoph Dicks
Head of Certification/Notified Body

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SHENZHEN DELICA MEDICAL EQUIPMENT CO.,LTD.

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

MANUFACTURER:	SHENZHEN DELICA MEDICAL EQUIPMENT CO.,LTD. *18F, BUILDING B, HIGH-TECH PARK, GUANGQIAO ROAD,* *TIANLIAO COMMUNITY, YUTANG STREET, GUANGMING DISTRICT,* *SHENZHEN, 518107, P.R. CHINA*
EUROPEAN REPRESENTATIVE:	SHANGHAI INTERNATIONAL HOLDING CORP.GMBH(EUROPE) *EIFFESTRASSE 80, 20537 HAMBURG, GERMANY*
PRODUCT:	TRANSCRANIAL DOPPLER ULTRASOUND SYSTEM *10429* *EMS-9PB ,EMS-9U1,EMS-9U2,EMS-9UA, EMS-9D,* *EMS-9F,EMS-9D EXP,EMS-9D PRO,EMS-9M1,EMS-9M2*
CLASSIFICATION:	*CLASS IIA, RULE 10*
CONFORMITY ASSESSMENT ROUTE:	*ANNEX II, EXCLUDING SECTION 4*

WE, SHENZHEN DELICA MEDICAL EQUIPMENT CO., LTD. HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES.
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED:

IEC 60601-1:2005/A1:2012; IEC 60601-1-2: 2014; IEC 60601-2-37:2007/AMD1:2015; ISO 10993-1:2018; ISO 10993-5:2009; ISO 10993-10:2010; EN1041:2008, EN ISO 15223-1:2016, EN 62304:2006+A1:2015, EN 62366-1:2015.

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
IDENTIFICATION NUMBER	0123
(EC) CERTIFICATE(S):	G1 049512 0018 Rev.02
START OF CE-MARKING:	2005-12-06
PLACE, DATE OF ISSUE:	SHENZHEN 2021-09-09
SIGNATURE:	Xiao Zhenhua *POSITION : QUALITY MANAGER*

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 049512 0020 Rev. 03

Holder of Certificate: **Shenzhen Delica Medical Equipment Co., Ltd.**
18F, Building B, High-tech park
Guangqiao Road, Tianliao Community, Yutang Street
Guangming Distrct
518107 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production, Distribution, Installation and Servicing of Transcranial Doppler Ultrasound system, Neuro Monitor System, Multifunctional Vascular Ultrasound, Electroencephalograph (EEG), Cerebral-Somatic Oximetry System, Depth of Anesthesia Monitor.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 049512 0020 Rev. 03

Report No.: BJ21089705

Valid from: 2022-04-04
Valid until: 2025-03-31

Date, 2022-04-04

Christoph Dicks
Head of Certification/Notified Body

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DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 049512 0020 Rev. 03

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Shenzhen Delica Medical Equipment Co., Ltd.
18F, Building B, High-tech park, Guangqiao Road, Tianliao Community, Yutang Street, Guangming Distrct, 518107 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production, Distribution, Installation and Servicing of Transcranial Doppler Ultrasound system, Neuro Monitor System, Multifunctional Vascular Ultrasound, Electroencephalograph (EEG), Cerebral-Somatic Oximetry System, Depth of Anesthesia Monitor.

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EMS-9D Specifications

General

Power supply: 110V-240V, 50-60Hz
Weight: 6.5±0.3 kg
Dimension: 360× 155× 345（L×W×H）
Doppler Frequencies:
1.6/2MHz PW
4, 8MHz CW&PW
16MHz PW
Technology: Full digital with Unique combination

Display

Size: 15'' color LCD with touch screen

Computer

CPU: Inter core i2 2.1G
RAM: 4GB
Graphics card: support 1024×768 or better, 32bit color
Hard disk: 500GB or higher
4* USB 2.0 + 2*USB 3.0
Operating System: MS Wes 7/Win 10

