DATOSPIR TOUCH

MIP-MEP Module

USER'S MANUAL

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Sibelmed®

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1. INSTRUCTIONS FOR USE AND INSTALLATION

1.1. INTRODUCTION

The **DATOSPIR TOUCH** Spirometer includes an optional module to measure Maximal Respiratory Pressures (Maximal Inspiratory Pressure - Maximal Expiratory Pressure, MIP-MEP).

This manual is an addendum to the manual of the Spirometer **DATOSPIR TOUCH**, dedicated exclusively to the operation of this module, and it is designed for use alongside the general manual.

The MIP-MEP module has been developed in collaboration with the "Pulmonary Function Laboratory" of the *Hospital de la Santa Creu i Sant Pau* of Barcelona. It is based on the criteria expressed by **J.L. Clausen** in the Thoracic Society of California.

The Maximal Respiratory Pressures option allows a measurement range of ±295 hPa (±300 cmH_2O) in both inspiratory and expiratory tests, and provides several predicted sets to choose.

The test requieres a strong patient's effort. Check the patients health status before performing this test.

In the Maximal Pressure Tests (MIP-MEP) only adult subjects are considered.

Therefore, the intended patient population for these modules is:

a) Age: more than 14 years until elderly
b) Weight: > 30 Kg
c) Height: > 140 cm

d) Health status: physical and mental condition that allows the performance of the forced maneuver

1.1.1 PACKING LIST

The PIM-PEM Module (09891) includes the Plugging Probe (03052) to which the PM-PEM nozzle is connected to perform the test (09803).

Also included:

07241	This user manual
03030	MIP-MEP option for W20s software
07209	Activation code card

1.1.2 MODULE ACTIVATION

To activate the option in the spirometer, consult section **5.3 ADDING MODULE, OPTIONS AND/OR TRANSDUCER** of the device user's manual.

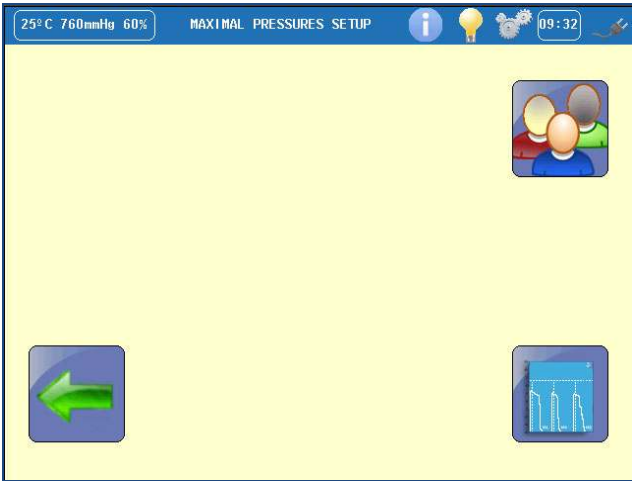
1.2. MIP-MEP CUSTOMIZATION

Access the MIP-MEP customization menu to configure the Maximal Respiratory Pressure option according to your needs:

Press , from the startup screen, then  and finally 

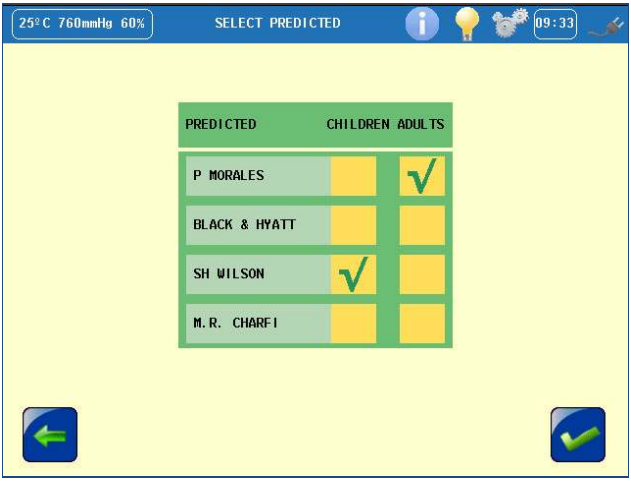
.

