



# User Manual SPIROLYSER<sup>®</sup> Q13<sup>®</sup>



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## 1. Introduction



## 1.1. Supplied Equipment

The following equipment should be found when the package is opened:

- SPIROLYSER® Q13® device with its USB lead
- CD containing the User Manual as well as the SPIROWIN® EXPERT software
- Information sheet
- Check certificate
- 2 Qflow® sensors

**Note:** The SPIROLYSER® Q13® should be returned to After Sales Service (for calibration or other interventions) in its original packaging with all the cushioning material. Repairs will not be considered under warranty without the original packaging box.

## 1.2. Spirometer Presentation

The SPIROLYSER® Q13® is an electronic spirometer operating on a PC, for the exploration of respiratory function.

The spirometer is composed of a single-use sensor that propels the air (FLEISCH principle) and obtains a difference in pressure. The SPIROWIN® EXPERT software acquires samples sent by the spirometer and determines a flow and a volume so as to display the curves and deduce results.

The SPIROLYSER® Q13® spirometer is a portable device. In normal use, the patient holds it by the handle, placing the single-use sensor in the mouth.

The SPIROLYSER® Q13® is directly powered by the computer USB port via its USB lead.



Figure 1. USB plug



The SPIROWIN® EXPERT software calculates, displays and stores data to help the practitioner in the exploration of a patient's respiratory function.



### 1.3. Technical Features

SPIROLYSER® Q13® Technical Features	
Tests	Slow and Forced Vital Capacity, Maximum Voluntary Ventilation, Post-medication
Sensor	Fleisch type digital pneumotachograph
Flows Measurement Range	-14L/s to +14L/s
Volume Measurement Range	0L to 10L
Digital Resolution	15 bits
Measurement Accuracy	± 3% maximum
Lead Length	3 metres
Storage Temperature	0 - 50°C
Temperature for Use	17 - 35°C
Atmospheric Pressure	850 - 1060 hPa
Humidity	75% maximum
Operational Altitude	< 2000 metres
Voltage	5VDC (via USB port)
Current	200mW maximum
Reference Standards	IEC 60601-1, IEC 60601-1-2, ATS 2005
Medical Class	Ila
Applied Part	Type BF (Qflow® sensor and device shell)
Size	90x180x60mm
Device Weight	250g



## 1.4. Symbols

Serial number labels contain the following markings:



CE marking 93/42/CEE directive + N° of notified body



Type BF applied part



Must not be discarded with usual household waste. To discard this product at the end of its life, contact the manufacturer.



Consult accompanying documents

**SN**

Serial number



Manufacturer identification



Do not reuse. Single-use.



Storage temperature to respect



## 2. Safety



## 2.1. General

---

### **Caution:**

- Do not use the SPIROLYSER® Q13® in a non-medical environment
- Only use the SPIROLYSER® Q13® with the single-use Qflow® sensors intended by the manufacturer
- Do not dismantle or handle the internal components
- No modification of equipment is authorised
- Do not use or connect the SPIROLYSER® Q13® in an explosive environment or in the presence of anaesthetic gases
- Do not pull on the leads
- Do not make sudden movements when the sensor/device is positioned in the mouth
- Do not let the computer and SPIROLYSER® Q13® leads trail on the ground and become tangled. This could cause the device to fall off the table or deteriorate the electrical connections
- To avoid problems of electromagnetic or other interference with other devices, do not use the SPIROLYSER® Q13® in surroundings with interferences, or too close to other devices
- Never clean the SPIROLYSER® Q13® under running water, or immerse it directly into any sort of liquid
- Always use the SPIROLYSER® Q13® linked to a computer that conforms to the IEC 60950-1 standard
- The SPIROLYSER® Q13® and the computer to which it is connected is considered as an electro-medical system
- For safety reasons, access to the computer USB lead plug should remain accessible

## 2.1. Users

---

The SPIROLYSER® Q13® should only be used by health professionals (doctor, lung specialist, allergist ...).

With their level of training, health professionals should have no problems using the device.

Results should only be interpreted by health professionals having undergone pneumology training.

With their medical training background, health professionals are aware of the rules of hygiene and bacterial contamination.

If in doubt, the health professional should refer to the User Manual and/or contact the FIM MEDICAL company or the distributor.

Predicted values available on the software are used to perform spirometries on children from age 6.

## 2.2. Medical Contra-indications

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**It is strictly prohibited to perform respiratory function tests in the following cases:**

- Recent or current pneumothorax
- Recent puncture or pleural biopsy
- Current haemoptysis
- Severe asthma attack
- Smear-positive tuberculosis (risk for personnel)
- Bronchial infections, infectious pneumopathy
- Acute asthma attack
- Decompensation of chronic respiratory insufficiency
- Impossibility to carry out manoeuvres; ventilatory motor incoordination
- Pain, fatigue



### 3. Installation



### 3.1. Minimum Requirements

- Supported operating systems: **Windows XP SP3, Windows Vista, Windows 7, Windows 8, Windows 8.1**
- 3 Ghz processor for single core or 1Ghz for dual core or more
- 1 GB RAM
- 3 GB of free space on the hard disk
- A graphic board (or graphic chipset) with minimum resolution of 1024x748 and 256 MB of RAM (graphics hardware acceleration for incentive)
- A screen with minimum resolution of 1024x748
- USB 2.0 port

### 3.2. Software Use Conditions

The SPIROWIN® EXPERT software is licenced under the following conditions. If, before installation, or 48 hours after receipt of the software, you refuse these conditions, please return it to the distributor who sold you the product, to obtain a refund.

Use implies your entire agreement of the following conditions:

The software supplied under licence remains the property of FIM MEDICAL who grants the right to use the product, on condition the present conditions are respected.

This licence is granted for installation on one workstation only (desktop computer, laptop or terminal).

All new installations require the purchase of extra licences, or uninstallation of the programme on the initial workstation. The licence is nominative; if the device is no longer used, please refer to the supplied licence contract for the procedure. Copy or reproduction of the FIM MEDICAL software supplied under licence is prohibited. Reproduction, even partial, of the screens or computer processes constitutes a violation of this agreement. You agree to take all the necessary measures to avoid pirated copies or use by unauthorized third parties.

The FIM MEDICAL company can in no way be held responsible for any malfunction related to the installation of one of its software programmes on a computer. Nor can the FIM MEDICAL company be held responsible for consequences related to the installation of one of its software programmes, such as partial or total data loss.

The user should be trained in the basic rules of computer use, and will take all precautions against the risk of software pirating, the distribution of confidential data, infiltration of whatever type of computer virus, or incorrect use.

The user shall take special care to back up data recorded on the computer as often as possible on a reliable support. FIM MEDICAL recommends daily backups.



### 3.3. Requirements

List of packages installed with the SPIROWIN® EXPERT software:

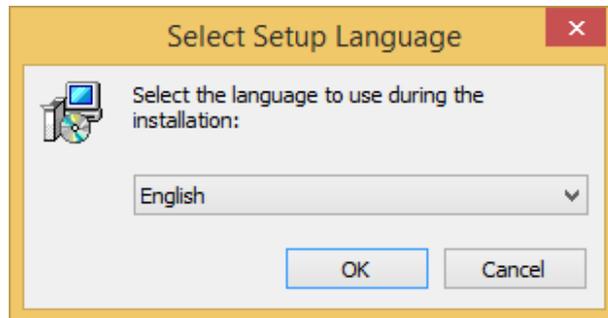
- Framework 4.0 Full
- Framework Language Package 4.0 (French, Italian, German, Spanish, Dutch, Portuguese)
- Access database engine redistributable
- Sql Server Compact Runtime 4.0

Adobe Reader V9 minimum software is required to read the manual from the software.

### 3.4. Installation Procedure

**Note:** You must be in administrator mode to install SPIROWIN® EXPERT.

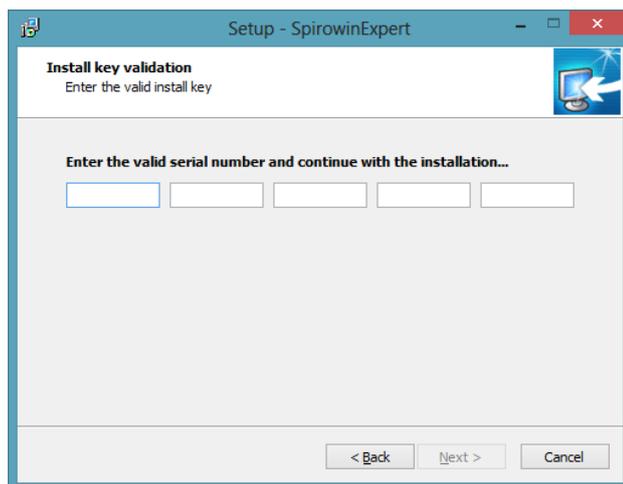
1. Insert the SPIROWIN® EXPERT installation CD.
2. Run the installation.
3. Choose the software and installation language.



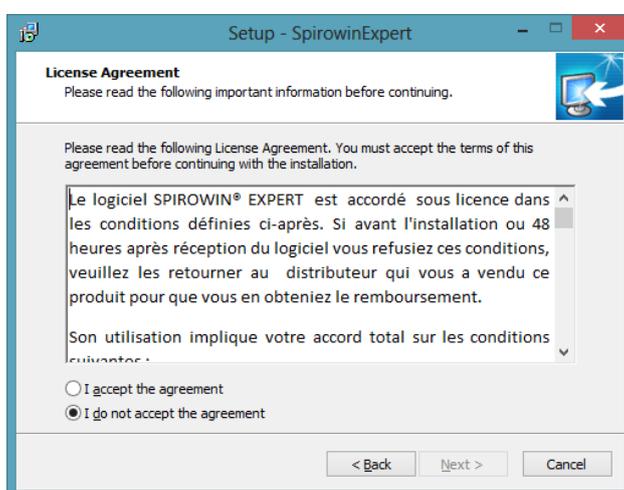
4. Click «OK».



