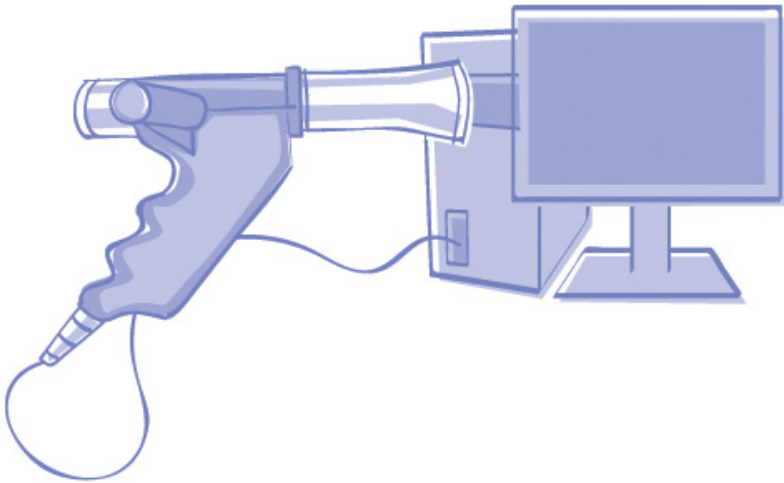




Easy on-PC

Operator's Manual



Version V03b

Note

The information in this manual applies to software version V1.5.x.x only. It does not apply to earlier software versions.

Due to continuing product innovation, specifications in this manual are subject to change without notice.

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1	Introduction	5
	1.1 CE Marking Information	5
	1.2 Licence Terms	5
	1.3 Revision History	6
	1.4 Manual Purpose	6
	1.5 Intended Audience	6
	1.6 Styles	6
	1.7 Safety Information	7
	1.8 Intended Use	12
	1.9 Description of the Medical Electrical Device	13
	1.10 Easy on-PC Sensor Design and Operation	13
	1.11 System Requirements	14
2	Start-up and Preparation	15
	2.1 Software Installation	15
	2.2 Connecting the Flow Sensor	21
	2.3 Preparing the Flow Sensor	24
	2.4 Starting the Software Program	25
3	Performing a Test	26
	3.1 Selecting/Admitting a Patient	26
	3.2 Selecting a Test	31
	3.3 Forced Vital Capacity (FVC/FVL)	32
	3.4 Vital Capacity (SVC)	42
	3.5 Maximum Voluntary Ventilation (MVV)	45
	3.6 Bronchial Provocation	47
	3.7 Quick Test	53
	3.8 Ending the Test	53
	3.9 Retrieving/Printing Stored Tests	54
	3.10 Trend View	57
	3.11 Definition of Important Parameters	59
	3.12 Editing Patient Daa	61
	3.13 Quality Messages / Grades (Details)	62
	3.14 System Interpretation	67
	3.15 Retrospective Test Assessment, Entering Comments	67
4	Hygiene, Cleaning, Maintenance, Disposal	70
5	System Settings	76
6	Troubleshooting Tips	92

7	Specifications	93
8	Technical Description	95
9	Order Information	97
10	Appendix	98
	10.1 Interpretation	98
	10.2 Predicted Values	102
	10.3 GDT Interface	103
	10.4 Report Designer	109
	10.5 Electromagnetic Compatibility (EMC)	113
	10.6 Quick Reference Guide to the Screen Displays	118
	10.7 Literature	132

1 Introduction

1.1 CE Marking Information

- The product *Easy on-PC* bears the CE marking CE-120 (notified body SGS) indicating its compliance with the provisions of the Council Directive 93/42/EEC about medical devices and fulfills the essential requirements of Annex I of this directive.
- The flow sensor has been assigned to class IIa as specified in Annex IX of the Directive 93/42/EEC.
- The device fulfills the requirements of standard EN 60601-1 "Medical Electrical Equipment, Part 1: General Requirements for Safety" as well as the electromagnetic immunity requirements of standard EN 60601-1-2 "Electromagnetic Compatibility – Medical Electrical Equipment".
- The radio-interference emitted by the flow sensor is within the limits specified in EN 55011, class B.
- The CE marking covers only the accessories listed in the Order Information chapter.
- Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the equipment comply with the relevant EMC requirements. X-ray equipment, MRI devices, radio systems, and cellular telephones are possible sources of interference as they may emit higher levels of electromagnetic radiation. Keep the equipment away from these devices and verify its performance before use.
- The country of manufacture appears on the device label.

1.2 Licence Terms

By installing the software, you accept the following terms. If you do not accept these terms, please return the product, including all documentation and hardware supplied with the product, to your supplier in return for the reimbursement of the purchase price.

The subject of the contract is the grant of a licence to use the software and the product documentation. n d d grants you a personal, non-exclusive and non-transferable right of use. The software and the accompanying documentation are protected by copyright. The licensee shall comply with the provisions of copyright law.

Ownership and all other rights to the software are retained by n d d. You may not transfer the software by network or data channel to another computer.

The software and the accompanying product documentation may not be altered or copied or, in an altered version, combined with other software and made accessible to third parties. The licensee shall be liable for all damage incurred by the licensor as the result of a violation of copyright in breach of these terms of contract.

1.3 Revision History

Edition	Date	Comment
Version V01	2008-07-22	Initial Release
Version V01 Rev. A	2008-09-18	Revised Version
Version V01 Rev. B	2010-03-04	Revised Version
Version V02	2010-04-06	Revised Version
Version V03	2012-11-26	Revised Version
Version V03b	2012-12-06	Revised Version

1.4 Manual Purpose

This manual contains the instructions necessary to employ the product safely and in accordance with its function and intended use.

1.5 Intended Audience

This manual is geared for clinical professionals. Clinical professionals are expected to have working knowledge of medical procedures, practices, and terminology as required for completing these examinations.

1.6 Styles

Keys (softkeys and hardware elements) are represented in **bold print**, e.g. **New Patient, Select Patient**.

Terms appearing on the display and product names are italicized, e.g. *Last Name, First Name, Easy on-PC*.

1.7 Safety Information

General Information

- This manual is an integral part of the device. It should be available to the equipment operator at all times. Close observance of the information given in the manual is a prerequisite for proper device performance and correct operation and ensures patient and operator safety. **Please note that information pertinent to several chapters is given only once. Therefore, read the manual once in its entirety.**
- To ensure patient safety, the specified measuring accuracy, and interference-free operation, we recommend using only original accessories available through ndd. The user is responsible if using non-ndd accessories.
- ndd is responsible for the effects on safety, reliability, and performance of the device, only if
 - ◆ assembly operations, extensions, readjustments, modifications, or repairs are carried out by ndd or by ndd-authorized personnel
 - ◆ the device is used in accordance with the instructions given in this manual.
- The warranty does not cover damage resulting from the use of unsuitable accessories and consumables from other manufacturers.
- Always consult with ndd, if you intend to connect equipment not mentioned in this manual.
- Components and accessories must comply with the applicable IEC 60601 safety standards and/or the configured system must comply with the electromedical equipment standard IEC 60601-1-1.
- All publications are in conformity with the device specifications and standards on safety of electromedical equipment valid at the time of printing. All rights are reserved for devices, circuits, techniques, software programs, and names appearing in this manual.
- The illustrations in this manual are only examples. They are not binding in any way.
- No part of this manual may be reproduced without written permission from ndd.

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Definitions

In this manual the safety information is classified as follows:

Danger

indicates an imminent hazard. If not avoided, the hazard will result in death or serious injury.

Warning

indicates a hazard. If not avoided, the hazard can result in death or serious injury.

Caution

indicates a potential hazard. If not avoided, the hazard may result in minor injury and/or product/property damage.

Safety Information

Danger

Explosion Hazard—The flow sensor is not designed for use in areas of medical locations where an explosion hazard may occur. Explosion hazards may result from the use of flammable anesthetics, skin cleansing agents or disinfectants. Great care must be exercised when the system is used in an oxygen-enriched atmosphere. The atmosphere is considered to be oxygen-enriched when the room air contains more than 25% of oxygen or nitrous oxide.

Warning

Shock Hazard—

- ◆ If the flow sensor is connected to a PC, this PC must meet the requirements outlined in the Technical Description chapter.
- ◆ Devices may be connected to other devices or to parts of systems only when it has been made certain that there is no danger to the patient, the operators, or the environment as a result. In those instances where there is

any element of doubt concerning the safety of connected equipment, the user must contact the manufacturers concerned or other informed experts to find out whether there is any possible danger to the patient, the operator, or the environment as a result of the proposed combination of equipment. Standards IEC 60601-1-1/EN60601-1-1 must be complied with in all cases.

- ◆ Before using the device, the operator must ascertain that it is in correct working order and operating condition. The cables, in particular, must be checked for signs of damage. Damaged cables and connectors must be replaced immediately, before use.
- ◆ Liquids must not be allowed to enter the flow sensor or the PC. Devices into which liquids have entered must immediately be cleaned and checked by a service technician, before they can be reused.

Warning

Patient Hazard—The operator must be trained in the use of the device.

Patient Hazard—Before performing any tests on patients, refer to the ATS/ERS Taskforce recommendations (literature [11] ("[Literature](#)" on page 132)).

Patient Hazard—User-configured printouts bear the label "Custom Report". The user is entirely responsible for the design, content and use of the printouts.

Risk of Infection—Follow all cleaning procedures carefully, and thoroughly inspect the components after they are cleaned and before each patient is tested. Cleaning residue, particulate matter, and other contaminants (including pieces of torn or broken components) in the breathing circuit create a safety risk to the patient during test procedures. Aspiration of contaminants can be potentially life-threatening.

Risk of Infection—Proper use of the *spirette*TM provides a reliable infection barrier. The use of other accessories is not permitted.

Cross Contamination Between Patients—The *spirette*TM is intended for single patient use. Use a new one for each patient to prevent cross contamination between patients.

Suffocation Hazard—Dispose of the packaging material, observing the applicable waste-control regulations. Keep the packaging material out of children's reach.

Danger

Patient hazard — Observe the following point when performing bronchial provocation tests:

- ◆ Bronchial provocation tests can be dangerous for patients! A primary condition for safe provocation test procedures is a trained and experienced physician.
- ◆ Above all, these physicians must be familiar with appropriate precautions and guidelines, warnings, procedures, contraindications, when to stop further testing, etc. as defined in the medication documentation and in the standards.
- ◆ Observe the contraindications for the medication used, such as
 - general clinical instability of the patient
 - severely reduced lung function
 - treatment with beta blockers
 - hyperresponsiveness
 - pregnancy.
- ◆ A physician or specially trained staff must be present while bronchial provocation tests are being performed. The patient should never be left unattended during the tests.
- ◆ The following should be available throughout provocation tests:
 - a medical specialist capable of treating acute bronchospams
 - appropriate medication as well as resuscitation equipment (defibrillator, cardiac pacemaker)
- ◆ Refer to the relevant literature for creating safe protocols for bronchial provocation tests. Examples are: Sterk PJ, Fabbri LM, Quanjer PhH, et al. Airway responsiveness. Standardized challenge testing with pharmacological,



physical and sensitizing stimuli in adults. Report Working Party Standardization of Lung Function Tests. European Community for Steel and Coal. Official position of the European Respiratory Society. Eur Respir J 1993; 6: Suppl.16, 53–83).

Caution

U.S. Federal law restricts this device to sale by or on the order of a physician.

Equipment Symbols



Observe to the information given in the Operator Manual.



Single-patient use



CE marked per the Medical Device Directive 93/42/EEC of the European Union.



The number found under this symbol is the date of manufacture in the YYYY-MM format.



Manufacturer



Type BF applied part



This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Consult Operator Manual!

1.8 Intended Use

The software program *Easy on-PC* in conjunction with the flow sensor is designed for spirometric measurements in adults and children over the age of 4. The *Easy on-PC* system is used by general practitioners, specialists, in occupational medicine and in hospitals; it may also be used in frontline applications (pharmacies, screening places, first aid centers). *Easy on-PC* is used in combination with the *spirette™* respiratory tube to conduct slow and forced spirometric maneuvers and MVV tests. The *Easy on-PC* software contains data management functions such as displaying, reporting and exporting of test data.

1.9 Description of the Medical Electrical Device

The *Easy on-PC* software is installed on a PC or laptop computer to which the flow sensor is connected by means of a USB cable.

The PC or laptop computer which is not part of the equipment supplied by ndd Medizintechnik AG is thus considered a requisite accessory necessary for the intended use of the device. The requirements for the PC and laptop computer as well as for other peripheral devices such as the monitor and the printer are specified in chapter "[Technical Description](#)" on page 95.

The applied part comprises the handle and the spirette™. The connection cable is not included.

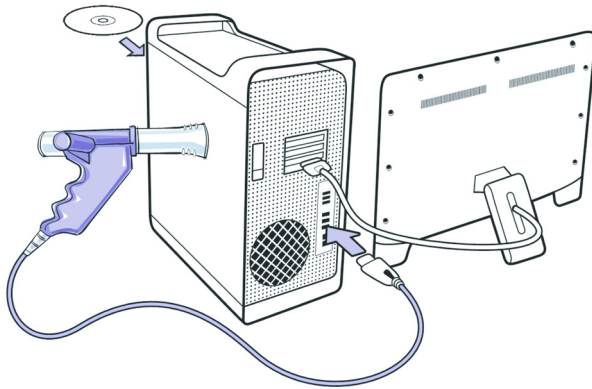


Fig. 1-1 Medical electrical device

1.10 Easy on-PC Sensor Design and Operation

The ultrasound flow sensor measures the transit time to determine flow velocity, volume and molar mass of the gas (molecular weight \times concentration). The illustration below explains the measuring principle: two ultrasound sensors emit very short ultrasound pulses that travel along the transmission path to the opposite ultrasound transducer. Measuring the transit times allows the flow velocity to be determined very accurately and independently of temperature, humidity and molar mass of the gas. Since the measuring principle is based on a digital measurement technique, the sensor requires only one single calibration. The sensor calibration does not change during the sensor's lifetime.

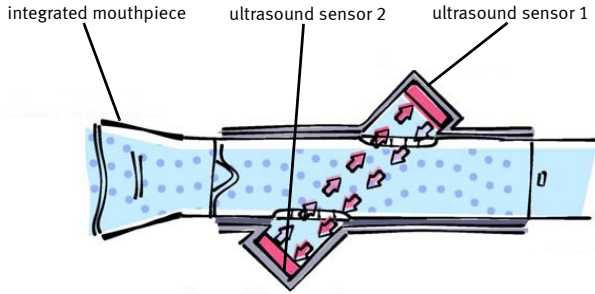


Fig. 1-2 Flow sensor

1.11 System Requirements

	minimum requirements
operating system	Windows 7 [®] , Windows 8 [®] , ¹⁾ Windows XP [®] SP3, Windows Vista [®] (32 bit and 64 bit) ¹⁾ Windows 8 [®] : EasyOne-line (Screen-Connector) and units with serial numbers <80000 are not currently supported.
Web browser	Internet Explorer 6 or later
processor	Intel [®] -/Pentium [®] processor or compatible, 1 GHz
monitor resolution	1024 x 600
hard drive memory	installation/system: 1 GB data memory 4 GB
RAM	512 MB

Beyond the minimum requirements, a larger RAM of >1 GB and a larger monitor with a resolution of 1280 x 960, for example, would be recommended.

Note

The software supports only 100% DPI (if a value different than 100% is selected, information may not be displayed completely).

Use ClearType to enhance screen fonts (for Windows XP, refer to <http://support.microsoft.com/kb/306527/en-us>; for Windows Vista or newer operating systems, ClearType is the default setting).

2 Start-up and Preparation

2.1 Software Installation

Note

Install the software on the PC before connecting the flow sensor.

You will require Administrator privileges to install the software on the PC.

The installation dialogs are available in English only.

- Exit all programs and insert the *Easy on-PC* CD in the CD ROM drive. As a rule, the installation routine starts automatically within 30 seconds of inserting the CD. If the installation routine does not start automatically, go to the CD-ROM directory and start the *EasyWareProStarter.exe* program.

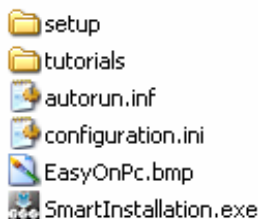


Fig. 2-1

Installation with Windows 7®

(For installation in a Windows XP® environment, please refer to "Installation with Windows XP®" on page 20)

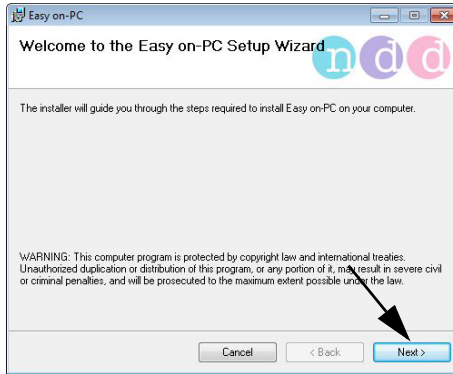


Fig. 2-2

- Click **Next**.



Fig. 2-3

- Confirm with / *Agree*.

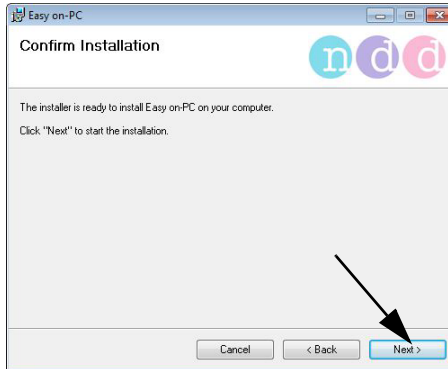


Fig. 2-4

- Click **Next >**.

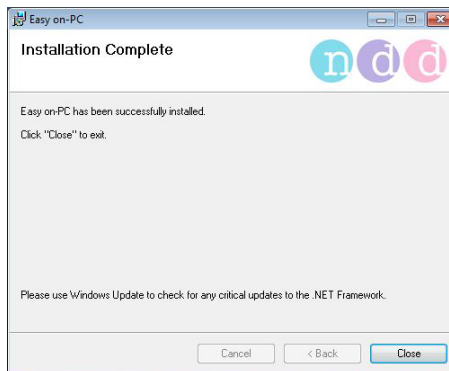
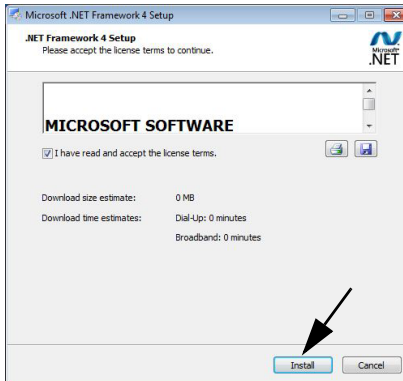
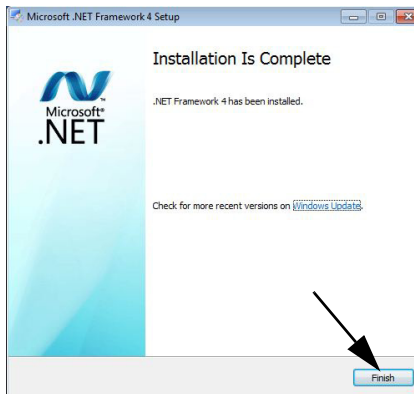


Fig. 2-5

Option: Installing .NET Framework 4 (if not already installed)*Fig. 2-6*

- Click **Install**.

*Fig. 2-7*

- Confirm with **Finish**.

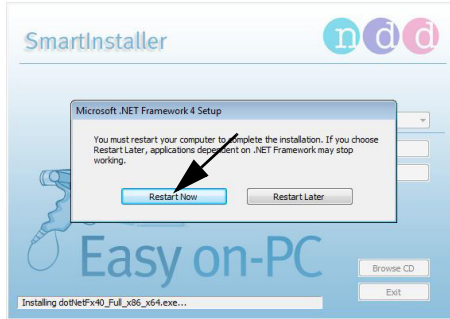


Fig. 2-8

- When this dialog is displayed, select **Restart Now**.

Installation with Windows XP®

- ◆ System requirements: Windows XP® SP3.
- ◆ Before the installation, confirm the *Run As...* dialog to obtain Admin privileges (Admin privileges must be confirmed before the installation of each sub-module, i.e., the user is **repeatedly** asked to confirm).
- ◆ Users with Admin privileges should clear the *Protect my computer ..* check box.

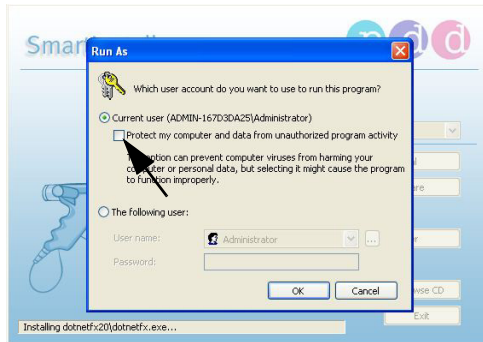


Fig. 2-9

- Install *.NET Framework 4* and restart the computer if prompted to do so.

2.2 Connecting the Flow Sensor

For operation of the flow sensor, the corresponding driver must be installed.

Note

In most situations the CD-ROM will not be required for installation of the driver, because the driver already exists on the PC.

- After installation of the *Easy on-PC* software program, connect the USB connector of the flow sensor to a free USB port on your PC.

The message *New hardware found* will appear. You will also see the *Found New Hardware Wizard*.

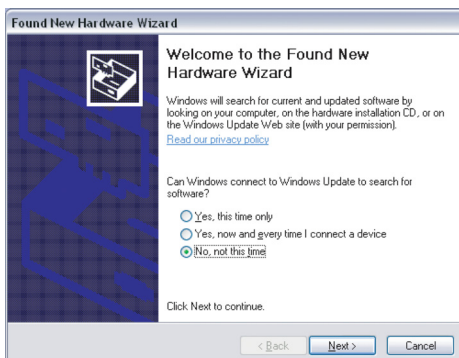


Fig. 2-10

- Answer the prompt *Can Windows connect to Windows Update to search for software* with *No, not this time* and click **Next >**.

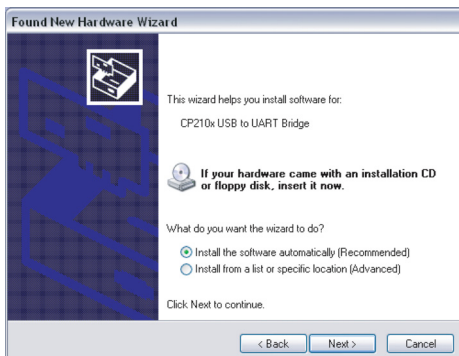


Fig. 2-11

- At the prompt *What do you want the wizard to do?* select *Install the software automatically (Recommended)* and click **Next >**.

