DATOSPIR TOUCH

SPIROMETER

USER'S MANUAL

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The **DATOSPIR TOUCH Spirometer** has been designed by the **R+D+I** Department of **SIBEL S.A.**, 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 2005** (American Thoracic Society/ European Respiratory Society) and National Institutions: **SEPAR** (Spanish Pneumology and Thoracic Surgery Society).

CE 0197 **COMPLIANT PRODUCT**
93/42/EEC Medical Device Directive.
Class IIa

Revised
Date: 2014-06
Technical Director

Approved
Date: 2014-06
Sales Director

1. SAFETY

SPECIAL PRECAUTIONS

The **DATOSPIR TOUCH** spirometer 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.

INTENDED USE

a) Measurement of lung flows and volumes for the diagnostic and control of respiratory diseases (Asthma, COPD, etc.).
b) Measurement of peripheral blood oxygen saturation and cardiac pulse for the respiratory diagnostic.
c) Measurement of inspiratory and expiratory maxima pressures for the respiratory diagnostic.

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

INDICATIONS FOR USE

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.

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.

The spirometer is intended to be used in the following patient population:
a) Age: more than 4 years until elderly
b) Weight: > 15 Kg
c) Height: > 50 cm

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

USER PROFILE

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

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

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 technique or on the product, contact SIBEL S.A. or your dealer.

EFFECTS ON PATIENTS USING THE SPIROMETER

The spirometry tests require patient cooperation.

Complete forced expiration is required to obtain meaningful patient FVC values. 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.

LIMITATIONS FOR USE. CONTRAINDICATIONS

An analysis of the results of spirometry 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 patient's symptoms and capacity to perform a spirometry test must be taken into account by medical staff before any spirometric testing is undertaken. Acceptability of a test is the responsibility of the medical professionals.

The spirometer should not be used when it is likely that the validity of the results could be compromised by external factors.

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 device should **NOT** be used stacked or adjacent to other equipment.

All accessories and spare parts must be originals and they must be requested from the manufacturer or authorized dealer in order to ensure the safety of the patient and the correct working order of the spirometer. Failure to do so may result in an increase of emissions or in a decrease of the immunity of the equipment.

The equipment must be stored and used within the temperature, pressure and humidity ranges specified in the section **6.1.**

WATER INGRESS PROTECTION LEVEL

IPX2. Equipment Protected against falling water equivalent to 3-5mm rainfall per minute during 10 minutes. Unit placed tilted 15 degrees, in each direction, from normal operating position. In compliance with ISO 80601-2-61:2011.

ELECTRICAL RISKS

To avoid the risk of electric shock, this equipment must be connected to a power supply with protective earth only.

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.

ELECTRICAL DISCHARGE

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 EN60950 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.

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

RISKS OF EXPLOSION

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

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.

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.

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

Never dispose of the DATOSPIR TOUCH, its accessories and 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.

Devices commercialized before July 22nd, 2014:
The device contains lead for the electric soldering.

It 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.

2. INSTRUCTIONS FOR USE AND INSTALLATION

2.1 INTRODUCTION

The **DATOSPIR TOUCH** spirometer 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 or Bluetooth. In addition, it may incorporate a **Weather Station** to measure pressure and humidity (it includes a **temperature sensor**); a **MIP-MEP** module to measure Maximal Inspiratory and Expiratory Pressures, an electronic **Pulse oximetry** module, exclusively for taking Oxygen Saturation and Pulse Rate samples (SpO_2) and an **Ethernet** module.

Furthermore, the spirometer may be connected in real or deferred time to a **PC** via **USB**, **Bluetooth** or **Ethernet**, 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. Thus, it allows carrying out interactive real-time testing on your PC and transfer status device data

2.2 MODELS AND OPERATING MODES

2.2.1. MODELS

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** spirometer. Therefore, only specific options and functions of the model available will be applicable in each case.

The following table shows the **standard** 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						
Turbine						
Fleisch						
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						
Ethernet module						
Bluetooth module						

Included Optional Not included

2.2.2. 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	PC	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			

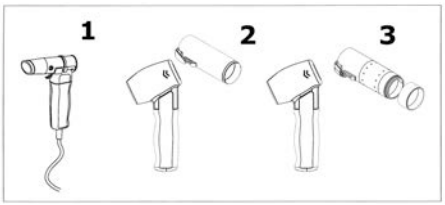
Included Optional Not included

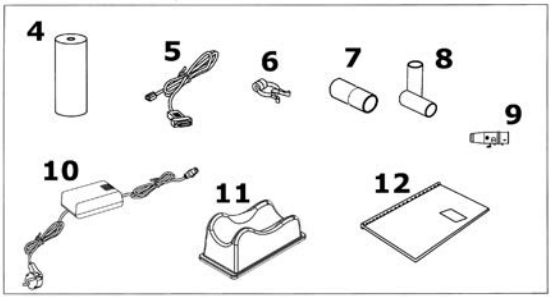
A model can be upgraded at any time by adding the corresponding parts. To do so, please contact the **SIBEL S.A. Sales Department** or your dealer.

