

User Manual v 1.0

OT-Emg Feedback



 **Read this manual carefully before using the OT-EmgFeedback.**

This product is manufactured in compliance with the European Standard 93/42/CEE about medical instrumentation, and according to the EN 60601 rules for Medical Electrical Equipment



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1. OVERVIEW

The OT-EmgFeedback is a biofeedback instrument based on the analysis of surface electromyographic (sEMG) signals. The OT-EmgFeedback was developed to detect signals generated by the human body and provide feedback from one to eight channels.

The bioelectrical signals are detected in single differential mode, with bipolar electrodes. Such signals are amplified, filtered, digitally converted and then visualized on the display of the device (optionally stored on an SD board).

The biofeedback implemented in the OT-EmgFeedback is both visual (display of the device) and audio (internal buzzer).

With OT-EmgFeedback the user can detect different values of maximal contraction level from up to 8 muscles and then set a different feedback threshold for each muscle.

A freeware software called OT BioLab has been designed by OT Bioelettronica to review and process the data stored on the SD board (optional) with OT-EMG-Feedback. OT BioLab is available for download on the website www.otbioelettronica.it, at the download page.

The OT-EmgFeedback 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 according to the CEI EN60601 rules.

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



2. OT-EmgFeedback KIT CONTENT

- 1 OT-EmgFeedback amplifier.
- 1 to 2 cable adapters to connect electrodes to the amplifier.
- 1 reference strap WS1.
- 1 OT-EmgFeedback user manual.

3. END USER

The OT-EmgFeedback allows non invasive recording of sEMG signals detected in single differential mode with electrodes positioned on the skin. For a correct use of the OT-EmgFeedback, the end user must be familiar with the technique and have received a proper training in EMG detection and interpretation.

Contraindications

The OT-EmgFeedback has no particular contraindications since it is a battery powered device.

Side effects

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 sEMG signal acquisitions.

4. SAFETY CAUTIONS AND OTHER WARNINGS

The use of the OT-EmgFeedback amplifier is forbidden in the following conditions:

- When 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: OT-EmgFeedback 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 OT-EmgFeedback (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 OT-EmgFeedback 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). Anyway, this interference may affect the measurements of the physiological variables derived from the EMG or EEG 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.
- The use of the OT-EmgFeedback is restricted to skilled personnel.
- Incorrect measurements can arise when unskilled personnel use the device in presence of strong sources of electromagnetic interference (e.g. strong electromagnetic fields). The presence of interference in the signals is easily detected by skilled personnel.

5. SYMBOLS USED ON OT-EmgFeedback AND IN THE USER MANUAL



Multifunction keys to select and to modify the parameters.



Multifunction key to enter the selected parameter value.



Multifunction key to exit the menu and leave the parameter settings.

6. TECHNICAL SPECIFICATIONS

The OT-EmgFeedback is a battery powered device designed to guarantee a high safety level for the patient and the operator in all operating conditions. The signals amplified by the device are shown on the screen and can be stored on the SD card (optional) in a proprietary format. TAB. 1 shows the technical specifications of the OT-EmgFeedback.

OT-EmgFeedback	
Maximum input range	6,6 mV _{PP}
Bandwidth	34 ÷ 340Hz
Noise level referred to input	< 3 μV _{RMS}
Gain	805 V/V
Input impedance	> 90 MΩ on all the bandwidth
CMRR	>96 dB
Output range	0 ÷ 3.3 V

TAB. 1: OT-EmgFeedback technical specifications.

7. DETAILED DESCRIPTION

FRONT PANEL

FIG. 7.1 shows controls, indicators and connectors present on the front panel of the OT-EmgFeedback and described in the following sections.

