Magstim BiStim²
Operating Manual

MOP02-EN
Revision 02

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GUARANTEE

Equipment manufactured by The Magstim Company Limited is fully guaranteed, covering both materials and workmanship, for a period of one year from the date of shipment. The Magstim Company Limited reserves the right to perform guarantee services in its factory, at an authorised repair station, or at the customer's installation.

Any obligations which The Magstim Company Limited has under this guarantee are limited to repairs or, should the company so choose, replacement of any defective parts of the equipment, except batteries, without charge provided that the said defects occur during normal service.

Claims for damages during shipment must be filed promptly with the transportation company. All correspondence concerning the equipment must specify the model name and/or number as well as the serial number exactly as they appear on the invoice for the equipment.

Improper use, mishandling, tampering with, or operation of the equipment without following specific operating instructions will void this guarantee and release The Magstim Company Limited from any further guarantee obligations.

The Magstim Company Limited will only accept responsibility for effects on safety, reliability and performance of the equipment if:

- modifications or repairs are carried out by persons authorised by The Magstim Company Limited;
- the electrical installation of the relevant room complies with local regulations; and
- the equipment is used in accordance with the instructions for use.

SECTION 1 INTRODUCTION

1.1 Indications for Use

The Magstim Bistim² is a magnetic nerve stimulator intended for the stimulation of cortical and peripheral nerves for diagnostic, research and therapeutic purposes.

The Magstim Bistim² consists of two Magstim 200² units and a Magstim Bistim² Connecting Module. This enables the outputs of the two Magstim 200² units to output into a single stimulating coil either as a single high energy pulse or as a pair of individual spaced pulses.

The Magstim Bistim² is capable of stimulating by inducing small currents in the nerve using a brief pulse of electromagnetic energy.

This method of stimulation enables deep, and otherwise inaccessible, nerves to be stimulated easily and relatively painlessly. In addition, no skin preparation is required and stimulation can be achieved through clothing.

The Magstim Bistim² is intended for use by, or under the supervision of, a medical practitioner or investigator and is to be used in a laboratory or a medical consulting room environment. The medical practitioner or investigator should have knowledge about the principles of TMS, physiology and potential side effects of TMS.

The Magstim Bistim² is a non-sterile reusable medical device intended for multi-patient use. The Magstim Bistim² is not intended to come into contact with the patient as this achieved through use of a stimulating coil.

The Magstim Bistim² is intended to be stationary during use however, can be moved if necessary when not in use.

The Magstim Bistim² should only be used on a conscious patient.

USA Only: The Magstim BiStim² has not been cleared by the FDA for cortical stimulation. Investigational uses require an IDE.

1.2 Contraindications

The Magstim Bistim² should not be;

- used on or in the vicinity of patients or users with cardiac demand pacemakers, implanted medication pumps, cochlear devices, implanted defibrillators and/or implanted neurostimulators
- used on or in the vicinity of patients with implanted metal objects of a ferrous nature
- used on patients where the skin in the area to be contacted is broken
- used on patients who suffer from multiple sclerosis
- used on those with large ischaemic scars
- used on pregnant women
- used on infants under the age of 2 years

Magstim recommends that a standard questionnaire is completed to screen a patient's suitability prior to using any Magstim product on that patient and concurs with the recommendations given in the paper titled "Safety, ethical considerations, and application guidelines for the use of transcranial magnetic stimulation in clinical practice and research" by Rossi et al (2009).

1.3 Devices Covered

This document is applicable to the following device:

- Magstim Bistim² System

This consists of:

- 2 x Magstim 200² Unit (P/N: 3010-00)
- Magstim Bistim² Connecting Module (P/N: 3330-00)
- Footswitch (P/N: 9525-01)
- Magstim Bistim² UI Controller (P/N: 3021-00)
- Magstim 200² UI Controller (P/N: 3020-00)

All parts of the Magstim BiStim² system, referenced above are suitable for use within the patient environment.

Note: When the Bistim² Connecting Module is not connected, the Magstim 200² Units will operate as if they were a standalone device. Please consult the Magstim 200² Operating Manual before using the Magstim 200² Units as standalone devices.

- Magstim 200² stimulator - MOP01

Note: Please also consult any labelling and information accompanying stimulating coils and other accessories for safety and use information regarding these devices.

1.4 Frequently Used Functions

- Frequently used functions as defined during Magstim's usability process are identified with (*). Frequently used functions are functions of the BiStim² that frequently involve user interaction.

SECTION 2 WARNINGS AND PRECAUTIONS

Attention Consult Operating Manual: Consult the operating manual before using this device.

Operating Manual: Further information can be located in the operating manual.

Type BF Applied Part: Refer to Section 6.1 for further information.

High Voltages: High voltages are present in the Magstim Bistim² System and its accessories during operation and for up to 20 minutes following operation. Therefore:

- do not remove covers. Refer servicing to qualified personnel.
- if there is any sign of external damage or if any parts are damp or wet, they must not be used.
- ensure that the system is disarmed prior to disconnecting the stimulating coil and BiStim² connecting module.

Replace coil indicator*: The system monitors the coil temperature and if this reaches 40°C, the stimulator will be disabled. The coil surface temperature may continue to rise after this point; therefore, the coil must be removed from the subject as soon as the replace coil indicator is illuminated.

Rear Panel Outputs*: Only equipment that meets the relevant IEC standard should be connected to the Magstim Bistim².

This connection must be configured in compliance with IEC 60601-1-1:2000 or Clause 16 of IEC 60601-1:2005 (Second edition: IEC 60601-1-1) with the following interface voltage limitation: Max signalling voltage +5.3V; Max voltage with respect to protective earth potential 30V peak

Magnetic Pulses: the system generates high intensity magnetic pulses through its coils, which induce eddy currents in any conductive medium, such as the human body, nearby metallic objects or electronic devices. Therefore, the system:

- must not be used on, or in the vicinity of subjects with cardiac demand pacemakers, implanted defibrillators, or other electronic or metallic implants;
- must not be used in a position where the current can be induced in cables or wires that are directly connected to the subject;
- must not be used in the vicinity of objects that are sensitive to magnetic fields, such as watches, credit cards and electronic equipment; and
- must not be used when in contact with metallic objects, as these objects may be propelled or damaged by the magnetic field of the coil.

Damage: If there are any signs of damage to the Magstim BiStim² System, or if any parts are damp or wet, the system must not be used. If damaged, the Magstim BiStim² should be returned to the Magstim Company Limited for servicing and repair (see Section 7.2 for contact details).

