

*winspiroLIGHT*

## **User Manual**

User Manual Rev. 2.1

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If this software presents a problem, please contact a service centre or the manufacturer.

**The manufacturer has a policy of continuous product development and improvement, and the manufacturer therefore reserves the right to modify and to update the information contained in this Manual. Any suggestions and/or comments should be sent via email to: [mir@spirometry.com](mailto:mir@spirometry.com). Thank you.**

**The manufacturer accepts no responsibility for any loss or damage caused by the User of the device due to the use of this Manual and/or due to an incorrect use of the product.**

**Note that due to printing limitations the screenshots shown in this manual may differ from the display of the machine and/or from the keyboard graphics. Copying this manual in whole or in part is strictly forbidden.**

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# 1 INTRODUCTION TO WINSPIROLIGHT

winspiroLIGHT is a database for the management of spirometry testing made with any compatible spirometer. All of the measurement functions are carried out by the spirometer(s) which can be connected to the software.

winspiroLIGHT is also invaluable to create a specific database for each patient and to compare the tests made by each patient, thus enabling the doctor to manage the patients within the database.

The software gives a graphic presentation of a series of parameters relating to human respiratory function.

winspiroLIGHT can also create a clinical history for each patient, allowing for test comparisons and helping the doctor to make an efficient data management.

Before installing winspiroLIGHT, check the PC system requirements for compatibility:

The following system requirements must be met when installing winspiroLIGHT:

Local installation (from CD) requirements:

- Operating system Windows 2000, Windows XP, Windows Vista, windows Seven 32 bit, windows Seven 64bit and windows Vista 64bit
- Pentium III-class PC 500 MHz or higher recommended
- RAM 128 MB of RAM (256 MB preferred)
- Display Designed for XGA resolution at 1024 × 600 or higher
- Hard Disk 300MB free space
- Administrative privileges on the system
- USB port

We also recommend having an additional 100 MB of free disk space on your C: drive for use by Windows during the installation. If your system does not meet these requirements, the program may not run correctly.

## 1.1 *Intended use*

This software is destined specifically for use by medical or paramedical personnel, in any case under the supervision of a doctor.

Qualified personnel are required to use, to interpret the results and to maintain this software program.

The software is intended to be used in the doctor's office or within a hospital or health care facility.

## 1.2 *Limitations of use and Contraindications*

An analysis of the results of a spirometry test is not by itself sufficient to make a correct diagnosis of the clinical condition of a subject. A detailed clinical history of the subject is also required, together with the results of any other test(s) suggested or prescribed by a doctor. Test comments, a test interpretation and suggested courses of treatment must be given by a doctor. Any symptoms which the patient may have must be fully evaluated by the doctor before any spirometric tests are made. The user must evaluate the psycho/physical conditions of the patient to carry out the test and assess the ability of the patient to collaborate with the test.

The user is responsible for the test acceptability. Special attention must be paid in the case of elderly people, children and handicapped people. The software must not be used in the case of situations which could interfere with the correct operation and therefore compromise the test results.

## 1.3 *Main features*

winspiroLIGHT allows you to use and to manage your spirometry data. The presentation of the results is more logical and activities within the database are faster and more intuitive.

winspiroLIGHT simplifies the following activities:

- View patient information
- Make spirometry testing
- Use the paediatric incentive
- Print or Export diagnostic reports in the most spread format (.doc, .pdf)
- Calibrate the turbine
- Upgrade the internal software of the compatible devices

## 1.4 Licence contract and registration

This software is protected by international copyright laws and by other laws and treaties governing intellectual propriety. Copyright and other intellectual propriety laws protect the rights of the software owners including the right to copy the software. Duplication of this software without the written permission of the copyright owner is an "infringement under copyright law" and anyone breaking these laws is subject to penalties and sanctions.

Registration enables you to be informed on product updates/upgrades and also to obtain technical support.

Software registration is compulsory for winspiroLIGHT. Proceed as described in the following chapter to make the registration.

### WARNING

**To have a full access to winspiroLIGHT the windows user must have a full control (read/write/modify permission) on the winspiroLIGHT folder (C:\MIR\WINSPIROLIGHT\)**

### 1.4.1 winspiroLIGHT Registration

Open the winspiroLIGHT software; At start-up of winspiroLIGHT the following window appears warning the user how many days are left to register the program.



### WARNING

**Once the days to register have expired the software will automatically remain blocked until the user registers the software.**

To register follow the procedure below:

Upon opening the software click on “Register winspiroLIGHT now” at the same time a window on the right will appear with the link to [www.spirometry.com/reg](http://www.spirometry.com/reg) The user must click on the link and insert the necessary information to register. The window also displays the PIN code.



If the user has already registered on “[www.spirometry.com](http://www.spirometry.com)” insert the proper email and password in the “already registered” area, otherwise proceed with the registration by filling in all the empty fields in the area “NEW REGISTRATION”.

