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Omnia Software User manual, VII Edition

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COSMED Srl - Italy

<http://www.cosmed.com>

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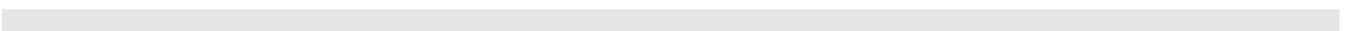
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Getting started



□ *Overview of the manual*

Omnia Software manual consists of the following chapters:

Getting started is an overview of the manual.

Installation: how to install the software.

User interface: describes user interface.

Settings: describes where to access custom settings.

Utilities: describes software utilities.

Calibration. Outlines all calibration procedures and how to access control panel.

Database management. Description of all database features, accessing subject's archive, backup.

Spirometry: how to perform spirometry tests (FVC etc.).

Dosimeter: how to use the dosimeter function for broncho-provocation tests.

Lung Volumes: how to perform Multi-Breath and Single-Breath Nitrogen Washout tests.

Lung Diffusing Capacity: how to perform DLCO tests.

Respiratory Mechanics: how to perform MIP/MEP and P0.1 tests.

Airways resistance measurement: how to perform Rocc tests.

Body Plethysmography: how to perform body plethysmography tests (Raw and TGV).

Six Minute Walk Test: how to view a Six Minute Walk Test.

Exercise testing. Explains how to conduct exercise testing, view results and edit data.

Resting Energy Expenditure. Describes the Resting Energy Expenditure testing (REE) procedure. Describes viewing and editing test results.

Sub-maximal testing. Introduces concepts for sub-maximal exercise testing, while integrating the exercise testing chapter.

The mixing chamber. Describes the mixing chamber and the preparation for exercise and resting tests with the classic mixing chamber technique.

□ Important Keynotes

Below are important notes describing the organization of this manual. This will make the manual easier to follow.

■ **Typographic keynotes**

Typographic keynotes used in the manual are as follows:

<i>Style</i>	<i>Description</i>
Bold	Indicates a control or key to be pressed
<i>Italic</i>	Indicates a message displayed by the software

■ **Availability of functions**

Not all the functions described in this user manual are available to every user. Options are dependent on which device and which software options are purchased.

Similarly, the software panels can differ from the ones shown in this manual depending on the device and the purchased options.

The icons listed below are for specific COSMED products and their configurations:

<i>Icon</i>	<i>Device(s)</i>
mQ	microQuark
PFX	Pony FX, Pony FX Flowsafe, Pony FX MIP/MEP
Sp	Spiropalm, Spiropalm Plus, Spiropalm 6MWT
SPIRO	Quark Spiro
PFT	Quark PFT
CPET	Quark CPET
RMR	Quark RMR
K4	K4 b2
K5	K5
Q-Box	Q-Box (Quark PFT Body)

If a section only refers to a limited number of devices, all of its subsections refer the same devices unless otherwise specified.

Note: At this time, this software is **ONLY** compatible with the devices specified above. For all other COSMED devices please refer to Suite Software. In order to update the existing archives to this software, please read the installation chapter. Please be careful and adhere to the recommendations described in order to avoid archive corruption, compatibility problems and software crashes.

Note: At this time, the compatibility with K4 b² is limited to the test download feature. No real time testing is possible on K4 b² with OMNIA software.

Installation



□ Minimum System Requirements

- Intel Core i3 series processor or higher (Intel Core i5 recommended)
- OS Stand-alone/Network Client: Windows 7 SP1, 8, 8.1, 10 (32 or 64 bit)
OS Network Server: Windows Server 2008 SP2, 2008 R2 SP1, 2012, 2012 R2
- RAM 4GB (8GB recommended)
- HD with 10GB of free space
- Monitor with resolution of 1366x768 or greater (1920x1080 recommended)
- CD/DVD drive (for installation)
- A pdf reader software for opening the installed user manuals
-          Available USB port *
-  RS232 port available. If no RS232 port is available, an USB-to-Serial Adapter will be required (COSMED REF A-388-410-001)
-  For K5 units without the Bluetooth Long Distance module, a PC with internal Bluetooth or an external Bluetooth adapter will be required.

Depending on the Operating System configuration, it may be necessary to install one or more of the following packages:

- Windows Installer 4.5 (redistributable)
- Microsoft Framework 4.6.2 (redistributable)
- SQL Server 2014 SP1 Express (redistributable)
- Microsoft SQL Server 2014 Shared Management Object
- Microsoft SQL Server 2014 System CLR Types

The above packages are included in the OMNIA installation CD/folder. They can also be downloaded from the Microsoft website at the below links:

- <http://www.microsoft.com/en-us/download/details.aspx?id=8483> (for Windows Installer 4.5)
- <http://www.microsoft.com/en-us/download/details.aspx?id=53345> (for Microsoft Framework 4.6.2)
- <http://www.microsoft.com/en-us/download/details.aspx?id=46694> (for SQL Server 2014 SP1 Express)
- <http://www.microsoft.com/en-us/download/details.aspx?id=42295> (for SQL Server 2014, all the items)

* For devices with a dongle key, 2 USB ports are necessary (one for the dongle key, the other one for the device).

Important note: *In order to guarantee a proper and correct functioning of the software, and the safety and integrity of data stored into its database, we strongly recommend to use a PC optimized and dedicated exclusively to OMNIA. We furthermore strongly recommend to adequately protect the PC from viruses and other attacks from the Internet and/or local units.*

□ Software installation

■ Introduction

Note: If you are upgrading from an old OMNIA version, please create a backup of the database.

OMNIA comes in two different versions: Standalone and Network. The first one can be installed on a standalone PC only, the second one can be used in a network environment (client/server). For the installation of the Network version, please refer to the Network manual distributed together with the Network version.

Note: The installation of the Network version requires a local IT manager.

■ General warnings and notes

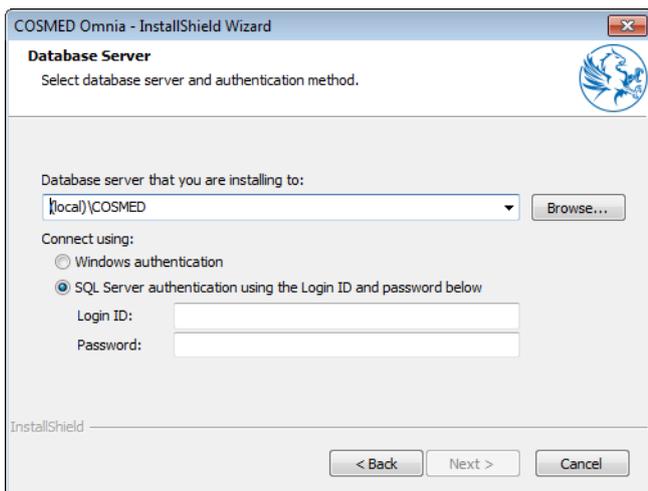
Important note: Due to a Microsoft SQL feature, the PC name and the Windows user name cannot be the same. If needed, either change one of those in order to perform the installation.

Do not connect the COSMED device to the PC before installing the software.

For devices with a dongle key, after installing the Omnia software and after transmitting the new firmware to the device, it won't be possible to use the device with the Suite software (the transmitted firmware is not compatible with the Suite software).

SQL Server installation can take several minutes (30 minutes or more, depending on the PC configuration).

In case an OMNIA SQL Server instance has been already installed please contact the local IT department and ask SQL administrator credentials of the SQL instance where the OMNIA database will be installed.



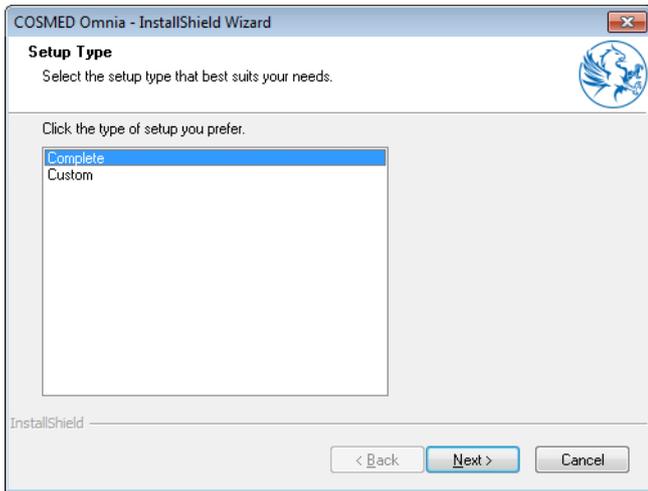
■ Installing the software (standalone installation)

Note: The software is copyright protected and should only be installed from the original disk.

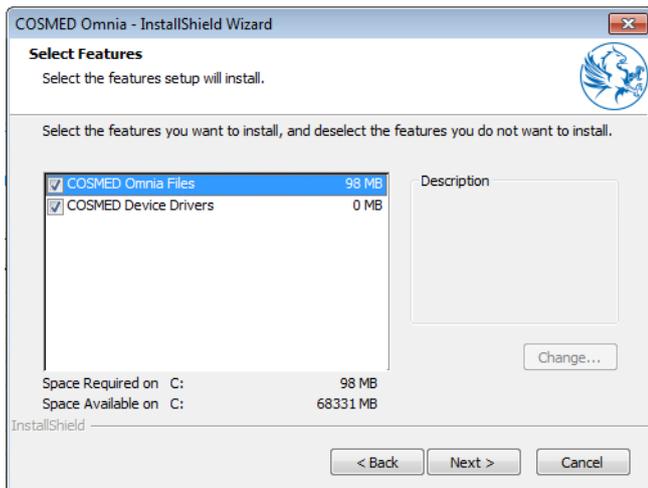
1. Please insert the OMNIA installation CD or run the executable file in the root directory of the installation package and select *Install Omnia*.
2. Follow the on-screen instructions to complete the installation.

Note: if additional components (e.g. .net framework) are required, OMNIA will ask for installation of these components.

3. During the installation, the following dialog boxes will open:

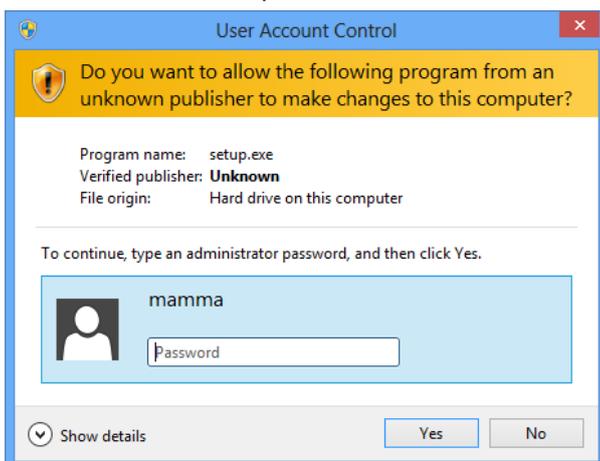


4. Select *Complete* to begin the complete installation (including all the features), select *Custom* to customize the installation. If you select *Custom*, the following dialog box will open:



You can select the following options:

- install Omnia files (mandatory, to install the software)
 - install COSMED device drivers (mandatory, to use the COSMED devices with the software)
5. If the Windows UAC is activated and you are not logged as Administrator, enter the Administrator password when required by the software. Click **Yes** to confirm and proceed.



6. Wait until installation completes.
7. If you have the Suite software already installed, it is mandatory to perform the steps reported in the following section before using OMNIA in order to successfully complete the upgrade.

Note: The software requires the firmware on the device to be version 3.0 or higher, it is included in the installation CD. This firmware is not compatible with old software (Suite), as well as the old firmware (up to 2.99) is not

compatible with this software. Only the old microQuark model (up to S/N 2012033999) is compatible with both software versions starting with firmware version 1.3 included.

□ Importing COSMED Suite archive into OMNIA

Note: For the Network version, please refer to the corresponding section on the OMNIA Network User Manual.

Note: Archives can only be imported from Suite Software version 10.0 and higher.

In order to upgrade from COSMED Suite (version 10.0 or higher) to OMNIA, follow the instructions below. Please contact COSMED Support for Suite versions earlier than 10.0.

1. **PFX Sp K4** Connect the COSMED device to the PC and download the tests to the Suite Software (please refer to the Suite Software user manual).
2. Perform a backup of the archive in the Suite Software (please refer to the Suite Software user manual).
3. Close the Suite Software.

Important note: The Suite Software and the OMNIA Software are not compatible. DO NOT USE the Suite Software anymore after this step.

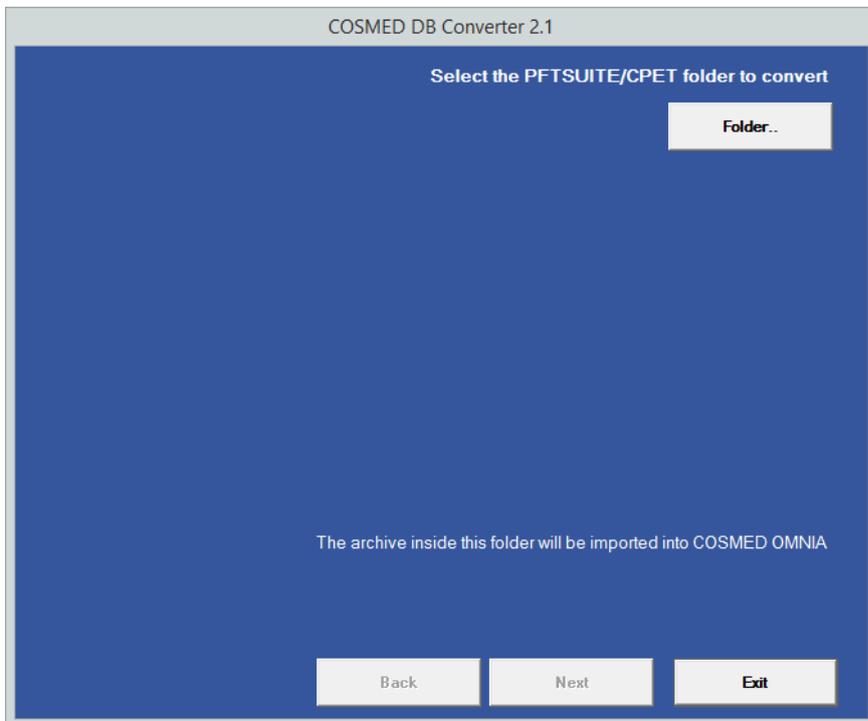
4. If necessary, copy the Suite Software installation folder to the same PC where OMNIA has been installed.
5. Please insert the OMNIA installation CD or run the executable file in the root directory of the installation package and select *Install DB Converter*.

Note: Install the *COSMED_DB_Converter* program only after the Omnia Software installation, otherwise it won't work.

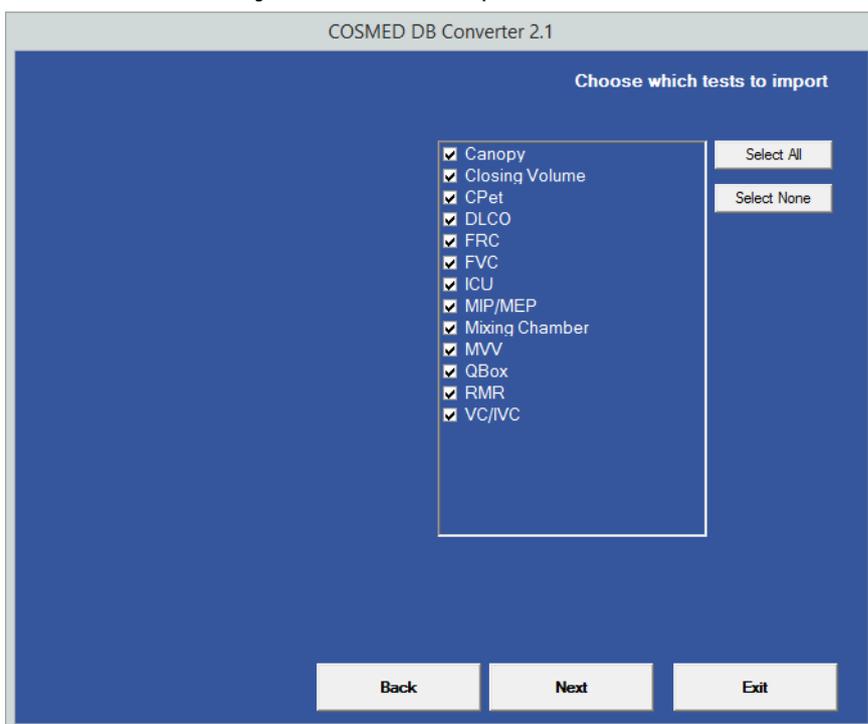
6. Follow the on-screen instructions to complete the installation.
7. If the Windows UAC is activated and you are not logged as Administrator, enter the Administrator user name and password.



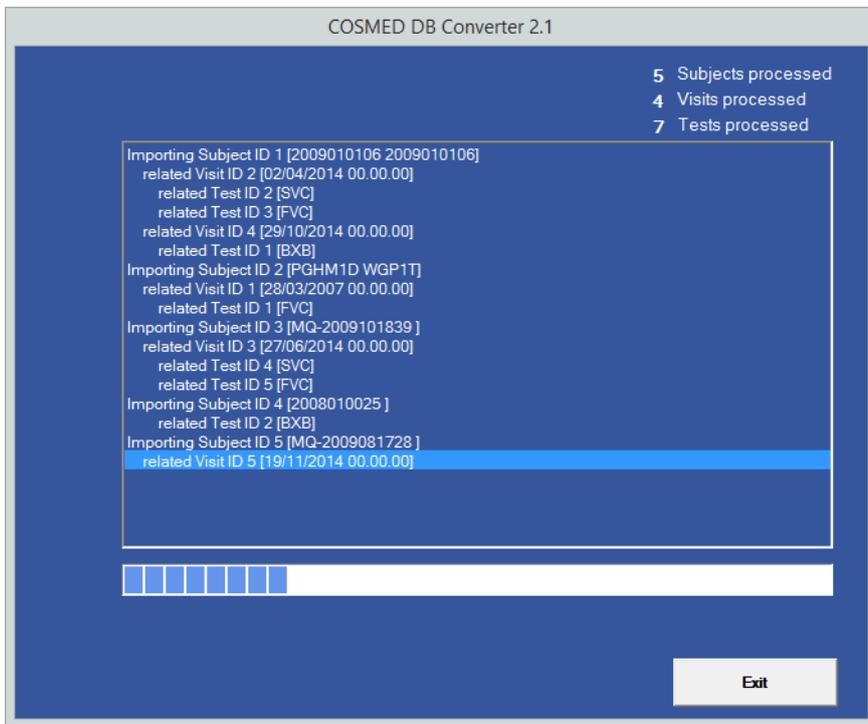
8. Wait until installation completes.
9. Start the *COSMED_DB_Converter* program by clicking on the Windows **Start** menu and selecting *COSMED/COSMED_DB_Converter/COSMED_DB_Converter*.



10. Press **Folder...** to select which archive you would like to convert.
11. Browse the folder containing the Suite Software and press **OK**.



12. Select the tests to be converted and press *Next*, then *START* to start the conversion.



13. To stop conversion, press *Exit* during the process, otherwise wait for the end of the operation and press *Exit* to complete.

Note: if the operation is stopped before the end, when the same conversion is launched for the second time, the tests already converted are automatically skipped.

14. Start OMNIA and make sure the archive has been successfully converted.

15. In order to avoid fatal errors, we strongly recommend to uninstall the Suite software by deleting the installation directory.

□ Open and close the software

When the installation is complete a Cosmed program group will be added to the Windows **Start/Programs** and an icon will be added to the desktop.

■ The Domain - an introduction

OMNIA users must be authenticated before accessing the software. A local domain or the network domain (if available) can be chosen in the authentication mask.

If the local domain is chosen, the user must enter the username and the password stored in the OMNIA database, if the network domain is chosen, the user must enter the network username and password.

■ Running the software for the very first time only - ADMINISTRATOR ONLY

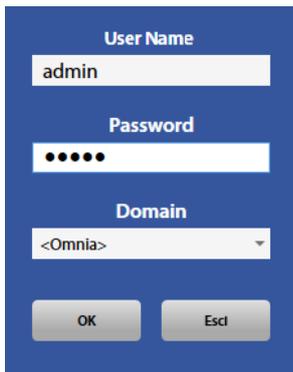
Note: This section is reserved for the first access to the software by the Administrator, just after the installation or after resetting the password.

1. Connect the USB dongle key (for devices with a dongle key, stand-alone version) or an authorized device (for devices without a dongle key, stand-alone version) to the PC.

Note: Network version does not require the USB dongle key nor the device in order to start the software. The dongle connected to the server is enough.

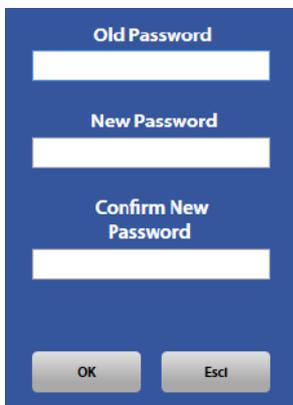
A dongle or a device is necessary in order to connect to the device (e.g. for calibration or testing purposes).

2. Open the Windows **Start** menu and select **COSMED/Cosmed Omnia/Cosmed Omnia** or press the *Cosmed Omnia* icon on the PC desktop.



3. Type the User Name *admin* and the password *admin*. Press **OK**.

Note: For this first time, please keep *<Omnia>* in the Domain field.



4. A new dialog box will appear, the software requires you to change the password. To do so, enter the old password (*admin*), a new password selected by the user and the confirmation of this new password. Press **OK**.

Warning: Please be very careful to store this new password in a safe place. If you forget it, perform the password reset according to the instructions in the section "Reinstall the software". This reset can be performed by the system administrator only.

■ Running the software for the very first time - NEW USER ONLY

A new user is a user added by the Administrator. This section is reserved for the first access to the software by a user just added by the Administrator.

1. Connect the USB dongle key (for devices with a dongle key, standalone version) or an authorized device (for devices without a dongle key, stand-alone version) to the PC.

Note: Network version does not require the USB dongle key nor the device in order to start the software. The dongle connected to the server is enough.

A dongle or a device is necessary in order to connect to the device (e.g. for calibration or testing purposes).

2. Open the Windows **Start** menu and select **COSMED/Cosmed Omnia/Cosmed Omnia** or press the *Cosmed Omnia* icon on the PC desktop.



3. If the user belongs to the *Omnia* domain, type the user name and ignore the password, leaving this field blank. If the user belongs to the network domain, enter the network user name and the password. Press **OK**.



4. If the user belongs to the *Omnia* domain, a new dialog box will appear, the software requires you to enter a password to login. To do so, enter the selected password and the confirmation on this one. Press **OK**.

Warning: Please be very careful to store this new password in a safe place. If you forget the it, perform the password reset according to the instructions in the section "Reinstall the software". This reset can be performed by the system administrator only.

■ Running the software

1. Connect the USB dongle key (for devices with a dongle key) or an authorized device (for devices without a dongle key) to the PC.
2. Open the Windows Start menu and select **COSMED/Cosmed Omnia/Cosmed Omnia** or press the *Cosmed Omnia* icon on the PC desktop.
3. Enter the User Name, the password and the domain. Press **OK**.

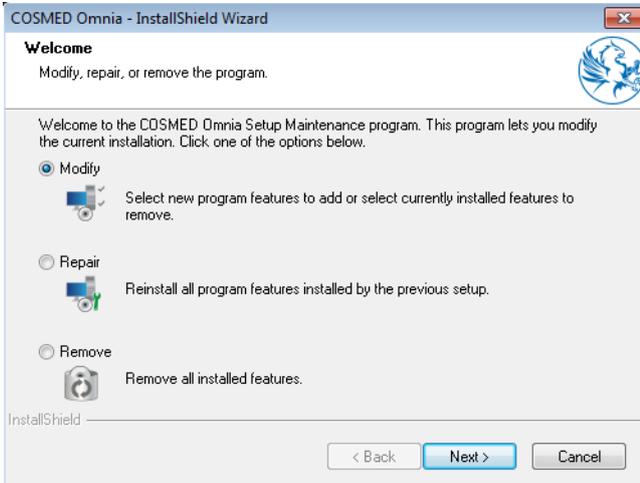
■ Quit the software

Press the  icon in the top right corner. Confirm by pressing **Yes**.

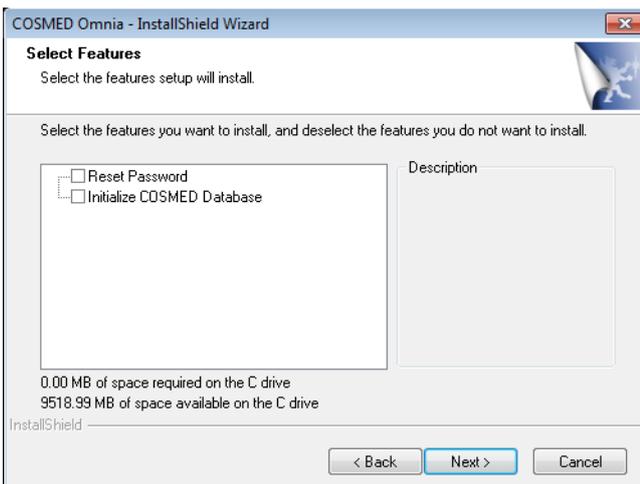
□ **Modify/repair/remove software**

Note: The operations described in this section are valid only if the software release in the installation CD is identical to the one already installed.

If you start the software installation procedure when the software is already installed, the following dialog box will appear:



Select **Modify** if you want to modify the installed features.



Note: By selecting **Modify**, you can also select to initialize the database (for example, if it is corrupted, or if you want to delete all the data in the database) or reset the password (for example, if the password was forgotten).

Note: Initializing the database will delete all the data included in it.

Select **Repair** if you want to repair the software files.

Select **Remove** if you want to uninstall the software.

■ **Alternative way to uninstall the software (for OMNIA 1.1 or higher)**

Important note: This section is not applicable to OMNIA 1.0 version. Do not try to uninstall the 1.0 software version using the methods described in this section.

Instead of starting the installation procedure as described above, OMNIA (starting from version 1.1) can be uninstalled by selecting **Cosmed Omnia** in the Windows control panel or selecting **Uninstall Cosmed Omnia in the Start/Cosmed/Cosmed Omnia** menu.

Follow the on-screen instructions in the dialog boxes to complete the operation.

□ License management

In order to allow the software and device to operate properly together, both software and device must be authorized.

For database access and consultation only, the Network version doesn't need a local authorization (see below).

The authorization works differently depending on the device (with or without dongle key).

■ Devices supplied with a dongle key

The devices supplied with dongle key must work together with an USB dongle key that contains the license for this software version.

Note: The dongle is associated to a specific device and S/N. A dongle doesn't work with a different device. The dongle also contains the software and firmware versions for which it is authorized. Do not attempt to update software and/or firmware without having a valid license, otherwise the software and/or the device will become inoperable.

Note: If you change the dongle when the software is running, in order to use a different device, please close and restart the software in order to acquire the proper license.

■ Devices supplied without a dongle key

The devices supplied without a dongle key already arrive authorized by COSMED to operate with the software release included in the packaging, and contain the corresponding license.

Note: The license stored on the device contains the software and firmware versions for which it is authorized. Do not attempt to update software and/or firmware without having a valid licence, otherwise the software and/or the device will become unusable

Note: If you connect another device when the software is running, please close and restart the application in order to acquire the proper licenses

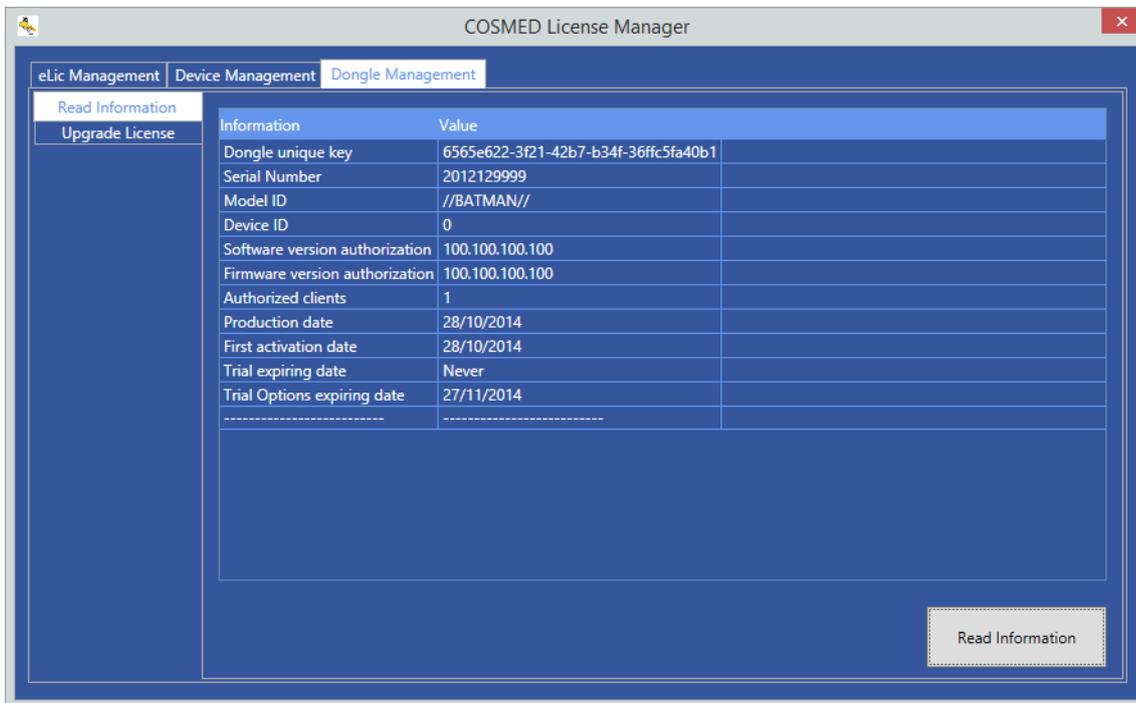
■ Licensers

Licensers is an external program supplied with the Software Omnia. Open the Windows **Start** menu and select **COSMED/Cosmed Omnia/Omnia Licensers**.

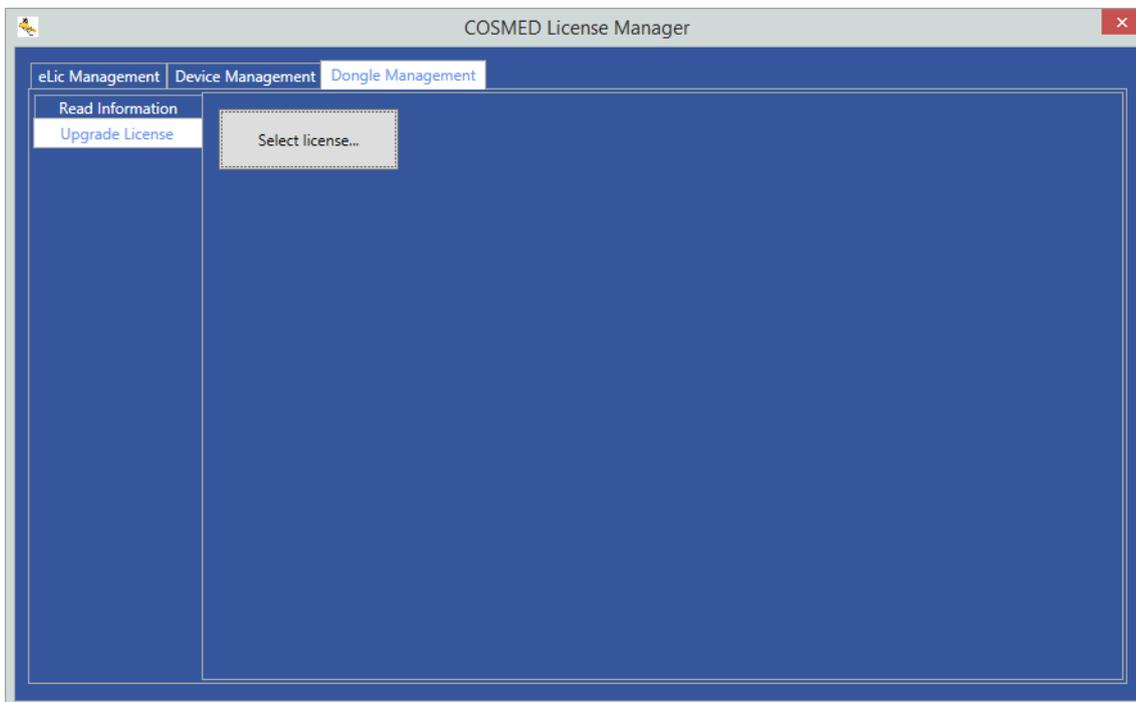
You can manage the licences on the device or on the dongle, access them, update them (for future software and firmware releases) and obtaining useful information about them.

Dongle management (for devices supplied with a dongle key)

For these devices, the Dongle management tab must be used.



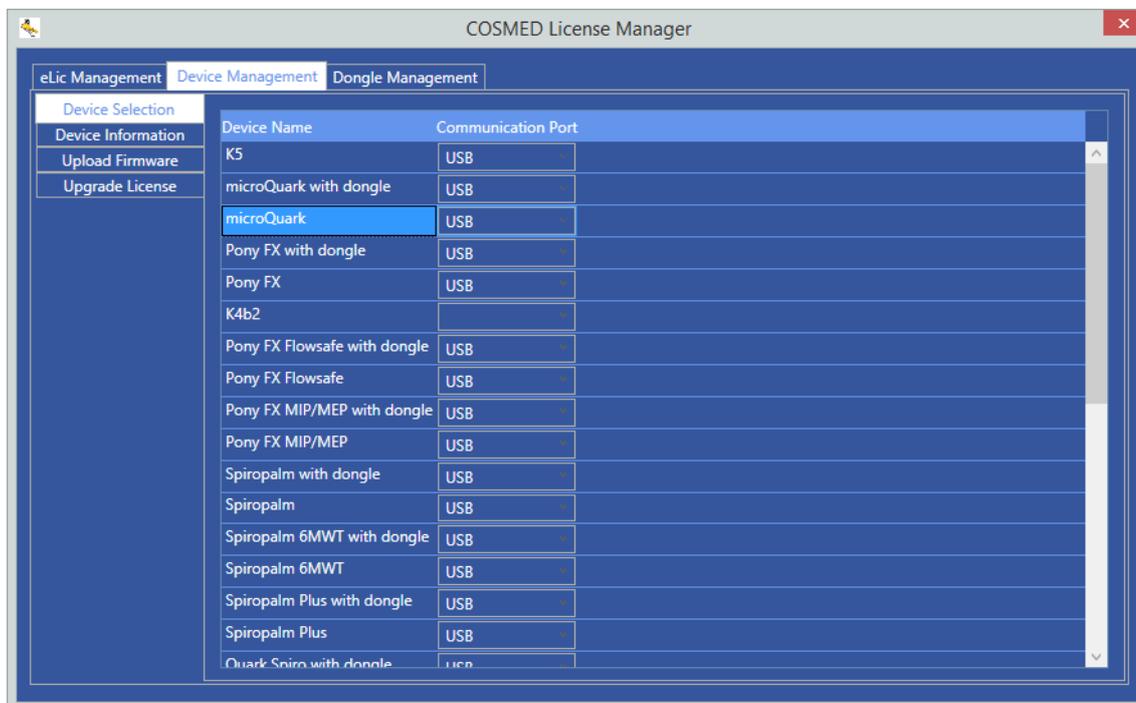
In the *Read Information* Tab, press **Read Information** in order to obtain the license information contained in the dongle key.



In order to update the license on the dongle key, please open the Update Dongle License tab and press **Select License**. ... Select the license file to be sent to the dongle key. The new license will be sent to the dongle, and it will be updated accordingly.

Device management (for devices supplied without a dongle key)

For these devices, the **Device management** tab must be used.

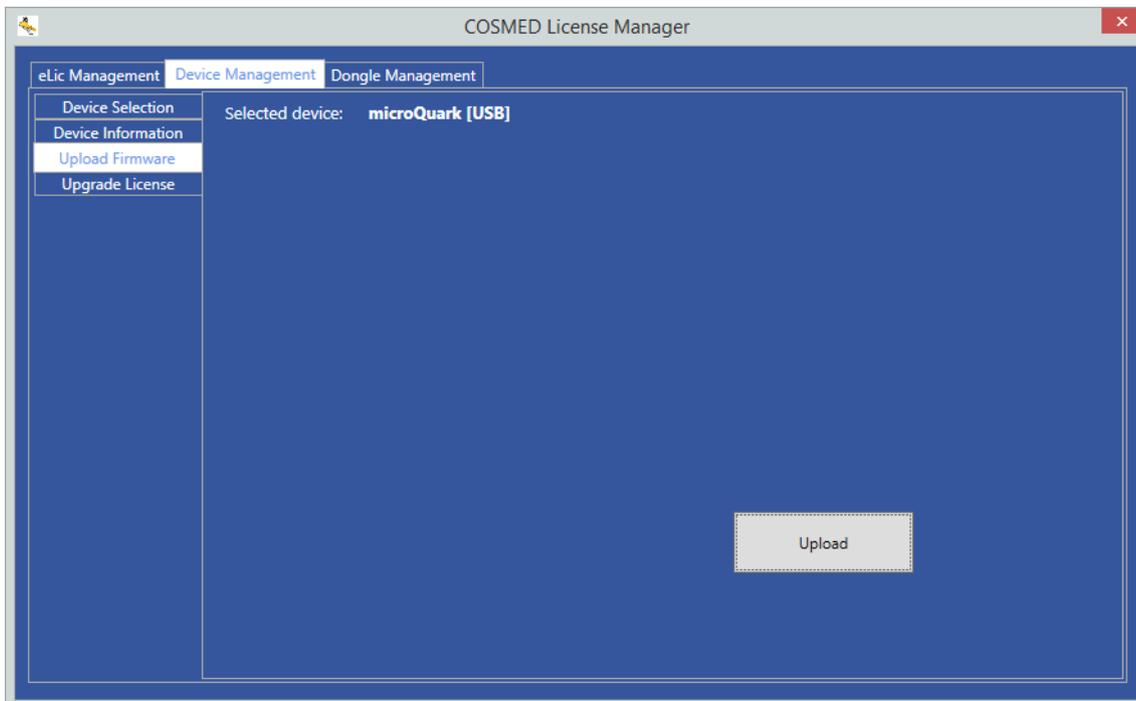


In the *Device Selection* tab, please select the device currently connected to the PC. When the device is selected, the other tabs become active.

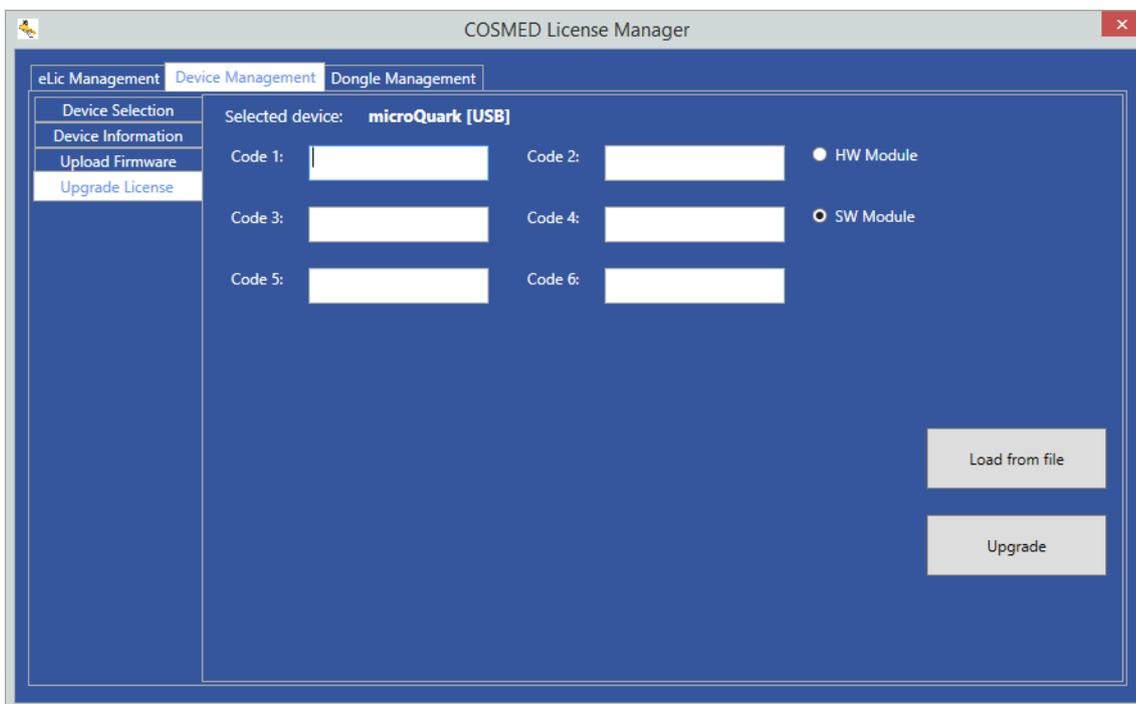


In the *Device Information* tab, press **Read Information** in order to obtain the license information contained on the device
Press **Clear cache** in order to clear the cached files on the PC hard drive.

Note: The cached files contain the information about the authorized devices. Clearing the cached files, the 30-day period for this device will be cancelled. In order to start the software, an authorized device must be connected to the PC again.



In order to update the firmware on the device, select the Upload Firmware tab and press **Upload**.



In order to update the license on the device, please open the Upgrade Device License tab, enter the license codes and press **Upgrade**.

Alternatively, if you already have a file with the license, it is possible to load the license from this file, by pressing the **Load from file** button and selecting the proper file.

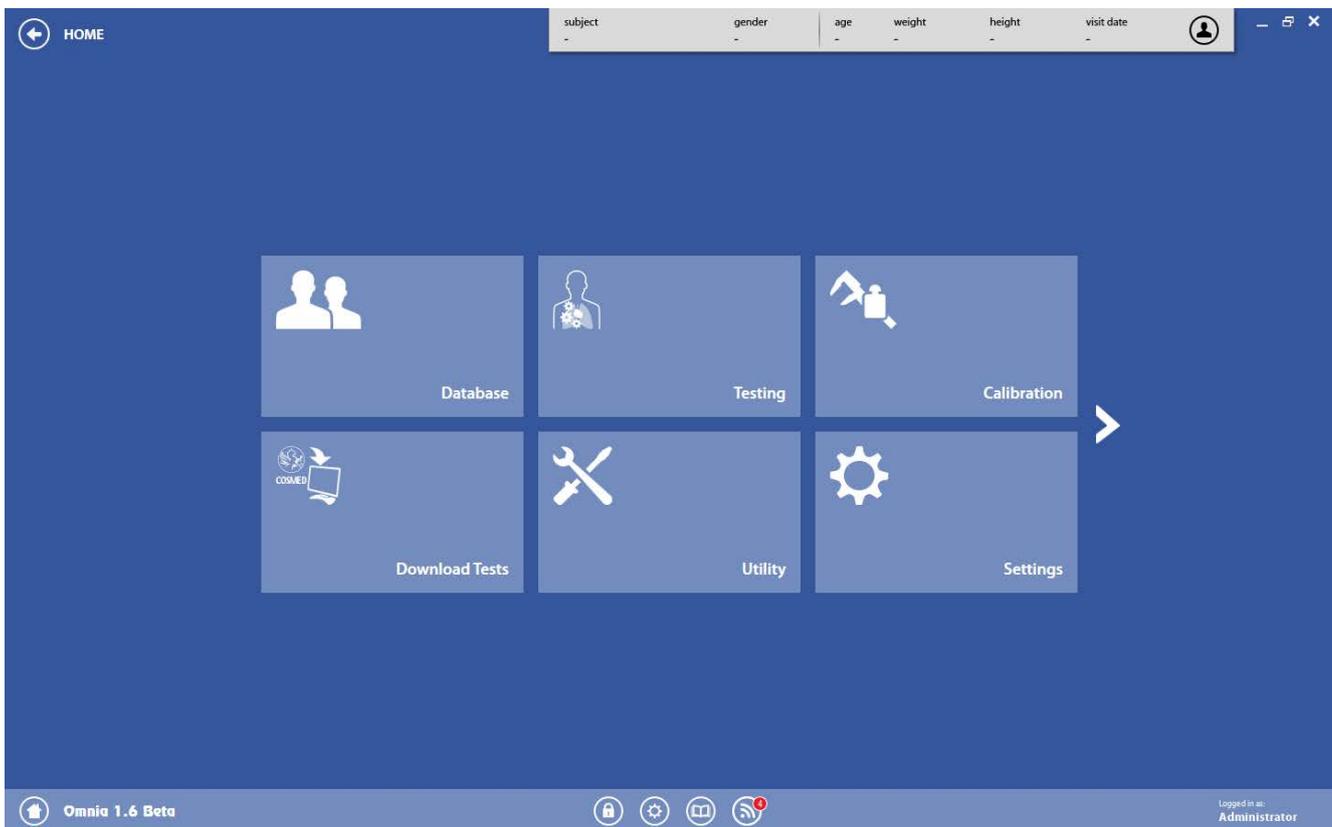
The new license will be sent to the device, and will be updated accordingly.

User interface



□ *Functioning principles of the software*

The software panels include some central tiles and some icons at the four corners. Below, the home panel is shown:



The central tiles lead to the corresponding section of the software. On the home panel, there are six tiles which allow the user to:

- **Database:** open the subject database
- **Testing:** start a test
- **Calibration:** start the calibration program
- **Download tests:** start the test download interface
- **Utility:** open the utility tools
- **Settings:** open the Settings window
- **Support:** connect to the COSMED support website

Note: *In order to have the Support function working, you must have an active Internet connection.*

The  and  icons allow you to navigate through the different pages of the panel.

The other icons have the following meanings:

-  Returns to the previous screen
-  Minimizes the window
-  Resize the full screen in a window (active for full screen view only)
-  Resize the window in full screen (active for windows view only)
-  Closes the software

Note: *this icon doesn't close the current panel, it closes the entire software program (the user is prompted for a confirmation).*

-  Returns to the home panel



Logouts user



Opens the Settings window

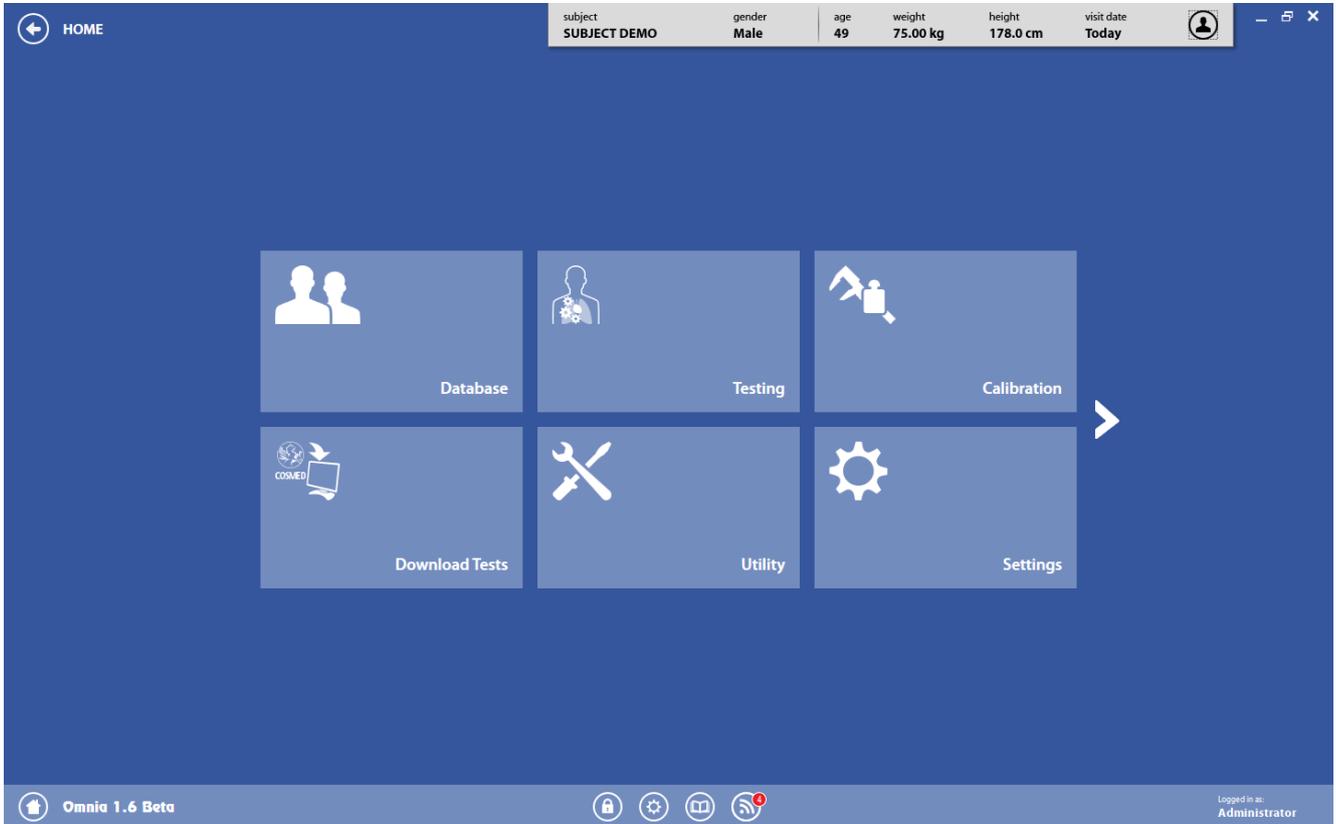


Opens this user manual



If the corresponding checkbox is enabled (see the *Settings/General* section), it shows how many new messages from COSMED are present.

An **USB** icon is displayed in the lower right part of the screen when a device is connected to the PC through the USB port.



On the top part of the panel, as well as on all the other panels, the selected subject data and his/her anthropometric data are displayed, if a subject was already selected from the database.



By clicking on the subject icon, it is possible to:

- Start a new visit (*New Visit*).
- Start a new test (*New Test*), enabled only if a visit for the current day was previously created.
- Access the database (*Database*).
- Apply/remove the privacy settings (*Set privacy*), showing the subject data on the panel.

User interface

Dialog windows

The typical operating environment of Microsoft Windows is the Dialog box. This window includes a series of fields which allows you to enter information.

Using the keyboard

- To move the cursor between fields press the **Tab** key until you reach the desired field.
- Press **Enter** to confirm the information input on the dialog box or press **Esc** to cancel the changes.

Using the mouse

- To move the cursor among fields move the mouse to the desired field and left-click.
- Left-click on **OK** to confirm the information input in the dialog box or click to **Cancel** the changes.

Scroll bars

Some windows have scroll bars that allow you to see data exceeding the window space available.

- To move the scroll bar by row, click the arrows at the end of the scroll bars.
- To move the scroll bar by page, click the grey area on either side of the scroll field.

Data tables

Many of the tables in which data are presented exhibit the same behavior:

- By clicking on the column header, the table will be sorted by this column (ascending or descending)
- By clicking on the funnel symbol near the column header, it is possible to filter according to different criteria.
- The order of the columns can be modified by clicking and dragging them in the desired position.

Fields

In order to fill in a field, you can type the desired value in it. If a field has predefined options, by clicking on the arrow near the field you can select the item to be entered in it.

If the choice is restricted to a limited number of values, the options can be listed by clicking anywhere in the field.

Shortcuts

The following shortcuts are available in the software:

- Esc** Returns to the previous screen
- F1** Opens the software user's manual
- F2** Returns to the Home panel
- F5** Start key (in test execution)
- F6** Stop key (in test execution)
- F7** Redo key (in test execution)
- F8** Abort key (in test execution)
- F9** Starts the turbine calibration
- F10** Opens the control panel

Shortcuts are also shown near the icons during the operation of the software.

Settings



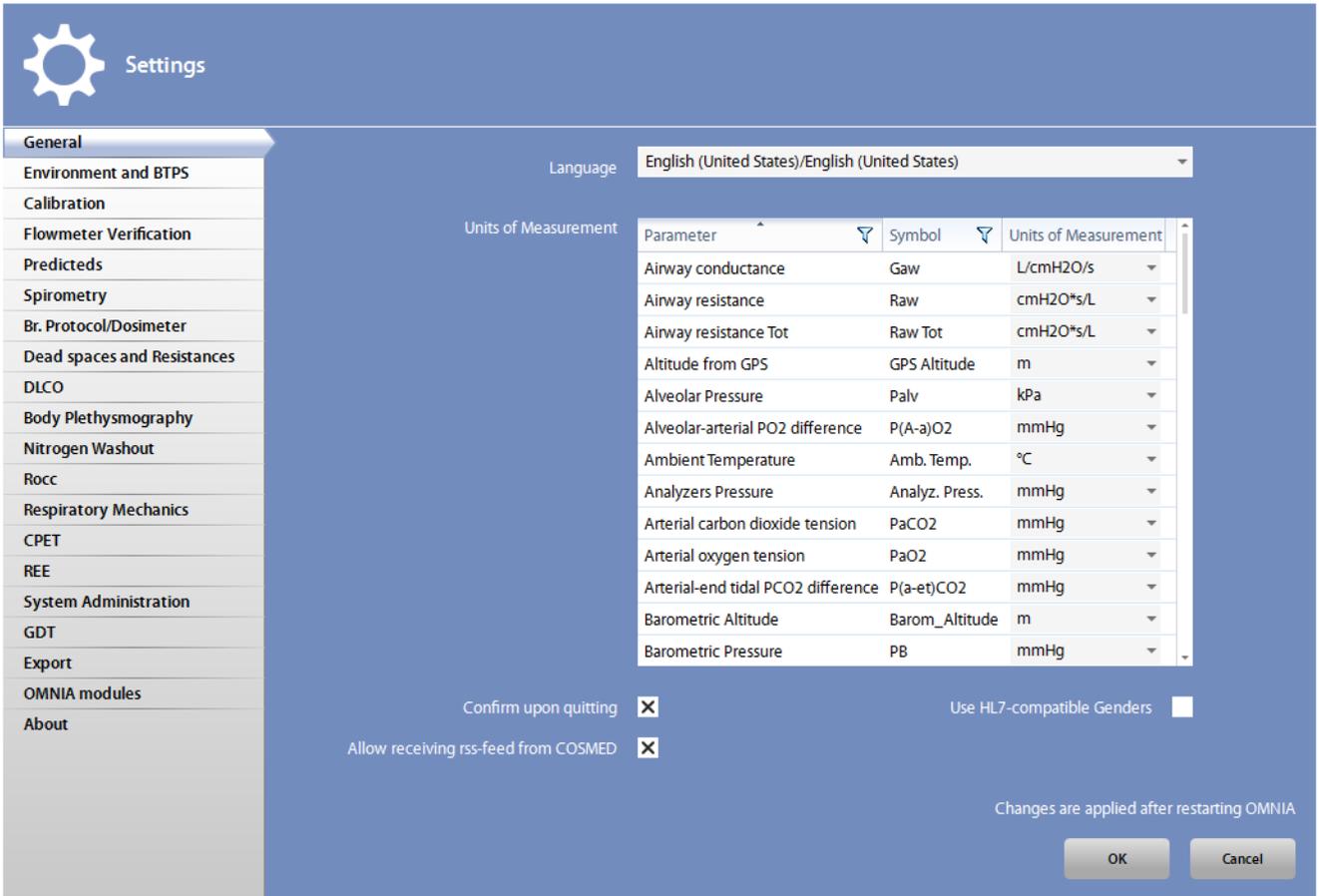
□ Introduction



To enter in the Settings dialog box, press the  icon in the lower-right corner of the screen or the **Settings** tile on the home panel. The *Settings* dialog box is divided into subsections, each of them can be accessed through the list on the left side of the box.

To confirm the settings, press **OK** or **Cancel** to cancel the changes.

All the settings remain if the software is uninstalled and reinstalled.



The screenshot shows the 'Settings' window with the 'General' tab selected. On the left is a sidebar menu with various settings categories. The main area contains the following settings:

- Language:** English (United States)/English (United States)
- Units of Measurement:** A table with columns for Parameter, Symbol, and Units of Measurement.
- Confirm upon quitting:** (indicated by an 'X' icon)
- Use HL7-compatible Genders:**
- Allow receiving rss-feed from COSMED:** (indicated by an 'X' icon)

At the bottom right, there are 'OK' and 'Cancel' buttons, and a note: 'Changes are applied after restarting OMNIA'.

Parameter	Symbol	Units of Measurement
Airway conductance	Gaw	L/cmH2O/s
Airway resistance	Raw	cmH2O*s/L
Airway resistance Tot	Raw Tot	cmH2O*s/L
Altitude from GPS	GPS Altitude	m
Alveolar Pressure	Palv	kPa
Alveolar-arterial PO2 difference	P(A-a)O2	mmHg
Ambient Temperature	Amb. Temp.	°C
Analyzers Pressure	Analyz. Press.	mmHg
Arterial carbon dioxide tension	PaCO2	mmHg
Arterial oxygen tension	PaO2	mmHg
Arterial-end tidal PCO2 difference	P(a-et)CO2	mmHg
Barometric Altitude	Barom_Altitude	m
Barometric Pressure	PB	mmHg

In this tab you can select:

- *Language:* the software language.
- *Units of measurement:* the unit of measurement for each parameter.
- *Confirm upon quitting:* if the software must ask a confirmation when the  icon is pressed
- *Use HL-7 compatible genders:* if the allowed genders are all the genders included in the HL7 protocol, instead of *Male* and *Female*. HL7 genders are: *Female, Male, Transgender, Hermaphrodite/Undetermined, Other*.
- *Allow receiving rss-feed from COSMED:* if the user choose to receive RSS-feed directly from COSMED (for example, for new software releases). If enabled, in the lower part of the screen the  icon will be shown together with the number of new messages (if any).

Changes will be applied only after restarting the software.

The screenshot shows the 'Settings' application with the 'Environment and BTPS' tab selected. The sidebar menu includes: General, Environment and BTPS (selected), Calibration, Flowmeter Verification, Predicteds, Spirometry, Br. Protocol/Dosimeter, Dead spaces and Resistances, DLCO, Body Plethysmography, Nitrogen Washout, Rocc, Respiratory Mechanics, CPET, REE, System Administration, GDT, Export, OMNIA modules, and About. The main content area is divided into two sections: 'Environment' and 'Flowmeter'. The 'Environment' section has input fields for Temperature (25 °C), Pressure (760 mmHg), and RH (50 %). The 'Flowmeter' section has input fields for Temperature (34 °C) and RH (100 %). Below these sections are two checkboxes: 'Apply Inspiratory BTPS' (checked) and 'Apply Expiratory BTPS' (checked). At the bottom right, there are 'OK' and 'Cancel' buttons.

In this tab you can set:

- *Environment* section
 - *Temperature*: the environmental temperature
 - *Pressure*: the environmental pressure
 - *RH*: the relative humidity.
- *Flowmeter* section
 - *Temperature*: the temperature at the flowmeter (we suggest to maintain the default value 34°C).
 - *RH*: the humidity at the flowmeter (we suggest to maintain the default value 100%).
- *Apply Inspiratory BTPS*: if the BTPS correction must be applied on the inspiration
- *Apply Expiratory BTPS*: if the BTPS correction must be applied on the expiration.

Note: For the environmental parameters, if the device has an embedded sensor, this value will be overwritten by the measured value when a test is started. At this time, only the environmental temperature sensor is included in the devices.

Settings

Calibration

Syringe
Volume mL

DLCO Reference Gas (%)
CH4 CO O2

N2 Gas References (%)
O2 CO2 O2 100%

ERGO/REE/ICU Reference Gas (%)
O2 CO2

Room Air Reference (%)
O2 CO2

O2 Span During Test (%)
Ergo ICU

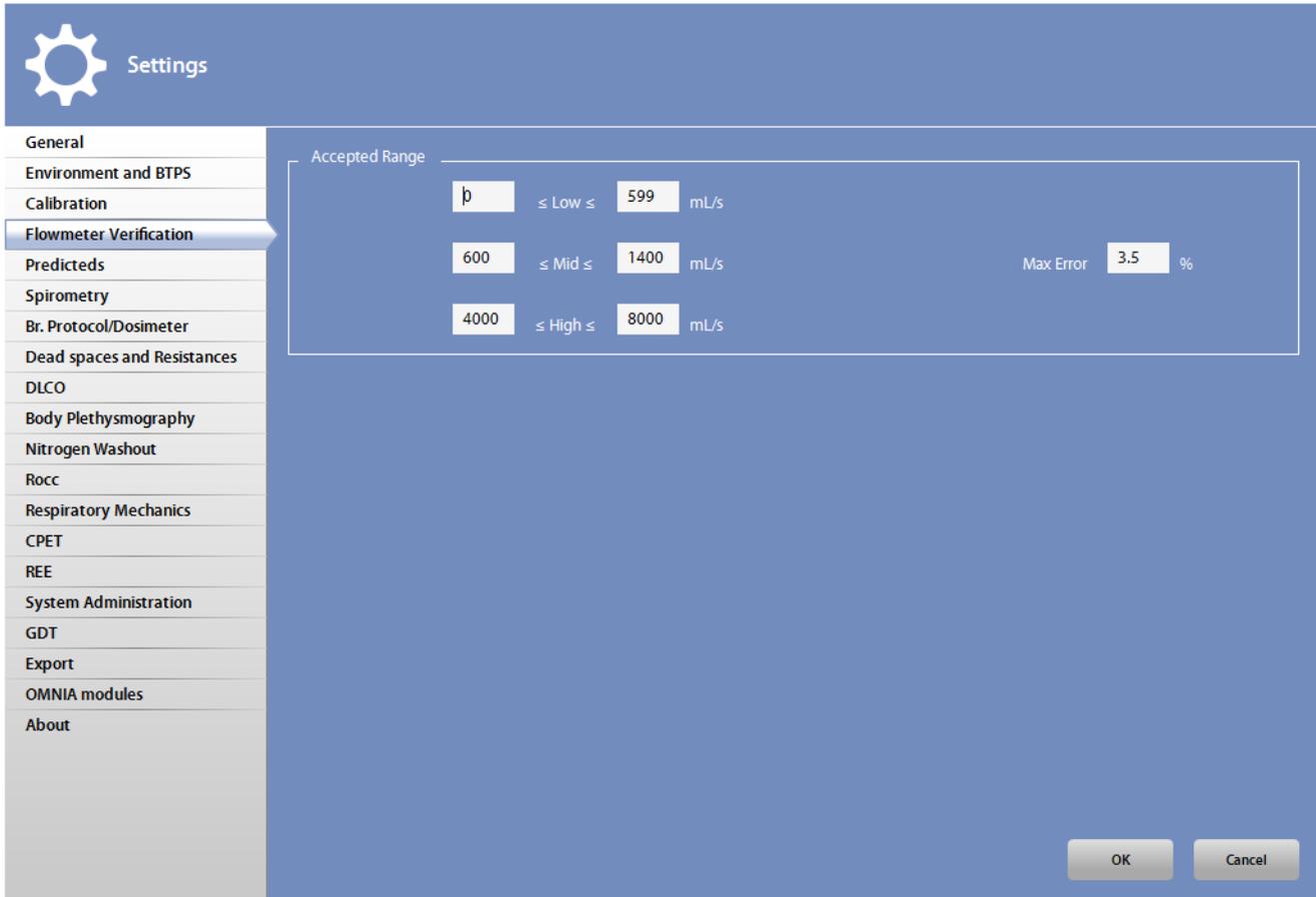
Body Box
Target Pressure cmH2O

OK Cancel

In this tab you can set:

- *Syringe/Volume*: the volume of the calibration syringe used for volume/flow calibration (in ml).
- *DLCO Reference gas*: the concentration of the reference gas for DLCO.
- *N2 Gas References*: the concentration of the reference gases for FRC.
- *ERGO/REE/ICU Reference gas*: the concentration of the reference gas for ergometry tests (CPET, REE and ICU tests).
- *Room Air Reference*: the concentration of the room air gas (value are set to 20.93% for oxygen and 0.04% for CO₂, and they cannot be modified by the user).
- *O₂ span during test*: The range of the O₂ sensor used during ERGO (22% as default) and ICU (70% as default) tests. Please change these values only if you are using an application requiring a different range for the oxygen sensor.
- *Body Box/Target Pressure*: the target pressure of the Q-Box.

The icon in the lower part of the screen allows to restore the factory settings.



Settings

General

Environment and BTPS

Calibration

Flowmeter Verification

Predicteds

Spirometry

Br. Protocol/Dosimeter

Dead spaces and Resistances

DLCO

Body Plethysmography

Nitrogen Washout

Rocc

Respiratory Mechanics

CPET

REE

System Administration

GDT

Export

OMNIA modules

About

Accepted Range

≤ Low ≤ mL/s

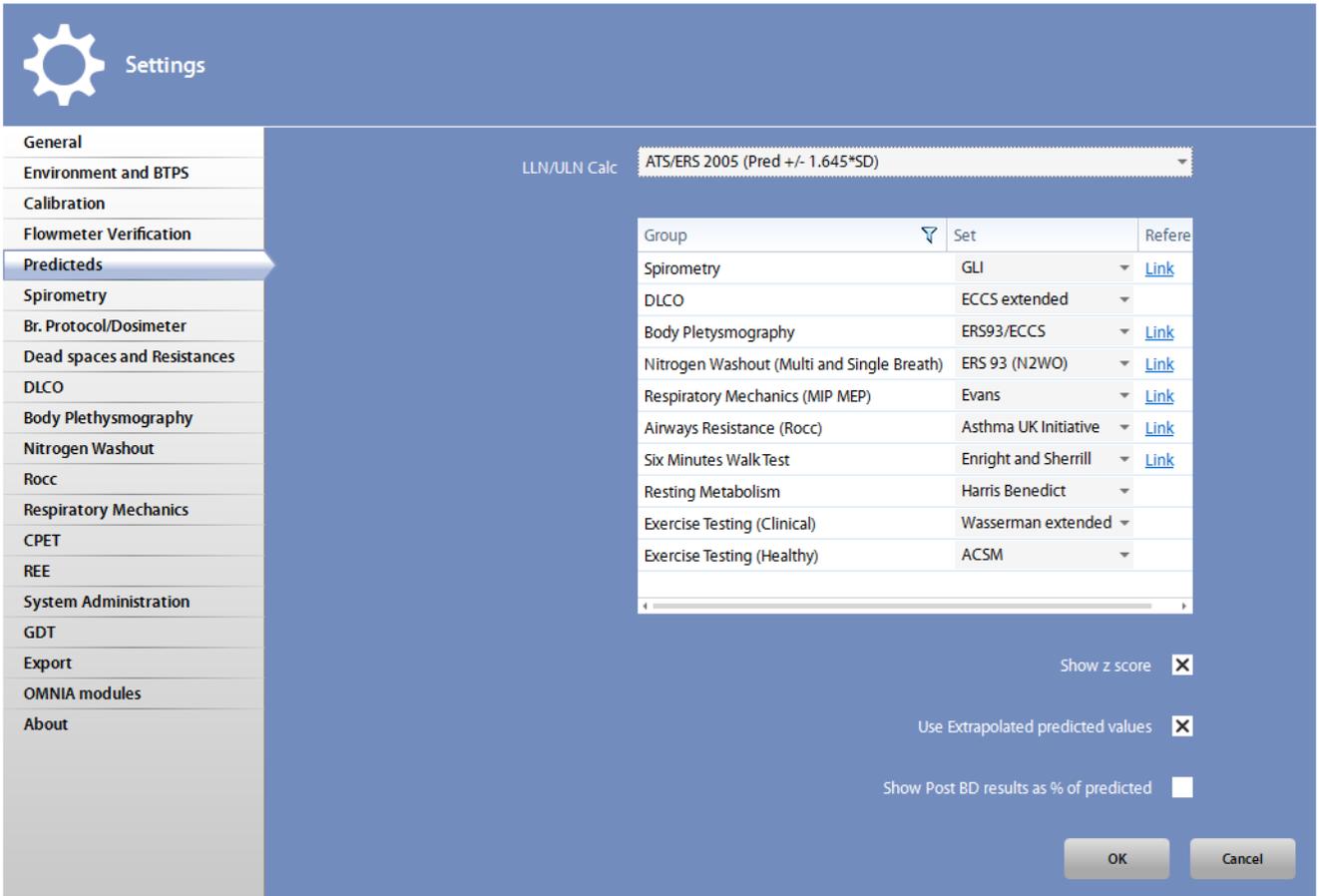
≤ Mid ≤ mL/s

≤ High ≤ mL/s

Max Error %

In this tab you can set:

- *Accepted Range*: The acceptable flow range during the flowmeter verification for low, medium and high flows
- *Max error*: The maximum accepted error for the volume measured during the flowmeter verification



LLN/ULN Calc ATS/ERS 2005 (Pred +/- 1.645*SD)

Group	Set	Refere
Spirometry	GLI	Link
DLCO	ECCS extended	
Body Pletysmography	ERS93/ECCS	Link
Nitrogen Washout (Multi and Single Breath)	ERS 93 (N2WO)	Link
Respiratory Mechanics (MIP MEP)	Evans	Link
Airways Resistance (Rocc)	Asthma UK Initiative	Link
Six Minutes Walk Test	Enright and Sherrill	Link
Resting Metabolism	Harris Benedict	
Exercise Testing (Clinical)	Wasserman extended	
Exercise Testing (Healthy)	ACSM	

Show z score
 Use Extrapolated predicted values
 Show Post BD results as % of predicted

OK Cancel

In this tab you can select:

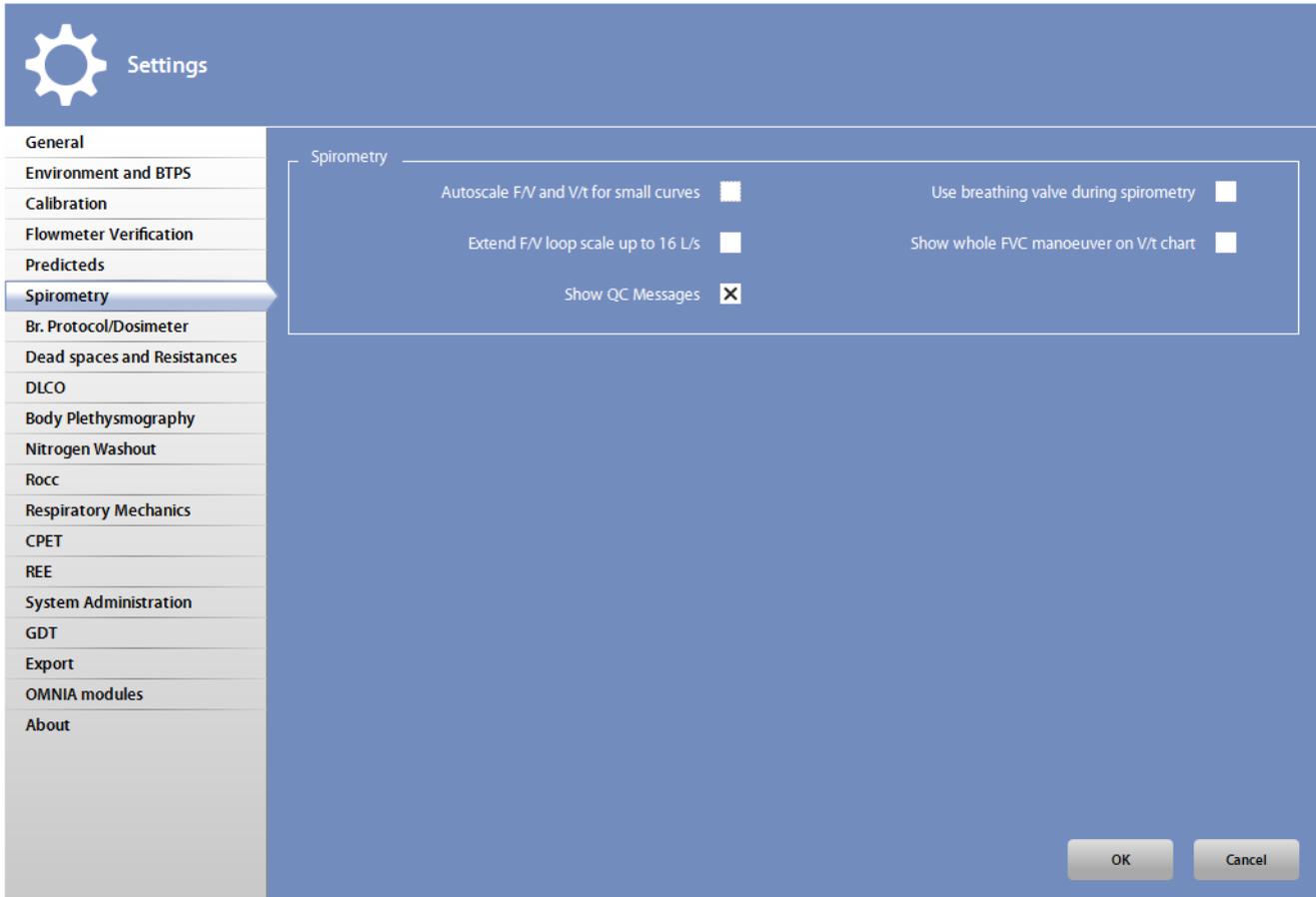
- *LLN/ULN Calc*: the algorithm for *LLN* (lower limit of normal) and *ULN* (upper limit of normal) calculation.
- For each test group, the default predicted set in use. This is the default predicted set in each visit card when it is created. It is possible to use a different set for specific users, to be specified when creating a visit card.

By clicking on the link, the Internet Browser will be opened and you will be redirected to the webpage of the scientific publication for this predicted set.

Note: You must have an active Internet connection in order to access to the linked pages.

- *Show Z-Score*: if the Z-Score must be shown near the results. The Z-Score is how many SD (standard deviation) the measured value is above or below the predicted value.
- *Use extrapolated predicted values*: if the predicted values can be extrapolated, in case some data (age, weight, height, ...) is outside the allowed range for the selected predicted set.
- *Show Post BD results as % of predicted*: the results of the post BD test are displayed as percentage of the predicted values instead of the PRE results

Note: Only a subset of the predicted sets can be extrapolated. For the other sets the extrapolation cannot be applied and the corresponding predicted values are blank (in case of extrapolation required) even if the box is checked.



In this tab you can select:

- *Autoscale F/V and V/t for small curves*: to activate the autoscale for F/V and V/t curves. The autoscale doubles the scale for both flow and volume if the measured values and the predicted values are small (in the range $-4/+7$ l/s and $0/+8$ l respectively).
- *Use breathing valve during spirometry*: if the spirometry tests are performed with the breathing valve. This function is enabled for Quark series only.
- *Extend F/V loop scale up to 16 L/s*: if the F/V graph must be scaled with a flow range up to 16 L/s (only during test edit and test results).
- *Show whole FVC manoeuvre on V/t chart*: if a Spirogram is shown instead of the V/t plot. This is applied only for the tests performed with this options activated and only for the real-time visualization.
- *Show QC messages*: if the Quality Control messages must be shown at the end of the test.

Settings

- General
- Environment and BTPS
- Calibration
- Flowmeter Verification
- Predicteds
- Spirometry
- Br. Protocol/Dosimeter**
- Dead spaces and Resistances
- DLCO
- Body Plethysmography
- Nitrogen Washout
- Rocc
- Respiratory Mechanics
- CPET
- REE
- System Administration
- GDT
- Export
- OMNIA modules
- About

Bronchoprovocation Protocol

Default

Dosimeter

Nebulizer Driving Pressure: 37 psi

Nebulizer Output: 0.9 mL/min

Accepted Pressure Error: 10 %

Start Delay: 0 ms

Triggering flowmeter: Turbine 28mm

OK Cancel

This tab is divided in two sections.

In the *Bronchoprovocation protocol* section you can select:

- The default protocol for bronchoprovocation tests (*Default*).

In the *Dosimeter* section you can select:

- *Nebulizer Driving Pressure*: pressure at the nebulizer input (Quark *Nebulizer* output)
- *Nebulizer Output*: flow at the nebulizer output
- *Accepted Pressure Error*: accepted error of the nebulizer driving pressure
- *Start Delay*: delay for agent delivery after the start of the inspiration
- *Triggering flowmeter*: the flowmeter connected to the nebulizer, used for detecting the flow during the maneuver

The screenshot shows the 'Settings' window with the 'Dead spaces and Resistances' tab selected. The sidebar on the left lists various settings categories, with 'Dead spaces and Resistances' highlighted. The main area contains the following settings:

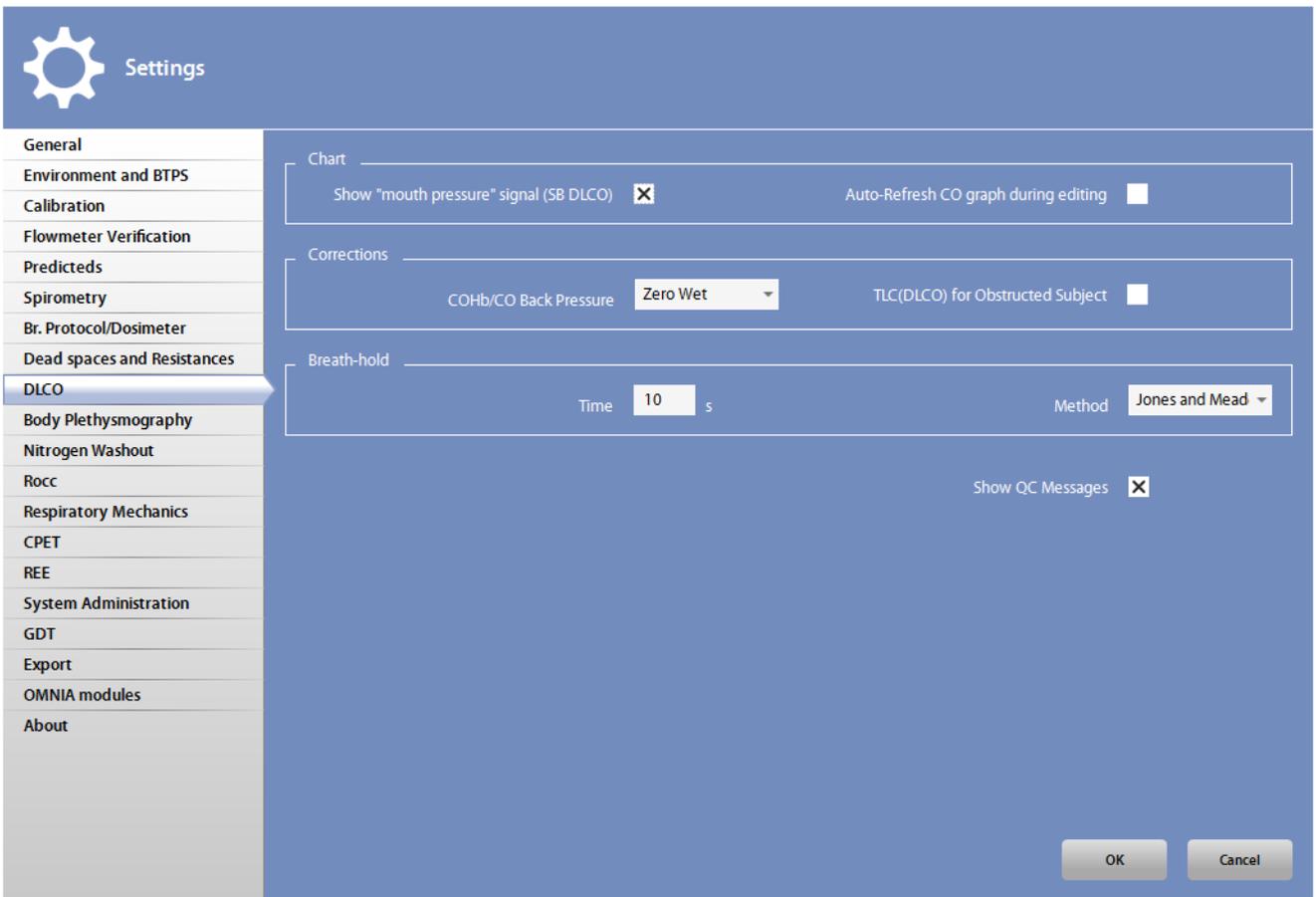
Setting	Value	Unit
X9 system dead space (VDs)	110	mL
Turbine system dead space (VDs)	95	mL
COSMED Filter dead space (VDf)	60	mL
Anatomic dead space (VDa)	0	mL
Valve Dead Space (VDv)	75	mL
Use ATS VDa	<input checked="" type="checkbox"/>	
Filter Resistance	0.5	cmH ₂ O/L/s

At the bottom right of the window, there is a 'Reset' icon (a square with a circular arrow) and 'OK' and 'Cancel' buttons.

In this tab you can set:

- The system dead spaces for the different items
- If the ATS dead space value must be used for the anatomic dead space (*Use ATS VDa*)
- The resistance of the antibacterial filter used (*Filter Resistance*).

Press the  icon to restore data to the factory presets.



In this tab you can set:

- **Chart section:**
 - *Show "mouth pressure" signal (SB DLCO):* if (in single breath DLCO tests) the mouth pressure signal is presented to the user, both in real time and in test viewing (only available for Q-Box with X9).
 - *Auto-refresh CO curve during editing:* if the CO curve (during the edit) must be updated with the zero wet correction.
- **Corrections section:**
 - *COHb/CO back pressure:* which correction method should be applied for carboxyhemoglobin and CO back pressure. The COHb corrects the values if the entered COHb value is more than 2%. COHb value is entered in the visit card, Other data section, Additional info.
 - *TLC(DLCO) for Obstructed Subject:* if the TLC(DLCO) must be corrected for obstructed patients. An obstructed patient is a patient with FEV1/FVC ratio < 0.70.
- **Breath hold section:** the breath hold time (*Time*) and the method of breath hold (*Method*).
- **Show QC messages :** if the Quality Control messages must be shown at the end of the test.

Settings

- General
- Environment and BTPS
- Calibration
- Flowmeter Verification
- Predicteds
- Spirometry
- Br. Protocol/Dosimeter
- Dead spaces and Resistances
- DLCO
- Body Plethysmography**
- Nitrogen Washout
- Rocc
- Respiratory Mechanics
- CPET
- REE
- System Administration
- GDT
- Export
- OMNIA modules
- About

General

- Thermal equilibrium lead time: 60 s
- Ventilation valve opening time: 4 s
- Shutter closing timeout: 3 s
- Raw Algorithm: sR0.5
- Multi sRaw consecutive captures: 5

Simulated

- Erlenmeyer Flask Vol.: 5.58 L

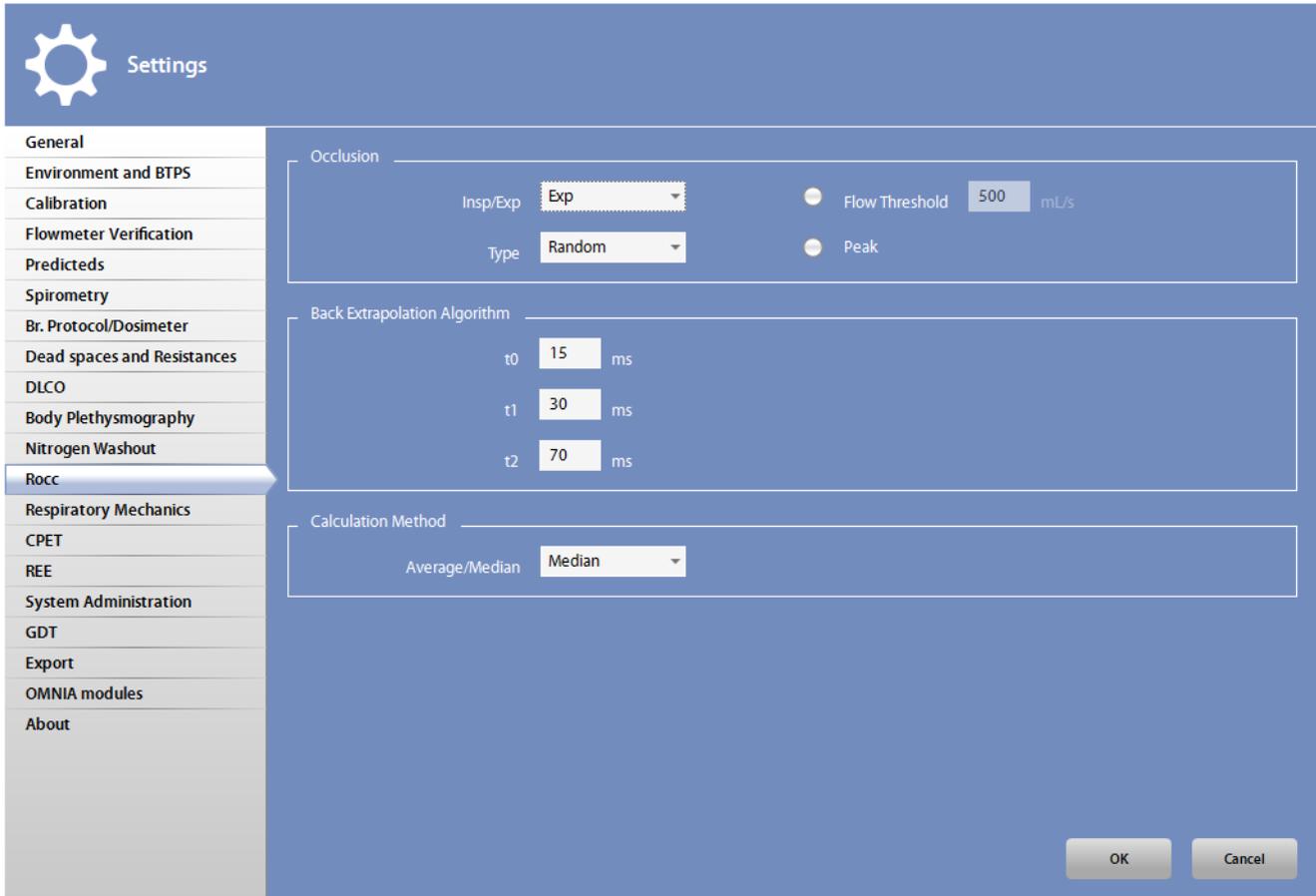
OK Cancel

In this tab you can set:

- *Thermal equilibrium lead time*: the time to be elapsed for reaching thermal equilibrium, before starting the test
- *Ventilation valve opening time*: how long the ventilation valve is opened, before starting the test, in order to reach the pressure equilibrium in a shorter time.
- *Shutter closing timeout*: how long the shutter is closed during a test
- *Raw algorithm*: the algorithm to be used for the Raw calculation.
Three algorithms are selectable:
 - sRaw 0.5: uses the linear portion of the sRaw loop between inspiratory and expiratory flow rates of 0.5 l/s
 - sRaw 0.2: uses the linear portion of the sRaw loop between inspiratory and expiratory flow rates of 0.2 l/s
 - sRaw Fmax: is the parameter line connecting the maximum flow points.
- *Multi sRaw consecutive captures*: the number of sequential sRaw captured with a single control.
- *Erlenmeyer Flask Vol.*: the Erlenmeyer flask volume, for simulated tests

In this tab you can set:

- **General section:**
 - *Calculation method:* the calculation method of the lung volumes.
 - *Vt Stability Threshold:* the stability threshold for the Vt during the FRC test (to start inhaling oxygen).
 - *Show QC messages :* if the Quality Control messages must be shown at the end of the test.
- **Multi-Breath section:**
 - *End Test Criteria (FetN2):* the N₂ threshold to detect the end of test.
 - If the *Enable* checkbox is selected, the criteria for detecting a good depth of breathing and respiratory frequency (acceptable range).
 - *Fin2:* the N₂ concentration of the inhaled mixture (if any).
- **Single-Breath/Calculation method:** the calculation method for the SIII during the Closing Volume tests.



Settings

- General
- Environment and BTPS
- Calibration
- Flowmeter Verification
- Predicteds
- Spirometry
- Br. Protocol/Dosimeter
- Dead spaces and Resistances
- DLCO
- Body Plethysmography
- Nitrogen Washout
- Rocc**
- Respiratory Mechanics
- CPET
- REE
- System Administration
- GDT
- Export
- OMNIA modules
- About

Occlusion

Insp/Exp: Exp

Type: Random

Flow Threshold: 500 mL/s

Peak

Back Extrapolation Algorithm

t0: 15 ms

t1: 30 ms

t2: 70 ms

Calculation Method

Average/Median: Median

OK Cancel

In this tab you can set:

- **Occlusion section:**
 - *Insp/Exp*: if the occlusion occurs on the inspiration or the expiration phase.
 - *Type*: if the occlusion is random performed (*Random*) or directed by the user (*Manual*).
 - If the occlusion occurs when the entered flow threshold is reached (*Flow Threshold*) or at the ventilation peak (*Peak*).
- **Back Extrapolation Algorithm section:**
 - The parameters *t0*, *t1* and *t2* for the back extrapolation algorithm.
- **Calculation Method section:**
 - If the parameter is calculated as the average or the median of the measured values.

The screenshot shows the 'Settings' application window. On the left is a sidebar menu with the following items: General, Environment and BTPS, Calibration, Flowmeter Verification, Predicteds, Spirometry, Br. Protocol/Dosimeter, Dead spaces and Resistances, DLCO, Body Plethysmography, Nitrogen Washout, Rocc, Respiratory Mechanics (highlighted), CPET, REE, System Administration, GDT, Export, OMNIA modules, and About. The main content area is titled 'P0.1' and contains three settings: 'Vt Stability Threshold' with a dropdown menu showing '400' and 'mL' to its right; 'Modality' with a dropdown menu showing 'Environment'; and 'Always use it for this test' with an unchecked checkbox. At the bottom right of the window are 'OK' and 'Cancel' buttons.

In this tab you can set:

- *Vt stability Threshold*: the stability threshold for the Vt
- *Modality*: if the test is performed in air (*Environment*) or after inhalation of O₂ or CO₂.
- *Always use it for this test*: if these settings must be used for all the P0.1 tests without asking confirmation to the user.

In this tab you can set:

- *Start recording after 2 minutes*: if the data recording automatically starts after two minutes of test.
- *Calculate MVV based on*: if an MVV test was not performed, the MVV is calculated as this value multiplied by the FEV1 (if an FVC was performed).
- *Data filtering*: How the data are shown to the user. You can select among the following:
 - *None*: data are presented every breath
 - *Time average*: data are presented every this number of seconds
 - *Smoothing*: data are presented breath by breath but averaged on this number of steps
 - *Rolling time average*: data are presented every 10 seconds, averaged on the last 30 seconds
- *Accepted range*: if the *Enable* checkbox is selected, invalid data according to the criteria specified in this section are discarded. Criteria include a minimum value for the VT and a value range for VO₂, RF and R.
- *Subject Type*: the default subject type for the tests (*Clinical* or *Healthy*).
- *Dyspnea/Leg Pain*: the Rating of Perceived Exertion scale used (*Borg* or *Modified Borg*)
- *Print Stored ECG*: if the ecg must be printed as soon as it is stored

In this tab you can set:

- *Start recording after 2 minutes*: if the data recording automatically starts after two minutes of test.
- *Data filtering*: How the data are shown to the user. You can select among the following:
 - *None*: data are presented every breath
 - *Time average*: data are presented every this number of seconds
 - *Smoothing*: data are presented breath by breath but averaged on this number of steps
 - *Rolling time average*: data are presented every 10 seconds, averaged on the last 30 seconds
- *Accepted range*: if the *Enable* checkbox is selected, invalid data according to the criteria specified in this section are discarded. Criteria include a minimum value for the VT and a value range for VO₂, RF and R.
- *Canopy section*:
 - *Normal range*: The FeCO₂ range considered as normal for Canopy tests (see corresponding section in this manual for further details)
 - *Quark RMR blower adjustment*: if the blower adjustment must be done manually, by rotating the knob, or via software¹.
 - *Temp RH @ Flowmeter*: if the temperature and the humidity at the flowmeter must be measured by the ambient probe or entered manually
 - *Temperature*: the temperature at the flowmeter (enabled only if *Insert values* is selected in the field *Temp RH @ Flowmeter*)
 - *RH*: the humidity at the flowmeter (enabled only if *Insert values* is selected in the field *Temp RH @ Flowmeter*)
 - *Enable FIO₂ reading*: if this checkbox is selected, the FIO₂ is read also during the test¹.
 - *Every*: the interval time between two subsequent FIO₂ reading (enabled only if the checkbox *Enable FIO₂ reading* is selected)¹.
- *ICU*: The Flow-Ree dead space

¹ Available in most recent Quark RMR models only. These units can be recognized if the last four digits of their S/N are 1000 or above.

