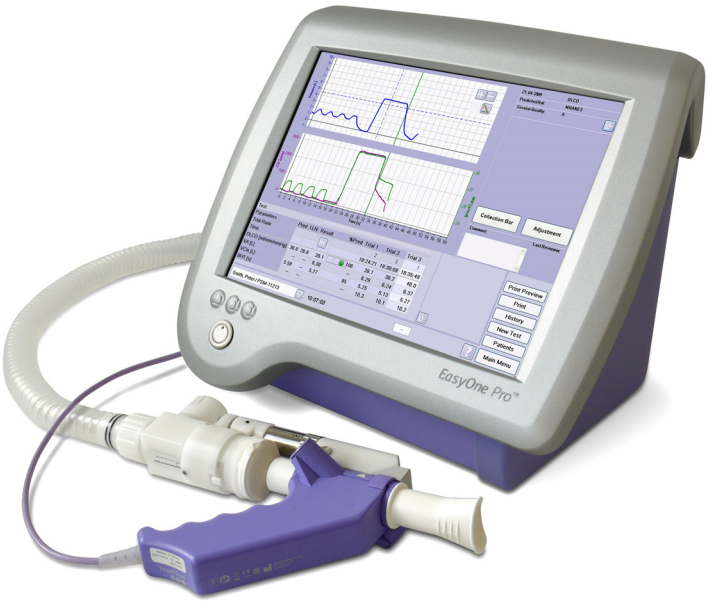
EasyOne Pro™
EasyOne Pro™ LAB

Operator's Manual



Version V04b

Note

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

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

This manual describes the product *EasyOne Pro™* and its variant *EasyOne Pro™ LAB*. The safety information and all operating instructions apply to both devices. Safety information and operating instructions that apply only to *EasyOne Pro™ LAB* are accompanied by the symbol shown at left and by the word LAB.

CE
0120

ndd
Medizintechnik AG
Technoparkstrasse 1
CH-8005 Zürich, Switzerland
Tel: +41(44) 445 2530
Fax: +41(44) 445 2531

www.ndd.ch

ndd Medical Technologies
2 Dundee Park
Andover, MA 01810, USA
Tel: 1 978 470 0923
Fax: 1 978 470 0924

www.nddmed.com

1 Introduction

1.1 CE Marking Information

- The product *EasyOne Pro™* bears the CE marking CE-120 (notified body SGS) indicating its compliance with the provisions of the Council Directive 93/42/EEC about medical devices and fulfills the essential requirements of Annex I of this directive.
- The flow sensor has been assigned to class IIa as specified in Annex IX of the Directive 93/42/EEC.
- The device fulfills the requirements of standard EN 60601-1 "Medical electrical equipment, Part 1: General requirements for basic safety and essential performance" as well as the electromagnetic immunity requirements of standard EN 60601-1-2 "Electromagnetic compatibility – Medical electrical equipment".
- The radio-interference emitted by *EasyOne Pro™* 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 device is suitable for continuous operation.
- The product fulfills the requirements of the following standards:
  - EN ISO 14971
  - IEC60601-1: 2005
  - EN 60601-1: 2006
  - EN 60601-1-2: 2007
  - EN 60601-1-6: 2007
- The country of manufacture is indicated on the device label.

1.2 Revision History

Edition	Date	Comment
Version V01.01	2008-07-22	Initial Release
Version V01.02	2009-11-23	Revised Edition
Version V02	2010-04-06	Revised Edition
Version V03	2011-11-29	Revised Edition
Version V03A	2012-01-27	Revised Edition
Version V03B	2012-05-23	Revised Edition
Version V03C	2012-08-23	Revised Edition
Version V04	2012-11-26	Revised Edition
Version V04b	2012-11-30	Revised Edition

1.3 Manual Purpose

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

1.4 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.

1.5 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, EasyOne Pro™*.

1.6 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 collateral standard IEC 60601-1-1 "Requirements for the safety of medical electrical systems".
- The power cord must be an approved type acceptable to the authorities in the country where the equipment is used.
- *EasyOne Pro™* must not be exposed to low temperatures during storage and transport to avoid moisture condensation at the application site. Wait until all moisture has vaporized before using the device. Allow the device to reach room temperature before using it.
- All publications are in conformity with the device specifications and standards on safety of electromedical equipment valid at the time of printing. All rights are reserved for devices, circuits, techniques, software programs, and names appearing in this manual.
- The illustrations in this manual are only examples. They are not binding in any way.
- No part of this manual may be reproduced without written permission from ndd.

Definitions

In this manual the safety information is classified as follows:

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

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

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

Safety Notices

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

Warning
Shock Hazard—

- Before using the system, make sure that it is in correct working order and operating condition. Check the cables and connectors, in particular, for signs of damage. Replace damaged cables and connectors immediately, before use.
- Do not expose *EasyOne Pro™* to direct sunlight to prevent system components from reaching inadmissible, high temperatures. Furthermore, *EasyOne Pro™* has no additional protection against the ingress of humidity.
- When disconnecting the device from the power line, remove the plug from the wall outlet first, before disconnecting the cable from the device. Otherwise there is a risk of coming in contact with line voltage by inadvertently introducing metal parts in the sockets of the power cord.
- Do not use multiple portable socket outlets (MPSO) to connect the devices to the power line.
- Printers operated in the patient vicinity must meet the requirements of IEC 60601. If they do not, they must be modified and be connected to earth ground (PE, potential equalization).
- All devices of a system must be connected to the same power supply circuit. Devices that are not connected to the same circuit must be electrically isolated when operated, e.g., with an isolated RS232 interface (this is not a requirement in the USA).
- 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.

- Liquids must not be allowed to enter the device or the sensor. Devices and sensors into which liquids have penetrated must be immediately cleaned and checked by a service technician, before they can be reused.
- Do not open the device or the sensor. There are no user-replaceable components inside the device or the sensor.
- Do not insert objects of any kind into the device. They may touch live components and you might suffer an electric shock, cause fire, or damage the device.

Warning

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

Patient Hazard—Before performing any tests on patients, refer to the ATS/ERS Taskforce recommendations (literature [11] ("Literature" on page 182).

Patient Hazard—Custom configured reports bear the label *Custom Report* at the bottom of each page. The user is responsible for the content and use of all custom configured reports.

Patient Hazard—Do not touch the accessible contacts of connectors located at the rear panel and the patient at the same time.

Patient Hazard, Equipment Damage—Do not modify *EasyOne Pro™* in any way.

Patient Hazard—When used at 230-240 V, 60 Hz equipment must be connected to a center-tapped 240 V single phase transformer (US requirement).

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

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

Cross Contamination Between Patients—The *spirette™* and the *DLCO barriette™/FRC barriette™* are intended for

single patient use. Use a new one for each patient to prevent cross contamination between patients.

Risk of Poisoning—Observe all information provided by the manufacturers of chemical products required for the use and care of the product. Always keep these chemical products in their original containers to avoid any confusion which may have severe consequences.

RF Interference—Known RF sources, such as cell phones, radio or TV stations, and two-way radios, may cause unexpected or adverse operation of this device. Check the device performance before each use.

Risk to Persons—If the display is broken, avoid contact with the liquid crystal.

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

Danger

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

- Bronchial provocation tests can be dangerous for patients! A primary condition for safe provocation test procedures is a trained and experienced physician.
- Above all, these physicians must be familiar with appropriate precautions and guidelines, warnings, procedures, contraindications, when to stop further testing, etc. as defined in the medication documentation and in the standards.
- Observe the contraindications for the medication used, such as
  - general clinical instability of the patient
  - severely reduced lung function
  - treatment with beta blockers
  - hyperresponsiveness
  - pregnancy.
- A physician or specially trained staff must be present while bronchial provocation tests are being performed.

The patient should never be left unattended during the tests.

- The following should be available throughout provocation tests:
  - a medical specialist capable of treating acute bronchospams
  - appropriate medication as well as resuscitation equipment (defibrillator, cardiac pacemaker)
- Refer to the relevant literature for creating safe protocols for bronchial provocation tests. Examples are: Sterk PJ, Fabbri LM, Quanjer PhH, et al. Airway responsiveness. Standardized challenge testing with pharmacological, physical and sensitizing stimuli in adults. Report Working Party Standardization of Lung Function Tests. European Community for Steel and Coal. Official position of the European Respiratory Society. Eur Respir J 1993; 6: Suppl.16, 53–83).

Caution

Equipment Damage—Before connecting the device to the power line, check that the voltage and frequency ratings of your power line match the values indicated on the device nameplate.

Equipment Damage—Protect the equipment from viruses, malware, etc. Always check the USB flash drive for viruses, before connecting it to the equipment.

Equipment Damage—Do not set up *EasyOne Pro™* in the direct vicinity of a window. Rain, humidity and sunlight may damage *EasyOne Pro™*. Do not operate *EasyOne Pro™* in the vicinity of heating appliances (radiators). Do not block air vents and do not place any objects on the device.

Equipment Damage—Do not drop *EasyOne Pro™*.

Equipment Damage—For equipment transport, switch off *EasyOne Pro™* and store it in its original packing.

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

LAB *EasyOne Pro™ LAB* only

Danger
Explosion Hazard—

- Ensure that persons working with oxygen have undergone special training and are aware of the particular properties of oxygen to guarantee safe handling of oxygen without accidents. Furthermore, these persons must be familiar with this operator manual and must have understood its content.
- Do not use hand cream or other skin care products.
- Oxygen intensively promotes combustion; therefore, flammable substances must be kept away from oxygen.
- Unintended release of oxygen in confined spaces increases risk of fire; smoking and open flames are prohibited. Possible sources of ignition must be eliminated. Rooms must be well ventilated.
- The oxygen inlet must periodically be checked for leaks (at least once a month).
- Use only fittings approved for use with oxygen; these fittings must be properly connected. All fittings, downstream lines and devices must be free of oil and grease.
- Connect a pressure relief valve to the pressurized gas cylinder before opening it! Before connecting the pressure relief valve, check the connection sleeve of the pressurized gas cylinder for contamination. Contaminated connections must be cleaned with a clean cloth. The valve of the pressurized gas cylinder may be opened only if the connected fittings are closed. Open the valve of the compressed gas cylinder very slowly.

Equipment Symbols

Observe the information given in the operator manual.

Do not reuse (single patient use).

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

Product certification for the USA and Canada.

Connection to power line ON (mains power switch).

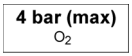
Connection to power line OFF (mains power switch).

Temperature and humidity sensor.

Potential equalization pin.

Alternating voltage.

Gas inlet for DLCO gas.



Gas inlet for O2 (oxygen).

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!

Rev.: X.Y

Hardware revision.

1.7 Intended Use

The ndd *EasyOne Pro™* Respiratory Analysis System is designed for conducting lung function measurements in general or specialist practices or in hospitals.

The *EasyOne Pro™* Respiratory Analysis System can also be used outside of the laboratory when performing lung function screenings or measurements in occupational medicine.

The *EasyOne Pro™* Respiratory Analysis System is used to conduct lung function measurements on adults and children starting at age 4, except measurements of Diffusing Capacity of the lung based on CO (DLCO), which can be performed on adults and children starting at age 6.

1.8 Contraindications to Performing DLCO Tests

Do not perform a DLCO test

- in the presence of carbon monoxide toxicity
- in case of dangerous levels of oxyhemoglobin desaturation without supplemental oxygen

1.9 Additional Functions of *EasyOne Pro™ LAB*

LAB

EasyOne Pro™ LAB includes the measurement of the FRC (Functional Residual Capacity) based on the Multiple Breath Nitrogen (N_2) Washout method. This method is based on washing out the N_2 from the lungs, while the patient breathes 100% oxygen. The analysis of the expired N_2 trace is used to compute the FRC and other parameters like LCI (Lung Clearance Index) that are used to quantify distribution inhomogeneities of the lung. The test is based on tidal breathing only and can easily be performed in adults and children starting at age 4.

1.10 Components and Functional Description of *EasyOne Pro™*

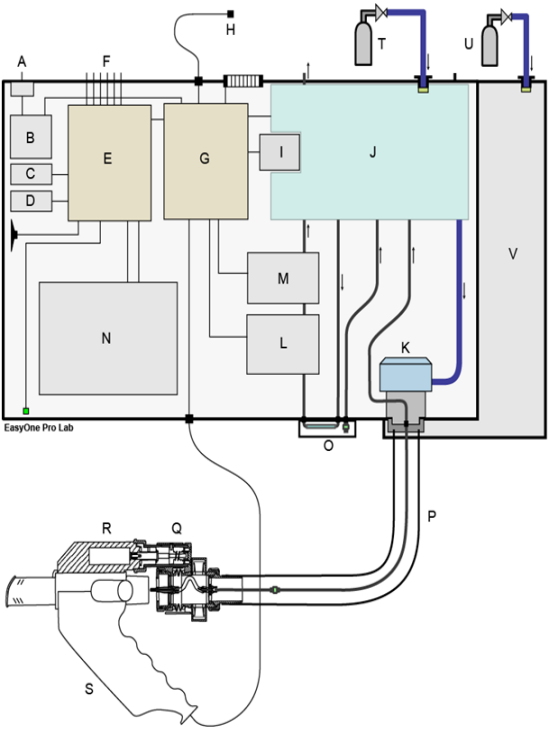


Fig. 1-1 EasyOne Pro™, block diagram

A Mains connector
B Power supply unit
C Hard disk
D Storage disk (backup)
E Industrial standard PC
F PC ports (USB, LAN, etc.)
G Automatic data acquisition
H Sensor for ambient temperature and humidity
I Pump
J Pneumatic system
K Demand valve
L CO sensor
M Molar mass sensor
N Display with touch screen
O Replaceable filter pack
P Gas supply tubing
Q DLCO valve
R Motor block
S Sensor
T Gas cylinder for DLCO tests

LAB

U Oxygen cylinder for FRC test or wall outlet (EasyOne Pro™ LAB only)
V Oxygen supply unit (EasyOne Pro™ LAB only)

EasyOne Pro™ consists of a compact main unit and a hand-held flow sensor **S** with removable DLCO valve unit **Q**. The hand-held sensor is electrically connected to the device. For DLCO tests, a gas supply tube **P** delivers gas to the DLCO valve. The sensor measures flow velocity, volume and molar mass of the gases that the patient inhales and exhales.

The mains connector **A** connects the device to line power. The gas cylinder **T** supplies the medical gas mixture that is required to perform DLCO tests (normally 0.3% CO, 10% He, 21% O_2 in N_2).

A temperature and humidity sensor **H** measures the temperature and humidity in the examination room.

The device contains an industrial standard PC **E** (*Windows XP embedded*) that performs data acquisition, data analysis and storage of test results.

The user interface for display and control consists of a flat panel display with touch screen **N**. If required a keyboard and/or a mouse can be connected to the PC. A pneumatic system **J** delivers gas to the patient, allows flushing of the DLCO gas delivery hose and draws gas samples from the patient's inspiratory and expiratory breath. The side stream flow used for gas analysis is driven by a pump **I**. CO gas is analyzed by a sensor based on infrared absorption **L**. A molar mass sensor **M** based on ultrasound transit time measurement determines the helium content of the respired air.

LAB The oxygen supply unit **V** required by the *EasyOne Pro™ LAB* version is located on the left side of the device.

Note

EasyOne Pro™ includes the *Touch-It Virtual Keyboard* developped by Chessware SA.

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

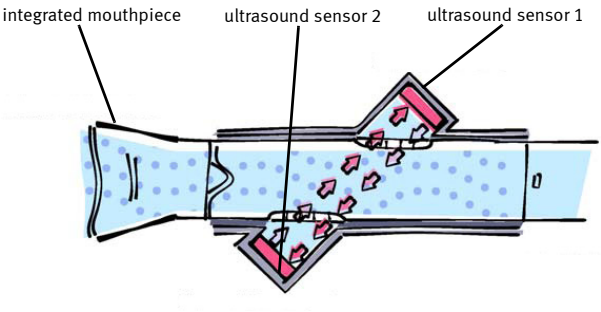


Fig. 1-2 Flow sensor

1.12 Test Gas Requirements

DLCO Test Gas

Caution
Patient Hazard, Incorrect Measurements—

Observe local regulations. Use only medical-grade gases, if required.

Make sure that only ndd-approved gas mixtures are used. If the gases used do not meet the ndd specifications, equipment malfunction may occur and the test results may be incorrect.

Gas mixture: 10% helium, accuracy ±10%; 0.3% carbon monoxide, accuracy ±10%;18 to 25% oxygen, balance nitrogen

DLCO simulator test require gas mixtures with an accuracy ≤2%.

Note
You can purchase all necessary gases and cylinders as well as the fittings from your local supplier of medical gases. Equipment not intended for mobile use can also be used with large gas cylinders.

Use only the supplied original tubing to connect the gas cylinder to the device.

Use only the original gas supply tube to connect the valve unit to the device.

Warning
Improper handling of gas cylinders represents a major risk to persons and the environment. The relevant regulations must be observed without exception. Protect the gas cylinders from falling. The content and fill level must be clearly visible at all times. Valves, fittings, connections and tubing must be free of oil and grease. Have the cylinder inspected regularly by an official test authority. The user is liable for any damage. Close the main valve whenever the gas cylinder is not in use!

LAB

FRC Gas (100% O_2), *EasyOne Pro™ LAB* **only**

Medical grade oxygen; 100 % O_2. From compressed gas cylinders or the hospital's oxygen supply system.

Note
When using the wall outlet, please observe the hospital's in-house instructions and requirements.

2 Start-up and Initial Preparation

2.1 Unpacking, Environmental Conditions

Transport Damage

Upon arrival, immediately check that the shipment is complete and undamaged. If you have a complaint, promptly notify the shipping agent and your local ndd dealer.

Check each of the following items:

- the housing
- the sensor and its connection cable
- the valve unit including the overpressure valves and the one-way valve
- the gas supply tube
- the power cord
- the gas cylinder fittings.

Cleaning Before Initial Use

EasyOne Pro™ does not require cleaning before its first use.

The gas supply tube and the valve unit are cleaned before shipping, but not disinfected. These parts can be thoroughly cleaned as described in chapter "Hygiene, Cleaning, Maintenance, Disposal" on page 100.

Ambient Conditions

Excessive amounts of dust, lint, and miscellaneous clutter around the instrument could result in malfunctions due to internal tubing blockages, overheating of components, clogged ventilation ports, etc.

EasyOne Pro™ can be operated under the following ambient conditions:

- temperature +5 to +40 °C (41 to 104 °F)
  (LAB: 10 to 40 °C (50 to 104 °F))
- relative humidity 15 to 95%, no condensation
  (LAB: 30 to 75%, no condensation)
- atmospheric pressure 700 to 1060 hPa.

  Note
  Also observe the information given in section "Electromagnetic Compatibility (EMC)" on page 154.

2.2 Equipment Description

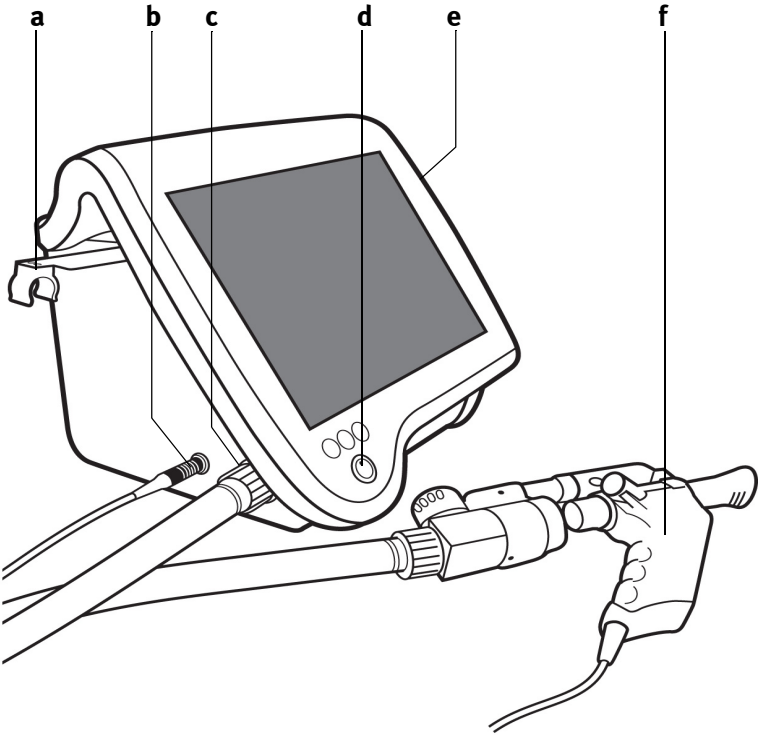


Fig. 2-1 EasyOne Pro™

a Sensor holder, extendible
b Sensor cable connection
c Connection for gas supply tube to sensor
d ON/OFF switch
e Touch stylus
f Sensor (see Fig. 2-3)

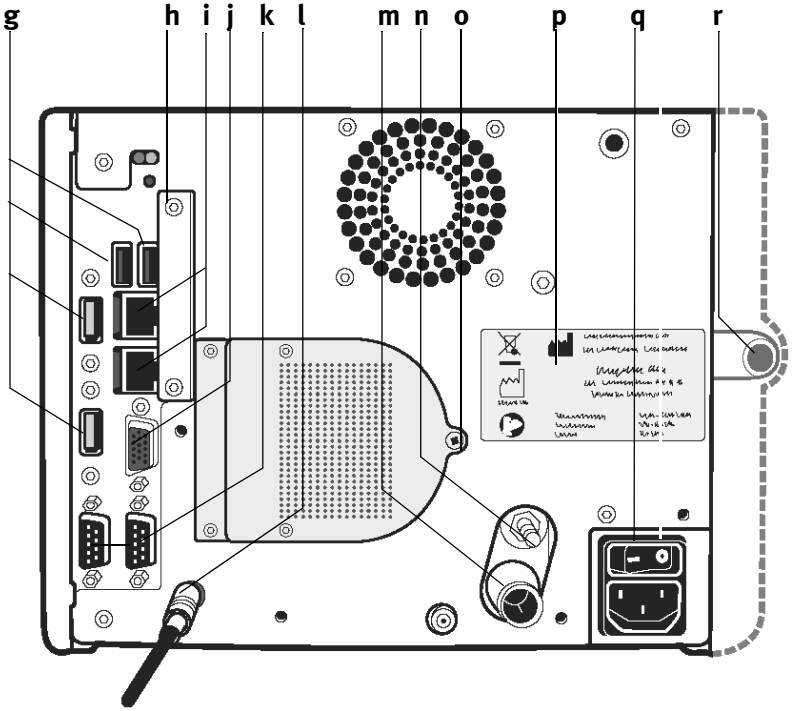


Fig. 2-2 EasyOne Pro™, rear panel

g USB ports (keyboard, mouse, printer)

h Memory card slot cover (Flash card, see "Data Backup on Memory Card" on page 102)

i LAN ports (printer)

j Monitor

k Serial RS232 ports

l Connection for temperature and humidity sensor

m Connection for tube from DLCO gas cylinder

n Potential equalization pin

o Screw to secure the filter pack (must be removed before the filter can be replaced)

p Nameplate

q Mains connector, mains power switch

LAB

r Connection for O_2 gas supply system (EasyOne Pro™ LAB only)

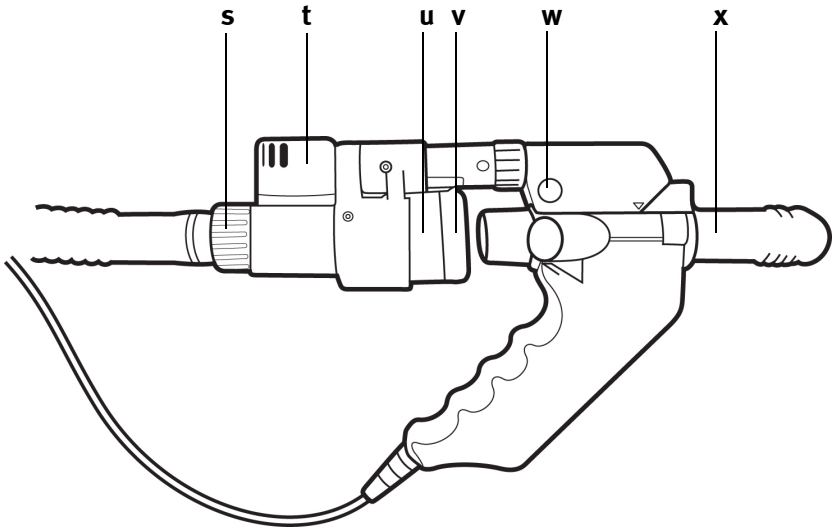


Fig. 2-3 Sensor

s Coupling ring for the gas supply tube
t Overpressure valves
u One-way valve
v DLCO barriette™ or for LAB FRC barriette™
w Motor block, release button
x spirette™

2.3 Preparing the Device

- Connect the sensor cable to the device.

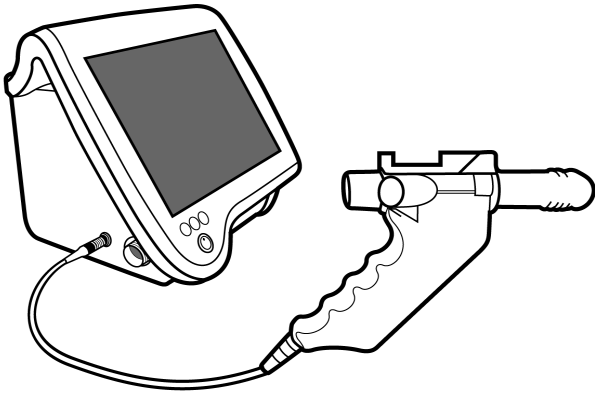


Fig. 2-4 Connecting the sensor cable

- Connect the gas supply tube to the valve unit:

  Note
  Be sure to connect the side of the tube with the colored coupling ring to the device.

  - Slip tubing connector onto connection at sensor
  - Screw coupling ring tight.

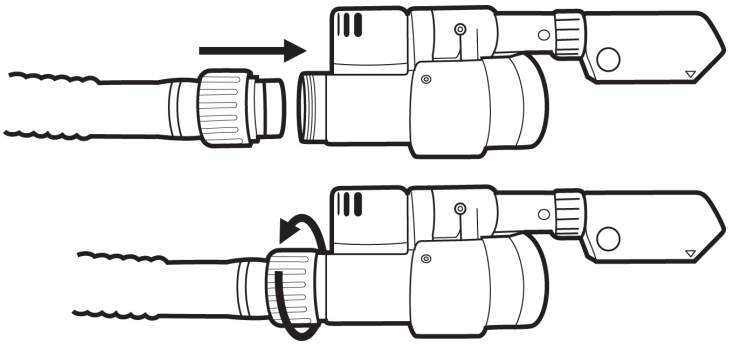


Fig. 2-5 Connect gas supply tube to valve unit

- Connect the other end of the gas supply tube to the device and tighten the coupling ring.

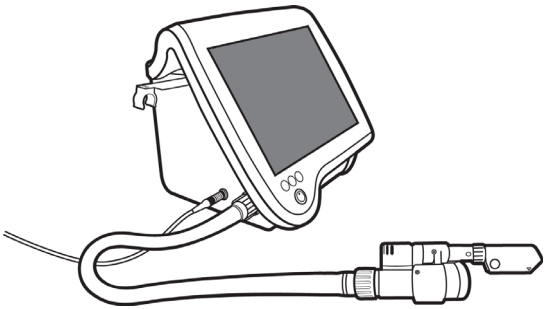


Fig. 2-6 Connecting the gas supply tube to the device

- Attach the valve unit to the sensor (aligning the arrow) and advance the valve unit until you hear it click into place (press button **a** to unlock).

  Note
  The valve unit must be mounted on the sensor only for DLCO and FRC tests. All other tests are performed without the valve unit.

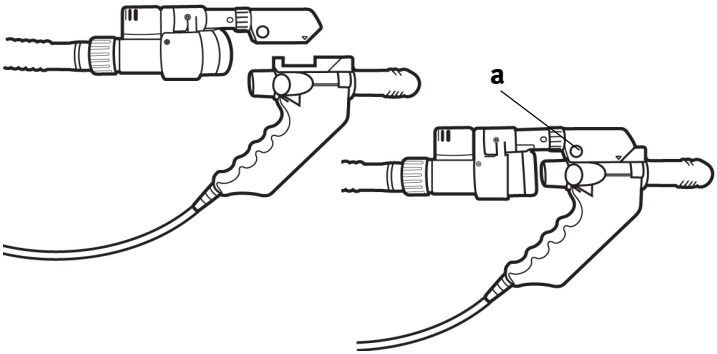


Fig. 2-7 Attaching the valve unit to the sensor

- Pull out the sensor holder on the left side of the device (**a**, Fig. 2-1) and place the sensor in the holder.

If you are working with the sensor stand (optional accessory), you can position the sensor such that the patient is not required to hold it during the tests.

- Using the clamp, screw the sensor stand to the table top.
- Open the catch and insert the sensor.
- Close the catch.

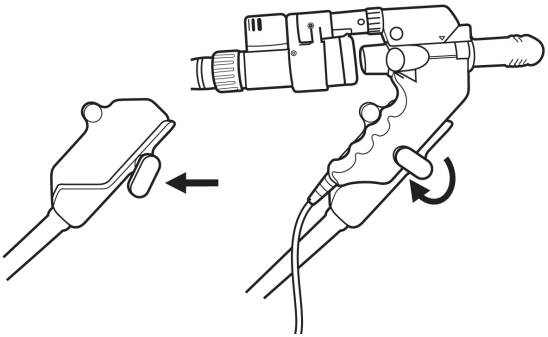


Fig. 2-8 Inserting the sensor in its stand

- Connect the temperature and humidity sensor.

Note
Ensure that the sensor is exposed to the normal room temperature and that it will not measure incorrect values because of exposure to a draft from the blower, to lamps or direct sunlight.

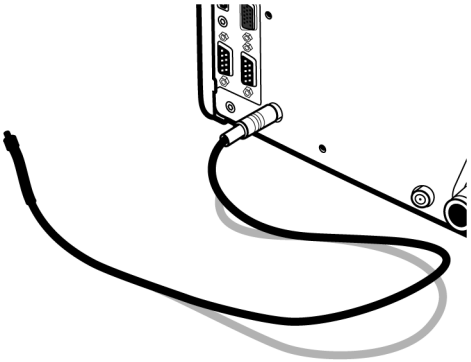


Fig. 2-9 Temperature and humidity sensor

2.4 Gas Supply

DLCO Gas

Note
It is very important to comply with the information given in chapter "Test Gas Requirements" on page 18.

The gas cylinder fittings (pressure relief valve) must meet the following minimum requirements:

- input pressure on primary side: 150 to 300 bar (depending on max. cylinder pressure)
- output pressure on secondary side: 0 to 6 bar
- flow rate: 6 L/s minimum

You can purchase all necessary gases and cylinders as well as the fittings from your local supplier of medical gases.

Equipment not intended for mobile use can also be used with large gas cylinders.

Use only the supplied original tubing to connect the gas cylinder to the device.

Use only the original gas supply tube to connect the valve unit to the device.

Warning
Improper handling of gas cylinders represents a major risk to persons and the environment. The relevant regulations must be observed without exception. Protect the gas cylinders from falling. The content and fill level must be clearly visible at all times. Valves, fittings, connections and tubing must be free of oil and grease. Have the cylinder inspected regularly by an official test authority. The user is liable for any damage. Close the main valve whenever the gas cylinder is not in use!

- Check that the gas meets ndd specifications.
- Check that the main valve **a** and the pressure relief valve **c** are closed.

