Sibelmed®

SPIROMETER DATOSPIR touch

USB

Bluetooth

Ethernet

HL7

- **3 operating modes:**
  Primary Care, Occupational Health or Diagnostic.

- **Transducers: Turbine, Disposable or Fleisch.**

- **Spirometry quality control program.**

- **Connectivity to the Internet for sending tests and remote monitoring.**

- **Optional modules:**
  SpO_2, MIP-MEP, Sniff and electronic weather station.

Creating the future

DATOSPIR TOUCH · spirometer

EXPERIENCE IS OUR GUARANTEE

RDI

The DATOSPIR touch spirometer has been designed by the **RDI** department of **SIBEL S.A.** with the collaboration of the Pneumology Department of the "**Hospital de la Santa Creu i Sant Pau de Barcelona**" and the **Biophysics and Bioengineering Unit of the University of Barcelona**, fulfilling the standardization criteria of the **ATS/ERS TASK FORCE 2005 & SEPAR**.

Quality control program

● **Spirometry quality control program:**

DATOSPIR touch includes an automatic function for spirometry quality control, based on the recommendations of the **National Lung & Health Education Program (NLHEP).**

QC Prompts: Helps the technician to provide good instructions to the patient in order to obtain high quality spirometry tests. At the end of a maneuver, an on-screen notification will inform of its acceptability.

QC Grades: At the end of the test, a quality grade from A to F will be shown to indicate the reliability of the results, according to the NLHEP criteria.

● **Accuracy verification program:**

ATS/ERS 2005 recommends to check periodically volume spirometers.

In order to check that the transducer is measuring correctly, the spirometer includes a simple verification procedure, to be performed in a few seconds if required.

Main features:

- High resolution color touchscreen.
- Internal printer.
- Rechargeable battery.
- 3 operating modes:
  Primary Care, Occupational Health or Diagnostic.
- Spirometry quality control program:
  quality grades for tests, accuracy verification, and calibration program.
- Modules: SpO_2, MIP-MEP, Sniff and electronic weather station
- Database with more than 3000 tests with graphs
- Tests: FVC, VC, MVV, Bronchodilation, Bronchoconstriction.
- Simultaneous F/V and V/T graphs.
- Adult and pediatric incentive graphs.
- On-screen help.
- Integrated temperature sensor.
- Connectivity via USB, BLUETOOTH, or ETHERNET[*].
- Interoperability compatible with HL7 (spirometry CDA)[**].
- Suitable for telemedicine.
- PIN available (In compliance with the European standards for data protection, 95/46/EC).

[*]Ethernet: Connectivity to the Internet for sending tests by e-mail and for remote data monitoring.
[**]HL7: Health Level Seven is an international standard for the interoperability of health information systems. (With W20s software)
CDA: Clinical Document Architecture.

Transducers

Fleisch · Turbine · Disposable

Connectivity

Customizable

OPERATING MODES	Occupational Health	Primary Care	Diagnostic
FVC (Forced Vital Capacity)	■	■	■
VC (Slow Vital Capacity)	--	■	■
MVV (Maximum Voluntary Ventilation)	--	■	■
Bronchodilation (Post)	■	■	■
Bronchoconstriction (Bronquial challenge test)	●	●	■
Parameter and graph selection (Customization)	■	■	■
Flow/Volume and Volume/Time graphs (F/V and V/T)	■	■	■
Simultaneous F/V and V/T graphs	●	●	■
Maneuvers overlapping	■	■	■
Report graphs in ATS/ERS format	■	■	■
Save/print 3 maneuvers	--	■	■
Print 3 PRE maneuvers (Parameters and graphs)	--	■	■
Spirometry quality control	--	■	■
Help screens on all the menus	■	■	■
End of maneuver acoustic signal	■	■	■
Time bar incentive	■	■	■
Volume incentive	■	■	■
Pediatric incentive	--	■	■
Test time control	■	■	■
Miller diagnosis	■	■	■
Snider, Kory & Lyons diagnosis	■	■	■
NLHEP (Ferguson) diagnosis	■	■	■
ATS/ERS (Pellegrino) diagnosis	■	■	■
Import of work list from software*	■	■	■
Export data to HIS (Health Information System)	■	■	■
Calibration program	■	■	■
Self-check program	■	■	■

■ Included   ● Optional   -- Not available

*Available in 2012

Occupational Health Mode (OC): Intended for occupational health clinics and insurance companies. Performs FVC and bronchodilation tests quick and easy for early detection of work-related lung diseases.