Explosive and Flammable Atmospheres: The Magstim Bistim² and accessories must not be used in an explosive atmosphere, around explosive gases or in the presence of flammable anaesthetics.

Protective Earth: To avoid the risk of electric shock, the Magstim Bistim² must only be connected to a supply mains with protective earth.

Modification: No modification of this equipment is allowed.

Discharge noise: when the magnetic pulse is delivered, a discharge click is produced that may startle. The use of ear protection is recommended.

Seizures: cortical magnetic stimulation runs the risk of inducing seizures. Magstim concurs with the advice given in the paper titled “Safety, ethical considerations and application guidelines for the use of TMS in clinical practice and research” by Rossi et al (2009) in respect to screening candidates prior to administering TMS.

Environmental Conditions*: The system must not be used or stored under environmental conditions that fall outside those specified in section 6.3 of this operating manual.

Stacking Limit: Magstim 200² units may be stacked on top of each other, but must not exceed the stacking limit specified in Section 6 of this operating manual. If this limit is exceeded, the stack may become unstable and overbalance risking injury to patients or users and risking damage to the unit’s themselves.

If the stacking limit is reached it can have a weight of up to 80kg. Ensure that the surface upon which to system is to be placed is capable of supporting this weight. Failure to do so may result in injury or damage. The weight for each individual 200² unit is in excess of 20kg

Carrying*: On no account should the Bistim² connecting module be used as a carrying/gripping point when transporting its host Magstim 200² unit. The Bistim² connecting module and its fixings are not designed to be subjected to this level of force and the Bistim² connecting module will become detached from its host unit. This could result in damage to Magstim 200² unit, Bistim² connecting module, or those transporting the equipment

Connecting Equipment: Only equipment listed in Section 1.3 may be connected to the Magstim BiStim². Equipment that meets the relevant IEC standard may be connected to the rear interface ports at the rear of the Magstim Bistim². See Appendix B for further details.

SECTION 3 PRODUCT DESCRIPTIONS

3.1 Front Panel

The front panel, shown below, allows control of the Magstim Bistim² and provides the connection for the stimulating coil.

Note: UI functions described in this section are to be performed on the master unit UI (Bistim² UI). Control functions/buttons are not activated on the slave unit UI (200² UI) therefore cannot be used to control system. The only function/button that may be used is the system stop button.

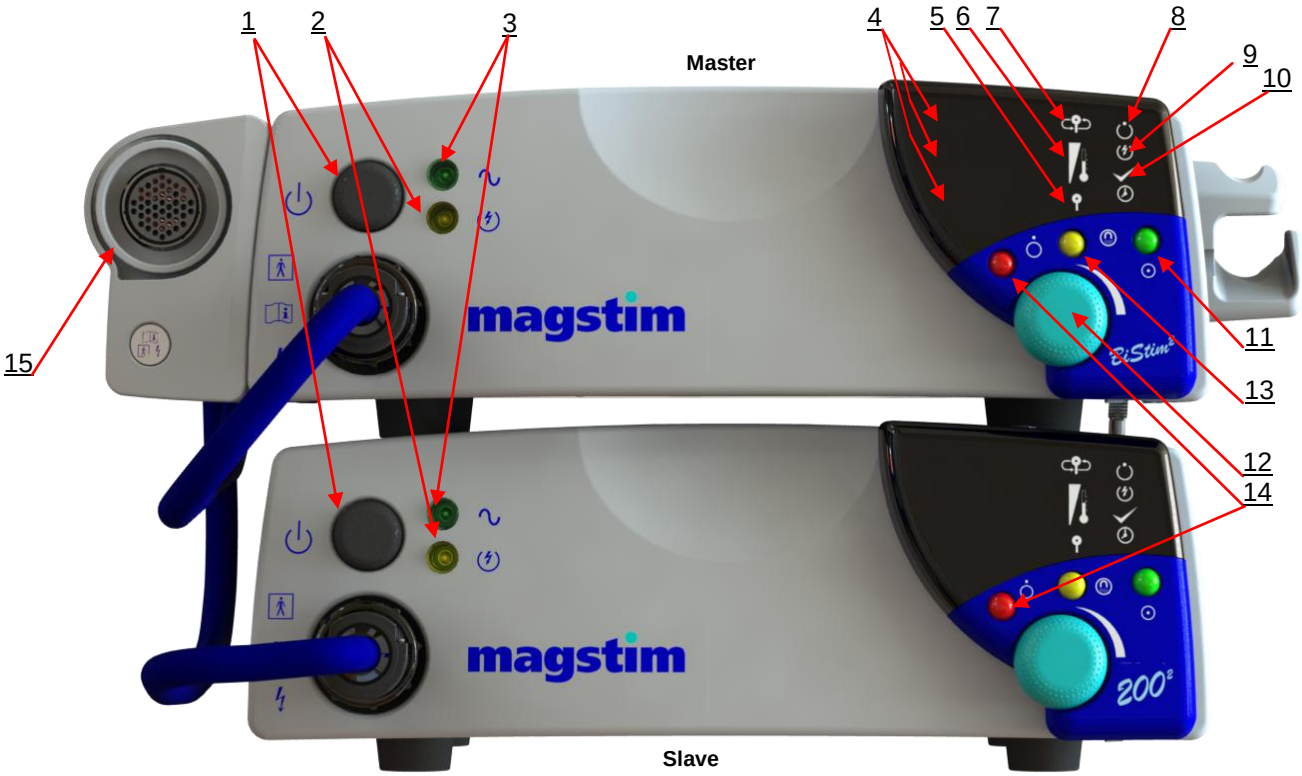


Figure 3.1: Detailed front panel

The upper unit is considered the master unit. The lower unit is considered the slave unit.

All operating functions described in this section assume that the mains power switches, located on the rear panel of the master and slave units, are switched on.

3.1.1 On/Off Button* (1)

The on/off button toggles the master and slave units of the Magstim Bistim² between on and standby.

3.1.2 Armed Indicator* (2) & (9)

The armed indicator illuminates when the unit is armed allowing it to be triggered.

3.1.3 Power Indicator* (3)

The power indicator flashes when the Magstim Bistim² is in standby, and illuminates when the Magstim Bistim² is on. When power is initially applied to the Magstim Bistim², the power indicator should flash indicating the unit is in standby state.

3.1.4 Output Display* (4)

The output display consists of 3 lines. The first and second lines display the power output as a percentage of maximum of the master and slave units respectively. The third line displays the inter-pulse spacing. The default value displayed after initially switching on the master and slave units are 30% for both power outputs and 10ms for the inter-pulse spacing.

