3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia
Notified Body No. 2265

EC CERTIFICATE

No. 2018-MDD/QS-031

issued in compliance with the Council Directive 93/42/EEC as amended by 2007/47/EC, which is implemented by the Slovak Government Decree No. 582/2008 Coll. as amended by 215/2013 Coll. certifies that the medical device of Class IIa

Polysomnograph SomniPro PSG
Type: CL and PT

manufactured by company

DEYMED Diagnostic s.r.o.
Kudrnáčova 533, 549 31 Hronov, Czech Republic

is manufactured under conditions fulfilling the quality system requirements of Annex II, excluding (4), of the Directive 93/42/EEC as amended by 2007/47/EC.

The Notified Body No. 2265 has performed an audit of the above device quality system. The full quality assurance system has been assessed and found that it meets the requirements above. The quality system is subject to continuous surveillance according to Annex II, Sections 3.3, and 5, of the Directive 93/42/EEC as amended by 2007/47/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. SK-0570-M/18 and in the Final Protocol No. 310353/2018.

This certificate is issued under the following conditions:

It applies only to the quality system maintained in the manufacture of the above referenced model of medical device and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until Dec 2, 2023 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfilment of relevant legal and other requirements by manufacturer.

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Dr. Katarína Tomin Srdošová
Responsible to act on behalf of NB 2265

In Bratislava on December 3, 2018

Digitally signed by Cârstocea Ioan-Răzvan
Date: 2022.09.14 19:25:37 EEST
Reason: MoldSign Signature
Location: Moldova

3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia
Notified Body No. 2265

EC CERTIFICATE

No. 2018-MDD/QS-029

issued in compliance with the Council Directive 93/42/EEC as amended by 2007/47/EC, which is implemented by the Slovak Government Decree No. 582/2008 Coll. as amended by 215/2013 Coll. certifies that the medical device of Class IIa

Electroencephalograph TruScan EEG
Type: CL 24 / 32 / 64 / 128 / 256 and PT 24 / 32 / 64 / 128

manufactured by company

DEYMED Diagnostic s.r.o.
Kudrnáčova 533, 549 31 Hronov, Czech Republic

is manufactured under conditions fulfilling the quality system requirements of Annex II, excluding (4), of the Directive 93/42/EEC as amended by 2007/47/EC.

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This certificate is issued under the following conditions:

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Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Dr. Katarína Tomin Srdošová
Responsible to act on behalf of NB 2265

In Bratislava, on December 3, 2018

SomniPro® PSG

PSG / EEG / LTM | SYSTEM

Multi-Use WIRELESS

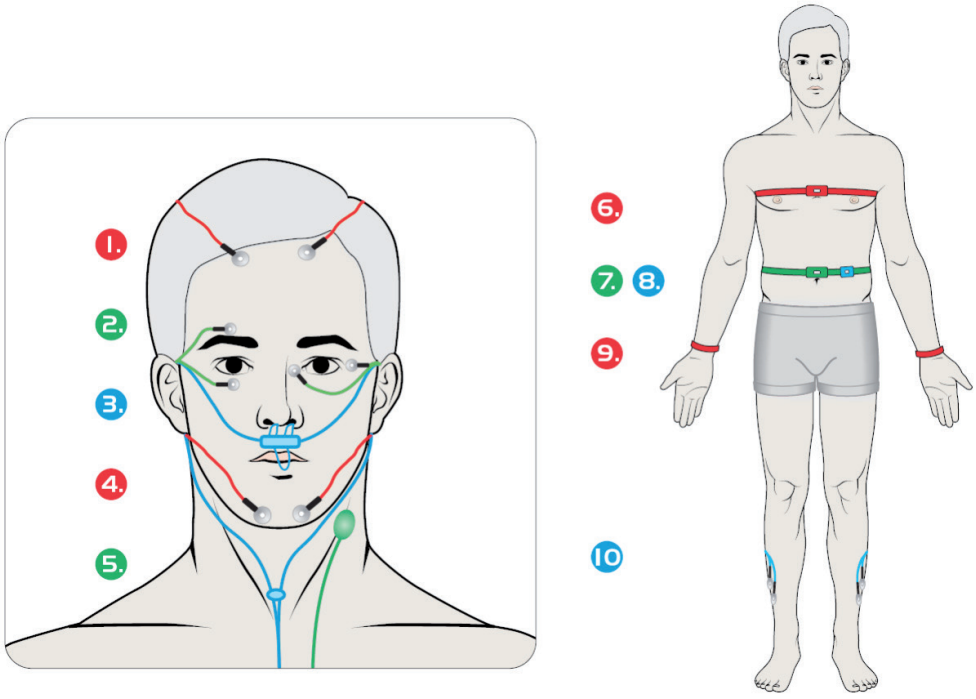
PSG/EEG SYSTEM

Deymed DIAGNOSTIC

What is PSG?

Polysomnography is multi-parametric test used in the study of sleep and as a diagnostic tool in sleep medicine. The test result is called a polysomnogram, also abbreviated PSG.

Video-EEG polysomnography is a technique combining polysomnography and video-recording, which has been described to be even more effective than only polysomnography for the evaluation of some sleep troubles such as parasomnias, because it allows to more easily correlate EEG signals, polysomnography and behaviors.



1. EEG electrodes
2. EOG electrodes
3. Airflow
4. Chin
5. Snore
6. Thorax
7. Abnomen
8. Body
9. ECG
10. LEG

Headbox

Advantages of SomniPro PSG

Deymed manufactures reliable and high-quality neurodiagnostic and neurocare systems. Our goal is to advance the Neurology and Neurophysiology fields to new heights with engineering innovation. All Deymed Neurocare systems are designed for ease-of-use and durability with advanced features that simplify your work.

Battery Operated

Offering the highest signal quality possible and lasting months on a single charge, Deymed systems significantly reduce artifacts and outside noise by running 100% on batteries.

Wireless Use

In wireless mode the amplifier can record for up to 20 hours on a single charge. Wireless range of 100 meters from the base system for maximum patient comfort and freedom to move.

Intelligent Charging

Deymed's new ultra-low capacitance induction charging keeps the batteries full when the headbox is connected to system. This ensures the highest quality signal is possible with full battery operation during sensitive neurophysiology tests.

Optical Isolation

Optical isolation greatly improves signal quality and patient safety. This feature combined with long-lasting battery operation, offers the best-in-class technology for neurophysiological recordings.

High Sample Rates

Designed with Digital Signal Processor technology, Deymed systems can sample at very high sample rates while changing any parameter on the fly digitally. DSP offers numerous advantages over standard analog processing.

Always on Impedance

Always-on impedance monitoring displays impedances during recording and has alerts to ensure electrodes are in-range at all times. The values are saved to the EEG file for post quality-assurance review.

HD Network Camera with PTZ

Full HD network video camera that already compresses the video in the camera, so no internal capture card is required, which minimizes the hardware requirements on the PC. Video can be streamed via a UDP viewer station for up to four EEG/Video stations on a single screen.

Advanced HD Video HUB

The HD Video Hub greatly simplifies a typically complex dual-video and audio capture, as well as integrating an microphone and ambient light sensor. combines and synchronizes video from up to two HD or SD camera sources.

SomniPro Explorer Keyboard

A unique innovation in the PSG/EEG field, the SomniPro Explorer Keyboard was developed to speed up and streamline the review of PSG recordings with video. Ergonomically-designed buttons include all common features available on one click, minimizing the need for complex use of the mouse.

Isolation Power Supply

Medical grade built-in Isolation Transformer that meets the highest medical safety standards. On/off switch with LED indicators for status. Non-patient Grounding plug included on side.

IR Night Lamp

High-power IR lamp that can light up the entire room with in-direct positioning, ie by pointing the lamp at the ceiling and letting the light bounce off the walls, so the light source is not visible to the patient.

LED Photo-stim Lamp

Powerful photic stimulation lamp with two switchable colors, red and white. The red light makes it possible to use special glasses that greatly eliminates the flash for the operator and gives more options for evoking a seizure. The red light has a mean wavelength of 660nm and white with a color temperature of 6500K.

Intelligent Charger

Intelligent Headbox Charger. The Intelligent charging is built into the rotating metal arm with the holder for the headbox. It charges the headbox batteries via inductive charging, ie without direct contact, which maintains the optical isolation and safety benefits of battery operation as well as allowing the headbox batteries to be charged when the headbox is connected to system.

Powerful and Silent PC

The Deymed integrated computer is optimized for use in healthcare. Thanks to the absence of a cooling fan, the system runs virtually silent, allowing the exam room to be undisturbed.

CONFIGURATIONS

FlexiCart PSG Video

FlexiCart with integrated computer and one PSG headbox connected via USB adapter along with dual video monitoring and infra-red lamp.

