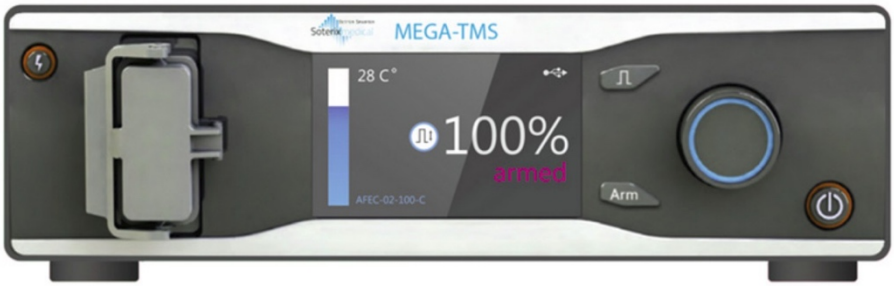
MEGA-TMS



Operator's Manual

Version 1.0.7

TM063.04.001.00
(01.17.2022)

US-edition

1480 US 9 North, 204, Woodbridge, NJ,
07095, USA Phone: +1-888-990-8327
E-mail: contact@soterixmedical.com Internet: www.soterixmedical.com

Contents

Introduction

This technical manual (hereinafter referred to as “manual”) is the combined document describing operation and servicing of **MEGA-TMS** magnetic stimulator (hereinafter referred to as “stimulator”).

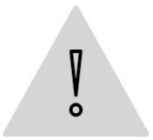
This manual is the document which certifies the stimulator specifications guaranteed by the manufacturer.

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

Indications for Use

Stimulation of peripheral nerves for diagnostic purposes.

Contraindications



Although the magnetic stimulation in single pulse mode is a safe procedure, before the stimulation, each patient must be screened for contraindications.

The absolute contraindications include implanted devices that are activated or controlled in any way by physiological signals (examples: cardiac demand pacemakers, implanted electronic devices, cochlear implants, pregnant women).

All the rest contraindications are relative ones. In each individual case the benefit of the test should be weighed against possible adverse effects. This judgement is best left to a skilled clinician familiar with the characteristics of the device.

Do not use the peripheral magnetic stimulation in the following patient groups or clinical conditions:

Patients who have conductive, ferromagnetic or other magnetic-sensitive metals implanted in their head or within 30 cm of the coil (examples: magnetically activated dental implants, ferromagnetic ocular implants, pellets, bullets and its fragments, facial tattoos with metallic ink, metal cuts, aneurysm clips or coils, carotid or cerebral stents, implanted chips, implants with radioactive drugs, etc.)

Possible Side Effects

1. Muscle twitches.
2. Pain at stimulation side.
3. Local allergic reactions to adhesive and working surfaces of EMG electrodes.
4. Syncope.

Compared to seizure, syncope is more likely to occur during a TMS study, but this is a rare event too. Vasodepressor (neurocardiogenic) syncope is a common reaction to anxiety and physical discomfort and it can take place following TMS, as with many other noninvasive or minimally invasive medical procedures. The loss of consciousness lasts for a few seconds. The patient may faint or “pass out” and may

complain to shortness of breath, anxiety, sweating, dizziness, nausea, pallor, weak pulse, bradycardia, narrowing and blacking out of the visual field.

It should be noted that patients who develop syncope under TMS often have experienced similar episodes in the past.

5. Dermatalgia at stimulation site.
6. Transient hearing impairment at single pulse stimulation can occur only theoretically. However, both patient and operators should always wear earplugs.

Warning and Precautions

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

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

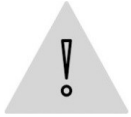
While working with the stimulator it is required to observe the working regulations concerning the safety rules while operating electrical equipment.

High voltages (2800 V) are presented within the stimulator.

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

- **to use the stimulator which was mounted and installed incorrectly, without following this manual's instruction;**
- **to eliminate faults connected with opening of the components included in the delivery set;**
- **to work with the stimulator when the electronic unit box, computer or other devices used together with the stimulator are open.**

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



It is prohibited to connect the stimulator to the mains outlet that is not grounded properly.

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

Do not allow the coil to come into close proximity (less than 1 meter) with electronic equipment (monitor, computer, etc.) and magnetic carriers (credit cards, etc.). The magnetic field emitted by the coil can result in its damage and information loss.

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

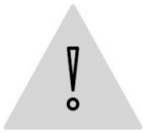
The pulse evoked by the stimulator generates a loud click that can frighten a patient. Tell a patient about the stimulation beginning or give her/him ear plugs.

The stimulator must not be used together with the anesthetic gases as it may ignite / catch fire

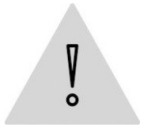
The operator must be protected from the continuous impact of the magnetic field. It is recommended to use the holder to fixate the coil.

If a coil heats over 41°C, the stimulator stops functioning and indicates overheating. As coil surface temperature still increases even after stimulation stop (owing to the thermal lag), it is essential to move the coil immediately from the patient's scalp to avoid potential burn and discomfort.

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



The use of accessories, spare parts and cables other than in delivery set may result in decreased EMC immunity and increased emissions of the equipment.



The user must not install third-party software

The general principles of safety regulations are stated in:

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

1. Description

1.1. Main Specifications

Table 1. Main specifications of magnetic stimulator

Parameters	Values
Stimulation Parameters	
Peak magnetic field at 100% output (depends on coil): • monophasic (FEC-03-0100) • monophasic (AFEC-03-0100)	 0 –1.5 T 0 –1.8 T
Duration of raise part of pulse: • monophasic	 80±15 μs
Maximum frequency depending on pulse intensity:	• 100% – 0.3 Hz • 75% – 0.5 Hz • 50% – 1 Hz • 30% – 1.4 Hz
Power Supply	
Supply voltage	110 V ~ 50/60 Hz 220/230 V ~ 50/60 Hz
Maximum power consumption during the stimulation: • average • peak	 not more than 1250 V·A not more than 2000 V·A
Supply-line fuses when powered from • 220/230 V mains socket • 110 V mains socket	 5 A – 2 pcs. 10 A – 2 pcs.
Trig-in/out	
Trig-in	TTL/CMOS
Trig-out	TTL/CMOS
Trig-in pulse width	≥ 100 μs
Stimulus delay relative to trig-in signal	≤10 μs
Trig-out pulse width (user-defined)	see Table 2
General Parameters and Specifications	
Auto discharge time	3 min
Interface	USB
Safety class	I
Applied parts	BF type
Degree of protection provided by enclosures of • electronic unit • footswitch	 IP20 IPX1
Unit dimensions	530×500×180 mm

Table 2. Continued

Parameters	Values

Unit weight	not more than 30 kg
Operating Conditions	
Temperature	+ (10–35)°C
Relative humidity	from 30 to 85% (non-condensing)
Atmospheric pressure	from 70 to 106 kPa
Transportation Conditions	
Temperature	-25 to +60°C
Humidity	from 20 to 95% non-condensing
Atmospheric pressure	from 70 kPa
Storage Conditions	
Temperature	+5 to +40°C
Humidity	from 30 to 85% non-condensing
Atmospheric pressure	70-106 kPa

Table 2. Range of Controlled Parameters and Frequency Step

Parameter	Range of Permissible Values	Frequency Step
Stimulation Parameters		
Stimulus intensity	0–100 %	1%
Trig-out		
Trig-out pulse width	100 μs–10 ms	100 μs

Table 3. Stimulation Modes

Stimulation Type	For Configuration 1	For Configuration 2
Monophasic	+	+

The specifications of coils are provided in the corresponding technical manual.

Safety and Electromagnetic Compatibility

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

The magnetic stimulator is intended for operation in electromagnetic environment, as specified in Appendix 1.

The mobile radio-frequency devices may impact the system.

The use of accessories not listed in Table 5 and Table 6 of this technical manual can cause the increase of electromagnetic emissions or decrease of the electromagnetic immunity.

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

Delivery Set

The delivery set includes the electronic unit (monophasic) with the set of coils and cables. The delivery set of the stimulator corresponds to Table 4 and Table 5.

The figures in “Quantity, pcs.” column of Table 4 and Table 5 indicate:

1 — **MEGA-TMS** magnetic stimulator (configuration for single pulse stimulation (hereinafter referred to as “configuration 1”).

The complete delivery set of the stimulator is shown in Fig. 1.

