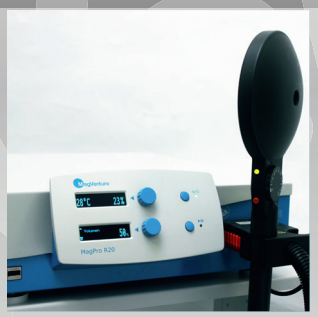
UK edition

MagPro R20

- with Short Pulse Width Option

User Guide



MagVenture

Versatility in Magnetic Stimulation

At the time of printing this manual correctly described the device and its functions. However, as modifications may have been carried out since the production of this manual, the system package may contain one or more addenda to the manual. This manual including any such addenda must be thoroughly read, before using the device.

The following situations void any guarantee(s) and obligations for Tonica Elektronik A/S:
- The device is not used according to the enclosed manuals and other accompanying documentation.
- The device is installed or modified by persons other than Tonica Elektronik A/S or other authorized service technicians.

Software version 1.0.7

Table of Contents

Safety Information

This section contains information on safety, intended use, contraindications, general warnings, cautions and daily safety checks.
Please also find extract of IEC 60601-1 Medical Electrical Equipment and Classification requirements.

This device has been designed and tested in accordance with IEC Publication 60601-1 Medical Electrical Equipment. The present manual contains information and warnings, which will have to be followed by the user to ensure safe operation and to retain the device in safe condition.

This device has been designed for indoor use at room temperatures between +10°C and +30°C (+50°F to +86°F).

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.

WARNING Any interruption to the protective earth conductor inside or outside the device or disconnection of the protective earth connector terminal is likely to make the device dangerous. Intentional interruption is prohibited. The protective earth (ground) conductor should be checked regularly.

When the device is producing maximum output, the power consumption is very high. To prevent any equipment nearby from malfunctioning or light flicker in lamps during stimulations, the device *must* be supplied from a separate wall outlet. This is especially important if the total installed power is low. If a problem arises it is usually recommended to seek the advice of a local electrician on this matter. Make sure you use the correct power cord supplied with the device.

For the combination of this device with other devices and / or for its connection to installations, the following applies:

- When connecting medical equipment being supplied from an outlet located in a non-medically used room, or when connecting non-medical electrical equipment to this device, please pay attention to the requirements of IEC 60601-1, Safety Requirements for medical electrical systems. Please find an extract of IEC 60601-1 later in this section.
- When the device is connected to its mains supply, connectors may be live, and any opening of covers or removal of parts possible only with the aid of a tool is likely to expose live parts.
- Service must only be referred to Tonica or other authorized service personnel, except for such works described in this manual as being performed by the operator. The device must be disconnected from all voltage sources before being opened for any adjustment, replacement, maintenance or repair.
- Where more than one piece of equipment is connected to a patient, attention must be paid to the summation of patient leakage currents.
- Whenever it is likely that the safety protection has been impaired, the device must be disconnected and be secured against any unintended operation.

- The protection is likely to be impaired if, for example, the device:
  - shows visible damage.
  - fails to perform the intended function
  -has been subjected to severe transport stresses.
  - has insufficient earth protection
  - has been subjected to moisture
- In that case, call qualified service personnel to conduct at least a functional test and additionally a safety check including 1) an insulation test, 2) a ground continuity test and 3) a leakage current test, according to IEC 60601-1.

Intended use

Diagnostic Use
The MagPro is intended as an electro-physiological aid to assess diagnosis and to monitor diseases of the central and peripheral nervous system, based on the use of Motor Evoked Potentials (MEP).

Operator

Magnetic stimulation is a non-invasive technique to be used under constant supervision by qualified medical personal e.g. MD, PhD, neurophysiologists, psychiatrist, nurses and medical assistants, only on patients who are not anaesthetized and only for short term use.

Contraindications

Implanted Electronic Devices and/or Conductive Objects near the coil

- Patients who have an implanted device that is activated or controlled in any way by physiological signals (examples: pacemakers, implantable cardioverter-defibrillators [ICD's], vagus nerve stimulators [VNS] and wearable cardioverter-defibrillators [WCD's], ocular implants, deep brain stimulators, implanted medication pumps, intracardiac lines, even when removed. Contraindicated use could result in serious injury or death.

Non-Removable Metallic Objects near the coil

- Patients who have conductive, ferromagnetic or other magnetic-sensitive metals implanted in their head or within 30 cm of the treatment coil (examples: cochlear implants, implanted electrodes/stimulators, aneurysm clips or coils, stents and bullet fragments). Failure to follow this restriction could result in serious injury or death.
  NOTE: Standard amalgam dental fillings are not affected by the magnetic field and are acceptable in patients.

Precautions

Safety and effectiveness of magnetic stimulation could not be established in special patient populations, examples below:

- Patients with a history of epilepsy or unexplained seizures.
- Patients medicated with drugs lowering the seizure threshold (examples: neuroleptic agents and tricyclic antidepressants).
- Patients suffering from vascular, traumatic, tumoral, infectious, or metabolic lesions of the brain, even without a history of seizure, or without anticonvulsant medication.
- Patients with history of strokes, head injury or severe headaches.
- Patient suffering from sleep deprivation or alcoholism.
- Pregnant or nursing patients.
- Patients with severe or recent cardiac disease.

To identify if the patient suffer from one or more of the above listed contraindications and precautions a standard questionnaire is recommended. See an example below:

1. Do you have epilepsy or have you ever had a convulsion or a seizure?
2. Have you ever had a fainting spell or syncope? If yes, please describe on which occasion(s)?
3. Have you ever had a head trauma that was diagnosed as a concussion or was associated with loss of consciousness?
4. Do you have any hearing problems or ringing in your ears?
5. Do you have cochlear implants?
6. Are you pregnant or is there any chance that you might be?
7. Do you have metal in the brain, skull or elsewhere in your body (e.g., splinters, fragments, clips, etc.)? If so, specify the type of metal.
8. Do you have an implanted neurostimulator (e.g., DBS, epidural/subdural, VNS)?
9. Do you have a cardiac pacemaker or intracardiac lines?
10. Do you have a medication infusion device?
11. Are you taking any medications? (please list)
12. Did you ever undergo TMS in the past? If so, were there any problems.
13. Did you ever undergo MRI in the past? If so, were there any problems.

Affirmative answers to one or more of questions 1–13 do not represent absolute contraindications to TMS, but the risk/benefit ratio should be carefully balanced by the operator.

General Warnings

See the accompanying documentation and carefully read the following warnings and cautions.

Warnings

- Do not use this equipment for anything else than it is intended for by the manufacturer.
- The MagPro R20 must only be used under the constant supervision of qualified medical personal, only on patients who are not anaesthetized and only for short term use.
- Patients undergoing rTMS should be observed closely for clinical worsening and in absolutely worst case seizure.
- To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

- Any interruption to the protective earth conductor inside or outside the device or disconnection of the protective earth connector terminal is likely to make the device dangerous. Intentional interruption is prohibited. The protective earth (ground) conductor should be checked regularly.
- The device is not compatible for use in an MR magnetic field. Please consult the manufacturer for available special solutions.
- Rapid cortical stimulation can induce seizures. Ensure that appropriate safety measures are taken before using the equipment. See patient safety later in this section.
- To protect patients from excessive exposure to magnetic gradients keep the number of stimulations as low as possible.
- Do not use the equipment when other equipment/device is within a distance of 1m from the connected coil.
- Never touch the metal pads in the large orange connector.
- Do not touch the Lemo connector on the front panel and the coil cable while touching the patient
- Do not touch the trigger connector on the rear panel while touching the patient
- The device is not intended for use with anesthetic gases or any other flammable media – danger of electrical ignition.
- The operator must be protected against long-term magnetic fields (e.g. by using a holding device as the Flexible Arm).
- Hearing protection is recommended if the coil is used near the head or when operating with more than 100 stimuli a day.
- Do not perform single-pulse or paired-pulse TMS on children younger than 2 years.
- Do not perform rTMS on patients younger than 18 years.
- Keep out of reach of children.
- Precautions should be taken when stimulating patients with suspected or diagnosed labile or hypertensive blood pressure.
- Do not use the equipment on patients who have an implanted device that is activated or controlled in any way by physiological signals (examples: pacemakers, implantable cardioverter-defibrillators [ICD's], vagus nerve stimulators [VNS] and wearable cardioverter-defibrillators [WCD's], ocular implants, deep brain stimulators, implanted medication pumps, intracardiac lines, even when removed. Contraindicated use could result in serious injury or death.
- Do not use the equipment on patients who have conductive, ferromagnetic or other magnetic-sensitive metals implanted in their head or within 30 cm of the treatment coil (examples: cochlear implants, implanted electrodes/stimulators, aneurysm clips or coils, stents and bullet fragments). Failure to follow this restriction could result in serious injury or death. NOTE: Standard amalgam dental fillings are not affected by the magnetic field and are acceptable in patients.