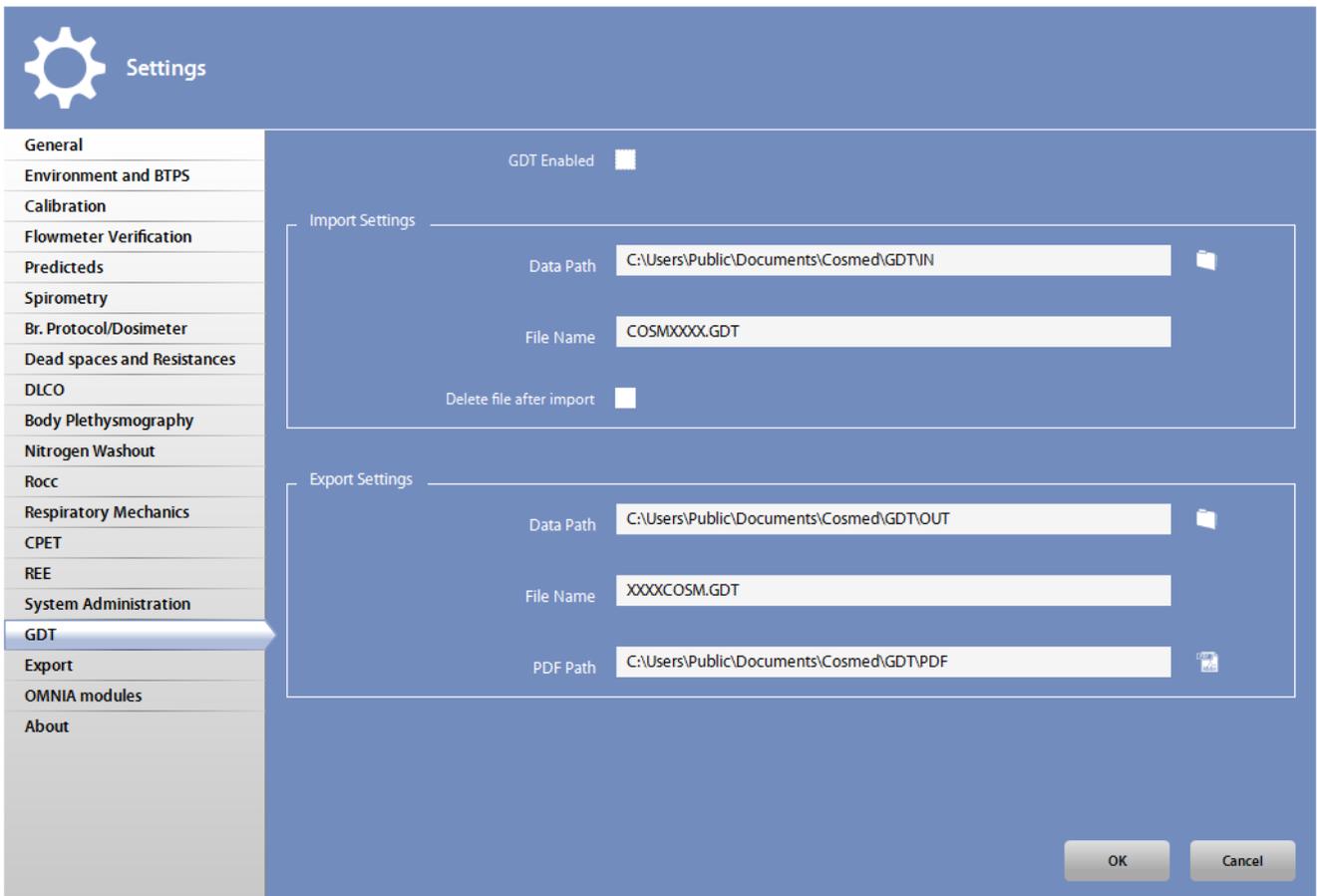
The screenshot shows the 'Settings' window with a sidebar on the left containing various configuration categories. The 'System Administration' category is selected and highlighted. The main content area displays three settings: 'Login session timeout' set to 15 minutes, 'Password expires in' set to 180 days, and 'Automatic login authentication using Active Directory' which is currently unchecked. At the bottom right, there is a note stating 'Changes are applied after restarting OMNIA' and two buttons labeled 'OK' and 'Cancel'.

Note: This tab is available for the Administrator only.

In this tab you can set:

- *Login session timeout (min)*: the interval time for automatic logout when the software is not used. After this time, the software will automatically logout and you are required to enter your credentials (user name and password) another time.
- *Password expires in (days)*: the interval time for changing the password . After this time, for safety reasons, you are required to change your password for accessing the software.
- *Automatic login authentication using Active Directory*: if the current user can skip the authentication when OMNIA is started (if authenticated through the network domain).

Changes will be applied only after restarting the software.

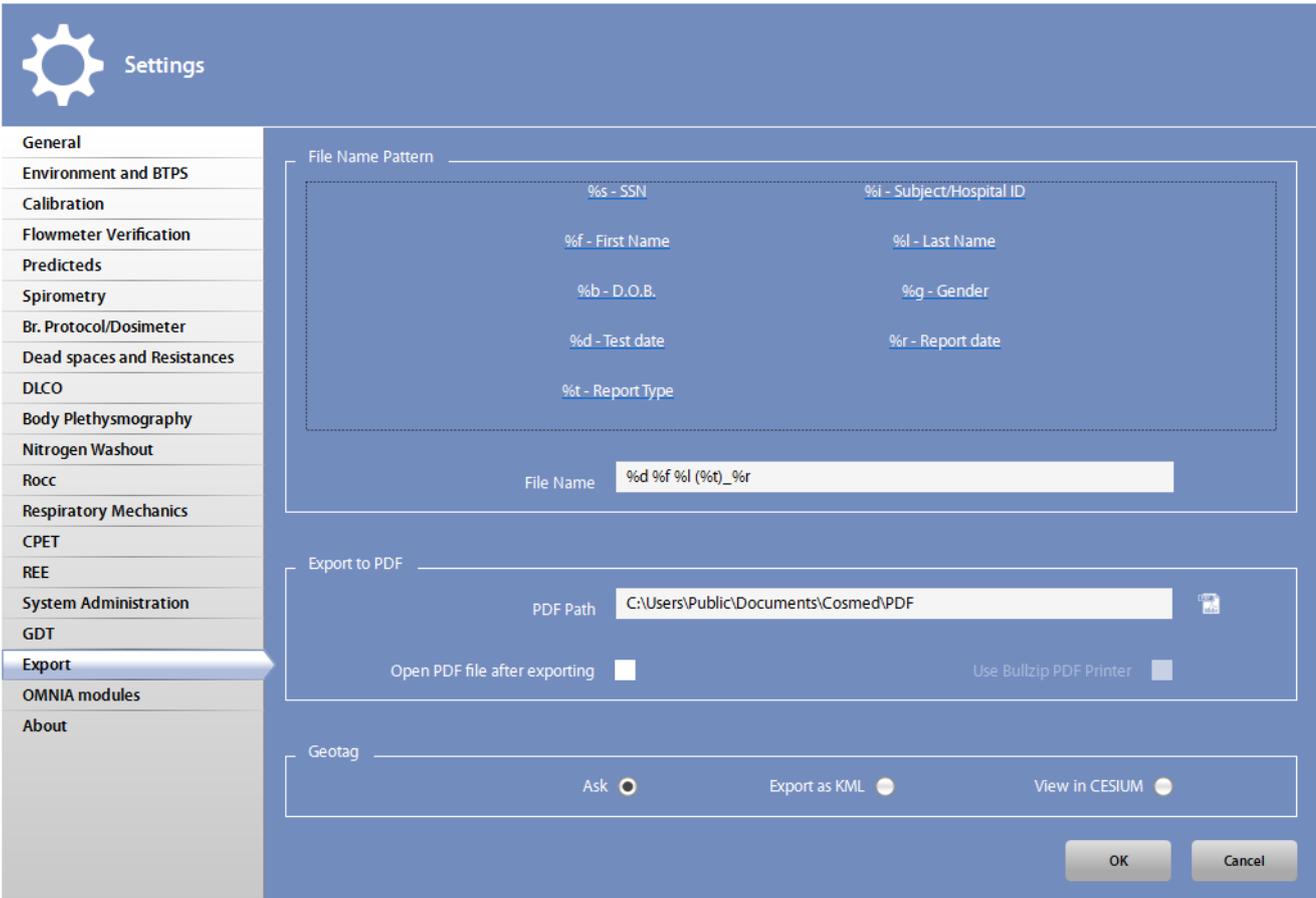


GDT is a standardized protocol used by the software for the exchange of data between health facilities.

In this tab you can select:

- *GDT enabled*: if the GDT is enabled.
- *Data Path* : the directory, *File Name* : the filename in the *Importing Settings* section for importing data.
- *Delete File after import* :if the protocol files must be deleted after the import. The GDT exchange protocol uses files in order to exchange the information. This option permits these files to be deleted at the end of the import procedure.
- *Data Path*: the directory, *File Name*: the filename and *PDF Path*: the report directory for exporting data. Reports will be exported in PDF format.

If you click the icons near the paths, you can choose the folder in the standard Windows browse dialog box.



This tab allows you to select the standard filename and path for exporting the reports in pdf format.

The *File Name* allows you to define the name to be assigned to the file. Press a link under *Available fields* to enter a value for one of the fields listed or type the chars in the box in order to create the filename template.

If the format selected is, for example: “%d - %l %f”, the filename will be composed by <date of the test>, space, line, space, <last name>, space, <first name>.

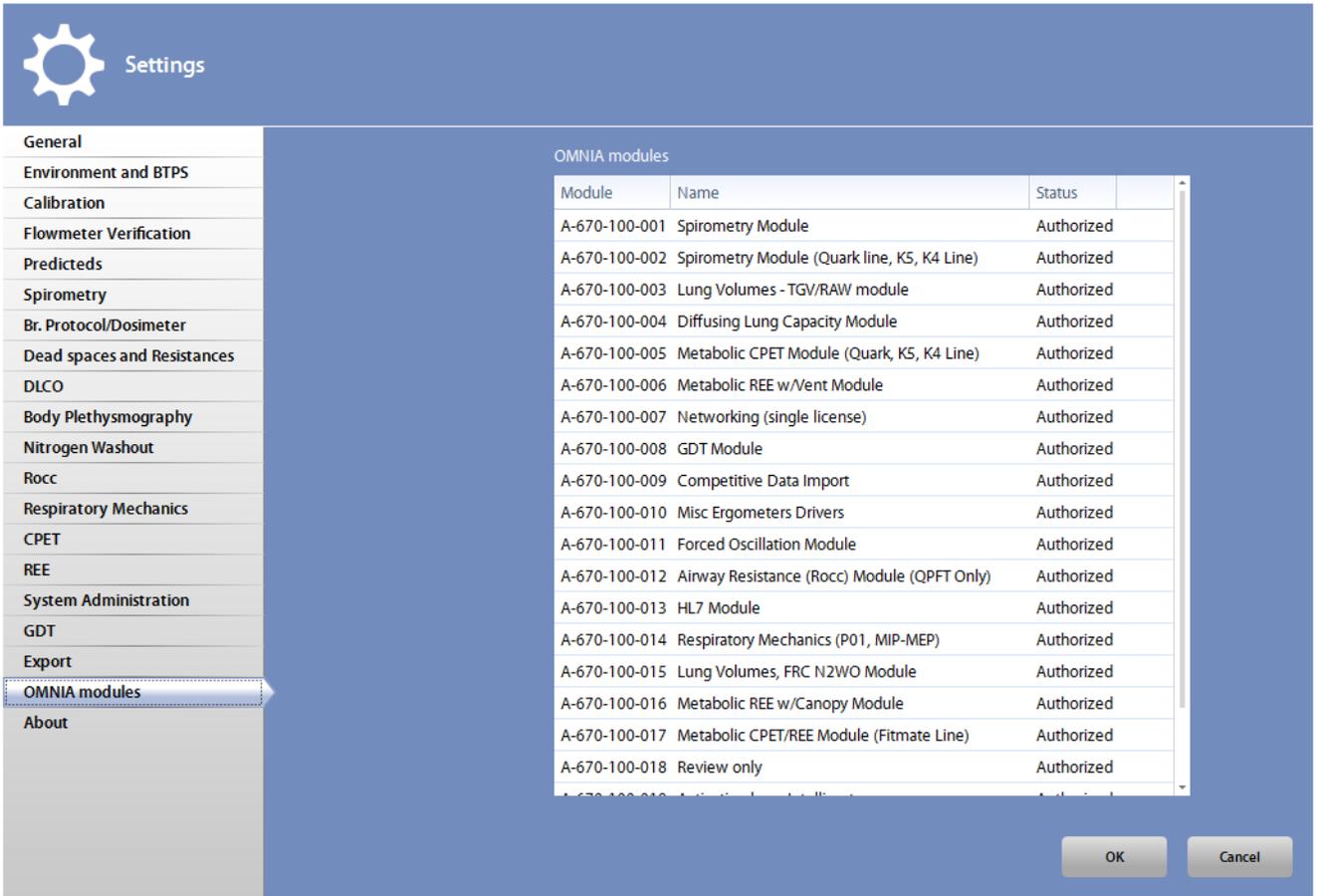
This tool is very useful for network archiving data, particularly when the central unit requires that the file name is formatted in a specific manner.

If you click the icon near the path field, you can choose the folder in the standard Windows browse dialog box, instead of entering it in the box.

By selecting *Open PDF file after exporting*, the file will be automatically opened after the export is completed.

By selecting *Use Bullzip PDF Printer*, this printer is used for preparing the pdf file (available only if this printer is installed on the PC).

The section *Geotag* allows the user to export GPS data (K5 only) as a KML file or to view them in CESIUM software. Select *Ask* if you want to be asked your choice each time you export a test.



Settings

General

Environment and BTPS

Calibration

Flowmeter Verification

Predicteds

Spirometry

Br. Protocol/Dosimeter

Dead spaces and Resistances

DLCO

Body Plethysmography

Nitrogen Washout

Rocc

Respiratory Mechanics

CPET

REE

System Administration

GDT

Export

OMNIA modules

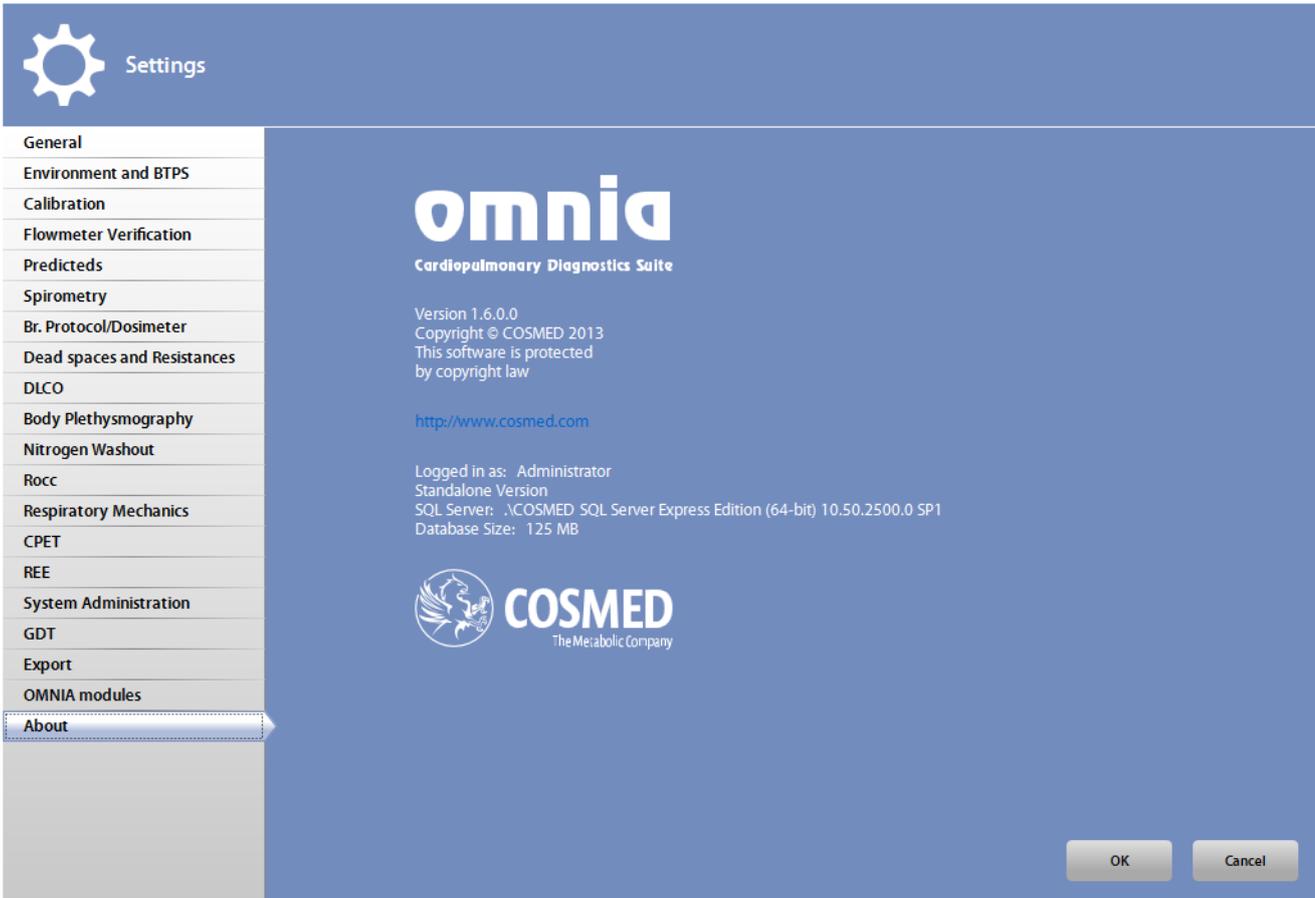
About

OMNIA modules

Module	Name	Status
A-670-100-001	Spirometry Module	Authorized
A-670-100-002	Spirometry Module (Quark line, K5, K4 Line)	Authorized
A-670-100-003	Lung Volumes - TGV/RAW module	Authorized
A-670-100-004	Diffusing Lung Capacity Module	Authorized
A-670-100-005	Metabolic CPET Module (Quark, K5, K4 Line)	Authorized
A-670-100-006	Metabolic REE w/Vent Module	Authorized
A-670-100-007	Networking (single license)	Authorized
A-670-100-008	GDT Module	Authorized
A-670-100-009	Competitive Data Import	Authorized
A-670-100-010	Misc Ergometers Drivers	Authorized
A-670-100-011	Forced Oscillation Module	Authorized
A-670-100-012	Airway Resistance (Rocc) Module (QPFT Only)	Authorized
A-670-100-013	HL7 Module	Authorized
A-670-100-014	Respiratory Mechanics (P01, MIP-MEP)	Authorized
A-670-100-015	Lung Volumes, FRC N2WO Module	Authorized
A-670-100-016	Metabolic REE w/Canopy Module	Authorized
A-670-100-017	Metabolic CPET/REE Module (Fitmate Line)	Authorized
A-670-100-018	Review only	Authorized

OK Cancel

In this tab all the active OMNIA modules are summarized and shown to the user.



Settings

- General
- Environment and BTPS
- Calibration
- Flowmeter Verification
- Predicteds
- Spirometry
- Br. Protocol/Dosimeter
- Dead spaces and Resistances
- DLCO
- Body Plethysmography
- Nitrogen Washout
- Rocc
- Respiratory Mechanics
- CPET
- REE
- System Administration
- GDT
- Export
- OMNIA modules
- About**

omnia
Cardiopulmonary Diagnostics Suite

Version 1.6.0.0
Copyright © COSMED 2013
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by copyright law

<http://www.cosmed.com>

Logged in as: Administrator
Standalone Version
SQL Server: \COSMED SQL Server Express Edition (64-bit) 10.50.2500.0 SP1
Database Size: 125 MB

 **COSMED**
The Metabolic Company

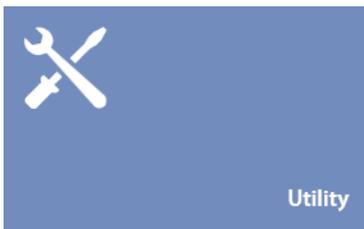
OK Cancel

This tab includes information about the software release and copyright information.
A link to the COSMED website is also present.

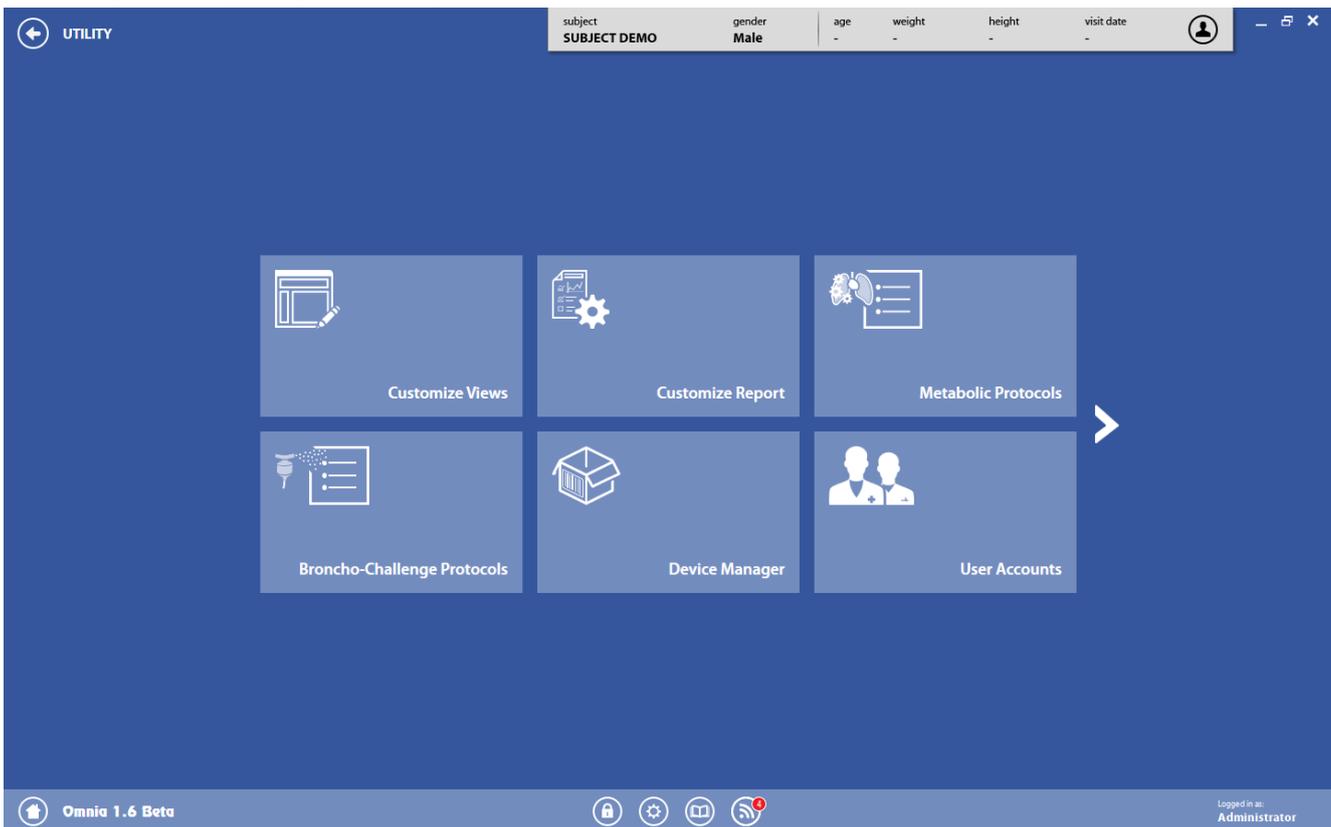
Utilities



Introduction



In order to open the utility tools, press the **Utility** tile on the home panel.



The central tiles lead to the corresponding tool of the utilities, allowing the user to:

- **Customize Views** customizes the display for the ergometry tests (in real time and during data presentation)
- **Customize Report** customizes the report
- **Metabolic Protocols** customizes the protocols used during metabolic tests
- **Broncho-Challenge Protocols** opens the broncho-challenge protocol interface
- **Device Manager** opens the device manager (for configuring all connected devices)
- **User Accounts** opens the user accounts interface
- **Backup Database** backups the database to a backup file
- **Restore Database** restores the database from a previously backed up file
- **Import Data from CSV** imports data from a CSV file (only with a specific license to be bought separately)
- **Resources Center** manages a dictionary of common expressions used in the software
- **Event Log** opens the event log (for support purposes)

The  and  icons allow you to navigate through the different pages of the panel.

Note: Backup and restore tiles are available in the Stand-alone version only and for Administrators only.

Customize Views



In this panel you can customize the views during ergometry tests (CPET and REE, including ICU).

For each test, one or more views can be customized. Different customizations are allowed for every test and both for real time and results visualization.

The following views can be customized:

- Dashboards (real time):
 - Dashboards: CPET - Breath by Breath
 - Dashboards: CPET - Mixing Chamber
 - Dashboards: REE - Canopy
 - Dashboards: REE - Mask
 - Dashboards: REE - Ventilator
- Results:
 - Results: CPET - Breath by Breath
 - Results: CPET - Mixing Chamber
 - Results: REE - Canopy
 - Results: REE - Mask
 - Results: REE - Ventilator

Dashboard customization

subject: SUBJECT DEMO, gender: Male, age: -, weight: -, height: -, visit date: -

Select a view: Dashboards: REE - Canopy

Widgets displayed:

- VO2, VCO2 vs t
- EEkc, RQ vs t
- REE AVG
- Variability AVG
- VP, FeCO2 vs t
- CHO%, FAT% vs t
- Substrates AVG
- Dilution

t	VP	VO2	VCO2	RQ	EEkc	FeO2	FeCO2	FIO2	FICO2	FAT%	CHO%	PRO%	Phase
hh:mm:ss	L/min	mL/min	mL/min	---	kcal/day	%	%	%	%	%	%	%	---
00:10	40.6	428	354	0.83	2966	19.60	1.18	20.93	0.03	59.0	41.0	0.0	None
00:20	40.6	369	305	0.83	2554	19.78	1.02	20.93	0.03	59.1	40.9	0.0	None
00:30	40.6	337	276	0.82	2328	19.88	0.92	20.93	0.03	62.1	37.9	0.0	None

Views management bar: < REE Canopy Widgets X > REE Canopy REE Canopy Printout QC

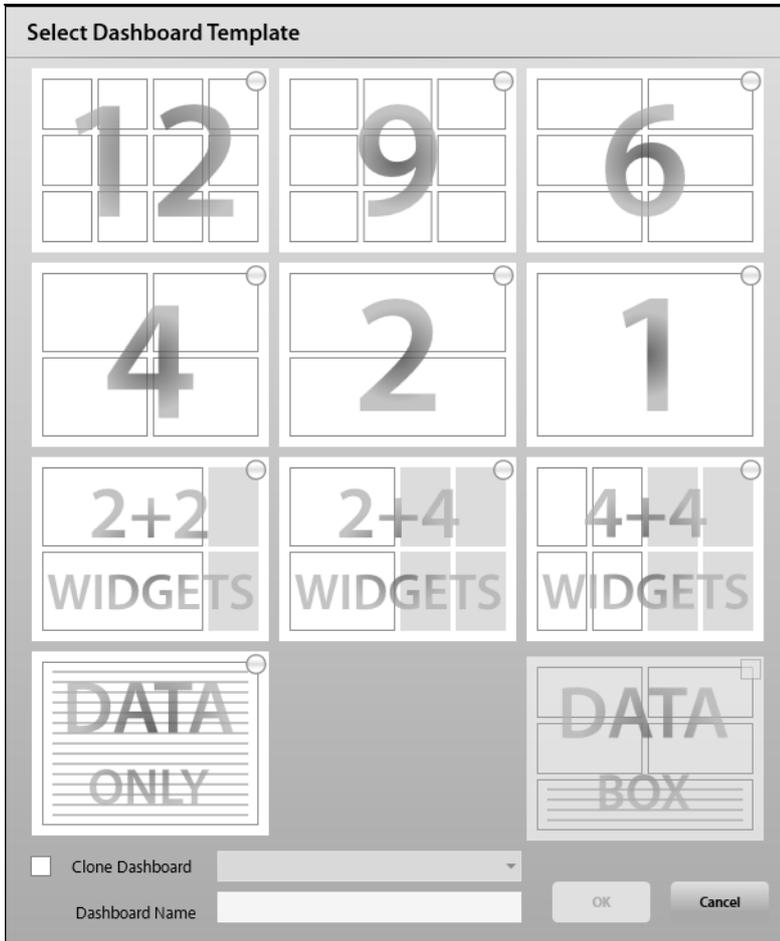
Views management

+ < REE Canopy Widgets X > REE Canopy REE Canopy Printout QC

In the lower part of the window some predefined views are shown to the user.

- To select one view, click on it.
- To hide a view during the test execution, deselect the checkbox near the name of the view.
- To move a view and change their order, click on the arrow at the right and at the left of the name of the view
- To add a new view, click on the + sign at the left of the row.

By pressing the + sign, you can select a preferred layout for this new view (one or more graphs, with or without data, data only, with one or more widgets,...)



Select the preferred layout by checking the corresponding checkbox.

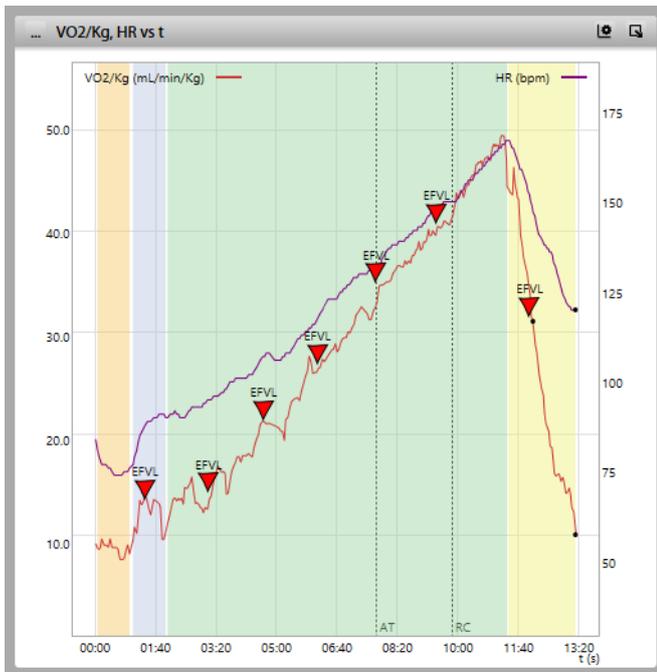
If you prefer to duplicate an existent dashboard (in order to simplify its customization), select *Clone Dashboard* and select the clone you would like to duplicate.

Enter the dashboard name and press **OK** to confirm, **Cancel** to abort.



In order to delete a view, press **Delete**. In order to restore the view to the default settings, press **Restore**.

Graphs



Note: By moving the mouse on the graph, one dot for each plot indicate the value on the plot corresponding to the position of the mouse

Each graph can be customized by pressing the  icon in the upper left corner. You can select a predefined graph or create a new one (*Edit Chart*)

Edit Chart

Chart	Y1	Y2	Y3	Y4	X	Options
Parameter	VO2/Kg	HR	--	--	t	Hide Recovery <input type="checkbox"/>
Autoscale	<input checked="" type="checkbox"/>	Squared Chart <input type="checkbox"/>				
Show Major Grid	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Enable Tooltips <input type="checkbox"/>
Show Minor Grid	<input type="checkbox"/>	Ignore 0 <input type="checkbox"/>				
Min Scale	0	30			0	Show Events <input checked="" type="checkbox"/>
Max Scale	100	220			0	Show key variables <input checked="" type="checkbox"/>
Show Normal Range	<input type="checkbox"/>	Show Phases <input checked="" type="checkbox"/>				
Resolution	0	0			0	Set Scale According To VE <input type="checkbox"/>
Style	--	--	--	--		
Color	--	--	--	--		
Thickness	---	---	---	---		

This window allow the user to create a graph according to his/her preferences.

It is possible to select up to 4 y-axis (Y1, Y2, Y3 and Y4) in order to plot up to 4 parameters vs. a single parameter (X). For each of these parameters you can select:

- The parameter name (*Parameter*)
- If the graph of scale must be automatically set by the PC (*Autoscale*)
- If the main grid must be shown in the graph (*Show Major Grid*)
- If the secondary grid must be shown in the graph (*Show Minor Grid*)
- The minimum value of the axis (*Min Scale*, enabled only if *Autoscale* is deselected)
- The maximum value of the axis (*Max Scale*, enabled only if *Autoscale* is deselected)
- If the normal range must be highlighted on the graph (*Show Normal Range*). The normal range will be shown only if available for the selected parameter
- The resolution of the main grid (*Resolution*)

- The plot aspect (*Style*)
- The color (*Color*) and the thickness (*Thickness*) of the graphs.

On the right side of the window more options can be selected:

- *Hide Recovery*, if the Recovery phase must be hidden in the graphs
- *Square Chart*, if the graph must have a squared aspect ratio
- *Enable Tooltips*, if labels with data must be shown during the test
- *Ignore 0*, if the zero values must be ignored for plot purposes
- *Show events*, if the events stored by the user must be shown on the graphs
- *Show key variables*, if principal parameters determined through calculation (e.g. AT, RC, . . .) must be shown on the graphs
- *Show Phases*, if the different phases must be shown in different colors on the graphs (dark yellow for rest, light blue for warm up, green for exercise and yellow for recovery)
- *Set Scale According To VE*, if the Y-scale of the parameters depending on VE (e.g. VO_2 , VCO_2 , SpO_2 , . . .) is set on the basis of the estimated VE max. This VE max value is set by the user by means of the cursor on the right of this checkbox.

The  icon in the upper right corner allows the user to set the Y-scale according to the estimated VE (see previous point)

The icon in the very upper right corner maximizes () or minimizes () the graph.

Widget

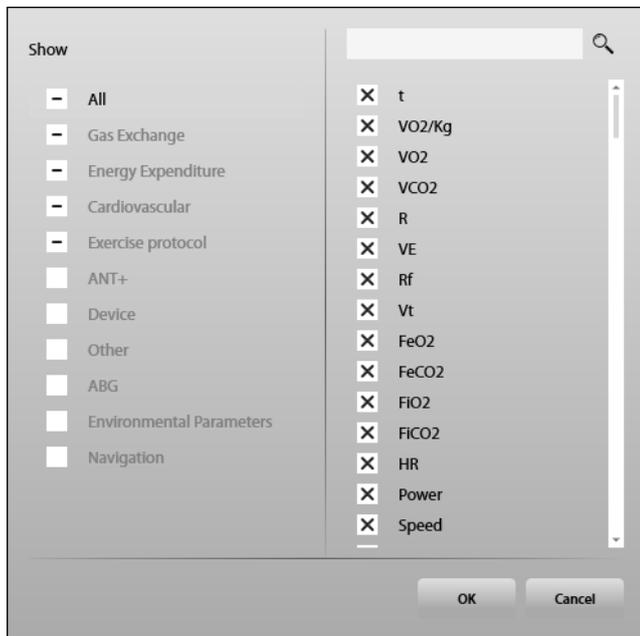


In order to select the widget, press the  icon in the upper left corner.

Data

...	t	VP	VO ₂	VCO ₂	R	EEkc	FeO ₂	FeCO ₂	FIO ₂	FICO ₂	FAT%	CHO%	PRO%	Phase
	hh:mm:ss	L/min	mL/min	mL/min	---	kcal/day	%	%	%	%	%	%	%	---

In order to add/delete columns, press the  icon in the upper left corner.



In the right side of the window, you can select the parameters to be displayed. You can search among parameters by typing in the above field a search string.

In the left side the categories of the parameters are shown. By clicking on a category, the list on the right is filtered, showing only the parameters included in that category. By selecting/deselecting the checkbox near the category, all the parameters included in that category will be selected/deselected.

Parameters



On the right side of the window, you can see all the parameters whose value will be shown during the test.

You can:

- Add a new parameter, by clicking on the + dotted tile and selecting the parameter to be shown (you can search among parameters by typing in the above field a search string)
- Modify a selected parameter, by clicking on it. You can change the parameter, delete the parameter or change the color of the tile.
- Change the size of the tile, by rotating the mouse wheel when the pointer is on it.
- Move the tile by dragging it in the desired position.

Results customization

The above screenshot is only an example of the available results views. There are many different views. The main elements are described below.

Views

For each results view, one or more views can be customized, depending on the selected results view. In particular, different views can be customized depending on the subject type (healthy or clinical) and on the test type (maximal, submaximal or other).

In order to delete a view, press **Delete**. In order to restore the view to the default settings, press **Restore**.

Results

On the left side, you can select/deselect parameters or sections to be displayed, by selecting/deselecting the corresponding checkbox. Some checkboxes cannot be deselected.

Graphs

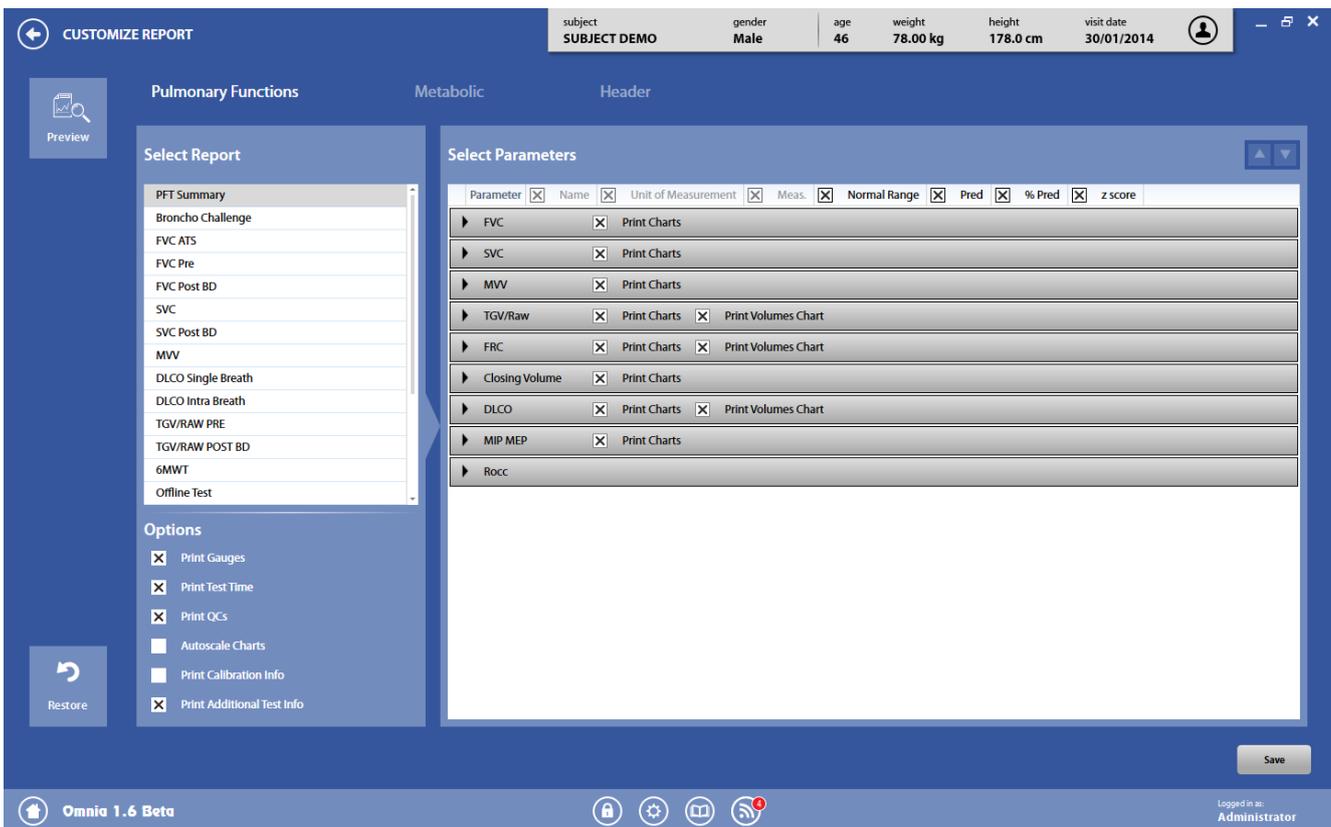
Graphs, on the right side, can be customized as described in the *Dashboard customization* above.

Customize Report



The customize report panel allows you to customize the reports printed by the software. It contains three tabs: *Pulmonary Functions*, *Metabolic* and *Header*, depending on the section to be customized.

Pulmonary Functions



Parameter	Name	Unit of Measurement	Meas.	Normal Range	Pred	% Pred	z score
FVC	<input checked="" type="checkbox"/>	Print Charts	<input checked="" type="checkbox"/>				
SVC	<input checked="" type="checkbox"/>	Print Charts	<input checked="" type="checkbox"/>				
MVV	<input checked="" type="checkbox"/>	Print Charts	<input checked="" type="checkbox"/>				
TGV/Raw	<input checked="" type="checkbox"/>	Print Charts <input checked="" type="checkbox"/> Print Volumes Chart	<input checked="" type="checkbox"/>				
FRC	<input checked="" type="checkbox"/>	Print Charts <input checked="" type="checkbox"/> Print Volumes Chart	<input checked="" type="checkbox"/>				
Closing Volume	<input checked="" type="checkbox"/>	Print Charts	<input checked="" type="checkbox"/>				
DLCO	<input checked="" type="checkbox"/>	Print Charts <input checked="" type="checkbox"/> Print Volumes Chart	<input checked="" type="checkbox"/>				
MIP MEP	<input checked="" type="checkbox"/>	Print Charts	<input checked="" type="checkbox"/>				
Rocc	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>				

The *Pulmonary Functions* tab contains a lot of predefined reports. It is not possible to add new reports, but you can easily customize the predefined ones.

The left side of the panel contains a list of the reports. By clicking on one of them, you can access to the corresponding customization.

The right side of the panel contains the parameters to be included in the report. You can:

- Select/deselect a parameter, by clicking on the corresponding checkbox. Parameters are arranged according to the corresponding test.
- Select/deselect a column, by clicking on the corresponding checkbox. Some columns cannot be deselected.
- Select/deselect a chart, by clicking on the corresponding checkbox near the related test.



- Move a selected parameter (after having highlighted it by clicking on it with the mouse), through the arrows above the table.

Below the list of the report, you can set the following options (some of these options are available for specific tests only):

- *Print Gauges*, if the gauges must be printed on the report. Gauges are horizontal bars which shows graphically the parameter and the predicted value (if available).
- *Print Test Time*, if the test time must be printed near the test header
- *Print QCs*, if the quality controls must be printed on the report
- *Autoscale Charts*, if the graphs must be automatically scaled

- *Print Calibration Info*, if the calibration information must be printed on the report
- *Print Additional Test Information*, if additional test information, like environmental data, must be printed on the report.
- *Print best FVC + 2 trials*, if the best FVC must be printed together with 2 subsequent best trials.
- *Print Trials Results*, if the report must include the trials results also.
- *Print Volumes Chart*, if the volumes chart must be printed on the report.
- *Print 6MWT steps detail*, if details about the steps of the 6-minute walking test must be printed on the report.



Restore will restore the report to the default settings, **Preview** will show a preview of the selected report.

Metabolic

The *Metabolic* tab contains a lot of predefined reports. It is possible to customize these reports, as well as to add new ones.

The left side of the panel contains a list of the reports. By clicking on one of them, you can access to the corresponding customization.

The right side of the panel contains the parameters and the charts to be included in the report. You can:

- Select/deselect a chart, by clicking on the corresponding checkbox.
- Select/deselect a parameter, by clicking on the corresponding checkbox.

You can select one or more parameters also by clicking on the icon in the upper left corner.

In the right side of the window, you can select the parameters to be displayed. You can search among parameters by typing in the above field a search string.

In the left side the categories of the parameters are shown. By clicking on a category, the list on the right is filtered, showing only the parameters included in that category. By selecting/deselecting the checkbox near the category, all the parameters included in that category will be selected/deselected.



- Move a selected parameter (after having highlighted it by clicking on it with the mouse), through the arrows above the table.

Below the list of the report, you can set the following options:

- *Default Report*, if the selected report is a default report (this option cannot be modified)
- *Print Summary*, if the summary of the test must be printed before the graphs.

- *Print Gauges*, if the gauges must be printed on the report. Gauges are horizontal bars which shows graphically the parameter and the predicted value (if available).
- *Print Test Time*, if the test time must be printed near the test header
- *Print Calibration Info*, if the calibration information must be printed on the report
- *Print Additional Test Information*, if additional test information, like environmental data, calibration information, etc. must be printed on the report.
- *Print F/V loops* (available for specific tests only), if the flow/volume loops must be printed on the report.
- *Page orientation*, vertical (portrait) or horizontal (landscape).



New will add a new report, **Delete** will delete the selected report (not available for the default reports), **Rename** will rename the selected report, **Charts and Summary** will open the *Customize Views* panel (Results section), **Restore** will restore the report to the default settings, **Preview** will show a preview of the selected report.

Header

In the *Header* tab it is possible to select which fields must be enabled in the report. By clicking on the corresponding checkbox in the list, the corresponding field will be enabled/disabled. It is also possible to change the field content by clicking on the arrow near the field name in the list and selecting the desired field.

Shaded fields, with "--" in it, will be hidden in the report.

In the bottom section you can set the information which is to be printed at the header of the reports.

It is also possible to add a logo by clicking on the square near the Logo tag. Only bitmap (*.bmp, *.dib, *.rle), JPEG (*.jpg, *.jpeg, *.jpe, *.jif), *.gif, *.tif, *.tiff and *.png files can be selected.

We advise to use images not too big and with the same aspect ratio of the field, in order to avoid distortions due to adaptation of the logo to the field size.

Print interpretation with signature enables printing the diagnosis and the physician's signature on the report.

Metabolic Protocols



In this panel you can view/customize/add metabolic protocols.

METABOLIC PROTOCOLS

subject: **SUBJECT DEMO** | gender: **Male** | age: **46** | weight: **78.00 kg** | height: **178.0 cm** | visit date: **30/01/2014**

Exercise Protocol

Resting Protocol

Edit

Duplicate

Delete

Export

Import

Protocol Name	Ergometer
10 Watt Ramp	Bike
15 Watt Ramp	Bike
20 Watt Ramp	Bike
25 Watt Ramp	Bike
30 Watt Ramp	Bike
35 Watt Ramp	Bike
40 Watt Ramp	Bike
50 Watt Ramp	Bike
Astrand F	Bike
Astrand M	Bike
Balke_Kmh	Treadmill
Balke_Mph	Treadmill
BRUCE_Bike	Bike
Bruce_Kmh	Treadmill
Bruce_Mph	Treadmill
Inc15W	Bike
Inc20W	Bike
Inc25W	Bike
Inc30W	Bike
Inc35W	Bike
Inc40W	Bike
Inc50W	Bike
Mod_BRUCE_Kmh	Treadmill
Mod_BRUCE_Mph	Treadmill
Naughton_Kmh	Treadmill
Naughton_Mph	Treadmill
O.C.(50W/3min)	Bike

Time (min)	Duration (s)	Phase	Power (—)	BP	ABG	ECG	EFVL
00:00	5	Rest	0	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
00:05	55	Rest	0	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
01:00	60	Warm Up	0	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
02:00	2	Exercise	5	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
02:02	2	Exercise	6	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
02:04	2	Exercise	7	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
02:06	2	Exercise	8	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
02:08	2	Exercise	9	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
02:10	2	Exercise	10	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
02:12	2	Exercise	11	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
02:14	2	Exercise	12	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
02:16	2	Exercise	13	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Omnia 1.6 Beta

Cancel

On the left side, a list of the protocols is shown. By clicking on a protocol, you can see in the right side its corresponding graph and table. The phases are highlighted with the following colors:

Phase	Color
Rest	Dark yellow
Warm up	Light blue
Exercise	Green
Recovery	Yellow

Add a new protocol



In order to add a new protocol, press **Exercise Protocol** or **Resting Protocol**, depending on the Protocol to be added.

New Exercise Protocol

NEW PROTOCOL MANAGER

subject: SUBJECT DEMO gender: Male age: 48 weight: 52.0 kg height: 160 cm

Name: Ergometer: Treadmill Speed u.m.:

Mode: Incremental/Ramp

Rest
Duration: mm:ss Speed: — Incline: %

Warm Up
Duration: mm:ss Speed: — Incline: %

Exercise
Duration: mm:ss

Ramp
Speed: —/min Incline: %/min

Incremental
Speed: — Incline: %
Step Duration: s Step Duration: s

Recovery
Duration: mm:ss Speed: — Incline: %

Graph: Speed (m/min) / Incline (%) vs Time (min)

Time (min)	Duration (s)	Phase	Speed (m/min)	Incline (%)	BP	ABG	ECG

Save Cancel

Omnia 1.3

In the upper fields, enter the required data (name, ergometer, mode and unit of measurement).

If the *Incremental/Ramp* mode is selected, enter data for the 4 phases.

If the *Manual* mode is selected, enter data for each step and press **New Step** in order to add a new step.

New Resting Protocol

NEW PROTOCOL MANAGER

subject: SUBJECT DEMO gender: Male age: 48 weight: 52.0 kg height: 160 cm

Name:

Rest
Start Time: mm:ss End Time: mm:ss

Graph: Time (min)

Time (min)	Duration (s)	Phase

Save Cancel

Omnia 1.3

Enter the protocol name, the start time and the end time.

Common operations

You can edit a single step by entering the information in the table.



The  icon near each step allows to delete one or more steps. The subsequent steps will remain at the same timing or shifted up depending on the icon pressed.

The graph can be zoomed in or out through the mouse wheel (you can zoom the graph or the single axis depending on the position of the mouse), or by dragging a rectangle with the mouse itself. A double click will scale the axis to the default zoom.

The graph and the table on the right will update following the entered data. At the end press save (**Save**) or cancel (**Cancel**) the operation.

■ Edit a protocol



In order to edit a protocol, press **Edit**.



The  icon near each step allows to delete one or more steps. The subsequent steps will remain at the same timing or shifted up depending on the icon pressed.

In order to add a step at the end of the protocol, please enter data and press **New Step**.

The graph can be zoomed in or out through the mouse wheel (you can zoom the graph or the single axis depending on the position of the mouse), or by dragging a rectangle with the mouse itself. A double click will scale the axis to the default zoom.

The graph and the table on the right will update following the entered data. At the end press save (**Save**) or cancel (**Cancel**) the operation.

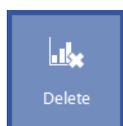
■ Duplicate a protocol



In order to duplicate a protocol, press **Duplicate**.

The Edit panel will open, allowing the renaming of the duplicated protocol, as well as all the other editing described above.

■ Delete a protocol



In order to delete a protocol, press **Delete**.

■ Export and import a protocol



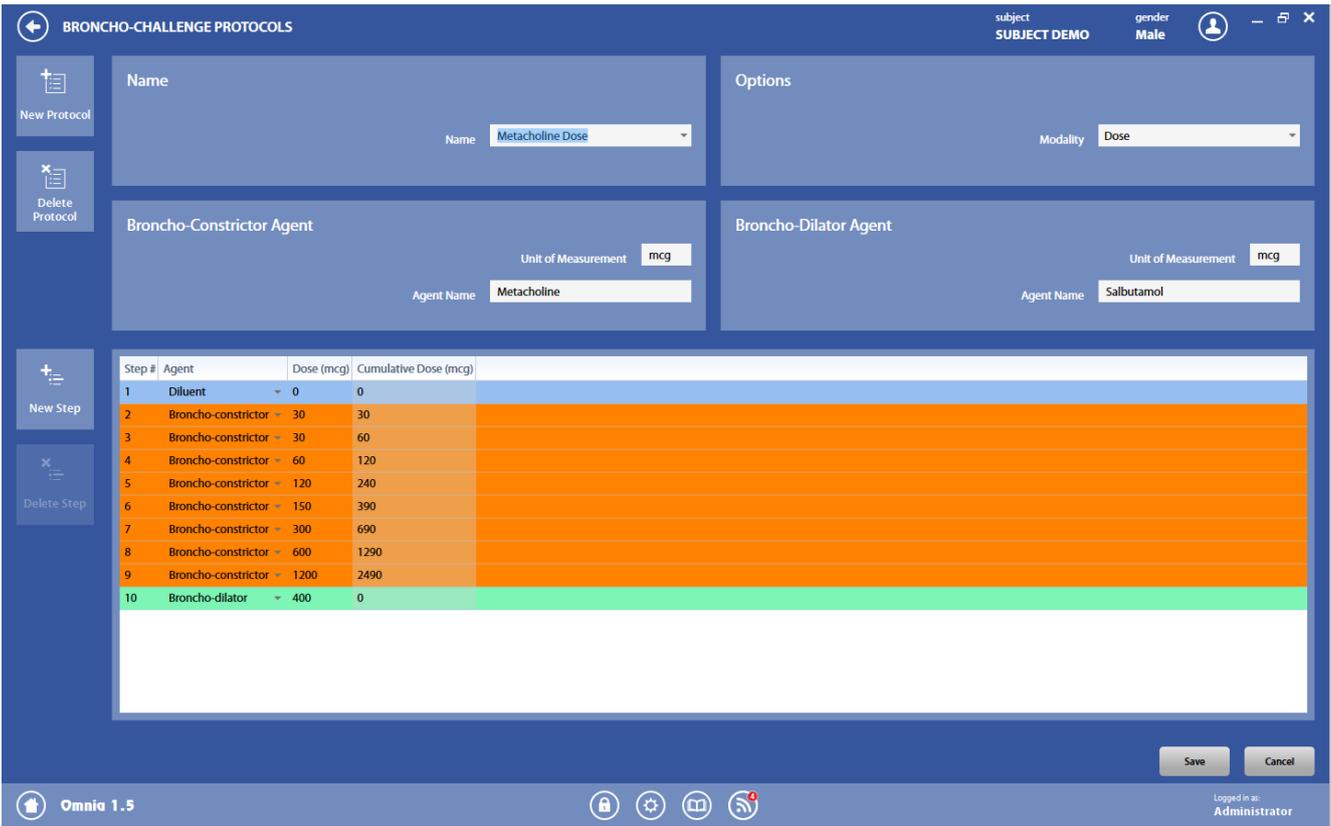
In order to export or import a protocol (*.xml format), press **Export** or **Import**.

Broncho-Challenge protocols



In this panel you can select the broncho-challenge protocol to be used for broncho-challenge tests.

The protocol can be selected among one of the predefined protocols or can be customized by the user (both by modifying an existent protocol or creating a new one).



Step #	Agent	Dose (mcg)	Cumulative Dose (mcg)
1	Diluent	0	0
2	Broncho-constrictor	30	30
3	Broncho-constrictor	30	60
4	Broncho-constrictor	60	120
5	Broncho-constrictor	120	240
6	Broncho-constrictor	150	390
7	Broncho-constrictor	300	690
8	Broncho-constrictor	600	1290
9	Broncho-constrictor	1200	2490
10	Broncho-dilator	400	0

Select an existent protocol

A protocol can be selected under the field *Name*. All the related information will appear in each field after having selected it.

Delete an existent protocol

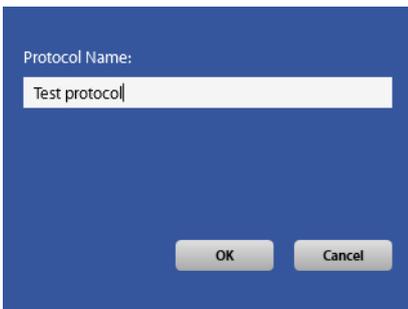


It is possible to delete the selected protocol by clicking on the button **Delete Protocol**. Confirm with **Yes**, cancel with **No**.

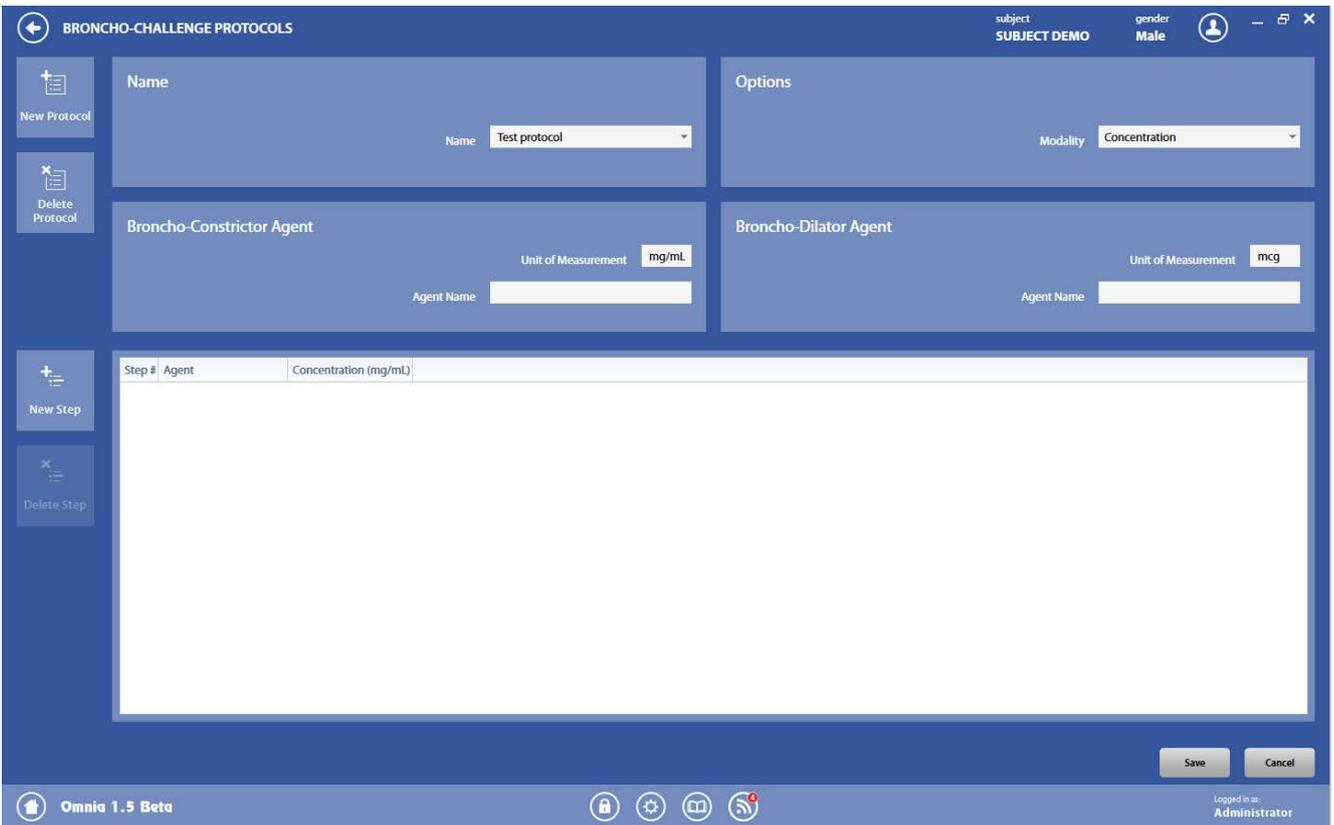
Add a new protocol



To add a new protocol, press the button **New Protocol**.



Enter the protocol name in the dialog box and confirm with **OK**.



Enter the required information in the fields:

- **Options-Modality:** enter the modality for defining each step.
 - **Concentration:** the step is defined by entering the agent and the concentration for each step. When creating a bronchodilator step, please use the dose instead of concentration.
 - **Dose:** the step is defined by entering the agent and the dose at each step.
 - **Exercise:** the step is defined by entering the agent and the time for each step. When creating a bronchodilator step, please use the dose instead of time. (feature not active yet)
 - **Dosimeter:** the step is defined by entering for each step:
 - the agent: broncho-constrictor, broncho-dilator, diluent
 - the nebulizer output, i.e. the dosimeter output flow, default value is defined in the settings, but it can be changed according to personal needs
 - the concentration of the agent used in the nebulizer
 - the breaths, i.e. how many deliveries must be performed in this step
 - the actuation time, automatically calculated by the software starting from the other entered parameters
 - the dose
 - the cumulative dose, automatically calculated by the software on the basis of the previous steps and current one.When creating a bronchodilator step, please use the dose instead of concentration.
- **Bronchoconstrictor agent:** enter the name of the agent (agent name) and its measurement unit (unit of measurement)
- **Bronchodilator agent:** enter the name of the agent (agent name) and its measurement unit (unit of measurement)



By pressing the button **New step**, you can add a step in the protocol. In order to change the entered values, please click on the desired field to change the shown value. Please be careful to select the correct agent (diluent, bronchoconstrictor or bronchodilator) and to enter dose instead of concentration when using a bronchodilator.

Steps are colored according to the administered drug:

- 1 Diluent 0 Light blue, for the diluent
- 2 Broncho-constrictor 0.0625 Orange, for the bronchoconstrictor
- 7 Broncho-dilator 400 Green, for the bronchodilator

Other colors are used for:

- 4 Broncho-constrictor 1 Selected step (grey)
- 5 Broncho-constrictor 4 Mouse over the step (light grey)



By pressing the button **Delete Step**, you can delete the selected step.

When all the data are entered, press **Save** in order to save the protocol.

■ **Modify an existing protocol**

In order to modify an existing protocol, change the data in the fields and press **Save**. Please see the section above (*Add a new protocol*) for a description of each field.



The device manager allows to configure all connected devices.

Device Name	Enabled	Port	Serial Number	Bluetooth
K5	<input checked="" type="checkbox"/>	USB	Show	Discover
microQuark with dongle	<input checked="" type="checkbox"/>	USB	Show	
microQuark	<input checked="" type="checkbox"/>	USB	Show	
Pony FX with dongle	<input checked="" type="checkbox"/>	USB	Show	
Pony FX	<input checked="" type="checkbox"/>	USB	Show	
K4b2	<input checked="" type="checkbox"/>	COM3	Show	
Pony FX Flowsafe with dongle	<input checked="" type="checkbox"/>	USB	Show	
Pony FX Flowsafe	<input checked="" type="checkbox"/>	USB	Show	
Pony FX MIP/MEP with dongle	<input checked="" type="checkbox"/>	USB	Show	
Pony FX MIP/MEP	<input checked="" type="checkbox"/>	USB	Show	
Spiropalm with dongle	<input checked="" type="checkbox"/>	USB	Show	
Spiropalm	<input checked="" type="checkbox"/>	USB	Show	
Spiropalm 6MWT with dongle	<input checked="" type="checkbox"/>	USB	Show	
Spiropalm 6MWT	<input checked="" type="checkbox"/>	USB	Show	
Spiropalm Plus with dongle	<input checked="" type="checkbox"/>	USB	Show	
Spiropalm Plus	<input checked="" type="checkbox"/>	USB	Show	
Quark Spiro with dongle	<input checked="" type="checkbox"/>	USB	Show	
Quark Spiro	<input checked="" type="checkbox"/>	USB	Show	
Quark PFT with dongle	<input checked="" type="checkbox"/>	USB	Show	
Quark PFT	<input checked="" type="checkbox"/>	USB	Show	
Quark RMR	<input checked="" type="checkbox"/>	USB	Show	
Quark PFT Body with dongle	<input checked="" type="checkbox"/>	USB	Show	
Quark RMR with dongle	<input checked="" type="checkbox"/>	USB	Show	
Quark PFT Body	<input checked="" type="checkbox"/>	USB	Show	
Quark CPET with dongle	<input checked="" type="checkbox"/>	USB	Show	
Quark CPET	<input checked="" type="checkbox"/>	USB	Show	

On the left side, a list of all COSMED devices that can be interfaced with this software is shown.

As a default, only the enabled devices are shown. In order to see all the devices, please select the checkbox **Show all devices** under the list.

To enable/disable the communication of a device with the software, please check/uncheck the Enabled checkbox.

To select the communication port, click on the corresponding drop-down menu under the Port column and select the proper item.

On the right side, you can select which device and flowmeter are the default ones for each test.

By clicking on the **Show** button, you can see the serial number(s) of the connected device(s).



To upload the firmware to a device, please highlight the device in the list and click on **Upload firmware**: the software will send the firmware stored on the hard drive to the selected device. A progress bar is displayed during the transmission.

PPX Note: When uploading the firmware to a device with a Bootloader up to 1.5 (excluded), at the end of the transmission the SW confirms the upload, but the firmware could hang on 99%. In this case, a manual reset of the device is necessary. In any case, the firmware is successfully uploaded. The Bootloader version is displayed as soon as the device is powered on (before the COSMED logo).



The **Scan Devices** button will scan all the connected (and authorized) devices and will update the list on the left accordingly.



SPIRO **PFT** **CPET** **RMR** **Q-Box** The **Device Info** button allows to visualize the information for the selected device. It is possible to print this information by pressing the **Print** button.



PFT **CPET** **RMR** **Q-Box** The **Speed Factor Settings** button allows to visualize and (in case) edit the calibration parameter for the O₂ sensor time response.

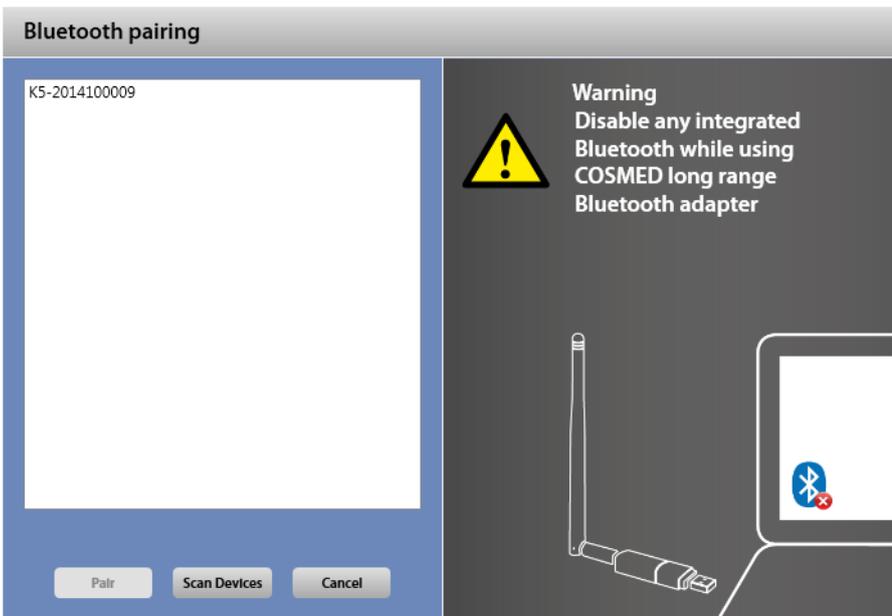
Press **Save** to save the choices, **Cancel** to cancel the operation.

■ **Pair the K5 unit via Bluetooth**

K5

After connecting the Bluetooth receiver to the USB port of the PC, turn on the K5.

Press **Discover** in the Bluetooth column of the **Device Manager** panel. The software will start searching the K5 via Bluetooth.

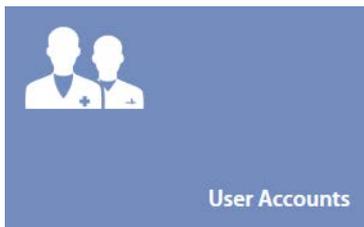


At the end of the searching procedure, select the device to be paired.

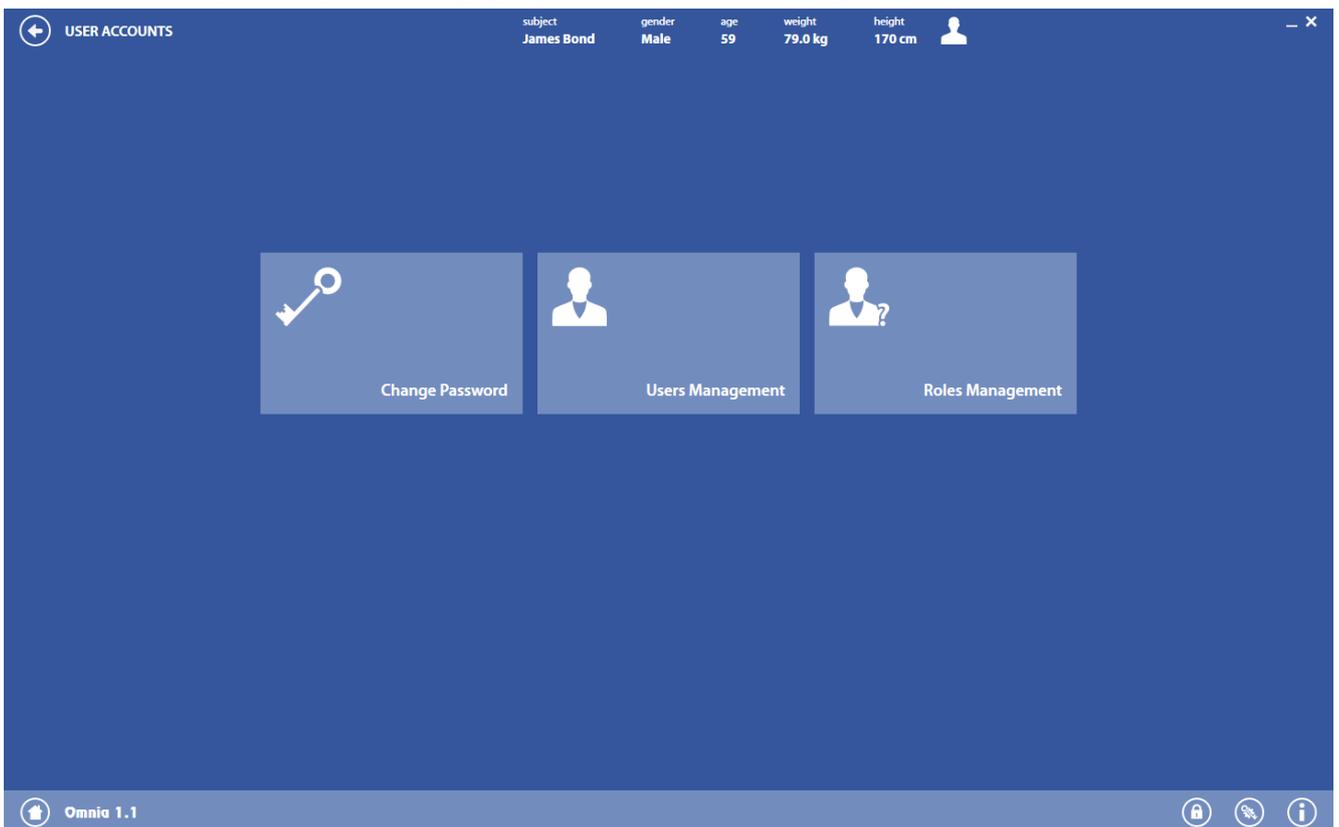
The **Device Manager** panel will display, in the **Port** column, the paired device, creating a virtual communication channel.

In case of problems experienced during the pairing, please refer to the **Troubleshooting** section of the K5 user manual.

User Accounts



The **User Account** tile opens a new panel, for changing the password and for the users management.



This panel allows the user to:

- **Change Password:** changes the password of the current user
- **Users Management:** opens the users management utility (editing reserved to the Administrator only)
- **Roles Management:** opens the roles management utility (editing reserved to the Administrator only)

Change Password



In this panel, you can change your password, by typing the old password and the new password in the proper fields.

Old Password

New Password

Confirm New Password

OK Esc

Press **OK** to confirm, **Cancel** to abort.

■ Users management (editing reserved to the Administrator only)



The users management panel allows the Administrator to add users, delete users or the ability to request one or more user to change the password. Other users can only view the information.

USERS MANAGEMENT

subject: SUBJECT DEMO gender: Male age: 48 weight: 97.00 kg height: 195 cm logged in as: Administrator

Domain	Login Name	First Name	Last Name	Inactive	Change PWD @ 1st Login	PWD never expires
<Omnia>	admin	Administrator		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<Omnia>	support	Technical Support		<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<Omnia>	UserName	First Name	Last Name	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Roles

- PFT Technicians
- Technical Support
- Administrators

Omnia 1.4 logged in as: Administrator

The panel is divided in two sections: the users list (on the left) and the roles list (on the right).

The users list lists all the users that can access the software. Two users are predetermined and cannot be changed, nor deleted: *admin* (the Administrator) and *support* (for the technician who must service the software and/or the device). Other users can be added or deleted by the Administrator.

The roles list lists all the roles defined in the *Roles management* panel (see below). For each user, you can set the roles he/she belongs to.

One or more roles can be assigned to an user.

Add a new user



In order to add a user, press the **Add User** button.

A screenshot of the "Add User" dialog box. It has a blue header with the title "Add User". The main area is white with a blue border. On the left, there are input fields for "User Name", "First Name", and "Last Name". Above "User Name" is a "Domain" dropdown menu set to "<Omnia>". To the right of "User Name" is a "Users" button. Below the input fields are three checkboxes: "Change PWD @ 1st Login" (checked), "PWD never expires", and "Inactive". On the right side, there is a "Roles" table with a filter icon and an "Assign" button. The table lists "PFT Technicians", "Technical Support", "Administrators", and "Physicians", each with an unchecked checkbox. At the bottom right are "Save" and "Cancel" buttons.

The above window will open. Select the domain and the roles.

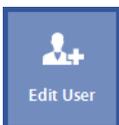
If the Omnia domain is chosen, please select User Name, First Name, Last Name, the roles and the following options:

- *Change PWD @ 1st login*: requires (if checked) the selected user to change his/her password when he/she authenticates next time.
- *PWD never expires*: allows (if checked) the password to be valid forever (independently from the system settings).
- *Inactive*: disables (if checked) the selected user: it means that this user cannot access to the software until re-enabled.

If the network domain is chosen, please press **Users** in order to enter the information of the selected user of the network, select the roles and the following option:

- *Inactive*: disables (if checked) the selected user: it means that this user cannot access to the software until re-enabled.

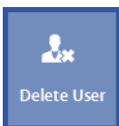
Edit a user



In order to edit a user, select it and press the **Edit User** button. The same dialog boxes used for adding a new user will open.

Edit data and press **OK**.

Delete a user



In order to delete a user, select it and press the **Delete User** button. Confirm the operation or cancel.

Reset the password



The **Reset Password** button allows one to reset the password of the selected user. The next time he/she authenticates, he/she will be required to create his/her password (i.e. an "user reset", a re-initialization of the user, as it was a new user).

Roles management (editing reserved to the Administrator only)

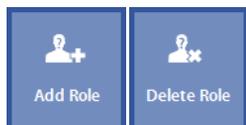


The roles management panel allows the Administrator to add roles, delete roles or change the rights for each role. Other users can only view the information.

A screenshot of the 'ROLES MANAGEMENT' interface. The top bar shows user information: 'subject SUBJECT DEMO', 'gender Male', 'age 46', 'weight 98.0 kg', and 'height 195 cm'. The main area is split into two panels. The left panel, titled 'Roles', lists 'Administrators', 'PFT Technicians', 'Physicians', and 'Technical Support'. The right panel, titled 'Rights', lists various permissions with checkboxes for assignment. A 'Save' button is at the bottom right. The footer shows 'Omnia 1.2' and system icons.

The panel is divided in two sections: the roles list (on the left) and the rights for each role (on the right).

The *Administrator* and the *Technical Support* roles are predetermined and cannot be changed. For each of the other roles (and for the roles defined by the Administrator) you can change the rights by selecting or deselecting the corresponding checkboxes on the right section.



To add or to delete a role, respectively press the **Add Role** or **Delete Role** button.

Press **Save** to save changes.

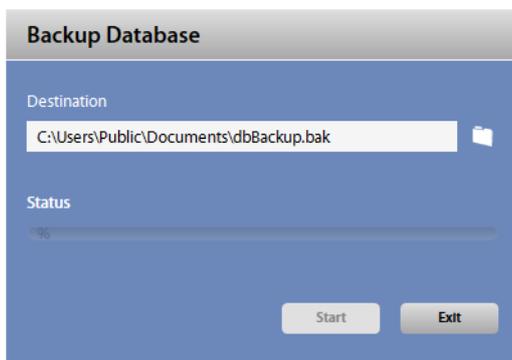
□ Backup database (Standalone version only)



We recommend that you periodically back-up the archives, in order to avoid damage or loss of data.

Data can be backed-up on the PC itself or on an external device (CD, DVD, external hard disk). If you back-up your data on an external device, the data is protected against PC crashes and/or damage, or against internal hard drive crashes or damage. On the contrary, if data are backed-up only on an external device, they cannot be protected against damage of that external device.

COSMED does not assume any liability for damage or loss of data, for example if a hard drive, a PC, a DVD damage should occur. We suggest to create multiple back-ups of data in order to overcome these potential problems. Media damages occur more frequently than you can imagine!



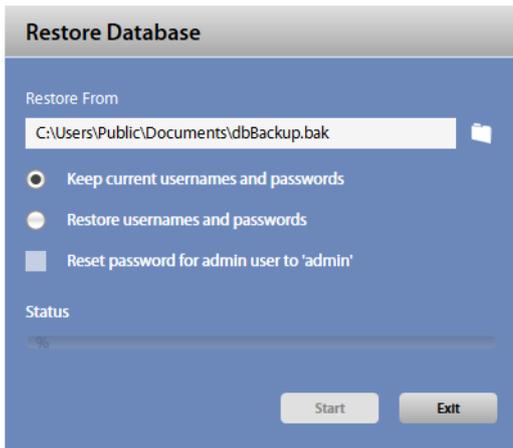
Enter the path and the name of the backup file (by clicking on the  icon) and press **Start**. A progress bar will show the operation status..

Note: the backup must be stored in a folder not connected to the current user (i.e. the desktop or the Documents folder). We suggest to save the file in a dedicated folder of the main disk, for example in C:/Backup.

Restore database (Standalone version only)



Restore the database from a previously backed-up file.



In order to restore a database, select a backup file by clicking on the  icon and press **Start**. A progress bar will show the status of the operation. For restoring database, it is possible to keep the current usernames and passwords (without restoring them) or to restore them. It is also possible to reset the Administrator password to the default one. Please check the desired option before starting the restore.

□ *Backup and restore on server PC (Network version only)*

In Network version, backup and restore cannot be performed by means of the Omnia software.
It can be performed by the IT department directly operating on the database stored in the server PC.

□ **Data import from CSV (option)**

Note: This is an optional module, that must be bought separately.



Competitive Data Import is an optional software module, available with OMNIA starting from version 1.5, which allows users importing external data into the OMNIA database.

This feature can be very useful whenever there is the requirement to import old archives/data from equipment made by other manufacturers.

Note: COSMED does not guarantee that data exported in *.csv format are correct and suitable for importing in OMNIA database. Please verify that the *.csv file contains correct data.

■ **Before importing data**

Before importing data into OMNIA you must create a backup of your database. To do so please run **Backup Database** from *Utility* menu. In case of wrong data import choose **Restore Database** from *Utility* menu to return to original database.

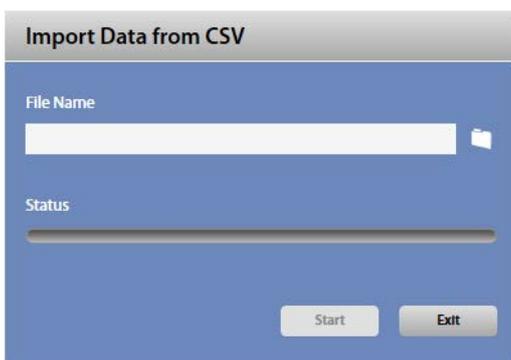
■ **Importing Data into OMNIA**

The process to import is simple. Users must use a predefined *.csv (comma separated values) file that is provided with OMNIA. This file is located in the OMNIA install folder. The *.csv file is a plain text file in which each line is a data record. Each record consists of one or more fields, separated by semicolon.

A description of the file and of the fields data structure can be found in the next pages, as well as a list of mandatory fields.

Note: Once you are ready to import data, be sure to save the Excel file as "CSV (Comma delimited) (*.csv)" file format. OMNIA will not accept the file unless is a *.csv type.

Note: If any error occurs during import in progress no data will be imported in the OMNIA database.



In order to import data, select a *.csv file by clicking on the  icon and press **Start**. A progress bar will show the status of the operation.

■ **How to view Imported Data into OMNIA**

Once you have completed the import process, OMNIA handles data in the same way of data generated through COSMED products. You can access data via the database management panel.

subject: SUBJECT DEMO gender: Male age: 44 weight: 73.00 kg height: 178.0 cm

Search by Name or SSN Test Type

Subject

Last Name	First Name	DOB	Gender
DEMO	SUBJECT	04/03/1967	Male

Visits

Date	Physician	Operator	Height	Weight	Compe
25/02/2012	Dr. House	Mr. Q	178.0	73.00	COSME

Tests

Time	Type	Details
00.00.00	Offline Test	FVC, SVC, MVV, Body P

Omnia 1.5 Logged in as: Administrator

To recognize the imported test vs. the one performed with the equipment the database mark the test as *Offline Test*.

You can review data imported into OMNIA by clicking on View icon or double click on the row. OMNIA shows the imported parameters in the following way.

subject: SUBJECT DEMO gender: Male age: 44 weight: 73.00 kg height: 178.0 cm

OFFLINE TEST

Edit

Print

FVC		Meas.	Normal Range	Pred	% Pred	z score
FVC	L	6.32	3.91 - 6.08	4.99	127	2.00
FEV1	L	5.10	3.08 - 4.81	3.97	129	2.22
FEV1/FVC%	%	80.7	68.3 - 89.7	79.8	101	0.14
FVC Post BD	L	6.50	3.91 - 6.08	4.99	130	2.27
FEV1 Post BD	L	5.22	3.08 - 4.81	3.97	132	2.46
FEV1/FVC% Post BD	%	80.3	68.3 - 89.7	79.8	101	0.08
PEF	L/s	13.51	---	-	-	-
FEF25-75%	L/s	4.80	2.02 - 5.75	3.64	132	0.95
MEF25%	L/s	2.00	0.64 - 2.70	1.36	148	0.91
MEF50%	L/s	6.02	---	-	-	-
MEF75%	L/s	12.47	---	-	-	-
FEV6	L	6.10	---	-	-	-
FVC	L	5.80	3.91 - 6.08	4.99	116	1.22
PIF	L/s	7.73	---	-	-	-
FIV1	L	5.41	---	-	-	-
FET100%	s	7.2	---	-	-	-
SVC		Meas.	Normal Range	Pred	% Pred	z score
VC	L	6.50	3.91 - 6.08	4.99	130	2.27
IC	L	5.00	---	3.67	136	-
ERV	L	1.50	---	1.40	107	-
IRV	L	4.50	---	-	-	-
VT	L(btps)	0.500	---	-	-	-
MVV		Meas.	Normal Range	Pred	% Pred	z score
MVV	L/min	142.6	---	-	-	-
MVf	l/min	60.1	---	-	-	-
MVT	L	2.37	---	-	-	-
Body Plethysmography		Meas.	Normal Range	Pred	% Pred	z score
TLC(Pleth)	L	8.40	5.99 - 8.29	7.14	118	1.80
FRC(Pleth)	L	4.20	2.48 - 4.46	3.47	121	1.21
RV(Pleth)	L	1.40	1.40 - 2.74	2.07	68	-1.63

Omnia 1.5 Logged in as: Administrator

Edit an Offline test



In order to edit an offline test, press **Edit**. After editing, confirm by pressing **Save**, otherwise press **Cancel** to cancel editings.

The screenshot shows a software interface for editing an offline test. The title bar reads "EDIT OFFLINE TEST - SUBJECT: SUBJECT DEMO - DATE: 25/02/2012". The subject information is displayed as: subject: SUBJECT DEMO, gender: Male, age: 44, weight: 73.00 kg, height: 178.0 cm. The interface is divided into several sections for different lung function parameters:

- FVC:** FVC (L) 6.32, FEV1 (L) 5.10, FEV1/FVC% (%) 80.7, FVC Post BD (L) 6.50, FEV1 Post BD (L) 5.22, FEV1/FVC% Post BD (%) 80.3, PEF (L/s) 13.51, FEF25-75% (L/s) 4.80, MEF25% (L/s) 2.00, MEF50% (L/s) 6.02, MEF75% (L/s) 12.47, FEV6 (L) 6.10, FVC (L) 5.80, PIF (L/s) 7.73, FIV1 (L) 5.41, FET100% (s) 7.2.
- SVC:** VC (L) 6.50, VC Post BD (L) -, IC (L) 5.00, ERV (L) 1.50, IRV (L) 4.50, VT (L(bits)) 0.500.
- MVV:** MVV (L/min) 142.6, MRf (1/min) 60.1, MVT (L) 2.37.
- Body Plethysmography:** (This section is currently empty).

At the bottom right, there are "Save" and "Cancel" buttons. The footer shows "Omnia 1.5" and "Logged in as Administrator".

File description and field data structure

Each line can be one of the following three types:

- Comment
- Header
- Data

The decimal separator used is '.' (dot).

The encoding for the CSV file is UTF-8.

Comment lines

Comment lines must be preceded by a # and can be everywhere in the file.

Header line

Only one header line is allowed in each file, and must be placed before any data line in the file.

The header line contains the field descriptors (see below)

Data line

Data lines contain data related to the subject and/or to the test.

All fields are optional, except the following ones related to the subject:

- First name
- Last name
- Day of birth
- Gender

- Ethnic group

If a visit or test parameters are present, mandatory fields for visit are:

- Visit date
- Height
- Weight

Data structure - subject data

Field description (header line)	Data type
ID	Alphanumeric
SSN	Alphanumeric
FIRSTNAME	Mandatory. Alphanumeric
MIDDLENAME	Alphanumeric
LASTNAME	Mandatory. Alphanumeric
DOB (day of birth)	Mandatory. Date. Allowed format: dd-mm-yyyy
GENDER	Mandatory. Number. Allowed values: 0 – Female 1 – Male 2 – Other (HL7-compatible genders enabled) 3 – Transgender (HL7-compatible genders enabled) 4 – Hermaphrodite/undetermined (HL7-compatible genders enabled)
ETHNICGROUP	Mandatory. Number. Allowed values: 0 – Other 1 – Indian 2 – Caucasian 3 – Mexicans 4 – South India 5 – Hispanic 6 – Chinese 7 – Polynesian 8 – North East Asia 9 – North Indian Pakistan 10 – Thai 11 – South East Asia 12 – African Descendant 13 – Japanese
ADDRESS	Alphanumeric
CITY	Alphanumeric
ZIPCODE	Alphanumeric
COUNTRY	Alphanumeric
MOBPHONE	Alphanumeric
WORKPHONE	Alphanumeric
HOMEPHONE	Alphanumeric
FAX	Alphanumeric
EMAIL	Alphanumeric
INSURANCECOMPANY	Alphanumeric

INSURANCENUMBER	Alphanumeric
SUBJCOMMENTSSUBJ	Alphanumeric
Data structure - visit data	
Field description (header line)	Data type
VISITDATE	Mandatory, if visit data is present. Date. Allowed format: dd-mm-yyyy
HEIGHT	Mandatory, if visit data is present. Decimal, UM: cm
WEIGHT	Mandatory, if visit data is present. Decimal, UM: Kg
COMPANY	Alphanumeric
DEPARTMENT	Alphanumeric
OCCUPATION	Alphanumeric
REFPHYSICIAN	Alphanumeric
PHYSICIAN	Alphanumeric
TECHNICIAN	Alphanumeric
SMOKE	Number. Allowed values: 0 – No 1 – Yes 2 – Ex
CIGDAY	Number. Allowed values: 0-255
TOBACCO	Number. Allowed values: 0 – Other 1 – Cigarette 2 – Cigar 3 – Pipe
SMOKINGYEARS	Number. Allowed values: 0-255
NONSMOKINGYEARS	Number. Allowed values: 0-255
LIFESTYLE	Number. Allowed values: 0 – Unknown 1 – Bed rest 2 – Sedentary 3 – Active 4 – Athletic
INTERPRETATION	Alphanumeric
VISITREASON	Alphanumeric
SYMPTOMS	Alphanumeric
MEDICALPRESCRIPTION	Alphanumeric
DIABETES	Number. Allowed values: 0 – No 1 – Yes
HRMAXPRED	Integer, UM: bpm

CVDHISTORY	Number. Allowed values: 0 – No cardiovascular disease 1 – Mother or sister before age 65 2 – Father or brother before age 65 3 – More than 1 individual
CVDSYMPTOMS	Number. Allowed values: 0 – No symptoms 1 – Angina 2 – Shortness of breath at rest or with mild exertion 3 – Dizziness or syncope 4 – Orthoepa or paroxysmal nocturnal dyspnea 5 – Ankle edema 6 – Palpitations or tachycardia 7 – Intermittent claudication 8 – Known heart murmur 9 – Unusual fatigue
TECHNOTES	Alphanumeric
PHYSNOTES	Alphanumeric
NOTES	Alphanumeric

Data structure - test data

Test category	Parameter	Unit of measurement
FVC	FVC	L
	FEV1	L
	FEV1FVC	%
	FVC_POSTBD	L
	FEV1_POSTBD	L
	FEV1FVC_POSTBD	%
	PEF	L/s
	FEF25_75	L/s
	MEF25	L/s
	MEF50	L/s
	MEF75	L/s
	FEV6	L
	FIVC	L
	PIF	L/s
	FIV1	L
FET100	s	
SVC	VC	L
	VC_POSTBD	L
	IC	L
	ERV	L
	IRV	L

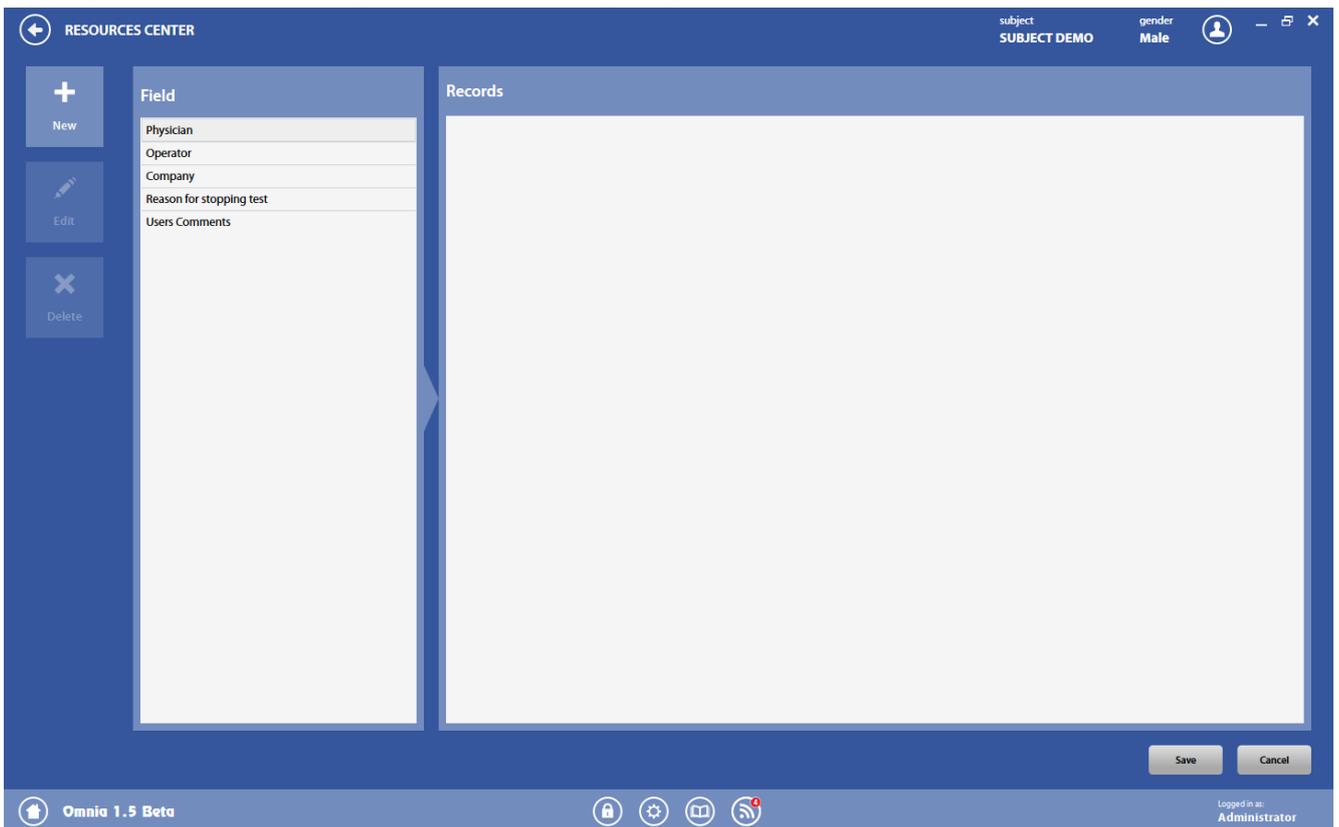
	VT	L(btps)
MVV	MVV	L/min
	MRF	1/min
	MVT	L
Bodt plethysmography	TLC_PLETH	L
	TGV	L
	RV_PLETH	L
	RV_TLC_PLETH	%
	TGV_TLC_PLETH	%
	SRAW	mmHg*s
	SGAW	1/mmHg/s
	RAW_EFF	mmHg*s/L
	SRAW_EFF	mmHg*s
	RAW_INS	mmHg*s/L
	RAW_EXP	mmHg*s/L
	RAW	mmHg*s/L
	GAW	L/mmHg/s
DLCO	DLCO	mL/min/mmHg
	DLCO_CORR	mL/min/mmHg
	DLCOVA	mL/min/mmHg/L
	VA	L
	TLC_DLCO	L
	RV_DLCO	L
	FRC_DLCO	L
	ALV_BLOOD_VOL	mL
	DLCO_MEMB_DIFF	mL/min/mmHg
	IV_DLCO	L
	BREATH_HOLD_TIME	s
N2 Multi-Breath Washout	FRC	L
	TLC_N2WO	L
	RV_N2WO	L
	CEV	L
	LCI	
	FETN2	%
	WASHOUT_TIME	mm:ss
N2 Single-Breath Washout	CV	mL
	CC	L
	DELTA_N2	%
	SIII	%/L
	V_I	mL

	V_II	mL
	V_III	mL
	VC_DURING_CV	mL
MIP/MEP	MIP	mmHg
	MEP	mmHg
ROCC	ROCC_EXP	kg*m
	GOCC_EXP	mmHg/L/s
	ROCC_INSP	L/s/mmHg
	GOCC_INSP	mmHg/L/s
	ROCC_EXP_POSTBD	L/s/mmHg
	GOCC_EXP_POSTBD	mmHg/L/s
	ROCC_INSP_POSTBD	L/s/mmHg
	GOCC_INSP_POSTBD	mmHg/L/s
Six Minute Walk Test	SIXMWD	kg*m
	TEST_TIME	mm:ss
	BL_DYSPNEA	
	FINAL_DYSPNEA	
	BL_FATIGUE	
	FINAL_FATIGUE	
	HR_START	bpm
	HR_END	bpm
	INITIAL_SPO2	%
	FINAL_SPO2	%
	SUPPL_O2_FLOW	L/min
CPET	VO2	mL/min
	VO2KG	mL/min/Kg
	VEVC02_SLOPE	
	OUES	ml/min/l/min
	R	
	VE	L/min
	VO2AT	mL/min
	VO2HR	mL/beat
	VO2WR_SLOPE	mL/min/Watt
	HRR_1_MINUTE	bpm
REE	RMR	kcal/day
	R_REE	
	VO2_REE	mL/min
	VC02_REE	mL/min
	VE_REE	L/min
	RF_ERGO	1/min

	FATPERC	%
	CHOPERC	%
	PROPERC	%
Other	HB	g/dL
	COHB	%
	SUPPL_O2	%
	UN	g/day
	FENO	ppb
	PACO2	mmHg
	PAO2	mmHg
	PH	
	SAO2	%
	HCO3	mmol/L
	LA	mmol/L
	BE	mmol/L
	FI02	%
	VDVT	
	SBP	mmol/L
	DBP	mmol/L
	HDL	mg/dL
	TOTAL_CHOLESTEROL	mg/dL



By clicking on the *Resources Center* tile, you can access to the corresponding function.