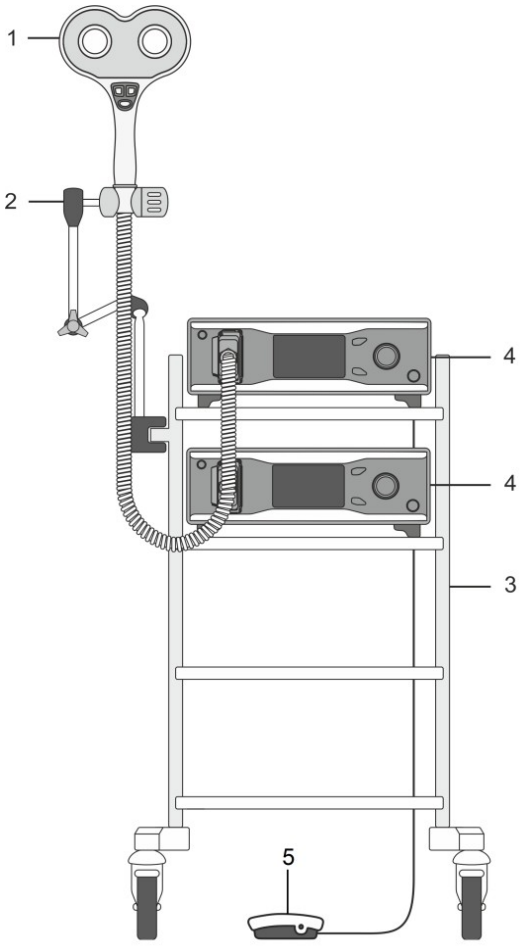


Fig. 1. The external view of assembled magnetic stimulator.

1. coil;
2. flexible arm for coil positioning K-3 or K-7;
3. Trolley T-4/A with castors for magnetic stimulator (4 shelves);
4. MEGA-TMS main stimulator unit;
5. footswitch.

Table 4. Base Delivery Set

Name	Order code or main specifications	Quant., pcs.	
		1	2

MEGA-TMS main stimulator unit	NS063201.001-02	1	2
End cap	NS063105.001	1	2
Footswitch	NS063353.001	1	1
Coils:			
Figure-of-eight coil 100 mm FEC-03-100	NS063304.008	1	2
Big ring coil 125 mm RC-03-125	NS063304.002	1	1
Cables:			
High-voltage cable for extra unit conneciton	NS063103.007	–	1
Equipotential cable	NS058103.032-050	–	1
CEE 7/7 – IEC C13 mains supply cable	220 V, 10 A, 1.8 m (3G×0.75 sq. mm)	1	2
USB cable (A→B)	NS007103.005	1	1
Trolleys:			
Trolley T-4/A	NS059998.009	–	1
Holders:			
K-8 coil holder (trolley/wall mounted)	NS059998.004	–	1
Operating Documentation:			
MEGA-TMS technical manual	TM063.01.001.001	1	1
Coils for magnetic stimulators “MEGA-TMS” and “MEGA-TMS” technical manual	TM058.02.003.000	1	1
Package:			
Cardboard package (set)	–	1	1
MEGA-TMS unit package	NS063901.001	1	2

Table 5. Additional Equipment, Accessories and Software Included in Delivery Set by Customer’s Request

Name	**Order code or main specifications**	**Quant., pcs.**	
		1	**2**
Coils:			
Angulated figure-of-eight coil 100 mm AFEC-03-100	NS063304.011	1	1
Cables:			
Trig-in cable for synchronization via electrical stimulator: DIN8ßDIN5 (240°)	NS063103.010	1	1
Trigger cable: BNC – BNC	NS063103.009	1	1
Holders:			
K-3 flexible arm for coil positioning	NS016998.012	1	1
K-7 flexible arm for coil positioning	NS016998.018	1	1
K-8 coil holder (trolley/wall mounted)	NS059998.004	1	–
Trolleys:			
Trolley T-4/A	NS059998.009	1	–

1.2. Structure and Operation

Depending on the selected configuration, MEGA-TMS magnetic stimulator can include one stimulator unit (hereinafter referred to as “stimulator”). Stimulator unit allows to generate single electromagnetic pulses of specified intensity.

The block diagram of system with 1 stimulator unit intended for single stimulation is shown in Fig. 2.

The block diagram of the magnetic stimulator unit (Fig. 2) consists of control circuitry, capacitor, capacitor charging circuitry intended for the capacitor charge up to achieving the voltage specified by the control circuitry and the high-voltage electronic switch (Fig. 2).

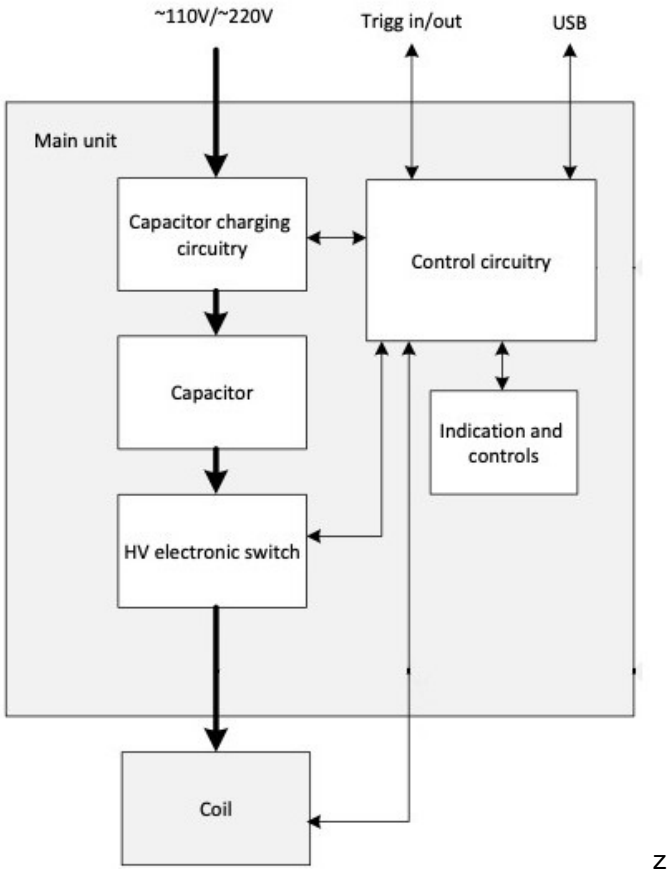


Fig. 2. The block diagram of stimulator.

The principle of operation of magnetic stimulator is based on discharge of high voltage capacitor (max 2.8 kV) through copper winding at the moment the electronic switch is being closed. At this time the discharge current (up to 12 kA) generates the electromagnetic field. This field induces the current in nearby body tissues which causes nerve pulse as during usual electrical stimulation.

The magnetic stimulator generates the following pulse waveform:

- ***Monophasic pulse*** – is a pulse when current in the coil flows in one direction increasing sinusoidally and decreasing exponentially (Fig. 3Fig. 3).

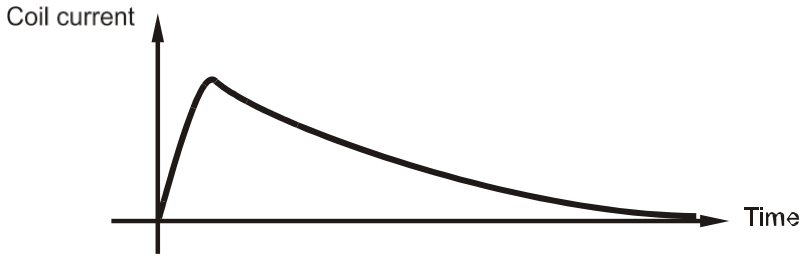


Fig. 3. Monophasic waveform.

The current flowing through the coil results in heating. The higher is the pulse intensity and stimulation frequency, the quicker is the heating of the operating surface of the coil. The contact with this heated surface can evoke hyperaemia or burn. To control the temperature, the coils are equipped with the temperature sensors. The indications of these sensors are controlled by the stimulator control system. In case the coil heats up to 41º C, the stimulation is stopped, and the stimulator notifies a user about it.

