User Manual

CloudTMS

Magnetic Stimulator

Contents

Introduction

This user manual (hereinafter referred to as "manual") is the combined document describing operation and servicing of **CloudTMS** magnetic stimulator (hereinafter referred to as "stimulator").

This manual is the document which certifies the stimulator specifications guaranteed by the manufacturer.

Do not start working with stimulator before you have read this document!

You can send your responses and recommendations to **Neurosoft** Company by the following address:

P.O. Box 10, Ivanovo, 153000, Russia

or by e-mail:

help@neurosoft.ru.

You can find additional information on Neurosoft products in the Internet:

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+7 (4932) 95-99-99; +7 (4932) 24-04-34.

Safety Requirements

Indications for Use

The stimulator is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medications in the current episode.

Contraindications

CloudTMS is a safe and effective device when it is used as intended.

During the treatment session the coil should be positioned over the patient's cranium (head and scalp). Other coil position is contraindicated.

> **Before the treatment start each patient must be screened for contraindications! (see Annex 14.4)**

1) Patients who have an implanted device that is activated or controlled in any way by physiological signals (examples: deep brain stimulators, cochlear implants, and vagus nerve stimulators). Contraindicated use could result in serious injury or death.

2) Patients who have conductive, ferromagnetic or other magnetic-sensitive metals implanted in their head or within 12 in. (30 cm) of the treatment coil (examples: cochlear implants, implanted electrodes/stimulators, aneurysm clips or coils, stents and bullet fragments). Failure to follow this restriction could result in serious injury or death.

   Note: Standard amalgam dental fillings are not affected by the magnetic field and are acceptable in patients.

   See Table 1 below for details.

Table 1. Devices that are known to be adversely affected by the treatment.

Device or Object	Action required by Operator before treatment			Possible Interaction with the CloudTMS Therapy System			Potential Consequences of Operator Inaction
	TMS treatment is contraindicated	Keep treatment coil >12 in. (>30 cm) from device/object	Remove device from patient area	Device/Object becomes disabled	Device/Object may dislodge or move	Device/Object may overheat	
Magnetically activated dental implants	X			X			Patient injury
Aneurysm clips or coils	X				X		Serious patient injury or death
Carotid or cerebral stents	X				X		Patient injury or death
Cochlear, otologic implants	X			X		X	Patient injury
Cerebral Spinal Fluid (CSF) shunt	X				X	X	Patient injury
Ferromagnetic ocular implants	X				X	X	Patient injury
Pellets, bullets, fragments <12 in. (<30 cm) from coil	X				X	X	Patient injury, irritation
Facial tattoos with metallic ink	X				X	X	Patient injury, irritation
Electroencephalography (EEG) electrodes	X					X	Patient injury
Deep Brain Stimulation (DBS) electrodes	X			X	X	X	Patient injury or death
Metallic devices implanted in the head	X			X	X	X	Patient injury or death
Cardiac Pacemakers, Implantable Cardiac Defibrillators (ICD's)	X			X			Affected therapy; patient injury
Vagus Nerve Stimulator	X			X			Affected therapy; patient injury
Wearable cardioverter defibrillator (WCD)	X			X			Affected therapy; patient injury
Wearable infusion pumps		X		X			Affected therapy; patient injury
Implanted insulin pump		X		X			Affected therapy; patient injury
Stents, filters, heart valves		X			X	X	Patient injury or death
Magnetically programmable shunt valves		X		X		X	Affected therapy; patient injury
Cervical fixation devices		X				X	Patient injury
Staples, sutures		X			X		Patient injury
Radioactive seeds		X				X	Affected therapy; patient injury
VeriChip microtransponder		X		X	X	X	Inconvenience
Wearable physiologic monitors			X	X			Inconvenience
Bone growth stimulators			X	X			Inconvenience
Portable glucose monitors			X	X			Inconvenience
Hearing aids			X	X			Inconvenience
Magnetic resonance imaging system (MRI)	X			X			Serious patient injury

3) The safety and effectiveness of TMS therapy has not been established in the following patient groups or clinical conditions:

   3.1 age less than 22;

3.2   pregnant women;

3.3   nursing women;

3.4   patients suffering from epilepsy;

3.5   patients with family history of convulsions;

3.6   patients suffering from sleep deprivation during rTMS procedures;

3.7   patients suffering from excessive alcohol consumption;

3.8   patients taking tricycling antidepressants, neuroleptic agents or any other drugs that may decrease seizure threshold;

3.9   patients taking epileptogenic drugs;

3.10 patients with increased intracranial pressure;

3.11 patients suffering fron uncontrolled migraine;

3.12 patients with severe heart disease;

3.13 patients with brain injures that may change the seizure threshold;

3.14 suicide plan or recent suicide attempt;

3.15 varying degrees of medication resistance in either the current or previous episode;

3.16 on concurrent antidepressant medication, i.e., cannot tolerate discontinuation of current antidepressant medication;

3.17 history or concurrent use of electroconvulsive therapy or vagus nerve stimulation;

3.18 depression secondary to a general medical condition or substance-induced;

3.19 seasonal affective disorder;

3.20 history of substance abuse, obsessive compulsive disorder or post-traumatic stress disorder;

3.21 a psychotic disorder, including schizoaffective disorder, bipolar disease, or major depression with psychotic features;

3.22 neurological disorders, including a history of seizures, cerebrovascular disease, primary or secondary tumors in CNS, cerebral aneurysm, dementia, or movement disorders;

3.23 history of increased intracranial pressure or head trauma.

4)   Before the treatment start the patient should take off and remove from patient area all removable devices and objects that may be affected by magnetic field:

adornments (for example earrings), eyeglasses, cell phones, MP3 players, PDA devices, headphones, coins.

Warnings and Precautions

Read carefully the following warnings and precautions before starting to use CloudTMS magnetic stimulator.

During rTMC session you must keep watching over the signs of seizure and terminate the treatment session if those signs appear.

If patient has taken a medication that may alter the seizure threshold, detect the motor threshold before the treatment session start!

The risk of seizure during rTMC session is increased in patients having history of convulsion including of unknown etiology, patients with epilepsy, head injuries, stroke, severe headache, neurological diseases that that may affect a seizure threshold altering and also patients taking tricycling antidepressants, neuroleptic agents and other epileptogenic drugs.

Discuss the risk of clinical worsening of depression and suicidality with the patient prior to starting treatment. During the treatment observe carefully the patients for clinical worsening of depression and suicidality. If the signs of worsening of depression and suicidality (behaviour) continue to appear, terminate the treatment with the use of CloudTMS magnetic stimulator.

Inform patient that the long term effects of treatment rTMS have not established.

The safety and the effectiveness of the specified treatment parameters that go beyond the recommended ones are not established.

It is not safe to operate CloudTMS in close proximity to a magnetic Resonance Imaging (MRI) system.

Do not start working with stimulator before you have read this document!

The stimulator must be used by the qualified medical personnel trained to operate on it and knowledgeable of magnetic stimulation application.

During the work on the stimulator it is required to observe the working regulations concerning the safety rules while operating on electrical installations.

No modification of this equipment is allowed.

High voltages (1800V) are presented within the stimulator.

To provide safety measures and exclude the hazard of medical staff's or patient's electric shock, the medical staff is PROHIBITED:

• **to use the stimulator which was mounted and installed incorrectly, without following this manual instructions;**

• **to eliminate faults connected with opening of the components included in the delivery set;**

• **to work with the stimulator when the electronic unit box, computer or other devices used together with the stimulator are open.**

Always check the stimulator and coils for the absence of cracks and other defects.

Do not open and do not try to repair the electronic units of magnetic stimulator!

All parts of the system shall not be serviced or maintained while in use with a patient.

Before the stimulation make sure, that there are no patient cables or electrodes connected to a patient and also metal parts contacting with a patient in impact area (within 5 cm and less from the coil) as far as the electromagnetic field can create the electrical current leaking through a patient.

Do not allow the coil to come into close proximity (less than 1 meter) with electronic equipment (monitor, computer, etc.), the magnetic carriers (credit cards, floppy disks, CD disks, audio recording tapes, hotel room keys, electronic automotive ignition keys, watches, etc.) and also other medical equipments/devices. The magnetic field emitted by the coil can result in its damage and information loss.

It is prohibited to immerse the coil in water, ice or refrigerate to cool it off.

Do not use CloudTMS stimulator near water or other liquids. Do not place liquids on/near the case of magnetic stimulator, its cables and coils.

It is prohibited to use cooled coils without cooling unit. It can cause coil surface overheating (even after the stimulation stop), patient's burn and magnetic stimulator damage.

The stimulus evoked by the stimulator generates a loud click that can frighten a patient. Tell a patient about the stimulation start and give her/him the ear plugs.

Hearing protection is also advised for the clinical operator if he/she is located within 3 meters of coil during patient treatment.

The stimulator must not be used in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

The operator must be protected from the continuous impact of the magnetic field. It is recommended to use the holder to fix the coil.

If the coil heats over 41°C, the magnetic stimulator stops the stimulation and indicates the overheating. As far as the coil temperature on its surface still grows even after the stimulation stop owing to the thermal lag, it is required to remove immediately the coil from the patient surface to avoid the patient's burn and discomfort.

To protect a patient from excessive impact by the electromagnetic field, generate the minimal required number of pulses.

Keep out of the reach of children.

It is recommended to replace the coil with a new one after a year of use.

Patient Safety

The general principles of safety regulations are stated in:

• "Risk and safety of repetitive transcranial magnetic stimulation: report and suggested guidelines from the International Workshop on the safety of repetitive magnetic stimulation, June 5-7. 1996" by Eric M. Wassermann (accepted for publication: 23 May 1997).

• "Safety of different inter-train intervals for repetitive transcranial magnetic stimulation and recommendations for safe ranges of stimulation parameters" by Robert Chen, Christian Gerloff, Joseph Classen, Eric M. Wassermann, Mark Hallet, Leonardo G. Cohen (accepted for publication: 23 May 1997).

• "Safety, ethical considerations, and application guidelines for the use of transcranial magnetic stimulation in clinical practice.and research" by Simone Rossi, Mark Hallet, Paolo M. Rossini, Alvaro Pascual-Leone and The Safety of TMS Consensus Group (accepted for publication: 21 August 2009).

The main issues to consider are intensity, frequency, train duration and intertrain interval (Table 2, Table 3 and Table 4).

Table 2. Table of safe train duration (s) of single trains of rTMS based on the NINDS experience[a]

Frequency (Hz)	Intensity (% of Motor threshold)												
	100	110	120	130	140	150	160	170	180	190	200	210	220
1	>1800	>1800	360	>50	>50	>50	>50	27	11	11	8	7	6
5	>10	>10	>10	>10	7.6	5.2	3.6	2.6	2.4	1.6	1.4	1.6	1.2
10	>5	>5	4.2	2.9	1.3	0.8	0.9	0.8	0.5	0.6	0.4	0.3	0.3
20	2.05	1.6	1.0	0.55	0.35	0.25	0.25	0.15	0.2	0.25	0.2	0.1	0.1
25	1.28	0.84	0.4	0.24	0.2	0.24	0.2	0.12	0.08	0.12	0.12	0.08	0.08

a) *Based on Wassermann et al. (1996), [6] and Rossi et al. (2009), [4].*

Table 3. Safety recommendations for inter-train intervals for 10 trains of rTMS at < 20 Hz

Inter- train interval (s)	Stimulus intensity (% of MT)			
	100%	105%	110%	120%
5	Safe	Safe	Safe	Insufficient data
1	Unsafe (3)	Unsafe[a]	Unsafe (2)	Unsafe (2)
0.25	Unsafe[a]	Unsafe[a]	Unsafe (2)	Unsafe (3)

a) *These stimulus parameters are considered unsafe because adverse events occurred with stimulation of lower intensity or longer inter-train interval, but no adverse event was observed with these parameters.*

Table 4. Parameter safety issues: commonly employed stimulation parameters

rTMS frequency	No. of studies	Average train duration	Average inter-train interval	Average no. of trials
4-9Hz	>10	Variable	Variable	Variable
10 Hz	>50	5-6 pulse-trains for 400-500 ms	3,2 s	250
20-25 Hz	>20	10 pulse-trains for 400-500 ms	17,1 s	80

[a)] *Based on Rossini P.M. et al. (1994) [5].*

Side Effects

The knowledge of side effects allows informing patients about what can happen and how to deal with these effects. The risk of accidental seizure is the most troubling unintended effect of this technique. It is important to know what has happened, the limits to reduce the risk of the treatment, and how best to handle a seizure if it happens.

The main side effects can be divided into systemic, psychiatric and neurological.

1   Systemic:

• Gastrointestinal tract: nausea;

• Cardiovascular: theoretical risk of induction of arrhythmia if the coil is applied directly to the precordium;

• Skeletal muscle: pain, muscle contraction, arthralgia;

• Skin: erythema.

2   Psychiatric:

• Anxiety;

• Acute disforia/crying;

• Attack of laughter (during Broca area stimulation at a speech arrest study);

• Suicidal ideation;

• Induced mania.

3   Neurological:

General:

• Local pain on the scalp muscles and superficial nerves (trigeminal) and facial twitch (e.g.: stimulation of the facial nerve). It may be helpful to pause the session, rotate and move the coil towards the center of the scalp on the left plane and reduce the intensity (% MT);

- Headache, discomfort and local pain. It may be helpful to treat with an analgesic, make coil adjustments and reduce the intensity (%MT);

- Fatigue;

- Dizziness;

- Hearing loss: increases in auditory thresholds (with clinically available coils: transient in humansand permanent in animals) have been described. Patients and operators should always wear earplugs. All individuals who complain of hearing loss or tinnitus should be referred for audiometric assessment. Those with known pre-existing noise, induced hearing loss or concurrent treatment with ototoxic medications (Aminoglycosides, Cisplatine, for example) should be evaluated to evaluate risk/benefit ratio.

4   Induction of accidental seizure:

• Before the publication of the first safety guidelines with limits for stimulations (Wassermann 1998), there were seven cases of induction of accidental seizure with high frequencies of rTMS (Wasserman 1998). Six of them occurred in healthy volunteers during safety testing studies and one in a patient with depression. Most of those studies were using parameters outside the safety guidelines or with another explanation (for instance: introduction of antidepressant or antipsychotic medications). Safety, ethical considerations, and application guidelines for the use of transcranial magnetic stimulation in clinical practice and research (Rossi et al. 2009) present data on nine new cases of induction of accidental seizure. Four of the new seizures (two following single-pulse and two following rTMS) induced by TMS since publication of the prior guidelines appear to have been induced by ''safe'' stimulation parameters, four cases have occured in studies using parameters outside the previous safety guidelines and a single seizure has occurred during theta burst stimulation.

1. Description

1.1 Main Specifications

Table 5. Main Specifications of Stimulator

Parameters	Values
Stimulation Parameters	
Duration of raise part of pulse: • biphasic mode	280µs
Power Supply	
Supply voltage	220/230/240 V 50/60 Hz
Maximum power consumption during the stimulation: • main unit • cooling unit • extra power supply unit	≤1000 V·A ≤1000 V·A ≤3000 V·A
General Specifications and Parameters	
Interface	USB
Safety	I
Work parts	BF type
Cooling unit tank volume while filling up to the maximal level	3.5 l
Type of cooling agent	Silicone oil 5 cSt
Ingress protection	IP20
Operation temperature	(10–35)º C
Dimensions: • main unit • cooling unit • extra power supply unit	460×215×525 mm 470×215×525 mm 360×170×525 mm
Weight of packed stimulator (with accessories)	not more 225 kg
Length of cable: • HV cable to attach extra power supply unit • Control cable for CloudTMS cooling unit • Equipotential cable	not less than 0.8 m not less than 0.4 m not less than 0.48 m

Table 6. Range of Controlled Parameters and Frequency Step

Parameter	Range of Permissible Values	Frequency Step
Stimulation Parameters		
Stimulation frequency in repetitive stimulation mode	(0.1–30) Hz (Stand-alone mode) (0.1 – 100) Hz (PC mode)	0.1 Hz (0.1 -10 Hz) 1 Hz (10-100 Hz)
Pulse train duration range	(0.5 – 100) s	0.5s (0.5-9.5 s) 5s (10-100 s)
Inter-train interval range	(0 – 300) s	0.5s (0-29.5s) 1s (30-100 s)
Session	(0.5-40) min	0.5 min
Capacitor Charge Control		
Delay for the capacitor charge start (analysis epoch)	(0–9.90) s	0.01 s (0–0.99 s), 0.1 s (1.00–9.90 s)
Trig-out		
Trig-out pulse width	10 µs, 1 ms–50 ms	1 ms

The FDA-recommended treatment protocol for Major Depressive Disorder is shown in Table 7.

Table 7. Recommended treatment parameters

Parameters	Values
Magnetic field intensity	120% of the MT
Frequency	10 Hz
Train duration	4 sec
Inter-train interval	26 sec
Number of trains	75
Magnetic pulses per session	3000
Treatment session duration	~ 37.0 min
Sessions/wk	5
Treatment schedule	5 daily sessions for 6 weeks
Area of brain to be stimulated	Frontal Cortex
The motor threshold determination	be repeated every 5-10 treatment sessions

The specifications of coils are provided in the "Coils for CloudTMS Magnetic Stimulator" technical manual.

Safety and Electromagnetic Compatibility

Electromagnetic compatibility (EMC) is ensured by conformance to International standard IEC 60601-1-2:2007 requirements.

The magnetic stimulator is intended for operation in electromagnetic environment, as specified in the Annex 14.1.

As for safety, magnetic stimulator complies with AAMI/ANSI ES 60601-1:2005/(R)2012 requirements, it is referred to class I and has BF type work parts complying with AAMI/ANSI ES 60601-1:2005/(R)2012 requirements.

1.2   Delivery Set

The delivery set includes the electronic units with the set of coils and cables. The delivery set of the stimulator corresponds to Table 8.

The stimulator is shown in Fig. 1
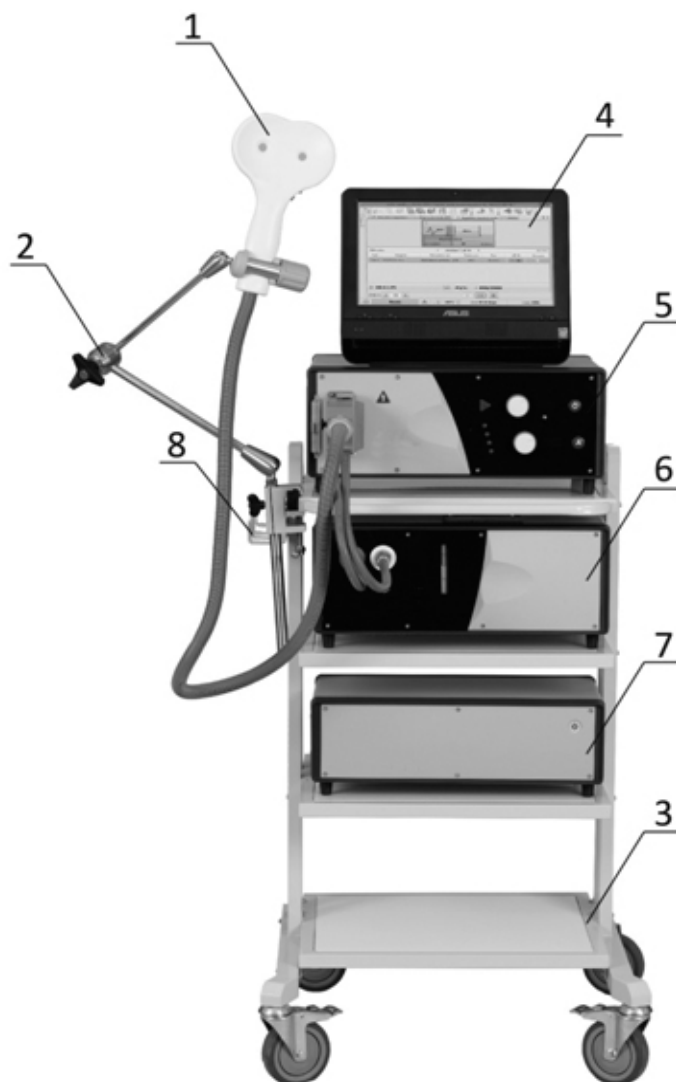
Fig. 1. The external view of assembled magnetic stimulator.

1   Cooled angulated figure-of-eight coil 100 mm AFEC-02-100-C (the cooled coil is used together with the cooling unit);

2   Flexible arm for coil positioning K-3;

3   Trolley with custors for magnetic stimulator (4 shelves);

4   Touchscreen computer (is not included in the delivery set);

5   Main unit;

6   Cooling unit;

7   Extra power supply unit;

8   Coil holder (trolley/wall mounted) K-8.

Table 8. Base Delivery Set

Name	Document name or main specifications	Quan-tity, pcs.
CloudTMS main unit	NS058201.014-022	1
CloudTMS cooling unit	NS058201.017-022	1
CloudTMS extra power supply unit	NS058201.016-022	1
End cap	NS058105.002	1
Silicone oil	NS058998.005	1
Coils:		
Cooled figure-of-eight coil 100 mm FEC-02-100-C	NS058304.010	1
Cooled angulated figure-of-eight coil AFEC-02-100-C	NS058304.012	1
Hydraulic system adapter	NS058214.001	2
Cables:		
Control cable for **CloudTMS** cooling unit	NS058103.070	1
HV cable for **CloudTMS** extra power supply unit	NS058103.102	1
Equipotential cable	NS058103.032-050	2
IEC C13 – IEC C14 mains supply cable (to connect cooling unit)[1]	220 V, 10 A, 1,8 m (3G×0.75 sq.mm.)	1
IEC C13 NEMA L6-20P mains supply cable[1]	250 V, 15 A, 2,4 m (3×14 AWG)	2
USB (A→B) cable	NS007103.005	1
Holders:		
Flexible arm for coil positioning K-3	NS016998.012	1
Coil holder (trolley/wall mounted) K-8	NS059998.004	1
Trolleys:		
Assembled Trolley "T-4/A" for magnetic stimulator	NS059998.009	1
Spare Parts and Accessories:		
Quick connect coupling	NS4D42006 3/8''	1
Patient cap	NS058213.001 (size 42-54)	10
	NS058213.001-01 (size 54-66)	10
Marker	Water-based, diameter of 5 mm	1
Measuring reel	1 m	1

Table 8. Continued

Name	Document name or main specifications	Quantity, pcs.
Software:		
Neuro-MS.NET software license	without additional modules	1
Operational Documentation:		
"CloudTMS Magnetic Stimulator" user manual	TM058.05.002.000	1
"Coils for Magnetic CloudTMS Stimulator" technical manual	TM058.03.001.000	1
"Flexible arm for coil positioning K-3" technical manual	TM016.12.001.000	1
"Coil holder (trolley/wall mounted) K-8" technical manual	TM016.19.001.000	1
Package:		
Cardboard package (set)	–	1
Main unit package	NS058201.014	1
Cooling unit package	NS058201.013	1
Extra power supply unit package	NS058201.016	1

[1] *Appliance coupler conforms to the requirements of IEC 60320-1.*

Table 9. Optional Accessories

Name	Document code or main specifications	Quantity, pcs.
Patient button	NS028201.006	1
Footswitch	NS028353.004	1
Figure-of-eight coil FEC-02-100	NS058304.013	1
Angulated figure-of-eight coil 100 mm AFEC-02-100	NS058304.014	1

1.3   Structure and Operation

The block diagram of the units included in the stimulator complex and their connections are shown in Fig. 2. The block diagram of the main unit of the magnetic stimulator (Fig. 2) consists of the control circuitry, capacitor, capacitor charging circuitry intended for the capacitor charge up to achieving the voltage specified by the control circuitry and the high-voltage electronic switch.

Magnetic stimulator principle of operation is based on discharge of high voltage capacitor (1.8 kV) through stimulation coil made of copper wire at the moment of electronic switch opening. At this time the discharge current (up to 10 kA) generates the magnetic field. This field induces the current in body tissues located near which causes nerve impulse as during usual electrical stimulation.

Maximum achieved intensity of magnetic field depends on stimulation frequency and decreases with its increase. This dependence is caused by limited capability of capacitor charge circuit to charge the capacitor to required voltage during the pause between stimuli. If you set higher stimulus amplitude than stimulator can deliver at specified stimulation frequency, the first train stimulus (series of stimuli) can be delivered with the specified amplitude; the amplitudes of next stimuli will decrease to maximal achieved one at stated frequency.

The current flowing through the coil provokes its heating. The higher is the stimulus intensity and stimulation frequency, the quicker is the heating of the operating surface of the coil. The contact with this heated surface can evoke the hyperaemia or burn. To control the temperature, the coils are equipped with the temperature sensors. The indications of these sensors are controlled by the stimulator control system. In case the coil heats up to 41° C, the stimulation is stopped and the stimulator notifies a user about it (p. 3 of 1.4.1 section).

The use of coils with the force cooling allows increasing the time of the continuous operation without overheating. In this type of coils the coil winding is made of copper tube where the cooling agent circulates. The cooling process occurs in the cooling unit.

The cooling unit provides the forced circulation of cooling agent and heat rejection using the cooling elements (Thermoelectric Cooler). The control system regulates the temperature of the cooling agent and switches off the cooling at the temperature decrease to exclude the condensate formation on the coil surface.
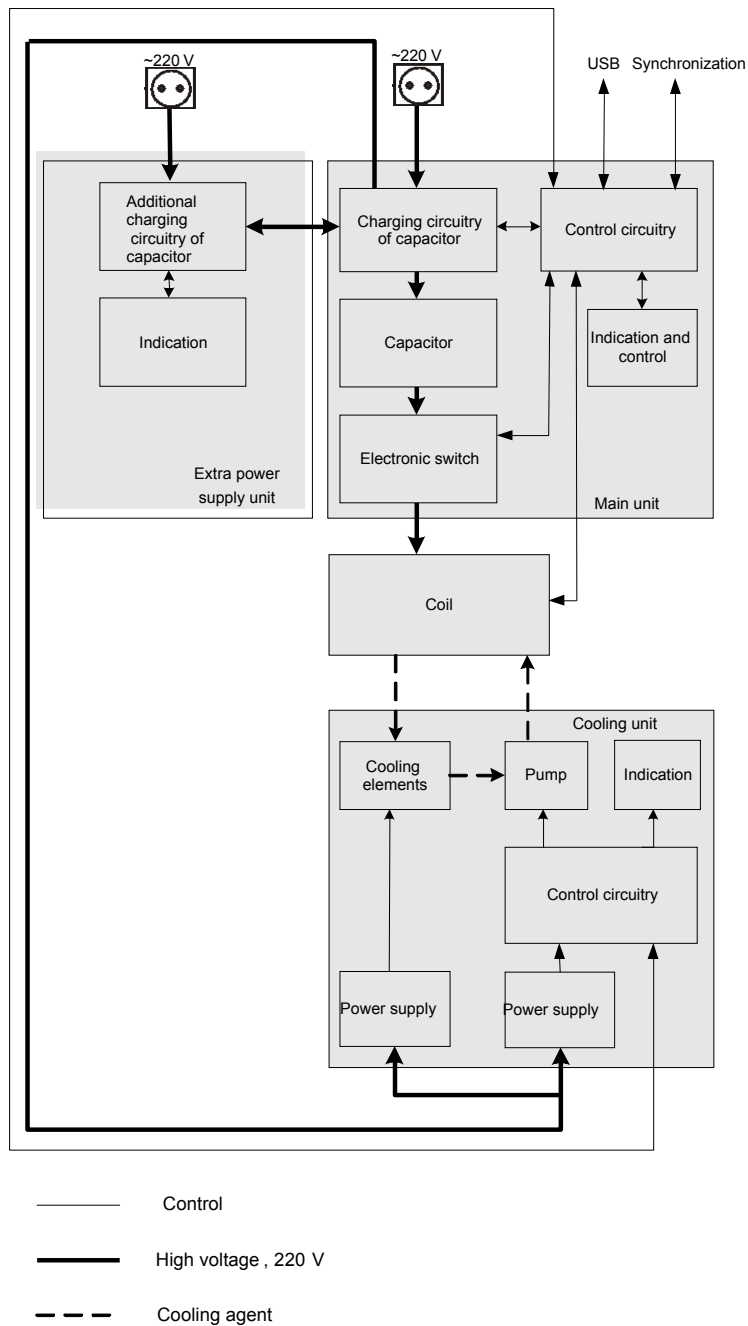
Fig. 2. CloudTMS block diagram.

The magnetic stimulator generates ***biphasic stimulus*** (current in the coil is changed as one period of damped sinusoid) (Fig. 3).
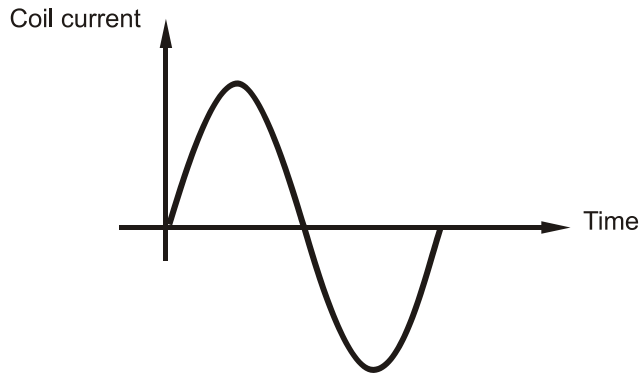
Fig. 3. Biphasic stimulus.

The magnetic stimulator can operate in stand-alone mode or under control of specialized **Neuro-MS.NET** software allowing to perform the therapeutic medical procedures. At that, the electronic unit of the stimulator is connected with USB connector of the personal computer using the removable interface cable included in the delivery set.

In the above-mentioned mode the stimulator can perform the following types of stimulation:

• single pulse of the specified amplitude;

• in repetitive stimulation – the series of stimulation trains and pulses during some period of time (session time). These trains have certain duration and specified pauses between them.

1.4 Description of Controls, Connectors and Indicators

1.4.1 Controls, Connectors and Indicators of Main Unit
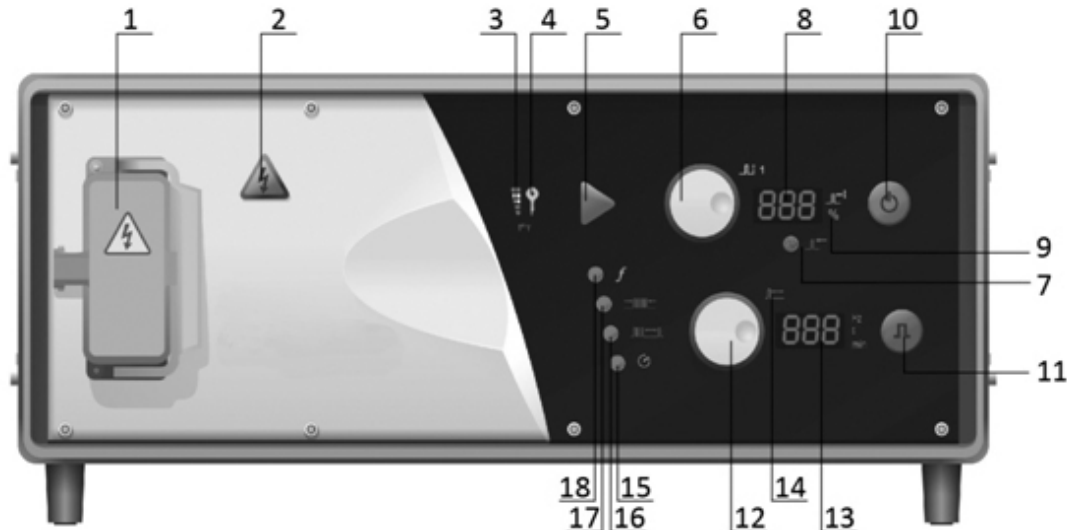
Fig. 4. The front panel of the main unit.

The front panel of the main unit contains the following (Fig. 4):

1. "Coil connector" high-voltage connector intended for the coil attachment.

2. "Coil change" button combined with "High voltage" indicator.

The "High voltage" indicator highlights yellow when the stimulator is switched on and 1800 V high voltage is supplied inside the stimulator. As far as the high voltage is supplied to coil connector at the moment of stimulus delivery, it is dangerous to disconnect the coil. To replace the coil, press "Coil change" button which switches off the internal high-voltage power supply and discharges instantly the high-voltage capacitor to the safe voltage. After that the "High voltage" indicator stops illuminating. If you press the button again, the high-voltage power supply switches on and the capacitor charging up to the specified voltage is started. The "High voltage" indicator highlights yellow. In case you press the "Coil change" button during the repetitive stimulation, the stimulator will stop the stimulation. After the coil replacement the next pressing of this button will resume the stimulation from the stop moment. The given function is used to replace the "overheated" coil to the "cool" one to continue the repetitive stimulation.

3. "Coil temperature" indicator.

"Coil temperature" indicator is a 5-segment three-colored temperature scale. The segments of this scale highlight one by one after achieving the following temperature:

First green segment — at less than 30ºC temperature.

Second green segment – at coil temperature from 30º up to 34ºC.

First yellow segment – at coil temperature from 34º up to 38ºC.

Second yellow segment – at coil temperature from 38º up to 41ºC.

Red segment – if the coil temperature exceeds 41ºC, at that "Pulse" button and stimulus delivery commands from all the external devices are disabled.

4. "Coil" indicator.

"Coil" indicator glows green when the coil is connected and ready for operation. When the coil is overheated, it starts blinking red.

5. "Pulse" button combined with "Ready" indicator.

"Ready" indicator highlights green, if the stimulator is ready to produce the pulse of the specified amplitude. The single pressing of "Pulse" button activates the single or repetitive stimulation depending on the current operation mode. To stop the repetitive stimulation, press "Pulse" button again. This button is duplicated with "Pulse" button located on the coil (1.4.4 "Coil Controls, Connectors and Indicators").

6. "Amplitude" knob.

"Amplitude" knob allows increasing/decreasing the current value of the amplitude by rotating the knob clockwise or counterclockwise correspondingly

7. "Amplitude" indicator.

Depending on the stimulator state it indicates:

• the stimulus amplitude in percents from the maximum output or from MT. After the stimulator switching off the current amplitude is stored in the memory and is indicated at the next switching on. The amplitude adjust is performed with the use of "Amplitude" knob (6);

• information concerning the fault presence (section 4.4 "Troubleshooting");

• information concerning the overheating (see 4.4)

8. "MT fixation" button.

"MT fixation" button is intended to fix the amplitude of motor threshold (MT). If the threshold is not set, the button does not highlight. In case you press

the button, the current amplitude value is taken as 100% MT and it is displayed on "Amplitude" indicator (7) as 100%. The button and "MT" icon (9) are highlighted green.

9.   "MT" icon.

The "MT" icon is illuminated green when the pulse intensity on "Amplitude" indicator (7) is shown relative to MT (%). If "MT" icon is not illuminated, the amplitude is shown in percents from maximum output.

10. "On/Off" button and "Power" indicator.

"On/Off" button toggles the stimulator between the operational mode and standby mode. If you push "Mains power" switch to "I" position (2 in Fig. 5), the stimulator enters the standby mode. This is indicated by the yellow light of "Power" indicator. Pushing the "On/Off" button in the standby mode will set the stimulator into the operational mode. This is indicated by green light of the "Power" indicator. All indicators and symbols will illuminate within a period of 3 seconds. After the expiring of 3 seconds the stimulator switches to the "Single pulse" mode. At the end of the session the stimulator can be returned to its standby mode by pushing the "On/Off" button.

11. "Single pulse" button.

The "Single pulse" button and "Delay" icon (13) are highlighted green in the "Single pulse" mode. In this mode the "Stimulation parameters" indicator (12) shows the delay for stimulator capacitor charge (ms). To adjust the delay, use the "Stimulation parameters" knob (14). In this mode press "Pulse" button (5) to produce the single pulse. After the stimulus obtaining the pushing of "Pulse" button (5) once again is ignored during the period of the capacitor charge delay.

If you press "Single pulse" button illuminated green, the stimulator switches to the "Stimulation frequency setting" mode, at that "Single pulse" button stops illuminating and "Frequency" button and icon (18) should highlight green. In case you press "Single pulse" button again, you will switch to the "Single pulse" mode.

12. "Stimulation parameters" knob.

The "Stimulation parameters" knob is intended to set the stimulation parameters. The selection of the specified parameter is carried out by pressing the corresponding button:

• "Single pulse" (11) – the delay for stimulator capacitor charge.

• "Frequency" (18) – the stimulation frequency;

• "Train" (17) – the train duration;

• "Pause" (16) – the pause duration;

• "Session" (15) – the session duration.

The value of the changed parameter is displayed on "Stimulation parameters" indicator (13).

13. "Stimulation parameters" indicator.

 Depending on the stimulator operation mode the indicator displays:

- in "Single pulse" mode – the delay for stimulator capacitor charge (in milliseconds).

- in "Stimulation frequency" setup mode – the stimulation frequency (in hertz);

- in "Train duration" setup mode – the train duration (in seconds);

- in "Pause" setup mode – the pause duration (in seconds);

- in "Session duration" setup mode – the session duration (in minutes);

- in "Repetitive stimulation" mode – time remained to the session end.

Also the error code or the information concerning the overheating is displayed.

The parameters can be changed using "Stimulation parameters" knob (12).

14. "Delay" icon.

 The icon is highlighted green in the "Single pulse" mode. At that the "Stimulation parameters" indicator (13) displays the delay for stimulator capacitor charge (in milliseconds) and the "Stimulation parameters" knob (12) is used to change this delay.

15. "Session" button.

 In case you press "Session" button, the stimulator switches to the session duration setting mode for the repetitive stimulation. At that, this button is highlighted green. In this mode "Stimulation parameters" indicator (13) displays the current session duration (in minutes). To adjust the session duration the "Stimulation parameters" knob (12) is used. If you press "Pulse" button (5) in the mode, you will start the repetitive stimulation, the "Session" button will start blinking green and the "Stimulation parameters" indicator (13) will show the time left before the stimulation stop.

16. "Pause" button.

In case you press "Pause" button, the stimulator will switch to pause duration setting mode. You can set pauses between the trains during the repetitive stimulation, and the button will highlight green. In this mode "Stimulation parameters" indicator (13) displays the current value of pause between trains (in seconds). To adjust the pause, use "Stimulation parameters" knob (12). If you press "Pulse" button (5) in this mode, you will run the repetitive stimulation. The "Session" button will start blinking green and "Stimulation parameters" indicator will display the time left before the stimulation stop.

17. "Train" button.

In case you press "Train" button, the stimulator will switch to train duration setting mode. At that, the button will highlight green. In this mode "Stimulation parameters" indicator (13) displays the current train duration (in seconds). To adjust the pause, use "Stimulation parameters" knob (12). If you press "Pulse" button (5) in this mode, you will run the repetitive stimulation. The "Session" button will start blinking green and "Stimulation parameters" indicator will display the time left before the stimulation stop.

18. "Frequency" button.

In case you press "Frequency" button, the stimulator will switch to the repetitive stimulation frequency setting mode. At that, the button will highlight green. In this mode "Stimulation parameters" indicator (13) displays the current frequency of the repetitive stimulation (in hertz). To adjust the frequency, use "Stimulation parameters" knob (12). If you press "Pulse" button (5) in this mode, you will run the repetitive stimulation. The "Session" button will start blinking green and "Stimulation parameters" indicator will display the time left before the stimulation stop.
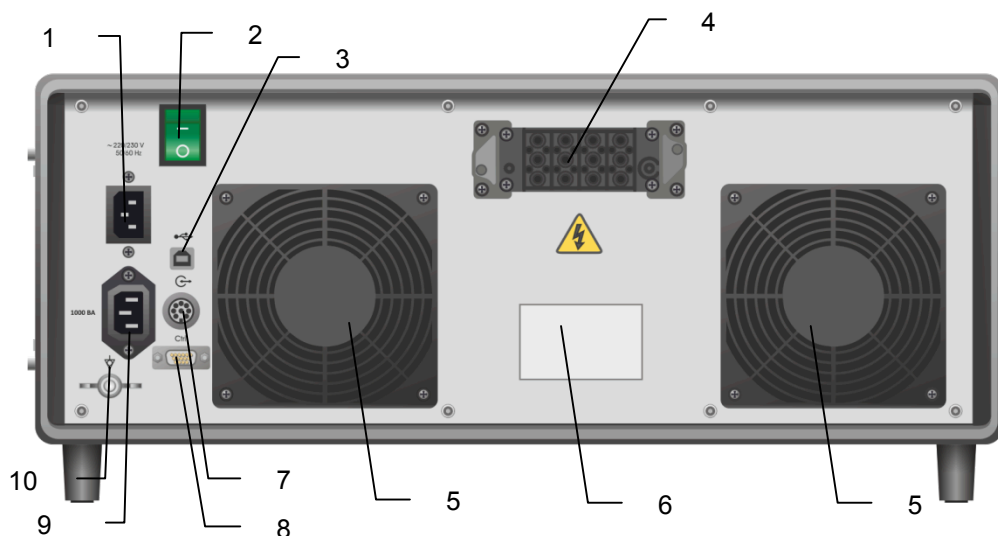
Fig. 5. The rear panel of main unit.

The rear panel of main unit contains (Fig. 5):

1   Connector for mains supply cable attachment.

2   "Mains power" switch.

The "Mains power" switch allows the power supplying the unit to be switched on (labeled **I**) or off (labeled **O**).

3   USB connector.

The connector is intended to attach the stimulator to the computer using USB cable.

4   High-voltage connector for the extra power supply unit. The high-voltage connector is intended to attach the high-voltage communication cable to the extra power supply unit. If you use the main unit without the extra power supply unit, plug in and fix the end cap on this connector using two screws.

