DATOSPIR TOUCH

USER'S MANUAL

CE 0318

511-B00-MU2 • REV. 2.04 • 2025-07

Sibelmed®

SIBEL S.A.U.,
Raimon Casellas, 6-8. 08205-Sabadell (Barcelona). Spain.
National Sales: Tel. 93 436 00 08 e-mail: comercial@sibelmed.com
International Sales: Tel. +34 93 436 00 07 e-mail:export@sibelmed.com
Technical service: Tel. +34 93 433 54 50 e-mail: sat@sibelmed.com
Web: www.sibelmed.com

COPYRIGHT
No part of this publication may be reproduced, transmitted, transcribed, stored in a backup system or translated into any language or computer language in any form or by any means, electronic, mechanical, optical, chemical or manual without the express written consent from SIBEL S.A.U.

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.
• The repairs, revisions or modifications, in warranty or not, are made by technical staff of SIBEL S.A.U
• The device is used by qualified staff in accordance with the recommendations stated in this User's Manual.

INDEX

1. SAFETY 6
1.1 INTENDED USE 6
1.2 INTENDED USERS 6
1.3 INDICATIONS FOR USE 7
1.4 INTENDED PATIENT POPULATION 7
1.5 LIMITATIONS FOR USE 8
1.6 CONTRAINDICATIONS 8
1.7 SIDE EFFECTS 8
1.8 ESSENTIAL PERFORMANCE 8
1.9 RESIDUAL RISKS 9
1.10 WARNINGS: ELECTRICAL RISKS 9
1.11 WARNINGS: RISKS OF EXPLOSION 10
1.12 WARNINGS: RISKS OF CONTAMINATION 10
1.13 WARNINGS: RISKS OF INTERFERENCE 10
1.14 OTHER WARNINGS 11
1.15 DISPOSAL OF ELECTRICAL AND ELECTRONIC DEVICES BY DOMESTIC USERS IN THE EUROPEAN UNION 11
2. INSTRUCTIONS FOR INSTALLATION 12
2.1 INTRODUCTION 12
2.2 MODELS AND OPERATING MODES 13
2.3 LAYOUT OF CONTROLS AND CONNECTORS 18
2.4 INSTALLATION AND START-UP 19
3. DEVICE CONFIGURATION 25
3.1 SETUP 25
3.2 CUSTOMIZATION 25
3.3 INTERNAL DATABASE 31
3.4 MAINTENANCE PROGRAM 32
3.5 QUALITY CONTROL: CALIBRATION CHECK 33
3.6 CALIBRATION PROCEDURE 36
3.7 CALIBRATION RECORD 37
4. SPIROMETRIC TESTS PROCEDURES 38
4.1 FORCED VITAL CAPACITY «FVC» TEST 38
4.2 QUALITY OF FVC TEST 48
4.3 POST BRONCHODILATION TEST 51
4.4 SLOW VITAL CAPACITY «VC» TEST 53
4.5 MAXIMUM VOLUNTARY VENTILATION «MVV» TEST 53
5. COMUNICATION SYSTEM 55
5.1 TRANSFERRING TESTS TO THE PC 55
5.2 TRANSFERRING EQUIPMENT CHECK DATA 55
5.3 ADDING MODULES, OPTIONS AND/OR TRANSDUCER 57

5.4 UPDATING FIRMWARE 57
5.5 EXPORTING TESTS TO OTHER SYSTEMS.....59
6. TECHNICAL SPECIFICATIONS.....60
6.1 GENERAL SPECIFICATIONS 60
6.2 SYMBOLS.....62
6.3 TESTS, FUNCTIONS AND PARAMETERS 63
6.4 PREDICTED SETS.....65
6.5 FVC INTERPRETATION (DIAGNOSIS).....66
6.6 TRANSDUCERS 66
6.7 MANUFACTURER'S LIABILITY.....67
7. CLEANING / DISINFECTION 68
7.1 CLEANING THE DEVICE 68
7.2 PREVENTIVE MAINTENANCE 71
7.3 CORRECTIVE MAINTENANCE.....72
Annex 1. ELECTROMAGNETIC COMPATIBILITY 73
Annex 2. COMPLIANCE WITH GENERAL DATA PROTECTION REGULATION.....75

DATOSPIR touch has been designed by the **R+D+I Department** of **SIBEL S.A.U.**, with the collaboration of the Pneumology Service of Hospital de la Santa Creu i Sant Pau de Barcelona, in line with the standardization criteria of International Institutions: **ATS/ERS TASK FORCE 2019** (American Thoracic Society/ European Respiratory Society) and National Institutions: **SEPAR** (Spanish Pneumology and Thoracic Surgery Society).

CE 0318 **COMPLIANT PRODUCT WITH MEDICAL DEVICE REGULATION (UE) 2017/745**
Class IIa

Revised
Date: 2025-07
Technical Director

Approved
Date: 2025-07
Sales Director

1. SAFETY

This user manual includes the necessary information for:
- the use of the **DATOSPIR** touch (Easy-D, Easy-F, Easy-T, Diagnostic-D, Diagnostic-F, Diagnostic-T) with the Transducer Module (Disposable, Fleisch or Turbine) to perform spirometry tests (measurement of lung flows and volumes),
- and the **DATOSPIR** touch with the MIP-MEP Module for maximum pressure testing. Additional information for MIP-MEP testing can be found in a specific user manual.

DATOSPIR touch (including the Modules) 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.
Report any serious incident to the manufacturer and competent authority.

1.1 INTENDED USE

a) Measurement of lung flows and volumes for the diagnostic and control of respiratory diseases (Asthma, COPD, etc.).
b) Measurement of inspiratory and expiratory maxima pressures for the respiratory diagnostic.

Use in a health centre or similar indoor use (not for outdoor use). Not intended for home use or for use in moving transport vehicles.

1.2 INTENDED USERS

The device is intended to be used by or under the direction of a medical professional. Specific training in the technique of Spirometry and Maximum Pressures is recommended.

⚠ **The spirometric bronchoconstriction test must be supervised by a technician qualified in this technique.**

⚠ **Before using the spirometer on patients, you should be familiar with the operation of equipment. All information necessary for its operation is available in this Manual.**

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

1.3 INDICATIONS FOR USE

DATOSPIR touch is a portable desktop spirometer to measure the amount (volume) and speed (flow) of air that a patient breathes in and out in a given time. The graphical representation of flow and volume curves and the calculated parameters are helpful in assessing the lung function of patients.

DATOSPIR touch 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 spirometer is also indicated for evaluating the health status of individuals in occupational medicine, for assessing preoperative risk or for medicolegal assessment.

DATOSPIR touch is a useful tool for providing an accessible and accurate diagnosis of 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.

1.4 INTENDED PATIENT POPULATION

The intended patient population for spirometry testing is as follows:

a) Age: more than 4 years until elderly
b) Weight: > 15 Kg
c) Height: > 90 cm
d) Health status: physical and mental condition that allows the performance of the forced manoeuvre.

The intended patient population for Maximal Respiratory Pressures testing is defined in the MIP-MEP Module User's Manual.

1.5 LIMITATIONS FOR USE

An analysis of the results of spirometry or maximum pressures tests is not enough to give a correct diagnosis of the patient's clinical condition. The patient's records and any tests that the clinician believes necessary must therefore also be considered. A doctor must interpret all data to determine the course of treatment required.

⚠ **The symptoms presented by the patient prior to performing a test should be considered by the healthcare personnel. The acceptability of a test is the responsibility of the health personnel.**

⚠ **Spirometry and maximum pressures tests require the patient's cooperation. The physician should assess the patient's ability to perform these tests. Pay special attention to children, elderly and handicapped persons.**

1.6 CONTRAINDICATIONS

No contraindication has been identified for spirometry nor for 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.

1.7 SIDE EFFECTS

Some patients may occasionally experience exhaustion during spirometry. In such a case, the test should be stopped and the patient's condition reassessed.
No side effects have been identified for the MIP-MEP test.

1.8 ESSENTIAL PERFORMANCE

It is considered essential performance the measurement of parameters related with spirometry (flow and volume) and maximal pressures (fulfilling

the specified accuracy and/or indicating that the manoeuvre is not correct), the display of results, saving and integrity of data in memory. It is not considered essential performance the communication with the computer nor the printing of the results.

1.9 RESIDUAL RISKS

According to the application of the EN ISO 14971 standard, all risks related to the use of the **DATOSPIR** touch equipment 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: ELECTRICAL RISKS

According to EN 60601-1 the device is classified as continuous operation mode.
To avoid the risk of electric shock, this equipment must be connected to a power supply with protective earth only.
The spirometer is **NOT** designed for use under other conditions or using other power sources not indicated in this manual. Use only accessories specified in this manual.
DO NOT tamper with the integrity of the system's electric earth connection. Protection against electrical discharge is provided by the connection of the chassis to an electrical earth connection.
The earth connection is only effective when the three-wire power cable supplied with the equipment is connected to a suitably earthed electrical socket.
DO NOT use multiple mains sockets to NOT degrade the electrical safety.
DO NOT disassemble the equipment or accessories casing.
The device must only be serviced and repaired by skilled personnel.
The contact with voltage inside the device may cause serious injury.
DO NOT connect a line phone to the MIP-MEP connector.
DO NOT use damaged accessories.
DO NOT use the equipment if the power cable is in poor condition or cracked.

Take care **NOT** to place the equipment where it could be splashed by water or other liquids or cover it with objects that prevent air

from circulating around it while it is running.
The equipment should **NOT** be used adjacent to or stacked with other equipment.
To ensure vital safety features under the EN 60601-1 standard, only equipment compliant with the electrical safety standards in force may be connected to this device. To connect **DATOSPIR** touch to a non-medical device as a printer or PC, they must be compliant with EN 60950 and the installation must provide an additional safeguard. This safeguard could be an additional ground conductor connected to the metallic enclosure of the non-medical device (contact to Technical Support to see if it is practicable) or a USB separation device provided by the manufacturer **SIBEL S.A.U.**

NEVER immerse any part of the equipment in liquid. **THIS COULD CAUSE AN ELECTRIC SHOCK**. Consult the section **7.1.**

1.11 ⚠ WARNINGS: RISKS OF EXPLOSION

NOT suitable for use in the presence of volatile anaesthetics, flammable gases or in oxygen-rich environments. **THIS MAY CAUSE AN EXPLOSION.**

1.12 ⚠ WARNINGS: RISKS OF CONTAMINATION

To avoid the risk of contamination or cross infection, the **Turbine** and **Fleisch** transducers and some of the optional modules must be disinfected before use in a new patient or must be used with an **adequate protective barrier filter** compatible with the equipment (see section 7.1).
Reusable mouthpieces must also be disinfected. **Disposable** transducers and disposable mouthpieces must **NOT** be reused.

DO NOT use mouthpieces or other supplies from manufacturers that have not tested their biocompatibility, since it could endanger patient health.

1.13 ⚠ WARNINGS: RISKS OF INTERFERENCE

This is an electronic medical device; therefore, requires special precautions regarding electromagnetic compatibility (EMC): it must be installed and put in service according to the information attached in **Annex 1. ELECTROMAGNETIC COMPATIBILITY**.

As this is an electronic product, high frequency emissions may interfere with its correct use. Thus, keep the spirometer away from products that may generate interference (radios, cell phones, etc). All accessories, transducers, cables and spare parts must be original and must be requested from the manufacturer or dealer, to ensure patient safety and ensuring the proper operation of the spirometer. Failure to do so may increase the emissions or decrease the immunity of the equipment

1.14 ⚠ OTHER WARNINGS

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

The equipment should be placed in a safe position to avoid falling that may result in equipment damage or harm to the patient and/or user.

