

Sibelmed®

35
años
years

1 poz Computerized spirometer for the
diagnosis of respiratory diseases such as
ASTHMA and **COPD**.

5 poz
4 poz

SPIROMETER **DATOSPIR** *aira*



Bluetooth®

USB



aira
Wireless Spirometry

DATOSPIR *aira* · Computerized Spirometer

DATOSPIR *aira* represents the 8th generation of spirometers developed by SIBELMED's RDi department, complying with the latest ERS/ATS and SEPAR standards.

- 1p DATOSPIR *aira* is the only computerized spirometer that combines Bluetooth and USB connectivity and that, at the same time, allows the choice of 3 transducers:
- 2p DISPOSABLE (Lilly), FLEISCH and TURBINE.

DISPOSABLE: Very precise pressure transducer that avoids cross contamination. Without filters or mouthpieces!

2 poz

FLEISCH: Very precise pressure transducer used in a multitude of pulmonary units.

TURBINE: Turbine transducer.



Bluetooth Connectivity

Wireless connection to the computer



Ergonomic handle

Designed for maximum convenience



Temperature sensor

Integrated into the appliance



Visual indicator

Reports on the appliance status



2 poz

Auto-shutdown

Battery saving auto-shutdown system



2 poz

USB connectivity

Connects to the computer via USB



The versatility of the DATOSPIR *aira* makes it the ideal spirometer for occupational health, primary care, pulmonary function units, private practice and platform integration environments.

aira



DATOSPIR *aira* · Computerized Spirometer

Technical Specifications

2 poz

Models by transducer	Disposable	Fleisch	Turbine
Weight (g.)	124	185	173
Dimensions (cm.)	15.5 x 10 x 3.5	18 x 9 x 5	18 x 9 x 5
Measurement range (BTPS) Flow Volume	0 to ±16 l/s 0 to 10 l		
Resistance to: 14 l/s (cmH ₂ O / l/s)	<1.2	<1.4	<0.6
Measurement accuracy (BTPS) Volume Flow PEF	(whichever is greater) 3% or 50 ml 5% or 200 ml/s 10% or 300 ml (ATS/ERS 2005) 10% or 170 ml/s (EN ISO 23747:2015)		
Connectivity	Bluetooth 2.0 USB 2.0 and 3.0		
Batteries	2 alkaline AAA batteries (standard) 2 rechargeable AAA batteries		

Tests and Parameters

FVC/Bronchodilation
VC
MVV
Bronchoconstriction

- FVC
- FEV0.5
- FEV0.75
- FEV1
- FEV0.5/FVC
- FEV0.75/FVC
- FEV1/FVC
- PEF
- FEF25%-75%
- ...

3 poz

4 poz

More than 40 parameters

DATOSPIR *aira*
DISPOSABLE



Code 09064

DATOSPIR *aira*
FLEISCH



Code 09063

DATOSPIR *aira*
TURBINE



Code 09065

Adult and Pediatric References

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

Standard Accessories

- 1 Plastic mouthpiece
- 1 Nose clip
- 1 Travel bag
- 1 CD software + instructions manual
- 1 Quick guide
- 1 USB cable
- 2 Alkaline AAA batteries
- Disposable Model:
 - 1 Bag of 25 disposable transducers
 - 1 Calibration adapter
- Fleisch/Turbine model:
 - 1 Bag of 50 cardboard mouthpieces

Optional Accessories

- 01145 Bluetooth adapter
- 01739 Charger for Ni-Mh batteries
- 01149 Pediatric mouthpiece adapter (for Turbine and Fleisch transducers)
- 07155 Spirometer support
- 08290 Calibration syringe

Consumable

- 03169 Disposable transducer (50 u.)
- 08268 Bacterial filter (100 u.)
- 01555 Cardboard mouthpieces (100 u.)
- 02692 Plastic nose clip (5 u.)