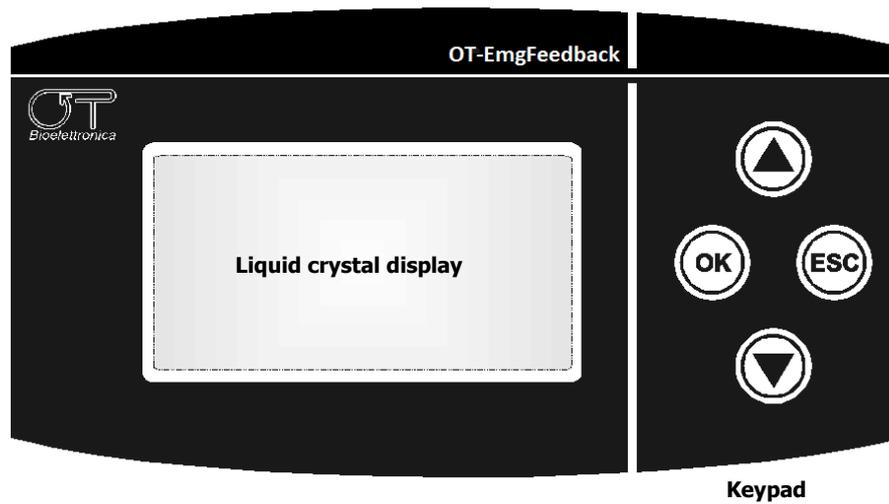


FIG. 7.1: OT-EmgFeedback front panel.

Liquid crystal display

The liquid crystal display is turned on when the OT-EmgFeedback amplifier is switched on. After an introducing screen-shot, the OT-EmgFeedback settings are presented as shown in FIG. 7.2.

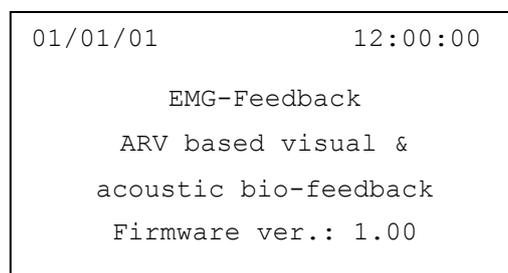


FIG. 7.2: Liquid crystal display screen-shot example with introducing screen-shot

Keypad

The keys on the keypad allow to enter and exit the submenus, edit the parameters, start and stop recordings on the SD board (optional).

Each time a key is pressed the instrument produces a “bip” indicating that the action was identified.

The keys “arrow up” and “arrow down” allow to browse the menu inputs, or to increase or decrease the parameter values when edited.

The “OK” key, according to the state of the device, allows to enter the selected menu, to edit the value of a parameter, to confirm the modified value and to start the data recording on the SD board (optional).

The “ESC” key, according to the state of the device, allows to exit the current menu, exit the phase of parameter setting, and to stop the data acquisition on the SD board (optional).

SIDE PANEL

FIG. 7.3 shows the connectors on the side panel of the device, described in the following sections.

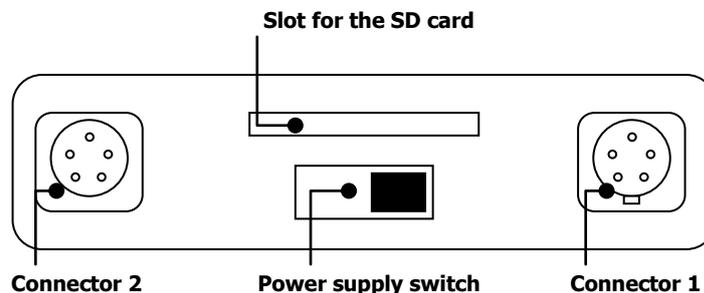


FIG. 7.3: Side panel of the OT-EmgFeedback

Power supply switch

The Power Supply Switch turns on/off the OT-EmgFeedback. The left position of the switch turns the OT-EmgFeedback on; the right position of the switch turns it off.

The switch must be kept in position ON (left) also during the battery charge phase.

SD card Slot

In this slot it is possible to insert a SD memory card to record the signals (optional).