5. Click «Next».
6. Enter the SPIROWIN® EXPERT install key, located on the back of the CD sleeve.

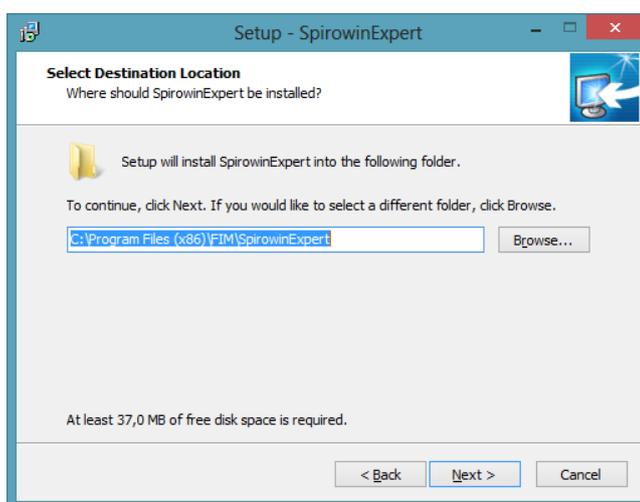


7. Click «Next».



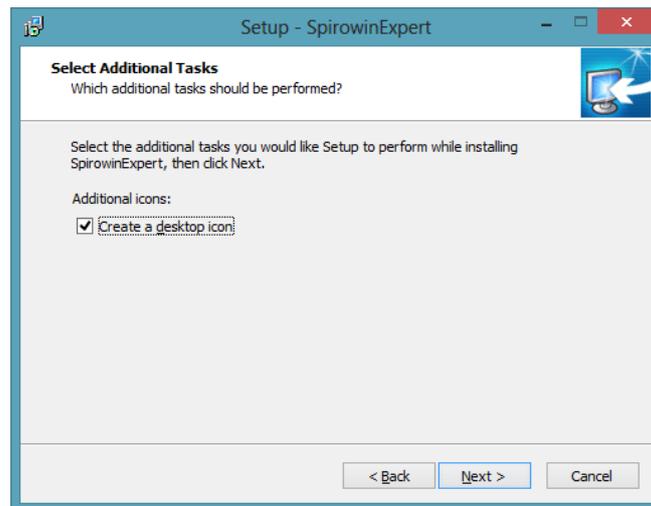
8. Accept the licence contract terms.

9. Click «Next».

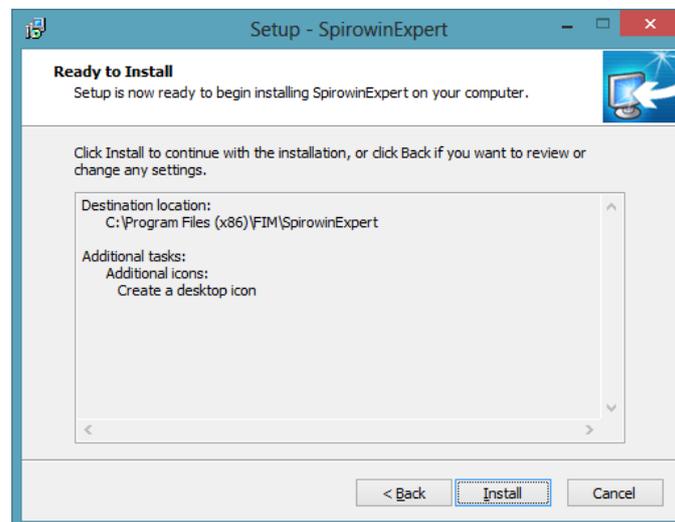


10. Modify the install path if necessary.

11. Click «Next».

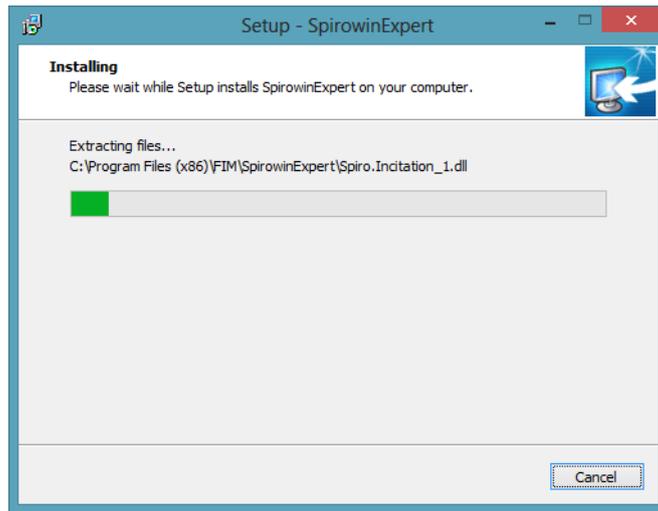


12. Click «Next».



13. Click «Install».

14. Installation of SPIROWIN® EXPERT is in progress.



15. Click «Finish».



## 3.5. Database

### 3.5.1. SPIROWIN® EXPERT database

SPIROWIN® EXPERT can use two database formats:

- A local database (SQL Compact Server) file type
- A distant database (SQL Server)

When the application is first run, you can choose the database type. You can also migrate from one base to another, from the software.

### 3.5.2. Retrieve data from old database

If you have an old FIM MEDICAL database (fim.mdb type), you are able to:

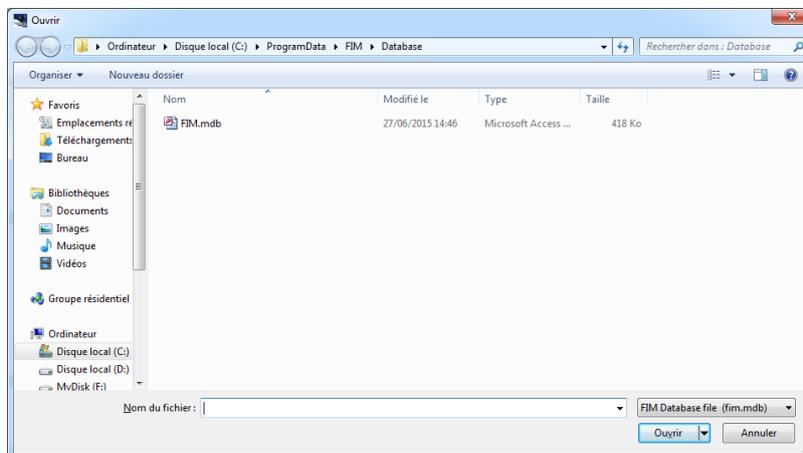
- Retrieve old patient identification
- Synchronize patient identification between two databases (other FIM MEDICAL software)
- Retrieve old tests from Spirowin V6

To do this, click «Synchronize with old database» in the settings software panel (after install).

Synchronization with old FIM  
MEDICAL database

Synchronize with old database

Then choose your fim.mdb file.



Click “Open” and wait for the end of process to retrieve old patient identification.

If old tests are detected in a database, a window appears with the choice of import.

After import, save synchronization with old database by clicking “Save settings”.



**Note:**

- If fim.mdb file is deleted later, the software automatically stops synchronization
- Import errors are written in log file in C:\ProgramData\FIM\SpirowinExpert
- SQL Server format does not allow permanent synchronization with an old database

### 3.6. Spirometer Connection/Disconnection

The spirometer should be connected to the computer via the USB plug.

Spirometer connection is displayed on the screen.



Embedded software version : V01.00.00

Ambient temperature : 25.2 °C

Serial number : 140110

Atmospheric pressure : 100.6 kPa

Next factory check date : 29/12/2015

Humidity : 24 %

To disconnect the device, remove the USB lead from the computer. The device is no longer connected.

### 3.7. Uninstallation

**SPIROWIN® EXPERT** can be uninstalled from your computer if you no longer use it. Use «Programmes and Features» to uninstall programmes.

1. Open «Programmes and Features» in the Windows Control Panel. Click «**Programmes**», then «**Programmes and Features**» (Note: access to the uninstallation panel may vary according to different Windows versions).
2. Select **SPIROWIN® EXPERT** then click «**Uninstall**».

**Note:** For security reasons, the database will never be deleted when the software is uninstalled.



## 4. Use



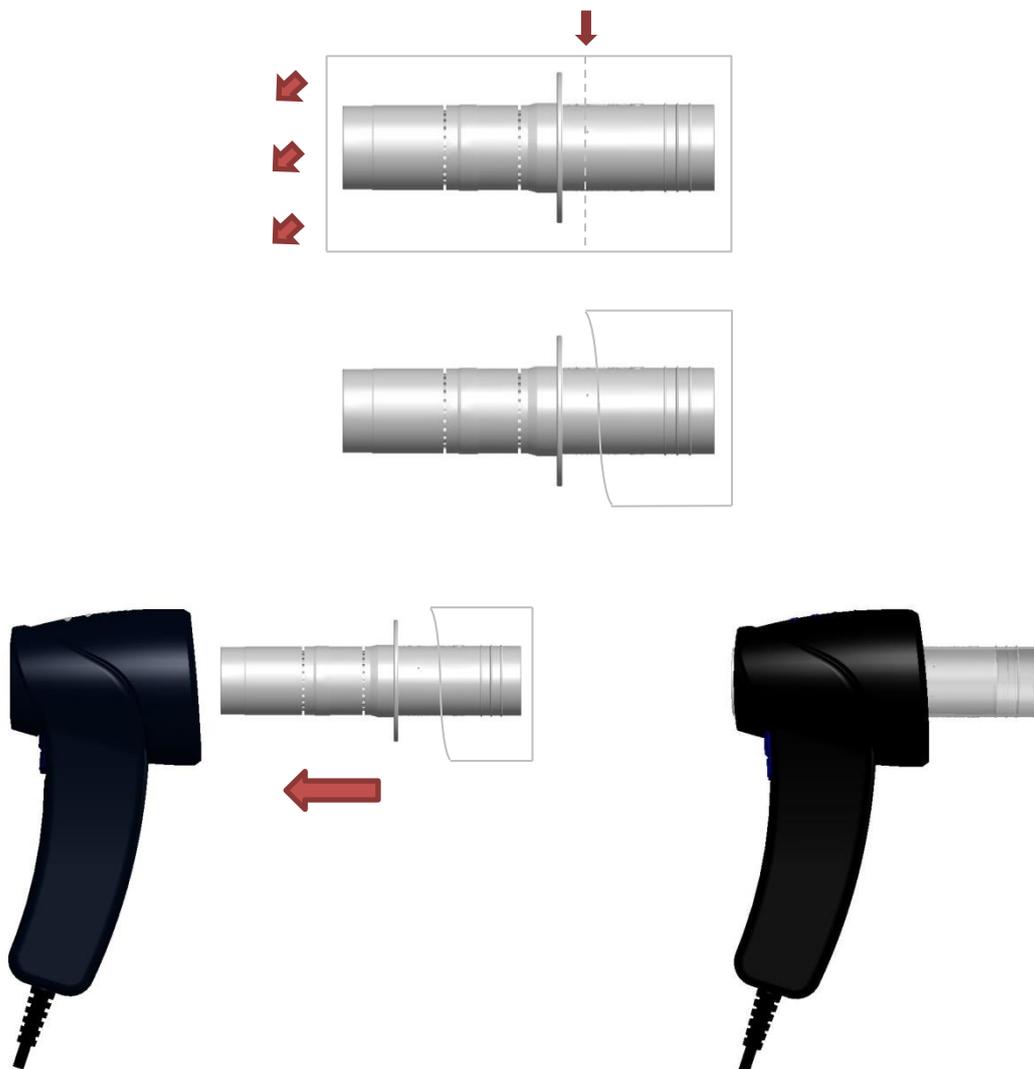
## 4.1. Position the Single-Use Qflow® Sensor

Qflow® sensors are single-use sensors specifically developed to operate with the SPIROLYSER® Q13® spirometer.

