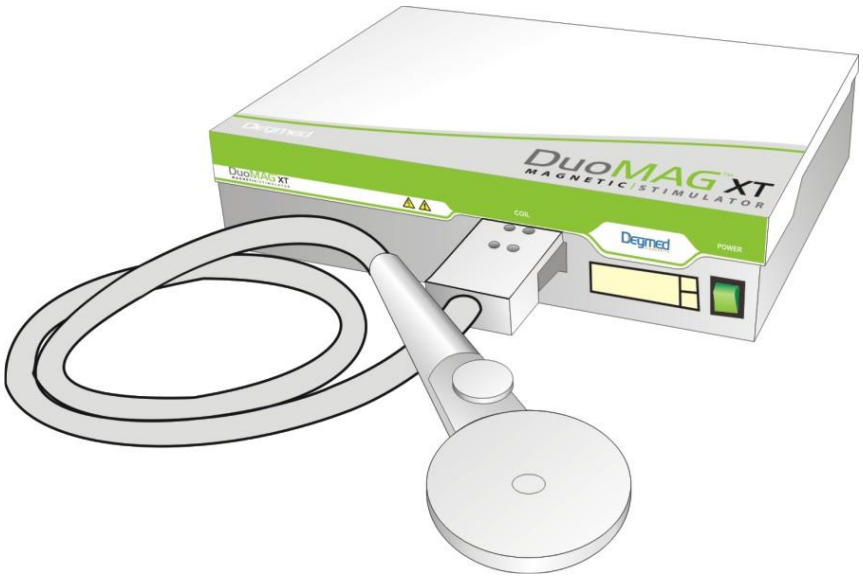
DuoMAG™

MAGNETIC | STIMULATION

Technical description and instructions for use



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DuoMAG TMS technical description and instructions for use
Revision: DM004-IFU1902EN
Date of issue: 14. 02. 2019

Content

1. Identification of the Product

Manufacturer

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Web: www.deymed.com
IČO: 25284584
DIČ: CZ25284584

Product type designation

DuoMAG comes in two types.

DuoMAG, type MP
DuoMAG, type XT

- model XT-10
- model XT-35
- model XT-100

Intended Use

Magnetic stimulator DuoMAG is intended to stimulate peripheral nerves and central nervous system by induced electrical current for diagnostic and treatment purposes.

It is manufactured in two versions, type MP - monophasic and type XT - biphasic, varying the shape of the stimulation pulse.

The Magnetic Stimulator type MP - Monophasic version is designed for low frequency stimulation of cortical, spinal and peripheral nerves.

The Magnetic Stimulator type XT - Biphasic variant is designed for both low and high frequency stimulation of cortical, spinal and peripheral nerves.

The magnetic stimulator is typically used for testing MEP (motor evoked potentials) may also substitute electrical stimulation upon examination of motor or sensory nerves.

High-frequency stimulation is used mainly for research purposes. The system is intended solely for use in a health care environment by users with professional medical qualifications, preferably with a neurological or psychiatrical specialisation.

The Magnetic Stimulator is usually used in conjunction with an EMG/EP or EEG device. The Magnetic Stimulator can be also connected with a frameless neuronavigation system.

	low-frequency* diagnostic application	low-frequency therapeutic application	high-frequency** mainly therapeutic application
DuoMAG, type MP	YES	YES	NO***
DuoMAG, type XT	YES	YES	YES

*) According to technical literature, low-frequency transcranial magnetic stimulation is considered to be frequencies lower than about 1 Hz.
**) According to technical literature, high-frequency transcranial magnetic stimulation is considered to be frequencies higher than about 1 Hz.
***) The monophasic type Magnetic Stimulator (DuoMAG type MP) is not physically capable of performing high-frequency repetitive stimulation.

Classification of DuoMAG Magnetic Stimulator

Classification according to Annex No. 9 Government Regulation No. 54/2015 Sb. as amended by Implementing Rule no.10 to Class IIa, active, non-sterile.

The Magnetic Stimulator is powered from the mains and is in safety class I (classification according to ČSN EN 60601-1).

Safety classification for Magnetic Stimulator: IP 20 (protected from touch by fingers, not protected from liquids).

The device is designed for continuous operation in non-explosive environments without anaesthetics.

Classification of the Stimulation Coils

Patient electrical isolation classification: BF.
Safety classification for stimulation coils: IP 20

Stimulation Coils 100R, 125R, 50BF, 50BFT, 70BF, 70BFP, 70BF-Cool, 70BFP-Cool and 120BFV are intended solely for use with DuoMAG Magnetic Stimulators. They are compatible with both types of magnetic stimulators, i.e. DuoMAG XT and DuoMAG MP.
A complete version of the declaration of conformity and certificate from the notified body confirming the requirements of the above-mentioned directive are available upon request from the Supplier.

Expected lifetime

The shelf life of the Magnetic Stimulator is set at 8 years from the date of installation. Life expectancy is at least 20,000 operating hours.

The shelf life of the Stimulation Coils 100R, 125R, 50BF, 50BFT, 70BF, 70BFP, 70BF-Cool, 70BFP-Cool and 120BFV is 5 years.

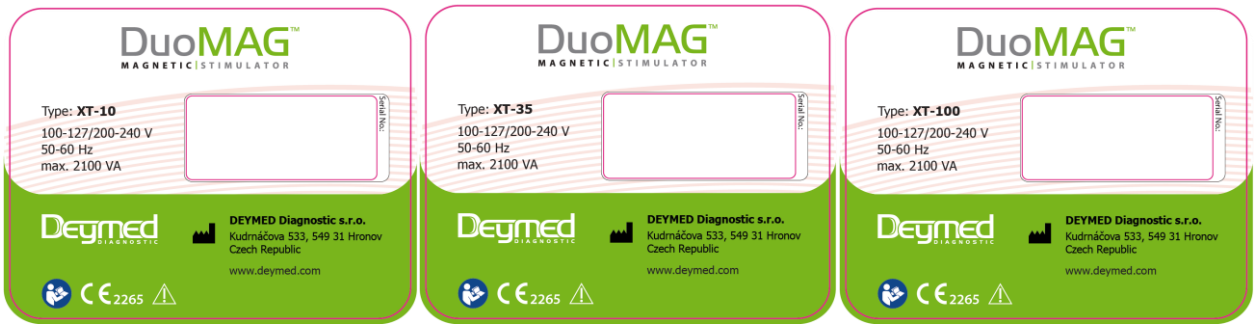
Production labels

Labeling of the DuoMAG Magnetic Stimulator

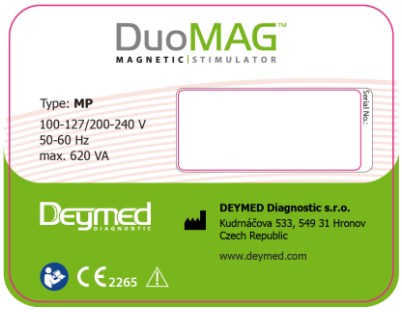
Patterns of magnetic stimulator DuoMAG XT and MP labels

Labeling of the magnetic stimulator DuoMAG

Sample DuoMAG type XT System label.



Sample DuoMAG type MP System label.



Labeling of the Stimulation Coil

The 100R, 125R, 50BF, 50BFT, 70BF, 70BFP, 70BF-Cool, 70BFP-Cool and 120BFV Stimulation Coil labels:

A description of used signs

Before connecting the device and its use to first carefully read the complete documentation

Using the device is accompanied by a number of risks, take note of warnings and cautions in this documentation, particularly in chapter 2

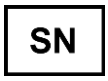
Warning **"DANGEROUS VOLTAGE"** Inside the device is a high voltage dangerous to life. The stimulator or stimulation coil is not allowed to repair, modify or open the cover.

Applied part: BF (classification of insulation according to ČSN EN 60601-1).

The manufacturer declares conformity with applicable standards assessed by notified person no. 2265

Manufacturer

Date of manufacture



Serial number

The device includes an RF transmitter

This product and its electronic accessories should not be mixed with other commercial wastes for disposal! For more information see chapter Disposal of the product.

Other definitions

Supplier = Manufacturer or its Authorized Representative.

Control PC / Control Software = Software in an external PC, laptop or similar device which controls the Magnetic Stimulator and displays its current state.

Description of light indicators

Location of indicator lights is shown in chapter Description of the Device.

Meaning of colored indicators:

- Red and Green indicators on = unconnected coil, overheated coil or defective Stimulation Coil.
- Red LED indicator only = overheated Stimulator or defective Stimulator.
- Green indicator lights only = the Stimulator is in the inactive (standby) mode or a stimulation is currently being given.
- The Green and the Orange indicator = Stimulator is charged at the set level and prepared for use.

2. Cautions and Warnings

To avoid risk of electric shock, the Magnetic Stimulator must be connected to a mains with a protected ground!

The Magnetic Stimulator must NOT BE USED on patients with electronic implants such as cardiac pacemakers, cochlear implants or other implanted electronic devices, doing so may lead to temporary disabling its function or permanent damage of the implanted devices.

The Magnetic Stimulator is also not allowed to be used in the immediate vicinity (approx. 30 cm) from metal spinal or joint implants! There could be an undesirable mechanical affect on the metal part and/ or heating to a level above their safety limits.

The Magnetic Stimulator can not be operated by a person with an implanted electronic device whose proper function can affect his life or health. Even a single stimulation pulse at inappropriate Stimulation Coil position may lead to damage of the implanted device or to affect its function. Implanted device is particularly intended a pacemaker and defibrillator (including retained electrodes after deplantation), neurostimulator, infusion device, vital signs monitor (heart rate monitor), aneurysmal vascular clips, cochlear implants.

The Magnetic Stimulator can not be operated by a person who has metal or ferromagnetic objects placed in or on the body. These objects if positioned in sufficient proximity to the Stimulation Coil and sufficient intensity of the stimulation pulse may get very hot or rapidly change their position. It is a ferromagnetic or metal bone or joint implants, intravascular implants (stents, venous filters), metallic valve replacement, ventricular brain drainage, metal fragments, splinters, also implanted electronic devices that are formed from metallic or ferromagnetic materials.

Cortical stimulation of higher intensity can cause epileptic seizures!

Stimulation of higher intensity near the heart can cause cardiac fibrillation!

The Stimulator is not allowed to be used near flammable or explosive gases or anaesthetics!

If the surface of the Stimulation Coils are not dry, it is forbidden to stimulate!

Do not attempt to disassemble the Stimulator, even after disconnecting the mains cable. The only user serviceable part is the replacement of fuses and the mains supply cable. Inside the Stimulator, a fault in the discharge circuit could give off life-threatening high voltages up to thirty minutes after shutting down and disconnecting the stimulator from the wall socket.

During stimulation there is an intense short sound, with the shape and sound very similar to an audio stimulation.

If it is necessary to stimulate at higher intensities near the ears, it is advisable to use protective ear plugs.

When attempting cortical stimulation in the vicinity of the ears, it is also advisable to remove any metal earrings. In this case, also remove any metal clips in your hair. The same applies to glasses, which the patient should also remove before any cortical stimulation. The main concern in this case would be the chance of the frames of the glasses being broken due to the stimulation. If it is necessary to stimulate patients with piercings, proceed in small steps from lower to higher stimulation intensities. Keep in mind that the resulting stresses exerted on the metal object are not linear with the applied intensity of stimulation, but with its square (raised to the second power). This means that with the increasing intensity of the stimulation, the effect sharply increases. The distance, orientation (with asymmetrical spot objects) and the position of the Stimulation Coil can have a major influence on the mechanical and thermal effects. Mechanical and thermal effects are otherwise directly related to each other. When stimulating peripheral nerves, the patient should take off watches, metal rings or any other metal jewellery.

Testing pregnant women is currently not recommended as there is not yet enough information to eliminate the safety risks of magnetic stimulation!

Increased intracranial pressure is a contraindication for repetitive magnetic stimulation.

Another magnetic stimulation contraindication is the presence of implants (cochlear, ocular, stents, clamps) and also for rTMS, electrically conductive ink tattoos placed near the stimulated position. Proximity means distance up to about 20 cm from the coil centre.

It is recommended that every hospital or lab using the TMS should provide patients with a questionnaire prior to receiving TMS/rTMS. This questionnaire should include questions on the presence of all conditions that could present contraindications and other potential problems.

Note: Unlike NMR (Nuclear Magnetic Resonance) the magnetic stimulator doesn't affect active magnetic units (Fe, Co, Ni - iron, cobalt, nickel alloys and magnets based on rare earth metals). It affects electric conductive materials no matter their magnetic activity. This is observable especially on loose parts approx. 2 cm diameter and bigger. It is also not allowed to stimulate near or around large metal surfaces, which in contrast, could damage the coils and/or destroy the stimulator.

Stimulation Coils 100R, 125R, 50BF, 50BFT, 70BF, 70BFP, 70BF-Cool, 70BFP-Cool and 120BFV are NOT intended for use inside a diagnostic NMR (nuclear magnetic resonance) imaging device. This may not only damage the coils due to larger mechanical stress, but also the expensive NMR equipment.

The Magnetic Stimulator, of its functional nature, must emit a relatively strong magnetic pulse that can affect the operation or even damage other medical devices, especially electronic. Risk of damage to electronic devices should be considered during stimulation in the immediate vicinity (less than about 30 cm) of these devices. Stimulation in the vicinity of about 30 cm to about 2 m from diagnostic medical devices can cause jamming of its signal or scanned image, but it should not affect their basic function (i.e., system failure, loss of data, interruption of communications, etc. should not occur).

Before turning on the power switch, be sure to first connect the Stimulation Coil. Before exchanging or swapping Stimulation Coils, either for the same or a different type of Coil (due to overheating or other reasons), first turn off the main power switch!

Before turning on the Magnetic Stimulator, check the power cord connection into the outlet. Check the integrity of the Stimulation Coil body, Stimulation Coil cable integrity and proper connection of the Stimulation Coil into the Magnetic Stimulator.

If when using the software interface of the Magnetic Stimulator, the intensity value displayed in the software and the intensity value displayed on the stimulator unit do not match, unplug the USB cable from the Control PC as you may have a defective Control PC or software problem.

If during stimulation the Stimulation Coil emits sounds noticeably different than you are used to, gives off any strange smell, changes its color, shape, or starts to overheat such that when touched, it burns the skin, discontinue use of the Coil and contact your supplier.

The surface of the Stimulation Coils can get hot during and after a longterm stimulation! It is expected that there may be incidental or accidental contact, although the Stimulation Coil is not intended for direct contact with the patient's skin.

During and after stimulation, the temperature on the surface of the Stimulation Coil may increase for several minutes (up to 60 °C), which is due to its high thermal inertia.

Stimulation coil is forbidden to cool liquids or ice. Cooling of the stimulation coil is only allowed under the following conditions: the stimulation coil must be disconnected from the magnetic stimulator, and the cooling requirements must be met with the requirement to maintain non-condensing air humidity on the surface of the coil during rapid transition between environments.

For power supply, use only the supplied power cord if it is damaged, do not repair it, but contact your supplier. It is forbidden to use extension cords!

The Magnetic Stimulator and/or Stimulation Coil are not allowed to be repaired by anyone not directly Certified and Authorized by the Manufacturer (except for replacing fuses of the same type). The Magnetic Stimulator can only be used with Stimulation Coils approved by the manufacturer! Some types of Stimulation Coils from other manufacturers can have a similar type of connector, but are still not made for use with this Magnetic Stimulator.

Do not block the fan vents at any time, even after use of the Stimulator. Keeping the fan unblocked prevents excessive heat from building up in the Stimulator and prolongs its life.

Any unqualified repair or modification of the Magnetic Stimulator could lead to the patient or operator threat or to damage or destruction of the device. Any modification of the Magnetic Stimulator, its Coils or included cables is not allowed!

When performing cortical stimulation, it is recommended to follow the maximum intensity and the frequency of stimulation limits, as described in Literature [1].

While the digital display and indicator lights are industrial quality parts, they could have failures which would be manifested by one or more of them not lighting up However, it is very unlikely, that the digital display or indicator LEDs would turn on in a situation when they shouldn't. To minimize the risk of misinterpretation, the user should check each time the stimulator is turned on to see that all LED indicators briefly light up (red, orange and green), and the numeric display briefly shows the number '188'. This potential warning is especially true if the device is operated independently without connecting to a control PC.

Please pay attention to these potentially misleading situations:

Video equipment is often equipped with the same type of connector and connects using the same or very similar cables (BNC connectors and cables). If you accidentally connect

the input or output BNC connector of the Stimulator to a video device, you would most likely not damage the video device or Stimulator. However, this is no way to guarantee. It is possible and even likely that the connection to the video input of the BNC connector would start a high frequency stimulation!

The RJ45 connector placed on the back of the Magnetic Stimulator is intended for use only with Deymed EEG/EMG devices. As with the previously mentioned BNC connectors, this connector is also designed for synchronization and starting the stimulation. If you connect a standard network UTP cable to this connector, it should probably not lead to the damage of the network components or the Magnetic Stimulator. However, this is no way to guarantee. It is possible that this kind of connection would start a high frequency stimulation, it is necessary before connecting any cables turn off the magnetic stimulator!