Primary Care Mode (PC): Intended for Primary Care centers. Performs the main tests with interactive help in order to obtain spirometries with similar quality to the ones performed at a specialized center (Spirometry quality control). Helps to detect and follow-up most common respiratory diseases such as Asthma or COPD.

Diagnostic Mode (DG): Intended for Pulmonary Function Laboratories specialized in lung diseases, providing the highest spirometry test control. It is the most complete mode that includes Bronchoconstriction Test, Occupational Health and Primary Care modes among other options.

INNOVATION AND TECHNOLOGY

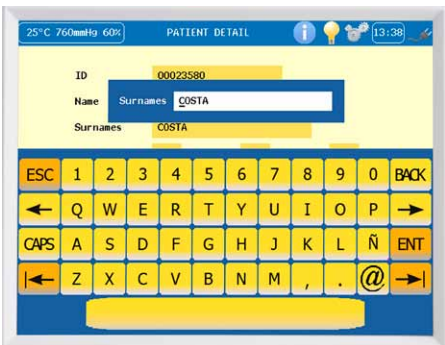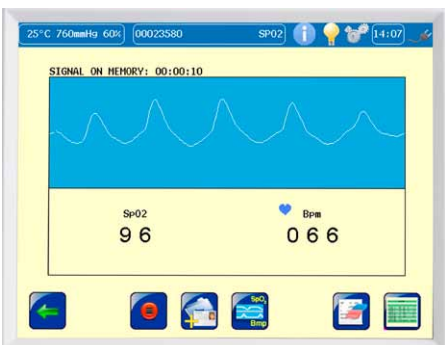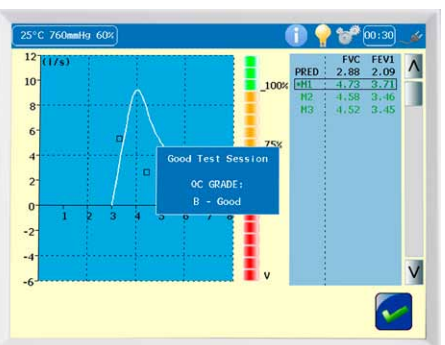

CUSTOMIZATION

PATIENT DATA

FVC

QWERTY KEYBOARD

PEDIATRIC INCENTIVE

PULSE OXIMETRY

QUALITY CONTROL

OPTIONAL MODULES · SOFTWARE

Pulse oximetry

DATOSPIR touch may incorporate a module dedicated exclusively to taking oxygen saturation data and plethysmographic pulse. This option allows you to take pulse oximetry measurements independently or during a spirometry test. It also allows you to visualize the plethysmographic wave in real time and carry out occasional measurements of oxygen saturation (SpO_2) and Pulse Rate (PR) or long-term studies (approximately 8 hours), specially designed for OSAS screening or in any other situation.
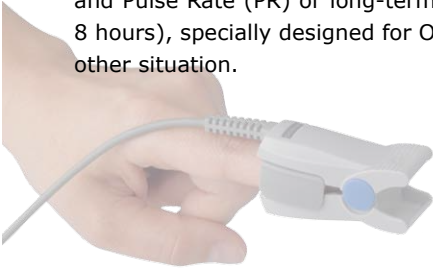
Electronic Weather Station

The electronic weather station is a module of the spirometer that measures atmospheric pressure and humidity.
DATOSPIR touch has a built-in temperature sensor as a standard accessory.

> The Plug & Play technology of the optional modules allows you to upgrade the spirometer easily by yourself.