1.3. Controls, Connectors and Indicators

1.3.1. Controls, Connectors and Indicators of Stimulator

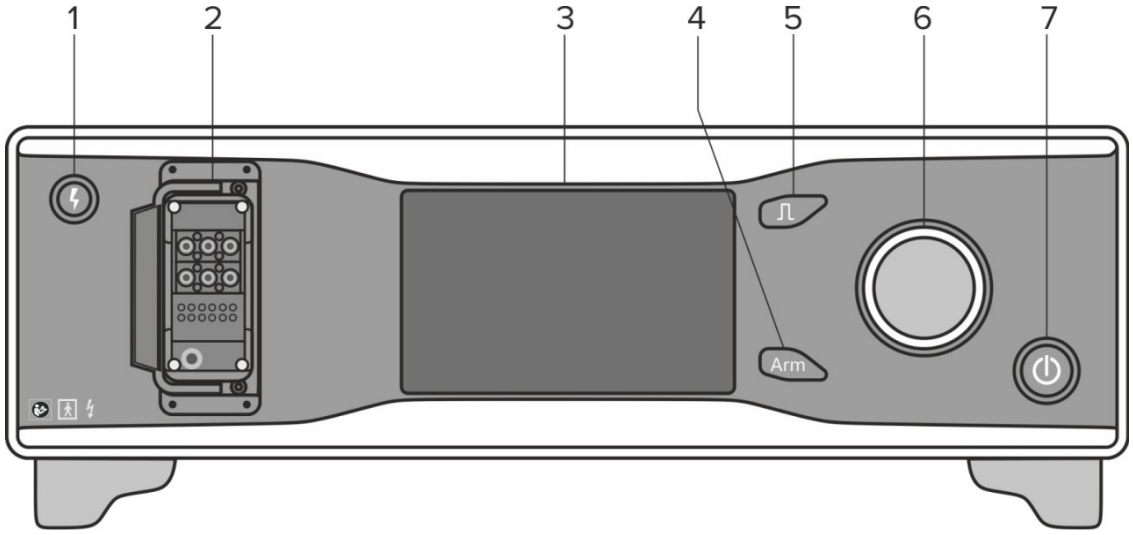


Fig. 4. The front panel of stimulator.

The front panel of stimulator contains:

1. “Coil change” button combined with “High voltage” indicator.

The “High voltage” indicator highlights yellow when the stimulator is switched on and up to 2800 V high voltage is supplied inside the stimulator. While the high voltage is supplied to coil connector at the moment of pulse delivery, it is dangerous to disconnect the coil. To replace the coil, press “Coil change” button which switches off the internal high-voltage power supply and discharges instantly the high-voltage capacitor to the safe voltage. After that the “High voltage” indicator stops illuminating. After the coil replacement press “Arm” button to resume the capacitor charge up to specified value.

2. “Coil connector” high-voltage connector to plug in the coil.

3. Multifunctional LCD display intended to show information on current mode and other parameters. The detailed description is given in 1.4 “Stimulator Menu” section.

4. “Arm” button.

If stimulator is in disarmed state, press “Arm” button to initiate capacitor charge. The “Charging” symbol first appears on display. On charge process completion, the stimulator then enters the “Arm” state and is ready to deliver pulses. At that time, “Armed” symbol appears on display.

5. “Trigger” button.

When stimulator is in “Armed” state, the single pressing of “Trigger” button activates the single stimulation. To perform continuous stimulation, press and hold “Trigger” button. The pulse is generated continuously when stimulator reaches “Armed” state. To stop the stimulation, release “Trigger” button. This button is duplicated with “Trigger” button located on the coil handle and with footswitch pedal.
When pulse safety interlock function is enabled, press any two controls simultaneously (“Trigger” button, “Trigger” button on coil handle and footswitch pedal).

6. “Stimulation parameters” knob.

The “Stimulation parameters” knob allows to increase/decrease the current value of selected parameter by turning the knob clock-wise/anticlockwise respectively.

7. “On/Off” button.

“On/Off” button toggles the operational mode of the stimulator. When mains power is delivered, the stimulator enters the standby mode. This is indicated by the yellow light of the “Power” indicator. Push the “On/Off” button in the standby mode to set the stimulator into the operational mode. This is indicated by green light of the “Power” indicator. At that time, the stimulator switches to “Disarmed” mode. On operation completion, the stimulator can be switched to standby mode by pushing “On/Off” button.

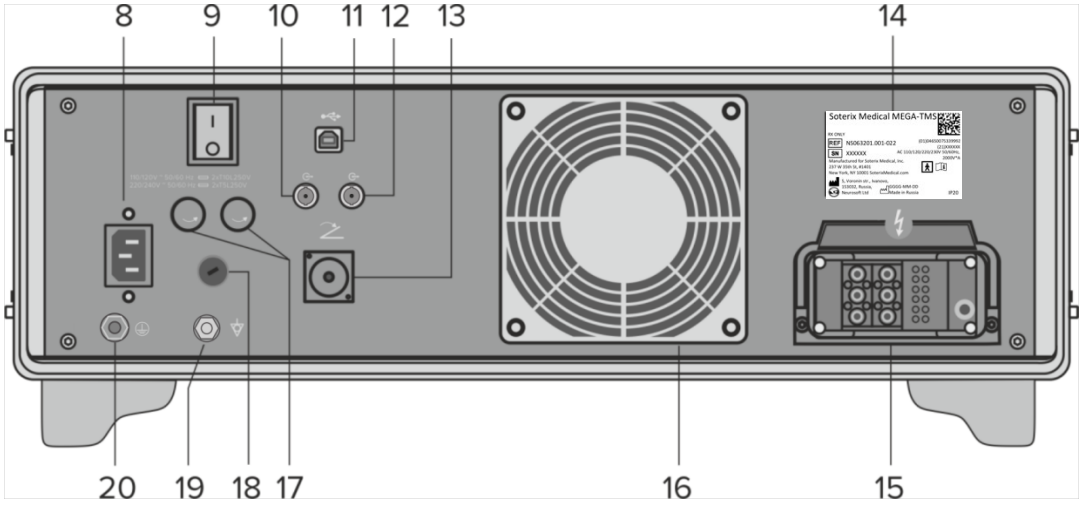


Fig. 5. The rear panel of stimulator.

The rear panel contains:

8. Connector to plug in mains supply cable.

9. “Mains power” switch.

To deliver the mains supply to the magnetic stimulator, turn “Mains power” switch to **On (I)** position. To disconnect from the mains supply, set the “Mains power” switch to **Off (0)** position.

10. Trigger In

11. USB connector.

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

12. Trigger Out

13. Footswitch connector.

The connector is used to plug in the footswitch intended to control the stimulation. See details in 1.4.2 “Setup Mode” section.

14. Labeling.

15. Plug in and fix the end cap (NS063105.001) on this connector using two screws. If this connector is not plugged, the corresponding error will appear at display (see 3.5 “Troubleshooting” section).

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

17. Fuses.

The mount of fuses.

18. Mains voltage selector.

19. Equipotential clamp  . The clamp to attach the equipotential cable connecting the cases of units included in the system.

20. Ground clamp  .

1.3.2. Controls, Connectors and Indicators of Coil

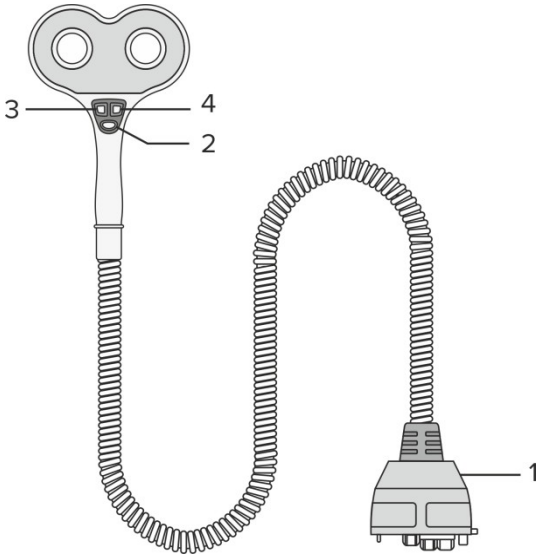


Fig. 6. Coil.

The coil contains:

1. HV connector into plug into stimulator unit.

2. “Trigger” button combined with “Armed/Overheating” indicator.

   The indicator illuminates with:

   - “red” – the coil is overheated; the stimulation is impossible;
   - “green” – the stimulator is ready to deliver pulses.

Press the button to evoke a pulse. If pulse safety interlock option is enabled, press “Trigger” button at the unit or footswitch pedal. If the coil is equipped with buttons on both sides, press “Trigger” button at the second side of this coil.

If the stimulator is in disarmed state, press and hold “Trigger” button and press “+” button to start capacitor charge. It is the same as to press “Arm” button on the front panel of the stimulator.

3. “–” button. Press this button to decrease the pulse intensity.

4. “+” button. Press this button to increase the pulse intensity.