5   Cooling fans outlet.

The fans provide the air circulation inside the main stimulator unit. The air is sucked through the holes located on the bottom panel and blown out via the cooling fan outlet, at the rear panel.

6   Labeling.

7   "Trig in/out" connector.

"Trig in/out" connector is intended to synchronize the stimulator with other devices. The connector is not used for above-mentioned techniques.

8   "Control" connector.

"Control" connector is intended to attach the communication cable to cooling unit.

9   The connector for the attachment of mains cable for cooling unit. When you switch on the operational mode using "On/Off" button, the mains voltage is supplied to this connector.

10   Equipotential connector.

The connector for the attachment of equipotential cable connecting the cases of units included in the system.

1.4.2 Controls, Connectors and Indicators of Cooling Unit
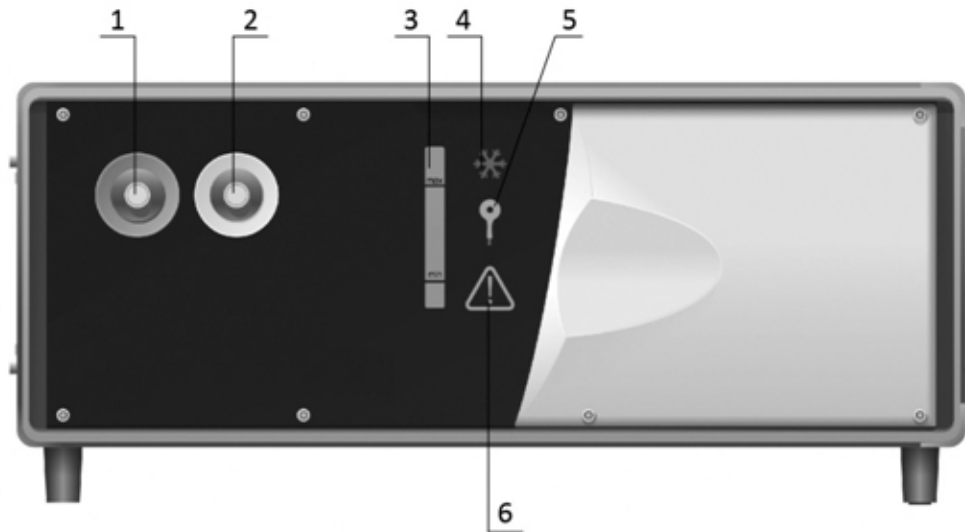
Fig. 6. The front panel of the cooling unit.

The front panel of the cooling unit contains the following (Fig. 6)

1   Quick connect coupling of cooling agent input for coil connection (marked by green ring);

2   Quick connect coupling of cooling agent output for coil connection;

3   Measuring tube to indicate the cooling agent level with minimum (**min**) and maximum (**max**) marks;

4   "Cooling" indicator;

The "Cooling" indicator can:
- illuminate – the cooling unit is switched on, the cooling agent circulates inside the coil. The coil is being cooled.
- flash – the cooling unit is switched on, the cooling agent circulates inside the coil. The coil is cooled up to minimum possible temperature and further cooling does not occur.

If you plan to perform long-term stimulation session with high power and frequency, it is recommended to cool the coil up to minimum temperature. To do this, switch on the cooling unit with connected coil and wail till

indicator starts flashing (without starting stimulation). It ensures the maximum coil operation without overheating.

5   "Coil is not connected" indicator;

It highlights red if the coil is not connected or the cooling agent does not circulate.

6   "Fault" indicator.

It does not illuminate if the system is in working order.
It blinks red if the fault is detected during the operation.
It highlights red if after the switching on the self-diagnosis system detected a fault.
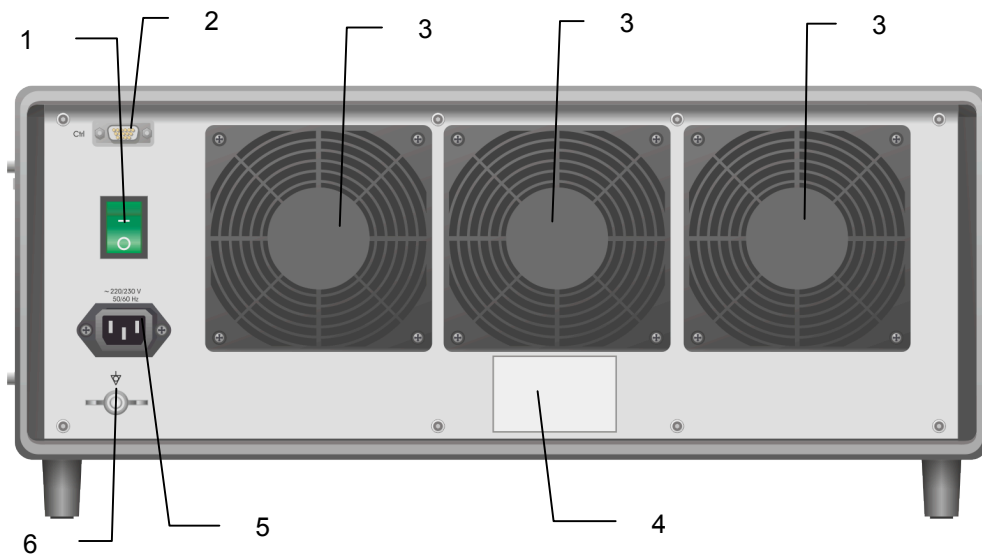
Fig. 7. The rear panel of the cooling unit.

The rear panel of the cooling unit contains the following (Fig. 7):

1   "Mains power" switch.

To connect the mains supply to the cooling unit, turn "Mains power" switch to **On (I)** position. To disconnect from the mains supply, set the "Mains power" switch to **Off (0)** position.

2   "Control" connector.

"Control" connector is intended to attach the communication cable to main unit.

3   Cooling fan outlet.

The fans provide the air circulation inside the cooling unit. The air is sucked through the holes located on the bottom panel and blown out via the cooling fan outlet, at the rear panel.

4   Labeling.

5   Connector for mains supply cable attachment.

6   Equipotential connector.

The connector for the attachment of equipotential cable connecting the cases of units included in the system.

1.4.3 Controls, Connectors and Indicators of Extra Power Supply Unit

Fig. 8. The front panel of extra power supply unit.

The front panel of extra power supply unit contains (Fig. 8):

1.   "Power" indicator.

Depending on mode "Power" indicator lights:

• orange – standby mode;

• green – extra power supply unit is switched on and functions properly;

• flashes red – the overheating of internal components occurs. At that the stimulation is stopped and error code Alt-t-3 appears on the front panel of main unit. It is recommended to pause the stimulation for 15-30 min to cool down.
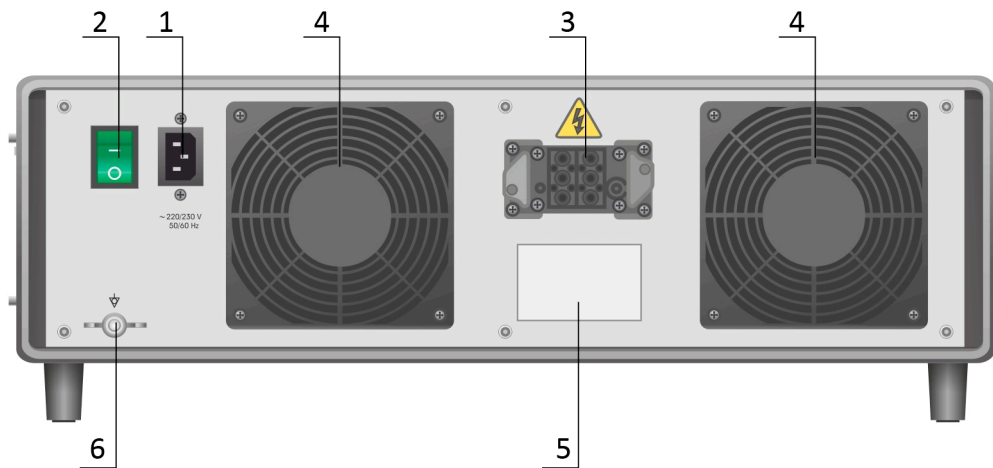
Fig. 9. The rear panel of extra power supply unit.

The rear panel of extra power supply unit contains the following (Fig. 9):

1   Connector for mains supply cable attachment.

2   "Mains power" switch.

To connect the mains supply to this unit, turn "Mains power" switch to **On (I)** position. To disconnect from the mains supply, set the "Mains power" switch to **Off (0)** position.

3   High-voltage connector to attach the main unit. The high-voltage connector is intended to attach the high-voltage cable to the unit and opposite part of this cable is plugged into the main unit.

4   Cooling fans outlet

The fans provide the air circulation inside the main stimulator unit. The air is sucked through the holes located on the bottom panel and blown out via the cooling fan outlet, at the rear panel.

5   Labeling.

6   Equipotential connector.

The connector for the attachment of equipotential cable connecting the cases of units included in the system.

1.4.4 Coil Controls, Connectors and Indicators

Fig. 10. Cooled coil.

The cooled coil contains the following (Fig. 10):

1   High-voltage connector for main unit connection.

2   Quick connect couplings for cooling unit connection.

3   "Ready" indicator duplicating the "Ready" indicator located on the front panel of the main unit (1.4.1).

4   The "Pulse" button functioning is analogous to the "Pulse" button on the front panel of the main unit (1.4.1).

Please refer to "Coils for CloudTMS Magnetic Stimulator" technical manual on how to safely attach the coil to CloudTMS. Safe use of the coil component requires strict adherence to the precautions and warnings listed in this manual and in "Coils for CloudTMS Magnetic Stimulator" technical manual.

The use of the correct accessories is essential to the functioning of the CloudTMS. Neurosoft cannot guarantee the instrument's performance unless accessories used are obtained from Neurosoft Ltd.

1.5   Labeling

The sample of CloudTMS electronic unit label is shown in Fig. 11.

CloudTMS
Main unit
RX ONLY
REF NS058201.014-022
SN 0728TZ
2016-10-27
Made in Russia
5, Voronin str., Ivanovo,
153032, Russia
Neurosoft

(01)04650075330159
(21)0728TZ
AC 220/230/240V 50/60Hz, <1000V*A
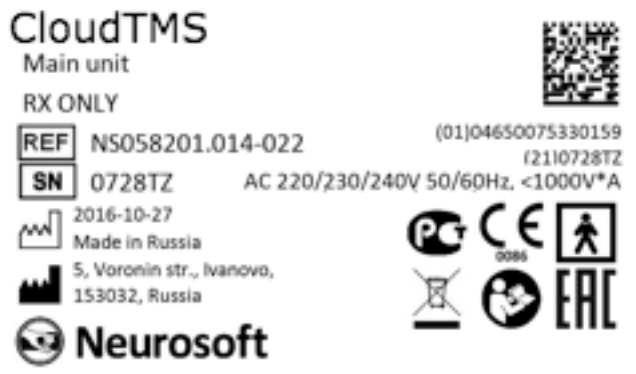
Fig. 11. CloudTMS main unit label.

Interpretation of Symbols on Electronic Unit:

– attention: consult operational documentation.

– work parts of BF type according to AAMI/ANSI ES 60601-1:2005/(R)2012.

– sign of conformance to Russian standards requirements.

– sign of the Member State of the Eurasian Economic Community and the Customs Union.

– mark of conformance to 93/42/EEC "Concerning Medical Devices" directive.

– mark of conformance to 2012/19/EC "On waste electrical and electronic equipment (WEEE)" directive.

– manufacturer by ISO 15223-1-2012.

– number according to catalogue by ISO 15223-1-2012.

– serial number by ISO 15223-1-2012.

– federal law restricts this device to sale by or on the order of a physician.

– manufacturing date by ISO 15223-1-2012.

The equipment is identified with the GS1-128 barcode that includes the GTIN code and the serial number (Fig.12).

GTIN

(01)   (0 465007533 009 8)   (21)   (XXXXXXXX)

1   2   3   4   5   6   7

Fig. 12. The GS1-128 barcode

1 – identification key: GTIN;

2 – start digit;

3 – company number;

4 – article reference;

5 – check digit;

6 – serial number identifier;

7 – serial number.

GTIN – global trade item number can be used by a company to uniquely identify all of its trade items. GS1 defines trade items as products or services that are priced, ordered or invoiced at any point in the supply chain.

To ensure the automatic data reading the GS1-128 code is integrated to the barcode in DataMatrix format (Fig. 13).

Fig. 13. DataMatrix barcode.

Data Matrix is a two-dimensional matrix barcode, consisting of black and white "cells" or modules of different brightness arranged in either a square or rectangular pattern. The DataMatrix barcode is described in ISO/IEC 16022:2006 standard.

To decode the data on device, the barcode can be read quickly by a barcode reader or by the smartphone camera as a two-dimensional image.

2   Setting-Up Procedures

2.1   Requirements to Personnel Conducting Stimulator Assembly and Installation

The stimulator should be installed by the person who is authorized by the manufacturer or the technical personnel of the medical institution which is going to use it. It is necessary to know that safety and quality of operation depend on the proper assembly of the magnetic stimulator. Further assembly and installation requirements which define the product safety will be marked by **bold and italic font** in the text.

The weight of some stimulator units exceeds 20 kg. See the recommendations on carrying over as shown in Fig. 14. It is recommended to distribute the weigh between two persons.

Move the units by grasping the special grooves at side panels.
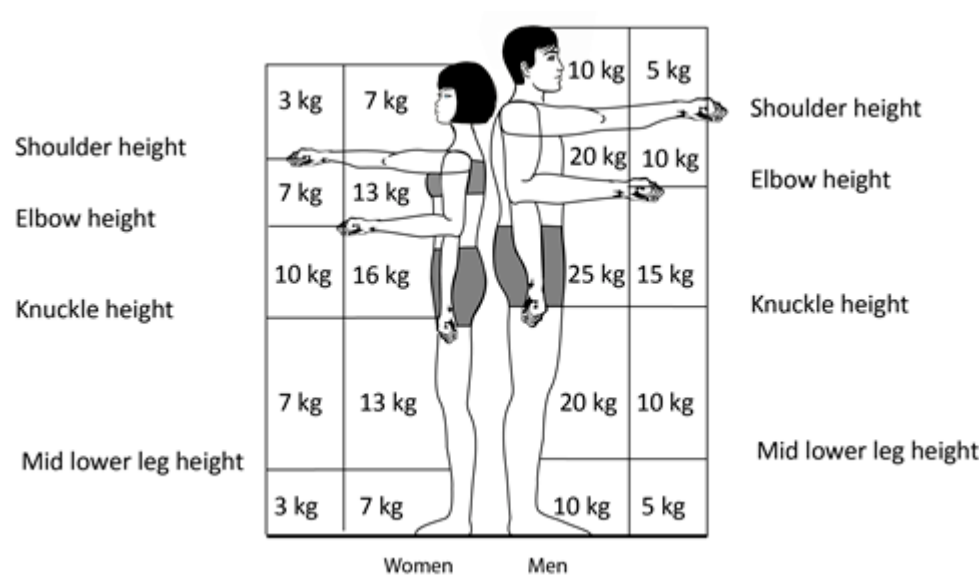
Fig. 14. Recommendations on lifting and transportation.

2.2   Room Selection and Placement

Before assembly and setup of stimulator, it is necessary to select a place for it, taking into consideration power wiring and protective ground in the room, and also to read the following requirements and recommendations.

In the selected place an access to multiple mains socket outlets should be ensured. There should be at least two 220/230/240 V, 15 A socket outlets to plug in the magnetic stimulator units. Also there should be the required number of socket outlets to plug in office equipment. These socket outlets should have protective earth (ground) contact. The use of multi-socket electric mains extenders or splitters is prohibited.

If isolation transformer with multiple sockets is used, ensure the extra grounding in compliance with AAMI/ANSI ES 60601-1:2005/(R)2012 requirements.

Requirements concerning room selection and equipment placement:

• The device has been designed for indoor use at room temperatures between +10°C and +35°C 80% maximum relative humidity.
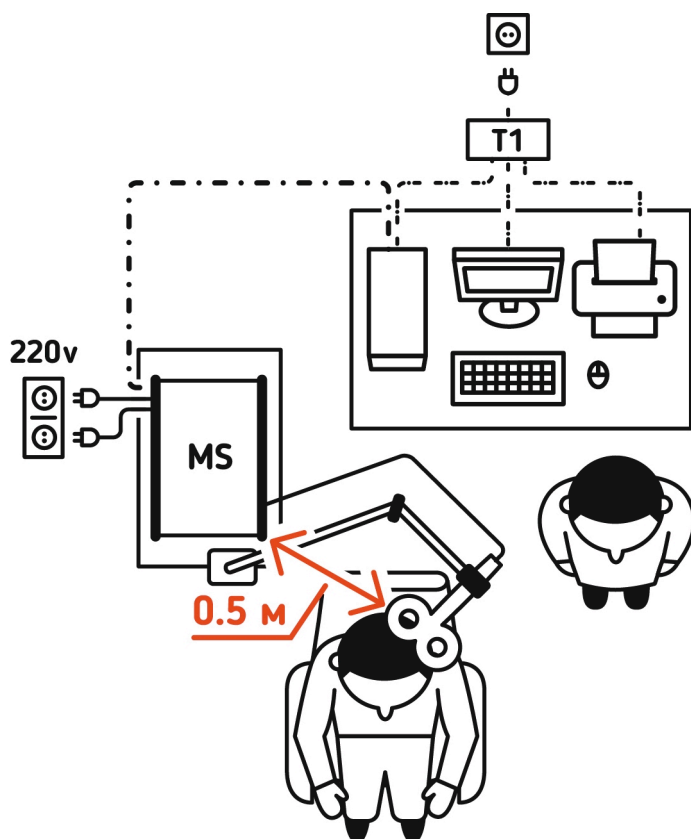
Fig. 15. Variant of placement when connecting to desktop PC. The scheme drawing of stimulator placement when magnetic stimulator is used together with Neuro-MS.NET software.
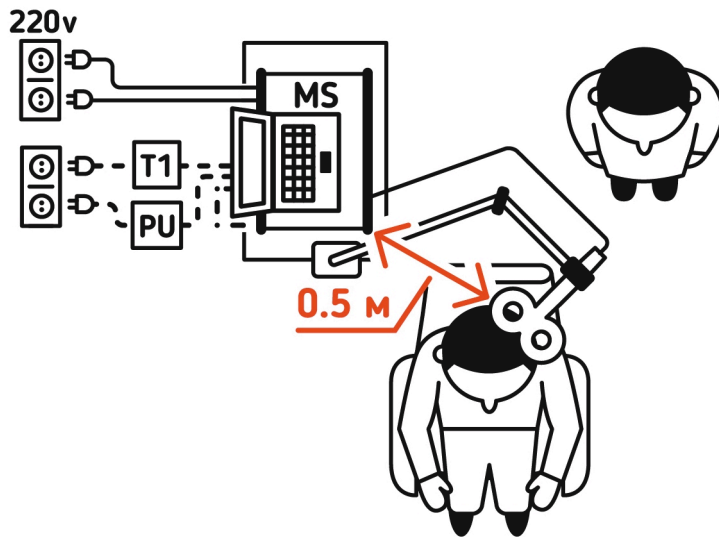
Fig. 16. Variant of placement when connecting to notebook PC powered by internal power source.

The following abbreviations are used on the figures:

- MS – magnetic stimulator;

- PU – notebook PC power unit;

- T1 – isolation transformer which complies with AAMI/ANSI ES 60601-1:2005/(R)2012 standard requirements;

- ───── – power cables (220/230/240 V) of magnetic stimulator ;

- ─·─·─· –USB cable standard.

To provide the normal cooling of the internal components during the stimulator operation, the stimulator should be placed on a firm surface. The clearance from the cooling fan outlet up to the wall (not less than 50 mm) should be provided. The fans provide the air circulation inside the main stimulator unit. The air is sucked through the holes located on the bottom panel and blown out via the cooling fan outlet, at the rear panel.

- ***The patient environment (within 1.5 meters) should contain only the electronic units being the medical device with the required safety level. The fact is that the safety level of the computer equipment is insufficient for the use in the patient environment. Hence, a patient must not contact with the metal parts of computer equipment cases and the personnel must not touch simultaneously these parts and patient body. The computer equipment used in the system should correspond to AAMI/ANSI ES 60601-1:2005/(R)2012 or be connected via the isolation transformer (specialized power supply unit – for notebook PC) corresponding to above-mentioned requirements.***

Requirements to mains:

- *To avoid electrical shock, magnetic stimulator mains plug must only be inserted in an appropriate mains socket outlet provided with a protective earth (ground) contact.*

- *The use of multi-socket electric mains extenders without additional protective actions is prohibited. The fact is that the probable break of the protective ground circuit of the multi-socket electric mains extender can lead to summation of leakage current in all connected units on their metal parts to dangerous values.*

- *Before the magnetic stimulator placement, the electrician must check the quality of standard tripolar sockets and the integrity of the protective ground circuit.*

- *In case the stimulator components are connected to several tripolar sockets, make sure they are grounded to the same protective ground circuit. Otherwise, there is a danger of several tens of Ampers leveling current leakage through the system connecting cables that leads to the equipment breakdown.*

- *Any interruption to the protective ground conductor inside or outside the device is likely to make the device dangerous. Intentional interruption is prohibited. The protective ground conductor should be checked regularly.*

2.3   Unpacking and Check of Delivery Set

If the box with the stimulator was under conditions of the excessive moisture or low temperature which differs sharply from working conditions, it is necessary to place it in the room and leave for 24 hours in normal conditions.

Unpack the box and extract the stimulator components. The delivery set should correspond to the packing report list.

Check visually the stimulator components to make sure that there is no visible damage.

2.4 Assembly and Connection of Stimulator

2.4.1 General Requirements to Assembly

> **Use standard Windows administration tools to protect data located on your PC from unauthorized access.**

Install the software.

> **The software must be installed before the first connection of stimulator to PC! Read carefully chapter 5 "General Principles of Working with Neuro-MS.NET Program" of this manual.**

> **You can download all required software modules and latest software version from our site: http://neurosoft.com/en/index/downloads. To get an access to the files, enter login and password that you can inquire in commercial department of Neurosoft Ltd.**

Placement of the units, performing of inter-unit connection and connection to the mains is carried out only when the "Mains power" switch of all units is switched off ("0" position of the power switch).

2.4.2 Preparation of Cooling Unit to Operation

The cooling system should be filled with cooling agent during the operation.

The cooling unit is supplied free from cooling agent. The cooling agent is supplied in a separate bottle. Fill the system with cooling agent before starting to work.

The silicone oil (polydimethylsiloxane) 5 cSt is used as a cooling agent for the cooling unit.

The silicone oil is filled via filler located on the top cover of the cooling unit. Before the filling unscrew the lid and pour the oil up to "max" level. It is recommended to use the special hose.

After filling completion screw the lid tightly.

The system does not consume the oil and its level should be within "min" and "max" levels during the whole life time of cooling unit.

The oil level may decrease if you connect the cooled coil that is not filed with oil. If the oil level is below the "min" level, add the oil (Fig. 17). If the oil level is decreased

without changing the coil, observe the system carefully in order to find the cracks of leakage. In case of leakage, stop using the system and call to nearest service.

If the level of the cooling agent is below the **min** mark, screw off the lid and add the cooling agent up to the max level (not more) using special hose. The lid should be screwed tightly.

Fig. 17 Filling an oil to cooling unit using special hose.

2.4.3 System Assembling

The components of the system are placed according to recommendations listed in p. 2.2. If you do not intend to use the stimulator together with PC and prefer the Stand-alone mode, take the steps from 2.4.3.1 to 2.4.3.10. It is required to perform the steps from p.2.4.3.11 to 2.4.3.18 only if you decided to use the stimulator in PC-mode.

2.4.3.1   Assemble the trolley according to technical manual for the trolley.

2.4.3.2   Fix K-8 coil holder on the trolley according to technical manuals for the holder and the trolley.

2.4.3.3   Make sure the cooling unit is filled with cooling agent (see section 2.4.2).

2.4.3.4   Position the stimulator units on trolley shelves according to recommendation and secure them with the required fastenings (see chapter 4 of technical manual for the trolley).

2.4.3.5   Interconnect the units according to Fig. 18. Do not plug them into the mains sockets and PC.
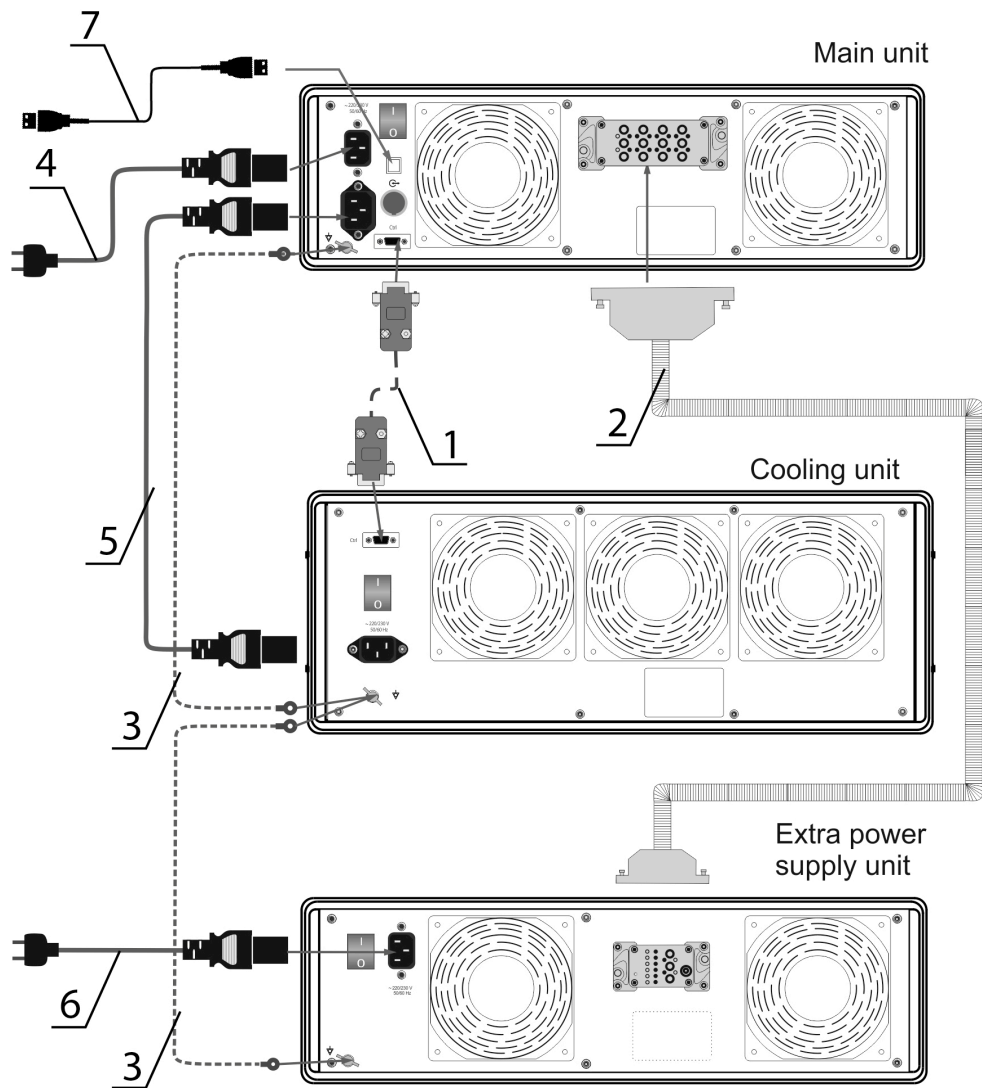
Fig. 18. Connection diagram.

The figures in Fig. 18 indicate the following:

1) Control cable;

2) HV cable;

3) Equipotential cable;

4) Mains supply cable for the main unit;

5) Mains supply cable for the cooling unit;

6) Mains supply cable for extra power supply unit.

7) USB cable.

2.4.3.6 Fix K-3 flexible arm for coil positioning on a trolley according to technical manual for the arm.

2.4.3.7 Secure AFEC-02-100-C coil in K-3 flexible arm (Fig. 19) (see technical manual for K-3 flexible arm).

Fig. 19. Fixing a coil.

2.4.3.8   Plug in the HV socket of coil cable to main unit (Fig. 20).

Fig. 20. Connected coil.

2.4.3.9   Connect the cooled coil hoses to cooling unit (Fig. 21).

Fig. 21. Connecting cooled coil hoses to cooling unit.

2.4.3.10   Move the trolley with stimulator in a required place and make sure that "Mains power" switches on the rear panels of units are in "0" position. Plug in the stimulator to mains socket outlet (220/230/240 V).

In the selected place an access to multiple mains socket outlets should be ensured. These sockets should have protective earth (ground) contact. The use of multi-socket electric mains extenders or splitters is prohibited. The mains socket outlet should ensure 15A/16A current rating.

The assembled system is shown in Fig. 1.

2.4.3.11   Place a PC near the stimulator following recommendations listed in p. 2.2. The position of PC depends on its type:

- Notebook – can be placed on or near the stimulator (on the table).

- Touchscreen computer – can be secured in a holder fixed on the trolley. Also the touchscreen computer can be placed on a table near the stimulator.

- Desktop PC – is placed on a table near the stimulator.

The computer equipment used together with the stimulator should comply with AAMI/ANSI ES 60601-1:2005/(R)2012 requirements or be connected via the isolation transformer (specialized power supply unit – for notebook PC) complying with above-mentioned requirements.

2.4.3.12   Install the software using the distributive supplied on electronic media supplied (USB flash drive, CD, etc.). Recommendations on selection of PC and software settings are listed in section 4.1.3

2.4.3.13   Switch on the power on stimulator units by toggling the required switches on the rear panels to "I" positions.

2.4.3.14   Connect the stimulator to switched on PC using USB cable.

Use USB cable supplied with the stimulator. If you use desktop PC, plug in the cable to USB connectors located on the rear panel.

If the stimulator is connected to this USB port for the first time, the dialog box shown in Fig. 22 will appear.
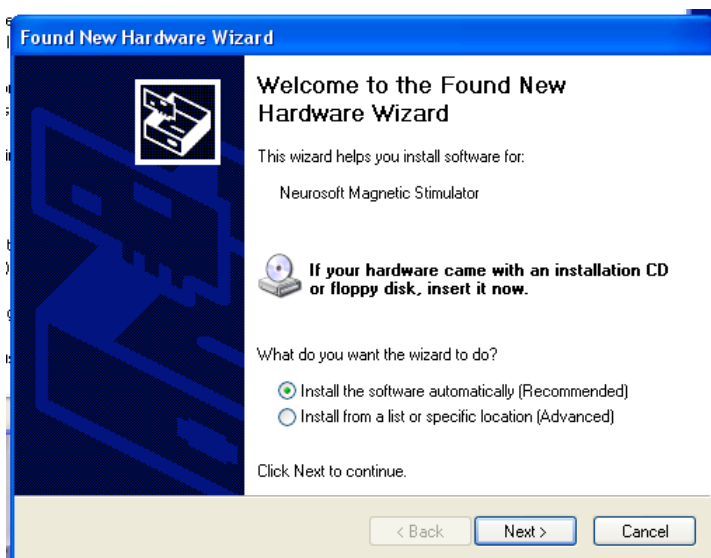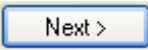
Fig. 22. "Found New Hardware Wizard" dialog box.

Press [Next >] button.

"New hardware wizard" will perform the stimulator installation. After the installation completion the dialog box shown in Fig. 23 will appear on the screen. Press
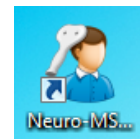
[Finish] button and start using the stimulator.

Fig. 23. "Found New Hardware Wizard" dialog box after the installation completion.

2.4.3.15 To run Neuro-MS.NET program, click "Start" button and choose **All pro-grams|Neurosoft|Neuro-MS.NET|Neuro-MS.NET** Windows
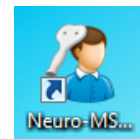
Start menu commands or double-click on [Neuro-MS...] icon on the desktop.

> **At the first program start the program offers to specify the region of pro-gam use. Select the USA.**
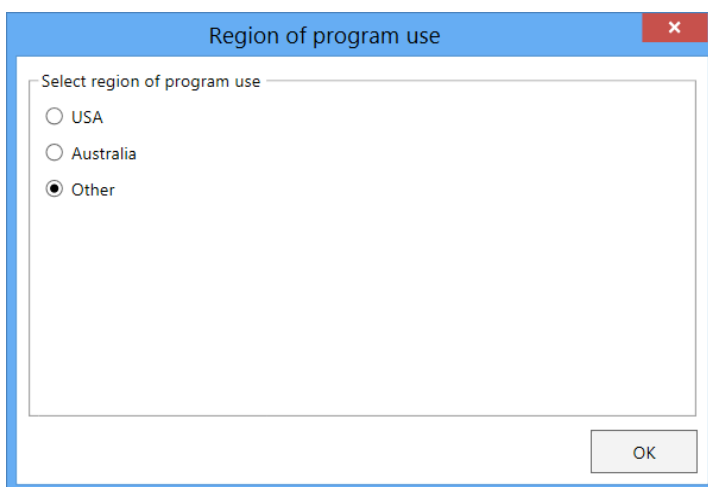
Fig. 24. Region of program use.

2.4.3.16   All the indicators highlight for 3 seconds which allows controlling its operability. During this period the stimulator is in self-diagnosis mode.

2.4.3.17   Now your stimulator can work with Neuro-MS.NET program and you can start the treatments (see 4 chapter).

2.4.3.18   To switch off the stimulator, close the program. Switch off the stimulator using "On/Off" button. Turn "Mains power" switches located on the rear panels of the main unit, the cooling unit and extra power unit to "Off" (0) position.

3   Operating Order

3.1   Operation in Stand-alone Mode

> **Before TMS ask a patient to fulfill "Safety Screening Questionnaire for Transcranial Magnetic Stimulation" (see Annex 14.4). Make sure that patient doesn't have contraindication for TMS (see Table 1 on page 7).**

In stand-alone mode of operation the stimulator can:

- produce single pulses that are intended to detect the motor area and define motor threshold;

- perform the repetitive stimulation by trains that is intended to stimulate using the selected protocol.

After the power supply switch on, the stimulator stands in the "Single stimulation" mode, at that, the "Single pulse" button highlights green. If you press "Single pulse" button, the stimulator will switch to the setting mode of repetitive stimulation frequency. At that, the "Single pulse" button does not illuminate and "Frequency" button is highlighted green. The next pressing of "Single pulse" button switches the stimulator to single pulse mode.

The parameters of the repetitive stimulation are specified before the stimulation beginning.

> **The safety and the effectiveness of the specified treatment parameters that go beyond the recommended ones are not established.**

To do this, press "Session", "Pause", "Train" or "Frequency" button to select the corresponding mode. To adjust the corresponding parameter, use "Stimulation parameters" knob. This current value will be displayed on "Stimulation parameters" indicator. The range of the specified values and the frequency step are listed in 1.1 "Main Specifications" section. When you switch off the stimulator using "On/off" button, the stimulator keeps current stimulation setting in a nonvolatile memory and restores them at next switch on.

If you use only one treatment protocol, you may adjust the settings once and just control them at next switch on. To adjust the settings of depression treatment protocol and save them in a nonvolatile memory, do the following steps:

1. Switch on the magnetic stimulator using "On/off" button.

2. Push "Frequency" button and adjust 10 Hz frequency with "Stimulation parameters" knob. The selected frequency value is displayed on "Stimulation parameters" indicator.

3. Press "Train" button and adjust 4.0 sec train duration with "Stimulation parameters" knob. The selected train value is displayed on "Stimulation parameters" indicator.

4. Press "Pause" button and adjust 26 sec pause with "Stimulation parameters" knob. The selected pause value is displayed on "Stimulation parameters" indicator.

5. Press "Session" button and adjust 37.5 min session duration with "Stimulation parameters" knob. The selected session value is displayed on "Stimulation parameters" indicator.

6. Switch off the stimulator with "On/off" button.

When stimulator is switched off, the current settings are saved in the nonvolatile memory and are restored at next switch on.

To continue the treatment session, find the motor area and detect the motor threshold. When detecting the MT, single pulse mode is used. During the treatment session itself, the coil is moved relative to motor area according to recommendations listed below. At that the stimulator is switched to repetitive stimulation mode.

The order of treatment session:

1. Assemble the system, plug in to the mains and switch on the stimulator using the "Mains power" switch on the rear panel (see chapter 2 "Setting-Up Procedures").

2. Press "On/off" button on stimulator. At that the stimulator enters the single pulse mode. The "Single pulse" button starts illuminating green.

3. Adjust 30% stimulus amplitude with "Amplitude" knob.

4. The technique how to detect the motor threshold is described in section 4.2.1 "Getting Ready".

5. When MT is defined, press "MT detection" button. After this button pressing the current amplitude value is taken as 100% and it is displayed on "Amplitude" indicator. The button and "MT" indicator are highlighted green.

6. Adjust 120% stimulus amplitude. At that "MT" threshold indicator illuminates green.

7. Press "Session", "Pause", "Train" or "Frequency" to check the preset stimulation parameters.

8. Position the coil as described in section 4.2.2 "First Visit of a Patient First Visit of a Patient".

9. To start stimulation, press "Pulse" button on the coil or on the stimulator case when one of the buttons: "Frequency", "Train", "Pause" or "Session" is illuminated. During the repetitive stimulation "Session" button and "min" indicator blink. The "Stimulation parameters" indicator displays the countdown of the session duration. When the session time is expired, the stimulation is stopped. Press "Pulse" button on the coil or the stimulator case during the stimulation to stop the session.

10. Switch off the stimulator using "On/Off" button. Turn "Mains power" switches located on the rear panels of the main unit, the cooling unit and extra power unit to "Off" (0) position.

3.2   Operation in PC-mode

> **Warning! Before TMS ask a patient to fulfill "Safety Screening Questionnaire for Transcranial Magnetic Stimulation" (see Annex 14.4). Make sure that patient doesn't have contraindication for TMS (see Table 1 on page 7).**

The stimulator can operate under control of Neuro-MS.NET software. In this mode the stimulator is connected to PC via USB and controlled by the corresponding software. The order of the stimulator connection to PC and the process of software installation are described in the chapter 2.

In PC-mode the "Amplitude" knob allows to adjust the required amplitude value, and all the rest stimulation parameters are set in the software.

> **The safety and the effectiveness of the specified treatment parameters that go beyond the recommended ones are not established.**

The stimulus can be evoked by pushing of "Pulse" button on the coil or on the stimulator panel or by selecting menu command in the software.

To switch off the stimulator, close the program. Switch off the stimulator using "On/Off" button. Turn "Mains power" switches located on the rear panels of the main unit, the cooling unit and extra power unit to "Off" (0) position.

4 Proper Use

4.1 PC-mode

4.1.1 Getting Ready

The technical preparation of magnetic stimulator is done only once at the beginning of the working day.

1. Make sure that the electronic units of the stimulator and coil do not have the visible mechanical failures which can be dangerous.

2. Make sure that high-voltage connector of the coil is plugged in firmly and the spring-lock is locked (Fig. 20).

3. Make sure that cooling unit hoses are fixed securely.

4. Make sure the stimulator "Mains power" switches are in "0" positions. Connect the main unit and extra power supply unit to mains socket outlets.

5. Toggle the "Mains power" switches on the rear panels of all units to "I" positions (2 in Fig. 5; 1 in Fig. 7; 2 in Fig. 9) .

4.1.2 First Visit of a Patient

1. Ensure the chair settings are not restrictive to make it easy for the patient to enter and sit down.

2. When the patient arrives, seat him/her comfortably in the chair.

3. Ask a patient to fulfill "Safety Screening Questionnaire for Transcranial Magnetic Stimulation" (see Annex 14.4). Make sure that patient doesn't have contraindication for TMS (see Table 1 on page 7).