2.2.3 ACCESSORIES

	Easy			Diagnostic		
	D	T	F	D	T	F
TRANSDUCERS						
1. Disposable		Optional	Optional		Optional	Optional
2. Turbine	Optional		Optional	Optional		Optional
3. Fleisch	Optional	Optional		Optional	Optional	
ACCESSORIES STANDARD						
4. Thermal paper 110x50						
5. USB and printer cable connection						
6. Nose clip						
7. Plastic Mouthpiece	Not included			Not included		
8. Disposable mouthpiece pack (25 u)	Not included			Not included		
9. Disposable transducers pack (25 u)		Not included	Not included		Not included	Not included
10. External power supply						
11. Transducer holder						
12. User's manual						

Included Optional Not included

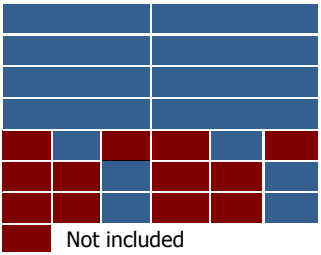




2.2.4 ACCESSORIES, OPTIONS AND SPARE PARTS

REF.	OPTIONAL ACCESSORIES	Easy			Diagnostic		
		D	T	F	D	T	F
	TRANSDUCERS KITS						
07046	Disposable		■	■	■		
07053	Turbine	■		■	■		■
07052	Fleisch	■	■		■	■	
	OPTIONS						
07272	Pulse oximetry module	■	■	■	■	■	■
07144	MIP-MEP module	■	■	■	■	■	■
07146	Sniff module	■	■	■	■	■	■
	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 Bluetooh modules	■	■	■			
	ACCESORIES						
02249	Calibration syringe (3 L)	■	■	■	■	■	■
02692	Nose clip (5 u)						
01569	Plastic Mouthpiece	■	■	■	■	■	■
01555	Cartoon mouthpiece 28x60 (100 u)	■	■	■	■	■	■
03169	Disposable transducers (25 u)	■	■	■	■	■	■
06391	SpO_2 soft sensor adult (M50B)	■	■	■	■	■	■
07725	SpO_2 soft sensor children (M50E)	■	■	■	■	■	■
02117	Antibacterial filter disposable	■	■	■	■	■	■
02118	Antibacterial filter reusable	■	■	■	■	■	■
02759	Antibacterial filter disposable membrane (50u)	■	■	■	■	■	■
03175	Turbine transducer	■		■	■		■
07828	Software W20s CD						
	SPARE PARTS AND COMPONENTS						
07233	Weather station module	■	■	■			
07193	Bluetooth module	■	■	■			
06610	Ethernet 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	■	■	■	■	■	■

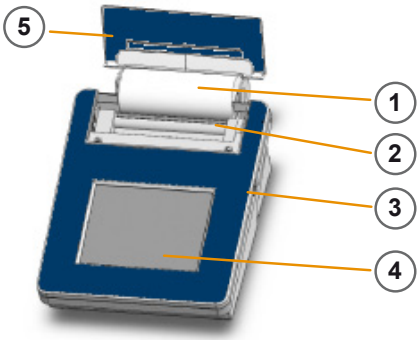
06611	Ethernet cable	
03052	MIP-MEP Shutter probe	
07147	Sniff probe (for MIP-MEP module)	
05602	MIP-MEP mouthpiece	
01149	Paediatric Mouthpiece adapter	
06186	Fleisch Transducer	
08187	Fleisch filter (3u.)	



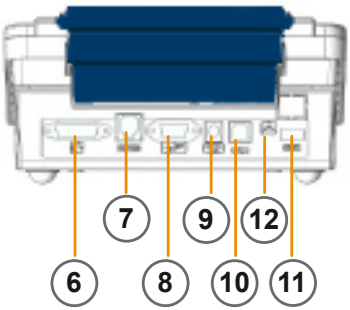
Included Optional Not included

2.3 LAYOUT OF CONTROLS AND CONNECTORS

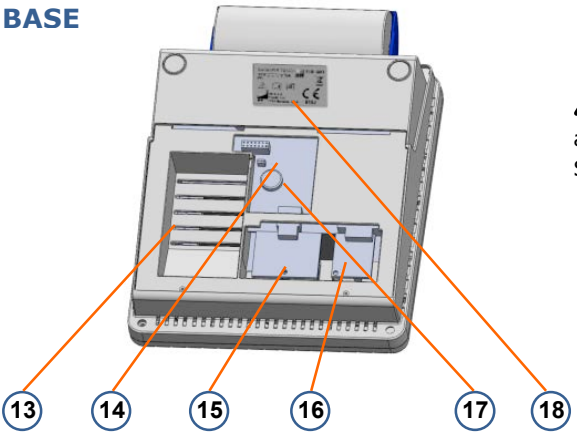
FRONT PANNEL



REAR PANNEL



BASE



Do not connect accessories not supplied by SIBEL,S.A.

