Discovery Module User's Manual



BrainMaster Discovery 24E Modules Hardware User Manual

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Certificate Of Conformance

BrainMaster EEG devices including the 2E (390-001), 2EW (390-001W), 2EB (390-020), 2EA (390-040 Atlantis), 4EA (390-030 Atlantis), and 24E (390-060 Discovery) are legally marketed worldwide. They conform to the requirements of the US FDA (Food and Drug Administration) under 510(K) 990538, and are covered abroad by a CE mark as Class I Biofeedback devices. BrainMaster EEG devices are indicated for biofeedback training using EEG. Our FDA registration includes classification 882.5050 (Biofeedback Device) and 882.1400 (Electroencephalograph). The stated functions in the FDA registration include "use EEG," "measure EEG," and "process [EEG] to produce frequency band energy."

The BrainMaster EEG line of biofeedback systems includes a series of models, all of which follow the same line of technology evolution, and all of which have the same level of safety and efficacy, and the same intended use. The differences between the devices consist solely of the specific circuits used in their construction, and the number of channels supported. Newer devices are more accurate, and offer more channels of EEG. There are no other pertinent differences in these devices.

Our internal record keeping is managed according to FDA GMP standards, and documents the required controls for design and testing. Devices are covered by the cited 510(K), in the form of internal Engineering Change Orders documenting and validating the design improvements. This fulfills the requirements to be legally marketed for their intended use in the US and abroad.

The CE mark information has been kept current by providing to our European agent the technical information to update their files as the technology has been improved. This fulfills the requirements for CE marking and sales in Europe.

All devices conform to all required testing and certification including IEC 60601, AAMI, and FCC, for safety and for electromagnetic emissions. Test reports are on file for all marketed devices.

Therefore, all current BrainMaster EEG devices may be legally marketed worldwide for the purpose of EEG biofeedback by using, measuring, and processing EEG.

Thomas F. Collura, Ph.D. President BrainMaster Technologies, Inc.

Minimum PC Computer Requirements

BrainMaster 3.0 CPU:	Software or Discovery 1.0 Software with up to 4-Channel LZT* Dual-Core 2.2GHz Processor
Operating System:	Windows XP, Windows Vista, Windows 7
Memory(RAM):	Windows XP - 1GB (Minimum) 2GB (Recommended) +Windows Vista - 2GB (Minimum) 4GB (Recommended)
	Windows 7 - 2GB (Minimum) 4GB (Recommended)
Craphics Card	
Graphics Card:	512MB Dedicated OR 1GB Shared Graphics
Optical Drives:	DVD-ROM Drive: Required for BMrDVD**
Input:	1 USB Port
Additional SW:	Microsoft Office: Required for Certain reports and EEGAudio
	Windows Media Player or 3rd Party DVD Decoder:
	Required for BMrDVD Adobe Acrobat Reader
	Adobe Flash Player: Required for BMrFlash Player
	Adobe Shockwave Player: Required for BMrFlash Player
	ftware with BMrMMP** and up to 19-Channel LZT*
CPU:	Quad-core or above
Operating System:	Windows Vista, Windows 7
Memory(RAM):	4GB
Graphics Card:	Direct x 10 or above compatible graphics card
	1GB Dedicated
Optical Drives:	DVD-ROM Drive: Required for BMrDVD**
Input:	1 USB Port
Additional SW:	Microsoft Office: Required for certain reports and EEGAudio**
	Windows Media Player or 3rd Party DVD Decoder:
	Required for BMrDVD** Adobe Acrobat Reader
	Adobe Flash Player: Required for BMrFlash Player
	Adobe Shockwave Player: Required for BMrFlash Player
BrainAvatar™ 4.0	0 Software
CPU:	Quad-core or above
Operating System:	Windows Vista, Windows 7
Memory(RAM):	4GB
Graphics Card:	Direct x 10 or above compatible graphics card
	1GB Dedicated
Optical Drives:	DVD-ROM Drive: Required for BMrDVD**
Input:	1 USB Port
Additional SW:	Microsoft Office: Required for certain reports and EEGAudio**
	Windows Media Player or 3rd Party DVD Decoder:
	Required for BMrDVD** Adobe Acrobat Reader
	Adobe Flash Player: Required for BMrFlash Player
	Adobe Shockwave Player: Required for BMrFlash Player
*Live Z-Score Training	g is an optional purchase