- Bystanders with implanted device of any kind or implanted metallic objects MUST stay in distance of least 1m from the coil in operation.
- To minimize uncertainty it is important always keeping the coil in direct contact and as tangent to the scalp surface, direct over the actual wanted exposed area.
- Electrical equipment for medical use requires special EMC precautions and needs to be installed and serviced according to the EMC documentation of the device.
- The equipment should not be used adjacent, or stacked with other equipment. If adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.
- The surface temperature of the coil against the patient's skin can exceed 41°C. The temperature allowed by the system is maximum 43°C for non-MCF-coils, and maximum 48°C for MCF-coils, and only between 44°C and 48°C for less than 10 minutes. The system will automatically disable if this maximum temperature is reached.
- If high speed stimulation protocols are performed some increased temperature on the coil surface against the patient's skin can occur. According to the IEC 60601-1:2005 standard a maximum temperature of 48°C is allowed for a time up to 10 minutes.

Cautions

- Before connecting, please read this user guide.
- When connecting, attention must be paid to IEC 60601-1. See page 14.
- Metallic (conductive) objects in the field may be propelled forcibly by the stimulus pulse. Make sure there are no rings, coins or similar metal objects near the coil when it is activated.
- Do not place the stimulation coil on or near: video monitors, watches, calculators, credit cards, computer disks or magnetizable surfaces. Damage or erasure may occur.
- Be careful when you stimulate patients with implanted devices or metallic objects located also in areas outside the 30cm distance from the coil during rTMS. Examples include: sutures and implanted insulin pumps.
- Adverse effects as scalp pain, headache and burning sensation can appear during and after stimulation on the head. Ref.: the guideline "Safety of TMS Consensus Group, Safety, ethical considerations, and application guidelines for the use of transcranial magnetic stimulation in clinical practice and research" by Rossi S, Hallett M, Rossini PM, Pascual-Leone A. Clin Neurophysiology. 2009 Dec; 120(12):2008-39.
- Longer term effects of exposure to the MagPro R20 magnetic field on the head are not known. Experimental and observational evidence indicates that exposure to the type of magnetic fields produced by the MagPro R20 coil does not present any significant risk of acute or long-term adverse effects. Ref.: the guideline "Safety of TMS Consensus Group, Safety, ethical considerations, and application guidelines for the use of transcranial magnetic stimulation in clinical practice and research" by Rossi S, Hallett M, Rossini PM, Pascual-Leone A. Clin Neurophysiology. 2009 Dec; 120(12):2008-39.

- Disable the device when it is not being used by pressing the enable/disable button.
- Before changing the stimulation coil, press disable to avoid damage on personnel and equipment.
- Always use the Flexible Arm to hold the MCF-Magnetic Stimulation Coils during stimulations.
- When transporting the equipment on the trolley, please keep the Flexible Arm in upright position.
- Always place the system with trolley on a flat horizontal surface and lock the two front wheels. Risk of sliding if placed on a non-flat horizontal surface.
- If a coil is mounted in the Flexible Arm on the trolley, the coil must be placed above the MagPro R20 cabinet and with the arm locked, to protect the coil from impacts during transport of the system.
- Changes in noise level or sound frequency from the coil during stimulation may indicate beginning damages inside the coil. Stop using the coil and contact a Service Center; otherwise it may disintegrate.
- Always carefully examine the coil handle, housing and cables for cracks, marks, deformations, color changes and other signs of damage before using it. Do not use the coil if there is any evidence of stress failure; otherwise it may disintegrate.
- The coil must not be submersed into any conductive liquid, including water. The encapsulation tolerates low levels of surface moist - but in general care should be taken to keep all surfaces clean and dry.
- Do not remove cover; Electric shock hazard. Any maintenance inside the device must be performed by qualified service personnel.
- Service must be referred to your local distributor.
- Do not connect USB cables to the USB port.
- Cool coils are not supported by MagPro R20.

Daily Safety Checks

The following safety checks should be conducted by the operator daily before use:

- Inspection for visible damage to the device.
- Inspection of mains cord and connecting cables.
- Check the coil for damages, cracks, marks, deformations, color changes and other irregularities. Do not use the coil if there is any evidence of stress failure and contact Tonica or a service center.

The following safety checks should be conducted (by qualified personnel only) at least once a year and in the event of repair:

- Insulation resistance.
- Measurement of leakage currents.
- Measurement of resistance of protective earth conductor.

Patient Safety

When using rTMS, please take the following information as a general guideline. For more information on the subject always consult the literature, e.g. the articles referred on the next page.

A note of caution must be sounded concerning the use of fast repetition rate cortical stimulation. Low repetition rate cortical stimulation is generally safe and has been used on many thousands of subjects, both patients and normal volunteers, with few adverse effects. Fast repetition rate cortical stimulation, at intensities above motor threshold, has however been reported to cause seizures in persons whether any prior abnormality. Because of the number of technical variables involved (stimulus strength, pulse repetition rate, pulse burst length, inter-burst interval, coil geometry, coil position and stimulator waveform) as well as possible seizure threshold variations between subjects, it may be very difficult to predict with accuracy a safe upper limit for any given stimulation protocol. Until further progress is made in defining safe regimes, the use of rapid rate cortical magnetic stimulation at levels approaching motor threshold should be treated with considerable caution.

(Nilsson, Panizza, Grandofi)

To read more about Safety, please refer to the following references:

1. "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. Electroencephalography and clinical neurophysiology. 1997 Dec; 105(6):415-21.

2. "Risk and Safety of Repetitive Transcranial Magnetic Stimulation: Report and suggested guidelines from the International Workshop on the safety of Repetitive Magnetic Stimulation, June 5-7, 1996" by Eric M. Wassermann. Electroencephalography and clinical neurophysiology. 1998 Jan; 108(1):1-16.

3. "Tolerability and Safety of High Daily Doses of Repetitive Transcranial Magnetic Stimulation in Healthy Young Men" by: Anderson B, Mishory A, Nahas Z, Borckardt JJ, Yamanaka K, Rastogi K, George MS. The journal of ECT. 2006 Mar; 22(1):49-53.

4. "Efficacy and safety of transcranial magnetic stimulation in the acute treatment of major depression: a multisite randomized controlled trial" by: O'Reardon JP, Solvason HB, Janicak PG, Sampson S, Isenberg KE, Nahas Z, McDonald WM, Avery D, Fitzgerald PB, Loo C, Demitrack MA, George MS, Sackeim HA. Biol Psychiatry. 2007 Dec 1;62(11):1208-16.

5. "Safety of TMS Consensus Group. Safety, ethical considerations, and application guidelines for the use of transcranial magnetic stimulation in clinical practice and research" by Rossi S, Hallett M, Rossini PM, Pascual-Leone A. Clin Neurophysiology. 2009 Dec;120(12):2008-39.

The articles are available at the Pubmed online database (www.pubmed.gov).

Safety Guideline

Warning: Rapid cortical stimulation can induce seizures. Ensure that appropriate safety measures are taken before using the equipment. NEVER exceed the maximum safety recommendations stated in Figure and

Figure below and be aware of the dependency of pulse frequency and % of MT.

Safety Guideline is taken from "Safety of TMS Consensus Group. Safety, ethical considerations, and application guidelines for the use of transcranial magnetic stimulation in clinical practice and research" by Rossi S, Hallett M, Rossini PM, Pascual-Leone A. Clin Neurophysiology.2009 Dec;120(12):2008-39.

Table 4
Maximum safe duration (expressed in seconds) of single trains of rTMS. Safety defined as absence of seizure, spread of excitation or afterdischarge of EMG activity. Numbers preceded by > are longest duration tested. Consensus has been reached for this table.

Frequency (Hz)	Intensity (% of MT)				
	90%	100%	110%	120%	130%
1	>1800[a]	>1800	>1800	>360	>50
5	>10	>10	>10	>10	>10
10	>5	>5	>5	4.2	2.9
20	2.05	2.05	1.6	1.0	0.55
25	1.28	1.28	0.84	0.4	0.24

[a] In Japan, up to 5000 pulses have been applied without safety problems (communication of Y. Ugawa).

Figure 1: Safety recommendations for rTMS stimulation applied outside the motor cortex

Adapted from Table 4 (Part A) and Table 3 (part B) of Chen et al., 1997, with permission from the authors. Safety recommendations for inter-train intervals for 10 trains at <20 Hz. The maximum duration of pulses for individual rTMS trains at each stimulus intensity should not exceed those listed in the Part B of the table. A consensus has been reached in adopting this table at this point. However, there is a need to extend these investigations and provide more detailed guidelines that may apply also to non-motor areas.