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

⚠ **Never dispose the DATOSPIR TOUCH, the Modules, its accessories and/or its batteries in the household trash. It must be disposed of properly and may need to be recycled in accordance with the statutory requirements in your country.**

The device uses a lithium battery and could use an optional NiMh battery.
Information on proper disposal is available from your dealer or from Technical Support at **SIBEL, S.A.U.**

2. INSTRUCTIONS FOR INSTALLATION

2.1 INTRODUCTION

DATOSPIR touch is a compact device based on different types of transducers: **Fleisch, Turbine** or **Lilly disposable**, a wide high-resolution color touch screen and an internal thermal printer. Has an internal database to store the performed tests and also allows connection to an external printer via USB. In addition, it may incorporate a **Weather Station** to measure pressure and humidity (it includes a **temperature sensor**) and a **MIP-MEP** module to measure Maximal Inspiratory and Expiratory Pressures.

Furthermore, the spirometer may be connected in real or deferred time to a **PC** via **USB** or **Bluetooth®** technology, using the **W20s Spirometry software** to perform tests, download tests results from the device to permanent records, print hard copies of selected data or transfer test to telemedicine platforms or clinical information systems, interactively test the device and transfer information on the status of the device.

The spirometric Pulmonary Function Tests that the **DATOSPIR** touch can perform 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 spirometer. These algorithms compare the measured values against predicted normal values. **DATOSPIR** touchincludes 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.

2.2 MODELS AND OPERATING MODES

The **DATOSPIR** touch series is available in 6 different models

- **DATOSPIR** touch EASY-T
- **DATOSPIR** touch EASY-F
- **DATOSPIR** touch EASY-D
- **DATOSPIR** touch DIAGNOSTIC-T
- **DATOSPIR** touch DIAGNOSTIC-F
- **DATOSPIR** touch DIAGNOSTIC-D

This manual is intended for all models and options of the **DATOSPIR** touch. Therefore, only specific options and functions of the model available will be applicable in each case.

The following table shows the **standar**d features and **optional** functions for each model.

The spirometer has three possible different transducers:
- Turbine Transducer
- Fleisch Transducer
- Disposable Transducer (Lilly type)

And two software configuration choices:
- Easy – for occupational and primary care
- Diagnostic – for lung function laboratories (occupational and primary care also included).

	Easy			Diagnostic		
	D	T	F	D	T	F
TRANSDUCERS						
Disposable transducer		■	■		■	■
Turbine transducer	■		■	■		■
Fleisch transducer	■	■		■	■	
SETTINGS						
Occupational Medicine Mode						
Primary care Mode						
Diagnostic mode	▲	▲	▲			
1.000 test internal database with graphics				▲	▲	▲
3.000 test internal database with graphics	■	■	■			
Bronchoconstriction module	■	■	■			
W20s Spirometry software						
CONNECTIVITY						
USB to extern printer connection						
USB to PC						
Bluetooth technology module	■	■	■			

Included □ Optional ■ Not included ▲

2.2.1 OPERATING MODES

There are 3 operating modes available. Choose the settings that best fit your needs:

• **Diagnostic Mode (DG):** Orientated to **Lung Function Laboratories**. This is the most complete mode. Practically all the functionalities of the device are available and it allows you to use whatever operating mode.

• **Primary care Mode (PC):** Orientated to **Primary Care**.
It includes quality alerts to assist you in producing high quality spirometry tests. Direct access to FVC, Bronchodilatation, VC and MVV tests.

• **Occupational Medicine Mode (OC):** Orientated to **Prevention Centers and Mutual**. Ideal for "screening", it is easy to use and allows you to perform FVC and Bronchodilatation tests.

FUNCTIONALITIES	OC	AP	DIAG
FVC			
VC			
MVV			
Bronchodilation (Post)			
Bronchoconstriction			
Alternated V-T & F-V plots			
Simultaneous V-T & F-V plots			
Superposed curves			
Acoustic signal for begin and end of maneuver			
Time-based progress bar (adult incentive)			
Volume-based progress bar (adult incentive)			
Parameter and plot selection (customization)			
Calibration program			
Cal-check			
Large graphs on reports			
Print/save 3 maneuvers			
Print 3 PRE maneuvers (data and graphs)			
Time-audit module			
Miller Interpretation			
Snider, Kory&Lyons, NLHEP (Ferguson) Interpretation			
ATS/ERS (McKay) Interpretation			
Quality of the FVC test (NLHEP: QC prompts, QC grades)			
Help screen in all menus			
Pediatric incentives			
Device auto-check program			
Import external patient data			
Export data to Health Information Systems			
Exportación de datos a HIS			

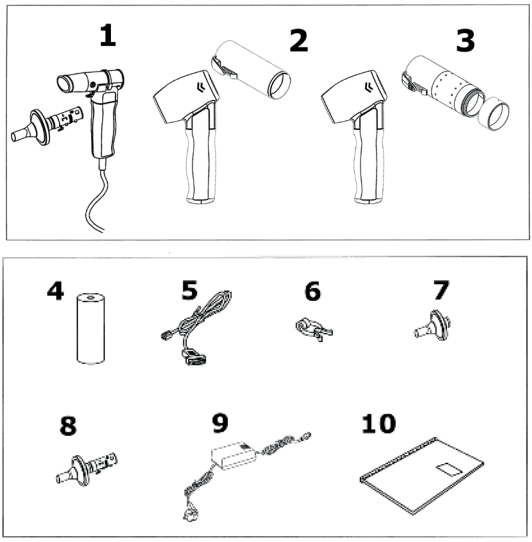
Included Optional Optional

A model can be upgraded at any time by adding the corresponding parts. To do so, please contact the **SIBEL S.A.U. Sales Department** or your dealer.

2.2.2 PACKING LIST

	Easy			Diagnostic		
	D	T	F	D	T	F
TRANSDUCERS						
1. Disposable transducer module	Included	Optional	Optional	Included	Optional	Optional
2. Turbine transducer module	Optional	Included	Optional	Optional	Included	Optional
3. Fleisch transducer module	Optional	Optional	Included	Optional	Optional	Included
ACCESSORIES STANDARD						
4. Thermal paper 110x50 (2 u)	Included	Included	Included	Included	Included	Included
5. USB and printer cable connection	Included	Included	Included	Included	Included	Included
6. Nose clip (5 u)	Included	Included	Included	Included	Included	Included
7. Bacterial-viral filter (5 u)	Not included	Included	Included	Not included	Included	Included
8. Disposable transducers with filter (5 u)	Included	Not included	Not included	Included	Not included	Not included
9. External power supply	Included	Included	Included	Included	Included	Included
10. User's manual	Included	Included	Included	Included	Included	Included

Included Optional Not included



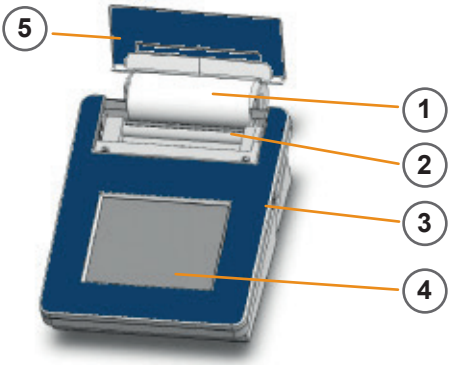
2.2.3 OTHER PRODUCTS, ACCESSORIES OR SPARE PARTS

COD.		Easy			Diagnostic		
		D	T	F	D	T	F
	TRANSDUCER MODULES						
09888	Disposable transducer module						
09890	Turbine transducer module						
09889	Fleisch transducer module						
	OPTIONS						
09891	MIP-MEP module (includes probe 03052 and mouthpiece 09803)						
	FIRMWARE OPTIONS						
07060	Bronchoconstriction module						
07061	Concurrent display of V/t & F/V						
07062	Database upgrade to 3000 records						
07068	Diagnostic model Upgrade. Includes weather station and Bluetooth technology modules						
	PRODUCTS AND ACCESORIES						
08290	Calibration syringe (3 L)						
02692	Nose clip bag (5 u)						
09698	Bacterial-Viral filter (5 u)						
03169	Disposable transducers (50 u)						
09718	Disposable transducer with filter (5u)						
03175	Turbine transducer						
09887	Software W20s						
01149	Paediatric Mouthpiece adapter						
06186	Fleisch Transducer						
06187	Fleisch filter (3u.)						
	SPARE PARTS AND COMPONENTS						
05636	Calibration adapter for disposable transducer						
07155	Transducer holder						
07233	Weather station module						
07193	Bluetootht technology module						
02634	Thermal paper 110x50 (5 u)						
07238	Rechargeable battery						
07283	Carrying Bag						
01145	Bluetooth adapter for PC						
03658	USB 2.0 and printer cable connection						
08165	Galvanic isolator for USB 2.0						

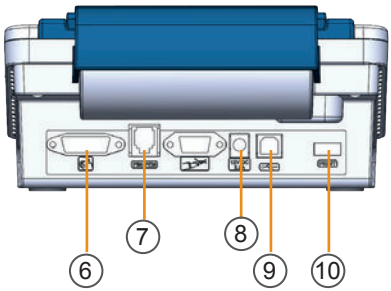
Included Optional Not included

2.3 LAYOUT OF CONTROLS AND CONNECTORS

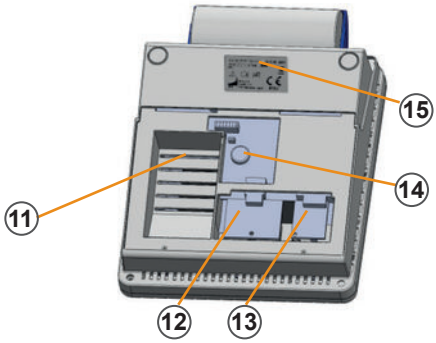
FRONT PANNEL



REAR PANNEL



BASE



⚠ Do not connect any product, accessory or component not provided by SIBEL,S.A.U.

1. Internal printer (thermal paper roll).
2. Lever to lock/unlock the paper roll.
3. ON/OFF button
4. Color graphic touch screen (640 x480 pixels).
5. Printer casing
6. Transducer Connection: Fleisch, turbine or Lilly disposable
7. MIP-MEP Connection
8. Power supply connection
9. USB connector for PC
10. USB connector for external printer
11. Rechargeable battery location
12. Electronic Weather Station board connection
13. Bluetooth technology board connection
14. Lithium battery CR1632
15. Specifications plate

2.4 INSTALLATION AND START-UP

This device has been manufactured using solid-state professional components under strict quality controls. However, accidents may occur during the transportation or storage of the equipment, and it is therefore wise to initially check its condition and that of its accessories before installing them.

⚠ **If you detect any damage to the packaging, contact the haulier agency and distributor immediately before starting the installation. Packaging must not be disposed of until the correct working order of the device has been fully verified.**

2.4.1 START-UP

⚠ **DO NOT get them wet or expose them to very abrupt changes of temperature.**
Handle accessories by their strongest parts (e.g., the connectors when manipulating the USB cable). DO NOT apply excessive stress to the accessories, avoid pulling or bending any part of the cables.
DO NOT disconnect the cable from the device by pulling the cable. You can damage the device or accessories reducing the product's safety. Hold always the cable by the connector.

1 Connect the **external power supply** to the socket no.9, located on the rear of the device, and to the mains.
The power supply should be placed to allow an easy disconnection for any emergency situation. The disconnection from electrical main is performed through the plug of the power supply.

2 Insert the plug of the **transduce**r cord into the socket no.6

3 Connect the other **optional modules** that you have acquired. Consult the specific user's manuals.

4 Press the **ON/OFF button** (no.3).

5 Choose the language

6 Enter the **PIN** number, if equipment protection is enabled.

See the chapter **3.2.4 EQUIPMENT PROTECTION.**

The first time the equipment is started, the protection is disabled and the **PIN** is set to **0000**.

