

Winspiro Light[®]

User guide

I. Installing the Winspiro Light[®] Software

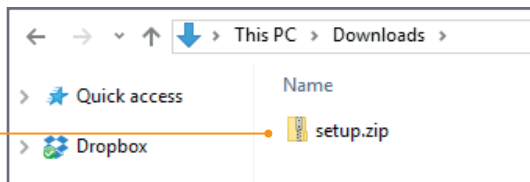
Insert the Winspiro Light[®] software CD (supplied with the device) in your computer's CD drive.

If you do not have a CD drive, Winspiro Light[®] can be downloaded from the Internet here:

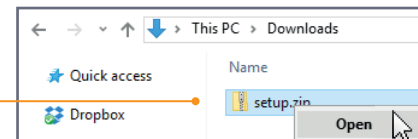
<http://www.spirometry.com/download.asp?path=winspiroLIGHT/setup.zip>

In this case save the file **setup.zip** on your computer

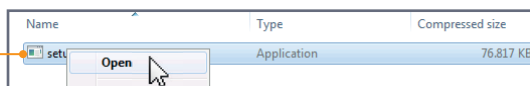
1 Find the file **setup.zip**



2 Open the file **setup.zip**



3 Open the file **setup.exe**



4 Follow the installation assistant.

II. First start

The first time that Winspiro Light® is launched, the window **First activation** opens.

These settings are required to allow the Winspiro Light® to function. Once they have been configured, you will not be asked again.

Complete the settings as follows:

The screenshot shows the 'Regional Settings' dialog box with the following settings:

- 1 Language:** ENGLISH
- 2 Measurement:** cm, kg
- 3 Predicted FVC-FEV1:** NHANES III
- 4 Turbine in use:** Disposable

Once these parameters have been entered, press **OK**

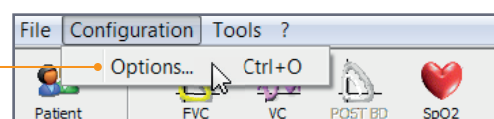
! On subsequent occasions when Winspiro Light® is launched, registration will be requested. See page 14 for more information about this registration.

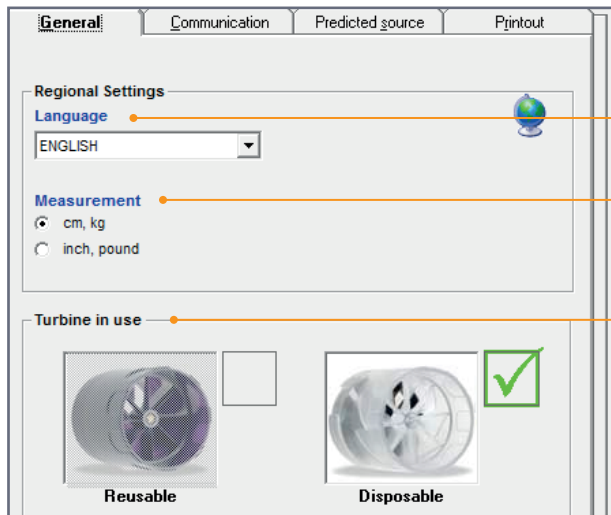
III. Changing the settings

It is possible to change the settings at any time using the Winspiro Light® options.

1 Plug the USB device into the PC.

2 Open the **Configuration** menu then **Options**.

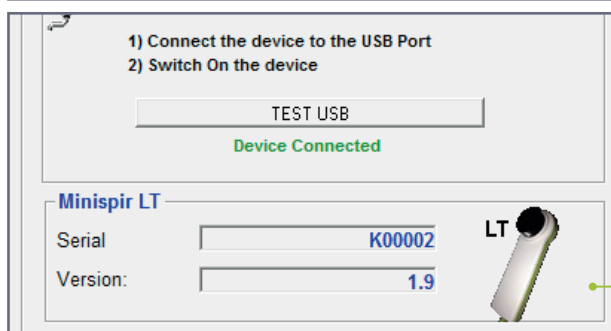




3 In the **General** tab change the basic settings such as the language, the unit of measurement or the type of turbine in use.