Inter-train interval (ms)	Stimulus intensity (% of MT)							
	100%		105%	110%		120%		
Part A								
5000	Safe		Safe	Safe		Insufficient data		
1000	Unsafe (EMG spread after 3 trains)		Unsafe[a]	Unsafe (EMG spread after 2 trains)		Unsafe (EMG spread after 2 trains)		
250	Unsafe[a]		Unsafe[a]	Unsafe (EMG spread after 2 trains)		Unsafe (EMG spread after 3 trains)		
Frequency (Hz)	100%		110%		120%		130%	
	Duration (s)/pulses		Duration (s)/pulses		Duration (s)/pulses		Duration (s)/pulses	
Part B								
1	>270	>270	>270	>270	>180	>180	50	50
5	10	50	10	50	10	50	10	50
10	5	50	5	50	3.2	32	2.2	22
20	1.5	30	1.2	24	0.8	16	0.4	8
25	1.0	25	0.7	17	0.3	7	0.2	5

[a] These stimulus parameters are considered unsafe because adverse events occurred with stimulation of lower intensity or longer inter-train interval, but no adverse effects were observed with these parameters.

Figure 2: Safety recommendations for rTMS stimulation applied to the motor cortex

IEC 60601-1 Medical Electrical Equipment

CAUTION
When connecting, attention must be paid to:

IEC 60601-1
Medical Electrical Equipment -
Part 1: General Requirements for Basic Safety and Essential Performance

When connecting to a medical appliance with an F-type applied part or some additional equipment complying not with IEC 60601-1, but with the relevant safety standard for such equipment, the additional equipment:

1. Must either be placed outside the patient environment (the patient environment is any area in which intentional or unintentional contact can occur between patient and parts of the system or as a result of some other person touching parts of the system)

or

2. if placed within the patient environment, must be:

    a. Provided with additional protective earthing,

or

    b. Supplied from an extra isolating transformer, limiting the enclosure leakage current to a value not exceeding 0.5 mA,

or

    c. Supplied from a floating power supply, limiting the enclosure leakage current to a value not exceeding 0.5 mA.

Please refer to IEC 60601-1.

Glossary

Applied part: Refers to the part of the MagPro R20 which comes into physical contact with the patient in order for the MagPro R20 to carry out its intended function.

F-Type Applied Part: Electrically isolated from Earth and other parts of the medical equipment, i.e. floating. F-type applied parts are either type BF or type CF.

IEC 60601-1 Classification Requirements

Type of protection against electric shock:

- *Class I:* Equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions.

Method(s) of sterilization or disinfection recommended by the manufacturer:

- Please see the section on "Maintenance".

Degree of protection against electric shock:

- *Type BF:* Applied part providing a particular degree of protection against electric shock, Particularly regarding:
  - Allowable leakage current
  - The applied part is electrically isolated (floating).
  - Not intended for direct cardiac application.

Degree of protection against harmful ingress of water:

- *IPx0:* Ordinary equipment (enclosed equipment without protection against ingress of water).

Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide:

- Equipment not suitable for use in the presence of such a mixture.

Mode of operation:

- Continuous operation.

Glossary

Applied part: Refers to the part of the MagPro R20 which comes into physical contact with the patient in order for the MagPro R20 to carry out its intended function, i.e. a coil.

Type BF: Is generally for devices that have conductive contact with the patient, or having medium or long term contact with the patient.

IP: Ingress Protection Rating

What is Magnetic Stimulation?

Magnetic stimulation is a non-invasive, pain free technique used to excite and depolarize neurons in the brain and peripheral nervous system using induced currents. The excitation is caused by weak electric currents induced in the tissue by rapidly changing magnetic fields. The discovery is based on the principle of electromagnetic induction – discovered in 1831 by British scientist Michael Faraday.

When used to stimulate the brain, it is normally referred to as Transcranial Magnetic Stimulation (TMS). TMS can be either single or paired pulse TMS or repetitive Transcranial Magnetic Stimulation (rTMS). Single/paired pulse TMS is mainly used for physiological research and diagnostic purposes. When the magnetic stimulation is delivered at regular intervals, it is termed rTMS. When stimulating the brain rTMS can produce lasting effects on cerebral functions, such as improvement of mood in depression.

Application possibilities

Magnetic stimulation has become an invaluable tool for the evaluation of the human motor system in both health and disease.

In clinical neurophysiology and neurology magnetic stimulation can be used to study central motor pathways and to examine patients with radiculopathies and plexopathies.

Magnetic stimulation is also applicable for purposes of mapping the cortical areas and their functions, for the study of connectivity in the neural networks and the functional significance of elements in a neural network for a given task.

It can be used to evaluate intra-cortical excitability and modulate the level of excitability of a given cortical target beyond the duration of the stimulation.

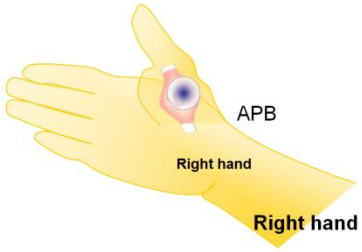
Magnetic stimulation may not only help in our understanding of the neurophysiology of the human brain, but it also promises to enhance the value of imaging studies by adding information regarding the functional role of different (brain) areas.

Motor Threshold (MT) determination

This section contains information on how to perform measurement of a patient's motor threshold level.

When a magnetic coil is discharged over the motor cortex and the discharge energy is above threshold value (MT), neurons are activated and the targeted muscles twitch. The MT is defined as: the minimum single pulse TMS energy needed to observe an Abductor Pollicis Brevis (APB) contraction.

A stimulation protocol is often defined at a specified level related to the MT level, e.g. 120 % of MT.



Consequently, MT determination is an important first step in the treatment procedure. Also, MT is patient specific and although it is relatively stable it can vary with time.

The initial MT determination has two purposes:

1) to determine the location of the hand area of the motor cortex
2) to determine the minimum stimulation level (the MT) required for eliciting repeated twitching of the thumb.

The MT determination is performed on the left hemisphere of the brain over the motor cortex area to activate the APB in the right hand. If stimulating the right hemisphere the activation is in the left hand.
The patient is placed upright in a normal chair or a treatment chair.

The hand area of the motor cortex is approximately 5 cm below the centerline of the head (the vertex Cz) and on the interauricular line. When locating the hand area of the motor cortex, use single stimulations with the MagPro stimulator intensity adjusted to 70%. For most patients this will ensure that the stimulation is above MT level. A few patients will have a higher MT value and for those a higher stimulation intensity has to be applied. Move the coil anteroposteriorly and mediolaterally in relation to the starting point in steps of 0.5 cm for locating of hot spot and muscle twitch is observed.

An active muscle will lower the MT so it may help to ask the patient to tense up the thumb while searching for the optimal location. When an observable twitch of the right hand thumb is seen, the right localization has been found.

When the right localization is found the MT value can be determined. Ask the patient to relax the thumb muscle in the right hand so that the resting MT level can be determined. During determination of the MT, keep the intervals between pulses random and with at least 3 seconds in between. Higher repetition rates may lead to a higher MT. Reduce the stimulation intensity to the lowest value which still induces a visible twitch in the right hand thumb 3 out of 5 stimuli or 5 out of 10 stimuli.

Please note that sometimes it is not possible to stimulate the thumb alone and more fingers are stimulated simultaneously.

How to operate the MagPro R20

This section contains a step-to-step guide on how to turn on the MagPro R20 with Short Pulse Width Option (MagPro R20), how to set a protocol, and how to run a protocol.

The MagPro R20 has been designed to be easy to operate. Follow the simple steps below and you are ready to use MagPro R20. Before you proceed, please make sure that you have read and understood the section on Safety Information (see page 5).