NOTE: For a correct function of the device, the card should be formatted with FAT format. The device does not work with NTFS or FAT32 format.

Active adapter connectors

Connector 1 allows the connection with active adapter for differential inputs 1 to 4. Connector 2 allows the connection with active adapter for differential inputs 5 to 8.

8. MENU STRUCTURE

TAB. 8.1 shows a synthetic description of the OT-EmgFeedback menu.

Mode		Description	
MVC Record		Records the maximal muscle contraction value	
Relative Feedback		Visualization Under Threshold Visualization Keep Level	
Working Mode	Under Threshold	Selects the relative mode which works with threshold reaching.	
	Keep Level	Selects the relative mode which works with keeping the level within a range fixed by means of target level and target error values.	
Edit Target		Sets the thresholds of Keep Level mode	
Settings	Firmware Gain Set.		Allows to change the visualization scale x1, x2, x4, x8
	Active Channels		Sets the active channels
	Thresholds		Allows to change the threshold of each channel; by default is set to 50%
	Time/Data Set		Allows to set date and time.
	Save/Load Settings		Saves the current settings in one of the 4 memory slots / Loads the settings stored on one of the 4 memory slots..
	Advance Settings	Epoch Size	Sets the length of the epoch on which the detected signal amplitude is computed (0,25 – 0,5 – 1 s)
		Filename ID	Allows to edit the name of the file stored on SD card (special function for systems with SD card optional)
		Bklight Time	Allows to set the display backlight time (off, 5s, 10s, 15s, ON)
		Target Error	Allows to set the percentage of positive and negative error with respect to the threshold set for the Keep Level mode
		SD Check	Test of SD card

TAB. 8.1 Summary of the settings in the screenshots shown in the OT-EmgFeedback display.

FIG. 8.1 right panel shows the screenshot appearing when selecting the maximal voluntary contraction (MVC) record mode.

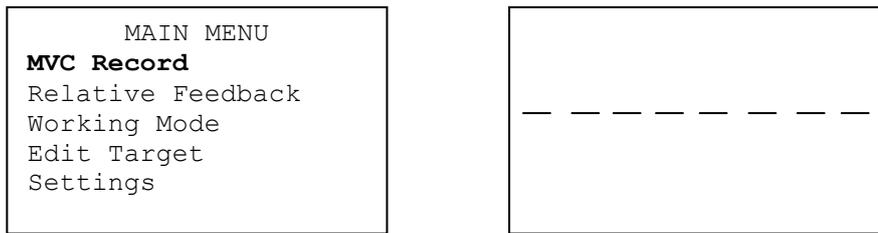


FIG. 8.1: MVC Record screenshot

FIG. 8.2 right panel shows the two screenshots relative to Under Threshold (A) and Keep Level (B) feedback modalities.

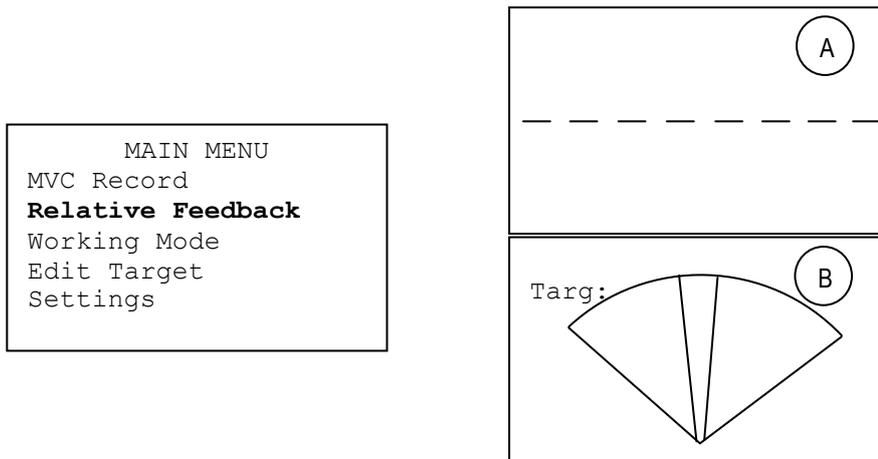


FIG. 8.2: Relative Feedback screenshots: Under Threshold (A), Keep Level (B).