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- Pulse oximetry sensor connection
9- Power supply connection
10- USB connector for PC
11- USB connector for external printer
12- Ethernet Connection
13- Rechargeable battery location
14- Pulse oximetry board connection
15- Electronic Weather Station board connection
16- Bluetooth board connection
17- Lithium battery CR1815
18- Specifications plate

2.4 INSTALLATION AND START-UP

This spirometer 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

1. Connect the **external power supply** to the socket no.9, located on the rear of the device, and to the mains.
2. Insert the plug of the **transducer** 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 **3.3 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:

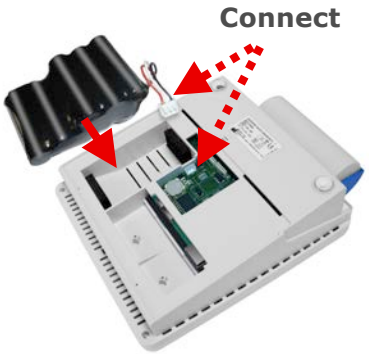
	Access to the FVC test
	Access to the Post Bronchodilation test
	Access to the VC test
	Access to the MVV test
	Access to the Bronchoconstriction test
	Access to the Pulse oximetry test
	Access to the MIP-MEP test
	Quality control procedure: Calibration check
	Access to the Internal database/ Database 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 LOAD

The **DATOSPIR TOUCH** spirometer operates optionally with **rechargeable Ni-Mh battery** (9.6V 2500mAh) with an autonomy of **1.5 hours** approx.

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



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

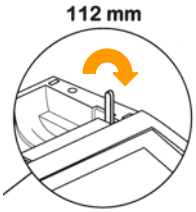
DO NOT charge other type of batteries, they could EXPLODE. Remove old batteries to avoid they could spill its substances.

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.

When the spirometer 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



Open the printer cover, lift the lever that unlocks the pull cylinder and insert the paper roll. Pull a small amount of paper out, put down the header lever, pass the paper through the slot of the cover and close it. A screen will appear to pull the paper in/out. Cut the paper pulling it forwards.

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 spirometer, it will be already installed. Otherwise, you must remove the cover from the base of the spirometer and insert the **bluetooth board** where is shown in Figure.

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 link option, consult the **W20s Spirometry Software User's Manual,** included in the CD.

The Bluetooth is enabled (and disabled) by accessing the Bluetooth option on the **COMMON CUSTOMIZATION** screen of the spirometer. (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 spirometer, it will be ready to use. Otherwise, remove the bottom case of the spirometer and insert the **weather station's board,** as shown in the figure.

3. SPIROMETER CONFIGURATION

3.1 SETUP

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

1. CUSTOMIZATION 

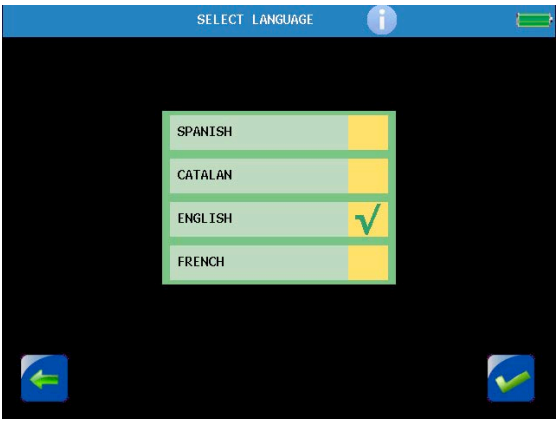
2. MAINTENANCE 

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 spirometer, by pressing on the yellow square. This mark √ will 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 spirometer 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: Touch the displayed time to adjust time and date.


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 COMMON CUSTOMIZATION

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)


Ethernet: (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


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
- 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 Spirometer without Calibration check.

 Bronchodilation test customization

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

 **Pulse oximetry customization** (See the Pulse oximetry 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 **data protection Act. Directive 95/46/EC**, 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
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 **CUSTOMIZATION MENU** (Section **3.2.3**).

⚠ It is possible to save spirometric, Bronchoconstriction, MIP-MEP or pulse oximetry test.

⚠ 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-sales service to enable the new option purchased.

Display the current activation code.

3.5 QUALITY CONTROL: CALIBRATION CHECK

The **2005 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 drop and the airflow depends on the gas viscosity. This viscosity is also depending of 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.

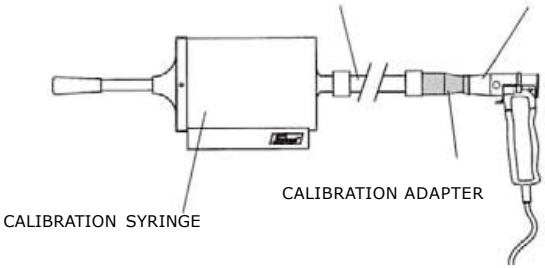
To verify that transducer operates properly, the spirometer includes a simple check-up procedure based on measuring the known volume of a calibration syringe.

Test procedure:

1 Connect the spirometer to the 3 or 6L-syringe, as in the following figure, inserting a tube one meter long to avoid the influence of the turbulence caused by the abrupt departure of the air:

SYRINGE HOSE

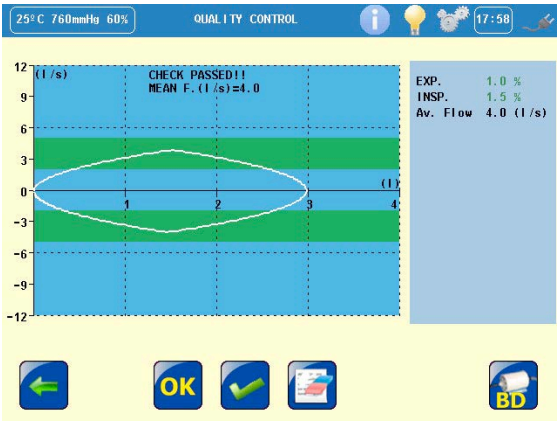
DISPOSABLE TRANSDUCER



1 Power up the **DATOSPIR TOUCH** and press  from the main menu.

2 Discharge the syringe **once** at any range of the following flows varying between 0-12L/s:

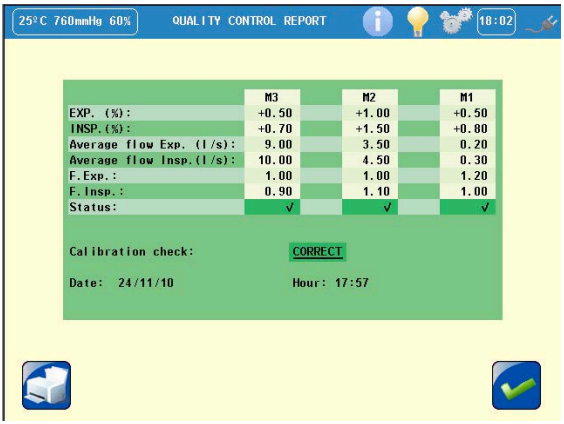
Low flow level: 0,4 – 1,2 L/s
Mid-flow level: 2 - 5 L/s
High flow level: 6 - 12 L/s



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

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

4 At the end of the operation, press OK 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.



5 If the session is correct, the results will be automatically saved to the **calibration record.**

Press BD to see the data of the record (See section **3.7**).

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

7 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 spirometer, 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  and then  . Enter the necessary data described below and follow the instructions detailed in the section **3.6.**

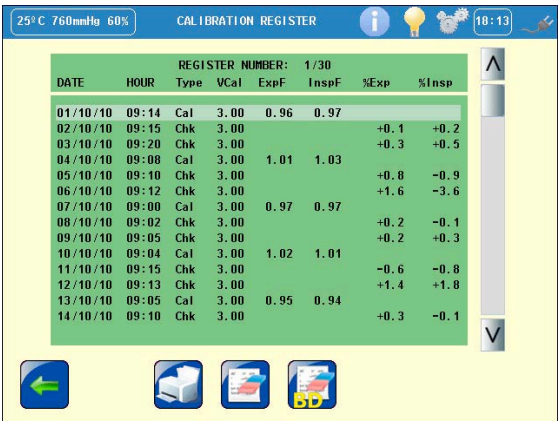
- **Volume of the syringe:** 1-6L.
- **No. of Pulses** of the **Turbine transducer**. Each turbine is factory calibrated individually and is associated to a factor (3-digits) equivalent to the pulses/liter detected and printed on it.
- **Transducer Factor:** the Lilly Disposable transducers are factory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

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 **30 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

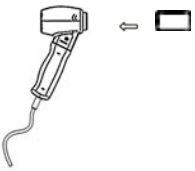
The procedures to be completed to carry out the **Forced Vital Capacity «FVC», slow Vital Capacity «VC» and Maximum Voluntary Ventilation «MVV»** tests are very similar. Therefore, only one detailed description will be given in this section.

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



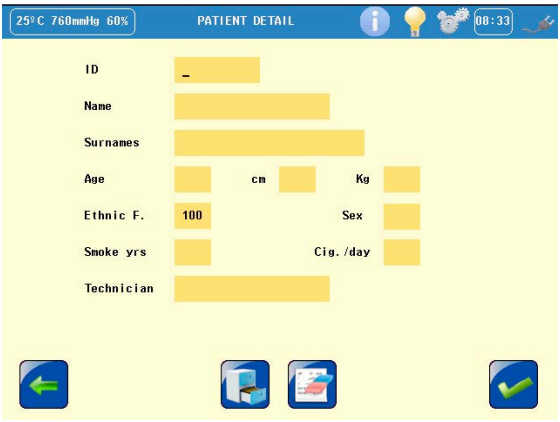
2 Turn on the spirometer and press 

on the Main Screen.

The first time per day, you carry out a spirometric test, the spirometer may advise you to **check the calibration,** as TAS-ERS recommends. 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. 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.
Smoke yrs:	Number of years the patient has been smoking
C/d:	Cigarettes smoked per day. Between 0 and 100. This helps to calculate the COPD index parameter.
Technician	10-character alphanumerical technician's code or name.
Transducer Code:	Transducer's pre-calibration factor (1)

(1) The disposable and Fleisch transducers are factory pre-calibrated with an associated calibration code that have to be entered into the spirometer 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 mathces with the one of the transducer that you are currently using.

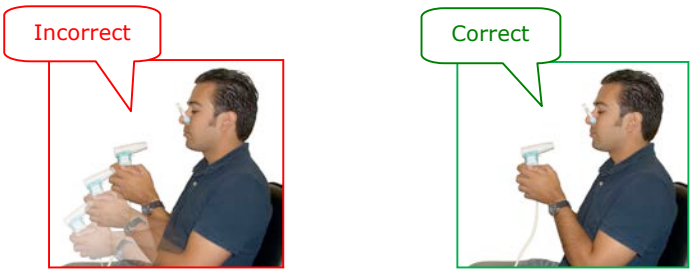
3 Enter the patient's details by pressing on each field. An alphanumeric or numeric keyboard that will appear, depending on the field data type required. Enter patient's data and press ENT.

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 the screen. When finish press  to go to the test screen.