Resource dictionary function allow users to manage (adding, editing and deleting items):

- Physician, Operator and Company lists
- Reasons for stopping test list
- User Comments



The buttons on the left allows the user to add (**New**), edit (**Edit**) or delete (**Delete**) an item.



The **Event log** panel shows all the events logged by the software.

The screenshot shows the 'EVENT LOG' window. On the left is a calendar for February 2014. Below the calendar is a 'Show Severity' section with two checkboxes: 'Failed audit' (checked) and 'Success audit' (checked). The main area contains a table of events:

Date	Severity	User Name	Machine
04/02/2014 11:46:22 AM	Success audit	admin	COSMED
04/02/2014 11:46:18 AM	Failed audit	admin	COSMED
04/02/2014 10:53:49 AM	Success audit	admin	COSMED
04/02/2014 10:48:45 AM	Success audit	admin	COSMED
04/02/2014 10:32:49 AM	Success audit	admin	COSMED
04/02/2014 10:24:19 AM	Success audit	admin	COSMED
04/02/2014 10:20:46 AM	Success audit	admin	COSMED
04/02/2014 10:19:59 AM	Success audit	admin	COSMED
04/02/2014 10:19:59 AM	Success audit	admin	COSMED
04/02/2014 10:19:45 AM	Failed audit	admin	COSMED

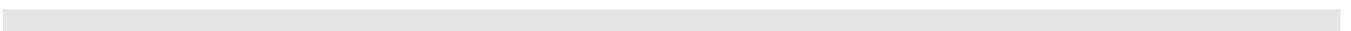
Below the table, a message reads: 'User cannot login, reason: User must change password before login'. A 'Cancel' button is located at the bottom right of the window. The software version 'Omnia 1.2' is displayed in the bottom left corner.

It is possible to sort these events by date (by clicking on the desired date on the calendar) and/or by type (by checking/unchecking the type in the *Show Severity* section below the calendar).

To remove the date filter, please double click on the selected date.

The event log can be useful for maintenance activities.

Calibration



□ Introduction

Regular calibration is necessary to assure your system is acquiring reliable measurements. Each device requires different calibrations depending on the features of each product.

■ Flow/volume calibration

Flow/volume calibration is performed using a 3-liter calibration syringe. If the syringe is not included in the packaging it can be ordered directly from COSMED, REF C00600-01-11.

Each flowmeter requires a separate calibration.

Note: If an anti-bacterial filter is used during testing, you should also use one when performing the turbine calibration.

?

Turbine calibration

Flows and volumes are measured by the bidirectional digital turbine, which offers a very low resistance to flow. Air passing through the helical conveyors cause the spiral rotation of the turbine rotor.

The rotating blade interrupts the infrared light beamed by the three diodes of the optoelectronic reader.

The turbine flowmeter does not require daily calibration since it is not affected by pressure, humidity and/or temperature. However, regular calibration should still be performed as well as the recommended maintenance procedures (see *System maintenance* chapter of the device user's manual).

PNT Flowsafe calibration

PFX Sp SPIRO PFT Q-Box

The PNT Flowsafe is a disposable flow transducer (pneumatich) which calculates the flow by measuring the pressure differential between the two sides of a screen. COSMED recommends that you perform a daily calibration and a calibration every time a new box of pneumatichs is opened.

PNT X9 calibration

PFX Sp SPIRO PFT Q-Box

The PNT X9 is a flow transducer (pneumatich) which calculates the flow by measuring the pressure differential between the two sides of a screen. ATS recommends a daily calibration of the pneumatich.

Note: The PNT X9 must be calibrated with the COSMED antibacterial filter.

Flow Ree calibration

RMR

The Flow Ree is a disposable flow transducer (pneumatich) used in ICU testing only, which calculates the flow by measuring the pressure differential between the two sides of a screen. COSMED recommends that you perform a calibration every time a new pneumatich is used.

Note: The Flow Ree must be calibrated with the HME filter.

■ Analyzer calibration

PFT CPET RMR Q-Box K5

The software allows you to automatically calibrate the zero, gain and delay of the gas sensors. We strongly recommend that you perform these calibrations prior to each test.

Note: Before using the device you must allow for the required warm-up period, which is different depending on which test is being performed. The first chapter of the User manual of the device specifies the minimum warm-up times.

The device should be powered on in order to warm-up the system. It is not necessary that the PC software is open during the warm-up period. You should not perform calibrations or testing procedures until the system has completed the required warm-up period.

for how long?

■ Body Box calibration

Q-Box

The software allows you to verify the box leakage and to calibrate the polytrophic factor.

The first operation checks that the global system time constant is within the acceptability range, the second one calculates that the polytrophic factor.

If one or both these calibrations fail, please don't perform any test and contact COSMED technical support.

■ Calibration frequency

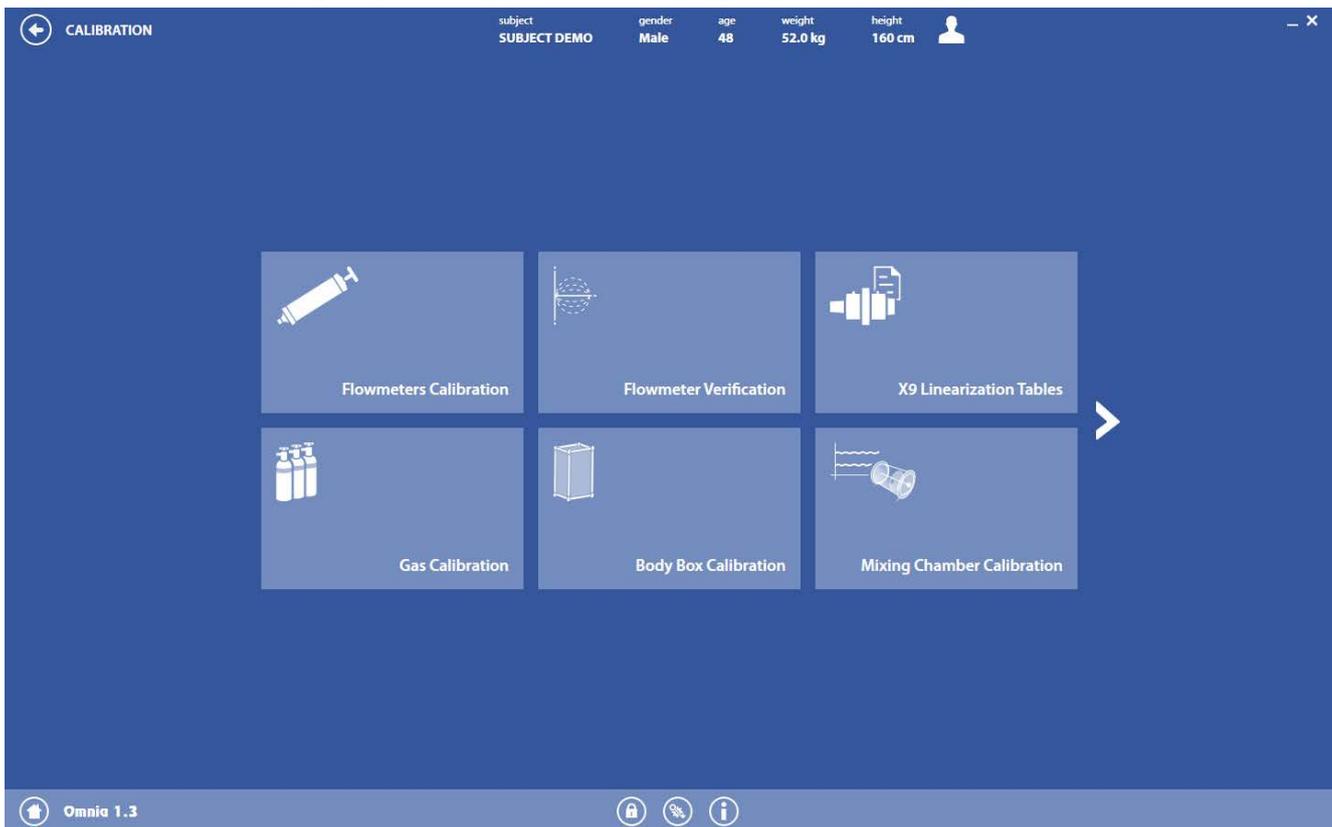
The table below shows a summary with the calibration intervals recommended by COSMED.

Calibration	Device(s)	Recommended interval
Turbine	All	Each week, if the flowmeter is changed, if the ambient conditions (temperature, humidity and pressure) change significantly and in all the cases you suspect that the measurements are not reliable anymore
PNT Flowsafe	PFX Sp SPIRO PFT Q-Box	Each time the flowmeter is changed (the PNT Flowsafe is a disposable device)
PNT X9	PFX Sp SPIRO PFT Q-Box	Each day, if the flowmeter is changed, if the ambient conditions (temperature, humidity and pressure) change significantly and in all the cases you suspect that the measurements are not reliable anymore
Flow Ree	RMR	Each time the flowmeter is changed (the Flow Ree is a disposable device)
Metabolic - ERGO	PFT CPET RMR K5	Each day or if the ambient conditions (temperature, humidity and pressure) change significantly
DLCO	PFT Q-Box	Each day or if the ambient conditions (temperature, humidity and pressure) change significantly
N2 Washout	PFT	Each day or if the ambient conditions (temperature, humidity and pressure) change significantly
Air	PFT CPET RMR K5	Each day or if the ambient conditions (temperature, humidity and pressure) change significantly
Metabolic - ICU	RMR	Each day or if the ambient conditions (temperature, humidity and pressure) change significantly
Mixing Chamber	PFT CPET RMR K5	Each day or if the ambient conditions (temperature, humidity and pressure) change significantly
Leakages	SPIRO PFT Q-Box	Each day
Polytropic factor	SPIRO PFT Q-Box	Each day or if the ambient conditions (temperature, humidity and pressure) change significantly

Running the Calibration program



In order to start the calibration program, press the **Calibration** tile in the home panel.



The tiles in the calibration program are:

- **Flowmeter calibration:** begins a flowmeter calibration
- **Flowmeter Verification:** begins a flowmeter verification
- **X9 Linearization Tables:** enters or creates the linearization tables for the PNT X9
- **Gas Calibration:** begins a gas calibration
- **Body Box Calibration:** begins a Q-Box leakages or polytropic factor check
- **Mixing Chamber Calibration:** begins a flowmeter calibration for tests with mixing chamber
- **Control Panel:** opens the control panel
- **Calibration Archive:** opens the flowmeter calibration archive

The  and  icons allow to navigate through the different pages of the panel.

□ Flowmeter calibration

In this chapter, the calibration procedure for both turbine, Flowsafe and PNT X9 is described.

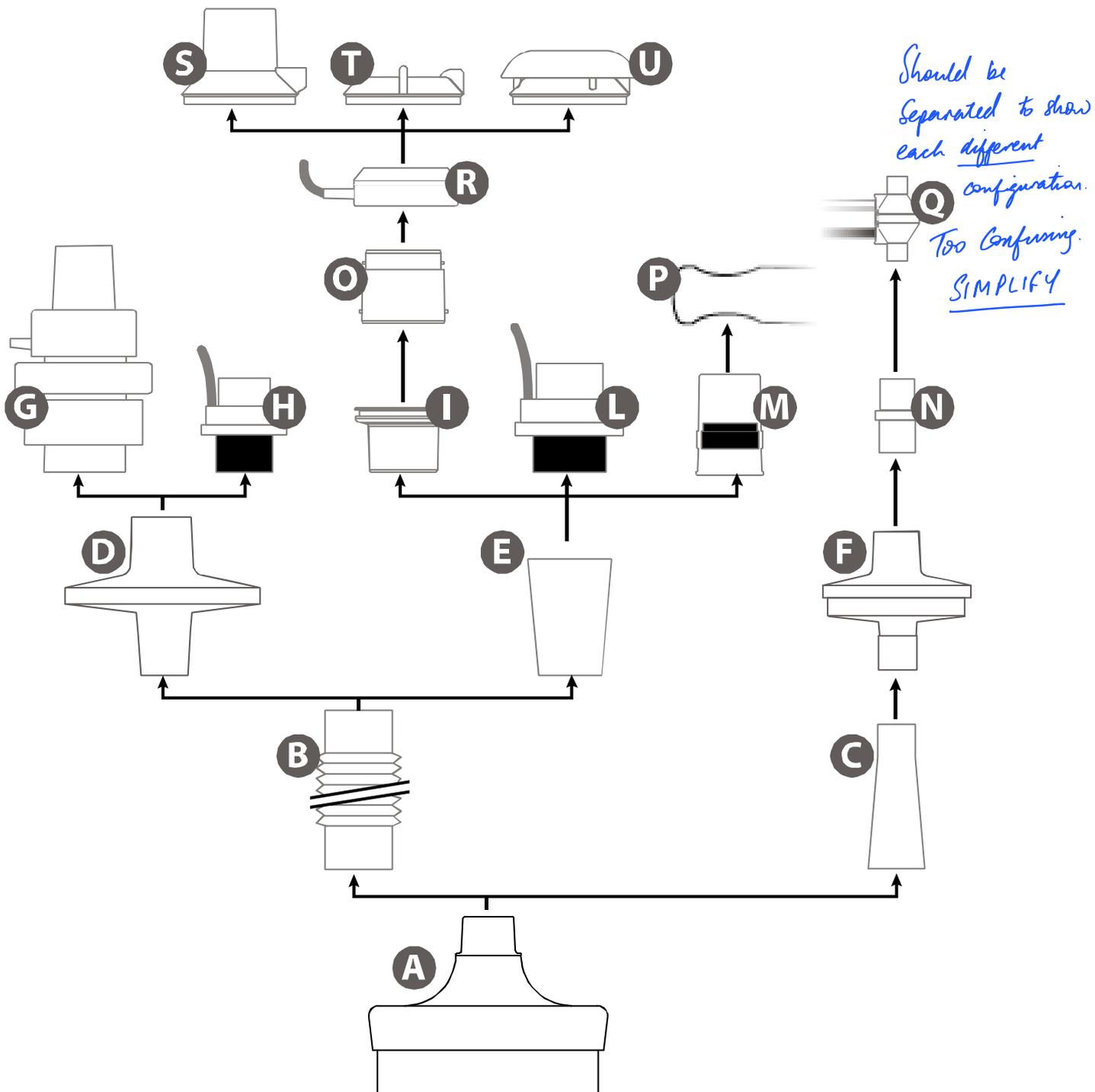
■ Setup

In order to perform flow and volume calibrations you should connect the syringe to the flowmeter of choice, as shown in the picture below.

A flowmeter calibration is mandatory when you change the flowmeter, when the ambient conditions (temperature, humidity and pressure) change significantly and in all the cases you suspect that the measurements are not reliable anymore. COSMED also suggests to repeat the calibration each week.

You should check that the correct reference values are used (see page 44) before performing the calibration.

Note: If a bacterial filter is used for testing you should also include one during the flowmeter calibration.



A. Calibration syringe	C00600-01-11
B. Wrinkled tube	A-108-300-012
C. ID18 turbine adapter	C03047-01-20
D. Antibacterial filter	A-182-300-004
E. Conic adapter	C00063-01-20
F. HME Filter	A-182-300-006
G. PNT X9	C03600-01-05
H. ID18 turbine	C02500-01-04
I. Optoelectronic reader mouthpiece adapter	C02106-01-08
L. ID28 turbine	C03400-01-04
M. Pony turbine	C02235-01-05
N. Flow Ree adapter	part of A-662-250-003
O. Turbine 2000	C02120-01-05
P. Digital flowmeter for Pony Turbine	C02364-01-05
Q. Flow-Ree	part of A-662-250-003
R. Opto-reader 2000	C02111-01-06
S. Opto-reader 2000, PFT adapter	C02229-01-08
T. Opto-reader 2000, closing ring	C02155-01-08
U. Opto-reader 2000, wind shield	C02107-01-08

■ Calibration procedure

PFX Sp K5 **Note:** It is not possible to perform the calibration via software for the stand-alone devices. It must be performed directly on the device.

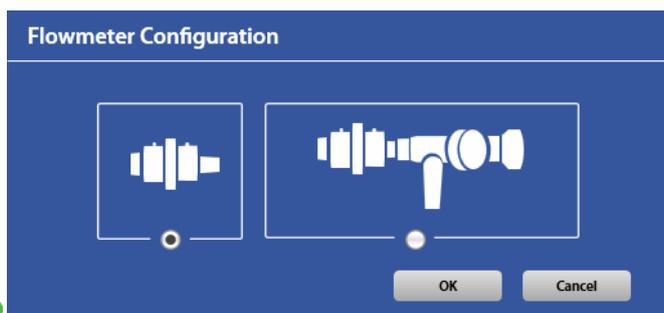
PFT CPET RMR K5 **Note:** Since ventilation is very low during REE testing (normally <10 litres/min), the turbine calibration should be performed with very slow manoeuvres (each manoeuvre lasting between 10-15 seconds).



1. In the *Calibration* panel, press the **Flowmeters calibration** tile.
2. Begin with the syringe piston pushed all the way in.

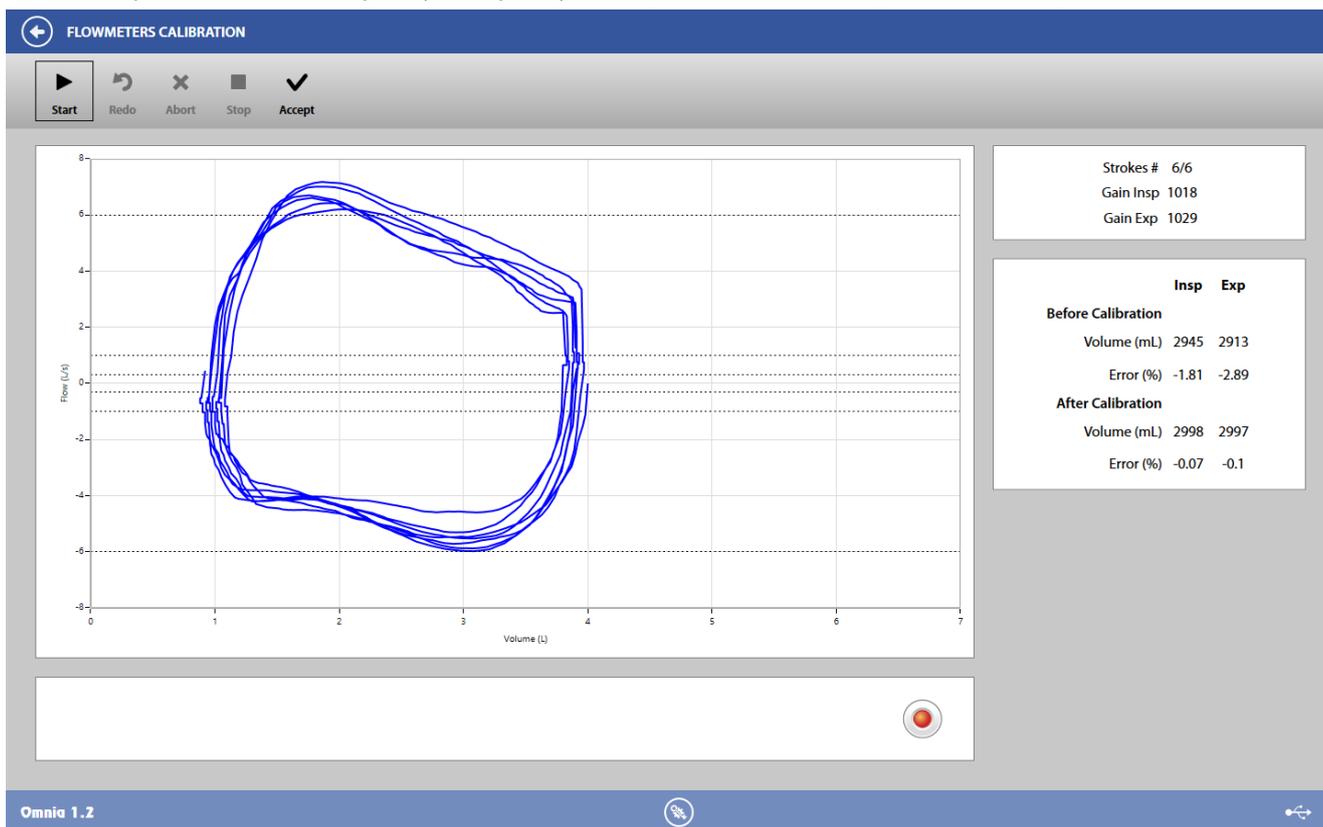


3. Press the **Start** button
4. Select the device and the flowmeter.



5. **SPIRO PFT Q-Box** Select if the breathing valve is used or not.

6. Wait until that the red dot in the lower right part of the screen becomes green.
7. Move the piston in and out for 6 inspiratory and expiratory strokes (2 strokes for ID18 turbine, Flow Ree and Rocc).



The graph on the left will display the F/V graph. On the right you will see the current stroke and, at the end of the calibration manoeuvre, the inspiratory and expiratory gains, and the measured volumes with their relative errors (both inspiratory and expiratory) before and after the calibration.



8. During the manoeuvre, in order to restart the calibration, press **Redo**, to end the calibration press **Stop**, to cancel it press **Abort**.



9. At the end of the calibration, press **Accept**. New values will be stored.

□ Flowmeter verification

The flowmeter verification is useful in order to check the flowmeter response at different flows, using the gains stored at the end of the last calibration. ATS recommends a weekly linearity check.

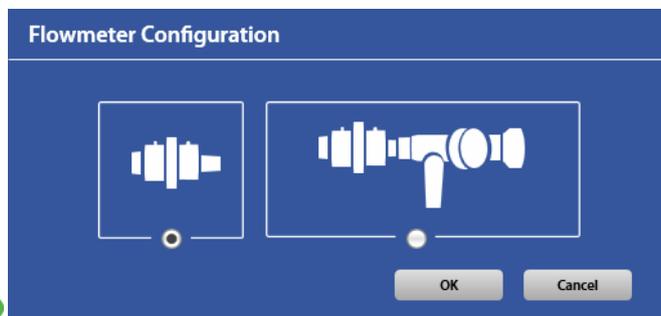


Specify which flowmeter

1. To start the check, press **Flowmeter Verification** in the *Calibration* panel.
2. Begin with the syringe piston pushed all the way in.



3. Press the **Start** button
4. Select the device and the flowmeter.



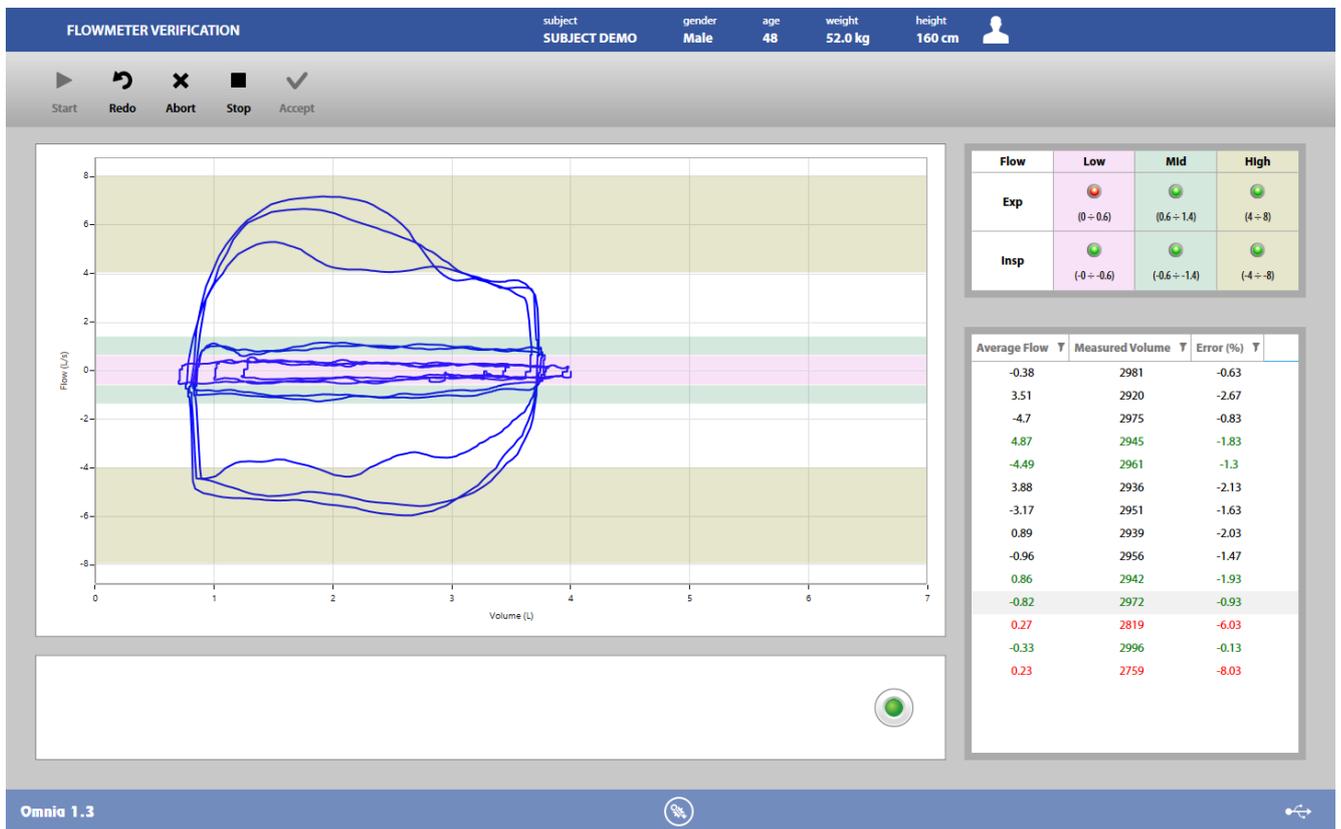
5. **SPIRO** **PFT** **Q-Box** Select if the breathing valve is used or not.
6. Wait until that the red dot in the lower right part of the screen becomes green.
7. Perform strokes at low, mid and high flows in order to let all the red icons in the upper right corner become green.

These icons show the status of the check for low, mid and high flows both for inspiratory and expiratory strokes: they are red if the corresponding check is not completed and green if it is completed.

Each check is completed if a stroke has the mean flow and the measured volume within the acceptable range (according to the *Flowmeter verification* settings).

In the left side of the panel, you can see the F/V graph. In it, six colored bands (for inspiratory and expiratory flows) represents the ranges for low (light pink), mid (light green) and high flows (light brown). When you perform the linearity check, it is important to remain as close as possible with one of the bands in order to complete the corresponding check. Please note that ID18 and Flow Ree have 4 bands only, excluding the *high flows* one.

In the right side of the panel, you can see for each stroke the measured flow, volume and the corresponding relative error, and the status of the checks (low, mid and high flows for both inspiratory and expiratory flows). The color of the icons is red if the corresponding check has not been performed yet or it is not good, green if the corresponding check has passed.



The colors of the stroke values are:

- green, if the stroke is accepted (both flow and volume in the acceptable range). Only the first accepted stroke for each check is green
- black, if the stroke is accepted but there is another accepted stroke for this flow range or if the flow is not in one of the three (low, medium or high) ranges
- red, if the volume is outside the acceptable range according to the *Flowmeter verification* settings.



During the manoeuvre, in order to restart the check, press **Redo**, to end the check press **Stop**, to cancel it press **Abort**.



Press **Accept** to accept the entire check.

Note: The flowmeter linearity check can be stopped even if the six checks are not completed

This function allows the user to create or import the linearization tables for the PNT X9.

Note: The linearization tables are specific for a single X9. If you change the X9 used, you must import (or create) the linearization tables for this new X9.



To start the procedure, press **X9 linearization tables** in the *Calibration* panel.

Import existent linearization tables



1. To import an existent linearization table, press the **Upload** button.
2. Select the device.

Why not make it 'import' instead of upload ?

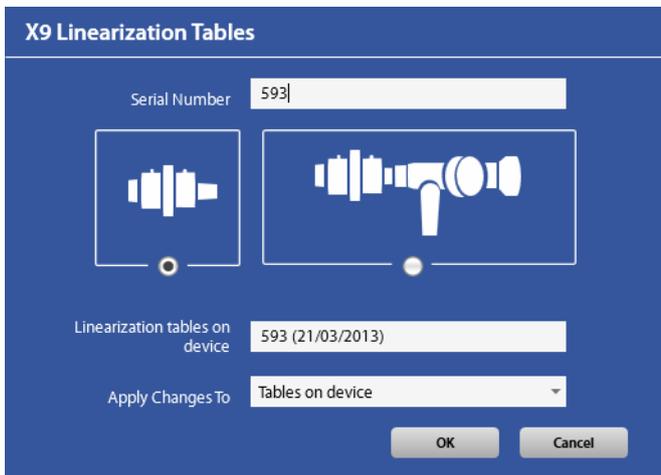
A blue dialog box titled "X9 Linearization Tables" with three input fields: "Serial Number", "Linearization tables on device" (containing "593 (21/03/2013)"), and "File Name" with a folder icon. At the bottom are "OK" and "Cancel" buttons. The "Upload" button from the previous step is circled in blue and points to the "File Name" field.

3. Enter the X9 Serial Number and search (through the  icon) the file containing the linearization table.
4. Press **OK** to confirm or **Cancel** to abort. An acoustic signal will confirm the operation success.

Create new linearization tables



1. Press **Start**.
2. If requested, select the device.



3. Enter the X9 Serial Number, select if the breathing valve is used or not and select *the Apply change to*. The changes can be applied to the generic table (*generic table*, if no linearization table was already imported or created), an imported table (*imported table*, if a linearization table was already imported for the selected serial number) or an existing table (*latest table*, if a linearization table was already created for the selected serial number).
4. Wait until that the red dot in the lower right part of the screen becomes green.
5. Perform strokes at different flows in order to complete all the 8 green bar on the left of the graph. Each bar fills in if the stroke flow is within a predetermined range corresponding to that bar.

	Prev		Current	
EX (8)	2423	19.23	2908	3.07
	mL	%	mL	%
	Volume	Error	Volume	Error
IN (31)	2415	19.50	2838	5.40
	mL	%	mL	%
	Volume	Error	Volume	Error

During the manoeuvre, in the upper right section the measured volume and its relative error (both for inspiration and exhalation, using the existent and the current tables) are shown, while in the lower right section two graphs show the linearization tables (one for the existent table, the other one for the current table). The data for current table are updated in real time, according to the changes to the existent table.



6. During the manoeuvre, press **Redo** in order to restart, press **Zero** to perform the baseline, press **Abort** to cancel, press **Stop** to end the operation.



7. Press **Accept** to accept the results.

This function allows the user to calibrate the gas analyzers.

Connections

In order to calibrate the analyzers you should disconnect the sampling line from the reader and connect it to the front panel of the Quark.

The cylinders used for the calibration must be properly connected to the rear panel of the Quark and the output pressure should be set according the ranges reported on the rear panel of the Quark.

Before starting the calibration you should make sure that the reference values are correct (see the Setting Reference Values section).

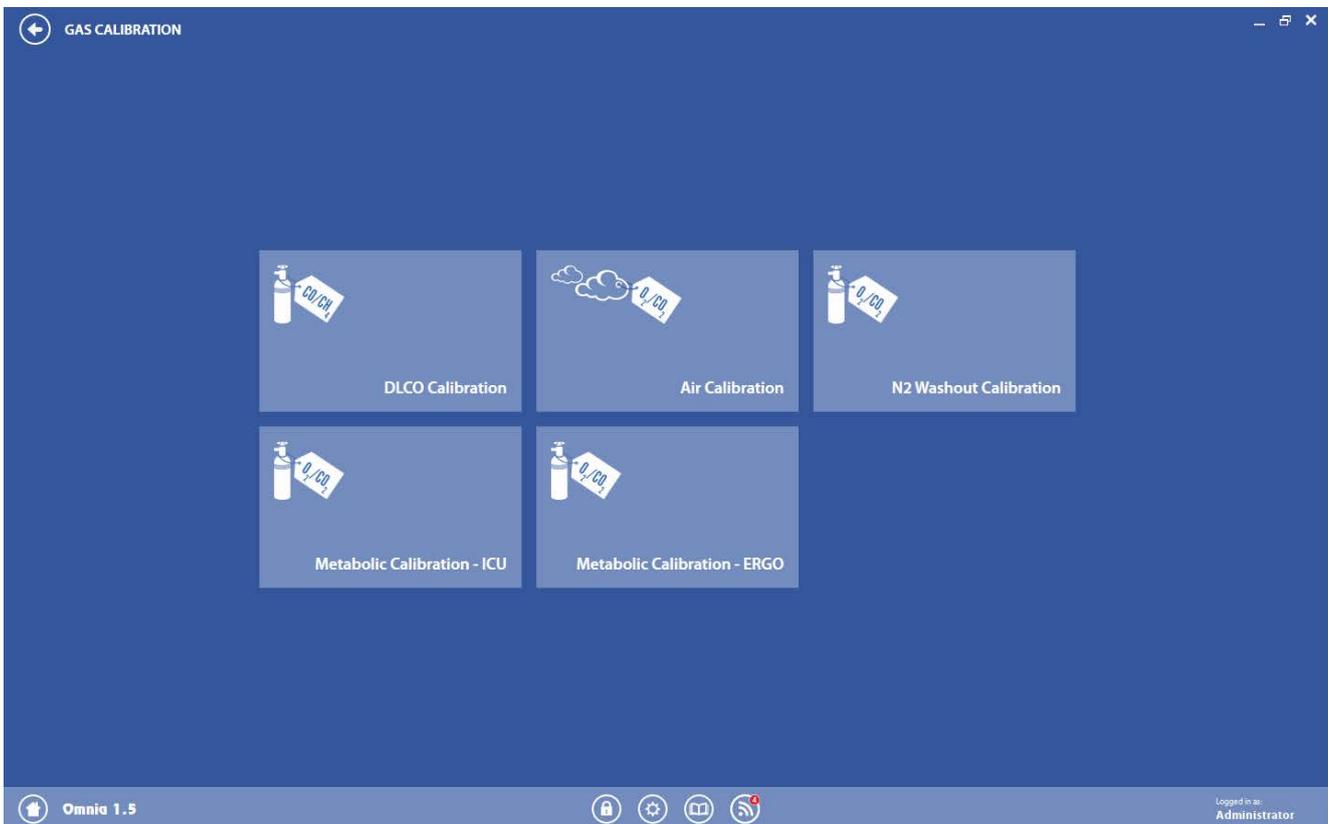
Note: Cellular phones should be turned off to eliminate potential electrical interferences.

Note: If a "gas absent" error appears during the calibration, please check that the cylinder's residual pressure is above 10 bar and that the cocks are open.

Start the calibration panel



To start the calibration, press **Gas calibration** in the *Calibration* panel.



Another panel will open, in which you can select which gas calibration must be performed.

■ The gas calibration

State how long.

Warning: After turning the Quark on you should allow the system to warm-up prior to beginning any calibration.

Any gas calibration should be performed daily and repeated prior to each test, according to the following table.

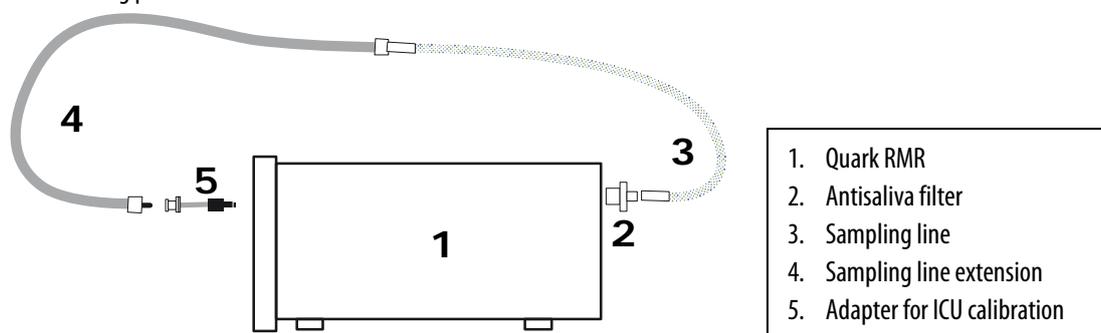
Calibration	Test
DLCO	DLCO
Air	Ergometry (CPET and REE)
N2 Washout	Lung Volumes (FRC and CV)
Metabolic ICU	ICU
Metabolic ERGO	Ergometry (CPET and REE)

Should be removed from the standard user manual and introduced as a tech. tool only

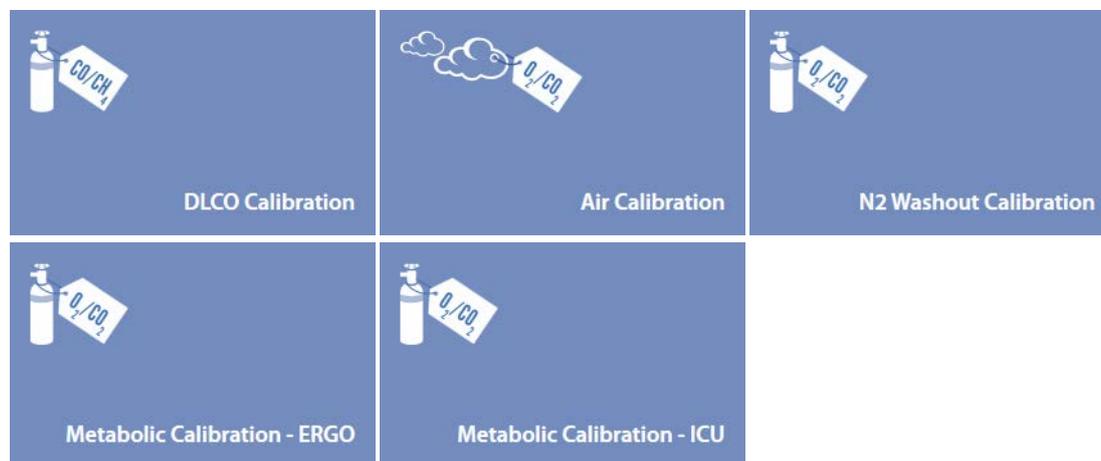
Prepare the device for the calibration

The sampling line must be disconnected from the flowmeter and connected to the front panel, except for the Air calibration.

In ICU calibration, the sampling line extension must be connected to the Quark RMR front panel through the adapter for ICU calibration, as shown in the following picture



Perform the calibration



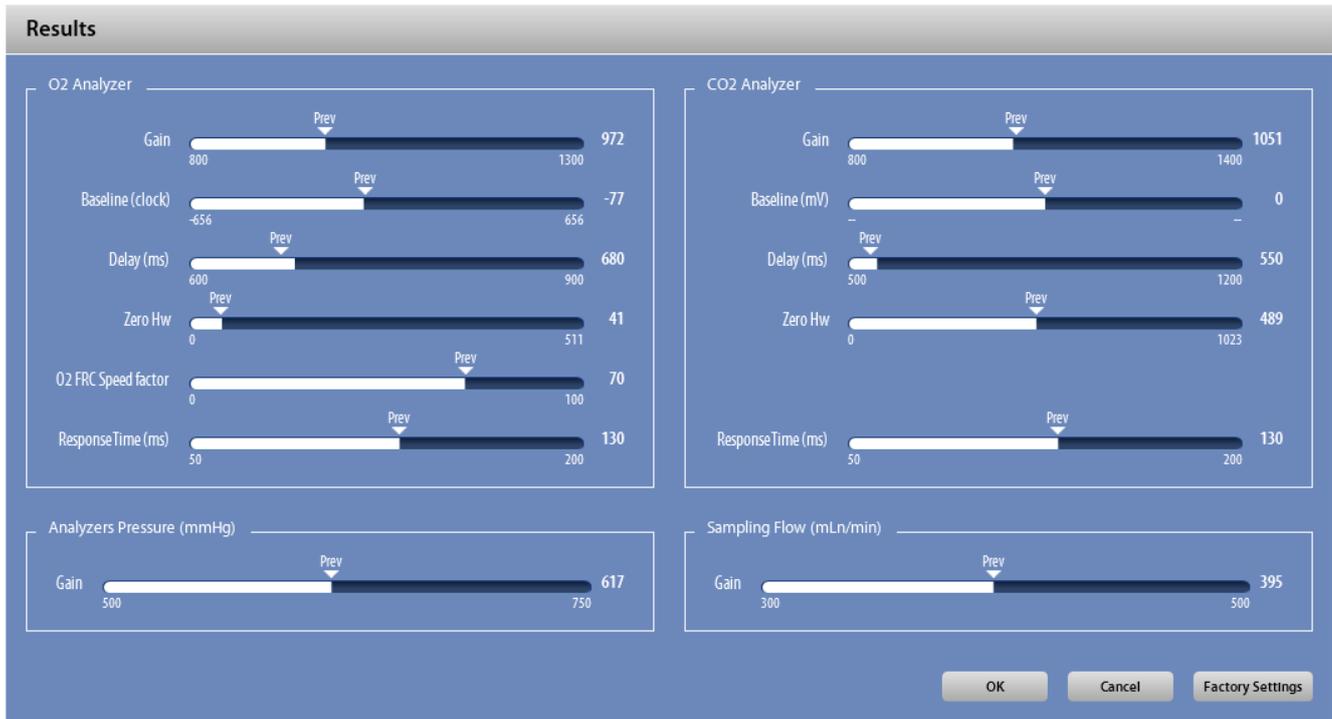
1. To start a calibration, press the corresponding *calibration* tile in the *Gas calibration* panel.



2. Press **Start**.
3. Select the device.
4. Check the warnings, the cylinder gas concentrations and the O₂ span.
5. In case, edit the gas concentrations values according to the cylinder's certificate of analysis and the O₂ span according to your needs.
6. Press **OK**.
7. Wait till the end of the calibration.



8. During the manoeuvre, press **Redo** in order to restart, press **Abort** to cancel.



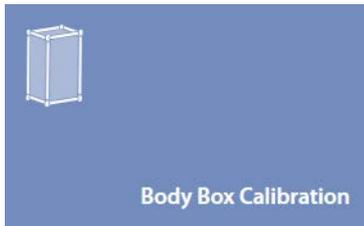
At the end of the manoeuvre, the calibration results are shown in numerical and graphical format. The bars near each parameter show their current value and their previous one.

Press **OK** to accept the check, **Cancel** to abort and **Factory Setting** to restore the factory settings.

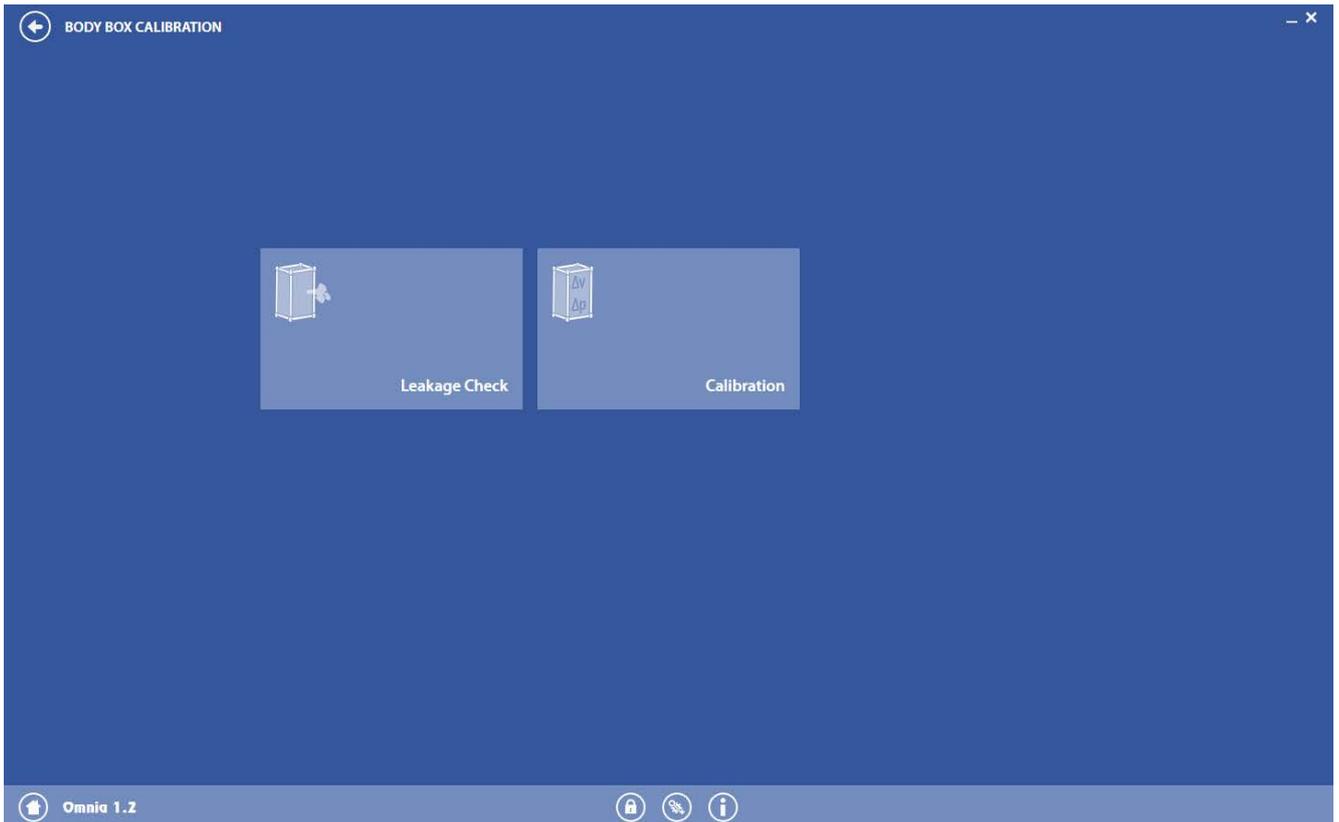
If a value is out of range, the corresponding field is highlighted. Repeat the calibration and, if the problem persists please contact the COSMED support.

Show an example

This function allows the user to perform the two calibrations of the Q-Box.



To start the calibration, press **Body Box calibration** in the *Calibration* panel.



Another panel will open, in which you can select which calibration must be performed.

Note: The box must be empty (without the patient), the door closed, the O₂/CO₂ cylinder open and the Q-Box unit switched on in order to perform these checks. Wait at least 2 minutes after closing the door before starting the check.

Errors during the calibration procedures can be due to:

- Unit off
- RH/TA probe not properly connected
- Door not closed
- Cylinders closed or with insufficient pressure
- Pneumatic tube not connected or damaged
- Gasket damaged
- Other minor causes

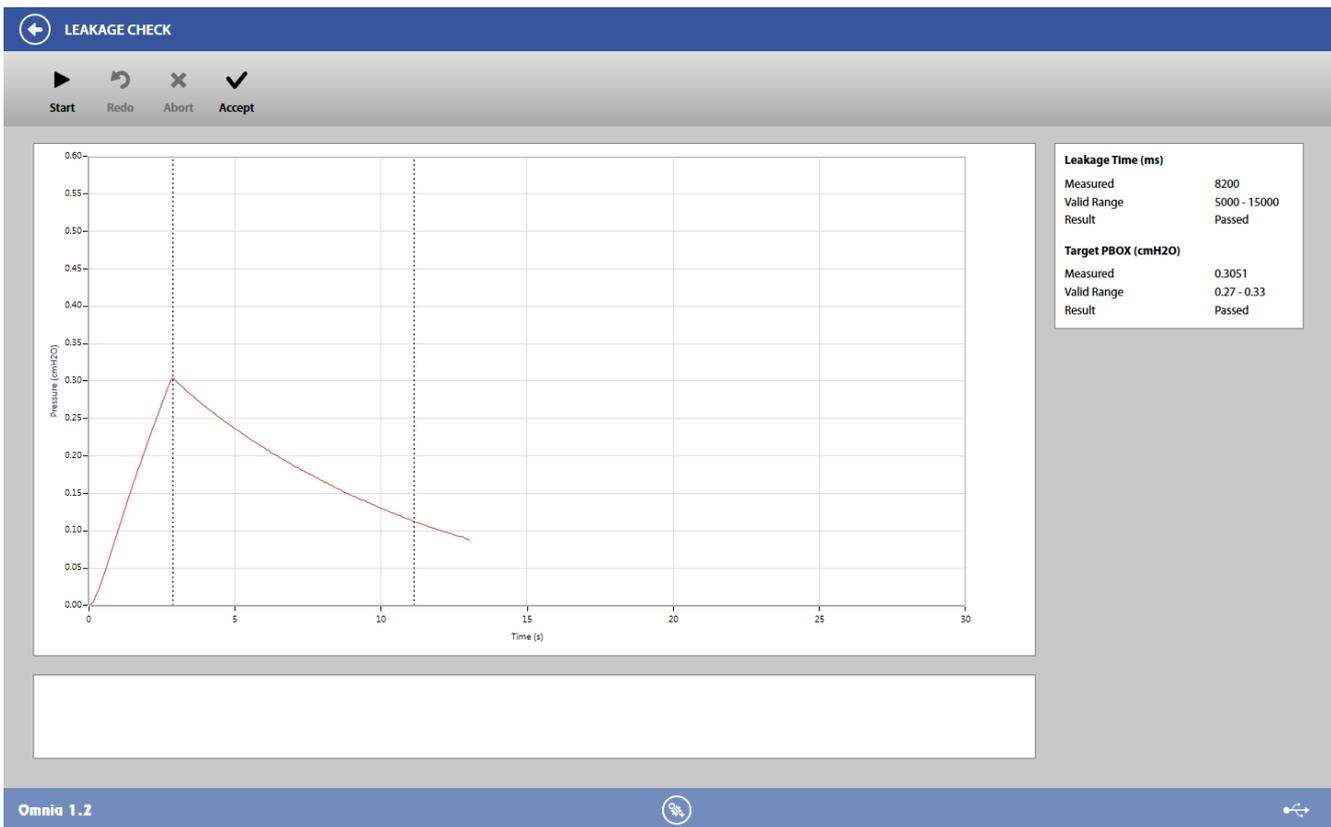
Leakage check



1. To start a leakage check, press **Leakage check** in the *Body Box calibration* panel.



2. Press **Start**.
3. If requested, select the device.
4. Wait till the end of the calibration.



5. During the manoeuvre, press **Redo** in order to restart, press **Abort** to cancel.



6. Press **Accept** to accept the entire check.

Polytropic factor calibration



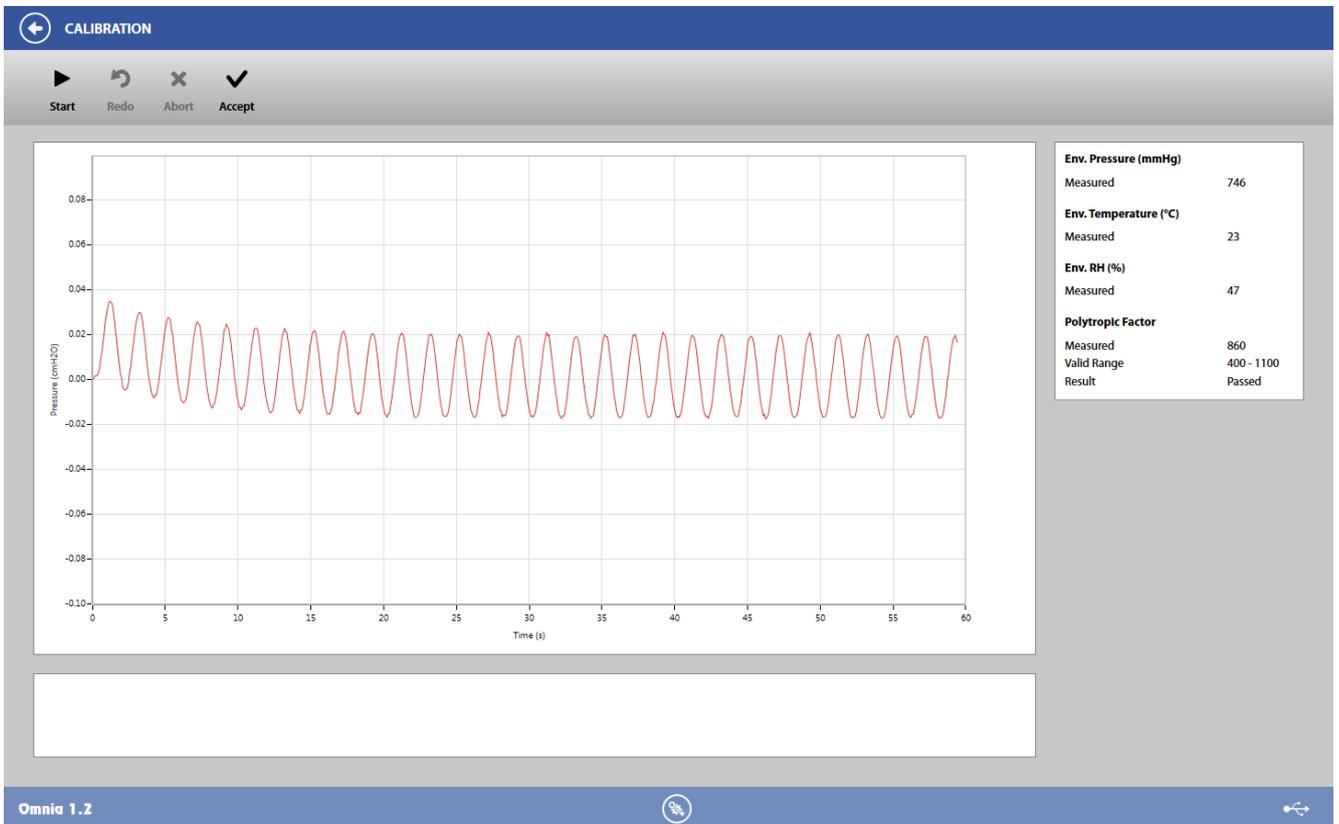
1. To start the polytropic factor check, press **Calibration** in the *Body Box calibration* panel.



2. Press **Start**.

3. If requested, select the device.

4. Wait till the end of the calibration

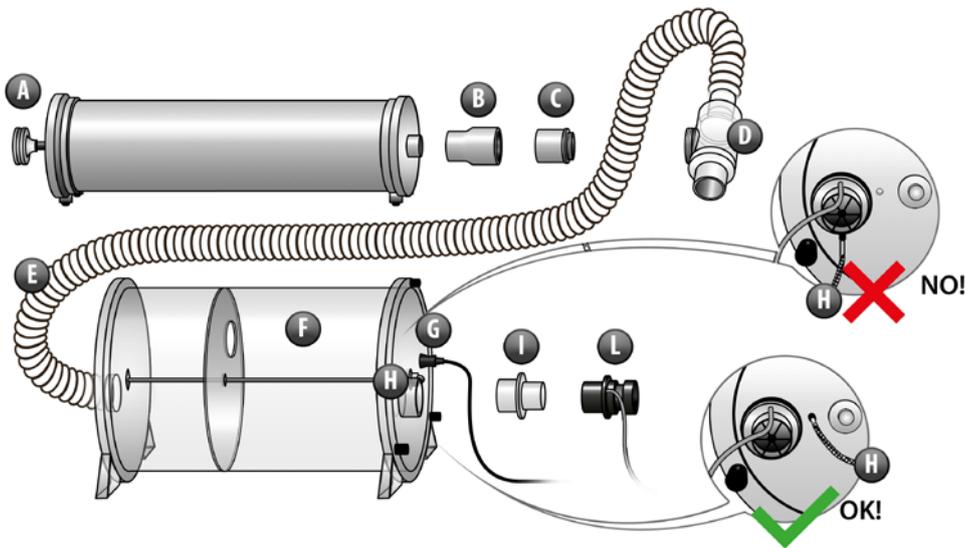


5. During the manoeuvre, press **Redo** in order to restart, press **Abort** to cancel.



6. Press **Accept** to accept the entire check.

This function allows the user to perform the calibration for using the mixing chamber.



- | | |
|--------------------------------|---------------------------|
| A. Calibration syringe | F. Mixing chamber |
| B. Syringe rubber adapter | G. RH/TA probe |
| C. Syringe port tube | H. Hole for sampling line |
| D. 2-way non rebreathing valve | I. Adapter |
| E. Corrugated tube | L. Turbine |

Connect the mixing chamber to the turbine and to a calibration syringe according to the above picture.



To start the calibration, press **Mixing chamber calibration** in the *Calibration* panel.

Perform the calibration as explained in *Turbine calibration*.

Please note that, due to the 2-way valve, only the expiratory section of the flow-volume graph will be presented to the user.

Calibration database

The flowmeter calibration archive summarizes, for each device, the calibrations and the linearity checks performed.



Settings
 Linearity is not checked, it is loaded or set.
 Verification 'checks' linearity

To access the archive, press **Calibration Database** in the *Calibration* panel.

CALIBRATION ARCHIVE

Select a device: Quark PFT with dongle

Date - Time	Type	Flowmeter	Serial #
30/01/2014 12:18 PM	Body Box Polytropic Factor	X9	333333
30/01/2014 12:16 PM	Body Box Leakage Check	X9	333333
30/01/2014 12:13 PM	DLCO Calibration	X9	333333

Graph showing linearity checks for CH4 (%), Cal. CH4 (%), CO (%), Cal. CO (%), and PA (mmHg) over time (s).

Calibration Date: 30/01/2014 12:13 PM

Gain Exp: [input field]

Gain Insp: [input field]

CH4 Analyzer		CO Analyzer	
Gain	891 (800:1400)	Gain	1012 (800:1400)
Zero (mV)	90 (5:300)	Zero (mV)	90 (5:300)
Delay (ms)	820 (400:1200)	Delay (ms)	680 (400:1200)
Zero Hw	262 (0:511)	Zero Hw	250 (0:511)
Response Time (ms)	270 (0:400)	Response Time (ms)	260 (0:400)

Analizers Pressure (mmHg): 566 (500:700)

Sampling Flow (mL/min): 612 (500:750)

Omnio 1.2

Select the device in the top left corner, a list of all the performed calibrations and checks will be displayed. In this list, for each calibration the serial number of the device on which that calibration was performed is shown.

On the right side the graph and the check data will be displayed (if available).

If you click on the column header of the table on the left side, the table is sorted by the respective column.



To restore the factory settings, press the **Factory settings** button. The default values for the selected calibration and the selected device are stored, replacing the current ones.

Printing a report

Be specific so not to confuse with test reports



Print prints a report with the selected linearity check and the corresponding calibration. By clicking on **Print** you will access to the print preview.

Print preview

You can export a pdf file of the calibration report selecting File/Export to PDF.

On the top part of the panel, there are icons which allow you to:

- | | | | |
|---|----------------------|---|----------------------------------|
|  | Print the report |  | Copy the selected text (if any) |
|  | Zoom in the report |  | Zoom out the report |
|  | Set the zoom at 100% |  | Fit the page width to the screen |
|  | View the whole page |  | View two pages |

Control panel

The control panel allows you to check the main hardware functions of the device.



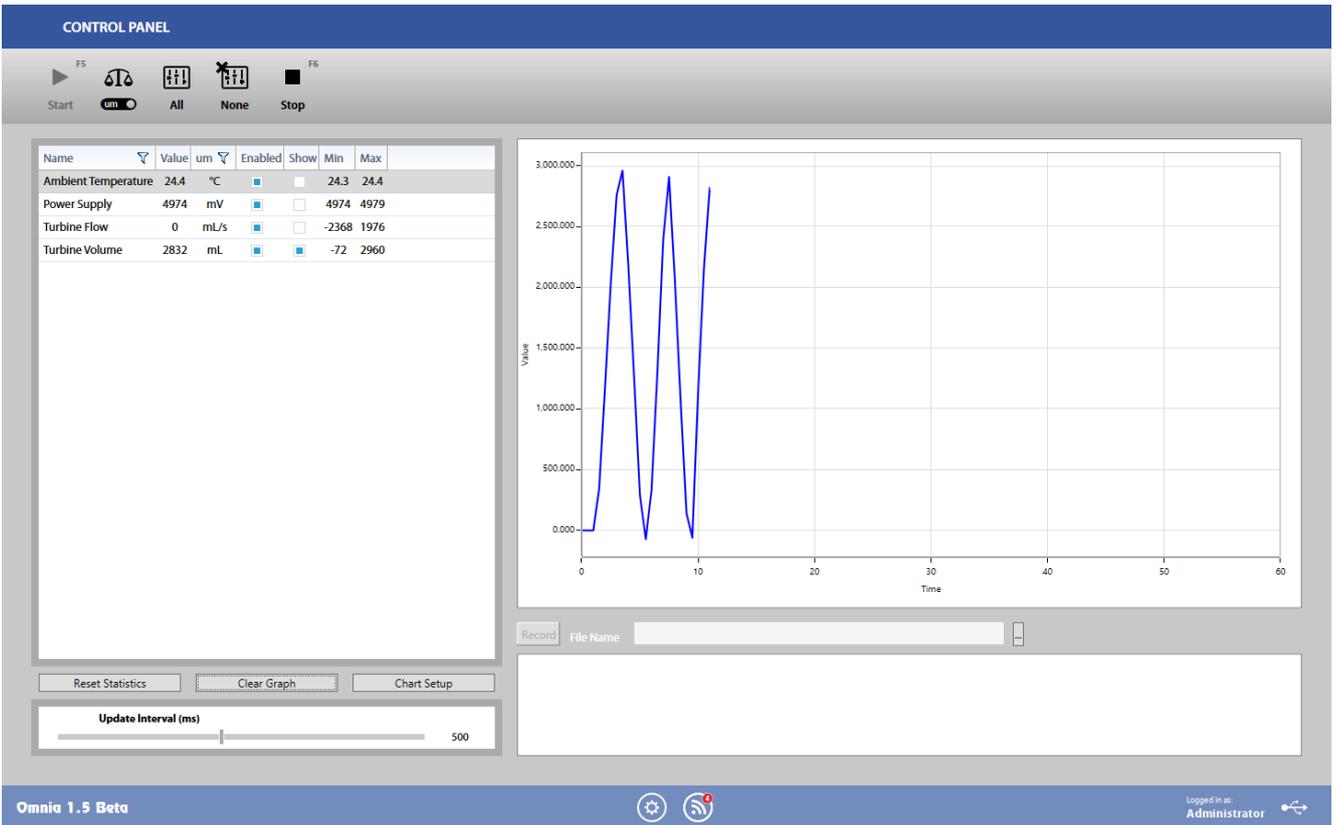
To access the control panel, press **Control panel** in the *Calibration* panel. The control panel will open. Two different control panels are displayed depending on the device used.

Control panel for portable devices

mQ PFX Sp



1. To start the control panel data acquisition, press **Start**.
2. If requested, select the device.



The screenshot shows the 'CONTROL PANEL' interface. At the top, there are icons for 'Start', 'mV', 'um', 'All', 'None', and 'Stop'. Below this is a table of measured quantities and a graph of value vs. time.

Name	Value	um	Enabled	Show	Min	Max
Ambient Temperature	24.4	°C	<input checked="" type="checkbox"/>	<input type="checkbox"/>	24.3	24.4
Power Supply	4974	mV	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4974	4979
Turbine Flow	0	mL/s	<input checked="" type="checkbox"/>	<input type="checkbox"/>	-2368	1976
Turbine Volume	2832	mL	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	-72	2960

The graph shows a blue line representing the value of a selected quantity over time. The y-axis is labeled 'Value' and ranges from 0.000.000 to 3.000.000. The x-axis is labeled 'Time' and ranges from 0 to 60. The graph shows a periodic waveform with three peaks reaching approximately 2.8 million units.

At the bottom of the interface, there are buttons for 'Reset Statistics', 'Clear Graph', and 'Chart Setup'. Below these is a slider for 'Update Interval (ms)' set to 500. The bottom status bar shows 'Omnia 1.5 Beta', a settings icon, a help icon, and 'Logged in as: Administrator'.

The panel is divided in three sections:

- On the right side, a graph of the selected value vs. time
- On the top left, a list of the measured quantities, their measured values, the unit of measurement, if they are enabled (measured), if the quantity must be shown in the graph (only one at time can be shown in the graph), the minimum and the maximum measured value.
- On the bottom left, the sample time for the measurement of the quantities.



In the top bar, press **mV** or **um** to switch from showing measurements in **mV** and in the current unit of measurement, press **All** to enable all the quantities, **None** to disable all the quantities and **Stop** to exit from control panel.

If desired, it is possible to store data coming from a specific signal (the one plotted on the graph) in *.txt format. In order to save data, press the ... button under the graph and select the filename where data must be saved.

Press **Record** to start saving data (the button turns red). Press **Record** again to stop saving (the button turns grey).

Control panel for other devices

SPIRO PFT CPET RMR Q-Box K5



In order to start the control panel data acquisition, press **Start**.

If requested, select the device.

The panel is divided in four sections:

- On the right side, a graph of the selected value vs. time
- In the center, buttons and controls for hardware control of the device (cylinders, valves, trimmers, ...)
- On the top left, a list of the measured quantities, their measured values, the unit of measurement, if they are enabled (measured), if the quantity must be shown in the graph (only one at time can be shown in the graph), the minimum and the maximum measured value.
- On the bottom left, the sample time for the measurement of the quantities.



On the top bar, press **mV** or **um** to switch from showing measurements in **mV** and in the current unit of measurement, press **All** to enable all the quantities, **None** to disable all the quantities and **Stop** to exit from control panel.

If desired, it is possible to store data coming from a specific signal (the one plotted on the graph) in *.txt format. In order to save data, press the ... button under the graph and select the filename where data must be saved.

Press **Record** to start saving data (the button turns red). Press **Record** again to stop saving (the button turns grey).

Database management

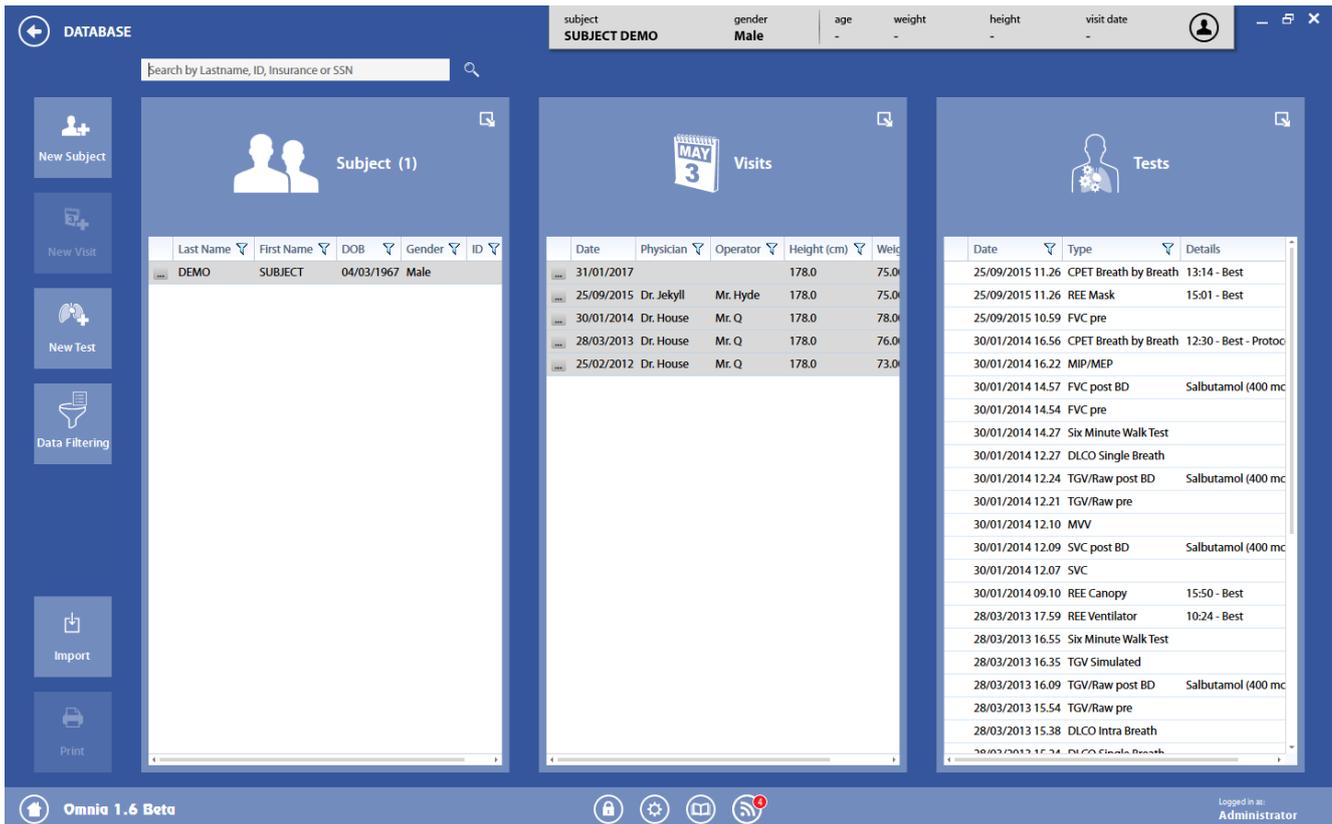


Subject database

The subject database consists of Subject Cards, Visit Cards and Test Cards, which are displayed on one screen when the database is opened.



To open the database, press the **Database** tile on the *Home* panel.



The screenshot displays the 'DATABASE' window with a search bar at the top. The main area is divided into three panels:

- Subject (1):** A table with columns: Last Name, First Name, DOB, Gender, ID. A single row is visible: DEMO, SUBJECT, 04/03/1967, Male.
- Visits:** A table with columns: Date, Physician, Operator, Height (cm), Weight. Five rows are visible:

Date	Physician	Operator	Height (cm)	Weight
31/01/2017			178.0	75.0
25/09/2015	Dr. Jekyll	Mr. Hyde	178.0	75.0
30/01/2014	Dr. House	Mr. Q	178.0	78.0
28/03/2013	Dr. House	Mr. Q	178.0	76.0
25/02/2012	Dr. House	Mr. Q	178.0	73.0
- Tests:** A table with columns: Date, Type, Details. Multiple rows are visible, including: 25/09/2015 11.26 CPET Breath by Breath 13:14 - Best, 25/09/2015 11.26 REE Mask 15:01 - Best, 25/09/2015 10.59 FVC pre, 30/01/2014 16.56 CPET Breath by Breath 12:30 - Best - Protoc, 30/01/2014 16.22 MIP/MEP, 30/01/2014 14.57 FVC post BD Salbutamol (400 mc), 30/01/2014 14.54 FVC pre, 30/01/2014 14.27 Six Minute Walk Test, 30/01/2014 12.27 DLCO Single Breath, 30/01/2014 12.24 TGV/Raw post BD Salbutamol (400 mc), 30/01/2014 12.21 TGV/Raw pre, 30/01/2014 12.10 MVV, 30/01/2014 12.09 SVC post BD Salbutamol (400 mc), 30/01/2014 12.07 SVC, 30/01/2014 09.10 REE Canopy 15:50 - Best, 28/03/2013 17.59 REE Ventilator 10:24 - Best, 28/03/2013 16.55 Six Minute Walk Test, 28/03/2013 16.35 TGV Simulated, 28/03/2013 16.09 TGV/Raw post BD Salbutamol (400 mc), 28/03/2013 15.54 TGV/Raw pre, 28/03/2013 15.38 DLCO Intra Breath, 28/03/2013 15.24 DLCO Single Breath.

The panel is divided into three sections:

- **Subject** (on the left), which shows the list of the subjects with their main data.
- **Visits** (in the center), which shows the list of the visits for the selected subject with his main data. Please note that a list of the visits is displayed only when a subject is selected from the list on the left.
- **Tests** (on the right), which shows the list of the tests performed during a visit with additional info (if available). Please note that a list of the tests is displayed only when a visit is selected from the list in the centre and this visit contains one test at least. Please also note that a test can include one or more trials.

Inside each visit card, there can be maximum one test for each test type (i.e. 1 FVC, 1 SVC, 1 MVV). All of the trials performed during the current visit are stored as trials of the single test and not as several tests. For example, if you perform three consecutive trials of FVC, they are stored as three trials of the FVC test. If you later perform (but during the same visit) two other trials of a FVC, they will be stored as the trials #4 and #5 of the single FVC test of the current visit.

In order to find a subject, you can type the subject name in the field in the top part of the panel. A filter will be activated, filtering all the subjects with the entered string in their name.

Note: When the archive is opened for the first time after having run the software, no subject is shown. You need to search for a subject (see above) or to filter the archive according to chosen parameters (see below, data filtering). The total number of subjects is shown near the Subject tag.

You can order each table by a desired field by pressing the corresponding column header.

The icons  and  allows you to respectively expand or compress the corresponding section, in order to view the data that cannot be displayed for space reasons.

On the left, there are some buttons that allow the user to:



add a new subject



add a new visit



add a new test



filter data according to selected criteria



import external xml data (subject, visit or test, depending on the contents of the selected file)



print a report for the selected subject (a summary or a specific test)

■ **Subjects**

Add a new subject



1. Press the **New Subject** button in the left part of the panel.

2. The **New** subject panel is divided into three sections (General, Contacts and Other data).
3. Enter the required data. Mandatory fields are highlighted with a red border.
4. Press **Save** to save the data, **Cancel** to cancel the operation. The **Save** button activates only when the mandatory fields are completed with valid data.
5. When data are saved, another panel will open, for creating a visit card with the visit data (see below).

Edit a subject



Edit

Select a subject, press the  on the left of the patient and then the **Edit** button.

The shown panel is the same used for adding a new subject. Edit the desired data and press **Save** to save or, **Cancel** to cancel the operation.

Delete a subject



Delete

Select a subject, press the  on the left of the patient and then the **Delete** button. Confirm the action by pressing **OK** or cancel the operation by pressing **Cancel**.

Note: All the subject data (including visits and tests) will be deleted.

Open the Trend analysis

The Trend analysis is available for subject cards containing two or more visits.



Trend

1. Select a subject, press the  on the left of the patient and then the **Trend** button.

Range Selection

Start Date
28/03/2013

End Date
19/02/2015

OK Cancel

2. Select a date range (by default, the start and the end dates are respectively the ones of the first and of the last visit).



The Trend panel will open.

Each graph has a green band which shows, for each date, the normal range (LLN-ULN) of the most significant parameters of each test.

On the left, six buttons allow to:



print the trend report



return to the database panel



change the unit (measured value, % of predicted value or the Z-score)



show/hide the lines connecting the dots



show/hide the labels with the measured data



use vertical bars to visualize data instead of dots

The shaded arrows on the left and/or on the right of the panel allows viewing other graphs, if the selected tests don't allow the visualization on one panel.

The graph shows the sentence No data available to trend this parameter if:

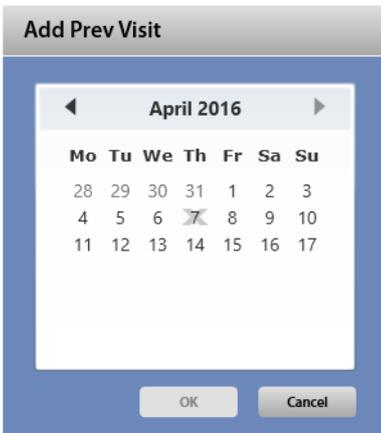
- No test was performed in this date range
- The predicted value is not available (in the % of the predicted values visualization)

Add a visit



It is possible to add the results of a previous visit, for example because the test was performed with another device.

In order to add a previous visit, press the  on the left of the patient and then the **Add Prev Visit** button.



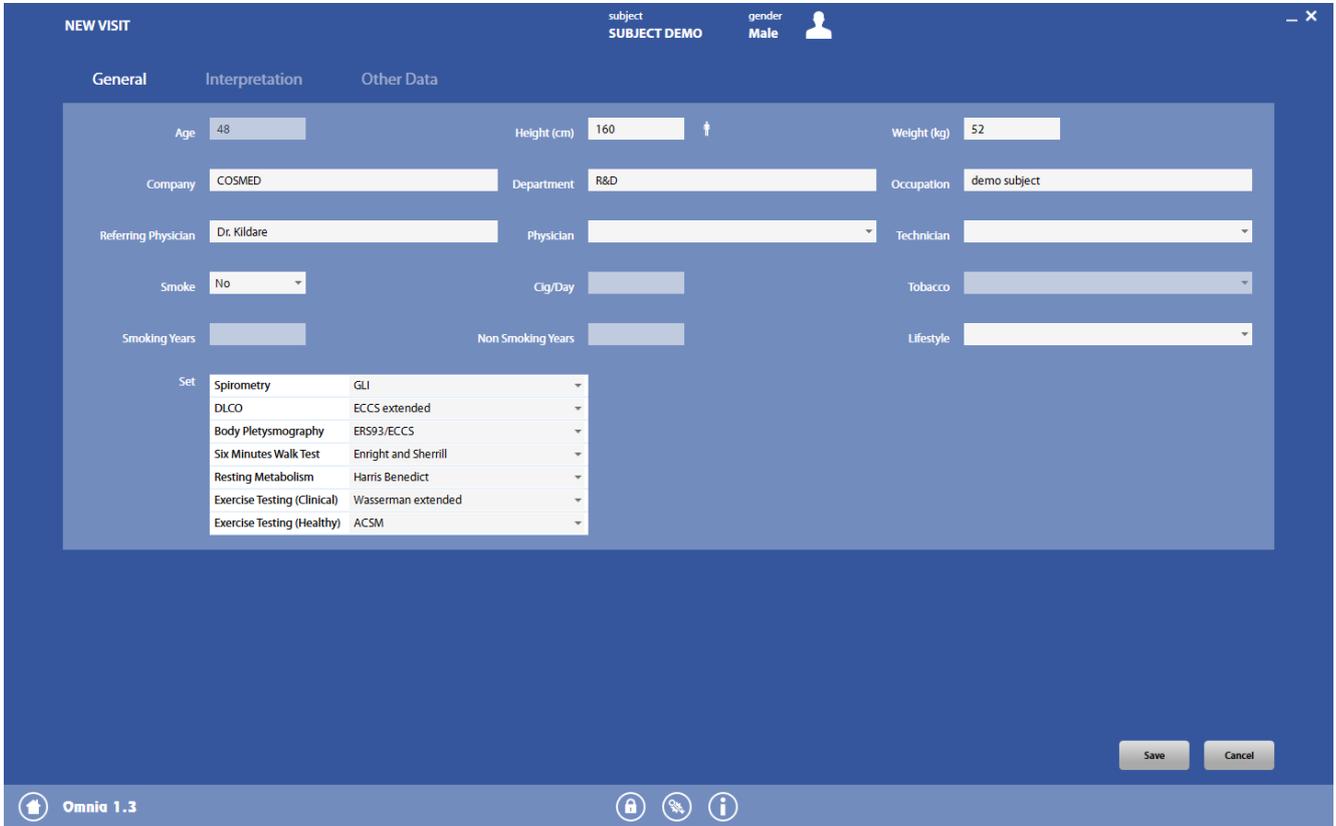
Select the visit date and press **OK** to confirm.

Enter the requested data in the three tabs (see below for further details, *Visits*) and press **Save** to confirm.

Add a new visit card



Press the **New Visit** button in the left part of the panel. The *New visit* panel is divided into three tabs.

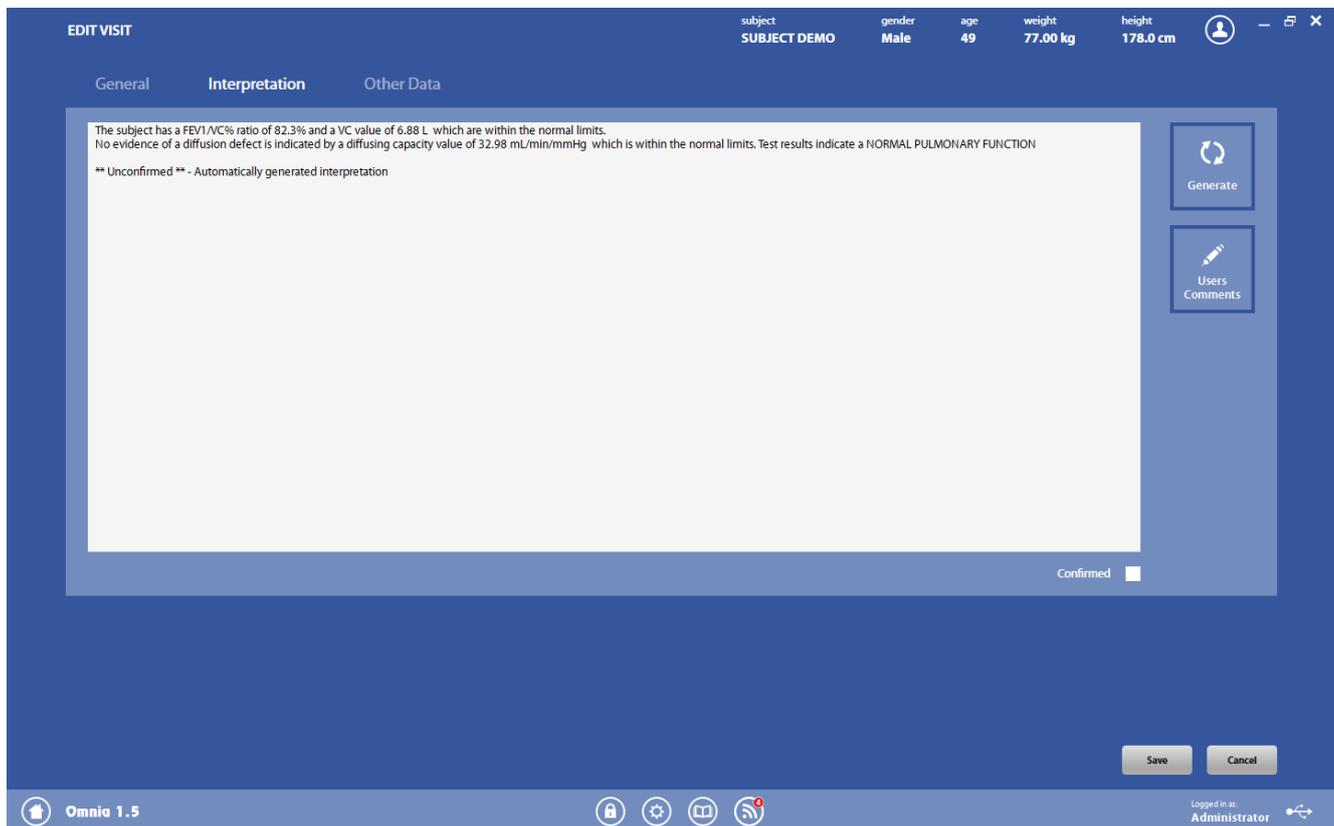


The *General* section is the one shown by default. The other sections can be viewed/hidden by using the  /  icons.

Enter the required data. Mandatory fields are highlighted with a red border. In the field Predicted set you can set a predicted set different from the default one selected in *Settings*.

To calculate the subject height from the arm span, press the  icon.

If a subject already has a visit card previously created, the fields are pre-set with the data stored during the last visit. Please change these values if necessary.



The *Interpretation* section allows the user to enter an interpretation for the current visit. This tab can be completed only when at least one test has been performed and stored for the current visit. This section can also be accessed with the **Edit** interpretation button at the end of a test (see in the corresponding chapters describing the test execution).



The interpretation can be entered by the physician by typing the text in the box, or automatically entered by the software, by pressing the **Generate** button. In this case, the interpretation will remain Unconfirmed until the physician confirms it (he/she evaluates the interpretation as acceptable) by clicking in the **Confirmed** checkbox. The unconfirmed status is shown with a statement at the end of the automatic interpretation.

Note: If you already entered an interpretation and press the **Generate** button, the automatic interpretation will overwrite the existing one.



To add a predefined comment, press **Users Comments** and select the comment to be added.

Users Comments

Find...

Subject must be re-analyzed within six months

Problems during test execution

More investigations required

Subject must be re-analyzed within a year

Test was performed in the right way

Subject must be re-analyzed within three months

OK Cancel

EDIT VISIT

subject: SUBJECT DEMO gender: Male age: 48 weight: 75.00 kg height: 178.0 cm   

General Interpretation **Other Data**

Reason for visit Symptoms Medical Prescription

Diabetes

HR Max Pred (bpm)

CVD Family History Operator Notes Physician Notes

Major CVD Symptoms

Save Cancel

Omnia 1.5     Logged in as: Administrator 

The *Other Data* section allows the user to enter other data for the current visit (i.e. reason for the visit, symptoms, prescription, clinical data, other notes, ...).

To enter additional info in the corresponding section, press the + icon under it and fill in the fields.

Press **Save** to save the data, **Cancel** to cancel the operation. The **Save** button activates only when the mandatory fields are completed with valid data.

Edit a visit card



Select a visit, press the **⋮** on the left of the visit and then the **Edit** button.

The shown panel is the same used for adding a new visit card. Edit the desired data and press **Save** to save the data, **Cancel** to cancel the operation.

Delete a visit card



Select a visit, press the **⋮** on the left of the visit and then the **Delete** button. Confirm the action by pressing **OK** or cancel the operation with **Cancel**.

Note: All the visit data (including tests) will be deleted.

Print a visit card



Select a visit card and press the **Print** button in the left part of the panel.



Select which reports must be printed (for some reports you must also select which kind of report), and press **Print** to open a print preview or **Create Pdf** to directly create a pdf file of the report in the default folder.

In the **Print preview** window, you can export a pdf file of the report selecting **File/Export to PDF**.

In the top part of the panel, there are icons which allows you to:

- | | |
|----------------------|----------------------------------|
| Print the report | Copy the selected text (if any) |
| Zoom in the report | Zoom out the report |
| Set the zoom at 100% | Fit the page width to the screen |
| View the whole page | View two pages |

Add a test



It is possible to add the results of a previous test, for example because it was performed with another device.

In order to add an offline test, press the **⋮** on the left of the visit and then the **Offline Test** button.