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Sibel is a member
of HL7 Spain

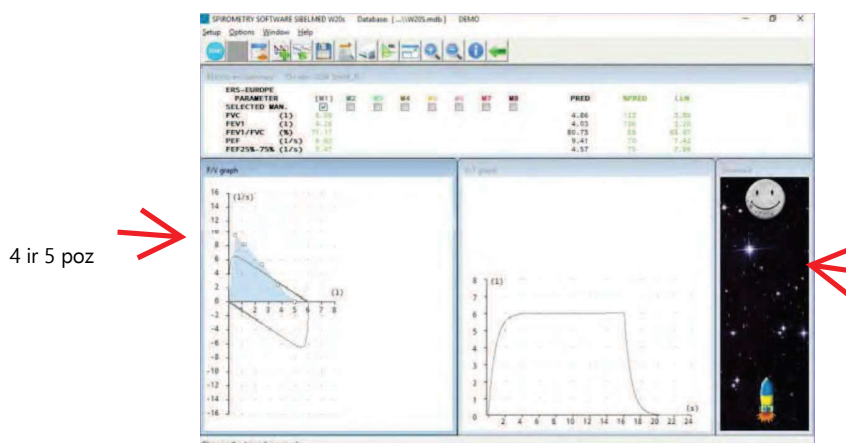


Management
System
ISO 9001:2008
www.tuv.com
00 807298260



CE0197 EN-ISO 9001:2008 EN-ISO 13485:2012+AC:2012





2.9.3. MANEUVER DATA

After having performed, at least, one spirometric maneuver, the resulting data can be consulted in the Maneuver Data window through **OPTIONS - MANEUVER DATA** (MANEUVER DATA Icon).

This window presents all the information related to each performed maneuver. A * is added to REF when the predicted values have been extrapolated and in the report appears the text: «Warning: Reference values extrapolated!». In a similar way if the low limit of normal value is not available in the selected predicted set the message «Warning: LLN = 80%» is also shown, indicating that the LLN value will be calculated as the 80% of the predicted value.

The following data are available in this window:

03169	Disposables transducers bag 50u.					
01569	Plastic mouthpieces bag 10u.					
01149	Pediatric mouthpiece adapter					
08920	Calibration syringe (3 L)					
COD.	COMPONENTS AND SPARE PARTS					
01145	Bluetooth PC adapter					
06186	Fleisch transducer					
03175	Turbine transducer					

Optional

Not included

2.4 CALIBRATION



Verify the device calibration daily. Otherwise you can obtain incorrect measurements.

Connect the calibration syringe output to the transducer input by the same side for blowing to verify the calibration.

Consult the User's Manual of the **W20s Spirometry Software** to obtain more information about the calibration or verification procedure.

3. INSTRUCTIONS FOR USE

Install the **W20s Spirometry Software** to use the device with a PC. Consult the **User's Manual of W20s Software**.

1 poz

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

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

2.7.2. PARAMETERS AND PREDICTEDS

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

Parameters and predicted

FVC parameters

<input checked="" type="checkbox"/> FVC (l)	<input checked="" type="checkbox"/> FEV3/FVC (%)	<input checked="" type="checkbox"/> FET25%-75% (s)	<input checked="" type="checkbox"/> FIV1 (l)	<input checked="" type="checkbox"/> FEV1/FEV6 (%)
<input checked="" type="checkbox"/> FEV0.5 (l)	<input checked="" type="checkbox"/> FEV1/VC (%)	<input checked="" type="checkbox"/> FET100% (s)	<input checked="" type="checkbox"/> FIV1/FIVC (%)	<input checked="" type="checkbox"/> COPD index (%)
<input checked="" type="checkbox"/> FEV0.75 (l)	<input checked="" type="checkbox"/> PEF (l/s)	<input checked="" type="checkbox"/> FEF50%/FIF50%	<input checked="" type="checkbox"/> FEV1/FIV1 (%)	<input checked="" type="checkbox"/> Lung Age
<input checked="" type="checkbox"/> FEV1 (l)	<input checked="" type="checkbox"/> FEF75% (l/s)	<input checked="" type="checkbox"/> MTT (s)	<input checked="" type="checkbox"/> PIF (l/s)	<input checked="" type="checkbox"/> QC Grade
<input checked="" type="checkbox"/> FEV3 (l)	<input checked="" type="checkbox"/> FEF50% (l/s)	<input checked="" type="checkbox"/> FEV1/FEV0.5	<input checked="" type="checkbox"/> PEF/PIF	
<input checked="" type="checkbox"/> FEV0.5/FVC (%)	<input checked="" type="checkbox"/> FEF25% (l/s)	<input checked="" type="checkbox"/> FEV1/PEF (%)	<input checked="" type="checkbox"/> Vext. (l)	
<input checked="" type="checkbox"/> FEV0.75/FVC (%)	<input checked="" type="checkbox"/> FEF25%-75% (l/s)	<input checked="" type="checkbox"/> FIF50% (l/s)	<input checked="" type="checkbox"/> MVV ind (l/min)	
<input checked="" type="checkbox"/> FEV1/FVC (%)	<input checked="" type="checkbox"/> FEF75%-85% (l/s)	<input checked="" type="checkbox"/> FIVC (l)	<input checked="" type="checkbox"/> FEV6 (l)	

