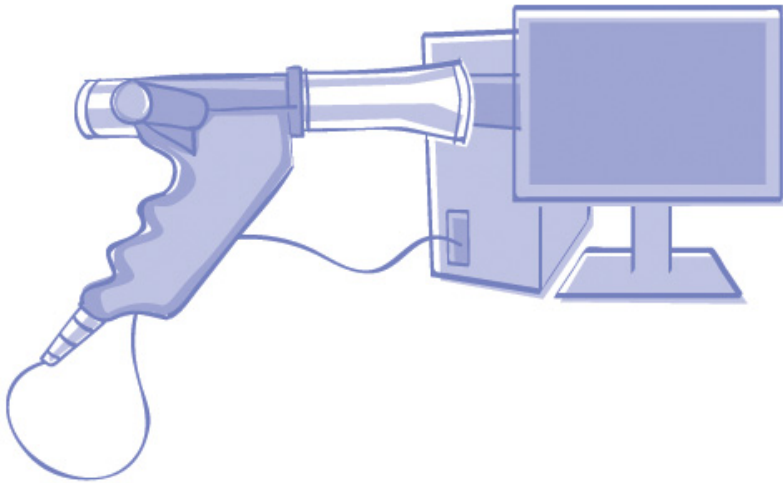




# Easy on-PC

## Operator's Manual



Version V02

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**Note**

The information in this manual applies to software version V01.02 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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<b>1</b>	<b>Introduction</b>	<b>4</b>
	1.1 CE Marking Information	4
	1.2 Licence Terms	4
	1.3 Revision History	5
	1.4 Manual Purpose	5
	1.5 Intended Audience	5
	1.6 Styles	5
	1.7 Safety Information	6
	1.8 Intended Use	9
	1.9 Description of the Medical Electrical Device	9
	1.10 Easy on-PC Sensor Design and Operation	10
	1.11 System Requirements	11
<b>2</b>	<b>Start-up and Preparation</b>	<b>12</b>
	2.1 Software Installation	12
	2.2 Connecting the Easy on-PC Sensor	17
	2.3 Preparing the Easy on-PC Sensor	20
	2.4 Starting the Software Program	21
<b>3</b>	<b>Performing a Test</b>	<b>22</b>
	3.1 Selecting/Admitting a Patient	22
	3.2 Selecting a Test	25
	3.3 Forced Vital Capacity (FVC/FVL)	25
	3.4 Vital Capacity (SVC)	36
	3.5 Maximum Voluntary Ventilation (MVV)	38
	3.6 Quick Test	40
	3.7 Ending the Test	40
	3.8 Retrieving/Printing Stored Tests	40
	3.9 Trend View	43
	3.10 Editing Patient Data	45
	3.11 Quality Messages / Grades (Details)	46
	3.12 System Interpretation	51
	3.13 Retrospective Test Assessment, Entering Comments	51
	3.14 Parameter Definitions	54
<b>4</b>	<b>Hygiene, Cleaning, Maintenance, Disposal</b>	<b>56</b>
<b>5</b>	<b>System Settings</b>	<b>58</b>
<b>6</b>	<b>Troubleshooting Tips</b>	<b>74</b>
<b>7</b>	<b>Specifications</b>	<b>75</b>
<b>8</b>	<b>Technical Description</b>	<b>77</b>
<b>9</b>	<b>Order Information</b>	<b>79</b>
<b>10</b>	<b>Appendix</b>	<b>80</b>
	10.1 Interpretation	80
	10.2 Predicted Values	84
	10.3 GDT Interface	88
	10.4 Report Designer	94
	10.5 Electromagnetic Compatibility (EMC)	98
	10.6 Quick Reference Guide to the Screen Displays	103
	10.7 Literature	116

# 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 product *Easy on-PC 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 *Easy on-PC 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. ndd 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 ndd. 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

### 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.
- 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:

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### **Danger**

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

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### **Warning**

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

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### **Caution**

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

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## Safety Information

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### **Danger**

Explosion Hazard—The *Easy on-PC 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.

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### **Warning**

Shock Hazard—

- ◆ If the *Easy on-PC 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 *Easy on-PC 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.

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**Warning**

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

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

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.

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

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**Caution**

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

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## 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

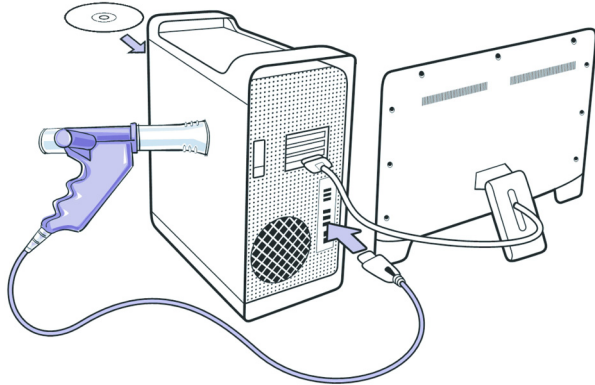
The software program *Easy on-PC* in conjunction with the *Easy on-PC* Sensor is designed for spirometric measurements in adults and children over the age of 4. The *Easy on-PC* system is used by general practitioners, specialists, in occupational medicine and in hospitals; it may also be used in frontline 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 *Easy on-PC* 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 77.

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.

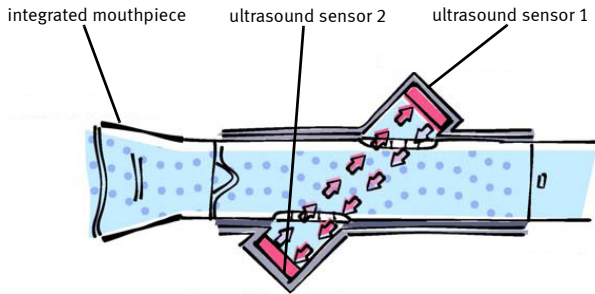


Fig. 1-2: Easy on-PC Sensor

## 1.11 System Requirements

	minimum requirements
operating system	Windows 2000 <sup>®</sup> SP4, Windows Server <sup>®</sup> 2003, Windows XP <sup>®</sup> SP2, Windows Vista <sup>®</sup>
Web browser	Internet Explorer 6 or later
processor	Intel <sup>®</sup> -/Pentium <sup>®</sup> 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.

## 2 Start-up and Preparation

### 2.1 Software Installation

#### Note

Install the software on the PC before connecting the *Easy on-PC 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.

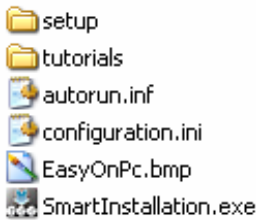


Fig. 2-1:

- The following window will be displayed:

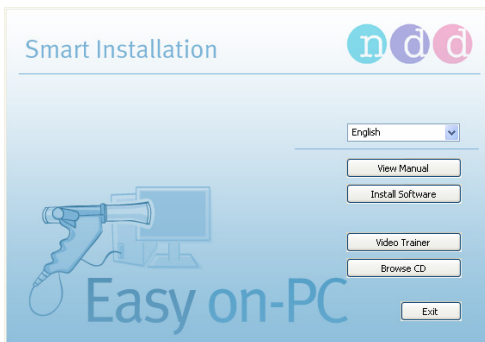


Fig. 2-2:



## Note

To view the Operator Manual, select the language and click **View Manual**. If no PDF viewing program is installed, the Adobe Reader will be installed first.

- Click **Install Software** to initiate the installation routine.

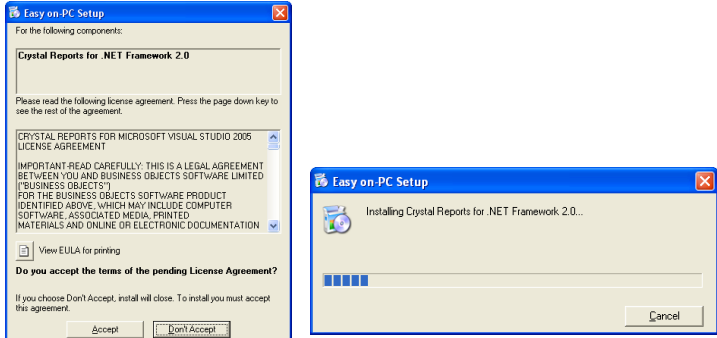


Fig. 2-3:

- Click **Accept**.

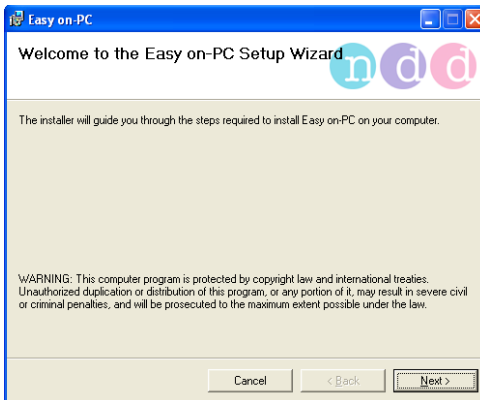


Fig. 2-4:

- Click **Next >**.

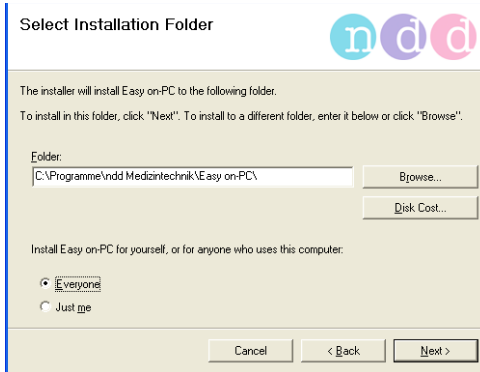


Fig. 2-5:

- Click **Next>** to confirm the proposed installation path. Click **Browse...**, if you wish to select another installation path.

In the lower area of the window you determine the program users: *Everyone* means the program will be accessible to all users, *Just me* means that only you will have access to the program.

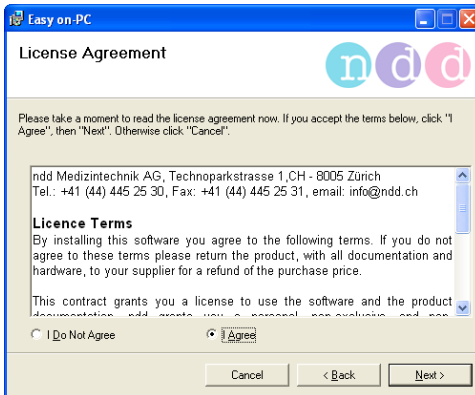


Fig. 2-6:

- Read the licence terms. You accept these terms with *I Agree*.
- Click **Next>**.

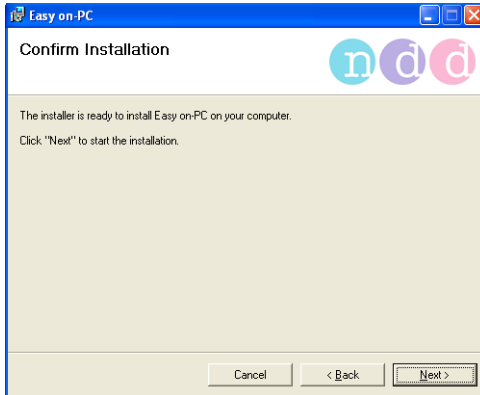


Fig. 2-7:

- Click **Next >** to start the actual software installation routine.

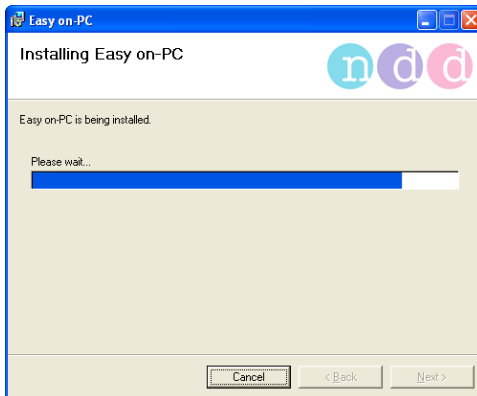


Fig. 2-8:



Fig. 2-9:

- Click **Continue Anyway**.

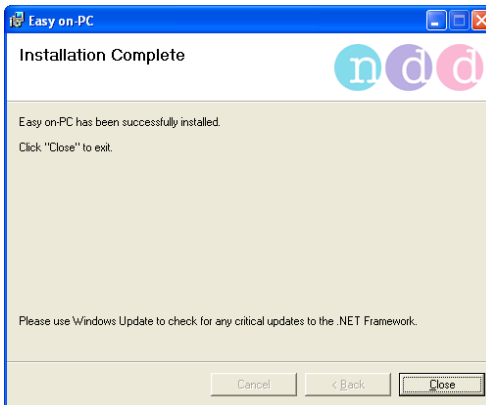



Fig. 2-10:

- Click **Close** to finish the installation routine. Remove the CD from the drive.

After a successful installation you will find the *Easy on-PC* icon  on your desktop.

## 2.2 Connecting the *Easy on-PC Sensor*

For operation of the *Easy on-PC 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 *Easy on-PC 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*.

