MADOC1 EEG ACQUISITION MODULE

USER MANUAL

Controles S.A y Dr. D. Cibils
Av. Rivera 3314
Montevideo URUGUAY

Tel. +5982 6220651
Fax +5982 6222048
www.controles.com

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INTRODUCTION

About this manual

This manual contains all of the information to operate the MADOC1 module. It also includes cleaning and test procedures that may be required occasionally.

Before attempting to use the MADOC1 module, please familiarize with the safety information provided in the "SAFETY PRECAUTIONS" section.

Introduction

The MADOC1 module is an one EEG channel amplifier intended for patient monitoring. It acquires the EEG signal by 3 standard ECG electrodes. It amplifies and digitizes the signal, and then transmits the digital data via Bluetooth. It checks the skin to electrode contact, automatically each minute or when pressing the "Electrode check" button on the device.

The MADOC1 is intended for use in operating rooms and in intensive care units.

SAFETY PRECAUTIONS

Warnings, cautions and notes

The terms warning, caution and note have specific meanings in this manual:

- A WARNING advises against certain actions or situations that could result in personal injury or death
- A CAUTION advises against actions or situations that could produce inaccurate data
- A NOTE provides useful information regarding a function or procedure.

Warnings

DO NOT USE THE EQUIPMENT IN A FLAMMABLE ATMOSPHERE OR WHERE CONCENTRATIONS OF FLAMMABLE ANESTHETICS MAY OCCUR.

NOT DESIGNED FOR USE IN MRI ENVIRONMENT.

SHOCK HAZARD: DO NOT ATTEMPT TO DISCONNECT THE POWER CORD WITH WET OR DIRTY HANDS.

AVOID THE CONTACT OF CONDUCTIVE PARTS OF ELECTRODES TO OTHER CONDUCTIVE PARTS, INCLUDING EARTH.

IN CASE OF SURGICAL MONITORING, DO NOT LOCATE ELECTRODES BETWEEN THE SURGICAL SITE AND THE ELECTROSURGICAL UNIT RETURN ELECTRODE, TO REDUCE THE HAZARD OF BURNS DUE TO THE HIGH-FREQUENCY SURGICAL CURRENTS TO THE NEUTRAL ELECTRODE CONNECTION.

APPLIED PARTS ARE NOT PROTECTED FROM THE EFFECT OF CARDIAC DEFIBRILLATION ACCORDING TO IEC 60601-2-26.

WHEN A DEFIBRILLATOR IS USED ON A PATIENT CONNECTED TO THE MODULE, THE ELECTRODES SHALL NOT BE LOCATED BETWEEN DEFIBRILLATOR PADS.

THE MODULE SHALL BE MOUNTED SECURELY TO AVOID PERSONAL OR PATIENT INJURY.

CHECK GROUND WIRE LEAKAGE CURRENT AFTER AN EQUIPMENT CASE OPENING AND CLOSING.

ELECTRICAL SHOCK HAZARD: DO NOT REMOVE EQUIPMENT COVERS WHILE POWER IS CONNECTED.

ELECTRICAL SHOCK HAZARD: THE MANUFACTURER VERIFIED THAT THE GROUND LEAKAGE CURRENT AND THE PATIENT SAFETY CURRENT WERE LESS THAN THE SPECIFIED LIMITS ESTABLISHED IN THE IEC60601-2-26 STANDARD. THESE CURRENTS SHOULD BE VERIFIED PERIODICALLY. WHENEVER A LIQUID SPILLAGE OCCURS, VERIFY THE CURRENTS BEFORE FURTHER USE.

TAKE UNIVERSAL PRECAUTIONS TO PREVENT CONTACT WITH BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIALS.

CAUTIONS

Good skin to electrode contact is essential for the proper performance of the equipment.

Strictly follow the electrode placement procedure described in this manual.

To proper patch to skin adhesion, avoid wetting the electrode self-adhesive part when placing the electrodes.

During normal use, "+5V", "-5V", "TX" and "BTC" LED indicators shall be active.

Automatic impedance checking may need to be disabled if the 6 uA 128 Hz impedance check current interferes with other equipment, e.g., evoked potential monitors.

Do not autoclave the equipment. It will be damaged.

Do not open the equipment. Equipment waterproofing may be damaged. Service should be performed only by qualified technicians.

Do not wet the electrode clips. Liquids may degrade the module function.

Operation of the module may affect or be affected by other equipment in the vicinity due to electromagnetic interference (EMI). If this occurs:

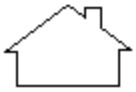
- **increase separation between devices**
- **re-orient device cabling**
- **plug devices into separate outlet circuit branches.**

Do not touch the exposed parts of connectors when connecting or disconnecting the modle. Damage due to electrostatic discharge may result.

