User Manual v 1.10

P-ForceMet

Portable acquisition system for force signals

⚠ **Read this manual carefully before using the P-ForceMet.**

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

TABLE OF CONTENTS

1. GENERAL DESCRIPTION

The P-ForceMet is a tool for measuring signals from force transducers or torque.
The signals amplified and conditioned by the instrument can be displayed in the form of visual biofeedback to help you achieve a predetermined target and can be saved on a memory such as Secure Digital (SD).

The P-ForceMet 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. P-ForceMet KIT CONTENT

- 1 P-ForceMet force amplifier
- 1 force transducer or torque cable connection to the instrument
- 2 Rechargeable Batteries NiMH format AA 1.2V
- 1 Charger
- 1 Memory Card Secur Digital (SD)
- 1 P-ForceMet user manual.

3. INTENDED USE

The P-ForceMet is a device that allows the detection of the force generated by a voluntary muscle contraction. It can be used for the measurement of force produced by various joints according to the force sensor used and its purpose is to provide an objective evaluation of the force exerted on the sensor.

Contraindications

The P-ForceMet has no particular contraindications since it is a battery powered device.

Side effects.

No significant side effects are known.

4. WARNINGS

The use of the P-ForceMet is forbidden in the following conditions:

- By mentally impaired people.
- By even momentarily incapacitated persons unless assisted by qualified personnel (e.g., doctor or therapist).
- In proximity of inflammable substances or in environments with high concentration of oxygen.

The following cautions should be observed:

- Contact the manufacturer immediately if extraneous materials permeate into the device (liquids, powders, etc.). In case of hard shocks suffered by the P-ForceMet (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 P-ForceMet 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 force. These measurements are not meant to be used for diagnostic purposes, and thus these signal alterations cannot be dangerous for the patient.
- The presence of electric motors or other types of electrical equipment (relays, contactors, fluorescent lights not properly balanced, etc ...) operating in the vicinity Delp-ForceMet can be a source of electromagnetic interference for the latter. The presence of electromagnetic fields is not dangerous for the patient, although it can still modify and distort the detected signals and the assessments of the force produced.
- The use of P-ForceMet inadequate personnel constitutes no danger to the patient, but it is not recommended because a correct interpretation of the results can only be performed by properly trained personnel who has the necessary clinical and basic physiological knowledge.
- 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.
- The P-ForceMet is a portable force measurement system. It can be transported, it is suggested to ensure proper packaging and limited exposure to vibration during transport, which could lead to loosening of the screws inside.

5. SYMBOLS USED ON THE P-ForceMet 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 P-ForceMet is a battery powered device designed to guarantee a high safety level for the patient and the operator in all operating conditions.

The technical characteristics of the instrument are summarized in TAB. 1.

Supply voltage of transducers	+5 V_{DC}
Nominal bandpass	DC ÷ 40 Hz
Equivalent input noise	< 1.2 μV_{RMS}
Signal Amplification	300 ÷ 600 V/V*
Sampling frequency	128 Hz
CMRR	>110 dB
Input impedance	> 500 MΩ in all the bandwidth
A/D Converter Resolution	10 bit
Input dynamic of the A/D converter	0 ÷ 5 V

* The value of amplification is calibrated as a function of the transducer used in the testing.

TAB. 1: Specifications of the P-ForceMet

7. DETAILED DESCRIPTION

FRONT PANEL

FIG. 1 shows a graphical representation of the front panel of the P-ForceMet, the various parts are described in the following sections.