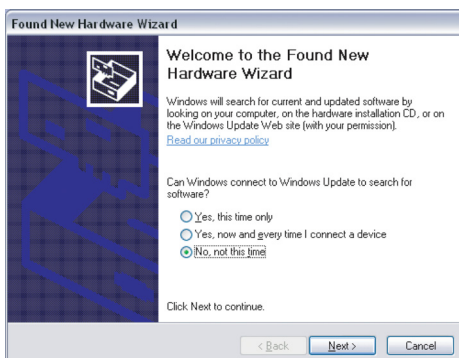


Fig. 2-11:

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

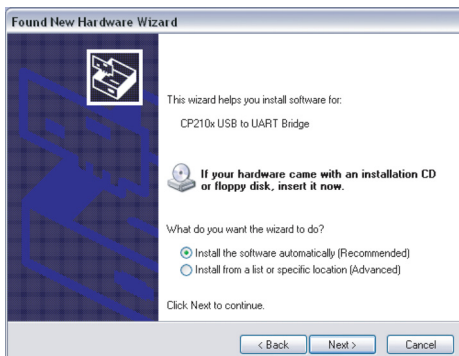


Fig. 2-12:

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

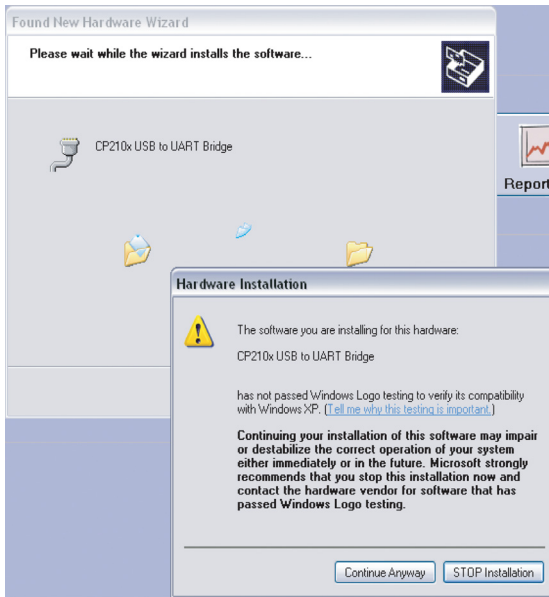


Fig. 2-13:

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

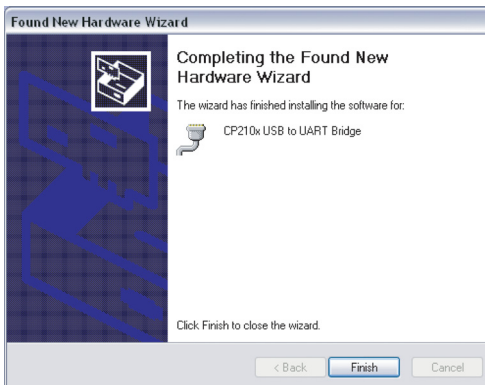


Fig. 2-14:

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



Fig. 2-15:

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

### **Note**

Please note that you will have to install the driver again, if the *Easy on-PC Sensor* is connected to a USB port on which it was not used before.

## 2.3 Preparing the *Easy on-PC Sensor*

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### Warning

Shock Hazard—If the *Easy on-PC Sensor* is connected to a PC, this PC must meet the requirements of IEC standard 60950-1.

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- Tear open the plastic bag containing the *spirette™* and fold the bag back, allowing you to insert the *spirette™* into the *Easy on-PC Sensor*. Ensure that the plastic bag protects the mouthpiece of the *spirette™* until you hand over the *Easy on-PC 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 *Easy on-PC Sensor* as far as possible. When doing this, please ensure that the arrow on the *spirette™* is lined up with the arrow on the *Easy on-PC Sensor*.
- You remove the *spirette™* by pushing it out of the sensor from below.

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### 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.

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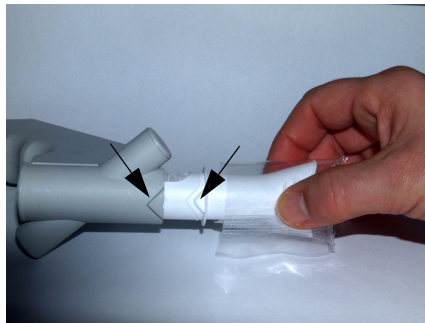


Fig. 2-16: *Inserting the spirette™*



## 2.4 Starting the Software Program

- Click  .

The initial screen is displayed.

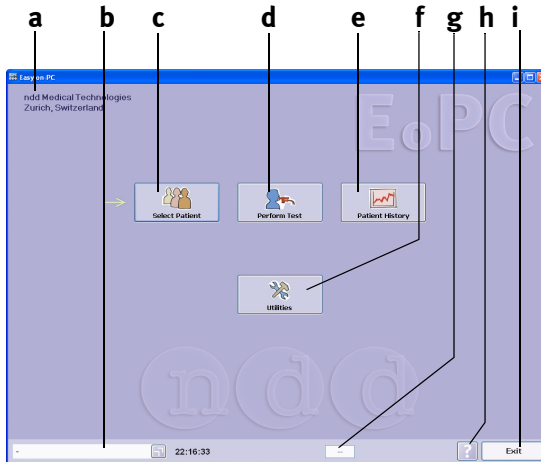


Fig. 2-17: Initial screen

- |   |  |
|---|--|
| <p><i>a</i> Practice, office, hospital (see "General Tab" on page 59 for details about entering the data)</p> <p><i>b</i> Selected patient</p> <p><i>c</i> Click to select a patient or admit a new patient</p> <p><i>d</i> Click to perform a test</p> | <p><i>e</i> Click to review the results from previous tests</p> <p><i>f</i> Click to view the setup screen</p> <p><i>g</i> Sensor status (sensor icon, if sensor is connected)</p> <p><i>h</i> Help button</p> <p><i>i</i> Click to quit the program</p> |
|---|--|

### Note

Before working with the program, setup the system as described in "System Settings" on page 58

- ◆ 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 64)
- ◆ 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 40).

#### 3.1 Selecting/Admitting a Patient

- Click **Select Patient**.

The patient list will be displayed.

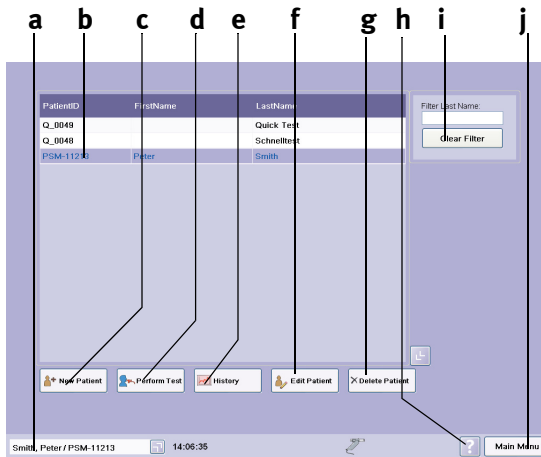


Fig. 3-1: Patient list

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



## 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 **h**.
- 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.

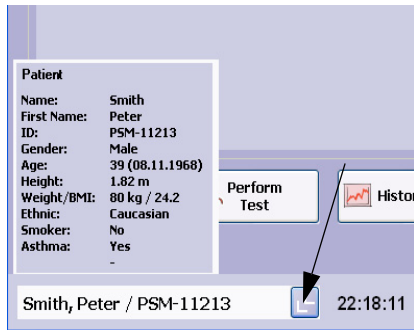


Fig. 3-2: Window showing patient data

## Admitting a New Patient

- Click **New Patient**.
- Enter a patient ID and press the **TAB** key or the **Enter** key.
- Enter the last and first names in the same way.
- Click **a** (Fig. 3-3) to select the gender and press the **TAB** key.
- Enter the date of birth: dd.mm.yyyy, the height and the weight.
- Select the ethnic origin **d** and the smoker status **c**.

If deemed appropriate, you can add information about asthma and/or COPD (chronic, obstructive pulmonary disease) **b** to the patient data.

- Close the window with **OK**.

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

### Note

This information must be correct, because it is used to calculate the predicted values and to interpret the acquired data.

The screenshot shows a 'Patient data window' with the following fields and labels:

- a**: Points to the **Gender** dropdown menu.
- b**: Points to the **Asthma** and **COPD** checkboxes.
- c**: Points to the **Smoker** dropdown menu.
- d**: Points to the **Ethnic** dropdown menu.

Other fields in the window include: Patient ID, Last Name, First Name, Date Of Birth (dd.mm.yyyy), Age, Height (cm), and Weight (kg). Asterisks (\*) indicate required fields. A legend at the bottom right states '\* Required'.

Fig. 3-3: Patient data window

## 3.2 Selecting a Test

The test menu will appear either directly after entry of the patient data or it can be opened with **Perform Test** on the initial screen.



Fig. 3-4: Test menu

## 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

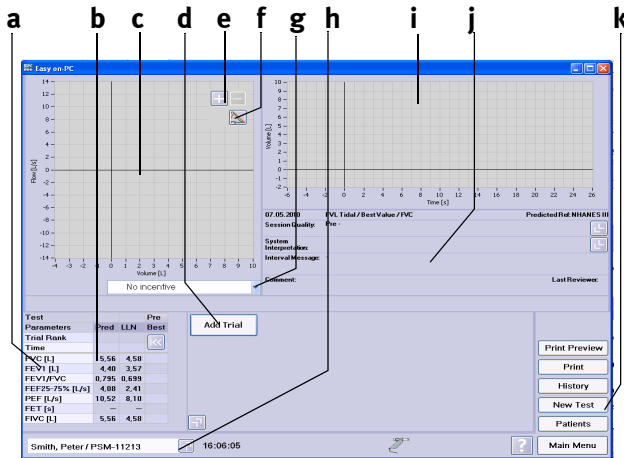


Fig. 3-5: Expiratory FVC acquisition screen

- 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*<sup>TM</sup> into the mouth with the lips sealing around the *spirette*<sup>TM</sup>, taking care not to block its opening with the tongue or bite down excessively on the *spirette*<sup>TM</sup>
- ◆ 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. 3-6: Patient using the spirette™ respiratory tube

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**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™ is designed for single use. Use a fresh spirette™ for each new patient.

Risk of Infection—Clean the nose clip after each 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.

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## Measurement

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

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

### Note

ndd 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*<sup>TM</sup> 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 64), 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.



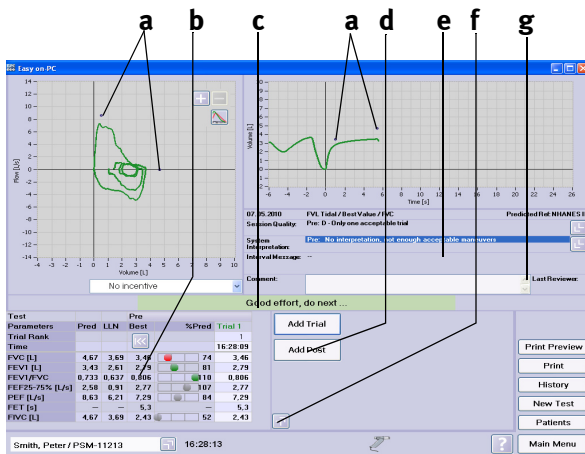


Fig. 3-7: Acceptable FVC test

- 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 33)
- 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 51)
- 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 51). 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.

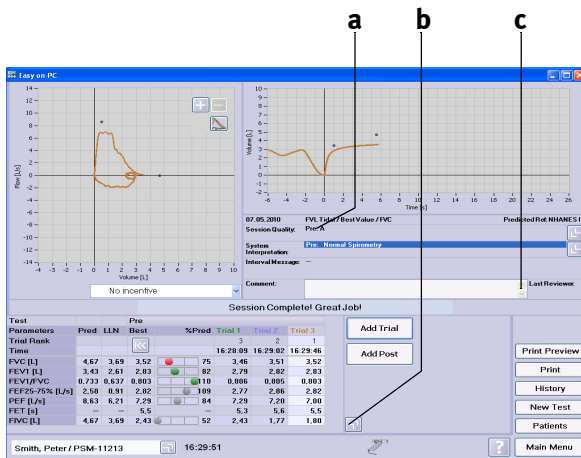


Fig. 3-8: Acquisition screen after three acceptable, expiratory FVC tests  
**a** Quality grade **c** Area for review comments  
**b** Click to perform a post-test (see "Bronchodilation (Post-Tests)" on page 33)

### 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.

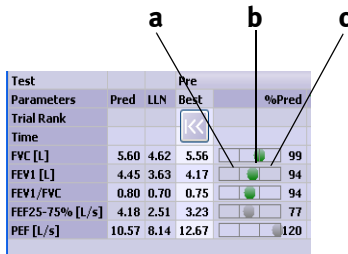


Fig. 3-9: %Pred graph

### 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.

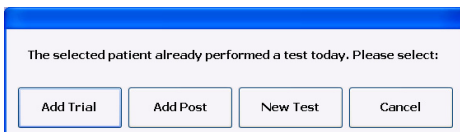


Fig. 3-10: Test menu

- 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.

Fig. 3-11: Window showing the ambient conditions

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

- 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 26) and explain the test maneuvers:
  - ◆ take the *spirette*<sup>TM</sup> into the mouth with the lips sealing around the *spirette*<sup>TM</sup>, taking care not to block its opening with the tongue or bite down excessively on the *spirette*<sup>TM</sup>
  - ◆ 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 28.


### Note

The volume-time curve (Fig. 3-13): 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. 3-12: left) you display the detailed results of the *Pre* tests (Fig. 3-12: right).

Test	Pre			Post									
Parameters	Pred	LLN	Best	Best	Parameters	Pred	LLN	Best	%Pred	Trial 1	Trial 2	Trial 3	Post
Trial Rank					Trial Rank					1	3	2	
Time					Time					09:53:14	10:22:28	10:22:58	
FVC [L]	4.50	3.69	3.98		FVC [L]	4.50	3.69	3.98		88	3.98	3.85	3.92
FEV1 [L]	3.62	2.94	3.71		FEV1 [L]	3.62	2.94	3.71		102	3.71	3.68	3.70
FEV1/FVC	0.80	0.70	0.93		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		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		PEF [L/s]	9.10	7.10	10.45		115	10.14	9.90	10.45

Fig. 3-12: Detailed test results

- Conduct the tests as described in section "Measurement" on page 28.

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 46).

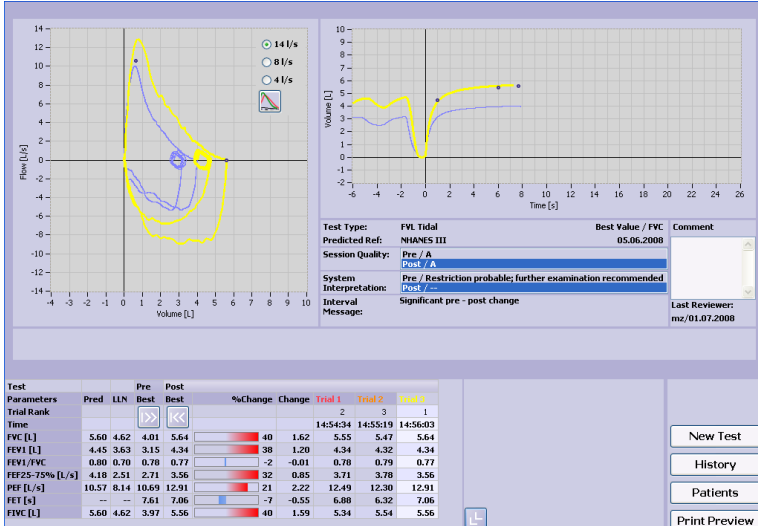


Fig. 3-13: Acquisition screen after three acceptable post-tests

### Note

To zoom into the curve display, hold the Shift key down while selecting the region of interest with the left mouse button depressed. Use the right mouse button to zoom out.