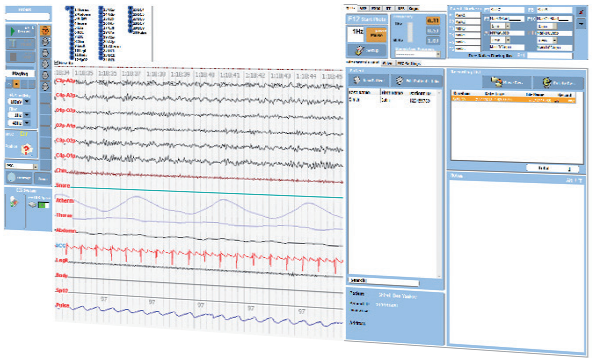
FlexiTrolley and PSG

Computer and FlexiTrolley with one PSG headbox connected via USB adapter and camera wall mount kit for dual camera.

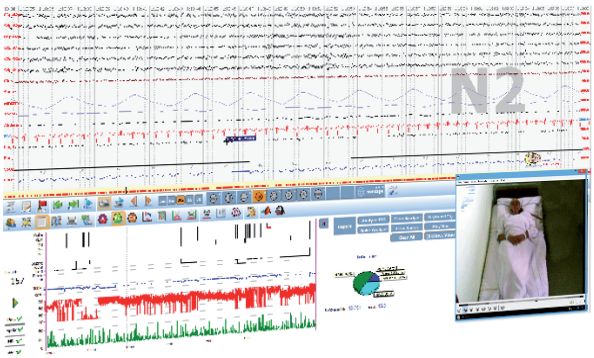
Portable

Includes laptop with 24ch, 32ch or 2x32ch EEG headboxes connected to the USB adapter.

SomniPro Acquisition



- Configure and Acquire any PSG or PSG/EEG configuration
- View all channels plus body position and SpO2 values
- Montage editor built-in
- Quick pre-sets for easy use
- Video view with PTZ camera control

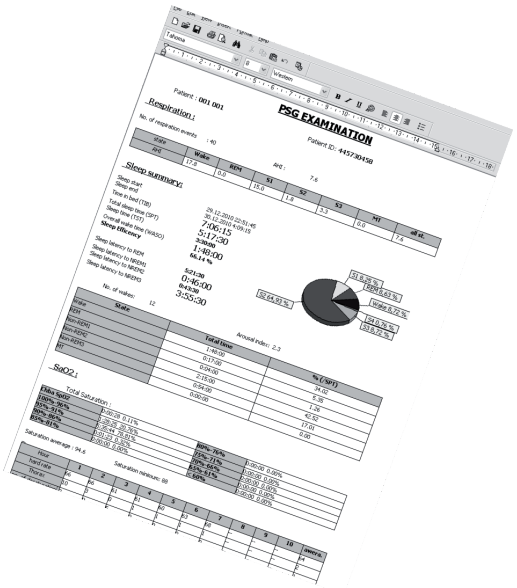


SomniPro Explorer

- Full PSG/EEG review features
- Sleep Stage Scoring according to AASM Rules
- Various report templates (customizable)
- Works with Quick-Score PSG keyboard
- Montage Editor
- Data Export to EDF+ and other formats

Customizable Report Generator

Create full clinical PSG reports with customization of any recorded parameters including calculations for AHI and RDI.



SomniPro RS / LT Wireless

24 Ref EEG
8 Differential ExG (for flow & snore, breathing effort - RIP, EMG, ECG etc.)
Pressure
3D sensor (position/activity)
SpO2 (pulse rate, plethysmogram)
Ambient light
Patient marker

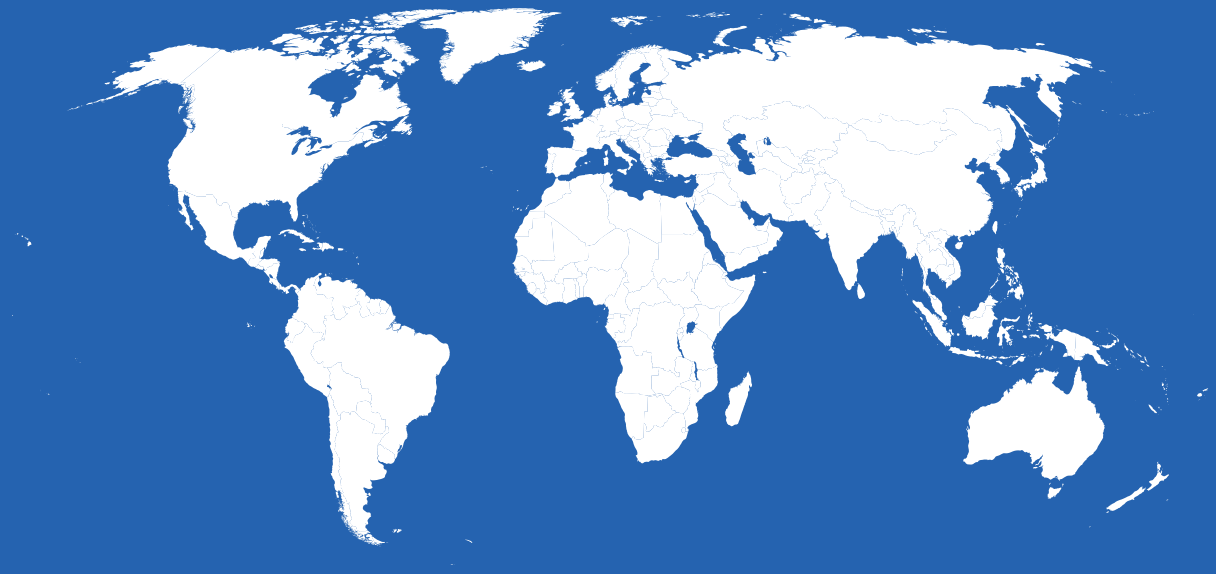
SomniPro RS Wireless

Somnipro RS is designed more for portable use.
Thanks to the channels located on the side of the headbox, the electrodes can be comfortably connected when the headbox is placed on or beside a patient's body.

SomniPro LT Wireless

SomniPro LT is designed for cart use when the headbox is connected to a cart - thanks to the channels located on the top of the headbox.

SomniPro PSG rev PSG-BD211



Deymed
DIAGNOSTIC

DEYMED Diagnostic s.r.o.

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549 31 Hronov

Czech Republic

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www.deymed.com

+420 491 481 038

Neurophysiology
EMG

Magnetic stimulators
TMS

Somnography
PSG

Epileptology
EEG

Neurofeedback
BFB / qEEG

Name of the medical device: SomniPro PSG

Types of the medical device: CL, PT

Variants of the medical device: CL, PT

Technical parameters of the device

Maximum number of headboxes	1x PSG + 3x EEG
Power supply of the whole device - Type CL	100-120 V 50/60 Hz or 220-240 V 50/60 Hz
Power consumption of the whole device - Type CL	450 VA max
Dimensions of the whole device - Type CL basic assembly (W x H x D)	85cm x 137cm x 56 cm
Weight of the whole device - Type CL basic assembly	approx 50 kg
Maximum weight of the whole device - Type CL	65 kg
Power supply of the whole device - Type PT	5 V from USB port of the PC
Power consumption of the whole device - Type PT	5 VA max
Power supply of the headbox	2pcs x 3,7V/2200 mAh battery Li-ion 16650 or 2pcs x 3,7V/3500 mAh battery Li-ion 16650 or 4pcs x 3,7V/3500 mAh battery Li-ion 16650 or directly from the charger in the intelligent charging arm
Operating temperature	15°C to 30°C
Storage temperature	5°C to 35°C
Operating relative humidity	10 to 80 % (non-condensing)
Storage relative humidity	5 to 90 % (non-condensing)
Operating atmospheric pressure	50 kPa – 106 kPa
Storage atmospheric pressure	50 kPa – 106 kPa
Medical device risk class	IIa
Class of protection against electric shock	I (equipment according to IEC 60601)
Degree of protection by cover	IP 20 (protected against contact with dangerous parts by finger, without protection against ingress of liquids).
Electrical installation must comply with standard	EN 332140

Note: atmospheric pressure 50 kPa corresponds to an altitude of about 5500 m

Technical parameters of the headboxes

Parameters \ Headbox	SomniPro PSG LT	SomniPro PSG RS
Number of dedicated EEG channels	21	22
Number of additional EEG channels if differential ExG inputs are not used	10	10
Number of EMG channels	3 bipolar (0 in case of 31 ch EEG)	3 bipolar (0 in case of 32 ch EEG)
Number of EOG channels	2 bipolar (0 in case of 31 ch EEG)	2 bipolar (0 in case of 32 ch EEG)
Number of EKG channels	1 bipolar (0 in case of 31 ch EEG)	1 bipolar (0 in case of 32 ch EEG)
Number of channels for chest straps	2 (1x Thorax, 1x Abdomen)	2 (1x Thorax, 1x Abdomen)
Number of channels for the thermocouple	1	1
Number of channels for the position sensor	1	1
Number of channels for the snoring detector microphone	1	1
Number of breath detection channels	1	1
Number of SpO2 channels	1	1
Number of lighting detection channels	1	1
Number of accelerometer channels	0	1
Continuous operation at full charge ****	up to 50 h	up to 75 h
Continuous operation at full charge and radio operation ****	up to 20 h	up to 32 h
Dimensions (W x H x D)	100 x 55 x 142	105 x 40 x 150
Weight (including batteries)	420 g	405 g