NEW OFFLINE TEST - SUBJECT: SUBJECT DEMO - DATE: 25/09/2015

subject: SUBJECT DEMO gender: Male age: 48 weight: 75.00 kg height: 178.0 cm visit date: 25/09/2015

FVC

FVC (L)	FEV1 (L)	FEV1/FVC% (%)	FVC Post BD (L)	FEV1 Post BD (L)	FEV1/FVC% Post BD (%)	PEF (L/s)	FEF25-75% (L/s)	MEF25% (L/s)	MEF50% (L/s)	MEF75% (L/s)	FEV6 (L)	FVC (L)	PIF (L/s)	FIV1 (L)	FET100% (s)
-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

SVC

VC (L)	VC Post BD (L)	IC (L)	ERV (L)	IRV (L)	VT (L)(btpps)
-	-	-	-	-	-

MVV

MVV (L/min)	MRf (l/min)	MVT (L)
-	-	-

Body Plethysmography

TLC(Pleth) (L)	FRC(Pleth) (L)	RV(Pleth) (L)	RV/TLC(Pleth) (%)	FRC(Pleth)/TLC(Pleth) (%)	sRaw (cmH2O*s)	sGaw (l/cmH2O/s)	Raw eff (cmH2O*s/L)	sRaw eff (cmH2O*s)	Raw Ins (cmH2O*s/L)	Raw exp (cmH2O*s/L)	Raw (cmH2O*s/L)	Gaw (L/cmH2O/s)
-	-	-	-	-	-	-	-	-	-	-	-	-

DLCO

DLCO (ml/min/mmHg)	DLCO corr (ml/min/mmHg)	DLCO/VA (ml/min/mmHg/L)	VA (L)	TLC(DLCO) (L)	RV(DLCO) (L)	FRC(DLCO) (L)	Vc (mL)	DM (ml/min/mmHg)	IV(DLCO) (L)	Breath Hold Time (s)
-	-	-	-	-	-	-	-	-	-	-

Save Cancel

Omnia 1.6 Beta Logged in as: Administrator

Enter the test results and press **Save**.

■ Tests

Start a new test



Press the **New Test** button in the left part of the panel.

Refer to the following chapters for test execution.

Alternatively, in order to start a test, it is possible to press the **Testing** tile in the home panel, selecting the desired test.

In this case, a subject must be already selected (the name is shown in the top part of the panel) and his/her visit card must be already created (his/her anthropometric data are shown on the top part of the panel). Otherwise, the **Database** and/or **New visit** panel is shown in order to respectively create/select a subject and add a visit.

View a test



Select a test, press the **⋮** on the left of the test and then the **View** button.

Refer to the following chapters for test viewing.

Edit a test



Select a test, press the **⋮** on the left of the visit and then the **Edit** button.

Refer to the following chapters for test editing.

Delete a test



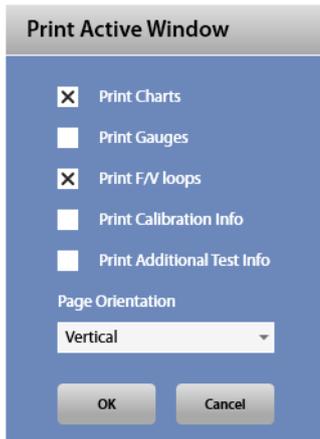
Select a test, press the  on the left of the visit and then the Delete button. Confirm the action by pressing **OK** or cancel the operation with **Cancel**.

Note: All the test data (all the trials of the selected test) will be deleted.

Printing the results from test viewing



When, in a test viewing panel, the Print button is pressed, the following dialog box is shown.



Select the items to be printed and the page orientation and press **OK**. The print preview is shown.

In the *Print preview* window, you can export a pdf file of the report selecting **File/Export to PDF**.

In the top part of the panel, there are icons which allows you to:

- | | |
|--|--|
|  Print the report |  Copy the selected text (if any) |
|  Zoom in the report |  Zoom out the report |
|  Set the zoom at 100% |  Fit the page width to the screen |
|  View the whole page |  View two pages |

Export and import data

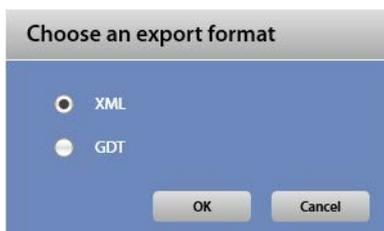
Export data

The software allows to export in xml or GDT format:

- A subject, together with all his/her visits and tests
- A visit, together with the subject's data and the tests performed during this visit
- A test, together with the subject's and visit data.



In order to export data, highlight the desired item (subject, visit or test), press the  on the left and then the **Export** button.



Select the export format and, for xml format, the path and the filename.

Import data

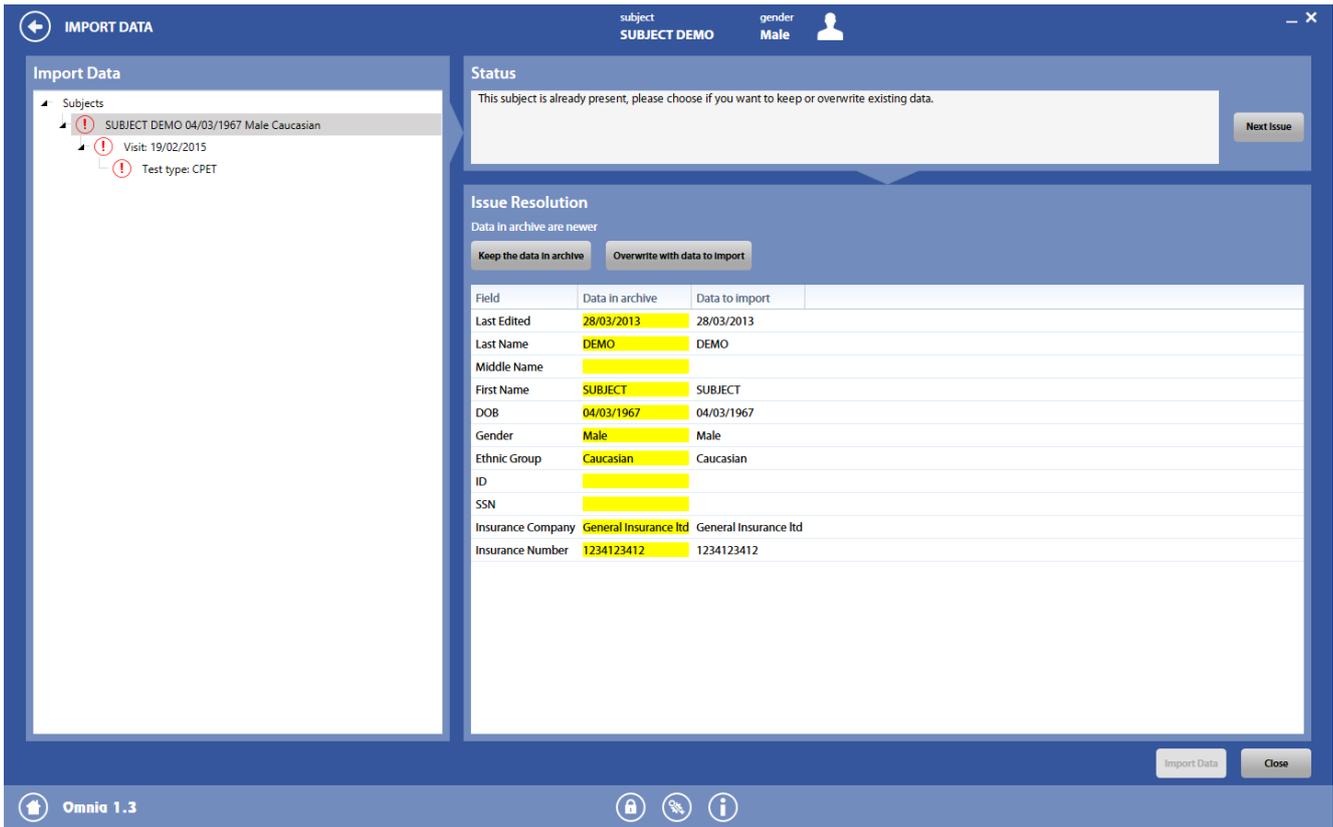
The software allows to import (from xml files):

- A subject, together with all his/her visits and tests
- A visit, together with the subject's data and the tests performed during this visit
- A test, together with the subject's and visit data.



In order to import data, press the **Import** button in the left part of the panel.

Select the file to be imported and confirm.



IMPORT DATA subject: SUBJECT DEMO gender: Male

Import Data

- Subjects
 - ! SUBJECT DEMO 04/03/1967 Male Caucasian
 - ! Visit: 19/02/2015
 - ! Test type: CPET

Status

This subject is already present, please choose if you want to keep or overwrite existing data. Next Issue

Issue Resolution

Data in archive are newer

Keep the data in archive Overwrite with data to Import

Field	Data in archive	Data to import
Last Edited	28/03/2013	28/03/2013
Last Name	DEMO	DEMO
Middle Name		
First Name	SUBJECT	SUBJECT
DOB	04/03/1967	04/03/1967
Gender	Male	Male
Ethnic Group	Caucasian	Caucasian
ID		
SSN		
Insurance Company	General Insurance ltd	General Insurance ltd
Insurance Number	1234123412	1234123412

Import Data Close

Omnia 1.3

In case of conflicts with data already in archive, you will be asked if you prefer to maintain the existent data (subject, data and/or test) or overwrite them with the data in the imported file.

Conflicts are detected if the subject to be imported and the one in archive have the same data (first name, last name, date of birth, sex and ethnic group). Conflicts are detected even if the subject's data are changed after the export, since each xml record has a unique identifier.

■ Data filtering (for searching or printing)



In order to make easier the search activities, the **Data Filtering** button on the left allows the user to filter the database according to selected criteria.

Query all records matching...

Date

Visit On From To

Spirometry

FVC pre FVC post BD FVC post
 SVC SVC post BD MW

Pulmonary Functions

TGV/Raw pre TGV/Raw post BD DLCO Single Breath
 DLCO Intra Breath N2 Multi-Breath Washout N2 Single-Breath Washout
 Six Minute Walk Test MIP/MEP TGV Simulated

Metabolic

REE Mask REE Canopy REE Ventilator
 CPET Breath by Breath CPET Mixing Chamber

Other

Company Offline Test

Print **OK** **Cancel**

Enter the filter criteria and press **OK** to confirm.

In order to print one or more tests sorted out with the query with a single click, select the filter criteria and press **Print**.

Select reports to print:

PFT Summary

Broncho Challenge

FVC ATS

FVC Pre

FVC Post BD

N2 Multi-Breath Washout

N2 Single-Breath Washout

Print **Create Pdf** **Cancel**

Select which reports should be printed and press **Print** to print them, **Create Pdf** to create a pdf file of these tests, **Cancel** to cancel.

Test Type

To remove filters, press the x near the corresponding criteria in the top part of the screen.



In order to download the tests performed and stored on the unit, please connect the unit to the PC and press the **Download Tests** tile in the *Home* panel.

The *Download Tests* panel will open.



Press **View data**.

If requested, select the device from which you want to download the tests.

The screenshot shows the 'DOWNLOAD TESTS' interface. At the top, there are search bars and user information: 'subject SUBJECT DEMO', 'gender Male', 'age 49', 'weight 77.00 kg', 'height 178.0 cm'. Below the search bars, there are two main panels. The left panel is titled 'Device' and contains a table of test data. The right panel is titled 'PC' and contains a table of subject data. At the bottom, there is a footer with 'Omnia 1.5' and 'Logged in as Administrator'.

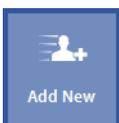
Test date	Test Type	Last Name	First Name	D.O.B.	Gender
11/04/2016 16.33.29	FVC Pre	PFX	DOWNLOAD	04/04/1984	Male
11/04/2016 16.33.52	SVC	PFX	DOWNLOAD	04/04/1984	Male
11/04/2016 16.34.18	Maximum Voluntary Ventilation	PFX	DOWNLOAD	04/04/1984	Male
11/04/2016 16.35.32	FVC Post BD	PFX	DOWNLOAD	04/04/1984	Male
11/04/2016 16.35.12	FVC Post BC	PFX	DOWNLOAD	04/04/1984	Male
13/04/2016 16.47.35	FVC Pre	PFX	DOWNLOAD	04/04/1984	Male

Last Name	First Name	D.O.B.	Gender	ID
DEMO	SUBJECT	04/03/1967	Male	

In the *Device* section, the test list stored on the device is shown. Before downloading the tests, it is possible to edit the subject data for each of the test directly on the list.

The checkbox *Select only new tests* allows to select only the tests not yet downloaded in OMNIA.

Select the tests to download onto the *Device* list.



If the subject is not present in the PC archive, press **Add New**, in order to create a new subject with the data of the one stored in the device. The subject and its visits and tests is now imported in the PC database.



If the subject is already present in the PC archive, type in the field above the PC section the first letters of the subject, select the subject in the PC list (his/her data will be shown in the top part of the panel) and press **Add To** in order to associate the visits of the subject selected in the Device list to the subject selected in the PC list.

At the end, a message confirms the end of the download.

Import data through the GDT protocol

Data can be imported in the software through the GDT protocol.

When a GDT file is placed in the importing GDT directory (as defined in *GDT Settings*), the software (if GDT is enabled in *GDT Settings*) informs the user of this message with the GDT icon in the bottom bar. In order to be detected, the GDT file must be named as defined in the *GDT Settings*.

The screenshot displays the 'Omnia 1.3' software interface. At the top, there's a 'DATABASE' header with a search bar and user information (subject: SUBJECT DEMO, gender: Male). The main area is split into three columns: 'Subject', 'Visits', and 'Tests'. The 'Subject' column contains a table with one row: DEMO, SUBJECT, 04/03/1967, Male. The 'Visits' column contains a table with five rows of visit data. The 'Tests' column contains a table with ten rows of test data. A red arrow points to the GDT icon in the bottom bar, which is circled in red.

If the user clicks the **GDT** icon or opens the *Subject Database*, a message will appear, asking to the user if he/she wants to process this message or not. In any case the **GDT** icon will disappear from the bottom bar.

- If you don't accept to process the message now, the software continues working ignoring the GDT message. Whenever you open the *Subject Database*, the message asking if the GDT message must be processed now will appear.
- If you accept to process the message now, the GDT message is processed.

Note: Since the GDT filename set in the *GDT Settings* is defined, it is necessary to send and process one GDT file at time, otherwise the old GDT file will be overwritten by the new GDT file before being processed.

Processing the GDT message

What the software allows to do with incoming GDT files

The software allows only GDT messages asking to:

- Add a subject and a visit to the archive
- Overwrite a subject and a visit in the archive
- Add a subject and a visit and start a test
- Start a test on an existing subject
- View a test result for an existing subject

The first four activities are managed by the same GDT message type (GDT message type 6301 or 6302), while the last activity is managed by the GDT message type 6311. No other GDT message types are compatible with the software

See next sections for further details on how the software processes these messages.

How to process a GDT message 6301 or 6302

The GDT message allows adding or modifying a subject and its visit, and it can start a test (or not, depending on the message data). Only FVC pre, SVC and MVV tests are supported by the GDT protocol.

When the processing starts, a dialog box will open, showing the subject and the visit data.

The software tries to match the subject data present in the message and in the PC database by ID or by subject data (first and last name, date of birth and sex). If this operation ends successfully, the right section will contain the patient's data. You can keep this selection or select another subject in archive (by typing part of his/her identifier in the search field).

If the software doesn't succeed in matching the subject data, no subject is shown, and you can select a subject in archive or not.



By pressing **New**, a new subject with a visit card for the current day is created.



By pressing **Existing** (enabled only if a subject in the right section of the dialog box is shown), a visit card for the selected subject and for the current day is created (if it already exists, it will be overwritten).

Note: By pressing *Existing*, the visit card for the selected subject is overwritten (if existent), while the subject data stored in the PC database are not modified in any case.

Please note that if some mandatory fields are blank (they appear with highlighted red border), the message cannot be processed and neither **New** nor **Existing** are enabled. The GDT file remains in the importing directory and you need to manually delete it or re-send the GDT message, complete with all mandatory data.

If the GDT message contains also a "Start test" command, the corresponding test is started, or the generic test selection panel is shown, depending on the message content.

When the GDT processing is over, the GDT file is deleted (if selected in the GDT Settings) or renamed in order to be ignored by the software in the future.

How to process a GDT message 6311

The GDT message shows the results for the subject, the visit and the test specified in it.

The window is the same as the one appearing when you press **View** in the test section of the *Subject database*.

When the GDT processing is over, the GDT file is deleted (if selected in the *GDT Settings*) or renamed in order to be ignored by the software in the future.

Spirometry

mQ PFX Sp SPIRO PFT CPET Q-Box



□ General warnings

Note: Please note the contraindications listed in the first chapter of the User manual of the device prior to testing.

1. The device must be enabled in the Device Manager, it must be properly connected to the PC with the appropriate communication port selected and it must be enabled to perform this kind of test.
2. The name shown in the top part of the panel must correspond to the subject performing the test (if a subject has not been selected, the Subject database will be opened when a test is selected).
3. If a visit card doesn't exist for the current testing date, the New visit panel will be displayed in order to enter the visit data.
4. **PFT Q-Box** If the flowmeter is attached to the breathing valve during the tests, please be sure that the corresponding checkbox in the Spirometry settings is enabled.
5. **PFT Q-Box** The sampling line should be disconnected from the flowmeter for spirometry testing.
6. If you are using the turbine, either a paper mouthpiece or an antibacterial filter should be connected to the flowmeter prior to executing the tests.
7. **PFX Sp SPIRO PFT Q-Box** If you are using the pneumotachograph (Flowsafe or X9), do not breathe into the flowmeter, until the green led on the lower right part of the screen appears.
8. For hygienic reasons, the use of an antibacterial filter is strongly recommended. When using the PNT X9, the use of an antibacterial filter is mandatory.
9. The ID28 turbine, the PNT Flowsafe or the PNT X9 should be the flowmeter used during spirometry testing (FVC, SVC, MVV).
10. A calibration for the current flowmeter must be recently performed and the linearity check should be performed successfully.
11. **PFT Q-Box** To avoid potential damage to the items, do not hang your hand/arm on the breathing valve during the test.

Note: Mobile phones should be turned off prior to testing to eliminate potential interference.

■ Subject preparation

Using the turbine

Connect the turbine to the unit.

PFT Q-Box Disconnect the sampling line from the flowmeter and attach the flowmeter to the handle.

Calibrate the turbine as indicated in the chapter *Calibration* (ATS recommends a daily calibration).

Using the PNT

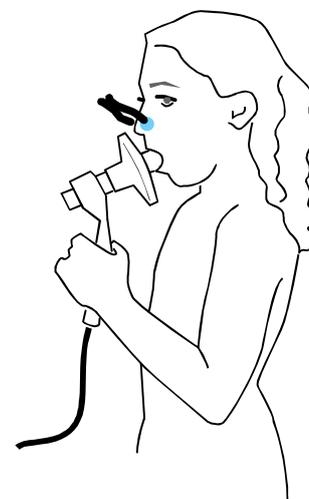
Connect the PNT to the unit through its pneumatic line.

Calibrate (if needed) the PNT as indicated in the chapter *Calibration*.

Other operations

Instruct the subject to apply the nose clip.

PFX Sp SPIRO PFT Q-Box



□ **Forced Vital Capacity (pre)**

FVC testing is used to verify obstructive and restrictive lung disorders. a messages are available to ensure acceptable manoeuvres are performed for interpretation.

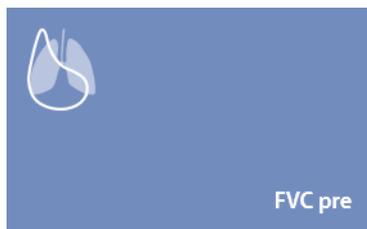
Parameters measured during FVC tests include the following:

Symbol	UM	Parameter
FVC*	L	Forced Expiratory Vital Capacity
FEV1*	L	Forced Expiratory Volume in 1 sec
FEV1/FVC%*	%	FEV1 as a percentage of FVC
PEF*	L/s	Peak Expiratory Flow
FEF25-75%	L/s	Mid-exp flow between 25-75%FVC
MEF25%	L/s	Expiratory Flow when 75% of the FVC remains to be exhaled
MEF50%	L/s	Expiratory Flow when 50% of the FVC remains to be exhaled
MEF75%	L/s	Expiratory Flow when 25% of the FVC remains to be exhaled
FEF50-75%	L/s	Mid-exp flow between 50-75%FVC
FEF25-50%	L/s	Mid-exp flow between 25-50%FVC
FEF75-85%	L/s	Mid-exp flow between 75-85%FVC
FEV0.5	L	Forced Expiratory Volume in 0.5 sec
FEV6	L	Forced Expiratory Volume in 6 sec
FEV1/FEV6%	%	FEV1 as a percentage of FEV6
FET100%	s	Forced expiratory time
VEXT	ml	Extrapolated Volume (back extrapolation)
FEV2	L	Forced Expiratory Volume in 2 sec
FEV3	L	Forced Expiratory Volume in 3 sec
FEV3/FVC%	%	FEV3 as a percentage of FVC
PEFr	l/min	PEF calculated in litres per minute
PEFT	ms	Time to PEF (10% - 90%)
FEV6/FVC%	%	FEV6 as a percentage of FVC
FEF0.2-1.2%	L/s	Mid-exp flow between 0.2 l - 1.2 l
FEV2/FVC%	%	FEV2 as a percentage of FVC
FIVC	L	Inspiratory Forced Vital Capacity
FIV1	L/s	Forced Inspiratory Volume in 1 sec
PIF	L/s	Peak Inspiratory Flow
FIF25-75%	L/s	Forced mid-inspiratory flow
FIF25-50%	L/s	Mid-inspiratory flow between 25-50%FIVC
FIF50-75%	L/s	Mid-inspiratory flow between 50-75%FIVC
FIF75-85%	L/s	Mid-inspiratory flow between 75-85%FIVC
MIF25%	L/s	Inspiratory Flow when 75% of the FIVC remains to be inhaled
MIF50%	L/s	Inspiratory Flow when 50% of the FIVC remains to be inhaled

MIF75%	L/s	Inspiratory Flow when 25% of the FIVC remains to be inhaled
FIV0.5	L	Forced Inspiratory Volume in 0.5 sec
FIT100%	s	Forced Inspiratory time
FIV3	L	Forced Inspiratory Volume in 3 sec
FIV2	L	Forced Inspiratory Volume in 2 sec
FIV6	L	Forced Inspiratory Volume in 6 sec
PIFT	ms	Time to PIF (10% - 90%)
FIF 0.2-1.2	L/s	Mid-insp flow between 0.2 l - 1.2 l
MIF/MEF50%	-	MIF50%/MEF50% ratio
FEV1/VC%	%	Tiffenau index
FEV1/VCmax%	%	FEV1/VCmax ratio
VEVT/FVC%	%	VEVT/FVC ratio

* The first four parameters of the previous list are the main parameters. These parameters are not customizable by the user. See the Test editing section below for more information.

■ Perform a FVC (pre) test



Press the **Testing** tile in the home panel, or start a new test from the subject database, then **Spirometry** and **FVCpre**.

If no subject was selected (in the top part of the panel there is no subject information), when pressing the **Testing** tile in the home panel the software will open the Subject database. If no visit card is present for the current day for the selected subject, the New visit panel is opened before starting the test.

A panel will open with the F/V and V/t graphs.

Explain the maneuver to the subject prior to testing (breathe normally, then perform a maximal inspiration followed by a maximal forced exhalation).

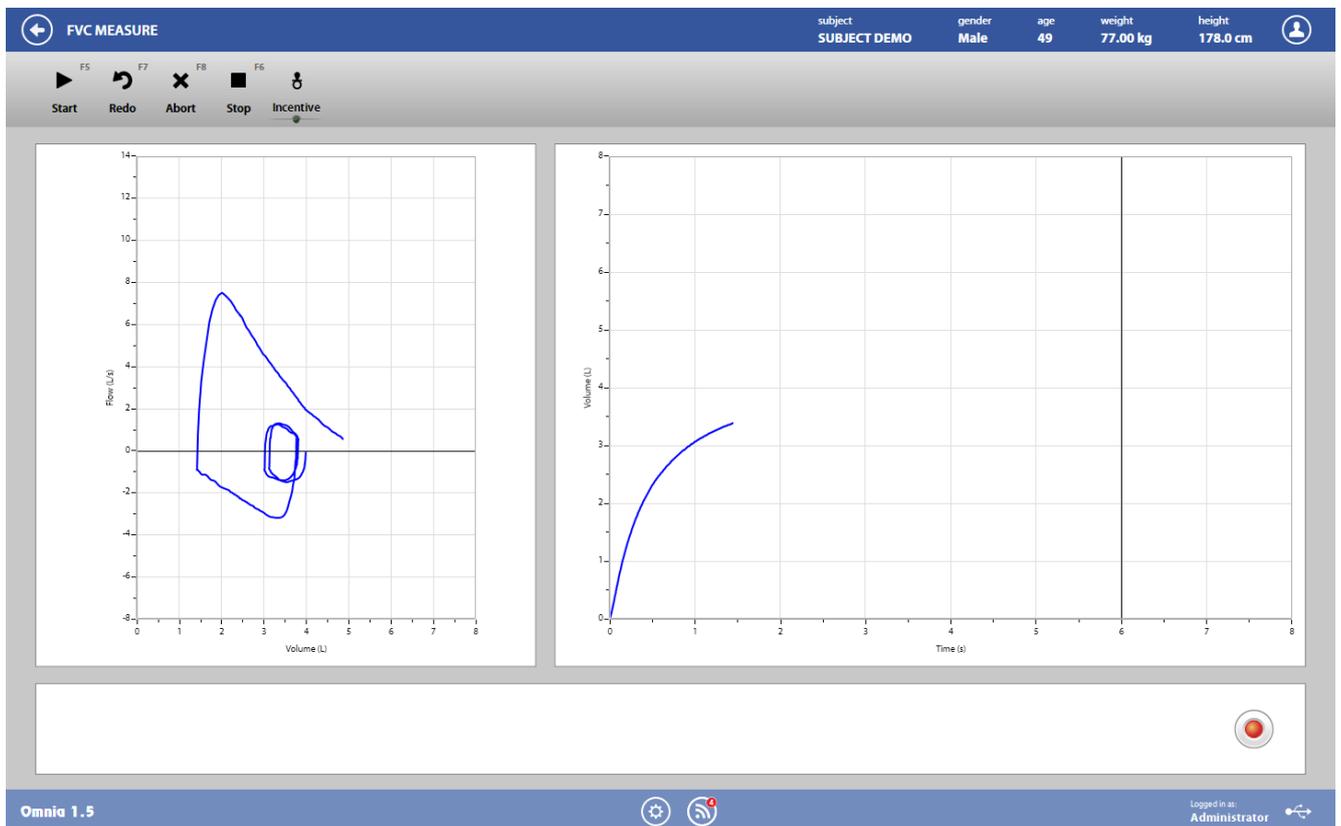


When the subject and the software are ready press **Start** to perform the trial.

If requested, select the device and the flowmeter to be used for performing the test. Check *Always use it for this test* if you want to use the selected choice every time this test is started.

Wait until that the red dot in the lower right part of the screen becomes green.

Start the trial.



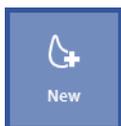
The curves are updated in real time.



When the effort is complete, press **Stop** or wait for the automatic end (5 seconds without flow variation). The software will display the F/V and V/t graphs, the parameters and the predicted values. For a description of the panel, see below, *Test editing*.



To abort the trial, press **Abort**. To restart the trial, press **Redo**. Both these commands discard the current trial and don't save any data (it is not stored in the archive).



Repeat the trials by pressing **New** until the desired number of manoeuvres has been performed.

Please note that in a single visit there can be only one test per type, each of them including all the performed trials. This means that all the FVC trials performed during a visit (i.e. in the same day) are stored under the same test.

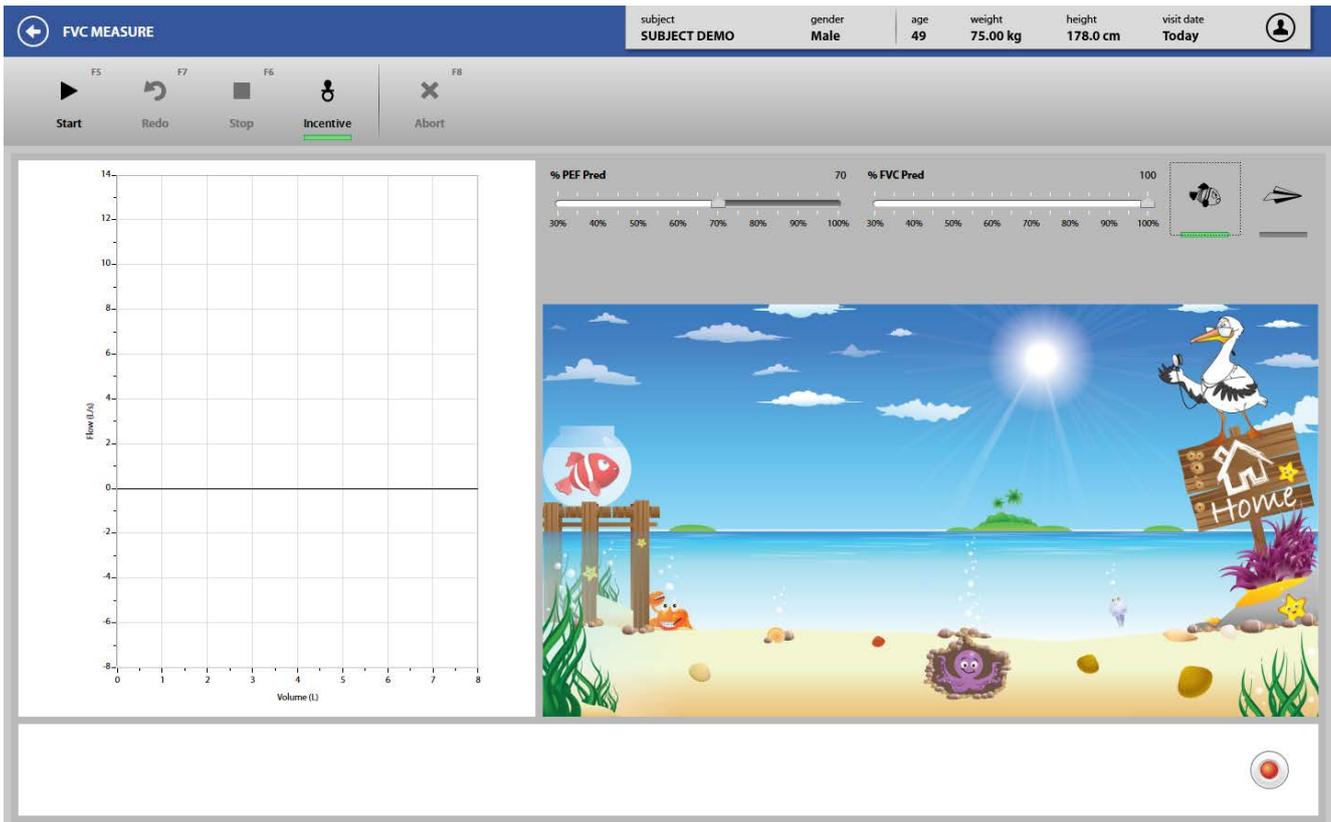
Pediatric incentive



The above icon, displayed during real time FVC testing (both pre and post), enables/disables the pediatric incentive.

Pediatric incentive is on by default if the subject is 7 years old or less, off if the subject is 8 years old or more. In either case, the incentive can be enabled/disabled for all patients by clicking on the above button.

When on, the pediatric incentive shows, instead of the classic V/t graph, the following one (it is possible to choose among two different animations by clicking on the icons above the picture).



The aim of the two animations is to let start the fish (or the plane) and arrive home. In order to start, and to arrive home, the subject must reach a target value for both the PEF and the FVC.

These values are established in the two bars above the animation: the first one defines the % of the predicted PEF to be reached in order to start, the second one defines the % of the predicted FVC to be reached in order to arrive home.



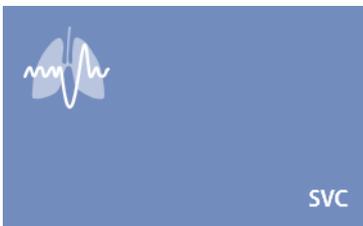
□ *Slow Vital Capacity (pre)*

The Slow Vital Capacity measurement is an important tool in the assessment of COPD (Chronic Obstructive Pulmonary Disease). Parameters measured during SVC tests include the following:

<i>Symbol</i>	<i>UM</i>	<i>Parameter</i>
ERV*	L	Expiratory Reserve Volume
IC*	L	Inspiratory Capacity
VC*	L	Vital Capacity
VE	L/min	Expiratory Minute Ventilation
Te	s	Duration of Expiration
IVC	L	Inspiratory Vital Capacity
IRV	L	Inspiratory Reserve Volume
VT/Ti	L/s	VT/Ti ratio
Ti/Ttot	---	Ti/Ttot ratio
EVC	L	Expiratory Vital Capacity
Vt	l	Tidal Volume
RF	1/min	Respiratory Frequency

* The first three parameters of the previous list are the main parameters. These parameters are not customizable by the user. See the *Test editing* section below for more information.

■ *Perform a SVC test*



Press the **Testing** tile in the home panel, or start a new test from the subject database, then **Spirometry** and **SVC**.

If no subject was selected (in the top part of the panel there is no subject information), pressing the **Testing** tile in the home panel of the software will open the *Subject database*. If no visit card is present for the current day for the selected subject, the *New visit* panel is opened before starting the test.

A panel will open with the V/t graph.

Explain the procedure to the subject prior to beginning the test (breathe normally, then perform a maximal inspiration followed by a slow maximal exhalation for the EVC, or perform a maximal exhalation followed by a slow maximal inspiration for the IVC).

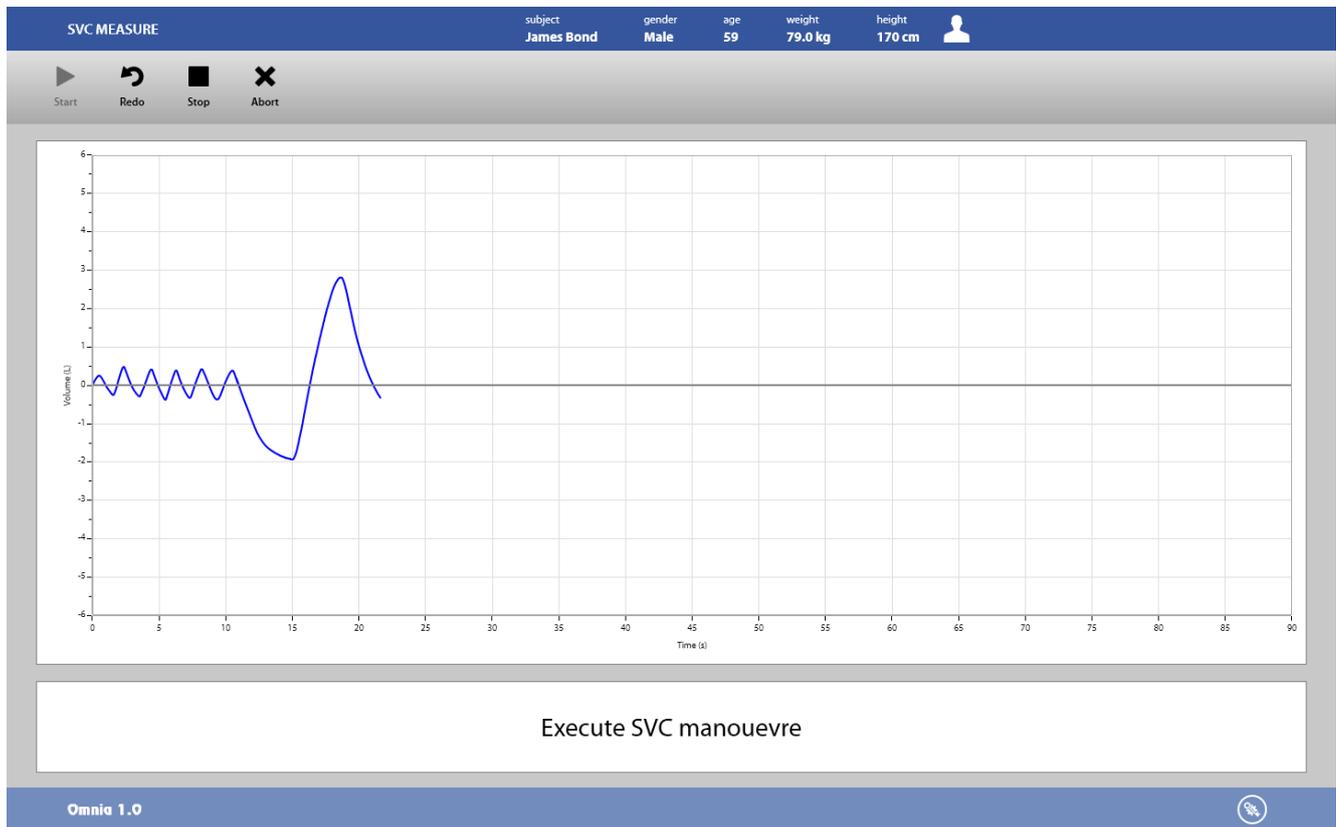


When the subject and the software are ready, press **Start** to perform the trial.

If requested, select the device and the flowmeter to be used for performing the test. Check *Always use it for this test* if you want to use the selected choice every time this test is started.

Wait until that the red dot in the lower right part of the screen becomes green.

Start the trial following the indication in the lower part of the panel (breathe normally and then perform the SVC manoeuvre when prompted).



The curves are updated in real time.



When the effort is complete, press **Stop** or wait for the automatic end (5 seconds without flow variation). The software will display the V/t graph, the parameters and the predicted values. For a description of the panel, see *Test results and editing* below.



To abort the trial, press **Abort**. To restart the trial, press **Redo**. Both these commands discard the current trial and don't save any data (it is not stored in the archive).



Repeat the trials by pressing **New** until the desired number of manoeuvres has been obtained.

Please note that in a single visit there can be only one test per type, each of them including all the performed trials. This means that all the SVC trials performed during a visit (i.e. in the same day) are stored under the same test.

□ *Maximum Voluntary Ventilation*

Measurements of Maximum Voluntary Ventilation are commonly performed when exercise testing is also being conducted. MVV measurements are an index of the subject's maximum ventilatory capacity. The procedure consists of breathing in and out as deep and fast as possible for 12 seconds. The expired volume during the 12 second period is then extrapolated to 1 minute. Parameters measured during MVV testing include the following:

<i>Symbol</i>	<i>UM</i>	<i>Parameter</i>
MVV*	L/min	Maximum Voluntary Ventilation
MRF*	1/min	Maximum Respiratory frequency
MVt*	L	Tidal Volume (during MVV)
MVVt	s	MVV duration time

* The first three parameters of the previous list are the main parameters. These parameters are not customizable by the user. See the Test editing section below for more information.

■ *Perform a MVV test*



Press the **Testing** tile in the home panel, or start a new test from the subject database, then **Spirometry** and **MVV**.

If no subject was selected (in the top part of the panel there is no subject information), pressing the **Testing** tile in the home panel of the software will open the *Subject database*. If no visit card is present for the current day for the selected subject, the *New visit* panel is opened before starting the test.

A panel will open with the V/t graph.

Explain the procedure to the subject prior to beginning the test (breathe as deep and fast as possible for 12 seconds).

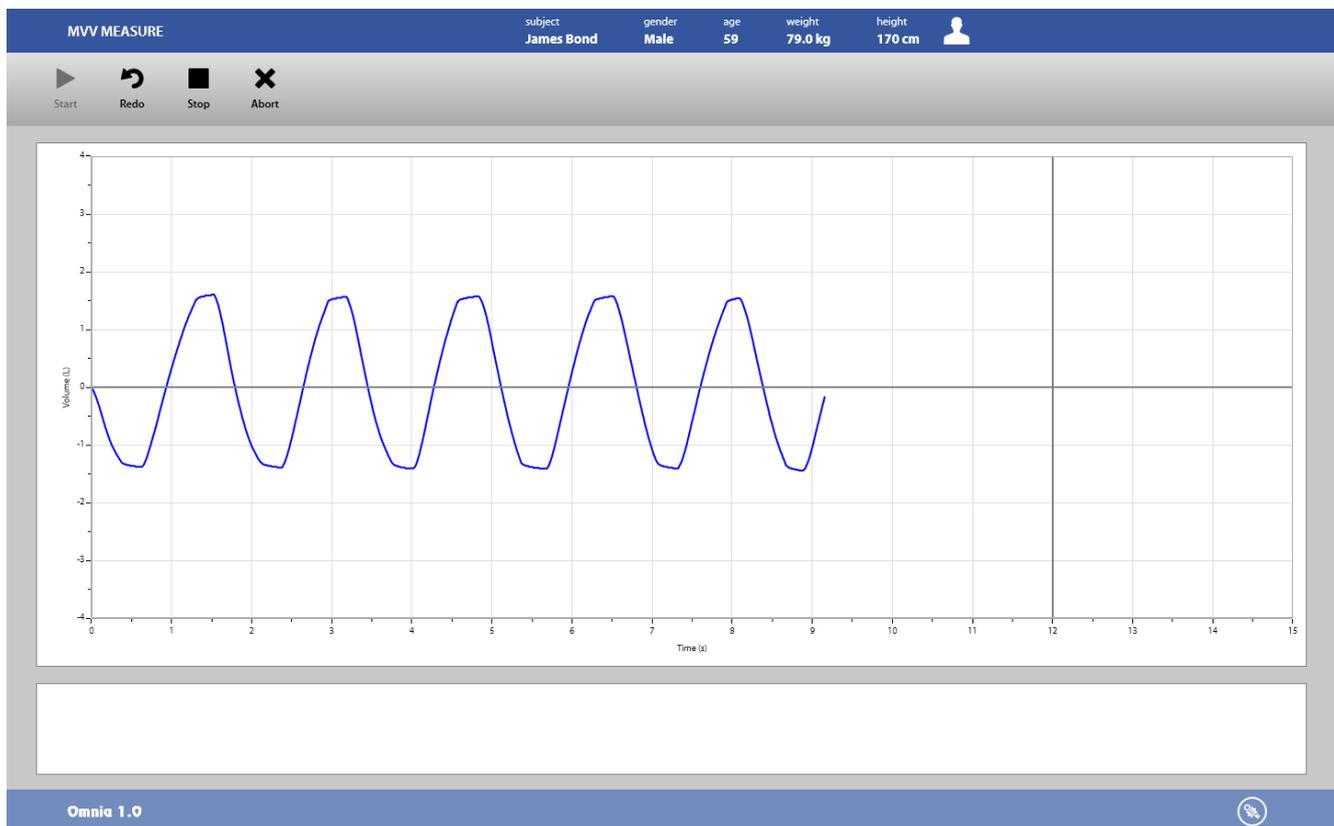


When the subject and the software are ready press **Start** to perform the trial.

If requested, select the device and the flowmeter to be used for performing the test. Check *Always use it for this test* if you want to use the selected choice every time this test is started.

Wait until that the red dot in the lower right part of the screen becomes green.

Start the trial.



The curves are updated in real time.



When the effort is complete, press **Stop** or wait for the automatic end. The software will display the V/t graph, the parameters and the predicted values. For a description of the panel, see *Test results and editing* below.



To abort the trial, press **Abort**. To restart the trial, press **Redo**. Both these commands discard the current trial and don't save any data (it is not stored in the archive).



Repeat the trials by pressing **New** until the desired number of manoeuvres has been obtained.

Please note that in a single visit there can be only one test per type, each of them including all the performed trials. This means that all the MVV trials performed during a visit (i.e. in the same day) are stored under the same test.

□ **Forced Vital Capacity post Bronchodilator**

Bronchodilators are administered during pulmonary function studies to determine if the subject's airflow obstruction is reversible. Bronchodilators can increase airway size by relaxing the smooth muscle.

This test consists of comparing the results between a reference FVC and the FVC obtained after administering the drug (FVC postBD). An increase in the FEV1 of 10-12%, with respect to the baseline value indicates the presence of reversible airway obstruction.

The reference FVC is normally an FVC pre (an FVC test performed during the same visit). The software will allow the user to perform a FVC postBD if a FVC pre is not performed. In this case, the software uses the predicted value as the reference FVC.

■ **Perform a FVC (postBD) test**



Press the **Testing** tile in the home panel, or start a new test from the subject database, then **Spirometry** and **FVCpostBD**.

If no subject was selected (in the top part of the panel there is no subject information), pressing the Testing tile in the home panel of the software will open the Subject database. If no visit card is present for the current day for the selected subject, the New visit panel is opened before starting the test.

A panel will open with the F/V and V/t graphs.

Explain the manoeuvre to the subject prior to testing (the same as the FVC pre: breathe normally, then perform a maximal inspiration followed by a maximal forced exhalation).

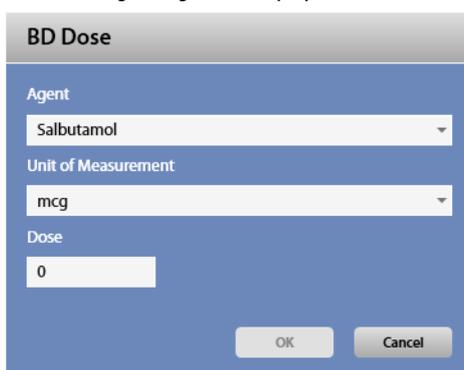


When the subject and the software are ready press **Start** to perform the trial.

If requested, select the device and the flowmeter to be used for performing the test. Check *Always use it for this test* if you want to use the selected choice every time this test is started.

Wait until that the red dot in the lower right part of the screen becomes green.

The following dialog box is displayed:



BD Dose

Agent
Salbutamol

Unit of Measurement
mcg

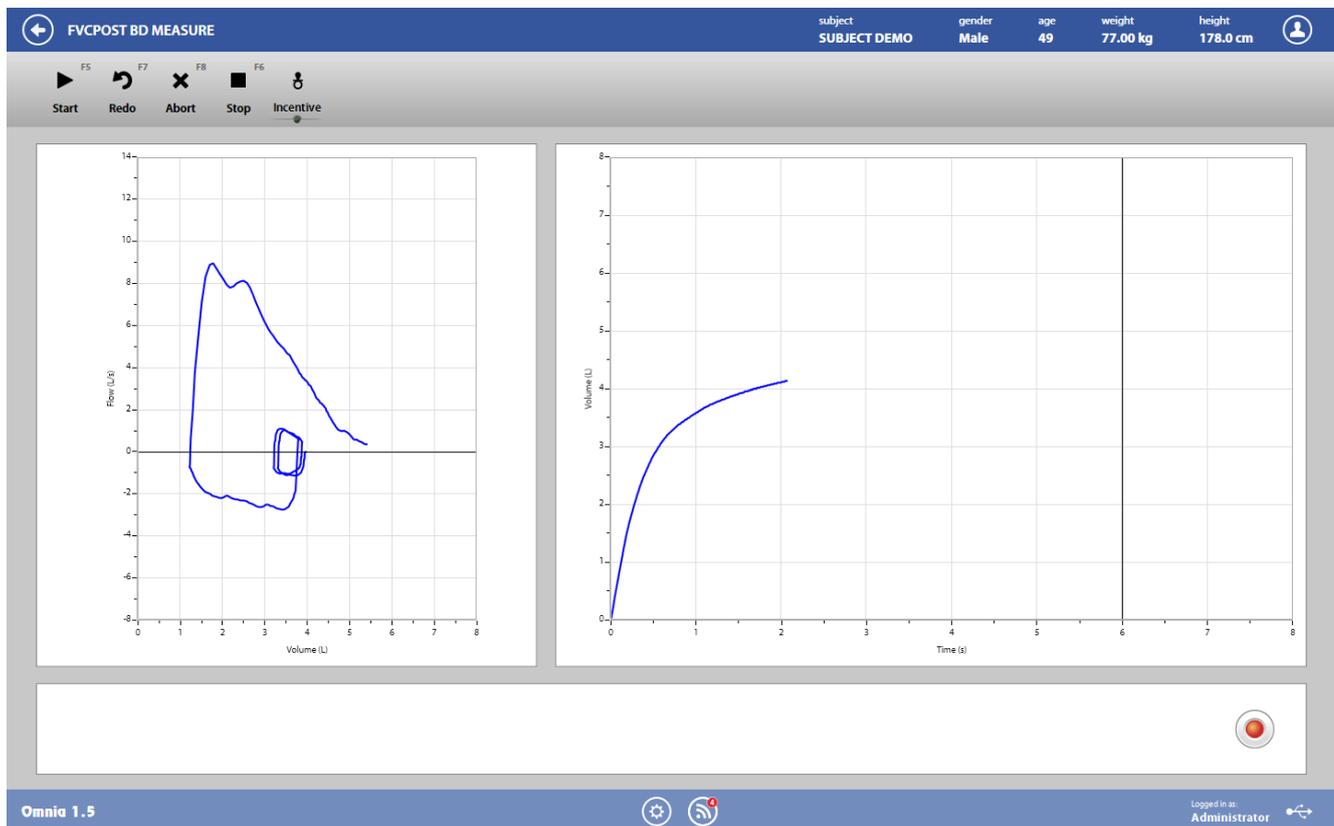
Dose
0

OK Cancel

Enter the agent, the unit of measurement (if necessary), and the dose.

Administer the agent to the subject.

Press **OK** to confirm and start the trial, **Cancel** to abort.



The curves are updated in real time.



When the effort is complete, press **Stop** or wait for the automatic end (5 seconds without flow variation). The software will display the F/V and V/t graphs, the parameters and the predicted values. For a description of the panel, see below, Test editing.



To abort the trial, press **Abort**. To restart the trial, press **Redo**. Both these commands discard the current trial and don't save any data (it is not stored in the archive).



Repeat the trials by pressing **New** until the desired number of manoeuvres has been obtained.

Please note that in a single visit there can be only one test per type, each of them including all the performed trials. This means that all the FVC postBD trials performed during a visit (i.e. in the same day) are stored under the same test.

□ *Slow Vital Capacity post Bronchodilator*

Bronchodilators are administered during pulmonary function studies to determine if the subject's airflow obstruction is reversible. Bronchodilators can increase airway size by relaxing the smooth muscle.

This test consists of comparing the results between a reference SVC and the SVC obtained after administering the drug (SVC postBD).

The reference SVC is normally a SVC pre (a SVC test performed during the same visit). The software will allow the user to perform the SVC postBD if the SVC pre is not performed. In that case, the software uses the predicted SVC value as the reference.

■ *Perform a SVC (post BD) test*



Press the **Testing** tile in the home panel, or start a new test from the subject database, then **Spirometry** and **SVC post BD**.

If no subject was selected (in the top part of the panel there is no subject information), pressing the **Testing** tile in the home panel of the software will open the *Subject database*. If no visit card is present for the current day for the selected subject, the *New visit* panel is opened before starting the test.

A panel will open with the V/t graph.

Explain the procedure to the subject prior to beginning the test (breathe normally, then perform a maximal inspiration followed by a slow maximal exhalation for the EVC, or perform a maximal exhalation followed by a slow maximal inspiration for the IVC).



When the subject and the software are ready press **Start** to perform the trial.

If requested, select the device and the flowmeter to be used for performing the test. Check *Always use it for this test* if you want to use the selected choice every time this test is started.

Wait until that the red dot in the lower right part of the screen becomes green.

The following dialog box is displayed:

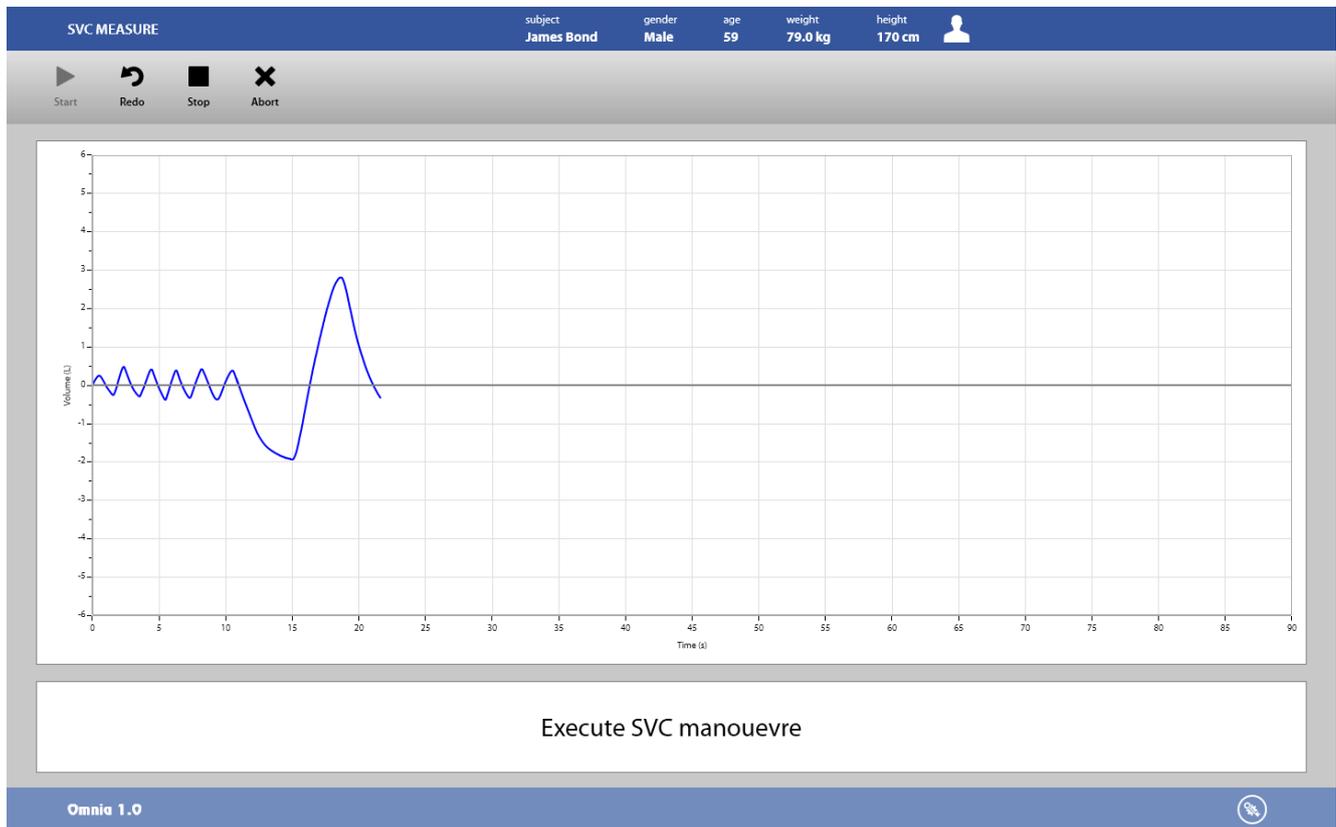
A dialog box titled "BD Dose" with a blue background. It contains three dropdown menus: "Agent" with "Salbutamol" selected, "Unit of Measurement" with "mcg" selected, and "Dose" with "0" entered. At the bottom are "OK" and "Cancel" buttons.

Enter the agent, the unit of measurement, if necessary, and the dose.

Administer the agent to the subject.

Press **OK** to confirm and start the trial, **Cancel** to abort.

Start the trial following the indication in the lower part of the panel (breathe normally and then perform the SVC manoeuvre when prompted).



The curves are updated in real time.



When the effort is complete, press Stop or wait for the automatic end (5 seconds without flow variation). The software will display the V/t graph, the parameters and the predicted values. For a description of the panel, see Test results and editing below.



To abort the trial, press Abort. To restart the trial, press Redo. Both these commands discard the current trial and don't save any data (it is not stored in the archive).



Repeat the trials by pressing New until the desired number of manoeuvres has been obtained.

Please note that in a single visit there can be only one test per type, each of them including all the performed trials. This means that all the SVC trials performed during a visit (i.e. in the same day) are stored under the same test.

Test editing

This section applies to the following spirometry tests: FVC, SVC, MVV, FVC post and SVC Post.

Images and icons described in this section are examples and may be different depending on the test displayed.



The test editing panel shows the parameters measured in the trials performed during the tests and can be accessed through the **Edit** button appearing when the near the selected test is pressed or at the end of each trial.

Accepted Trials

FVC	L	6.56	6.64	6.81	FVC	L	6.81	3.71 - 5.72	4.72	144	3.43								
FEV1	L	5.39	5.44	5.66	FEV1	L	5.66	2.99 - 4.67	3.83	148	3.60								
FEV1/FVC%	%	82.1	81.9	83.2	FEV1/FVC%	%	83.2	67.1 - 90.7	78.9	105	0.60								
PEF	L/s	13.90	13.52	14.24	PEF	L/s	14.24	7.11 - 11.09	9.10	156	4.24								
FEF25-75%	L/s	5.24	5.41	5.84	FEF25-75%	L/s	5.84	2.46 - 5.89	4.18	140	1.60								
FET100%	s	6.6	8.5	6.8	FET100%	s	6.8	---	-	-	-								
VEXT	mL	281	286	253	VEXT	mL	253	---	-	-	-								
MEF75%	L/s	2.28	2.18	2.50	MEF75%	L/s	2.50	0.83 - 2.20	2.11	110	0.51								

The panel is divided into three sections: graphs, QC and notes, and results.

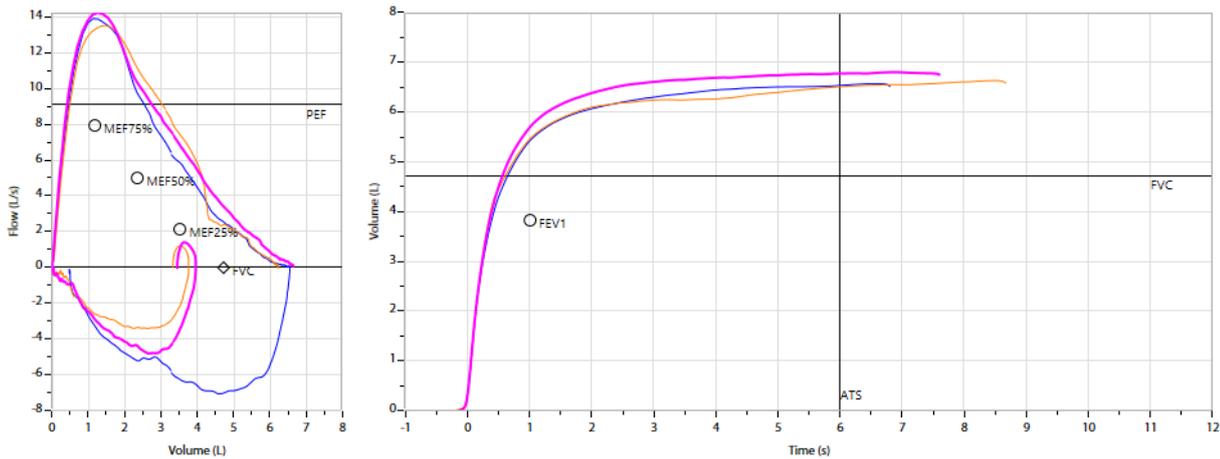


The button in the upper-left part of the panel allows the user to start a new trial (**New**).

The **Calibration** button shows the calibration data for the current test.

The **Save** button allows the user to exit the edit panel and saves the results. By pressing **Save**, the Test results panel will be displayed (see below).

Graphs



In this section of the panel the F/V and V/t graphs of the accepted trials are shown. The curves are colored according to the *results* section.

Test	Symbols
FVC (pre/post)	<p>In the F/V graph the following predicted values (if available) are reported:</p> <ul style="list-style-type: none"> ○ MEF25%, MEF50% and MEF75% ◇ FVC — PEF <p>In the V/t graph the following predicted values (if available) are reported:</p> <ul style="list-style-type: none"> ○ FEV1 6s, according to the ATS standard — FVC <p>The bold curves are the ones corresponding to the best insp and best exp.</p>
SVC (pre/post), MVV	The bold curve is the one corresponding to the <i>best curve</i>

QC and notes

System QC

C - Satisfactory

System QC Criteria

• $\Delta FEV1$ and ΔFVC (best trials) $\leq 0.25L$

Operator QC

B - Good

Test Position

Standing

Operator Notes

In this section the following are displayed:

- An automatic quality control by the PC about the trials reproducibility (not editable by the user), except for the MVV, and the corresponding criteria
- A quality control entered by the technician
- The position of the subject during the test
- Notes entered by the technician

The quality control is graded in 6 levels: A - excellent, B - good, C - satisfactory, D - barely passing, E, F - failing, plus an "Invalid" level (the last one for technician quality control only).

If test is classified as "invalid" by the operator, a watermark "Invalid test" is also placed on the corresponding printout.

Results

			Accepted Trials									
			Meas.	Normal Range	Pred	% Pred	z score					
Accepted	<input type="checkbox"/>	<input type="checkbox"/>										
Best EXP	<input type="radio"/>	<input type="radio"/>										
Best INSP	<input type="radio"/>	<input type="radio"/>										
Show	<input type="checkbox"/>	<input type="checkbox"/>										
Rank	3	2	1									
FVC	L	6.56	6.64	6.81	FVC	L	6.81	3.71 - 5.72	4.72	144	3.43	<input type="text"/>
FEV1	L	5.39	5.44	5.66	FEV1	L	5.66	2.99 - 4.67	3.83	148	3.60	<input type="text"/>
FEV1/FVC%	%	82.1	81.9	83.2	FEV1/FVC%	%	83.2	67.1 - 90.7	78.9	105	0.60	<input type="text"/>
PEF	L/s	13.90	13.52	14.24	PEF	L/s	14.24	7.11 - 11.09	9.10	156	4.24	<input type="text"/>
FEF25-75%	L/s	5.24	5.41	5.84	FEF25-75%	L/s	5.84	2.46 - 5.89	4.18	140	1.60	<input type="text"/>
FET100%	s	6.6	8.5	6.8	FET100%	s	6.8	---	-	-	-	<input type="text"/>
VEVT	mL	281	286	253	VEVT	mL	253	---	-	-	-	<input type="text"/>
MFF25%	L/s	2.28	2.15	2.50	MFF25%	L/s	2.50	0.83 - 3.30	2.11	110	0.51	<input type="text"/>

The results section is divided into two parts:

- The left side shows all the measured parameters for the trials performed
- On the right side, for PRE tests, the best value for each parameter is shown together with the normal range, the predicted value, the % of the value with respect of the predicted and the Z-Score. Measured values are displayed in italics if they are out of the normal range.
- On the right side, for POST tests, the best value for each parameter is shown together with the change compared to the PRE (both absolute and relative), the % of the value with respect of the predicted and the Z-Score. If the PRE is not present, the change is not displayed. Measured values are displayed in italics if they are out of the normal range. Above these data, the agent and the dose referring to the *best* step are displayed.

A scroll bar allows the user to scroll the parameters in order to view all of them.

The normal range is defined by the LLN-ULN range, as set in the Predicted settings. The Z-Score is how many SD's (standard deviation) the measured value is above or below the predicted value (displayed only if enabled in the Predicted settings).

The best value is chosen according to the following criteria:

Test	Criteria
FVC (pre/post)	<ul style="list-style-type: none"> • For main parameters (except for FEV1/FVC), the maximum value among all the accepted trials • For FEV1/FVC, the ratio between the Best FEV1 and the Best FVC • For other parameters, the values in the trials chosen as the Best EXP (for expiratory parameters) and the Best INSP (for inspiratory parameters)
SVC (pre/post)	<ul style="list-style-type: none"> • For main parameters, the maximum value among all the accepted trial
MVV	<ul style="list-style-type: none"> • For other parameters, the values in the trials chosen as the Best

The best values are highlighted in the left part of this section with a grey background.

On the left side, above the measured parameters, the following appear for each trial:

- If the trial is accepted. By default the software accepts all of the trials. The user can discard some of them, but these trials won't be deleted from the archive when the user saves and exits from this panel.¹ At least 1 trial must be accepted.
- If the trial is the best one (both insp and exp for FVC tests). This selection is automatically determined using the ATS criteria, but the user can select another trial as the best portion. Changing the selection of the best trial, the selected curve is automatically displayed and it cannot be hidden.¹
- If the trial is shown in the graph. The box can be selected or de-selected, determining whether the trial will be shown on the graph. The Best trials cannot be hidden.¹
- An Edit button (only for SVC-SVC POST tests) represented by the  icon. – See below, *Trial editing*
- The rank, starting from 1 for the best trial. The rank is according the FVC+FEV1, starting from the highest value and decreasing. The rank doesn't correspond to the trials sequence.
- The color representing this trial in the graph above. It is not possible to customize the colors.

¹ The color of the check boxes can be white () if selectable, blue () if de-selectable or grey () if not editable.



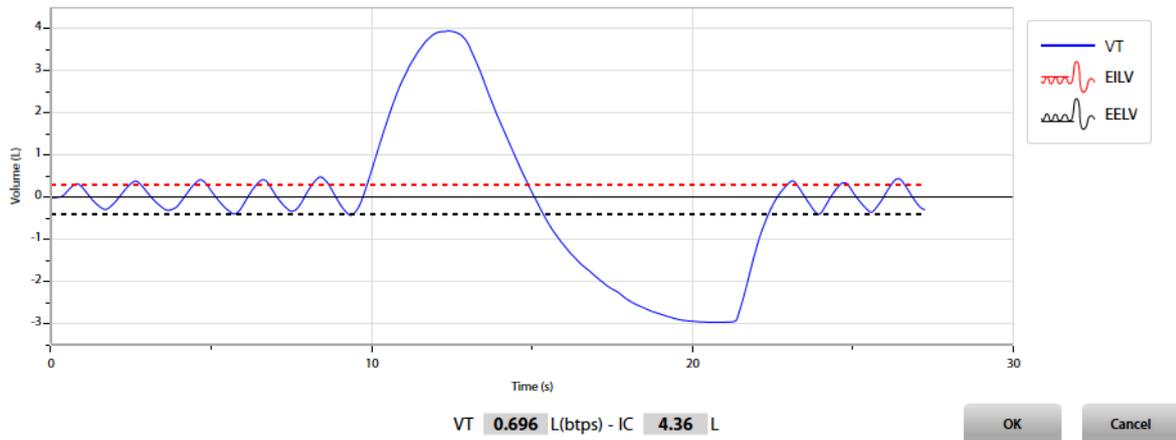
Near these items, on the left, four buttons allow the user to:

- Accept all the trials (**Select All**)
- Automatically select the best trial according to ATS criteria (**ATS/ERS**), that has the maximum FVC+FEV1 value.
- Accept only the 3 best curves (**3 Best**), according to the three highest values of FVC+FEV1 values.
- Restore the last save (**Restore**).

□ Trial editing

This function is applicable only to SVC and SVC Post.

By pressing the  icon, it is possible to change graphically the EELV (end expiratory level) and the EILV (end inspiratory level) of the selected curve, which detect the current volume. Press **OK** to confirm changes or **Cancel** to cancel them. The EELV and EILV are represented on the graph with dotted horizontal lines, black for EELV and red for EILV. The Vt and IC parameters under the graph are automatically updated each time the EELV and EILV values are changed.



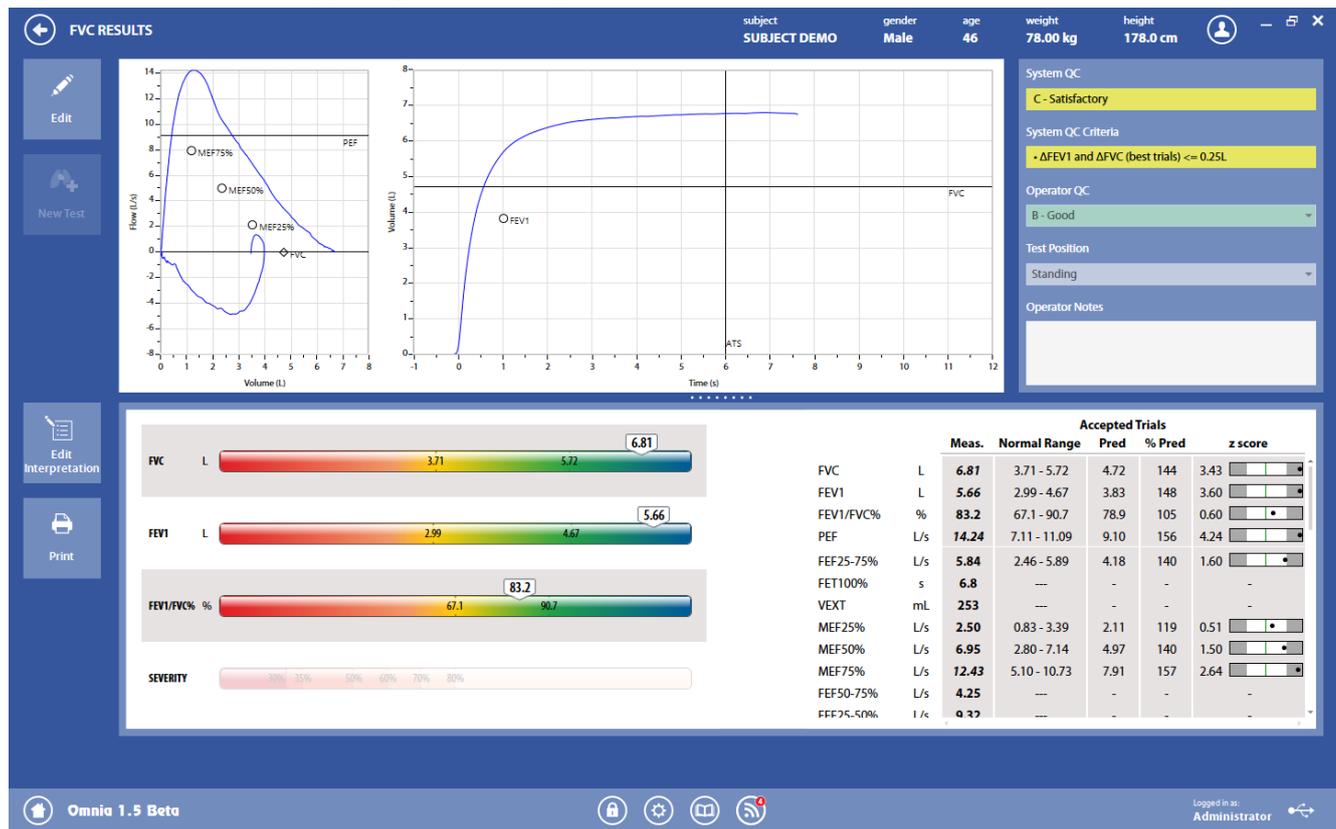
Test results

Images and icons described in this section are examples and may be different depending on the test displayed.



To view a test, press in the subject database the on the left of the test and then the **View** button or double click on the test. In this panel, data and graphs are not editable by the user.

Test results can also be accessed by pressing **Save** in the Edit panel.



The panel is divided into three sections.

The *graphs* section shows the graph for the *best* trials.

The *QC and notes* section is the same as described above in Test editing.

The *results* section is divided into two parts:

- The left side shows a graphical interpretation of the results

On the left side, colored bars are shown for the main parameters, with an indicator representing the current status of the subject. The bars also report the normal range. For POST tests, the PRE and POST values are displayed.

For FVC tests only, the last bar is highlighted in color only if the subject has an obstruction or a possible restriction, otherwise it is shadowed.

- The right side displays data for each parameter.

For PRE tests, the best value for each parameter is shown together with the normal range, the predicted value, the % of the value with respect of the predicted, and the Z-score (if enabled in the *Predicted settings*).

For POST tests, the data presented to the user are different depending on the presence of the corresponding PRE in the current visit.

- If the PRE is performed, both the PRE and the POST results are reported. For the PRE the best value for each parameter is shown, together with the normal range, the predicted value, the % of the value with respect to the predicted and the Z-Score (if enabled in the *Predicted settings*); for the POST the best value for each parameter is shown, together with the change compared to the PRE (both absolute and relative), the % of the predicted value and the Z-Score (if enabled in the *Predicted settings*). Above the "post" data, the agent and the dose referring to the best step.
- If the PRE is not performed, the best value for each parameter is shown, together with the normal range, the predicted value, the % of the value with respect to the predicted and the Z-Score. Above the data, the agent and the dose referring to the best step.



The buttons on the left part of the panel allow the user to:

- Edit the test (**Edit**): the panel shown under Test editing is displayed
- Start a new test (**New Test**). The **New Test** is enabled if the test is performed on the current day.
- Edit the interpretation (**Edit Interpretation**): the panel Interpretation of the visit card is displayed
- Print a report (**Print**).

□ Bronchochallenge

The most common indication for performing bronchial challenges is to diagnose hyperresponsive airways. Subjects may demonstrate normal baseline pulmonary function testing and show little or no response when administered a bronchodilator, despite repeated complaints of respiratory symptoms (chest tightness, wheezing, cough). In such cases, bronchial challenges can be used to confirm or rule out a diagnosis of hyperreactive airways.

Indications for bronchial challenges include the following:

- Diagnosing Asthma.
- Confirming a diagnosis of Asthma.
- Documenting the severity of airway hyperresponsiveness.
- Following changes in airway hyperresponsiveness.

Subjects with hyperreactive airways will demonstrate a response to the inhalation of challenging agents (Methacholine or Histamine) by displaying signs of airway constriction.

The testing procedure involves executing repeated FVC manoeuvres following the inhalation of pharmacologic agents according to an established protocol. A subsequent decrease in FEV1 can be used to determine the presence and severity of bronchial hyperresponsiveness. The PD20 (or PC20, depending on the modality: dose or concentration) is the drug dosage that leads to a 20% reduction of the FEV1 with respect to the baseline value.

Parameters measured in bronchoprovocation testing include the following:

<i>Symbol</i>	<i>UM</i>	<i>Parameter</i>
FallFEV1	%	Fall in FEV1 from baseline or post diluent
PD10 (or PC10)	---	Provocative dose causing FEV1 to fall 10% from baseline
PD15 (or PC15)	---	Provocative dose causing FEV1 to fall 15% from baseline
PD20 (or PC20)	---	Provocative dose causing FEV1 to fall 20% from baseline

The software associates all FVC efforts conducted throughout the procedure to the FVC pre (baseline FVC) obtained during that date's visit.

It is not necessary to perform an FVC pre. The test can be compared to the "diluent" step (the first step, without bronchoconstrictor) or to the predicted values if the diluent step is not present.

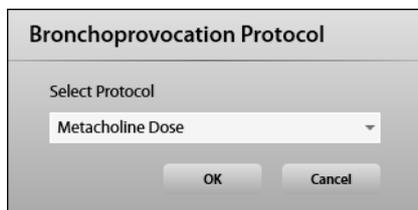
■ Perform a Bronchochallenge test



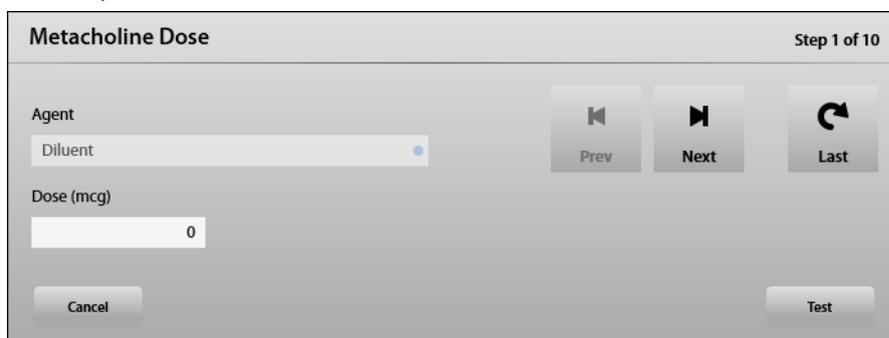
1. Press the **Testing** tile in the home panel, or start a new test from the subject database, then **Spirometry** and **FVC Challenge**.
2. If no subject was selected (in the top part of the panel there is no subject information), pressing the **Testing** tile in the home panel of the software will open the *Subject database*. If no visit card is present for the current day for the selected subject, the *New visit* panel is opened before starting the test.
3. A panel will open with the F/V and V/t graphs.
4. Explain the maneuver to the subject prior to testing (the same as the FVC pre: breathe normally, then perform a maximal inspiration followed by a maximal forced exhalation).



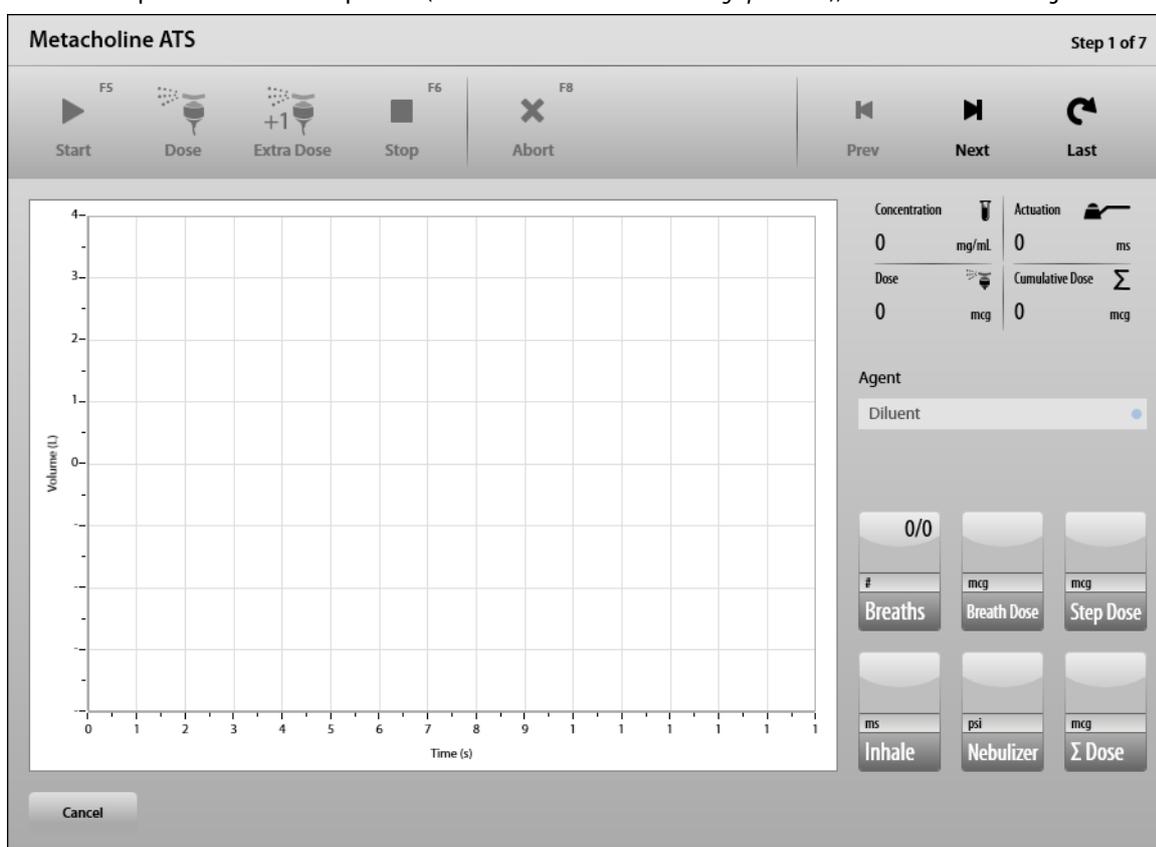
5. When the subject and the software are ready press **Start** to perform the trial.
6. If requested, select the device and the flowmeter to be used for performing the test. Check *Always use it for this test* if you want to use the selected choice every time this test is started.



7. Select the protocol.



If the selected protocol is a *Dosimeter* protocol (as defined in the *Bronchochallenge protocols*), the interface will change into the next one.



8. Please refer to the *Dosimeter* chapter for information about this window.



9. The first step is displayed. Use the **Prev** and **Next** buttons to select the desired step. Modify the agent dose, if needed. Press **OK**.

The **Last** button allows to skip to the last step (usually, the bronchodilator one).

10. If necessary, administer the agent to the subject (only if a new step is selected).

11. Perform the test as for the FVC pre.



12. When the effort is complete, press **Stop** or wait for the automatic end (5 seconds without flow variation). The software will display the F/V and V/t graphs, the parameters and the predicted values. For a description of the panel, see *Test editing* below.

Warning: If the FEV1 falls more than 20% compared to the FVC pre value (or to the diluent step if the FVC pre is not present), please end the test since it can become dangerous. Pay attention to this value at the end of each trial.



13. To abort the trial, press **Abort**. To restart the trial, press **Redo**. Both these commands discard the current trial and don't save any data (it is not stored in the archive).

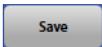


14. You can perform another trial by pressing **New** until the desired number of maneuvers has been obtained.

When **New** is pressed, and the trial is started, the current step is repeated and another maneuver will be stored.

Caution: When you repeat the step, the drug must not be administered. The drug must be administered ONLY if the selected step is a new one.

If the **New** button is pressed, this procedure restart from step 11.



15. Press **Save** to save this step.



16. You can perform one of the next steps by pressing **Broncho Challenge**. The proposed step is the next one, but it is possible to repeat the last step, to go to one of the following steps or to go to the last step respectively by means of the **Prev**, **Next** or **Last** button. It is not possible to go back to a previous step.

Caution: When you repeat the step, the drug must not be administered. The drug must be administered ONLY if the selected step is a new one.

If the **Broncho Challenge** button is pressed, select the step to be performed, press **Test** and restart this procedure from step 11.

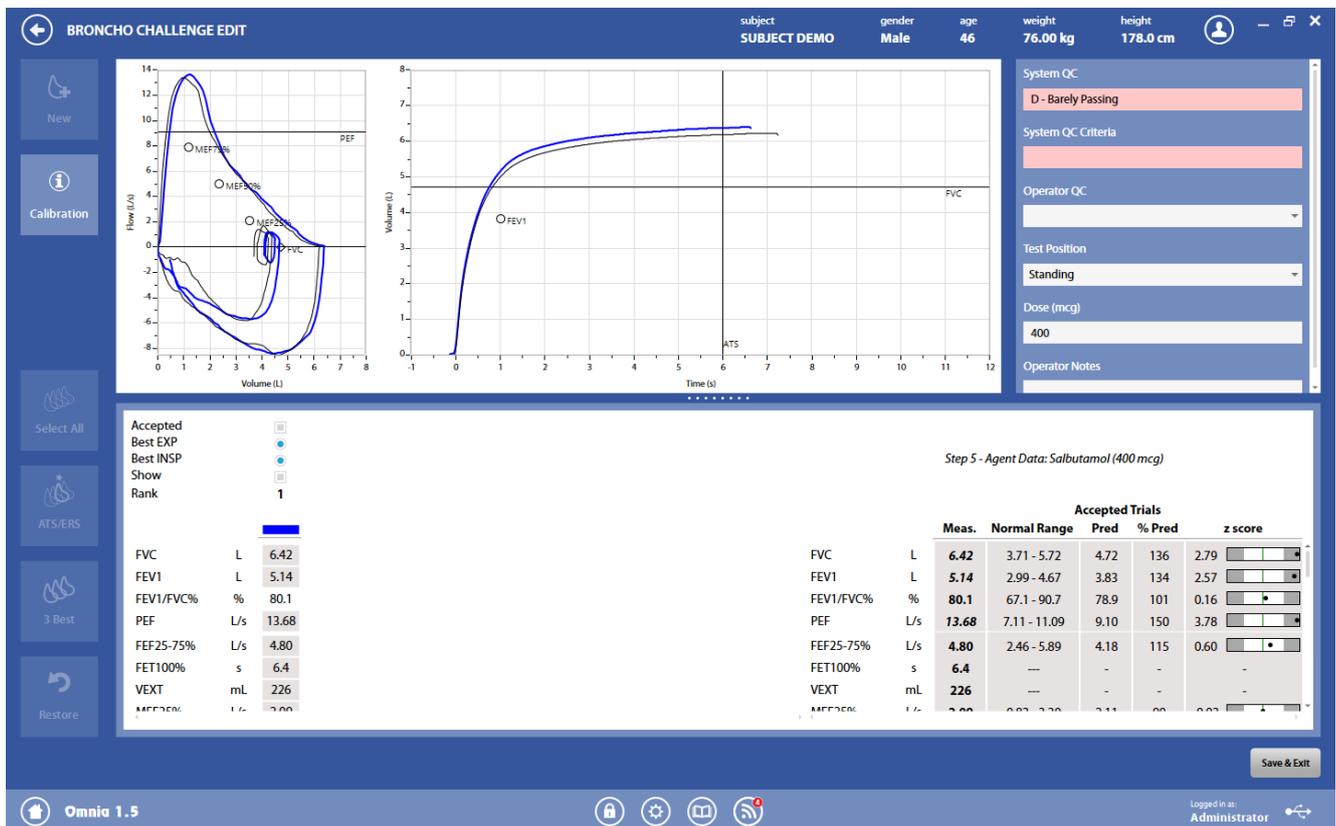
In the Bronchochallenge protocol, each step corresponds to one test in the same visit card. In each step different trials are stored. For example there can be a Bronchochallenge test (the 1st step) with three trials performed with the diluent, then another test (the 2nd step) with one trial performed with 30 mcg of metacholine, another one (the 3rd step) with two trials performed with 60 mcg of metacholine, etc.

This means that all the Bronchochallenge trials performed with a defined quantity of drug during a visit (i.e. in the same day) are stored under the same test. Other trials performed with different quantities of drug are stored under other tests.

■ Test editing



The test editing panel shows the parameters measured in the trials performed during this step, and can be accessed through the **Edit** button appearing when the  near the selected test is pressed or at the end of each trial.



The panel is divided into three sections: graphs, QC and notes, and results.

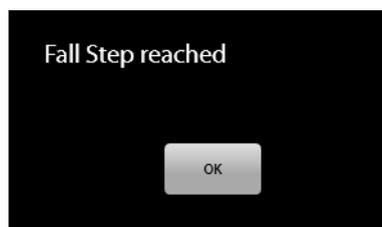


The button in the upper-left part of the panel allows the user to start a new trial (**New**).

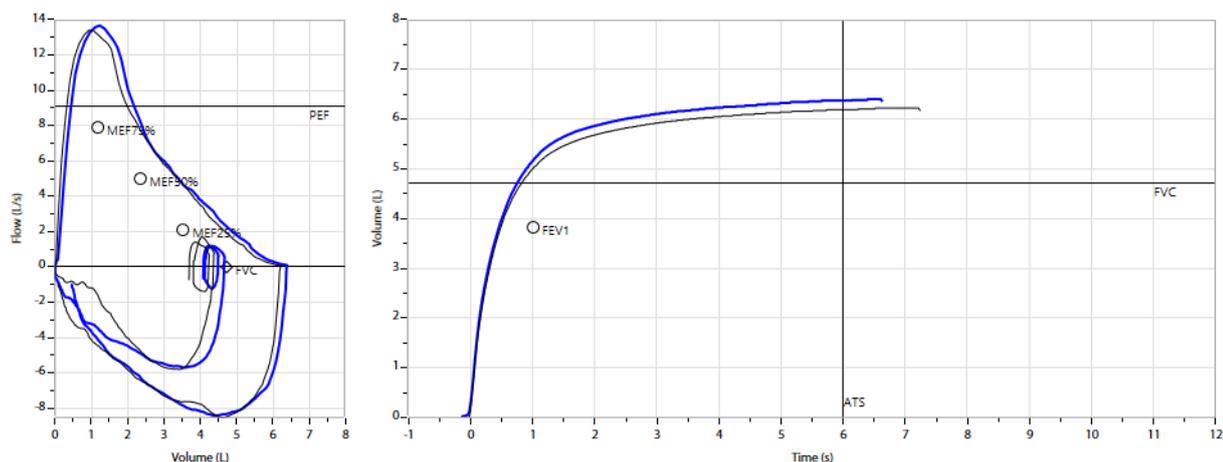
The **Calibration** button shows the calibration data for the current test.

The **Save** button allows the user to exit the edit panel and saves the results. By pressing **Save**, the Test results panel will be displayed (see below). It shows all the protocol steps (as a summary), and not a single step.

Warning: If the FEV1 falls more than 20% compared to the FVC pre value (or to the diluent step if the FVC pre is not present), when the Test results panel is displayed a message warns the user that a limit is reached. Please end the test as it can become dangerous.



Graphs



In this section of the panel the F/V and V/t graphs of the accepted trials are shown, together with the graphs of the FVC pre (black, thin curves). The curves are colored according to the results section.

Test	Symbols
FVC (pre/post)	In the F/V graph the following predicted values (if available) are reported:
	○ MEF25%, MEF50% and MEF75%
	◇ FVC
	— PEF
	In the V/t graph the following predicted values (if available) are reported:
	○ FEV1
	6s, according to the ATS standard
	— FVC
	The bold curves are the ones corresponding to the best insp and best exp.

QC and notes

System QC

D - Barely Passing

System QC Criteria

Operator QC

Test Position

Standing

Dose (mcg)

400

Operator Notes

In this section, the following are displayed:

- An automatic quality control by the PC about the trials reproducibility (not editable by the user), and the corresponding criteria
- A quality control entered by the technician
- The position of the subject during the test
- The dose of the current step
- Notes entered by the technician

The quality control is graded in 6 levels: A - excellent, B - good, C - satisfactory, D - barely passing, E, F - failing, plus an "Invalid" level (the last one for technician quality control only).

If test is classified as "invalid" by the operator, a watermark "Invalid test" is also placed on the corresponding printout.

Results

				Accepted Trials						
		Meas.	Normal Range	Pred	% Pred	z score				
FVC	L	6.42	3.71 - 5.72	4.72	136	2.79				
FEV1	L	5.14	2.99 - 4.67	3.83	134	2.57				
FEV1/FVC%	%	80.1	67.1 - 90.7	78.9	101	0.16				
PEF	L/s	13.68	7.11 - 11.09	9.10	150	3.78				
FEF25-75%	L/s	4.80	2.46 - 5.89	4.18	115	0.60				
FET100%	s	6.4	---	-	-	-				
VEXT	mL	226	---	-	-	-				
MFF25%	L/s	2.00	0.00 - 3.00	2.11	90	0.00				

The results section is divided into two parts:

- The left side shows all the measured parameters for all the performed trials
- The right side shows the best value for each parameter, together with the change compared to the FVC pre (both absolute and relative) and the % of the predicted value. Above the data, the step number, the agent and the dose referring to the best step. If the FVC pre is not present, the data is compared to the diluent step. If the diluent step is also not present, the data is compared to the predicted values, and the absolute and relative changes are not displayed. Measured values are displayed in italics if they are out of the normal range.

A scroll bar allows the user to scroll the parameters in order to view all of them.

The normal range is defined by the LLN-ULN range, as set in the *Predicted settings*. The Z-Score is how many SD's (standard deviation) the measured value is above or below the predicted value (displayed only if enabled in the *Predicted settings*).

The best value is chosen according to the following criteria:

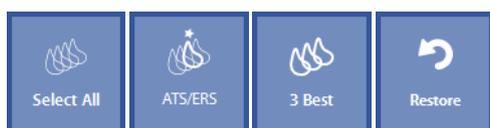
- For main parameters (except for FEV1/FVC), the maximum value among all the accepted trials
- For FEV1/FVC, the ratio between the Best FEV1 and the Best FVC
- For other parameters, the values in the trials chosen as the Best EXP (for expiratory parameters) and the Best INSP (for inspiratory parameters)

The best values are highlighted in the left part of this section with a grey background.

On the left side, above the measured parameters, the following appears in order from top to bottom for each trial:

- If the trial is accepted. By default the software accepts all the trials. The user can discard some of them, but these trials won't be deleted from the archive when the user saves and exits from this panel.¹ At least 1 trial must be accepted.
- If the trial is the best one (inspiratory and expiratory). This selection is automatically determined using the ATS criteria, but the user can select another trial as the best portion. By changing the selection of the best trial, the selected curve is automatically displayed and it cannot be hidden.¹
- If the trial is shown in the graph. The box can be selected or de-selected, determining whether the trial will be shown in the graph. The Best trials cannot be hidden.¹
- The rank, starting from 1 for the best trial. The rank is according the FVC+FEV1, starting from the highest value and decreasing. The rank doesn't correspond to the trials sequence.
- The color representing this trial in the graph above. It is not possible to customize the colors.

¹ The color of the check boxes can be white (☐) if selectable, blue (■) if de-selectable or grey (◻) if not editable.