If an error code needs to be displayed, the power output is replaced by error code(s). These are detailed in Appendix A – System Error Codes.

3.1.5 Coil Indicator* (5)

This green LED will illuminate if there is a coil detected as being connected correctly to the Magstim Bistim².

3.1.6 Coil Temperature Indicators* (6)

These LED's represent the surface temperature of the coil. The LED's illuminate sequentially as the coil temperature rises, beginning with the bottom green LED and ending with the amber LED. When the amber LED is lit, it means that the coil is getting close to its maximum operating temperature. As soon as it reaches its maximum operating temperature, the replace coil indicator will illuminate and the Magstim Bistim² will disarm itself.

Note: If the temperature of the coil is below 5°C, the system will not operate. The Magstim Bistim² will remain in its inactive default condition until it detects that the coil temperature has risen above 5°C.

3.1.7 Replace Coil Indicator* (7)

This red LED will illuminate if any of the following conditions are present:

1. The coil connected is not compatible with the Magstim Bistim².
2. The surface temperature of the connected coil has risen above its set limit.
3. The connected coil is faulty.
4. There is no coil connected.

If this LED is illuminated the Magstim Bistim² will not arm until the reason for the indicator being lit is resolved.

3.1.8 Disarmed Indicator* (8)

This LED is illuminated when the Magstim Bistim² has been put into its safe disarmed state.

3.1.9 Ready Indicator* (10)

When the Magstim Bistim² is armed, this LED will illuminated when the Magstim Bistim² is charged and ready to be triggered.

3.1.10 Run Button* (11)

The Magstim Bistim² can be armed pushing the green run button. The Magstim Bistim² will charge to the power level indicated on the output display. The Magstim Bistim² will not arm if the replace coil indicator is illuminated.

3.1.11 Output Control* (12)

The output control allows the master power level, slave power level and inter-pulse spacing displayed on the master unit UI to be adjusted. The master output power, slave output power and inter-pulse spacing can be adjusted by rotating the output control clockwise to increases the level and rotating anti-clockwise to decreases the level. To toggle between the master power, slave power and inter-pulse spacing press the output control.
Each complete 360º rotation changes the master/slave power output level by approximately 20%.

3.1.12 Trigger Button* (13)

The Magstim Bistim² can be triggered to deliver the stimulus by pressing the yellow trigger button along with one of the trigger buttons located on the coil. The instrument will continuously charge and discharge if the trigger buttons are pressed and held.

3.1.13 System Stop Button* (14)

The Magstim Bistim² can be disarmed by pushing the red stop button. In this mode the disarmed indicator will illuminate and the instrument will discharge internally.

Note: The Magstim Bistim² will disarm if the coil is disconnected, becomes faulty, the surface temperature of the connected coil has risen above its set limit, the system stop button is activated, the instrument detects an internal fault, or if the ready symbol has been illuminated for over 1 minute without the instrument having been triggered.

3.1.14 Coil Output Socket* (15)

This socket is used to connect the stimulating coil to the Magstim Bistim² system.

Note: It is normal for the pin indicated on the label to protrude from the coil socket on the master and slave stimulator units. This is an intentional design feature.

Figure 3.2: Coil output socket front view

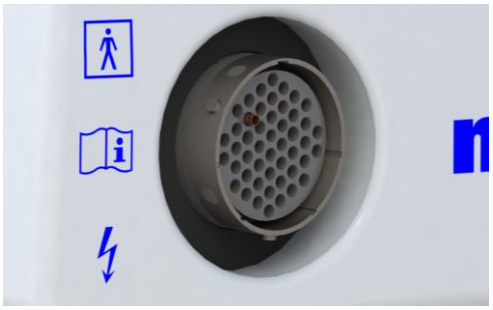


Figure 3.3: Coil output socket angled view

3.2 Rear Panel

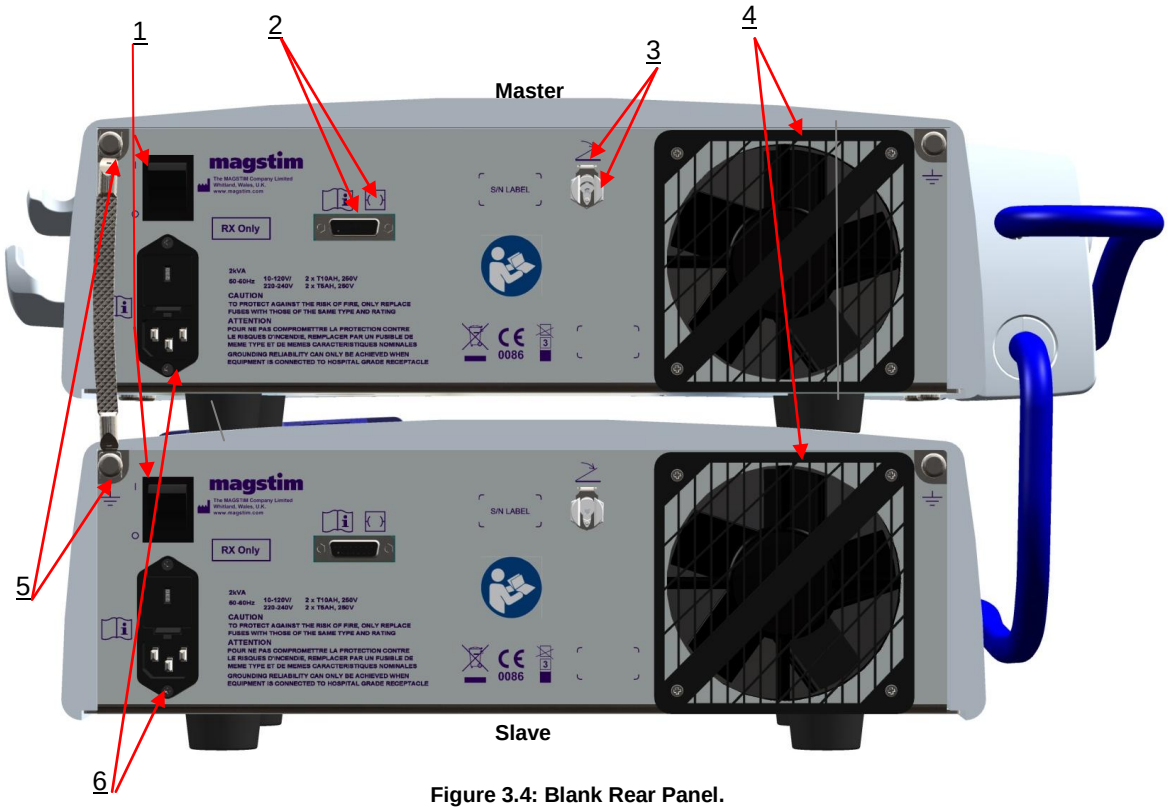


Figure 3.4: Blank Rear Panel.

