winspiro*PRO*

User Manual

User Manual Rev. 3.3

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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. 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.

INDEX

1 INTRODUCTION TO WINSPIROPRO

winspiroPRO is a database for the management of spirometry and oximetry 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.
winspiroPRO has several powerful features:

Internal software update
winspiroPRO enables the real-time updating of the internal software of your spirometer, to increase the features and or the performance of the spirometer.
Post Bd and Bronchial provocation area
winspiroPRO enables the evaluation of the efficiency of a particular drug on the patient, a bronchodilator or a bronchorestrictor, and the results are linked to a specific dose and protocol.
Home Care area
The health of a patient can be monitored remotely, with test data gathered via a network and/or the Internet.
Spirometry Area
The data stored by a compatible instrument, and can be downloaded to a PC using the options in the dedicated area can develop specific tests to assess the state of health of the patient at rest and under stress.

Oximetry Area
As with the Spirometry Area you can store the data related to tests performed on the patient with the devices in "stand alone" mode , or you can make test "on line" mode or perform in-depth studies on tests done on the patient, for example, during the hours of sleep

The types of oximetry tests available range from simple monitoring of oxygen saturation and heart rate, tests during sleep to assess desaturations or sleep apnea, and the specific walk test performed according to international standards, which allows the evaluation of specific parameters (such as calculating the area under the curve obtained from the decrease in the percentage of SpO2 during the walk phase from baseline: AUC / Distance) which gives a complete and detailed examination of the patient's condition. The latest updates also allow us to estimate the percentage of oxygen to be administered to the patient and to assess the VMU parameter that provides information relating to the movement performed during a test.

winspiroPRO 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.
winspiroPRO 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 winspiroPRO, check the PC system requirements for compatibility:

The following system requirements must be met when installing winspiroPRO:
Local installation (from CD) requirements:

- Operating System Windows 2000 or Windows XP, Windows Vista (32 bit/64 bit), windows Seven (32 bit/64 bit), windows 8 (32 bit/64 bit)
- Recommended Pentium IV PC class 1 GHz or greater
- RAM 512 MB of RAM (preferred 1024 MB)
- Display resolution set to XGA at 1024 × 768 or greater
- Free space on Hard Disk 500MB
- Administrative priviledges on the operating system
- USB Port
- Serial Port or USB-RS232 converter for devices with RS232 connection

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 New improved features

winspiroPRO 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.
winspiroPRO simplifies the following activities:

- View patient and visit information
- Make POST bronchial testing
- Obtain accurate data from the pediatric incentive program
- Download test data from the spirometer and link it to patient files.

1.4 Licence contract and registration

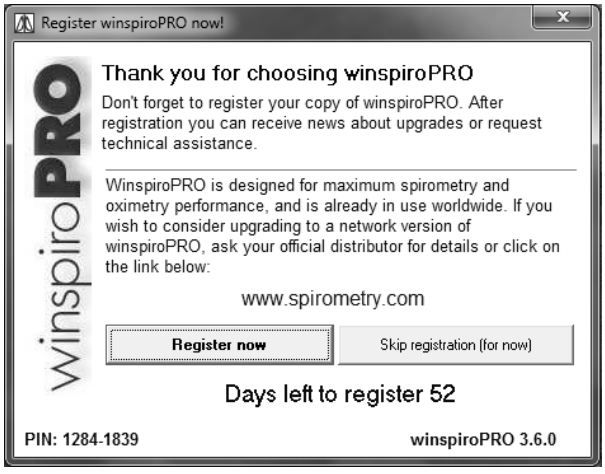
This software is protected by international copyright laws and by other laws and treaties governing intellectual propriety. Copyright and other intellectual propriety laws protect the rights of the software owners including the right to copy the software. Duplication of this software without the written 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 both winspiroPRO NET and for winspiroPRO. Proceed as described in the following chapter to make the registration.

WARNING ⚠

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

1.4.1 **winspiroPRO** Registration

Open the winspiroPRO software; At start-up of winspiroPRO 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.

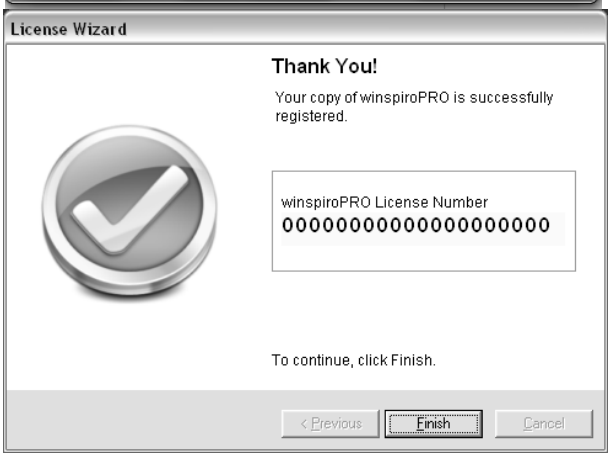
To register follow the procedure below:

Upon opening the software click on “Register winspiroPRO now” at the same time a window on the right will appear with the link to 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” 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 winspiroPRO software.



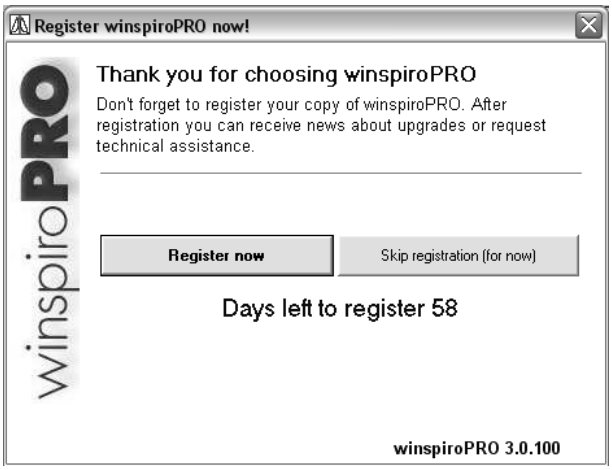
1.4.2 winspiroPRO NET registration

WARNING ⚠

Registration must be carried out from every software installed PC. Registration can be performed by the administrator or a user. The registration system takes into account the license in use and will issue and send the relative PAN codes to the originally furnished email address.

Open winspiroPRO software.
User identification to access the net version of the software is necessary. Just insert the User name and password in the following window.
The initial password is: “winspiro”
If the user has already modified the password make sure to use the new password.
Then click on OK.

Upon opening the software a window will warn the user how many days are left to register.



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:

Click on “Register now” inside the window displayed upon opening the software. A new window will appear which requires to enter the winspiroPRO license number written on the software CD. Once the license number has been installed click on “Next”.

The next window will display the “PIN” code.

To register access the internet site

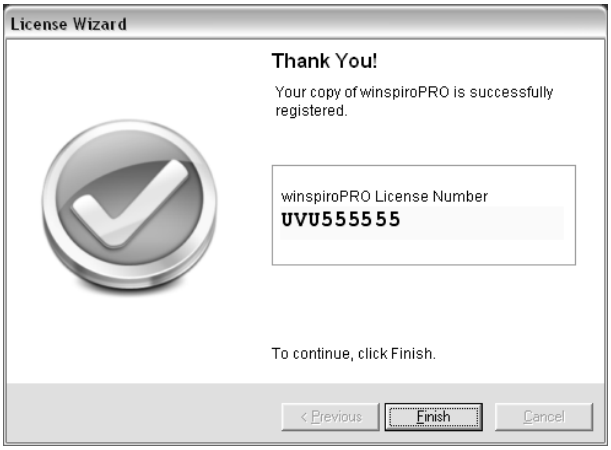
www.spirometry.com/reg

The user may access the website with the internet brouser in use or by using the link in the previous page.

If the user has already registered on “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 winspiroPRO software.

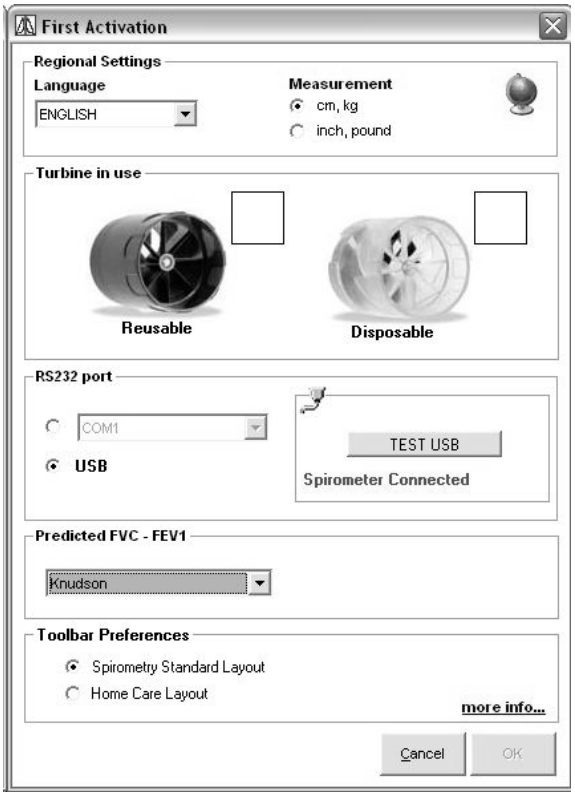


1.5 First activation of winspiroPro

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

- Operating language
- Units format
- Type of turbine in use
- PC port in use
- Predicted values
- Main toolbar set up

Having selected the PC port, use the test box to check that the device is correctly connected to the PC.
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.



Suggestions for new users

Here follows a list of the frequent tasks that a new user will carry out when using winspiroPRO. Click on a link for more details:

- Change password
- Modify set up

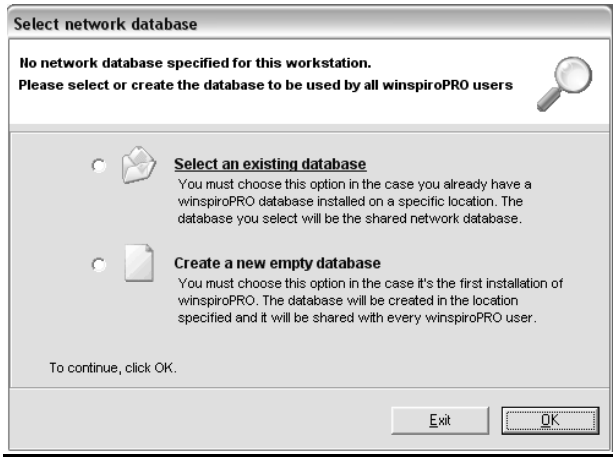
1.6 Rules for a correct installation of winspiroPRO NET

Several settings must be made to ensure a correct operation of the program.

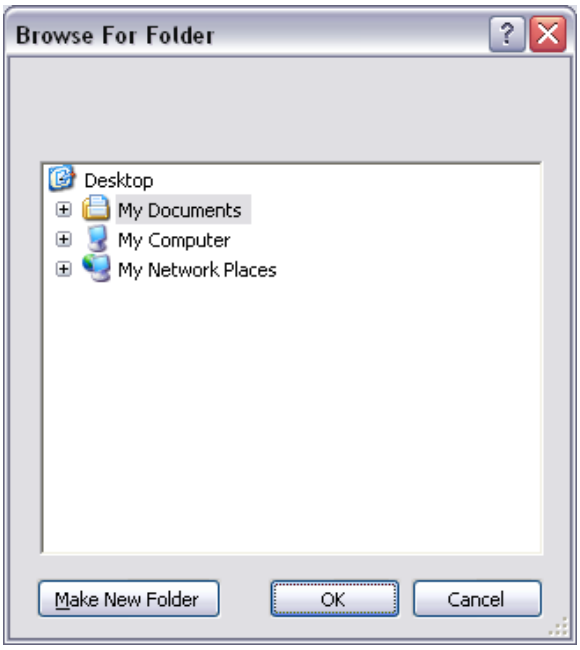
WARNING ⚠

The Windows user who will use winspiroPRO NET must have:
1) full control (the right to read/write/modify) in the directory of winspiroPRO (C:\MIR\WINSPIROPRO\)
2) full control (the right to read/write/modify) in the shared database folder.

Define the location of the database:
When the program is started for the first time the following window is shown, to enable the user to define the location of the working database. Select an existing database or create a new one.Click "Select an existing database" to make a link to an existing database or "Create a new empty database" to make a new database.
Then click OK.



Choose the database location:
Depending on the selection made in the previous screen, the next screen then allows you to select the location for the working database, either an existing one or a new one. Select the location and click OK.



WARNING ⚠

The authorisation for the supervisor are as follows:

User Name: **WINSPIRO**
Password: **WINSPIRO**

A description of how to use the authorisation follows.

Access to the program with user name and password:
Insert User name and password in this window:

At the first access the default supervisor settings are:
User Name: WINSPIRO
Password: WINSPIRO

Then the icons enable database management functions:

Security	set up/modify users in winspiroPRO NET (see point 1.7)
Backup	make a backup of the database
Restore	restore database
Export	a step by step procedure to export the database in Excel format (see point 11)
Firmware	a step by step procedure to update the internal software of the devices (see point 16)
Database	select and/or modify the the working database (see point 1.6)
Help	to enter the on-line guide or the manual

When the required setup and or modifications have been made, exit the program and re enter with the supervisor or new user username and password as required.

1.7 Managing users and passwords

WARNING ⚠

This function is reserved for the user Supervisor. Only the Supervisor can see the Protection menu, from which he must choose Users and then password.

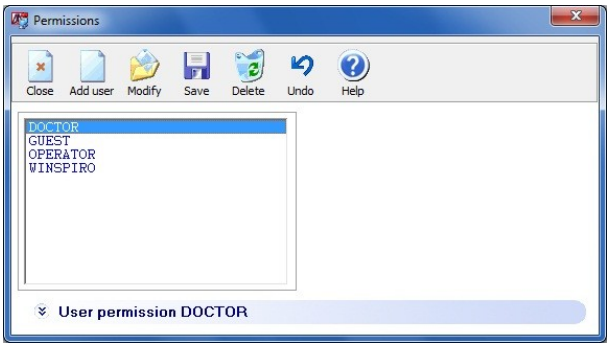
Creation of a new user:

To insert a new user click 

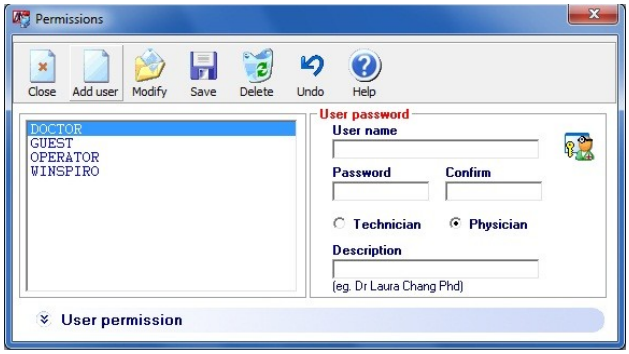
from the main window as shown below:

Then from the menu shown on the right click "Add" to see the fields for the new user:

- User name
- Password
- Confirm
- Technician Doctor
- Description



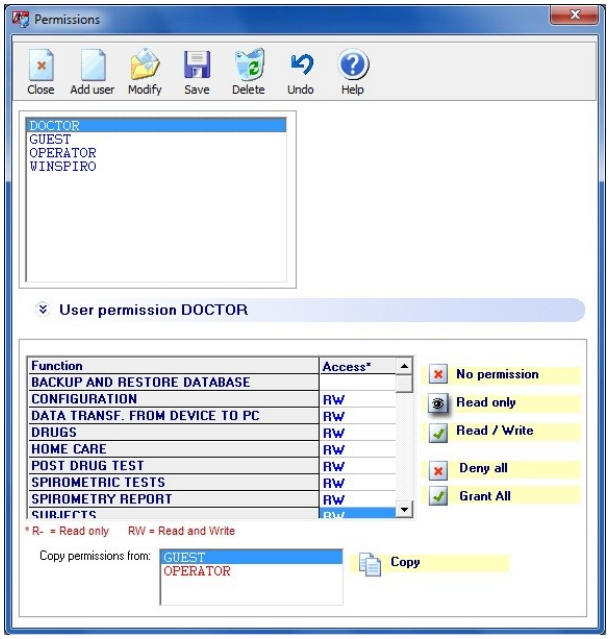
Having filled in all of the required fields click “Save”; then to create other users repeat the same sequence.
To modify the authorisation of any user select that user and then click “User authorisation” at the bottom of the window.
Click “Close” when finished.



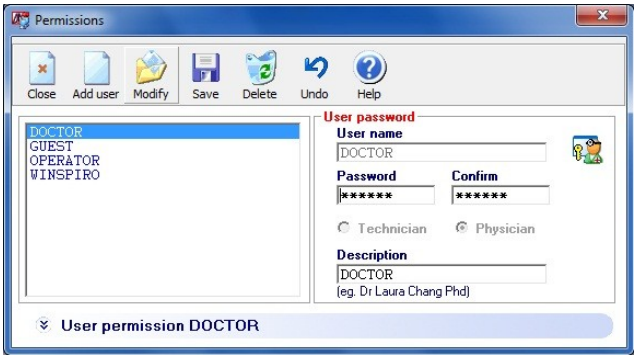
From the menu bar you can:

- ✓ Insert new users,
- ✓ Modify name and/or password of selected user
- ✓ Save modifications
- ✓ Eliminate a user profile
- ✓ Cancel the modifications
- ✓ Obtain explanation of a procedure

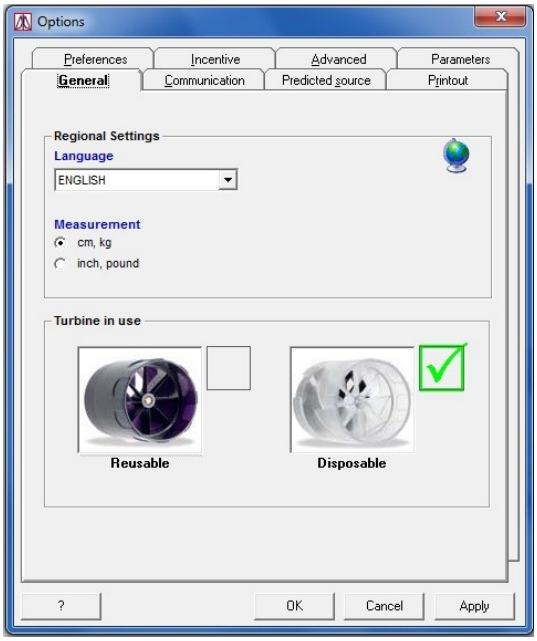
For each user (except the Supervisor) it is possible to set up the authorisations as required to access and to modify the data in the database, by clicking on User Authorisations. Then by using the icons on the right you can set up the level of access for each single operation and if required copy an existing configuration from another profile.



The option “Request password” is only available in winspiroPRO; winspiroPRO NET instead required the user profile to be defined for each new user.
This function enables either free access OR requires a password to start winspiroPRO; if the access is free then each user will have full access to the database as the Supervisor so if winspiroPRO is used by more than one user we suggest putting password protection at start up.



1.8 Options



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

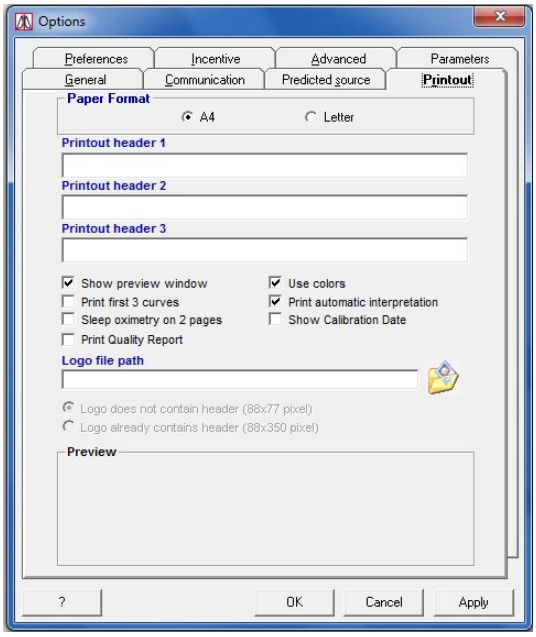
In the “General” folder the user may select:

- The language
- The units of measurement
- The type of turbine selection.

In the “Communication” folder the user may:

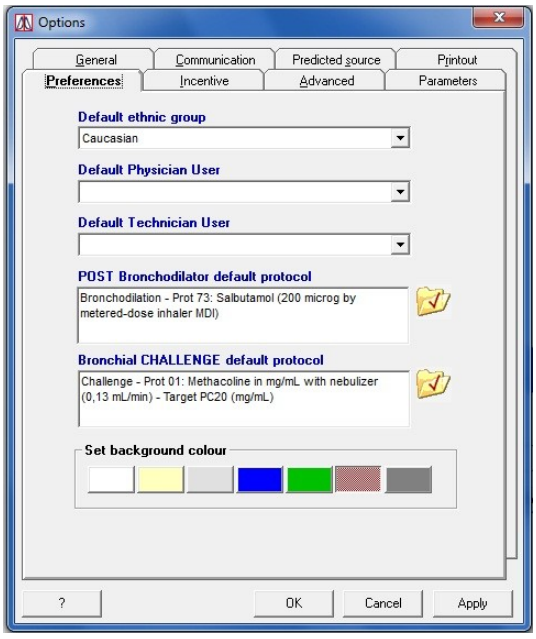
- Select the RS232 port
- Select the USB port and test the connection

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
- Color od black and white printing
- To print only the Best curve of the spirometry session or the three best curves
- To print the automatic interpretation or not
- To print the sleep oximetry on two pages on on one page only
- 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 Preferences folder of the user allows to specify:

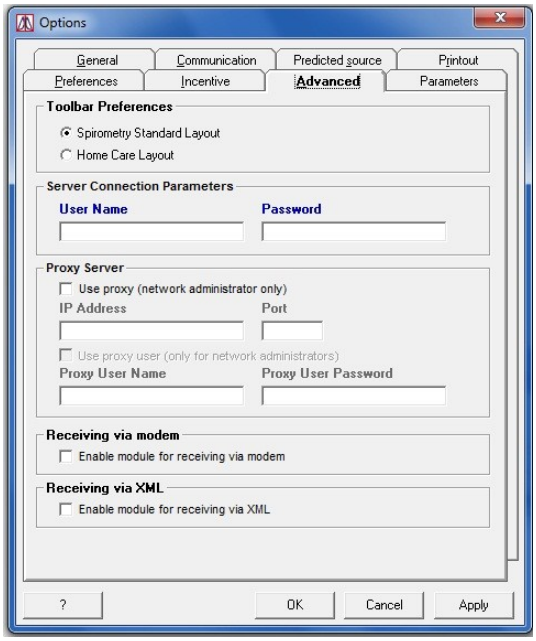


- The default ethnic group for new patients
- The default protocol for the POST broncodilator trials
- The default protocol for the bronchial provocation trials CHALLENGE
- Wether to display the toolbar icons in colour or greyscale
- The background colour of the main window

In the incentive tab you can choose whether to display the pediatric incentive during the FVC test. You can select the age limit until which the pediatric incentive is shown. You can pick the type of image or animation incentive to be used, or select a particular incentive uploaded from the internet.

From the “Advanced” tab set:

- Toolbar preferences (more icons are contained in the Spirometry Standard Layout, less are available in the Home Care Layout).
- Telemedicine server connection parameters
- Server proxy parameters (for LAN Administrator)
- Enable module for receiving data via modem directly from the patient.
- Enable data reception via XML

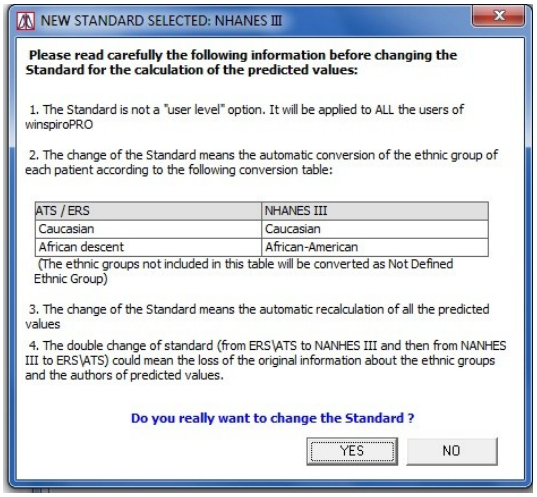


1.9 Predicted values

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 ⚠

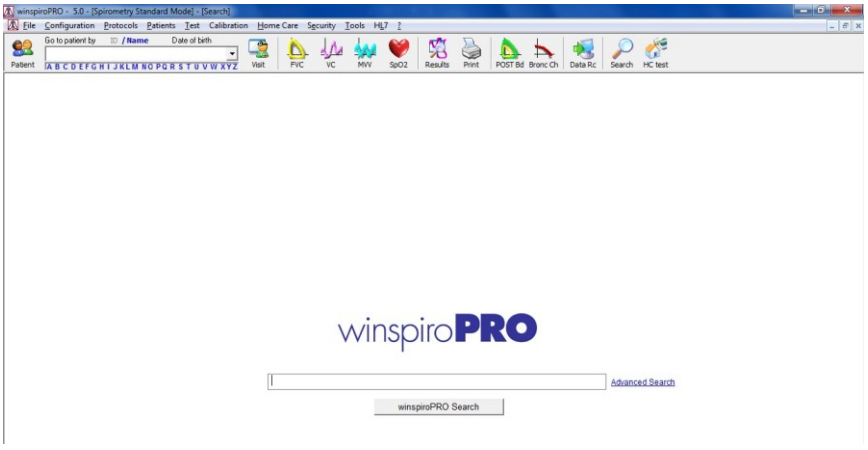
By selecting the NHANES III standard all the data stored within the database will be modified.



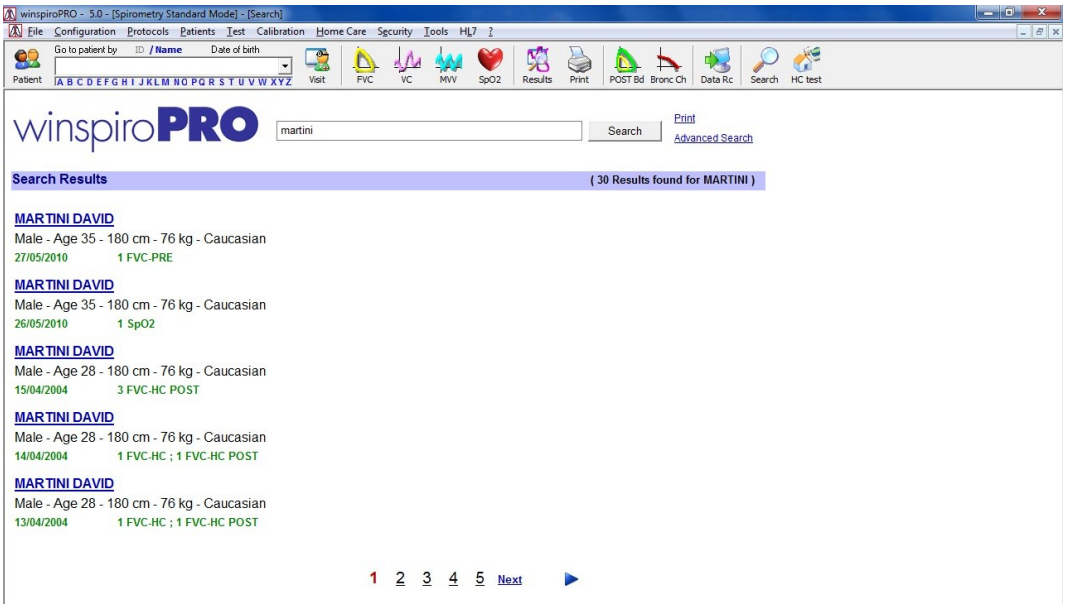
By selecting the ATS/ERS standard the user may choose one Author of the predicted values or a pair of Authors; one for Adults and the other for children. Lastly the user may opt for either the shaded area or the dotted lines to represent the theoretical flow/volume curve.