Protocols

User define protocols for all application

Examination

Unilateral/Bilateral
CW/PW probes
Power/Phasic M Mode
Customized screen layout
HITS detection: classic algorithm provides a reliable counts information.
Post processing: Depth, Gain, Scale, Gate, etc
With Raw data saved, every depth could be replayed.
1.6MHz Depth Range: up to 140mm
Gain steps: 40
Power steps: 19
PRF (scale): up to 722 cm/s
Sweep time: 4 sec to 32 secs in routine mode
Up to 4 hour in monitoring mode
Units: kHz or cm/s
Angle: 0-89 deg
Filter: 0-2700 Hz
Adjustable zero line
Adjustable Volume
Noise rejection option
Color resolution: 20 colors
Multiple FFT color palettes
M mode resolution: 128 depths combined into 8000 gates
Multi-depth display: up to 8 spectrums
On Screen Cursors
Velocity Profile
Depth scan
Unique Robotic probes for monitoring applications
Grid display
Manual Interpretation Labels
Automatic Interpretation figures

Displayed Parameters

Peak, Mean, Dias, PI, RI, STI, DMean, HR, SD, SBI, HITS, LI, VMR, EtCO2, CO2R
With integral NIBP system:
Sys, Dia, Map, reBAP, finBAP, Hite,IBI,HR,LVET,SV,CO,TPR,PS*HR, etc

Software Features

Interactive Summary Screen
Local Language import system
One key setup/restore system
Easy printer installation
Vessel configuration before/after test
Password protection for whole system

Reporting

Report format: BMP, XML, PDF, DOC and XLS
Customized report for each user
Editable template

Connectivity

Analog input channels:8
Analog output channels:8
Digital input channels:8
Digital output channels:8
CO2 module support
NIBP module support
Review patient database over network
DICOM worklist
DICOM store
DICOM structure report

Accessories

Remote control
Keyboard/mouse
Probe holder

Regulatory Approvals

ISO 13485
IEC60601 / IEC61010
IEC60601-1-2
EN 60601-2-37
CE marked
FDA approval

Technical Report

Portable Transcranial Doppler System

EMS-9D PRO

EMS-9D PRO
Image for illustrative purposes

Bilateral portable TCD for the evaluation of intracranial and extracranial hemodynamics

FOCUS ON

- **Lightweight, smart, compact, all in one portable doppler**
- **Signal acquired with absolute fidelity**
- Fast, flexible, intuitive software
- **Exclusive monitoring system with robotic probes**

GENERAL INTRODUCTION

EMS-9D PRO is an integrated digital transcranial Doppler, with all-in-one medical PC and 15 ”touchscreen LCD monitor, of the highest quality made with cutting-edge technology,

Complete and compact, it can be used for intracranial examinations, examinations of peripheral and microvascular vascular districts. It has probes with a frequency range from 1/1.6 / 2MHz to 16 MHz CW and PW and two channels active simultaneously. The two doppler channels record in multigates from different depths. The spectrum of the signal can be represented both in M-Mode up to 128 depths (with direct choice of depth), and up to 1,500 micro gates, and in monogate mode.

The proposed system can be built on a compact, ultra-light and easily transportable trolley and is designed for connection to the company network. Its ease of use derives from the presence of icons that guide the user in an intuitive way, allowing a considerable speed of execution of the examination, as well as a management of patient information and automated reports. The tool offers the possibility to manage the flow of exams with maximum versatility, with the opportunity to control all the graphic, personal and numeric information with freeze and scroll functions via mouse, keyboard, dedicated remote control. The system provides complete programmability of the working protocols, excellent signal quality and automatic saving of data in different reworkable formats. It also offers complete management of reference values and clinical indices by age group, highlighting out-of-range results in the report. It also allows you to perform statistics on the speed and clinical indices of each individual vessel.

The audio section is equipped with a very high fidelity stereo system.

The deliverable power of ultrasound benefits from protection according to the ALARA principle, and guarantees total patient safety. It is possible in any case, for particular situations, to expand the available power over 100% for a limited period, with notice in the stimulation parameters section.