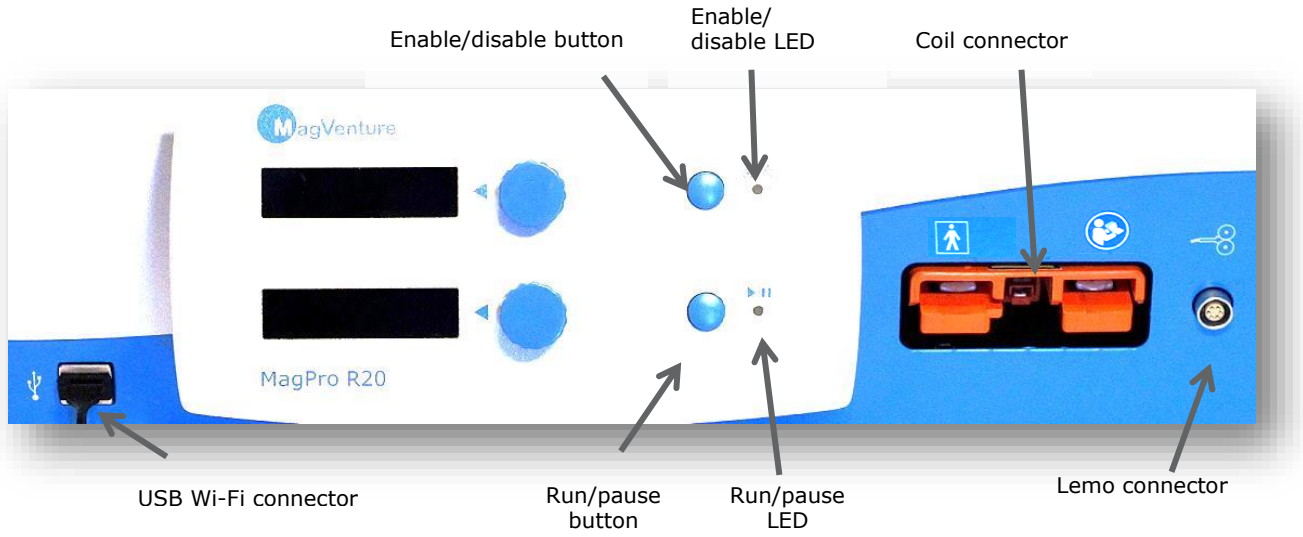


Figure 3: MagPro R20 front panel

Figure 4: MagPro R20 back panel

Turn on the MagPro R20

Step 1: Connect the power cord to the wall outlet. Then insert the large orange coil connector into its counterpart in the right front of the cabinet. See Figure. The large orange connector carries the very high coil current (up to 7,000 amps' capacity) as well as information regarding the coil temperature. Due to a safety resistance, the orange connector can be a bit difficult to insert. Please make sure that the connector is completely inserted, otherwise the device will not operate.

Step 2: Insert the control input (Lemo connector) into its counterpart in the right front of the cabinet. See Figure. Please make sure that the control input is completely inserted, otherwise the device will not operate.

Step 3: Turn on the MagPro R20 by pressing the power switch located at the right back of the cabinet. See Figure. The enable LED flashes yellow while the MagPro R20 warms up for 10-15 seconds. The MagPro R20 is ready to operate when the displays on the MagPro R20 front panel light up.

It is possible to change the coil without turning off the MagPro R20. When a new coil has been successfully inserted, this screen will appear:

If the coil is not recognized, this screens appears:

Should an error occur during start up, please turn to page 45 for a list of error states and error messages and how to correct them.

Quick guide on how to enter and exit stimulation mode

How to enter stimulation mode

It is possible to enter the stimulation mode in two different ways:

- From the MagPro R20: Press the enable button (⊙/Ȯ). The intensity is automatically set to the last used intensity or to 10%.
- From the coil: Turn the intensity control knob on the handle of the coil to the minimum zone on the dial scale. Press the trigger button for one second and the light on the coil turns green. The intensity is automatically set to 10%.

You can now adjust the stimulus intensity to a desired level and begin delivering pulses.

How to operate in stimulation mode

Once the MagPro R20 is in stimulation mode (it is enabled) it is possible to:

- Give single stimuli from the coil trigger at the intensity allowed at the given protocol setting).
- It is possible to start and stop a train/protocol from the coil if the coil is equipped with a trigger button by pressing and holding the trigger button on the coil for 2 seconds to either start or stop a train/protocol.

For all MCF coils, the machine will disable when the train/protocol has finished.
For all standard coils, the machine stays enabled and the intensity is kept, when the train/protocol has finished
Further, the intensity can be set from the coil if the coil is equipped with an intensity control knob.

How to exit the stimulation mode

You exit the stimulation mode to avoid giving unintentional stimulus. Please note that the MagPro R20 will automatically disable 10 minutes after the last delivered pulse.

It is possible to exit manual mode in two different ways:

- From the MagPro R20: Press the enable button (⊙/Ȯ)
- From the coil: Turn the intensity control knob to 0 – and the MagPro R20 will disable after 1 second. The enable/disable LED on the MagPro R20 turns yellow

Set protocol

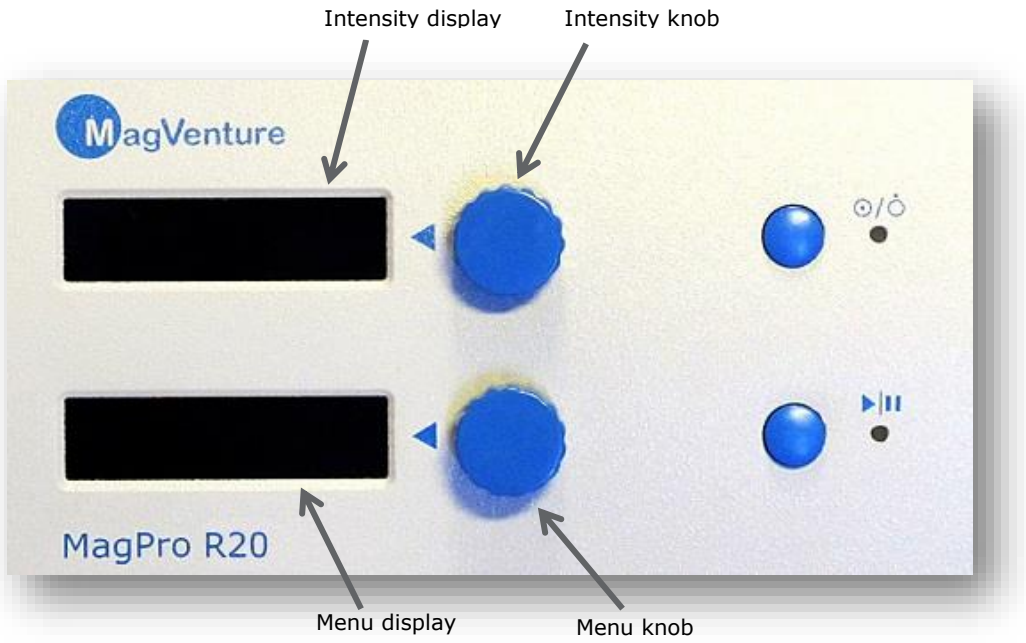


Figure 5: MagPro R20 front

The MagPro R20 has two displays – an intensity display at the top and a menu display at the bottom.

The intensity display shows the intensity and the temperature of the coil. The menu display shows rep. rate, pulses in train, number of trains, inter train interval, start delay, and volume.

When you make the MagPro R20 ready to operate, please turn to the menu display first.

Step 4 – Menu display: When you turn the Menu knob next to the menu display (see Figure), you switch between rep. rate, pulses in train, number of trains, inter train interval, start delay and volume. When you push the button instead of turning it, you are ready to adjust values for rep. rate, pulses in train, number of trains, inter train interval, start delay, and volume, respectively.

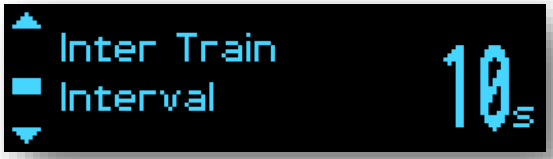
Step 4.1 – Repetition Rate: It is important that you first set repetition rate. Repetition rate is defined as the number of pulses per second. To set the repetition rate, make sure that "Repetition rate" is visible in the display – then push the Menu knob at the bottom in order to choose repetition rate. When repetition rate has been chosen, an arrow appears in the left side of the display. Now you are able to adjust the value for the repetition rate.

The limits are 0.1-100 pps (pulses per second). Push the Menu knob again to lock the selected value. Note that when you set the repetition rate, the intensity in the intensity menu turns to 0.

Step 4.2 - Pulses in train: Pulses in train is defined as the number of pulses per train. Make sure that "pulses in train" is visible in the display – then push the Menu knob in order to choose pulses in train. When Pulses in train has been chosen, an arrow appears in the left side of the display. Now you can adjust the value for the pulses in train. The limits are 1-600. Push the Menu knob again to lock the selected value.

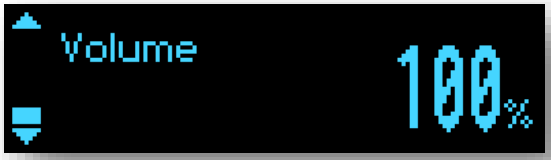
Step 4.3 - Number of trains: Number of trains is defined as the number of pulse trains in each protocol. Make sure that "Number of trains" is visible in the display – then push the Menu knob in order to choose number of trains. When number of trains has been chosen, an arrow appears in the left side of the display. Now you can adjust the value for the number of trains. The limits are 1-100. Push the Menu knob again to lock the selected value.