*Live Z-Score Training is an optional purchase **BMrMMP is an optional purchase

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Discovery Device Description

Executive Summary and Device Description

The Discovery system is a physiological monitoring and feedback system that offers monitoring and feedback of brain signals including electroencephalography (EEG) and DC and slow cortical potentials (DC/SCP). All recordings are made noninvasively from the surface of the body using standard sensors of tin, gold, or silver chloride.

The system provides a visual or auditory signal corresponding to the status of one or more of a patient's EEG (e.g., brain alpha wave activity) so that the patient can undergo operant learning. Signal processing and feedback are provided by the user's PC running the software provided by BrainMaster. Information is derived from spectral analysis of the electroencephalogram (EEG).

The system incorporates optical and magnetic isolation/coupling technology to provide a safe and low-noise interface to the user's PC. The Discovery is provided with 24 channels. When used with the supplied software, the system provides EEG biofeedback monitoring, analysis, and reports using a Windows PC.

For European Market Only

The Discovery can be used for measurement and diagnostic purposes, when the EEG levels are used for this intended use.

Intended Uses

The Discovery system is intended for relaxation training using EEG biofeedback. In the protocol for relaxation, Discovery provides a visual or auditory signal that corresponds to the patient's changes in EEG activity as an indicator of the state of relaxation.

For European Markets Only

The Discovery can be used to measure the levels of EEG parameters for diagnostic use.

Symbols Used

"Caution, consult accompanying documents" or "Attention, see instructions for use."



Shock ProtectionType BF -- for devices that have conductive contact with the patient.



On BrainMaster devices and cables, indicates Functional Earth Terminal. Note that on BrainMaster devices and cables, the Functional Earth Terminal is not connected to the power line, or "mains" ground or neutral.

Abbreviations Used

A1, A2, Fp1, A/D Aux	Analog-to-Digital Auxiliary
BMr C	BrainMaster Technologies, Inc Celsius
CMRR dB	Common-mode Rejection Ratio
DC	Direct Current
EEG	Electroencephalograph
GB	Gigabyte
GHz	Gigahertz
GOhms	Gigiaohms
Hz	Hertz
LZT	Live Z-Score Training
m	meter
MMP	Multi Media Player
mV	millivolt
RMS	Root-Mean-Square
USB	Universal Serial Bus

BrainMaster Technologies Notes and Safety Precautions

All Cautions will be written in bold and underlined All points will be written in bold PLEASE NOTE: All notes will be written in red and bold

- <u>Read the user manual thoroughly prior to installing or using The</u> <u>BrainMaster System</u>
- <u>This User Manual should be kept near your BrainMaster System at all times</u> for ease of reference
- <u>The BrainMaster System is to be used under the supervision of a licensed</u> practitioner at all times
- Do not use The BrainMaster System for any purpose outside of its stated intended use
- The BrainMaster System is not to be used to monitor critical life functions
- The BrainMaster System should never be submerged in water
- Do not use harsh solvents to clean The BrainMaster System as this can cause damage to the equipment
- <u>Do not use The BrainMaster System in a high static environment as this</u> <u>can cause damage to the equipment</u>
- <u>Never connect any equipment to The BrainMaster System that has not been</u> <u>approved by BrainMaster Technologies Inc.</u>
- Do not use The BrainMaster System in a flammable gas environment
- <u>The BrainMaster System is not designed for use in a sterile environment</u> and should not be sterilized using any method as this would render the system inoperable
- There are NO USER SERVICABLE PARTS within the BrainMaster System
- <u>Always use the same type of electrodes (gold, silver, tin) when connecting</u> <u>a patient</u>. <u>Do not mix metals as this can degrade system performance and</u> <u>cause inaccurate readings</u>
- <u>Always visually inspect all electrodes prior to use as cracked or damaged</u> <u>leads can cause inaccurate readings</u>