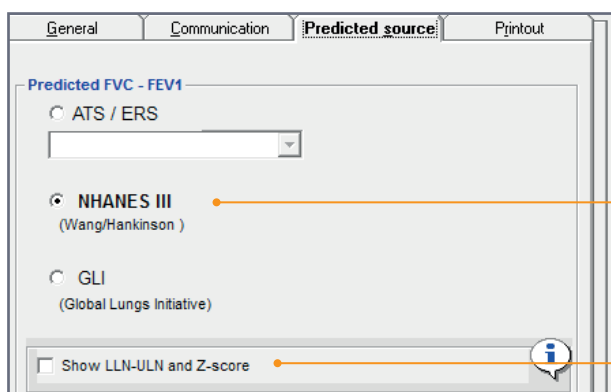
4 In the **Communication** tab, press **TEST USB** to check if the spirometer is well connected.



The serial number and the model of the device are displayed if the device has been correctly identified.



! If the message **Device NOT connected** appears, this means that there is a problem related to communication with the device. In this case, contact support (details at the bottom of the page).



5 In the **Predicted source** tab, change the predicted source used for the spirometry tests to **ATS/ERS**, **NHANES III** or **GLI**.

If the box **Show LLN-ULN and Z-score** is ticked, untick it.

6 Go to the **Printout** tab.

Fill out the header of the document, that will be printed when a spirometry session is exported.

NOTE
The following boxes should be ticked:
- **Show preview window**
- **Print automatic interpretation**

IV. Creating a patient

The first stage is to create a patient in the database of Winspiro Light®.

- To create a patient click on the **Patient** button at the top left of Winspiro Light®.
- Press **New**.
- Fill out all the fields in the form.

Information about ethnic group: *Caucasian* includes all patients of European origin and from around the Mediterranean.
- When the form has been completed press **Save**.
The patient is now registered in the database of Winspiro Light®.

V. Preparing the device for the test

- 1 Take a FlowMir® turbine and take it out of its blister pack.



- 2 Insert the turbine into the device.

- ! The back of the turbine (black side) should be on the same side as the device serial number (grey label) once the turbine is in place. Once the turbine has been inserted, the patient taking the test should not see the grey label with the serial number on the back of the device.



- 3 Turn the turbine a quarter turn clockwise.



VI. Carrying out an FVC on a patient

Age limit for spirometry:

For counter-indications relating to this test, see the international ATS/ERS guidelines.

BEFORE THE TEST



Do not smoke less than two hours before the test



Do not drink alcohol less than two hours before the test



Do not eat a heavy meal less than two hours before the test



Wear loose clothing



No intense exercise less than the 30 minutes before the test



No bronchodilator use for half a day beforehand

CORRECT PATIENT POSITION FOR CARRYING OUT THE TEST

It is preferable for the lung function test to be done in a sitting position, on a chair with arm-rests and no wheels for two reasons:

- The best values currently obtained by spirometry come from patients who were sitting down for safety reasons.
- The vigorous test causes a significant reduction in venous return, which can cause dizziness or faintness.

PREPARATION OF THE TEST

Remove tight clothing, remove all objects from the patient's mouth (chewing gum, sweets, removable dentures etc.)

CORRECT HEAD POSITION

In a sitting position, patients must keep their backs straight and their heads well up.

THE IMPORTANCE OF USING A NOSE CLIP

To carry out the spirometry test correctly, we recommend that you use a nose clip (or block the nose if this is not available). Not blocking the nostrils could easily have a negative effect on the results of the test, and this might be difficult for the spirometer to detect.

HOW THE PATIENT SHOULD HOLD THE SPIROMETER

The spirometer should be held with two hands. Fingers should be kept away from the other end of the turbine to avoid blocking the air.

CORRECT USE OF THE MOUTHPIECE

The mouthpiece should be held “hermetically” between the patients’ lips so air does not escape from the corners of their mouths. Patients should not hold the mouthpiece with their teeth.

EXPLAINING THE PROCEDURE TO THE PATIENT

The Forced Vital Capacity test requires collaboration by the patient and good understanding on the part of the doctor or technician in charge of carrying out the test. The doctor can help patients by encouraging them during the test... For example by telling them: “Blow... blow... blow...”

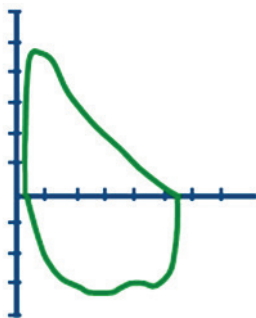
CARRYING OUT THE MANOEUVRE

FVC Phase 1: Resting breathing (Normal volume)	Take several resting breaths (3 or 4)
FVC Phase 2: Fast maximum inhalation	When starting from rest, quickly inhale as much air as possible
FVC Phase 3: Respiratory phase	Prepare for the forced exhalation by holding your breath for less than a second
FVC Phase 4: Maximum forced exhalation	Exhale as quickly and forcefully as possible for at least 6 seconds without stopping
FVC Phase 5: Maximum forced inhalation	Following the same principle as exhalation, carry out a forced inhalation to breath in all the air as quickly as possible.