When all the mandatory fields have been filled in click on “Confirm” in the lower area.

At this point a message warning the user on the outcome of the registration will appear; if the registration was successful the user will receive an email to the specified address with a “PAN” code which must be inserted in the registration window; as can be seen in the window on the right. If the registration was not successful the user will be sent to the previous window to complete inserting the required missing information.



Now click on next. If the registration procedure was successful the window on the right will appear. Click on “End” to complete the registration procedure thereby entering the winspiroLIGHT software.



## 1.5 First activation of winspiroLIGHT

This window (shown on the right) appears only the first time winspiroLIGHT is opened, and allows you to set:

- Operating language
- Units format
- Predicted values

After completing the set up, click OK to enter the program.

All of the parameters set up in this window can be modified later as required.



## 1.6 Options

In the “Configuration” menu by clicking on “Options” the user may modify the basic setup of the software.

In the “General” folder the user may select:

- The language
- The units of measurement



In the “Communication” folder the user may:

test the USB connection and get information about the connected device



The "Printout" folder is used to customize the heading of the printouts. It also allows to select the following:

- The header lines
- View the printout preview or print directly
- To print the automatic interpretation or not
- The path to upload the image file of the logo for the heading and if it already contains the header text . If the logo already contains the header text the header lines will not be displayed.

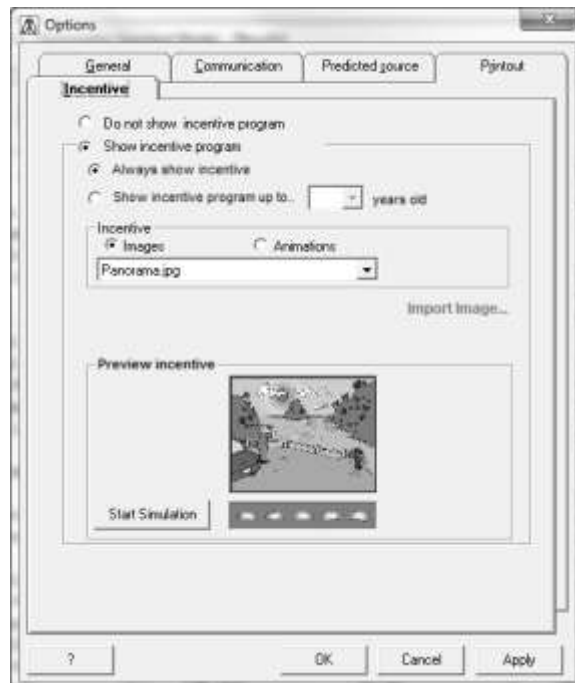


The "Predicted source" folder is used to select the standard for the calculation of predicted values (ATS/ERS or NHANES III). If the standard selected is ATS/ERS it is mandatory to select the "source" from the drop down list





From the Incentive tab, select whether to display an incentive (graphical animation) for children during the FVC test, the age corresponding to the required pediatric incentive program, the type of incentive (graphic images or animation), or set up a specific incentive program (for example downloaded from internet), and lastly simulate the chosen incentive



## 1.7 Predicted values

In the "Predicted source" folder of the "options" menu the user may select either the ATS/ERS or the NHANES III standard.

If the user selects the NHANES III standard, by clicking on either "apply" or "Ok" a window will appear to explain the modifications that will affect the database. Click on "Yes" to select the NHANES III standard.