1.4. Stimulator Menu

1.4.1. Single Pulse Mode

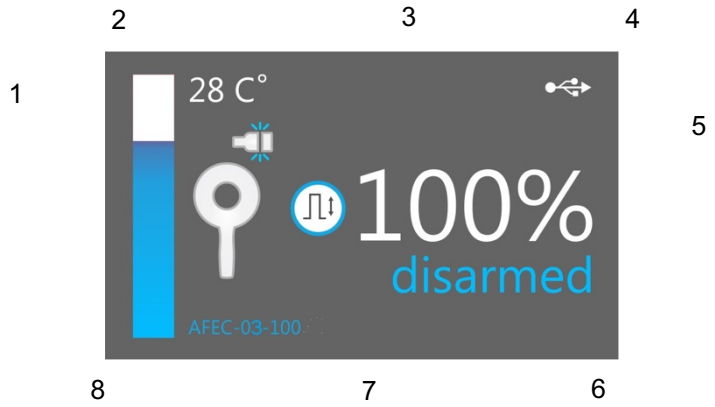


Fig. 7. The single pulse mode.

The stimulator display in single pulse mode shows the following (Fig. 7):

1. “Coil temperature” indicator.

The “Coil temperature” indicator is a scale showing coil heating:

- white color indicator – the coil temperature is below 10^0C;
- indicator is filled but not completely – the coil temperature is from 10 to 40^0C;
- the indicator is filled completely, red segment illuminates – the coil temperature is more than 41^0C. At that temperature, pulse delivery is disabled.

2. Current coil temperature in Celsius degrees.

3. Indicator of “Intensity” parameter.

Blue frame around an icon informs a user that this parameter is active and can be adjusted with the “Stimulation parameters” knob.

4. “USB control” indicator

If this icon is displayed, it means that the stimulator is connected to computer via USB and is controlled with the related software.

5. “Intensity” indicator. It shows pulse intensity in percentage from maximum one (1). The default value at stimulator switch on is 30%.

6. “State” indicator shows the current state of stimulator:

    - “Disarmed” – the stimulator is powered and switched on, high voltage is not delivered, the stimulator cannot deliver pulses;
    - “Charging” – the stimulator is powered and switched on, high voltage is delivered, the capacitor is being charged, the stimulator cannot deliver pulses;
    - “Armed” – the stimulator is powered and switched on, high voltage is delivered, the stimulator can deliver pulses;
    - “Discharging” – the stimulator is powered and switched on, high voltage is delivered, the capacitor is being discharged, the stimulator cannot deliver pulses.

7. “Coil type” indicator.

    The code of coil type. The detailed information on coil types and specifications is given in corresponding technical manual.

8. “Coil state” indicator.

– Coil is connected and the temperature is in the permissible range.

Coil is overheated. Wait till the coil cools down or replace it.

Coil is not connected.

Overheating of internal stimulator components. Wait for 15 to 30 minutes to cool down. The unit should be switched on.

1.4.2. Setup Mode

To adjust the settings (Fig. 8), press On/Off button to exit the standby mode and hold simultaneously the “Stimulation parameters” knob.

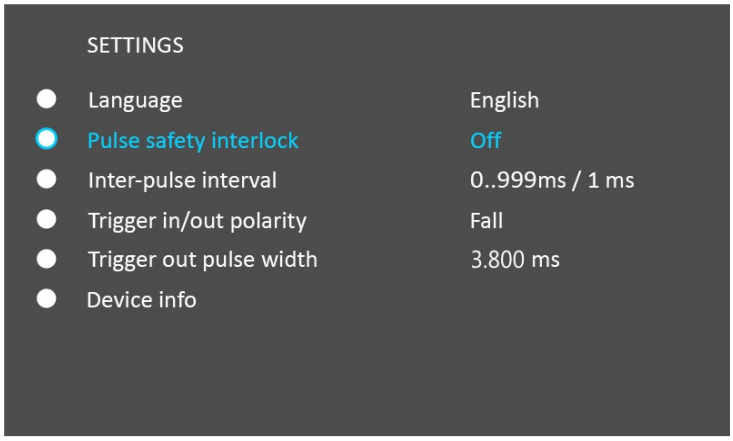


Fig. 8. “Settings” menu.

The “Settings” menu is intended to customize the stimulator settings according to operational requirements. Here you can adjust the following:

- Language – selection of interface language of stimulator.
- Pulse safety interlock – setup of pulse delivery control. There are two options:
  - Single interlock– the stimulator generates a pulse when one button intended to deliver pulse is pressed (button on coil, “Trigger” button on stimulator or footswitch pedal).
  - Double interlock – the stimulator generates a pulse when two buttons intended to deliver stimuli are pressed simultaneously.
- Inter-pulse interval – an interval is set depending on used technique. One of two intervals 0 ms..999 ms in 1 ms resolution or 0 ms..99.9 ms in 0.1 ms resolution is selected. It is not specified when the stimulator is connected to PC via USB.
- Trigger in/out polarity – the logical level change synchronized with pulse delivery. The polarity can be either rise or fall.
- Trigger out pulse width – the width of trigger out is set (see Table 2).

- Device info (Fig. 9) – when this item is selected, the device switches to “DEVICE INFORMATION” menu. It shows information on stimulator and coil if it is connected.

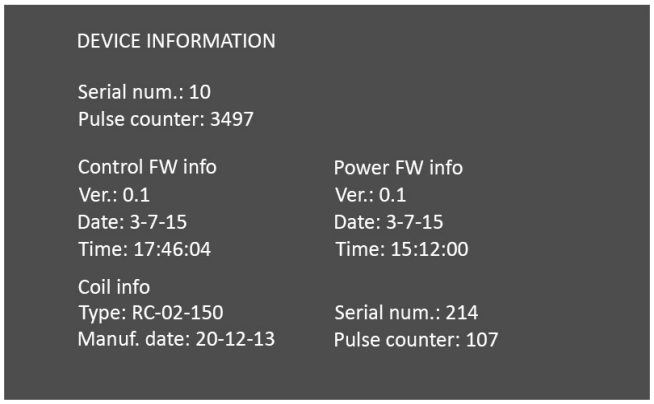


Fig. 9. “Device information” menu.

1.5. Labeling

Fig. 10. Labeling

– attention: consult operational documentation.

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

– manufacturer by ISO 15223-1-2012.

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

SN – serial number by ISO 15223-1-2012.

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

– manufacturing date by ISO 15223-1-2012.

Equipment is identified with the GS1-128 barcode that includes the GTIN code and the serial number (Fig. 11).

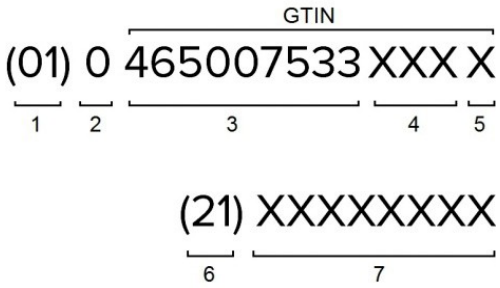


Fig. 11. The GS1-128 barcode.

1 — identification key: GTIN;

2 — start digit;

3 — company number;

4 — article reference;

5 — check digit;

6 — serial number identifier;

7 — serial number.

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

To ensure automatic data reading the GS1-128 code is integrated to the barcode in DataMatrix format (Fig. 12).

Fig. 12. DataMatrix barcode.

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

To decode the information about the item DataMatrix code can be read by a scanner or a smartphone camera as a two-dimensional image.

2. Assembly and Installation

2.1. Requirements to Personnel Conducting Stimulator Assembly and Installation

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

The stimulator weight exceeds 20 kg. See the recommendations on carrying over as shown in Fig. 13. It is recommended to distribute the weigh between two persons.

Move the units by grasping the special grooves at side panels.

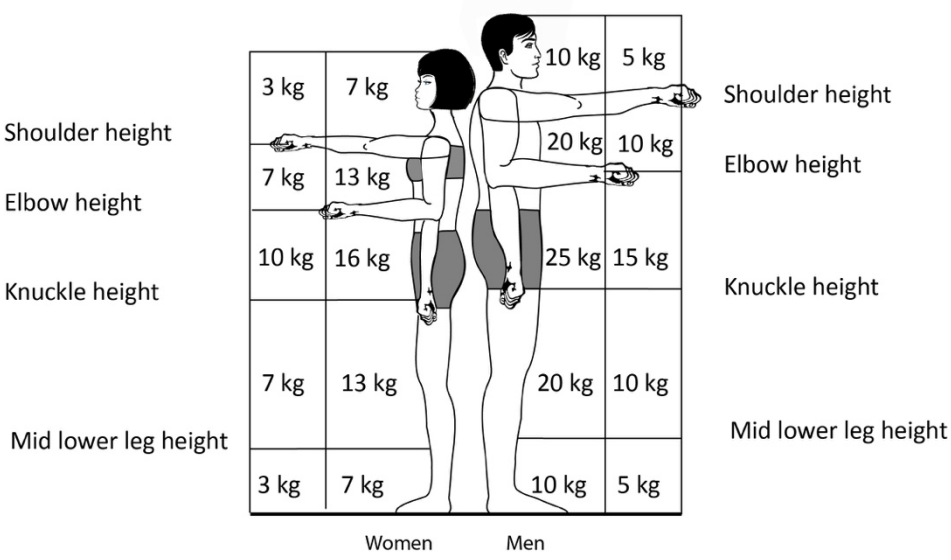


Fig. 13. Recommendations on lifting and transportation.