In the event of mechanical or electrical failure of the Stimulator, turn the Stimulator off and contact the supplier, as the only allowable repair by the user is changing the fuses of the same type and nominal current. However, it is appropriate to entrust the replacement of fuses to professional staff. After replacing the fuse or fuses, do not forget to tighten their cover. With repeated interruptions of protective fuses turn off the device by main switch, unplug it and contact the supplier. Before replacing any fuses of the Stimulator, be sure to disconnect it from the power mains!

To the control PC it is forbidden to connect any device that does not meet the standards of ČSN EN 60601-1, especially external drives with its own power supply.

Ethernet cable (connected via RJ45 connector) must not be connected without the use of a network switch or separator that meets the standards of ČSN EN 60601-1.

3. Indications and Contraindications

Indications

Diagnostic application

Multiple sclerosis (MS),
Amyotrophic lateral sclerosis (ALS),
Cerebrovascular accident (CVA)
Parkinson's disease,
Dystonia,
Traumatic brain injury,
Spinal cord injury,
Bell's palsy,
Guillain-Barré syndrome,
Demyelinating polyneuropathy,
Epilepsy,
Corpus callosum agenesis / disgenesis.

Therapeutic application

Depression

Contraindications

Absolute:

1. electronic implants - cardiac pacemakers,
2. metal spinal or joint implants in the immediate vicinity (approx. 30 cm) to the stimulation position,
3. increased intracranial pressure,
4. implants (cochlear, ocular, stents, clamps) and electrically conductive ink tattoos placed near the stimulated position (approx. 20 cm)

Relative:

1. gravidity,
2. childhood - risk acceptance should be considered in connection with not fully developed hearing.

4. Installation and commissioning

Operation, Storage and Transportation conditions

Operation conditions:

- temperature: 5 °C to 35 °C
- relative humidity: 10-80 %, non-condensing
- atmospheric pressure: 50 kPa -107 kPa

Storage and transportation conditions:

- temperature: -25 °C to 45 °C
- relative humidity: 10-80 %, non-condensing
- atmospheric pressure: 50 kPa -107 kPa

Note: atmospheric pressure of 50 kPa corresponds to an altitude of about 5,500 m above sea level.

Note: If the device has been moved from a long stay in a cold area to a warmer area, let it acclimatise for at least an hour before using. This will ensure evaporation of condensed humidity. When transporting, it should be noted that the weight inside the unit may not be distributed evenly.

When transporting the Magnetic Stimulator in a position other than lying down, it can damage the BNC or display panel due to its own weight, therefore, in transport, use the supplied shipping container or transport stimulator in working position (lying down) and keep it from shifting or moving under its own weight in the transport area. Disconnect the Stimulation Coil during transport to avoid mechanically stressing the mount socket or connector.

Situate the device so the power cord of the Magnetic Stimulator is accessible and it can be simply unplugged from the mains power socket.

Recommended room equipment

The following recommendations are not neccessary, however they lead to improved durability, performance parameters and quality of operation.

Use a separate electrical circuit wiring for the device.

Do not mechanically or thermally stress the power cable. Keep the cable leading directly from the socket to the device and do not conflict it with other cables.

Utilising air-conditioning capable of maintaining the temperature at 20 °C, especially for performing longer therapeutic protocols, extends the maximum duration of the protocol until the Stimulation Coil overheats.

An electromagnetically shielded room has an impact, particularly on the signal quality in measurements related to the TMS method (such as EEG or EMG).

Device installation

The device is installed on site by the service technician of the supplier.

Device commissioning

When the device is installed, the service technician will test the device, introduce it to the user and give the training course.

Electromagnetic Compatibility

Class and group of emission

Group 1 – Class A

Environment description

The device can be operated only in a professional health care environment.

NOTE: The EMISSIONS characteristics of this device make it suitable for use in industrial areas and hospitals (class A according CISPR 11). If it is used in a residential environment (for which is normally required class B according CISPR) this device might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Functionality of the device when used with other devices

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

The magnetic stimulator has been tested in a block or adjacent configuration with the following devices:

- Elektromyograph TruTrace EMG
- Elektroencefalograph TruScan EEG
- Neuronavigation Brainsight TMS
- Control PC (only types specified or provided by the manufacturer)
- USB hub (only types specified or provided by the manufacturer)

List of all cables and maximum lengths and other accessories

The list is provided in chapter Consumables.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Magnetic stimulator DuoMAG, including cables specified by the manufacturer. Otherwise, it may cause functionality deterioration of this device

RF transmitter contained in the control PC

The control PC may contain an RF transmitter.

All operating frequencies or frequency bands for the transmission of this RF transmitter are given in the accompanying documentation of the control PC, which also contains information on the declaration of conformity with the requirements of the standards.

Effect of other devices and influencing by other devices

The Magnetic Stimulator, of its functional nature, must emit a relatively strong magnetic pulse that can affect the operation or even damage other medical devices, especially electronic.

Risk of damage to electronic devices should be considered during stimulation in the immediate vicinity (less than about 30 cm) of these devices. Distances mean the distance from the nearest point of the application portion of the stimulation coil. During stimulation at this distance from another electronic medical device, there is real risk of data loss, disturbance or interruptions of communication, failure or the restarting of the system, etc.

Stimulation in the vicinity of about 30 cm to about 2 m from diagnostic medical devices can cause jamming of the signal or scanned image, but it should not affect their basic function (i.e. system failure, loss of data, interruption of communications, etc.).

Extremely sensitive, especially electrophysiological devices (EEG, EKG, EMG, etc.) often interfere with the so-called stimulation artifact into the input electrodes of amplifiers even at relatively large distances (more than 2 m), more in the chapter Use in Conjunction with EMG / EP, EEG device or neuronavigation.

Stimulation coils DuoMAG type: 100R, 125R, 50BF, 50BFT, 70BF, 70BFP, 70BF-Cool, 70BFP-Cool and 120BFV are not intended for use with the NMR device, however, the magnetic stimulator alone may be used in rooms or near the NMR of the instrument after its additional interference. NMR instruments are extremely sensitive to electromagnetic radiation in the range of tens of MHz. To use the Magnetic Stimulator near an NMR device, contact the vendor, as you may need to provide additional electromagnetic shielding of the electric mains inputs from the Magnetic Stimulator using additional filters.

One of the few basic ways to eliminate or reduce interference to nearby devices, is to increase the distance between the point of stimulation and these devices. When using instruments sensitive to fluctuations in the mains voltage, it is appropriate to connect the Magnetic Stimulator to a separate outlet circuit.

On the other hand, the magnetic stimulator is not affected by other medical devices.

Compliance for each emission and immunity standard

Emission

The DuoMAG Magnetic Stimulator meets the requirements for conduction-disturbed emission and electromagnetic emissions for group 1, class A according to ČSN EN 55011 ed. 4:2010+A1:2017

Conducted emisions on network clamps according to ČSN EN 55011

Frequency range MHz	Limit value dB [µV]	
	Quasi-peak value	Mean value
0,15 – 0,50	79	66
0,5 – 5	73	60
5 – 30	73	60

Radiated emissions (distance 10 meters) according to ČSN EN 55011

Frequency range MHz	Limit value dB [µV/m]
	Quasi-peak value
30	40
230 - 1000	47

Radiated emissions (distance 3 m) according to ČSN EN 55032

Frequency range MHz	Limit value dB [μA]	
	Quasi-peak value	Mean value
1000 - 3000	76	56
3000 - 6000	80	60

Magnetic stimulator DuoMAG meets the requirements of ČSN EN 61000-3-2 ed. 4: 2015 to the harmonic currents injected into the public grid for class A.

Magnetic stimulator DuoMAG meets the requirements of ČSN EN 61000-3-3 ed.3:2014 for voltage changes, voltage fluctuations and flicker in low voltage grids for equipment with a rated phase current ≤ 16 A not subject to conditional connection.

Immunity

The magnetic stimulator DuoMAG meets the immunity requirements:
Electrostatic discharge according to ČSN EN 61000-4-2 ed. 2:2009
test level of immunity:

- for contact discharge: ± 8kV
- electrostatic discharge (ESD): ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV

Radiated high-frequency electromagnetic field according to ČSN EN 61000-4-3 ed. 3: 2006 + A1: 2008 + Z1: 2010 + A2: 2011

Frequency	AM	Frequency of modulation	Polarization	Intensity of field [V]
80 MHz - 2.7 GHz	80%	1 kHz	Horizontal	3
80 MHz - 2.7 GHz	80%	1 kHz	Vertical	3

Frequency [MHz]	Band [MHz]	Function	Modulation	Power [W]	Intensity of field [V]
385	380 - 390	TETRA 400	PM 18 Hz	1,8	27
450	430 - 470	GMRS 460, FRS 460	PM 18 Hz	2	28
710	704 - 787	LTE 13,17	PM 217 Hz	0,2	9
745					
780					
810	800 - 960	GSM800/900, 800 TETRA, iDEN 820, CDMA 850, LTE 5	PM 18 Hz	2	28
870					
930					
1720	1700 - 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE 1,3,4,25, UMTS	PM 217 Hz	2	28
1845					
1970					

Fast electrical transient phenomena/groups of impulses according to ČSN EN 61000-4-4 ed. 3:2013

- test level of immunity: ± 1kV, ± 2kV
- repetition frequency: 100 kHz

Surge impulse according to ČSN EN 61000-4-5 ed. 3:2015
test level of immunity:

- between the line: ± 0,5, ±1kV
- between leadership(s) and ground: ± 0,5, ±1kV ± 2kV

Immunity to interference caused by power lines, induced by high-frequency fields according to ČSN EN 61000-4-6 ed. 4:2014
test level of immunity:

- 3 V/m for radiated high frequency: 0,15 MHz to 80 MHz
- 6 V/m for radiated high frequency: in ISM bands between 0,15 MHz to 80 MHz 80% AM at 1kHz

Magnetic field of network frequency according to ČSN EN 61000-4-8 ed. 2:2010
test level of immunity of the magnetic field of the network frequency (50/60 Hz):

- 30 A/m 50 or 60 Hz

Short-term voltage drops, short interruptions and slow voltage changes according to ČSN EN 61000-4-11 ed. 2:2005

test level of immunity, short-term voltage drops:

- 0 % UT per 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°;
- 0 % UT, 1 cycle;
- 70 % UT, 25/30 cycle;
- Single phase: at 0°.

test level of immunity, voltage interruptions:

- 0 % UT, 250/300 cycle

Standards have been applied without any deviations.

5. Description of the Device

Front Panel

1 2 Power connector	5 Yellow indicator
3 Stimulator display	6 Green indicator
4 Red indicator	7 Main switch

1 2 Power connector
It is used to connect the stimulation coil (1), including the communication connector (2).

3 Stimulator display
Display showing the set stimulation intensity of the stimulator as a percentage of its maximum value.

4 Red indicator
FAILURE - lights up when the Stimulation Coil is disconnected or defective, or due to malfunction of the stimulator.

5 Yellow indicator
FULL CHARGE - lights up when the unit is ready for stimulation (charged to a preset intensity).

6 Green indicator
READY - lights when the unit is in operation and ready for use.

7 Main switch
O = OFF, I = ON

The Rear Panel

1	C20	5	RJ45 connector
2	Fuses	6	BNC connector
3	USB-B	7	Fuses
4	BNC connector	8	AC OUT

1 C20

Appliance inlet for connection of the power cord connector C19.

2 Fuses

Fuse housing of supply fuses, see technical data

3 USB-B

Socket (type B) connected to the Control PC.

4 BNC connector

BNC connector TTL IN provides external synchronized control of stimulation, see technical data.

5 RJ45 connector

Connect a cable to the I/O port of the Deymed USB Adapter, see technical data.

6 BNC connector

BNC connector TTL OUT used to output the synchronization trigger, see technical data.

7 Fuses

Fuse housing of supply for the external DuoMAG Touch-screen Control PC (T1, 25A), see technical data

8 AC OUT

AC OUT 110/230V max 100 VA for power supply to DuoMAG Touch Screen Control PC.

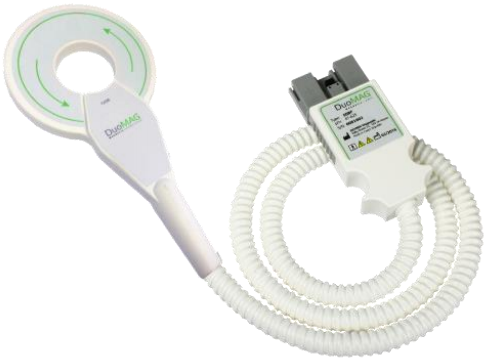
Assembly of the Magnetic Stimulator

Insert the Stimulation Coil connector fully into the socket **(1)** in the centre of the front panel of the Magnetic Stimulator (with the label **COIL**). Connect the power cord of the Magnetic Stimulator into the mains power socket. Now the Magnetic Stimulator is ready to run. The Magnetic Stimulator can also be connected to a PC with the Control Software, via a standard USB cable but the Stimulator is still able to work without the Control PC, albeit with only single pulses.

Stimulation Coils

Stimulation Coil DuoMAG 100R
Typical use:
Stimulation of peripheral nerves or shallow cortical stimulation.

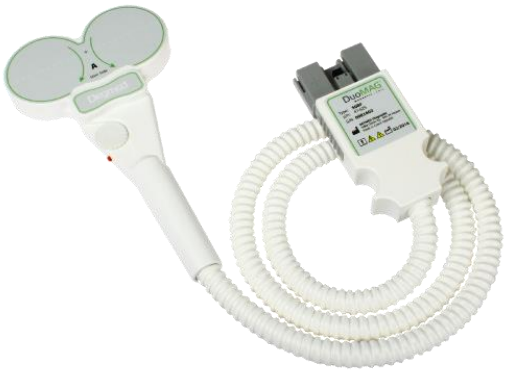
Stimulation Coil DuoMAG 125R
Typical use:
Spinal stimulation.



Stimulation Coil DuoMAG 50BF

Typical use:

Very focused cortical stimulation, mainly for rTMS. Paired pulse stimulation with twin coil configuration due to smaller size.



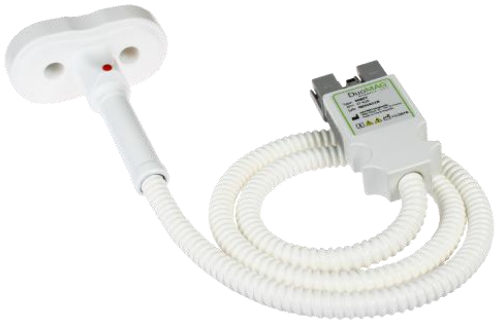
Stimulation Coil DuoMAG 50BFT

No intensity control wheel on this type.

Typical use:

Very focused cortical stimulation, mainly for rTMS. Paired pulse stimulation with twin coil configuration due to smaller size.

Coil handle oriented perpendicular to the coil plane.



Stimulation Coil DuoMAG 70BF

Typical use:

Focused cortical stimulation, mainly for rTMS.

Stimulation Coil DuoMAG 70BFP (70BFP1, 70BFP2)

Typical use:

For blinded studies.

Stimulation Coil DuoMAG 70BF-Cool

Typical use:

Focused long-term cortical stimulation, mainly for rTMS.

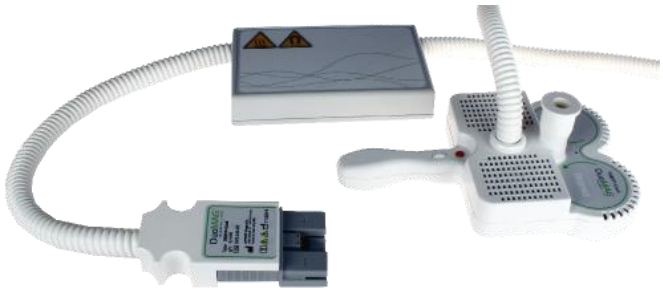
Can be used with the counterweight balanced coil-holder. on MagTower Configuration.

Stimulation Coil DuoMAG 70BFP-Cool (70BFP1-Cool, 70BFP2-Cool)

Typical use:

For blinded studies.

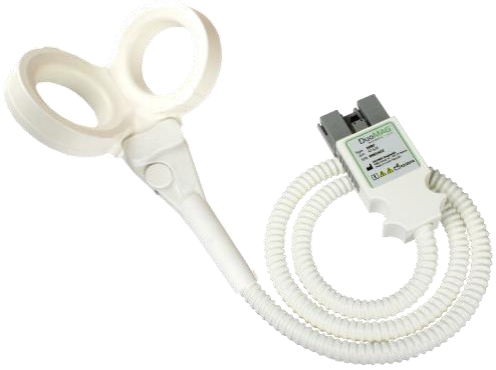
Can be used with the counterweight balanced coil-holder. on MagTower Configuration.



Stimulation Coil DuoMAG 120BFV

Typical use:

Deep cortical stimulation.

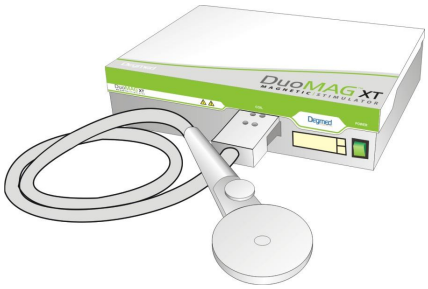


Configuration and assembly

DuoMAG , type XT

Desktop Configuration

The DuoMAG XT can be put on a desktop or similar in this compact space-saving configuration.



