User manual

smart *pft*lab

It is obligatory to read this manual before the first use

smart*pft*lab ™

Contents:

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Preface

We want to thank you for the trust you place in us by purchasing this device.
It is our aim to optimize production standards, thus optimizing the product quality all time.

Disclaimers

To avoid patient and / or users injury, we point out, that the device may only be used for the specified purpose and only by trained and experienced persons.
We accept no liability for any damage caused by misuse of the device caused to write and / or semantic errors in this document.
Similarly, we assume no liability for personal injury or property damage incurred by use of the device. Any potential liability is limited to the refund of the purchase price.
We point out that the representations and images of this manual are only examples, they can be changed in its form and appearance

Software License Agreement

The buyer has to accept the software license agreement of the Medical Equipment Europe GmbH to use the device. This also applies to software license agreements from third parties whose software is included as an integral part of the device.
We expressly point out that the bundled software may be used only for the specified purpose. We accept no liability for damages resulting from the use of our software, in particular not, when this software is used in conjunction with combined third-party software.

Copy right

This document may not be copied or reproduced in whole or in part without the express permission of the Medical Equipment Europe GmbH..

Warranties

The manufacturer offers a warranty of 12 months from the date of purchase for damage to the device on production and / or material defect.

Trademarks

WINDOWS, WINXP, WINDOWS7, are registered trademarks of Microsoft corporation

smartPFT, are registered trademarks of Medical Equipment Europe GmbH

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Important information for the use of this manual

The information shown in a red window rimmed by the solid line is taken to prevent serious injury or death of patients and / or users.

The information shown in a red window rimmed with a dotted line is observed to prevent patient injury and / or users and / or serious damage to the equipment

Important safety advices

The device may only be used by persons who have read and understood the instructions.

The device may only be used by trained persons.

The user must have knowledge of:

> How to set up the device,
> How the measuring hoses and cables are connected,
> How the device is to be disinfected,
> What maintenance work is required,
> How the device is verified.

Prior to the daily operation, all connections and sensors must be checked. In the event of a recognizable damage, the device must by serviced by a qualified service person before it can be used again.

Other devices may only be connected to the system by the manufacturer or after explicit approval.

Devices that need to be electrically connected to the system have to be operated in combination with the supplied isolation transformer. If this is not possible, the connection must isolated by a suitable insulator.

Warning on use of the Bodyplethysmography:

This device is an absolutely pressure-tight chamber which is sealed with electromagnets. With the door closed, living subjects should not be captured too long. To eliminate any risk of suffocation, the unit must be operated under supervision, the chamber must be opened temporarily at the expiration of 10 minutes. In an emergency the patient can disable the door magnets by a red button in the chamber. The door magnets are attracted with such force that the locked doors can be opened from inside or outside manually by pressing or pulling at the door bars.

Please use this irregular kind of opening only in the case of an emergency to avoid damage on the door locking system.

Warning on use of CO-Diffusion test:

The test gas is applied by a demand valve. there is a pressure tube connected to the demand valve with an operating pressure up to 5.5 bars. The demand valve has to be serviced after a period of 2 years. After this time period, the membrane has to be changed. No changes of demand valve or pressure regulator are allowed. The maximum allowed pressure applied to the demand valve is 5.5 bars, the pressure regulator used has to have permission to be used for medical equipment. Make sure all pressure connectors are connected safely.

Explosive: This product must not be operated in hazardous locations.

In the standard delivery the smartPFT lab does not include a PC system. Any PC system connected to the device has to fulfill EN 60950 and has to be connected via our isolation transformer. The isolation transformer has to meet the requirements of EN 60601/1, starting from 2012 EN 60601/3.

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CE marking

Our smart pft lab unit is declared as a class IIa device in relation to directives 93/42/EEC annex I.

The following standards are met.

The smart *pft* lab device is declared as a class IIa device related to the guidelines 93/42/EWG annex I.

The device fulfils the standards.

EN 60601-1 part I   for electronic safety

EN 60601-1-2 :   for electromagnetic compatibility

The CE marking includes only the one in the delivery overview listed accessories.

Magnetic and electric fields can affect the function of the device.
When you operate the product, ensure that all third-party operated devices in the vicinity meet their relevant EMC requirements. X-ray, MRI, radio equipment, cell phones, etc. can interfere with other devices, because they may have approval pursuant to higher electromagnetic interference. Keep a safe distance from such equipment and check the device functions prior to the use in case of such interferences.

The device is suitable for continuous operation.

