SIBELMED W20s

SPIROMETRY SOFTWARE

USER'S MANUAL

CE 0318

511-BL0-MU2 • REV. 3.02 • 2024-05

Sibelmed W20s User Manual
Revision: 511-BL0-MU2 REV.3.02

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DISCLAIMER
SIBEL S.A.U. is responsible for the security, reliability and performance of this equipment only if:
• The place where the system is installed or used meets the requirements for electrical installations IEC and other applicable regulations.
• All repairs, revisions or modifications, both in and out of the warranty period, are made by technical staff of SIBEL S.A.U.
• The system is used by qualified staff in accordance with the recommendations stated in this User's Manual.

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The **SIBELMED W20s Spirometry Software** has been developed by the **R+D+I department** of **SIBEL S.A.U.** with the collaboration of the Lung Function Laboratory of *Hospital de la Santa Creu i Sant Pau de Barcelona*, meeting the standardization criteria of both International Institutions: ATS/ERS TASK FORCE 2019 (American Thoracic Society / European Respiratory Society) and National Institutions: SEPAR (Spanish Society of Pneumology and Thoracic Surgery)

CE 0318 **PRODUCT IN COMPLIANCE WITH MEDICAL DEVICE REGULATION (EU) 2017/745. CLASS IIa.**

Revised
Date: 2024-05
Technical Manager

Approved
Date: 2024-05
Sales Manager

1. SAFETY

The **SIBELMED W20s** spirometry software has been designed for use with the safety in mind. All operating instructions must be read before using it. Failure to do so could cause injury to the user or patient and damage to the equipment and/or accessories.
This spirometry software can be used in conjunction with several spirometers manufactured by SIBEL S.A.U. It is very important to carefully read the User's Manual of the spirometer before using it with the software, especially the SAFETY section where all the safety considerations related to the spirometer are explained in detail.

Report any serious incident to the manufacturer and competent authority.

1.1. INTENDED USE

The intended uses of W20s software when used stand-alone are:

a) Numerical and/or graphical representation of stored measurement tests (lung flows and volumes, blood oxygen saturation and respiratory pressures)
b) Diagnosis and control of respiratory diseases (Asthma, COPD, etc.)
c) Test import and export from/to patient data base

Furthermore, when the W20s software is connected to compatible devices it has the following intended uses:

d) Signal acquisition and parametric calculus of lung flows and volumes for the diagnostic and control of respiratory diseases (Asthma, COPD, etc.).
e) Signal acquisition and parametric calculus of peripheral blood oxygen saturation and cardiac pulse for the respiratory diagnostic.
f) Signal acquisition and parametric calculus of inspiratory and expiratory maximal pressures for the respiratory diagnosis.

1.2. INTENDED USER

The spirometry software is intended to be used by or under the direction of a medical professional. Specific training on the Spirometry technique is recommended.

Bronchoconstriction test and pulse oximetry test must be supervised by a qualified technician in the art.

Before using the spirometry software on patients, you should be familiar with its operation. All information necessary for its operation is available in this Manual.

For additional training on the technique or on the product, contact SIBEL S.A.U. or your dealer.

1.3. INDICATIONS FOR USE

The software is intended to be used in combination with compatible devices or as a stand-alone product.

The devices capatible with W20s software are DATOSPIR Aira, DATOSPIR Touch (including MEP-MIP module), DATOSPIR Micro and Nonin 3231 USB pulseoximeter.

The W20s spirometry software is indicated to be used for the diagnosis and control of respiratory diseases like asthma, Chronic Obstructive Pulmonary Disease (COPD) or other respiratory diseases.

The spirometry software is also indicated for evaluating the health status of individuals in occupational medicine, for assessing preoperative risk or for medicolegal assessment.
W20s is a useful tool for providing an accessible and accurate diagnosis of the respiratory diseases. It also allows the clinical management of respiratory patients and an early identification of individuals at risk of developing respiratory diseases.

MIP-MEP test is indicated in patients where muscle weakness could be contributing to abnormal results from routine tests, like in

dyspnea, respiratory failure, neuromuscular or multisystem diseases or to follow the progress of patient with chronic diseases. It allows the evaluation of respiratory muscle strength for the diagnosis and follow-up of these respiratory diseases.

Pulse oximetry test is indicated for measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate of patients who are well or poorly perfused (see pulse oximeter user manual). It allows fast, accurate, real-time and non-invasive oxygen measurements for the management of patients' medical conditions.

1.4. INTENDED PATIENT POPULATION

The intended patient population of each of the supported devices can be found in the corresponding user manual. Patients do not interact with the software and the software does not introduce any additional restrictions.

Generally, in spirometry, the characteristics of the patients are:

- Age: more than 4 years until elderly
- Weight: > 15kg
- Height: > 90cm
- Health status: mental and physical condition that allows the performance of the forced spirometry maneuver.

And for the maximum pressure tests:

- Age: over 14 years until elderly
- Weight: > 30 Kg
- Height: > 140cm
- Health status: physical and mental condition that allows the performance of the forced maneuver

1.5. LIMITATIONS IN USE

An analysis of the results of a spirometry or maximal pressures test is not enough to make a correct diagnosis of the patient's clinical condition. The interpretation of the tests must be complemented with the clinical history or other tests that the doctor considers to determine the required treatment.

The spirometry and maximal pressure tests require patient cooperation. The clinician administering the test must assess the patient's capacity to perform the spirometry test. Special attention must be paid to children, the elderly and the disabled.

Medical staff must consider the symptoms showed by the patient. The acceptability of a spirometry or maximal pressures test is the responsibility of the sanitary staff.

There are no usage limitations related to pulse oximetry testing in W20s. Refer to the pulse oximeter user manual for additional information.

1.6. CONTRAINDICATIONS

No contraindication has been identified for spirometry or MIP-MEP tests. However, special precautions must be considered when performing these tests in patients with medical conditions that could be adversely affected by maximal pressures generated in the thorax during the forced maneuvers.

No contraindication has been identified for oximetry tests with 3231 pulseoximeter.

1.7. SIDE EFFECTS

During spirometry testing, some patients may occasionally experience exhaustion during the test. In such a case, the test should be stopped and the patient's condition reassessed.

There are no side effects related to PIM-PEM and pulse oximetry testing in the W20s Software.

1.8. ESSENTIAL OPERATION

The transmission of data in real time, the downloading of data stored in the device, the storage of data in the software database and the presentation of results are considered essential functions of the W20s software.

1.9. RESIDUAL RISK

According to the application of the EN ISO 14971 standard, all risks related to the use of the W20s software have been reduced to maximum, as much as possible. It is important to read carefully all indications of use, contraindications, warnings and recommendations provided in this manual.

1.10. WARNINGS

Please read this manual carefully before using the W20s software. Please use the W20s software according to the instructions included in the W20s user manual.

Pay special attention to warnings like this.

To comply with Medical Device Regulation (EU) 2017/745 and for safety and reliability reasons, please ensure that the W20s software is used by personnel who are adequately trained in the intended use of the system.

The user must have a minimum computer knowledge allowing the safely operation of the W20s software and the Windows environment. It is important that the IT infrastructure manager trains and informs the user about the computer security measures adopted at workstation and network system level. These measures may include access control, software installation policy, data sharing, external access, etc.

The computer, monitor and accessories on which the software is used must comply with the Low Voltage Directive (in particular the EN60950 standard) and the EMC Directive (in particular the EN55022, EN61000-3-2, EN61000- 3-3 and EN55024).

Liquid contact with the USB flash memory drive should always be avoided.

Check that your PC hardware is working properly.

The W20s software must be used in a secure computing environment. It is important that you or your IT infrastructure manager establish security policies, including access control to the system, control of the installation of new software, management of backup copies, protection of the system against viruses and malware, guarantee of confidentiality and integrity of data transmission, confidentiality of personal data storage, regular system updating and installation of security patches. Using the program outside of its intended environment could result in a loss of data integrity.

Periodically check for updates to the W20s software.

This manual is available in PDF format on the provided USB flash drive to install the W20s software.
Once installed, the user manual is also available in the "Help" folder, which is located in the installation folder (normally C:\SIBEL\W20s\Help).
You can also request a printed copy from SIBEL S.A.U. or through your authorized dealer.

The W20s software runs on a PC, make sure to save the test before

turning off the PC or unplugging the communications cable.

The W20s software should NOT be used under high ambient noise levels to ensure that the patient may hear the acoustic signal of the software.

In accordance with the different regulations, it is advisable to check and/or calibrate medical products periodically, to guarantee the safety of the patient, the user and the environment; and guarantee the reliability and precision of the functions for which it has been developed.

It is advisable to carry out a general review of security systems, settings, functionality, etc. on an annual basis. Do not exceed eighteen months without doing it in any case. Perform a check at any time when a product malfunction is suspected.

These reviews must be carried out according to the manufacturer's Verification and Adjustment Procedures (SIBEL S.A.U.), by the manufacturer itself or by qualified personnel authorized by SIBEL S.A.U.

1.11.  DISPOSAL OF ELECTRICAL AND ELECTRONIC DEVICES BY DOMESTIC USERS IN THE EUROPEAN UNION

The software is delivered on a USB Flash memory drive. The USB Flash memory drive is an electronic product and therefore should not be disposed of in organic waste. Deliver to a designated recycling collection point in accordance with the legal requirements of your country.
You can obtain more information on proper disposal by contacting the SIBEL S.A.U. Technical Service. or with your dealer.

2. INSTRUCTIONS FOR USE AND INSTALLATION

2.1 INTRODUCTION

The **SIBELMED W20s** is a software application for the transfer, analysis, storage and/or register of spirometric signals which works under Microsoft Windows.

The Pulmonary Function Tests that can be performed with the W20s software are:

- FVC: Forced Vital Capacity
- VC: (Slow) Vital Capacity
- MVV: Maximum Voluntary Ventilation
- FVC, VC and MVV with bronchodilation response
- FVC with bronchoconstriction response (challenge test)

With these spirometric tests, a set of parameters are calculated and can be evaluated using four user-selectable interpretative algorithms programmed in the software. These algorithms compare the measured values against predicted normal values. W20s includes several user-selectable predicted sets obtained in clinical studies and based on equations or reference tables that depend on anthropometric parameters, such as ethnicity, sex, age (years, adult or children), height and weight.

It is compatible with different DATOSPIR spirometers, among them, the **DATOSPIR TOUCH** and **DATOSPIR AIRA**, and it can work in real time or deferred time, depending on the spirometer characteristics.

It allows:

- The management of different databases
- The performance of FVC, VC, MVV, Postbronchodilation and bronchoconstriction tests when connected to a compatible spirometer
- The graphic presentation in F/V and V/T modes
- The selection of different Reference Parameters
- The selection of different types of diagnosis

- The printing of different reports
- The presentation of graphics for motivated tests for children
- To carry out the PIM-PEM test, it is necessary to connect a compatible spirometer that supports this feature.
- To carry out the pulse oximetry tests (SpO2) it is necessary to connect a compatible USB pulse oximeter to the PC.

The MEP-MIP test allows a direct measure of the maximal expiratory and/or inspiratory pressures. The W20s software compares in percent the ratio between the measured value and a predicted normal value according to several user-selectable predicted sets, but it does not perform any interpretation or diagnosis.

2.2 PREVIEW

This product is manufactured under strict quality controls. Nevertheless, accidents may happen in the transport or storage, so it is convenient to make a status check before installing it, as well as of its accessories.

The **Spirometry Software SIBELMED W20s** consists of:

REF	Qty	Description
09887	1	Spirometry Software W20s
511-BL0-MU2	1	Spirometry Software W20s User Manual English Language

The software has the possibility to enable the next software options:

REF	Description
07969	Bronchoconstriction Software option for W20s (1)
07070	MIP-MEP Software option for W20s
07071	Pulse oximetry Software option for W20s
08535	W20s connectivity option with ILLA system (2)

(1) Default option for Datospir Aira F, T and D..

(2) French market only

2.3 INSTALLATION AND SETUP

2.3.1 SPIROMETRY SOFTWARE INSTALLATION

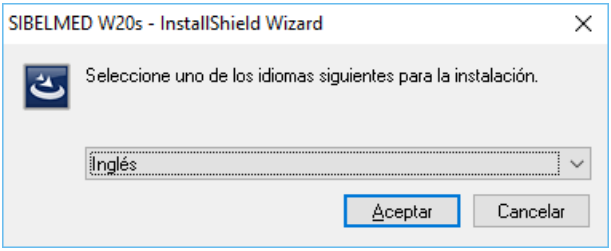
The user must have administrator rights in order to install all the program's features. In case of any doubts, contact your System Administrator or check the help of the Operating System.

For the Software installation in PC hard disk media, you should proceed as follows:

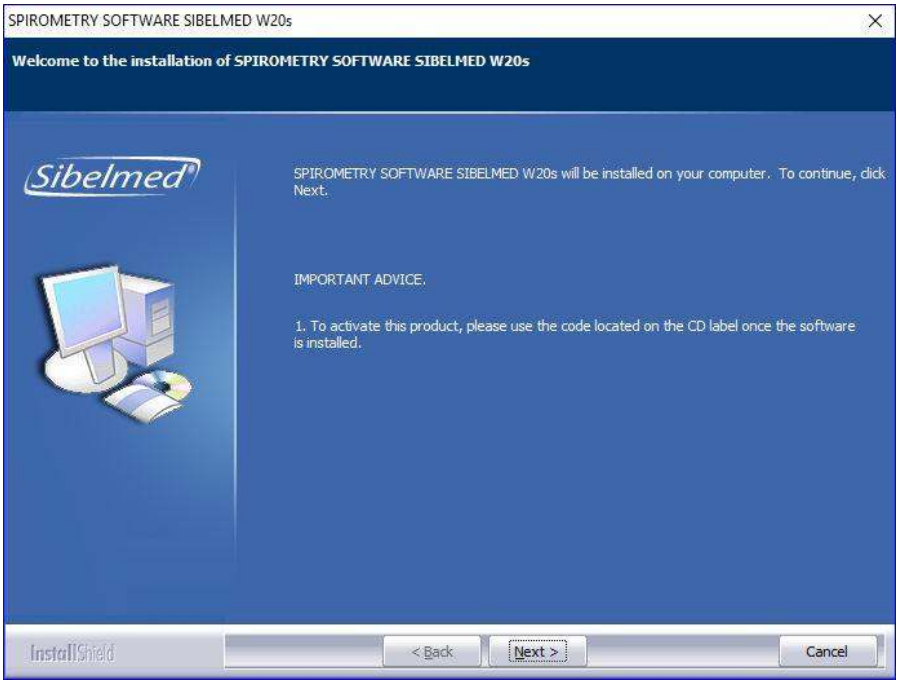
1 Plug the USB memory drive into any of the PC's USB ports.

2 Run the program **Setup.exe** in the USB memory drive.

3 In the next window select the language for the setup process.



4 Please choose the directory where to install the program and the group of programs' name. The program's default installation directory is**: C:\SIBEL\W20s**.



5 Once the installation is done, it will create the **SIBEL** group of programs' or the one chosen by the user and a shortcut will be created on the desktop.

2.3.2 OPTIONAL MODULES ACTIVATION

In case you have acquired one or more optional modules of the W20s software (**Bronchoconstriction, SpO_2 or MIP-MEP**), you will have to enter the correct 15-digit key supplied, in order to activate them. (Main Menu **Setup > Utilities > Options Activation).**

In case you have acquired the options but do not have the key available, please consult our after sales department.

2.3.3 BLUETOOTH MODULE INSTALLATION

A Bluetooth module needs to be installed on the PC for Bluetooth compatible spirometers.

The Bluetooth interface allows data to transfer to the computer, both for performing real-time testing and for transferring tests saved in the internal spirometer database.

The Bluetooth chip installed in the spirometer uses the «Bluetooth Series Port» service or profile (known as SPP). This will be the profile that must be installed in the computer to allow communications with the equipment.

The installation of the Bluetooth device on the computer may vary according to the device brand and according to the operating system that it is installed on. Consult the INSTALLATION MANUAL FOR BLUETOOTH ADAPTER provided with the Bluetooth module of each SIBELMED spirometer and the User's Manual of each Bluetooth adapter.

2.3.4 USB DRIVER INSTALLATION

For USB compatible spirometers, a driver needs to be installed on the computer.

This driver is installed automatically during the installation of the W20s software. To perform this process, simply disconnect the USB cable from the computer, install W20s software and plug in the USB cable with the audiometer switched on. From this moment, the driver is installed and you can start communications with the device.

In addition to the automatic procedure, it is possible to install the driver manually. To perform this, follow these steps:

1 Start up the spirometer (Consult the corresponding manual for use).

2 Plug the USB memory drive into any of the PC's USB ports.

Windows 7,8.1, Windows 10 and Windows 11:

3 Open the device manager via «Start > Control panel > Hardware and sound > Device manager». In the «Device manager» dialog, locate the entry that corresponds to your device and double click on it.

4 Choose the «Driver tab» and click on the button «Update driver».

5 If the operating system is Windows 7 or Windows 8.1 32-bit version, select the directory D:\Driver_spiro\WIN_XP_7_8.1\x86; for a 64-bit version, select the directory D:\Driver_spiro\WIN_XP_7_8.1\x64.
If the operating system is Windows 10 32bit, select the directory D:\Driver_spiro\WIN_10\x86; for Windows 10 64bit or Windows 11, select the directory D:\Driver_spiro\WIN_10\x64.
Hit next and the driver will install. Click OK.

6 Click on Next and Finish. The Driver will be installed.

2.3.5 SETUP

Start the PC and run the program:

Press once over the icon **W20s** found inside the folder of the start menu **Programs/SIBEL**.

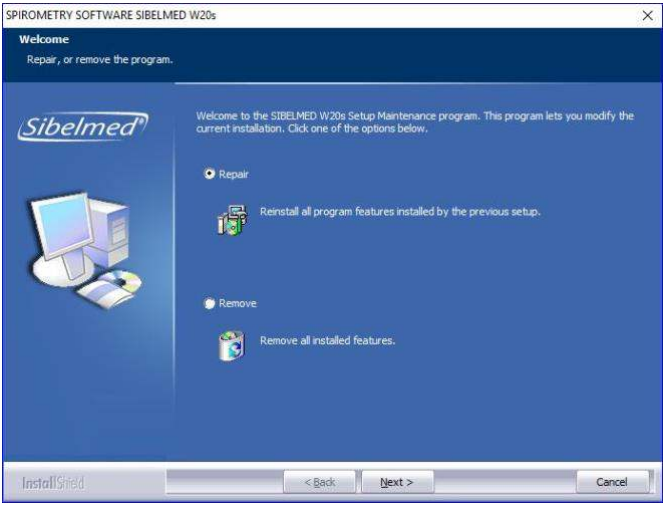
Press **OK** on the screen **ABOUT …** to enter the **DATABASE WINDOW**.
Connect the spirometer to the computer.

2.3.6 SPIROMETRY SOFTWARE UNINSTALLATION

1 Plug the USB memory drive into any of the PC's USB ports.

2 Run the program **Setup.exe** in the spirometry USB memory drive.

The next options can be chosen when the following window appears:



- **Repair**: It reinstalls the program. If there is a damaged or lost file, it will repair it.

- **Remove**: It uninstalls the software, but the database of the program is not deleted. It can be found in the folder where the software was installed.

2.4 ABOUT ON SCREEN HELP

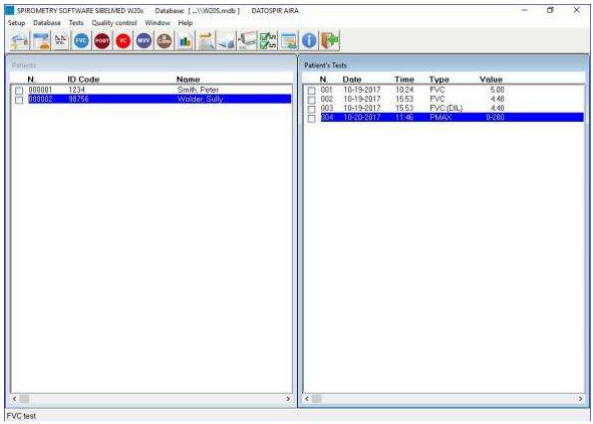
The Spirometry Software **SIBELMED W20s** provides a link to the user manual to help the user to handle properly the different software options.

Generally, every screen has a Help menu that allows to open the user manual. This help is indicated in every screen with an icon, with text or both.

The user manual is in PDF format and is opened automatically with the software that Windows has registered as viewer of PDF files. If there is none, Windows will ask to select one.

2.5 DATABASE MENU

This screen presents the main options available in the **Spirometry Software SIBELMED W20s** with the corresponding sub options.



SETUP

- Spirometry
  - Graphs and incentive
  - Parameters and predicteds
  - Transducer code
  - Bronchoconstriction
  - NIOSH Mode
- Maximal pressure
- Units
- Printer selection

- Report header
- Printer selection

Language
Interoperability
Links
Utilities (depending on the connected spirometer)
- Activation code (Datospir Micro)
- Software purchase (Datospir Micro)
- Update spirometer (Datospir Touch, Datospir Aira) 
- Update BIOS (Datospir Micro)
- Update Flash (Datospir Micro)
- Download spirometer configuration (Datospir Touch, Datospir Micro)
- Spirometer configuration (Datospir Aira)
- Options activation 

Exit 

DATABASE

New patient 
Patient data 
Test data 
Trends 
Download spirometer data 
Mark all
Unmark all
Delete records
Delete all records
Sorting by
- Record
- Last name
- ID code

Maintenance
- Select database
- Change password

Export tests
- CSV
- PDF
- XML

Mail
Import tests CSV format

TESTS
FVC 
Post-bronchodilation 
VC 
MVV 
Constriction 
Maximal pressure 
Pulse oximetry 
Preview report 
Complete report 

QUALITY CONTROL
Calibration (Datospir Aira)
Quality control (Datospir Aira)
Calibration database (Datospir Aira)

WINDOW
Cascade windows
Tile windows horizontally
Tile windows vertically

HELP
About the software 
Visit SIBEL S.A.U. web Site / About…

Some of these menu options may not be available, depending on the spirometer being used. By entering each of these options, the corresponding information is available.
Next, a description of each function available with the **SIBELMED W20s** is made.

2.6 SOFTWARE CONFIGURATION

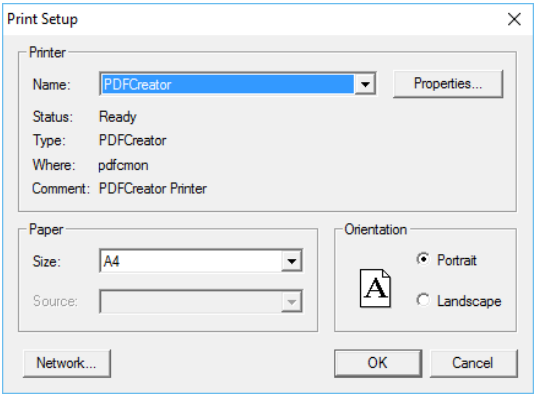
The **Spirometry Software SIBELMED W20s** is a versatile program with multiple possibilities of functioning. Some of them could be of no use for certain users. So, once the

Installation and Configuration process has finished, it is necessary to adapt it to the needs of each user. Thus, the system will be configured in each case and its handling and understanding of the functioning will be easier.

Next the different options that can be configured are detailed.

2.6.1 PRINTER SELECTION

Select the option **PRINT SETUP - PRINTER SELECTION** into the **SETUP**. The selection is made by placing the mouse cursor over the label SETUP and pressing the mouse left button. Next, do the same over the label PRINTER SELECTION.



The screen shows the printer selected by the operative system, as well as the available printers at that moment.

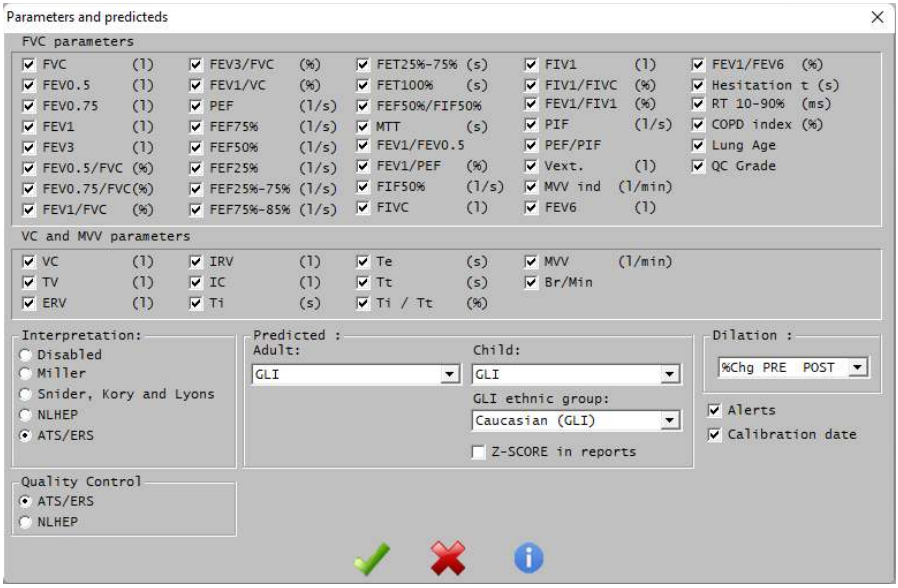
If the printer in use is not found in the relation, it is necessary to install it using the process defined by the system. Consult the computer Operative System Manual.

In the printed report includes a header with three customizable lines by the user. For example: name of the centre, doctor, address, etc. A logo in BMP may also be selected and will be printed in the top right corner of each report.

Change the report header from **PRINT SETUP – REPORT HEADER** in the **SETUP** menu."

2.6.2 PARAMETERS AND PREDICTEDS

Select the option **SPIROMETRY – PARAMETERS AND PREDICTEDS** in the **SETUP** menu.



This option allows the user to setup or select the following:

- **FVC Tests Parameters**
- **VC and MVV Parameters**
- **Interpretation algorithms (Diagnosis)**
  - Disabled
  - Miller chart
  - Snider, Kory & Lyons
  - Interpretation ATS/ERS.
  - Interpretation NLHEP.

See section **INTERPRETATION ALGORITHMS**

(DIAGNOSIS) in the **TECHNICAL SPECIFICATIONS** chapter for a detailed description.

- **Predicted sets available for Adults and Children**

  - SEPAR 2013
  - ERS
  - KNUDSON
  - CRAPO
  - ZAPLETAL
  - MORRIS
  - AUSTRIA
  - GUTIERREZ (1996)
  - SER 2014
  - CASTRO - PEREIRA 2002
  - POLGAR - WENG
  - HANKINSON - NHANES III
  - PEREZ - PADILLA
  - A.J. CRUZ
  - GOLSHAN
  - GARCIA RIO
  - CANDELA
  - PLATINO
  - THAI 2000
  - GLI
  - CASTRO - PEREIRA 2007

  See the section **PREDICTED SETS** in the **TECHNICAL SPECIFICATIONS** chapter for a detailed description.