3 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.**

4 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.**



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

- Starting the maneuver with **FORCED EXPIRATION** 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.

6 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.**

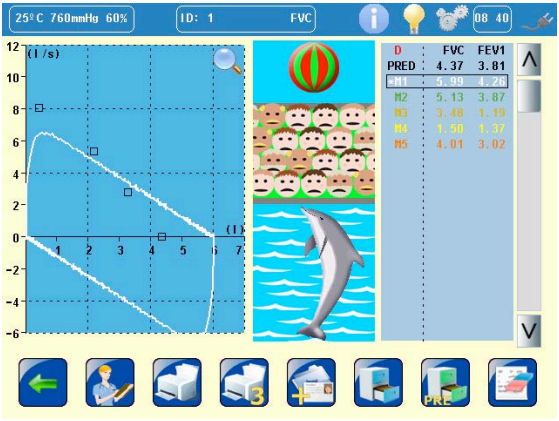
ATS/ERS Criteria: The maneuver with least warnings is considered the best (ET, EX). With the same number of ATS/ERS warnings (ET, EX), the maneuver with the highest

sum of FVC+FEV1 is considered the best.

7 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 FEV_1 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 criteria 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



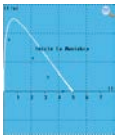
At the end of the test:

- The current, predicted and best maneuver graphs are shown.
- On the summary frame, the **FVC** and **FEV_1** values of all the maneuvers performed will appear:

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

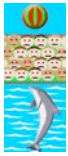
Maneuvers are sorted from best (M1) to worst (M8) according to **ATS/ERS criteria** and are shown in different colors: green for those that are acceptable and repetitive and from yellow to red the lower-quality maneuvers. In white, the current maneuver.

- 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:**

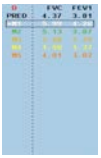
  a **Temporal bar:** Progress bar in function of time, in three colors: red indicating less than 4 seconds, orange between 4 and 6 seconds and green for more than 6 seconds.

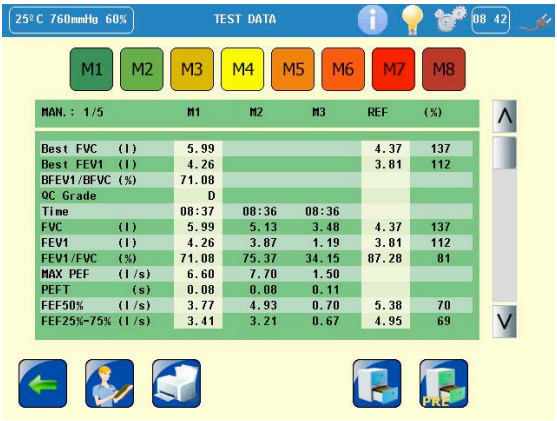
  b **Volume bar:** Progress bar in terms of the expired volume. Red indicates 75% below the predicted value, the orange between 75% and 100% and green 100% above the predicted value.

  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 or 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 

The **DATOSPIR TOUCH** spirometer 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 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)

4.3 POST BRONCHODILATION TEST

The **DATOSPIR TOUCH** spirometer 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.

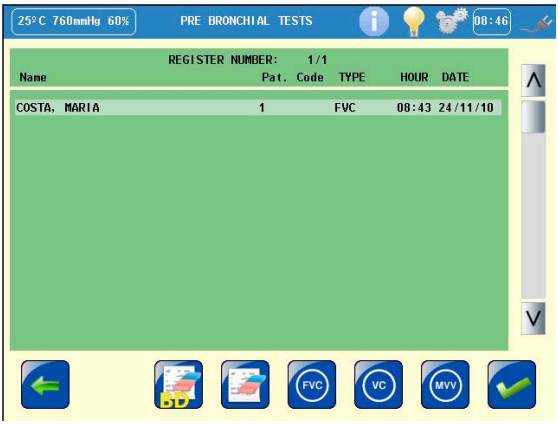
2 Save the **PRE test** in the database 

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 

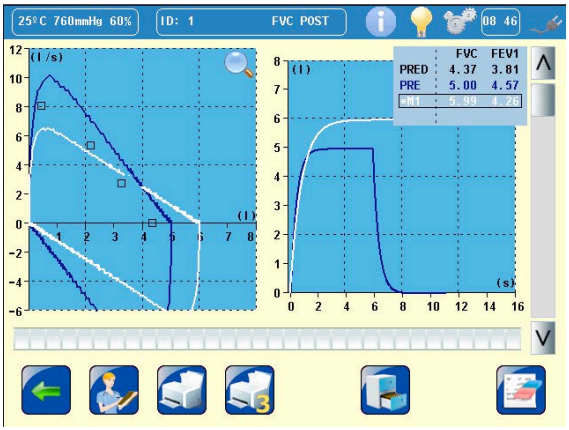
. A screen similar to the following will appear which displays the tests saved in PRE mode.



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**.