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Manufactoring and service by:

Medical Equipment Europe GmbH
Dr. Georg-Schäfer-Str. 14
97762 Hammelburg
Germany

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Technical data: bodybox

technical data: flowsensor

type	pneumotachograph variable Blende	
housing material	POM	
screen material	Hostaphab RN50	
weight	34	g
dimensions. oval (R1/ R2 / L)	42 / 29 / 88	mm
effective deadspace	< 30	ml
resistance @ 0,1 l/s	0,072	kPa/l*s
resistance @ 15 l/s	0,068	kPa/l*s
range	0,01 - 16	l/s
resolution	0,007	l/s
linearity errror	±3	%
volume resolution	0,01	ml
effective deadspace including filter & mouth piece	< 80	ml
resistance: sensor & filter @ 1 l/s **	< 0,11	kPa/l*s

technical data: bodybox & table

bodybox:		
type	volume constant	
materials mainly used	coted wood, glas, stainless steel	
weight	169	kg
dimensions oval (R1/R2/H)	1160 / 835 / 1830	mm
volume	≈ 900	l
pressure calibration syringe volume	50	ml
reference volume for mouth pressure calibration.	2660	ml
door locking	electromagnetic	
table system:		
dimensions (B / T / H)	692 / 1038 / 740	mm
weight	37	kg

technical data: electronic device

material	aluminium	
weight	2800	g
dimensions (L / B / H)	250 / 250 / 90	mm
PC-connectore	mini USB	
PC-interface	USB 2.0	
power supply	230	VAC
maximum power consumption	100	VA
flow pressure transducer	piezo resistive	
range	12,5	mbar
linearity error	±0,05	% fs
ADC resolution	12	bit
mouth pressure transducer	piezo resistive	
range	75	mbar
linearity error	±0,05	% fs
ADC resolution	12	bit
box pressure transducer	piezo resistive	
range	2,5	mbar
linearity error	±0,05	% fs
ADC resolution	12	bit
ambient pressure transducer	800 - 1100	mbar
max. error	±0,05	% fs
temperature range	-40 - 125	°C
temparature error	± 2	K
humidity sensor range	0-100	%rel
humidity sensor error	1,8	%rel
sampling rate	125	Hz
operating system required	WIN7 & WINXP	*

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Technical data: Option CO-Diffusion

technical data   analyzer device

CO/CH4 gas analyzer		
type	infrarot Absorpt.	
zero drift/ 24 h	< 1	% fs
linearity error	< 2	% fs
maximum sensitivity	< 0.5	% fs
reproducibility error	< ± 1	% fs
temperature cross sensitivity	< 1	% fs
ambient pressure cross sens.	< 1	% fs
rise time	< 600	ms
range CO	0 to 3000	ppm
range CH4	0 to 3000	ppm
heating up time	5	min
working temperature	10 to 40	°C
humidity range allowed during operations (non condensing)	0 to 95	%rel

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ISO Symbols

□ (within square)	Safety class IIa device
(human figure in square)	A product with this label, is part of the application in accordance with DIN EN 60601-1, type BF
⚠	Attention! Accompanying documents!
IPX0	No protection against drops of water!
(crossed-out wheelie bin)	Do not dispose in domestic waste!
C **€**0535	The so-labeled product is conformed with the guidelines for Medical devices 93/42/EEC of 14 June 1993 and the MPG (1994). The number is the identification number of the notified body that has reviewed this. It is at the Institute Eurocat GmbH Darmstadt. The relevant certificates, which entitle us this sign applied to the product.

Important Safety Advice

Achtung: Um das Risiko eines Elektrischen Schlages zu vermeiden, darf diese Gerät nur an ein Versorgungsnetz mit Schutzleiter angeschlossen werden !!!

Caution: To avoid risk of electrical shock, this unit must only be connected to the grounding conductor !!!