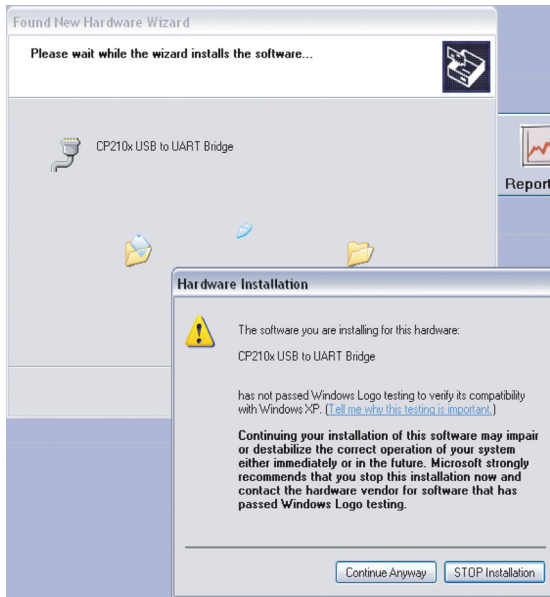


Fig. 2-12

- After the driver has been found on the system, the following message displays:

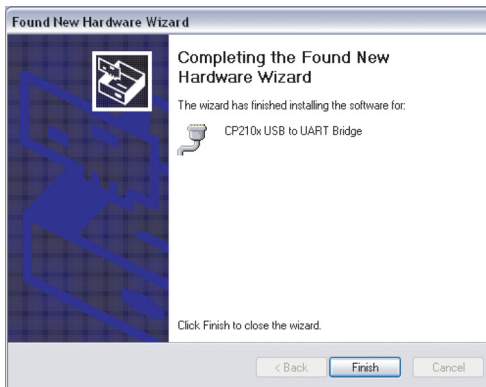


Fig. 2-13

- Accept the proposed driver and click **Finish**.



Fig. 2-14

- Click **OK** to save the new COM port.

Note

Please note that you will have to install the driver again, if the flow sensor is connected to a USB port on which it was not used before.

2.3 Preparing the Flow Sensor

Warning

Shock Hazard—If the flow sensor is connected to a PC, this PC must meet the requirements of IEC standard 60950-1.

- Tear open the plastic bag containing the *spirette™* and fold the bag back, allowing you to insert the *spirette™* into the flow sensor. Ensure that the plastic bag protects the mouthpiece of the *spirette™* until you hand over the flow sensor to the patient.

This approach not only ensures perfectly hygienic conditions, it also keeps the *spirette™* closed for the subsequent determination of the baseline.

- Introduce the *spirette™* - as shown in the illustration - into the flow sensor as far as possible. When doing this, please ensure that the arrow on the *spirette™* is lined up with the arrow on the flow sensor.
- You remove the *spirette™* by pushing it out of the sensor from below.

Warning

Cross Contamination Between Patients—The *spirette™* is intended for single patient use. Use a new one for each patient to prevent cross contamination between patients.

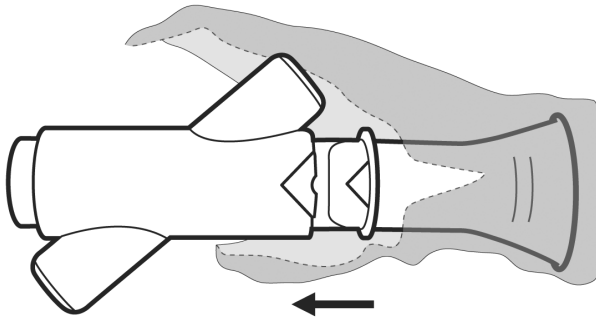


Fig. 2-15 Inserting the *spirette™*

2.4 Starting the Software Program

- Click  .

The initial screen is displayed.

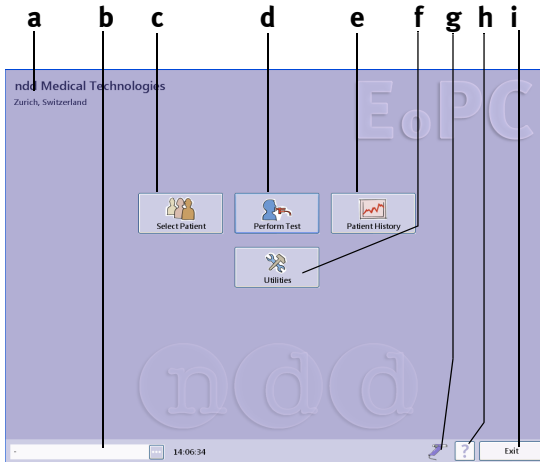


Fig. 2-16 Initial screen

- | | |
|---|--|
| <p><i>a Practice, office, hospital (see "General Tab" on page 77 for details about entering the data)</i></p> <p><i>b Selected patient</i></p> <p><i>c Click to select a patient or admit a new patient</i></p> <p><i>d Click to perform a test</i></p> | <p><i>e Click to review the results from previous tests</i></p> <p><i>f Click to view the setup screen</i></p> <p><i>g Sensor status (sensor icon, if sensor is connected)</i></p> <p><i>h Help button</i></p> <p><i>i Click to quit the program</i></p> |
|---|--|

Note

Before working with the program, setup the system as described in "System Settings" on page 76

- ◆ enter the practice/office or hospital name
- ◆ select the language
- ◆ select the test types and parameters

3 Performing a Test

Note

Before performing a test, you must do the following:

- ◆ select the test details
(e.g. only expiratory or inspiratory and expiratory FVC measurement, predicted value calculation, etc., see "Test Tab" on page 81)
- ◆ select a patient from the database, as described below, or enter a new patient in the database. As an alternative you can perform a *Quick Test* which will be saved to the database with an automatically assigned ID (e.g. Q_0033) (see "Quick Test" on page 53).

3.1 Selecting/Admitting a Patient

- Click **Select Patient**.

The patient list will be displayed.

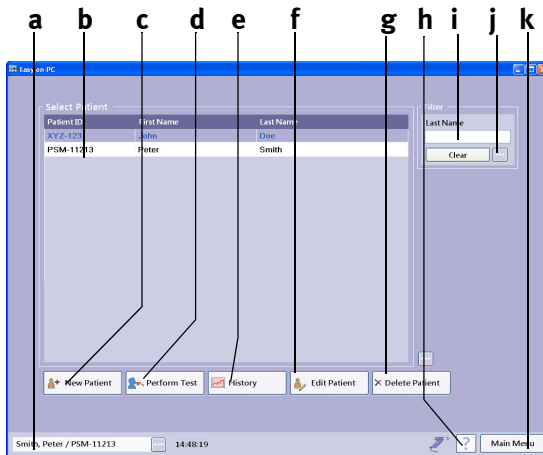


Fig. 3-1 Patient list



- | | |
|---|--|
| <p><i>a</i> Selected patient</p> <p><i>b</i> Bar cursor for patient selection</p> <p><i>c</i> Click to admit a new patient</p> <p><i>d</i> Click to perform a test with the selected patient</p> <p><i>e</i> Click to view the selected patient's test results</p> <p><i>f</i> Click to edit the selected patient's data</p> <p><i>g</i> Click to delete the data of the selected</p> | <p><i>h</i> Help button</p> <p><i>i</i> Filter Last Name; by entering one or more letters, you limit the number of patients to those meeting the filter criteria</p> <p><i>j</i> Additional parameters</p> <p><i>k</i> Back to main menu</p> |
|---|--|
- patient (password-protected, EOPTM or 8005)*

Selecting the Patient

The displayed patients can be sorted by

- ◆ Patient ID
 - ◆ Last Name
 - ◆ First Name
 - ◆ Date of Last Test
- To do so, click on the appropriate title in the column headers.
 - To search for a specific patient, you enter the first letter(s) of the patient's last name at **i** (Fig. 3-1).
 - You select a patient by clicking in the corresponding line of the list: the bar cursor highlights the selected patient. At the same time, the patient's name appears at **a**.

Note

Click  to view the patient data. Click  again to close the window.

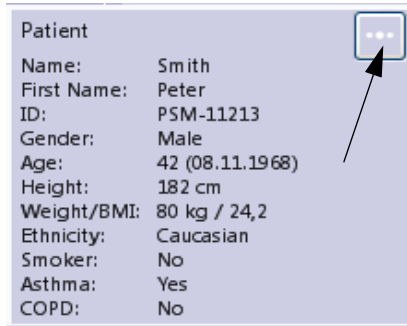



Fig. 3-2 Window showing patient data

Admitting a New Patient

- Click **New Patient**.
- Enter a patient ID and press the **TAB** key or the **Enter** key (click  to enter an automatically generated ID).
- Enter the last and first names in the same way.
- Click **a** (Fig. 3-3) to select the gender and press the **TAB** key.
- Also, select the ethnic origin **b**.
- Enter the date of birth, height and weight.

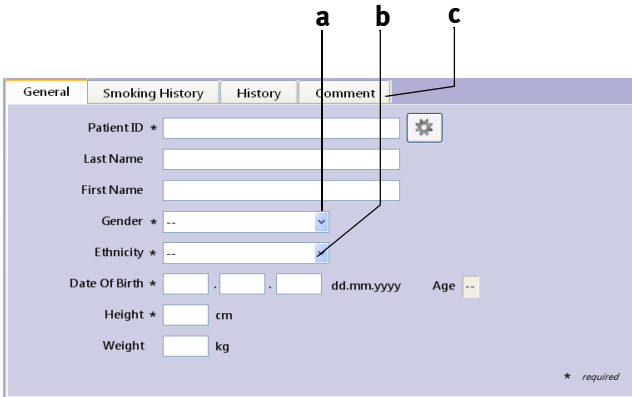
Note

The information regarding gender, age, height, weight and ethnic origin must be correct, because it is used to calculate the predicted values and to interpret the acquired data.

Additional information can be entered on the *Smoking History* (see Fig. 3-4), *History* and *Comment* tabs **c**.

- Close the window with **OK**.

The patient list will be displayed and the new patient is selected.



The screenshot shows a software window titled "Patient data window" with four tabs: "General", "Smoking History", "History", and "Comment". The "General" tab is active. It contains the following fields:

- PatientID * (text input, with a gear icon to its right)
- Last Name (text input)
- First Name (text input)
- Gender * (dropdown menu, labeled 'a')
- Ethnicity * (dropdown menu, labeled 'b')
- Date Of Birth * (text input in format dd.mm.yyyy)
- Age (dropdown menu)
- Height * (text input, unit cm)
- Weight (text input, unit kg)

A small asterisk with the text "* required" is located at the bottom right of the form area. Labels 'a', 'b', and 'c' are positioned above the Gender, Ethnicity, and Comment tabs respectively, with lines pointing to them.

Fig. 3-3 Patient data window

The screenshot shows a software window with four tabs: General, Smoking History, History, and Comment. The 'Smoking History' tab is selected. The form contains the following fields:

- Smoker: A dropdown menu with "--" selected.
- Intensity: A text input field, followed by the label "Cigarette(s) per Day".
- Years Smoking: A text input field, followed by the label "-- Pack Years".
- Non-Smoker Since: A text input field.
- Smoking History: A large, empty text area.
- Asthma: A dropdown menu with "--" selected.
- COPD: A dropdown menu with "--" selected.

Fig. 3-4 Smoking History tab

Merging a Patient's Data Records

You can merge data records for one and the same patient, for example, if they were acquired with different tests or if different spellings of the patient's name exist. Use Drag & Drop (right mouse button) to merge data records.



Fig. 3-5 Merging a patient's data records

3.2 Selecting a Test

The test selection screen will appear either directly after entry of the patient data or it can be accessed from the initial screen with **Perform Test**.

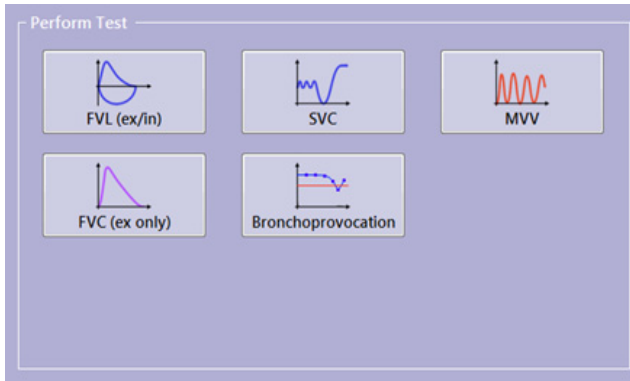



Fig. 3-6 Test menu

Note

If the unit selected is *EasyOne*  (see "Device Tab" on page 86), you will see Fig. 3-7.

Observe the instructions shown on the monitor screen and on the display of the *EasyOne* when performing tests and the subsequent synchronization.

Refer to the *EasyOne* tab (see "EasyOne Tab" on page 87) for configuration options.

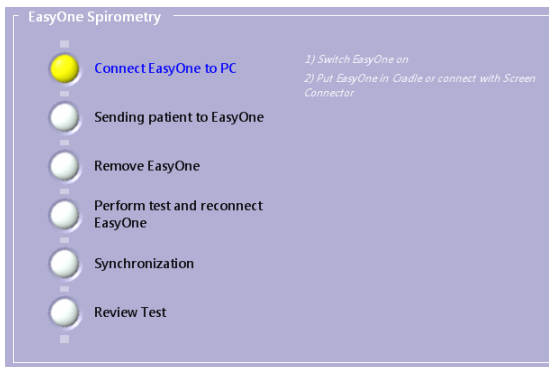


Fig. 3-7 Selection screen when the selected device is *EasyOne*

3.3 Forced Vital Capacity (FVC/FVL)

- Click **FVC/FVL**.

The acquisition screen will be displayed.

Note

The scale for the flow-volume loop depends on the selected test (only expiratory or inspiratory and expiratory, tidal breathing yes/no).

Expiratory FVC Measurement

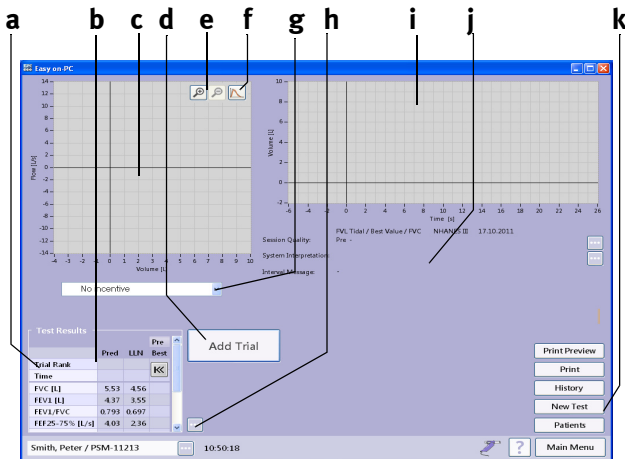


Fig. 3-8 Expiratory FVC acquisition screen

- a Selected test parameters
- b Predicted values, past test results of the patient
- c Flow-volume loop area
- d Start button
- e Scaling
- f Displayed curve selection: best test, best test and pre test, all
- g Click to show and hide the animation program
- h Show/hide expanded parameter list
- i Volume-time curve area
- j Test information and system interpretation area
- k Click to perform a new test, to view the patient's test list, to select a new patient and to print a test

Preparations

The patient should be relaxed and should not wear tight clothing. The patient may stand or sit during the test. In exceptional cases, the patient may feel dizzy when performing the test. Therefore, watch your patients closely, if they are standing for the test.

Explain that the purpose of the test is to determine how much air a person's lungs can hold and how quickly that air can be expelled. Since the spirometry test requires active participation by the patient, it is very important to explain the test maneuver:

- ◆ take the *spirette*TM into the mouth with the lips sealing around the *spirette*TM, taking care not to block its opening with the tongue or bite down excessively on the *spirette*TM
- ◆ breathe calmly
- ◆ fill lungs completely
- ◆ exhale as hard and fast as possible
- ◆ continue blowing out until the lungs are completely empty
- ◆ breathe in again.

If you are new to spirometry, you should practice testing yourself and others prior to testing patients. You will learn to recognize the cause of problems by interpreting the Quality Messages displayed by the program after each effort and how to avoid these problems. After a poor effort explain to your patient how to improve the maneuver.



Fig. 3-9 Patient using the *spirette*TM respiratory tube

Caution

Risk of Injury—Pulmonary function tests require maximum effort on the part of the patient and may lead to dizziness.

Risk of Infection—The *spirette*TM is designed for single use. Use a fresh *spirette*TM for each new patient.

Risk of Infection—In settings where tuberculosis or other diseases that are spread by droplet nuclei are likely to be encountered, proper attention to environmental engineering controls, such as ventilation, air filtration or ultraviolet decontamination of air, should be used to prevent disease transmission.

Risk of Infection—Clean the nose clip after each patient.

Measurement

- Insert the new *spirette*TM in the sensor.
- Attach the nose clip to the patient.
- Click **Start**.

The device advises you to keep the *spirette*TM closed until the test start prompt is displayed. This is necessary to set the baseline correctly.

Note

n dd Medizintechnik AG recommends removing the rest of the *spirette* packaging which wraps the mouthpiece and keeps it closed only after the baseline has been set.

- Block off the *spirette*TM on one end and confirm the message with **OK**.
- When the start test prompt is displayed, hand the sensor over to your patient and instruct him or her to perform the maneuver as explained earlier.

Note

When the system is set up for *Manual Test Stop* (see "**Test Tab**" on page 81), the operator is required to end the test (click the **Test End** button or press the **Space** bar or **Enter** key).

During the test, you will see the flow-volume loop and the volume-time curve on the monitor screen. All curves and measured values will be displayed after the test.

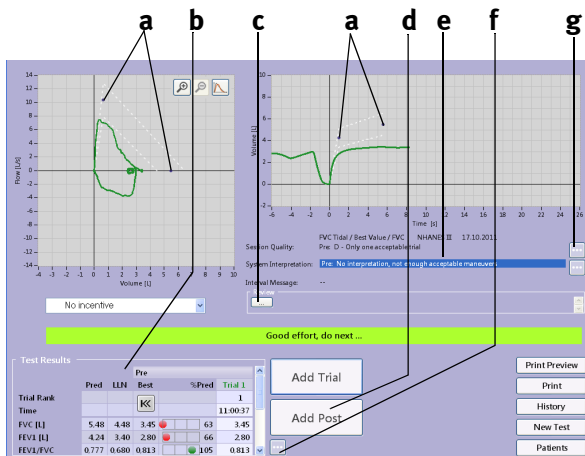


Fig. 3-10 Acceptable FVC test

- a Predicted values
- b Test result
- c Quality message: Quality control result
- d Click to perform a post-test (see "Bronchodilation (Post-Tests)" on page 39)
- e Test information, system interpretation
- f Click for a retrospective test evaluation or to expand the parameter list (see "Retrospective Test Assessment, Entering Comments" on page 67)
- g Area for review comments

In order to assess the patient's pulmonary function, it is necessary to obtain an acceptable test quality. The test quality depends on the co-operation on the part of the patient which, in turn, depends on the quality of the physician's instructions. *Easy on-PC* incorporates an automatic quality control function. This function analyzes the test quality and outputs a message to inform you as to whether the maneuver was acceptable or not (see "System Interpretation" on page 67). At the same time this function allows the physician to improve patient instructions.

When three acceptable maneuvers have been performed, the message *Session complete* appears. If, even after repeated attempts, it is not possible to obtain an adequate number of good maneuvers, you should take a break, depending on how the patient feels or stop measurement. Even after a break, the measurement results remain stored.

- Click **Add Trial** for each subsequent spirometry maneuver.

A review comment can be entered in area **c** or the results can be edited (do not forget to give the reviewer's name).

As soon as three acceptable tests have been performed, the message *Session complete* appears and a quality grade from **A** (optimal) to **F a** is displayed.

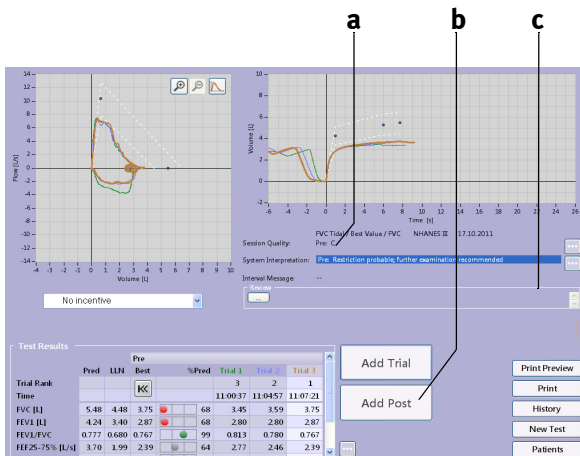


Fig. 3-11 Acquisition screen after three acceptable, expiratory FVC tests
a Quality grade **c** Area for review comments
b Click to perform a post-test (see "Bronchodilation (Post-Tests)" on page 39)

Note

If FEV6 is selected (instead of FVC), the measurement will stop automatically after 6 seconds.

%Pred Graph

The %Pred graph is a three-segment bar. The left segment **a** indicates a value below the lower limit of normal, the middle segment **b** represents a value between the lower limit and the predicted value and the right segment **c** indicates a value above the predicted value. Only the most important parameters are displayed in color, all other parameters are grey.

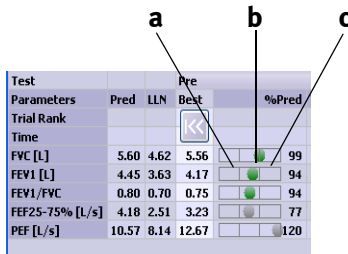


Fig. 3-12 %Pred graph

Adding a Spirometry Trial

If you would like to add trials to a previous test, e.g. if the patient needed a break or if other patients were tested in between, please proceed as follows. Bear in mind, however, that it is only possible to add a trial to a previous test that was performed on the same day.

- Select the patient.
- Click **Perform Test**.
- Select the test, e.g. **FVC**.

A menu will appear.

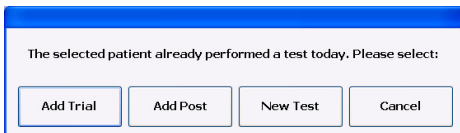


Fig. 3-13 Test menu

- Click **Add Trial** or **Add Post**.

The acquisition screen will be displayed.

- Perform the new spirometry maneuvers.

FVL Test (inspiratory and expiratory measurement)

Ambient Conditions

The ATPS values (**A**mbient **T**emperature **P**ressure **S**aturated = spirometer conditions) of inspiratory measurements must be converted to BTPS values (**B**ody **T**emperature **P**ressure **S**aturated = body conditions). For this conversion, the system needs the following data:

- ◆ relative humidity
- ◆ room temperature
- ◆ atmospheric pressure or altitude.

Before the inspiratory test can be started, a window pops up with these data. Check the data. For the pending test you can now edit the data, if necessary, or you confirm them, if they are correct.