VC and MVV parameters

<input checked="" type="checkbox"/> VC (l)	<input checked="" type="checkbox"/> IRV (l)	<input checked="" type="checkbox"/> Te (s)	<input checked="" type="checkbox"/> MVV (l/min)
<input checked="" type="checkbox"/> TV (l)	<input checked="" type="checkbox"/> IC (l)	<input checked="" type="checkbox"/> Tt (s)	<input checked="" type="checkbox"/> Br/Min
<input checked="" type="checkbox"/> ERV (l)	<input checked="" type="checkbox"/> Tl (s)	<input checked="" type="checkbox"/> Tl / Tt (%)	

Interpretation:

☐ Disabled
☐ Miller
☐ Snider, Kory and Lyons
☐ NLHEP
☒ ATS/ERS

Predicted :

Adult: Child:
 GLI ethnic group:
☒ Z-SCORE in reports

Dilation :

☒ Alerts
☒ Calibration date

Quality Control

☒ ATS/ERS
☐ NLHEP

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

- **FVC Tests Parameters**
- **VC and MVV Parameters**
- **Interpretation algorithms (Diagnosis)**

3.2 TESTS, FUNCTIONS AND PARAMETERS

3.2.1 FORCED VITAL CAPACITY

Parameters:

3 poz

• FVC	(l) Forced Vital Capacity
• FEV.5	(l) Forced Expiratory Volume in 0.5 seconds
• FEV1	(l) Idem in 1 second
• FEV3	(l) Idem in 3 seconds
• FEV.5/FVC	(%) Relation
• FEV.75/FVC	(%) Relation
• FEV.75	(l) Forced Expiratory Volume in 0.75 seconds
• FEV1/FVC	(%) Relation
• FEV3/FVC	(%) Relation
• FEV1/VC	(%) Relation
• PEF	(l/s) Peak Expiratory Flow
• FEF25%	(l/s) Instantaneous forced expiratory flow when 25% has been expired.
• FEF50%	(l/s) Idem, at 50%
• FEF75%	(l/s) Idem, at 75%
• FEF25-75%	(l/s) Forced Mesoexpiratory Flow
• FEF75-85%	(l/s) Medium Flow between 75-85% of FVC
• FET25-75	(s) Time passed between 25-75% of FVC
• FET100	(s) Forced Expiratory Time
• FEF50/FIF50	(-) Relation
• FEV1/FEV.5	(-) Relation
• FEV1/PEF	(-) Relation
• FIF50%	(l/s) Maximum Inspiratory Flow when 50% of FVC has been inspired
• FIVC	(l) Forced Inspiratory Vital Capacity