Near these items, on the left, four buttons allow the user to:

- Accept all the trials (**Add All**)
- Automatically select the best trial according to ATS criteria (**ATS**), that is the one which has the maximum FVC+FEV1 value.
- Accept only the 3 best curves (**3 Best**), according to the three highest values of FVC+FEV1 values.
- Restore the last save (**Restore**).

Test results

Note: In this section, where FVC pre is referred, it means that (if selected through the **Change** button, see below) the diluent step can be used instead of FVC pre step.



View

To view a test, press in the subject database the on the left of the test and then the **View** button or double click on the test. In this panel, data and graphs are not editable by the user. Test results includes all the steps of the Bronchochallenge test.

Test results are accessed also by pressing **Save** in the **Edit** panel.



The panel is divided into three sections.

The *graphs* section reports F/V and V/t graphs for each step (the FVC pre and all the steps of the bronchochallenge test, the best trial only for each step).

The *QC and notes* section reports only the Technician notes (the QC is not displayed, since it can be different for each step)

The *results* section is divided into two parts:

- The left side shows, for each parameter and each step, the measured values and, for FVC pre, the % of the predicted values. Above the parameter list, the step (its color corresponds to the color of the curve in the graphs section), the time of the trial, the dose/concentration and the %Fall FEV1.
- The right side shows a graph of the Fall FEV1% compared to the FVC pre (or the percentage of the FEV1 compared to the FVC pre) vs. the administered dose/concentration. The drop-down menus above the graph allow the user to choose if the graph must be drawn using the dose or cumulated dose (when available) for the x-axis and the Fall FEV1 (Fall FEV1%) or its 1-complement (FEV1 (%baseline)) for the y-axis.
- Below the graph, the agent dose that caused a 20%, 15% and 10% of the Fall FEV1. If at the first step the Fall FEV1% is >20%, the agent dose is indicated as < of the dose of the first step; if the Fall FEV1% at the last step is <20%, the agent dose is indicated as > of the cumulated dose of the last step. In other cases, the displayed value is calculated with an interpolation (according to the ATS Standard) between the previous and the current step.
- The dose/concentration causing a 20% of the Fall FEV1 is highlighted in orange.



The buttons in the left part of the panel allows the user to:

- Continue the Bronchochallenge test (Bronchochallenge). Test starts from the last step performed.
- Start a new test (**New Test**)
- Swap the FVC pre and the Diluent step (**Change**): the FVC pre step is replaced by the Diluent step. This is the reference step for the calculation of the Fall FEV1% in all the subsequent steps
- Edit the interpretation (**Edit Interpretation**): the panel *Interpretation* of the visit card is displayed
- Print a report (**Print**).

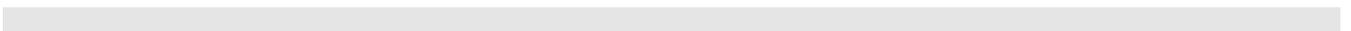
■ **Edit function**

Since the **Edit** button is not available in the *Test results* panel, you can access the edit function from the subject database only.



When a step of the Bronchochallenge test is selected, the **Edit** button will allow access to the edit panel of the selected step only, while the View button will allow access to the test results (summary) as described above.

Dosimeter **SPIRO** **PFT** **Q-Box**



□ General warnings

1. The dosimeter must only be used for bronchial provocation tests.
2. The substances and their doses must be chosen by the physician which uses the dosimeter.
3. Overdosage must be avoided, especially with specific bronchoprovocation tests (allergenes). Severe overdosage can result in anaphylactic shock. Please note that specific provocation tests are part of an allergy test and should be performed only when an experienced allergist is present.
4. Non-specific bronchoprovocation tests also require tremendous experience and are not without risks when performed by physicians in private practice.
5. After provocation tests are performed (with or without response) a bronchodilator must be administered. If a subsequent response test yields normal values (Post values are equal to the Pre ones), the test can be terminated. Otherwise, if the values are still limited, one more additional dilatation steps must be performed.
6. We recommend to periodically check the nebulizer supply quantities according to page 316 ("Nebulizers for the five-breath dosimeter method") of the ATS Recommendation Guidelines for Methacholine and Exercise Challenge Testing - 1999 - Am. J. Respir. Crit. Care Med. - Vol, 161, pp.309-329, 2000.
7. The test must be performed with the flowmeter attached to the nebulizer (see diagram later in manual) without the breathing valve connected.
8. The device must be enabled in the Device Manager, it must be properly connected to the PC with the appropriate communication port selected and it must be enabled to perform this kind of test.
9. The name shown in the top part of the panel must correspond to the subject performing the test (if a subject has not been selected, the Subject database will be opened when a test is selected).
10. If a visit card doesn't exist for the current testing date, the New visit panel will be displayed in order to enter the visit data.
11. **PFT Q-Box** If the flowmeter is attached to the breathing valve during the tests, please be sure that the corresponding checkbox in the Spirometry settings is enabled.
12. **PFT Q-Box** The sampling line should be disconnected from the flowmeter for spirometry testing.
13. If you are using the turbine, either a paper mouthpiece or an antibacterial filter should be connected to the flowmeter prior to executing the tests.
14. If you are using the pneumotachograph (Flowsafe or X9), do not breathe into the flowmeter, until the green led on the lower right part of the screen appears.
15. For hygienic reasons, the use of an antibacterial filter is strongly recommended. When using the PNT X9, the use of an antibacterial filter is mandatory.
16. A calibration for the current flowmeter must be recently performed and the linearity check should be performed successfully.
17. **PFT Q-Box** To avoid potential damage to the items, do not hang your hand/arm on the breathing valve during the test.

Note: Cellular phones should be turned off prior to testing to eliminate potential interferences.

■ Preparation for tests

Disconnect the sampling line from the flowmeter (if present).

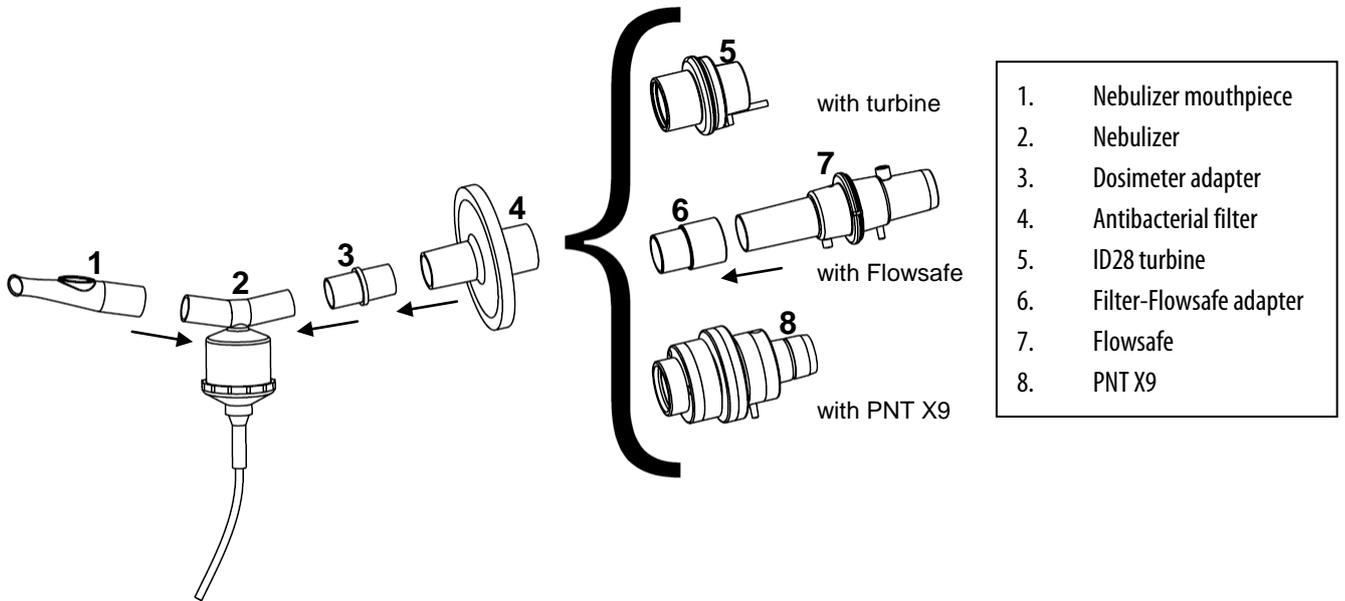
If necessary, calibrate the flowmeter (ID28 turbine, Flowsafe or PNT X9) as shown in the chapter *Calibration*.

Connect the dosimeter hose to the dosimeter and to the proper connector on the Quark rear panel.

Connect a medical air cylinder to the proper connector on the Quark rear panel. The output pressure must be adjusted according to the indication near the connector on the rear panel of the Quark..

Connect the parts as shown in the next page, according to the flowmeter used.

Instruct the patient to apply the nose clips.



■ Performing the test

Warning: During provocation testing, the patient's response to the challenge agent may require the suspension of the test. This procedure can be dangerous, and should only be performed with a physician and appropriate emergency equipment available. Always review the information provided with the challenge agent very carefully.

Start a Broncho Challenge test as described in the *Spirometry* chapter. The test is identical to the Broncho Challenge one, except for the interface of the single step, here described.

In order to exit from this window, press **Cancel**.



As already described in the *Broncho Challenge test* section, press **Prev** or **Next** to move to the previous or to the next step. Please note that if you press **Prev**, you can only perform other FVC post trials of the selected step (**Test**), without any agent delivery.



1. Press **Start** to start the step. The step includes one or more breaths, as defined in the corresponding protocol.
2. Breathe at rest.



3. During a deep expiration (till RV), press **Dose** to administer a dose during the next inhalation. This button is enabled until the required number of breaths (i.e. the number of doses) are performed.



4. Press **Extra Dose** (only once) in order to administer an extra dose (for example, it is useful if a dose was not properly administered).



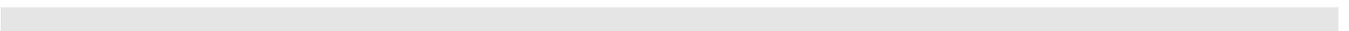
5. At the end of the step, press **Stop**. The standard spirometry interface will open, you can perform an FVC. You can press the **Stop** button also before the required number of deliveries. In this case the software will ask you if you intend to really terminate this step.



Press **Abort** to exit this step before the required number of deliveries. Please note that the next time the current step will be repeated from the beginning, irrespectively of the administered doses.

Edit and results are illustrated in the *Spirometry* chapter.

Lung Volumes **PFT**



□ General warnings

1. The device must be enabled in the Device Manager, it must be properly connected to the PC with the appropriate communication port selected and it must be enabled to perform this type of test.
2. The name shown in the top part of the panel must correspond to the subject performing the test (if a subject has not been selected, the Subject database will be opened when a test is selected).
3. If a visit card does not exist for the current testing date, the New visit panel will be displayed in order to enter the visit data.
4. Nitrogen Washout testing must be performed using the ID 28 turbine or the PNT X9 with the sampling line connected.
5. The Quark must be properly connected to the PC with the appropriate communication port selected.
6. The oxygen cylinder must be open and the output pressure should be within 5 and 6 bars.
7. The soft mouthpiece, flowmeter and antibacterial filter must be assembled correctly prior to testing.
8. For hygienic reasons, the use of an antibacterial filter is strongly recommended. In case of using the PNT X9, the use of an antibacterial filter is mandatory.

Note: After powering the device on wait at least the recommended warm-up time before beginning calibration or testing procedures.

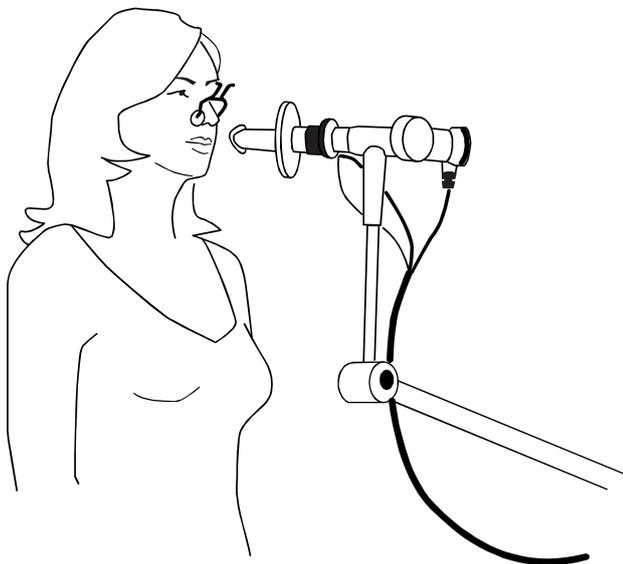
Notice: Cellular phones should be turned off to eliminate potential electrical interferences.

■ Patient preparation

1. Calibrate the turbine or the PNT X9 as indicated in the chapter *Calibration* (ATS recommends a daily calibration).
2. Perform a N2 Washout calibration (see *Calibration*).
3. Connect the sampling line to the flowmeter and connect the turbine to the breathing valve.
4. Instruct the patient to apply the nose clips.

The use of antibacterial filters is strongly recommended.

selected flowmeter



□ **Multi-Breath Nitrogen Washout test**

Lung volume measurements typically include the Total Lung Capacity (TLC), Residual Volume (RV), Functional Residual Capacity (FRC), and Vital Capacity (VC). These measurements are essential to assess lung function and assist in the diagnosis of obstructive and restrictive lung disorders.

FRC can be determined by using one of the following techniques:

1. Multiple-breath open circuit Nitrogen washout
2. Single-breath open circuit Nitrogen washout (see below, Closing Volume test)
3. Body Plethysmography (see the corresponding chapter)
4. Multiple-breath closed circuit Helium dilution (not performed by the Quark system)

The nitrogen wash-out technique involves removing or “washing-out” the N_2 gas present within the lung by allowing the patient to breathe 100% O_2 for several minutes. The washout is complete after 7 minutes of rebreathing has occurred or when the final concentration of expired N_2 is below 1.5 - 2.5% for three consecutive breaths. The exhaled nitrogen represents the patient’s initial lung volume which allows the measurement of FRC to be calculated.

The main parameters measured during FRC test include (some units of measurements can be changed in the settings):

Symbol	UM	Parameter
FRC	l	Functional Residual Capacity
ERV	l	Expiratory Reserve Volume
IC	l	Inspiratory Capacity
VC	l	Vital Capacity
VT	l (BTPS)	Tidal Volume
TLC (N2 WO)	l	Total Lung Capacity
RV (N2 WO)	l	Residual Volume
RV/TLC (N2 WO)	%	RV/TLC ratio (Motley index)
FRC/TLC (N2 WO)	%	FRC/TLC ratio
LCI	-	Lung Clearance Index
FRC SD	-	FRC Standard Deviation
FRC CoV	-	FRC Covariance

■ **Performing the test**



1. Press the **Testing** tile in the home panel, or start a new test from the subject database, then **Nitrogen Washout** and **N2 Multi-Breath Washout**.
2. If no subject was selected (in the top part of the panel there is no subject information), when pressing the **Testing** tile in the home panel the software will open the *Subject database*. If no visit card is present for the current day for the selected subject, the New visit panel is opened before starting the test.
3. A panel will open with graphs and data.
4. Explain the maneuver to the subject prior to testing



When the subject and the software are ready press **Start** to perform the trial.

If requested, select the device and the flowmeter to be used for performing the test. Check *Always use it for this test* if you want to use the selected choice every time this test is started.

Wait until the red dot in the lower right part of the screen becomes green.

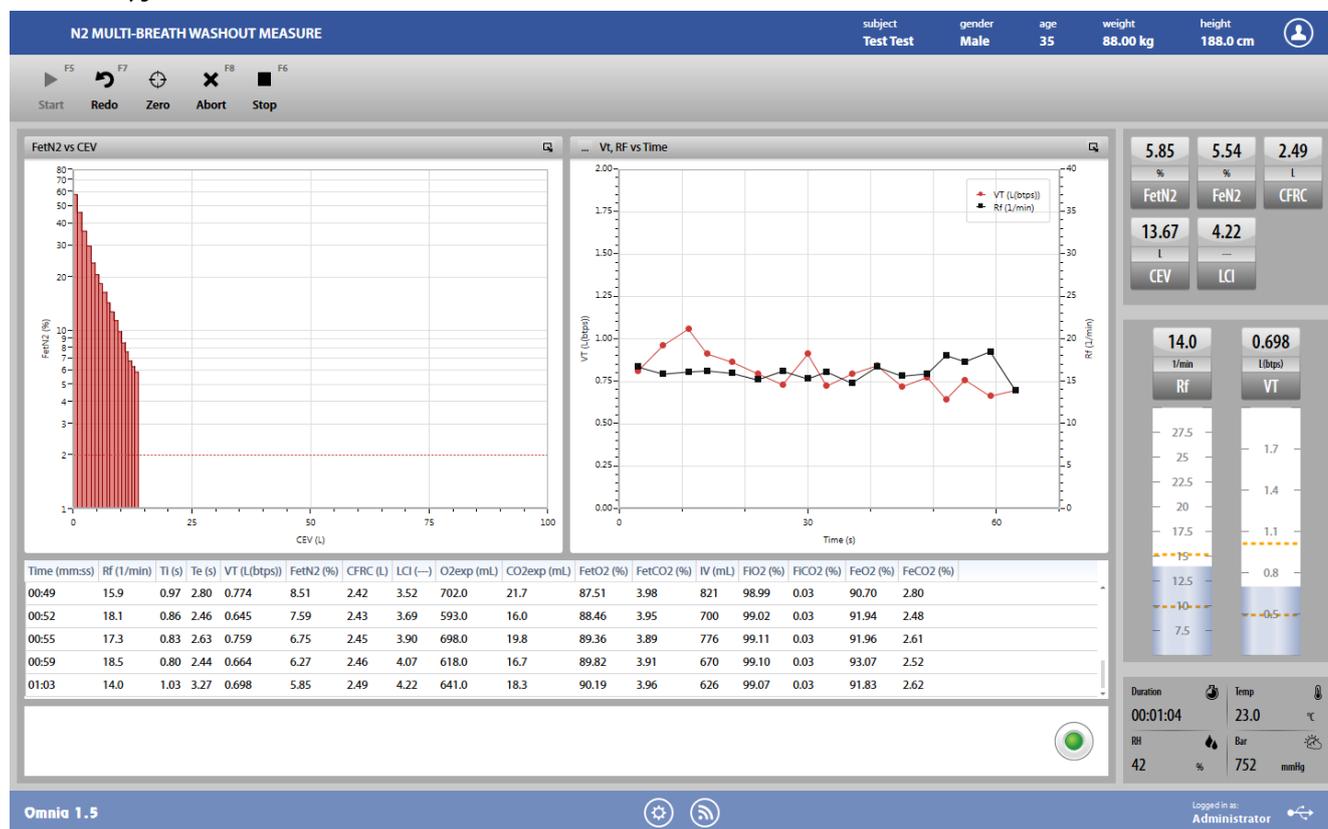
Start the trial, following the next steps:

1. Breathe normally



Start

2. When the message appears (the Vt stability threshold is reached, as defined in *Settings/Nitrogen Washout*), press start. The subject will start to inhale oxygen.



3. Ask the patient to continue to breathe normally until the test comes to an automatic end. A normal breathing pattern can be identified when the bars on the right side of the screen are within the two yellow dotted lines (customizable in *Settings/Nitrogen Washout*).



Stop

4. When the maneuver is completed press Stop or wait for the automatic end. The software will display the Trial edit panel (see below).

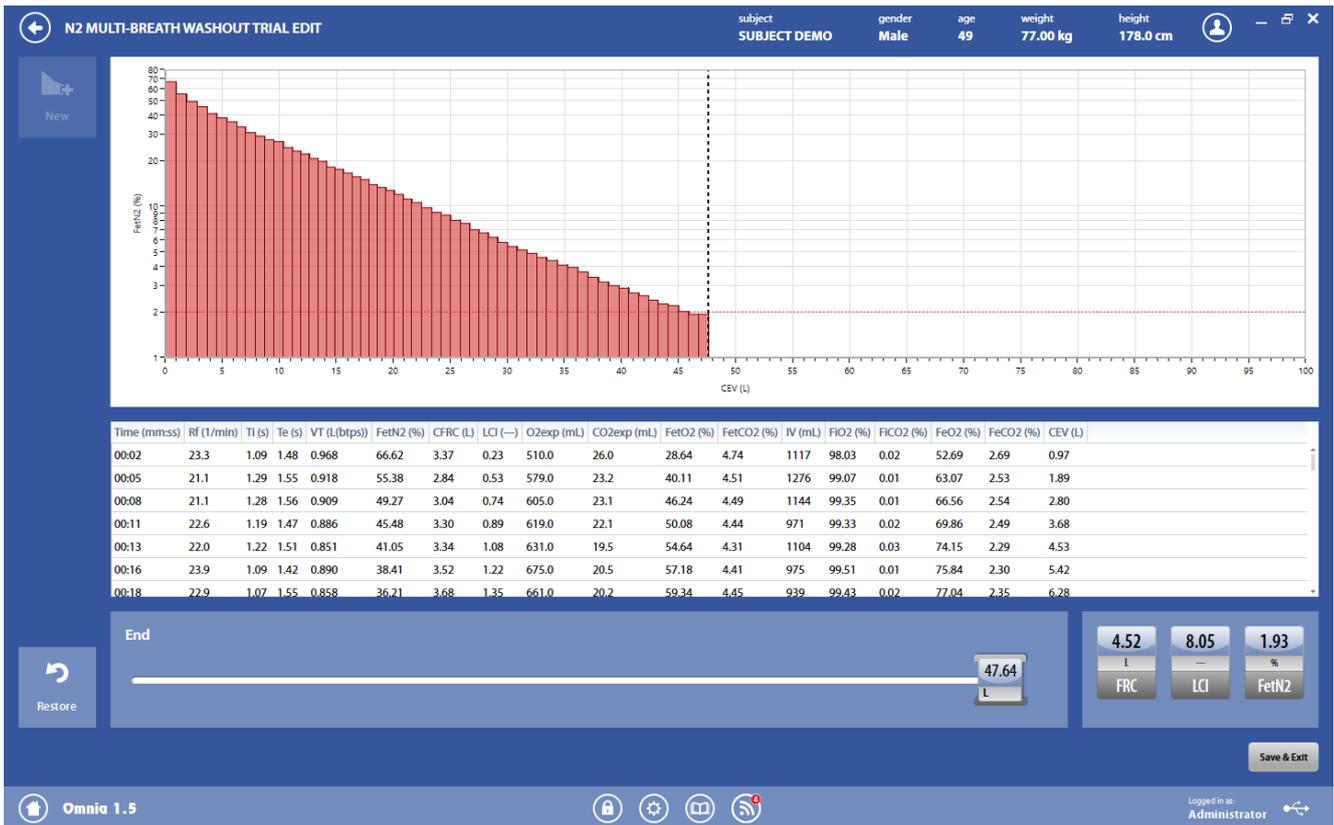


Redo

Abort

To abort the trial, press **Abort**. To restart the trial, press **Redo**. Both these commands discard the current trial and don't save any data (it is not stored in the archive).

Trial editing



At the end of the trial, the trial edit panel is shown.

The trial edit panel shows the parameters measured in the selected trial, and can be accessed at the end of the trial or through the icon shown in the test edit panel above each trial.

The graph shows the FRC graph (FetN₂ vs. cumulated expired volume) of the current trial. In the graph, the vertical dotted line defines the end of the phase for the FRC calculation. This limit is customizable by moving it through the mouse or by moving the slider shown below the graph (useful for avoiding invalidation of all the test if, for example, the patient inhaled some room air during the test incrementing the FetN₂). The horizontal line is the N₂ threshold (as defined in the *Settings*).

Under the graph, test data are shown.

In the bottom right part of the screen, the calculated values, updated in real time according to the edits.



The buttons in the upper left part of the panel allows the user to:

- Start a new trial (**New**)
- Restore the original data, ignoring all the editing (**Restore**)

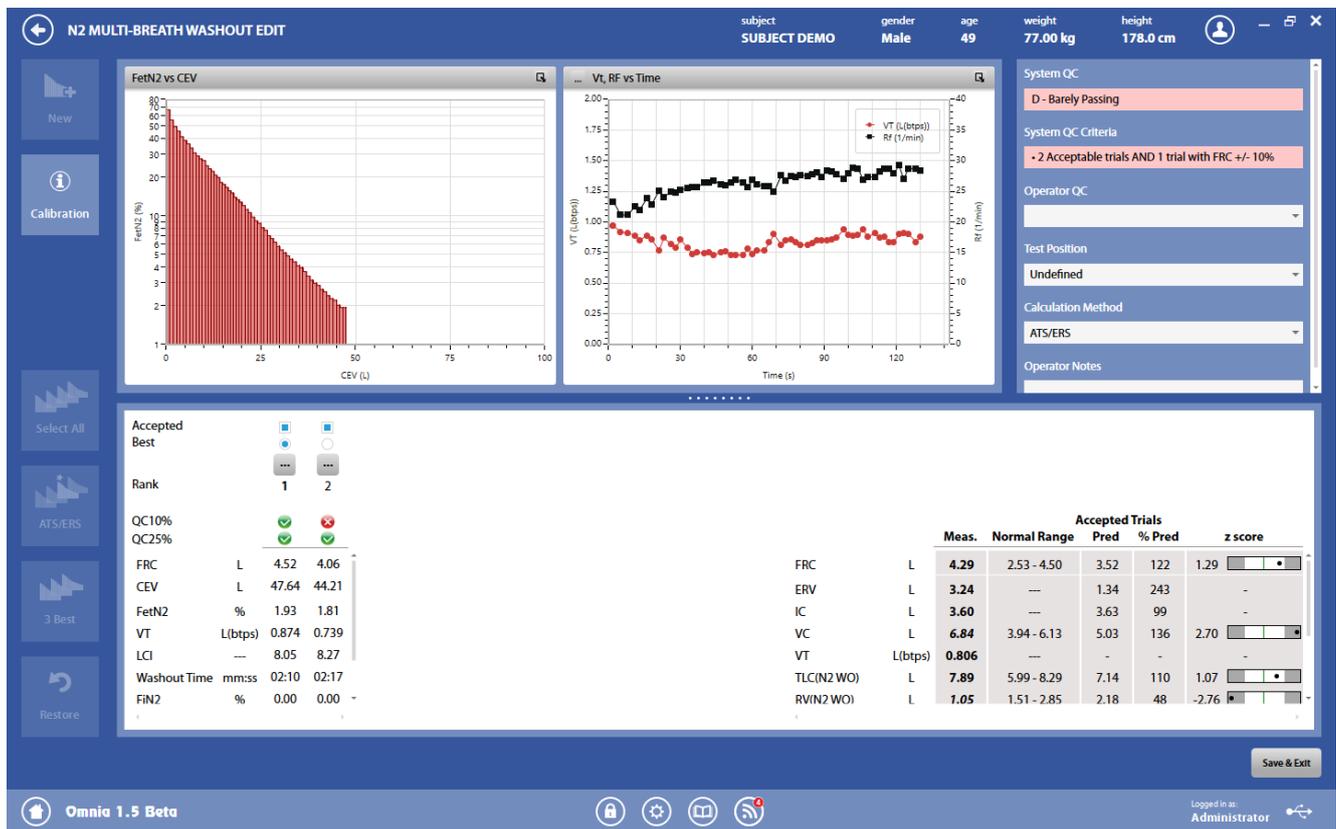
The **Save** button allows the user to exit from the trial edit panel saving the results. The test edit panel will be shown.

Test editing



Where? from Database?

The test editing panel shows the parameters measured in the trials performed during this test, and can be accessed through the **Edit** button appearing when the near the selected test is pressed or pressing the **Save** button in the *Trial edit* panel.



The panel is divided into three sections: graphs, QC and notes, and results.

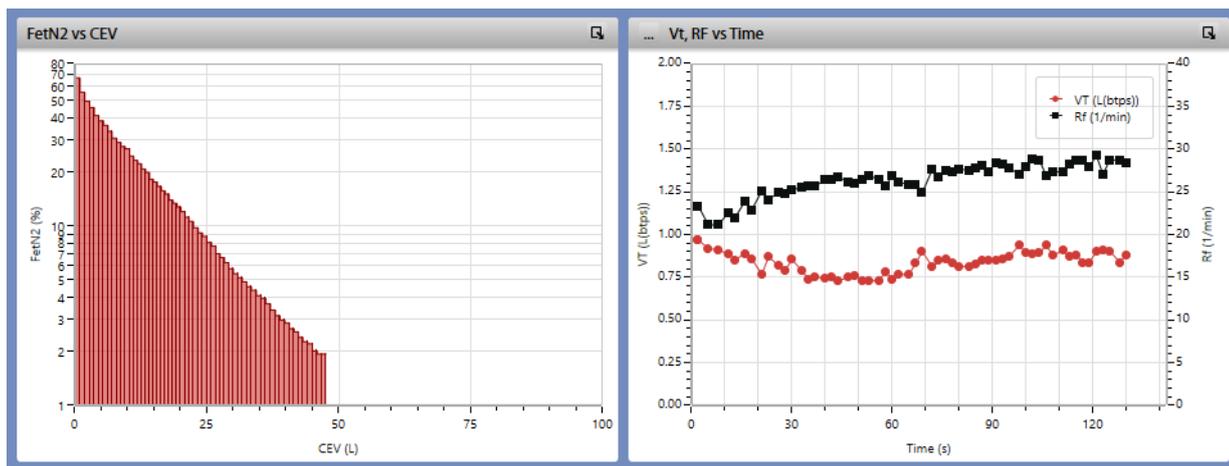


The button in the upper-left part of the panel allows the user to start a new trial (**New**).

The **Calibration** button shows the calibration data for the current test.

The **Save** button allows the user to exit the edit panel and saves the results. By pressing **Save**, the Test results panel will be displayed (see below).

Graphs



In this section of the panel FRC graphs of the best trial are shown. The first graph is predefined and cannot be customized by the user, the second one can be chosen between VT, Rf vs. time and CFRC vs. time.

QC and notes

System QC
D - Barely Passing

System QC Criteria
2 Acceptable trials AND 1 trial with FRC +/- 10%

Operator QC

Test Position
Undefined

Calculation Method
ATS/ERS

Operator Notes

In this section it is displayed:

- An automatic quality control by the PC about the trials reproducibility (not editable by the user), and the corresponding criteria
- A quality control entered by the technician
- The position of the subject during the test
- The method for calculation of the FRC
- Notes entered by the technician

The technician quality control is graded in 6 levels: A - excellent, B - good, C - satisfactory, D - barely passing, E, F - failing, plus an "Invalid" level (the last one for technician quality control only).

If test is classified as "invalid" by the operator, a watermark "Invalid test" is also placed on the corresponding printout.

Results

				Accepted Trials				
				Meas.	Normal Range	Pred	% Pred	z score
FRC	L	4.52	4.06	4.29	2.53 - 4.50	3.52	122	1.29
CEV	L	47.64	44.21	3.24	---	1.34	243	-
FetN2	%	1.93	1.81	3.60	---	3.63	99	-
VT	L(btps)	0.874	0.739	6.84	3.94 - 6.13	5.03	136	2.70
LCI	---	8.05	8.27	0.806	---	-	-	-
Washout Time	mm:ss	02:10	02:17	7.89	5.99 - 8.29	7.14	110	1.07
FIN2	%	0.00	0.00	1.05	1.51 - 2.85	2.18	48	-2.76

The results section is divided into two parts:

- The left side shows all the measured parameters for all the performed trials
- The right side, the mean value for each parameter is shown, together with the normal range, the predicted value, the % of the value with respect of the predicted and the Z-Score. Measured values are displayed in italics if they are out of the normal range.

A scroll bar allows the user to scroll the parameters in order to view all of them.

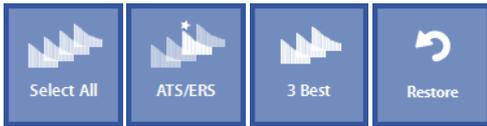
The normal range is defined by the LLN-ULN range, as set in the *Predicted settings*. The Z-Score is how many SD's (standard deviation) the measured value is above or below the predicted value (displayed only if enabled in the *Predicted settings*).

In the left side, for each trial, above the measured parameters, it appears, in order from the top to the bottom:

- If the trial is accepted. By default the software accepts all the trials. The user can discard some of them, but these trials won't be deleted from the archive also when the user saves and exits from this panel.¹ At least 1 trial must be accepted.
- If the trial is the best one (the one with the maximum value of the FRC), but the user can select another trial as the best one. Changing the selection of the best trial, the selected curve is automatically displayed.¹
- An Edit button represented by the icon. – See *Trial editing*
- The rank, starting from 1 for the best trial. The rank is according the FRC, starting from the highest value and decreasing. The rank doesn't correspond to the trials sequence.

- QC10%, i.e. if the FRC is not less than 90% of the best FRC (among the accepted ones)
- QC25%, i.e. if the FRC is within 25% of the median FRC (among the accepted ones)

¹ The color of the check boxes can be white (☐) if selectable, blue (☑) if de-selectable or grey (☐) if not editable.



Near these items, on the left, four buttons allow the user to:

- Accept all the trials (**Select All**)
- Automatically select the best trial according to ATS criteria (ATS), that is the one which has the maximum FRC value.
- Accept only the 3 best curves (**3 Best**), according to the three highest values of FRC values.
- Restore the last save (**Restore**).

Test results



To view a test, press in the subject database the on the left of the test and then the **View** button or double click on the test. In this panel, data and graphs are not editable by the user.

Test results are accessed also by pressing *Save* in the *Edit* panel.

Meas.	Normal Range	Accepted Trials		z score
		Pred	% Pred	
FRC	L 2.53 - 4.50	3.52	122	1.29
ERV	L 3.24	1.34	243	-
IC	L 3.60	3.63	99	-
VC	L 6.84	5.03	136	2.70
VT	L(btps) 0.806	-	-	-
TLC(N2 WO)	L 7.89	7.14	110	1.07
RV(N2 WO)	L 1.05	2.18	48	-2.76
RV/TLC(N2 WO)	% 13.3	33.1	40	-3.63
FRC/TLC(N2 WO)	% 54.3	54.1	100	0.04
LCI	8.16	6.37	128	5.44
FRC SD	0.327	-	-	-

The panel is divided into three sections

The *graphs* section show the graphs for the selected FRC trial.

The *QC and notes* section is the same as described above in Test editing.

The *results* section is divided into two parts:

- The left side shows a graphical interpretation of the results
- The right side, the mean value for each parameter is shown, together with the normal range, the predicted value, the % of the value with respect of the predicted and the Z-Score (if enabled in the Predicted settings).

In the left side, two bars are shown: for *FRC* and *TLC(N2 WO)*. Near these parameters, a colored bar with an indicator representing the current status of the subject. The bars also report the normal range.



The buttons in the left part of the panel allows the user to:

- Edit the test (**Edit**): the panel shown under *Test editing* is displayed
- Start a new test (**New Test**). The **New Test** is enabled if the test is performed on the current day.
- Edit the interpretation (**Edit Interpretation**): the panel *Interpretation* of the visit card is displayed
- Print a report (**Print**).

□ **Single-Breath Nitrogen Washout test**

The Single-Breath Nitrogen Washout (Closing Volume) testing procedure consists of instructing the patient to perform a single inspiration of 100% oxygen followed by a complete, however, not forced expiration to RV. The complete exhalation allows for the measurements of the instantaneous N_2 concentration and the total expired flow.

The expired nitrogen is plotted on a N_2 -Volume graph which displays four phases:

Phase	Definition	Description
Phase I	Absolute dead space	Gas expired during Phase I represents the oxygen contained in the patient's upper airways which does not participate in gas exchange
Phase II	Bronchial phase	Phase II displays a rise in the $N_2\%$ and represents ventilation from the patient's upper and lower airways where the initial N_2 has been diluted with inspired oxygen. The anatomical dead space may also be calculated via the Fowler method
Phase III	Alveolar phase	The Alveolar Plateau is visible during Phase III, which represents the average concentration of N_2 expired after the patient's initial Residual Volume has been diluted with the inspired oxygen. The slope of this plateau is a useful tool for assessing distribution disorders. Normal subjects typically demonstrate a slope of 1.5%, whereas patients affected by severe emphysema may display a slope of up to 10%
Phase IV	Fast rising phase at the end of expiration	The end of Phase III corresponds to the beginning of the Closing Volume which includes the last portion of the Vital Capacity before the Residual Volume has been reached. The quick increase of the $N_2\%$ which can be seen in Phase IV is due to the emptying of the last alveoli, which contain the highest concentration of N_2 . The nitrogen concentration increases because this air has not been contaminated by the inspired oxygen. Increased values of CV can be used to determine the presence of lung disease

The parameters calculated during this test include the following:

Symbol	UM	Parameter
CV	ml	Closing Volume
SIII	%/l	Slope of Phase III
SIII*VC	%	SIII multiplied by VC (during closing volume)
ΔN_2	%	Difference in N_2 concentration between 750 ml and 1250 ml of expired volume
CC	l	Closing Capacity
VC (CV)	ml	Expired volume during wash-out
CV/VC (CV) %	%	CV as a percentage of VC (during closing volume)
VDFowler	ml	Dead space volume (via the Fowler method)
V_I	ml	Related volume at the end of phase I
V_II	ml	Related volume at the end of phase II
V_III	ml	Related volume at the end of phase III

■ **Performing the test**



1. Press the **Testing** tile in the home panel, or start a new test from the subject database, then **Nitrogen Washout** and **N2 Single-Breath Washout**.

- If no subject was selected (in the top part of the panel there is no subject information), when pressing the **Testing** tile in the home panel the software will open the *Subject database*. If no visit card is present for the current day for the selected subject, the New visit panel is opened before starting the test.
- A panel will open with the V/t graph.
- Explain the maneuver to the subject prior to testing



When the subject and the software are ready press **Start** to perform the trial.

If requested, select the device and the flowmeter to be used for performing the test. Check *Always use it for this test* if you want to use the selected choice every time this test is started.

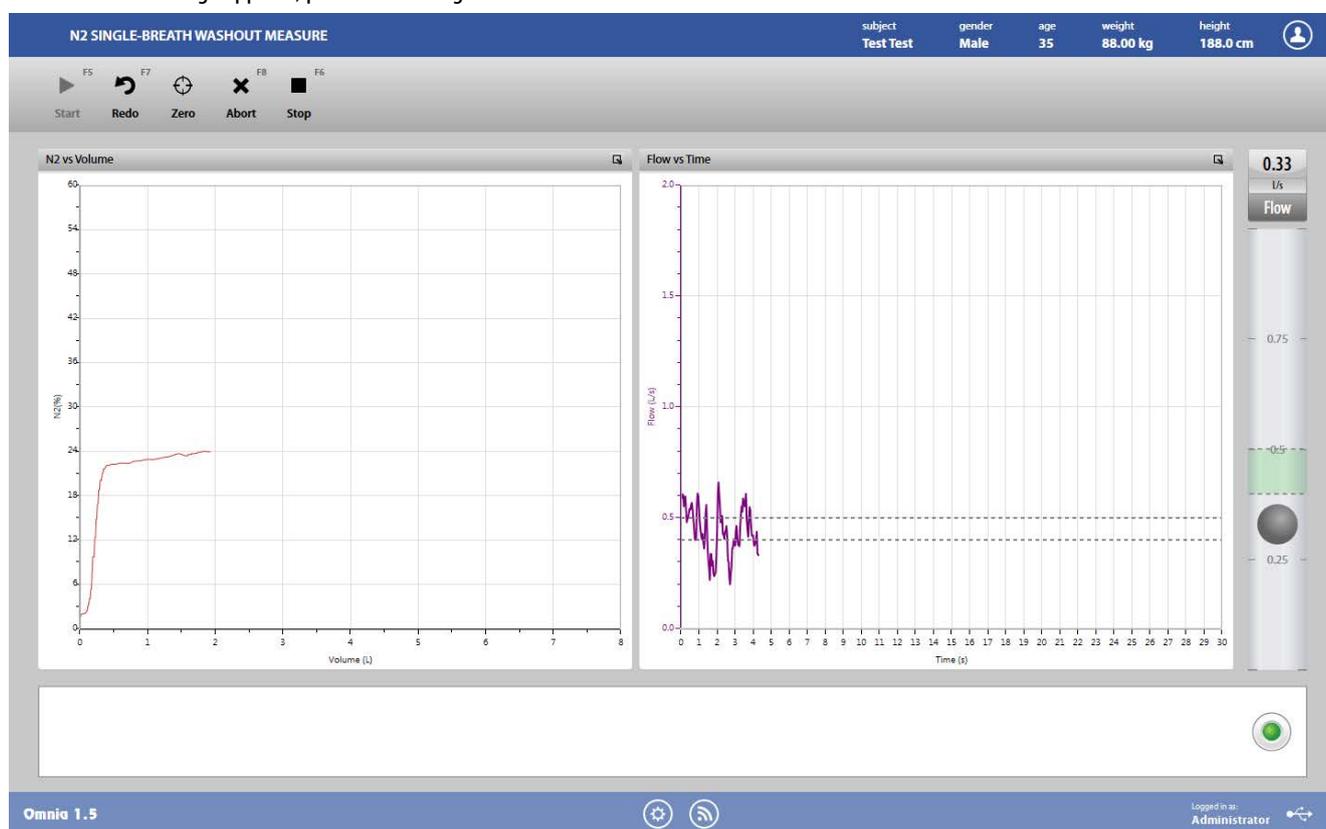
Wait until that the red dot in the lower right part of the screen becomes green.

Start the trial, following the next steps:

- Breathe normally



- When the message appears, press start during an exhalation to residual volume.



- Ask the patient to inspire oxygen to the TLC level and then expire slowly while maintaining a constant flow rate. The two dotted lines displayed on the second graph and on the right of the screen (between 400 ml/min and 500 ml/min) can be used as a target interval.

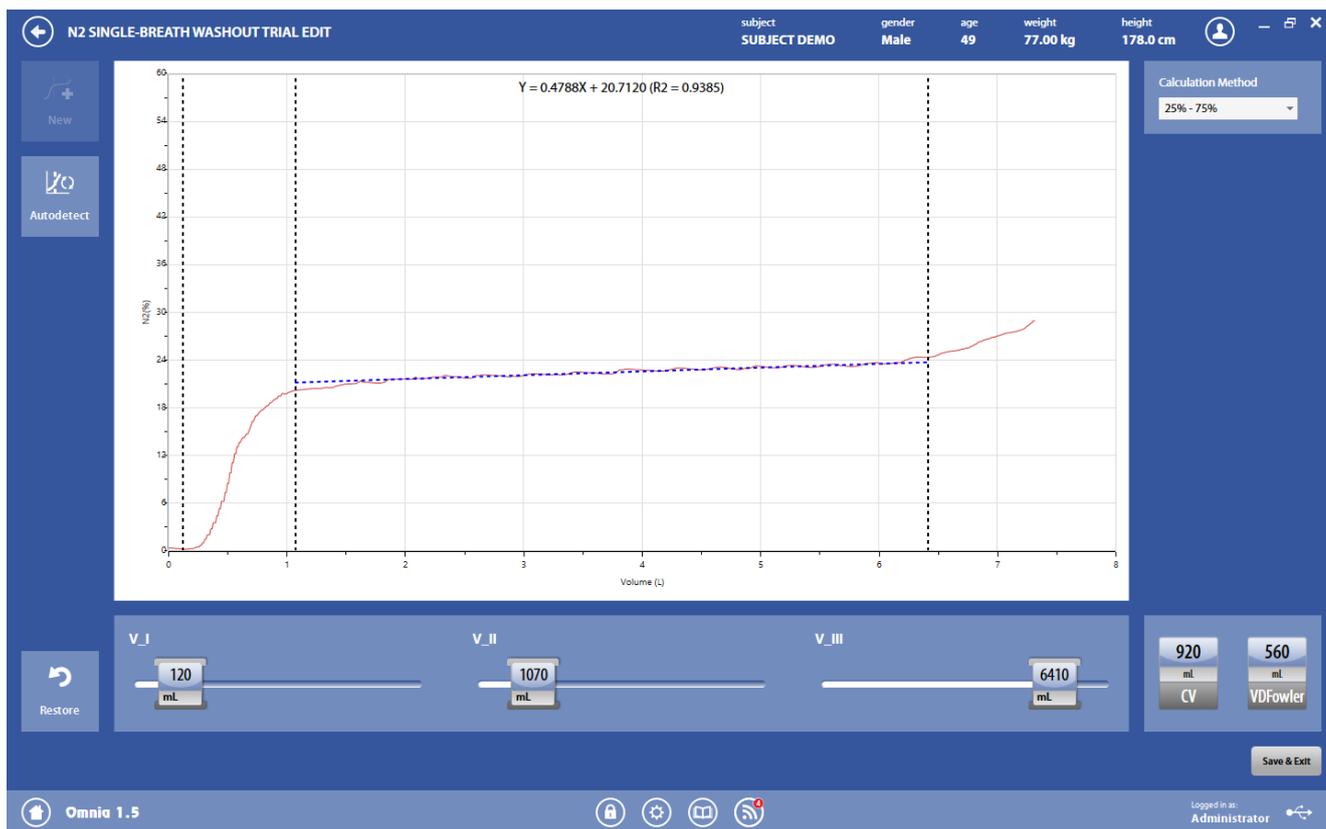


- When the maneuver is completed press Stop or wait for the automatic end. The software will display the Trial edit panel (see below).



To abort the trial, press **Abort**. To restart the trial, press **Redo**. Both these commands discard the current trial and don't save any data (it is not stored in the archive).

Trial editing



At the end of the trial, the trial edit panel is shown.

The trial edit panel shows the parameters measured in the selected trial, and can be accessed at the end of the trial or through the  icon shown in the test edit panel above each trial.

The graph at the center shows the CV graph of the current trial. In the graph, vertical dotted lines show the limit of the phases. These limits are customizable by moving them through the mouse or by moving the sliders shown below the graph. The dotted sloped line in Phase III is the regression line (whose equation is shown at the top) of N₂ in this phase.

At the right of the graph, the calculation method for SIII.

In the bottom right part of the screen, the calculated values, updated in real time according to the edits.



The buttons in the upper left part of the panel allows the user to:

- Start a new trial (**New**)
- Restore the original data, ignoring all the editing (**Restore**)

The **Save** button allows the user to exit from the trial edit panel saving the results. The test edit panel will be shown.

Test editing



The test editing panel shows the parameters measured in the trials performed during this test, and can be accessed through the **Edit** button appearing when the  near the selected test is pressed or pressing the **Save** button in the *Trial edit* panel.



The panel is divided into three sections: graphs, QC and notes, and results.

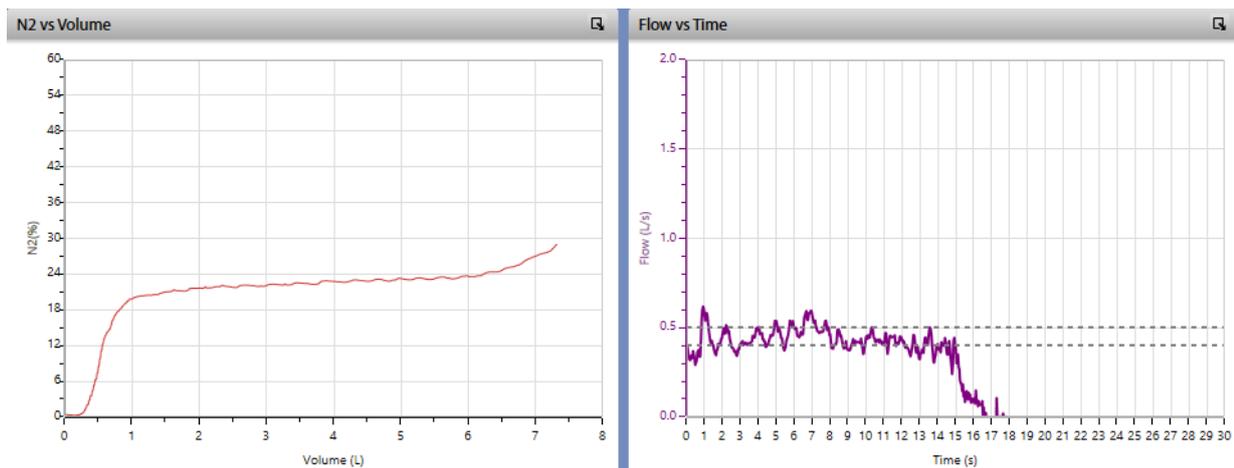


The button in the upper-left part of the panel allows the user to start a new trial (**New**).

The **Calibration** button shows the calibration data for the current test.

The **Save** button allows the user to exit the edit panel and saves the results. By pressing **Save**, the Test results panel will be displayed (see below).

Graphs



In this section of the panel CV graphs of the best trial are shown.

QC and notes

System QC

F - Failing

System QC Criteria

<2 Acceptable trials

Operator QC

Test Position

Undefined

Calculation Method

ATS/ERS

Operator Notes

In this section it is displayed:

- An automatic quality control by the PC about the trials reproducibility (not editable by the user), and the corresponding criteria
- A quality control entered by the technician
- The position of the subject during the test
- The method for calculation of the closing volume
- Notes entered by the technician

The technician quality control is graded in 6 levels: A - excellent, B - good, C - satisfactory, D - barely passing, E, F - failing, plus an "Invalid" level (the last one for technician quality control only).

If test is classified as "invalid" by the operator, a watermark "Invalid test" is also placed on the corresponding printout.

Results

Accepted				Accepted Trials					
Best				Meas.	Normal Range	Pred	% Pred	z score	
CV	mL	920	CV	mL	920	---	-	-	
CC	L	1.97	CC	L	1.97	---	-	-	
VC(CV)	mL	7330	VC(CV)	mL	7330	---	-	-	
CV/VC(CV)%	%	12.55	CV/VC(CV)%	%	12.55	---	18.06	70	
VDFowler	mL	560	VDFowler	mL	560	---	-	-	
SIII	%/L	0.4788	SIII	%/L	0.4788	---	-	-	
SIIVC	%	3.5	SIIVC	%	3.5	---	-	-	
V_I	mL	120	V_I	mL	120	---	-	-	

The results section is divided into two parts:

- The left side shows all the measured parameters for all the performed trials
- The right side, the mean value for each parameter is shown, together with the normal range, the predicted value, the % of the value with respect of the predicted and the Z-Score. Measured values are displayed in italics if they are out of the normal range.

A scroll bar allows the user to scroll the parameters in order to view all of them.

The normal range is defined by the LLN-ULN range, as set in the *Predicted settings*. The Z-Score is how many SD's (standard deviation) the measured value is above or below the predicted value (displayed only if enabled in the *Predicted settings*).

In the left side, for each trial, above the measured parameters, it appears, in order from the top to the bottom:

- If the trial is accepted. By default the software accepts all the trials. The user can discard some of them, but these trials won't be deleted from the archive also when the user saves and exits from this panel.¹ At least 1 trial must be accepted.
- If the trial is the best one. The user can select a trial as the best one. Changing the selection of the best trial, the selected curve is automatically displayed.¹
- An Edit button represented by the  icon. – See *Trial editing*

¹ The color of the check boxes can be white (☐) if selectable, blue (■) if de-selectable or grey (■) if not editable.



Near these items, on the left, four buttons allow the user to:

- Accept all the trials (**Select All**)
- Restore the last save (**Restore**).

■ Test results



To view a test, press in the subject database the  on the left of the test and then the **View** button or double click on the test. In this panel, data and graphs are not editable by the user.

Test results are accessed also by pressing **Save** in the *Edit* panel.

		Accepted Trials				
		Meas.	Normal Range	Pred	% Pred	z score
CV	mL	920	---	-	-	-
CC	L	1.97	---	-	-	-
VC(CV)	mL	7330	---	-	-	-
CV/VC(CV)%	%	12.55	---	18.06	70	-
VDFowler	mL	560	---	-	-	-
SIII	%/L	0.4788	---	-	-	-
SIIVC	%	3.5	---	-	-	-
V_I	mL	120	---	-	-	-
V_II	mL	1070	---	-	-	-
V_III	mL	6410	---	-	-	-
Δ N2	%	3.43	---	1.20	286	-

The panel is divided into three sections

The *graphs* section show the graph for the selected DLCO trial.

The *QC and notes* section is the same as described above in Test editing.

The *results* section is divided into two parts:

- The left side shows a graphical interpretation of the results
- The right side, the mean value for each parameter is shown, together with the normal range, the predicted value, the % of the value with respect of the predicted and the Z-Score (if enabled in the Predicted settings).

In the left side, two bars are shown: for $CV/VC(CV)\%$ and $\Delta N2$. Near these parameters, a colored bar with an indicator representing the current status of the subject. The bars also report the normal range (if available).



The buttons in the left part of the panel allows the user to:

- Edit the test (**Edit**): the panel shown under *Test editing* is displayed

-
- Start a new test (**New Test**). The **New Test** is enabled if the test is performed on the current day.
 - Edit the interpretation (**Edit Interpretation**): the panel *Interpretation* of the visit card is displayed
 - Print a report (**Print**).

Lung Diffusing Capacity **PFT** **Q-Box**



□ General warnings

1. The device must be enabled in the Device Manager, it must be properly connected to the PC with the appropriate communication port selected and it must be enabled to perform this type of test.
2. The name shown in the top part of the panel must correspond to the subject performing the test (if a subject has not been selected, the Subject database will be opened when a test is selected).
3. If a visit card does not exist for the current testing date, the New visit panel will be displayed in order to enter the visit data.
4. DLCO testing must be performed using the ID 28 turbine or the PNT X9 with the sampling line connected.
5. The Quark must be properly connected to the PC with the appropriate communication port selected.
6. The DLCO cylinder must be open and the output pressure should be within 5 and 6 bars.
7. The mouthpiece should be connected to the flowmeter and the antibacterial filter appropriately.
8. For hygienic reasons, the use of an antibacterial filter is strongly recommended. In case of using the PNT X9, the use of an antibacterial filter is mandatory.

Note: When performing several trials, it is recommended that you wait at least 5-minutes between trials.

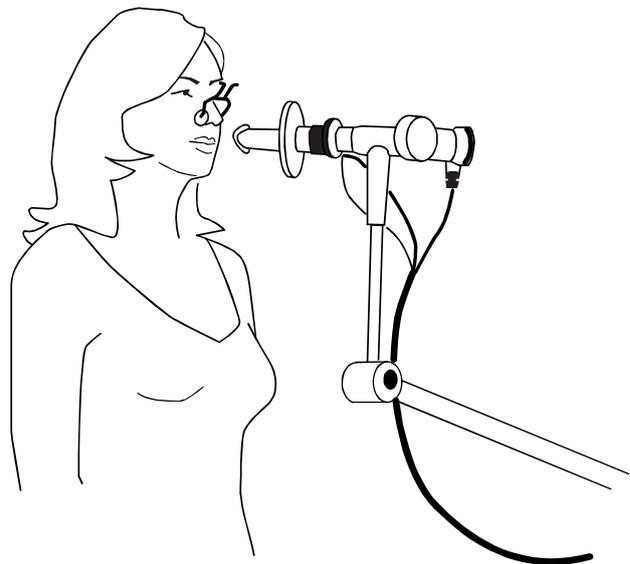
Note: After turning the device on wait at least the recommended warm-up time before beginning calibration or testing procedures.

Notice: Cellular phones should be turned off to eliminate potential electrical interferences.

■ Patient preparation

1. Calibrate the turbine or the PNT X9 as indicated in the chapter Calibration (ATS recommends a daily calibration).
2. Perform a DLCO calibration (see *Calibration*).
3. Connect the sampling line to the flowmeter and connect it to the breathing valve.
4. Instruct the patient to apply the nose clips.

The use of antibacterial filters is strongly recommended.



□ CO Diffusing Capacity (DLCO) Test

Diffusion can be defined as the flow of particles from an area of higher concentration to an area of lower concentration. Measuring diffusion in pulmonary function laboratories can provide information about the transfer of gas between the alveoli and the pulmonary capillary blood. Oxygen and Carbon Dioxide must move across both the alveolar-capillary membrane and the blood plasma barrier during the diffusion process.

The rate of diffusion across these barriers is limited by several factors: the surface area available for diffusion to take place, the distance the gas molecules must travel, the solubility coefficient of the gases in the liquid, and the partial pressure gradient between air and blood and the density of each gas.

Measurement of the diffusing capacity is usually performed by using an inspired gas containing Carbon Monoxide (CO) because of its high affinity for Hemoglobin (approximately 210 times greater than its affinity for oxygen). Carbon Monoxide is soluble in the blood and has an insignificant concentration in venous blood.

DLCO measurements may be obtained by the following methods:

1. Single Breath with Apnea (ATS/ERS standard)
2. Single Breath without Apnea (requires a fast response CO analyzer)

The main parameters measured during DLCO testing include (some units of measurements can be changed in the settings):

<i>Symbol</i>	<i>UM</i>	<i>Parameter</i>
DLco	ml/min/mmHg	CO Diffusion Capacity
DLco corr	ml/min/mmHg	CO Diffusion Capacity corrected for Hb, COHb, PB.
DLco/VA	ml/min/mmHg	Krogh factor
VA	l	Alveolar volume
TLC (DLCO)	l	Total Lung Capacity
Dm	ml/min/mmHg	Membrane Diffusion capacity
Vc	ml	Capillary Volume

■ DLCO single breath (standard technique)

This procedure consists of instructing the patient to carry out a maximal inspiration and an 8-10 second breath hold (during which the expiratory valve is closed), followed by a slow exhalation to the level of Residual Volume. The inhaled mixture contains a low concentration of CO (0.3%) and a tracer gas which is not metabolized (CH₄, Methane).

The expired concentrations of CO and the Tracer gas (CH₄) are analyzed and the test results are determined.

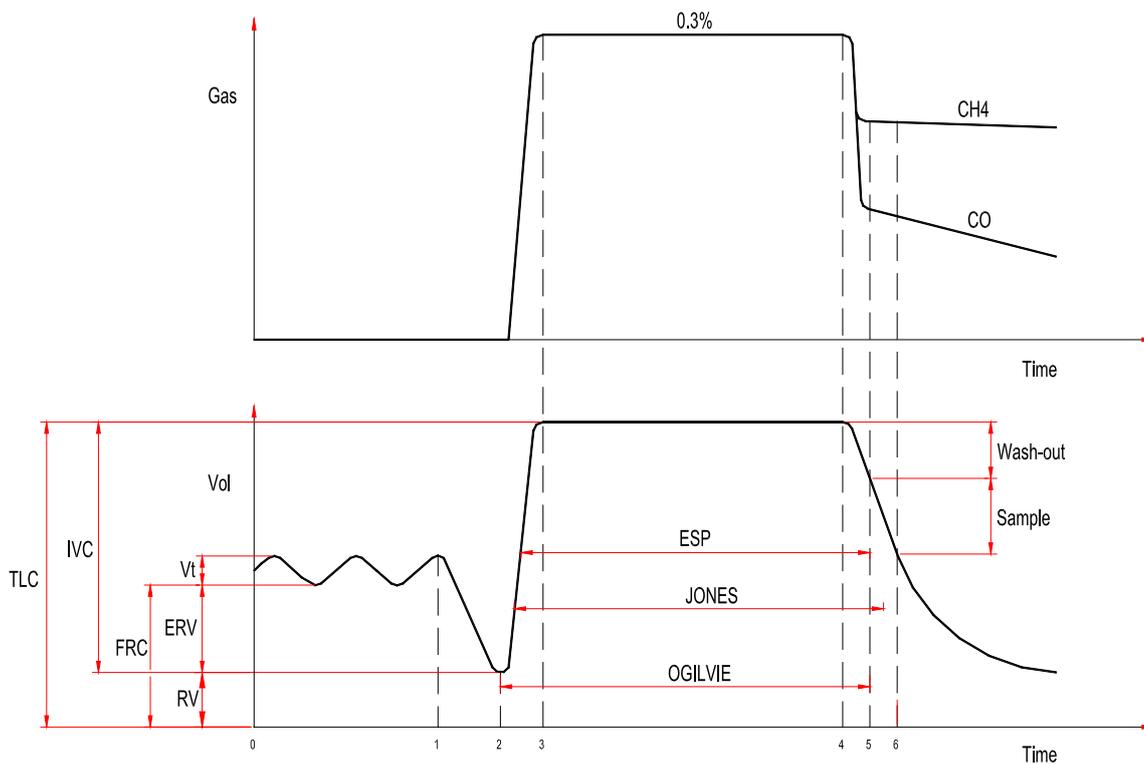
The “wash-out volume”, “collected volume”, and “breath hold time” must be within a specific range which has been established by ATS and ERS standards.

You do have the option to customize the optimal range of “wash-out” and “collected” volumes according to the Vital Capacity demonstrated by the patient being tested. This function may be useful when patients demonstrate a lower than normal VC and have difficulty exhaling the typical “collected volume” required to obtain measurements.

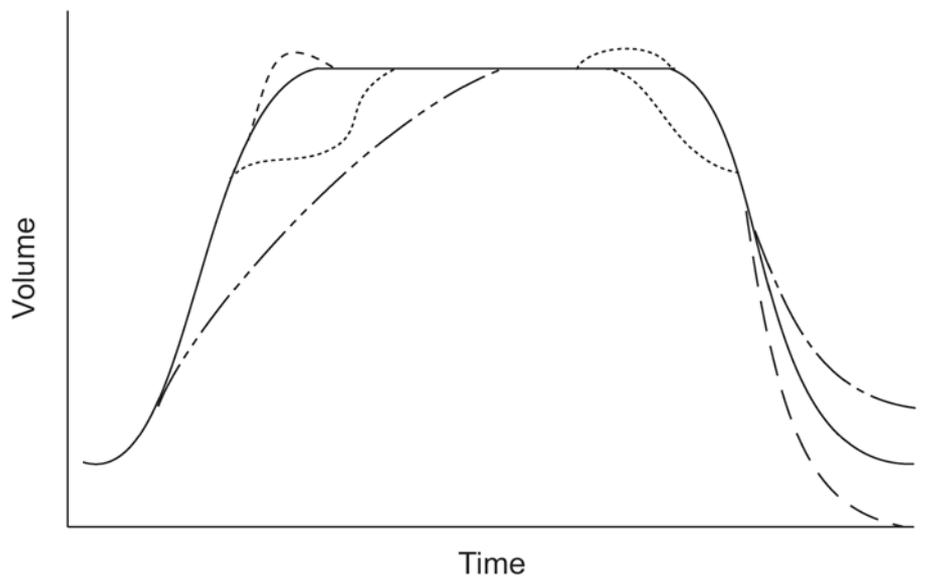
■ DLCO single breath test procedure

1. Instruct the patient to begin the procedure by breathing normally.
2. Ask the patient to exhale completely to Residual Volume. ATS-ERS standards recommends that this portion of the manoeuvre be limited to 6 seconds. In patients with severe obstructive lung disease exhalation to RV may require additional time.
3. Next, instruct the patient to inhale the DLCO gas mixture to Total Lung Capacity. The inspiration should be rapid since the calculations assume instantaneous lung filling. ATS and ERS standards state that 85% of the patient’s inspiratory volume should be inhaled in less than 4 seconds. It should be noted on the post-test notes if longer inspiratory times are necessary to achieve the recommended 85% VI goal.
4. When the patient completes a full inspiration, instruct him/her to hold their breath for the required apnea time.
5. Last, the patient should empty their lungs with a smooth, unforced exhalation. The expired breath should not contain any hesitations or interruptions and the total exhalation time should not exceed 4 seconds. It should be noted in the post test notes if the patient requires a longer expiratory time to provide an adequate alveolar gas sample.

The following is an example of a correctly performed test:



Visual examples of errors that could occur during testing:



- Correct manoeuvre
- Stepwise inhalation or exhalation;
- Maximum exhalation not completed (exhaled volume larger than inhaled volume)
- - - Exhaled gas leak
- - - - Inhalation too slow
- Transient overshoot from high flows and changing gas temperatures

Tips for obtaining acceptable DLCO testing efforts:

1. Ask the patient to perform the simulated test (see below) as many times as necessary until he/she is comfortable with the procedure prior to performing the test.
2. Open the cylinder and the pressure regulator completely.
3. Assure that the patient's inspiration (IVC (DLCO)) is at least 90% of the maximum SVC.
4. Maintain the apnoea time between 9 and 11 seconds.
5. Obtain a sampling volume near 1000 ml.

Patients with severe obstructive lung disease may not have the ability to meet all of the conditions described above. In such cases DLCO measurements may not be completely accurate, but can still be used when making comparisons to prior DLCO measurements obtained from the same patient.

■ Perform a DLCO test single breath (standard method)

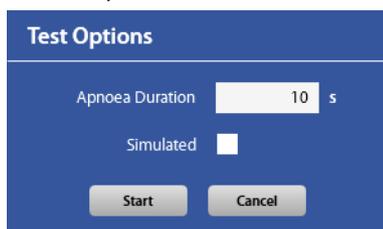


1. Press the **Testing** tile in the home panel, or start a new test from the subject database, then **Lung Diffusion Capacity** and **DLCO Single Breath**.
2. If no subject was selected (in the top part of the panel there is no subject information), when pressing the **Testing** tile in the home panel the software will open the *Subject database*. If no visit card is present for the current day for the selected subject, the New visit panel is opened before starting the test.
3. A panel will open with the V/t graph.
4. Explain the maneuver to the subject prior to testing



When the subject and the software are ready press **Start** to perform the trial.

If requested, select the device and the flowmeter to be used for performing the test. Check *Always use it for this test* if you want to use the selected choice every time this test is started.



Select the apnoea time (10 seconds is the standard and recommended value) and if the current trial is a simulated test. The simulated test is useful if you wish to conduct a procedure without having the patient inhale CO and CH₄. This function may be useful when familiarizing the patient with the manoeuvre prior to performing the actual test.

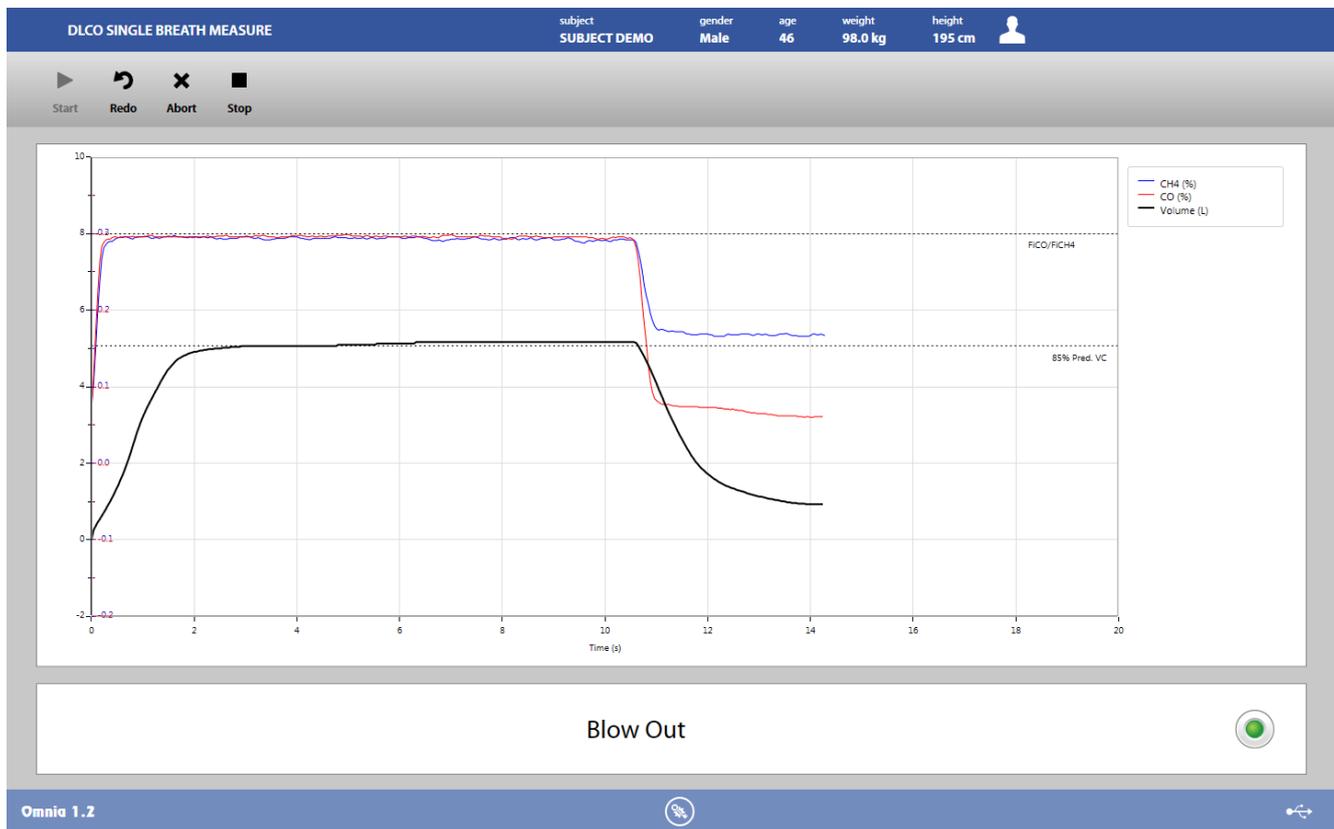
Wait until that the red dot in the lower right part of the screen becomes green.

Start the trial, following the next steps:

1. Breathe normally



2. When the message appears, press start during a maximal exhalation



3. Instruct the patient to inhale the DLCO gas mixture up to a TLC level. At the end of inspiration the valve will close and the patient will be forced to hold their breath. When the breath hold time is completed instruct the patient to exhale to Residual Volume.



4. When the maneuver is completed press Stop or wait for the automatic end. The software will display the Trial edit panel (see below).



To abort the trial, press **Abort**. To restart the trial, press **Redo**. Both these commands discard the current trial and don't save any data (it is not stored in the archive).

■ DLCO Intra Breath

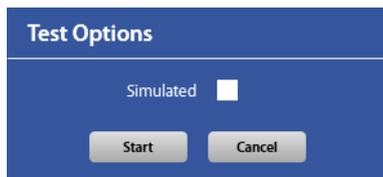


1. Press the **Testing** tile in the home panel, or start a new test from the subject database, then **Lung Diffusion Capacity** and **DLCO Single Breath**.
2. If no subject was selected (in the top part of the panel there is no subject information), when pressing the Testing tile in the home panel the software will open the Subject database. If no visit card is present for the current day for the selected subject, the **New visit** panel is opened before starting the test.
3. A panel will open with the V/t graph.
4. Explain the manoeuvre to the subject prior to testing.



When the subject and the software are ready press **Start** to perform the trial.

If requested, select the device and the flowmeter to be used for performing the test. Check *Always use it for this test* if you want to use the selected choice every time this test is started.



Select if the current trial is a simulated test. The simulated test is useful if you wish to conduct a procedure without having the patient inhale CO and CH4. This function may be useful when familiarizing the patient with the manoeuvre prior to performing the actual test.

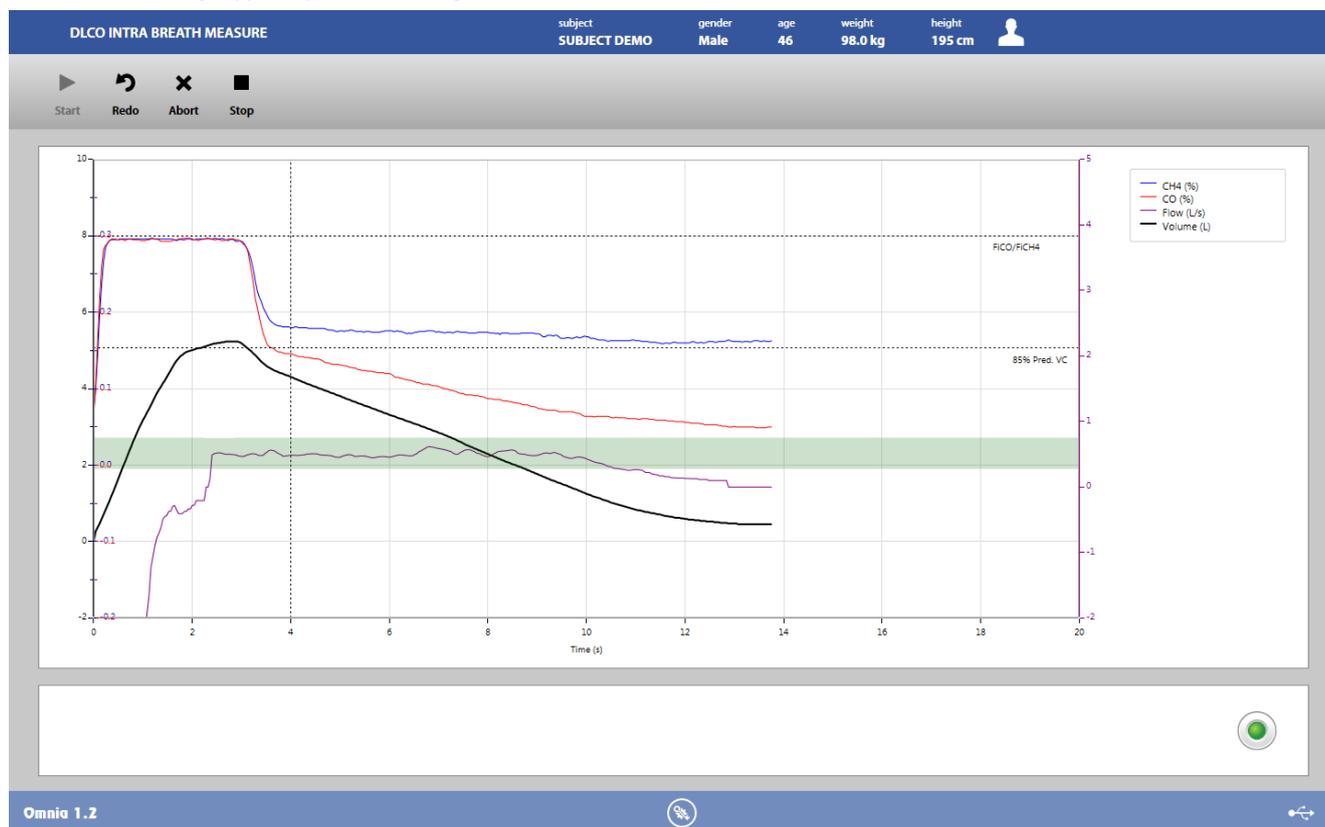
Wait until that the red dot in the lower right part of the screen becomes green.

Start the trial, following the next steps:

1. Breathe normally



2. When the message appears, press start during a maximal exhalation



3. Instruct the patient to inhale the DLCO gas mixture up to a TLC level. At the end of inspiration ask the patient to exhale slowly to Residual Volume, while maintaining a constant flow rate (between 250 and 750 ml/s). The flow rate is highlighted with a green horizontal bar, the flow graph must remain within this bar as long as possible.



4. When the maneuver is completed press Stop or wait for the automatic end. The software will display the Trial edit panel (see below).



To abort the trial, press **Abort**. To restart the trial, press **Redo**. Both these commands discard the current trial and don't save any data (it is not stored in the archive).

Trial editing



At the end of the trial, the trial edit panel is shown. This panel is slightly different depending on the DLCO test performed (single breath or intra breath), but the main features are the same for both tests.

The trial edit panel shows the parameters measured in the selected trial, and can be accessed at the end of the trial or through the  icon shown in the test edit panel above each trial.

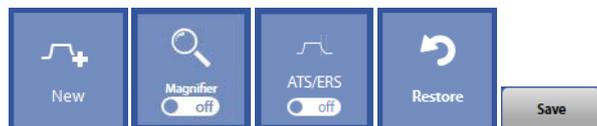
The graph at the center shows the DLCO graph of the current trial. In the graph, vertical dotted lines show the limit of the washout and sampling volumes. These limits are customizable by moving them through the mouse or by moving the sliders shown below the graph.

If the checkbox *ATS criteria* (below the graph) is checked, these limits are not editable, since they are calculated starting from the ATS criteria.

For the intra breath tests, the green bar for the exhalation flow is also shown.

On the right, four sections allow to change the default settings (as set in the *DLCO settings*):

1. *Dead space* allows to change the default dead spaces; the meaning of each field is explained in the *DLCO settings* section.
2. *Correction factors* allows to change the default correction factors; the meaning of each field is explained in the *DLCO settings* section.
3. *Membrane diffusion* allows to use this trial as one of the trials for the membrane diffusion test. In order to do that, please check the Enabled checkbox and enter the O₂ % of the gas used during this trial. The membrane diffusion results will be shown in the test edit and results panels only if two or more trials are selected for this test.
4. *Breath hold method* (shown only in case of single breath test) allows to change the default breath hold method; the meaning of each field is explained in the *DLCO settings* section.



The buttons in the upper left part of the panel allow the user to:

- Start a new trial (**New**)
- Magnify a part of the graph (**Magnifier**). A magnifying glass will appear on the graph, and it can be moved through the mouse.
- Automatically detect the wash-out and sampling phases of the maneuver according to ATS/ERS criteria (**ATS/ERS**)
- Restore the original data, ignoring all the editing (**Restore**)

The **Save** button allows the user to exit from the trial edit panel saving the results. The test edit panel will be shown.

Test editing



The test editing panel shows the parameters measured in the trials performed during this test, and can be accessed through the **Edit** button appearing when the **...** near the selected test is pressed or pressing the **Save** button in the *Trial edit* panel.

DLCO SINGLE BREATH EDIT

subject: SUBJECT DEMO, gender: Male, age: 46, weight: 78.00 kg, height: 178.00 cm

System QC
B - Good

System QC Criteria

- At least one ATS1995 criterion is not satisfied
- ATS1995:
 - IV% ≥ 90
 - Breath-hold time 9-11 s
 - DLCO variation $\leq 7.5\%$ or 2 mL/min/mmHg
 - Inspiratory time < 4 s
 - Expiratory time < 4 s
 - Sample collection time < 3 s

Operator QC
A - Excellent

Test Position
Standing

Accepted Best

Rank	1	2
DLCO	mmol/min/kPa 11.28	10.88
DLCO corr	mL/min/mmHg 33.70	32.50
DLCO/VA	mL/min/mmHg/L 4.26	3.93
VA	L 7.91	8.27
BTPS Exp	---	1.2050
BTPS Ins	---	1.2125
TLC(DLCO)	L 8.08	8.44
VC(DLCO)	L 8.04	8.67

Accepted Trials

Meas.	Normal Range	Pred	% Pred	z score
DLCO	8.38 - 13.03	10.71	104	0.27
DLCO corr	25.04 - 38.92	31.98	104	0.27
DLCO/VA	3.19 - 5.96	4.57	89	-0.57
VA	5.84 - 8.14	6.99	116	1.57
ERV	---	1.38	184	-
IC	---	3.65	119	-
TLC(DLCO)	5.99 - 8.29	7.14	116	1.60
VC(DLCO)	5.88 - 8.14	6.99	116	1.57

Save & Exit

Omnia 1.5, Logged in as: Administrator

The panel is divided into three sections: graphs, QC and notes, and results.

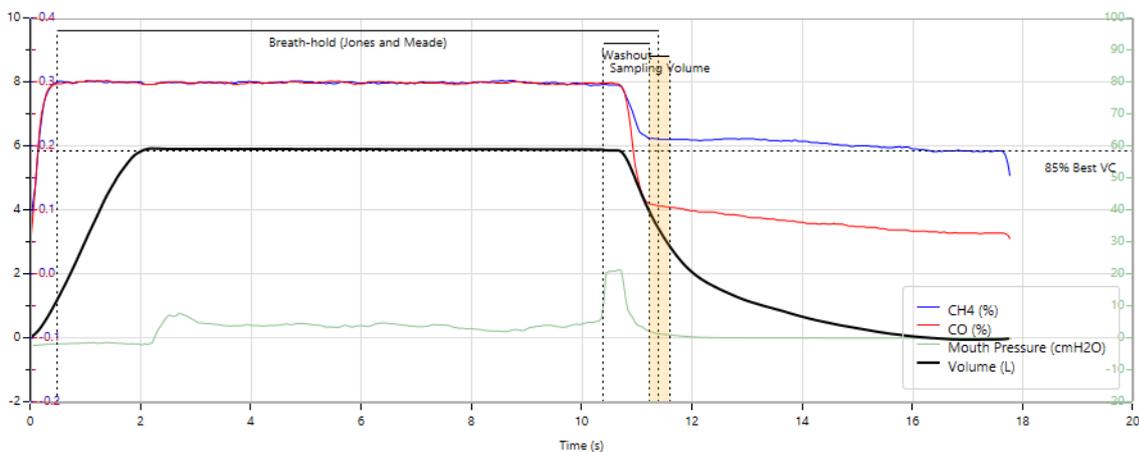


The button in the upper-left part of the panel allows the user to start a new trial (**New**).

The **Calibration** button shows the calibration data for the current test.

The **Save** button allows the user to exit the edit panel and saves the results. By pressing **Save**, the **Test results** panel will be displayed (see below).

Graphs



In this section of the panel DLCO graph of the best trial is shown.

In the graph, the mouth pressure (only for DLCO breath hold), the breath hold (only for DLCO breath hold), the washout and the sampling volume are shown.

QC and notes

System QC

B - Good

System QC Criteria

- At least one ATS1995 criterion is not satisfied
- ATS1995:
 - IV% ≥ 90
 - Breath-hold time 9-11 s
 - DLCO variation $\leq 7.5\%$ or 2 ml/min/mmHg
 - Inspiratory time < 4 s
 - Expiratory time < 4 s
 - Sample collection time < 3 s

Operator QC

A - Excellent

Test Position

Standing

In this section it is displayed:

- An automatic quality control by the PC about the trials reproducibility (not editable by the user), and the corresponding criteria
- A quality control entered by the technician
- The position of the subject during the test
- The Hb and COHb values (if available)
- Notes entered by the technician

The quality control is graded in 6 levels: A - excellent, B - good, C - satisfactory, D - barely passing, E, F - failing, plus an "Invalid" level (the last one for technician quality control only).

If test is classified as "invalid" by the operator, a watermark "Invalid test" is also placed on the corresponding printout.

Results

		Accepted		Best		Accepted Trials				
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	Meas.	Normal Range	Pred	% Pred	z score
Rank		1	2					
DLCO	mmol/min/kPa	11.28	10.88			11.08	8.38 - 13.03	10.71	104	0.27
DLCO corr	mL/min/mmHg	33.70	32.50			33.10	25.04 - 38.92	31.98	104	0.27
DLCO/VA	mL/min/mmHg/L	4.26	3.93			4.09	3.19 - 5.96	4.57	89	-0.57
VA	L	7.91	8.27			8.09	5.84 - 8.14	6.99	116	1.57
BTPS Exp	---	1.2050	1.2050			2.53	---	1.38	184	-
BTPS Ins	---	1.2125	1.2125			4.35	---	3.65	119	-
TLC(DLCO)	L	8.08	8.44			8.26	5.99 - 8.29	7.14	116	1.60
IV(DLCO)	L	5.04	6.57			6.08	4.00 - 5.84	4.00	140	2.50

The results section is divided into two parts:

- The left side shows all the measured parameters for all the performed trials
- The right side, the mean value for each parameter is shown, together with the normal range, the predicted value, the % of the value with respect of the predicted and the Z-Score. Measured values are displayed in italics if they are out of the normal range.

A scroll bar allows the user to scroll the parameters in order to view all of them.

The normal range is defined by the LLN-ULN range, as set in the *Predicted settings*. The Z-Score is how many SD's (standard deviation) the measured value is above or below the predicted value (displayed only if enabled in the *Predicted settings*).

In the left side, for each trial, above the measured parameters, it appears, in order from the top to the bottom:

- If the trial is accepted. By default the software accepts all the trials. The user can discard some of them, but these trials won't be deleted from the archive also when the user saves and exits from this panel.¹ At least 1 trial must be accepted.
- If the trial is the best one (the one with the maximum value of the DLCO), but the user can select another trial as the best one. Changing the selection of the best trial, the selected curve is automatically displayed.¹

- An Edit button represented by the  icon. – See *Trial editing*
- The rank, starting from 1 for the best trial. The rank is according the DLCO, starting from the highest value and decreasing. The rank doesn't correspond to the trials sequence.

¹ The color of the check boxes can be white () if selectable, blue () if de-selectable or grey () if not editable.



Near these items, on the left, four buttons allow the user to:

- Accept all the trials (**Select All**)
- Automatically select the best trial according to ATS criteria (ATS), that is the one which has the maximum DLCO value.
- Accept only the 3 best curves (**3 Best**), according to the three highest values of DLCO values.
- Restore the last save (**Restore**).

Test results



To view a test, press in the subject database the  on the left of the test and then the **View** button or double click on the test. In this panel, data and graphs are not editable by the user.

Test results are accessed also by pressing *Save* in the *Edit* panel.



The panel is divided into three sections

The *graphs* section show the graph for the selected DLCO trial.

The *QC and notes* section is the same as described above in Test editing.

The *results* section is divided into two parts:

- The left side shows a graphical interpretation of the results
- The right side, the mean value for each parameter is shown, together with the normal range, the predicted value, the % of the value with respect of the predicted and the Z-Score (if enabled in the Predicted settings).

In the left side, two bars are shown: for *DLCO corr* and *DLCO/VA*. Near these parameters, a colored bar with an indicator representing the current status of the subject. The bars also report the normal range.



The buttons in the left part of the panel allows the user to:

- Edit the test (**Edit**): the panel shown under *Test editing* is displayed
- Start a new test (**New Test**). The **New Test** is enabled if the test is performed on the current day.
- Edit the interpretation (**Edit Interpretation**): the panel *Interpretation* of the visit card is displayed
- Print a report (**Print**).

Respiratory Mechanics

PFT

Q-Box



□ General warnings

1. MIP/MEP and P0.1 tests must be performed either with the ID 28 turbine and the pressure line connected, or with the PNT (Flowsafe or X9).
2. The device must be enabled in the Device Manager, it must be properly connected to the PC with the appropriate communication port selected and it must be enabled to perform this type of test.
3. The name shown in the top part of the panel must correspond to the subject performing the test (if a subject has not been selected, the Subject database will be opened when a test is selected).
4. If a visit card does not exist for the current testing date, the New visit panel will be displayed in order to enter the visit data.
5. The mouthpiece should be connected to the flowmeter and the antibacterial filter properly.
6. For the P0.1 test only: the O₂ cylinder (if used) must be closed during the test.
7. For hygienic reasons, the use of an antibacterial filter is strongly recommended. In case of using the PNT X9, the use of an antibacterial filter is mandatory.

Notice: Cellular phones should be turned off to eliminate potential electrical interferences.

■ Patient preparation

Using the turbine

Calibrate the turbine as indicated in the chapter Calibration (ATS recommends a daily calibration).

Connect the ID28 turbine to the Quark.

Connect the pneumatic line on the turbine to the Pneumotach connector on the rear side of the Quark through the pressure line. On the pressure line, the switch must be placed as in the following picture:



Connect the turbine to the breathing valve and the breathing valve to the Quark.

Using the PNT

Calibrate (if needed) the PNT as indicated in the chapter Calibration.

Connect the PNT to the unit through its pneumatic line.

For P0.1 test only: Connect the sampling line from the PNT to the unit.

Note: For MIP/MEP tests the sampling line must be removed.

Other operations

Ask the patient to apply the nose clips.



The MIP/MEP test

The MIP/MEP test measures the patient's maximal inspiratory/expiratory pressure. You should instruct the patient to begin by breathing normally, perform a maximal expiration/inspiration and then inspire/expire maximally against a closed valve.

The parameters measured during MIP/MEP testing include (units of measurements can be changed in the settings):

<i>Symbol</i>	<i>UM</i>	<i>Parameter</i>
MIP	cmH ₂ O	Maximum inspiratory pressure
MEP	cmH ₂ O	Maximum expiratory pressure

Perform a MIP/MEP test



1. Press the **Testing** tile in the home panel, or start a new test from the subject database, then **Respiratory Mechanics** and **MIP/MEP**.
2. If no subject was selected (in the top part of the panel there is no subject information), when pressing the Testing tile in the home panel the software will open the Subject database. If no visit card is present for the current day for the selected subject, the **New visit** panel is opened before starting the test.
3. A panel will open with the V/t and P_{mouth}/t graphs.
4. Explain the maneuver to the subject prior to testing.



5. When the subject and the software are ready press **Start** to perform the trial.
6. If requested, select the device and the flowmeter to be used for performing the test. Check *Always use it for this test* if you want to use the selected choice every time this test is started.
7. Wait until that the red dot in the lower right part of the screen becomes green.



8. Breathe into the flowmeter. The left part of the screen shows the V/t graph. For performing a MIP, press **MIP/MEP** during an expiration, for performing a MEP, press **MIP/MEP** during an inhalation. The button is enabled only after some stable tidal breaths.

The right part of the screen will show the P_{mouth}/t graph during the maneuver. The software will show an error message if the P_{mouth} value doesn't exceed 20 cmH₂O.



9. When the maneuver is completed press Stop or wait for the automatic end. The software will display the Test edit panel (see below).

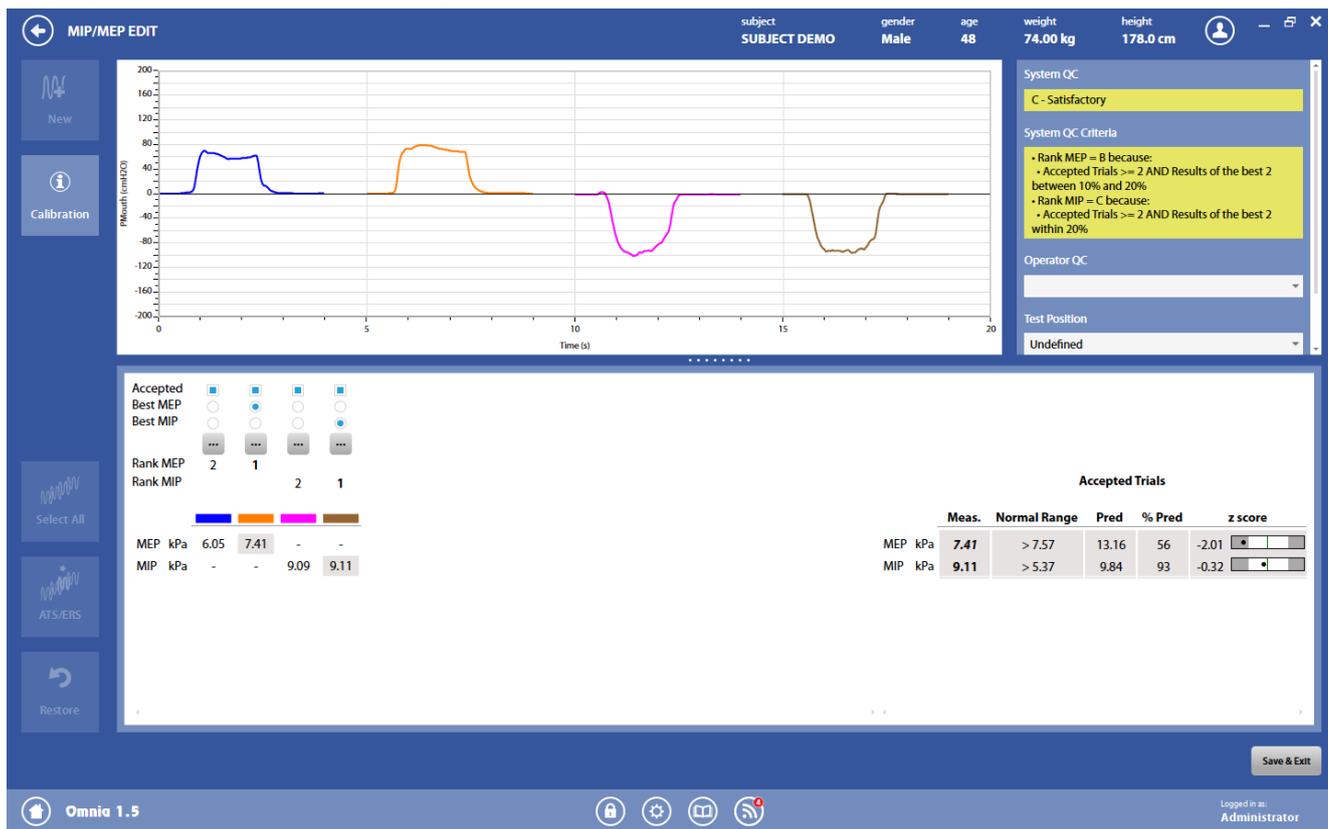


To abort the trial, press **Abort**. To restart the trial, press **Redo**. Both these commands discard the current trial and don't save any data (it is not stored in the archive).