## Animation Program for Children

An animation program for children is available for FVC and FVL tests. 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 64).

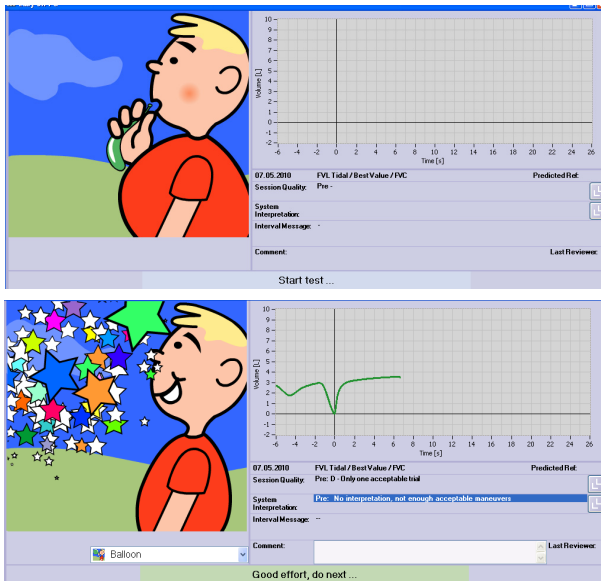


Abb. 3-14: Animation program for children, test start, successful test





- Conduct the tests as described in section "Measurement" on page 28.

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 46).

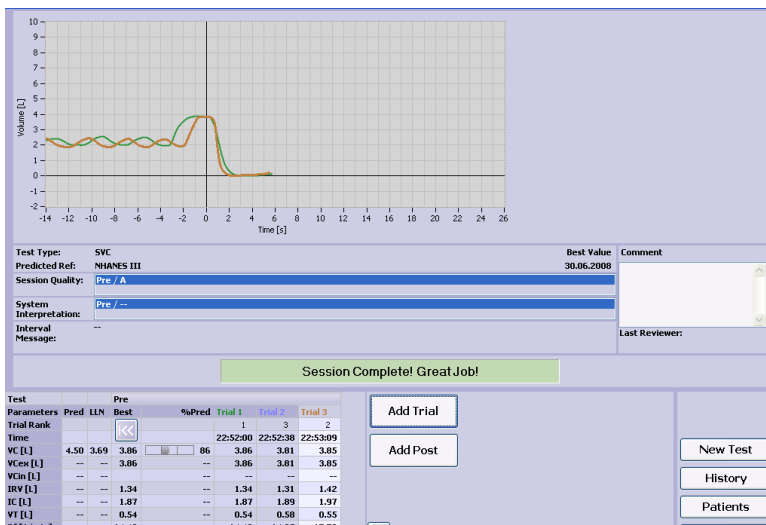


Fig. 3-16: Acquisition screen after three acceptable SVC tests

### 3.5 Maximum Voluntary Ventilation (MVV)

In these tests, the maximum tidal volume over an uninterrupted period of 12 seconds is measured. For this test type, too, the ATPS values (**A**mbient **T**emperature **P**ressure **S**aturated = spirometer conditions) must be converted to BTPS values (**B**ody **T**emperature **P**ressure **S**aturated = body conditions) (see "[Ambient Conditions](#)" on page 32).

- Select the patient (see "[Selecting/Admitting a Patient](#)" on page 22).
- Prepare the patient (see "[Preparations](#)" on page 26) and explain the test maneuvers:
  - ◆ take the *spirette*<sup>TM</sup> into the mouth with the lips sealing around the *spirette*<sup>TM</sup>, taking care not to block its opening with the tongue or bite down excessively on the *spirette*<sup>TM</sup>
  - ◆ 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.

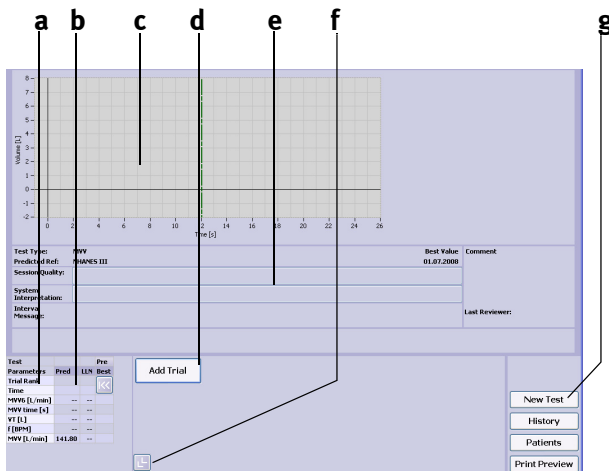


Fig. 3-17: MVV acquisition screen

- 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 51)
- g 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 28.



Fig. 3-18: Acquisition screen after six acceptable MVV tests

### 3.6 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.

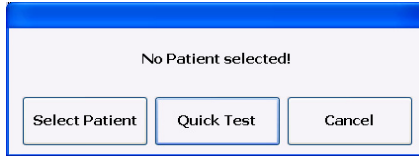


Fig. 3-19: Menu

- 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.

### 3.7 Ending the Test

At the end of the test, push the *spirette*<sup>TM</sup> out of the sensor from below. Dispose of and do not reuse. Refer to section "[Hygiene, Cleaning, Maintenance, Disposal](#)" on page 56 for sensor cleaning instructions.

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#### **Warning**

Risk of Infection— The *spirette*<sup>TM</sup> is for single use only and must not be reused.

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### 3.8 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 31).

- Select the patient (see "[Selecting/Admitting a Patient](#)" on page 22).
- Click the **History** button (Fig. 3-20:).

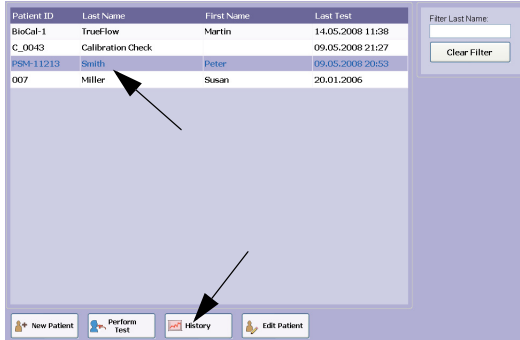


Fig. 3-20: Retrieving/printing stored tests

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

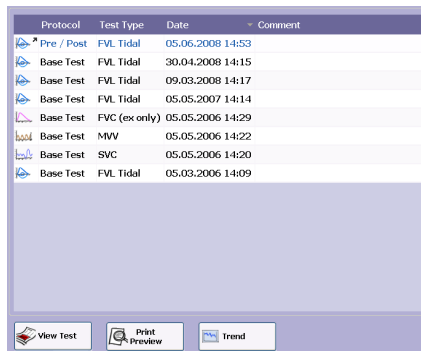


Fig. 3-21: Test list

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, or **Print Preview** to print the test, or **Trend** to view the trend display (see "Trend View" on page 43).

### Note

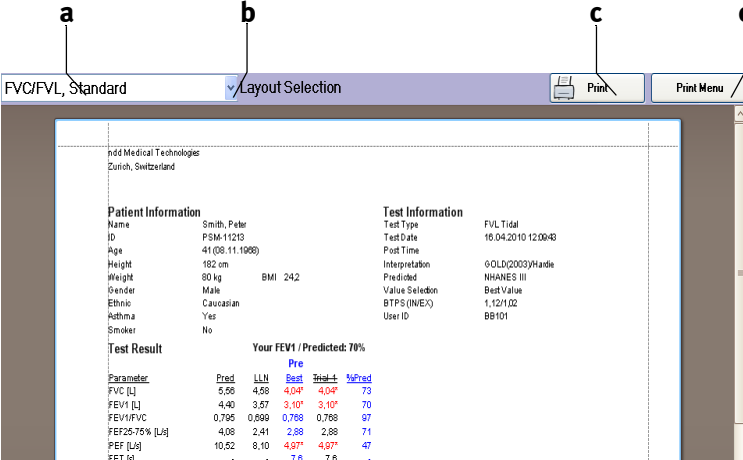
Alternative: Double-click on a test to display it.

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.



ddd Medical Technologies  
Zurich, Switzerland

**Patient Information**

Name: Smith, Peter  
ID: PSM-11213  
Age: 41 (08.11.1968)  
Height: 192 cm  
Weight: 80 kg BMI: 24.2  
Gender: Male  
Ethnic: Caucasian  
Asthma: Yes  
Smoker: No

**Test Information**

Test Type: FVL Tidal  
Test Date: 16.04.2010 12:00:43  
Post Time:  
Interpretation: GOLD(2003)/Hardie  
Predicted: NHANES III  
Value Selection: Best Value  
BTPS (N/EX): 1.12/1.02  
User ID: BB101

**Test Result** Your FEV1 / Predicted: 70%

Parameter	Pred	LLL	Best	%Pred
FVC [L]	4.56	4.56	4.04*	73
FEV1 [L]	4.40	3.57	3.10*	70
FEV1/FVC	0.795	0.690	0.768	97
FEF25-75% [L/s]	4.08	2.41	2.88	71
PEF [L/s]	10.52	8.10	4.97*	47
PFT [s]	.	.	7 R	7 R

Fig. 3-22: 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

### 3.9 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.

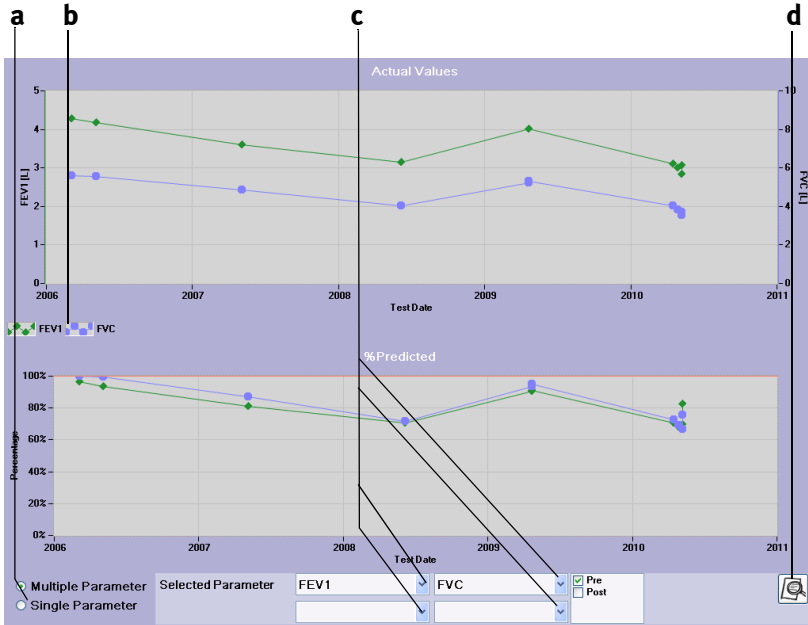


Fig. 3-23: Trend view of multiple parameters

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

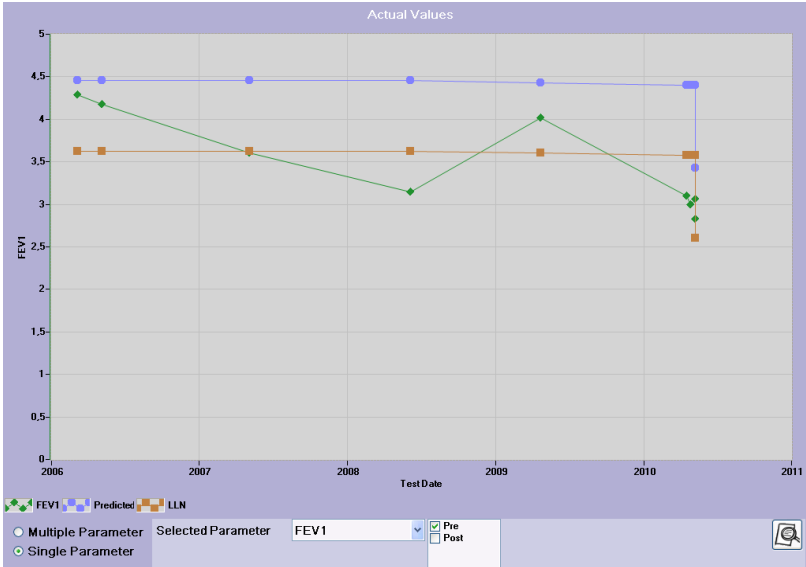


Fig. 3-24: Trend view of a single parameter and its predicted normals



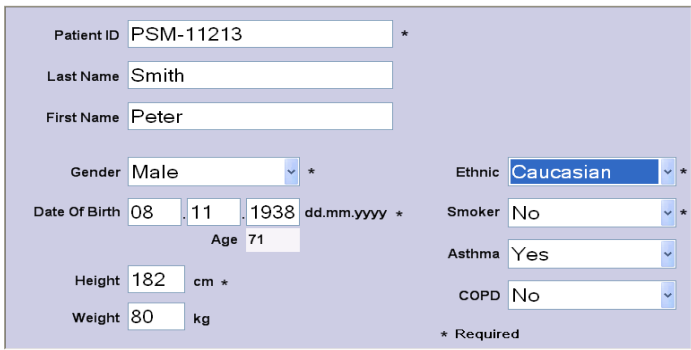
## 3.10 Editing Patient Data

### 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 entry form with the following fields and values:

Patient ID	PSM-11213	*
Last Name	Smith	
First Name	Peter	
Gender	Male	*
Ethnic	Caucasian	*
Date Of Birth	08 / 11 / 1938	dd.mm.yyyy *
Age	71	
Height	182	cm *
Weight	80	kg
Smoker	No	*
Asthma	Yes	
COPD	No	

\* Required

Fig. 3-25: Patient data window

- Change or add data and click **OK** to close the window.

## 3.11 Quality Messages / Grades (Details)

### FVC/FVL

End-of-Test criteria, quality criteria and quality grading in *Easy on-PC* are based upon the following published standards:

- [1] Standardization of Spirometry. 1994 Update, Am J Respir Crit Care Med, Vol 152.
- [2] Office Spirometry for Lung Health Assessment in Adults: A Consensus Statement from the National Lung Health Education Program. Respir Care, 2000, Vol 45, No 5.
- [3] ATS/ERS Task Force: Standardization of Lung Function Testing. Eur Respir J 2005; 26.
- [4] An Official American Thoracic Society/European Respiratory Society Statement: Pulmonary Function Testing in Preschool Children. Am J Respir Crit Care Med, 2007, Vol 175.