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Germany 97762 Hammelburg

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Delivery Bodybox

N°	Article	Quantity	Standard	Ordering N°.
1	Bodybox	1	☑	
2	Table	1	☑	
3	Safety transformer	1	☑	
4	Computer system	1	☐	
5	Printer	1	☐	
6	Data acquisition device	1	☑	
7	Flow sensor	2	☑	
8	Shutter	1	☑	
9	Box valve	1	☑	
10	Remote control	1	☑	
11	Adapter for filters	2	☑	
12	Adapter for calibration syringe	1	☑	
13	Calibration syringe 3 L	1	☐	
14	Calibration syringe 1 L	1	☐	
15	Memory stick with installation software	2	☑	
16	User manual	2	☑	
17			☐	
18			☐	
19			☐	
20			☐	

Delivery CO-Diffusion (optional):

N°	Article	Quantity	Standard	Ordering N°
1	Gas analyzer CO/CH4	1	☑	
2	Demand valve	1	☑	
3	Gas regulator	1	☐	
4	Shutter with connector for demand valve	1	☑	
5	Flow sensor with gas sample connector	2	☑	
6	Extension to fix gas bottle	1	☐	
7				
8				
9				
10				

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Software installation

The user software is delivered on a Memory Stick named smartSoftMEE.
The software is supplied based on a user license and the license rights must be accepted prior an installation.
The right to use the software is limited to one installation at the same time.
Any type of reproduction complete or in part, requires the expressed consent of the Medical Equipment Europe GmbH

Run Setup.exe file to start installation.
The installation takes about 20 minutes.
The software runs on computers with operating system WIN XP or WIN 7 installed.
To achieve a good performance, the system should have a high computing power, we recommend i5 or i7 processor systems.

In installations running on WIN7 systems, no issues are known, in case of WIN XP versions use, depending on the version, PowerShell has to be installed and run independent.

Installation instruction for smart**SOFT**mee

Plug USB Stick into the a USB port of the Computer. Please check orientation of the stick, if the stick was connected well, it is lighted up with blue color.

After an automatic driver installation of the USB-stick a window is displayed to select options. Please click on the line ***OPEN FOLDER***.

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Please follow the Instructions on the screen
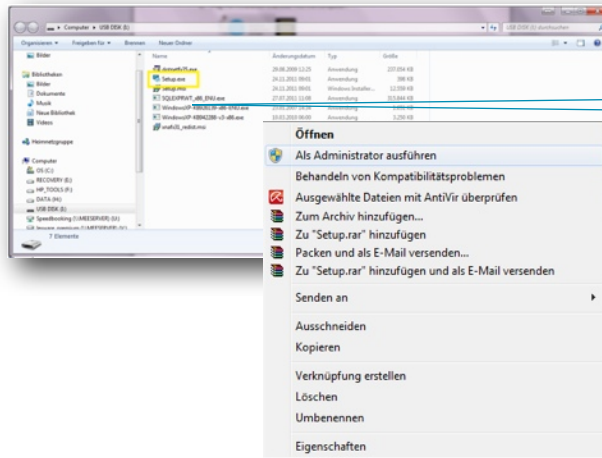
Please note ! It is obligatory to run the setup program logged in as ADMIN. Run the Setup as Administrator (this is not required for Windows XP installation)

To run the install program as an admin, click on the setup.exe ICON by the right mouse button and select in the next window the line *Execute program as Admin.*
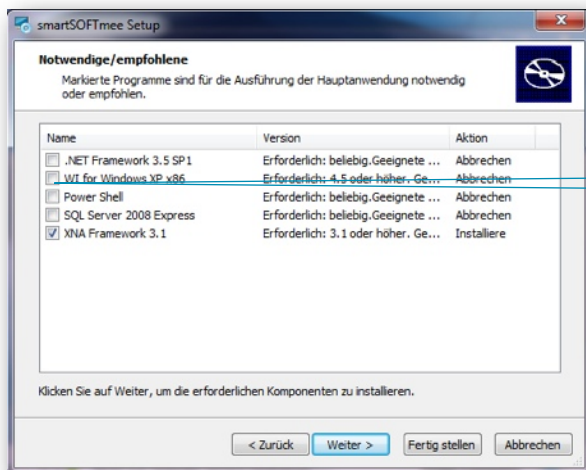
The Installation Program is automatically checking what components you need to install.
There are no changes required, you can continue by pressing the *NEXT* button in the bottom line of he window.
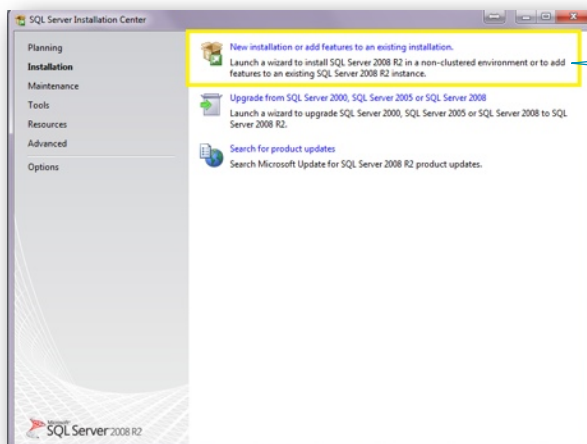
In case of a new installation select the first line to start a complete new data base.