HARDWARE

The EMS-9D PRO system is composed of the following units:

- Doppler acquisition module
- Integrated 15 "LCD color touch screen monitor
- Dedicated keyboard for remote control
- Wireless mouse and keyboard
- N. 1 manual probe: 1.6 MHz and 1 probe 4 MHz
- Probe holder support
- Loudspeakers with very high fidelity and quality
- Ultrasonic gel bottle
- Helmet support for monitoring with two 1.6 MHz probes

The dedicated USB keyboard, is made of elastomeric material at die-cast mold. The total absence of cavities in its form, protects the system from the attack of liquids that could accidentally come in contact, moreover, given the consistency of the mold the remote control is resistant to shocks and mechanical stresses.

The dedicated keyboard has the following 3 sections:

- *change of functions*
- *change of the acquisition parameters/ selection/saving*
- *selection / saving functions*

In the "functions and mode change" there are the first 4 keys (F1, F2, F3, F4) that can be associated in a personalized way with specific functions according to the user's needs, such as for example printing the screenshot, setting the scale range, exam mode change, probe type selection and sound enable / disable

In the "variation of the acquisition parameters" section there are buttons dedicated to setting the main acquisition parameters during the examination, such as depth, amplitude, gain, window size, zero scale adjustment, M Mode gain.

Finally, in the last section, there are 4 directional keys to scroll through the various options, as well as keys for freeze / unfreeze, data saving, recording of videos, changing of vessels and flow directions.

Probes can be connected laterally on the acquisition unit through special Lemo connectors, such as to guarantee a stable and long-lasting connection over time.

The 1.6MHz probes are to be considered improvement elements compared to the classic 2 MHz probes, as 1.6 MHz frequencies have a greater penetration depth and require a lower dose of energy for the same duration exposure, ensuring greater safety.

SOFTWARE

The software of the EMS-9D PRO system, easy to use and structured in a very intuitive way, allows the visualization of the Doppler signal online, the management of the examination and patient data archive, the implementation of customizable work protocols and the generation of the reports automatically.

The EMS-9D PRO software is structured for two different types of exam: routine and monitoring. In both modes there are indications on the type of exam, patient data, time and date of registration. There is also a bar where you can access the main exam setup menus and the parameters displayed, to manage the patient and exam archive and to proceed with their reporting. In addition, to guarantee the user quick and intuitive access to the main management operations, it is possible to configure a toolbar with icons that immediately recall the function of the same.

All images can be exported in BMP format, monitoring recordings in AVI format and sounds can be exported in WAV format.

They are displayed on the screen:

- *Window of the current Doppler spectrum*, having the passage of time on the abscissa (in seconds) and the flow rate on the ordinate (in cm / sec or frequency)
- *Window of Doppler spectra previews at different depths* *to get a complete overview of the explored district*
- *Type of probe*
- *Vase*
- *Flow direction*
- *Acquisition parameters* (depth, window size, gain, amplitude, power, range)

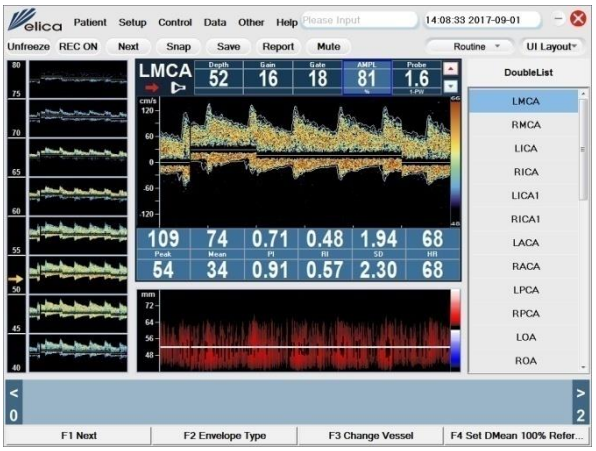
- *Clinical Indexes* (Peak systolic and diastolic speed, Average value, Pulsatility index, Resistance index, Systolic / diastolic ratio, Spectral amplitude index, Heart rate, Thermal index, Percentage variation Vmed, Lindegaard index)
- *Dynamic image window* (screenshot, audio files, video files)
- *Event window*
- *Current examination protocol* (freely configurable by the user, both in the choice of vessels and in the setting of the parameters associated with them)
- *M mode multigate with possibility to select sensitivity and display mode*