Technical parameters of the headboxes PLUS

Parameters \ Headbox	SomniPro PSG LT 32 Plus	SomniPro PSG RS 32 Plus	SomniPro PSG RS 64 Plus
Number of dedicated EEG channels	26	22	48
Number of additional EEG channels if differential ExG inputs are not used	8	10	16
Number of EMG channels	up to 8 bipolar	up to 8 bipolar	up to 16 bipolar
Number of EOG channels			
Number of EKG channels			
Number of channels for chest straps			
Number of channels for the thermocouple			
Number of channels for the position sensor			
Number of channels for the snoring detector microphone			
Number of breath detection channels			
Number of SpO2 channels	1	1	1
Number of lighting detection channels	1	1	1
Number of accelerometer channels	3	3	3
Continuous operation at full charge ****	up to 50 h	up to 50 h	up to 45 h
Continuous operation at full charge and radio operation ****	up to 35 h	up to 35 h	up to 35 h
Dimensions (W x H x D)	100 x 55 x 142	105 x 40 x 150	105 x 48 x 150
Weight (including batteries)	430 g	420 g	650 g

Parameters of EEG, EMG, EOG and ECG channels

Frequency range *	0,1 - 450 Hz
Bandwidth *	450 Hz per channel
Voltage measurement accuracy	± 5 %
Time measurement accuracy	± 1 %
Internal analog sampling frequency	6000 Hz per channel
A/D conversion	up to 24 bits
In-phase component suppression **	> 106 dB
IMR ***	> 140 dB

Parameters of EEG, EMG, EOG and ECG channels of the headboxes Plus

Frequency range *	0 – 4000 Hz
Bandwidth *	4000 Hz per channel
Voltage measurement accuracy	± 5 %
Time measurement accuracy	± 1 %
Internal analog sampling frequency	6000 Hz per channel
A/D conversion	up to 24 bits
In-phase component suppression **	> 106 dB
IMR ***	> 140 dB

Parameters of EEG, EMG, EOG, EKG channels, chest straps, thermocouple and snoring

Bandwidth *	460 Hz per channel
Analog time constant	1 s ± 5 %
Maximum input range	± 2 mV
The highest component input DC	± 340 mV
Equivalent own input noise voltage *****	2 µV p-p
Voltage measurement accuracy	± 2 %
Time measurement accuracy	± 0,1 %
A/D conversion	up to 24 bits
Internal analog sampling frequency	4096 Hz per channel
In-phase component suppression **	102 dB
Transient impedance measurement range	0-50 kΩ

Channel parameters of position detection, light detection, breath detection (common for both types of headboxes)

Analog time constant	DC
Bandwidth	15 Hz

SpO2 measurement parameters (common for both types of headboxes)

SpO2 measuring range	0 - 100 %
SpO2 measurement accuracy	70% - 100% : +/- 2 % 0% - 70% : unspecified
SpO2 measurements averaging	8 seconds
Heart rate measurement range	30 – 248 bpm
Heart rate measurement accuracy	+- 3/min
Heart rate measurement averaging	8 beats
Algorithm	Classic "Split Pulse Wave Algorithm"

** at a sampling frequency of 1000 Hz, at a standard sampling frequency of 250 Hz, the bandwidth is 105 Hz*
*** for EEG channels in the frequency range of 0 - 60 Hz with short-circuit inputs*
**** battery-powered devices use IMR instead of CMRR*
***** on batteries (in DirectPower mode it is not limited and the signal can be recorded continuously)*
****** for EEG channels in the frequency range of 0.16 Hz - 100 Hz it is relative to averaged - AVG electrode at transient impedance skin - electrode max. 10 kΩ*

TruScan® EEG

EEG / EP / LTM | SYSTEM

ADVANCED CLINICAL

EEG SYSTEM

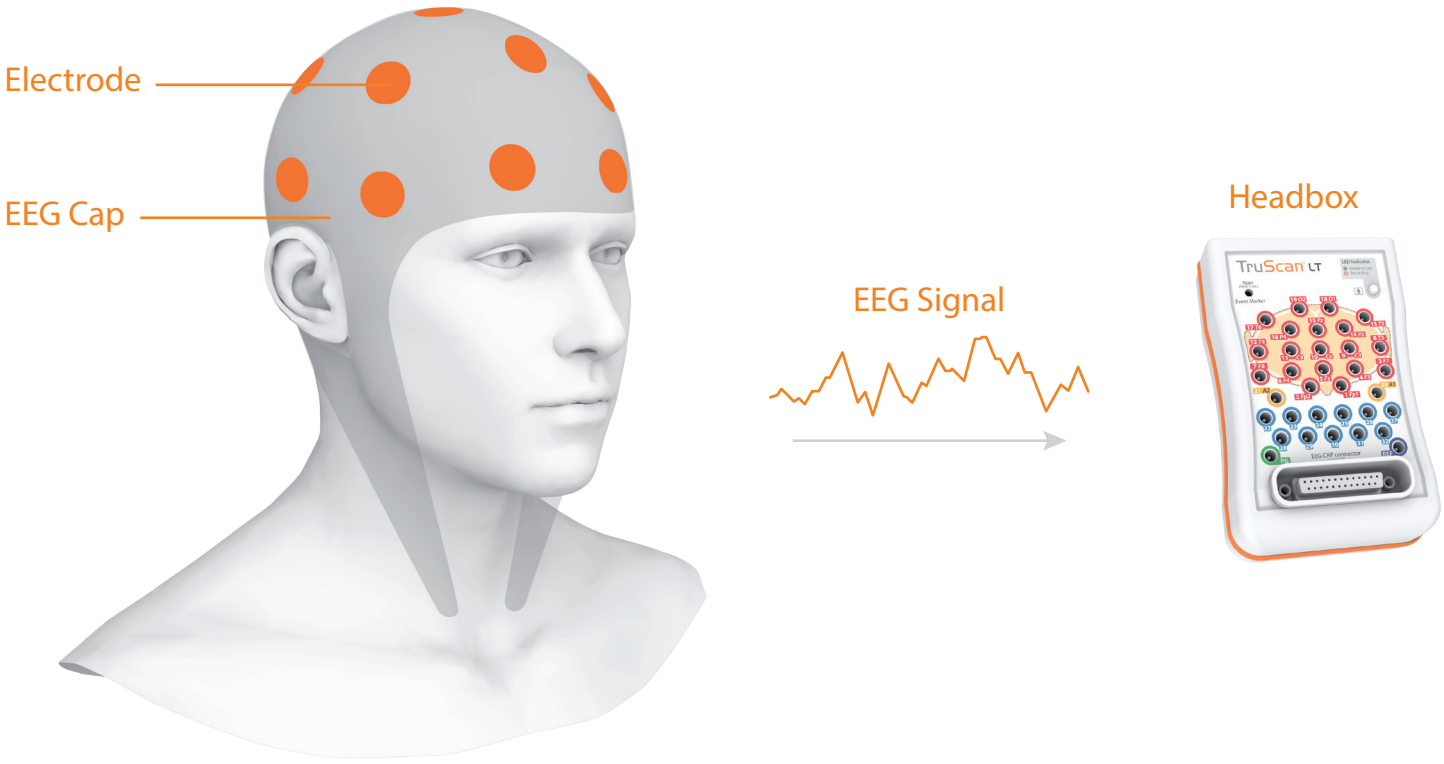
Deymed DIAGNOSTIC

What is EEG?

Electroencephalography (EEG) is non-invasive method to record electrical activity of the brain. Electrodes are placed along the scalp, usually according to the standard placement 10/20 or 10/10. EEG measures voltage fluctuations resulting from ionic current within the neurons of the brain. Clinically, EEG refers to the recording of the brain's spontaneous electrical activity over a period of time, as recorded from multiple electrodes placed on the scalp.

EEG is most often used to diagnose epilepsy, which causes abnormalities in EEG readings. It is also used to diagnose sleep disorders, depth of anesthesia, coma, encephalopathies, and brain death. EEG is valuable tool for research and diagnosis. It is one of the few mobile techniques available and offers millisecond-range temporal resolution which is not possible with CT, PET or MRI.

Derivatives of the EEG technique include evoked potentials (EP), which involves averaging the EEG activity time-locked to the presentation of a stimulus of some sort (TMS stimulation, visual, somatosensory, or auditory).



Advantages of TruScan EEG

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Battery Operated

Offering the highest signal quality possible and lasting months on a single charge, Deymed systems significantly reduce artifacts and outside noise by running 100% on batteries.

Wireless Use

In wireless mode the amplifier can record for up to 20 hours on a singe charge. Wireless range of 100 meters from the base system for maximum patient comfort and freedom to move.

Intelligent Charging

Deymed's new ultra-low capacitance induction charging keeps the batteries full when the headbox is connected to system. This ensures the highest quality signal is possible with full battery operation during sensitive neurophysiology tests.

Optical Isolation

Optical isolation greatly improves signal quality and patient safety. This feature combined with long-lasting battery operation, offers the best-in-class technology for neurophysiological recordings.

Click N' Go System

Easily detach your system from the cart with a single click and be on-the-go with a laptop. You are no longer forced to choose between a hospital cart or a portable system. You can now have both in one.