- **Ethnic Factor**

  The ethnic factor modifies the Predicted values according to the selected percentage. **If no correction is to be included, the factor must be 100**.

- **Ethnic Group**

  The ethnic group can only be selected when using the GLI predicted values.

- **Comparing mode in the Bronchodilator Tests**

% Average between PRE and POST	{100x2(POST-PRE)/ (POST+PRE)}
% between REF and POST	{100(POST)/REF}
% between PRE and POST	{100(POST-PRE)/PRE}
Difference between PRE and POST	{POST-PRE}

The second comparison mode (% between REF and POST) is fixed and is always shown, independently of the mode selected.

- **Alerts**

If this option is activated, the report will show some indications about the quality criteria according to ATS/ERS (ET, EX) or according to NLHEP (ET, EX, PEFT), as well as symptoms that have experienced the patient during the test (Cought, Weezing, Dyspnea, Sputum)"

- **Calibration F.**

When activated, shows the date of the last calibration in the report.

- **ATS/ERS Quality Control**

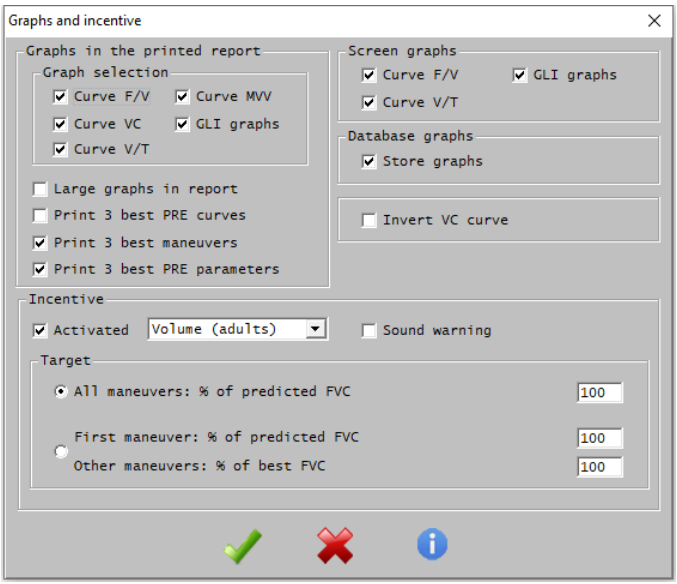
The **Spirometry Software SIBELMED W20s** incorporates an automatic quality control function, based on the recommendations of the **ATS/ERS societies**, that evaluates the **acceptability** and **repeatability** of maneuvers and the quality **grade** of the test session, to assist the technician in achieving high quality spirometry tests.

- **NLHEP Quality control**

Alternatively, **the software W20s** also incorporates a similar quality control function, based on the recommendations of the **National Lung Health Education Program (NLHEP)**, with **prompts** and **grades** to assist the technician in providing adequate instructions to the patient to produce high quality spirometry tests."

See section **QUALITY OF FVC TEST** in the **TECHNICAL SPECIFICATIONS** chapter for a detailed explanation of these quality control algorithms.

2.6.3 SPIROMETRY – GRAPHS AND INCENTIVE



This option allows the user to select the following:

- **Graphs in the printed report**
  Curve F/V
  Curve V/T
  GLI graphs
  Curve VC
  Curve MVV
  Large graphs in report
  Print 3 Best PRE curves
  Print 3 Best maneuvers
  Print 3 Best PRE parameters

- **Graphs on the Screen**
  Curve F/V

Curve V/T
Curves F/V and V/T
Graphs GLI

- **Store graphs in the database**
  Store graphs
- **Motivation for pediatric/adult tests**
  Several graphic incentives are available for both children (dolphin and rocket) and adults (volume and time).
  The following parameters regarding the incentive can be configured:
  - The target the patient must reach in the maneuvers can be set in two differenmt ways:
    - A percentage of the predicted FVC value, in all maneuvers.
    - A percentage of the predicted FVC value (for the first maneuver) or a percentage of the best maneuver's FVC value (for the remaining maneuvers).
  - Activation of a sound alarm if the goal is reached

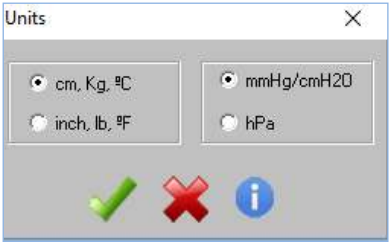
2.6.4 NIOSH MODE

Select **NIOSH MODE** in the **SETUP** menu.
Enable the NIOSH mode from this dialog. When this mode is activated, the following changes are made to FVC tests:
- Reports conform to the format specified by NIOSH.
- ATS / ERS quality control, NHANES III spirometric references, Anglo-Saxon system units and certain spirometric parameters are activated.

The user is able to set the body position of the patient in the window MANEUVER DATA.
This window is also used to enter the data for the report header when the NIOSH mode is active.
NIOSH mode is available for the Datospir Touch and Datospir Aira spirometers.

2.6.5 UNITS

Select the option UNITS and the units you want to use in the software.

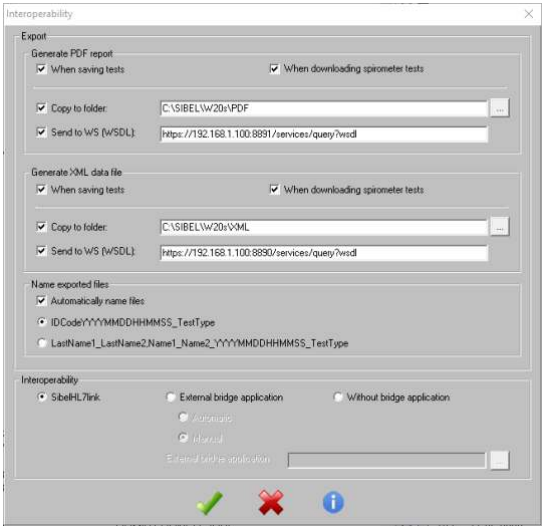


2.6.6 LANGUAGES

This dialog is used to select the language used in the messages and windows of the W20s software. Go to SETUP- LANGUAGE to open this window.

2.6.7 INTEROPERABILITY CONFIGURATION

This menu allows you to configure the export of spirometry (FVC, VC, MVV and Dilation) tests to XML and PDF format when you save the test in progress in the database or when tests are downloaded from the spirometer.
Select the **INTEROPERABILITY** option within the **SETUP** menu.



This option allows the user to select the following:

- **Generate PDF report**
  - When saving tests: creates the report in PDF format automatically when saving tests in real time. The file is stored in the PDF_TEMP folder of the W20s installation path.
  - When downloading spirometer tests: creates the report in PDF format automatically when downloading tests from the device database. The file is stored in the PDF_TEMP folder of the W20s installation path.
  - Copy to folder: enable this option so that the PDF file is also copied to the specified folder.
  - Send to WS (WSDL): when this option is activated, the program will send the PDF report to the specified webservice. The WSDL URL must be indicated.
- **Generate XML data file**
  - When saving tests: creates the XML file automatically when saving tests in real time. The file is stored in the XML_TEMP folder of the W20s installation path.

- When downloading spirometer tests: creates the XML file automatically when downloading tests from the device database. The file is stored in the XML_TEMP folder of the W20s installation path.

- Copy to folder: enable this option so that the XML file is also copied to the specified folder.

- Send to WS (WSDL): when this option is activated, the program will send the XML file to the specified webservice. The WSDL URL must be indicated.

- **File name format**, both PDF as XML files.

- **SibelHL7link**
  This option allows you to convert the XML file to CDA format of spirometry which can be viewed through a browser, and use a work list with the scheduled patients.
  This option is only available if the W20sLink option is purchased.

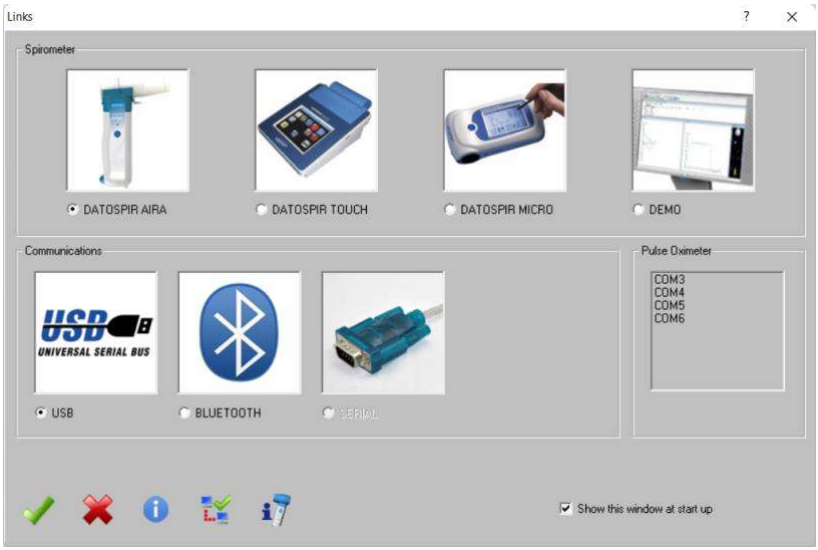
- **External Bridge Application**

  This option allows linking the W20s with a proprietary application of the client that generates the work list with the scheduled patients and export the generated PDF and XML files to external systems.
  This option is only available if the W20sLink option is purchased.

  Automatic / Manual options allow you to configure if the external bridge application is executed automatically (for example, applications that run in the background) or must run from the W20s. In the second case, you must indicate its path and name in the **External Bridge Application** field and must be run using the icon  in the main menu.

- **Without Bridge Application**
  This option allows you to use the W20s without the work list of scheduled patients. However, it continues generating the PDF file and the XML file.

2.6.8 COMMUNICATIONS



This dialog is used to select the spirometer used to make the tests and the communications link used to transfer data to the PC.

Select your device model under Spirometer. The option labeled as Demo lets the user select the ATS standard curves included with the software. These can be used for learning purposes, not being necessary to blow air in the transducer, or for the verification of the software operation.

Communications links include USB, Bluetooth and serial port. Select the option suitable for your spirometer. In case of Bluetooth or serial communications the COM port must also be selected. Verify how many serial ports are available in the computer. For a Bluetooth connection you have to select the serial port assigned by the Bluetooth driver (check the software included with the Bluetooth Adapter). For a USB connection this option is not used.

The button Communications test should be used to check the functioning of the communications between the spirometer and the PC. For this purpose, it is necessary to connect the spirometer to the computer and click the button.

Next, verify that the information is transferred, so no error window should appear.

Finally, in the Pulse Oximeter section, you must select the COM port created when connecting the pulse oximeter to the computer. The pulse oximeter COM port only appears if the device is connected. If you do not know the COM port corresponding to the pulse oximeter, do the following:

1 Go to the Windows "Control Panel" and click the "Device Manager" icon.

2 In the "Device Manager" list, locate the "Ports (COM and LPT)" item and expand it.

3 Find the item "USB Serial Device". The COM port is indicated in brackets.

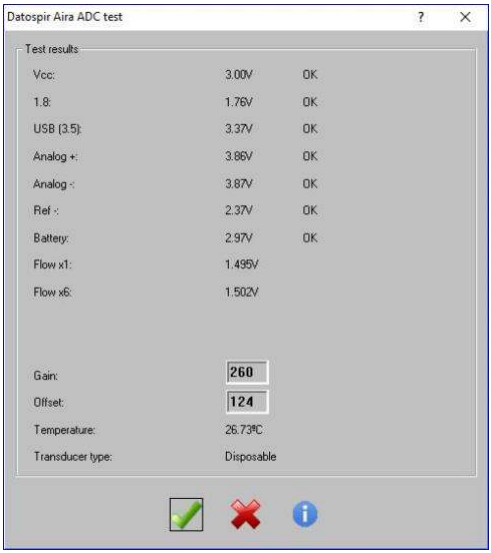
Skip this section if you will not be performing pulse oximetry tests.

Datospir Aira information

This option displays a window with information related to the connected DATOSPIR AIRA, whenever such spirometer is connected to the PC, including the model, serial number, firmware version, type and level of battery charge, connection type, date of last calibration, date of last servicing, total number of maneuvers performed with the spirometer, maneuvers since the last maintenance, transducer code (number of pulses for the turbine, code for the nozzles of the disposable transducer and transducer code of the Fleisch transducer), temperature measured by the spirometer, humidity and pressure.

CPU test: checks the proper functioning of the spirometers's electronics.

A/D test: gets the voltage values of the spirometer and transducer, as well as the temperature.



2.6.9 UTILITIES

Depending on the selected device, the Utilities menu will appear in the Links menu with the next options:

DATOSPIR AIRA SPIROMETER
- Update spirometer
- Spirometer configuration
- Options activation

DATOSPIR TOUCH SPIROMETER
- Update spirometer
- Download spirometer configuration
- Options activation

DATOSPIR MICRO SPIROMETER
- Activation code
- Software purchase

- BIOS update
- Flash update
- Download spirometer configuration
- Options activation

These options are explained in detail in sections ACTIVATION CODE, SOFTWARE PURCHASE, SOFTWARE UPDATE, FIRMWARE UPDATE, DATA DOWNLOAD FROM THE DEVICE and CONFIGURATION OF THE DATOSPIR AIRA SPIROMETER, at the end of this chapter.

2.6.10 ABOUT

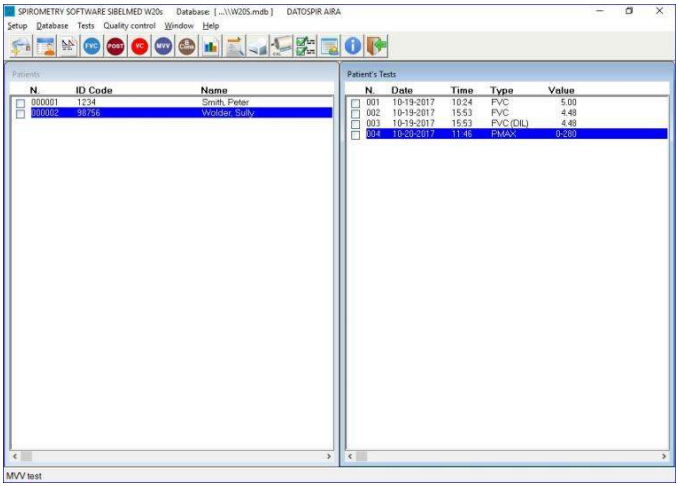
This option shows an information window with the program's data:

- Version
- Date
- Manufacturer's Data

2.7 DATABASE

The **Spirometry Software SIBELMED W20s** can work with different databases. All the information related to spirometric tests is stored in the database.

2.7.1 EXPLORING THE DATABASE

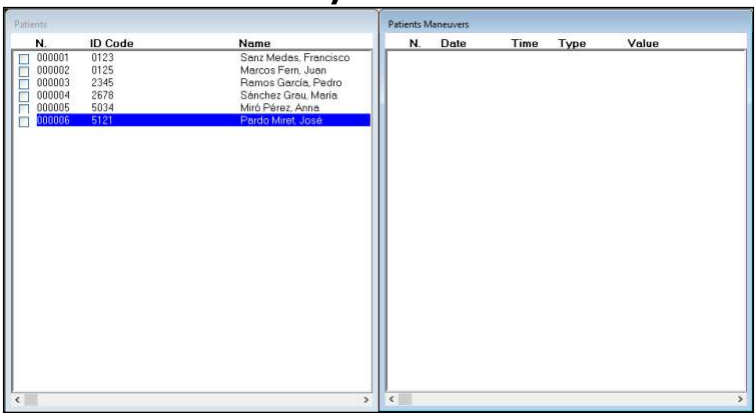


This window shows the database patient's list and their corresponding tests.
Double-click on a **patient** to view the patient's data or a test to open the test.
FVC, VC and MVV tests can be continued if the time elapsed between the first maneuver is less than six hours.
The window «Patient Maneuvers» (on the right in the above image) is complementary to the window «Patients». Only the tests of the selected patient will appear in the window «Patient Maneuvers».

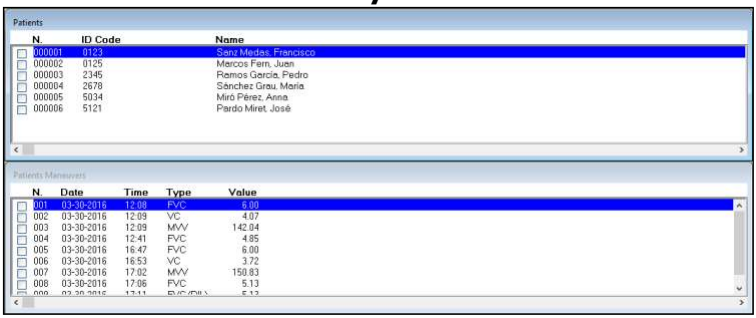
2.7.2 WINDOW ARRANGEMENT

Windows may be arranged by pulling any edge with the cursor or selecting the options available in the menu «Patients», like in the following pictures:

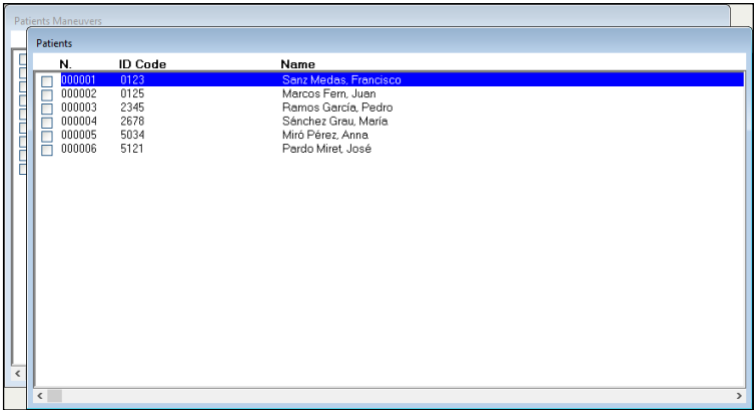
Tile windows vertically:



Tile windows horizontally:

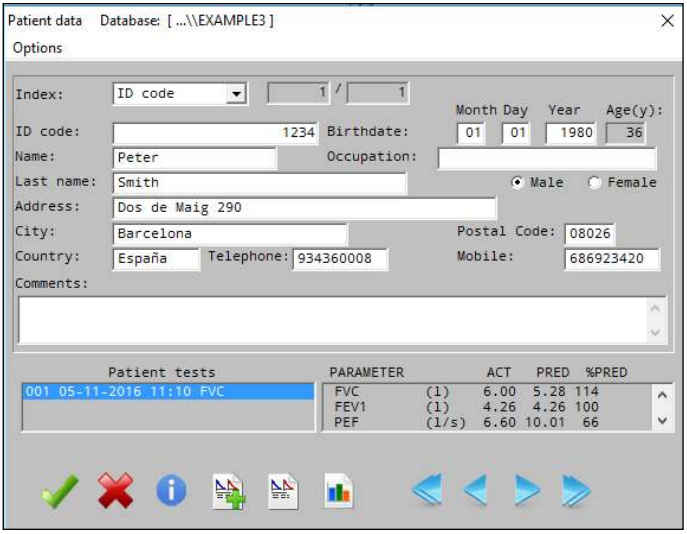


Cascade windows:



2.7.3 PATIENT DATA

Select **DATABASE – PATIENT DATA**
This screen allows to:



A – Open the window menu by selecting Options to:

- **NEW:** Enter a new patient
- **DELETE:** Delete a patient and all his corresponding tests
- **CONSULT:** Search a patient record.
- **TRENDS:** Shows a report of all selected tests of the patient.
- **EXPORT:** Opens the exporting module, to select tests of this patient, configure the export destination and export the tests with the format implied by the quotation marks.

The fields containing the patient's information are:

Field	**Type**	**Nr. Characters**
Reference	A/N	10
Date of Birth	N	8 (dd/mm/yyyy)
Name	A/N	20

Surname	A/N	38
Profession	A/N	20
Sex		
Address	A/N	50
City	A/N	30
Postal Code	A/N	5
Country	A/N	11
Telephone	A/N	10
Mobile	A/N	10
Comments (5 lines)	A/N	74 x 5

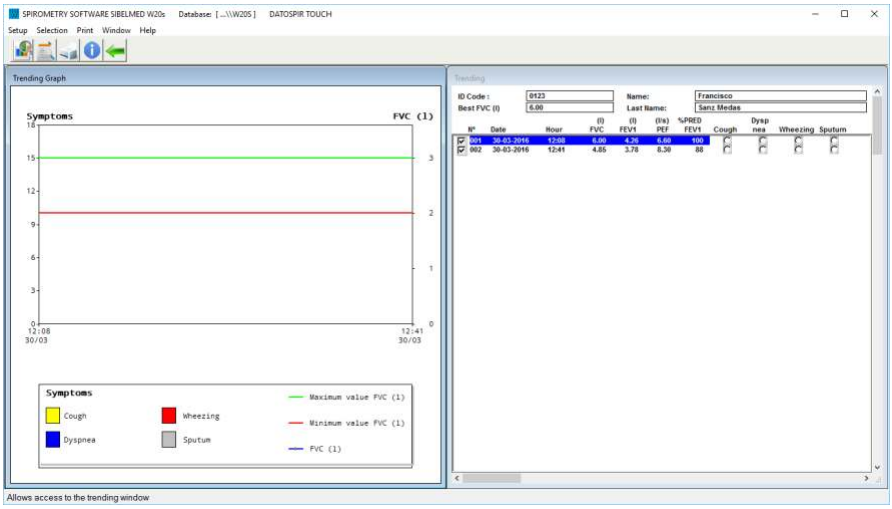
A/N = Alphanumeric Field
N = Numeric Field
Date format: dd= 01, 02 ..... 09, 10 ...
mm= 01,02 ..... 09, 10, 11, 12.
yyyy= 1998

B - Display in **Tests** the different tests of a patient with the most important parameters. In order to display all the **Test Data**, there are two ways: one is to choose the test **(selecting it in the list of tests of the patient card)** and double click on it. The other way consists of choosing the test and clicking the button **Tests** in the Patient Record dialog.

C - Search a patient already existent in the database. For this purpose, order the base through the **INDEX** by:
- Reference
- Surname
- Nr. of Record

Next, use the **CONSULT** option in the menu and enter the information corresponding to the patient being searched. It is also possible to navigate through the patient records with the buttons **slow advance** (record by record) and **fast advance** (by 10 records). The dialog shows the total number of patients in the base and the number of the selected one.

When clicking the button **TRENDS,** the next screen appears:



In this window all the patient tests **FVC** are displayed, in order to make a report of the trend for parameters **FVC, FEV1, PEF and its variability**.

The following options are presented:

Setup: this option is used to **setup the printer type**, and the display parameters.

Selection: use this option to select a test to include it in the trends report. It is possible to mark all the tests or one by one.

In order to select a group in a quick way, follow these steps: Mark the first test of the group and then with the **Shift** key pressed, choose the last test of the group with the mouse (by doing this, the group will be selected).

It is also possible to add tests, for this purpose press the **Control** key and select one by one with the mouse.

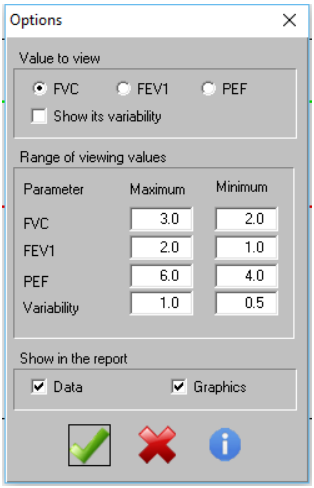
Print: prints a report in the printer.
Window: allows organizing the windows automatically.
Help: show the help file.

In the **Trending Graph** symptoms of each test may be displayed as overlapped areas and the numeric values of the selected parameter in the X and Y axis.

The warnings are represented with a color code indicating its severity. These codes are the following:

White	Nothing (No symptom)
Green	Low
Yellow	Medium
Red	High

When clicking on **Viewing Parameters** in the **Setup** menu, the next dialog appears:



In this window it is possible to set up the maximum and minimum values for each parameter appearing in the trends report. These parameters are the following: **FVC, FEV1,**

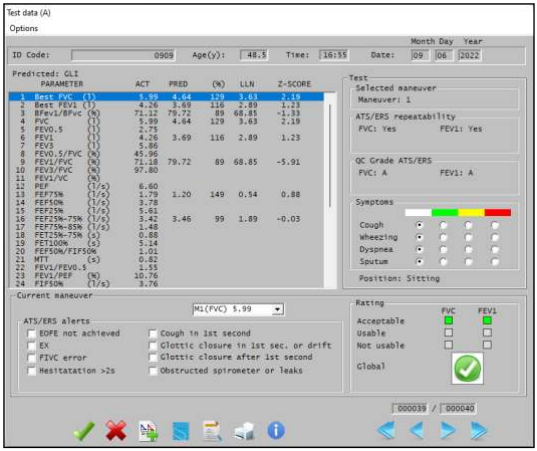
PEF and the Variability of each.
For each parameter a range of values is defined (maximum and minimum). These values are represented in the graph with green and red lines in order to identify clearly when these limits are surpassed. The variability graph is represented through variation percentage for the selected parameter between A.M. and P.M. The calculation of the variability value is defined in this way: **100 * (A.M. Value - P.M. Value) / A.M. Value.**

The tests being made from 0h until 12:00h are considered to be performed during the A.M. and the ones being made from 12:00h up to 0h are considered to be performed during the P.M.

Use the option **Show in the report** to select whether numeric data, graphs or both will be displayed simultaneously in the report.

2.7.4 TEST DATA

This screen presents the Test Data performed to the patient in the date and time indicated in the same window.



The following options are allowed in the window's menu and the different buttons:

Delete: deletes all the information related to this test.

Test Data: presents the information related to the test.

Graphic: displays the graphic corresponding to the test.

Print: creates the report of the test.

Export: exports the test in the files PRUEBAS.CSV and GRAF001.CSV, by default in the folder C:\ESPWIN\TMP.

Preliminary View: shows a preliminary view of the report.

The screen also presents the following information:

- The Observed and Predicted values of the different parameters, as well as the %.

- The Quality Control alerts according to ATS/ERS or NLHEP criteria regarding the following:

ATS/ERS:
EOFE not achieved - none of the three indicators of the end of forced expiration have been reached.
EX - error at the start of the test (back-extrapolated volume).
FIVC error – Forced Inspiratory Capacity error.
Hesitation >2s – time between maximum inspiration and forced expiration.
Cough in 1st second – cough in the first second of expiration
Glottic closure in 1st sec. or drift – Glottic closure in 1st second of expiration or faulty zero-flow setting.
Glottic closure after 1st second - Glottic closure after 1st second of expiration
Obstructed spirometer or leaks – Obstructed mouthpiece or spirometer, leaks.