7 If equipment protection is not enabled or if the correct **PIN** has been entered, the **MAIN MENU** will then be displayed, which varies according to the model:





Access to the FVC test



Access to the Post Bronchodilation test



Access to the VC test



Access to the MVV test



Access to the Bronchoconstriction test



Access to the MIP-MEP test



Quality control procedure: Calibration check



Access to the Internal database/ Database customization



Printing a report



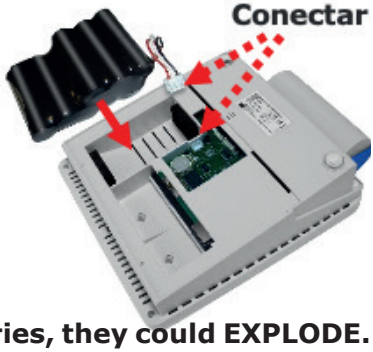
Access to the Setup options: Calibration, Customization and Maintenance.

Pressing on the black area of the screen you may enable / disable the main menu buttons.

2.4.2 RECHARGEABLE BATTERY: INSTALLATION AND CHARGE

El **DATOSPIR** touch operates optionally with r**echargeable Ni-Mh battery** (9.6V ≥2000mAh) with an autonomy of **1.5 hours** approx.

⚠ **Installation must be carried out by qualified technical personnel accustomed to handling electronic devices.**



To install the battery, remove the base cover and insert it where indicated in the figure.

The battery is recharged by connecting the device to the power supply, even though the device is turned off.
The charging time is about 20 hours.

⚠ **DO NOT charge other type of batteries, they could EXPLODE.**

Remove old batteries to avoid they could spill its substances.

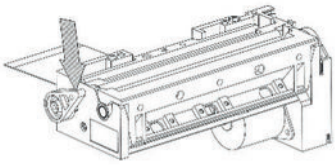
2.4.3 POWER SAVING

To save power, when working with battery, the device includes an auto switch off system that turns the equipment off when the screen is not accessed for **one minute**, except in tests screens. In this case, you will be prompted to save the data before powering off.

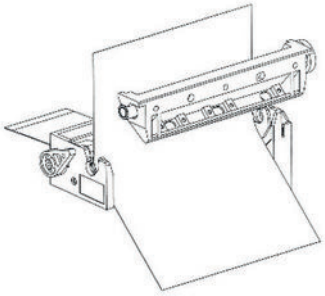
The state of the battery shoud be checked periodically and extracted from the device if it is not going to be used for a long time.
When the device is connected to the power supply, the backlight turns off after not accessing the screen for **two minutes**. The device will sleep until one key is pressed, recovering the information previously displayed.

2.4.4 PLACEMENT OF THE PAPER INTO THE INTERNAL PRINTER

Lift the printer cover and press the tab located on the right-hand side of the printer to unlock the cylinder.



Place the paper roll into its housing and pull out about 20 cm of paper towards the unit screen, ensuring that it is properly aligned. Reinsert the cylinder into the printer, on top of the paper, with the cogwheel on the left-hand side, press until it clicks. Pass the paper through the slot in the cover and close it.
A screen will appear to pull the paper forwards/backwards. Pull out the amount of paper that you deem necessary. To cut the paper, pull it sideways.



2.4.5 CONNECTION TO AN EXTERNAL PRINTER

Select the **external printer** option in the **COMMON CUSTOMIZATION** menu. Connect the USB cable into the socket n.11 (PRINT) and the other end to the printer..



Contact the manufacturer or dealer for a list of compatible printers.

2.4.6 USB CONNECTION TO PC

To connect the device to a PC, install the **USB driver** and the **W20s Spirometry Software** in the PC. Consult the **W20s Spirometry Software User's Manual.** Then, connect the correct end of the USB cable to the socket n.10, and the other end to the computer.



2.4.7 BLUETOOTH CONNECTION TO PC

If you have purchased this module with the device, it will be already installed. Otherwise, you must remove the cover from the base of the device and insert the **Bluetooth technology board** where is shown in Figure.

⚠ **The following steps must only be carried out by technical personeel used to dealing with electronic devices.**

Then, in both cases, connect the

Bluetooth adapter to the PC and simply install the software included. To do so, consult the **Bluetooth adapter user's manual.**



Install the **W20s Spirometry Software** to the PC and choose the Bluetooth technology link option, consult the **W20s Spirometry Software User's Manual**, included in USB.

The Bluetooth technology is enabled (and disabled) by accessing the Bluetooth technology option on the **COMMON CUSTOMIZATION** screen of the device. (See section **3.2.3**). Once the Bluetooth adapter has been configured in the PC, a connection will be established every time the equipment and the PC are started. The PC is then ready to receive the data transmitted by the equipment.

2.4.8 INSTALLATION OF THE WEATHER STATION

As in the previous case, if you have purchased the weather station module with the device, it will be ready to use. Otherwise, remove the bottom case of the device and insert the **weather station's board**, as shown in the figure.



⚠ **The following steps must only be carried out by technical personeel used to dealing with electronic devices.**

3. DEVICE CONFIGURATION

3.1 SETUP

Press  and access to the options of the **SETUP MENU:**

1. CUSTOMIZATION 

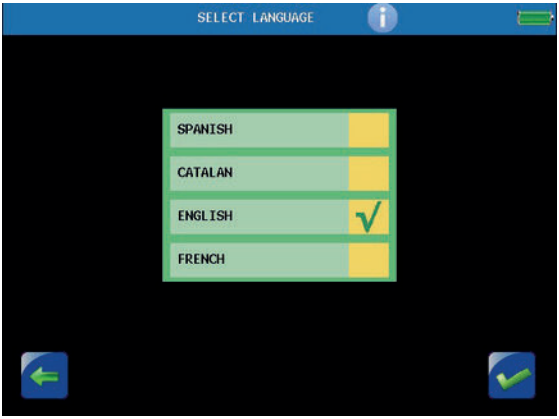
2. MAINTENANCE 

3. CALIBRATION 

3.2 CUSTOMIZATION

3.2.1 INITIAL CUSTOMIZATION

When the unit is turned on for the first time, the following screen will appear:



Select the desired language to operate with the device, by pressing on the yellow square. This mark √ ewill appear on the option selected. Validate the selection by pressing  .

3.2.2 TOOLBAR CUSTOMIZATION





It displays the values of atmospheric parameters: **Temperature, Pressure** and **Humidity**. The temperature is automatically obtained from an internal sensor incorporated to the spirometer and its value will always appear in the tools bar. If you acquire the **weather station** module; besides temperature, will be shown the real values of pressure and humidity. Otherwise, touch this label to enter them, manually.



Touch on this label to choose the operating mode among Occupational Medicine, Primary Care or Diagnostic. (EASY: OC, AP / DIAGNOSTIC: OC, AP DG).



The device has been developed to make it user-friendly. Ease of use is assured through **context sensitive help screens** that explain every **DATOSPIR TOUCH** feature, by touching this icon .

Touch this icon to adjust **brightness**.



Clock – Calendar: Pulse encima de este icono para ajustar la hora y la fecha.

Power supply cord detection / **Battery status:** It displays the levels of battery charge by the segmented battery icon. When this icon turns red the battery is nearly discharged and it must be recharged. See the battery's charging procedure in section **2.4.2**.

Touch this icon to enter directly to the **SETUP MENU.**

3.2.3 PERSONALIZACIÓN COMÚN

If you wish to change any logging parameter, do so under this menu.

Access this option by pressing  , from the main screen,

and then  .

The options included in the **CUSTOMIZATION MENU** are:

 **Default Configuration:** This option memorizes a user-defined customization program status.

 Load configuration: restores the default customization.

 Save configuration: Allows you to save the current configuration as the default.

 **Internal Database customization**

- Number of registers to be advanced if performing a fast advance using the database search engine
- Save 3 maneuvers from the FVC test
- Sort database

 **Common customization**

 Language

 Enter a report header

 Select the printer type: internal or external

 Set clock-calendar: time and date

 Set units: cm/Kg, in/lb, ºC/ºF or mmHg/hPa

 Main menu icons (enable/disable)



Equipment Protection code (PIN)

 Bluetooth: (enable/disable)

 Initial customization: main menu icons, spirometry parameters, units, predicted, interpretation, incentive chart, pin, printer configuration and report header.



Spirometry customization

 Select the Operating mode.



Selection of mode NIOSH. Enables the check and printing of the report in accordance with the recommendations of the program CWHSP of the US National Institute for Occupational Safety and Health (NIOSH).

 Incentive for children and adults



Time audit: (enable/disable) show the time when the spirometry maneuver was performed

 Predicted sets :

- Choose predicted set among several authors for children and adults
- Prioritizes the age range selected for adults if a different table is chosen for children.
- Extrapolates the values for the ages outside the selected table range.
- Ethnic factor

 Observed parameters: (This is only at display level or for the report. All the parameters are saved on the database and can be enabled at any time).



Graphs and report customization:
- Save graphs on the database
- F/V- FVC Report
- V/T- FVC Report
- VC Report
- MVV Report
- D/R Report
- Present ZSCORE
- Print large curves
- Print 3 curves PRE
- Print Data of 3 best maneuvers PRE



Interpretation: Select diagnosis according to **ATS/ERS, Miller, Snider/Kory/Lyons or NLHEP**. Printing the interpretation.



Quality control alerts:
- Display of quality alerts to assure compliance with **ATS/ERS (EX, ET) or NLHEP** criteria (QC Prompts)



Calibration check alerts:
- Date of the last calibration
- Require a daily Calibration check
- Enable the use of the Device without Calibration check.



Bronchodilation test customization



Bronchoconstriction test customization (See the Bronchoconstriction user's manual)



MIP-MEP customization (See the MIP-MEP user's manual)

Press  to validate the values entered and to pass to the following screen,  to cancel and  to escapes the actual screen and to move back to the previous one.

3.2.4 EQUIPMENT PROTECTION 

In compliance with the General Data Protection Regulation, the **DATOSPIR** touch has a protection option accessed by a PIN of 4 digits to prevent access to the equipment and, more specifically, to the private data it contains by unauthorized people.

Enable this option in the CUSTOMIZATION MENU (consult section 3.2.3), by ticking the "PIN Enabled" checkbox and enter the PIN in the "New Pin" boxes. To change the PIN, you must enter the current one in the "Current Pin" box and then the new one in the "New Pin" boxes. The PIN can be disabled again by entering the current PIN and unticking the "PIN-enabled" checkbox.

If enabled, a screen will appear requesting the PIN, when the equipment is turned on:

ENTER PIN
0000

Enter the PIN and you may access to the main menu screen. If an erroneous PIN is entered three times, the equipment will lock and switch off. On restarting it, a screen will appear requesting the **unlock code or PUK** (supplied upon purchasing the equipment).

UNLOCK CODE (PUK)
0000000000000000

If the correct code is entered, the device will unlock and the main screen will appear. From then on, the equipment will return to its initial status (Protection disabled and PIN 0000). If an erroneous code is entered, the equipment will remain locked.

3.3 INTERNAL DATABASE 

The **DATOSPIR** touch has an internal database to store the tests performed for later review, print and / or transfer to a computer (using the **W20s Spirometry Software**) or other computerized systems.

There are two storage capacities:

Database «L» (1000 tests)
Database «H» (3000 tests)

The database always saves all the spirometric parameters, despite them not being selected in  from the C**USTOMIZATION MENU (3.2.3).**

It is possible to save spirometric, Bronchoconstriction or MIP-MEP tests.

The base information remains, even when the equipment is turned off or the rechargeable battery is removed.

Press  from the main menu:

 **Browse database:** Display of the registers saved.

 Search patient: by **ID** code or **last name**. In addition, you may:

- Display tests
- Print tests
- Delete tests

 Delete database.