FIG. 8.3 right panel shows the screenshot appearing in Working Mode.

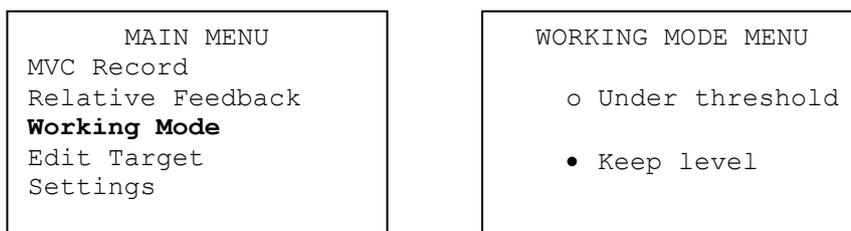


FIG. 8.3: screenshot appearing during Working Mode

FIG. 8.4 right panel shows the screenshot appearing in Edit Target mode. FIG. 8.5 shows all the Setting mode screenshots.

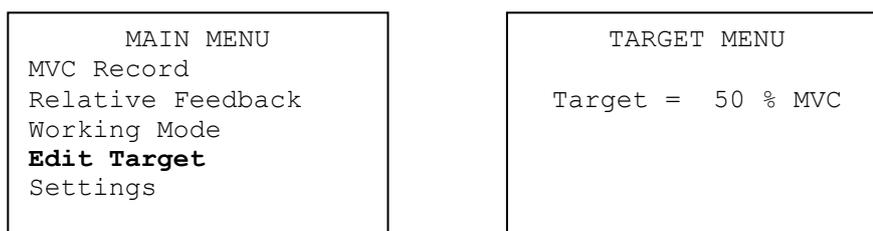


FIG. 8.4: Edit Target screenshot

<p>MAIN MENU</p> <p>MVC Record</p> <p>Relative Feedback</p> <p>Working Mode</p> <p>Edit Target</p> <p>Settings</p>	<p>SETTINGS</p> <p>Firmware Gain Set.</p> <p>Active Channels</p> <p>Thresholds</p> <p>Time/Date Set</p> <p>Load/Save Settings</p> <p>Advanced Settings</p>	<p>GAIN MENU</p> <p>Ch1: x1 Ch5: x2</p> <p>Ch2: x2 Ch6: x2</p> <p>Ch3: x2 Ch7: x2</p> <p>Ch4: x4 Ch8: x2</p>
<p>SETTINGS</p> <p>Firmware Gain Set.</p> <p>Active Channels</p> <p>Thresholds</p> <p>Time/Date Set</p> <p>Load/Save Settings</p> <p>Advanced Settings</p>	<p>CHANNELS MENU</p> <p>Ch1: OFF Ch5: OFF</p> <p>Ch2: OFF Ch6: OFF</p> <p>Ch3: OFF Ch7: OFF</p> <p>Ch4: OFF Ch8: OFF</p>	
<p>SETTINGS</p> <p>Firmware Gain Set.</p> <p>Active Channels</p> <p>Thresholds</p> <p>Time/Date Set</p> <p>Load/Save Settings</p> <p>Advanced Settings</p>	<p>THRESHOLD MENU</p> <p>Ch1: 50% Ch5: 50%</p> <p>Ch2: 50% Ch6: 50%</p> <p>Ch3: 50% Ch7: 50%</p> <p>Ch4: 50% Ch8: 50%</p>	
<p>SETTINGS</p> <p>Firmware Gain Set.</p> <p>Active Channels</p> <p>Thresholds</p> <p>Time/Date Set</p> <p>Load/Save Settings</p> <p>Advanced Settings</p>	<p>TIME - DATE SET</p> <p>Time:</p> <p>Date:</p>	
<p>SETTINGS</p> <p>Firmware Gain Set.</p> <p>Active Channels</p> <p>Thresholds</p> <p>Time/Date Set</p> <p>Load/Save Settings</p> <p>Advanced Settings</p>	<p>SAVE & LOAD MENU</p> <p>Save Curr. Settings</p> <p>Load Settings</p>	
<p>SETTINGS</p> <p>Firmware Gain Set.</p> <p>Active Channels</p> <p>Thresholds</p> <p>Time/Date Set</p> <p>Load/Save Settings</p> <p>Advanced Settings</p>	<p>ADVANCED SETTINGS</p> <p>Epoch Size</p> <p>Filename ID:</p> <p>Bklight time:</p> <p>Target Error: %</p> <p>SD check:</p>	