Always on Impedance

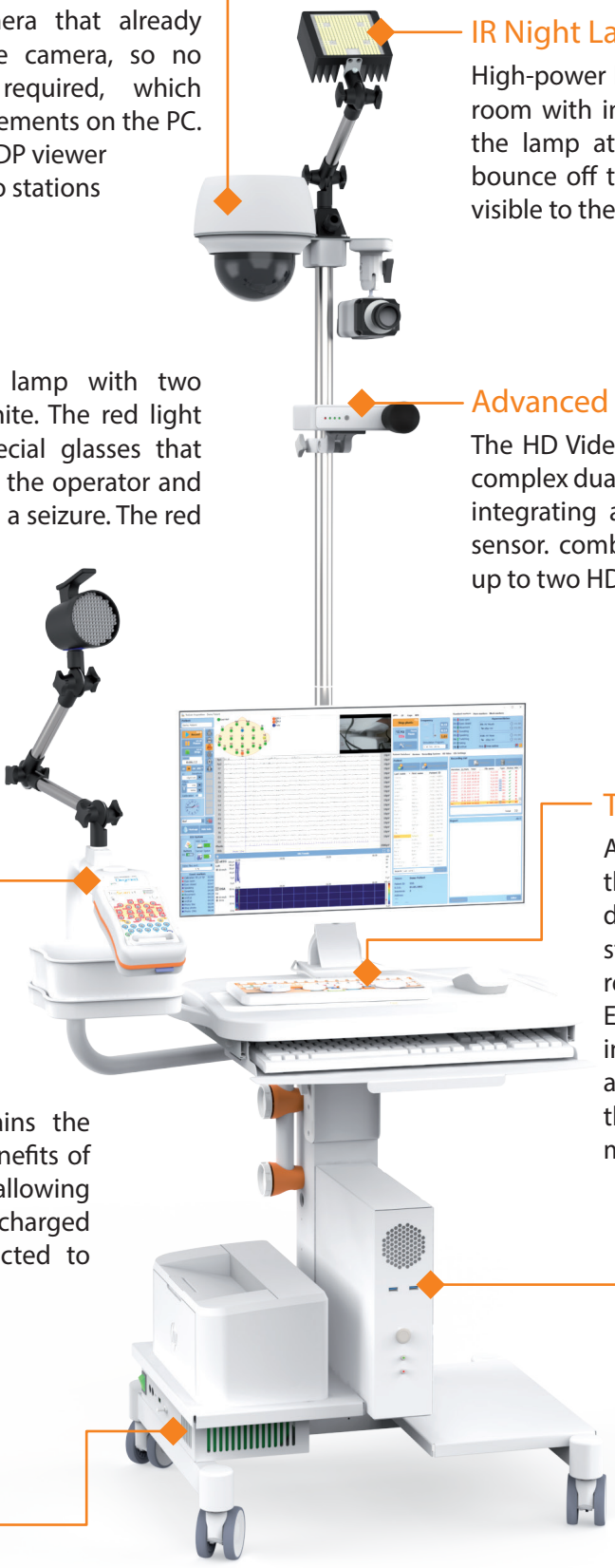
Always-on impedance monitoring displays impedances during recording and has alerts to ensure electrodes are in-range at all times. The values are saved to the EEG file for post quality-assurance review.

HD Network Camera with PTZ

Full HD network video camera that already compresses the video in the camera, so no internal capture card is required, which minimizes the hardware requirements on the PC. Video can be streamed via a UDP viewer station for up to four EEG/Video stations on a single screen.

LED Photo-stim Lamp

Powerful photic stimulation lamp with two switchable colors, red and white. The red light makes it possible to use special glasses that greatly eliminates the flash for the operator and gives more options for evoking a seizure. The red light has a mean wavelength of 660nm and white with a color temperature of 6500K.



IR Night Lamp

High-power IR lamp that can light up the entire room with in-direct positioning, ie by pointing the lamp at the ceiling and letting the light bounce off the walls, so the light source is not visible to the patient.

Advanced HD Video HUB

The HD Video Hub greatly simplifies a typically complex dual-video and audio capture, as well as integrating an microphone and ambient light sensor. combines and synchronizes video from up to two HD or SD camera sources.

TruScan Explorer Keyboard

A unique innovation in the EEG field, the TruScan Explorer Keyboard was developed to speed up and streamline the review of EEG recordings with video. Ergonomically-designed buttons include all common features available on one click, minimizing the need for complex use of the mouse.

Intelligent Charger

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Powerful and Silent PC

The Deymed integrated computer is optimized for use in healthcare. Thanks to the absence of a cooling fan, the system runs virtually silent, allowing the exam room to be undisturbed.

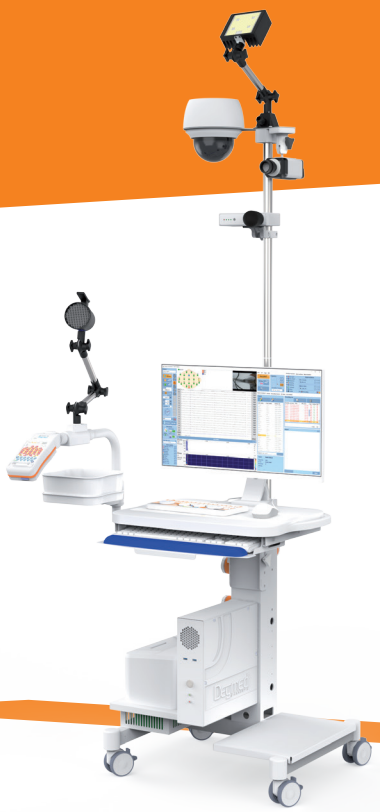
Isolation Power Supply

Medical grade built-in Isolation Transformer that meets the highest medical safety standards. On/off switch with LED indicators for status. Non-patient Grounding plug included on side.

CONFIGURATIONS

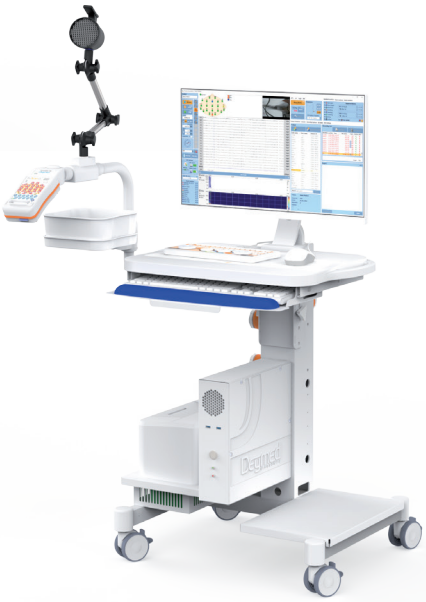
FlexiCart LTM

Includes FlexiCart with integrated computer and photostim, with 24ch, 32ch or 2x32ch EEG headboxes connected to a USB adapter and two HD camera's and infra-red lamp.



FlexiCart with Satellite Trolley-photo-stim

Includes computer with FlexiTrolley, Satellite Trolley with photo-stim, 24ch, 32ch or 2x32ch EEG headboxes connected to a USB adapter.



FlexiCart w/photo-stim

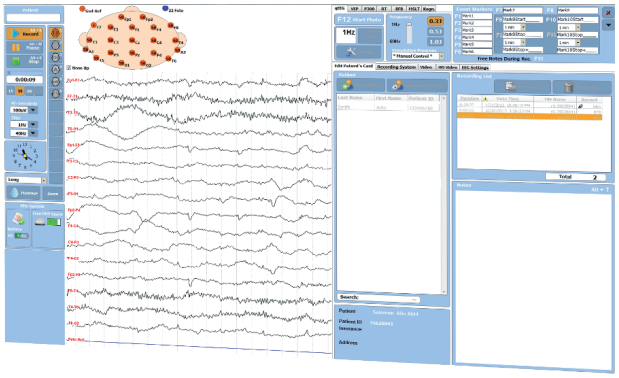
Includes FlexiCart with silent computer and photo-stim, with 24ch, 32ch or 2x32ch EEG headboxes connected to a USB adapter.

Portable

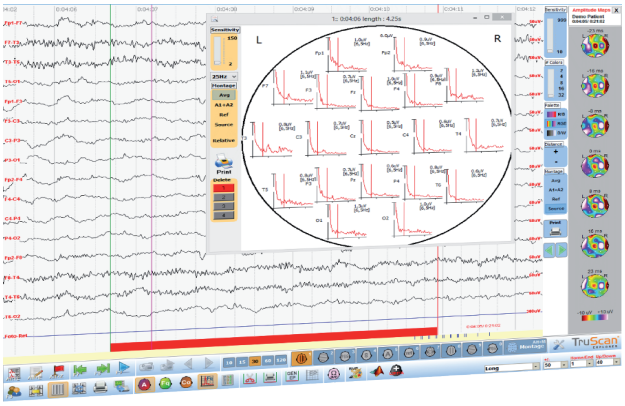
Includes laptop with 24ch, 32ch or 2x32ch EEG headboxes connected to the USB adapter.