The quality grading is based on [2], [3] and [4].

### 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: "Result not reproducible" OR only one acceptable trial. Quality message: "Only one acceptable trial".
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  $\leq 30$  ml (test time  $\leq 6$  s)  $\leq 45$  ml (test time  $> 6$  s), or if an inspiratory volume  $\geq 120$  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 $\leq 150$ 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

### 3.12 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 80 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.

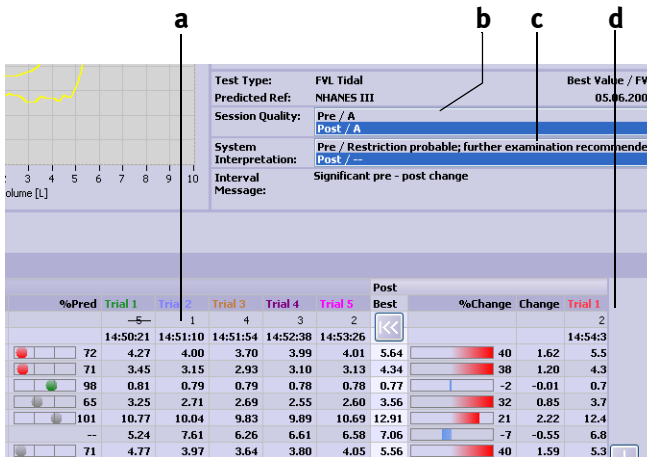


Fig. 3-26: Test results, system interpretation

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

### 3.13 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. 3-27:).

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

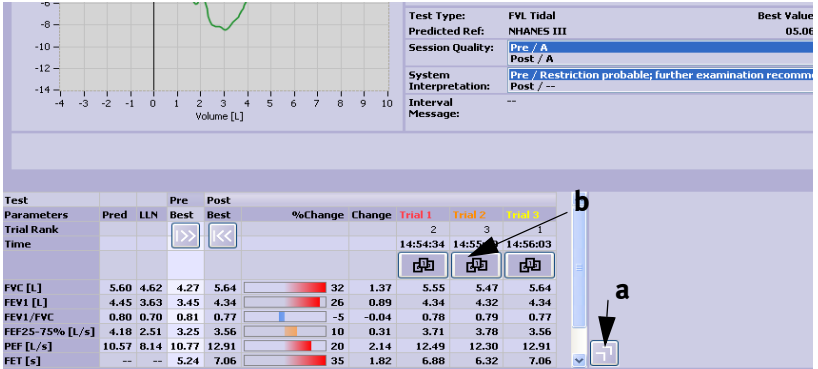


Fig. 3-27: Changing the trial acceptability

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. 3-28: 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. 3-29).



**Note**

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



Fig. 3-29: Changing the trial ranking

**Entering Comments**

- Click in the comment area.
- 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.

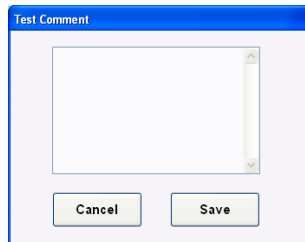


Fig. 3-30: Entering comments

### 3.14 Parameter Definitions

FVC	Forced Vital Capacity (expiratory)	forced expiratory vital capacity
FIVC	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 <sub>max</sub>		ratio of FEV1 to VC <sub>max</sub>
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 VCmax	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 84 [8]

## 4 Hygiene, Cleaning, Maintenance, Disposal

### Hygiene

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**Caution**

Risk of Infection—

- ◆ Thoroughly clean the Easy on-PC Sensor when you suspect it to be contaminated.
  - ◆ Users with open wounds or contagious diseases must wear gloves.
  - ◆ The *spirette*<sup>TM</sup> must be properly disposed immediately after use.
- 
- 

**Note**

ATS / ERS Guidelines recommend washing hands between patients. <sup>1)</sup>

### Cleaning

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**Warning**

Shock Hazard—Disconnect the Easy on-PC Sensor from the PC before cleaning.

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**Caution**

Equipment Damage—

- ◆ Liquids must not be allowed to enter the Easy on-PC Sensor. Sensors into which liquids have entered must be checked by a service technician before they can be reused.
  - ◆ Do not immerse any part of the Easy on-PC Sensor into cleaning liquids or sterilize it with hot water, steam or air.
- 
- 

<sup>1)</sup> ATS/ERS Task Force: Standardization of Lung Function Testing. Eur Respir J 2005.

Proper use of the disposable *spirette*<sup>TM</sup> respiratory tube prevents exhaled breath or sputum from contaminating the Easy on-PC Sensor. Simply replace the single-patient-use *spirette*<sup>TM</sup> between patients. There is no need to clean the sensor after each patient.

For removing dust or fingerprints, wipe the Easy on-PC Sensor with a damp cloth.

For a more thorough cleaning, you can use any common alcohol-based detergent, containing up to 70% alcohol. Dampen a cloth with detergent and wipe the external surfaces of the Easy on-PC Sensor. Use the established procedures at your facility for the proper use and disposal of these agents.

**Note**

The housing of the sensor is made of ABS plastic.

**Note**

It is not necessary to clean the connection cable, unless it is contaminated with blood or sputum. In this case wipe the cable using a damp cloth with an alcohol-based detergent as described above. Do not immerse the cable in liquids.

**Maintenance**

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.

**Disposal**

The product described in this operator manual must not be disposed of 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).

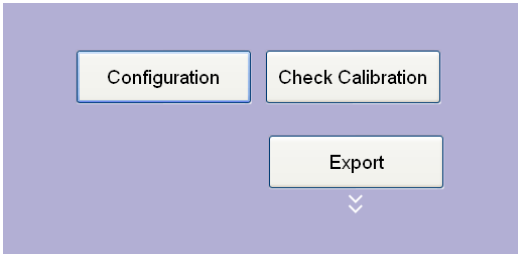


Fig. 5-1: System settings menu

### Configuration

These are the tabs of the Configuration menu

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

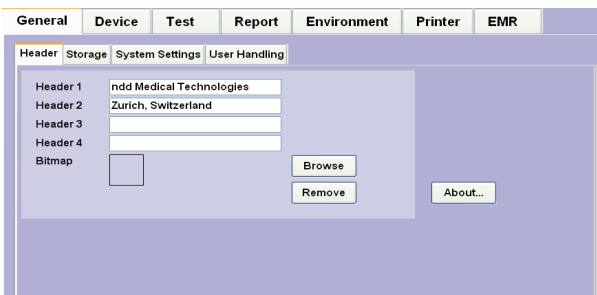


Fig. 5-2: Configuration menu, "General" tab

## 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**.

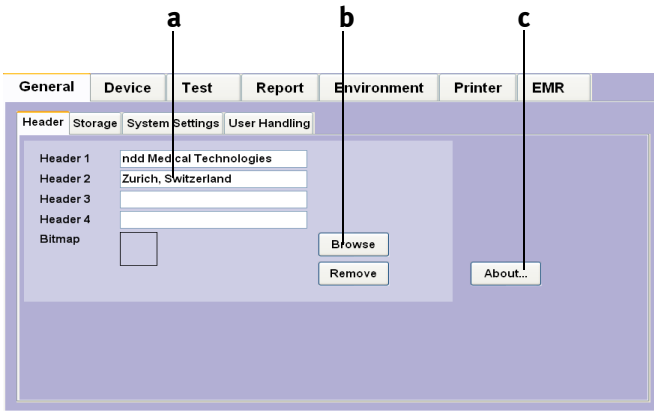


Fig. 5-3: "Header" tab

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

## Storage Tab

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

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

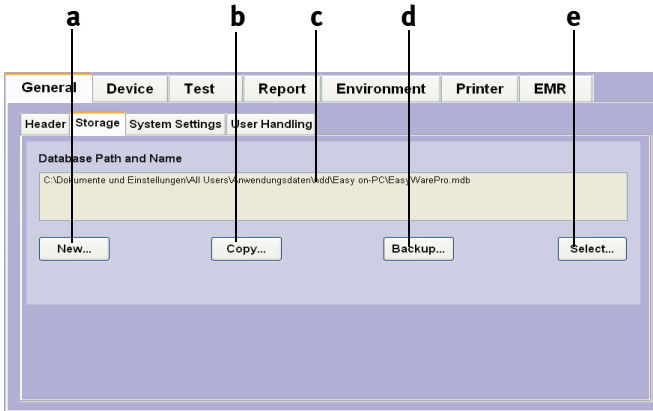


Fig. 5-4: Storage tab

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



## System Settings Tab

On this tab

- ◆ you select the units for length, temperature and weight **a**
- ◆ select the language **b**.

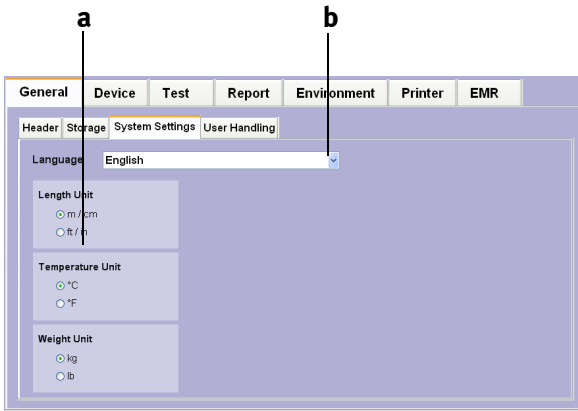


Fig. 5-5: "System Settings" tab

*a* Click to select the units

*b* Click to select the language

## User Handling Tab

This tab is protected with a password (password EOPTM). 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.

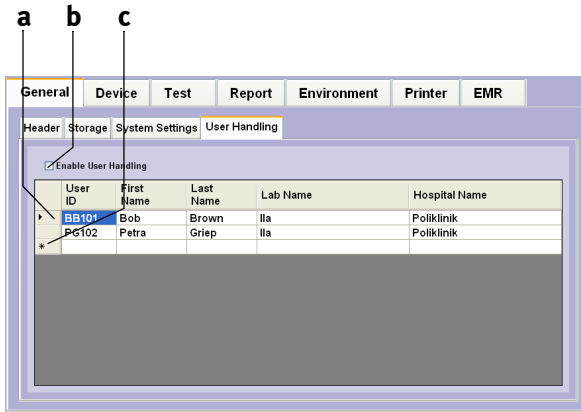


Fig. 5-6: User Handling tab

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

## Device Tab

On this tab you specify the *Easy on-PC 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.

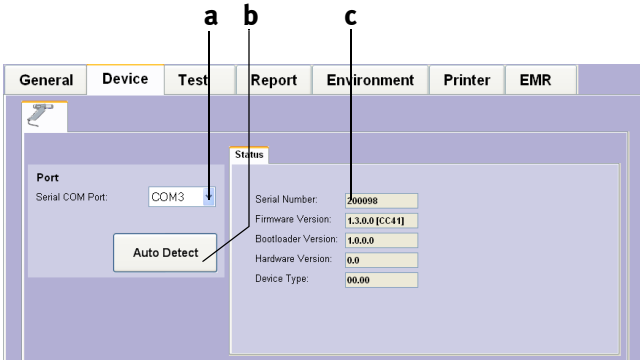


Fig. 5-7: Device tab

a Click to select the sensor port

b Click to auto detect the sensor port

c Sensor information area

## Test Tab

The tab comprises the following sub-menus

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

## General Tab

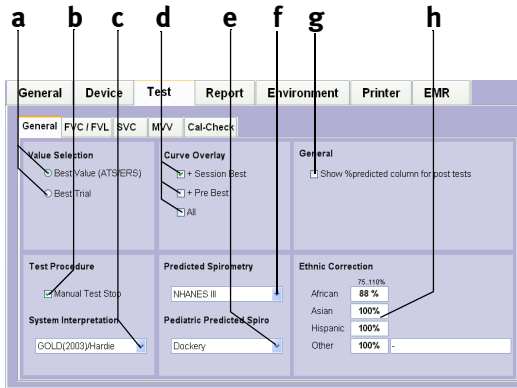


Fig. 5-8: *General tab*

- a Option buttons to select the value (Best Value/Best Trial)*
- b Select this check box, if you want to stop tests manually*
- c Use the drop-down list to select or deactivate the system interpretation*
- d Curve selection criteria*
- e Click to select the predicted values for children*
- f Click to select the predicted values for adults*
- g Select check box to display a column with the deviation in percent from the predicted value for bronchodilation tests*
- h Boxes for entry of correction factors (see Note below)*

### Note

The predicted normal is corrected by the factor **h**, 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, FEF50 / VC<sub>max</sub> , MTC1 are recalculated.

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

### FVC/FVL Tab

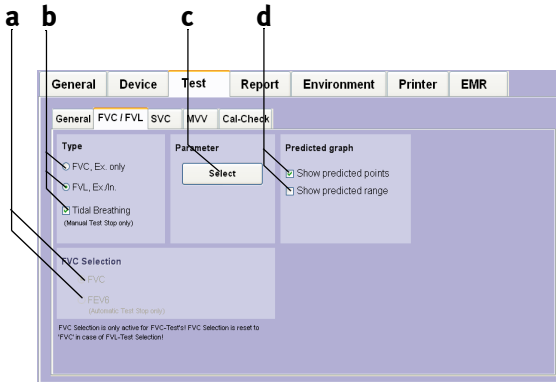


Fig. 5-9: "FVC / FVL" tab

a Select FVC/FVC6

b Select the test type

c Select the parameter

d Predicted values are represented by points or as a range

### 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, FEF50, 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.

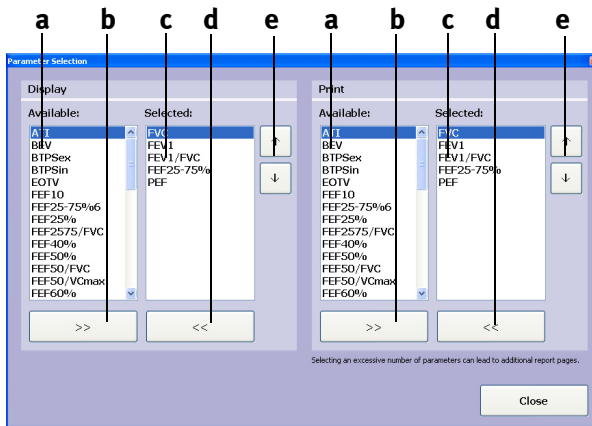


Fig. 5-10: FVC tab

## Report Tab

On the Report tab, you can:

- display the Report Designer (Layout Editor, see "Report Designer" on page 94)
- Load layouts (Load Layout)
- Save layouts (Export Layout).

