User Manual v 1.0

EMG2

2 channels Biomedical analog equipment

⚠ **Read this manual carefully before using the EMG2 amplifier.**

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1. GENERAL DESCRIPTION

The EMG2 is a multichannel amplifier for bioelectrical signals. It can detect surface electromyographic signals (sEMG).
The EMG2 allows the detection and recording of the electric signals generated by the human body. The signals acquired by the instrument are amplified, filtered, digitally converted optocoupled and than analogue converted and then available at BNC output connectors.

The EMG2 is a research instrument designed for clinical research carried out by qualified researchers.

The EMG2 can amplify 2 bioelectrical signals.

EMG2 instrument is completely safe for the patient. The safety is achieved by means of medical grade electrical insulation of all the circuitry connected to the patient.

This user manual refers to all hardware versions of the instrument.

2. EMG2 KIT CONTENT

- 1 amplifier EMG2;
- 1 external power supply;
- 1 cable adapter to connect electrodes to the amplifier;
- 1 reference straps;
- electrodes of different sizes and shapes, depending on the customer request;
- 1 EMG2 user manual

3. END USER

EMG2 multichannel amplifier allows non invasive recording of biopotentials (sEMG) detected by superficial electrodes.

Contraindications

EMG2 has no particular contraindications when used jointly with other equipment (e.g.: oscilloscope), provided that all the electrical devices connected to it and to the power lines comply with safety rules and standards concerning grounding and leakage currents.

Side effects

In the case of superficial EMG detection no significant side effects are known. The materials used for manufacturing all the parts in contact with the patient are biocompatible. Possible slight cutaneous allergic reactions (e.g. skin reddening) are reduced to a minimum during short duration electromyographic signal acquisitions.

4. SAFETY CAUTIONS AND OTHER WARNINGS

The use of the multichannel EMG2 amplifier is **absolutely forbidden** in the following conditions:

- While other monitoring devices are in use with the patient.
- While electro surgery equipment, short waves or microwaves therapy devices are used.
- By mentally impaired people. Whenever the equipment is damaged.
- In proximity of inflammable substances (especially inflammable liquids and gases) or in environments with high concentration of oxygen.
- On patients carrying life-supporting equipment that might be adversely affected by electromagnetic interferences, such as pacemakers, etc.

The following cautions should be observed:

- Only use electrodes supplied by the manufacturer: EMG2 is guaranteed to achieve tested performance only if used with electrodes supplied by the manufacturer.
- Contact the manufacturer immediately if extraneous materials permeate into the device (liquids, powders, etc.). In case of hard shocks suffered by the EMG2 (like a drop to the floor, etc.), verify that no crack or any other kind of damage of the box resulted from the shock. In case of doubt, please contact the manufacturer.
- The EMG2 is subject to electromagnetic interference that is not dangerous for the patient (such as electrostatic or electromagnetic interference generated by electrical motors and other sources). This interference may affect the measurements of the physiological variables derived from the EMG signals. These measurements are not meant to be used for diagnostic purposes, and thus these signal alterations cannot be dangerous for the patient, please always take into account the presence of noise in your signal processing tasks and evaluations.
- Before making any measurement, it is mandatory to check the quality of the grounding of the power line to which the EMG2 is connected. **The use of electrical devices with grounding connections not compliant with safety standards represents a high risk for the patient and the operator.**
- The connection between EMG2 and other electrical devices (e.g. a PC) must be done in compliance with the European standard EN 60601-1-1 on medical devices.
- Electrical motors and other electrical devices (relay, remote control switch, neon lights, etc.) near the EMG2 electromyography can be a source of electromagnetic interference that disturbs the amplifier. The presence of such electromagnetic fields is not dangerous for the patient, but can alter the electromyographic signals and cause unreliable measurements.

- The use of the EMG2 is restricted to skilled personnel.
- Incorrect measurements can arise when unskilled personnel use the device in presence of strong sources electromagnetic interference (e.g. strong electromagnetic fields). The presence of interference in the signals is easily recognised by skilled personnel.
- EMG2 is not designed to be portable equipment. Should it be necessary to move the EMG2 amplifier, it must be properly packaged to avoid typical vibrations and shocks arising from transportations. Vibrations could cause the release of metallic particles inside the appliance, such as screws, nuts and bolts, that could compromise the safety of the patient and the integrity of the appliance.