NLHEP:
ET – End of Test
EX - Start of test.
PEFT - Time to reach Peak Expiratory Flow.

- Selected Maneuver: indicates the best maneuver automatically selected by the software or selected by the technician.

- Repeatability ATS/ERS: indicates the fulfillment of the repeatability criteria for FVC and FEV1.

- Quality Grade (ATS/ERS or NLHEP): indicates the quality grade of each test session. The QC Grades will be displayed when 2 or more maneuvers are performed during the test session. If the ATS/ERS is selected, a separate grade for FVC and FEV1 is displayed. In case of a Bronchodilation test, the grades for the PRE and the POST sessions will be shown.

- Symptoms:

Shows whether the patient had cough, weezing, dyspnea or sputum during the test. Each of these symptoms can have the following values:

White No symptom
Green Mild symptom
Yellow Moderate symptom
Red Severe symptom

- Tests made to the same patient can be browsed by using the buttons **Next / Previous** (test by tests) or **Next 10 / Previous 10** (shift 10 tests).
- Indicates the patient's body position during the performance of FVC tests.
- Rating: indication of the acceptability criteria of FVC and FEV1 of the maneuver, as well as an overall assessment of the maneuver.

2.7.5 SELECTING PATIENTS AND TESTS

Use the checkboxes located in the left side of each patient and test to select them one by one. Select patients and tests in

order to delete or export them, as explained in the following sections.
You can also use the following options in the menu DATABASE to select patients and tests:

Mark All

If the Patient window is active, all the patients and their tests are selected.
If the Tests window is active, all the tests of the selected patient are selected.

Unmark All

If the patient window is active, all patients and tests are unmarked.
If the Tests window is active, all the tests of the selected patient are unmarked.

2.7.6 DELETING PATIENTS AND TESTS

Clicking with the mouse's right button on a patient or test will pop-up a menu with the option **Delete** which deletes the selected patient/s and/or test/s from the database.

This action cannot be undone. Please make sure you really want to delete the patient and its associated tests.

2.7.7 EXPORT TESTS IN CSV/XML/PDF FORMAT

Use this option to export the select tests and patients to different file formats:

- CSV: format delimited by quotes, files with CSV extension. The information of the generated files are fields between inverted comas, separated by a semicolon: (...);»17/02/1999";»08:21";»24";»56";»165";»0 Woman»;»1SEPAR»; (...)

The file structure is a table with the same number of columns for each line. Each line represents a maneuver within a test. FVC, VC and MVV tests always store 8 maneuvers for every test. Bronchodilation tests store 16 maneuvers (8 pre-bronchodilator maneuvers and 8 post-bronchodilator maneuvers). Maximal pressure tests store 2 maneuvers for every test. Bronchoconstriction tests store 14 maneuvers for every test.
The first record is reserved for the name of the fields.
There are two fields in the PRUEBAS.CSV file, «Graph file» and «Graph Column», which enable to associate the dots of the graphic pressure-time to the test. For example, if File Graphic=1 and Graphic Column=23, the dots for the graphic for this record are located in the GRAF001.CSV, column 23.

- XML: data format formed by XML tags (<>), files with XML extension.
- PDF: test report saved in PDF format.

To start the export process:

1 Mark the tests to be exported as explained previously.

2 Select the menu option Database / Export tests / CSV – XML - PDF. The destination folder used by default by the program is TMP, which is to be located in the folder where the program was installed. In the case of CSV files data concerning the tests are stored in the file PRUEBAS.CSV, data related to patients are stored in the file PATIENT.CSV and the pressure graphs are stored in the files GRAF001.CSV, GRAF002.CSV, … If these files are already in the folder, they will be deleted and replaced by the new ones, including the exported tests.

3 Click Open to start the process. A dialog will appear showing the progress of the export process

2.7.8 EXPORT TESTS TO E-MAIL

Use this module to export tests to files with .CSV extension and text format delimited by quotation marks, and send them via email for use with other software programs.
In the main menu go to **Database / Export tests CSV format / Email**.

To perform the export:

1 Mark the tests to be sent.

2 Next, the email assistant installed in the computer will pop up, cerating a new message with the attached documents PRUEBAS, PATIENT and GRAFxxx, which contain the selected tests.

3 Introduce the address email and the desired information.

4 Press Send to transmit de mail.

2.7.9 TESTS IMPORT FROM A REMOTE HEALTHCARE CENTER

The export module in combination with the import module enables the browsing in the local examination room of the tests performed in a remote healthcare center. Both healthcare centers must have the spirometry software **SIBELMED W20s** available.
For that, after having made all the spirometric tests of maximal pressures, and / or pulse oximetry, the following steps must be performed:

EXPORT -> TRANSPORT -> IMPORT

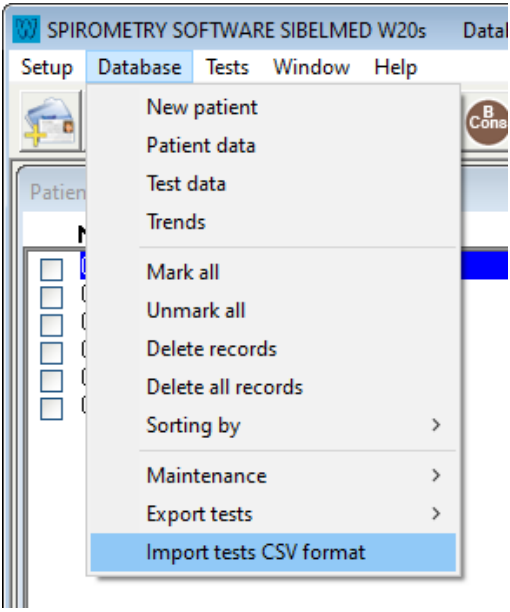
A. EXPORT: Use the option **Export tests - CSV** in the remote PC to store the tests to be explored in the local PC, as indicated in the previous paragraphs. The tests will be stored in the selected directory, in the files PRUEBAS.CSV,

PATIENT.CSV and GRAFxxx.CSV (usually GRAF001.CSV).

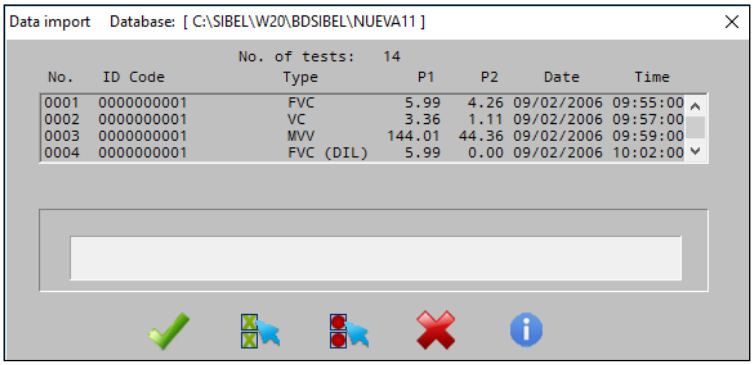
B. TRANSPORT: These files will be sent via e-mail or transferred through an interchangeable USB memory drive or portable hard disk to the other healthcare center.

C. IMPORT: Execute the CSV import process, as indicated below: Enter the option **Database /Import tests CSV format** in the main menu.

The following window appears:

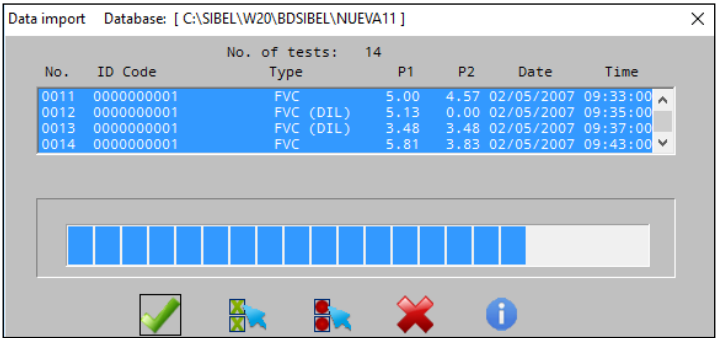


Choose the directory and the .csv file you want to import.
The following window appears:



Click with the mouse over the tests to be imported to the database of the spirometry software SIBELMED W20s, or click over the button **Select all** in order to select all the tests.

Click **OK**. The program will show the progression of the import process



2.7.10 ORDERING THE PATIENTS

Select the menu option «Database / Sort by» to order patients list by the selected criteria (register, surname, reference).

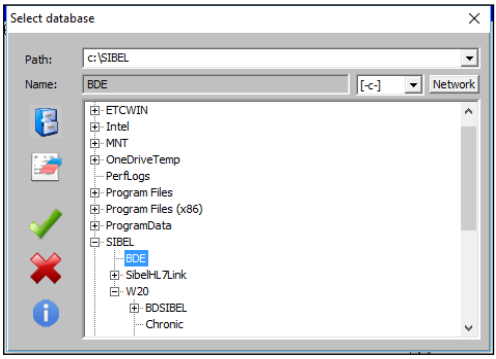
2.7.11 DATABASE MAINTENANCE

The **Maintenance** option included here is oriented only to the database and not to the device hardware. The information regarding the spirometer's database must be consulted in the corresponding chapter of the spirometer **User Manual.**

Select database

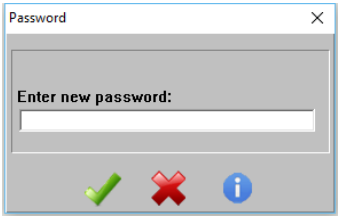
Use this option to create a new database or select an existing one.
The selected database may also be deleted by clicking the «Erase» button.

Deleting the database will erase all information about patients and its related tests. If you just want to delete one patient, or some of the tests use the Delete patient or Delete test options in the Database Window. This action cannot be undone. Please make sure you really want to delete the database before continuing.



Change password
To modify the password of a database, the working password must be introduced before pressing ENTER. Then, the system asks for the new password and its confirmation.
It is highly recommended that you set a database access key.

Assign a sufficiently complex password, including letters, numbers, upper and lower case. If you forget the password, contact the SIBEL S.A.U. After-Sales Service, who will explain the process to follow.

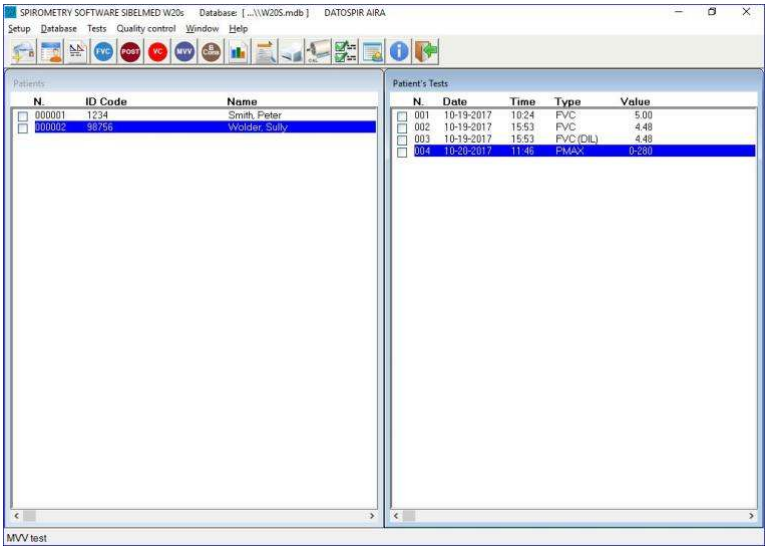


2.8 FORCED VITAL CAPACITY «FVC» TEST PROCEDURE

The procedures to be used for the spirometric test of **Forced Vital Capacity "FVC"**, **Slow Vital Capacity "VC" and** the **Maximum Voluntary Ventilation "MVV"**, as well as the **Postbronchodilation "POST"** mode are very similar. Only a detailed explanation of this procedure will be made in this section.

The use of bacterial filters is recommended for performing spirometric tests.

2.8.1.1 ENTERING PATIENT AND ENVIRONMENTAL DATA

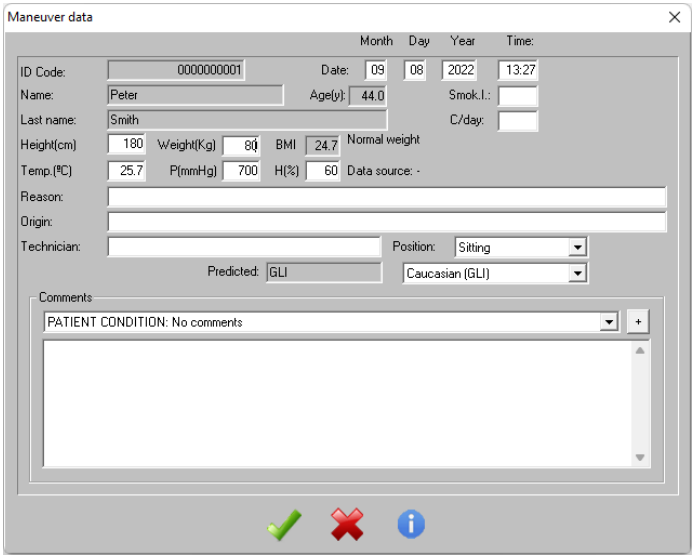


If the patient is not already in the database or if you want to search him by Reference or Surname then select the menu option DATABASE - NEW PATIENT or directly click the icon in the toolbar. Next, enter the number of Patient Reference to add a new patient to the database and the Reference or Surname if patient already exits.

In the first case, after pressing OK, the Patient Card appears which must be completed with the convenient data. At least the fields Reference, Date of Birth (the age is automatically calculated) and Sex must be filled, since they are needed for the calculation of the Spirometric Predicted Set.

Once the card is filled in, press OK.

Next, select the patient in the database and click the icon «FVC» in the toolbar or select the menu option TESTS - FVC. A new window with the test data will be shown.



When performing a spirometric test it is necessary to enter certain data related to the patient, to the environment or others that vary from one test to another.

Among them, we point out:

- **Date** and **time** of test performance

- **Smoker Ind.** (Smoker Index) Between 0 and 200

It is equal to the number of cigarettes smoked in one day divided by 20 and multiplied by the number of years as a smoker

(Cigarettes day x years as a smoker/20)

- **Cigar/d:** Cigarettes per day (to calculate the Lung's Age)

- **Age** in **years**, it is automatically calculated from the birth date of the patient.

- **Height** in **Inch** / **cm** between 20 and 90 Inch / 50 and 230 cm.

 **Patient data affect the predicted values and diagnosis, so make sure data are correct.**

- **Weight** in **Pound** / **Kg** between 22 and 440 Pound / 10 and 200 Kg.

- **Temperature** in the room in Cº

- **Pressure** in hPa / mmHg

- **Humidity** in the environment, in % (These last three values are automatically taken from the Sibelmed USB Weather Station if it is connected to the PC. Otherwise, the software obtains the data from the spirometer weather station if it is equipped with it).

 **Environmental conditions affect the BTPS factor and the calculation of the volume, make sure data are correct.**

There are other fields like:

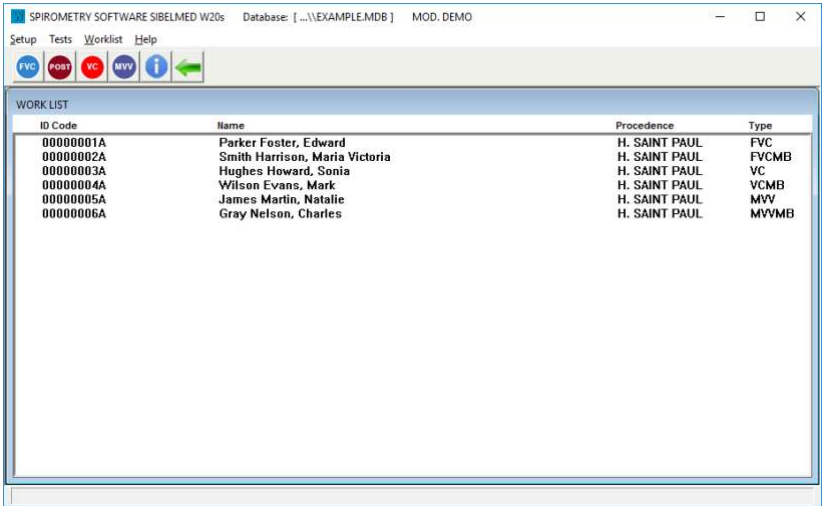
- **Motive** or cause for performing this test
- **Precedence** or centre, department, doctor, etc. where the patient comes from
- **Technician** who makes the test
- **Patient's body position** during the test (only available if the NIOSH mode is active)
- **Ethnic Factor** and **Theoretic Values** used in the test
- **Comments** on the test. Enter your own comments by hand or select predefined phrases from the list and add them to the

comments field. Default phrases are defined in the text file "Comments\comments_en.txt". Each line added to this file appears as a new option in the list of predefined comments.

2.8.1.2 ENTERING THE PATIENT AND ENVIRONMENTAL PARAMETERS THROUGH WORK LIST

If the W20sLink option has been purchased and **SibelHL7link** or **External Bridge Application** is selected in the **Interoperability** menu, it is not necessary to enter patient data to initiate spirometry tests, since they are included in the work list that is imported from the external Information System (HIS).

Click the «Work list» icon in the toolbar and the work list screen will be displayed:

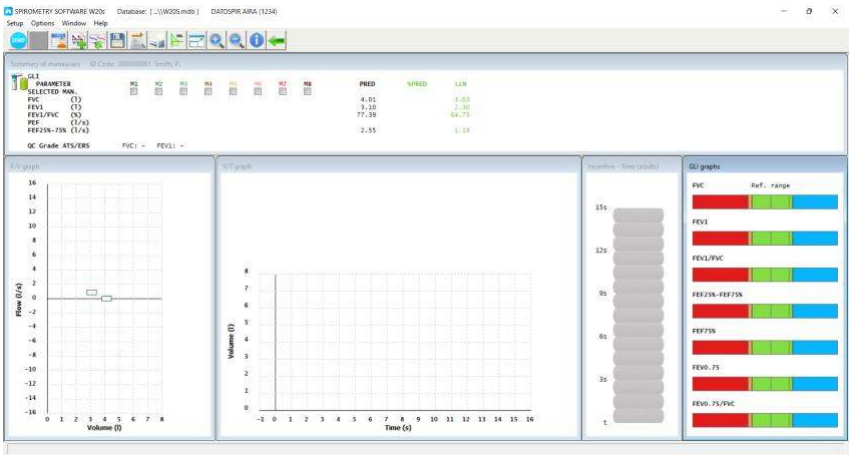


This list shows the data of scheduled patients to perform spirometry tests (ID Code, Name, Origin, Type of Test and Hour of the test). To select a patient you must simply double click on it. Then, the test data tab is displayed, enabling the

modification of any parameter. After clicking the OK button the test is automatically started.

Every demanded test in the work list must be generated from the external Information System (HIS). Then, **SibelHL7link** or the **External Bridge Application** are responsible for transferring the work list to the W20s.

2.8.2 ENTERING FORCED VITAL CAPACITY TESTS



This screen is the essential core where the spirometric maneuvers are performed. In this case, the window includes the Flow/Volume and Volume/Time graphs, the incentive and the GLI graphs**.** The user can select another configuration in **SETUP – PARAMETERS AND OTHERS - GRAPHS AND INCENTIVE**.

If the graph windows are not adjusted to the size of the general window or if they are not organized, click on WINDOW - MOSAIC to the let the program automatically resize them.

In this screen the following parts or windows can be pointed out:

MENUS AND TOOLBAR ICONS

The **SETUP** menu allows to:

Spirometry

Graphs and incentive (Check SETUP / GRAPHS AND INCENTIVE)

Parameters and references (Check SETUP / PARAMETERS AND REFERENCES)

Transducer code 
This option is enabled when using a disposable transducer.

Show NLHEP analysis

Units

Report header

Printer Selection (Check SETUP / PRINTER SELECTION)

Return 

The **OPTIONS** menu allows to:

Maneuver start/finish 
When activating this option, the device is ready to start the spirometric maneuver.

Patient Data 
Opens the Patient Data dialog window.

Test data 
Opens the Test Data window with some patient data, environmental data or other data related to the test being performed.

Maneuver data 
Allows to:

- Display the available information of the performed maneuvers
- Save the maneuvers to the database
- Delete a maneuver
- Create a report based on the maneuver data
- Present the diagnosis

Save test 
Saves the test to the database.

Report preview 
Opens the report preview window.

Report 
Creates a report corresponding to the selected maneuver in the **Maneuver Data** window.

Graphic selection 
This option opens a window to select the visibility of the graphs of the performed maneuvers. The asterisks indicate the position taken by the last maneuver.

Auto scale 
When activating this option, axes of the graphs adjust their dimensions, without losing the relation 2 l/s, they are equal to 1 l in the F/V graph and 1 l is equal to 2 s in the V/T graph and only in FVC mode.

Zoom +  **and -** 
Enlarges or reduces the graphs while maintaining the relations previously indicated.

The **WINDOW** menu allows to:

Mosaic
This option allows the user to organize the different windows and fill the whole main window. The user can adjust the sizes

manually by using the mouse and moving any side or edge of a window.

The **HELP** menu has the following options:
About the software
Visit SIBEL S.A.U. web site
About

MANEUVERS SUMMARY WINDOW

Forced Vital Capacity Mode
While performing the FVC test the following parameters are shown in this window: the predicted set being used, FVC, FEV1, FEV1/FVC PEF and FEF25%-75% of the eight best performed maneuvers (M1-M8), the best values according to ATS criteria (green color), the predicted value, the percentage difference of the best values according to the predicted value and the low limit of normal value. In POST bronchodilation mode the predicted values are changed by the ones obtained in PRE bronchodilation mode.

The ATS / ERS or NLHEP quality grade is shown below the parameters if the corresponding option is selected in the PARAMETERS AND PREDICTED dialog box.

The maneuvers are ordered from best M1 to worst M8, according to the ATS criteria of the maximum addition of FVC+FEV1 and according to the detected errors in each maneuver.
The labels M1-M8 indicate the color for the associated graphic. The square brackets (e.g. [M3]) indicate the position taken by the last performed maneuver. The curve corresponding to the last performed maneuver is drawn in grey in the graph.

Click the left mouse button on the parameters of any of the maneuvers to show / hide the graph of the maneuver on the charts. Click the right mouse button to directly open the window "Maneuvers data" for the maneuver on which the click was made.

Finally, the best maneuver (by default always labeled as M1) is that with the check mark in row " SELECTED MAN." activated. If you want to select any other maneuver as the best one then check the box corresponding to the desired maneuver.

Slow Vital Capacity Mode
The following parameters are displayed in VC tests: VC, VT and ERV.

Maximum Voluntary Ventilation Mode
The following parameters are displayed in MVV tests: MVV and Br/min.

If working with the DATOSPIR AIRA spirometer, you can find an indication of the battery level in the top left of the Summary window:


High level


Medium level


Low level


Not available

GRAPHS

Presents the graphic windows selected in the menu **SETUP – SPIROMETRY - GRAPHS AND INCENTIVE**.

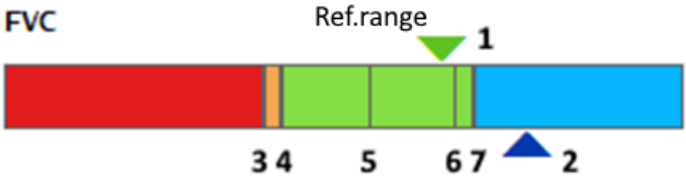
The squares shown in the **F/V** graph are equal to the patient predicted values for the parameters **FVC, FEF75%, FEF50%, FEF25%** and **PEF**. These indications only appear if the predicted values exist. The **PEF** is placed at 10% of the FVC reference volume.

INCENTIVES

The incentive is a graphic possibility useful for motivating children and adults during the performance of **FVC** spirometric maneuvers. This option can be activated or deactivated by entering **SETUP – ESPIROMETRY - GRAPHS AND INCENTIVE,** as well as selecting among different incentive pictures and a sound warning.

GLI GRAPHS

This window is shown when the GLI predicted sets are selected and the corresponding option is enabled in **SETUP - SPIROMETRY – GRAPHS AND INCENTIVE**. The window shows a bar for each selected parameter with the following information:



1. PRE value
2. POST value
3. Z-SCORE -2
4. LLN
5. Reference value
6. ULN
7. Z-SCORE +2

TEST EXECUTION

It is desirable that the technician performing the forced spirometry tests knows the usual procedure required for the patient to properly perform them. If not, he/she should review any related documentation.

In the performance of the spirometry, the following steps must be taken into account:

1 Verify that the spirometer is connected to the computer and setup correctly.

2 Train the patient about the performance of the test, since his cooperation is essential for proper execution.

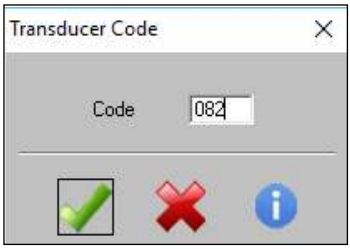
ATS/ERS divides the spirometric maneuver into four distinct phases: maximal inspiration, a "blast" of expiration, continued complete expiration for a maximum of 15 seconds, and inspiration at maximal flow back to maximum lung volume.

3 Indicate the patient the most convenient way of taking the transducer without obstructing the air passing through when making the spirometric maneuver and put him the nasal tweezers.

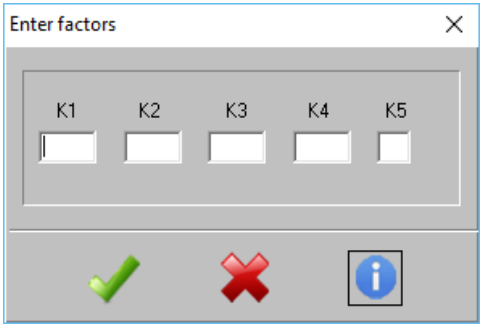
4 Ask the patient to start the maneuver (Datospir Aira and Datospir Touch) or click on the START icon (Datospir Micro). In the case of the Datapir Micro, the patient has 30 seconds to start the forced maneuver.

Just before pressing the START icon, and only when the transducer connected to the equipment is a disposable one, the TRANSDUCER ICON is enabled to change the disposable transducer code.