Qflow® sensors are designed and adapted for respiratory function exploration tests (spirometry); their resistance does not exceed the ATS/ERS recommendations.

### **Qflow® sensor installation:**

- Locate the dotted line opening part
- Hold everything with one hand by the mouthpiece side (small side of packaging)
- With the other hand, open the detachable part of the Qflow® packaging along the dotted line
- Insert the Qflow® into the opening of the sensor until it stops
- Remove and discard the rest of the packaging

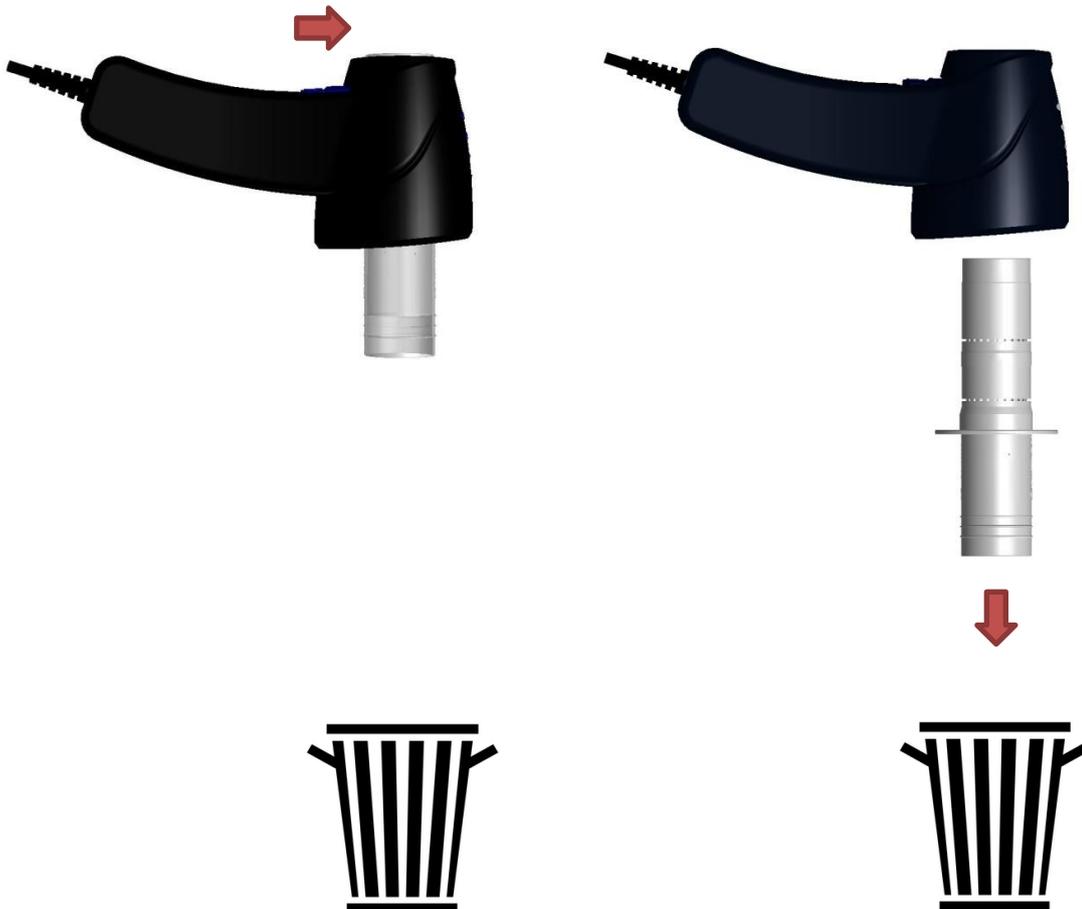


## 4.2. Eject the Single-Use Qflow® Sensor

At the end of a patient's tests the single-use sensor must systematically be removed and discarded. The device is equipped with a no-contact ejection system. The sensor is thus ejected without the operator having to touch it.

### Ejection of Qflow® sensor:

Turn the device downwards, above a rubbish bin and push the trigger upwards.



### 4.3. Presentation

SPIROWIN® EXPERT is spirometry software. It is used in association with the SPIROLYSER® Q13® sensor to perform tests to help the practitioner in the respiratory function exploration of a patient.

Its user-friendly interface has been specifically studied and designed to help the operator to screen possible respiratory illnesses within the field of preventive medicine.

Using this application, the operator can identify a patient, perform spirometric tests such as Slow Vital Capacity, Forced Vital Capacity and Maximum Voluntary Ventilation. The operator can print test reports and compare them over time.

#### 4.3.1. Main user interface

The spirometry software user interface is designed as follows:



## 4.4. Device Status Bar

### 4.4.1. Presentation

The status bar shows the operator the device features and other extra information.



Embedded software version : V01.00.00    Ambient temperature : 25.2 °C  
Serial number : 140110    Atmospheric pressure : 100.6 kPa  
Next factory check date : 29/12/2015    Humidity : 24 %

### 4.4.2. Organisation

List of parameters displayed in the status bar:

Name	Unit	Description
State of connection	-	Displays a logo showing the communication state between the software and the device
Firmware version	VXX.XX.XX	Displays the version of embedded software in the device
Serial number	XXXXXXXX	Displays the device serial number. (identical to type label)
Date of next factory check	-	Display of next return date of device to manufacturer
Ambient temperature	°C/°F	Ambient temperature of device handle
Atmospheric pressure	kPa/mmHg	Ambient atmospheric pressure of device handle
Humidity	%	Level of air humidity in the device handle

**Note:** Meteorological parameters are updated regularly. Device information is initialised only when the sensor is connected or when the application is run.

**Warning:** The sensor factory check date indicates the date by which the device must be returned to the manufacturer for a complete checkover. If this date expires, you will receive an automatic alert in red that **FIM MEDICAL declines all responsibility for possible measurement errors.**



## 4.5. Initial Run

The software initial run requires particular attention.

### 4.5.1. Database choice

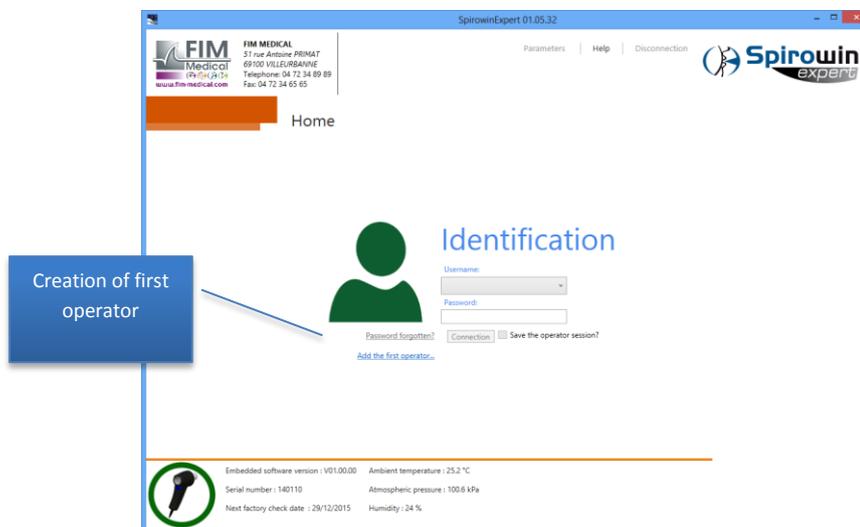
During the initial run the operator chooses a database type (default choice is SQL Compact in local mode)

If an old database is detected, you may keep a synchronization of patient files.

If the SPIROWIN® V6 software is detected, you can also import old tests.

### 4.5.2. Identification system

For the safety of medical data, SPIROWIN® EXPERT uses an operator identification system. The system requires a password supplied upon creation of each operator account.



For the initial application run, an account can be made directly from the identification screen. Other operator accounts can be made with the relevant interface. The password protection system can be disabled. Access can be memorised with an account of your choice so no need to re-identify.

The screenshot shows the 'Operator identification' form. It contains several input fields: 'Surname:', 'First name:', 'Occupation:', 'Answer question to reinitialise password', 'Question:', 'Answer:', 'Password:', and 'Password confirmation:'. Each field has a red error message below it: 'Empty field' and 'Field must have between 3 and 50 characters' for Surname and First name; 'Empty field' for Occupation; 'Empty field' for Answer; 'Empty field' for Password; and 'Empty field' for Password confirmation. The 'Question' dropdown is set to 'What is the name of your first pet?'. At the bottom right, there are 'Cancel' and 'Save' buttons.

Once identified, the operator can access all the application functions. To protect access, or change operator, click on the «Disconnection» button in the secondary menu bar.

### 4.5.3. Forgotten password

If the password associated with your operator account is forgotten or lost, it can be reset by giving the same response to the question chosen when your account was created.