## 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 32).

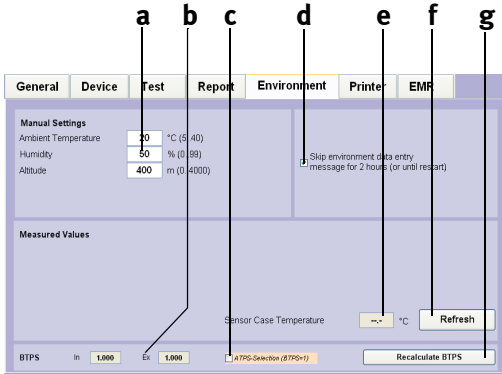


Fig. 5-11: Environment tab

- 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)

### Printer Tab

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

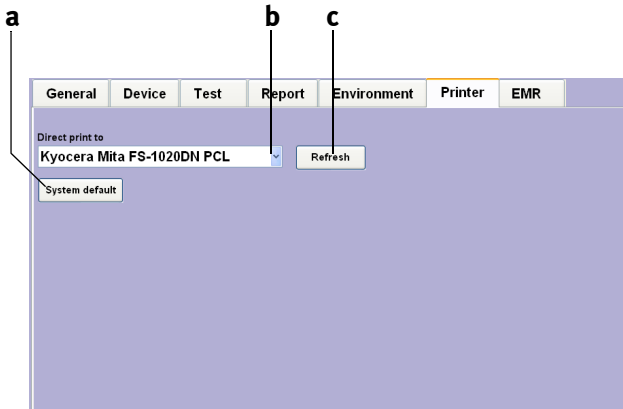


Fig. 5-12: Printer tab

a Select the default printer

c Press to update the printer list

b Press to open the printer list

### EMR Tab

Here you select the EMR system and the corresponding settings (see).

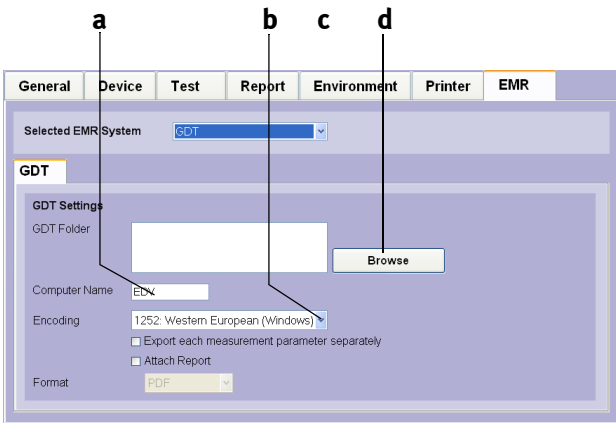


Fig. 5-13: "EMR" tab

a Enter the name of the EMR computer here

c Select the EMR system from the list

b Select the character set from the list

d Press button to search for the GDT folder



## Calibration

### Calibration Check with Syringe

#### Note

As an alternative, the calibration can be checked with a test subject (see "[Calibration Check with Test Subject](#)" on page 71).

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 *Easy on-PC 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 74. Should you not be able to remedy the defect by following these instructions either, please consult *ndd* or one of their representatives.



*Fig. 5-14: Calibration syringe*

## Calibration Check with Test Subject

### Some Basic Facts

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

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

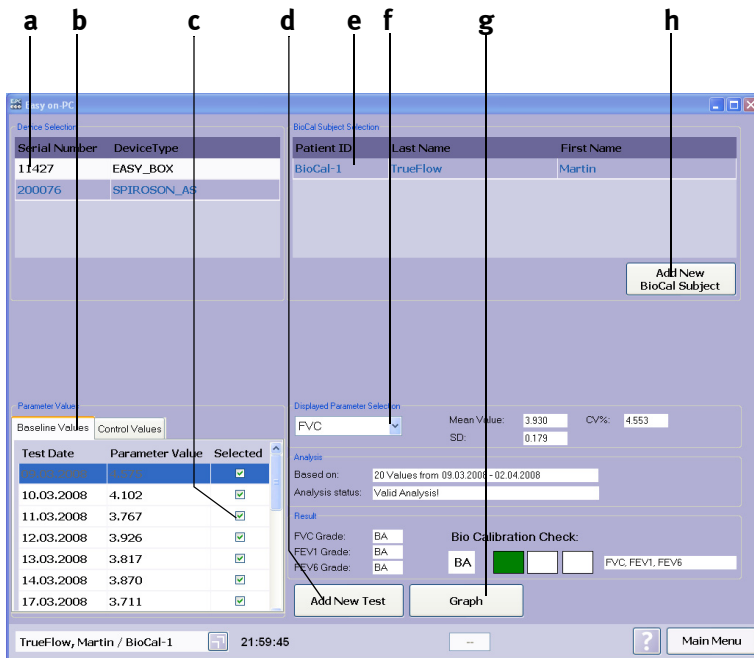


Fig. 5-15: BioCal Check main screen

- a Sensor selection
- b "Parameter Values" tabs
- c Deselecting a test (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, ... is according to configuration settings).

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

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

- Click **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 limit are  $\pm 2$  SD (Standard Deviation).

## Specifications of the BioCal-Check QC Grades

For each parameter (FEV1, FVC and FEV6) 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 out $\pm 2$ SD	-
<i>BC</i>	1 value out $\pm 3$ SD	-
<i>BD</i>	$\geq 4$ values out of $\pm 1$ SD	only consecutive values on same side of mean
	$\geq 2$ values out of $\pm 2$ SD	only consecutive values on same side of mean
	$\geq 1$ value out $\pm 3$ SD	-
	$\geq 10$ values, consecutive on same side of mean	-
<i>BF</i>	$< 20$ baseline values	-

## 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 " <a href="#">Preparing the Easy on-PC Sensor</a> " on page 20.
	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 &gt; Test &gt; Cal-Check</i> .

### Note

The most recent information and frequently asked questions can be found on our web site at [www.ndd.ch](http://www.ndd.ch).

## 7 Specifications

<b>Measurement principle</b>	ultrasound transit time measurement	
<b>Measuring accuracy</b>	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
<b>Measuring range</b>	volume:	±12 l
	flow	±16 l/s
<b>Resistance</b>	less than 0.3 cm H <sub>2</sub> O/l/s	
<b>Parameters</b>	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)	
<b>Respiratory tube</b>	<i>spirette</i> <sup>TM</sup> respiratory tube	
<b>Predicted values (adults)</b>	NHANES-III, Knudson_83, Knudson_76, Crapo, Morris, ERS (ECCS/EGKS), Forche (Austria), Sapaldia (Switzerland), Roca (Spain), Berglund, Gulsvik, Hedenström, Gore, Chermiak (for MVV only)	
<b>Predicted values (children)</b>	Dockery (Harvard), Hsu, Zapletal, Polgar, Hibbert	
<b>Report format</b>	A4 (210 mm x 297 mm)	
<b>Operating conditions (sensor)</b>	temperature	0 to 40 °C (32 to 104 °F)
	relative humidity	5% to 95%,
	atmospheric pressure	500 hPa to 1060 hPa
<b>Storage</b>	temperature	-20 to 50 °C (-4 to +122 °F)
	relative humidity	5% to 95%,
	atmospheric pressure	500 hPa to 1060 hPa
<b>Certifications</b>	CE Declaration of Conformity	

<b>Device classification (sensor)</b>	type BF applied part device not suitable for operation in the presence of flammable, gaseous anesthetic agents, mixtures with O <sub>2</sub> , or NO
<b>Life time</b>	7 years



## 8 Technical Description

### PC/Laptop Requirements

The *Easy on-PC* software is installed on a PC or laptop computer to which the *Easy on-PC* 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).

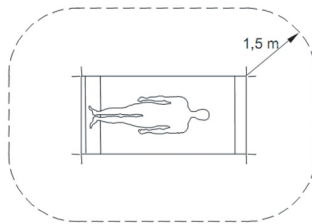


Fig. 8-1: Patient environment

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  $\mu$ A
- with interruption of the (not permanently connected) protective earth conductor: 500  $\mu$ A.

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.

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**Warning**

Patient Hazard, Equipment Damage—Do NOT modify the *Easy on-PC Sensor* unless authorized by the manufacturer.

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## 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.

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**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.

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**Note**

If updates of the operating system are performed automatically (e.g Windows updates), we recommend checking the calibration on a regular basis (see "[Calibration Check with Test Subject](#)" on page 71).

## 9 Order Information

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

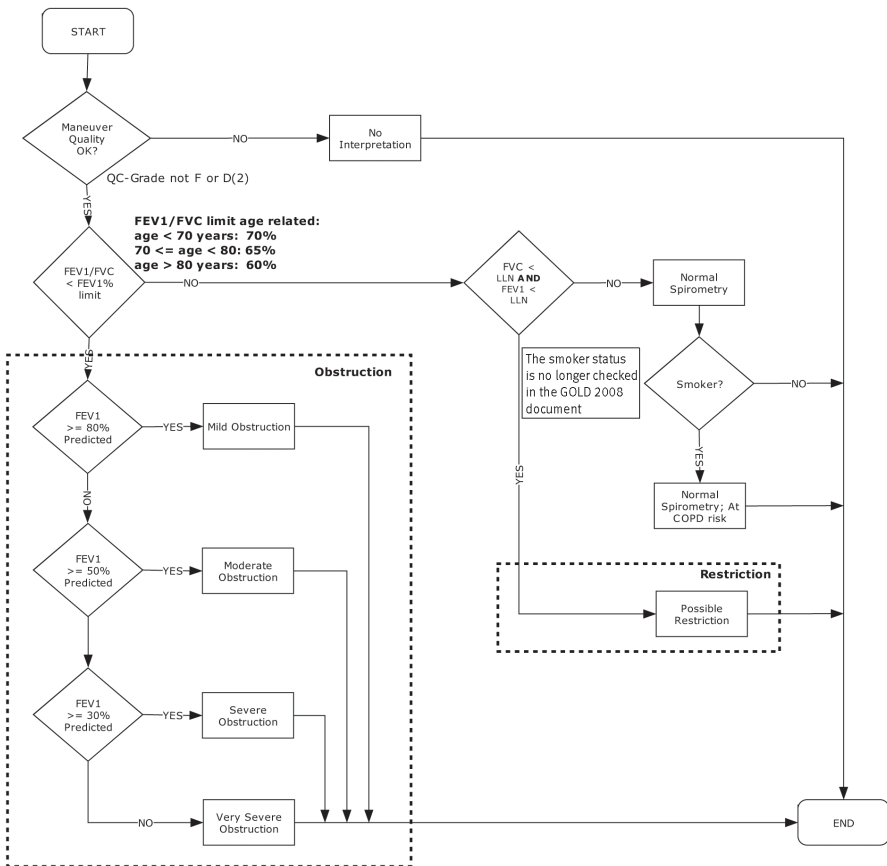
# 10 Appendix

## 10.1 Interpretation

The automatic system interpretation can be selected and deselected on the configuration tab (see c, "General Tab" on page 64).

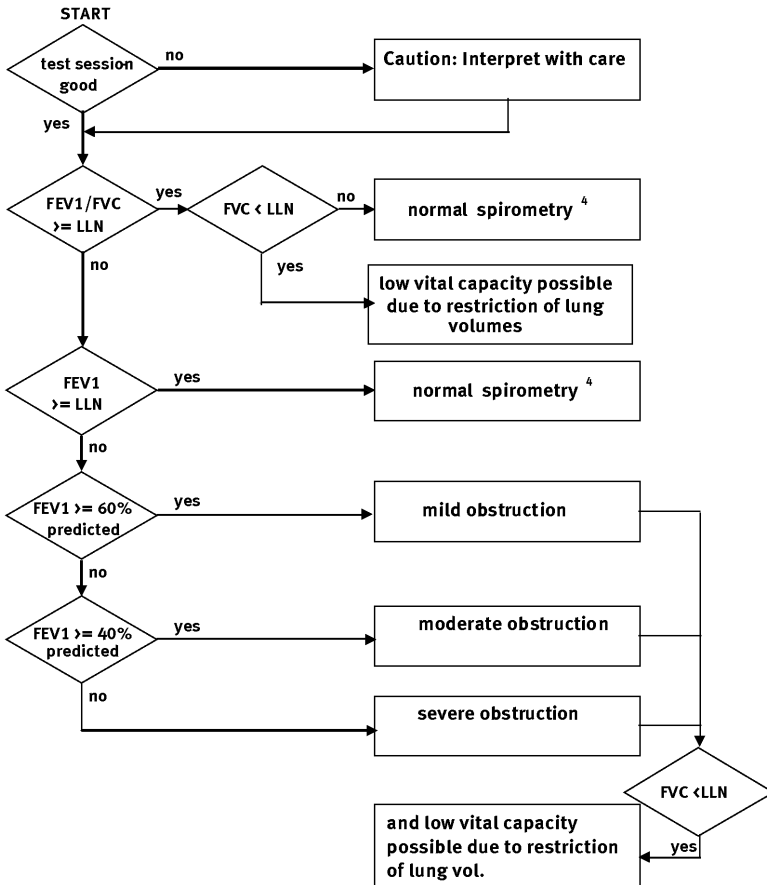
### GOLD-Hardie Interpretation

The following diagram outlines the criteria EasyOne Pro applies in the automatic interpretation after GOLD/HARDIE (see "Literature" on page 116).



## NLHEP Interpretation

The following diagram outlines the criteria EasyOn PC applies in the automatic interpretation after NLHEP (see "[Literature](#)" on page 116, [4]).