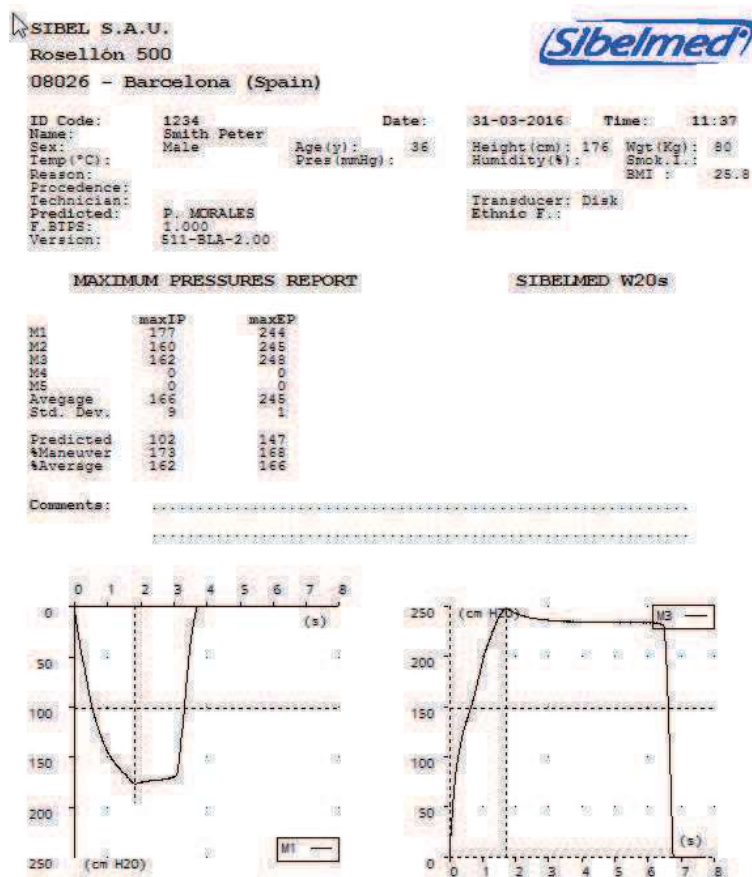
3 poz

- FIV1 (l) Forced Inspiratory Volume in 1 second
- FIV1/FIVC (%) Relation
- FEV1/FIV1 (%) Relation
- PIF (l/s) Peak Inspiratory Flow
- MTT (s) Measured Transit Time
- PEF/PIF (-) Relation
- Vext (l) Extrapolated Volume related to FVC
- MVVInd (l/min) Maximum Voluntary Ventilation indirect (30 x FEV1)
- FEV6 (l) Forced Expiratory Volume in 6 seconds
- FEV1/FEV6 (%) Ratio
- COPD rate Parameter that depends on the number of cigarettes smoked a day, the age and FEV1. It indicates the risk of COPD.
- Lung Age Parameter that depends on the height and FEV1. It indicates the equivalent age of the lung.
- QC grade Quality Control Grade According to NLHEP criteria.

3.2.2 QUALITY OF FVC TEST

In order to assess the pulmonary function of the patient, it is necessary to obtain measurements of high quality. The quality of maneuvers (and of the complete test) depends on patient cooperation and this, in turn, depends on the instructions provided by the technician.

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



B. SAVING TO THE INTERNAL DATABASE

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

GRADE	TEST	CRITERIA
A	VERY GOOD	At least 2 acceptable maneuvers with the largest 2 FEV ₁ values matching within 100mL and the largest 2 FEV ₆ values matching better than 100mL.
B	GOOD	At least 2 acceptable maneuvers with FEV ₁ values matching between 101 and 150mL
C	ACCEPTABLE	At least 2 acceptable maneuvers with FEV ₁ values matching between 151 and 200 mL
D	POOR	Only one acceptable maneuver, or more than one, but the FEV ₁ values match > 200 ml (with no interpretation)
F	NOT ACCEPTABLE	No acceptable maneuvers (with no interpretation)

3.2.3 INTERPRETATION ALGORITHMS (DIAGNOSIS)

7 poz

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

Miller Diagnosis

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

Snider, Kory & Lyons Diagnosis

It is based on the following criteria:

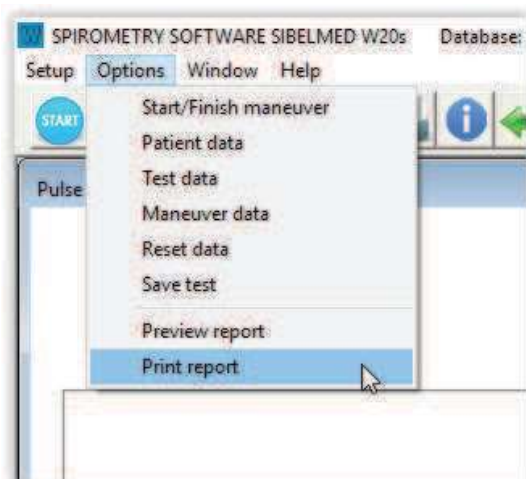
- If FVC > 80% of FVC Reference and FEV₁ > 80% of FEV₁ Reference --> **Values in reference range. Normal Diagnosis**
- If FEV₁/FVC% < FEV₁/FVC% Reference and FEV₁ < 80% of FEV₁ Reference --> **Ventilatory alteration of Obstructive type**

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

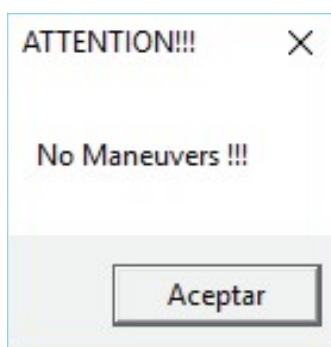
A1.4.3. PRINTING AND/OR SAVING IN THE DATABASE

7 poz **A. PRINTING OF THE RESULTS**

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



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



Otherwise the following report will be printed:

7 poz

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

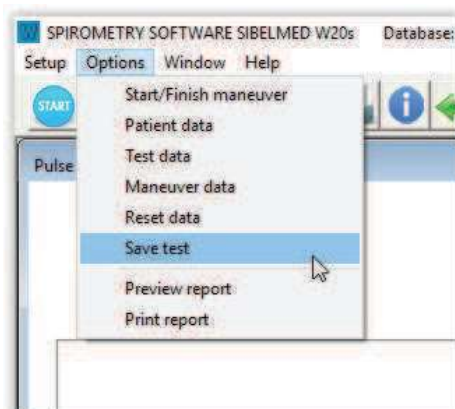
ID Code: 1234 **Date:** 31-03-2016 **Time:** 10:20
Name: Smith Peter
Sex: Female **Age (y):** 36 **Height (cm):** 180 **Wgt (Kg):** 75
Reason: **BMI :** 23.1
Procedure:
Technician: **Transducer:** Disk
Version: 511-BLA-2.00

**PULSEOXIMETRY REPORT****SIBELMED W20s**

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

B. SAVING IN THE INTERNAL DATABASE

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



3.3.2 ANALYSIS CRITERIA

- Start expiration FVC

Calculated by the back-extrapolation method.

- Final expiration FVC

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

- Selection of tests FVC

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

- Selection of parameters

The displayed parameters are the corresponding to the selected maneuver (selected by the operator or by the best FVC + FEV1 default criteria) Also are displayed the best FVC and best FEV1 as the highest values recorded among the performed and stored maneuvers.

- Start of expiration in VC and MVV by signal level

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

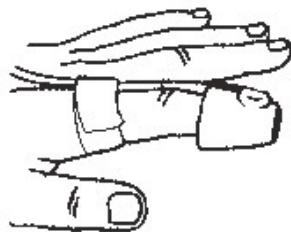
3.3.3 USEFUL LIFE

The useful life is 7 years

3.3.4 STORAGE

It is recommended to store a 25°C, at this temperature manufacturers guarantee 1000.000h. At 70 ° C the life is reduced to 2000 h. See specifications of CD ROM for more information.

8 poz



A1.4. PERFORMANCE OF PULSE OXIMETRY TESTS

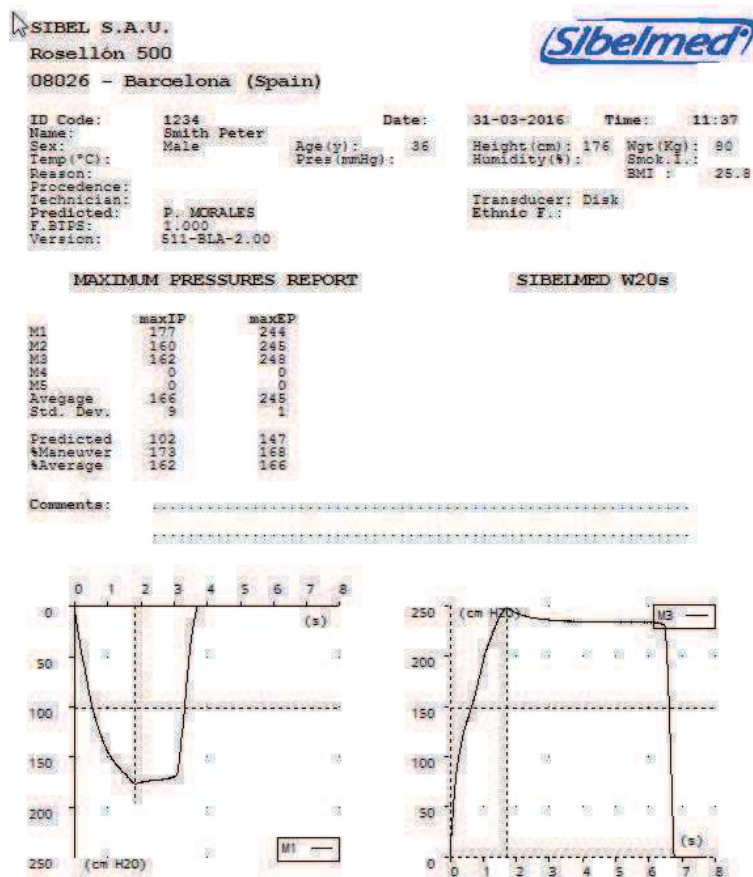
To start a new pulse oximetry test select the patient in the database or create a new one, then click the Pulse Oximetry button in the toolbar or select the menu option Tests / Pulse Oximetry.