1. Choose your user account.
2. Click «Password forgotten?».

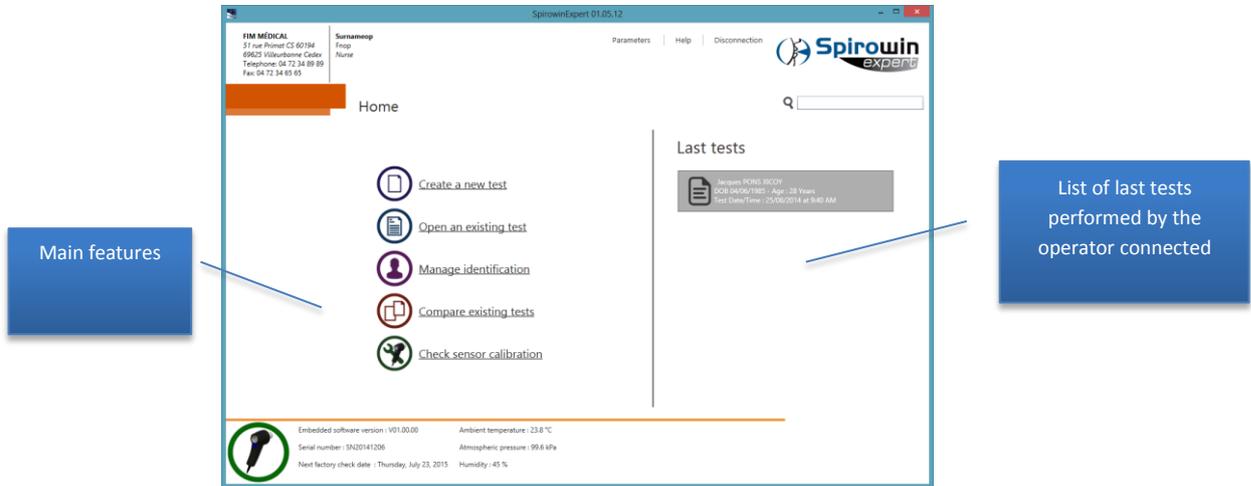
3. Answer the question and enter your new password in the relevant fields.
4. Click «OK»

**Note:** An administrator account (unmodifiable) permits interface access if operator identification information is lost. Contact the manufacturer, FIM MEDICAL for instructions.

## 4.6. SPIROWIN® EXPERT Home Page

### 4.6.1. Presentation

The interface is designed to be simple, with easy access. For this, all the application features are performed from the Home page:



### 4.6.2. Home page main features

#### 4.6.2.1. Presentation

Direct access to SPIROWIN® EXPERT application features

-  [Create a new test](#)
-  [Open an existing test](#)
-  [Manage identification](#)
-  [Compare existing tests](#)
-  [Check sensor calibration](#)

#### 4.6.2.2. Organisation

Name	Description
<b>Create a new test</b>	Enter into the process to create a new test
<b>Open an existing test</b>	Enter into the management of existing tests
<b>Manage identifications</b>	Enter into the management of application identifications
<b>Compare tests</b>	Compare results of several tests from the same patient
<b>Check sensor calibration</b>	Check sensor calibration according to ATS recommendations



## 4.7. Test Creation

SPIROWIN® EXPERT proposes a totally new method of performing a spirometric test to that of the existing Spirowin® software.

SPIROWIN® EXPERT presents a process defined by a series of screens to help the operator perform spirometry tests. List of series of screens presented:



### 4.7.1. Test initialisation

In this first stage, information required for performing a test is input. List of information entered by the operator:

- Choice of patient file or creation of a new file
- Choice of tests to perform (VC, FVC, MVV)

**Note:** The choice of tests to perform is saved for the next tests.

Input information on the form of the following screen to create a new file. If you have selected an existing file from the list, it will be modified.

#### 4.7.1.1. Interface presentation

The screenshot shows the 'Test initialisation' screen. Key elements include:

- Patient identification:** Fields for Surname, First name, DOB, Height, Weight, Gender, Ethnic group, Prescriber, Smoker, Occupation, and Exposure.
- List of existing patients:** A search bar and a list of patient records (e.g., PONS XICOY, NAN Epimanuel).
- Test options:** A panel with checkboxes for Vital Capacity, Forced Vital Capacity, and Maximum volume per minute.
- Control Panel:** Buttons for 'New patient', 'Previous', 'Next', and 'Cancel'.

**Note:** Meteorological parameters are retrieved by the SPIROLYSER® Q13®. However, to obtain more precise measurements, you may wish to equip yourself with your own weather station and enter the data manually (option in software parametering).

### 4.7.2. Slow Vital Capacity Test

Slow Vital Capacity is a spirometric test that measures the amount of air that can be slowly exhaled after inhaling as deeply as possible, and is mainly used to quantify the maximum volume of air the lungs can contain. The procedure for performing this test varies from one practitioner to another, however the principle is that the patient inhales as deeply as possible, and slowly exhales all the air in the lungs.

#### 4.7.2.1. Available features

Name	Description	Required	Result
<b>Curve validation</b>	Indicator to define the best curve realised by the patient. Only one curve can be validated per test. <b>(ATTENTION: Automatic validation can be chosen).</b>	A curve selected	Curve validated
<b>Curve deletion</b>	Deletes a curve from the graph	A curve selected	Curve deleted
<b>Pre/post medication mode</b>	Used to identify a curve to compare with others after going to post medication mode	A curve selected	The selected curve becomes the «pre» curve. All other curves are deleted.
<b>Curve creation</b>	Used to create a curve by pressing on the Start button to perform a spirometry test	SENSOLYSER® Q13® device connected	At the end of the test, the operator presses on the «Stop» button. The graph adapts to the displayed curves.
<b>Curve selection</b>	To calculate and display results, the operator can select a curve by clicking on the desired curve in the graph legend	Curves performed	Curve selected. Results calculated. Certain actions unlocked.

#### 4.7.2.2. Interface presentation

The screenshot shows the Spirowin Expert software interface. On the left, a graph displays Volume (L) over Time (s) with a purple curve. A callout box points to the graph legend. In the center, a 'Results table' displays the following data:

Results	Value	Predicted values
VC	6.24 L	5.07 L
ERV	2.68 L	-
IRV	2.44 L	-
IC	3.56 L	-
Total Volume	1.12 L	-

On the right, a 'Patient information' panel shows details for 'Pascal KIRBY' (Age: 28 Years, Height: 174 cm, Room number). Below this is a 'Control Panel' with buttons for 'Start', 'Previous', 'Next', and 'Cancel'. A callout box points to the 'Name of screen in progress' which is 'Vital Capacity'.

**Note:** Certain results from this type of test require a specific curve shape: ERV, IRV, IC and TV results, which require three normal inhalations and exhalations before the test.

#### 4.7.2.3. Contextual menu

Test reports can be printed out or exported by right-clicking on the curves graph. A contextual menu appears with the following options:

- Print
- Export in PDF

### 4.7.3. Forced Vital Capacity test

Forced Vital Capacity test is a measurement of forced exhalation, i.e. the amount of air that can be exhaled with force after inhaling as deeply as possible. The patient remains upright. After 2 or 3 normal breaths, the patient inhales as deeply as possible and exhales all the air from the lungs into the spirometer, as forcefully as possible. The spirometry results are compared to the predicted values, which are calculated according to the age, gender, height and ethnic group of the patient. The FVC% expresses the percentage of the FVC in relation to this predicted value.

**Note:** The operator should ensure the patient empties **all** the air from the lungs.

#### 4.7.3.1. Available features

Name	Description	Required	Result
<b>Curve validation</b>	Indicator to define the best curve realised by the patient. Only one curve can be validated per test. <b>(ATTENTION: Automatic validation can be chosen)</b>	A curve selected	Curve validated
<b>Curve deletion</b>	Deletes a curve from the graph	A curve selected	Curve deleted
<b>Pre/post medication mode</b>	Used to identify a curve to compare with others after going to post medication mode	A curve selected	The selected curve becomes the «pre» curve. All other curves are deleted.
<b>Curve creation</b>	Used to create a curve by pressing on the Start button to perform a spirometry test	SENSOLYSER® Q13® device connected	At the end of the test, the operator presses on the «Stop» button. The graph adapts to the displayed curves.
<b>Curve selection</b>	To calculate and display results, the operator can select a curve by clicking on the desired curve in the graph legend	Curves performed	Curve selected. Results calculated. Certain actions unlocked.

#### 4.7.3.2. Interface presentation

The screenshot shows the SpirowinExpert software interface. On the left, there is a flow-time graph (Flow (L/s) vs Time (s)) and a volume-time graph (Volume (L) vs Time (s)). The control panel on the right includes buttons for 'Start', 'Unvalidate', 'Delete', and 'Post mode'. A results table at the bottom displays the following data:

Results	Value	Predicted values
FVC	5.82 L	5.07 L 114.7%
FEV1	5.09 L	4.24 L 120.0%
PEF	12.23 L/s	9.39 L/s 130.2%
FEV1/FVC	-	0.84

Labels on the left side of the screenshot point to various interface elements: 'Name of screen in progress', 'Volume/time graph', and 'Graph legend'. Labels on the right side point to: 'Patient information', 'Timed exhalation', 'Control Panel', 'Volume/time graph', and 'Results table'.

The timer starts with each new inhalation and is zeroed each time the exhalation is stopped. FVC exhalation time is calculated and displayed in the results table.

#### 4.7.3.3. Contextual menu

Test reports can be printed out or exported by right-clicking on the curves graph. A contextual menu appears with the following options:

- Print
- Export in PDF

#### 4.7.3.4. Incentive

For this Forced Vital Capacity test, SPIROWIN® EXPERT includes an Incentive to know whether the patient performs the test correctly.

**Hang-glider Incentive:** When the patient breathes normally, CAPSULITE walks across a field with his hang-glider. When the patient inhales deeply, CAPSULITE starts running. When the patient exhales all of the air in the lungs, CAPSULITE takes off and glides until the patient finishes breathing out. If the patient goes over the predicted FVC, the hang-glider lands correctly. If not, CAPSULITE falls to the ground.

**Shot put Incentive:** When the patient breathes normally, CAPSULITE spins slowly, holding the shot. When the patient inhales deeply, CAPSULITE starts spinning faster. When the patient exhales all of the air in the lungs, CAPSULITE throws the shot, which flies until the patient finishes breathing out. If the patient goes over the predicted FVC, CAPSULITE is happy with his result. If not, CAPSULITE is disappointed.

**Note:** The Incentive is displayed once the test is run. The Incentive window can be moved wherever the operator wishes, with a long click on it.

**Caution:** normal breathing flows should not be above +/-2 L/s in order to detect small flows.

#### 4.7.4. Maximum Voluntary Ventilation test

The Maximum Voluntary Ventilation test quantifies the volume of air that can be mobilised for one minute, thus showing respiratory efficiency. The patient must breathe (inhalation/exhalation) as deeply and rapidly as possible for 12 seconds. The measurement is then extrapolated over 1 minute.

**Caution:** This test is not often performed in spirometry screening. It is potentially dangerous for the patient due to the fatigue and over-ventilation it causes.