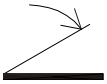
3.2.1 Power * (1)

The Power switch allows the power supplying the unit to be switched on (labelled I) or off (labelled O).

3.2.2 Isolated Interface* (2)

The trigger input is used to synchronise the Magstim Bistim² system to an external trigger input. This is only functional on the master unit. Please see Appendix B for more information.

3.2.3 Foot Switch Socket* (3)



This socket is used to connect the pneumatic foot switch to the Magstim Bistim² system. The foot switch can be used to trigger the instrument when one of the trigger buttons located on the coil is also pressed. The instrument will continuously charge and discharge if the trigger buttons are pressed and held. The foot switch socket is only functional on the master unit when.

3.2.4 Cooling Fan Outlet (4)

With the Magstim Bistim² turned on, air is drawn through slots at the bottom of the instrument and expelled through the fan outlet. There should be no obstructions placed closer than 50mm to the fan outlet.

3.2.5 Functional Earth (5)

Functional earth connections of the master and slave units should be connected using the supplied functional earth strap.

3.2.6 Power Entry Module & Fuse Access (6)

The standard IEC mains lead supplied by the Magstim Company Ltd should be connected to the unit prior to the unit being switched on.

3.3 Accessories

A range of stimulating coils are available for use with the Magstim range of products. For more details, please contact the Sales department. Contact details are shown in Section 7.3.

Please note, only “category A” high power stimulating coils will work with the Magstim Bistim².

Note: The use of the correct accessories is essential to the functioning of the Magstim Bistim². The Magstim Company Limited cannot guarantee the instrument’s performance unless accessories used are obtained from The Magstim Company Limited. Only Magstim accessories purchased from the The Magstim Company Limited should be used with the Magstim Bistim².

Note: The Magstim BiStim² should only be powered using the power lead supplied by The Magstim Company Ltd.

SECTION 4 OPERATING INSTRUCTIONS

Note: to avoid problems with interference, the Magstim Bistim² system should not be used in the vicinity of any equipment not in compliance with the EMC Standard EN 60601-1-2, including mobile phones.

Note: Please ensure you are familiar with all sections of this operating manual prior to following these operating instructions.

Note: Please consult any labelling and information accompanying stimulating coils and other accessories for safety and use information regarding these devices.

Note: UI functions described in this section are to be performed on the master unit UI (Bistim² UI). Control functions/buttons are not activated on the slave unit UI (200² UI) therefore cannot be used to control system. The only function/button that may be used is the system stop button.

4.1 Preparation

1. At the start of each session the operator must check the Magstim Bistim² system and any accessories used for any signs of external damage and to identify any cleaning required*. If any cracks are visible in the housing, or there is damage to any of the cables, the items must not be used and should be returned to The Magstim Company Limited for servicing and repair. If cleaning is required, please follow the instructions in Section 5 of this Operating Manual.

   Note: The contacts in the coil connector, Bistim² connecting module and the stimulator coil output socket should be checked regularly for any signs of tarnishing or burning*. See Section 5.2 for an example of contact burning.

4.2 Set-up

Note: The Magstim BiStim² should be assembled following the instructions provided within this section to ensure continued compliance of IEC 60601-1:2005.

Note: ensure not to position the Magstim BiStim², so it is difficult to disconnect the power lead.

1. Ensure that the master and slave units of the Magstim Bistim² are switched off on the rear*.

2. Place the master unit on top of the slave unit ensuring the feet of the master unit fit into the recesses on the slave unit*.

3. Remove the two blanking plugs from the threaded inserts on the left-hand side of the master unit.

4. Insert the two M6x60 hexagon bolt into the mounting holes on the Bistim² Connecting Module. Place the Bistim² Connecting Module against the side of the master unit so that the bolts locate in the threaded inserts. Ensure that the coil output socket is facing the front*. (See Figure 4.1)

5. Using the supplied hexagon key tighten the bolts so as to secure the Bistim² Connecting Module to the side of the master unit*. Do not over tighten the bolts as this may damage the cases of the units.

6. Fit the two supplied blanking inserts to the mounting holes in the Bistim² Connecting Module. These blanking plugs are a push fit but care is needed with the positioning of the inserts to ensure that the tops are flush with the case surface.

Figure 4.1: Attaching the Bistim² connecting module

7. Remove the two blanking plugs from the threaded inserts on the right-hand side of the master unit.

8. Insert the two M6x12 hexagon bolt into the mounting holes on the coil holder. Place the coil holder against the right-hand side of the master unit so that the bolts locate in the threaded inserts. (See Figure 4.2) *

9. Using the supplied hexagon key tighten the bolts so as to secure the coil holder to the right-hand side of the master unit. Do not over tighten the bolts as this may damage the cases of the units.

Figure 4.2: Attaching the coil holder

10. Connect the supplied earth strap between a functional earth connection on the master and slave unit*

    To do this, unscrew the screw adjacent to the functional earth symbol on the rear of the master unit using a Phillips screw driver. Place one end of the earth strap over the screw as shown in figure 4.3 and re-attach to the unit back panel.

11. **Figure 4.3: Attaching the earth strap**

    Repeat the above, to attach the opposite end of the earth strap to the slave unit.

4.3 Connection

1. If a foot switch is to be used, insert the pneumatic connector of the foot switch to the rear panel Foot Switch Socket on the master unit of the Magstim Bistim² system*.

2. If an external triggering or recording device is to be used, connect it to the Isolated Interface on the rear of the master unit of the Magstim Bistim² system*. Refer to Appendix B for more details on the Isolated Interface.

3. Connect the lead marked “A” from the Bistim² Connecting Module to the coil output socket on the master unit, connect the lead marked “B” from the Bistim² Connecting Module to the coil output socket on the slave unit*.

4. Place the stimulating coil to be used into the coil holder on the right hand side of the stimulator* as instructed in Figure 4.3.