 Print summarized report of all the test saved into the database


Database customization:

- Number of records
- Save 1 or 3 maneuvers in tests, etc.
- Choose type of organization (ID or last name)

3.4 MAINTENANCE PROGRAM

The equipment has an internal diagnostic program to perform system checks and several adjustments.

⚠ DO NOT OPEN the instrument to carry out the maintenance program. Doing so, within the WARRANTY PERIOD WILL VOID THE WARRANTY.

From the main screen, press  and then . The MAINTEANCE MENU options are:


Equipment's hardware Check-up:



CPU



ADCs check-up


Touch panel


Printer


Reindex the database


Reset all variables


ATS curves pre-saved: checkup of the product with pre-saved standard curves FVC, VC, MVV


Calibration and/or maintenance alerts.

 Adjust of screen brightness and Internal printer contrast.

 **Dealer's data.**

 **Equipment configuration:** change from positive VC to negative VC or vice versa-

 **Adding a new transducer.** Enter the pre-calibration code, delivered by the After-sales service with the new transducer, to activate it and to load the corresponding calibration factors.

 **Adding a new option.** Enter the new Activation code delivered by the After-sa**les service to enable the new option purchased.**

 **Display the current activation code.**

3.5 QUALITY CONTROL: CALIBRATION CHECK

The ATS/ERS TASK FORCE recommends that all spirometers be daily checked for calibration before further testing begins.

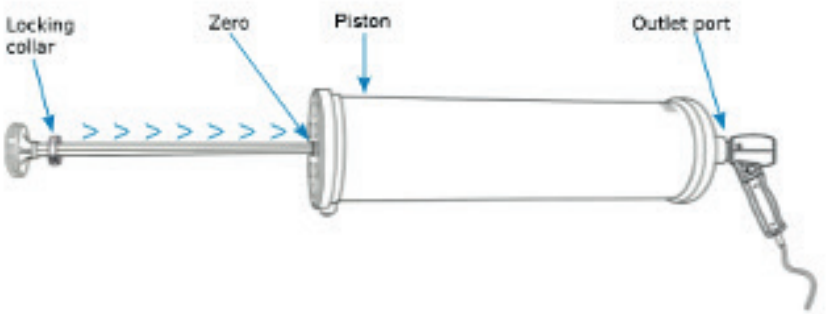
The possible aging or the accumulated dirt of transducers may do an inaccurate measure. In the Pneumotachometers, the relationship between the pressure drops and the airflow depends on the gas viscosity. This viscosity is also depending on atmospheric conditions of temperature, pressure, and humidity. This is the reason to carry out a calibration check every day to validate that the device is within calibration limits.

If a device fails its calibration check, then new calibration procedure or equipment maintenance is required to ensure the proper use of the Spirometer.

To verify that transducer operates properly, the spirometer includes a simple check-up procedure based on measuring the known volume of a calibration syringe.

Test procedure:

1 Couple the transducer to the outlet port of the syringe (between 3 and 6 L):



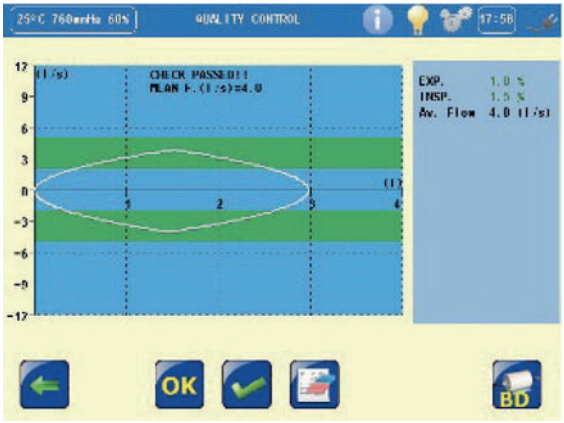
2 Power up the **DATOSPIR** touch and press  from the main menu.

3 Discharge the syringe **once** at every one of the following flow rates between 0-12L/s:

Low flow level: 0,4 – 1,2 L/s

Mid-flow level: 2 – 5 L/s

High flow level: 6 – 12 L/s



To simplify the procedure, the spirometer allows you to carry out a single maneuver at Mid-flow level: **2 - 5 l/s**.

4 Press  to cancel the maneuver or  pto accept it and go to the next range of flow.

5 At the end of the operation, press  to see the results of the maneuvers performed: the percentages of variation and calibration factors calculated as the average of all the maneuvers performed on a range flow.

6 If the session is correct, the results will be automatically saved to the **calibration record**. Press  to see the data of the record (**3.7**).

7 Once calibration check performed satisfactorily, access the Spirometry program to begin the tests.

8 If the calibration check is not correct, do a full calibration of the instrument. To do so, see **3.6 CALIBRATION PROCEDURE.**

The error at each flow should be less than **±3.5%**. The **expiratory and inspiratory factors remain unchanged** in this routine.

You can program the device, in the **COMMON CUSTOMIZATION**

menu, to **require a daily calibration check** before allowing access to any test. By default, this option is disabled.

3.6 CALIBRATION PROCEDURE

This procedure should be followed if the calibration check is not correct. The Calibration procedure is similar to the Calibration check, but in this case the **calibration factors** (expiratory and inspiratory) will be recalculated as the average of all maneuvers performed and applied on the spirometer. It will be necessary to perform 3 maneuvers at each flow level within the flow range 0 - 12 L/s.

To simplify the Calibration procedure, the spirometer allows you to carry out at least **3 maneuvers** at Mid-flow level: **2 - 5 l/s.**

To carry out the calibration procedure, press , then  and, finally, . Enter the necessary data described below and follow the instructions detailed in the section **3.6.**

- **Volume of the syringe:** 1-6L.
- **No. of Pulses** of the **Turbine transducer**. Each turbine is factory calibrated individually and is associated to a factor (3-digits) equivalent to the pulses/liter detected and printed on it.

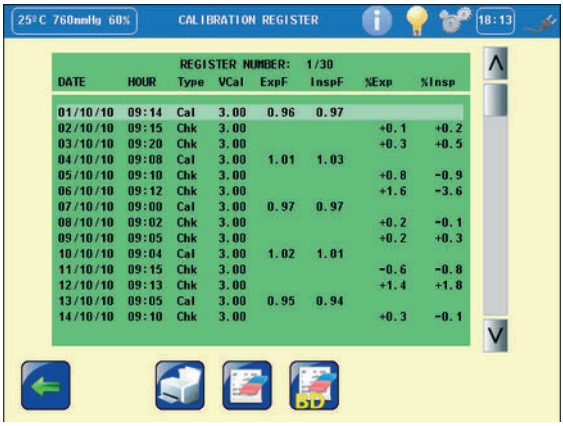
- **Transducer Factor:** the Lilly Disposable transducers are factory pre-calibrated with an associated calibration factor printed on each lot (3 digits). The Fleisch transducers are also Factory pre-calibrated with a calibration factor engraved on the side of each transducer (4 digits).

If several sessions have been performed, only the correct last one will be saved. Then, you can print a report with the calibration record. If calibration is performed to more than one level of flow, the results on screen and on the report will be sorted from lowest to highest flow.

3.7 CALIBRATION RECORD

The spirometer has a record containing the information of the last **350 calibrations check and calibrations performed**, indicating: date, time, volume accuracy percentage and average flow for inspiratory and expiratory factors. This is extremely useful for centers requiring a quality control of the processes they use and also to help define day-to-day laboratory variability.

From the results screen:



Press  to delete a record and  to delete the entire database.

Press  to print the calibration report. Use  to select the record desired.

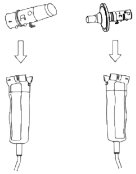
4. SPIROMETRIC TESTS PROCEDURES

The procedures to be completed to carry out the **Forced Vital Capacity «FVC», slow Vital Capacity «VC» and Maximum Voluntary Ventilation «MVV»** tests are very similar. Therefore, only one detailed description will be given in this section.

4.1 FORCED VITAL CAPACITY «FVC» TEST

1 Ensure that the transducer is plugged in the correct socket. Insert the antibacterial filter and/or the **disposable mouthpiece** into the transducer, as in the figures:

Lilly disposable



Fleisch and turbine



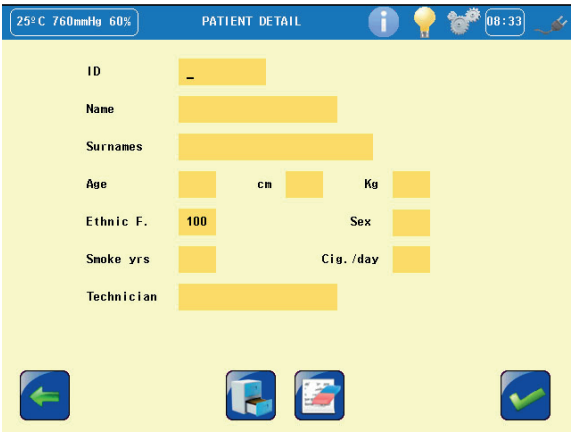
2 Turn on the device and press 

on the Main Screen.

The first time you carry out a spirometric test in a day, the device can advise you to **check the calibration**, according to ATS-ERS recommendations. Enable this option on the **SETUP MENU**.

4.1.1 ENTERING PATIENT DATA

Then, the following screens will appear:



ID: Patient identifier, 10-character alphanumeric.

Name: 20-character alphanumeric field

Surname: 25-character alphanumeric field

Age: Number of years, between 4 and 100.

Weight: Between 15 and 200 kg / Between 33 and 440 Lb

Height: Between 50 and 230 cm / Between 20 and 90 In

Sex: Male or female

Race: Ethnic Factor, between 80 and 120%. It is used in areas without their own predicted equations, so data needs to be corrected to a specific percentage. 100% is equivalent to the unmodified standard value of the predicted.

Smoke years: If the NHANESIII predicted set has been chosen, in the Customization menu, the RACE can be changed from the following groups: Caucasian, Afro-American and Hispanic.

C/d: Number of years the patient has been smoking

Technician Cigarettes smoked per day. Between 0 and 100. This helps to calculate the COPD index parameter.

Transducer 10-character alphanumerical technician's code or name.

Code: Transducer's pre-calibration factor (1)

(1) The disposable and Fleisch transducers are factory pre-calibrated with an associated calibration code that must be entered into the device for a correct measurement (a unique factor for each Fleisch transducer or for each lot of disposable transducers).

⚠ **The calibration factor may vary between Fleisch transducers or between disposable transducers lots. Verify that the factor entered into the equipment matches with the transducer that you are currently using.**

3 Enter the patient's details by pressing on each field.
An alphanumeric or numeric keyboard that will appear, depending on the field data type required. Enter patient's data and pres ENT .

If patient already exists in the database, press  to retrieve the patient's details from memory.