1.10 Search information in the database

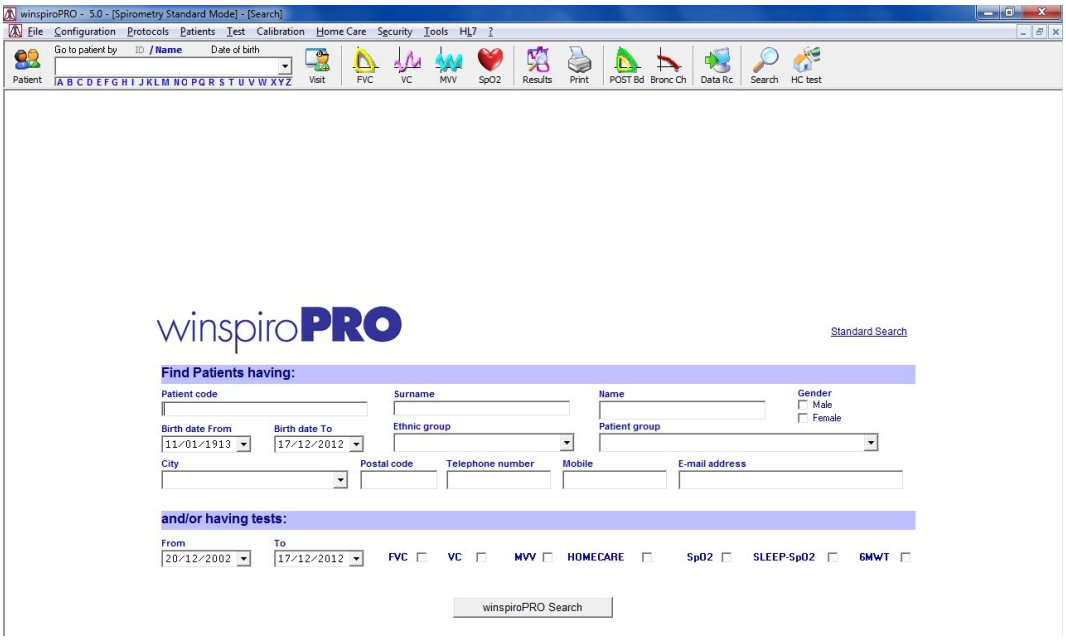
Opening winspiroPRO the following windows appears:



It is possible to insert a key word (example: FVC, 6MWT, MVV, HOMECARE, or POST and OXI) to research information about previous tests or patients; just clic on “winspiroPRO Search”. If the software finds information the search results are shown as follows:

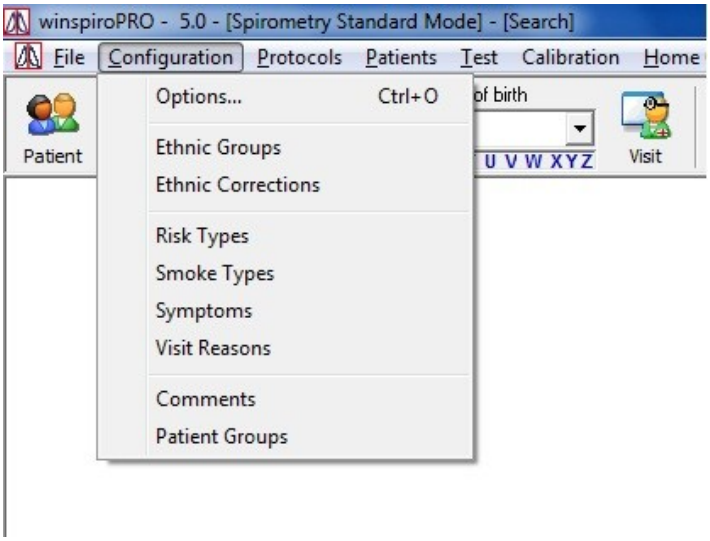


Check the data in the same manner as you would with a simple internet browser.
Alternatively to the Standard research an Advanced research is available. The advanced research allows to set up filters for the entire patient archive. For example it is possible to select all patients belonging to a certain group such as a group of VC tested patients within a specific time span. The display of the results is the same for both modalities of research.



2 CONFIGURATION (BASIC CONFIGURATION)

winspiroPRO can manage the database items contained in the Configuration menu. To access, click on the Configuration menu bar; this opens the drop down menu:



The elements in this database are then easy to select from other windows contained in winspiroPRO. The correct setting of patient characteristics enables the doctor promptly to analyse the received spirometry data and to make an accurate diagnosis. More specifically, defining both the related ethnical groups and corrections is of fundamental importance, since it allows the linking of the data to the physical characteristics of the patient.

Each item has a bar with the icons for carrying out data operation, in detail the icons correspond to the following operations:


Close


New


Delete


Help


Edit


Save


Undo

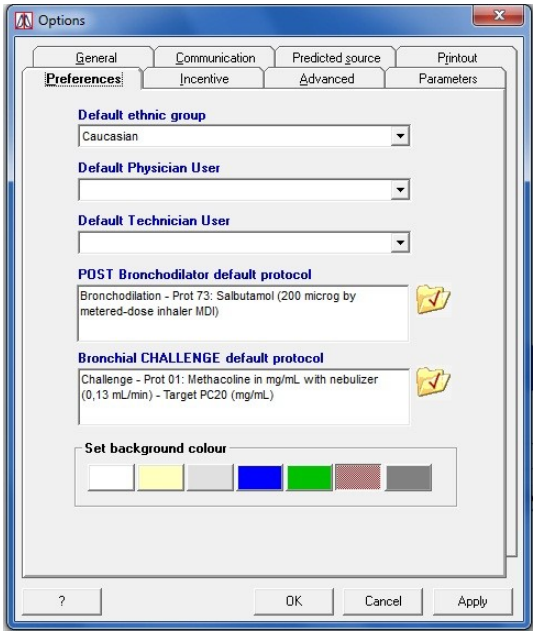
If you try to open a data element entered by another user in another language, a label will appear indicating the original language used for that expression:

Any translated expressions will be saved in the new language.
The elements contained in the database are considered critical and any changes made to these elements will be noted in the registry of critical operations, together with the user and the date and time of the change. It is not possible to cancel an element which is already used in another winspiroPRO function; for example, you cannot cancel “Cough” if it is already in use on a visit card of a patient.

3 PROTOCOLS OF BRONCHIAL PROVOCATION

Bronchostimulation tests can be made with winspiroPRO using predefined (default) protocols. Click on the “Protocols” menu on the menu bar.

The following items are contained:

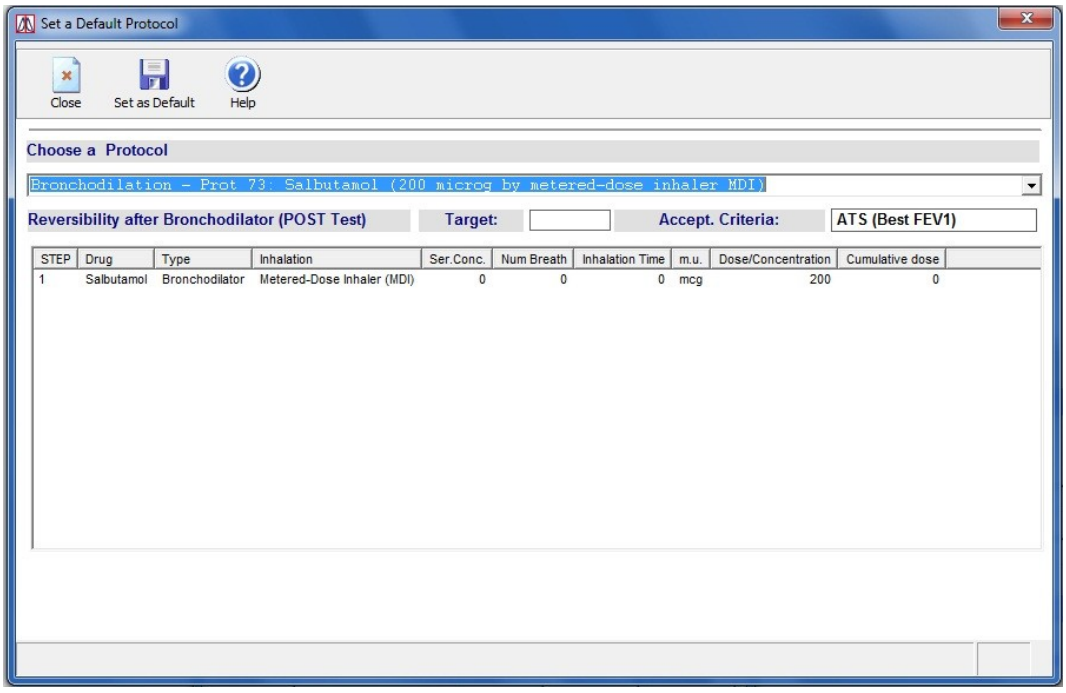


POST BD and Bronc Ch protocols

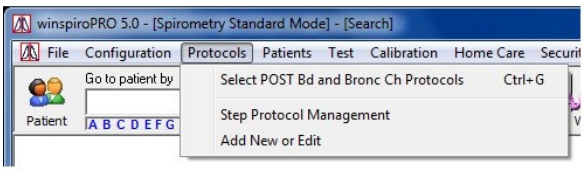
Set protocols by selecting them from the protocol list. To set a protocol use  corresponding to the POST Bronchodilator, or the icon corresponding to the Bronchial Challenge.

The same window is used from the "Configuration-Options" menu to select the display mode of the toolbar icons and set the background colour.

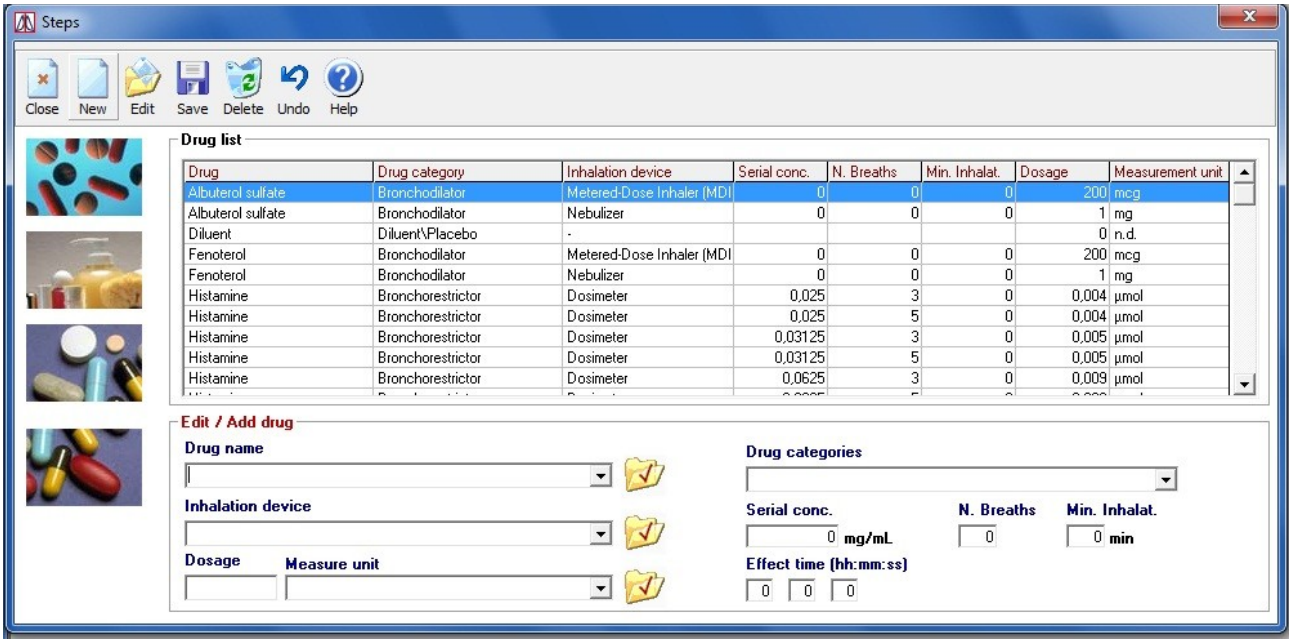
Use next window to choose one of the types of protocols available and to set it as default by clicking  . Check the characteristics of the selected protocol from the section on the bottom of the window.



The selected protocols will be used during the bronchostimulation test made by the user.



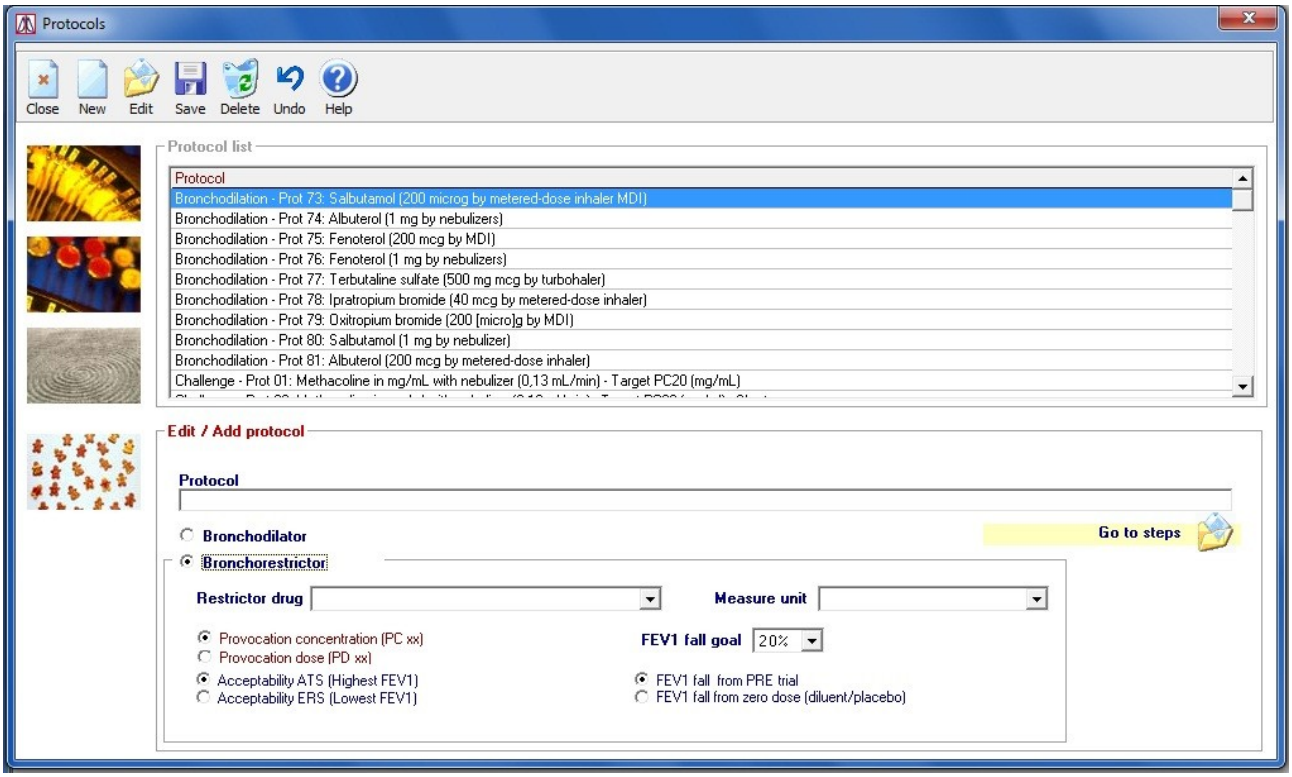
This contains the list of steps available. The steps list can be modified and new steps inserted from the toolbar. A step cannot be deleted from any protocol. The default steps in winspiroPRO cannot be modified whereas new steps can be inserted. The bottom part of the window is displayed only when new steps are to be inserted. Use  to create, modify or cancel a default drug parameter.



Insert new or modify

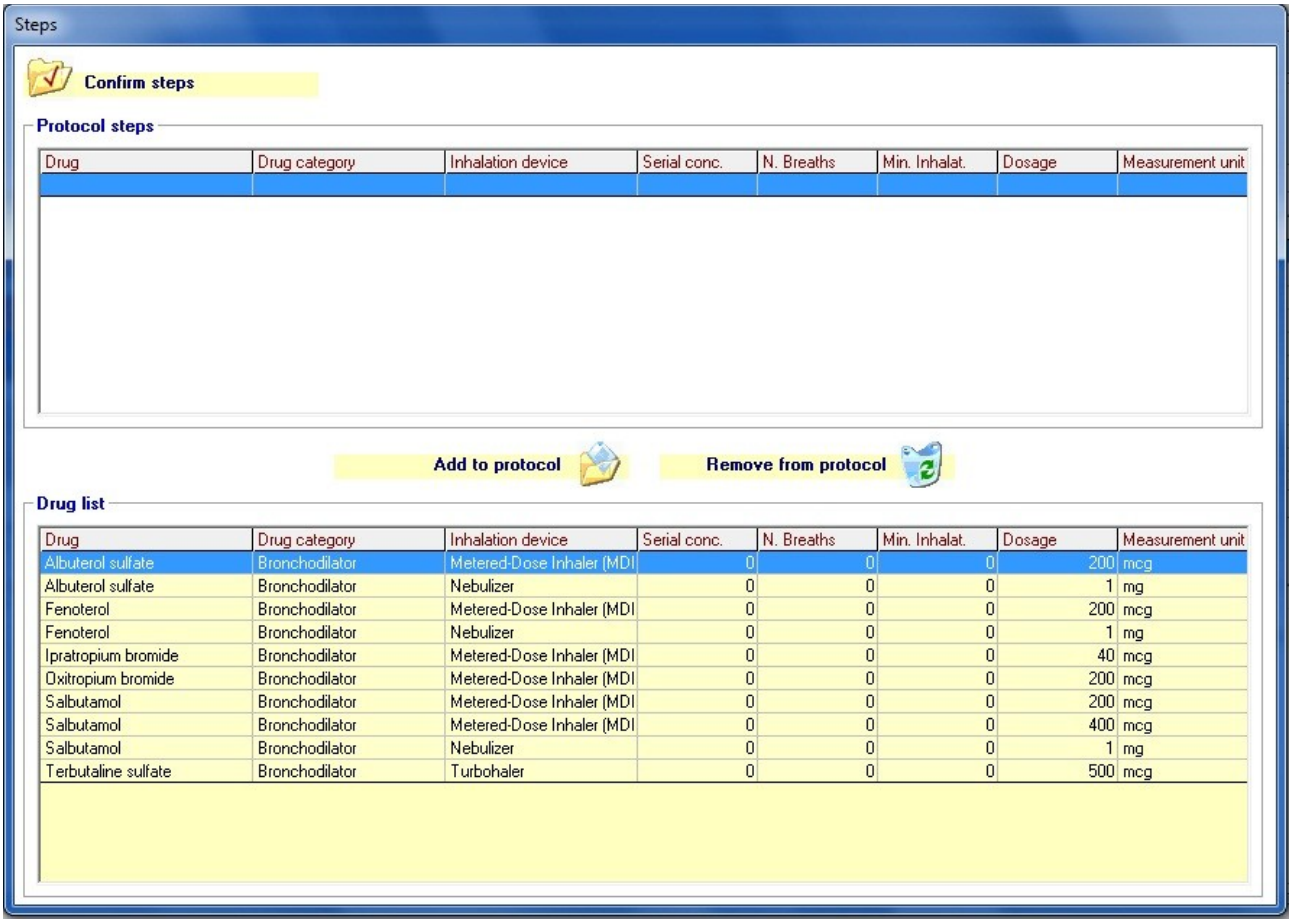
To add a new step or to modify an existing step. In addition, some information within the default protocols can be modified, e.g. the Objectives.

If a new Bronc Ch ( )protocol is added, specify the drug name before entering the steps; and before going on to the next step, set the phase where the protocol will be used (bronchodilator/bronchorestrictor); e.g. to define the protocol for the bronchorestrictor enter the parameters in the bottom part of the window.



In addition to the drug and the measurement unit, enter the administration method used to reach the set FEV1 fall goal: cumulative (Provocation Concentration, PC xx) or single (Provocation Dose, PD xx). Select final parameter used for acceptability: use highest (ATS) or lowest (ERS), FEV1 results obtained from the three tests made for each drug administration.

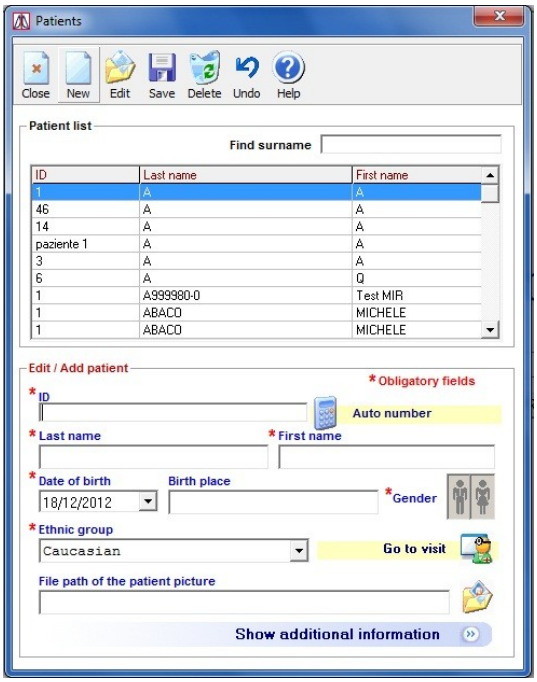
Click “Go to steps” to select the required steps for the correct protocol format (see list of steps available).

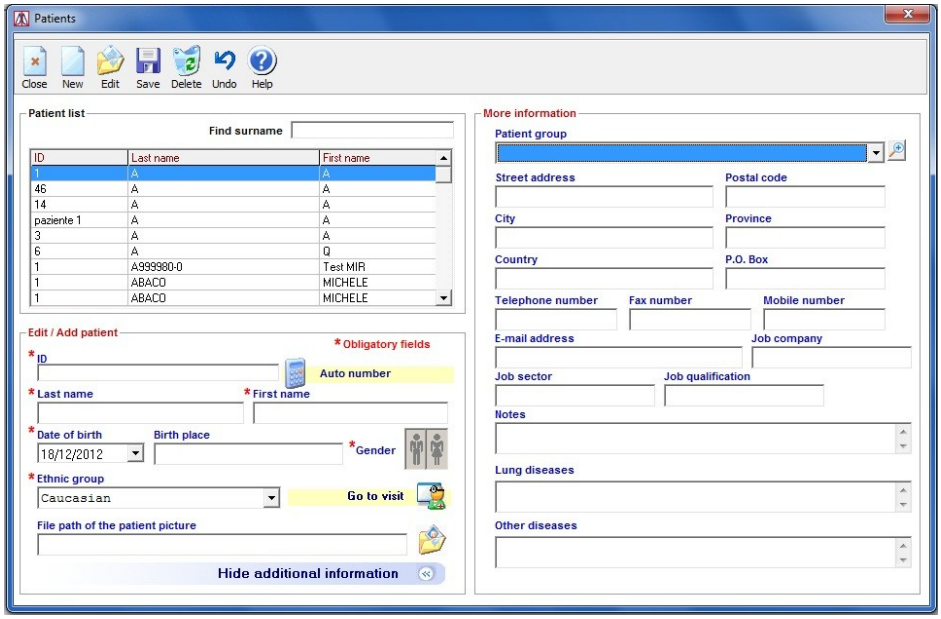


To create a personalized protocol, select drug from the bottom part of the window and use “Add to protocol” or “Remove from protocol”; after completing the selections, click on “Confirm steps” on the upper left of the window. The new protocol is now entered and available within the list.

4 PATIENTS

Click “Patients” from the toolbar, to create a new patient card select “Add patient” or “Edit”. From Patient list check patient data and edit information or enter new patient data using  .
This window displays the compulsory fields (marked with *), which must be filled in to correctly enter patient data and then to search patients. Use “Show additional information” at the bottom to access and enter further patient information.

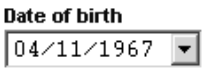


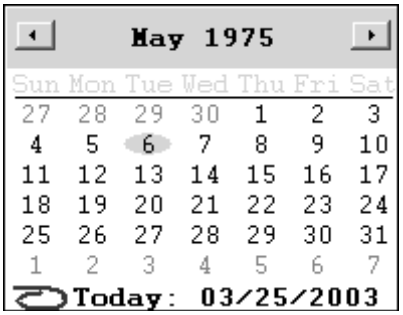


Use “Patient group” to identify a group of patients. For example, patients (workers) of the ABC company, or primary school children, or people residing near an industrial zone. The items in the “Patient group” combo box are the same as those found in the “Patient groups” database, which can be accessed from the Configuration menu.
The information contained in the Notes, Lung diseases and Other diseases fields is also displayed in the patient visit card and is useful for making the diagnosis.

Click  to access patient visits; click  to specify the path of a picture of the patient.

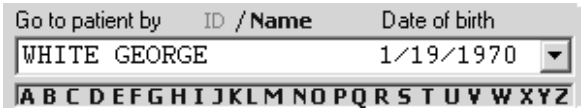
“Date of birth” can be inserted either by selecting it from the calendar or by entering the date, using the format set up in the operating system:





To modify patient data use 

from the toolbar of the main window.
Select patient from the field on the window



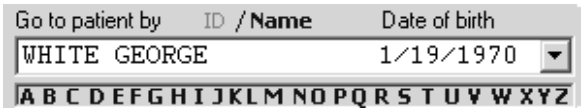
to open the corresponding visit card.

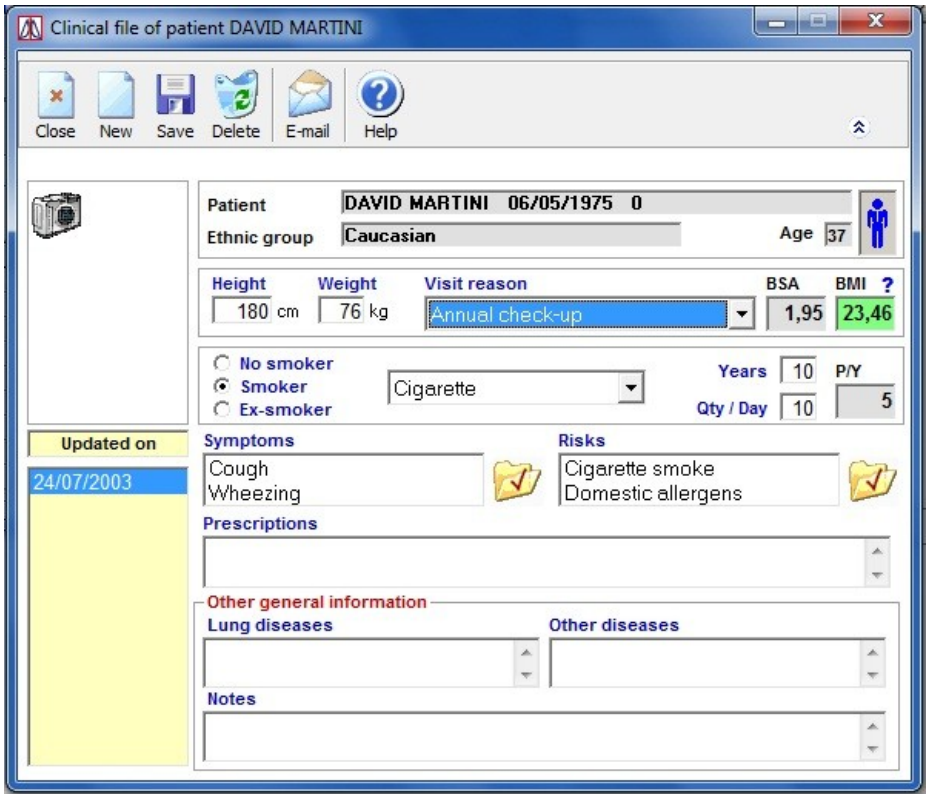
From the patient visit card, you can manage patient data and general information.
If a patient is deleted then all of the data linked to this patient is also deleted from the database, including any visits and tests.