By activating the M-Mode it is possible to monitor several different depths simultaneously. Once the useful signal depth range has been identified, by simply clicking on this range it is possible to show the spectrum. The M-Mode is a powerful aid for identifying the vessels and for managing the soundproofing parameters, as it offers immediate reception of signals at different depths together with their direction of flow (red approaching, blue moving away).

EMS9-D PRO allows you to view the spectra at different depths on the same screen, providing a complete overview of the hemodynamic scenarios of the analyzed district. By selecting a Doppler spectrum from those displayed (for which it is possible to define the resolution of the depth scale) the relative signal will be displayed in the main window and parameters and indices will be shown.

It is possible to obtain the envelope on the positive side, the negative side or both, as well as deciding whether to display it superimposed on the Doppler signal or isolated.

Adaptive Baseline



The adaptive baseline allows, if selected by the user, to automatically modify, based on the signal, the baseline in order to avoid the aliasing effect.

The software allows an analysis of the sound of the portion of the saved track. The interval on which to perform the sound analysis can be freely set by the user. It is possible to insert markers for making measurements and create labels to label relevant events.

BI-CHANNEL MONITORING

In the monitoring section it is possible to use simultaneously nr. 2 1,6 or 2 MHz probes. For each it is possible to display two depths per channel as the main signal and 4 previews at different depths. The trends, grouped by type of index, can be viewed for each window, with different colors based on the values of the vessels monitored. Also on trends it is possible to measure and insert event labels.

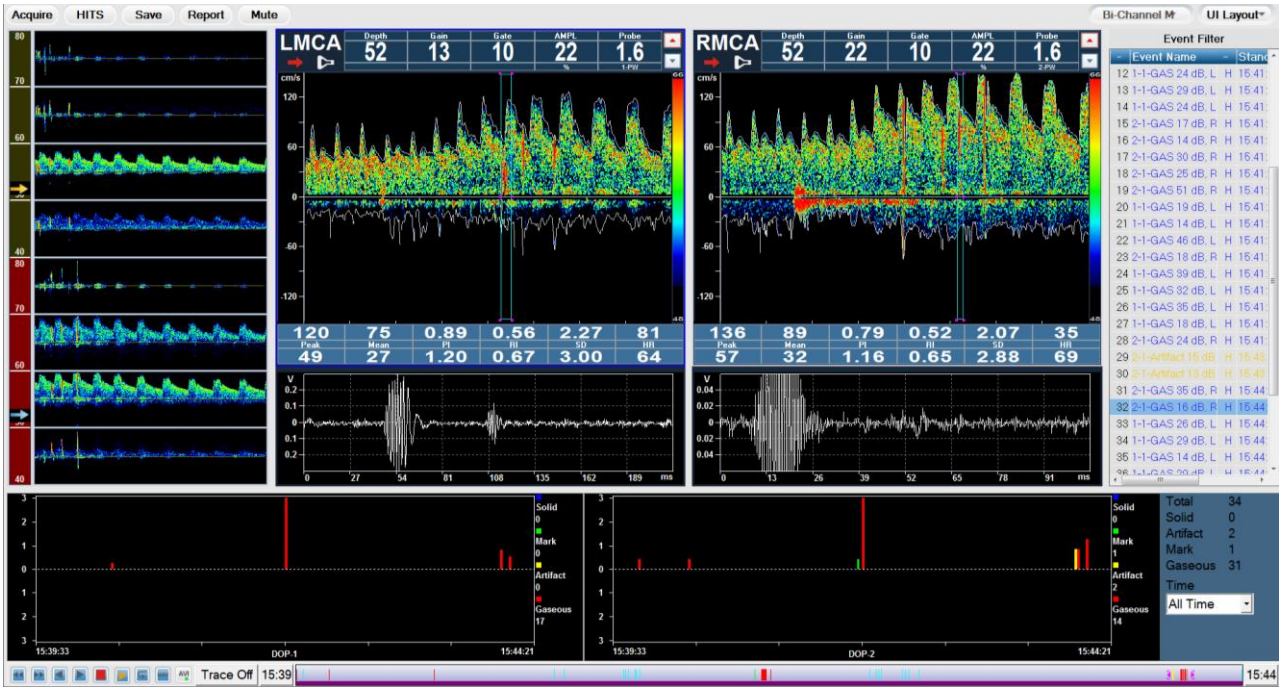
The comfortable helmet complete with nr. 2 1,6 or 2 MHz monitoring probes has been designed to guarantee maximum ease of use and maximum ergonomics for the patient.