The screenshot shows a software window titled 'Manually Entered Values'. It is divided into two main sections: 'Manually Entered Values' and 'BTPS'.
 In the 'Manually Entered Values' section, there are three input fields:
 - 'Ambient Temperature' with a value of 20 °C (5.40).
 - 'Humidity' with a value of 50 % (0.99).
 - 'Altitude' with a value of 400 m (0.4000).
 In the 'BTPS' section, there are two output fields:
 - 'In' with a value of 1.118.
 - 'Ex' with a value of 1.020.
 At the bottom right of the window is a button labeled 'Recalculate BTPS'. At the bottom left is a 'Cancel' button, and at the bottom right is a 'Confirm >>' button.
 Labels a through f are placed above the window with lines pointing to specific elements: a points to the conversion factor '1.118', b points to the humidity input box, c points to the temperature input box, d points to the altitude input box, e points to the 'Recalculate BTPS' button, and f points to the 'Confirm >>' button.

Fig. 3-14 Window showing the ambient conditions

- | | |
|--|--|
| a Conversion factor | e Click to recalculate the BTPS factor (if the ambient conditions were modified) |
| b Box for entry of the humidity | f Click to confirm and accept the values |
| c Box for entry of the room temperature | |
| d Box for entry of the altitude (atmospheric pressure) | |

- Edit the values, if necessary, and click **Confirm >>** to close the window.

Warning

Erroneous Measurement Results— Incorrect entries may lead to erroneous test readings and incorrect system interpretations. The specified measuring accuracy is ensured only when all entries are correct.

The inspiratory and expiratory FVL test acquisition screen appears.

Measurement

- Prepare the patient (see "Preparations" on page 33) and explain the test maneuvers:
 - ◆ take the *spirette*TM into the mouth with the lips sealing around the *spirette*TM, taking care not to block its opening with the tongue or bite down excessively on the *spirette*TM
 - ◆ breathe calmly
 - ◆ fill lungs completely
 - ◆ exhale as hard and fast as possible
 - ◆ continue blowing out until the lungs are completely empty
 - ◆ inhale as hard and fast as possible.
- Conduct the tests as described in section "Measurement" on page 34.


Note

The volume-time curve (Fig. 3-16) does not represent the forced inspiration at the end of the maneuver.

Bronchodilation (*Post-Tests*)

The *Post*-test is usually performed to determine the patient's response to bronchodilating asthma medication. This is done by administering a bronchodilator to the patient after he or she has performed a spirometric test (*Pre-Test*). Approximately 10 to 20 minutes after the medication (when bronchodilator shows effect, observe information supplied with the medication) a second spirometric test is performed. After the test the *Pre* and *Post* results are compared. *Post*-tests can only be added to previous tests on the same day.

- Select the patient.
- Select the test, then click **Add Post** to close the window.

The window with the patient's existing tests appears. With  (Fig. 3-15 left) you display the detailed results of the *Pre* tests (Fig. 3-15 right).

Test Parameters	Pred	LLN	Pre Best	Post Best
Trial Rank			➤	⏪
Time				
FVC [L]	4.50	3.69	3.98	
FEV1 [L]	3.62	2.94	3.71	
FEV1/FVC	0.80	0.70	0.93	
FEF25-75% [L/s]	3.57	2.19	5.58	
PEF [L/s]	9.10	7.10	10.45	

Test Parameters	Pred	LLN	Pre Best	%Pred	Trial 1	Trial 2	Trial 3	Post Best
Trial Rank			⏪		1	3	2	⏪
Time					09:53:14	10:22:28	10:22:58	
FVC [L]	4.50	3.69	3.98	88	3.98	3.85	3.92	
FEV1 [L]	3.62	2.94	3.71	102	3.71	3.68	3.70	
FEV1/FVC	0.80	0.70	0.93	117	0.93	0.96	0.94	
FEF25-75% [L/s]	3.57	2.19	5.58	156	5.58	5.74	5.87	
PEF [L/s]	9.10	7.10	10.45	115	10.14	9.90	10.45	

Fig. 3-15 Detailed test results

- Conduct the tests as described in section "Measurement" on page 34.

As soon as three acceptable tests have been performed, the message *Session complete* appears and a quality grade from A (optimal) to F is displayed (see "Quality Messages / Grades (Details)" on page 62).

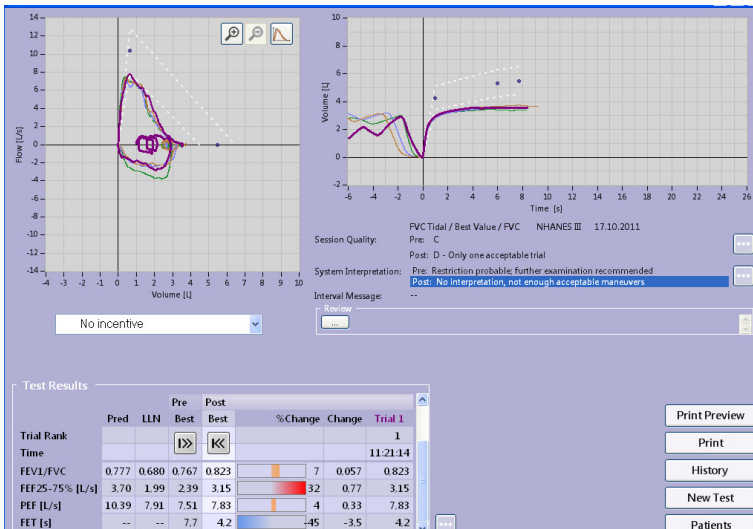


Fig. 3-16 Acquisition screen after three acceptable post-tests

Animation Program for Children

An animation program for children is available for FVC, FVL and SVC tests. You can choose between two animations: *Balloon* and *Monkey*. When the animation program is activated, we recommend disabling the manual test stop and working with the automatic test stop (see "General Tab" on page 81).

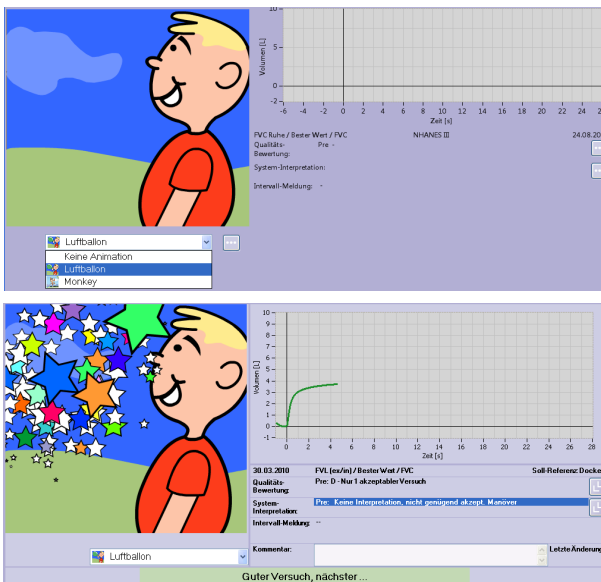


Fig. 3-17 Animation program for children, test start, successful test

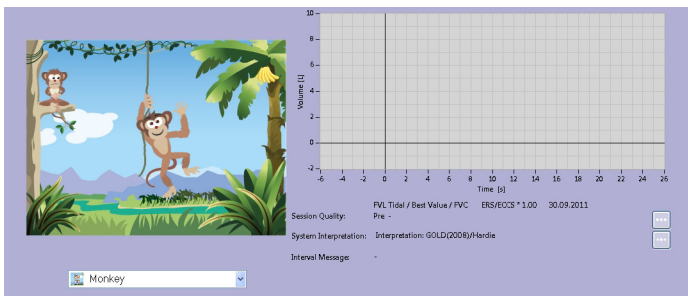



Fig. 3-18 Animation program for children, test start, successful test

The *Monkey* animation can be viewed in full-screen mode .

3.4 Vital Capacity (SVC)

Slow vital capacity measurements determine the vital capacity, starting from tidal breathing. Slow vital capacity measurements determine the vital capacity, starting from tidal breathing. (You can configure the device for direct measurement of the vital capacity, i.e., without initial tidal breathing (see "SVC Tab" on page 84). For this test type, too, the ATPS values (Ambient Temperature Pressure Saturated = spirometer conditions) must be converted to BTPS values (Body Temperature Pressure Saturated = body conditions) (see "Ambient Conditions" on page 38).

After three acceptable maneuvers the message *Session complete* appears.

- Select the patient (see "Selecting/Admitting a Patient" on page 26).
- Prepare the patient (see "Preparations" on page 33) and explain the test maneuvers:
 - ◆ take the *spirette*TM into the mouth with the lips sealing around the *spirette*TM, taking care not to block its opening with the tongue or bite down excessively on the *spirette*TM
 - ◆ breathe calmly in and out
 - ◆ when the start test prompt appears, take a maximum inspiration followed by an immediate, but unhurried, exhalation.
- Select the test with **SVC**.

The slow vital capacity acquisition screen appears.

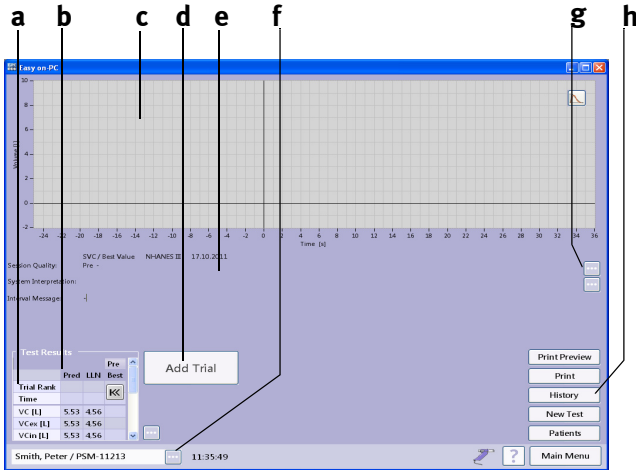


Fig. 3-19 Slow vital capacity acquisition screen

a Selected test parameters

b Predicted values

c Volume-time curve area

d Start button

e Test information and system interpretation area

f Click for a retrospective test evaluation or to expand the parameter list (see "Retrospective Test Assessment,

Entering Comments" on page 67)

g Click to view additional information

h Click to perform a new test, to view the patient's test list, to select a new patient and to print a test

- Conduct the tests as described in section "Measurement" on page 34.

As soon as three acceptable tests have been performed, the message *Session complete* appears and a quality grade from *A* (optimal) to *F* is displayed (see "[Quality Messages / Grades \(Details\)](#)" on page 62).

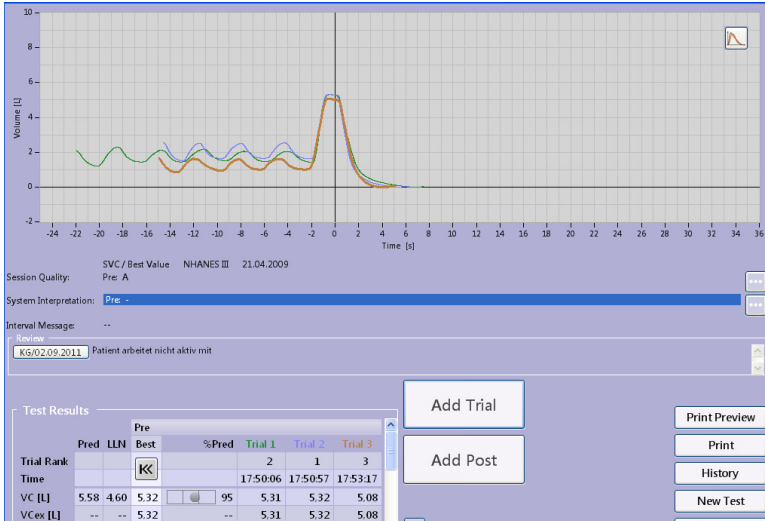


Fig. 3-20 Acquisition screen after three acceptable SVC tests

3.5 Maximum Voluntary Ventilation (MVV)

In these tests, the maximum ventilation volume over an uninterrupted period of 12 seconds is measured. For this test type, too, the ATPS values (Ambient Temperature Pressure Saturated = spirometer conditions) must be converted to BTPS values (Body Temperature Pressure Saturated = body conditions) (see "Ambient Conditions" on page 38).

- Select the patient (see "Selecting/Admitting a Patient" on page 26).
- Prepare the patient (see "Preparations" on page 33) and explain the test maneuvers:
 - ◆ take the *spirette*TM into the mouth with the lips sealing around the *spirette*TM, taking care not to block its opening with the tongue or bite down excessively on the *spirette*TM
 - ◆ when the test start prompt is displayed, breathe in and out as deeply and as fast as possible over a period of 12 seconds.
- Select the test with **MVV**.

The MVV acquisition screen appears.

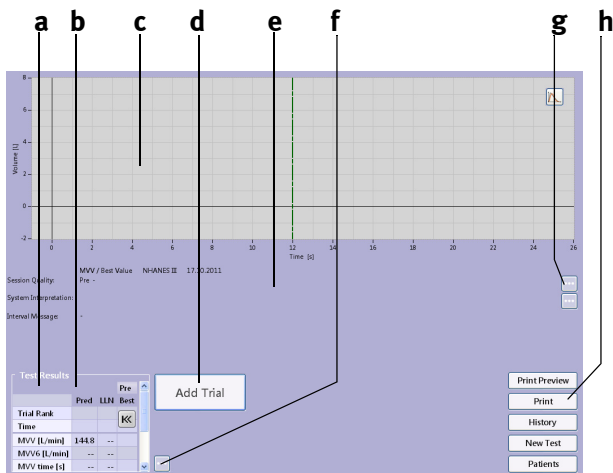


Fig. 3-21 MVV acquisition screen

a Selected test parameters

b Predicted values

c Volume-time curve area

d Start button

e Test information and system interpretation area

f Click for a retrospective test evaluation or to expand the parameter list (see "Retrospective Test Assessment, Entering Comments" on page 67)

g Click to view additional information

h Click to perform a new test, to view the patient's test list, to select a new patient and to print a test

- Conduct the tests as described in section "Measurement" on page 34.

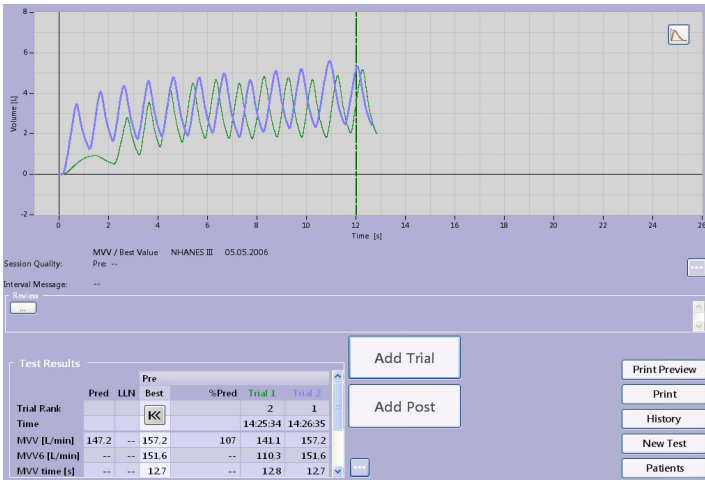


Fig. 3-22 Acquisition screen after six acceptable MVV tests

3.6 Bronchial Provocation

Introduction and Safety Information

Bronchial provocation tests are performed by administering increasing doses of an airway irritant. The reaction of the respiratory system to these substances is measured. A number of standardized substances are available as provocative agents.

Danger

Patient Hazard —

- ◆ Bronchial provocation tests can be dangerous for patients! A primary condition for safe provocation test procedures is a trained and experienced physician.
 - ◆ Physicians must be familiar with appropriate precautions and guidelines, warnings, procedures, contraindications, when to stop further testing, etc. as defined in the medication documentation and in the standards.
 - ◆ Observe the contraindications for the medication used, such as
 - general clinical instability of the patient
 - severely reduced lung function
 - treatment with beta blockers
 - hyperresponsiveness
 - pregnancy.
 - ◆ A physician or specially trained staff must be present while bronchial provocation tests are being performed. The patient should never be left unattended during the tests.
 - ◆ The following should be available throughout provocation tests:
 - a medical specialist capable of treating acute bronchospams
 - appropriate medication as well as resuscitation equipment (defibrillator, cardiac pacemaker)
 - ◆ Refer to the relevant literature for creating safe protocols for bronchial provocation tests. Examples are: Sterk PJ, Fabbri LM, Quanjer PhH, et al. Airway responsiveness. Standardized challenge testing with pharmacological, physical and sensitizing stimuli in adults. Report Working Party Standardization of Lung Function Tests. European Community for Steel and Coal. Official position of the European Respiratory Society. Eur Respir J 1993; 6: Suppl.16, 53–83).
-
-

Performing a Test

- Select a medication (Challenge Test Protocol, see "[Provocation Tab](#)" on page 85). The following is a brief description of how to perform a measurement with the *Methacholine ATS short protocol (5 breaths)*.
- Select the patient (see "[Selecting/Admitting a Patient](#)" on page 26).
- Explain the test maneuver to your patient and attach the nose clip.
- Select **Provocation**.

The initial screen is displayed.

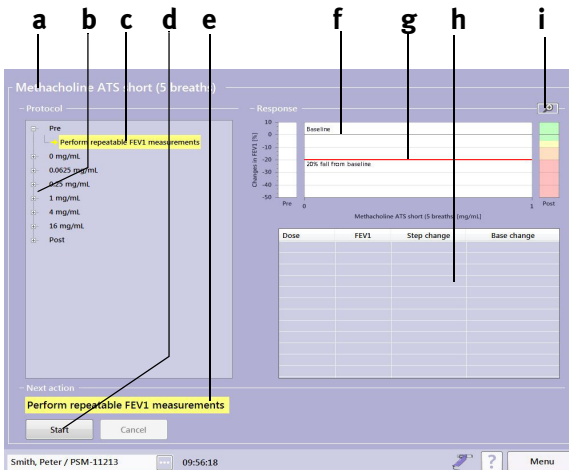


Fig. 3-23 Initial screen for bronchial provocation tests

- | | |
|--|---|
| <p>a Selected protocol</p> <p>b Protocol steps</p> <p>c Current test step</p> <p>d Start button</p> <p>e Next action</p> | <p>f Baseline</p> <p>g Threshold line</p> <p>h Measured values in tabular form</p> <p>i Zoom icon to change the scale</p> |
|--|---|

The baseline is determined either at the pre-test stage or at the 0 mg/ml level, depending on the test protocol. Three acceptable FEV1 measurements should be available for the baseline determination (see "[Forced Vital Capacity \(FVC/FVL\)](#)" on page 32).

- Click **Start** to initiate the measurement.

When three acceptable maneuvers have been performed, the message *Session complete! Great Job!* appears.

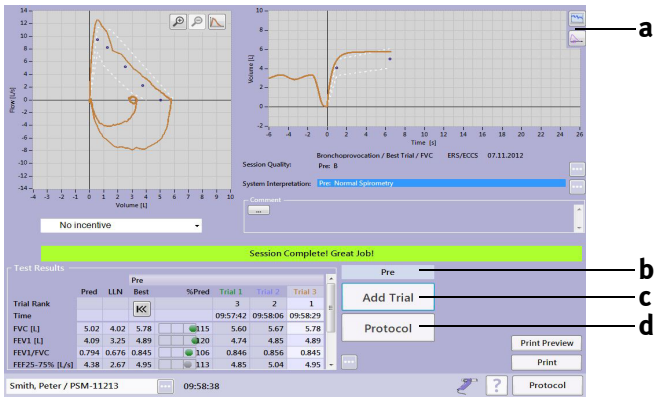


Fig. 3-24 Screen after three acceptable expiratory FVC measurements
 a Toggles between volume-time and test diagramm
 b Current test step
 c Click to add an FEV1 measurement
 d Click to display the protocol screen

- Click **Protocol** (d, Fig. 3-24) to display the protocol screen.

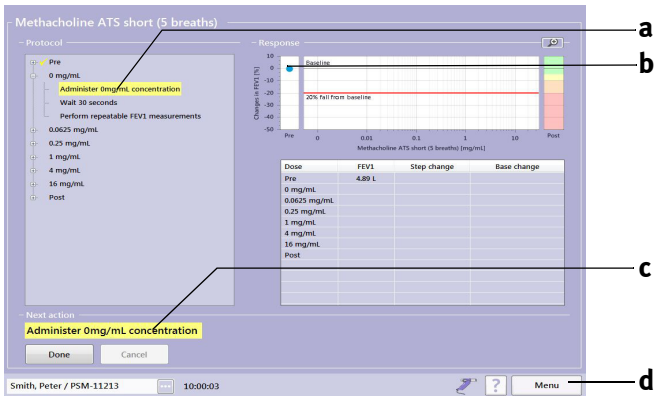


Fig. 3-25 Protocol screen
 a Current test step
 b Pre-test value
 c Next action
 d Menu button

Note

If a reduced lung function is determined, the physician needs to decide if and how to continue the test.

With **Menu d**, you can display a number of keys and then return to the FVC acquisition screen with **Spirometry**, for example.

- Now proceed to the next test step (**c**, Fig. 3-25) and confirm with **Done**.

The next step will be displayed and the next action indicated at **c** is *Wait 30 seconds*.

- When the waiting time is over, click **Done** (you can abort the waiting time at any time with **Done**).

The next step will be displayed and the next action is *Perform repeatable FEV1 measurements*.

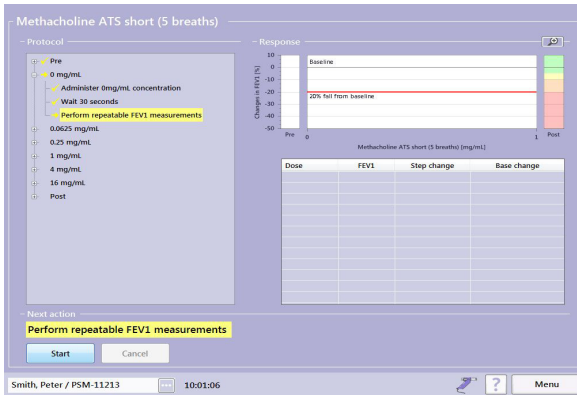


Fig. 3-26 Protocol screen

- Click **Start** to initiate the FEV1 measurement.

Note

After the FEV1 measurement, you need to check whether the measurement quality is sufficient or whether additional trials are required.

With key **a** (Fig. 3-24) you can display the test diagram (response curve) at any time during the test.

- Click **Protocol** to display the protocol screen: the measurement and the next step will be displayed and the next action shown in this example is *Administer 0.0625 mg/mL concentration*.

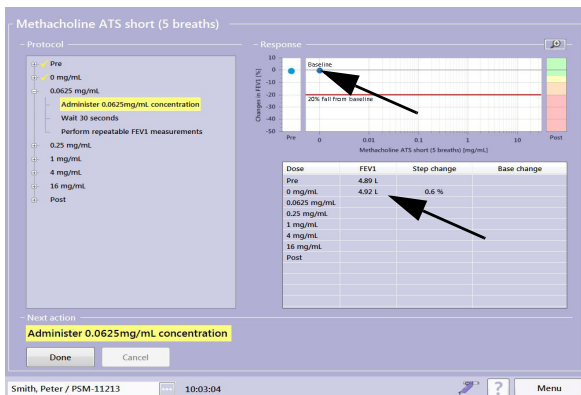


Fig. 3-27 Protocol screen

- Continue executing the remaining levels. As soon as you reach the 20% limit, the message POSITIVE TEST RESULT... will appear, the next level (Post) and the next action *Administer a bronchodilator* will be displayed.