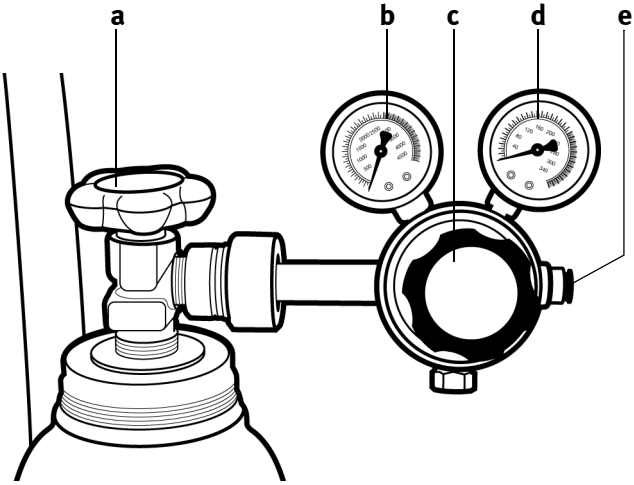


Fig. 2-10 Gas cylinder fittings

a Gas cylinder main valve
b Manometer, primary side
c Pressure relief valve, secondary side
d Manometer, secondary side
e Port for EasyOne Pro™ connection tube (DLCO gas)

- Connect the tube to the DLCO gas port on *EasyOne Pro™*: push the tube onto the stud, exerting sufficient force to overcome the initial resistance; then advance the tube as far as it will go.

Note
It is important to slide the tube at least 19 mm onto the stud.

To remove the tube, push the bushing ring back and pull the tube off the stud.

If the tube end shows signs of mechanical damage (grooves), cut off the damaged portion.

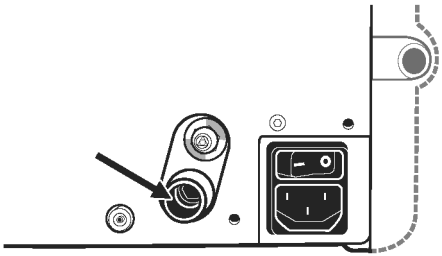


Fig. 2-11 Connection for tube from DLCO gas cylinder

- Connect the other end of the tube to the pressure relief valve **c**.
- Open the main valve **a** of the gas cylinder completely.
- Slowly open the pressure relief valve **c** and set the manometer **d** to a secondary pressure of 4 to 5 bar.

Note
A DLCO overpressure valve that opens at 7.5 bar is integrated in the device. If you select a higher secondary pressure, the overpressure valve will open and gas will escape.

Exchange the gas cylinder if the primary pressure drops below 10 bar!

Warning
Be sure not to confuse the DLCO gas inlet and the FRC gas inlet.

FRC Gas (100% O2), *EasyOne Pro™ LAB* only

LAB Medical grade oxygen is used for FRC measurements with *EasyOne Pro™ LAB*.

Note
Observe the information given in the section "Test Gas Requirements" on page 18.

Pressurised Gas Cylinder

The cylinder fitting (pressure relief valve) must meet these minimum requirements:

- input pressure on primary side: 150 to 300 bar (depending on max. cylinder pressure)
- output pressure on secondary side: 3 to 4 bar
- flow rate: 0.7 L/s at minimum (at 3 bar)

- Connect the gas supply as described on the following pages.

Warning
Improper handling of gas cylinders represents a major risk to persons and the environment. The relevant regulations must be observed without exception. Protect the gas cylinders from falling. The content and fill level must be clearly visible at all times. Valves, fittings, connections and tubing must be free of oil and grease. Have the cylinder inspected regularly by an official test authority. The user is liable for any damage. Close the main valve whenever the gas cylinder is not in use!

Central Gas Supply

The supply system must meet these minimum requirements:

- output pressure: 3 to 4 bar
- flow rate: 0.7 L/s at minimum (at 3 bar)

- Obtain a suitable O_2 adapter.
- Connect the O_2 adapter to the quick connect coupler at the device.
- Connect the quick connect coupler to the FRC gas inlet at the *EasyOne Pro™ LAB* (Fig. 2-13).

- As an alternative, use a 6-mm nipple with a suitable adapter. Slip on the gas supply tube and secure it with a tube clip.
- Check that the main valve **a** and the pressure relief valve **c** are closed.

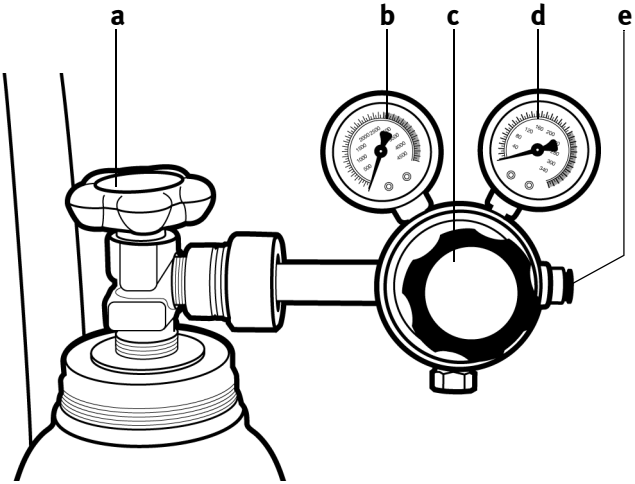


Fig. 2-12 Gas cylinder fittings

a Gas cylinder main valve
b Manometer, primary side
c Pressure relief valve, secondary side
d Manometer, secondary side
e Port for EasyOne Pro™ LAB connection tube (FRC gas)

- Connect the tube to the FRC gas inlet at the *EasyOne Pro™ LAB* (Fig. 2-13): push the tube onto the stud, exerting sufficient force to overcome the initial resistance; then advance the tube until the stop.

Note

It is important to slide the tube at least 19 mm onto the stud.

To remove the tube, push the bushing ring back and pull the tube off the stud.
If the tube end shows signs of mechanical damage (grooves), cut off the damaged portion.

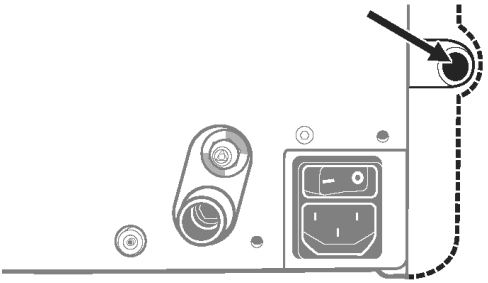


Fig. 2-13 Connection for tube from FRC gas cylinder

- Connect the other end of the tube to the pressure relief valve **c**.
- Open the main valve **a** of the gas cylinder completely.
- Slowly open the pressure relief valve **c** and set the manometer **d** to a secondary pressure of 3 bar.

Danger
Explosion Hazard—An FRC overpressure valve that opens at 5 bar, is integrated in the device. If you select a higher secondary pressure, the overpressure valve will open and gas will escape.

Note
Exchange the gas cylinder if the primary pressure drops below 10 bar!

2.5 Connecting the Keyboard and the Mouse

EasyOne Pro™ is equipped with a touch screen display and can thus be operated without a keyboard or a mouse. However, if you prefer working with a keyboard and a mouse, connect them to a USB port (**g**, Fig. 2-2).

2.6 Connecting the Printer

Depending on the printer used, connect it to one of the USB ports (**g**, Fig. 2-2) or to one of the LAN ports **i**.

Note
Preinstalled and compatible printer models (please contact your ndd dealer to find out about other options):

- HP Deskjet 6988

- HP Deskjet 6940
- HP Officejet H470
- HP Universal Printing PCL5 (see below).

- In the main menu, select **Utilities -> Configuration -> Printer**.
- Open the printer list and select the printer.

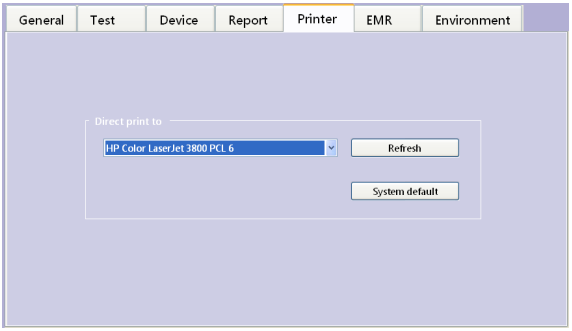


Fig. 2-14 Printer tab

Printing with HP Universal Printing PCL5 (network printer)

- In the drop-down list, select "HP Universal Printing PCL" and confirm with **OK**.
- Select the test to print.

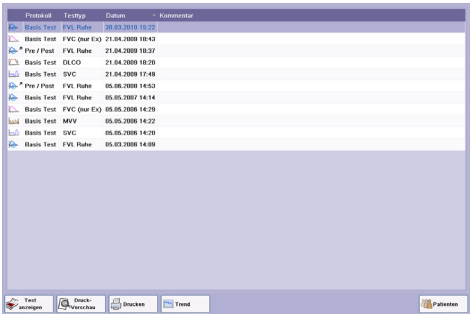


Fig. 2-15 Test selection

- Press **Print**: the printer window will appear.

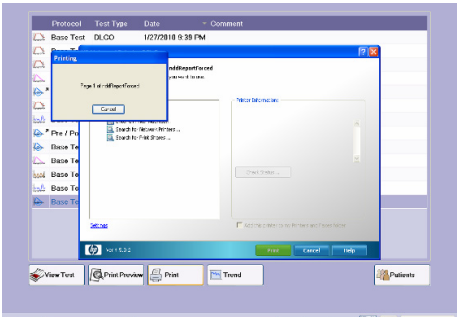


Fig. 2-16 Printer window

- Select *Search for Network printers....*

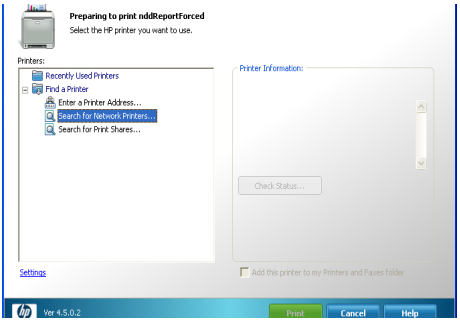


Fig. 2-17 Printer window

- Select the printer to use.

2.7 Power

Caution

Equipment Damage—Before connecting the device to the power line, verify that the ratings of your local power line are those indicated on the device nameplate.

Warning

Shock Hazard—Do not use this equipment unless it is properly connected to earth ground.

Use only the original ndd power cord supplied with the device.

If the device is used within a medical system, it must be connected with the room's central potential equalization system (pin **a**, Fig. 2-18).

Using improperly grounded equipment could result in serious injury or death and severe damage to the equipment and interconnected equipment. Grounding reliability and leakage current suppression can only be assured when the power connectors are properly connected to earth-grounded receptacles.

Note

EasyOne Pro™ meets the safety requirements of UL, NFPA, LACTL, CSA, TUV, BSI, and IEC-60601 for leakage currents.

The device is checked for leakage current before shipment. The ndd service representative (or distributor representative) will assist hospital personnel in verification, if requested.

Leave the mains power switch **c** on all the time and use the ON/OFF switch on the front panel to switch the device on and off. Turn off power with the mains power switch only when the device will not be used for some time.

- Connect the power cord to connector **b**, then plug it into the wall outlet.

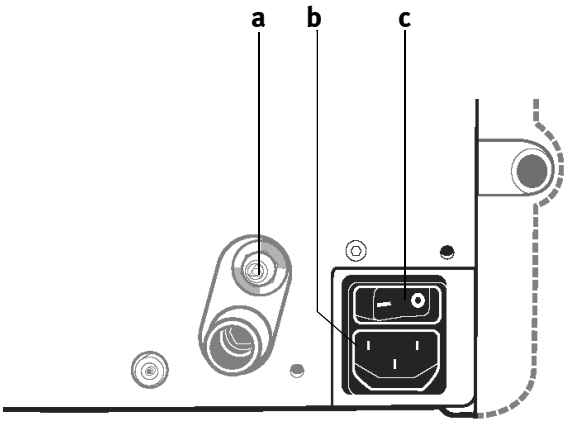


Fig. 2-18 Mains connection
a Potential equalization pin
b Mains connector
c Mains power switch

2.8 Inserting the One-Way Valve, *DLCO barriette™/FRC barriette™* and *spirette™*

One-Way Valve, *DLCO barriette™*

Note
The valve unit is only required for DLCO and FRC tests. All other tests are performed without the valve unit. The device is to be operated only with the original ndd *DLCO barriette™*.

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

- Attach the one-way valve to the valve unit (aligning the arrows) as shown in Fig. 2-19 and turn it clockwise as far as possible.

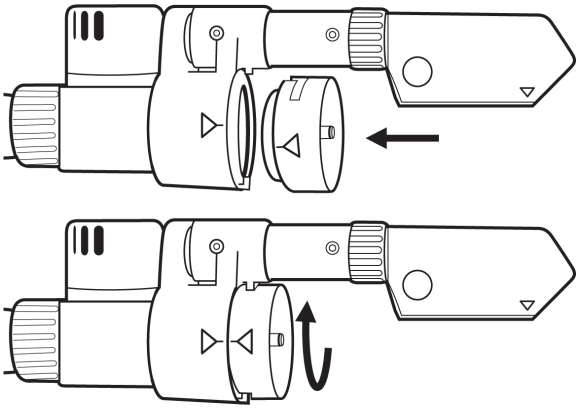


Fig. 2-19 Attaching the one-way valve

- Insert the *DLCO barriette™* in the one-way valve (aligning the arrows) as shown in Fig. 2-20 and check that it sits tight.

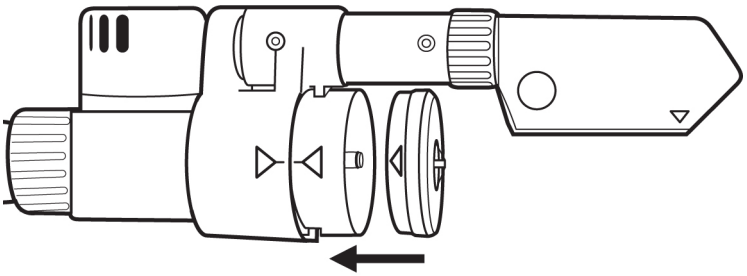


Fig. 2-20 Inserting the DLCO barriette™

LAB *FRC barriette™* **(***EasyOne Pro™ LAB* **only)**

Note

The *FRC barriette™* is required only when also FRC tests will be performed with the *EasyOne Pro™ LAB*. If the *EasyOne Pro™ LAB* is used for DLCO testing, the *DLCO barriette™* will also have to be attached here.
The device is to be operated only with the original ndd *FRC barriette™*.

Warning

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

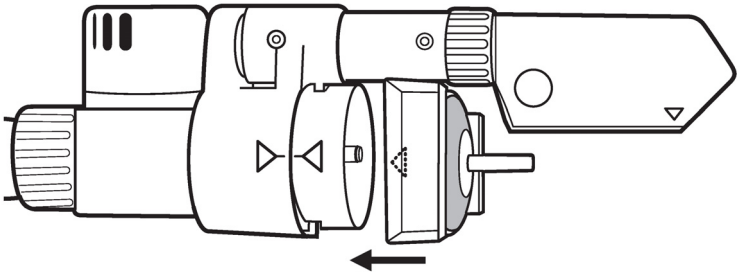


Fig. 2-21 Inserting the FRC barriette™

spirette™

Note
The device is to be operated only with the original ndd *spirette™*.

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.

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

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

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

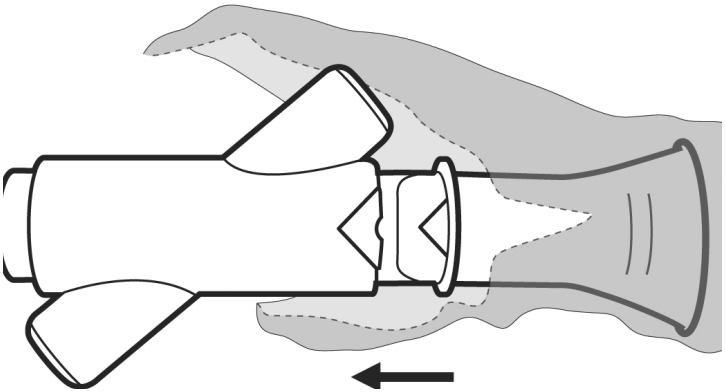


Fig. 2-22 Inserting the spirette™

2.9 Switching the Device On, Functional Test

- Open the main valve of the gas cylinder(s) completely.
- Check the secondary pressure: for DLCO gas , it must be 4 to 5 bar, and for FRC gas, it must be 3 bar (*EasyOne Pro™ LAB* only).
- Turn on the mains power switch on the rear panel of the device.
- Turn on the device with the power button: the green indicator is illuminated.

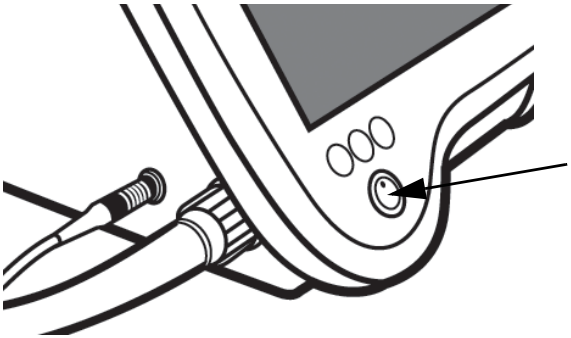


Fig. 2-23 Power button

After a short start-up phase, the initial screen will be displayed.

Note
If the initial screen appears and no error messages display, the device is in perfect operating condition.

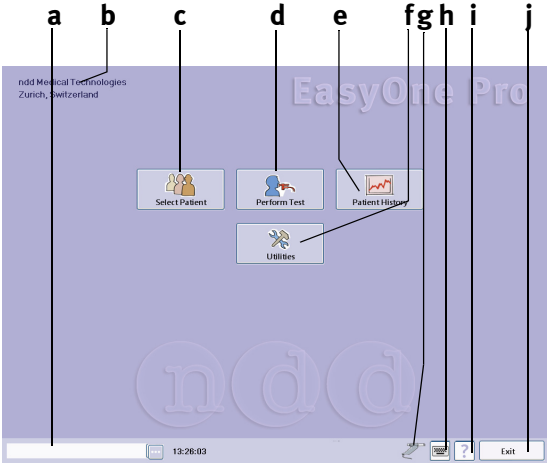


Fig. 2-24 Initial Screen

a Selected patient

b Practice, office, hospital (see "General Tab" on page 111 for details about entering the data)

c Click to select a patient or add a new patient

d Click to perform a test

e Click to review the results from previous tests

f Click to view the setup screen

g Sensor status (sensor icon, if sensor is connected)

h Click to display the keypad

i Help button

j Click to quit the program

Note

EasyOne Pro™ is equipped with a touch screen display. You activate a button by touching it on the display.

 (**h**, Fig. 2-24) is used to display and remove the touch keypad that allows you to make all entries.

Before the first test, you should follow the instructions given in "System Settings" on page 110 and

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

Note

After each exchange of the gas cylinder, check whether the gas concentration in the program corresponds to the specifications on the cylinder. Follow these steps:

- Select *Utilities -› Configuration -› Test -› DLCO*.
- Compare the displayed values with the data on the gas cylinder.
- Close the tab with **OK**.

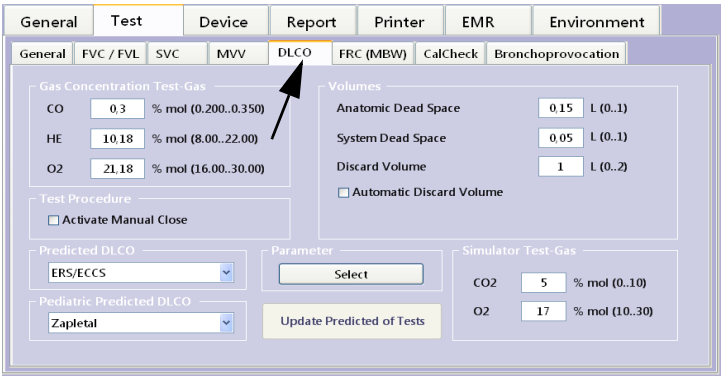


Fig. 2-25 DLCO tab

3 Performing a Test

Note

Before performing a test, you should 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 116)
- 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 66).

3.1 Selecting/Adding a Patient

- Click **Select Patient**.

The patient list will be displayed.

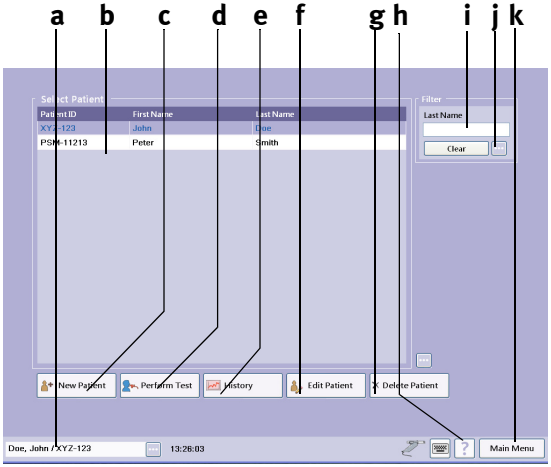


Fig. 3-1 Patient list

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

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.

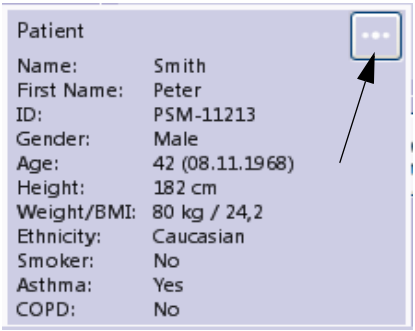


Fig. 3-2 Window showing patient data

Adding a New Patient

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

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

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

- Close the window with **OK**.

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

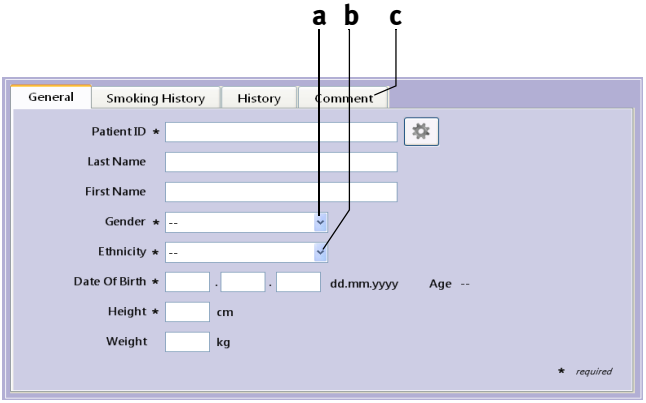


Fig. 3-3 Patient data window

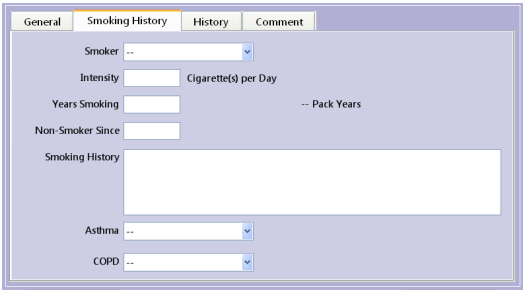


Fig. 3-4 Smoking History tab

Merging a Patient's Data Records

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

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

3.2 Selecting a Test

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

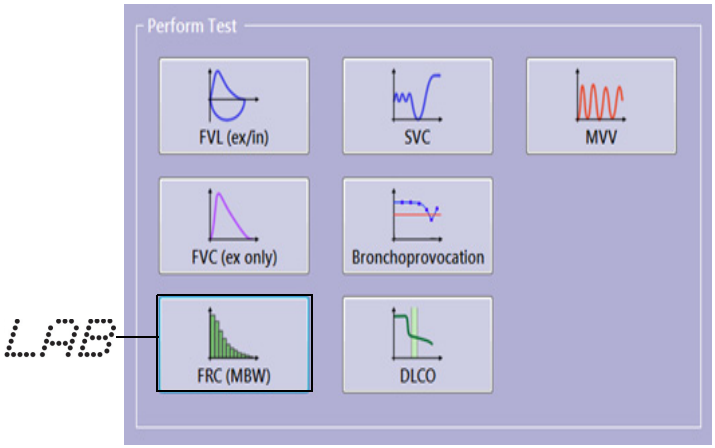


Fig. 3-6 Test selection screen

Note

If the unit selected is *EasyOne*  (see "Device Tab" on page 124), you will see Fig. 3-7.

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

Refer to the *EasyOne* tab (see "EasyOne Tab" on page 125) for configuration options.

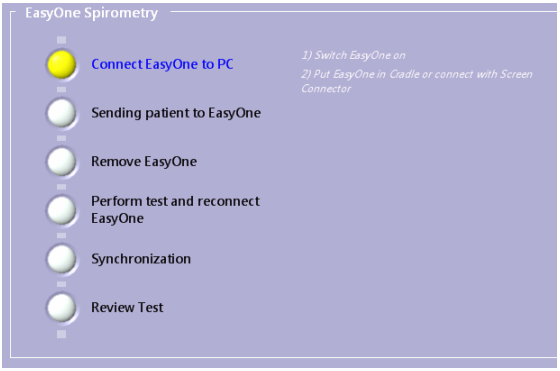


Fig. 3-7 Selection screen when the selected device is EasyOne

3.3 Forced Vital Capacity (FVC/FVL)

- Click **FVL (ex/in)**.

The acquisition screen will be displayed.

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

Expiratory FVC Measurement

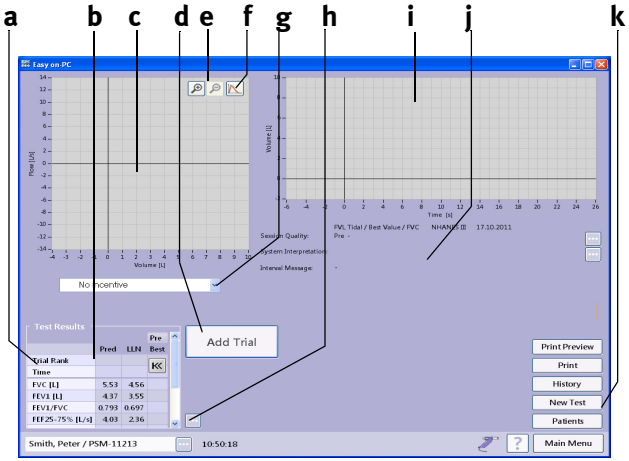


Fig. 3-8 Expiratory FVC acquisition screen

a Selected test parameters
b Predicted values, past test results of the patient
c Flow-volume loop area
d Start button
e Scaling
f Displayed curve selection: best trial, best trial and pre trial, all trials
g Show/hide the animation program for children (incentive)
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™* into the mouth with the lips sealing around the *spirette™*, taking care not to block its opening with the tongue or bite down excessively on the *spirette™*
- 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 perform spirometry tests with *EasyOne Pro™* on patients for the first time, you should practice testing yourself and others prior to testing patients. You will learn to recognize the cause of problems by interpreting the Quality Messages displayed by the program after each effort and how to avoid these problems. After a poor effort explain to your patient how to improve the maneuver.

Fig. 3-9 Patient using the sensor

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—In settings where tuberculosis or other diseases that are spread by droplet nuclei are likely to be encountered, proper attention to environmental engineering

controls, such as ventilation, air filtration or ultraviolet decontamination of air, should be used to prevent disease transmission.

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

Measurement

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

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

Note
ndd recommends leaving the spirette™ packaging in place until after the baseline has been set.

- Block off the *spirette™* 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
If the "Manual Test Stop" option was selected in the configuration (see "Test Tab" on page 116), the operator must terminate the measurement by clicking the Test End button or by pressing the space bar or the Enter key.

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

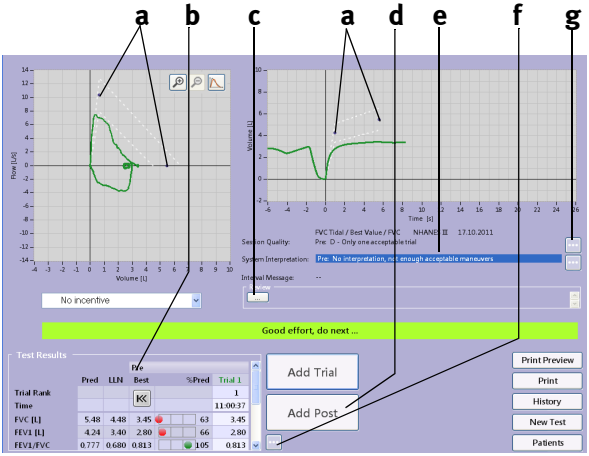


Fig. 3-10 Acceptable FVC test

a Predicted values

b Test results

c Area for review comments

d Click to perform a post-test (see "Bronchodilation (Post-Tests)" on page 53)

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 97)

g Click to view more test information and system interpretation statements

In order to assess the patient's pulmonary function, it is necessary to achieve acceptable test quality. The test quality depends on the co-operation of the patient which, in turn, depends on the quality of the physician's instructions. *EasyOne Pro™* incorporates an automatic quality control function. This function analyzes the test quality and displays a message to inform you as to whether the maneuver was acceptable or not (see "System Interpretation" on page 96). This function also 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 the 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).

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

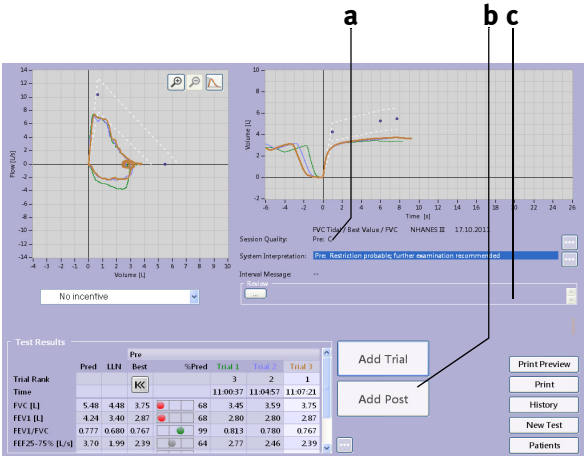


Fig. 3-11 Acquisition screen after three acceptable, expiratory FVC tests

a Quality grade

b Click to perform a post-trial (see "Bronchodilation (Post-Tests)" on page 53)

c Area for review comments

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. FVC, FEV1 and FEV1/FVC are displayed in color, all other parameters are grey.

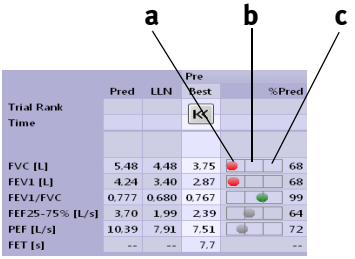


Fig. 3-12 %Pred graph

Adding a Spirometry Trial

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

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

A menu will appear.

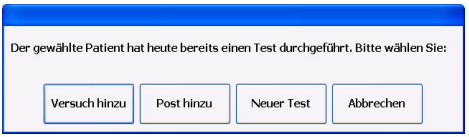


Fig. 3-13 Menu

- 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 confirm them, if they are correct.

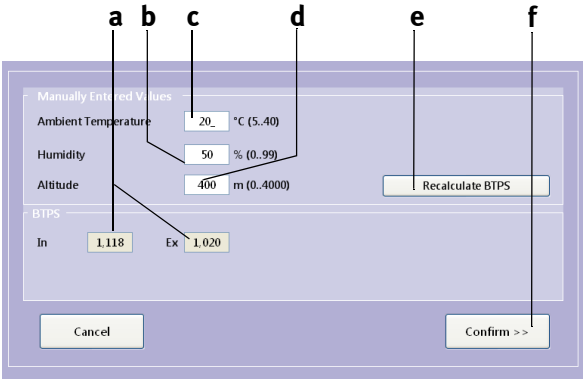


Fig. 3-14 Window showing the ambient conditions

a Conversion factors
b Box for entry of the humidity
c Box for entry of the ambient 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 46) and explain the test maneuvers to him or her:
  - take the *spirette™* into the mouth with the lips sealing around the *spirette™*, taking care not to block its opening with the tongue or bite down excessively on the *spirette™*
  - 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 48.