In the monitoring mode it is possible to view the main TRENDS and analyze the time series. The selection and display can also be done offline. In the trend section there is a dedicated scroll bar and it is possible to insert and view user-defined markers

HITS detection

The analysis for the recognition of the emboli is one of the main strengths of the EMS-9D PRO transcranial Doppler, it is based on the following analysis:

- *Analysis of the signal intensity*
- *Analysis of the duration of the event*
- *Analysis of the zero-crossing dynamics of the audio signal*



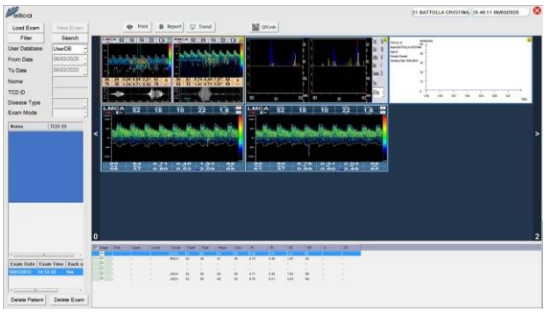
The module has a multilayer neural network that classifies events into micro-emboli (MES) signals or artifacts.

It is possible to display a double doppler window on each side, at different depths, which can be set as desired, in order to have evidence of the direction of the MES.

In any case, it is possible to analyze the track in playback and decide to manually add or remove HITS, thus allowing the user to further discriminate the presence of emboli from the artifacts. Emboli and artifacts are automatically presented in the event list and can be represented in the form of histograms.

Management of patient database and reports

The information relating to the patient (name, surname, age, gender, home, etc.) can be freely inserted and changed at the beginning of the examination session or at any time during the examination session (online). The fields entered will then be automatically displayed in the report. The reports are in XML format and fully configurable by the user, who may decide to insert images, numeric values, reference values and statistics. The report will automatically report values that exceed the range of reference values. The reporting of the trace is dynamic or the user is able to immediately view the composition of the report by adding or removing images, values and other stored data, by simply selecting them on the relevant checkboxes.

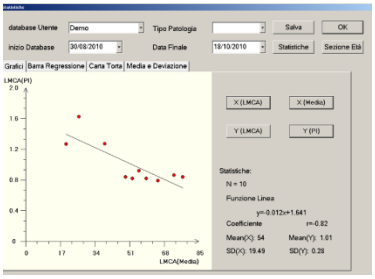


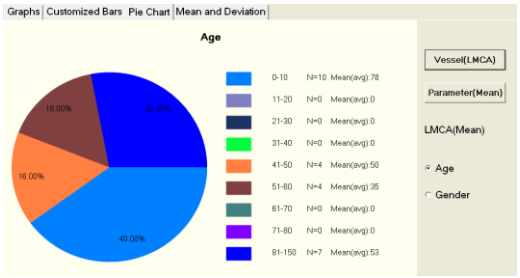
The storage system allows you to save data and reports on any storage device, both internal (hard disk) and external (CD, DVD, USB pen)

The reports can be exported to XML, DOC, RTF and PDF.

Statistics

The stored information can be processed statistically with the special "Statistics" function dedicated to the real-time display of bar graphs, histograms, cakes according to various research parameters such as: exam date, pathology, gender, age group, vase, index, etc .