Note

Some protocols require the administration of a bronchodilator even for tests with a negative result.

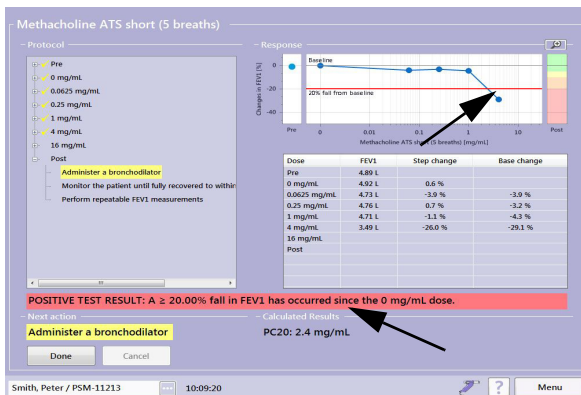


Fig. 3-28 Protocol screen with a positive test result

- Perform the post test according to the instructions. Then the final protocol screen with the post-rest results will be displayed.

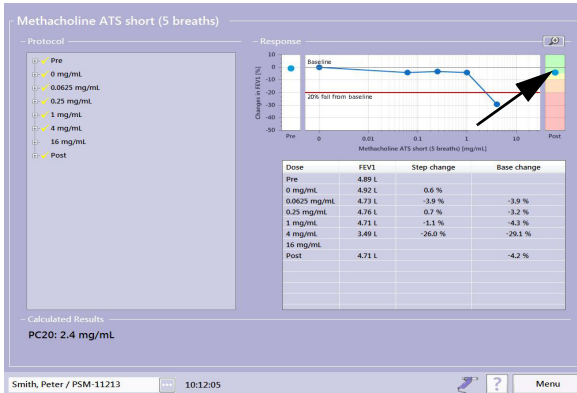


Fig. 3-29 Protocol screen

Note

After the test, the patient should leave the laboratory only after the obstruction is reversed either spontaneously or upon administration of a bronchodilator substance. The reversal should be documented with a lung function test.

3.7 Quick Test

You have the option to perform a quick test without entering patient data. When Quick Test is selected, no predicted values are available, because they are calculated on the basis of the patient data.

- In the main menu, select **Perform Test**.

A menu will appear.

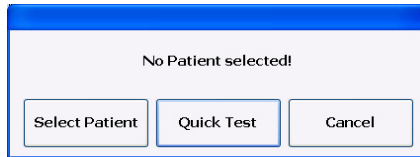


Fig. 3-30 Menu

- Click **Quick Test** and perform the test as usual.

Note

It is not possible to edit the predicted values retrospectively once measurements have been taken.

3.8 Ending the Test

At the end of the test, push the *spirette*TM out of the sensor from below. Dispose of and do not reuse. Refer to section "[Hygiene, Cleaning, Maintenance, Disposal](#)" on page 70 for sensor cleaning instructions.

Warning

Risk of Infection—

- ◆ The *spirette*TM is for single use only and must not be reused.
 - ◆ After tests on patients with an infection of the respiratory tract or patients with a suspected infection of the respiratory tract, it is recommended to clean all parts (outside of the sensor) that were touched during the test, before testing a new patient (see "[Hygiene, Cleaning, Maintenance, Disposal](#)" on page 70).
-
-

3.9 Retrieving/Printing Stored Tests

Easy on-PC saves all tests. Old measurements can be called up at any time to

- ◆ perform a new test with the same patient
- ◆ add a spirometry trial
- ◆ add a post-medication test
- ◆ review or print the results.

Note

Bear in mind that it is only possible to add a trial to a previous test that was performed on the same day (see "[Adding a Spirometry Trial](#)" on page 37).

- Select the patient (see "[Selecting/Admitting a Patient](#)" on page 26).
- Click the **History** button (Fig. 3-31).

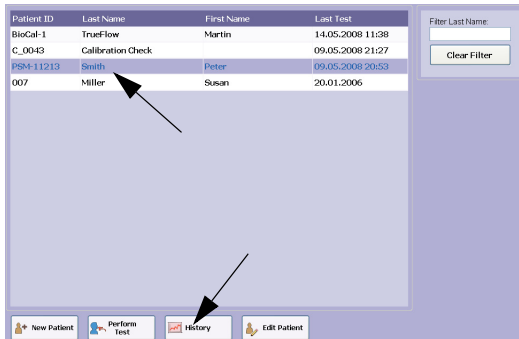


Fig. 3-31 Retrieving/printing stored tests

A window listing all tests stored for this patient will appear.

Protocol	Test Type	Date	Comment
Pre / Post	FVC Tidal	17.10.2011 11:20	
Base-Test	FVC (MBW)	11.08.2011 11:37	
Base-Test	FRC (MBW)	11.08.2011 11:15	
Base-Test	FRC (MBW)	11.08.2011 17:45	
Base-Test	DLCO	11.08.2011 17:30	
Base-Test	SVC	11.08.2011 17:28	
Base-Test	FVL (ex/in)	11.08.2011 17:26	

Fig. 3-32 Test list

The displayed tests can be sorted by

- ◆ test protocol (*Base, Pre, Post*)
 - ◆ test type (*FVC, SVC, MVV*)
 - ◆ test date
 - ◆ comment.
- To do so, click on the appropriate title in the column headers.
 - Highlight the test to view.
 - Click **View Test** to view the test, **Print Preview** to view the test before printing it, **Print** to print the test, or **Trend** to view the trend display (see "**Trend View**" on page 57). Click **Patients** to display the patient list and click **New Test** to display the test selection menu.

Note

Alternative: Double-click on a test to display it.

Examinations for which a *Post*-test exists, are identified by a

small arrow symbol .

When you select **Print Preview**, you will see the print preview of the test:

- ◆ select **b** to choose the test
- ◆ select **c** to print the test
- ◆ select **d** to display the print menu.

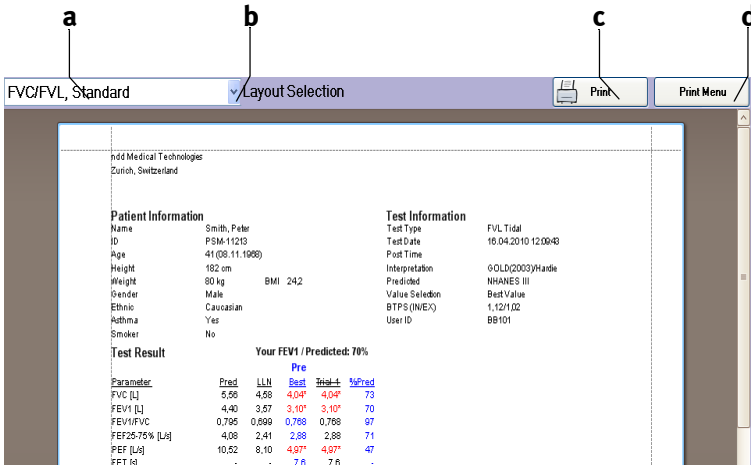


Fig. 3-33 Print preview of the test

a Selected test

b Click to select another test

c Click to print the test

d Click to display the print menu

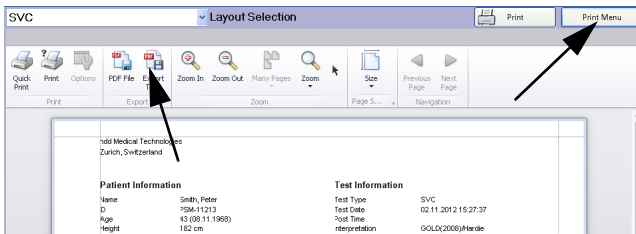


Fig. 3-34 Menu bar when the Print Menu button is pressed

3.10 Trend View

The trend views allow you to observe the measured parameter values over a longer period of time. You can choose between two different views:

- One of the views simultaneously presents up to four parameters, allowing them to be compared. Each parameter has its own vertical axis and scale.
- In the second view, a single parameter can be compared with the predicted normals.

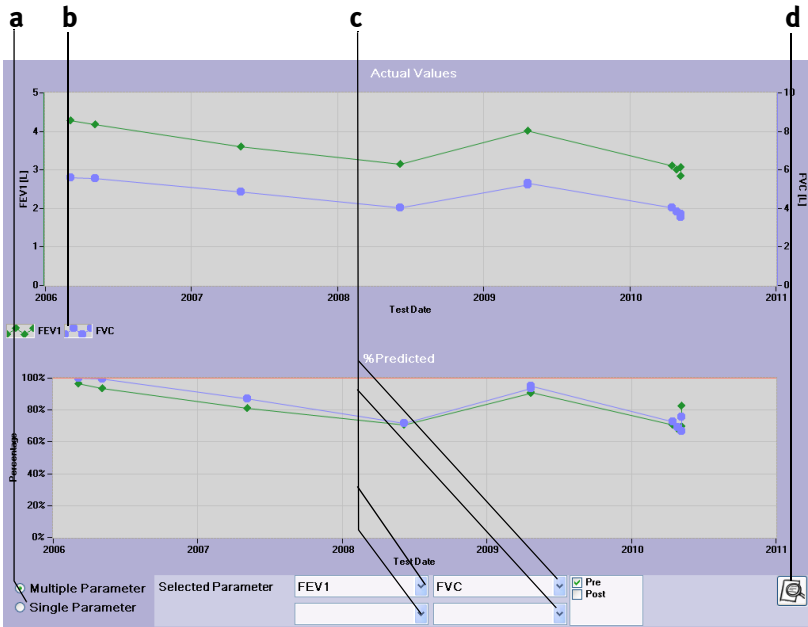


Fig. 3-35 Trend view of multiple parameters

- a Option buttons for selection of the view c List boxes for parameter selection
 b Displayed parameter labels d Icon to initiate the trend printout

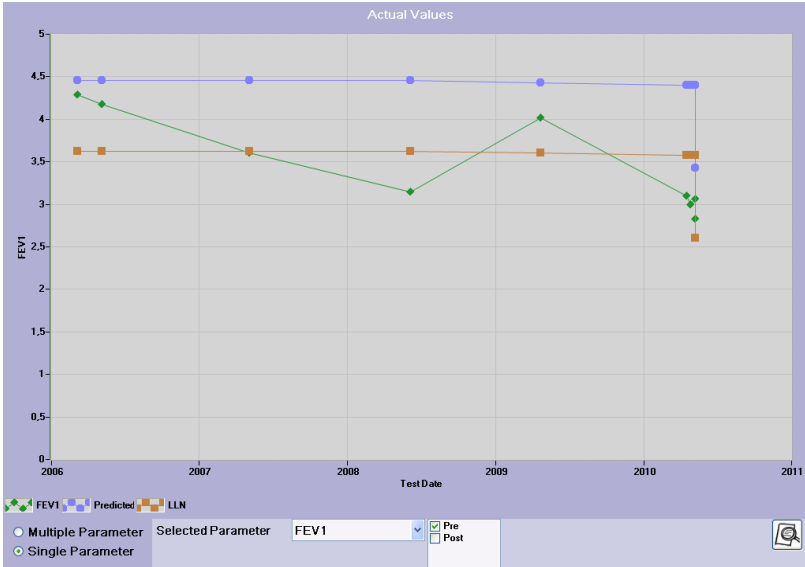


Fig. 3-36 Trend view of a single parameter and its predicted normals

3.11 Definition of Important Parameters

FVC	Forced Vital Capacity (expiratory)	forced expiratory vital capacity
FVC	Forced Vital Capacity (inspiratory)	forced inspiratory vital capacity
FEV1	Forced Expiratory Volume (1 s)	forced expiratory volume after 1 second
FEV6	Forced Expiratory Volume (6 s)	forced expiratory volume after 6 seconds
FEV1/FVC		ratio of FEV1 to FVC
FEV1/VC _{max}		ratio of FEV1 to VC _{max}
FEV1/FEV6		ratio of FEV1 to FEV6
FEF 75 (MEF 25)	Mid-Expiratory Flow (25%)	flow at 75% of expiratory vital capacity
FEF 50 (MEF 50)	Mid-Expiratory Flow (50%)	flow at 50% of expiratory vital capacity
FEF 25 (MEF 75)	Mid-Expiratory Flow (75%)	flow at 25% of expiratory vital capacity
MEF 25-75	Mid-Expiratory Flow (25%-75%)	flow at 25% to 75% of expiratory vital capacity
PEF	Peak Expiratory Flow	peak expiratory flow
PIF	Peak Inspiratory Flow	peak inspiratory flow
FET	Forced Expiratory Time	duration of expiratory phase
BEV	Back Extrapolated Volume	backextrapolated volume
VT	Tidal Volume	tidal volume at rest
ERV	Expiratory Reserve Volume	expiratory reserve volume
IRV	Inspiratory Reserve Volume	inspiratory reserve volume
VC or VC _{max}	Maximum Vital Capacity	maximum vital capacity of a slow spirometric test

VCex	Expiratory Vital Capacity	expiratory vital capacity of a slow spirometric test
VCin	Inspiratory Vital Capacity	inspiratory vital capacity of a slow spirometric test
IC	Inspiratory Capacity	inspiratory capacity(VT + IRV)
MVV	Maximum Voluntary Ventilation	maximum ventilation volume per minute

% Diff (PRE/ POST %)		percentage deviation of the pre and post medication values (bronchodilation test)
LLN		lower limit of normal
Lung Age		lung age, see section "Predicted Values" on page 102 [8]

Note

The parameter names used by *ndd Medizintechnik AG* are those standardized by ATS and ERS. (See literature references [14] and [11] ("Literature" on page 132).

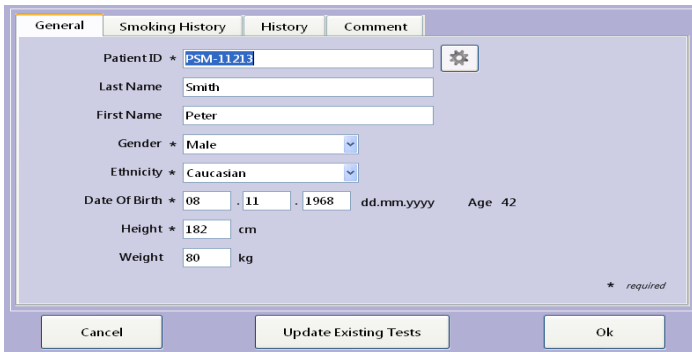
3.12 Editing Patient Daa

Note

Changes to the patient data will only affect future measurements. Stored tests will not be affected.

- Click **Select Patient** on the initial screen.
- Select the patient.
- Click **Edit Patient**.

The patient data window will appear.



The screenshot shows a 'Patient data window' with a light purple background. At the top, there are four tabs: 'General' (selected), 'Smoking History', 'History', and 'Comment'. Below the tabs, there are several input fields and dropdown menus. The 'Patient ID' field contains 'PSM-11213' and has a gear icon to its right. The 'Last Name' field contains 'Smith', and the 'First Name' field contains 'Peter'. The 'Gender' dropdown is set to 'Male', and the 'Ethnicity' dropdown is set to 'Caucasian'. The 'Date Of Birth' field is split into three parts: '08', '.11', and '.1968', with 'dd.mm.yyyy' and 'Age 42' to the right. The 'Height' field contains '182' and 'cm', and the 'Weight' field contains '80' and 'kg'. A small asterisk with the word 'required' is in the bottom right corner of the form area. At the bottom of the window, there are three buttons: 'Cancel', 'Update Existing Tests', and 'Ok'.

Fig. 3-37 Patient data window

- Change or add data.
- Click **Update existing tests** to close the window (for example, if the entered patient data were incorrect and the tests need to be recalculated) or close the window with **OK** if you want to apply the edited data to future tests only.

3.13 Quality Messages / Grades (Details)

Some Basic Facts

End-of-Test criteria, quality criteria and quality grading are based upon the published standards [1], [4], [11], [15] ("**Literature**" on page 132).

Quality grading is based on [4], [11], [15] ("**Literature**" on page 132).

Additional remarks

- The main articles [2] and [3] do not numerically define the minimum expiratory peak flow time (PEFT) that is required for an acceptable test. In this case, 160 ms is used.
- The end-of-test criteria for FVC tests are as follows: A test ends when the volume change during the last 2 seconds is <45 ml, or an inspiratory volume >150 ml is detected. This end-of-test criterion slightly differs from the published criterion in [3] which is 25 ml in the last second. Reason: When the 25 ml in 1 second criterion is applied to the 24 waveforms also defined in [1] and [2], several curves will end too early, and these tests might fail. We therefore decided to slightly change the criterion to 45 ml in 2 seconds.
- In the following tables the quality messages and the quality criteria applied in *Easy on-PC software* are detailed.

FVC/FVL Quality Messages for *Easy on-PC*

The end-of-test criterion for an FVC test is as follows: A test ends when the volume change during the last 2 seconds is <45 ml, or an inspiratory volume >150 ml is detected. When this end-of-test criterion is met, the following quality messages are checked:

Message	Criterion	Recommended action
Don't hesitate ...	Back-extrapolated volume greater than 150 ml or 5% of FVC whichever is greater (for age <= 6: 80ml or 12.5% of FVC whichever is greater)	The patient must exhale all air at once and not exhale in short bursts.
Blast out faster ...	Time until peak flow greater than 160 ms	The patient must exhale more explosively and as firmly and quickly as possible.
Blow out longer ...	Expiration time less than 2 seconds OR volume in the last 0.5 seconds of the expiration larger than 100 ml	The patient stopped exhaling too early. The patient must exhale still further and force as much air as possible out of his or her lungs.
Test Abrupt End!	FVC Test only: Expiration time less than 2 seconds OR volume during last 0.5 seconds >40 ml when expiration time is <6 seconds OR volume during last second >25 ml when end-of-test was initiated by an inspiration.	The patient stopped exhaling too early. The patient must exhale still further and force as much air as possible out of his or her lungs.
Good effort, do next ...	Test meets above criteria.	Good trial. Only one to two more good trials and the test is complete.
Do not start too early!	The time to peak flow (PEFT) is less than 30 ms or flow detected before sensor was initialized (Wait until 'Start Maneuver ...' is displayed)	Instruct the patient to wait until the baseline setting is finished and the device signals that the trial can start ('Start maneuver ...')
Cough detected. Try again...	A cough has been detected (PEF or PIF > 19l/s)	Instruct the patient to avoid coughing during the first second. Repeat the test.

Message	Criterion	Recommended action
Deeper breath ...	FEV1 or FVC* not reproducible. Difference with respect to best test greater than 150 ml or 100 ml if FVC is < 1.0L (for age ≤ 6: 100 ml or 10% of FEV1 or FVC* whichever is greater)	The test differs greatly from previous tests. The patient can inhale even more deeply and exhale even more air.
No maneuver detected!	No parameter calculation possible	Instruct the patient to perform the maneuver according to its definition.
Session complete! Great Job!	QC grade A or B reached.	The test is complete. An adequate number of good tests is available.

* When using FEV6 instead of FVC, FEV6 is also used for the determination of the quality message.

FVC/FVL Quality Grades for *Easy on-PC*

Rating	Criteria
A	At least 3 acceptable tests (for age ≤ 6: 2 acceptable) AND the difference between the best two FEV1 and FVC values is equal to or less than 100 ml (80 ml if FVC < 1.0 L) (for age ≤ 6: 80ml or 8% of FVC whichever is greater)
B	At least 3 acceptable tests (for age ≤ 6: 2 acceptable) AND the difference between the best two FEV1 and FVC values is equal to or less than 150 ml (100 ml if FVC < 1.0 L) (for age ≤ 6: 100 ml or 10% of FVC whichever is greater)
C	At least 2 acceptable tests AND the difference between the best two FEV1 and FVC values is equal to or less than 200 ml (150 ml if FVC < 1.0 L) (for age ≤ 6: 150 ml or 15% of FVC whichever is greater)
D (1)	At least 2 acceptable trials but the results are not reproducible according to 'C'. Quality message: " <i>Result not reproducible</i> " OR only one acceptable trial. Quality message: " <i>Only one acceptable trial</i> ".
D (2)	Only one acceptable trial
F	No acceptable trial available

SVC

The quality grading is based on [3].

SVC Quality Messages

The end-of-test criterion for an SVC is the same as for an FVC test: *A test ends when the volume change during the last 2 seconds is ≤ 30 ml (test time ≤ 6 s) ≤ 45 ml (test time > 6 s), or if an inspiratory volume ≥ 120 ml is detected.*

When this end-of-test criterion is met, the following quality messages are checked:

Message	Criterion	Recommended action
Deeper breath	VC of the two largest trials are not reproducible. Difference with respect to best test greater than 150 ml.	The test differs greatly from previous tests. The patient can inhale even more deeply and exhale even more air.
No Steady-Tidal breathing detected	All end-inspiratory volumes of the last 3 breaths within 200 ml.	Instruct patient to breathe quietly and steadily.
Maneuver incomplete	No ERV and/or no IRV could be calculated due an incomplete maneuver session.	Perform SVC test according to ERS/ATS recommendation.
Do not start too early!	Too early, flow detected.	Instruct the patient to wait until the baseline setting is finished and the device signals that the trial can start ('Start maneuver ...')
Good effort, do next	Test meets above criteria.	Good trial. Only one to two more good trials and the test is complete.
Session complete! Great Job!	QC grade A, VC variability ≤ 150 ml and at least 3 acceptable trials available.	The test is complete. An adequate number of good tests is available.

SVC Quality Grades

Rating	Criteria
A	At least 3 acceptable tests AND the difference between the best VC values is equal to or less than 150 ml.
B	At least 2 acceptable tests AND the difference between the best VC values is equal to or less than 150 ml.
D (1)	At least 2 acceptable trials but the results are not reproducible according to 'B'.
D (2)	Only one acceptable trial
F	No acceptable trial available

3.14 System Interpretation

In assessing the system interpretation, it is important to consider the quality grade **b** of the test. Quality grades *A* to *C* indicate a reliable result. A quality grade of *D* or *F* indicates inadequate test quality. The result must then be interpreted with caution (see section "Interpretation" on page 98 for details).

You can view the test result on the monitor screen as soon as you see message "Session Complete! Great Job!" after performing a test.