4. Switch on the computer with installed Neuro-MS.NET software.

5. Run **Neuro-MS.NET** program.

6. Press "New treatment" button on start page (Fig. 25).
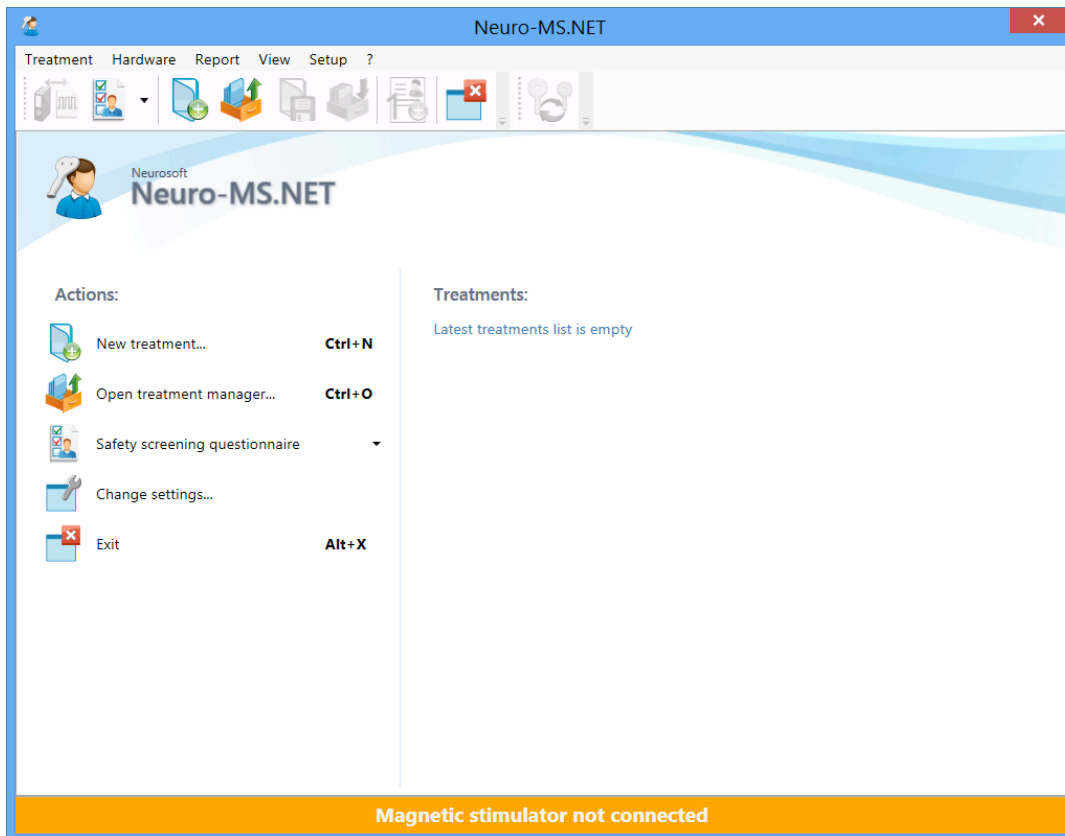
Fig. 25 Start page.

7. In the "Treatment" window that appears enter patient's data (Fig. 26).
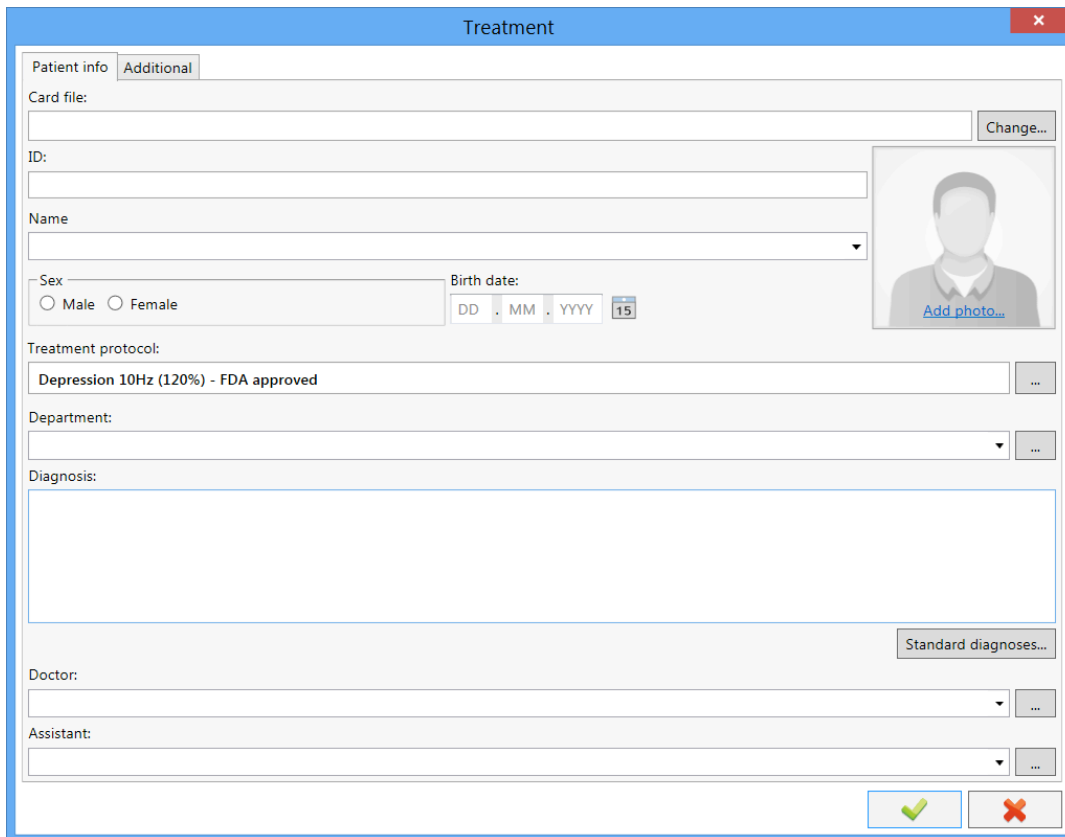
Fig. 26. "Treatment" window.

8. Make sure that FDA recommended protocol is selected in "Treatment protocol". If FDA recommended protocol isn't selected press [...] button in "Treatment protocol" (Fig. 26) and in the appeared "Treatment course selection" dialog box choose FDA recommended protocol (Fig. 27).
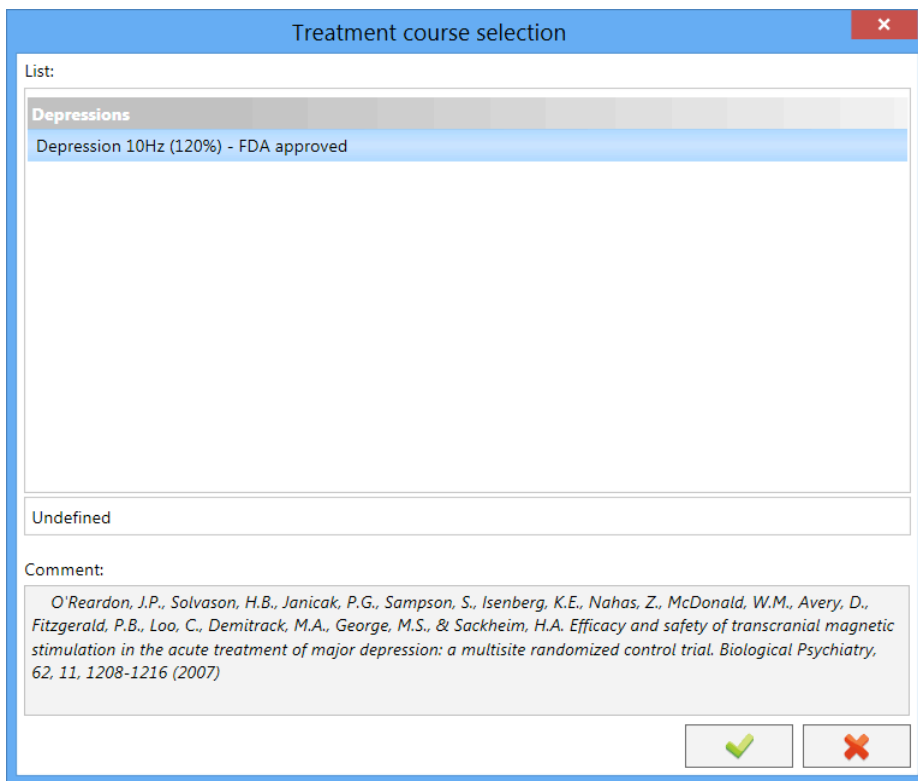
Fig. 27. "Treatment course selection" dialog box.

9. Confirm your choice. Press [✔] button in "Treatment course selection" dialog box (Fig. 27).

10. Press [✔] button in "Treatment" window (Fig. 26).

Determine Motor Threshold (MT)

The minimal intensity required to elicit an EMG response of at least 50 µV with 50% probability in fully relaxed muscle (Rossini et al., 1994) is the resting motor threshold (MT). Also it is possible to define the MT by the visual twitch of the target muscle in 5 cases of 10.

11. MT is detected in "MT" tab (Fig. 28).
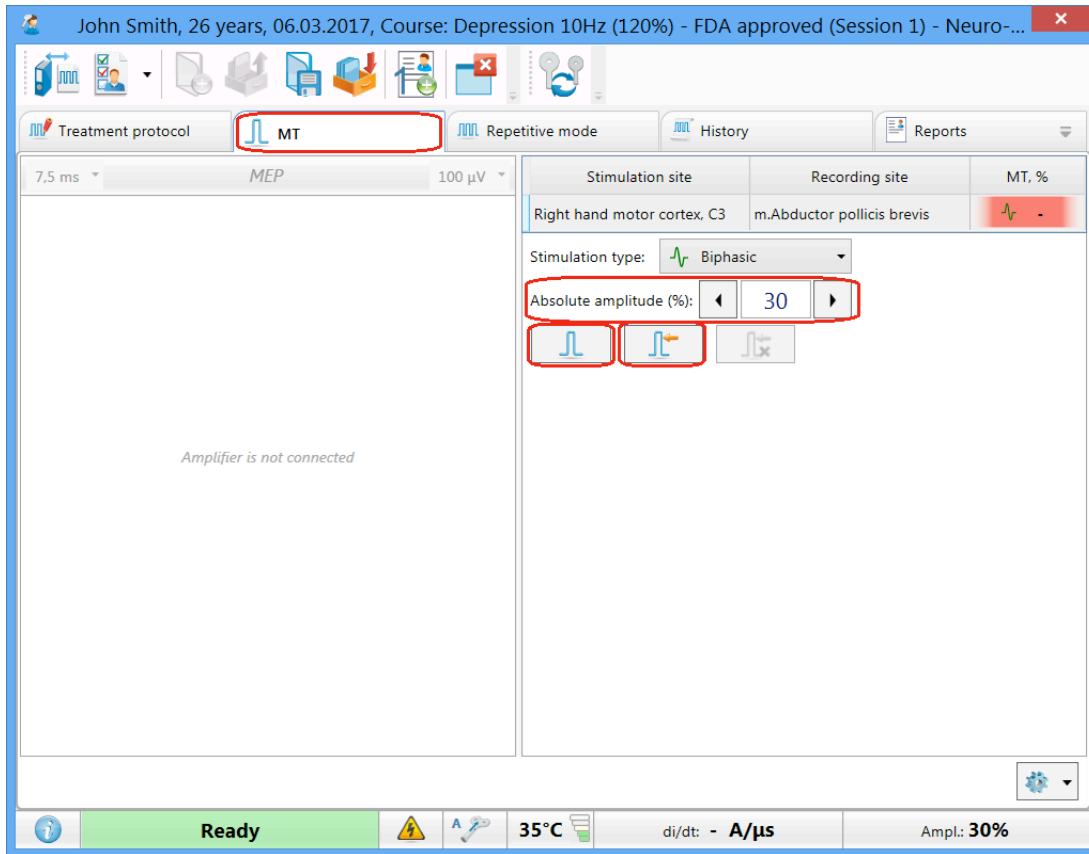
Fig. 28. Single pulse mode (MT) tab.

12. To ensure correct coil positioning on the patient's head during all treatment sessions use a cap for each individual patient. The cap is supplied in 2 different sizes: size 42-54 and size 54-66. Select the cap size which best fits the patient's head. Use cap size 42-54 if the head perimeter is 21.3–22.9 (in)/42-54 (cm) and size 54-66 if the head perimeter is 22.9–24.4(in)/54-66 (cm). Make sure that the cap fits tightly to the patient's head and is not easy to move around the head and the midline of the cap follows the center line of the patient's head.

Write the patient's name or ID in the "Name/ID" field of the cap to ensure that a cap is used for all future patient treatments (Fig. 29).

Measure the distance from the nasion (the ridge above the nose) to the lower edge of the cap in mm with the measuring reel. Write the distance on the cap in the "Length" field (Fig. 29)

(Note: If it is observed over time, during subsequent treatment sessions, that the patient cap no longer fits as expected, due to significant change in hair-style, due to damage to the cap or other reasons, then you must use a new cap and mark it again as described in steps 13-16 below.)

Fig. 29. "Name/ID" and "Length" fields.

13. Measure distance from the nasion to inion (the lump on the back of the head), and mark a small line at the halfway point. Measure distance between the external auditory meatuses and mark the point at which it crosses your fist mark. This is Cz or Vertex (Fig. 30).
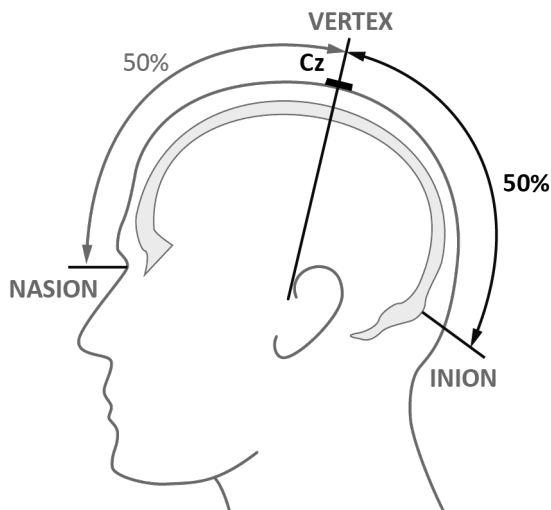
Fig. 30. Cz.

14. From this point measure 20% of the distance between the external auditory meatuses towards patient's left ear, and mark the point. This is C3. **C3 is motor threshold detection location** (Fig. 31).
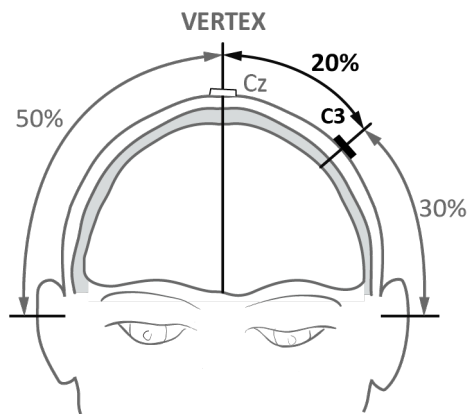
Fig. 31. C3.

15. Ask the patient to relax his/her pronated right hand.

16. Ensure both the patient and the technician insert ear plugs.

17. Start stimulation with a moderate intensity (≈ 30% of maximum output). Make sure that 30% intensity is specified in Neuro-MS.NET program (Fig. 32) and on "Amplitude" indicator of magnetic stimulator (1 in Fig. 33). In case of discomfort or local pain, the stimulation can be started at lower intensities.
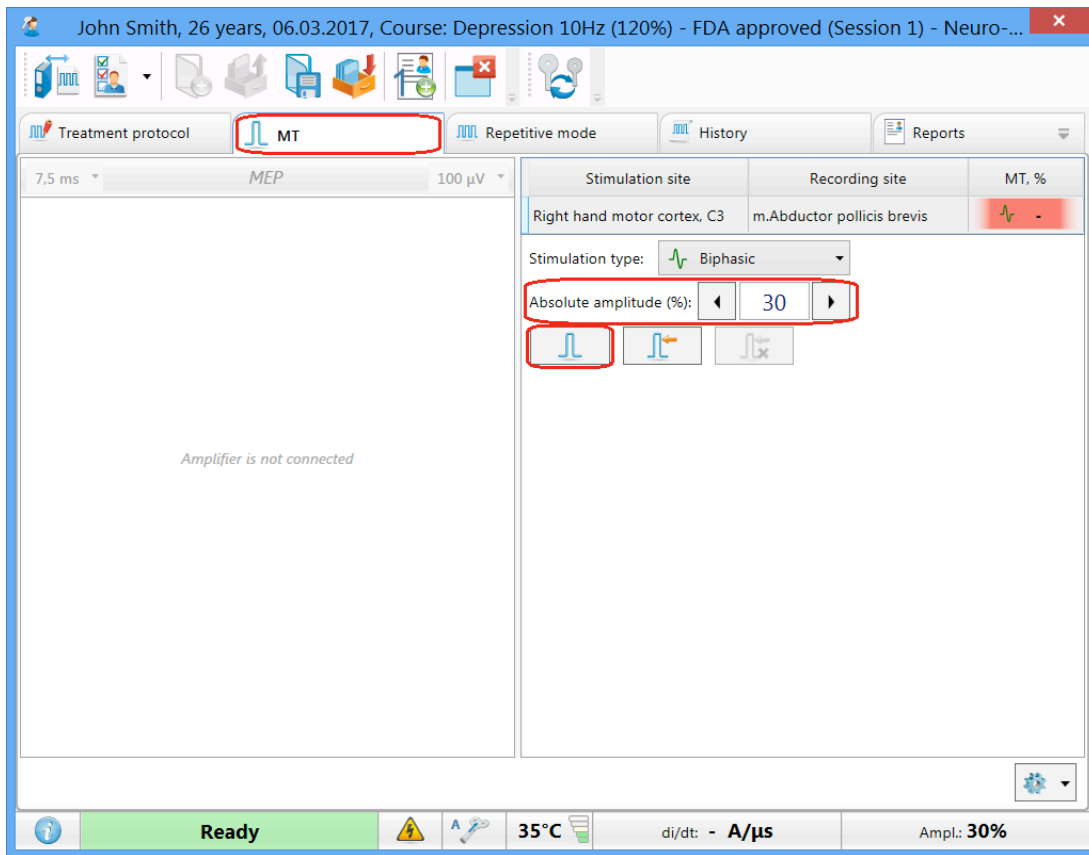
Fig. 32. MT tab.

Fig. 33. The fragment of the front panel of main unit.

18. To move a coil, loosen the screw on flexible arm (Fig. 34).
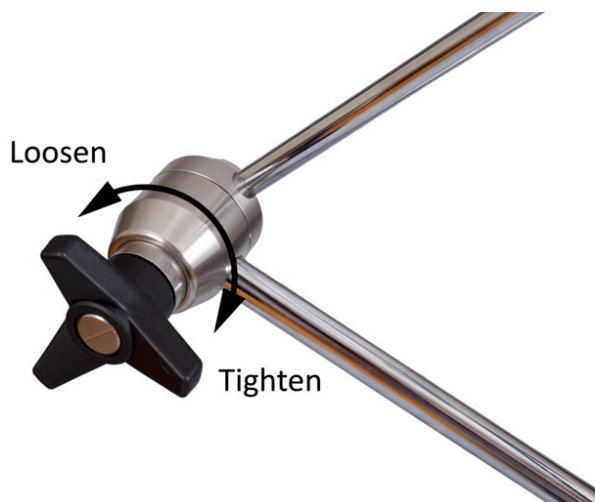
Fig. 34. Screw on holder arm.

19. Place the coil **on C3** at 45° in relation to horizontal plane, with the arrow pointing toward the upfront and the handle downward and backward (Fig. 35).
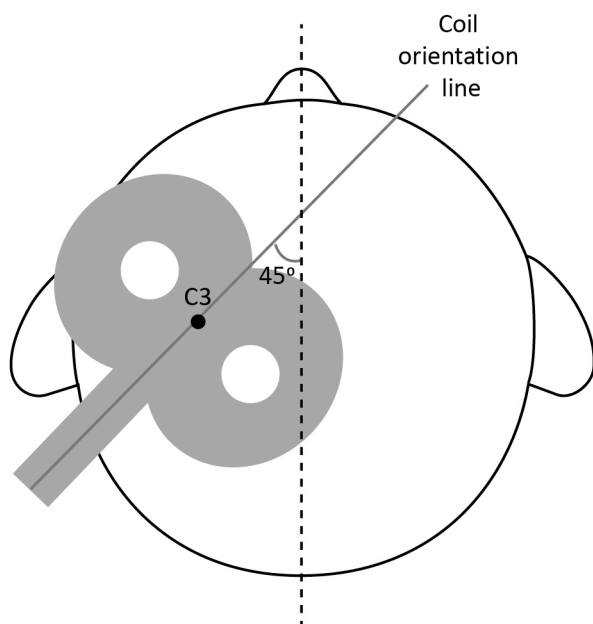
Fig. 35. Correct coil positioning for MT-detection.

20. To deliver stimulus you can push button on coil or "Pulse" button on magnetic stimulator (3 in Fig. 33) or [button] button in the program (Fig. 32). To adjust amplitude, use "Amplitude" knob on magnetic stimulator (2 in Fig. 33) or [◄] and [►] buttons in Neuro-MS.NET software (Fig. 32). Do not deliver stimulus often, make 5-10 sec pause between stimuli.

21. Deliver single pulse and observe muscle contraction (movement elicitation of finger or thumb). Try to move a coil about 2 cm around C3 in a grid like pattern (Fig. 36). Each time you move a coil deliver a stimulus. If no muscle contraction is observed, gradually increase the intensity (5% step). Continue moving a

coil increasing amplitude and delivering pulse till muscle twitch is observed visually.
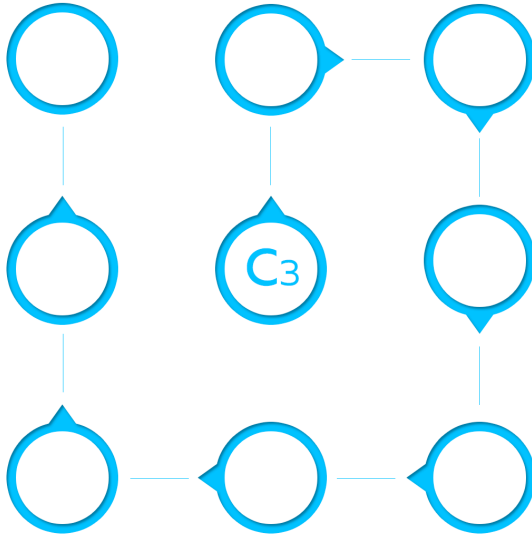
Fig. 36. Grid like pattern.

22. Now keeping the same intensity move the coil 2 cm around C3 to find the point where the stimulus elicits the highest visible muscle contraction. This is hotspot for MT detection.

23. Fix the coil position securely using screw on holder arm.

24. Gradually reduce the intensity (5% step) until the finger or thumb movement is not seen anymore.

25. Gradually increase the intensity (2% step) until the finger or thumb movement is seen.

26. Gradually reduce the intensity (1% step) until the motor threshold is found (5 contractions of 10 stimuli). Press [button] to fix MT (Fig. 32).

Patient Treatment

27. Go to the "Repetitive mode" tab (Fig. 37).
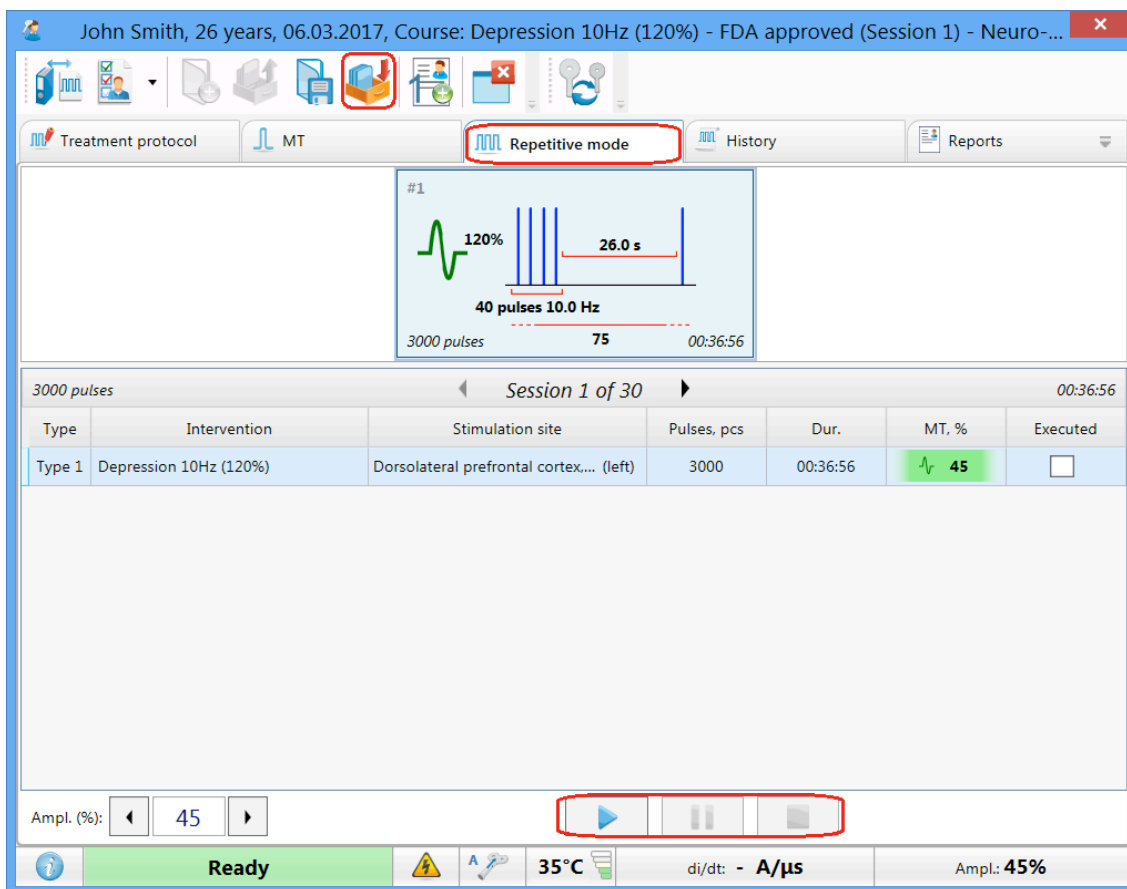
Fig. 37. Repetitive mode tab.

28. To start the repetitive stimulation session use button on coil, or "Pulse" button on magnetic stimulator (3 in Fig. 33) or "Start stimulation" [▶] button in the program (Fig. 37). The treatment parameters are preloaded into the device. Stimulation will be generated at 120% motor threshold with a pulse sequence of 10 Hz for 4 seconds, followed by a 26 second quiet period. Treatment will last for a total of about 37 minutes. This is a total of 3.000 pulses.

29. Once stimulation button is pressed, the message box offering you to move the coil appears on the display (Fig. 38).
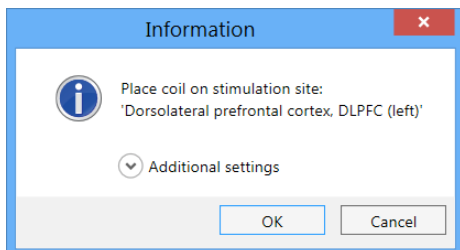
Fig. 38. "Information" message box.

30. Measure 5 cm (2 inches) with measuring reel forward from anterior rim of the coil parallel to the middle line of the cap. Mark the point.

31. Loosen the screw on holder arm and move the anterior rim of the coil to marked point (you have found it at step 30). (Fig. 39). Keep the coil orientation.
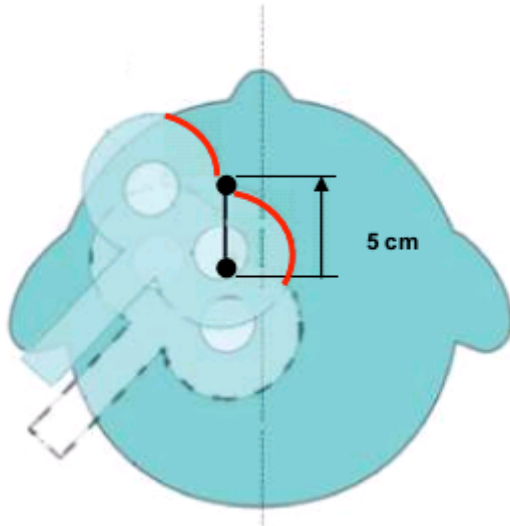
Fig. 39. Correct coil positioning for treatment.

32. Fix the coil position securely using the screw on holder arm.

33. Once the coil position has been fixed, the anterior rim of the coil should be marked on the cap (see Fig.38). It will be required for second and next visits.

34. Ensure the coil is making contact with the patient's head and ask the patient to remain still for the duration of the treatment. Make sure a patient feels comfortable and can stand the treatment otherwise the treatment will be ineffective.

35. Press "OK" button in the message box (Fig. 38). The same action can be performed if you just press button on the coil.

36. During the treatment, stay in the room with the patient and periodically check to ensure the coil and the patient are in the same position. The remaining time up to session completion is displayed in the bottom left area of the screen. Session can be paused by pressing [❚❚] button. Stimulation can be stopped with "Stop" [◼] button (Fig. 37). The same action can be performed if you just press button on the coil.

37. When intervention is completed, the software will display a message box informing on intervention completion. Press "OK" button (Fig. 40). Move the coil up and away from the patient's head.
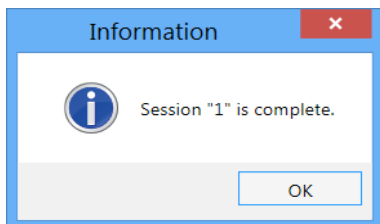
Fig. 40. "Information" message box.

38. Assist the patient as he/she stands up.

39. Remove ear plugs and cap. Pack the cap in individual plastic bag. Make sure that patient's name or ID is written on bag correctly.

40. To end (close) the treatment, use toolbar button (Fig. 37). Press "Yes" button in the appeared dialog box (Fig. 41).
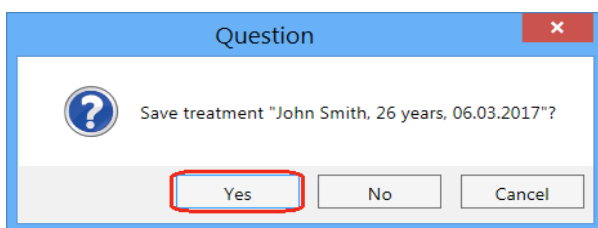
Fig. 41. Treatment saving.

41. To close the program, use toolbar button (Fig. 42).
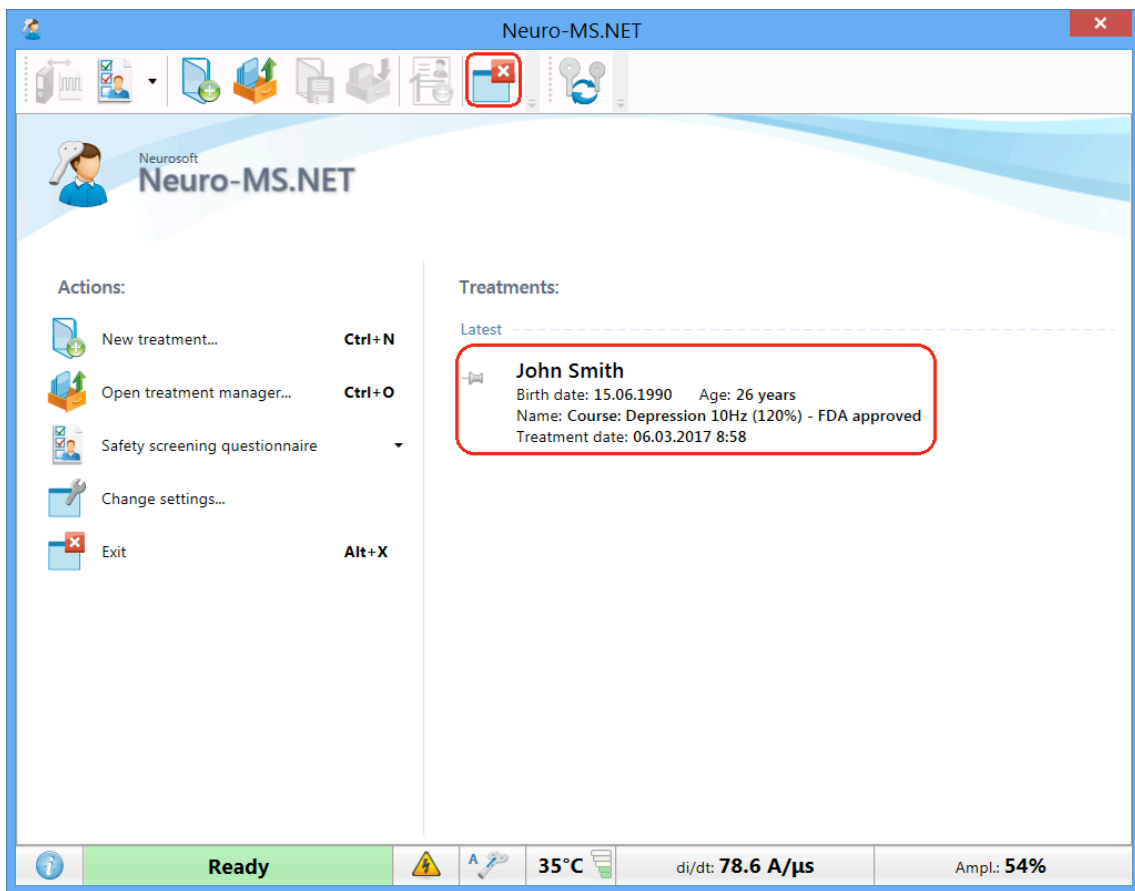
Fig. 42. "Start" page.

42. The treatment session is done. You should schedule next session for the patient. During the treatment we recommend to assess patient treatment progress regularly using standard techniques related to depression.

4.1.3 Second and Next Visits

1. Repeat steps from 1 to 6 of "First Visit of a Patient" section.

2. Make sure that the patient name/ID match the name/ID on the patient cap.

3. Put personal cap on. Changes in hairstyle may affect head cap fit on patient.

> **That's why new selection of the cap size with the best fit to the patient's head is highly recommended in this situation.**

4. Make sure that a cap is properly aligned such that the middle line of the cap follows the central line of the patient's head.

5. Control that the distance from the nasion to the lower edge of the cap is the same as the distance written on the cap.

6. Ensure both the patient and the technician insert ear plugs.

7. Find a patient in "Latest" list of start window and left-click it (Fig. 42).

8. The program will automatically open the next unexecuted session (Fig. 43).
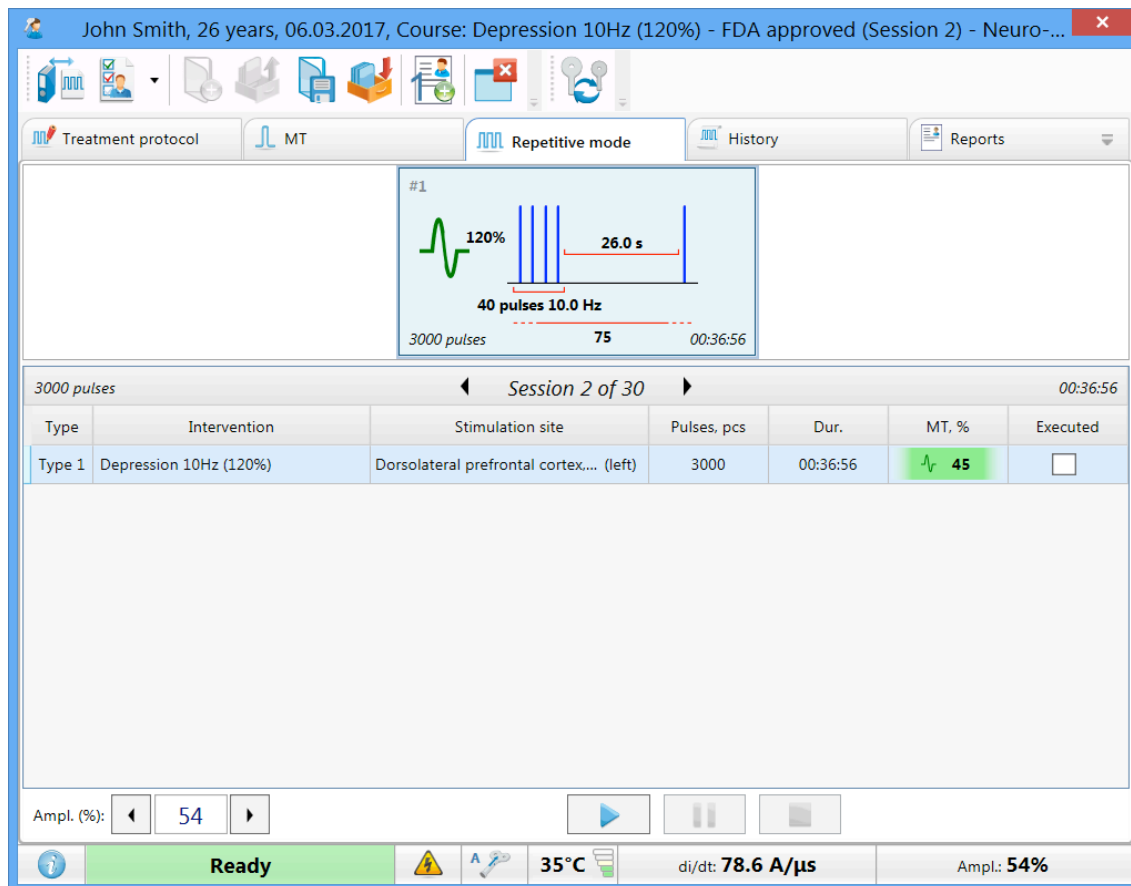
Fig. 43. Unexecuted session.

9. To start the repetitive stimulation session use button on coil, or "Pulse" button on magnetic stimulator or "Start stimulation" ▶ button in the program.

10. Once stimulation button is pressed, the message box inviting you to place the coil appears on the display.

11. Loosen the screw on holder arm and move the coil to the marked line on the cap (see Fig.38). Make sure that the anterior rim of the coil matches the marked line.

12. Fix the coil position securely using the screws on holder arm.

13. Ensure the coil is making contact with the patient's head and ask the patient to remain still for the duration of the treatment. Also make sure a patient feels comfortable and can stand the treatment otherwise the treatment will be ineffective.

14. Press "OK" button in the dialog box (the same action can be performed if you just press button on the coil).

15. Repeat steps 23-29 of "First Visit of a Patient" section.

16. Most of MDD patients respond on TMS therapy. When you carefully follow abovementioned steps dealing with MDD patients you should expect remission rate and responder amount in average to be equal to figures published in TMS and Depression related research results. Dealing with non-responders, maintenance and other similar questions are widely reviewed and discussed in the literature.

4.1.4   Work Completion

To switch off the stimulator, close the program. Switch off the stimulator using "On/Off" button. Turn "Mains power" switches located on the rear panels of the main unit, the cooling unit and extra power unit to "Off" (0) position.

4.2   Stand-alone Mode

4.2.1 Getting Ready

The technical preparation of magnetic stimulator is done only once at the beginning of the working day.

1. Make sure that the electronic units of the stimulator and coil do not have the visible mechanical failures which can be dangerous.

2. Make sure that high-voltage connector of the coil is plugged in firmly and the spring-lock is locked (Fig. 20).

3. Make sure that cooling unit hoses are fixed securely.

4. Make sure the stimulator "Mains power" switches are in "0" positions. Connect the main unit and extra power supply unit to mains socket outlets.

5. Toggle the "Mains power" switches on the rear panels of all units to "I" positions (2 in Fig. 5; 1 in Fig. 7; 2 in Fig. 9) .

6. Switch on the magnetic stimulator using "On/off" button .

4.2.2 First Visit of a Patient

1. Ensure the chair settings are not restrictive to make it easy for the patient to enter and sit down.

2. When the patient arrives, seat him/her comfortably in the chair.

3. Ask a patient to fulfill "Safety Screening Questionnaire for Transcranial Magnetic Stimulation" (see Annex 14.4). Make sure that patient doesn't have contraindication for TMS (see Table 1 on page 7).

Determine Motor Threshold (MT)

The minimal intensity required to elicit an EMG response of at least 50 μV with 50% probability in fully relaxed muscle (Rossini et al., 1994) is the resting motor threshold (MT). Also it is possible to define the MT by the visual twitch of the target muscle in 5 cases of 10.

4. To ensure correct coil positioning on the patient's head during all treatment sessions use a cap for each patient. The cap is supplied in 2 different sizes: size 42-54 and size 54-66. Select the cap size which best fits the patient's head. Use cap size 42-54 if the head perimeter is 21.3–22.9 (in)/42-54 (cm) and size 54-66 if the head perimeter is 22.9–24.4(in)/54-66 (cm). Make sure that the cap fits tightly to the patient's head and is not easy to move around the head and the midline of the cap follows the center line of the patient's head.

   Write the patient's name or ID in the "Name/ID" field of the cap to ensure that a cap is used for all future patient treatments (Fig. 44).

   Measure the distance from the nasion (the ridge above the nose) to the lower edge of the cap in mm with the measuring reel. Write the distance on the cap in the "Length" field (Fig. 44).

   (Note: If it is observed over time, during subsequent treatment sessions, that the patient cap no longer fits as expected, due to significant change in hair-style, due to damage to the cap or other reasons, then you must use a new cap and mark it again as described in steps 5-8 below.)
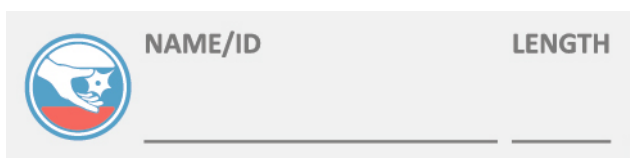
Fig. 44. "Name/ID" and "Length" fields.

5. Measure distance from the nasion to inion (the lump on the back of the head), and mark a small line at the halfway point. Measure distance between the external auditory meatuses and mark the point at which it crosses your first mark. This is Cz or Vertex (Fig. 45).
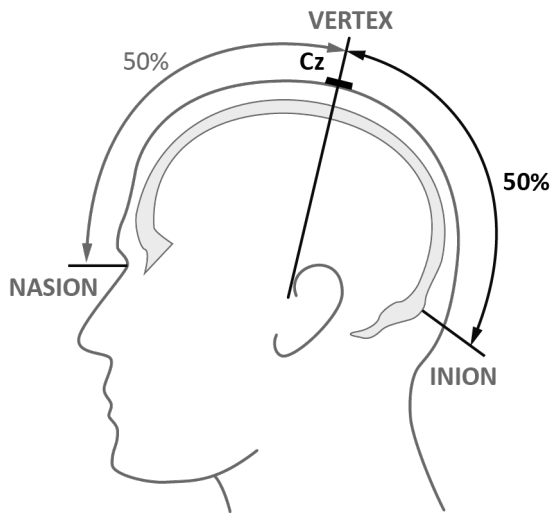
Fig. 45. Cz.