WARNING

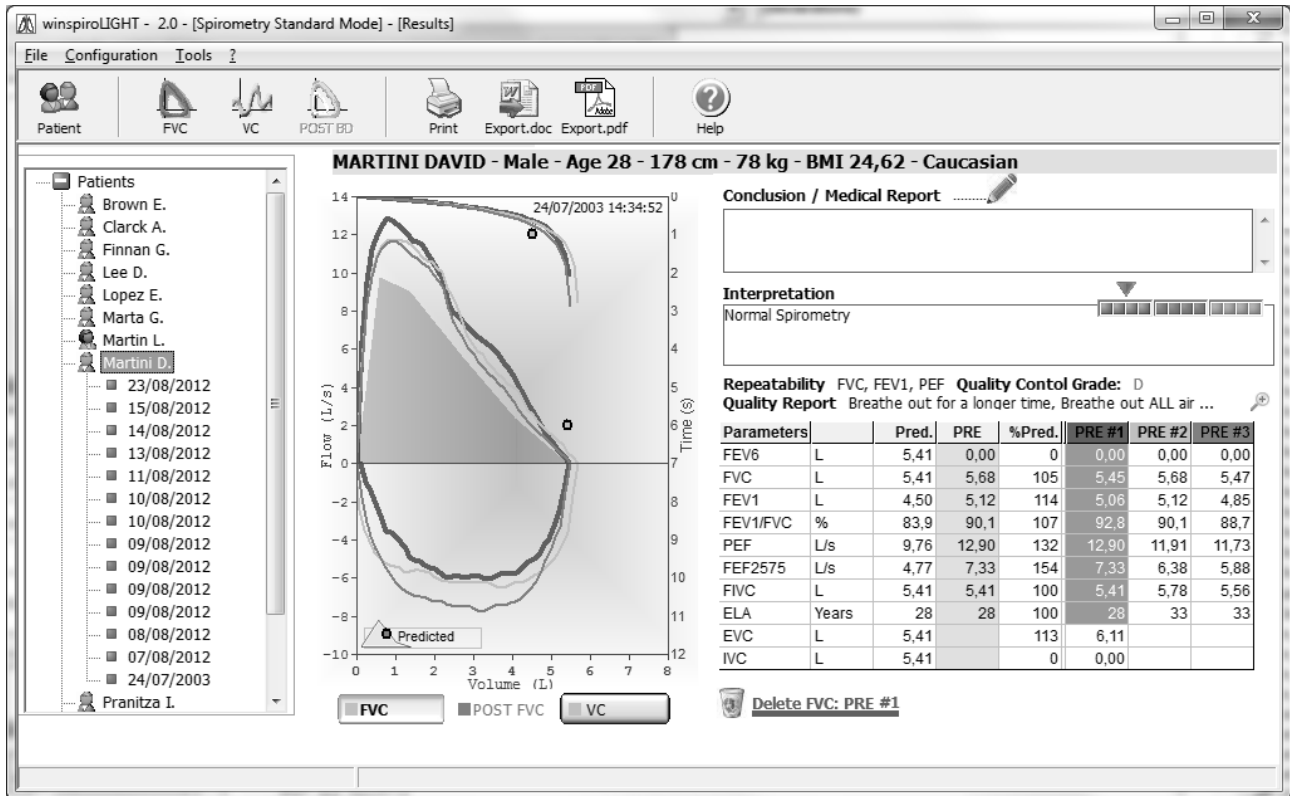
**By selecting the NHANES III standard all the data stored within the database will be modified.**



By selecting the ATS/ERS standard the user may choose one Author of the predicted values or a pair of Authors; one for Adults and the other for children. Lastly the user may opt for either the shaded area or the dotted lines to represent the theoretical flow/volume curve.

## 1.8 Search information in the database

Opening winspiroLIGHT the following window appears:



On the left side of the window there is the list of all the patients stored into the database. When the user clicks on a patient icon, that patient is selected and all his spirometry sessions are automatically displayed. To browse patients and sessions it can be used either the mouse or the arrow keys (up and down). To search a specific patient digit the first letters of his last name.

## 2 PATIENTS

Click "Patients" from the toolbar, to open the Patient card of the selected patient. From this window the user can:

- Edit the anagraphic / anthropometric data of the current patient
- Add new patient
- Delete the current patient.

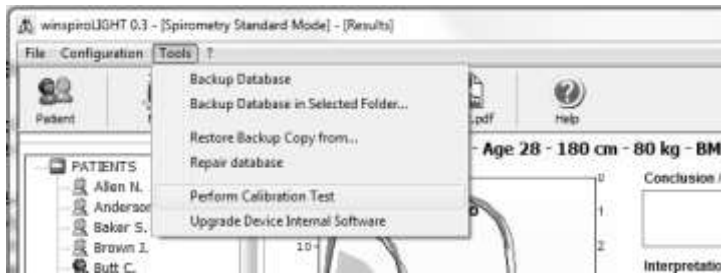
By deleting a patient all his data, included the spirometries, will be permanently erased.

The 'Patient' window contains the following fields and controls:

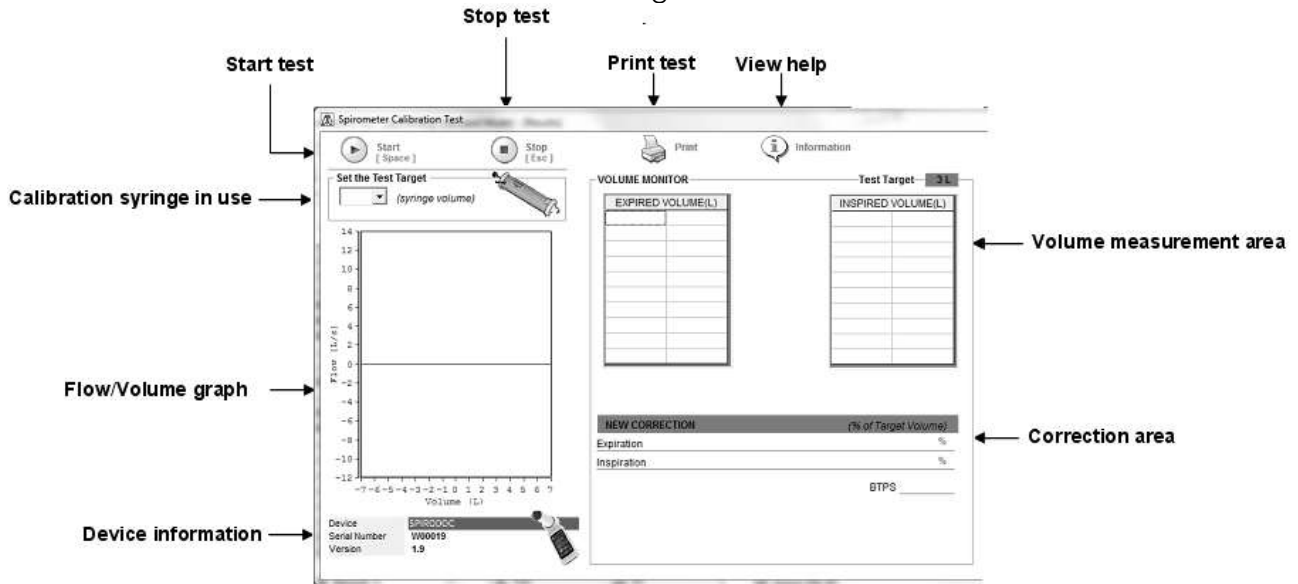
- Buttons: Save, Undo, New, Delete
- Section: Edit / Add patient
- ID: 0
- Last name: Martini
- First name: David
- Height: 180 cm
- Weight: 76 kg
- BMI: 23,46
- Gender: Male (indicated by a male icon)
- Date of birth: 30/06/1975
- Ethnic group: Caucasian

## 3 CALIBRATION

To enter the calibration routine select "Tools" and then "Perform Calibration Test"



The calibration function is divided into the following areas:



**WARNING** ⚠

Some calibration syringes enable the user to vary the volume. Before making a calibration check ensure that the “stop” of the piston is set correctly for the desired volume of air. For instance for a 3L syringe ensure that the “stop” is set exactly to the 3 mark.

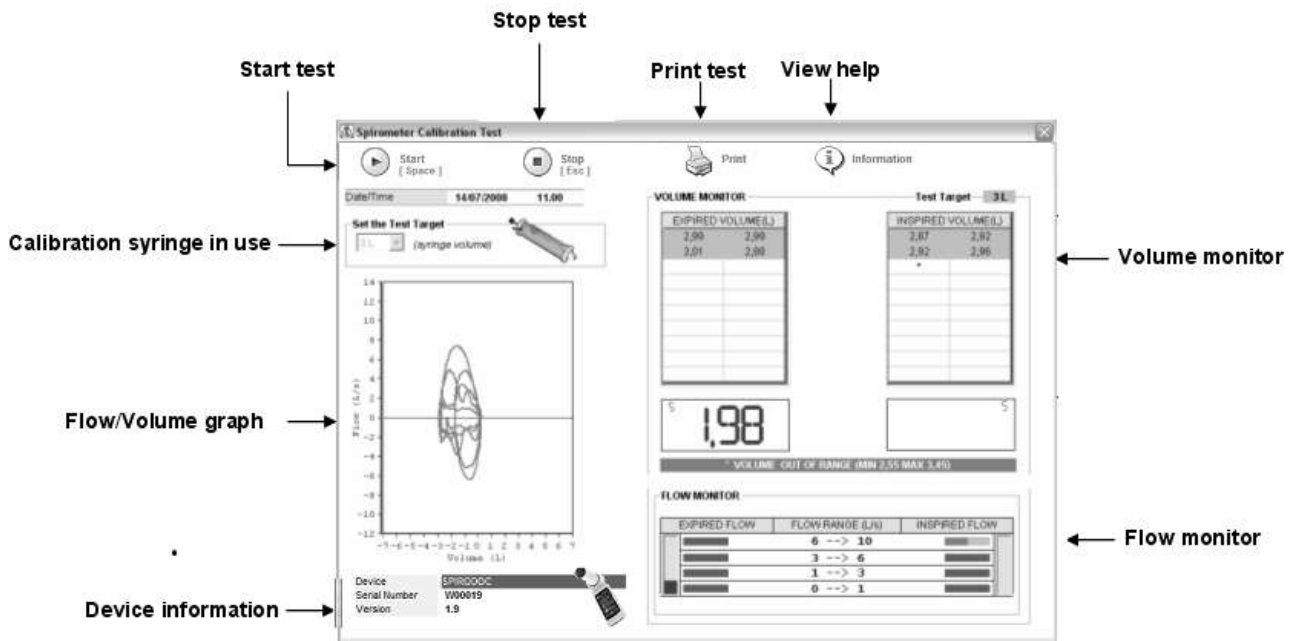
To start a calibration proceed as follows:

- 1 Connect the device to the PC through the USB port
- 2 Connect the turbine of the device to the calibration syringe (ensure that there are no air leaks between the turbine and the syringe and that the turbine remains firmly in place inside the device)
- 3 Check that the device to be tested is correctly shown at the top right hand side of the screen (Device type, serial number and version of firmware) as the calibration will then be carried out on the device shown.