This button opens a window where the transducer code should be entered:

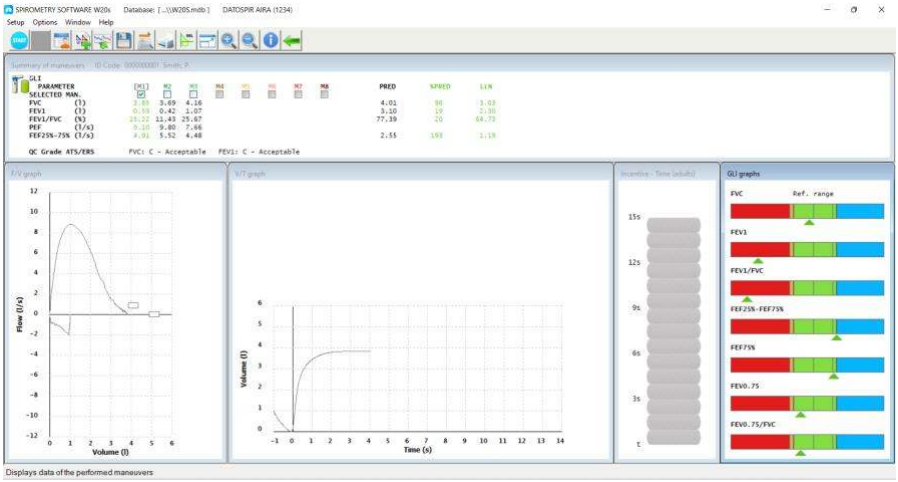


This code will be applied by the equipment, and will always appear in the title line of the results summary window. It is also possible to modify this code through the Transducer Code option in the Setup menu. This code must be entered only once while the code of the disposable transducers remains the same. If the lot is not yet added to the program, the next window will appear to enter the K values:



5 The program indicates the end of forced expiration with a single acoustic signal if the respiratory plateau is reached (<0.025L in the last second) or with a double acoustic signal if forced expiration is maintained for 15 seconds.

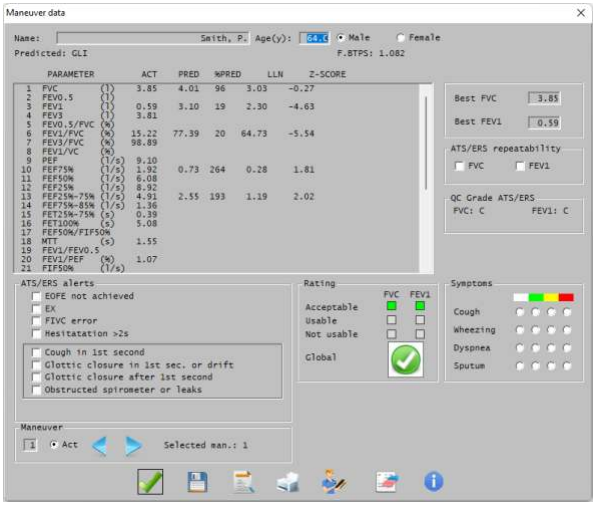
6 After performing the first spirometric maneuver, the patient can perform as many maneuvers as the technician deems appropriate, although a minimum of three acceptable FVC and FEV1 measurements is recommended."



2.8.3 MANEUVER DATA

After having performed, at least, one spirometric maneuver, the resulting data can be consulted in the Maneuver Data window through **OPTIONS - MANEUVER DATA** (MANEUVER DATA Icon). This window presents all the information related to each performed maneuver. A * is added to REF when the predicted values have been extrapolated and in the report appears the text: «Warning: Reference values extrapolated!». In a similar way if the low limit of normal value is not available in the selected predicted set the message «Warning: LLN = 80%» is also shown, indicating that the LLN value will be calculated as the 80% of the predicted value.

The following data are available in this window:



PARAMETERS

The list presents all the parameters selected in Setup / Spirometry / Parameters and predicted, together with the actual measured values (ACT), the predicted values (PRED), the percentage of the predicted value (ACT/PRED) (%) and the lower limit of normal values (LLN) of the current maneuver. During a Postbronchodilation test, the following columns appear:

- **PRE.** - Prebronchodilation value of the best or the best 3 maneuvers performed (depending on the option selected on Setup / Spirometry / Graphs and Incentive).
- **PRED** - Predicted value.
- **(%)** - Percentage of the predicted value (ACT/PRED).
- **LLN** - Lower limit of normal of the predicted value.
- **Z-SCORE** – Z-score value.
- **POST** - Postbronchodilation value.
- **(%M)** – Average percentage between POST/PRE or other according to Setup / Spirometry / Parameters and predicteds.

- **%PRED** - Percentage of POST vs PRED value. This column appears depending on the configuration of the previous parameter.

ATS/ERS ALERTS
For each maneuver, the ATS/ERS criteria that are not fulfilled are indicated:

EOFE not achieved: End of Forced Expiration; when there is no plateau, FET< 15 s and FVC is out of the repeatability tolerance.
EX: the start of the maneuver does not meet the volume criteria based on back extrapolation.
FIVC error: If there is inspiration after the EOFE this warning indicates a significant difference between the forced expiration and the forced inspiration.
Hesitation >2s: Time between maximum inspiration and forced expiration is greater than two seconds.
Cough in 1st second: Cough in the first second of expiration. This warning must be manually marked by the user.
Glottic clossure in 1st sec. or drift: Glottic closure in the first second of expiration or faulty zero-flow setting. This warning must be manually marked by the user.
Glottic clossure after 1st second: Glottic closure after the first second of expiration. This warning must be manually marked by the user.
Obstructed spirometer or leaks: Includes evidence of obstructed mouthpiece or spirometer; or air leakage. This warning must be manually marked by the user when any of these situations occur during the test.

For a complete description of these alerts, consult section QUALITY OF FVC TEST in the TECHNICAL SPECIFICATIONS chapter.

NLHEP ALERTS
For each maneuver, the NLHEP criteria that **are not fulfilled** are indicated:

- **ET** – End of Test; based on the EOTV and FET criteria (the user can change the status of the FET criterion if he/she considers that the patient has tried to exhale for a longer period than the criterion).
- **PEFT** – Time to reach the PEF.
- **EX** – Start of test based on back extrapolation.

For a complete description of these alerts, consult section QUALITY OF FVC TEST in the TECHNICAL SPECIFICATIONS chapter.

RATING
Indication of the acceptability criteria of FVC and FEV1 of the maneuver, as well as an overall assessment.

MANEUVER
Shows the number of the maneuver being displayed on screen. Any of the available maneuvers can be displayed up to a maximum of eight. The order of the maneuvers is presented according to **ATS/ERS** or **NLHEP** criteria (depending on what is selected in **Setup / Spirometry / Parameters and predicteds**). It is based on the errors of each maneuver and on the **highest value of FVC+FEV1,** being number 1 (best maneuver) the maneuver with less errors and/or highest addition, and number 8 (worst maneuver), the one with more errors and/or lowest addition.
«Last» option will be automatically checked if the one being displayed is the last performed maneuver. «Selected man.» shows the maneuver selected by the technician as the best one (M1 by default if the technician has not selected any one).

BEST
Shows the highest FVC and FEV1 values from those maneuvers with an acceptable start (without EX alert).

REPEATABILITY ATS/ERS
If three or more **acceptable** maneuvers have been performed, the repeatability criteria for FVC or FEV1 parameters in patients **over 6 years** is indicated if the difference between

the **two largest values of FVC or FEV1** (from maneuvers with an acceptable start, without EX alert) **are within 150 ml**. In patients **6 years of age or less** the criterion is **100 ml or 10% of the highest value**, whichever is greater. If there are no maneuvers with an acceptable start, the ATS / ERS repeatability criteria are not met.

SYMPTOMS
Allows noting down events like cough, wheezing, dyspnea or sputum that the patient may experience during the test. Each of these symptoms can have the following values:
White No symptom
Green Mild symptom
Yellow Moderate symptom
Red Severe symptom

QC GRADES
Shows the quality control grade for each test sessions according to ATS/ERS o NLHEP criteria, depending on the selection in **Setup / Spirometry / Parameters and predicted**. For ATS/ERS criteria, separate grades for FVC and FEV1 are displayed. Besides the previously said, the following can be made from this screen:

SAVE
Saves the test in the database and marks as selected maneuver by the technician, the maneuver that is being displayed in this window.

PREVIEW REPORT
Shows the preview report of the maneuver displayed in this window.

INFORME
Creates the report of the maneuver displayed in this window.

DIAGNOSIS
Presents the diagnosis of the selected maneuver. The type of diagnosis can be selected in **SETUP - PARAMETERS AND**

OTHERS - SPIROMETRY.

DELETE
Deletes the selected maneuver.

2.8.4 PRINTING THE REPORT

It is possible to make a report of any maneuver performed. This option is found in the Maneuver Data window, in the MANEUVER DATA section.
It is also possible to print a general, grouped report with the different spirometric tests made to a patient in a certain session. This option is accessible through the Printer Icon.

SIBEL S.A.U.
Rosellón 500, bajos
08026, Barcelona

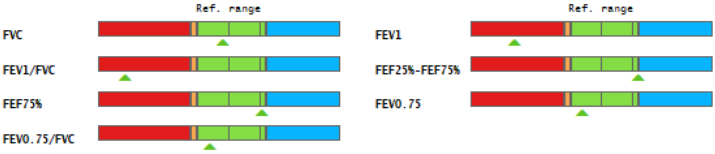
ID Code: 0000000001 Date: 08-09-2022 Time: 14:36
Name: Smith Peter
Sex: Male Age(y): 64.0 Height(cm): 170.0 Wgt(Kg): 70.0
Temp(°C): 27.2 Pres(mmHg): 700 Humidity(%): 60 Smok.I.: BMI : 24.2
Reason:
Origin:
Technician: Transducer: Turbine
Predicted: GLI (Caucasian (GLI))
LastCalibration: 09-02-2022 09:45
F.BTPS: 1.082
Position: Sitting Version: 511-BLA-3.01

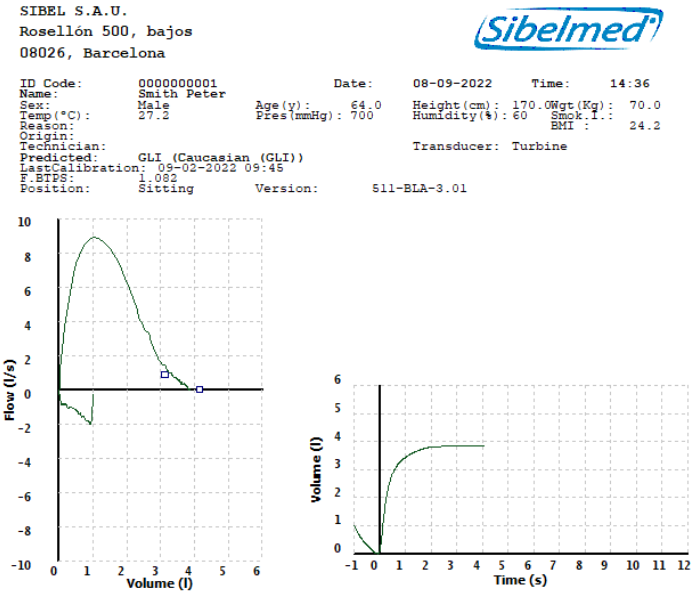
FVC REPORT **Maneuver No.: 1**

PARAMETER		ACT	(%)	PRED	LLN	Z-SCORE
Best FVC	(l)	3.85	96	4.01	3.03	-0.27
Best FEV1	(l)	0.59	19	3.10	2.30	-4.63
BFev1/BFvc	(%)	15.22	20	77.39	64.73	-5.54
FVC	(l)	3.85	96	4.01	3.03	-0.27
FEV0.5	(l)					
FEV1	(l)	0.59	19	3.10	2.30	-4.63
FEV3	(l)	3.81				
FEV0.5/FVC	(%)					
FEV1/FVC	(%)	15.22	20	77.39	64.73	-5.54
FEV3/FVC	(%)	98.89				
FEV1/VC	(%)					
PEF	(l/s)	9.10				
FEF75%	(l/s)	1.92	264	0.73	0.28	1.81
FEF50%	(l/s)	6.08				
FEF25%	(l/s)	8.92				
FEF25%-75%	(l/s)	4.91	193	2.55	1.19	2.02
FEF75%-85%	(l/s)	1.36				
FET25%-75%	(s)	0.39				
FET100%	(s)	5.08				
FEF50%/FIF50%						
MTT	(s)	1.55				
FEV1/FEV0.5						
FEV1/PEF	(%)	1.07				
FIF50%	(l/s)					
FIVC	(l)					
FIV1	(l)					
FIV1/FIVC	(%)					
FEV1/FIV1	(%)					
PIF	(l/s)					
PEF/PIF						
Vext.	(l)	0.15				
MVV ind	(l/min)	17.59				
FEV6	(l)	3.85				
FEV1/FEV6	(%)	15.22				
COPD index	(%)	100.00				
Lung Age		134.39				
FEV0.75	(l)					
FEV0.75/FVC	(%)					

Hesitation t (s) 0.07
QC Grade ATS/ERS: FVC: C, FEV1: C
ATS/ERS repeatability: FVC: No, FEV1: No

Interpretation: ATS/ERS
NORMAL





The report format of those FVC tests performed in NIOSH mode is slightly different and fits the needs of NIOSH.

Report: It allows printing the report.

Forward / Backward: It allows advancing or moving back through the report to visualize each one of its sheets.

Help: It allows entering to the preliminary view help.

Return: It allows getting back to the previous screen.

2.9 SLOW VITAL CAPACITY «VC» TEST PROCEDURE

The procedure to perform the slow Vital Capacity test is similar to the one described in the **FORCED VITAL CAPACITY "FVC" TEST PROCEDURE** section but with the following variations:

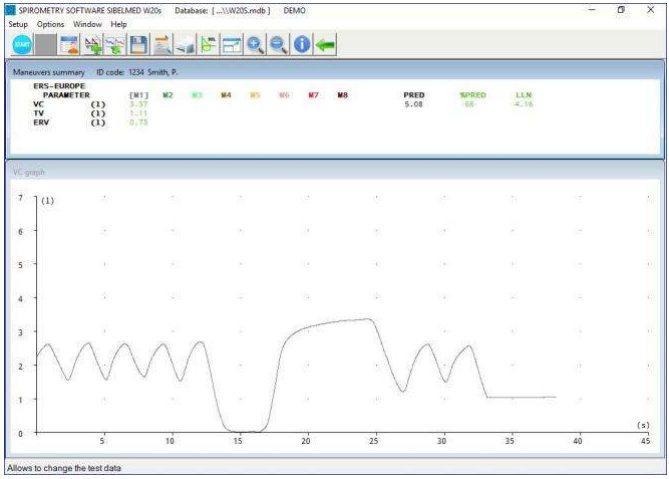
1 Select the patient in the database or create a new one as described previously, then click the button **VC**.

2 Train the patient about the performance of this kind of test, as his collaboration is essential for its correct execution.

3 The maximum time to make the maneuver is 60 seconds. The device stores a maximum of eight ordered maneuvers according to VC value and being M1 the one of highest VC and M8 the one of lowest.

4 The maneuver begins with the patient breathing normally. When a stable tidal volume is achieved, the program emits a simple acoustic signal, at which point the patient must either a) take a deep breath to TLC with no hesitation and expire to RV or b) breathe all the way out to RV and then take a deep breath in to TLC. The program emits a double acoustic signal when a respiratory plateau is reached (<0.025L in the last second) or expiration is maintained for 15 seconds. The maneuver ends with a normal breath.

5 The graph is displayed in Volume/Time mode and the graphic incentive is not available.



6 The report with the parameters and graphics is displayed next.

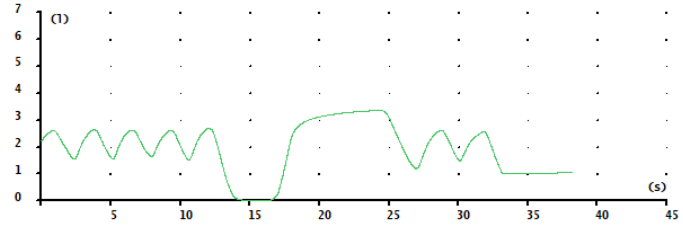
SIBEL S.A.U.
Rosellón 500, bajos
08026, Barcelona

ID Code:	0000000001		Date:	08-09-2022	Time:	14:57	
Name:	Smith Peter						
Sex:	Male	Age(y):	64.0	Height(cm):	170.0	Wgt(Kg):	70.0
Temp(°C):	27.2	Pres(mmHg):	700	Humidity(%):	60	Smok.i.:	
Reason:						BMI :	24.2
Origin:							
Technician:				Transducer:	Disk		
Predicted:	GLI (Caucasian (GLI))						
F.BTPS:	1.082						
Position:	Sitting	Version:	511-BLA-3.01				

VC REPORT Maneuver No.: 3

PARAMETER		ACT	(%)	PRED	LLN	Z-SCORE
VC	(l)	3.37				
TV	(l)	1.11				
ERV	(l)	0.73				
IRV	(l)	1.54				
IC	(l)	2.64				
Ti	(s)	1.65				
Te	(s)	2.58				
Tt	(s)	4.43				
Ti / Tt	(%)	41.69				

ATS/ERS repeatability: VC: No



2.10 MAXIMUM VOLUNTARY VENTILATION «MVV» TEST PROCEDURE

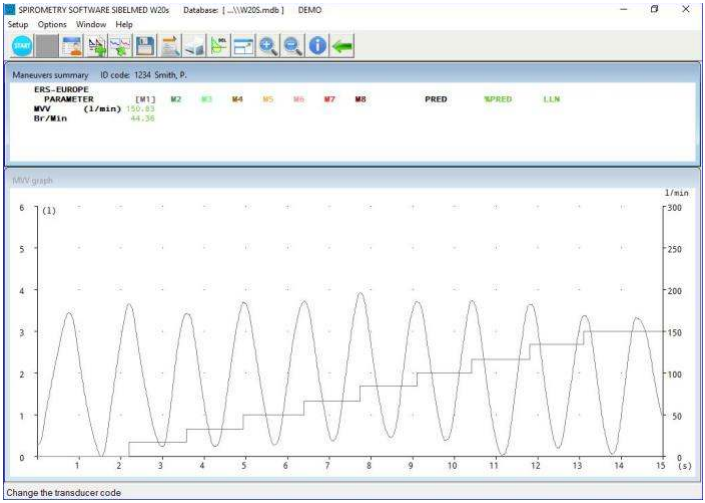
The procedure to make the test of Maximum Voluntary Ventilation "MVV" is similar to the one described in the **FORCED VITAL CAPACITY "FVC" TEST PROCEDURE** section but with the following variations:

1 Select the patient in the database or create a new one as described previously, then click the button **MVV**.

2 Train the patient about the performance of this kind of test, as his collaboration is essential for its correct execution.

3 In the database select the test that will be used as Prebronchodilation and click the button POST.
When saving a PRE maneuver when using the disposable transducer, it also saves the Transducer Calibration Code and it is recovered in the POST maneuver.

4 The graph is represented in Volume/Time mode and no graphic incentive is available.



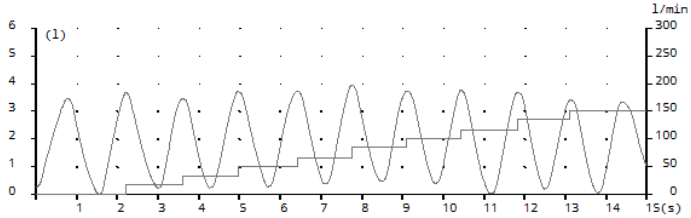
5 The report with the parameters and graphics is displayed next:

SIBEL S.A.U.
SIBEL S.A.U.
SIBEL S.A.U.

ID Code:	0123	Date:	30-03-2016	Time:	17:02
Name:	Sanz Medas Francisco				
Sex:	Male	Age(y): 40	Height(cm): 180	Wgt(Kg):	80
Temp(°C):	24	Pres(mmHg): 760	Humidity(%): 60	Smok.I.:	
Reason:				BMI :	24.7
Procedence:					
Technician:			Transducer: Disk		
Predicted:	ERS-EUROPE		Ethnic F.: 100		
F.BTPS:	1.093				
Version:	511-BLA-2.00				

MVV REPORT Maneuver No.: 1

PARAMETER	ACT	(%)	PRED	LLN
MVV (l/min)	150.83			
Br/Min	44.36			



2.11 BRONCHODILATION TESTS

The **Spirometry Software SIBELMED W20s** offers the possibility of making Postbronchodilation tests in Forced Vital Capacity «FVC» mode, Slow Vital Capacity «VC» and Maximum Voluntary Ventilation «MVV».

The purpose of this operation mode is to have in the same report the spirometric results before (PRE) and after (POST) the application of a bronchodilator substance in order to compare them.

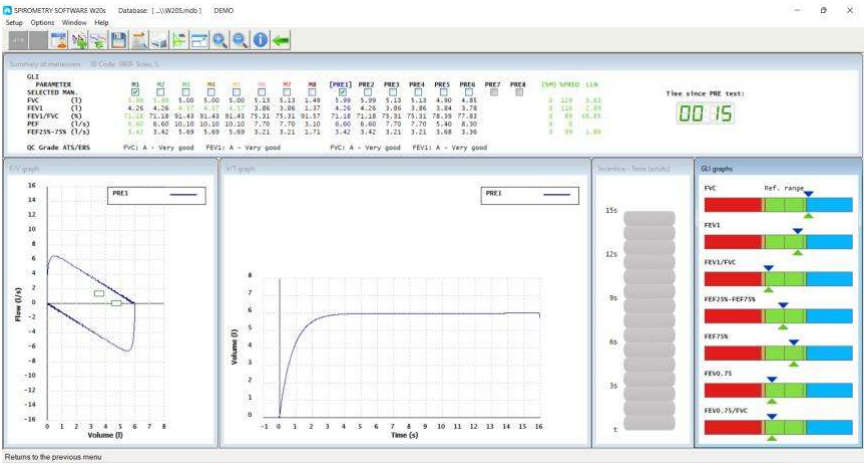
The procedure to make the Postbronchodilation Spirometry Test is the following:

1 Perform a «FVC», «VC» or «MVV» test, according to the previous sections.
Store the test as described in the section FVC PROCEDURE.

2 Apply to the patient the bronchodilator agent determined by the doctor. Tests made to other patients may be conducted while the bronchodilator effect takes place.

3 In the database select the test that will be used as Prebronchodilation and click the button **POST**."

4 Select the Prebronchodilation with which the POST data will be compared. Press **OK**.
When saving a PRE maneuver when using the disposable transducer, it also saves the Transducer Calibration Code and it is recovered in the POST maneuver.



5 If the printed report is required, data are represented in a similar way to this:

SIBEL S.A.U.
Rosellón 500, bajos
08026, Barcelona

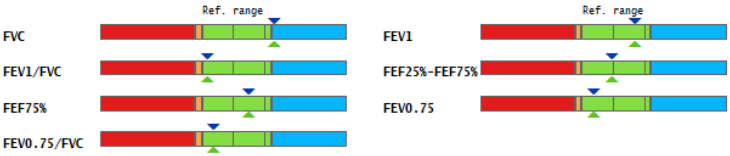
ID Code:	0909		Date:	06-09-2022	Time:	16:55	
Name:	Solas Samuel						
Sex:	Male	Age(y):	48.5	Height(cm):	172.0	Wgt(Kg):	74.0
Temp(°C):	23.0	Pres(mmHg):	700	Humidity(%):	60	Smok.i.:	
Reason:						BMI :	25.0
Origin:							
Technician:				Transducer:	Disk		
Predicted:	GLI (Caucasian (GLI))						
F.BTPS:	1.103						
Position:	Sitting	Version:	511-BLA-3.01				

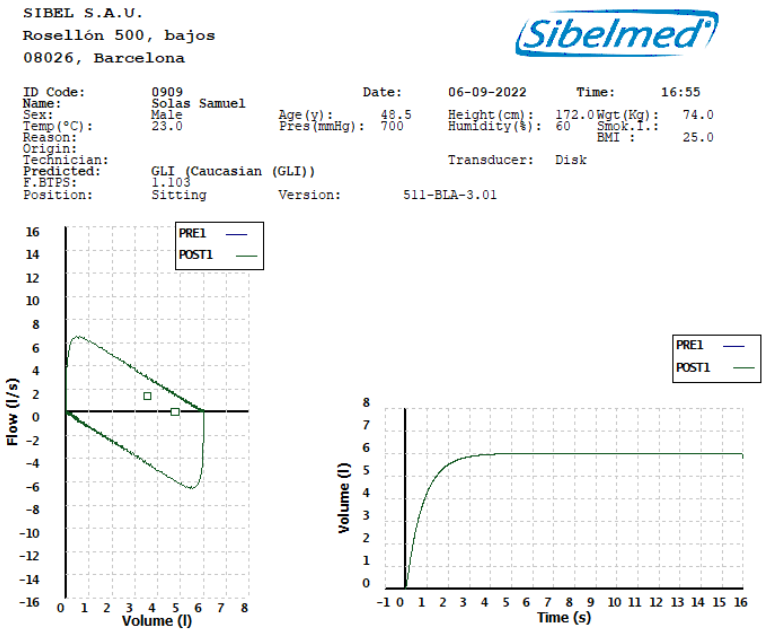
FVC REPORT **Maneuver No.: 1**

PARAMETER		PRE M.	PRE %PRED	PRED	LLN	Z-SCORE	POST M	POST (%M)	POST %PRED
Best FVC (1)		**5.99**	**129**	**4.64**	**3.63**	**2.19**	**5.99**	**0**	**129**
Best FEV1 (1)		**4.26**	**116**	**3.69**	**2.89**	**1.23**	**4.57**	**7**	**124**
BFev1/BFvc (%)		**71.12**	**89**	**79.72**	**68.85**	**-1.33**	**76.29**	**7**	**96**
FVC	(l)	5.99	129	4.64	3.63	2.19	5.99	0	129
FEV0.5	(l)	2.75					2.75	0	
FEV1	(l)	4.26	116	3.69	2.89	1.23	4.26	0	116
FEV3	(l)	5.86					5.86	0	
FEV0.5/FVC	(%)	45.96					45.96	0	
FEV1/FVC	(%)	71.18	89	79.72	68.85	-1.32	71.18	0	89
FEV3/FVC	(%)	97.80					97.80	0	
FEV1/VC	(%)								
PEF	(l/s)	6.60					6.60	0	
FEF75%	(l/s)	1.79	149	1.20	0.54	0.88	1.79	0	149
FEF50%	(l/s)	3.78					3.78	0	
FEF25%	(l/s)	5.61					5.61	0	
FEF25%-75%	(l/s)	3.42	99	3.46	1.89	-0.03	3.42	0	99
FEF75%-85%	(l/s)	1.48					1.48	0	
FET25%-75%	(s)	0.88					0.88	0	
FET100%	(s)	5.14					5.14	0	
FEF50%/FIF50%		1.01					1.01	0	
MTT	(s)	0.82					0.82	0	
FEV1/FEV0.5		1.55					1.55	0	
FEV1/PEF	(%)	10.76					10.76	0	
FIF50%	(l/s)	3.76					3.76	0	
FIVC	(l)	6.00					6.00	0	
FIV1	(l)	4.26					4.26	0	
FIV1/FIVC	(%)	71.09					71.09	0	
FEV1/FIV1	(%)	1.00					1.00	0	
PIF	(l/s)	6.50					6.50	0	
PEF/PIF		1.02					1.02	0	
Vext.	(l)	0.06					0.06	0	
MVV ind	(l/min)	127.86					127.86	0	
FEV6	(l)	5.99					5.99	0	
FEV1/FEV6	(%)	71.18					71.18	0	
COPD index	(%)								
Lung Age		21.79					21.79	0	
FEV0.75	(l)	3.62					3.62	0	
FEV0.75/FVC	(%)	60.50					60.50	0	
Hesitation t	(s)	0.03					0.03	0	

QC Grade ATS/ERS (PRE): FVC: A, FEV1: A
QC Grade ATS/ERS (POST): FVC: A, FEV1: A
ATS/ERS repeatability (PRE): FVC:Yes, FEV1:Yes
ATS/ERS repeatability (POST): FVC:Yes, FEV1:Yes

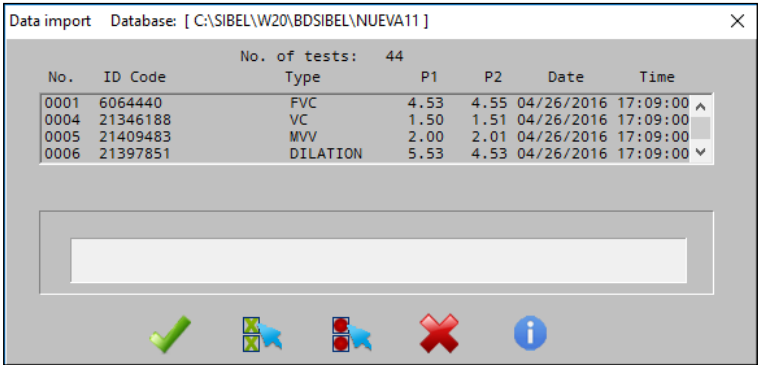
Interpretation: ATS/ERS
NORMAL
Post-BD: No significant response





2.12 IMPORTING TESTS FROM THE SPIROMETER

Click the button **Download spirometer data** or select the option in the menu **Database**



This option allows to transfer or import tests which are stored in the spirometer (**DATOSPIR TOUCH** or **DATOSPIR MICRO**) to the computer database.