A1.4.1. INPUT OF TEST DATA

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

A screenshot of a software window titled "Maneuver Data". It contains various input fields for patient and test information. The fields are organized into rows: ID Code (1234), Date (03/31/2016, 10:19), Name (Peter), Age (36), Last Name (Smith), Height (180 cm), Weight (75 kg), BMI (23.1), Temp (°C), P/100 (mmHg), H/100 (mmHg), Reason, Precedence, Technician, Ethnicity, and Comments. Some fields are disabled (grayed out). At the bottom, there are three icons: a green checkmark, a red X, and an information icon (i).

9 poz



1.6

1.7

B. SAVING TO THE INTERNAL DATABASE

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

4. CLEANING AND MAINTENANCE



Do not use abrasives substances or solvents. The device can be damaged.

DATOSPIR aira spirometer requires, like other electromedical equipment, maintenance aimed at assuring patient safety as well as operator and environment safety; and at ensuring reliability and accuracy of the functions for which it has been developed.

4.1 SPIROMETER CLEANING

Clean the spirometer with a cloth moistened with water and neutral soap or with 96° alcohol. Dry the remaining moisture. Make sure no liquid or foreign material enters the equipment nor connectors or connections, especially in the pressure ports of the disposable transducer handle (wipe the handle downwards).

4.2 TRANSDUCERS DISINFECTION

The transducer is the main part exposed directly to the patient. Therefore, it is necessary to keep it in perfect physical and hygienic conditions.

To disinfect the transducer, proceed as follows:

A) TRANSDUCER FLEISCH

1. Remove the filter and then the transducer by slightly pressing the tab to release it from its housing.
2. Immerse the transducer and filter in a **CIDEX® OPA** disinfectant solution (see manufacturer's instructions).

Rinse with distilled water.

3. Shake the transducer to remove residual water, dry it at room temperature and assemble again.





Turbine and Fleisch transducers and reusable mouthpieces must be disinfected before using them in new patients or disposable mouthpieces or antibacterial / antiviral filters must be used in order to avoid the risk of contamination or cross-infection.

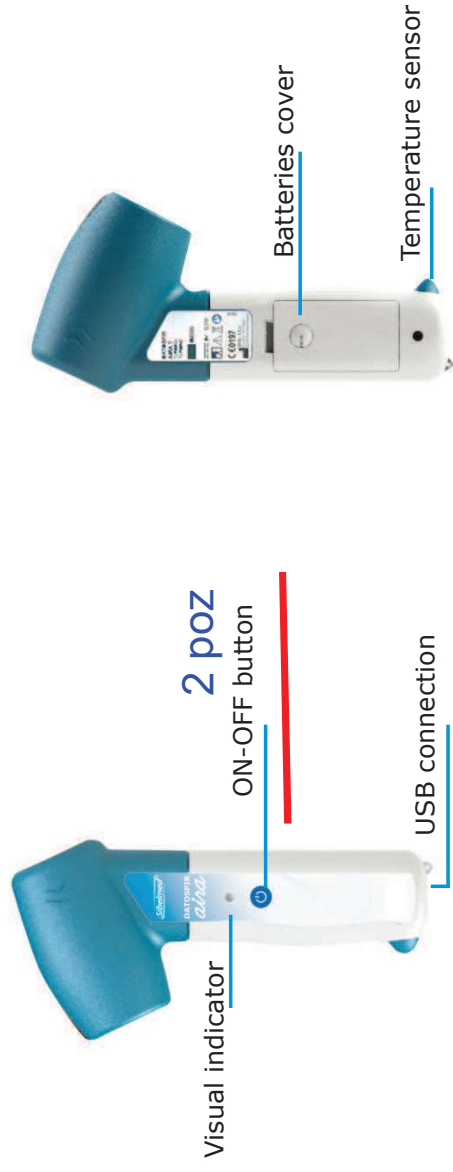
11 poz

Use disposable mouthpieces or antibacterials filters if you suspect about contamination risk.

Place the transducer onto the cradle when it is not being used to avoid falls. If you have to travel with the device, consult the paragraph TRANSPORT AND STORAGE.

For information on test quality results, please consult the user's manual of the W20sSpirometry Software.

3.2 CONTROL AND CONNECTORS DISTRIBUTION



13 poz

DATOSPIR *aira* is powered with two AAA NiMH or Alkaline batteries or through the USB port when connected to a computer.