TruScan Acquisition

- Intuitive Dashboard interface
- Pre-set text markers for quick insert
- Integrated patient database and HL7 (optional)
- On-screen always-on impedance monitor
- Visual drag and drop custom montage creation
- View live data and review data with split screen
- Programmable photo-stim setup with pre-sets
- EP and Neurofeedback modules
- Patient remote alarm and event trigger
- Live HD video display

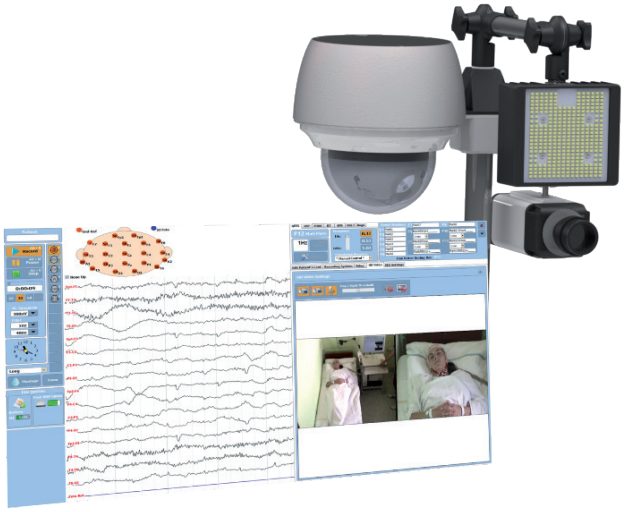


TruScan Explorer



- Full set of review tools including Brain Mapping
- Export EEG with included viewer to flash drive
- Interpretation editor with custom text pre-sets
- Database with un-interpreted To-Do list
- Full search and sortable patient list
- EDF, LORETA, Matlab and Excel output of data
- Spectral Analysis overlay of multiple segments
- Common controls via TruScan control keyboard
- Synchronized frame by frame video with EEG
- EP epoch generator with full post-analysis

HD Video Monitoring



- HD PTZ camera for close-up and full view
- Side-by-side dual view capture
- Video trimming to save hard disk space
- Clear night time view with Infra-red lamp
- Adjust light sensitivity for Day / Night detection
- High quality MPEG-4 (h.264) video
- Remote Network HD video / EEG Viewer
- Multi-room monitoring (4 beds per viewer)
- Mounts to wall or Hospital cart for portability
- Wide-band microphone with high sensitivity

TruScan RS / LT Wireless

The TruScan LT Wireless EEG system can be used for Ambulatory, Wireless, Long Term Monitoring and standard clinical use.

Connected or Ambulatory Mode: In Connected or Ambulatory mode, the TruScan LT system can record up to 45 hours and TruScan RS up to 90 hours on a single charge.

Wireless Mode: In Wireless mode, the TruScan LT system can record for up to 30 hours and TruScan RS up to 40 hours on a single charge.

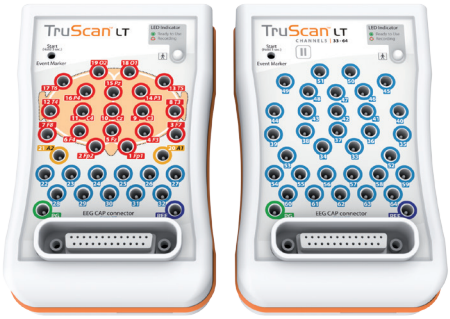
The TruScan LT has a wireless range of 100 meters from the base system. With additional wireless signal extenders this range can be extended to 300+ meters.

When a patient is out of wireless range, the TruScan Headbox will continue to record to internal memory and will automatically re-sync the backup data when the patient comes back into the wireless communication range.

TruScan LT - 24, 32, 64, 128, 256

Numbers of single electrode connectors depends on headbox
1x Easy connect Cap connector
Online Impedance Check
Battery operated - removable batteries
Optional Holter recording to SD card
Compact dimensions 90 x 47 x 140 mm

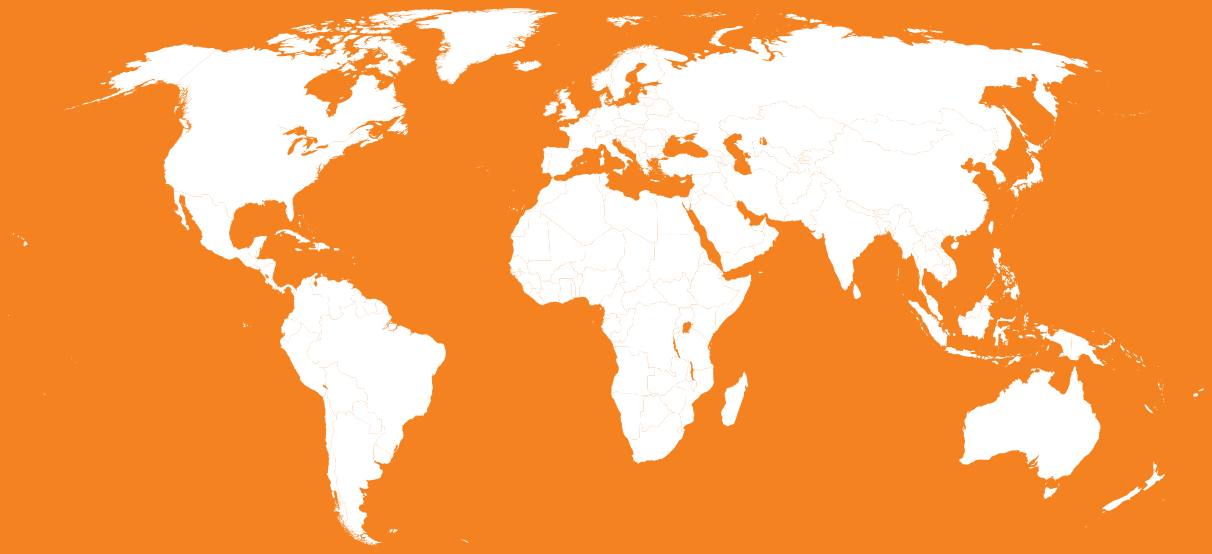
32ch



64ch

24ch

TruScan LT-RS EEG rev TSLTRS-BD211



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DIAGNOSTIC

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Neurophysiology
EMG

Magnetic stimulators
TMS

Epileptology
EEG

Somnography
PSG

Neurofeedback
BFB / qEEG

Name of the medical device: TruScan EEG

Types of the medical device: CL, PT

Variants of the medical device: CL 24, CL 32, CL 64, CL 128, CL 256

PT 24, PT 32, PT 64, PT 128

Technical parameters of the device

Maximum number of headboxes	8x EEG
Power supply of the whole device - Type CL	100-120 V 50/60 Hz or 220-240 V 50/60 Hz
Power consumption of the whole device - Type CL	450 VA max
Dimensions of the whole device - Type CL basic assembly (W x H x D)	85cm x 137cm x 56 cm
Weight of the whole device - Type CL basic assembly	approx 50 kg
Maximum weight of the whole device - Type CL	65 kg
Power supply of the whole device - Type PT	5 V from USB port of the PC
Power consumption of the whole device - Type PT	5 VA max
Power supply of the headbox	A) 2 x 3,7V/2200mAh battery Li-ion 16650 B) 4 x 3,7V/2200mAh battery Li-ion 16650 C) 2 x 3,7V/3500mAh battery Li-ion 18650 D) and/or directly from the charger in the intelligent charging arm
Operating temperature	15°C to 30°C
Storage temperature	5°C to 35°C
Operating relative humidity	10 to 80 % (non-condensing)
Storage	5 to 90 % (non-condensing)
Operating atmospheric pressure	50 kPa – 106 kPa
Storage atmospheric pressure	50 kPa – 106 kPa
Tin electrode	applied part type BF
EEG cap	applied part type BF
Medical device risk class	IIa
Class of protection against electric shock	I (equipment according to IEC 60601)
Degree of protection by cover	IP 20 (protected against contact with dangerous parts by finger, without protection against ingress of liquids).
Electrical installation must comply with standard	EN 332140

Note: atmospheric pressure 50 kPa corresponds to an altitude of about 5500 m

Technical parameters of the headboxes

Parameter	TruScan LT	TruScan RS	TruScan RE
Number of channels	24, 32	32	32
Sample rate	200, 1000, 3000 Hz		
Frequency range	0,01 – 1000 Hz		
Bandwidth	1000 Hz per channel		
A/D conversion	up to 24 bits		
Equivalent input noise	<1,2 µV p-p	<2 µV p-p	<1,2 µV p-p
IMR *	140 dB		
Power supply	High-capacity battery		
Continuous operation **	Up to 60 hours	Up to 96 hours	Up to 50 hours
Wireless operation	Up to 34 hours	Up to 45 hours	Up to 30 hours
Dimensions (W x H x D)	90 x 47 x 140 mm	100 x 35 x 140 mm	90 x 47 x 140 mm
Weight (including batteries)	380 g	350 g	390 g
TMS compatibility	No	No	Yes