The following screen will appear:



1.2.1 PREDICTED SET SELECTION

Press  and the following screen will appear:



Choose the desired predicted set for adults and/or children by pressing on them. A √ will appear on the option selected.

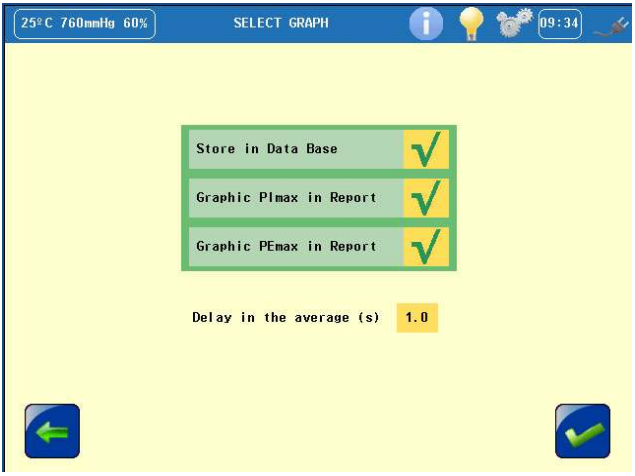
 Escapes this screen and moves back to the previous one

 Validates the input data and goes to the next screen.

Not all the sets have predicted values for adults and children; the program will not allow you to select predicted sets that do not exist.

1.2.2 GRAPHS AND DELAY TIME SELECTION

Press  and the following screen will appear:



Activate desired graphics options and enter the delay time by pressing on them. A √ will appear on the option selected

 Escapes this screen and moves back to the previous one

 Validates the input data and goes to the next screen.

The default value for the delay is **1.0 s**, although the user can on the calculation of the measurement since no value in this first second (or the time configured by the user) is taken into account.

The options for graphics allow saving the graphics in the database and/or print the curves of MEP or MIP.

1.3. START-UP AND MIP-MEP TEST PROCEDURE

Access to the MIP-MEP test by pressing , from the main screen.

1.3.1. ENTERING PATIENT DATA

When accessing the MIP-MEP Program, enter the patient details.

Consult the section **ENTERING PATIENT DATA** of the general user's manual of the **DATOSPIR TOUCH** spirometer.

After entering the patient data, press ENTER to validate them and go to the test screen.

If a performed test is still in memory, the program will go directly to the next screen (section **1.3.2**).

1.3.2. MIP-MEP TEST PROCEDURE

We suggest consulting some bibliography on the usual procedure required to perform the tests correctly. See section 4 of this manual.

During the performance of the test, follow these steps:

MIP-MEP PROBE

1 Connect the MIP-MEP module to the spirometer (see section 2.3 of general user's manual). The equipment detects automatically that the module is connected. If the module is not connected, the equipment will show it on screen and it will not allow entering the screen of tests performance.

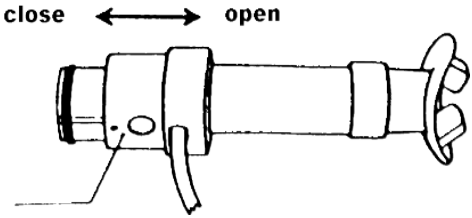
2 Make sure that the shutter probe is connected to the module.



3 Train the patient about the test performance, as his/her collaboration is essential for the correct execution. Put the nose clip to the patient.

4 Press  and wait until a blinking arrow appears on the screen to start the test.

5 The shutter valve must be in open position, in order to allow the patient to breath normally.



Once the patient has reached the position of Total Pulmonary Capacity, move the cursor to the closed position and perform the maneuver.