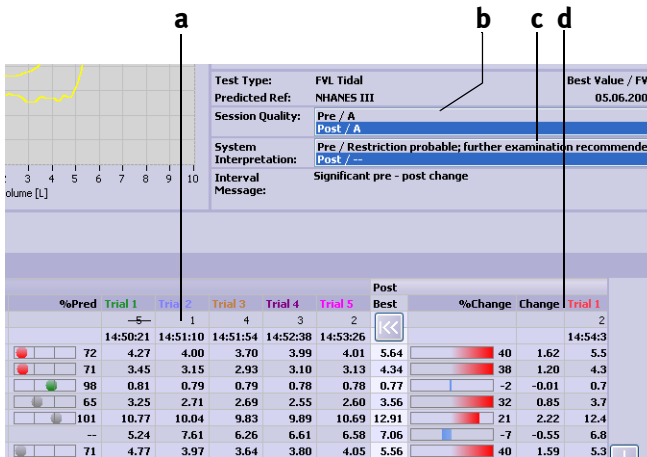


Fig. 3-38 Test results, system interpretation

- a Pre-medication test results
- b Quality grade
- c System interpretation
- d Post-medication test results and deviation from Pre-test results

3.15 Retrospective Test Assessment, Entering Comments

Note

You must be logged in as a user to be able to enter a test assessment and comments.

Changing the Trial Acceptability

The trial acceptability and ranking of tests can be changed retrospectively. This means that you can make tests unacceptable that the system judged acceptable and vice versa. You can also change the trial ranking (rank 1, 2 or 3).

- Click a (Fig. 3-39).

The test assessment icons **b** appear on the test results screen.

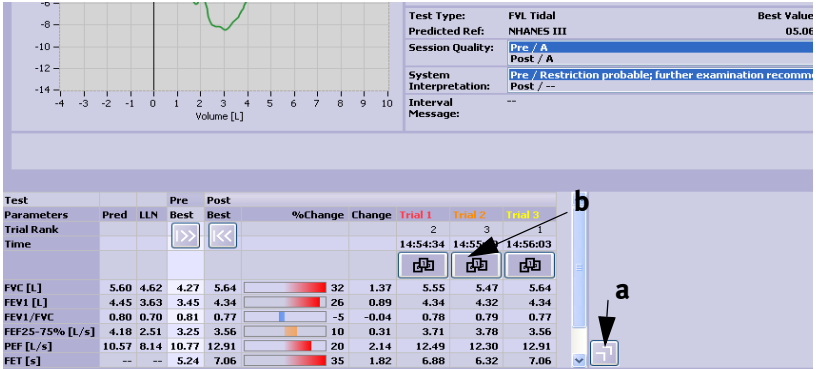


Fig. 3-39 Changing the trial acceptability

Follow these steps to make a test acceptable that the system judged unacceptable:

- Click the icon.
- In the ensuing window, select the *Acceptable* check box.

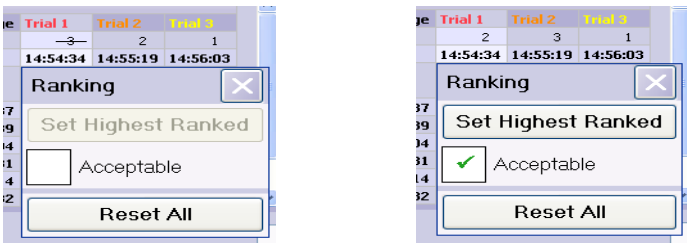


Fig. 3-40 Changing the trial ranking

To assign the highest rank to a test

- click the icon and
- in the ensuing window, click *Set Highest Ranked* (Fig. 3-41).


Note

To assign ranks 1, 2 and 3, please start with rank 3, etc.



Fig. 3-41 Changing the trial ranking

Entering Comments

- Click in the comment area or click .
- Write the text in the window and click **Save** to close the window.

The text will appear in the comment area; the reviewer's name and the date of the last review are displayed below the area.

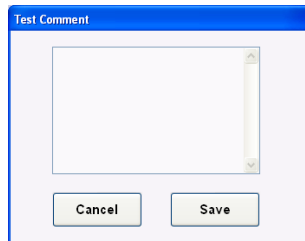


Fig. 3-42 Entering comments

4 Hygiene, Cleaning, Maintenance, Disposal

Hygiene

Caution

Risk of Infection—

- ◆ Thoroughly clean the sensor when you suspect it to be contaminated.
 - ◆ Users with open wounds or contagious diseases must wear gloves.
 - ◆ For the user's own safety and to prevent cross-contamination, wash hands after each patient.
 - ◆ The *spirette*TM must be properly disposed of immediately after use.
-
-

Cleaning

Warning

Shock Hazard—Disconnect the flow sensor from the PC before cleaning.

A risk of infection is eliminated by disinfection of all contaminated surfaces. For an efficient disinfection of the surfaces, thoroughly clean the device first.

Do not use abrasive cleaning agents.

Wipe the flow sensor and the connection cable down with a cloth moistened with alcohol (70% max.).

Caution

Equipment Damage—Liquids must not be allowed to enter the flow sensor. Sensors into which liquids have entered must be checked by a service technician before they can be reused.

Note

It is not necessary to clean the connection cable, unless it is contaminated with blood or sputum. For disinfection, wipe the cable down with a disinfectant. Do not immerse the cable in liquids.

Maintenance**Before each use**

Before each use, visually inspect the device, the cables, the tubing and the sensor for signs of mechanical damage.

If you detect damage or impaired functions that may adversely affect the safety of the patient or user, do not use the system before it has been repaired.

The sensor does not require any routine maintenance.

Do not open the housing. There are no parts inside the housing that can be maintained or repaired by the user.

Check Measuring Accuracy**With Syringe****Note**

As an alternative, the calibration can be checked with a test subject (see "[With Test Subject](#)" on page 72).

The *Easy on-PC* calibration can be checked with a syringe using the calibration check function. The American Thoracic Society (ATS) recommends that the spirometer calibration be checked on a regular basis. Owing to the ultrasound technology used in the flow sensor, the device requires no calibration, even if used frequently. To comply with the recommendations, you can check the calibration as follows:

You need the ndd calibration adapter and a calibration syringe (order number 2030-2).

- Using the calibration adapter, connect the sensor to the syringe as shown below. Ensure that the piston is fully inserted and at the stop position.
- In the *Utilities* menu, click **Calibration Check**, then select **Syringe Calibration Check**.
- On the test screen, click **Start**.
- Wait until the baseline has been set.

- Now execute one full inspiratory pump stroke followed by one full expiratory pump stroke at moderate speed.
- Three full trials are required for the **Single Flow** calibration check, whereas three tests comprising three trials each with different flow rates are required for the **Multiflow** calibration check.

After you perform the maneuver, you will see the text *Accuracy confirmed* and, beneath it, the percentage deviation and the average flow velocity of the pump stroke.

You can repeat the test, print the result or quit the program. The calibration test remains stored and can also be viewed or printed out later.

If you do not reach $\pm 3\%$ accuracy, please follow the troubleshooting instructions in chapter "**Troubleshooting Tips**" on page 92. Should you not be able to remedy the defect by following these instructions either, please consult *ndd* or one of their representatives.



Fig. 4-1 Calibration syringe

With Test Subject

Some Basic Facts

Instead of a syringe a Biological Standard subject with known spirometry values (BioCal Subject) performs a series of spirometry tests. These tests are observed and statistically controlled, if they are within an expected range.

The data is collected on individual healthy, non-smoking BioCal Subjects (e.g. physician, respiratory therapist, ...).

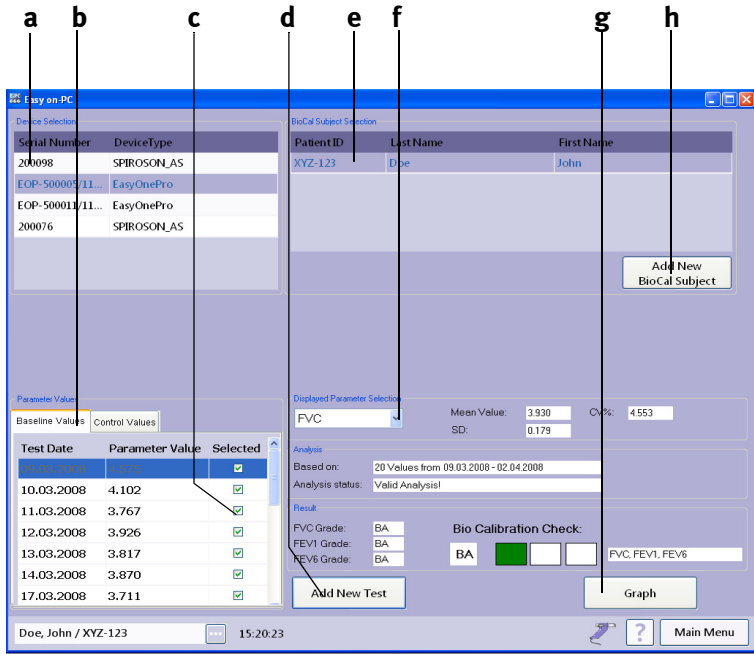


Fig. 4-2 BioCal Check main screen

- a Sensor selection
- b Parameter value tabs
- c Deselect tests (remove check mark)
- d Click to conduct a new test
- e Click to select the BioCal Subject
- f Click to select a parameter
- g Click to display the graphic trends
- h Click to add a new BioCal Subject

Selecting a Test Subject and Performing the Calibration Check

- Start the program.
- Select the **Utilities** menu.
- Open the **Calibration Test** menu and select **Biological Calibration Check**.

The *Biological Calibration Check* menu (BioCal-Check main screen) is open.

- Select the device according to its serial number **a** (check label on sensor).
- Select the BioCal Test Subject **e**. If the subject is not in the list, press **Add New BioCal Subject h** and select the subject or add a new one.

Recommendation: Set the Patient ID to "Bio-1", "Bio-2", ...

- Afterwards return to the BioCal-Check main screen.
- Click **Add New Test d**.
- Perform the test (test selection: FVC, FVL, Test-End, ... according to configuration settings)

Recommendation: Try to blow a QC grade "A" test.

Recommendation: Perform only one BioCal-Check test a day.

- Press **Finish Test**.
- To show the graphic trend, click the **Graph** button **g**.
- To select another review parameter, change the selection in **Displayed Parameter Selection f**.

The parameter values are divided into two tab sheets **b**: *Baseline Values* (used to calculate warning levels) and *Control Values* (controlled values for BioCal-Check QC grade calculation).

To deselect a Test (Baseline and Control Values) remove the check mark **c** of the corresponding test. A deselected test is not used for calculations any more. This means also that by deselecting a baseline value, the first control value is moved to the baseline values, because a minimum number (20) of baseline tests is required for a valid analysis.

Detailed Description

FEV1, FVC and FEV6 are the spirometry parameters used for BioCal-Check quality control. The software will establish a baseline mean value (precision range) for each BioCal Subject and sensor from trials repeated daily for 20 days. This baseline will then be used to trend all subsequent BioCal-Check sessions for the BioCal Subject and sensor. Immediate quality feedback will be provided by the software in accordance with the BioCal-Check QC grades alerting the user of quality warning conditions for the parameters collected.

The BioCal-Check data will be plotted against time. The BioCal-Check reference lines will be mean (precision range), upper limit and lower limit. The upper and lower limits are +/- 2 SD (Standard Deviation).

Specifications of the BioCal-Check QC Grades

For each parameter (FEV1, FVC, FEV6, DLCO, VI, VA) an individual BioCal-Check QC grade is calculated. Additionally the lowest grade of all parameters is reported.

Bio-QC Grade	Limitation	Additional Limitation
<i>BA</i>	-	-
<i>BB</i>	1 value outside $\pm 2SD$	-
<i>BC</i>	1 value outside $\pm 3SD$	-
<i>BD</i>	≥ 4 values outside $\pm 1SD$	only consecutive values on same side of mean
	≥ 2 values outside $\pm 2SD$	only consecutive values on same side of mean
	> 1 value outside $\pm 3SD$	-
	≥ 10 values, consecutive values on same side of mean	-
<i>BF</i>	< 20 baseline values	-

Disposal

The product described in this operator manual must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

5 System Settings

System Settings Menu

The system settings menu is displayed with **Utilities** on the initial screen. The menu offers the following option keys

- ◆ **Configuration** (general settings)
- ◆ **Check Calibration** (calibration verification)
- ◆ **Export** (data export)
- ◆ **XML export.**

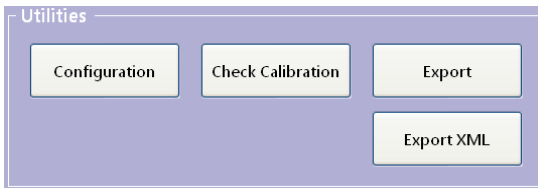


Fig. 5-1 System settings menu

Configuration

These are the tabs of the Configuration menu

- ◆ *General*
- ◆ *Test*
- ◆ *Device*
- ◆ *Report*
- ◆ *Printer*
- ◆ *EMR*
- ◆ *Environment.*

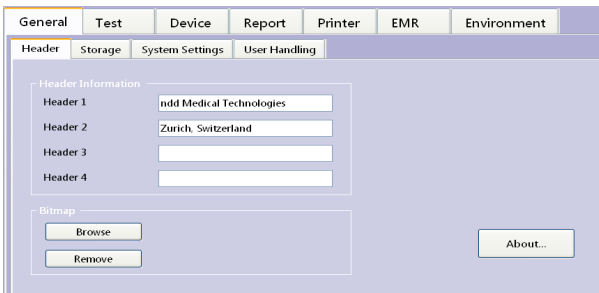


Fig. 5-2 Configuration menu, "General" tab

General Tab

These are the tabs of the *General* tab:

- ◆ *Header*
- ◆ *Storage*
- ◆ *System Settings*
- ◆ *User Handling*

Header Tab

On this tab

- ◆ you enter the hospital/practice name (will appear on the initial screen and all printed reports) **a**
- ◆ you can add and remove an illustration (e.g. a logo, max. size 260 x 80 pixel (bmp)) **b**
- ◆ you open a window with information about the software program **c**.

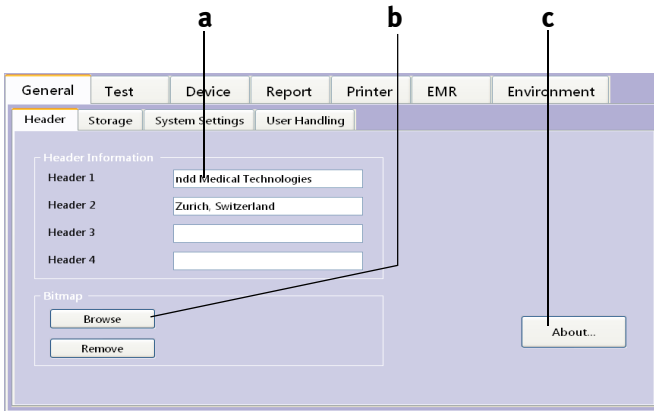


Fig. 5-3 "Header" tab

- a* Fields for entry of the hospital/practice name
- c* Click to display information about the software program
- b* Click to search for an illustration (logo) to display

Storage Tab

This tab is protected with a password (password EOPTM or 8005). On this tab you can

- ◆ create a new database folder **a**
- ◆ import a database **b**
- ◆ export a database **e**
- ◆ copy data (from/to a storage medium) **c**
- ◆ perform a data backup **f**
- ◆ select a target folder for the current tests **g** (path and name are shown at **d**).

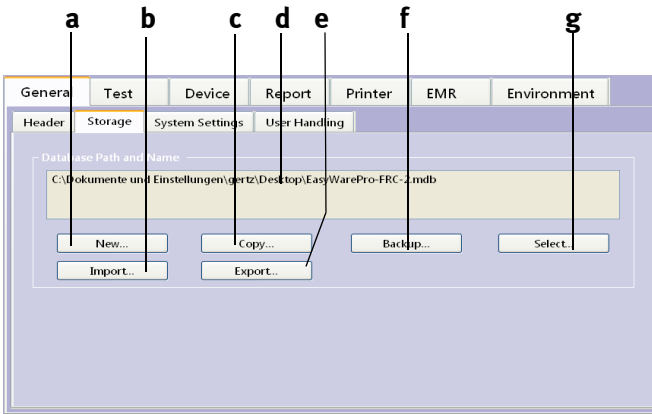


Fig. 5-4 Storage tab

- a* Click to create a new database folder
- b* Click to import a database
- c* Click to copy data from/to a storage medium
- d* Path and name of the currently used

- e* Click to export a database
- f* Click to perform a data backup
- g* Click to select the database folder

System Settings Tab

On this tab

- ◆ you select the units for length, temperature, weight, hemoglobin and pressure **a**
- ◆ you choose whether all options are to be visible on the *Test* and *Device* tabs (even options not currently implemented in the device) **b**
- ◆ select the language **c**.

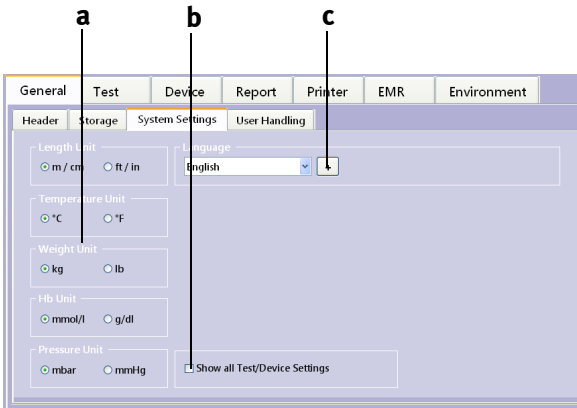


Fig. 5-5 "System Settings" tab

a Click to select the units

c Click to select the language

b Select check box to always view all possible test and device settings, or deselect

User Handling Tab

This tab is protected with a password (password EOPTM or 8005). On this tab you can enter an ID for each user. To start the system, users are then required to log on with their ID. Condition: the function is enabled with "Enable user handling" (**b**, Fig. 5-6). All tests will be annotated with the user who performed the test.

The ID of the user who is logged on is shown next to the time.

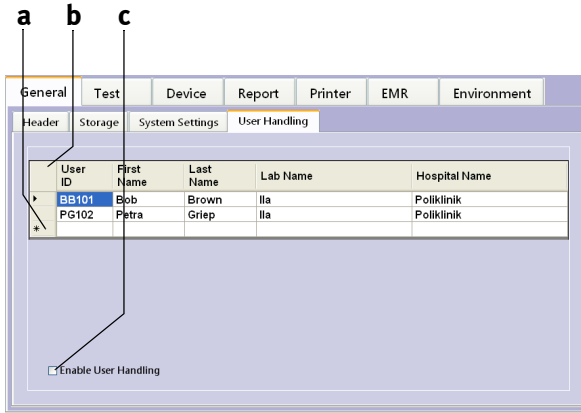


Fig. 5-6 User Handling tab

- a Select line to edit logged on users c Select to enter a new user
 b Select check box to enable/disable the function

Test Tab

The tab comprises the following sub-menus

- ◆ *General*
- ◆ *FVC/FVL*
- ◆ *SVC*
- ◆ *MVV*
- ◆ *Cal-Check*
- ◆ *Provocation.*

General Tab

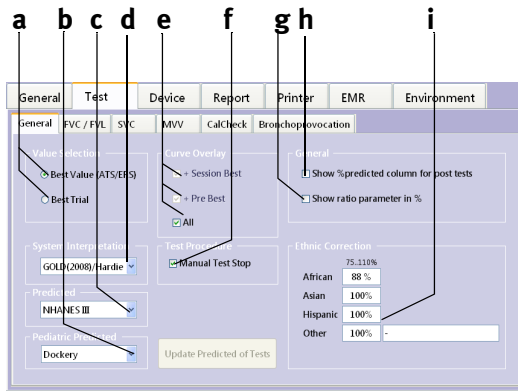


Fig. 5-7 General tab

- a Option buttons to select the value (Best Value/Best Trial)
- b Click to select the predicted values for children
- c Click to select the predicted values for adults
- d Select/deselect the system interpretation
- e Curve selection criteria
- f Select this check box, if you want to stop tests manually
- g Select the check box to display the ratio parameter as a percentage value
- h Select the check box to display the percentage deviation from predicted for bronchodilation tests; otherwise, remove the check mark by clicking again
- i Boxes for entry of correction factors (see Note below)

Note

The predicted normal is corrected by the factor **i**, if no specific calculation is defined for the ethnic group in the selected predicted normal publication.

Note

The settings selected here affect the predicted normals, the interpretation and the displayed parameter readings.

Note

When the "Best Value" option is selected, the values for the "Best" column are determined as follows:

The IC, IRV, VT and ERV parameters are calculated from the average of all accepted trials.

For PEF, PIF and the volume parameters, the best value is the highest value from all accepted trials.

Ratios such as FEV1/FVC, FEV50 / VC_{max}, MTC1 are recalculated.

All other parameters are taken from the highest ranked trial (= 1).

FVC/FVL Tab

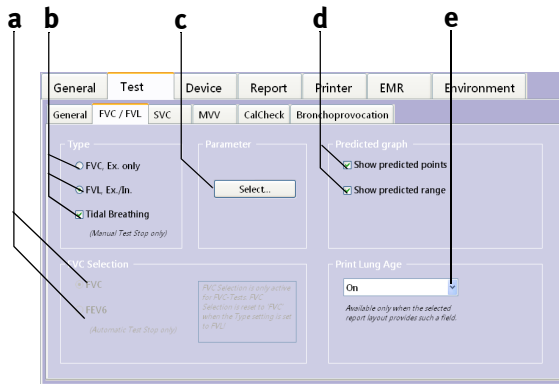


Fig. 5-8 "FVC / FVL" tab

a Select FVC/FEC6

b Select the test type

c Click to select a parameter

d Predicted values are represented by points or as a range

e Select one of the options if you wish to print the lung age

Note

Additional information for FVC-FEV6 selection: FEV6 indicates the exhaled volume after 6 seconds. When set to FEV6, the program stops the measurement after 6 seconds. Several parameters such as FEF25, FEF75 and FEF25-75 are not reported with this selection.

Note

The settings selected here affect the predicted normals, the interpretation and the displayed parameter readings.

With *Parameter Select c* you open a window for selection of the parameters to be calculated. Different parameters can be selected for the display and for the printout.

- ◆ Choose a parameter in the "Available" list **a**
- ◆ click **b** to transfer it to the "Selected" list.

Follow these steps to remove a parameter from the list

- ◆ select it in the "Selected" list **c**
- ◆ click **d** to remove it from the list.
- ◆ Click **e** to scroll the list up and down.

Note

The parameter selection relates to the current test only. Different parameters can be selected for each test.

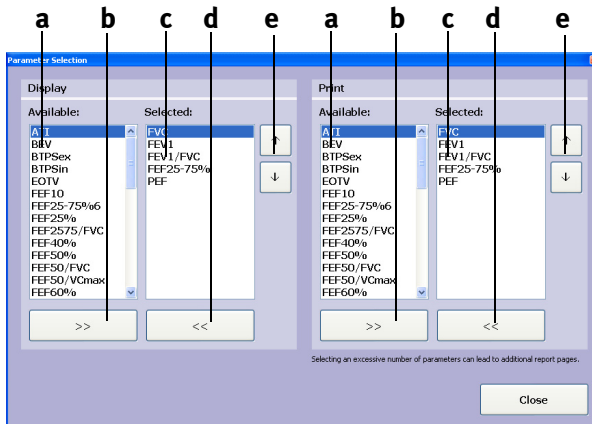


Fig. 5-9 FVC tab

SVC Tab

On this screen you determine the start condition for measurement of the vital capacity: after a phase of tidal breathing or directly without an initial tidal breathing phase.