FIG. 8.5: Settings screenshots

9. USE OF OT-EmgFeedback

MAIN MENU

The main menu appears on the display when starting the OT-EmgFeedback with the following items:

- MVC Record
- Relative Feedback
- Working Mode
- Edit Target
- Settings

Press the "OK" key when one of the items is selected to access the relative submenu.

In the screenshot of the main menu the date, the battery level and time are also shown on top of the screen. The files created during force recording are saved with date and time of the device.

MVC RECORD FUNCTION

This feature allows the recording of maximum voluntary contraction level for each channel (each channel is associated with a pair of electrodes).

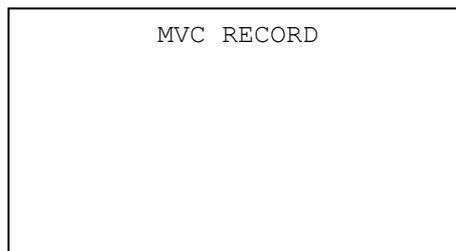


FIG. 9.1: Example of display screenshot during MVC recording.

In this mode the instrument shows electromyographic signal amplitude normalized to the maximum acceptable value as a visual biofeedback. The OT-EmgFeedback system automatically records the maximum value of the signal from each of the active channels.

The "ESC" button allows to exit the MVC record and return to the main menu, the buttons "arrow up" and "arrow down" have no effect in this mode.

Every time you enter in MVC Record mode the previous maximum values are cleared and can be re-evaluated.

Once inside the MVC mode, to record on the SD card (optional) the values of amplitude (ARV) of the contraction in progress, press once on the "OK" button. To close the file press the "OK" button again. The format of the saved file is described in section 10 of this manual.

RELATIVE FEEDBACK FUNCTION

In this mode a visual and audible feedback is provided to the patient, as a percentage of MVC, which was previously recorded for each channel. The screenshots are different depending on the type of mode (Working Mode) is selected (Keep Level or Under Threshold).

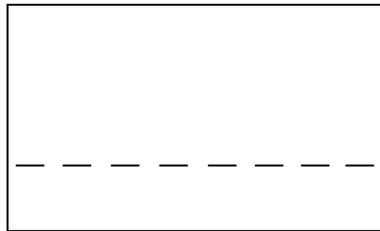


FIG. 9.2: Example of display screenshot in Relative Feedback (Under Threshold).

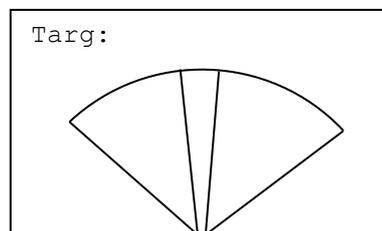


FIG. 9.3: Example of display screenshot in Relative Feedback (Keep Level).

FIG. 9.2 shows Under-Threshold mode, the system displays eight horizontal bars indicating the threshold level set of each of the eight channels (in the case of Figure 9.2 all the thresholds are set at 50%, which is the default value at startup). Depending on the contraction of the channel, a vertical bar increases or decreases its amplitude until you reach the top of the display which corresponds to the maximum of that channel.