##### 4.7.4.1. Available features

Name	Description	Required	Result
<b>Curve validation</b>	Indicator to define the best curve realised by the patient. Only one curve can be validated per test. <b>(ATTENTION: Automatic validation can be chosen).</b>	A curve selected	Curve validated
<b>Curve deletion</b>	Deletes a curve from the graph	A curve selected	Curve deleted
<b>Pre/post medication mode</b>	Used to identify a curve to compare with others after going to post medication mode	A curve selected	The selected curve becomes the «pre» curve. All other

<b>Curve creation</b>	Used to create a curve by pressing on the Start button to perform a spirometry test	SENSOLYSER® Q13® device connected	curves are deleted. At the end of the test, the operator presses on the «Stop» button. The graph adapts to the displayed curves.
<b>Curve selection</b>	To calculate and display results, the operator can select a curve by clicking on the desired curve in the graph legend	Curves performed	Curve selected. Results calculated. Certain actions unlocked.

#### 4.7.4.2. Interface presentation

The screenshot shows the Spirowin Expert software interface. Callouts point to the following elements:

- Name of screen in progress:** Points to the 'Home' title in the top left of the main window.
- Volume/time graph:** Points to the central graph showing volume (L) over time (s).
- Graph legend:** Points to the bottom-left corner of the graph area.
- Patient information:** Points to the 'Patient:' panel on the right, which includes details for 'Pons Xicoy Jacques' (Age: 28 Years, Height: 174 cm, Non smoker).
- Control Panel:** Points to the 'Start' button in the patient panel.
- Results table:** Points to the table showing 'Results', 'Value', and 'Predicted values' (e.g., MVV: 517.87 L, 163.58 L).

#### 4.7.4.3. Contextual menu

Test reports can be printed out or exported by right-clicking on the curves graph. A contextual menu appears with the following options:

- Print
- Export in PDF

#### 4.7.5. Test Assessment (This screen can be masked in the parameters)

At the end of the process, SPIROWIN® EXPERT displays a review of the test performed. A recapitulative of curves validated per test is displayed with the results. A comment can be added to the test in progress.

Interpretation Help for the Forced Vital Capacity test is supplied and is based on the curve validated for this test. Interpretation Help is detailed in chapter: §4.7.5.2.

#### 4.7.5.1. Interface presentation

The screenshot shows the SpirowinExpert 01.05.12 interface. It features a header with the company name and logo, a patient information sidebar, a main data display area, and a control panel at the bottom right. Callout boxes point to various elements:

- Name of screen in progress:** Points to the 'Test report' button.
- Recapitulative of results:** Points to the 'Vital Capacity' section.
- Interpretation Help:** Points to the 'Interpretation' text area.
- Patient information:** Points to the 'Patient:' sidebar.
- Control Panel:** Points to the 'Print' and 'PDF export' buttons.
- Test comments:** Points to the 'Comments:' text area.

**Visible Data:**

Parameter	Value	Predicted values
VC	6.24 L	5.07 L
ERV	2.68 L	0 L
IRV	2.44 L	0 L

**Interpretation:** Group n°1: Normal tracing. This result should be reassuring. Nonetheless, already been suggested in the guide user above, use of the drift in time of obtained figures, quoted in each individual's abacus in order to see if the regression gradient is superior.

**Footer:** Embedded software version : V01.00.00, Ambient temperature : 23.6 °C, Serial number : SN20141206, Atmospheric pressure : 99.6 kPa, Next factory check date : Thursday, July 23, 2015, Humidity : 45 %

**Note:** An up, down or straight arrow icon immediately indicates the trend of the result between the predicted values and the obtained values.

**Note:** The test is recorded automatically after clicking the «END» button of the process.

#### 4.7.5.2. Interpretation Help groups

A. Perdrix, MCU-PH Lung specialist. Head of professional pathologies and work ability consultations, Grenoble CHU

It has appeared useful to simultaneously use several parameters including the two ratios FEV1/ FVC and MMEF25-75/FVC in order to see if people's diagnostic accumulation could enable earlier care in the genesis of certain respiratory problems.

Eventually, a 9-group classification was suggested, of which a part is represented in the attached outline.

The spirographic limits defining each group are reproduced in annex 1.

For more specific or particular information, refer to the book: " Guide pratique d'explorations fonctionnelles respiratoires. Utilisation en milieu professionnel ". A. Perdrix - Masson. 1994, 184p.

This logigram has been used partly in work and work ability pathology consultations in the framework of the CRAM convention, as well as in the framework of car-body painter craftsmen and industrial painters, CMR convention. It has also been validated in two metallurgic companies in Haute-Savoie by Dr. LEVAIN.

#### **What are the recommendations according to each group?**

The use of portable, validated spirometric equipment allows for detection in the work environment. Not all abnormal spirometric recordings indicate a pathology; at the very most, a functional abnormality, providing this abnormality is validated. This implies repeating the examination. Nevertheless, a specific case distorts these outlines: work-related asthma with variability of its reactivity. Effectively, it is not rare to find a large spirometric variation in a work-related asthmatic from one day to another. So, an abnormality noticed one day can very well be accompanied by a normal spirometric tracing the next day. If this is true, there are two plausible explanations: technique incorrectly performed, whatever the cause, or effectively, the second hypothesis which is related to the variability of work-related asthma. But, we will search for other simultaneous or successive criteria before casting a definitive diagnosis.

##### 4.7.5.2.1. Group 1:

Normal tracing. This result should be reassuring. Nonetheless, it has already been suggested in the guide cited above, use of the drift in time of obtained figures, quoted in each individual's abacus in order to see if the regression gradient is superior to the physiological gradient of his reference group. A subject can be quite normal, but have a rapid regression in his performance while remaining above the normal limit values (refer to annex 2).

##### 4.7.5.2.2. Group 2:

The subject presents a decrease of the ratios to a level esteemed still normal when each one is used separately. If the performances are verified, group 2 is the group which, 5 or 10 years later, strongly risks developing into an obstructive expiratory problem patent of a COAD. Work assessment is imperative in the search for harmful irritants, allergens or toxins inhaled via the respiratory tract. Enquiries must also be made into smoking and history. It is certainly a group to which preventative



efforts must be brought considering this progressive threat. A spirographic check every two years is necessary with the same portable machine.

#### *4.7.5.2.3. Group 3:*

Includes those which we call carriers of small airways disease.

Recommence the test to be sure of the validity of the figures. That being so, the subject has 4 possible developments

- recovery and passage into group 1 due to numerous short-lived inflammatory pathologies
- persistence of the unchanged problem
- progressive passage towards an obstructive ventilation problem of the COAD (chronic obstructive airways disease) type, thereby joining the following group
- some cases can evolve into a restrictive problem. Spirographic checking every two years. Enquiries as for group 2 into respiratory history, irritants and work-related inhaled toxins and smoking.

#### *4.7.5.2.4. Groups 4-5-6-7:*

The significance of obstructive expiratory problems is defined by a decrease of FEV1/FVC lower than - 10% in relation to the norm.

If the abnormality is found, group 4 can again be considered as work medicine detection.

Previously unknown, groups 5, 6 and 7 (of a COAD) show the failure of early detection. A case already indicated above is the sudden appearance of an unknown obstructive problem. It can enter into the framework of an asthma for which a respiratory workup with betamimetic and methacholine tests are to be done. The other strategic tests for the research of work-related tendencies are to be seen. The diagnosis of group 4 noted for the first time warrants a lung specialist assessment.

For the groups 5, 6 and 7 it is not normally a question of detection but of known people, more or less followed by lung specialists. Surveillance by portable spirometry every year or every two years appears sufficient for a professional follow-up, independent of the surveillance organized by lung specialists. In all these groups, obtain very precise information on the diagnosis and the possible influence of added aggravating factors: inhaled irritants and toxins and smoking.

#### *4.7.5.2.5. Group 8:*

Or restrictive tendency. The word tendency is used because, with a portable spirometer, the absence of residual volume does not allow for calculation of total pulmonary capacity and thus, confirmation of restrictive syndrome. On the other hand, significant lowering of vital capacity with FEV1/VC still within the norm directs us towards a restrictive tendency. There also, before this reality is confirmed, it is necessary to recheck with a portable spirometry. The aetiologies which give restrictive tendencies do not develop from one second to the next as in the obstructive problem of asthma. There is more time to check. If the new results are identical, check the ethnic group and the associated correction (refer to: "Guide pratique.....") It is usual to admit that a reduction of volumes



and flows lower than the inferior limits of the norm should lead to a lung specialist check if this abnormality is unknown and if there is no history or obesity that can give indications. Displace the discussion with clinical and radiological elements.

#### 4.7.5.2.6. Group 9:

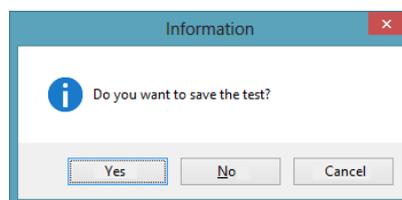
Mixed problems. With only a simple spirometry, and no residual volume, it is a group with an extremely difficult approach. It is the case where lowering of volumes and flows is very large with a minimal but still significant lowering of ratios. Mixed problems can only be confirmed by a lung specialist measurement of residual volume. In the case of an unexpected discovery, refer to the aetiology dictionary (refer to: “Guide pratique...”) and the recommendations it suggests.

#### 4.7.5.3. Available features

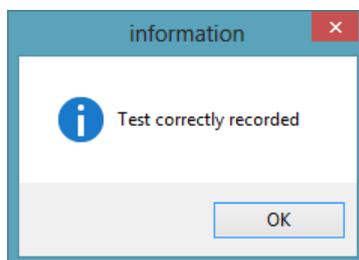
Name	Description	Required	Result
<b>Add a comment</b>	The operator or practitioner can add a comment at the end of the test. This is linked only to the test in progress and not to the patient.	Tests performed	Conclusion comment on test performed
<b>Print</b>	Test report printed according to application setup	Tests performed	Printout on selected printer
<b>PDF Export</b>	Test report exported according to application print setup	Tests performed	Export of test report in a PDF file to selected place

**Note:** If «PDF Export Automatic» is selected in the setup, this will take place during recording, when «END» button is clicked.

At the end of the test and after printing, the operator should click or press on «END» button to exit Create a Test mode. The application then asks the operator if the test is to be saved.



This message is then displayed for correct recording:



## 4.8. Test Management

For data safety reasons, a test performed and recorded in the database can no longer be modified.

However, it can be:

- viewed
- printed
- exported
- deleted

A test can be opened by several ways:

In the Home page is a list of the last tests performed on the application. Click right on the desired test to open, print, export or delete the test.

From the «Open a Test» link on the Home page, access management of all tests recorded in the database screen. Searches can be made by patient and date performed.