The Icons give access to:

 Escapes this screen and goes back to the previous one

 Enables to modify the Patient data

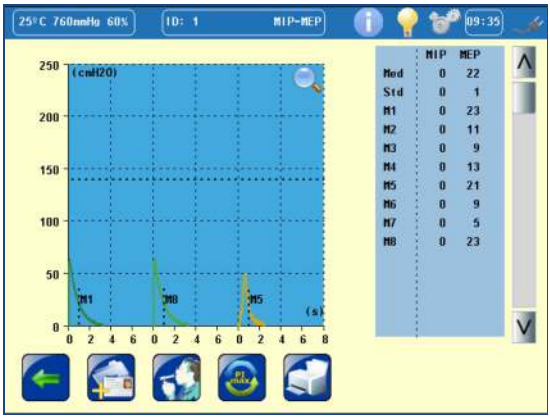
 Starts the maneuver

 /  Changes the test, from MEP to MIP or vice versa

 Performs the Report (If there are performed maneuvers)

6 Once the maneuver is finished, repeat step 3 in order to perform more maneuvers.

It is advisable a minimum of 3 maneuvers. The best 3 maneuvers should not differ more than 5 % between them, and the last maneuver should not be the best.



7 The previous screen presents (or can present) the following information:

- Date, patient code and type of test.
- Warnings:

  >5%: indicates that the variation between the best 3 maneuvers is over 5%.
- Pressure/time Graphic for the best 3 maneuvers.
- Pressure/time Graphic for the selected maneuver (pressing one of the keys M1 to M5).
- Horizontal line of dots showing the reference value
- Vertical line of dots showing the maximal value for each maneuver.
- Values of maximal pressure of the performed maneuvers, average and standard deviation of the best 3 ones.

The maneuvers of maximal pressure are ordered chronologically according to their performance. This is made because it is important to follow the evolution of the patient maneuvers.
Anyway, although the maneuvers are saved in the memory in temporal order, the best 3 maneuvers are displayed on screen

ordered from the best to the worst (the maneuver of highest pressure value is considered as the best).
It is also important to point out that more than 5 maneuvers may be performed, despite the fact that the device has space only for 5 maneuvers.
When performing the sixth maneuver, the first performed will be deleted (M1), if this is not the best. Should it be the best maneuver, the second one would be deleted (M2).
Once the corresponding maneuver has been deleted, the system will reorder them, being the performed maneuver the M5, the M5 will be the M4; the M4 will be M3, and so on.

NOTE: The  **key let you to move back in the menu without losing the information available up to that moment. Only if you change of patient by entering a new code, or you perform other operations, the data might be lost. Anyway, the device will always warn you with a message on screen, before deleting the information.**

1.3.3 DISPLAYING THE RESULTS

Pressing on the parameters, at the upper right part of the test screen and new screen will appear containing the data on the maneuvers (up to 8 maneuvers).



The following data will be displayed:

- The maximal pressure values for the expiratory and inspiratory tests (up to 8 maneuvers), as well as for the average and standard deviation of the best three maneuvers.
- The predicted value, as well as the percentage with regard to the reference of:
  - the selected maneuver
  - the average of the best 3 maneuvers
- The selected inspiratory and expiratory maneuvers.
- The predicted set selected in the setup.

1.3.4. OPTIONS FROM THE DATA MENU

After performing the wanted maneuvers, of both expiratory and inspiratory pressure, the following operations can be performed:

A. - PRINTING THE RESULTS

Press  and a report of Maximal or Minimal Pressures will be printed out with the same information displayed on the data screen: patient's data and curves of selected maneuvers

B. - SAVING TESTS IN THE INTERNAL DATABASE

Press  and the test will be saved in the internal database of the spirometer, in order to display it afterwards, print it out and/or transfer it to a computer.

The system displays, saves or prints the values for all the maneuvers, but only one curve for each maneuver is saved or printed in the data base.
By default, the system selects the curve of the best maneuver (unlike the spirometry, it may not be number 1). If the specialist prefers, he/she can select another curve, as it is explained next.

To select a maneuver different to the one selected by default for the system, press on the corresponding maneuver (M1 to M8).

C.- DELETING A TEST

Press  to delete the selected maneuver of the desired test.

D.- CHANGING OF TEST

Press  /  to change from the expiratory test (MEP) to the inspiratory test (MIP) and vice versa

E.- TRANSFERRING TESTS

The MIP-MEP saved in the database can be transferred to a computer (See section **5.1** of the general manual).