5. SYMBOLS USED ON EMG2 AND IN THE USER MANUAL

	Class BF for circuitry applied to patient.
	Read carefully the instruction remarks before use.
	Dangerous voltage level, power line voltage.

6. TECHNICAL SPECIFICATIONS

EMG2 is an optically and galvanically insulated device designed to guarantee a high safety level for the patient and the operator in all operating conditions. The optical and galvanic insulation separates the circuitry connected to the patient from the circuitry connected to external non-medical devices, such as the oscilloscope used for display or acquire data. By pressing the front panel button is possible to change EMG2 amplification values

Table 1 shows EMG2 technical characteristics

Technical Characteristics	
Selectable gain	500, 1000, 2500, 5000 V/V
Bandwidth	High pass filter: 10, Hz Low pass filter: 500 Hz
Maximum input range	50 mV_{PP}
Noise level referred to input	< 4 μV_{RMS}
Input impedance	> 10^{11} Ω
CMRR	> 95 dB
Output range	0 ÷ 5 V
Insulation voltage	4.000 V_{DC}
A/D Converter	16 bit

TAB. 1: EMG2 technical characteristics

7. DETAILED DESCRIPTION

FRONT PANEL

FIG. 1 shows controls, indicators and connectors present on the front panel of the EMG2 as described in the following sections.

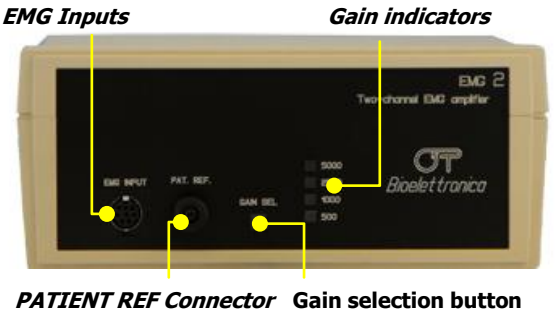

FIG. 1: *EMG2 front panel*

EMG Inputs

These inputs allow the connection of the adapter for electrodes to detect differential EMG signals produced by two different muscles.

PATIENT REF Connector

The *PATIENT REF* connector is used to connect the EMG2 reference point of the amplifier to the patient. The reference point must be connected to a point on the patient's body without myoelectric activity (e.g. the ankle or the wrist) using the supplied ground strip. The strip must be wet with water to ensure a good electric contact with the patient.

⚠ **REMARK: failure in connecting this electrode prevents the correct acquisition of the EMG signal.**

GAIN Selection Button

Using gain selection button is possible to change simultaneously the gain of both channels of EMG2 equipment.

Gain Indicators

Each one of the four led display the selected gain.

REAR PANEL

Figure 2 shows the connectors on the rear panel of EMG2 described in the following sections.

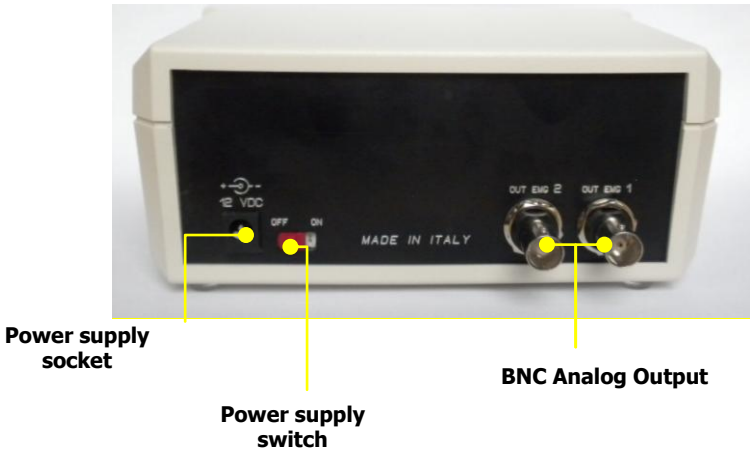

FIG. 2: EMG2 rear panel view

Power supply socket

To this socket the operator has to conenct the external power supply.

Power supply switch

The Power Supply Switch turns on/off the EMG2. The switch position **ON** turns the EMG2 on; the switch position **OFF** turns it off.

BNC Analog Outputs

On the rear panel are also available two BNC connectors that represents two analog outputs of the EMG2 equipment.