- BrainMaster Recommends replacing your electrodes at minimum in 1 year cycles in order to maintain proper functioning equipment
- Only approved 3rd Party devices may be used in conjunction with your BrainMaster Device
- <u>The BrainMaster Device does not produce any electro-magnetic fields and</u> <u>should not interfere with the operability of other devices.</u>
- <u>To avoid electro-magnetic interference from other equipment, only use</u> <u>approved devices in conjunction with the BrainMaster Device.</u>
- Ensure when connecting a Patient that your electrodes and Patient Cables do not come in contact with any other conductive parts including neutral or earth ground.
- BrainMaster Devices are not for use in conjunction with High Frequency Surgical equipment.
- When using the equipment at the same time with other instruments, it is necessary to remember that the sum of the dispersion currents determined by each instrument may exceed the value of the maximum leakage current.
- <u>The BrainMaster Device is not intended to be used simultaneously with</u> <u>electrical stimulators.</u>
- <u>The use of a cardiac pacemaker may cause undesirable artifacts within the</u> <u>EEG signal acquired by the BrainMaster Device.</u> Care should be taken to <u>ensure that your data is usable.</u>

General Care Instructions for your BrainMaster System

These instructions apply to all products in the BrainMaster line such as the 2EB, Atlantis, Discovery, and all other peripherals that BrainMaster Technologies Inc. sells for use with the BrainMaster System.

Standard environmental conditions for indoor use are: Altitude: up to 2000m, Temperature: 5 to 40 deg C, maximum relative humidity is 80% for temperatures up to 31 deg C decreasing linearly to 50% at 40 deg C.

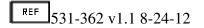


Hardware Care

1. After every session wipe down your equipment with a damp cloth or paper towel in order to remove any paste or gel that has spilled onto the unit.



- a. The use of solvents such as Windex, glass cleaner, etc is not recommended as it could damage the equipment.
- b. If you have gel or paste that has dried to the unit we recommend using a small amount of rubbing alcohol on the affected area only and it should be wiped away as soon as possible.
- c. Removal of these substances will prevent them from possibly damaging the front end connectors and the USB port and switch on the rear of the unit.
- 2. Wipe all of your patient cables down with either a damp cloth or rubbing alcohol after each use in order to keep them clean and free of contaminants.
- **3**. If the USB cable has become dirty it is also recommended that you wipe it down as well using either a damp cloth or rubbing alcohol.



Electrode Care

Please Note: BrainMaster sells multiple types of electrodes, gold, tin, and silver, these should never be mixed with use on patients. You must use the same metal type in all electrodes during a recording or your collected data will not be valid. Each metal type has its own properties and will cause an unstable recording environment if mixed.

Always use the same type of electrodes (gold, silver, tin) when connecting a patient. Do not mix metals as this can degrade system performance and cause inaccurate readings

Prior to hooking up a patient

- 1. Inspect all lead wires for cracks and kinks in the wiring.
 - a. Pay close attention to the ends nearest the female connector and the connection closest to the electrode itself as these areas tend to crack and break the easiest.
- 2. Inspect the electrode itself for any corrosion, or loss of metal plating as this will affect your ability to acquire clean, low impedance, low dc offset (Discovery only) recordings.
- 3. If damage to an electrode is suspected do not use it.

Always visually inspect all electrodes prior to use as cracked or damaged leads can cause inaccurate readings

After your session

- 1. Immediately after your session remove excess material and then soak your electrodes (cup end only) in warm soapy water for approximately 20 minutes to loosen up the remaining paste.
 - a. Avoid submerging the female connector jack in water if possible
- 2. Clean your electrodes using warm running water and a q-tip or other nonabrasive item to remove all remaining paste from the electrode.
- 3. Remove excess liquid by wiping the electrode down with a paper towel and hang them to dry.

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a. If they are needed immediately ensure that the electrode is completely dry using a paper towel or other non-abrasive cloth.

Other considerations

The cleaning instructions above can be used with the **Electro-Cap Ear-Clips only**. Consult the Electro-Cap manual for care and cleaning procedures for your Electro-Cap.