### 4.8.1. Test Management screen presentation

The screenshot displays the SpirowinExpert interface. At the top, there is a header with the FIM Medical logo and contact information, and the SpirowinExpert logo. Below the header, there is a navigation bar with 'Home' and 'Open an existing test' buttons. The main area is divided into two sections: a list of tests on the left and a search form on the right. The list of tests includes patient names, DOB, age, and test date/time. The search form has a search bar, 'From' and 'To' date pickers, a 'Search' button, and a 'Sort order' dropdown menu. The control panel at the bottom right has 'Open', 'Delete', and 'Cancel' buttons. Callouts point to the 'List of tests', 'Search form', and 'Control Panel'.

Click «Search» button to validate the search filter.

Select a test to open or delete.

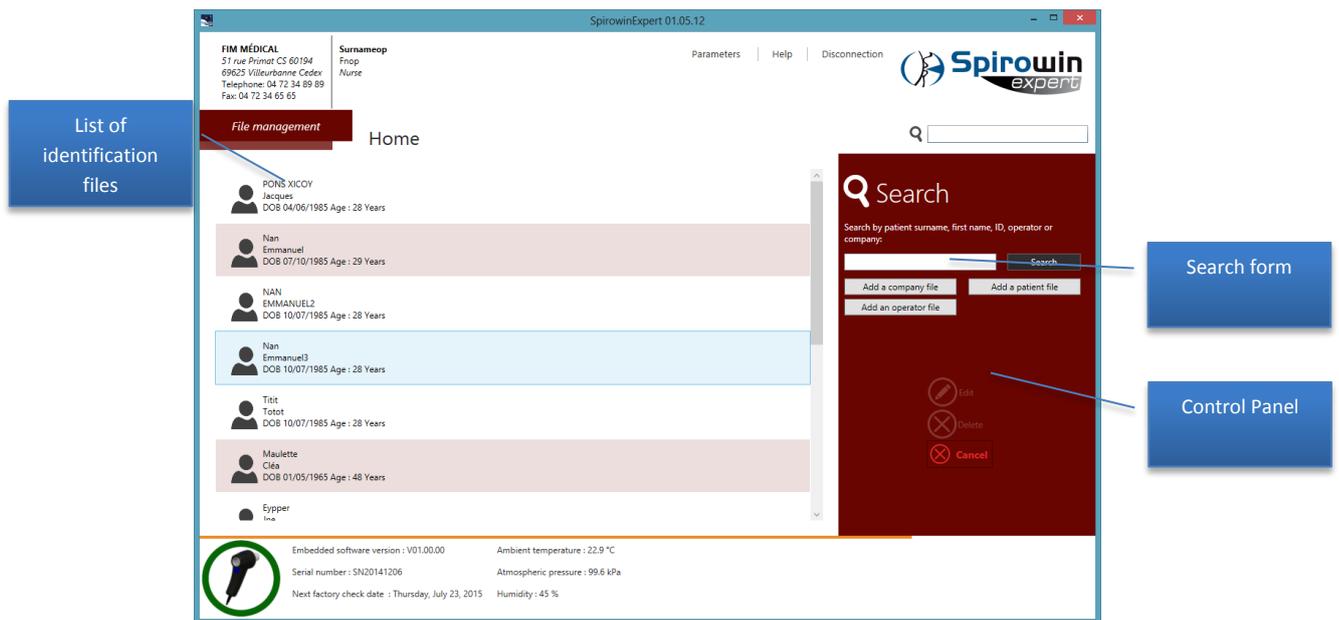
*Note: Click on right button to: Open, Delete, Print or Export in Pdf file.*

## 4.9. Identification Management

As stated in preceding chapters, each file in the SPIROWIN® EXPERT application is an identification file. This can be:

- Patient
- Operator
- Company

The management of all identification files is done through the same interface, accessible via the Home page, by clicking «Identification Management».



Use this screen to:

- Add a new file
- Modify existing files
- Delete one or several files
- Search for a file
- Define a company file as default company by the contextual menu

### 4.9.1. Add a new file

To add a new file, click one of the «Add» buttons on the Control Panel on the right of the screen.

A window appears with the identification fields. Certain fields are compulsory or have their own properties. Each of these indications is displayed below the relevant field.

### 4.9.2. Modify an existing file

To modify an existing file, click twice on the relevant file in the list.

A window appears with the identification fields. Certain fields are compulsory or have their own properties. Each of these indications is displayed below the relevant field.

### 4.9.3. Delete a file

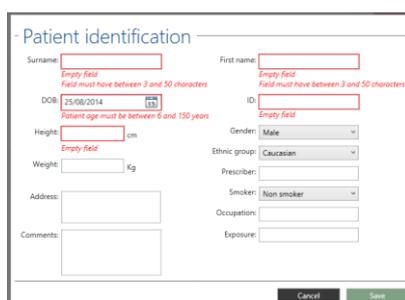
To delete a file, click on a file in the list of identifications and click «Delete» button.

To delete several files, select several files by holding down the Control key whilst selecting other files. Then click «Delete» button.

### 4.9.4. File search

To search for a patient, company or operator file, use the last name, first name or ID in the search field of the Control Panel on the right of the screen. Validate the search by clicking or pressing «Search» button.

### 4.9.5. Patient file



The patient file is used to define information concerning the patient. It is composed of the following elements:

Name	Compulsory	Field can be masked	Description
Last name	X		Patient last name
First name	X		Patient first name
DOB	X		Patient DOB
ID	X		Identification field used by operator
Height	X		Patient height in cm or inch according to parametering
Gender	X		Male or female
Ethnic group		X	Defines ethnic group of a patient for specificity of certain predicted values
Weight			Patient weight in kg or lb depending on parametering
Prescriber			Name of prescriber requesting spirometry test
Smoker	X		Cigarettes (smoker, ex-smoker, non-smoker)
Occupation			Patient occupation
Exposure			Patient respiratory exposure
Address			Patient address
Comments			Operator comment on the to patient

### 4.9.6. Operator file

The definition of a password and response to a question is compulsory for operator files to reset the password. Even if the system is down.

Name	Compulsory	Description
Last name	X	Operator last name
First name	X	Operator first name
Occupation		Operator occupation
Password	X	Operator password
Password confirmation	X	Confirms password identical
Question	X	Chooses password recovery question
Answer	X	Answers password recovery question

#### 4.9.7. Company file

Test reports can be personalised with the company name, details and logo. The FIM MEDICAL company is recorded by default.

Name	Compulsory	Description
<b>Name</b>	X	Operator last name
<b>Address</b>		Company address (in 2 fields)
<b>Logo</b>		Company logo (bmp, jpg, png, gif)
<b>Telephone number</b>		Company telephone number
<b>Fax number</b>		Company fax number
<b>Company selected for the application</b>		Defines the company as selected for the application

### **Selection of a company for the application:**

In the SPIROWIN® EXPERT application, only one company can be defined as default company. By defining a default company, the company identity can be used on test, check and software reports.

To define a company by default in the application, either:

- Tick the box in the creation/modification of a company file.
- Click right on a company file, then «Define as Default Company» in the displayed contextual menu.



## 4.10. Test Comparison

Through the Home page, the operator can compare several tests performed on the **same** patient by clicking on «Compare Existing Tests».

### 4.10.1. Comparison presentation

To compare existing tests please select a patient and the type of test.

**Compare existing tests**

**Patient:**

Search by surname:

**Select the type of test to compare:**

Vital Capacity

Cancel Ok

Patient choice

Test type choice



Then click «Compare the Curves » (**button clickable only when two or more curves selected**). This screen appears:

The screenshot shows the SpirowinExpert 01.05.12 interface. At the top left, there is contact information for FIM MEDICAL. The main area is titled 'Results comparison' and 'Home'. A dropdown menu shows 'Name: FVC' with 'Predicted values: 5,07 L'. Below this is a table:

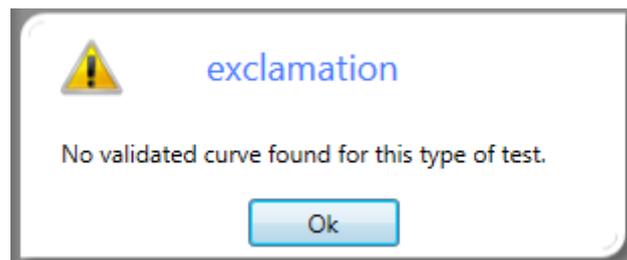
Name	Results	Percentage
Curve n°0 24/07/2014	5,7 L	112,43 %
Curve n°1 21/07/2014	4,01 L	79,29 %

The graph displays 'Flow (L/s)' on the y-axis and 'Volume (L)' on the x-axis. It shows two curves: a green one for the first curve and a purple one for the second. A 'Patient' panel on the right shows: 'Pons Xicry Jacques', 'Age: 28 Years', 'Height: 174 cm', 'Non smoker'. At the bottom, there is a 'Control Panel' with 'Previous', 'End', and 'Cancel' buttons. Environmental data at the bottom includes: 'Ambient temperature: 22,2 °C', 'Atmospheric pressure: 99,6 kPa', and 'Humidity: 45 %'.

The graph shows the course of the selected result. It is refreshed at each change of results in the list.

Tests are only compared to help the practitioner with patient follow-up. No report or printing of comparisons can be done with the SPIROWIN® EXPERT software.

Note: If the operator did not validate a curve for this type of test, the software displays a user information message.



## 4.11. Device Calibration Check Certificate

Using the QFlow<sup>®</sup> sensors, the SPIROLYSER<sup>®</sup> Q13<sup>®</sup> device measures a difference in pressure to obtain flows and volumes according to the FLEISCH principle. With this patented system the SPIROLYSER<sup>®</sup> Q13<sup>®</sup> does not need calibration. However, and according to the ATS 2005 recommendations, SPIROWIN<sup>®</sup> EXPERT proposes to certify that the entire device is functioning correctly.

To access the check, click «Check Sensor Calibration» in the Home page. The following screen appears:

The screenshot displays the SpirowinExpert software interface. At the top, there is a header with FIM Medical contact information and user login details. The main area is titled 'Home' and 'Check sensor calibration'. On the left, a graph plots Flow (L/s) on the y-axis (ranging from -13 to 13) against Volume (L) on the x-axis. A blue shaded area represents the 'Calibration predicted values area'. In the center, 'Step 1' instructions are provided: 'Connect the sensor to the syringe. Click on the "Start" button. Perform an inhalation/expiration with the syringe whilst trying to remain in the blue areas. Then click on "Stop". If the curve is not satisfactory, redo it as many times as required. Click \*'. Below the instructions is a table with columns: Flow reached (L/s), Measured volume (L), Theoretical volume (L), Difference (L), Error (%), and Maximum permissible error (%). On the right, a 'Syringe' identification form contains fields for Manufacturer (HANZ RUDOLPH), Designation (SYRINGE), Type (RS454), Serial number (787687), Volume (L) (3), Tolerance (%) (0.5), and Next verification date (29/01/2015). A 'Start' button is at the bottom of the form. At the bottom of the screen, there are three control buttons: 'Cancelled', 'Next', and 'Start/Stop'. A status bar at the very bottom shows embedded software version (V01.00.00), ambient temperature (25.2 °C), serial number (140110), atmospheric pressure (100.6 kPa), next factory check date (29/12/2015), and humidity (24 %).