6. From this point measure 20% of the distance between the external auditory meatuses towards patient's left ear, and mark the point. This is C3. **C3 is motor threshold detection location** (Fig. 46).
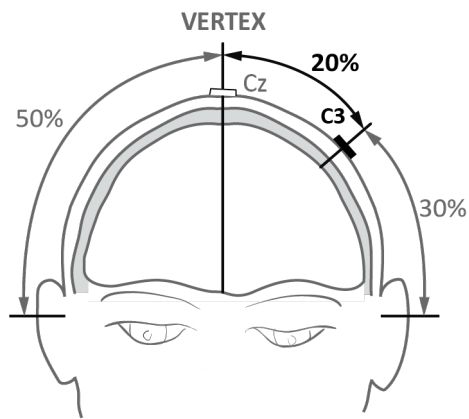
Fig. 46. C3.

7. Ask the patient to relax his/her pronated right hand.

8. Ensure both the patient and the technician insert ear plugs.

9. Start stimulation with a moderate intensity (≈ 30% of maximum output). Make sure that 30% intensity is specified on "Amplitude" indicator of magnetic stimulator (1 in Fig. 47). In case of discomfort or local pain, the stimulation can begin at lower intensities.

Fig. 47. The fragment of the front panel of main unit.

10. To move a coil, loosen the screw on flexible arm (Fig. 48).
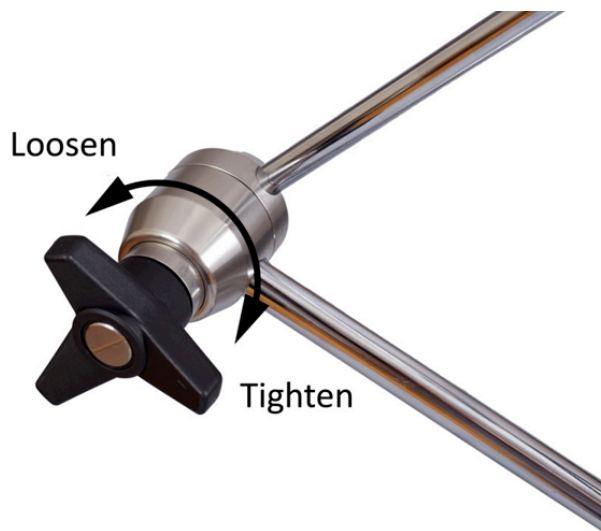
Fig. 48. Screw on holder arm.

11. Place the coil **on C3** at 45° in relation to horizontal plane, with the arrow pointing toward the upfront and the handle downward and backward (Fig. 49).
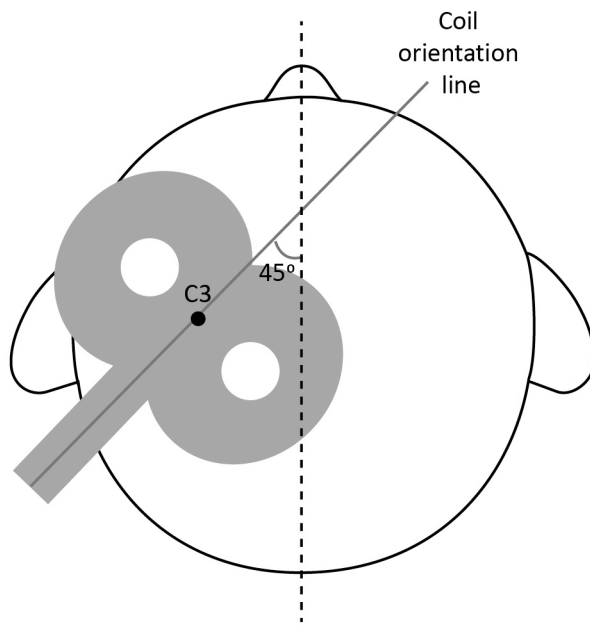
Fig. 49. Correct coil positioning for MT-detection.

12. To deliver stimulus, you can push button on coil or "Pulse" button on magnetic stimulator (3 in Fig. 47). To adjust amplitude, use "Amplitude" knob on magnetic stimulator (2 in Fig. 47). Do not deliver stimulus often, make 5-10 sec pause between stimuli.

13. Deliver single pulse and observe muscle contraction (movement elicitation of finger or thumb). Try to move a coil about 2 cm around the reference point in a grid like pattern (Fig. 50). Each time you move a coil deliver a stimulus. If it is not seen any muscle contraction, gradually increase the intensity (5% step). Continue moving a coil increasing amplitude and delivering pulse till muscle twitch is observed visually.
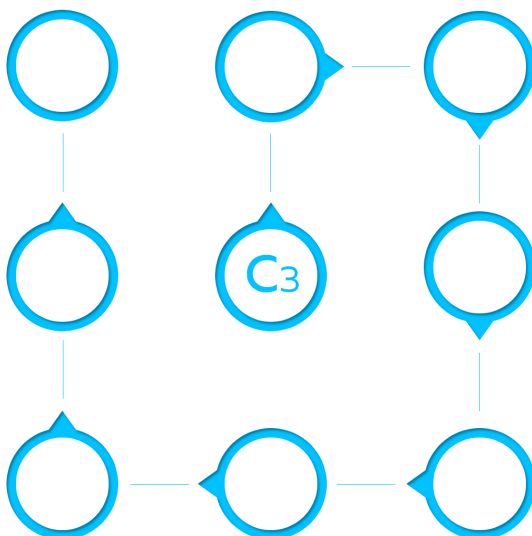
Fig. 50. Grid like pattern.

14. Now keeping the same intensity move the coil 2 cm around C3 the reference point in order to find the point where the stimulus elicits the highest visible muscle contraction. This is hotspot for MT detection.

15. Fix the coil position securely using screw on holder arm.

16. Gradually reduce the intensity (5% step) until the finger or thumb movement is not seen anymore.

17. Gradually increase the intensity (2% step) until the finger or thumb movement is seen.

18. Gradually reduce the intensity (1% step) until the motor threshold is found (5 contractions of 10 stimuli).

19. Enter the MT value to "Motor threshold measured" column of Patient Treatment Record form (see Annex 14.5).

20. When MT is defined, press "MT detection" button . After this button pressing the current amplitude value is taken as 100% and it is displayed on "Amplitude" indicator. The button and "MT" indicator are highlighted green.

Patient Treatment

> **The safety and the effectiveness of the specified treatment parameters that go beyond the recommended ones are not established.**

1. Measure 5 cm (2 inches) with measuring reel forward from anterior rim of the coil parallel to the middle line of the cap. Mark the point.

2. Loosen the screw on holder arm and move the anterior rim of the coil to marked point (you have found it at step 1). (Fig.50). Keep the coil orientation.

3. Fix the coil position securely using the screw on holder arm.

4. Once the coil position has been fixed, the anterior rim of the coil should be marked on the cap (see Fig.50). It will be required for second and next visits.
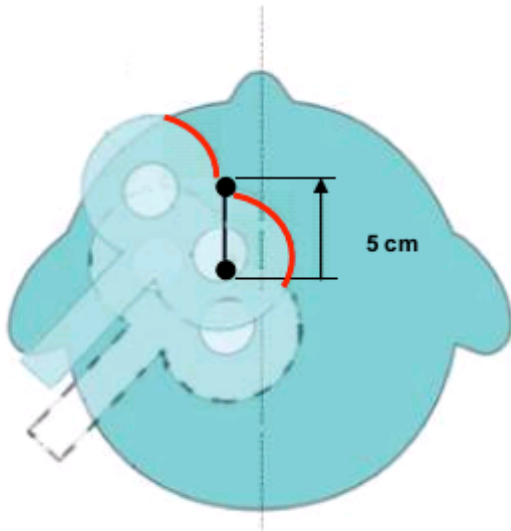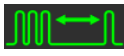
Fig. 51. Correct coil positioning for treatment.

5. Adjust 120% stimulus amplitude using "Amplitude" knob.

6. Press "MT detection" button again. Now you can see calculated treatment intensity on "Amplitude" indicator.

7. Enter this value to "Treatment Power calculated" column of Patient Treatment Record form (see Annex 14.5).

8. Push "Frequency" button f and make sure that 10 Hz frequency is adjusted. The frequency value is displayed on "Stimulation parameters" indicator.

9. Press "Train" button and make sure that 4.0 sec train duration is adjusted. The train value is displayed on "Stimulation parameters" indicator.

10. Press "Pause" button and make sure that 26 sec pause is adjusted. The pause value is displayed on "Stimulation parameters" indicator.

11. Press "Session" button and adjust 37.5 min session duration with "Stimulation parameters" knob. The selected session value is displayed on "Stimulation parameters" indicator.

12. To start the repetitive stimulation session use button on coil, or "Pulse" button on magnetic stimulator (3 in Fig. 47) when one of the buttons: "Frequency", "Train", "Pause" or "Session" is illuminated. Stimulation will be generated at 120% motor threshold with a pulse sequence of 10 Hz for 4 seconds, followed by a 26 second quiet period. Treatment will last for a total of about 37,5 minutes. This is a total of 3.000 pulses.

13. During treatment, remain in the room with the patient and periodically check to ensure the coil and the patient are in the same position.

14. During the repetitive stimulation "Session" button and "min" indicator blink (Fig. 52). The "Stimulation parameters" indicator displays the countdown of the session duration. At any time treatment can be stopped totally by pressing "Pulse" button on the coil or on the front panel of stimulator.

Fig. 52"min" indicator

15. When the session time is expired, the stimulation is stopped.

16. Loosen the screw on holder arm and move the coil up and away from a patient's head.

17. Remove ear plugs and cap. Pack the cap in individual plastic bag. Make sure that patient's name or ID is written on bag correctly.

18. Assist the patient as he/she stands up.

19. The treatment session is done. Fulfill patient treatment record form (see Annex 14.5). You should schedule next session for the patient. During the treatment we recommend to assess patient treatment progress regularly using standard techniques related to depression.

4.2.3 Second and Next Visits

The safety and the effectiveness of the specified treatment parameters that go beyond the recommended ones are not established.

1. Ensure the chair settings are not restrictive to make it easy for the patient to enter and sit down.

2. When the patient arrives, seat him/her comfortably in the chair.

3. Find Patient Treatment Record form of this patient.

4. Make sure that the patient name/ID match the name/ID on the patient cap.

5. Put personal cap on. Changes in hairstyle may affect head cap fit on patient.

That's why new selection of the cap size with the best fit to the patient's head is highly recommended in this situation.

6. Make sure that a cap is properly aligned such that the middle line of the cap follows the central line of the patient's head.

7. Control that the distance from the nasion to the lower edge of the cap is the same as the distance written on the cap.

8. Ensure both the patient and the technician insert ear plugs.

9. Loosen the screw on holder arm and move the coil to the marked line on the cap (see Fig. 50). Make sure that the anterior rim of the coil matches the marked line.

10. Adjust the amplitude according to treatment intensity calculated (see Patient Treatment Record form) using "Amplitude" knob on magnetic stimulator (2 in Fig. 47).

11. Press "Session", "Pause", "Train" and "Frequency" to check the preset stimulation parameters. Make sure that the stimulation will be generated with a pulse sequence of 10 Hz for 4 seconds, followed by a 26 second pause for 37.5 min.

12. To start the repetitive stimulation session use button on coil, or "Pulse" button on magnetic stimulator (3 in Fig. 47).

13. During treatment, remain in the room with the patient and periodically check to ensure the coil and the patient are in the same position.

14. During the repetitive stimulation "Session" button ⟳ and "min" indicator blink (Fig. 53). The "Stimulation parameters" indicator displays the countdown of the session duration. At any time treatment can be stopped totally by pressing "Pulse" button on the coil or on the front panel of the stimulator.

Fig. 53. "min" indicator.

15. When the session time is expired, the stimulation is stopped.

16. Loosen the screw on holder arm and move the coil up and away from a patient's head.

17. Remove ear plugs and cap. Pack the cap in individual plastic bag. Make sure that patient's name or ID on the cap match the ones written on bag.

18. Assist the patient as he/she stands up.

19. The treatment session is done. Fulfill Patient Treatment Record form (see Annex 14.5). You should schedule next session for the patient. During the treat-

ment we recommend to assess patient treatment progress regularly using standard techniques related to depression.

20. Most of MDD patients respond on TMS therapy. When you carefully follow abovementioned steps dealing with MDD patients, you should expect remission rate and responder amount in average to be equal to figures published in TMS and Depression related research results. Dealing with non-responders, maintenance and other similar questions are widely reviewed and discussed in the literature.

4.2.4 Work Completion

Switch off the stimulator using "On/Off" button. Turn "Mains power" switches located on the rear panels of the main unit, the cooling unit and extra power unit to "Off" (0) position.

4.3 Actions in the Emergency

If electrical insulation any digital system component is disturbed in the result of the emergency (fire, mechanical failure, flood, medical staff evacuation) and electrical trauma risk for patient or staff occurs, de-energize the digital system completely.

4.4 Troubleshooting

The possible stimulator troubles are listed in Table 10.

Table 10. Troubleshooting

Trouble Symptom	Cause	Way of Removal
If you use the stimulator operating in PC- Mode, the program displays the message concerning the data exchange error with the stimulator or stimulator missing. In stand-alone mode the stimulator operates regularly.	The faulty USB cable is used to connect to computer.	Replace USB cable. It is recommended to use the cable included in the stimulator delivery set.
The stimulator is controlled by **Neuro-MS.NET** program manufactured by Neurosoft Ltd. via USB. After the finishing of the operation with the program and its closing, USB inscription still illuminates on "Stimulation parameters" indicator.	The failure has occurred during the finishing of operation of **Neuro-MS.NET** program manufactured by Neurosoft Ltd.	Switch off and then on the "Mains power" switch located on the rear panel.

The stimulator is equipped with self-diagnosis system which controls the operability of the main elements while power switching on and during the operation. In case the fault is detected, the stimulator stops the stimulation, initiates the beep and indicates the fault type on "Amplitude" indicator and fault code on "Parameters" indicator. The faults detected by the stimulator are divided into three groups:

- User – emerging in the result of incorrect connection of the stimulator or incorrect actions of the personnel and indicated as ⟦UEr⟧. These faults can be removed by a user.

- Service – emerging when the electronic components of the stimulator break down. These errors are indicated as ⟦SEr⟧. If this fault emerges, address to service center of Neurosoft Ltd.

- Overheating. During the continuous use of the stimulator the overheating of internal components of the main unit and the extra power supply unit is possible. If it occurs, the stimulation is stopped and the error codes are displayed on "Amplitude" indicator and "Stimulation parameters" indicator of main unit and "Power" indicator of extra power supply unit starts flashing red.

The possible troubles are listed in Table 11. In case you cannot eliminate the trouble by yourself, you should contact the manufacturer or their representative.

Table 11. Troubleshooting

"Amplitude" indicator	"Stimulation parameters" indicator	Cause	Way of Removal
UEr	01	The "Pulse" button is pressed for a long time (button sticking).	1. Check the "Pulse" buttons located on stimulator case and on the coil. These buttons should switch on/off without any sticking. 2. The coil is placed so the "Pulse" button is pressed.
UEr	02	The coil is not connected or is connected incorrectly.	Check if the coil connector is attached properly.
UEr	30	Data loss while transferring via USB.	It can happen when the faulty USB cable is used. Only the cable supplied together with the stimulator should be used.
UEr	31	USB disconnection during the operation.	It is not recommended to disconnect the USB connector from the computer during the operation.
UEr	42	Missing data from the cooling unit (the control cable for the cooling unit is not connected).	Check the connection of control cable to the cooling unit. Check the type of the control cable (it should be NS 058103.070).
UEr	43	Invalid data from the cooling unit (the control cable for the cooling unit is not connected).	Check the connection of control cable to the cooling unit. Check the type of the control cable (it should be NS 058103.070).
Att	t-1	The overheating of the main unit.	Wait for about 30 min till the internal components cool down.
	t-3	The overheating of the extra power supply unit	Wait for about 30 min till the internal components cool down.

5 General Principles of Working with Neuro-MS.NET Program

5.1   General Requirements

Neuro-MS.NET software is intended to control magnetic stimulator of **CloudTMS** series manufactured by **Neurosoft** Ltd using the computer.

Most of program functions can be carried out in several ways. For instance, open "MT" tab and start single pulse stimulation with:

- **Stimulation|Pulse** menu command (you can choose the command using a mouse (left-click) or keyboard (**[Alt]** to open the menu, arrow keys to navigate through the menu and **[Enter]** to select the item));

- ⎍ "Pulse" button at the bottom of the screen (point the mouse cursor on the button and left-click). If you use touchscreen, touch the controls with your finger instead of mouse;

- "Stimulus" button on a coil;

5.2   Scale and Touch-style

Neuro-MS.NET interface has touch input option (i.e. touching a monitor screen with a finger). Program provides an opportunity to:

- use special style (Touch-style) to display any windows. To activate or to deactivate Touch-style, use **Setup|Use Touchscreen style** menu command. Touch-style is enabled by default.

- set the appropriate scale for all interface elements. To change the scale, use **Setup|Scale…** menu command and set the appropriate scale. Default scale value is "1.2".

> **If you use Touch-style, press the main window icon to show or hide the menu as shown in Fig. 54.**
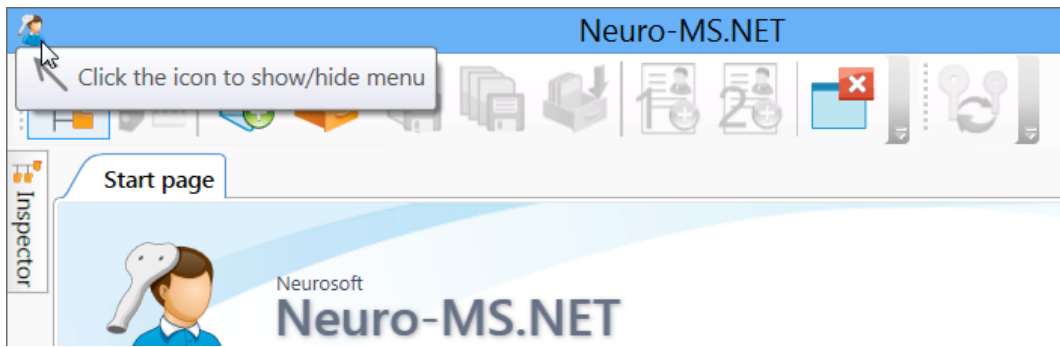
Fig. 54. The show/hide menu icon.

5.3   Software Setup and Computer Requirements

Neuro-MS.NET software can run properly on any computer with Intel Celeron 2.4 GHz processor (Intel Pentium Core 2 Duo is recommended) and higher, with not less than 2 Gb memory, and Windows XP (SP3 and above), Windows Vista (SP1 and above), Windows 7, Windows 8 operating systems and higher. Besides a computer should be equipped with at least one USB port to attach the magnetic stimulator. For software setup there should be 1 Gb of free hard disk space and 1 Gb of free hard disk space for a patient database.

Neuro-MS.NET interface provides touch input option (i.e. by touching a monitor screen with a finger). To facilitate text entry using virtual keyboard, it is recommended to work on computer with Windows 7 or Windows 8 operating system and higher.

All data of treatments performed with the use of the program are saved on hard disk in a database common for all Neurosoft Company systems.

The program can be downloaded from Neurosoft site using the link: http://neurosoft.com/en/index/downloads.

The installation process is executed in the following order:

1. Log in the system as administrator.

2. Insert the compact disk to the disk drive (or flash drive to USB port) and wait for the installation program to start (

3. Fig. 55). If the autorun hasn't started and the window hasn't appeared (

4. Fig. 55), find AUTORUN.EXE file and run it.
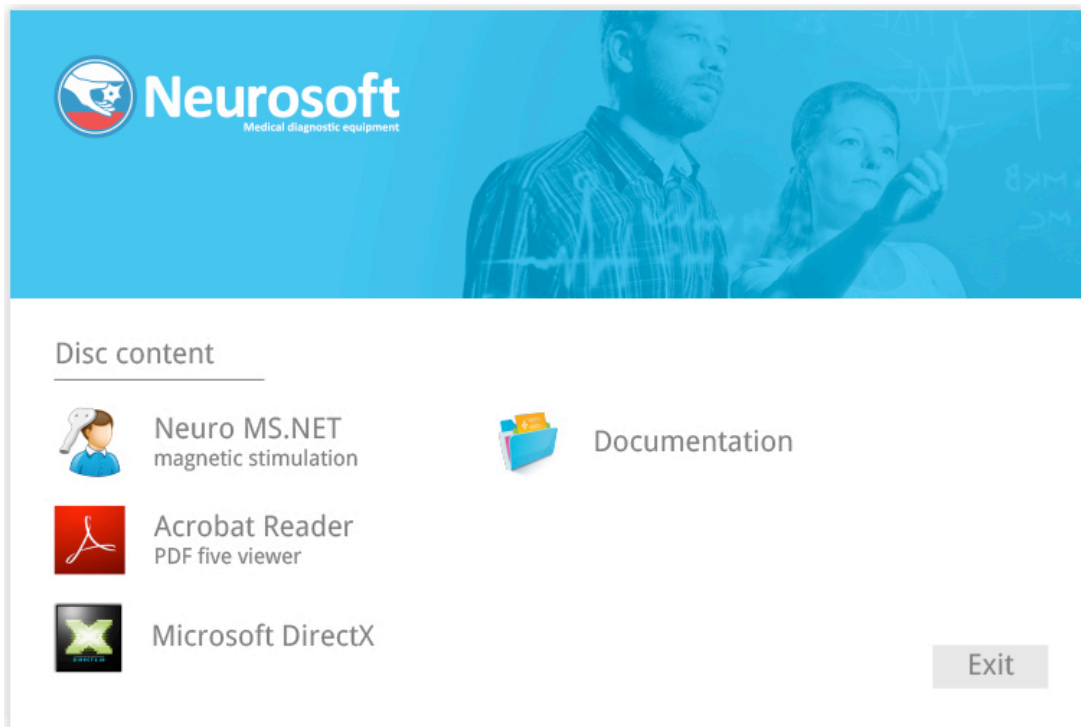
Fig. 55. Software installation wizard.

5. Point the mouse cursor at **Neuro-MS.NET** line and left-click. Follow the installation instructions. If you have no Internet connection, ignore program attempts to download updating files. The program proceeds installation after several failed attempts.

6. To set up the software and hardware, run the program (see the next section) and choose [icon] **Change settings…** menu command at the start page. You can find more information in 5.15 "Hardware and Software Configuration Settings" section.

5.4 General Principles

Neuro-MS.NET works under Windows operating system and complies with Windows software requirements. If you have worked with Windows programs, for example Microsoft Word, you can master **Neuro-MS.NET** easily. If you have not worked with Windows operating system, you should learn basic Windows concepts.

After you run the program, the main window is displayed (Fig. 56). At the top of the screen you can find **Treatment, Hardware, Report**, etc. menu items. Below the menu you can find toolbar buttons activated with mouse.

All the rest part of the window is the start page intended to display the list of last opened treatments and the main available actions.

> **If Touch-style is selected (see 5.2 "Scale and Touch-style" section), then after program run the main program menu is always hidden. To show or hide this menu, click the main window icon (Fig. 56).**
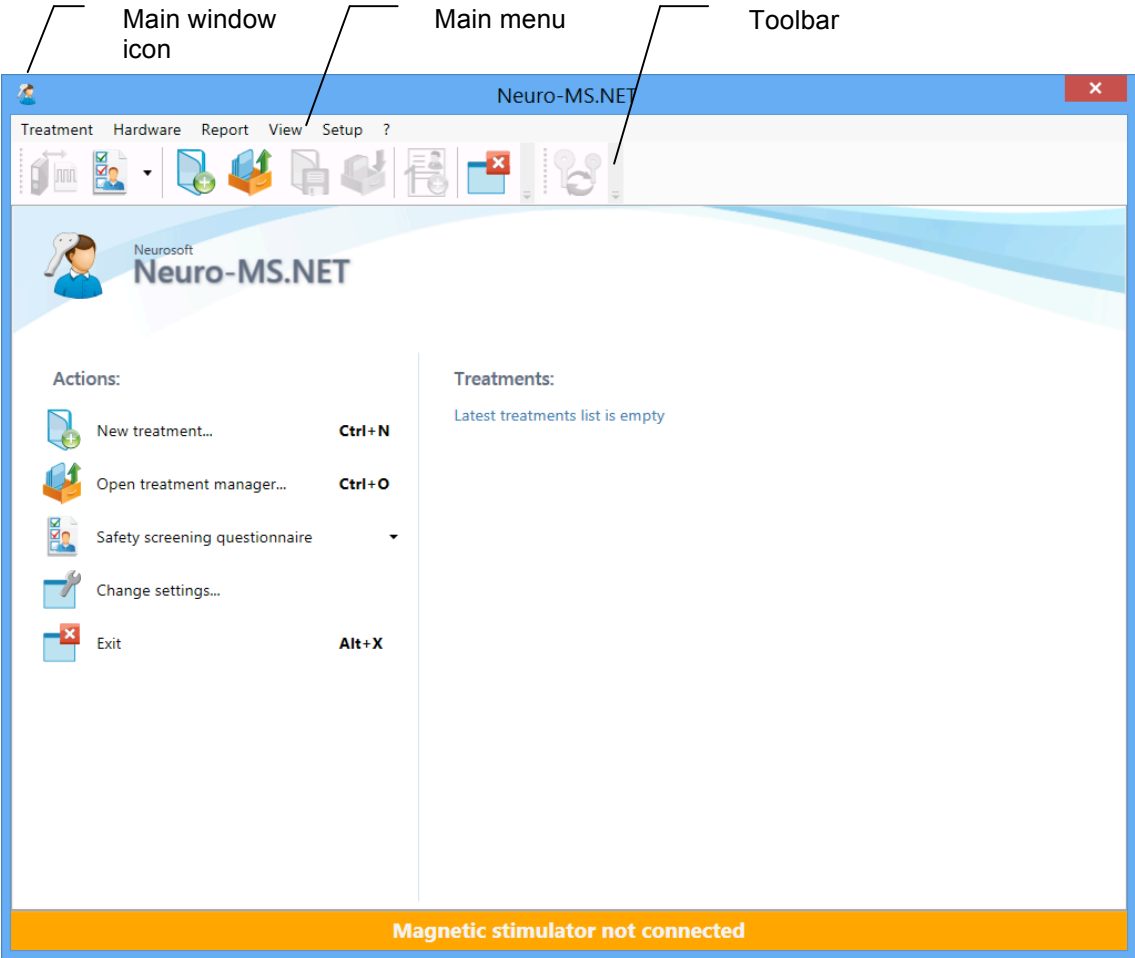
Fig. 56. Neuro-MS.NET main window.

The program is controlled using menu items. Besides toolbar buttons duplicate most frequently used menu commands.

Toolbars can be placed at the top, bottom or on the side of the window (Fig. 57). To change toolbar position, point the mouse cursor to the drag marker and drag the toolbar to a new place. To show or hide the toolbar or adjust the view (button size, inscriptions, visibility and sequence, hotkeys, etc.), right-click on the toolbar and select **Setup…** menu item. You can find more information in 5.16 "Toolbar" section.
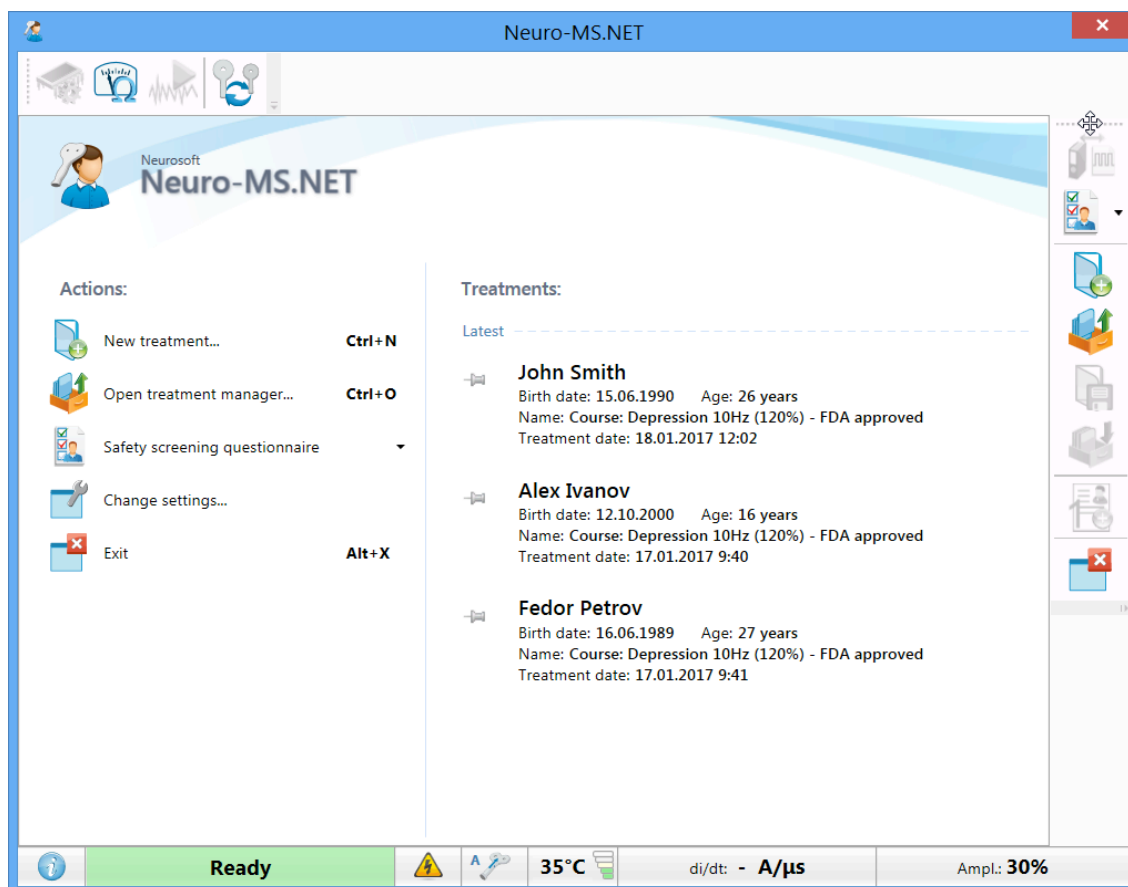
Fig. 57. Toolbar arrangement.

All the data on performed treatment courses are saved in the database (card-file system). During the first start the database is created automatically in *C:\cardbaseMdb* directory on a hard disk of computer. Then, you will be able to create new databases and connect any available ones created by Neurosoft .NET programs. The database is described using such terms as *card-file, patient card* and *treatment*.

"Treatment" in **Neuro-MS.NET** program refers to a collection of data, obtained during a medical treatment using magnetic stimulator produced by **Neurosoft** Ltd.

Treatments are saved in a patient card.

"Patient card" contains basic patient data (name, date of birth, etc.) and may include any number of treatments and exams, carried out on any Neurosoft devices at different times.

Patient cards are saved in card-files.

"Card-file" is a pool of any quantity of patient cards. Each card-file has a unique name and may contain, besides patient cards, nested card-files. Cards can be combined into card-file by any feature. Well-thought out card-file system will allow you to collate all stored information and to speed up an access to it.

Experienced user should know that card-file system (database) is composed of several files saved in a directory (folder) on a hard drive of computer. If it is necessary, you can create several databases on a hard disk (see details below).

5.5   The Very Beginning: New Treatment

To start a new treatment, use " **New treatment… [Ctrl+N]**" button on the start

page or button on the toolbar.
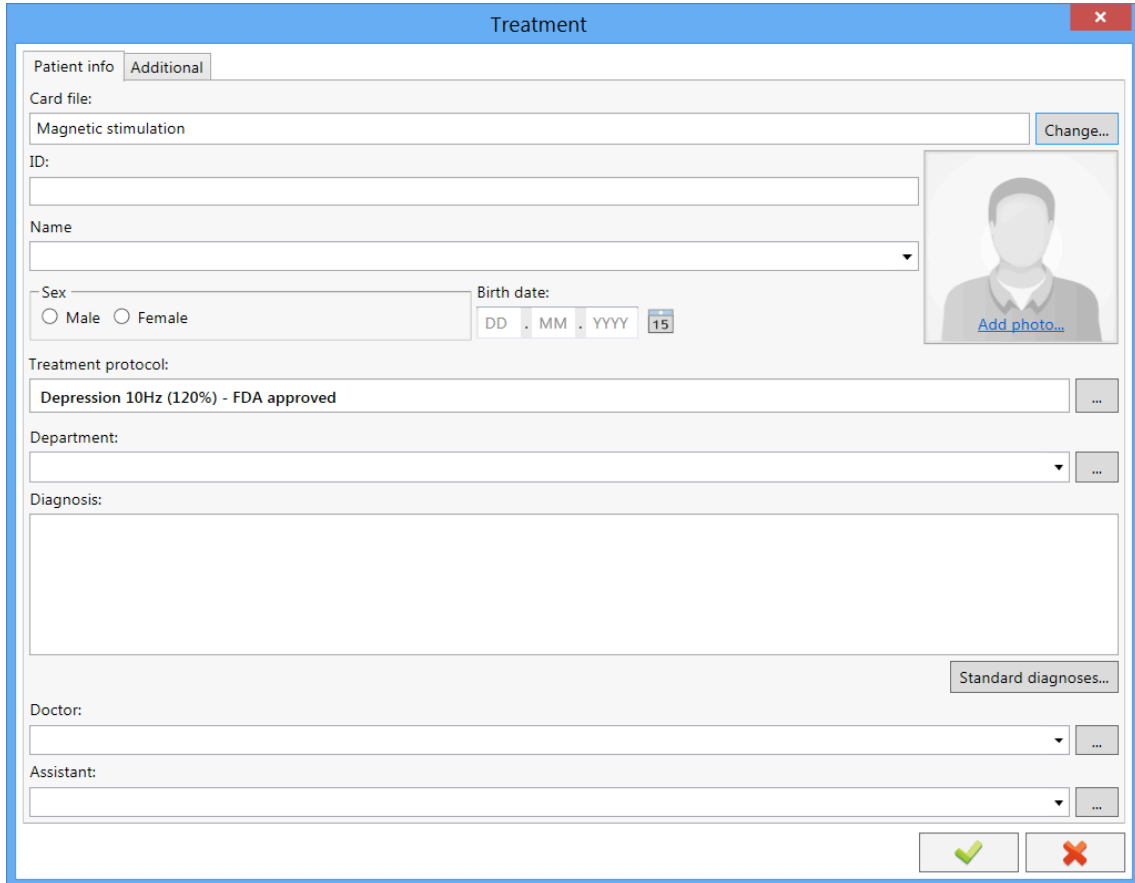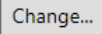
Fig. 58. The new treatment window.

In the appeared "Treatment" dialog box (Fig. 58) enter the following patient's data (fulfil the required fields):

- name;

- sex;

- date of birth;

- choose treatment protocol if it is required;

- department (the number of ward, hospital, etc.);

- provisional diagnosis if it is required;

- additional data (e.g. social security number, address, telephone number, etc.). To enter them, switch to "Additional" tab.

By default the database does not contain card-files (all treatments are saved together). You can press Change... button and create new card-file or select the existing one.

If a patient has already been examined or received treatment and his/her card already exists in the database, then a program will offer you to choose from patients with the most appropriate names while entering patient's name. If a patient card already exists in the database, then a new treatment will be saved to the existing patient card.

To add patient's photo, click on "Add photo…" image box and upload a graphic file with an image. If the video camera is connected to the computer (for example, USB camera), the photo of patient can be made with it. To do it, just press [camera icon] button. This button and the option to select the video camera appear only if the video cameras are connected to the computer.

Besides, you can type your name in "Doctor:" input box and technician's name in "Assistant:" input box.

The external view of "Treatment" window can be customized with **Customize elements view…** context menu item opened by the right-click. Here you can choose which input boxes should be displayed or hide the unnecessary ones. Also you can specify the default elements. These are the elements where the text cursor is positioned by default when the window is opened. Besides, you can show all patient data on one page instead of two ones ("Show all patient data on one page" checkbox).

To create treatment on the basis of entered data, press [checkmark icon] button.

If the magnetic stimulator is plugged in to the mains and is connected to USB port of computer, then it will be switched on automatically after you create the new treatment or open the existing one.

The device could be switched on using **Hardware|Device reset** (**[Ctrl+Shift+Del]**) menu command.

To switch off the device, use **Hardware|Turn device off** menu command or [power icon] button on the front panel of the magnetic stimulator.

If some patient's details were entered by mistake, you can correct them using **Treatment|Properties…** menu item.

5.6   Status Bar

At the bottom part of **Neuro-MS.NET** main window you can see status bar which shows the current state of the magnetic stimulator (Fig. 59).
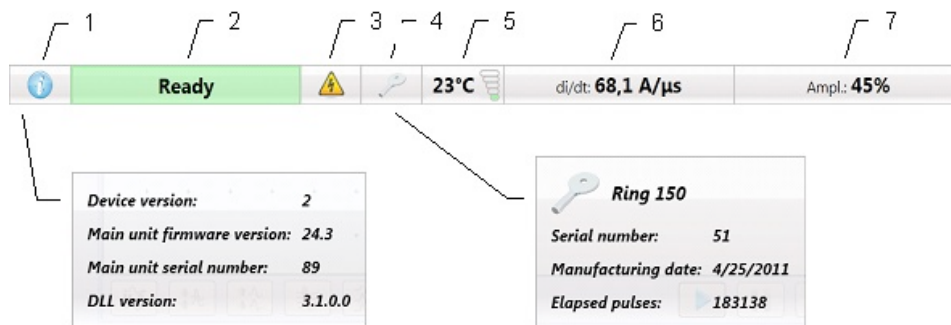
Fig. 59. The status bar of the magnetic stimulator.

If magnetic stimulator is switched on, status bar displays the following information:

1. **Information** — the icon with drop-down menu which contains detailed information about connected magnetic stimulator (firmware version of main unit, serial number of main unit, etc.). To open the drop-down menu, click on "I" icon.

2. **Ready** — the readiness indicator of magnetic stimulator. The indicator highlights green, if the stimulator is ready to deliver a pulse of the specified amplitude.

3. **High voltage** — the high-voltage indicator. The indicator highlights yellow when the stimulator is switched on and high voltage is supplied inside the stimulator.

4. **Coil type** — the icon with drop-down menu which contains information about the type of used coil (manufacturing date, serial number, elapsed pulses). To open the drop-down menu, click on the icon.

5. **Coil temperature** — the icon shows the coil temperature. It contains the temperature value and a 5-segment three-colored temperature scale. The segments of this scale start illuminating one by one after achieving the following temperature: first green segment – less than 30º C temperature, second green segment – from 30º up to 34ºC, first yellow segment – from 34º up to 38ºC, second yellow segment – from 38º up to 41ºC, red segment – above 41ºC.

6. **di/dt** — shows the strength of magnetic field induced by the magnetic stimulator.

7. **Absolute amplitude** — shows the stimulus amplitude in percents from the maximal power of the magnetic stimulator.

5.7   Treatment Protocols

Perform steps described in 5.5 "The Very Beginning: New Treatment" section.

Use "Treatment protocol" tab (Fig. 60) to view and edit the existing protocol.
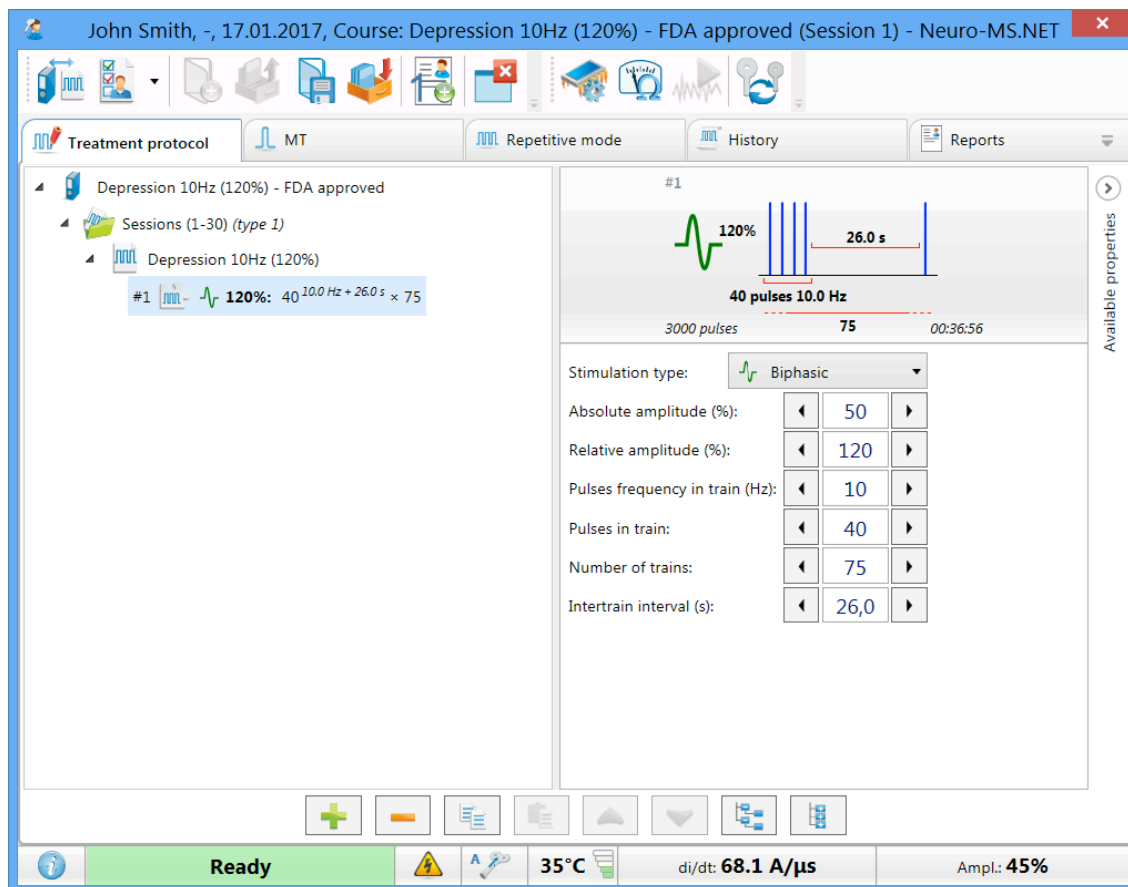
Fig. 60. The "Treatment protocol" tab.