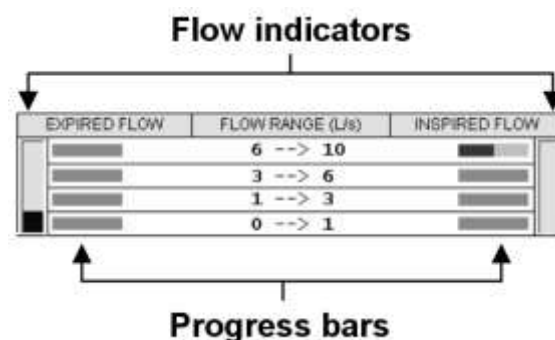
**WARNING** ⚠

Only devices with a direct USB connection can be calibrated on line on the PC. Devices using the RS232 or the RS232/USB converter cannot be calibrated on line.

- 4 Select the type of syringe in use, using the maximum volume possible, in the window “Select test objective”
- 5 Click “Start” and the following window is shown:



6 Start to make some syringe movements in and out at various flow rates from low flow to high to cover the range of flows shown within the "Flow monitor" window. This operation is guided by the progress bars;

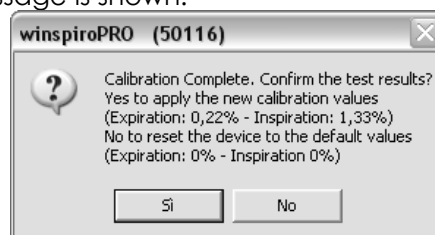


7 when all of the progress bars become green **invert the piston position** to end the test:

### WARNING

If the syringe's piston position is not inverted within 10 seconds after all the progress bar became green, test will be aborted with a timeout message number 50126 (see below)

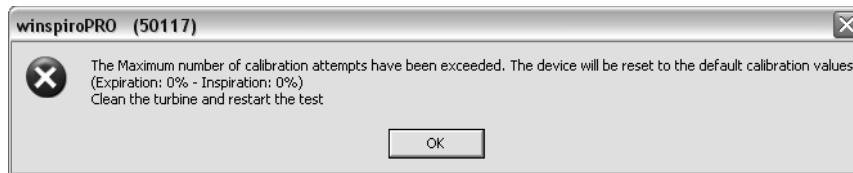
When the test is finished this message is shown:



click "yes" to load the calculated correction factor into the device, click "no" to leave the factory default values

8 during the syringe movements the Flow/Volume curve is shown in real time at the left of the window. During testing if the device reads a syringe volume outside of the range  $\pm 15\%$  then that syringe movement is not taken into account and the results are substituted by an asterisk in the "Volume Monitor" table and the operator is alerted with the following message:

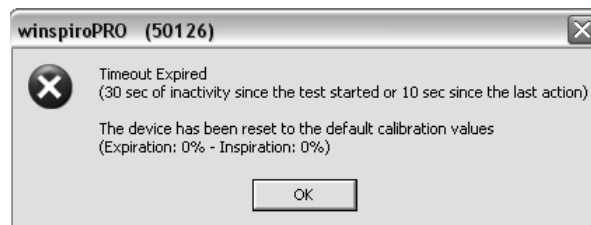
In the "Volume Monitor" table. The maximum number of inspiratory and expiratory syringe movements is set to 20 inspiratory and 20 expiratory. If within this total number of syringe movements the green flow bars do not all turn green then the calibration routine is stopped and this message is shown:



in this case check the turbine carefully as shown in the Users Manual, clean the turbine and then repeat the calibration test.

**WARNING** 

**If the calibration test is not started within 30 seconds of clicking "Start", OR if the test is started but not finished, then 10 seconds after the last syringe movement the following message is shown:**



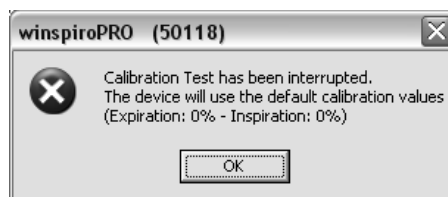
**the test is stopped and the default values are loaded in the device**

**WARNING** 

**Whenever a calibration test is started the previous calibration correction values within the spirometer are cancelled.**

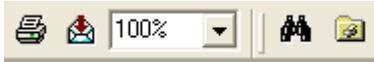
**WARNING** 

**If the test is interrupted by clicking "Stop" then this window is shown:**



**so the factory default values are automatically restored.**

9 When a test is completed the report can be printed from the "print" icon at the top right of the window. A print preview similar to the one on the right is shown, set up the print out using the icons on the left.