- !** NOTE:
- The patient must take care to do the test comprehensively (maximum inhalation and exhalation) to obtain consistent values. For repeatability and to be sure of the results, we recommend that you carry out at least 3 lung function tests during the same session (without exceeding the maximum authorised number of 8).

TEST AND NORMAL CURVE

A well implemented spirometry test is shown below.



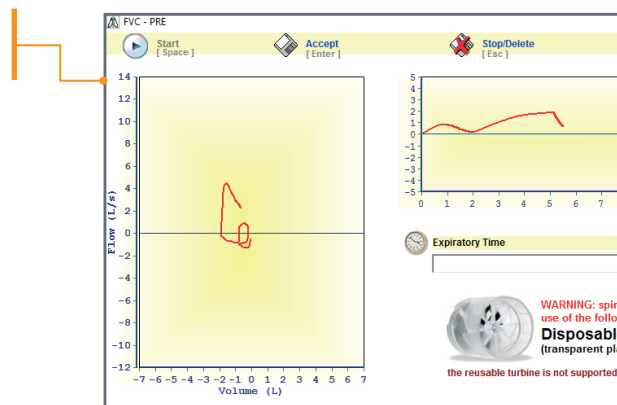
- 1 Select the patient in the menu on the left of the screen.



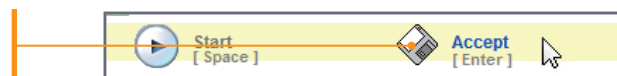
- 2 Press the **FVC** button.



- 3 The test window opens. Now carry out the lung function test.

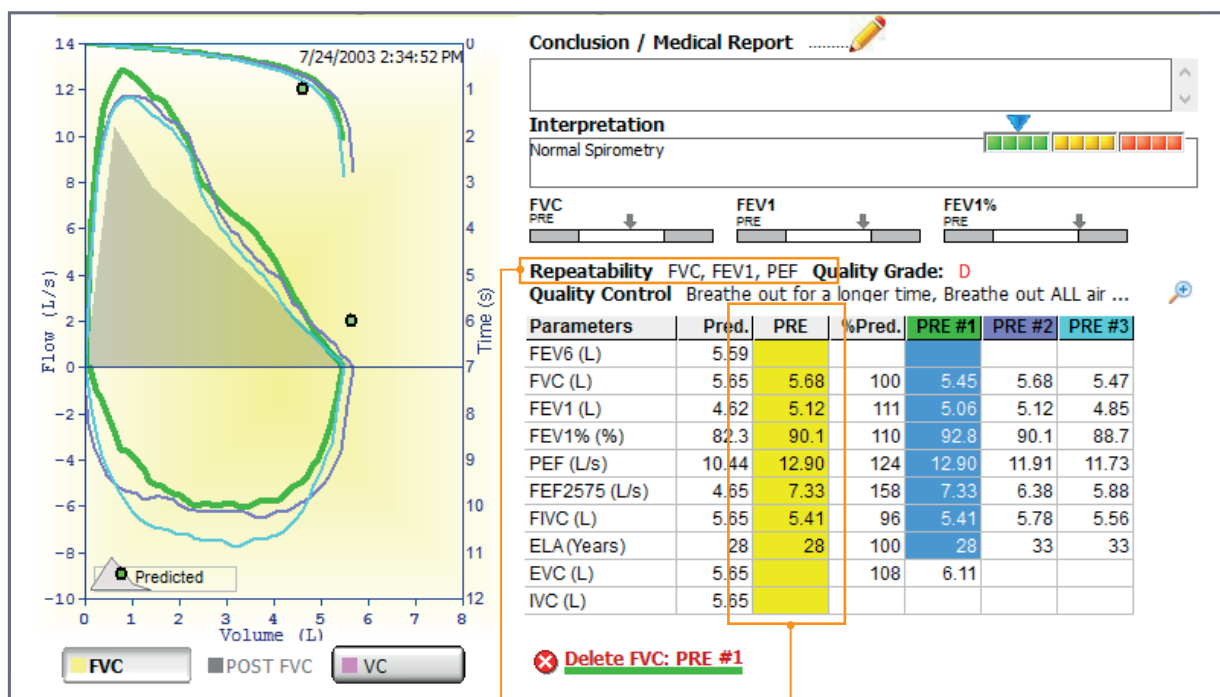


- 4 Press **Accept** or press **Enter** on the keyboard when the test is finished.



