510(K) SUMMARY

JAN 0 7 2013

BRAINSWAY DEEP TMS SYSTEM

510(k) Number K122288

Applicant Name:

Company Name: Brainsway Ltd.
Address: 19 Hartum St. (Bynet Bldg)
Har Hotzvim, Jerusalem, ISRAEL 91451
Tel: +972-2-5813140
Fax: +972-2-5812517
E-mail: hila@Brainsway.com

Contact Person:

Official Correspondent: Ahava Stein
Company Name: A. Stein – Regulatory Affairs Consulting Ltd.
Address: 20 Hata'as Str., Suite 102
Kfar Saba 44425
Israel
Tel: +972-9-7670002
Fax: +972-9-7668534
E-mail: ahava@asteinrac.com

Date Prepared: July 10, 2012

Trade Name: Repetitive Transcranial Magnetic Stimulator

Classification Name: CFR Classification section 882.5805 (Product code OBP)

Classification: Class II Medical Device

Predicate Device:

The Brainsway Deep TMS System is substantially equivalent to the following predicate device:

Manufacturer	Device	510(k) No.	Product Code
Neuronetics	NEUROSTAR TMS SYSTEM	K061053	OBP
Neuronetics	NEUROSTAR TMS THERAPY SYSTEM, MODEL 1.1	K083538	OBP

Device Description:

The Brainsway Deep TMS (DTMS) System is intended for the treatment of depressive episodes in patients suffering from MDD. Transcranial magnetic stimulation (TMS) is a non-invasive technique used to apply brief magnetic pulses to the brain. The pulses are administered by passing high currents through an electromagnetic coil placed adjacent to a patient's scalp. The pulses induce an electric field in the underlying brain tissue. When the induced field is above a certain threshold, and is directed in an appropriate orientation relative the brain's neuronal pathways, localized axonal depolarizations are produced, thus activating neurons in the targeted brain structure.

The electromagnetic radiation emitted is at a low frequency (b)(4) [redacted]
The only interaction with the human body is caused by the briefly changing magnetic field, and its effect may be neuronal activation.

Many neurological and psychiatric disorders are associated with abnormal neuronal activity patterns in deep brain regions. These regions cannot be affected directly, but only indirectly, through secondary processes involving cortical structures, which are directly activated by TMS and then affect the deeper structures.

The Brainsway DTMS System's unique design enables to produce directed electromagnetic fields that can induce excitation or inhibition of neurons deep inside the brain non-invasively.

The Brainsway Deep TMS (DTMS) System is composed of the following main components:

1. An Electromagnetic Coil (H1 Coil)
2. A TMS Neurostimulator
3. A Cooling System
4. A Positioning Device
5. A cart

Intended Use/Indication for Use:

The Brainsway Deep TMS System is indicated for the treatment of depressive episodes in adult patients suffering from Major Depressive Disorder who failed to achieve satisfactory improvement from previous anti-depressant medication treatment in the current episode.

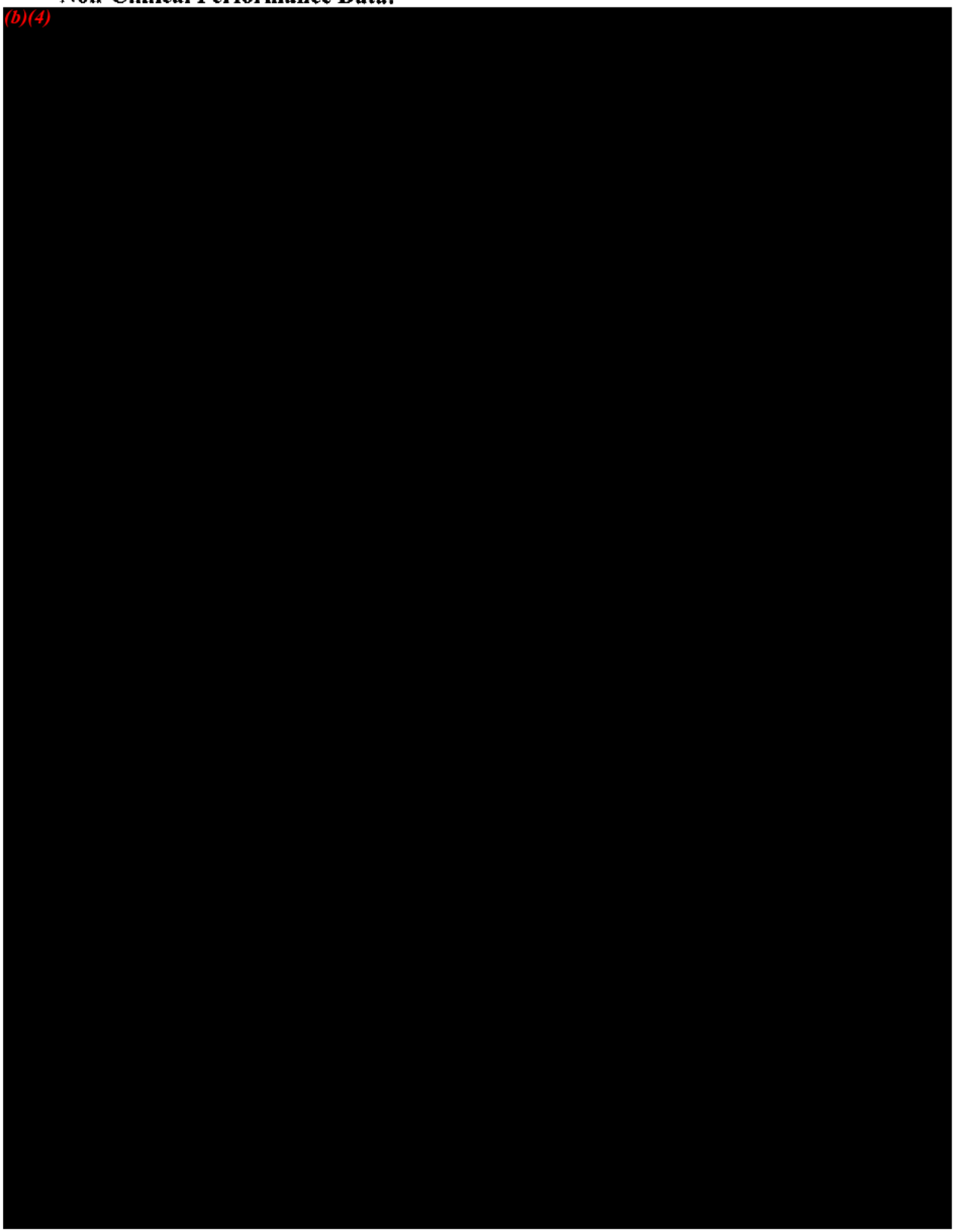
Performance Standards:

The Brainsway Deep TMS System has been tested and complies with the following voluntary recognized standards:

- Electrical & Mechanical Safety testing according to IEC 60601-1
- Electromagnetic Compatibility testing according to IEC 60601-1-2
- ETSI EN 301 489-1 V1.8.1 Electromagnetic Compatibility and Radio Spectrum Matters (ERM); Electromagnetic Compatibility (EMC) Standard for Radio Equipment and Services; Part 1: Common Technical Requirements (2008) Immunity

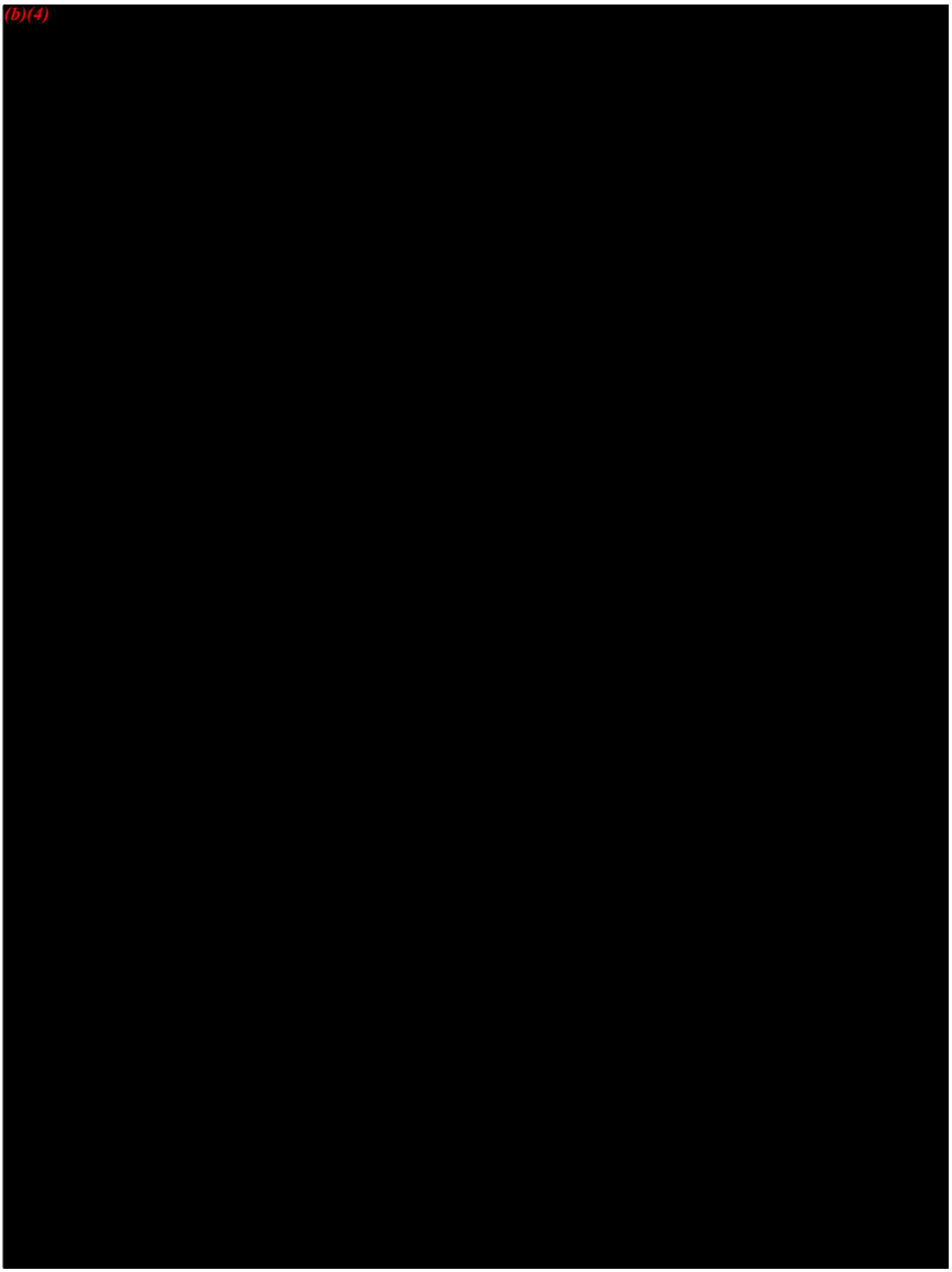
Non-Clinical Performance Data:

(b)(4)

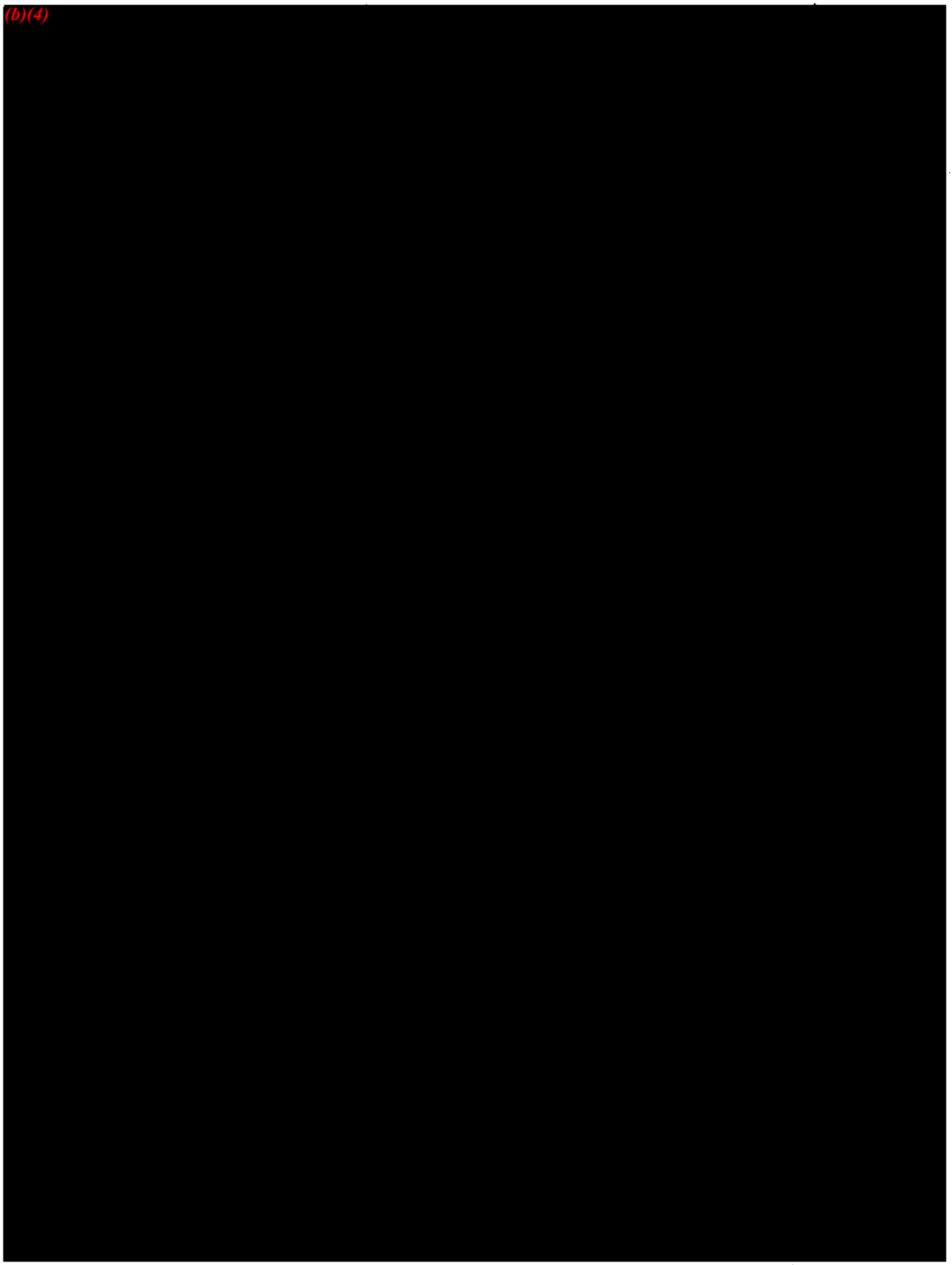


Clinical Performance Data:

(b)(4)



(b)(4)



(b)(4)

[redacted]

Conclusions:

(b)(4)

[redacted]

(b)(4)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 7, 2013

Brainsway, Ltd
c/o Ahava Stein
A. Stein Regulatory Affairs Consulting
20 Hata'as St. (POB 124)
44425 Kfar Saba
ISRAEL

Re: K122288
Trade/Device Name: Brainsway Deep TMS System
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulator for Treatment of Major Depressive Disorder
Regulatory Class: Class II
Product Code: OBP
Dated: October 29, 2012
Received: November 1, 2012

Dear Ms. Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Victor Krauthamer -S

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K122288

Device Name: Brainsway Deep TMS System

Indications For Use:

The Brainsway Deep TMS System is indicated for the treatment of depressive episodes in adult patients suffering from Major Depressive Disorder who failed to achieve satisfactory improvement from previous anti-depressant medication treatment in the current episode.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Brian D. Pullin -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K122288

K122288

v.1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

January 7, 2013

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Brainsway, Ltd
c/o Ahava Stein
A. Stein Regulatory Affairs Consulting
20 Hata'as St. (POB 124)
44425 Kfar Saba
ISRAEL

Re: K122288
Trade/Device Name: Brainsway Deep TMS System
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulator for Treatment of Major Depressive Disorder
Regulatory Class: Class II
Product Code: OBP
Dated: October 29, 2012
Received: November 1, 2012

Dear Ms. Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Victor Krauthamer -S

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K122288

Device Name: Brainsway Deep TMS System

Indications For Use:

The Brainsway Deep TMS System is indicated for the treatment of depressive episodes in adult patients suffering from Major Depressive Disorder who failed to achieve satisfactory improvement from previous anti-depressant medication treatment in the current episode.

Prescription Use √ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Brian D. Pullin -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K122288

* * * COMMUNICATION RESULT REPORT (JAN. 8. 2013 1:59PM) * * *

FAX HEADER 1:
FAX HEADER 2:

NSMITTED/STORED : JAN. 8. 2013 1:57PM

E MODE	OPTION	ADDRESS	RESULT	PAGE
2349 MEMORY TX		901197297668534	OK	3/3

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

January 7, 2013

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Brainsway, Ltd
c/o Ahava Stein
A. Stein Regulatory Affairs Consulting
20 Hata'as St. (POB 124)
44425 Kfar Saba
ISRAEL

Re: K122288
Trade/Device Name: Brainsway Deep TMS System
Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulator for Treatment of Major Depressive Disorder
Regulatory Class: Class II
Product Code: OBP
Dated: October 29, 2012
Received: November 1, 2012

Dear Ms. Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review
Traditional

K122288/S1

Date: January 3, 2013
To: The Record
From: Michael Hoffmann, Engineer, NSDB
Review Team:

Larry Park	Clinical	ODE/DNPMD/PNDB
Scott Miller	Statistics	OSB/DBS/GSDB

Office: ODE
Division: DNPMD

510(k) Holder: Brainsway Ltd
Device Name: Brainsway Deep TMS System
Contact: Ms. Ahava Stein
Phone: +972-9-7670002
Fax: +972-9-7668534
Email: ahava@asteinrac.com

I. Purpose

This submission is a response to a Request for Additional Information issued by email on September 19, 2012. There were several concerns regarding the clinical data provided as well as some missing information about the device description. Additionally, the device was to be provided without a critical component – the stimulator. While the sponsor noted that a specific currently marketed stimulator could be used with their device (a coil), the currently marketed stimulator is not approved for a) use on the head or b) therapeutic use.

Please note that boxed comments contain previous *Deficiencies* as well as the response from the sponsor and the **review team comments**.

(b)(4)

[redacted]

(b)(4)

[redacted]

Recommendation

I recommend that this device be deemed SUBSTANTIALLY EQUIVALENT to the identified predicate device. The sponsor has addressed several concerns with the data that the team identified. The sponsor has also made substantial changes to the labeling and 510(k) summary to more fully describe the subject population studied and provide warnings/precautions for the unstudied patient populations.

(b)(4)

[redacted]

(b)(4)

[redacted]

as the predicate device and has a similar low-risk profile as the predicate device. Therefore, we recommend that that the device be deemed SUBSTANTIALLY EQUIVALENT.

Indications for Use:

The Brainsway Deep TMS System is indicated for the treatment of depressive episodes in adult patients suffering from Major Depressive Disorder who failed to achieve satisfactory improvement from previous anti-depressant medication treatment in the current episode.

Comment: This is adequate. The sponsor previously had a more general indication of

"treatment of subjects with MDD". The sponsor was asked to revise the indications for use to the above since this most appropriately reflects the population studied in the trial. Additionally, the sponsor a requested sub-population analysis (by # of anti depressant medications failed) to demonstrate that the effectiveness did not vary greatly among the sub-populations. The sponsor revised their indication as requested in all of the associated documents. This is adequate.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?		X	
Are "cleaning" instructions included for the end user?		X	

Device Description

The Brainsway DTMS System enables direct non-invasive activation of deep brain structures. Transcranial magnetic stimulation (TMS) is a non-invasive technique used to apply brief magnetic pulses to the brain. The pulses are administered by passing high currents through an electromagnetic coil placed adjacent to a patient's scalp. The pulses induce an electric field in the underlying brain tissue. When the induced field is above a certain threshold, and is directed in an appropriate orientation relative the brain's neuronal pathways, localized axonal depolarizations are produced, thus activating neurons in the targeted brain structure.

The Brainsway DTMS System's unique design enables to produce directed electromagnetic fields that can induce excitation or inhibition of neurons deep inside the brain non-invasively.

The Brainsway Deep TMS (DTMS) System is composed of the following main components:

1. An Electromagnetic Coil (H Coil)

(b)(4)

[redacted]

Components

(b)(4)

[redacted]

(b)(4)

(b)(4)

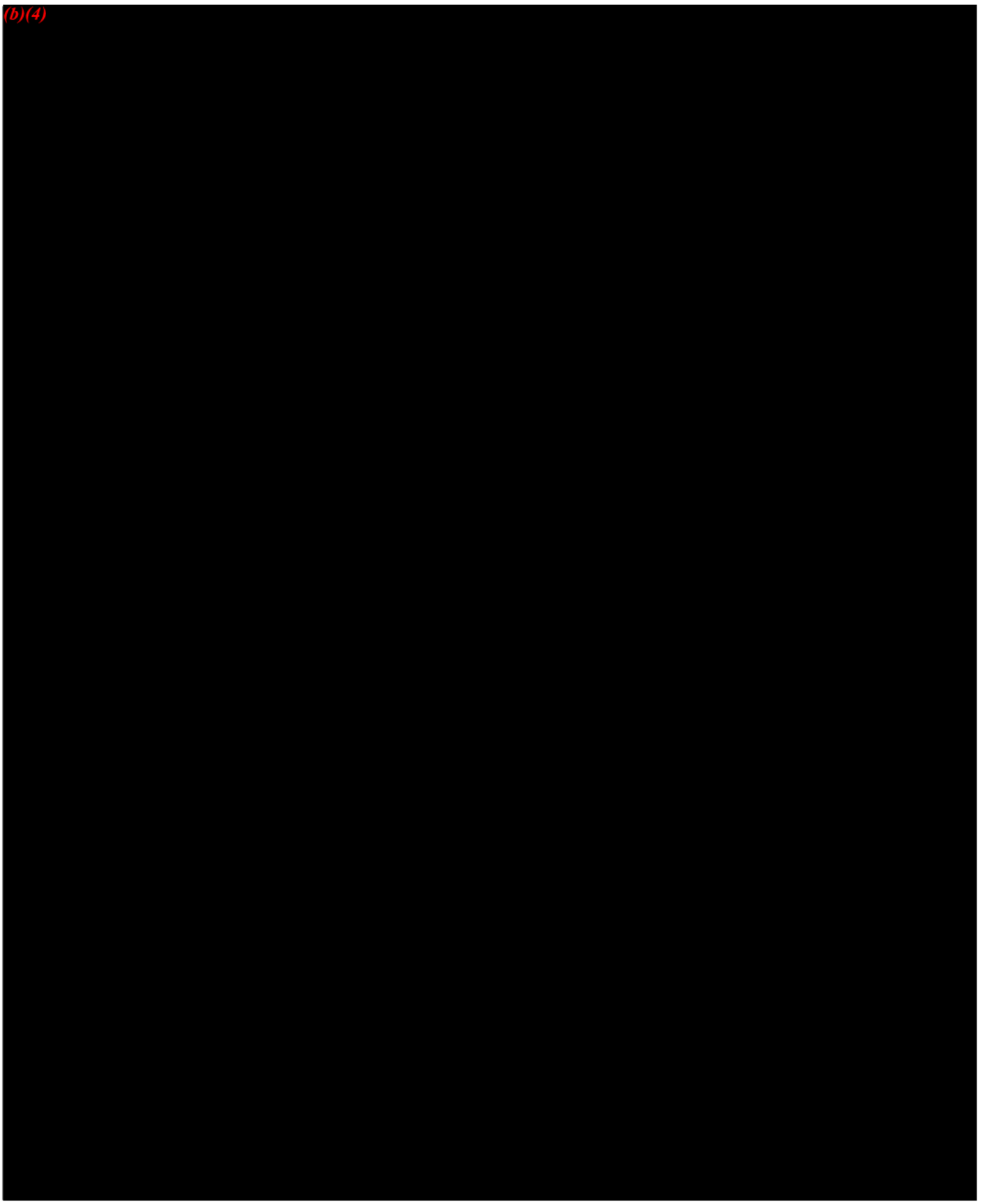
[redacted]

(b)(4)

Commercial TMS Neurostimulator

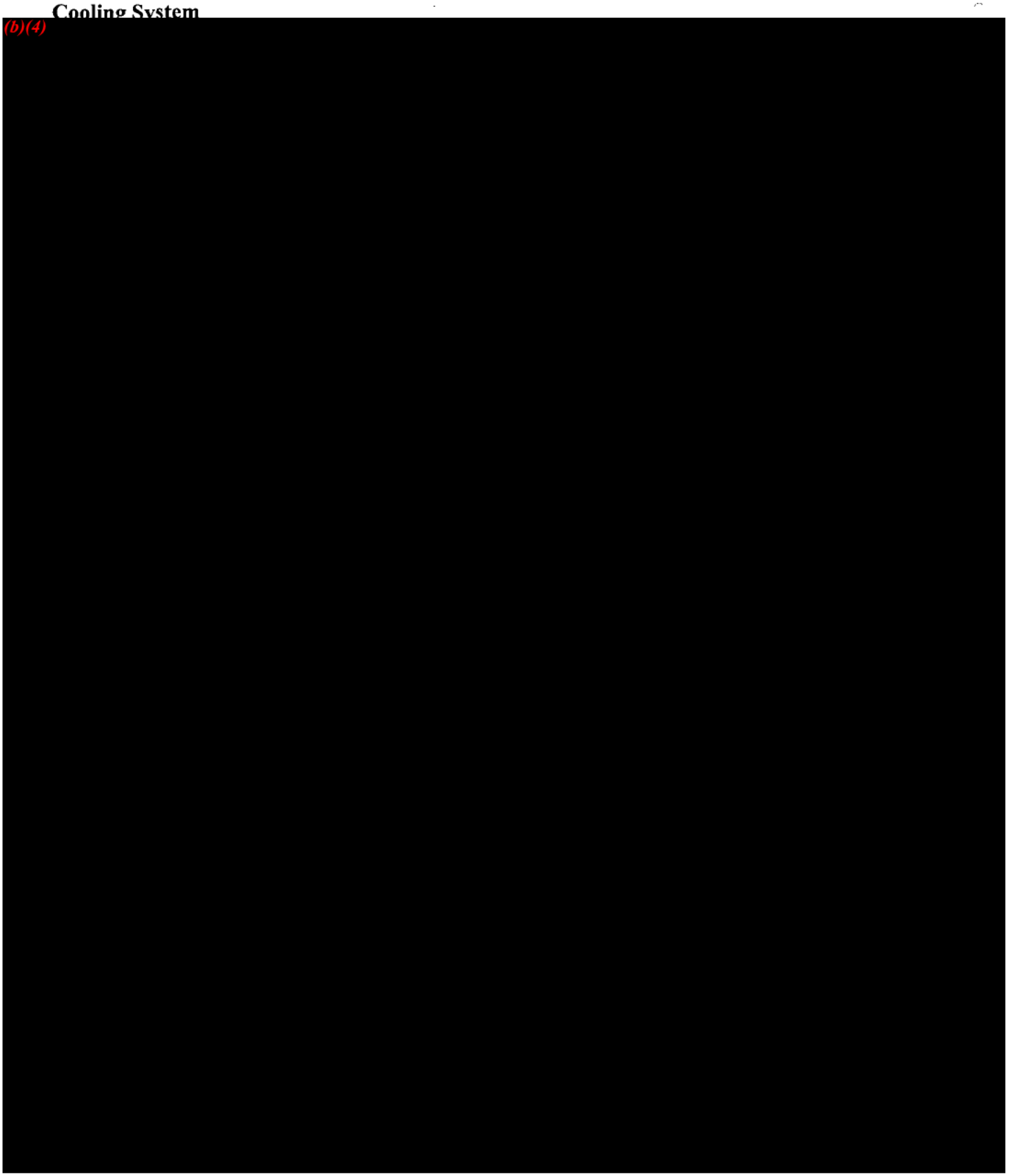
(b)(4)

(b)(4)



Cooling System

(b)(4)



(b)(4)

[redacted]

Positioning System

(b)(4)

[redacted]

System Specifications

(b)(4)

[redacted]

(b)(4)

[redacted]

Materials

(b)(4)

[redacted]

Device Mechanism of Action

(b)(4)

[redacted]

(b)(4)

[redacted]

Device Operation

Treatment Parameters

(b)(4)

[redacted]

(b)(4)

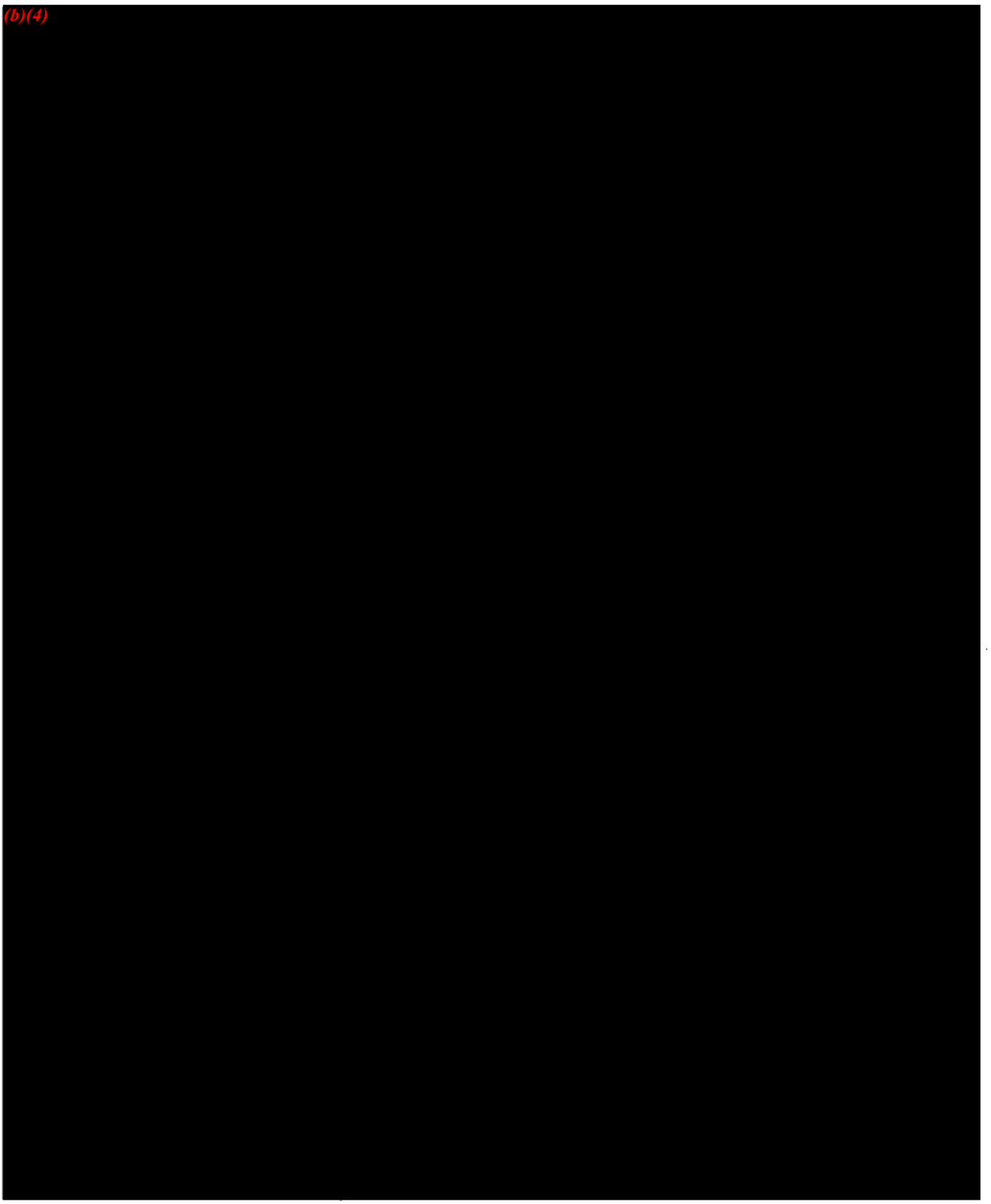
[redacted]