Once patient selected, the patient's ID will appear at the top of 

⚠ **To achieve high quality results, always use the nose clip.**

⚠ **Always use bacterial filters when you suspect of patient infection.**

4 Instruct the patient on the test performance, his cooperation is essential for proper implementation.

⚠ **The test must be carried out by medical staff. Review spirometry technique bibliography or request information about spirometry courses to SIBEL S.A.U.**

5 When the patient is ready and have assumed a correct posture, fit the nose clip. The subject must hold the transducer, without moving it, and wait until a blinking arrow appears on the screen. **The transducer must remain in the same position until the end of the maneuver.**

Incorrect



Correct



6 Patients can carry out the spirometry maneuvers in either of two different ways:

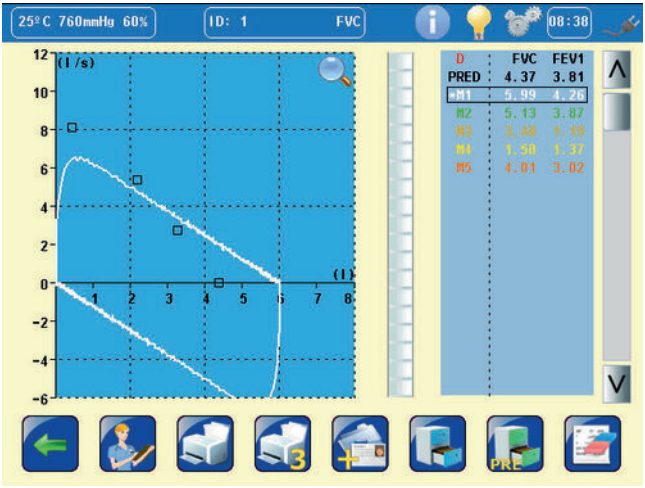
• Starting the maneuver with **FORCED EXPIRATIO**N followed by **FORCED INSPIRATION**, if desired.

• The patient breathes normally and when indicated by the technician, takes a deep breath completely filling his lungs, and then performs a **FORCED EXPIRATION** followed by **FORCED INSPIRATION**, if desired.



7 The device will detect the end **of maneuver** as ATS/ERS criteria and then will display the resulting graph and the parameters.

The maneuver performance can be ended at any time by pressing  which will appear on the bottom left-hand of the screen.



At the end of the maneuver, one or more of the QC Alerts (if the option is enabled in the Customization menu) may appear, alerting the technician as to whether the maneuver is in compliance with **ATS/ERS or NLHEP Quality Control criteria**. Consult the section 4.2.

ATS/ERS Criteria: The maneuver with least warnings is considered the best (ET, EX). With the same number of ATS/ERS warnings (ET, EX), the maneuver with the highest sum of FVC+FEV1 is considered the best.

8 Perform at least 3 maneuvers, but no more than 8, as this would tire the patient.

If 3 or more maneuvers have been performed and the FVC and/or FEV1 parameters blink on and off, this indicates that the **repeatability criteria** has been fulfilled for one or both parameters, according to the **ATS/ERS criteria**. This criterion indicates that the two best **FVC or FEV_1** values do not differ by **more than 150 ml if FVC is more than 1 liter or more than 100 ml if FVC is less than or equal to one liter**.

4.1.2 DISPLAYING RESULTS AND OPTIONS



At the end of the test:

- The current, predicted and best maneuver graphs are shown.
- On the summary frame, the FVC and FEV1 values of all the maneuvers performed will appear:

PRED: indicates the patient's Predicted value
*: indicates the current maneuver
Mx: indicates the selected maneuver

Maneuvers are sorted from best (M1) to worst (M8) according to **ATS/ERS criteria** and are shown in different colors: green for those that are acceptable and repetitive and from yellow to red the lower-quality maneuvers. In white, the current maneuver.

- Press  to enlarge or reduce the graph.

- Press on the plot  to switch from one graphic type to the other: Flow/Volume, Volume/Time, both or incentive and a small Flow/Volume graph.

• **Selection of the desired maneuver Mx:**

The scroll  allows you to move over the maneuvers performed and select the desired one **to see the graph, view the parameters, consult the diagnosis, delete or save a maneuver or print out a report.** (Consult the sections from 4.1.4 to 4.1.9)
By default, the maneuver selected is the best, M1.

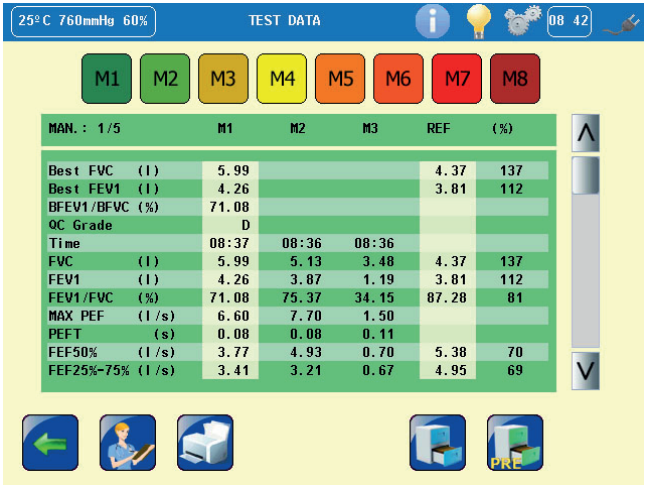
• Press  to change the **Incentive chart**

a Temporal bar: Progress bar in function of time, in three colors: red indicating less than 4 seconds, orange between 4 and 6 seconds and green for more than 6 seconds.
b Volume bar: Progress bar in terms of the expired volume. Red indicates 75% below the predicted value, the orange between 75% and 100% and green 100% above the predicted value.
c Incentives for children

• **Time audit:** show the exact time of testing have been carried out in the reports for a further monitoring.

• Press on ID area  to access the patient's data Screen.

• Press the  to display all parameters data of maneuvers performed.



• **Observed values** of the parameters selected in the **CUSTOMIZATION MENU.**
• **Predicted values** <REF> (If patient's data has been filled in)
• **% between both parameters. If an * appears after the REF test, this means that the predicted values have been extrapolated**
• The best **FVC** and **FEV1 values** (not necessary from the same maneuver).
• **QC grade**
• **ATS/ERS alerts**
• **Time audit.**

The screen only displays the results of 3 maneuvers and the predicted. By default, it appears the data of the 3 best maneuvers: M1, M2 and M3. To view the data of the other maneuvers performed, press on its button: M4, M5, M6, M7 o M8. The BEST maneuver is set at M1. Therefore, this will be used to display the interpretation, to print the report or to save the maneuver. The technician has the option to override this selection by **pressing**

M1, M2, M3, M4, M5, M6, M7 or M8.

4.1.3 DELETING AN EXISTING MANEUVER

Select the maneuver that you want to delete and press .

4.1.4 SAVING A TEST TO THE INTERNAL DATABASE

1 Select the maneuver you wish to save. The maneuver selected by default is the best (M1).

2 Press  to save **the best maneuver** or **the 3 best maneuvers** on the database, according to the option selected in **SETUP MENU** (Option not available in OC mode)..

4.1.5 VIEWING THE INTERPRETATION

Press  to view the interpretation According to the diagnosis available on your device's operating mode or depending on the customized option selected on the **CONFIGURATION MENU**: **Miller - ATS/ERS - Snider, Kory & Lyons or NLHEP.**

4.1.6 PRINTING A MANEUVER

Print the test report via the **internal or external** printer.
Select the desired printer on the **CUSTOMIZATION menu**.

Then, select the maneuver to be printed and press  to print the report of the maneuver selected and  to print the report of the 3 best maneuvers, if the "Save 3 Maneuvers" option is activated.

The report will include the parameters and graphs corresponding to the selected maneuver o 3 maneuvers. If you do not want graphs, certain parameters, the diagnosis and/or ATS/ERS warnings to appear, disable them on the **CUSTOMIZATION MENU**.

Moreover, by pressing  in the Main menu you may print:

 The last test performed



All the tests carried out during the day

 Whatever test you want of the database

4.1.7 OTHER TESTS ON THE SAME PATIENT

After carrying out the FVC test on a patient, you may do the following:

- A **VC** test on the same patient
- An **MVV** test on the same patient
- A **Post bronchodilator** test on the same patient
- Enter data for a new patient.
- Print the **general report** of all tests on the same patient

The spirometer saves the best maneuver of each FVC, VC, MVV and/or bronchodilator test to print a general report.

4.1.8 CHANGING PATIENT DATA/ ENTER A NEW PATIENT

 This option allows you to enter a new patient data or to modify existing patient data. (Follow the procedure described in the section **ENTERING PATIENT PARAMETERS**).

You may access to this menu by pressing on the ID area from the tool bar in any test.

If you have modified existing patient data (age, height, sex, etc.) the predicted parameters will be calculated again.

4.2 QUALITY OF FVC TEST 

DATOSPIR touch includes quality alerts to assist you in producing high quality spirometry tests. These alerts may be enabled or disabled in the **CUSTOMIZATION MENU**.

I. ATS/ERS ALERTS

To ensure good spirometry, the technician will 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 to preventing expiration from ending too soon.

Once the maneuver is finished, **one** or **two Alerts** may appear on the screen indicating that the maneuver has not been performed according to the **ATS/ERS criteria**:

ET This indicates that expiration did not end satisfactorily because the variation of accumulated volume during the last second of the maneuver was over 25 ml, or that the maneuver lasted for less than 6 seconds (in individuals 10 or older) or less than 3 seconds (in children under 10).

EX This indicates that the **expiration did not start satisfactorily** because the extrapolated volume was greater than 5% of the FVC or 0.15 liters. According to the ATS/ERS recommendations, this volume should be lower than 5% of the FVC or 0.15 liters, whichever is greater.

The technician performing the spirometry may disable these alerts in the **CUSTOMIZATION 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 classifying the order of the maneuvers.

II. NLHEP ALERTS: QC PROMPTS

In order to assess the pulmonary function of the patient, it is necessary to obtain acceptable test quality. The test quality depends on cooperation of the patient and this, in turn, depends on the quality of the technician's instructions.

Accordingly, **DATOSPIR** touch incorporates an automatic quality control function, based on the recommendations of the **National Lung Health Education Program** (**NLHEP**), with **prompts** to assist the technician in providing the good instructions to the patient to produce high quality spirometry tests.

At the end of a maneuver, a message on the screen will inform you as to whether the maneuver was acceptable or not. If not, a prompt will guide you on how to coach the patient to do it better. (See the rows in white of the following table).

As soon as the message "**Good test Session**" appears, do not carry out further maneuvers. If, even after repeated attempts, it is not possible to obtain an adequate number of good maneuvers, you should take a break, depending on how the patient feels or stop 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	The patient must start exhaling harder.
Blast Out Faster	Time to PEF higher than 120ms	The patient must exhale as hard, firm and fast as possible.
Blow Out Longer	ET error	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 at least the largest 2 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 at least the largest 2 FVC values matching within 150mL and 1L/s for PEF.	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 with at least the best 2 maneuvers match.	TEST COMPLETE. Adequate number of good maneuvers.

Referring to the quality of the last maneuver performed

Referring to the reproducibility of the maneuvers performed

III. 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 FEV1 values matching within 100mL and the largest 2 FEV6 values matching better than 100mL.
B	GOOD	At least 2 acceptable maneuvers with FEV1 values matching between 101 and 150mL
C	ACCEPTABLE	At least 2 acceptable maneuvers with FEV1 values matching between 151 and 200 mL
D	POOR	Only one acceptable maneuver, or more than one, but the FEV1 values match > 200 ml (with no interpretation)
F	NOT ACCEPTABLE	No acceptable maneuvers (with no interpretation)

4.3 POST BRONCHODILATION TEST

DATOSPIR touch allows spirometry tests: FVC, VC or MVV after the administration of a bronchodilator drug. For this, the tests should have previously been completed in PRE bronchodilator mode and saved to the PRE database.

The procedure to carry out POST-Bronchodilator spirometry is:

1 Complete an FVC, VC or MVV test to the patient as described in the **4.1** section before administration of the bronchodilating drug.