5 VISITS

Select patient from the combo window. Click 

from the toolbar of the main window to access the clinical file of that patient:





The same window will appear when clicking on the item “Patient” on the toolbar menu and selecting “Visit”; an error message will appear if no patient is selected.
From the patient clinical file, all patient details can be managed as required including the anthropometric details, risk information, symptoms, smoking history, test comments and prescriptions. On the left side of the visit card there is a list of visit cards which are present in the database for the current patient. The most recent visit card for that patient is automatically selected, so the most up to date information is displayed; to view an earlier visit card use the scroll bar on the right of the list.

Some fields, for example Symptoms and Risks, can be selected from a default list using  ; other fields such as “Prescriptions” are free text.
General information such as Lung diseases, Other diseases and Notes come from the patient card and therefore will be the same regardless of which visit is selected.
A visit card must be created before a test is made on a patient. It is not strictly necessary (though advisable) to create a new visit card for every successive test session made by that patient. The successive test session will be added to the existing visit card providing the date of the new test session is the same or later than the original visit card.
The calculation of BMI, BSA and smoking Pack/Years is made automatically by the software and cannot be modified by the user.

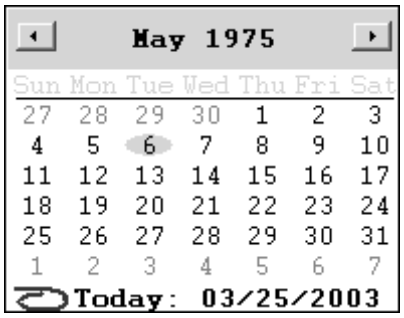
Use  on the upper right to reduce the information viewed to a summary. Click again to return to the standard view.

Use  , to add a new visit card, and then access the following window to enter data related to the new test session;

A new visit card can be created with a date between two existing visits, providing that the Height and Weight are not modified. When a spirometry test has been made on a patient the Height and Weight of that patient can no longer be modified.

If a visit is deleted then all of the data connected to this visit is also deleted. A visit card cannot be deleted if tests are present and connected to that visit card.

When a new visit card is created then date of visit, height and weight of the patient must be entered.
From "Visit card valid from …" select date from the calendar or enter the date directly using the format set up in the operating system.



The visit details from the previous visit card can be copied to the new visit either by selecting the option or by manually re-entering the data. Click  to insert the arm span to calculate the height.

NOTE:

If the date of the new visit is after the last date in memory, then the previous data can be copied.
If the patient is less than 18 years of age and the last visit card was created more than 30 days before, then the height is always requested in order to follow the growth of the patient and to maintain the data as accurate as possible.

Use "E-mail" 

to send data to a patient as an email attachment from the default client account set up on the PC.

NOTE:

This can be performed only if the "Patients" window contains the email address. To attach a file to an email all data must be defined, as described within this section

Having defined a visit session, use "Results" 

on the main toolbar to view the overall test results. A screen will be displayed containing the summary of all tests made by the patient during that visit. For more information refer to the "Results" section in the manual.

Use "Print" 

, on the main toolbar to print the best FVC test of the session.

From "Print preview" use  to export and save the document in the required format; if using Outlook Express, select MAPI as Destination to attach the file directly to the patient's email address.

6 CALIBRATION

WARNING ⚠

Before performing a calibration with winspiroPRO make sure the device is set to the turbine actually in use.
The calibration test can be performed with either the "reusable" or the " disposable" turbine.

The"disposable" turbine is used with a single patient for a single spirometry session, and offers an accuracy of measurement assured by the quality control carried out at the production stage. Each turbine is supplied already calibrated and ready to use out of the box.

the disposable turbine is singularly packaged and placed in a container that protects it from contamination, shock, etc.. Prolonged use of the disposable turbine is not recommended by the manufacturer, however, calibration can be carried out prior to its use even if it would have no practical utility as a diagnostic tool, since it would not maintain its own characteristics of accuracy over a prolonged period of use.

The user can verify turbine accuracy by performing a calibration check with a calibration syringe, bearing in mind that the results will be expressed under the conditions BTPS (Body Temperature Pressure Saturated).

When performing a calibration test the syringe replaces the patient. As such it is important to understand how the BTPS value is calculated automaticallv by winspiroPRO software.

EXHALATION: exhaled gas from the mouth is considered to be at a temperature between 33-34 ° C. This temperature corresponds to an expiratory value of BTPS = 1.026.

INSPIRATION: the inspired gas depends on the value of the ambient temperature. For example, if the environment is at a temperature of 20 ° C the value of inspiratory BTPS = 1115.
This corresponds to a conversion, and as such to an increase of the inspired volume of more than 10%!

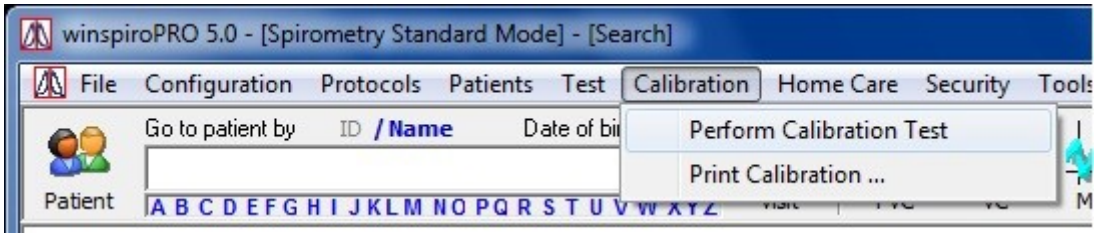
All this is not surprising and is perfectly normal. A volume of inspired gas at a temperature of 20 ° C will reach the lungs, heat up and expand due to the body temperature being higher by 17 ° C above environment (37 ° C - 20 ° C = 17 ° C).
With these simple considerations, by performing a test with a 3-liter syringe, if the turbine is operating correctly the value of FVC (in this case represented by the volume of the syringe) will be:

EXHALATION: FVC (BTPS) = 3.00 L x 1.026 = 3.08 L
INSPIRATION : FIVC (BTPS) = 3.00 L x 1.115 = 3.34 L

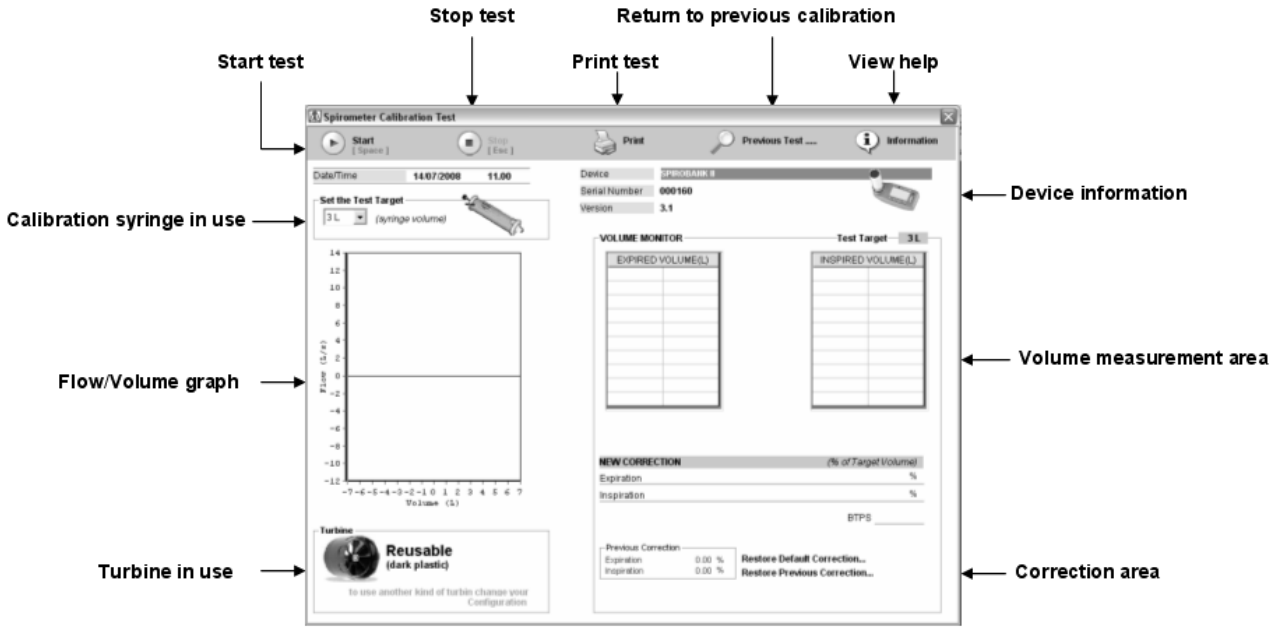
The turbine is accurate if the FVC values does not differ from what is expected by more than ± 3.5%.

In the example above we have:
EPIRATION: FVC (BTPS) expected = 3.08 Limit of acceptability at ± 3.5% 2.97 - 3.19 Liters
INSPIRATION: FIVC (BTPS) expected = 3.34 Limit of acceptability at ± 3.5% 3.22.- 3.46 Liters

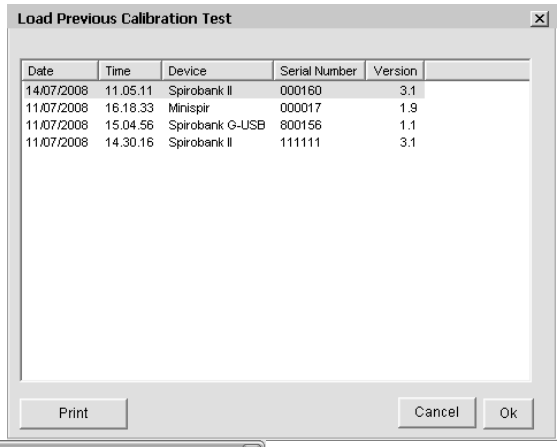
To enter the calibration routine select “Calibration” and then “Make Calibration Test”

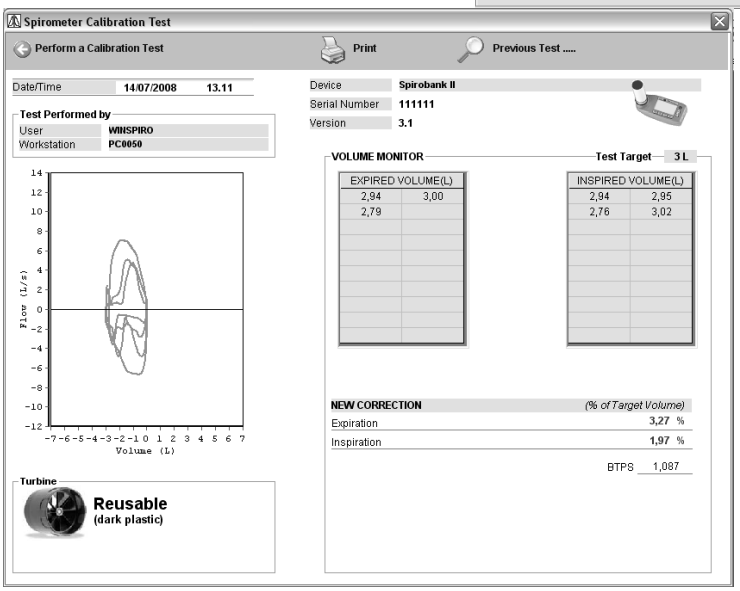


The calibration function is divided into three areas:



The calibration history can be viewed from the icon “Previous Tests” at the top of this screen. This then shows a list of the device or devices calibrated so they can be reprinted if required.
By selecting one of these tests, this window is shown with a summary of the calibration(s) carried out, and these can be reprinted OR proceed to make a new calibration by selecting directly “Make Calibration Test”. Alternatively select “Print Calibration” directly from the main manu to arrive at the same screen.





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.

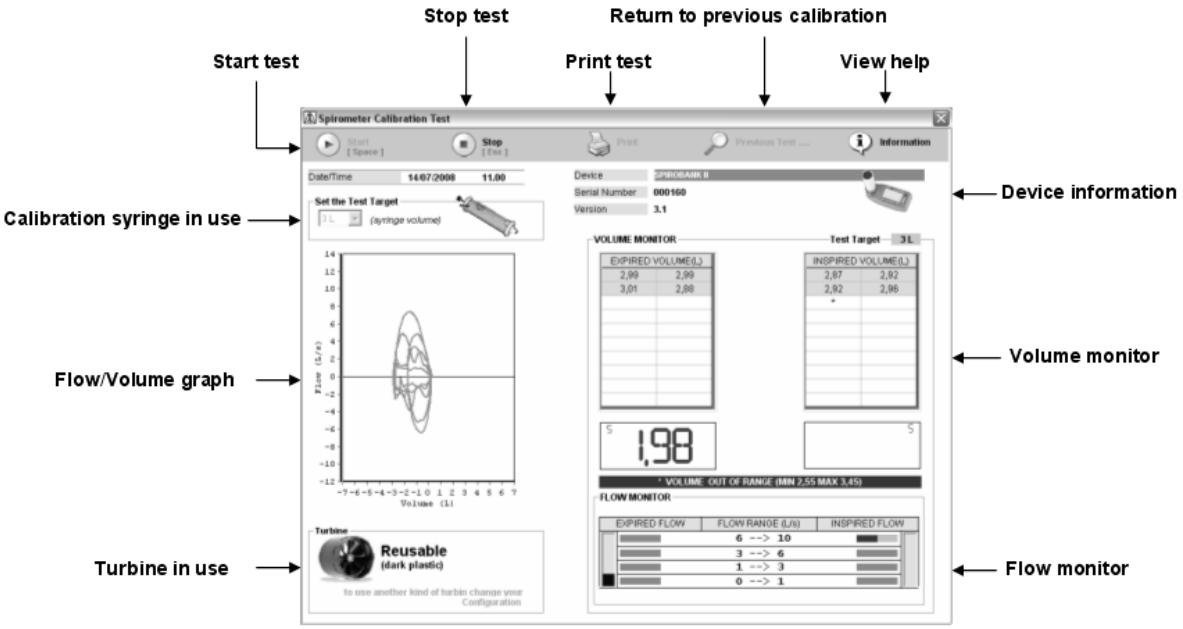
To start a calibration proceed as follows:

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.

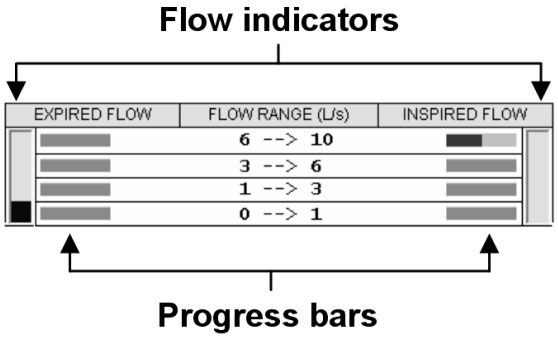
WARNING ⚠

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.

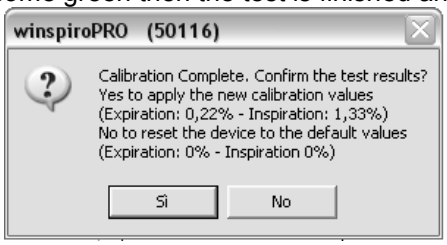
4 Select the type of syringe in use, using the maximum volume possible, in the window “Select test objective”
5 Click “Start” and the following window is shown:



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;



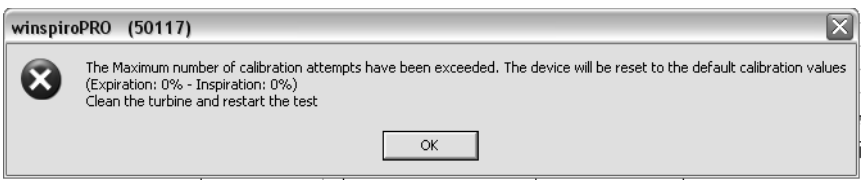
7 when all of the progress bars become green then the test is finished and this message is shown:



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 ±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:

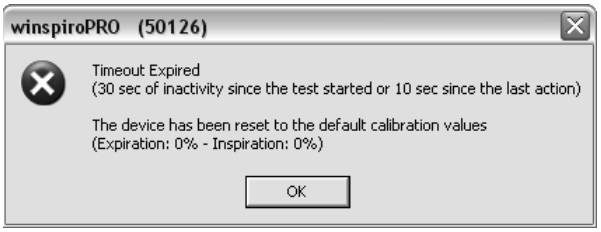
In the “Volume Monitor” table. The maximum number of inspiratory and expiratory syringe movements is set to 20 inspiratory and 20 expiratory. If within this total number of syringe movements the green flow bars do not all turn green then the calibration routine is stopped and this message is shown:



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

WARNING ⚠

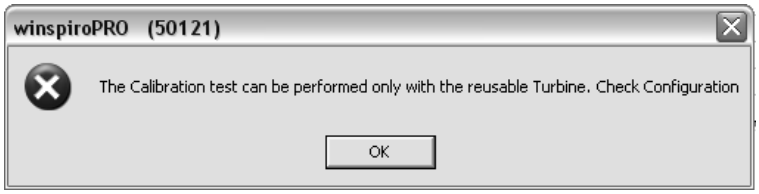
If the calibration test is not started within 15 seconds of clicking "Start", OR if the test is started but not finished, then 15 seconds after the last syringe movement the following message is shown:



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

WARNING ⚠

If the turbine selected is the disposable turbine then this message is shown:



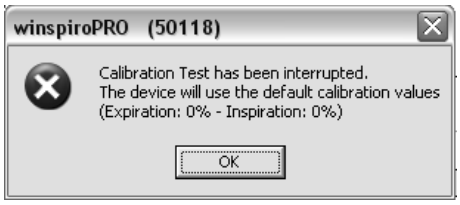
so check the configuration and then "Select turbine in use".

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:

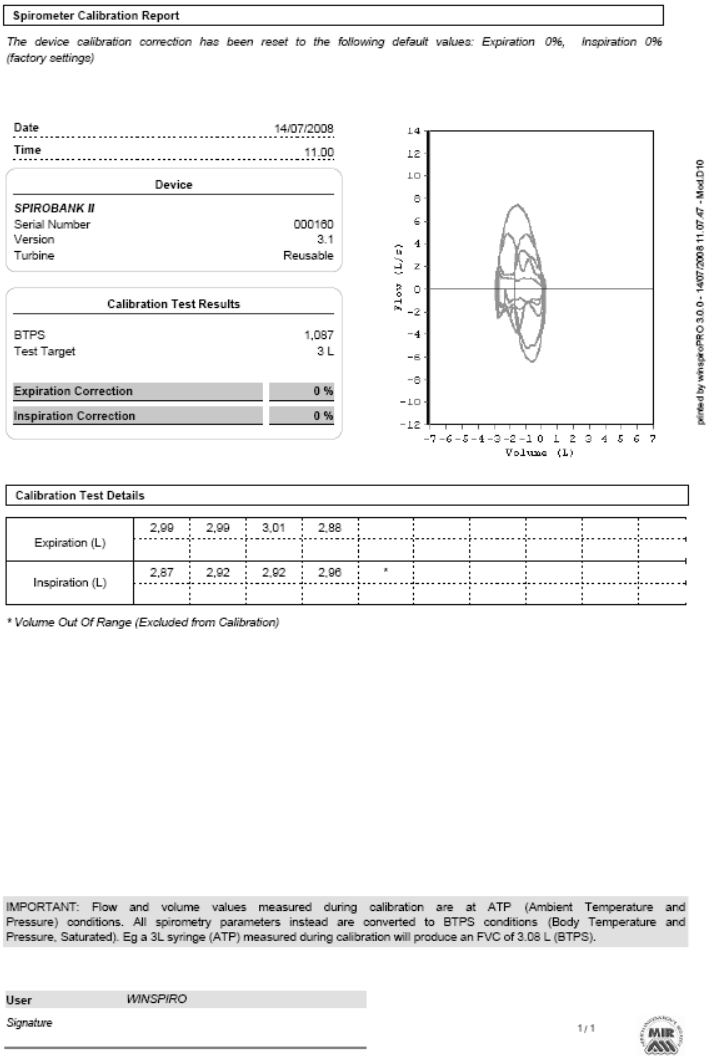


so the factory default values are automatically restored.

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

The device calibration correction has been reset to the following default values: Expiration 0%, Inspiration 0% (factory settings)

Date	14/07/2008
Time	11.00

Device

SPIROBANK II	
Serial Number	000160
Version	3.1
Turbine	Reusable

Calibration Test Results

BTPS	1,087
Test Target	3 L
Expiration Correction	0 %
Inspiration Correction	0 %

Calibration Test Details

Expiration (L)	2,99	2,99	3,01	2,88						
Inspiration (L)	2,87	2,92	2,92	2,96	*					

** 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).

User *WINSPIRO*

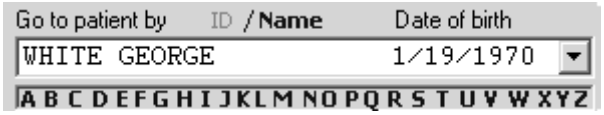
Signature

1/1

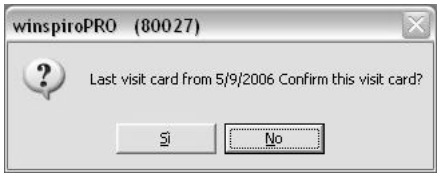
7 TEST

7.1 FVC - VC – MVV test

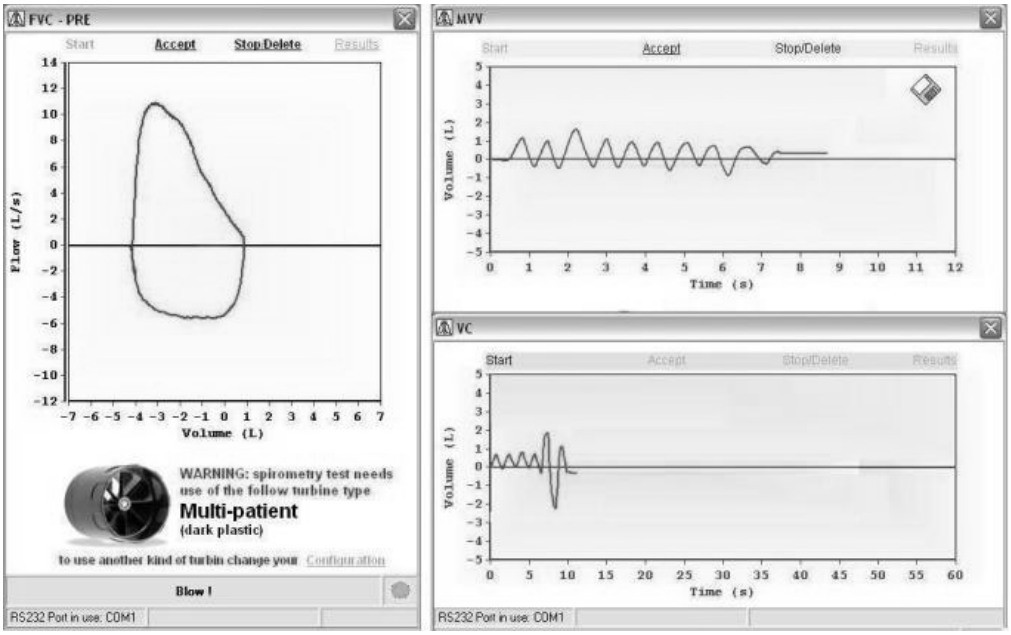
winspiroPRO is able to perform (PRE) FVC - VC – MVV – SpO2 tests. Before making a test, insert patient data (if not already in memory) and enter the visit card corresponding to the test. If the patient is already on file and a new updated visit card is not required, then it will be sufficient to select the subject from the list on the right.
Click on one of these icons on the main toolbar to launch a spirometry or an oximetry test.



Having selected the test to be performed, a message will appear to confirm the visit to the test results (if the previous visit was dated prior to the present test):



Click “Yes” to associate data from the previous visit. By selecting “No” the visits window will appear and a new visit for that patient can be entered. Depending on the test selected, one of the following windows will then open and the testing will be shown in real time:



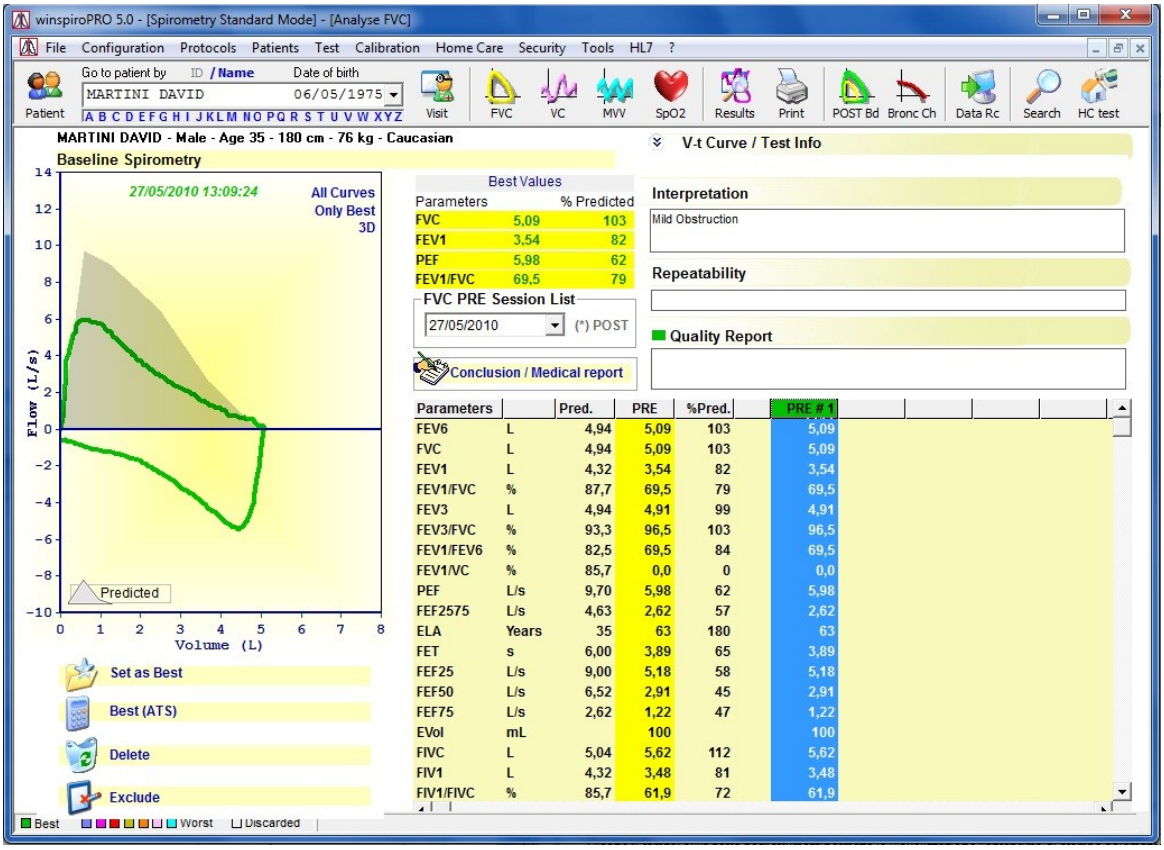
Each window will show a message indicating the type of turbine configured and used for calculating test results.
To change the type of turbine in use click on “Configuration”; from the “Options” window in the “General” folder and select the turbine.

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

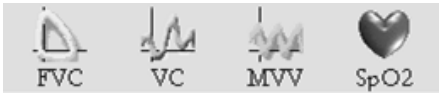
Commands	Function
Start	To start a test when the pediatric incentive is being used or when cancelling a previous test (otherwise data reception from the connected device will initiate as soon as the window is opened)
Accept	To memorise the related test data (a few seconds after the test is completed the data will be automatically memorised 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 memorised.
Results	To display the complete test results in the test information window, after they have been memorised.