2.2. Room Selection and Placement

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

The selected place should be equipped with a number of mains socket outlets to plug in the stimulator and EMG system used together with the stimulator. The mains plug must only be inserted in an appropriate mains socket outlet provided with a protective earth contact. It is forbidden to use extension cords.

Requirements and recommendations on equipment placement:

- The device has been designed for indoor use at room temperatures between +10°C and +35°C with 80% maximum relative humidity.
- When placing the electronic unit of stimulator in the immediate vicinity of any electronic equipment, see the block diagrams shown in Fig. 14 and Fig. 15.

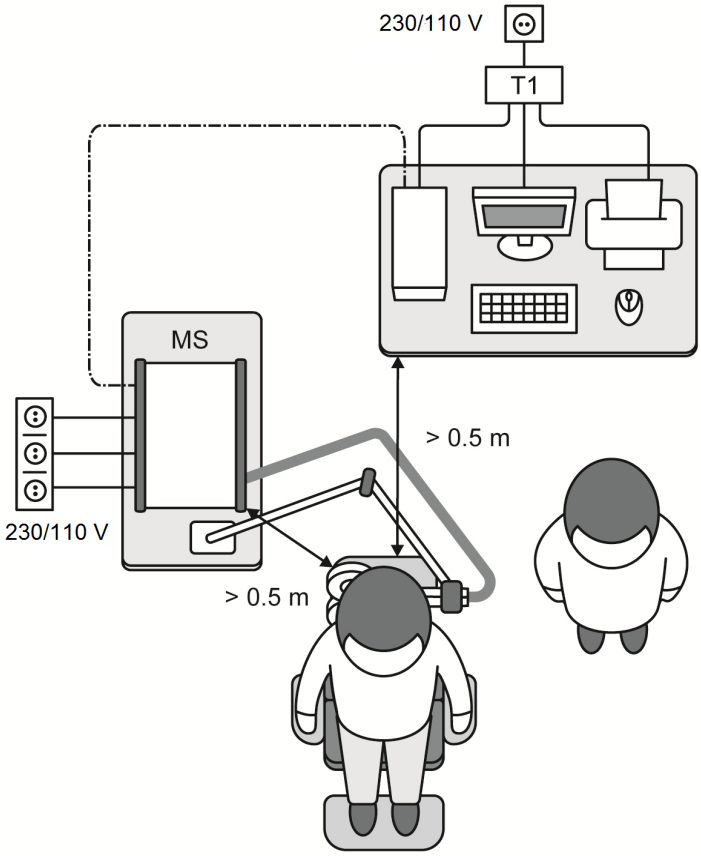


Fig. 14. The block diagram of stimulator placement when connecting to digital EMG systems.

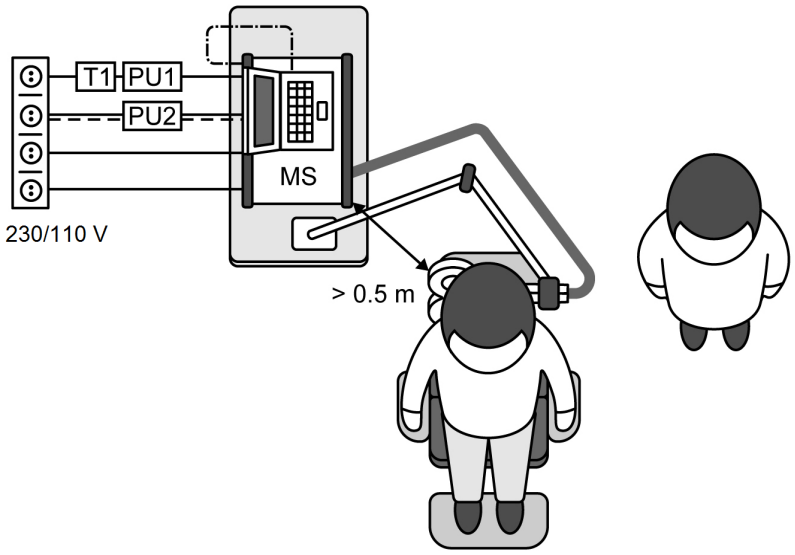


Fig. 15. The block diagram of stimulator placement when connecting to digital EMG systems produced by other manufacturers.

The following abbreviations are used in the figures:

- EMG – electronic unit of digital EMG system;
- MS – magnetic stimulator;
- PU1 – notebook PC power unit that does not comply with IEC 60601-1 standard requirements;
- PU2 – notebook PC power unit that complies with IEC 60601-1 standard requirements;
- T – isolation transformer that complies with AAMI/ANSI ES 60601-1:2005/(R)2012 standard requirements;
- ——— – power cables (230/110 V) of magnetic stimulator;
- – – – – alternative connection 230/110 V;
- –·–·–· – USB cable standard.
- To provide the normal cooling of the internal components during the stimulator operation, the stimulator should be placed on a firm surface. The clearance from the cooling fan output up to the wall (not less than 50 mm) should be provided. The fans ensure the air circulation inside the main stimulator unit. The air is sucked through the holes located on the bottom panel and blown out via the cooling fan outlet, at the rear panel.
- ***The patient environment (defined to be within 1.5 meters) should contain only the electronic units that are part of the medical device with the required safety level. The fact is that the safety level of the computer equipment is insufficient for the use in the patient environment. Hence, a patient must not come in contact with the metal parts of computer equipment cases and the personnel***

must not touch simultaneously these parts and patient body. The computer equip- ment used with the stimulator should comply with AAMI/ANSI ES 60601-1:2005/(R)2012 requirements or be connected via the isolation transformer (specialized power supply unit – for notebook PC) that meets the above- mentioned requirements.

Requirements to mains:

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

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

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

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

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

Requirements when connecting PC to LAN (Local Area Network)

- ***To avoid electrical shock, the PC can be connected to LAN according to 10/100/1000-BaseT-Ethernet standard only if the LAN complies with the safety requirements for medical items and devices or if the isolation transformer complying with the above-mentioned requirements is used.***

2.3. Unpacking and Delivery Set Check

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

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

Check visually the stimulator components to make sure that there are no visible damages.

2.4. Assembly and Connection of Stimulator

2.4.1. General Requirements for Assembly

Place the desktop PC-based system (if it is to be used together with EMG equipment) and magnetic stimulator according to instructions provided by manufacturer. Similarly, connect computer equipment only according to operational documentation for the corresponding devices.

If you purchase the stimulator together with EMG equipment and with the personal computer (PC), it is supplied with the appropriate installed and configured program. If you purchase the stimulator together with EMG equipment but without the PC, install the software from the electronic media included in the delivery set.

The software included in EMG equipment delivery set must be installed before the first connection of stimulator to PC! Read carefully the related sections of the user manual for the EMG device.

Contact Soterix Medical for additional information.

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

Before plugging in to mains socket, set the “Mains voltage” selector located at the rear panel of the stimulator to the corresponding position and set the fuses considering the modes (see **Table 6**):

Table 6. Fuse selection

Supply Voltage	Requirements to Fuse	
	Operating current	Type
220/230 V	5 A	5.2 mm×20 mm slow blow fuses. It is not allowed to use fast acting fuses.
110 V	10 A	

2.4.2. Assembling the System

The system components should be placed according to p. 2.2.

2.4.2.1 Assemble Trolley T-4/A[1] according to technical manual for the trolley.

2.4.2.2 Secure K-8 coil holder (Fig. 16) on the trolley according to technical manuals for the holder and the trolley. If the trolley is not included to delivery set, the coil holder can be fixed on any vertical surface, for example on the wall.

2.4.2.3 Place the unused coil in K-8 holder (Fig. 17).

[1]It is recommended to use the trolley ensuring the secure fixation of units and facilitating the system moving.