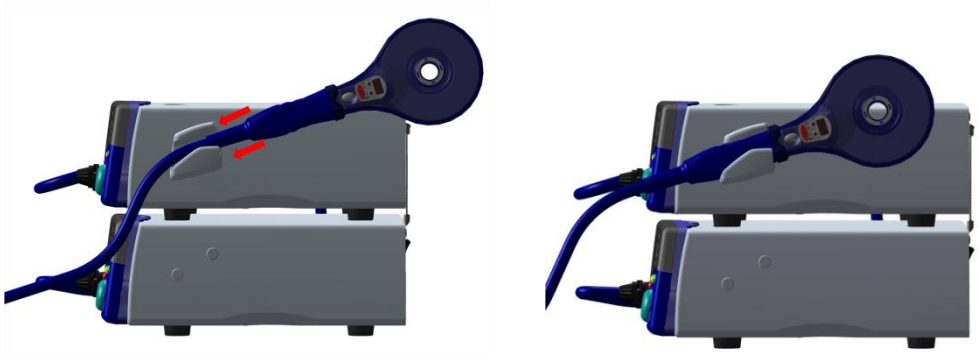


Figure 4.4: Attaching the coil to the coil holder

5. Connect the stimulating coil to be used to the coil output socket on the Bistim² Connecting Module*.

   Note: There is locating key on the coil connector (Stimulating coil and Bistim² connecting module leads A+B), which needs to be aligned with the corresponding receptor on the coil output socket. It is then possible to rotate the outer collar of the coil connector clockwise, in order to lock the coil to the stimulator/ Bistim² connecting module. (see Figure 4.4)

Figure 4.5: Locating key on the coil connector (left) and the receptor on the coil output socket (right)

Care must be taken to attach the coil connector to coil output socket correctly (see Figure 4.5). Failure to do so can cause damage to the connector pins and in severe cases, internal damage to the coil and the stimulator.

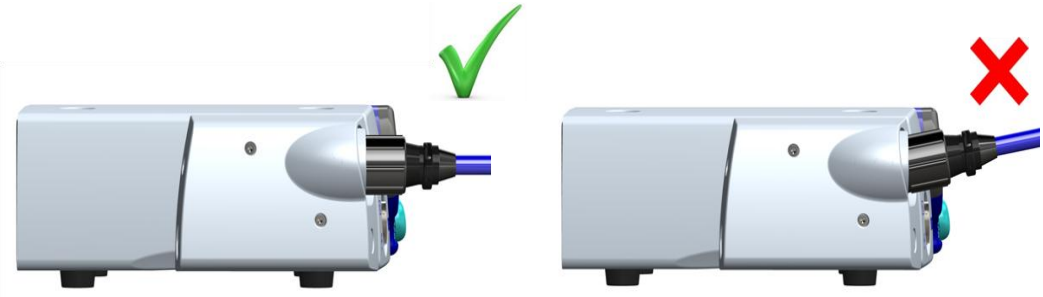


Figure 4.6: Diagram showing correct and incorrect ways to connect the coil to the stimulator

6. Connect the power leads to the rear of the master and slave units*.

4.4 Operation

1. Set the power switch on the rear of the master and slave units to the on (I) position. The power indicators will flash indicating that the units are in standby*.

2. Push the on/off button on the front of the master and slave units*. The power indicators will become continuously lit. The Magstim Bistim² system will start an initialisation sequence during which the armed indicator will flash three times and LED's in the user interface will light sequentially.

   Once the initialisation sequence is complete, the coil indicator and disarmed indicator LED's will be lit and the output display will read 30% on the first line, 30% on the second line and 10ms on the third line.

   Note: During the initialisation sequence, the operator must check that all LED's are lit. If they do not, the items must not be used and should be returned to The Magstim Company Limited for servicing and repair.

3. Use the output control on the master unit UI to adjust the power level or the inter-pulse spacing to the desired setting*. Rotating the control clockwise increases the power level, rotating anti-clockwise decreases the power level.

4. Depress the output control to toggle the value being adjusted between the master power output, the slave power output and the inter-pulse spacing*.

   The inter-pulse spacing range can be change between 0-999ms and 0-99.9ms, when adjusting the inter-pulse spacing, rotating the control knob on the clockwise several times until the display shows the maximum inter-pulse spacing (999ms or 99.9ms). Press and hold the stop button on the user interface and rotate the control knob clockwise at the same time. The display should revert to either 1.0ms or 10ms. Turn off the Bistim² system and then turn on again and the default inter-pulse time displayed should be in the new range (1.0ms or 10ms).

5. Press the run(green) button on the master unit UI to arm the Magstim Bistim²*. The armed indicators of both the master and the slave system should light, and once the system is charged, the ready indicators will also illuminate*.

   Note: If the system is not triggered within a minute of being armed, it will revert back to the disarmed state and will need to be re-armed before continuing.

6. Remove the stimulating coil from the coil holder* and position the coil over the desired target.

7. When ready to trigger the system, engage and hold one of the trigger/interlock switches located on the stimulating coil, then press either the trigger(yellow) button on the on the master unit UI or the foot switch*.

   A clicking noise should be heard from both the stimulating coil and the Magstim Bistim² system. If the inter-pulse spacing is large enough, two clicks should be audible.

8. When necessary, reposition the coil and/or modify the output power or inter-pulse spacing to suit requirements for the next stimulus. Meanwhile, the stimulator will recharge and the ready indicator will be illuminated when charging is complete.

9. At the end of the session, place the stimulating coil back into the coil holder and engage the stop(red) button of the master unit UI to discharge the stimulator internally and put it into stopped mode*.

10. Set the power switch on the rear of the master and slave units to the (O) position to switch the unit off*

11. Sections 4.3 and 4.2 should be repeated in reverse to disconnect the Magstim Bistim²*.

Note: Ensure that the system is disarmed prior to disconnecting the stimulating coil and BiStim² connecting module.

4.5 Independent BiStim² Triggering (IBT)

When the system is set in IBT Mode, triggering of the master unit does not automatically trigger the slave unit, allowing an alternate, external trigger to be used via the isolated interface.

The output from the master unit is used to initiate a triggering window in the slave unit. This allows the slave to be triggered externally any time between 1ms and 2s after the master has been triggered. This external triggering can be achieved only via the isolated interface. When in IBT Mode, the slave cannot be triggered by the footswitch or the UI controller.

To set the Magstim Bistim² System in IBT Mode, with an inter-pulse spacing of zero, hold down the UI stop button and rotate the power level knob anticlockwise. The bottom display should show an “E”.

Note: When you are in this mode you cannot adjust the inter-pulse timing.

The Magstim Bistim² System will remain set in IBT Mode following power-down. It will only revert to standard operation when its mode is actively reset. To reset to standard operation, select the inter-pulse time window, hold down the stop button and rotate the control knob clockwise.