W20s software

SIBELMED W20s is a powerful software for the transfer, analysis, storage and/or registration of spirometric signals which operates on Microsoft Windows®·

It is compatible with all DATOSPIR spirometers, and its operation can be in real or deferred time, depending on the characteristics of the spirometer. It includes, among other functions:

- Patient DB management.
- FVC, VC, MVV tests.
- Bronchodilation tests.
- F/V and V/T graphs.
- Parameter selection.
- Auto diagnosis selection.
- Patient's trend graph.
- Printing reports set up.
- Graphic display, with incentive tests for children and adults.
- Pulse oximetry (SpO_2) and Maximum Pressures Modules (MIP-MEP).
- Compatible with HL7(spirometry CDA). Available in 2012

Bronchoconstriction

The bronchoconstriction module is an option available with the DATOSPIR touch spirometer. It has the possibility of performing the test with two different methods:

- **Normal or continuous method**: It consists of administering a certain concentration of medication to a patient for a specified quantity of time.

- **Short method**: It consists of administering a patient a certain number of inhalations of a certain concentration to a patient.

MIP-MEP and Sniff

DATOSPIR touch has an external Maximum Respiratory Pressures module available. It allows measurement pressures ±295 hPa (up to ±300 cmH_2O) both during inspiratory and expiratorion tests, and has several reference values which can be configured by the user. With the SNIFF probe, you can also take the measurement of maximum nasal pressures.
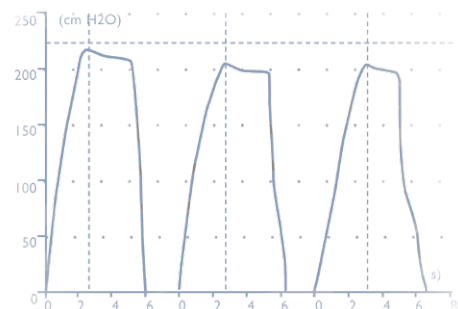
FVC WITH INCENTIVE
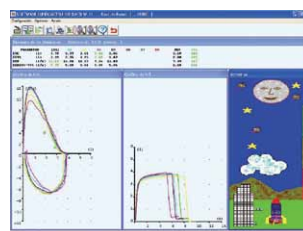
BRONCHOCONSTRICTION
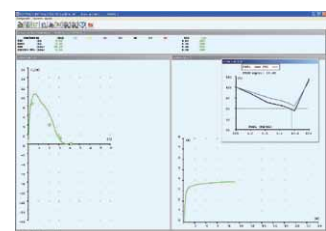
TREND

PULSE OXIMETRY

DATOSPIR TOUCH · spirometer

MODELS

	Easy			Diagnostic		
	D	T	F	D	T	F
TRANSDUCERS						
Disposable	■	●	●	■	●	●
Turbine	●	■	●	●	■	●
Fleisch	●	●	■	●	●	■
OPERATING MODES						
Primary Care	■	■	■	■	■	■
Occupational Health	■	■	■	■	■	■
Diagnostic	--	--	--	■	■	■
DATABASE						
Database >1,000 tests with graphs	■	■	■	--	--	--
Database >3,000 tests with graphs	●	●	●	■	■	■
SOFTWARE						
W20s spirometry software license*	■	■	■	■	■	■
CONNECTIVITY / INTEROPERABILITY						
USB to external printer and PC	■	■	■	■	■	■
Ethernet	●	●	●	●	●	●
HL7 (spirometry CDA)**	●	●	●	●	●	●
Bluetooth	●	●	●	●	●	●
MODULES						
Bronchoconstriction	●	●	●	■	■	■
Electronic Weather Station	●	●	●	■	■	■
Pulse oximetry	●	●	●	●	●	●
MIP-MEP	●	●	●	●	●	●
Sniff	●	●	●	●	●	●
ACCESSORIES						
Thermal Paper 110 x 50 mm	■	■	■	■	■	■
Reusable mouthpiece	--	■	■	--	■	■
Cardboard mouthpiece (25u)	--	■	■	--	■	■
Disposable transducer (25u)	■	--	--	■	--	--
USB cable for PC / printer	■	■	■	■	■	■
Nose clip	■	■	■	■	■	■
External power supply	■	■	■	■	■	■
User manual	■	■	■	■	■	■
Rechargeable battery	●	●	●	●	●	●
Calibration syringe	●	●	●	●	●	●
Carrying bag	●	●	●	●	●	●