Electrodes **WILL** need to be replaced eventually they will not last forever, however proper care will ensure that your electrodes will last. The typical life of an electrode depends on several factors:

- 1. The type of metal (Gold, Tin, or Silver)
- 2. The amount of use they receive
 - a. Once a week verses several times a day
- 3. How well they are cared for

How Long will my Electrodes Last?

- Gold and Silver electrodes can last up to 2 years again depending on usage and care
- Tin electrodes can last from 6 month to a year

BrainMaster Recommends replacing your electrodes at minimum in 6 month cycles in order to maintain proper functioning equipment.

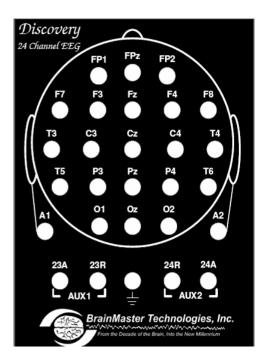
Please Note: BrainMaster only warrantees your electrodes for 90-days from the time of purchase as they are considered a consumable item. Please inspect all electrodes upon receipt for damage. Consult your BrainMaster Warranty for further information or contact BrainMaster Support at 1-440-232-6000 M-F 9:30 to 6:00 PM EST or email support@brainm.com with any questions.

Please Note: These instructions apply to electrodes only they do not apply to the Electro-Cap products sold by BrainMaster. Consult the Electro-Cap manual and training video for proper cleaning and care. Contact Electro-Cap International at 800-527-2193 or view their website at <u>http://www.electro-cap.com/information.htm</u> for Electro-Cap related issues.

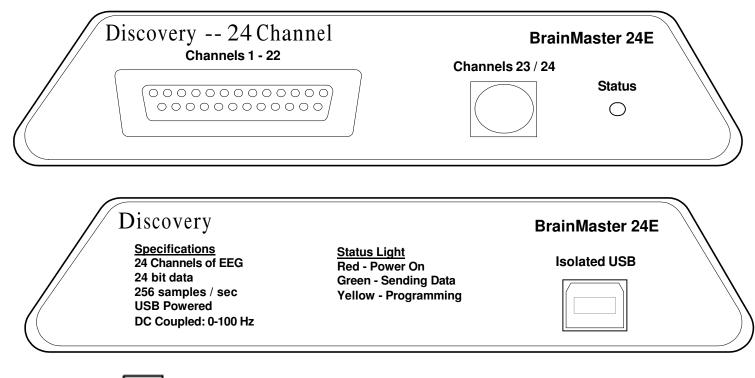
Discovery 24E Specifications

Discovery 24E Specifications

- Number of channels: 24
 - Channels 1 19 are 10-20 sites.
 - Channel 20 is A2, referenced to A1. (A2-A1)
 - Channel 21 is Fpz
 - Channel 22 is Oz
 - Channels 23 and 24 are differential with separate active and reference inputs on external
- "Atlantis" style connector (cable & standard touch-proof leads).
- All channels acquired referenced to A1
- Amplifier type: DC, differential
- A/D accuracy: 24 bits; resolution 0.01microvolts EEG, 0.4 microvolts DC
- Input range: +/- 100 millivolts EEG, +/- 4 volts DC
- Input impedance > 1000GOhms
- Common-mode Rejection Ratio (CMRR) > 110 dB
- Amplifier bandwidth: 0.000 100 Hz
- EEG channel bandwidth: 0.43 80 Hz
- DC offset signal bandwidth: 0.000 2 Hz
- Input noise < 2.0 microvolt RMS (0.43 60 Hz)
- Sensor contact quality monitored via offset voltage
- Sampling Rate: 1024 samples/second
- Data rate to PC: 256 samples/second
- Line speed: 480600 baud
- Data rate: 19200 bytes / second
- Connection to PC: USB, optically and magnetically isolated



Discovery 24E Top, Front and Rear Panels



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Discovery Basics

Connecting to the PC

The Discovery module is connected to the PC using a standard USB cable. This both powers the unit, and also provides a communication channel to and from the PC. When the module is first connected, it will be necessary to install the "driver" software, by following the instructions provided. The Discovery module will not operate, , until it is recognized by a PC, and the PC provides the device with power.