- 5 At the end of each test the results window shows the patient's overall situation by displaying the patient's curves, parameters and anthropometric data in an automatic diagnostic.

Automatic interpretation and information about the quality of the test (repeatability, quality control, quality grade) is shown on the right of the screen.



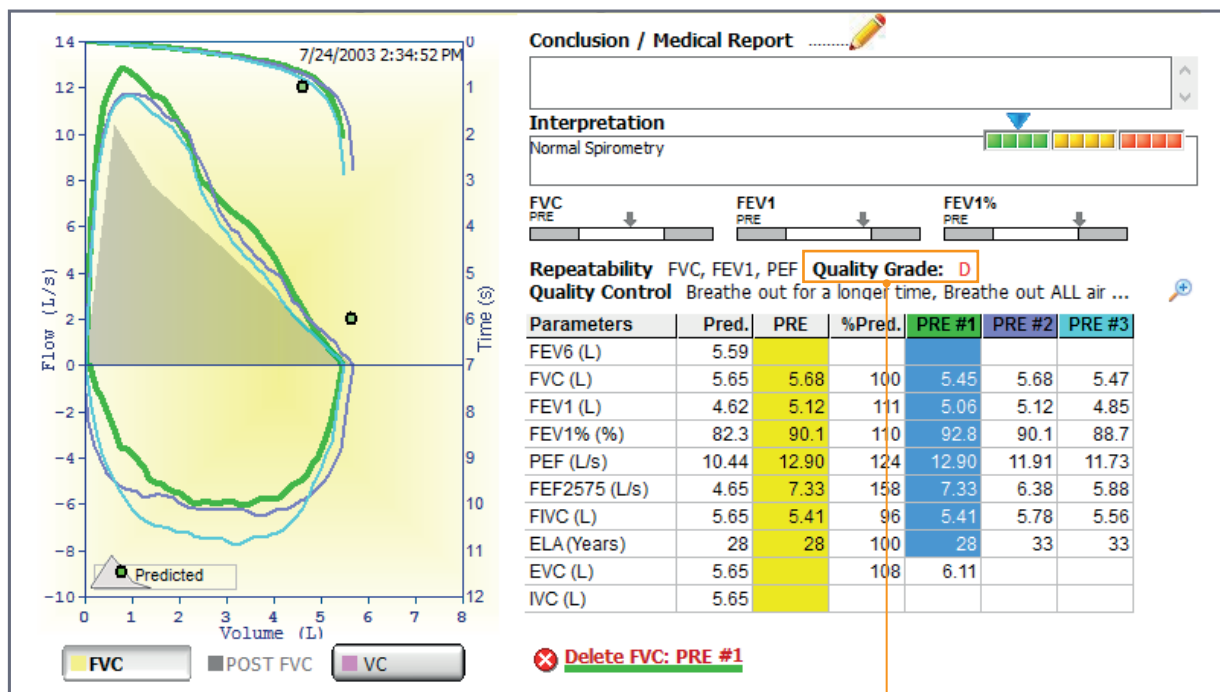
Reproducibility, it is required to perform **at least 3 measurements**. It is compulsory that at least 2 measurements are acceptable and reproducible.

This is calculated according to the international algorithms used by the scientific community in Europe and the U.S.

Patients should continue to carry out tests until they manage to achieve repeatability.

This proves that the differences between the FVC and the FEV1 are small... This makes it possible to establish a good diagnostic.

The yellow column groups the best values obtained in the course of the various tests carried out during the spirometry session.



INFORMATION ABOUT THE "QUALITY GRADE"