SECTION 5 MAINTENANCE

5.1 User Maintenance and Calibration

There are no user maintenance or calibration requirements for the Magstim Bistim² system and accessories. However, it is important that they are checked for any sign of damage at the start of each session*. If any cracks are visible in the plastics, or if there is damage to any of the cables, the items must not be used and should be returned to The Magstim Company Limited for servicing and repair (see Section 7.2 for contact details).

5.2 Technical Maintenance

The contacts in the coil connector, Bistim² connecting module and the stimulator coil socket should be checked regularly for any signs of tarnishing or burning*. Under conditions of exceptionally intense use, it is possible for localised heating to manifest itself in the connector, which causes damage to the contacts. Continued use in this condition will eventually cause the contacts to deteriorate and loose electrical connection, which will cause damage to the system.

Repair is a specialised procedure and can only be undertaken by The Magstim Company Limited or an authorised service centre. If any pins show damage, however slight, contact The Magstim Company Limited service department for further advice or to arrange a return (see Section 7.2 for contact details).

Warning: contact burning is communicable, so any coil with damaged contacts will infect a stimulator with healthy contacts and vice-versa. Therefore, if damage is noticed on any coil connector or stimulator coil socket the entire system must not be used until all contacts are carefully examined and repaired where appropriate. If this is not done thoroughly there is a risk that the cycle of pin damage will continue.

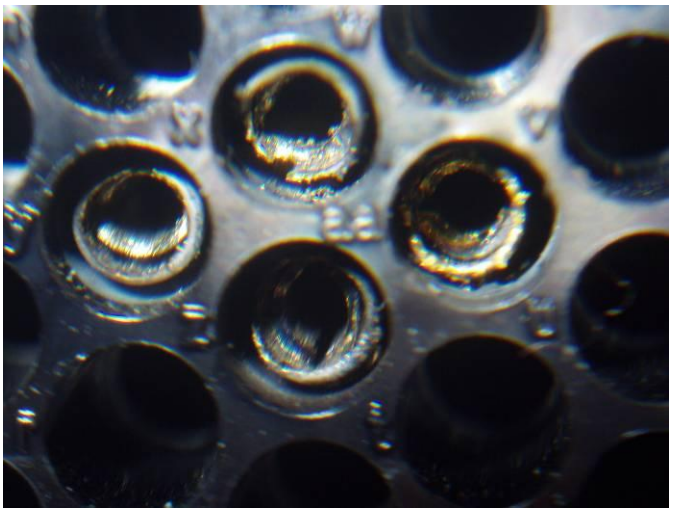


Figure 5.1: Example of contact burning

5.3 Voltage Selection and Fuse Rating

The Magstim Bistim² system is preset at the factory to operate at 110V-120V or 220V-240V A.C., as appropriate. The following are the fuse ratings for both the master and slave units:

Supply Voltage	Qty	Fuse Size	Rating	Voltage Selector Setting
110V-120V~	2	20 x 5mm	T10AH, 250V	115
220V-240V~	2	20 x 5mm	T5AH, 250V	230

T denotes timed or antisurge fuses. Fast acting fuses are not recommended.
H denotes high breaking capacity (ceramic fuse).

Fuse Replacement: The Magstim Bistim² must be disconnected from the mains by disconnecting the power cord from both of the 200² units. Insert the tip of a small blade screwdriver or similar tool into the slot below the arrow to lever the retaining lip enabling the fuse tray to be pulled out. Replace the blown fuse(s) with one of the correct rating (See above to ensure the correct fuse is replaced) and locate and push home the tray ensuring the retaining lip clicks into place.

Changing The Voltage Selector Setting: The Magstim Bistim² must be disconnected from the mains by disconnecting the power cord from both of the 200² units. Remove the fuse tray as instructed above, rotate the voltage selector to the desired setting and replace the cover. A legend will indicate the voltage selected when the fuse cover is replaced.

Note: Only replace fuses with those of the correct rating, and only operate the instrument with the voltage selector set at the appropriate voltage. Failure to do so may cause serious damage to the device(s).

5.4 Cleaning and Disinfecting*

The Magstim Bistim² system and accessories cannot be sterilised; therefore, do not allow them to become contaminated with bodily fluids. They may be cleaned using a cloth moistened with isopropyl alcohol, however ensure that the Magstim Bistim² and accessories have dried thoroughly before use.

It is the responsibility of the user to ensure the Magstim BiStim² is cleaned when necessary.

Note: The Magstim Company Ltd recommends that a solution of 70% isopropyl alcohol should be used.

5.5 Servicing

The Magstim Bistim² contains no user serviceable parts. Servicing of Magstim Bistim² system and accessories must only be carried out by The Magstim Company Limited or one of its authorised service centres. To arrange a return or for further information, contact the service department at The Magstim Company Limited (see Section 7.2 for contact details).

5.6 Device Lifetime

The lifetime of the Magstim Bistim² system is defined as being five years from the date of shipment. The Magstim Company Limited will support the products for the duration of their lifetime.

5.7 Disposal

When a Magstim Bistim² system or accessory reaches the end of its serviceable life, it should **not** be disposed of in general waste. The Magstim Company Limited should be contacted (see Section 7.2 for contact details) for advice on its disposal in compliance with the appropriate environmental regulations. Failure to do so could cause an environmental hazard as a result of decomposition of materials used in its construction.

SECTION 6 SPECIFICATIONS

6.1 Safety Specifications

During use, the type of protection against electric shock provided by the Magstim Bistim² system is classified as Class 1.

The degree of protection against electric shock for applied part accessories is classified as Type BF Applied Parts. This means that the Stimulating Coils are electrically isolated from the other parts of the equipment and meet Type BF leakage current limits as required by IEC 60601-1.

The Magstim Bistim² system and accessories comply with the requirements of Safety Standard IEC 60601-1 and with EMC Standard EN 60601-1-2.

To avoid problems with EMC interference, the Magstim Bistim² and accessories should not be used in the vicinity of any equipment that does not comply with EMC Safety Standard EN 60601-1-2, including mobile phones. Any interface cable which connects the Magstim Bistim² unit to an external piece of equipment must be no more than 1.5m in length.

Only equipment that meets the relevant IEC standard should be connected to the Magstim Bistim²*.

This connection must be configured in compliance with IEC 60601-1-1:2000 or Clause 16 of IEC 60601-1:2005 with the following interface voltage limitation: Max signalling voltage +5.3V; Max voltage with respect to protective earth potential 30V peak

The Magstim Bistim² system and accessories are classified as IPX0 (Not Protected), as there is no specialised protection provided against the ingress of liquids.

The Magstim Bistim² system and accessories are not protected against flammable anaesthetic mixtures. They are not suitable for use in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide.