The use of accessories other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the MADOC1 module.

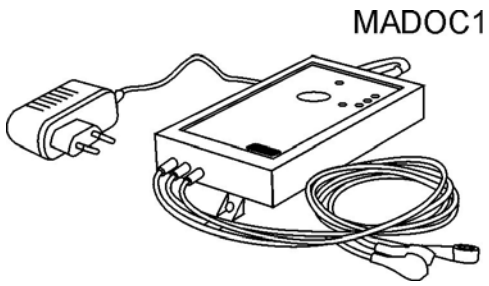
The MADOC1 module should not be used over or close to other equipment. If this situation is unavoidable, check the normal function for the particular case.

Table of symbols

	Caution: Consult Accompanying Documents
	Class II Equipment
	Type BF Equipment
	Alternating Current (AC)
	Direct Current (DC)
	Storage temperature
	Manufacturer
	Latex-free product
	Packaging Labeling: Fragile, Do Not Get Wet, and This Side Up
	Non-ionizing radiation
	Only for indoor use

INSTALLATION AND PREPARATION FOR USE

Caution:
Carefully read this section before installing the equipment.



Accessories

The following accessories are required by the MADOC1 module:

- One MADOC1 dongle which plugs into an USB port. It receives the data transmitted by MADOC1. Each MADOC1 module is set up to communicate exclusively to one MADOC1 dongle. Given a specific MADOC1 dongle, the serial number of the correspondent MADOC1 is found in the field “MADOC1” within the label.
- Software which support the PTOCC-1 data transmission protocol from Controles S.A.
- Standard pre-gelled silver/silver chloride electrodes normally used for ECG, e.g. “Swaromed” or “Medi-Trace” ECG electrodes.

Storage environment

Temperature: -20ºC to 60ºC.

Humidity: 15% to 95% HR (non-condensing).

Operating environment

WARNING!

DO NOT USE THE EQUIPMENT IN A FLAMMABLE ATMOSPHERE OR WHERE CONCENTRATIONS OF FLAMMABLE ANESTHETICS MAY OCCUR.

NOT DESIGNED FOR USE IN MRI ENVIRONMENT.

Temperature: 0ºC to 40ºC.

Humidity: 15% to 95% HR (non-condensing).

Power requirements

The MADOC1 module requires a power source of 100-240 VAC, 0.3 A (max), 50/60 Hz.

Electromagnetic Compatibility Requirements

The MADOC1 module shall be installed and used according to the specifications in "Electromagnetic Compatibility Specifications".

Caution:

The MADOC1 module complies with the electromagnetic compatibility requirements of IEC 60601-1-2.
Operation of the module may affect or be affected by other equipment in the vicinity due to electromagnetic interference (EMI). If this occurs:
- increase separation between devices
- re-orient device cabling
- plug devices into separate outlet circuit branches.
Refer to section "Electromagnetic Compatibility Specifications".

Mounting

The MADOC1 module includes a clip for attaching the device at a convenient location near the patient's head.

WARNING!
THE MODULE SHALL BE MOUNTED SECURELY TO AVOID PERSONAL OR PATIENT INJURY.

Connections

The MADOC1 has three cables with snap connectors for electrodes and one power cord.

The power cord attaches into a properly power outlet (refer to the “Power requirements” section).

The cables with snap connectors connect to the patient through standard ECG electrodes. The red snap connector and the white snap connector attach respectively to the positive and negative electrode of the EEG differential channel, while the black connector attaches to the reference electrode.

Two green indicator LED labeled as “+5V” and “-5V” indicate power presence. One green LED indicator labeled “TX” indicate data transmission from the microcontroller. One bicolor LED indicator labeled “BTC” indicates Bluetooth connection. One green LED indicator labeled “ZON” indicates that the automatic skin to electrode contact checking is enabled.

A button labeled “Electrode check” allows to manually verify the skin to electrode contact or to disable automatic skin to electrode contact checking.

Caution:

Do not open the equipment. Equipment waterproofing may be damaged. Service should be performed only by qualified technicians.

Communications

Data transmission from the MADOC1 module to the MADOC1 dongle is done via the PTOCC-1 protocol, by Controles S.A. . Data transmission is done by Bluetooth in master-slave mode, where MADOC1 module is the slave and the corresponding dongle is the master. The dongle receives the data transmitted by the MADOC1 device, and transmits the data to the USB port.

A driver for Windows operating system allows to install the MADOC1 dongle as a serial device.

Software

Patient monitoring by MADOC1 requires a software compatible to the PTOCC-1 protocol and a Bluetooth master set up by the manufacturer.

USING THE MODULE

Caution:
Carefully read this section before using the module in a clinical setting.