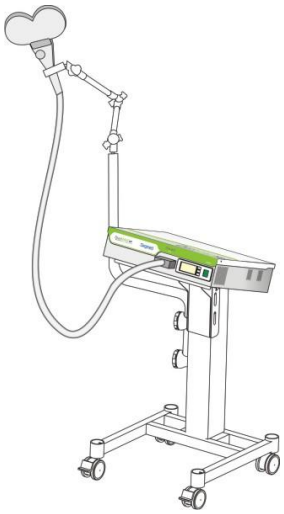
MagCart Configuration

The MagCart configuration is an easy to move configuration that takes up minimal space. An articulating arm allows the coils to be quickly locked into place after positioning.

It is not allowed to put on the arms any devices except the ones specified by the manufacturer (typically EMG headbox, All-In-One PC, Stimulation coil).

Before unbraking the cart it is necessary to put the arms as close to the cart as possible and lock it.

Release all the wheel brakes to move the Magnetic Stimulator cart. Before using the Magnetic Stimulator on the cart reapply all the wheel brakes.



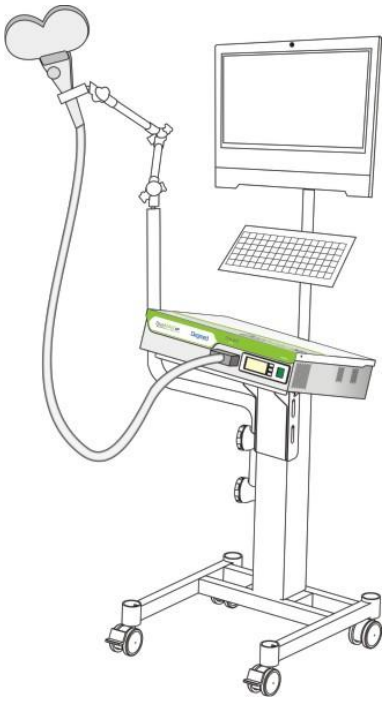
MagCart Configuration with PC

The MagCart configuration is an easy to move configuration that takes up minimal space. An articulating arm allows the coils to be quickly locked into place after positioning. A touch-screen is optional and may be added.

It is not allowed to put on the arms any devices except the ones specified by the manufacturer (typically EMG headbox, e PC, Stimulation coil).

Before unbraking the cart it is necessary to put the arms as close to the cart as possible and lock it.

Release all the wheel brakes to move the Magnetic Stimulator cart. Before using the Magnetic Stimulator on the cart reapply all the wheel brakes.



MagTower Configuration

The MagTower is an innovative counterweight balanced coil-holder for TMS. This significantly lowers the weight of the coils for use in any scenario where the user doesn’t want to struggle with difficult coil positioning, especially when finding the motor threshold. Locking the position is easy with the click of a footswitch. A touch-screen interface includes protocol design and control and MEP visualisation with EMG module.

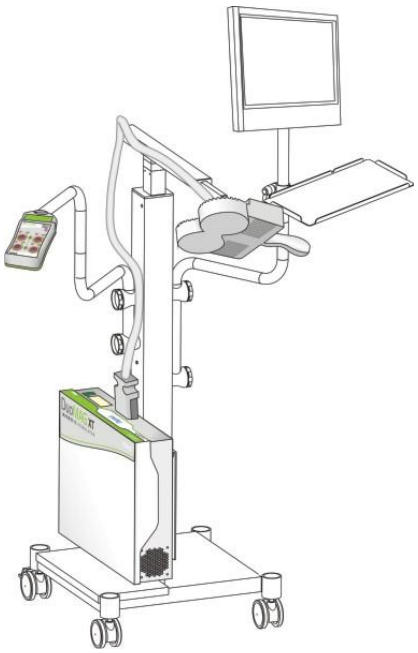
It is not allowed to put on the arms any devices except the ones specified by the manufacturer (typically EMG headbox, All-In-One PC, Stimulation coil)

Stimulation Coil position can be electromagnetically locked.

Magnetic Stimulator can be controlled from the Touch-screen PC. The cart is supplied with the EMG recording headbox.

Before unbraking the cart it is necessary to put all the arms as close to the cart as possible and lock it.

Release all the wheel brakes to move the Magnetic Stimulator cart. Before using the Magnetic Stimulator on the cart reapply all the wheel brakes.



DuoMAG , type MP

Desktop Configuration

The DuoMAG MP or DuoMAG MP-Dual can be placed on a desktop or similar in a compact space.

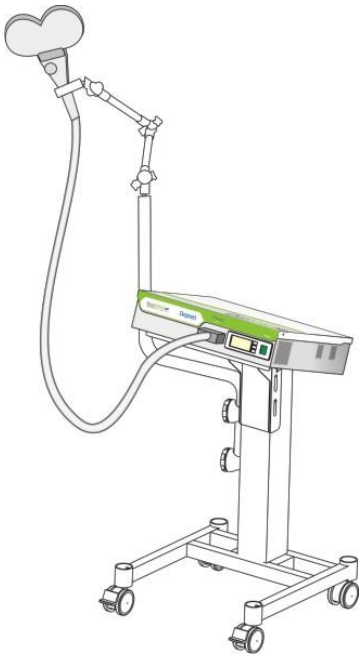
MagCart Configuration

The MagCart configuration is an easy to move configuration that takes up minimal space. An articulating arm allows the coils to be quickly locked into place after positioning.

It is not allowed to put on the arms any devices except the ones specified by the manufacturer (typically EMG headbox, All-In-One PC, Stimulation coil)

Before unbraking the cart it is necessary to put the arms as close to the cart as possible and lock it.

Release all the wheel brakes to move the Magnetic Stimulator cart. Before using the Magnetic Stimulator on the cart reapply all the wheel brakes.



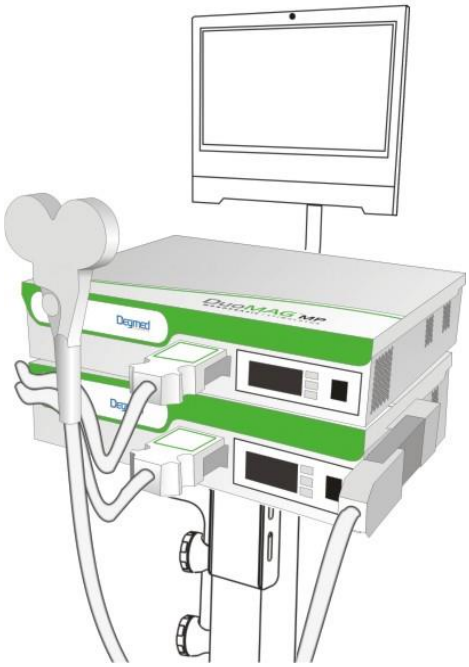
DuoMAG MP-Dual Configuration on cart

The MP-Dual with Cart is a flexible configuration for advanced research and clinical uses of two or more of Deymed's Mono-phasic stimulators. This configuration allows the user to perform paired-pulse mono-phasic stimulation with full control of all stimulation parameters at the touch of the screen. This configuration allows the user to easily move the system from room-to-room.

It is not allowed to put on the arms any devices except the ones specified by the manufacturer (typically EMG headbox, All-In-One PC, Stimulation coil)

Before unbraking the cart it is necessary to put the arms as close to the cart as possible and lock it.

Release all the wheel brakes to move the Magnetic Stimulator cart. Before using the Magnetic Stimulator on the cart reapply all the wheel brakes.



Use in Conjunction with EMG / EP, EEG device or neuronavigation

The DuoMAG system can be used in conjunction with Deymed TruScan EEG, Deymed TruTrace EMG, Brainsight TMS Neuronavigation.

All devices that you intend to connect, either via BNC connectors or the USB interface, must meet the standards of ČSN EN 60601-1 The minimum distance from the Stimulation Coil surface should be at least 30 cm. Wires from electrodes should not be, in any scenario, twisted in such a way as to form a coil!

The magnetic stimulation creates a relatively large stimulus artifact. It can be reduced in several ways:

Using shielded cables or a twisted pair of electrodes for each bipolar lead, or group wires that are close to each otherwithout creating a loop. The grounding electrode should also be as close as possible to the active electrodes. Be careful not to stimulate in the direct vicinity of user placed electrodes. At higher stimulation intensities, this can cause a severe mechanical bias, even causing the firing off of the electrode in any direction. It can also lead to rapid heating to a temperature that is able to cause thermal irritation, in extreme cases, this heating can even cause a burn. Also, in extreme circumstances, it can not be excluded that damage may occur to the input circuitry of the EMG / EP or EEG devices. Yet, in compliance with the above rules, damage is not likely to occur. Reduction of

transient impedance at this type of stimulation, usually only partially decreases the stimulating artifact.

The Magnetic Stimulator can affect sensitive electrophysiological devices during the short interval of stimulation and also after the stimulation during the charging of the high voltage capacitors. As a general rule, the effect of interference field decreases for distances greater than the diameter of the Stimulation Coil cubed (to the third power).

It is advisable to use a separate power outlet with other electrophysiological devices. This will ensure not only a lower penetration of the stimulus artifact to the electrophysiological signal, but also protects against and suppresses a slight fluctuation of the mains power during recharging of the high power Magnetic Stimulator's high voltage capacitors, which can also cause artifacts to the signal.

Connection with neuronavigation systems improves accuracy of the Stimulation Coil positioning. To connect the neuronavigation with the DuoMAG system use a BNC cable to connect the stimulators TTL OUT connector with the TTL IN connector of the neuronavigation. There are no other necessary settings on the stimulator side. For settings of the neuronavigation see the relevant Instructions for use.

All the supported devices connectable to the DuoMAG system are supplied with the Instructions for Use.

Note:
While we call it a magnetic stimulator, the actual electrophysiological effect is to provide an electrical field. The size of the induced voltage in practical terms does not depend on the impedance of the stimulated tissue. In this way, stimulation using a magnetic stimulator is not unlike using a voltage stimulator.

6. Operating the system

Operating the Magnetic Stimulator

Only a trained authorised personnel with knowledge of the TMS / rTMS methods should operate the system. Patients are not allowed to operate the system!

Description of the Device Controls

Turning on and operating the Magnetic Stimulator

Before turning on the Magnetic Stimulator, check the power cord connection into the outlet. Check the integrity of the Stimulation Coil body, Stimulation Coil cable integrity and proper connection of the Stimulation Coil into the Magnetic Stimulator.

Turn the power switch to the ON position **(I) (7)**. When the power is switched on, all the display segments and color indicators shine for 2 seconds. At this moment the indicators correct function can be checked. The display shows a value 188 and Red, Orange and Green indicators shine together. If one of the display segments or color indicators do not shine, turn off the device, stop using it and contact your supplier. Non-functional light indicators could lead to misunderstanding of the current device state for the user.

If a Stimulation Coil is connected and the Stimulator recognizes its parameters correctly, the display of the Magnetic Stimulator **(3)** shows two dashes (– –) and the Green indicator **READY (6)**. This is the default error-free condition of the Magnetic Stimulator - status **STANDBY**, when the device is ready for use, but the internal capacitors to provide power for the Stimulation Coil are exhausted or not yet fully recharged.

If the unit is turned on without being connected to a Stimulation Coil or a fault has been indicated due to overheating of the coil, both the Green and Red LED indicator lights will be lit, indicating **FAULT (4)**. This will automatically turn off when a suitable coil is connected to the Stimulator or when the temperature limits of the coil have dropped below its allowed temperature in order to stimulate. If the Red and Green LED indicators are illuminated for a long time (more than 30 minutes) without interruption and the indicator remains, an internal fault is detected on the coil. In this case, do not use the coil, even after it has cooled.

If during stimulation, the Stimulation Coil temperature reaches a critical level (approx. 50 °C), the Red and Green stimulator LED indicator lights will turn on, and the stimulator will discharge its high voltage capacitor. The coil can then be replaced with a cold coil, or simply wait for it to cool. When the Red LED indicator goes off and the Green LED indicator is still on, the user may then set the desired stimulation level and start again to stimulate.

If overheating of the Magnetic Stimulator occurs during stimulation, or shortly thereafter in idle mode, only the Red LED indicator light will be on. Other indicators in this situation will remain off. If this state remains for a long time (about 15 minutes or more), there has been an internal fault detected in the stimulator. In this case, turn off the main power switch, disconnect the main plug from the wall outlet and contact your supplier.

The intensity of the stimulation can be set in two ways. First, by turning the knob on the Stimulation Coil **(1)**, select the desired stimulation level in the range of 1-100%. Turning the wheel quickly will change the intensity at a faster rate. The second way is by using PC Control Software that communicates with the Stimulator via the USB port. Ready for stimulation is indicated by the Orange LED indicator being lit (together with the Green LED indicator).

Starting stimulation can be performed in three ways:
A) by pressing the button **(2)** on the side of the coil.
B) by applying an appropriate signal (see Specifications) to the TTL input.
C) by a command sent via the USB port of the PC Control Software. In this case, you can use a reverse sync from TTL OUT output.

Setting the stimulation intensity and start stimulation

Stimulation is accompanied by a characteristic clicking sound inside the Magnetic Stimulator, which is audible from intensities of about 15 %. Immediately after stimulation, the stimulator is recharged again to the preset intensity. When within about 100 seconds there is no activity (stimulation, or change of the intensity), the unit automatically switches to the default STANDBY mode where the high voltage capacitors are discharged. This step increases the life of the Stimulator and minimizes the risk of unwanted stimulation. If you do not plan to use the Stimulator for a long time, turn off the main switch, thereby further increasing the service life of the Stimulator.

Changing the Stimulation Coil

The Stimulation Coil can be changed for another coil of the same or different type. Compatible coils are listed in the chapter Stimulation Coils of this document. It is not allowed to use any other Stimulation Coil except the listed ones.

Before disconnecting the Stimulation Coil the Magnetic Stimulator needs to be switched off. When switched off the display and all the color LEDs turn off. After that it is allowed to unplug the stimulation coil connector and plug in another coil. When another coil is properly connected the Magnetic Stimulator can be switched on again.

Before using the Stimulation Coil, check the integrity of the Stimulation Coil body, Stimulation Coil cable integrity and proper connection of the Stimulation Coil into the Magnetic Stimulator.

Turning off the Magnetic Stimulator

Turn the power switch to the OFF position (O)**(7)**. The display and all the color LEDs will turn off.

Operating the system with the control PC (XT models only)

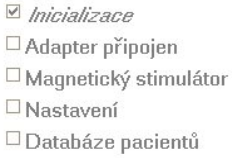
This Control Software documentation is intended for use with DuoMAG rTMS software version 1.3.

Starting the system

Switch on the Magnetic Stimulator as described in the chapter Turning on and operating the Magnetic Stimulator. Switch on the Control PC pressing the button. After the operating system starts the Control Software is started automatically.

Application starting sequence
Application starts in five steps. Correct completion of each step is indicated. In progress:

1. Application initialization,
2. EMG USB adapter connection check,
3. Magnetic Stimulator connection check,
4. Loading configuration,
5. Loading the patient database.



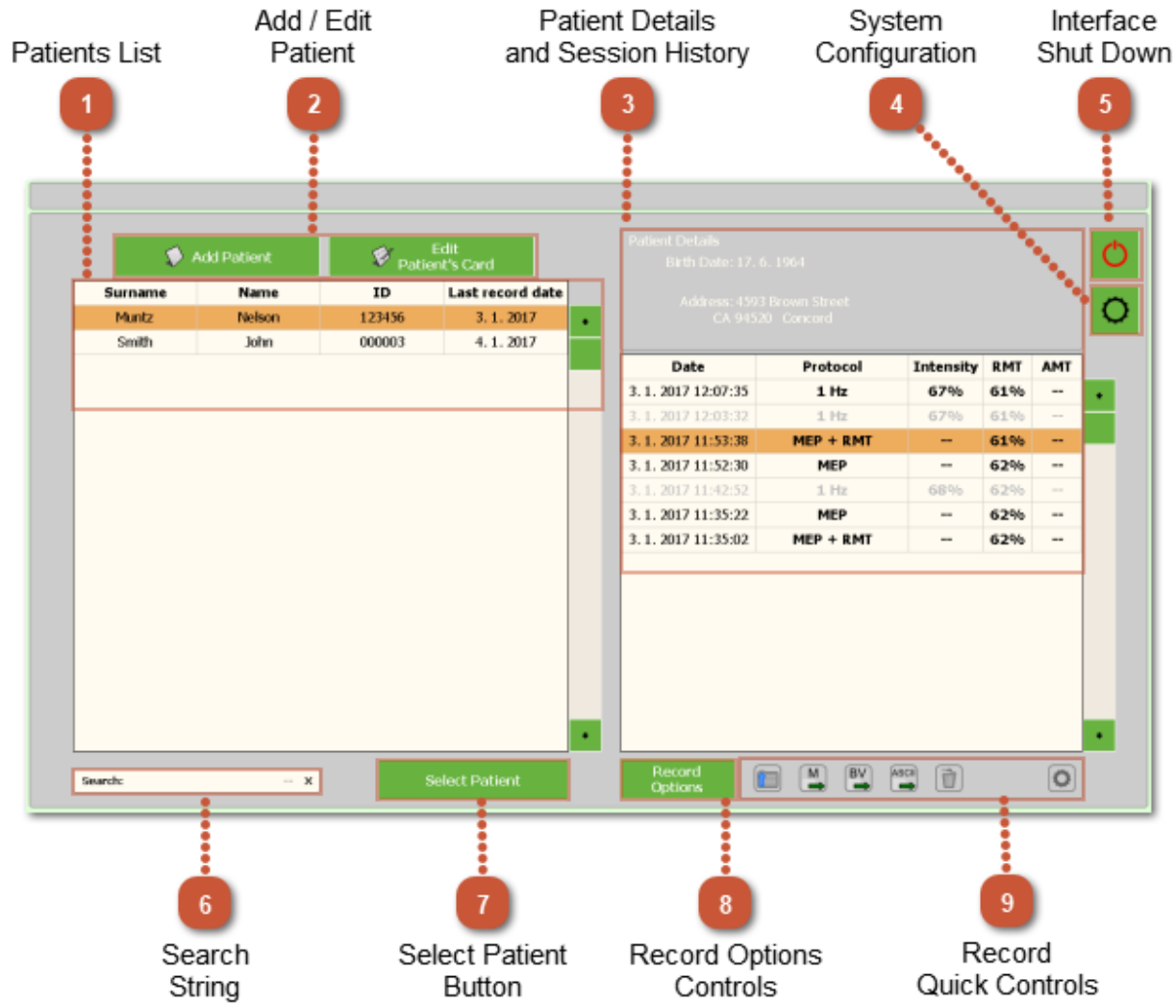
If one of the steps is not finished correctly, it is not checked.