The process to follow is this:

1 Connect the spirometer to the computer serial port.

2 Verify that the spirometer is turned on.

3 Select the tests to be transferred with the mouse if they are

4 Press the key **IMPORT** to transfer.

The screen presents the following information:

Nr	Number of test order
Reference	Corresponding to the patient
Type	Corresponding to the type of test, being: **FVC** Forced Vital Capacity **VC** Slow Vital Capacity **MVV** Maximum Voluntary Ventilation **Dilat** Postbronchodilation Test in FVC mode
P1 and P2	Parameters corresponding to:

	P1	**P2**
FVC	FVC	FEV1
VC	VC	VT
MVV	MVV	Breath/min
Dilat	FVC-pre	FVC-post

Date and Time	Performance of the test

Each test transfers all the available parameters. The two previously mentioned are approximate for the user.

The information transferred is stored in the operative **Database** at that moment and in each corresponding patient card. The XML and PDF files corresponding to each

downloaded test are also generated if the corresponding options is selected in the INTEROPERABILITY dialog.

2.13 CALIBRATION PROCEDURE IN THE DATOSPIR AIRA SPIROMETER

The Spirometry Software SIBELMED W20s does not include any calibration system, as this is performed from the linked spirometer, except while using with the DATOSPIR AIRA, as this device don't have an user interface and the calibration is done through this software.

COMMON REMARKS

As previously mentioned, the current standards for the spirometry recommend that all the spirometers must be calibrated periodically. This is due to the alterations which can modify the characteristics of the electronic circuits and mechanical elements, and produce a change in the spirometer calibration factors. For this reason, a calibration system has been integrated using a signal of reference volume (for example, a syringe).
Besides this calibration factor, the changes in volume associated to the weather conditions (temperature, relative humidity and pressure) must be taken into account. The most influential factor is the temperature, followed by the humidity degree.
DATOSPIR AIRA has a built-in Calibration Program, which in a quick and easy way (less than two minutes) verifies and self-corrects the deviations of the performed measurements. The periodicity of the calibration depends on the user criteria. SIBEL S.A.U., as the manufacturer, recommends, according to the different standards, a daily or weekly calibration.

TRANSDUCER TYPES

The **DATOSPIR AIRA** can work with three different transducer types:

- **Fleisch pneumotachometer**

- **Turbine transducer**
- **Disposable transducer**

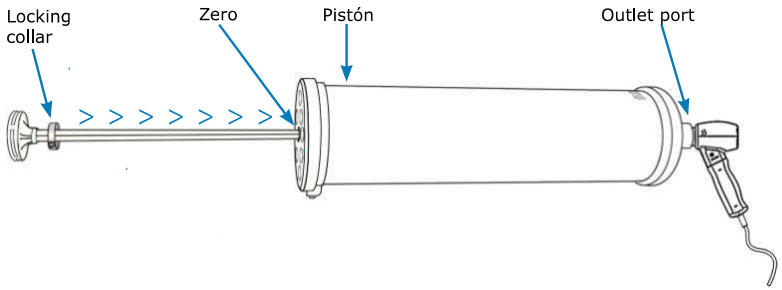
The Fleisch pneumotachometer is the flow measurement system with the highest acknowledgment in the pulmonary field due to its great reliability, reproducibility and duration.

The turbine transducer type is a system of good reliability and reproducibility. Its duration is limited to the use and care applied to the transducer.

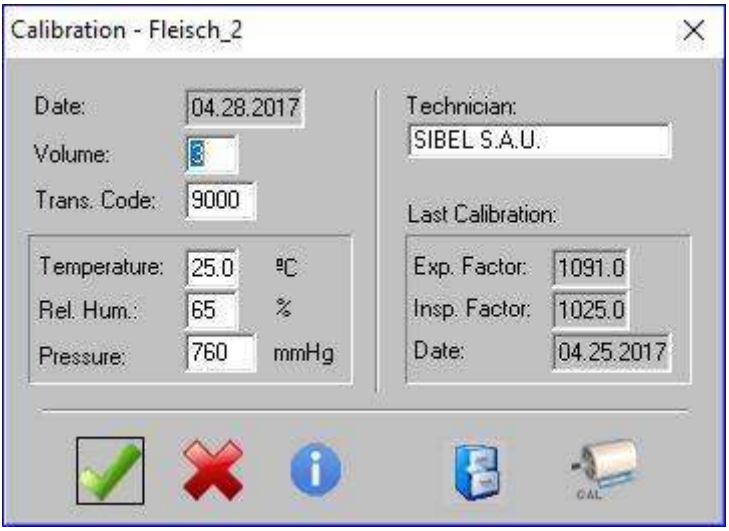
The disposable transducer type is a reliable element with good reproducibility. Its use is adequate in cases where it is necessary to avoid possible infections between patients, caused by undetected or not eradicated contaminations due to lack of cleanness in the used pneumotachometer or transducer.

CALIBRATION PROCEDURE

1 Connect the pneumotachometer or transducer to the syringe, according to the illustration. The Fleisch and turbine trabnsducers can be connected directly, while the disposable transducer needs the use of an adapter piece.



2 In the database window click on  or select the menú option **QUALITY CONTROL - CALIBRATION**.



OK	Exits the calibration updating the values.
Cancel	Exits the calibration without updating.
Help	Shows the help file.
Calibrate	Starts the calibration process.
Base	Shows the database with the last calibrations made.

3 Fill in the data of the screen according to:

- Date: the date is filled automatically.
- Volume (l): volume of the syringe in liters, between 1 and 6 liters.
- Nr. of pulses/Transducer code: number printed in the turbine corresponding to the number of pulses/turn or the code of the disposable nozzles or the Fleisch transducer.
- Temperature (ºC/ºF): value of temperature in ºC (ºF).
- Humidity (%): value of humidity in %.
- Pressure (mmHg): value of room pressure in mmHg.
- Technician: name or code of the person who performs the calibration (optional).

Data from last calibration (expiratory / inspiratory factors and date) are not modifiable. These are the factors applied by the device.

Click on the Calibrate button.

Calibration window in the DATOSPIR AIRA spirometer.

4 When using the DATOSPIR AIRA it is advisable to perform the calibration process with three different flows, from 0 to 12 l/s: medium, high and slow. Start the calibration process by emptying the syringe for three consecutive cycles (one cycle consists of emptying and filling again the syringe). The syringe piston rod must displace the total volumen of air taken as reference, both during the emptying and filling cycles. If this is not done properly, the computer will detect it as "incorrect maneuvers". Furthermore, this process should be performed in a regular and uniform way, not causing too high or low flows. The time of each cycle should not be less than three seconds and no more than six. Start the maneuver with the syringe piston rod completely out. During the maneuvers try to keep the curve within the green areas of the graph.
For simplicity, it is allowed to calíbrate the DATOSPIR AIRA with at least **3 maneuvers in the medium flow level: 2 - 5 l/s**.

The screen presents the expiratory and inspiratory factors taken by the device. If they are below 20% (only in the case of Fleisch transducer) the button 

will be enabled to go to the next flow level. Ater the three flow levels are calibrated click  .

5 Once calibrated, exit the Calibration process. If the calibration factors differ by more than 6% from the previous factors or ±2 standard deviations from the mean calibration factor, the program will inform the spirometer may require cleaning, maintenance and/or repair.

NOTE: If the Calibration Volume (l) is set to 0, the system sets the calibration factors to 1.00 (F. ESP. and F. INS). These are the original manufacturer´s calibration factors. It is convenient to use these calibration factors only as an indication and only if a syringe is not available.

CALIBRATION REPORT

After the spirometer is calibrated you can click  to create a calibration report.

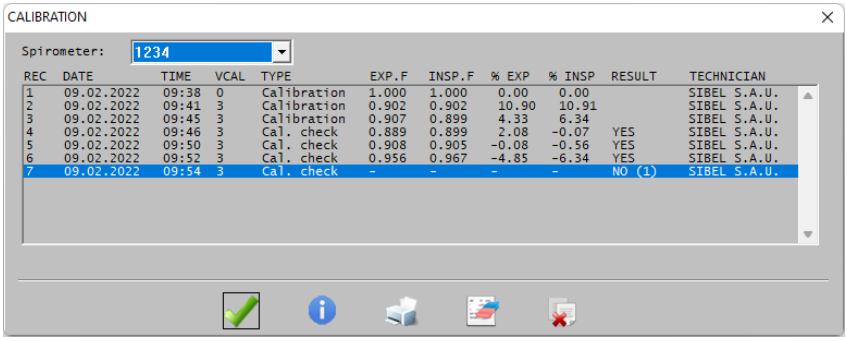
CALIBRATION DATABASE

The software has a database which stores the expiratory and inspiratory factors calculated of the **last one hundred performed calibrations**. This is useful for those centers which require a quality control in the processes they use.

Click the Database button  in the initial window of the calibration process or select the menu option **QUALITY**

CONTROL – CALIBRATION DATABASE

Window of the calibration database in the DATOSPIR AIRA:



OK	Returns to the initial calibration window.
Help	Shows the help file.
Report	Prints all the records in the calibration database.
Delete	Deletes the selected record.
Delete all records	Deletes the whole calibration database.

The drop-down list in the upper left corner of the window allows to filter the calibration records with the selected serial number.
The information displayed in the report includes:

Serial number of the calibrated device
Number of record
Date of calibration
Time of calibration
Calibration volume
Type of maneuver (calibration / check)
Expiratory factor
Inspiratory factor
Expiratory volume error
Inspiratory volume error
Calibration check result: Yes / No (number of failed calibration checks is included in parentheses)
Technician who performed the calibration

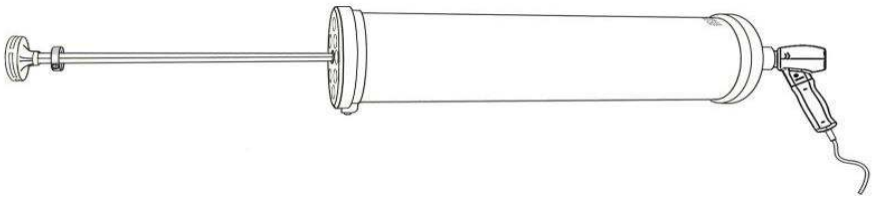
CALIBRATION CHECK

The ATS/ERS TASK FORCE recommends that all spirometers be daily checked for calibration, before further testing begins.
The possible aging or the accumulated dirt of transducers may lead to inaccurate measurements. In the Pneumotachometers, the relationship between the pressure drop and the airflow depends on the gas viscosity. This viscosity also depends on the atmospheric conditions (temperature, pressure and humidity). For this reason it is necessary to perform a daily calibration check in **order to validate that the equipment operates within calibration limits.**

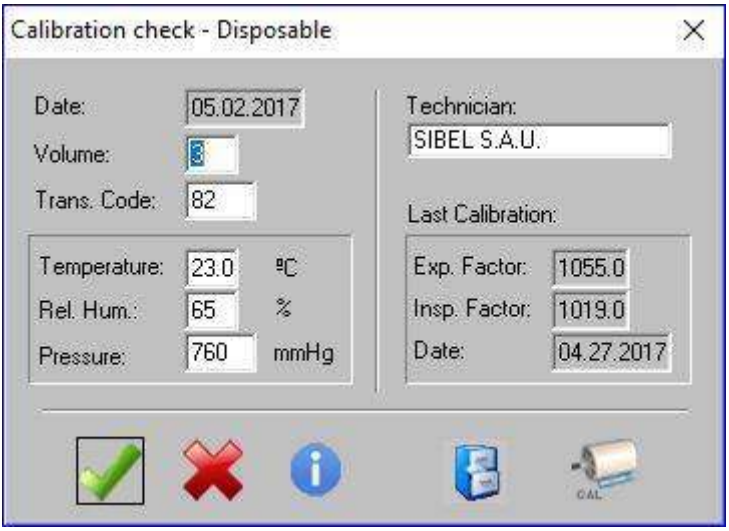
If the spirometer does not pass **the calibration check**, then it will be necessary to carry out the calibration procedure or maintenance of the device to ensure the proper use of the spirometer.

To verify that the transducer operates properly, the program includes a simple verification procedure based on measuring the known volume of a calibration syringe.

1 Couple the transducer to the syringe (between 3 and 6 L) according to figure.



2 Select the menú option **QUALITY CONTROL – QUALITY CONTROL**. Fill in the required fields and click on button .



3 Discharge the syringe **one time** at each of the following flow ranges between 0-12L/s:

Low flow level: 0,4 – 1,2 L/s
Medium flow level: 2 - 5 L/s
High flow level: 6 - 12 L/s

For simplicity, it is possible to carry out the calibration check with a single maneuver at the medium flow level: **2 - 5 L/s**.

4 Press  to accept the maneuver and move to the next flow level.

5 Press  to finish the calibration check procedure.

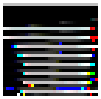
6 If calibration check has been correct, results will be saved automatically in the **calibration database**. Otherwise, the calibration check will be stored as failed. Press  to view the record data.

7 Once the calibration check is completed, access the desired spirometry test.

8 If the calibration check is not correct, proceed to calibrate the spirometer. See the previous section **CALIBRATION PROCEDURE**.

Note:
The error for each flow must be less than ± 3%. The inspiratory and expiratory factors are not modified in this procedure.

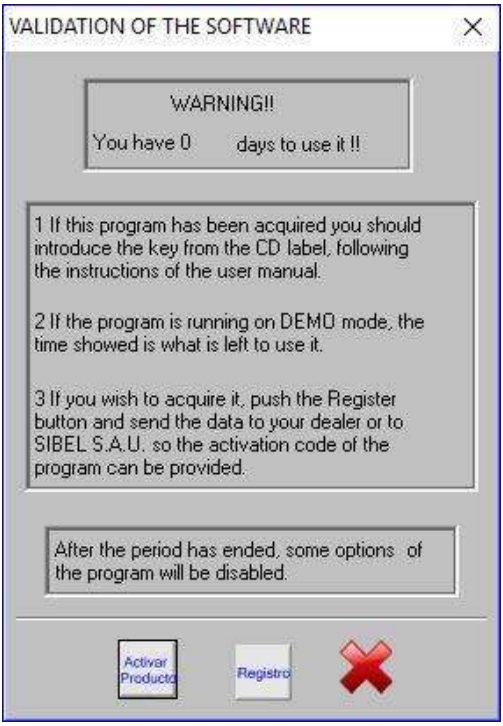
CALIBRATION CHECK REPORT

After finishing the calibration check you can click  to create a calibration check report

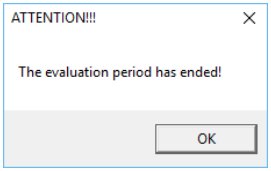
2.14 ACTIVATION CODE

This option is used to activate the program once the evaluation period has ended.

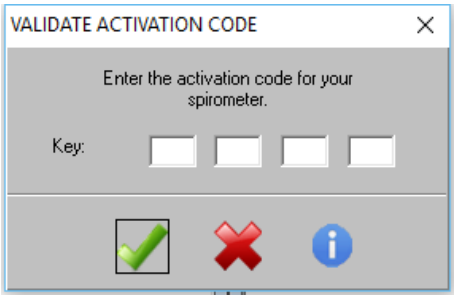
During this 30-day period, the program warns about the remaining days until the end of the trial period.



This allows registration at the moment. If the specified period is over, the program will no longer be able to be used without activating it, showing the next warning message:



For the activation of the program, select the option «Utilities/ Activation Code» from the Setup menu. The next box will appear:



Enter the activation code that has been provided when acquiring this software. From now on the Sibelmed W20s will be unblocked to be used freely without any problems.

2.15 SOFTWARE PURCHASE

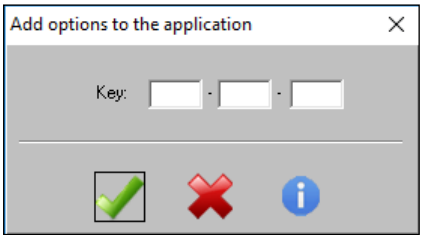
This option opens the SOFTWARE VALIDATION screen (previous page), from which it is possible to:

• Register
Opens a form with the needed data in order to obtain the activation code and send it through e-mail to SIBEL, S.A.U. or your local dealer.

• Product Activation
Opens a dialog box to enter the activation code. This will register the device and the DEMO mode will be deactivated.

2.16 SOFTWARE UPDATE

Some of the software features, like the maximal pressure test or the pulse oximetry are optional modules and are disabled by default.



If you purchased these options please go to SETUP - UTILITIES – OPTIONS ACTIVATION or clic the icon in the toolbar. The next window will be shown. Enter the code supplied by SIBEL S.A.U. or your authorized distributor.

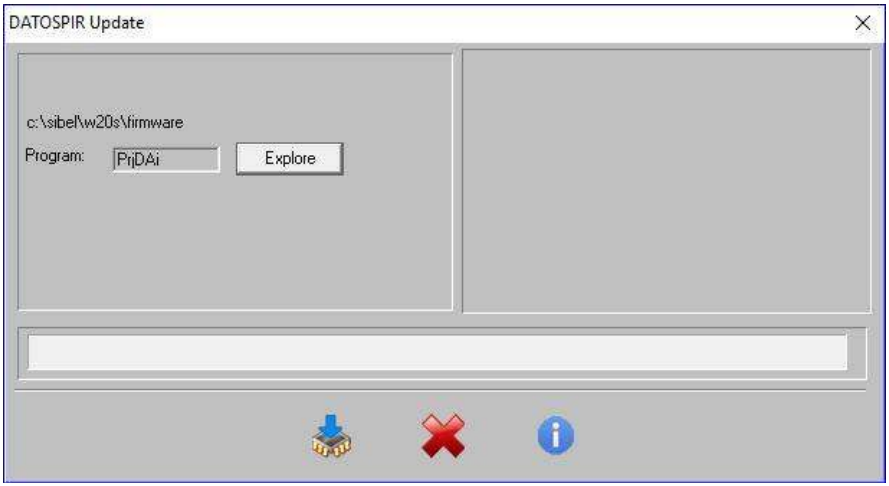
The new options will be available now in the Software W20s.

2.17 FIRMWARE UPDATE

The **DATOSPIR** spirometers from **SIBEL S.A.U.** have the option of updating the internal software. To update the software version follow these instructions:

DATOSPIR AIRA
To update the internal software of the and DATOSPIR AIRA spirometers select the menu option "Settings / Utilities / Update" spirometer.

The following screen will appear:



Firmware update in the DATOSPIR AIRA

DO NOT CANCEL THE UPDATE PROCESS UNTIL IS COMPLETED.

Check the device is turned ON and connected to the computer. If not, proceed as explained previously in the Links section.

Select the file containing the firmware version among the available ones (PrjDAi.prj for the DATOSPIR AIRA and should be located in the folder where the program was installed, by default C:\SIBEL\W20s\Firmware). Click the START button and verify the progress of the update process in the screen.

When the update is completed a «transmission completed» message will appear. Finally, you must close the update screen, turn off the device and turn it back on.

2.18 DATA DOWNLOAD FROM THE DEVICE

The spirometers **DATOSPIR MICRO** and **DATOSPIR TOUCH** have the option of transferring information to the computer. This information is saved in internal files and contains data

about:

- Hardware verification
- Software verification
- Device customization
- Calibration register
- FVC Tests

If you detect any problem with the device that you cannot solve, send this information to the **SIBEL S.A.U. After Sales Department** or to your local **Dealer,** who will analyze and evaluate the origin of the problem and will try to offer you the most suitable solution.

To transfer this information follow the next steps:

1 Turn on the device and select the option **Auto-checking**. Execute all the sub options following the on-screen instructions.
2 Connect the device to the computer and select the link parameters in «**Setup/Links**».

3 Select the option «**Setup/Download spirometer configuration**».

4 Click on **OK** to transfer the information.

All downloaded data is stored in the application folder, in the following files:

STATUS.CSV contains the detected errors
CALIBRA.CSV contains the calibration data
CONFIG.CSV contains the device customization
PRUEBAS.CSV contains the tests of the database
GRAFICAS.CSV contains the graph in Flow/Time format

In case there are files from a previous download they will be renamed with the extension **.OLD**

5 If you want to visualize the information of any of the

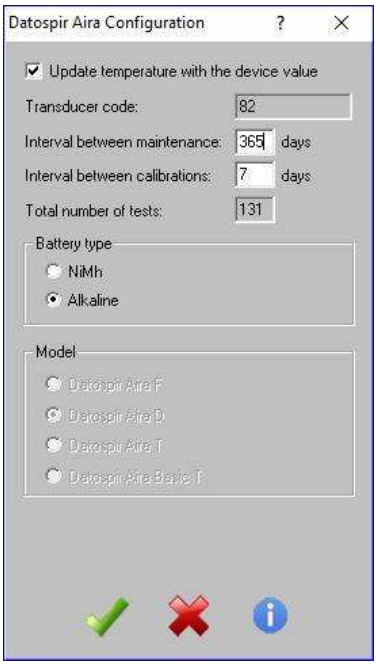
files, open them with MICROSOFT EXCEL

6 Attach the files in your e-mail program and send them to **SIBEL S.A.U. Technical Department** or to your local **Dealer**.

2.19 CONFIGURATION OF THE DATOSPIR AIRA SPIROMETER

Make sure your spirometer is running and connected to the PC. Check that the selected port is correct. Otherwise proceed as discussed above in the "Settings / Links" menu option.

Select the "Setup / Utilities / Spirometer configuration" menu option. The following parameters can be set in the "Datospir Aira configuration" window:



Update temperature with the device value	When this option is enabled the program will use the temperature value measured by the spirometer. Uncheck this option to manually enter the temperature at the beginning of the spirometry test.
Transducer code	Numeric value that models the behavior of the transducer. Not modifiable by the user.
Interval between maintenance	Time elapsed for the program to advise on the desirability of a new preventive maintenance of the spirometer. Value between 0 and 999 days. If the value is 0, the message is never displayed.
Interval between calibrations	Time elapsed for the program to advise on whether to perform a calibration of the spirometer. Value between 0 and 999 days. If the value is 0, the message is never displayed.
Total number of tests	Total number of maneuvers performed with the spirometer. Not modifiable by the user.
Battery type	Indicate whether you are using NiMh (rechargeable) or alkaline batteries.
Model	Indicates the spirometer model (DATOSPIR AIRA F, DATOSPIR AIRA D, DATOSPIR AIRA T, DATOSPIR AIRA BASIC T). It also indicates whether the spirometer has Bluetooth connectivity, as well as USB connection.