Figure 9.3 shows Keep Level mode, the two vertical lines indicate the maximum and minimum force level within which the user must keep the force to fulfill the requirement of maintaining the level.

These vertical bars are inclined symmetrically at a distance which is a percentage of the value of target to maintain. The deviation of the vertical bars on the value of the target can be changed in the Advanced Settings section described in detail in the following paragraphs.

The target value set in the Keep Level is calculated as the average of the amplitudes of active channels. In this mode, when the registration system on an SD card is allowed (optional), the "OK" button starts the recording of force and the "ESC" button ends the recording and also allows you to return to the main menu. The buttons "arrow up" and "arrow down" have no effect in this mode. In both modes of Relative Feedback to record the signals on each active channel, press the "OK" button to start recording and press again to stop it. The format of recorded files is described in section 10 of this manual.

WORKING MODE FUNCTION

With the buttons "arrow up" and "arrow down" from the main window you enter the submenu for selecting the relative mode of operation of the instrument, where it is possible to set the desired function. The "OK" button saves the function chosen by the operator while the "ESC" to go back to previous menu.

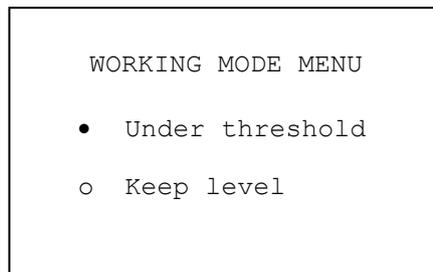


FIG. 9.4: Example of display screenshot in relative Working mode: Under Threshold and Keep Level

EDIT TARGET FUNCTION

This parameter adjusts the level of deviation from the maximum and minimum threshold set by the OT-EmgFeedback system for the mode Relative Feedback → Keep Level. The value of the target can be set from 0 to 98% with increments of 2%. The buttons "arrow up" and "arrow down" change the value of the target offset. The "OK" button saves the new value and automatically return to the previous screen while the "ESC" button takes you back to the previous screen without saving the set.

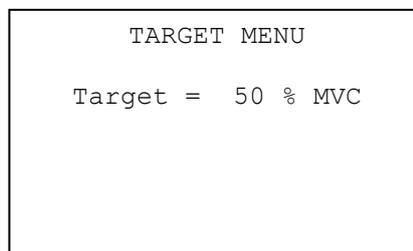


FIG. 9.5: Example of screenshot in Edit target mode.

SETTINGS FUNCTION

In this modality it is possible to modify the device settings. The parameters that can be edited are:

Firmware Gain Settings: this parameter allows to change the visualization scale. The value x2 is set by default. Press "ESC" key to return to previous menu.

GAIN MENU	
Ch1: X2	Ch5: X2
Ch2: X2	Ch6: X2
Ch3: X2	Ch7: X2
Ch4: X2	Ch8: X2

FIG. 9.6: Display screenshot of the visualization scale appearing during Firmware Gain Settings.

Active Channels: This parameter allows to set the number of active channels. The "arrow up" and "arrow down" keys allow to browse the channels, press "OK" to activate or deactivate a channel. Press "ESC" key to return to previous menu..

CHANNELS MENU	
Ch1: OFF	Ch5: OFF
Ch2: OFF	Ch6: OFF
Ch3: OFF	Ch7: OFF
Ch4: OFF	Ch8: OFF

FIG. 9.7: Display screenshot of the Active Channels mode.

Thresholds Menu: This parameter allows to regulate the target for each muscle, that is the force level to keep in Relative Feedback → Under Threshold. The "arrow up" and "arrow down" keys allow to browse the channels. Press "OK" to activate or deactivate a channel. Then the value can be modified with "arrow up" and "arrow down" keys and confirmed with "OK" key. Press "ESC" key to return to previous menu.