Turning off the system

Switch off the Magnetic Stimulator way described in the chapter Turning off the Magnetic Stimulator. Switch off the Control PC with the button Switch Off in the Control software (see chapter Patient screen, item 5).

Patient screen

The Main Patient Screen is the first screen that is visible when the user turns on the DuoMAG rTMS Control PC. The Patient information, including session information, is entered and displayed here. A Touch-screen may be used to navigate as well as a connected mouse.



1 Patient List	6 Search String
2 Add / Edit Patient	7 Select Patient Button
3 Patient Details and Session History	8 Record Options Controls
4 System Configuration	9 Record Quick Controls
5 Interface Shut Down	

1 Patient List

The Patient List shows all Patients entered into the system. This displays the First and Last Name, Patient ID and Last record date. You can search for any patient that may already be listed in the system by clicking in any column and by typing the text of the information you are searching for. If a match is found, it will highlight the record that best matches the search text entered.

2 Add / Edit Patient

See more about the Add Patient and Edit Patient Card functions in the Add / Edit Patient Section of this guide.

3 Patient Details and Session History

The Patient Details and Session History window area displays the selected patient's data as entered in the Patient's Card, as well as all of the previous sessions of this particular patient. The displayed information is the date of the session, the type of session, the stimulation intensity used for the training and current Motoric Threshold. The Motoric Threshold type is preset in the System Configuration Screen. For more information on the Motoric Threshold see The Motoric Threshold Mode part of this guide (item 7 in the System Configuration Screen).

When a session is grayed out (not black) it indicates the protocol was interrupted or did not come to the end of the session. Information about who or what stopped the session, is indicated on the top bar of the Patient screen.

4 System Configuration

Click here to make changes to the basic settings of the system. You can read more info about this in the System Configuration Screen section of this user guide.

5 Interface Shut Down

This button allows the user to Shut Down the DuoMAG Touch-screen Interface. **This Shut Down** button does not, however, turn off the stimulator unit, their own stimulator to be switched off separately (for more information see Turning off the Magnetic Stimulator). Always use this Shutdown first, before turning off the Stimulator.

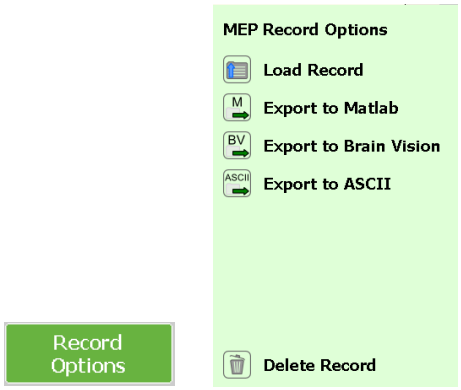
6 Search String

The Search String Display area shows the data entered when searching the patient database. This window is not clickable or selectable, as it is only to display data as the user types.

7 Select Patient Button

Once the correct patient has been selected on the screen, use this Patient **Select** button to enter the Stimulation Control Screen.

8 Record Options Controls



Record Options button open the list of features that can be used for current session. The list of features changes depending on whether a MEP or Therapy session is selected. When a Therapy session is selected, only Delete Session is available. Available features in MEP are:

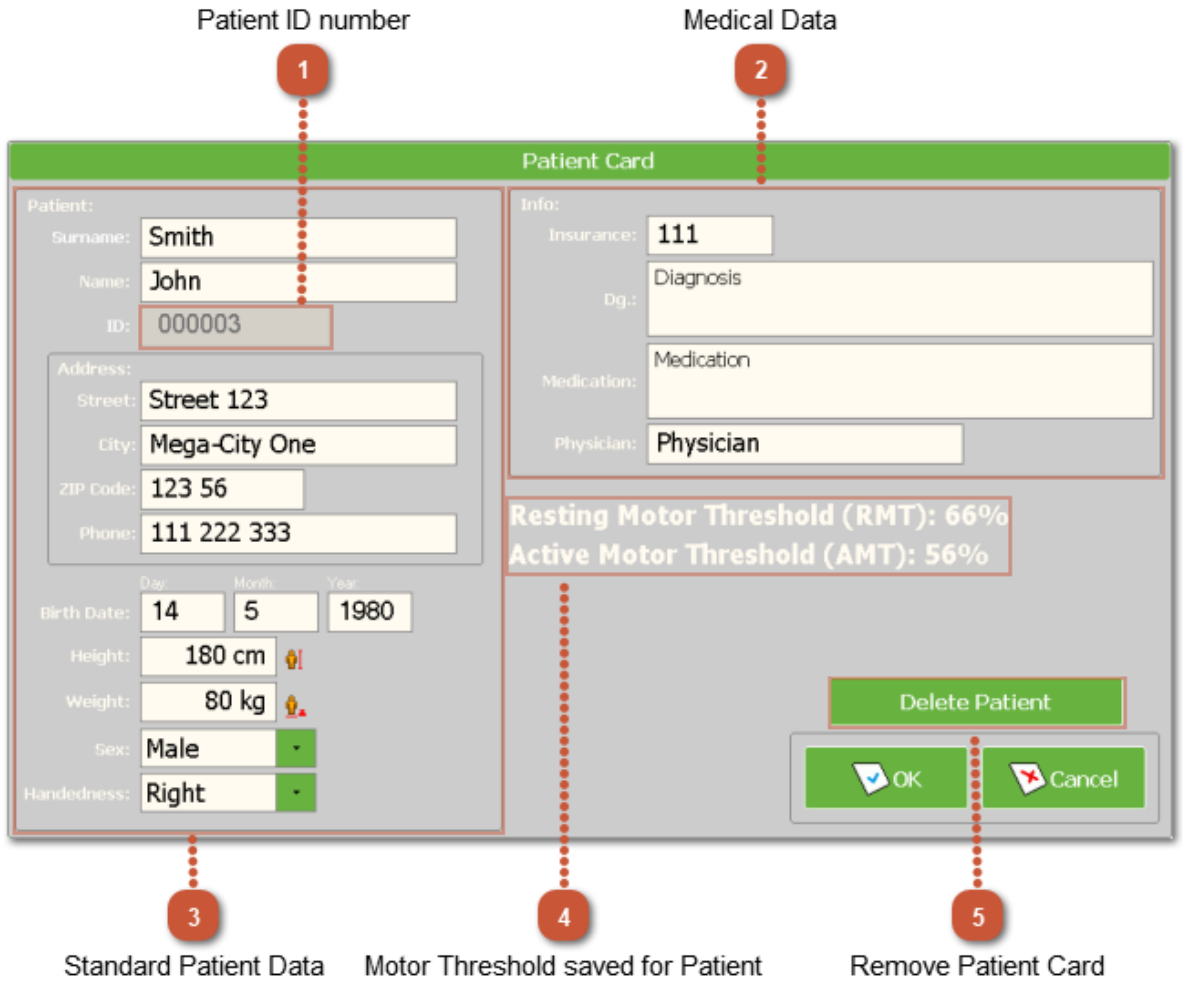
1. Load Record - load the selected session and open the recorded data and all the data can be browsed in the MEP History window.
2. Export to Matlab - generate the text file and save it to the selected destination. The file can be loaded into Matlab. The data is loaded to the predefined structure in the workspace.
3. Export to Brain Vision - generate three files and save them to the selected destination. These files can be loaded to the software supporting the Brain Vision format.
4. Export to ASCII - generate the text file and save it to the selected destination. The file contains the data and comments explaining the file structure.
5. Export to GDT - is available if permitted function GDT. Exports the data to the GDT with the preset parameters (see GDT settings in Advanced System Configuration Screen, item 3)
6. Delete Record - delete the selected record.

9 Record Quick Controls

The Record quick controls tab is located below the session list of the selected patient. The tab content changes if MEP or Therapy session is selected. The Quick Controls settings button on the right side of the tab allow the user to preset which features should be visible on the tab.

Add / Edit Patient

The Add/Edit Patient Data screen shows the key values that may be entered for each patient. This dialog will appear when selecting the 'Add Patient' or 'Edit Patient Data' button from the Patient screen. To quickly jump the cursor between each field for fast data entry simply use the TAB button on your computer keyboard. You can make quick entry of information without using the mouse.



1 Patient ID number	4 Motor Threshold saved for Patient
2 Medical Data	5 Remove Patient Card
3 Standard Patient Data	

1 Patient ID number

The Patient ID number is a unique number that cannot be duplicated in the system. If you choose to change the generated number to a new number, please be aware that the number may only be numeric and may not contain any alpha characters or spaces. Each patient must be assigned a unique number and this number is used to identify any data files saved in the system for that patient. This ID can not be changed in the future.

2 Medical Data

The Medical Data can include the values listed above. These values will be saved in the patient records.

3 Standard Patient Data

The Standard Patient Data can be entered here to be saved with the patient records. To start an rTMS session, the only required value needed is ID. The ID number is automatically generated but can be changed to any desired number. The ID, however, must only contain numeric characters. All other data is optional.

4 Motor Threshold saved for Patient

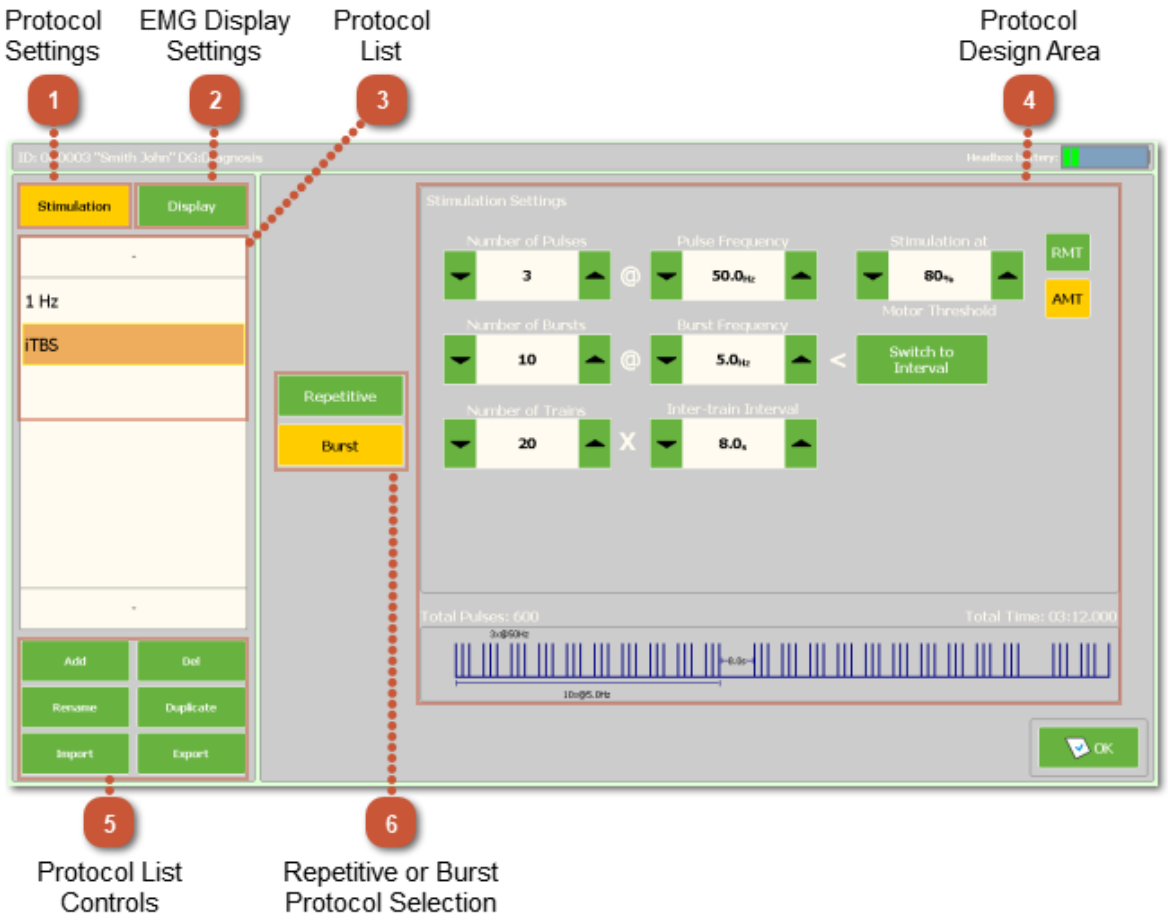
Saves the Motor Threshold (MT) for the patient. Depending on the selected Motor Threshold Mode set in the System Configuration the Resting Motor Threshold (RMT) or Active Motor Threshold (AMT) or both are displayed. When starting a protocol, this value will be used for the MT if it has been saved for the patient (for more infromation on the Motor Threshold modes see chapter System Configuration Screen, item 7) The MT value is saved to the patient file when the Set RMT or Set AMT button is pressed in the MEP screen.

5 Remove Patient Card

The Delete Patient button will delete all the data of the selected patient. The Patient Card as well as all the session data will be permanently removed.

Protocol Setup Screen

The Protocol Setup Screen gives the options needed to configure any standard Repetitive or Burst protocol. The Burst protocol is available only when used with DuoMAG XT-100 Magnetic Stimulator.



1	Protocol Settings	4	Protocol Design Area
2	EMG Display Settings	5	Protocol List Controls
3	Protocol List	6	Repeated / Burst Protocol Selection

1 Protocol Settings

The **Stimulation** button is selected when the user wants to change the protocol settings. Once selected, the protocol settings are shown on the right half of the screen.

2 EMG Display Settings

The **Display** button is selected when the user wants to change the EMG display settings. Once selected, the protocol settings are shown on the right half of the screen.

3 Protocol List

The Stimulation Protocol list shows what protocols are entered in the system and corresponding to the selected MT mode. The user can Add, Delete, Rename, Duplicate, Import (from file) or Export (to file) a protocol listed here.

4 Protocol Design Area

The Protocol Design Area allows the user to create or customize protocols in the system. Specific adjustable parameters depend on the type of protocol. There are two types of protocols in the system. The first is a Repetitive Protocol and the second is a Burst Protocol.

To learn more about repetitive protocols, see the Repetitive Protocol Setup section of this user guide.
To learn more about burst protocols, see the Burst Protocol Setup (for DuoMAG XT-100 only) section of this user guide. The Burst protocol is available only when used with DuoMAG XT-100 Magnetic Stimulator.
A visual representation of the selected protocol is available in the bottom part of the window. It displays a protocol design, total number of pulses and total duration of the protocol.