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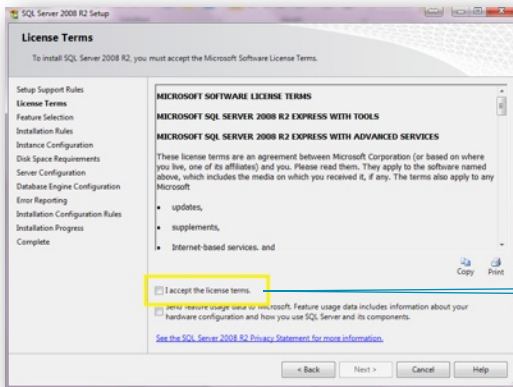
To continue with the installation you have to agree to the license conditions. Click into the square left to the line named *I accept the license terms* and continue with *NEXT*.
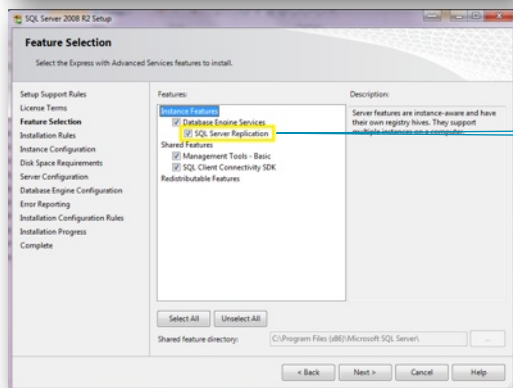
Deselect the option *SQL Server Replication* by clicking into the square with and o.k. symbol. The line is deselected when the ✓ sign in the square disappeared.
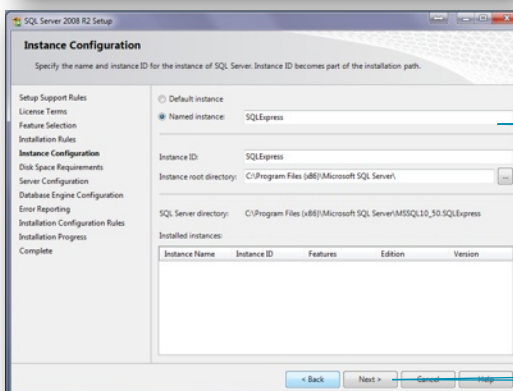
Activate line *Normal instance*: *SQLExpress* is automatically selected entered.

Click in the bottom line *Next* to continue
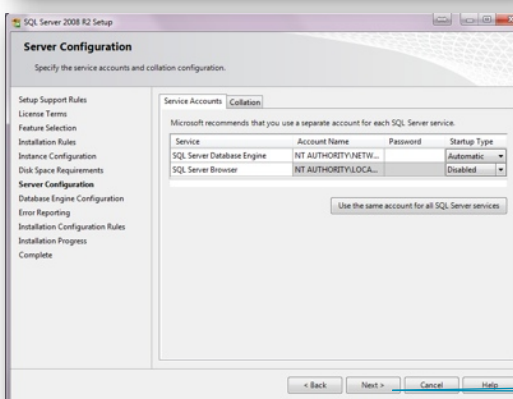
This entries are made automatically

Click in the bottom line *Next* to continue

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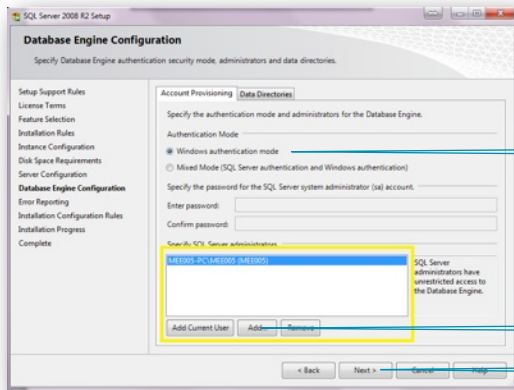
Window authentication mode has to be activated

One user is automatically installed as current user, you can add more user by clicking the *Add* button