** battery-powered devices use IMR instead of CMRR*

*** on batteries (in DirectPower mode it is not limited and the signal can be recorded continuously)*

Technical parameters of the headboxes PLUS

Parameter	TruScan LT 32 PLUS	TruScan LT 72 PLUS	TruScan RS 32 PLUS	TruScan RS 68 PLUS	TruScan RE 32 PLUS	TruScan RE 72 PLUS
Number of channels	32	72	34	68	32	72
Sample rate	250, 500, 1000, 2000, 4000, 8000, 16000 Hz					
Frequency range	0 – 4000 Hz					
Bandwidth	4000 Hz per channel					
A/D conversion	up to 24 bits					
Equivalent input noise	<1 µV p-p					
IMR *	140 dB					
Power supply	High-capacity battery					
Continuous operation **	Up to 50 hours	Up to 30 hours	Up to 50 hours	Up to 45 hours	Up to 50 hours	Up to 30 hours
Wireless operation	Up to 35 hours	Up to 25 hours	Up to 35 hours	Up to 35 hours	Up to 35 hours	Up to 25 hours
Dimensions (W x H x D)	90 x 47 x 146	135 x 47 x 146	100 x 35 x 140	100 x 46 x 140	90 x 47 x 146	135 x 47 x 146
Weight (including batteries)	400 g	610 g	380 g	630 g	400 g	610 g
TMS compatibility	No	No	No	No	Yes	Yes

** battery-powered devices use IMR instead of CMRR*

*** on batteries (in DirectPower mode it is not limited and the signal can be recorded continuously)*

Introduction

This technical instruction is an extension of Instruction for use (IFU). It adds special operations done by service personal and/or responsible company.

Electroencephalograph TruScan EEG a Polysomnograph SomniPro PSG are almost identical in terms of components. Only difference is the headbox.

That is why this service manual doesn't make any difference between the devices and pictures are illustrative and are showing the most common configurations. Each shown or described configuration can be both TruScan EEG and SomniPro PSG depending on the headbox used ("master" headbox is decisive should that be multi-headbox configuration). The term "device" refers to both devices without any distinction.

This device is commonly supplied as ME device or it could be used as part of ME system under specific conditions.

Assemblies and components

Each configuration of devices assembly can be different according to their order. Review station can be part of the data network into which is device connected. It consists of standard computer and TruScan Explorer software. Review station computer is not a medical device and can be connected to standard power grid. However, the TruScan Explorer software is considered to be medical device.

CL types:

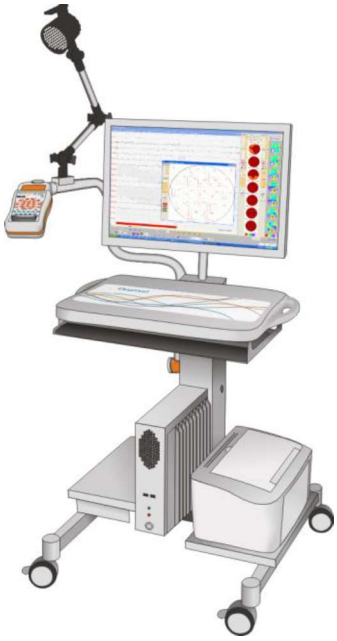
There are following CL types: **CL 24, CL 32, CL 64, CL 128 and CL 256** (number after CL stands for the number of recording channels).

Each headbox has either 24 or 32 channels. It is necessary to connect multiple scanning headboxes in order to assemble version with more than 32 channels. Up to four headboxes can be connected to one USB adapter. Therefore 256 channel version has to have eight headboxes and two USB adapters. Up to the configuration with 256 channels are the total auxiliary and leakage currents values compliant with the ČSN 60601-2-26 ed.3.:2016 requirements. Headboxes connection is described in the chapter Wiring diagram.

TruScan EEG/SomniPro PSG CL type – basic assembly, without photostimulation lamp, on a flexi cart

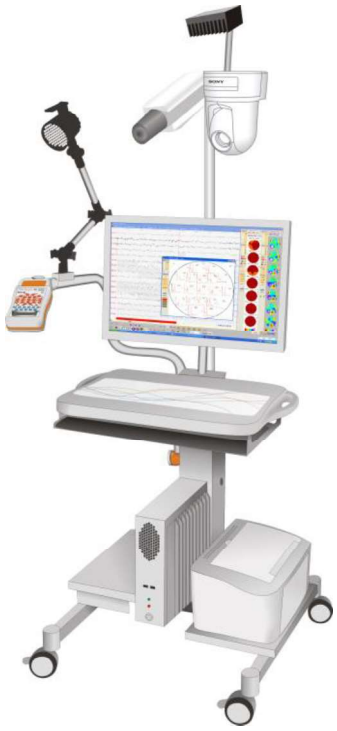
Simplest Electroencephalograph TruScan CL type assembly on a flexi cart.

TruScan EEG/SomniPro PSG CL type - basic assembly on a flexi cart



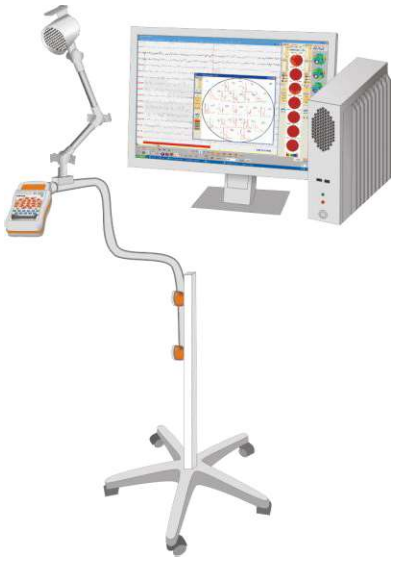
Basic assembly on a flexi cart, headbox and photostimulation lamp attached to a flexi arm.

TruScan EEG/SomniPro PSG CL type – basic set on a flexi cart with long-term monitoring



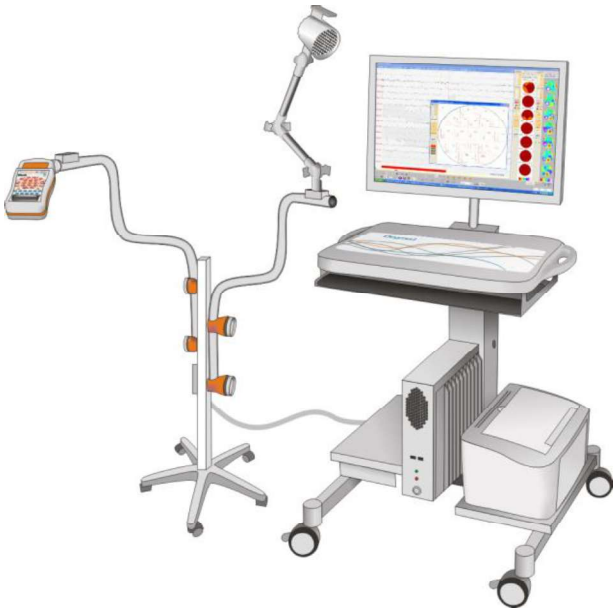
This assembly offers high examination amount, including long-term monitoring even in dark.

TruScan EEG/SomniPro PSG CL type – basic assembly on a table with a flexi arm



Basic assembly placed on a table with a flexi arm is ideal for small ordinations where computer and monitor movement is not necessary.

TruScan EEG/SomniPro PSG CL type - basic assembly on a flexi cart with a double flexi arm



Basic assembly on a flexi cart with a double flexi arm offers comfort of working by the table while the flexi arm can be placed as close to the patient as possible.

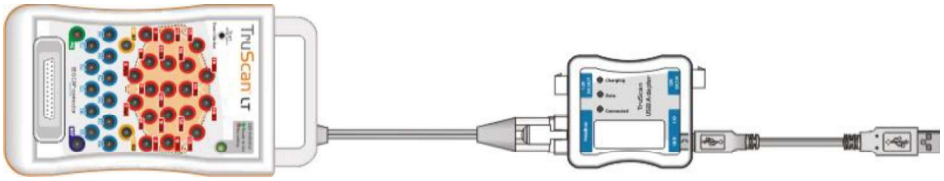
PT types:

Mobile version powered from notebook (5V DC from USB connector)

PT 24, PT 32, PT 64 and PT 128 (number after PT stands for number of recording channels). Four headboxes and one USB adapter are required for 128 channels variant. The total auxiliary and leakage currents values are compliant with the ČSN 60601-2-26 ed.3.:2016 requirements up to the configuration with 128 channels. Headboxes connection is described in the chapter Wiring diagram.

PT type device always consists of headbox, USB adapter and component connection cables. There can be traveler (replaces USB adapter, cables and keyboard) and photostimulation lamp included for specific configurations.

TruScan EEG/SomniPro PSG PT type – basic assembly



ME device/ME system installation/modification procedure

Warning:

It is necessary to thoroughly check the content and device condition should the packaging be damaged or any unauthorised opening is found during unpackaging in order to minimalize risk of preliminary unpacked device. Pay extra attention to sterile packaged electrodes.

Warning:

Relevant checks and tests according to the IEC/EN 60601 has to be done to ensure permanent safe usage of the device during installation or any modification of ME system. No clinical ME system utilization is allowed before.