2. TECHNICAL SPECIFICATIONS

2.1 PARAMETERS

In both expiratory and inspiratory tests, the next values are measured:

- Maximal pressure of the 8 maneuvers.
- Average of the best 3.
- Standard deviation of the best 3

2.2 RANGES AND MEASUREMENTS

Range of measurement	**±295 hPa (±300 cmH_2O)**
Resolution	**1 hPa (1 cmH_2O)**
Accuracy	**5 %**
Sample rate (Hz)	**100**
Components lifetime:	
- MIP-MEP connection module	**7 years**
- Shutter probe	**3 years**

*Maneuvers below 9,8 hPa (10 cmH_2O), are rejected

2.3 CONTROL

- **Number of maneuvers:** Up to 8 maneuvers for each type can be performed (MEP and MIP)
- **Duration of the maneuvers:** The maximum duration is 8 seconds.
- **Start of Maneuver:** When the threshold of 2,95 hPa (±3 cmH_2O) is surpassed.

- **End of Maneuver:** Variation lower than 1 hPa (1 cmH_2O) in the last 2 seconds.
- **Delay in the calculation of the maximum pressure value:** Selectable between 0.1 and 4.9 seconds, in the setup; 1 second as a default.
- **Internal Database:** The Spirometer shares the internal data base for all test types.

3. PRINCIPLES OF OPERATION

3.1. SIGNAL ACQUISITION

The module of maximal pressures includes basically a pressure sensor, a differential amplifier and a filter.

The pressure sensor covers the range from ±295 hPa (±300 cmH_2O), while maneuvering below 9.8 hPa (10 cmH2O), are rejected. The output of this sensor is amplified and filtered so that the analogical signal has the intended range and bandwidth. Then, this signal is transformed into digital with an A/D converter. The converter used is the same as the one used in the spirometry.

3.2. CONTROL PROGRAM

The control program performs the processing of the acquired signal. Among the important calculations, we must point out:

- **Start and end of the maneuver** The start of a maneuver is considered when the level of 2,95 hPa (3 cmH_2O) is surpassed. The end of the maneuver is considered when there is a pressure variation lower than 1 hPa (1 cmH_2O).
- **Delay for the calculation:** For the calculation of the maximal pressure, an initial period of time is discarded to avoid

artifacts. This period is set to 1 s by default but it can be set up between 0.1 and 4.9s.

- **Order of the maneuvers:** The maneuvers are saved in the memory in the same order as they have been performed.
- **Automatic deleting of a remaining maneuver** When the 8 memories are full, and a new maneuver is performed, the first maneuver is always deleted, if this is not the best. If the first is the best, then the second one is deleted.

4. MEASUREMENT TECHNIQUE AND PREDICTED SETS

The maximal inspiratory pressure (MIP) depends directly on the strength developed by the inspiratory muscles. Its measurement is very useful in the diagnosis and follow up of patients with neuro-muscular illnesses, specific alterations of the respiratory muscles, different processes of the thoracic area, air trapping or modifications produced by breath depressive medicines, among other clinic situations The maximal expiratory pressure (MEP) also informs about the cough efficacy and the drainage of the bronchial secretions. In both cases, they are measures easy to perform and comfortable for the patient. They can be obtained near the patient and allow to follow his/her evolution.

The procedure to obtain the MIP and the MEP must complete the following aspects:

1. Correct collaboration of the patient to get a maximum effort in the maneuvers.
2. The patient must keep his/her hands against the cheeks and leave them flaccid to attenuate the pressure generated by the facial muscles.

3 To measure the MIP, the patient must perform a deep inspiration from the position of Residual Volume and maintain the effort for at least 3 seconds.

4 To measure the MEP, the patient has to inspire previously up from the position of Total Pulmonary Capacity and from there blow with the maximum effort.

5 It is advisable a minimum of three satisfactory maneuvers for each pressure.

If you suspect of measuring errors, make sure that there are no leaks in the system and the patient is cooperating to obtain meaningful maximum effort maneuvers.

The Module of Maximal Respiratory Pressures is useful for Pneumology, Anesthesiology, ICU and Neurology units, for isolated determinations or interned patients monitoring.