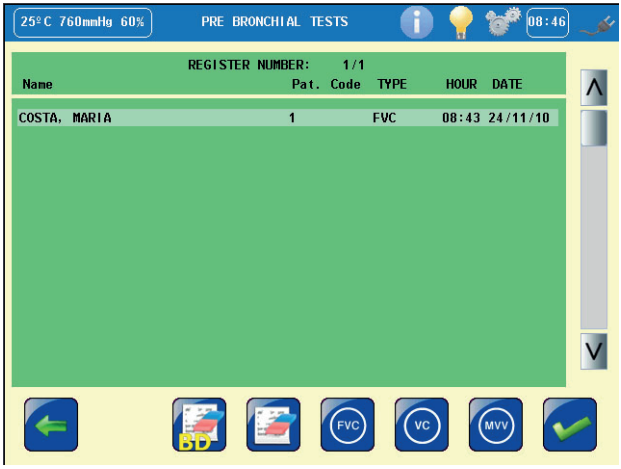
2 Save the **PRE** test in the database 

for comparison to the **POST**-Drug test.

3 Administer the dose of the bronchodilator drug prescribed and wait for the standardized period.

4 On the main screen, press 

. A screen similar to the following will appear which displays the tests saved in PRE mode.



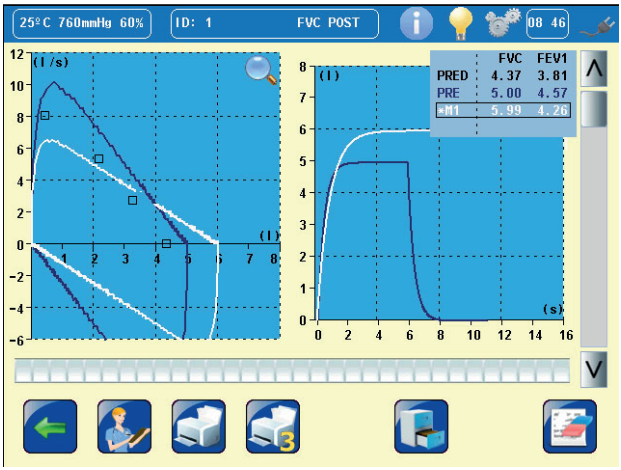
5 Select the PRE test with which to be compared and press  (FVC selected by default).

6 Using keys 

and 

, the VC and MVV tests can be seen and saved in PRE mode.

The screen then shows the two graphs (PRE and POST) for comparison purposes:



The data screen shows the observed values in PRE and POST mode and the method of comparison between them, depending on the option selected in the **CUSTOMIZATION MENU**.

- **Weighted % between PRE and POST**
- **% between REF (Predicted) and POST**
- **% between PRE and POST**
- **Difference between PRE and POST**

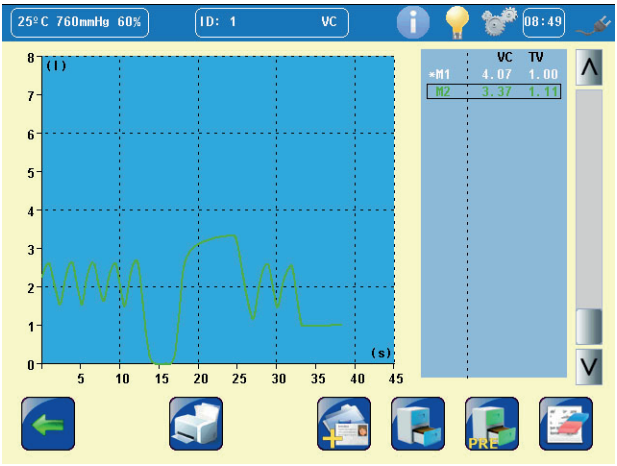
Thus, it may provide a single report of spirometric results before (PRE) and after (POST) application of a bronchodilator drug.

4.4 SLOW VITAL CAPACITY «VC» TEST

1 Access the test by pressing 

from the main screen.

- The **axes** are always displayed in **VOLUME/TIME** mode.
- The equipment saves a maximum of **8** maneuvers ordered according to the VC value, where M1 is the best VC and M8 the worst.
- The **maximum time** allowed for the maneuver is **45 seconds**.
- To measure the **ERV** and **TV** parameters correctly, each maneuver must **have at least four respiratory cycles**.



4.5 MAXIMUM VOLUNTARY VENTILATION «MVV» TEST

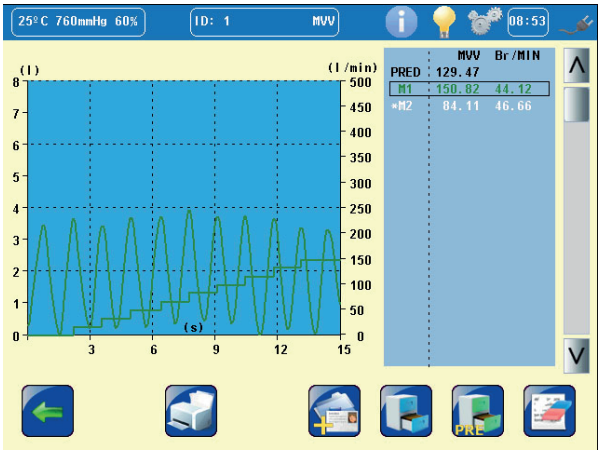
1 Press 

from the main screen.

2 Inhale and exhale completely without interruption for at least 12 seconds.

- The **axe**s are displayed in VOLUME/TIME mode.
- The **maximum time** allowed for the maneuver is **15 seconds**.
- The equipment saves a maximum of 8 maneuvers, ordered

according to the MVV value, where M1 is the best MVV and M8 the worst.



5. COMUNICATION SYSTEM

One of the strengths of the **DATOSPIR** touch is its Communications System, which allows the user to:

1. Transfer patient tests to a PC
2. Transfer Equipment Checking Data
3. Update Internal Software
4. Export patient tests to other Management Systems

Comunication can be made via USB (standard) or Bluetooth technology (optional).

5.1 TRANSFERRING TESTS TO THE PC

If you want to view, print, manage and/or save the tests to the PC, you must have **W20s Spirometry Software**.

The process to follow is:

1 Save the tests required in the device's internal Database

2 Install the **W20s Spirometry Software**, as detailed in its **User's manual**.

3 Load the data to the PC, by pressing  on the W20s Software. The screen shows a list of the tests transferred and you can select those to be imported to the PC Database selected in the W20s Software SETUP option.

4 Then you can select, view or print any of the tests imported or transferred to the PC.

5.2 TRANSFERRING EQUIPMENT CHECK DATA

The **DATOSPIR** touch includes a program that auto-checks the working order of certain parts of the equipment, displaying the information on the screen and saving it in an internal file.

• Hardware checkup

- Firmware checkup
- Equipment customization
- Calibration Record
- FVC test with standard curves

1 Start up the device, press  from the main menu and select **MANITENANCE**. Access the **Equipment Check option** and run all the sub options, following the instructions on the screen.

2 Connect the equipment and the PC via USB or Bluetooth technology.

3 Run the W20s Software, previously installed.

Run the previously installed **W20s Spirometry Software**, making sure that "**DATOSPIR** touch" is selected in **Configuration - Links** and access the **Configuration - Utilities - Download Data option**.

The transferred information is saved in the DATA directory of the application, in the files:

STATUS.CSV	Contains the errors detected
CALIBRA.CSV	Contains the calibration data
CONFIG.CSV	Contains the equipment customization
PRUEBAS.CSV	Contains the database tests
GRAFXxx.CSV	Contains the graphs in Flow/Time mode

The files from the previous transfer are renamed with the extension .OLD

4 If you want to view the information of any of the files, load them using EXCEL MICROSOFT.

5 If a problem is detected that the user is unable to solve, send the auto-check information by e-mail or fax to the **SIBEL S.A.U. After-sales Service or to your distributor**, who will analyze it and assess the cause of the problem, providing or proposing a suitable solution.

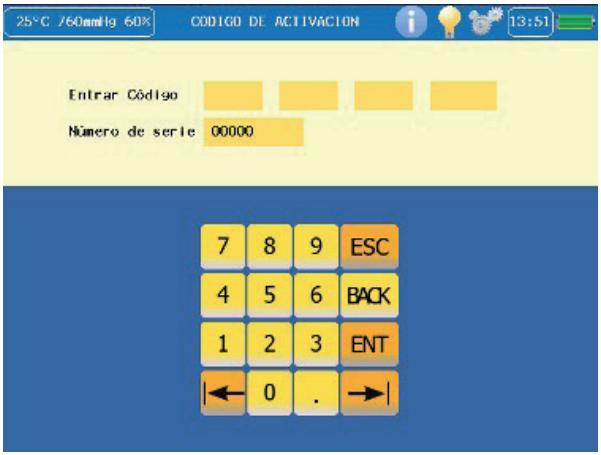
5.3 ADDING MODULES, OPTIONS AND/OR TRANSDUCER

If you want to add a module / option (MIP-MEP, bluetooth technology, weather station, bronchoconstriction, etc.) and/or a new transducer; please contact the **After-sales Service** who will send you the necessary components and the activation code.

Enter this code to the device by pressing on  from the main screen, and then  **(MAINTEANCE MENU)**.

Press  to add a new transducer and / or press  to activate a new module / option.

In both cases, the following screen will appear, where you must enter the activation code that will be delivered with the module or transducer.



5.4 UPDATING FIRMWARE

DATOSPIR touch contains internal software (firmware). **SIBEL, SAU** carries out improvements on it continuously. If you want to incorporate them into your device and use the last version of the

program, contact **After-sales Service**. This will send you some files to be stored in the same location and then follow these instructions:

1 Switch on the device.

2 Run the **W20s Spirometry Software** (the W20s in demo mode provided, upon purchasing the equipment, is enough).

3 Access the **Configuration - Links option**. Then, check that the **DATOSPIR** touch is selected. Access the **Configuration - Hardware Test option**. Run a communications test to check that the connections are correct

4 Access the **Configuration - Utilities - Update Flash option**. A dialogue box will be opened.
Next step number 5 is only necessary to update from version 1.07 to a new version.

5 Select in the computer system the file D150B.tsk and press "**Send**" (selecting previously [TSK] type files). The new file will transmitted in one minute depending on the computer. Switch off and on the device.

6 Select now in the computer the file **Load.prj** and press again the button "**Send**". The new program will be transmitted. The process may take around 10 minutes, depending on the PC.

7 Switch off the **DATOSPIR** touch .

8 Once loaded the program, **turn on the device holding pressed the ON / OFF button for 5 seconds.**

5.5 EXPORTING TESTS TO OTHER SYSTEMS

DATOSPIR touch can export the tests saved previously in the **Internal Database** to other management systems at other locations.
The equipment shows the information in **comma-delimited mode**, making it compatible with many different systems.

The information is available in the following files:

PRUEBAS. CSV	Contains the database tests
PATIENTS.CSV	Contains the database patients
GRAFxx. CSV	Contains the graphs in Flow/Time mode

The graph file, as indicated, contains the graphs for each test in Flow/Time mode. If you want to display the graphs in Volume/ Time or Flow/Volume mode in the new management system, the following aspects must be taken into account:

- The Flow signal is sampled at 100Hz.
- The ratio of the axes in the Volume/Time graph must be adjusted to 1 liter = 2 seconds.
- The ratio of the axes in the Flow/Volume graph must be adjusted to 2 l/s = 1 l.

In the event of doubt or queries, contact the **SIBEL S.A.U. Technical Support** or your distributor, who will provide any further information you may require.