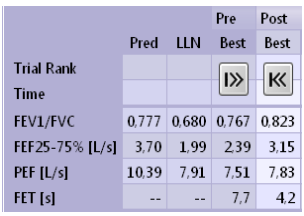
Note
The volume-time curve (Fig. 3-16) does not display the forced inspiration at the end of the maneuver.

Bronchodilation (*Post*-Tests)

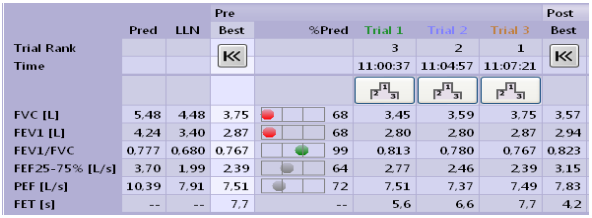
The *Post* test is usually performed to determine the patient's response to bronchodilating asthma medication. This is done by administering a bronchodilator to the patient after he or she has performed a spirometry test (*Pre*-Test). Approximately 10 to 20 minutes after the medication (when bronchodilator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

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

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



	Pred	LLN	Pre Best	Post Best
Trial Rank				
Time				
FEV1/FVC	0.777	0.680	0.767	0.823
FEF25-75% [L/s]	3.70	1.99	2.39	3.15
PEF [L/s]	10.39	7.91	7.51	7.83
FET [s]	--	--	7.7	4.2



	Pred	LLN	Pre Best	%Pred	Trial 1	Trial 2	Trial 3	Post Best
Trial Rank					3	2	1	
Time					11:00:37	11:04:57	11:07:21	
FVC [L]	5.48	4.48	3.75	68	3.45	3.59	3.75	3.57
FEV1 [L]	4.24	3.40	2.87	68	2.80	2.80	2.87	2.94
FEV1/FVC	0.777	0.680	0.767	99	0.813	0.780	0.767	0.823
FEF25-75% [L/s]	3.70	1.99	2.39	64	2.77	2.46	2.39	3.15
PEF [L/s]	10.39	7.91	7.51	72	7.51	7.37	7.49	7.83
FET [s]	--	--	7.7	--	5.6	6.6	7.7	4.2

Fig. 3-15 Detailed test results

- Conduct the tests as described in section "Measurement" on page 48.

As soon as three acceptable trials have been performed, the message *Session complete!* appears and a quality grade from *A* (optimal) to *F* is displayed (see "Quality Messages and Quality Grades" on page 84).

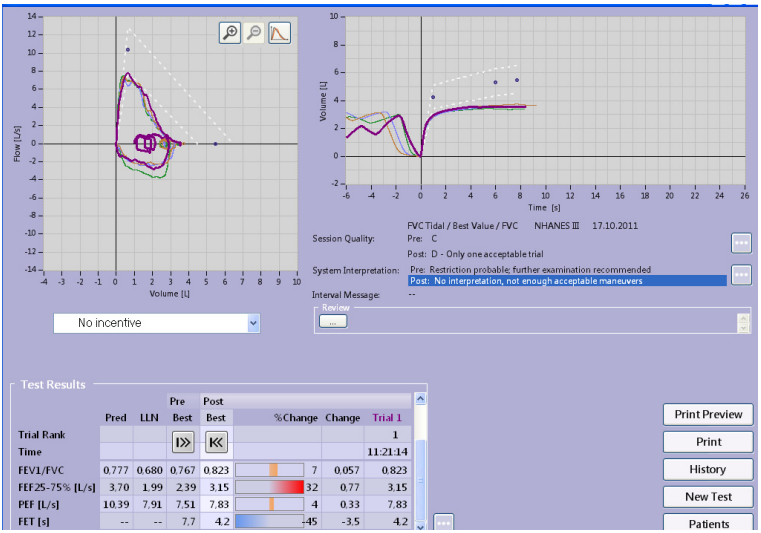


Fig. 3-16 Acquisition screen after three acceptable post-trials

Animation Program for Children

An animation program for children is available for FVC, FVL and SVC tests. You can choose between two animations: *Balloon* and *Monkey*. When the animation program is activated, we recommend disabling the manual test stop and working with the automatic test stop (see "General Tab" on page 111).

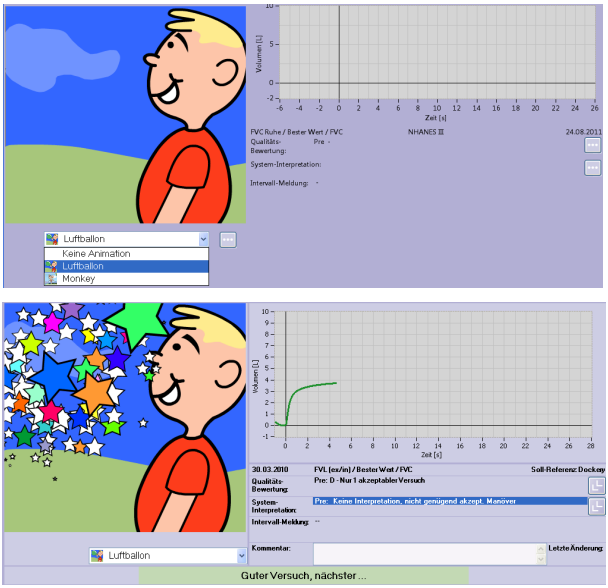


Fig. 3-17 Balloon animation program for children, test start, successful test

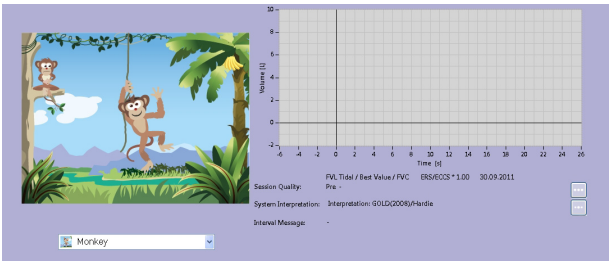


Fig. 3-18 Monkey animation program for children, test start

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

3.4 Vital Capacity (SVC)

Slow vital capacity measurements determine the vital capacity, starting from tidal breathing. (You can configure the device for direct measurement of the vital capacity, i.e., without initial tidal breathing (see "SVC Tab" on page 120). 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 51).
After three acceptable trials, the message *Session complete!* appears.

- Select the patient (see "Selecting/Adding a Patient" on page 41).
- Prepare the patient (see "Preparations" on page 46) and explain the test maneuvers to him or her:
  - take the *spirette™* into the mouth with the lips sealing around the *spirette™*, taking care not to block its opening with the tongue or bite down excessively on the *spirette™*
  - breathe calmly in and out
  - when the start test prompt appears, take a maximum inspiration followed by an immediate, but unhurried, exhalation.
- Select **SVC**.

The slow vital capacity acquisition screen appears.

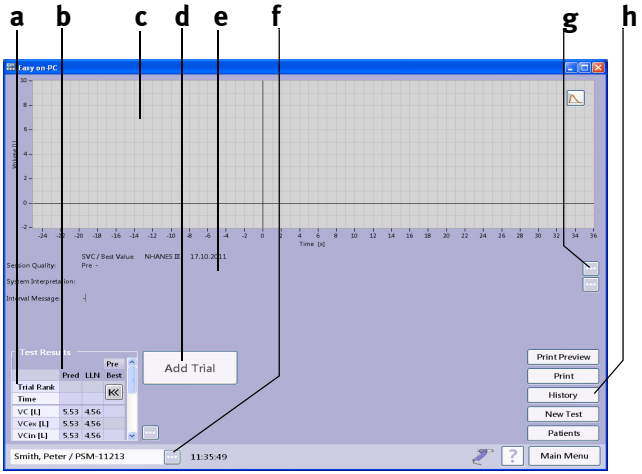


Fig. 3-19 Slow vital capacity acquisition screen

a Selected test parameters
b Predicted values
c Volume-time curve area
d Start button
e Test information and system interpretation area
f Click for a retrospective test evaluation or to expand the parameter list (see "Retrospective Test Assessment, Entering Comments" on page 97)
g Click to view additional information
h Click to perform a new test, to view the patient's test list, to select a new patient and to print a test

- Conduct the tests as described in section "Measurement" on page 48.

When three acceptable trials have been performed, the message *Session complete!* appears and a quality grade from *A* (optimal) to *F* is displayed (see "Quality Messages and Quality Grades" on page 84).

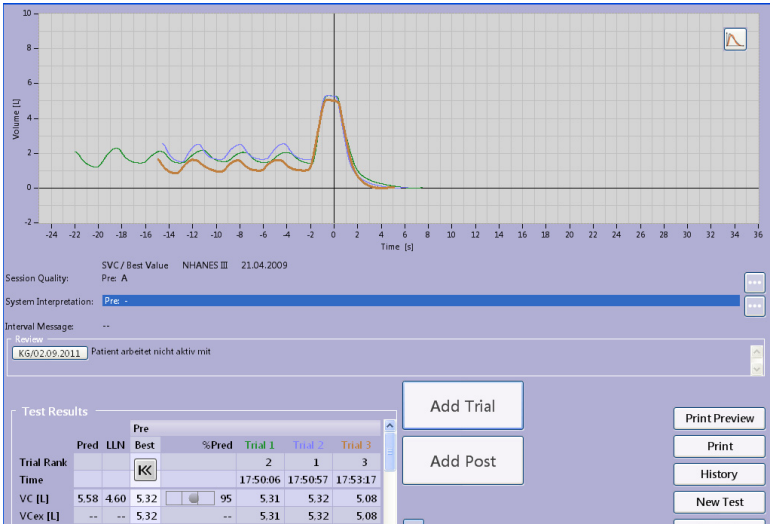


Fig. 3-20 Acquisition screen after three acceptable SVC trials

3.5 Maximum Voluntary Ventilation (MVV)

In these tests, the maximum ventilation volume over an uninterrupted period of 12 seconds is measured. For this test type, too, the ATPS values (**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 51).

- Select the patient (see "Selecting/Adding a Patient" on page 41).
- Prepare the patient (see "Preparations" on page 46) and explain the test maneuvers to him or her:
  - take the *spirette™* into the mouth with the lips sealing around the *spirette™*, taking care not to block its opening with the tongue or bite down excessively on the *spirette™*
  - 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 **MVV**.

The MVV acquisition screen appears.

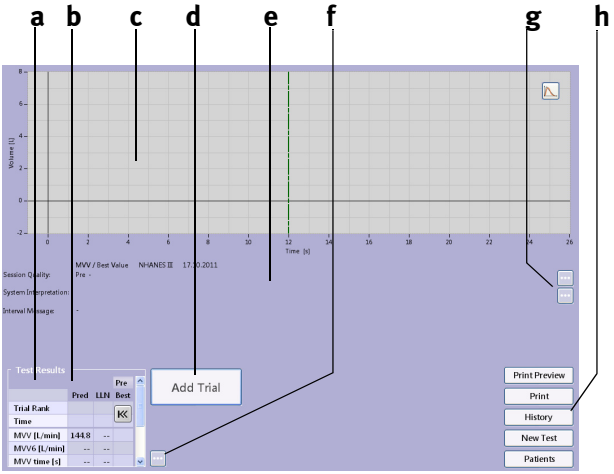


Fig. 3-21 MVV acquisition screen

a Selected test parameters
b Predicted values
c Volume-time curve area
d Start button
e Test information and system interpretation area
f Click for a retrospective test evaluation or to expand the parameter list (see "Retrospective Test Assessment, Entering Comments" on page 97)
g Click to view additional information
h Click to perform a new test, to view the patient's test list, to select a new patient and to print a test

- Conduct the tests as described in section "Measurement" on page 48.

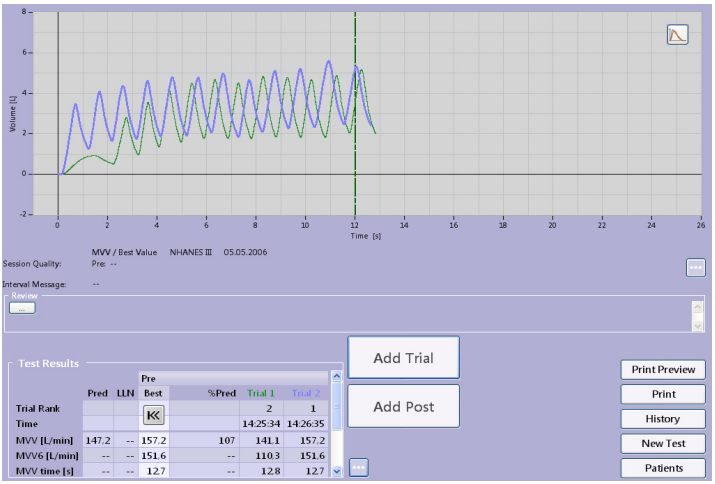


Fig. 3-22 Acquisition screen after two acceptable MVV tests

3.6 Bronchial Provocation

Introduction and Safety Information

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

Danger

Patient Hazard —

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

European Respiratory Society. Eur Respir J 1993; 6: Suppl.16, 53–83).

Performing a Test

- Select a medication (Challenge Test Protocol, see "Provocation Tab" on page 123). The following is a brief description of how to perform a measurement with the *Methacholine ATS short protocol (5 breaths)*.
- Select the patient (see "Selecting/Adding a Patient" on page 41).
- Explain the test maneuver to your patient and attach the nose clip.
- Select **Provocation**.

The initial screen is displayed.

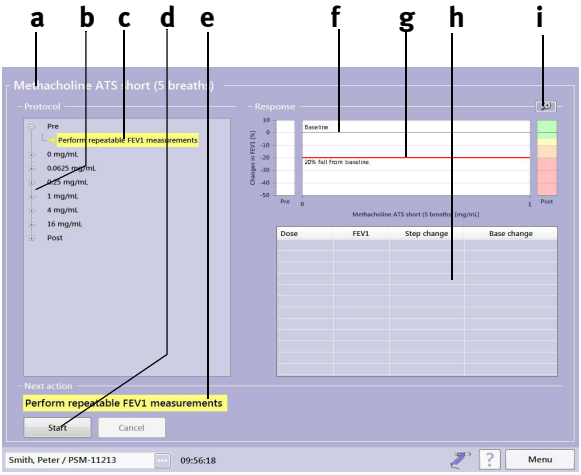


Fig. 3-23 Initial screen for bronchial provocation tests

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

The baseline is determined either at the pre-test stage or at the 0 mg/ml level, depending on the test protocol. Three acceptable FEV1 measurements should be available for the baseline determination (see "Forced Vital Capacity (FVC/FVL)" on page 46).

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

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

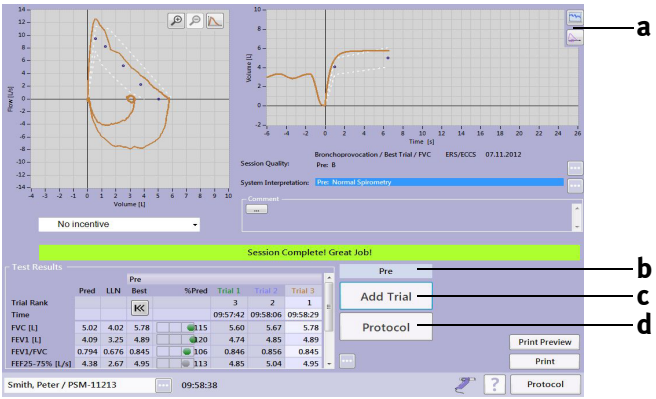


Fig. 3-24 Screen after three acceptable expiratory FVC measurements

a Toggles between volume-time and test diagramm
b Current test step
c Click to add an FEV1 measurement
d Click to display the protocol screen

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

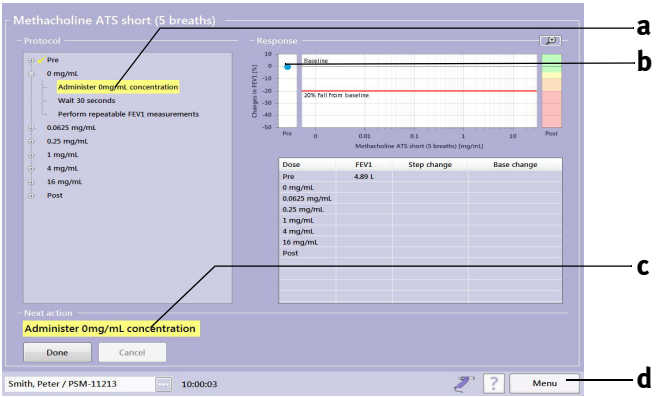


Fig. 3-25 Protocol screen

a Current test step
b Pre-test value
c Next action
d Menu button

Note

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

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

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

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

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

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

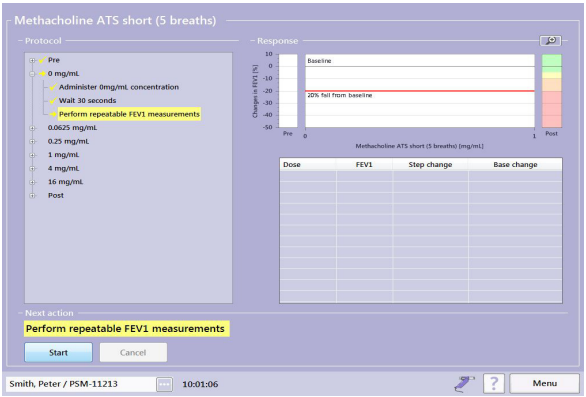


Fig. 3-26 Protocol screen

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

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

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

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

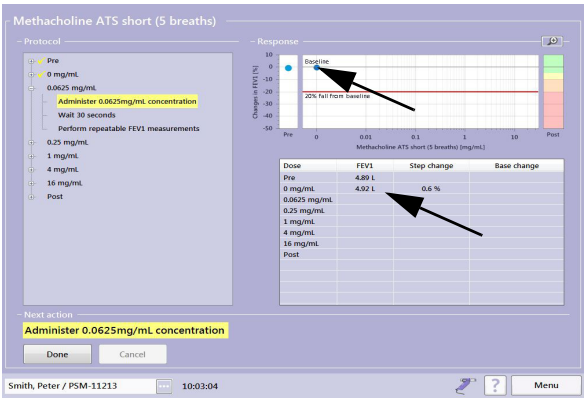


Fig. 3-27 Protocol screen

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

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

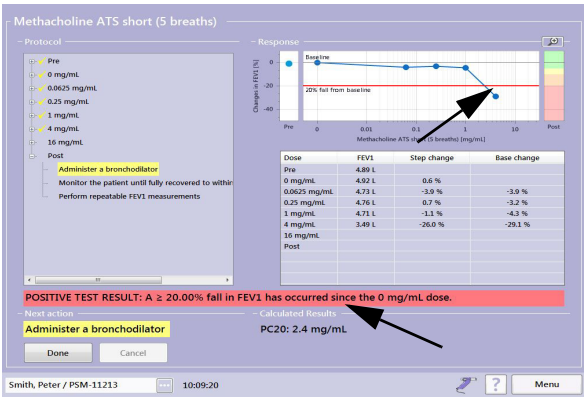


Fig. 3-28 Protocol screen with a positive test result

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

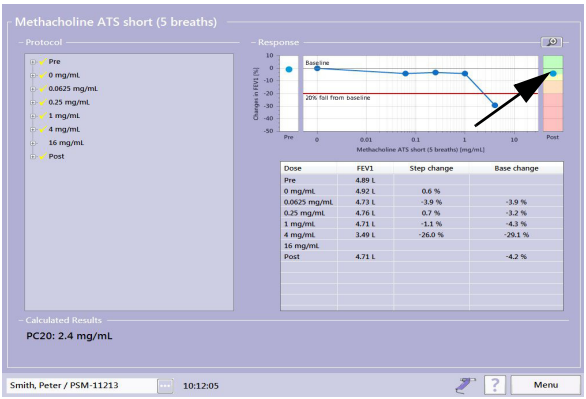


Fig. 3-29 Protocol screen

Note

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

3.7 Quick Test

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

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

A menu will appear.

Fig. 3-30 Menu

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

Note

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

The Quick Test feature is not available for DLCO tests.

3.8 CO Diffusing Capacity (DLCO)

Note

Before conducting the DLCO test, the valve unit must be attached to the sensor (see Fig. 2-7). Furthermore, a new *barriette™* and, in case of a new patient, a new *spirette™* must be inserted (see "Inserting the One-Way Valve, DLCO barriette™/FRC barriette™ and spirette™" on page 35).

Before performing the first DLCO test, check that the valve unit is properly attached and that the metal coupling ring of the motor is tight.

Before performing a DLCO test, you should measure the vital capacity.

It is recommended to perform two DLCO tests. The pause between the two tests must be at least 4 minutes. However, do not perform more than five consecutive DLCO tests on one patient (ATS/ERS Taskforce recommendations, literature [11] ("Literature" on page 182).

- Select the patient (see "Selecting/Adding a Patient" on page 41).
- Attach the nose clip to the patient and explain the test maneuvers to him or her:
- Select **DLCO**.
- In the BTPS window, confirm the values for relative humidity, temperature and atmospheric pressure with **Confirm**.
- Check that the patient sits fully upright and wears the nose clip.
- Instruct the patient to hold the sensor straight (not at an angle) in front of his or her mouth without taking the *spirette™* into the mouth yet.

Fig. 3-31 shows the patient during a test, using the sensor stand (optional accessory).

Fig. 3-31 Patient using the sensor (with optional stand)

- Press **Start** on the acquisition screen. *EasyOne Pro™* will automatically complete a start-up routine in about 15 seconds.
  - Initialization
  - Test preparation
  - Tidal breathing
- When you see the message *Start tidal breathing*, instruct the patient to take the sensor into the mouth with the lips sealing around the *spirette™* and to start the tidal breathing maneuver.
- After 3 or 4 breaths, the **Activate** button appears. Now instruct the patient to fully exhale.
- During exhalation, press the **Activate** button: the valve will automatically close at the end of exhalation. it is also possible to manually close the valve by pressing the **Manual Close** button.
- Now instruct the patient to fully inhale (the patient is expected to inhale 85% of their vital capacity within 2 to 4 seconds) and then hold their breath for 10 seconds (wait for the valve to close before breathing in).
- After the 10 seconds, the valve opens and the patient is required to exhale normally (avoiding forced or slow exhalation) and continue tidal breathing until the test stops.

After a successful test, the message *Good effort* will be displayed.

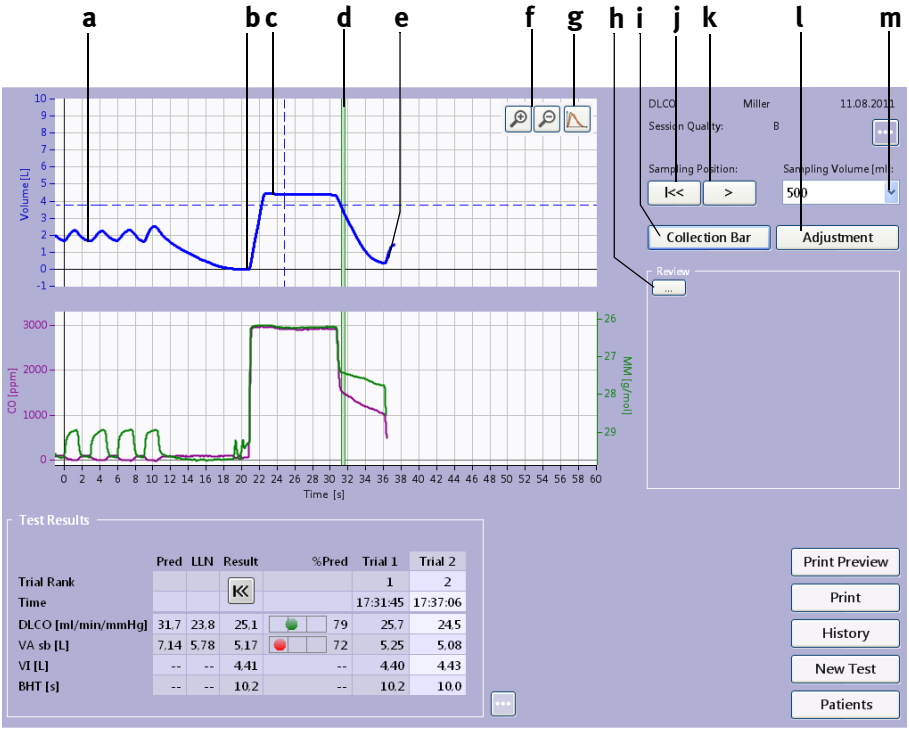


Fig. 3-32 DLCO test

- *a Tidal breathing*
- *b Complete exhalation*
- *c Holding breath for 10 seconds*
- *d Collection bar (its width depends on the selected sampling volume m)*
- *e Complete exhalation*
- *f Keys to expand the curve (to check the collection bar for artifacts)*
- *g Click to show/hide more curves (mouth pressure, flow)*
- *h Box for comments (touch to display the keypad)*
- *i Click to show and hide control buttons for the collection bar*
- *j Click to reset the collection bar*
- *k Click to move the collection bar to the right*
- *l Click to adjust the DLCO measurement (see "Introduction to Adjustment of DLCO Measurements" on page 146)*
- *m Click to select the sampling volume*

The collection bar identifies the range that was analyzed.

With the **+** button **f**, you can expand the curve to check the collection bar range for artifacts (click **-** to reset the bar to its original width).

With **Collection Bar i** you can show and hide control buttons for the collection bar (**j**, **k**, **m**).

With **› k** you can move the collection bar to the right. The resulting, new values will immediately be calculated and displayed.

With **I‹‹ j** you return the collection bar to its original position.

The text box **h** provides space for comments. A keypad will be displayed as soon as you touch the area.

You can double-click on a point in the curve windows to hide a curve. The curve reappears when you double-click once more.

LAB 3.9 FRC Test (*EasyOne Pro™ LAB* only)

Introduction

FRC measurement is based on the nitrogen (N_2) washout method where N_2 is washed out from the lungs while the patient breathes 100% oxygen. The test is performed during tidal breathing within the range indicated at **a** (Fig. 3-26). After a (configurable) number of breaths, the measurement starts automatically or it can be started manually with the **Activate** button.

Note

Before conducting the FRC test, the valve unit must be attached to the flow sensor (see Fig. 2-7). Furthermore, a new *FRC barriette™* and, if a new patient is tested, a new *spirette™* must be inserted (see "Inserting the One-Way Valve, DLCO barriette™/FRC barriette™ and spirette™" on page 35).

Before performing the first FRC test, check that the valve unit is properly attached and that the metal coupling ring of the motor is tight.

Inform patients that they may experience a feeling of dryness during inhalation. Also, they will hear oxygen escape during the washout phase.

You can choose between the following tests:

- manual mode
- automatic mode.

Additionally, the FRC test linked with SVC is available (*Linked FRC Test with SVC (online)*), see "FRC (mbw) Tab" on page 122):

- No linked SVC
- SVC before washout
- SVC after washout.

Note

The method recommended by ATS/ERS is the linked SVC test.

No linked SVC

Only a plain FRC washout is performed. If an SVC test has been performed before, the lung volume parameters, such as TLC, ERV and RV, will be calculated based on this external SVC test.

Note
Interpret these results with caution because different breathing baselines are possible.

SVC before washout

Relaxed tidal breathing until a stable breathing baseline is detected (indicated with a line in the VT-diagram representing the breathing baseline line). Then perform a full SVC maneuver; after that continue with the FRC washout maneuver. Lung volume parameters will be calculated based on this linked SVC maneuver (data from an "external" SVC test will not be used).

Note
Perform the SVC maneuver according to ATS/ERS guidelines to ensure accurate results.

SVC after washout

First perform an FRC washout maneuver. After the washout continue with relaxed tidal breathing until a stable breathing baseline is detected (indicated with a line in the VT-diagram representing the breathing baseline line). Then perform a full SVC maneuver. Lung volume parameters will be calculated based on this linked SVC maneuver (data from an "external" SVC test will not be used).

Note
Perform the SVC maneuver according to ATS/ERS guidelines to ensure accurate results.

Performing a Test

Note
The patient wears a nose clip during the measurement and the lips must seal around the mouthpiece to prevent ambient air from being inhaled.

- Instruct the patient according to the displayed on-line messages. The messages depend on the mode settings "Automatic" or "Manual" and on the selected option "Linked SVC".
- Attach the *FRC barriette™* (see "FRC Test (EasyOne Pro™ LAB only)" on page 71).
- Select the patient (see "Selecting/Adding a Patient" on page 41).
- Select the test with **FRC**.
- The FRC test acquisition screen appears.

- Explain the test maneuver to the patient and prepare him or her for the test:
  - attach the nose clip
  - take the *spirette™* into the mouth with the lips sealing around the *spirette™* , taking care not to bite down excessively on the *spirette™*
  - sit upright
  - during the test, the patient should breathe quietly and steadily. The respiratory flow should not exceed the displayed range (**a** , Fig. 3-26).

In automatic mode, the test starts automatically after the "Number of breaths before test start" and ends automatically when the measured concentration drops repeatedly below the limit of 2 % (as configured under "FRC (mbw) Tab" on page 122).

In manual mode, beginning and end of the *Washout phase* must be manually determined.

After a successful test, the message *Good effort* will be displayed.

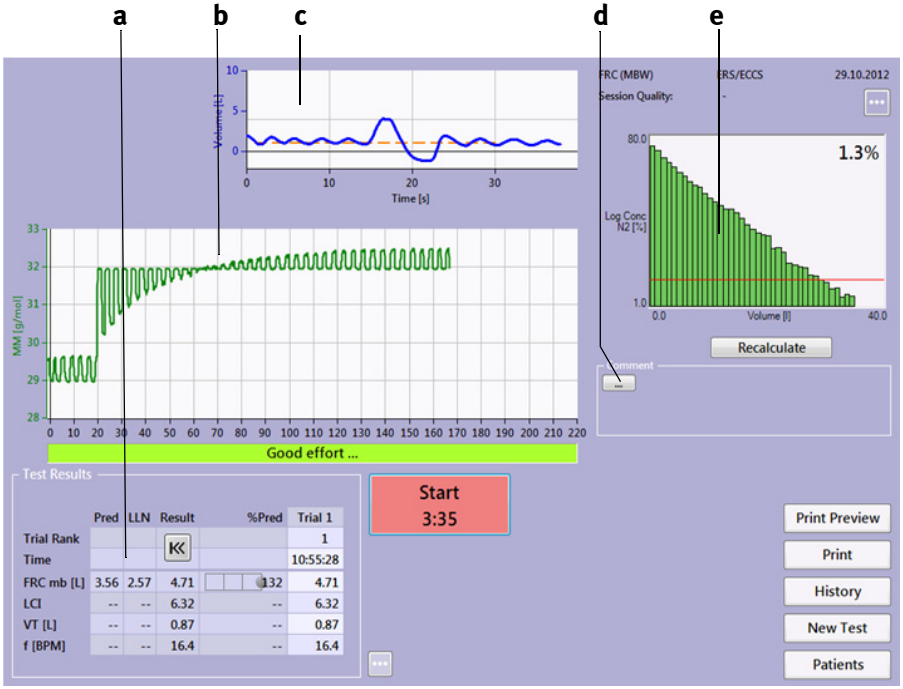


Fig. 3-33 FRC test (offline linked)

a Test result
b Measuring curve
c Volume-time curve (only shown for "linked" measurements)
d Click to enter a comment
e Tracer curve (logarithmic representation, see "FRC (mbw) Tab" on page 122)
f Flow indicator (during the washout phase, the flow should remain in the green range)

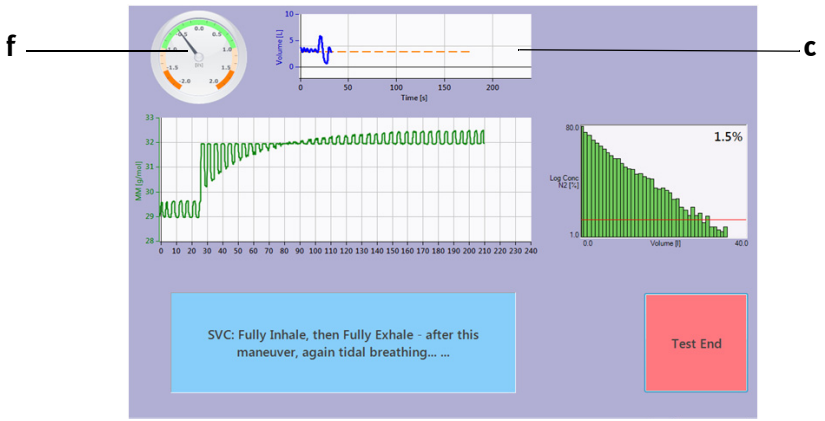


Fig. 3-34 FRC test (online linked)

3.10 Ending the Test

At the end of the test, push the *spirette™* out of the sensor from below. Dispose of it and do not reuse. Also, replace the *barriette™* after each patient. Refer to section "Hygiene, Cleaning, Maintenance, Disposal" on page 100 for sensor cleaning instructions.