EMG2 full amplification chain is composed by:

- Row data amplification and filtering
- A/D conversion
- Optocoupling
- D/A conversion

8. USE OF EMG2

MAKE AN ACQUISITION

To perform an acquisition the operator has to follow steps reported below:

1. Connect the reference strap in a point without EMG activity;
2. Connect the impedance adapter to the EMG input at one side and to the electrodes at the other side;
3. Place the electrode on the investigated muscle;
4. Switch on the equipment;
5. Select the proper gain;
6. Connect one or both BNC connector the a visualization or acquisition equipment.

9. TROUBLESHOOTING

This section describes the most common problems that may be found by EMG2 users, with some suggestions to solve them.

For problems not described in this section contact the Technical Support Service of OT Bioelettronica.

Problem	Possible cause	Solution
The amplifier does not turn on	Power supply switched off	Turn to "**ON**" the power supply switch.
	Power supply cable is not inserted properly in the amplifier or into the wall socket	Check the power supply cable and the socket connection
Gain indicators does not switch on	External temperature too low	Wait that the amplifier come back to the operative temperature

TAB. 2: Troubleshooting of the general problem that can occur using the EMG2 amplifier

10. EMG2 MAINTENANCE AND STORAGE

EMG2 has to be used in the following ambient conditions:

Temperature: **from 0°C to +40°C**
Maximum relative humidity: **75%**
Atmospheric pressure: **from 700 hPa to 1060 hPa**

It is recommended to turn off the EMG2 at the end of each measurement session, and to remove all the cables and connections. The EMG2 should be stored with all the enclosed accessories on a safe desk far from all the situations listed in the section *Warnings.*

AnEMG12 should be stored in the following ambient conditions:

Temperature: **from –20°C to +40°C**
Maximum relative humidity: **75%**
Atmospheric pressure: **from 700 hPa to 1060 hPa**

Cleaning: use only a dry cloth to clean the device.

It is recommended to plan a device check every 24 months with the manufacturer. The EMG2 should be repaired by the manufacturer only. Every repair executed by unauthorized personnel will be considered as a device violation voids the manufacturer's warranty.

Disposal

The device and the accessories should be disposed in compliance with the relative standards in special equipped areas or with special waste.

11. TECHNICAL CHARACTERISTICS

Model:	*EMG2*	
Risk class:	IIa in compliance with the standard 93/42/CEE.	
Insulation class:	BF type applied part, in compliance with the European standard EN 60601-1.	
Classification:	- class I, about the protection from indirect contact. - IP20, about the penetration of fluids and dust; device not protected.	
Case:	plastic with insulated metallic front and rear panels.	
Power supply:	voltage from 90Vac to 260Vac ± 10%, frequency from 47 to 400Hz.	
Consumption:	5 W.	
Limitations:	the device is not suitable for use in environments with high oxygen concentration and/or flammable fluids and/or gases; do not use with electro-surgery or short wave/microwave therapy equipment.	
Working conditions:	device suitable for continuative work.	
Input channels:	2 totally independent channels	
Bioelectrical Amplifier:	Maximum input range:	50 mV_{PP}
	Bandwidth:	10 ÷ 500 Hz
	Total noise (RTI)	< 4μV_{RMS} (monopolar)
		< 1μV_{RMS} (differential)
	Selectable gain:	500, 1000, 2500, 5000
	Input impedance	> $10^{11}\Omega$ on the entire bandwidth
	CMRR	> 95 dB
Commands:	gain selector	
Dimensions:	155 x 65 x 105 mm	
Weight:	310 gr.	

12. WARRANTY

EMG2 is covered by a 24 months warranty starting from the purchasing date of the electronic parts.

Connection cables are covered by a 24 months warranty.

The warranty is void in case of device violation or in case of intervention from unauthorized staff.

Warranty conditions are reported hereinafter.

Warranty conditions

1. The warranty lasts 24 months on the electronic parts. Warranty is provided by the manufacturer.
2. The warranty covers only device damages that cause malfunctioning. The product must have the same serial number indicated on this certificate, or the warranty is released.
3. The warranty covers only the cost of repair or substitutions of defective components, including the costs of labour.
4. The warranty is void in case of damages caused by negligence, use not compliant with the instructions supplied, unauthorized repairs and accidental circumstances, especially for the external part.
5. The warranty is void with damages caused by incorrect power supply.
6. The warranty is not applied on all the parts subject to wear and tear.
7. The warranty does not include the shipment costs.
8. After 24 months the warranty is released. All the substituted parts, the labour costs and the shipment costs will be charged to the purchaser according to the rates in force.

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