If you have not chosen treatment protocol while creating a new treatment, then the program should open the "Treatment protocol" tab to offer you to configure treatment protocol.

The program offers two treatment modes: "Course" and "Intervention". "Course" mode is the main treatment mode generated on the basis of protocol. This mode implies several sessions. "Intervention" mode is a special treatment mode. It allows performing stimulation with the use of one or more interventions and implies only one session. To switch between modes, use **Treatment|'Course'-'Intervention'** menu command or toolbar button.

Using "Treatment protocol" tab you can change any treatment parameters of a certain patient quickly.

You can find more information about configuring and editing of treatment protocols in the following chapters of the user manual (see 5.18.4 "Treatment Courses" section to find information about "Course" mode and 5.18.3 "Interventions" section to find information about "Intervention" mode).

5.8   MT

"MT" tab (Fig. 61) allows to perform single pulse stimulation or to detect motor threshold (MT) using a target muscle.
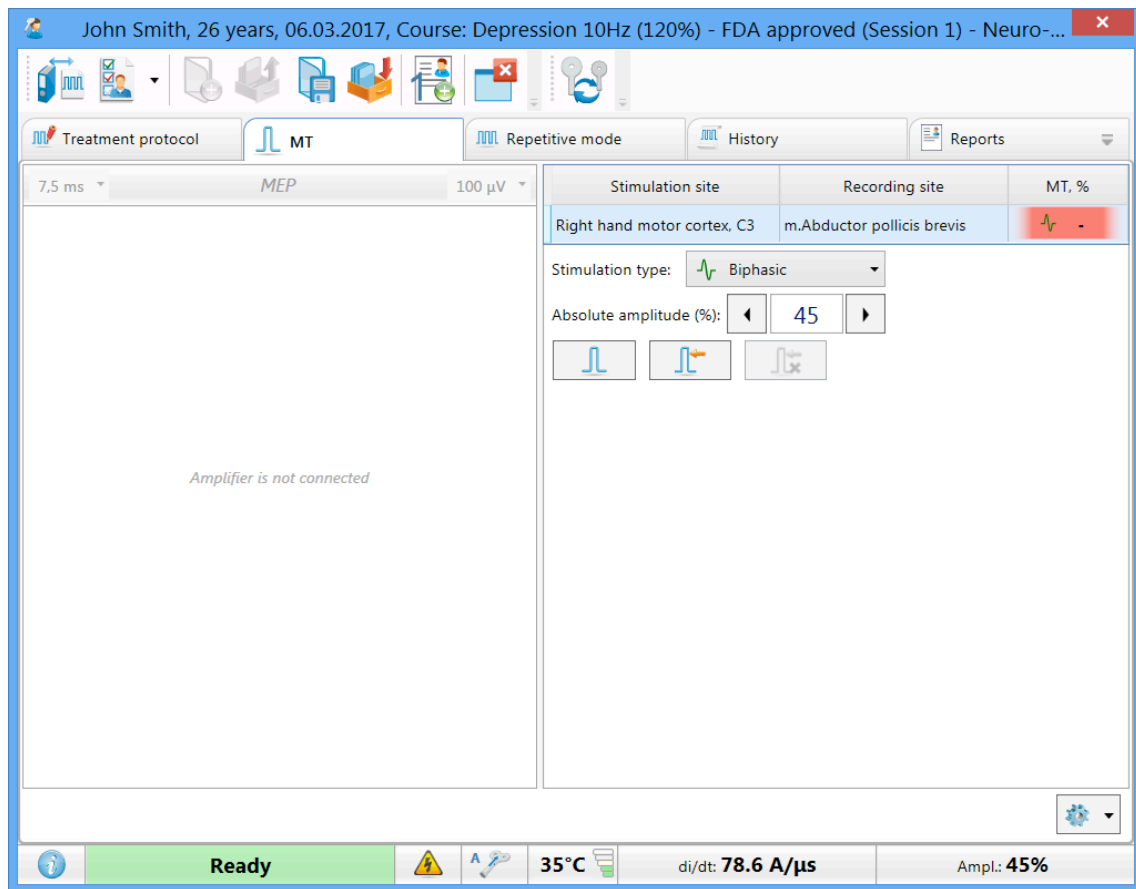
Fig. 61. The "MT" page.

Before MT detecting, make sure that you have chosen the appropriate treatment protocol (see 5.7 "Treatment Protocols" section). Each treatment protocol has information about area which must be stimulated to evoke response (stimulation site) and muscle that must twitch (recording site).

The stimulation and recording sites required to detect motor thresholds for selected treatment protocol are displayed in the right part of the window.

Single pulse stimulation parameters are also displayed in the right part of the window.

The current value of MT is highlighted with different colors:

- Red — MT is not detected and it is required to detect it or there are critical differences between used equipment configurations (for example, last time motor threshold was detected using other type of coil).

- Yellow — *only for "Course" mode*. MT is not detected and it is not required to detect it during the current session.

- Green — MT is detected.

To find the cause of MT value invalidity, left-click on the "MT, %" field.

In the "Course" mode MT validity depends on "MT update period" parameter. This parameter is set in course properties (see 5.7 "Treatment Protocols" section). For example, if this parameter is set to 5 and MT was detected during the first session, then the program will remind you to update MT value only during the sixth session ("MT, %" background highlighting will be changed from green to red).

MT detection can be performed using digital EMG and EP system or observing the contraction of muscles during the stimulation.

In "Absolute amplitude" input box set the minimum value which should be enough to elicit the qualitative motor response.

Place the coil above the stimulation site.

Use "Stimulus" button at the bottom of the window or the same button on the coil to perform the single pulse stimulation.

Deliver several pulses moving the coil around the target point to detect the minimum stimulus intensity required to evoke the qualitative response (motor evoked potential). It is the motor threshold (MT). Finish the stimulation. To save the obtained result, press "Fix MT" button. To reset results, press "Reset MT" button.

In the same way obtain and fix MT for other sites.

If reference data for stimulation site and recording site is available, you can review it using **View|Help window ([F1])** menu command or toolbar button. You can find the detailed information about adding and editing the reference data in 5.18.1 "Recording sites" and 5.18.2 "Stimulation Sites" sections.

5.9   Repetitive Mode

"Repetitive mode" tab (Fig. 62) is intended to perform repetitive magnetic stimulation according to preset interventions (see 5.7 "Treatment Protocol" section). When you first open "Repetitive mode" tab, the first unexecuted treatment intervention is selected automatically.
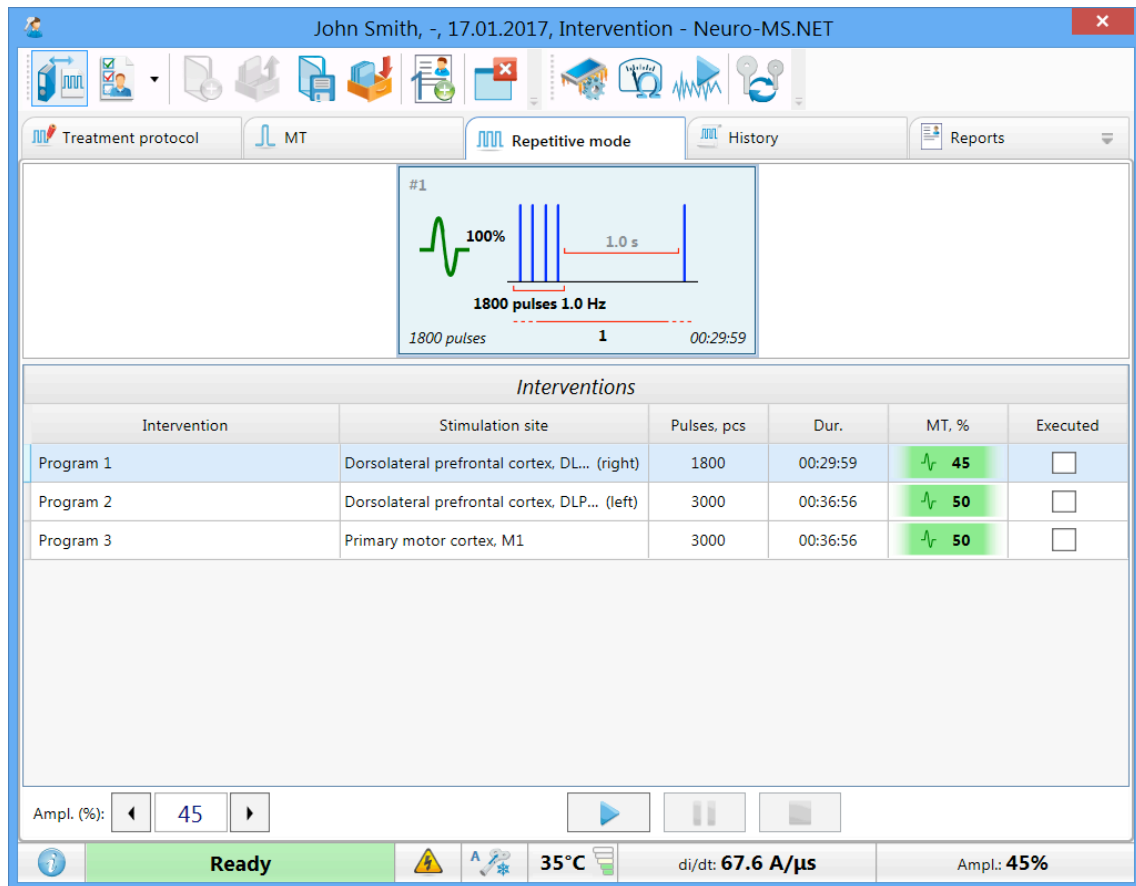
Fig. 62. The "Repetitive mode" tab. "Interventions" mode.

The table of stimulation interventions contains intervention names and stimulation parameters:

• Stimulation site — a specific area to perform the repetitive magnetic stimulation.

• Pulses, pcs — the number of pulses in the intervention.

• Dur., s — the intervention duration in seconds.

• MT, % — MT value used to calculate stimulation amplitude for each block. To estimate the validity of current MT value, see background highlighting (as described in 5.8 "MT" section).

• Executed — checkbox to show stimulation intervention fulfillment (is selected automatically on stimulation intervention completion, but you can select it manually (see below)).

In the "Course" mode open "Repetitive mode" tab to observe all stimulation interventions available in the current session (Fig. 63).

In this mode the stimulation intervention table contains information on the intervention belonging to a certain session type. The term "Session type" is described in 5.18.4 "Treatment Courses" section. The table header allows to move to the next or to the previous session.
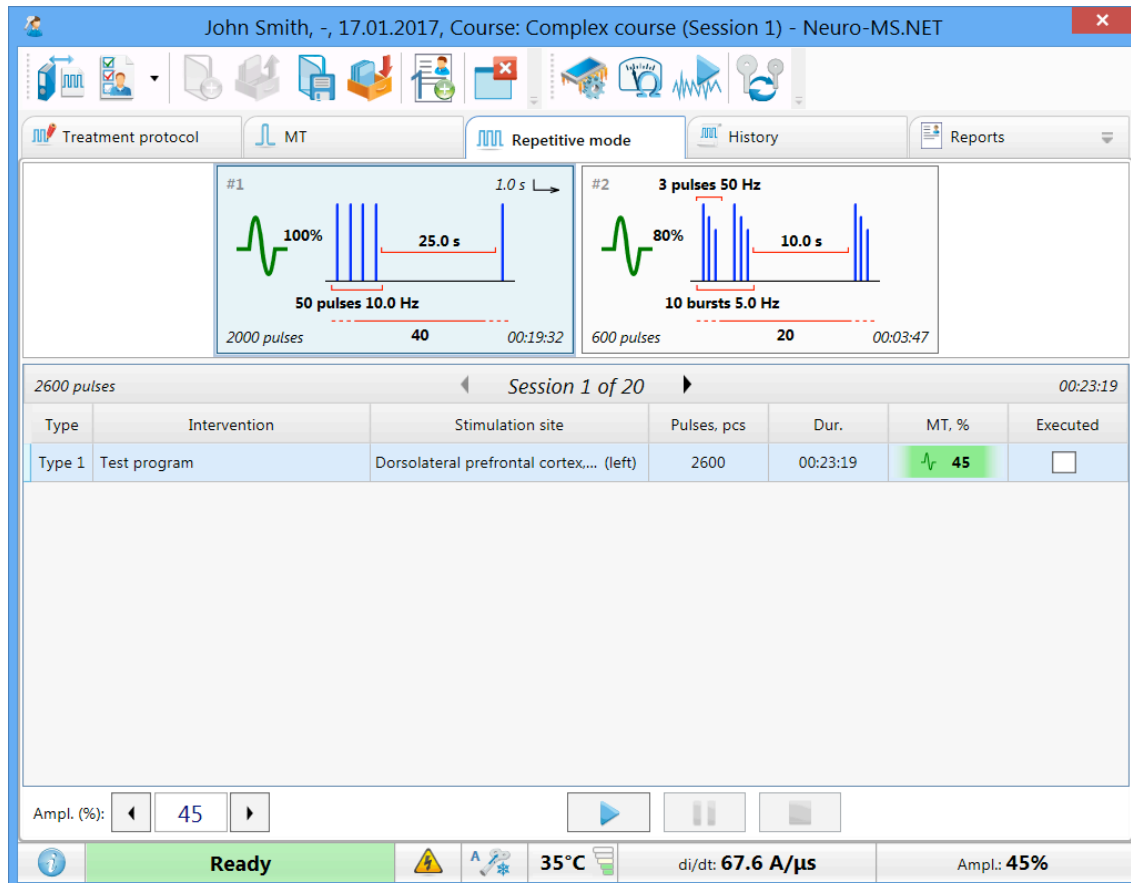
Fig. 63. The "Repetitive mode" tab. "Course" mode

The stimulation intervention can include several blocks. At the top part of "Repetitive mode" tab you can see the information graphics of stimulation blocks. The graphics interpretation can be found in the "Basic Notions" section. In case a complex stimulation intervention is used, you can select the block to start the stimulation with. To select other stimulation block, left-click its graphics. After that, the selected block will be framed with blue.

To control repetitive stimulation, use three buttons located at the bottom part of "Repetitive mode" tab:

- — start stimulation;

- — suspend/resume stimulation;

- — stop stimulation.

Also you can use "Pulse" button on a coil to start, pause or stop the stimulation. Also "Pulse" button emulates **[Enter]** key pressing in opened dialog boxes. After stimulation start the autotesting of stimulation intervention is launched to define the ability to perform it. Then you may see a warning message that stimulation start is impossible. In case the intervention parameters do not comply with the device hardware, you will be also offered to change the stimulation parameters according to the device capabilities (Fig. 64).
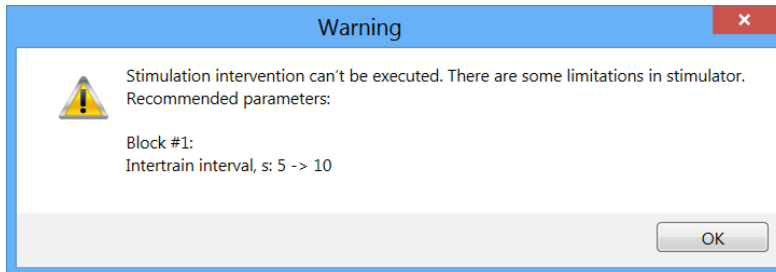
Fig. 64. The example of warning message.

The stimulation parameters are not changed automatically because of high safety requirements to rTMS.

If the stimulation intervention autotesting is successful, the message box reminding of desired coil position appears. The stimulation starts after this requirement is confirmed.

You can monitor the stimulation process using the popup window. The element is active only during the stimulation and contains the information about the stimulation intervention being executed (Fig. 65).
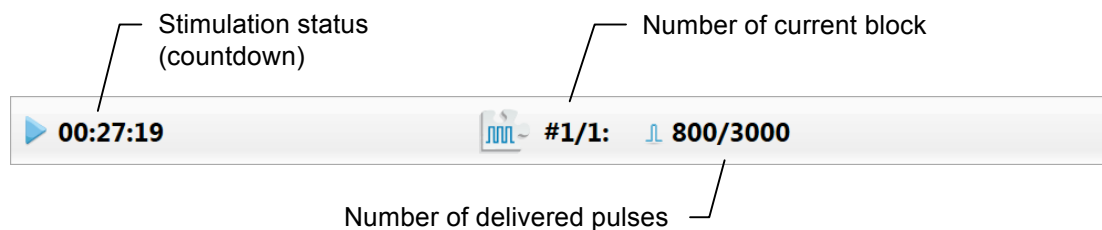
Fig. 65. Information about stimulation process.

The stimulation process is shown on the stimulation block graphics with background highlighting (Fig. 66).
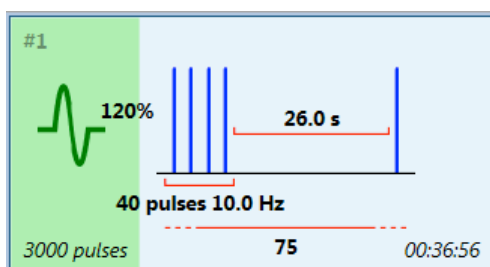
Fig. 66. The stimulation block graphics.

If the coil is overheated and you have a reserve coil, you can use the quick coil replacement function. You can do it using **Hardware|Coil replacement** menu command or by pressing button at the beginning and at the end of replacement. In case you start "Coil replacement" process during the performing of the stimulation intervention, the intervention execution will be paused and continued automatically after the coil replacement.

On completion of each stimulation intervention, if all blocks are fulfilled, it is automatically checked as "Executed" and corresponding data is saved in history. Then the intervention goes automatically to the next unexecuted intervention, autotests it and, if the stimulation site has not changed, continues the stimulation.

> **Stimulation interventions can be executed in consecutive order automatically only in "Course" mode.**

To check the intervention as "Executed" manually, left-click on the "Executed" checkbox and confirm your actions. To run again the executed intervention, uncheck the "Executed" checkbox. Please, pay attention that the corresponding information will be deleted from the history.

In "Course" mode after the last stimulation intervention completion the program will offer you to finish the session. If you agree, the program will go automatically to the next session.

5.10   History

"History" tab (Fig. 67) contains information about stimulation history. The history contains data about fixed motor threshold and about performed stimulation interventions. On the basis of the history Neuro-MS.NET defines executed and unexecuted interventions and the necessity to update MT value.

In the left part of the window the list of events sorted by date is shown. In the right part of the window you can see the detailed description of every event.
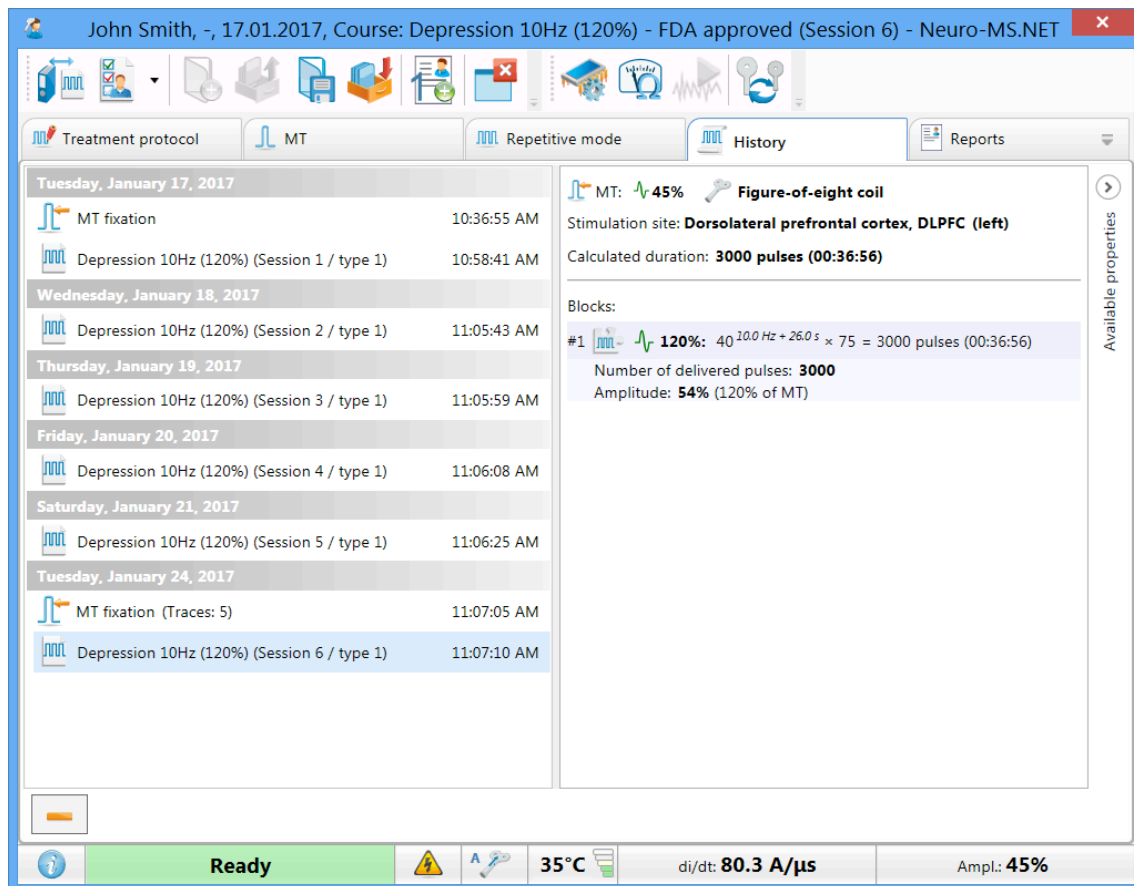
Fig. 67. The "History" tab.

5.11   Reports

The "Reports" tab is intended to review and edit the treatment reports.

Along with the text the report may contain the tables, graphs and images.

The report is generated according to a special report template. It defines the type of data to be included to the report and its view. Any number of templates can be created. By default the program contains only one report template. This is a "Basic report". The work with the report templates is described in section 5.14 "Treatment Report Templates".

The program allows creating two types of reports: built-in and Microsoft Word format (Microsoft Word 2007 or later version is required). The type of the created report is selected using the command **Report|Use Microsoft Word** (Fig. 68).
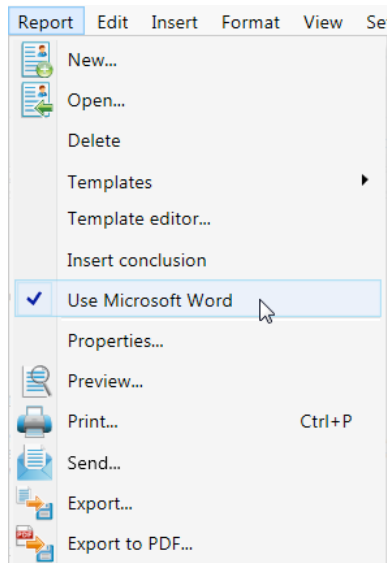
Fig. 68. Selection of report type.

To a large extent the built-in report is identical to WordPad program of Windows operating system. The advantages of such editor are the fast work, no need to install additional software, reliable quality of the created report (Fig. 69).

The Microsoft Word report ensures the access to all facilities of Word editor developed by Microsoft Company (Fig. 70). However, if you plan to use this editor, it should be installed on your computer.

To create a treatment report, use **Report|Templates** menu command. Here it is required to select the template name for the report generation. To speed up the work, the first template in the list is added as toolbar button (**Ctrl+R**).

The number of the created reports for the particular treatment is not limited.
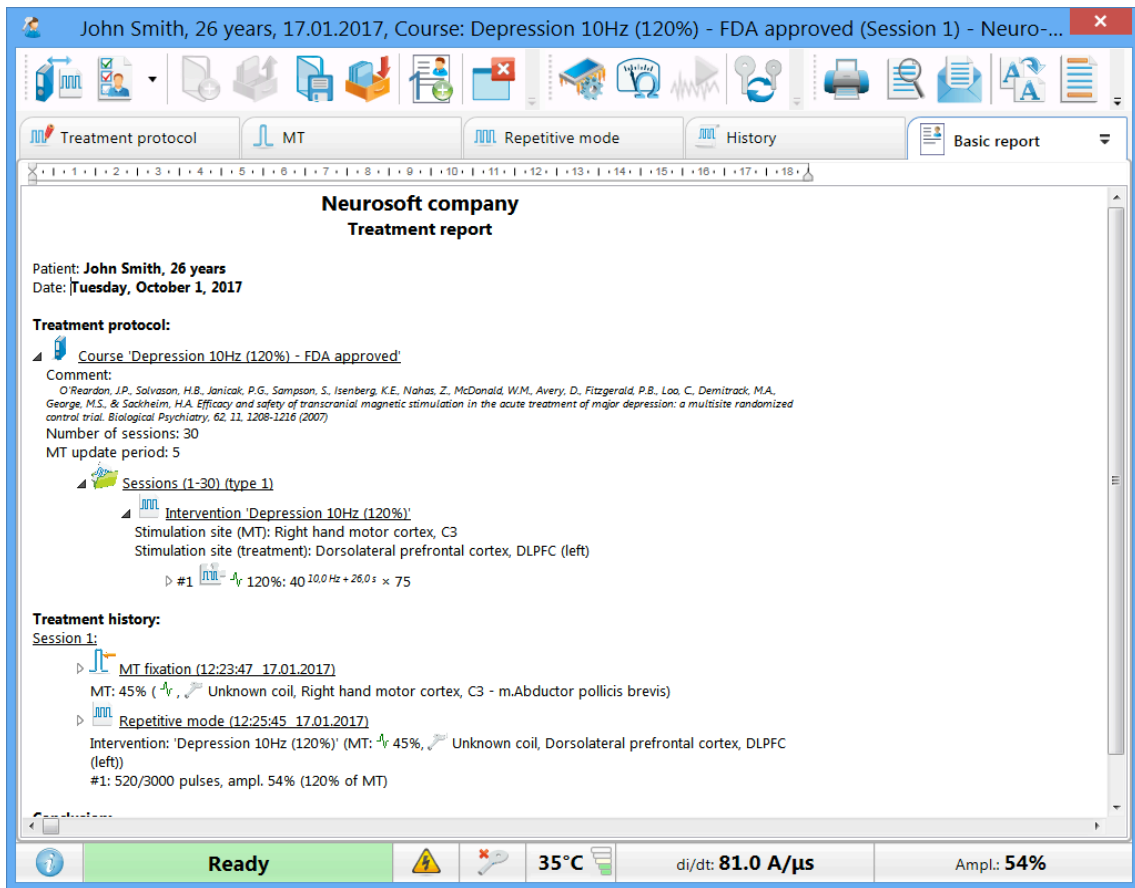
Fig. 69. Build-in report.
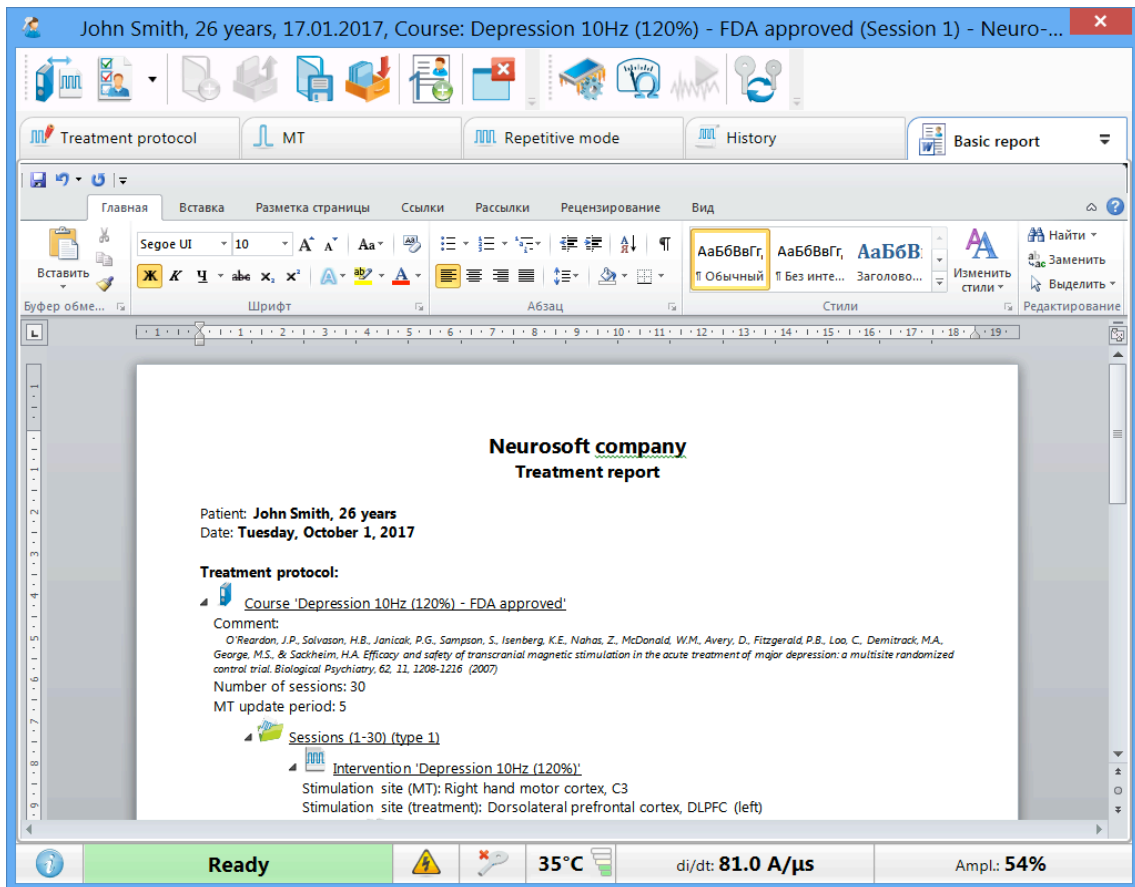
Fig. 70. Microsoft Word report.

To view the whole list of reports generated for this treatment, press button at "Reports" tab. Here you can select other report using the drop-down list or remove the unnecessary report with button.

By default, reports are saved to the database together with the treatment data. To copy reports simultaneously to any folder on a computer disk, check "Copy reports to folder" checkbox (see 5.15 "Hardware and Software Configuration Settings" section, "Report" tab) and select folder name. Therefore, when the report is saved to the database, it is simultaneously copied to the indicated folder.

To print the report, use **Report|Print…** (**[Ctrl+P]**) menu command. Before printing out the report can be reviewed and edited (all report content is editable).

Also the report can be exported to the external file (**Report|Export…** menu command) or sent by e-mail (**Report|Send…** menu command).

Working with a new treatment it is convenient to enter some information to "Clinical info" and "Conclusion" windows. Further their contents can be copied to the exam report manually (**Report|Insert conclusion**) or using the report template.

5.12 How to Review Previous Treatments

To review (analyse) or continue the created treatment, use **Treatment|Open treatments manager…** menu command or press **[Ctrl+O]** or toolbar button). After that "Treatment manager" dialog box appears (Fig. 71).

The list of treatments in "Treatment manager" can contain information not only about treatments performed by **Neuro-MS.NET**, but also data (examinations) performed by other **Neurosoft** programs. It is possible only if you use common Neurosoft database to store the results.
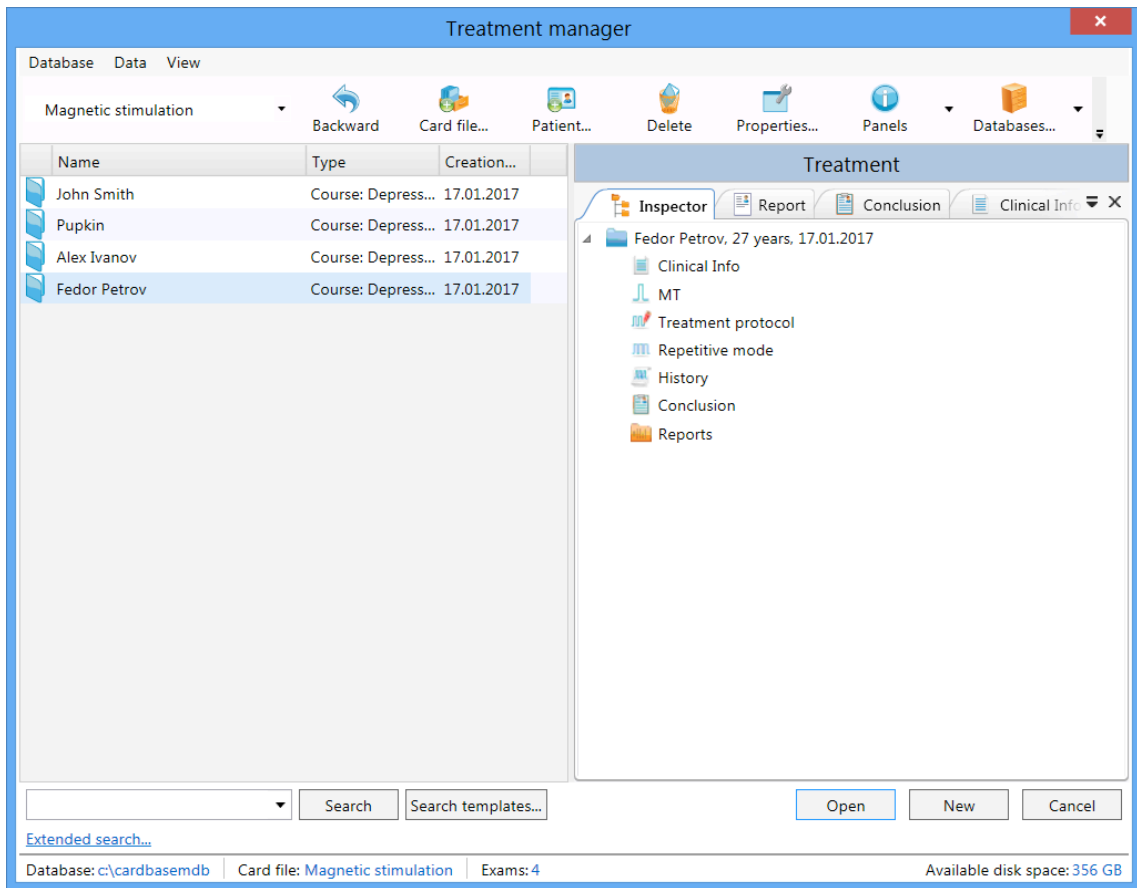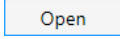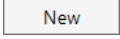
Fig. 71. "Treatment manager" dialog box.

To open the treatment, select it in the list and press [Open] button or double-click a patient's name.

To create a new treatment for selected patient, press [New] button. The same can be done with **Treatment|New** menu command. The difference is that you select a patient from the list.

To switch between "Patients" and "Treatments" view modes in "Treatment manager" dialog box, use "View" drop-down menu (Fig. 72). In "Patients" mode the list of performed treatments is shown in the right part of the dialog box. To open the treatment, double-click the treatment name. To open a patient card, double-click patient's name (Fig. 73). To return to the list of patients, press [⤺] button.
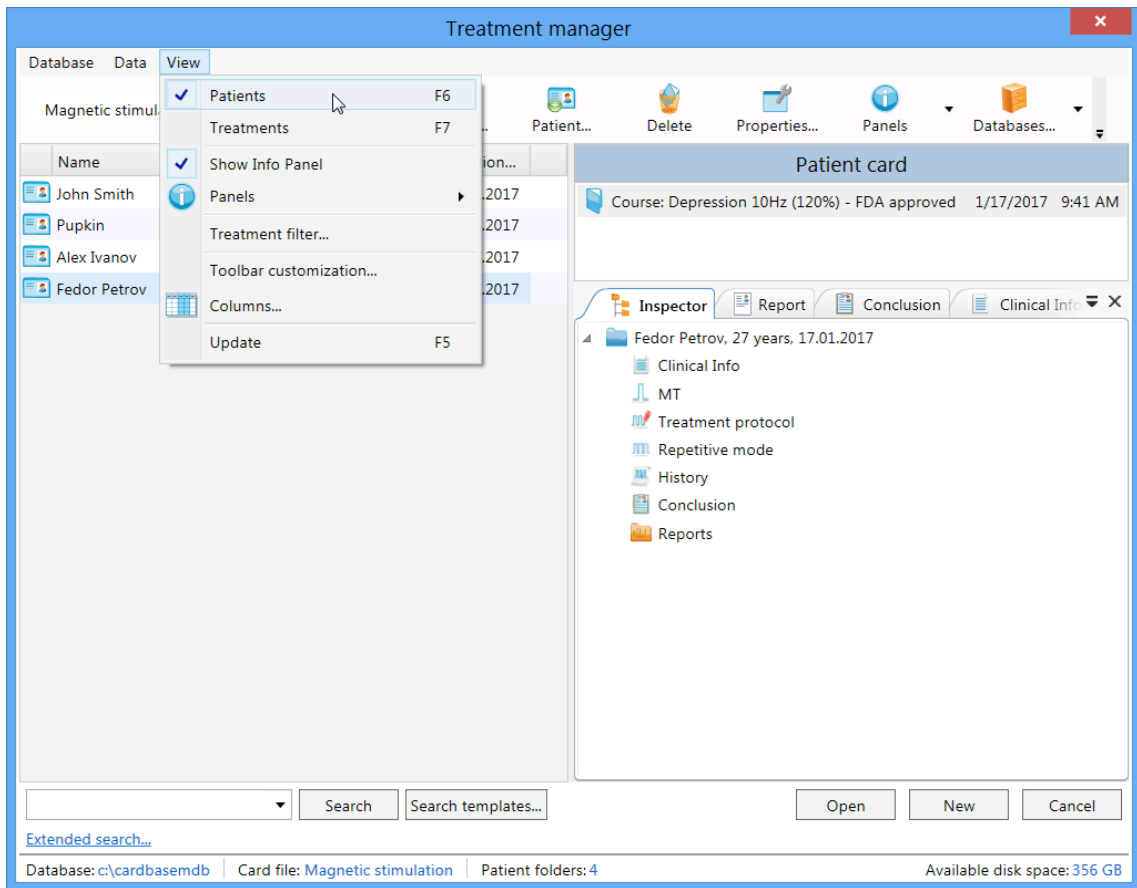
Fig. 72. Switching between view modes.
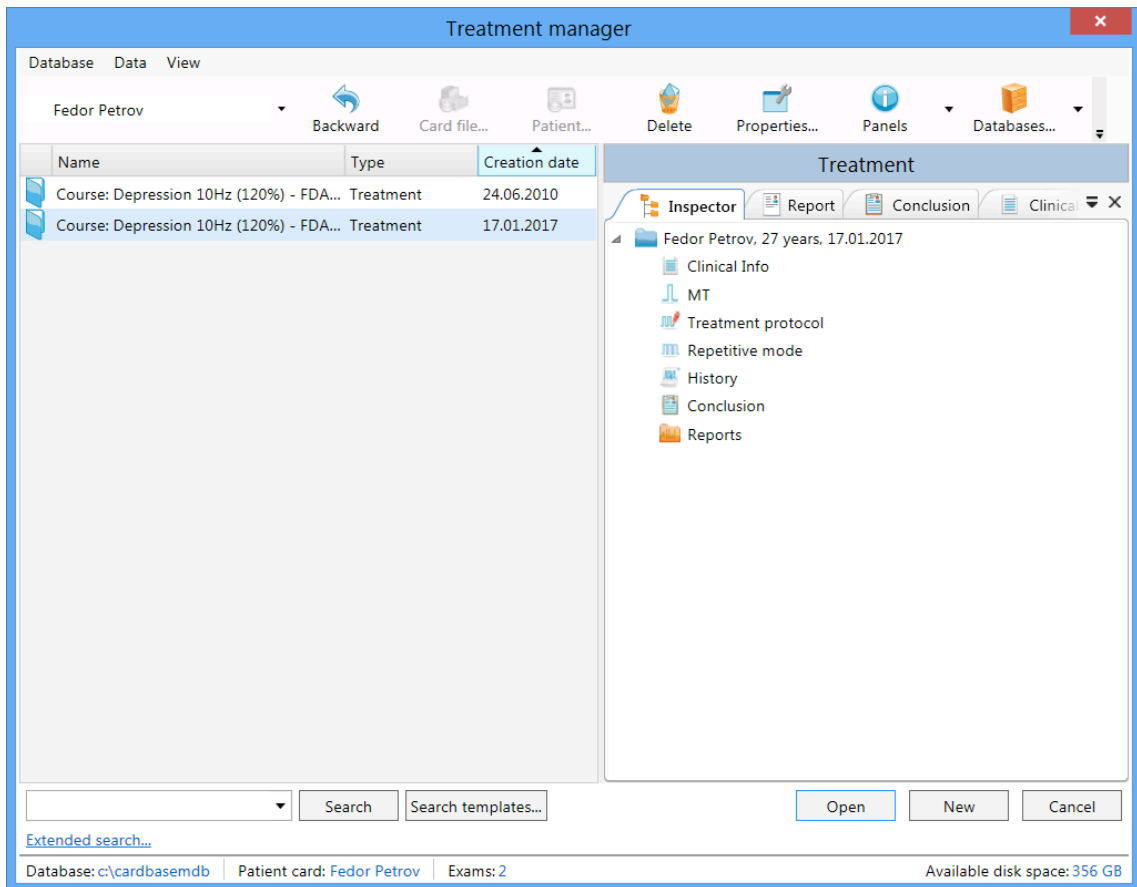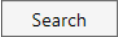
Fig. 73. Patient card.