Test editing



The test editing panel shows the parameters measured in the trials performed during the tests and can be accessed through the **Edit** button appearing when the **...** near the selected test is pressed or at the end of each trial.



The panel is divided into three sections: graphs, QC and notes, and results.

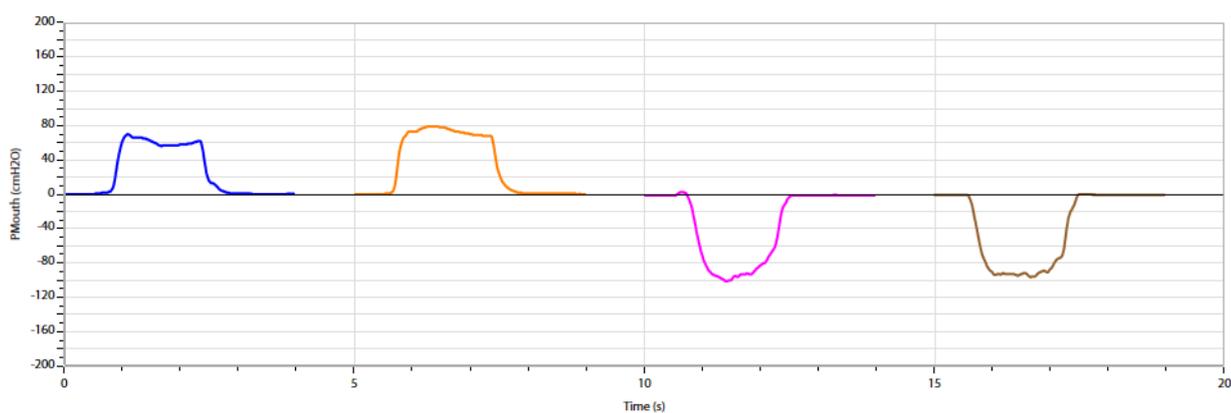


The button in the upper-left part of the panel allows the user to start a new trial (**New**).

The **Calibration** button shows the calibration data for the current test.

The **Save** button allows the user to exit the edit panel and saves the results. By pressing **Save**, the **Test results** panel will be displayed (see below).

Graphs



In this section of the panel MIP/MEP graphs of all the accepted trials are shown.

QC and notes

System QC

C - Satisfactory

System QC Criteria

- Rank MEP = B because:
 - Accepted Trials ≥ 2 AND Results of the best 2 between 10% and 20%
- Rank MIP = C because:
 - Accepted Trials ≥ 2 AND Results of the best 2 within 20%

Operator QC

Test Position

Undefined

In this section it is displayed:

- An automatic quality control by the PC about the trials reproducibility (not editable by the user), and the corresponding criteria
- A quality control entered by the technician
- The position of the subject during the test
- Notes entered by the technician

The quality control is graded in 6 levels: A - excellent, B - good, C - satisfactory, D - barely passing, E, F - failing, plus an "Invalid" level (the last one for technician quality control only).

If test is classified as "invalid" by the operator, a watermark "Invalid test" is also placed on the corresponding printout.

Results

	Accepted	Best MEP	Best MIP	Rank MEP	Rank MIP	Accepted Trials	Meas.	Normal Range	Pred	% Pred	z score
MEP kPa	6.05	<i>7.41</i>	-	-	-	2	<i>7.41</i>	> 7.57	13.16	56	-2.01
MIP kPa	-	-	9.09	9.11	1	1	<i>9.11</i>	> 5.37	9.84	93	-0.32

The results section is divided into two parts:

- The left side shows all the measured parameters for all the performed trials
- The right side, the mean value for each parameter is shown, together with the normal range, the predicted value, the % of the value with respect of the predicted and the Z-Score. Measured values are displayed in italics if they are out of the normal range.

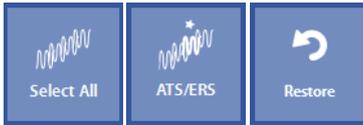
A scroll bar allows the user to scroll the parameters in order to view all of them.

The Z-Score is how many SD's (standard deviation) the measured value is above or below the predicted value (displayed only if enabled in the *Predicted settings*).

In the left side, for each trial, above the measured parameters, it appears, in order from the top to the bottom:

- If the trial is accepted. By default the software accepts all the trials. The user can discard some of them, but these trials won't be deleted from the archive also when the user saves and exits from this panel.¹ At least 1 trial must be accepted.
- Both for MIP and MEP, if the trial is the best one (the one with the maximum value of the MIP or MEP), but the user can select another trial as the best one.¹
- An Edit button represented by the  icon. – See *Trial editing*
- The rank, starting from 1 for the best trial. The rank is according the MIP or MEP, starting from the highest value and decreasing. The rank doesn't correspond to the trials sequence.

¹ The color of the check boxes can be white (☐) if selectable, blue (☑) if de-selectable or grey (☐) if not editable.



Near these items, on the left, three buttons allow the user to:

- Accept all the trials (**Select All**)
- Automatically select the best trial according to ATS/ERS criteria (**ATS/ERS**), that is the one which has the maximum MIP or MEP value.
- Restore the last save (**Restore**).

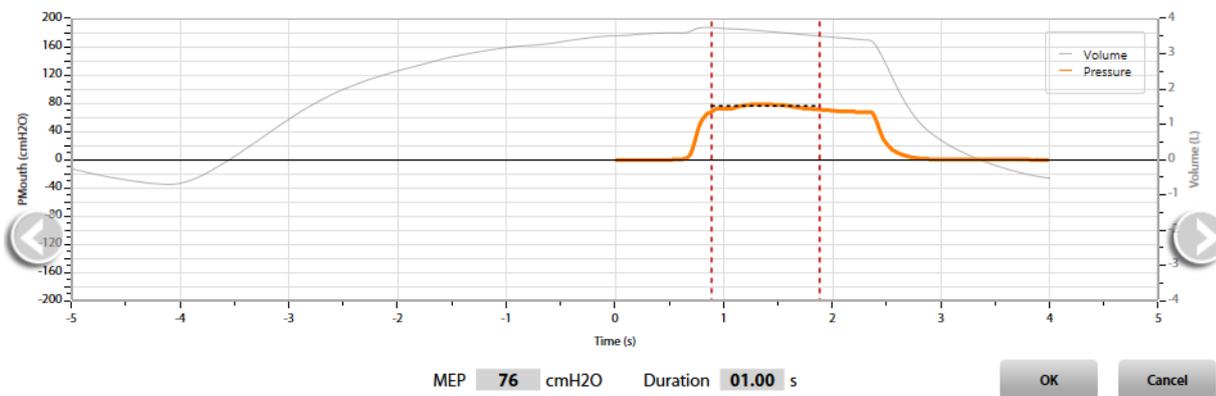
■ Trial editing

By pressing the  icon in the *Test edit* panel, you can graphically change the start and the end of the MIP/MEP plateau, in order to properly calculate the MIP (or MEP) parameter. The graph shows with a grey line the volume vs. time and with a colored thick line the P_{mouth} vs. time graph.

The MIP (or MEP) value is represented on the graph with a dotted horizontal line. The MIP (MEP) value and the duration are automatically updated each time the start or the end line is moved.

The arrows on the left and on the right allows to view the previous or the next MIP/MEP trial.

Press **OK** to confirm changes or **Cancel** to cancel.

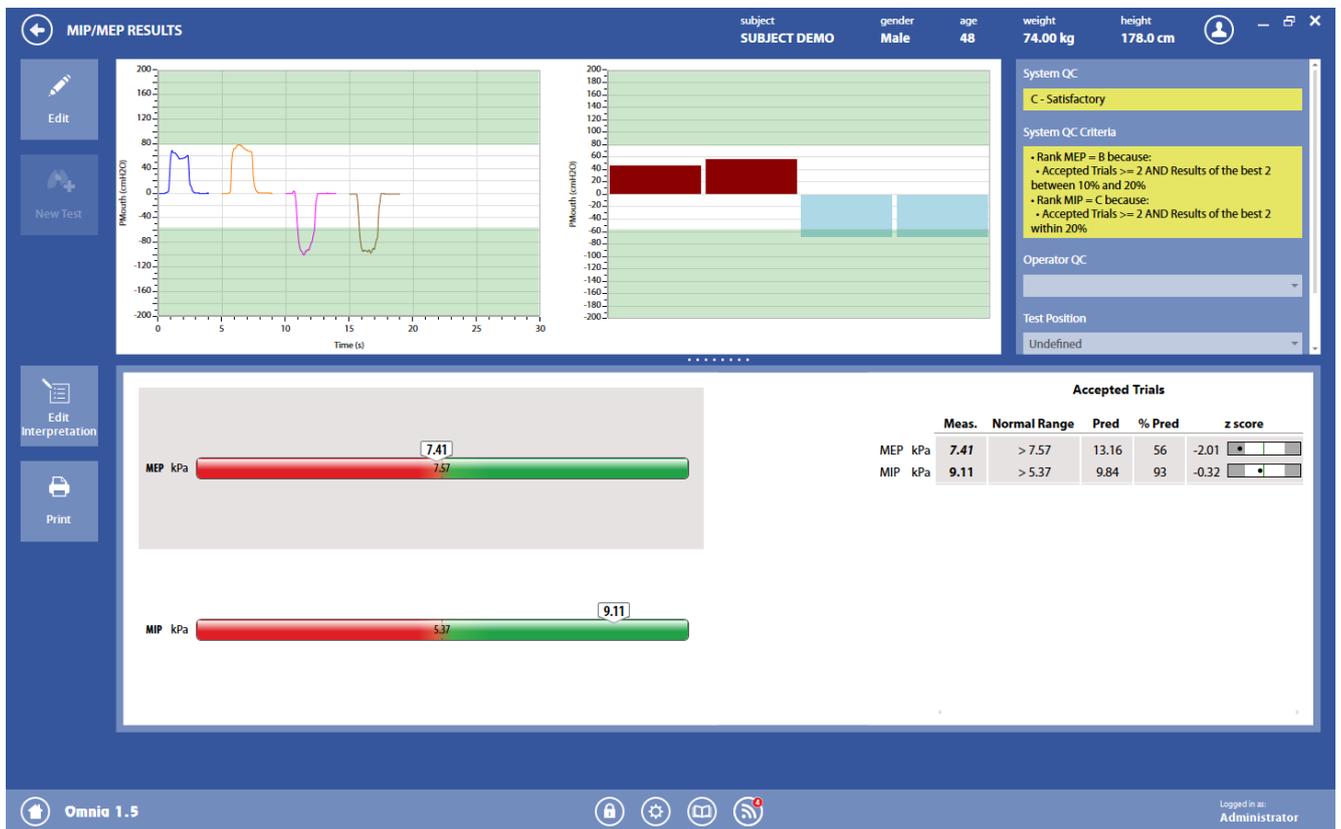


■ Test results



To view a test, press in the subject database the  on the left of the test and then the **View** button or double click on the test. In this panel, data and graphs are not editable by the user.

Test results are accessed also by pressing *Save* in the *Edit* panel.



The panel is divided into three sections

The *graphs* section show the graph for all the selected trials. If the number of maneuvers exceed the available space, it is possible to scroll the graph in order to visualize all the other ones.

The *QC and notes* section is the same as described above in *Test editing*.

The *results* section is divided into two parts:

- The left side shows a graphical interpretation of the results. Two bars are shown, one for MIP and the other one for MEP. Near these parameters, a colored bar with an indicator representing the current status of the subject. The bars also report the normal range.
- The right side, the mean value for each parameter is shown, together with the normal range, the predicted value, the % of the value with respect of the predicted and the Z-Score (if enabled in the *Predicted settings*).



The buttons in the left part of the panel allows the user to:

- Edit the test (**Edit**): the panel shown under *Test editing* is displayed
- Start a new test (**New Test**). The **New Test** is enabled if the test is performed on the current day.
- Edit the interpretation (**Edit Interpretation**): the panel *Interpretation* of the visit card is displayed
- Print a report (**Print**).

□ The P0.1 (Respiratory drive) test

The P0.1 or Respiratory Drive test evaluates the reduction of pressure which is caused by the patient's inhalation.

The subject must breathe into a mouthpiece which contains a shutter and a pressure detector. The shutter becomes occluded for 100 msec at the beginning of the patient's inhalation, while the patient continues to breathe normally. Discontinuing the airflow to the patient allows the reduction of pressure to be measured.

The parameters measured during P0.1 testing include (units of measurements can be changed in the settings):

<i>Symbol</i>	<i>UM</i>	<i>Parameter</i>
P0.1	cmH ₂ O	Respiratory Drive
FiCO ₂	%	Inspiratory CO ₂
FiO ₂	%	Inspiratory O ₂
RF	1/min	Respiratory Frequency
Vt	l	Tidal Volume

■ Perform a P0.1 test



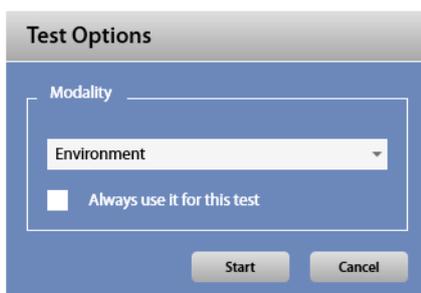
1. Press the **Testing** tile in the home panel, or start a new test from the subject database, then **Respiratory Mechanics** and **P0.1**.
2. If no subject was selected (in the top part of the panel there is no subject information), when pressing the Testing tile in the home panel the software will open the Subject database. If no visit card is present for the current day for the selected subject, the **New visit** panel is opened before starting the test.
3. A panel will open with different views depending on the P0.1 settings.
4. Explain the maneuver to the subject prior to testing.



5. When the subject and the software are ready press **Start** to perform the trial.

Note: Each test contains a single trial only.

6. If requested, select the device and the flowmeter to be used for performing the test. Check *Always use it for this test* if you want to use the selected choice every time this test is started.



7. Select the modality for the test (see *Settings* for further details). Check *Always use it for this test* if you want to use the selected choice every time this test is started.
8. Close the O₂ cylinder before proceeding (if used).
9. Wait until that the red dot in the lower right part of the screen becomes green.
10. Breathe into the flowmeter. The left graph shows the P0.1 measurements and the tidal volume vs. time. The right graph shows:

- For Environment or CO2 modality: P0.1 vs. FiCO₂ (or vs. PetCO₂ if available).
- For O2 modality: P0.1 vs. FiO₂ (or vs. PetO₂ if available).

Note: PetO₂ and PetCO₂ are measured only when gas analyzers are available.



For performing a P0.1 measurement, press *Shutter*. The button is enabled only after some stable tidal breaths. A single test can contain more than one measurement.

The lower part of the screen shows all the breaths, highlighting the ones corresponding to the P0.1 measurements.



11. Only for O₂ or CO₂ modality: if a different O₂ or CO₂ inspiratory concentrations are used, it is possible to enter their values by clicking on the **FI** button.

In Environment modality, FiO₂ and FiCO₂ are set by defaults to 20.93% and 0.038%.

Note: It is not possible to breathe gas mixture directly from the breathing valve connected to the Quark.



12. When the maneuver is completed press **Stop**. The software will display the *Test edit* panel (see below).

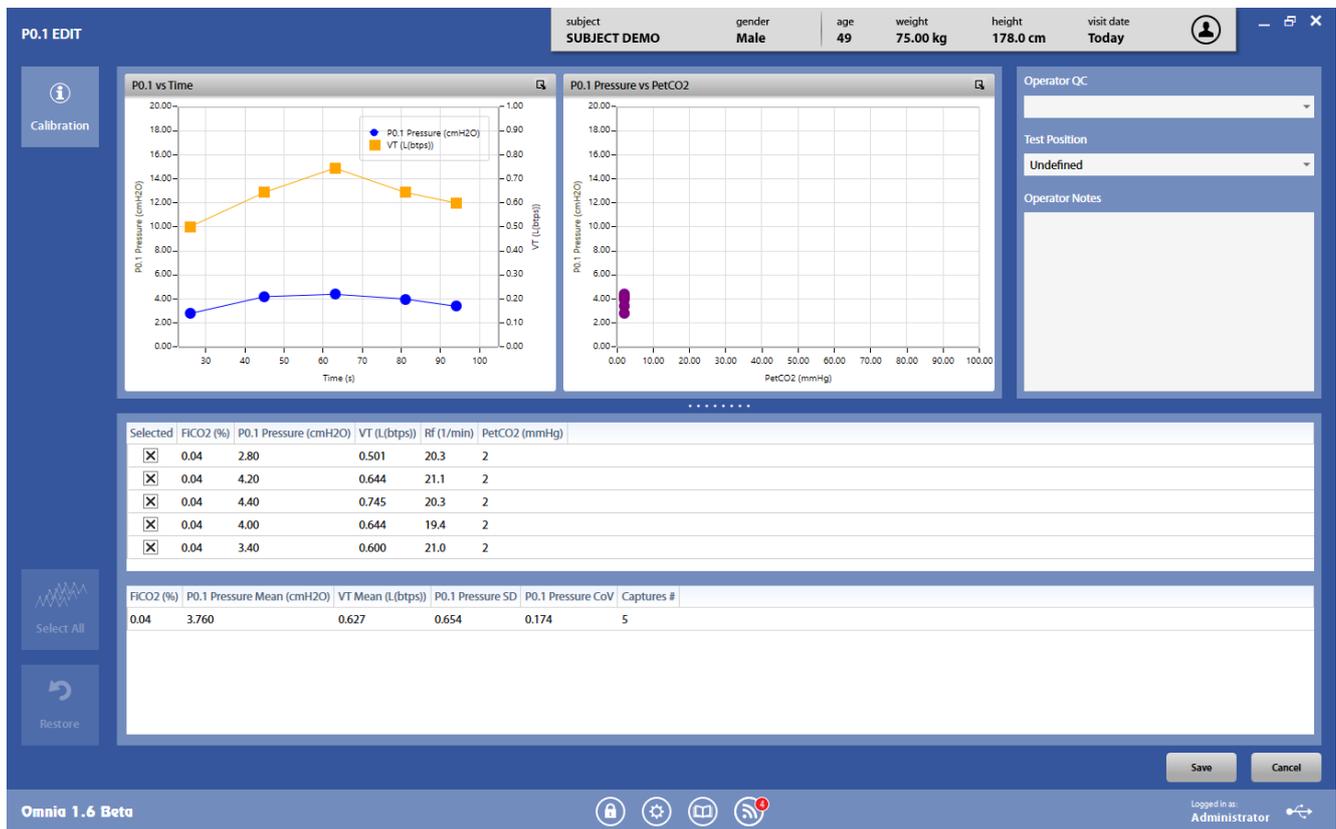


To abort the trial, press **Abort**. To restart the trial, press **Redo**. Both these commands discard the current trial and don't save any data (it is not stored in the archive).

■ Test editing



The test editing panel shows the parameters measured in the trials performed during the tests and can be accessed through the **Edit** button appearing when the  near the selected test is pressed or at the end of each trial.



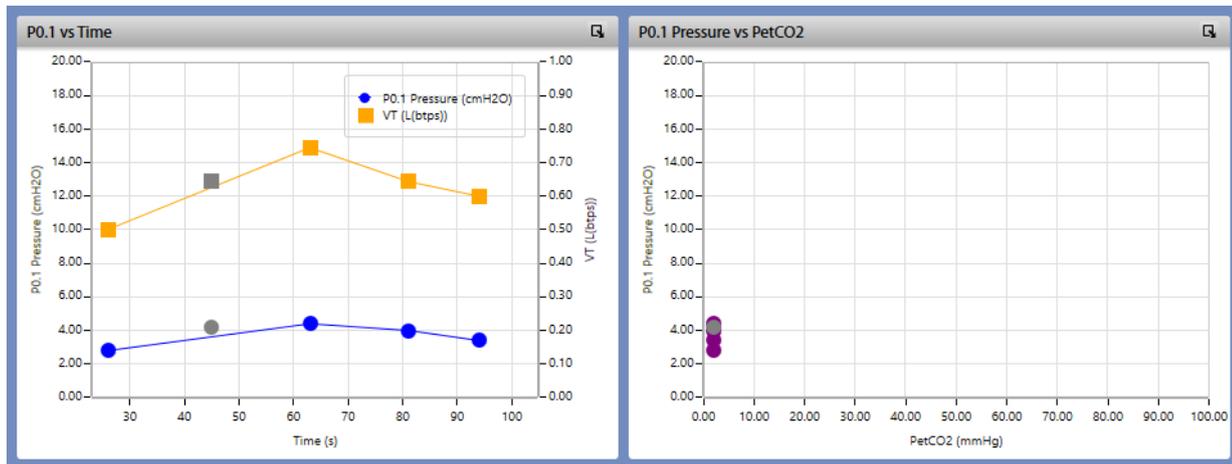
The panel is divided into three sections: graphs, QC and notes, and results.



The **Calibration** button shows the calibration data for the current test.

The **Save** button allows the user to exit the edit panel and saves the results. By pressing **Save**, the **Test results** panel will be displayed (see below).

Graphs



In this section of the panel P0.1 graphs of all the accepted measurements are shown.

Not accepted measurements are shown in grey.

QC and notes

Operator QC
C - Satisfactory

Test Position
Standing

Operator Notes

In this section it is displayed:

- A quality control entered by the technician
- The position of the subject during the test
- Notes entered by the technician

The quality control is graded in 6 levels: A - excellent, B - good, C - satisfactory, D - barely passing, E, F - failing, plus an "Invalid" level (the last one for technician quality control only).

If test is classified as "invalid" by the operator, a watermark "Invalid test" is also placed on the corresponding printout.

Results

Selected	FiCO ₂ (%)	P0.1 Pressure (cmH ₂ O)	VT (L(btps))	Rf (1/min)	PetCO ₂ (mmHg)	
<input checked="" type="checkbox"/>	0.04	2.80	0.501	20.3	2	
<input checked="" type="checkbox"/>	0.04	4.20	0.644	21.1	2	
<input checked="" type="checkbox"/>	0.04	4.40	0.745	20.3	2	
<input checked="" type="checkbox"/>	0.04	4.00	0.644	19.4	2	
<input checked="" type="checkbox"/>	0.04	3.40	0.600	21.0	2	

FiCO ₂ (%)	P0.1 Pressure Mean (cmH ₂ O)	VT Mean (L(btps))	P0.1 Pressure SD	P0.1 Pressure CoV	Captures #
0.04	3.760	0.627	0.654	0.174	5

The results section is divided into two parts:

- The upper section shows all the measurements.
- The lower section shows the results for each FiCO₂ or FiO₂ (depending on the modality). Results are mean or median values depending on the P0.1 settings. It is also shown the standard deviation and the coefficient of variation for P0.1 and the number of capture for each FiCO₂ or FiO₂ value.



Near these items, on the left, two buttons allow the user to:

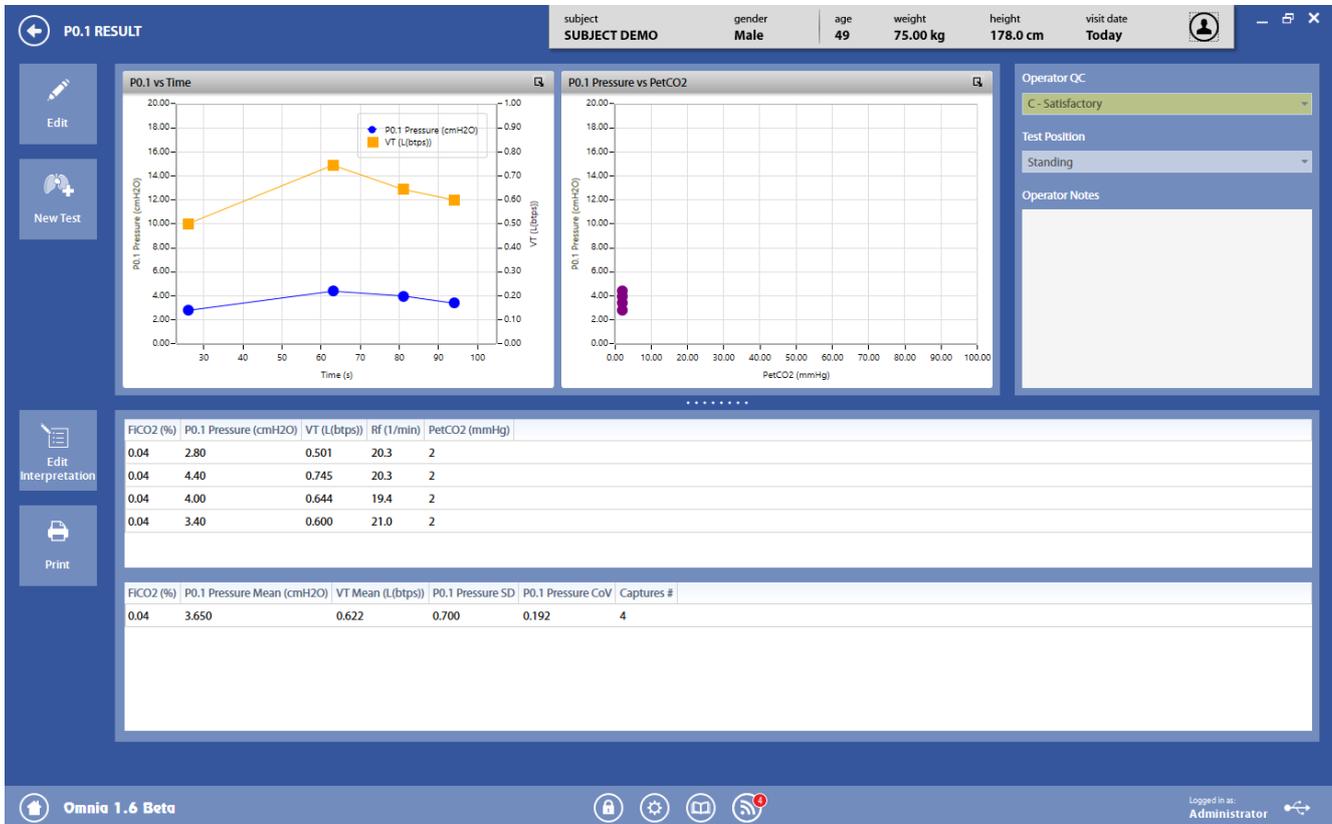
- Select all measurements (**Select all**) - all measurements are selected by default.
- Restore the last save (**Restore**).

Test results



To view a test, press in the subject database the **...** on the left of the test and then the **View** button or double click on the test. In this panel, data and graphs are not editable by the user.

Test results are accessed also by pressing **Save** in the **Edit** panel.



The panel is divided into three sections

The *graphs* section show the graph for all the selected measurements.

The *QC and notes* and *Results* sections are the same as described above in *Test editing*.



The buttons in the left part of the panel allows the user to:

- Edit the test (**Edit**): the panel shown under *Test editing* is displayed
- Start a new test (**New Test**). The **New Test** is enabled if the test is performed on the current day.
- Edit the interpretation (**Edit Interpretation**): the panel *Interpretation* of the visit card is displayed
- Print a report (**Print**).

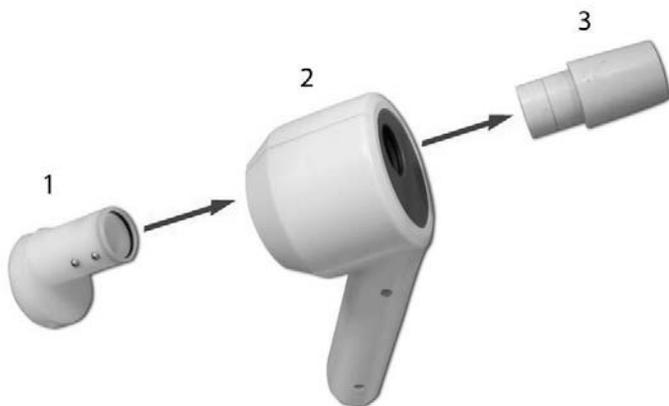
Airways resistance measurement

PFT

Q-Box

□ General warnings

1. This test must be performed with the R_{0CC} module connected to the SpO₂/R_{0CC} port on the rear panel of Quark.
2. The R_{0CC} should be assembled as shown in the following picture.



- | |
|--------------------|
| 1. Occlusion valve |
| 2. Reader |
| 3. PNT |

3. The device must be enabled in the Device Manager, it must be properly connected to the PC with the appropriate communication port selected and it must be enabled to perform this type of test.
4. The name shown in the top part of the panel must correspond to the subject performing the test (if a subject has not been selected, the Subject database will be opened when a test is selected).
5. If a visit card does not exist for the current testing date, the New visit panel will be displayed in order to enter the visit data.
6. The mouthpiece should be connected to the flowmeter and the antibacterial filter properly.

Note: Cellular phones should be turned off to eliminate potential electrical interferences.

■ Patient preparation

Prior to testing, the R_{0CC} should be calibrated as described in the chapter Calibration.

Ask the patient to apply the nose clips.

The use of antibacterial filters is strongly recommended.



□ The Airways Resistance measurement test

Traditional methods of measuring airways resistance are based on body plethysmography which requires a great degree of patient cooperation along with extensive testing equipment and skilled clinical technicians.

Many patients are unable to perform plethysmography testing due to the testing conditions involved. Patient populations which may benefit from measuring airway resistance using alternative methods include critically ill patients, acute Asthmatics, geriatrics, unconscious patients, neonates and pre-school children. Instruments based on the interrupter technique provide reliable resistance measurements and are very well tolerated by all patient populations.

The interrupter technique implements a transient airflow interruption and measures the pressure at the mouth immediately after the interruption occurs. Since the pressure at the mouth is proportional to the patient's alveolar pressure, airway resistance can be identified as the ratio between the mouth pressure and the value of flow before the interruption.

The Appendix reports bibliographic references, which demonstrate a high reproducibility and correlation between values measured via the interruption technique and those measured by body plethysmography.

The parameters measured during airway resistance testing include (units of measurements can be changed in the settings):

<i>Symbol</i>	<i>UM</i>	<i>Parameter</i>
R_{occ_ex}	kPa/(l/s)	Expiratory resistance
G_{occ_ex}	(l/s)/kPa	Expiratory conductance
R_{occ_in}	kPa/(l/s)	Inspiratory resistance
G_{occ_in}	(l/s)/kPa	Inspiratory conductance
Foccl	ml/s	Flow at the occlusion time
Palv	kPa	Alveolar pressure at occlusion time

■ Perform a R_{occ} test



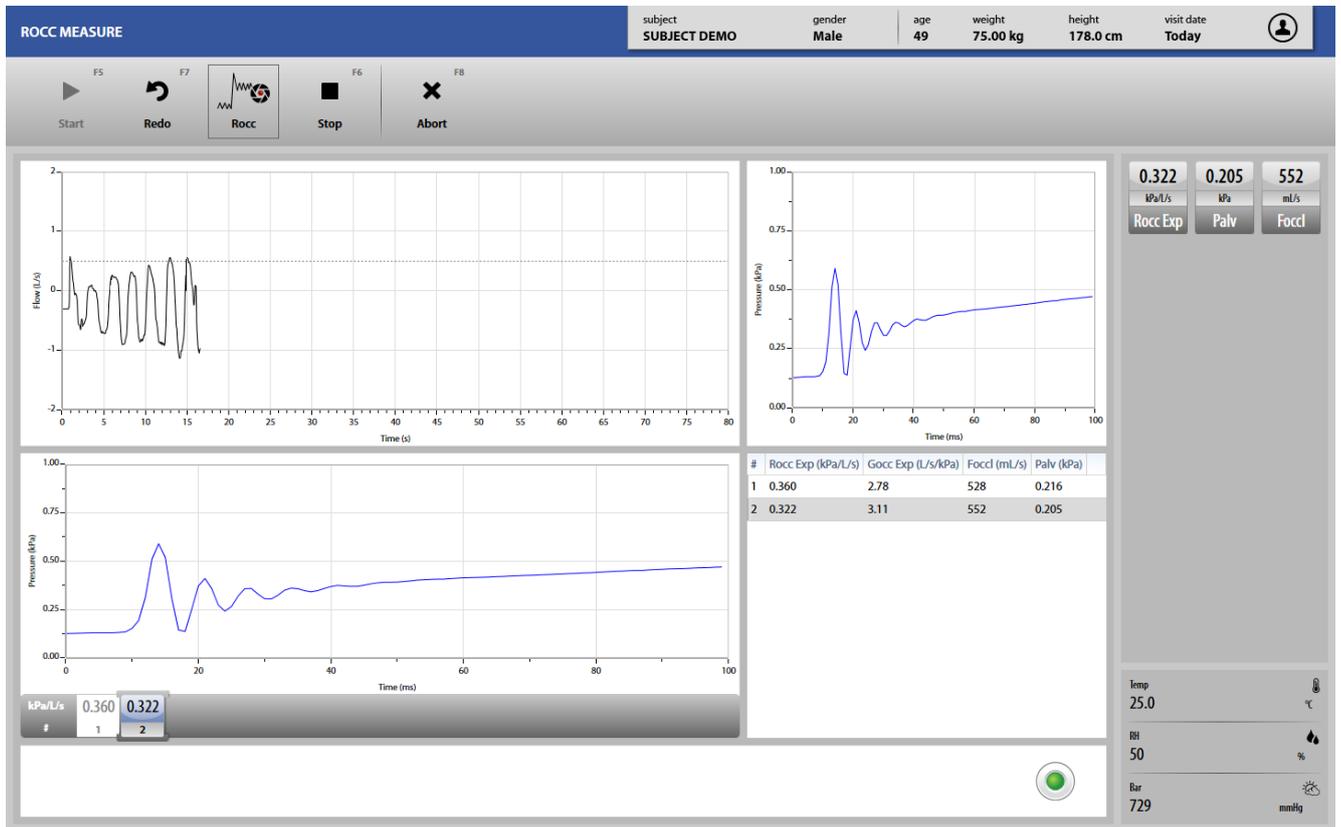
1. Press the **Testing** tile in the home panel, or start a new test from the subject database, then **Respiratory Mechanics** and **Occlusion Resistance**.
2. If no subject was selected (in the top part of the panel there is no subject information), when pressing the Testing tile in the home panel the software will open the Subject database. If no visit card is present for the current day for the selected subject, the **New visit** panel is opened before starting the test.
3. A panel will open with the F/t and P/t graphs.
4. Explain the maneuver to the subject prior to testing.



5. When the subject and the software are ready press **Start** to perform the trial.

Note: do not breathe inside the Rocc flowmeter until the red dot becomes green in order to allow the PNT zeroing.

6. If requested, select the device and the flowmeter to be used for performing the test. Check *Always use it for this test* if you want to use the selected choice every time this test is started.
7. Wait until that the red dot in the lower right part of the screen becomes green.



8. Breathe into the flowmeter. The screen is divided in four parts:

- the upper left graph shows flow vs. time
- the lower left panel contains the archive of all the captures. It shows the pressure vs. time graph for the selected capture, that can be changed both during the trial and at the end of the trial.
- the upper right graph shows the pressure vs. time for the last capture
- the lower right graph shows the measured values for each capture.



Captures can be performed random or manually (according to the settings). In the last option, press ROCC to perform a capture. The button is enabled only after some stable tidal breaths. A single trial can contain more than one capture.



9. When the maneuver is completed press **Stop**. The software will display the *Trial edit* panel (see below).



To abort the trial, press **Abort**. To restart the trial, press **Redo**. Both these commands discard the current trial and don't save any data (it is not stored in the archive).

□ *The Airways Resistance measurement test post BD*

The R_{OCC} POST test is a R_{OCC} test after bronchodilator administration, comparing results before and after the administration. Bronchodilators are administered during lung function studies to determine if the subject's airflow obstruction is reversible. Bronchodilators can increase airway size by relaxing the smooth muscle.

■ *Test execution*



1. Press the **Testing** tile in the home panel, or start a new test from the subject database, then **Respiratory Mechanics** and **Occlusion Resistance post BD**.
2. If no subject was selected (in the top part of the panel there is no subject information), when pressing the Testing tile in the home panel the software will open the *Subject database*. If no visit card is present for the current day for the selected subject, the *New visit* panel is opened before starting the test.
3. Start and perform the test as indicated in the previous section.

□ Viewing and editing test results

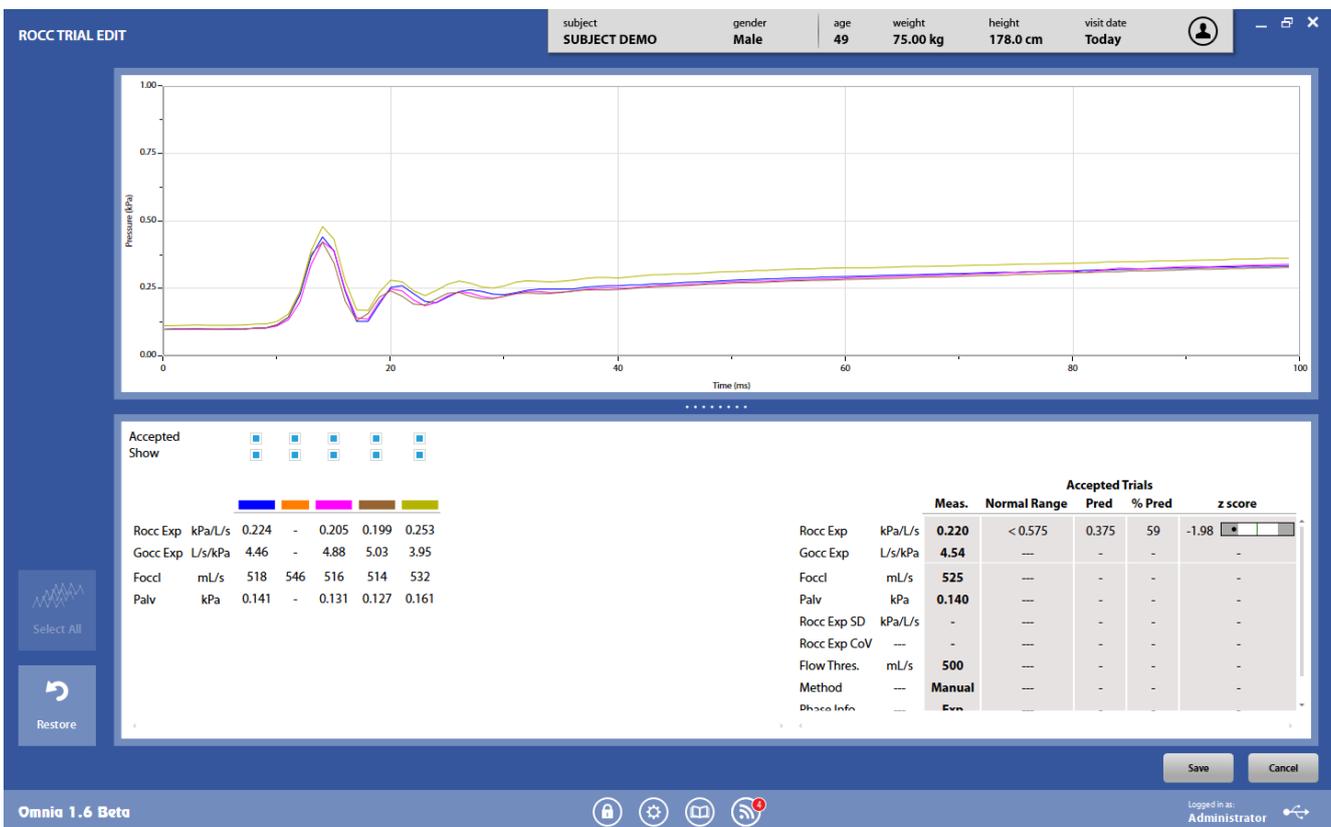
For Rocc tests, the software allows for two editing levels: trial edit and test edit.

The *Trial edit* panel is shown at the end of each test, and is accessible from the *Test edit* panel when the  near the selected trial is pressed. It shows the parameters measured in the captures performed during the selected trial and it allows the user to select the captures to be used for the results of the selected trial.

The *Test edit* panel shows the parameters measured in the trials performed during the test and it allows the user to select the trials to be used for the final results. It can also be accessed through the Edit button appearing when the  near the selected test is pressed.

■ Trial editing

The *Trial edit* panel is shown at the end of each trial. It shows the parameters measured in the captures performed during the trial and allows the user to select the captures to be used for the results of the trial. It can be also accessed from the test edit panel when the  near the selected trial is pressed.



ROCC TRIAL EDIT

subject: SUBJECT DEMO | gender: Male | age: 49 | weight: 75.00 kg | height: 178.0 cm | visit date: Today

Accepted

Show

		Accepted Trials				
		Meas.	Normal Range	Pred	% Pred	z score
Rocc Exp	kPa/L/s	0.224	< 0.575	0.375	59	-1.98
Gocc Exp	L/s/kPa	4.46	---	-	-	-
Foccl	mL/s	518	---	-	-	-
Palv	kPa	0.141	---	-	-	-
Rocc Exp SD	kPa/L/s	-	---	-	-	-
Rocc Exp CoV	---	---	---	-	-	-
Flow Thres.	mL/s	500	---	-	-	-
Method	---	Manual	---	-	-	-
Phase Info	---	---	---	-	-	-

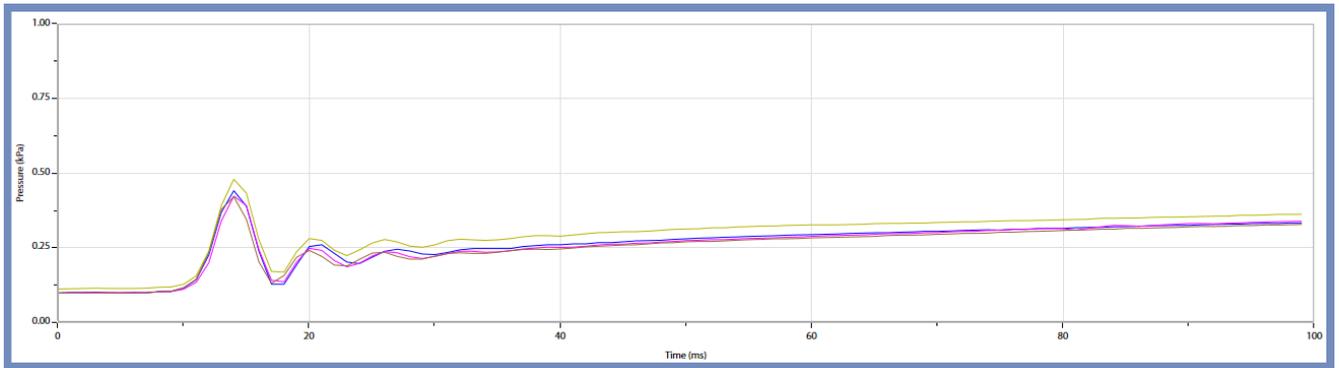
Omnia 1.6 Beta | Logged in as: Administrator

The panel is divided into two sections: graphs and results.



The **Save** button allows the user to exit the panel and saves the results. By pressing **Save**, the *Test edit* panel will be displayed (see below).

Graphs



In this section of the panel Pressure vs. time graphs of all the selected captures are shown.

Results

		Accepted Trials				
		Meas.	Normal Range	Pred	% Pred	z score
Accepted	<input type="checkbox"/>					
Show	<input type="checkbox"/>					
Rocc Exp	kPa/L/s	<i>0.516</i>	0.530	0.516	0.365	0.543
Gocc Exp	L/s/kPa	<i>1.94</i>	1.89	1.94	2.74	1.84
Foccl	mL/s	<i>520</i>	535	502	566	549
Palv	kPa	<i>0.294</i>	0.310	0.284	0.234	0.325
Rocc Exp	kPa/L/s	0.494	< 0.575	0.375	132	1.22 <input type="checkbox"/>
Gocc Exp	L/s/kPa	2.02	---	-	-	-
Foccl	mL/s	534	---	-	-	-
Palv	kPa	0.289	---	-	-	-
Rocc Exp SD	kPa/L/s	0.073	---	-	-	-
Rocc Exp CoV	---	0.148	---	-	-	-
Flow Thres.	mL/s	500	---	-	-	-
Method	---	Manual	---	-	-	-
Phase Info	---	Exp	---	-	-	-
Filter Res.	kPa/L/s	0.049	---	-	-	-

The results section is divided into two parts:

- The left side shows all the measured parameters for all the performed captures
- The right side shows the mean or median value (according to the settings) for each parameter is shown, together with the normal range, the predicted value, the % of the value with respect of the predicted and the Z-Score. Measured values are displayed in italics if they are out of the normal range.

A scroll bar allows the user to scroll the parameters in order to view all of them.

The Z-Score is how many SD's (standard deviation) the measured value is above or below the predicted value (displayed only if enabled in the *Predicted settings*).

In the left side, for each capture, above the measured parameters, it appears, in order from the top to the bottom:

- If the capture is accepted (accepted captures are used for the calculations of mean or median values). By default the software accepts all the captures. The user can discard some of them, but these captures won't be deleted from the archive also when the user saves and exits from this panel.¹ At least 1 capture must be accepted.
- If the capture is shown in the above graph.

¹ The color of the check boxes can be white () if selectable, blue () if de-selectable or grey () if not editable.



Near these items, on the left, two buttons allow the user to:

- Accept all the captures (**Select All**)
- Restore the last save (**Restore**).

Test editing



The test editing panel shows the parameters measured in the trials performed during the tests and can be accessed through the **Edit** button appearing when the **...** near the selected test is pressed or at the end of each trial.

The panel is divided into three sections: graphs, QC and notes, and results.

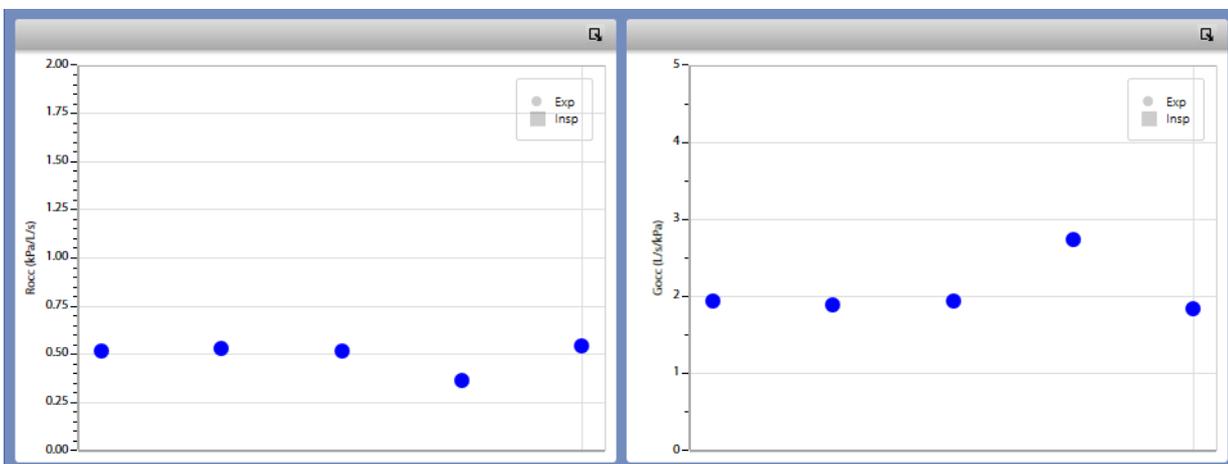


The button in the upper-left part of the panel allows the user to start a new trial (**New**).

The **Calibration** button shows the calibration data for the current test.

The **Save** button allows the user to exit the edit panel and saves the results. By pressing **Save**, the **Test results** panel will be displayed (see below).

Graphs



In this section of the panel R_{occ} and G_{occ} graphs of all the accepted trials are shown.

QC and notes

System QC

A - Excellent

System QC Criteria

• Exp = A because:
 - Accepted captures >= 5
 - AND CoV <= 0.15

Operator QC

Test Position

Operator Notes

In this section it is displayed:

- An automatic quality control by the PC about the trials reproducibility (not editable by the user), and the corresponding criteria
- A quality control entered by the technician
- The position of the subject during the test
- Notes entered by the technician

The quality control is graded in 6 levels: A - excellent, B - good, C - satisfactory, D - barely passing, E, F - failing, plus an “Invalid” level (the last one for technician quality control only).

If test is classified as “invalid” by the operator, a watermark “Invalid test” is also placed on the corresponding printout.

Results

Accepted
☰

			Accepted Trials					
			Meas.	Normal Range	Pred	% Pred	z score	
Rocc Exp	kPa/L/s	0.494	<i>0.494</i>	< 0.575	0.375	132	1.22	<input type="checkbox"/>
Gocc Exp	L/s/kPa	2.02	<i>2.02</i>	---	-	-	-	<input type="checkbox"/>
Foccl	mL/s	534						
Palv	kPa	0.289						
Rocc Exp SD	kPa/L/s	0.073	<i>0.073</i>	---	-	-	-	<input type="checkbox"/>
Rocc Exp CoV	---	0.148	<i>0.148</i>	---	-	-	-	<input type="checkbox"/>
Flow Thres.	mL/s	500						
Method	---	Manual						
Phase Info	---	Exp						

The results section is divided into two parts:

- The left side shows all the measured parameters for all the performed trials. Besides the parameters, standard deviation (SD) and coefficient of variation (CoV) are reported for each trial, as well as test settings (method, phase and threshold trigger).
- The right side, the mean or median value (according to the settings) for each parameter is shown, together with the normal range, the predicted value, the % of the value with respect of the predicted and the Z-Score. Measured values are displayed in italics if they are out of the normal range.

A scroll bar allows the user to scroll the parameters in order to view all of them.

The Z-Score is how many SD’s (standard deviation) the measured value is above or below the predicted value (displayed only if enabled in the *Predicted settings*).

In the left side, for each trial, above the measured parameters, it appears, in order from the top to the bottom:

- If the trial is accepted. By default the software accepts all the trials. The user can discard some of them, but these trials won’t be deleted from the archive also when the user saves and exits from this panel.¹ At least 1 trial must be accepted.
- An Edit button represented by the ☰ icon. – See *Trial editing*

¹ The color of the check boxes can be white (☐) if selectable, blue (■) if de-selectable or grey (◻) if not editable.



Near these items, on the left, two buttons allow the user to:

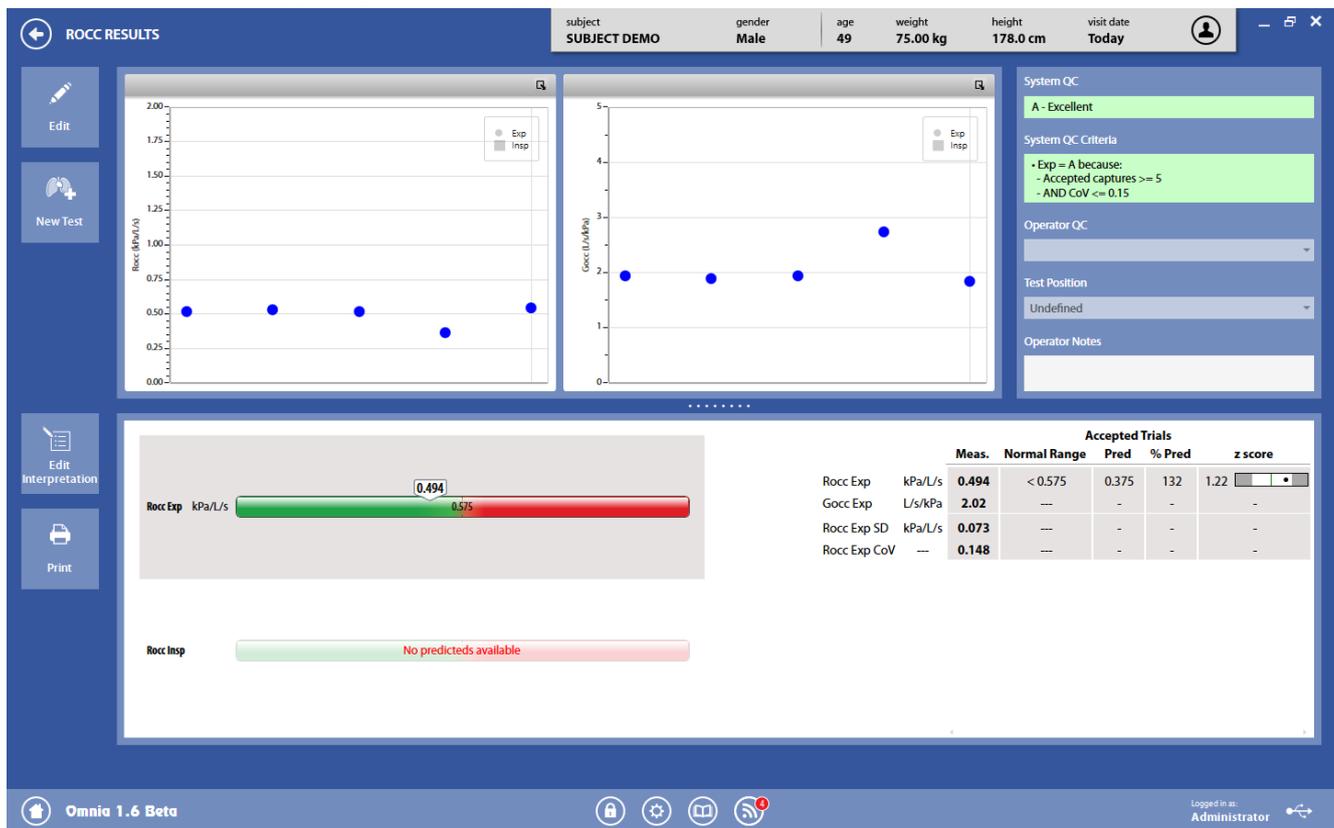
- Accept all the trials (**Select All**)
- Restore the last save (**Restore**).

Test results



To view a test, press in the subject database the on the left of the test and then the **View** button or double click on the test. In this panel, data and graphs are not editable by the user.

Test results are accessed also by pressing **Save** in the *Edit* panel.



The panel is divided into three sections

The *graphs* and *QC and notes* sections are the same as described above in *Test editing*.

The *results* section is divided into two parts:

- The left side shows a graphical interpretation of the results. Two colored bars are shown, for expiratory R_{OCC} and inspiratory R_{OCC} (one or both bars are shown depending on available data). The bars have an indicator representing the current status of the subject and also report the normal range.
- The right side, the mean or median value (according to the settings) for each parameter is shown, together with the normal range, the predicted value, the % of the value with respect of the predicted and the Z-Score (if enabled in the *Predicted settings*).

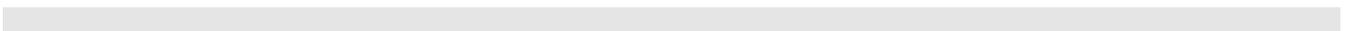


The buttons in the left part of the panel allows the user to:

- Edit the test (**Edit**): the panel shown under *Test editing* is displayed
- Start a new test (**New Test**). The **New Test** is enabled if the test is performed on the current day.

-
- Edit the interpretation (**Edit Interpretation**): the panel *Interpretation* of the visit card is displayed
 - Print a report (**Print**).

Body Plethysmography **Q-Box**



□ **General warnings**

Note: Please note the contraindications listed in the first chapter of the User manual of the Q-Box prior to testing.

1. The device must be enabled in the Device Manager, it must be properly connected to the PC with the appropriate communication port selected and it must be enabled to perform this kind of test.
2. The name shown in the top part of the panel must correspond to the subject performing the test (if a subject has not been selected, the Subject database will be opened when a test is selected).
3. If a visit card doesn't exist for the current testing date, the New visit panel will be displayed in order to enter the visit data.
4. The test must be performed with the included PNT X9 with the sampling line connected.
5. The Q-Box must be properly connected to the PC and the Quark PFT with the appropriate communication port selected.
6. The Cal. (5% CO₂, 16% O₂, Bal. N₂) cylinder must be opened and contain a pressure between 5 and 6 bars.
7. The use of an antibacterial filter is mandatory.
8. Do not touch the Body Box, the pneumatic tubes and the cart during the test.
9. Avoid air displacements in the room where the test will be performed (e.g. a slamming door, an opening window, etc.), since the pressure transducers are very sensitive.
10. When ending a test, please wait for adequate air change inside the Body Box before starting another one.

Note: Cellular phones should be turned off prior to testing to eliminate potential interferences.

■ **Preparation for a test**

Calibrate the PNT and the Body Box (leakage and polytropic factor) as indicated in the chapter Calibration.

Connect the PNT and the breathing valve inside the Q-Box unit.

Patient preparation

The equipment is adjusted so that the patient can sit comfortably in the chamber and reach the mouthpiece without having to flex or extend the neck.

The patient must be seated comfortably, there is no need to remove dentures. The procedure is explained in detail, including that the door will be closed, the patient's cheeks are to be supported by both hands (TGV only), and a nose clip is to be used.

Let the patient enter into the Body Box, paying attention to avoid bumping the head while entering (if necessary, he/she can use the proper handle).

The patient is instructed to insert the mouthpiece in their mouth and breathe quietly until a stable end-expiratory level is achieved (usually 3–10 tidal breaths).



Note: Control of shutter closure includes a program to reopen it after 3 seconds (TGV only), to minimize patient discomfort and avoid the subject experiencing fear when (s)he is trying to breathe when the shutter is closed. Patients

should always be informed to remove the mouthpiece from their mouth in the event the shutter does not open or if the subject senses substantial difficulty breathing.

Instruct the patient to apply the nose clips.

Close the door.

The plethysmograph door is closed, and time is allowed for the thermal transients to stabilize and the patient to relax (normally 2-minutes).

□ Test execution - overview

This test measures the TGV (thoracic gas volume) and the Raw (airway resistance).

In particular, the plethysmograph relates pressure variations inside the Body Box with volume variations of the air within the lungs, by means of the Boyle's law. It states that, under isothermal conditions, the product of volume and pressure of a gas is constant.

During a panting maneuver (respiratory frequency about 60 breaths per minute), the apnea valve is closed and patient is asked to perform short and rapid breaths. While the patient try to breathe, he/she expands the gas within the lungs and causes the pulmonary volume to increase. Consequently, the body box pressure increases, since its volume decreases. When the patient exhales, the opposite occurs.

In healthy individuals, there is a little difference between the FRC measured with nitrogen wash-out technique (or other dilution techniques) and the TGV measured by means of a Body Box. This is not true for patients with particular pulmonary pathologies: for these patients the TGV is often much higher than the FRC.

Parameters measured during the tests include the following (some units of measurements can be changed in the settings):

<i>Symbol</i>	<i>UM</i>	<i>Parameter</i>
sRaw	cmH ₂ O*s	Specific Airway Resistance
Raw	cmH ₂ O/l/s	Airway Resistance
sGAW	1/(cmH ₂ O*s)	Specific Airway Conductance
GAW	l/s/cmH ₂ O	Airway Conductance
FRC (Pleth)	l	Thoracic Gas Volume
ERV	l	Expiratory Reserve Volume
IRV	l	Inspiratory Reserve Volume
IC	l	Inspiratory Capacity
VC	l	Vital Capacity
TLC (pleth.)	l	Total Lung Capacity
RV (pleth.)	l	Residual Volume
RV/TLC (pleth.)	%	Motley Index
TGV (pleth.)/TLC (pleth.)	%	TGV/TLC ratio
Raw Tot	cmH ₂ O*s/l	Total Airway Resistance
Raw ins	cmH ₂ O*s/l	Inspiratory Airway Resistance
Raw exp	cmH ₂ O*s/l	Expiratory Airway Resistance
sRaw eff	cmH ₂ O*s	Effective Specific Airway Resistance

■ Performing a test

The software allows three test types:

1. TGV/Raw pre
2. TGV/Raw post Bronchodilator
3. A simulated TGV (for verification only)

□ TGV/Raw (pre)

Test includes three different manoeuvres:

1. sRaw (specific Airways Resistance)
2. TGV (Thoracic Gas Volume)
3. SVC (Slow Vital Capacity)

The order of the manoeuvres is not necessarily the one mentioned above. The only constraint is that the SVC must be performed immediately after a TGV.

Note: The maximum test duration is 5 minutes. After that time, the test automatically ends and the measured values are saved. The thermal equilibrium (as defined in the Body Box settings) is not included in these 5 minutes.

Preliminary operations



1. Press the **Testing** tile in the home panel, or start a new test from the subject database, then **Body Plethysmography** and **TGV/RAW PRE**.
2. If no subject was selected (in the top part of the panel there is no subject information), when pressing the **Testing** tile in the home panel the software will open the *Subject database*. If no visit card is present for the current day for the selected subject, the New visit panel is opened before starting the test.
3. A panel will open with some graphs.

Graphs and data shown in this panel are explained here below:

- On the top left, a V/T graph showing 30 seconds of subject's breaths. After 30 seconds, the graph is cleared and it starts graphing from beginning.
 - On the top center, the Flow/Pbox graph, showing the subject's current loop and his/her last one. The shown loops are not stored. These loops are not shown during the SVC or IC tests.
 - On the top right, three vertical bars (and the correspondent values) for respiratory frequency, tidal volume and box pressure, updated in real time, useful for monitoring these values.
 - On the bottom left, the last captured sRaw and the values of all the captured sRaws. It is possible to view another sRaw by selecting the corresponding value on the list below the graph.
 - On the bottom center, the last captured TGV and the values of all the captured TGVs. It is possible to view another TGV by selecting the corresponding value on the list below the graph.
 - On the bottom right, the last SVC/IC and the values of all the performed SVC/IC. It is possible to view another SVC/IC manoeuvre by selecting the corresponding value on the list below the graph.
 - On the very bottom of the screen, a status bar that can show informative messages during the test.
4. Explain the maneuver to the subject prior to testing.

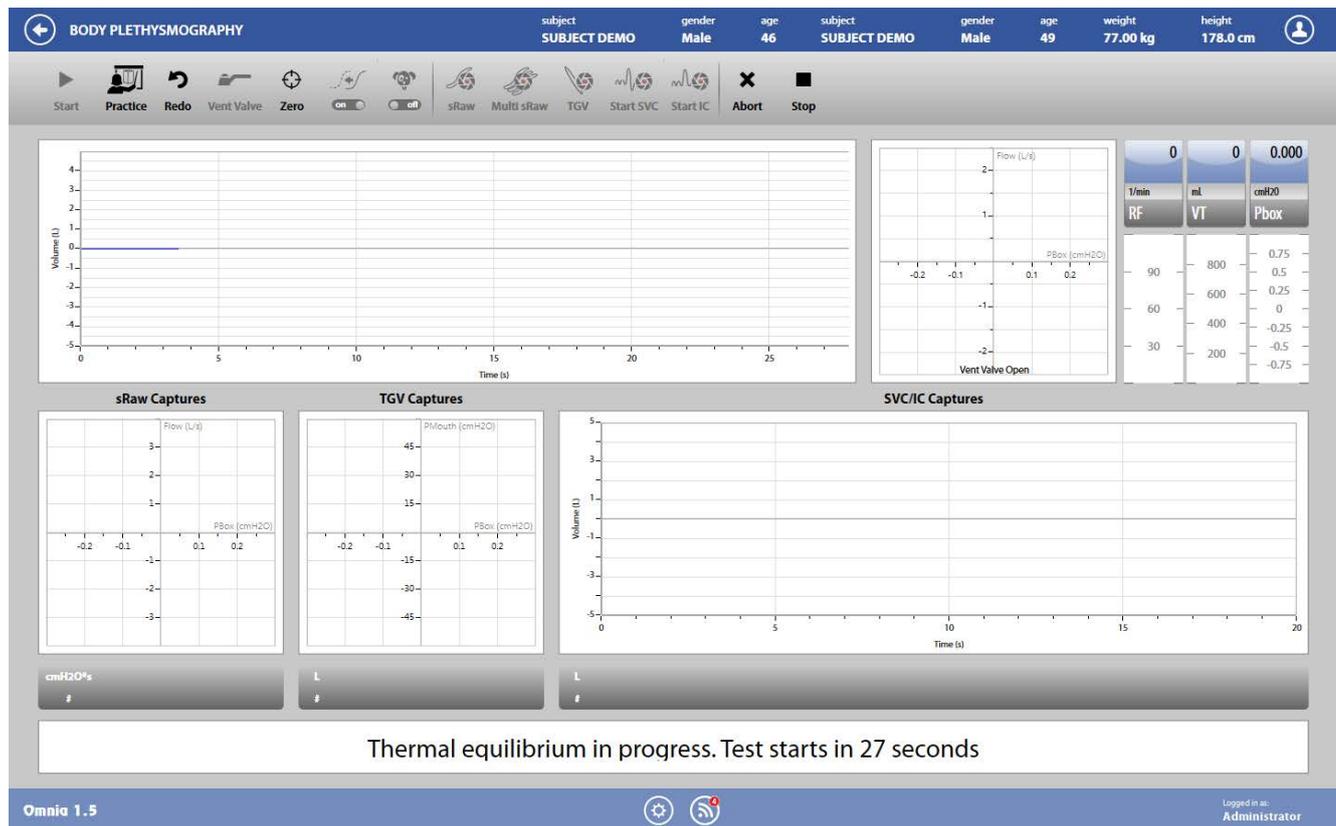


If desired, the **Practice** button allows to demonstrate the Body Plethysmography test with the Q-Box door open, also acting on the breathing valve to demonstrate the TGV capture.



5. When the subject and the software are ready press **Start** to perform the trial.
6. If more than one device was enabled in the device manager, a window will appear asking the user to select which device will perform the test. Check *Always use it for this test* if you want to use the selected device every time this test is started.

Thermal equilibrium phase



This is the first phase of each test, and it is automatically performed before any subsequent maneuver (sRaw, TGV or SVC/IC)

1. Wait until the end of the thermal equilibrium phase (the duration of this phase is defined in *the Body Box settings*). In this first phase, the operator is waiting for the thermal equilibrium between the inside and the outside of the Body Box. In the meanwhile the patient will begin to relax inside the box, and he/she can breathe within the PNT, in order to familiarize themselves with the device and the technique. During this phase, all the buttons are disabled, and the vent valve between the inside and the outside of the Body Box is open, to allow reaching the equilibrium. In this phase, the Body Box pressure column oscillates around the zero. Under the volume/time graph a countdown is shown.

Note:  The PNT can always be re-zeroed by pressing the ZERO button. Ensure that the patient is disconnected from the breathing valve.



2. When the phase is over, the vent valve closes and the pressure (monitored in the right column) oscillates following the patient's breaths. If the value drifts towards higher or lower values, the thermal equilibrium was not reached, and it is necessary to open the vent valve, by pressing the icon VENT VALVE.
3. When the vent valve closes (after a time specified in the Body Box settings), observe the pressure column, and, if necessary, repeat the previous step until the pressure no longer drifts.
4. At this point, the system is ready for the test. Ask the patient to breathe quietly, with the nose clips.



5. Press **START** to start the test and the visualization of the measured data.

sRaw test



1. The patient must breathe at a constant rate. If the above button is OFF, he/she can breathe at current frequency, otherwise (ON) the frequency must be faster than normal (about 1 breath/second, 60 breaths/minute). The physician must indicate to the patient if he/she needs to increase or decrease his/her respiratory frequency in order to normalize the breath. Panting frequencies >1.5 Hz (90 breaths/minute) may lead to

errors, and those <0.5 Hz (30 breaths/min) may cause problems with the controlled leak of the body plethysmograph system. It is possible to use a metronome to give rhythm to the patient.



- To capture a sRaw, press one of the two above buttons. The first one captures a single sRaw, the second one more than one sRaw, sequentially, as defined in the Body Box settings. The graph and the measured value are shown in the corresponding box in the lower part of the screen. The values shown are calculated starting from the predicted TGV.

Note: When the test has been completed, the sRaw will be recalculated starting from the actual TGV (if performed). It is normal that the real time sRaw measurements are different from the one shown when the test is completed (unless the calculated TGV is equal to the predicted one or no TGV are performed during the test).



- The above button allows the alignment of the loop with the axes origin.
- Capture at least three sRaw within 5% (the difference between the higher and the lower value divided for their mean value must be <0.05) to guarantee repeatability of the manoeuvre.

TGV test

- The patient must breathe at a respiratory frequency of about 60 breaths/minute, at least during the occlusion, supporting his/her cheeks with the hands.



- To capture a TGV, press the above button. The graph and the measured value are shown in the corresponding box in the lower part of the screen.



- The above button allows the alignment of the loop with the axes origin.
- Capture at least three TGV within 5% (the difference between the higher and the lower value divided for their mean value must be <0.05) to guarantee repeatability of the manoeuvre.

SVC (or IC) manoeuvre

Note: The SVC (or IC) can only be performed immediately after a TGV. For this reason, the button to start this manoeuvre is enabled only if the TGV is the last capture.

- If necessary, the patient can remove the mouthpiece and breathe between the TGV and the SVC. Patients with severe dyspnoea may have difficulty performing the preferred VC method (i.e. ERV immediately after TGV, followed by a slow IVC). To overcome this, the patient can be instructed to take two or three tidal breaths after the panting manoeuvre, prior to performing the linked ERV and IVC manoeuvres.



- Start the SVC or the IC by pressing one of the two buttons shown above. The Flow/Pbox graph become blank. The subject can perform the manoeuvre when he/she wants.



- At the end of the manoeuvre, press one of the two buttons shown above (the one corresponding to the performed manoeuvre).

End/abort the test



When the test is completed press **Stop**. The software will display the test edit panel. For a description of the panel, see below, *Test editing*.



To abort the trial, press **Abort**. To restart the trial, press **Redo**. Both these commands discard the current trial and don't save any data (it is not stored in the archive).

□ TGV/Raw post Bronchodilator

The Body Box POST test is a Body Box test after bronchodilator administration, comparing results before and after the administration. Bronchodilators are administered during lung function studies to determine if the subject's airflow obstruction is reversible. Bronchodilators can increase airway size by relaxing the smooth muscle.

■ Test execution



4. Press the **Testing** tile in the home panel, or start a new test from the subject database, then **Body Plethysmography** and **TGV/RAW post BD**.
5. If no subject was selected (in the top part of the panel there is no subject information), when pressing the Testing tile in the home panel the software will open the *Subject database*. If no visit card is present for the current day for the selected subject, the *New visit* panel is opened before starting the test.
6. A panel will open with some graphs.

T/min	ml	cmH2O
RF	VT	Pbox
90	800	0.75
60	600	0.25
30	400	0
	200	-0.25
		-0.5
		-0.75

7. Start and perform the test as indicated in the previous section.

Simulated TGV

The simulated TGV test is useful to verify if the TGV measurement meets the accuracy requirements, through the Erlenmayer flask standardized method.

To perform this check, please prepare the flask as described in J. Wanger et al.: *Standardisation of Lung Volume Measurement*, Eur.Resp.J, 2005, 26, 511-522 and reported below.

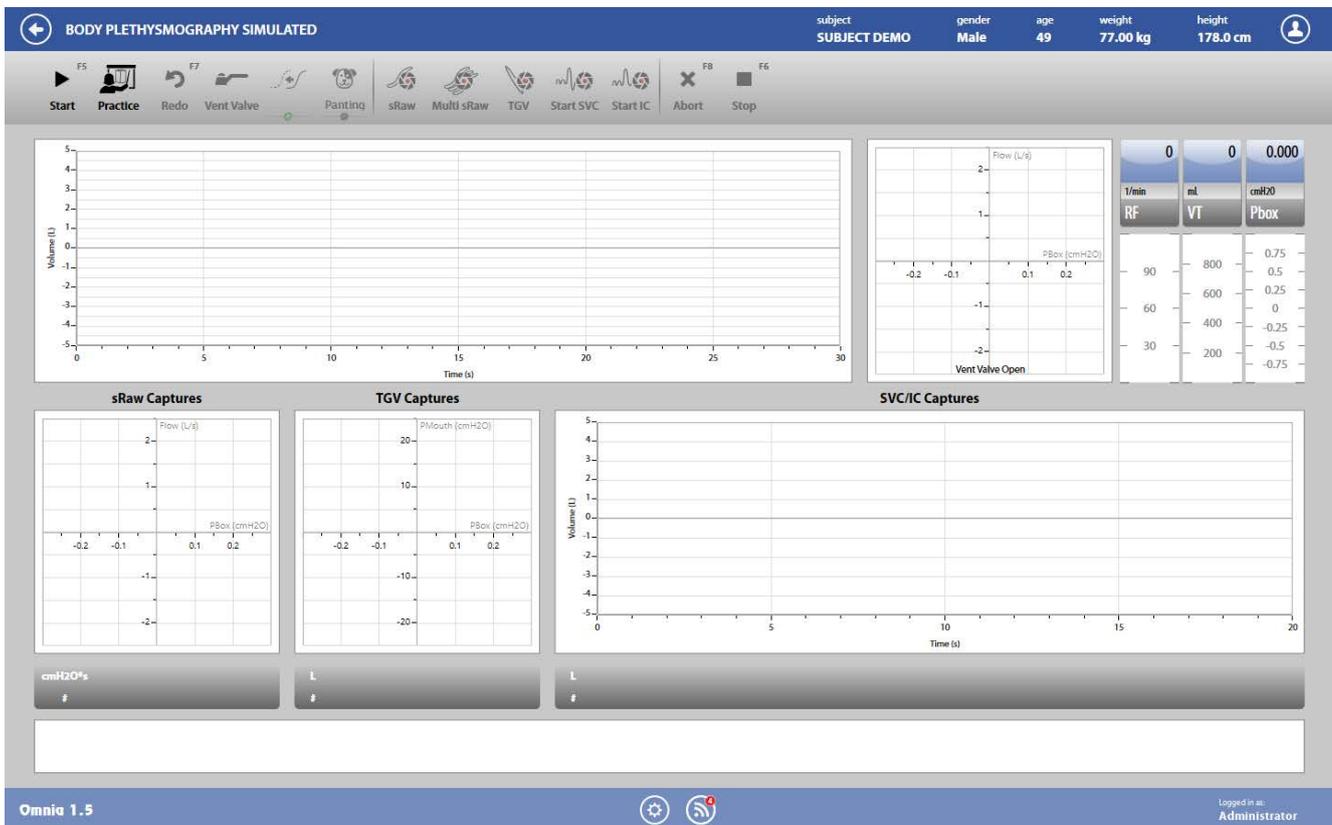
Fill a flask of known volume with thermal mass (e.g. copper wool) in order to simulate the isothermal conditions within the lung. The accuracy of adult plethysmographs in measuring the gas volume of the container should be 50 mL or 3%, whichever is greater, based on a mean of five determinations.

Connect the flask to the PNT and close the box door.

Test execution



1. Press the Testing tile in the home panel, or start a new test from the subject database, then **Body Plethysmography** and **TGV Simulated**.
2. If no subject was selected (in the top part of the panel there is no subject information), when pressing the **Testing** tile in the home panel the software will open the *Subject database*. If no visit card is present for the current day for the selected subject, the *New visit* panel is opened before starting the test.
3. A panel will open with some graphs.



4. Start and perform the test as indicated in the previous section (the user can capture TGV only).

□ *Limitations of the measurement method*

Below are some limitations of this procedure, according to the international scientific community:

- Overestimation of TGV in subjects with severe obstruction or induced bronchospasm unless slow 'panting' speed (ie, approximately 1 cycle/s) is maintained.
- Erroneous measurement of TGV, Raw, or sGaw due to improper panting technique. Excessive pressure fluctuations or signal drift during panting may invalidate TGV, Raw, or sGaw.
- Non-panting measurements have been suggested for use in children or others who have difficulty mastering the panting maneuver. Non-panting maneuvers in plethysmographs with built-in thermal leaks may invalidate TGV or Raw measurements.
- Computer-determined slopes of either TGV or Raw tangents may be inaccurate. All slopes should be visually inspected and adjusted according to an established laboratory procedure.
- Excessive abdominal gas or panting techniques that employ accessory muscles may increase the measured TGV, due to compression effects.
- Plethysmography is a complex test. Careful calibration of multiple transducers is required. Attention to frequency response, thermal stability, and leaks is necessary.
- Choice and application of reference values affect interpretation. Reference values for TGV using plethysmographically determined lung volumes are not widely available.
- Make a tentative selection from whatever published reference values are available. The characteristics of the healthy reference population should match the study group with respect to age, body size, gender, and race. The equipment, techniques, and measurement conditions should be similar.
- Following selection of seemingly appropriate reference values, compare measurements obtained from a representative sample of healthy individuals (10-20 subjects, over an appropriate age range) to the predicted values obtained from the selected reference values. If an appreciable number of the sample fall outside of the normal range, more appropriate reference values should be sought.

□ Viewing and editing test results

For Body plethysmography the software allows for three editing levels: test edit, trial edit and capture edit.

The test edit panel is shown at the end of each test, it shows the parameters measured in the trials performed during the test and it allows the user to select the trials to be used for the final results. It can also be accessed through the Edit button appearing when the  near the selected test is pressed or at the end of each trial.

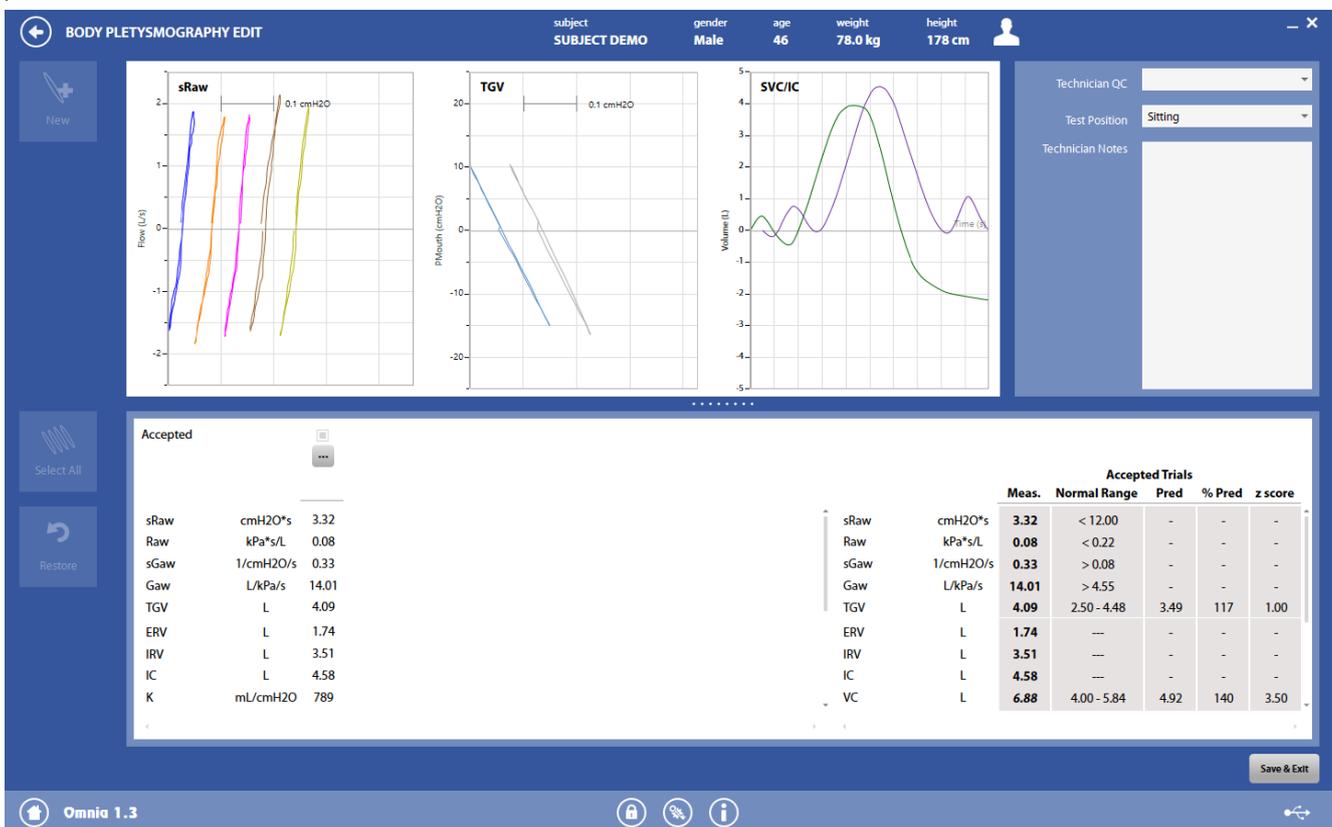
The trial edit panel is accessible from the test edit panel, it shows the parameters measured in the captures performed during the selected trial and it allows the user to select the captures to be used for the results of the selected trial.

The capture edit panel is accessible from the trial edit panel and it allows the user to edit each single capture (sRaw, TGV or SVC).

■ Test editing



The test edit panel is shown at the end of each test, it shows the parameters measured in the trials performed during the test and it allows the user to select the trials to be used for the final results. It can also be accessed through the **Edit** button appearing when the  near the selected test is pressed or at the end of each trial.



The panel is divided into three sections: graphs, QC and notes, and results.

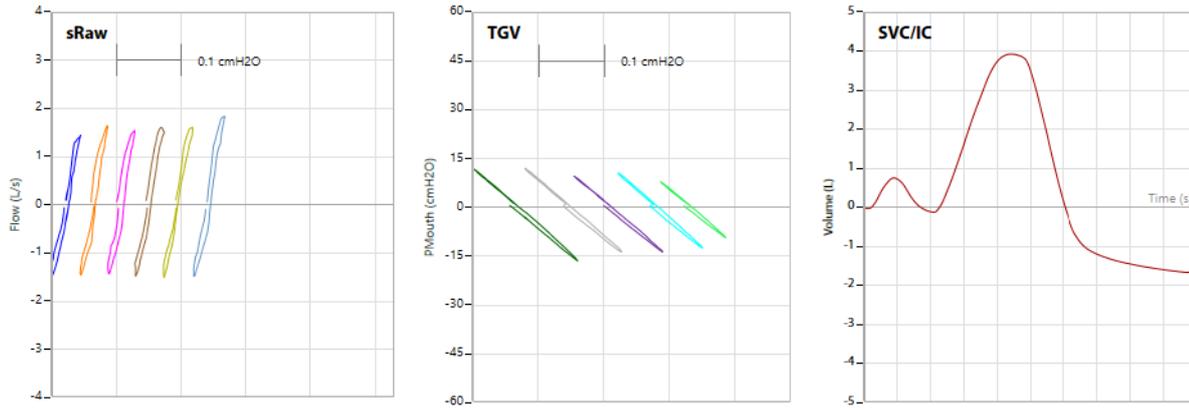


The button in the upper-left part of the panel allows the user to start a new trial (**New**).

The **Calibration** button shows the calibration data for the current test.

The **Save** button allows the user to exit the edit panel and saves the results. By pressing **Save**, the **Test results** panel will be displayed (see below).

Graphs



In this section of the panel all the accepted captures (for each accepted trial) are shown. Each maneuver type is displayed on a different graph. Through the mouse, it is possible to horizontally move each graph in order to visualize all the captures, if some of them are hidden for space reasons.

QC and notes

The screenshot shows a user interface for quality control and notes. It features three main sections: 'Technician QC' with a dropdown menu, 'Test Position' with a dropdown menu set to 'Sitting', and 'Technician Notes' with a large text input area.

In this section it is displayed:

- A quality control entered by the technician
- The position of the subject during the test
- Notes entered by the technician

Results

Accepted				Accepted Trials					
				Meas.	Normal Range	Pred	% Pred	z score	
sRaw	cmH2O*s	3.32	sRaw	cmH2O*s	3.32	< 12.00	-	-	-
Raw	cmH2O*s/L	0.79	Raw	cmH2O*s/L	0.79	< 2.24	-	-	-
sGaw	1/cmH2O/s	0.33	sGaw	1/cmH2O/s	0.33	> 0.08	-	-	-
Gaw	L/cmH2O/s	1.37	Gaw	L/cmH2O/s	1.37	> 0.45	-	-	-
FRC(Pleth)	L	4.09	FRC(Pleth)	L	4.09	2.50 - 4.48	3.49	117	1.00
ERV	L	2.39	ERV	L	2.39	---	1.38	174	-
IC	L	4.49	IC	L	4.49	---	3.65	123	-
K	mL/cmH2O	789	VC	L	6.88	4.00 - 5.84	4.92	140	3.50
VC	L	6.88	TLC(Pleth)	L	8.58	5.99 - 8.29	7.14	120	2.05

The results section is divided into two parts:

- The left side shows all the measured parameters for all the performed trials

- The right side presents a subset of the parameters. For each of them, its measured value (see below for information about how this value is chosen), together with the normal range, the predicted value, the % of the value with respect of the predicted and the Z-Score. Measured values are displayed in italics if they are out of the normal range.

A scroll bar allows the user to scroll the parameters in order to view all of them.

The value is chosen according to the following criteria:

- For parameters linked to Raw and FRC_{pleth} , a mean of the values in the accepted trials
- For VC and TLC, the maximum value among all the accepted trials
- RV is calculated as $TLC - VC$
- For other parameters, the values in the trials corresponding to the VC max.

On the left side, for each trial, above the measured parameters, it appears in order from the top to the bottom:

- If the trial is accepted. By default the software accepts all the trials. The user can discard some of them, but these trials won't be deleted from the archive also when the user saves and exits from this panel.¹ At least 1 trial must be accepted.
- An Edit button (represented by the  icon). By pressing this button, the trial edit panel will open.

¹ The color of the check boxes can be white () if selectable, blue () if deselected or grey () if not editable.



Near these items, on the left, two buttons allow the user to:

- Accept all the trials (**Select All**)
- Restore the last save (**Restore**).

Trial editing

The **trial edit** panel is accessible from the test edit panel, it shows the parameters measured in the captures performed during the selected trial and it allows the user to select the captures to be used for the results of the selected trial.

		6.19	5.34	3.57	5.13	6.28	3.95	-	-	-	-	-	-	-	-	-	-	-	-
sRaw	cmH2O*s	6.19	5.34	3.57	5.13	6.28	3.95	-	-	-	-	-	-	-	-	-	-	-	-
Raw	cmH2O*s/L	1.65	1.42	0.95	1.36	1.67	1.05	-	-	-	-	-	-	-	-	-	-	-	-
sGaw	l/cmH2O/s	0.16	0.18	0.27	0.19	0.15	0.25	-	-	-	-	-	-	-	-	-	-	-	-
Gaw	L/cmH2O/s	0.60	0.70	1.04	0.73	0.59	0.94	-	-	-	-	-	-	-	-	-	-	-	-
TGV	L	-	-	-	-	-	-	3.75	3.89	4.02	3.85	4.01	-	-	-	-	-	-	-
ERV	L	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1.55
IRV	L	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	3.17
IC	L	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	4.01
Voccl	L	-	-	-	-	-	-	0.148	0.129	0.030	0.029	0.020	-	-	-	-	-	-	-
VC	L	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	5.57
TLC(Pleth)	L	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	8.02

		5.08	< 12.00	-	-	-
sRaw	cmH2O*s	5.08	< 12.00	-	-	-
Raw	cmH2O*s/L	1.35	< 2.24	-	-	-
sGaw	l/cmH2O/s	0.20	> 0.08	-	-	-
Gaw	L/cmH2O/s	0.77	> 0.44	-	-	-
TGV	L	3.91	3.11 - 4.66	3.88	101	0.04
ERV	L	1.55	---	-	-	-
IRV	L	3.17	---	-	-	-
IC	L	4.01	---	-	-	-
K	mL/cmH2O	776	---	-	-	-
VC	L	5.57	4.76 - 7.14	5.95	94	-0.68
TLC(Pleth)	L	8.02	6.80 - 10.20	8.50	94	-0.67

The panel is quite identical to the test edit panel. The only difference is that each capture is identified through a color, shown above the measured parameters of that capture.

Two observations must be pointed out:

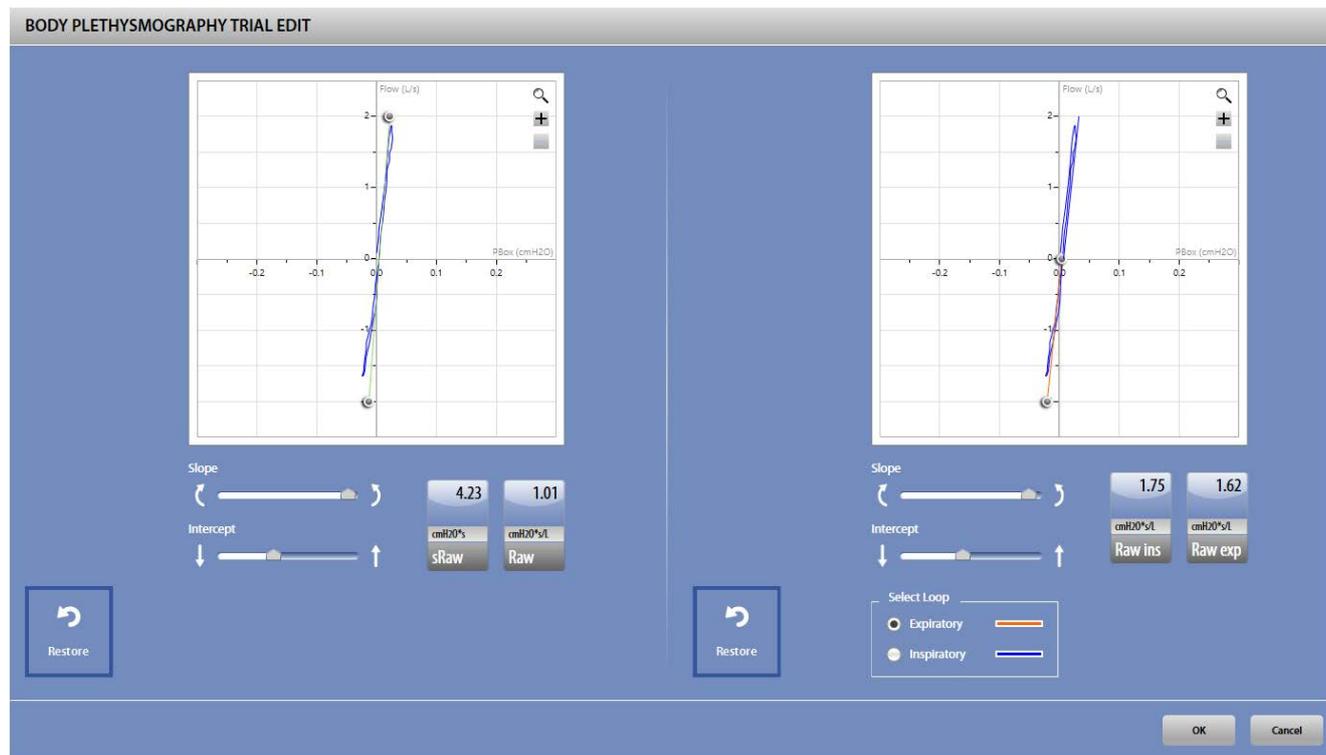
1. The calculation of the sRaw and Raw is based on the first accepted TGV capture.
2. If a TGV is deselected (i.e. the Accepted checkbox is not checked), and an SVC was performed immediately after that TGV, also this SVC is deselected. If that TGV is selected again, the corresponding SVC remains deselected. If all the SVC are deselected, OMNIA will use the SVC test belonging to the same visit card (if available).