Determination of Individual Motor Threshold (MT)

(b)(4)

[redacted]

(b)(4)



(b)(4)

[redacted]

Administration of Treatment

(b)(4)

[redacted]

(b)(4)

(b)(4)

TECHNOLOGICAL CHARACTERISTICS:

(b)(4)

Motor Threshold (MT) Determination:

(b)(4)

X. Performance Testing – Animal

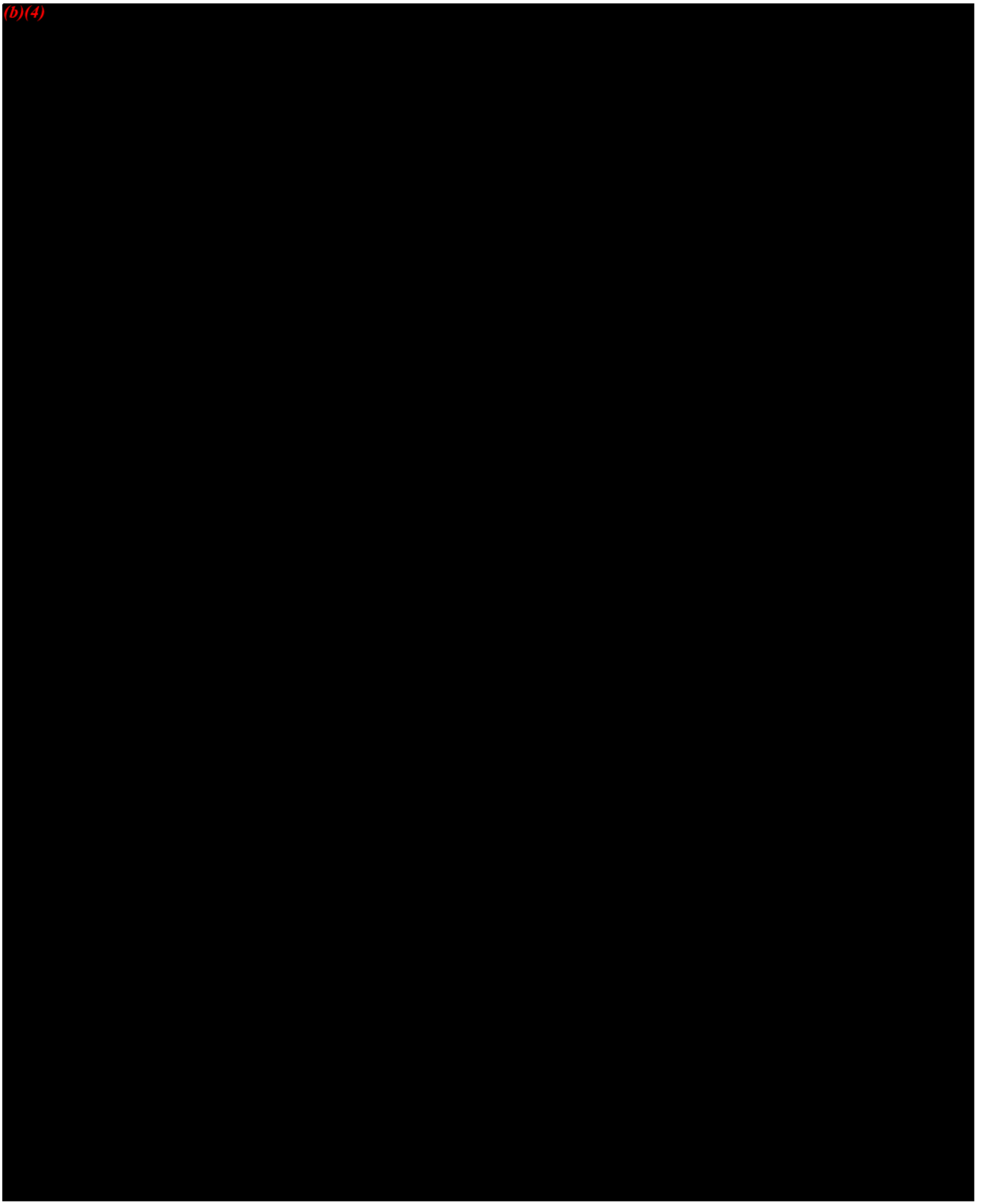
None. No animal data are provided.

XI. Performance Testing – Clinical

(b)(4)

[redacted]

(b)(4)



(b)(4)

(b)(4)

[redacted]

XIII. Other Previous Deficiencies

(b)(4)

[redacted]

Recommendation

I recommend that this device be deemed SUBSTANTIALLY EQUIVALENT to the predicate device in all respects. The sponsor has adequately addressed all outstanding concerns regarding this submission.

Regulation Number: 21 CFR 882.5805
Regulation Name: Repetitive Transcranial Magnetic Stimulator for Treatment of Major Depressive Disorder
Regulatory Class: Class II
Product Code: OBP

Reviewer Sign-Off:	Michael J. Hoffmann 2013.01.03 15:23:09 -05'00'
Branch Chief Sign-Off:	Brian D. Pullin -S 2013.01.04 14:45:08 -05'00'

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug
Administration

Memorandum

OFFICE OF DEVICE EVALUATION
510(k) CLINICAL REVIEW

Date: 3 January 2013

To: Michael Hoffman, Lead Reviewer
NNDB/DONED/ODE/CDRH/FDA

From: Lawrence Park, M.D., Medical Officer
PNDB/DONED/ODE/CDRH/FDA

Subject: K122288/S001

Device: Brainsway Deep Transcranial Magnetic Stimulator (DTMS) Device

Sponsor: A. STEIN–REGULATORY AFFAIRS CONSULTING
Ms. Ahava Stein
242 Sunset Blvd
Englewood, New Jersey 07631
Tel: +972 9 7670002
Fax: +972 9 7338534
Email: ahave@asteinrac.com

Manufacturer (b)(4)
(b)(4)
[redacted]

RECOMMENDATION: Substantially Equivalent (SE)

Introduction

(b)(4)
[redacted]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

MEMORANDUM

Date: December 17, 2012

To: Michael Hoffmann
Biomedical Engineer
ODE\DONED\Ear, Nose, & Throat Devices Branch

From: Scott W. Miller
Mathematical Statistician
OSB\DBS\General & Surgical Devices Branch

Subject: Statistical review of 510(k) K122288 \ S001
Deep repetitive transcranial magnetic stimulation (dTMS) for major depressive disorder
Brainsway, Ltd.

1. Executive Summary

(b)(4)

[redacted]

(b)(4)

[redacted]

3. Study design synopsis

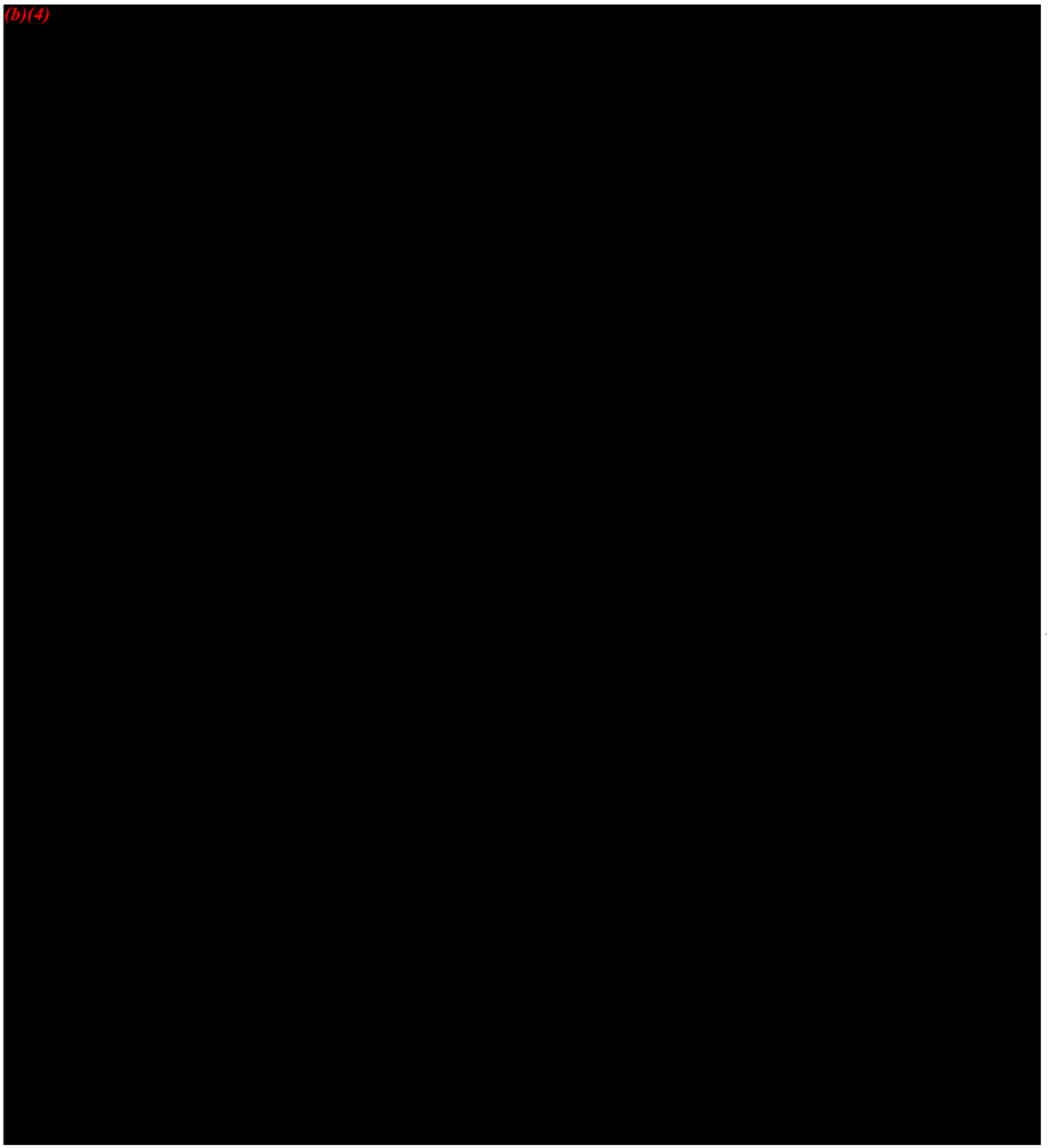
3.1 Design

(b)(4)

[redacted]

3.2 Analysis

(b)(4)



Brainsway

DEEP TMS SYSTEM FOR TREATMENT OF MAJOR DEPRESSIVE DISORDER

MODEL 102B

INSTRUCTIONS FOR USE

Federal (U.S.A.) law restricts this device to sale by or on the order of a psychiatrist.

BRAINSWAY LTD.
19 HARTOM STR., BYNET BLDG
JERUSALEM, 91451 ISRAEL

The Brainsway Deep TMS System Instructions for Use provide instructions for the users and administrators of the Deep TMS System necessary for the safe and effective operation of the system. Please read and thoroughly understand the Instructions for Use before operating the system. If any part of the Instructions for Use is not clear, contact the Brainsway Customer Support for clarifications. The Instructions for Use should always accompany the unit, and all personnel operating the unit must know its location.

TABLE OF CONTENTS

1. CONVENTIONS USED IN THE INSTRUCTIONS FOR USE

This section contains important regulatory information and safety warnings regarding use of the Brainsway Deep TMS System. To enhance readability, emphasized text and graphic symbols are used to identify important Warnings, Cautions, Procedure Instructions and special Notes. Examples of these elements are shown below.

Points of Emphasis

Italic or **bold** text denotes points of emphasis.

Warnings and Precautions

Warnings provide important information and are used to identify conditions or actions which will result in equipment damage if the instructions are ignored.

Warning and Precautions
Use of the Brainsway DTMS System requires the user to observe the warnings and precautions detailed below.

Notes

General notes are used to provide general information or references to other sections in the manual. An example is shown below.

NOTE

Instructions for Placement of the Personal Cap are provided in section 12.2.2.

Important notes are used to identify procedures or steps that must be performed to ensure normal or optimal system performance. A typical example is shown below.

NOTE

These treatment parameters serve as the default treatment setting for the Brainsway Deep TMS System and should be used as the treatment setting for all patients. These settings were used to establish safety and efficacy in the Brainsway Deep TMS System clinical trials.

2. USER REQUIREMENTS

- The Brainsway Deep TMS System should be operated by a qualified user trained by a representative of Brainsway Ltd.
- Before operating the Brainsway Deep TMS System, the following document should be carefully reviewed by the user.
- In addition, since the Brainsway Deep TMS coils are operated by a Magstim Rapid or Rapid^2 stimulator, the stimulator's Operating Manual must be consulted before use. The Magstim Rapid/Rapid2 Operating Manual is provided in Appendix C.
- The user should provide the patient with the Patient Guide prior to treatment so that the patient has sufficient time to review the information about the device and the procedure and discuss this information with his/her physician and family.
- The treatment administrator or other healthcare provider must be qualified to monitor the patient for seizure activity and to provide seizure management care.
- The treatment administrator must be able to observe patients and identify significant adverse reaction during or immediately after treatment and if necessary make adjustments (consistent with the Operator Manual) or determine if interruption of the treatment or termination of the treatment should be considered.

3. INDICATIONS

The Brainsway Deep TMS System is indicated for the treatment of depressive episodes in adult patients suffering from Major Depressive Disorder who failed to achieve satisfactory improvement from previous anti-depressant medication treatment in the current episode.

Clinical study results demonstrating safety and effectiveness of the Brainsway Deep TMS System for treatment of Major Depressive Disorder are provided in Appendix A of the Instructions for Use.

4. CONTRA-INDICATIONS

The Brainsway Deep TMS System **must not** be used on, or in the vicinity of, patients or subjects with the following conditions:

- Cardiac demand pacemakers, implanted defibrillators, or other electronic implants.
- History of metal implants in the head (except dental fillings).
- Known history of any metallic particles in the eye, wearable cardioverters, implanted cardiac pacemakers or any intracardiac lines, implanted neurostimulators, implanted electrodes, stents, surgical clips, medical pumps or any metallic particles in the head.
- Known history of cochlear implants.
- Inadequate communication with the patient.

5. GENERAL WARNINGS AND PRECAUTIONS

Use of the Brainsway DTMS System requires the user to observe the warnings and precautions detailed below.

Patient Monitoring Warnings and Precautions:

- ❖ Long-term effects of exposure to rTMS are unknown. Experimental and observational evidence indicates that exposure to the type of magnetic fields produced by the Deep TMS System does not present any significant risk of acute or long-term adverse effects.
- ❖ Patients with major depressive disorder are at risk of worsening of their depression and/or the emergence of suicidal ideation and suicide attempts. Treatment provider must observe patients and advise patients and their families to monitor behavioral changes, such as increases in depression, suicide attempts and ideations, increased aggressiveness, euphoria or irritability; and that if such behavioral changes appear, they should inform their physician immediately.
- ❖ Deep TMS may induce short lasting changes in heart rate and blood pressure. Therefore, patients with unstable hypertension should be carefully considered for

treatment.

- ❖ Brainsway Deep TMS treatment should be discontinued in any patient who has a continued significant adverse reaction or discomfort during or immediately after treatment. Temporary mild discomfort at the site of stimulation is normal during and/or shortly after treatment.
- ❖ During treatment with the Deep TMS System, the patient must use earplugs with a rating of at least 30 dB of noise reduction. Verify proper use of earplugs and stop rTMS if earplugs become loose or fall out.
- ❖ The head cap supplied by Brainsway is intended for personal use due to hygiene reasons. The cap must not be used on open wounds.

Seizure Monitoring Warnings and Precautions:

- ❖ Generalized seizures have been reported with the use of TMS in the clinical trial literature. The Brainsway DTMS system should be used with caution in patients who have a history of seizures, or a potential for alteration in seizure threshold, as stated below. In order to reduce the potential risk of seizure, observe the published 2009 Consensus Statement from the International Workshop on "Present and Future of TMS: Safety and Ethical Guidelines", [Rossi S et al. Safety, ethical considerations, and application guidelines for the use of transcranial magnetic stimulation in clinical practice and research. Clin Neurophysiol.2009 Dec;120(12):2008-39]. Treatment with stimulation parameters outside of these guidelines is not recommended.
- ❖ Be alert for signs of an imminent seizure and terminate the treatment session if those signs appear. If a medication that may alter the seizure threshold has been taken since the last treatment session, the motor threshold determination should be repeated prior to the next treatment session. Patients at potential increased risk of seizure include those who have:
    - o History (or family history) of seizure or epilepsy;
    - o History of stroke, head injury, or unexplained seizures;
    - o Presence of other neurological disease that may be associated with an altered seizure threshold (such as cerebrovascular accident [CVA],

cerebral aneurysm, dementia, increased intracranial pressure, head trauma, or movement disorder);

- Concurrent medication use such as tricyclic antidepressants, neuroleptic medications, or other drugs that are known to lower the seizure threshold;
- Secondary conditions that may significantly alter electrolyte balance or lower seizure threshold; and
- No quantifiable motor threshold such that TMS dosage cannot be accurately determined.

- Deep TMS treatments can induce seizures, although the probability of this occurring is very low. Therefore, visual monitoring by treatment administrator for signs of seizures must be maintained throughout the treatment. For example, hand or leg tremors continuing after the end of a train may be an indication of seizure onset. The treatment session must be terminated immediately if such signs appear. Furthermore, patients should be instructed that alcohol consumption or certain medications may increase probability of a seizure, in order to prevent or minimize the risk of seizure occurrence.
- The treatment administrator or other healthcare provider must be qualified to monitor the patient for seizure activity and to provide seizure management care. Seizure management procedures should be available.

Device Interaction with the Environment Warnings and Precautions:

- The strong magnetic pulses generated by the H-Coil induce eddy currents in any conductive medium such as the human body, nearby metallic objects or electronic devices.
- Particular care must be taken to ensure that leads connected directly to the patient or to other equipment are not in a position where the H-Coil can couple with them, as this would cause currents to be induced in them.
- Prior to treatment, each patient should be screened for the presence of metallic objects or implants that could affect the safe use of the Deep TMS System.
- Do not discharge the Deep TMS System with the H-Coil in the vicinity of metallic objects, as this may cause them to be moved and/or damaged.

- Patients must remove any object or device that may be affected by the electric or magnetic field of the Deep TMS System prior to treatment, including earrings, jewelry, hair barrettes and hearing aids.
- Do not discharge the H-Coil in the vicinity of objects sensitive to magnetic fields. Examples are credit cards, floppy disks, cell phones and computer screens.
- The Deep TMS System must not be used in an explosive atmosphere or in the presence of flammable anesthetics.
- The Deep TMS System must not be placed in the restricted access area of a magnetic resonance imaging (MRI) device.
- The Deep TMS System and its accessories must be used in the environmental conditions specified in these Instructions for Use only.

Device Electrical and Heating Warnings and Precautions:

- High voltages are present within this System. Do not remove covers. Refer servicing to qualified personnel. There are no user-serviceable parts in the system. Ensure that the System is not subject to conditions where water/ liquid may be accidentally spilled onto it.
- To ensure grounding safety, all mains power connections should be made directly to wall power sockets. All of the customer's electrical cabling must conform to local electrical standards. Do not use a terminal block if insufficient sockets are available, as this will form a potential electrical hazard.
- The device must be used in a mains system with surge protection.
- The device is not intended for use in a low voltage public network.
- The Deep TMS System and accessories must not be used if there are any signs of external damage or if any parts are damp or wet.
- Protection circuits disable the equipment if the temperature of the H-Coil exceeds 38°C.
- The H-Coil must not be immersed in water, put in an ice bucket, or refrigerated, even if placed within a plastic bag, as condensation may form within the coil. The coils do not have any specialized protection against the ingress of liquids; therefore, conditions where ingress of liquid or the forming of condensation

within the coil can occur must be avoided, as the electrical insulation will be compromised.

- ❖ Cooling must only be performed by using Brainsway's cooling system unit.
- ❖ Coil Overheating - due to thermal lag, the surface temperature of the H-Coil may continue to rise after the coil over-temperature protection has been activated and has forced the main unit into a standby condition. Therefore, the coil must be removed from the patient as soon as the stimulator's user interface indicates that the coil is over-temperature.
- ❖ A 10 minute interval between treatment sessions is recommended to minimize system shut down due to coil over-heating.

Other Warnings and Precautions:

- ❖ When the magnetic pulse is delivered, a discharge click is produced by the Deep TMS System and the H-Coil. This discharge click may startle.
- ❖ Subjects who require a stimulator settings of 72% or greater to reach their Motor Threshold should not be treated with the Brainsway Deep TMS treatment.

6. USER TRAINING

The Brainsway Deep TMS System is restricted to sale by or on the order of a psychiatrist trained in the use of the system.

The user should provide the patient with the Patient Guide prior to treatment so that the patient has sufficient time to review the information about the device and the procedure and discuss this information with his/her physician and family.

The treatment administrator may be a health care provider approved by the psychiatrist. The treatment administrator should have sufficient clinical expertise to monitor the patient during the treatment. That is, the treatment administrator should be able to observe the patient for the potential occurrence of adverse events, including identification of seizure activity. The treatment administrator should be able to determine when treatment interruption or termination should be considered. The treatment administrator should be present in the treatment room with the patient during the treatment session.

7. SPECIAL POPULATIONS

The safety of treatment with the Brainsway DTMS device in conjunction with antidepressant medication has not been evaluated in double-blind controlled clinical trials. The treating physician should review the patient's current treatment history and determine whether or not it is clinically appropriate to administer the Brainsway DTMS treatment in conjunction with an antidepressant or to treat the patient with the Brainsway DTMS treatment as a monotherapy antidepressant treatment. If antidepressant medication is administered in conjunction with the treatment, than the patient's motor threshold should be measured in the case of any medication change and prior to the next treatment session.

If the Brainsway Deep TMS System is administered as a monotherapy antidepressant treatment, antidepressant medications may be tapered down gradually prior to the first treatment session. The patient should be clinically monitored during this period, as some patients may experience worsening of depression and/or suicidal ideation.

The safety and effectiveness of the Brainsway DTMS System has not been established in the following patient populations or clinical conditions through a double-blind controlled clinical trial.

- Patients who do not meet DSM IV criteria for major depressive disorder.
- Patients less than 22 years of age or older than 68 years of age.
- Patients with history of substance abuse, obsessive compulsive disorder or post-traumatic stress disorder.
- Patients with psychotic disorder, including schizoaffective disorder, schizophrenic disorder, bipolar disease, or major depression with psychotic features.
- Patients who have a suicide plan or have recently attempted suicide.
- Patients with neurological conditions that include epilepsy, cerebrovascular disease, dementia, increased intracranial pressure, having a history of repetitive or severe head trauma or with primary or secondary tumors in the CNS.
- Patients with metal in or around the head, including metal plates, aneurysm coils, cochlear implants, ocular implants, deep brain stimulation devices and stents.
- Patients with implants controlled by physiological signals, including pacemakers, implantable cardioverter defibrillators, and vagus nerve stimulators.
- Patients who have had no prior antidepressant medication failure or intolerance.
- Patients who have failed to receive benefit from more than four antidepressant medications given at or above the minimal effective dose and duration.
- Patients who cannot tolerate withdrawal of antidepressant medications.
- Patients with major depressive disorder who have failed to receive clinical benefit from ECT or VNS.
- Patient who have failed previous rTMS treatment. (This patient population was not studied in order to maintain study blindness).
- Patients who are pregnant or nursing.

Brainsway DTMS Treatment has not been evaluated in patients with psychoses or with psychiatric emergencies where a rapid clinical response is needed, such as immediate suicide risk. Use of Brainsway DTMS Treatment in the treatment of these patients is not recommended since rapid onset of effect in these high-risk populations has not been

established.

8. TREATMENT ADMINISTRATION

Treatment parameters for Brainsway Deep TMS System are standardized for each treatment session as follows:

- Magnetic Field Intensity: 120% of the patient's measured Motor Threshold (MT).
- Frequency: 18 Hz
- Treatment train duration: 2 seconds
- Inter-train interval: 20 seconds.
- Treatment Session Duration: 20.2 minutes
- Number of pulses administered per session: 1980

These treatment parameters serve as the default treatment setting for the Brainsway Deep TMS System and should be used as the treatment setting for all patients. These settings were used to establish safety and efficacy in the Brainsway clinical trials.

The number of treatment sessions consists of 5 daily sessions for 4 weeks. This treatment course may be followed by biweekly sessions for an additional 12 weeks. Although, treatment success was observed at the end of the 5 weeks of treatment sessions, patients should be encouraged to complete the additional maintenance treatments, i.e., the 12 weeks of biweekly sessions, unless adverse effects or safety concerns arise.

13. USER INSTRUCTIONS

Detailed instructions for operation of Brainsway's Deep TMS System are provided below:

12.1 Preparing the System

12.1.1 Operating Environment

For the proper operation of the cooling system, the treatment room must be equipped with an air conditioning system, which maintains the room temperature 16-25°C.

12.1.2 System Assembly and Positioning

12.1.2.1 Position the system such that the rear side of the cart is at least 20 cm from any wall or surface, to ensure appropriate air exchange for the cooling system.

NOTE **Do NOT block the rear vent or position the rear vents against a wall or other surface in order to prevent overheating.**

12.1.2.2 Make sure that the cart's wheels are locked before operation.

12.1.2.3 Turn on the air conditioner in the treatment room, and set the temperature between 20°C and 25°C.

12.1.2.4 Connect the H-Coil's power cable to the Magstim Stimulator's Main Unit, which is located in the cart.

12.1.3 Cooling System Instructions

12.1.3.1 For first-time use at a new site, the system should be operated only by a qualified treatment administrator.

12.1.3.2 Turn on the cooling system at least two minutes before treatment by pushing the button on the front panel of the cooling system.

12.1.3.3 At the end of the treatment, turn off the Cooling System.

12.1.3.4 Do not touch any of the cooling system buttons except for the power button (Fig. 27).

12.1.4 Magstim Stimulator Instructions

12.1.4.1 Make sure all switches are turned off.

12.1.4.2 The Magstim stimulator has two gray cables connected to the mains. In addition the cooling system cable is connected to the mains. Ensure that all three cables are connected to three separate power outlets.

NOTE **The power cables may present a tripping hazard. Ensure that all three cables are safely out of the user and the patient's path.**

12.1.4.3 Refer to the Magstim Rapid or Rapid^2 Stimulator operation instructions provided in Appendix C.

12.2 Treatment Instructions

12.2.1 Initial Preparations

12.2.1.1 Ask the patient to complete the TMS safety questionnaire provided in Appendix B of the Instructions for Use.

12.2.1.2 Make sure the H-Coil's air cooling hose is connected between the Helmet and the cooling system.

12.2.1.3 Seat the patient in a (hospital supplied) chair in a comfortable position. Ensure that the patient is positioned at the proper height such that the helmet may be comfortably positioned on the patient's head.

12.2.1.4 Ensure that the patient puts earplugs in his/her ears. Verify that the earplugs are properly in place. Instruct the patient to report any loosening or detachment of the earplugs during the treatment.

12.2.1.5 Ensure that the patient removes any hair jewelry, barrettes, other hair accessories and earrings.

12.2.1.6 Ensure that the first joint of the arm, projects from the cart at an angle of about 45°. This should be the state of the arm during the process of finding the Motor Threshold (MT), and during the treatment.

NOTE **Ensure that the positioning arm and the helmet are out of the way to avoid collision with the patient's head.**

12.2.2 Placement of the Personal Head Cap

NOTE

For hygienic purposes use a new Personal Head Cap for each patient. The patient's personal head cap may be re-used during all of his/her treatment sessions.

12.2.2.1 Put the personal head cap (supplied by Brainsway) on the patient's head, with the frontal strap attached to the forehead close to the eyebrows (Fig. 3). Make sure that the cap's middle red line is along the head midline (Fig. 3).

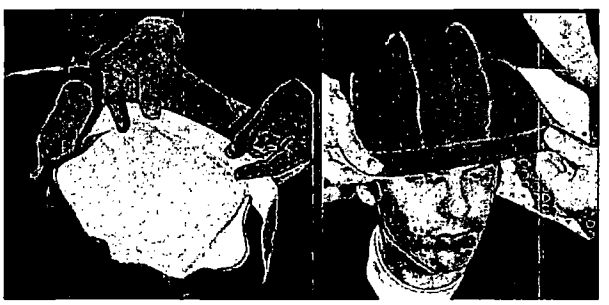


Figure 3: Holding the cap by the frontal strap (left), and attaching it to the patient's forehead, such that the frontal strap is above the eyebrows (right).

12.2.2.2 Pull the cap's ear covers down in order to stretch the cap over the head and stretch the left and right peripheral straps across the left and right ear covers (Fig. 4).

Figure 4: Pulling the cap's ear covers downward (left), and stretching the peripheral straps across them along the sides of the cap (right).

12.2.2.3 Stretch the left and right peripheral straps and fasten them at the back of the patient's head using the Velcro straps (Fig. 5).