■ Included   ● Optional   -- Not included   *Interoperability compatible with HL7 (spirometry CDA)   **Available in 2012

Parameters

FVC / Bronchodilation
- FVC (l)
- FEV1 (l)
- FEV1/FVC (%)
- PEF (l/s)
- FEF50%(l/s)
- FEF25-75% (l/s)
- FEV6 (l)
- FEV1/FEV0.5 (-)
- PEFT
- Vext (l)
- FIVC (l)
- FIF50%
- FEF50/FIF50
- QC Grades
- FEV.5 (l)
- FEV3 (l)
- FEV.5/FVC (%)
- FEV3/FVC (%)
- FEV1/VC (%)
- FEV1/FEV6 (%)
- FEV1/PEF (%)
- FEV1/FIV1 (-)
- PEF/PIF (-)
- FEF25% (l/s)
- FEF75% (l/s)
- FEF75-85% (l/s)
- FET25-75 (s)
- FET100 (s)
- FIV1 (l)
- FIV1/FIVC (%)
- PIF (l/s)
- MTT (s)
- MVVInd (l/min)
- COPD Index (%)
- Lung age (years)

VC
- VC (l)
- TV (l)
- ERV (l)
- IRV (l)
- IC (l)
- Ti (s)
- Te (s)
- Tt (s)
- Ti/Tt (%)

MVV
- MVV (l/min)
- Br./min (Br/min)

Bronchoconstriction
- FVC (l)
- FEV1 (l)
- PEF (l/s)
- FEF25-75% (l/s)
- PDx

SpO$_2$
- Maximum SpO$_2$ (%)
- Average SpO$_2$ (%)
- Minimum SpO$_2$ (%)
- SpO$_2$ Std Dev (%)
- Maximum PR (BPM)
- Average PR (BPM)
- Minimum PR (BPM)
- PR Std Dev (BPM)
- CT90 (%)
- CT80 (%)
- CT70 (%)
- ODI-4
- ODI-3
- ODI-2
- Test time (hh:mm:ss)

Technical Specifications

Flow transducer: Fleisch, turbine or disposable (Lilly)
Measurement range (BTPS): Flow 0 ± 16 l/s; Volume 0 to 10 l
Accuracy (BTPS): Flow 5% or 200 ml/s; Volume: 3% or 50ml (ATS/ERS)
Dynamic resistance: <1.47 hPa (<1.5 cmH$_2$0) / (l/s) at 14 l/s
Display: 640 x 480 px and 5.7 inch high resolution color VGA touchscreen
Printer: 112 mm thermal graphic printer
Rechargeable battery: Ni-Mh 10.8V 2500mAh. Duration 1.5h approx.
No. of maneuvers per patient: 8 FVC, 8 VC, 8 MVV
Operating Temperature-Humidity: 5 to 40ºC. < 85% (without condensation)
Power supply: 100 to 240V, 50 to 60Hz
Power: 30W
Dimensions: 195 x 270 x 100 mm
Weight: 1.7 kg
Storage temperature: -20ºC to 70ºC
Directive: 93/42/CEE on Medical Devices, Class IIa Product
Standards: EN 60601-1:2006, EN 60601-1-2:2007, EN 60601-1-6:2007, EN ISO 10993-1:2009, EN ISO 23747:2009, EN ISO 26782:2009, EN 62304:2006, EN 62366:2008, EN 1041:2008, EN 980:2008, EN ISO 14971:2009, EN ISO 9919:2009

References

- SEPAR
- ERS
- KNUDSON
- CRAPO
- ZAPLETAL
- MORRIS
- AUSTRIA
- GUTIERREZ
- CASTRO-PEREIRA
- POLGAR-WENG
- HANKINSON - NHANES III
- PEREZ – PADILLA
- CRUZ-MORALES
- GOLSHAN
- GARCIA RIO
- CANDELA
- PLATINO*

*Available in 2012

Ask for a free spirometry training course.

Sibel is member of HL7 Spain

HL7 Spain   CERT ISO 9001

Q   CE 0197   ISO 9001:2008   EN-ISO 13485:2003

SIBEL S.A. reserves the right to modify the technical specifications without prior notice.

Sibelmed®