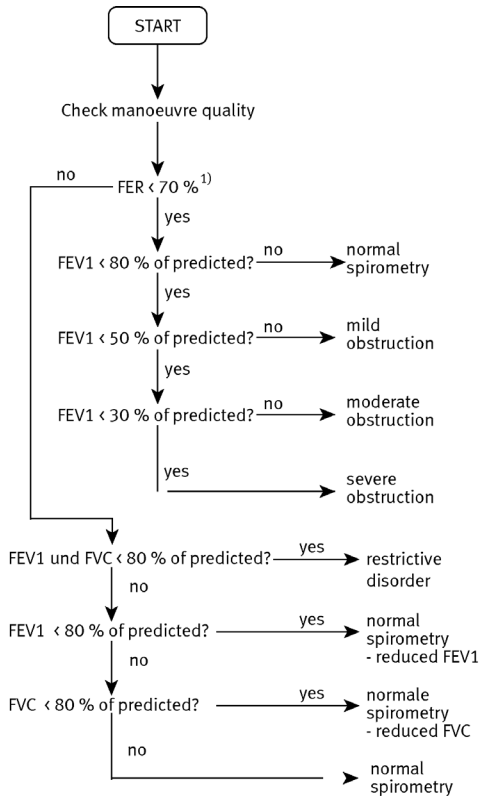


Note:

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

## System Interpretation Messages

<b>Printed Text</b>
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

This document describes in detail which predicted normals are implemented in the current version of *Easy on-PC*. The following table shows implementation details and the publications on which the reference values are based.

The first table has the following entries:

Reference	Name of predicted normal reference used in <i>Easy on-PC</i> . The name is the study name, or the name of the authors of the publication.
Publ. Year	Year when the study was published
Abbrev.	Abbreviation for the study. The abbreviation is used if parameters from other studies are copied. Example: For most studies 'Cherniak' (CH) values are used for the MVV parameter.
Age Range	Age range of the study. If range was extended beyond the study range, the extended range is shown in parentheses.
Height Range	Height range of the study. Extended range also listed in parentheses, as in age range.
Weight Range	Weight range of the study. In most studies weight is not used.
Ethnic	Ethnic group that is supported by the study.
Parameter	<ul style="list-style-type: none"> <li>o The parameter is available in the study.</li> <li>o (green) The parameter is available in the study and it is used in <i>Easy on-PC</i>.</li> <li>o (orange) The LLN of the parameter (see below) is computed according to the ATS recommendations: <math>LLN = Predicted - 1.645 * SEE</math> (Standard Error of Estimate)</li> <li>FVC, IVC The value of the parameter is copied from listed parameter of the same source.</li> <li>FEV1/FVC FEV1/FVC% is computed from the predicted of FEV1 and FVC of the same source.</li> </ul>



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Lower Limit of Normal of Parameter	This table lists which lower limits of normal (LLN) are provided by the study. If the study does not have a formula for LLN, the LLN is set to 80% of the predicted for normal parameters (FVC, FEV1 etc.) and 90% of predicted for relative parameters like FEV1/FVC%.
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**Additional remarks:**

Lung Age	Lung Age is computed according to the following publication: Spirometric "Lung Age" Estimation for Motivating Smoking Cessation. J.F. Morris, W. Temple. <i>Prev Med</i> 14, 655-662 (1985).
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Scandinavian References	These predicted normals are always combined with the Zapletal references for children.
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If the patient data lies outside of the range defined in the publication, but inside the extended range which appears in parentheses in the following table, *Easy on-PC* uses extrapolated values. The report explicitly points out that the predicted values are extrapolated values and that, consequently, particular caution must be taken when interpreting the results.



Reference	Abbrev.	Publication
NHAMES III (Hamkinson)	NH	John L. Hamkinson, John R. Odenrantz, and Kathleen B. Fedan. Spirometric Reference Values from a Sample of the General U.S. Population. <i>Am J Respir Crit Care Med</i> . Vol 159, p 179-187, 1999
Knudson 1983	KN83	Knudson, Ronald J., Michael Lebowitz, Holberg Catherine J., Benjamin Burrows. Changes in the Normal Maximal Expiratory Flow-Volume Curve with Aging. <i>American Review of Respiratory Disease</i> , Volume 127, p. 725-734, 1983.
Knudson 1976	KN76	Knudson, Ronald J., Ronald Slavin, Michael Lebowitz, Benjamin Burrows. The maximal Expiratory Flow-Volume Curve. <i>American Review of Respiratory Disease</i> , Volume 113, p. 587-600, 1976
Crapo	CR	Crapo RO, Morris AH, Gardner RM. Reference spirometric values using techniques and equipment that meets ATS recommendations. <i>Am Rev Respir Dis</i> Volume 123, p.659-664, 1981.
Morris	MO	Morris, James F., Koski, Arthur, Lavon Johnson. Spirometric Standards for Healthy Non-Smoking Adults. <i>American Review of Respiratory Disease</i> , Volume 10-3, p. 57-67, 1971
Hsu	HS	Hsu KH, Bartholomew PH, Thompson V, Hsieh GSJ. Ventilatory Functions of Normal children and Young Adults- Mexican- American, White, Black. I. Spirometry. <i>J Pediatr</i> Volume 95, p. 14-23, 1979.
Dockery, Wang (Harvard)	DO	X. Wang, D.W. Dockery, D. Wypij, M.E. Fay, B.G. Ferris. Pulmonary Function Between 6 and 18 Years of Age. <i>J Pediatr Pulmonol</i> . 1993; 15:75-88.
Pogzar	PO	Pogzar. Promadhat. Pulmonary Function Testing in Children: Techniques and Standards. W.B. Saunders Co., Philadelphia, 1971
Chemiak	CH	Chemiak, R.M., and Rober M.B. Normal Standards for Ventilatory Function using an Automated Wedge Spirometer. <i>American Review of Respiratory Disease</i> . Volume 106, p.38-46, 1972
Pereira 1992	PE92	Carlos Alberto de Castro Pereira, Sueli da Penha Barreto, João Geraldo Simões, Francisco W.L. Pereira, José Gerson Gerstler, Jorge Nakatani. Valores de referência para a espirometria em uma amostra da população brasileira adulta. <i>Jornal de Pneumologia</i> 18(O):10-22, maio de 1992
Pereira 2006	PE06	Pereira CAC et al. Espirometria em adultos 2006
ERS (ECCS, E6KS)	ER	P.H. Quanjer. Lung Volumes and Forced Ventilatory Flows. <i>Eur Respir J</i> , Vol 6, Suppl 16, p. 5-40, 1993
Zapletal	ZA	A. Zapletal, T. Paul, M. Samanek. Die Bedeutung heutiger Methoden der Lungenfunktionsdiagnostik zur Feststellung einer Obstruktion der Atemwege bei Kindern und Jugendlichen. <i>Z. Erkrank. Atm.-Org.</i> . Volume 149, 343-371, 1977.
Austria (Forche)	FO	G. Forche, K. Harmoncourt, E. Stadlober. Neue spirometrische Bezugswerte für Kinder, Jugendliche und Erwachsene. <i>Öst. Arzteztg</i> . 43, 15-16, 1988.
Sapaldia	SA	SAPALDIA team, O Brandli, CH, Schindler, N. Künzli, R. Kelller, A.P. Perruchoud. Lung function in healthy never smoking adults: reference values and lower limits of normal of a Swiss population. <i>Thorax</i> 1996; 51:277-283
Spain (Roca)	BA	J. Roca et al. spirometric reference values for a Mediterranean population. <i>Bull Eur Physiopathol Respir</i> . 18:101-102, 1982.
Hedenström	HE	H. Hedenström, P. MalMBERG, K. Agarwal. Reference values for lung function tests in females. <i>Bull. Eur. Physiopathol. Respir</i> . 21, p. 551-557, 1985.
Gulsvik	GU	H. Hedenström, P. MalMBERG, H.V. Fridriksson. Reference values for lung function tests in men. <i>Upsala J. Med. Sci.</i> , 91:299-310, 1986
Berglund	BE	A. Gulsvik. Spirometri (Korrespondansen). <i>Idtskr Nor Loegeforen</i> nr. 31, 105:2240-3, 1985.
Finnish	FI	E. Berglund, G. Birath, J. Bjure, G. Grimby, I. Kjellmer, L. Sandqvist, B. Söderholm. Spirometric Studies in Normal Subjects. <i>Acta Medica Scandinavica</i> , Vol. 173, fasc. 2, p. 185-206, 1963.
Hibbert	HI	Adult: The Scandinavian Journal of Clinical & Laboratory Investigation, Vol. 42 - Suppl 1159, 1982. <i>Pediatric: Suomen Lääkärilehti</i> . Vol. 53, 395-402, 1998.
Gore, Crockett	GO	Marienne E. Hibbert, M App SCI, Anna Lanning, RN, Louis L Lemaou, MD, Peter D. Phelan, MD. Lung Function Values From a Longitudinal Study of Healthy Children Adolescents, <i>Pediatric Pulmonology</i> 7:101-109 (1989)
Asia 1,2,3,4	A1-4	C.J. Gore, A.J. Crockett, D.G. Pederson, M.L. Booth, A. Bauman, N. Owen. Spirometric standards for healthy adult lifetime nonsmokers in Australia. <i>Eur Respir J</i> , 1995, 8, 773-782
JRS2001	JR	n/a
Fukuda Standard	FU	日本人のスパイログラムと動脈血液ガス分圧基準値 日本呼吸器学会肺生理事務専門委員会 2 0 0 1 年 4 月 Mixed references from: Ishida, Kanagami, Baldwin, Bjure, Berglund, Dickman, Schmidt, Chemiak, Needham.

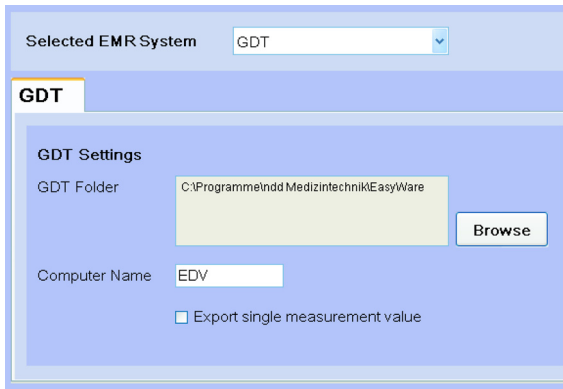
## 10.3 GDT Interface

### 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:



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\nddturbomed.gdt	Name and path of the export file.
Import File	c:\niddmed\turbomedndd.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:

- 014810000202
- 01380006302
- 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.

## View of tests with *Easy on-PC*

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

As of *EasyWare* V2.8 GDT record type 6311 is supported. In the transmission of test results using GDT record type 6310, record type 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 name, ID, date and time and will be shown.

### 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**.

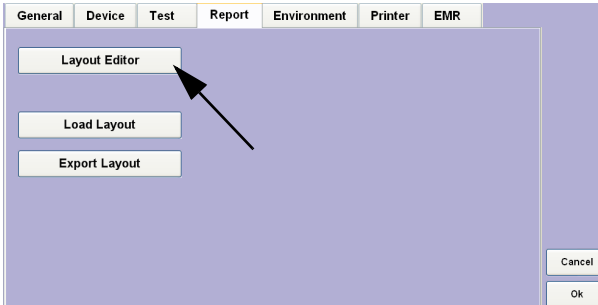


Fig. 10-1: "Report" tab

### Adding a Logo to an Existing Test

- On the Report Designer tab, select **New Report** (Fig. 10-2: left).

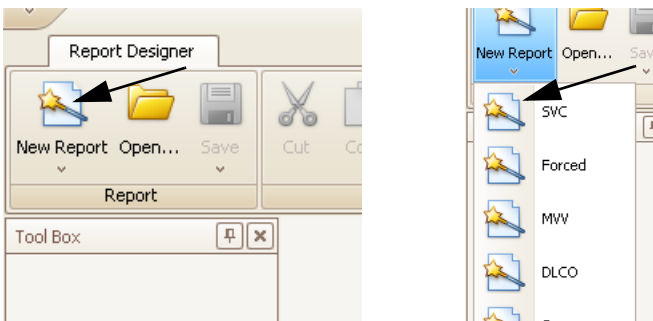


Fig. 10-2: New Report button (left), test selection (right)

- Select the test to which you want to add the logo (Fig. 10-2: right).

- Select the **Picture Box** (Fig. 10-3:).

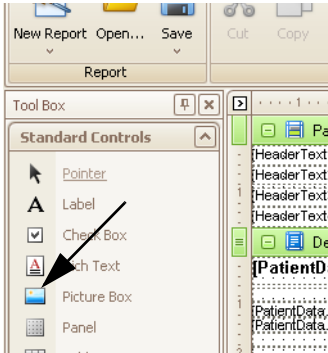


Fig. 10-3: Picture Box button

- Insert the frame in the appropriate position (Fig. 10-4:).

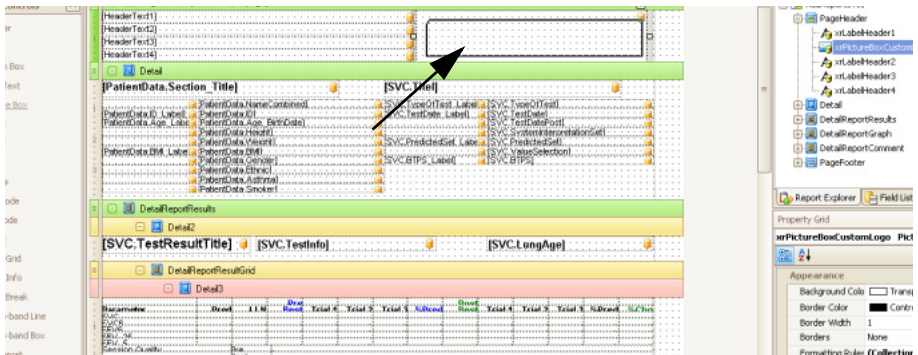



Fig. 10-4: Positioning the frame

- Select **Image** and click  to open the Explorer (Fig. 10-5).

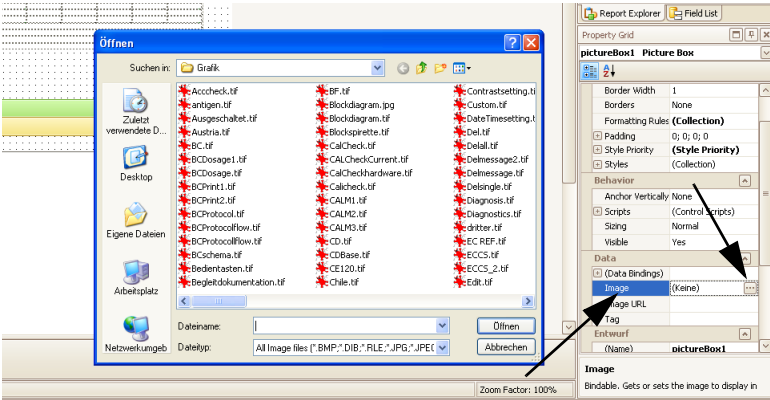


Fig. 10-5: Image button

- Select the logo. (Fig. 10-5). 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**.