The check is done in three steps, by validating for each flow, that the measurement of the volume does not exceed  $\pm 3.5\%$  (including syringe check error) compared with the volume sent.

The screen has three control buttons on the bottom right of the check screen:

- Cancelled => Exits check screen
- Next => To go to following step. Only possible if the curve of the step in progress is traced
- Start/Stop=> Check curve is traced (if a curve exists, it is automatically replaced)

#### 4.11.1. *ATS 2005 recommendations check procedure*

##### **Stage 1 (2L/s flow):**

Connect the check syringe to the spirometer which is connected to the computer running the SPIROWIN® EXPERT software. Press the «Start» button and pull the syringe piston, whilst aiming to keep the curve within the template traced on the graph. At the end, repeat in the opposite direction. At the end, click on the «Stop» button. If the tracing is unsatisfactory, repeat this stage by re-clicking on the «Start» button. Or click on the «Next» button to validate stage 1 and go to stage 2.

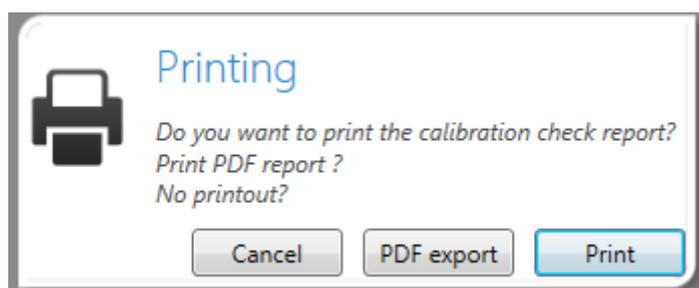
##### **Stage 2 (6L/s flow):**

Press on the «Start» button and pull the syringe piston whilst aiming to keep the curve within the template traced on the graph. At the end, repeat in the opposite direction. At the end, click on the «Stop» button. If the tracing is unsatisfactory, repeat this stage by re-clicking on the «Start» button. Or click on the «Next» button to validate stage 2 and go to stage 3.

##### **Stage 3 (12L/s flow):**

Press on the «Start» button and pull the syringe piston whilst aiming to keep the curve within the template traced on the graph. At the end, repeat in the opposite direction. At the end, click on the «Stop» button. If the tracing is unsatisfactory, repeat this stage by re-clicking on the «Start» button. Or click on «End» to validate stage 3, and print out your device calibration check certificate.

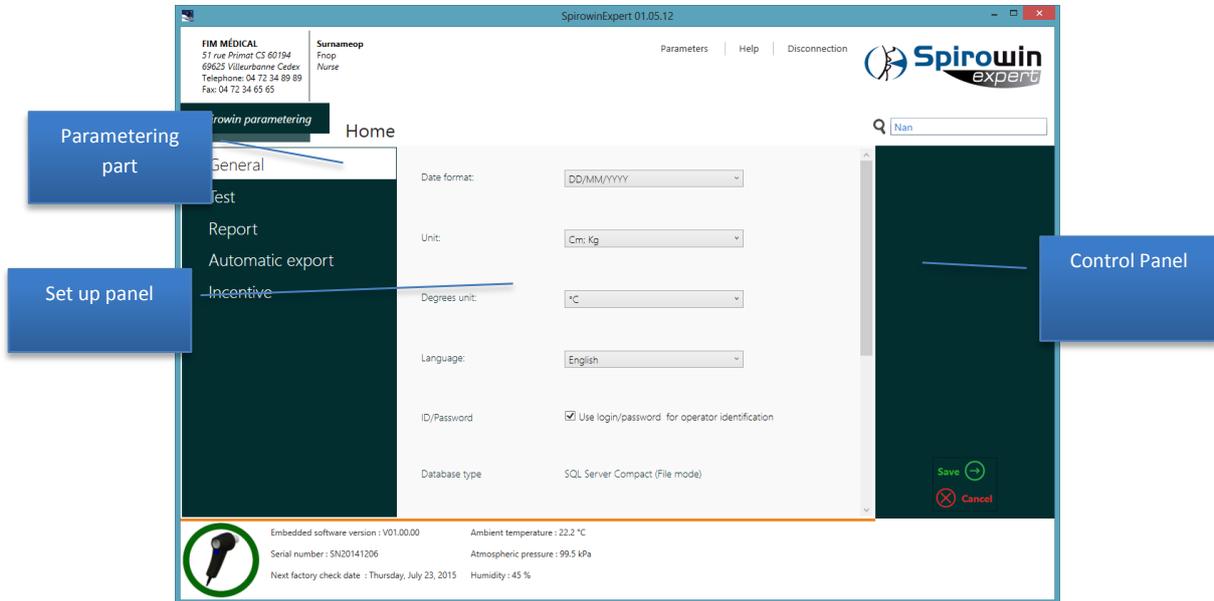
**Note:** The SPYROLYSER® Q13® device check report is printed out at the end of the procedure. Printing can be done normally or as PDF export.



## 4.12. Application Parametering

### 4.12.1. Presentation

All of the application parameters can be modified in this part. The screen is composed of the following parts:



### 4.12.2. General

#### Available Parameters:

Name	Action
<b>Date format</b>	Formats application dates
<b>Height/weight units</b>	Changes height and weight units
<b>Temperature units</b>	Changes temperature units
<b>Atmospheric pressure units</b>	Changes atmospheric pressure units
<b>Language</b>	Application language
<b>Id/Password</b>	Use of authentication system when application is run
<b>Database type</b>	Application database type (local or network)
<b>Database file</b>	Directory of database in local mode
<b>Synchronisation of old FIM MEDICAL database</b>	Uses old database to synchronise patient files between all the FIM MEDICAL software
<b>User Manual file</b>	Defines the User Manual directory

### 4.12.3. Tests

Test parameters define the features of performing a test.

#### Available Parameters:

Name	Action
<b>Predicted values</b>	Choice of predicted values for Interpretation Help <ul style="list-style-type: none"> <li>• Knudson</li> <li>• ITS (Crapo)</li> <li>• ECCS (CECA)</li> <li>• Polgar</li> <li>• NHannes III</li> </ul>
<b>Ethnic groups</b>	Use of ethnic groups in patient identification and calculation of predicted values

<b>Order of DE25 and DE75 values</b>	Definition of DE25 or DE75 parameters
<b>Choice of results</b>	Defines the results displayed by type of test in the application
<b>Lung age</b>	Activates/deactivates lung age calculation (calculation for information only)
<b>Curve smoothing</b>	SPIROWIN® EXPERT displays the real image of the breath that passes through the QFlow® sensor. For clearer viewing, the curve display can be averaged and thus, the curve is smoothed.
<b>Manual meteorological parameters</b>	The software proposes the user to enter his own temperature, humidity or pressure values
<b>Display of assessment at the end of a test</b>	Deletes the last assessment display panel at the end of a test
<b>Interpretation Help</b>	Activates/Deactivates Interpretation Help
<b>Automatic validation of curves</b>	For each test, the practitioner must choose a curve from those traced. With this option, the software automatically chooses the best of each new curve traced by calculating the best (FVC+FEV1) sum.

➡ **Caution:** Meteorological information displayed by the software is informative only, and not guaranteed. Only a weather station calibrated and located in the test room could give exact information.

#### 4.12.4. Printing

The print parameters define the test report features for standard printing as well as for PDF export.

##### Available Parameters:

Name	Action
<b>Type of report</b>	Defines either summarised or complete report
<b>Choice of results</b>	To choose the results to display in the test report
<b>Only validated curves</b>	Activates/Deactivates if the application uses the validated curves for the test reports

#### 4.12.5. Automatic PDF export

The automatic PDF report export option enables exportation at the end of the test without operator request.

##### Available Parameters:

Name	Action
<b>Activation</b>	Activates/deactivates PDF report automatic export
<b>Export path</b>	Choice of automatic export file of PDF reports
<b>File name</b>	Choice of variables for creation of automatic PDF report: [NAME] => Patient last name [FIRSTNAME] => Patient first name [ID] => Patient ID [DATE] => Test date ( <b>Compulsory</b> ) [HOUR] => Test time ( <b>Compulsory</b> )

#### 4.12.6. Incentive

The Incentive guides the user and the operator during a Forced Vital Capacity test.

##### Available Parameters:

Nom	Action
<b>Activation</b>	Activates/Deactivates Incentive during the test
<b>Choice of Incentive</b>	Changes Incentive theme

## 4.13. User Manual

The User Manual file is defined in the application parametering. The choice of file is done automatically when the application is installed.

**Note:** A version of Adobe Reader must be installed at the workstation to display the User Manual.

To display the User Manual in the software, click on the «Help» menu at the top of the software window.

## 4.14. Third Party Software Use Mode (GUEST Mode)

### 4.14.1. Presentation

The SPIROWIN® EXPERT application has several extra commands so as to meet the needs of third party software using SPIROWIN® EXPERT. For this, parameters can be added in the running command line of the application.

### 4.14.2. Table of available commands

Name	Default Value (if existing)	Description
<b>/GUEST3</b>		Defines going to Host mode
<b>/T</b>	Mode by default if not specified	Text mode
<b>/F :&lt;File path&gt;</b>	Local database path	Forces the path and the file name to Text mode
<b>/X</b>		XML format
<b>/O:&lt; File path &gt;</b>	Local database path	Forces the path and the XML file name (OutData)
<b>/I:&lt; File path &gt;</b>	Local database path	Forces the path and the XML file name (InData)
<b>/H</b>		Application goes to Icon mode when minimised
<b>/S</b>		Polling mode of swap file
<b>/Usebdd</b>		Use of test recording and patient file in database

### 4.14.3. Host mode

#### 4.14.3.1. Presentation

Host mode used for the exchange of data between SPIROWIN® EXPERT and a third party software. This is run with the /GUEST3 command.