Click on *NEXT* to continue
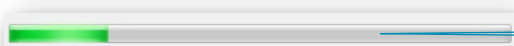
The indication bar shows the installation progress, wait until the green line reaches the right end.
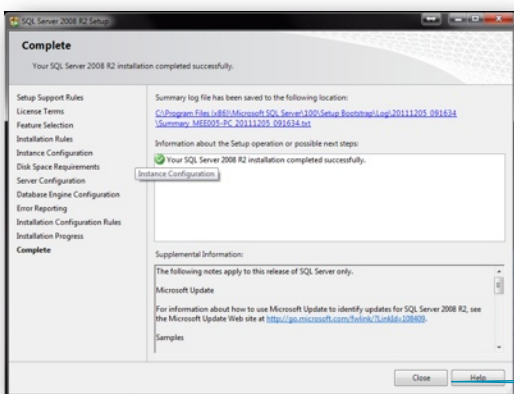
After the installation is completed close this window by clicking *Close*
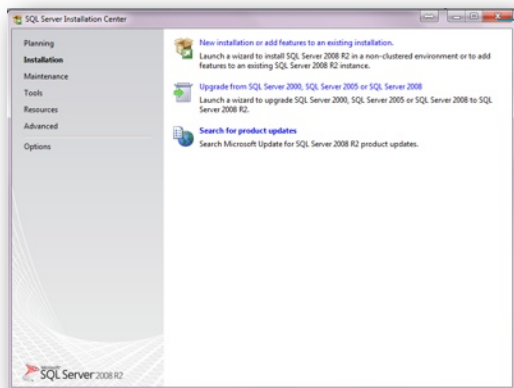
Close by clicking the red cross also the SQL Server Installation Center

This window appears to install the XNA framework which is required for the incentive graph program.

Click on *NEXT* to start installation and follow the instructions.

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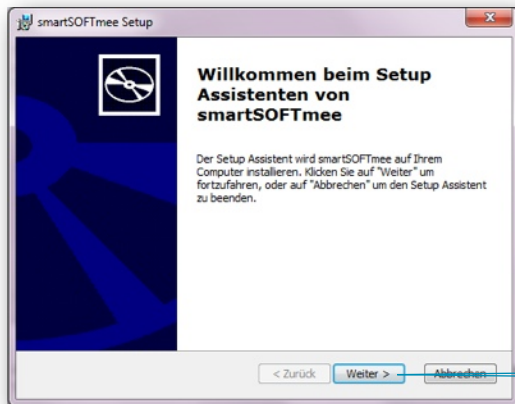
Click on **Continue** to continue with the installation
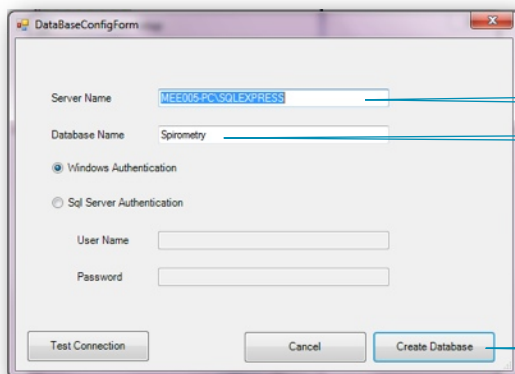
This entry must include the name PC-NAME\SQLEXPRESS
PC-NAME is the name of the computer.

Enter the name **Spirometry**, it is important to write the name exactly this way.

Click onto **Create Database** to create a new data base or click on **Cancel** to keep an older version. If you create a new one, all previous data will get lost.
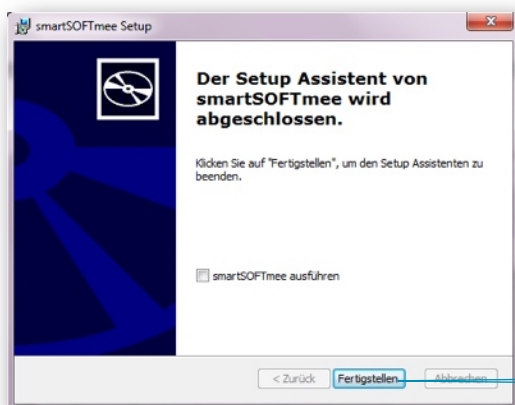
Click on **Complete installation**
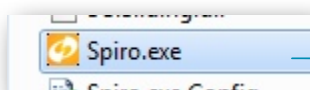
After Installation you need to open C:/TTSpiro to make a right mouse click on **Spiro**