You also select the parameters for the SVC measurement.

The screenshot shows a software interface with a top navigation bar containing tabs: General, Test, Device, Report, Printer, EMR, and Environment. Below this, a secondary bar shows sub-tabs: General, FVC / FVL, SVC, MVV, DLCO, FRC (MBW), CalCheck, and Bronchoprovocation. The 'SVC' sub-tab is selected. The main area contains two sections: 'Type' with a checked checkbox for 'Tidal Breathing', and 'Parameter' with a 'Select...' button.

Fig. 5-10 SVC tab

MVV Tab

On this screen, you select the parameters for the MVV measurement.

The screenshot shows the same software interface as Fig. 5-10, but with the 'MVV' sub-tab selected. The 'Type' section is not visible, and the 'Parameter' section contains a 'Select' button.

Fig. 5-11 MVV tab

Provocation Tab

You select the test protocol from this tab.

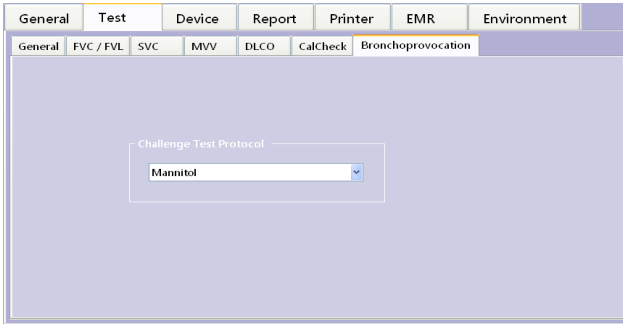


Fig. 5-12 Provocation tab

Device Tab

The tab comprises the following sub-menus

- ◆ *Flow sensor (USB connector)*
- ◆ *EasyOne*
- ◆ *Selection*

Flow Sensor Tab

On this tab you specify flow sensor port or let the system determine the port automatically with *Auto Detect*, e.g., after installation of the driver. The tab also presents detailed sensor information **a**.

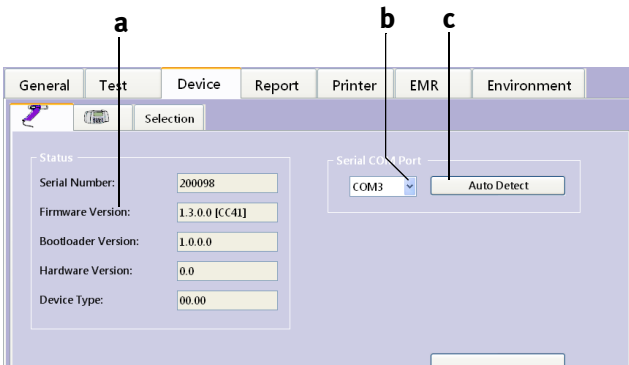


Fig. 5-13 Flow sensor tab

a Detailed information about the flow sensor

b Click to select the sensor port

c Click to auto detect the sensor port

EasyOne Tab

The tab comprises the following sub-menus

- ◆ *Status*
- ◆ *Test Configuration*
- ◆ *General Configuration*
- ◆ *Report Configuration*

Consult the *EasyOne* operator manual for details.

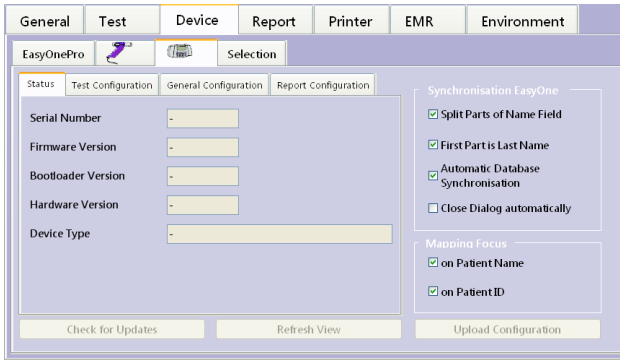


Fig. 5-14 EasyOne tab

Selection Tab

Select your preferred sensor type on this tab.



Fig. 5-15 Selection tab

Report Tab

On the Report tab, you can:

- ◆ display the Report Designer (Layout Editor, see "Report Designer" on page 109)
- ◆ load layouts (Load layout, also refer to www.ndd.ch. Application Note "EasyOne Pro import Layout") **b**
- ◆ save layouts (Export layout) **c**
- ◆ select the files for an XML export **d**

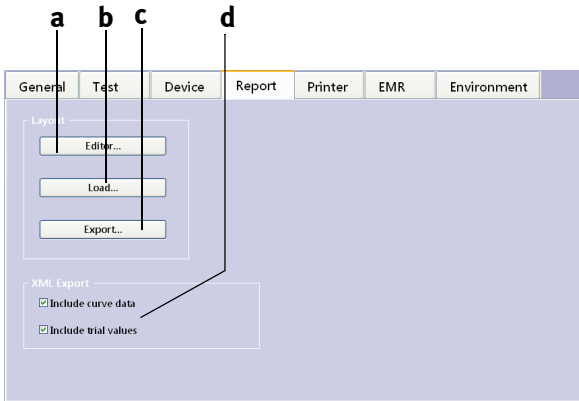


Fig. 5-16 Report tab

a Press to display the Report Designer
b Press to load report layouts
c Press to save (export) layouts

d Press to select the data for an XML export

Printer Tab

Here you choose the printer if you do not want to print the tests on the default printer.

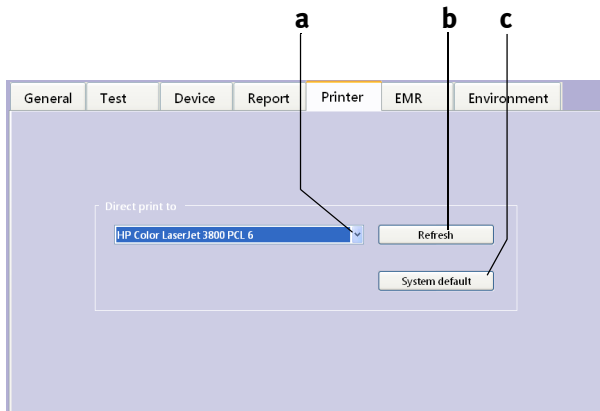


Fig. 5-17 Printer tab

a Select the default printer

b Press to open the printer list

c Press to update the printer list

EMR Tab

Here you select the EMR system and the corresponding settings (see "GDT Interface" on page 103).

This tab also allows you perform a new installation of the program **e**.

Note

Administrator privileges are required for the new installation of a program.

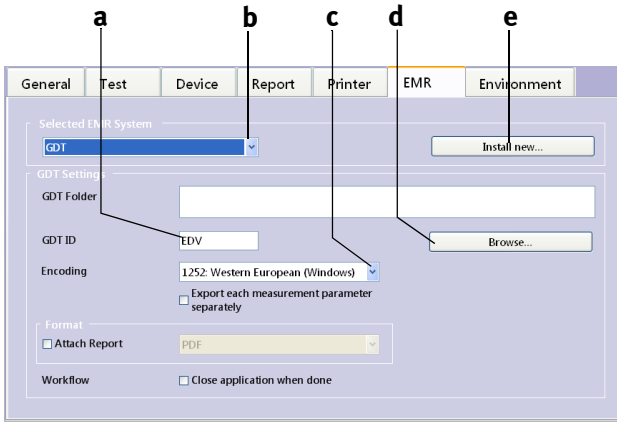


Fig. 5-18 "EMR" tab

- a Enter the GDT ID.
- b Select the EMR system from the list.
- c Select the character set from the list.
- d Press button to search for the GDT folder.
- e Click to install a new EMR system.

Environment Tab

On this tab you enter the ambient conditions. These will be overwritten by values entered prior to the test (see "FVL Test (inspiratory and expiratory measurement)" on page 38).

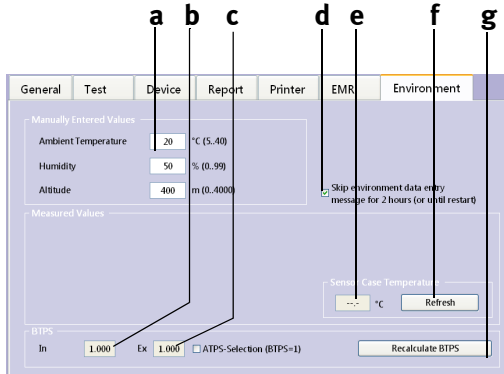


Fig. 5-19 Environment tab

- a Boxes for entry of room temperature, relative humidity and altitude (above sea level) of the examination site
- b BTPS conversion factor
- c ATPS values will be used, yes/no (no BTPS conversion)
- d Select the check box, if you do not want to enter ambient conditions for two hours or until a restart. Otherwise, remove the check mark by clicking again.
- e Case temperature of the flow sensor
- f Click to close the window, saving the data
- g Recalculate BTPS conversion factor (e.g. after a change of the ambient conditions)

6 Troubleshooting Tips

Should you encounter problems operating your spirometer, please consult the table below for troubleshooting tips.

When the <i>Easy on-PC</i> is switched on, you see the following error message on the display:	Self-test failed	Quit the program and restart. If you receive the same message again, contact your <i>Easy on-PC</i> dealer.
When you start a test, you see the message <i>spirette™</i> .	The <i>spirette™</i> is not correctly positioned.	Ensure that the triangle on the spirometer is lined up with the triangle on the <i>spirette™</i> .
Calibration check outside of $\pm 3.5\%$.	The <i>spirette™</i> is not correctly positioned.	Insert the <i>spirette™</i> as described in section " Preparing the Flow Sensor " on page 24.
	You have not used an ndd adapter.	Use the ndd calibration adapter.
	There are leaks in the syringe connection.	Check the connections.
	The specified syringe volume differs from the actual syringe volume.	Choose the correct syringe volume via <i>Configuration > Test > Cal-Check</i> .

Note

The most recent information and frequently asked questions can be found on our web site at www.ndd.ch.

7 Specifications

Measurement principle	ultrasound transit time measurement	
Measuring accuracy	volume:	±2 % or 0.050 l
	flow	±2 % or 0.020 l/s, (except PEF)
	PEF	±5 % or 0.200 l/s
	MVV	±5 % or 5 l/min
Measuring range	volume:	±12 l
	flow	±16 l/s
Resistance	less than 0.3 cm H ₂ O/l/s	
Parameters	FVC, FVL, slow VC, MVV, Pre/Post, FVC, MVV6, FEV6, FEV1, FEV1/FVC, FEV1/VCmax, FEV1/FEV6, FEF25 (MEF75), FEF50 (MEF50), FEF75 (MEF25), FEF25-75% (MEF25-75%), PEF, FET, FIVC, PIF, ERV, IRV, Pre/Post % variation, lung age (only the most important parameters are listed)	
Respiratory tube	<i>spirette</i> TM respiratory tube	
Predicted values (adults)	NHANES III, Knudson_83, Knudson_76, Crapo, Morris, Hsu, Dockery (Harvard), Polgar, Gutierrez (Canada), Eigen, Pereira, Pereira 2006/2008, Pérez-Padilla (PLATINO), Pérez Padilla (Mexico), Pérez Padilla (Mexico, Ped.), Chile 2010, 1997, ERS (ECCS/EGKS), Zapletal 1977, Zapletal 2003, Stanojevic 2009 (GLI), Quanjer 2012 (GLI), Rosenthal, Austria 1988, Austria 1994, Sapaldia (Swiss), Roca (Spain, SEPAR), Viložni 2005, Falaschetti, Klement (Russia), Hedenström (Sweden), Gulsvik, (Norway), Berglund, Birath (Sweden), Langhammer (Norway), Finnish, Nystad, Hibbert, Gore, Crockett, Ethiopia, Asia 1-4, JRS 2001, Fukuda Standard	
Predicted values (children)	Dockery (Harvard), Hsu, Zapletal, Polgar, Hibbert	
Report format	A4 (210 mm x 297 mm)	
Operating conditions (sensor)	temperature	0 to 40 °C (32 to 104 °F)
	relative humidity	5% to 95%,
	atmospheric pressure	500 hPa to 1060 hPa

Storage	temperature	-20 to 50 °C (-4 to +122 °F)
	relative humidity	5% to 95%,
	atmospheric pressure	500 hPa to 1060 hPa
Certifications	CE Declaration of Conformity	
Device classification (sensor)	type BF applied part device not suitable for operation in the presence of flammable, gaseous anesthetic agents, mixtures with O ₂ , or NO	
Life time	7 years	

8 Technical Description

PC/Laptop Requirements

The *Easy on-PC* software is installed on a PC or laptop computer to which the flow sensor is connected by means of a USB cable.

The PC or laptop computer which is not part of the equipment supplied by ndd Medizintechnik AG is thus considered a requisite accessory necessary for the intended use of the device.

In your capacity as the operator of the medical electrical device you are obliged to ensure that the specific, applicable requirements of the standard EN 60601-1:2006 are complied with. The following conditions must be met:

- All equipment operated in the patient environment must meet the requirements of IEC 60601-1.
- All equipment set up outside the patient environment must meet the requirements of the applicable IEC or ISO safety standards (e.g. IEC 60950-1).

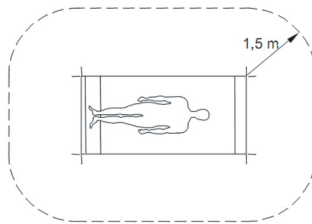


Fig. 8-1 Patient environment

If IEC XXXXX devices (devices that do not fulfill the requirements of IEC standard 60601-1) are operated in the patient environment, it must be ensured that the maximum allowed touch currents will not be exceeded. These are the applicable limits:

- normal condition: 100 μA
- with interruption of the (not permanently connected) protective earth conductor: 500 μA .

Appropriate measures must be taken, if these limits are exceeded.

Suggestions:

- additional protective earth connection of the PC or
- isolating transformer for the PC or

- isolating transformer with built-in power outlet strip for the PC and the devices connected to it.

Note

EN 6060-1:2006 specifies the requirements for power outlet strips.

Bear in mind that the touch currents may vary with the system configuration.

Warning

Patient Hazard, Equipment Damage—Do NOT modify the flow sensor unless authorized by the manufacturer.

PC Maintenance

- Back up the data on a regular basis.
- Regular safety updates (incl. anti-virus software, firewall) are mandatory for computers integrated in a data network.
- The calibration must be checked after each update.

Warning

Equipment Damage—Viruses and malware may degrade the *Easy on-PC* software performance. Therefore the PC must be protected by adequate measures, such as anti-virus software or a firewall.

Note

If updates of the operating system are performed automatically (e.g Windows updates), we recommend checking the calibration on a regular basis (see "[With Test Subject](#)" on page 72).

9 Order Information

2700-3	Easy on-PC, software program incl. accessories and packaging
2050-1	<i>spirette™</i> standard, case of 50
2050-5	<i>spirette™</i> standard, case of 200
2030-2	Calibration syringe with calibration adapter

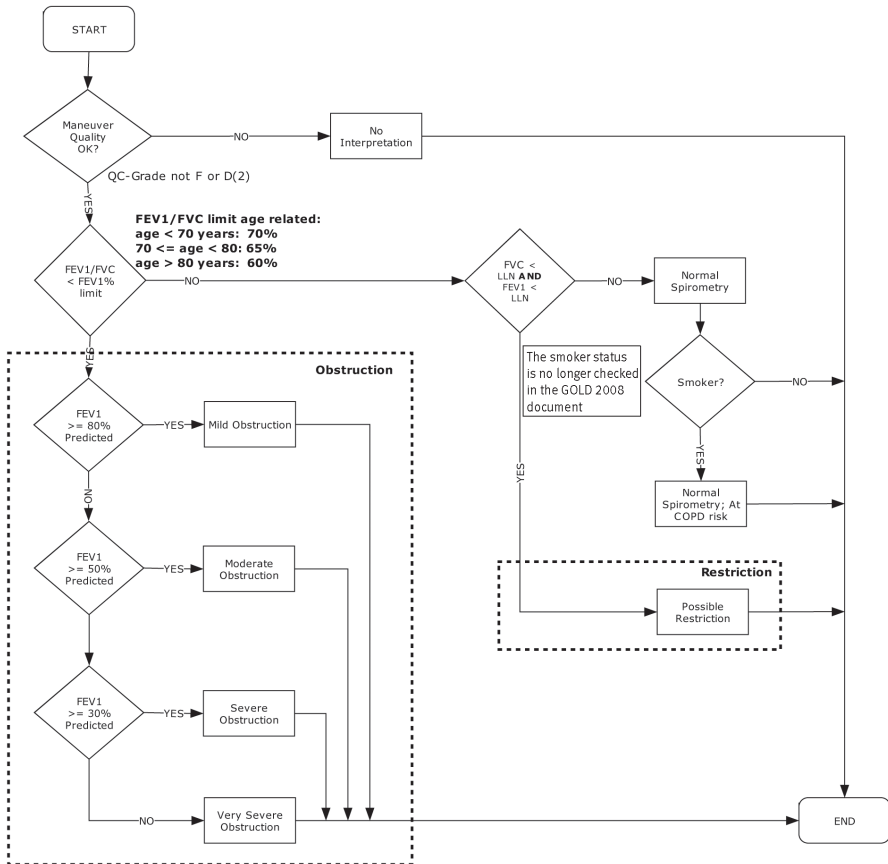
10 Appendix

10.1 Interpretation

The automatic system interpretation can be selected and deselected on the configuration tab (see **c**, "**General Tab**" on page 81).

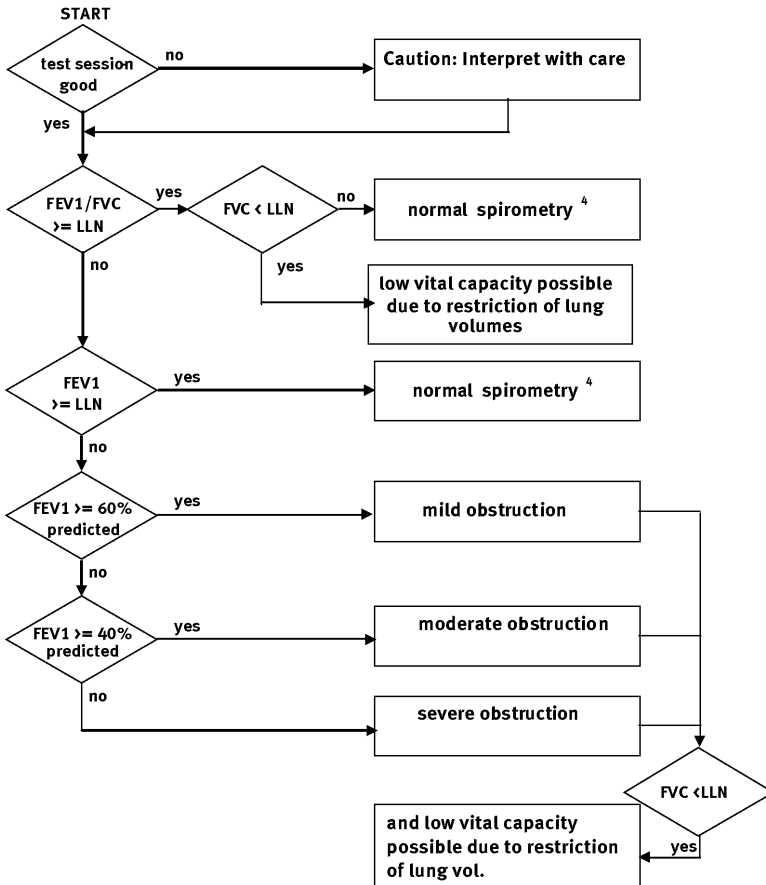
GOLD-Hardie Interpretation

The following diagram outlines the criteria EasyOne Pro applies in the automatic interpretation after GOLD/HARDIE (see "**Literature**" on page 132).



NLHEP Interpretation

The following diagram outlines the criteria EasyOn PC applies in the automatic interpretation after NLHEP (see "Literature" on page 132, [4]).

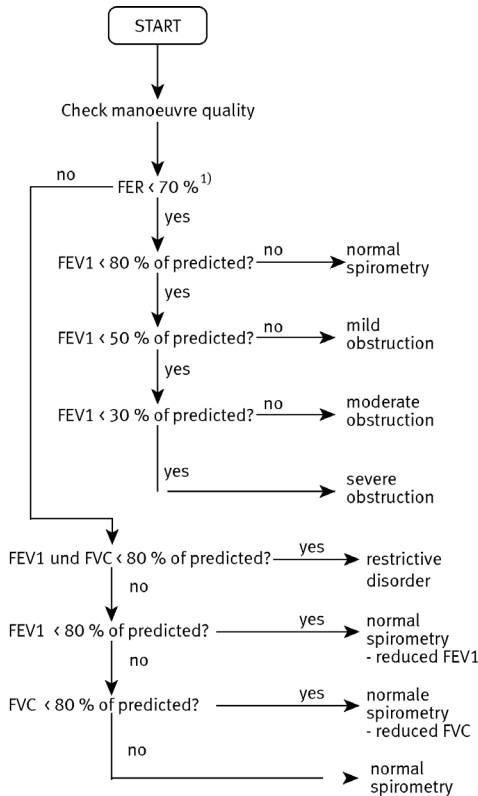


Note:

1. LLN = Lower limit of normal
2. If FEV6 is selected instead of FVC, FEV6 will be used for the interpretation instead of FVC.
3. If the selected predicted value publication does not define a lower limit of normal (LLN), LLN is calculated as predicted value - 1.645 x RSD (residual standard deviation). If RSD is not defined, the LLN for FEV1/FVC is set at 90% of the predicted value, the LLN for FEV1 at 80% of the predicted value and the LLN for FVC at 80% of the predicted value.
4. If the quality grade is D and the results are within the limits, the following interpretation will be output: "normal spirometry, insufficient test quality, data not suitable for comparison".

NICE Interpretation

Predominantly used in Great Britain. Source unknown.



1) $FER = FEV1/FVC$

NICE 2010 Interpretation

COPD Management of chronic obstructive pulmonary disease in adults in primary and secondary care (partial update). NICE clinical guideline 101.

The NICE 2010 interpretation according to this algorithm (Fig. 10-1) does not detect restrictive disorders. Our application, however, always identifies restrictive disorders if FVC and $FEV1 < LLN$.