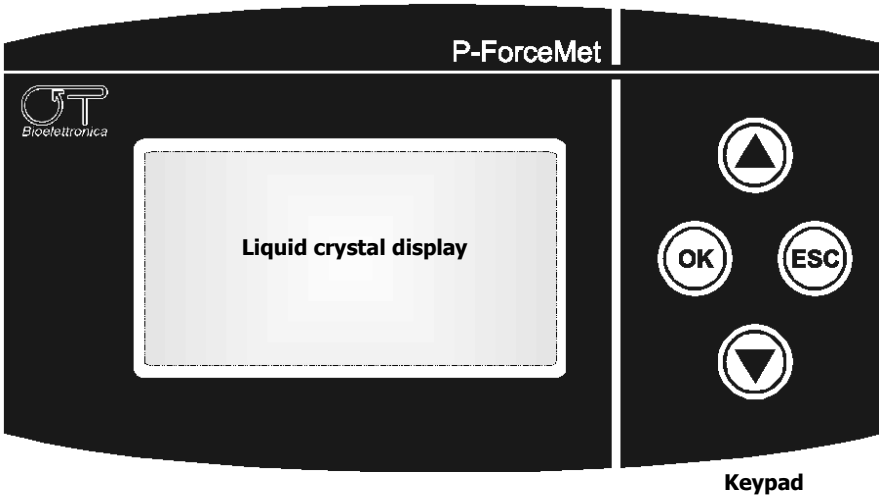

FIG. 1: Front panel of the P-ForceMet

Liquid Crystal Display

The liquid crystal display is active at the start-up. After a presentation screen, main menu is displayed with a screen similar to that of FIG. 2.

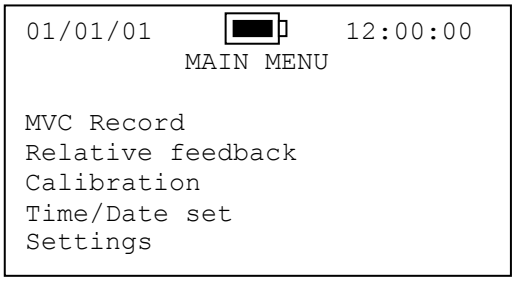

FIG. 2: Main menu shown on the liquid crystal display at the startup

When an item or a parameter is selected it is indicated in negative. It is possible to change parameters and settings using the buttons located to the right of the display.

Keypad

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

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.

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.

SIDE PANEL

FIG. 3 shows the connectors on the side panel of the device, described in the following sections.

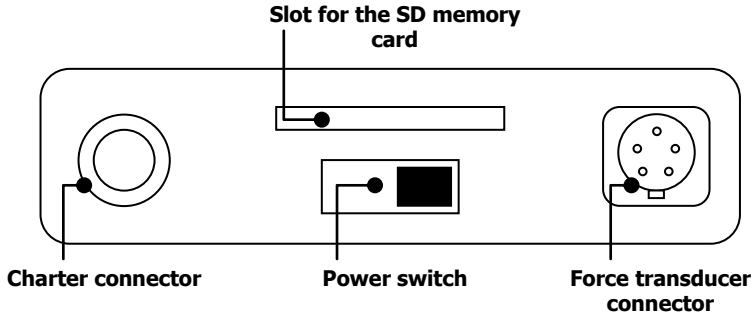

FIG. 3: Side panel of the P-ForceMet

Power supply switch

To turn on the instrument, move the power switch to the left (ON position) to turn it off, return it to the right (OFF).

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

Charger connector

Connect to this connector as the output of the charger provided. A normal power supply with stabilized output voltage between 9V and 20V and with the positive central pin can be used to recharge the batteries.

⚠ **WARNING: It is important not to connect the charger if the batteries inserted into the instrument are not rechargeable.**

SD card Slot

In this slot it is possible to insert a SD memory card Secur Digital type to record the signals.

⚠ **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.**

Force transducer connector

The force transducer supplied must be connected to this connector.

8. USE OF THE P-ForceMet

MAIN MENU

The main menu appears on the LCD screen at instrument and provides the following items:

- MVC Record
- Relative Feedback
- Calibration
- Time/Date set
- Settings

Press the "OK" when an item is selected to enter the submenu.

In the main menu screen is also displayed at the top of the screen date, battery level and time. The files created during the recording of the force are saved with the date and time of the instrument.

MVC RECORD

This feature allows the recording of maximum voluntary contraction and a sub maximal value called “Spontaneous contraction”.