**WARNING**

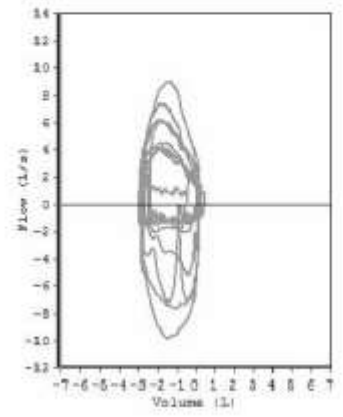
During the calibration test all flows and volumes are measured at ATP conditions (Ambient Temperature and Pressure). During a spirometry test all of the parameters are instead measured at BTPS conditions (Body Temperature and Pressure, Saturated). Eg a syringe with a volume of 3 Litres at (ATP) corresponds to an FVC of 3.08 Litres (BTPS).

**Spirometer Calibration Report**  
 Calibration test SUCCESSFULLY COMPLETED. The Device is now using the following correction values:  
 (Expiration: -1.42% ,Inspiration: -2.62%)

Date ..... 16/12/2011  
 Time ..... 14:15

Device	
SPIRODOC	
Serial Number	W00019
Version	1.9
Turbine	Disposable

Calibration Test Results	
BTPS	1,082
Test Target	3 L
Expiration Correction	-1.42 %
Inspiration Correction	-2.62 %



Printed by winspirolIGHT 6.0.0 - 16/12/2011 - 14:17:37 - User: D18

Calibration Test Details										
Expiration (L)	3,00	2,95	2,94	2,93	2,93	2,99	2,98	2,99		
Inspiration (L)	2,93	2,87	*	3,00	*	3,00	2,88	*	2,83	2,87

\* Volume Out Of Range (Excluded from Calibration)

**IMPORTANT:** Flow and volume values measured during calibration are at ATP (Ambient Temperature and Pressure) conditions. All spirometry parameters instead are converted to BTPS conditions (Body Temperature and Pressure, Saturated). Eg a 3L syringe (ATP) measured during calibration will produce an FVC of 3.08 L (BTPS).

Signature \_\_\_\_\_

1/1



## 4 TEST

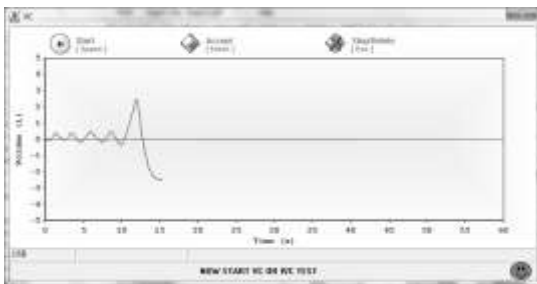
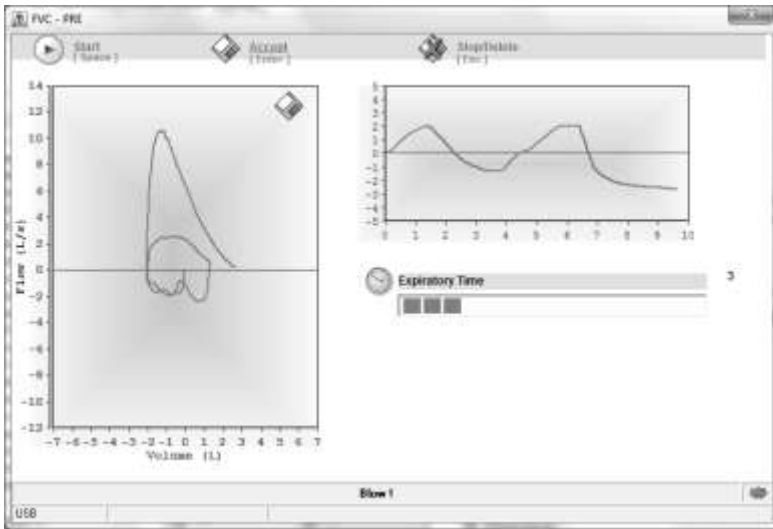
### 4.1 FVC - VC

- Hernández E.
- Hill L.
- Jackson N.
- Johnson J.
- Lee W.
- López E.
- Martin F.
- Martínez W.
- Martini D.**
- 24-07-2003

winspiroLIGHT is able to perform FVC (PRE and POST BRONCHODILATOR) and VC (PRE) tests. Before making a test, insert patient data (if not already in memory) using the "Patients" window. If the patient is already on file then it will be sufficient to select the subject from the patient list of the main window  
 Click on one of these icons on the main toolbar to launch a spirometry test.