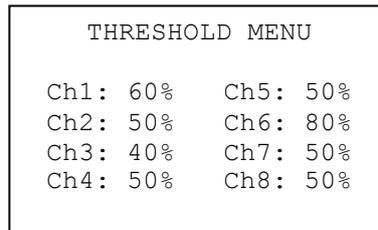


FIG. 9.8: Display screenshot with each channel threshold in Threshold Menu.

Time/Date Set: In this modality it is possible to modify the device time and date which are visualized and used to save the files. With the “arrow up” and “arrow down” keys is possible to increase or decrease the hours, minutes and seconds and the date.

The “OK” key sets one value and switches to the next. To set the date and time it is necessary to set each value of hour and date. If the “ESC” key is pressed the procedure is interrupted, no parameter is changed and the device shows the main menu.

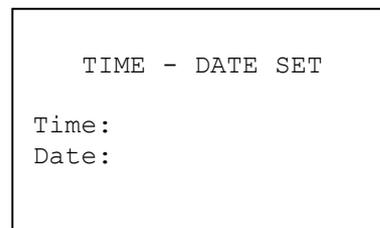


FIG. 9.8 Display screenshot for Time/Date Set.

Save/Load Settings: This function allows to save the current parameters or load previously stored parameters.

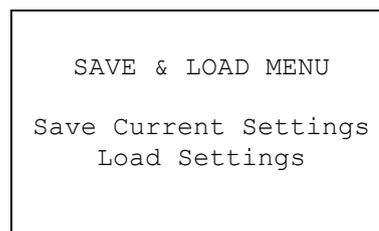


FIG. 9.9: Display screenshot for load and set of new or previously stored parameters.

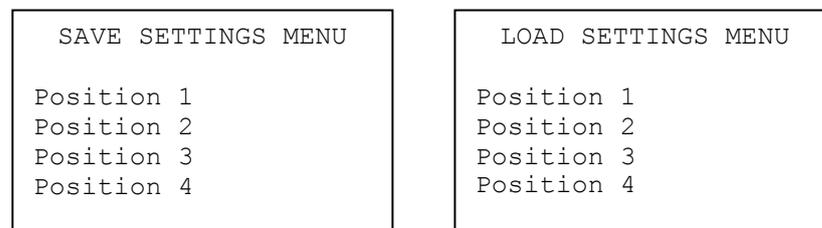


FIG. 9.10: Display screenshots during load or save of the settings.

Advanced Settings: In this section the user can modify all the device parameters

- Epoch Size: the parameters allowed are 0.25 s, 0.5 s, 1 s. This values indicate the interval for the amplitude computation for each channel.
- Filename ID: With this function can modify the name of the file which will be stored on the SD card (optional).
- Bklight time: this parameter allows to modify the display backlight time. The selectable values are: OFF, 5 s, 10 s, 15 s e ON. In case is selected OFF o ON the backlight is always off or always on. In the other cases the backlight is on after pressing any button and turned off after the time interval selected.
- Target Error: with this function the user can set the error which is allowed in modality Keep Level with respect to the selected target. The values can be selected between 1 and 9 %.
- SD check: this parameter is a flag indicating the status of the SD card (optional). The value can be "OK" when the SD card is correctly inserted and formatted or "KO" in case the device cannot access to the card.

From the Advanced Settings menu it is necessary to press "ESC" key to go back to the previous screenshot.

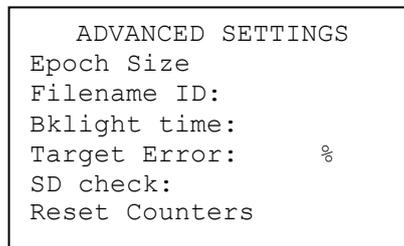


FIG. 9.11: Display screenshot for Advanced Settings.