Step 4.4 – Inter Train Interval: Inter Train Interval is defined as the length of the pause between the trains. Make sure that "Inter Train Interval" is visible in the display–then push the Menu knob in order to choose Inter Train Interval. When Inter Train Interval has been chosen, an arrow appears in the left side of the display. Now you can adjust the value for the Inter Train Interval. The limits are 1-300 seconds. Push the Menu knob again to lock the selected value.



Step 4.5 - Start delay: Start delay is defined as the time delay in seconds from you push start until the MagPro R20 begins the selected protocol. Make sure that "start delay" is visible in the display – then push the Menu knob at the bottom in order to choose start delay. When start delay has been chosen, an arrow appears in the left side of the display. Now you can adjust the value for the start delay. The limits are 0-60 seconds. Push the Menu knob again to lock the selected value.

Step 4.6 - Volume: Make sure that "volume" is visible in the display – then push the Menu knob at the bottom in order to choose volume. When volume has been chosen, an arrow appears in the left side of the display. Now you can insert the values for the volume. The limits are 0-100 %. Push the Menu knob again to lock the selected value.



When you are done adjusting the values in the menu, please turn to the upper display.

Step 5 – Intensity display: Set the intensity by turning the Intensity knob. This will increase the intensity 1% at a time. The intensity will increase 10% at a time if you push the Intensity knob instead of turning it. To reset the intensity, push and hold the Intensity knob for one second. Please note that it is only possible to adjust the intensity from 10%-100%. It will skip 1-9%. Please note that it is possible to turn the intensity down to 0.

It is also possible to control the intensity directly from the coil if the coil is equipped with an intensity control knob (C-100, C-B60, MMC-140-II, RT-120-II). Simply turn the intensity control knob to the desired level.

Temperature display: It is not possible to change the temperature of the coil. The temperature of the coil is monitored automatically and will appear at the left side of the intensity display of the MagPro R20. If the temperature reaches 44ºC, the coil is too hot and the MagPro R20 disables and cannot be enabled before the coil temperature reaches 43ºC or below. The MagPro R20 will also disable if the coil temperature is below 5ºC.

For quicker cooling, put the coil in the refrigerator (NB: Do **NOT** put the coil in the freezer).

Especially for MCF coils: The temperature can be 44-48ºC for 10 minutes. When the coil reaches 44ºC, the temperature displayed on the MagPro R20 begins to flash. It will flash for 10 minutes. After 10 minutes, the MagPro R20 will disable. The MagPro R20 will automatically disable if the temperature is above 48ºC.

Motor Threshold (MT): The MagPro R20 supports automatic multiplication of motor threshold and intensity. The motor threshold ratio (MT ratio) is default set to 1.2.

When the intensity for motor threshold has been found, please push and hold the Intensity knob on the MagPro R20 for 2 seconds and it will multiply the current intensity with the motor threshold ratio.

The intensity is automatically calculated and set on the MagPro R20. It will appear on the screen that the intensity is calculated from the MT ratio:

In this mode, the Intensity is locked. To turn off the motor threshold mode, push and hold the Intensity knob for 2 seconds and the intensity returns to its former value.

Performance Chart

The maximum intensity level reachable is 100%, but will often be lower than that depending on the chosen repetition rate, the Inter Train Interval and the number of pulses in the trains. The stimulator automatically calculates the maximum intensity. Below is an in-depth explanation about how the maximum intensity level is calculated.

How to calculate the maximum intensity level

The maximum intensity level depends on the repetition rate and the average repetition rate. The average repetition rate is defined as the number of pulses in the train divided by the length of the train in seconds including the inter train interval.

To establish the maximum intensity level reachable at a given number of pulses with a given protocol, it is necessary to find the maximum intensity allowed for both the repetition rate (Figure 6) and the average repetition rate (Figure 7) and after that choose the lower of the two intensities.

Examples:

1) With a protocol defined as 68 pps in repetition rate, 10 trains, 140 pulses in train, Inter Train Interval of 2 seconds, the average rep rate will be:

$$140/(140/68+2) = 140/4.06 \approx 34.5$$

When looking in the two figures, you see that in the maximum intensity at 68 pps is approximately 36% and in the second figure the maximum intensity for an average repetition rate of 34.5 pps is approximately 29%. Your maximum intensity for the given protocol is thus 29%.

2) With a protocol defined as 10 pps in repetition rate, 40 trains, 50 pulses in train and an Inter Train Interval of 20 seconds, the average rep. rate will be:

$$50/(50/10+20) = 50/25 = 2.00 = 2$$

When looking in the two tables on the next page, you see that in Figure 6 the maximum intensity at 10 pps is 100% and in the Figure 7 the maximum intensity for an average rep. rate of 2 pps is 100%. Your maximum intensity for the given protocol is thus 100%.

Rep. Rate	Maximum Intensity
≤10 pps	100%
15 pps	87%
20 pps	75%
25 pps	67%
30 pps	60%
35 pps	55%
40 pps	50%
45 pps	47%
50 pps	45%
55 pps	42%
60 pps	39%
65 pps	37%
70 pps	35%
75 pps	33%
80 pps	32%
85 pps	30%
90 pps	29%
95 pps	28%
100 pps	27%

Figure 6: Rep. rate and max. intensity

Avg. Rep. Rate	Maximum Intensity
≤2 pps	100%
3 pps	96%
4 pps	83%
5 pps	75%
6 pps	68%
7 pps	63%
8 pps	59%
9 pps	55%
10 pps	53%
15 pps	43%
20 pps	37%
25 pps	33%
30 pps	30%
35 pps	28%
40 pps	26%
45 pps	25%
50 pps	23%
55 pps	22%
60 pps	21%
70 pps	20%
80 pps	18%

Figure 7: Average rep. rate and max. intensity

Selected protocols and maximum intensity

Example 1: *Repetition rate is 5pps, pulses in train is 50, inter train interval is 20 seconds, average repetition rate is 1.67. Maximum intensity= 82%*

Example 2: *Repetition rate is 5pps, pulses in train is 30, inter train interval is 2 seconds, average repetition rate is 3.75. Maximum intensity= 54%*

Example 3: *Repetition rate is 10pps, pulses in train is 50, inter train interval is 20 seconds, average repetition rate is 2.00. Maximum intensity= 75%*

Example 4: *Repetition rate is 10pps, pulses in train is 40, inter train interval is 26 seconds, average repetition rate is 1.33. Maximum intensity= 75%*

Example 5: *Repetition rate is 20pps, pulses in train is 40, inter train interval is 32 seconds, average repetition rate is 1.18. Maximum intensity= 35%*

Example 6: *Repetition rate is 15pps, pulses in train is 30, inter train interval is 2 seconds, average repetition rate is . Maximum intensity= 38%*

Example 6: *Repetition rate is 70pps, pulses in train is 15, inter train interval is 8 seconds, average repetition rate is 1.8. Maximum intensity= 35%*

Run Protocol

When you have entered all the values in the two displays, you are ready to run the selected protocol. Press the start/pause button (▶II). If the enable/disable button (⊙/○) was disabled, it will now enable automatically when you press the start/pause button. When the protocol is running, the start/pause light will flash green. Please note that it is only possible to run a protocol when the intensity is set to a value greater than 0.

You can also start the protocol directly from the coil by pushing the coil trig button for two seconds. This can only be done when the MagPro R20 is activated.

If start delay is > 0, this screen will appear before the protocol starts:

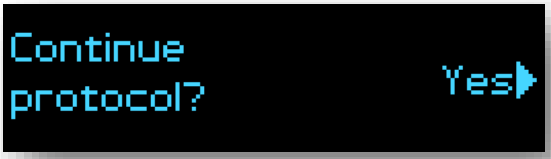
When the MagPro R20 is running the protocol, the menu display will continuously show the status. It will show the present train number and the number of minutes and seconds left in the selected protocol.

When the protocol has been completed, this screen will appear in the menu display.
For all standard coils, the MagPro R20 stays enabled and the intensity level is kept.
For all MCF-coils, the MagPro R20 disables, but the intensity is kept.

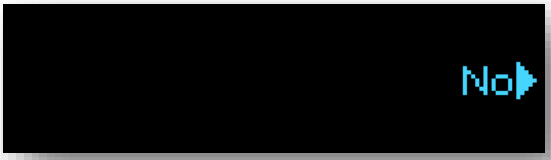
The MagPro R20 will automatically stop if the coil is too hot (see page 25). If the protocol is stopped due to heating of the coil, the MagPro R20

will disable. The enable/disable LED light turns yellow and the run LED will flash green (pause mode). At this point it is possible to change the coil to another coil of the same type and then continue the protocol.

When the new coil is inserted, the Intensity display writes "Continue protocol?". It is possible to continue the protocol where it stopped or to discard the protocol and start the MagPro R20 in default mode.