Figure 5: Stretching the left and right peripheral straps and fastening them over the back of the patient's head.

12.2.2.4 Fasten the cap's chin strap using the Velcro straps (Fig. 6). After fastening, lift the left side of the strap, pull down the left ear cover, and re-attach the chin strap (Fig. 6). Follow the same procedure on the right side (Fig. 6).

Figure 6: Fastening the cap's chin strap.

12.2.2.5 Attach the midline flexible ruler along the midline of the cap, with the zero mark on the patient's nasion (Fig. 7). The ruler's scale lines must be contiguous with the cap's midline.

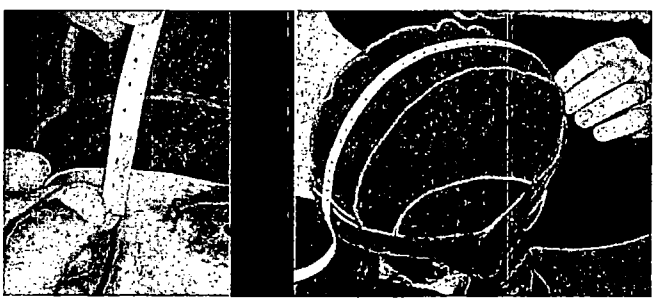


Figure 7: Attaching the flexible ruler along the cap's midline, with the 0 mark on the patient's nasion.

12.2.2.6 Measure the distance from nasion to inion, DN-I (Fig. 8), using the midline ruler.

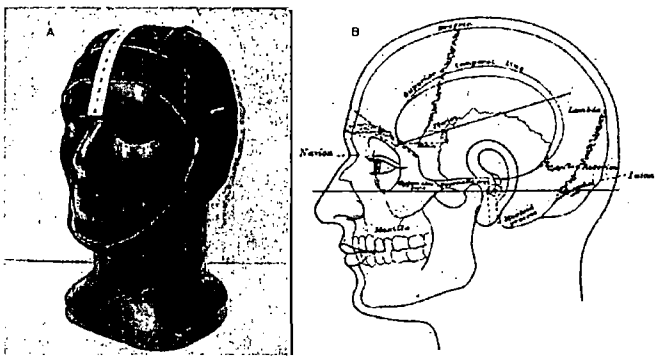


Figure 8: A. Image of the Brainsway personal cap on phantom head. A flexible ruler is attached along the cap's midline, with the zero mark at the patient's nasion. This ruler is used to measure the distances from nasion to inion and from nasion to APB motor cortex location, and for moving the coil to the treatment location. B. An image of human skull landmarks, showing the location of the nasion and the inion, which are used for coil placement. See text for details.

12.2.2.7 Place the lateral-medial flexible ruler, such that the 25 cm scale mark on this ruler lines up with the point along the midline ruler whose distance from the nasion is 40% of the nasion-inion distance (DN-I). In the example shown in Fig. 9, this point is "14.8" (14.8 cm from nasion).

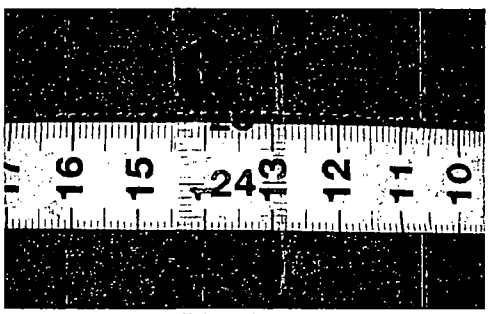


Figure 9: Placing the lateral-medial flexible ruler at the point along the midline ruler with a distance from the nasion equal to 40% of the nasion-inion distance (DN-I).

12.2.2.8 Attach the lateral-medial ruler perpendicular to the midline ruler, with the zero mark on the left side of the patient (Fig. 10).

Figure 10: Attaching the lateral-medial flexible ruler perpendicular to the midline ruler, with the zero mark on the left side.

12.2.3 Finding the Individual Motor Threshold (MT)

Individual motor threshold (MT) determination must be performed before the first treatment session and once a week, thereafter.

Motor threshold may be determined by visual indication, or by EMG. Yet, in any case that a twitch was observed at certain stimulator intensity in 5 out of 10 trials, the minimal threshold must be at or below this value.

12.2.3.1 Finding MT by Visual Indication:

12.2.3.1.1 Position the H-Coil over the patient's head at the appropriate location for Abductor Pollicis Brevis (APB) motor stimulation. The front end of the coil cover should intersect the cap's midline ruler at the midline ruler's 7 cm mark. The coordinate on the coil cover at which the cover intersects the cap's midline ruler must be "0" (Fig.11). The front end of the coil cover must be perpendicular to the cap's midline ruler.

Figure 11: Positioning the coil cover preparatory to MT determination.

12.2.3.1.2 From this point, move the coil 2 cm to the right, along the cap's lateral-medial ruler. The coil position on the head should be similar to the position shown in Fig. 13.

12.2.3.1.3 Turn on the stimulator. The stimulator will perform a system self-test to verify system proper functioning, coil connection and coil ambient temperature.

NOTE

Wait for the stimulator self-test to finish before proceeding to measure the patient's MT. Subjects who require a stimulator settings of 72% or greater to reach their Motor Threshold should not be treated with the Brainsway Deep TMS treatment.

12.2.3.1.4 Set the stimulator output to an initial value of 60%, and apply single pulses. Wait at least 5 sec between consecutive pulses. In case of no motor response, increase the power output in increments of 5%. Find the minimal threshold for motor activation at the initial position.

12.2.3.1.5 Set the stimulator power output to be 5% above the minimal threshold found at the initial location. Find the exact location of the left APB-associated motor cortex by fine displacement of the coil. The coil can be moved upward-downward by the arm, and backward-forward by the connection box axis (See Fig. 12a). In addition the helmet can be rotated freely in three dimensions, and when desired the helmet position and orientation can be fixed with the fixation screw (Fig. 12b). Move the helmet in increments of 1 cm along lateral-medial and posterior-anterior axes, using the coordinates on the cap's rulers. After finding the threshold at a certain point, and moving the coil to a new point, increase the stimulator power output to be 5% more than the minimal threshold found so far, and then gradually reduce the power output, until the threshold at the new location is found. The APB motor cortex is identified as the site of lowest stimulus intensity capable of inducing motor evoked potentials (MEPs) or an observable twitch in the APB muscle. The motor threshold is determined by the intensity of the stimulator at this site. Twitches in any digit muscles in five out of ten stimulations may indicate that, the minimal threshold is at or below this value.

12.2.3.1.6 After finding an optimal position, move the coil 1 cm in each direction (right, left, front, back), and find where the threshold to elicit motor response is minimal.

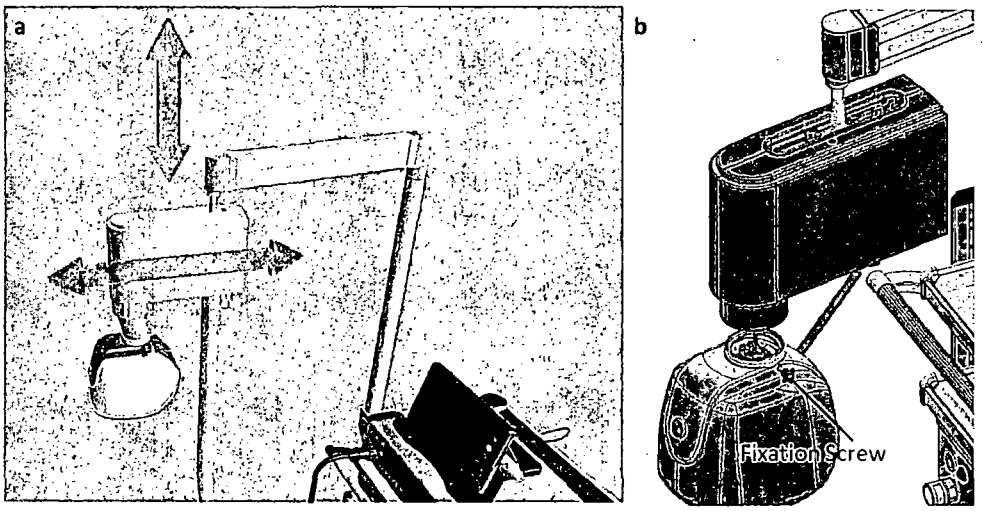


Figure 12: a. A Positioning Device with the H1-Coil helmet, showing the means of displacement along the upward-downward and the antero-posterior axes. b. The connection box and the helmet with the fixation screw enabling to fix the helmet at a desired position and orientation.

12.2.3.1.7 In most cases, the optimal location for activation of the left APB-associated motor cortical region can be found by shifting the coil slightly (usually 1-3 cm) to the right (Fig. 13). With the coil in this position, the maximal field produced by it is located at the APB-associated area of the M1 region of the left motor cortex.

12.2.3.1.8

Figure 13: A typical positioning of the coil at the optimal location for activation of the left-hemisphere APB-associated motor cortex.

12.2.3.2 Using EMG for Motor Threshold Determination

When using an EMG device, the motor threshold is determined as the lowest stimulator intensity capable of eliciting a motor evoked potential (MEP) of at least 50 μV in five out of ten stimulations.

NOTE

This section presents a demonstration of finding an individual MT using the EMG pod supplied with the Magstim Rapid2 stimulator. This is an example only, and this procedure may be done with any appropriate EMG device.

12.2.3.2.1 Clean the palm of the right hand with alcohol (Fig. 14).

Figure 14: Cleaning the subject's hand with alcohol.

12.2.3.2.2 In order to reduce noise, it is recommended to further clean the hand with an abrasive paste (Fig. 15). It may also be worthwhile to add an electrode gel for reducing the impedance, in order to improve the electrical connection between the electrodes and the skin.

Figure 15: Cleaning the subject's hand with an abrasive paste. The image is an example only, and no recommendation for any specific product is made.

12.2.3.2.3 Attach the positive, ground and reference electrodes, as shown in Fig. 16. Connect the electrode leads to the appropriate connectors in the EMG pod (Fig. 16). The EMG pod must be connected to the Rapid^2 I/O screen, as explained in the Rapid^2 user manual.

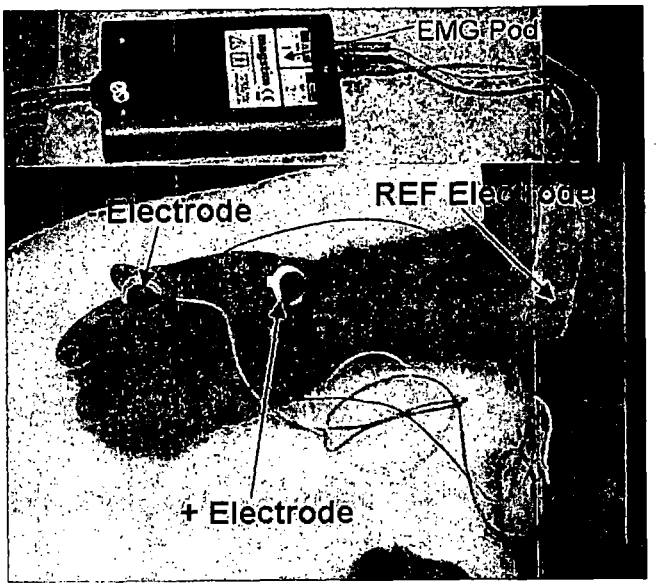


Figure 16: Attachment of electrodes for measurement of APB MT.

12.2.3.2.4 Set the parameters on the Rapid2 I/O screen as shown in Fig. 17: Time Base - 50 ms; Filters - 2 Hz – 10 kHz; Display the channel to which the electrodes are connected; 200 μV/div.

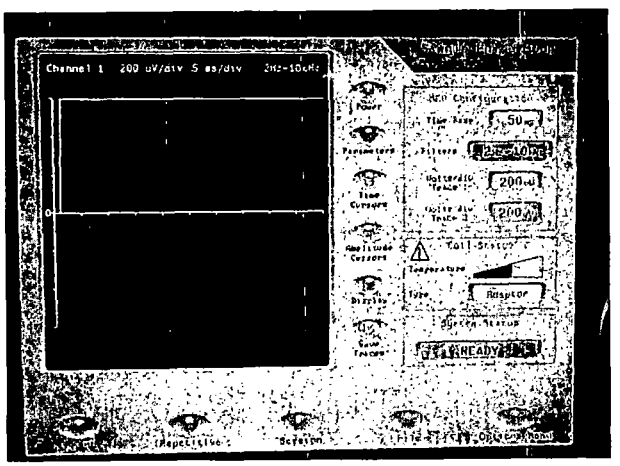


Figure 17: Setting the parameters on the Rapid2 I/O screen.

12.2.3.2.5 Set the amplitude cursor for the appropriate channel (Fig. 18).

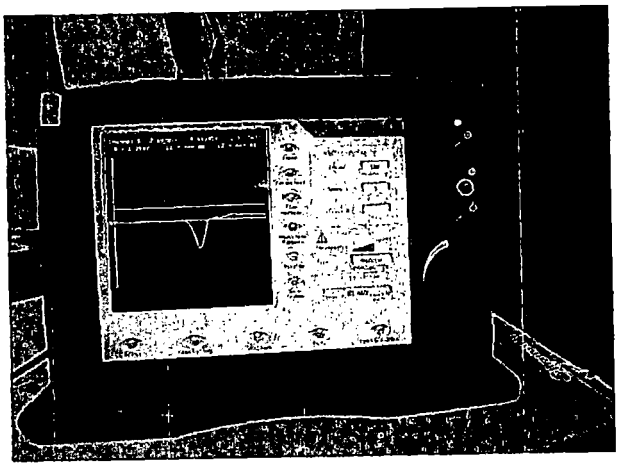


Figure 18: Setting the amplitude cursor.

12.2.3.2.6 Set the time cursors, such that the 1st line (L1) is at the initial deflection of the signal, and the 2nd one (L2) is approximately at the peak (Fig. 19). L1 should be at a distance of at least 20 ms from the TMS pulse trigger. Repeat the process of threshold determination until you find the location at which the stimulator intensity required to elicit a motor evoked potential (MEP) of at least 100 μV in five out of ten stimulations is the lowest. This minimal stimulator intensity defines the motor threshold value. In the example in Fig. 18, this threshold intensity was found to be a power output of 39%.

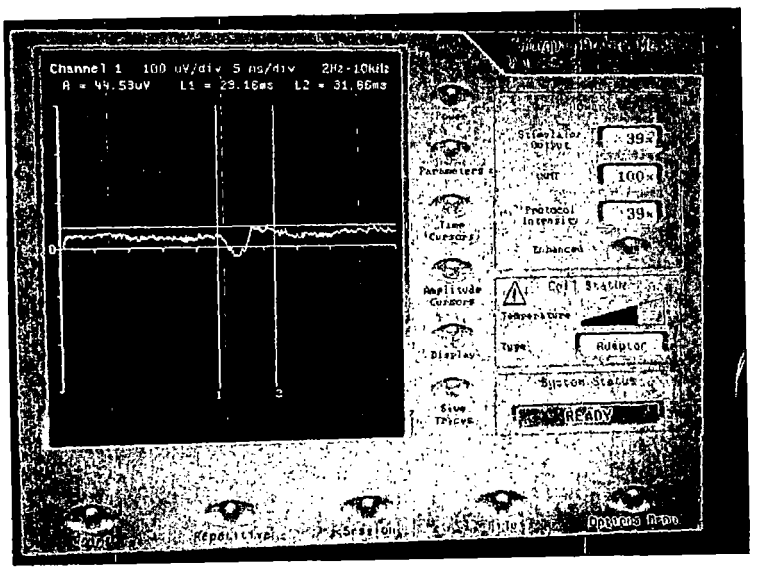


Figure 19: An example of a threshold MEP. Note the power output, the amplitude, and the time cursors.

12.2.4 Recording APB Motor Cortex Location

12.2.4.1 Write down the value along the cap's midline ruler at which the ruler intersects the coil cover's front end. This value is denoted DN-MC (distance from nasion to motor cortex location). Also write down the value on the front end of the coil cover at this location. This value must always be 0.

12.2.4.2 Write down the value along the cap's lateral-medial ruler at which the ruler intersects the coil cover. Also write down the value on the front end of the coil cover at this location.

12.2.4.3 Write down the value along the cap's midline ruler at the patient's inion. This value is denoted DN-I (distance from nasion to inion).

12.2.4.4 The coordinates found in the previous sections can be used to position the coil for the next treatment. In future treatment sessions, the procedure of finding the intensity and location of the MT may be considerably shortened compared to the first treatment by initially positioning the coil at the recorded location of the APB motor cortex.

NOTE **Be careful in recording the MT coordinates. A mistake in recording these coordinates will result in an incorrect treatment location. To ensure that the coordinates are within the acceptable range, the distance from nasion to motor cortex location (DN-MC) should be larger than 3 cm and smaller than 15 cm.**

12.2.4.5 If the distance from nasion to motor cortex location (DN-MC) is smaller than 3 cm or larger than 15 cm, repeat stage 6.2.3.1 (to find the exact location of APB motor cortex).

12.2.4.6 In case there was use of EMG electrodes, remove the EMG electrodes from the patient.

12.2.5 Positioning the Coil at the Treatment Location

12.2.5.1 Move the coil 6 cm anterior to the APB MT location, along the cap's midline ruler. The point of intersection of the cap's midline ruler with the coil cover must be 6 cm from the point of intersection found at the APB motor cortex location (section 6.2.4.2). The coil cover coordinate must be the same as the coordinate found at the APB motor cortex location (section 6.2.4.2).

12.2.5.2 If the point of intersection of the cap's midline ruler found at the APB motor cortex location (section 6.2.4.2) is at less than 7 cm, move the coil to the point marked 1 cm along the cap's midline ruler.

12.2.5.3 After positioning the coil at the treatment location, fasten it to the patient's head using the chin strap (Fig. 20).

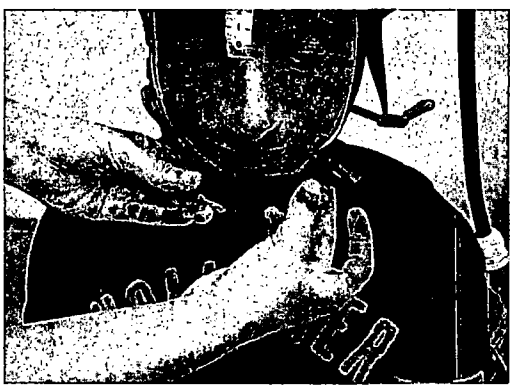


Figure 20: Fastening the coil to the patient's head at the treatment location using the chin strap.

12.2.5.4 Stretch the peripheral strap downward, and pull the bi-directional buckle forward (Fig. 21).

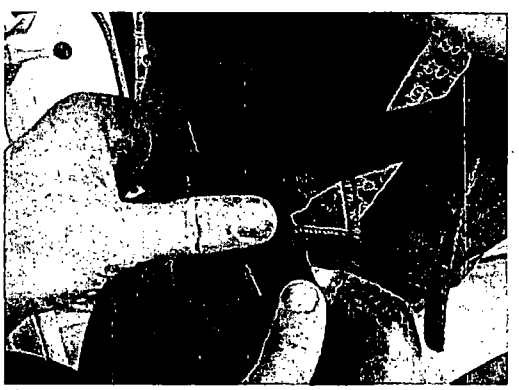


Figure 21: Stretching the peripheral strap downward and pull the bi-directional buckle forward

12.2.5.5 Stretch the chin strap ends on both sides of the subject (Fig. 22).

Figure 22: Stretching the chin strap end.

12.2.5.6 Strengthen the tightening on the back with the two straps ends (Fig. 23).

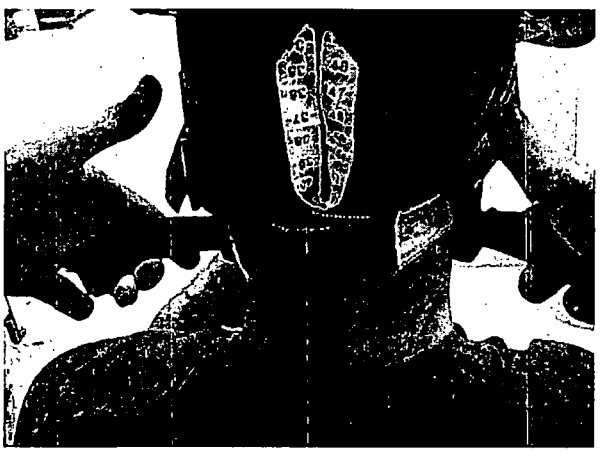


Figure 23: Tightening on the back with the two straps ends.

12.2.5.7 Tighten the upper strap with the two blue strap ends on both sides (Fig. 24).

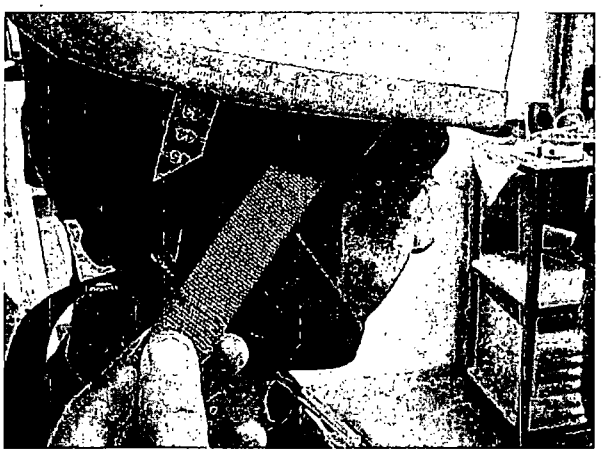


Figure 24: Tightening the upper strap with the blue strap end on both sides.

12.2.5.8 The final attachment of the coil elements to the head is done with an air pump. Close the pump tap and blow air until the coil is attached tightly to the head (Fig. 25).

Figure 25: Close the pump tap and blowing with the air pump.

12.2.5.9 A typical position of the helmet at the treatment location is shown in Fig. 26.

Figure 26: The coil helmet attached to the head at the treatment location.

12.2.6 Administration of Treatment

12.2.6.1 Turn on the cooling system, by pushing the power button at the front of the cooling system (Fig. 27). Wait two minutes before beginning a session. After two minutes of operation the temperature displayed on the front panel of the cooling system should be below 13°C.

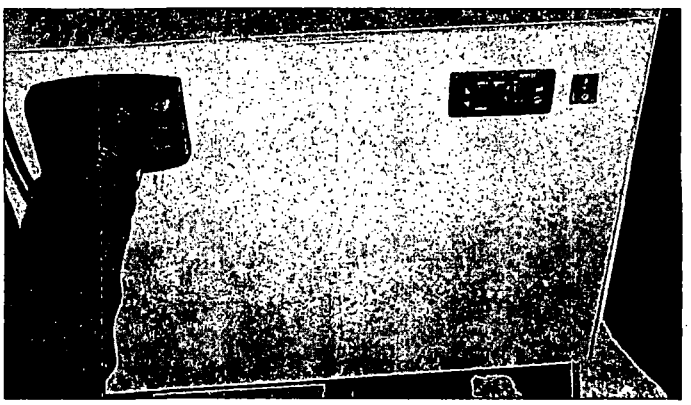


Figure 27: Operating the cooling system, by pushing the green power button.

NOTE

Accurate placement of the coil is critical for the reproducible application of TMS. The treatment administration section assumes that MT location has already been determined for the specific patient. If not, return to Section 12.2.3, "Finding the Individual Motor Threshold". Consider re-evaluating the patient's motor threshold level in case of any change, e.g., change in patient antidepressant medications, change in patient's hairstyle which may alter the distance from the coil to the patient's scalp.

NOTE

Make sure that both the system user and the patient are wearing ear plugs.

12.2.6.2 Apply one short trial train of 0.5 sec, 18 Hz, at a power output of 120% of the MT. Test whether the patient responds well to the train. Ask the patient if the treatment is tolerable. In case of excessive motor activation or patient discomfort, move the coil up to 1 cm forward, and test whether the problem has resolved. After the maximum allowable forward displacement, the coil will be positioned such that its front end intersects the cap's midline ruler at the point marked 0 cm.

12.2.6.3 In case the patient has difficulty to sustain the trial train, treatment may be ramped up as follows, to increase patient comfort and help accommodate the treatment:

a. Apply a trial train of 0.5 sec, 18 Hz, at a power output of 100% of the MT.
b. Apply a trial train of 0.5 sec, 18 Hz, at a power output of 105% of the MT.
c. Apply a trial train of 0.5 sec, 18 Hz, at a power output of 110% of the MT.
d. Apply a trial train of 0.5 sec, 18 Hz, at a power output of 120% of the MT.
e. Apply a trial train of 1 sec, 18 Hz, at a power output of 120% of the MT.
f. Apply a trial train of 2 sec, 18 Hz, at a power output of 120% of the MT.

NOTE

Remind the patient that scalp discomfort is attenuated with successive treatments.

12.2.6.4 Apply the remainder of the treatment according to the following treatment parameters:

Stimulator power output: 120% of the measured motor threshold (MT).

Frequency: 18 Hz.

Train duration: 2 sec.

Inter-train interval: 20 sec.

Number of trains: 55.

NOTE

These treatment parameters serve as the default treatment setting for the Brainsway Deep TMS System and should be used as the treatment setting for all patients. These settings were used to establish safety and efficacy in the Brainsway Deep TMS System clinical trials.

12.2.6.5 During the treatment, monitor the patient and pay attention to any excessive motor activation, which may indicate a risk of seizure. In any case of excessive hand motor activation, the treatment must be stopped. In any case of any leg motor activation, the treatment must be stopped. In any case of any motor activation which lasts after the end of the train, the treatment must be stopped and the treatment terminated.

NOTE

In case of emergency treatment may be immediately ceased by pushing the RED stop button. If a seizure occurs, follow your institution's standard operating procedures for first response emergency.

12.2.6.6 Remind the patient that the Brainsway Deep TMS treatment will cause a clicking sound and may produce a tapping sensation on the head. This discharge click may startle.

12.2.6.7 During the treatment, monitor the temperature displayed on the stimulator UI screen. It is normal for the coil to feel warm during treatment. In the event of overheating, the stimulator software should disable the system's operation. If this occurs, release the H-Coil's chin strap and remove the coil from the patient's head. The cooling system will cool the coil to normal temperature within three minutes and then the coil may be replaced on the patient's head and treatment may be resumed.

12.2.6.8 In case the stimulator stopped in the middle of a session without any indication of overheating, resume the session by pushing the icon "Resume" on the stimulator UI screen.

12.2.6.9 Acetaminophen or other medications for treatment of local pain, dental pain or headaches may be administered, as necessary.

12.2.6.10 At the end of treatment, turn off the cooling system. A 10 minute interval between treatment sessions is recommended to minimize system shut down due to coil over-heating.

12.2.6.11 At the end of the treatments day, turn off the stimulator and the cooling system.

14. MAINTENANCE & CALIBRATION

Each coil should be returned to Brainsway every three years for a thorough examination. Brainsway will send a reminder regarding the required replacement two months prior to the expiry of the three-year period. A replacement coil will be sent prior to the expiry of the two-year period. A Brainsway technician will be responsible for replacing the coil.

For stimulator maintenance and calibration, please refer to the stimulator user's manual.

15. CLEANING

The coil helmet, positioning device, cart and stimulator components may be cleaned using an isopropyl alcohol-moistened cloth. Ensure that the equipment has dried thoroughly before use.

16. LIFE EXPECTANCY

The life expectancy of the system depends on the cooling system. The life expectancy of the system is approximately 4,500 treatment (calculated based on a maximum of 20 minutes per treatment).

17. TROUBLESHOOTING

If the unit fails to operate normally, check the following points to determine whether the fault can be corrected by the simple measures suggested below. If it cannot be corrected, or if the fault is not listed in the malfunction column, disconnect the power cord and contact your service center at Brainsway Ltd. for assistance.

Malfunction	Troubleshooting
Session stopped without over-heating	In case the stimulator stopped in the middle of a session without any indication of overheating, resume the session as follows: Push the red STOP button, push the green ARM button, and push the icon "Resume" on the stimulator UI screen. The session will proceed from where it stopped.
Session stopped due to coil over-heating	If the session stopped and there is an indication of over-heating on the stimulator screen, release the H-Coil's chin strap and remove the coil from the patient's head. The cooling system will cool the coil to normal temperature within three minutes and then the coil may be replaced on the patient's head and treatment may be resumed.
H-Coil Falls	Contact Brainsway immediately and send the coil to Brainsway for a thorough examination. Continued use of the coil after a fall might result in a malfunction.