Depending on the test selected one of the following windows will then open and the testing will be shown in real time:



The following commands and the related functions are shown on the upper part of each window:

Commands	Function
Start	To start a test. This command is not enabled as soon as the window is opened because in this case the test data reception from the connected device initiates automatically
Accept	To save the related test data (a few seconds after the test is completed the data will be automatically saved if you do not click on "Accept")
Stop/Delete	To stop the test for any reason; the data collected up to that moment will not be saved.

A test is not acceptable if the Expired Volume is less than 100 mL and it will be automatically deleted.

If the test is acceptable then it is automatically saved and then from the main window you can:

- View parameters and curves
  - Delete tests previously saved, by clicking on  having selected them from the grid or from the graph

To make further tests click again on one of the following icons:

Note that the POST BD button is enabled only if, at least, 1 PRE FVC trial (Basal) exists in the current session.



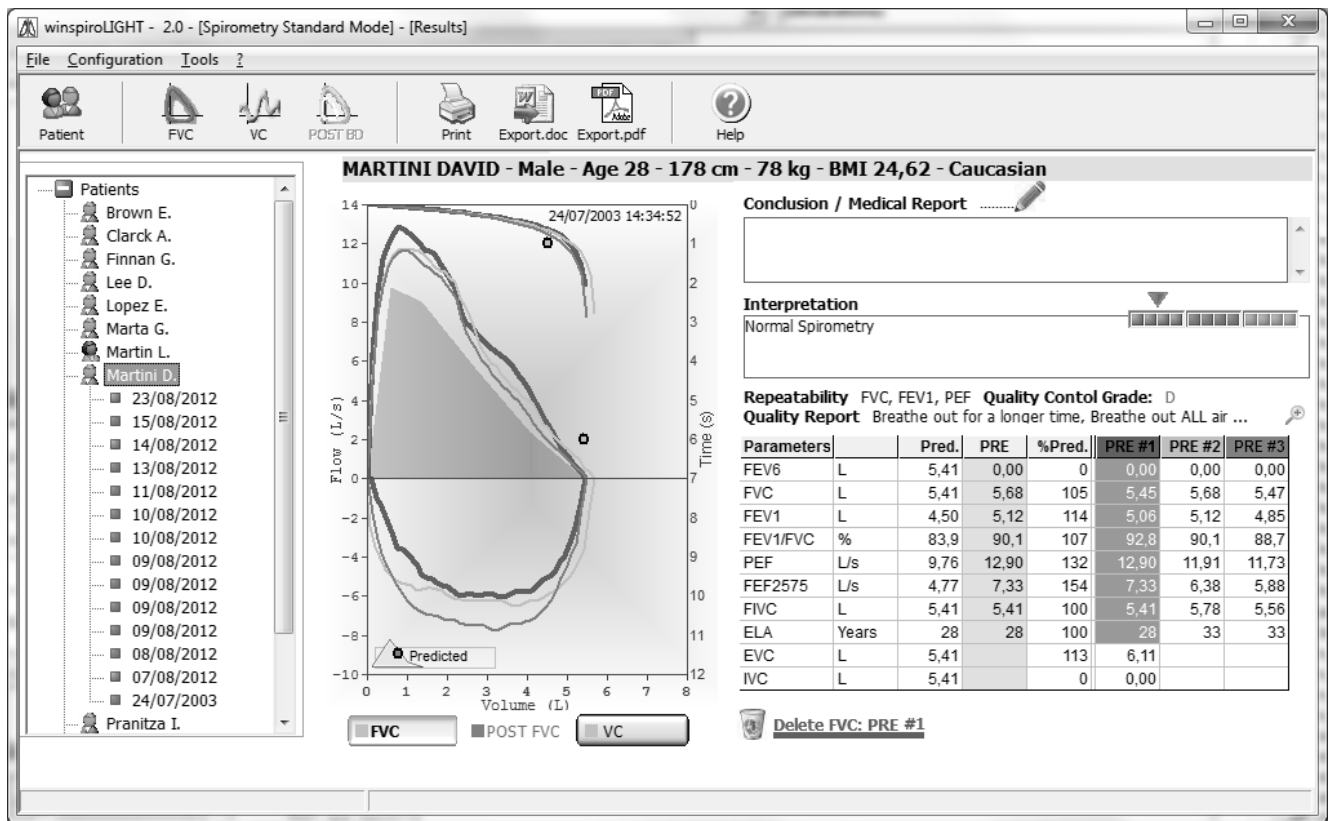
from the toolbar click "Print" to show the print preview.

## 5 RESULTS

After each spirometry test, the main window gives a complete overview of the current patient, including the anagraphic and anthropometric details, the numeric and graphical details of the tests carried out

At the same time it shows the automatic interpretation, the repeatability and the quality report of the current session.

The buttons "FVC" "POST FVC" and "VC" at the bottom of the chart, allows to switch between: the PRE FVC/VT graph, the POST FVC/VT graph, the VC graph



The Conclusion/Medical Report box displays the diagnosis. Clicking the pencil icon the user can add or edit the diagnosis.