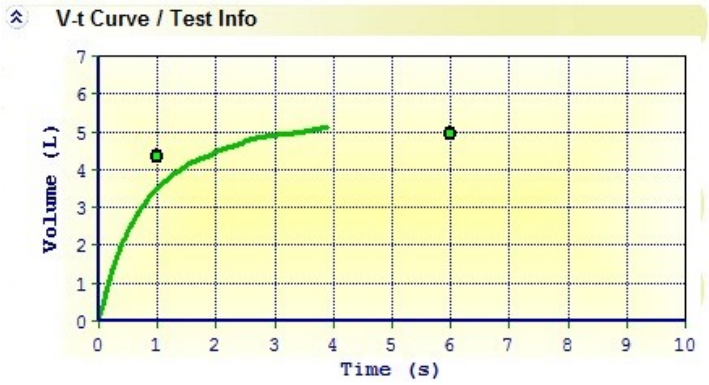
A test is not acceptable if the Expired Volume is less than 100 mL and it will be automatically deleted.
If the test is acceptable then it is automatically saved and then from the test information window you can:

- View parameters and curves
- Modify the BEST test by selecting it from the graph and clicking on “set as best” icon
- Delete tests previously saved, by clicking on having selected them from the graph
- Discard tests to exclude them from calculation (but without eliminating them) by clicking on and access other functions to view the test results.



For FVC tests, press to show or to hide the Volume/Time curve. The origin can be set on the top or bottom.
The bottom part of the window of the current test session will give the measured parameters, to be compared to the default predicted values.
To make further tests click again on one of the following icons:





If the test is set as BEST, from the toolbar click “Print” to show the print preview.

7.2 Oximetry test

Click 

to access the window for monitoring the oximetry test.

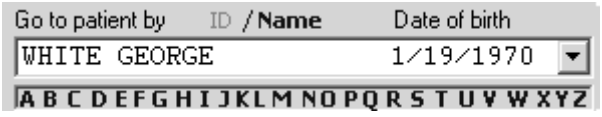
This window will show on the left the graphic trend of both the SpO2 parameters and the heart beat. On the right, the instant measured parameters of SpO2 and BPM are shown. At the bottom of the window the icons show that the device is receiving the signal and that the cable is correctly attached; the other 2 icons are used to set up the warning signals corresponding to the measured parameters and the use of the 'beep' during the test.
The upper part of the window contains the commands to: start test, accept results, stop current test and delete results.

8 RESULTS

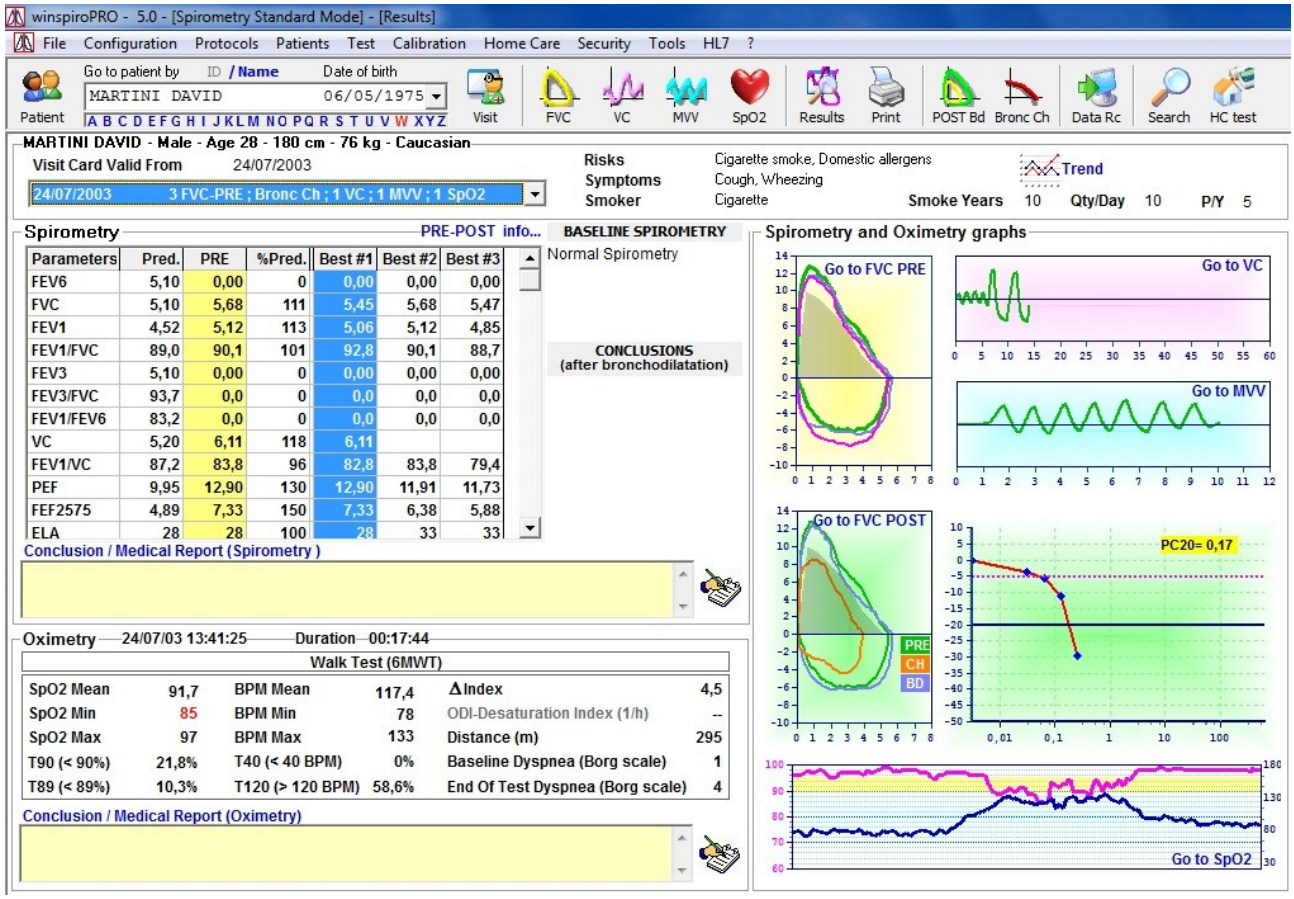
8.1 Spirometry

Having selected a patient from the combo box, click 

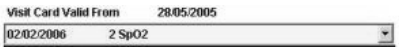
on the toolbar of the main window to view the spirometry results of that patient.



The test information window gives a complete overview of the patient, including the anagraphic and anthropometric details, the parameters, the medical report, prescription and at the same time a preview of the tests carried out.

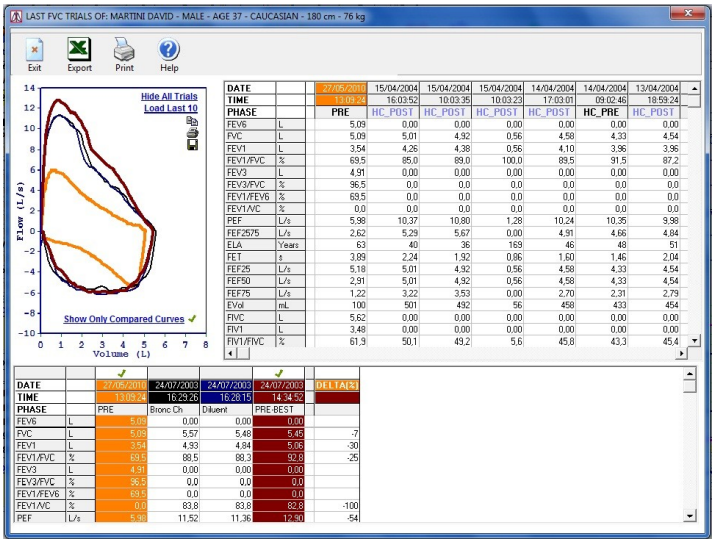


From the “List of sessions” the results of all of the test sessions made by the current patient can be viewed.



To see the details of any test, simply click on the link shown. For example, from "Go to FVC PRE" to see the detailed FVC tests shown in the preview window.

Double click on the graph to view the following window, a complete FVC trials history of the selected Patient.
The user can select two or more FVC test (from different sessions) and compare the measured values (delta for each parameter) on the bottom grid. Use Exit to return to the results screen.



The icons , and , shown in the previous image allow respectively to: copy in the notes, print the curves displayed and save the image (in several formats) or to enclose it directly to an e-mail message.

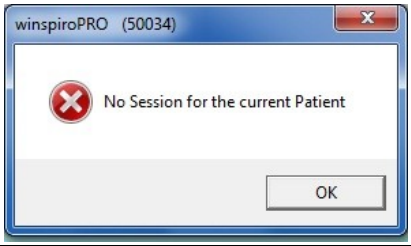
8.1.1 PRINTING DIAGNOSTIC TREND

On the Icon 

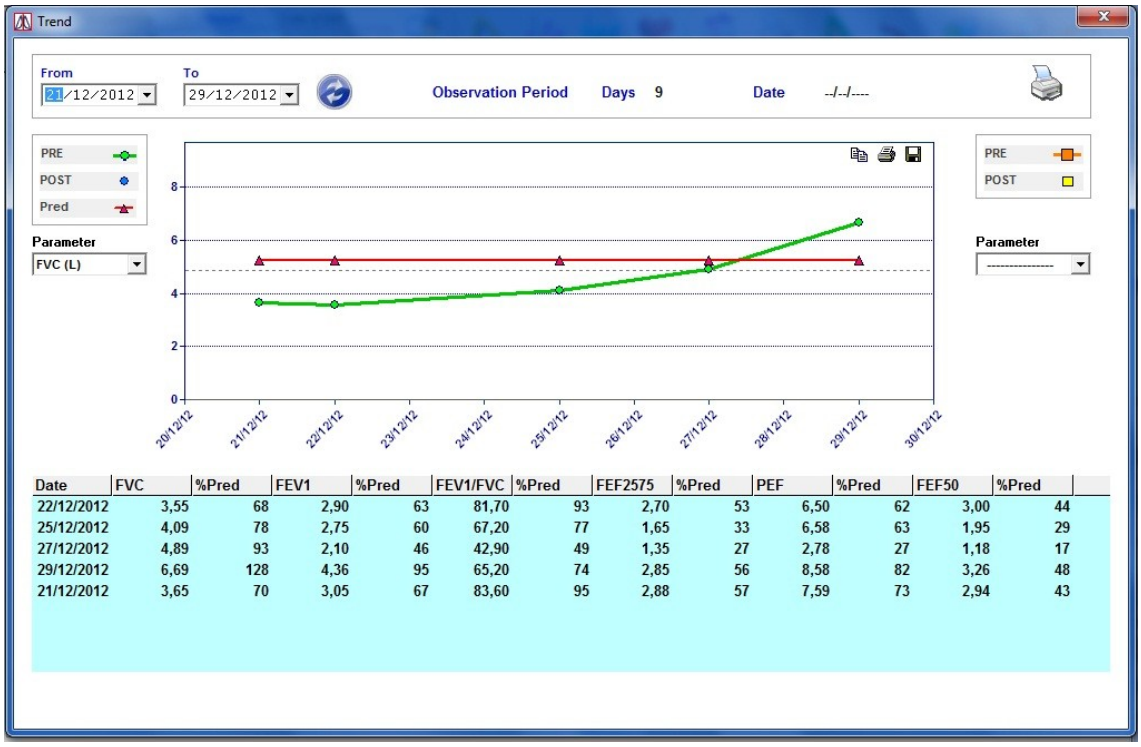
in the top right corner of image 60, you can access the screen display and printout of the diagnostic trends.

Warning

The trend is visible only if at least two sessions for each patient are saved, otherwise the following message will appear:

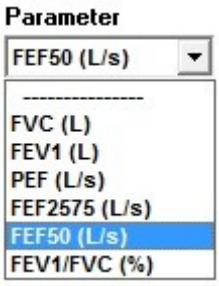


The diagnostic trend graph automatically displays parameter FEV1, the trend of the (BEST) PRE test (green line) and POST (if any) and the corresponding theoretical value (red line)

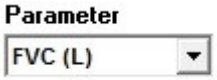


Date	FVC	%Pred	FEV1	%Pred	FEV1/FVC	%Pred	FEF2575	%Pred	PEF	%Pred	FEF50	%Pred
22/12/2012	3,55	68	2,90	63	81,70	93	2,70	53	6,50	62	3,00	44
25/12/2012	4,09	78	2,75	60	67,20	77	1,65	33	6,58	63	1,95	29
27/12/2012	4,89	93	2,10	46	42,90	49	1,35	27	2,78	27	1,18	17
29/12/2012	6,69	128	4,36	95	65,20	74	2,85	56	8,58	82	3,26	48
21/12/2012	3,65	70	3,05	67	83,60	95	2,88	57	7,59	73	2,94	43

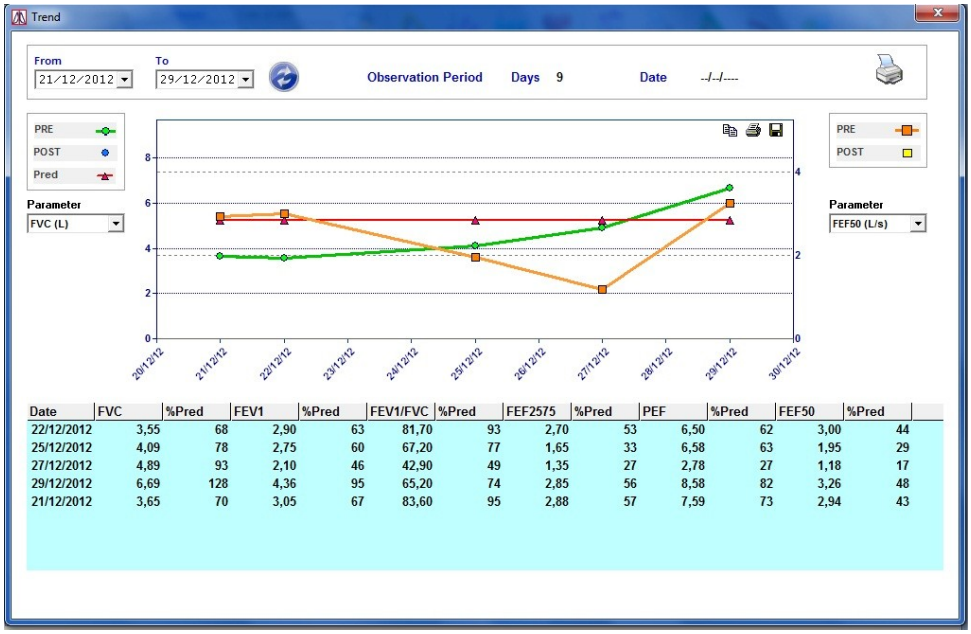
You may select the parameter by using the selection list to the left of the graph:



The scale of values in the left axis will vary as a function of the selected parameter
The graph allows the simultaneous display of the test trends compared to another additional parameter by means of the selection from the list to the right of the graph



The scale of the right axis values will vary as a function of the selected parameter in the right side.

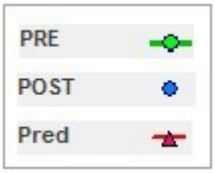


Date	FVC	%Pred	FEV1	%Pred	FEV1/FVC	%Pred	FEF2575	%Pred	PEF	%Pred	FEF50	%Pred
22/12/2012	3,55	68	2,90	63	81,70	93	2,70	53	6,50	62	3,00	44
25/12/2012	4,09	78	2,75	60	67,20	77	1,65	33	6,58	63	1,95	29
27/12/2012	4,89	93	2,10	46	42,90	49	1,35	27	2,78	27	1,18	17
29/12/2012	6,69	128	4,36	95	65,20	74	2,85	56	8,58	82	3,26	48
21/12/2012	3,65	70	3,05	67	83,60	95	2,88	57	7,59	73	2,94	43

In Summary:

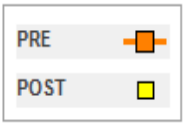
The green line shows the trend of the BEST PRE trials of the selected parameter on the left side of the graph.

The blue dot on the graph shows the values of the BEST post trials (if detected)
The red line shows the trend of the theoretical values for the selected parameter on the left side of the graph.

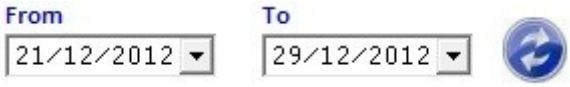


The orange line shows the trend of the BEST PRE trials related to the selected parameter on the right side of the graph.

The yellow square shows the BEST POST tests related to the parameter on the right side of the graph (if detected)



It is possible reduce or extend the period of observation by changing the start and end date fields at the top left of the window.



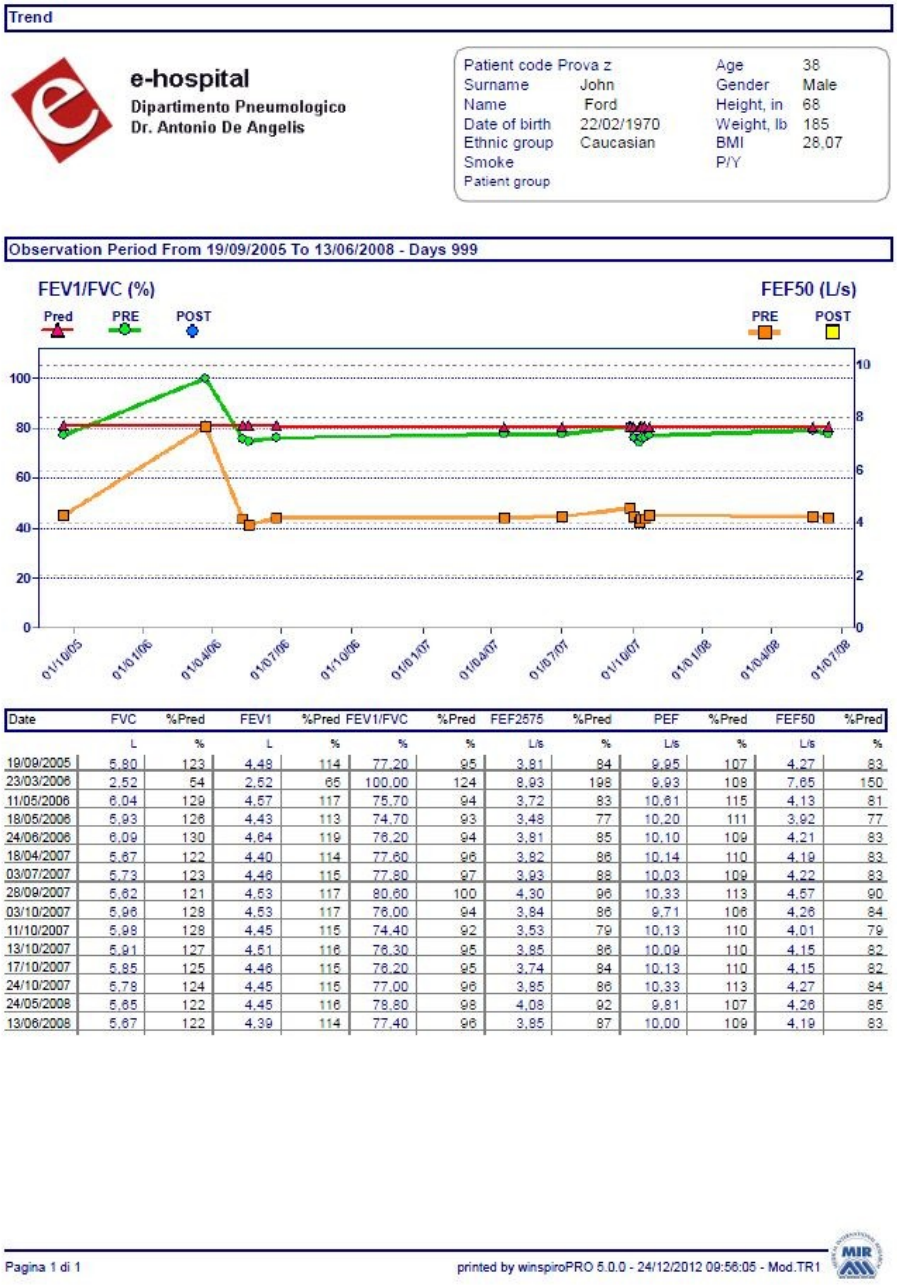
The table below the graph shows in chronological order the Best PRE test values and the deviation from the theoretical value of the following parameters: FVC, FEV1, FEV1%, FEF2575, PEF, FEF50.

Date	FVC	%Pred	FEV1	%Pred	FEV1/FVC	%Pred	FEF2575	%Pred	PEF	%Pred	FEF50	%Pred
22/12/2012	3,55	68	2,90	63	81,70	93	2,70	53	6,50	62	3,00	44
25/12/2012	4,09	78	2,75	60	67,20	77	1,65	33	6,58	63	1,95	29
27/12/2012	4,89	93	2,10	46	42,90	49	1,35	27	2,78	27	1,18	17
29/12/2012	6,69	128	4,36	95	65,20	74	2,85	56	8,58	82	3,26	48
21/12/2012	3,65	70	3,05	67	83,60	95	2,88	57	7,59	73	2,94	43

Upon closing the diagnostic trend screen the combination of the parameters selected among the general preferences of the user will be stored. Upon opening the diagnostic trend screen the last combination of parameters selected by the user in the previous display will be applied.

By clicking on the print symbol  on the top right hand side of the window, you can preview and print the report of the diagnostic Trend containing:
- the data of the selected patient;
- the current graph of the diagnostic trend;

- the summary table in chronological order of the values of Best PRE of the following parameters: FVC, FEV1, FEV1%, FEF2575, PEF, FEF50;



Trend

e-hospital
Dipartimento Pneumologico
Dr. Antonio De Angelis

Patient code	Prova z	Age	38
Surname	John	Gender	Male
Name	Ford	Height, in	68
Date of birth	22/02/1970	Weight, lb	185
Ethnic group	Caucasian	BMI	28,07
Smoke		P/Y	
Patient group			

Observation Period From 19/09/2005 To 13/06/2008 - Days 999

Date	FVC	%Pred	FEV1	%Pred	FEV1/FVC	%Pred	FEF2575	%Pred	PEF	%Pred	FEF50	%Pred
	L	%	L	%	%	%	L/s	%	L/s	%	L/s	%
19/09/2005	5,80	123	4,48	114	77,20	95	3,81	84	9,95	107	4,27	83
23/03/2006	2,52	54	2,52	65	100,00	124	8,93	198	9,93	108	7,65	150
11/05/2006	6,04	129	4,57	117	75,70	94	3,72	83	10,61	115	4,13	81
18/05/2006	5,93	126	4,43	113	74,70	93	3,48	77	10,20	111	3,92	77
24/06/2006	6,09	130	4,64	119	76,20	94	3,81	85	10,10	109	4,21	83
18/04/2007	5,67	122	4,40	114	77,60	96	3,82	86	10,14	110	4,19	83
03/07/2007	5,73	123	4,46	115	77,80	97	3,93	88	10,03	109	4,22	83
28/09/2007	5,62	121	4,53	117	80,60	100	4,30	96	10,33	113	4,57	90
03/10/2007	5,96	128	4,53	117	76,00	94	3,84	86	9,71	106	4,26	84
11/10/2007	5,98	128	4,45	115	74,40	92	3,53	79	10,13	110	4,01	79
13/10/2007	5,91	127	4,51	116	76,30	95	3,85	86	10,09	110	4,15	82
17/10/2007	5,85	125	4,46	115	76,20	95	3,74	84	10,13	110	4,15	82
24/10/2007	5,78	124	4,45	115	77,00	96	3,85	86	10,33	113	4,27	84
24/05/2008	5,65	122	4,45	116	78,80	98	4,08	92	9,81	107	4,26	85
13/06/2008	5,67	122	4,39	114	77,40	96	3,85	87	10,00	109	4,19	83

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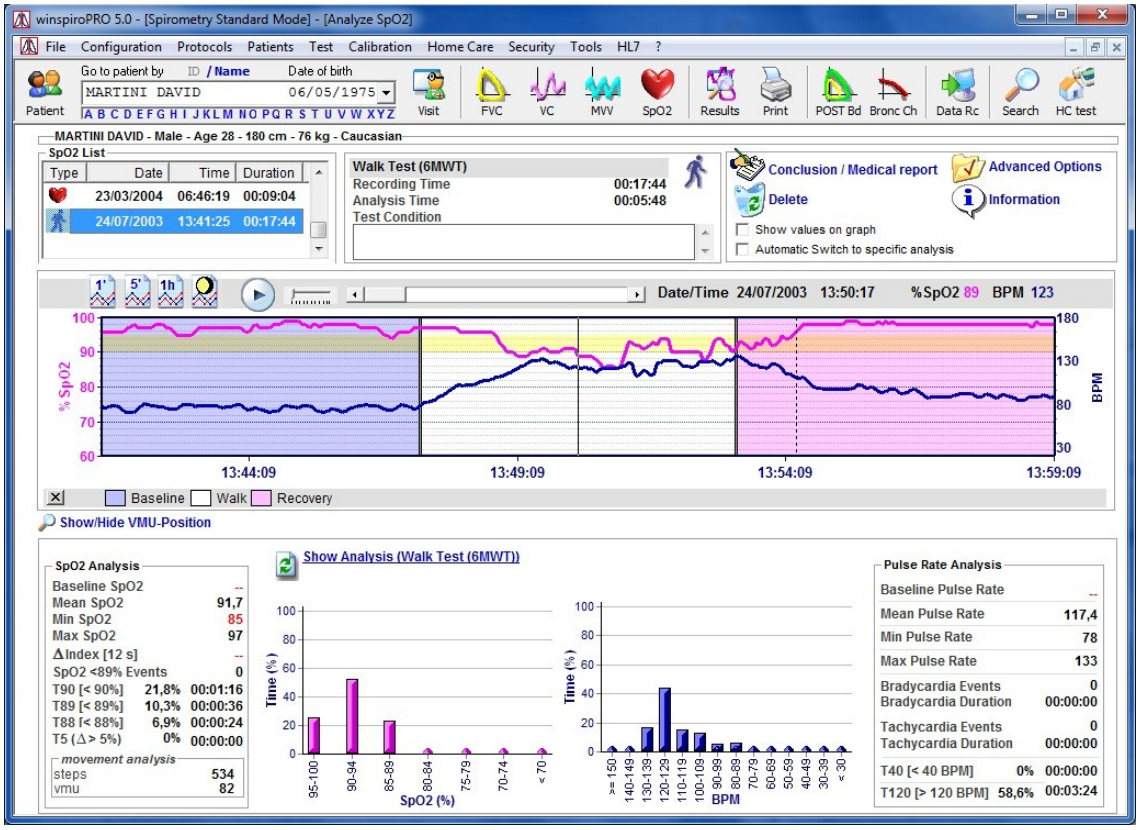
printed by winspiroPRO 5.0.0 - 24/12/2012 09:56:05 - Mod.TR1

8.2 Oximetry

While viewing the oximetry test data, click on Go to SpO2 as shown in the graph preview to access an overall view.



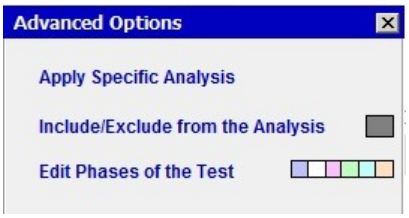
The upper left part of the window shows the list of oximetry tests made by the selected patient. On the left there is an icon corresponding to the type of test made (walk test, SpO2/BPM monitoring, sleep test) plus the date, time and duration of each test.

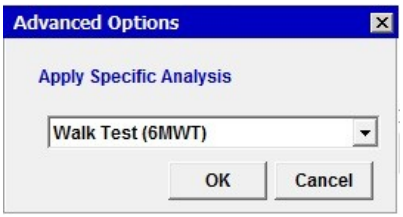
On the upper right part of the window the linked test comments (Oximetry Comment), can be entered. From the additional window enter any elements useful for a correct test interpretation. Use the Delete icon to delete the selected test; the box: “Show values on graph” will show the values contained on the graph on the bottom of the window. “Automatic switch to specific analysis” will show only the specific analysis (this is valid only when going from a specific analysis to another, for example sleep oximetry or walk test).