Warning
Risk of Infection—

- *spirette™* and *DLCO barriette™/FRC barriette™* are intended for single patient use. Use new ones for each new patient.
- After tests on patients with an infection of the respiratory tract or patients with a suspected infection of the respiratory tract, it is recommended to clean all parts (outside of the sensor) that were touched during the test, before testing a new patient (see "Hygiene, Cleaning, Maintenance, Disposal" on page 100).

3.11 Retrieving/Printing Stored Tests

EasyOne Pro™ 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
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 51).

- Select the patient (see "Selecting/Adding a Patient" on page 41).

- Click the **History** button (Fig. 3-35).

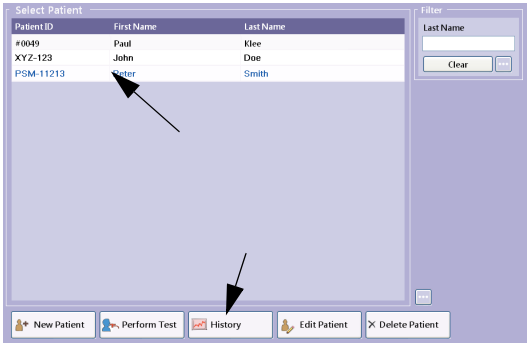


Fig. 3-35 Retrieving/printing stored tests

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

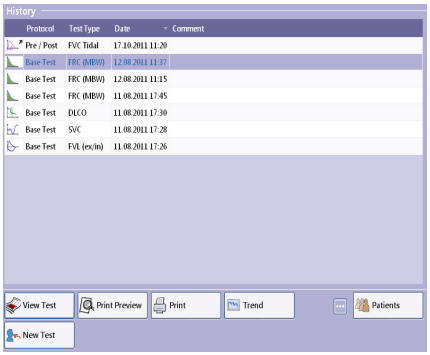


Fig. 3-36 Test list

The displayed tests can be sorted by

- test protocol (*Base*, *Pre*, *Post*)
- test type (*FVC*, *SVC*, *MVV*)
- test date
- comment.

- To do so, click on the appropriate title in the column headers.
- Highlight the test to view.
- Click **View Test** to view the test, **Print Preview** to view the test before printing it, **Print** to print the test, or **Trend** to view the trend display (see "Trend View" on page 78). Click **Patients** to display the patient list and click **New Test** to display the test selection menu.

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

Examinations for which a *Post*-test exist, are identified by a small arrow symbol  .

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

- select **b** to display the test report menu (report layout)
- select **c** to print the test (select the printer)
- select **d** to change the display scale.

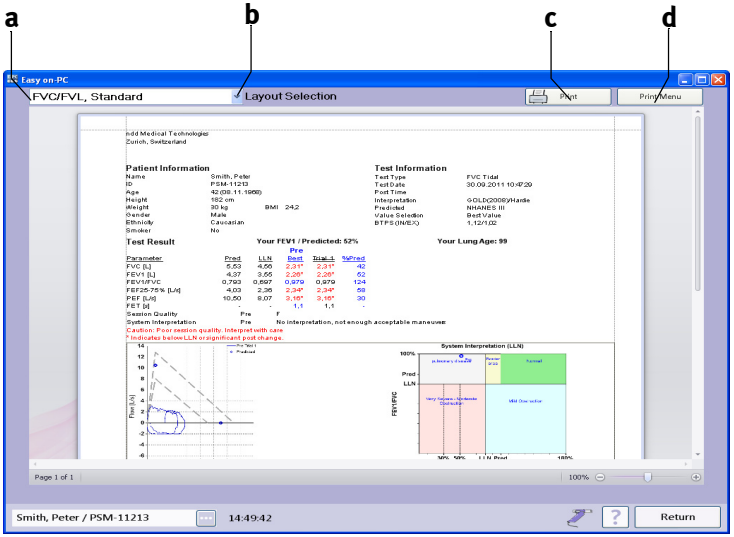


Fig. 3-37 Print preview of the test

a Window showing the currently selected test report

b Click to open the layout selection menu

c Click to print the displayed report

d Click to access a submenu with options for zooming, exporting, viewing, printer selection and additional print functions

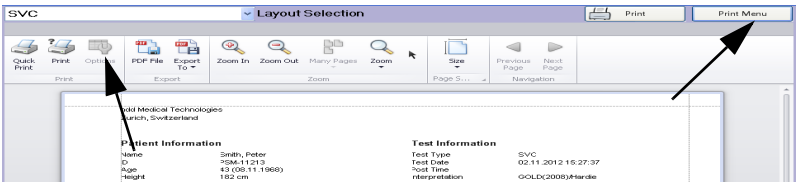


Fig. 3-38 Menu bar when the Print Menu button is pressed

3.12 Trend View

The trend views allow you to observe the measured parameter values over a 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.

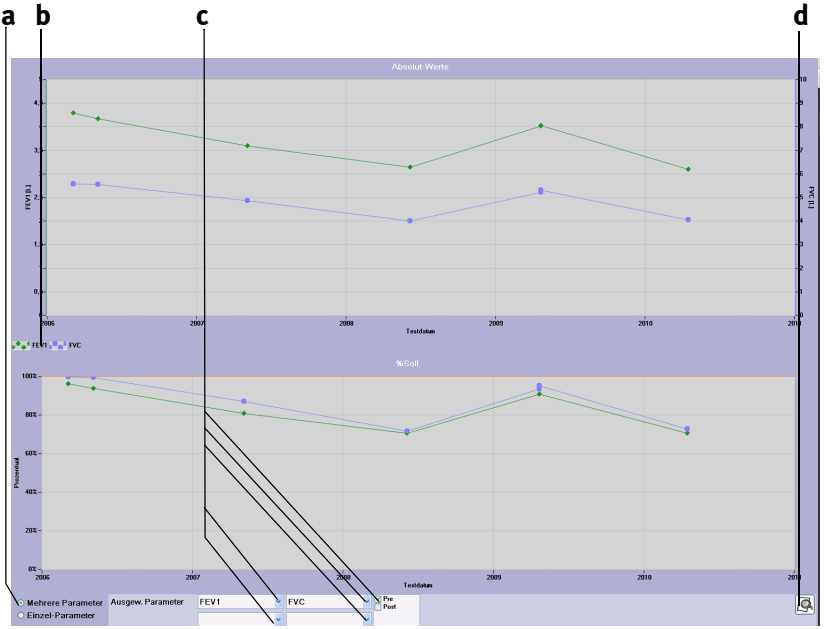


Fig. 3-39 Trend view of multiple parameters

a Option buttons for selection of the view
b Displayed parameter labels
c Click to select a parameter
d Icon to initiate the trend printout

Fig. 3-40 Trend view of a single parameter and its predicted normals

3.13 Definition of Important Parameters

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_{max}		ratio of FEV1 to VC_{max}
FEV1/FEV6		ratio of FEV1 to FEV6
FEF 50 (MEF 50)	Mid-Expiratory Flow (50%)	flow at 50% of expiratory vital capacity
FEF 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
VT	Tidal Volume	Tidal volume at rest
ERV	Expiratory Reserve Volume	expiratory reserve volume
IRV	Inspiratory Reserve Volume	inspiratory reserve volume
VCmax	Maximum Vital Capacity	maximum vital capacity of an SVC, FVC, FVL or DLCO 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
VC	Vital Capacity	vital capacity of a slow spirometric test

IC	Inspiratory Capacity	inspiratory capacity (VT + IRV)
MVV	Maximum Voluntary Ventilation	maximum ventilation volume per minute
LLN	Lower Limit of Normal	lower limit of normal
Lung Age		lung age, see section "Predicted Values" on page 139 [8]
DLCO	CO diffusing capacity (ml/min/mmHg)	CO diffusing capacity (ml/min/mmHg)
TLCO	CO diffusing capacity (mmol/min/kPa)	CO diffusing capacity (mmol/min/kPa)
DLadj	Diffusing capacity adjusted (Hb, PaO_2, COhb, altitude)	adjusted diffusing capacity
VA	Alveolar volume (BTPS)	alveolar volume (BTPS)
VI	Inspiratory Capacity from DLCO maneuver	inspiratory capacity from a DLCO test
DLCO/VA	Krogh Factor	Krogh factor
TLC	Total Lung Capacity	total lung capacity

Note
The parameter names used by ndd Medizintechnik AG are those standardized by ATS and ERS. (See literature references [14] and[11] ("Literature" on page 182).

For forced spirometric tests and depending on your configuration, the "Best" column in the result table shows the "Best Value" of all accepted trials or the "Best Trial", i.e., the value of the best trial ("Test Tab" on page 116).

The most important parameters will be explained below:

For slow spirometry (SVC), the mean value of the accepted trials will be shown with the following exceptions: VT, ERV, IRV, IC.

For DLCO, the mean values will be displayed in the "Result" column for the following parameters: DLCO, VA, TLCO, DLAdj and TLC.

LAB

FRC

FRC_{MB}	Functional Residual Capacity
LCI	Lung Clearance Index (equals CEV divided by FRC at 1/40th of initial tracer concentration (2% N2), see "Literature" on page 182 [16])
CEV	Cumulative Expired Volume
VT	Tidal Volume
VT/kg	Tidal Volume/kg
f	Breathing Frequency
M0, MR1, MR2	Moment Value and Moment Ratios 1 and 2 from nitrogen washout moment analysis. Clinical use of these parameters is limited since the available reference data is based on a small number of patients (see "Literature" on page 182 [17] to [21]); for a detailed description, please refer to chapter "EasyOne Pro LAB Washout Moment Analysis" on page 180 in the Appendix of this manual.

These definitions apply to FRC:

mean value: FRC, IC, ERV, VT, IRV , LCI, CEV, VT, M0, MR1, MR2

Get largest VC from FRC maneuver

RV[reported] = FRC[average] - ERV[average]

TLC[reported] = RV[reported] + VC[largest] = FRC[average] - ERV[average] + VC[largest]

4 Editing Patient Data

- On the initial screen, click **Select Patient**.
- Select the patient.
- Click **Edit Patient**.

The patient data window will appear.

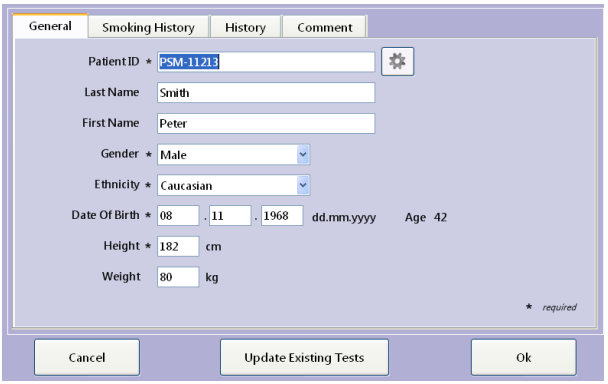


Fig. 4-1 Patient data window

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

5 Quality Messages and Quality Grades

5.1 FVC/FVL Quality Messages and Quality Grades

Some Basic Facts

End-of-Test criteria, quality criteria and quality grading are based upon the published standards [1], [4], [11], [15] ("Literature" on page 182).

Quality grading is based on [4], [11], [15] ("Literature" on page 182).

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 are detailed.

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:

FVC/FVL Quality Messages

Message	Criterion	Recommended action
Don't hesitate ...	Back-extrapolated volume greater than 150 ml or 5% of FVC whichever is greater (for age ≤6: 80 ml 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 ›19 l/s)	Instruct the patient to avoid coughing during the measurement. 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

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: 80 ml 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

5.2 SVC Quality Messages and Quality Grades

The quality grading is based on [3].

SVC Quality Messages

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

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

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

SVC Quality Grades

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

5.3 DLCO Quality Messages and Quality Grades

The quality grading is based on ATS/ERS Guidelines [3].

DLCO Quality Messages

Message	Criterion	Recommended action
Breath Hold Time out of Range Maneuver not acceptable. Breath Hold Time is outside the 8-12 seconds range	Breath-hold time outside 8 to 12 seconds	Exhale immediately when the valve opens
Parameter out of Range Test cannot be evaluated; sensor signals do not pass QC check	A parameter is out of range, e.g. a gas concentration is higher or lower than permitted 0) Helium concentration out of range 1) CO at zero not within 80 ppm 2) CO at DLCO test gas not within 500 ppm 3) Alveolar CO out of range 4) Expiratory CO out of range 5) VA out of range 6) DLCO out of range	Check for leaks; make sure concentrations of gas cylinder are entered correctly

Message	Criterion	Recommended action
Low Inspiratory Volume Maneuver not acceptable. Inspiratory volume too low	The inspiratory volume is smaller than 85% FVC/VC/Predicted	Make sure to perform a full expiration before the valve closes, and then a full inhalation of test gas
Inspiratory Time Too Long Maneuver not acceptable. Inspiration time exceeds the maximum of 4 seconds	Inspiratory time › 4 seconds	Inhale test gas faster
Sampling volume at this position too large	Sample volume not correctly determined	Reduce sample volume
Difference Preparation and Maneuver Test cannot be evaluated; gas sensor signals do not pass QC check, possibly due to leaks	Reference gas measurement and inspiratory gas measurements do not match within 80 ppm. This means that most probably there is a leak in the DLCO hose	Check for leaks; check gas supply
Sampling volume at maximum position Test cannot be evaluated; exhaled volume too small	Can happen when very small volumes are exhaled Collection bar is beyond rightmost position	Activate „Automatically rejected volume“ After the breath hold, do not exhale too fast.
DLCO-Warning: High inspiratory CO during tidal breathing!	An increased CO level was detected during the tidal breathing phase.	Check the DLCO valve unit. If the error occurs repeatedly then please contact service.
Test error: # of breaths Test cannot be evaluated; DLCO maneuver cannot be detected	Number of breaths during DLCO expiration could not be detected	Perform the DLCO maneuver with full effort

Message	Criterion	Recommended action
Test error: CO-Calib CO calibration could not be performed: no gas connected to the system or Instrument failure	CO calibration could not be performed: Instrument failure and/or no gas connected to the system	Make sure the gas supply is connected and open
Test error: Time delay Test cannot be evaluated; gas signals do not pass QC check, automatic delay correction failed	Automatic time delay correction failed	Repeat test correctly
Test error: Tidal breathing Test cannot be evaluated; no tidal breathing detected prior to DLCO maneuver	No tidal breathing has been detected before the test	Repeat test correctly
Test error: CO-Insp Drift Maneuver not acceptable; no stable CO signal during breath-hold	During breath-hold, CO signal drifts up or down	Check *spirette™* und *barriette™* position, check connections, check DLCO valve unit
3-point calibration failed (1)	S-factor of the CO sensor outside 0.16 to 0.375	If the error occurs repeatedly, then please contact service.
3-point calibration failed (2)	3-point calibration mixture outside 750 to 1600 ppm CO	If the error occurs repeatedly, then please contact service.
3-point calibration failed (3)	Standard deviation of CO during 3-point calibration greater than 25 ppm	If the error occurs repeatedly, then please contact service.
CO concentration too high (clip)	CO sensor out of range	If the error occurs repeatedly, then please contact service.
CO sensor drift too high	CO drift during measurement › 150 ppm	Repeat the test. If the error occurs again after the device has warmed-up, then please contact service.

Message	Criterion	Recommended action
Test error: data error	General error in DLCO calculation	If the error occurs repeatedly, then please contact service.
DLCO warning: High CO sensor drift!	CO drift during measurement › 60 ppm	The test result must be interpreted with caution

DLCO Acceptability and Quality Grades

Currently, there are not standardized quality grades for DLCO tests. These are the quality grades implemented in *EasyOne Pro™ LAB*:

Quality Grade	Accept. Trials	DLCO Variability[1)]
A	›=2	‹1 ml/min/mmHg
B	›=2	‹2 ml/min/mmHg
C	›=2	‹3 ml/min/mmHg
D	1 or ›=2	›3 ml/min/mmHg
F	-	-

[1)] referring to the two nearest values

The following parameters determine the score and quality grades:

- DLCO variability as a percentage and as an absolute value
- number of accepted trials.

Trials that fulfill the following criteria are accepted:

- VCin ›80 % VCtarget
- breath hold time (BHT) 8.0 to 12.0 s
- inspiratory time ‹4 s
- sample volume ›0.1 L.

Legend

VCin as a percentage of VCtarget: Inspired volume as a percentage of FVC, VC from a previous test. If none of these is available, the target value is taken from the test itself.

BHT: Breath-hold time in seconds.

Sample Volume: Sampling volume for CO and helium measurement (also called collection window). The sampling volume will be outside this window only under special circumstances (e.g. for very small VCs).

Inspiratory time in seconds.

The quality grades are recomputed if the user manually changes the sampling window position (repositioning of the collection bar).

LAB 5.4 FRC Quality Messages

Message	Criterion	Recommended action
FRC(MBW) Warning: Extrapolated volume computation failed (set to zero)!	The extrapolated volume could not be calculated.	Contact service.
FRC(MBW) Warning: Extrapolated volume computation too high (set to zero)!	The extrapolated volume (i.e., the volume that would be washed out after cancellation of the test) is greater than 1 liter.	Do not stop too soon.
FRC(MBW) Warning: Inspiratory leak!	Air entered from outside during inspiration. The end-inspiratory molar mass deviates from the tracer gas molar mass by more than 0.2 g/mol. This is indicative of air drawn in from outside during inspiration.	Check *FRC barriette™*: are valves jammed or was the *FRC barriette™* not been properly inserted? Check position of *spirette™* and of nose clip. Ask patient to breathe calmly.
FRC(MBW) Warning: In- or expiratory pressure too high!	Pressure in sensor tube is too high. The pressure in the sensor tube exceeds ±5 mbar; possible reasons are: 1) Insufficient pressure at the O2 gas port. 2) Patient's breaths are too deep; the respiratory resistance and thus the pressure drop increase from about 2 l/s.	Check O2 gas supply: Is the inlet pressure 3 bar? Only minimal pressure variations are allowed during the test. Is the patient's breathing too deep/too fast? Ask the patient to breathe within the limits of ±1.5 l/s.

Message	Criterion	Recommended action
FRC(MBW) Warning: Side-Stream Flow out of range!	During the test, the gas extraction was not within the limits of 7.5 and 13 ml/s.	Contact service.
FRC(MBW) Warning: CO2 sensor scaling warning!	Automatic scaling of the CO_2 signal failed.	Contact service.
FRC(MBW) Warning: Tracer concentration at test end too high!	No breath with an N_2 concentration below 2% was measured.	Repeat test.
FRC(MBW) Warning: Perform deeper breaths (too small tidal volume)!	Tidal volume outside 4 to 30 mL/kg body weight or outside 0.25 to 0.3 L if the body weight is not stated	Ask patient to breathe regularly and calmly
FRC(MBW) Error: No start of washout detected!	Multi Breath Washout not found.	Perform washout procedure correctly.
FRC(MBW) Error: Error in Gas Signal Delay Correction!	An error occurred during the automatic determination of the delay between gas signals and flow (i.e., the delay is not within the desired range).	Check *FRC barriette™* position. Contact service.
FRC(MBW) Error: Not enough breaths for washout computation!	The number of breaths required for calculation of FRC was not reached.	FRC test was stopped prematurely.

Message	Criterion	Recommended action
FRC(MBW) Error: Error in Tracer Gas Concentration!	The molar mass change caused by the tracer gas does not correspond to the theoretical values.	Check whether O2 is used. Check gas connections for leaks. Check *FRC barriette™* position.
FRC(MBW) Error: Error in Alveolar Curve Computation!	An error occurred during calculation of the alveolar gas curve (from the first breaths of the washout).	Check that the test is correctly performed. Check position of *spirette™* and of nose clip. Contact service.
FRC(MBW) Error: DLCO Valve Unit NOT mounted on handle sensor!		Mount valve unit and repeat procedure.

5.5 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 135 for details).

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

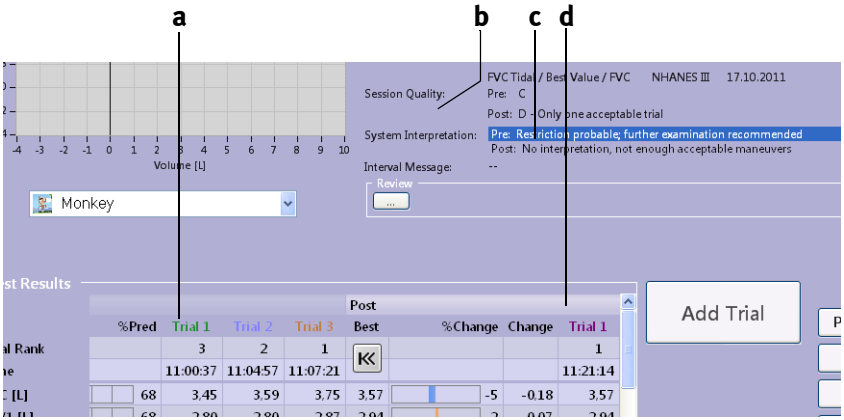


Fig. 5-1 Test results, system interpretation

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

5.6 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. 5-2).

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

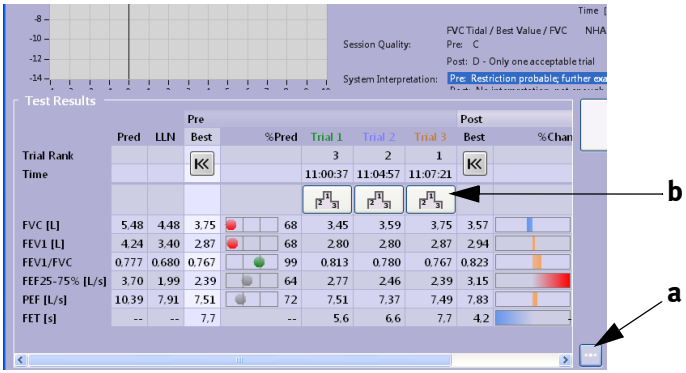


Fig. 5-2 Changing the trial acceptability

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.

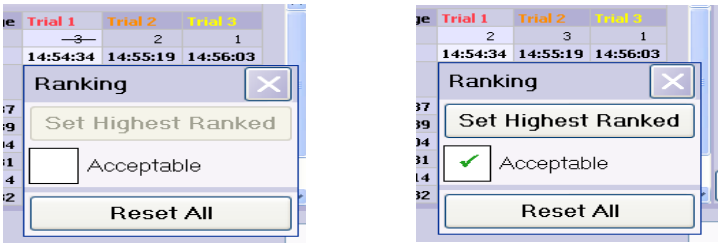


Fig. 5-3 Changing the trial ranking

To assign the highest rank to a test

- click the  icon and
- in the ensuing window, click *Set Highest Ranked* (Fig. 5-4).

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

Fig. 5-4 Changing the trial ranking

Entering comments

- Click in the comment area or click  .
- Enter a user ID, followed by the comment.
- Close the window with **Save**.
  The text will be shown in the comment window, including the user ID and the date.

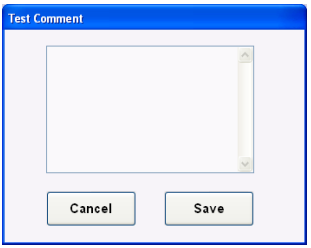


Fig. 5-5 Entering comments

6 Switching the Device Off

Caution
Loss of Data—Be sure to correctly terminate the program before switching *EasyOne Pro™* off with the mains power switch on the back.

- Close the main valve of the gas cylinder.

LAB

- Close the main valve of the O2 gas cylinder or disconnect the wall outlet.

Note
When using the wall outlet, please observe the hospital's in-house instructions and requirements.

- Quit the program with Exit .

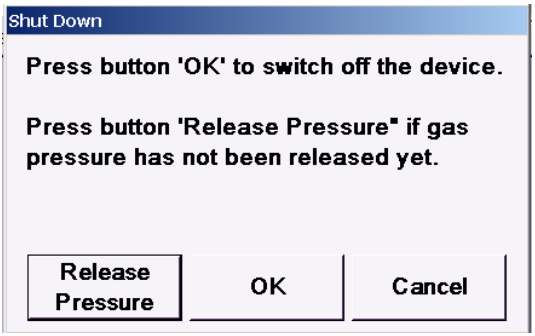


Fig. 6-1

- Switch off *EasyOne Pro™* with **OK**, or release gas pressure with **Release pressure**, if you need to replace a gas cylinder. Then click **OK** to confirm the message. *EasyOne Pro™* will automatically switch off.

Caution
The device will switch off, but it remains connected to line power. Only with the mains power switch at the back will *EasyOne Pro™* be disconnected from line power.

7 Hygiene, Cleaning, Maintenance, Disposal

Hygiene

Caution
Risk of Infection—

- Users with open wounds or contagious diseases on their hands must wear gloves.
- Wash your hands after each patient to protect yourself and to prevent cross contamination.
- The *spirette™* and the *barriette™* must be properly disposed of immediately after use.

Cleaning

Warning
Shock Hazard—Disconnect the device from the power line before cleaning.

- Wipe the device surface down with a cloth moistened with alcohol (70% max.), avoiding the display, the rear panel and the temperature and humidity sensor. Do not let liquid enter the device.
- To clean the rear panel and the temperature and humidity sensor, simply wipe them off with a dry cloth.
- The display is also cleaned with a soft, dry cloth. In case of major contamination, you can use a cloth moistened with alcohol (50% max.).
- Wipe the sensor, the valve unit, the gas supply tube and the power cord down with a cloth moistened with alcohol (70% max.). Do not let liquid enter the parts. Replace the gas supply tube each year.
- The connecting tube to the gas cylinder and the touch stylus can be cleaned with a cloth moistened with alcohol (70% max.).
- The one-way valve can be rubbed down with a cloth moistened with alcohol (50% max.). Clean only the side facing the *barriette™* and the housing. The one-way valve must be replaced each year.

Maintenance

Before each use

Before each use, visually inspect the device, the cables, the tubing and the sensor for signs of mechanical damage. Particularly inspect the gas cylinder(s) and fittings.

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

Once a year

The following parts must be replaced once a year (see "Start-up and Initial Preparation" on page 20):

- the filter pack
- the gas supply tube
- the one-way valve
- the overpressure valve.

All parts are included in the "Yearly Maintenance Kit" 3000-50.50SP (see "Order Information" on page 134).

The filter pack at the back of the device consists of the air inlet with filter and a Nafion tube to dry the sampled gas. Open the screw on the right to replace the filter pack (Fig. 7-1).

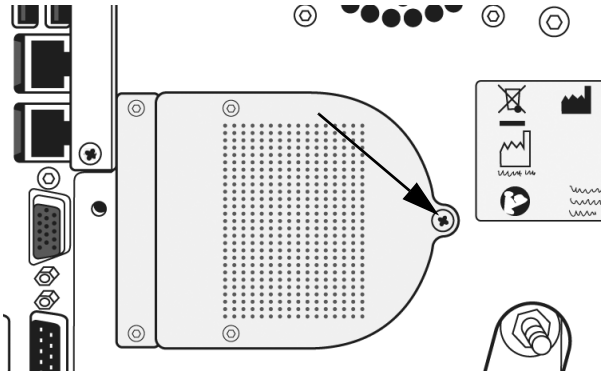


Fig. 7-1 Screw to replace the filter pack

Data Backup on Memory Card

Each time the device shuts down, the patient and configuration data are saved to a memory card (Flash card) (**h**, Fig. 2-2). In case of equipment failure, the memory card can be inserted into another device and you can continue working with the same patient database and equipment configuration.

Follow these steps to exchange the memory card:

- Quit the program with Exit and switch off *EasyOne Pro™* with **OK** (see "Switching the Device Off" on page 99).
- Open the two screws and take off the cover.
- Grasp the tab of the memory card and remove the card from device.
- Insert the memory card into the backup device.
- When the backup device starts up, confirm loading the data from the memory card.

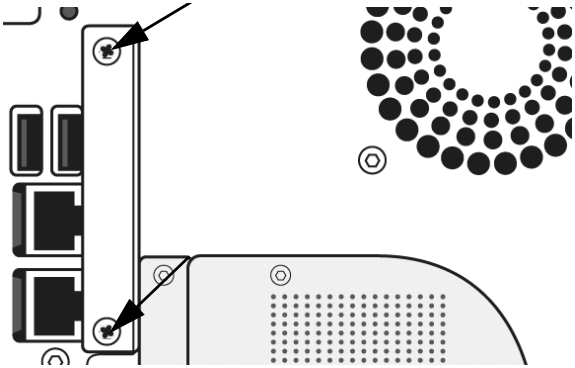


Fig. 7-2 Screws for removing the cover

Data Backup on External Media

To prevent loss of data, we recommend to backup the data on a regular basis, using the *Export* function

- On the initial screen, select *Utilities -› Advanced* and enter the password (EOPTM or 8005).
- Choose *Export* and select the files for the backup.
- Click *Export* to backup the data.

Software Update

The files necessary for a software update are made available by ndd. For a detailed description of the installation procedure, please go to www.ndd.ch, Application Note “Update EasyOne Pro Firmware” or “Update EasyOne Pro-LAB Firmware”.

> **Note**
> Before installing the update, close *Adobe Reader* or the Operator's Manual.

These are the steps of the installation procedure:

1. Data backup
   - Save the patient data to a USB flash drive (memory stick).
2. Preparation
   - Download the most recent revision of the *EasyOne Pro* software from the ndd website: http://www.ndd.ch/Downloads/Software.aspx and copy the data to a USB flash drive (memory stick).
3. Software Update
   - Connect the USB flash drive to *EasyOne Pro™*.
   - Click **Utilities** -› **Advanced**.
   - Enter the password (EOPTM or 8005).
   - Click **Software Update** and double-click the update file on the USB flash drive.
   - Follow the on-screen instructions.
4. Check settings
   - Check whether the sensor symbol is displayed.
5. Check function
   - Perform a calibration test (**Utilities** -› **Calibration test**).

Calibrating the Touch Screen

When you notice that you are no longer able to activate system functions by touching the keys or fields on the display or that the positions have moved, it is necessary to calibrate the touch screen:

- On the initial screen, select *Utilities* -› *Advanced* and enter the password (EOPTM or 8005).
- Select T*ouch calibration*.
- In the ensuing window, select *Configure* -› *Standard Configuration* and follow the displayed prompts.

Caution: When you miss the correct spots, the window will disappear. In this case you have to restart the device and the calibration procedure.

Technical Inspections

For safety, the device requires regular maintenance. To ensure functional and operational safety of the device, Technical Inspections should be carried out on an annual basis.