6. TECHNICAL SPECIFICATIONS

6.1 GENERAL SPECIFICATIONS

Power supply	Input 100 to 240VAC, 50 - 60Hz Output 12V 2.5 A (Electrical Protection: Class I)			
Compatible external power supplies	- MEANWELL GSM40A12 - DANUBE FRM030-S124			
Medical device classification	Clase IIa			
Dimensions and Weight	195 x 270 x 100mm 1,7 kg (with battery) approx.			
Database	• 2 types of databases according to their storage capacity: «L»: Small DB: >1000 tests including F/V loops and V/t curves. «H»: Large DB: >3000 tests including F/V loops and V/t curves. • Storage of spirometry and MIP-MEP tests.			
Communications	• PC: USB 2.0, Bluetooth® technology 5.1 Dual-mode Classic (BR/EDR) (op.) • Printer: USB 2.0			
Printer protocol	PCL 3 HPA, PCL 5e			
Display	High resolution touch screen LCD, VGA of 640x480			
Battery pack	Ni-Mh Rechargeable, 9.6V 2.5Ah			
Operating Conditions	Temperature: 5 to 40 ºC Humidity < 85% (without condensation) Pressure: 700 to 1060 hPa. (525 a 795 mmHg / 3000 a -380 m aprox.)			
Recommended Conditions of measurement		Peak Flow (EN ISO 23747:2015)	Forced expiratory volume (EN ISO 2678:2009)	ATS / ERS
	Temp.	10-35 ºC	17-35 ºC	>17ºC
	Hum.	30-75% (without condensation)		
	Pres.	850-1060 hPa (638 a 795 mmHg / 1500 a -380 m aprox.)		
Transport and storage	Temperature: -20 a 70 ºC 0 a 50 ºC (disposable transducer with filter and bacterial filter) -20 a 30 ºC (recommended with battery included) Humidity: <85 % (No condensation)			

Internal temperature sensor	5 a 40 ºC ± 1 ºC
Max. Nº of maneuvers per subject	8 FVC maneuvers, 8 VC maneuvers, 8 MVV maneuvers
Device lifetime	7 years (see section 6.6 for each transducer and the User's Manuals of the modules)
Weather station	Pressure: 500 to 1040 hPa, accuracy: ± 6.67 hPa (375 to 780mmHg, accuracy: ± 5 mmHg) Humidity: 0 to 100% (accuracy: ± 5%)
Applicable standards	• Medical Device Regulation (EU) 2017/745 • Quality (EN ISO 13485:2016+A11:2021, EN ISO 9001:2015 and EN ISO 14971:2019 + A11:2021) • Compliance with Data Protection Regulation (EU) 2016/679 • Safety Medical devices (EN 60601-1:2006 + AC:2010 + A11:2011 + A1:2013+ A12:2014 + A2:2021 + A13:2024) • Electromagnetic Compatibility EMC – Healthcare Environment (EN 60601-1-2:2015 + A1:2021) • Biocompatibility: Biological evaluation of medical devices. (EN ISO 10993-1: 2009 + AC: 2010, EN ISO 18562-1:2020, EN ISO 18562-2 and EN ISO 18562-3:2020) • Usability (EN 60601-1-6:2010 + A1:2015 + A2:2021) • Usability (EN 62366-1:2015+A1:2020) • Spirometers for forced spiratory volumes measurement (EN ISO 26782:2009 + AC:2009) • Spirometers for peak spiratory flow (EN ISO 23747:2015) • Software of medical devices (EN 62304:2006+AC:2008+A1:2015) • Vibration and temperature: (EN 60068-2-1:2007, EN 60068-2-2:2007, EN 60068-2-14:2009, EN 60068-2-27:2009 and EN 60068-2-64:2008 + A1:2020) • Documentation and information (EN ISO 20417:2021, EN ISO 15223-1:2021) • Radio equipment directive 2014/53/EU (RED). • Directive 94/62/EC on packaging and packaging waste. • Directive 2006/66/EC on batteries and accumulators and waste. • Waste disposal according to WEEE Directive 2012/19/EU. • Directive 2011/65/EU on the restriction of the use of the certain hazardous substances (RoHS). • Regulation (EC) 1272/2008 on classification, labeling and packaging of substances and mixtures (REACH).
Spirometry recommendations	• ATS/ ERS Standards: 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. • SEPAR: Sanchis et al Normativa para la espirometría forzada. Recomendaciones SEPAR núm. 1. Arch Bronconeumol 1989; 25: 132-142. • NLHEP: Ferguson et al. Office Spirometry for Lung Health Assessment in Adults. Chest 2000; 117:1146-1161.

6.2 SYMBOLS



SERIAL NUMBER


MANUFACTURER (Manufacturing date, manufacturer's name and address)



LOT NUMBER



PRODUCT REFERENCE


EXPIRATION DATE


DO NOT REUSE


TEMPERATURE LIMITATION


MOISTURE LIMITATION


PRESSURE LIMITATION


PRECAUTION


WARNING, IDENTIFIED RISK



MEDICAL DEVICE


START-UP (STANDBY)


BF APPLIED PART


WASTE DISPOSAL ACCORDING THE WAEE DIRECTIVE


INPUT (EXTERNAL POWER SUPPLY)

6.3 TESTS, FUNCTIONS AND PARAMETERS

Available Information on tests:

- Percentage deviation in relation to predicted values.
- Standardized values of predicted that can be selected from several standards.
- Patient's ID details.
- Atmospheric data on temperature, pressure and relative humidity.
- Availability of up to 8 maneuvers in the same study.
- Graphs in flow/volume and volume/time for FVC, Bronchodilatation and Bronchoconstriction tests.
- Graphs in flow/volume for VC and MVV tests.

FORCED VITAL CAPACITY FVC

- FVC (l) Forced Vital Capacity
- FEV0.5 (l) Forced Expiratory Volume in 0.5seconds
- FEV1 (l) Same in 1 second
- FEV3 (l) Same in 3 seconds
- FEV.5/FVC (%) Ratio
- FEV1/FVC (%) Ratio
- FEV3/FVC (%) Ratio
- FEV1/VC (%) Ratio
- PEF (l/s) Peak Expiratory Flow
- PEFT (s) Peak Expiratory Flow
- MEF25% (l/s) Forced Expiratory Flow 25% into the maneuver
- MEF50% (l/s) Same, 50% into the maneuver
- MEF75% (l/s) Same, 75% into the maneuver
- FEF25-75% (l/s) Mean expiratory flow between 25% and 75% of the FVC
- FEF75-85% (l/s) Mean flow between 75-85% of FVC
- FET25-75 (s) Forced expiratory time between 25-75% of FVC
- FET100 (s) Forced Expiratory Time
- FEF50/FIF50 (-) Ratio
- FEV1/FEV.5 (-) Ratio
- FEV1/PEF (-) Ratio
- FIF50% (l/s) Maximum Inspiratory flow with 50% of FVC inspired
- FIVC (l) Forced Inspiratory Vital Capacity

- FIV1 (l) Forced Inspiratory Volume in 1 second
- FIV1/FIVC (%) Ratio
- FEV1/FIV1 (%) Ratio
- PIF (l/s) Inspiratory Flow Apex
- MTT (s) Mean Transit Time
- PEF/PIF (-) Ratio
- BEV (%) Extrapolated Volume
- MVVInd (l/min) Maximum Voluntary Ventilation (30 x FEV1)
- FEV6 (l) Forced Expiratory Volume in 6seconds
- FEV1/FEV6 (%) Ratio
- EPOC rate Parameter that depends on the number of cigarettes smoked a day, the age and FEV1. Indicates the risk of EPOC.
- Lung Age Parameter that depends on the height and FEV1. This indicates the equivalent age of the lung.
- FEV075 Forced Expiratory Volume in 0.75 seconds
- FEV075/FVC (-) Ratio
- Quality alerts to assure compliance with ATS/ERS and NLHEP criteria
- Acoustic and graphic indication of the start and end of each maneuver
- Start FVC expiration: Using the retrograde extrapolation method
- End FVC expiration: When the volume accumulated in the last second is below 25ml.

PRUEBA POSTBRONCODILATACIÓN

- Same parameters and characteristics as in FVC.
- Several methods of comparison among PRE, POST and REF values.
- Superimposing of PRE and POST graphs.

CAPACIDAD VITAL LENTA

- VC (l) Slow vital capacity
- TV (l) Tidal volume
- ERV (l) Expiratory Residual Volume
- IRV (l) Inspiratory Residual Volume
- IC (l) Inspiratory Capacity
- Ti (s) Inspiratory time
- Te (s) Expiratory time
- Tt (s) Total time
- Ti/Tt (-) Ratio

MAXIMUM VOLUNTARY VENTILATION

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

6.4 PREDICTED SETS

The spirometer includes several predicted tables that the user can select in the **CUSTOMIZATION MENU\ Spirometry.**

Predicted set	Contry / Region	Age range (years)
SEPAR	SPAIN	6 to 70 (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	6 to 90 (1)
GUTIERREZ	XILE	5 to 100 (1)
CASTRO - PEREIRA	BRAZIL	6 a 86 (1)
POLGAR - WENG		4 to 100
HANKINSON -	EEUU	4 to 100
NHANES III	EEUU	4 to 100
PEREZ - PADILLA	MEXICO	7 to 100 (1)
A.J.CRUZ	MEXICO	17 to 64 (1)
GOLSHAN	IRAN	6 to 81 (1)
GARCIA RIO	EUROPE	65 to 85
CANDELA	SPAIN	2 to 7
PLATINO	LATIN AMERICA	40 to 90
THAI 2000	THAILAND	>10
GLI	INTERNATIONAL	3 to 95
SER 2014 CHILE	CHILE	19 to 94

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

6.5 FVC INTERPRETATION (DIAGNOSIS)

- **Miller chart**

- **Snider, Kory & Lyons**

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

- **Interpretation NLHEP.** (Only valid for predicted values that calculates the LLN. For example: Hankinson). Ferguson et al. Office Spirometry for Lung Health Assessment in Adults. Chest 2000; 117: 1146-1161.

6.6 TRANSDUCERS

(i) RANGES AND MEASUREMENTS

The most demanding value among ATS-ERS 2019, EN ISO 26782:2009 + AC:2009 and EN ISO 23747:2015 is specified.

	FLEISCH	TURBINE	LILLY DISPOSABLE	LILLY DISPOSABLE WITH FILTER
Measurement Scale (BTPS) Flow Volume	0 a ±16 l/s 0 a 16 l			
Dynamic flow resistance @ 14 l/s	<1,4 hPa/(l/s)	<0,7 hPa/(l/s)	<1,2 hPa/(l/s)	<1,4 hPa/(l/s)
Precision of measurements (BPTS) Volume Flujo PEF	2,5% or 50 ml 3% o 150 ml/s 10% o 170 ml/s			
Time related precision	0,50%			
Volume resolution	<10ml	<10ml	<10ml	<10ml
Sampling frequency	100Hz	100Hz	100Hz	100Hz
Transducer lifetime	1400 desinfec. or 3 years	1400 desinfec. or 3 years	Only one use (Expiration 3 years)	Only one use (Expiration 5 years)

6.7 MANUFACTURER'S LIABILITY

SIBEL, S.A.U. is only liable for the safety, reliability and working order of this equipment if:

• The place where the equipment is installed or used is compliant with the requirements related to the IEC electrical installation and other applicable regulations.

• All repairs, services and modifications inside and outside the guarantee period are carried out by SIBEL S.A.U. technical staff.

• The equipment is used by skilled staff according to the recommendations of this User's Manual.

7. CLEANING AND MAINTENANCE

DATOSPIR touch requires cleaning and maintenance aimed at keeping the equipment functioning correctly and at ensuring safety of patients and operators.

7.1 CLEANING / DISINFECTION

The person who carries them out does not require any special technical knowledge other than their own understanding of the functioning and handling of the equipment. It is usually done by the normal user of the equipment.

⚠ **For your safety, disconnect the equipment from electrical power or remove the battery before cleaning.**

7.1.1 CLEANING THE DEVICE

The device case can be cleaned with a wipe moistened with soapy (neutral) water or with 96º alcohol or with 0.1% sodium hypochlorite solution (equivalent to a 1:50 dilution of bleach in water if the bleach concentration is 5%). Then, they can be wiped dry. Take particular care to ensure that no liquid enters the interior of the device or the connectors and connections.