The Advanced Options icon accesses the window on the right to carry out various functions on the selected test data. In detail:

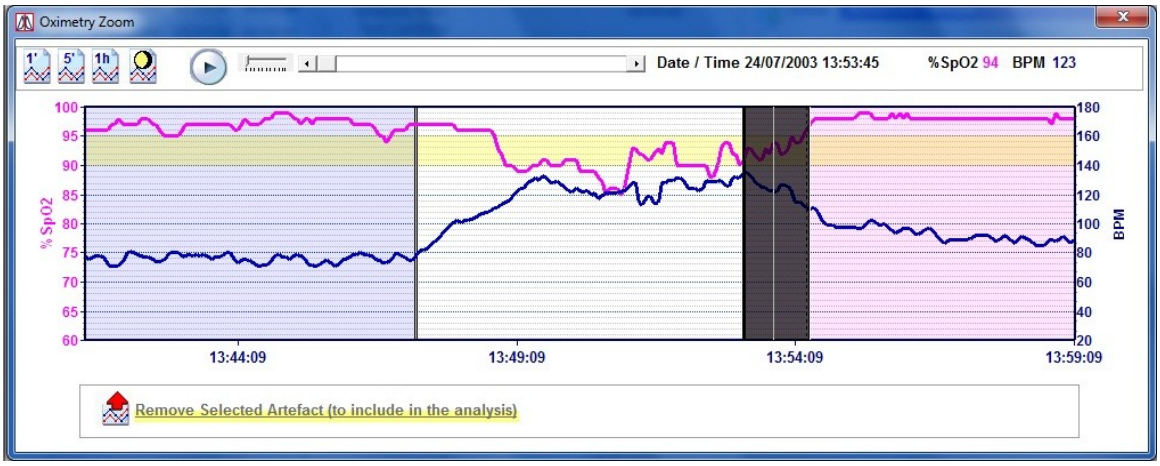
- **Apply specific analysis**: this function allows to edit or to apply a particular analysis to the selected test phases; this is useful in case an incorrect analysis has been applied to a test or when analysing the characteristics, type, time and duration of the test, it can be analysed in-depth through the typical parameters of a test.

NOTE: it is not feasible for example to apply a specific analysis on a walk test to sleep oximetry data and vice versa, while on the other hand, this option could be useful to modify a simple monitoring of a sleep oximetry test.

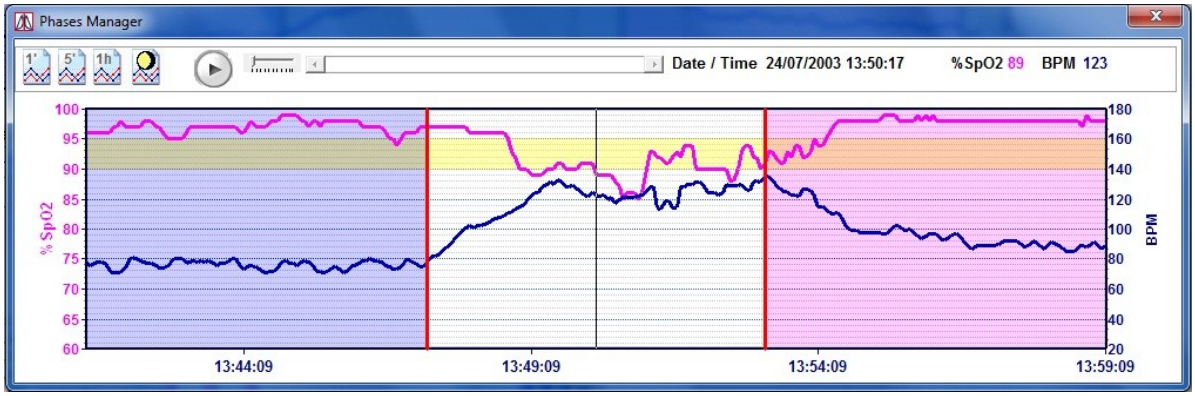




- **Include/Exclude from the analysis:** This function allows to exclude portions of test from the analysis and from the parameters calculation (i.e. in case of artefacts). To add an “Exclusion Area” just click and drag the mouse over the area to exclude.

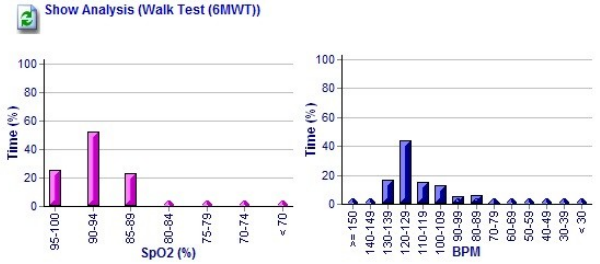


- **Editing test phases:** A test phase is a part of test performed under specific condition (the patient is sleeping/awake, is walking, under oxygen delivery systems....). Just click and drag the mouse to select an area of the test and choose the phase to mark the selected area from the popup menu.

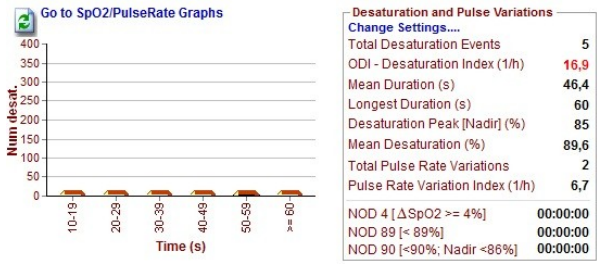


On the right part of the window the 

icon opens a glossary containing information on all parameters calculated by winspiroPro.
The options contained in the bottom part of the window can be modified according to previous settings; the graphs on the bottom centre show or display the graphs related to the test or to the applied specific analysis.

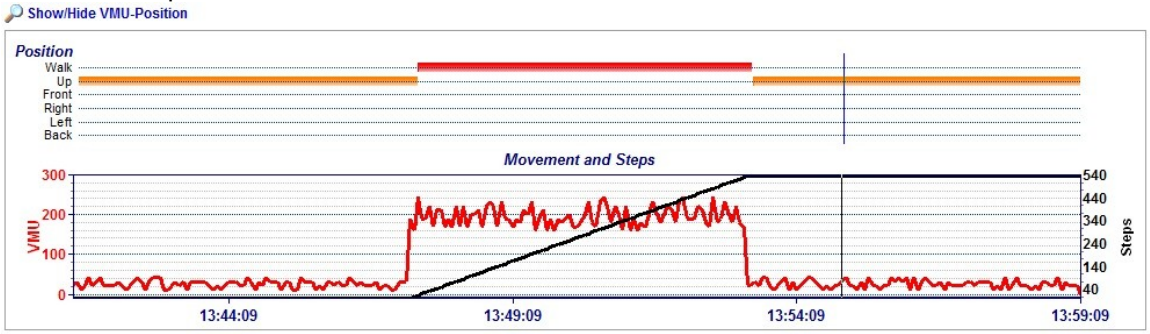


Graphs related to test



Applied analysis

Finally, by using the icon "Show / Hide VMU-Position" you can view the graphs of these trends for the exercise test or sleep test.



The graphs display:

- Patient position
- VMU
- Steps

The three parameters are placed in relation with the performance of the test so as to be able to compare the overall status of the patient from moment to moment, also with the trend of the SpO2 and BPM in the graphs shown in the upper part of the window.

The steps taken are as follows:

the following positions are recognized by the device:

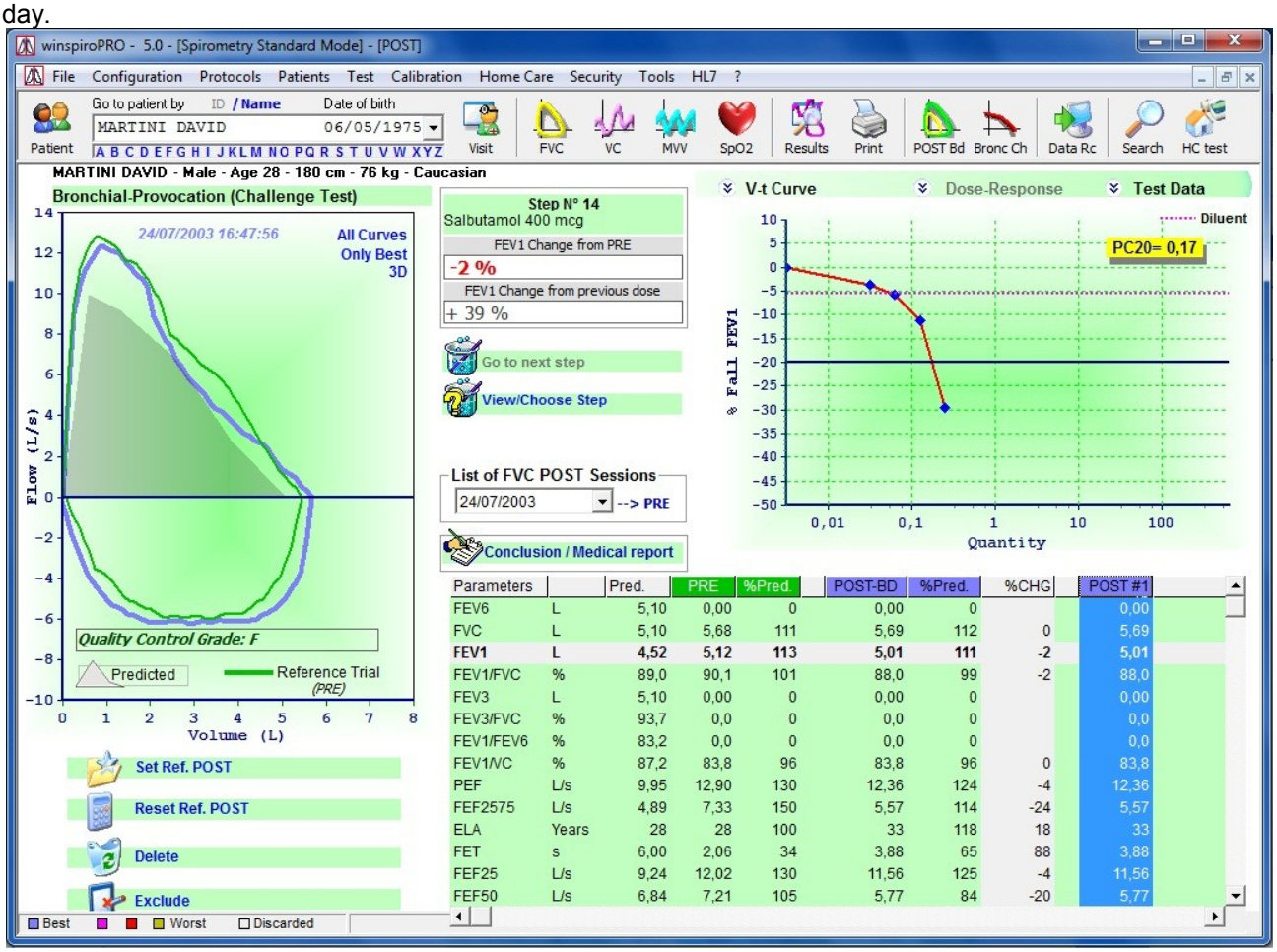
- Walking
- Standing-up
- Prone
- Lying on the right
- Lying on the left
- Supine

The VMU is a dimensionless parameter, while the steps are counted during the entire test.

9 BRONCHODILATOR (POST) TEST

Click 

on the main toolbar to open the POST testing phase for the selected patient. The green curve will then show the best PRE test from the current session.
At least one PRE test must be present in order to make POST drug testing on that patient.
A POST test cannot be made if the patient has already made a Challenge test (bronchorestrictor) on that day.



Parameters		Pred.	PRE	%Pred.	POST-BD	%Pred.	%CHG	POST #1
FEV6	L	5,10	0,00	0	0,00	0		0,00
FVC	L	5,10	5,68	111	5,69	112	0	5,69
FEV1	**L**	**4,52**	**5,12**	**113**	**5,01**	**111**	-2	**5,01**
FEV1/FVC	%	89,0	90,1	101	88,0	99	-2	88,0
FEV3	L	5,10	0,00	0	0,00	0		0,00
FEV3/FVC	%	93,7	0,0	0	0,0	0		0,0
FEV1/FEV6	%	83,2	0,0	0	0,0	0		0,0
FEV1/VC	%	87,2	83,8	96	83,8	96	0	83,8
PEF	L/s	9,95	12,90	130	12,36	124	-4	12,36
FEF2575	L/s	4,89	7,33	150	5,57	114	-24	5,57
ELA	Years	28	28	100	33	118	18	33
FET	s	6,00	2,06	34	3,88	65	88	3,88
FEF25	L/s	9,24	12,02	130	11,56	125	-4	11,56
FEF50	L/s	6,84	7,21	105	5,77	84	-20	5,77

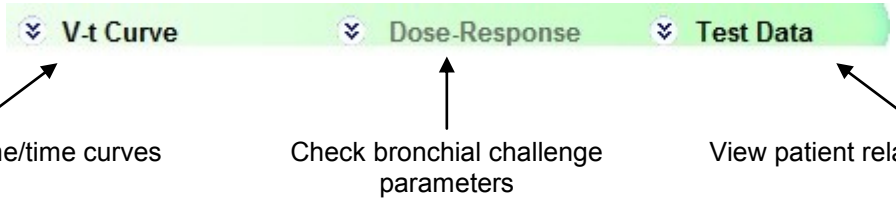
To start POST testing click on FVC from the main toolbar.
The “FVC-POST” on the test window header shows that it has been selected.

If the test is an acceptable one then it is automatically saved.
The bronchodilator test consists of only one step, which is defined within the bronchodilator protocol of the current user.

The resulting graphic will then show the PRE curve and the best 4 POST tests. The parameter table shows the predicted values as well as the measured parameters of the PRE test and of the 4 best POST tests.

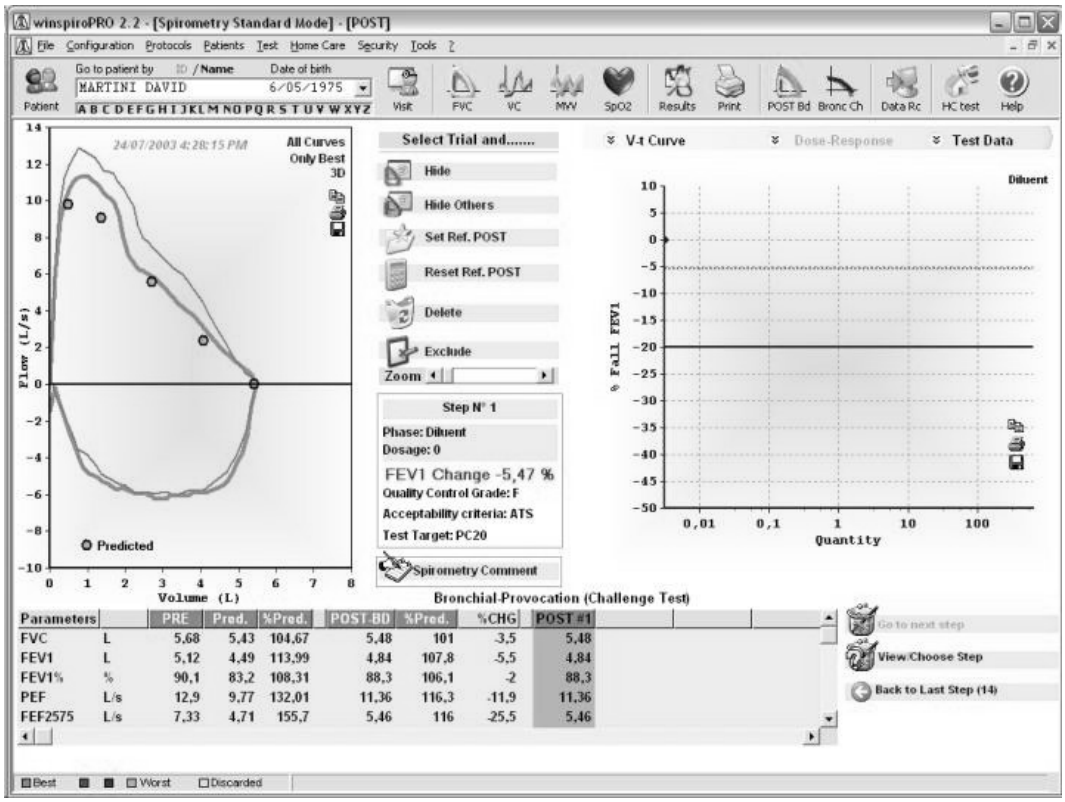
All of the test sessions of the current patient can be viewed by selecting the List of sessions for that patient.

Use  and  to show/hide one or more tests on the graph.
At the bottom of the screen are the functions that analyse and compare the POST values with the PRE reference values.
Use the icons for the following functions:



10 BRONCHIAL PROVOCATION (CHALLENGE) TESTING

Click  from the main toolbar to open the bronchial challenge window for the current patient. The green curve shows the best PRE test from the current test session.
A challenge test cannot be made unless at least one PRE test has been made today on that patient.
Also, a Challenge test cannot be made if one or more POST tests have already been made on that patient, today.



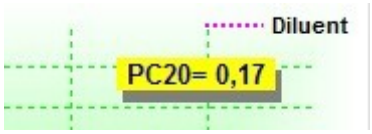
To start the Challenge test, for the current step, click on FVC from the main window.

WARNING

Select the step required before starting the test. The suggested procedure is as follows:

- **Select the required step from the current protocol (Go to next step)**
- **Administer the relevant dose of the substance shown in the active step**
- **Make the spirometry test**
- **Select the next step (View/Choose Step)**

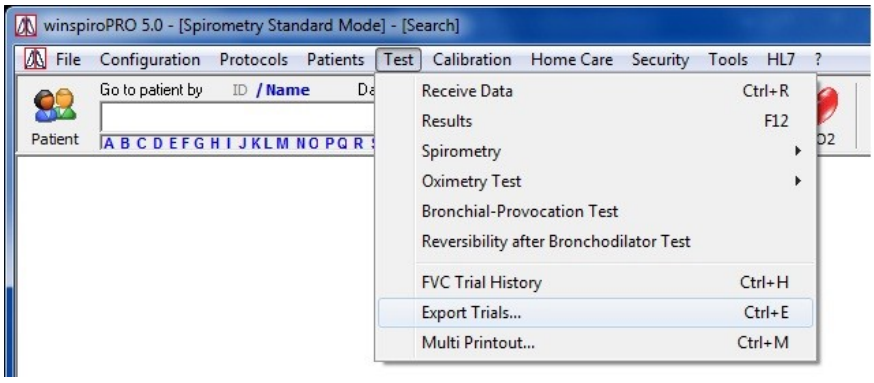
Providing the test is acceptable then it is automatically saved.
The bronchial provocation test is made up of several steps, and these steps are defined in the current active user protocol.
Use Go to next step and View/Choose Step to view details of the current Step. Use "Go to next step" to go to the next step of the current protocol, to view the various steps and then manually select the next step use "View/Choose Step".
The Flow/Volume curve shown is the PRE curve and the best 4 Challenge tests are also shown. The table of parameters contains the predicted values and also the measured values from the PRE test and from the best 4 Challenge tests. The Dose/Response curve shows the fall of the FEV1 (red line). As soon as the fall of the FEV1 exceeds the limit set within the protocol (blue line) then the test is terminated and the result of the test is shown on the graph (PCx or PDx).



Use the List of Sessions box to view the results of the various test sessions made by the patient.
One or more of these tests can be shown/hidden.
Use Print on the main toolbar to print the report of the bronchial provocation test.
The Copy ( ), Print ( ) and Save ( ) keys allow you to copy to the clipboard, print the current test and save the image on the hard disk (and to export it in various formats) or to send it directly as an email attachment.

11 EXPORT ARCHIVE IN EXCEL FORMAT

This function enables the user to export all or part of the winspiroPRO database into an Excel file.
Click “Test” from the main menu bar, and then “Export to Excel” …



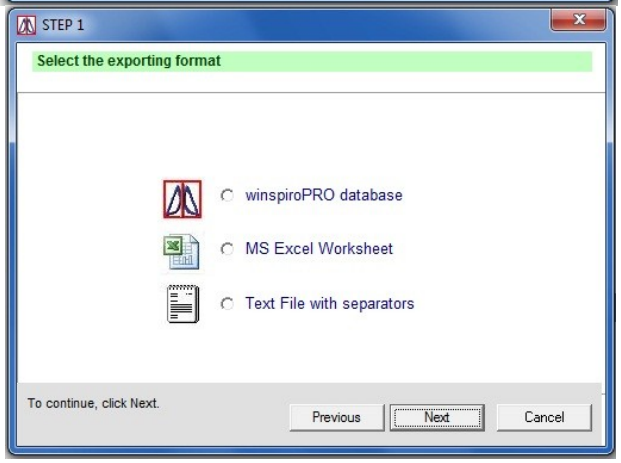
this then launches a Wizard is a guided procedure to prepare the data export process.

The first screen is an introduction to the export process, “Next” to continue or “Cancel” to return to the main menu.

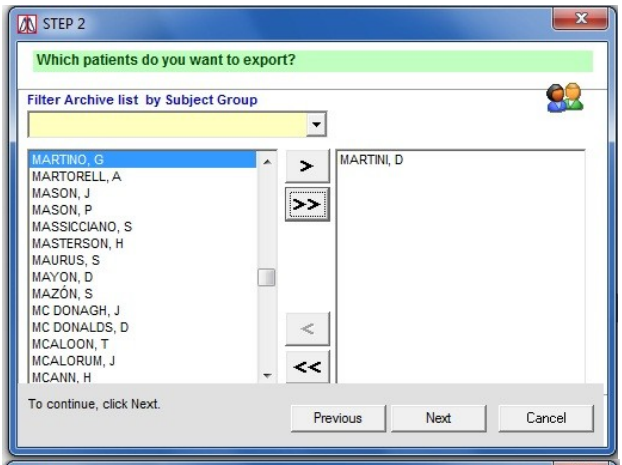
First step:
The first step is to choose the export format
You may select from:

- winspiroPRO database
- a file in Excel format
- a simple text file in txt format with separators between data

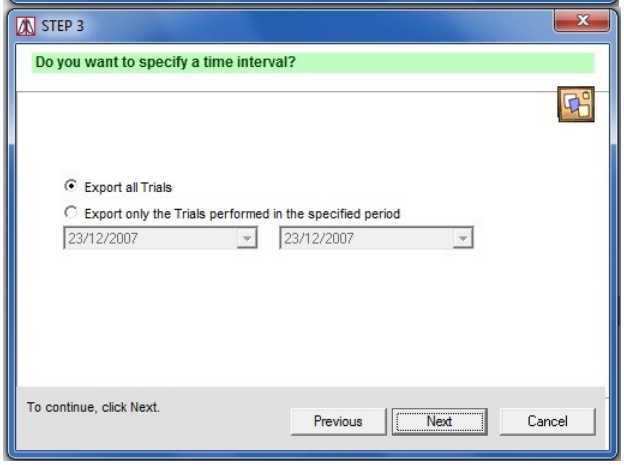
you then proceed by clicking "Next". Use "Back" and "Cancel" respectively to return to the previous step or to terminate the export process.



Step two:
select the patient or patients to include in the export file, then click > , or use >> to select all of the patients. The patients selected are then shown in the box on the right hand side of the screen.
“Next” to continue or “Cancel” to exit.
Use < and << to deselect a single patient or all of the patients from the export file, or “Previous” to return to the previous screen.



Step three:
at this stage either all tests performed by the selected patient(s) are exported OR a time period can be defined so that only tests carried out within that interval are included in the export file. To define the time period click on “Export only the trials performed in the specified period” and select the start and finish dates required. “Next” to continue.



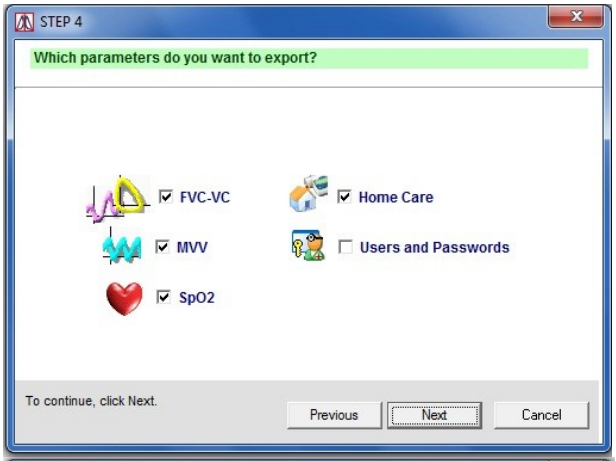
Step four:
at this stage, the parameters to include in the export file can be selected, either by selecting one or more tests (FVC, VC, MVV, SpO2) OR by selecting the individual parameters within a single test; in addition the Predicted Values and the Quality Report relating to the selected tests can be exported.

ATTENTION ⚠

At least one parameter must be selected, to proceed with the data export.

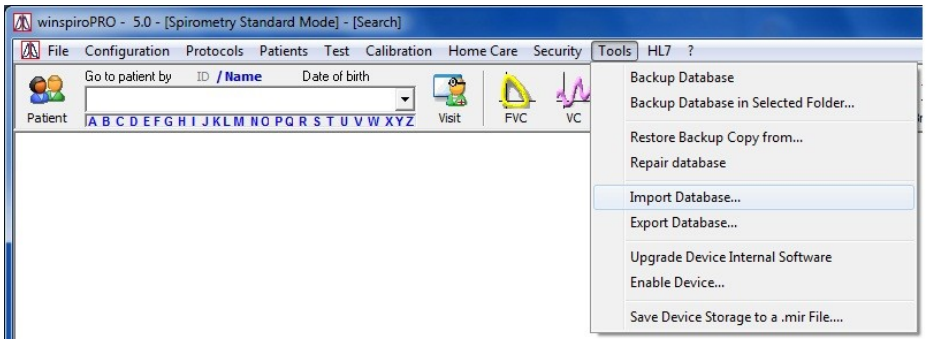
When the parameter and/or test selection is made click “Next” to continue.

Now all of the selections have been made, click on “Next” to create the Excel file containing the selected data. This file can then be saved as required, in the normal way.

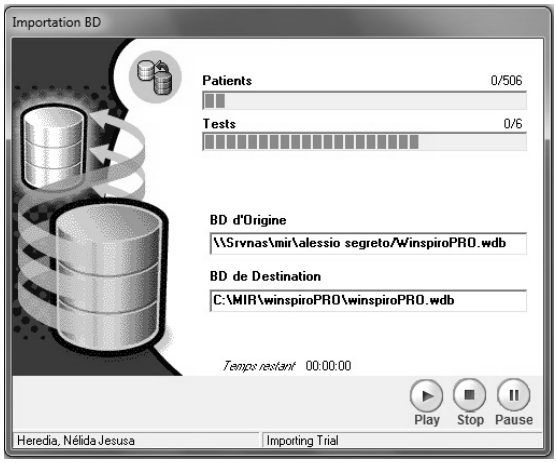


12 DATABASE IMPORT

The user may import information from other databases as long as these are in wdb or wsp format.
To activate this function the user must click on “Tools” in the menu bar. Next the user must click on “Import database”



Now the user is required to insert the supervisor password.
Next the user will select the file to import. Once the file has been selected the the procedure will commence automatically. The next window indicateds the status of the import procedure.



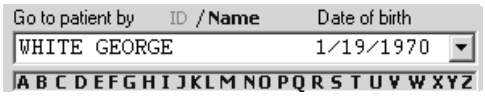
By using the icons in the bottom the user may start, end or pause the import procedure

When the import procedure is complete the window will close automatically and the user will return to the main screen.