If you want to continue the protocol, choose "Yes" by pressing the Intensity knob next to the Intensity display. If you do not want to continue the protocol, choose "No" by pressing the Menu knob next to the menu display.



When the protocol is finished, it is possible to reenter values in step 4 and 5 (see "Set Protocol" on page 21) – or it is safe to turn off the MagPro R20. The next time you turn on the MagPro R20, it will retain the protocol values set when the stimulator was turned off.

Quick stop	Pause protocol	Stop protocol
If you need to make a quick stop, press the enable/disable button (⊙/Ȯ) or turn off the MagPro R20 by pressing the power switch at the back.	If you press the start/pause button (▶|❚❚), the protocol will be paused. Click the start/pause button again to continue the protocol. While the protocol is paused, the start/pause light will flash green. It is possible to give single pulse stimulations while the MagPro R20 is paused.	To stop a running protocol either • Press the enable/disable button (⊙/Ȯ). The MagPro R20 disables • Press and hold the start/pause button for 2 seconds. The MagPro R20 stays enabled • Press and hold the trigger button on the coil for 2 seconds. The MagPro R20 stays enabled. Remember to disable the MagPro R20 when not in use Remember to always turn off the MagPro R20 before leaving it Before changing the coil, press disable to avoid damage on personnel and equipment (unless the protocol is still running, but the coil is too hot).

MagPro R20 Components

This section contains information about the main devices and optional components including description of magnetic stimulation coils supported and part numbers.

All the coils equipped with a trigger button and an intensity wheel can be used to operate the MagPro R20.

The behavior of the MagPro R20 dependents on the type of coil (standard or MCF coil)

For the standard coils the MagPro R20 stays enabled after the end of the protocol and the intensity is kept.

For the MCF coils, the MagPro R20 disables after the end of the protocol and the intensity is kept.

Magnetic Stimulation Coils

The following coils can be used with the MagPro R20:

Standard coils

C-100: Suitable for general-purpose stimulation. Equipped with intensity control (power control) and trigger button to support clinical operation.

C-B60: Suitable for focused stimulation. Equipped with intensity control (power control) and trigger button to support clinical operation.

MC-B70 (with coil interface cable): Suitable for focused stimulation. Has a slightly bent surface to follow the shape of the head. Equipped with trigger button to support clinical operation.

MC-125 (with coil interface cable): Suitable for general purpose stimulation. Equipped with trigger button to support clinical operation.

MMC-90 (with coil interface cable): Provides a powerful and focused stimulation and is suitable for stimulation of jaw, neck and popliteal region. Equipped with trigger button to support clinical operation.

MMC-140 (with coil interface cable): Provides a powerful and focused stimulation. Equipped with trigger button to support clinical operation.

MMC-140-II: Parabolic in shape to provide powerful and focused stimulation. Equipped with intensity control (power control) and trigger button to support clinical operation.

RT-120 (with coil interface cable): Suitable for stimulation of wider areas such as bigger muscles. Equipped with trigger button to support clinical operation.

RT-120-II: Elliptic in shape and especially suitable for stimulation of wider areas such as bigger muscles. Equipped with intensity control (power control) and trigger button to support clinical operation.

D-B80 (with coil interface cable): Open butterfly design for powerful stimulation. Suitable for deep stimulation. It has a slightly bent surface to closely follow curved shapes. Equipped with trigger button to support clinical operation.

MC-B65-HO-2m and 8m (with coil interface cable): The coil handle is placed orthogonal to the coil surface. Choose between a cable length of either 2m or 8m.

MCF coils

MCF-B65: Designed for demanding stimulation protocols, requiring a high number of stimuli. Equipped with trigger button to support clinical operation.

MCF-B70: Designed for demanding stimulation protocols, requiring a high number of stimuli. Has a slightly bent surface. Equipped with trigger button to support clinical operation.

MCF-75: Designed for demanding stimulation protocols, requiring a high number of stimuli without the need for external cooling. Equipped with trigger button to support clinical operation.

MCF-125: Designed for demanding stimulation protocols, requiring a high number of stimuli. Equipped with trigger button to support clinical operation.

MCF-P-B65: Placebo coil which has a mechanical outline and sound level identical to MCF-B65. Equipped with trigger button to support clinical operation.

MC-P-B70 (with coil interface cable): Placebo coil which has a mechanical outline and sound level identical to MC-B70. Slightly bent surface to closely follow the shape of the head. Equipped with trigger button to support clinical operation.

MCF-P-B70: Placebo coil which has a mechanical outline and sound level identical to MCF-B70. Large ergonomic handle. Equipped with trigger button to support clinical operation.

Coil Interface Cable: Adapter to be used to connect 4 pole coils to the MagPro R20.

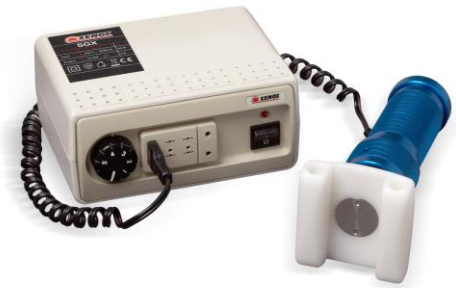
WARNING
The surface temperature of the coil against the patient's skin can exceed 41°C. The temperature allowed by the system is maximum 43°C for non-MCF-coils, and maximum 48ºC for MCF-coils, and only between 44°C and 48°C for less than 10 minutes. The system will automatically disable if this maximum temperature is reached.
If high speed stimulation protocols are performed, some increased temperature on the coil surface against the patient's skin can occur. According to the IEC 60601-1:2005 standard, a maximum temperature of 48°C is allowed for a time up to 10 minutes.

Neuro 3D vibration Tool

The Neuro 3D vibration tool is a handheld vibration tool helping relieve pain and tension through loosening adhesions of tendons, ligaments and fascia. The Neuro 3D vibration tool serves as an excellent add-on to functional magnetic stimulation.

The Neuro 3D vibration tool consists of:

- Hand unit Neuro3D
- Different heads
- Power unit
- Carrying case



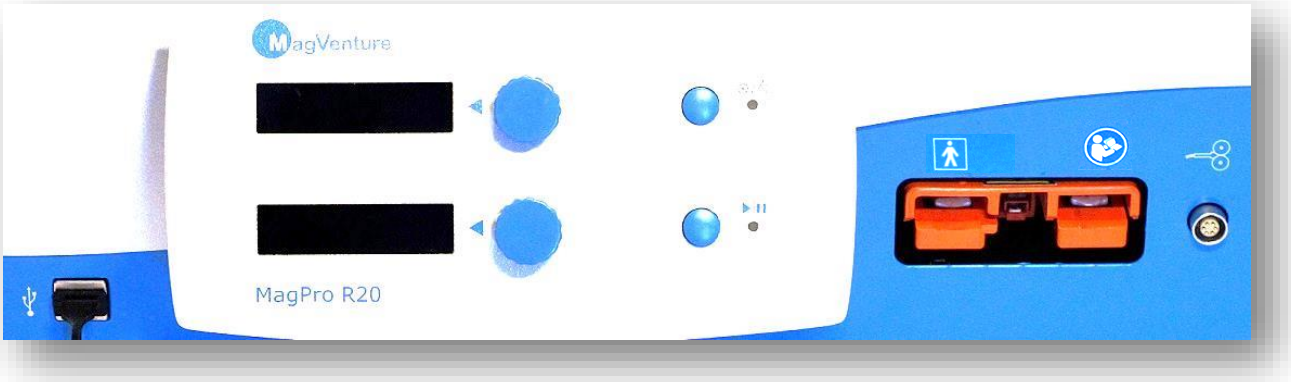
Part Numbers

MagPro device	
MagPro R20	9016E0861
MagPro R20 with Short Pulse Width Option	9016C0101
Standard Coils	
C-100	9016E0582
C-B60	9016E0482
MC-B70	9016E0564
MC-125	9016E0555
MMC-90	9016E0211
MMC-140	9016E0573
MMC-140-II	9016E0631
RT-120	9016E0641
RT-120-II	9016E0651
D-B80	9016E0431
MC-B65-HO-2	9016E0462
MC-B65-HO-8	9016E0472
MCF Coils	
MCF-B65	9016E0423
MCF-B70	9016E0401
MCF-75	9016E0442
MCF-125	9016E0413
Placebo Coils	
MC-P-B70	9016E0592
MCF-P-B65	9016E0601
MCF-P-B70	9016E0201
Coil Interface Cable	9016E4641
Optional Components	
Neuro 3D Vibration Tool	9016M0011
Trolley	9016B0381
Super Flex Arm for Coils (long)	9016B0171
Super Flex Arm for Coils (short)	9016B0181
Wall mount bracket for Super Flexible Arm	9016B0371
Table bracket for Super Flexible Arm	9016B0391
Isolation Transformer for MagPro X/R, 120V/230V	9016D0031
Isolation Transformer for MagPro X/R, 230V/230V	9016D0041
Isolation Transformer for MagPro X/R, 100V/230V	9016D0051
Trigger cable, MagPro for MagPro (for connecting two MagPro)	9016E4571
Cable Ext. Trig with 9p D-Sub (Keypoint)	9016E4551
Cable Ext. Trig with BNC	9016E4561

Symbols, Terms and Definitions

This section contains information of symbols used on MagPro R20 front and back

MagPro R20 front

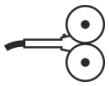



Follow instruction for use


Apparatus is of type BF, i.e. the applied part is electrically isolated


Enable/Disable


Run/Pause

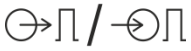

Coil trigger connector


USB port, only to be used for devices delivered by MagVenture.