The  button above each trial will open the *capture edit* panel.

■ Capture editing

The *capture edit* panel is accessible from the *trial edit* panel and it allows the user to edit each single capture (sRaw, TGV or SVC).

sRaw editing



The *sRaw edit* panel is divided in two sections: the left one allows the editing of the sRaw and Raw, the right one allows the editing of inspiratory and expiratory Raw.

It is possible to change the slope and the intercept of each loop both graphically and using the bars below the graph. The values are automatically updated in the corresponding boxes.

For the right graph, before editing it is necessary to select which section of the loop (inspiratory or expiratory) must be edited.

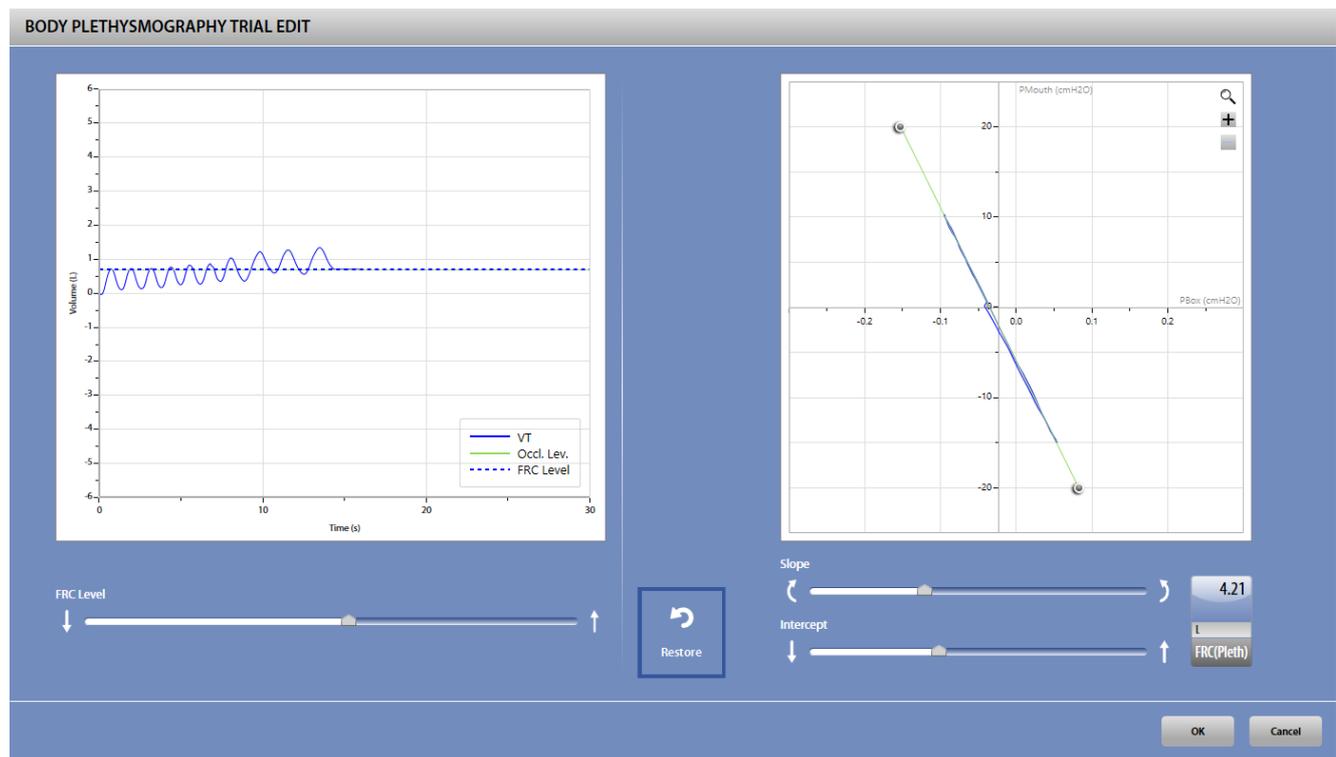
The + and - icons on the graphs allow to respectively zoom in or out the graphs.



The Restore button near each graph allows the user to discard all the edits performed on the loop.

Press **OK** to confirm changes or **Cancel** to cancel them.

TGV editing



The *TGV edit* panel is divided in two sections: the left one allows the editing of the V/T curve, the right one allows the editing of the slope and intercept of the TGV loop.

In the graph on the left, in particular, it is possible to adjust the TGV level (the dotted blue line) to match the subject's actual TGV value, in order to obtain a reliable value of the TGV (note that the occlusion level cannot be edited).

In the graph on the right, it is possible to change the slope and the intercept of the TGV loop both graphically and using the bars below the graph.

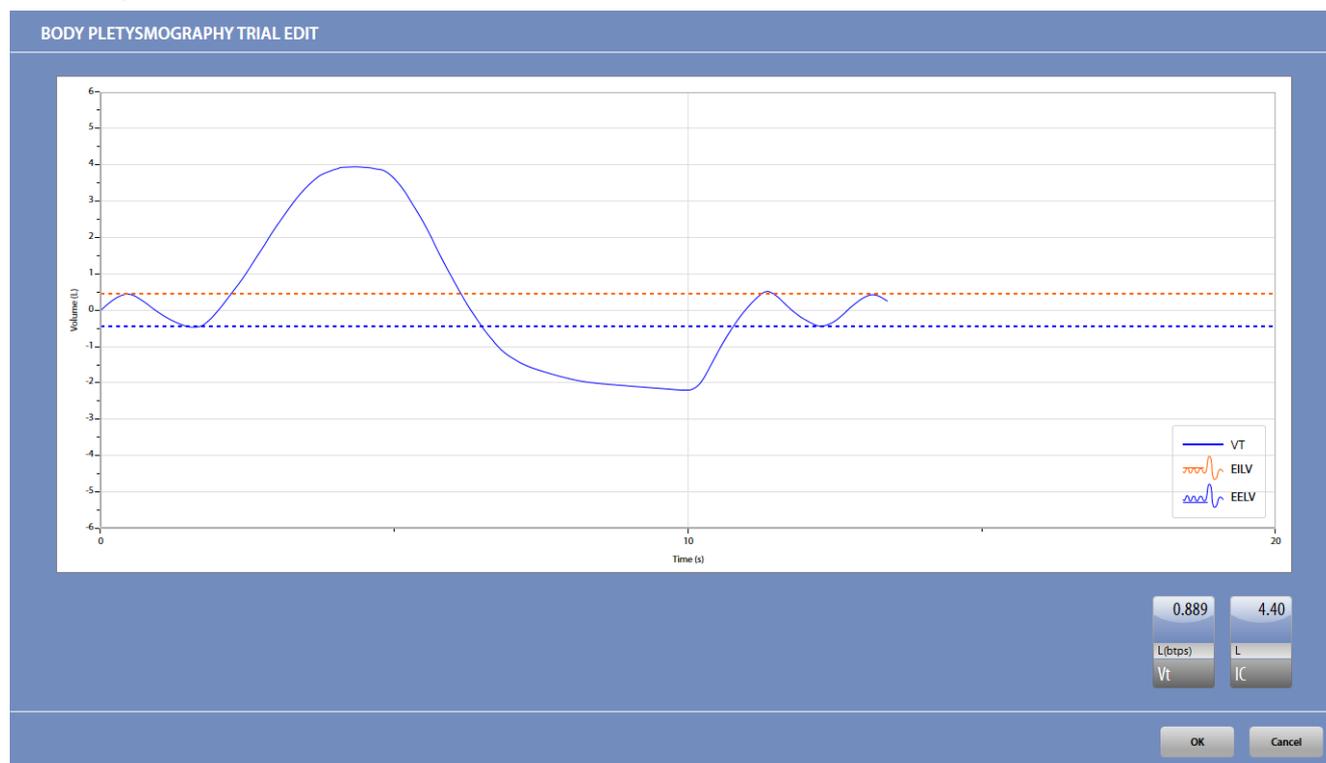
The value is automatically updated in the corresponding box after each edit.

The + and - icons on the graphs allow to respectively zoom in or out the graphs.



The **Restore** button near each graph allows the user to discard all the edits performed on the loop.

Press **OK** to confirm changes or **Cancel** to cancel them.



The *SVC/IC edit* panel is used to graphically edit the EELV (end expiratory level) and the EILV (end inspiratory level) of the selected curve, which detect the current volume. The EELV and EILV are represented on the graph with dotted horizontal lines. The Vt and IC parameters near the graph are automatically updated each time the EELV and EILV values are changed.

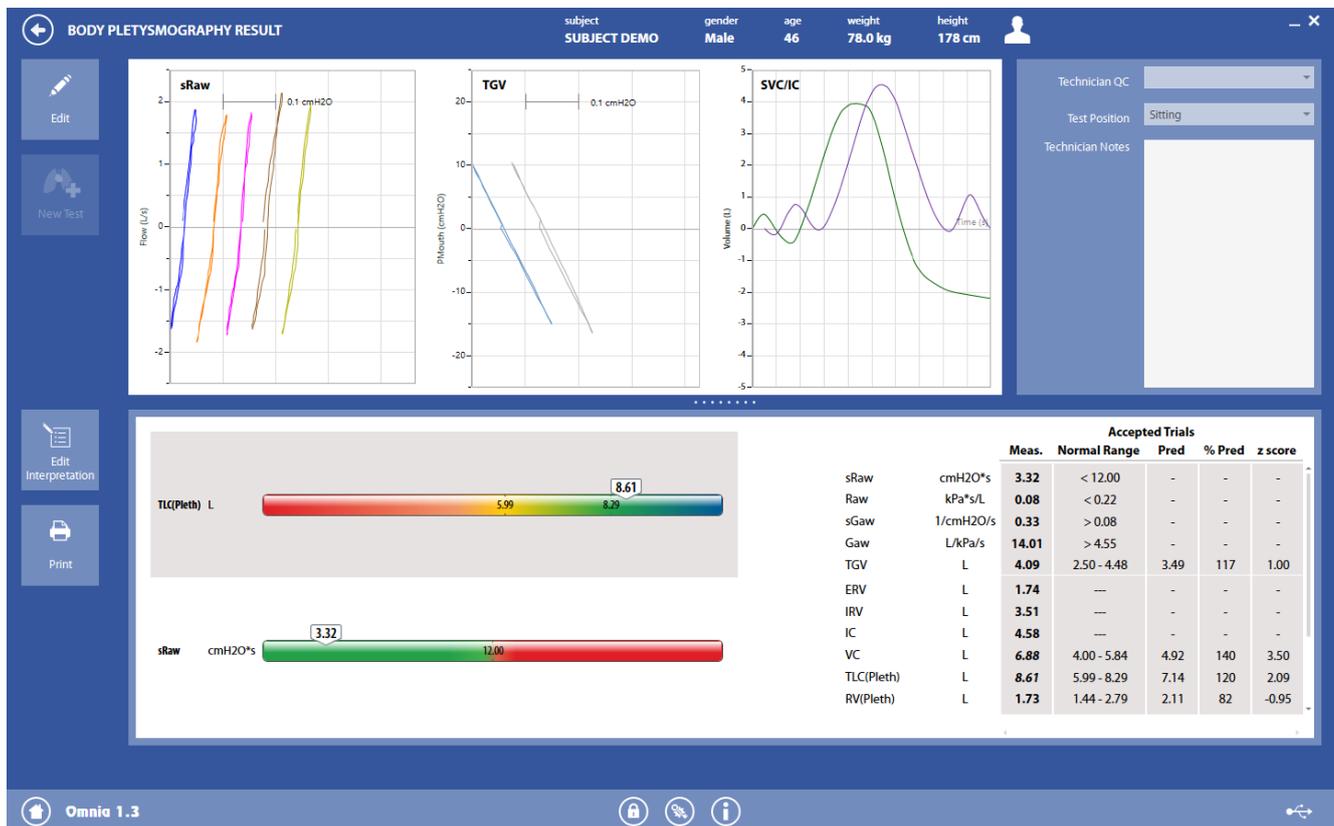
Press **OK** to confirm changes or **Cancel** to cancel them.

■ Test results



To view a test, press in the subject database the **...** on the left of the test and then the **View** button or double click on the test. In this panel, data and graphs are not editable by the user.

Test results are accessed also by pressing **Save** in the *Test edit* panel.



The panel is divided into three sections

The *graphs* section is the same as described above in Test editing.

The *QC and notes* section is the same as described above in Test editing.

The *results* section is divided into two parts:

- The left side shows a graphical interpretation of the results
- The right side, the value for each parameter is shown, together with the normal range, the predicted value, the % of the value with respect of the predicted and the Z-Score (if enabled in the Predicted settings).

In the left side, two bars are shown: for TLCpleth and for sRaw. Near these parameters, a colored bar with an indicator representing the current status of the subject. The bars also report the normal range.



The buttons in the left part of the panel allows the user to:

- Edit the test (**Edit**): the panel shown under Test editing is displayed
- Start a new test (**New Test**). The New Test is enabled if the test is performed on the current day.
- Edit the interpretation (**Edit Interpretation**): the panel Interpretation of the visit card is displayed
- Print a report (**Print**).

■ Predicted values interpretation

Predicted values for Raw and sRaw are the maximum predicted for the patient. It means that a lower value is positive, thus the lower the value, the more positive the result.

Predicted values for Gaw and sGaw are the minimum predicted for the patient. It means that an higher value is positive, thus the higher the value, the more positive the result.

■ Check the test quality

TGV maneuvers are acceptable when the displayed or recorded tracing indicates proper panting technique (the loop generated against a closed shutter should be closed or nearly so).

During the TGV maneuver, the patient should support his/her cheeks with the hands to prevent pressure changes induced by the mouth. This should be done without supporting the elbows or elevating the shoulders.

Recorded pressure changes should be within the calibrated pressure range of each transducer. The entire tracing should be visible. Pressure changes that are too large or too small may yield erroneous results.

Thermal equilibrium should be evident; tracings should not drift on the display or recording.

The panting frequency is approximately 1 Hz if the filter is not applied. Frequency should be held constant for within-testing session comparisons (ie, pre- and post-bronchodilator testing) and serial testing.

Raw and sGaw maneuvers may be considered acceptable if the open-shutter panting maneuver shows a relatively closed loop, particularly in the range of +0.5 to -0.5 L/s.

□ RAW Challenge

The RAW Challenge test is a Body Box test after bronchoconstrictor administration, comparing results before and after the administration.

Subjects with hyperreactive airways will demonstrate a response to the inhalation of challenging agents (Methacholine or Histamine) by displaying signs of airway constriction.

The testing procedure involves executing repeated manoeuvres following the inhalation of pharmacologic agents according to an established protocol. A subsequent decrease in sGaw and increment in sRaw can be used to determine the presence and severity of bronchial hyperresponsiveness. The PD45 (or PC45, depending on the modality: dose or concentration) for sGaw is the drug dosage that leads to a 45% reduction of the sGaw with respect to the baseline value. The PD100 (or PC100) for sRaw is the drug dosage that leads to a 100% increment of the sRaw with respect to the baseline value.

Parameters measured in RAW Challenge testing include the following (some units of measurements can be changed in the settings):

<i>Symbol</i>	<i>UM</i>	<i>Parameter</i>
% Decr. sGaw	%	Fall in sGaw from baseline or post diluent
% Incr. sRaw	%	Relative increment in sRaw from baseline or post diluent
Δ sRaw	cmH ₂ O*s	Absolute increment in sRaw from baseline or post diluent
PD35 (or PC35)	---	Provocative dose causing sGaw to fall 35% from baseline
PD40 (or PC40)	---	Provocative dose causing sGaw to fall 40% from baseline
PD45 (or PC45)	---	Provocative dose causing sGaw to fall 45% from baseline
PD100 (or PC100)	---	Provocative dose causing sRaw to increment 100% from baseline

The software associates all efforts conducted throughout the procedure to the RAW pre (baseline RAW) obtained during that date's visit.

It is not necessary to perform a RAW pre. The test can be compared to the "diluent" step (the first step, without bronchoconstrictor) or to the predicted values if the diluent step is not present.

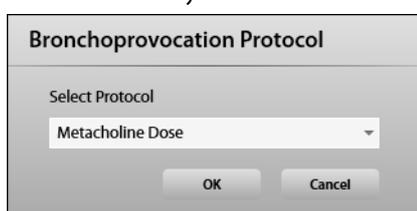
■ Test execution



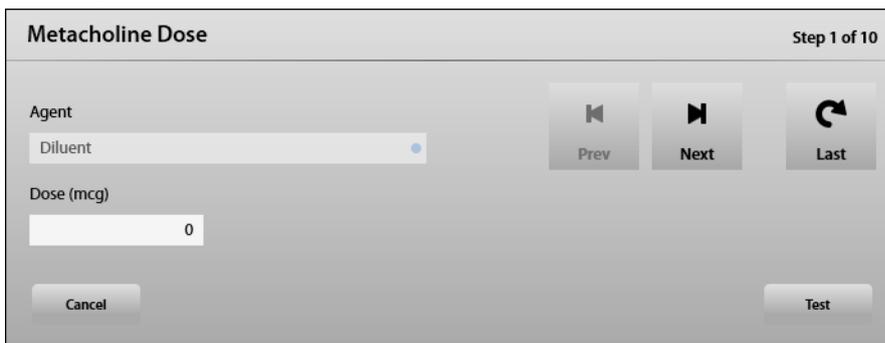
1. Press the **Testing** tile in the home panel, or start a new test from the subject database, then **Body Plethysmography** and **RAW Challenge**.
2. If no subject was selected (in the top part of the panel there is no subject information), when pressing the Testing tile in the home panel the software will open the *Subject database*. If no visit card is present for the current day for the selected subject, the *New visit* panel is opened before starting the test.
3. A panel similar to the one shown in the pre test will open.
4. Explain the maneuver to the subject prior to testing (the same as the RAW pre).



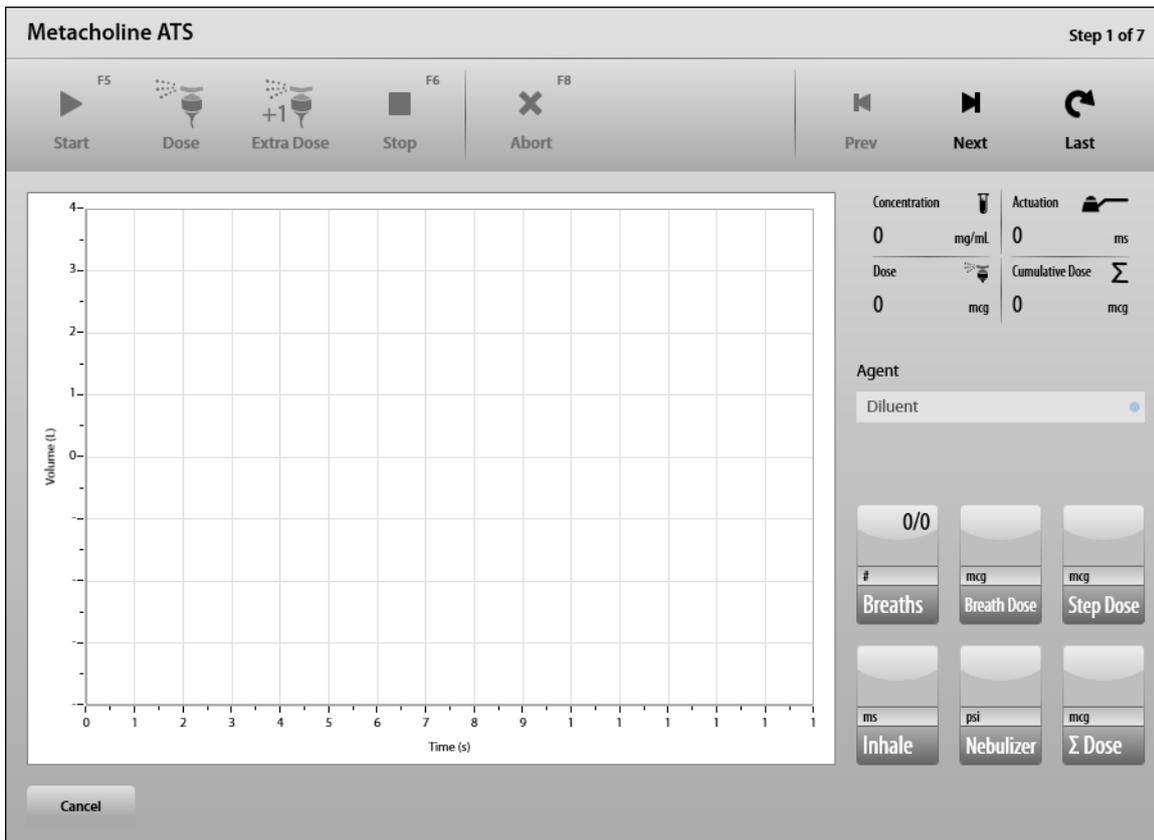
5. When the subject and the software are ready press **Start** to perform the trial.
6. If requested, select the device and the flowmeter to be used for performing the test. Check *Always use it for this test* if you want to use the selected choice every time this test is started.



- Select the protocol.



If the selected protocol is a *Dosimeter* protocol (as defined in the *Bronchchallenge protocols*), the interface will change into the next one.



- Please refer to the *Dosimeter* chapter for information about this window.



- The first step is displayed. Use the **Prev** and **Next** buttons to select the desired step. Modify the agent dose, if needed. Press **OK**. The **Last** button allows to skip to the last step (usually, the bronchodilator one).
- If necessary, administer the agent to the subject (only if a new step is selected).
- Perform the test as for the RAW pre (only RAW captures can be performed).



- At the end of the maneuver, press **Stop**. The software will display the graphs, the parameters and the predicted values. For a description of the panel, see *Test editing* below.

Warning: Different international guidelines exist for determining when the subject's response to bronchial provocation test is considered positive. OMNIA software suggests sGaw decrement of 45% or sRaw increment of 100% (with absolute difference more than 2 kPa*s) with respect to the baseline value. Notwithstanding, the user can follow his preferred guideline. OMNIA detects PD35, PD40 and PD45 for sGaw decrement and PD100 for sRaw increment only.



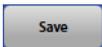
13. To abort the trial, press **Abort**. To restart the trial, press **Redo**. Both these commands discard the current trial and don't save any data (it is not stored in the archive).



14. You can perform another trial by pressing **New** until the desired number of maneuvers has been obtained.
When **New** is pressed, and the trial is started, the current step is repeated and another trial with one or more captures will be stored.

Caution: When you repeat the step, the drug must not be administered. The drug must be administered ONLY if the selected step is a new one.

If the **New** button is pressed, this procedure restart from step 11.



15. Press **Save** to save this step.



16. You can perform one of the next steps by pressing **RAW Challenge**. The proposed step is the next one, but it is possible to repeat the last step, to go to one of the following steps or to go to the last step respectively by means of the **Prev**, **Next** or **Last** button. It is not possible to go back to a previous step.

Caution: When you repeat the step, the drug must not be administered. The drug must be administered ONLY if the selected step is a new one.

If the **RAW Challenge** button is pressed, select the step to be performed, press **Test** and restart this procedure from step 11.

In the Bronchochallenge protocol, each step corresponds to one test in the same visit card. In each step different trials are stored. For example there can be a Bronchochallenge test (the 1st step) with three trials performed with the diluent, then another test (the 2nd step) with one trial performed with 30 mcg of metacholine, another one (the 3rd step) with two trials performed with 60 mcg of metacholine, etc.

This means that all the Bronchochallenge trials performed with a defined quantity of drug during a visit (i.e. in the same day) are stored under the same test. Other trials performed with different quantities of drug are stored under other tests.

■ Test editing



The test edit panel is shown at the end of each test, it shows the parameters measured in the trials performed during the test and it allows the user to select the trials to be used for the final results. It can also be accessed through the **Edit** button appearing when the  near the selected test is pressed or at the end of each trial.

BODY PLETHYSMOGRAPHY EDIT

subject: SUBJECT DEMO gender: Male age: 49 weight: 77.00 kg height: 178.0 cm visit date: Today

Operator QC:

Test Position:

Operator Notes:

Accepted

Accepted Trials			Agent Data: Metacholine (30 mcg)			
Meas.	Normal Range	Pred	% Pred	z score		
sGaw 1/cmH2O/s	0.11	0.11	> 0.08	-	-	-
sRaw cmH2O*s	10.15	10.15	< 12.00	-	-	-

Omnia 1.6 Beta Logged in as: Administrator

The panel is divided into three sections: graphs, QC and notes, and results.

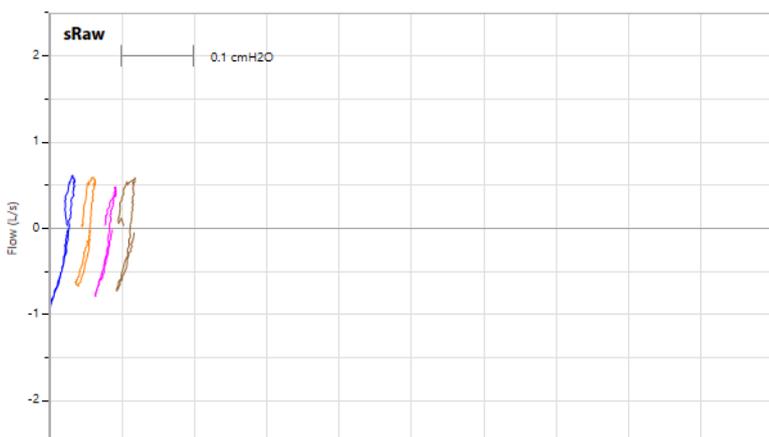


The button in the upper-left part of the panel allows the user to start a new trial (**New**).

The **Calibration** button shows the calibration data for the current test.

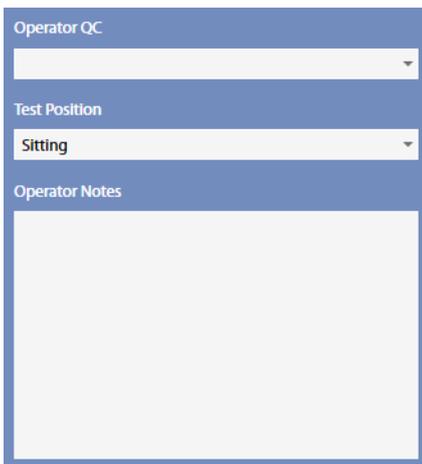
The **Save** button allows the user to exit the edit panel and saves the results. By pressing **Save**, the *Test results* panel will be displayed (see below).

Graphs



In this section of the panel all the accepted captures (for each accepted trial) are shown.

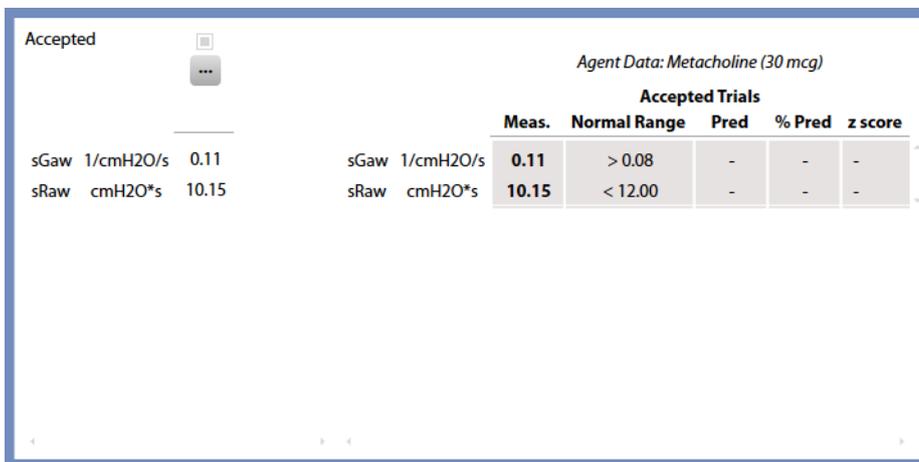
QC and notes



In this section it is displayed:

- A quality control entered by the technician
- The position of the subject during the test
- Notes entered by the technician

Results



Accepted		Agent Data: Metacholine (30 mcg)				
		Accepted Trials				
		Meas.	Normal Range	Pred	% Pred	z score
sGaw	1/cmH2O/s	<i>0.11</i>	> 0.08	-	-	-
sRaw	cmH2O*s	<i>10.15</i>	< 12.00	-	-	-

The results section is divided into two parts:

- The left side shows all the measured parameters for all the performed trials
- The right side presents a subset of the parameters. For each of them, its measured value, together with the normal range, the predicted value, the % of the value with respect of the predicted and the Z-Score. Measured values are displayed in italics if they are out of the normal range.

A scroll bar allows the user to scroll the parameters in order to view all of them.

On the left side, for each trial, above the measured parameters, it appears in order from the top to the bottom:

- If the trial is accepted. By default the software accepts all the trials. The user can discard some of them, but these trials won't be deleted from the archive also when the user saves and exits from this panel.¹ At least 1 trial must be accepted.
- An Edit button (represented by the  icon). By pressing this button, the *trial edit* panel will open.

¹ The color of the check boxes can be white () if selectable, blue () if deselectable or grey () if not editable.



Near these items, on the left, two buttons allow the user to:

- Accept all the trials (**Select All**)
- Restore the last save (**Restore**).

■ Trial editing

The **trial edit** panel is accessible from the test edit panel, it shows the parameters measured in the captures performed during the selected trial and it allows the user to select the captures to be used for the results of the selected trial.

Accepted Show

Meas.	Normal Range	Pred	% Pred	z score		
sGaw 1/cmH2O/s	0.10 0.14 0.06 0.13	0.11	> 0.08	-	-	-
sRaw cmH2O*s	9.70 7.09 15.93 7.90	10.15	< 12.00	-	-	-

Agent Data: Metacholine (30 mcg)

Accepted Trials

Omnia 1.6 Beta

Logged in as: Administrator

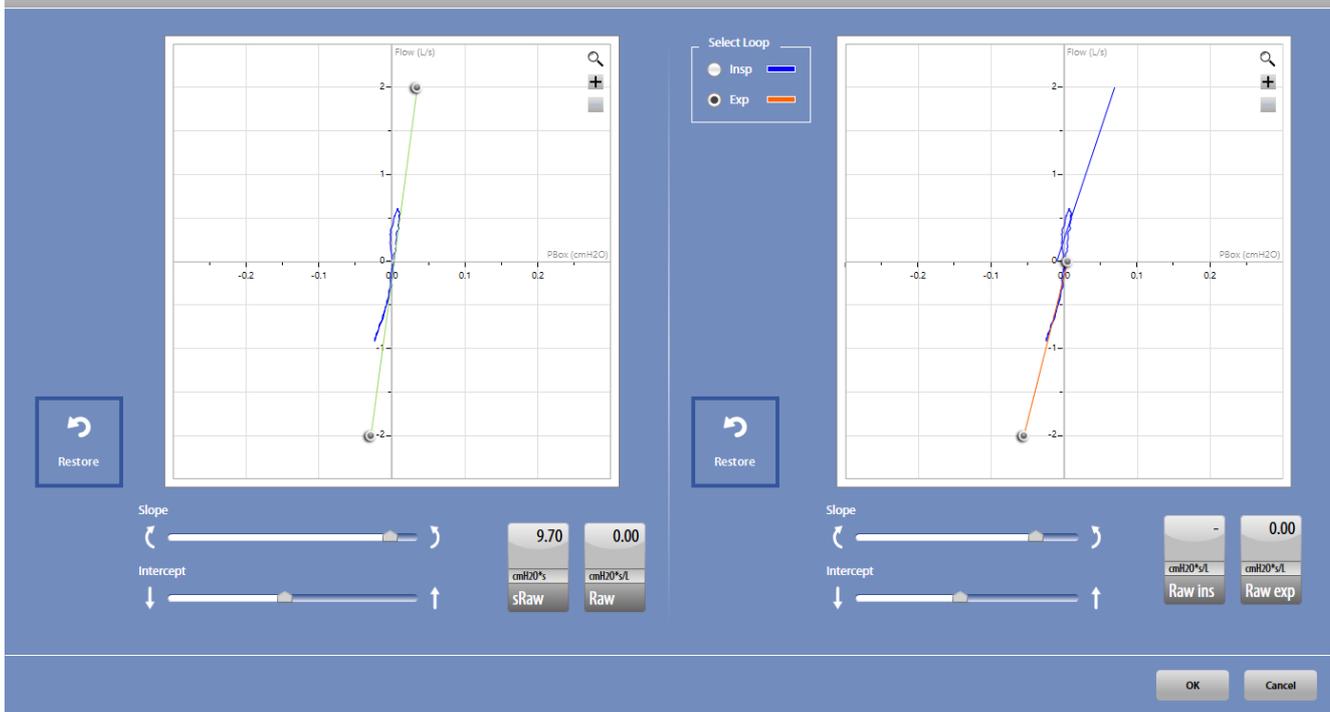
The panel is quite identical to the test edit panel. The only difference is that each capture is identified through a color, shown above the measured parameters of that capture.

Please note that TGV and SVC/IC graphs are blank because no TGV nor SVC tests are performed during a RAW Challenge.

The button above each trial will open the *capture edit* panel.

■ Capture editing

The *capture edit* panel is accessible from the *trial edit* panel and it allows the user to edit each single capture.



The *sRaw edit* panel is divided in two sections: the left one allows the editing of the *sRaw*, the right one allows the editing of inspiratory and expiratory *Raw*.

It is possible to change the slope and the intercept of each loop both graphically and using the bars below the graph. The values are automatically updated in the corresponding boxes.

For the right graph, before editing it is necessary to select which section of the loop (inspiratory or expiratory) must be edited.

The + and - icons on the graphs allow to respectively zoom in or out the graphs.



The Restore button near each graph allows the user to discard all the edits performed on the loop.

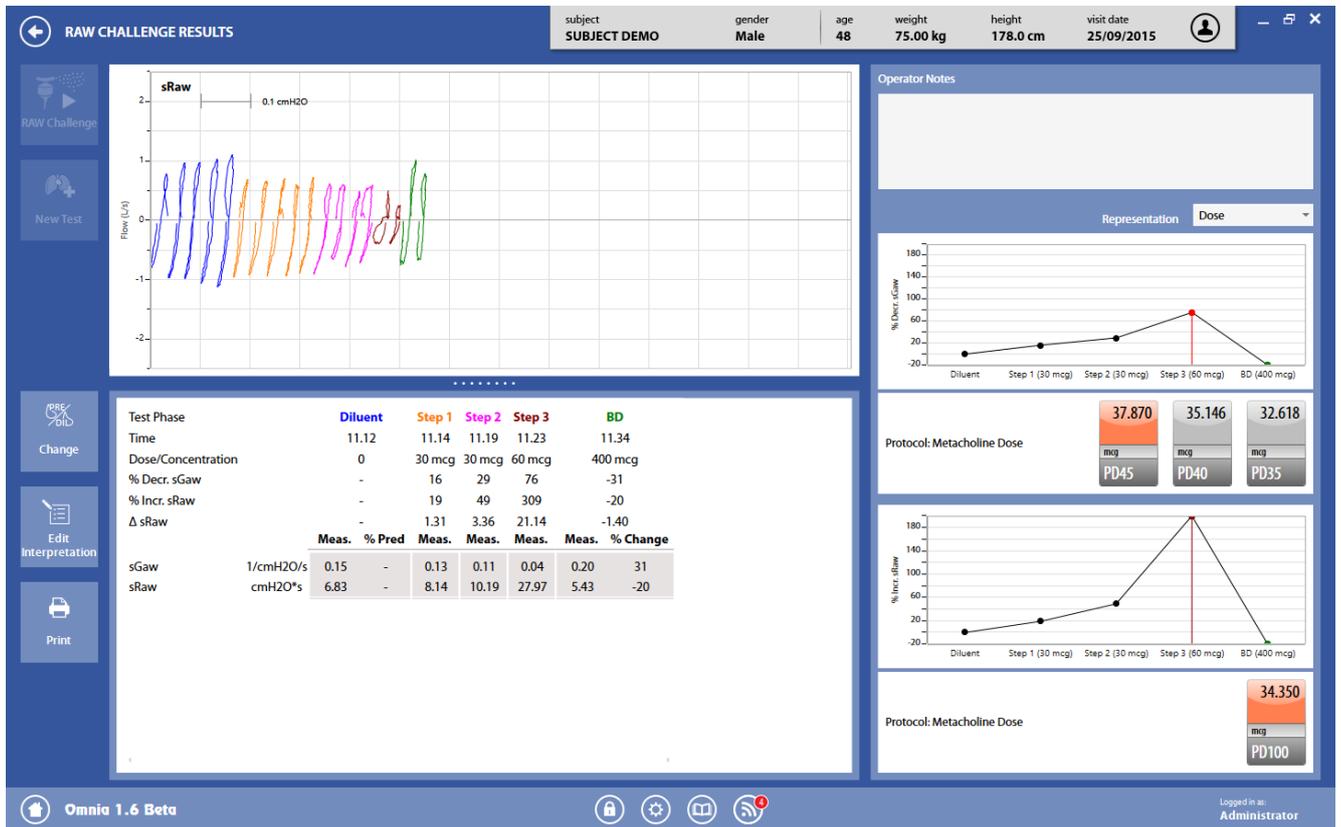
Press **OK** to confirm changes or **Cancel** to cancel them.

■ Test results



To view a test, press in the subject database the **...** on the left of the test and then the **View** button or double click on the test. In this panel, data and graphs are not editable by the user.

Test results are accessed also by pressing **Save** in the *Test edit* panel.



The panel is divided into four sections

The *graphs* section is the same as described above in Test editing.

The *QC and notes* section reports only the Technician notes (the QC is not displayed, since it can be different for each step).

The *results* section shows, for each parameter and each step, the measured values and, for RAW pre, the % of the predicted values. Above the parameter list, the step (its color corresponds to the color of the curves in the graphs section), the time of the trial, the dose/concentration and the variations of sGaw and sRaw.

The right bottom section shows two graphs: for the decrement of sGaw compared to the pre and for the increment of sRaw compared to the pre, both vs. the administered dose/concentration. The drop-down menus above the graph allow the user to choose if the graph must be drawn using the dose or cumulated dose (when available) for the x-axis.

Below the first graph, the agent dose that caused a 45%, 40% and 35% of decrement of the sGaw. Below the second graph, the agent dose that caused a 100% of increment of the sRaw together with an absolute difference of 2 kPa*s.

If the above event is reached at the first step, the agent dose is indicated as < of the dose of the first step, if the above event is not reached at the last step, the agent dose is indicated as > of the cumulated dose of the last step. In other cases, the displayed value is calculated with an interpolation between the previous and the current step. The dose/concentration causing the event is highlighted in orange.



The buttons in the left part of the panel allows the user to:

- Continue the RAW Challenge test (**RAW Challenge**). Test starts from the last step performed.
- Start a new test (**New Test**)
- Swap the RAW pre and the Diluent step (**Change**): the RAW pre step is replaced by the Diluent step. This is the reference step for the calculation of variations in all the subsequent steps
- Edit the interpretation (**Edit Interpretation**): the panel *Interpretation* of the visit card is displayed.
- Print a report (**Print**).

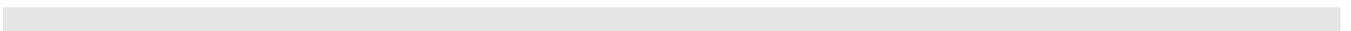
■ Edit function

Since the **Edit** button is not available in the *Test results* panel, you can access the edit function from the subject database only.



When a step of the Bronchochallenge test is selected, the **Edit** button will allow access to the edit panel of the selected step only, while the View button will allow access to the test results (summary) as described above.

Six Minute Walk Test **Sp**



The Six Minute Walk Test

Overview

The Six Minute Walk Test is a test that can be performed on the Spiropalm 6MWT only, and it is downloadable in the software OMNIA.

Note: The test cannot be performed through the software. The software allows viewing and editing of the test only.

To download the test from the Spiropalm 6MWT, please refer to the corresponding section of this manual (*Receiving data from the unit*).

Test editing



The test *edit* panel can be accessed through the **Edit** button appearing when the near the selected test is pressed or from the test *results* panel.

The screenshot shows the 'SIX MINUTE WALK TEST TRIALS' window in the Omnia 1.3 software. The interface is divided into four main sections:

- Summary:** A table of test parameters. Key values include: Test Time 00:06:00, 6MWD 620 m, Baseline SpO2 98%, Max HR 130 bpm, and Peak VE 97.8 L/min.
- Results:** A list of parameters for the selected trial, including 6MWD (620 m), Max HR (130 bpm), Peak VE (97.8 L/min), and Min BR (43.1%).
- SpO2 and Cardiovascular Graph:** A line graph showing SpO2 (%) on the left y-axis (orange line) and HR (bpm) on the right y-axis (green line) over a 6-minute period. SpO2 remains stable around 95-98%, while HR increases from approximately 60 bpm to 130 bpm.
- Ventilatory response Graph:** A line graph showing VE (L/min) on the left y-axis (blue line) and RR (1/min) on the right y-axis (grey line) over a 6-minute period. VE increases from about 10 L/min to 20 L/min, and RR increases from about 15 1/min to 20 1/min. A horizontal dashed line at RR = 30% indicates 'Ventilatory Limitation'.

The panel is divided into four sections: summary, results, and two graphs.



The **Save** button allows the user to exit the edit panel and saves the results.

By pressing **Save**, the *Test results* panel will be displayed (see below).

Summary

This section of the panel contains two tabs:

- the first one (*Summary*) contains a summary of the results of the selected trial
- the second one (*Steps Data*) contains the measured data of the selected trial every 15 seconds. If a step is selected, the corresponding step on the graphs on the right is highlighted.

Results

The results section shows the measured parameters for all the performed trials.

A scroll bar allows the user to scroll the parameters in order to view all of them.

For each trial, above the measured parameters, it appears, in order from the top to the bottom:

- If the trial is accepted. ¹ Only one trial can be accepted. At least 1 trial must be accepted.
- If the trial is the best. The trial with the highest distance is automatically selected as the best and the selection cannot be changed. ¹
- An Edit button (represented by the  icon). By pressing this button, the trial edit panel will open.

¹ The color of the check boxes can be white () if selectable, blue () if de-selectable or grey () if not editable.

Graphs

The two graphs on the right show:

- the SpO₂ and HR vs. time
- Ve, RF and IC (if at least one IC step is selected, see below in the trial editing section) vs. time.

Trial editing

The *Trial edit* panel is accessible from the test edit panel, it shows the details of the selected trial and it allows the user to select the steps during which the subject performed an IC.

The panel is divided into four parts: test data, measured data, and two graphs.

The *test data* section of the panel contains the test data that was entered in the Spiropalm unit before the test.

If some data are erroneous or were not entered, they can be edited.

The *measured data* section contains the measured data presented every 15 seconds (all the parameters are the mean of the measured values in a 15-seconds period, except for the IVmax, which is the maximum value in this period).

It is possible to select if during a step the subject performed an IC manoeuvre.

The graph in the upper right section contains a representation of the mean IV (bar graph) and maximum IV (dot graph) every 15 seconds.

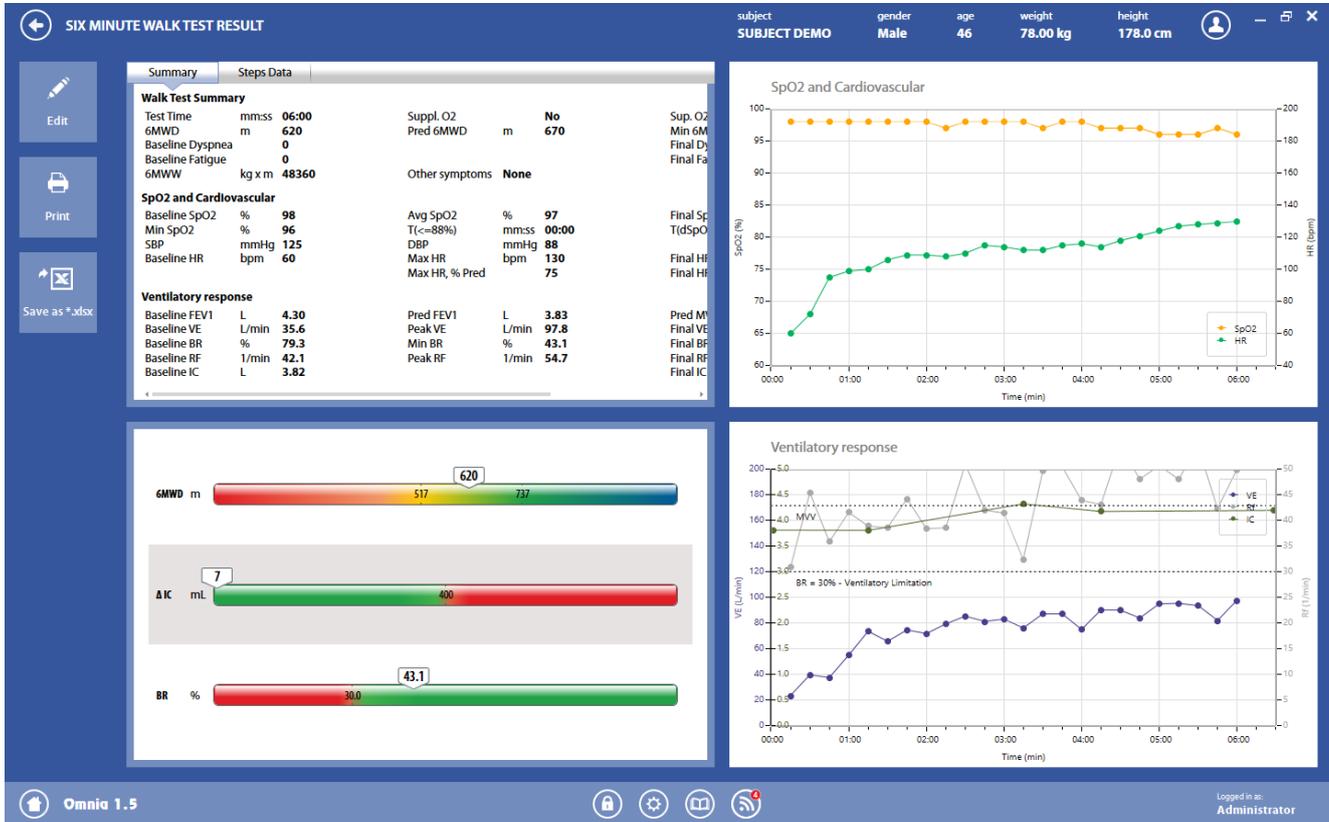
The graph in the lower right section contains a representation of the IC, Ve and RF vs. time.

Test results



To view a downloaded test, press in the subject database the on the left of the test and then the **View** button or double click on the test. In this panel, data and graphs are not editable by the user.

Test results are accessed also by pressing **Save** in the test *edit* panel.

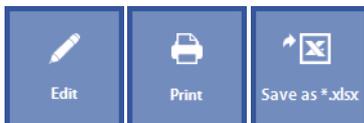


The panel is divided into four sections: summary, results (graphical interpretation) and two graphs.

The *summary* and the *graph* sections are the same as described above in *Test editing*.

The *results* section shows a graphical interpretation of the results.

Three bars are shown: the Six minute distance (the distance covered during the test), the Δ IC, calculated as the difference between the baseline IC (performed on the Spiropalm before the test) and the minimum IC during the test among the selected ICs, and the BR (Breathing Reserve). Near these parameters, a colored bar with an indicator representing the current status of the subject. The bars also report the normal range.



The buttons in the left part of the panel allows the user to:

- Edit the test (**Edit**): the panel shown under *Test editing* is displayed
- Print a report (**Print**)
- Export data in *.xlsx (**Save as *.xlsx**).

Exercise testing

PFT

CPET

K5

□ **Recommendations for exercise testing**

■ **Evaluation of the cardiorespiratory function**

Exercise creates an increased demand of energy and gas exchange which must be supplied by the cardiovascular and respiratory systems. The increase in energy expenditure during exercise creates an increase of oxygen in the muscles. The muscles also generate excess CO₂ which must be removed to avoid lactic acid build up.

■ **Precautions**

Laboratory

The room in which testing is performed must be large enough to accommodate the necessary equipment and allow access to the patient in case of an emergency.

A thermometer and a hygrometer should be present in the testing area and monitored regularly. The subject's heart rate and perceived exertion may rise with increased temperatures and/or humidity levels greater than 60%, which may lead to variable cardiovascular responses. An adequate temperature for testing conditions is 22°C, but temperatures as high as 26°C may be acceptable with efficient air ventilation.

Ending the test

The patient should be monitored with an ECG in resting conditions for at least 8 minutes following the test or until he/she returns to pre-exercise conditions.

■ **Preparing the patient**

To receive the most accurate test results it is necessary to communicate with the patient before, during and after the procedure. The patient should be well informed of the testing details and receive appropriate instructions prior to the test.

Before testing

The physician conducting the procedure must be provided with a written request including a diagnosis (confirmed or suspected), the indication for the test and the subject's current medications.

To standardize the test results and to reduce the patient's anxiety, you should provide him/her with either written or oral information prior to the test. When scheduling the exam patients should be instructed to avoid smoking, caffeine and eating for three hours prior to the test. He/she should also be informed to wear comfortable clothing and shoes during the procedure.

Medications which could impair the effort response and reduce the diagnostic accuracy of the exam may need to be stopped prior to testing (i.e. Beta Blockers or Calcium Antagonists).

A detailed medical history should be acquired from the patient before performing the test. Medications, tobacco use, current activity levels, nutritional habits and the presence of any abnormal symptoms should be noted.

Patient assent

The patient should be informed that he/she will be subjected to a maximal or submaximal effort along with the risks of the testing procedure.

Ending the test

The test should end when the maximum value of the oxygen consumption has been reached and the patient's response has been established or when the subject requests to stop the test.

□ Measured parameters

The main parameters measured or calculated during an exercise test include (parameters are grouped according to the OMNIA classification) (some units of measurements can be changed in the settings):

<i>Group</i>	<i>Symbol</i>	<i>UM</i>	<i>Parameter</i>
Spirometry	FVC	L	Forced Vital Capacity
	FEV1	L	Forced Expiratory Volume in the first second
	MVV	L/min	Maximum Voluntary Ventilation
Protocol	t	s	Time
	Speed	kmh	Speed (in case of treadmill)
	Grade	%	Grade (in case of treadmill)
	Power	W	Power (in case of bike)
	Revolution	rpm	Revolutions per minute
	RPE	--	Ratings of perceived exertion
Metabolic	VO ₂	ml/min	Oxygen consumption
	VO ₂ /kg	ml/min/kg	Oxygen consumption per kg
	METS	--	Metabolic Equivalent
	R	--	Respiratory Exchange Ratio
Ventilatory	VE/VCO ₂ slope	--	Slope of the VE/VCO ₂ regression line
	OUES	ml/min/l/min	Oxygen Uptake Efficiency Slope
	VE	L/min	Ventilation
	BR	%	Breathing Reserve
	Vt	L(btps)	Tidal Volume
	Rf	1/min	Respiratory frequency
Cardiovascular	HR	bpm	Heart rate
	HRR	bpm	Heart rate reserve
	HRR_1_minute	bpm	Heart rate recovery after a minute
	VO ₂ /WR Slope	ml/min/W	Slope of the VO ₂ /WR regression line
	VO ₂ /WR	ml/beat	VO ₂ /WR
	SBP	mmHg	Systolic Blood Pressure
	DBP	mmHg	Diastolic Blood Pressure
Gas Exchange	VO ₂ @AT	ml/min	Oxygen consumption at Anaerobic Threshold
	PetCO ₂	mmHg	End tidal carbon dioxide tension
	PetO ₂	mmHg	End tidal oxygen tension
	VE/VO ₂	--	VE/VO ₂ ratio
	VE/VCO ₂	--	VE/VCO ₂ ratio
	SpO ₂	%	Oxygen saturation
	dSpO ₂	%	Difference between SpO ₂ at rest and minimum SpO ₂ during exercise

Note: *the parameters listed above are the ones that can be shown in the results section. The tabular data presentation can contain many more parameters, according to the settings.*

□ **Preparing the device and the patient**

In this chapter it is described the preparation for the breath by breath exercise testing. For the exercise testing performed with the mixing chamber, please refer to the *Mixing chamber* chapter.

Carefully read the contraindication reported in the User manual of the device.

Follow the instructions described in the chapter *Installation* of the User manual for the specific device you have.

Note: *If the exercise test must include flow/volume loop events, it is mandatory to use masks without valves (REF C04490-01-10 extrasmall, C04490-02-10 small, C04490-03-10 medium)*

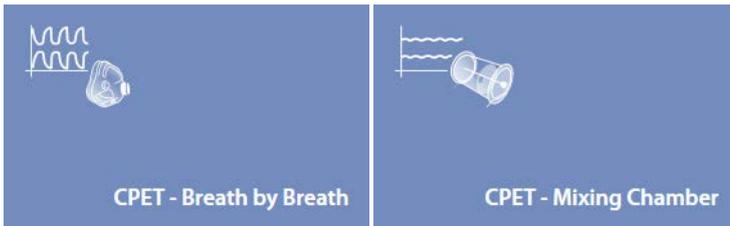
□ Performing the test

The software allows two main ergometry test types:

1. Breath by breath
2. Mixing chamber

The execution of these two test types is the same, and it will be described below. The chapter *The mixing chamber* describes the setup of the system only.

■ Starting the test



Press the **Testing** tile in the home panel, or start a new test from the subject database, then **Metabolic** and **Cardio Pulmonary Exercise Testing**, then select (depending on the test type) **CPET - Breath by Breath** or **CPET - Mixing Chamber**.



The system is ready to read the subject's breaths. Press **Start** to start the data acquisition.

Start Test / Select Options

Test

Type: Maximal

Data Filtering: None

Subject Type: Healthy Simulated

Ergometer

Ergometer: None Protocol: None Port: None

Spirometry

FEV1: 0.00 L FVC: 0.00 L

IC: 0.00 L VC: 0.00 L

Integrated Devices

HR Source: Metabolic Cart Physioflow: Blood Pressure: None Port:

OK Cancel

The above window (that includes a subset of the settings) will be prompted. In this window you can select:

- The test type (maximal or submaximal)
- The data filtering algorithm (according to the options already described in the *Settings* chapter)
- The subject type (healthy or clinical)
- If the test is a simulated test (in order perform a simulated test by means of a syringe or a pulmonary waveform generator, without involving a real subject)
- The ergometer used and its protocol (if any), and the port to which the ergometer is connected
- The main spirometry values of the subject under test (if available, the fields already contain these values)

- The device used to detect the HR, the port connected with a Physioflow device (if any), the device used to detect the blood pressure and the port used for the connection with it.

Press **OK** to start the test, or **Cancel** to abort.

The system will start to display data according to the selected dashboard. This data are not saved until REC is pressed (see below). Anyway, test starts automatically and begins to store data after the time set in *Settings*.

■ **Execution of the test (real time visualization)**



In order to start data storage, press **Rec**. The display will be cleared and data will now be saved in the database.

Data are displayed according to the selected dashboard. Please refer to the *Utilities/Customize views* section for more details about the dashboards and the presentation of data.

During the execution of the test, it is possible to perform many activities, explained here below.

Pause the test



In order to pause the test, press **Pause**. Data are not stored and the protocol will be paused too.

Restore the test



To restart data acquisition, press **Rec**.

Add a phase change



To add a phase change, press **Phase** and select the proper phase.

If you select *Recovery*, a message will be prompted to verify that you really want to start the recovery phase.

Enter a marker



To add a marker, press **Marker** and enter a label for it. Markers are useful to refer particular events occurred during the test.

Enter a Blood Pressure value



To enter blood pressure values, press **BP** and enter data.

Enter a RPE value



To enter a RPE value, according to the Borg scale or to the modified Borg scale, press **Dyspnea** or **Leg pain** and select the desired value.

The scale used to enter data is selected in the *Settings*.

Enter an ABG (arterial blood gases) marker



To enter an ABG sample value, press **ABG**. This will enter a marker, and during the editing it will be possible to enter the measured value for ABG.

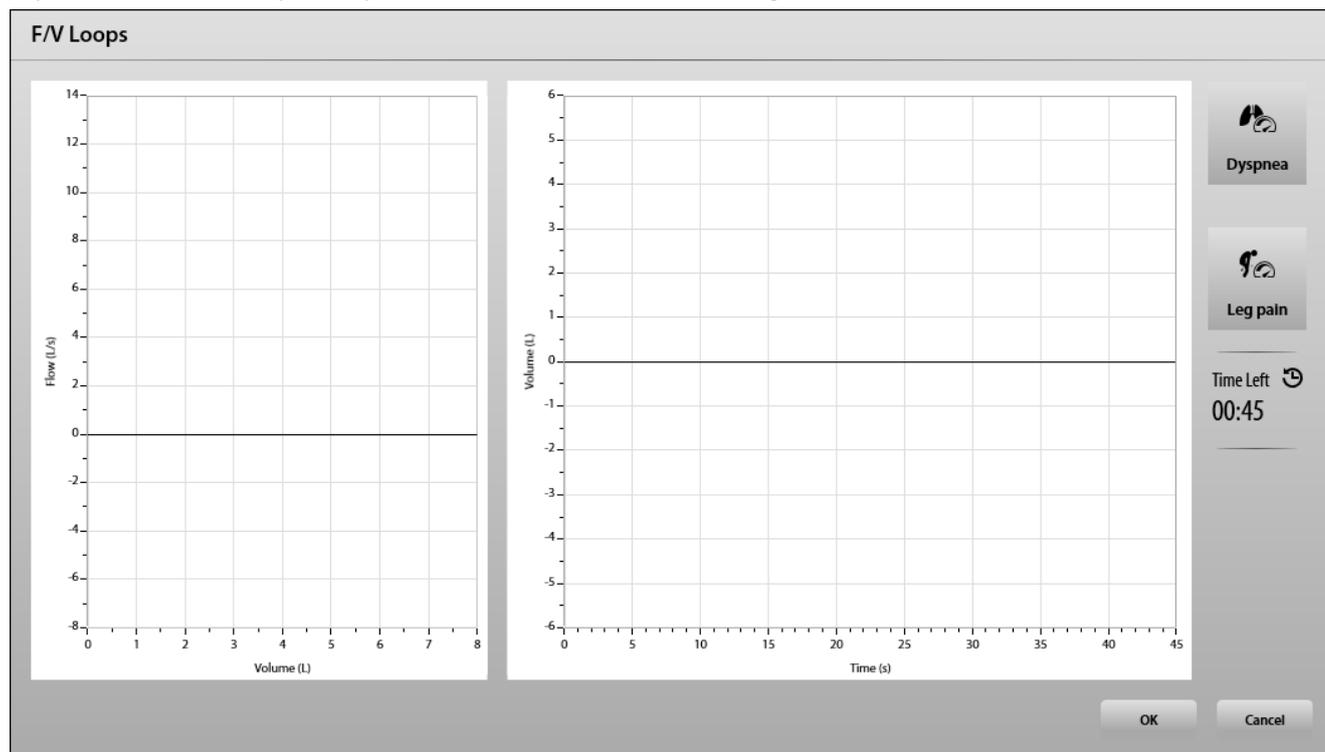
Flow/volume loops

Pulmonary function measurements may be useful during exercise testing to detect abnormalities in the mechanics of ventilation in patients with ventilatory limitations to exercise.

The test consists in acquiring Flow-Volume loops during exercise at different workloads and overlapping them on the subject's resting Flow-Volume loop.



To perform a flow/volume loops event, press **Events** and select **FV+VT**. The following window is shown.



Breathe at rest for some cycles, then perform an IC. Enter (if any) dyspnea and leg pain symptoms by clicking on the correspondent button.

At the end, press **OK** to confirm and save the loops.

It is possible to save an unlimited number of events during an exercise test.

Start the recovery phase



To start the recovery phase, press **Recovery**. A message will be prompted to verify that you really want to start the recovery phase.

Customize a graph

All the graphs can be customized in real time as described in the *Utilities/Customize views* section. Please refer to that section for more details.

Graphs can be zoomed in or out through the mouse wheel. It is possible to zoom a single axis positioning the mouse on the selected one. The zoom is centered on the position of the mouse.

Customize the tabular presentation of data

The data table can be customized according to the description reported in the *Utilities/Customize views* section. Please refer to that section for more details.

Change the selected dashboard



The dashboard can be changed by clicking on the desired dashboard in the lower part of the screen. A new dashboard can be added by pressing the + in the dashboard bar.

Change the main parameters visualization

The visualization of the main parameters (on the right of the panel) can be customized according to the description reported in the *Utilities/Customize views* section. Please refer to that section for more details.

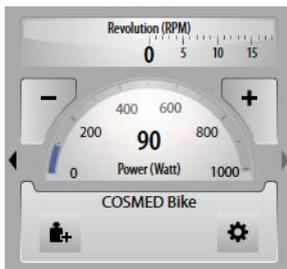
Modify the current protocol

The current protocol can be manually changed through the protocols widget. It is shown in the right lower part of the panel, only if an ergometer was selected before starting the test.

Two interfaces can be used to manually change the protocol, they can be switched through the arrows on the left or on the right side of the protocols widget.



The first one (it can be displayed only if a protocol is selected before starting the test) allows to pause the current protocol (data are stored, but the protocol doesn't proceed) or to jump to the next step.

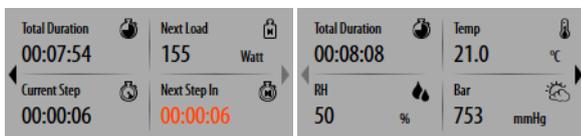


The second one shows data on the ergometer (i.e. power for the bikes, speed for the treadmills) and allows to change the load by a predetermined amount of units, through the + and - buttons.

The  icon will stop the protocol, switching to manual controls, the  icon will set the increment used with the + and - buttons.

Note: If you manually change the load, the automatic protocol (if selected) will be left, and from now on any other protocol change (load, phase, etc. . .) must be manually entered. A prompt will ask confirmation to the user.

General data widget



Under the protocols widget, the general data widget shows information about the current test (total duration, next load, duration of the current step, time to the reach the next step) and ambient data (temperature, relative humidity and barometric pressure). The two interfaces can be switched through the arrows on the left or on the right side of the general data widget.

Press the EMERGENCY STOP button (only an ergometer is selected)



The red EMERGENCY STOP button on the top right will stop the ergometer in case of emergency.

■ *Ending the test*



In order to end the test saving the data, press **Stop**. Test results will be displayed in the *Edit test* panel. See below, *Editing the test*.



In order to abort the test, without saving any data, press **Abort**.

Editing the test

When the test is ended, the *Test Edit* panel is shown to the user.



It can be also opened from the *Test Results* panel, by pressing the **Edit** button.



If an exercise phase was defined, the *Test Edit* panel includes different tabs, each of them allowing the calculation of one or more parameters.

Immediately after the conclusion of the test, only the VO_{2max} parameter is automatically calculated (its value is shown in the results table on the left and a tick is shown near the corresponding tab). All the other parameters must be calculated (manually or automatically, see below). As the calculations are performed, the parameters in the results table are updated with the calculated data and the corresponding tabs are ticked.

Note: The **Save** button saves all the changes and exits from the *Test Edit* panel, showing the *Test Results* panel. To save a single change on one of the tabs, it is enough to change tab. Changes will be automatically saved.

In any case, the original test won't be overwritten. You always can restore the original test by pressing Upload Raw Data (see below).

Overview tab

This tab is divided in four sections.

The first one (on the top left corner) reports the test information (subject type, test type, FVC and FEV1 post exercise, if performed), and can be modified by the user.

Note: If the test type is changed, all the parameters must be recalculated.

The second one (below the test information one) reports the calculated parameters, together with their normal range, the predicted values and the percentage of the predicted.

The third one (bottom left) reports other test information (the time of the test, the ergometer and the protocol used).

On the right side, four graphs show the main parameters. Each graph can be customized as described in the *Utilities/Customize views* section. Please refer to that section for more details.

Graphs can be zoomed in or out through the mouse wheel. It is possible to zoom a single axis positioning the mouse on the selected one. The zoom is centered on the position of the mouse.



Buttons on the left allows to:

- Show general information on the test (**Info**)
- Show the calibration data for the current test (**Calibration**)
- Edit and filter the test steps (**Edit & Filter**)
- Edit the ABG information (**Edit ABG**)

General information

Info

Ambient Temperature (°C): 26.0
 Ambient Relative Humidity (%): 50
 Barometric Pressure (mmHg): 760
 Flowmeter temperature (°C): 34.0
 Flowmeter Relative Humidity (%): 100
 STPD correction factor (→): 0.8261
 Inspiratory BTPS correction factor (→): 1.087
 Expiratory BTPS correction factor (→): 1.020

OK

This window shows ambient data and correction factors in the current test.

Edit and filter the steps

Note: If data are edited / filtered, all the parameters must be recalculated.

subject: SUBJECT DEMO gender: Male age: 48 weight: 97.00 kg height: 195 cm

CPET BREATH BY BREATH EDIT

Data Filtering: None

Delete Steps

Discard Invalid Steps

Load Protocol

Advanced Edit

Restore

Upload Raw data

VO₂, VCO₂ vs t

VE, Rf vs t

t	h:mm:ss	Ignore	Marker	Phase	HR bpm	Amb. Temp. °C	Analyz. Press. mmHg	PB mmHg	RH Amb %	FIO ₂ %	FICO ₂ %	SpO ₂ %	Tl s	Te s
<input type="checkbox"/>	00:01	<input type="checkbox"/>		None	85	25.3	626	746	52	20.87	0.08	98	1.15	0.83
<input type="checkbox"/>	00:04	<input type="checkbox"/>		Rest	82	25.3	626	746	52	20.86	0.09	98	1.17	1.51
<input type="checkbox"/>	00:07	<input type="checkbox"/>		Rest	80	25.3	625	746	52	20.87	0.09	98	1.14	1.42
<input type="checkbox"/>	00:09	<input type="checkbox"/>		Rest	79	25.3	625	746	52	20.88	0.09	98	1.13	1.81
<input type="checkbox"/>	00:11	<input type="checkbox"/>		Rest	78	25.3	625	746	52	20.88	0.08	98	1.11	1.87
<input type="checkbox"/>	00:15	<input type="checkbox"/>		Rest	78	25.3	625	746	52	20.85	0.10	97	1.12	1.96
<input type="checkbox"/>	00:18	<input type="checkbox"/>		Rest	78	25.3	625	746	52	20.85	0.10	97	1.12	2.10
<input type="checkbox"/>	00:22	<input type="checkbox"/>		Rest	77	25.3	625	746	52	20.85	0.10	97	1.15	2.20
<input type="checkbox"/>	00:25	<input type="checkbox"/>		Rest	77	25.3	625	746	52	20.85	0.10	97	1.18	2.10
<input type="checkbox"/>	00:28	<input type="checkbox"/>		Rest	76	25.3	625	746	52	20.85	0.10	97	1.19	2.04
<input type="checkbox"/>	00:32	<input type="checkbox"/>		Rest	75	25.3	625	746	52	20.88	0.08	97	1.20	1.98
<input type="checkbox"/>	00:35	<input type="checkbox"/>		Rest	75	25.3	625	746	52	20.88	0.08	97	1.19	1.96
<input type="checkbox"/>	00:38	<input type="checkbox"/>		Rest	75	25.2	625	746	52	20.84	0.10	97	1.20	2.02
<input type="checkbox"/>	00:41	<input type="checkbox"/>		Rest	75	25.2	625	746	52	20.82	0.11	97	1.20	1.97
<input type="checkbox"/>	00:44	<input type="checkbox"/>		Rest	75	25.1	625	746	52	20.82	0.11	97	1.23	1.96
<input type="checkbox"/>	00:48	<input type="checkbox"/>		Rest	76	25.1	625	746	52	20.82	0.11	97	1.22	2.02
<input type="checkbox"/>	00:51	<input type="checkbox"/>		Rest	76	25.1	625	746	52	20.82	0.11	97	1.23	2.07
<input type="checkbox"/>	00:54	<input type="checkbox"/>		Rest	76	25.1	625	746	52	20.86	0.09	97	1.39	2.18
<input type="checkbox"/>	00:57	<input type="checkbox"/>		Rest	77	25.1	625	746	52	20.88	0.08	98	1.50	2.09

Phase Filter: None Rest Warm Up Exercise Recovery

Time Filter: 00:01 - 13:15

00:01 13:15

Accept Cancel

The *Edit and filter* panel allows to edit and/or filter the steps of the test.

On the top left, it is possible to set the data filtering option (according to the options already described in the *Settings* chapter), by selecting the desired algorithm in the list.

It is also possible to edit single steps by clicking on the value to be changed and entering the new value.

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To ignore one or more steps, select the corresponding checkbox(es) in the *Ignore* column.

In order to make easier the search of a step, you can use the tools below the data table. You can filter data by phase (checking the phases to be shown) or by time (moving the cursors of the time bar).

Note: these filters do not affect the test data, they are a search tool only.

You can also add ABG markers in a desired step, by checking the corresponding checkbox in the *ABG* column (you should right-scroll the table in order to view the ABG column).



The **Delete Steps** button deletes the steps selected in the table on the right.



The **Discard Invalid Steps** button deletes the invalid steps (according to the custom settings, see the *Settings* chapter).



The **Load Protocol** button allows to load a different ergometer and protocol on a selected time interval.



Select the ergometer, the protocol and the time interval, and press **OK** to confirm, **Cancel** to abort. The time interval can be selected through the time bar below the graph or by moving the start and end markers (the dotted vertical lines) with the mouse.



The **Advanced Edit** button allows to perform an advanced edit of the steps.

Advanced Edit

Delete Step

Edit Parameter

Parameter: ▾

Value

Correction %

Offset

Smoothing ▾

Time Range

Parameter Range

Parameter	Condition	Value
<input type="text" value="Amb. Temp."/> ▾	<input type="text" value="<"/> ▾	<input type="text" value="0"/>

In particular, it is possible to delete steps (*Delete Step*) or edit parameters (*Edit Parameter*) according to the criteria defined in the same window.

If you want to edit a parameter, you can select in the *Edit Parameter* section the parameter to be edited, together with the correction to be applied:

- *Value* replace all the values with the entered one
- *Correction %* changes all the values by the entered percentage
- *Offset* adds the entered offset to the values
- *Smoothing* performs a smoothing on the entered number of steps

The deletion or the edits are applied to the steps in the defined time range (if the *Time Range* checkbox is selected) or according to the values of a specified parameter (if the *Parameter Range* checkbox is selected).

- If the *Time Range* checkbox is selected, please select the time range by moving the cursors on the time bar
- If the *Parameter Range* checkbox is selected, please select the conditioning parameter, the condition (equal [=], different [<>], minor [<], minor or equal [<=], major or equal [>=], major [>]) and the value to be compared.



The **Restore** button allows to restore steps as they were after the last data saving.



The **Upload Raw Data** button allows to restore steps in raw format (breath by breath), discarding all the edits performed on this test, even if they were saved.

To accept change press **Accept**, to abort the operation press **Cancel**.

Edit ABG information

Edit ABG Markers

t hh:mm:ss	PaCO2 mmHg	pH	SaO2 %	HCO3- meq/L	La- mmol/L	BE meq/L	Hb mmol/L	PaO2 mmHg
02:02	-	-	-	-	-	-	-	-
04:25	-	-	-	-	-	-	-	-
06:35	-	-	-	-	-	-	-	-
09:21	-	-	-	-	-	-	-	-
11:24	-	-	-	-	-	-	-	-
13:59	-	-	-	-	-	-	-	-
18:23	-	-	-	-	-	-	-	-

It is possible to enter the ABG values for all the ABG markers entered during or after the test (if present). Double click on a cell to enter a value for this cell.

VO2 Max tab



The VO_2 Max tab allows the calculation of the VO_2 Max, and it is the only tab automatically calculated at the end of the test.

However, it is possible to change the time interval for the VO_2 Max calculation, through the time bar below the graphs or by moving the start and end markers (the dotted vertical lines on the VO_2 vs time graph) with the mouse. The purple horizontal line represents the VO_2 Max value.

The *Max Effort Confirmed* checkbox should be checked if the operator detects that the maximum effort has been reached during the test, according to the international guidelines.

You can fully customize only the graph on the bottom right. Other graphs allows limited customization.



Buttons on the left allows to:

- Show general information on the test (**Info**)
- Show the calibration data for the current test (**Calibration**)

- Autodetect the time interval for the VO_2Max calculation (**Autodetect**)
- Restore the changes to the last saving (**Restore**)

On the bottom left, the main parameters (VO_2 , VO_2/Kg , R_{max} , RPE_{max} and HR_{max}) are updated according to your choices.

■ Thresholds tab



The *Thresholds* tab allows the calculation of the AT (anaerobic threshold) and of the RC (Respiratory Compensation).

Note: This tab requires that the test includes Exercise and Recovery phases.

It is possible to select the time of the AT and RC through the time bar below the graphs or by moving the two markers (the dotted vertical lines on the graphs) with the mouse.

If you are not able to identify AT and/or RC, press the *No AT Point* and/or *No RC Point* button(s).

You can fully customize only the graph on the bottom right. Other graphs allows limited customization.

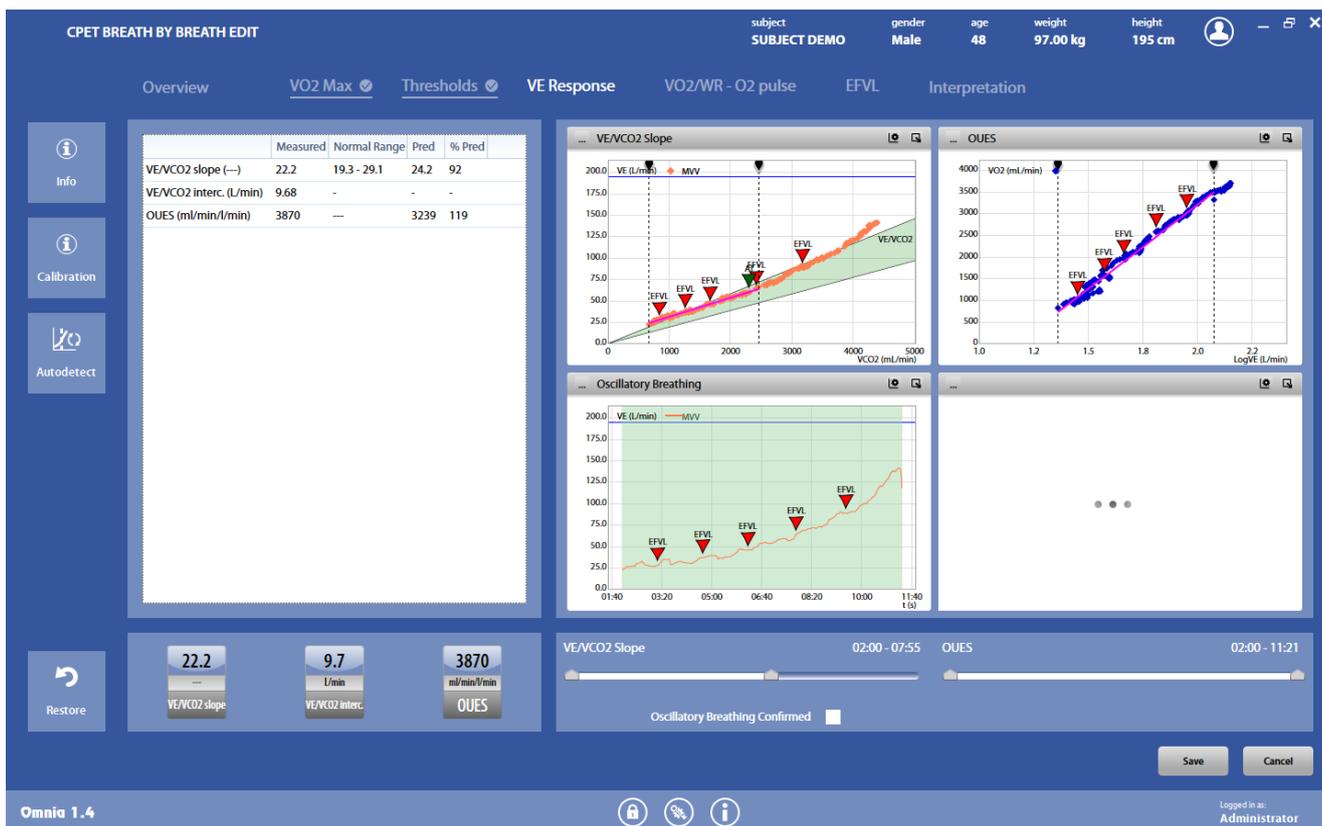


Buttons on the left allows to:

- Show general information on the test (**Info**)
- Autodetect the time intervals for the AT and the RC (**Autodetect**)
- Show the regression lines for the detection of the anaerobic threshold (**Regressions**)
- Show a square on the VCO_2 vs VO_2 graph in order to simplify the AT detection (**Square**). The square can be moved with the mouse or through the two *Square* bars below the graphs.
- Show a magnifier on the VCO_2 vs VO_2 graph (**Magnifier**). The magnifier can be moved with the mouse
- Restore the changes to the last saving (**Restore**)

On the bottom left, the main parameters (AT, AT as percentage of the VO_2max , RC, RC as percentage of the VO_2Max) are updated according to your choices.

■ VE Response tab



The *VE Response* tab allows the calculation of the VE/VCO_2 slope and of the OUES (Oxygen Uptake Efficiency Slope).

It is possible to change the time interval for the VE/VCO_2 slope calculation and for the OUES calculation through the corresponding time bars below the graphs or by moving the start and end markers (the dotted vertical lines on the corresponding graph) with the mouse.

The *Oscillatory Breathing Confirmed* checkbox should be checked if the operator confirms the presence of oscillatory breathing.

You can fully customize only the graph on the bottom right. Other graphs allows limited customization.



Buttons on the left allows to:

- Show general information on the test (**Info**)
- Show the calibration data for the current test (**Calibration**)
- Autodetect the time intervals for the VE/VCO_2 slope and the OUES (**Autodetect**)
- Restore the changes to the last saving (**Restore**)

On the bottom left, the main parameters (VE/VCO_2 slope, OUES) are updated according to your choices.

VO₂/WR - O₂ pulse tab

CPET BREATH BY BREATH EDIT

subject: SUBJECT DEMO, gender: Male, age: 48, weight: 97.00 kg, height: 195 cm

Overview | VO₂ Max | Thresholds | VE Response | **VO₂/WR - O₂ pulse** | EFVL | Interpretation

	Measured	Normal Range	Pred	% Pred
VO ₂ /WR Slope (mL/min/Watt)	9.46	8.40 - 11.00	10.00	95
R ²	0.99	-	-	-

Info | Calibration | Autodetect | Restore

VO₂ vs Power: Graph showing VO₂ (mL/min) vs Power (Watt) with EFVL markers.

VO₂/HR vs t: Graph showing VO₂/HR (mL/beat) vs time (t) with EFVL markers.

Exercise Phase Interval: 03:37 - 11:12

VO₂/WR Behaviour: Continual Rise | VO₂/HR Behaviour: Continual Rise Throughout Exercise

Save | Cancel

Omnia 1.4 | Logged in as: Administrator

The VO₂/WR - O₂ pulse tab allows the calculation of the VO₂/WR slope.

It is possible to change the exercise phase interval for the VO₂/WR slope calculation through the corresponding time bar below the graphs or by moving the start and end markers (the dotted vertical lines on the VO₂ vs Power graph) with the mouse.

It is also possible to define the VO₂/WR and VO₂/HR behaviours after the observation of the graphs.

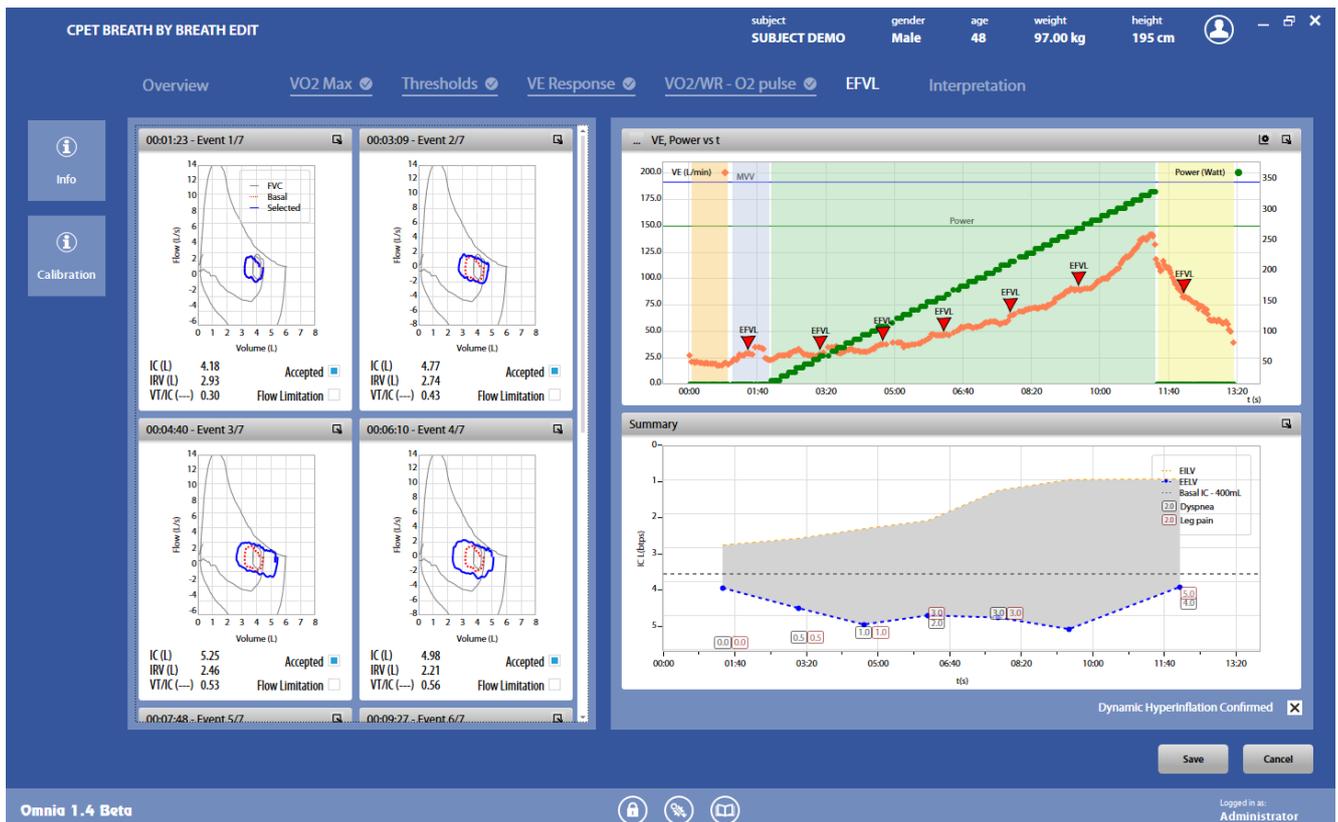
Both graphs allows limited customization.



Buttons on the left allows to:

- Show general information on the test (**Info**)
- Show the calibration data for the current test (**Calibration**)
- Autodetect the time interval for the VO₂/WR slope (**Autodetect**)
- Restore the changes to the last saving (**Restore**)

On the bottom left, the main parameters (VO₂/WR slope, R² for the regression line) are updated according to your choices.



The EFLV tab allows the visualization of the flow/volume loop events stored during the tests, overlapped with the FVC-pre curve, if available in the same visit card.

Each event can be accepted or not, and for each event one of the loops must be selected.

On the left side, all the flow/volume loops events stored during the test are shown. For each event, the curves are colored as follows:

- the FVC-pre curve in grey
- the basal loop (i.e. the selected loop of the first accepted event) in orange
- the accepted loop of the current event in blue

Not accepted events are also shown in this side, but an X watermark is superimposed on them.

On the right side, two graphs show:

- the VE and Power vs. time (this graph can be however fully customized)
- the summary of all the accepted events. For each accepted event, it is shown the EILV, the EELV, the dyspnea and the leg pain values for the corresponding selected loop. It is also shown an horizontal dotted line representing the basal IC minus 400 ml. If an EELV value is less than this line (i.e. the graph is above the line), a possible dynamic hyperinflation is detected, and the corresponding checkbox must be checked if the operator confirms it. The distance between the EILV and EELV, graphically represented by the grey area, is the Vt (Tidal volume).



Buttons on the left allows to:

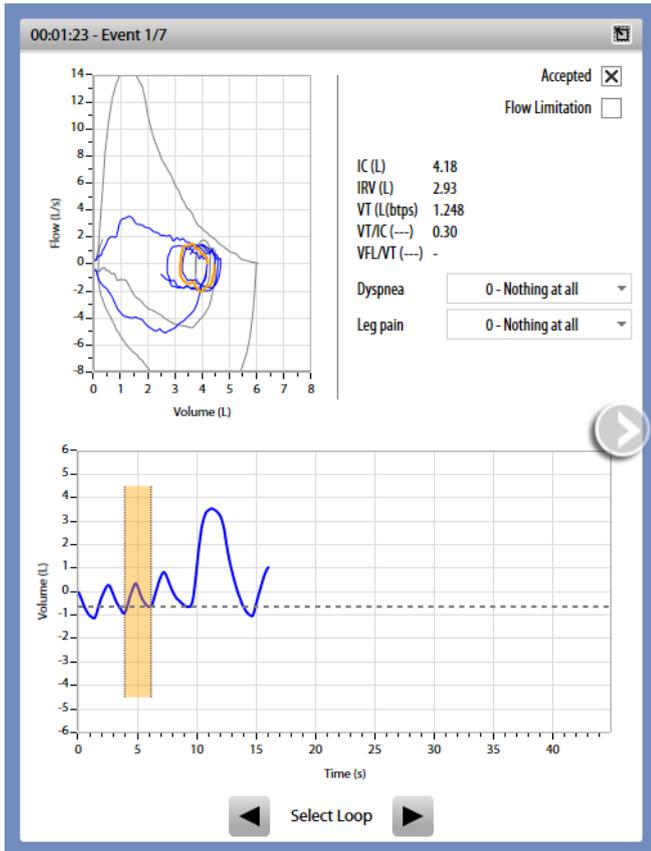
- Show general information on the test (**Info**)
- Show the calibration data for the current test (**Calibration**)

Events edit

By pressing the  icon in an event window, you can access the corresponding edit interface. Each edit will reflect in real time in the graphs on the right side.

- The event is accepted if the *Accepted* checkbox is checked. If the event is not accepted, its values are not shown in the graphs on the right.
- It is possible to choose the representative loop for this event by means of the arrows below the V/t graph, and to edit the symptoms (dyspnea and leg pain).

- The values shown near the F/V graph refer to the selected loop.
- If the selected loop is partially above the FVC curve, a flow limitation occurs, and the VFL/VT value is shown, indicating the portion of the loop above the FVC curve. In this case, the operator can check the checkbox *Flow limitation* to confirm it.



The dotted line in the V/t graph shows the EELV value.

By means of the arrows on the left and on the right you can access the other F/V events.

■ Interpretation tab

CPET BREATH BY BREATH EDIT

subject: SUBJECT DEMO, gender: Male, age: 48, weight: 97.00 kg, height: 195 cm

Overview | VO2 Max | Thresholds | VE Response | VO2/WR - O2 pulse | EFVL | Interpretation

Reason for test: Exercise Capacity
Reason for stopping test: LegFatigue
Test Purpose: Educational
Test Position: Sitting
ECG Response: None
Best: X

Tech. Notes

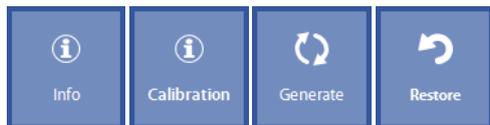
Interpretation: At peak of exercise respiratory exchange ratio is 1.17, heart rate is 98% of predicted and maximum Rate of Perceived Exertion is Somewhat strong for dyspnoea and Strong for leg pain. Subject achieved maximal effort. Maximum oxygen uptake is 3610 mL/min (117% of the predicted value) indicating a normal Aerobic Exercise Capacity. Anaerobic threshold has been identified at 2478 mL/min and at 80% of the VO2max predicted (69% of measured VO2max), which is normal. VE/VO2 slope is 22.2 and VE/CO2@AT is 26.2, which are both within normal range. This indicates a normal ventilatory efficiency. Breathing Reserve at peak exercise is 39.4%, which is normal. This indicates an absence of exercise ventilatory limitation. Variation of IC is -0.03 L. Dynamic hyperinflation is confirmed. Heart rate reserve is 4 bpm, which is normal. Heart rate recovery after 1 minute is 29 bpm, which is normal. Oxygen pulse at peak exercise is 21.5 mL/beat, corresponding to 120% of predicted, which is normal. VO2/WR slope is 9.46 mL/min/Watt. This indicates a normal aerobic work efficiency. Maximal systolic blood pressure achieved during exercise is 130 mmHg, which is normal. SpO2 during exercise did not significantly decrease.

Info | Calibration | Generate | Restore

Save | Cancel

Omnia 1.4 Beta | Logged in as: Administrator

The *Interpretation* tab allows entering custom information of the test and a personal interpretation by the physician.



Buttons on the left allows to:

- Show general information on the test (**Info**)
- Show the calibration data for the current test (**Calibration**)
- Automatically generate an interpretation (**Generate**) according to international guidelines (ESC, AHA, ACSM, ...)
- Restore the changes to the last saving (**Restore**)

Viewing the results



To view a test, press in the subject database the **...** on the left of the test and then the **View** button or double click on the test. In this panel, data and graphs are not editable by the user.

Test results are accessed also by pressing **Save** in the *Test edit* panel.

The screenshot shows the 'CPET BREATHE BY BREATH RESULTS' interface. At the top, subject information is displayed: SUBJECT DEMO, Male, 48 years old, 75.00 kg, 178.0 cm, visit date 25/09/2015. Below this are tabs for Results, EFVL, Dashboards, and Interpretation. The main area is divided into several sections:

- Information:** Test Time 11:26, Test Duration 13:14, Exercise Duration 09:21, Subject Type Clinical, Test Type Maximal, Ergometer COSMED Bike, Protocol 35 Watt Ramp. Maximal Effort Confirmed, ECG Response None, Reason for test Exercise Capacity, Reason for stopping test Leg pain, Test Position Sitting, Test Purpose Educational.
- Spirometry Table:**

	Pre	% Pred	Normal	Class
FVC	L 6.07	120		
FEV1	L 4.80	120	> 4.32	
MVV	L/min 192.0	-		
- Protocol Table:**

	Meas.	Rest	Warm Up	AT	RC	Max	Normal
t	s		07:46	09:51	11:21		
Power	Watt		0	203	280	329	> 213
Revolution	RPM		78	76	76	88	
- Metabolic Table:**

	Meas.	Rest	Warm Up	AT	RC	Max	Normal
VO2	mL/min	646	897	2478	3112	3610	> 2138
VO2/Kg	mL/min/Kg	8.6	12.0	33.0	41.5	48.1	> 28.5
METS	---	2.5	3.4	9.4	11.9	13.8	> 8.1
RQ	---	0.78	0.85	0.93	1.06	1.17	> 1.10
- Ventilatory Table:**

	Meas.	Rest	Warm Up	AT	RC	Max	Normal
VE/VCO2 slope	---	22.2					< 30.4
OUES	ml/min/l/min	3870					> 2724
VE	L/min	19.8	27.8	60.4	93.2	118.3	
BR	%			68.6	51.5	38.4	> 15.0
- Cardiovascular Table:**

	Meas.	Rest	Warm Up	AT	RC	Max	Normal
HR	bpm	76	88	132	151	168	> 155
HRR	bpm	4					< 15
- Graph:** A line graph titled 'VO2/Kg, HR vs t' showing VO2 (red line) and HR (purple line) over time. The x-axis is time in minutes (00:00 to 13:20). The y-axis for VO2 is mL/min/Kg (0 to 50.0) and for HR is bpm (50 to 175). Key points are marked with red triangles and labeled 'EFVL'.
- VO2 Progress Bar:** A horizontal bar at the bottom right shows the current VO2 value of 3610 mL/min, with a scale from 2138 to 3610.