Please see 531-319 for Hardware Installation instructions for more information.

Discovery Power on Sequence

After the Discovery is properly installed on the PC, the PC will be providing power to the module. Each time the module is connected to the PC and the PC is powered, the Status light on the front panel will turn on. This light will be red without any software running.

Connecting EEG Sensors through the Lid

The sensors are connected by using the lid of the device. Insert the respective sensor leads using the "touch proof" jacks into each site that you will be using.

Please Note: It is essential to first obtain a good ground connection and A1. If either of these connections is poor, all other signals will be compromised. For a secure ground, any suitable connection can be used. Connect this sensor first, and make sure the connection is secure.

Please Note: No matter what type of connection, please note that A1, A2 and GND must always be connected. If you do not connect these sites, you will not get a proper connection.

Connecting EEG Sensors through 25-Pin Connector

Make sure to properly connect all sites, per the manufacturer's specifications. Once the device is fully connected, plug the male connector of the female connector of the Discoverv.

Please see the manufacturer's instructions for more information on connections.

DC Offsets Information

The Discovery does not monitor sensor impedance as the Atlantis does. Instead, it monitors the DC offset potential on all 24 channels, and uses them to assess sensor connection quality. While there does not seem to be an exact correspondence between sensor offset and sensor impedance, we have found that when sensor offsets below 25 millivolts are achieved, then good recordings can be expected. Below, is a recommended level for the different type of sensors:

Gold	below 50mV
Ag/AgCL	below 10mV
Tin	below 30mV

In the BrainMaster Discovery Software, we have built in the ability to monitor DC Offsets to assure the optimal connection. This has also been color-coded for you convenience:

White	below 25mV
Green	below 50mV
Yellow	below 75mV
Red	above 100mV

Please see 531-349 for for more information on the BrainMaster Discovery Software.

Discovery Firmware Field Programming

 Firmware Field programming is performed in the Training/Control Screen. Begin by clicking the "Data" tab, then choosing "Discovery Setup". PLEASE NOTE: You must be running the latest updated version of the Discovery software in order to update the Discovery Firmware.



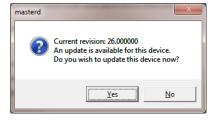
2. When the "Discovery Hardware Module Maintenance" Window appears, click the "Check Module" Button.



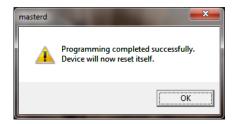
3. When the following box appears, click "OK" to continue. **PLEASE NOTE:** The text that appears might be different to the text that appears on your screen.



4. The following screen will you know your current firmware revision. Click "Yes" to continue.



- 5. The following window will give you instructions. Be sure to follow these instructions, and click "OK" to continue.
- The "Discovery Hardware Module Maintenance" Menu will now begin to update the firmware. PLEASE NOTE: During this process, make sure that nothing else is to be occurring as this can cause problems in writing the Discovery Firmware. You can tell that this is occurring, because, the Status line number will be changing.
- When the following screen appears, click "OK" to continue. On the "Discovery Hardware Module Maintenance" menu, click "Close"



Programming will take about 20 seconds

le Maintenance

Updating Firmware... Please wait

Device Serial Number: Serial Number: 60334 Current Firmware Revision: first pass: 24 s1:1 s2:13 s3:-1 fw is: 24

Available Firmware Revision: Revised Firmware Found

Check Module

Status:

this control unless instructed to do so by BrainMaster Technologies, Inc

te use of this control could cause you to have to return your device to the fi

Writing Line: 194 of 1550 to Discovery Length: 43

Close

Do not disconnect theDiscoveryduring this time Press OK when ready or Cancel to cancel

OK

masterd

X

Cancel

Your Discovery is now using the most up-to-date Firmware

Please see 531-349 for for more information on the BrainMaster Discovery Software.

Discovery Module User's Manual



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