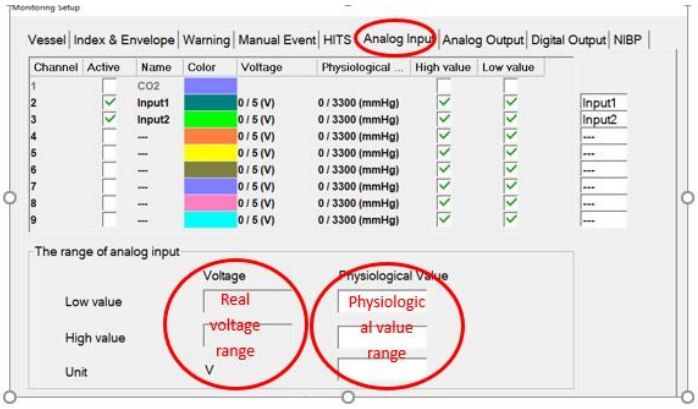


In addition, the average values and the standard deviation for the group of data analyzed are automatically calculated.

ANALOG INPUT MODE (VMR, external analog inputs)

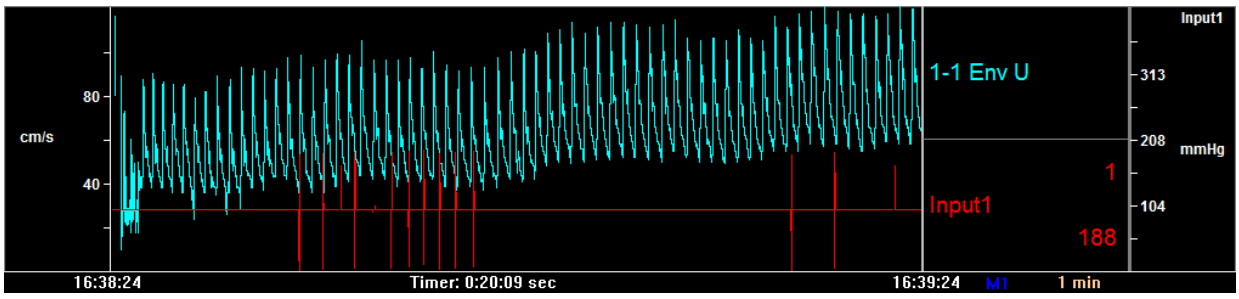
The ANALOG INPUT mode introduces *nr. 8 different external analog signals at the same time* to the EMS9D PRO system to evaluate their variation together with the TCD signal.

To start the analog input analysis it is necessary to enter the Monitoring mode, and set the input parameters with the appropriate ranges, related to the properties of the analogic signal

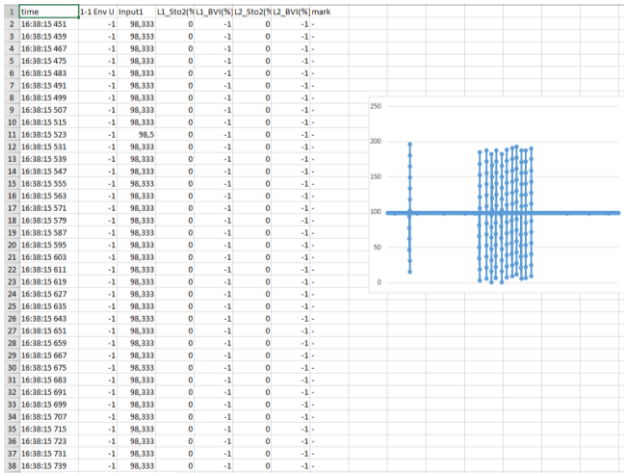


The synchronization with the TCD signal is 100% guaranteed and this allows, for example, to carry out CO2 tests and evaluate the VMR vasomotor response, or to manage the input signal of the NANORE module for the real time non-invasive evaluation of blood pressure.