LED placed in Coil Handle (Lemo 6 Coil)

LED Color	Coil status
Yellow	Disabled
Green	Enabled

MagPro R20 back

	Follow instruction for use
	ON/OFF button
	Trig out / Trig in for connection to an external device like a neurodiagnostic EMG/EP amplifier, e.g. the Keypoint®.
SN xxx	Serial Number
P/N	Part Number
	The device complies with the EC directive 93/42/EEC on medical device.
	Waste Electrical and Electronic Equipment: Compliance information.
 2014-02	Date of manufacture (Year-Month)

Ventilation
Make sure that the fan opening on the rear panel of the main unit is not blocked by any objects. In order to allow free passage of air to the fan let there be a distance of minimum 15cm (6 inches) to the wall.

Mains
When the MagPro R20 is producing maximum output, power consumption is high — up to approx. 800 Watts. To prevent other equipment from malfunctioning, we recommend that the device is supplied from a separate wall outlet. The mains plug must be inserted into a mains socket outlet provided with a protective earth contact. Do not use extension cords!

External Trig in/ Trig out
The external trig out pin gives a signal each time the R20 gives a stimulation, whether the source of the stimulation is a click on the coil button, a part of a running protocol or caused by the external trig in.

The external trig input pin can be used to make the R20 give stimulations.
Stimulation occurs, without delay, at the time of reception of a trig-in signal at a maximum frequency of 1Hz. More frequent signals are ignored.
Stimulations can only be caused by the external trig input when the R20 is enabled, not running a protocol and not locked.

The External Trig Connector can for instance be used to connect the MagPro R20 to an EMG/EP/EEG system for synchronization of data acquisition and stimulation time.

The cable for this purpose was delivered with the MagPro R20.

Two R20 devices may also be connected using the external trig connector. One of the devices then acts as a master which controls the stimulation. The other will then act as a slave and give stimulations simultaneous with the master. Note that the slave will only give stimulations at a frequency of 1 Hz or less. Only use the special trigger cable "MagPro to MagPro" (part number 9016E4571) which can be ordered at MagVenture.
Remember to turn off the MagPro R20 before connecting or disconnecting any equipment to the device.

Only connect external devices with low voltage TTL signals, e.g. to an external device like a neurodiagnostic EMG/EP amplifier, e.g. the Keypoint®.

CAUTION Equipment intended for connection to the MagPro R20 must be certified according to IEC60601-1:2005

Auto disabling
If the system is left unused for more than 10 minutes it automatically shuts down the high voltage parts and disables any triggering.

Interference

WARNING Electrical equipment for medical use requires special EMC precautions and needs to be installed and serviced according to the EMC documentation of the device, see page 49.

Coils

General warning, read instruction for use

Indicates the current direction on coil

Operating period

DANGER The Magnetic Coils have a restricted operating period.
Mechanical vibrations and thermal stress during stimulation can degenerate the coil over time. Even if the coil is not used, aging of materials and liquid inside the coil over time can occur. Storage of the coil must always be within the range of temperature and humidity specified.

Some MCF-coils are specified with a fixed expiration date and other coils have a built-in timer and counter for electronic system for time out.

Operating period for coils with fixed expiration date
Magnetic Stimulation Coils must not be used after the expiration date.

The expiration date is shown on the label, which is situated on top of the large orange coil connector, as YYYY-MM

2018-10

Operating period for coils with a built-in timer and counter
Built-in timer and counter: Preset to an operating period of typical 1825 days (approximately 5 years) or a maximum Equivalent Pulse Value (EPV) of 18,000.000 whichever occurs first. After the time out period the coil must be disposed of separately as electronic waste.

The remaining operating period is indicated on the display on top of the coil connector: N indicates the equivalent pulses left and D the lifetime in days left. When the N or D values are near the time out, the display will start to blink with the hourglass symbol.

Caution

The lifetime of the coil is limited due to various stress-effects. Even if the coil is not used, aging of materials and liquid inside the coil over time can occur, whereby a limitation in days is defined. The mechanical, magnetic, and thermal stress on the coil-winding reduces the lifetime dependent on the stimulation current waveform and amplitude. The equivalent pulse values are found in the scheme below.

Equivalent Pulse Value (EPV) - Down count number

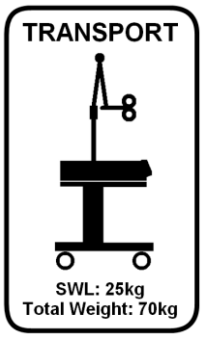
MagPro R20 w. SPW-Option Intensity (%)	Biphasic Pulse Short Pulse Width
0 - 40	1
40 - 80	2
80 - 100	4

Example:

Running a protocol of 1,500 pulses at 75% MagPro indicated output power, using standard biphasic pulses:

The EPV is 2, and the 1,500 pulses is equivalent to 3,000 EPV's. With a maximum EPV of 18,000.000 the protocol above can be performed 6,000 times during the operating period.

Trolley



Transportation of equipment; make sure the Flexible Arm is in upright position.

Safe Working Load (SWL) = 25kg
E.g. Isolation Transformer and extra coil

Total weight incl. SWL = 70kg
MagPro R20, Trolley, Flexible Arm, Coil and SWL items

CAUTION Always place the system with trolley on a flat horizontal surface and lock the two front wheels. Risk of sliding if placed on a non-flat horizontal surface.

CAUTION If a coil is mounted in the Flexible Arm on the trolley, the coil must be placed above the MagPro R20 cabinet and with the arm locked, to protect the coil from impacts during transport of the system.

Terms and Definitions

Below please find a list of the abbreviations used in this user guide. The list is sorted alphabetically.

Abbreviations

DBS:	Deep Brain Stimulators
EC:	European Community
EEC:	European Economic Community
EEG:	Electroencephalography (recording of electrical activity along the scalp)
EMC:	Electromagnetic compatibility
EMG:	Electromyography (a technique for evaluating and recording the electrical activity produced by skeletal muscles)
EP:	Evoked Potentials
ICD's:	Implantable Cardioverter-defibrillators
IEC:	International Electrotechnical Commission
ITI:	Inter Train Interval
LED:	Light-Emitting Diode
MCF:	Magnetic Coil with Fluid cooling (e.g. MCF-coils such as MCF-B70)
MEP:	Motor Evoked Potentials
MRi:	Magnetic Resonance imaging
MT:	Motor Threshold
PPS:	Pulses per Second
Rep. Rate:	Repetition Rate
rTMS:	Repetitive Transcranial Magnetic Stimulation
TMS:	Transcranial Magnetic Stimulation
VNS:	Vagus Nerve Stimulator
WCD's:	Wearable Cardioverter-defibrillators

Technical Data, Technical Description and Maintenance

This section contains information on technical data – electromagnetic data, triggering, mechanical data, environmental data, power supply, and lifetime, This section also contains information on how to maintain your MagPro R20 equipment and how the equipment must be disposed of.

Technical Data

Electromagnetic Data

Pulse Width: 220 µsec Biphasic.
Magnetic Gradient: 40 - 60 kTesla/s. Depending on stimulation coil.
Peak Magnetic Field: 1 - 4 Tesla. Depending on stimulation coil.

External Triggering

Only connect external devices with low voltage TTL signals, e.g. to an external device like a neurodiagnostic EMG/EP amplifier, e.g. the Keypoint®.

CAUTION Equipment intended for connection to the MagPro R20 must be certified according to IEC60601-1:2005.

For the connections, see the table below:

External trig in/out: 9p DSUB.
Connections:

Pin1: Trig-Input	Pin6: 5V, max 200mA
Pin2: Trig-Output	Pin7: Do not connect
Pin3: Gnd	Pin8: Do not connect
Pin4: Do not connect	Pin9: Do not connect
Pin5: Do not connect	

Trig in:
TTL and CMOS compatible.
Pulse width ≥ 10 µsec.
Input impedance ≥ 10kΩ.
Falling edge trigger.
Max. Frequency: 1Hz.