3. TECHNICAL SPECIFICATIONS

3.1 SOFTWARE SPECIFICATIONS

3.1.1 COMPUTER INSTALLATION AND REQUIREMENTS

The computer installation will be carried out according to the User Manual. The computer must meet the following **minimum requirements**:

	Minimum	**Recommended**
RAM Memory:	1 GByte	2 GByte or more
Hard Disk:	20 MByte	200 GByte or more
Graphic Card:	1024x768	1280x1024 or more
Monitor:	15"	17"
Communications:	USB 2.0	USB 2.0 USB 3.0

Backup Unit: Recommended

3.1.2 OPERATING SYSTEM COMPATIBILITY

- Windows 7 (32 or 64 bits; SP1)
- Windows 8.1 (32 or 64 bits)
- Windows 10 (32 or 64 bits)
- Windows 11 (32 or 64 bits)

3.1.3 SPIROMETER COMPATIBILITY

The software can be connected to the following DATOSPIR spirometers and its accessories:

- DATOSPIR Aira models F, D, T and Basic T
- DATOSPIR Touch models Easy-T, Easy-F, Easy-D, Diagnostic-T, Diagnostic-F & Diagnostic-D with or without:
  - MEP-MEP module
- DATOSPIR Micro models A, B & C

3.1.4 COMPATIBILITY WITH PULSE OXIMETERS

The software can be used with the following pulse oximeters:

- NONIN Model 3231 USB

3.1.5 PC – SPIROMETER CONNECTIVITY

The software installed on a PC can be connected to spirometer via:

- USB port
- Bluetooth wireless port

3.1.6 PROGRAM CONFIGURATION

Software setup by the user in the following aspects:

- Type of printer
- Parameters, diagnosis, references and others
- Graphs, pediatric / adults incentive and language
- NIOSH functioning mode
- Databases
- Communication Links with the software
- Getting of meteorological data

3.1.7 DATABASES

- Possibility to work with different databases
- Storing of spirometric tests in FVC, VC, Postbronchodilation or MVV

- Storing of tests and graphics
- Creation, deletion, modification in the patient cards
- Fast consulting in the database by:
  - Record
  - Reference
  - Surname
- Printing Reports from the database

3.2 TESTS, FUNCTIONS AND PARAMETERS

3.2.1 FORCED VITAL CAPACITY

Parameters:

- FVC (l) Forced Vital Capacity
- FEV.5 (l) Forced Expiratory Volume in 0.5 seconds
- FEV1 (l) Idem in 1 second
- FEV3 (l) Idem in 3 seconds
- FEV.5/FVC (%) Relation
- FEV.75/FVC (%) Relation
- FEV.75 (l) Forced Expiratory Volume in 0.75 seconds
- FEV1/FVC (%) Relation
- FEV3/FVC (%) Relation
- FEV1/VC (%) Relation
- PEF (l/s) Peak Expiratory Flow
- FEF25% (l/s) Instantaneous forced expiratory flow when 25% has been expired.
- FEF50% (l/s) Idem, at 50%
- FEF75% (l/s) Idem, at 75%
- FEF25-75% (l/s) Forced Mesoexpiratory Flow
- FEF75-85% (l/s) Medium Flow between 75-85% of FVC
- FET25-75 (s) Time passed between 25-75% of FVC

- FET100 (s) Forced Expiratory Time
- FEF50/FIF50 (-) Relation
- FEV1/FEV.5 (-) Relation
- FEV1/PEF (-) Relation
- FIF50% (l/s) Maximum Inspiratory Flow when 50% of FVC has been inspired
- FIVC (l) Forced Inspiratory Vital Capacity
- FIV1 (l) Forced Inspiratory Volume in 1 second
- FIV1/FIVC (%) Relation
- FEV1/FIV1 (%) Relation
- PIF (l/s) Peak Inspiratory Flow
- MTT (s) Measured Transit Time
- PEF/PIF (-) Relation
- Vext (l) Extrapolated Volume related to FVC
- MVVInd (l/min) Maximum Voluntary Ventilation indirect (30 x FEV1)
- FEV6 (l) Forced Expiratory Volume in 6 seconds
- FEV1/FEV6 (%) Ratio
- Hesitation time (s) Time elapsed between the end of maximum inspiration and the beginning of forced expiration
- RT 10-90% (ms) Rise time from 10% to 90% del PEF

- COPD rate Parameter that depends on the number of cigarettes smoked a day, the age and FEV1. It indicates the risk of COPD.
- Lung Age Parameter that depends on the height and FEV1. It indicates the equivalent age of the lung.
- QC grade Quality control grade according to ATS/ERS or NLHEP criteria.

3.2.2 QUALITY OF FVC TEST

In order to assess the pulmonary function of the patient, it is necessary to obtain measurements of high quality. The quality of maneuvers (and of the complete test) depends on patient

cooperation and this, in turn, depends on the instructions provided by the technician.

To ensure good quality spirometry tests, the technician has to pay particular attention to ensure that the patient has made the utmost effort, that the start has been good and that no coughing or Valsava's maneuver due to glottis closure has occurred. Special attention must be paid for preventing an early termination of the expiration.

The **SIBELMED W20s Spirometry Software** includes quality alerts to assist you on achieving high quality spirometry tests. These alerts are based on the recommendations of ATS/ERS or NLHEP (National Lung Health Education Program), which can be selected from the **SETUP - SPIROMETRY - PARAMETERS AND PREDICTEDS** menu.

I. ATS/ERS ALERTS

The ATS/ERS recommendations define the following acceptability criteria for the maneuvers. Once the maneuver is finished, some of these warnings may appear on the screen when the maneuver is not acceptable:

EOFE (End Of Forced Expiration) not achieved - Indicates that the end of forced expiration is not satisfactory, because none of the following conditions are met: expiratory plateau (≤25 ml in the last second of expiration); expiratory time ≥15 s; FVC is within the repeatability tolerance of or is greater than the largest prior observed FVC.

EX – BEV (Back-Extrapolated Volume) must be ≤ 5% of FVC or 0.100 L, whichever is greater.

FIVC error – If the maximal inspiration after EOFE is greater than FVC, then FIVC - FVC must be ≤ 100 ml or 5% of FVC, whichever is greater. Otherwise this warning is activated.

Hesitation >2s: Indicates that the time elapsed between the end of maximum inspiration and the beginning of forced expiration is greater than 2 seconds. The user can change the value of this warning.

Cough 1st sec. - Cough in the first second of expiration. This warning must be manually marked by the user.
Glottic closure in 1st sec. or drift – Glottic closure in the first second of expiration or faulty zero-flow setting. This warning must be manually marked by the user.
Glottic closure after 1st second . – Glottic closure after the first second of expiration. This warning must be manually marked by the user.
Obstructed spirometer or leaks - Includes evidence of obstructed mouthpiece or spirometer; or air leakage. This warning must be manually marked by the user when any of these situations occur during the test.

These alerts may be disabled in the **SETUP - SPIROMETRY - PARAMETERS AND REFERENCES** menu. In this case, they will also be removed from the printed report. This disabling is only at display level. The warnings are still taken into account when ordering the maneuvers and will be displayed in the "Maneuver Data" window.

QC Prompt	Criteria	How to improve the maneuver?
Hesitant start	BEV exceeds limit	Blast out immediately when completely full
Slow start	Rise time > 150 ms	Blast out immediately when completely full
No plateau	No plateau and expiration < 15 s	Keep going until completely empty
Hesitation at maximum volume	Hesitation time > 2 s	Blast out when completely full
Low forced expiratory volume	FVC less than max FVC from previous maneuvers	Take the deepest breath possible and keep going until completely empty
Incomplete inspiration prior to FVC	FIVC > FVC	Fill your lungs completely before blasting out – take the deepest breath possible
Low final inspiration	FIVC < 90% FVC	After completely emptying your lungs, remember to breathe in - back to the top
Slow filling	Mean inspiratory flow of the breath just prior to forced expiration is less than 2 L/s	Breathe in faster before blasting out
Abrupt stop	Suspected glottis closure	If you feel your throat closing, relax, but keep pushing
Cough in first second of expiration	Suspected cough in first second of expiration	Try having a sip of water before the next blow

II. ATS/ERS QUALITY GRADING

At the end of the test (maneuvers session) a quality grade will be displayed to indicate the reliability of the results. A separate quality grade is provided for FVC and FEV1 values.

Grades vary from A to E, depending on the number of acceptable maneuvers and their repeatability. Grade U indicates there are usable, but not acceptable, maneuvers; while grade F implies there are no usable, nor acceptable maneuvers.

GRADE	TEST	CRITERIA
A	VERY GOOD	≥ 3 acceptable maneuvers. > 6 years: ≤ 150 ml between the two best values of FVC and FEV1. ≤ 6 years: ≤ 100 ml between the two best values of FVC and FEV1 or up to 10% of the highest value of FVC and / or FEV1, whichever is greater.
B	GOOD	2 acceptable maneuvers. > 6 years: ≤ 150 ml between the two best values of FVC and FEV1. ≤ 6 years: ≤ 100 ml between the two best values of FVC and FEV1 or up to 10% of the highest value of FVC and / or FEV1, whichever is greater.
C	ACCEPTABLE	≥ 2 acceptable maneuvers. > 6 years: ≤ 200 ml between the two best values of FVC and FEV1. ≤ 6 years: ≤ 150 ml between the two best values of FVC and FEV1 or up to 10% of the highest value of FVC and / or FEV1, whichever is greater.
D	SUSPECT	≥ 2 acceptable maneuvers. > 6 years: ≤ 250 ml between the two best values of FVC and FEV1. ≤ 6 years: ≤ 200 ml between the two best values of FVC and FEV1 or up to 10% of the highest value of FVC and / or FEV1, whichever is greater.

E	POOR	≥ 2 acceptable maneuvers. > 6 years: > 250 ml between the two best values of FVC and FEV1. ≤ 6 years: > 200 ml between the two best values of FVC and FEV1 or up to 10% of the highest value of FVC and / or FEV1, whichever is greater. OR 1 acceptable maneuver, without checking the FVC and FEV1 values.
U	USABLE	No acceptable maneuver and 1 usable maneuver.
F	NOT ACCEPTABLE	No acceptable or usable maneuver.

III. NLHEP ALERTS: QC PROMPTS

The **SIBELMED W20s** software includes an automatic quality control function, based on the recommendations of the **NLHEP** (National Lung Health Education Program), with **prompts** to assist the technician in providing instructions to the patient to produce high quality spirometry tests.

At the end of a maneuver, a message on the screen will inform you about the acceptability of the maneuver. If it is considered not acceptable, provide instructions to the patient for improving the maneuver based on the messages indicated in the following table (see the rows in white).

When the message **"Good test Session"** appears, it is not necessary to carry out further maneuvers. If after repeated attempts, it is not possible to obtain an adequate number of good maneuvers, let the patient take a break or stop the measurement.

Only one of the following QC prompts is displayed after a performed maneuver (in the order of priority listed below).

QC Prompt	Criteria	How to improve the maneuver?
Don't Hesitate	EX error (see ATS/ERS alerts)	The patient must start exhaling harder.
Blast Out Faster	PEFT error (time to reach PEF higher than 120 ms)	The patient must exhale as hard, firm and fast as possible.
Blow Out Longer	ET error (FET < 6 seg and EOTV > 100 ml during the last 0.5 s of the maneuver)	The patient has abruptly interrupted exhalation. The patient must exhale even more and expel as much air as possible from his/her lungs.
Blast Out Harder	If there are not 2 acceptable maneuvers, with the two largest PEF values matching within 1 L/s	The maneuver differs significantly from the previous ones The patient can exhale even more vigorously and achieve a higher peak flow.
Deeper Breath	If there are not 2 acceptable maneuvers, with the two largest FEV6 values matching within 150 mL	The maneuver differs significantly from the previous ones. The patient must inhale more deeply and exhale even more air.
Good Test Session	After 2 acceptable maneuvers that match.	TEST COMPLETE. Adequate number of good maneuvers.

Refering to the **acceptability** of the last maneuver performed
Refering to the **repeatability** of the maneuvers

IV. NLHEP QUALITY GRADING (QC GRADES)

At the end of the test (maneuvers session), a quality grading from A to F will be displayed to indicate the reliability of the results, according to NLHEP criteria.
A, B and C grades indicate a reliable result, but a grade D or F indicates a poor quality test (in this case, the results should be interpreted with caution).

GRADE	TEST	CRITERIA
A	VERY GOOD	At least 2 acceptable maneuvers with the largest 2 FEV_1 values matching within 100mL and the largest 2 FEV_6 values matching better than 100mL.
B	GOOD	At least 2 acceptable maneuvers with FEV_1 values matching between 101 and 150mL
C	ACCEPTABLE	At least 2 acceptable maneuvers with FEV_1 values matching between 151 and 200 mL
D	POOR	Only one acceptable maneuver, or more than one, but the FEV_1 values match > 200 ml (with no interpretation)
F	NOT ACCEPTABLE	No acceptable maneuvers (with no interpretation)

3.2.3 INTERPRETATION ALGORITHMS (DIAGNOSIS)

The **Spirometry Software SIBELMED W20s** includes two types of diagnosis available through **SETUP – SPIROMETRY - PARAMETERS AND REFERENCES - SELECTION**.

Miller Diagnosis
It presents the following information NORMAL, RESTRICTIVE, OBSTRUCTIVE or COMBINED.

Snider, Kory & Lyons Diagnosis
It is based on the following criteria:

- If FVC > 80% of FVC Reference and FEV1 > 80% of FEV1 Reference --> **Values in reference range. Normal**

Diagnosis

● If FEV1/FVC% < FEV1/FVC% Reference and FEV1 < 80% of FEV1 Reference --> **Ventilatory alteration of Obstructive type**

FEV1 < 80%	**Light**
FEV1< 65%	**Moderate**
FEV1 < 50%	**Strong**
FEV1 < 35%	**Very Strong**

● If FEV1/FVC% > FEV1/FVC% Reference and FVC < 80% of FVC Reference --> **Ventilatory alteration of non Obstructive type**

FVC < 80%	**Light**
FVC < 65%	**Moderate**
FVC < 50%	**Strong**
FVC < 35%	**Very Strong**

● If FEV1/FVC% > FEV1/FVC% Reference and FVC > 80% of FVC Reference --> **Ventilatory alteration of Mixed type suspected**

● If FEV1/FVC% < FEV1/FVC% Reference and FEV1 > 80% of FEV1 Reference --> **Ventilatory alteration of Mixed type suspected**

● If a bronchodilation test is made and the FEV1 POST surpasses in 15% to the FEV1 basal or PRE --> **There is a positive reaction to the bronchodilater substance**

Interpretation ATS/ERS.
According to Pellegrino et al. Task force: Standardisation of Lung Function Testing. Eur Respir J 2005; 26: 948–968

Interpretation NLHEP.
Only valid for references that calculates the LLN. For example: Hankinson. According to Ferguson et al. Office Spirometry for Lung Health Assessment in Adults. Chest 2000; 117: 1146-1161.

3.2.4 PREDICTED SETS

Predicted set	Country / Region	Age range (years)
SEPAR 2013	SPAIN	6 to 85 (1)
ERS	EUROPE	18 to 70 (1)
KNUDSON	EEUU	6 to 84 (1)
CRAPO	EEUU	4 to 91 (1)
ZAPLETAL	EUROPE	4 to 17
MORRIS	EEUU	24 to 100
AUSTRIA	AUSTRIA	5 to 90 (1)
GUTIERREZ 1996	CHILE	5 to 100 (1)
SER 2014	CHILE	19 to 94
CASTRO- PEREIRA 2002	BRAZIL	6 to 25
POLGAR - WENG		4 to 100
HANKINSON - NHANES III	EEUU	4 to 100
PEREZ - PADILLA	MEXICO	7 to 100 (1)
A.J. CRUZ	MEXICO	17 to 65 (1)
GOLSHAN	IRAN	5 to 82 (1)
GARCIA RIO	EUROPE	65 to 85
CANDELA	SPAIN	2 to 7
PLATINO	LATIN-AMERICA (Mexic, Chile, Venezuela, Brazil, Uruguay)	40 to 90
THAI 2000	THAILAND	10 to 100
GLI	INTERNATIONAL	3 to 95
CASTRO-PEREIRA 2007	BRAZIL	26 to 86

(1) If other ages are used, the predicted values are extrapolated

It is possible to include other references. For this purpose, contact **SIBEL S.A.U. Technical staff.**

Ethnic Factor for Predicted values

Patient Identification Data

Environmental Data: temperature, pressure and relative humidity

Graphics in FLOW/VOLUME and VOLUME/TIME mode

Acoustic and visual warnings about the performance of the maneuver

Incentive graphics in pediatric tests

Concordance Maneuver Warnings with the ATS/ERS criteria

3.2.5 SLOW VITAL CAPACITY

Parameters:

- VC (l) Slow Vital Capacity
- TV (l) Tidal Volume
- ERV (l) Expiratory Reserve Volume
- IRV (l) Inspiratory Reserve Volume
- IC (l) Inspiratory Capacity
- Ti (s) Inspiratory Time
- Te (s) Expiratory Time
- Tt (s) Total Time
- Ti/Tt (-) Relation

Normalized Predicted Sets to be selected among different standards

Ethnic Factor for Predicted values

Patient Identification Data

Environmental Data: temperature, pressure and relative humidity

Graphics in VOLUME/TIME mode

3.2.6 MAXIMUM VOLUNTARY VENTILATION

Parameters:

- MVV (l/min) Maximum Voluntary Ventilation
- Br./min (Br/min) Breathing Frequency of MVV

Normalized Predicted sets to be selected among different standards

Ethnic Factor for Predicted values

Patient Identification Data

Environmental Data: temperature, pressure and relative humidity

Graphics in VOLUME/TIME mode

Acoustic and visual warnings about the performance of the maneuver

3.2.7 POSTBRONCHODILATION TEST

Same parameters as FVC tests

Comparing methods between PRE and POST

- % Average between PRE and POST
- % between REF and POST
- % between PRE and POST
- Difference between PRE and POST

Superposition of PRE and POST maneuvers graphs in the external printer

3.2.8 BRONCHOCONSTRICTION TEST

Parameters

- FVC (l) Forced Vital Capacity
- FEV1 (l) Idem in 1 second
- PEF (l/s) Peak Expiratory Flow
- FEF25-75% (l/s) Forced Mesoexpiratory Flow
- All the parameters of the FVC tests can be selected

Patient Identification Data

Environmental Data: temperature, pressure and relative humidity

Continuous and short functioning modes
Deviation Percentage between Basal & Dissolution

Superimposition of graphics in FLOW/VOLUME or VOLUME/TIME mode

Stopwatch to control the steps

Type of drug and accumulated dose

Calculation of PD20 (FEV1) by mathematic adjustment or linear interpolation

Numeric and graphic (dose/response) data summary on

screen

Link with bronchodilation test

3.2.9 MAXIMAL PRESSURES OPTION

PARAMETERS

The following paramaters are calculated for both expiratory and inspiratory tests:

- Maximum Pressure of the 5 maneuvers.
- Mean of the best 3.
- Standard Deviation of the best 3.

RANGES AND MEASUREMENTS

- Measurement Range ±295 hPa (±300 cmH_2O)
- Resolution 1 hPa (1 cmH_2O)
- Precision 5 %
- Sampling Frequency 100 Hz
- Maneuvers under 9,8 hPa (10 cmH_2O), are dismissed
- Start of Maneuver: When the threshold of 2.95 hPa (3 cmH2O) is exceeded
- End of Maneuver: Variation less than 1 hPa (1 cmH2O) in the last 2 sec.

CONTROL

- Number of maneuvers.
  A maximum of 5 maneuvers of each type can be performed (MEP and MIP)

- Maneuver Duration.
  The maximum duration is 8 seconds

- Delay in the maximum pressure value calculation.
  1 second by default. Can be configured in the Setup

- Database
  The spirometer shares the database for all the different tests

3.2.10 PULSE OXIMETRY OPTION

TESTS AND PARAMETERS

The software allows punctual or long-term measurements using a compatible external pulse oximeter connected to the computer via USB.

- **CT90** % of the time in which the **SpO_2** is under 90%
- **CT80** % of the time in which the **SpO_2** is under 80%
- **CT70** % of the time in which the **SpO_2** is under 70%
- **IDH-4** index of desaturations (>= 4%) per hour
- **IDH-3** index of desaturations (>= 3%) per hour
- **IDH-2** index of dessaturations (>= 2%) per hour
- **SpO2 Max** maximum value of the Saturation
- **SpO2 Mean** mean value of the Saturation
- **SpO2 Min** minimum value of the Saturation
- **SpO2 Std** standard deviation of the Saturation
- **PR Max** maximum value of the pulse rate
- **PR Mean** mean value of the pulse rate
- **PR Minimum** minimum value of the pulse rate
- **PR Std** standard deviation of the pulse rate
- **Test Time** time of use of the test (the finger probe unplugged time is not count)

RANGES AND MEASUREMENTS

NONIN 3231 USB(*)		
	SpO2 (%)	**Pulse (BPM)**
Measurement Range	0 - 100	18-321
Resolution	1	1
Accuracy (normal)	70 to 100: +/- 2 <70: Not specified	20 to 250: +/- 3 (remaining range): Not specified
Accuracy (low perfusion)	70 to 100: +/- 2 <70: Not specified	40 to 240: +/- 3 (remaining range): Not specified

(*) See the detailed specifications in the user manual.

- Start and ending of the maneuver suitable to the user.
- One only valid study until the change of patient.

- When initializing the data, the program allows starting a new study for the same patient.

3.3 GENERAL DATA

3.3.1 MEASUREMENT SYSTEM

- Transducer Turbine type, Fleisch type or Disposable type depending on the spirometer

- Measurement Scale:
  - Flow from -16 l/s to +16 l/s
  - Volume from 0 to 16 l

- Measurement accuracy (BPTS):
  - Volume 2,5% or 50 ml
  - Flow 3% o 150 ml/s
  - PEF 10% or 170 ml/s

- Accumulative Volume Time
  - Eight curves FVC of maximum 60 seconds each
  - Eight curves VC of maximum 60 seconds each
  - Eight curves MVV of maximum 60 seconds each

3.3.2 ANALYSIS CRITERIA

- Start expiration FVC

Calculated by the back-extrapolation method.

- Final expiration FVC

  Calculated according the ATS/ERS or NLHEP criteria, depending on the selection in SETUP / SPIROMETRY / PARAMETERS AND PREDICTED (see section 3.2.2. QUALITY OF FVC TEST).

- Selection of tests FVC

  Performed according to the criteria of maximum addition of FVC+FEV1 or at the operator convenience

- Selection of parameters

  The displayed parameters are the corresponding to the selected maneuver (selected by the operator or by the best

FVC + FEV1 default criteria) Also are displayed the best FVC and best FEV1 as the highest values recorded among the performed and stored maneuvers.

- Start of expiration in VC and MVV by signal level

- Selection of tests and parameters in VC and MVV
  . Highest value in VC or MVV

3.3.3 USEFUL LIFE

The useful life is 7 years

3.3.4 STORAGE

Store the USB Flash memory drive between -25ºC and 70ºC. Relative humidity must be below 90% (without condensation)

3.3.5 STANDARDS

-European Medical Device Regulation (EU) 2017/745.
-General Data Protection Regulation (EU) 2016/679.
-Implementing Regulation (EU) 2021/2226 regarding electronic instructions for use of medical devices.
-Quality (EN ISO 13485:2016+A11:2021, EN ISO 9001:2015)
-Risk management (EN ISO 14971:2019 + A11:2021)
-Spirometers for peak expiratory flow (EN ISO 23747:2015)
-Spirometers for measurement of forced expiratory volumes (EN ISO 26782:2009 + AC:2009)
-Medical equipment software (EN 62304:2006 + AC:2008 + A1:2015)
-Usability (EN 62366-1:2015 + A1:2020)
-Documentation and information (EN ISO 20417:2021, EN ISO 15223-1:2021)
-Pulse oximetry (EN ISO 80601-2-61:2011) Only for the SpO2
-Module of the Software Safety of medical equipment (EN 60601-1:2006+AC:2010+A11:2011+A1:2013)

3.3.6 SPIROMETRY RECOMMENDATIONS

-ATS/ERS:
Graham BL et al. Standardization of Spirometry 2019 Update. An official American Thoracic Society and European Respiratory Society Technical statement. Am J Respir Crit Care Med. 2019;200(8):e70–88

- SEPARATE:
García-Rio F et al. SEPAR regulations. Spirometry. Arch Bronconeumol 2013; 49(9): 388-401.

- NLHEP:
Ferguson et al. Office Spirometry for Lung Health Assessment in Adults. Chest 2000; 117: 1146-1161.

3.4 SYMBOLS

MANUFACTURER (Manufacture data, name and address of the manufacturer)

DATA OF ANUFACTURE

TEMPERATURE LIMIT

HUMIDITY LIMITATION

ATMOSPHERIC PRESSURE LIMITATION

WARNING, RISK IDENTIFIED

MEDICAL DEVICE

BATCH NUMBER

REFERENCE

FOLLOW INSTRUCTIONS FOR USE

DISPOSAL OF WASTE ELECTRICAL / ELECTRONIC ACORDING TO THE WEEE DIRECTIVE

4. MAINTENANCE

The **Spirometry Software SIBELMED W20s** does not require any specific maintenance, except that for any computer program handling information.

- Make a copy of the USB memory drive in case the original gets damaged.

- Make regular backup copies of the database and the program's configuration in order to be able to restore in case of loss of information on the computer. See Appendix 4 for more information on backups.

If any problem, doubt, suggestion arises before, during or after the use of the product, it is recommended to follow these steps:

1. **Use the help windows available in the program**
2. **Use this User's Manual properly**
3. **Keep the program updated. You can check your current version in "HELP - ABOUT". Check the availability of new versions at https://www.sibelmed.com/support**
4. **Contact with the Technical Service of SIBEL S.A.U. at**

   SIBEL S.A.U.
   Rosellón 500 bajos, 08026 BARCELONA (Spain)
   TECHNICAL SERVICE
   Tel. +34 93 433 54 50
   FAX +34 93 436 16 11
   e-mail : sat@sibelmed.es

4.1 CLEANING

The USB memory drive should be gently cleaned with a cloth moistened with soapy (neutral) water. Then it can be wiped dry. Particular care must be taken to ensure that no liquid enters the interior of the USB connector. Abrasive substances or solvents must be avoided. Keep the flash memory drive into its package when not in use.

ANNEX 1

PULSE OXIMETRY TEST (OPTION)

A.1.1 INTRODUCTION

With the Pulse oximetry option, the software can perform specific measurements of the **Oxygen Saturation** (**SpO_2**) and the **Pulse Rate** (**PR**), or long term studies, especially aimed at the control of patients during sleep or in any other situation (saturation measurement, etc...).

The spirometer calculates statistical parameters for the reading of **SpO_2** and **PR**, as well as the desaturation Index per hour (**IDH4, IDH3 and IDH2**), the percentage of desaturations under some value (**CT90, CT80 and CT70**), the standard deviation, the mean, and the maximum and minimum values.

It is possible to print the parameters, store them in the database, export and import them.

Before using the pulse oximetry option for the first time it is necessary to activate the option in the W20s software. Enter the password provided on the card shipped with the pulse oximeter, as detailed in section 2.16 SOFTWARE UPDATE.

See section 2.6.8 COMMUNICATIONS for information on how to configure the pulse oximeter for use.

A.1.2 PULSE OXIMETRY PROGRAM

These are the different options available in the pulse oximetry program:

- **Patient Data**
  Name and code of the patient
  Birthdate and sex
  Address, telephone, occupation and comments

- **Test Data**
  Name and code of the patient

Height and Weight
Motive, origin, technician and comments

- **Start of the maneuver**
- **Data of the maneuver**
- **Rest data**
- **Test Data**
- **Store the test**
- **Report**
- **Organize Windows**

The operative windows allow the display of the pulse oximeter values, receive alarm messages and display the calculated parameters.

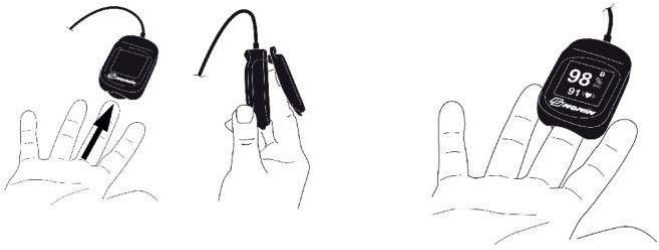
They are the following ones:

- **Pulse Oximetry Window**
- **Data Window**

A.1.3 PULSE OXIMETRY TEST PROCEDURE

As it has been said before, it is possible to make single measures and long term studies (8 hours approximately).