These checks should be performed by persons with adequate training and experience.

The inspections include the following checks:

- Visually inspect the device and the accessories for signs of mechanical damage that may impair the device functions.
- Check that the device safety labelling is legible.
- Run a functional test.
- Check measuring accuracy (see following section).

Check Measuring Accuracy

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 107).

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

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

- Using the calibration adapter, connect the sensor to the syringe as shown below. Ensure that the piston is fully inserted and at the stop position.
- In the *Utilities* menu, click **Calibration Check**, then select **Syringe Calibration Check**.
- On the test screen, click **Start**.
- Wait until the baseline has been set.
- Now execute one full inspiratory pump stroke followed by one full expiratory pump stroke at moderate speed.

- Three full trials are required for the **Single Flow** calibration check, whereas three tests comprising three trials each with different flow rates are required for the **Multiflow** calibration check.

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

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

If you do not reach ±3% accuracy, please follow the troubleshooting instructions in chapter "Troubleshooting Tips" on page 130. Should you not be able to remedy the defect by following these instructions either, please consult *ndd* or one of their representatives.

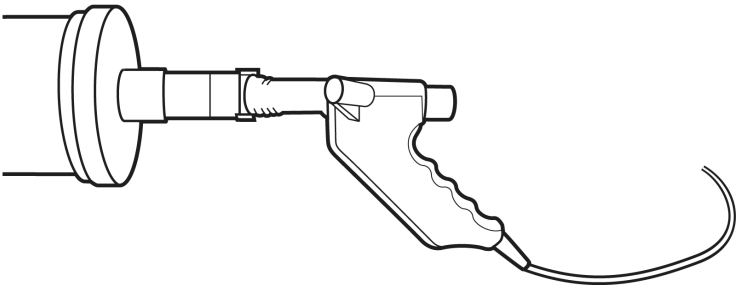


Fig. 7-3 Calibration syringe

DLCO Calibration Check

The American Thoracic Society (ATS) recommends checking DLCO calibration on a weekly basis or whenever irregularities are suspected. DLCO calibration can be checked with a DLCO simulator (see following section) or with a test subject (see "Calibration Check with Test Subject" on page 107).

In addition, the ATS/ERS guidelines (Literature [11], page 182) describe a third method for checking DLCO calibration for which a 3-L syringe is used.

Calibration Check with DLCO Simulator

In the **Utilities** menu, click **Calibration check**, then select **DLCO simulator**.

The test procedure is the same as in a human test ("CO Diffusing Capacity (DLCO)" on page 67). For correct handling of the DLCO simulator, please read the manual of the simulator manufacturer.

Note

We strongly recommend using only DLCO simulators manufactured by Hans Rudolph (DLCO Simulator, 5560 Series).

Also refer to the DLCO simulator operator manual or to the training clip at www.ndd.ch.

As an alternative to checking calibration with a DLCO simulator, the calibration can be checked with a test subject (see "Calibration Check with Test Subject" on page 107).

Make sure the gas concentrations of the test gas AND the Simulator Test Gas are entered correctly as shown in Fig. 8-13.

FRC Calibration Check

LAB

The American Thoracic Society (ATS) recommends that testing of biological controls should be performed at least monthly.

For that purpose use a biological subject and the standard trending functionality.

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 spirometry tests or DLCO tests. These tests are observed and statistically controlled, if they are within an expected range.

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

Note
Also refer to www.ndd.ch. Application Note "DLCO Bio-Calcheck EasyOne Pro".

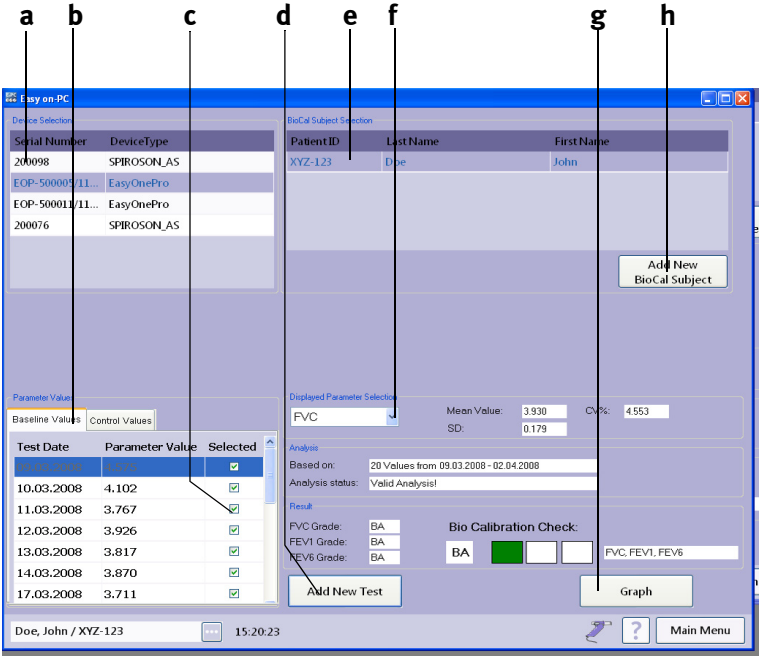


Fig. 7-4 BioCal Check main screen

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

Selecting a Test Subject and Performing the Calibration Check

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

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

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

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

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

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

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

- Press **Finish Test**.
- To show the graphic trend, click the **Graph** button **g**.
- To select another review parameter, change the selection in **Displayed Parameter Selection f**.
- If you selected a spirometry parameter, the spirometry BioCal quality grades will be displayed. If you selected a DLCO parameter, the DLCO BioCal quality grades will be displayed.

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

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

Detailed Description

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

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

Specifications of the BioCal-Check QC Grades

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

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

Disposal

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

8 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** (measuring accuracy check, see "Check Measuring Accuracy" on page 104)
- **Advanced** (password-protected (EOPTM or 8005): installation of software updates, data export, touch screen calibration).

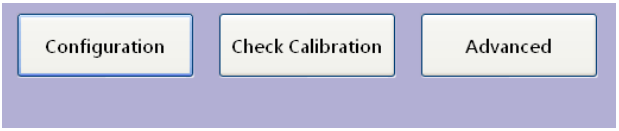


Fig. 8-1 System settings menu

Configuration

These are the tabs of the configuration menu:

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

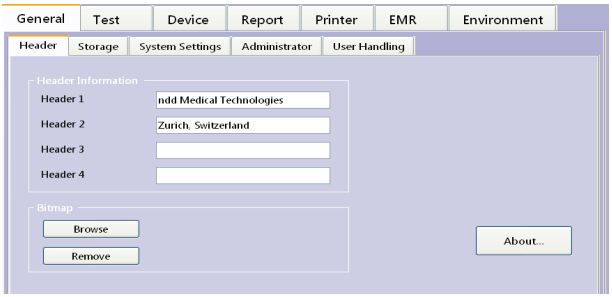


Fig. 8-2 Configuration menu, General tab

General **Tab**

These are the tabs of the *General* tab:

- *Header*
- *Storage*
- *System Settings*
- *Administrator*
- *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, maximum size of the bitmap: 260x80 pixels) **b**
- you open a window with information about the software program **c**.

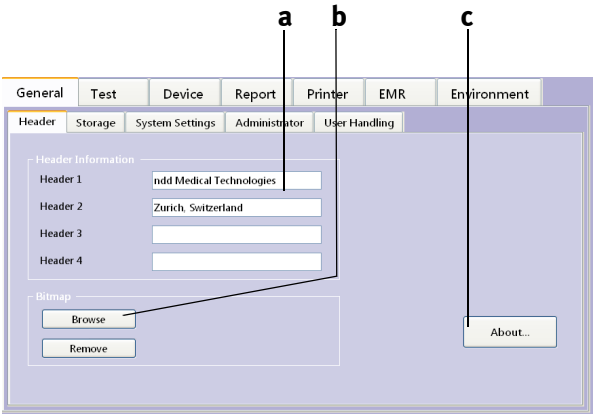


Fig. 8-3 Header tab

a Fields for entry of the hospital/practice name

b Click to display an illustration (logo)

c Click to display information about the software program

Storage **Tab**

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

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

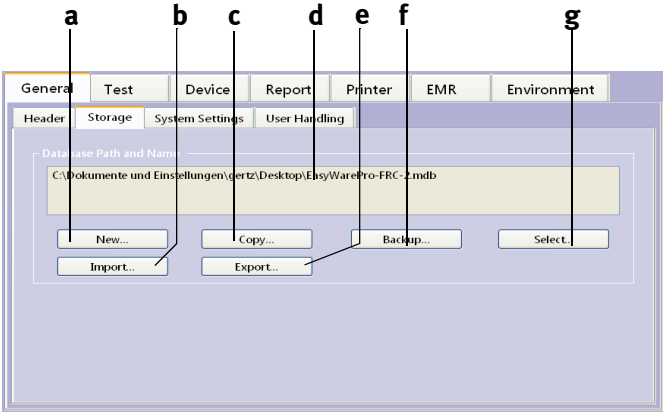


Fig. 8-4 Storage tab

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

System Settings **Tab**

On this tab

- you select the units for length, temperature, weight, hemoglobin and pressure **a**
- you choose whether or not the cursor is always visible, whether a beep is to sound when you click a button and whether all options are to be visible on the *Test* and *Device* tabs (even options not currently implemented in the device) **b**
- you select the regional settings (e.g., the data and time format) **c**
- you select date and time **d**
- you select the language **e**
- you select the keyboard layout **f**
- you select the width of the scroll bar **g**
- you select the volume for the audio signals **h**.

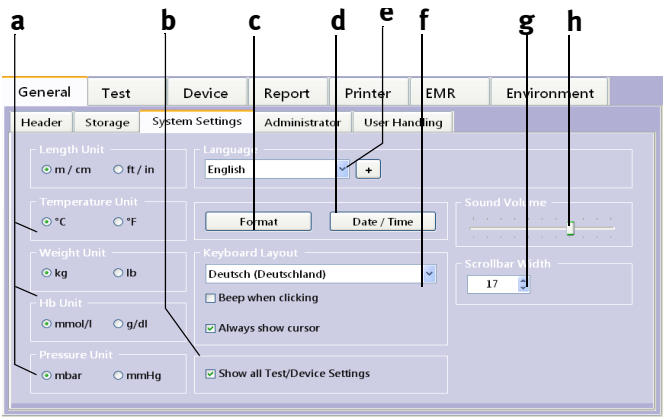


Fig. 8-5 System Settings tab

a Click option button to select the units

b Select check box to always show the cursor, select check box to hear a beep for each key click, and select check box to always view all possible test and device settings, or deselect

c Click to select the regional settings (date and time format)

d Click to select the date and time

e Click to select the language

f Click to select the keyboard layout

g Select the scroll bar width

h Adjust the volume

Administrator **Tab**

On this tab you can do the following (password-protected (EOPTM or 8005):

- map a network drive **a**
- disconnect a network drive **b**
- enter an IP address **c**.

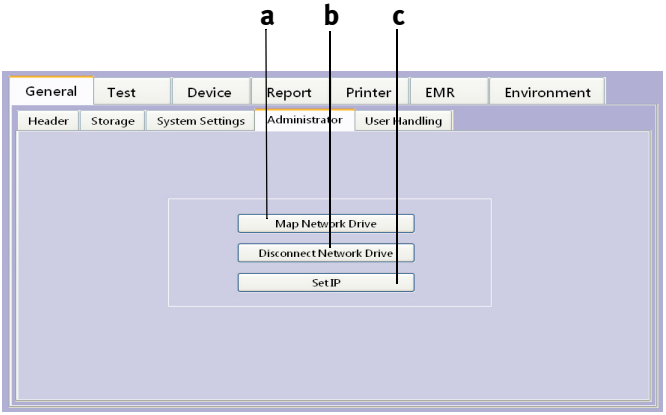


Fig. 8-6 Administrator tab

a Click to map a network drive

b Click to disconnect a network drive

c Click to enter an IP address

User Handling **Tab**

This tab is protected with a password (password EOPTM or 8005). On this tab you can enter an ID for each user. To start the system, users are then required to log on with their ID. Condition: the function is enabled with "Enable user handling" (**c**, Fig. 8-7). 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.

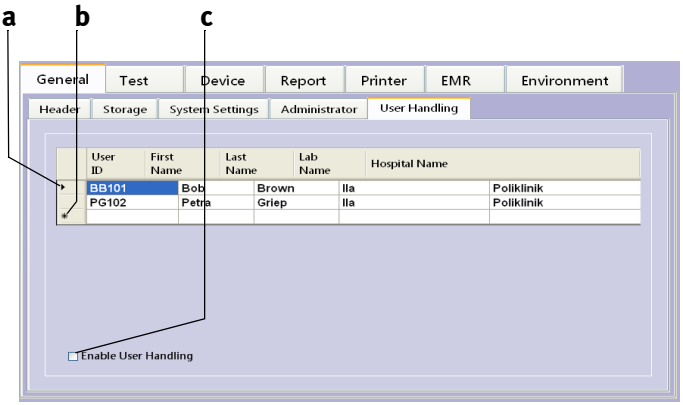


Fig. 8-7 User Handling tab

a Select line to edit logged on users

b Select to enter a new user

c Select check box to enable/disable the function

Test **Tab**

The tab comprises the following sub-menus

- *General*
- *FVC/FVL*
- *SVC*
- *MVV*
- *DLCO*
- *FRC (mbw)*
- *Cal Check*
- *Provocation*

General **Tab**

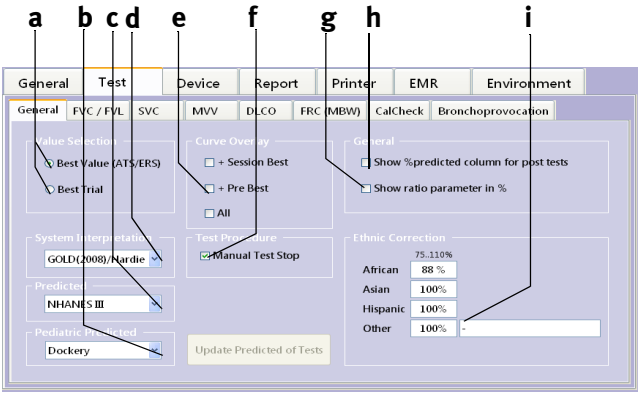


Fig. 8-8 General tab

a Option buttons to select the value (Best Value/Best Trial)

b Click to select the predicted values for children

c Click to select the predicted values for adults

d Select/deselect the system interpretation

e Curve selection criteria

f Select this check box, if you want to stop tests manually

g Select the check box to display the ratio parameter as a percentage value

h Select the check box to display the percentage deviation from predicted for bronchodilation tests; otherwise, remove the check mark by clicking again

i Boxes for entry of correction factors (see Note below)

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

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

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

For the parameters listed below, the best value is the highest value from all accepted trials:

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 / VCmax , MTC1 are recalculated.

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

For DLCO tests, the "Best Value" / "Best Trial" selection is irrelevant. The values are calculated from the average of all accepted trials.

FVC/FVL **Tab**

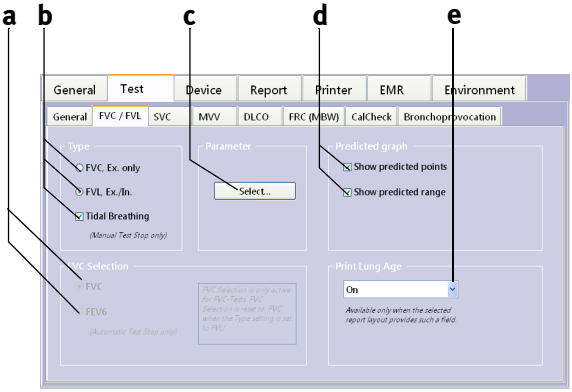


Fig. 8-9 FVC / FVL tab

a Select FVC/FEC6
b Select the test type
c Click to select a parameter
d Predicted values are represented by points or as a range
e Select one of the options if you wish to print the lung age

Note
Additional information for FVC-FEV6 selection: FEV6 indicates the exhaled volume after 6 seconds. When set to FEV6, the program stops the measurement after 6 seconds. Several parameters such as FEF25, FEF50, FEF75 and FEF25-75 are not reported in that setting.

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

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

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

Follow these steps to remove a parameter from the list

- select it in the "Selected" list **c**
- click **d** to remove it from the list.

Click **e** to scroll the list up and down.

Note

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

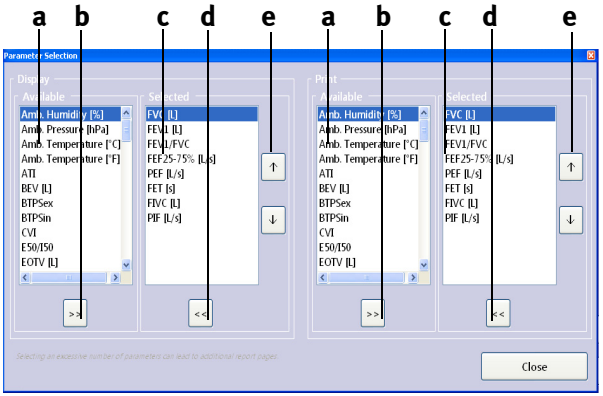


Fig. 8-10 FVC parameters tab

SVC **Tab**

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

You also select the parameters for the SVC measurement.

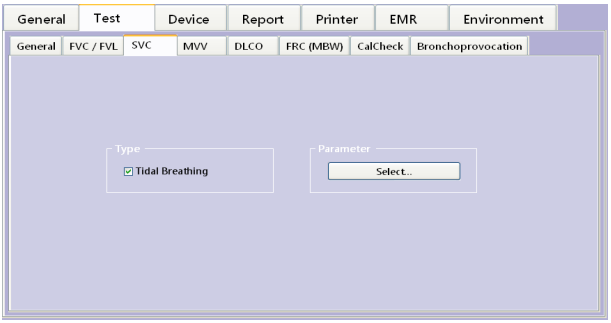


Fig. 8-11 SVC tab

MVV **Tab**

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

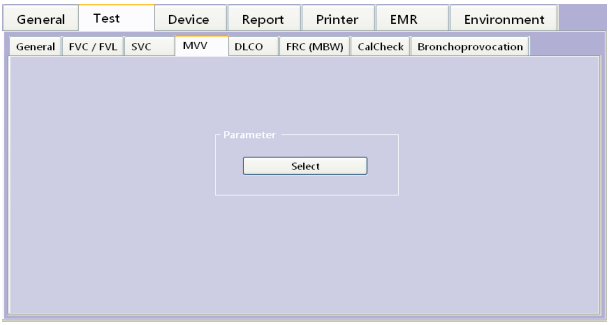


Fig. 8-12 MVV tab

DLCO Tab

On this tab, you set up the device for DLCO tests.

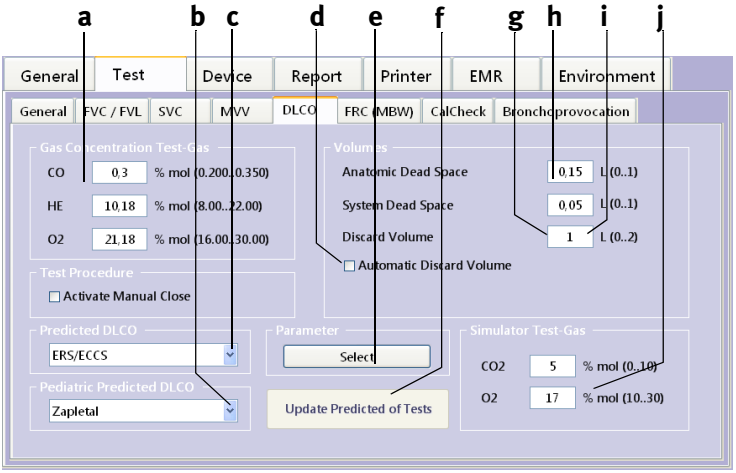


Fig. 8-13 DLCO tab

- *a Selected gas concentration. Compare the displayed values with the data on the gas cylinder. The concentration must be within the range indicated in parentheses.*
- *b Click to select the predicted values for children*
- *c Click to select the predicted values for adults*
- *d Select check box to automatically determine the discard volume*
- *e Click to select a parameter (see Fig. 8-10)*
- *f Click to update the predicted values (e.g., after selecting another predicted value formula)*
- *g System dead space*
- *h Anatomic dead space*
- *i Discarded volume*
- *j Selected concentration of the simulator test gas. Compare the displayed values with the data on the gas cylinder. The concentration must be within the range indicated in parentheses.*

Warning

Inaccurate Test Results—Incorrect gas concentration entries cause inaccurate test results.

LAB

FRC (mbw) **Tab**

On this tab, you set up the device for FRC tests.

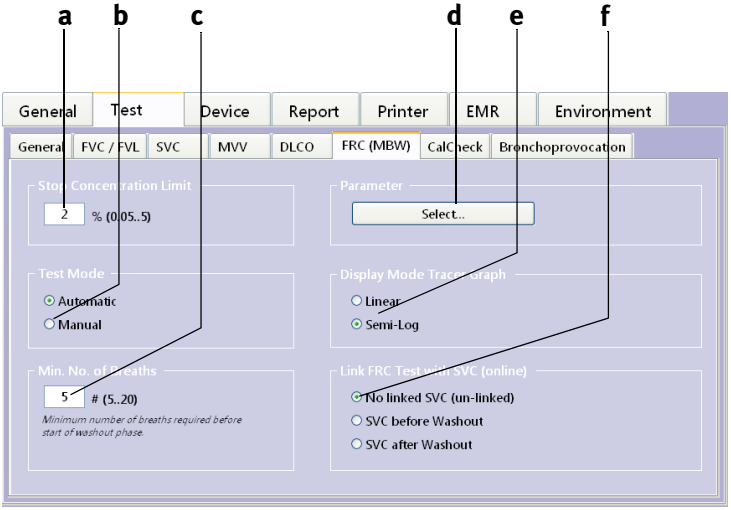


Fig. 8-14 FRC tab

a Gas concentration for automatic termination of the test (default 2 %)

b After the number of breaths specified at c the test either starts automatically or the "Activate" button will be displayed for manually starting the test

c Minimum number of breaths before the washout phase

d Click to select parameters (see Fig. 8-10)

e Choose the tracer curve format

f Click to enable/disable tests linked with SVC

Provocation **Tab**

You select the test protocol from this tab.

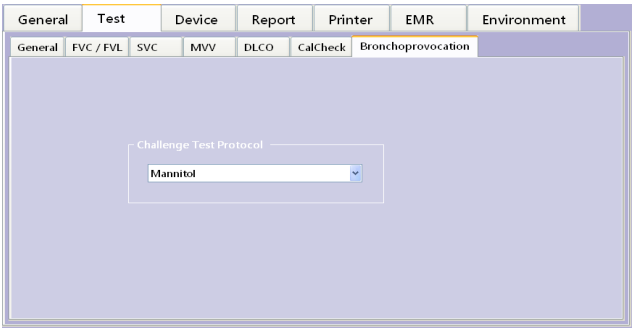


Fig. 8-15 Provocation tab

Device **Tab**

The tab comprises the following sub-menus

- *EasyOnePro*
- *Easy on-PC sensor (USB connector)*
- *EasyOne*
- *Selection*

EasyOne Pro **Tab**

This tab presents detailed information about the device and the CO sensor **a**.

Additionally, you can:

- release the gas pressure **c**
- switch the pump on and off **b**
- open and close the DLCO valve **d**.

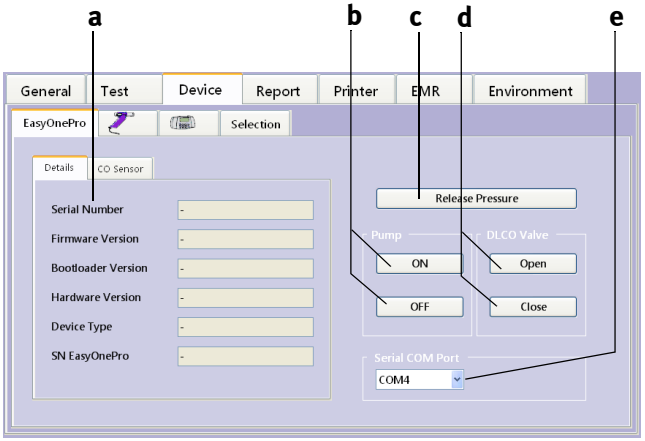


Fig. 8-16 EasyOne Pro tab

a Detailed information about the device and the CO sensor

b Click to switch the pump manually off and on

c Click to release pressure if the gas cylinder has to be exchanged

d Click button to open or close the DLCO valve

e Click to select the sensor port from the dropdown list

EasyOne **Tab**

The tab comprises the following sub-menus

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

Consult the *EasyOne* operator manual for details.

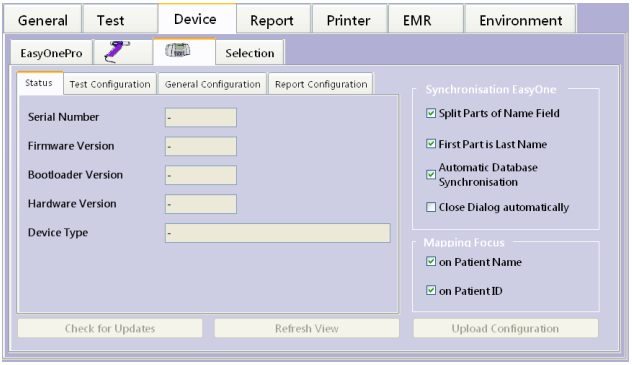


Fig. 8-17 EasyOne tab

Selection **Tab**

Select your preferred sensor type on this tab.

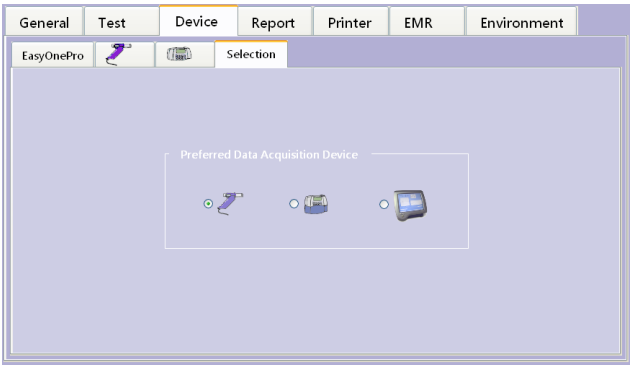


Fig. 8-18 Selection tab

Report **Tab**

On the *Report* tab, you can:

- display the Report Designer (Layout Editor, see "Report Designer" on page 150) **a**
- load layouts (Load layout, also refer to www.ndd.ch. Application Note "EasyOne Pro import Layout") **b**
- save layouts (Export layout) **c**
- select the files for an XML export **d**

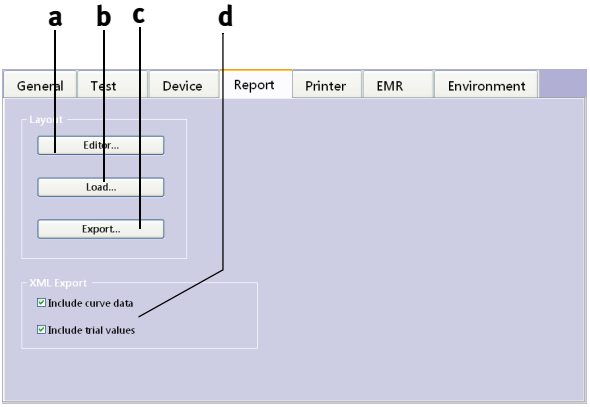


Fig. 8-19 Report tab

a Press to display the Report Designer
b Press to load report layouts
c Press to save (export) layouts
d Press to select the data for an XML export

Printer **Tab**

After connection of the printer you select the printer driver on this tab (see "Connecting the Printer" on page 31).

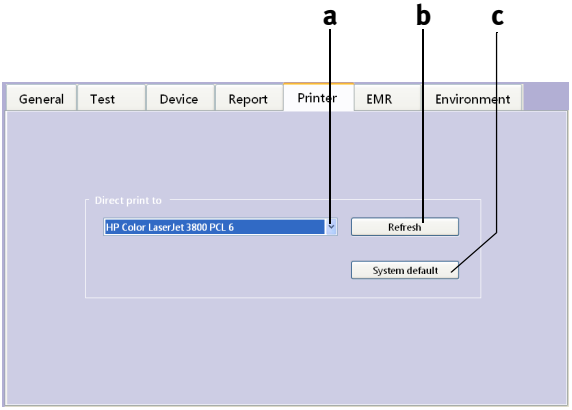


Fig. 8-20 Printer tab

a Press to open the printer list
b Press to update the printer list
c Select the default printer

EMR **Tab**

Here you select the EMR system and the corresponding settings (see "GDT Interface" on page 140).

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

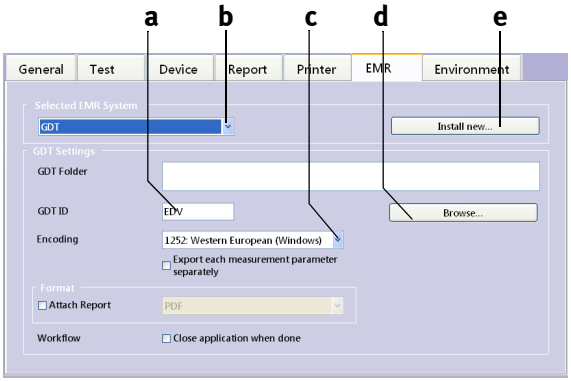


Fig. 8-21 EMR tab

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

Environment **Tab**

On this tab you enter the ambient conditions. These will be overwritten by values entered prior to the test (see "FVL Test (inspiratory and expiratory measurement)" on page 51).

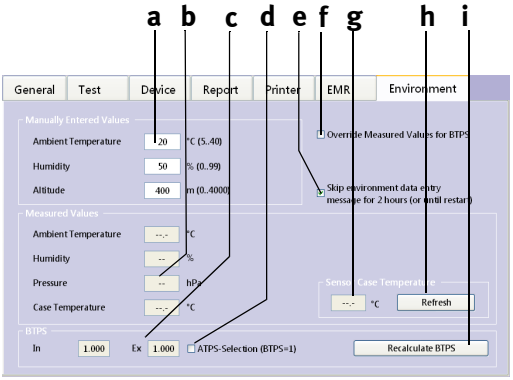


Fig. 8-22 Environment tab

a Boxes for entry of room temperature, relative humidity and altitude (above sea level) of the examination site

b Measured values for room temperature, relative humidity, altitude (above sea level), and case temperature

c BTPS conversion factor

d ATPS values will be used, yes/no (no BTPS conversion)

e 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.

f The values entered at a will be used for BTPS calculation.

g Sensor case temperature

h Click to close the window, saving the data

i Recalculate BTPS conversion factor (e.g. after a change of the ambient conditions)

9 Troubleshooting Tips

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

When the *EasyOne Pro™* 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 ndd dealer.
When you start a test, you see the message *Check spirette insertion*.	The *spirette™* is not correctly positioned.	Ensure that the triangle on the spirometer is lined up with the triangle on the *spirette™*
Calibration check outside ±3.5%.	The *spirette™* is not correctly positioned.	Insert the *spirette™* as described in section "Inserting the One-Way Valve, DLCO barriette™/FRC barriette™ and spirette™" on page 35.
	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 *Configuration* › *Test* › *Cal-Check*.