Step by step

1. Plug the device power cord into a properly power outlet

2. Attach the electrodes to the patient

   The MADOC1 module uses 3 standard patch ECG electrodes. It should be used with standard pre-gelled silver/silver chloride electrodes. "Swaromed" ECG electrodes or "Medi-Trace" ECG electrodes are recommended.

   For electrode placement follow steps in figure.

A	Rub the skin 10 times in a circular motion using a gauze and 70% isopropanol or alcohol	
B	Remove the electrode protective foil	
C	Wet the electrode with a drop of saline, with special care to not wet the self-adhesive part	
D	Attach the electrode to skin, ensuring complete adherence of self-adhesive part	

Caution:

Good skin to electrode contact is essential for the proper performance of the equipment.

Strictly follow the electrode placement procedure described in this manual.

To proper patch to skin adhesion, avoid wetting the electrode self-adhesive part when placing the electrodes.

Connect the red snap connector to the positive electrode of the EEG differential channel, the white snap connector to the negative electrode of the EEG differential channel, and the black snap connector to the reference electrode.

WARNING!

AVOID THE CONTACT OF CONDUCTIVE PARTS OF ELECTRODES TO OTHER CONDUCTIVE PARTS, INCLUDING EARTH.

IN CASE OF SURGICAL MONITORING, DO NOT LOCATE ELECTRODES BETWEEN THE SURGICAL SITE AND THE ELECTROSURGICAL UNIT RETURN ELECTRODE, TO REDUCE THE HAZARD OF BURNS DUE TO THE HIGH-FREQUENCY SURGICAL CURRENTS TO THE NEUTRAL ELECTRODE CONNECTION.

APPLIED PARTS ARE NOT PROTECTED FROM THE EFFECT OF CARDIAC DEFIBRILLATION ACCORDING TO IEC 60601-2-26.

WHEN A DEFIBRILLATOR IS USED ON A PATIENT CONNECTED TO THE MODULE, THE ELECTRODES SHALL NOT BE LOCATED BETWEEN DEFIBRILLATOR PADS.

3. Start the monitoring software.

Caution:

During normal use, "+5V", "-5V", "TX" and "BTC" LED indicators shall be active.

Checking skin to electrode contact

The MADOC1 skin to electrode contact check is done automatically each minute, or when pressing the "Electrode check" button on the device. It determines the impedance of electrode "+" (red snap connector) to the reference electrode (black snap connector), and the impedance of electrode "-" (white snap connector) to reference electrode.

Enabling and disabling automatic checking

To disable the skin to electrode contact automatic check, keep the "Electrode check" button pressed for 4 s. To re-enable the skin to electrode contact automatic check, keep the "Electrode check" button pressed for 4 s.

Caution:

Automatic impedance checking may need to be disabled if the 6 uA 128 Hz impedance check current interferes with other equipment, e.g., evoked potential monitors.

Monitoring end

Follow these steps:

1. Disconnect the electrode snap connectors from the electrodes

2. Remove the electrodes from the patient

3. Disconnect the device power cord from the power outlet.

WARNING!

SHOCK HAZARD: DO NOT ATTEMPT TO DISCONNECT THE POWER CORD WITH WET OR DIRTY HANDS.

PREVENTIVE MAINTENANCE, CARE AND CLEANING

Care and cleaning

WARNING!
TAKE UNIVERSAL PRECAUTIONS TO PREVENT CONTACT WITH BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIALS.

Care and cleaning of MADOC1

Clean any spillage of blood or solutions on the MADOC1 module as soon as possible. Dried blood is difficult to remove. Use lint-free absorbent towels for spill cleanups. Dampen the towel with detergent and lukewarm water for eaiser cleaning. Wipe the snap connectors with alcohol and allow to dry completely. Residual moisture may affect device performance.

Disinfecting

Use lint-free absorbent towels dampened either with a 10% bleach solution or a commercial disinfectant.

WARNING!
ELECTRICAL SHOCK HAZARD: THE MANUFACTURER VERIFIED THAT THE GROUND LEAKAGE CURRENT AND THE PATIENT SAFETY CURRENT WERE LESS THAN THE SPECIFIED LIMITS ESTABLISHED IN THE IEC60601-2-26 STANDARD. THESE CURRENTS SHOULD BE VERIFIED PERIODICALLY. WHENEVER A LIQUID SPILLAGE OCCURS, VERIFY THE CURRENTS BEFORE FURTHER USE.

Identification

MADOC1 identification information is permanently marked on the top cover. This information includes equipment batch and serial numbers. The information on the

bottom cover includes the equipment name and general information about Controles S.A.

MADOC1 dongle identification information is permanently marked on the top cover. This information includes the device serial number, the device name and the manufacturer name.

TECHNICAL SPECIFICATIONS

General specifications

Product description: one EEG channel amplifier intended for patient monitoring.

Weight: 0,4 kg.