Using "Treatment manager" you can create both card files of any nesting level (button), and new patient cards (button). To configure data presentation at the right part of the dialog box, use button. Treatments can be exported to the external archive (for example, to move to another computer) using button and imported from the archive using button .

To connect existing database or to create new one, use button. By default the program creates MDB *(Microsoft Access)* database in *C:\cardbaseMdb* directory (folder). You can create not only MDB, but also Microsoft SQL and MySQL databases.

To find a patient or a treatment, use search box located in the left bottom corner of "Treatment manager" dialog box (Fig. 74). You can type only the part of a name, diagnosis or other data and press Search button. After that the program will display all treatments starting from entered letters.
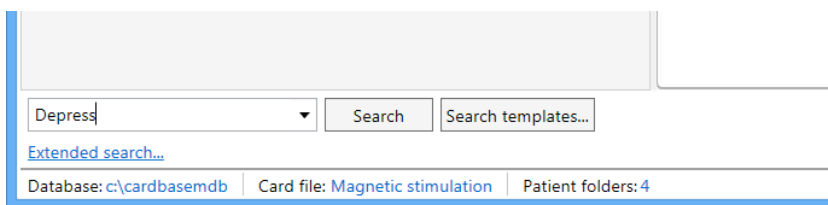
Fig. 74. Search box.

After treatment course opening the first unexecuted session is chosen automatically.

5.13   How to Exit Program

To exit (close) treatment, use **Treatment|Close** menu command or press toolbar button.

To exit the program, choose one of the following ways:

• **Treatment|Exit** (**[Alt+X]**) menu command;

• toolbar button;

• click on close button in the right upper corner of the program window.

5.14   Treatment Report Templates

The treatment report template is a powerful tool to speed up the report creation. The sequence, composition and type of information included in the report are defined in the template. The preset template is provided with the program but you can change

this template and create new one taking into account the specific requirements. This mechanism provides the flexible system of report generation.

To edit the report template, use **Report|Template editor…** menu command. The report template editor is shown in the Fig. 75.
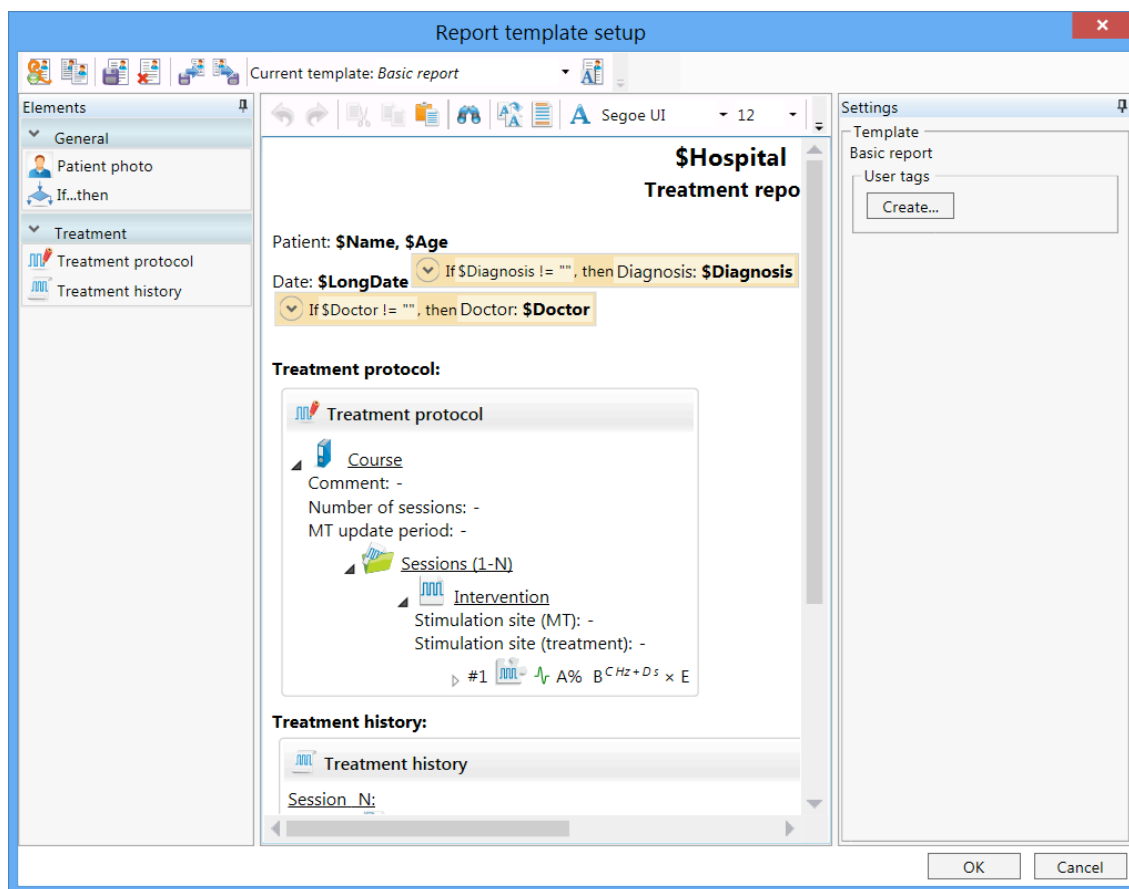
Fig. 75. Report template setup.

The report template toolbar is located at the top part of the window. Using the toolbar buttons you can create new report templates, remove the existing ones, import the templates from files, export the templates to files (for example, to copy to another computer) and rename them.

The drop-down list with the available report templates is located to the right. After the selection of the required report template from this list, you can start its editing. The "Report template setup" window is divided into three parts. The left part contains the list of information to be added to the report (list of elements). All the report elements are divided into groups with their names on the tabs. Left-click it to open/hide the elements of group. To include the required element to the report template, drag it with the mouse to the middle part of the window.

The editor of report template is located at the middle part of the window. It contains the elements which can be included in the treatment report. It is possible to change the report template using the keyboard and by adding the elements from the list. The template has a tree structure, i.e. some elements can have nested elements.

You can add some data to report (for example, name and age of a patient) using tags. When generating a report, all tags will be replaced by its values. The examples of tag usage ($Name, $Age) are shown in Fig. 76. In this case after report generation patient's name appears instead of $Name tag and patient's age appears instead of $Age tag. To look though the list of all available tags, press **[Ctrl+Space]** key combination or ![icon] button on the toolbar (Fig. 77) while editing the template. Please, pay attention, that the text replacing the tag will be of the same style (size, typeface, bold letters, etc.) as the tag itself.
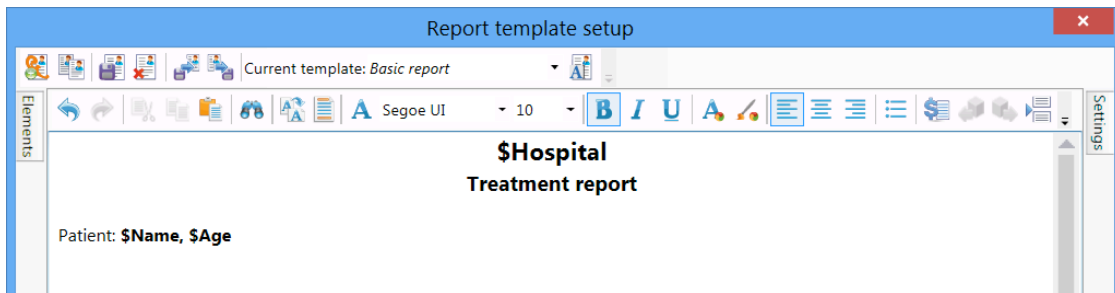
Fig. 76. Tag usage.
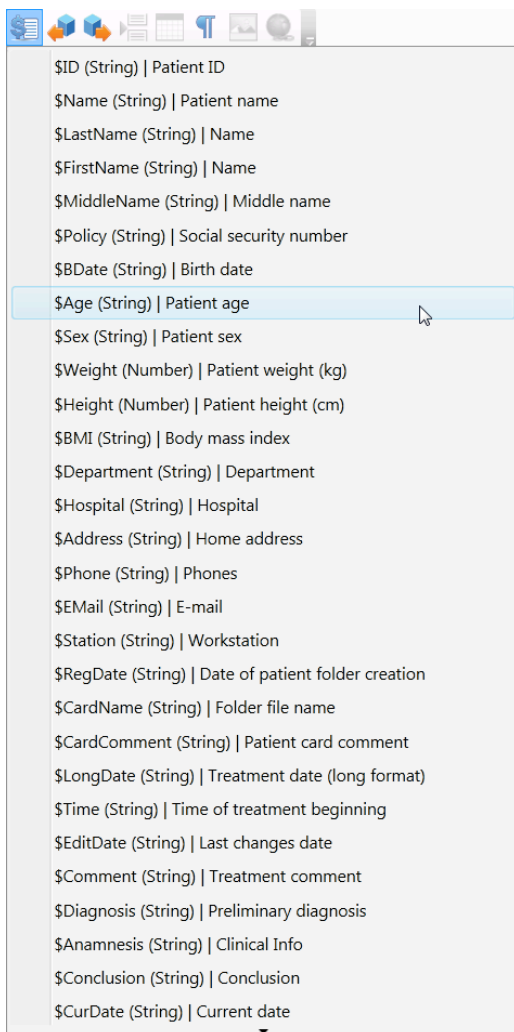
Fig. 77. List of available tags.

To change the template text, use the corresponding buttons (they are standard for most text editors) located over the editor. Also among these buttons you can find the following ones: ▦ button to insert the table-container to the template, 🖼 button to insert the image from file, the buttons to move the selected fragment one position forward ➡ and backward ⬅. Besides you can copy, insert, insert image from file and insert table-container using the context menu of the editor.

In the right part of the window you can see the settings of the current report element. Each element has its own settings to change the appearance of the information included in the report. The default settings are shown in Fig. 78.
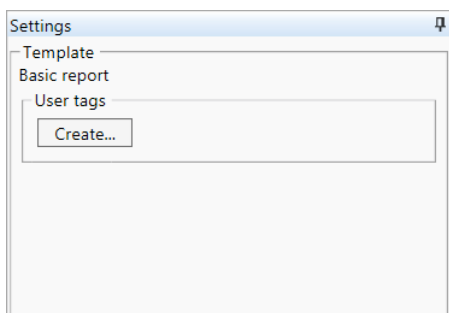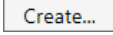
Fig. 78. Template settings.

The user tags could be created by report template developer. These tags, as already mentioned ones, can be inserted to any part of treatment report. However their actual values are requested from a user during the generation of treatment report. Let us see the example.

Suppose that it is required to add the information about a patient's temperament type to a report. There are no such data in the treatment options and usually doctors have no wish to enter such data to the report manually (it is easy to forget about). In this case you can apply user tags. As soon as you press Create... button (Fig. 78), the following dialog box appears on the screen (Fig. 79).
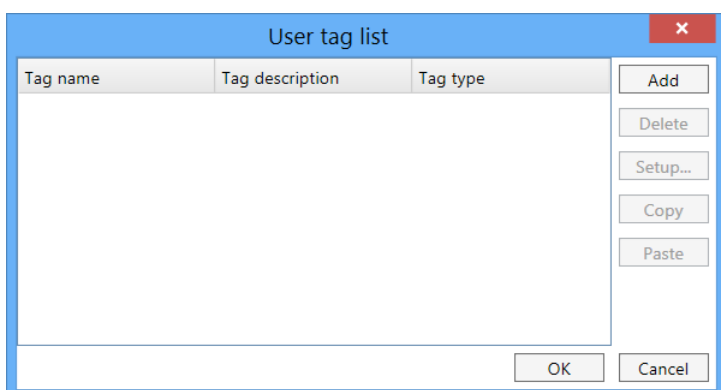
Fig. 79. The list of user tags.

Press [Add] button, specify "$Temperament" tag name, enter "Temperament" tag description and select "List" tag type (Fig. 80).
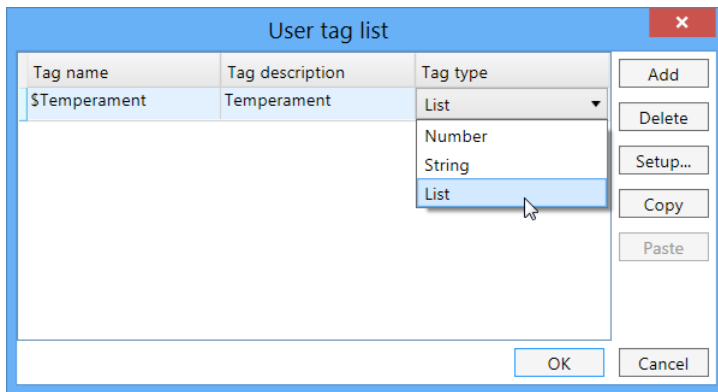
Fig. 80. Type of user tag.

In the appeared "User tag setup" dialog box (Fig. 81) create the list of four temperament types.
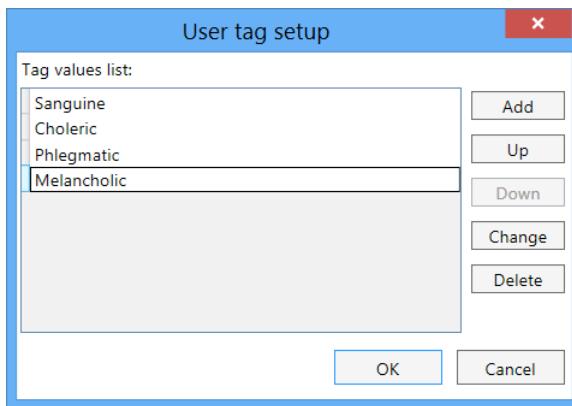
Fig. 81. User tag setup.

When you close these dialog boxes, the created tag will appear in "Settings" panel as shown in Fig. 82. Besides, the new "$Temperament" tag will appear in the list of available tags activated with **[Ctrl+Space]** key combination or by pressing [$≡] button.
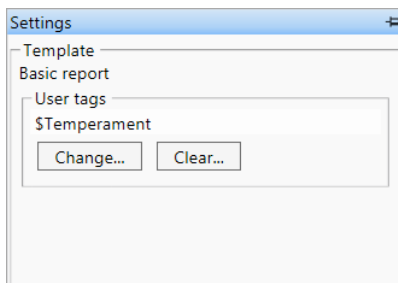
Fig. 82. "Settings" panel.

Now this tag can be used in the report template, for example, this way (Fig. 83).
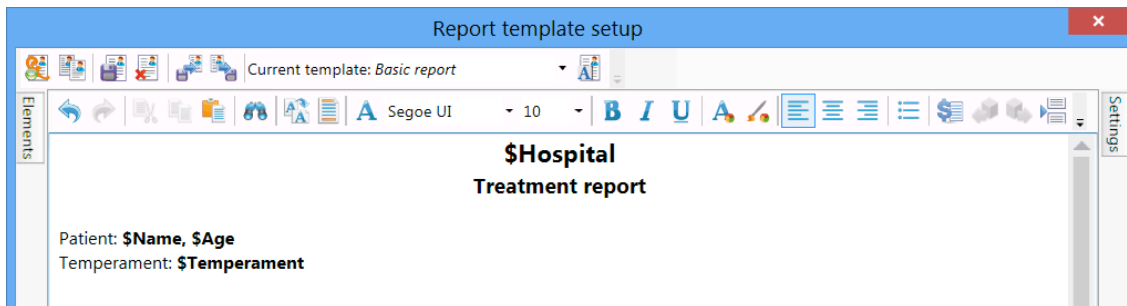
Fig. 83. User tags.

While generating the treatment report the dialog box shown in Fig. 84 will appear on the screen. Here you should select a patient temperament.
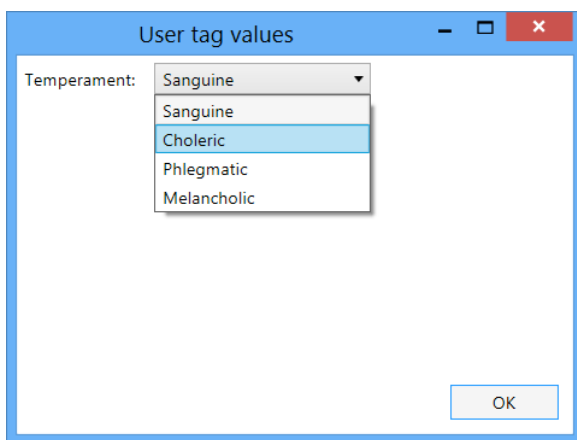
Fig. 84. Input of user tag values.

The report is shown in Fig. 85.

Fig. 85. Built-in report with data about patient temperament.

Let us review several main elements that can be used to create the report template.

5.15.1   Patient Photo

To add a patient photo to report template, left-click a "Patient photo" element (at the left part of the screen) (Fig. 86). Then left-click at the editor template to position patient photo (Fig. 87). The settings of "Patient photo" element will appear at the right part of the window (Fig. 88). Using this window you can adjust the element appearance.
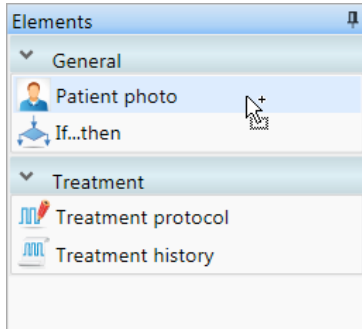
Fig. 86. Selection of "Patient photo" element.
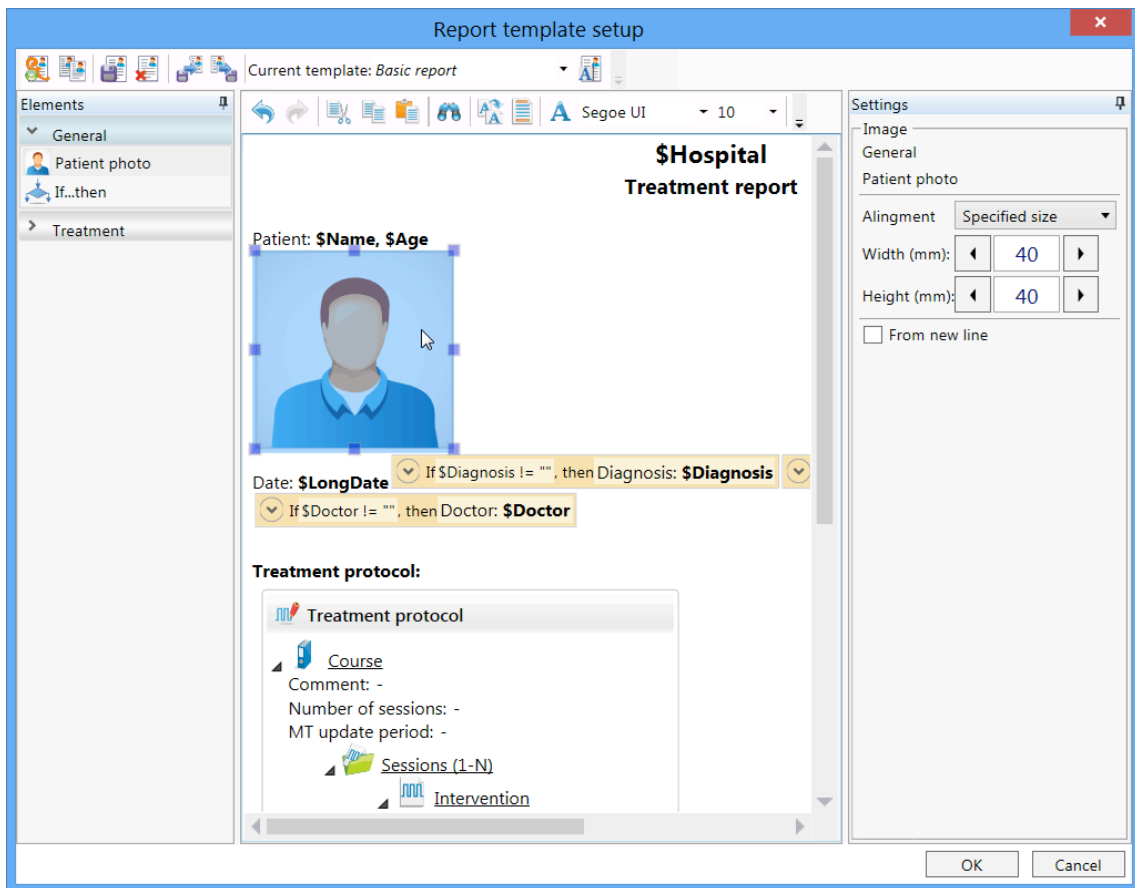
Fig. 87. Adding "Patient photo" element.
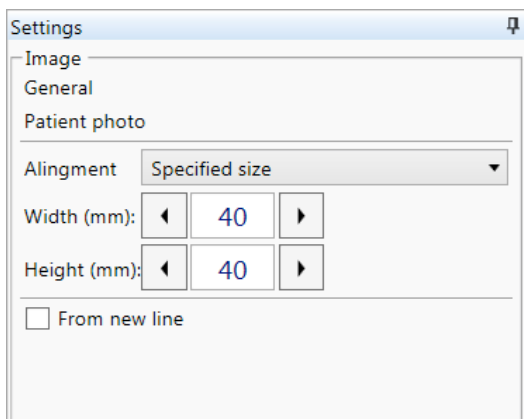
Fig. 88. Settings of "Patient photo" element.

On report generation, the patient photo icon (Fig. 87) will be replaced by actual patient photo.

5.15.2   Treatment Protocol

To add the information about treatment protocol to the report template, left-click on "Treatment protocol" element located at the left part of the dialog box (Fig. 89) and then left-click on the place of possible element location at the template editor (Fig. 90). The settings of "Treatment protocol" element will appear at the right part of the dialog box (Fig. 91).
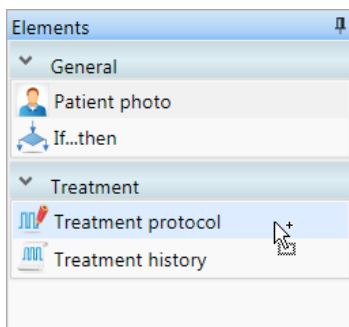
Fig. 89. Selection of "Treatment protocol" element.
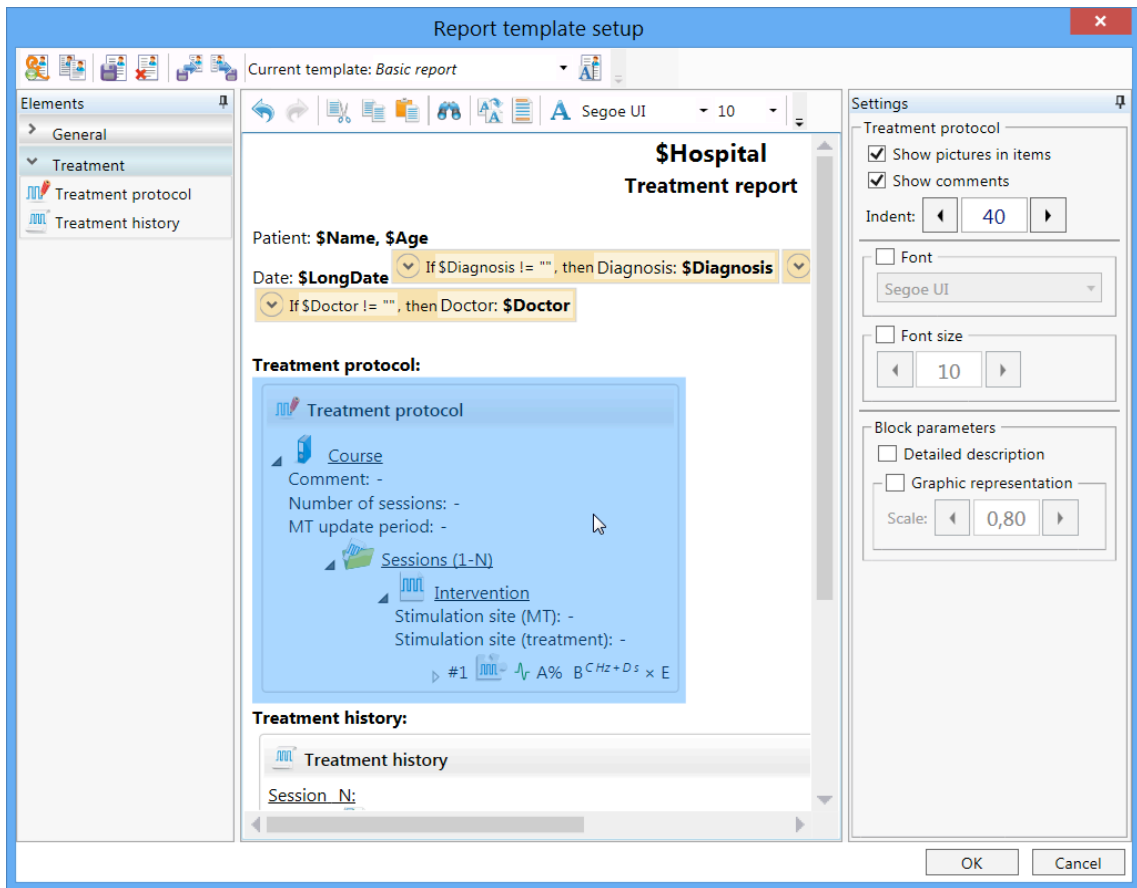
Fig. 90. Adding of "Treatment protocol" element.
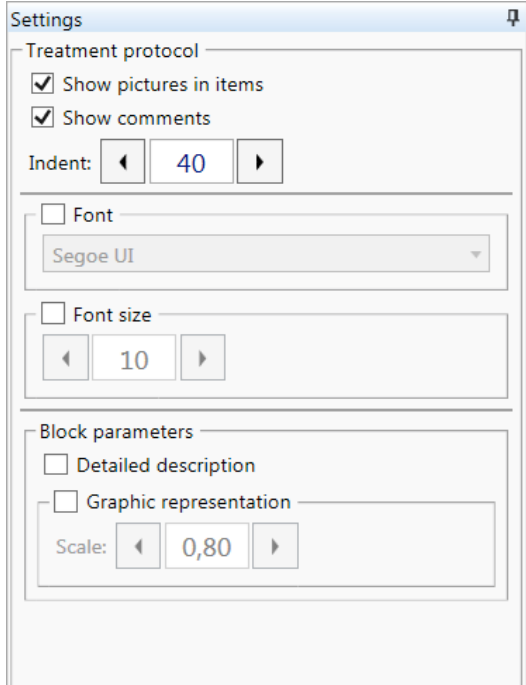
Fig. 91. Settings of treatment protocol.

During the report generation the treatment protocol icon (Fig. 90) will be replaced with tree structure describing treatment protocol with actual data.

5.15.3 Treatment History

To add the information about treatment history to report template, select the "Treatment history" element (in the left part of the window) using left mouse button (Fig. 92), and then left-click on the place of possible element location at the template editor (Fig. 93). The settings of "Treatment history" element will appear at the right part of the window (Fig. 95). The "Treatment history" element settings will appear at the right part of the window (Fig. 94).
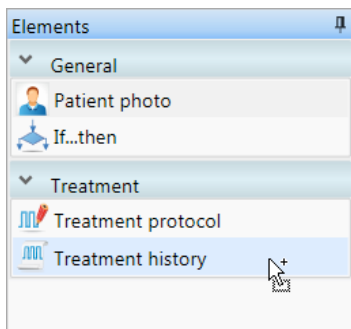
Fig. 92. Selection of "Treatment history" element.
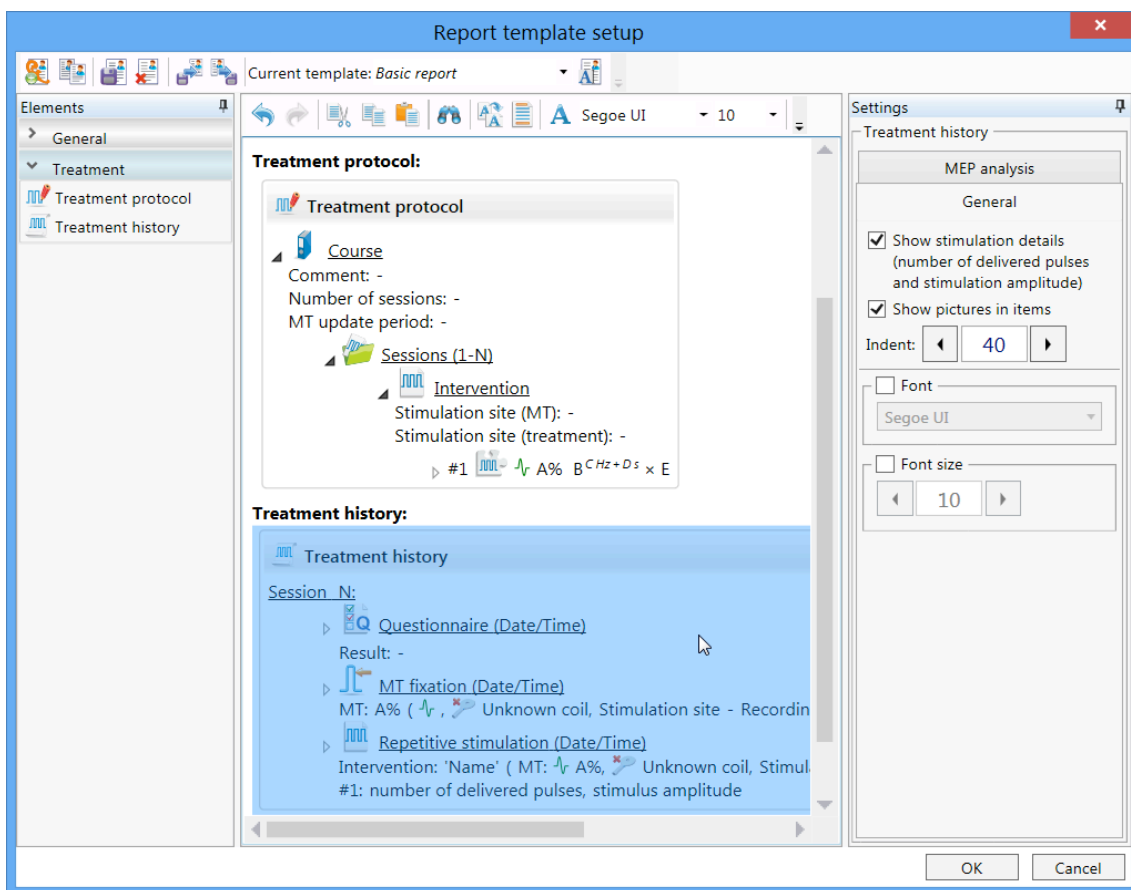
Fig. 93. Adding "Treatment history" element.
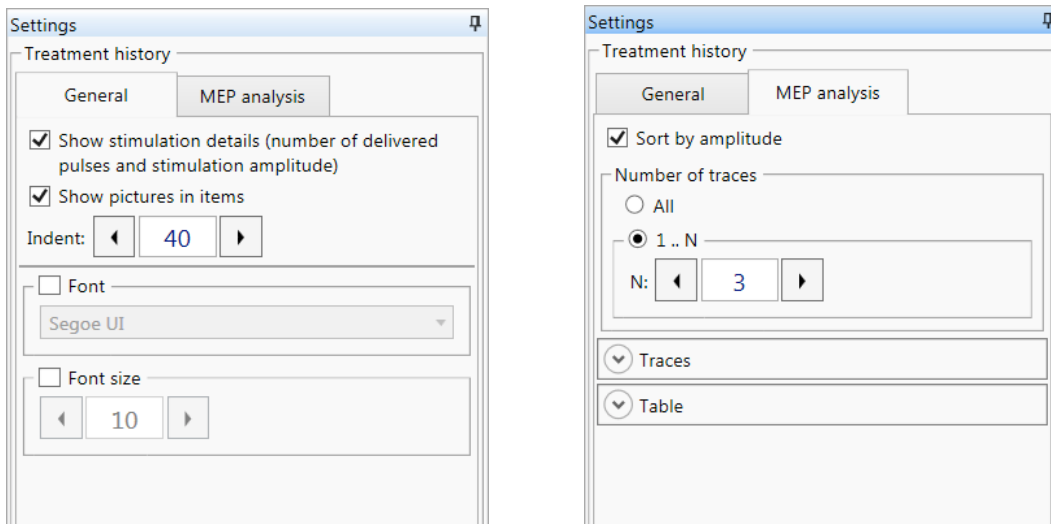
Fig. 94.Treatment history settings.

During the report generation the treatment history icon (Fig. 93) will be replaced with list of events saved in the treatment history.

5.15.4 "If…then" Conditional Element

Sometimes you have to include some information to the report depending on some other conditions. For example if a patient is diagnosed (the corresponding information is entered), then the diagnosis can be included to the report; else it has no sense to include this information to the report. In this case the special conditional elements "If... then" can be used. These elements allow to include some data to the report if one condition is fulfilled and include other information (or do not include any information) in the report if the condition is not fulfilled.

To add the conditional element to the report template, left-click on "If…then" element located in the left part of the window (Fig. 95) and then left-click on the place of possible element location at the template editor (Fig. 96). The element settings (Fig. 97) will appear at the right part of the window.
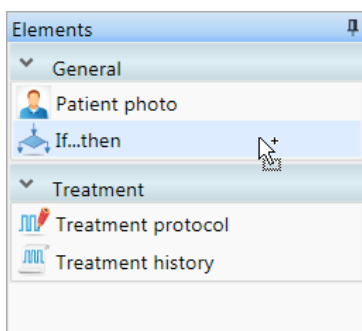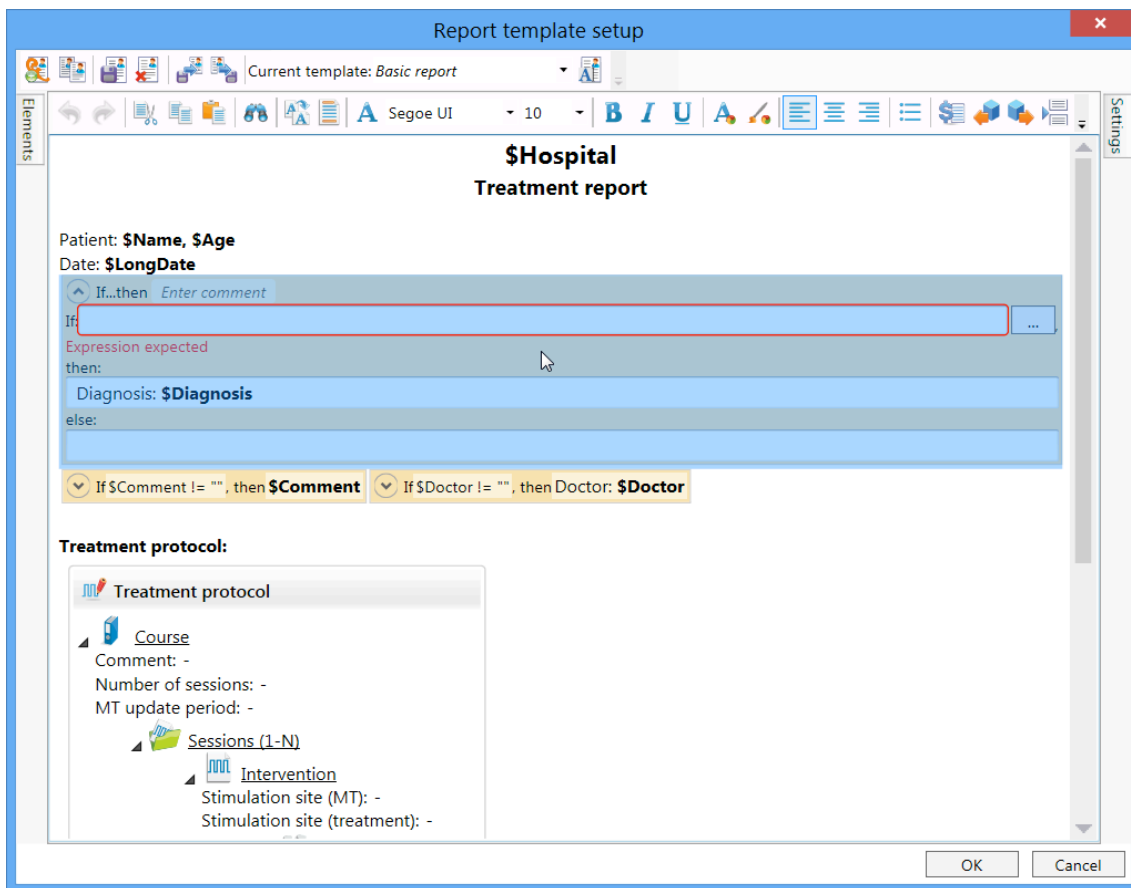

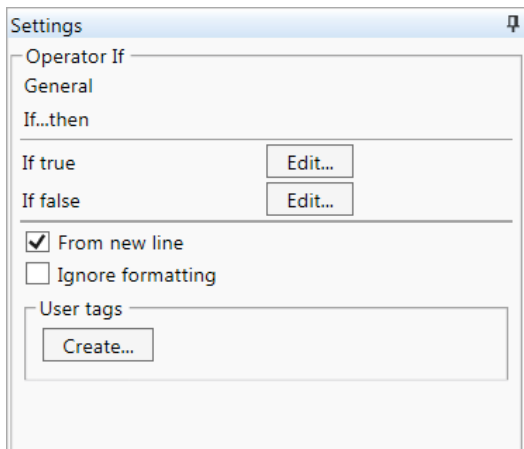Fig. 95. Selection of "If…then" element.

Fig. 96. Adding "If…then" element.

Fig. 97. Settings of "If…then" element settings.

Let us consider the above-mentioned example of diagnosis (Fig. 98).

Fig. 98.Parameters of "If…then" element.

If the information about diagnosis is entered ($Diagnosis tag), the "Diagnosis: **[infor-mation about diagnosis]**" text will be added to the report, otherwise the report will

not contain this information. Let us consider the "If $Diagnosis != """, then" string in details. It should be read as: if diagnosis ($Diagnosis) is not equal to (!=) an empty string (""), i.e. not empty, then…. To read a tip on generation of such logical expressions, press [...] button (Fig. 98).

The element can contain not only text, but any other elements.

5.15.5 Table-container

The table-container allows aligning information in the report by rows and columns. Using it, you can display any information side-by-side.

To add the table-container to the report template, left-click on [⊞] icon located on the toolbar or select "Insert table-container" menu command in the local menu (Fig. 99). After that the table-container will appear on the template editor at the text cursor position (Fig. 100). The element settings will appear rightward (Fig. 101).
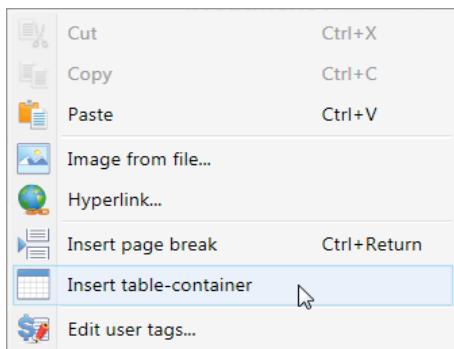

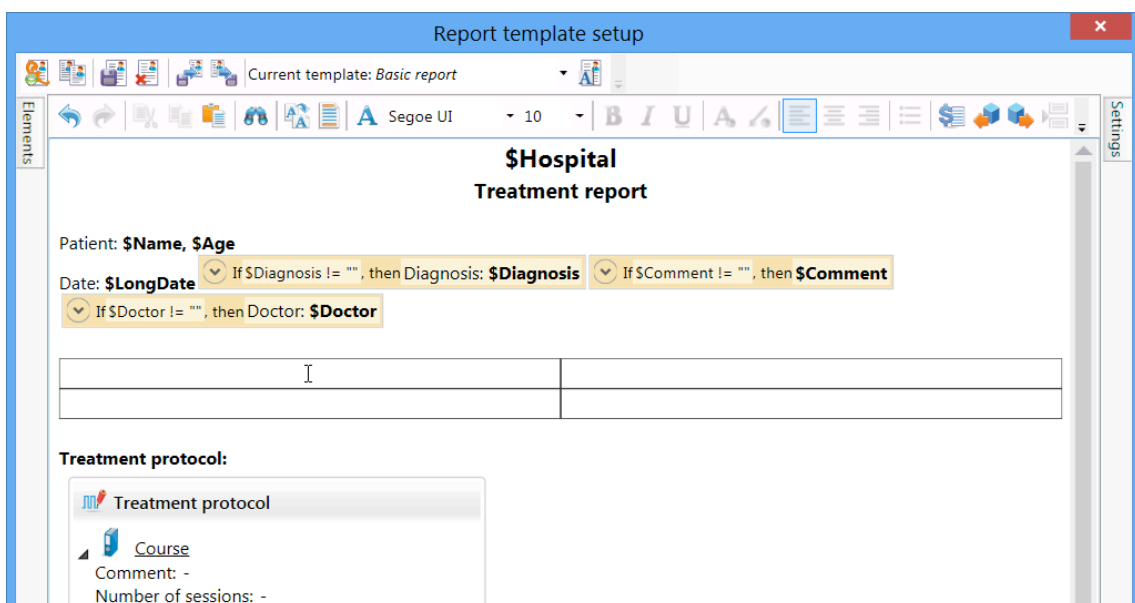Fig. 99. Selection of "Insert table-container" element.