Trig out:
TTL-levels.
Falling edge.
Pulse width = 50 µsec.
Output impedance ≤ 100Ω.

Error States

Error States	Explanation
Please connect the coil connector.	The orange coil connector has not been completely inserted, or the coil is below 5ºC
Please connect the Lemo connector.	The Lemo connector has not been completely inserted.
Please connect a compatible coil.	The inserted coil is not compatible with the MagPro R20.
The coil is too hot.	The maximum coil temperature has been exceeded. Wait for the coil to cool down to 43ºC.
The R20 is too hot. Wait for it to cool.	The MagPro R20 is too hot. Wait for it to cool down.
Selftest failed. Please contact support.	The MagPro R20 has a hardware failure. Contact your local distributor.
Snubberboard error.	The MagPro R20 has a hardware failure. Contact your local distributor.

Messages

Messages are shown for a brief period of time, and the display returns to the previous state. Some messages are spoken only.

Messages	Explanation
Please set intensity.	If an attempt to enable the device while the Intensity is set to 0%, this error is shown. Set the Intensity between 10%-100% and enable the device again.
Please confirm settings.	If an attempt to enable the device without having locked selected value in the menu display, this message is shown
Device could not be enabled (spoken only).	An error has occurred. Turn off the MagPro R20 and turn it on again.
Device could not be disabled (spoken only).	An error has occurred. Turn off the MagPro R20 and turn it on again.

In general, if the above-mentioned error states or messages keep appearing despite following the suggestions under “explanation”, call an authorized service technician.

Mechanical Data, MagPro R20

Dimensions (HxWxD):	150 x 390 x 440mm
Weight:	17kg

Environmental Data

Operating Temperature:	10 – 30°C (50-86°F)
Storage Temperature:	5 – 50°C (41-122°F)
Operating Humidity:	30 – 60% RH
Storage Humidity:	20 – 80% RH
Operating Pressure:	80-106kPa
Operating Altitude:	-400m to 2.000m
Storage/transport Pressure	24-106kPa
Storage/transport Altitude	-400m to 10.000m

Pollution degree 2: Micro-environment with non-conductive pollution, except occasional conductivity caused by condensation.

Storage/transport symbols on packaging label


Temperature limit


Humidity limitation


Atmospheric pressure limitation

Power Supply

Power Supply: 230Vac, 50/60 Hz.
According to IEC 60601-1.

Power Consumption: Maximum 800 VA.

Ventilation: Forced cooling by low noise fan.

Fuses: Internal. 2pcs T4A/250V~

For connection to 100V~ or 120V~ mains power outlet use a separate transformer.

Part Numbers:

Isolation Transformer for MagPro X/R, 120V/230V	9016D0031
Isolation Transformer for MagPro X/R, 100V/230V	9016D0051

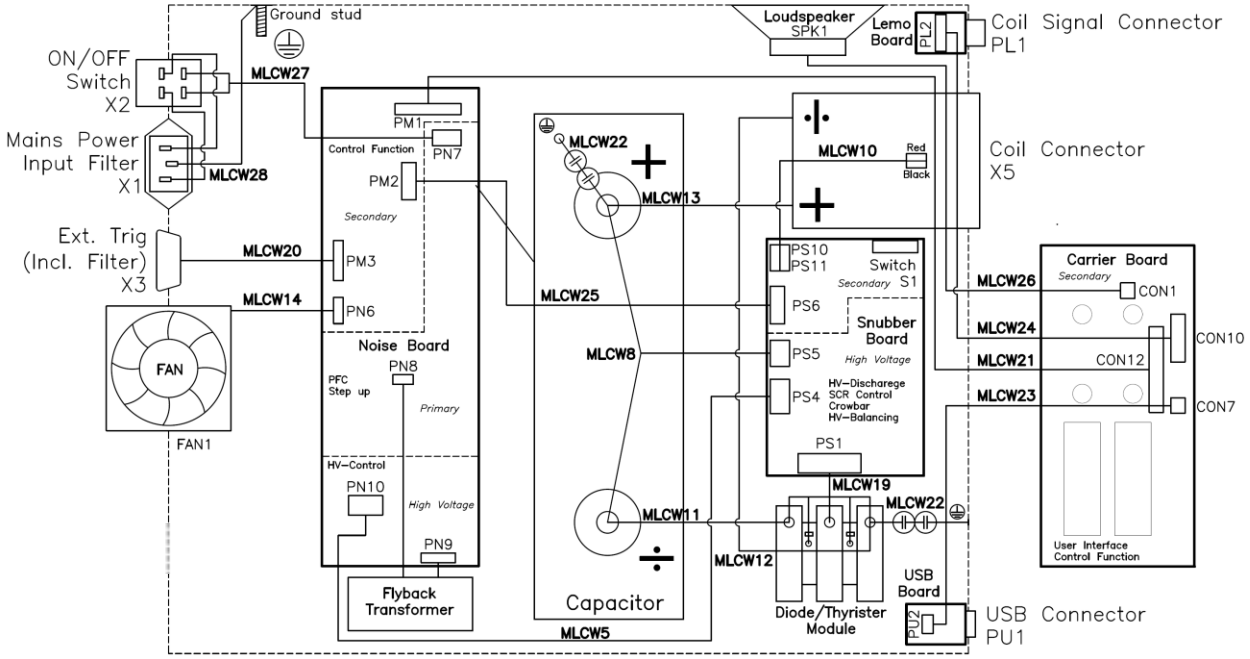
Technical Description

Warning: Do not modify this equipment without authorization of the manufacturer.

Caution: Do not remove cover; Electric shock hazard. Any maintenance inside the device must be performed by qualified service personnel.

Service must only be referred to Tonica or other authorized service personnel, except for such works described in this manual as being performed by the operator. The device must be disconnected from all voltage sources before being opened for any adjustment, replacement, maintenance or repair.

Cable diagram



The device has two internal fuses on the Noise board: F1, F2: T4A/250V~, 5x20mm, ceramic type. Spare part no. 358-0245.

Caution: Replace fuse with same type and rating.

The control part of the system includes a Real Time Clock backup battery of lithium type: 3V, CR2032. Spare part no. 355-0010.

Warning: Risk of explosion if battery is replaced by an incorrect type or recharged.

For a list of available spare parts please contact Tonica Elektronik A/S

Maintenance

CAUTION Do not remove cover; Electric shock hazard. Any maintenance inside the device must be performed by qualified service personnel.

Cleaning and Disinfecting Procedures

The maintenance that can be performed by the operator is limited to cleaning and disinfecting the device.

- The Main Unit, Coil and Trolley:
  - Before cleaning the device units, switch off the mains. Use a cloth gently wrung in a recommended disinfectant as listed below.
  - Dilute the disinfectant properly, as stated by the manufacturer.

For routine cleaning use
Phenoles (Bacillotex® etc.) or 70% alcohol, 0.5% chlorohexidine.

If hepatitis or any other dangerous virus contamination is suspected: Aldehydes (Cidex®, Korsolin®) or chlorinates (Diversol BX®).

Be careful not to drip water or disinfectant directly into the input and output plugs and other openings in the cover. Remove excess disinfectant with a dry cloth.

Do not use solvent silicon-based or abrasive cleaning agents.

Before using disinfectants other than those specified, please contact your local distributor for further information.

Lifetime

8 years.

Waste Management

The device and its accessories must be disposed of separately as electronic waste.

Waste Electrical and Electronic Equipment, user information:
Do not dispose of this product in the unsorted municipal waste stream.
Dispose of this product according to local regulations.

Electromagnetic Compatibility

Electromagnetic Emissions

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

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

WARNING the equipment should not be used adjacent, or stacked with other equipment. If adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.

Electromagnetic Immunity

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

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment — guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
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.
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 40% U_T (60 % dip in U_T) for 5 cycles 70% U_T (30 % dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40% U_T (60 % dip in U_T) for 5 cycles 70% U_T (30 % dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MagPro requires continued operation during power mains interruptions, it is recommended that the MagPro be powered from an uninterruptible power supply or a battery.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the MagPro, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 0.15 to 80 MHz	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = 1.2\sqrt{P}$, 80 MHz to 800MHz $d = 2.3\sqrt{P}$, 800 MHz to 2.5 GHz

Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacture, and *d* is the recommended separation distance in meter (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]

Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 and 800 MHz, the higher frequency range applies.

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

[a] 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 MagPro is used exceeds the applicable RF compliance level above, the MagPro should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting, or locating the MagPro.

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

Recommended separation distances between portable and mobile RF communications equipment and the MagPro

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter Meter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated 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.

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

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

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