Through an appropriate analog converter (not included) it is possible to manage triggers and external signals, *such as light stimuli for the evaluation of the Evoked Flows.*

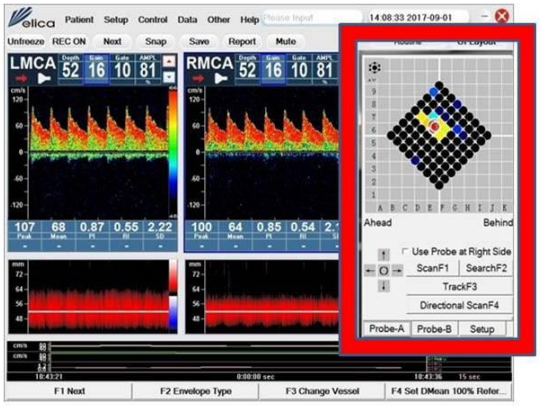


At the end of the recording, it is possible to export the full trend in txt or excel format. In this format, it is possible to evaluate the selected parameters of the TCD, the mV of the analog signal and relative time.



ROBOTIC PROBES MONITORING SYSTEM

With the new TCD EMS-9D PRO system, a robotic helmet and dedicated probes with mechatronic controls with high technological performance are available which allow monitoring of the highest signal quality and guaranteed stability over time. This module, based on an extremely simple and intuitive interface, is structured on two distinct types of operation: search for the best signal in relation to the selected depth and keep the acquired signal stable over time.



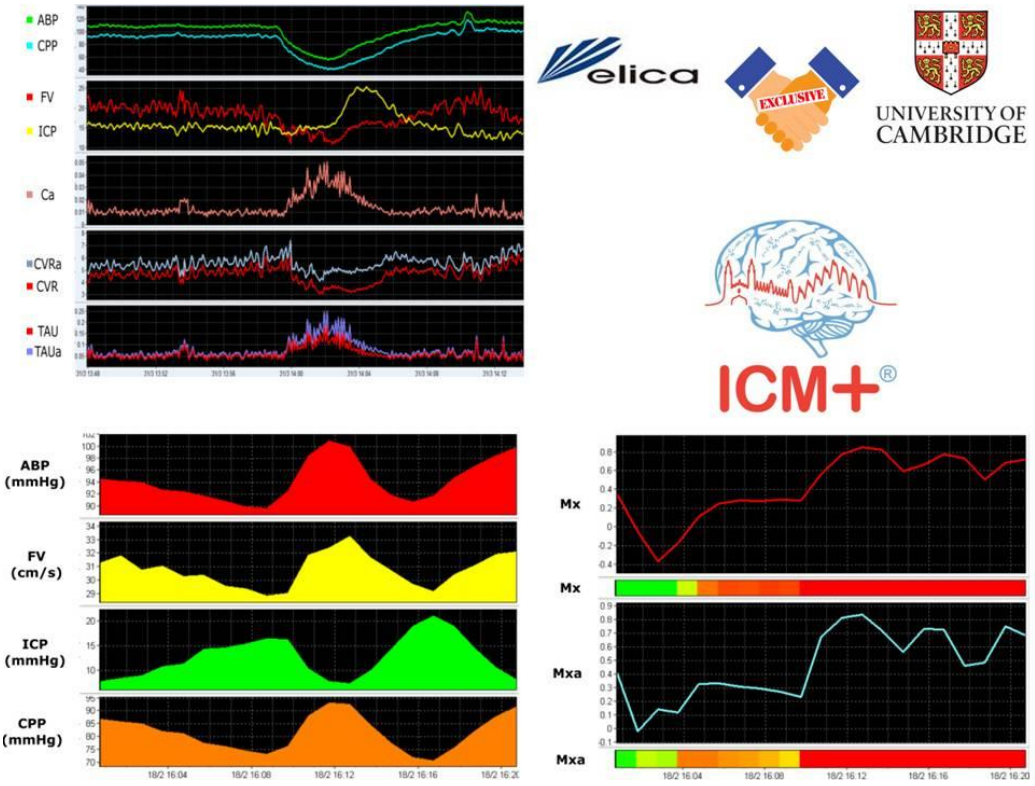
Signal search: through 3 distinct modes of space navigation (Scan, Search, Directional Scan), fully automated, it is possible, through accurate software analysis, to find the signal with greater stability and intensity. After fixing the probes above the time window, a

generic scan is initially possible in the area adjacent to the probe. Afterwards, once a first valid signal has been found, it is possible to scan with greater resolution around the previously found point. Finally, a further scan at higher resolution allows you to find the best quality signal for both channels.