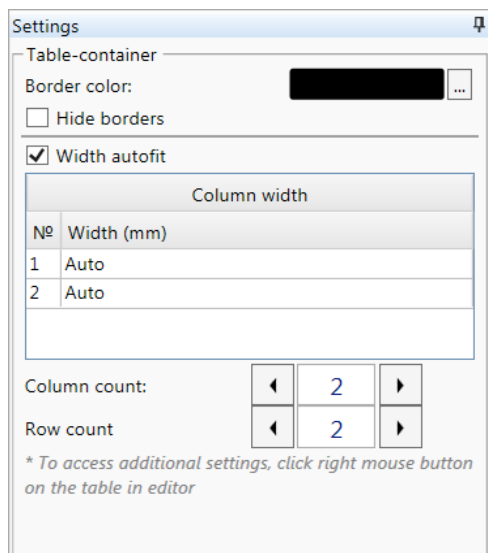Fig. 100. Adding of table-container.

Fig. 101. Table-container settings.

5.15.6   Safety Screening Questionnaire

To ensure safe treatment, it is required to screen a patient for contraindications before TMS session start. Ask the patient to fulfill a safety screening questionnaire. You can create and print it using Neuro-MS.NET software.

By default Neuro-MS.NET software ensures a preset standard questionnaire created according to International recommendations on TMS safety (Rossi et al., 2009, 2011).

However, you can edit the available questionnaire or create a new one. It is created or edited in the same way as treatment report template (5.14 "Treatment Report Templates").

To go to safety screening questionnaire editor, use **Treatment|Safety screening questionnaire|Setup…** menu command.

To create a safety screening questionnaire, use **Treatment|Safety screening questionnaire** menu command and select the template to be used for new questionnaire creation.

It can also be done with button located on main window toolbar. If you press this button, a safety screening questionnaire template used previous time will be applied. If you want to select other template to create your questionnaire, use the drop-down menu of this button.

The sample of generated safety screening questionnaire is shown in Fig. 102.

Fig. 102. The safety screening questionnaire.

To print a questionnaire, press button.

5.15 Hardware and Software Configuration Settings

The main program settings can be adjusted using **Setup| Edit…** menu command.

"General" page (Fig. 103).

Fig. 103. "General" page.

"User".

"Login". The user name to login. Each user can customize the own settings (e.g., the possibility to change toolbar settings, to connect databases, etc.). It does not impact the settings of any other user. To add a new user, use "Administration" tab of the window.

"Password". A password is required at each program start. Keep in mind that it is impossible to restore the password in case you forget it. In this case you will have to address to Neurosoft center for help. You can leave this field empty (log on without password).

"Request login and password". If the checkbox is selected, user login and password will be required after the program startup.

"Protect settings with password:" If the checkbox is selected, you are allowed to change the program settings only after the password entering.

"Hospital" – a name of medical establishment indicated in the treatment report ($Hospital tag value).

"Program start". Action carried out automatically after the program startup.

"After closing of treatment". Action carried out automatically after the treatment closing.

"Database. Use data compression for archiving". You can compress data to save the space on a disk but it can slow down the operation with archives.

"Optimize traces drawing (turn off if you have some problems with traces view)". It is recommended to check this checkbox. It allows speeding up trace rendering on the screen. If have problems with trace rendering (image "freezing"; markers can not be moved using mouse, etc.), uncheck this checkbox.
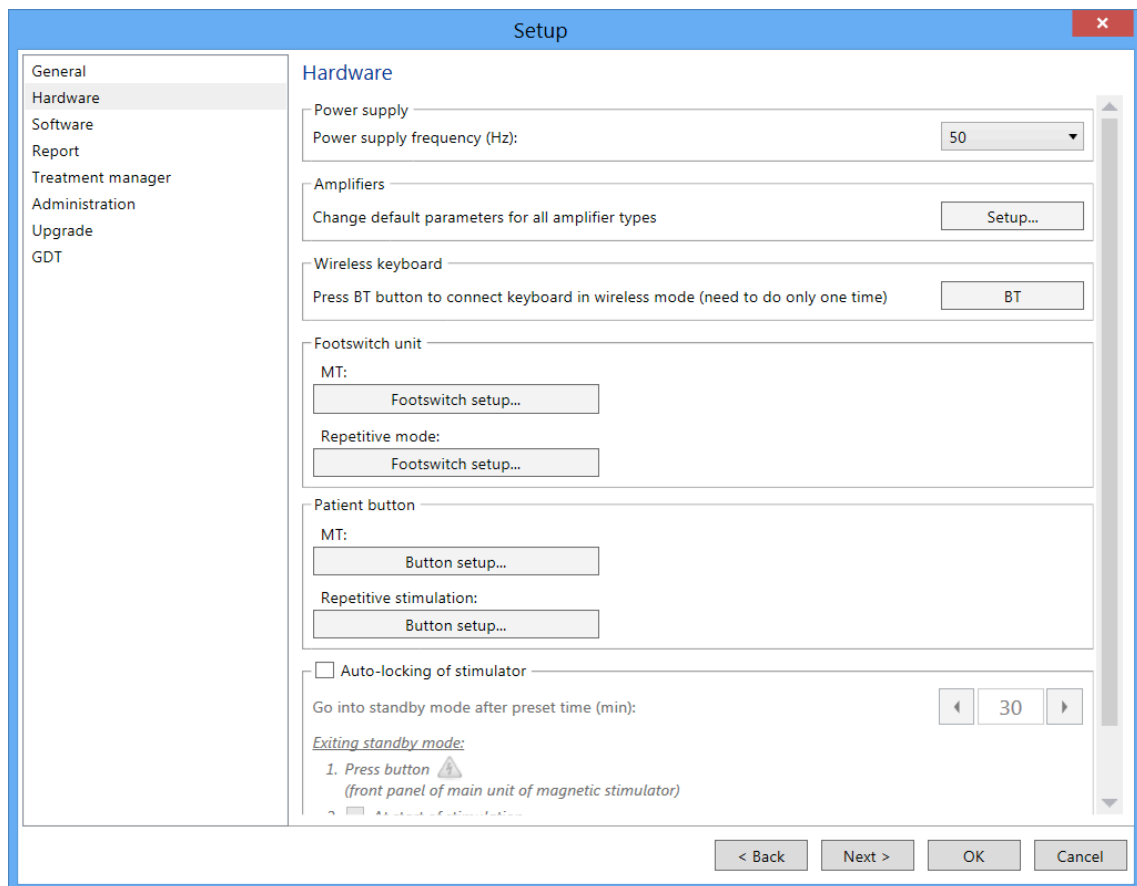
"Hardware" page (Fig. 104).

Fig. 104. "Hardware" page.

"Power supply. Power supply frequency (Hz)". The mains frequency in your region, in Hz, to adjust the notch filter. In Russia and Europe this value equals to 50 Hz, in USA – 60 Hz.

"Amplifiers" group box allows customizing the default settings of all available amplifiers.

"Wireless keyboard". Button for Bluetooth keyboard connection via wireless Bluetooth interface. Press the button once when you connect the wireless keyboard to your computer for the first time. If the Bluetooth keyboard is connected through USB port, it will function without pressing this button.

"Footswitch unit". Press "Footswitch setup…" button to establish connections between footswitch pedals and menu commands. Adjust footswitch separately for single pulse mode and repetitive stimulation mode.

"Patient button" — this option links the patient button to this or that command. The setup is done separately for single pulse stimulation and repetitive stimulation.

"Auto-locking of stimulator" – this option allows the magnetic stimulator to enter the stand-by mode (switches off the internal high-voltage power supply unit) in a specified period of time. The delay of stand-by mode entering is set from 1 to 60 minutes. The time is reckoned from the last stimulus delivery. If it is necessary, specify the alternative ways to exit the stand-by mode (select the required checkboxes).
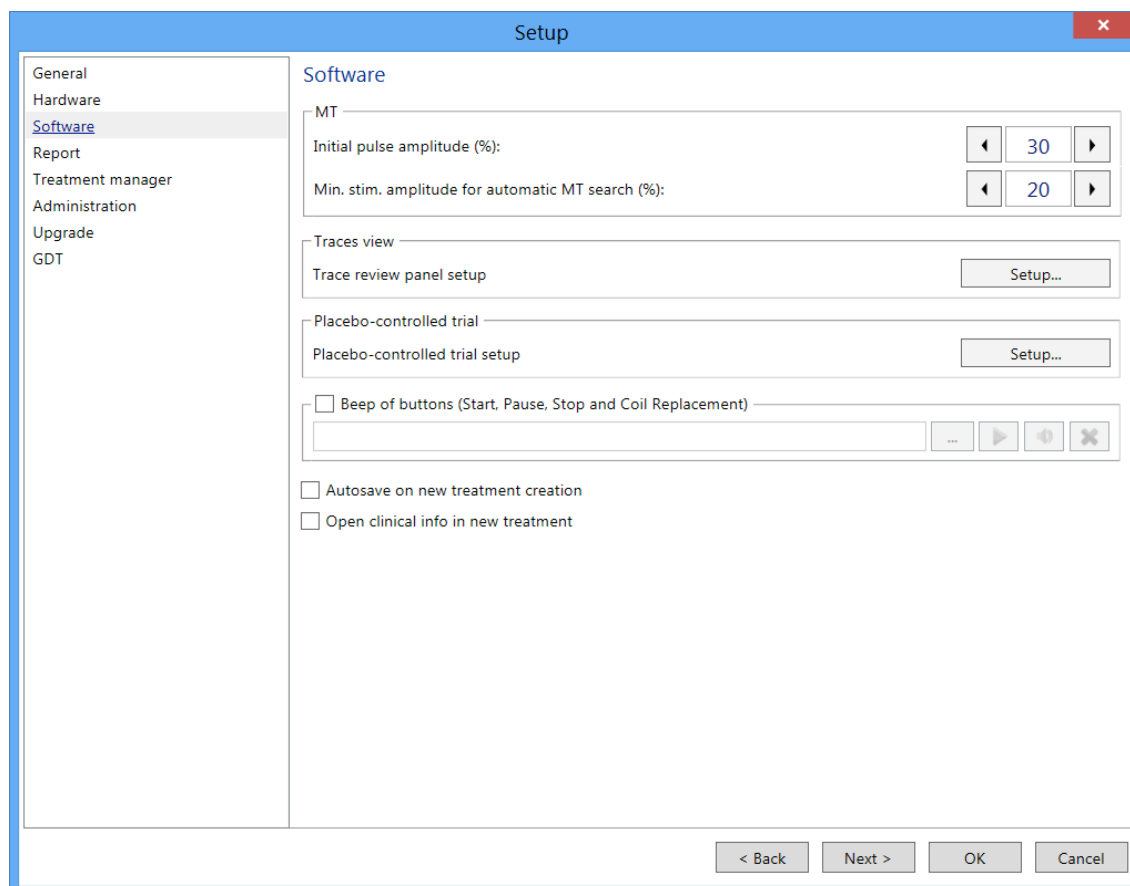
"Software" page (Fig. 105).

Fig. 105. "Software" page.

"MT" group box.

"Initial pulse amplitude, %" input box allows to change the initial stimulation amplitude to be applied at the creation of new treatment.

"Min. stim. amplitude for automatic MT search, %" — the lower limit of search range by amplitude at automatic MT detection.

"Traces view" group box helps to set up the appearance of acquisition window, select the actions with traces at signal acquisition, change names and adjust marker visibility on traces.

"Placebo-controlled trial" — placebo-controlled trial setup.

"Beep of buttons (Start, Pause, Stop and Coil Replacement)" — this option allows specifying the audio file that is played back when the main actions are performed (start, pause, stop, coil replacement).

"Autosave on new treatment creation". If the checkbox is selected, **Treatment|Save** command is executed automatically after the new treatment creation.

"Open clinical info in new treatment". If this checkbox is selected, the window to enter clinical information of a patient is opened just after a new treatment creation.
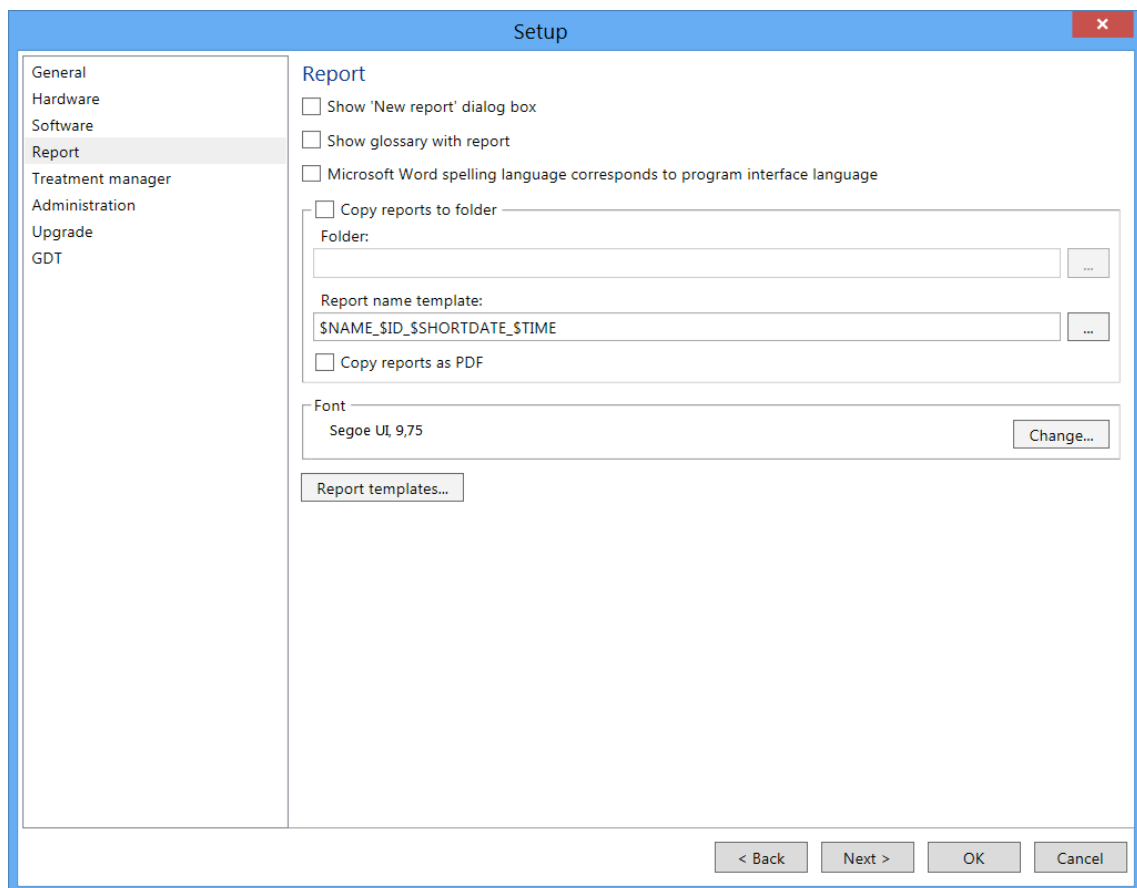
"Report" page (Fig. 106).

Fig. 106. "Report" page.

"Show "New report" dialog box". If the checkbox is selected, the dialog box inquiring report name and comment will be displayed before creating a new treatment report.

"Show glossary with report". If this checkbox is selected, the glossary window will be displayed each time you open a treatment report.

"Microsoft Word spelling language corresponds to program interface language". If this checkbox is selected, the program automatically defines the interface language and the spell check in Microsoft Word reports is done in this language.

"Copy reports to the folder". If this checkbox is selected, the treatment reports are simultaneously copied to the indicated folder on a computer disk when you save the treatment.

"Report name template". The file name template for the treatment report. In this template you can use the same tags as in the treatment report. It allows making the file name clearer. For example, in this case ("$NAME_$ID_$SHORTDATE_$TIME") the file name will consist of a patient's name, an ID, date and time of treatment creation.

"Font". The preset font of the treatment report. The same font is used by default in "Clinical info" and "Conclusion" windows.

"The Report templates... button". Changing of the treatment report templates.

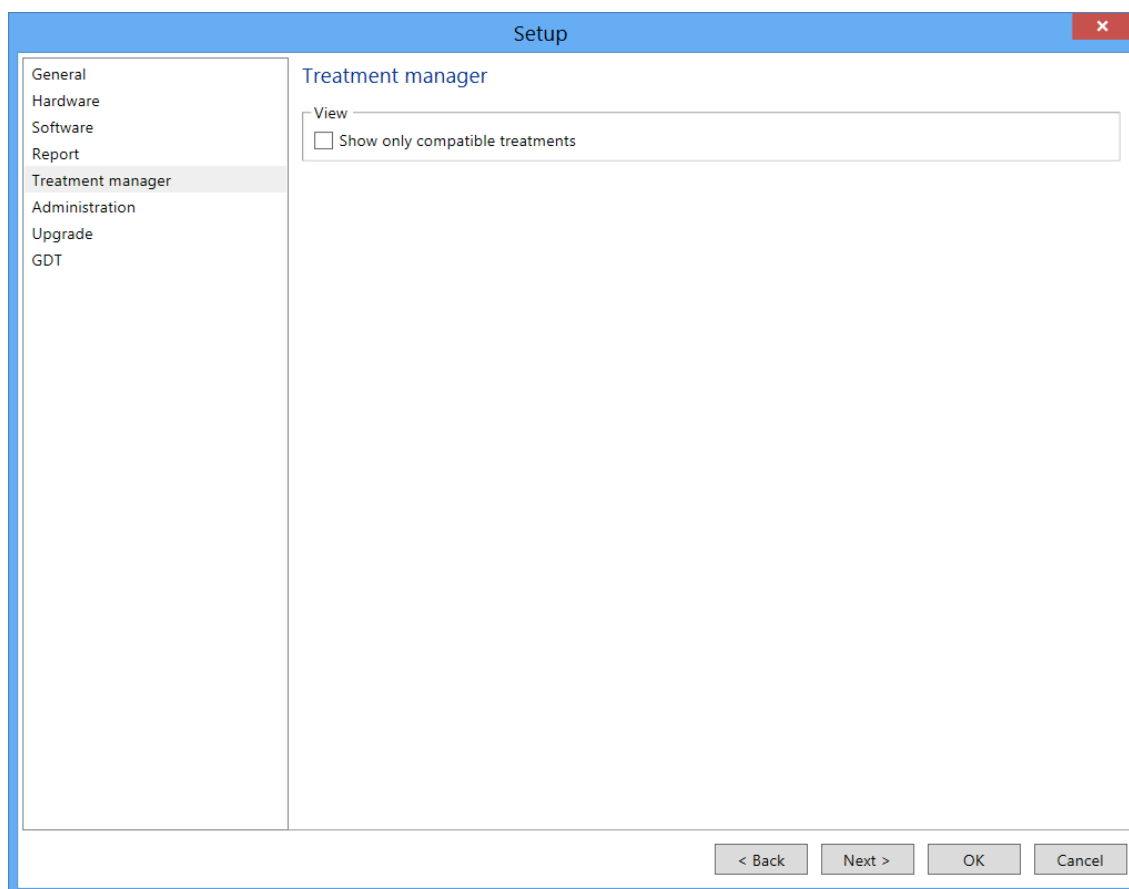"Treatment manager" page (Fig. 107).

Fig. 107. "Treatment manager" page.

"View. Show only compatible treatments". If the checkbox is selected, the "Treatment Manager" will display only those treatments that can be reviewed (opened) with this program.

"Administration" page (Fig. 108).
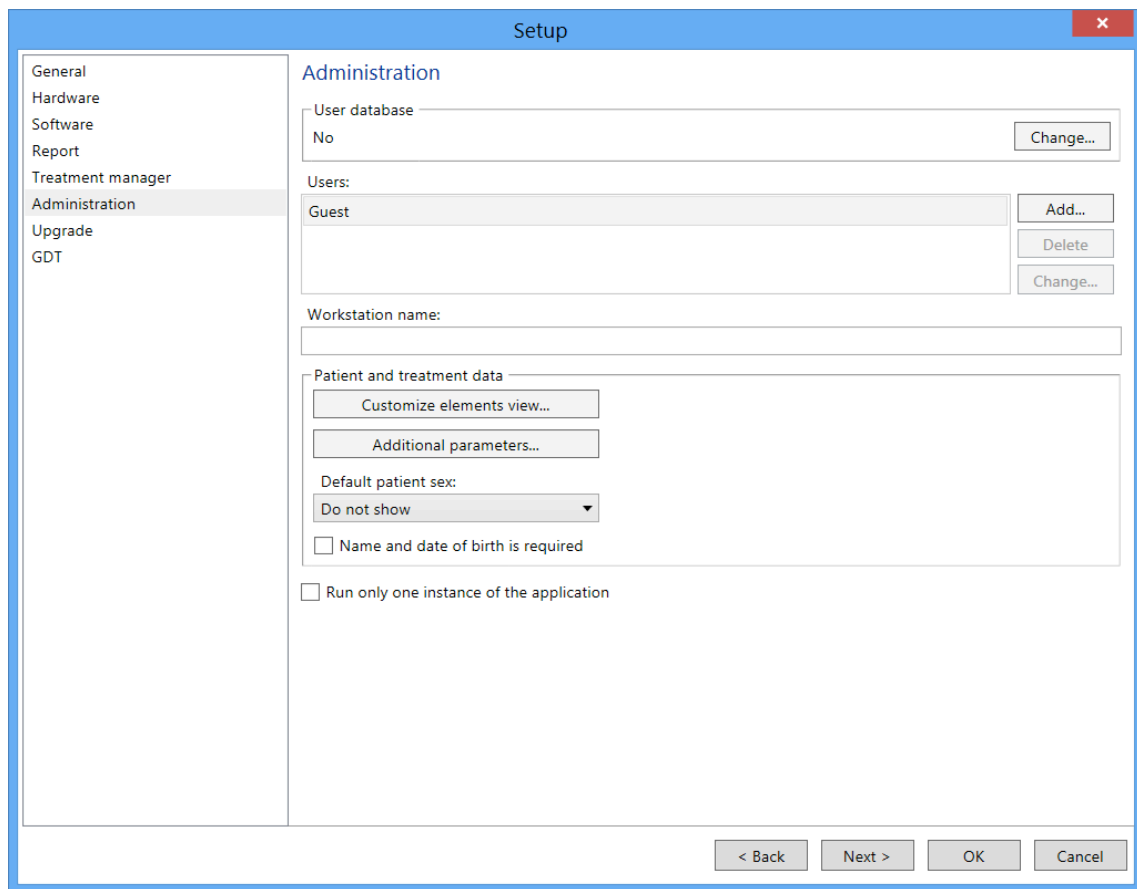
Fig. 108. "Administration" page.

"User database". The network database where the list of users and software settings are saved. This option is handy if there are common list of users and individual software settings for each user within the network, regardless of which PC is used by a specialist.

"Users". The list of users. Add… , Delete and Change… buttons are intended to edit the list of users.

"Workstation name". The name of network station (computer) in case of operation with network database.

"Patient and treatment data".

"Customize elements view…". The setup of patient card appearance, requested at the beginning of each new treatment. Select the required checkboxes.

"Additional parameters…". The setup of additional (user) parameters entered in patient card.

"Default patient sex". This element allows to specify patient' sex by default at the beginning of each treatment.

"Name and date of birth is required". If the checkbox is selected, the check of availability of entered patient name and date of birth is carried out at the beginning of each new treatment before patient card closing.

"Run only one instance of the application". If the checkbox is selected, the second instance of the application is disabled.

"Upgrade" page (Fig. 109).
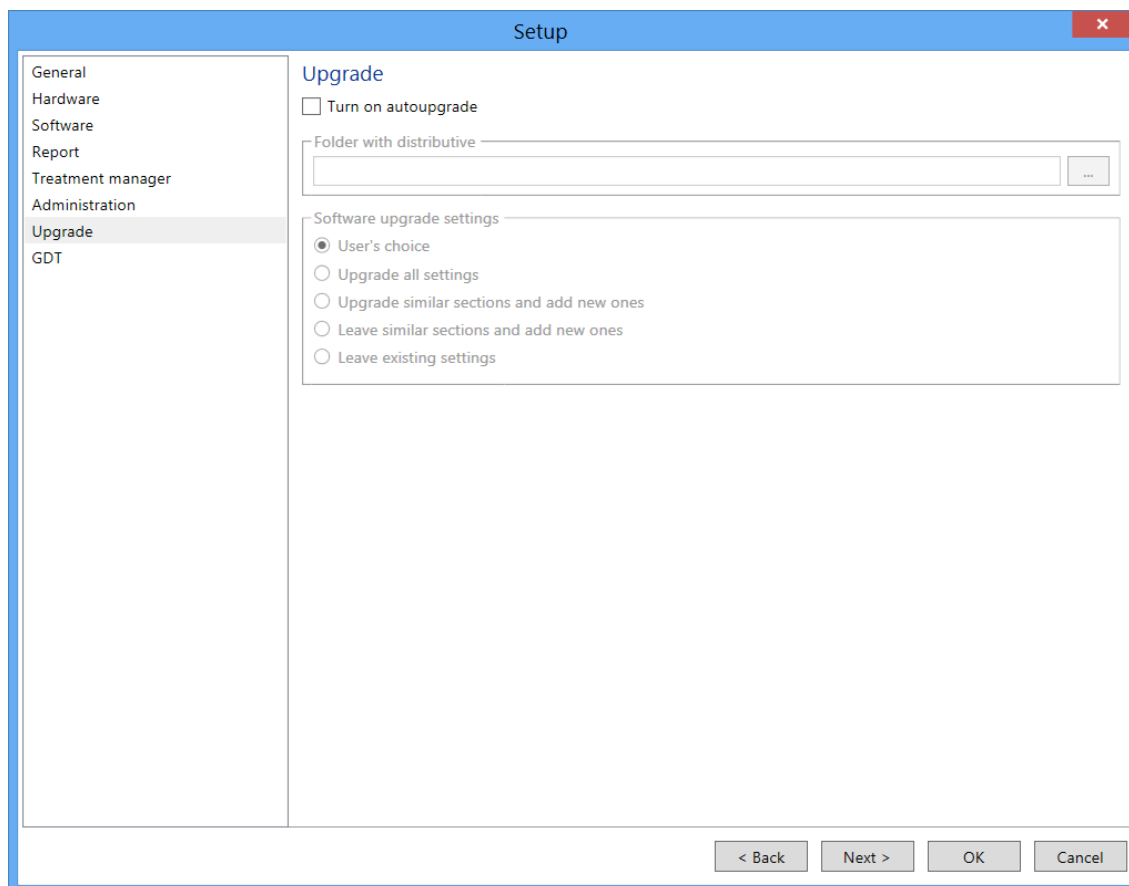
Fig. 109. "Upgrade" page.

"Turn on autoupgrade". If the checkbox is selected, the program is updated automatically. The program checks the presense of new program version in the specified folder at each program start and, if it is available, updates automatically.

"Software upgrade settings". Choose the variant of software upgrade using radio buttons located in this group box.

"GDT" page (Fig. 110).

Fig. 110. "GDT" page.

The folder names with input and output data to synchronize the treatments and GDT integration protocol of a hospital are entered on this page.

5.16 Toolbar

The toolbars contain the most frequently used commands. The program has flexible system of toolbar setup. This system al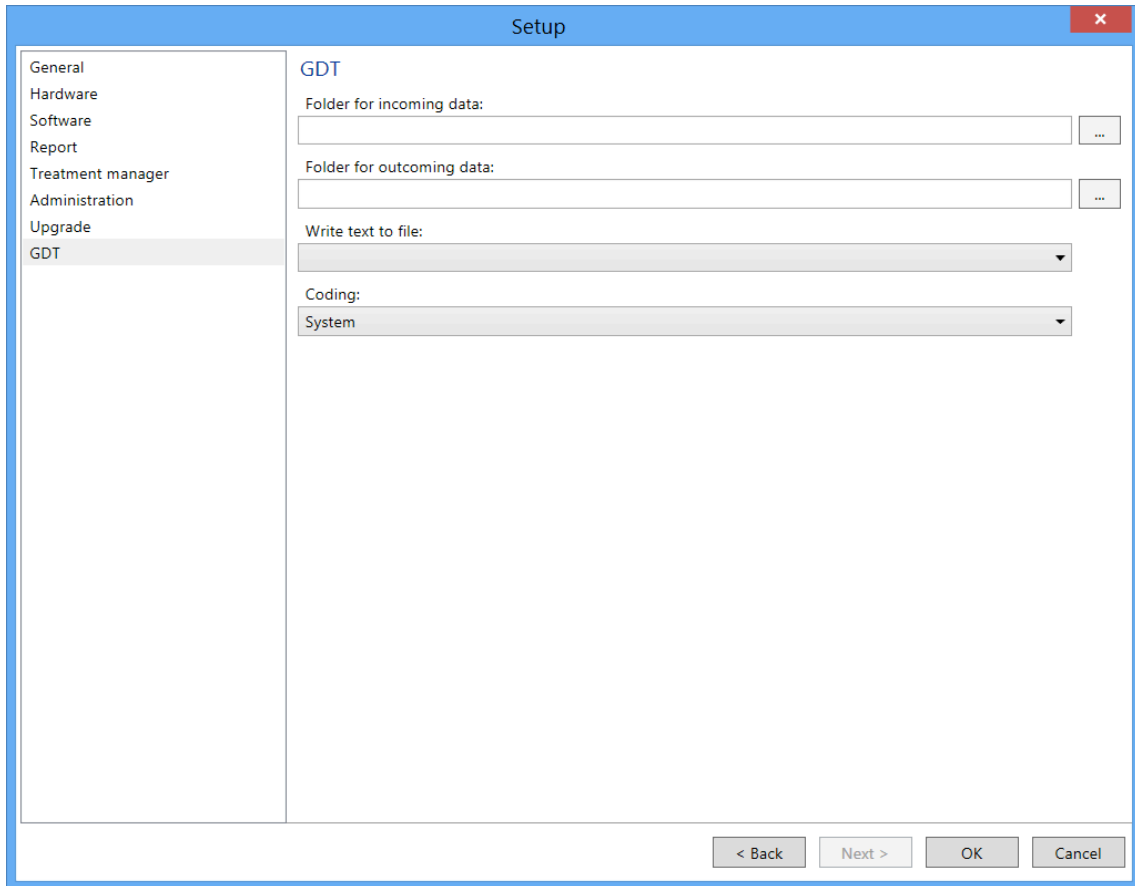lows customizing toolbars and assigning "hot-keys" to menu commands. Besides, you can drag the toolbars with the mouse and position them at any convenient place along the perimeter of main program window.

To set up the toolbar, right-click on it and select "**Setup…"** local menu command (Fig. 111). After that "Toolbar setup" window (Fig. 112) will appear on the screen.
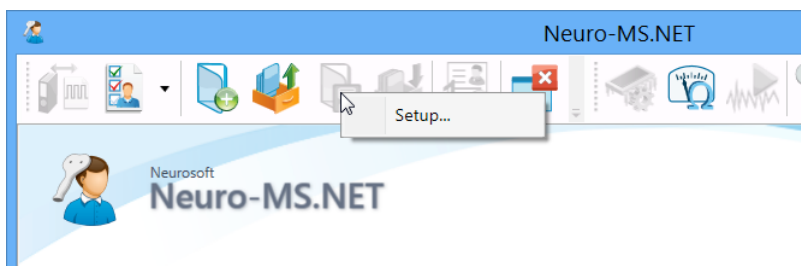

Fig. 111. The local menu of toolbar setup.
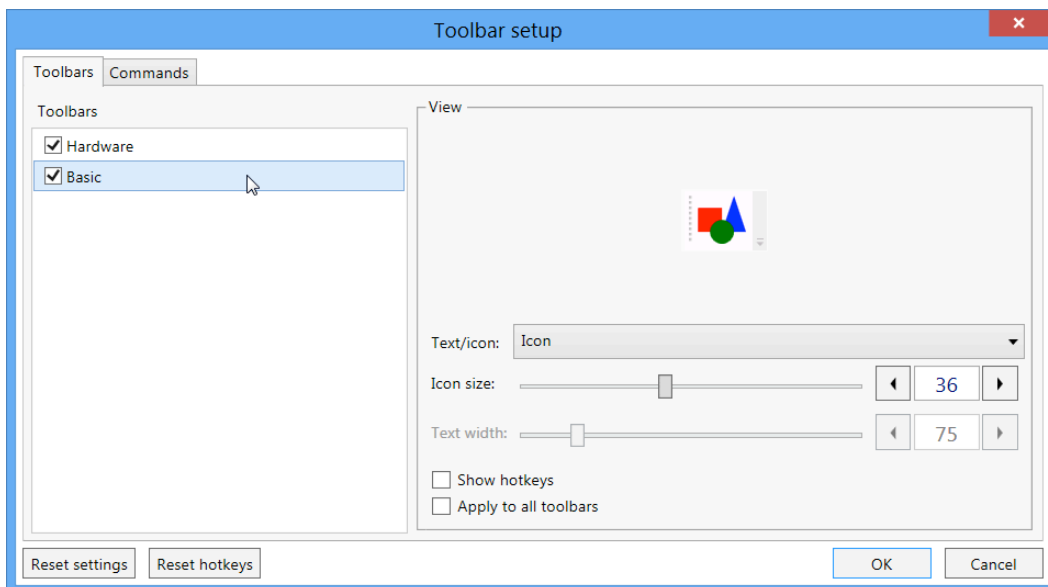
Fig. 112. "Toolbar setup" window. "Toolbars" page.

Using this window you can setup the toolbar appearance: text/icon ratio, icon size, text width, hotkeys if they are required.

The "Commands" tab of "Toolbar setup" window (Fig. 113) allows customizing the information panels. In this window you can see all available menu commands (i.e. when "Toolbar setup" window is opened). Any of these commands can be added to any toolbar as a button.

Fig. 113. "Toolbar setup" window. "Commands" page.

To add a button to the toolbar, select the required element from the list of commands and drag it with the mouse to any place of any toolbar. Besides in this mode you can drag the available buttons between the toolbars, remove them from the toolbars by pulling them out of the toolbars boundaries.

To assign new hotkeys for the commands, use Hotkey button.

5.17 Treatment Protocols

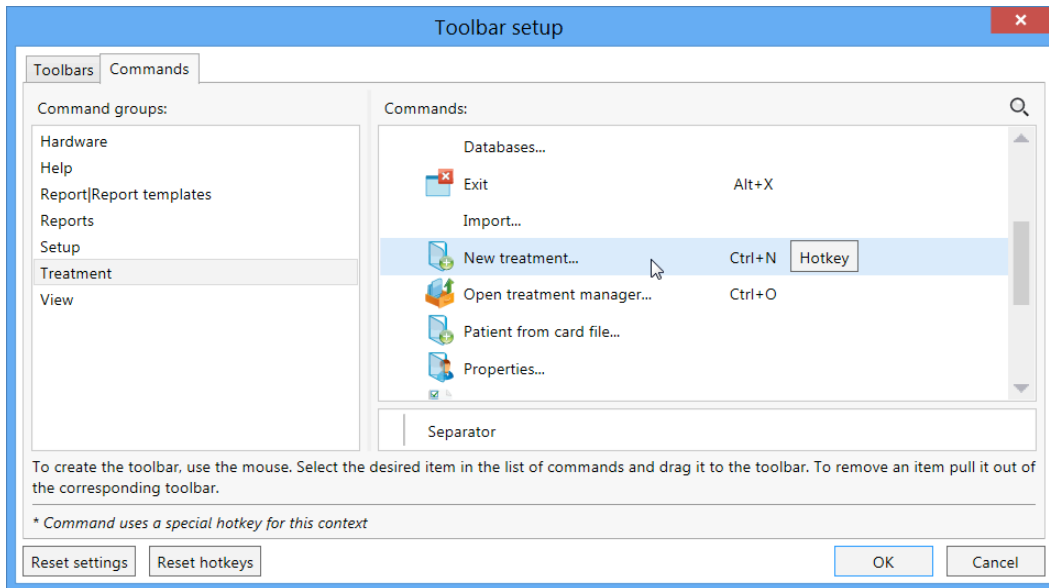The program offers two operation modes: "Course" and "Interventions". "Course" mode - the main treatment mode that implies several sessions. "Interventions" mode is a special treatment mode. It allows performing stimulation using one or more interventions and implies only one session.

To facilitate a practitioner's work, speed up treatment creation and performing, **Neuro-MS.NET** contains preset course and intervention protocols. To unify names of recording sites and stimulation sites, use the corresponding lists.

To edit mentioned lists and protocols, choose **Setup|Treatment protocols** menu command.

Created lists of recording sites, stimulation sites, intervention and course protocols can be exported selectively to external file using **Setup|Treatment protocols|Export…** menu command. To import settings, use **Setup|Treatment protocols|Import…** menu command.

5.18.1 Recording Sites

To adjust the list of recording sites (target muscles), use **Setup|Treatment protocols** menu command and then choose **Recording sites…** in drop-down menu.

"Recording sites" dialog box (Fig. 114) has two parts. The list of recording sites is located leftward and parameters to adjust are found rightward.

You can name each recording site, add a comment and set the content of help window.

To change the content of help window, click on the [✎] button.

Using control buttons located at the bottom of the dialog box, you can perform following actions:

- [➕] — add new recording site;

- [➖] — delete the selected recording site;

- [🔼] — move the selected recording site one position higher;

- [🔽] — move the selected recording site one position below;

To save settings press [✔] button and to cancel the changes press [✖] button.
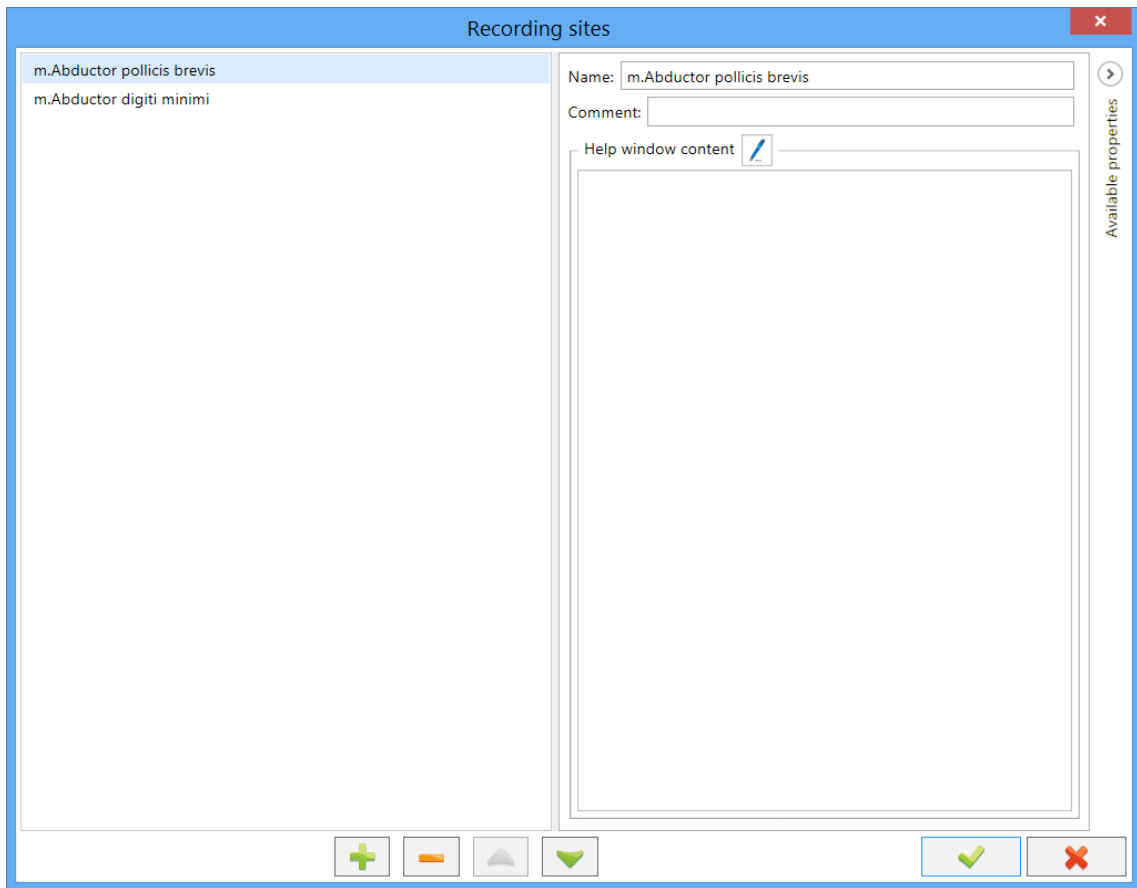
Fig. 114. "Recording sites" dialog box.

5.18.2 Stimulation Sites

To edit the list of stimulation sites use **Stimulation sites…** command in **Setup|Treatment protocols** menu.

"Stimulation sites" dialog box (Fig. 115) has two parts. The list of stimulation sites is located rightward and the settings to adjust are found leftward.

You can name each stimulation site, add a comment and set a content of help window. If a stimulation site is used to detect motor threshold, you can set a list of corresponding recording sites. Recording site list is based on preset one (see 5.18.1 "Recording Sites" section) and recording sites are listed according to usage priority.

To change the content of help window, click on [/] button.