Place the patient's finger on the pulse oximeter as shown in the figure. You will find more information on the use of the pulse oximeter in its manual.

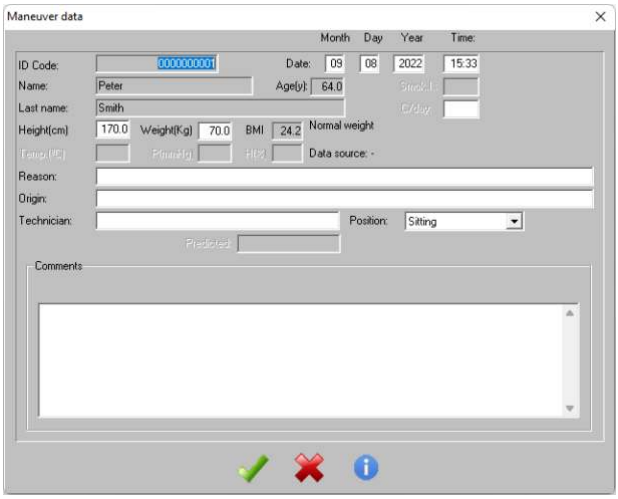


A.1.4 PERFORMANCE OF PULSE OXIMETRY TESTS

To start a new pulse oximetry test select the patient in the database or create a new one, then click the Pulse Oximetry button in the toolbar or select the menu option Tests / Pulse Oximetry.

A.1.4.1 INPUT OF TEST DATA

Enter the data for the test and click OK. Some fields are disabled since they are not used in the pulse oximetry test.



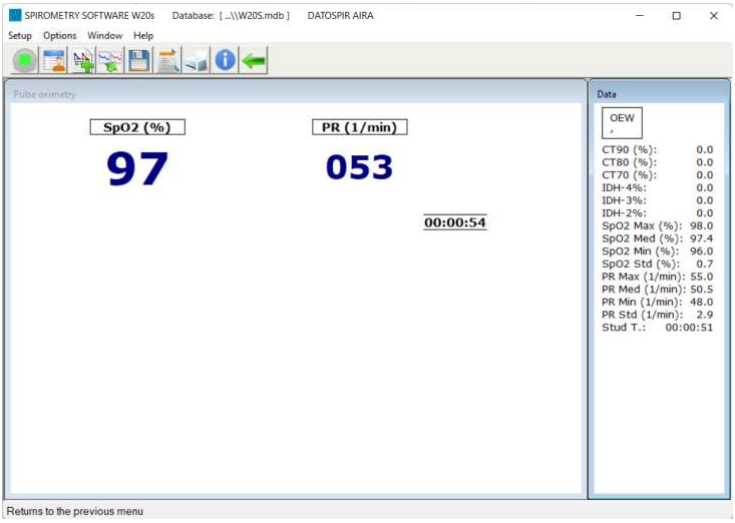
A.1.4.2 PERFORMANCE OF PULSE OXIMETRY TESTS

After having validated the test data Pulse oximetry screen will be shown.
The screen shows the message «READY» in green color.

If the pulse oximeter is not connected to the PC, connect it now. Insert the patient's finger into the pulse oximeter so that it turns on.
Press the «START» button to start the study. Click OK on the warning message that is displayed. The pulse oximeter will start sampling. Oxygen saturation (SpO2) and heart rate (PR) values are represented.

The message "APPLY THIMBLE" may also appear in yellow when no peripheral pulse is detected. In this case the SpO2 and PR values will remain at zero. The message "SEARCHING FOR CONSECUTIVE PULSE" may appear for a few moments at the start of the test or if the finger moves within the pulse oximeter.

The following screen shows an example of display in the course of a study:



In the course of a study, you can:

- Alter the pulse oximetry configuration.
- Hide, show the data window.
- Initialize the statistical parameters of the data window.
- Consult / Modify the test data.
- Store the parameters.
- Print a report of the study.

When the estimated time of study has passed, press again the button «START» to store the test and update the data.

A. SPECIFIC TESTS

In the specific pulse oximetry tests, the screen will indicate the SpO_2 and PR values according to the configured average.
If you want to store the data in the database or print them, stop the study and proceed according to the manual.

B. LONG TERM TESTS

In long term tests, the statistical data calculated are useful for the observation of the patient's evolution, without being present all the time.

It is important to point out that the signal is associated to the patient's code entered. If you start and stop the study before changing the patient' s code without initializing the data, fragments of signals will be stored, one after the other until a maximum of eight hours. The device interprets that all the fragments belong to the same patient and the calculation of

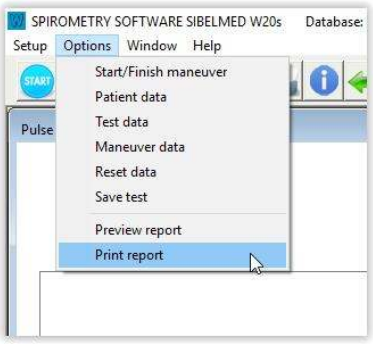
parameters will be made with the whole memory.

If the thimble probe is disconnected, the signals of SpO2 and PR will be presented with 0 value. **These periods of time will not be taken into account** when calculating the parameters and the duration of the study.

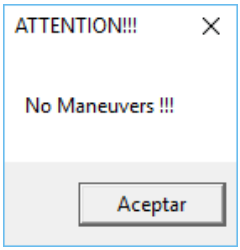
A.1.4.3 PRINTING AND/OR SAVING IN THE DATABASE

A. PRINTING OF THE RESULTS

At any moment you can enter the option report from the pulse oximetry tests screen.



If the parameters have not been calculated, because the thimble probe has not been applied during the study or because no study has been performed, the following message will be displayed:



Otherwise the following report will be printed:

SIBEL S.A.U.
Rosellón 500
08026 - Barcelona (Spain)

ID Code: 1234 Date: 31-03-2016 Time: 10:20
Name: Smith Peter
Sex: Female Age(y): 36 Height(cm): 180 Wgt(Kg): 75

Reason: BMI : 23.1
Procedence:
Technician: Transducer: Disk

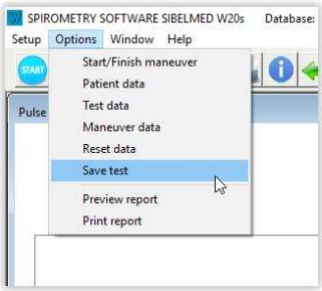
Version: 511-BLA-2.00

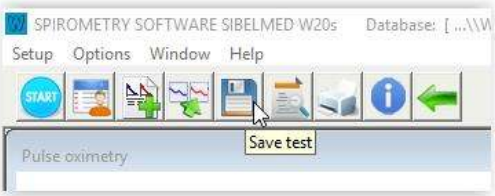
PULSEOXIMETRY REPORT SIBELMED W20s

PARAMETER		ACT
CT90	(%)	0.0
CT80	(%)	0.0
CT70	(%)	0.0
IDH-4%		0.0
IDH-3%		0.0
IDH-2%		0.0
SpO2 Max	(%)	98.0
SpO2 Avg	(%)	97.1
SpO2 Min	(%)	97.0
SpO2 Std	(%)	0.4
PR Max	(1/min)	73.0
PR Avg	(1/min)	65.9
PR Min	(1/min)	60.0
PR Std	(1/min)	3.4
T.Study		00:07:43

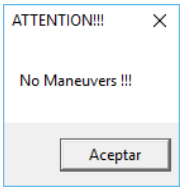
B. SAVING IN THE INTERNAL DATABASE

At any moment you can select the option Save Test from the pulse oximetry tests screen.

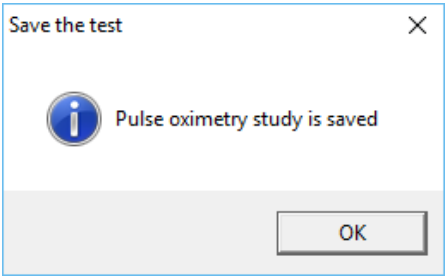




If the parameters have not been calculated, because the thimble probe has not been applied during the study or because no study has been performed, the following message will be displayed:



If the calculated parameters for the study have been stored correctly, this message will be displayed:



ANNEX 2

MAXIMAL PRESSURES TEST (OPTION)

A2.1. INTRODUCTION

The maximal pressure module has been designed in collaboration with the «Laboratory of Pulmonary Function» of the Hospital de San Pablo of Barcelona. It is based on the criteria expressed by J.L. Clausen to the Thoracic Society of California.

It enables a measurement range of ±295 hPa (±300 cmH_2O) in inspiratory and expiratory tests. It has several reference values available, to be set up by the user.

A2.2. MAXIMAL PRESSURES PROGRAM

Next, the options of the maximal pressure program are displayed:

- **Patient Data**
  Name and surname
  Date of birth and sex
  Address, telephone, occupation and comments

- **Test Data**
  Patient name and code
  Height and weight
  Motive, origin, technician and comments

- **Maximal pressures setup**
  Initial
  time
  Referenc
  es Colors

- **Start of maneuver**

- **Change from MEP to MIP or vice versa**

- **Selection of maneuver**

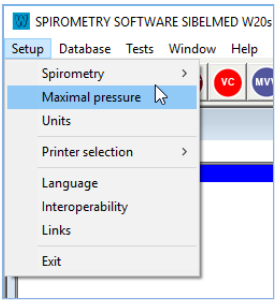
- **Delete the selected maneuver**
- **Save to database**
- **Creation of reports**
- **Zoom+, Zoom- and organize windows**

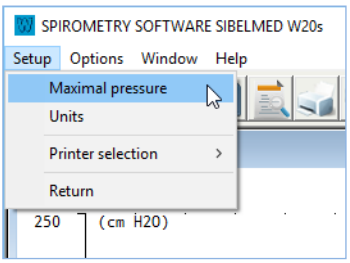
The operative windows are used to represent the maneuvers and the test data. These are the following:

- **Window of the best 3 maneuvers**
- **«Summary» window of the test (data)**
- **Window of maneuver in process**
- **Window of memory display**

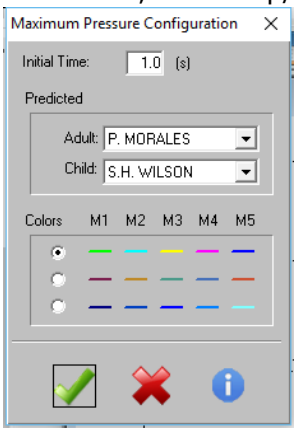
A2.3. MAXIMAL PRESSURES CONFIGURATION

Every user should configure the **Maximal Pressure** module, according to his/her needs.
The Maximal Pressure configuration menu is accessible from





the main screen in «Setup / Maximal Pressures», or from the maximal pressure tests screen, in «Setup/Maximal Pressure»:



The following dialog will be shown:

OK	Closes the dialog and applies the changes.
Cancel	Closes the dialog loosing the changes.
Help	Opens the help file.

Not all the references have predicted values for adults and children, so they will not be available for selection.

The measurement delay has as default **value of 1.0 s.**, although the user can set it up between 0.1s.and 4.9 s.

This delay time affects the measurement calculation, so no value within the first second (or the value set up by the user) is taken into account.
Select one of the three color sets for the drawing of the stored curves.

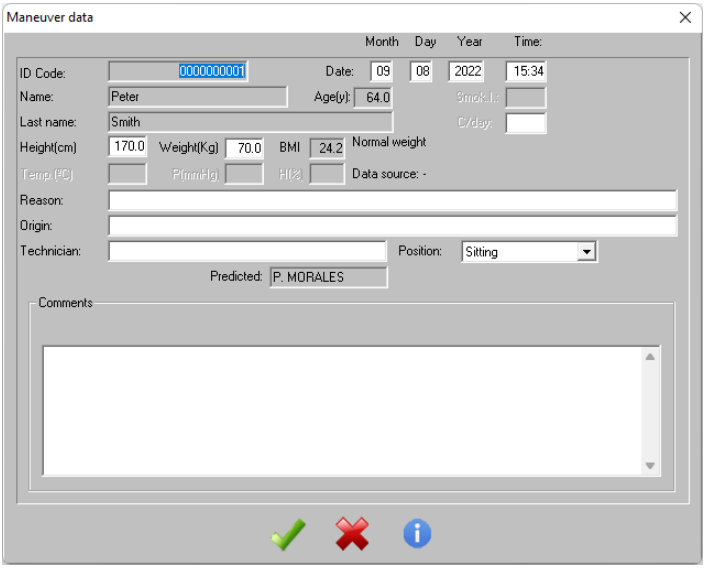
A2.4. MAXIMAL PRESSURES TEST PROCEDURE

To start a new maximal pressures test select the patient in the database or create a new one, then click the Maximal

Pressures button in the toolbar or select the menu option Tests / Maximal Pressures.

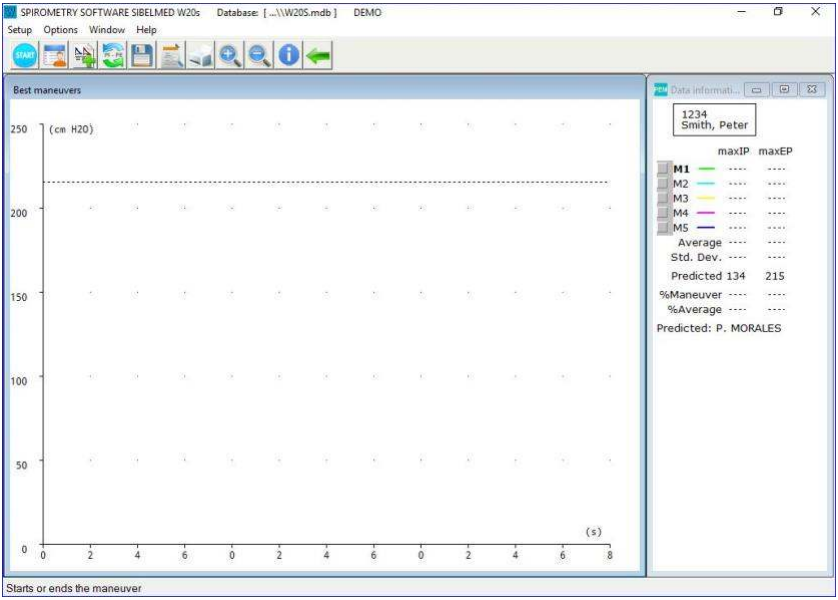
A2.4.1. INPUT OF PATIENT AND TEST DATA

Enter the data for the test and click OK. Some fields are disabled since they are not used in the maximal pressures test.



A2.4.2. PERFORMANCE OF MAXIMAL PRESSSURE TESTS

After the test data have been validated with the OK button, the screen of tests performance is accessible.



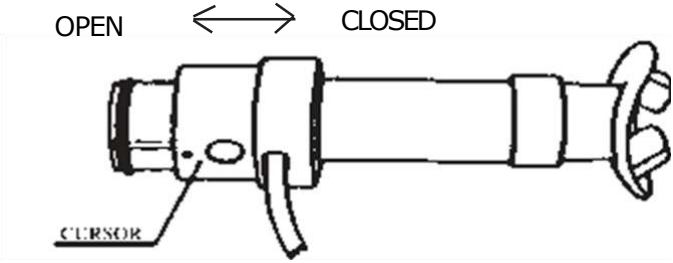
It is recommendable for the technician, who is performing the maximal pressure tests, to know the usual required procedure, so that the patient performs the test correctly. Otherwise, it is advisable to check some bibliography on this subject.

Follow these steps to perform the test:

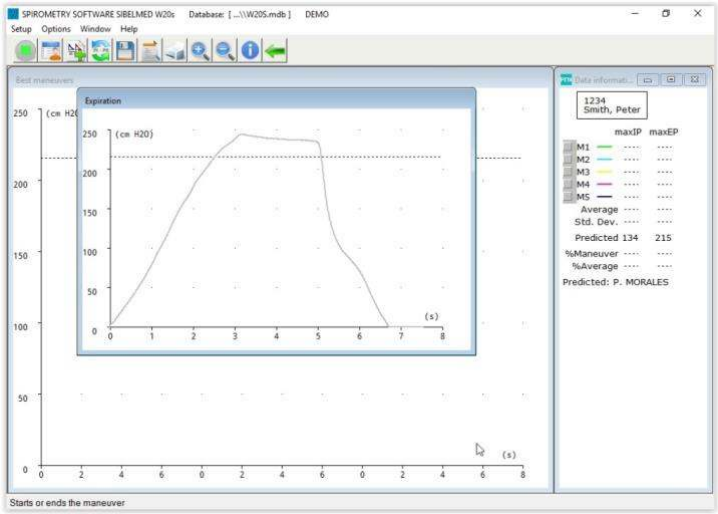
1 Connect the module to the connector no. 9. The device automatically detects that the module is connected. The device will indicate if the module is not connected, and it will not allow starting the maneuver.
Ensure also that the Shutter Probe is connected to the module.

2 Train the patient on the test performance, as his/her collaboration is essential for the correct execution. Put him/her the nose clip.

3 Press the «START» button and wait until the icon changes into green color. The shutter probe must be in open position, in order to enable the patient to breathe normally.



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



4 Once the maneuver is finished, repeat the step 3 to perform additional maneuvers.

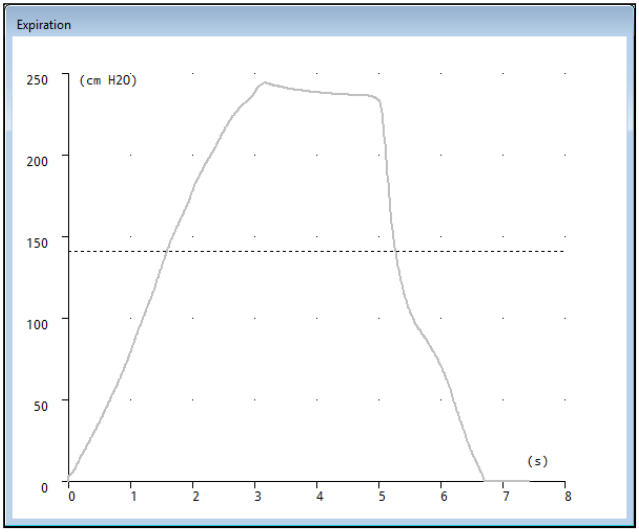
A minimum of 3 maneuvers is advisable. The best 3 must not differ more than 5 % among them, and the last one must not be the best.

A2.5. TEST INFORMATION

A2.5.1. WINDOWS DESCRIPTION. SELECTING AND DELETING MANEUVERS.

For the study of the evolution of the Maximal Pressure test, the program has four windows. These windows are detailed below.

A. Window of maneuver in progress

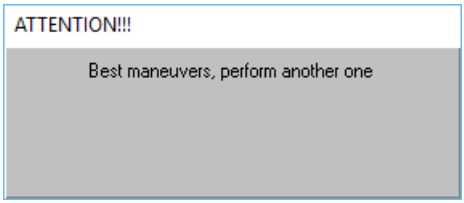


This graph represents the variation of pressure as the maneuver is taking place.

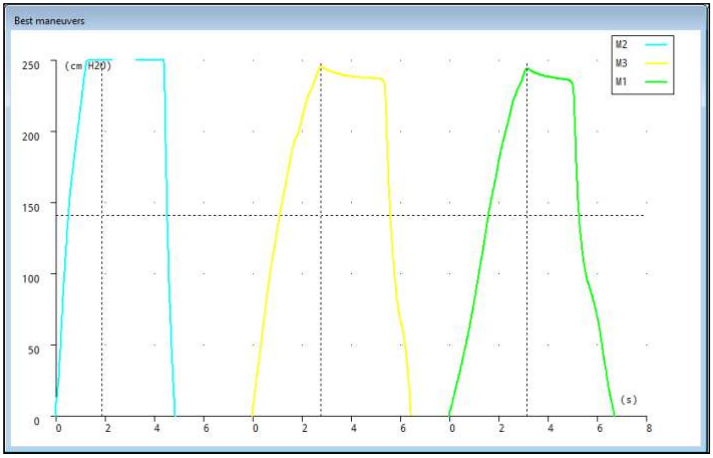
This window is displayed by clicking the «START» button and disappears when the the maneuver is finished, when the «START» button is clicked, by waiting for 8 seconds or when a pressure lower than 0.98 hPa (1 cmH_2O) during 2 seconds is found.

The horizontal line of dots indicates the reference value.

Once the maneuver is finished, the position for the maximal pressure and its value are calculated. The next message is shown if this value is higher than the maximal pressure of the previous maneuvers:



B. Window of the best three maneuvers



In this window, the best 3 maneuvers are ordered, according to the maximal calculated value of pressure. In the example of the

upper graphic, for M2 («Memory 2»), the higher maximal value, the expiratory pressure would be calculated. M3 would be in the second place, and M1, in the third place. (See the corresponding data window «Summary» or data window in the next page).
If the three maneuvers differ in more than 5%, this will be indicated through an intermittent red message «>5%».
The horizontal line of dots indicates the reference value.
The vertical line of dots indicates the position of maximal pressure for each maneuver.

C. Test Summary window or data window

This window displays the test data as the maneuvers are being performed. The data are updated after each maneuver and when the references are changed in the setup option.

The average values and the standard deviation are calculated from the best three maneuvers.

In a rectangle with white background, there is information about the reference and patient name.

Unlike in the spirometry, in the maximal pressure test the maneuvers are ordered as they are being performed. This is made because it is important to follow the patient evolution.

Although the maneuvers are stored in the memories in temporal order, the best three maneuvers in the window «Best maneuvers» are ordered from worst to best one (the best maneuver is the one with a higher pressure value).

It is important to point out that, although the program has space for 5 maneuvers, more maneuvers can be performed.

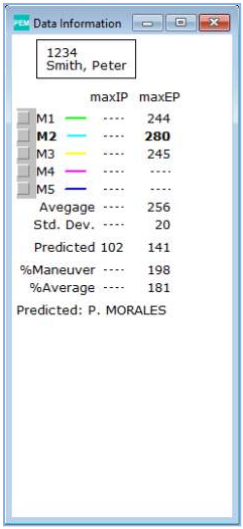
After performing the sixth maneuver, the first performed maneuver will be deleted (M1), provided that this is not the best. If this were the best maneuver, then the second one would be

deleted (M2). Once the corresponding maneuver has been deleted, the system will reorder them, and the performed maneuver will be M5, the M5 will be M4, the M4 will be M3, and so on.

D. Selecting and deleting maneuvers

The value of the selected maneuver is shown in bold type, to indicate that it will be used in certain actions, specially to delete it through the menu option Tests / Delete, to store the maneuver in the database, and to represent its curve in the report. (Check «Printing and/or saving to the database»).

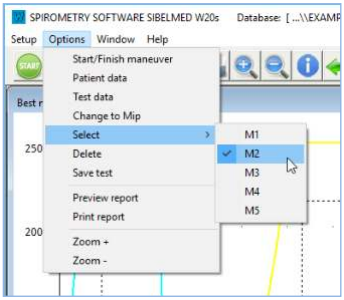
By default, the program automatically selects the best of the maneuvers.

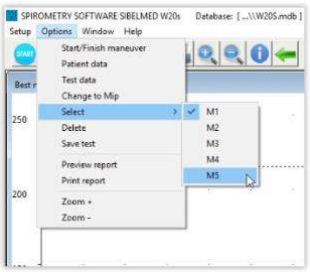


To select a memory maxIP different to the best:

1 Make sure that the inspiratory procedure is activated through the icon MEP MIP or the menu option Test / Change to MIP (the time axis in the window «Best maneuver» must be in the upper part).

1 In the menu Test / Select, click on the desired maneuver, or in the window «Summary», click with the

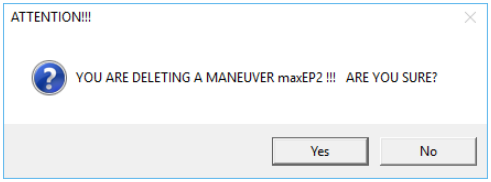




cursor over the maneuver to be selected, within the area limited by the emphasized rectangle, as indicated next:

To select a different MEP memory, perform also the step 2, previously making sure that the expiratory procedure is activated after step 1.

To delete a maneuver, first select it, and then enter the menu option Test / Delete. The following window will appear, requesting the confirmation."

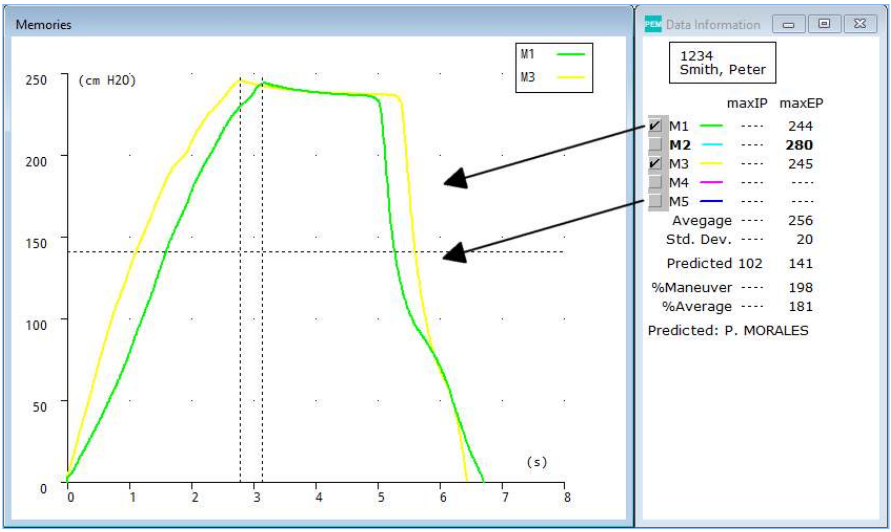


E. Window of memory display

This is a complementary window to the «Summary» window. It is activated when some of its check boxes are selected.

This window displays in one time axis the overlapping graphs

of the selected maneuvers. The user can adjust the graphs to the desired size.



It is useful for comparing the shape of maneuvers and to observe the difference between the instants when the values of maximal pressure took place.

A2.6. PRINTING AND/OR SAVING TO THE DATABASE

The system displays, stores or prints the values for all the maneuvers. However, only the curve for one maneuver is printed and stored in the database.

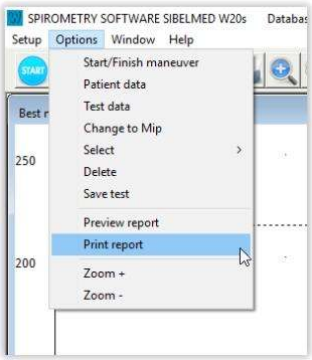
The system selects by default the curve for the best. Depending on the technician's opinion another curve can be selected.