5 Protocol List Controls

Controls to work with the protocol list allows to:

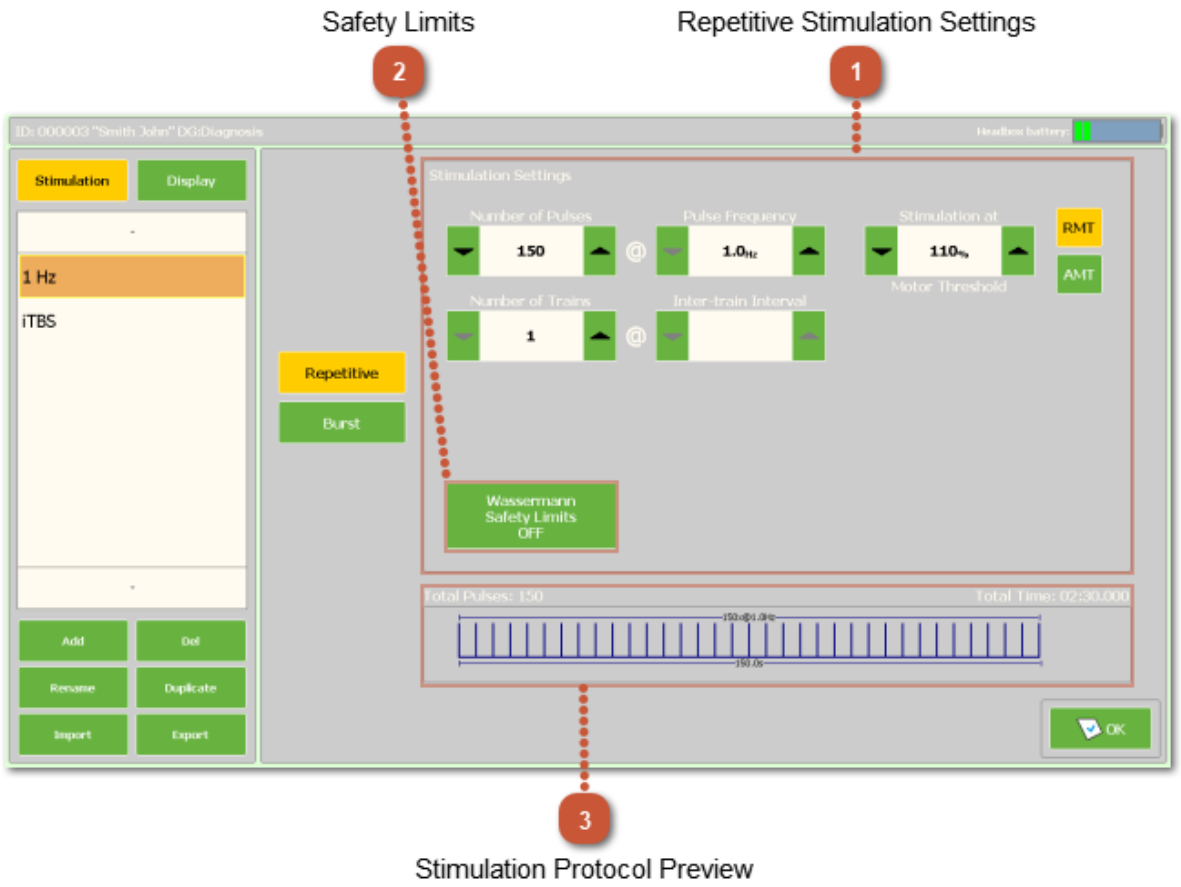
1. Add **New** protocol,
2. **Delete** selected protocol,
3. **Rename** selected protocol,
4. **Duplicate** selected protocol,
5. **Import** protocol from file,
6. **Export** protocol to file.

6 Repeated / Burst Protocol Selection

The selected protocol may be Repetitive stimulation or Burst stimulation. The **Repetitive** button is selected when the user wants the selected protocol from the list to be a Repetitive protocol. On the right side of the screen displays adjustable parameters corresponding to the selected protocol type. To see more about this function, go to the Repetitive Protocol Setup section of this user guide.

The **Burst** button is selected when the user wants the selected protocol from the list to be a Burst protocol. On the right side of the screen displays adjustable parameters corresponding to the selected protocol type. To see more about this function, go to the Burst Protocol Setup (for DuoMAG XT-100 only) section of this user guide.

Repetitive Protocol Setup



1	Repetitive Stimulation Settings	3	Stimulation Protocol Preview
2	Safety limits		

1 Repetitive Stimulation Settings

There are six parameters of a Repetitive protocol that can be set. These parameters are:

Number of Pulses: Sets the total number of pulses (per each Train) in the protocol. This setting may NOT be changed or adjusted on the Therapy/Protocol Screen However, the number of trains may be limited by stopping the protocol manually. To do so, click the STOP button on the Therapy/ Protocol Screen before the protocol comes to its end.

Frequency: Sets the frequency of pulses for all stimulations in the protocol, measured in Hertz (stimulations per second). During use of the protocol, this setting may not be adjusted.

Number of Trains: Sets the number of consecutive trains per protocol. A "Train" is defined as a single cycle of the 'Frequency' and total 'Number of Pulses' as set in the previous two settings, as well as the 'Inter-train Interval' setting described below. This setting may NOT be adjusted on the Therapy/Protocol Screen during a session. However, the number of trains may be limited by stopping the protocol manually. To do so, click the STOP button on the Therapy/ Protocol Screen before the protocol comes to its end.

Inter-train Interval: Sets the time delay, in seconds, at the end of each train before the next train starts. This setting cannot be changed on the Therapy/Protocol Screen.

Motor Threshold Percentage: Sets the protocol stimulation intensity based on the set percentage of the patient's Motor Threshold (MT). The minimum value is 80% and the maximum value is 120 %.

Motor Threshold Mode: Sets the protocol Motor Threshold Mode. If Resting MT (RMT) is selected, only a patient with a resting motor threshold set can be stimulated with this protocol. If Active MT (AMT) is selected, only a patient with an active motor threshold set can be stimulated with this protocol. If the RMT mode or AMT mode is set in the System Configuration, this control is not available and the protocol is automatically assigned to the mode selected in the System Configuration. If the mode RMT + AMT is selected in the System Configuration, then the control is available and the user can select whether the protocol is RMT or AMT.

2 Safety limits

When the Wassermann Safety Limits button is pressed, all the parameters of the Repetitive protocol are limited so the final protocol meet the safety limits described in the Wassermann Safety guidelines [1]. If the button is released, the parameters are limited only with the system technical capabilities. Even with the button released, if the protocol does not meet the safety limits, the user is still warned when attempting to start the protocol.

3 Stimulation Protocol Preview

The Protocol Preview area shows a graphical representation of the protocol to help the user visually recognize the protocol design.

This display shows only one cycle of a single train in the protocol. All following cycles are the same.

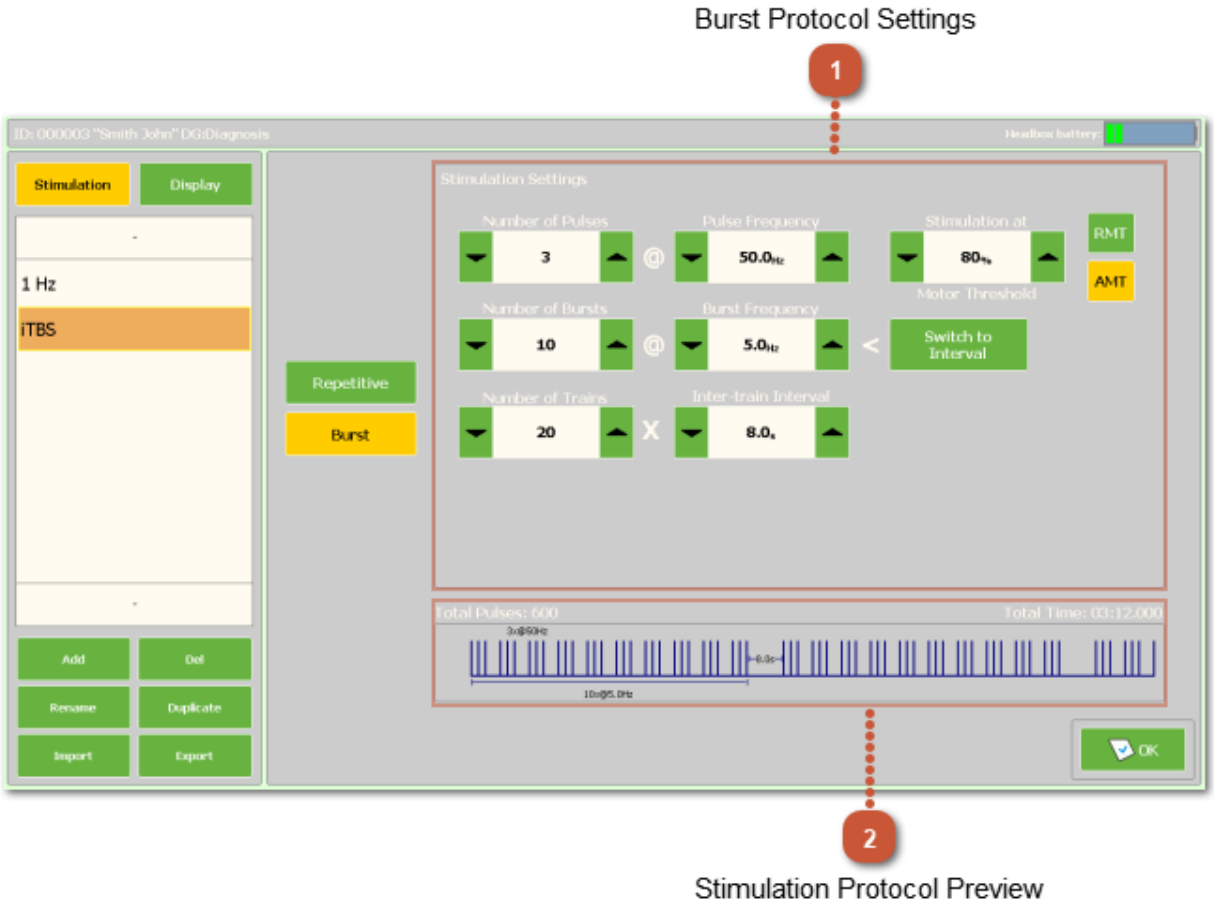
Listed at the top left of this area is the **Total Pulses** which gives the total amount of pulses for the entire protocol (not just a single Train or cycle).

Listed at the top right of this area is the **Total Time** which gives the total running time of the entire protocol, from start to finish.

Burst Protocol Setup (for DuoMAG XT-100 only)

The Burst Protocol Setup allows for a special kind of repetitive protocol that includes 'bursts' typically of three to five pulses at a high frequency (for example at 50Hz). For Burst protocol there are no safety limits by Wasserman [1]. The system allows the user to set arbitrary protocol parameter values. When user tries to run a protocol, the system will check it for safety limits regarding the publication [2]. If the protocol does not meet the safety standards regarding the [2], system will warn user. In this case the user should make a responsible decision whether to use this protocol or not.

The settings on the figure below describe how a Burst protocol is configured.



1 Burst Protocol Settings	2 Stimulation Protocol Preview

1 Burst Protocol Settings

There are eight parameters of a Burst protocol that can be set. A protocol consists of a single or multiple Trains. A Train consists of a group of bursts at a high frequency.

The parameters are:

Number of pulses: Sets the total number of pulses per Burst. This setting may NOT be changed or adjusted during a protocol. However, the number of trains may be limited by stopping the protocol manually. To do so, click the STOP button on the Therapy/ Protocol Screen before the protocol comes to its end.

Frequency: Sets the frequency of pulses for all stimulations in the protocol, measured in Hertz (stimulations per second). During use of the protocol, this setting may not be adjusted.

Burst Frequency / Time Delay between Bursts: Sets the frequency of 'Bursts' per second or the Time Delay between 'Bursts'.

Number of Bursts: Sets the total number of 'Bursts' per Train. This setting cannot be changed during a protocol.

Inter-train Interval: Sets the time delay, in seconds, at the end of each train before the next train starts. This setting cannot be changed during a protocol.

Number of Trains: Sets the number of consecutive trains per protocol. A "Train" is defined as a single cycle of the 'Frequency' and total 'Number of Pulses' as set in the previous two settings, as well as the 'Inter-train Interval' setting described below. This setting may NOT be adjusted on the Therapy/Protocol Screen during a session However, the number of trains may be limited by stopping the protocol manually. To do so, click the STOP button on the Therapy/ Protocol Screen before the protocol comes to its end.

Motor Threshold Percentage: Sets the protocol stimulation intensity based on the set percentage of the patient's Motor Threshold. The minimum value is 80% and the maximum value is 120%.

Motor Threshold Mode: Sets the protocol Motor Threshold Mode. If Resting MT (RMT) is selected, only a patient with a resting motor threshold set can be stimulated with this protocol. If Active MT (AMT) is selected, only a patient with an active motor threshold set can be stimulated with this protocol. If the RMT mode or AMT mode is set in the System Configuration, this control is not available and the protocol is automatically assigned to the mode selected in the System Configuration. If the mode RMT + AMT is selected in the System Configuration, then the control is available and the user can select whether the protocol is RMT or AMT.

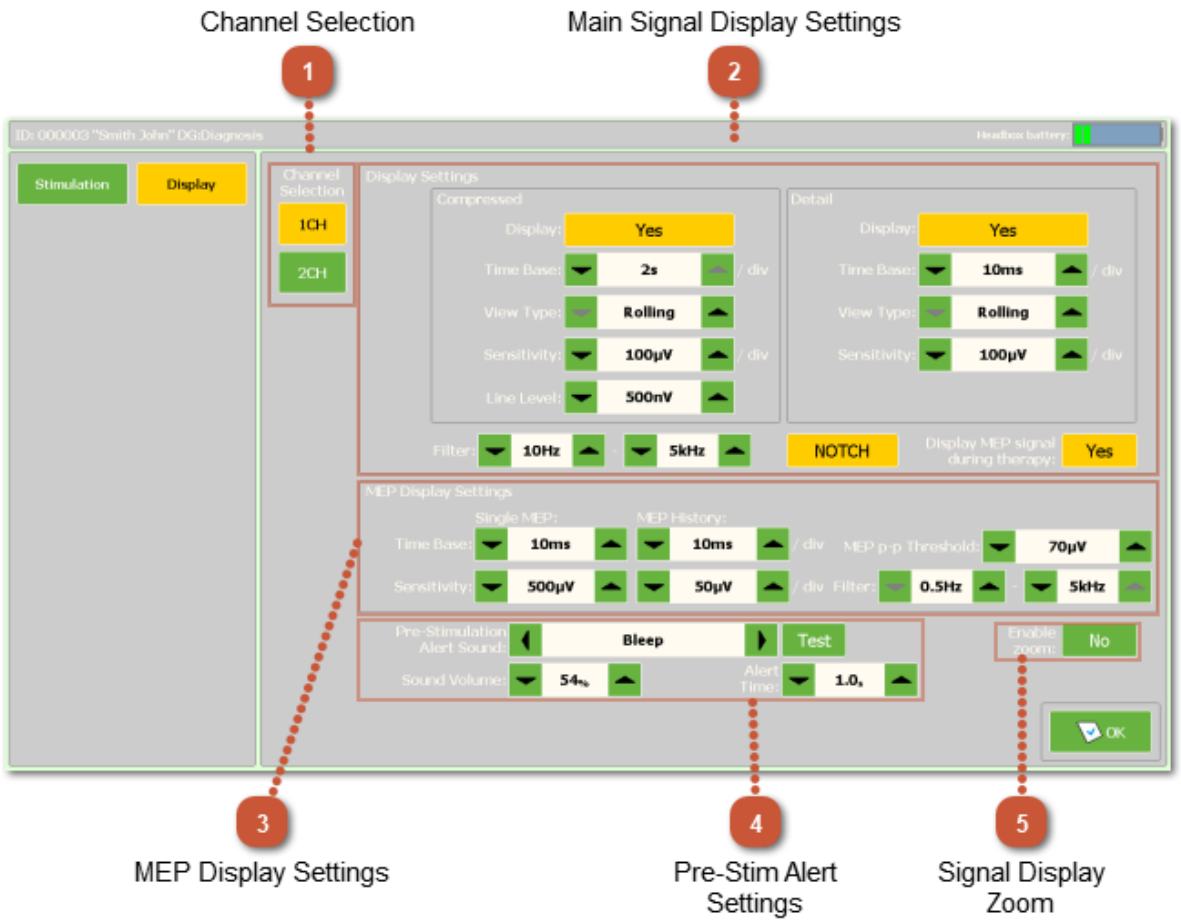
2 Protocol Preview

Visualization of stimulus protocol displays a graphical representation of the protocol for a better idea of setting a visual inspection protocol parameter. This display shows only several cycles / Trains (including multiple Bursts per Train) in the protocol.

Listed at the top left of this area is the **Total Pulses** which gives the total amount of pulses for the entire protocol (not just a single Train or cycle).

Listed at the top right of this area is the **Total Time** which gives the total running time of the entire protocol, from start to finish.

Display Setup Screen



1 Channel Selection	4 Pre-Stim Alert Settings
2 Main Signal Display Settings	5 Signal Display Zoom
3 MEP Display settings	

1 Channel Selection

Choose the number of EMG channels to display, by selecting either 1CH, 2CH or both (button will be Orange when selected).

2 Main Signal Display Settings

Display Settings include Compressed, Detail and Additional settings. Additional settings including Filters, Time Base and Sensitivity settings.

Compressed window settings:

- **Time Base**: 50, 100, 200, 500 ms ,1 s or 2 s per division.
- **View type**:
    1. Overwrite: the current signal overwrites the previous signal.
    2. Stack: the top line always contains the current signal. Each previous segment is dropped to the next line.
    3. Rolling: behavior is similar to an analog display, i.e. a continuous display of signal.
- **Sensitivity**: Various incremental steps from 10 µV to 10 mV.
- **Line Level**: Set a visual line (not a trigger) as a visual reference help. This value is calculated as zero to peak or 0-P.
  Note: The line is not visible if sensitivity settings are out of this range.