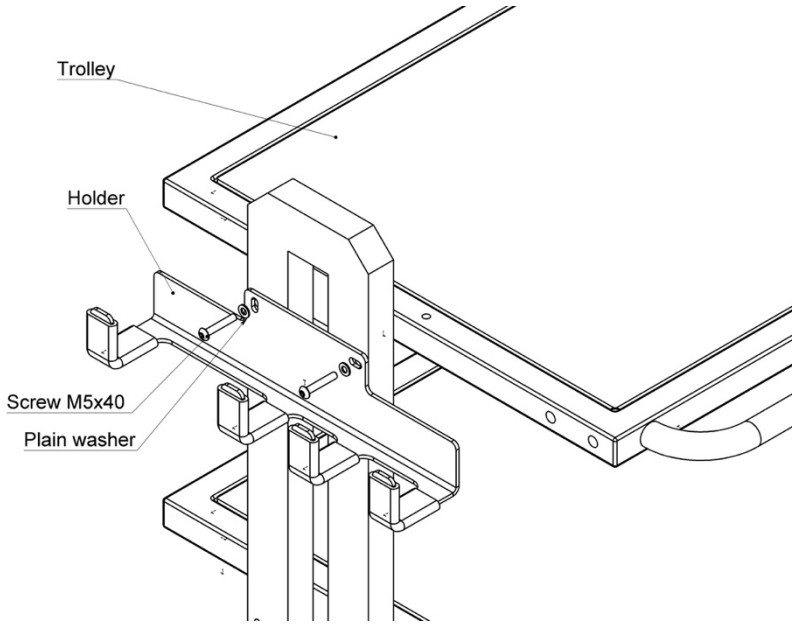


Fig. 16. The fixation of holder on the trolley.

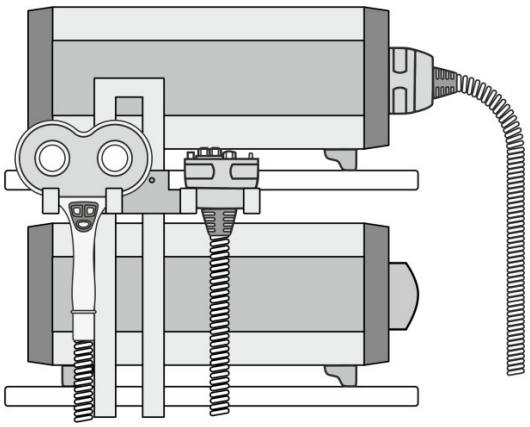


Fig. 17. The fixation of coil on the holder.

2.4.2.4 Position the stimulator unit(s) on trolley shelves according to recommendations and secure them with the required fastenings (see chapter 4 of technical manual for the trolley). If the trolley is not included to delivery set, the unit(s) can be positioned on any flat surface, for example on the table.

2.4.2.5 Interconnect the system components depending on the purchased configuration and planned application:

- configuration for single pulse stimulation – p. 2.4.3;

Do not plug the unit(s) into the mains sockets and PC.

The coil connector should be fixed with locking plate (Fig. 18).

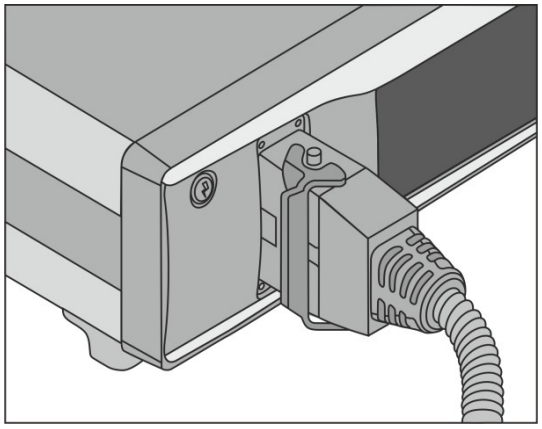


Fig. 18. The coil connection to the stimulator.

2.4.2.6 Fix K-3/K-7 flexible arm for coil positioning on a trolley according to technical manual for the arm. If the trolley is not included to delivery set, the arm is fixed to any surface, for example the table or the bed.

2.4.2.7 Secure the coil in a flexible arm (Fig. 20) (see technical manual for the flexible arm).

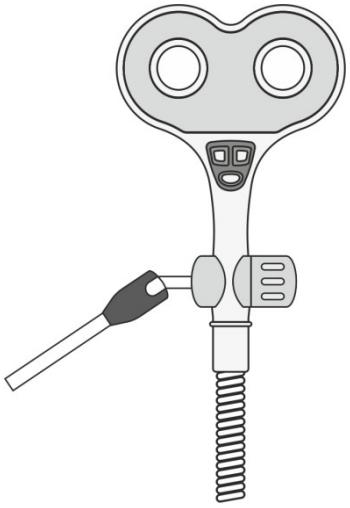


Fig. 19. Fixing the coil in an arm.

2.4.2.8 Move the trolley with stimulator to selected location and make sure that “Mains power” switches on the rear panel of unit is in “0” position. Plug in the stimulator to mains socket outlet.

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

2.4.2.9 If the stimulator is used together with desktop-based systems place the PC near the stimulator according to recommendations stated in p. 2.2 “Room Selection and Placement”. The position of PC depends on its type:

- Notebook – can be placed on or near the stimulator (on the table).
- Touchscreen computer – can be secured in a holder fixed on the trolley. Also, the touchscreen computer can be placed on a table near the stimulator.
- Desktop PC – is placed on a table near the stimulator.

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

2.4.2.10 If the stimulator is used together with EMG equipment of third-party manufacturers, plug in the related equipment to the stimulator using trig-in/out sockets.

2.4.2.11 If the stimulator is used together with EMG equipment manufactured by a particular vendor (Neurosoft), plug in the related equipment to computer according to technical manual. Attach the stimulator to computer via USB cable (see section 3.3 “USB Control Mode”). Please note, the software included in EMG system delivery set must be installed before the first stimulator connection to computer (see section 2.4.1 “General Requirements for Assembly”).

2.4.2.12 Switch on the power to the stimulator unit by toggling the required switch on the rear panels to “I” position.

2.4.2.13 Connect the stimulator to the PC (that is powered on) using USB cable.

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

The PC that the EMG software is installed on, should not be connected to an external network, except during maintenance by an authorized technician when the software is not in use. Installation of antivirus software on PC and maintaining virus databases is recommended in accordance with the company security policy.

If the dialog box shown in Fig. 20 appears after stimulator connection to computer, press Next > button, ***without inserting the electronic media***.

Fig. 20. “Found New Hardware Wizard” dialog box.

“New hardware wizard” will perform the stimulator installation. On installation completion the dialog box shown in Fig. 21 will appear at the screen. Press Finish button and start using the stimulator.

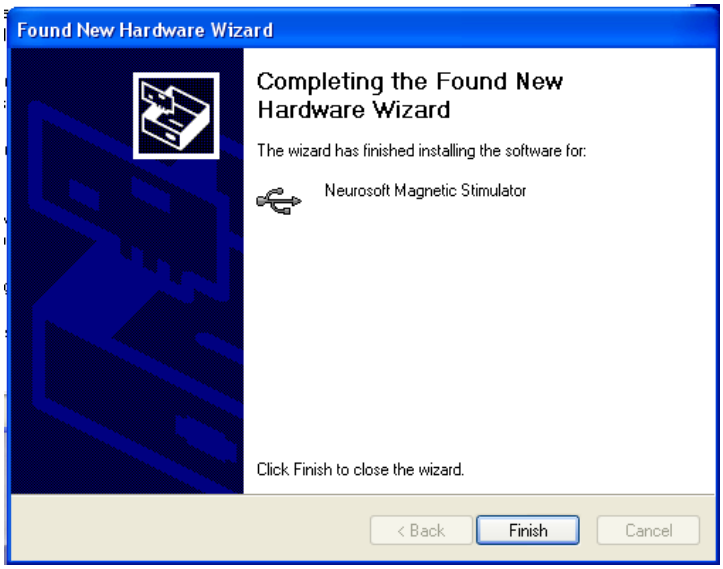


Fig. 21. “Found New Hardware Wizard” dialog box after the installation completion.

The start and the operation with the Neurosoft EMG software are described in the respective user manuals for the digital system.

To switch off the stimulator, close the program. Switch off the stimulator using “On/Off” button. Turn “Mains power” switch located on the rear panel of the unit to “Off” (0) position (pos. 9 in Fig. 5).

2.4.3. Assembling Configuration for Single Pulse Stimulation

If you use a trolley for magnetic stimulator, the stimulator unit (Fig. 22) is placed on a top shelf. The stimulator is connected to the mains via the mains supply cable. The end cap is placed at HV connector located at the rear panel and is fixed with the locking plate.