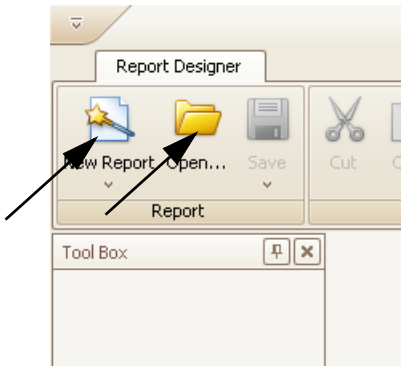


Fig. 10-6: New Report, Open buttons

- Select **Windows** and then **Report Explorer** (Fig. 10-7:).
- Select **Detail Report Graph** (Fig. 10-7:).
- Click **graphVT1**.

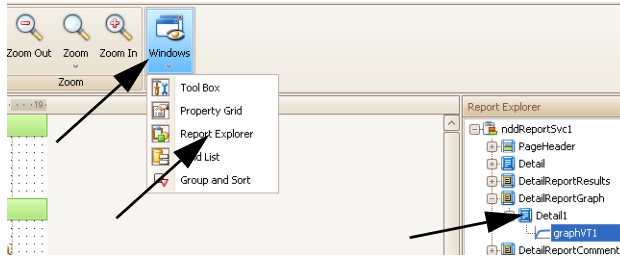


Fig. 10-7: Windows, Report Explorer, Detail Report Graph buttons

- Click the small arrow in the upper right corner of the "Detail Report Graph" window (Fig. 10-7:).
- Click **Run Designer**. The Spiro Graph Configuration window will be displayed (Fig. 10-9:).

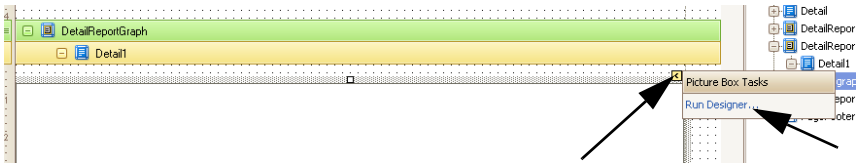


Fig. 10-8: Detail Report Graph window

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

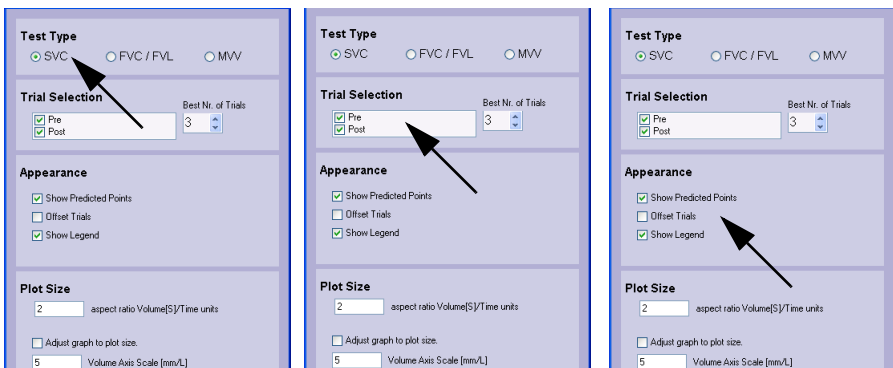


Fig. 10-9: Fenster „Spiro Graph Configuration“

- 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 n d d 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.

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### 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	<b>Electromagnetic Environment - Guidance</b>
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 <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>a</sup>, should be less than the compliance level in each frequency range<sup>b</sup>.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol</p> <div style="text-align: center;"> </div>



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.

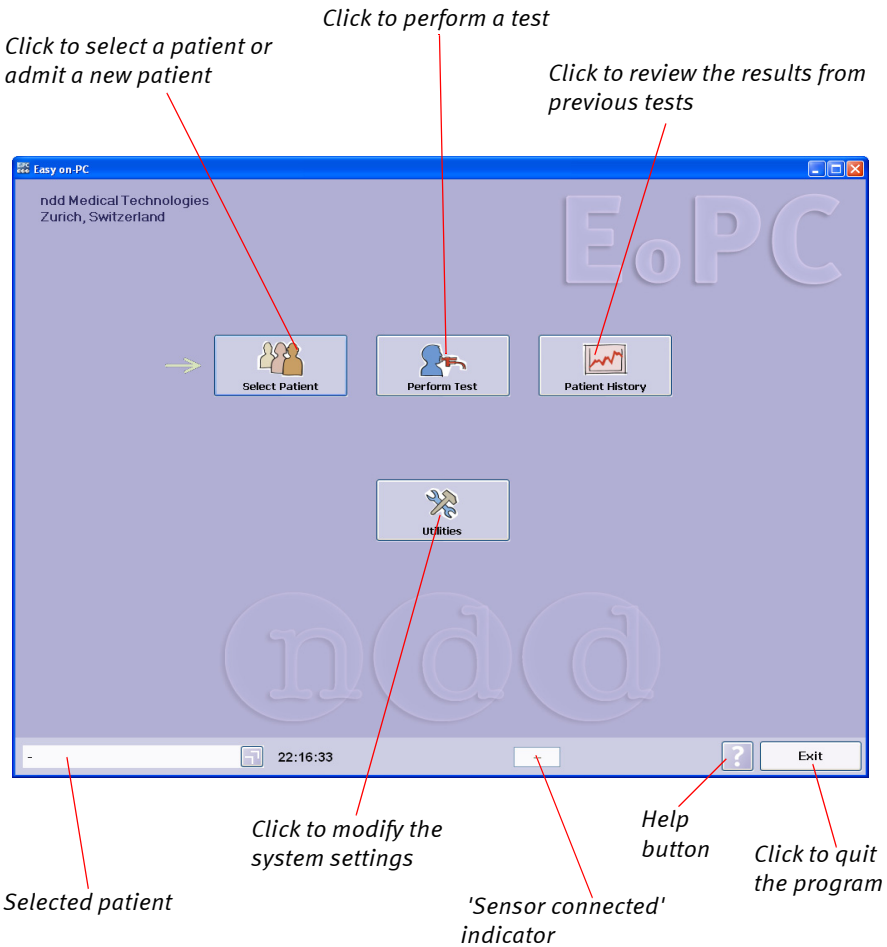
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

### **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 6«

"Start-up and Preparation" on page 12

"Performing a Test" on page 22

"System Settings" on page 58

"Index" on page 117

## 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*

PatientID	FirstName	LastName
Q_0049		Quick Test
Q_0048		Schnelltest
PSM-11213	Peter	Smith

*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*

*Help button*

*Click to delete the patient data*

*Click to display the menu options*

### Also refer to

"Selecting/Admitting a Patient" on page 22«

"Editing Patient Data" on page 45

"Performing a Test" on page 22

"Index" on page 117

## Admitting a Patient

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

Click to select the smoker status

Click to select the asthma status

Click to select the ethnic origin

Click to select the gender

General

Patient ID  \*

Last Name

First Name

Gender  \*

Date Of Birth  .  .  dd.mm.yyyy \*

Age

Height  cm \*

Weight  kg

Ethnic  \*

Smoker  \*

Asthma

COPD

\* Required

Cancel

Ok

Smith, Peter / PSM-11213 17:06:42

Help button

Menu

COPD (chronic obstructive pulmonary disease), Yes/No

'Sensor connected' indicator

Click to close the window without saving the data

Click to display the menu options

Click to close the window, saving the data

### Also refer to

"Selecting/Admitting a Patient" on page 22«

"Editing Patient Data" on page 45

"Performing a Test" on page 22

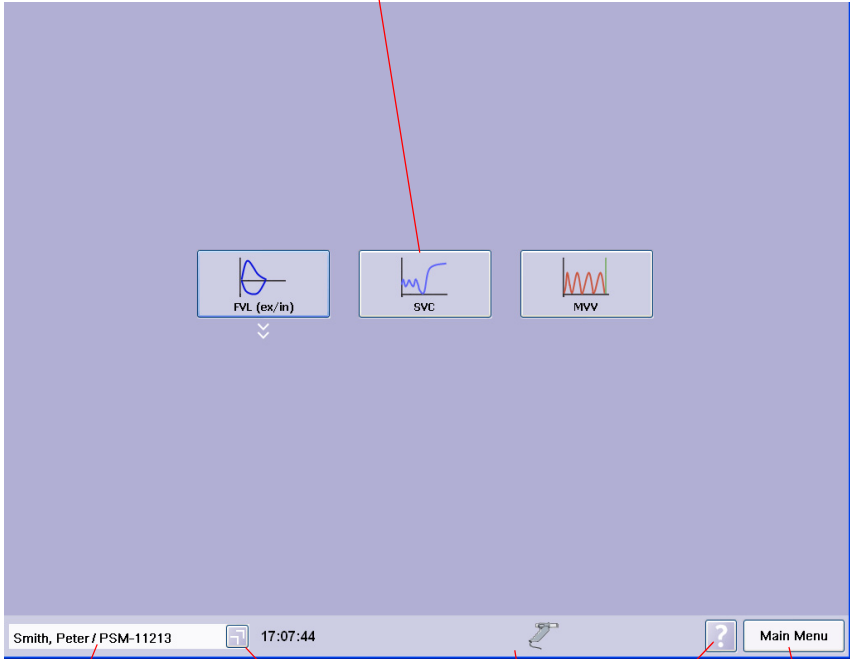
"Index" on page 117

## 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 25«

"Forced Vital Capacity (FVC/FVL)" on page 25

"Vital Capacity (SVC)" on page 36

"Maximum Voluntary Ventilation (MVV)" on page 38

"Index" on page 117

## Entering Ambient Conditions

Box for entry of the altitude  
(atmospheric pressure)

Box for entry of the room temperature

Box for entry of the humidity

Conversion factor

Click to recalculate BTPS

**Manually Entered Values**

Ambient Temperature	20	°C (5..40)
Humidity	50	% (0..99)
Altitude	400	m (0..4000)

BTPS In 1,118 Ex 1,020 Recalculate BTPS

Cancel Confirm >>

Smith, Peter / PSM-1/213 17:08:39 ? Main Menu

Selected patient

Click to view patient data

Help button

Back to main menu

Click to close the window  
without saving the data

Click to close the window,  
saving the data

'Sensor connected' indicator

### Also refer to

"FVL Test (inspiratory and expiratory measurement)" on page 32«

"Easy on-PC Sensor Design and Operation" on page 10

"Index" on page 117

## Retrieving/Printing Stored Tests

*Test with Post-test data*

*Click to view patients*

*Click column header to sort the list*

Protocol	Test type	Date	Comment
Base Test	FVL Tidal	05.03.2006 14:09	
Base Test	SVC	05.05.2006 14:20	
Base Test	MVV	05.05.2006 14:22	
Base Test	FVC (ex only)	05.05.2006 14:29	
Base Test	FVL Tidal	05.05.2007 14:14	
Pre / Post	FVL Tidal	05.06.2008 14:53	
Base Test	SVC	21.04.2009 17:49	
Base Test	DLCO	21.04.2009 18:20	
Pre / Post	FVL Tidal	21.04.2009 18:37	
Base Test	FVC (ex only)	21.04.2009 18:43	
Base Test	FVL Tidal	16.04.2010 12:09	
Base Test	FVL Tidal	27.04.2010 13:02	
Base Test	FVL Tidal	07.05.2010 16:17	
Base Test	FVL Tidal	07.05.2010 16:27	

View Test | Print Preview | Print | Trend | Patients

Smith, Peter / PSM-11213 | 17:09:32 | Help button | Main Menu

*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 40«

"Quality Messages / Grades (Details)" on page 46

"Index" on page 117



## Test Result

Predicted values display  
 Click to select curve  
 Click to select a new patient  
 Click to conduct a new test  
 Click to select the scale  
 Click to enter a test evaluation  
 Click to view the test list

27.04.2010 FVL Tidal / Best Value / FVC Predicted Ref: MHANES III  
 Session Quality: Pre: A  
 System Interpretation: Pre: Restriction probable; further examination recommended  
 Interval Message: --  
 Comment: Last Reviewer:

Test Parameters	Pred	LLN	Best	%Pred	Trial 1	Trial 2	Trial 3
Trial Rank					3	1	2
Time					13:15:35	13:26:13	13:28:04
FVC [L]	5.56	4.58	3.84	69	3.67	3.84	3.75
FEV1 [L]	4.40	3.57	2.99	68	2.95	2.99	2.88
FEV1/FVC	0.795	0.699	0.780	98	0.805	0.780	0.767
FEF25-75% [L/s]	4.08	2.41	2.65	65	2.98	2.65	2.40
PEF [L/s]	10.52	8.10	8.22	78	7.86	8.22	8.08
FET [s]	—	—	6.1	—	5.1	6.1	6.3
FIVC [L]	5.56	4.58	4.06	73	3.65	4.06	3.81

Smith, Peter / PSM-11213 17:11:46  
 Help button  
 Back to main menu

Selected patient  
 Click to view patient data  
 'Sensor connected' indicator  
 Click to view the test

Print Preview  
 Print  
 History  
 New Test  
 Patients  
 Main Menu

### Also refer to

"Retrieving/Printing Stored Tests" on page 40«

"System Settings" on page 58

"Quality Messages / Grades (Details)" on page 46

"Index" on page 117

## 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

Ind Medical Technologies  
Zurich, Switzerland

**Patient Information**

Name	Smith, Peter
ID	PSM-11213
Age	41:00:11.1900
Height	182 cm
Weight	80 kg BMI 24.2
Gender	Male
Ethnic	Caucasian
Asthma	Yes
Smoker	No

**Test Information**

Test Type	FVL:Tidal
Test Date	16.04.2010 12:00:48
Post Time	
Interpretation	GOLD(2003)Hardie
Predicted	NHANES III
Best Value	Best Value
BTPS (ONEX)	1.121102
User ID	BB101

**Test Result** Your FEV1 / Predicted: 70%

Parameter	Pred	LLN	Pre		%Pred
			Best	Inter-L	
FVC [L]	5.50	4.50	4.04*	4.04*	73
FEV1 [L]	4.40	3.67	3.10*	3.10*	70
FEV1/FVC	0.795	0.800	0.768	0.768	97
FEF25-75% [L/s]	4.00	2.61	2.88	2.88	71
PEF [L/s]	10.52	8.10	4.97*	4.97*	47
FET [s]	-	-	7.6	7.6	-
FIVC [L]	5.50	4.88	4.12*	4.12*	74
PIF [L/s]	-	-	3.90	3.90	-

Session Quality: Pre F 3.90 3.90

System Interpretation: Pre No interpretation, not enough acceptable maneuvers  
Caution: Poor session quality. Interpret with care  
\* Indicator below LLN or significant post change

Flow [L/s] vs Time [s] graph showing tidal volume and flow curves.