Detail window settings:

- **Time Base**: 1, 2, 5, 10, 20, 50 or 100 ms per division.
- **View type**: Same as described for Compressed signal above.
- **Sensitivity**: Various incremental steps from 10 µV to 10 mV.

Filter for Compressed and Detail signal:

- **Filter**: High Pass in steps from 1 Hz to 300 Hz. Low Pass in steps from 500 Hz to 20 kHz.
- **Notch filter**: The Notch Filter can be set to on or off. It will suppress 50 or 60 Hz signal noise based on the setting in the System Configuration screen.

Display MEP signal during Therapy: The button enable / disable online EMG signal during the protocol therapy. In the MEP / MT mode the signal is always visible.

3 The MEP Display settings

MEP Display settings

- **Time Base**: 1, 2, 5, 10, 20 ms per division.
- **Sensitivity**: Various incremental steps from 20 µV to 30 mV.
- **Filter**: High Pass in steps from 0.5 Hz to 200 Hz. Low Pass in steps from 40 Hz to 5 kHz.

MEP P-P Threshold: Sets the MEP amplitude threshold to indicate when a minimum pre-set value for peak-to-peak amplitude has been met. If the setpoint is reached, the values in the table of results MEP will be highlighted.

4 Pre-Stim Alert Settings

The Pre-Stim alert lets the patient know that a stimulation is about to occur. The settings below can be set:

- **Pre-Stim Alert Sound**: Choose from a large list of sounds for the alert
- **Alert Time**: Indicates the amount of time before the next stimulation.
- **Sound** Volume: Sets the volume for the alert.

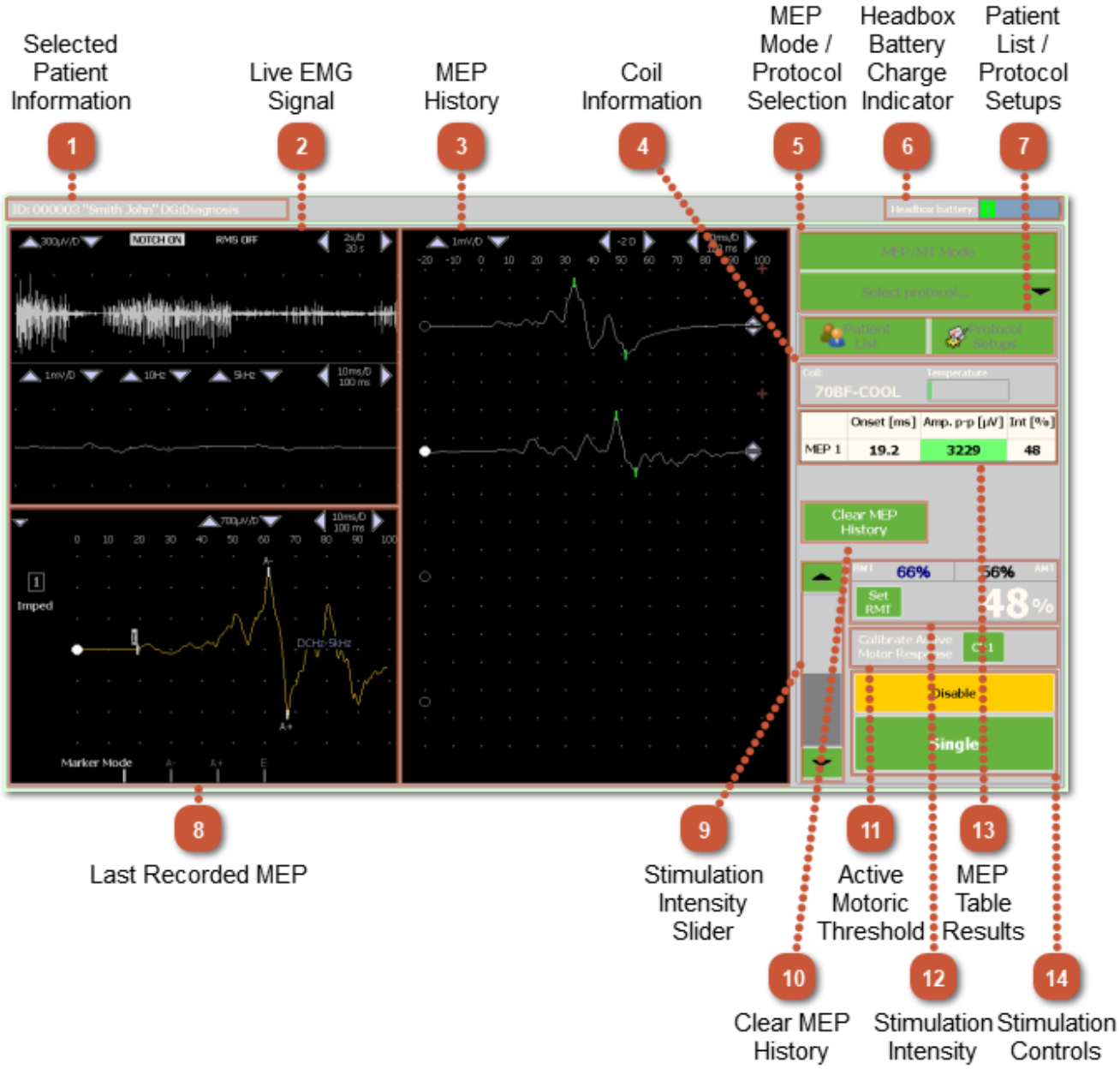
The **Test** button allows the user to try out the current sound settings.

5 Signal Display Zoom

The Enable Zoom button will allows the user to enlarge the selected signal window to full screen. Double-tap / click to the selected window to enlarge it. Double-tap / click again to get back to the standard layout.

MEP/MT Single Pulse Screen

The MEP/MT Single Pulse Screen allows the user to give single pulses and search for the patient's motor cortex and to determine their Motor Threshold (MT). The user may also view the EMG live signal and MEP signal. All controls can be manipulated via the Touch Screen interface or via a connected mouse.



1	Selected Patient Information	8	Last Recorded MEP
2	Live EMG Signal	9	Stimulation Intensity Slider
3	MEP History	10	Clear MEP History
4	Coil Information	11	Active Motoric Threshold
5	MEP Mode / Protocol Selection	12	Stimulation Intensity
6	Headbox Battery Charge Indicator	13	MEP Table Results
7	Patient List / Protocol Setups	14	Stimulation Controls

1 Selected Patient Information

Selected patient brief information as ID, Name and Surname and Diagnosis as it is stored in the patient card.

2 Live EMG Signal

The Live EMG signal screen displays the raw EMG from the supplied surface electrodes connected to the EMG Amplifier. The settings are preset to defaults via the Display Setup, but can be adjusted on this screen with the arrows next to each value or by turning the Notch filter On or Off.

3 MEP History

The MEP History screen displays all the MEP signals captured in the current session. Newer on the top, later on the bottom The last captured signal is displayed in Last Recorded MEP (see item 8), until the next MEP is captured. The screen settings are preset to defaults via the Display Setup, but can be adjusted on this screen with the arrows next to each value.

4 Coil Information

The Coil Information shows the connected Coil type and its temperature.

Presence of the Coil type information depends on the Stimulator firmware. If the Stimulator and the Coil allows this feature, the current connected Coil type will be displayed.

The Coil Temperature indicator shows when the Coil is ready for use and also when it is too hot to use. The Coil may still be used until the indicator bars have filled up completely to the far right of this display. When the coil reaches its maximum temperature, temperature indicator turns red. It also Yellow Triangle Alert sign is displayed to the right of this display, indicating that the Coil is too hot to be used. The Stimulator will not allow another stimulation until the Coil temperature again drops below the alert level.

5 MEP Mode/Protocol Selection

The **MEP/MT Mode** button activate the Single Pulse mode.

The **Select protocol** button activates the Therapy / Protocol Mode (see Section Therapy / Protocol Screen this manual) and opens the predefined protocol list.

6 Headbox Battery Charge Indicator

The Headbox Battery indicator shows in percentage the battery level of the connected EMG Headbox. When the battery is below 10 %, it should be recharged.

7 Patient List/Protocol Setups

The **Patient List** button takes the user back to the main Patient List screen to add or select a new patient for training.

The **Protocol Setup** button takes the user to the Protocol Setup screen to manage the predefined protocols.

8 Last Recorded MEP

The MEP window displays one or two channels of MEP signal for use in finding the Motor Threshold of the patient or for other research purposes. Each time a stimulation is given, the syncronized signal appears and can be marked using the markers listed at the botom of this window. When in touch-screen mode, simply select the marker with your finger and then tap on the signal where you'd like the marker to appear. The marker labeled 'I' is the onset marker, used to show the time duration from stimulation to the onset of the MEP response. The 'A-' marker is used as the top amplitude marker, to placed at the top peak of the MEP. The 'A+' marker is used as the bottom amplitude marker, to placed at the bottom peak of the MEP. Together the 'A-' and 'A+' markers will give the Peak-to-Peak amplitude value in the MEP Table results.

Auto-markers will generally appear when the MEP is found by the system. It may not however place the markers where you would like them to be. You should manually adjust

them by selecting the marker and dragging it to its proper location. Once a marker is selected, you may also just tap the new location and the marker will move there.

The screen settings are preset to defaults via the Display Setup, but can be adjusted on this screen with the arrows next to each value.

The Imped button is short for Impedance. Once selected, the system will show the impedance of the connected electrodes. Good impedance is important to have good MEP results. Values should be around 25 kOhm or less. The lower the value, the better.

9 Stimulation Intensity Slider

The Stimulation Intensity Slider allows the user to change the intensity of stimulation from 0-100 which is a percentage of the maximum output power of the Stimulator.

10 Clear MEP History

When active, this button allows the user to delete any MEP's that have collected in the MEP History screen.

11 Active Motoric Threshold

The Active Motor Threshold window is available if the AMT mode is enabled in the System Configuration. For more information on the work with the Active Motor Threshold see chapter Advanced System Configuration Screen, (item 2).

12 Stimulation Intensity

The stimulation power is viewable on the Stimulator and on the PC display in large white numbers. It can be changed using the touch screen controls or with the wheel on the Stimulation Coil.

13 MEP Table Results

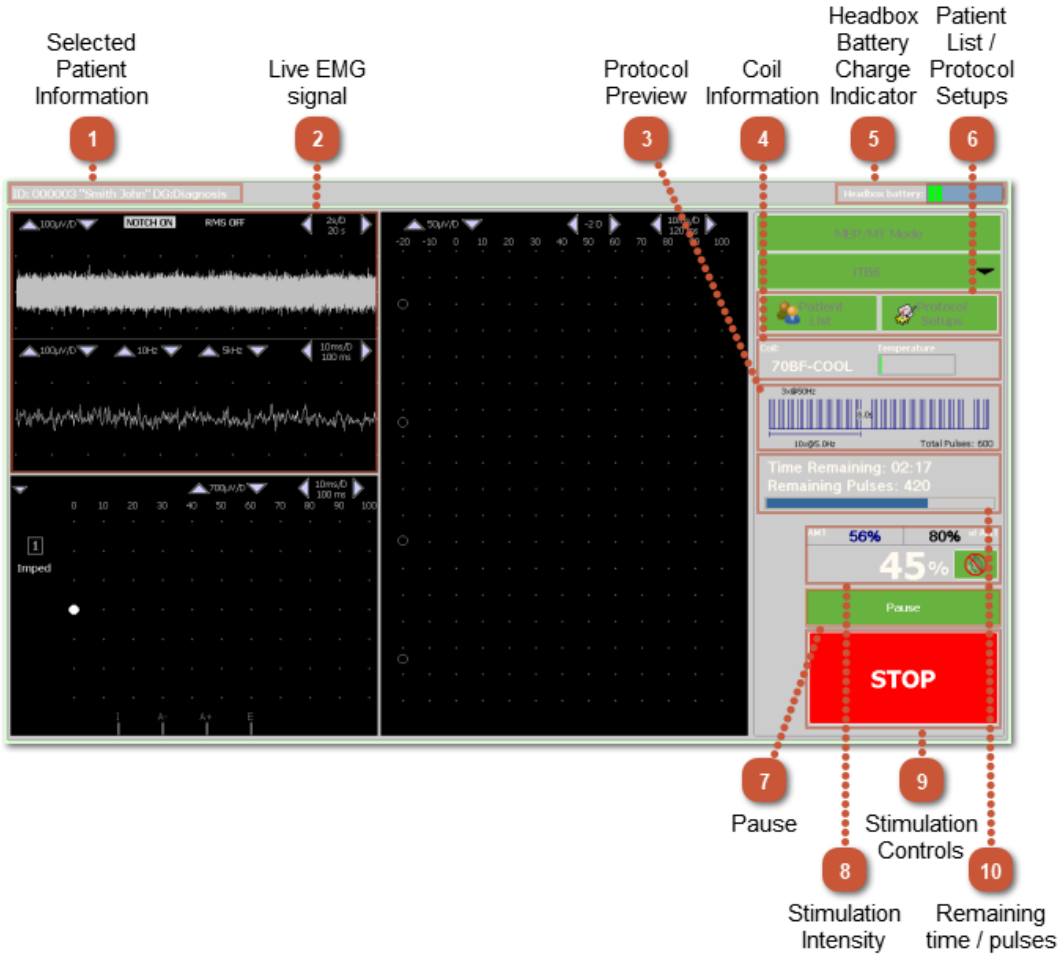
This MEP display area shows the resulting values from the MEP markers on the Single MEP screen. Onset indicates the start of the upward deflection of the MEP waveform, displayed in milliseconds, and the Amplitude shows the maximum Peak- to-peak value in microvolts of the MEP response. If the Peak-to-peak value exceeds the predefined value (see Display Setup Screen, item 3, MEP p-p threshold) it is highlighted in green. „Int" indicates the current intensity of stimulation during which the MEP was recorded.

14 Stimulation Controls

The **Enable** button is available to Activate the stimulator and load the capacitors to the predefined value. The magnetic stimulator is charged to the desired value and pressing **Single** button or on stimulation coil is possible to perform a single pulse. Performing the Single Pulses is possible while the stimulator is Active. When the session is finished, press the **Disable** button to set the Stimulator to sleep mode and discharged the capacitors. If the Enabled Stimulator is not Active for a while (a time predefined in the System Configuration Screen, item 6), it will Disable automatically.

Therapy / Protocol Screen

The Repetitive / Burst Control Screen allows the user to select, view and run any protocol set in the system and view the Live EMG. All controls can be manipulated via the Touch Screen interface or via a connected mouse.



1	Selected Patient Information	6	Patient List / Protocol Setups
2	Live EMG signal	7	Pause
3	Protocol Preview	8	Stimulation Intensity
4	Coil Information	9	Stimulation Controls
5	Headbox Battery Charge Indicator	10	Remaining time / pulses

1 Selected Patient Information

Selected patient brief information as ID, Name and Surname and Diagnosis as it is stored in the patient card.

2 Live EMG signal

The Live EMG signal screen displays the raw EMG from the supplied surface electrodes connected to the EMG Amplifier. The settings are preset to defaults via the Display Setup Screen, but can be adjusted on this screen with the arrows next to each value or by turning the Notch filter On or Off. Displaying the Live EMG signal can be disabled during the Therapy (see Display Setup, item 2).

3 Protocol Preview

The Protocol Preview is shown to give the user a graphical representation of the selected protocol. This does not display the entire protocol but will always display at least one Train (cycle) in the protocol.

4 Coil Information

The Coil Information shows the connected Coil type and its temperature.

Presence of the Coil type information depends on the Stimulator firmware. If the Stimulator and the Coil allows this feature, the current connected Coil type will be displayed.

The Coil Temperature indicator shows when the Coil is ready for use and also when it is too hot to use. The Coil may still be used until the indicator bars have filled up completely to the far right of this display. When the coil reaches its maximum temperature, temperature indicator turns red. It also Yellow Triangle Alert sign is displayed to the right of this display, indicating that the Coil is too hot to be used. The Stimulator will not allow another stimulation until the Coil temperature again drops below the alert level.

5 Headbox Battery Charge Indicator

The Headbox Battery indicator shows in percentage the battery level of the connected EMG Headbox. When the battery is below 10 %, it should be recharged.

6 Patient List / Protocol Setups

The **Patient List** button takes the user back to the main Patient List screen to add or select a new patient for training.

The **Protocol Setup** button takes the user to the Protocol Setup screen to manage the predefined protocols.

7 Pause

The **Pause** button allows a running protocol to be Paused and then continued as needed.

8 Stimulation Intensity

The Stimulation Intensity window displays the current (or previously saved) RMT/AMT for the selected patient (top left), the Motor Threshold percentage predefined in the currently selected protocol (top right). This value is further the resulting final stimulation intensity.

Percentage of motor threshold (RMT% /% AMT) (top right) is a parameter selected protocol, indicating the percentage of the patient's motor threshold, which will be stimulated. This value is multiplied by the value of the patient's motor threshold and thus gain resulting intensity of the stimulation protocol.

The **intensity of the stimulation protocol** (white middle number) shows the overall intensity of the performance stimulator, which will be executed selected protocol. The value is based on multiplying the value of the patient's motor threshold and the percent motor threshold selected protocol.