Cabinet:

- Plastic; black
- Width 160 mm x Height 25 mm x Depth 94mm.

Power requirements:

- 100-240 VAC, 0.3 A (max), 50/60 Hz.

Operating environment:

- Temperature: 0ºC to 40ºC
- Humidity: 15% to 95% HR (non-condensing).

Storage environment:

- Temperature: -20ºC to 60ºC.
- Humidity: 15% to 95% HR (non-condensing).

LED indicators:

- +5V power supply
- -5V power supply
- Bluetooth connection
- Microcontroller TX activity

- Automatic skin to electrode contact enabled

Communications

- ConnectBlue CB-OBS410I-04 Bluetooth transceivers
- Frequency band: 2402 to 2480 MHz
- Data transmission protocol: PTOCC-1.

EEG acquisition specifications

Patient connections:

- differential pair and reference electrode
- cable to electrode length : 60 cm.

Button for skin to electrode contact check.

Differential input:

- Differential input resistance > 1 M at 40 Hz
- Input amplifier range: -400 uV to +400 uV.

Filtering:

- High-pass: 1,0 Hz
- Low-pass: 43 Hz.

Frequency range:

- Frequency range: 1,0 Hz to 43 Hz
- Bandwidth: 42 Hz.

Analog to Digital Converter:

- Sampling Rate 256 samples / second
- Resolution: 12 bits.

Electrical safety specifications

Conforms to IEC 60601-2-26.

Type of Protection against Electric Shock of the System

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

Degree of Protection against Electric Shock of the System:

Type BF: equipment providing a degree of protection against electric shock regarding allowable leakage currents with an F-type applied part. An F-type applied part is isolated from all other parts of the equipment to such a degree that the patient leakage current allowable in single fault condition is not exceeded when a voltage equal to 1.1 times the highest rated AC supply voltage is applied between the applied part and earth. The circuitry inside the MADOC1 module is isolated from the mains in accordance with IEC 60601-1.

Degree of Protection against effects of Cardiac Defibrillation

Applied parts are not protected from the effect of cardiac defibrillation according to IEC 60601-2-26.

Degree of Protection against the Ingress of Water

Degree of protection rating: IPX0 according to IEC 529.

Mode of Operation of the System

Continuous operation.

Classification:

MEDICAL ELECTRONIC EQUIPMENT.

Electromagnetic Compatibility Specifications

The MADOC1 module requires special precautions regarding Electromagnetic Compatibility (EMC). It must be installed and put into service according to the EMC guidance information provided in this section.

Portable and mobile radio frequency communications equipment can affect the operation of the MADOC1 module. Refer to the EMC guidance information and cautions provided in this manual.

Accessories

The MADOC1 module complies with the requirements of IEC 60601-1-2:2001 when used with the accessories listed in section “Accessories”.

Caution:

The use of accessories other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the MADOC1 module.

IEC 60601-1-2:2001 Electromagnetic Compatibility Guidance

This section provides the appropriate specification tables for the MADOC1 module as per IEC 60601-1-2.

Electromagnetic Emissions

Prueba de emisiones	Conformidad	Entorno electromagnético
RF Emissions CISPR 11	Group 1	The MADOC1 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The MADOC1 module is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Caution:

The MADOC1 module should not be used over or close to other equipment. If this situation is unavoidable, check the normal function for the particular case.

Electromagnetic Immunity

The MADOC1 module is intended for use in the electromagnetic environment specified below. The customer or user of the MADOC1 module should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Do not apply for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle. 40% UT (60% dip in UT) for 5 cycles. 70% UT (30% dip in UT) for 25 cycles. <5% UT (>95% dip in UT) for 5 sec.	<5% UT (>95% dip in UT) for 0.5 cycle. 40% UT (60% dip in UT) for 5 cycles. 70% UT (30% dip in UT) for 25 cycles. <5% UT (>95% dip in UT) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MADOC1 module requires continued operation during power mains interruptions, it is recommended that the MADOC1 module be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field. IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of typical location in a typical commercial or hospital environment.
NOTE: UT is the AC mains voltage prior to the application of the test level.			

Electromagnetic Immunity

The MADOC1 module is intended for use in the electromagnetic environment specified below. The customer or user of the MADOC1 module 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the MADOC1 module, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by 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 field strength in the location in which the MADOC1 module is used exceeds the applicable RF compliance level above, the MADOC1 module should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the MADOC1 module.
[b] Over the frequency ranges 150kHz to 80 MHz field strength should be less than 3 V/m.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the MADOC1 module

The MADOC1 module System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the MADOC1 module can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MADOC1 module as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of equipment **W**	**Separation distance according to frequency of transmitter** **m**		
	150 kHz to 80 MHz $d = 1,2 \sqrt{P}$	80 to 800 MHz $d = 1,2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3 \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

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