System Interpretation (LLN) chart showing LLN ranges: Very Severe-High Grade Obstruction, Severe, Moderate, Mild Obstruction, Normal.

Page 1 of 1 100%

Smith, Peter / PSM-11213 Home 17:13:16 Sensor connected Help Return

Selected patient

Click to view patient data

'Sensor connected' indicator

Help button

### Also refer to

"Retrieving/Printing Stored Tests" on page 40

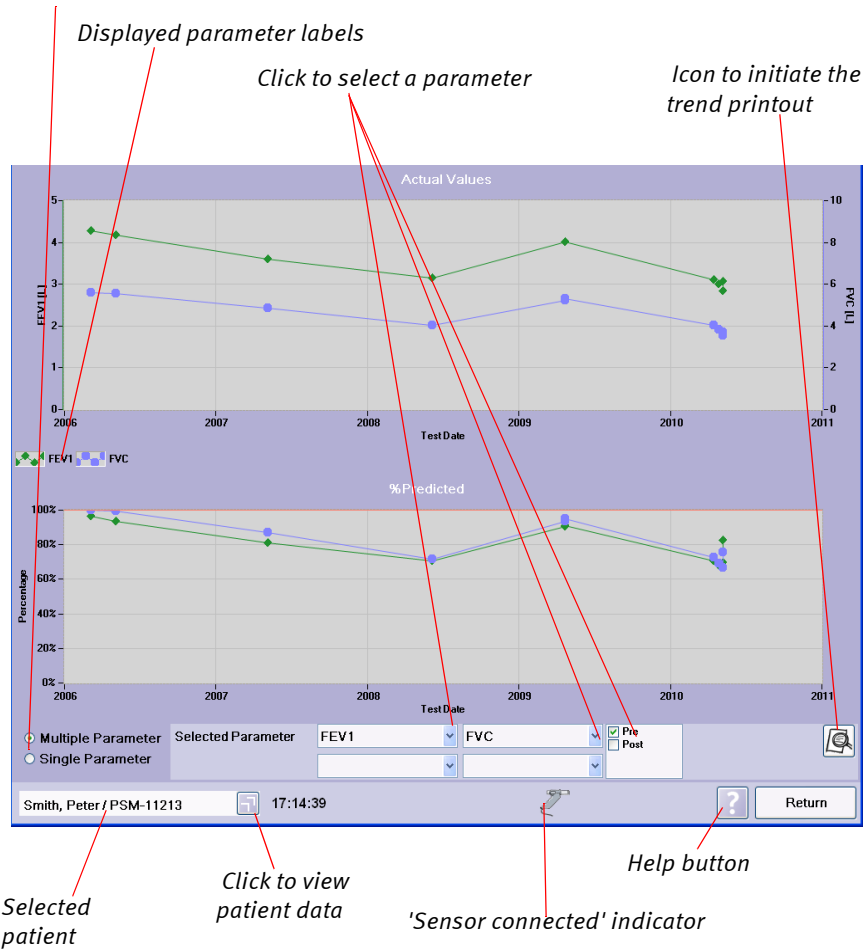
"System Settings" on page 58

"Quality Messages / Grades (Details)" on page 46

"Index" on page 117

## Trend Display

Option buttons for selection of the view



### Also refer to

"Trend View" on page 43«

"Parameter Definitions" on page 54

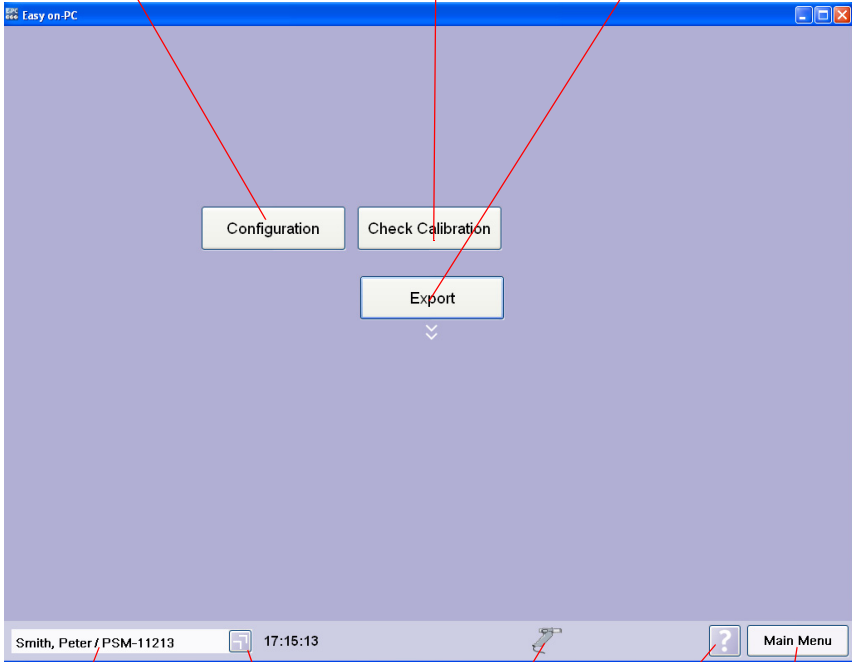
"Index" on page 117

## 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 58

"Index" on page 117

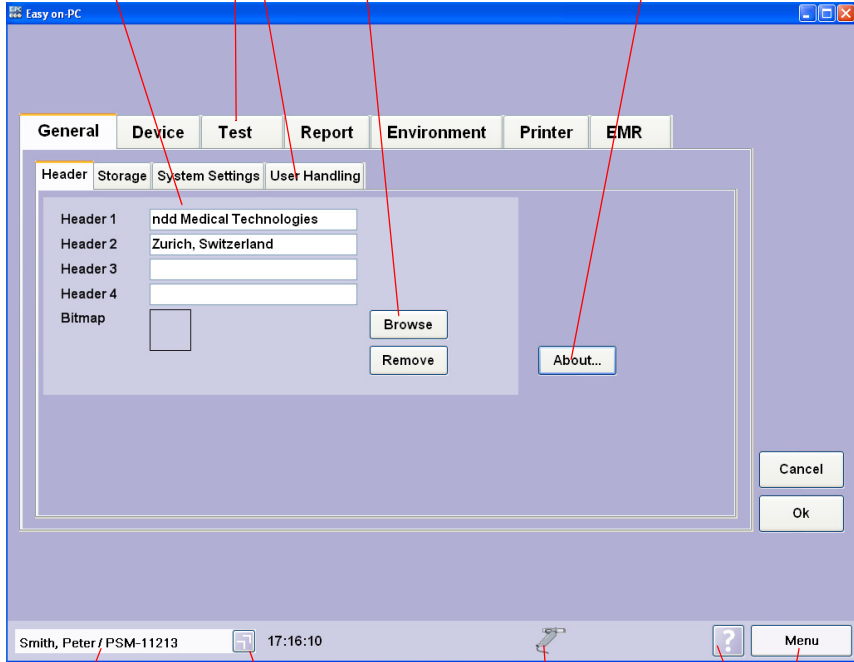
## Configuration Menu

*Click to display more tabs*

*Text boxes for entry of the header texts*

*Click to search for an illustration to be added*

*Click to view details about the software program*



*Selected patient*

*Click to view patient data*

*'Sensor connected' indicator*

*Help button*

*Back to System Settings menu*

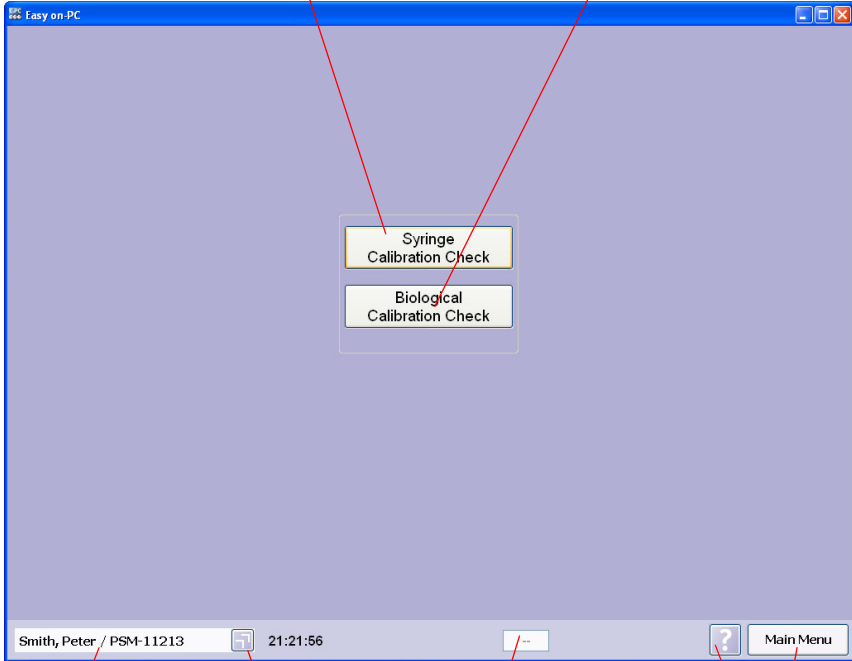
### Also refer to

["System Settings"](#) on page 58«

["Index"](#) on page 117

## 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

"Calibration Check with Syringe" on page 69«

"Easy on-PC Sensor Design and Operation" on page 10

"Specifications" on page 75

"Index" on page 117

## 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)

The screenshot shows the 'Easy on-PC' software interface. It features several tables and sections:

- Device Selection:** A table with columns 'Serial Number' and 'DeviceType'. It lists two devices: 11427 (EASY\_BOX) and 200076 (SPIROSON\_AS).
- BioCal Subject Selection:** A table with columns 'Patient ID', 'Last Name', and 'First Name'. It lists one subject: BioCal-1 (TrueFlow, Martin). There is an 'Add New BioCal Subject' button below this table.
- Parameter Values:** A table with columns 'Test Date', 'Parameter Value', and 'Selected'. It shows a list of tests from 09.03.2008 to 17.03.2008 with values ranging from 3.711 to 4.102. All 'Selected' checkboxes are checked.
- Displayed Parameter Selection:** A section showing 'FVC' selected as the parameter. It displays 'Mean Value: 3.930', 'CV%: 4.553', and 'SD: 0.179'. Below this is an 'Analysis' section with 'Based on: 20 Values from 09.03.2008 - 02.04.2008' and 'Analysis status: Valid Analysis!'. A 'Result' section shows 'Bio Calibration Check' with 'FVC Grade: BA', 'FEV1 Grade: BA', and 'FEV6 Grade: BA'. There are three colored boxes (green, yellow, red) representing different grades, with the green box being selected.
- Bottom Bar:** Displays 'TrueFlow, Martin / BioCal-1', a time '21:59:45', a 'Graph' button, a 'Help' button (with a question mark icon), and a 'Main Menu' button.

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

"Calibration Check with Test Subject" on page 71«

"Easy on-PC Sensor Design and Operation" on page 10

"Specifications" on page 75

"Index" on page 117

## 10.7 Literature

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## Index

### A

Ambient conditions ..... 32  
 Ambient conditions, enter ..... 67  
 ATPS values ..... 32

### B

BioCal Check ..... 71  
 BioCal Check QC grades ..... 73  
 Bronchodilation ..... 33  
 BTPS values ..... 32

### C

Calibration adapter ..... 69, 79  
 Calibration check ..... 69  
 Calibration syringe ..... 69, 79  
 Calibration with test subject ..... 71  
 Caution (definition) ..... 7  
 CE marking ..... 4  
 Cleaning ..... 56  
 Comments, enter ..... 51  
 Configuration ..... 58

### D

Danger (definition) ..... 7  
 Definition of the parameters ..... 54  
 Disposal ..... 57  
 Driver installation ..... 17

### E

Easy on-PC Sensor ..... 10  
 Electromagnetic Compatibility ..... 98  
 EMC ..... 98  
 EMR Tab ..... 68  
 Expiratory FVC measurement ..... 26

### F

FEV6 ..... 30  
 Forced vital capacity ..... 25  
 FVC ..... 25  
 FVL test (inspiratory and expiratory measurement) ..... 32

### G

GDT interface ..... 88  
 General Tab ..... 59  
 GOLD-Hardie Interpretation ..... 80

### H

Header Tab ..... 59  
 Hygiene ..... 56

### I

Initial screen ..... 21  
 Intended use ..... 9  
 Interpretation ..... 80  
 Interpretation, NICE ..... 82  
 Interpretation, NLHEP ..... 81

### L

Licence terms ..... 4  
 Literature ..... 116  
 Logo in Test einfügen ..... 94  
 Lung function test, select ..... 64

### M

Maintenance ..... 57  
 Maximum Voluntary Ventilation ..... 38  
 MVV ..... 38

### N

New patient, admit ..... 24  
 NICE Interpretation ..... 82  
 NLHEP Interpretation ..... 81

### O

Order Information ..... 79

### P

Parameter definitions ..... 54  
 Parameter, select ..... 66  
 Patient data, edit ..... 45  
 Patient, selection ..... 22, 23  
 PC maintenance ..... 78  
 Post-test ..... 33  
 Predicted values ..... 84  
 Pre-test ..... 33  
 Printer Tab ..... 68

### Q

Quality grade ..... 30  
 Quality grades ..... 46  
 Quality messages ..... 46  
 Quick Test ..... 40

### R

Revision history ..... 5

### S

Screen displays, quick reference ... 103  
 Sensor, connect ..... 17  
 Software installation ..... 12  
 Specifications ..... 75

spirette einsetzen.....	8, 20
spirette, insertion.....	20
Spirometry trial, add.....	31
Storage Tab.....	60
SVC .....	36
System interpretation.....	51
System requirements.....	11
<b>T</b>	
Technical description.....	77
Test assessment, retrospective.....	51
Test, end .....	40
Test, print .....	40
Test, retrieve .....	40
Test, selection.....	25
Trend view.....	43
Troubleshooting .....	74
<b>W</b>	
Warning (definition) .....	7
Warranty .....	6





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