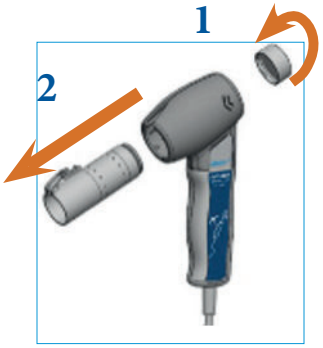
7.1.2 CLEANING / DISINFECTION OF THE TRANSDUCER

HIGH LEVEL DISINFECTION OF THE TRANSDUCERS

⚠ **The Fleisch and Turbine transducers must be disinfected before using them in a new patient, especially if you suspect microbial contamination.**

To do so, proceed as follows:

A) FLEISCH PNEUMOTACHOMETER



1 Remove the filter and then the transducer by pressing its tab so that it comes away from its fixtures. See the figure. .

2 Immerse the transducer and filter in a Orthophthaldehyde solution (CIDEX® OPA), or in a disinfectant solution based on peracetic acid, hydrogen peroxide or N-Duopropenide according to the concentration defined by the manufacturer (refer to the disinfectant manufacturer's instructions).

⚠ **Do not use abrasive substances or solvents.**

3 Then rinse them in distilled water.

4 Shake the transducer and filter for removing the water droplets, leave them to dry at room temperature and re-assemble the group again.

B) TURBINE TRANSDUCER



1 Remove the turbine from its housing by pressing slightly its tab so that it comes away from its fixtures.

2 Immerse the turbine in a Orthophthaldehyde solution (CIDEX® OPA), or in a disinfectant solution based on peracetic acid, hydrogen peroxide or N-Duopropenide according to the concentration defined by the manufacturer (refer to the disinfectant manufacturer's instructions).

⚠ **Do not use abrasive substances or solvents.**

3 Then rinse the turbine by immersion in distilled water. Do not rinse the turbine by holding it under running water.

4 Given that the turbine reliability depends on its good condition, examine it for possible damages.

5 Leave it to dry at room temperature and re-assemble the turbine in the housing.
When performing an intensive use of the device, it is recommended to have several transducers for replacing them while the used ones are being disinfected.

If a bacterial filter is used in conjunction with the Fleisch or Turbine transducers, the disinfectant solution indicated in Step 2 can be replaced by soapy (neutral) water.

C) LILLY DISPOSABLE PNEUMOTACHOMETER

This transducer does not need any kind of cleaning as they are only for single use. They must be thrown away once the patient has carried out the tests.

⚠ **Reutilization of the disposables transducers induces a risk of cross-infection between patients. The use of disinfectant products can affect the transducer's mesh inducing a loss of accuracy in the measurement.**

D) HANDLE AND TRANSDUCERS HOUSING

Clean the external parts of the transducer's housing and handle with a wipe moistened with soapy (neutral) water or with 96º alcohol or with 0.1% sodium hypochlorite solution (equivalent to a 1:50 dilution of bleach in water if the bleach concentration is 5%). Then, they can be wiped dry. Pay attention to avoid inserting strange elements into the pressure inlets of the Lilly handle (clean it with the handle in inverted position).

⚠ **Do not use abrasive substances or solvents.**

7.2 PREVENTIVE MAINTENANCE

Preventive maintenance consists of any actions aimed at keeping the equipment in a good working order

Actions which can be carried out by the same user:

1. Each time the device is turned on, the equipment will check certain parts and/or functions. In addition, the user can access the Maintenance Program to adjust and/or check any parts of the equipment, as indicated in detail in the corresponding section.
2. A second procedure, which can be performed by the user, consists of regular monitoring of the appearance of the different connections and other external parts of the equipment. Check that all connections are perfectly connected, that no cable and/or connector or any other element is broken or damaged.
3. Execute a calibration check with a 3-L syringe. Calibration checks must be undertaken daily.
4. Define the periods in days between calibrations or preventive maintenance work on the **CUSTOMIZATION MENU** of the equipment. If the days specified are exceeded, the equipment warns of such by displaying a sign every time it is started. If "0" days is entered, a warning is never given.
5. Keep the device firmware up to date. Check the BIOS and program version on the startup screen. Check the availability of new versions at https://www.sibelmed.com/support

In the event of detecting any problem that the user cannot solve, contact the **SIBEL S.A.U.** **After-Sales Service or your distributor** to review or repair it.

Actions carried out by skilled technical personnel:

This Technical check will be performed every year following the **DATOSPIR** touch Verification and Adjustment Procedures, available

from the manufacturer **SIBEL, S.A.U.** This type of operation must be carried out by skilled technical staff from the distributor's or manufacturer's **technical service**.
On all accounts, **SIBEL S.A.U.**, as **the manufacturer**, must provide written authorization, for at least the guarantee period, for the corresponding technical personnel to carry out said maintenance and will not be held liable under any circumstances for any damage, malfunction, etc. that may arise as a result of defective maintenance by people not employed by SIBEL S.A.U.

7.3 CORRECTIVE MAINTENANCE

Corrective maintenance consists of repairing the equipment that has stopped working, due to malfunctioning or misuse; leaving it in a good state.

On detecting any fault with equipment which interferes with its normal use, disconnect the equipment from the mains and contact SIBEL S.A.U. **After-Sales Service**. Specify the problem in as much detail as possible.

SIBEL S.A.U.
After-Sales Service
Tel. +34 93 433 54 50
e-mail: sat@sibelmed.com

Annex 1. ELECTROMAGNETIC COMPATIBILITY

1.1. GUIDANCE & MANUFACTURER'S DECLARATION

Guidance and manufacturer's declaration – electromagnetic emissions		
DATOSPIR touch is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.		
Emissions test	**Emissions test**	**Emissions test**
RF (Radiated) emissions CISPR 11 (EN 55011)	Group 1 Class B	
RF (Conducted) emissions CISPR 11 (EN 55011)	Group 1 Class B	
Harmonic emissions EN-IEC 61000-3-2	Class A	
Voltage fluctuations / Flicker emissions EN-IEC 61000-3-3	Cumple	

Guidance and manufacturer's declaration – electromagnetic immunity			
DATOSPIR touch eis intended for use in the electromagnetic environment specified below. The costumer or the user of **DATOSPIR touch** should assure that it is used in such an environment. Tests EN-IEC 61000-4-4 y -4-5 are applicable to AC/DC power inputs, and input/output signal. Test EN-IEC 61000-4-6 additionally applies to patient connections. Test EN-IEC 61000-4-11 only applies to AC power inputs.			
Immunity test	**EN-IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – Guidance**
Electrical fast transient/burst EN-IEC 61000-4-4	±2 kV for power supply lines and earth ±1 kV for input/output lines Frecuency 100 kHz	±2 kV for power supply lines and earth Not applicable	Mains power quality should be that of a typical commercial or hospital environment. The input/output line cables are shorter than 3 meters long.
Surge EN-IEC 61000-4-5	±0.5, ±1 kV differential mode (Line to line). ±0.5, ±1, ±2 kV common mode (Line to ground).	±0.5, ±1 kV differential mode (Line to line). ±0.5, ±1, ±2 kV common mode (Line to ground).	Mains power quality should be that of a typical commercial or hospital environment.
Conducted RF EN-IEC 61000-4-6	3 Vrms de 150KHz a 80 MHz 6 Vrms in ISM bands 80% AM a 1kHz	3 Vrms 6 Vrms	
Voltage dips, short interruptions and voltage variations on power supply input lines EN-IEC 61000-4-11	0% Ut; 0.5 cycles: 0º, 45º, 90º, 135º, 180º, 225º, 270º y 315º 0% Ut; 1 cycle 70% Ut; 25/30 cycles: 0º 0% Ut; 250/300 cycles (5 segundos)	0 % Ut ; 0.5 ciclos a: 0º, 45º, 90º, 135º, 180º, 225º, 270º y 315º 0 % Ut; 1 ciclo 70 % Ut; 25/30 ciclos a 0º 0 % Ut; 250/300 ciclos (5 segundos)	Mains power quality should be that of a typical commercial or hospital environment.
Note: Ut is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
DATOSPIR touch is intended for use in the electromagnetic environment specified below. The costumer or the user of **DATOSPIR** touch should assure that it is used in such an environment. Below mentioned tests are applicable to enclosure. Additionally, test EN-IEC 61000-4-2 is applicable to input/output signal and patient connections.			
Immunity test	**Immunity test**	**Immunity test**	**Immunity test**
Electrostatic discharge (ESD) EN-IEC 61000-4-2	±8 kV contact ±2, ±4, ±8, ±15 kV, air	±8 kV contact ±2, ±4, ±8, ±15 kV, air	
Radiated RF EN-IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	3 V/m	
Proximity fields from RF communications EN-IEC 61000-4-3	(View following table).		Portable and mobile RF communications equipment should be used no closer than 30cm to any part of **DATOSPIR** touch, including cables. The distance is calculated according to: $d = \left[\frac{6}{E}\right]\sqrt{P}$ where P is the output power rating of the transmitter in watts (W), d is the recommended separation in meters (m) and E is the immunity level in V/m.
Power frequency (50 / 60 Hz) magnetic field EN-IEC 61000-4-8	30 A/m	30 A/m	Only applicable to devices sensitive to magnetic fields.

Proximity fields EN-IEC 61000-4-3					
Frecuency (MHz)	Band (MHz)	Modulation	Power (W)	Distance (m)	E (V/m)
385	380-390	Pulse 18Hz	1.8	0.3	27
450	430-470	FM D:+/-5kHz 1kHz sinus	2	0.3	28
710 745 780	704-787	Pulse 217Hz	0.2	0.3	9
810 870 930	800-960	Pulse 18Hz	2	0.3	28
1720 1845 1970	1700-1990	Pulse 217Hz	2	0.3	28
2450	2400-2570	Pulse 217Hz	2	0.3	28
5240 5500 5785	5100-5800	Pulse 217Hz	0.2	0.3	9

Annex 2. COMPLIANCE WITH GENERAL DATA PROTECTION REGULATION

REQUIREMENTS AFFECTING THE USER OF THE EQUIPMENT

This section is aimed at facilitating the user to comply with the regulation in force related to the treatment of personal data that are regulated and covered by European Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data.

A brief description of the basic points of this regulation is provided and the issues to be considered for fulfilling the requirements of such regulation are detailed.

IMPORTANT WARNING

- According to the regulation in force, the user is the only party responsible for saving and processing the data of his patients according to the Law.

- The observance of the recommendations included in this section does not guarantee, in any case, the complete adequacy of the user's activity to the regulation on data protection.

CONFIGURATION OF DATOSPIR TOUCH PROTECTION

DATOSPIR touch has a device protection option that uses a PIN code, user-configurable that seeks to prevent access by unauthorized people to the equipment and, more specifically, to the private data it contains.

To comply with current legislation, users **must enable this option** and configure their PIN. They will be held responsible for providing this PIN to the authorized people. Thus, when the spirometer is started, the PIN will be requested and the equipment locked where this PIN is entered erroneously three times.
On restarting the equipment, the unlock code (PUK), provided by the manufacturer upon purchasing the equipment, will be requested. If this code is not available, the equipment will remain locked.

• **PRINTING DOCUMENTS:** In the event of saving paper printouts containing patient details, these documents must be properly stored so that only duly authorized personnel have access to them. Furthermore, in the event of users deciding to dispose of the printed documents, their effective physical destruction must be ensured to avoid unauthorized access to data.

• **DATA TRANSMISSION:** This spirometer can transmit files containing patient details via PC connection so that work can be subsequently carried out on them using the W20s Spirometry Software. This software is also compliant with the Data Protection Act, as explained in its User's Manual.

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by SIBEL SAU is under license. Other trademarks and trade names are those of theirrespective owners.