In case of any malfunction please contact Brainsway:

Brainsway

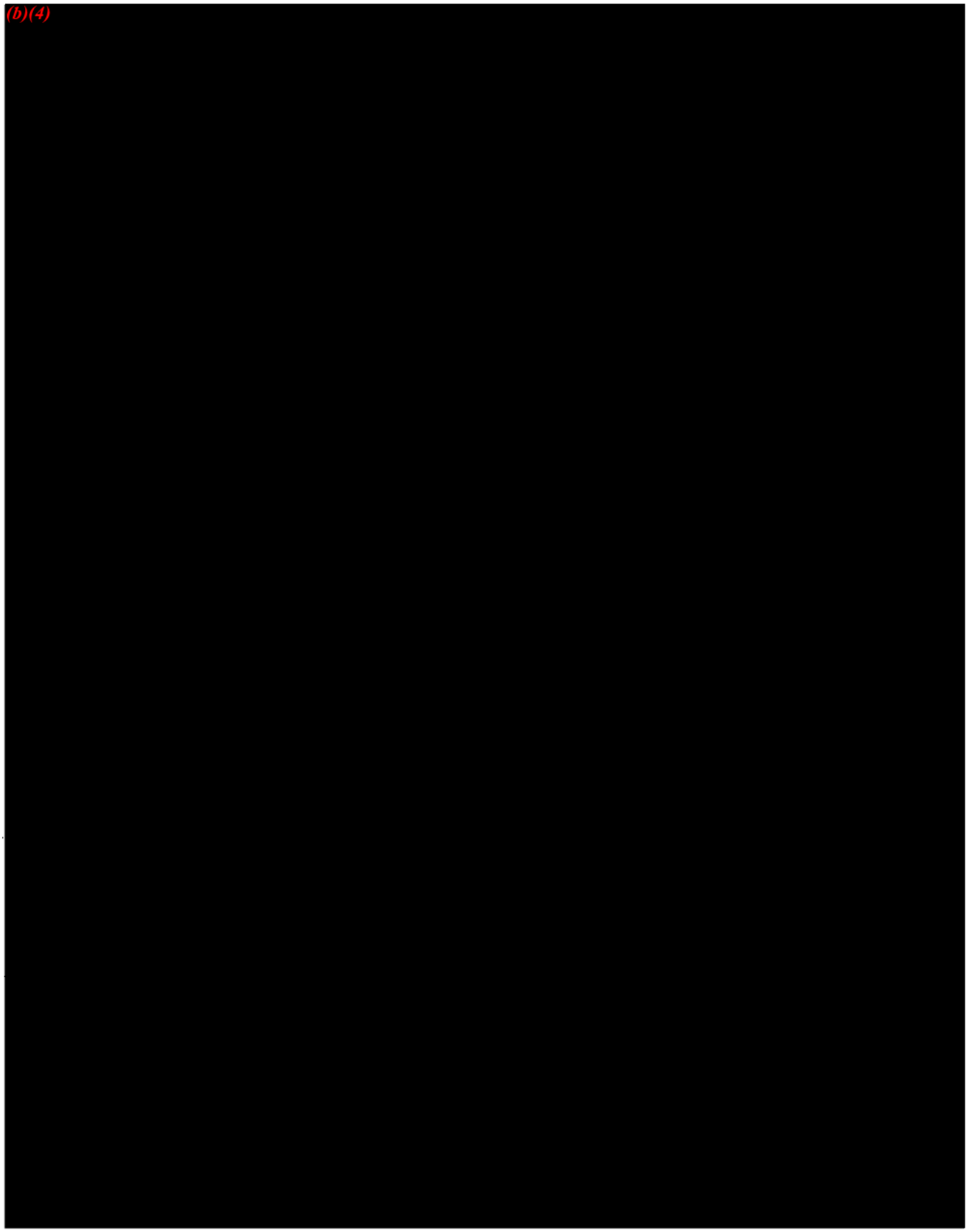
19 Hartom St., Bynet Building, 1st floor, Jerusalem, Israel
Tel: +972-2-5824030 Fax:+972-2-5812517

(b)(4) [redacted]

APPENDIX A:

CLINICAL STUDY RESULTS

(b)(4)



APPENDIX C:

MAGSTIM RAPID OR RAPID2 STIMULATOR OPERATION INSTRUCTIONS

K122288/S1

A. Stein

REGULATORY AFFAIRS CONSULTING LTD.
Beit Hapa'amon (Box 124)
20 Hata'as St., 44425 Kfar Saba ISRAEL
Tel: +972-9-767-0002 Fax: +972-9-766-8534
E-mail: ahava@asteinrac.com

K77

October 29, 2012

Michael Hoffman
Document Mail Center - WO66 – 0609
Center for Devices and Radiological Health - Office of Device Evaluation
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
U.S.A.

Re: **K122288 Brainsway Deep TMS System**
Company: **Brainsway Ltd.**

Dear Michael Hoffman,

Further to your e-mail communication, dated September 19, 2012, enclosed please find our responses. The enclosed response is arranged such that the questions from your e-mail letter are printed in bold lettering with our response following in regular print.

I trust that the information included in this supplement, will be adequate to allow for its prompt review. If you have any questions, please don't hesitate to contact me at the following telephone nos. +972-9-7670002 (office) or +972-52-2346927 (mobile), or by e-mail to ahava@asteinrac.com.

Thank you for your cooperation and understanding.

Sincerely yours,

Ahava Stein

Ms. Ahava Stein, General Manager
A. Stein – Regulatory Affairs Consulting Ltd., for
Brainsway Ltd.

Administrative

APPENDIX C:

MAGSTIM RAPID OR RAPID2 STIMULATOR OPERATION INSTRUCTIONS

Magstim_Rapid²_User_Manual.docx

MAGSTIM® RAPID²

(b)(4) [redacted]

As part of Brainsway
DTMS System

OPERATING MANUAL

Oct 2012

CE
0086

TABLE OF CONTENTS

GUARANTEE

Equipment manufactured by the Magstim Company Limited is fully guaranteed covering materials and workmanship for a period of one year from the date of shipment. The capacitor is guaranteed for one year, or 1,000,000 discharges, which ever comes first. 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.

The Magstim Company's obligations under this guarantee are limited to repairs or, at the company's option, replacement of any defective parts of our equipment, except batteries, without charge if 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 both, name and/or number and serial number, as it appears on the invoice for said 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.

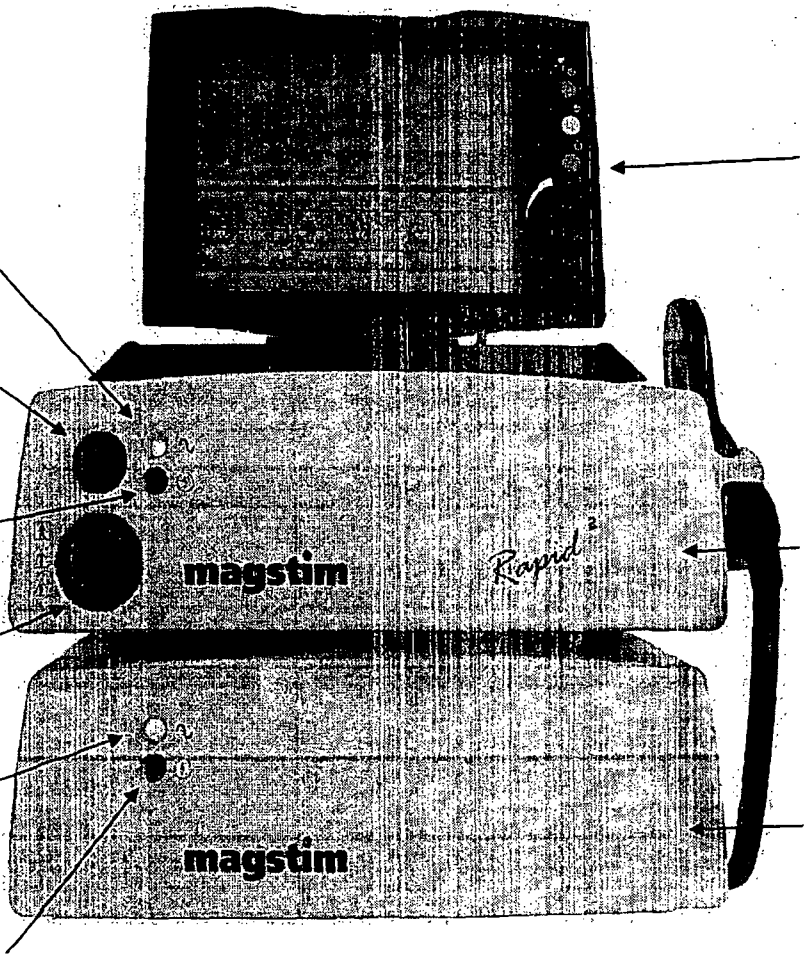
The Magstim Company Limited will only accept responsibility for the effects on safety, reliability and performance of the equipment if:

- 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. PRODUCT DESCRIPTION

1.1 RAPID²SYSTEMS

1.1.1 RAPID²



Unit Power Status Indicator
- Flashes when the system is in STANDBY.
- On continuously when the system is ON.

ON/OFF/STANDBY
This switch toggles the operational state of the Rapid².

ARMED Indicator
This LED is continuously illuminated when the system is armed and high voltages are present in the system.

Coil OUTPUT Socket
See below for description

PSU Power Status Indicator
- OFF when system is in STANDBY or OFF.
- On continuously when system is ON

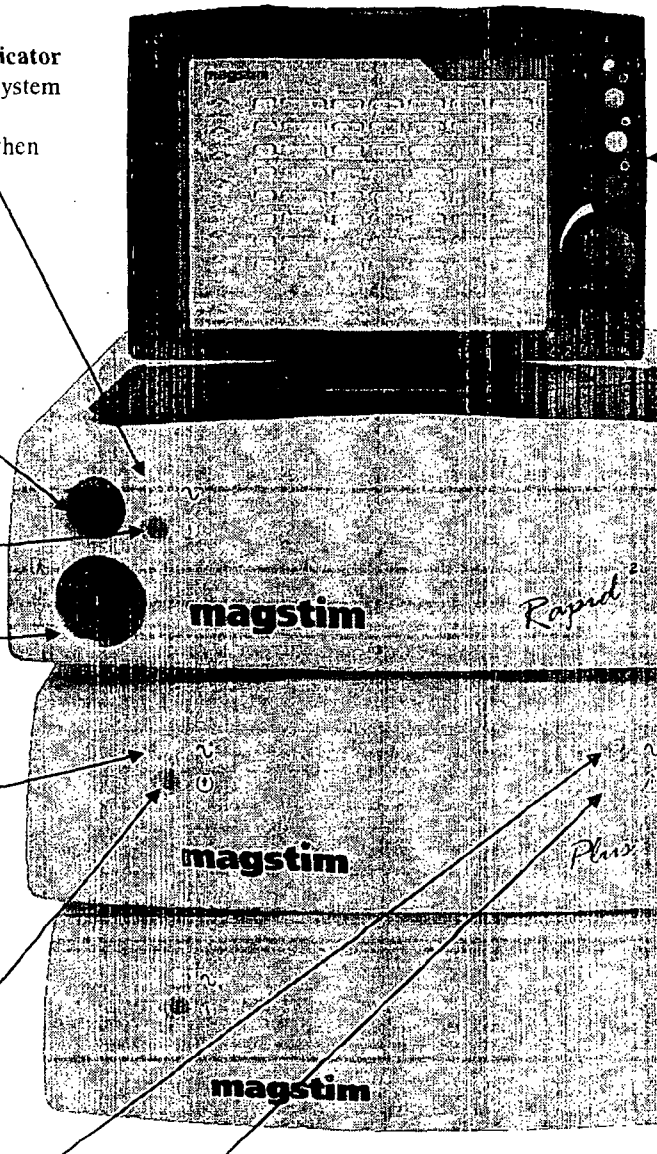
ARMED/FAULT Indicator
This LED is continuously illuminated when the system is armed and high voltages are present in the system. This LED turns RED when a fault has been detected in the PSU.

UI

Main Frame

PSU

1.1.2 RAPID² PLUS¹



Unit Power Status Indicator
- Flashes when the system is in STANDBY.
- On continuously when the system is ON.

ON/OFF/STANDBY
This switch toggles the operational state of the Rapid².

ARMED Indicator
This LED is continuously illuminated when the system is armed and high voltages are present in the system.

Coil OUTPUT Socket
See below for description

PSU Power Status Indicator
- OFF when system is in STANDBY or OFF.
- On continuously when system is ON

***ARMED/FAULT* Indicator**
This LED is continuously illuminated when the system is armed and high voltages are present in the system. This LED turns RED when a fault has been detected in the PSU.

POWER INDICATOR
This LED is continuously illuminated green when the Plus¹ module is powered on.

STATUS/FAULT Indicator
This LED is continuously illuminated green when the system is operating correctly. This LED turns RED when a fault has been detected in either the Dual PSU or Plus¹ Module.

UI

Main Frame

Plus¹ Module

Dual PSU

Coil OUTPUT Socket Operation and SYMBOLS

This socket is used to connect the stimulating coil to the Magstim Rapid². Note that the unit cannot be armed and triggered unless the stimulating coil is connected to this output. Ensure that the locating pin in the coil plug is correctly lined up with the coil output socket before inserting the plug. When the coil plug is fully engaged in the socket, lock the plug in place by turning the black locking ring clockwise.

To remove the coil, put the Magstim Rapid² into standby and turn the black locking ring anti-clockwise.

HIGH VOLTAGE Symbol
This sign warns that voltages in excess of 1500V are present within the instrument.

ATTENTION Symbol – Consult Operating Manual
See warnings in Section 1 regarding the use of the Magstim Rapid².

APPLIED PART Symbol
BF Type Applied Part.

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

1.2 MODE OF OPERATION

The Rapid² works by inducing electrical currents in tissue using a non-invasive stimulating coil at frequencies of up to 100Hz. The stimulating coil is placed near the intended site of stimulation and trigger pulses initiate brief magnetic pulses. The magnetic fields can pass through clothing, tissue and bone to reach otherwise inaccessible areas. One feature of magnetic stimulation is that it is less likely to stimulate pain fibers at the skin surface, reducing the discomfort when compared with conventional electrical stimulation. Magstim Rapid² magnetic stimulators combine stimulation frequencies from 1Hz to 100Hz with a touch screen interface which controls every aspect of the stimulator's control and operation.

CAUTION.

Check the Magstim Rapid² System and its accessories for any signs of damage. If the Magstim Rapid² System or any of its accessories are damaged in any way they must not be used.

Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

To avoid interference problems the Magstim Rapid², and its accessories, should not be used in the vicinity of any equipment that does not comply with EMC Standard EN 60601-1-2, including mobile phones.

For reasons of safety and reliability, if the system is set at 100% power, the user must not exceed 250 stimuli per minute, or 4000 stimuli per hour or 24,000 stimuli for every 24 hour period. This limitation is in addition to any other limitation imposed by the dedicated controller, or heating effects on the stimulating coil and charger circuitry.

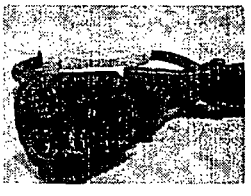
The entire Operating Manual should be studied prior to use and users should be aware, in particular, that high voltages and currents, which can prove lethal, are present if the covers are removed. The Magstim Rapid^2 system"s parts are detailed in Sections 3-6.

Each of the mains connections for the Rapid^2 System must be made via separate, permanent, mains outlets. On no account should a multi-way extension lead be used to connect more than one mains connector to a single mains outlet.
The Rapid^2 System must be used only with the supplied mains leads fitted with an integral filter, as they are required to maintain the System's compliance with EN 60601-1-2 regarding Electro-Magnetic emissions, as is the earth strap fitted between the stimulator and the power supply unit (PSU). In the case of the Super Rapid^2 Plus^1 there are two earth straps. The first between the stimulator and the Magstim Plus^1, the second between the Magstim Plus^1 and power supply unit (PSU).

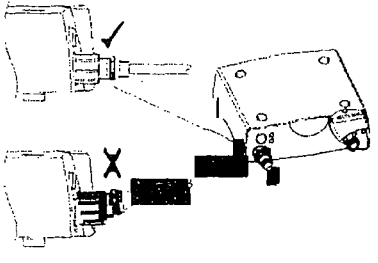
The MEP Pod is designed to be fitted to the Magstim Rapid^2 UI only. Do not attempt to connect it to a computer, or any other equipment, with a similar connector. To do so could result in electric shock/ burns to the patient at the site of electrode attachment. The MEP Pod connector has a hole deliberately blocked to prevent incorrect connection.

1.3 COIL ADAPTER

Coil Adapter



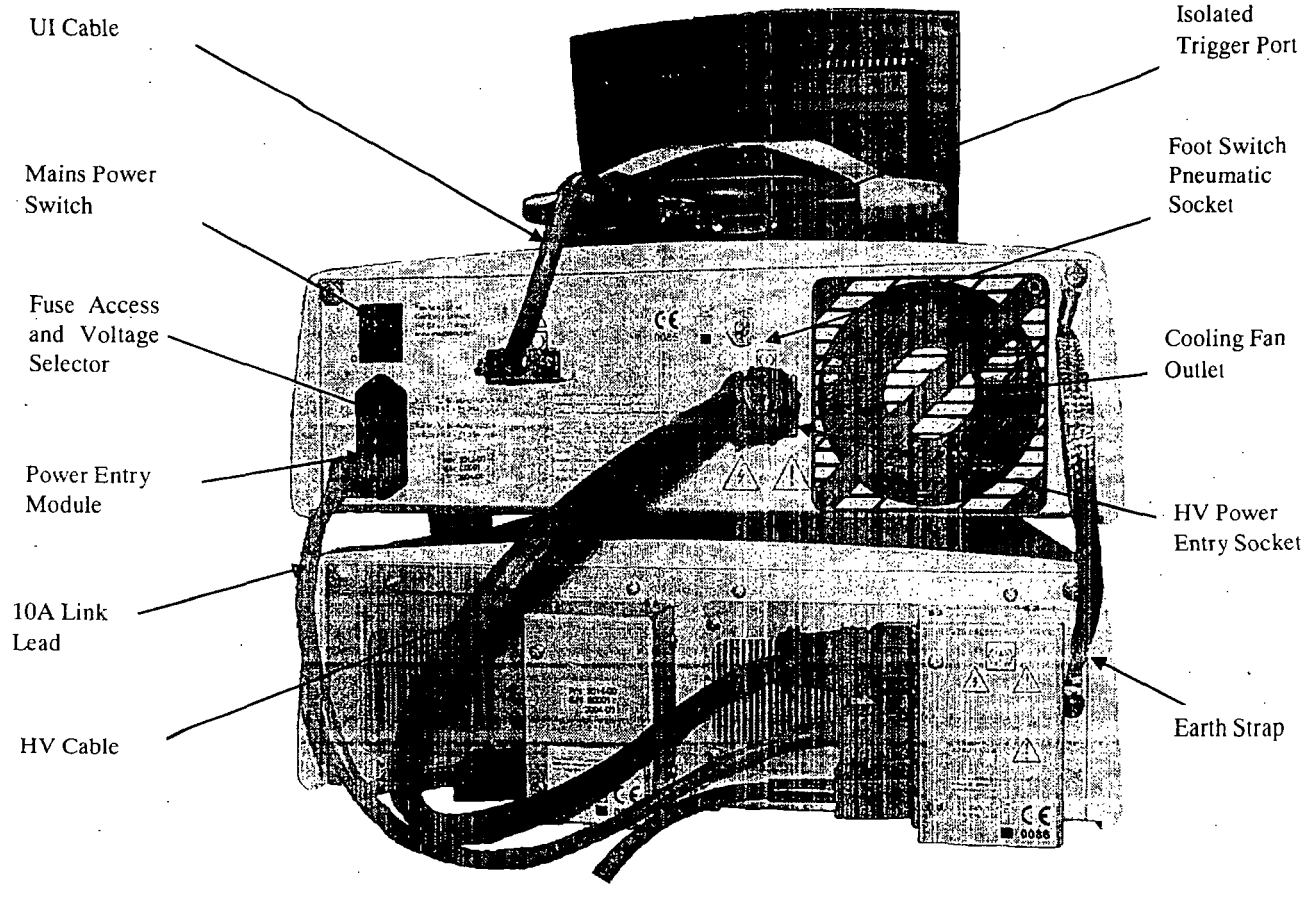
The DTMS coils must be connected to the stimulator via the supplied coil adaptor (P/N 3110-00).
Please note: it is important that the coil is connected correctly. If the coil appears to be misaligned, remove and re-connect the coil. Do not use if the coil appears misaligned.



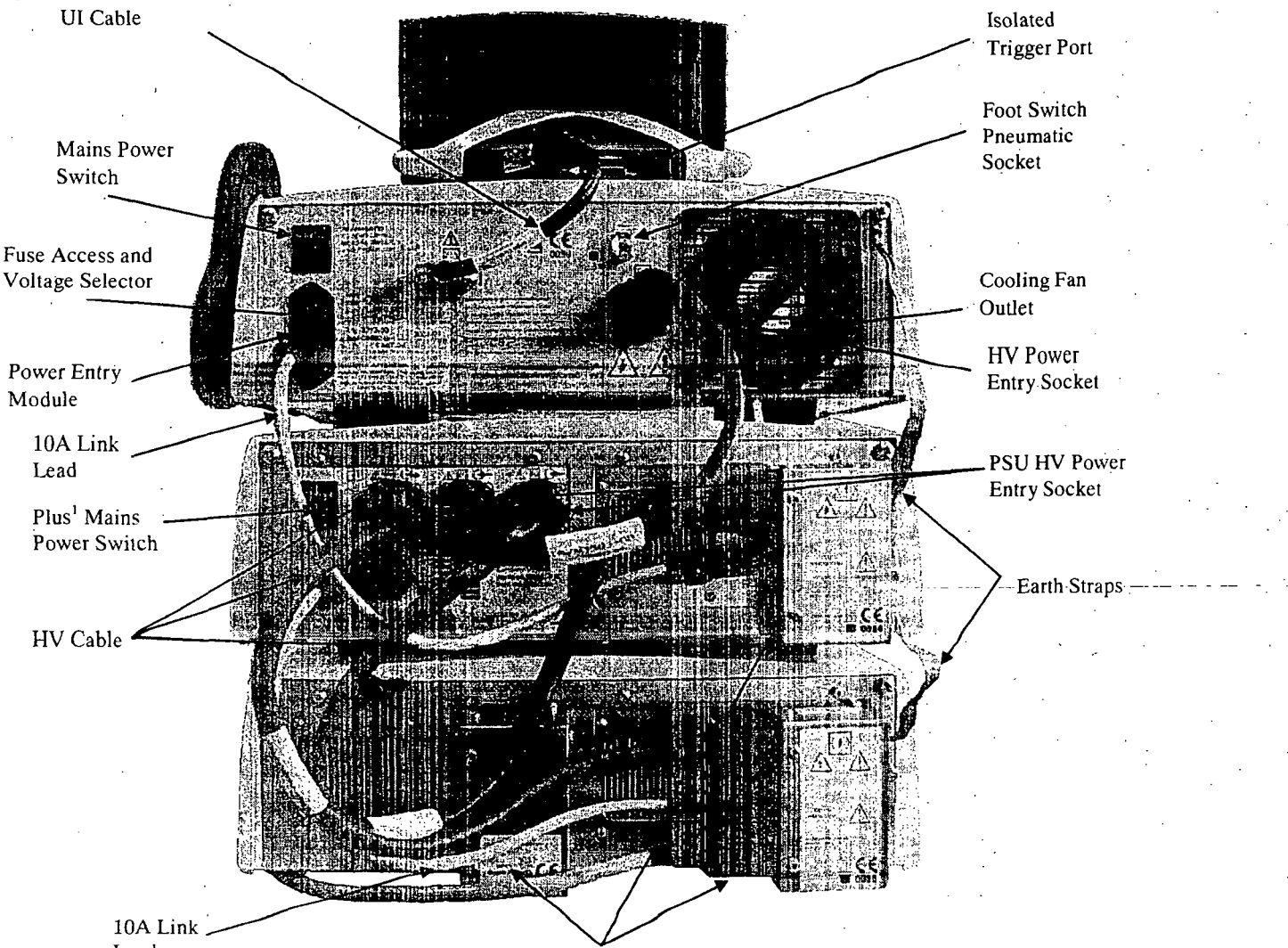
SECTION: 2. SYSTEM SETUP

2.1 REAR VIEW

2.1.1 RAPID^2



2.1.2 RAPID² PLUS¹



Back Panel Symbol Descriptions

Please refer to operating manual for connection instructions.

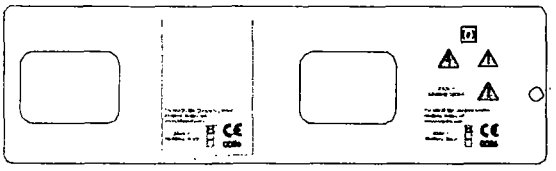
Warning Symbol. Care should be taken when connecting HV cables.

High Voltage can present on this connector.

Connector is an output. Connect the stimulator mainframe to this connector.

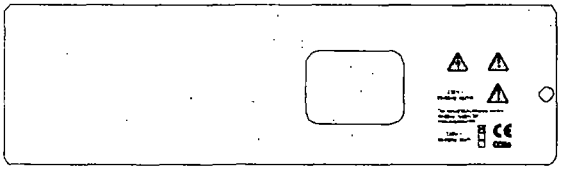
Connector is an input. Connect the HV power supply to this connector.

2.2 Power Supply Module (PSU – 3014-00)

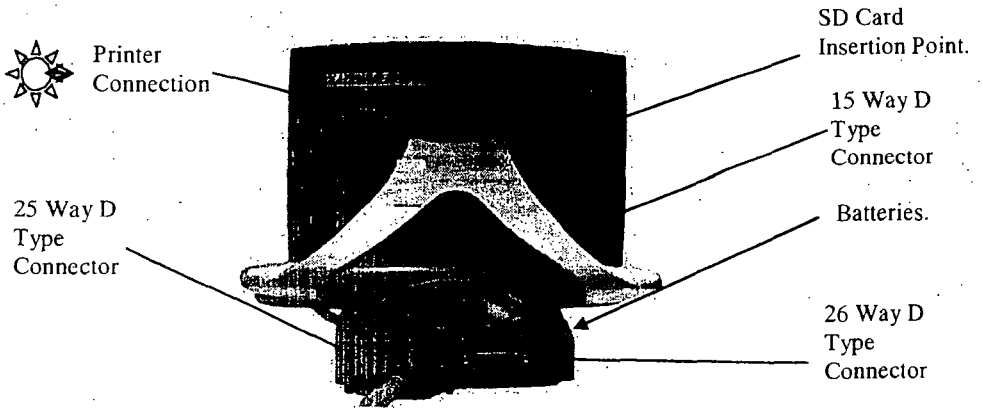


230VPSU units shown. 115V units are identical in appearance to the 230V units, with the exception of the voltage/power rating labels sited on the rear of the units.

Power Supply Module (PSU – 3013-00)



2.3 ADDITIONAL CONNECTIONS



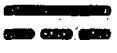
25 Way D Type Connector (situated on rear of the UI, 2 rows of pins)

This connector is situated on the rear of the UI, and has 2 rows of pins. The connector links the UI to the Magstim Rapid^2 as shown on the diagram on the previous page.

26 Way D Type Connector (situated on rear of UI, 3 rows of pins)

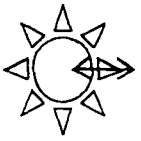
This connector is situated on the rear of the UI, and has 3 rows of pins. It provides trigger input and output signals (see page 43).

DC Power Jack (situated on rear of UI)



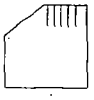
The DC Power Jack is situated on the rear of the UI. This connector allows an external 24V, 750mA DC power supply to be attached. A suitable medical grade supply must be used, conforming to IEC 60601-1. This is NOT required when the UI is connected to the Magstim Rapid^2.

Printer



The Printer is attached to the User Interface via an Optical/RS232 Interface Cable which slides into place on the right hand side at the rear of the UI.

SD Card Socket (situated on rear of the left side panel)



This socket is situated on the rear of the left hand side panel of the UI. This allows connection of an SD Card. This removable memory storage facility enables transfer of data between the UI and external devices, such as PCs.

15 Way D Type Connector (situated on rear of UI behind cover)

This connector is situated on the rear of the UI behind the removable cover. It is designed to accept the Motor Evoked Potential (MEP) pod, available as a separate item. It has type BF connection.

2.4 MEP POD CONNECTION

NOTE. The Rapid^2 must be switched off before connecting or disconnecting the MEP Pod.

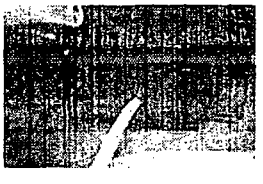
The Motor Evoked Potential (MEP) Pod is an optional component which allows the user to capture EMG signals and display them on the UI. 2 channels are available. The MEP Pod should be mounted as close as possible to the subject but should be kept away from sources of interference, such as power cables. It is recommended that all EMG cables are screened to minimise interference.

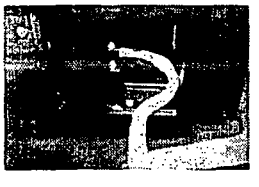
The MEP Pod is designed to be used with surface electrodes only.

The MEP Pod is designed to be fitted to the Magstim Rapid^2 UI only. Do not attempt to connect it to a computer, or any other equipment, with a similar connector. To do so could result in electric shock/ burns to the patient at the site of electrode attachment. The MEP Pod connector has a hole deliberately blocked to prevent incorrect connection.

CONNECTION

The MEP Pod is attached to the rear right hand side of the UI when viewed from the rear. Remove the plastic cover to expose a 15 way D Type socket. Attach the MEP Pod cable, ensuring that the plug is properly inserted. The plastic cover has a notch in its lower edge through which the cable must pass. This cover, when replaced, provides strain relief for the connector. Do not operate the equipment without replacing this cover, as damage to the connector and the internal electronics of the UI is likely.





USE

Attach the EMG cable to the MEP Pod and snap the free connectors onto surface type electrodes (for example, Kendall ARBO H124). Suitable electrodes are available from many medical supply companies, and no recommendation is made as to a particular type. Electrodes should be chosen which are suitable for the collection of EMG data, have snap connectors, and which are compliant with local regulations. When connecting the electrodes, follow the colour code on the MEP Pod.

The EMG connection cable should be screened and should be suitable for use when in direct contact with the skin. No latex should be present in the cable.

The electrodes should be positioned on the target muscle which is controlled by the neurons being stimulated. For example, if the area of the motor cortex which controls the hand is to be stimulated, the surface electrodes should be placed on abductor digiti minimi, about 1cm apart. The ground electrode should be placed on the wrist. Care should be exercised when placing surface electrodes. It is important that a consistent approach is observed, as the amplitude of the EMG signal is dependent on the position of the electrodes. Good practice in relation to skin cleaning should be observed.

CAUTION

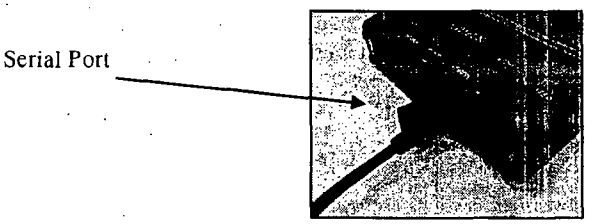
For safety reasons, do not leave patient cables attached to the MEP Pod if they are not being used. If an unused cable is left connected, and the patient is connected to the other channel, there is the possibility that the unused cable may touch an earthed surface which could allow current to flow through the patient to ground.

Do not allow the coil or the coil cable to come into close proximity with the MEP Pod patient cables. During discharge, current may be induced in these cables.

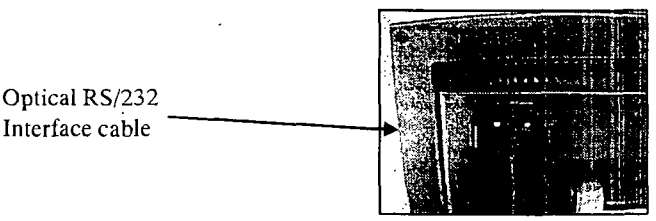
2.5 PRINTER

TO SET UP THE PRINTER

1. Insert the cable connector straight into the Printers Serial Port to power the printer via the Mains



2. Connect the other end of the cable to the back of the UI via an optical RS/232 Interface cable by sliding the connector into the slot until tight. Connect the printer to its power supply and the power supply to the mains.