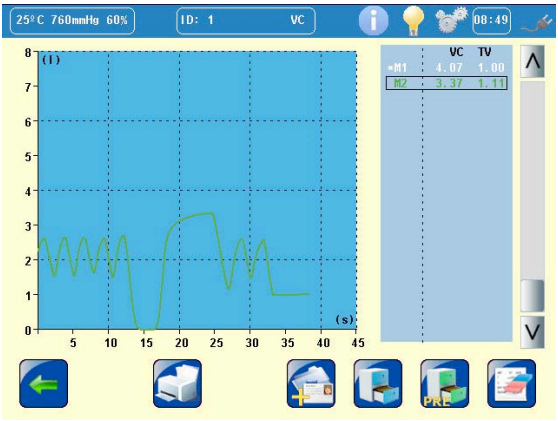
- **Weighted % between PRE and POST**
- **% between REF (Predicted) and POST**
- **% between PRE and POST**
- **Difference between PRE and POST**

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**.

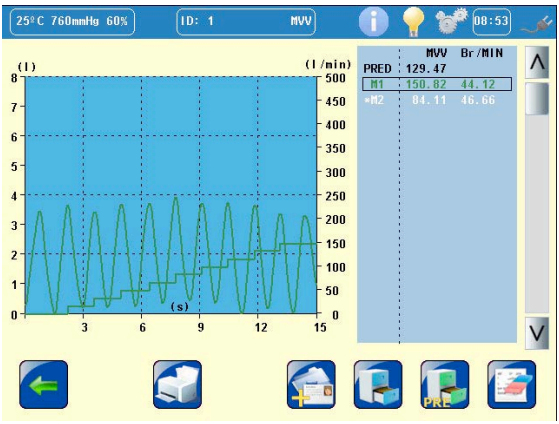
4.5 MAXIMUM VOLUNTARY VENTILATION «MVV» TEST

1 Press 

, from the main screen.

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

- The **axes** 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. COMMUNICATIONS SYSTEM

One of the strengths of the **DATOSPIR TOUCH** spirometer 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

Communications can be made via USB (standard), Bluetooth (optional) or Ethernet (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 equipment'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. For USB compatible spirometers, a driver must be installed on the PC.

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 spirometer, 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.

3 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.

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. After-sales Service** or to **your distributor**, who will analyze it and assess the cause of the problem, providing or proposing a suitable solution.

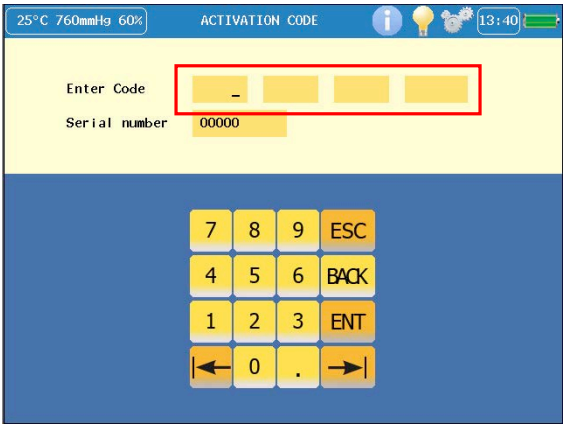
5.3 ADDING OPTIONS AND/OR TRANSDUCER

If you want to add a module / option (SpO_2, MIP-MEP, bluetooth, 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

The Datospir TOUCH contains internal software (firmware). SIBEL, SA carries out improvements on it continuously. If you want to incorporate them into your spirometer 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 spirometer holding pressed the ON / OFF button for 5 seconds.**

5.5 EXPORTING TESTS TO OTHER SYSTEMS

The DATOSPIR TOUCH spirometer 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. Technical Support** or your distributor, who will provide any further information you may require.