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

10 Specifications

Dimensions	270 x 335 x 270 mm^3 (h x w x d)	
Weight [kg]	‹ 8 kg, LAB ‹ 9 kg	
Flow/volume measurement	Accuracy, volume:	±2% or 0.050 l
	Accuracy, flow:	±2% or 0.020 l/s (except PEF)
	Accuracy, PEF:	±5% or 0.200 l
	Accuracy, MVV:	±5% or 5 l/min
	Resolution, volume	›1 ml
	Resolution, flow	›4 ml/s
	Measuring range, volume	±12 l
	Measuring range, flow	±16 l/s
	Resistance	‹1.5 cm H_2O/l/s at 12 l/s
Molar mass analyzer	Type	ultrasonic transit time
	Measuring range	9 to 50 g/mol
	Accuracy	‹0.02 g/mol
	Resolution	0.01 g/mol
Carbon monoxide analyzer	Type	NDIR
	Measuring range	0 to 0.35%
	Accuracy	±0.001%
	Resolution	0.0001%
CO2 analyzer (LAB only)	Type	nondispersive infrared
	Measuring range	0 to 15%
	Resolution	0.005%
	Accuracy	from 0 to 5%:±0.05% from 5 to 10%:±0.20% ›10%: not specified
Mouth pressure transducer	Measuring range	±100 mbar
	Accuracy	±5%

Predicted values (spirometry)	NHANES III, Knudson_83, Knudson_76, Crapo, Morris, Hsu, Dockery (Harvard), Polgar, Gutierrez (Canada), Eigen, Pereira, Pereira 2006/2008, Pérez-Padilla (PLATINO), Pérez Padilla (Mexico), Pérez Padilla (Mexico, Ped.), Chile 2010, 1997, ERS (ECCS/EGKS), Zapletal 1977, Zapletal 2003, Stanojevic 2009 (GLI), Quanjer 2012 (GLI), Rosenthal, Austria 1988, Austria 1994, Sapaldia (Swiss), Roca (Spain, SEPAR), Vilozni 2005, Falaschetti, Klement (Russia), Hedenström (Sweden), Gulsvik, (Norway), Berglund, Birath (Sweden), Langhammer (Norway), Finnish, Nystad, Hibbert, Gore, Crockett, Ethiopia, Asia 1-4, JRS 2001, Fukuda Standard (see "Predicted Values" on page 139)	
Predicted values (lung capacity and DLCO)	Ayers, Burrows, Crapo, Goldman & Becklake, Knudson, McGrath & Thompson, Miller, Gutierrez (Canada), Klement (Russia), NHANES, Polgar, ERS, Zapletal, Roca, Hedenström, Gulsvik, Pereira 2008, Thompson (see "Predicted Values" on page 139)	
Operating conditions	Temperature	5 to 40 °C (41 to 104 °F) LAB: 10 to 40 °C (50 to 104 °F)
	Relative humidity	15% to 95%, no condensation LAB: 30% to 75%, no condensation
	Atmospheric pressure	700 to 1060 hPa
Storage/ transport	Temperature	-20 to 50 °C (-4 to +122 °F)
	Relative humidity	5% to 95%, no condensation
	Atmospheric pressure	500 to 1060 hPa
Certifications	CE Declaration of conformity	
Device classification	Protection class I Type BF applied part Furthermore the device is not intended to be used in the presence of oxygen rich environments. However, where the device contains oxygen rich environments, it complies with applicable requirements for fire prevention.	
Operating voltage range	100 to 240 V, 50 to 60 Hz	

Power consumption [max.]	80 VA
Life time	7 years

11 Order Information

Accessories

2050-1	*spirette™* , pkg. of 50
2050-3	*spirette™* with lip seal, pkg. of 40
2050-5	*spirette™* , pkg. of 200
3050-1	*DLCO barriette™*, pkg. of 50
3050-2	*DLCO barriette™*, pkg. of 100
3150-1	*FRC barriette™*, pkg. of 40 (for *EasyOne Pro™ LAB* only)
3000-60.1	Stand
3000-60.2	Carry bag

Spare Parts

3000-50.1SP	Filter pack
3000-50.2SP	Motor block
3000-50.3SP	DLCO valve
3000-50.4SP	Pressure tube DLCO
3100-50.8SP	Pressure tube FRC (for *EasyOne Pro™ LAB* only)
3000-50.4.1SP	Quick Connect fitting for gas pressure regulator
3000-50.5SP	Flow sensor
3000-50.6SP	Touch stylus
3000-50.7SP	Temperature sensor
3000-50.8SP	Gas supply tube
3000-50.9SP	One-way valve
3000-50.10SP	Pressure relief valve
3000-50.50SP	Yearly Maintenance Kit

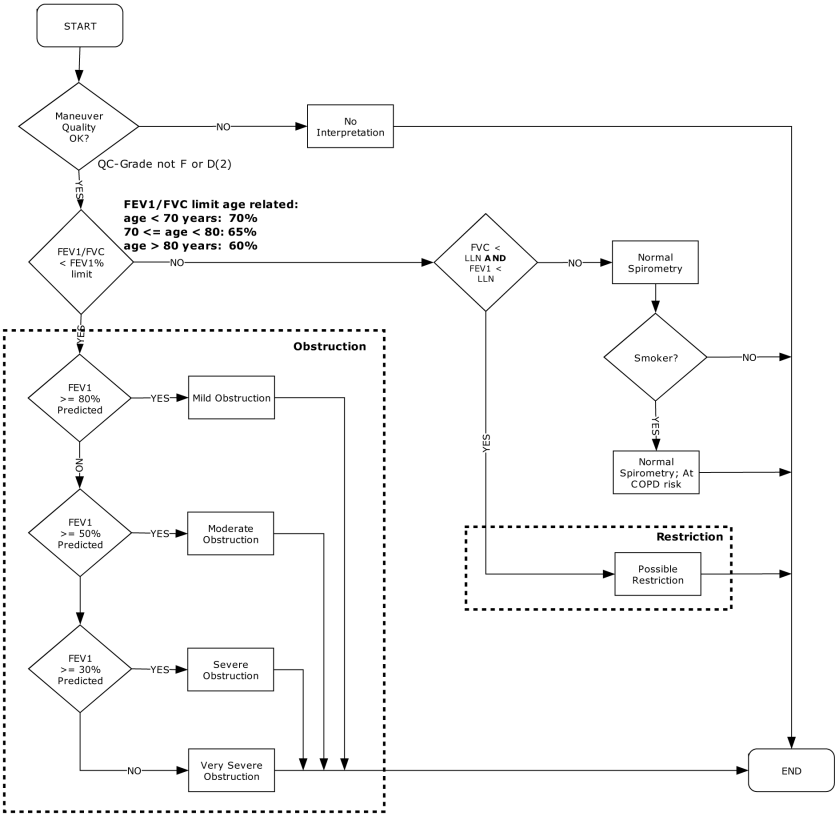
12 Appendix

12.1 Interpretation

The automatic system interpretation can be selected and deselected on the configuration tab (see "General Tab" on page 111).

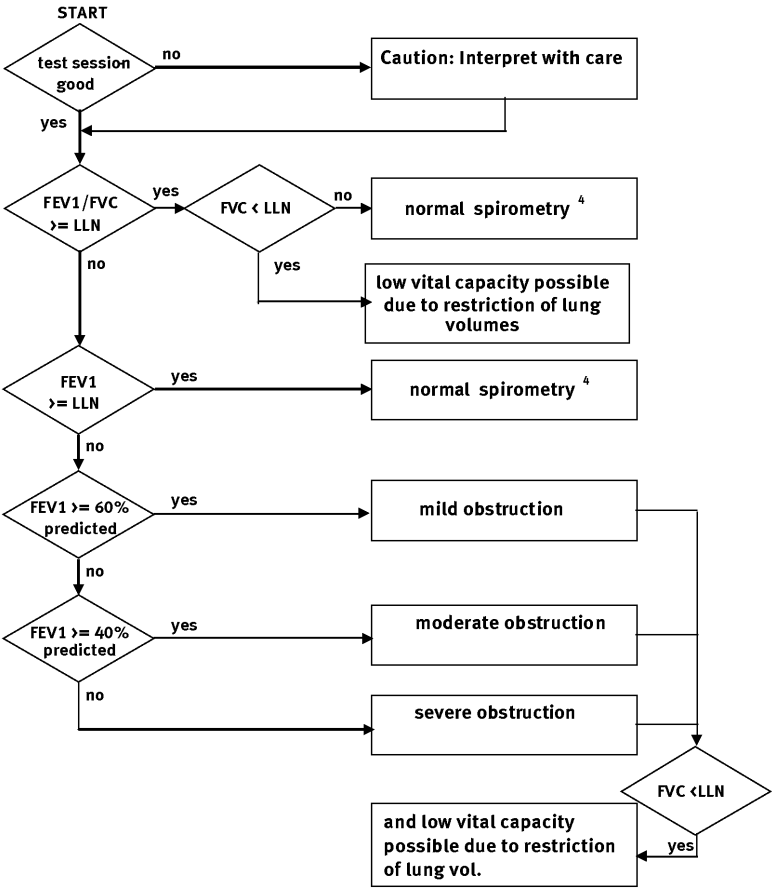
GOLD-Hardie Interpretation

The following diagram outlines the criteria *EasyOne Pro™* applies in the automatic interpretation after GOLD/HARDIE (see "Literature" on page 182 [12], [13]).



NLHEP Interpretation

The following diagram outlines the criteria *EasyOne Pro™* applies in the automatic interpretation after NLHEP (see "Literature" on page 182 [4]).

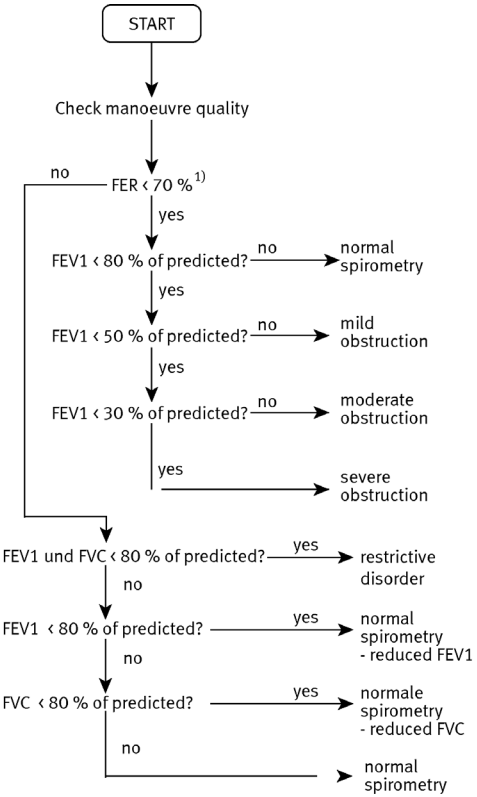


Note:

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

NICE Interpretation

Predominantly used in Great Britain. Source unknown.



1) FER = FEV1/FVC

NICE 2010 Interpretation

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

The NICE 2010 interpretation according to this algorithm (Fig. 12-1) does not detect restrictive disorders. Our application, however, always identifies restrictive disorders if FVC and FEV1 ‹ LLN.

Table 4 Gradation of severity of airflow obstruction

		NICE clinical guideline 12 (2004)	ATS/ERS[4] 2004	GOLD 2008[5]	NICE clinical guideline 101 (2010)
Post-bronchodilator FEV_1/FVC	**FEV_1 % predicted**	**Severity of airflow obstruction**			
			Post-bronchodilator	Post-bronchodilator	Post-bronchodilator
< 0.7	≥ 80%		Mild	Stage 1 – Mild	Stage 1 – Mild*
< 0.7	50–79%	Mild	Moderate	Stage 2 – Moderate	Stage 2 – Moderate
< 0.7	30–49%	Moderate	Severe	Stage 3 – Severe	Stage 3 – Severe
< 0.7	< 30%	Severe	Very severe	Stage 4 – Very severe**	Stage 4 – Very severe**

*Symptoms should be present to diagnose COPD in people with mild airflow obstruction (see recommendation 1.1.1.1).
**Or FEV_1 < 50% with respiratory failure.

Fig. 12-1

System Interpretation Messages

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

12.2 Predicted Values

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

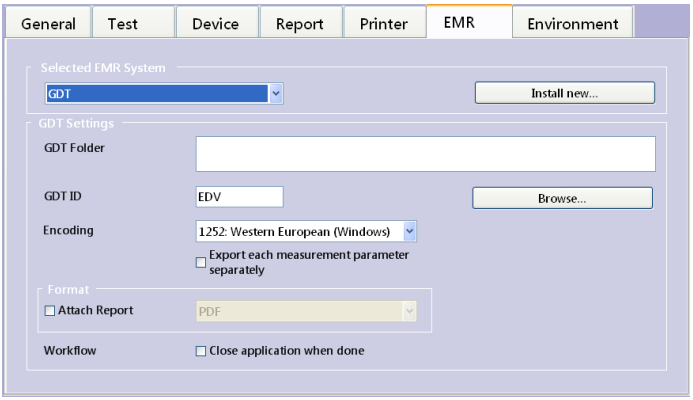
12.3 GDT Interface

Introduction

The following describes the interface set up to facilitate the data communication between *EasyOne Pro™* 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 *Browse* 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	*EasyOne Pro™*	Name of equipment
Program	c:\nddmed\EasyWarePro.exe	Complete path of EasyWare software.
Export File	c:\nddmed\nddturbomed.gdt	Name and path of the export file.
Import File	c:\nddmed\turbomedndd.gdt	Name and path of the import file. The path (in the example c:\nddmed\) 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 **End**.

These adjustments are sufficient for the set up of the EMR software. Now proceed with the set up of *EasyOne Pro™*.

Setup *EasyOne Pro™* Software

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

- Start *EasyOne Pro™*.
- 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:\nddmed\).
- Enter the EMR computer name as "TurboMed".
- Confirm the dialog with **OK**.
- Close *EasyOne Pro™*.

Performing a Measurement

The following describes the test procedure.

- Start *TurboMed*, select a patient and open that file.
- Select *Konsultationen / Geräteanbindung*.
- Select *EasyOne Pro™* 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 *EasyOne Pro™*).

TurboMed now receives the data.

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

Data accepted by *EasyOne Pro™* from EMR / GDT

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

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 (nddPCS.gdt), received from an EMR with the name PCS:

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

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

View of tests with *EasyOne Pro™*

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

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

8432ddmmyyyy	(day, month, year)
8439hhmmss	(hours, minutes, seconds)

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

Example "forced expiratory spirometry"

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

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

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

12.4 Introduction to Adjustment of DLCO Measurements

Adjustments of DLCO measurements are described in detail in the 2005 ERS/ATS statement.

In the paper, however, the adjustment is described as a change of the DLCO predicted values. After several discussions with opinion leaders, we have to conclude that it is more common to compute a DL_{adj} value that is computed from the measured DLCO value. This DL_{adj} value is then compared to the (unchanged) predicted values. The following table describes this:

Comment	Parameter	Predicted	% Predicted
	$DLCO_{meas}$	$DLCO_{pred}$	$DLCO_{pred}$ / $DLCO_{meas}$
ERS/ATS statement	$DLCO_{meas}$	$DLCO_{pred} \times \alpha$	$DLCO_{pred} \times \alpha$ / $DLCO_{meas}$
EasyOne Pro	$DL_{adj} = DLCO \times \beta$	$DLCO_{pred}$	$DLCO_{pred}$ / ($DLCO_{meas} \times \beta$)

As can be seen from the table above, the %Predicted is the same if $\beta = 1 / \alpha$.

This means that the equations of the ERS/ATS statement have to be inverted (e.g. factor is multiplied instead of divided). If compared to the original formulas in the ERS/ATS statement the following formulas are therefore 'inverted' (multiplication instead of division and vice versa).

Adjustment for hemoglobin

The following formula is applied to correct for hemoglobin:

Male adults (age ≥ 15): $DL_{adj} = DLCO / (1.7 \times Hb / (10.22 + Hb))$
Hb in g/dl

Female and children (age < 15): $DL_{adj} = DLCO / (1.7 \times Hb / (9.38 + Hb))$
Hb in g/dl

Unit conversion: Hb [g/dl] = Hb [mmol/l]/0.616
(according to other sources, the factor is 0.6206)

Allowed range for Hb: 0 to 100 g/dl

Default value male adults (age ≥ 15): 14.6 g/dl (9.00 mmol/l)

Default value female and children (age < 15): 13.4 g/dl (8.26 mmol/l

Adjustment for P_{AO2} or Altitude

The following formula for DL_{adj} is applied if the patient uses supplemental O_2:

$DL_{adj} = DLCO \times (1 + 0.0035 \times (P_{AO2} - 100))$ P_{AO2} in mm Hg

If no supplemental O2 is applied the following formula is always applied to correct for altitude. The partial pressure of O2 in the lungs is computed by subtracting the water vapor pressure in the lungs (47 mmHg) from the ambient pressure and multiplying it with the O2 concentration:

$DL_{adj} = DLCO \times (1 + 0.0031 \times (P_{IO2} - 150))$ P_{IO2} in mmHg

$P_{IO2} = (P_{amb} - 47) \times 0.20942$ P_{amb} and P_{H2O} in mm Hg

Unit conversion: P [mm Hg] = P [mbar] × 0.750

Pressure at altitude: $P_{amb} = 760 \cdot \left(1 - \frac{0,0065 \cdot h}{288}\right)^{5,255}$

P_{amb} in mm Hg, h in m

Allowed range for P: 100 to 750 mm Hg

Adjustment for COHb concentration and CO back pressure

Adjustment for carboxyhaemoglobin is performed as follows:

$DL_{adj} = DLCO / (102\ \% - CO\text{-}Hb\%)$ CO-Hb in %

Allowed range for CO-Hb: 0 bis 100 %

Default value: 2 % (at this value DL_{adj} equals DCLO)

Example of DLCO adjustment

The following example can be used to test the DLCO adjustment feature.

Factor		Adjustment for men	Adjustment for women and children (< 15 J)
Hemoglobin	32.4675 mmol/l	0.7023	0.69292
P_{A02}	400 mbar	1.7	1.7
CO-Hb	30 %	1.38889	1.38889
Total correction factor		1.6582	1.6361

12.5 How to interpret TLC from a single breath maneuver

Instruments for lung volume measurement (Body Plethysmography, Multi-breath Nitrogen Washout or Helium equilibration methods) today require well trained personnel, stable conditions and significant maintenance to provide reliable results. Therefore, these tests are normally performed in larger, hospital based lung function laboratories.

It has been shown that a total lung capacity (TLC) measured from a single breath maneuver (TLCsb) systematically underestimates the TLC when compared to Body Plethysmography (TLCpleth) or Multibreath washout (TLC-wash) methods. The degree of underestimation has been shown to increase as airflow obstruction worsens.

A study by Punjabi, et al [1] shows that an approximation of the TLCpleth and TLCwash is possible by applying a simple correction formula to the single breath TLCsb:

Without correction Punjabi showed:

- there is a very good correlation between TLCsb and TLCpleth (r=0.97-0.99) in patients with FEV1/FVC ›70%. Therefore, no correction of the TLCsb was necessary in patients without obstructive patterns.
- in patients with FEV1/FVC ‹70%, TLCsb is a systematically underestimated and showed poor correlation to TLCwash (r = 0.67-0.94)

After using the simple correction equation:

- they showed that in patients with FEV1/FVC ‹70% (range: 40-70%) had an acceptable correlation between TLCsb and TLCwash (r = 0.83-0.94, p‹0.05). The software labels of all Punjabi-corrected values (if any) with “Cor”, e.g., “TLC Cor.”.

This means that in patients with FEV1/FVC ratios › 70%, the TLCsb is reliable and can be used directly in the ATS/ERS interpretative strategies diagnostic algorithm. When the TLCsb is measured in the presence of an obstructive pattern (FEV1/FVC ‹ 70%), it needs adjustment by the equation of Punjabi and then applied to the ATS/ERS diagnostic algorithm. The only possibility of an difference in diagnosis between using a corrected TLCsb and a TLC measured with plethysmography or N2-wahout is when the corrected TLCsb falls below the lower limit of normal.

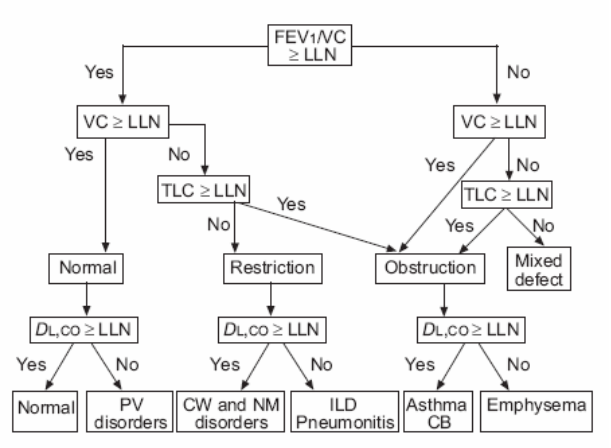
The decision Tree according to the ATS/ERS Task force

In the decision tree published by the ATS ERS Task Force(2) “Standardization of Lung Function Testing” some yes/no decisions are based on the TLC. The value being above or below the lower limit of normal (LLN) determines the diagnostic path:

- For the case that TLCsb from the single breath maneuver is above LLN, it is always correct to use the measured result in the ATS/ERS algorithm for

the decision. Note below, that in the both decision nodes, where the TLCsb › LLN, the diagnosis would be “Obstruction”.

- In the case that an uncorrected single breath TLCsb is below the lower limit of normal there is a risk of incorrectly concluding a “Restriction” or a “Mixed Defect” (Obstruction AND Restriction) when none is actually present. If the FEV1/FVC ratio is ‹ 70%, the regression equation can be used to correct the TLCsb to a value more consistent with the TLCpleth or TLC-wash, reducing the possibility of an incorrect decision.



12.6 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**.

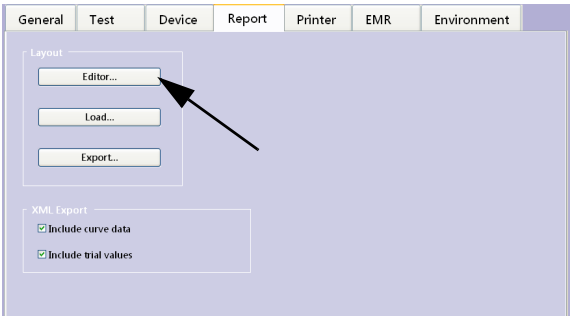
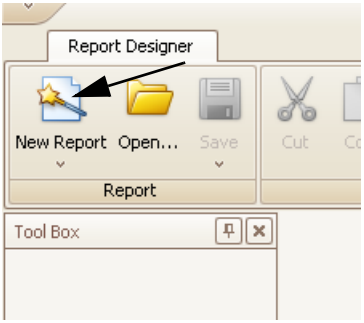


Fig. 12-2: Report tab

Adding a Logo to an Existing Test

- On the Report Designer tab, select **New Report** (Fig. 12-3: left).



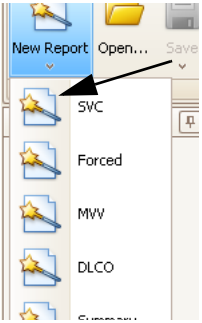


Fig. 12-3: New Report button (left), test selection (right)

- Select the test to which you want to add the logo (Fig. 12-3: right).

- Select the **Picture Box** (Fig. 12-4:).

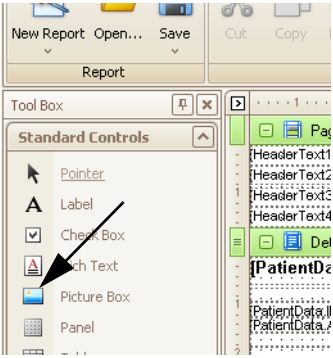


Fig. 12-4: Picture Box button

- Insert the frame in the appropriate position (Fig. 12-5:).

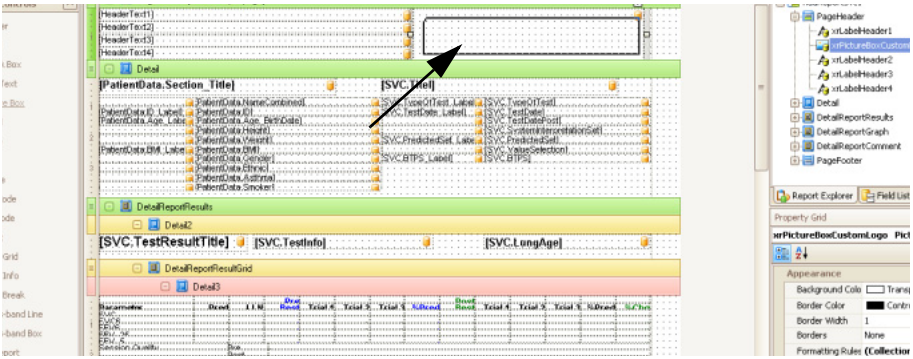


Fig. 12-5: Positioning the frame

- Select **Image** and click  to open the Explorer (Fig. 12-6:) .

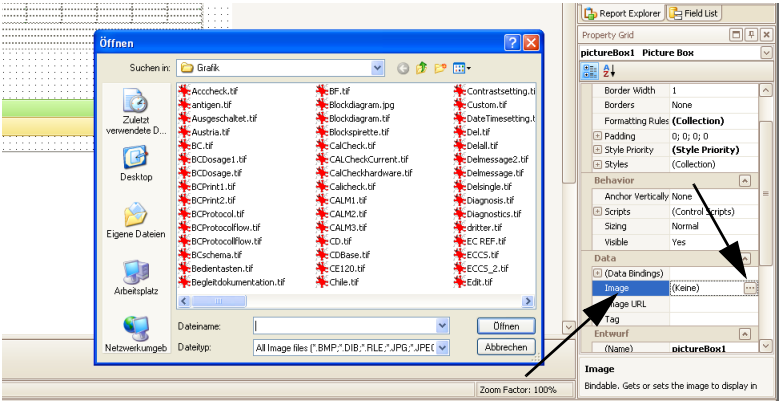


Fig. 12-6: Image button

- Select the logo (Fig. 12-6:). The logo will appear in the frame.
- Save the test under a new name.

Configuring the Graphic Representation of an Existing Test

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

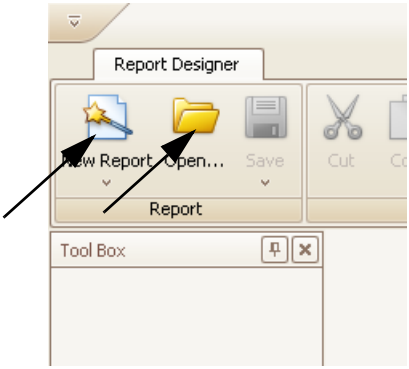


Fig. 12-7: New Report, Open buttons

- Select **Windows** and then **Report Explorer** (Fig. 12-8:).
- Select **Detail Report Graph** (Fig. 12-8:).
- Click **graphVT1.**

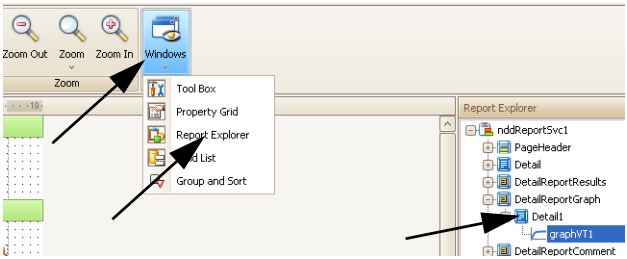


Fig. 12-8: Windows, Report Explorer, Detail Report Graph buttons

- Click the small arrow in the upper right corner of the *Detail Report Graph* window (Fig. 12-8:).
- Click **Run Designer**. The Spiro Graph Configuration window will be displayed (Fig. 12-10:).

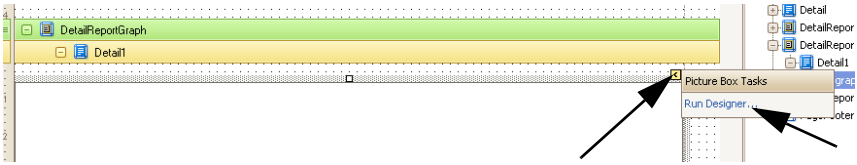


Fig. 12-9: Detail Report Graph window

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

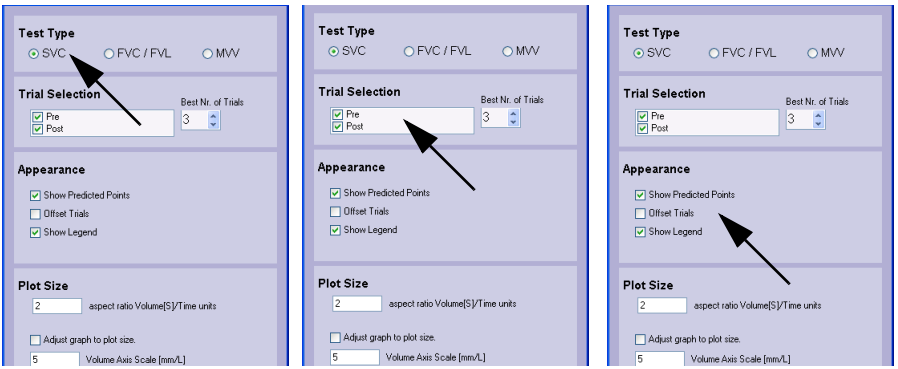


Fig. 12-10: Spiro Graph Configuration window

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

12.7 Electromagnetic Compatibility (EMC)

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

Warning

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

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
EasyOne Pro™ is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that *EasyOne Pro™* is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions to EN 55011	Group 1	*EasyOne Pro™* 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	*EasyOne Pro™* 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.
Harmonic emissions to EN61000-3-2/IEC61000-3-2	not applicable	
Voltage fluctuations/flicker to EN61000-3-3/IEC 61000-3-3	not applicable	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
EasyOne Pro™ is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that *EasyOne Pro™* 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			
EasyOne Pro™ is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that *EasyOne Pro™* is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	**Electromagnetic Environment - Guidance**
Conducted RF to EN 61000-4-6 Radiated RF to EN 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of *EasyOne Pro™*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ for 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol 
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 *EasyOne Pro™* is used exceeds the applicable RF compliance level above, *EasyOne Pro™* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating *EasyOne Pro™*.

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 communication equipment and *EasyOne Pro™*

EasyOne Pro™ is intended for use in the electromagnetic environment on which radiated RF disturbances are controlled. The customer or the user of *EasyOne Pro™* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and *EasyOne Pro™* 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	**0.38**	**0.38**	**0.73**
1	**1.2**	**1.2**	**2.3**
10	**3.8**	**3.8**	**7.3**
100	**12**	**12**	**23**

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

Warning
The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity performance of the equipment or system

The table below lists cables, transducers, and other applicable accessories with which ndd claims EMC compliance.

Note
Any supplied accessories that do not affect EMC compliance are not included.

Ethernet cable, 1.5 m, shielded
USB cable, 2 m, shielded
VGA cable including 2 ferrites, 1.8 m, shielded
Sensor cable, 1.7 m, shielded
Temperature / humidity sensor cable, 0.4 m, shielded

12.8 Microsoft Software License Terms for Windows® XP Embedded Runtime

These license terms are an agreement between you and *ndd Medizintechnik AG*. Please read them. They apply to the software included on this device. The software also includes any separate media on which you received the software.

The software on this device includes software licensed from Microsoft Corporation or its affiliate.

The terms also apply to any Microsoft

- Updates,
- Supplements,
- Internet-based services, and
- Support services

for this software, unless other terms accompany those items. If so, those terms apply. If you obtain updates or supplements directly from Microsoft, then Microsoft, and not *ndd Medizintechnik AG*, licenses those to you.

As described below, using some features also operates as your consent to the transmission of certain standard computer information for Internet-based services.

By using the software, you accept these terms. If you do not accept them, do not use or copy the software. Instead, contact *ndd Medizintechnik AG* **to determine its return policy for a refund or credit.**

If you comply with these license terms, you have the rights below.

1. Use Rights.

You may use the software on the device with which you acquired the software.