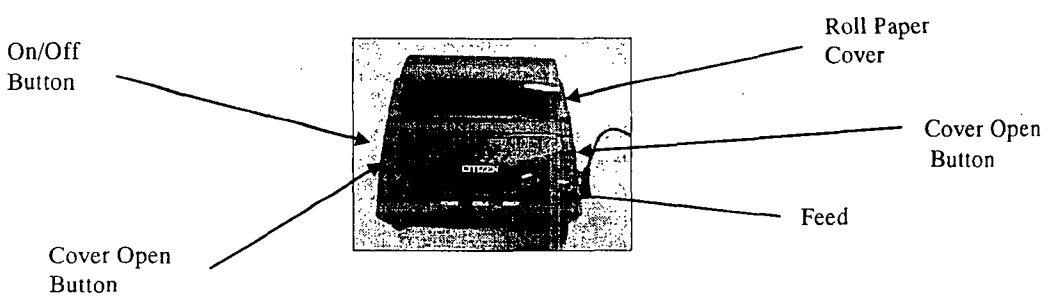


3. Switch the printer on via the green button on the left hand side of the printer. The „Power" LED should now be illuminated green.

TO LOAD THE PAPER

1. Push the Cover Open buttons on the side of the printer; this should open the Roll Paper Cover.
2. Align the edges of the paper roll against the paper holders and push down gently.
3. Pull the paper through and close the cover.

The Printer is now ready to be used.



2.6 SET-UP

1. Before using the instrument, ensure that the correct fuses are fitted and that the voltage selector is set to suit the country's supply voltage (this statement applies to the Rapid² Main Frame and Magstim Plus¹ only).

   The Rapid² Main Frame contains 2 fuses, rated at T 1.25A, while the Magstim Plus¹ contains 2 fuses, rated at T 250mA. These values apply to both 115V~ ±10% and 230V ~ ±10% mains input.

   For information on changing the fuses, please see Section 9.

2. Place the system in a room near multiple power sockets and ensure easy access to and around the equipment. Make sure to stack the system as shown in Section 2.1.

3. Label the entrances to the room to warn of the presence of strong magnetic fields and to exclude those wearing pacemakers and/or electronic implants.

4. Connect the power cables provided to the power supply socket(s) on the rear of the PSU. The power requirement of the Magstim Rapid² depends on the PSU used and the parameters set by the UI.

5. **The power cables must be connected directly to wall power outlet sockets,** and not via a terminal block. **The Rapid² System must be used only with the supplied mains leads fitted with an integral filter,** as they are required to maintain the System's compliance with EN 60601-1-2 regarding Electro-Magnetic emissions, as is the earth strap fitted between the stimulator and the power supply unit (PSU). Please refer to Section 3.1 for reference.

6. Rapid²
   Connect the HV cable from the PSU to the rear panel of the Main Frame. Connect the 10A link lead between the PSU Module and the stimulator Main Frame. Please refer to section 3.1.1 for reference.

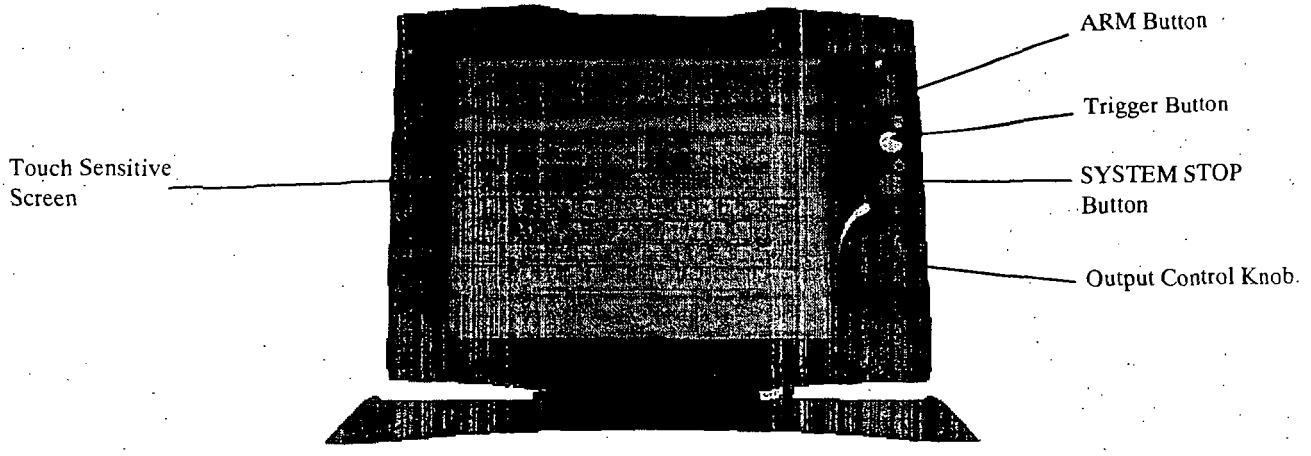
   Rapid² Plus¹
   Connect two of the HV cables from the two the PSUs to the two HV inputs (indicated by a pair of ⟜ symbols) located on the rear panel of the Magstim Plus¹. Connect the third HV cable between the HV ouput (indicated by a ⟜ symbol) on the rear panel of the Magstim Plus¹ to the HV input on the rear of the Main Frame. Connect a 10A link lead from the Dual PSU Module to the Magstim Plus¹ and from the the Magstim Plus¹ PSU module and the stimulator Main Frame. Please refer to section 3.1.2 for reference.

7. Connect the UI Controller to the Magstim Rapid² Main Frame via the interface cable supplied.

8. Connect the Stimulating Coil to the front panel connector of the Magstim Rapid².

9. Apply mains power to the Rapid² System by switching the mains power switch on the rear panel of the Rapid² Main Frame and, if relevant the mains power switch on the rear panel of the Magstim Plus¹ to the ON position.

2.7 USER INTERFACE (UI)



ARM Button

The Magstim Rapid² can be put into the **ARMED** mode by momentarily pushing the Green **RUN** button. This can only be achieved if the stimulating coil is connected to the **COIL OUTPUT** socket.

TRIGGER Button

The Magstim Rapid² can be triggered, and a magnetic pulse produced, by pushing the Yellow **TRIGGER** button.

SYSTEM STOP Button

The Magstim Rapid² can be put into the safe inactive default mode by momentarily pushing the Red **STOP** button. In this mode, the instrument will discharge internally.

OUTPUT CONTROL Knob

This control allows the user to change the screen-selected parameter to the desired value. It is therefore used to alter screen settings as well as changing the power output of the stimulator.

TOUCH-SENSITIVE SCREEN/ SYSTEM DISPLAY

All selections are made via the touch-screen. To select, touch the centre of the button symbol next to the desired menu option. Do not press hard, or use a sharp or pointed object to make the selection, as this may damage the touch screen.

In the set-up screens, all selectable items are coloured in pale blue; white items are non-selectable. The Rotary Control Knob can only be used to change parameters already selected. Details regarding the contents and operation of the UI Screens are given in Sections 4, 5 and 6

Note: If the UI is not used for 30 minutes it will go into a standby condition. In standby, the screen will appear blank and the blue LED in the upper right corner of the front bezel will pulse. Touch the screen to restore the UI.

2.8 STIMULATION

See Section 3 to select the desired mode, stimulating power, stimulation frequency, train duration and inter-train delay.

Activate the ARM button on the UI bezel to arm the unit. The system will charge and the UI will display READY in the system status window.

NOTE: The system cannot be armed if the footswitch is active.

Position the stimulating coil on the desired area of tissue. The system can be triggered by either pressing the footswitch on the trigger button or on the UI. A clicking noise will emanate from both the stimulating coil and the Magstim Rapid² each time the Magstim Rapid² is triggered. This indicates that a magnetic pulse is being delivered by the stimulating coil, which is stimulating the nerves beneath it.

When necessary, it is possible to reposition the stimulating coil and/or to modify the power level on the UI to suit the requirements for the next stimulus. Meanwhile, the system will have recharged and can be triggered once again in the normal manner.

When the stimulations have been completed, press the SYSTEM STOP button on the UI.

The system can only be fired when one of the following UI screens is displayed:

- Single Pulse Mode,
- Repetitive Mode
- Session Mode.

EXTERNAL TRIGGERING

If an external triggering device is used, the Rapid² uses the power set to govern the maximum discharge frequency. Therefore, if the external frequency is set higher than the power set will allow, the stimulator will discharge at the maximum rate the stimulator can achieve for the power set, and not at the rate from the external trigger source. In these situations, reducing the power will allow the discharge frequency to increase. However, during external triggering there are no duration limits on the trains. Therefore, it is probable under high frequency operation that enough energy will be discharged into the coil to result in its temperature rising rapidly above 40°C following the system going into a coil over-temp condition and reverting to its discharged state.
It is important that if this type of operation is intended the protocol be run prior to use on a patient and the surface temperature of the coil monitored to ensure that the patient is not exposed to excessive temperatures.

NOTE. If the external trigger is set to the level triggering option it is possible for auto-triggering to occur. Also note than when using a Rapid² Plus¹ with external triggering, the performance is limited to that of the Super Rapid².

IMPORTANT

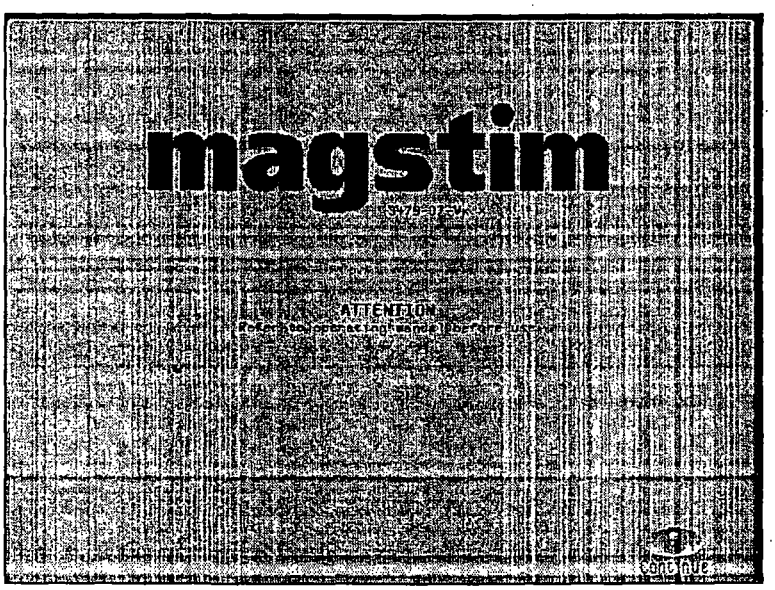
The temperature of the internal components become elevated during operation. The system should be left on, and uncovered, for approximately ten minutes following completion of stimulation to enable the fan to cool the internal system components.

SECTION: 3. SYSTEM OPERATION INSTRUCTIONS.

Switch on the system using the ON/OFF/STANDBY button on the front of the Rapid^2 Main Frame.

3.1 WELCOME SCREEN

The UI will activate automatically. The „Welcome Screen" will be displayed.



The system will fully initialise and the Options Menu will appear after 15 seconds.

Pressing the Continue button before the system has fully initialised gives access to the following options:

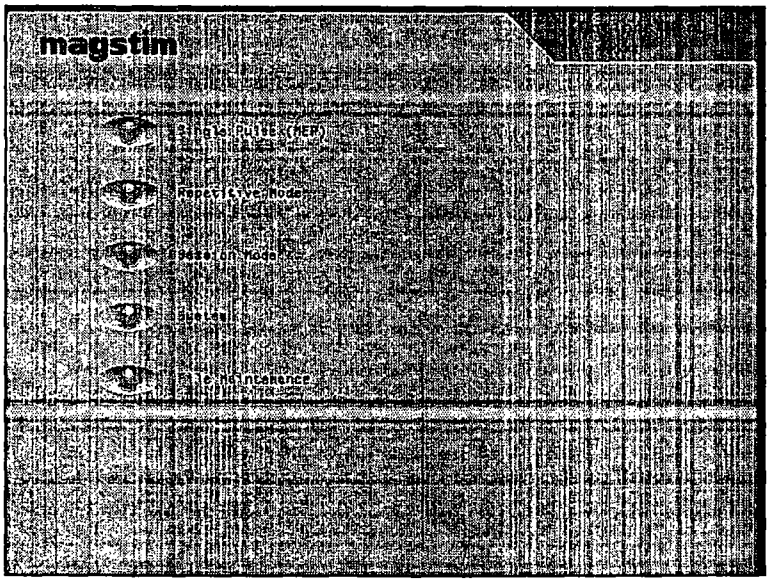
Single Pulse Mode

System

File Maintenance

The system needs to be fully initialised before ***Repetitive Mode*** and ***Session Mode*** are accessible.

3.2 MAIN OPTIONS MENU



All selections are made via the touch-screen. To select, touch the centre of the button symbols.

Single Pulse — Selecting this option will call up the ***Single Pulse Mode*** Screen.

This allows the system to be fired at a maximum rate of 1Hz, up to 100% power and 0.5 Hz from 101-110%. It also allows an MEP module to be configured.

Repetitive Mode — Selecting this option will call up the Repetitive Mode Set-up Screen. (See section 4.5) This allows the system to run a user defined train of pulses from a single trigger.

Session Mode — Selecting this option will call up the Session Mode Setup Screen. (See section 4.9) This allows the system to run a series of separately defined trains of pulses from a single trigger.

System — Selecting this option will call up the Systems Options Menu Screen. (See Section 5)

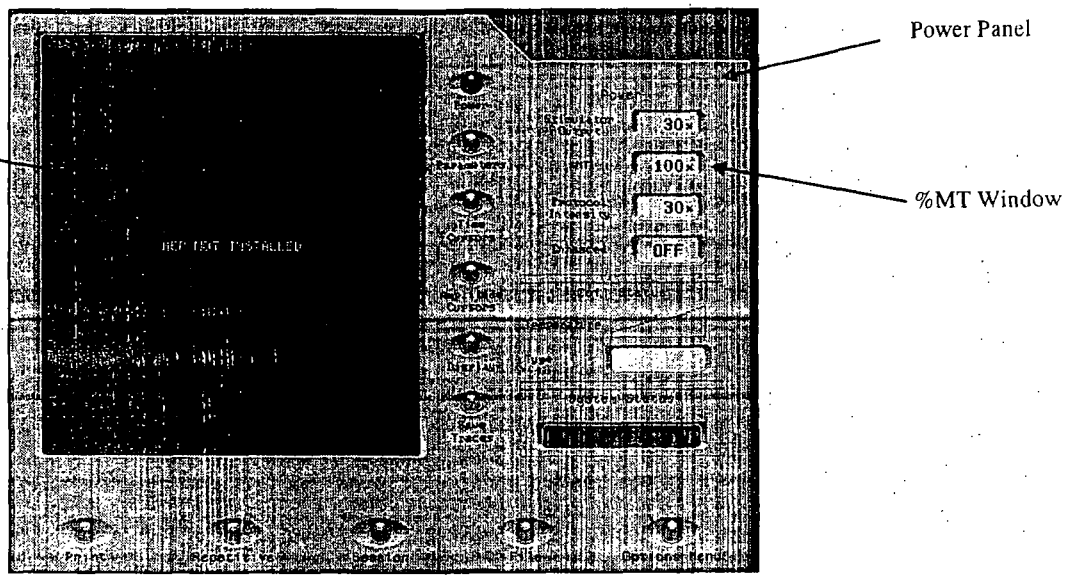
File Maintenance — Selecting this option will call up the File Maintenance Screen. (See section 6.1)

3.3 SINGLE PULSE MODE

The trace window is always active on this screen and is intended to display EMG response information from the MEP Pod. If no MEP pod is connected, the screen message will show „MEP NOT INSTALLED."

To alter the settings, touch the window next to the required setting. A dark blue margin will appear within the selected window. The settings can be quickly altered using the Rotary Control Knob.

POWER PANEL



The Power Panel is selected by pressing the Power button. When Power is selected, the button turns green.

Power	To adjust the system power level, touch the Stimulator Output window on the Power Panel. The power level is set to the default value of 30%. The power can be increased, or decreased, in 1% increments by using the Rotary Control Knob. Each complete 360° rotation changes the output level by approximately 20%.
%MT	The %MT (Motor Threshold) window, displays the percentage of stimulator output which is to be transferred to the Protocol Intensity window. The %MT cannot be adjusted to give more than the 100% in the Protocol Intensity window.
Enhanced	This option enables the power level to be increased up to 110% power. This option is only available in Single Pulse Mode.

If Repetitive Mode or Session Mode is accessed via Single Pulse Mode, the Protocol intensity value will be carried over into these modes.

All other configurable Single Pulse Mode options are available only when the MEP Pod is connected.

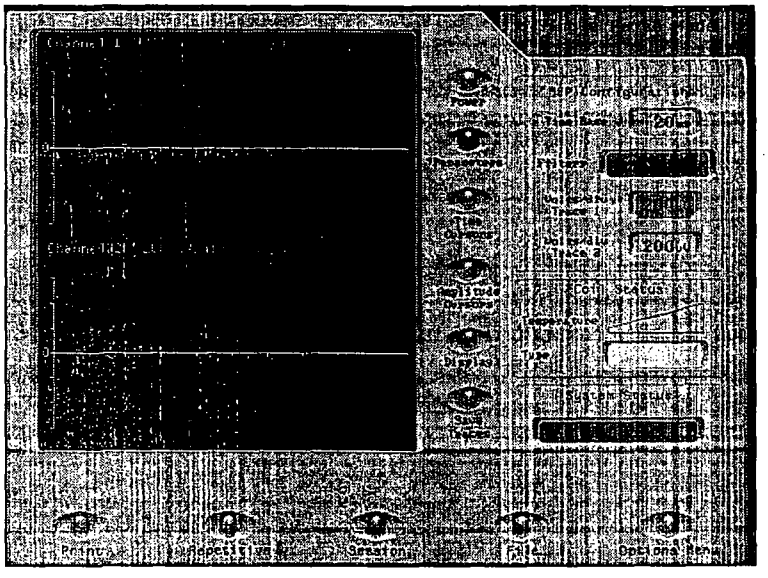
NOTE. The Rapid² must be switched off before connecting or disconnecting the MEP Pod.
NOTE. Enhanced mode is not available when using an Air Film Coil (P/N 3950-00)

3.4 SINGLE PULSE MODE (MEP POD CONNECTED.)

The MEP Pod must be connected to access the following options and to view the traces.

NOTE. The Rapid² must be switched off before connecting or disconnecting the MEP Pod.

PARAMETERS PANEL



Press the Parameters button (green when selected) to access the MEP Configuration panel.

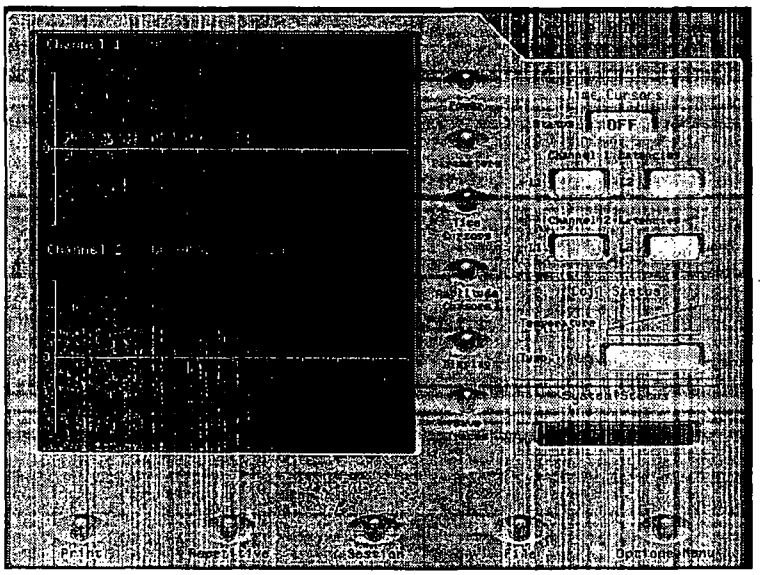
Time Base Selecting the Time Base window allows the user to set the MEP total sample period. The selectable options are; 20ms, 50ms, 100ms, 200ms and 500ms and are selected using the Rotary Control Knob. The trace width will show the whole of the selected sample period.

Filters Selecting the Filters window allows the user to set the MEP Filter using the Rotary Control Knob. Selectable options: 2Hz-10kHz and 20Hz-10kHz.

Volts/Div Trace 1 Selecting the Volts/Div Trace window allows the user to set the scaling factor for channel 1. Selectable options: 50µV, 100µV, 200µV, 500µV, 1mV, 2mV, 5mV and 10mV. The default setting is 200µV.

Volts/ Div Trace 2 Selecting the Volts/Div Trace window allows the user to set the scaling factor for channel 2. Selectable options: 50µV, 100µV, 200µV, 500µV, 1mV, 2mV, 5mV and 10mV. The default setting is 200µV.

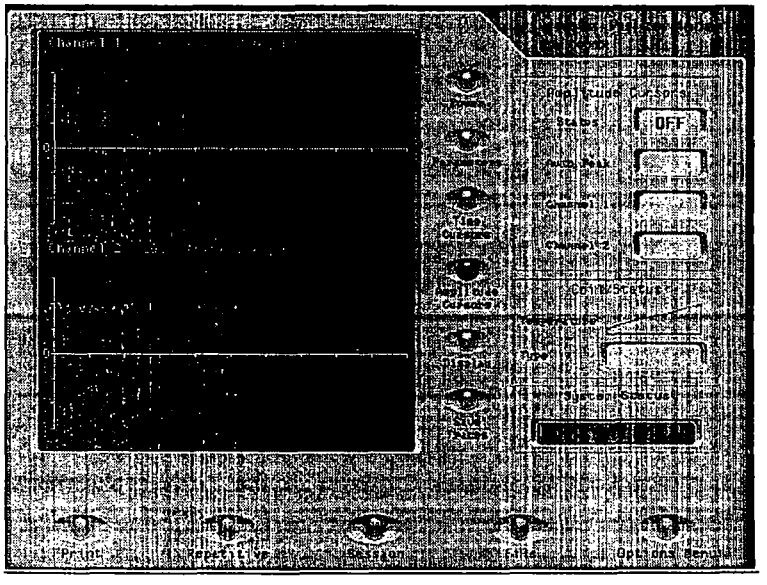
TIME CURSORS PANEL



Press the Time Cursors button (green when selected) to access the Time Cursors panel.

Status	Select the Status window to turn the Latency Cursors on and off. The default setting is OFF.
Channel 1 Latencies	Select L1 or L2 to activate a cursor for adjustment. When the cursors are active, their current screen time value will be displayed on the trace window. The trace of the selected cursor can be moved using the Rotary Control Knob, for example to identify the time of an event.
Channel 2 Latencies	Select L1 or L2 to activate a cursor for adjustment. When the cursors are active, their current screen time value will be displayed on the trace window. The trace of the selected cursor can be moved using the Rotary Control Knob, for example to identify the time of an event.

AMPLITUDE CURSORS PANEL



Press the Amplitude Cursors button (green when selected) to access the Amplitude Cursors panel.

Status Select the Status window to turn the Amplitude Cursors on and off. The default setting is OFF.

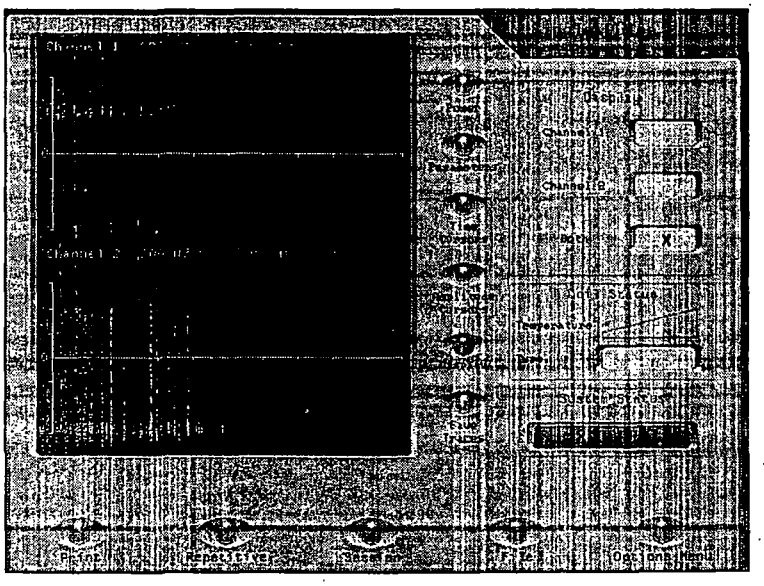
Auto Peak Select the Auto Peak window to turn auto peak on and off. The default value is ON. With this option ON, each time a new set of MEP waveforms are displayed, the cursors will automatically move to the peak values for each trace. With the option OFF, the amplitude cursors will remain at their previous values. Amplitude Cursors must be ON for this option to become available.

Channel 1 This window allows the Amplitude Cursor on Channel 1 to be moved, for example to mark peaks. Amplitude Cursors must be ON for this option to become available.

Channel 2 This window allows the Amplitude Cursor on Channel 2 to be moved, for example to mark peaks. Amplitude Cursors must be ON for this option to become available.

Note, in Repetitive Mode or Session Mode, the Amplitude Cursor positions set in Single Pulse Mode will remain marked by the Amplitude Cursor on the trace.

DISPLAY PANEL



Press the Display button (green when selected) to access the Display panel.

Channel 1. Select the Channel 1 window to show Channel 1 only in the trace window.

Channel 2. Select the Channel 2 window to show Channel 2 only in the trace window.

Both. Select the Both window to show both traces simultaneously in the trace window.

SAVE TRACES

Select Save Traces to save the current trace. If a file is already open the trace will be saved to this file. Alternatively go to File Maintenance and save the trace to a file (See section 6).

COIL STATUS PANEL

The Coil Status panel will show the temperature and type of coil.

SYSTEM STATUS PANEL

The System Status panel shows the system status.

TRACE WINDOW

The Trace window will be updated when a stimulation occurs. The maximum update rate for the trace window is 4 times a second, depending on the amount of information to be displayed.

Print For Print operations see Section 6.5.

Repetitive This takes the user to the ***Repetitive Setup*** Screen. (See Section 4.5)

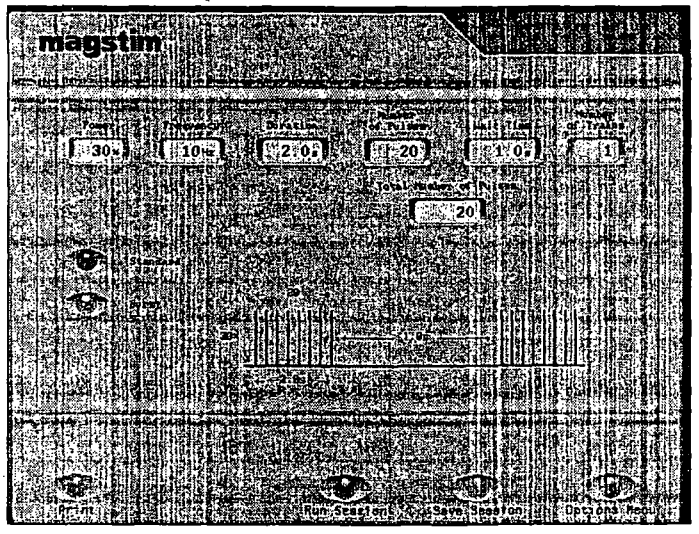
Session This takes the user to the ***Session Setup*** screen (see Section 4.9).

File This takes the user to the ***File Maintenance*** screen (see Section 6.1).

Options Menu Selection of this option will return the user to the ***Options Menu*** screen.

3.5 REPETITIVE MODE: STANDARD SETUP

The Repetitive Setup Screen allows the user to set the following adjustable parameters to the desired values to enable a session to be run. If Repetitive Setup is accessed from Single Pulse Mode, the protocol intensity value established in Single Pulse Mode will be carried over into the power window.



Power Select the power window and use the Rotary Control Knob to adjust the System Power Level. The power can be increased, or decreased, in 1% increments.

Frequency Selecting the Frequency window allows the user to set the frequency of the pulses to a value between 0 and F_{Max}Hz in 0.1Hz increments up to 30Hz, 1.0Hz thereafter. The maximum frequency can be up to 100Hz depending on the power level set and the system configuration. A table detailing the available power/ frequency combinations is included in Section 10.

Duration Selecting the Duration window allows the user to set the duration of the pulse train to between 0.1 up to a maximum of 600 seconds, in 0.1 second increments up to 30 seconds, and in 1.0 second increments thereafter. The maximum duration allowed depends on the power and frequency settings and the connected coil (see section 10.7 for coil compatibility information). On entering the duration and frequency, the number of pulses is automatically calculated by the UI and displayed.

Number of Pulses Selecting the Number of Pulses window allows the user to set the number of pulses in a train to between 1 and 60000 in steps of 1. The number of pulses cannot be set to exceed the maximum allowed duration. If the frequency is altered, the system will automatically adjust the duration to fit the current number of pulses.

Wait Time Selecting the „Wait Time" allows the user to set the wait time to between 1 and 540 seconds, in 0.1 second steps. However, if the minimum wait time required for the selected protocol is greater than that selected, the UI will display a message „Wait period too short, auto-set to minimum". Select „YES" to set the wait delay to the minimum allowed for the chosen protocol. Select „NO" to reset the protocol parameters manually.

No. of Trains Selection of this option allows the user to set the number of times that the specified train runs to a value between 1 and 999 in steps of 1. The number of trains cannot be set to exceed the maximum total number of pulses of 65000.

Information Window Appears at the bottom of the screen. The Information Window provides information such as „Coil OK to run," and alerts the user to actions required, protocols that are unable to be completed, or equipment which needs to be attached.

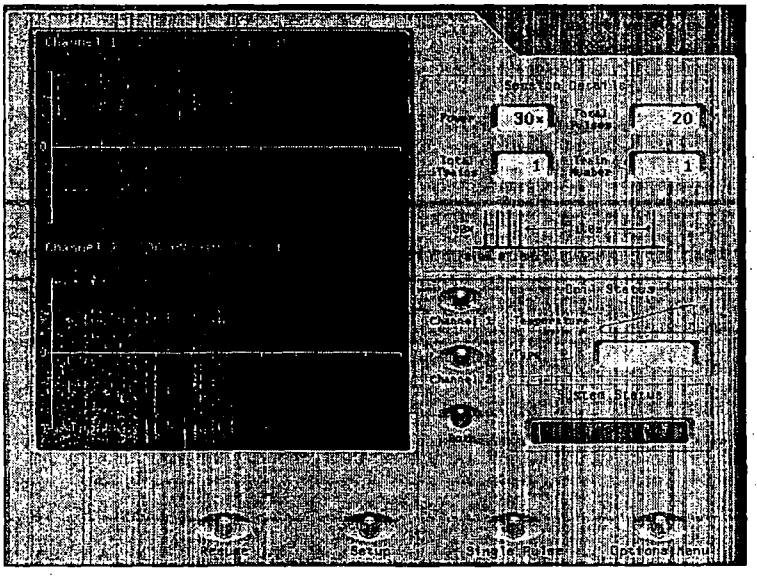
Print For Print operations see Section 6.5.