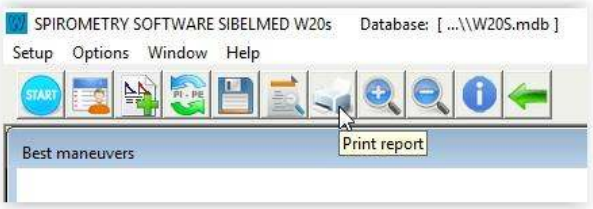
To select a different maneuver from the one automatically selected by the software, check the section «Selecting and deleting maneuvers».

After the desired maneuvers of expiratory and inspiratory pressure have been performed, the following operations can be performed:

A. PRINTING RESULTS

A report will be performed, which presents the same information of the window «Summary of the test», together with the patient data and the curves for the selected maneuvers.





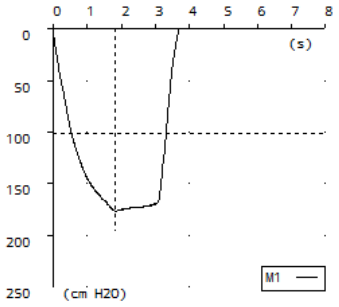
SIBEL S.A.U.
Rosellón 500
08026 – Barcelona (Spain)

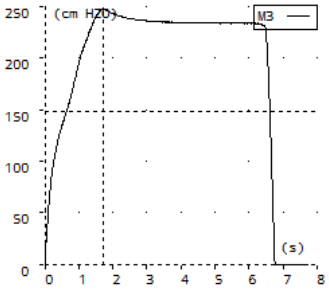
ID Code:	1234	Date:	31-03-2016	Time:	11:37
Name:	Smith Peter				
Sex:	Male	Age(y):	36	Height(cm): 176	Wgt(Kg): 80
Temp(°C):		Pres(mmHg):		Humidity(%):	Smok.I.:
Reason:					BMI : 25.8
Procedence:					
Technician:				Transducer: Disk	
Predicted:	P. MORALES			Ethnic F.:	
F.BTPS:	1.000				
Version:	511-BLA-2.00				

MAXIMUM PRESSURES REPORT SIBELMED W20s

	maxIP	maxEP
M1	177	244
M2	160	245
M3	162	248
M4	0	0
M5	0	0
Avegage	166	245
Std. Dev.	9	1
Predicted	102	147
%Maneuver	173	168
%Average	162	166

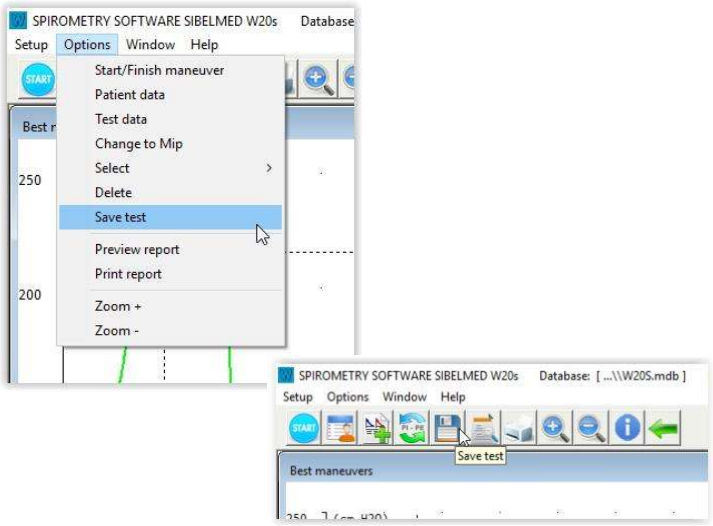
Comments: .....
.....



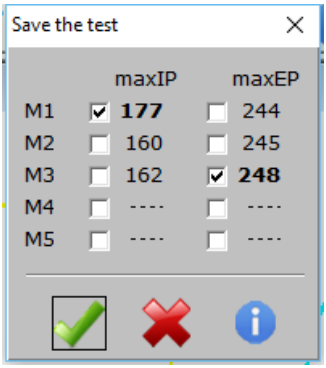


B. SAVING TO THE INTERNAL DATABASE

The following window will appear, where you can choose the maxIP and maxEP curves to store in the database. The results of all the maneuvers will be stored, indifferently of the selected curves



The test is stored in the internal database of the device. Then it can be displayed, printed and/or transferred to a computer. The following message window will confirm that the test has been correctly stored.



ANNEX 3

BRONCHOCONSTRICTION TEST (OPTION)

A3.1. BRONCHOCONSTRICTION TEST PROCEDURE

A3.1.1. TEST DESCRIPTION

For the performance of the bronchoconstriction test is recommended, to those people who are not familiarized with this type of test, to check some bibliography about it. See: The European Respiratory Journal (Volume 6, Supplement 16, March 1993) or «Normativa para los Tests de Provocación Bronquial Inespecífica» by the Sociedad Española de Neumología y Cirugía Torácica", among others.

The bronchoconstriction tests consist of performing a forced spirometric test, before and after the application of different pharmacological or physical stimulus to the patient, and then evaluate the changes produced in the spirometric parameters, specially the drop of FEV1. Notice the test has several forced spirometric maneuvers and the best maneuver is selected, to include it in the summary report according to the criteria in the different standards.

Next, there is a short description of the different steps taking part in the configuration process.

The steps described are not the only possible, although the most accepted ones.

The spirometer can perform the test according to two different methods:

- **Normal or continuous method**

This method consists of applying to the patient a certain concentration for a specified time.

- **Abbreviated method**

This method consists of applying to the patient a certain number of inhalations of a certain concentration.

The procedure in both cases is the same. The variation lies in the way of applying the medicine. In the first case the patient breaths the concentration for a while and in the second case inhalations are applied in order to make it quicker.

The steps of the test are:

1st **BASAL** (BAS)
Perform a basal spirometry.

2nd **DILUENT** (DIL)
Apply a diluent to the patient, if convenient, and perform a spirometry that compares to the basal.

3rd **CONSTRIC.** (BC1)
Apply first dose of bronchoconstrictor drug to the patient. After the stipulated time, perform the spirometry. It is compared to the DILUENT (DIS), or to the BASAL (BAS), if the diluent step has not been made. Go to the next step to continue with the test.

4th **CONSTRIC.** (BC2)
Repeat the last step, but with the second dose of drug.

5th **CONSTRIC.** (BC3)
Repeat the last step, but with the third dose of medicine. The process can be repeated while needed. The system allows the application of a maximum of 10 doses of bronchoconstrictor drug CONSTRIC. (BC10).

6th When the lung function parameters show a significant response, after a new confirmation, or according to the criteria of the operator who makes the test, the bronchoconstriction test can be finished. The system analyses and shows the value of PD20, both graphically and numerically.

7th **CONST + DILAT**
Finally, once the test is finished, the bronchodilator drug has to

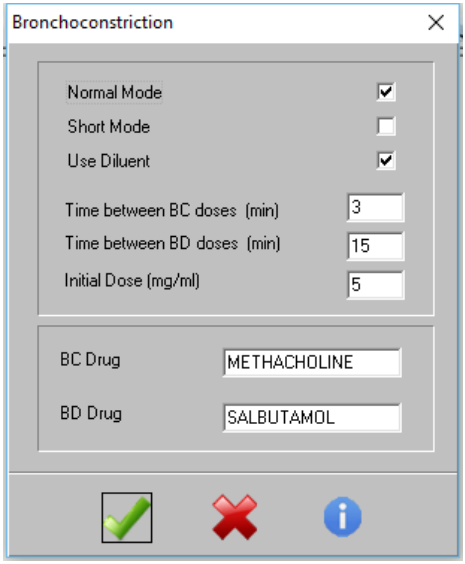
be applied to reverse the induced bronchoconstriction. Up to two steps can be made in this mode.

A3.1.2. INPUT OF TEST DATA

To start a bronchoconstriction test select the patient in the database or create a new patient as described in the chapter **«FORCED VITAL CAPACITY FVC TEST PROCEDURE»**.

Click the icon «BCONST» in the toolbar or select the menu option Tests / Bronchoconstriction. Enter the test data.

The following setup window will appear:



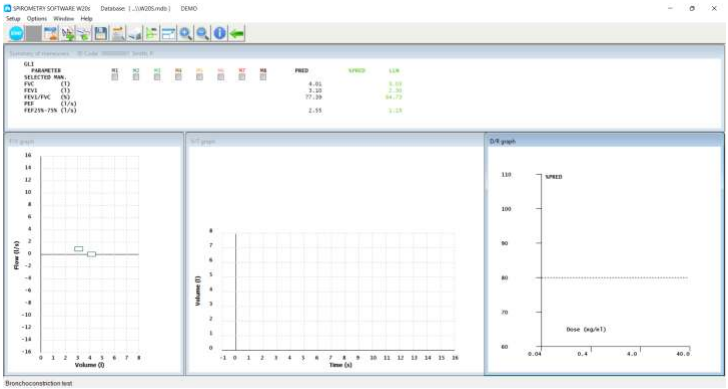
- Select the method or functioning mode
  - Normal mode
  - Abbreviated (short) mode
- Select if diluent is going to be used
- Define the time between the application of the ronchoconstrictor medicine and the start of the maneuvers.

- Define the time between the application of bronchodilator medicine and the start of the maneuvers.
- Enter the initial dose of the bronchoconstrictor medicine in mg/ml
- Write down the bronchoconstrictor medicine
- Write down the bronchodilator medicine

Once the previous data are filled in, press the OK button. In addition to the F/V and V/t graphs, a window displaying the D/R graph (Dose/Response) is also shown.

A3.1.3. TEST PROCEDURE

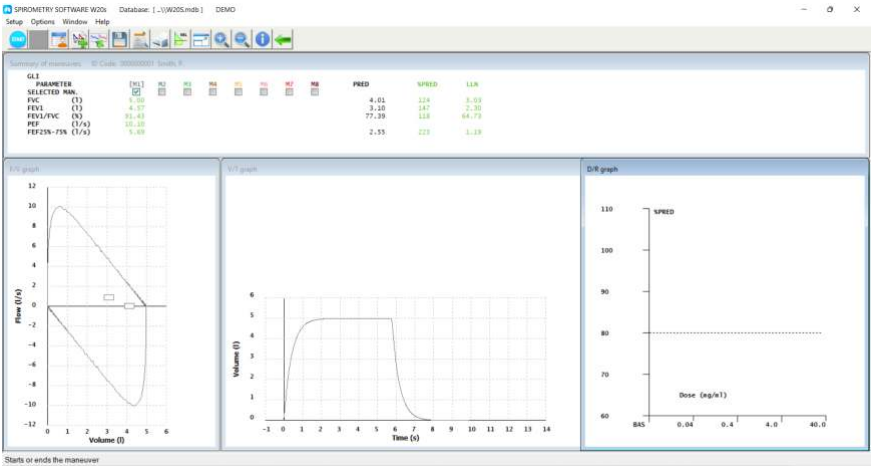
As commented above, the Bronchoconstriction test is based on performing forced spirometries after the application of different doses of medicines and controlling the drop of FEV1.



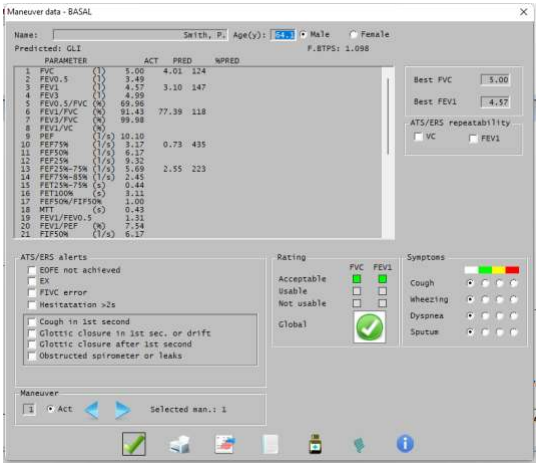
The steps for the test are the following:

1st Step: BASAL (BAS)

Start the process of forced maneuvers as described in **ENTERING FORCED VITAL CAPACITY TESTS** section.



Once the adequate maneuvers are performed, click the «Maneuvers data» icon.



● The maneuvers are compared to the values of the patient reference.

● The «Report» button brings out the test report up to the performed step.

● The «Delete» button deletes the selected maneuver.

● The «Summary» button shows the data summary of the performed steps.

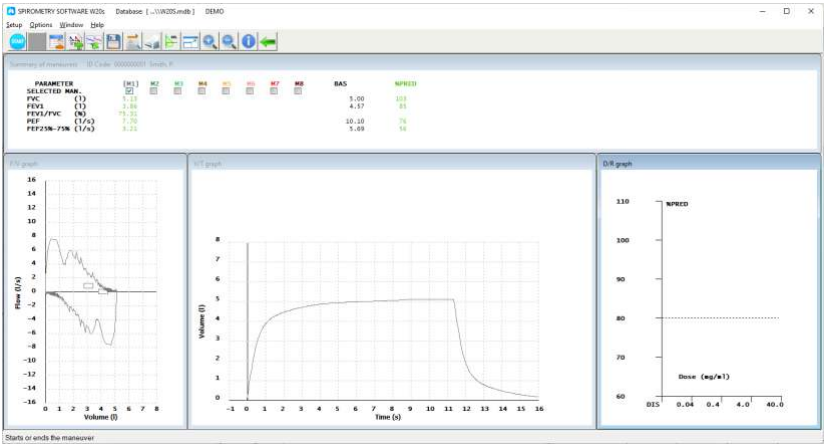
● The «Dose» button saves the best maneuver and goes on to the next step. This button is disabled when entering the bronchodilation stage.

● The «Dilat» button saves the best maneuver and goes to the bronchodilation step. This button is disabled unless the diluent stage has been performed.

Press «Dose» to save the maneuver and go to the next step.

2nd Step: DILUENT (DIL)

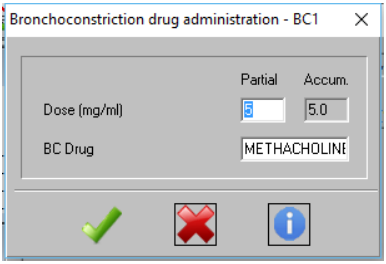
Apply the diluent with neutral PH to the patient, if you have selected this option. Start a new selection of forced maneuvers, once the normalized time has elapsed.



- The maneuvers are compared to the stored basal.

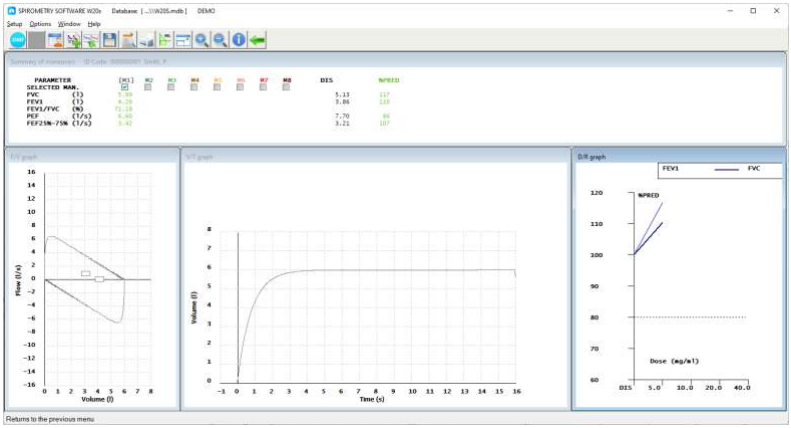
- The «Maneuvers data» button opens the dialog with the maneuver data.

After the adequate maneuvers have been performed, press the «Maneuvers data» button to display the data and again «Dose» to save the best maneuver and go to the next step.



3rd Step: CONSTRIC. (BC1)

Modify the data if necessary. Apply the first dose of bronchoconstrictor medicine and press «OK». Start a series of maneuvers again.



- The chronometer is activated at the top left of the dose/ response window after application of the medicine. When the countdown has finished, an alarm rings indicating that the programmed time has finished.

- The chronometer resets and goes off when the next maneuver begins.

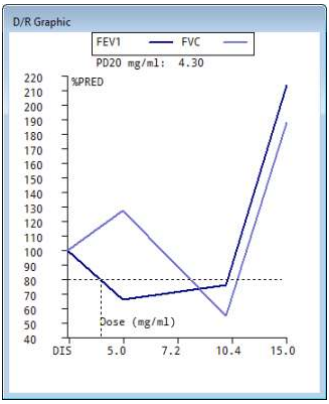
- At any time when the chronometer is on, you can click on it to stop the countdown, reset it or stop the alarm. The action taken over the chronometer depends on its state.

Store the best maneuver in a similar way to the previous steps, once the maneuvers of the constrictor step have been performed.

4th Step: CONSTRIC. (BC2, BC3, ... BC10)

The same procedure as in the previous step but for the second, third...tenth dose, as they are necessary.

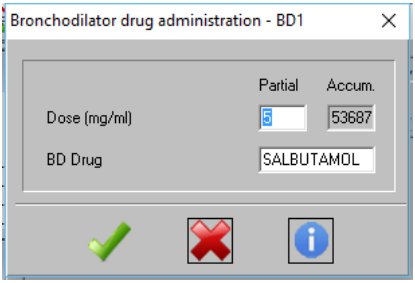
When the FEV1 value drops under 20%, with regard to the diluent or the basal values, if the diluent has not been made, the graphic dose / response shows the value for PD20.



The graphic dose /response is shown mathematically adjusted by means of a logarithmic function (y = C1 + C2 log (x)) if the determination coefficient is greater than the 80%. In this case, the calculation of PD20 is made solving it in the adjustment equation. If the determination coefficient is lower than 80%, the graphic is presented linearly and the calculation of PD20 is made by linear interpolation.

5th Step: CONSTRICTION + DILATATION (BD)

When finishing this test, if you need to give the patient a bronchodilator medicine in order to revert the resultant bronchoconstriction, click the «Dilat» button in the Maneuvers data dialog.



- Enter the data for the bronchodilator medicine and press «OK». The chronometer will be enabled and will return to the tests screen.

- Apply the bronchodilator to the patient.

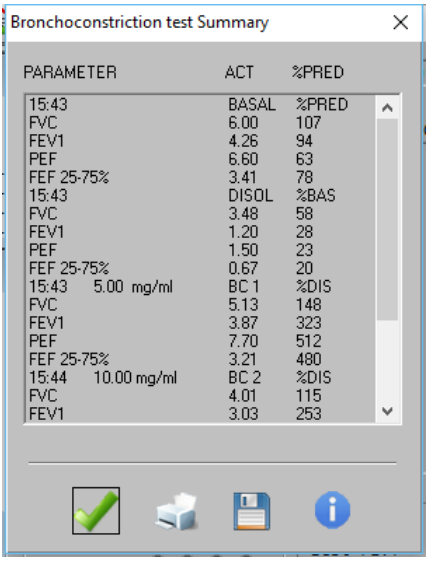
- After the normalized time, perform a series of maneuvers.

- Store the best maneuver, and repeat the previous process if necessary.

A3.1.4. SUMMARY, PRINTING and/or SAVING OF THE TEST

The summary of the bronchoconstriction is presented in graphic form (graphic dose/response previously shown) or in numeric form (summary of data displayed next).

Open the summary by clicking the «Summary» button in the Maneuvers data dialog.



- The «Report» button sends the report to the printer.

- The «Save test» button saves the test in the database. The graphs are saved if it is indicated in the setup options.

- Take into account that the observed values are compared to:

- Basal: to the selected reference

- Diluent: (if performed) to the Basal

- Constriction: to the Diluent step, if performed. Otherwise, to the Basal

- Dilatation, to the Basal.

ANNEX 4

COMPLIANCE WITH THE GENERAL DATA PROTECTION REGULATION AND PROTECTION MEASURES

A4.1. COMPLIANCE WITH THE GENERAL DATA PROTECTION REGULATION

This section is intended to facilitate the user compliance with the legislation in force in relation to the processing of personal data that are regulated and covered by the General Data Protection Regulation (EU) 2016/679 on the protection of individuals with regard to the processing of personal data personal data and to the free movement of such data.

A brief description of the fundamental points of said legislation is given and what needs be done with the **SIBELMED W20s** Spirometry Software and/or operating system in order to comply with the requirements of said law is described.

IMPORTANT WARNING

- **According to current legislation, the software's user is solely responsible for the storage and treatment of their patient data in accordance with the law.**
- **Observance of the recommendations included in this section does, in no case, guarantee the full adaptation of user activity to the standards relating to data protection.**

Requirements which specifically affect the use of the SIBELMED W20s Spirometry Software

Identification and Authentication

The processes for user identification and authentication for use of the **SOFTWARE W20s** are performed by the PC's

operating system. Therefore only Windows Operating Systems which allow the performance of said processes in a secure way are valid, i.e. Windows 7, Windows 8.1 and Windows 10 with an NTFS file structure. Windows 9x systems or FAT file structures are not valid.

The PC administrator must create a unique and personalized identification for each user and activate authorization verification. The operating system saves the passwords in an unintelligible way.

Access control

The Operating System must be set up to control the access to data, i.e. permit or deny access to data. Likewise, the PC administrator must set up the user account lock in order to impede reiterated attempts for unauthorized access, limiting 3 incorrect attempts. Consult the manual for the operating system in order to set up said system access controls.

Access register

Accesses to the different databases are stored on the one access register file.

Back-up copies (back-up and recovery)

The user must, at least once a week, make back-up copies of all data in order to guarantee full recovery of data in the case of a computer system failure. In the case of the Spirometry Software, full recovery of all database data is guaranteed if the entire BDSIBEL directory of the application directory is saved.
In order to restore the program configuration (visible parameters, selected predicted set and diagnostics, window layout, user data, etc.) you must incorporate to the backup copy the W20.INI and W20_LOCAL.INI files, located in the ..\SIBEL\W20s folder.

Said back-up copy must be stored at all times in a different place to where the equipment on which the software is used is located.

Operating System Setup

On a Windows operating system level (On a Windows operating system level (Windows 7, 8/8.1 and 10) and for NTFS partitions, it is possible to restrict the access to the different databases using the security characteristics of said file system. Generally speaking, the control of access to databases is covered by the following points:

Setup of Identification and authentication

Each user that accesses the system must have a unique username and password, whether a local user or a network user connecting to a domain. The passwords must be changed at least once a year and, whilst a series of passwords remain valid, they will be stored in an unintelligible way.

It is recommended to use the Windows password policy so that users use strong passwords (minimum password length, use of characters and numbers, upper and lower case, special characters) and to enable password history, so that users cannot use previous passwords. It is recommended that users do not have Administrator access level. In any case, the Administrator is responsible for users using their identification in the ways determined both technically and by documentation, as well as for informing them of their obligations regarding the processing of personal data.

It is also advisable to activate the security audit in order to register valid and erroneous accesses to the system.

Access setup and control: File access grants

The following step is to set up the access levels to the files which form the databases in relation to the previous users.

The database root can be found in the <W20s_HOME>\Bdsibel directory. Inside, there is a subdirectory per database, as well as the register file «log» ESPWIN.log. One possible setup is to provide full access to the <W20s_HOME>\Bdsibel directory to all users (or al least to the application users) and to restrict access to each of the subdirectoriesaccording to the user that they belong to. In any event, the owner must always have read and write access for their subdirectory and the files that make up the subdirectory. The rest of the users may have access to said database totally denied, for example. It must be taken into account that in this situation the users may only access their database from the application. On the log file ESPWIN.log level, it would be advisable for the users to only have read access so that the application could register the accesses to the different databases.

Permissions can be applied from Windows Explorer itself. Simply access the Properties of the directory of file to which you wish to establish permissions and select the Security tab. From this tab you can select both the users who may access and the permissions (total control, read, modification, write, etc.) of each user.

Encryption of data

It is advisable to proceed with the encryption of the data. For that, the tool Bitlocker, included in the operating system (in Pro versions), can be used or some other tool available from third parties.

File audit.

We recommend the activation of the log file audit in order to register on the security event viewer the actions performed upon it.

To activate this option, you must first enable the audit of

said file. At this level, you must specify the users (according to the users which access the <W20s_HOME>\Bdsibel directory) and types of access to be audited. The log file audit can be activated from the Security tab of the file Properties. Using the Advanced button you can access the Audit tab. From here, simply add the users and the type of access to be audited. It must be taken into account that if all actions upon the log file are audited, the security events viewer will have many more entries and will complicate the monitoring of unauthorized accesses.

The next stop is to activate the audit of access to objects in the local security setup. To do so, access the Administrative Tools icon from the Control Panel. Once there, you must select the Local Security Directive and the Local Directives branch from the directives. You must then access Audit Access to Objects. Both correct and erroneous accesses can be enabled.

Finally, other files must be audited, for example password files <W20S_HOME>\Bdsibel <<>NAME_DB>\PW.TXT if access to the NAME_DB database by other users has not been completely limited.

Access register description

Access to the different databases are stored on the one log file (ESPWIN.log) in the BDSIBEL folder of the directory where the application is installed (by default C:\SIBEL\W20s and from now on <W20S_HOME>\Bdsibel).

This file is created the first time that the application is executed and cannot be deactivated The system administrator is responsible for the maintenance of said file with regard to size, and the preparation of a monthly report where the periodic reviews carried out are analyzed and any problems detected are reported, should there be any.

The log file is saved by line:

- Time and date of access
- User
- Database accessed
- Action carried out on the database
- Type of access (authorized or denied)
- File path of database accessed
- Reference of the register accessed

The format of each of the lines is the following:

[DATE TIME], [USER], [DATABASE], [ACTION], [ACCESS], [PATH], [ID_CODE_RECORD]

The database is comprised of a directory and the file database_name.mdb. The actions to be registered are divided into:

- Action on the actual database itself (open, close, delete, etc.)

- Action on the registers stored on the .mdb data file (insert, consult, delete, etc.)

In any event, the register or access control «log» file, must be kept for a minimum period of two years.

Below, all actions registered on the log file are listed:

- Opening database
- Closing database
- Selecting database
- Creating database
- Removing database
- Deleting records (patients)
- Deleting records (tests)
- Changing access password
- Querying record (patient)

- Querying record (test)
- Adding record (patient)
- Adding record (test)
- Deleting record (patient)
- Deleting record (test)
- Changing record (patient)
- Changing record (test)
- Exporting record (patient)
- Exporting record (test)
- Importing record (patient)
- Importing record (test)

Other important subjects

· Printing documents:

In the case of storage for paper prints containing patient details, it is required that said documents remain duly safeguarded in such a way that only duly authorized personnel have access to them. Likewise, in the case of a user deciding to dispose of the printed documents, it will be necessary to ensure their effective physical destruction in order to avoid unauthorized access to data.

· Exporting tests

The software allows for tests to be exported only if the user is identified and authorized to read the database. Once the test has been exported to a file, the software user is responsible for the security of said file, and its later deletion.

· Data transmission:

The software permits the transmission of files with patient data via the internet. If this functionality is used, the user must configure their e-mail server so that the data is encrypted before transmission and is therefore converted into unintelligible data for any unauthorized access.