2. Additional Licensing Requirements and/or Use Rights.

- **Specific Use**. ndd Medizintechnik AG designed this device for a specific use. You may only use the software for that use.
- **Other Software**. You may use other programs with the software as long as the other programs
  - Directly support the manufacturer's specific use for the device, or
  - Provide system utilities, resource management, or anti-virus or similar protection.

  Software that provides consumer or business tasks or processes may not be run on the device. This includes email, word processing, spreadsheet, database, scheduling and personal finance software. The device may use terminal services protocols to access such software running on a server.

- **Device Connections.**
  - You may use terminal services protocols to connect the device to another device running business task or processes software such as email, word processing, scheduling or spreadsheets.
  - You may allow up to ten other devices to access the software to use
  - File Services,
  - Print Services,
  - Internet Information Services, and
  - Internet Connection Sharing and Telephony Services.

  The ten connection limit applies to devices that access the software indirectly through "multiplexing" or other software or hardware that pools connections. You may use unlimited inbound connections at any time via TCP/IP.

3. Scope of License. The software is licensed, not sold. This agreement only gives you some rights to use the software. *ndd Medizintechnik AG* and Microsoft reserve all other rights. Unless applicable law gives you more rights despite this limitation, you may use the software only as expressly permitted in this agreement. In doing so, you must comply with any technical limitations in the software that allow you to use it

only in certain ways. For more information, see the software documentation or contact *ndd Medizintechnik AG*. Except and only to the extent permitted by applicable law despite these limitations, you may not:

- Work around any technical limitations in the software;
- Reverse engineer, decompile or disassemble the software;
- Make more copies of the software than specified in this agreement;
- Publish the software for others to copy;
- Rent, lease or lend the software; or
- Use the software for commercial software hosting services.

Except as expressly provided in this agreement, rights to access the software on this device do not give you any right to implement Microsoft patents or other Microsoft intellectual property in software or devices that access this device.

You may use remote access technologies in the software such as Remote Desktop to access the software remotely from another device. You are responsible for obtaining any licenses required for use of these protocols to access other software.

- Remote Boot Feature. If the *ndd Medizintechnik AG* enabled the device Remote Boot feature of the software, you may
  - use the Remote Boot Installation Service (RBIS) tool only to install one copy of the software on your server and to deploy the software on licensed devices as part of the Remote Boot process; and
  - use the Remote Boot Installation Service only for deployment of the software to devices as part of the Remote Boot process; and
  - download the software to licensed devices and use it on them.

  For more information, please refer to the device documentation or contact *ndd Medizintechnik AG*.

- **Internet-Based Services**. Microsoft provides Internet-based services with the software. Microsoft may change or cancel them at any time.
  - **Consent for Internet-Based Services**. The software features described below connect to Microsoft or service provider computer systems over the Internet. In some cases, you will not receive a separate notice when they connect. You may switch off these features or not use them. For more information about these features, visit

    http://www.microsoft.com/windowsxp/downloads/updates/sp2/docs/privacy.mspx.

    By using these features, you consent to the transmission of this information. Microsoft does not use the information to identify or contact you.

- **Computer Information**. The following features use Internet protocols, which send to the appropriate systems computer information, such as your Internet protocol address, the type of operating system, browser and name and version of the software you are using, and the language code of the device where you installed the software. Microsoft uses this information to make the Internet-based services available to you.
  - *Web Content Features*. Features in the software can retrieve related content from Microsoft and provide it to you. To provide the content, these features send to Microsoft the type of operating system, name and version of the software you are using, type of browser and language code of the device where the software was installed. Examples of these features are clip art, templates, online training, online assistance and Appshelp. These features only operate when you activate them. You may choose to switch them off or not use them.
  - *Digital Certificates*. The software uses digital certificates. These digital certificates confirm the identity of Internet users sending X.509 standard encrypted information. The software retrieves certificates and updates certificate revocation lists. These security features operate only when you use the Internet.
  - *Auto Root Update*. The Auto Root Update feature updates the list of trusted certificate authorities. You can switch off the Auto Root Update feature.
    - *Windows Media Player*. When you use Windows Media Player, it checks with Microsoft for
    - Compatible online music services in your region;
    - New versions of the player; and
    - Codecs if your device does not have the correct ones for playing content. You can switch off this feature. For more information, go to: *http://microsoft.com/windows/windowsmedia/mp10/privacy.aspx.*
  - *Windows Media Digital Rights Management*. Content owners use Windows Media digital rights management technology (WMDRM) to protect their intellectual property, including copyrights. This software and third party software use WMDRM to play and copy WMDRM-protected content. If the software fails to protect the content, content owners may ask Microsoft to revoke the software's ability to use WMDRM to play or copy protected content. Revocation does not affect other content. When you download licenses for protected content, you agree that Microsoft may include a revocation list with the licenses. Content owners may require you to upgrade WMDRM to access their content. Microsoft software that includes WMDRM will ask for your consent prior to the upgrade. If you decline an upgrade, you will not be able to access content that requires the upgrade. You may switch off WMDRM features that access the Internet. When these features

are off, you can still play content for which you have a valid license.

- **Misuse of Internet-based Services.** You may not use these services in any way that could harm them or impair anyone else's use of them. You may not use the services to try to gain unauthorized access to any service, data, account or network by any means.

4. **Windows Update Agent (also known as Software Update Services).** The software on the device includes Windows Update Agent ("WUA") functionality that may enable your device to connect to and access updates ("Windows Updates") from a server installed with the required server component. Without limiting any other disclaimer in this Microsoft Software License Terms or any EULA accompanying a Windows Update, you acknowledge and agree that no warranty is provided by MS, Microsoft Corporation or their affiliates with respect to any Windows Update that you install or attempt to install on your device.
5. **Product Support.** Contact *ndd Medizintechnik AG* for support options. Refer to the support number provided with the device.
6. **Backup Copy.** You may make one backup copy of the software. You may use it only to reinstall the software on the device.
7. **Proof Of License.** If you acquired the software on the device, or on a disc or other media, a genuine Certificate of Authenticity label with a genuine copy of the software identifies licensed software. To be valid, this label must be affixed to the device, or included on or in *ndd Medizintechnik AG*'s software packaging. If you receive the label separately, it is not valid. You should keep the label on the device or packaging to prove that you are licensed to use the software. To identify genuine Microsoft software, see http://www.howtotell.com.
8. **Transfer to a Third Party.** You may transfer the software only with the device, the Certificate of Authenticity label, and these license terms directly to a third party. Before the transfer, that party must agree that these license terms apply to the transfer and use of the software. You may not retain any copies of the software including the backup copy.
9. **Not Fault Tolerant.** The software is not fault tolerant. *ndd Medizintechnik AG* installed the software on the device and is responsible for how it operates on the device.
10. **Restricted Use.** The Microsoft software was designed for systems that do not require fail-safe performance. You may not use the Microsoft software in any device or system in which a malfunction of the software would result in foreseeable risk of injury or death to any person. This includes operation of nuclear facilities, aircraft navigation or communication systems and air traffic control.
11. **No Warranties for the Software. The software is provided "as is". You bear all risks of using it. Microsoft gives no express warranties, guarantees or conditions. Any warranties you receive**

regarding the device or the software do not originate from, and are not binding on, Microsoft or its affiliates. When allowed by your local laws, *ndd Medizintechnik AG* **and Microsoft exclude implied warranties of merchantability, fitness for a particular purpose and non-infringement.**

12. **Liability Limitations. You can recover from Microsoft and its affiliates only direct damages up to two hundred fifty U.S. Dollars (U.S. $250.00). You cannot recover any other damages, including consequential, lost profits, special, indirect or incidental damages.**

    This limitation applies to:

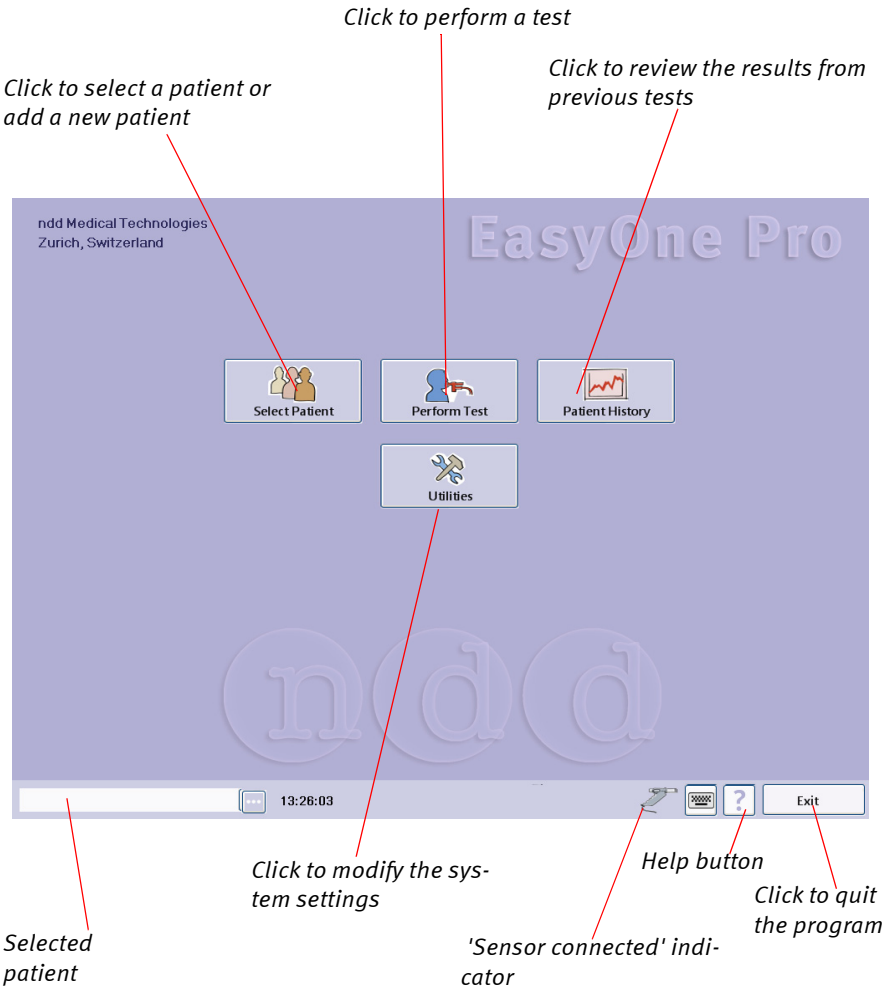
    - **Anything related to the software, services, content (including code) on third party internet sites, or third party programs; and**
    - **Claims for breach of contract, breach of warranty, guarantee or condition, strict liability, negligence, or other tort to the extent permitted by applicable law.**

    It also applies even if Microsoft should have been aware of the possibility of the damages. The above limitation may not apply to you because your country may not allow the exclusion or limitation of incidental, consequential or other damages.

13. **Export Restrictions.** The software is subject to United States export laws and regulations. You must comply with all domestic and international export laws and regulations that apply to the software. These laws include restrictions on destinations, end users and end use. For additional information, see www.microsoft.com/exporting.

12.9 Quick Reference Guide to the Screen Displays

Initial Screen



Also refer to

"Safety Information" on page 6

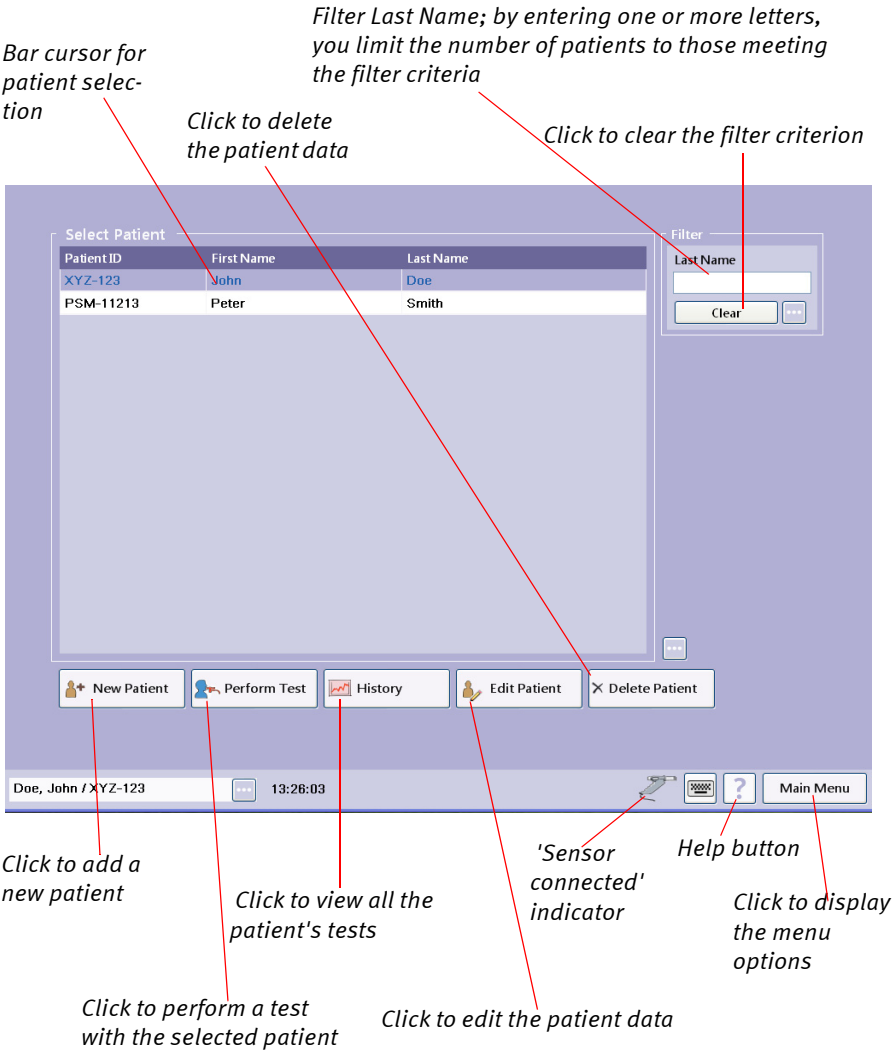
"Start-up and Initial Preparation" on page 20

"Performing a Test" on page 41

"System Settings" on page 110

"Index" on page 185

Selecting/Adding a Patient



Also refer to

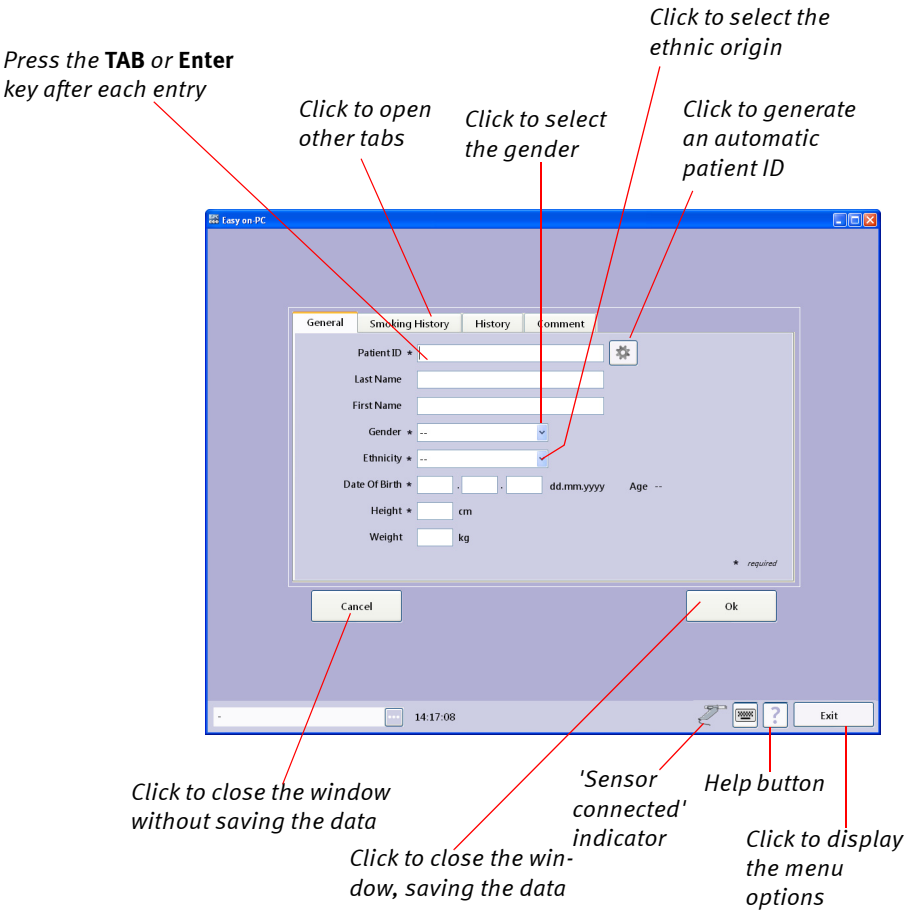
"Selecting/Adding a Patient" on page 41

"Editing Patient Data" on page 83

"Selecting a Test" on page 45

"Index" on page 185

Adding a Patient



Also refer to

"Selecting/Adding a Patient" on page 41

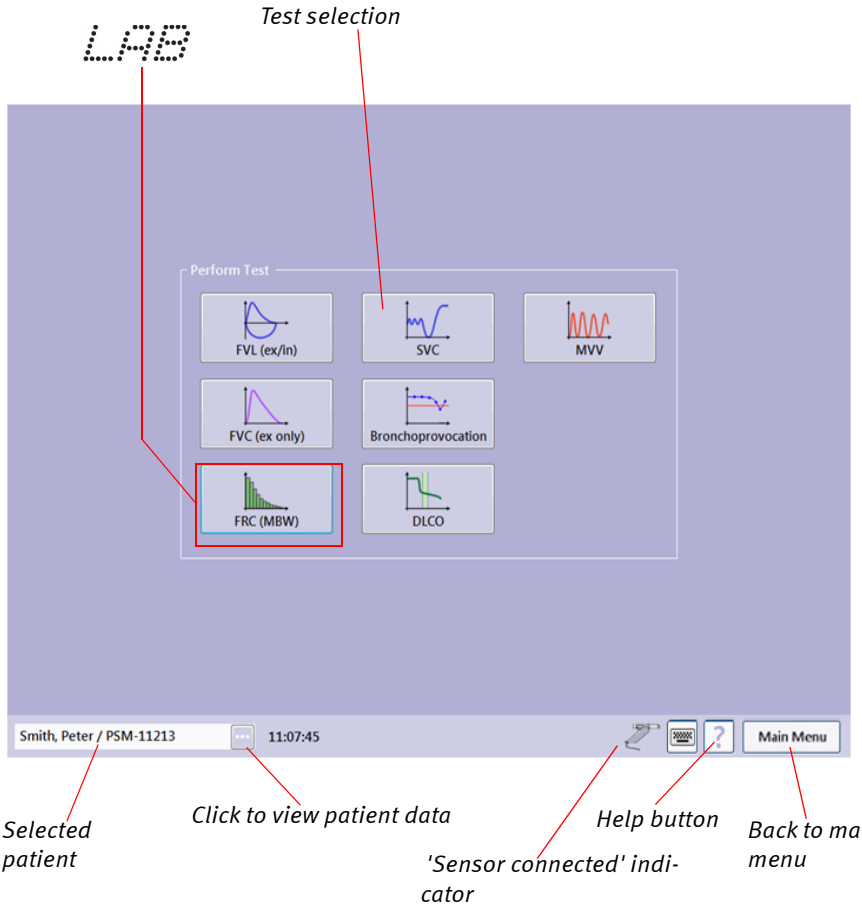
"Editing Patient Data" on page 83

"Selecting a Test" on page 45

"Index" on page 185

Test Menu

Note
The content of this menu depends on the device configuration.



Also refer to

"Selecting a Test" on page 45

"Forced Vital Capacity (FVC/FVL)" on page 46

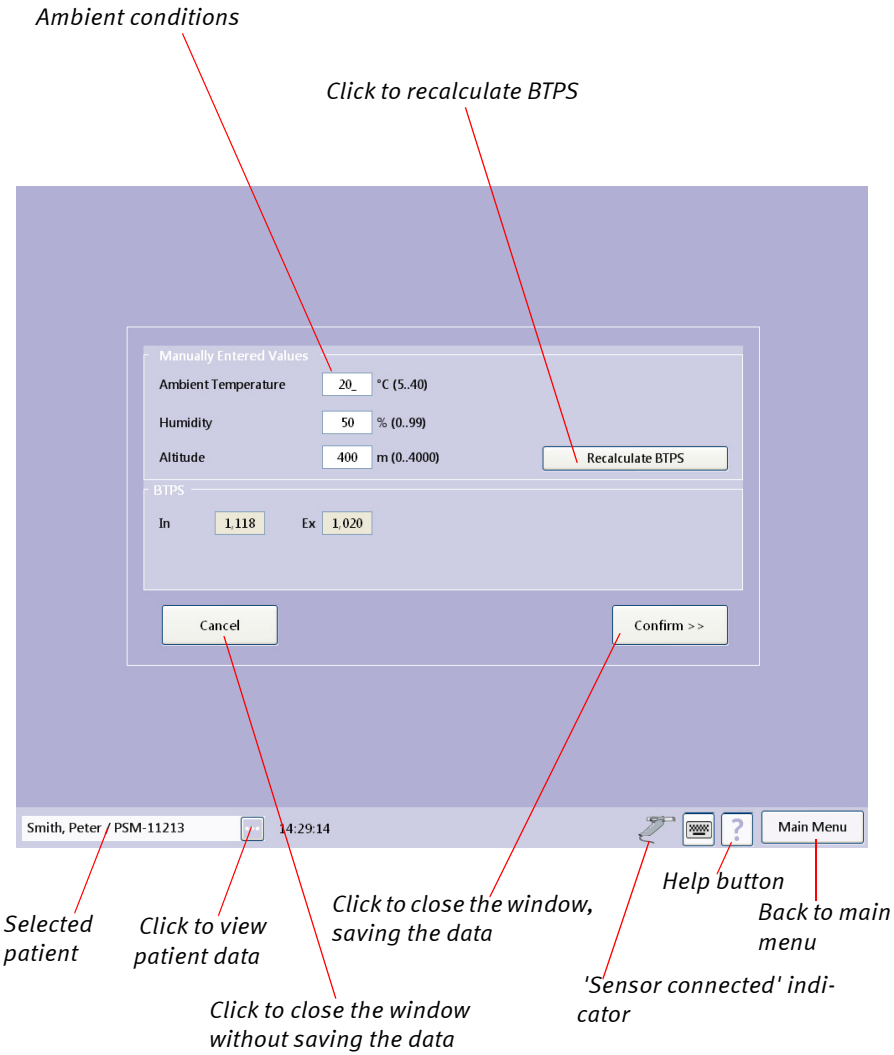
"Vital Capacity (SVC)" on page 56

"Maximum Voluntary Ventilation (MVV)" on page 58

"CO Diffusing Capacity (DLCO)" on page 67

"Index" on page 185

Viewing Ambient Conditions



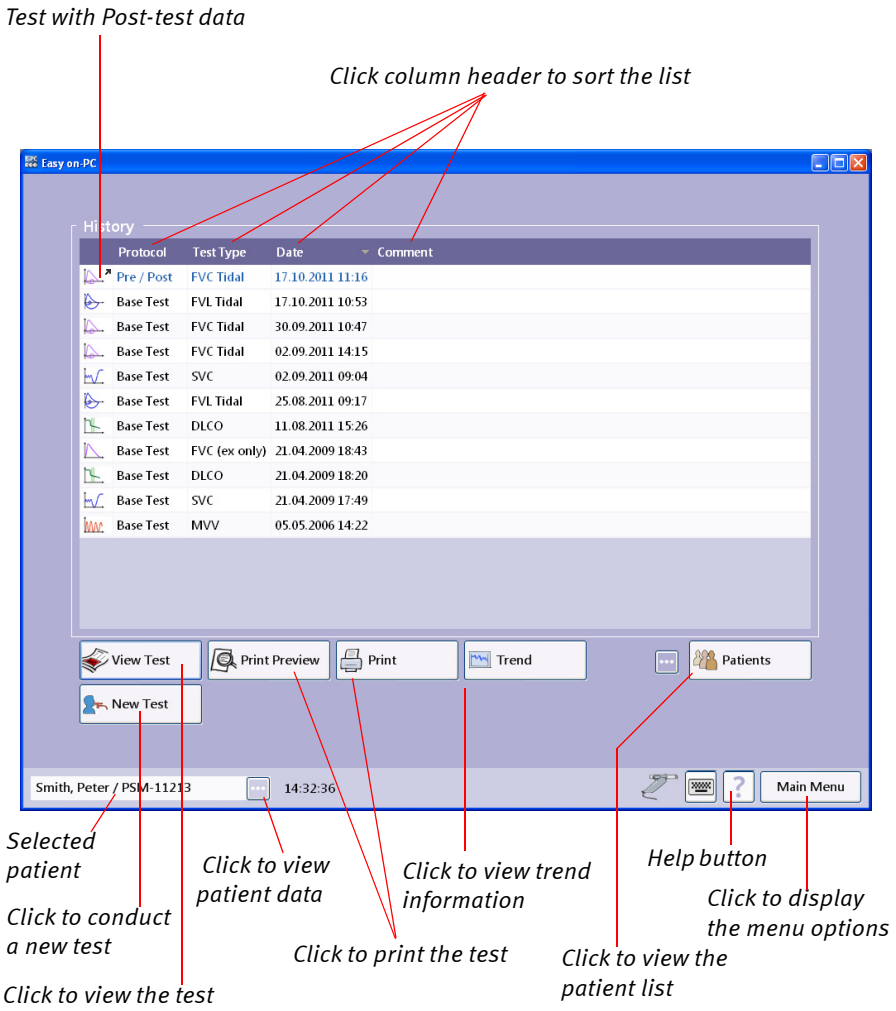
Also refer to

"FVL Test (inspiratory and expiratory measurement)" on page 51

"Components and Functional Description of EasyOne Pro™" on page 16

"Index" on page 185

Retrieving/Printing Stored Tests



Also refer to

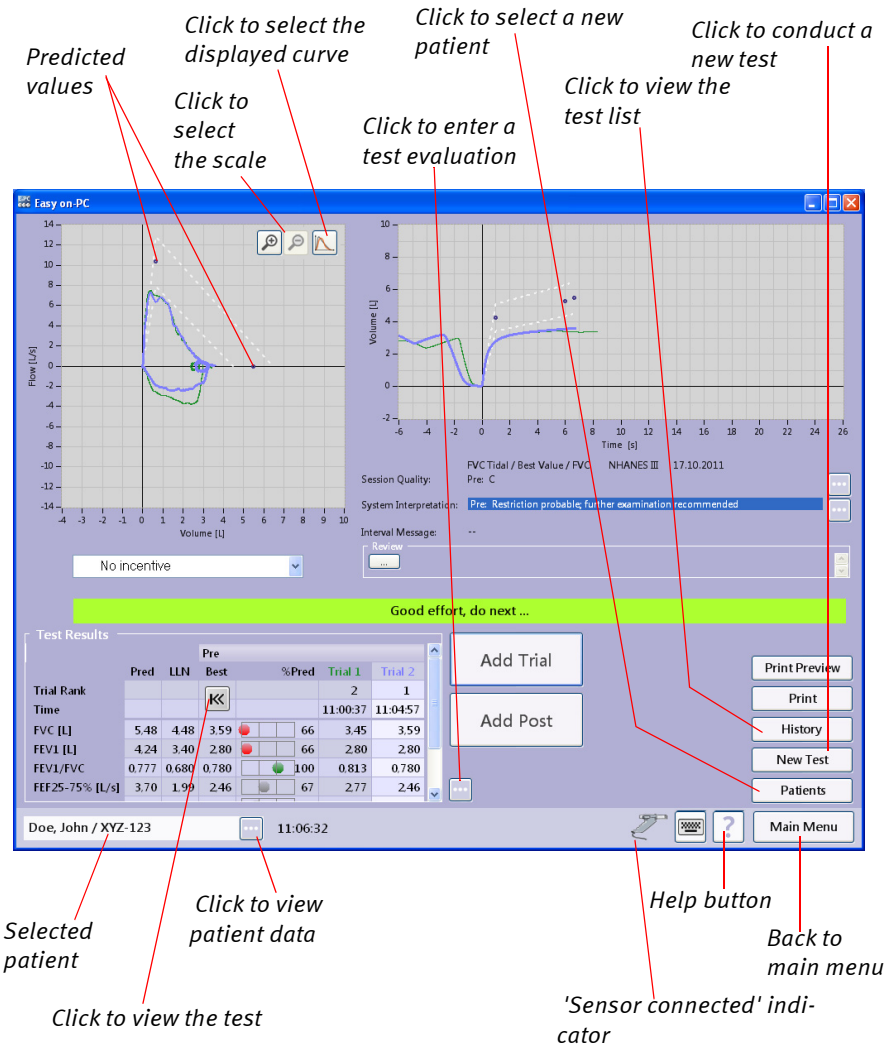
"Retrieving/Printing Stored Tests" on page 75