Save Session Save Session takes the user to the File Maintenance screen (See section 6.1)

Options Menu Selection of this option will return the user to the Options Menu screen.

RUN SESSION This screen takes the user to the Repetitive Mode screen in order to run a session.

3.6 REPETITIVE MODE: STANDARD



SESSION DETAILS

The Session Details panel shows a pictorial representation of the train currently running, and shows the settings established in Repetitive Setup.

Channels 1,2 and Both Selecting Channel 1, Channel 2 or Both determines whether both traces are shown simultaneously or individually.

COIL STATUS PANEL

The Coil Status panel will show the temperature and type of coil.

SYSTEM STATUS PANEL

The System Status panel shows the system status.

Trace Window The Trace window will be updated when a stimulation occurs. The maximum update rate for the trace window is, 4 times a second, depending on the amount of information to be displayed.

If the amplitude cursors are active then the last position set for each cursor in Single Pulse Mode will be displayed. The cursor position will remain fixed until Single Pulse Mode is re-entered

In order to save the traces it is necessary to return to Single Pulse Mode and save the data as before. The information will remain on each trace window until a new trace is generated, when the new trace will overwrite the previous trace.

Resume This option is available if the system is armed and the previous session was not completed. Selecting Resume will return the session to the point at which it was stopped, beginning at the start of the next train regardless of when the last train was stopped.

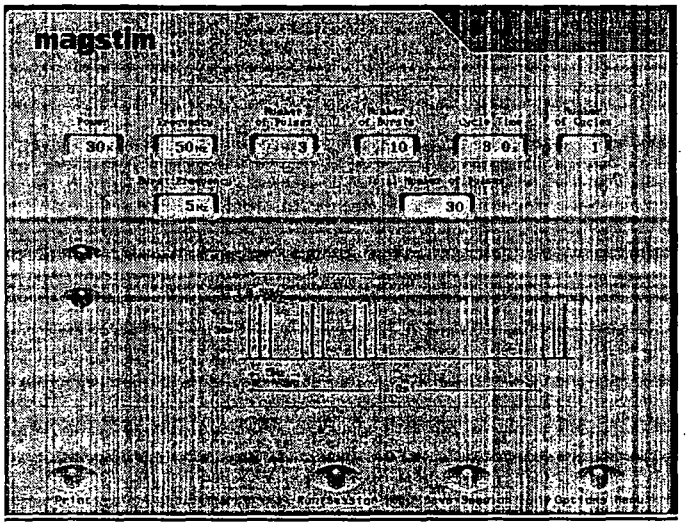
Setup Selection of this option will return the user to the Repetitive Setup screen.

Single Pulse Selecting this option will return the user to the Single Pulse Mode screen.

Options Menu Selection of this option will return the user to the Options Menu screen.

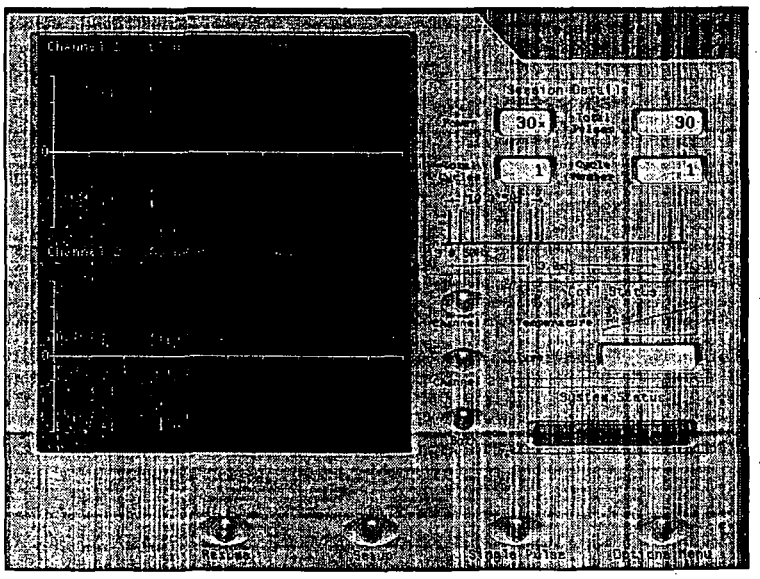
3.7 REPETITIVE MODE: BURST SETUP

Select Burst Mode from the Repetitive Setup screen to allow the following adjustable parameters to be set.
If Repetitive Setup is accessed from Single Pulse Mode, the protocol intensity value established in Single Pulse Mode will be carried over into the power window.



Power	Selecting the Power window allows you to adjust the power level between 0% and 100% using the Rotary Control Knob.
Frequency	Selecting the Frequency window will allow the user to set the frequency of the pulses to a value between 0 and F_{Max}Hz in 1Hz increments. The maximum frequency can be up to 100Hz depending on the power level set and the system configuration. A table detailing the available power/ frequency combinations is included in Section 10.
Number of Pulses	Selecting the „Number of Pulses" window allows the user to set the number of pulses per Burst. The Number of Pulses can be set between 1 and 10 using the Rotary Control Knob.
Number of Bursts	Selecting the „Number of Bursts" window allows the user to set the number of bursts in a cycle. The number can be set between 1 and 500 in increments of 1.
Burst Frequency	Selecting the „Burst Frequency" window allows the user to set the Burst frequency between 1Hz and 10Hz.
Cycle Time	Selecting the „Cycle Time" window allows the user to set the time for each cycle in seconds. The time can be set between 1 and 500 seconds in increments of 0.1 seconds. However, if the minimum cycle time required for the selected protocol is greater than that selected, the UI will display a message „Cycle time too short, auto-set to minimum". Select „YES" to set the cycle time to the minimum allowed for the chosen protocol. Select „NO" to reset the protocol parameters manually.
Number of Cycles	Selecting the „Number of Cycles" window allows the user to set the number of cycles in a session. The value may be set between 1 and 999 in increments of 1. The number of cycles cannot be set to exceed the maximum total number of pulses of 65000.
Print	For Print operations See Section 6.5.
Run Session	This screen takes the user to the Repetitive Mode Screen to run a session.
Save Session	Save Session takes the user to the File Maintenance screen (See section 6.1).
Options Menu	Selection of this option will return the user to the Options Menu screen.

3.8 REPETITIVE MODE: BURST



SESSION DETAILS PANEL.

The Session Details panel shows a pictorial representation of the cycle currently running, and shows the settings established in Repetitive Setup.

Channels 1,2 and Both Selecting Channel 1, Channel 2 and Both determines whether both traces are shown simultaneously, or individually.

Trace Window The Trace Window will be updated when a stimulation occurs. The maximum update rate for the trace window is, 4 times a second, depending on the amount of information to be displayed.

If the amplitude cursors are active then the last position set for each cursor in Single Pulse Mode will be displayed. The cursor position will remain fixed until Single Pulse Mode is re-entered.

In order to save the trace, it is necessary to go back to Single Pulse Mode and save the data as before. The information will remain on each trace window until a new trace is generated, when the new trace will overwrite the previous trace.

Resume This Option is available if the system is armed and the previous session was not completed. Selecting Resume will return the session to the point at which it was stopped at the beginning, at the start of the next cycle regardless of when the last cycle was stopped.

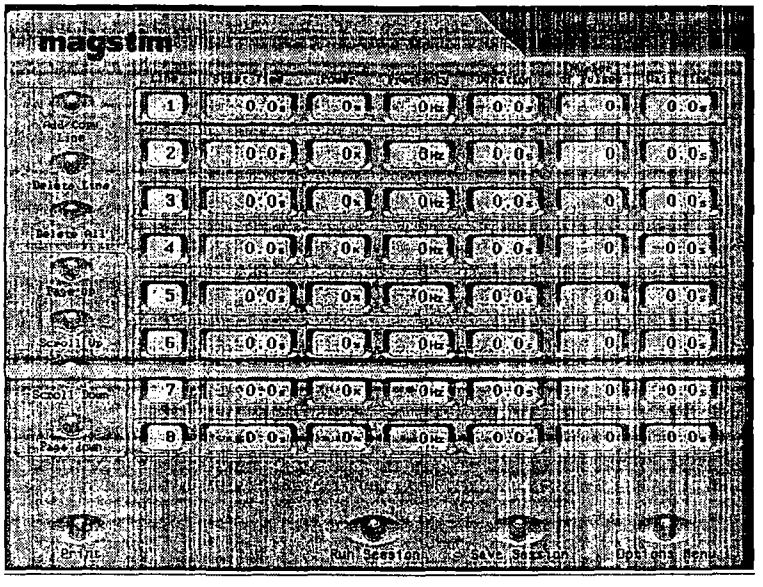
Setup Selection of this option will return the user to the Repetitive Setup screen.

Single Pulse Selecting this option will return the user to the Single Pulse Mode screen.

Options Menu Selection of this option will return the user to the Options Menu screen.

3.9 SESSION MODE: SETUP

This screen allows the user to set up a series of individual lines, each with different Power, Frequency, Duration and Number of Pulses parameters. See section 4.5 for limits. If Session Setup is accessed from Single Pulse Mode, the protocol intensity value established in Single Pulse Mode will be carried over into the power window.



Add/Copy Line Selection of this option (press the window to select) enables the user to copy the session line settings of the selected line and copy them into the next line.

Delete Line Selection of this option will delete the highlighted line.

Delete All This button will delete all lines, allowing the user to start writing a new protocol.

Page Up Pressing this button will allow the user to move up pages if the protocol has more lines than will fit on a single screen.

Scroll Up This allows the user to move up one line at a time.

Scroll Down Selection of this option allows the user to scroll down one line at the time to view train lines below those displayed on the screen. There are up to 30 lines available.

Page Down Moves down a page at a time if the Protocol has more lines than will fit on a single screen.

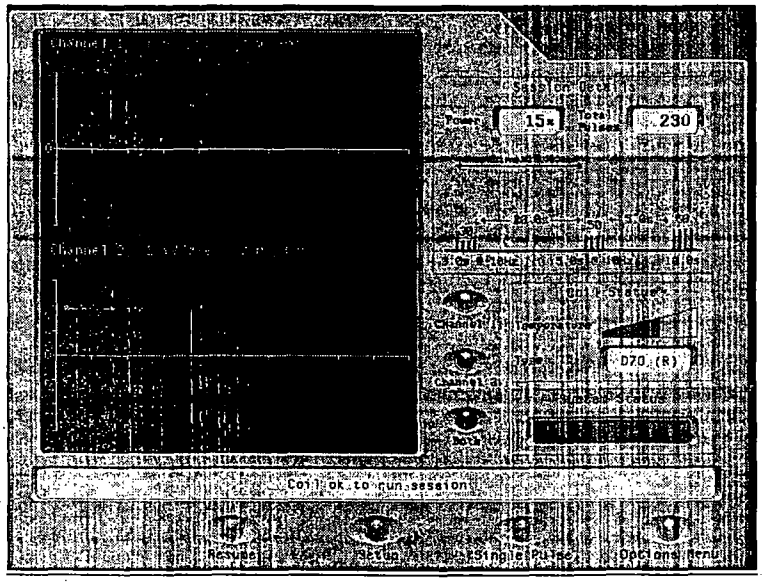
Print For Print operations see Section 5.5.

Run Session Selection of this option will call up the Session Mode screen.

Save Session Selection of this option will call up the File Maintenance screen (See section 5.1) and allows the user to save the session set up.

Options Menu Selection of this option will return the user to the Options Menu screen.

3.10 SESSION MODE



SESSION DETAILS

Session Details shows a pictorial representation of 3 lines of the session running currently.

Channels 1,2 and Both Selecting Channel 1, Channel 2 and Both determines whether both traces are shown simultaneously, or individually.

Trace Window The Trace Window will be updated when a stimulation occurs. The maximum update rate for the trace window is, 4 times a second, depending on the amount of information to be displayed.

If the amplitude cursors are active then the last position set for each cursor in Single Pulse Mode will be displayed. The cursor position will remain fixed until Single Pulse Mode is re-entered.

In order to save the trace, it is necessary to go back to Single Pulse Mode and save the data as before. The information will remain on each trace window until a new trace is generated, when the new trace will overwrite the previous trace.

Resume This Option is available if the system is armed and the previous session was not completed. This option will return the session to the point at which it was stopped. This will always begin at the start of the next session line regardless of when the last session line was stopped.

In order to save the traces, it is necessary to go back to Single Pulse Mode and save the data as before. The information will remain on each trace window until a new trace is generated. Then it will be overwritten by a new one.

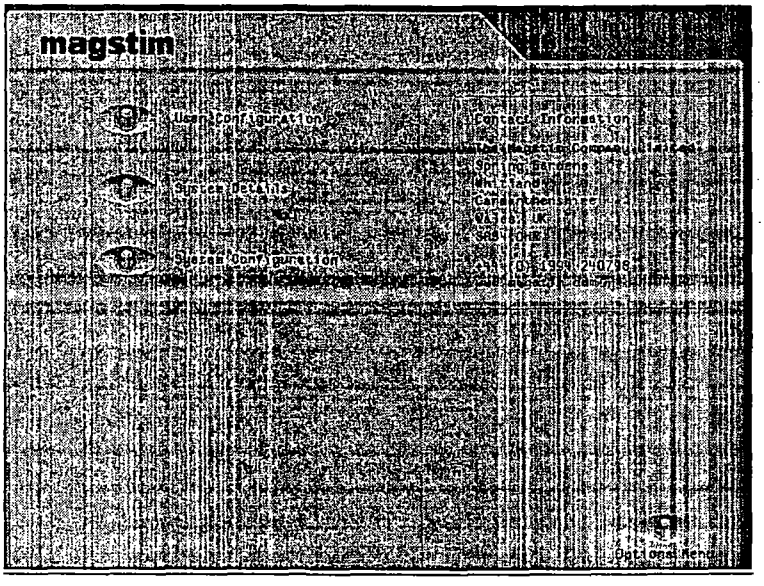
Setup Selection of this option will return the user to the Repetitive Setup screen.

Single Pulse Selecting this option will return the user to the Single Pulse Mode screen.

Options Menu Selection of this option will return the user to the Options Menu screen.

SECTION 4: SYSTEM

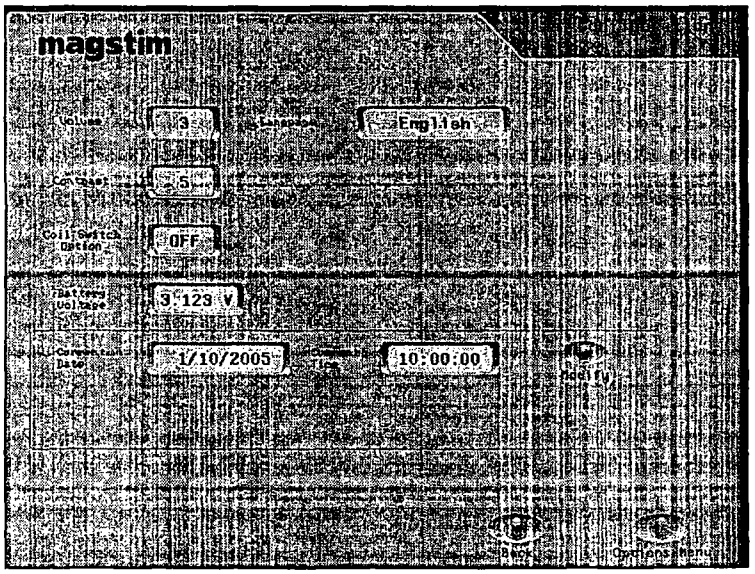
4.1 SYSTEM OPTIONS MENU.



User Configuration	Selection of this option will call up the ***User Configuration*** Screen.
System Details	Selection of this option will call up the ***System Details*** Screen.
System Configuration	Selection of this option will call up the ***System Configuration*** Screen.
Options Menu	Selection of this option will return the user to the ***Options Menu*** Screen.

4.2 USER CONFIGURATION

User Configuration This screen allows the user to set system parameters, which are stored in an area of the UI"s memory which is battery powered.



Volume This allows the user to set the screen selection beep volume by selecting the window and using the Rotary Control Knob.

Contrast This allows the user to adjust the TFT contrast option from 1 - 10, in steps of 1.

Coil Switch Option This gives the user the choice to use the coil safety switch or not each time the system is armed. When ON the System will prompt the user on a Run Screen to state if they wish to use the coil safety switch.

Note: If the coil switch option is set to ***ON***, each time the system is armed the user will have a ***YES/NO*** option on the screen to ignore the switches before the system can fire. When the „*YES*" button is selected a small yellow button will appear in the top right hand corner of the system status panel to indicate „ignore" option is active.
It is important that those in the vicinity of the system are made aware that the system is in this mode of operation, to ensure that inadvertent triggering does not occur.

Date Use „Modify" to alter the „Date Settings"

Time Use „Modify" to alter the „Date Settings"

Modify To change the date and the time settings, select the Modify button. Individual windows appear to allow date, month, year, hour, minute and second to be altered. Press to select a window and alter the information using the Rotary Control Knob. To save press the Set Time button.

Language Setup This option allows the user to change the language of the displays. German, English and French are available. English is the Default language.

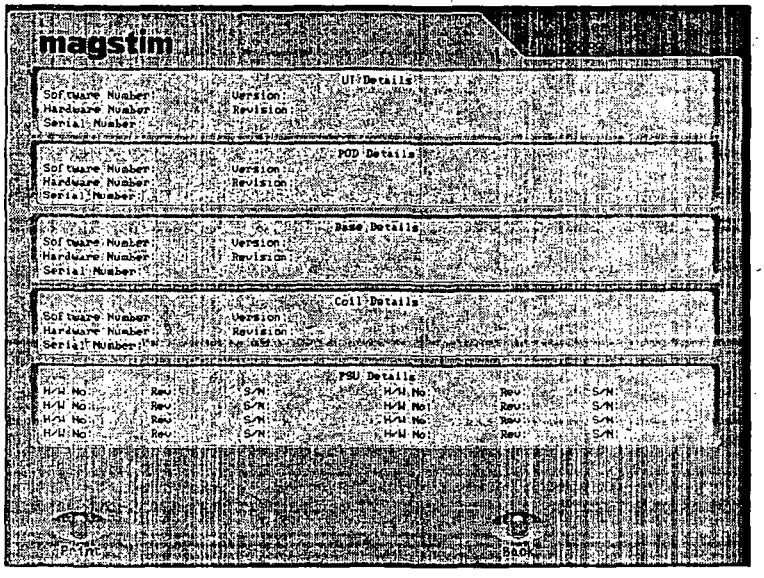
Battery Voltage This window displays the UI"s backup battery voltage.

Back Selection of this option takes you back to Systems Options Menu.

Options Menu Selection of this option will return the user to the Options Menu Screen.

4.3 SYSTEMS DETAILS

System Details This screen shows the part numbers, revision and serial number information for UI, MEP Pod, Main Frame, PSU, Plus[1] module (if applicable) and attached coil.

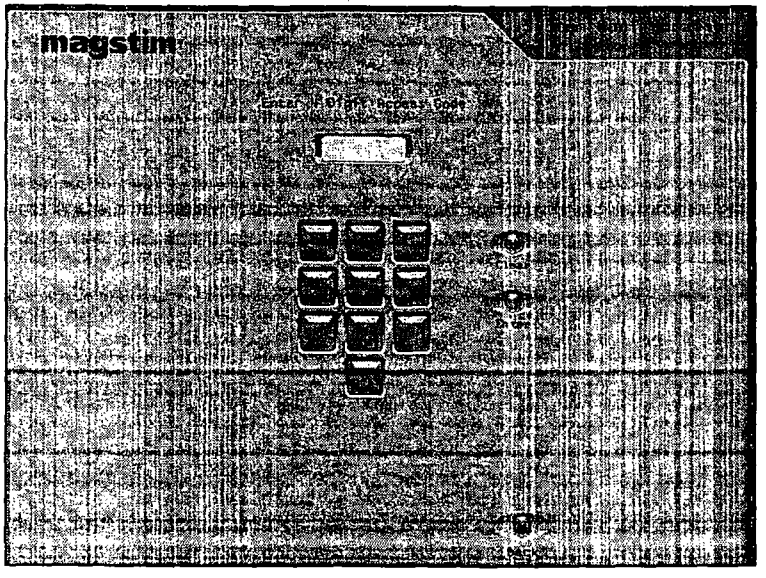


Print For Print Operations See Section 5.5.

Back Returns the user to the System Options Menu.

4.4 SYSTEM CONFIGURATION.

This screen is intended for Service Personnel.



Clear This button clears the password window.

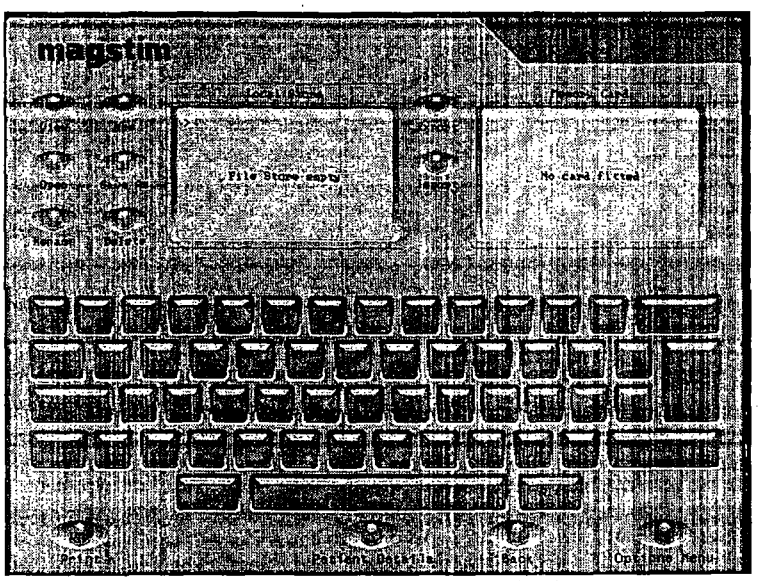
Enter This button enters the current number in the password window for verification. If correct, the service menus are displayed.

Back This option returns the user to the System Options Menu screen.

SECTION 5: DATA RETRIEVAL

5.1 FILE MAINTENANCE WINDOW

The file maintenance window allows the user to enter a file name and store protocols. These may be generic protocols which are chosen for a patient. The protocols may be stored internally, or may be stored on a memory card. (See section 5.3)



Keyboard The keyboard is touch sensitive. A file name needs to be selected in order to edit it. Select the Local Store screen and use the Rotary control knob to scroll between files.

View Selection of „View" reloads the data stored in the selected file located in the local store window. The file name will be displayed in the top right hand corner of the screen.

New Selection of „New" allows the user to create a new file in the local store window. The file name entered must be between 1 and 18 characters long, and different from any other file name.

Open Selection of „Open" will reload the data stored in the selected file. Once the file is opened the „Open" button will change to „Close" to enable the file to be closed. The file name will be displayed in the top right hand corner of the screen.

Rename Selection of this option will allow the user to enter a new name for a chosen File Name. Use the keyboard to make changes to the file name and press save (on the keyboard) to confirm.

Delete Selection of this option will allow the user to delete the selected file from the local store window after a „Yes" confirmation.

Export Export allows the user to export the selected File name in the Local Store window to the multi-media card. (See section 5.3)

Import Import transfers the selected file from the multimedia card, to the Local Store window.

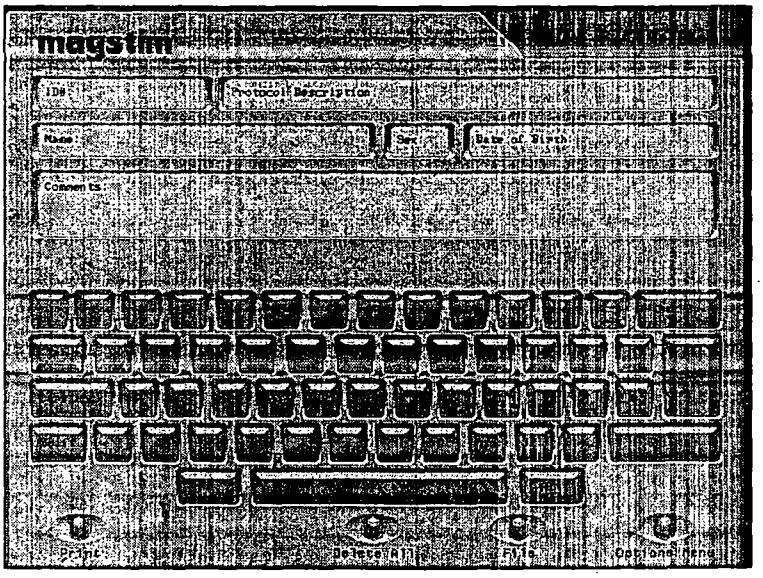
Print For Print operations See Section 5.5.

Patient Details Selection of this option will call up the Patient Details Screen.

Back Selection of this option returns the user to the previous screen.

Options Menu Selection of this option will return the user to the Options Menu Screen.

5.2 PATIENT DETAILS



Press **File** at any time to return to **File Maintenance.**

Keyboard The Keyboard is touch sensitive. To enter details into a field, first select the required field window so that it becomes active, showing a dark blue line around the window.

Save The „Save" key on the keyboard de-selects the active window and saves the information is saved in the current window.

Name Press the window to select. The Patient „Name" window can accept up to 40 characters. Enter details using the on-screen keyboard

Sex Press the window to select. The Patient „Sex" window can accept only 1 character. Enter details using the on-screen keyboard

ID# Press the window to select. The Patient „ID" window can accept up to 18 characters. Enter details using the on-screen keyboard

Date of Birth Press the window to select. The Patient „Date of Birth" window can accept up to 18 characters. Enter details using the on-screen keyboard

Protocol Description Press the window to select. Enter details using the on-screen keyboard.

Comments Press the window to select. The „Comments" window can accept up to 273 characters. Enter details using the on-screen keyboard.

Once the details have been entered into a window, further selection of the window will produce a „Save changes in the last window?" box. The changes made can be saved by selecting „Yes." To disregard the information entered, press „No."

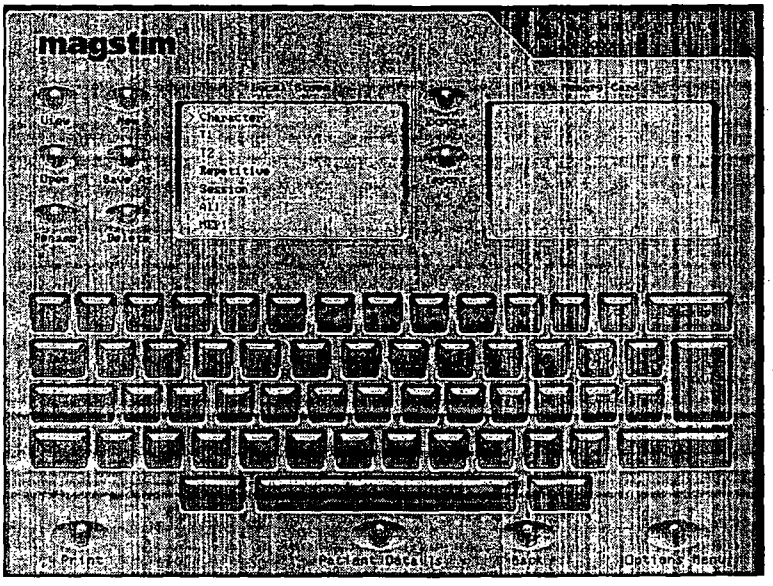
Print For Print Operations See Section 5.5

Delete All Selection of this option will clear the contents of all the patient details windows, after a „Yes" confirmation has been entered. If a patient file is open, the patient details will be removed from the file.

File Selection of this option will call up the File Maintenance screen.

Options Menu Selection of this option will return the user to the Options Menu Screen.

5.3 CREATING AND USING FILES.



TO CREATE A FILE

- Go to File Maintenance.
- Press the Local Store panel to select (a black line appears around the panel)
- Press New
- In the Local Store, an arrow will point to a blank line.
- Enter the new file name, using the on screen keyboard
- Press Save on the Keyboard.
- Make sure that the Local Store Screen is selected; use the Rotary control knob to move the arrow to point to a new file name.
- Press Open, then Patient Details. The File name will appear in the top right-hand corner.
- Select the required windows and enter details using the on- screen keyboard. Press Save on the Keyboard when the information is complete.
- Press File to return to File Maintenance.
- Press Close.

TO VIEW A FILE

- In file Maintenance select the Local Store Window. Use the Rotary Control Knob to select a file.
- Press View, then Patient Details.
- Press File to return to File Maintenance.

TO OPEN AND EDIT A FILE

- Select the Local Store Panel in File Maintenance
- Use the Rotary Control Knob to select a file
- Press „Open", then Patient Details
- Select the required window and make changes using the on-screen keyboard.
- Press „Save" on the keyboard to confirm
- Press „File" to return to File Maintenance
- Press „Close"

TO RENAME A FILE

- Select the File in the Local Store panel using the Rotary Control Knob.
- Press „rename" and use the on-screen keyboard to make changes.
- Press „Save" on the keyboard to confirm

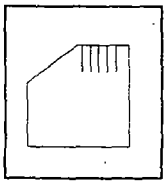
TO DELETE A FILE

- Select the file in the Local Store panel using the Rotary Control Knob.
- Press „Delete"
- The on screen prompt will ask „Are you sure you wish to delete selected file?"
- Press „Yes" or „No"

TO MANAGE FILES FROM SINGLE PULSE MODE, REPETITIVE MODE, AND SESSION MODE

- To save settings created in, for example, Single Pulse Mode, go to File Maintenance.
- Press New.
- Select the Local Store Panel and add the new file name using the keyboard.
- Press Save on the keyboard.
- Move the arrow to the new file name using the Rotary Control Knob.
- Press Save As.
- The prompt „Are you sure you wish to overwrite the selected file?" will appear whether the file currently contains information or not.
- Select „Yes"
- Use the on-screen buttons to navigate back to, for example, Single Pulse Mode.

5.4 SD CARD



An SD Card provides the opportunity for information that is stored on the Magstim Rapid² to be transferred to a PC and viewed using any standard PC text editing software package. Information is transferred onto the SD Card via the „File Maintenance" Screen.