Table 4 Gradation of severity of airflow obstruction

		NICE clinical guideline 12 (2004)	ATS/ERS ⁴ 2004	GOLD 2008 ⁵	NICE clinical guideline 101 (2010)
Post-bronchodilator FEV₁/FVC	FEV₁ % predicted	Severity of airflow obstruction			
			Post-bronchodilator	Post-bronchodilator	Post-bronchodilator
< 0.7	≥ 80%		Mild	Stage 1 – Mild	Stage 1 – Mild*
< 0.7	50–79%	Mild	Moderate	Stage 2 – Moderate	Stage 2 – Moderate
< 0.7	30–49%	Moderate	Severe	Stage 3 – Severe	Stage 3 – Severe
< 0.7	< 30%	Severe	Very severe	Stage 4 – Very severe**	Stage 4 – Very severe**

*Symptoms should be present to diagnose COPD in people with mild airflow obstruction (see recommendation 1.1.1.1).

**Or FEV₁ < 50% with respiratory failure.

Fig. 10-1

System Interpretation Messages

Printed Text
No interpretation, not enough acceptable maneuvers
Normal Spirometry
Mild Obstruction
Moderate Obstruction
Severe Obstruction
Very Severe Obstruction
Restriction probable; further examinations recommended.
Normal Spirometry; at COPD risk
No interpretation, no predicted values

10.2 Predicted Values

Note

For the most recent predicted value sets and other pertinent information, please visit our website at <http://www.ndd.ch>.

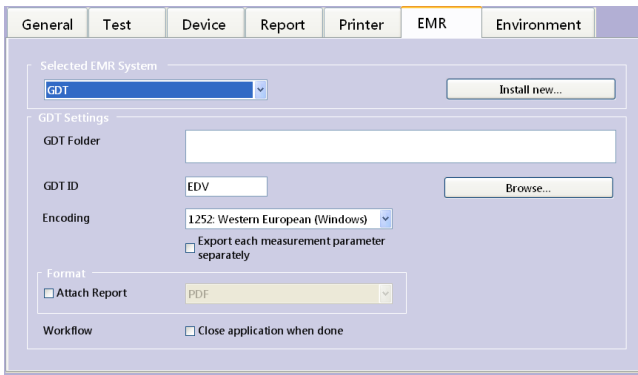
10.3 GDT Interface

Introduction

The following describes the interface set up to facilitate the data communication between *Easy on-PC* and an Electronic Medical Record System (EMR). As an example the integration of the German GDT standard is described.

Software Settings

The following settings need to be made in the *Configuration* menu:



The screenshot shows the 'EMR' tab in a configuration window. The 'Selected EMR System' dropdown is set to 'GDT'. Below it, the 'GDT Settings' section includes a text field for 'GDT Folder', a text field for 'GDT ID' containing 'EDV', and a dropdown for 'Encoding' set to '1252: Western European (Windows)'. There is an unchecked checkbox for 'Export each measurement parameter separately'. The 'Format' section has an unchecked checkbox for 'Attach Report' and a dropdown set to 'PDF'. The 'Workflow' section has an unchecked checkbox for 'Close application when done'.

Parameter	Description
GDT Folder	The GDT folder of the EMR system. This may also be a folder in a network drive. For convenient path entry the <i>Browse</i> button may be used. The GDT file will be written to this folder and read in from this folder.
Computer Name	Name of the EMR computer.
Export single measurement value	If this check box is selected, additionally the best values will be included as single measurement values.

Example: EMR Application "TurboMed"

TurboMed Software Settings

The following settings have to be applied only when the EMR interface is used.

- Start TurboMed software and select the record of a patient.
- In the patient record select "Konsultationen / Geräteanbindung".
- Select "Gerät anbinden".
- Enter the following:

Field	Entry	Description
Name	<i>Easy on-PC</i>	Name of equipment
Program	c:\niddmed\EasyWarePro.exe	Complete path of EasyWare software.
Export File	c:\niddmed\niddturbomed.gdt	Name and path of the export file.
Import File	c:\niddmed\turbomednidd.gdt	Name and path of the import file. The path (in the example c:\niddmed\) must be identical with the export file path.
Type	2	Version of the GDT / EMR interface

- Confirm the entry with: **Save**.
- Confirm the *Geräte anbinden* dialog with **Ende**.

These adjustments are sufficient for the set up of the EMR software. Now proceed with the set up of *Easy on-PC*.

Setup *Easy on-PC* Software

When the EMR interface is used for the first time, the following settings have to be made:

- Start *Easy on-PC*.
- Open the menu *Utilities / Configuration / EMR*.
- Enter the path of the EMR folder according to the export path set in EMR TurboMed (in the above example c:\niddmed\).
- Enter the EMR computer name as "TurboMed".
- Confirm the dialog with **OK**.
- Close *Easy on-PC*.

Performing a Measurement

The following describes the test procedure.

- Start *TurboMed*, select a patient and open that file.
- Select *Konsultationen / Geräteanbindung*.
- Select *Easy on-PC* and then **Start**.

The patient data entry window appears automatically.

- Enter the required data.
- Confirm with **OK**.
- Select the appropriate test type (FVC, FVL, SVC, MVV) and confirm with **Enter**.
- Perform a complete test with the patient.
- Print a report if required.
- Finish EMR (sends data to EMR and closes *Easy on-PC*).

TurboMed now receives the data.

- Confirm with **OK**.
- Close the program now with **Ende**.

Data accepted by *Easy on-PC* from EMR / GDT

The following data is read in by *Easy on-PC* from the GDT interface. The data that is actually transmitted depends on the EMR (GDT) system used. Excessive data is ignored by *Easy on-PC*.

GDT Field ID	Description	Comment
8000	Record ID	
8316	GDT-ID of EMR	
3000	Patient ID	The ID may include letters and numbers. Maximum length: 15
3101	Name	Last Name, maximum number of characters: 47
3102	First Name	First name, maximum number of characters: 47
3103	Date of Birth	

3110	Gender (1 = male)	
3622	Height (in cm)	
3623	Weight (in kg)	

Here is an example of a GDT file (nndPCS.gdt), received from an EMR with the name PCS:

- 01380006302
- 014810000202
- 0158315Extern
- 0128316PCS
- 014921802.00
- 01030001
- 0093100
- 0143101Meier
- 0163102Manfred
- 017310301011966
- 0093104
- 019310624106 Kiel
- 0203107Schulstr. 1
- 01031101
- 0123622185
- 011362363

In addition to some GDT specific information the file contains the following patient information: Name, date of birth, gender, height in cm, weight in kg.

Viewing tests with *Easy on-PC*

View test via GDT record type 6311 with patient name, ID and date and time of test

Record type 6311 is supported. In the transmission of test results using GDT record type 6310, field IDs 8432 (date) and 8439 (time) are always included:

8432ddmmyyyy (day, month, year)

8439hhmmss (hours, minutes, seconds)

In case of a recall via GDT record type 6311, the test can be identified by patient name, ID, test date and test time.

Example "forced expiratory spirometry"

Here the example transmission GDT Export with a forced loop test (FVL). The data marked grey will be exported only when the "Export single measurement value" check box is selected.

```

01380006310
014810001385
0128315EDV
0128316NDD
014921802.00
01230006-0
0183101Appeldorn
0173102Heinrich
017310323101945
01031101
0123622178
011362366
0158402LUFU02
017620024042008
017843224042008
017843918210004
0366228Your FEV1 / Predicted: 103%
0096228
0436228-----
0436228          Pre
0436228Parameter  Pred Best %Pred
0436228-----
0436228FVC       L 4.72 4.03 85
0436228FEV1     L 3.55 3.67 103
0436228FEV1/FVC  0.75 0.91 121

```

0436228FEF25-75% L/s 2.88 5.55 193
0436228PEF L/s 9.09 10.60 117
0436228FET s - 4.12 -
0436228FIVC L 4.72 3.67* 78
0436228PIF L/s - 9.38 -
0586228* indicates: below LLN or significant post change.
0096228
0408410SN:DT 200076:633446580643340000
0348470Predicted Set: NHANES III
0378470System Interpretation Set: -
0096227
0128410FVC
0128411FVC
01384204.03
0108421L
0138410FEV1
0138411FEV1
01384203.67
0108421L
0178410FEV1/FVC
0178411FEV1/FVC
01384200.91
0098421
0188410FEF25-75%
0188411FEF25-75%
01384205.55
0128421L/s
0128410PEF
0128411PEF
014842010.60
0128421L/s
0128410FET
0128411FET
01384204.12
0108421s
0138410FIVC
0138411FIVC
01484203.67*
0108421L
0128410PIF
0128411PIF
01384209.38
0128421L/s

10.4 Report Designer

Starting the Report Designer

- On the initial screen, select **Utilities**.
- Select **Configuration**.
- In the Configuration menu, select the **Report** tab.
- On the **Report** tab, select the **Layout Editor..**

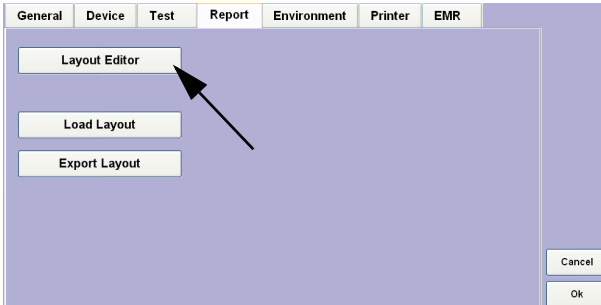


Fig. 10-2 "Report" tab

Adding a Logo to an Existing Test

- On the Report Designer tab, select **New Report** (Fig. 10-3 left).

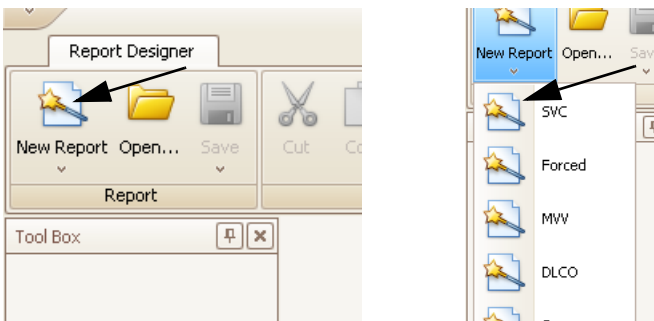


Fig. 10-3 New Report button (left), test selection (right)

- Select the test to which you want to add the logo (Fig. 10-3 right).

- Select the **Picture Box** (Fig. 10-4).

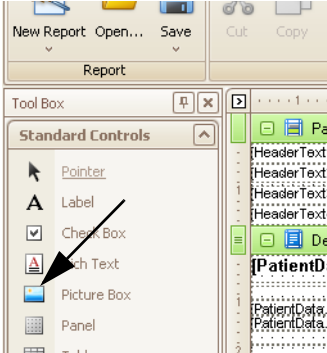


Fig. 10-4 Picture Box button

- Insert the frame in the appropriate position (Fig. 10-5).

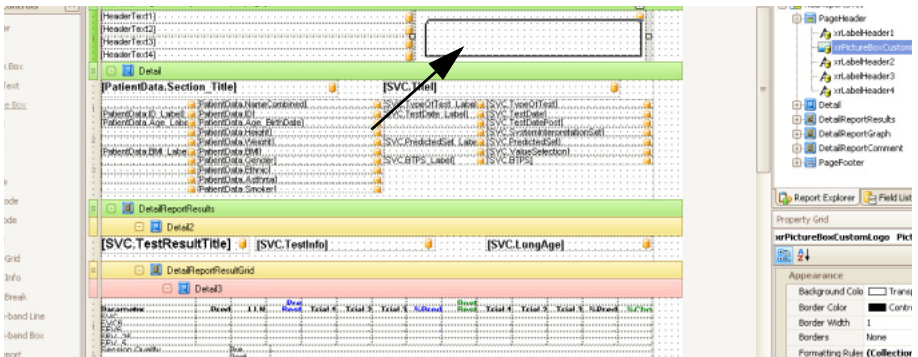


Fig. 10-5 Positioning the frame

- Select **Image** and click  to open the Explorer (Fig. 10-6).

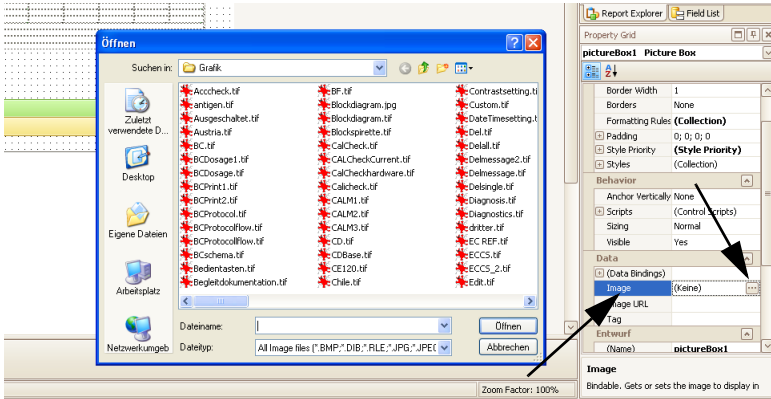


Fig. 10-6 Image button

- Select the logo. (Fig. 10-6). The logo will appear in the frame.
- Save the test under a new name.

Configuring the Graphic Representation of an Existing Test

- Select the test via **New Report** or **Open**.

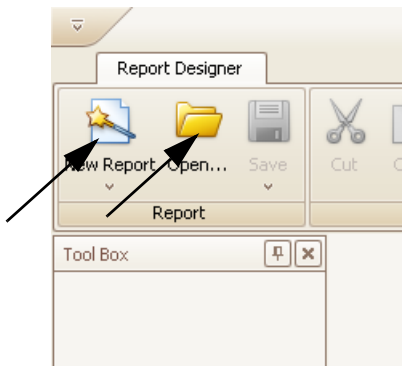


Fig. 10-7 New Report, Open buttons

- Select **Windows** and then **Report Explorer** (Fig. 10-8).
- Select **Detail Report Graph** (Fig. 10-8).
- Click **graphVT1**.

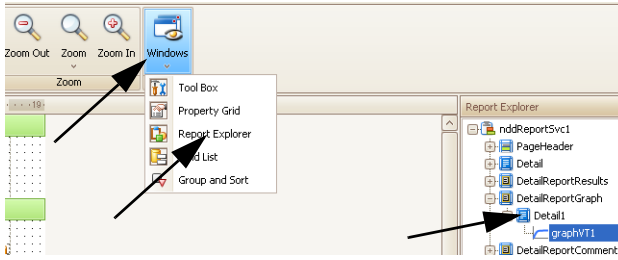


Fig. 10-8 Windows, Report Explorer, Detail Report Graph buttons

- Click the small arrow in the upper right corner of the "Detail Report Graph" window (Fig. 10-8).
- Click **Run Designer**. The Spiro Graph Configuration window will be displayed (Fig. 10-10).

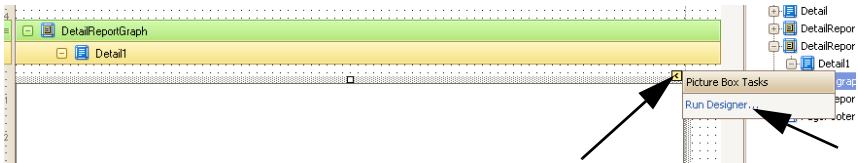


Fig. 10-9 Detail Report Graph window

- Select **Test Type**.
- Choose options in the **Trial Selection** pane.
- Choose options in the **Appearance** pane..

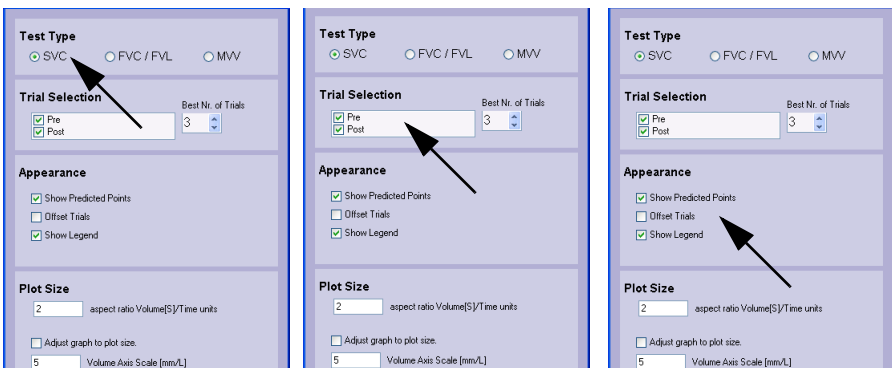


Fig. 10-10 Fenster „Spiro Graph Configuration“

- Close the window with **OK**.
- Save the test under a new name.

10.5 Electromagnetic Compatibility (EMC)

Changes or modifications to the *Easy on-PC* not expressly approved by ndd could cause EMC issues with this or other equipment. The *Easy on-PC* system is designed to comply with applicable regulations regarding EMC. Its compliance with these requirements has been verified. It needs to be installed and put into service according to the EMC information stated as follows.

Warning

- ◆ Use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation.
 - ◆ The equipment or system should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the equipment or system should be tested to verify normal operation in the configuration in which it is being used.
-
-

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The *Easy on-PC* is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the *Easy on-PC* is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions to EN 55011	Group 1	The <i>Easy on-PC</i> uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions to EN 55011	Class B	The <i>Easy on-PC</i> is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity


The *Easy on-PC* is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the *Easy on-PC* is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) to EN 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV ± 8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst to EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	the product has no power cords or input/output lines	
Surge to EN 61000-4-5	± 1 kV differential mode ± 2 kV common mode	the product has no power cords	
Voltage dips, short interruptions and voltage variations on power supply input lines to EN 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycles 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	the product has no power cords	
Power frequency (50/60 Hz) magnetic field to EN 61000-4-8	3 A/m	passed	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.

NOTE U_T is the AC mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The *Easy on-PC* is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the *Easy on-PC* is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF to EN 61000-4-6 Radiated RF to EN 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	<p>Portable and mobile RF communications equipment should be used no closer to any part of the <i>Easy on-PC</i>, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 2.3 \sqrt{P} \text{ 800 MHz to 2.5 GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol</p> 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

- a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *Easy on-PC* is used exceeds the applicable RF compliance level above, the *Easy on-PC* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the *Easy on-PC*.
- b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**Recommended separation distances between portable and mobile
RF communications equipment and the *Easy on-PC***

The *Easy on-PC* is intended for use in the electromagnetic environment on which radiated RF disturbances are controlled. The customer or the user of the *Easy on-PC* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *Easy on-PC* as recommended below, according to the maximum output power of the communications equipment.

rated maximum output power of transmitter [W]	separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.7	3.7	7.37
100	11.7	11.7	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

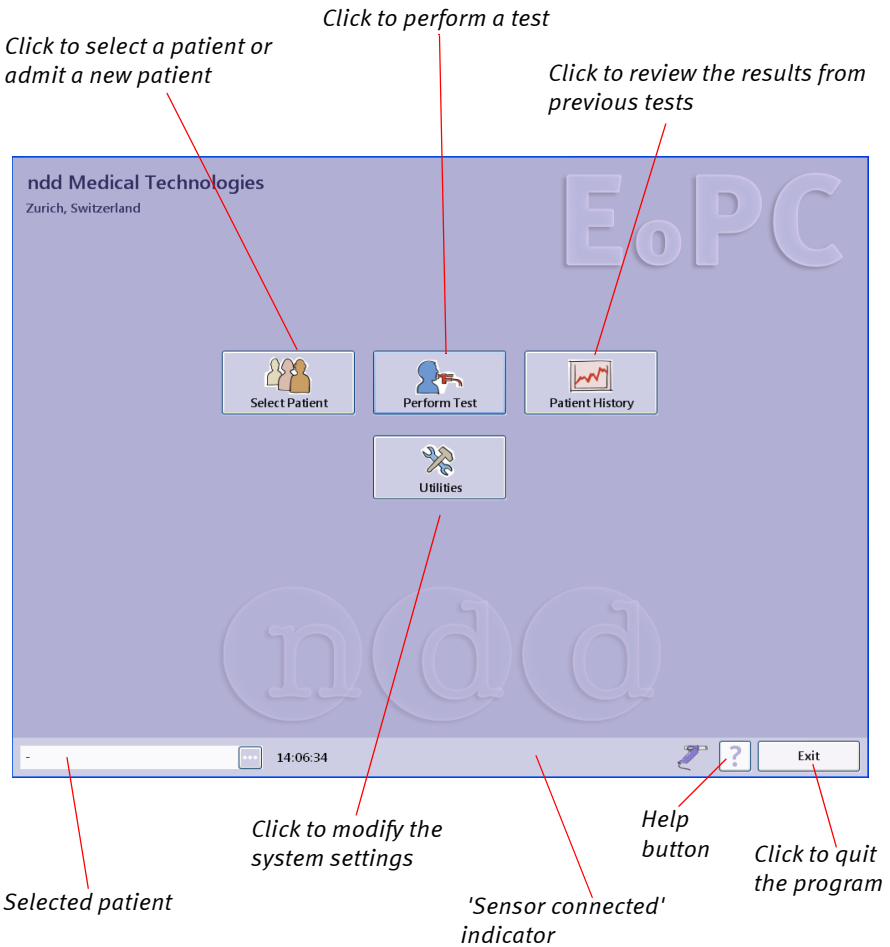
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Compliant Cables and Accessories

The *Easy on-PC* has no accessories that affect EMC compliance.

10.6 Quick Reference Guide to the Screen Displays

Initial Screen



Also refer to

"Safety Information" on page 7«

"Start-up and Preparation" on page 15

"Performing a Test" on page 26

"System Settings" on page 76

"Index" on page 135

Selecting/Admitting a Patient

Bar cursor for patient selection

Filter Last Name; by entering one or more letters, you limit the number of patients to those meeting the filter criteria

Click to clear the filter criterion

Click to admit a new patient

Click to perform a test with the selected patient

Click to view all the patient's tests

Click to edit the patient's data

'Sensor connected' indicator

Click to delete the patient data

Help button

Click to display the menu options

Also refer to

"Selecting/Admitting a Patient" on page 26«

"Editing Patient Daa" on page 61

"Performing a Test" on page 26

"Index" on page 135

Admitting a Patient

Press the **TAB** or **Enter** key after each entry.

Click to open the tabs.

Click to generate automatic patient ID.

Click to select the gender

Click to select the ethnic origin.