"Quality Messages and Quality Grades" on page 84

"Connecting the Printer" on page 31

"Index" on page 185

FVC Test Result



Also refer to

"Retrieving/Printing Stored Tests" on page 75

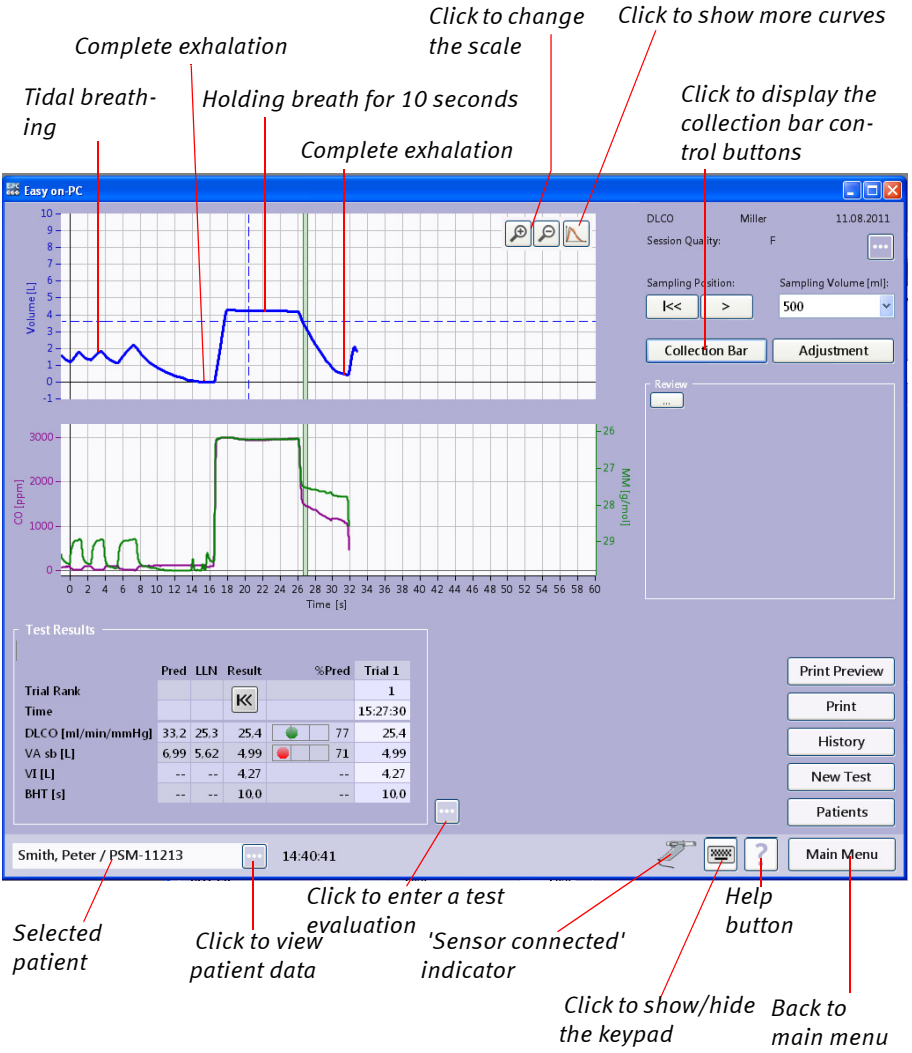
"System Settings" on page 110

"Quality Messages and Quality Grades" on page 84

"Connecting the Printer" on page 31

"Index" on page 185

DLCO Test Result



Also refer to

"Retrieving/Printing Stored Tests" on page 75

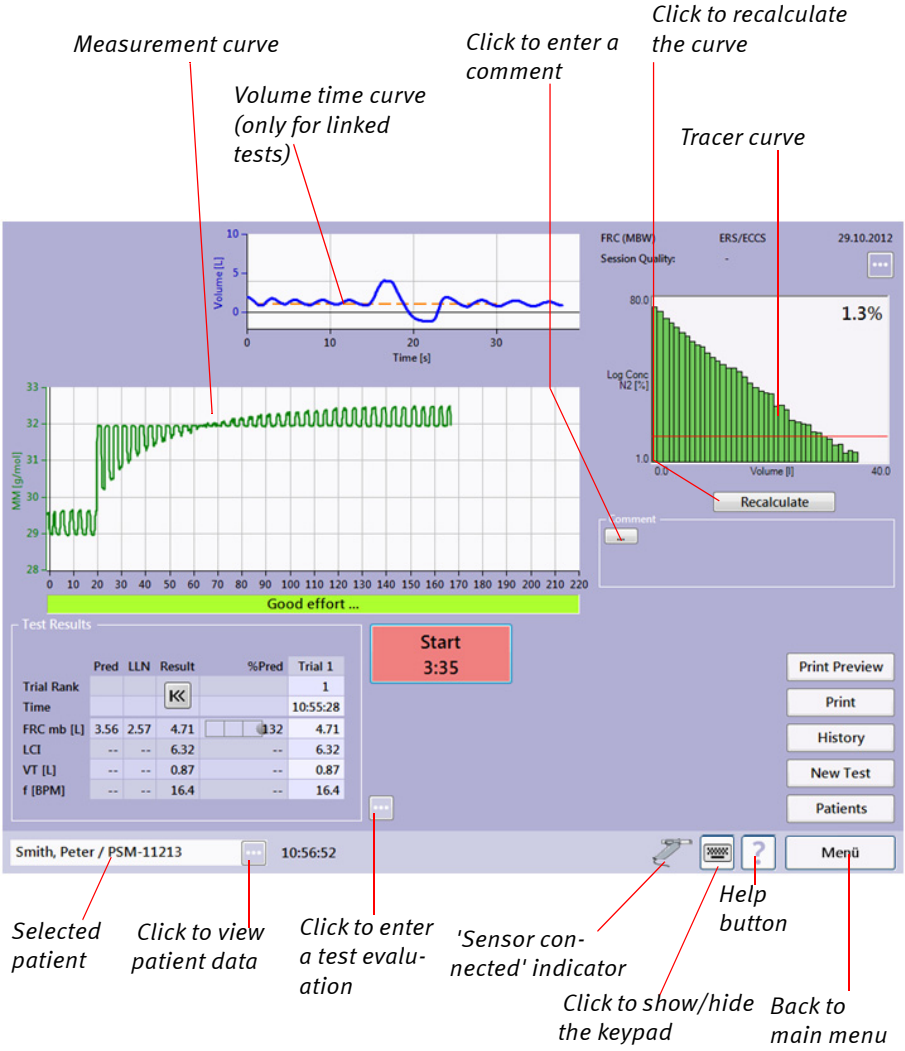
"System Settings" on page 110

"Quality Messages and Quality Grades" on page 84

"Connecting the Printer" on page 31

"Index" on page 185

FRC Test Result LAB



Also refer to

"Retrieving/Printing Stored Tests" on page 75

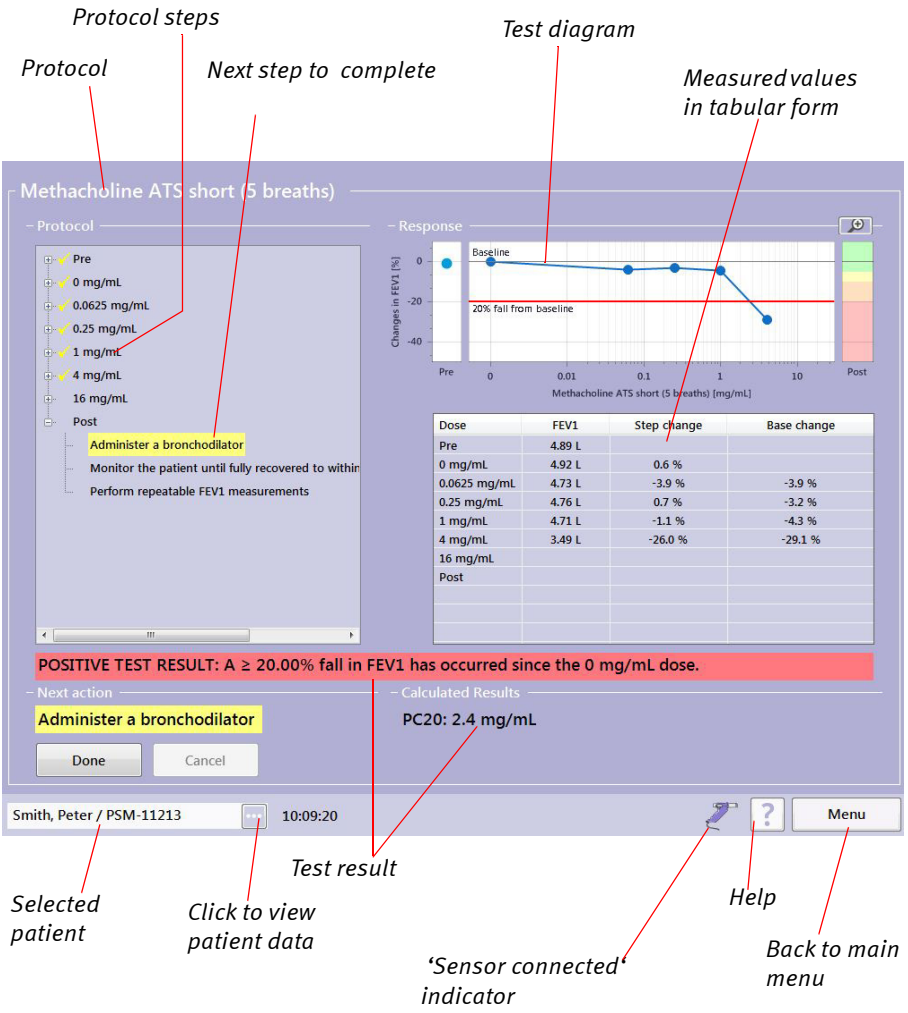
"System Settings" on page 110

"Quality Messages and Quality Grades" on page 84

"Connecting the Printer" on page 31

"Index" on page 185

Provovation Test Results



Also refer to

"Retrieving/Printing Stored Tests" on page 75

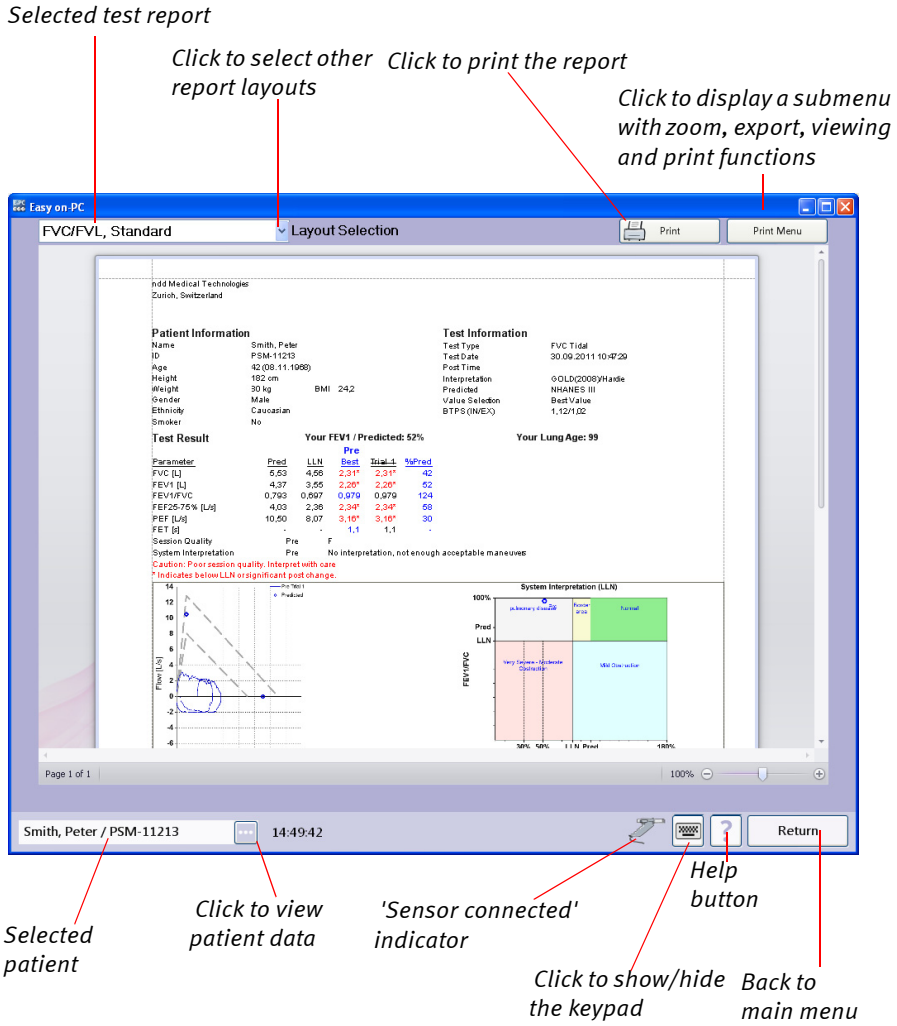
"System Settings" on page 110

"Quality Messages and Quality Grades" on page 84

"Connecting the Printer" on page 31

"Index" on page 185

Print Preview



Also refer to

"Retrieving/Printing Stored Tests" on page 75

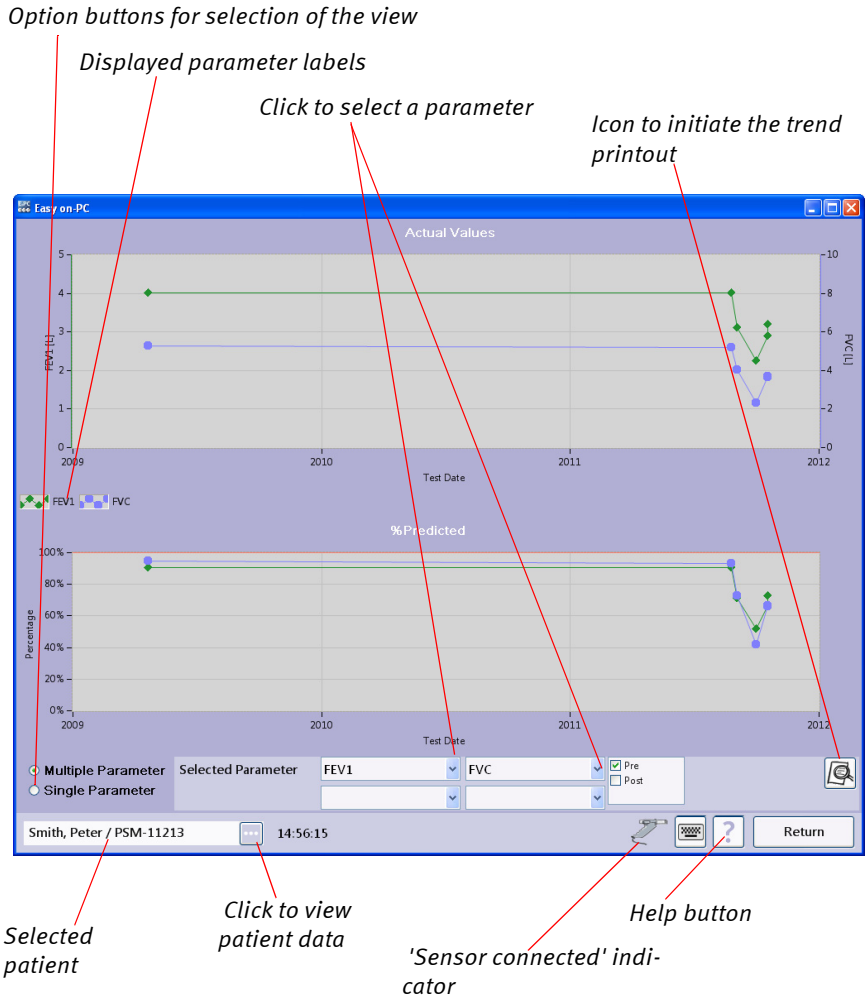
"System Settings" on page 110

"Quality Messages and Quality Grades" on page 84

"Connecting the Printer" on page 31

"Index" on page 185

Trend Display



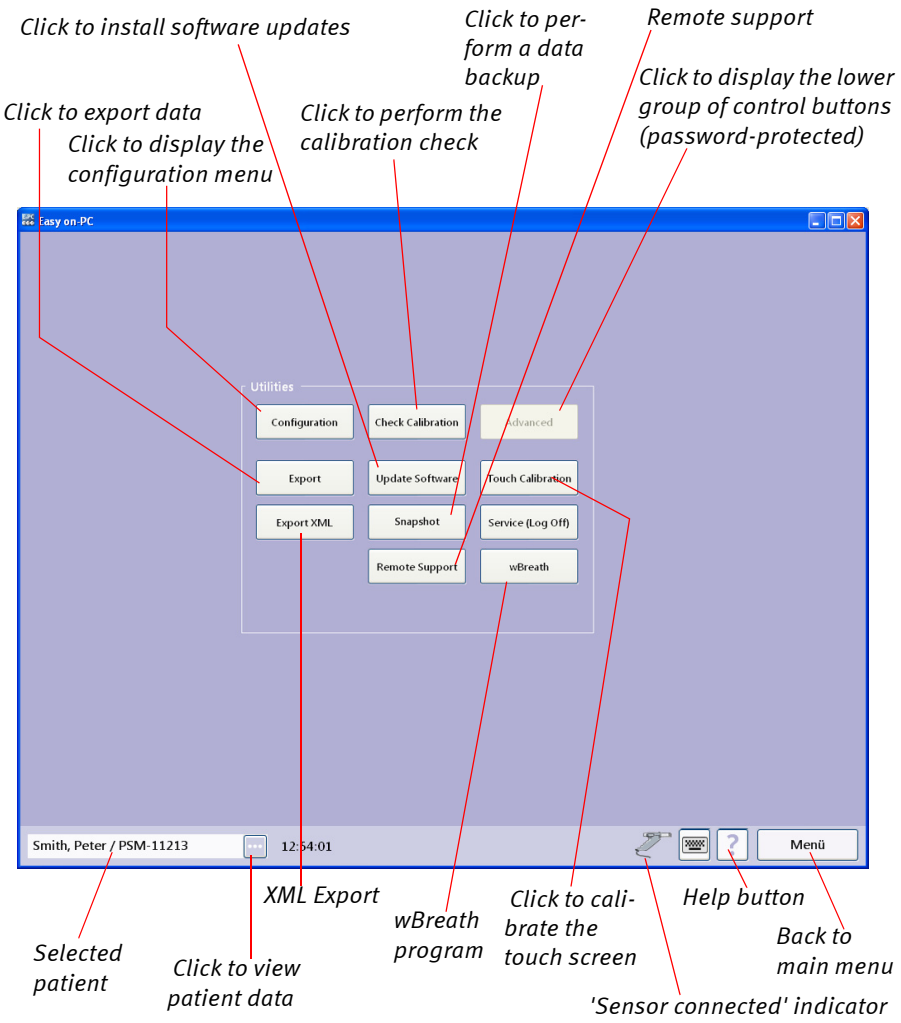
Also refer to

"Trend View" on page 78

"Switching the Device Off" on page 99

"Index" on page 185

System Settings Menu

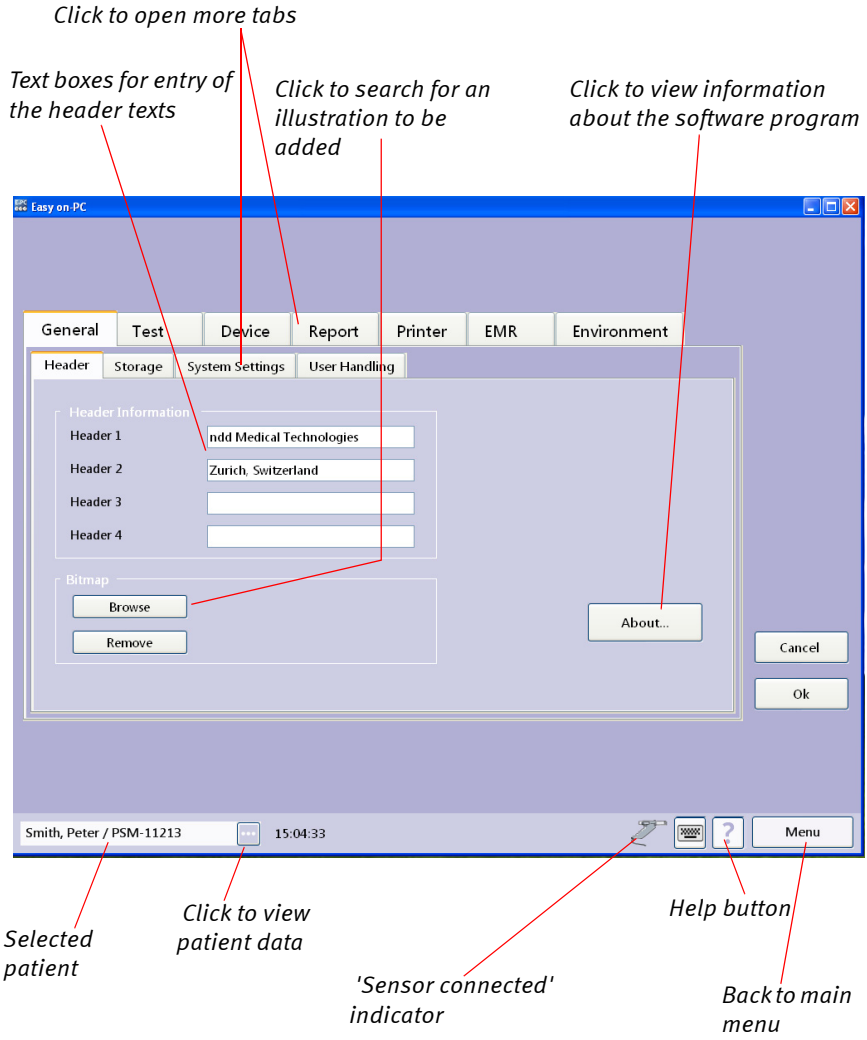


Also refer to

"System Settings" on page 110

"Index" on page 185

Configuration Menu

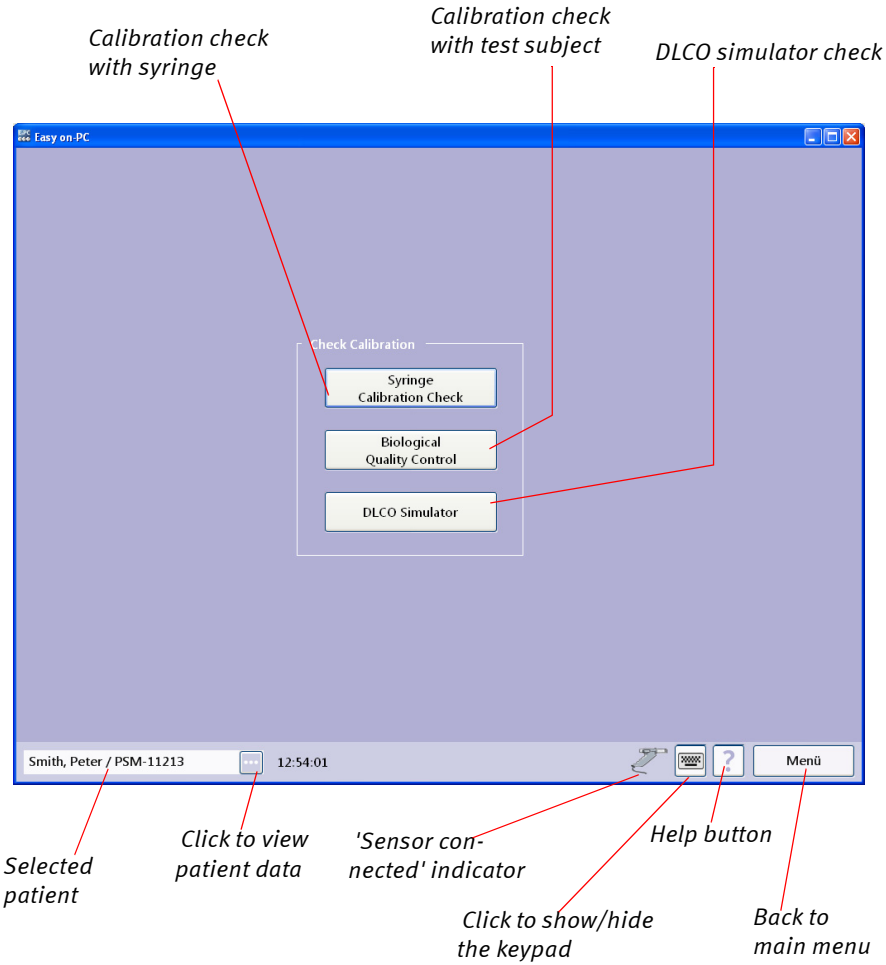


Also refer to

"System Settings" on page 110

"Index" on page 185

Calibration Check



Also refer to

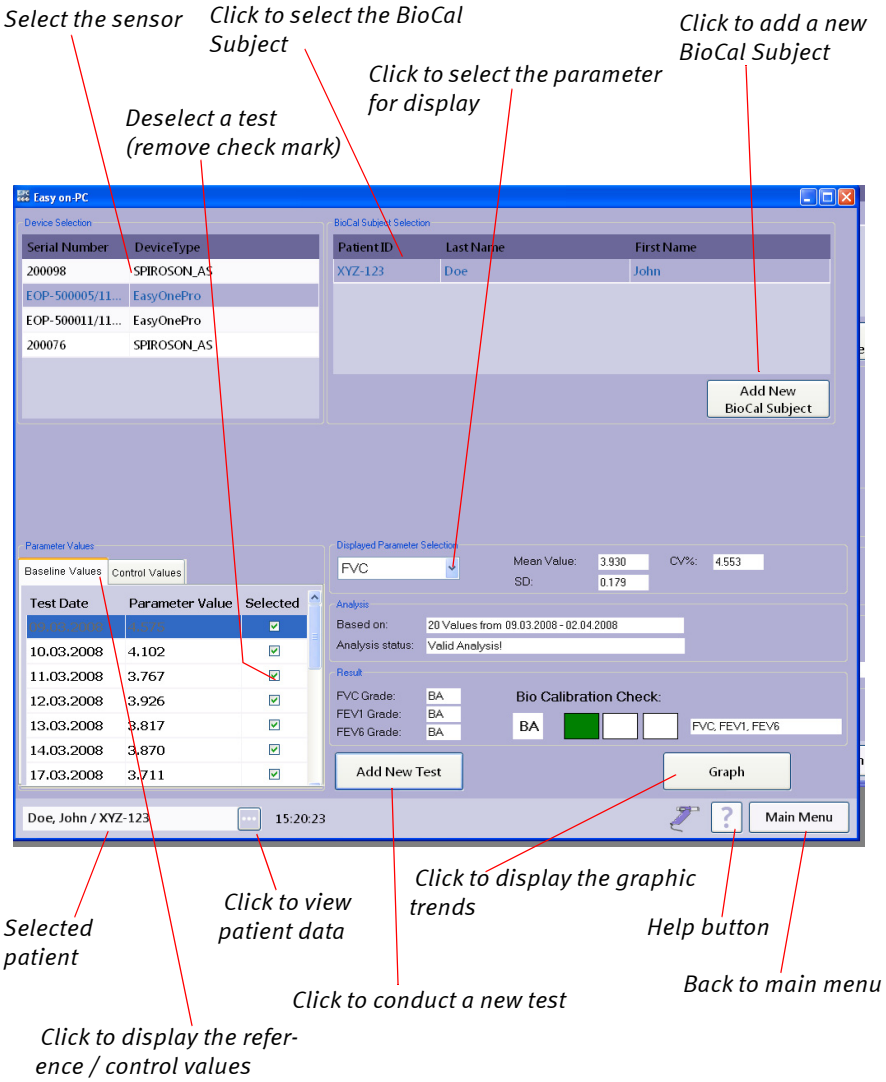
"Calibration Check" on page 178

"EasyOne Pro™ Flow Sensor Design and Operation" on page 17

"Specifications" on page 131

"Index" on page 185

Calibration Check with Test Subject



Also refer to

"Calibration Check with Test Subject" on page 179

"EasyOne Pro™ Flow Sensor Design and Operation" on page 17

"Specifications" on page 131

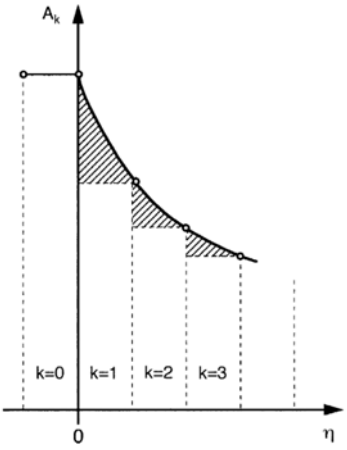
"Index" on page 185

12.10 *EasyOne Pro LAB* Washout Moment Analysis

The parameters Moment value (M0), Moment ratio 1 (MR1) and Moment ratio 2 (MR2) are calculated from measured values recorded during the multi-breath nitrogen washout test. Calculation of these parameters is defined in a paper published by Shao et al. [17].

Moment Analysis is performed using a standard mathematical technique. Once Functional residual capacity (FRC) is determined, a dilution number (η) is assigned to each breath: η_k is defined as the ratio of Cumulated Expired Volume (CEV) at the end of any breath k to FRC. End-tidal nitrogen concentrations are normalized and plotted versus dilution number for each breath, and this distribution is used for Moment Analysis. The normalized nitrogen concentration A_k is calculated as C_k/C_0, where C_k is end-tidal nitrogen concentration at the end of breath k, and C_0 is the end-tidal nitrogen concentration at the last breath prior to washout.

The following picture shows a diagram of A_k versus dilution number (η) (see "Literature" on page 182 [17]).



In Moment Analysis the r^{th} moment can be defined as

$$Mr = \int_0^\infty \eta^r A(\eta) d\eta$$

Calculation of the Moments requires the integral to be expressed in discretized form.

One convenient approach is

$$Mr = \sum_{k=0}^{x} \eta_k{}^r A_k(\eta_k - \eta_{k-1})$$

The Moment ratios MR1 = M_1/M_0 and MR2 = M_2/M_0 can then be calculated easily.

The parameters can be described as follows [17]: M0 can be considered as the area under the washout curve, while Moments of higher order are the sum of weighted area segments. The tail of the curve is given more weight for successively higher Moments.

LCI and Moment ratios are both related to the number of volume turnovers. LCI is a static value of the number of volume turnovers needed to reduce end-tidal nitrogen concentration to 2%, while the latter is a dynamic measure of MBNW.

Moment analysis has been described by several authors (see "Literature" on page 182 [17] to [21]). Clinical use of Moment Analysis is still limited since reference values from larger groups are not yet available.

12.11 Literature

[1] American Thoracic Society. Standardization of Spirometry: 1994 Update, Nov. 11,1994. Am J Resp Crit Care Med 1995; 152:1107-1136.

[2] Occupational Health and Safety Administration (OSHA), Pulmonary Function Standards for Cotton Dust, 29 CFR: 1910.1043 Appendix D.

[3] Social Security Administration Disability (SSD) Guidelines, CFR404: Appendix 1 to Subpart P.

[4] Ferguson GT, Enright PL, Buist AS, et al. Office spirometry for lung health assessment in adults: A consensus statement from the National Lung Health Education Program. Chest 2000; 117:1146-1161.

[5] ATS Pulmonary Function Laboratory Management and Procedure Manual, American Thoracic Society, New York, NY 10019.

[6] Enright PL, Hyatt RE. Office Spirometry. Lea & Febiger, Philadelphia, 1987.

[7] Hyatt, RE, Scanlon PD, Nakamura M. Interpretation of Pulmonary Function Tests - A Practical Guide. Lippincott - Raven, Philadelphia, 1997.

[8] American Thoracic Society. Lung Function Testing: Selection of Reference Values and Interpretative Strategies, Am Rev Respir Dis 1991; 144:1202-1218.

[9] Morris JF, Temple W. Short Report: Spirometric "Lung Age" Estimation for Motivating Smoking Cessation, Preventive Medicine 14. 655-662 (1985).

[10] Polgar, Promadhat, Pulmonary Function Testing in Children: Techniques and Standards. W.B. Saunders Co., Philadelphia, 1971.

[11] M.R. Miller, R. Crapo, J. Hankinson, et al. ATS/ERS Task Force: Standardization of Lung Function Testing. Numbers 1 to 5. Eur Respir J 2005; 26: 153-161, 319-338, 511-522, 720-735, 948-968.

[12] Global Strategy For The Diagnosis, Management, And Prevention Of Chronic Obstructive Pulmonary Disease, Executive Summary, Updated 2003 (GOLD).

[13] Hardie et.al., "Risk of over-diagnosis of COPD in asymptomatic elderly never-smokers" Eur Respir J2002;20: 1117-1122.

[14] ATS/ERS Task Force: Standardization of Lung Function Testing; Eur Respir J 2005;26:153–161.

[15] N. Beydon, S.D. Davis et al.; An Official American Thoracic Society/ European Respiratory Society Statement: Pulmonary Function Test-

ing in Preschool Children. Am J Respir Crit Care Med Vol 175. pp 1304–1345, 2007.

[16] Wanger, J.L. Clausen et al.; ATS/ERS Task Force: Standardization of Lung Function Testing. Standardisation of the measurement of lung volumes. Eur Respir J 2005; 26:511-522.

[17] Shao H, Sandberg K, Sjoqvist BA, Hjalmarson O.: Moment analysis of multibreath nitrogen washout in healthy preterm infants. Pediatr Pulmonol 1998: 25(1): 52-58.

[18] P Aurora, W Kozlowska, J Stocks. Gas mixing efficiency from birth to adulthood measured by multiple-breath washout. Respiratory Physiology & Neurobiology, 148: 125-139, 2005.

[19] AA Hutchinson, AC Sum, TA Demis, A Erben, LI Landau. Moment Analysis of Multiple Breath Nitrogen Washout in Children. Am Rev Repir Dis; 125:28-32, 1982.

[20] R Kraemer, B Meister. Fast real-time moment-ratio analysis of multibreath nitrogen washout in children. J Appl Physiol 59(4): 1137-1144, 1985.

[21] J Saniie, GM Saidel, EH Chester. Real-time moment analysis of pulmonary nitrogen washout. J Appl Physiol, 46(6): 1184-1190, 1979.

Index

H

I

K

L

M

N

O

P

Q

R

S

ndd Medical Technologies
Two Dundee Park
Andover, MA 01810
USA

www.nddmed.com

ndd Medizintechnik AG
Technoparkstr. 1
CH-8005 Zürich
Switzerland

www.ndd.ch