9 Stimulation Controls

Control of stimulation allows the user to start and stop stimulation and displays the value of the motor threshold selected patient and % of motor threshold, which will be stimulated.

The **Enable** button is available to Activate the Stimulator and load the capacitors to the predefined value. When the Enable button is pressed, the selected protocol parameters are checked for safety limits regarding the publications [1] and [2]. If the protocol meets the safety limits, it can be started. If not, the user is warned and must confirm whether to run the protocol or not.

The **Start** Stimulation button will be activated only after first selecting the Enable button. Once activated, the user can click on Start Stimulation, which starts the protocol stimulation.

When the Start Stimulation button is activated, it will change its status to **STOP**. This allows user to interrupt and stop protocol at any time, for any reason. When STOP button pressed the stimulator is automatically Disabled.

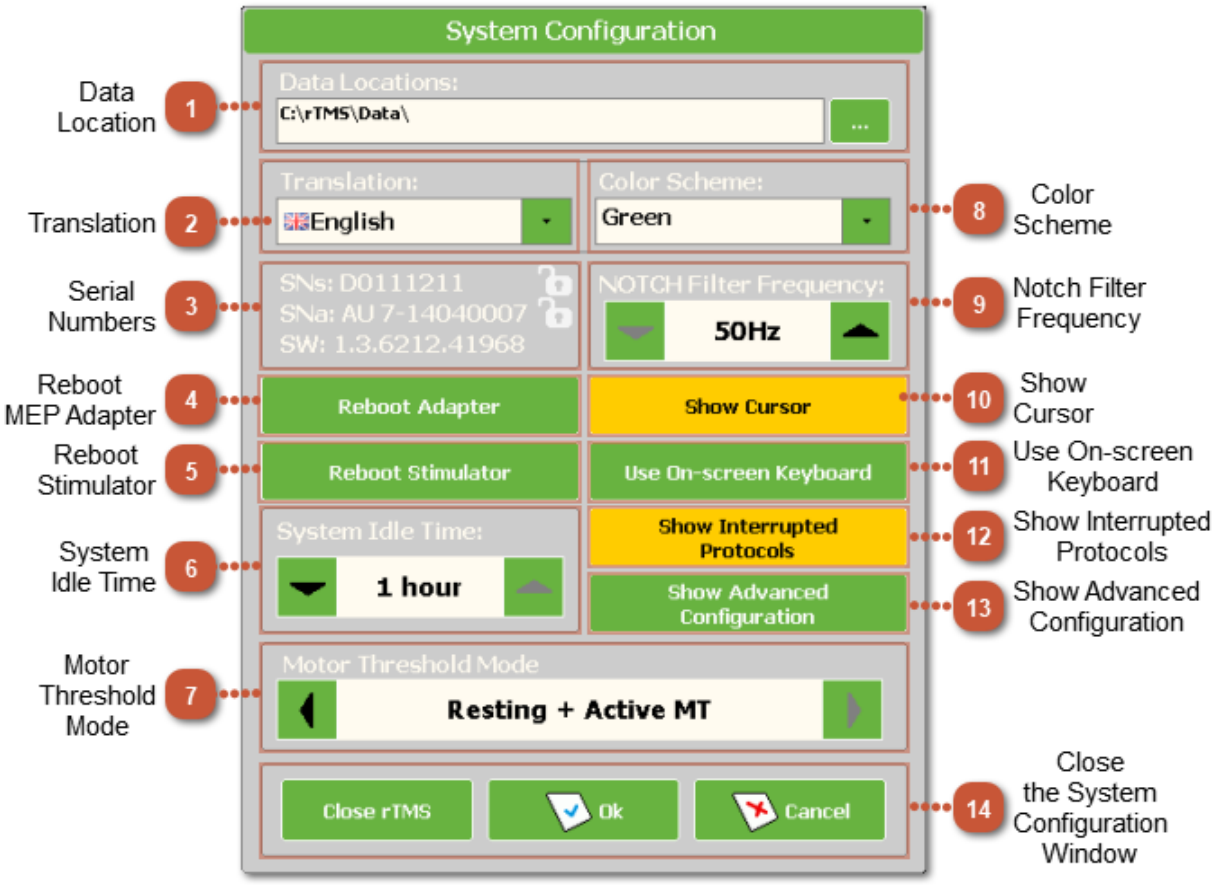
If the protocol is finished correctly, the stimulator is automatically Disabled.

10 Remaining time / pulses

The **Remaining Pulses** is used when the protocol is running and displays the number of stimulations remaining in the currently running protocol.

The **Time Remaining** is used when the protocol is running and displays the actual time to the end of the currently running protocol.

System Configuration Screen



1 Data Location	8 Color Scheme
2 Translation	9 Notch Filter Frequency
3 Serial Numbers	10 Show Cursor
4 Reboot MEP Adapter	11 Use On-screen Keyboard
5 Reboot Stimulator	12 Show Interrupted Protocols
6 System Idle Time	13 Show advanced settings
7 Motor Threshold Mode	14 Close the System Configuration Window

1 Data Location

Sets the path where the patient database and data are located.

2 Translation

Choose the desired language for the interface. The computer must be restarted for this change to take affect.

3 Serial Numbers

Indicates the serial number of the DuoMag system, serial number of the MEP Adapter and version of the Main Computer Control Unit. The serial numbers are viewable only when the Stimulator hardware is connected to the Main Computer Control Unit.

4 Reboot MEP Adapter

Used to reboot the USB adapter (only in case of an error message).

5 Reboot Stimulator

Used to reboot the Magnetic Stimulator (only in case of an error message).

6 System Idle Time

This value indicates when the system will Disable if there is no activity. This helps to prevent any unnecessary or inadvertent data to be written to a selected patient's record.

7 Motor Threshold Mode

The Motor Threshold Mode offers three modes:

- MT Sleep mode (RMT) - Work with resting motor threshold. When the Motor Threshold is found, it will be saved as RMT and also all the created stimulation protocols assume this motor threshold mode.
- Active Motor Threshold (AMT) allows the user to work with the Active Motor Threshold of the patient. When the Motor Threshold is found, it will be saved as AMT and also all the created stimulation protocols assume this motor threshold mode.
- Resting + Active MT Mode allows the user to work with both motor thresholds, Resting and Active. The system then shows both protocol types (RMT and AMT). When a new protocol is created in this MT Mode, the user should set whether the protocol will use RMT or AMT. Selected protocol can be used for stimulating the

patient only if the desired motor threshold (RMT or AMT) has been preset for the patient and the selected protocol is designed for the same MT mode. The user can either set the necessary motor threshold or select a different protocol.

8 Color Scheme

The color scheme allows the choice of a few interface color options.

9 Notch Filter Frequency

Sets the frequency of the Mains power supply for the country where you are using the equipment. This helps to suppress the unwanted noise from this frequency when the Notch filter is activated.

10 Show Cursor

Hide / show the mouse cursor on the screen (typically disabled on the touch interface).

11 Use On-screen Keyboard

Activates a virtual on-screen keyboard. The keyboard will be displayed automatically when a text field is selected.

12 Show Interrupted Protocols

If the Show Interrupted Protocols button is activated, the session list also displays the protocols that were finished before the end.

13 Show advanced settings

Opens the Advanced Configuration Window.

14 Close the System Configuration Window

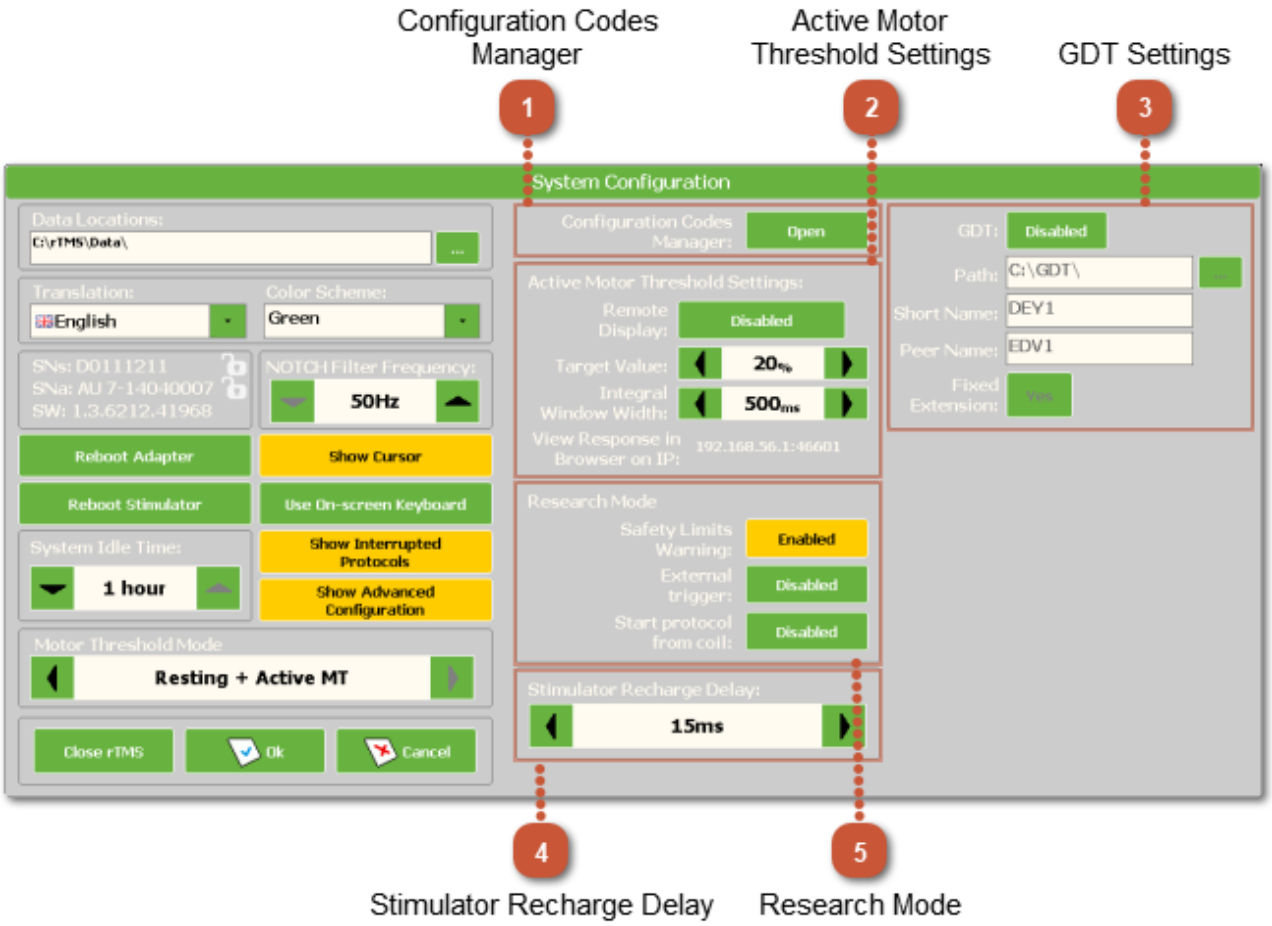
The **OK** button accepts any changes made to the settings and then closes the System Configuration window.

The **Cancel** button closes the System Configuration window without saving any changes made to the settings.

If the button **Close rTMS** is available, it will close the DuoMAG rTMS software without turning off the All-In-One PC.

NOTE: Changes to any setting in Windows should only be performed by a trained service technician.

Advanced System Configuration Screen



1	Configuration Codes Manager	4	Stimulator Recharge Delay
2	Active Motor Threshold Settings	5	Research Mode
3	GDT Settings		

1 Configuration Codes Manager

This button opens the Config Codes Manager.

2 Active Motor Threshold Settings

Active Motor Threshold Settings are available when Active Motor Threshold Mode is active (AMT or RMT + AMT modes).

A **Remote Display** of the current status of the AMT settings can be enabled. This function needs the DuoMAG PC to be connected to a local network and second PC with web browser connected to the same local network.

The **Target Value** is the percentage of maximum muscle contraction which should be held while finding the AMT. The maximum muscle contraction is calibrated on the start of each session. The patient is asked to give a maximum contraction which is then saved. Actual contraction is then displayed as a percentual part of the saved maximum value. Getting close to the desired value is color indicated. Green color when within 5 % of the Target Value, Yellow color when between 5 % and 10 % of the Target Valueand Red color when between 10 % and 15 % of the target value. Otherwise the color is black.

Integral Window Width is the time interval in which the EMG signal is used for calculating the actual muscle contration. Increasing the value leads to a slower response, decreasing the value leads to a faster response.

View Response in Browser on IP displays the current IP address and port. If this is entered into the address bar of a web browser on the PC in the same local network as the DuoMAG is, it will display current status of the Active Motor Threshold finding.

3 GDT Settings

The **GDT** button turns on or off the Settings for use of GDT protocol (Geräte-Daten-Träger).
Path is a GDT data path.
Short name is the first part of the GDT name.
Peer name is the second part of GDT name.
Fixed Extension is an option to use a fixed extension for GDT (.gdt) or iterativly changing extension.

4 Stimulator Recharge Delay

An option to delay the recharge of the capacitors for use in combination with EEG. The value can be set from 0 ms to 600 ms.

5 Research Mode

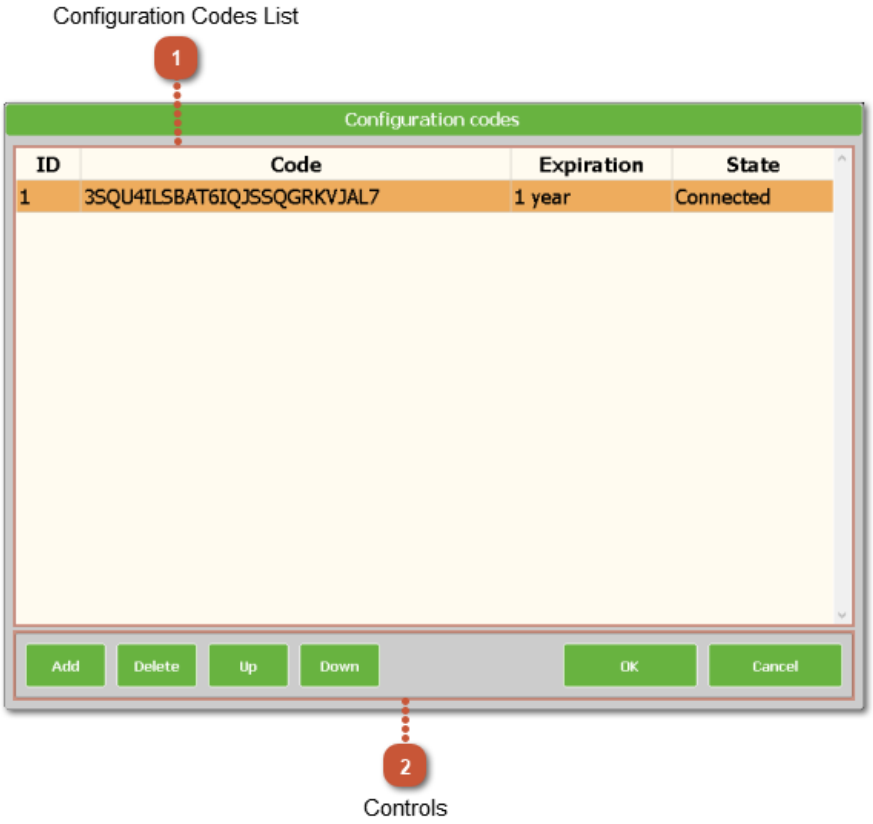
Safety Limits Warning enables the user to switch on or off the message warning when the starting protocol does not meet safety limits regarding the publications Wassermann (1998) or Rossi (2009). If Safety Limits Warning is switched off, there is still a warning symbol visible but there is no popup information that needs to be confirmed. Users may not actively confirm that wants protocol really run.

External Trigger function enables the stimulator to detect incoming TTL pulses from an external source. This requires using the Sync Merger box inserted between the TTL connection of the Magnetic Stimulator and EMG USB adapter. If this function is enabled, only external triggering is accepted. When an incoming TTL is detected in the Single Pulse mode, the MEP is recorded together with the stimulation. If this function is disabled, it is still possible to use the external trigger but no MEP will be recorded.

Start protocol from Coil function allows the user to start the preset protocol using the button on the Stimulation Coil. The protocol must be selected and the Stimulator Activated. When the Coil button is pressed again during the stimulation, the protocol is paused immediately. A second click on the coil button will start the protocol from the position where it was paused.

Config Codes Manager

Configuration Codes Manager stores all the config codes in the device. There can be multiple active codes at the same time. To be active the code needs to be time valid and hardware valid (a code must contain information on the device curently connected to the system). All advanced features in the system are given by the combination of all active codes



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1 Configuration Codes List	2 Controls

1 Configuration Codes List

The **ID** column contains ID of the code in the list.

The **Code** contains information on the connected device, time validity and particular software features.

The **Expiration** column shows the expiration date.

The **State** column shows if the code is in use.

2 Controls

Add: This button allows the user to add another code to the list. The new code will be added to the first position in the list.

Delete: This button removes the selected configuration code from the list.

Up: This button moves the selected code up one position in the list.

Down: This button moves the selected code down one position in the list.