- Text Mode (by default)
- XML Mode

#### 4.14.3.2. Text format

##### 4.14.3.2.1. Presentation

Host mode is in Text format by default. This Text format is chosen with the /T command. The name and path of the swap file can be passed as a parameter in SPIROWIN® EXPERT on the command line:



«/F :<file name>». This path will be used to store the file containing the samples of the curve (s). Without this parameter, SPIROWIN® EXPERT will work with a file named IO\_DATA.TXT in the application directory.

**Eg:**

```
C:\Program Files\Fim\Spirowin®\Spirowin®.exe /GUEST3 /F :C:\MyData\Ech.txt
```

Here the swap file will be Ech.txt and will be found in the C:\MyData\ directory.

#### 4.14.3.3. *Format of Swap File in Text Mode*

The format used is that used by WINDOWS with the \*.ini files. It is easily accessible with the WINDOWS API:

*[Section]*

*Entrée=Value*

Section is always the same: «Resultat»

File name is IO\_DATA.TXT

#### 4.14.3.4. *Use*

The input file is placed in the working directory of SPIROWIN® EXPERT, then the application is run with the «/GUEST3» parameter on the command line.

If the «Test Date» fields are filled in, SPIROWIN® EXPERT loads the tests according to the parameters found in the file. Otherwise, it is a new test.

Parameters required for calculation of standards are «DATE OF BIRTH», «HEIGHT» and «GENDER».

When the session is over SPIROWIN® EXPERT updates an output file with ID and results. The sample files are stored in the SPIROWIN® EXPERT folder. Their names are indicated in the results of each test. In this mode, SPIROWIN® EXPERT is not maintaining its database. Management of results and sample files is thus the responsibility of the application that has run it.

#### 4.14.3.5. *Parameter*

- [Resultat] ← Section name compulsory.
- Parameter = parameter value

Parameter	Type	Description
Nom	String	Patient surname
Prénom	String	Patient first name
Id	String	Patient ID
Date de naissance	String format (DD MM YYYY)	Patient birth date
Adresse	String	Patient address
Profession	String	Patient job
Exposition	String	Patient exposure
Notes	String	Patient note/comment
Age	Int	Patient age (not necessary)
Poids	Double (with a dot)	Patient weight
Taille	Double (with a dot)	Patient height
Sexe	String (Male/Female)	Patient gender
Fumeur	String (Yes/No/Ex)	
Norme	String (CECA/Knudson/Polgar/Nhannes/ITS)	Standard for predicted values

#### 4.14.3.6. *XML Format*

Contact FIM MEDICAL for more information.

#### 4.14.4. *Use of local database*

GUEST mode does not use recording in database by default. It can, however, be done by adding /usebdd to the list of parameters when running the application.

#### 4.14.5. *Polling mode*

Polling mode is used to swap data with a third party software that is unable to run the application with command lines. The SPIROWIN® EXPERT software should poll a folder to read regularly, if a new file has been created.

#### 4.14.6. *Icon mode*

This mode places SPIROWIN® EXPERT as an icon in the Windows taskbar. The software only opens to do a test. This mode peers with GUEST mode or Polling mode.



## 5. Cleaning – Maintenance



The technologically innovative design of the SPIROLYSER® Q13® and the Qflow® sensor minimise the risk of cross-contamination between patients.

Bacteriological tests performed by the **Public Health England** (Salisbury - UK) laboratory show that the internal design of the product, associated with the Qflow® sensor, decreases the risk of patient cross-contamination to 99.999% if the Qflow® sensor is changed between each patient. Its innovative design also avoids contamination in the non-accessible internal parts.

## 5.1. Clean the Housing

For hygiene measures, the surfaces of the SPIROLYSER® Q13® in contact with the skin (housing) must be disinfected between tests. The housing can be cleaned with a damp cloth and a generic bactericidal-fungicidal product. The FIM MEDICAL company recommends the use of Bactinyl® scent-free wipes.

- ➔ **Warning:** Never sterilise the SPIROLYSER® Q13® or its consumables
- ➔ **Warning:** Never clean the SPIROLYSER® Q13® under running water or immerse directly into any sort of liquid
- ➔ If the housing degrades, contact the FIM MEDICAL company or your distributor to change the equipment

## 5.2. Clean the Sensor Insertion Piece

The FIM MEDICAL company recommends the use of a bactericidal-fungicidal product such as scent-free Bactinyl® wipes to clean and disinfect the inside part of the sensor insertion piece (cylinder).

- ➔ **Warning:** The use of a single-use sensor does not exempt the equipment from disinfection
- ➔ **Warning:** Never sterilise the single-use Qflow® sensor
- ➔ If the device or the sensor insertion piece degrades, contact the FIM MEDICAL company or your distributor to change the equipment

## 5.3. Clean the Check Syringe

There are several calibrated syringe manufacturers on the market for checking spirometers. Whatever the syringe, it should only be used with a spirometer that has been disinfected, and a new Qflow® sensor.

Refer to the Instructions delivered with your syringe.

## 5.4. Daily Check

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Conform with ATS/ERS the spirometer should be checked daily to ensure the equipment is operating correctly. Use a 3L calibrated syringe and follow the procedure explained in the Calibration Check chapter.

If the device malfunctions, contact the FIM MEDICAL After Sales Service department.

**Warning:** Whatever the brand, ensure to check the calibration syringe validity date, as well as its conditions of use, especially environmental conditions.

Due to the specific design of the Qflow<sup>®</sup> sensor, to obtain precise inspiration/expiration values whilst checking with the calibrated syringe, it is imperative to use the specific FIM MEDICAL coupling connector between the Qflow<sup>®</sup> sensor and the syringe.

FIM MEDICAL recommends the use of a **HANZ RUDOLPH SERIES 5570** type syringe. If other syringe references are used, please contact FIM MEDICAL for a specific coupling connector.

## 5.5. Annual Maintenance

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The SPIROLYSER<sup>®</sup> Q13<sup>®</sup> spirometer must be checked annually.

Only the FIM MEDICAL company or its approved distributors are authorised to perform annual services of its spirometers.

A calibration certificate shall be issued.

**Warning:** The device must be recalibrated every year. After this date, a drift may falsify results.

## 5.6. Guarantee

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The SPIROLYSER<sup>®</sup> Q13<sup>®</sup> has a 2-year guarantee. Within the framework of the contractual guarantee, only repairs are covered. The guarantee is only applicable if normal and usual conditions of use are respected. During annual maintenance, a certain number of preventive operations are performed; breakdowns following annual maintenance are not covered by the guarantee.



## 6. Available Accessories



### 6.1. 3-Litre Check Syringe

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Conform with ATS/ERS, a fixed and calibrated volume is required to check correct function of the SPIROLYSER® Q13®. If you need a check syringe, contact the FIM MEDICAL company or your distributor.

### 6.2. Qflow® Single Use Sensor

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The FIM MEDICAL company developed specific single-use sensors to be used with the SPIROLYSER® Q13®.

This single-use sensor must **absolutely** be replaced between each patient.

If you need Qflow® sensors contact the FIM MEDICAL company or your distributor.

Different product packages are available.

### 6.3. Single Use Nose Clip

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Use of a nose-clip is recommended by the ATS / ERS. The single-use FIM MEDICAL nose clip, delivered in individual sachets, optimises results by guaranteeing minimal air leakage during patient inhalation and exhalation.

If you need nose clips, contact the FIM MEDICAL company or your distributor.

Different product packages are available.

## 7. F.A.Q.



Problems	Solution
<b>Software does not start</b>	<ul style="list-style-type: none"> <li>• Reinstall SPIROWIN® EXPERT</li> <li>• If the problem persists, check the directory rights c:\ProgramData\FIM\Spirowin®</li> <li>• If problem persists, contact After Sales Service</li> </ul>
<b>Patient files or tests not found</b>	<ul style="list-style-type: none"> <li>• Ensure recording is working</li> <li>• Contact After Sales Service</li> </ul>
<b>Software does not detect the spirometer</b>	<ul style="list-style-type: none"> <li>• Turn off the programme</li> <li>• Unplug the spirometer</li> <li>• Reconnect the spirometer</li> <li>• Run the programme and check</li> <li>• If problem persists, contact After Sales Service</li> </ul>
<b>Windows® does not detect the spirometer</b>	<ul style="list-style-type: none"> <li>• Contact After Sales Service</li> </ul>
<b>Spirometer is detected but no curve traced</b>	<ul style="list-style-type: none"> <li>• Turn off the programme</li> <li>• Unplug the spirometer</li> <li>• Reconnect the spirometer</li> <li>• Run the programme and check</li> <li>• If problem persists, contact After Sales Service</li> </ul>
<b>Installation key not working</b>	<ul style="list-style-type: none"> <li>• Check the key located on the back of the CD sleeve is used</li> <li>• Contact After Sales Service</li> </ul>

### **After Sales Service:**

*FIM Medical After Sales Service  
 51 Rue Antoine Primat  
 CS 60194  
 69625 Villeurbanne cedex  
 Tel: (+33) 04 72 34 30 34  
 Opening hours: Mon-Fri 8.45am – 12.15pm and 1pm – 5.30pm (4.30pm Fridays)*



## 8. Declaration of Conformity



## EC DECLARATION OF CONFORMITY

<u>Description</u>	<u>Version</u>	<u>Device Description</u>
SPIROLYSER®	Q13®	Digital spirometer

The device conforms to the following standards:

EN 60601-1:2006/AC: 2010: Medical electrical equipment - Part 1: General requirements for basic safety.

EN 60601-1-2:2007/AC: 2010: Medical electrical equipment - Part 1-2: General requirements for basic safety - Collateral standard: Electromagnetic compatibility - Requirements and tests.

IEC 60601-1-6:2007/AC: 2010: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.

EN ISO 10993-1:2009/AC: 2010: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

NF EN ISO 14971:2013: Medical devices - Application of risk management to medical devices.

NF EN 62304:2006 : Medical device software. Software life cycle.

NF EN 1041+A1:2013: Information supplied by the medical devices manufacturer.

I the undersigned, Marie-Ange DEREI, President of the FIM MEDICAL company located at 51 rue Antoine Primat Villeurbanne - FRANCE, assure and declare that the medical device listed above belongs to class IIa (Rule 10) and satisfies the provisions of annex VI (CE Attestation n° 27671 delivered by LNE/G-MED) and annex VII (Evaluation of Spirolyser® Q13® technical file) of the 93/42/EEC directive amended by the 2007/47EC directive.

04 December, 2014,

Marie-Ange DEREI

President





*Thank you for reading this manual.  
If you require further information please don't  
hesitate to contact us.*



FIM MEDICAL

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