Using control buttons located at the bottom of the dialog box, you can perform following actions:

- [+] — add new stimulation site;

- [−] — delete the selected stimulation site;

- [▲] — move the selected stimulation site one position higher;

- ⬇ — move the selected stimulation site one position below.
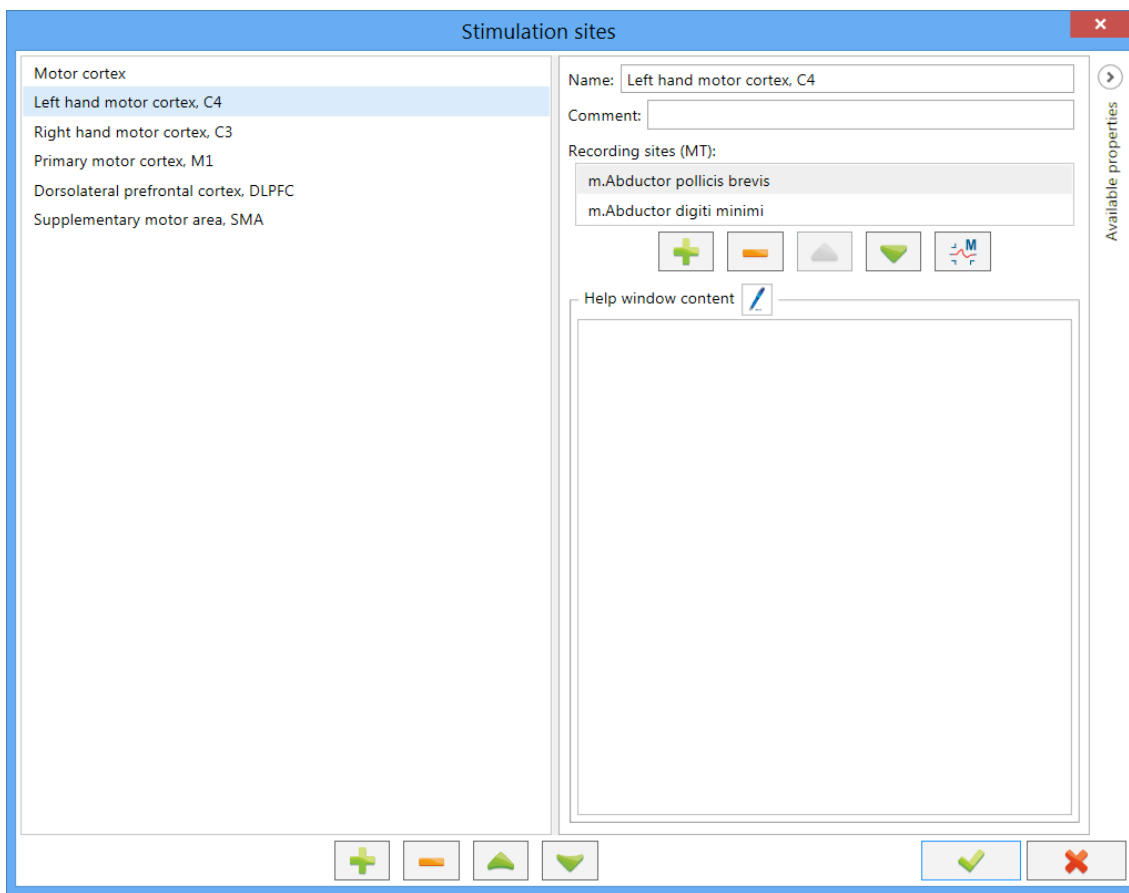
Fig. 115. "Stimulation sites" dialog box.

The same control buttons are used to generate the recording site list.

To save settings press ✓ button and to cancel the changes press ✗ button.

5.18.3 Interventions

To edit the intervention protocols, use **Setup|Treatment protocols** menu command. In the appeared drop-down menu select **Interventions**.

"Intervention setup" dialog box (Fig. 116) has two parts. The tree list of interventions divided into groups is located leftward and the settings to adjust are found rightward.

"Group of interventions" element contains interventions grouped by common feature. The parameters to adjust are name and comment.

"Intervention" element contains the list of stimulation blocks to be executed in consecutive order. Stimulation intervention can include one block (simple stimulation intervention) or several blocks (complex stimulation intervention). The parameters to adjust are name, comment, stimulation site to detect MT and stimulation site to perform the treatment (Fig. 116). Last two parameters are adjusted considering preset

stimulation site list (see 5.18.2 "Stimulation Sites" section). Also you can set the side of stimulation for each stimulation site.
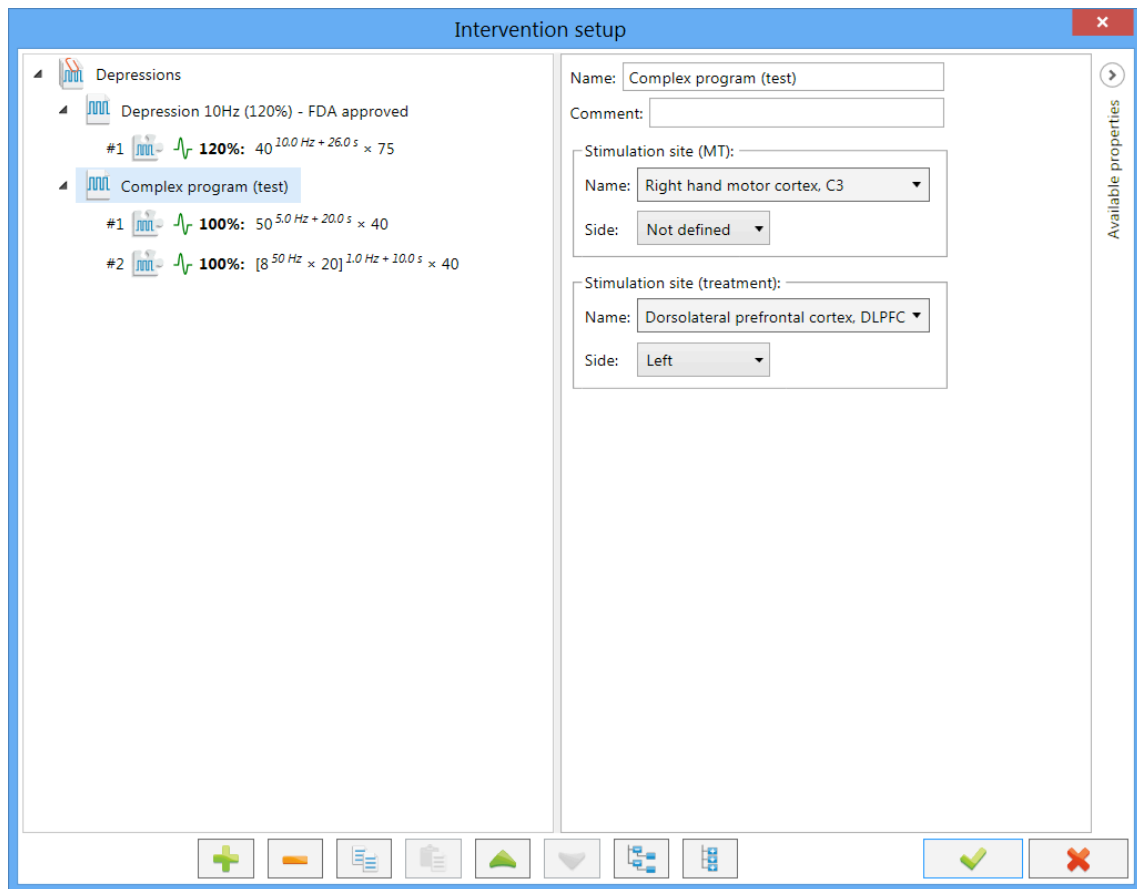
Fig. 116. Intervention protocols. "Intervention" element.

"Block" element contains the parameters to adjust the repetitive stimulation (right part of the dialog box in Fig. 117. The parameters to adjust are:

• Stimulation type: biphasic or burst.

• Absolute amplitude, % — stimulation amplitude if motor threshold (MT) is not detected.

• Relative amplitude, % — stimulation amplitude depending on fixed motor threshold (MT) value.

• Pulses (bursts) frequency in train, Hz.

• Pulses frequency in burst, Hz.

• Pulses (bursts) in train.

• Pulses in burst.

• Number of trains.

• Intertrain interval, s.

• Waiting time, s — time to the next block.
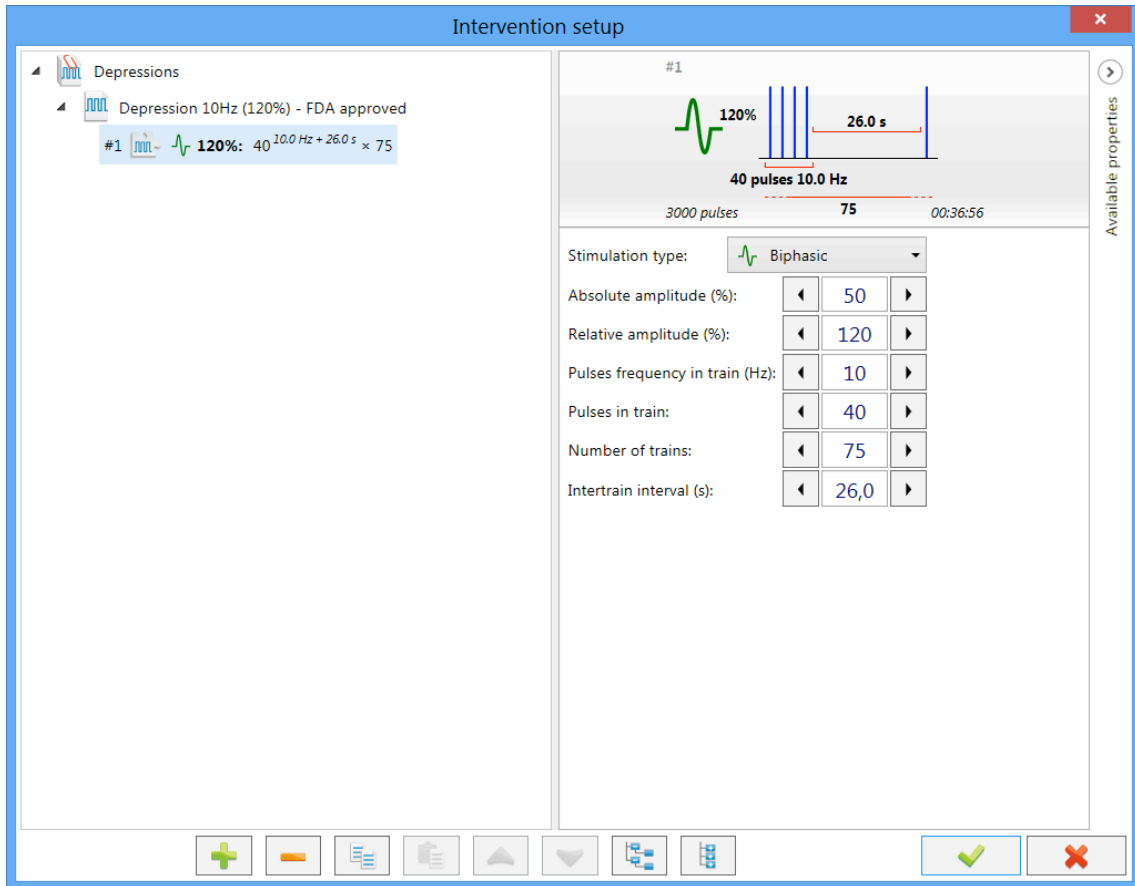
Fig. 117. Intervention protocols. "Block" element.

The ranges of the admissible stimulation parameters of blocks can be found in the list of specifications. However, the ranges of some parameters depend on current values of related parameters. For example, the range of "Pulses in burst" parameter is from 2 up to 10, but its maximal value depends on "Pulses frequency in burst" and "Bursts frequency in train" parameters. For more convenience Neuro-MS.NET software displays information windows about limitations of parameter ranges (Fig. 118). It occurs when some parameter reaches its boundary values when adjusting.
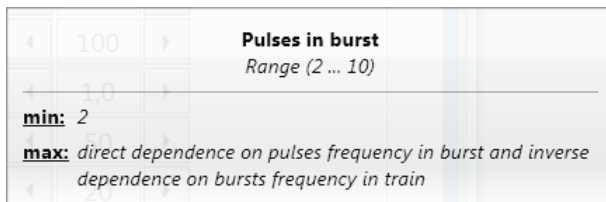
Fig. 118. The information window concerning limitations.

For the sake of simplicity all configured block parameters are shown graphically (see "Basic Notions" section).

> **Block name is based on its parameters. It makes record short and informative:**
>
> ▷ ⋀ **100%: 50** $^{5,0\ Hz\ +\ 20,0\ s}$ **× 40**
> Stimulation type: ⋀ Biphasic (⋀ Monophasic)
> Relative amplitude, %: 100
> Pulses in train: 50
> Pulses frequency in train, Hz: 5,0
> Intertrain interval, s: 20,0
> Number of trains: 40
>
> ▷ ⋀ **100%: [8** $^{50,0\ Hz}$ **× 20]** $^{1,0\ Hz\ +\ 10,0\ s}$ **× 40**
> Stimulation type: ⋀ Burst (designation: '**[**' '**]**')
> Relative amplitude, %: 100
> Pulses in burst: 8
> Pulses frequency in burst, Hz: 50
> Bursts in train: 20
> Bursts frequency in train, Hz: 1,0
> Intertrain interval, s: 10,0
> Number of trains: 40

Using control buttons located at the bottom of the dialog box, you can perform following actions:

- ➕ — add new group of interventions, new intervention or new block;

- ➖ — delete the selected element;

- 🗐 — copy the selected element;

- 📋 — insert the copied element;

- 🔺 — move the selected element one position higher;

- 🔻 — move the selected element one position below;

- 🔲 — expand all elements;

- 🔳 — collapse all elements;

To save settings press ✔ button and to cancel the changes press ✖ button.

5.18.4 Treatment Courses

To edit the course protocols, use **Setup|Treatment protocols** menu item. In the appeared drop-down menu choose **Treatment courses…**

> **The warning box appeared should inform you that any changes may result in the generation of treatment protocols that are not listed in the FDA recommended treatment protocols on rTMS (Fig. 119).**
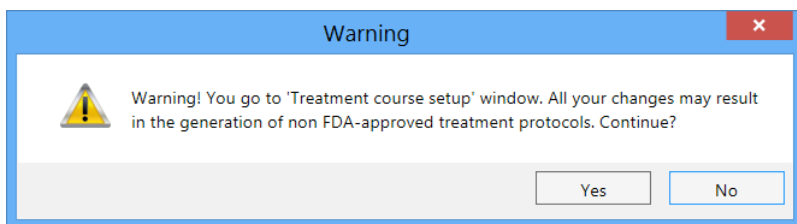
Fig. 119. Warning message.

"Treatment course setup" dialog box (Fig. 120) has two parts. The tree view list of courses divided into groups is located leftward and the list of settings to adjust is found rightward.

"Group of courses" element contains courses grouped by common feature. The parameters to adjust are name and comment.
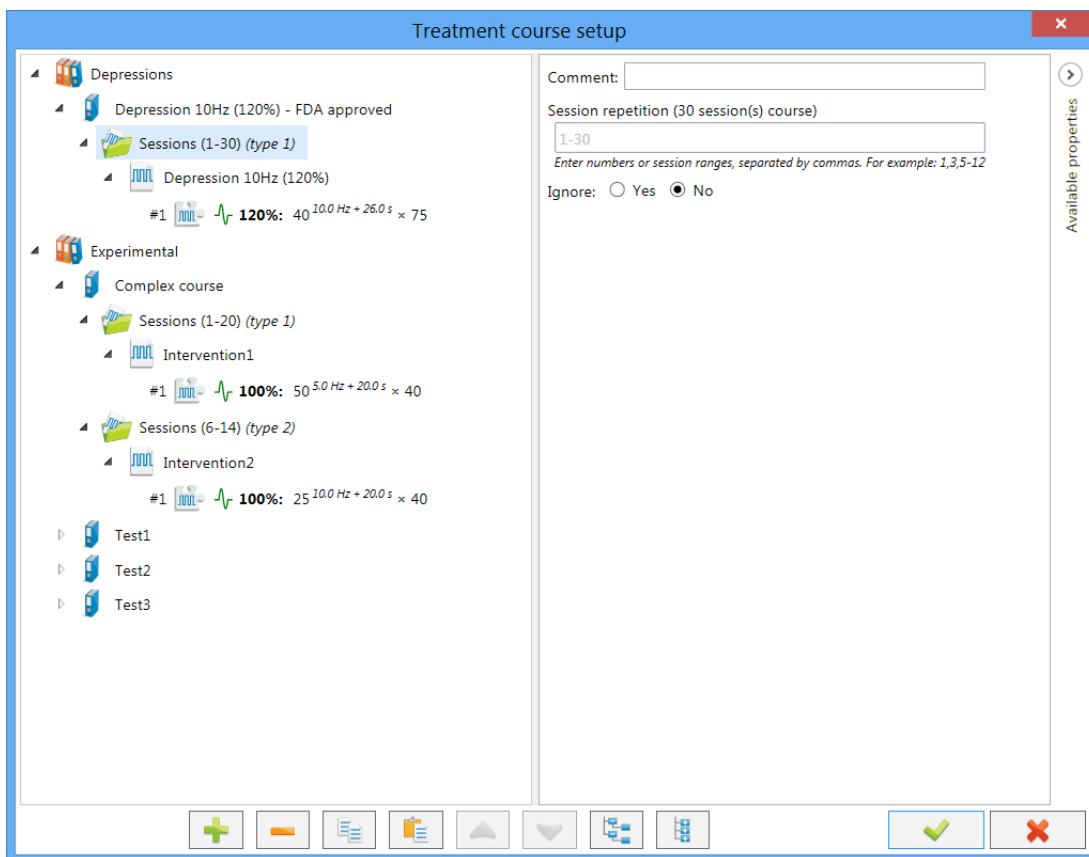
Fig. 120. "Treatment course setup" dialog box.

"Course" element contains treatment session types and allows to create simple and complex treatment courses. Besides course name and comment you can adjust two other parameters:

- "Number of sessions" —the maximum number of sessions in the course can be set. If this number is exceeded, the course is considered to be executed.

- "MT update period" — is used to define the validity of current MT value.

"Session type" element   describes treatment sessions with the same set of interventions. The most important parameters to adjust are:

- "Session repetition" — is used to set the range and/or numbers of sessions with the same set of stimulation interventions. If the repetition is not set, this session type will be used during the whole course.

- "Ignore" — is used to exclude temporarily the selected session type from course.

You can see the example of complex treatment course ("Complex course") in Fig. 120. It implies 20 sessions and contains two session types. "Intervention 1" of the first session type will be performed each time and "Intervention 2" of the second session type – only from 6 to 14 session. Thus, from 6 to 14 sessions the treatment will be performed using two interventions.

Descriptions of "Intervention" and "Block" elements are the same as in 4.18.3 "Interventions" section.

  button at the bottom of the dialog box is used to add new group of courses, new course, new session type, new intervention or block. Other buttons function in the same way as the ones described in 5.18.3 "Interventions" section.

To save settings press   button and to cancel the changes press   button.

6 Servicing

6.1 General Requirements

Safety measures when magnetic stimulator servicing conforms to the ones described in the chapter 4 "Proper Use".

Qualification requirements to the medical staff are listed in chapter 2.1 "Requirements to Personnel Conducting Stimulator Assembly and Installation

Servicing of the bought articles included in the magnetic stimulator delivery set is conducted according to user and technical manuals or typical rules.

When detecting the troubles it is recommended to use the information given in "Troubleshooting" section. If the troubles can't be eliminated using magnetic stimulator control units or by restart, it should be switched off and checked by the specialist.

Type, volume and periodicity of the servicing except specified in this chapter, are not determined.

The delivery set should correspond to the packing list of the medical equipment.

6.2 User Maintenance

Magnetic stimulator maintenance in the process of operation includes the external examination, check of connectors and cables, removal of contaminations from the surfaces of units using a cloth moistened in isopropyl alcohol. Make sure that the surfaces have dried before use.

6.3 Cleaning and Disinfection

1. Before cleaning the electronic units switch them off. Unplug the electronic unit from the mains socket. Before you clean, visually inspect the unit and its components for damage or wear. Contact Neurosoft if you notice damage to the exterior of the component.

2. For routine cleaning of electronic units use a cloth gently wrung in phenoles (Bacillotex® etc.) or 70% alcohol or 0,5% chlorohexidine.

3. If hepatitis or any other dangerous virus contamination is suspected use aldehydes (Cidex® etc.) or chlorinates (Diversol BX®).

4. Be careful not to drip disinfectant directly into the input and output plugs and other openings in the cover.

5. Remove disinfectant with a dry cloth.

Do not use abrasive agents, scrubbing pads or other abrasive applicators.

Keep all cleaning fluids away from electrical connectors.

6.4 Conservation

The magnetic stimulator components including accessories and operational documentation should be packed in separate plastic sachets and then placed in a manufacturer package.

6.5 Life Time

The stimulator life time is 5 years starting from the shipment date to a user. The life time of coils included in the delivery set is 1 year starting from the shipment date to a user. The manufacturer is obliged to provide the technical service of a stimulator and coils during its life time.

In case the coil is used intensely (more than 4 treatment sessions per day), it is recommended to replace it every 12 months.

The estimated service life of power capacitor is 20 000 000 stimuli. On generation of indicated number of stimuli perform the stimulus parameter diagnostics (is done by service engineer). The stimulator is equipped with nonvolatile counter of delivered stimuli. You can check its state using the system information menu (see chapter 6.7 "System Information").

6.6 Service Menu of Main Unit

The service menu of main unit is meant for the control of service functions, such as trigger pulse duration, turn on/off the cooling unit control.
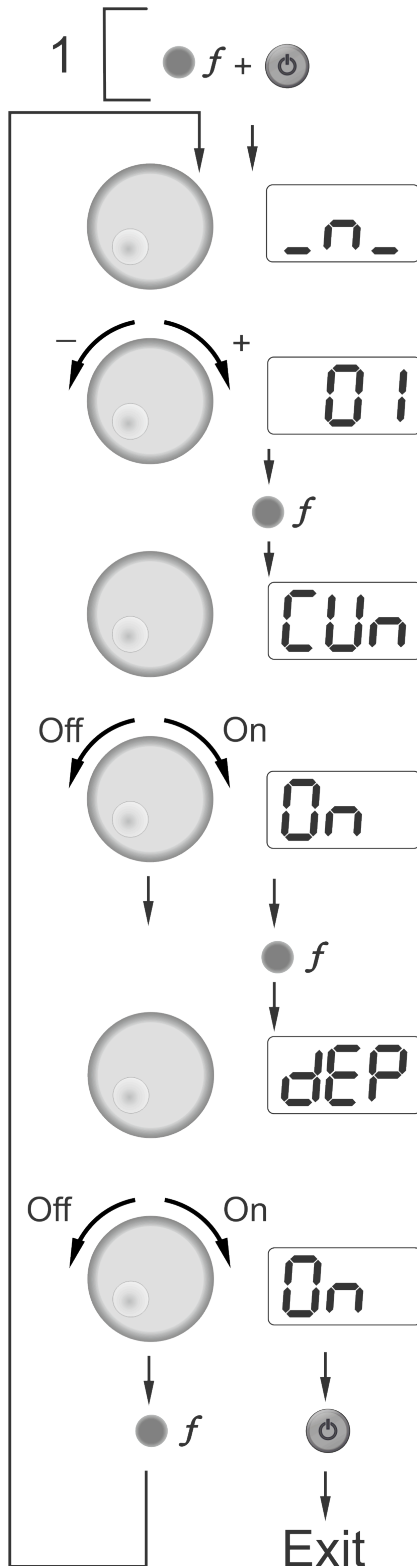
Fig. 121. Service menu of main unit.

1. To open the service menu press and hold "Stimulation frequency" button and press "On/Off" button located on the front panel when the stimulator is in stand-by mode.

2. The trigger pulse duration setup mode is activated. The symbol appears on "Amplitude" indicator and the trigger pulse width (in ms) (from 0 to 50, 0 position correspond to 10 µs pulse duration) is displayed on "Stimulation parameters" indicator. The duration is set by "Stimulation parameters" knob.

3. To activate the cooling unit control mode, press "Stimulation frequency" button once more. The "Amplitude" indicator displays and "Stimulation parameters" indicator displays setting state (— control is on, — control is off). To change the state, use "Stimulation parameters" knob. If you use the stimulator with NS058201.013 cooling unit, change setting to .

4. To activate the predefined protocol for depression treatment with the following parameters: frequency – 10 Hz, train – 5 sec, pause – 26 sec, session – 37.5 min, press "Frequency" button once again. The inscription will appear on "Intensity" indicator and "Stimulation parameters" indicator will show the current state (if -mode is enabled, the predefined settings are downloaded, if -mode is disabled, the settings saved before power supply switch off are downloaded). To change the state, use "Stimulation parameters" knob.

5. To return into the mode of trigger pulse duration setup, press "Stimulation frequency" button once again. To save settings and quit the service menu press "On/off" button on the front panel of the main unit.

6.7 System Information

The system information menu of main stimulator unit is used to check the number of delivered stimuli, firmware version and serial number of device (Fig. 122).
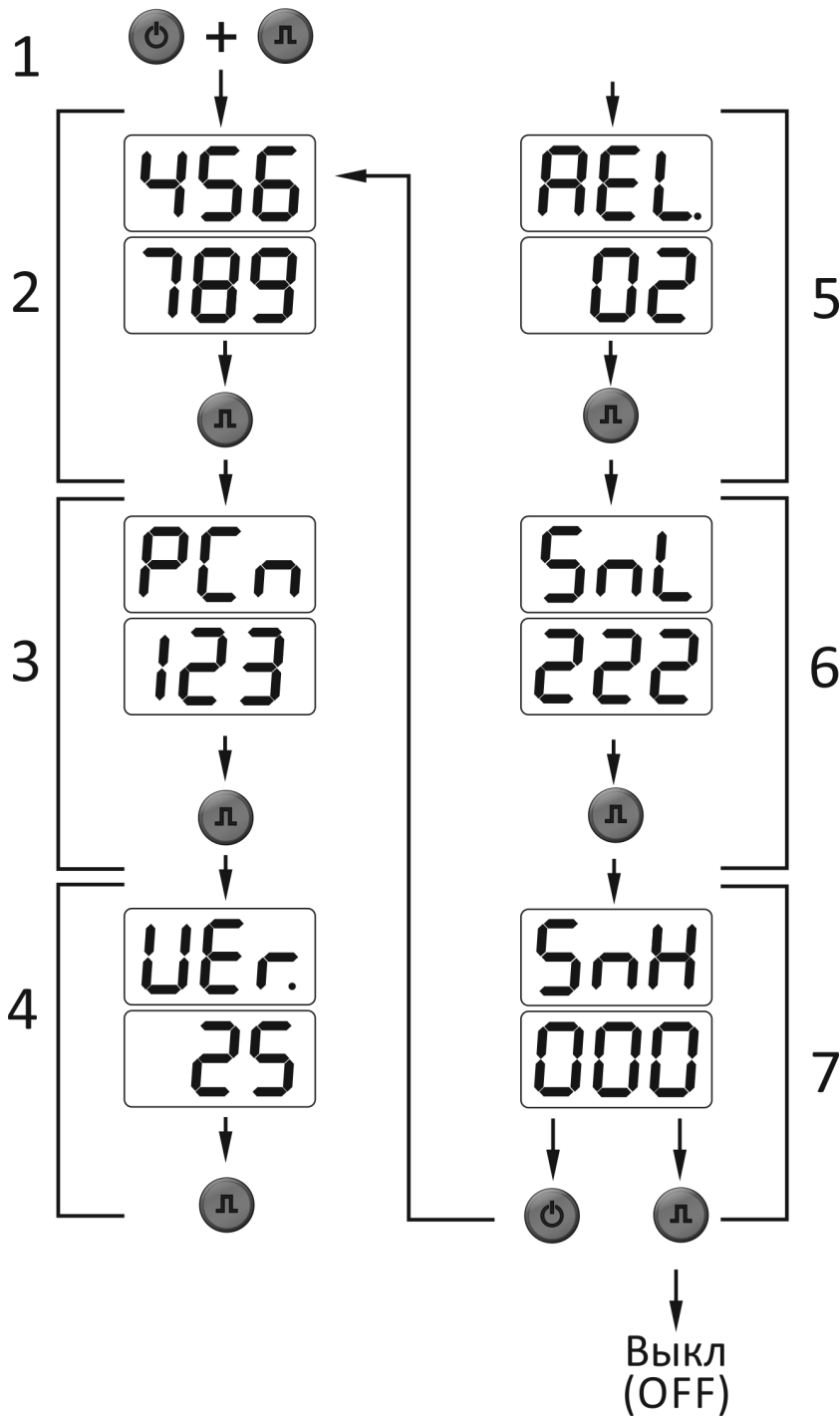
Fig. 122. System information menu.

1. When the stimulator is in stand-by mode you can enter the system information menu from the front panel of main unit. To do it, press and hold "Single pulse" button and press "On/Off" button.

2. On the first page of system information menu you can see the lower digits of delivered stimulus counter. The "Amplitude" indicator displays the stimulus value in thousands (from 000 to 999) and "Stimulation parameters" shows in units (from 000 to 999). To switch to second page, press "Single pulse" button.

3. On the second page of system information menu you can see the higher digits of delivered stimulus counter. The "Amplitude" indicator displays the PCn symbols (Pulse Counter) and "Stimulation parameters" shows the stimulus value in millions (from 000 to 999). To switch to third page, press "Single pulse" button.

4. On the third page of system information menu you can see the firmware version number. The "Amplitude" indicator displays VEr. (VErsion) symbols and "Stimulation parameters" indicator shows the firmware version. To switch to fourth page, press "Single pulse" button.

5. On the fourth page of system information menu you can see the number of the firmware release number. The "Amplitude" indicator displays REL. (RELease) symbols and "Stimulation parameters" indicator shows the firmware release number. To switch to fifth page, press "Single pulse" button.

6. On the fifth page of system information menu you can see the lower digits of serial number of device. The "Amplitude" indicator displays SnL (Serial number Low) symbols and "Stimulation parameters" indicator shows the serial number in units (from 000 to 999). To switch to sixth page, press "Single pulse" button.

7. On the sixth page of system information menu you can see the higher digits of serial number of device. The "Amplitude" indicator displays SnH (Serial number High) symbols and "Stimulation parameters" indicator shows the serial number in thousands (from 000 to 999). To switch to the first page, press "Single pulse" button. To return to stand-by mode, press "On/off" button.

7 Packing and Transportation

The package should conform to the accepted one when manufacturing and delivering. In case the factory package is damaged, but the long-term stimulator storage and transportation is expected, respect the following recommendations:

• The stimulator with operational documentation should be packed in plastic sachets and cardboard boxes.

• The cardboard boxes should be covered by the paper tape or pressure sensitive adhesive tape.

The stimulators can be transported by all kinds of covered carries (except non-heated airplane pods) according to rules of goods transportation for each mode of transport at temperature varying from -50 up to +50 C.

8   Storage

The magnetic stimulator should be stored in the manufacturer package in an enclosed room at from +5 up to +40°C and 80% maximum relative humidity (measured at 25°C temperature). The room air should be free from any dust, acid vapors, alkali vapors, corrosive gases and other injurous admixtures which can cause the corrosion.

The magnetic stimulator should be put on the shelves not more than in five lines.

If the system should be stored for a long time period it should be conserved in accordance with 9 "Conservation" chapter.

9   Conservation

The magnetic stimulator components including accessories and operational documentation should be packed in separate plastic sachets and then placed in a manufacturer package.

10   Disposal

The electronic units of magnetic stimulator and its accessories should not be disposed of in general waste. The device disposal should be performed according to your local regulations.

11   Delivery Set and Package Data

CloudTMS magnetic stimulator:

☐ main unit

serial number _____

☐ cooling unit

serial number _____

☐ extra power supply unit

serial number _____

is collected and packed according to TC 9442-009-13218158-2015.

Package report number _____

Package report date _____

The detailed information about the delivery set is described in the package report which is an integral part of the present document and should be kept along with it.

12   Warranty

12.1   The manufacturer guarantees the magnetic stimulator quality conformance to TC 9442-009-13218158-2015 requirements if the rules of operation, storage, transportation and mounting prescribed in the operational documentation are observed.

12.2   Warranty period for stimulator units is 24 months from the delivery date to the customer. The delivery date is the date of waybill for the stimulator. Warranty period for the coils is stated in "Coils for CloudTMS magnetic stimulator" technical manual.

There is no warranty for consumables.

The warranty period can be prolonged for the period from reclamation submission up to repair completion (chapters 13).

12.3   The operation of guarantee commitment is stopped if:

• the rules of operation, storage, transportation and mounting prescribed in the operational documentation are not observed;

• the warranty period is expired;

- a user brakes the seal without permission of the manufacturer.

12.4   The manufacturer is obliged to repair the equipment in case of breakdown during the warranty period free of charge. The repair is carried out in the service center of Neurosoft Company (5, Voronin str., Ivanovo, 153032, Russia) only if this manual is provided.

13   Reclamation Data

13.1   In case of system breakdown or faultiness in the period of warranty and also product defect detected when primary acceptance, the consumer should send written notification to Neurosoft Ltd., authorized European representative or nearest distributor. The actual list of Neurosoft Ltd. distributors is represented on the web site: http://www.neurosoft.com/en/pages/dealers. This notification should contain the following information:

- the consumer's name and the address;

- the serial number of the system (see the system labeling);

- the number and the date of the invoice or other document confirming the system purchase.

- the detailed description of failures. If it is possible indicate the reasons and circumstances preceding the fault detection (in addition it is recommended to add the test report, the exam data, photos and other materials allowing to solve the problem as soon as possible).

13.2   In case of system return to the service center for the repair or the replacement, the following rules should be observed:

- It should be decontaminated before sending to service center. Read rules of cleaning and disinfection in section 6.3 "Cleaning and Disinfection".

- it should be packed so to exclude the possibility of its damage during the transportation;

- the notice (see item 12.1) and these manual must be added to the system being returned.

14   Annex

14.1 Electromagnetic Emissions and Immunity

Guidance and manufacturer's declaration – electromagnetic emissions

The magnetic stimulator is intended for use in the electromagnetic environment specified below. The customer or the user of the magnetic stimulator should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment — guidance
RF emissions CISPR 11	Group 1	The magnetic stimulator uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The magnetic stimulator is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations' flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

The magnetic stimulator is intended for use in the electromagnetic environment specified below. The customer or the user of the magnetic stimulator should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV − contact	±6 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	±8 kV − air	±8 kV	
Electrical fast transient/burst IEC 61000-4-4	±2 kV − for power supply lines	±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
	±1 kV − for input/output lines	±1 kV	
Surge IEC 61000-4-5	±1 kV differential mode	±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
	±2 kV common mode	±2 kV	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 and 1cycle	20 ms	Mains power quality should be that of a typical commercial or hospital environment. If the user of the magnetic stimulator requires continued operation during power mains interruptions, it is recommended that the magnetic stimulator be powered from an uninterruptible power supply or a battery.
	40% U_T (60% dip in U_T) for 5 cycles	100 ms	
	70% U_T (30% dip in U_T) for 25 cycles	500 ms	
	120% U_T (20% dip in U_T) for 25 cycles	500 ms	
	<5% U_T (>95% dip in U_T) for 5 s	5000 ms	
Power frequency magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Note: U_T – is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The magnetic stimulator is intended for use in the electromagnetic environment specified below. The customer or the user of the magnetic stimulator should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the magnetic stimulator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands [1]	3 V	$$d = 1.17\sqrt{P}$$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$$d = 1.17\sqrt{P}$$ (80 MHz to 800 MHz); $$d = 2.33\sqrt{P}$$ (800 MHz to 2.5 GHz). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[1], should be less than the compliance level in each frequency range[2]. Interference may occur in the vicinity of equipment marked with the following symbol:

[1] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the magnetic stimulator is used exceeds the applicable RF compliance level above, the magnetic stimulator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the magnetic stimulator.
[2] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Notes:
1. At 80 MHz and 800 MHz, the higher frequency range applies.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended separation distances between portable and mobile RF communications equipment and magnetic stimulator

The magnetic stimulator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the magnetic stimulator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the magnetic stimulator as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter, W	Separation distance according to frequency of transmitter, m		
	150 kHz up to 80 MHz outside ISM bands $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.23\sqrt{P}$
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.689	3.689	7.379
100	11.667	11.667	23.333

Notes:

1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

3. For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

14.2 Footswitch Unit

The footswitch (Fig. 123) is included in the delivery set upon customer's request. It is connected to computer via USB interface. Pushing the pedal corresponds to execution of the menu command. You can also emulate the pressing of the buttons in dialog boxes using the pedals instead of keys (Table 12).

Table 12. Default footswitch commands.

Pedal	Menu command	Buttons in dialog boxes
"MT" tab		
Left	Stimulation|Fix MT	Enter
Middle	Stimulation|Intensity|Decrease	Tab
Right	Stimulation|Intensity|Increase	Esc
"Repetitive mode" tab		
Left	Stimulation|Start/Pause	Enter
Middle	Stimulation|Pause	Tab
Right	Stimulation|Stop	Esc

The footswitch can be customized (see section 5.15, "Hardware" page).

Fig. 123 The footswitch unit

Specifications of the footswitch are listed in the Table 13.

Table 13.

Parameters	Values
Dimensions	360x180x48 mm
Footswitch cable length	2.8 m
Footswitch weight	not more than 1.4 kg
Interface	USB

14.3 Patient Button

Patient button (Fig. 124) is included in the delivery set upon customer's request. It can be connected to computer via USB port and can be used for remote program control. Pressing on patient button corresponds to execution of menu command. If dialog boxes are opened, it corresponds to pressing of the keyboard button (Table 14).

Fig. 124 "Patient button" with two keys.

Table 14. Default "Patient button" commands

Button	Menu command	Buttons in dialog boxes
	"MT" tab	
1	**Stimulation|Intensity|Decrease**	**Enter**
2	**Stimulation|Intensity|Increase**	**Tab**
3	Stimulation|Fix MT	Esc
	"Repetitive mode" tab	
1	**Stimulation|Start/Pause**	**Enter**
2	**Stimulation|Pause**	**Tab**
3	Stimulation|Stop	Esc

Specifications of the patient button are listed in the Table 15.

Table 15.

Parameters	Values
Dimensions	100x48x25 mm
Patient button cable length	3 m
Patient button weight	not more than 0.12 kg
Interface	USB

14.4 Safety Screening Questionnaire for Transcranial Magnetic Stimulation (TMS)

Name/ID: _____ Date: _____

Current Age: _____ (in years)　Handedness: ☐ Left　☐ Right　☐ Ambi　Sex: ☐ M　☐ F　☐ Other

ALL INFORMATION WILL BE TREATED CONFIDENTIALLY

Table 16

Question	Yes	No
(1) Have you ever had an adverse reaction to TMS? If so, please describe. _____	☐	☐
(2) Do you have epilepsy or have you ever had a seizure/convulsion?	☐	☐
(3) Do you, or does any family member, have epilepsy/history of seizures?	☐	☐
(4) Have you ever had a fainting spell or syncope? If yes, describe. _____	☐	☐
(5) Have you ever had a stroke?	☐	☐
(6) Have you ever had a serious head injury (with loss of consciousness)?	☐	☐
(7) Have you ever had neurosurgery of any type (including brain or spinal cord)?	☐	☐
(8) Do you have any implanted device such as cardiac pacemaker, implantable cardioverter defibrillator (ICD), wearable cardioverter defibrillator (WCD), vagus nerve stimulators (VNS), aneurysm clips, cochlear implants, medical pump, deep brain stimulators, C SF shunt, intracardiac lines, magnetically activated dental implants, ferromagnetic ocular implants?	☐	☐
(9) Do you have any metal in your body such as shrapnel, pellets, bullets, surgical clips, facial tattoos with metallic ink or fragments from welding or metalwork?	☐	☐
(10) Do you have wearable infusion pump, implanted insulin pump, stents, filters, heart valves, magnetically programmable shunt valve, cervical fixation device, staples, sutures, VeryChip microtransponder or radioactive seeds?	☐	☐
(11) Do you suffer from frequent or severe headaches?	☐	☐

Table 18 (Continued)

(12) Have you ever had any other brain related condition (including psychiatric diagnoses)	Yes ☐	No ☐
(13) Have you ever had any illness that caused brain injury?	Yes ☐	No ☐
(14) Do you have hearing problems or ringing in your ears?	Yes ☐	No ☐
(15) Are you taking any psychiatric or neuroactive medications? For instance, antidepressants, antianxiety, antipsychotics, anticonvulsants, or anything else with nervous system effects? Please list. _____	Yes ☐	No ☐
(16) Are you taking any other medications or other drugs/substances? Please list. If any of these substances are illegal, please do still mark "yes" but do not write the name. We will contact you to confidentially discuss this in person to see whether TMS will be safe for you. _____	Yes ☐	No ☐
(17) Are you pregnant or do you have any reason to believe that you may be?	Yes ☐	No ☐
(18) Have you consumed alcohol in the past 24 hours?	Yes ☐	No ☐
(19) Did you have adequate sleep last night?	Yes ☐	No ☐
(20) Have you participated in a TMS study within the past 24 hours?	Yes ☐	No ☐

Signature_____   Date_____

14.5 Patient Treatment Record form

Table 17

Treatment Report					Name/ID:				
Date	Treatment session number	MT measurement number	Motor threshold measured	Treatment intensity calculated (120% of MT)	Rep. Rate	Pulses per train	Number of Trains	ITI, Inter Train Interval	Note
			%	%	pps			sec	

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