The mode of operation of the Magstim Bistim² system and accessories is classified as continuous.

6.2 Technical Specifications

Stimulator Output:

Output Range and Accuracy:	0%-100% of Maximum Voltage ± 1%
Stimulation Frequency:	0.25Hz in Bistim Mode
	0.50Hz at 01% to 49% Power Output in simultaneous discharge mode
	0.33Hz at 50% to 75% Power Output in simultaneous discharge mode
	0.25Hz at 76% to 100% Power Output in simultaneous discharge mode
Pulse Characteristics:	100µs rise time, 1ms duration
Inter-pulse Spacing:	0 – 999ms or 0 – 99.9ms

Note: Magnetic field strength and maximum number of stimulations produced before coil exceeds operating temperature are dependent on the stimulation coil being used. Please refer to the appropriate coil operating manual.

Capacitor Life Expectancy:

Life expectancy:	2×10^6 discharges at 70% power level
	8×10^5 discharges at 80% power level
	4×10^5 discharges at 90% power level
	2×10^5 discharges at 100% power level

Isolated Interface:

Logic High Voltage:	>4.0V
Max Voltage:	5.3V
Logic Low Voltage:	<0.8V
Min Voltage:	-0.3V

All voltages are with respect to Aux Gnd signal on the isolated interface connecter

Power Supply:

Power:	110V-120V~ 50-60Hz;
	220V-240V~ 50-60Hz;
	100VA during standby
	2000VA peak and 600VA average during discharge
Fuse(s):	2 x T10AH, 250V 20x5mm for 110V-120V~
	2 x T5AH, 250V 20x5mm for 220V-240V~

General Specifications:

Master and Slave Units:	
Dimensions:	460mm x 160mm x 375mm
Weight:	20.4kg
Stacking limit:	4 Units stacked on top of each other
Bistim² Connecting Module:	
Dimensions:	135mmx x 81mm x 165mm
Weight:	1.62kg

Software:

Controller Board Software:	Version 1.9 (Software ref: 3056)
UI Controller Software:	Version 1.1 (Software ref: 3026)

Please note: All specifications are subject to alteration.

6.3 Environmental Conditions*

Operating temperature:	5°C to 40°C
Transport and storage temperature:	-19°C to 60°C
Operating, transport and storage relative humidity:	10% to 80% (non-condensing)
Operating atmospheric pressure:	80kPa to 106kPa
Transport and storage atmospheric pressure:	50kPa to 106kPa

6.4 Handling

The master and slave units weigh in excess of 20kg. If it is necessary to move the units for any reason, the weight must be distributed between at least two persons. Please see diagram below for recommended manual handling methods. The master and slave units should be moved individually.

Note: The weight of Magstim Bistim² unit is unevenly distributed with the right hand side of the unit being considerably heavier than the left. Care should be taken when transporting the unit to ensure that this heavier side is adequately supported.

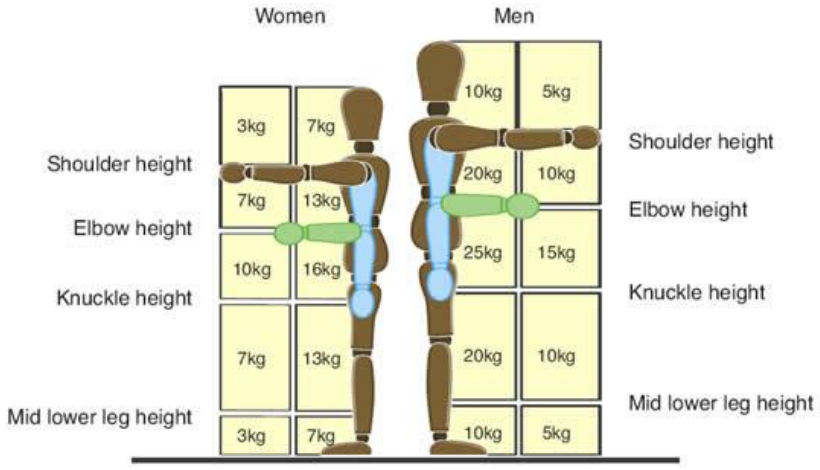


Figure 6.1: Guidelines on lifting and lowering

6.5 Packing Instructions

If, for any reason, it is necessary to return your Magstim Bistim² care should be taken to ensure that the equipment is adequately packed to prevent transit damage. Ideally the equipment should be returned in its original packing. If this or an adequate replacement is not available, replacement shipping cartons can be obtained from the Magstim Company Limited.

The Magstim Bistim² System must be completely disconnected before shipping, including removal of the coil holder and Bistim² Connecting Module on the side of the master unit. Failure to do so is likely to result in transit damage to the casing.

SECTION 7 CONTACT DETAILS

7.1 Product Enquiries

The Magstim Company Limited
Spring Gardens, Whitland, Carmarthenshire, SA34 0HR

Telephone: +44 (0)1994 240798
Fax: +44 (0)1994 240061
E-mail: info@magstim.com
Website: www.magstim.com

7.2 Servicing Enquiries

Telephone: +44 (0)1994 242900
Fax: +44 (0)1994 240061
E-mail: service@magstim.com

7.3 Sales Enquiries

Telephone: +44 (0)1994 241111
Fax: +44 (0)1994 242917
E-mail: sales@magstim.com

APPENDIX A – SYSTEM ERROR CODES

A1. Error Codes produced by the User Interface

Error Code	Description
U24	POWERDOWN
U25	Stack underflow
U26	Stack overflow
U27	RTS overrun
U28	Watchdog Timeout
U29	ROM Checksum Incorrect
U30	Unexpected RESET
U31	Unknown serial interrupt
U32	CSIO overrun
U33	Debug error
U34	No serial communications
U35	Loss of communication
U36	Bad NVRAM Checksum

A2. Error Codes produced by the Coil

Error Codes	Description
C01	ROM Checksum Incorrect.
C02	EEPROM Checksum Incorrect.
C03	Invalid coil Category.
C04	Invalid Power Identification .
C05	Temperature sensor circuit failure.
C06	Bad Serial command or received data checksum.
C07	Internal Software Error.
C08	Invalid Coil Temperature ID.
C09	Invalid temperature algorithm coefficient.
C10	Coil controller malfunction.
C11	Rapid coil algorithm constant checksum incorrect.
C12	Invalid enhanced power byte. (1's compliment comparison test failed)
C13	Average power checksum incorrect.
C21	Coil Disconnected/ Coil Under Temperature.
C22	Brown Out Detected.
C23	No serial Communications.
C24	Bad Serial command of received data checksum (outside TRIGGATE).
C25	EMC Detected (Coil adapter only).
C26	Invalid Coil Power Identification (Coil adapter only).
C27	Hardware Stop activated.
C28	Watchdog Timeout.
C29	Temperature Interlock 3 activation.
C30	Coil stop line fault.