The results panel contains four tabs, described below.



Buttons on the left (common to all the tabs) allows to:

- Edit the test (**Edit**)
- Show test info (**Info**)
- Open the corresponding ecg, if any (**Ecg**)
- Export the GPS track as a kml file or open it in CESIUM, according to the settings (**Geotag**). This function is available only for those tests with GPS data stored.
- Export the test in an Excel file (**Save as *.xlsx**)
- Print the test report (**Print**)

Results tab

The *Results* tab reports information and results of the test:

- On the top screen, general information on the test
- On the bottom left, the results, in summary format, as defined in *Utilities/Customize views*, according to the subject type.

- On the bottom right, a graph as defined in *Utilities/Customize views*. The graph can be customized as described in the *Utilities/Customize views* section. Please refer to that section for more details. It can also be zoomed in or out through the mouse wheel. It is possible to zoom a single axis positioning the mouse on the selected one. The zoom is centered on the position of the mouse.
- Under the graph, a gauge with a graphical interpretation of the result. For healthy subjects only, a rank assessment of it (from *very poor* to *superior*).

■ EFVL tab

CPET BREATH BY BREATH RESULTS subject: SUBJECT DEMO gender: Male age: 48 weight: 75.00 kg height: 178.0 cm visit date: 25/09/2015

Results **EFVL** Dashboards Interpretation

Information

Test Time: 11:26	Test Duration: 13:14	Exercise Duration: 09:21	Subject Type: Clinical	Test Type: Maximal	Ergometer: COSMED Bike	Protocol: 35 Watt Ramp
Maximal Effort: Confirmed	ECG Response: None	Reason for test: Exercise Capacity	Reason for stopping test: Leg pain	Test Position: Sitting	Test Purpose: Educational	

Data

F/V Loops		#1 (Basal)	#2	#3	#4	#5	#6	#7
t	s	01:23	03:09	04:40	06:10	07:48	09:27	12:02
Power	Watt	0	49	98	147	210	266	0
IRV	L	2.93	2.74	2.46	2.21	1.33	1.01	0.99
IC	L	4.18	4.77	5.25	4.99	5.05	5.39	4.15
VT	L (btps)	1.248	2.036	2.797	2.773	3.722	4.376	3.158
ERV	L	1.89	1.30	0.82	1.08	1.02	0.68	1.92
VT/IC	---	0.30	0.43	0.53	0.56	0.74	0.81	0.76
VT/FVC	---	0.21	0.34	0.46	0.46	0.61	0.72	0.52
IRV/FVC	---	0.48	0.45	0.40	0.36	0.22	0.17	0.16
ERV/FVC	---	0.31	0.21	0.13	0.18	0.17	0.11	0.32
Dyspnea	---	0	0.5	1	2	3	-	4
Leg Pain	---	0	0.5	1	3	3	-	5
Δ IC	L	0.00	0.59	1.07	0.80	0.87	1.21	-0.03

VE, Power vs t

Summary

Δ IC L: -0.03

The *EFVL* tab contains information about flow/volume loop events stored during the test, both in tabular and graphical format:

- On the top screen, general information on the test
- On the middle left, the results, in summary format, for each stored and accepted event. This section can be expanded or reduced by means of the arrow on the left.
- On the bottom left, the graphical representation of each stored and accepted event. This section can be expanded or reduced by means of the arrow on the left.
- On the bottom right, two graphs: the VE and Power vs. time graph and the summary graph. Both graphs has already been described in the *Edit* section.

The first graph can be customized as described in the *Utilities/Customize views* section. Please refer to that section for more details. It can also be zoomed in or out through the mouse wheel. It is possible to zoom a single axis positioning the mouse on the selected one. The zoom is centered on the position of the mouse.

- Under the graphs, a gauge with a graphical interpretation of the IC variation in order to detect dynamic hyperinflation.

■ Dashboards tab



The *Dashboard* tab contains the dashboards defined for real time viewing (left part only). Please refer to the *Utilities/Customize views* section for more details about the dashboards and the presentation of data.

The dashboard can be changed by clicking on the desired dashboard in the lower part of the screen. A new dashboard can be added by pressing the + in the dashboard bar.

■ Interpretation tab

The screenshot shows the 'Interpretation' tab of the CPET software. The top header includes a navigation bar with 'Results', 'EFVL', 'Dashboards', and 'Interpretation'. A subject information bar at the top right lists: subject (SUBJECT DEMO), gender (Male), age (48), weight (75.00 kg), height (178.0 cm), and visit date (25/09/2015). On the left side, there is a vertical toolbar with icons for 'Edit', 'Info', 'ECG', 'Geotag', 'Save as *.xlsx', and 'Print'. The main content area is divided into two sections: 'Operator Notes' (currently empty) and 'Interpretation'. The 'Interpretation' section contains the following text:

At peak of exercise respiratory exchange ratio is 1.17, heart rate is 98% of predicted and maximum Rate of Perceived Exertion is Somewhat strong for dyspnoea and Strong for leg pain. Subject achieved maximal effort.
Maximum oxygen uptake is 3610 mL/min (117% of the predicted value) indicating a normal Aerobic Exercise Capacity.
Anaerobic threshold has been identified at 2478 mL/min and at 80% of the VO2max predicted (69% of measured VO2max), which is normal.
VE/VCO2 slope is 22.2 and VE/VCO2@AT is 26.2, which are both within normal range. This indicates a normal ventilatory efficiency.
Breathing Reserve at peak exercise is 39.4%, which is normal. This indicates an absence of exercise ventilatory limitation.
Variation of IC is -0.03 L. Dynamic hyperinflation is confirmed.
Heart rate reserve is 4 bpm, which is normal.
Heart rate recovery after 1 minute is 29 bpm, which is normal.
Oxygen pulse at peak exercise is 21.5 mL/beat, corresponding to 120% of predicted, which is normal.
VO2/WR slope is 9.46 mL/min/Watt. This indicates a normal aerobic work efficiency.
Maximal systolic blood pressure achieved during exercise is 130 mmHg, which is normal.
SpO2 during exercise did not significantly decrease.

The bottom status bar shows 'Omnia 1.6 Beta', system icons, and 'Logged in as: Administrator'.

The *Interpretation* tab reports the technician notes and the interpretation, entered during the editing steps.

Resting Energy Expenditure Test

PFT

CPET

RMR

☐ **Metabolism**

Metabolism involves the process of converting food and accumulated fat into energy within the human body. Energy is used by the body to maintain a constant temperature, for movement and activity and to allow the organs to function. Metabolism is measured in kilocalories (kcal) or kilojoules (kJ).

■ **Total Metabolic Rate**

The Total Metabolic Rate is the number calories that the human body needs in order to perform daily functional activities.

■ **Resting Energy Expenditure (REE)**

The Resting Energy Expenditure is the minimum caloric requirement of the organism in order to sustain life. This includes calories for the vital organs to properly operate at rest (heart, brain, lungs, liver, kidneys, etc.). The REE accounts for 60 - 75% of the Total Metabolic Rate.

■ **Importance of measuring REE**

The REE measurement acts as a precise tool in determining a subject's basal nutritional requirements. The measurement provides information that allows for adequate planning of nutritional goals.

■ **Measuring Resting Energy Expenditure with Indirect Calorimetry**

Energy Expenditure can be measured with direct calorimetry by putting the subject in a calorimeter and measuring the amount of heat produced by the body mass.

Direct calorimetry can be very expensive and impractical and therefore is not commonly performed in the clinical setting. Energy Expenditure can also be measured indirectly with a metabolic cart. Gas exchange is analyzed to determine the volume of air passing through the lungs, the uptake of oxygen (VO_2) and the amount of Carbon Dioxide expelled to atmosphere (CO_2 output – VCO_2). These measurements allow the Resting Energy Expenditure (REE) and the Respiratory Quotient (RQ) to be calculated.

The RQ represents the ratio of carbon dioxide exhaled to the amount of oxygen consumed by the individual. RQ assists in the interpretation of the REE results.

The abbreviated Weir equation is a commonly used method to calculate the REE.

Abbreviated Weir equation:

$$\text{REE} = [3.9 (\text{VO}_2) + 1.1 (\text{VCO}_2)] 1.44$$

Recommendations for performing a REE measurement

General recommendations

To allow for optimal conditions prior to, during and after the REE measurement:

- The subject is recommended not to eat for at least 12 hours prior to the measurement. Smoking is refrained for at least 2 hours before the measurement
- Testing conditions should optimally remain quiet throughout the procedure, and a normal room temperature must be maintained.
- A steady state should be achieved during the test, which is defined as a 5 minute period when the average minute VO_2 and VCO_2 changes by less than 10% and the average RQ changes by less than 5%.
- The subject should refrain from moving during the test.
- Medications recently taken should be noted (particularly stimulants or depressants).
- A test of minimum 15-20 minutes is recommended to assure stable, interpretable measurements.
- The first 5 minutes of data acquisition should be discarded when performing the test.
- Patients requiring Renal Replacement Therapy (RRT) should not be tested during dialysis.

Before starting a REE test you should calibrate the ID18 turbine and the analyzers by performing the Ergo calibration. The calibration procedure can be reviewed in the *Calibration* chapter.

Note: After turning the device on wait at least the recommended warm-up time before beginning calibration or testing procedures.

Resting Energy Expenditure test using a Canopy

1. Do not measure a comatose or incapacitated patient with the canopy in a place without a source of back-up power to assure continuous operation of the flow generator in the event of a power failure.
2. Constant attention by a qualified individual is required whenever a patient is mechanically ventilated. Some equipment malfunctions require immediate action. A malfunction may pass unnoticed in spite of equipment alarms.
3. Constant attention by a qualified individual is required whenever a patient is measured with the canopy. Problems in delivery of fresh gas may pass unnoticed in spite of alarms. Use a pulse oximeter to ensure that the patient is sufficiently oxygenated.
4. Verify (before and during the test) that the FeCO_2 falls within the range 0.7%-1.3% and adjust the flow rate of the pump as necessary. If the FeCO_2 is too low you should decrease the flow rate and if the FeCO_2 is too high you should increase the flow rate. A low FeCO_2 may result in unreliable measurements, while a high FeCO_2 could be dangerous for the patient.

In order to adjust the flow, please rotate the knob (hardware or software, depending on the device used)

	<p>PFT CPET For Quark PFT and Quark CPET, placed on the Canopy unit (connected to the Quark).</p>
	<p>RMR For first generation Quark RMR devices, placed on the flow adjustment unit (connected to the Quark). These units can be recognized if the last four digits of their S/N are below 1000.</p>
	<p>RMR For most recent Quark RMR devices, control via software. These units can be recognized if the last four digits of their S/N are 1000 or above.</p>

The knob for flow adjustment is very sensitive. For this reason the adjustment must be performed by rotating the knob very carefully. After having modified the flow, please wait at least 30 seconds in order to visualize the variations.

7. Do not place the canopy hood over a patient's head before connecting the tube and applying a continuous flow from the canopy blower.
8. In order to obtain reliable results, check the integrity of hood, veil and gasket before testing.

■ Resting Energy Expenditure test on mechanically ventilated patients

RMR

Warning: Carefully re-check ventilator functionality after connection of the parts.

Warning for tests with turbine: Accurate measurements occur only if:

1. Ventilator output provides only patient's exhaled air and ventilator bias flow
2. Ventilator bias flow is properly detected and set in the Quark RMR.

If the points above cannot be complied, the measurement will not be valid.

Warning: This equipment must only be used under the supervision of qualified medical staff, so that help is available immediately if any faults or malfunctions occurred.

1. The REE measurement is compatible with all volume-controlled and pressure-controlled modes of mechanical ventilation as well as modes of spontaneous/assisted ventilation. For patients on non-invasive mechanical ventilation (NIV) the measurement cannot be applied.
2. Measurements with the Quark RMR ICU are not valid in mechanically ventilated patients with a FiO₂ above 60%. When overcoming a FiO₂ of 50%, the measurement becomes less reliable according to the bibliographic reference.
3. Make sure that all parts of the pneumatic circuit are properly connected and no leakages are present in the system. Leakages can cause the measurement to be incorrect.
4. In order to prevent leakages in the endotracheal tube/tracheostomy make sure that sufficient cuff-pressure has been obtained. Measurements performed on un-cuffed patients will not be valid.
5. For tests with turbine only: at the output of the ventilator only the exhaled patient air and the ventilator bias flow must be present.
6. Maximum REE test duration must be 30 minutes, and the humidifier cannot be on during the test.
7. Any measurement which reveals data outside of acceptable limits, should be questioned for accuracy. During measurements, efforts should be made to correct for errors in sampling of exhaled gases. It is important that the operator remains at the bedside during measurement to check for the quality of the measurement
8. Quark RMR cannot be used during nebulization therapy.

□ Measured parameters

The main parameters measured or calculated during a REE test include (parameters are grouped according to the OMNIA classification) (some units of measurements can be changed in the settings):

<i>Group</i>	<i>Symbol</i>	<i>UM</i>	<i>Parameter</i>
Metabolic	RMR	kcal/day	Resting Metabolic Rate
	R	---	Respiratory Exchange Ratio
	VO ₂	ml/min	Oxygen consumption
	VCO ₂	ml/min	Carbon dioxide production
Ventilatory	VE	l/min	Ventilation
	Rf	1/min	Respiratory frequency
	FeO ₂	%	Fractional concentration of expired oxygen
	FeCO ₂	%	Fractional concentration of expired carbon dioxide
	FiO ₂	%	Fractional concentration of inspired oxygen
Substrates	FiCO ₂	%	Fractional concentration of inspired carbon dioxide
	FAT	kcal/day	Fat
	FAT%	%	Fat%
	CHO	kcal/day	Carbohydrate
	CHO%	%	Carbohydrate%
	PRO	kcal/day	Protein
PRO%	%	Protein%	

Note: the parameters listed above are the ones that can be shown in the results section. The tabular data presentation can contain many more parameters, according to the settings.

□ **The test with mask**

A physician's presence is not necessary during REE testing as long as the clinical staff has been adequately trained and educated on the testing procedure and device.

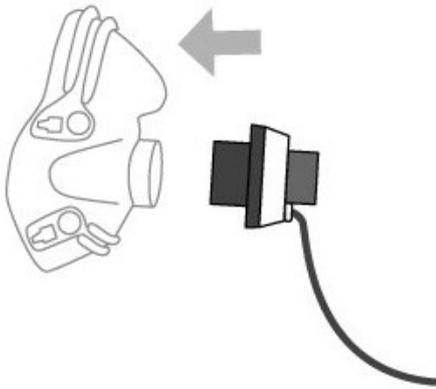
Note: Cellular phones should be turned off to eliminate potential electrical interferences.

■ **Calibrations**

Before performing the test an ERGO calibration must be performed (see *Calibration* chapter) and a Turbine calibration is recommended (see Recommendations in this chapter).

■ **Preparing the patient**

Connect the head cap, the RMR mask and the ID18 turbine as shown in the following picture:

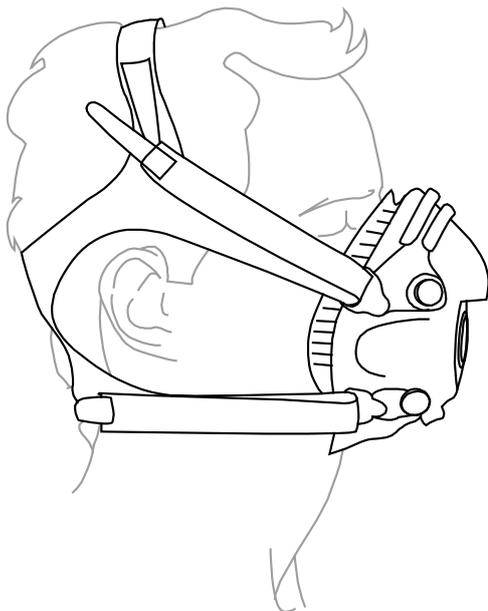


The head cap and mask can be connected by the white clips.

You should verify that the subject's health status is acceptable prior to executing the test.

Ask the subject to sit or lay on a comfortable chair or bed.

Fix the mask as illustrated in the picture below. Adjust the elastic bands on the head cap as necessary to eliminate possible leaks and create a tight seal around the subject's face.



Connect the RMR reader to the RMR mask.

□ **The test with mouthpiece**

A physician's presence is not necessary during REE testing as long as the clinical staff has been adequately trained and educated on the testing procedure and device.

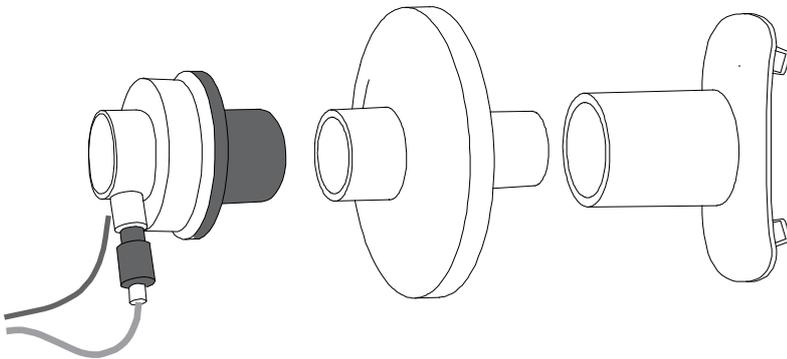
Note: Cellular phones should be turned off to eliminate potential electrical interferences.

■ **Calibrations**

Before performing the test an ERGO calibration must be performed (see *Calibration* chapter) and a Turbine calibration is recommended (see Recommendations in this chapter).

■ **Preparing the patient**

Connect the RMR reader to the bacterial filter and to the soft mouthpiece.



You should verify that the subject's health status is acceptable prior to executing the test.

Ask the subject to sit or lay on a comfortable chair or bed.

Let the subject apply the nose clips and the mouthpiece, according to the following picture.



□ The test with Canopy

The ventilated bubblehood system allows a stream of air to pass across the face of the subject and mix with the air being collected by the transparent hood over the subject's head. The flow rate measurement system will calculate the oxygen consumption, CO₂ production and the Energy Expenditure.

A physician's presence is not necessary during REE testing as long as the clinical staff has been adequately trained and educated on the testing procedure and device.

Note: Cellular phones should be turned off to eliminate potential electrical interferences.

■ Calibrations

Before the test an ERGO calibration is necessary (see *Calibration* chapter) and a Turbine calibration is recommended (see *Recommendations* in this chapter).

■ Preparing the canopy

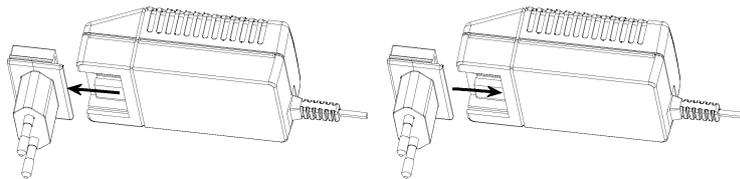
PFT CPET

Replacement of the power plug

If the power plug does not fit into the socket properly you will need to replace it with the additional plug in the packaging.

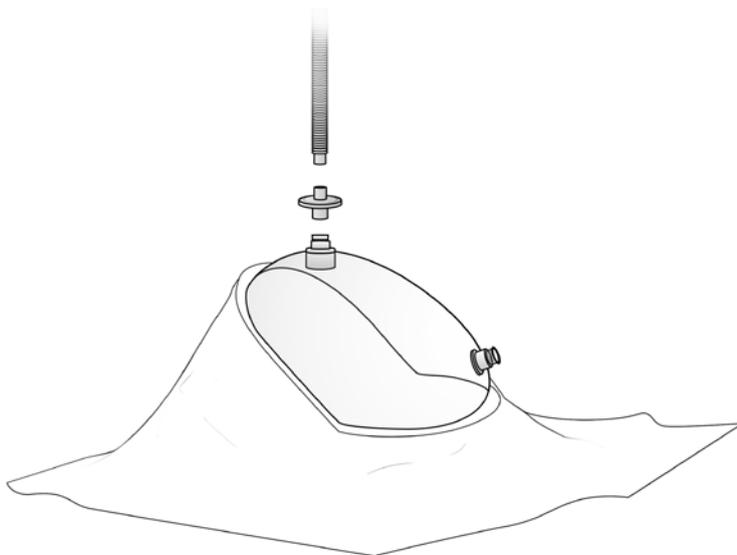
To replace the plug:

1. Extract the plug from the battery charger.
2. Insert the appropriate plug in the charger.



Connecting the Canopy

1. Connect the Canopy unit to the mains by means of the medical grade AC/DC adapter provided.
2. Attach the veil to the bubblehood through the velcro strips.
3. Insert the adapter into the bubblehood from the outside and connect it by screwing the ring from the inside as shown in the following picture.



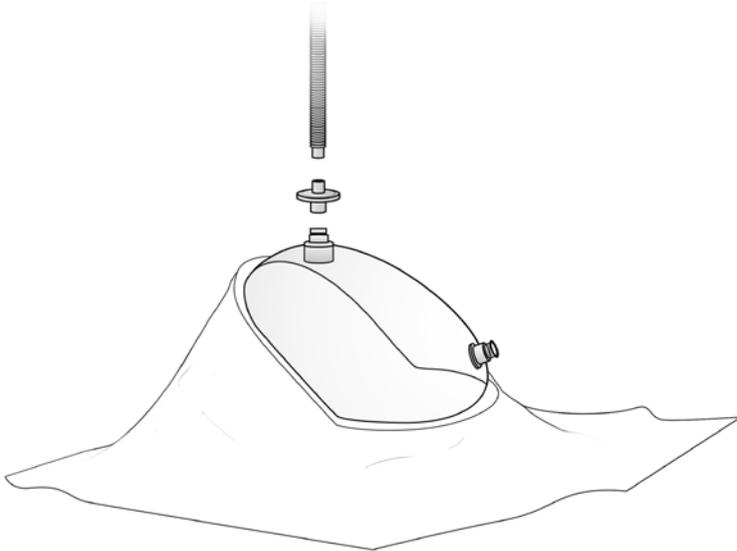
4. Connect the bubblehood to the wrinkled tube, interposing a bacterial filter.
5. Connect the wrinkled tube to the unit through the Flow in connector.
6. Connect the ID18 turbine to the output of the Canopy unit.



■ Preparing the canopy

RMR

1. Fix the veil to the bubblehood through the velcro strips.
2. Insert the adapter into the bubblehood from the outside and connect it by screwing the ring from the inside as shown in the following picture.



3. Connect the bubblehood to the corrugated tube, inserting an anti-bacterial filter.
4. Connect the wrinkled tube to the canopy hood connector on the rear panel of the Quark.
5. Connect the ID18 turbine to the RMR flowmeter connection on the rear panel of the Quark.
6. For first generation Quark RMR devices only: connect the flow adjustment unit to the *Flow adjustment* connector on the rear side of the Quark RMR. These units can be recognized if the last four digits of their S/N are below 1000.

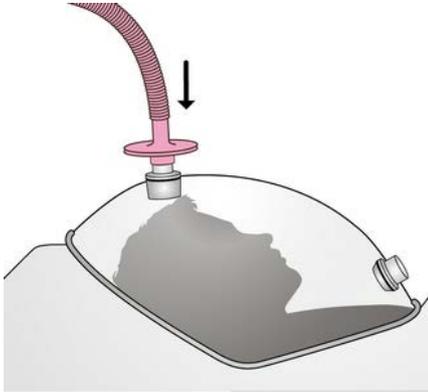


■ Preparing the patient

1. **PFT** **CPET** Switch the Canopy unit on.
2. **RMR** Switch the Canopy unit on (the switch is on the rear side of the Quark RMR).

3. The red led on the front panel of the unit should flash for few seconds followed by an alarm beep. If the led does not flash and/or the alarm does not beep the test cannot be performed because either the backup battery is exhausted or there is no backup battery.
4. When the green led turns on you may begin the test. If the green led does not turn on the test cannot be performed because the pump does not work or the mains is not powering the system.
5. After performing these checks, instruct the patient to lie in a supine position.
6. Place the bubblehood with the vail on the patient's head. The tube should be placed near the patient's mouth.

Warning: Do not place the canopy hood over a patient's head before the tube is properly connected and a continuous flow has been applied from the canopy blower.



Note: Cellular phones should be turned off to eliminate potential electrical interferences.

Measuring principles - tests with turbine flowmeter

In the following, technical details about the measurement of Resting Energy Expenditure on ventilated patients with COSMED Quark RMR are explained.

Operating Principles

Exhaled volume is measured at the exhalation port of the ventilator.

Fractional concentrations of inspiratory/expiratory O₂ and CO₂ are measured at the patient's airways, connecting the gas sampling port as close to the patient as possible.

The correct Bias Flow has been set, recorded and displayed on the Quark RMR Software before performing the measurement. See section on Bias Flow below.

It's mandatory that the Ventilator operates meeting the following conditions:

- The volume exhaled by the patient comes out from the ventilator where the turbine flowmeter is connected
- The eventual "bias flow" coming out from the exhalation port of the ventilator during the respiratory cycles must be set, recorded and displayed on the software.

Detection of the breathing cycle

Expiratory detection is based on a flow threshold: when the flow signal rises over a fixed threshold (Bias Flow + 80 ml/s) the expiratory phase starts.

Inspiratory detection is based on the first occurrence of the following conditions:

- CO₂ falls below a threshold (default 0.15%)
- Expiratory Flow falls below a threshold (default: BiasFlow + 55ml/s)

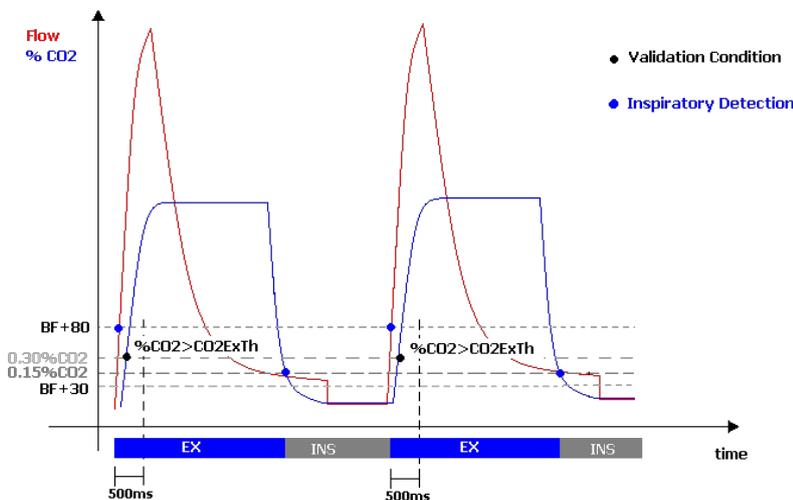
Note: There are two possible IN/EX detection modes: 1) Patient's exhaled gas detected and 2) Patient's exhaled gas not detected.

If no CO₂ is detected within the first 500ms from the beginning of expiration, the algorithm assumes that there is no exhaled gas. This mode is useful when testing the Quark connected to a ventilator without a real patient (anesthesiology bag connected): in this case only Flow is used to detect the end of exhalation.

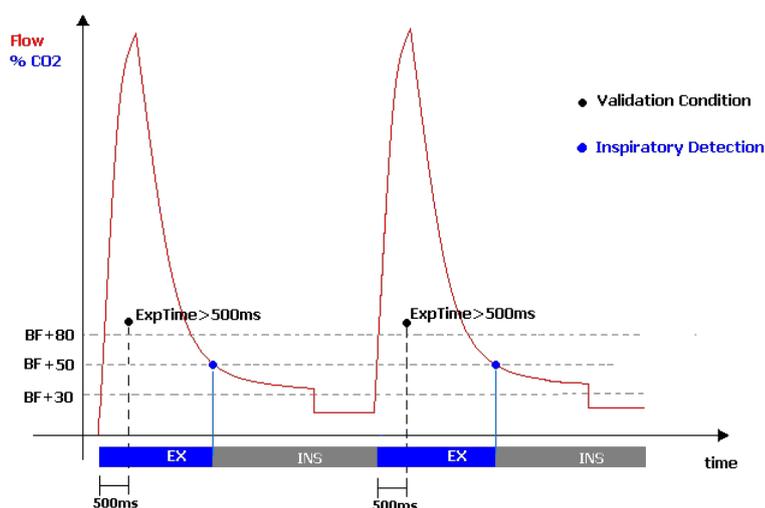
The maximal duration of the expiratory phase is 10 s, even if no inspiration is detected.

The following pictures explain how the detection works:

Expiration based on CO₂:



Expiration based on Flow level:



Bias Flow

Most of the ventilators on the market use a bias flow based detection system when operating according to spontaneous breathing modes.

A continuous flow (bias flow) circulates within the breathing circuit of the ventilator; its decrease from the base value is used to rapidly detect the beginning of the spontaneous inhalation of the patient and to trigger the activation of the vent.

Usually the ventilator allows the user to change two parameters: "bias flow value" or "bias flow sensitivity".

The presence of a bias flow affects the measurement of the exhaled volumes of air, O₂ and CO₂ calculated by the Quark RMR. An automatic correction is performed by the software according to the value set by the user.

The calculated exhaled patient's volume is corrected as follows:

$$\text{Corrected } V_t = V_t - \text{BIASFLOW} * T_e$$

Where T_e is the duration of the expiration.

Similarly other measured parameters such as exhaled oxygen volume (O₂exp) and exhaled Carbon Dioxide Volume (CO₂exp) are also corrected according to the value of bias flow specified by the user.

The correct specification of the bias flow guarantees the accuracy of the measurements.

- If bias flow is significantly smaller than what specified, V_t and all values are underestimated;
- If bias flow is significantly higher than what specified, it is possible that no breaths are detected.

Note: We suggest to read the nominal bias flow value of the ventilator on the user manual of the ventilator itself, and use this value for bias flow adjustment before and during the test (see below).

■ Calibrations

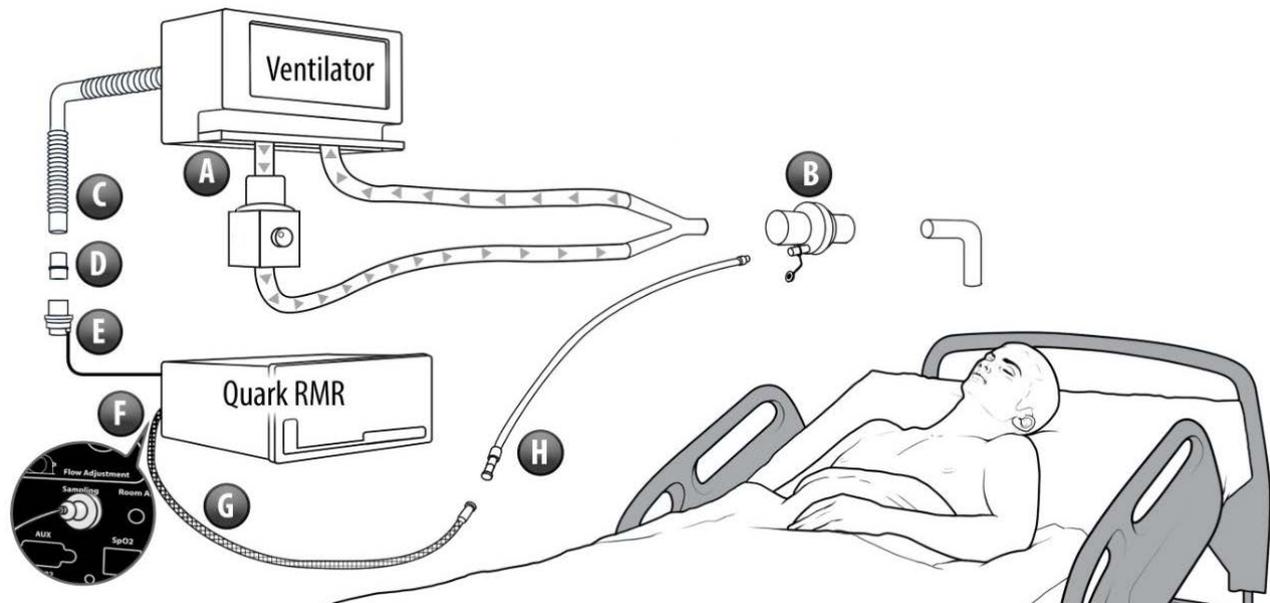
Before performing a REE measurement, an ICU calibration is necessary (see *Calibration* chapter) and a Turbine calibration is recommended (see *Recommendations* in this chapter).

■ Preliminary operations - using Quark RMR with turbine

1. Turn off the humidification system at least 10 minutes before starting the measurements, in order to reduce the presence of humidification in the system. When turning off the humidification system, the measurement should be limited to a maximum of 1 hour.
2. Connect the patient to the respiratory circuit through the HME filter (B). See drawing below.
3. Connect the turbine flowmeter (E) at the ventilator output with the proper adapter (C, D; adapters are available for the most common ventilators, according to their types).
4. Connect the HME filter (B) to the sampling inlet of the Quark RMR through the sampling line extension (H), the Permapure (G) and the antisaliva filter (F).

Be careful to connect the items as described, avoiding any air leakage.

Warning:
Do not interchange the Permapure (G) and the sampling line extension (H).



- | | |
|----------------------|----------------------------|
| A. Humidifier | E. RMR Flowmeter |
| B. HME filter | F. Antisaliva filter |
| C. ICU wrinkled tube | G. Permapure |
| D. Flowmeter adapter | H. Sampling line extension |

The ventilator is not included in the packaging.

Warning: Carefully re-check ventilator functionality after connection of the parts.

Warning: The HME filter (B) and the sampling line extension (H) are disposable.

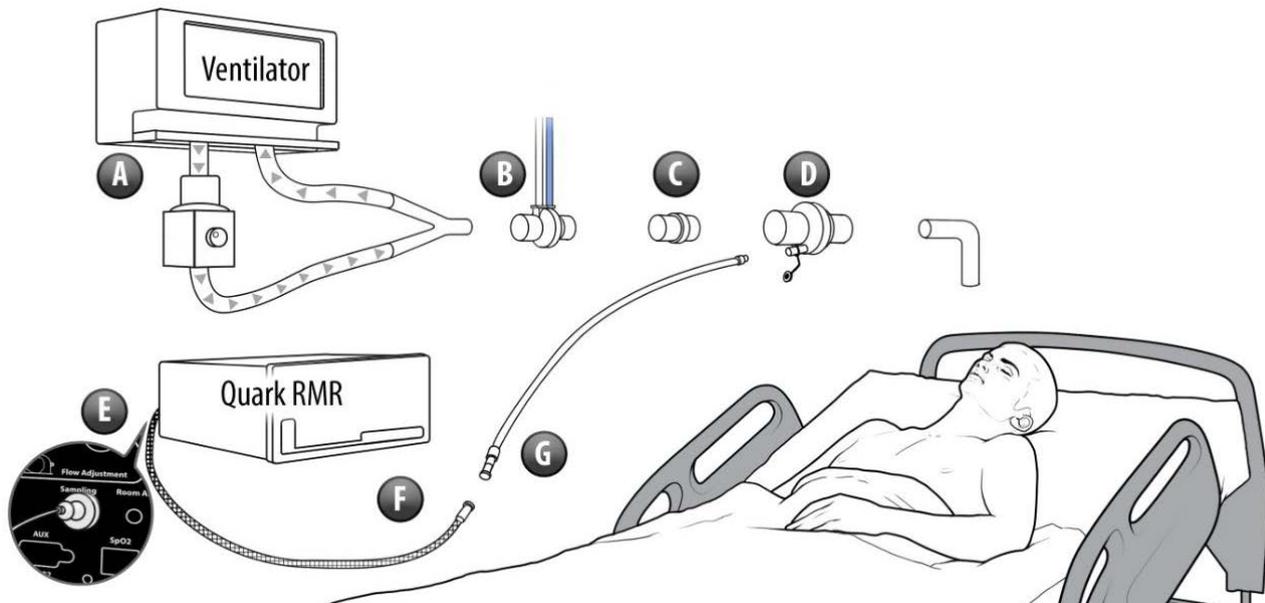
■ Preliminary operations - using Quark RMR with Flow-Ree

1. Turn off the humidification system of the ventilator at least 10 minutes before starting the measurements, in order to reduce the presence of humidification in the system. When turning off the humidification system, the measurement should be limited to a maximum of 1 hour.
2. Connect the patient to the ventilator through the the HME filter (D), the adapter (C) and the Flow-Ree (B). See drawing below.
3. Connect the HME filter (D) to the sampling inlet of the Quark RMR through the sampling line extension (G), the Permapure (F) and the antisaliva filter (E).
4. Make sure that the patients cuff pressure is sufficiently high to air avoid leakage.

Be careful to connect the items as described, avoiding any air leakage.

Warnings:

Do not interchange the Permapure (F) and the sampling line extension (G).
The tubes on the Flow-Ree (B) must be up, and the blue one must be on the patient's side.



- | | |
|---------------|----------------------------|
| A. Humidifier | E. Antisaliva filter |
| B. Flow-Ree | F. Permapure |
| C. Adapter | G. Sampling line extension |
| D. HME filter | |

The ventilator is not included in the packaging.

Warning: Carefully re-check ventilator functionality after connection of the parts.

Warning: The Flow-Ree (B), the HME filter (D) and the Sampling line extension (G) are disposable.

■ Limitations to the measurements

According to the literature, the main sources of error during a REE test on mechanically ventilated patients are:

1. Leaks of gas from the patient/ventilator system preventing collection of expired gases including:
 - Leaks in the ventilator circuit
 - Leaks around tracheal tube cuffs or uncuffed tubes
 - Leaks through chest tubes or bronchopleural fistula
2. Peritoneal and hemodialysis due to removal across the membrane of CO₂ that is not measured by the indirect calorimeter
3. Instability of delivered oxygen concentration (FiO₂) within a breath or breath to breath due to changes in source gas pressure and ventilator blender/mixing characteristics
4. FiO₂ > 50%
5. For tests with turbine only: inability to separate inspired and expired gases due to bias flow from flow triggering systems, IMV systems, or specific ventilator characteristics
6. Presence of anesthetic gases or gases other than O₂, CO₂ and N₂ in the ventilation system
7. Presence of water vapor
8. Inappropriate calibration
9. Connection of the Quark RMR to certain ventilators, with adverse effect on triggering mechanism, increased expiratory resistance, pressure measurement, or maintenance of the ventilator
10. Internal leaks
11. Inadequate length of measurement

□ Performing a Resting Energy Expenditure test

The software allows three main REE test types:

1. With mask
2. With Canopy
3. On mechanically ventilated patients

The execution of these three test types is the same, and it will be described below.

■ Starting the test



Press the **Testing** tile in the home panel, or start a new test from the subject database, then **Metabolic** and **Resting Energy Expenditure**, then select (depending on the test type) **REE - Mask**, **REE - Canopy** or **REE - Ventilator**.

Note: *REE - Mask* is also used for REE tests with mouthpiece.



The system is ready to read the subject's breaths. Press **Start** to start the data acquisition.

Start Test / Select Options

Test

Protocols

Data Filtering

Start Test / Select Options

Test

Protocols

Data Filtering

Sampling Rate 10 s

Canopy

Blower Control

Start Test / Select Options

Test

Protocols

Data Filtering

IntelliBridge

One of the above windows will be prompted, depending on the test type (with mask, with Canopy, ICU). In this window you can select:

- The test protocol
- The data filtering algorithm (according to the options already described in the *Settings* chapter)
- The Canopy blower control (manual or via software, this last option is available only for second generation of Quark RMR) - Only for tests with Canopy.
- The port for connection with Philips IntelliBridge System (if any) - Only for test on mechanically ventilated patients.

Press **OK** to start the test, or **Cancel** to abort.

The system will start to display data according to the selected dashboard. This data are not saved until REC is pressed (see below). Anyway, test starts automatically and begins to store data after the time set in *Settings*.

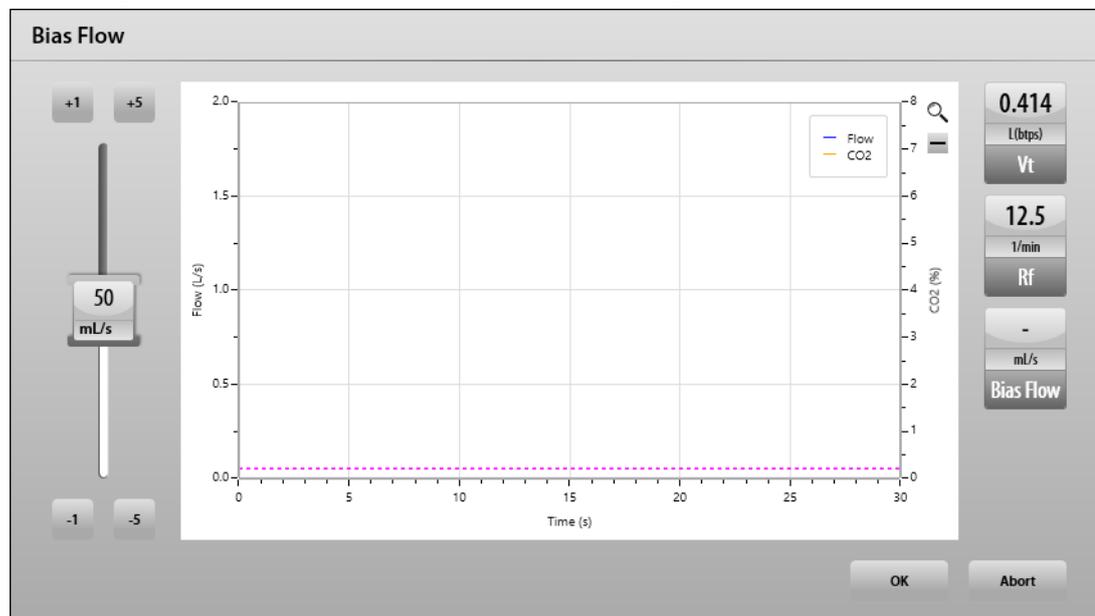
Particular requirements for tests on mechanically ventilated patients

Check if the subject's configuration corresponds to the one displayed. Press **OK** to continue.

Before starting data storage, if you are using the turbine flowmeter the Bias Flow Detection should be performed (see below).

■ Bias flow detection (test on mechanically ventilated patients only - turbine flowmeter only)

After starting an ICU test, the Bias flow detection screen is prompted. The graph shows the flow at the ventilator output.



The Bias Flow detection window shows:

- A graph with the flow and the measured CO₂
- Numerical data for Tidal volume, Respiratory frequency and Bias Flow.

The turbine at the ventilator output measures only the exhaled air from the patient. Therefore the dotted horizontal line must be placed onto the measured flow during the inspirations (usually the minimum, see the illustration above). In order to properly place the line, drag with the mouse the indicator on the left or click the **+1**, **+5**, **-1**, **-5** buttons until you reach the desired.

The best way for bias flow adjustment is to read the nominal bias flow value of the ventilator on the user manual of the ventilator itself, and enter this value in this mask.

Otherwise, we suggest to proceed manually, starting from a value of 30 ml/s and comparing the Vt (BTPS) read on the Quark RMR with the Vte (BTPS) read on the ventilator monitor.

Since the Vte values can vary depending on patient's conditions, the comparison between Vt and Vte must take into account a range of admitted variability (i.e. 10%).

Press **OK** to exit from the bias flow detection and to start the test.

Note: The correct placement of the Bias Flow is very important in order to avoid inaccuracies when measuring flows and volumes.

■ Execution of the test (real time visualization)



In order to start data storage, press **Rec**. The display will be cleared and data will now be saved in the database.

Note: During test with Canopy, before starting data storage, please check the FeCO₂ value in the Dilution widget. See below.

Data are displayed according to the selected dashboard. Please refer to the *Utilities/Customize views* section for more details about the dashboards and the presentation of data.

During the execution of the test, it is possible to perform many activities, explained here below.

Pause the test



In order to pause the test, press **Pause**. Data are not stored and the protocol will be paused too.

Restore the test



To restart data acquisition, press **Rec**.

Set the start of the average time interval



The software will average measured value on the whole test, or on a selected time interval.

To set the start of the average interval, press **AVG** and click with the mouse on the selected time.

Enter a marker



To add a marker, press **Marker** and enter a label for it. Markers are useful to refer particular events occurred during the test.

Checking and adjusting the bias flow during measurement (test on mechanically ventilated patients only - turbine flowmeter only)



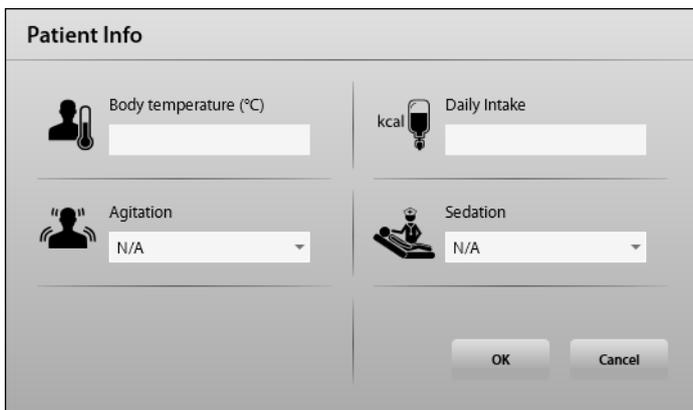
The check and (in case) adjust the bias flow during the measurement, press **Events** and select **BF**.

Refer to *Bias flow detection* above for further detail.

Enter patient info



To enter information about the patient, press **Patient Info** and enter desired data.

A dialog box titled "Patient Info" with a light gray background. It contains four input fields arranged in a 2x2 grid. The top-left field is labeled "Body temperature (°C)" and has a thermometer icon. The top-right field is labeled "Daily Intake" and has a "kcal" icon and a glass icon. The bottom-left field is labeled "Agitation" and has a person icon with sound waves. The bottom-right field is labeled "Sedation" and has a person icon with a syringe. Each field has a dropdown arrow. At the bottom of the dialog, there are two buttons: "OK" and "Cancel".

You can enter:

- The body temperature
- The daily intake
- Agitation
- Sedation

- Severity (Apache III) (ICU only)

Customize a graph

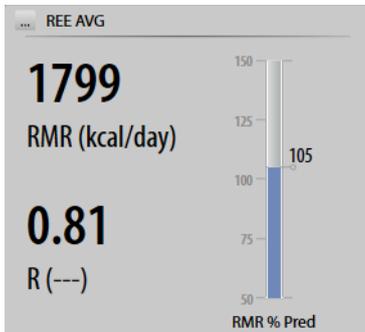
All the graphs can be customized in real time as described in the *Utilities/Customize views* section. Please refer to that section for more details.

Graphs can be zoomed in or out through the mouse wheel. It is possible to zoom a single axis positioning the mouse on the selected one. The zoom is centered on the position of the mouse.

Widgets

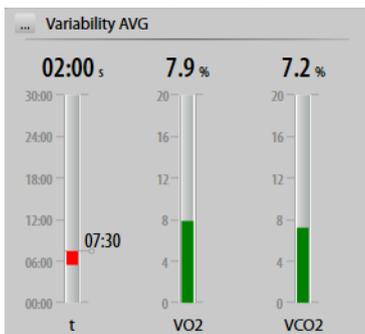
Widgets show to the user useful information about the current test, and cannot be customized.

- ▶ [REE AVG widget](#)



The *REE AVG* widget reports the resting energy expenditure, the respiratory quotient and the percentage of the predicted REE.

- ▶ [Variability AVG widget](#)



The *Variability AVG* widget reports the time and the variability of VO_2 and VCO_2 .

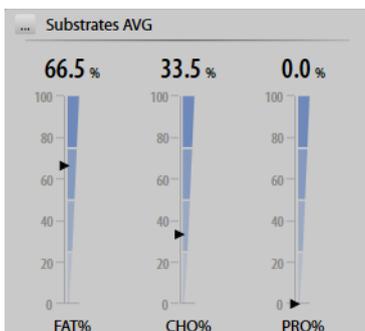
The colors of the vertical bars of the *Variability AVG* widget show the acceptability of the main values:

- Green: acceptable value
- Yellow: border line value
- Red: not acceptable value

If a bar is red (and possibly if it is yellow also), please operate in order to bring the value in the normal range. In particular:

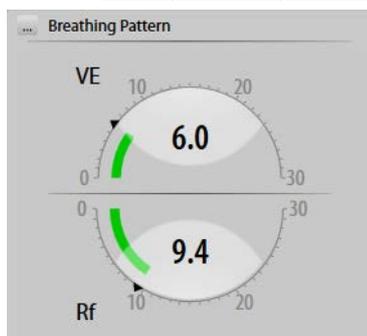
- The VO_2 or VCO_2 bar is red (or yellow) if the subject's breath is not enough regular. Please normalize the subject's breath.
- The time bar is red (or yellow) if the acquisition time is too short according to the international guidelines. It is green only if the acquisition time is more than 10 minutes.

- ▶ [Substrates AVG widget](#)



The *Substrates AVG* widget reports the mean values of the substrates (fats, carbohydrates and proteins).

▶ [Breathing Pattern widget \(test with mask only\)](#)



The *Breathing Pattern* widget (test with mask only) shows two values (ventilation and respiratory frequency). The values are graphically shown also through colors. The meaning of these colors are the same of the one described above:

- Green: acceptable value
- Yellow: border line value
- Red: not acceptable value

If an indicator is red (and possibly if it is yellow also), please operate in order to bring the value in the normal range. In particular:

- The ventilation indicator is red (or yellow) if the subject's ventilation is too high. Please let the subject to breathe more quietly.
- The respiratory frequency indicator is red (or yellow) if the acquisition time is too short according to the international guidelines. It is green only if the acquisition time is more than 10 minutes.

▶ [Dilution widget \(test with Canopy only\)](#)



The *Dilution* widget (test with Canopy only) shows the $FeCO_2$ value. As explained in the general warnings, this value must be kept within the acceptability range. The needle points in one of three different bands, whose color is described below:

- Green: acceptable value
- Red: $FeCO_2$ too high, please increment the flow
- Grey: $FeCO_2$ too low, please reduce the flow

This check should be performed before starting the data acquisition.

In order to adjust the flow, please rotate the knob (hardware or software, depending on the device used)

<p>Flow adjustment</p>	<p>PFT CPET For Quark PFT and Quark CPET, placed on the Canopy unit (connected to the Quark).</p>
<p>Flow adjustment</p>	<p>RMR For first generation Quark RMR devices, placed on the flow adjustment unit (connected to the Quark). These units can be recognized if the last four digits of their S/N are below 1000.</p>
<p>Blower Control</p>	<p>RMR For most recent Quark RMR devices, control via software. These units can be recognized if the last four digits of their S/N are 1000 or above.</p>

The knob for flow adjustment is very sensitive. For this reason the adjustment must be performed by rotating the knob very carefully. After having modified the flow, please wait at least 30 seconds in order to visualize the variations.

You should continue to verify that the measured FeCO_2 is within the acceptability range throughout the test and adjust the *Flow adjustment* handle as necessary.

Warning: If the green led turns off during the test, the red led flashes or the alarm beeps you should abort the test and remove the hood from the patient's head. This indicates that the pump does not work or the mains is not powering the system. If the mains is not powering the system, the pump is being powered by the backup battery, but the test must be stopped.

► [FiO2 Mix widget \(test on mechanically ventilated patients only\)](#)



The *FiO2 Mix* widget (test on mechanically ventilated patients only) shows the FiO_2 value.

Customize the tabular presentation of data

The data table can be customized according to the description reported in the *Utilities/Customize views* section. Please refer to that section for more details.

Change the selected dashboard

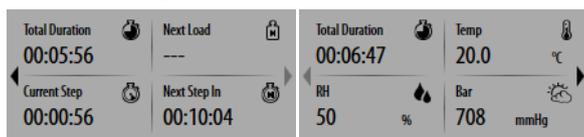


The dashboard can be changed by clicking on the desired dashboard in the lower part of the screen. A new dashboard can be added by pressing the + in the dashboard bar.

Change the main parameters visualization

The visualization of the main parameters (on the right of the panel) can be customized according to the description reported in the *Utilities/Customize views* section. Please refer to that section for more details.

General data widget



Under the protocols widget, the general data widget shows information about the current test (total duration, next load, duration of the current step, time to the reach the next step) and ambient data (temperature, relative humidity and barometric pressure). The two interfaces can be switched through the arrows on the left or on the right side of the general data widget.

Ending the test



In order to end the test saving the data, press **Stop**. Test results will be displayed in the *Edit test* panel. See below, *Editing the test*.



In order to abort the test, without saving any data, press **Abort**.

Editing the test

When the test is ended, the *Test Edit* panel is shown to the user.



It can be also opened from the *Test Results* panel, by pressing the **Edit** button.

The screenshot shows the CANOPY EDIT interface with the following details:

- Subject Information:** SUBJECT DEMO, gender Male, age 48, weight 75.50 kg, height 178.0 cm.
- Overview Tab:** Contains input fields for AMR (kcal/day) and UN (g/day), a table of parameters, and summary statistics.
- Parameters Table:**

Parameter	Measured	Pred	% Pred	Variation
Test Duration	15:50	-	-	-
Rest Phase Duration	09:40	-	-	-
RMR (kcal/day)	2216	1671	133	3
RQ (-)	0.82	0.85	97	2
VO2 (mL/min)	320	264	121	3
VCO2 (mL/min)	263	225	117	3
AMR (kcal/day)	-	-	-	-
FAT% (%)	60.5	-	-	8
CHO% (%)	39.5	-	-	12
PRO% (%)	0.0	-	-	0
UN (g/day)	-	-	-	-

- Summary Statistics:** Total Duration 15:50, Phase Duration 09:40.
- Graphs:** Three line graphs showing EEkc vs t, RQ vs t, and VO2, VCO2 vs t over time.
- Buttons:** Save & Exit, Cancel.
- Footer:** Omnia 1.5, Logged in as Administrator.

The *Test Edit* panel includes different tabs, each of them allowing the calculation of one or more parameters.

Note: The **Save** button saves all the changes and exits from the Test Edit panel, showing the Test Results panel. To save a single change on one of the tabs, it is enough to change tab. Changes will be automatically saved.

In any case, the original test won't be overwritten. You always can restore the original test by pressing Upload Raw Data (see below).

Overview tab

This tab is divided in four sections.

The first one (on the top left corner) reports the test information (Activity Metabolic Rate and Ureic Nitrogen), and can be modified by the user.

The second one (below the test information one) reports the calculated parameters, together with their predicted values, the percentage of the predicted and the variation of the parameter through all the test.

The third one (bottom left) reports other test information (the test duration and the duration of the average phase).

On the right side, three graphs show the main parameters. Each graph can be customized as described in the *Utilities/Customize views* section. Please refer to that section for more details.

Graphs can be zoomed in or out through the mouse wheel. It is possible to zoom a single axis positioning the mouse on the selected one. The zoom is centered on the position of the mouse.



Buttons on the left allows to:

- Show general information on the test (**Info**)
- Show the calibration data for the current test (**Calibration**)
- Edit and filter the test steps (**Edit & Filter**)

General information

Info

Ambient Temperature (°C): 26.0
 Ambient Relative Humidity (%): 50
 Barometric Pressure (mmHg): 760
 Flowmeter temperature (°C): 34.0
 Flowmeter Relative Humidity (%): 100
 STPD correction factor (—): 0.8261
 Inspiratory BTPS correction factor (—): 1.087
 Expiratory BTPS correction factor (—): 1.020

OK

This window shows ambient data and correction factors in the current test.

Edit and filter the steps

Note: If data are edited / filtered, all the parameters must be recalculated.

t	hh:mm:ss	Ignore	Marker	Phase	Rf	Vt	O2exp	CO2exp	FeO2	FeCO2	HR	FetO2	FetCO2	FIO2	FiCO2	T
					l/min	L.(btps)	mL	mL	%	%	bpm	%	%	%	%	s
<input type="checkbox"/>	00:30	<input type="checkbox"/>		None	0.9	1.030	173.3	49.2	16.83	4.78	0	15.81	5.88	20.93	0.00	2
<input type="checkbox"/>	01:00	<input type="checkbox"/>		None	0.9	0.946	159.9	43.5	16.90	4.60	0	15.82	5.78	20.92	0.00	2
<input type="checkbox"/>	01:30	<input type="checkbox"/>		None	0.7	0.847	140.8	40.1	16.61	4.73	0	15.40	5.92	20.93	0.00	2
<input type="checkbox"/>	02:00	<input type="checkbox"/>		None	0.9	0.748	122.0	34.6	16.30	4.62	0	15.03	5.89	20.92	0.00	2
<input type="checkbox"/>	02:30	<input type="checkbox"/>		None	0.8	0.774	124.6	36.3	16.11	4.70	0	14.70	6.00	20.91	0.00	2
<input type="checkbox"/>	03:00	<input type="checkbox"/>		None	0.8	0.799	126.0	37.8	15.76	4.73	0	14.38	6.03	20.91	0.00	2
<input type="checkbox"/>	03:30	<input type="checkbox"/>		None	0.9	0.737	117.7	33.4	15.97	4.53	0	14.54	5.91	20.91	0.01	2
<input type="checkbox"/>	04:00	<input type="checkbox"/>		None	0.7	0.739	114.8	34.8	15.54	4.71	0	14.01	6.10	20.91	0.01	2
<input type="checkbox"/>	04:30	<input type="checkbox"/>		None	0.8	0.764	116.9	36.3	15.31	4.76	0	13.80	6.13	20.91	0.01	2
<input type="checkbox"/>	05:00	<input type="checkbox"/>		None	0.9	0.740	116.5	33.9	15.74	4.58	0	14.08	6.04	20.91	0.00	2
<input type="checkbox"/>	05:30	<input type="checkbox"/>		Rest	0.9	0.608	95.8	26.4	15.76	4.35	0	13.80	6.10	20.90	0.01	2
<input type="checkbox"/>	06:00	<input type="checkbox"/>		Rest	0.8	0.660	102.2	30.2	15.47	4.57	0	13.67	6.18	20.91	0.01	2
<input type="checkbox"/>	06:30	<input type="checkbox"/>		Rest	0.8	0.713	109.6	33.2	15.36	4.65	0	13.57	6.22	20.91	0.01	2
<input type="checkbox"/>	07:00	<input type="checkbox"/>		Rest	0.9	0.602	94.3	26.7	15.66	4.44	0	13.46	6.23	20.90	0.01	2
<input type="checkbox"/>	07:30	<input type="checkbox"/>		Rest	0.9	0.639	98.3	29.3	15.38	4.58	0	13.33	6.26	20.90	0.01	2
<input type="checkbox"/>	08:00	<input type="checkbox"/>		Rest	1.2	0.554	87.8	23.5	15.84	4.24	0	13.57	6.17	20.90	0.02	1
<input type="checkbox"/>	08:30	<input type="checkbox"/>		Rest	0.9	0.635	97.6	29.3	15.37	4.61	0	13.39	6.28	20.90	0.01	2
<input type="checkbox"/>	09:00	<input type="checkbox"/>		Rest	1.0	0.583	91.6	25.6	15.71	4.40	0	13.64	6.21	20.90	0.01	2
<input type="checkbox"/>	09:30	<input type="checkbox"/>		Rest	1.0	0.563	87.7	24.8	15.56	4.40	0	13.22	6.33	20.89	0.01	2

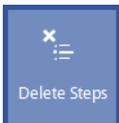
The *Edit and filter* panel allows to edit and/or filter the steps of the test.

On the top left, it is possible to set the data filtering option (according to the options already described in the *Settings* chapter), by selecting the desired algorithm in the list.

It is also possible to edit single steps by clicking on the value to be changed and entering the new value.

To ignore one or more steps, select the corresponding checkbox(es) in the *Ignore* column.

In order to make easier the search of a step, you can use the tools below the data table. You can filter data by phase (checking the phases to be shown) or by time (moving the cursors of the time bar). Note: this filters do not affect the test data, they are a search tool only.



The **Delete Steps** button deletes the steps selected in the table on the right.



The **Discard Invalid Steps** button deletes the invalid steps (according to the custom settings, see the *Settings* chapter).



The **Advanced Edit** button allows to perform an advanced edit of the steps.

The **Advanced Edit** dialog box is shown with the following options:

- Delete Step
- Edit Parameter
 - Parameter:
 - Value:
 - Correction %:
 - Offset:
 - Smoothing:
- Time Range: (with a time bar)
- Parameter Range
 - Parameter:
 - Condition:
 - Value:

Buttons:

In particular, it is possible to delete steps (*Delete Step*) or edit parameters (*Edit Parameter*) according to the criteria defined in the same window.

If you want to edit a parameter, you can select in the *Edit Parameter* section the parameter to be edited, together with the correction to be applied:

- *Value* replace all the values with the entered one
- *Correction %* changes all the values by the entered percentage
- *Offset* adds the entered offset to the values
- *Smoothing* performs a smoothing on the entered number of steps

The deletion or the edits are applied to the steps in the defined time range (if the *Time Range* checkbox is selected) or according to the values of a specified parameter (if the *Parameter Range* checkbox is selected).

- If the *Time Range* checkbox is selected, please select the time range by moving the cursors on the time bar
- If the *Parameter Range* checkbox is selected, please select the conditioning parameter, the condition (equal [=], different [$<>$], minor [$<$], minor or equal [$<=$], major or equal [$>=$], major [$>$]) and the value to be compared.



The **Restore** button allows to restore steps as they were after the last data saving.



The **Upload Raw Data** button allows to restore steps in raw format (breath by breath), discarding all the edits performed on this test, even if they were saved.

To accept change press **Accept**, to abort the operation press **Cancel**.

■ Edit AVG REE tab

The screenshot shows the 'CANOPY EDIT' software interface. At the top, there's a header with subject information: SUBJECT DEMO, gender Male, age 46, weight 78.00 kg, height 178.0 cm, and visit date 30/01/2014. Below this, there are three tabs: Overview, Edit AVG REE (selected), and Interpretation. On the left, there are five buttons: Add ->, Add <-, Cut, Delete, and Restore. The main area is divided into a table and two graphs. The table shows parameters like Rest Phase Duration, RMR, RQ, VO2, and VCO2 with measured, predicted, and variation values. The top graph is 'EEk vs t' showing energy expenditure over time, with a shaded interval from 06:00 to 15:20. The bottom graph is 'VO2, VCO2 vs t' showing oxygen and carbon dioxide consumption over time. At the bottom, there's a 'Time Interval' slider set to 06:00 - 15:20, and 'Save' and 'Cancel' buttons.

Parameter	Measured	Pred	% Pred	Variation
Rest Phase Duration	09:20	-	-	-
RMR (kcal/day)	2214	1719	129	3.2
RQ (-)	0.82	0.85	97	1.7
VO2 (mL/min)	320	273	117	3.3
VCO2 (mL/min)	263	232	113	3.2

The **Edit AVG REE** tab allows the selection of the time interval for the calculation of the REE. It is also possible to add new intervals or to split the interval in two or more for the calculation of the REE.

It is possible to change the time interval through the time bar below the graphs or by moving the start and end markers (the dotted vertical lines on the VO_2 vs time graph) with the mouse.



Buttons on the left allows to:

- Add a new interval at the right of the selected one (**Add ->**)
- Add a new interval at the left of the selected one (**Add <-**)
- Cut the selected interval in two intervals (**Cut**)
- Delete the selected interval (**Delete**)
- Restore the changes to the last saving (**Restore**)

Tip: to merge two intervals, delete one of them and extend the other one to cover all the desired interval.

■ Interpretation tab

The screenshot displays the 'CANOPY EDIT' software interface. At the top, there is a header with 'subject SUBJECT DEMO', 'gender Male', 'age 48', 'weight 75.50 kg', and 'height 178.0 cm'. Below the header, there are tabs for 'Overview', 'Edit AVG REE', and 'Interpretation', with 'Interpretation' being the active tab. On the left side, there are three buttons: 'Info', 'Calibration', and 'Restore'. The main area contains several dropdown menus for 'Fasting Period' (N/A), 'Resting Period' (N/A), 'Test Position' (Supine), 'Body T (°C)' (-), 'Agitation' (N/A), 'Sedation' (N/A), and 'Test Purpose' (None). There is also a 'Best' checkbox which is checked. To the right of these dropdowns is a large text area for 'Operator Notes'. Below the dropdowns is a large text area for 'Interpretation'. At the bottom right of the 'Interpretation' area, there is a 'Confirmed' checkbox which is unchecked. At the bottom right of the main area, there are 'Save & Exit' and 'Cancel' buttons. The bottom status bar shows 'Omnia 1.5', several system icons, and 'Logged in as: Administrator'.

The *Interpretation* tab allows entering custom information of the test and a personal interpretation by the physician.



Buttons on the left allows to:

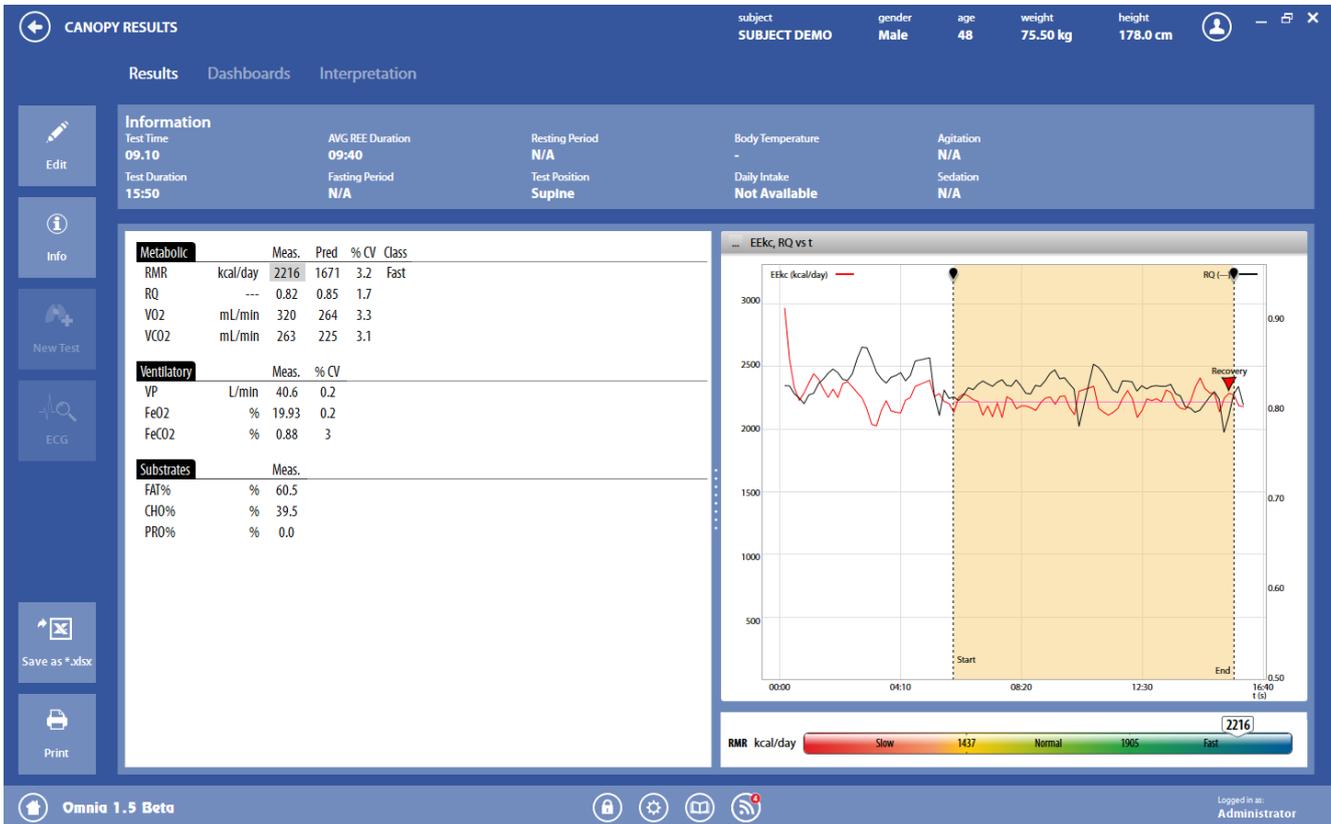
- Show general information on the test (**Info**)
- Show the calibration data for the current test (**Calibration**)
- Reset the changes to the last saving (**Reset**)

Viewing the results



To view a test, press in the subject database the **...** on the left of the test and then the **View** button or double click on the test. In this panel, data and graphs are not editable by the user.

Test results are accessed also by pressing **Save** in the *Test edit* panel.



The results panel contains three tabs, described below.



Buttons on the left (common to all the tabs) allows to:

- Edit the test (**Edit**)
- Show test info (**Info**)
- Start a new test (**New Test**)
- Open the corresponding ecg, if any (**Ecg**)
- Export the test in an Excel file (**Save as *.xlsx**)
- Print the test report (**Print**)

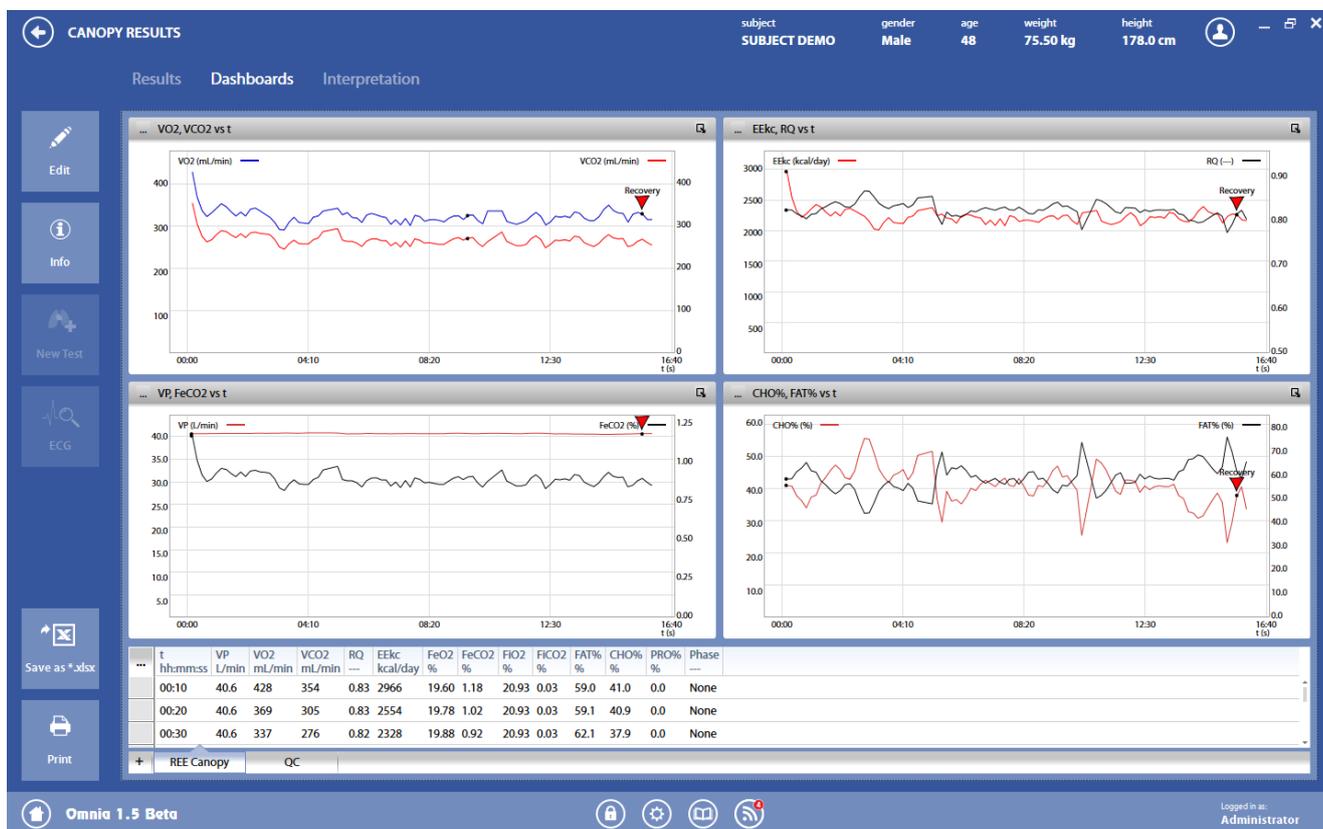
Results tab

The *Results* tab reports information and results of the test:

- On the top screen, general information on the test
- On the bottom left, the results, in summary format, as defined in *UtilityCustomize views*.

- On the bottom right, a graph as defined in *Utility/Customize views*. The graph can be customized as described in the *Utilities/Customize views* section. Please refer to that section for more details. It can also be zoomed in or out through the mouse wheel. It is possible to zoom a single axis positioning the mouse on the selected one. The zoom is centered on the position of the mouse.
- Under the graph, a gauge with a graphical interpretation of the result, with a rank assessment of it (from *very poor* to *superior*).

■ Dashboards tab



The *Dashboard* tab contains the dashboards defined for real time viewing (left part only). Please refer to the *Utilities/Customize views* section for more details about the dashboards and the presentation of data.

The dashboard can be changed by clicking on the desired dashboard in the lower part of the screen. A new dashboard can be added by pressing the + in the dashboard bar.

■ Interpretation tab

The screenshot displays the 'CANOPY RESULTS' application interface. At the top, the 'Interpretation' tab is selected among 'Results' and 'Dashboards'. The patient information at the top right includes: subject (SUBJECT DEMO), gender (Male), age (48), weight (75.50 kg), and height (178.0 cm). The left sidebar contains icons for 'Edit', 'Info', 'New Test', 'ECG', 'Save as *.xlsx', and 'Print'. The main content area is split into two large text input fields: 'Operator Notes' and 'Interpretation'. The bottom status bar indicates the software version 'Omnia 1.5 Beta' and the user is logged in as 'Administrator'.

The *Interpretation* tab reports the technician notes and the interpretation, entered during the editing steps.

Sub-maximal Exercise Testing

PFT

CPET

K5

□ Introduction

Physiological responses to exercise including oxygen consumption, heart rate, and blood pressure are used to evaluate cardiorespiratory fitness. These variables are also assessed during exercise when attempting to determine the presence of coronary artery disease or pulmonary disease.

Maximal exercise testing can be impractical at times due to the expense, clinical supervision required and the level of physical stress that the patient is subjected to. Maximal exercise testing may not be necessary depending on the clinical objectives of the test and is often reserved for clinical assessments, athletic evaluation and/or research.

A sub-maximal exercise test is less expensive and is physically less stressful on the individual. Although sub-maximal testing is less sensitive when detecting disease or estimating maximal oxygen consumption, a correctly performed test can be a reliable indicator of the subject's cardiorespiratory fitness.

■ Pre-test screening

Pre-test health screenings are essential for risk stratification and for determining the type of test that should be performed.

Screenings should include and detect the following conditions:

- Complete medical history.
- Medical contraindications to exercise.
- Symptoms suggesting cardiac or pulmonary disease.
- Angina or other forms of discomfort at rest or during exercise.
- Unusual shortness of breath at rest or during exercise.
- Dizziness or light-headedness.
- Orthopedic conditions that could prevent an adequate effort or compromise the validity of test results.
- Other unusual signs or symptoms that may preclude testing.
- Risk factors for coronary disease.
- History of major cardiorespiratory events.
- Current medications.
- Activity patterns.
- Nutritional habits.
- Reading and signing an informed consent.

□ *Sub-maximal exercise testing*

Heart rate should vary linearly with VO_2 to the point of maximum exertion. This allows the estimation of VO_{2max} without subjecting the individual to maximum levels of physical stress. During sub-maximal exercise testing, predetermined workloads are used to elicit a steady state of exertion (plateau of heart rate and VO_2). The steady-state heart rate at each work level is displayed graphically and extrapolated to the VO_2 at the subject's predicted maximal heart rate ($HR = 220 - \text{age}$). A variety of protocols for different exercise modalities (treadmill, stationary cycle, step increments) can be used assuming that VO_2 can be estimated with accuracy at each selected workload.

The objectives of cardiorespiratory fitness assessments are as follows:

- Determine the level of cardiorespiratory fitness and establish fitness program goals and objectives.
- Develop a safe, effective exercise prescription for the improvement of fitness levels.
- Document improvements in cardiorespiratory fitness as a result of exercise training and/or other interventions.
- Motivate individuals to initiate exercise programs or comply with established programs.
- Provide information concerning the health status of individuals.

The following conditions are necessary to ensure the accuracy of results when using sub-maximal exercise testing to estimate VO_{2max} :

- Selected workloads are reproducible. A steady-state heart rate is obtained during each stage of the test. Workload durations of 3 minutes or more are typically used to ensure a steady state.
- The maximal heart rate for a given age is uniform ($HR = 220 - \text{age}$).
- Heart rate and VO_2 have a linear relation over a wide range of values. Therefore, the slope of HR/VO_2 regression can be accurately extrapolated to an assumed maximum heart rate.
- Mechanical efficiency (VO_2 at a given work rate) is consistent.

Although sub-maximal exercise tests can provide valuable information concerning cardiorespiratory fitness, diagnostic capabilities are limited and results should not be used as a replacement for maximal exercise tests or other and/or clinical modalities.

■ *Sub-maximal exercise testing considerations*

Physical or clinical limitations that may preclude certain types of exercise include the subject's age, weight, level of fitness, exercise preference, a history of arthritis or other orthopaedic complications. These factors should be taken into consideration when selecting the type of protocol and equipment used for each test.

Some individuals may perform better on a non-weight-bearing modality (cycle vs. treadmill), while others may not have the required range of motion in the hip or knee to pedal adequately. Deconditioned, weak or elderly subjects may need to begin the test at a low work level and increase the workload in small increments. Field testing would not be appropriate for those requiring strict supervision during testing, do not understand the concept of pacing or whom you do not expect to demonstrate a valid effort. In such cases, a laboratory setting may allow you to obtain more consistent results. When selecting protocols you may choose to make alterations to commonly used protocols to accommodate athletes competing in specific sports. The same type of exercise and protocol should always be used if exercise testing is repeated to allow for a valid comparison of the results.

■ *Staffing*

Staff members conducting the testing are responsible for the following:

1. Establishing rapport with the subject and assuring that he/she is comfortable prior to executing the test.
2. Recognizing normal acute and chronic responses to exercise.
3. Recognizing abnormal signs and symptoms during exercise.
4. Providing basic life support measures as needed.
5. Adhering to established procedures and protocols.
6. Clearly explaining test results to the individual.

■ *Test termination*

Sub-maximal tests should be terminated when necessary according to ACSM or other preferred guidelines (see the following table). In the event of an abnormal response the test should be terminated, the medical director of the facility and the individual's primary care physician should be notified and all appropriate follow-up procedures should be performed. If a mechanical or electrical failure occurs the test should be stopped until the problem has been corrected.

Indications for stopping an exercise test

Onset of angina or angina-like symptoms.

Significant drop in Systolic Blood Pressure (20 mmHg) or failure of the SBP to rise with an increase in exercise intensity.

Excessive rise in blood pressure: SBP >260 mmHg or DBP >115 mmHg.

Signs of poor perfusion: dizziness, confusion, ataxia, pallor, cyanosis, nausea or cold and clammy skin.

Failure of heart rate to increase with increased exercise intensity.

Noticeable change in heart rhythm.

Subject requests to stop the test.

Physical or verbal manifestations of severe fatigue.

Failure of the testing equipment.

□ Considerations for accuracy

The ability to obtain valid, reproducible measurements is essential when making comparisons between pre-treatment and post-treatment test results. Inconsistencies in the testing conditions could create variable results.

- Sub-maximal heart rate can be influenced by the time of day, eating, smoking, and familiarization with the test procedure.
- Prediction equations for estimating VO_2max may overestimate trained individuals and underestimate untrained individuals capabilities.
- The efficiency of motion during walking, running, and cycling varies.
- Cardiac Output and VO_2 have a test-retest variability of 3-4%.

Psychological factors such as pre-test anxiety may influence the heart rate, specifically at low workloads. In such cases the resting heart rate and/or blood pressure may be higher than the values measured during the initial stages of exercise. Having the subject repeat the test may improve reliability, particularly if the subject has never previously performed exercise testing.

Factors that can cause variation in the heart rate response when testing include the following:

- Dehydration
- Prolonged exercise prior to testing
- Environmental conditions (heat, humidity, ventilation)
- Fever
- Use of alcohol, tobacco or caffeine 2 to 3 hours prior to testing

The following standard procedures should be followed during each test to ensure accurate and reproducible results and avoid inconsistencies in testing conditions:

- Standard testing protocol.
- Consistent ergometer and protocol used for repeat testing.
- A constant pedal speed maintained during cycle ergometry testing.
- Cycle seat height properly adjusted, recorded and duplicated in repeat testing.
- Consistent time of day when performing repeat testing.
- Data collection procedure used is standardized and consistent.
- Test conditions are standardized.
- Subjects are free of infection and display a normal sinus rhythm.
- Subjects do not engage in intense or prolonged exercise for 24 hours, smoke for 2-3 hours, ingest caffeine for 3 hours or eat a heavy meal for 3 hours prior to the test.
- Room temperature is maintained between 18-20°C (64-68°F) with adequate ventilation.

□ Performing the test

Before conducting a test you should read the *Exercise testing* chapter to review the details of the testing procedure, data viewing and analysis.

The sub-maximal exercise testing procedure is as follows:

1. Create or refer to an appropriate testing protocol for the subject being tested (guidelines for many protocols are reported in *ACSM's Guidelines for Exercise Testing and Prescription, 6th Edition Philadelphia: Williams&Wilkins, 2000:22-29*).
2. Perform the procedure as if you were conducting a maximal exercise test, only terminate the test when the subject's heart rate reaches 85% of their HRmax. The test should also be terminated if an event listed in the section *Test termination* should occur.

All the information reported in the *Exercise testing* chapter are valid for the submaximal test.

The only difference is the VO_2 Max calculation, performed extrapolating the regression line of the VO_2 /Kg vs. HR until the predicted HRmax.

■ Example of a test protocol

	<i>HR at the end of the previous step</i>	<i><80</i>	<i>80-89</i>	<i>90-100</i>	<i>>100</i>
1 st step	workload set at (kgm/min)	150	150	150	150
2 nd step	workload set at (kgm/min)	750	600	450	300
3 rd step	workload set at (kgm/min)	900	750	600	450
4 th step	workload set at (kgm/min)	1050	900	750	600

The mixing chamber **PFT** **CPET**

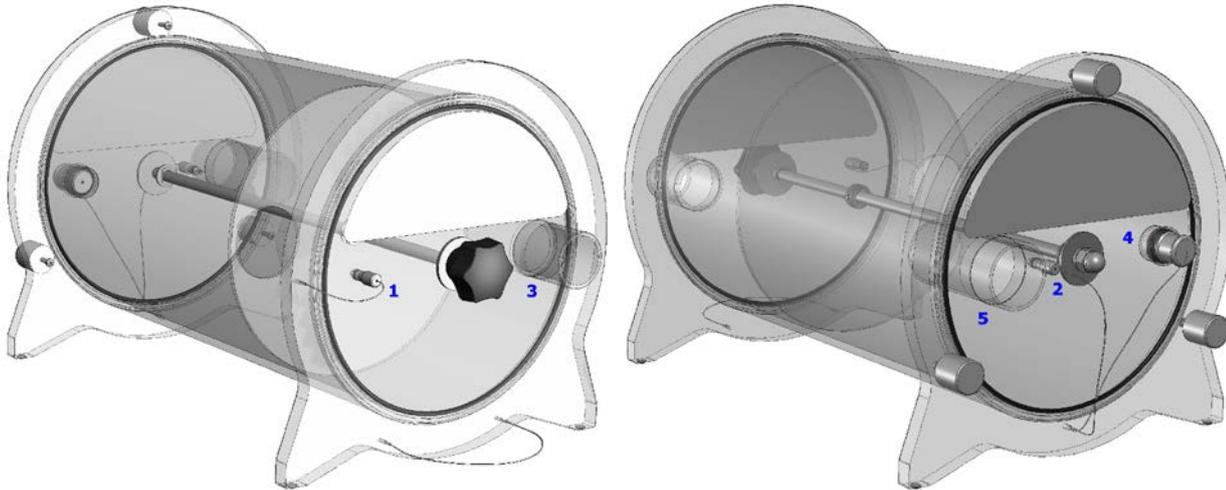


□ The mixing chamber

■ Overview

The mixing chamber is a 8.7-litres plexiglas box, for exercise or resting ($VE < 40$ l/min) tests. For resting tests only a part (about 2.5 litres) of the mixing chamber is used.

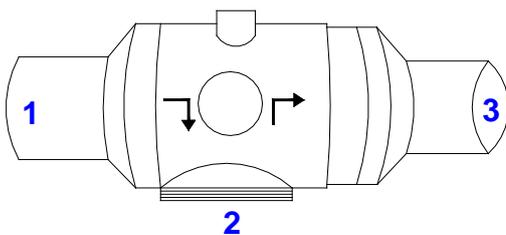
The mixing chamber is shown in the following picture:



1. Connector for the sampling line, for resting tests or tests with $VE < 40$ l/min.
2. Connector for the sampling line, for exercise tests or tests with $VE > 40$ l/min.
3. Inlet for patient's exhaled air.
4. Connector for RH/TA probe.
5. Outlet for patient's exhaled air.

■ Two-way non rebreathing valve description

The two-way non rebreathing valve is very important in order to perform the test properly. It is shown in the following picture:



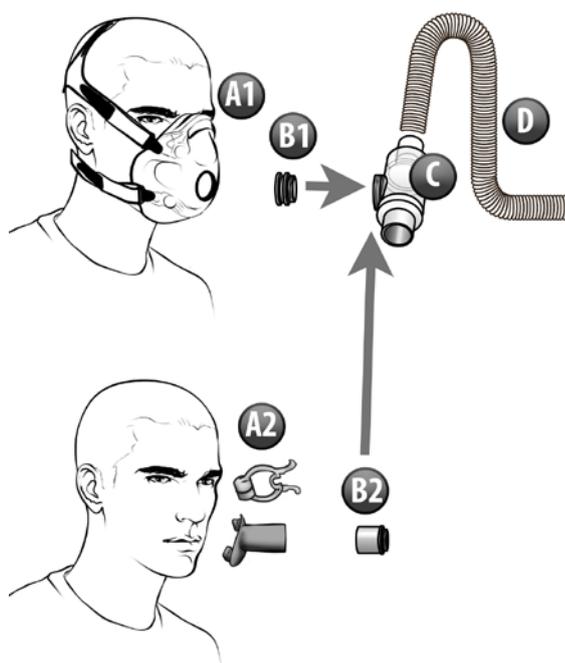
1. Valve inlet
2. Connector for the mask
3. Valve outlet

Note: be very careful in order to differentiate inlet from outlet. These two are not interchangeable, to guarantee proper functionality.

■ Patient's preparation

Mount the VO_2 mask on the patient's head as describe in the chapter *Installation* of the User manual for the specific device you have. Instead of the mask, the patient can use soft mouthpiece and nose clips, as shown in the below picture.

■ **Connecting the two-way non rebreathing valve to the mask**



A1. Mask with headgear

B1. Adapter (generally already assembled on the mask)

C. 2-way non rebreathing valve

A2. Soft mouthpiece and nose clips

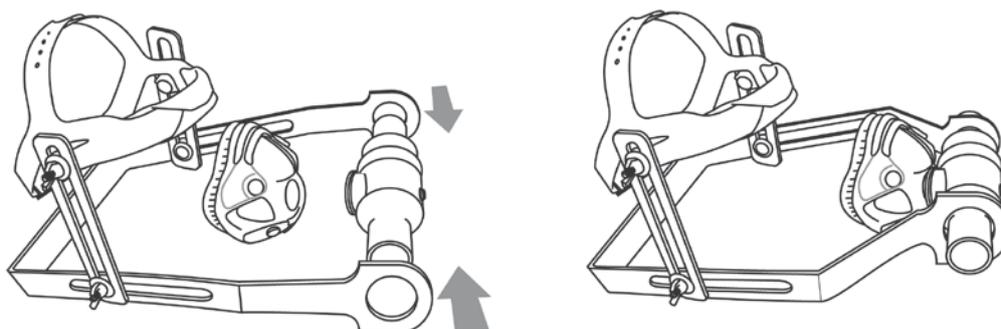
B2. Adapter

D. Corrugated tube

Connect the VO₂Max mask or the soft mouthpiece to the 2-way valve through the adapter.

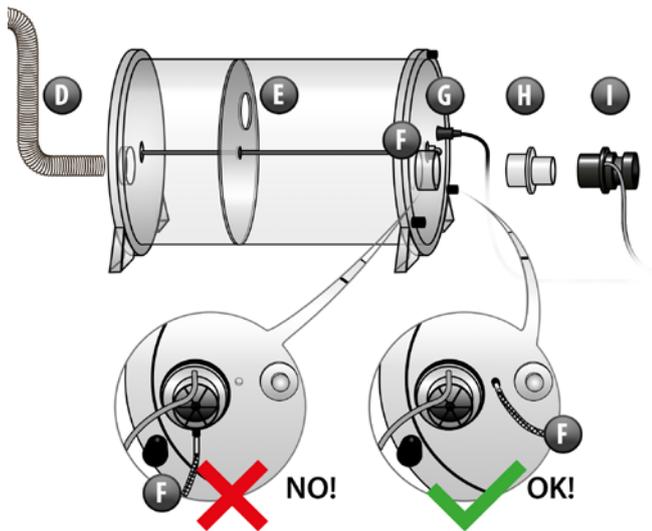
Connect the 2-way valve outlet to the corrugated tube.

■ **Connecting the above assembly to the head support (option)**



■ **Preparing the mixing chamber for a test**

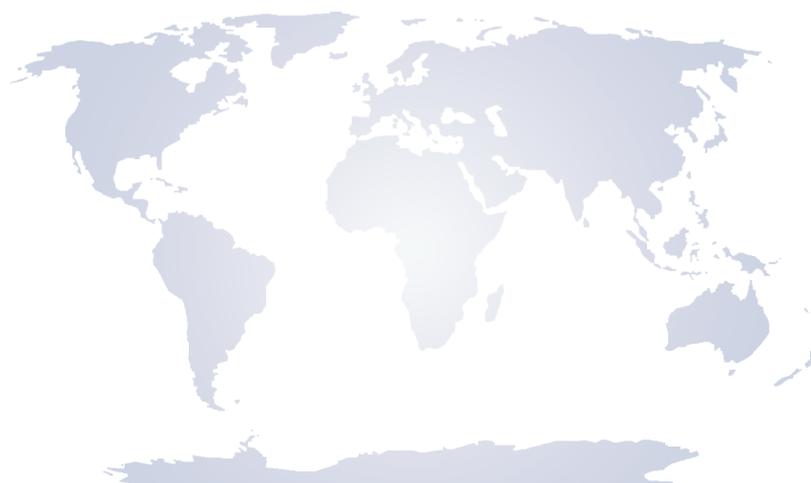
1. Connect the corrugated tube to the inlet #3 of the mixing chamber.
2. Disconnect the sampling line from the turbine and connect it to the connector #1 (for resting tests) or #2 (for exercise tests) of the mixing chamber.
3. Close the connector #2 (for resting tests) or #1 (for exercise tests) of the mixing chamber with the little plug.
4. Connect the RH/TA probe to the connector #4.
5. Connect the turbine through the adapter to the connector #5. See picture below.



- | | |
|---------------------------|----------------|
| D. Corrugated tube | G. RH/TA probe |
| E. Mixing chamber | H. Adapter |
| F. Hole for sampling line | I. Turbine |

■ **Performing the test**

Perform a turbine calibration and an ERGO calibration (see *Calibration* chapter for further details). Start an exercise test as described in the *Exercise testing* chapter.



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