To save a stored file onto an SD Card, insert the SD Card into the socket situated on the side of the UI (see Section 3). Select the „File Maintenance" screen and select the „Local Store" panel. Select a file by turning the Rotary Control Knob until the arrow points at the chosen file. Press the „Export" Button. The screen will display the command „Please wait, Data Transfer in Progress" the file will appear in the „Memory Card" store panel.
The file is now saved onto the SD Card.

The UI only supports the short DOS file name convention of 8 characters for the file name and 3 characters for the file extension when reading from or writing to the SD Card. Long file names on the UI will automatically be reduced down to 8 letters for export purposes onto the card. All Files exported from the UI onto the card will have the file extension „MRF." When the file is returned to the UI via the SD Card, its original file name will be displayed. See section 7.3 for saved data format.

The Rapid² is only compatible FAT 16 formatted SD cards.

The UI can only be used to read or to write a file from the card. It can not format, create directories or delete any data stored on the card

FORMATTING AN SD CARD WITH A PC

Make sure an SD Card Reader is connected to the system. Insert the SD card.

- Using Windows Explorer select the drive associated with the SD card.
- Select the Format option.
- Under File System select the FAT option.
- Follow the instructions on screen.

5.5 PRINT OPTIONS

The printer makes it possible to generate copies of the majority of the information that is stored within the Magstim Rapid². The Print option allows for screen or file information to be obtained on paper.

In any screen where the „Print" Button is visible the Printer can produce a reproduction of the information that is displayed on screen. This option is available in:

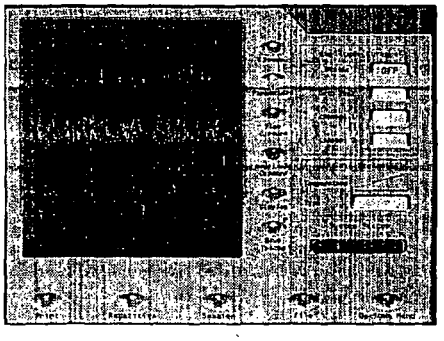
Single Pulse Mode Power Screen
Repetitive Setup
Session Setup
System Details
File Maintenance and Patient Details

Once the 'Print" Button is pressed the selected item automatically begins to print, unless the previous print process was cancelled, in which case, follow the instructions on screen. The print process may be cancelled at any time by pressing the „Cancel" button.

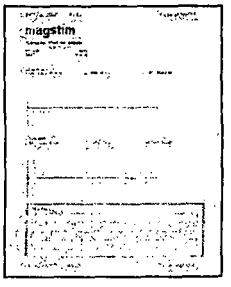
EXAMPLE: SINGLE PULSE MODE

Once the chosen information is generated up on screen the „Print" button can be pressed to produce a printout, see below.

Screen

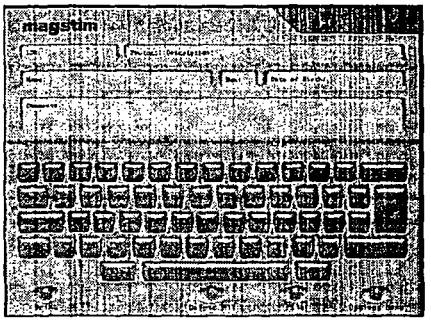


Printout

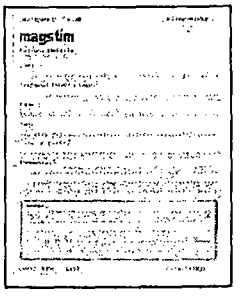


EXAMPLE: PATIENT DETAILS

Screen



Printout



SECTION: 6. SYSTEM STATUS CODES

6.1 SYSTEM STATUS CODES

BASE Controller Error Codes produced by the User Interface.

Error Codes	Description
U24	UI Power Supply Failure
U25	Stack underflow
U26	Stack overflow
U27	RTS overrun
U28	Watchdog Timeout
U29	ROM Checksum Incorrect
U34	No serial communications
U35	Loss of communication
U36	Bad NVRAM Checksum
U37	Battery Voltage Low
U38	Bad External Flash Checksum Detected.

Error codes produced by 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
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.
C31	Air Extraction Unit Not Operating Correctly (3530-00 coil only)

Error codes produced by base system.

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
E75	HVCAP 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 **WARNING** - high voltage may be present up to 20 minutes after use on internal high voltage capacitor.
E87	Invalid coil category for current system configuration.
E88	Invalid NVRAM Checksum.
E90	Base arm LED drive failure
E91	External PSU Fault
E92	Base over temperature
E93	Snubber Board over temperature
E94	Base under temperature
E95	HC CAP under temperature
E96	Snubber Board under temperature
E97	Ambient over temperature
E98	System failed to produce protocol

6.2 ISOLATED TRIGGER I/O PORT (1)

WARNING Only equipment complying with EN 60601-1, and configured in compliance with EN 60601-1, should be connected to the trigger output and/or trigger input. Connection must be via Trigger Input/ Output Cable P/N 600003 in order to maintain System EMC Compliance

I/O - 5V CMOS Logic Levels.

Pin Connections.

1. Aux GND	**14.** N/C
2. N/C	**15.** N/C
3. Tout- O/C	**16.** N/C
4. N/C	**17.** N/C
5. +ive Trigger In	**18.** N/C
6. -ive Trigger In	**19.** Aux GND
7. +ive Trigger Out	**20.** End Train
8. -ive Trigger Out	**21.** N/C
9. N/C	**22.** N/C
10. Aux +5V	**23.** N/C
11. Aux GND	**24.** Trigger Edge
12. N/C	**25.** N/C
13. N/C	**26.** N/C

6.3 SD CARD FILE DETAILS

- General

Each line of the file starts with a text string that describes the data that follows on that line.
Each line of data ends with a carriage return line feed request, <CR>.

- File Layout

The following details the order the data is stored in the Magstim UI generated file.

Version, <file format number>, <CR>
File, <system filename>, <CR>
Status, <system file status when exported>, <CR>
File Time, <seconds>, <minutes>, <hours>, <day>, <month>, <year>, <CR>
Name, <patient name>, <CR>
Sex, <patient sex>, <CR>
ID#, <patient ID>, <CR>
Date or birth, <patient date of birth>, <CR>
Protocol description, <patient protocol description text string>, <CR>
Comments, <patient comments string>, <CR>
Train, <power>, <frequency>, <duration>, <number of pulses>, <wait time>, <number of trains>, <CR>
Burst, <power>, <frequency>, <number of pulses>, <burst frequency>, <number of bursts>, <cycle time>, <number of cycles>, <CR> *see note1.
Session 1, <start time>, <power>, <frequency>, <duration>, <number of pulses>, <wait time>, <CR>
Session 2, <start time>, <power>, <frequency>, <duration>, <number of pulses>, <wait time>, <CR>

. . . . . .
. . . . . .

Session 30, <start time>, <power>, <frequency>, <duration>, <number of pulses>, <wait time>, <CR>
MEP 0, Trace 1,Trace 2, <CR>
MEP 1, <reading 1 trace1>, <reading 1 trace2>, <CR>
MEP 2, <reading 2 trace1>, <reading 2 trace2>, <CR>
MEP 3, <reading 3 trace1>, <reading 3 trace2>, <CR>
MEP 4, <reading 4 trace1>, <reading 4 trace2>, <CR>

. . . . .
. . . . .

MEP 300, <reading 300 trace1>, <reading 300 trace2>, <CR>
MEP Configuration, <time base index>, <channel 1 voltage range index>, <channel 2 voltage range index>, <special feature>, <filters index>, <CR>

Note 1. Line only added to files by UI software version V6.0 or greater.

- File line Details

The following details the content and data range limits for each data lines contained in the Magstim UI generated file.

Version. This number is created by the UI and must be present in the file and "**must not be altered**". An invalid number will result in the file not being imported correctly.

File. This is the file name used on the UI and must contain at least one character and not more than 18 characters. The file name can contain any standard alphanumeric character except a comma.

Status. This number is used by the UI to determine what state the file was in when it was exported and "**must not be altered**". An invalid number will result in the file not being imported correctly.

File Time. This line defines when the file was created on the UI. The range for each value is a follows: seconds 0-59, minutes 0-59, hours 1-23, day 1-31, month 1-12, year 1970 – 2100.

Name. This is the name that appears in the patient data name window on the UI and must not exceed 40 characters. The name can contain any character except a comma.

Sex. This is the character that appears in the patient data sex window and must not exceed 1 character. The character can be any character except a comma.

ID#. This is the string that appears in the patient ID window on the UI and must not exceed 18 characters. The string can contain any character except a comma.

Date of birth. This is the string that appears in the patient date of birth window on the UI and must not exceed 18 characters. The date string can contain any character except a comma.

Protocol description. This is the string that appears in the patient protocol description window on the UI and must not exceed 46 characters. The string can contain any character except a comma.

Comments. This is the string that appears in the patient comments window on the UI and must not exceed 273 characters. The string can contain any character except a comma.

Train. This line contains the parameters displayed on the repetitive set up screen on the UI, (Standard mode). The individual parameter value ranges are as follows:
Power 0 - 100% at a resolution of 1%.
Frequency 1 - 100 Hz at a resolution of 0.1Hz up to 30.0Hz, and at 1.0Hz thereafter.
Note the settable power to frequency values is determined by the system configuration, see user manual for Rapid system for more details.
Duration 0.1 - 600.0 seconds at a resolution of 0.1 seconds, up to 30.0s, and at 1.0s thereafter.
Number of pulses 1 – 60000 at a resolution of 1.
Wait time 1.0 – 540.0 seconds at a resolution of 0.1 seconds.
Number of trains 1 – 999 at a resolution of 1.
Note all time periods are specified in multiples of tenths of a second i.e. if a time period of 6.5 seconds is required then a value of 65 is entered between the commas.

Burst. This line contains the parameters displayed on the repetitive set up screen on the UI, (Burst mode). The individual parameter value ranges are as follows:
Power 0 - 100% at a resolution of 1%.
Frequency 1 - 100 Hz at a resolution of 1Hz.
Note the settable power to frequency values is determined by the system configuration, see user manual for Rapid system for more details.
Number of pulses 1 – 10 at a resolution of 1.
Burst frequency 1 – 10 Hz at a resolution of 1Hz.
Number of bursts 1 – 500 at a resolution of 1.
Cycle time 1.0 – 500.0 seconds at a resolution of 0.1 seconds.
Number of cycles 1 – 999 at a resolution of 1.
Note all time periods are specified in multiples of tenths of a second i.e. if a time period of 6.5 seconds is required then a value of 65 is entered between the commas.

Session x. These lines contain the parameters displayed on the session set up screen on the UI. The individual parameter value ranges for line 1 are the same for all 30 lines and are as follows:
Start time for line 1 has to be zero. The start time on the other lines should be determined using the following equation, start time = previous line (start time + duration + wait time).
Power 0 - 100% at a resolution of 1%.
Frequency 1 - 100 Hz at a resolution of 1Hz.
Note the settable power to frequency values is determined by the system configuration, see user manual for Rapid system for more details.
Duration 0.1 - 10.0 seconds at a resolution of 0.1 seconds.
Number of pulses 1 - 1000 at a resolution of 1.
Wait time 1.0 - 60.0 seconds at a resolution of 0.1 seconds.
Note all time periods are specified in multiples of tenths of a second i.e. if a time period of 6.5 seconds is required then a value of 65 is entered between the commas.

MEP 0. This line contains the MEP data column headings.
MEPS x. These lines contain a single reading for each trace stored in the file.
Trace 1 column contains the MEP waveform that was displayed on the UI for channel 1 when the "save traces" button on the single pulse screen on the UI was selected and the exported file was open for modification. Each of the 300 data values is within the range 0 - 255.

Trace 2 column contains the MEP waveform that was displayed on the UI for channel 2 when the "save traces" button on the single pulse screen on the UI was selected and the exported file was open for modification. Each of the 300 data values is within the range 0 - 255.

To determine the actual voltage recorded for each MEP data value, the value has to be scaled according to the voltage range that was selected at the time the reading was made. The voltage range setting for each channel is recorded on the "MEP Configuration" data line of the file.

MEP Configuration. This line contains the details of how the MEP was configured when the MEP waveforms were saved using "save traces" button on the single pulse screen on the UI. The meaning for each value are as follows:
Time base index, possible values and meanings are as follow:
0 = 20 ms; 1 = 50 ms; 2 = 100 ms; 3 = 200 ms; 4 = 500 ms.
Channel 1 voltage range index, possible values and meanings are as follows:
0 = ±150μV; 1 = ±300μV; 2 = ±600μV; 3 = ±1.5mV; 4 = ±3mV; 5 = ±6mV;
6 = ±15mV; 7 = ±30mV.
Channel 2 voltage range index, possible values and meanings are as follows:
0 = ±150μV; 1 = ±300μV; 2 = ±600μV; 3 = ±1.5mV; 4 = ±3mV; 5 = ±6mV;
6 = ±15mV; 7 = ±30mV.
Special feature, always 0.
Filters index, possible values and meanings are as follows:
0 = 2Hz - 10KHz; 1 = 20Hz - 10KHz.

Note: The information stored on the SD Card is of the text format, comma delimited. The file can be imported into any text editor to view or to modify the contents. The files may also be imported into spreadsheets, make sure the delimited option is highlighted and the file origin is set to "Arial- western European"

SECTION 7: SAFETY FEATURES

7.1 COIL TEMPERATURE PROTECTION

An indication of the coil temperature is given by the Coil Temperature information display on the User Interface.

If the coil surface temperature reaches its set limit, the display information will inform the user that this condition has occurred.
The normal operation of the equipment can then be resumed by allowing the coil to cool, or alternatively, by replacing the coil with a cool one.

7.2 COIL DISCONNECTION

If the coil is disconnected from the unit while the unit is charged, the Rapid^2 system will detect a break in communications and will automatically select the default mode and discharge internally. At the same time a message will be displayed on the UI screen indicating that the coil has been disconnected.

The **ARMED** indicator will extinguish, indicating that the unit is discharged.

7.3 OTHER SAFETY MEASURES

If the instrument has not been triggered for over 10 minutes after the system status window has displayed **READY,** the unit will automatically select the default mode and discharge internally

The Magstim Rapid^2 is capable of recognising automatically the type of stimulating coil being used.

SECTION 8: MAINTENANCE

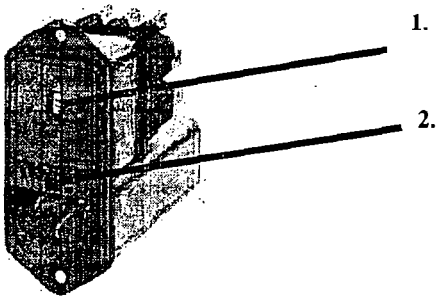
8.1 VOLTAGE SELECTION AND FUSE RATING

The Magstim Rapid² may be operated from supplies in the range of 115V ± 10% ~ 60Hz, 230V ± 10% ~ 50Hz and 240V ± 10% ~ 60Hz. The voltage selector on the rear panel of the Main Frame and if relevant, the Magstim Plus[1] along with the associated fuses must correspond to the supply voltage as indicated in the table below. The PSU, however, is not voltage selectable and is manufactured as either a 230V (240V) ± 10% unit, or a 115V ± 10% unit. The two are not interchangeable.

Supply Voltage	Set Voltage Selector To	Main Frame Fuse Rating	Required Quantity	Magstim Plus[1] Fuse Rating	Required Quantity
115V ± 10% ~ 60Hz	115V	1.25A T*	2	250mA T*	2
230V ± 10% ~ 50Hz	230V	1.25A T*	2	250mA T*	2
240V ± 10% ~ 60Hz	230V	1.25A T*	2	250mA T*	2

T* denotes timed, or antisurge, fuses. The use of fast acting fuses is not recommended

VOLTAGE SELECTION INSTRUCTIONS



IMPORTANT –Ensure that the Magstim Rapid² is disconnected from the mains supply before changing the fuse, or setting the voltage selector.

- Insert the tip of a small blade screwdriver, or similar tool, into slot no. 2, shown in diagram above. Gently lever up the retaining lip of the fuse holder. The fuse holder will then slide out
- Using a pair of narrow nosed pliers, grip the voltage selector unit on one of the metal connection plates and remove it from the Power Entry Module.
- Orient the voltage selector unit, such that the desired voltage is facing out from the Power Entry Module.
- Re-insert the voltage selector unit into the Power Entry Module.
- Replace the fuse holder, ensuring that the retaining lip is properly home, and verify that the voltage window (1) displays the correct voltage value.

CHANGING FUSE TYPE

- Insert the tip of a small blade screwdriver, or similar tool, into slot no.2, shown in diagram on previous page. Gently lever up the retaining lip of the fuse holder. The fuse holder will then slide out.
- Replace damaged fuse(s) with a suitable replacement.
- Replace the fuse holder, ensuring that the retaining lip is properly home.

8.2 USER MAINTENANCE

At the start of each session the Operator must check the Magstim Rapid2, PSU, UI and the stimulating coil for any signs of damage, paying particular attention to the plastic casing. If there are any signs of physical damage to the Magnetic Stimulator, PSU, UI or the stimulating coil, they must not be used.

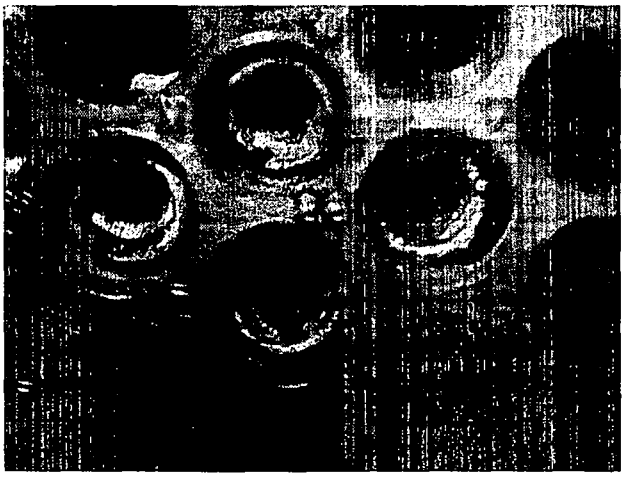
The cooling vents should also be checked to ensure that they have not become blocked, or obstructed.

The UI contains 2 AA cell batteries. These are not rechargeable, and will need to be replaced if patient information is stored on the system. It is important that regular checks are carried out to ensure that the batteries are replaced when necessary. Failure to do so will result in the information being lost. The Battery voltage can be viewed in the User Configuration Screen.

8.3 TECHNICAL MAINTENANCE

The coil pins should be checked before each session for any signs of pitting, or burning, as under conditions of exceptionally hard use at high energy levels, it is possible for the localised heating to manifest itself in the form of micro-welds. Continued used in this condition will eventually result in the coil pins/sockets becoming totally eroded and open circuit.

Note: The pin burning is communicable - any coil with good pins that are used on a stimulator with burned socket pins will have its pins damaged immediately. The reverse is also true; a socket with good pins that has a coil with burnt pins connected to it will have its pins damaged immediately. If damage is noticed on any coil connector or stimulator coil socket the complete system must not be used until all pins and sockets are carefully examined for any damage. If any contacts show damage, even if slight, they will need to be changed. If this is not done thoroughly there is the risk that the cycle of contact damage will continue.



As contact repair is a specialised procedure, it is recommended that contact replacement is undertaken by the Magstim Company, or one of its authorised service centres. If additional advice or information is required, please contact The Magstim Company.

BACKUP BATTERIES

Battery status can be checked on the user configuration screen and when low, is reported on the main Options Menu screen.

The batteries in the UI will require to be replaced every 2 years. To do so, unplug the UI connector, turn the UI upside down, remove the 4 cross-head screws visible, and detach the plastic bottom of the UI. Have the new batteries available. The UI has a small capacitor which will maintain the internal settings for about 20 seconds once the old batteries are removed. It is important that the batteries are replaced within the 20 seconds if data is not to be lost. Before removing the old batteries, ensure you have the correct replacements, and that you are clear about the orientation of the batteries. Once inserted, replace the bottom of the UI and fix using the screws. Do not over-tighten.

Do not use re-chargeable batteries.
When spent, the batteries should be disposed of under the appropriate environmental regulations

It is advisable that the batteries be removed from the UI if the equipment is likely to be un-used for a long period of time.

8.4 CLEANING AND DISINFECTING

The stimulating coil, exterior of main frame, PSU, UI, foot switch, MEP Pod and MEP Pod patient cables may be cleaned using an isopropyl alcohol moistened cloth. Ensure that the equipment has dried thoroughly before use.

Note: Do not clean or wipe the touch screen with anything abrasive as it will cause permanent damage.

8.5 DEVICE LIFETIME

The lifetime of the Magstim Rapid^2 System is defined as being 5 years from the date of shipment.

SECTION 9: SPECIFICATIONS

9.1 GENERAL SPECIFICATIONS

This equipment is classified as Class 1, with type BF Applied Parts.

It is designed to comply with the requirements of the Safety Standard EN60601-1 (90), including amendment 1 (91) and amendment 2 (95) and EMC Standard EN 60601-1-2, with the exception of immunity clause 36.202.5 "Surges."

Protection against ingress of liquids

The Magstim Rapid^2 System and its accessories are classified as **IPXO (Not Protected)**, as there is **no** specialised protection provided against the ingress of liquids.

Protection against flammable anaesthetic mixtures

Not Protected. Therefore, the Magstim Rapid^2 System and its accessories are **not** suitable for use in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide.

Mode of Operation

Continuous

EMC General

The Magstim Rapid^2 System should not be used adjacent to, or stacked with, other equipment and that 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.

EMC Susceptibility

The Magstim Rapid^2 System needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in Section 11 of this Operating Manual. NB. When the system is exposed to radiated RF between 80MHz and 100MHz, or conducted RF between 30MHz and 80MHz, when used with Coil Adapter P/N 3110-00 and Cooled Coil P/N 3380-00 system errors may occur, setting system into safe mode.

EMC Emissions

To avoid interference problems the Magstim Rapid^2 System, and its accessories, should not be used in the vicinity of any equipment that does not comply with EMC Standard EN 60601-1-2, including portable and mobile RF communications equipment, such as mobile phones.

The use of accessories, transducers and cables other than those specified by the Magstim Company Ltd., may result in increased emissions, or decreased immunity of the equipment. In order to ensure EMC compliance, the Magstim Rapid^2 System must be used only with those parts specified by the Magstim Company Ltd. for use with the Magstim Rapid^2 System.

9.2 POWER

Operating Voltage

115V±10% AC, 60Hz
230V ±10% AC, 50Hz
240V ±10% AC, 60Hz

Input Fuse Rating

Rapid^2 Main Frame	1.25A T x 2
Magstim Plus^1	250mA T x 2

Equipment should be used with the line cord provided. Where a fused line cord is used, the appropriate fuse should be fitted.

Maximum Power Requirements

230V/240V Rapid^2 Systems

Standby	All Systems	20VA
During Discharge	Standard Rapid^2	3kVA
	Super Rapid^2	6kVA
	Super Rapid^2 Plus^1	9kVA

Maximum Power Requirements (cont.)	115V Rapid² Systems		
	Standby	All Systems	20VA
	During Discharge	Standard Rapid²	2.3kVA
		Super Rapid²	4.6kVA
		Super Rapid² Plus[1]	6.9kVA

9.3 MEP Pod

Class Type	Class 1, BF
Channels	2
CMMR	> 90dB
Dynamic Range	± 30mV ±10%
Amplitude Accuracy	±10% at ½ full scale
Display Resolution	< 2%
Cursor Resolution	< 2%
Timebase Accuracy	<±1% of sample period
Timebase Resolution	0.33% of sample period
CALIBRATION	Calibration is not required.

9.4 AMBIENT TEMPERATURE

9.4.1 Permissible Environment Conditions for Transport

Ambient Temperature Range	-19°C to 60°C
Relative Humidity Range	10% to 80% Non Condensing
Atmosphere Pressure Range	50kPa to 106kPa

9.4.2 Storage and Operating Conditions

Operating Temperature Range	5°C to 40°C
Storage Temperature Range	-19°C to 60°C
Coil Temperature Range	5°C to 40°C

9.5 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

9.6 OUTPUT REPETITION RATE OF STIMULUS

Output Range: 0% - 100% of Maximum Voltage ±2%

Magnetic Field: The magnetic field produced by the Magstim Rapid^2 depends on the type of coil connected. In the case of the Double 70mm Coil supplied with the system, the field output is 1.2T at the surface of the coil.

Pulse Characteristics: Biphasic Single Cosine Cycle - 400μs period

230V/240V Rapid^2 Systems

Available Output Power (%)	Operating Frequency (Hz) Max. 100Hz		
	Standard Rapid^2	Super Rapid^2	Super Rapid^2 Plus^1
0 - 30%	50	100	100
31	46	98	100
32	45	95	100
33	44	93	100
34	42	90	100
35	41	88	100
36	41	85	100
37	39	83	100
38	39	80	100
39	38	78	100
40	37	75	100
41	36	73	100
42	34	70	100
43	33	68	100
44	33	65	100
45	33	63	100
46	33	60	100
47	33	58	100
48	32	55	100
49	31	53	98
50	30	50	97
51	30	50	95
52	29	49	93
53	29	49	91
54	28	48	88
55	28	48	88
56	27	47	87
57	27	47	85
58	26	46	84
59	26	46	82
60	25	45	80
61	25	45	79
62	24	44	77
63	24	44	74
64	23	43	74
65	23	43	74
66	22	42	74
67	22	42	71
68	21	41	70
69	21	41	69
70	20	40	68
71	20	40	68
72	20	39	66
73	20	39	65
74	19	38	62
75	19	38	62
76	19	37	62
77	19	37	60
78	19	36	59
79	18	36	58
80	18	35	57
81	18	35	57
82	18	34	56
83	18	34	55
84	18	33	55
85	17	33	53
86	17	32	52
87	17	32	51
88	17	31	50
89	17	31	50
90	17	30	49
91	17	30	48
92	16	29	47
93	16	29	46
94	16	28	46
95	16	28	45
96	16	27	44
97	16	27	43
98	15	26	42
99	15	26	42
100	15	25	41

115V Rapid² Systems

Available Output Power (%)	Frequency (Hz) Max. 60Hz		
	Standard Rapid²	Super Rapid²	Super Rapid² Plus¹
0-30	36	60	60
31	35	60	60
32	35	60	60
33	34	60	60
34	33	60	60
35	32	60	60
36	32	60	60
37	31	60	60
38	30	59	60
39	29	57	60
40	28	55	60
41	28	54	60
42	27	53	60
43	26	52	60
44	26	51	60
45	25	50	60
46	25	49	60
47	24	47	60
48	24	46	60
49	23	45	60
50	23	44	58
51	22	43	56
52	22	42	56
53	21	42	54
54	21	41	53
55	21	40	52
56	20	40	51
57	20	39	50
58	19	38	49
59	19	38	48
60	19	37	47
61	18	36	46
62	18	36	46
63	18	35	45
64	18	35	44
65	17	34	43
66	17	34	43
67	17	33	42
68	16	33	41
69	16	32	40
70	16	32	40
71	16	31	39
72	16	31	39
73	15	30	38
74	15	30	37
75	15	29	37
76	15	29	36
77	14	28	36
78	14	28	35
79	14	28	35
80	14	27	34
81	14	27	34
82	13	27	33
83	13	26	33
84	13	26	33
85	13	26	32
86	13	26	32
87	12	25	31
88	12	25	31
89	12	25	30
90	12	24	30
91	12	24	30
92	12	24	29
93	12	24	29
94	12	23	28
95	11	23	28
96	11	23	28
97	11	22	27
98	11	22	27
99	11	22	27
100	11	22	25

9.7 UI REAR PANEL

ISOLATED TRIGGER I/O Port

The maximum non-destructive voltage that can be applied to the external connections with respect to ground:

Connection	Not Less Than	Not Greater Than
	Logic Low	Logic High
Trigger Input	- 0.3 - 0.8 V	4 - 5.3V
Trigger Output	- 0.3 - 0.8 V	4 - 5.3V

9.8 GENERAL

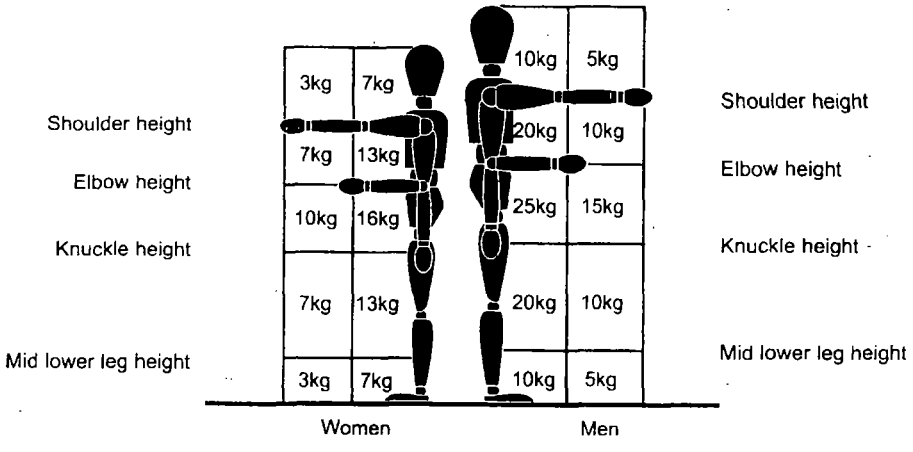
Rapid^2 Main Frame (3012-00)			
	Size:	Width	460mm
		Height	160mm
		Depth	375mm
	Weight	13.1kg	
Magstim Plus^1 (4040-00)			
	Size:	Width	460mm
		Height	160mm
		Depth	375mm
	Weight	15.7kg	
PSU 3013-00			
	Size:	Width	460mm
		Height	160mm
		Depth	375mm
	Weight	13.2kg	
PSU 3014-00			
	Size:	Width	460mm
		Height	160mm
		Depth	375mm
	Weight	23.4kg	
UI			
	Size:	Width	360mm
		Height	240mm
		Depth	280mm
	Weight	2.6kg	

IMPORTANT The system must be disassembled prior to being moved. The parts of the system are not locked together in any way and are likely to fall if moved together, resulting in damage to the equipment and possible injury to those near to or those transporting it.

9.9 HANDLING

CAUTION The Magstim Rapid² System Main Frame, Magstim Plus¹ and PSU weigh in excess of 20kg. Therefore, if it is necessary to move the units for any reason, the weight must be distributed between at least two persons.

NOTE - The weight of the PSU 3013-00 and Magstim Plus¹ is unevenly distributed - the left hand side of the unit being considerably heavier than the right hand side. Care should be taken when transporting the unit to ensure that this heavier side is adequately supported.