DATOSPIR AIRA is NOT designed for use under other conditions or using other power sources not indicated in this User's Manual. Only the accessories specified in the manual must be used.

1.3 USER PROFILE

DATOSPIR *aira* has been designed for its use by health professionals, being supervised or instructed by a physician. Specific training in the spirometry technique is recommended. The Bronchoconstriction test must be supervised by a technician qualified in this technique. The user must be familiar with the device functioning before using it on patients. All the required information for the correct use of the device is available in this User Manual. Although the patient can handle the device while blowing, the software application must be managed by a physician or a trained technician in spirometry.

DATOSPIR *aira* is indicated for patients older than 4 years, with weight over 15 Kg and height over 50 cm, and with a mental and physical condition allowing the performance of the forced maneuver.

1.4 LIMITATIONS FOR USE. CONTRAINDICATIONS

The analysis of the results of a spirometry test is not enough to make a correct diagnostic about the clinical condition of the patient. Interpretation of tests must be complemented by the clinical history or other test that the doctor considers appropriate for deciding the correct treatment.

The collaboration of the patient is required to make a spirometry test. Complete forced expiration is necessary to obtain significant FVC values. The physician must assess the patient's ability to perform these tests. Pay special attention to children, the elderly and people with disabilities.

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

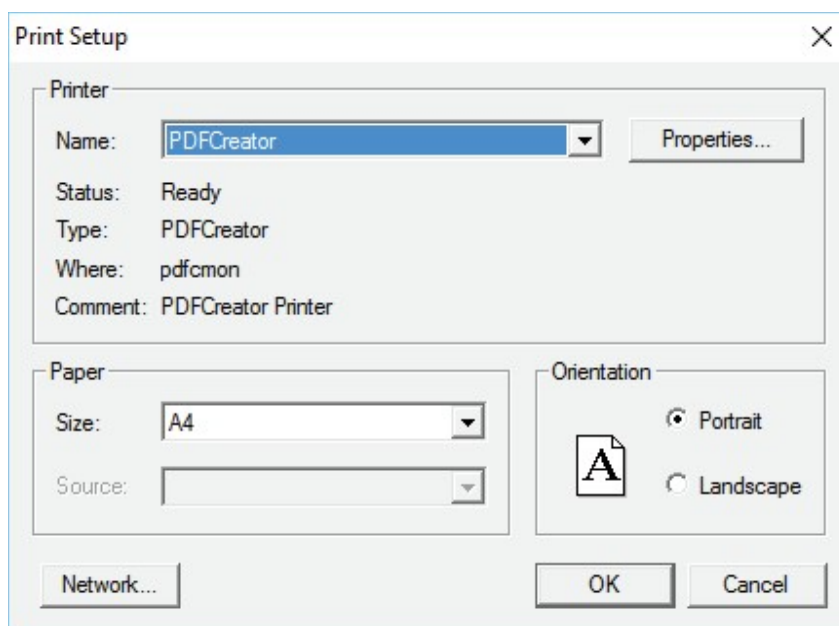
The device must not be used when the validity of the results can be compromised due to external causes.

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

Next the different options that can be configured are detailed.

2.7.1. PRINTER SELECTION

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



14 poz

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

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



The ATS/ERS recommend the daily calibration of the spirometer with a calibration syringe

CALIBRATION SYRINGE S3000



(3L)

15 poz

Creating future

FVC Forced Vital Capacity

VC Slow Vital Capacity

MVV Maximum Voluntary Ventilation

Dilat Postbronchodilation Test in FVC mode

P1 and P2

Parameters corresponding to:

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

Date and Time

Performance of the test

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

The information transferred is stored in the operative **Database** at that moment and in each corresponding patient card. The XML and PDF files corresponding to each downloaded test are also generated if the corresponding options is selected in the INTEROPERABILITY dialog.

15 poz

2.14. CALIBRATION PROCEDURE IN THE DATOSPIR 600 AND DATOSPIR AIRA SPIROMETERS

The Spirometry Software SIBELMED W20s requires another product to be able to fulfill its functions. As a consequence, it does not include any calibration system, as this is performed from the linked spirometer, except while using with the DATOSPIR-600 or DATOSPIR AIRA, as these devices don't have an user interface and the calibration is done through this software.