6. TECHNICAL SPECIFICATIONS

6.1 GENERAL SPECIFICATIONS

<table>
<tr><td>Power supply</td><td colspan="4">Input 100 to 240V, 50 to 60Hz
Output 12V 2.5 A (Electrical Protection: Class I)</td></tr>
<tr><td>Compatible external power supplies</td><td colspan="4">• MEANWELL MES30A-3P1J
• EMERSON DP4012N3M
• DANUBE FRM030-S124</td></tr>
<tr><td>Medical device classification</td><td colspan="4">Class IIa</td></tr>
<tr><td>Protection level</td><td colspan="4">IPX2: Device (not power supply) is protected against vertically dripping water when the enclosure is tilted up to 15 degrees</td></tr>
<tr><td>Dimensions and Weight</td><td colspan="4">195 x 270 x 100mm
1,7 kg (with battery) approx.</td></tr>
<tr><td>Storage capacity (Database)</td><td colspan="4">• 2 types of database 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, pulse oximetry and MIP-MEP tests.</td></tr>
<tr><td>Communications</td><td colspan="4">• PC: USB 2.0, Bluetooth 2.0 (op.), Ethernet (op.)
• Printer: USB 2.0 Bluetooth 2.0 (op.)</td></tr>
<tr><td>Printer protocol</td><td colspan="4">PCL 3 HPA, PCL 5e</td></tr>
<tr><td>Display</td><td colspan="4">high resolution touch screen LCD, VGA of 640x480</td></tr>
<tr><td>Battery pack</td><td colspan="4">Ni-Mh Rechargeable, 9.6V 2.5Ah</td></tr>
<tr><td>Operating Conditions</td><td colspan="4">Temperature: 5 to 40 ºC
Humidity < 85% (without condensation)
Pressure: 850 to 1060 hPa. (638 a 795 mmmHg/1500 a 0 m aprox.)</td></tr>
<tr><td rowspan="4">Recomended Conditions of measurement</td><td></td><td>Peak Flow
(EN ISO 23747:2007)</td><td>Forced expiratory volume
(EN ISO 2678:2009)</td><td>ATS/ERS Take Force</td></tr>
<tr><td>Temp</td><td>10-35 ºC</td><td>17-35 ºC</td><td>>17ºC</td></tr>
<tr><td>Hum</td><td colspan="3">30-75% (sin condesación)</td></tr>
<tr><td>Press</td><td colspan="3">850-1060 hPa
(638 a 795 mmHg / 1500 a Om aprox.)</td></tr>
<tr><td>Transport and storage</td><td colspan="4">Temperature: -20 to 70 ºC
Humidity < 85% (without condensation)</td></tr>
<tr><td>Internal temperature sensor</td><td colspan="4">5to 40 ºC ± 1 ºC</td></tr>
<tr><td>Max. Nº of maneuvers per subject</td><td colspan="4">8 FVC maneuvers, 8 VC maneuvers, 8 MVV maneuvers</td></tr>
<tr><td>Device lifetime</td><td colspan="4">7 years (see section 6.6 for each transducer and the User's Manuals of the modules)</td></tr>
<tr><td>Weather station</td><td colspan="4">Pressure: 500 to 1040 hPa, accuracy: ± 6.67 hPa
(375 to 780mmHg, accuracy: ± 5 mmHg)
Humidity: 0 to 100% (accuracy: ± 5%)</td></tr>
<tr><td>Applicable standards</td><td colspan="4">• European directive concerning medical devices 93/42/EEC (RD 1591:2009)
• Quality (EN ISO 13485:2012+AC:2012, EN ISO 9001:2008 and EN ISO 14971:2012)
• Compliance with data protection Act. Directive 95/46/EC
• Safety Medical devices (EN 60601-1:2006+AC:2010)
• Electro-magnetic Compatibility (EN 60601-1.2:2007+AC:2010)</td></tr>
</table>

	• Biocompatibility: Biological evaluation of medical devices. (EN ISO 10993.1: 2009+AC: 2010) • Usability (EN 60601-1-6:2010) • Usability (EN 62366:2008) • Spirometers for forced spiratory volumes measurement (EN ISO 26782:2009+AC:2009) • Spirometers for peak spiratory flow (EN ISO 23747:2009) • Software of medical devices (EN 62304:2006+AC:2008) • Pulsioximetry (ISO 80601-1-2-61:2011) • Vibration and temperature: (Series EN 60721:1995 and Series EN 60068:1999) • Documentation and information (EN 1041:2008, EN ISO 15223-1:2012, EN 980:2008) • Waste disposal according to WEEE Directive 2002/96/CE. • Electronic Device: 2011/65/EU Rohs Directive (starting on July 22nd, 2014)
Spirometry standards in force	• ATS/ ERS Standards: 1. Miller MR, Crapo R, Hankinson J, et al. General considerations for lung function testing. Eur Respir J 2005; 26:153–161. 2. Miller MR, Hankinson J, Brusasco V, et al. Standardisation of spirometry. Eur Respir J .2005; 26: 319–338. 3. V. Brusasco, R. Crapo and G. Viegi. Standardisation of the measurement of lung volumen Eur Respir J 2005; 26: 511-522 • 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


LIMITATION OF MOISTURE


LIMITATION OF PRESSURE


CONSULT THE INSTRUCTIONS FOR USE


PRECAUTION


START-UP (STANDBY)


BF APPLIED PART


NO PHISIOLOGICAL PULSE OXIMETRY ALARMS

IPX2 PROTECTED AGAINST DRIPPING WATER WHEN TILTED UP TO 15°


WASTE DISPOSAL ACCORDING THE WAEE DIRECTIVE


SENSITIVE CONNECTOR TO ELECTROSTATIC DISCHARGES (See Annex 1)


ENTRANCE (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
- FEF25% (l/s) Forced Expiratory Flow 25% into the maneuver
- FEF50% (l/s) Same, 50% into the maneuver
- FEF75% (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
- MEF50/MIF50 (-) Ratio
- FEV1/FEV.5 (-) Ratio
- FEV1/PEF (-) Ratio
- MIF50% (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
- Vext (%) 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.
- 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.

BRONCHODILATATION TEST

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

SLOW VITAL CAPACITY

- 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 to 76 (1)
POLGAR - WENG		4 to 100
HANKINSON - NHANES III	EEUU	4 to 100
PEREZ - PADILLA	MEXICO	7 to 100 (1)
CRUZ-MORALES	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

(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

RANGES AND MEASUREMENTS (According to ATS/ERS2005)

	Fleisch	Turbine	Lilly Dispos.
Measurement Scale (BTPS) Flow Volume	0 to ±16 l/s 0 to 10 l		
Dynamic flow resistance	< 1,47 hPa (1.5 cmH_20) / (l/s) a 14 l/s		
Precision of measurements (BPTS) Volume Flow PEF	(the highest value) 3% or 50 ml 5% or 200 ml/s 10% or 300 ml/s		
Time related precision	0,50%		
Volume resolution	<10ml	<10ml	<10ml
Sampling frequency	100Hz	100Hz	100Hz
Transducer lifetime	1400 disinfect. or 3 years	1400 disinfect. or 3 years	Only one use (Expir. 3 years)

6.7 MANUFACTURER'S LIABILITY

SIBEL S.A. 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. technical staff.