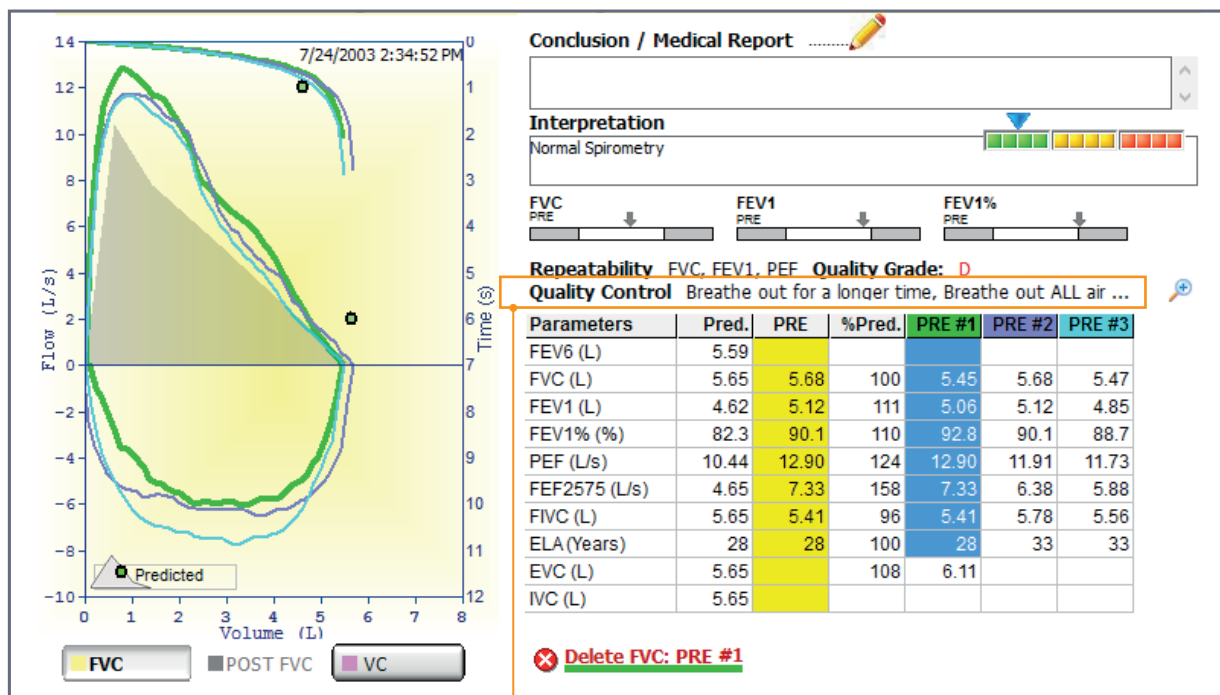
According to an international standard that is now widely accepted, the repeatability of spirometry can be evaluated using a scale based on the letters: **A, B, C, D, F**.

The letter **E** has been intentionally left out as it means "Excellent" in English-speaking countries.

The Quality Grade is automatically attributed by the software taking into consideration only the "acceptable" tests carried out by the patient.

QUALITY GRADE OF THE FVC PRE TEST

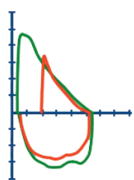
- A** At least two acceptable curves with a difference of less than 100 mL between the best FVC and the best FEV1
- B** At least two acceptable curves with a difference between 101 and 150 mL between the 2 best FEV1
- C** At least two acceptable curves, with a difference between 151 and 200 mL between the 2 best FEV1
- D** Just one acceptable curve (or more), with a difference of more than 200 mL between the 2 best FEV1
- F** No acceptable curves.



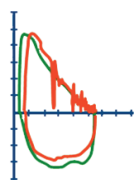
QUALITY CONTROL

The curves below show the most common errors made during spirometry tests. If you get one of these curves, restart the test. If a test is poorly carried out, the software will give you a simplified explanation of the error made by the patient.

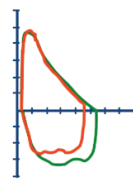
Most common errors



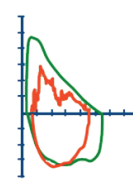
Preceding inhalation not maximum



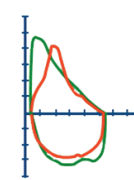
Cough during the test



Test stopped abruptly



Mouthpiece blocked



PEF too late and below the maximum

- Option of adding a conclusion about the test carried out. Comment that will be included in the test printout.



VII. Printing the results

On the results screen, press **Print** to print the results.



An example of a test printout is shown below.

Pulmonary Function Test Results

Visit date 7/24/2003

Patient code 0	Age	28
Surname MARTINI	Gender	Male
Name DAVID	Height, cm	180
Date of birth 5/6/1975	Weight, kg	76
Ethnic group Caucasian	BMI	23.46

Interpretation

FVC	FEV1	FEV1%
PRE	PRE	PRE

Normal Spirometry

Best values from all loops

Parameters	Pred	PRE	%Pred	POST	%Chg
VC L	5.65	5.68	100		
FVC L	5.65	5.68	100		
FEV1 L	4.62	5.12	111		
FEV1% %	82.3	90.10	110		