The device includes **4 predicted sets**, to be selected by the user:

A. P MORALES

Presiones respiratorias estáticas máximas en adultos. Valores de referencia de una población caucasiana mediterránea.
P. Morales, J. Sanchís, P.J. Cordero y J.L. Díez.
ARCHIVOS DE BRONCONEUMOLOGÍA. Vol 33, num 5, 1997.

B. SH WILSON

Predicted normal values for maximal respiratory pressures in Caucasian adults and children.
SH Wilson, NT Cooke, RHT Edwards, SG Spiro.
THORAX 1984; 39:535-538.

C. BLACK & HYATT

Maximal Respiratory Pressures: Normal values and relationship to age and sex
Black LF, Hyatt RE.
AM REV RESPIR DIS. 99:696-702, 1969

D. MR CHARFI

Les pressions ventilatoires maximales à la bouche chez l'adulte: valeurs normales et variables explicatives
MR Charfi, R Matran, J Regnard, MO Richard, J Champeau, J Dall'ava, A Lockhart. REV MAL RESP, 1991, 8, 367-374.

5. CLEANING AND MAINTENANCE

5.1. CLEANING / DISINFECTION

The MIP-MEP connection module can be cleaned with a wipe moistened with soapy (neutral) water, with 96º alcohol, or, with 0.1% sodium hypochlorite solution (equivalent to a 1:50 dilution of bleach in water if the bleach concentration is 5%). Then, wipe dry any remaining moisture. Take care that no liquid goes into the inner space or in the connectors or connections. **Do not use abrasive substances or solvents**.

HIGH LEVEL DISINFECTION

The shutter probe, including the measuring tube line, the adaptor and the Colder connector must be disinfected before their use in new patients, especially if you suspect microbial contamination.

To do so, proceed as follows:

1 Disassemble the parts of the shutter probe.

2. Immerse each part in a orthophthaldehyde solution (CIDEX® OPA) or in a disinfectant solution based on peracetic acid, hydrogen peroxide or N-Duopropenide according the concentration defined by the manufacturer (follow the manufacturer's instructions of disinfectant). Take care that the internal surfaces of all the parts get in contact with the solution.
3. Rinse each part with distilled water and leave them dry at room temperature.
4. Reassemble the parts of probe (lubricate the friction space between the probe and the cursor with Vaseline)
5. Finally check that the components are not obstructed and that the probes work correctly.

The PIM-PEM mouthpiece is reusable and must be disinfected according to the manufacturer's instructions.

Reutilization of the MIP-MEP mouthpiece between patients without prior disinfection induces a risk of cross-infection.

5.2. PREVENTIVE MAINTENANCE

Preventive maintenance consists of any actions aimed at keeping the device in a good state of use.

There are two types of preventive maintenance:

1. The first type, which can be performed by the user, consists of a periodical supervision of the appearance of the different connections and the other external parts of the device. Check that all the connections are perfectly connected, that no cable, no connector and/or any other element are broken or damaged.

In case of detecting any anomaly that the user cannot solve, contact the **after sales service of SIBEL S.A.U.** or **your distributor**, to proceed with the checking or repair.

2 The second type consists of a general technical verification of the safety systems, adjustments, functions, etc, forming the device.

This technical check should be performed every year according to the **DATOSPIR TOUCH's** Verification and Adjustment Procedure of the MAXIMAL PRESSURES MODULE, available from the manufacturer **SIBEL, S.AU.** This type of operation must be carried out by skilled technical staff from the hospital's maintenance department or from the distributor's or manufacturer's technical service.

SIBEL S.A.U., as the manufacturer, must provide written authorization, for at least the guarantee period, for the corresponding personnel to perform said maintenance and will not be held liable under any circumstances for any damage, malfunction, etc. that may arise as a result of defective maintenance by people not belonging to **SIBEL S.A.U.**

5.3. CORRECTIVE MAINTENANCE

Corrective maintenance consists of leaving equipment that has stopped working and must be repaired, due to malfunctioning or misuse, in a good state of repair.
Where a fault is detected in the equipment which prevents it from being used normally, contact the **SIBEL S.A.U. After-Sales Service** and specify the problem in as much detail as possible.