Click to close the window without saving the data

Click to close the window, saving the data

Help button

Click to display the menu options

'Sensor connected' indicator

Also refer to

"Selecting/Admitting a Patient" on page 26

"Editing Patient Daa" on page 61

"Performing a Test" on page 26

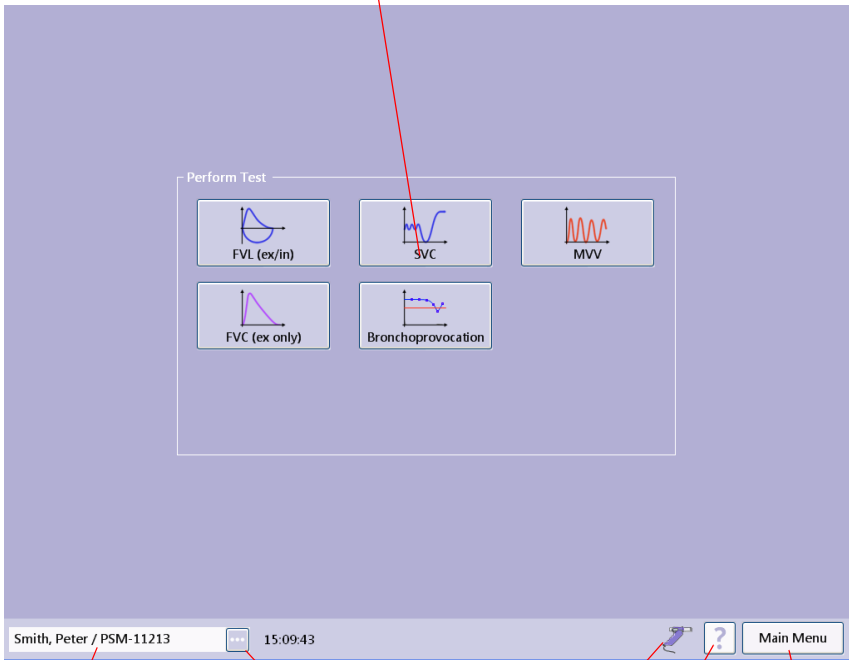
"Index" on page 135

Test Menu

Note

The content of this menu depends on the device configuration.

Click to select a test



Selected patient

Click to view patient data

'Sensor connected' indicator

Help button

Back to main menu

Also refer to

"Selecting a Test" on page 31«

"Forced Vital Capacity (FVC/FVL)" on page 32

"Vital Capacity (SVC)" on page 42

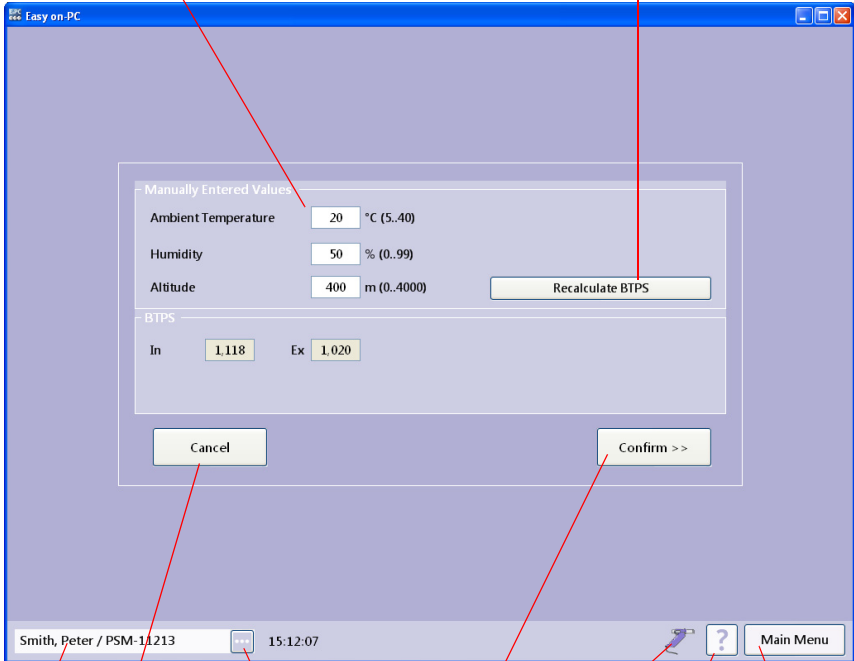
"Maximum Voluntary Ventilation (MVV)" on page 45

"Index" on page 135

Viewing Ambient Conditions

Ambient conditions

Click to recalculate BTPS



Selected patient

Click to view patient data

Click to close the window without saving the data

Click to close the window, saving the data

'Sensor connected' indicator

Help button

Back to main menu

Also refer to

"FVL Test (inspiratory and expiratory measurement)" on page 38«

"Easy on-PC Sensor Design and Operation" on page 13

"Index" on page 135

Retrieving/Printing Stored Tests

Test with Post-test data

Click to view patients

Click column header to sort the list

The screenshot shows a window titled "Easy on-PC" containing a "History" table. The table has columns for Protocol, Test Type, Date, and Comment. Below the table are buttons for "View Test", "Print Preview", "Print", "Trend", "New Test", and "Patients". At the bottom, there is a status bar with a patient name "Smith, Peter / PSM-11213", a time "15:14:08", a "Sensor connected" indicator, a "Help" button, and a "Main Menu" button.

Protocol	Test Type	Date	Comment
Base Test	SVC	02.11.2012 15:27	
Pre / Post	FVC Tidal	17.10.2011 11:16	
Base Test	FVL Tidal	17.10.2011 10:53	
Base Test	FVC Tidal	30.09.2011 10:47	
Base Test	FVC Tidal	02.09.2011 14:15	
Base Test	SVC	02.09.2011 09:04	
Base Test	FVL Tidal	25.08.2011 09:17	
Base Test	DLCO	11.08.2011 15:26	
Base Test	FVC (ex only)	21.04.2009 18:43	
Base Test	DLCO	21.04.2009 18:20	
Base Test	SVC	21.04.2009 17:49	Patient arbeitet nicht aktiv mit
Base Test	MVV	05.05.2006 14:22	

Selected patient

Click to view patient data

Click to view trend information

Help button

Back to main menu

Click to view the test

Click to Show print preview, print the test

'Sensor connected' indicator

Also refer to

"Retrieving/Printing Stored Tests" on page 54«

"Quality Messages / Grades (Details)" on page 62

"Index" on page 135

FVC Test Result

Predicted values

Click to select the scale

Click to select curve display

Click to select a new patient

Click to enter a test evaluation

Click to view the test list

Click to conduct a new test

Flow [L/s]

Volume [L]

Time [s]

Session Quality: FVC Tidal / Best Value / FVC
Pre: C NHANES III 17.10.2011

System Interpretation: Pre: Restriction probable, further examination recommended

Interval Message: --

Review

Good effort, do next ...

Test Results

	Pre				Trial	
Trial Rank	Pred	LLN	Best	%Pred	Trial 1	Trial 2
Time					11:00:37	11:04:57
FVC [L]	5.48	4.48	3.59	66	3.45	3.59
FEV1 [L]	4.24	3.40	2.80	66	2.80	2.80
FEV1/FVC	0.777	0.680	0.780	100	0.813	0.780
FEF25-75% [L/s]	3.70	1.99	2.46	67	2.77	2.46

Doe, John / XYZ-123 11:06:32

Add Trial

Add Post

Print Preview

Print

History

New Test

Patients

Help button

Back to main menu

Selected patient

Click to view patient data

Click to view the test

'Sensor connected' indicator

Also refer to

"Retrieving/Printing Stored Tests" on page 54«

"System Settings" on page 76

"Quality Messages / Grades (Details)" on page 62

"Index" on page 135

Provocation Test Results

Protocol steps

Protocol

Next step to complete

Test diagram

Measured values in tabular form

Methacholine ATS short (5 breaths)

– Protocol

- Pre
- 0 mg/mL
- 0.0625 mg/mL
- 0.25 mg/mL
- 1 mg/mL
- 4 mg/mL
- 16 mg/mL
- Post

Administer a bronchodilator

Monitor the patient until fully recovered to within

Perform repeatable FEV1 measurements

– Response

Changes in FEV1 [%]

Baseline

20% fall from baseline

Methacholine ATS short (5 breaths) [mg/mL]

Dose	FEV1	Step change	Base change
Pre	4.89 L	0.6 %	
0 mg/mL	4.92 L	0.6 %	-3.9 %
0.0625 mg/mL	4.73 L	-3.9 %	-3.2 %
0.25 mg/mL	4.76 L	0.7 %	-4.3 %
1 mg/mL	4.71 L	-1.1 %	-29.1 %
4 mg/mL	3.49 L	-26.0 %	
16 mg/mL			
Post			

POSITIVE TEST RESULT: A \geq 20.00% fall in FEV1 has occurred since the 0 mg/mL dose.

– Next action

Administer a bronchodilator

Done Cancel

– Calculated Results

PC20: 2.4 mg/mL

Smith, Peter / PSM-11213 10:09:20

Test result

Selected patient

Click to view patient data

‘Sensor connected’ indicator

Help

Back to main menu

Also refer to

"Retrieving/Printing Stored Tests" on page 54«

"System Settings" on page 76

"Quality Messages / Grades (Details)" on page 62

"Index" on page 135

Print Preview

Selected test report

Click to select other report layouts

Click to print the report

Click to display a submenu with zoom, export, viewing and print functions

FVC/FVL, Standard Layout Selection Print Print Menu

ndd Medical Technologies
Zurich, Switzerland

Patient Information
Name: Smith, Peter
ID: PSM-11213
Age: 42 (08.11.1968)
Height: 182 cm
Weight: 33 kg BMI: 24.2
Gender: Male
Ethnicity: Caucasian
Smoker: No

Test Information
Test Type: FVC Tidal
Test Date: 17.10.2011 10:55:34
Port Time: 17.10.2011 11:16:57
Interpretation: GOLD(2008)/Hardc
Predicted: NHANES III
Value Selection: Best Value
BTPS (N/EX): 1.12/1.02

Test Result Your FEV1 / Predicted: 73% Your Lung Age: 77

Parameter	Pre				Post				Trial 2	Trial 4	%Pred	%Chg
	Pred	LLN	Best	Total 4	%Pred	Best	Total 4	%Pred				
FVC [L]	4.53	4.56	3.00*	3.00*	66	3.90*	3.85*	3.54*	3.78*	67	1	
FEV1 [L]	4.37	3.55	3.19*	3.19*	73	2.90*	2.90*	2.90*	2.95*	66	-9	
FEV1/FVC	0.793	0.697	0.871	0.871	110	0.786	0.786	0.820	0.779	99	-10	
FEF25-75% [L/s]	4.03	2.38	4.03	4.03	100	2.58	2.58	3.02	2.76	84	-36	
PEF [L/s]	10.50	8.07	7.42*	7.42*	71	7.44*	7.44*	7.83*	5.95*	71	0	
FET [s]	-	-	3.3	3.3	-	5.5	5.5	4.1	7.8	-	67	

Session Quality: Pre F Post C (FEV1 Vam=0.01L (0.2%); FVC Vam=0.14L (3.6%))
System Interpretation: Pre No interpretation, not enough acceptable maneuvers Post Restriction probable, further examination recommended

Caution: Poor session quality. Interpret with care
* Indicates below LLN or significant post change.

Flow [L/s] vs Time [s] graph showing Pre-Trial 1, Pre-Trial 2, and Post-Trial 1 curves.

Page 1 of 1 100%

Smith, Peter / PSM-11213 16:14:13 Help button Return

Selected patient

Click to view patient data

'Sensor connected' indicator

Help button

Also refer to

"Retrieving/Printing Stored Tests" on page 54«

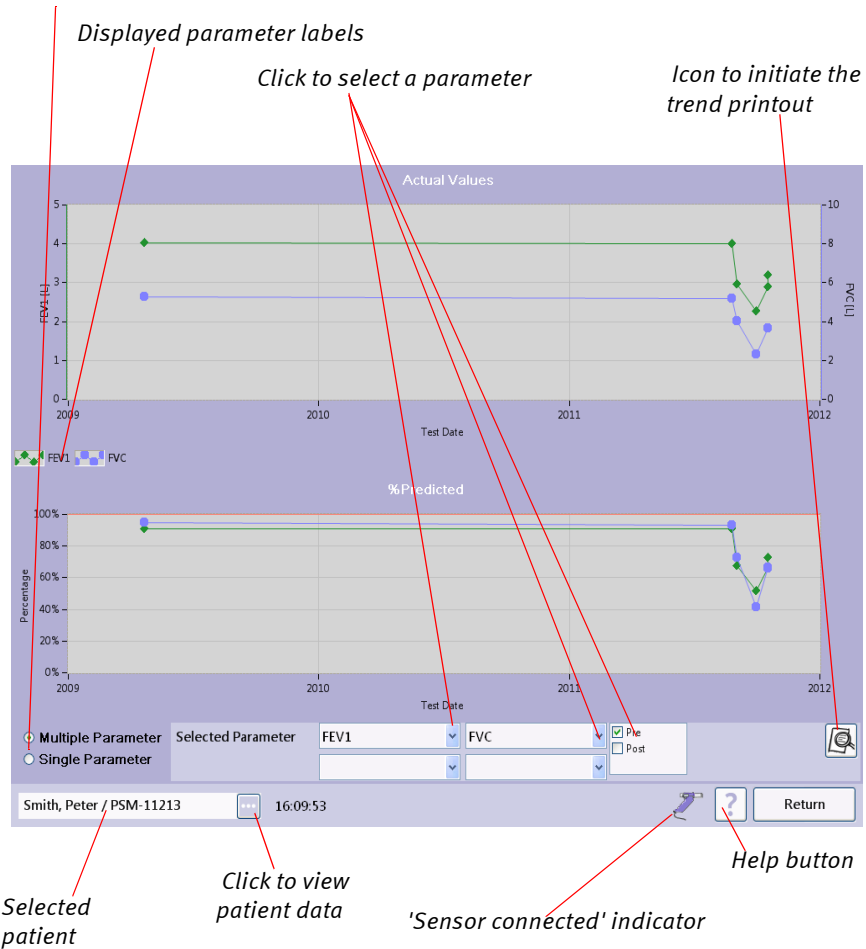
"System Settings" on page 76

"Quality Messages / Grades (Details)" on page 62

"Index" on page 135

Trend Display

Option buttons for selection of the view



Also refer to

"Trend View" on page 57«

"Hygiene, Cleaning, Maintenance, Disposal" on page 70

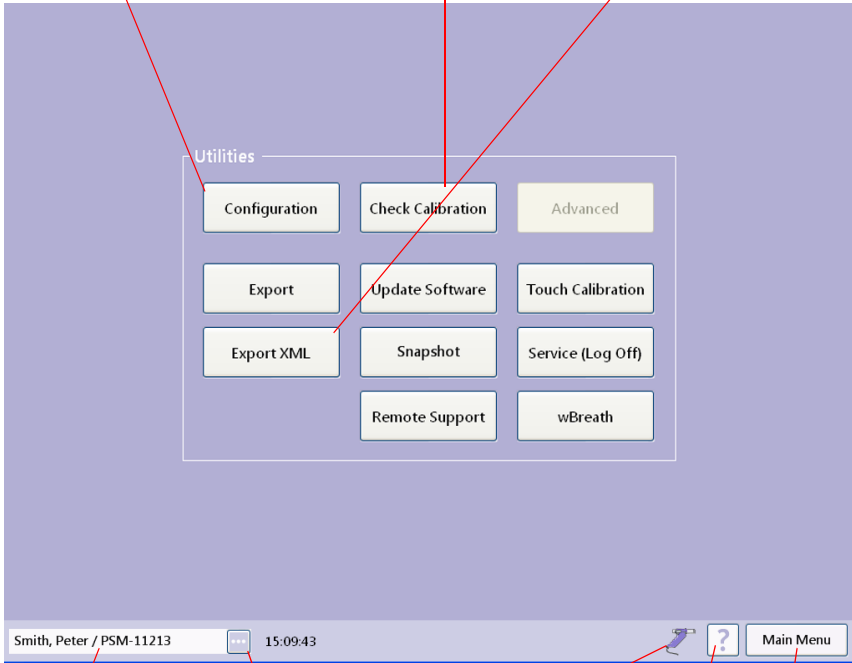
"Index" on page 135

System Settings Menu

Click to display the configuration menu

Click to perform the calibration check

Click to export data



Selected patient

Click to view patient data

'Sensor connected' indicator

Help button

Back to main menu

Also refer to

"System Settings" on page 76

"Index" on page 135

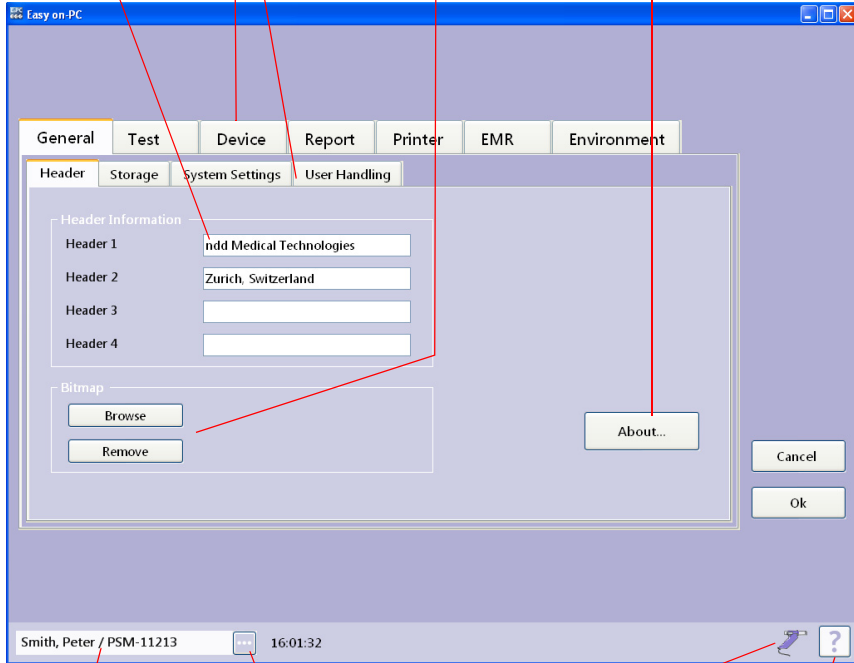
Configuration Menu

Click to display more tabs

Text boxes for entry of the header texts

Click to search for an illustration to be added or removed

Click to view details about the software program



Selected patient

Click to view patient data

'Sensor connected' indicator

Help button

Also refer to

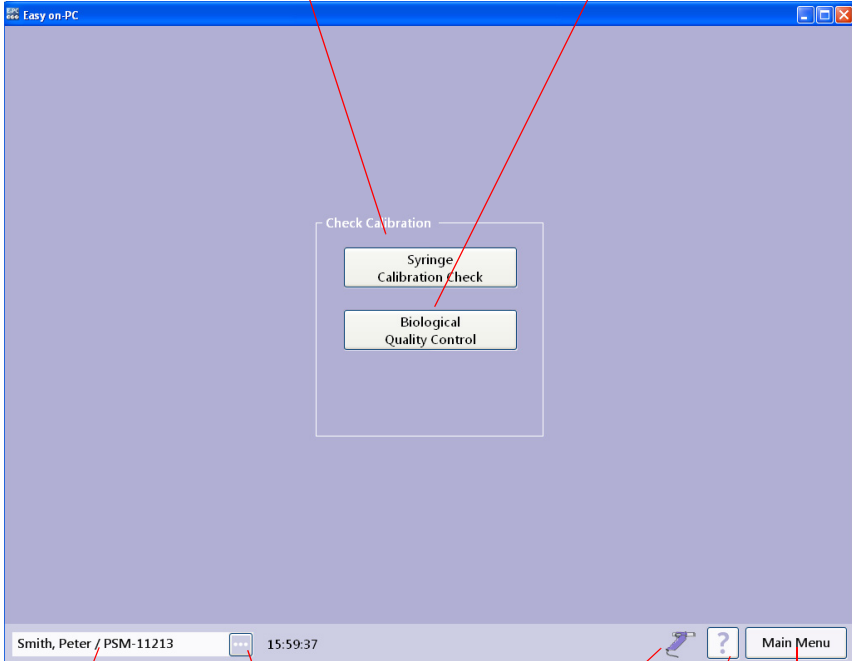
"System Settings" on page 76«

"Index" on page 135

Calibration Check

Calibration check with syringe

Calibration check with test subject



Selected patient

Click to view patient data

'Sensor connected' indicator

Help button

Back to main menu

Also refer to

"With Syringe" on page 71

"Easy on-PC Sensor Design and Operation" on page 13

"Specifications" on page 93

"Index" on page 135

Calibration Check with Test Subject

Select the sensor

Click to select the BioCal Subject

Click to select the parameter for display

Click to add a new BioCal Subject

Deselect a test (remove check mark)

Selected patient

Click to view patient data

Click to display the graphic trends

Help button

Back to main menu

Click to display the baseline / control values

Click to conduct a new test

Also refer to

"With Test Subject" on page 72

"Easy on-PC Sensor Design and Operation" on page 13

"Specifications" on page 93

"Index" on page 135

10.7 Literature

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Index

A

Ambient conditions 38
 Ambient conditions, enter 91
 ATPS values 38

B

BioCal Check 72
 BioCal Check QC grades 75
 Bronchial provocation
 introduction and safety information
 47
 performing a test 48
 safety information 10
 Bronchodilation 39
 BTPS values 38

C

Calibration adapter 71, 97
 Calibration syringe 71, 97
 Caution (definition) 8
 CE marking 5
 Check Measuring Accuracy 71
 Cleaning 70
 Comments, enter 67
 Configuration 76

D

Danger (definition) 8
 Data backup 78
 Data, copy 78
 Database folder, create 78
 Definition of the parameters 59
 Disposal 75
 Driver installation 21

E

EasyOne tab 87
 Electromagnetic Compatibility 113
 EMC 113
 EMR Tab 90
 Equipment checks before each use .. 71
 Expiratory FVC measurement 32

F

FEV6 36
 Flow sensor 13
 Forced vital capacity 32
 FVC 32
 FVL test (inspiratory and expiratory measurement) 38

G

GDT interface 103
 General Tab 77
 GOLD-Hardie Interpretation 98

H

Header Tab 77
 Hygiene 70

I

Initial screen 25
 Installation with Windows 7® 16
 Installation with Windows XP® 20
 Intended use 12
 Interpretation 98
 Interpretation, NICE 100
 Interpretation, NLHEP 99

L

Licence terms 5
 Literature 132
 Logo, add to test 109
 Lung function test, select 81

M


Maintenance 71
 Maximum Voluntary Ventilation 45
 Merging patient records 30
 MVV 45
 MVV tab 84

N

New patient, admit 29
 NICE Interpretation 100

NLHEP Interpretation	99
O	
Order Information	97
P	
Parameter definitions	70
Parameter, select	83
Patient data, edit	61
Patient, selection	26, 27
PC maintenance	96
Post-test	39
Predicted values	102
Pre-test	39
Printer Tab	89
Provocation tab	85
Q	
Quality grade	36
Quality grades	62
Quality messages	62
Quick Test	53
R	
Revision history	6
S	
Safety information	
bronchial provocation	10
Screen displays, quick reference ..	118
Selection tab	87
Sensor, connect	21
Software installation	15
Specifications	93
spirette, insertion	24
Spirometry trial, add	37
Storage Tab	78
SVC	42
SVC tab	84
System interpretation	67
System requirements	14

T	
Technical description	95
Test assessment, retrospective	67
Test, end	53
Test, print	54
Test, retrieve	54
Test, selection	31
Trend view	57
Troubleshooting	92
W	
Warning (definition)	8
Warranty	7



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