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

7. CLEANING AND MAINTENANCE

DATOSPIR TOUCH spirometer 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 SPIROMETER

The spirometer case can be cleaned with a wipe moistened with soapy (neutral) water or with 96º alcohol. 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. **Do not use abrasive substances or solvents.**

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, specially 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 **CIDEX® OPA** solution (follow the manufacturer's instructions). Then rinse them in destilled water. **Do not use abrasive substances or solvents.**

3 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 **CIDEX® OPA** solution (follow the manufacturer's instructions). Then rinse the turbine by immersion in destilled water. Do not rinse the turbine by holding it under running water. Do not use abrasive substances or solvents.

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

4 Leave it to dry at room temperature and re-assemble the turbine in the housing.

When performing an intensive use of the spirometer, 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 **CIDEX® OPA** 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. 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.**

7.1.3. CLEANING THE SPIROMETER

The spirometer case can be cleaned with a wipe moistened with soapy (neutral) water or with 96º alcohol. 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. **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 spirometer 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.

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

Actions carried out by skilled technical personnel:

According to the different regulations, particularly the **93/42/EEC Medical Device Directive**, electromedical devices should be verified and/or calibrated regularly to ensure reliable functions and the safety of patients, users and the environment.

This Technical check will be performed every year following the **DATOSPIR TOUCH** Verification and Adjustment Procedures, available from the manufacturer **SIBEL, S.A.** 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.**, 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.**

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**. **After-Sales Service**. Specify the problem in as much detail as possible.

Annex 1. ELECTROMAGNETIC COMPATIBILITY

1.1 ELECTROSTATIC DISCHARGE

The Datospir Touch uses the exception of electrostatic discharge test on the Ethernet connector as described in EN60601-1-2: 2007.

For this reason, as stated in paragraph 5.1.2 of the standard, the symbol  must be placed next to the Ethernet connector.

This symbol does not imply any problem of safety to the technician or to the patient. Neither implies that the Ethernet module is damaged. It would only cause that the Ethernet communication stops running for a moment.

However, to avoid any slightest problem, you should take the following precautions:

- Connect and disconnect the Ethernet cable when the device is turned off.

- During the functioning of the equipment, do not touch the connector with your fingers.

- Inform to all staff involved of the meaning of the symbol and the precautions about discharge sensitivity.

1.2 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	**Compliance**	**Electromagnetic environment - Guidance**
RF (Radiated) emissions CISPR 11 (EN 55011)	Group 1 Class B	DATOSPIR TOUCH uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF (Conducted) emissions CISPR 11 (EN 55011)	Group 1 Class B	DATOSPIR TOUCH uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions EN-IEC 61000-3-2	Class A	
Voltage fluctuations / Flicker emissions EN-IEC 61000-3-3	Yes	

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.			
Immunity test	**EN-IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – Guidance**
Electrostatic discharge (ESD) EN-IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst EN-IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment. To Ethernet cable.
Surge EN-IEC 61000-4-5	±1 kV differential ±2 kV common mode	±1 kV differential ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN-IEC 61000-4-11	<5 % Ut (>95 % dip in Ut)for 0.5 cycle 40 % Ut (60 % dip in Ut) for 5 cycles 70 % Ut (30 % dip in Ut) for 25 cycles <95 % Ut (>5 % dip in Ut) for 5 seconds	<5 % Ut (>95 % dip in Ut)for 0.5 cycle 40 % Ut (60 % dip in Ut)for 5 cycles 70 % Ut (30 % dip in Ut)for 25 cycles <95 % Ut (>5 % dip in Ut) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the DATOSPIR TOUCH requires continued operation during power mains interruptions, it is recommended that the DATOSPIR TOUCH be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field EN-IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial of 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.			
Immunity test	**EN-IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF EN-IEC 61000-4-6	3 Vrms 150KHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of DATOSPIR TOUCH, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{E}\right]\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF EN-IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \left[\frac{3.5}{E}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E}\right]\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1. At 80 MHz and 800 MHz, the higher frequency range applies. **Note 2**. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which DATOSPIR TOUCH is used exceeds the applicable RF compliance level above, DATOSPIR TOUCH should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such reorienting or relocating DATOSPIR TOUCH.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

Recommended separation distances between portable and mobile RF communications equipment and DATOSPIR TOUCH

DATOSPIR TOUCH is intended for use in an electronic environment in which radiated RF disturbances are controlled. The costumer or the user of **DATOSPIR TOUCH** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and **DATOSPIR TOUCH** as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	De 150 kHz a 80 MHz $d = \left[\frac{3.5}{3}\right]\sqrt{P}$	**De 80 MHz a 800 MHz** $d = \left[\frac{3.5}{3}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{3}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 800 MHz, the separation distance for the higher frequency applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absortion and reflection from structures, objects and people.

Annex 2. COMPLIANCE WITH THE DATA PROTECTION ACT. DIRECTIVE 95/46/EC

REQUIREMENTS AFFECTING THE USER OF THE EQUIPMENT

According to current legislation, the **user of this equipment is the only party responsible** for saving and processing the details of his patients according to the Law.

CONFIGURATION OF DATOSPIR TOUCH PROTECTION

The **DATOSPIR TOUCH** spirometer has an equipment 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 thereto.

- **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.