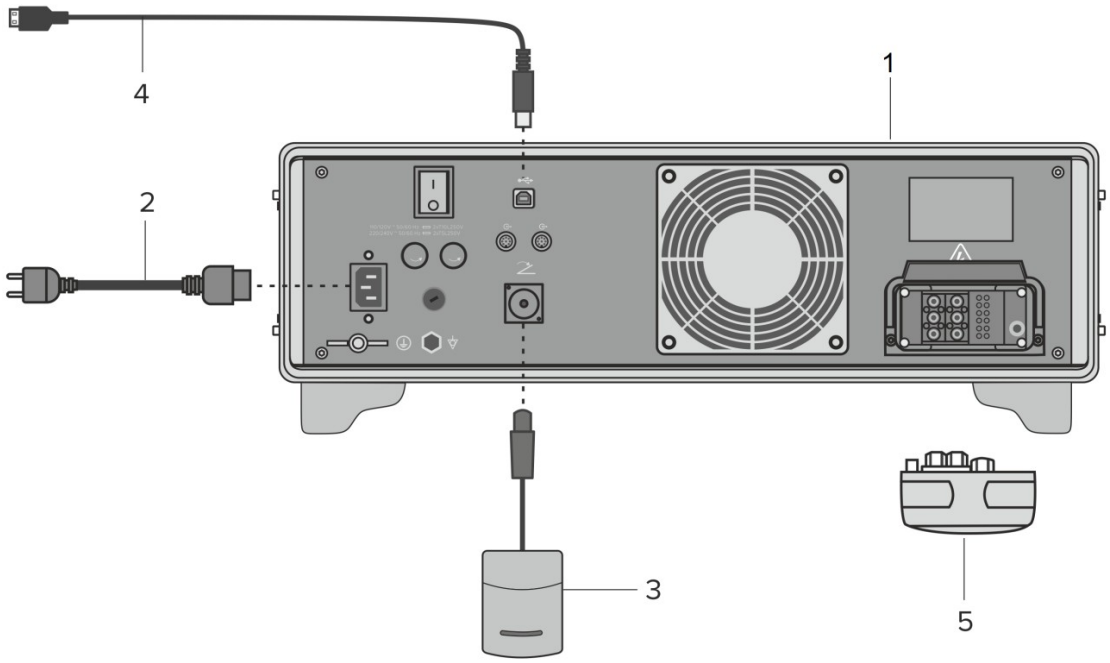


Fig. 22. MEGA-TMS stimulator assembling (configuration 1).

1. MEGA-TMS stimulator unit.
2. Mains supply cable.
3. Footswitch.
4. USB cable to connect to PC.
5. End cap.

It is prohibited to use the stimulator if the end cap is not fixed with locking plate.

3. Proper Use

3.1. Operation Order

Before powering on the stimulator, perform the assembly and the connection of the units according to chapter 2 “Assembly and Installation”. All the units should be connected to the mains.

Make sure that the units of the stimulator do not have any visible mechanical defects.

If any issue arises during stimulator operation, the error code should appear on the stimulator display. The error indication is accompanied by sound notification. In this case a user should read the section 3.5 “Troubleshooting”. Switch off the stimulator using  “On/off” button.

If during the stimulation the red segment of “Coil temperature” indicator lights up, it means that the coil has overheated and stimulation start cannot be initiated. You should wait till the coil cools down or replace it.

To replace the coil, press “Coil change”  button and wait till the indicator goes out and stimulator enters “Disarmed” state. After that the coil can be replaced.

It is prohibited to disconnect the coil from the stimulator while in “Armed”, “Discharging” or “Charging” state.

During the continuous use of the stimulator the overheating of internal components of the unit is possible. If any component is overheated,  icon will appear on the stimulator display. To cool the internal components of coil down, wait for 15 to 30 minutes for the internal components to cool down.

3.2. Stand-alone Mode

In stand-alone mode of operation the stimulator can produce:

- the single pulses of specified intensity;
- single pulses of specified intensity repeated when stimulator enters “Armed” state;

To start the stimulation, perform the following steps:

1. Turn “Mains power” switch on rear panel to **On (I)** position. The “Power” indicator on the front panel should light up yellow.

2. Plug in the required coil to the stimulator output. Make sure that the high-voltage connector of the coil is plugged in firmly and the spring-lock is locked. If the connector is plugged in incorrectly, the HV connector may burn.

3. Switch on the stimulator using  "On/off" button. After the power supply switch on, the stimulator stands in the "Disarmed" state. In this state, the pulse intensity is set to a default value of 30%. If it is required to set other than 30% intensity, use the "Stimulation parameters" knob (detailed description of stimulator controls and menu is given in 1.3 and 1.4 sections).

4. To charge the capacitor, press 

button. During stimulator charging "Charging" symbol is displayed. On charge completion "Armed" symbol appears at stimulator display. It means the stimulator is ready to be triggered.

5. Place the coil over stimulated area. If you use a coil holder, fix a coil in it.

6. Depending on selected way of stimulation run (see 1.4.2 section), it can be done at:

   - Single interlock – by pressing "Trigger"  button on a stimulator unit, "Trigger" button on coil or footswitch pedal.

   At pulse delivery a click is initiated. At this time, the stimulator enters the "Charging" state and starts the recharge process. On charge completion the stimulator displays "Armed" symbol showing that stimulator is ready to deliver next pulse. The delivery of next stimuli is done in the same way.

7. If you hold down the trigger button/buttons after pulse delivery, the stimulator starts to produce pulses when it enters the "Armed" state. In this state, stimulator generates automatically a pulse when switching from "Charging" to "Armed" state. To stop stimulation, it is required to release the button/buttons for the stimulation run.

8. If the stimulator stays more than 3 minutes in the "Armed" state and stimulation parameters are not changed during this time and stimulation is not fired, the capacitor discharge starts automatically. At that, "Discharging" symbol appears at display and on discharge completion it changes to "Discharging" state. This option is intended to prolong the life time of device and exclude accidental run of stimulation after long-term time-out. To charge the stimulator press "Arm" 

button.

9. Actions to replace the overheated coil or change to another coil type while the stimulator is switched on are described in section 3.1.

10. On operation completion, switch off the stimulator using  "On/Off" button. After that disconnect the coil and disinfect it according to recommendations stated in the technical manual for coils.

11. Turn "Mains power" switch on rear panel to **Off (0)** position.

3.3. USB Control Mode

The stimulator can operate under control of digital EMG systems manufactured by a particular vendor (Neurosoft). In this mode the stimulator is connected to PC via USB and controlled by the corresponding software. The order of the stimulator connection to PC and the software installation are described in Chapter 2 "Assembly and Installation".

The steps to fulfill:

1. Switch on the PC and wait till the operating system is booted.

2. Turn the "Mains power" switch on rear panel to **On (I)** position. The "Power" indicator on the front panel should light up yellow.

3. Run EMG software. Follow the recommendations stated in the user manual for the device software. Open the existing exam or create a new one that contains the TMS technique.

4. In this operation mode, the stimulator switch on/off and adjustment of stimulation parameters is done with the opened software via USB. If it is required, the intensity and the charge on/off can be changed/ adjusted using the front panel of the stimulator.

5. The pulse is produced by the pressing of "Trigger" button on a coil or stimulator case or footswitch pedal or using software.

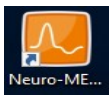
6. On operation completion, closing the program results in stimulator switch off.

Follow the steps below to pair with the Focus EMG device

When performing a diagnostic evaluation, patients can be examined while they are seated or lying on a bed or armchair. Although lying may be better for complete relaxation, the sitting position is also comfortable and adequate for all recordings, provided that the seat does not have a large backrest, preventing appropriate handling of the coil. The following information will go over how the device is set up and how it interacts with software hosted on the PC platform.

To perform the stimulation of the peripheral nerve, an operator should perform the following steps:

1. Connect the magnetic stimulator unit to mains socket outlet.
2. Toggle the "Mains power" switch on the rear panel of the magnetic stimulator to "I" position to switch it on.
3. Connect the digital EMG system (Focus EMG: K102601) via USB port.

4. Run Neuro-MEP.NET software by pressing 

icon. Neuro-MEP.NET is the software provided with Focus EMG device.

Refer to the Focus EMG manual for additional information.

3.4. Acquisition of Evoked Potentials

The acquisition of evoked responses to magnetic stimulation is done using the same techniques as for electrical stimulation. If stimulator is used together with EMG equipment, read section 3.3.

To avoid pulse artifacts occurred on the recording and also possible interferences from stimulator and coils, the following is recommended:

- Place the equipment as it is described in section 2.1.
- Place the coil and HV cable as far as possible from recording electrodes.
- Use recording electrodes with minimum cable length.
- Use shielded recording cables, if there are no such cables, twist the active recording and reference electrodes.
- Ensure minimum possible impedance of recording electrodes, for example, 4…5 kΩ.
- Use larger reference electrode to reduce impedance.
- Place the reference electrode closer to active recording electrodes.

It is recommended to start motor threshold detection using 30% intensity. This intensity can be increased with 10% step until motor threshold is fixed.