13 HOMECARE (HC TEST)

Click on 

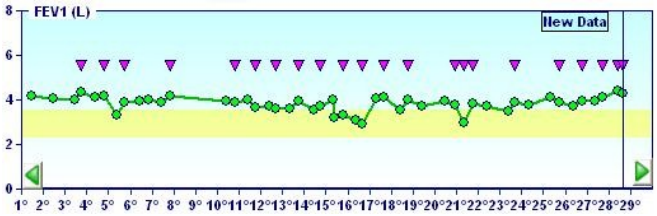
from the toolbar on the main menu to view the results of the homecare spirometry and oximetry tests, for the selected patient.



A complete list of the homecare tests is shown, in order of Date of Reception and Patient, even if there are no homecare tests present for the selected patient.

The HC test window gives an overall view of the patient's situation including the patient information and the graphs of the spirometry plus oximetry parameters, plus the symptom trends. The detailed results of each test can be viewed, together with a preview of the test graphs.
From the data reception window, the graphic of the latest best test is shown plus the best tests made in the previous 28 days.
If other tests for the same patient are present, they can be viewed by clicking on "Previous week" or on "Next week".
Use the icon on the upper right in the grey area to show/open the drop down window of the received data.

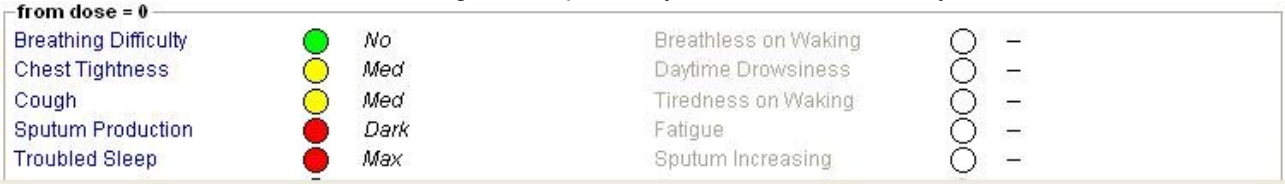
This graph shows the trend of the selected spirometry parameter(s) with any “Taken Drug” ( ) marker or, taken oxygen, working day, repeatability:



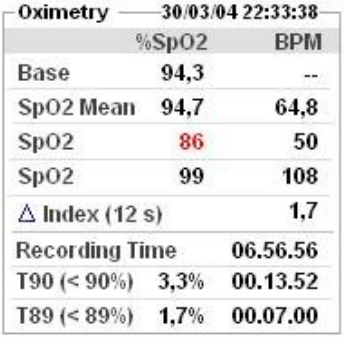
The blue coloured band “New Data” shows the last test received. The yellow coloured band highlights a critical situation, in other words a test in which the yellow traffic light “Caution” was reported.

Use the “Scale” box (on top of the spirometry options) to select Day or Week.
Use the “Parameter” box (next to scale) to select the parameter(s) to be viewed

The symptoms can be selected or hidden from view, as required.
On the right part of the screen, either the detailed results and the graphic of the FVC test OR the graph of the oximetry test are shown: to see the details of an individual test double click on the graph or click on the magnifying glass.
Use the Show SpO2 details bar to go from spirometry test results to oximetry test results.

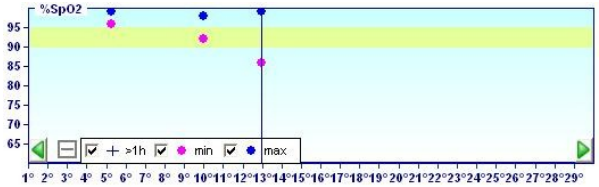


The “Oximetry” box shows the details of the oximetry test selected.



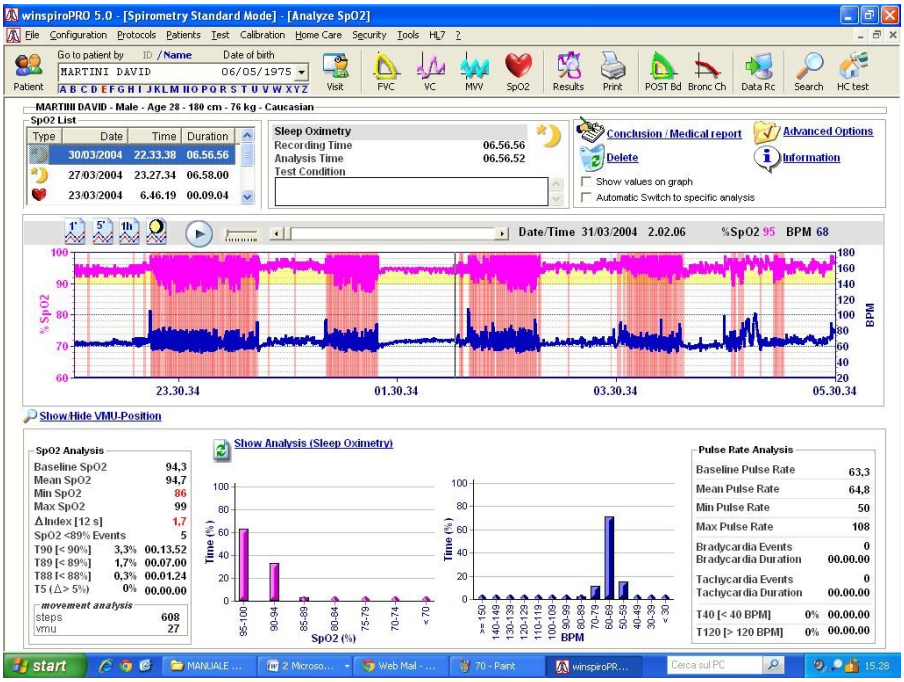
This graph allows the same spirometry operations as previously described. Select a parameter and click on the graph to view the trend of the selected test. The checks boxes on the bottom allow:

- highlight tests with duration of more than one hour ("+" appears on these tests)
- show or hide the minimum values registered during the test
- show or hide the maximum values recorded during the test.



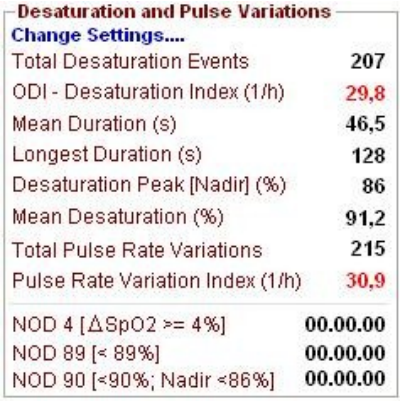
The Copy, Print and Save buttons in each screen enable the user to copy to the clipboard, to print the curve and to save the image on the hard disk; several file formats are available. The file can also be sent as an email attachment.

Use the SpO2 BPM icons to open the window of the selected trials.



This window shows the values related to the current test together with the trend graph. During an analysis of a sleep oximetry test the pink coloured line on the graph shows the desaturation events, click to enlarge the section of interest, to go back to the previous screen.

Use Show Analysis (Sleep Oximetry) to view the histogram related to the number and type of desaturation event plus the sleep oximetry values. In this case the area on the right shows the characteristic parameters of this test, including the number of desaturation events and the desaturation index (ODI).

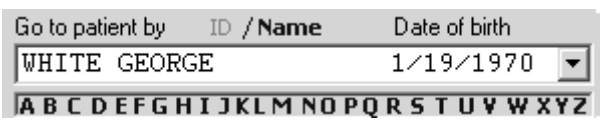


14 HC DEVICE PROGRAMMING

Some devices are enabled for patient homecare monitoring. The device must contain the patient's details in order to provide accurate data. Here follows the procedure to set up the patient parameters and to download test data through the USB or RS232 port.

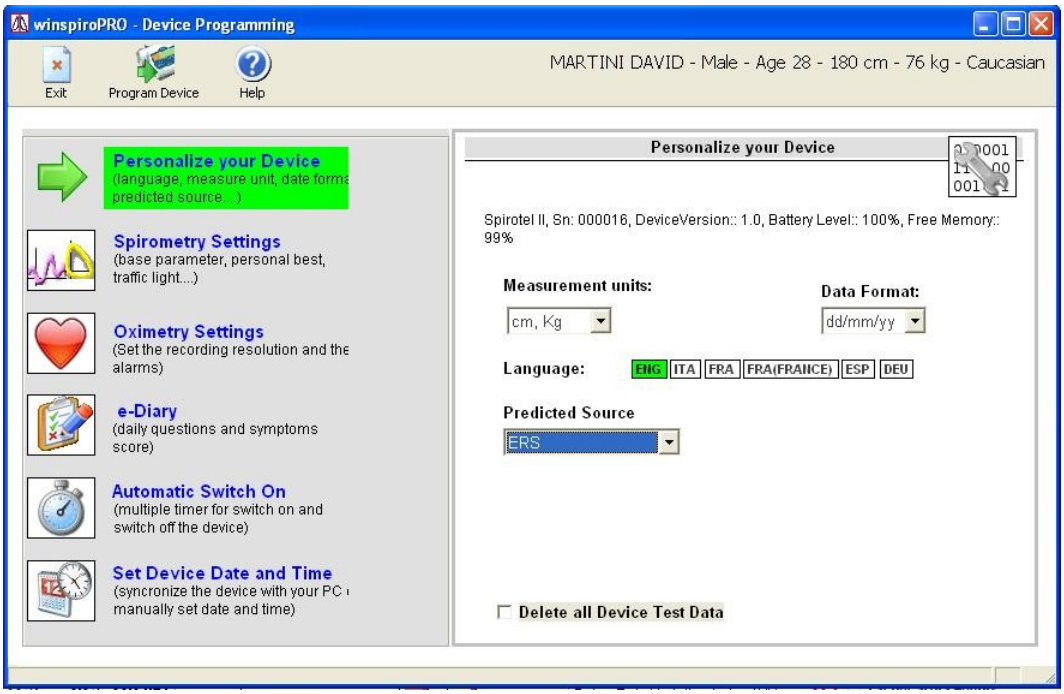
Connect the spirometer to the PC via either the COM or USB port as specified in the "Configuration" section.

Select patient.



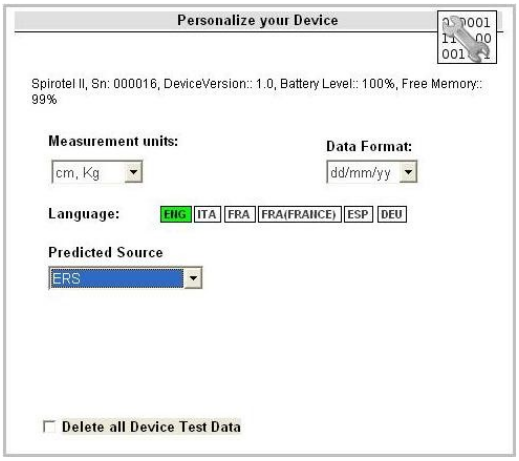
Then, to access the menu, "Home Care" select "Programming Tool."

The device data is read by winspiroPRO and entered into the following 6 sections corresponding to the following configuration areas:



Device customization

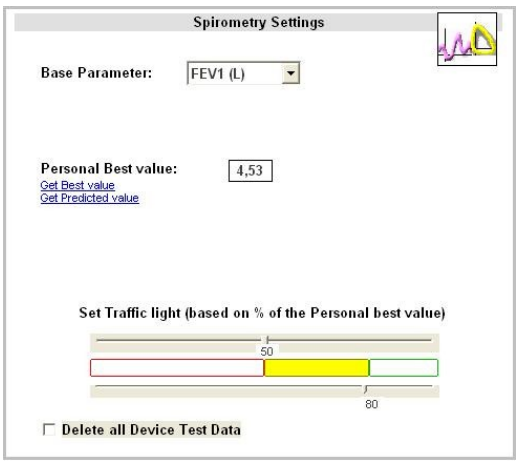
Allows you to set the language, the unit of measure, the date format and the theoretical author used by the device



Spirometry Settings

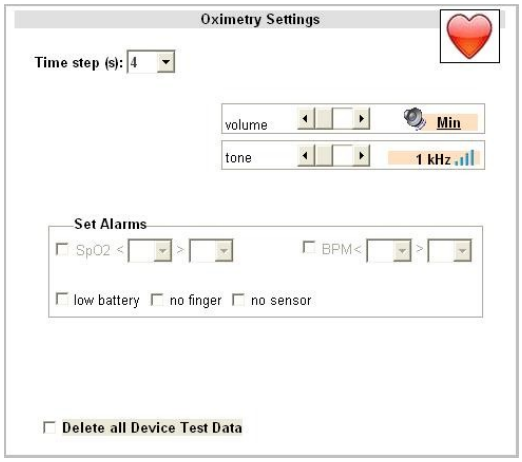
In this section you can:

- determine the basic parameter (FEV1 is normally used, however you can choose other parameters);
- Set personal best according to the theoretical value of the patient or the best value recorded
- configure a traffic light based on% of personal best



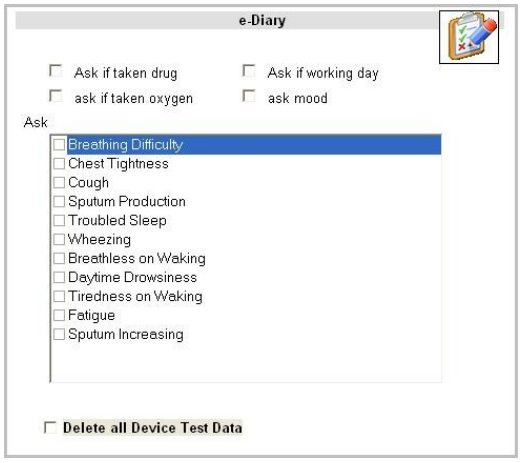
Oximetry settings

For the oximetry test, you can set the minimum and maximum values of SpO2 and BPM and the volume and tone of the acoustic signal associated with the limits set for the SpO2 and BPM.You may also set alarms for low battery indicator, finger inot inserted, and sensor not inserted.



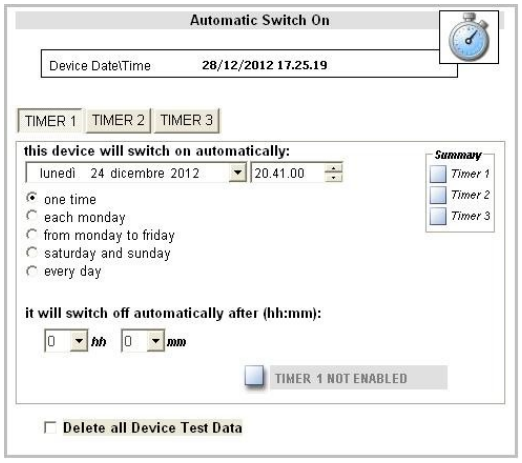
e-Diary

In this section you can set the questions that are submitted to the patient before making a spirometry test. The information given by the answers is a useful tool for a doctor to better interpret the results of a single test. However this information will not change the calculated values.



Automatic switch on

The instrument can be programmed for automatic switching on and off for predetermined periods.



Set device date and time

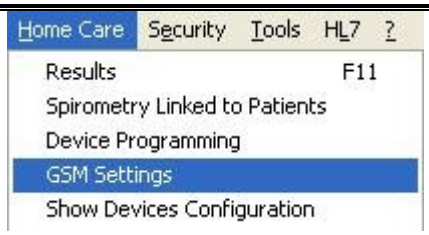
This section allows you to change the date and time on your device or sync it with the computer.

When the setup is concluded click on the button “Program the device” to activate all the changes on the connected device
Terminate tutte le impostazioni cliccare sul pulsante “Programma lo Strumento” per rendere effettive le modifiche sul dispositivo collegato.

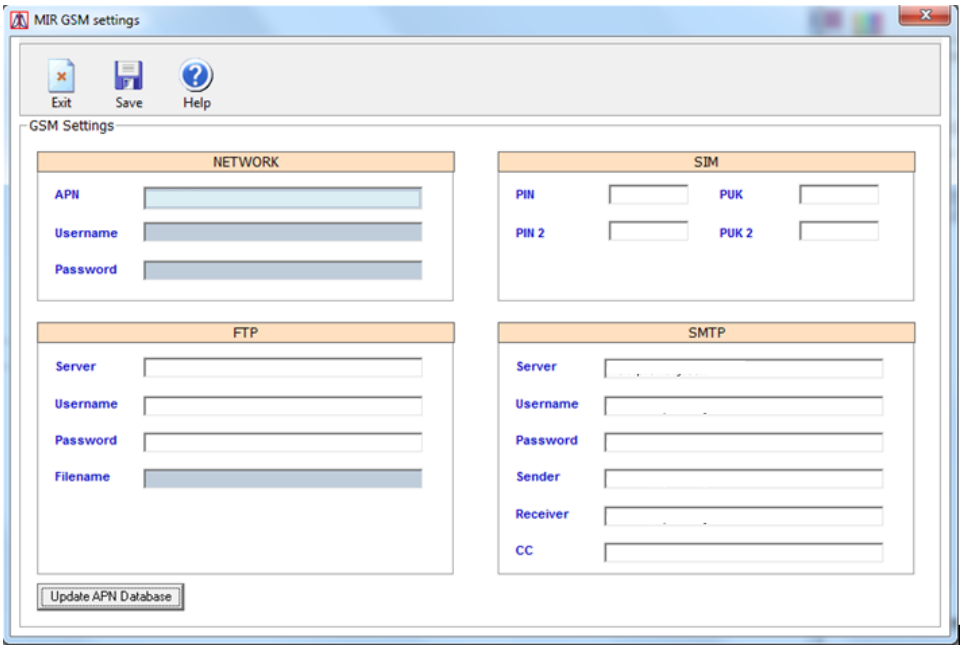
WARNING ⚠

If you enable the check box Delete all Device Test Data the device programming will earse all

14.2 GSM Card programming device

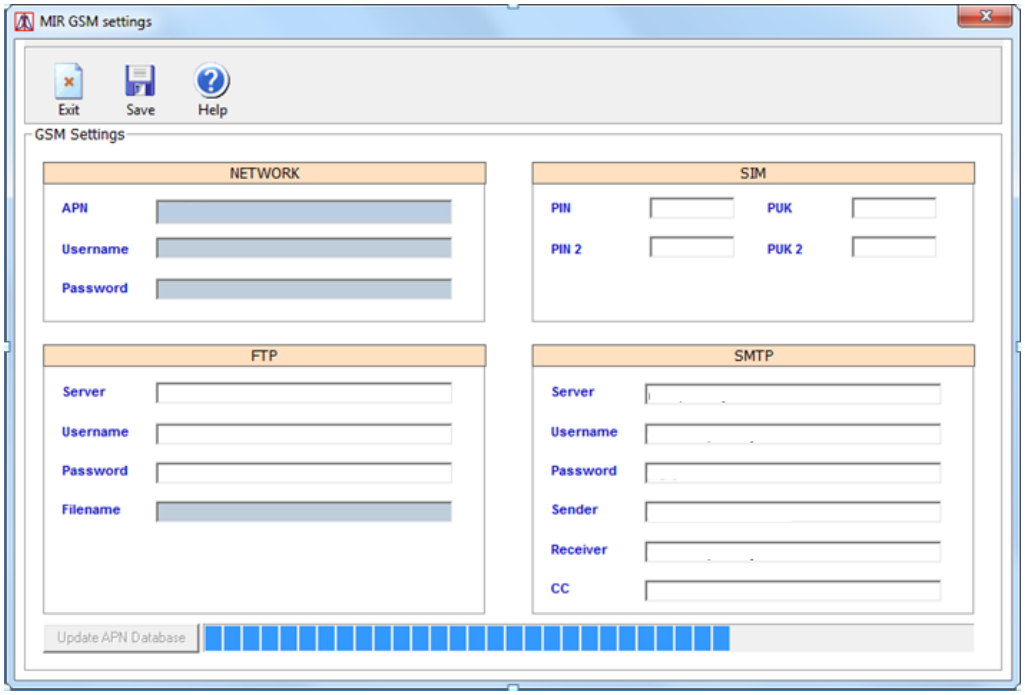


Some devices have a GSM card for data transmission by means of communication protocol FTP or SMTP.
To change the settings of the GSM card of your device click on the menu item GSM Setup from the Homecare menu.
The following window allows you to enter or change parameters FTP or SMTP and the PIN and PUK Card GSM.



The device is designed to automatically identify the APN (Access Point Name) parameters required for a connection to the provider. In case of lack of identification you can update the APN data archive of the device.

By Clicking on "Update APN Database" you can search for the most recent apn_mir.apn file and start the update process.



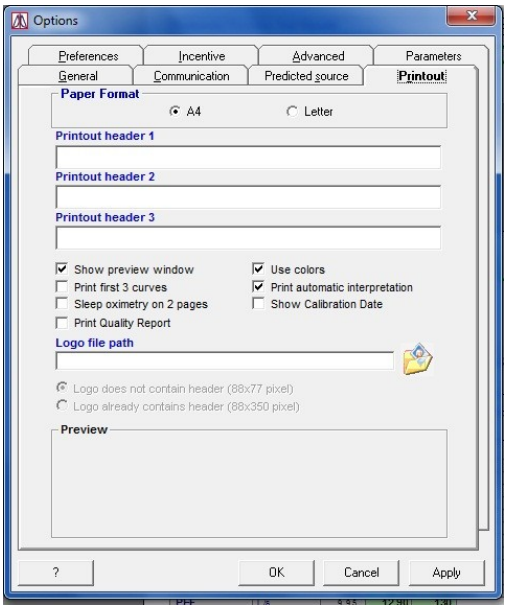
15 PRINT

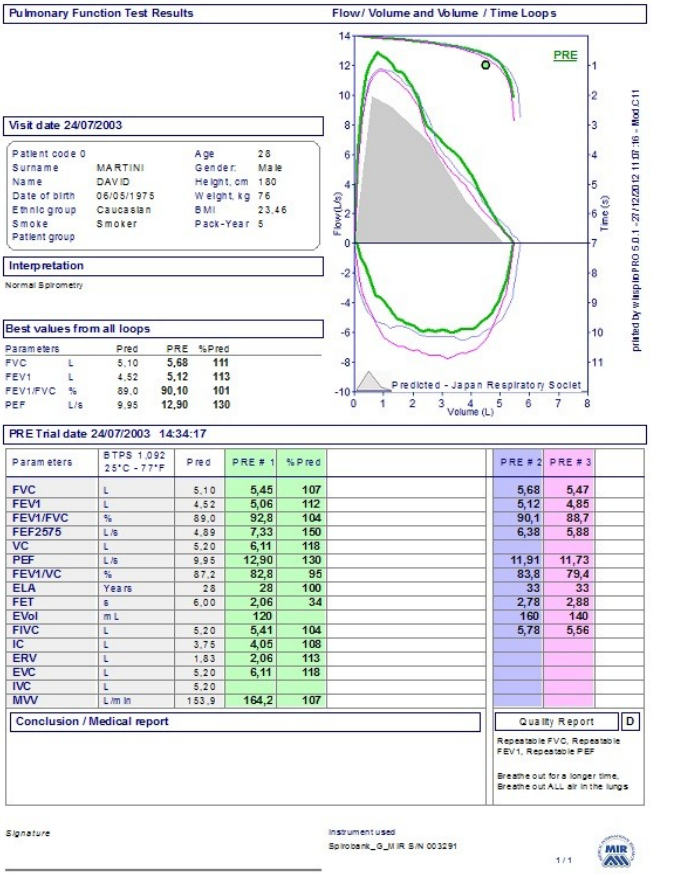
15.1 Spirometry printout

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 first 3 curves
- Sleep oximetry on 2 pages
- Use colour
- Print automatic interpretation





NOTE

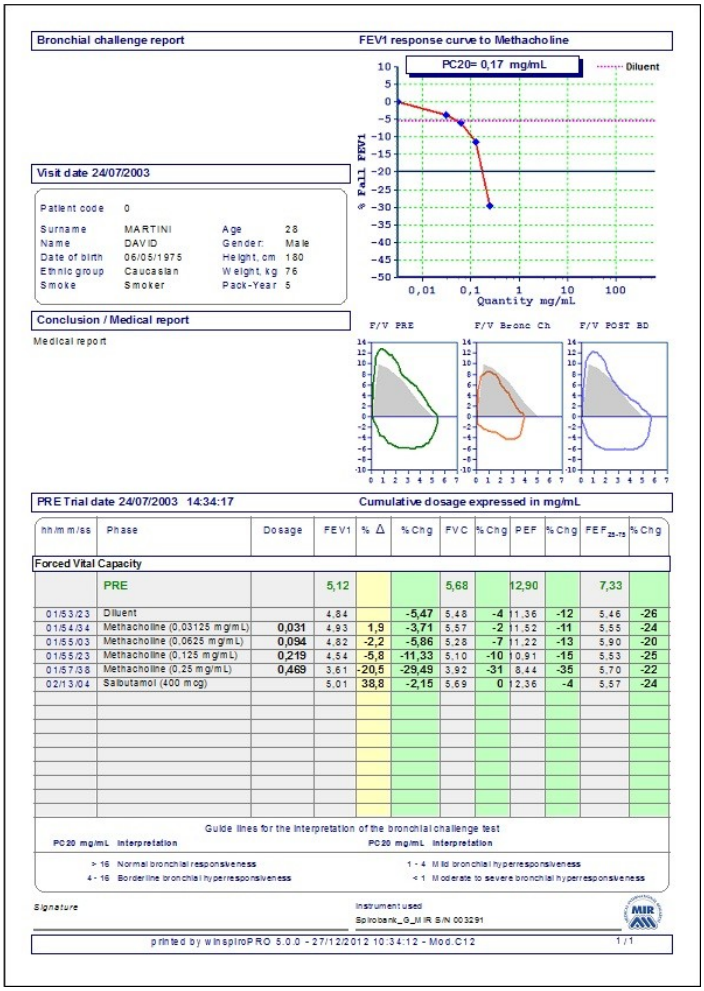
Always use print preview to check the correct settings of winspiroPRO with the default printer.

From the bronchial provocation window click 

to print a bronchial provocation test report.