SECTION 10: EMC EMISSIONS AND IMMUNITY

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Magstim Rapid² System 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 EN60601-1-2	Group 1	The Magstim Rapid² System must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions EN60601-1-2	Class A	The Magstim Rapid² System 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 EN60601-1-2	Class A (by equipment type)	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Magstim Rapid² System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Magstim Rapid² System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Magstim Rapid² System 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 $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ Where $V_1 = 3$	**80 MHz to 800 MHz** $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ Where $E_1 = 3$	**800 MHz to 2,5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 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 Rapid^2 System 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 (Resetting of the MEP Pod may be experienced during single shot mode under these conditions.)	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	Differential mode compliant. Common mode compliant to ± 1kV only.	Anti surge protection needs to be incorporated into the main supply to the equipment if surge protection is to be guaranteed.
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 Rapid^2 System requires continued operation during power interruptions, it is recommended that the Magstim Rapid^2 System 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	Coil adapter P/N 3110-00 and Cooled Coil P/N 3380-00 between 80MHz and 100MHz may produce system errors setting system into safe mode.	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	Coil adapter P/N 3110-00 and Cooled Coil P/N 3380-00 between 30MHz and 80MHz may produce system errors setting system into safe mode.	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			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Magstim Rapid^2 System 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**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	$[V_1]$ V	Portable and mobile RF communications equipment should be used no closer to any part of the Magstim Rapid^2 System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency transmitter. **Recommended separation distance** $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	$[E_1]$ V/m	$d = [\frac{7}{E_1}]\sqrt{P}$ 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: 
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.			

[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 Rapid^2 System is used exceeds the applicable RF compliance level above, the Magstim Rapid^2 System 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 Rapid^2 System.

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

SECTION 11: RAPID^2 SYSTEM PACKAGES

Standard Rapid^2	**P/N 3004-00**
1 x Rapid^2 Main Frame	P/N 3012-00
1 x Power Supply, Single Module	P/N 3013-00
1 x User Interface (UI)	P/N 3022-00
1 x Footswitch	P/N 9525-01
1 x Coil Adapter	P/N 3110-00
1 x MEP Pod	P/N 3526-00
1 x 230V UK Mains Lead with integral filter OR	P/N 3719-01
1 x 230V European Mains Lead with integral filter OR	P/N 3726-01
1 x 240V North American Lead with Integral filter OR	P/N 3764-01
1 x 115V North American Lead with Integral filter	P/N 3801-01
1 x 10A Link Lead	P/N 600002
1 x HV Cable	P/N 3583-00
1 x UI Cable	P/N 3582-00

Super Rapid^2	**P/N 3005-00**
1 x Rapid^2 Main Frame	P/N 3012-00
1 x Power Supply, Dual Module	P/N 3014-00
1 x User Interface (UI)	P/N 3022-00
1 x Footswitch	P/N 9525-01
1 x Coil Adapter	P/N 3110-00
1 x MEP Pod	P/N 3526-00
2 x 230V UK Mains Lead with integral filter OR	P/N 3719-01
2 x 230V European Mains Lead with integral filter OR	P/N 3726-01
2 x 240V North American Lead with Integral filter OR	P/N 3764-01
2 x 115V North American Lead with Integral filter	P/N 3801-01
1 x 10A Link Lead	P/N 600002
1 x HV Cable	P/N 3583-00
1 x UI Cable	P/N 3582-00
1 x Magstim SD Card	P/N 3844-00

Super Rapid^2 Plus^1	**P/N 4100-00**
1 x Rapid^2 Main Frame	P/N 3012-00
1 x Magstim Plus^1	P/N 4040-00
1 x Power Supply, Dual Module	P/N 3014-00
1 x User Interface (UI)	P/N 3022-00
1 x Footswitch	P/N 9525-01
1 x Coil Adapter	P/N 3110-00
1 x MEP Pod	P/N 3526-00
3 x 230V UK Mains Lead with integral filter OR	P/N 3719-01
3 x 230V European Mains Lead with integral filter OR	P/N 3726-01
3 x 240V North American Lead with Integral filter OR	P/N 3764-01
3 x 115V North American Lead with Integral filter	P/N 3801-01
2 x 10A Link Lead	P/N 600002
3 x HV Cable	P/N 3583-00
1 x UI Cable	P/N 3582-00
1 x Magstim SD Card	P/N 3844-00

Additional Items Available

Rapid^2 UI Printer Package	P/N 3804-00
Stimulator Interface Module	P/N 3901-00
Rapid^2 Trolley	P/N 3767-00
Rapid^2 Trolley with Integral Coil Holder	P/N 3862-00
Trolley Mounted Coil Stand	P/N 3863-00

APPENDIX B: MAGSTIM LABELS


Rapid booster.docx


Rapid main.docx


Rapid2 base.docx


Rapid2 PSU.docx


Rapid2 UI.docx

Rapid booster

P/N 2014-00

MADE IN U.K.
Brainsway

10/05/09

60135

SN

19 Hartom St., Jerusalem 91451 , ISRAEL. Tel 972-2-5824030. Fax 972-2-5812517

Rapid main

P/N 2012-00

MADE IN U.K.
Brainsway

10/05/09

1554357

SN

19 Hartom St., Jerusalem 91451 , ISRAEL. Tel 972-2-5824030. Fax 972-2-5812517

Rapid2 base

P/N 3012-00

MADE IN U.K.
Brainsway

18/08/12

SN C0662

19 Hartom St., Jerusalem 91451 , ISRAEL. Tel 972-2-5824030. Fax 972-2-5812517

Rapid2 PSU

P/N 3014-00

MADE IN U.K.
Brainsway

18/08/12

B0308

SN

19 Hartom St., Jerusalem 91451 , ISRAEL. Tel 972-2-5824030. Fax 972-2-5812517

Rapid2 UI

P/N 3022-00

MADE IN U.K.
Brainsway

18/08/12

D663

SN

19 Hartom St., Jerusalem 91451 , ISRAEL. Tel 972-2-5824030. Fax 972-2-5812517

178

APPENDIX C: REVISED INDICATIONS FOR USE STATEMENT

Appendix C - Section 04 IFU Statement.do

Section 4:

Indications for Use Statement

INDICATIONS FOR USE

510(k) Number (if known): K122288

Device Name: Brainsway Deep TMS System

Indications For Use:

The Brainsway Deep TMS System is indicated for the treatment of depressive episodes in adult patients suffering from Major Depressive Disorder.

Prescription Use __√___ AND/OR Over-The-Counter Use___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

— —

Concurrence of CDRH, Office of Device Evaluation (ODE)

Deep transcranial magnetic stimulation over the prefrontal cortex: Evaluation of antidepressant and cognitive effects in depressive patients

APPENDIX F: ELECTRICAL FIELD MAP DISTRIBUTION

120-110% Electrical
Field Distribution Map

BRAINSWAY DEEP TMS SYSTEM FOR TREATMENT OF MAJOR DEPRESSIVE DISORDER

CLINICAL STUDY REPORT

(b)(4) [redacted]

(b)(4) [redacted]

Study Conducted According to Protocol: A Prospective Multicenter Double Blind Randomized Controlled Trial to Explore the Tolerability, Safety and Efficacy of the H-Coil deep Transcranial Magnetic Stimulation (TMS) in Subjects with Major Depression Disorder (MDD) (b)(4) [redacted]

(b)(4) [redacted]

BRAINSWAY DEEP TMS SYSTEM FOR TREATMENT OF MAJOR DEPRESSIVE DISORDER

CLINICAL STUDY REPORT

(b)(4) [redacted]

(b)(4) [redacted]

Study Conducted According to Protocol: A Prospective Multicenter Double Blind Randomized Controlled Trial to Explore the Tolerability, Safety and Efficacy of the H-Coil deep Transcranial Magnetic Stimulation (TMS) in Subjects with Major Depression Disorder (MDD) (b)(4) [redacted]

(b)(4) [redacted]

BRAINSWAY DEEP TMS SYSTEM FOR TREATMENT OF MAJOR DEPRESSIVE DISORDER

CLINICAL STUDY REPORT

(b)(4) [redacted]

Study Conducted According to Protocol: A Prospective Multicenter Double Blind Randomized Controlled Trial to Explore the Tolerability, Safety and Efficacy of the H-Coil deep Transcranial Magnetic Stimulation (TMS) in Subjects with Major Depression Disorder (MDD) (b)(4) [redacted]

(b)(4) [redacted]

Data Submission Description

The goal of the present document is to describe the folders and files submitted.

(b)(4)

[redacted]

(b)(4) [redacted]

(b)(4) [redacted]

Applicant: ***Brainsway Ltd.***

Equipment Under Test:

Medical device used for transcranial magnetic stimulation (TMS) treatment

Product name: ***H-coil Deep TMS System***

Model: ***102***

Issued by:
The Standards Institution of Israel
Industry Division
Electronics & Telematics Laboratory
EMC Branch

(b)(4) [redacted]

(b)(4) [redacted]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 24, 2012

BRAINSWAY, LTD
C/O A STEIN REGULATORY AFFAIRS CONSULTING
20 HATA'AS ST. (POB 124)
KFAR SABA
ISRAEL 44425
ATTN: AHAVA STEIN

510k Number: K122288
Product: BRAINSWAY DEEP TMS SYSTEM
On Hold As of 9/19/2012

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Date: September 19, 2012

To: Brainsway Ltd.
% Ms. Ahava Stein
A. Stein Regulatory Affairs Consulting, Inc
Phone: +972-9-7670002
Fax: +972-9-7668534
Email: ahava@asteinrac.com

From: Michael Hoffmann

Subject: Telephone hold for K122288 for the Brainsway Deep TMS System

Dear Ms. Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided; this document serves to notify you that we have placed the file on hold. To complete the review of your submission, we require that you respond to the following deficiencies:

Administrative

(b)(4)

(b)(4)

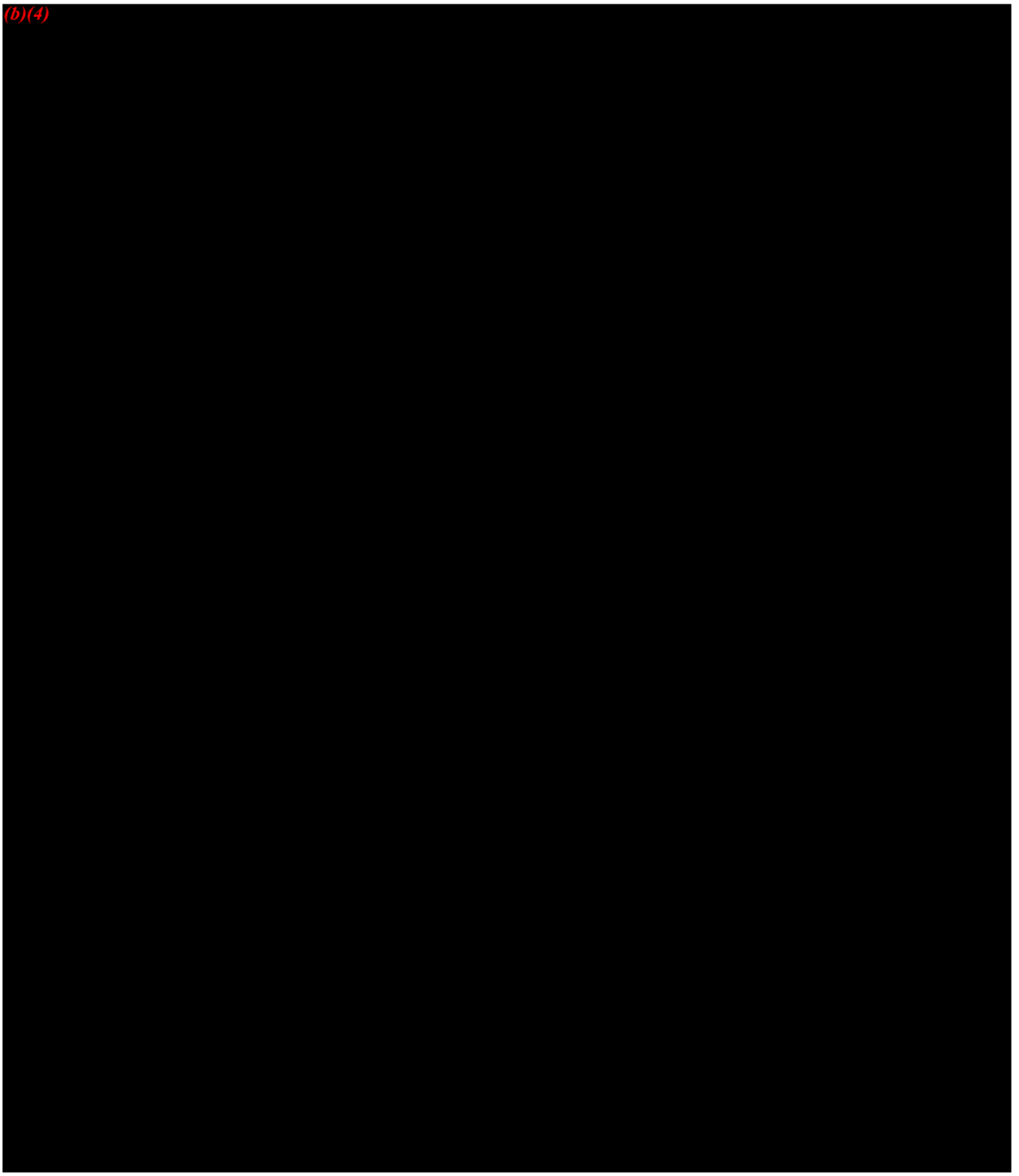
[redacted]

Clinical Trial Data Analysis

(b)(4)

[redacted]

(b)(4)



(b)(4)

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "Guidance for Industry and FDA Staff: Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements" at www.fda.gov/cdrh/ode/guidance/1655.html.

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact me by email at peter.como@fda.hhs.gov or by phone at (301) 796-6919. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

July 31, 2012

BRAINSWAY, LTD
C/O A STEIN REGULATORY AFFAIRS CONSULTING
20 HATA'AS ST. (POB 124)
KFAR SABA
ISRAEL 44425
ATTN: AHAVA STEIN

510k Number: K122288

Received: 7/30/2012

Product: BRAINSWAY DEEP TMS SYSTEM

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

Premarket Notification (510(k)) for the Brainsway Deep TMS System

VOLUME I

Brainsway Ltd.
19 Hartum St. (Bynet Bldg)
Har Hotzvim, Jerusalem, ISRAEL 91451
Tel: +972-2-5813140
Fax: +972-2-5812517
E-mail: hila@Brainsway.com

Section 1:

Medical Device User Fee Cover Sheet
(Form FDA 3601)

Form Approved. OMB No. 0910 (b)(4) [redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: [redacted] *Write the Payment Identification number on your check.*

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
BRAINSWAY LTD 19 Hartom Str. Jerusalem Israel 91451 IL	Ahava Stein 2.1 E-MAIL ADDRESS ahava@asteinrac.com 2.2 TELEPHONE NUMBER (include Area code) 972-9-7670002
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	2.3 FACSIMILE (FAX) NUMBER (Include Area code) +972-9-7668534

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) [redacted]

20-Jul-2012

Ahava Stein

"Close Window" Print Cover sheet

1-2

Section 2:

CDRH Premarket Review Submission Cover Sheet

Attachment 1 - FDA Form 3514.doc

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: May 31, 2007.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
ıly 10, 2012	MD 6062948-956733	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☐ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Brainsway Ltd.			
vision Name *(if applicable)*	Phone Number *(including area code)*		
	(+ 972) 2-5813140		
Street Address	FAX Number *(including area code)*		
19 Hartum St. (Bynet Building)	(+ 972) 2-5812517		
City	State / Province	ZIP/Postal Code	Country
Har Hotzvim, Jerusalem		91451	Israel
Contact Name			
Hila Rubinshtein			
Contact Title	Contact E-mail Address		
QA Manager	hila@Brainsway.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
A. Stein – Regulatory Affairs Consulting Ltd.			
Division Name *(if applicable)*	Phone Number *(including area code)*		
	(+ 972) 9-7670002		
Street Address	FAX Number *(including area code)*		
20 Hata'as St. (POB 124)	(+972) 9-7668534		
City	State / Province	ZIP/Postal Code	Country
Kfar Saba		44425	Israel
ɔntact Name			
.hava Stein			
Contact Title	Contact E-mail Address		
Regulatory Consultant	ahava@asteinrac.com		

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site
- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*
- ☐ Response to FDA correspondence:
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address
- ☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access
- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final
- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing
- ☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology
- ☐ Other Reason *(specify)*:

2-3

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	OBP	2		3		4	
		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*
1	K061053	NEUROSTAR TMS SYSTEM	NEURONETICS
2	K083538	NEUROSTAR TMS THERAPY SYSTEM, MODEL 1.1	NEURONETICS
3			
4			
5			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Repetitive Transcranial Magnetic Stimulator (TMS) System for treatment of Major Depressive Disorder

	Trade or Proprietary or Model Name for This Device		Model Number
	Brainsway Deep TMS System	1	N/A
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☒ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
OBP	§ 882.5805	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified
Classification Panel: Neurology		

Indications *(from labeling)*

The **Brainsway Deep TMS System** is intended for treatment of Major Depressive Disorder.

2-4

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

(b)(4)

[redacted]

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)* ( )	
Street Address		FAX Number *(including area code)* ( )	
City	State / Province	ZIP/Postal Code	Country
ontact Name	Contact Title	Contact E-mail Address	

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1	60601-1	IEC	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.		2005-2006
	Standards No.	Standards Organization	Standards Title	Version	Date
2	60601-1-2	IEC	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	Ed2.1	2005
	Standards No.	Standards Organization	Standards Title	Version	Date
3	301 489-1	ETSI EN	Electromagnetic Compatibility and Radio Spectrum Matters (ERM); Electromagnetic Compatibility (EMC) Standard for Radio Equipment and Services; Part 1: Common Technical Requirements (2008) Immunity.	V1.8.1	2008
	Standards No.	Standards Organization	Standards Title	Version	Date
4					
	Standards No.	Standards Organization	Standards Title	Version	Date
5					
	Standards No.	Standards Organization	Standards Title	Version	Date
6					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

2-6

Section 3:

510(k) Cover Letter

 K122288

A. Stein
REGULATORY AFFAIRS CONSULTING
Beit Hapa'amon (Box 124)
20 Hata'as St., 44425 Kfar Saba ISRAEL
Tel: +972-9-767-0002 Fax: +972-9-766-8534
E-mail: asteinra@netvision.net.il

July 19, 2012

510(k) Document Mail Center (WO66-0609)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
U.S.A.

Re: Premarket Notification (510(k)) for the Brainsway Deep TMS System

Attention: Document Mail Clerk

Brainsway Ltd. has requested that I represent them in the capacity of authorized regulatory agent for the purpose of obtaining FDA marketing clearance for the Brainsway Deep TMS System. It is in that capacity that I am communicating with you.

Attached please find the premarket notification submission for the Brainsway Deep TMS System. A table of contents for this 510(k) is presented following the cover letter.

Following is information required under 21 CFR 807.87 and suggested by FDA guidelines:

Type of 510(k) submission: Traditional

510(k) Submitter: Brainsway Ltd.
19 Hartum St. (Bynet Bldg)
Har Hotzvim, Jerusalem, ISRAEL 91451
Tel: +972-2-5813140
Fax: +972-2-5812517
E-mail: hila@Brainsway.com

Contact Person: Ahava Stein
A. Stein – Regulatory Affairs Consulting Ltd.
20 Hata'as Str., Suite 102
Kfar Saba 44425 Israel
Tel: + 972-9-7670002
Fax: +972-9-7668534
E-mail: ahava@asteinrac.com

This is to notify you of the intention of Brainsway Ltd., to manufacture and market the following device:

Device trade or proprietary name: Brainsway Deep TMS System

Common Name: Repetitive Transcranial Magnetic Stimulator

Classification and Product Code: The subject of this 510(k) is the Brainsway Deep TMS System, with the CFR classification section 882.5805; Repetitive Transcranial Magnetic Stimulator (TMS) System for treatment of Major Depressive Disorder, and product code OBP.

Device Class and Panel: An Repetitive Transcranial Magnetic Stimulator is a class II device. The classification panel is the Neurological Devices Panel.

Intended Use: Refer to 510(k) Indications for Use form.

Establishment Registration Number: The company has not applied yet for an Establishment Registration Number. This will be done at a later date.

514 Performance Standards: There are no performance standards or special controls under the Federal Food, Drug and Cosmetic Act, for a Repetitive Transcranial Magnetic Stimulator. However, the FDA has issued a Guidance Document "*Class II Special Controls Guidance Document: Repetitive Transcranial Magnetic Stimulation (rTMS) Systems*" which the Brainsway has followed in compiling this 510(k) submission. Furthermore, Brainsway has chosen to comply with the recognized consensus standards listed in FDA Form 3514 and Section 9 of this 510(k).

(b)(4)

Reason for Submission: New device.

Substantial Equivalence: The Brainsway Deep TMS System is substantially equivalent to the following predicate device:

Manufacturer	Device	510(k) No.
Neuronetics	NEUROSTAR TMS SYSTEM	K061053
Neuronetics	NEUROSTAR TMS THERAPY SYSTEM, MODEL 1.1	K083538

A comparison table and detailed discussion are presented in Section 12 – Substantial Equivalence Discussion of this application.

Proposed Labeling: The user's manual for the Brainsway Deep TMS System is attached in Section 13 (Proposed Labeling Section). These instructions describe the system, its intended use and the directions for its use. Packaging labels are also included in the Product Labeling Section.

Confidentiality: Brainsway Ltd. considers its intent to market the Brainsway DTMS System in the USA as confidential commercial information. The Company has not disclosed its intent to market this device to anyone except its employees, others with a financial interest in the Company, its advertising or law firms, and its consultants. The Company, therefore, requests FDA not to disclose the existence of this application until such time as final action on the submission is taken. In addition, some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 CFR § 20.61 and therefore not disclosable under the Freedom of Information Act, even after the existence of the application becomes public. We ask that FDA consult with the Company as provided in 21 CFR § 20.45 before making any part of this submission publicly available.

This document presents additional information and data that are intended to establish substantial equivalence and meet the requirements of a 510(k). This supportive information is divided into the following sections, according to the new FDA guidance document for the format of Premarket notification submissions;

1. Medical Device User Fee Cover Sheet
2. CDRH Premarket Review Submission Cover Sheet
3. 510(k) Cover Letter
4. Indications for use Statement
5. 510(k) Summary
6. Truthful and Accuracy Statement
7. Class III Summary and Certifications- Non Applicable
8. Financial Certifications or Disclosure Statements
9. Declaration of Conformity
10. Executive Summary
11. Device Description
12. Substantial Equivalence Discussion, including comparison table of predicate devices and discussion.
13. Proposed Labeling
14. Sterilization, Cleaning and Packaging, and Shelf Life Information
15. Biocompatibility Information
16. Software
17. Electromagnetic Compatibility and Electrical Safety
18. Performance Testing- Bench
19. Performance Testing – Animal – Not Applicable
20. Performance Testing – Clinical
21. Other- Not Applicable

In the following pages two additional tables are attached:

- A table with answers to general questions regarding the design and use of the device;
- The Table of Contents of the 510(k) submission

I trust that the information included in this application will be adequate to allow for its prompt review. If you have any questions or comments, please don't hesitate to contact me at the following telephone numbers: +972-9-767-0002 (office) or +972-52-2346927 (mobile), fax number: +972-9-7668534 or e-mail address: ahava@asteinrac.com.

Sincerely Yours,

Ahava Stein

Ahava Stein
A. Stein - Regulatory Affairs Consulting Ltd.
for Brainsway Ltd.

Design and use of the Device:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	√	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		√
Does the device contain components derived from a tissue or other biologic source?		√
Is the device provided sterile?		√
Is the device intended for single use?		√
Is the device a reprocessed device?		√
If yes, does this device type require reprocessed validation data?		√
Does the device contain a drug?		√
Does the device contain a biologic?		√
Does the device use software?		√
Does the submission include clinical information?	√	
Is the device implanted?		√

Table of Contents

Section 4:

Indications for Use Statement

INDICATIONS FOR USE

510(k) Number (if known): K_____

Device Name: Brainsway Deep TMS System

Intended Use Statement:

The Brainsway Deep TMS System is intended for treatment of Major Depressive Disorder.

Prescription Use __√___ (Per 21 C.F.R. 801 Subpart D)

OR

Over-The-Counter Use___ (Optional Format Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

— —

Concurrence of CDRH, Office of Device Evaluation (ODE)

15-3 Irritation Test Report

Appendix 15-3
DOC101 Skin Irritatio

TEST FACILITY

(b)(4)

SPONSOR

Hila Rubinshtein
Brainsway Ltd.
19 Hartom
Jerusalem, 91451
Israel

STUDY TITLE

ISO Skin Irritation Study

TEST ARTICLE NAME

Cap produced by Brainsway out of NuStim Wrap – Fabrifoam fabric

(b)(4)

TABLE OF CONTENTS Page

(b)(4)

[redacted]

(b)(4) [redacted]

Test Report No (b)(4) [redacted]

Applicant: Brainsway Ltd.

Equipment Under Test:

Medical device used for transcranial magnetic stimulation (TMS) treatment

Product name: H-coil Deep TMS System

Model: 102

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4)

[redacted]

Table of Contents

(b)(4)

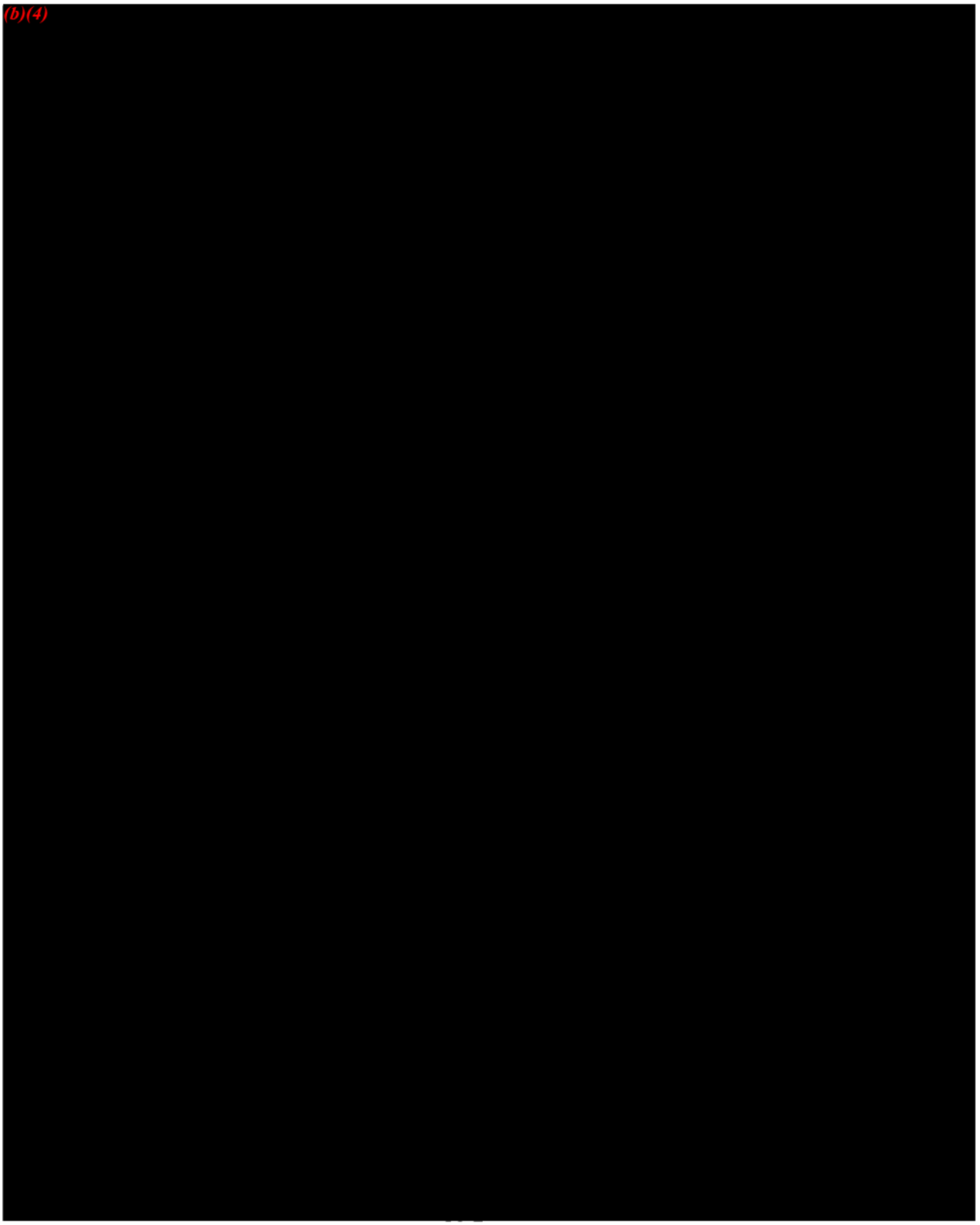
[redacted]

Section 18:

Performance Testing-Bench

Performance Testing

(b)(4)



Attachment 18-1:

H-Coil Output Tests Protocol (b)(4)

(b)(4)

H-Coil Output Test Report (b)(4)

(b)(4)

(b)(4)

[redacted]

H-COIL OUTPUT TESTS PROTOCOL

(b)(4)

[redacted]

Brainsway Ltd.*

Clinical Protocol

A Prospective Multicenter Double Blind Randomized Controlled Trial to Explore the Tolerability, Safety and Efficacy of the H-Coil deep Transcranial Magnetic Stimulation (TMS) in Subjects with Major Depression Disorder (MDD)

Protocol (b)(4) [redacted]

H-coil Deep TMS: Clinical Protocol

(b)(4) [redacted]

(b)(4)

[redacted]

Software Requirements Specification

for the

Randomization Program

(b)(4)

[redacted]

20-158

(b)(4) [redacted]

APPENDIX XIII

(b)(4) [redacted]

Quality Control Line Item Data

(b)(4) [redacted] (b)(4) [redacted]

APPENDIX XIV

Bidirectional Sequencing

(b)(4) [redacted] (b)(4) [redacted]

Bidirectional Sequencing of Discordant Results

(b)(4) [redacted]

(b)(4) [redacted] (b)(4) [redacted]

APPENDIX XV

Assay Cutoff/Validation Parameters

(6

(b)(4) [redacted]

(b)(4) [redacted]

APPENDIX XVII

Institutional Review Board Approval Letters

(b)(6)

(b)(6)

(b)(6)

(b)(6)

(b)(6)