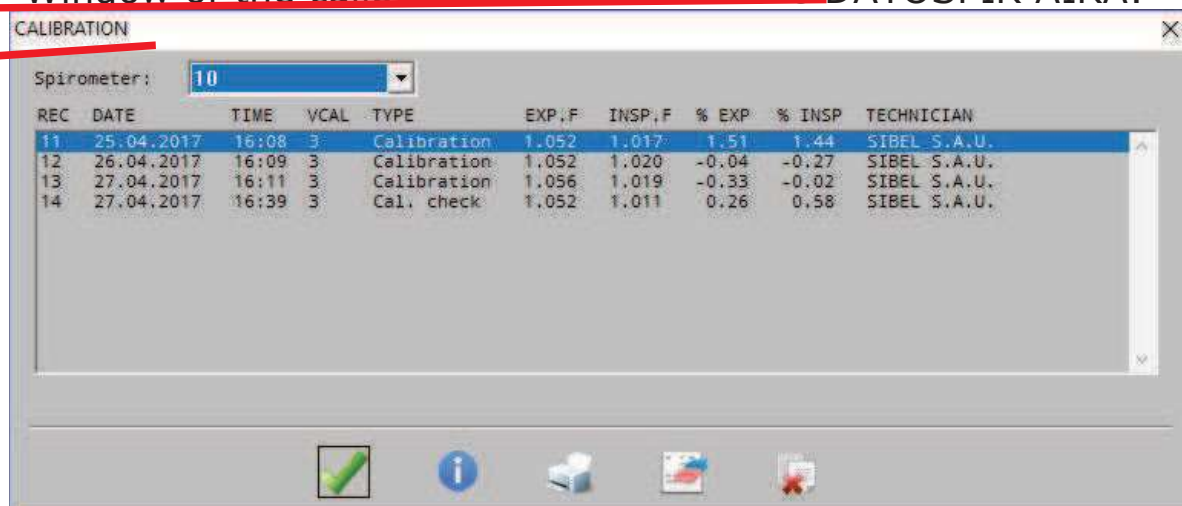
COMMON REMARKS

As previously mentioned, the current standards for the spirometry recommend that all the spirometers must be calibrated periodically. This is due to the alterations which can modify the characteristics of the electronic circuits and

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

16 poz

Window of the calibration database in the DATOSPIR AIRA:



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

16 poz

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

Serial number of the calibrated device

Number of record

Date of calibration

Time of calibration

Calibration volume

Type of maneuver (calibration / check)

Expiratory factor

Inspiratory factor

Expiratory volume error

Inspiratory volume error

Technician who performed the calibration

3.1 SOFTWARE SPECIFICATIONS

3.1.1 COMPUTER INSTALLATION AND REQUIREMENTS

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

17 poz

	Minimum	Recommended
RAM Memory:	1 GByte	2 GByte or more
Hard Disk:	20 MByte	200 GByte or more
Graphic Card:	1024x768	1280x1024 or more
Monitor:	15"	17"
Ports:	RS232, USB 1.1, USB 2.0	RS232, USB 2.0, USB 3.0, Ethernet

Backup Unit: Recommended

Printer: compatible with the operating system used.

3.1.2 OPERATING SYSTEM COMPATIBILITY

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

2 **poz** **DATOSPIR *aira*** is powered with two AAA NiMH or Alkaline batteries or through the USB port when connected to a computer. DATOSPIR AIRA is NOT designed for use under other conditions or using other power sources not indicated in this User's Manual. Only the accessories specified in the manual must be used.

1.3 USER PROFILE

DATOSPIR *aira* has been designed for its use by health professionals, being supervised or instructed by a physician. Specific training in the spirometry technique is recommended. The Bronchoconstriction test must be supervised by a technician qualified in this technique. The user must be familiar with the device functioning before using it on patients. All the required information for the correct use of the device is available in this User Manual. Although the patient can handle the device while blowing, the software application must be managed by a physician or a trained technician in spirometry.

DATOSPIR *aira* is indicated for patients older than 4 years, with weight over 15 Kg and height over 50 cm, and with a mental and physical condition allowing the performance of the forced maneuver.

1.4 LIMITATIONS FOR USE. CONTRAINDICATIONS

The analysis of the results of a spirometry test is not enough to make a correct diagnostic about the clinical condition of the patient. Interpretation of tests must be complemented by the clinical history or other test that the doctor considers appropriate for deciding the correct treatment.

The collaboration of the patient is required to make a spirometry test. Complete forced expiration is necessary to obtain significant FVC values. The physician must assess the patient's ability to perform these tests. Pay special attention to children, the elderly and people with disabilities.

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

The device must not be used when the validity of the results can be compromised due to external causes.