WARNING

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



Bronchial challenge report — FEV1 response curve to Methacholine

PC20= 0,17 mg/mL — Diluent

% Fall FEV1

Quantity mg/mL

Visit date 24/07/2003

Patient code 0

Surname	MARTINI	Age	28
Name	DAVID	Gender:	Male
Date of birth	06/05/1975	Height, cm	180
Ethnic group	Caucasian	Weight, kg	76
Smoke	Smoker	Pack-Year	5

Conclusion / Medical report

Medical report

F/V PRE — F/V Bronc Ch — F/V POST BD

PRE Trial date 24/07/2003 14:34:17 — Cumulative dosage expressed in mg/mL

hh:mm:ss	Phase	Dosage	FEV1	% Δ	% Chg	FVC	% Chg	PEF	% Chg	FEF_{25-75}	% Chg
Forced Vital Capacity											
	PRE		5,12			5,68		12,90		7,33	
01/53/23	Diluent		4,84		-5,47	5,48	-4	11,36	-12	5,46	-26
01/54/34	Methacholine (0.03125 mg/mL)	0,031	4,93	1,9	-3,71	5,57	-2	11,52	-11	5,55	-24
01/55/03	Methacholine (0.0625 mg/mL)	0,094	4,82	-2,2	-5,86	5,28	-7	11,22	-13	5,90	-20
01/55/23	Methacholine (0.125 mg/mL)	0,219	4,54	-5,8	-11,33	5,10	-10	10,91	-15	5,53	-25
01/57/38	Methacholine (0.25 mg/mL)	0,469	3,61	-20,5	-29,49	3,92	-31	8,44	-35	5,70	-22
02/13/04	Salbutamol (400 mcg)		5,01	38,8	-2,15	5,69	0	12,36	-4	5,57	-24

Guide lines for the interpretation of the bronchial challenge test

PC20 mg/mL	Interpretation	PC20 mg/mL	Interpretation
> 16	Normal bronchial responsiveness	1 - 4	Mild bronchial hyperresponsiveness
4 - 16	Borderline bronchial hyperresponsiveness	< 1	Moderate to severe bronchial hyperresponsiveness

Signature

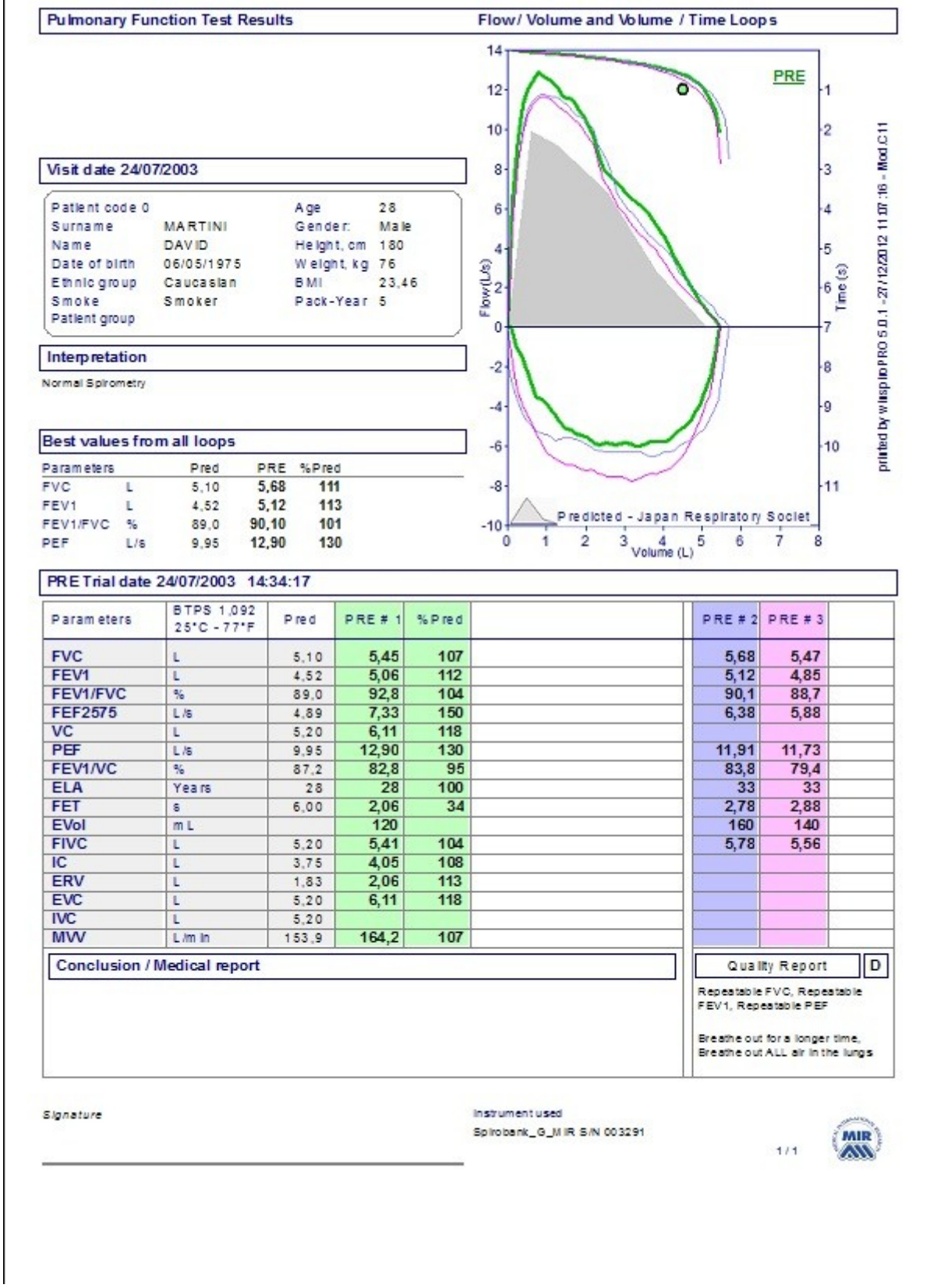
Instrument used

Spirobank_G_MIR S/N 003291

printed by winspiroPRO 5.0.0 - 27/12/2012 10:34:12 - Mod.C12 — 1/1

15.1.2 Custom printing

You can customize the FVC printout by adding or deleting parameters specified in the standard configuration. It is also possible to change the order of parameters and to include or exclude the quality control.



Pulmonary Function Test Results

Flow/ Volume and Volume / Time Loops

Visit date 24/07/2003

Patient code	0	Age	28
Surname	MARTINI	Gender:	Male
Name	DAVID	Height, cm	180
Date of birth	06/05/1975	Weight, kg	76
Ethnic group	Caucasian	BMI	23,46
Smoke	Smoker	Pack-Year	5
Patient group			

Interpretation

Normal Spirometry

Best values from all loops

Parameters		Pred	PRE	%Pred
FVC	L	5,10	**5,68**	**111**
FEV1	L	4,52	**5,12**	**113**
FEV1/FVC	%	89,0	**90,10**	**101**
PEF	L/s	9,95	**12,90**	**130**

PRE Trial date 24/07/2003 14:34:17

Parameters	BTPS 1,092 25°C - 77°F	Pred	PRE # 1	%Pred	PRE # 2	PRE # 3
FVC	L	5,10	5,45	107	5,68	5,47
FEV1	L	4,52	5,06	112	5,12	4,85
FEV1/FVC	%	89,0	92,8	104	90,1	88,7
FEF2575	L/s	4,89	7,33	150	6,38	5,88
VC	L	5,20	6,11	118		
PEF	L/s	9,95	12,90	130	11,91	11,73
FEV1/VC	%	87,2	82,8	95	83,8	79,4
ELA	Years	28	28	100	33	33
FET	s	6,00	2,06	34	2,78	2,88
EVol	mL		120		160	140
FIVC	L	5,20	5,41	104	5,78	5,56
IC	L	3,75	4,05	108		
ERV	L	1,83	2,06	113		
EVC	L	5,20	6,11	118		
IVC	L	5,20				
MVV	L/min	153,9	164,2	107		

Conclusion / Medical report

Quality Report D

Repeatable FVC, Repeatable FEV1, Repeatable PEF

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

Signature

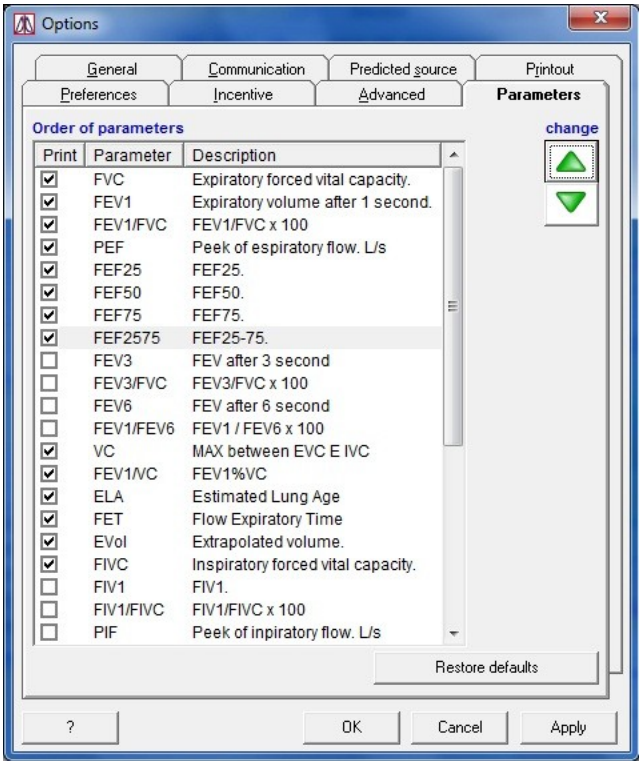
Instrument used

Spirobank_G_MIR S/N 003291

1 / 1

To change the FVC printout configuration click on the item options from the configuration menu.

In the Parameters window you can see the list of parameters to be displayed in the FVC printout.

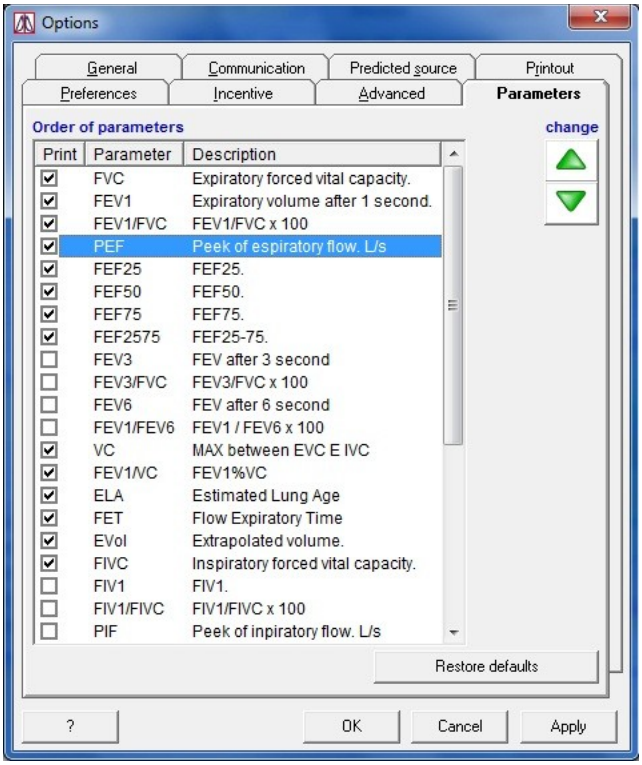


If there is a check in the check box of the Print column, then the corresponding parameter will be displayed in the FVC printout. To exclude the display of the parameter click on the check box corresponding to the parameter and remove the checkmark.

Warning ⚠

To make sure that the parameter is actually present in the FVC Printout, it must be included among the measurable parameters for the specific test.

To change the display order of the parameters in both the screen printout and in the customizable FVC printout click on the parameter to select it.



Then click on the directional buttons 

. To apply the changes click on 

or on 

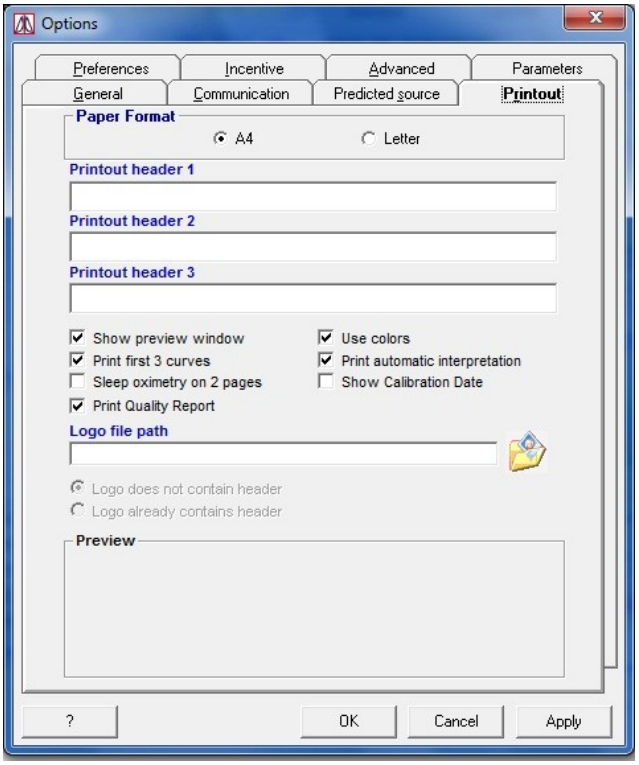
.
Printing preferences are stored in each user's profile.
To restore the default parameters (visible and sorting) click on

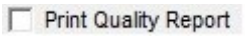

.

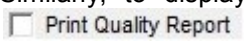
Warning ⚠

You can enter a maximum of 16 parameters for printing which will be calculated starting from the first selected.

To change the display settings of the quality control in the FVC printout click on “prints” in the window.



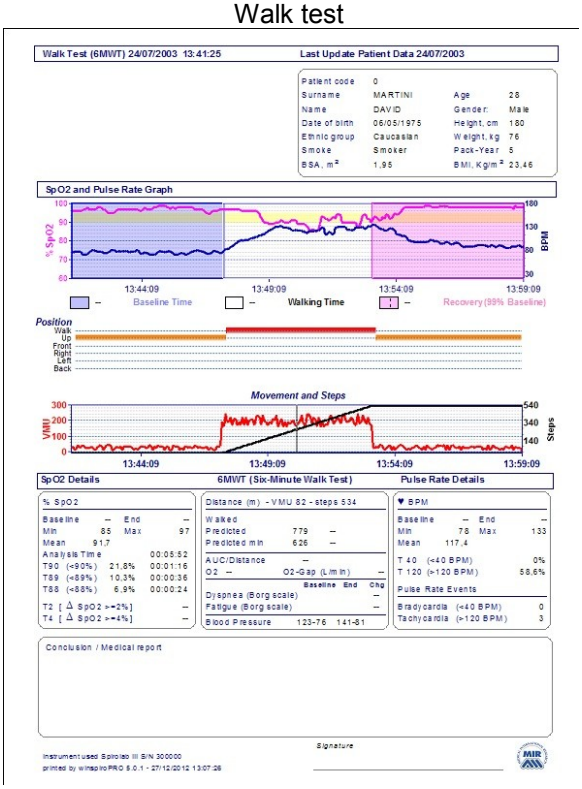
Remove the check mark in the check box next to the item 

.
Similarly, to display the quality control in the printout click on the check box to insert the check.


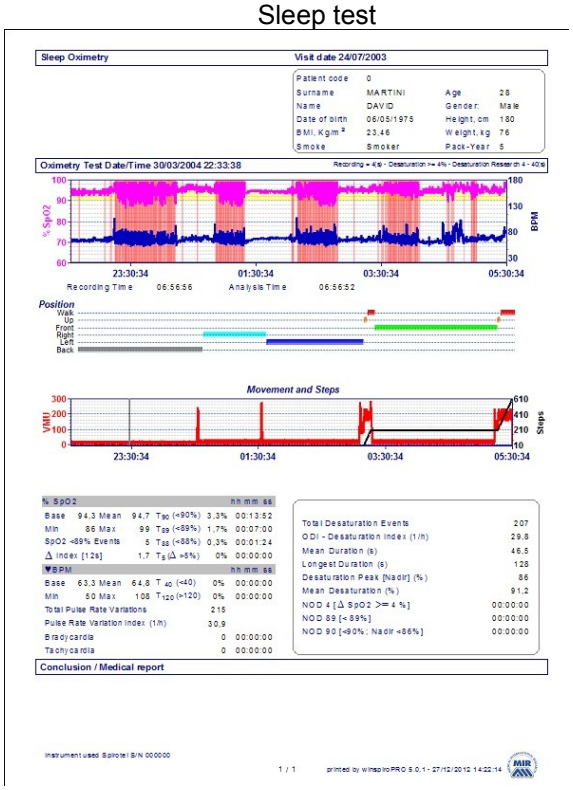
15.2 Oximetry printout

To print an oximetry test, following the same procedure described in the previous paragraph, it is possible to see the preview window. For each test type (walk test, sleep oximetry, SpO2/BPM) the following previews are shown:

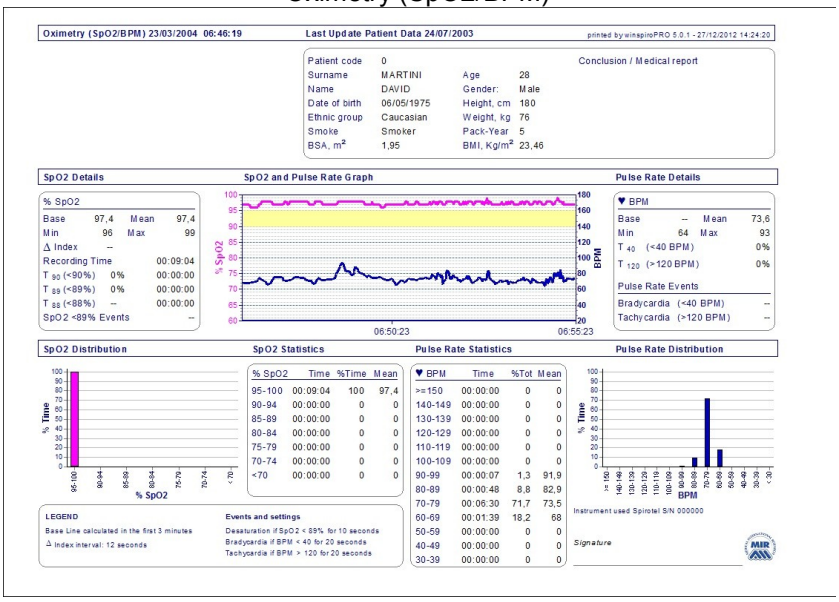
Walk test



Sleep test



Oximetry (SpO2/BPM)



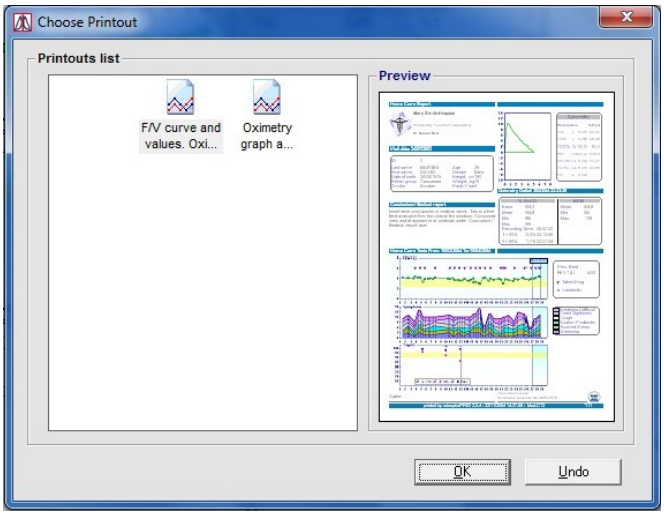
15.3 Home care printout

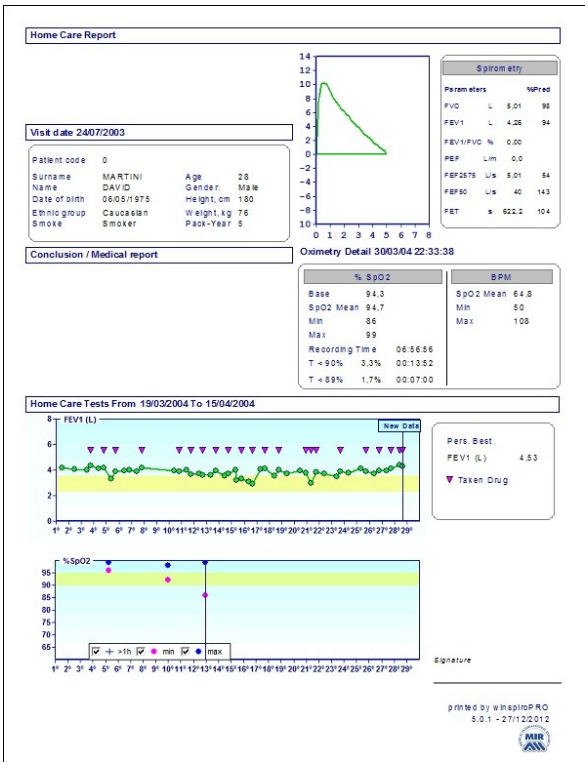
From the homecare results window, click 

to select one of the following options:

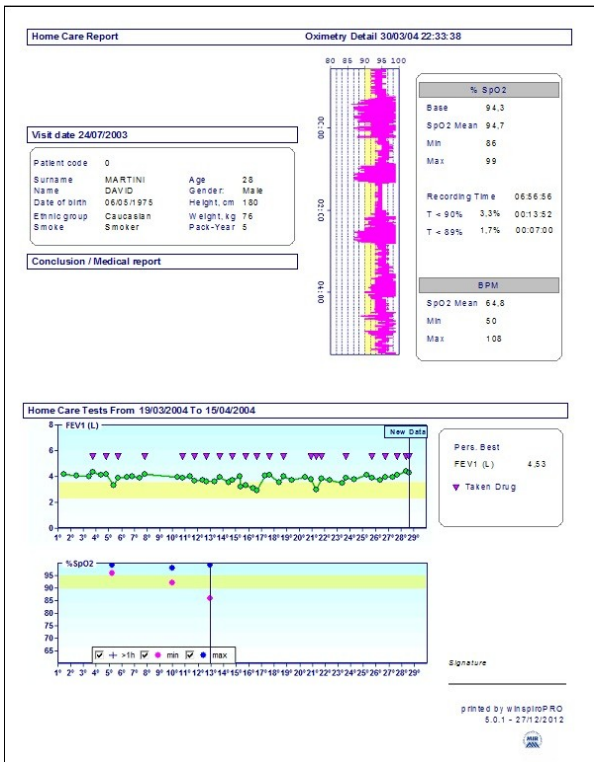
- F/V curve and values (oximetry and trend)
- Graph and Oximetry values

Selecting both, a small preview will appear on the right part of the window showing the difference between the two methods. Select and click on OK to see preview. The following types of data will be shown:





F/V curve and values (oximetry values and trend)



Graph and oximetry values

For each print preview use the following icons to:


Set printer and print the document


Export the report selecting the format (Pdf, Word, Excel) and destination (hard disk or MAPI to send as an email attachment)

Zoom/reduce print preview


Search for a word within report


Set print settings (printer, paper format, etc.)

From print preview click again 

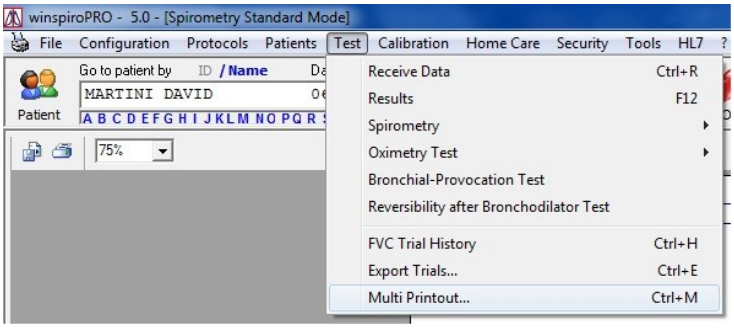
and this window will appear from where to select the number of copies and pages. Click OK to print.

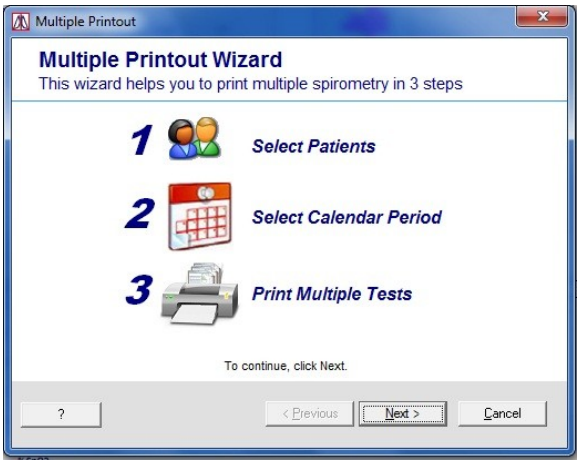
To cancel print preview and return to tests without printing click 

.

15.4 Multiple printouts

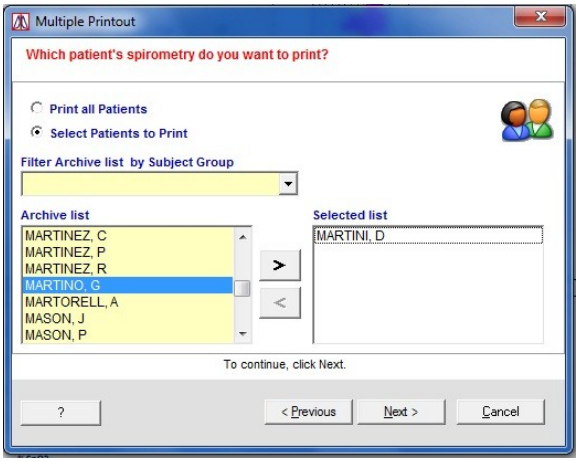
This function allows the user to print a selection of trials together instead of having to recall each trial one at a time.
The user must click on “Test” and then “Multi printout..”



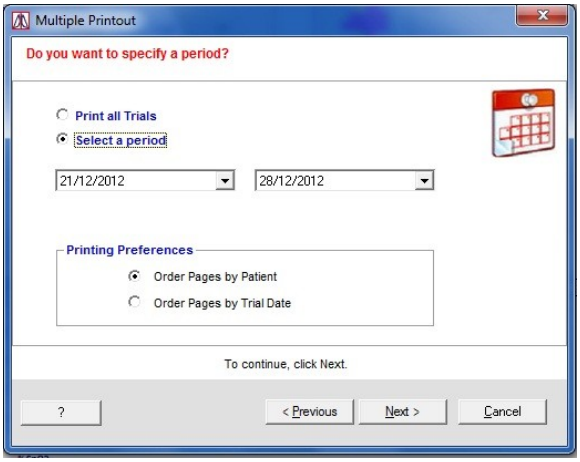


The window on the right shows the necessary steps to setup the multi printout function properly;
Click on “Next” to start the procedure.

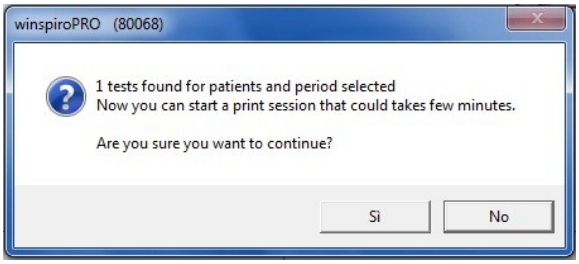
In the first step the user may select a list of patients by subject group or by selecting the patients individually from the entire database; if a subject group is selected the user may pick each patient or the entire subject group.
The user will select the patient from the left side of the screen by clicking on the > icon. The >> icon can be used to select all the visualized patients.
In the same manner the < and << icons will eliminate one or all patients which have been erroneously selected.



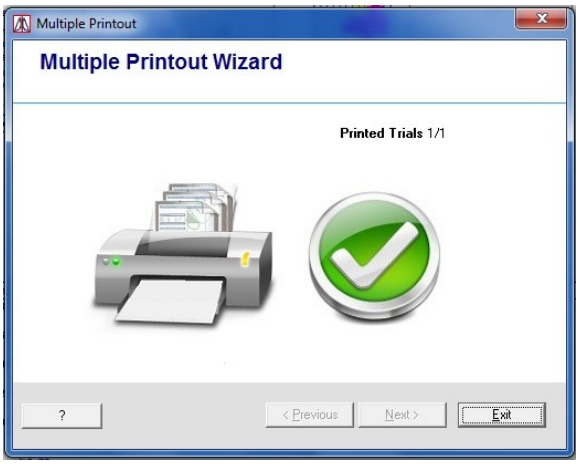
The second step entails the selection of the time frame of reference during which the tests were performed: the user may select to print all the tests or just those which were perfomed during a certain time period.
Once the selection has been made click on “Next”.



If the selected patients have actually performed one or more tests from the specified time period the message on the right will appear



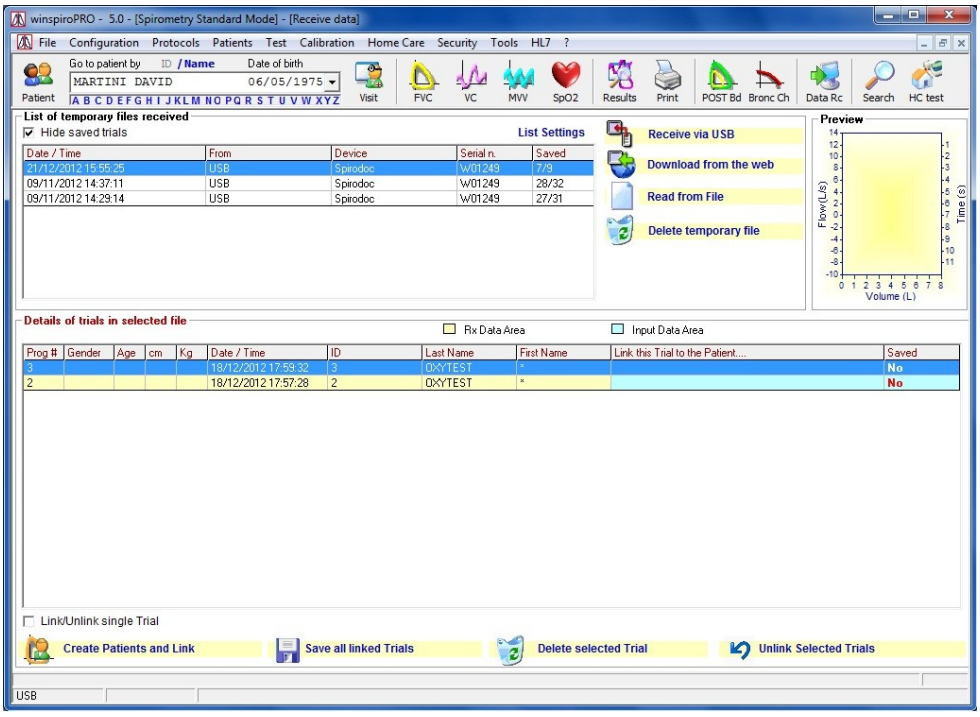
Next the user will click on “Yes” to commence the actual printout .
When the printout is complete the window on the right will appear.
By clicking on “exit” the user will return to the home page of winspiroPRO.