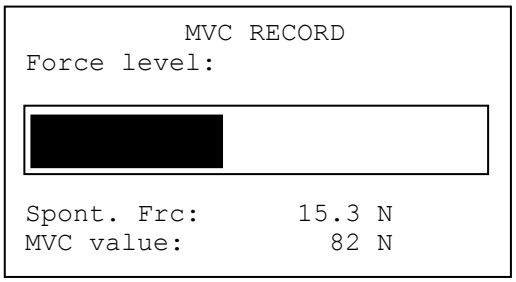

FIG. 4: Example of display on the LCD during recording of the MVC.

Before accessing the MVC Record, the device asks the user if the MVC value is relative to a new patient and if the MVC is recorded from the dominant side. Pressing the ESC button is considered as a negative response, pressing the OK button as a yes.

In this mode the instrument shows the form of visual biofeedback on the force transducer with a horizontal bar. The P-ForceMet also automatically records the maximum force exerted on the transducer and displays the value in N at the bottom of the display. Pressing the "OK" button you can record the actual force as the value of "Spontaneous contraction" which appears at the bottom of the screen.

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 access the MVC Record mode the previous values of MVC and Spontaneous contraction are cleared and can be re-evaluated.

RELATIVE FEEDBACK

This mode provides a visual biofeedback to the patient as a percentage of MVC, which has to be previously registered.

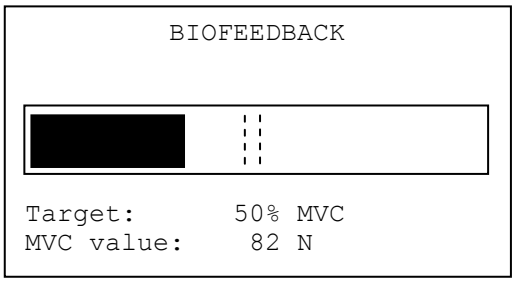

FIG. 4: Example of liquid crystal display during the feedback function.

Two dashed vertical bars indicate the level of force required, which can be changed by acting on the buttons "arrow up" or "arrow down". Available values are: 2.5%, 5%, 10%, 20%, 40%, 50%, 60% or 80% MVC. If the required force level is between 2.5% and 20% the MVC full scale of the biofeedback coincides with the 25% MVC. When levels above 20% MVC are select, the full scale of the biofeedback coincides with the 100% MVC.

At the bottom of the LCD, the value of the required level and the value of previously recorded MVC expressed in N are displayed.

In this mode, the "OK" button starts the recording of force, while the "ESC" button ends the recording and returns to the main menu.

CALIBRATION

In this mode you can calibrate the device.

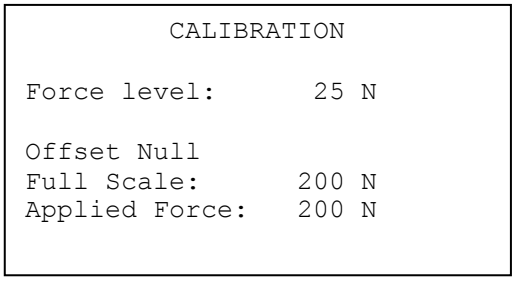

FIG. 5: Example of display on the LCD during the Calibration.

At the top of the display shows the value measured by the sensor expressed in N. In this mode 3 functions can be selected:

- Offset Null: resets the offset of the transducer. This operation must be performed when no force is applied to the sensor.
- Full Scale: pressing the "OK" when this function is selected, you can edit this value. To increase or decrease the full scale value is possible you use the "up arrow" and "down arrow". This value must be equal to or lower than the full scale value of the transducer, in case it is much less than the full scale, quantization effects of the transducer may become noticeable.
- Applied Force: to calibrate the instrument is necessary to apply a known force to the transducer (e.g. a known weight) and then edit the value of the applied force in N indicating the value of this force.

TIME/DATE SET

In this mode you can change the time and date of the instrument that are used for saving files. With the buttons "up arrow" and "down arrow" you can increase or decrease the values of hours, minutes, minutes, seconds

The "OK" button confirms the value and go to the next value. To confirm time and date the change is necessary to perform the procedure and set all parameters. If the button "ESC" is pressed the procedure is terminated, none of the parameters is changed and the device returns to the main menu.