Signal stabilization: once a signal has been detected, either manually or automatically, it is possible to stabilize that signal with the tracking function. Any movement of the patient's head, artifacts from breathing or random destabilizations of the helmet automatically activate the mechatronic control system which will automatically find the original signal. With this active control, the doctor has a guarantee of a quality and stable signal over time, without having to worry about finding the lost signal manually with laborious operations and therefore without any loss of time.

INNOVATIVE SOLUTION – SOFTWARE ICM + (optional)

The EMS-9D PRO system features an innovative operating mode, which, together with the flexibility of the connections available, make it an instrument capable of offering innovative diagnostic solutions, both in the *clinical* and *research* fields.



The EMS -9D PRO system is designed for dynamic and direct integration, in real time, with the Cambridge University ICM + software module for the visualization of the NPIB (non-invasive intracranial pressure), through Analog output license. Cambridge University ICM

+ software is not included in the offer, as it can be distributed but can be purchased directly by Cambridge University through educational networks.

TECHNICAL SHEET

EMS-9D PRO

N. of inputs	22 inputs: • Nr. 2 1MHz, 1,6MHz e 2MHz probes • Nr. 1 4MHz probe • Nr .1 8MHz probe • Nr. 1 16MHz probe • Nr. 2 for robotic probes 1,6MHz/2MHz • Nr. 1 Analog Input • Nr. 1 Analog Output • Nr. 2 LAN port • Nr. 1 HDMI • Nr. 4 2.0 USB port • Nr. 2 3.0 USB port • Nr. 2 VGA port • Nr. 2 NIPB (Nanocore Finapres)
Dimension	360 mm×155 mm×345 mm (L×W×H);
Weight	6,4 Kg

PC ALL IN ONE SPECIFICATIONS

Processor	Inter core i2 2.1G
RAM	RAM=4G
Hard Disk	500GB up to 1TB.
Graphic card	1024× 768 32bit color.
Audio card	Integrated
WIFI card	IEEE802.11 ac/n or above
Display	15'' color LCD touch screen
Operating System	Windows 10

PROBES

Type	PW: 1 MHz, 1.6 MHz, 2 MHz, 4 MHz, 8 MHz CW: 4 MHz, 8MHz, 16MHz

Depth	1,6 MHz: 5-150 mm, 2MH: 5-150 mm, 4MHz: 1-80 mm, 8MHz: 1-26 mm 16MHz: 0,1-9 mm
Depth steps	1,6 MHz: 1,2,3,5 mm, 2MH: 1,2,3,5 mm, 4MHz: 0.1,0.2, 0.3, 0.5mm , 8MHz: 0.1,0.2, 0.3, 0.5mm, 16 MHz: 0.1,0.2, 0.3, 0.5mm
Scale	1,6 MHz: 0-722cm/s, 2MH: 0-540cm/s, 4MHz: 0-518cm/s, 8MHz: 0-258cm/s, 16MHz: 0-128cm/s
Velocity	Cm/s or KHz
Gate	1,6MHz: 1-20 mm Sample V, step 1 mm 2MHz: 1-20 mm Sample V, step 1 mm 4MHz: 0.2 – 5mm Sample V, step 0.2 mm 8MHz: 0.1 – 3mm Sample V, step 0.1 mm 16MHz: 0.1 – 1.8mm Sample V, step 0.1 mm
FFT	64,128,256,512 FFT dots
PRF	Up to 24KHz

COMPLIANCE WITH QUALITY STANDARDS

Classe	I type BF
IEC	60601-1: 2005 / A1: 2012 60601-1-2: 2007 60601-2-37: 2007

MANUFACTURER

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