16 DATA RECEIVING (OFF-LINE)

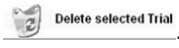
Click 

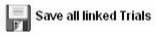
to go to the data transfer function, to transfer data via RS232, via USB, internet or from a file. Based on the type of connection used (USB or RS232) winspiroPRO will automatically update the icon on the upper central part of the window.



To download data into winspiroPRO, click on one of the receive data buttons shown. To download "from the web" (tests sent from patients to telemedicine server) the connection parameters must be set up in the Advanced tab sheet contained in the “Configuration”-“Options” menu.
To download "via Modem" (tests sent from patients through connected modem) the Receiving Module must have already been enabled in the Advanced tab sheet contained in “Configuration”.
Click on one of the received files in the Archive list to view the contents listed in the “Details of trials in selected file”. From the “Input Data Area”, select patient to link to each single test.
Multiple tests can be saved and linked to a patient within the database by pressing the Shift key and clicking on the tests.
To unlink a trial from a patient select the test and click on 

.
If data is received from spirometers which store patient details, then winspiroPRO will automatically generate the new patients by clicking on 

.
Select trial from the “List of temporary files received” to see the curve Preview on the upper right of the window.
To cancel a test selected from the “List of temporary files received” click on 

.
Click on 

to save the linked trials.

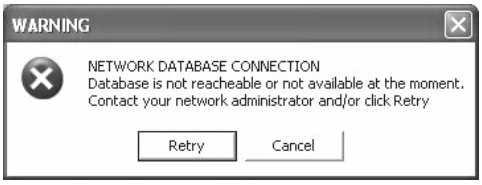
If the option Hide saved trials is selected, all of the saved trials will be hidden in the bottom grid. Also the temporary file in the top grid will be hidden when all the trials it contains have been saved by the user.
Unselect this option to unhide all.

17 EMERGENCY PROCEDURE, USING A TEMPORARY DATABASE

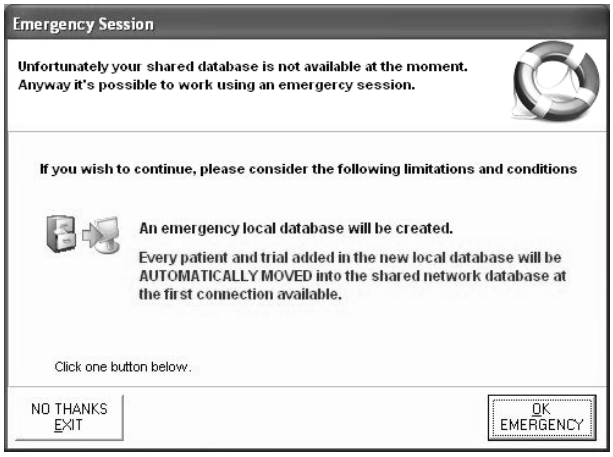
WARNING ⚠

This procedure is available only with winspiroPRO NET and enables the user to work while temporarily disconnected from the main working database.
The messages described will be shown in English as the User Configuration is not available unless connected to the database.

A check is carried out each time winspiroPRO NET is opened, to control if the program is correctly connected to its database. If the check does NOT find the connection then this message is shown:

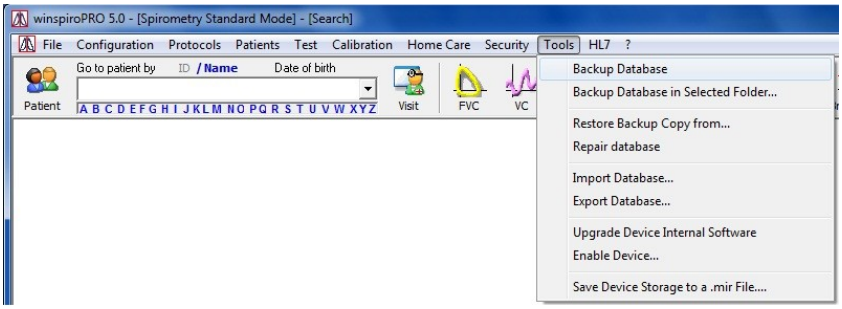


If the network was not available for any reason then you can try again by clicking “Retry”, otherwise if the connection is not available click “Cancel”.
Then this window is shown to enable the user to setup an emergency database.
1. this procedure creates a local, provisional database
2. the subjects and tests saved within the local database are automatically moved into the main working database as soon as the connection becomes available.
Click “OK EMERGENCY” to work with a provisional local database; or click “NO THANKS EXIT” to exit the program and to wait for the main working database to become available, at a future connection.

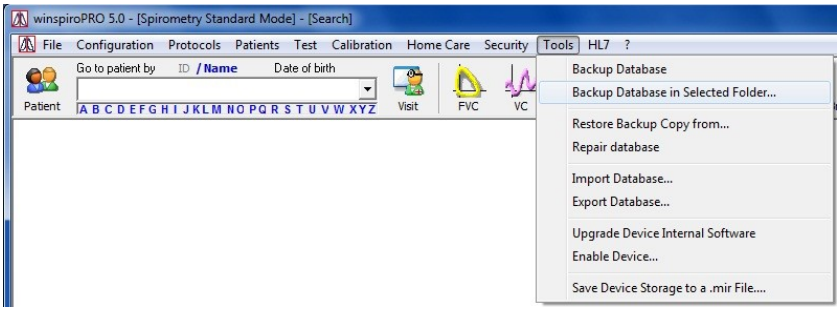


18 BACKUP DATABASE

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”. winspiroPRO will then automatically create a copy of the database in the folder:
winspiroPRO\Backup\LastBackup.



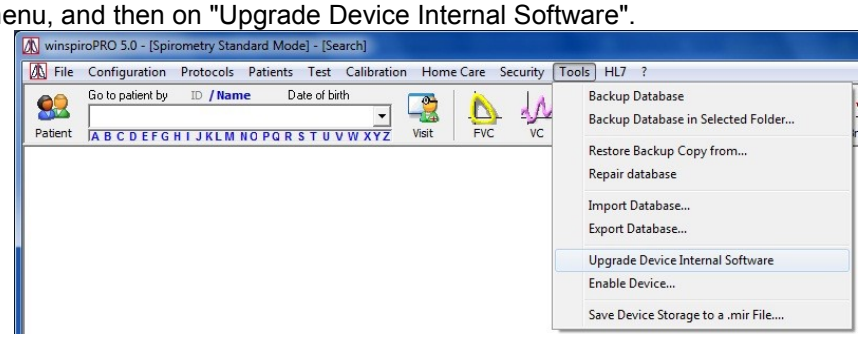
It is also possible to select a different directory; select “Tools” and then “Backup Database in the Selected Folder” specifying the location of the file to be saved.



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.

19 UPGRADE DEVICE INTERNAL SOFTWARE

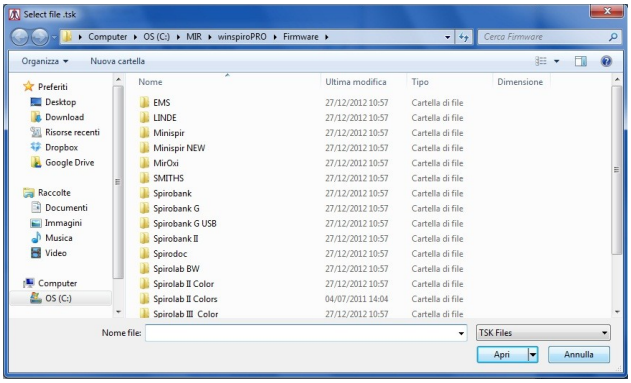
winspiroPRO can upgrade the internal software of the device. To download the new internal software version click on "Tools" menu, and then on "Upgrade Device Internal Software".



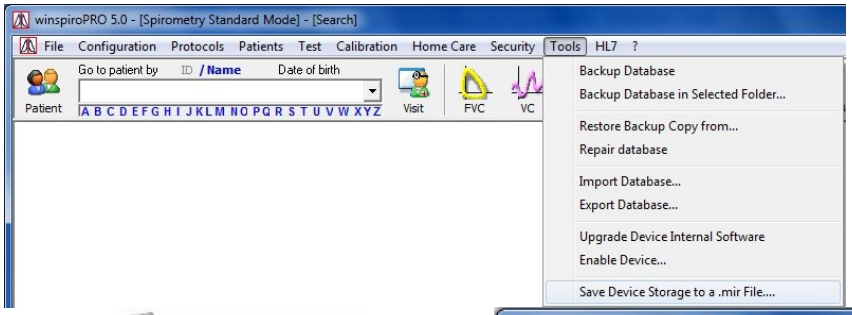
This wizard helps the user to select a connection to use from the device to the PC and then tests the connection, to check that the device is correctly connected to the PC.

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.

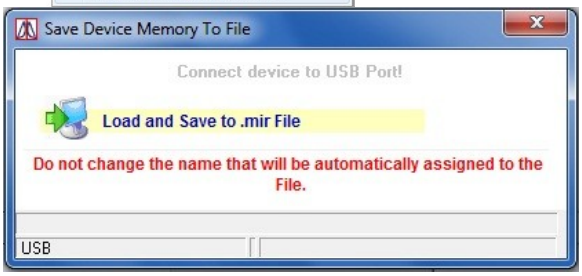


winspiroPro is also able to download the data from a spirometer onto a PC and to save it as a .mir file; as shown from the “Tools” menu click on item “Save Device Storage into a .mir File”.



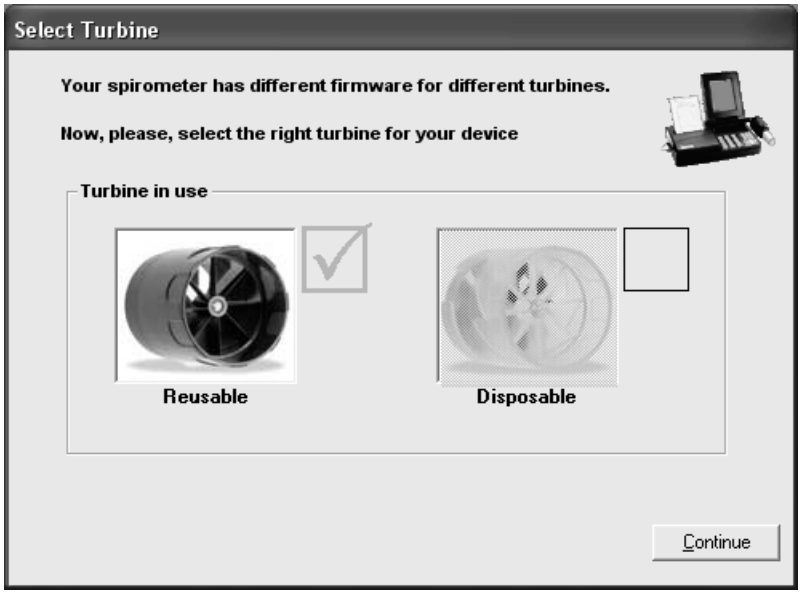
To start the procedure click 

All the test memory will be downloaded into a file .mir
This window will confirm that the file has been saved.
WARNING: Do not change the name that winspiroPRO automatically assign to the file.
Use the Read From File command in the Rx Data environment to import the .mir files



WARNING ⚠

When upgrading spirolab or spirolab II firmware, the following window is shown prior to the selection screen for the internal software:



Choose the turbine used and click “Continue”. Then the sequence continues as described.

20 INSTRUCTIONS FOR A CORRECT CONNECTION DEVICE-PC

WARNING ⚠

Winspiro PRO should be correctly installed before carrying out any of the activities described hereafter.

20.1 WinspiroPRO/PC minimum installation requirements

Local installation (from CD) requirements:

- Operating system Windows 2000 o Windows XP o 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 × 768 or higher
- Hard Disk 500MB free space
- Administrative privileges on the system
- USB port
- Serial port or USB-RS232 converter for RS232 devices

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. Only after winspiroPRO has been installed the user may connect the device through a USB port to the PC.

20.2 Windows 2000, USB installation procedure

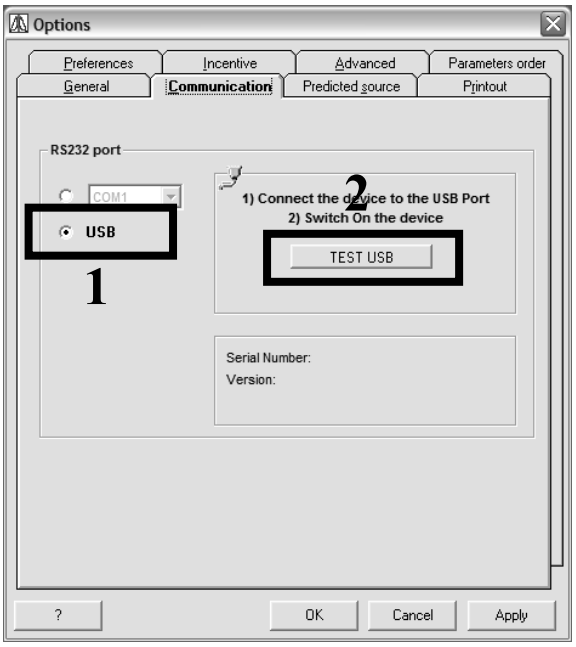
When the device is connected for the first time to the PC the following window will appear on the desktop:

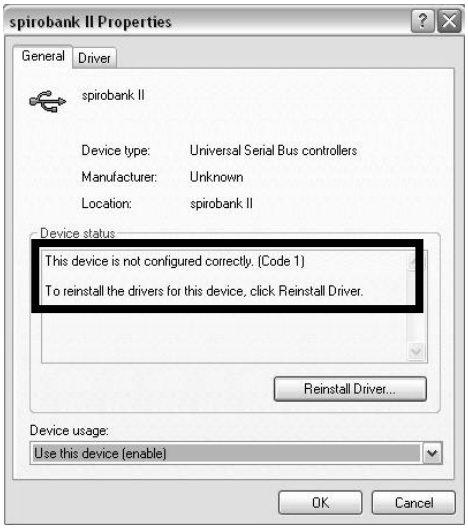
The MIR device drivers are certified by Microsoft for windows XP 32bit, windows Vista (32 e 64bit) windows Seven (32 and 64bit). Driver installation is automatic and only requires three to five seconds, after which the device is ready to be connected.

winspiroPRO software may now be opened and used to perform testing with the MIR device connected.
USB connection may be checked by following the procedure described in the following paragraph.

20.3 Control procedure for the correct connection device-PC

When winspiroPRO is opened you can control if the device is correctly connected to the software.
Click “Configuration” in the menu and then select “Options….”.
In “Communication” select USB on the left and then click “TEST USB” on the right.
If the following green message appears: “**Spirometer connected”**, then the communication is ok, otherwise: “**Spirometer NOT Connected”** is shown.
If the device in not connected the following windows appears (image 6):





Connect the device with the USB cable and repeat the connection test; if the problem differs repeat the procedure and pay attention to the Windows version, otherwise follow the instructions descried in the following paragraphs.

20.4 Troubleshooting

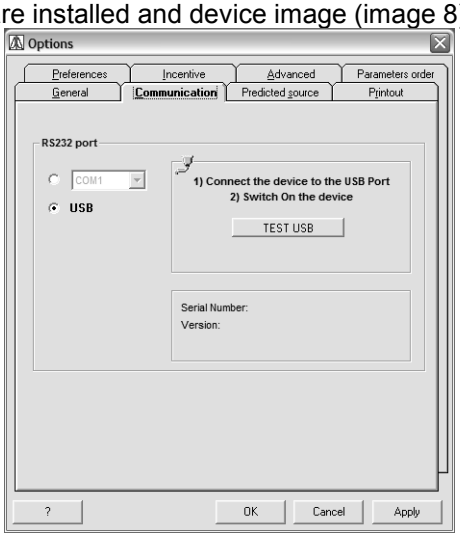
CAUTION ⚠

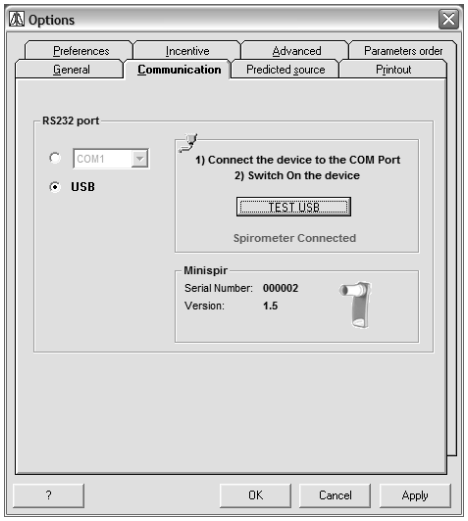
Do not connect the USB cable to PC until the WinspiroPRO software has been correctly installed. (See label on USB cable).

If the USB cable is connected before Winspiro PRO has been correctly installed as this is likely to cause errors or malfunctioning of the USB connection.

20.4.1 Malfunctioning when using Windows 2000 and XP

Check the connection between the device and the PC by going to the winspiroPRO window and selecting Options (image 7) from the configuration menu.
Check that the device is correctly connected to the USB port and switched on.
Click on “TEST USB” (image 7); if the device is working correctly the name, serial number, version of firmware installed and device image (image 8) will appear at the bottom of the screen





If there are problems with the connection the window in image 9 will appear from which there is the possibility to control the correct functioning of the peripheries and, if necessary, reinstall the driver…"; in the case everything is functioning correctly click on the tab "Driver" to carry out other operations. If the PC in use has been connected to more than one device, the screen in image 10 below will be visualised before the screen properties (image 9) so that you can select the device in use:

20.4.2 Malfunctioning when using Windows 98 and Me

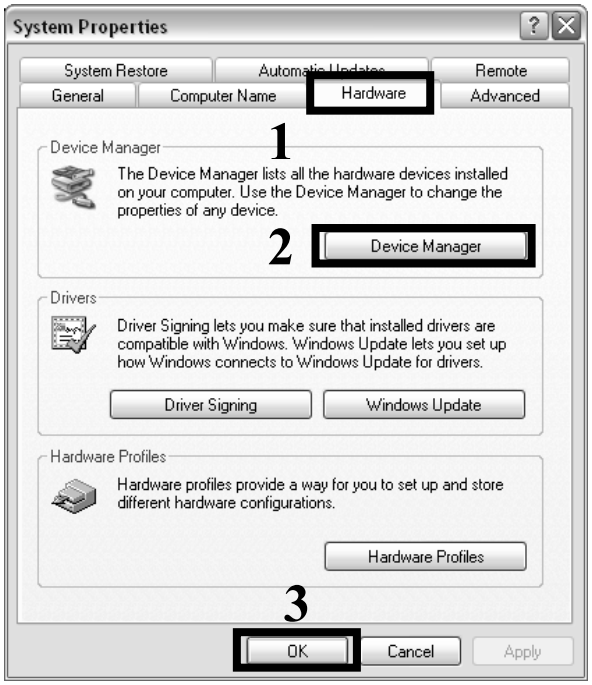
In this case it is necessary to uninstall the USB driver of the device. It is therefore necessary to:

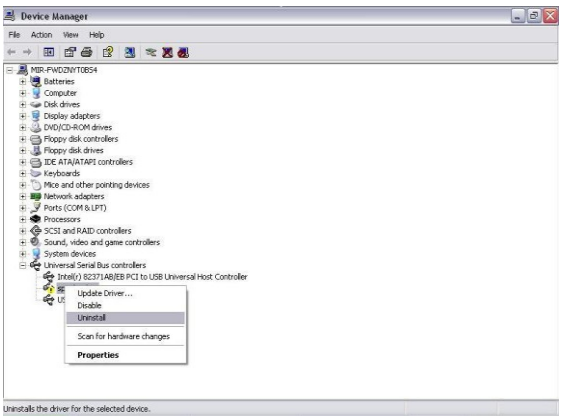
1) Go to the control panel:

Start → Set UP → Control Panel

2) click the "System" icon 

3) in the window "System properties" click on the "Hardware" tab
4) then click on "Device Manager" (image 11)
5) in this window access the USB controller
6) select device name
7) press the right mouse and select "Uninstall" (image 12)
8) at this point disconnect the USB cable, if connected, from the PC
9) install winspiroPRO software, by inserting the installation CD in the PC and following the guided steps





20.5 Procedure for installing the USB to SERIAL converter.

WARNING ⚠

The USB-serial converter is used to connect devices which only have a serial connection to a USB port. WinspiroPro will recognize these devices as if they were connected through a serial port.
Once the installation procedure is complete check the connection of the device by selecting the connecting system COMM port.

This procedure has two phases:

1) installation of the USB to Serial converter
2) installation of the device driver

Follow the steps illustrated below:

1) Connect the USB cable to the USB port of the PC.
2) After a few seconds the following message is shown (image 13):

3) Insert the floppy disk or CB ROM into the drive.

WARNING ⚠

If your PC, is one of the latest models it is unlikely to have drive A, so it is necessary to copy the entire contents of the Floppy onto a CD.

4) After a few seconds the following message appears image 14:
5) select from the menu or specified route
6) click on “Next”
7) in image 15 indicate drive A as file destination,

WARNING ⚠

If there is no DRIVE A indicate the DRIVE of the CD reader.

After a few seconds the following message appears :

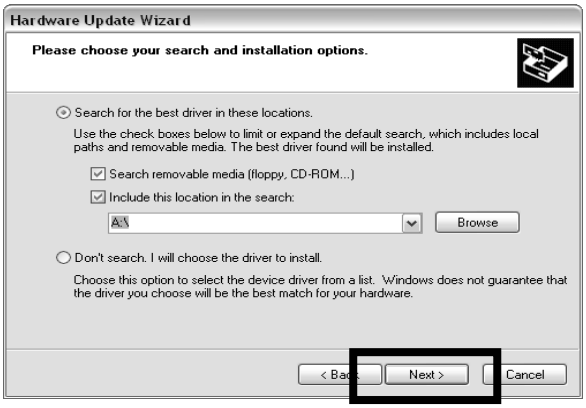
Select “Continue Anyway” to proceed.

8) Then the following message appears: (image 17)
This indicates that the DRIVER for the USB has been correctly installed.

9) The software will now pass to the installation of the COM port. (image 18). The message USB Serial Port appears on the menu bar of "New Hardware Found".

10) Use same procedure as above (image 19)

11) A message appears indicating the route of the installation, then click on "Next"



12) Click on the icon "Continue Anyway"

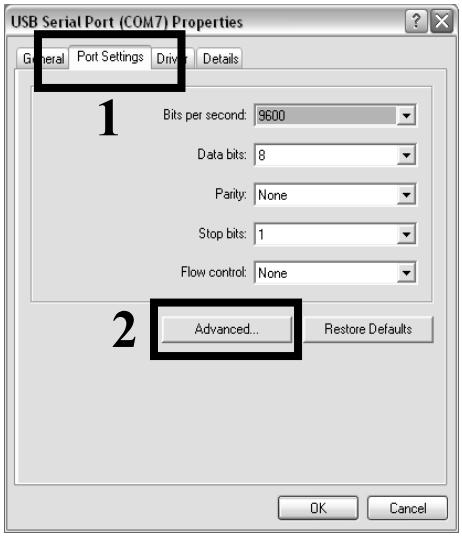
13) At the end in image 22 click on “Finish”
The software has been correctly installed and is ready to operate.

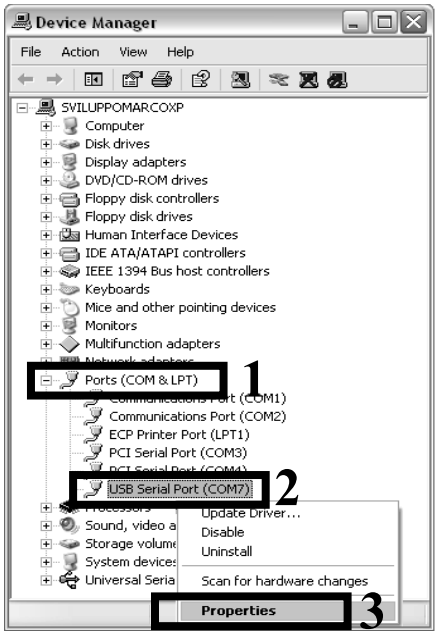
To check the correct connection read the operations described in paragraph 16.4.

20.6 Procedure for modifying the Com Port N°

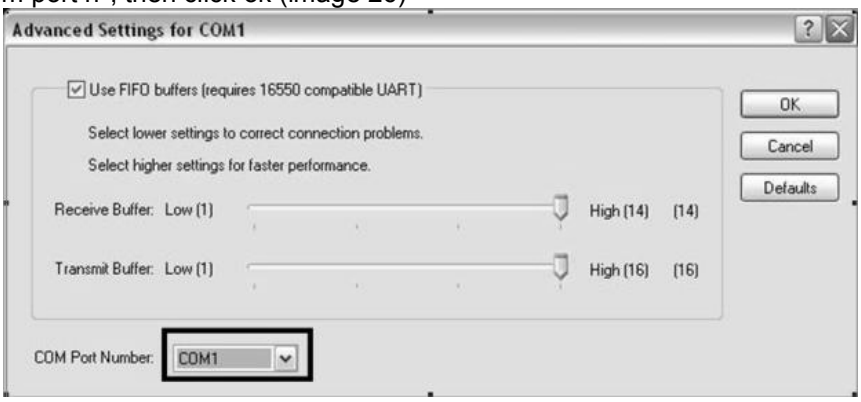
If an seriale-USB converter has been installed, and for whatever reason the USB port needs to be modified, then the following procedure should be followed:

1) Go to System within “Control Panel” and click “Hardware”
2) Click on “Hardware” and then on “Device Manager” (image 23)
3) In the following window click on “Ports (COM & LPT)”,then click on “USB Serial Port” and with the right mouse choose “Properties” in the tab (image 24)
4) In the “USB Serial Port Properties” click “Port Settings” and then “Advanced”, (image 25)





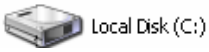
5) change the com port n°, then click ok (image 26)



6) Repeat control procedure on paragraph 16.4.

If, also in this case, the communication fails, contact a service centre or the manufacturer.

20.7 Procedure to uninstall previous installations of serial to USB converter

- In “My computer” click on 

- than on “Programs”;
- click on MIR
- click on winspiroPRO
- click on Drivers
- click on Serial to USB converter

- click on  FTDIUNIN and follow the procedure

Press the “finish” button to exit

Try to connect the device using serial-USB converter. If the message on the lower right of the display does not appear go to the following steps.

Click on “Control Panel” and then on System.
In the “System Properties” window click on “Hardware” and then on “Device Manager” (image 27).
In this window open the “Universal Serial Bus Controllers”, select “USB HS Serial converter” and cancel it (image 28).
At this point extract the cable converter from the PCs’ soket.

Try again to insert the serial-USB converter.
The following message should be displayed:

Otherwise contact a service centre or the manufacturer.