PRE Trial date 7/24/2003 2:34:17 PM

Parameters		Pred	PRE # 1	%Pred	PRE # 2	PRE # 3	POST#1	%Pred	%Chg
FEV6	L	5.59							
FVC	L	5.65	5.45	96	5.68	5.47			
FEV1	L	4.62	5.06	109	5.12	4.85			
FEV1%	%	82.3	92.8	113	90.1	88.7			
PEF	L/s	10.44	12.90	124	11.91	11.73			
PEF2575	L/s	4.65	7.33	158	6.38	5.88			
FIVC	L	5.65	5.41	96	5.78	5.56			
ELA	Years	28	28	100	33	33			
EVC	L	5.65	6.11	108					
IVC	L	5.65							

BTPS 1.092 25 °C 77 °F

Avg SpO2	91.7%	Avg HR	117.4 bpm
Min SpO2	85%	Min HR	78 bpm
Max SpO2	97%	Max HR	133 bpm

Conclusion / Medical report

Quality Control **D**

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Breathe out for a longer time,
Breathe out ALL air in the lungs

Instrument used
Minispir_Light_MIR_S/N K01324

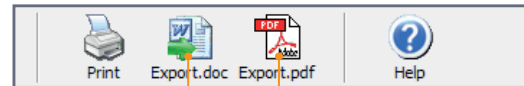
Signature

printed by winspiroLIGHT 2.7.0 - Mod.C11LT 1/1

MIR
MEDICAL INTERNATIONAL RESEARCH

VIII. Exporting the results

To export the results, press the **Export.pdf** button to get a PDF or the **Export.doc** to obtain a document for Word.



IX. Consulting the tests carried

For each patient, the sessions carried out are located under their surname and first name in the menu on the left.

The screenshot shows the software interface with three main sections:

- Patients List (Left):** A list of patients including 'Martini D.' and 'Nom P.', with a date filter set to '07/24/2003'.
- Flow-Volume Graph (Center):** A graph plotting Flow (L/s) on the y-axis (from -10 to 14) against Volume (L) on the x-axis (from 0 to 8). It shows multiple curves for different test types: FVC (yellow), POST FVC (grey), and VC (purple). A 'Predicted' curve is also shown. The date and time '7/24/2003 2:34:52 PM' are displayed at the top of the graph.
- Conclusion / Medical Report (Right):** A section containing an 'Interpretation' box with the text 'Normal Spirometry', a 'Repeatability' section with instructions to 'Breathe out for a longer time', and a 'Quality Control' table.

Parameters	Pred.	PRE	%Pred.	PRE
FEV6 (L)	5.59			
FVC (L)	5.65	5.68	100	5.
FEV1 (L)	4.62	5.12	111	5.
FEV1% (%)	82.3	90.1	110	92.
PEF (L/s)	10.44	12.90	124	12.
FEF2575 (L/s)	4.65	7.33	158	7.
FIVC (L)	5.65	5.41	96	5.
ELA (Years)	28	28	100	
EVC (L)	5.65		108	6.
IVC (L)	5.65			

Below the table, there is a red 'X' icon and the text 'Delete FVC: PRE #1'.

To consult a session, **click on the date** of the session in question.

The curves are shown on the **right** of the screen.

APPENDIX. Registering Winspiro Light®



1 On launching Winspiro Light®, press **Register now**.

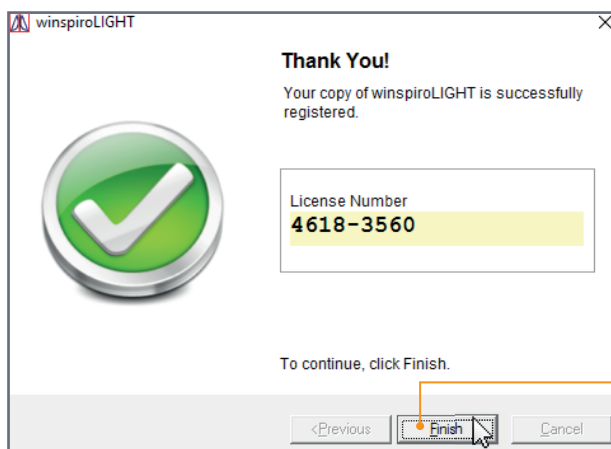
The website www.spirometry.com opens in your browser.

2 Fill out the form completely, then press **Confirm**.

- 3 Check your email inbox. There should be an email from register@spirometry.com there. This email includes a **PAN code**. Copy this code.



- 4 Return to Winspiro Light®, enter the PAN code and press **Next**.



- 5 To end the procedure click on **Finish**.