SETTINGS

In this mode you can change the settings of the instrument. In particular, the editable parameters are 4:

- Filename ID: With this parameter can be user can edit the first 4 letters in the names of files saved on the SD card from the instrument. Once you have selected the parameter, you can change the letters one by one to set the desired character. The file names consist of a total of 8 characters. The last 4 digits represent the number of patients and the number of contraction.
- Bklight time: this allows you to change the start time of the display backlight. The selectable values are: OFF, 5 s, 10 s, 15 and ON. If you select OFF or ON the backlight is always on or always off, respectively. In the other cases, the backlight is turned on by pressing any button, and it is turned off after the time selected.
- Target Error: this parameter allows you to adjust the distance of the vertical bars that indicate the level of contraction to maintain during the Relative Feedback mode. The distance is specified in pixels, low values correspond to demands for greater accuracy in maintaining the target.
- SD check: This parameter is a flag and indicates the status of the SD card. The values that can take are "OK", when the SD card is inserted and properly formatted, or "KO" in case the instrument is unable to access the card.
- Reset Counters: This feature allows you to reset the patient ID and the number of contraction that are used to generate the names of the files stored on the SD card.

9. FILE FORMAT

Files stored on an SD card from the instrument have the extension *FRC*. The file name is generated from 4 characters changed by the user (see the function settings) and a 4-digit number. The first two digits represent the number of patients, the third and fourth digits the number of contraction. The patient number can be increased by going to the MVC Record feature and pressing the OK button when you see the question "New Subject?". The number of contraction is increased automatically for each file saved. The numbering can be reset by using the reset function in the Settings menu.

The files can be opened with a text editing program (such as Wordpad or Word) or processing programs such as Excel or Matlab. The first part of the file contains a header indicating the sampling frequency of the signal, the value of MVC and of spontaneous contraction registered, indication about whether the side in question is the dominant side and the target level required for the patient.

After the header are listed in the column all the force values recorded and expressed as N, which can be imported into spreadsheet programs such as Excel or Matlab to do the necessary processing.

10. MAINTENANCE AND PRESERVATION OF P-ForceMet.

P-ForceMet should be used in the following conditions:

Temperature:	**0°C to +40°C**
Relative Humidity:	**75%**
Atmospheric pressure::	**700 hPa to 1060 hPa**

P-ForceMet will be stored along with all the elements that it has, and placed carefully on a plane safe and away from the situations listed in paragraph *Warnings*.

P-ForceMet should be stored in the following conditions:

Temperature:	**-20°C to +40°C**
Relative Humidity:	**75%**
Atmospheric pressure::	**700 hPa to 1060 hPa**

Cleaning: clean the device using only a dry cloth.

The manufacturer should perform a functional check of the device every 24 months. The manufacturer does not consider the device P-ForceMet repaired by anyone outside the company itself. Any intervention in this regard by anyone not authorized by the manufacturer will be considered tampering with the device, relieving the manufacturer's warranty and the dangers that can be subjected to operator or user.

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 SPECIFICATIONS.

Origin: OT-Bioelettronica

Model and Type: P-ForceMet

Classification: - Device with internal power supply

- IP50

- Device with Type BF applied parts, in accordance with EN 60601-1

Working conditions: device suitable for continuous operation

Case: plastic

Power supply: rechargeable NiMH AA batteries 1.2V

Average consumption: 60 mW with backlight off, 900 mW with backlight on

Amplifier: Supply voltage of the transducer: +5 V_{DC}

Bandwidth:	DC ÷ 40 Hz
Equivalent input noise:	< 1.2 μV_{RMS} (monopolar)
Signal Amplification:	300 ÷ 600 V/V
Input impedance:	> 500 MΩ on the entire bandwidth
CMRR:	> 110 dB

A/D converter resolution: 10 bit

Display: graphic LCD 128x64 pixel display with backlight

Controls: of 4 keys protected by polycarbonate membrane

Dimensions: 150 x 90 x 25 mm

Weight: 250g (including batteries)

12. Warranty

P-ForceMet 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 labor.
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 labor costs and the shipment costs will be charged to the purchaser according to the rates in force.

For additional information:

Designed and 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