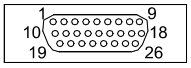
A3. Error Codes produced by Bistim² Unit.

Error Codes	Description
E61	Power fail
E62	Stack underflow
E63	Stack overflow
E64	RTS overrun
E65	WD Timeout
E66	Unexpected reset
E67	Bad checksum
E68	SYS debug error
E70	Coil under temperature
E71	Coil max difference
E72	Stack over temperature
E73	Stack under temperature
E74	Stack max difference
E75	HVCAP over temperature
E76	HV Transformer over temperature
E77	Charge threshold failure
E78	VREF check failure
E79	HVCAP voltage comparison failure
E80	Charging fault
E81	HV over voltage
E82	Invalid system configuration
E83	Stop line fault
E84	Base coil stop line fault
E85	UI stop line fault
E86	Dump system fault
E87	Invalid coil category for current system configuration.
E88	Invalid NVRAM Checksum.
E89	Faulty charging relay detected
E90	Base arm LED drive failure

For diagnosis, contact The Magstim Company Limited service department (see Section 7.2 for contact details).

APPENDIX B – TRIGGER INPUT / OUTPUT

The Isolated Interface on the rear of the Magstim Bistim² allows external equipment to be connected to enable synchronisation with an external device. Voltage levels for the signals are as specified in Section 6.2.



The Isolated Interface is a 26 Way High Density D-Type Female Connector.

The following tables detail the interface pins:

Location		Rear of Stimulator
Type		26 Way D-Type (Female)
Signal Levels		CMOS
Pin Signals	Tout – O/C	Pin 3 – will be connected to Aux. Gnd. when the system is triggered. (Open collector output, maximum external pull up voltage +5V, maximum sink current 50mA)
	Tin +	Pin 5 – will trigger the system when a logic high is applied.
	Tin -	Pin 6 – will trigger the system when a logic low is applied.
	Tout +	Pin 7 – a logic high will be visible when the system is triggered.
	Tout -	Pin 8 – a logic low will be visible when the system is triggered.
	Trigger Edge / Level	Pin 24 – unconnected sets to an edge trigger connected to Aux. Gnd. provides a level trigger.
	Aux. Gnd.	Pins 1, 11 & 19
	Aux. +5V	Pin 10

Trigger Edge / Level
When set to edge trigger, the Magstim Bistim² will only be triggered when the logic level being applied on the Tin+ or Tin- pin is changed. On the Tin+ pin, triggering will occur when the logic level is changed from low to high. On the Tin- pin, triggering will occur when the logic level is changed from high to low. Edge triggering will only allow one trigger per logic level change.

When set to level trigger, the Magstim Bistim² will be triggered when the appropriate logic level is applied to the Tin+ or Tin- pins. On the Tin+ pin, a logic high will need to be applied. On the Tin- pin, a logic low will need to be applied. The system re-fire when the system is ready until the logic state being applied changes or is removed.

Note: For the Tin trigger pulse to fire the system, it need to be in an armed state when the trigger is applied and another trigger will need to be applied i.e. coil switch.

Tout O/C
Tout O/C is connected to an open collector device inside the Magstim Bistim² meaning a pulled up resistor is required to use this feature.

Please Note: Only equipment that meets the relevant IEC standard should be connected to the Magstim Bistim²*.

This connection must be configured in compliance with IEC 60601-1-1:2000 or Clause 16 of IEC 60601-1:2005 with the following interface voltage limitation: Max signalling voltage +5.3V; Max voltage with respect to protective earth potential 30V peak

APPENDIX C – MANUFACTURER'S EMC DECLARATIONS

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Magstim Bistim² is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions EN55011	Group 1	The Magstim Bistim² must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions EN55011	Class B	The Magstim Bistim² 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 B (by equipment type)	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Magstim Bistim² is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Magstim Bistim² can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Magstim Bistim² as recommended below, according to the maximum output power of the communications.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$ Where $V_1 = 3$	**80 MHz to 800 MHz** $d = [\frac{3,5}{E_1}]\sqrt{P}$ Where $E_1 = 3$	**800 MHz to 2,5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$ Where $E_1 = 3$
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

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (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.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Magstim Bistim² is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment 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 61000-4-4	± 6 kV contact ± 8 kV air	Meets requirement	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 61000-4-11	± 2 kV for power supply lines ± 1 kV for input/ output lines	Meets requirement	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	Meets requirement	Mains power quality should be that of 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	Meets requirement	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Magstim Bistim² requires continued operation during power interruptions, it is recommended that the Magstim Bistim² be powered from an interruptible power supply.
Power Frequency (50/60Hz) Magnetic Field IEC 61000-4-8	3 A/m 50Hz	Meets requirement	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Radiated RF Immunity EN61000-4-3	80MHz – 2.5GHz 2Hz 80% amplitude modulation	Meets requirement	Equipment should only be used in the vicinity of other equipment compliant with EN60601-1-2.
Conducted RF Immunity EN61000-4-6	0.15MHz – 80MHz 2Hz 80% amplitude modulation	Meets requirement	Equipment should only be used in the vicinity of other equipment compliant with EN60601-1-2.
NOTE U_T is the a.c. mains voltage prior to application of the test level			

<table>
<tr><th colspan="4">Guidance and Manufacturer's Declaration – Electromagnetic Immunity</th></tr>
<tr><td colspan="4">The Magstim Bistim² is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity Test</th><th>IEC 60601
Test Level</th><th>Compliance
Level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td></td><td></td><td></td><td>Portable and mobile RF communications equipment should be used no closer to any part of the Magstim Bistim², including cables, than the recommended separation distance calculated from the equation applicable to the frequency transmitter.

Recommended separation distance
$d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$</td></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
150 kHz to
80 MHz</td><td>3 Vrms
150 kHz to
80 MHz</td><td>$d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz</td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to
2,5 GHz</td><td>3 V/m
80 MHz to
2,5 GHz</td><td>$d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2,5 GHz

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (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:
  </td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz 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.</td></tr>
<tr><td colspan="4">[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 filed strength in the location in which the Magstim Bistim² is used exceeds the applicable RF compliance level above, the Magstim Bistim² should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Magstim Bistim².

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.</td></tr>
</table>