Warning:

No modification of single ME device and/or non-ME device is allowed!

Warning:

The FlexiCart CL has to be completely braked and transport position has to be secured (flexi arms in the front side of the table in front of the monitor has to be secured so the table doesn’t flip over) during installation or any modification of the ME system.

Warning:

In order to secure permanent compliance with IEC/EN 60601 standard it is necessary to ensure especially:

- all devices have to be powered from isolation transformator with MSO located inside the CL table
- it is possible to power devices from other sources if it is necessary for operational reasons. These sources have to comply with 2xMOPP of the IEC/EN 60601 standard (e.g., video module, photostimulation lamp)
- no additional splitter socket (MSO) or extension cord are allowed
- only devices specified as part of ME system or are specified as ME system compatible can be connected
- highest allowed load of the isolation transformator delivered as a part of ME device TruScan EEG / SomniPro PSG (300 VA output with MSO and 135VA output for PC) has to be respected

- do not touch potentially dangerous metal devices, devices covers and the patient at the same time (potentially dangerous covers are defined in chapter 16.4 of the IEC/EN 60601-1 standard)

Warning:

If non-ME devices supplied as part of an ME system are plugged directly into a socket in a fixed installation (in a wall) in a room, despite the fact that these non-ME devices are intended to be powered from an isolation transformer power outlet, the requirements of the IEC/EN 60601 series standards will not be met and patient safety will be compromised! Possible risks are:

- exceeding leakage current through patient
- exceeding touch current limit
- dangerous electrical potential difference between devices

Warning:

Connecting devices not delivered as part of the ME system into the splitter socket with isolation transformator will result in violation of IEC/EN 60601 standard requirements, especially not respecting the Instructions for use. Also, the isolation transformator with MSO output may be overloaded.

Warning:

Even though non-ME devices can be securely connected to ME device/ME system using isolators (TTL, USB, Ethernet), however it still has to be done outside of the patient's environment. Also, the insulator has to be located outside of the patient's environment!

Installation

Device is delivered in partially disassembled condition. CL type table is assembled completely, including computer, adapters and cables. Not assembled are only these parts:

- Arms
- Headboxes
- Monitor
- Printer
- Modul Video
- VEP monitor

Installation is simple. Carefully unpackage the device and attach not assembled parts to it. If any cable was removed from its connector, please connect is back according to the wiring diagram.

It is necessary to check after installation:

- All mechanical parts and attachments firmness
- Proper insertion of all cables
- Wheels functionality including braking
- Compliance with IEC/EN 60601 standard in case of ME system assembly

ME system items specification:

Mandatory items:

- TruScan EEG / SomniPro PSG ME devices

Optional items, if they are not included in the device above:

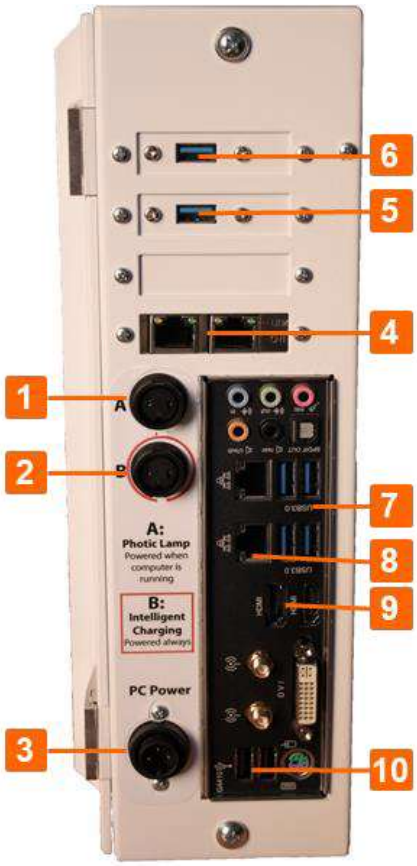
- PC
- Monitor
- Notebook
- Printer
- Photostimulation lamp
- Video module
- VEP monitor

All items are suitable for patient's environment operation if every condition in this technical description is met.

PC connection

Even though there are same connector types used for different purposes, there is no risk of injury by electrical current or damage of the connected components when connected improperly. Only the device might not properly fulfill some of its functions.

Please note: The configuration shown is illustrative and the layout of connectors such as additional USB or some ports on the motherboard may change.



1	Photostimulation lamp power	6	USB 3.0 extension connectors
2	Charger power	7	USB 3.0 connectors
3	PC power	8	PC LAN connection
4	PC LAN Connection with POE (for VideoHub)	9	Video output
5	USB 3.0 extension connectors	10	USB 2.0 connectors

1 ***Photostimulation lamp power***

Black round connector with “A” mark is for Photostimulation lamp power. It is empty should the lamp be not used.

2 ***Charger power***

Black round connector with “B” mark is for charger power. I.C. switch or TruScan USB adapter with I.C. switch is connected into it.

3 ***PC power***

Low end black connector with **"PC Power"** mark is for PC power. Isolation transformator is connected into it.

4 ***PC LAN Connection with POE (for VideoHub)***

Both RJ45 connectors on the PC back side is for VideoHub over a special RJ45 cable.

5 6 ***Extension USB 3.0 connectors***

USB connector may be used for external HDD or other components.

7 ***USB 3.0 connectors***

Upper left USB connector if for mouse connection, upper right for PC keyboard.

8 ***PC LAN connection***

Lower RJ45 connector on the PC back side is for local network, internet, etc. connection.

9 ***Video output***

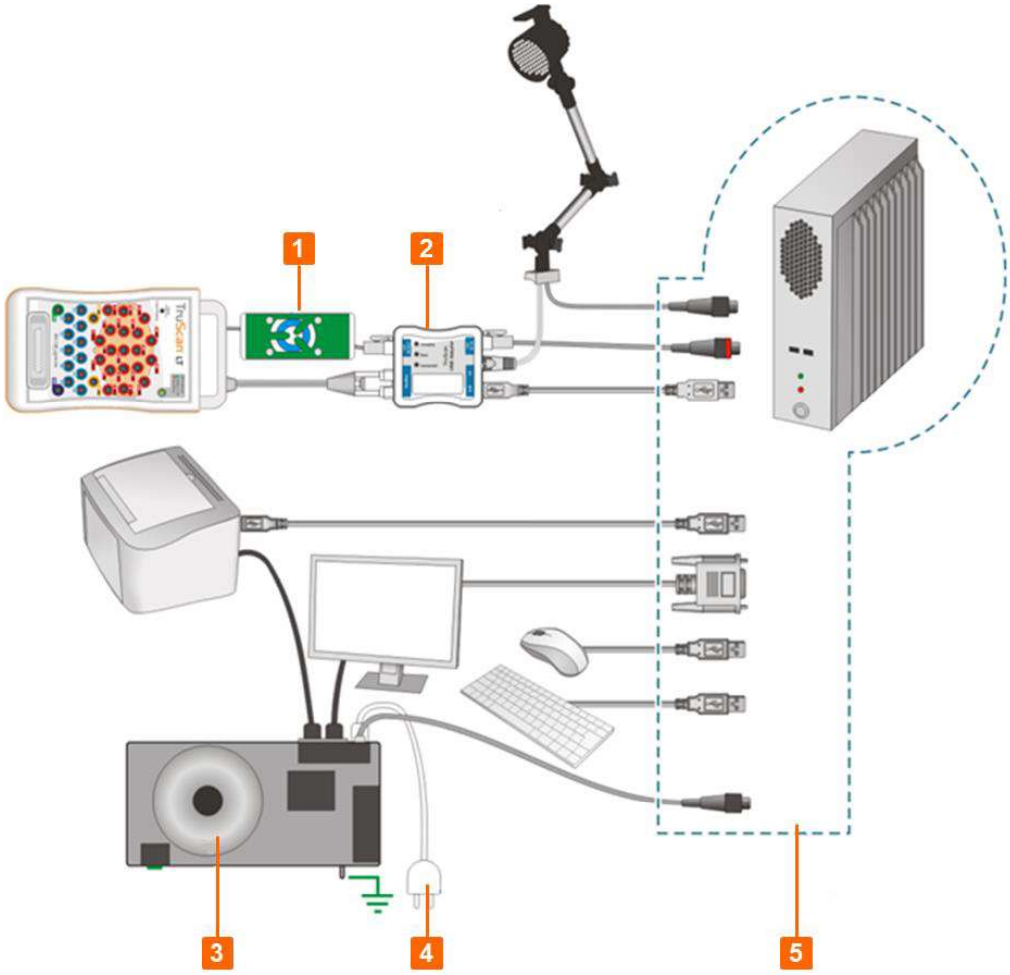
Left HDMI connector (from the picture view) is video output connector.

10 ***USB 2.0 connectors***

Left USB connector is for USB adapter, right one is for printer USB cable.