OK: This button confirms the changes. If changes were made, the user is asked to restart the software. All changes will take effect after the software restart. If the user does not restart the software immediately, the changes will take effect on the next start of the system.

Cancel: This button closes the configuration codes manager without saving any changes.

7. Conventional procedures for using the device

The basic positioning of the device and the patient affects the subsequent operator comfort during examination or therapy. Pay attention to the following chapters which contain tips on optimal configuration of the work environment and basic procedures for performing stimulation.

Spatial configuration

Before starting work with the DuoMAG Magnetic Stimulator, make sure the device is connected to the mains and the Stimulation Coil is connected to the Stimulator. Move the device near the patient so a stimulation position is easily reachable with the Stimulation Coil. If you are using a fixation arm either on a MagCart or a MagTower, make sure that the desired stimulation position is within range of the Coil placed on the arm.

Position the patient properly to have a good access to control the Magnetic Stimulator as well as the Stimulation Coil. Adjust the Magnetic Stimulator position so the operator has a good view of the coloured status indicators and the stimulation intensity value display on the stimulator.

In the case of using the XT type on the MagTower operated via a control PC, adjust the position of the touch screen to be easily visible and accessible for the user. In the case of using an EMG device, please refer to the separate instructions for use.

Single pulse stimulation

When using a Magnetic Stimulator in isolation and without additional accessories, it can only perform individual stimulation pulses that are executed using the buttons on the Stimulation Coil.

After completing the basic configuration of the workspace (see previous chapter) and turning on the Magnetic Stimulator (see chapter Turning on and operating the Magnetic Stimulator), it is possible to perform the stimulation. Adjust the stimulation intensity using the thumbwheel on the Stimulation Coil handle. The current value of the intensity is viewable on the Stimulator display. Press a button on the Stimulation Coil handle to perform a single pulse (see also Setting the stimulation intensity and start stimulation).

When using a Magnetic Stimulator with the control PC (for example on a MagTower), the single stimulation can be performed two ways. First, you need to select or create a patient in the control application on the PC (described in more detail in chapters Patient screen and Add / Edit Patient). After the patient selection window, move to the single stimulation screen (see MEP/MT Single Pulse Screen). Here it is possible to perform a single stimulation.

Setting the stimulation intensity and make own stimulul can be the same way as in the control of stimulator, on the handle coils. It is possible to see the intensity value not only on the Stimulator display, but also in the right part of the control application screen.

The second option is to set the stimulation intensity using the slider on the right side of the Touch-screen Control PC. Curent intensity is again indicated on both the Touch-screen and on Stimulator display. Before performing a pulse it is necessary to prepare the Magnetic Stimulator by pressing the Activate button. The stimulation can then be performed by pressing the 'Single' button on the touch screen.

The attached EMG device can monitor the patients response to a single stimulation, for example when searching for the Motor Threshold. When the Motor Threshold is found the, Set RMT / Set AMT can be used to save the current intensity of the stimulation as a value corresponding to the selected Motor Threshold Mode (for more details see chapter Add / Edit Patient).

Protocol Stimulation

Stimulation protocols can only be performed on a Magnetic Stimulator, controlled by the software application. As in the case of individual stimulation the patient must be selected first. The following is a selection stimulation protocol and the transition to the screen stimulation protocol. For this purpose, click Select protocol at the top right of the touch screen. The protocol can be selected from a list of previously preset protocols. See more about setting the protocols in chapters Repetitive Protocol Setup and Burst Protocol Setup (for DuoMAG XT-100 only). The overall intensity which is used for performing the selected protocol reflects the relative value preset in the protocol and the Motor Threshold value of the selected patient. The intensity value of the selected protocol is displayed on the screen in the right side of the screen well as on the Stimulator display.

Launching a Protocol consists of two steps. First pressing the Activate button on the Touch-screen which will enable the Start button. After pressing the Start button the selected protocol starts.

Prematurely ending of a running protocol is possible by pressing the STOP button on the Touch-screen.

In the Protocol Stimulation mode, all the controls on the Coil handle are usually inactive. If the function of starting the protocol from the Coil is available (see chapter Advanced System Configuration Screen, item 5) then the protocol can be started using the Coil button if the Stimulator is activated. If the protocol is currently running, it can be paused by pressing the Coil button.

8. Maintenance, Cleaning and Disinfection

The Magnetic Stimulator and its Stimulation Coils require no operational maintenance to be performed by the user. Any cleaning of the connectors should be performed during preventive inspection by an authorised service technician. The instrument does not need to be calibrated, and will maintain its main parameters for the duration of its expected shelf life.

Before cleaning or disinfection, turn off the main power switch. The Stimulation Coils and Stimulator surface may be cleaned or disinfected using a soft cloth. Before stimulation, make sure that the surface of the Stimulation Coil and Stimulator are dry.

Sterilisation of the Stimulation Coil is not allowed. Try to prevent any contamination via infectious material. If necessary to put in contact with an infected patient, wrap the Coil in plastic or in a fabric cover, but never with aluminum foil or thermal protection films, which often contain metalised surfaces. The cover must be thin enough to not significantly change the distance between the Coil and patients scalp. The cover material cannot be electrically or magnetically conductive. If the Air-Cooled Coil 70BF-Cool is used, do not cover the cooling air channels with the cover.

For cleaning and disinfection, use normal detergents (for example: propanol alcohol, isopropyl alcohol or ethyl alcohol). Do not use cleaning and disinfecting compositions based on chlorine.

9. Troubleshooting

The device contains no parts serviceable at the installation site, except fuses and power cable.

If the device will not start after being switched on, check the power cable and its connection. The power cable needs to be connected to the mains power socket. The power cable needs to be connected to the socket on position (2) (see chapter Description of the Device). The power cable along its entire length must not be mechanically damaged.

If the supply cable is OK, check the fuses.

In the case of the XT system with the Control PC If the control PC cannot be switched on but the Magnetic Stimulator still works, check the power cable to the PC. If is OK, check the fuses.

Replacing fuses

The magnetic stimulator can not run.

- Replace fuses on the position (1) (see chapter Description of the Device, rear panel) for the corresponding fuses mentioned in the Specifications of this manual or on a label on the rear panel of the Magnetic Stimulator.

On XT type controlled by the PC when PC can not be switched on but the Magnetic Stimulator works well.

- Replace fuses on the position (7) (see chapter Description of the Device, rear panel) for the corresponding fuses mentioned in the Specifications of this manual or on a label on the rear panel of the Magnetic Stimulator.

Changing the power cable

The power cable must be long enough and end with the C19 connector for connecting to the Magnetic Stimulator. Replace the supply cable when the appliance is switched off. Ensure that the power cable is not mechanically stressed.

10. Specifications

Input:
DuoMAG MP: 100 V~ - 127 V~, 50/60 Hz or 200 V~ - 240 V~, 50/60 Hz
DuoMAG XT: 100 V~ - 127 V~, 50/60 Hz or 200 V~ - 240 V~, 50/60 Hz

Power supply:
DuoMAG MP (monophasic type): 620 VA max, resting consumption 30 VA max
DuoMAG XT (biphasic type): 2100 VA max, resting consumption 115 VA max

Fusing:
DuoMAG MP:

- 2 x tube fuse 6.3 x 32 mm T 8AH, 250 V, for 100 V~ to 127 V~
- 2 x tube fuse 6.3 x 32 mm T 4AH, 250 V, for 200 V~ - 240 V~

DuoMAG XT-35 and XT-100:

- 2 x tube fuse 6.3 x 32 mm T 16AH, 250 V, for 100 V~ - 127 V~
- 2 x tube fuse 6.3 x 32 mm T 10AH, 250 V, for 200 V~ - 240 V~

DuoMAG XT - power of control PC:

- 2 x tube fuse 5 x 20 mm T 4AL, 250 V, for 100 V~ to 127 V~
- 2 x tube fuse 5 x 20 mm T 2.5AL, 250 V, for 200 V~ až 240 V~

The Magnetic Stimulator is designed for connection to the mains outlet on a TN-S circuit with the RCD as additional protection (according to CSN 33200-7-710) with a residual tripping current of 30 mA max.
This means that to minimize the risk of electrical shock, the Magnetic Stimulator can only be connected to the mains with protective grounding!

The highest frequency of stimulation:
DuoMAG MP (monophasic type): 0.5 Hz (100% intensity), 1.4 Hz (50%), maximum 2 Hz
DuoMAG XT (biphasic type):

- Model XT-100:22 Hz (100% intensity), 86 Hz (50%), maximum 100 Hz
- Model XT-35: 13 Hz (100% intensity), 35 Hz (50%), maximum 35 Hz
- Model XT-10: 5 Hz (100% intensity), 10 Hz (50%), maximum 10 Hz

Discharged energy (intensity 100%):
DuoMAG MP ..... 700 J
DuoMAG XT ..... 265 J (optionally 320 J)

Stimulation pulse waveform (electrical stimulation in the Coil, from which the magnetic field corresponds):

- DuoMAG MP (monophasic type): the harmonic quarter takes 100 μs followed by a slow wave lasting about 1 ms
- DuoMAG XT (biphasic type): approximately one harmonic wave with a total duration of 290 μs (optionally 320 μs for model with a discharge energy of 320 J)

Stimulation polarity:
The orientation of the active stimulus current is indicated by an arrow on the Stimulation Coil. The polarity of the stimulation of a biphasic pulse and the orientation of the coil, as a practical rule, does not matter.

Synchronization TTL inputs (BNC connectors)
Input impedance min. 10 kΩ, allowable input voltage range -0.2 ... 5.2 V vs shielding (does not guarantee correct operation, but that it does not affect the input circuit)
Output impedance max. 200 Ω
Input and Output ports are galvanically (electrically) connected, but they are isolated from the rest of the stimulator.
Logic levels:
Input: TTL (logic level zero 0 V to 0.8 V, logic level one 2 V to 5 V)
Output: CMOS, TTL compatible (logic zero max 0.1 V logic level one minute. 4.5 V)
Input pulse width: min. 10 μs, synchronization at the leading edge
Output pulse width: min. 200 μs, synchronization on the leading edge

USB port:
2.0 compatible

Dimensions: (Length, Width, Height):
DuoMAG MP: 49 cm x 38 cm x 11 cm
DuoMAG XT: 49 cm x 38 cm x 16 cm

Weight:
DuoMAG MP: 14.5 kg net (without Stimulation Coil)
DuoMAG XT: 15 kg net (without Stimulation Coil)

If national regulations require providing inspection nad preventive maintenance (IPM), the repetition is specified as once per year. IPM can be provided only by service personnel of the manufacturer or an authorised service center. If the device was not inspected within the period prescribed by the manufacturer or authorized service organization, it cannot be used.

Service personnel must meet the regulations for providing IPM.
During regular inspection service personnel will focus mainly on the Stimulator and Stimulation Coil electrical contact cleanness, integrity of the coil cable, integrity of the power cable to the device, integrity of the Stimulation Coil and the typical sound of the Coil during stimulation.
The device contains no parts serviceable at the installation site, except fuses and power cable.

11. Disposal of the product

The product is made of materials that are environmentally friendly. It does not contain any hazardous materials and its operative noise complies with all requirements for the public health protection from dangerous effects of the noise and the vibrations in controlled internal areas of the buildings.

All packaging waste resulting from the putting into service of the product is labeled in accordance with the applicable packaging regulations. Sort them according to the graphic symbols and pass them on to the authorized person for further use.

The graphic symbols are located on the back of the medical device label.

The product contains recyclable metal, plastic, glass and electronical parts. To dispose of the product after its use, contact a dedicated organization specializing in this activity or use the collection or recycling yards.

<u>This product and its electronic accessories should not be mixed with other commercial wastes for disposal!</u>

Correct disposal of this product (Waste Electrical & Electronic Equipment)

(Applicable in countries with separate collection systems)

This marking on the product, accessories or literature indicates that the product and its electronic accessories (e.g. electrical cables) should not be disposed of with other household waste at the end of their working life. Possible negative impacts on the environment or human health caused by uncontrolled disposal will prevent you from separating these products from other types of waste and responsible recycling for the sustainable use of secondary raw materials.

Proper disposal of batteries in this product

(Applicable in the European Union and other European countries with their own battery back-up systems)

This marking on battery, manual or packaging indicates that the batteries in this product should not be disposed of with other household waste at the end of their working life. Where marked, the chemical symbols Hg, Cd or Pb indicate that the battery contains mercury, cadmium or lead above the reference levels in EC Directive 2006/66. If batteries are not properly disposed of, these substances can cause harm to human health or the environment. To protect natural resources and to promote material reuse, please separate

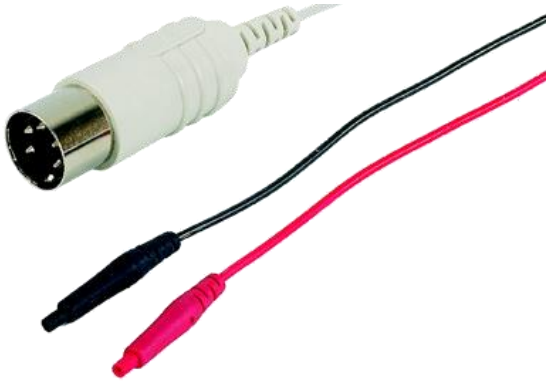
batteries from other types of waste and recycle them through your local, free battery return system.

As a result of an incorrect waste disposal procedure, penalties may be imposed in accordance with national rules.

12. Consumables

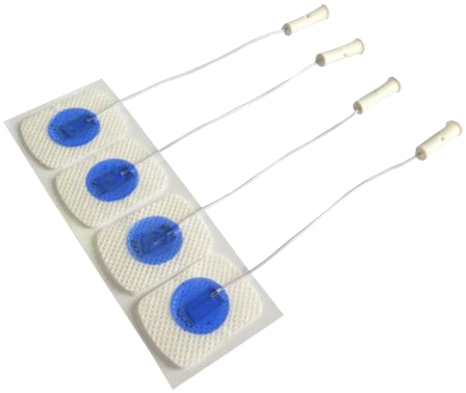
DuoMAG MEP Starter Kit (in case of the system with EMG)

Cable for Disposable EMG Surface Electrode (1,5 m)



Ground electrode 1.5 x 25 cm (2 m)

Deymed Self-Adhesive Disposable Electrodes (12 pieces)



Jumper cables designed to connect magnetic stimulator with other devices

The device may only connect the cables supplied by the manufacturer or supplier. Their possible lengths and order numbers are listed in the following table:

Cable type	Length	Catalog number
USB cable A-B (with ferrites)	0,5 m 0,9 m 1,8 m 3 m	71-220 71-221 71-222 71-223
BNB-BNC cable 50 Ohm (For TTL comunication, with ferrites)	0,5 m 3 m 5 m	71-420 71-421 71-422
UTP RJ45-RJ45 cable (For TTL comunication, s ferity)	1 m 2 m 3 m 5 m	71-440 71-441 71-442 71-443

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation

13. Clinical Recommendations and Literature

The literature [1] and [2] should be followed as the maximum stimulation time (in seconds), and as shown in the following table:

frequency of stimulation [Hz]	motoric threshold* [%]													
	90	100	110	120	130	140	150	160	170	180	190	200	210	220
1	> 1800	>1800	>1800	> 360	> 50	>50	>50	>50	27	11	11	8	7	6
5	> 10	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	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	2.05	1.6	1	0.55	0.35	0.25	0.25	0.15	0.2	0.25	0.2	0.1	0.1
25	1.28	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

*For determining the motoric threshold, EMG detection is suggested instead of visual confirmation. Using the visual confirmation usually leads to the higher threshold, see [3]

[1] Wassermann EM., Risk and safety of repetitive transcranial magnetic stimulation: report and suggested guidelines from the International Workshop on the Safety of Repetitive Transcranial Magnetic Stimulation, June 5-7, 1996, Electroencephalogr Clin Neurophysiol. 1998 Jan;108(1):1-16.

[2] Simone Rossi, Mark Hallett, Paolo M. Rossini, Alvaro Pascual-Leone, and The Safety of TMS Consensus Group, Safety, ethical considerations, and application guidelines for the use of transcranial magnetic stimulation in clinical practice and research, Clinical Neurophysiology 2009 Oct, 120, 2008-2039

[3] Westin GG, Bassi BD, Lisanby SH, Luber B. Determination of motor threshold using visual observation overestimates transcranial magnetic stimulation dosage: Safety implications Clin Neurophysiol International Federation of Clinical Neurophysiology: International Federation of Clinical Neurophysiology; 2013

[4] Lindsay Oberman, Dylan Edwards, Mark Eldaief, Alvaro Pascual-Leone, Safety of Theta Burst Transcranial Magnetic Stimulation, A Systematic Review of the Literature, Journal of Clinical Neurophysiology, Volume 28, Number 1, February 2011

[5] Jean-Pascal Lefaucheur, Nathalie André-Obadia, Andrea Antal, Samar S. Ayache, Chris Baeken, David H. Benninger, Roberto M. Cantello, Massimo Cincotta, Mamede de Carvalho, Dirk de Ridder et al. Evidence-based guidelines on the therapeutic use of repetitive transcranial magnetic stimulation (rTMS). Clinical Neurophysiology [online]. 2014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