3.5. Troubleshooting

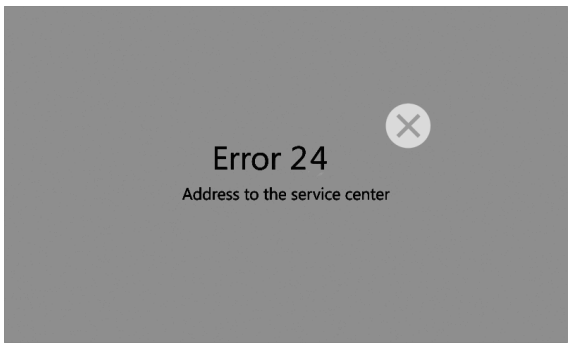
The possible troubles are listed in Table 7.

Table 7. Troubleshooting

Problems	Cause	Way of Removal
If the stimulator is controlled via USB, the program displays the error message on data exchange with the stimulator or on stimulator missing. In stand-alone mode the stimulator operates regularly.	The faulty USB cable is used to connect to computer.	Replace USB cable. It is recommended to use the cable included in the stimulator delivery set.
The stimulator is controlled by **Neuro-MEP.NET** program manufactured by Neurosoft Ltd. via USB. On program operation completion and its closing,  symbol appears.	The failure has occurred at **Neuro-MEP.NET** program (manufactured by Neurosoft Ltd) closing.	Switch off and then on the “Mains power” switch located at the rear panel.

The stimulator is equipped with self-diagnostics system to control the operability of the main elements while power switching on and during the operation. In case the fault is detected, the stimulator stops the stimulation, initiates the beep and shows the fault code on stimulator display. The faults detected by the stimulator are divided into two groups:

- Service – occurred when the electronic components of the stimulator break down. This type of errors is indicated as SError. If this fault occurs, address to Soterix Medical.



Error code

Fig. 23. The example of service error.

- User – occurred as a result of incorrect connection of the stimulator or incorrect actions of the personnel and indicated as UError. These faults can be removed by a user. The possible troubleshooting options are listed in Table 8.

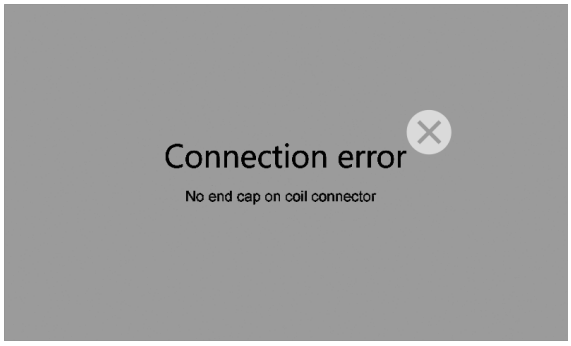


Fig. 24. The example of connection error.

Table 8. The possible user errors

Cause	Way of Removal
The end cap or HV cable in rear panel output is missing	Depending on the system configuration check the HV connector on the rear panel: § Configuration 1 – the end cap should be fixed. § Configuration 2 – the HV cable attached to the second stimulator unit should be plugged in.

If the above mentioned solutions do not work, contact Soterix Medical.

3.6. Cleaning and Disinfection

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

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

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

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

5. Remove disinfectant with a dry cloth.

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

Keep all cleaning fluids away from electrical connectors.

3.7. Actions in Emergency

In the cases of electrical insulation disturbance of any component included in the delivery set of the magnetic stimulator which causes the emergency (fire, mechanical failure, flood, medical staff evacuation) and threat of patient or staff electrical shock, it is required to de-energize the magnetic stimulator completely.

4. Servicing

4.1. General Requirements

Safety measures when stimulator servicing conforms to the ones described in 0 “Warning and Precautions” section.

Qualification requirements to the medical staff are listed in 2.1 “Requirements to Personnel Conducting Stimulator Assembly and Installation”.

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

When experiencing issues, it is recommended to use the information stated in 3.5 “Troubleshooting” section. If the issued can’t be eliminated using magnetic stimulator controls or by restart, it should be switched off and checked by a specialist.

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

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

4.2. Maintenance Service

Magnetic stimulator servicing in the process of operation includes the external examination, check on how connectors and cables are plugged in, removal of contaminations from the unit surface according to recommendations specified in 3.6 Cleaning and Disinfection section.

4.3. Life Time

The stimulator life time is 5 years starting from a shipment date to a user.

The life time of coils included in the delivery set is 12 months starting from the date of equipment shipment to a user.

The manufacturer is obliged to ensure the technical service of a stimulator and coils during its life time.

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

The estimated service life of power capacitor is 1 000 000 stimuli. On generation of indicated number of stimuli perform the pulse parameter diagnostics (is done by service engineer). The stimulator is equipped with nonvolatile counter of delivered stimuli. You can check its state using the system information menu (see 1.4.2 “Setup Mode” section).

5. Disposal

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

6. Acceptance, Delivery Set and Package Data

MEGA-TMS magnetic stimulator is collected, packed and ready for operation according to the requirements of TC 9442-063-13218158-2015.

The electronic units identified with the serial number are listed in Table 9.

Table 9. The electronic units

№ n/n	Electronic unit	Serial number
1	MEGA-TMS electronic unit (1)	
2	MEGA-TMS electronic unit (2)	

Package report number _____

Package report date _____

The detailed information on the delivery set is provided in the packing report which is the integral part of the manual and shall be kept with it.

7. Warranty

7.1. The manufacturer guarantees the magnetic stimulator quality conformance to TC 9442-063-13218158-2015 requirements if the rules of operation, storage, transportation and mounting prescribed in the operational documentation are observed.

7.2. Warranty period is 24 months from the delivery date to the customer. The delivery date is the date as stated by the tracking information of the shipping company.

There is no warranty for consumables.

The warranty period can be prolonged for the period of repair.

7.3. The operation of guarantee commitment is stopped if:

- the rules of operation, storage, transportation and mounting prescribed in the operational documentation are not observed;
- the warranty period is expired;
- a user brakes the seal without permission of the manufacturer.

7.4. The manufacturer is obliged to repair the equipment in case of breakdown during the warranty period free of charge. The repair is carried out in the service center. Contact Soterix Medical for additional information.

8. Reclamation Data

8.1. In case of stimulator breakdown or any fault/ defect during the period of warranty, the buyer should contact Soterix Medical. The notification should contain the following information:

- the buyer's name and the address;
- the serial number of the stimulator (see chapter 6 of this manual or the stimulator marking);
- the number and the date of the invoice or other document confirming the stimulator purchase.
- the detailed description of failures. If it is possible indicate the reasons and circumstances preceding the fault detection (in addition it is recommended to add the test report, the exam data, photos and other materials allowing to solve the problem as soon as possible).

8.2. In case of stimulator return to the service center for the repair or the replacement, the following rules should be observed:

- It should be decontaminated before sending to service center. Read rules of cleaning and disinfection in section 3.6 "Cleaning and Disinfection".
- it should be packed so to exclude the possibility of its damage during the transportation;
- the notice (see item 8.1) and this manual must be added to the stimulator being returned.

Annex 1. Electromagnetic Emissions and Immunity

Guidance and manufacturer's declaration – electromagnetic emissions

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

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

Guidance and manufacturer's declaration – electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV − contact	±6 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	±8 kV − air	±8 kV	
Electrical fast transient/burst IEC 61000-4-4	±2 kV − for power supply lines	±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
	±1 kV − for input/output lines	±1 kV	
Surge IEC 61000-4-5	±1 kV line(s) to line(s)	±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
	±2 kV line(s) to earth	±2 kV	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle	20 ms	Mains power quality should be that of a typical commercial or hospital environment. If the user of the magnetic stimulator requires continued operation during power mains interruptions, it is recommended that the magnetic stimulator be powered from an uninterruptible power supply or a battery.
	40% U_T (60% dip in U_T) for 5 cycles	100 ms	
	70% U_T (30% dip in U_T) for 25 cycles	500 ms	
	<5% U_T (>95% dip in U_T) for 5 s	5000 ms	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

Guidance and manufacturer's declaration – electromagnetic immunity

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

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

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

[2)] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Notes:

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

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

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

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

Notes:
1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
3. For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

References

1. Rossini, Paolo Maria, et al. "Non-invasive electrical and magnetic stimulation of the brain, spinal cord, roots and peripheral nerves: basic principles and procedures for routine clinical and research application. An updated report from an IFCN Committee." Clinical Neurophysiology 126.6 (2015): 1071-1107.

2. Groppa, S., et al. "A practical guide to diagnostic transcranial magnetic stimulation: report of an IFCN committee." Clinical Neurophysiology 123.5 (2012): 858-882.