10. FILE SAVE AND FORMAT

From section MVC you can record the files for maximum contractions. FIG. 10.1 shows an example of a file of a maximum contraction performed with two active channels and with the duration of 1.5 s (i.e. six epochs of 125ms). The file opens with Notepad or similar programs for reading text files. The values of amplitude (ARV) calculated on each epoch take into account the system amplification and indicate the values of amplitude in microV at the input of the system (i.e. values present on the skin).

```

EMGFeedback File
ARV values estimated over 125 ms epochs

Mode: MVC Recording

ARV values (uV):
CH1;  CH2;
17;   19;
17;   25;
19;   24;
17;   22;
17;   23;
17;   20;
    
```

FIG 10.1 Example of a file recorded on the SD card by OT-EmgFeedback during a maximal contraction.

From Relative Feedback section a file can be recorded during the contraction in two modes and Keep Level and Under Threshold, press the "OK" button once to start recording and re-press the "OK" button to stop. FIG. 10.2 shows an example of file recorded in mode Relative Feedback → Keep Level while FIG. 10.3 shows an example of file recorded in mode Relative Feedback → Under Threshold.

```

EMGFeedback File
ARV values estimated over 125 ms epochs

Mode: Keep Level

MVCs (uV):
CH1;  CH2;
2048; 2048;

Target value: 50%

ARV values (uV):
CH1;  CH2;
15;   17;
14;   13;
14;   14;
15;   18;
    
```

FIG 10.2 Example of file recorded on SD during a contraction in relative mode:
Relative Feedback → Keep Level

```
EMGFeedback File
ARV values estimated over 125 ms epochs
Mode: Under Threshold
MVCs (uV):
CH1; CH2;
2048; 2048;
Threshold values for each channel as a
percentage of MVC:
CH1; CH2;
50%; 50%;
ARV values (uV):
CH1; CH2;
16; 18;
14; 17;
14; 16;
15; 18;
13; 17;
```

FIG 10.3 Example of a file recorded on the SD card during a contraction in relative mode:

Relative Feedback → Under Threshold

11. OT-EmgFeedback MAINTENANCE AND STORAGE

OT-EmgFeedback 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

OT-EmgFeedback should be stored with all the enclosed accessories on a safe desk far from all the situations listed in the section *Warnings*.

OT-EmgFeedback 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.

The OT-EmgFeedback 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.

12. TECHNICAL CHARACTERISTICS

<i>Origin:</i>	OT-Bioelettronica	
<i>Model and Type:</i>	OT-EmgFeedback	
<i>Classification:</i>	- Device with internal power supply - IP50	
<i>Working conditions:</i>	device suitable for continuous operation	
<i>Case:</i>	plastic	
<i>Power supply:</i>	rechargeable NiMH AA batteries 1.2V	
<i>Amplifier:</i>	Maximum value of the input	60 mV _{PP}
	Bandwidth:	DC ÷ 40 Hz
	Equivalent input noise:	< 3 μ V _{RMS}
	Signal Amplification:	500 V/V
	Input impedance:	> 90 M Ω on the entire bandwidth
	CMRR:	> 96 dB
<i>Display:</i>	graphic LCD 128x64 pixel display with backlight	
<i>Controls:</i>	of 4 keys protected by polycarbonate membrane	
<i>Dimensions:</i>	150 x 90 x 25 mm	
<i>Weight:</i>	220g (including batteries)	

13. WARRANTY

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

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.

For additional information:

Distributed by:

OT Bioelettronica

C.so Unione Sovietica

10135 – Torino (TO) - ITALY

Tel:+39.011.6198498

Fax:+39.011.6198498

URL: www.otbioelettronica.it

e-mail: mail@otbioelettronica.it

Produced by:

Spes Medica srl

Via Europa

Zona Industriale

84091 Battipaglia (Sa)

tel. +39 010 390343

fax +39 010 3072345

URL: www.spesmedica.com

e-mail: info@spesmedica.com