Use the delete command, below the parameters grid, to delete the selected trial.

From the Results windows the user can browse the patients and all the spirometry sessions stored into the database (see chapter 1.8 search information in the database)

## 6 PRINT

From the test results window or a current test session or by selecting a patient from memory, click

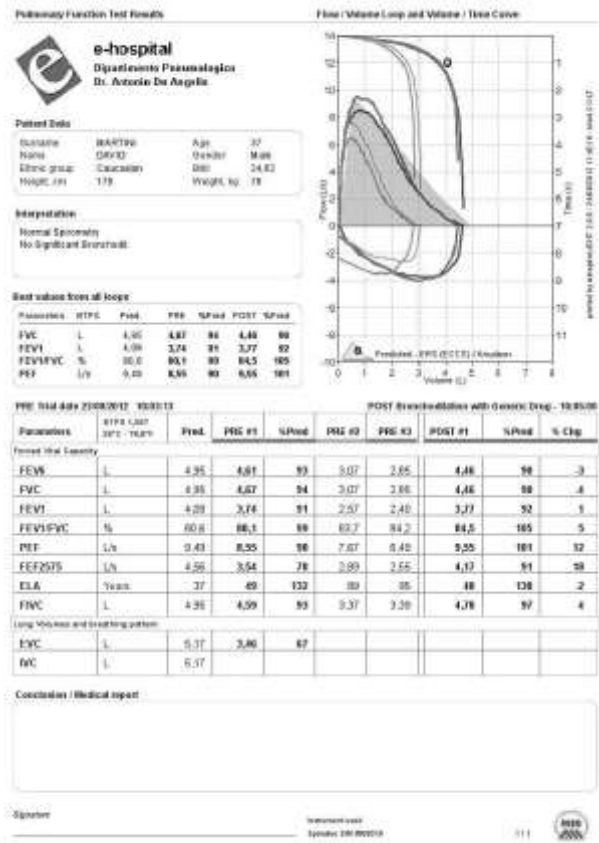


to print a report of the best FVC test.

Using option windows (Printout), the user can personalize the document on the right with the following characteristics:

- Show preview window
- Print automatic interpretation





**NOTE**

**Always use print preview to check the correct settings of winspiroLIGHT with the default printer.**

**WARNING**

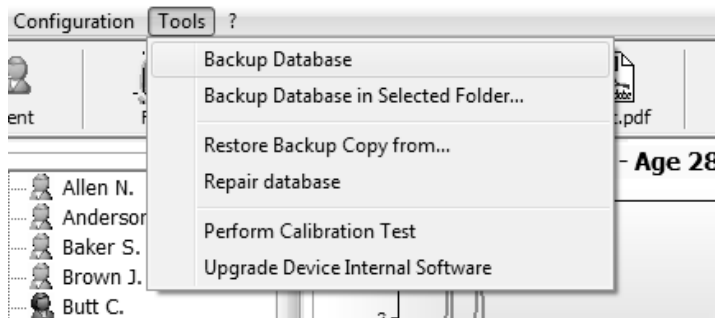
**The values of parameters on the bottom of the printout are always related to the best test.**

**7 BACKUP DATABASE**

The Backup utility enables you to make a copy of the data on the hard disk. This backup copy can then be used in the event that the original file is damaged or is overwritten or becomes inaccessible or lost, for whatever reason.

To make a backup of the database select "Tools" from the menu and then click on "Backup Database". winspiroLIGHT will then automatically create a copy of the database in the folder:  
winspiroLIGHT\Backup>LastBackup.

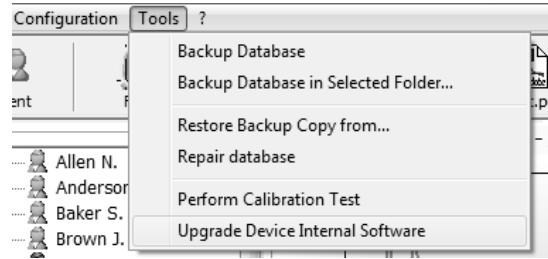
It is also possible to select a different directory; select "Tools" and then "Backup Database in the Selected Folder" specifying the location of the file to be saved.



To restore lost files, use the "Restore Backup Copy from ..." from the same "Tools" menu. The "Restore Backup Copy from..." is password protected and can be made only by the system user Administrator.

## 8 UPGRADE DEVICE INTERNAL SOFTWARE

winspiroLIGHT can upgrade the internal software of the device. To download the new internal software version click on "Tools" menu, and then on "Upgrade Device Internal Software".



This wizard helps the user to tests the connection and check that the device is correctly connected to the PC.



Search .tsk file to be downloaded into the spirometer. Choose either auto-install or manual file search.



If manual search is selected, browse the system resources through list of folders and select .tsk file. As soon as the file is selected the upgrade procedure starts automatically.