Wiring diagram

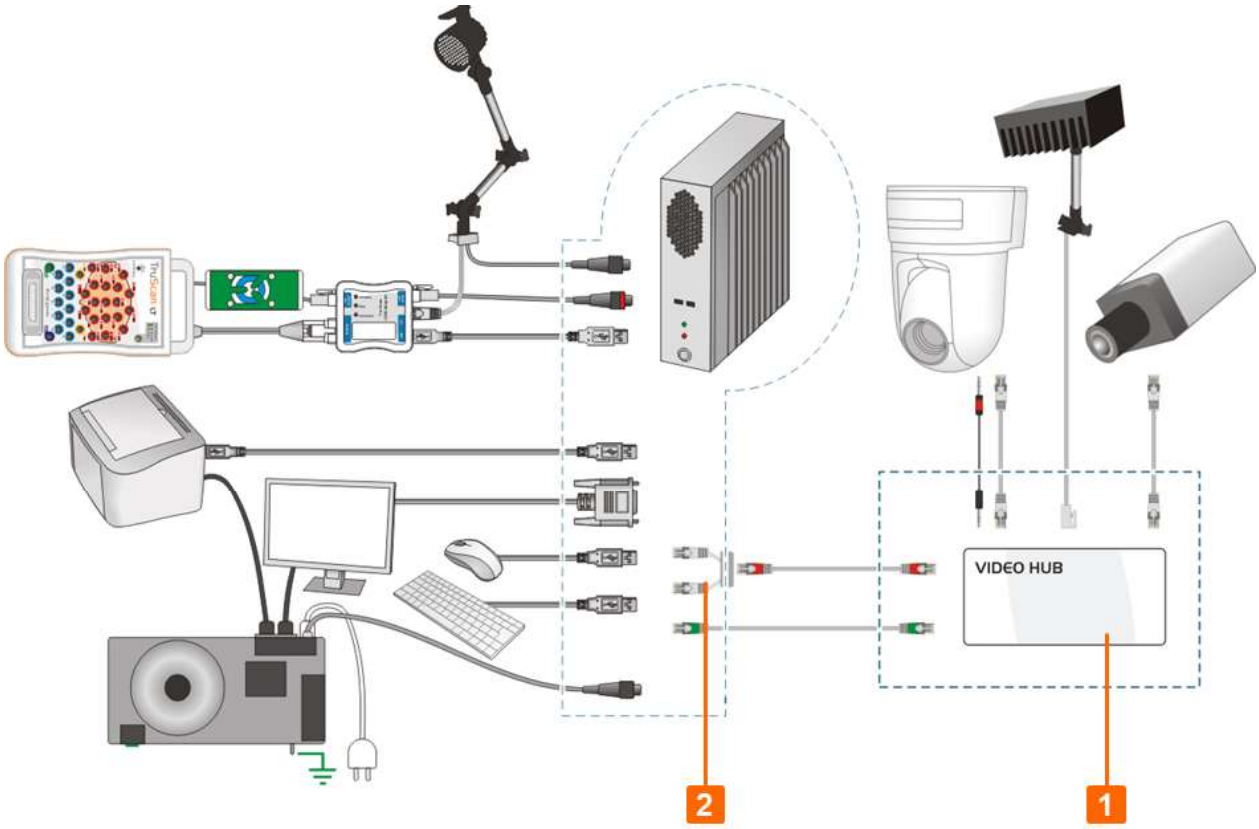
Block wiring diagram – basic assembly



1	Intelligent charger	4	Power cable
2	USB adapter with I.C. Switch	5	PC connected cables
3	Isolation transformator		

Block wiring diagram – CL type with long-term monitoring

CL type device with long-term monitoring is fairly complicated device. This variant can be extended for more screening devices up to 256 recording channels.



1 *Video HUB*

Video HUB HD is device for video and audio input, cameras power and IR lamp lightning power. Connectors for video HUB HD are in colors including description which shows their usage in graphic form.

2 *Network cable switch*

Network cable switch connector is on back side of the load-bearing leg on the flexi cart. Switch is inside of the leg.

Block wiring diagram – PT type

Connection of the PT type device is fairly straight forward. Connect headbox with USB adapter via optical cable and USB, then adapter with PC via cable. Use only original USB cables to ensure proper USB adapter function. Headbox charger is powered from the power grid. If the photostimulation lamp is used it has to be powered only from supplier selected source which will ensure compliance with safety limits given by the proper standard and is connected to the USB adapter. Photostimulation lamp is then connected to the USB adapter. Also, notebook can be powered only with delivered source type (source has to meet IEC/EN 60601 standard requirements). It is not allowed to replace it with standard power source even in case of malfunction.

EC DECLARATION OF CONFORMITY

Manufacturer:

DEYMED Diagnostic s.r.o.
Kudrnáčova 533, 549 31, Hronov, Czech Republic
Reg. No.: 25284584, VAT No.: CZ 25284584

hereby declare that declaration of conformity is issued under the sole responsibility of the manufacturer and that below products:

Polysomnograph and applicable accessories

SomniPro PSG

Type: CL and PT

are in compliance with the relevant harmonized European Union legislation:

Act No. 268/2014 Coll. as amended, on medical devices (Directive 93/42/EEC);
Government Order No. 54/2015 Coll. as amended, on technical requirements on medical devices (Directive 93/42/EEC) and
Government Order No. 481/2012 Coll. as amended, on the restriction of the use of certain hazardous substances in electrical and electronic devices (Directive 2011/65/EU).

Intended purpose: Polysomnograph SomniPro types CL and PT are intended to record and display PSG records respective video PSG records based on which the patient's diagnosis can be diagnosed by doctor.

Classification of medical device: Class IIa, active, non-sterile medical device according to Government Order No. 54/2015 Coll. as amended, Annex 9, Rule 10 (Directive, 93/42/EEC Annex IX, Rule 10).

Notified body: 3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia, Notified body No. 2265, has performed assessment of quality system according to Government Order No. 54/2015 Coll. as amended, Annex 2 excluding point 8 (Directive 93/42/EEC, Annex II excluding point 4) and issued EC Certificate No. 2018-MDD/QS-031.

Harmonized standard used in relation to which conformity is declared:

ČSN EN 60601-1 ed.2:2007 +A11:2012 +A1:2014+A12:2015	ČSN EN ISO 14971:2020
ČSN EN 60601-1-2 ed.3:2016	ČSN EN ISO 15223-1:2017
ČSN EN 60601-1-6:2010 / A1:2015	ČSN EN 62304:2007 / A1:2016
ČSN EN 60601-2-40 ed.2:2019	ČSN EN ISO 10993-1:2021
ČSN EN 60601-2-26 ed.3:2016	ČSN EN 1041 / A1:2014
	ČSN EN 50581:2013

The manufacturer further declares that under the normal conditions stated in Instruction of use, the above-mentioned product is safe, effective and suitable for provision of health services and that technical file is stored at the manufacturer.

Place, date of issue: Hronov, 24.5.2021

Seal and sign in behalf of manufacturer:

CE 2265

DEYMED Diagnostic s.r.o.
Kudrnáčova 533, 549 31 Hronov
IČO: 25284584 DIČ: CZ25284584
tel./fax: 491 481 298

Kamil Holub
CEO

EC DECLARATION OF CONFORMITY

Manufacturer:

DEYMED Diagnostic s.r.o.
Kudrnáčova 533, 549 31, Hronov, Czech Republic
Reg. No.: 25284584, VAT No.: CZ 25284584

hereby declare that declaration of conformity is issued under the sole responsibility of the manufacturer and that below products:

Electroencephalograph and applicable accessories

TruScan EEG

Type: CL 24 / 32 / 64 / 128 / 256 and PT 24 / 32 / 64 / 128

are in compliance with the relevant harmonized European Union legislation:

Act No. 268/2014 Coll. as amended, on medical devices (Directive 93/42/EEC);
Government Order No. 54/2015 Coll. as amended, on technical requirements on medical devices (Directive 93/42/EEC) and
Government Order No. 481/2012 Coll. as amended, on the restriction of the use of certain hazardous substances in electrical and electronic devices (Directive 2011/65/EU).

Intended purpose: Electroencephalograph TruScan types CL and PT are intended to record and display an electroencephalogram based on which the patient's diagnosis can be diagnosed by doctor.

Classification of medical device: Class IIa, active, non-sterile medical device according to Government Order No. 54/2015 Coll. as amended, Annex 9, Rule 10 (Directive, 93/42/EEC Annex IX, Rule 10).

Notified body: 3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia, Notified body No. 2265, has performed assessment of quality system according to Government Order No. 54/2015 Coll. as amended, Annex 2 excluding point 8 (Directive 93/42/EEC, Annex II excluding point 4) and issued EC Certificate No. 2018-MDD/QS-029.

Harmonized standard used in relation to which conformity is declared:

ČSN EN 60601-1 ed.2:2007 +A11:2012 +A1:2014+A12:2015	ČSN EN ISO 14971:2020
ČSN EN 60601-1-2 ed.3:2016	ČSN EN ISO 15223-1:2017
ČSN EN 60601-1-6:2010 / A1:2015	ČSN EN 62304:2007 / A1:2016
ČSN EN 60601-2-26 ed.3:2016	ČSN EN ISO 10993-1:2021
ČSN EN 60601-2-40 ed.2:2019	ČSN EN 1041 / A1:2014
	ČSN EN 50581:2013

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Place, date of issue: Hronov, 24.5.2021

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CEO