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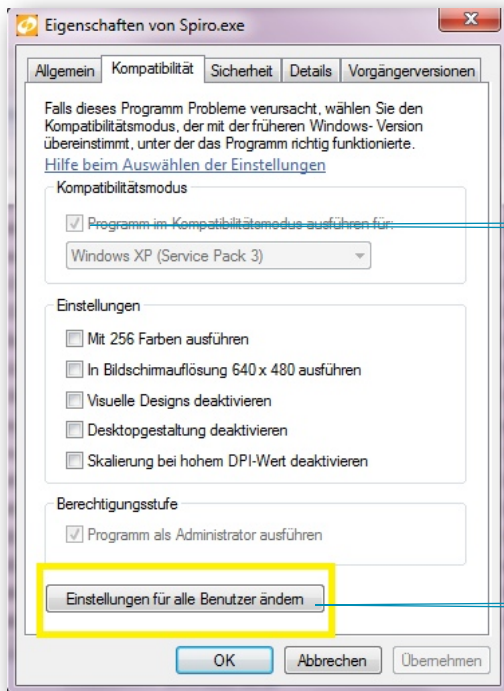
Open "Properties" and select *Compatibility mode*

Click now on *Change settings for all users*
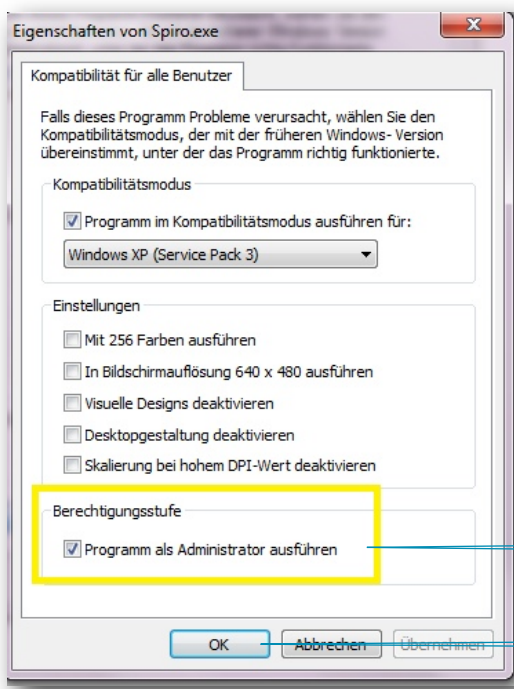
Select **authorization level** and activate the option
run program as administrator

Confirm this selection by clicking **OK**

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How to setup the Bodybox

The Bodyplethysmograph has to be installed by qualified persons only.

µC Sensor-and control unit
including CO/CH4 Gas-analyzer
(optional)

Pressure box, including flow
sensor,valve and patient chair

PC - System

2 side opening door with
electromagnetic door locking

System table with isolation
transformer

The measuring device consists of a pressure-tight chamber for the patient. On top of the chamber the electronics unit is located, it contains the signal sensors and the data acquisition unit (micro controller, sensor and control unit) with USB-interface.
In the chamber there is a chair for the patient who must sit quietly during the measurement.
The measurement data are sent by a USB cable for display and processing to the evaluation computer.
The entire system is operated through an isolating transformer to meet EN60601 security compliance requirements.

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How to place the device

The bodybox is very pressure sensitive and has to be placed in a location with low pressure changes caused by opening doors or windows or by air conditioning ventilators. The room air temperature should be constant all time between 18°C and 28°C. After transport, the device temperature has to equalized to the room temperature, this may take several hours. Do not start the electrical unit in case of a big temperature difference to avoid electrical shock or damage caused by condense water. The bottom of the box has to be stabilized by adjustable mud feet. Make sure all feet are well adjusted to the floor and check stability of the box before the first use.

Electrical connection

Make sure the electrical power cable can be disconnected easily and any time by unplugging it. The system components have to be connected to electrical power by the safety transformer. It is not allowed to change the electrical cable to the safety transformer. The system requires an electrical grounding.

Contraindications for use of the device

The bodybox can not be used if patient suffer from claustrophobia. In such a case, you still can do a spirometry, flow/volume , Rocc, and / or a DLCO test with an open door. Persons with very low body weight can not be checked in the box. In such a case, the dead space of the system can cause a CO_2 rebreathing risk. We do not take any liability if you want to measure small children or persons with small body weight. To reduce the risk of a dangerous rebreathing use a SpO2 device to check the O2 saturation drop caused by rebreathing, to stop the test in time.

Electrical fuses

Electrical fuses required : 2 AT.

System modifications

It is not allowed to connect any additional device to the system or to modify the system without permission of the manufacturer.

Storage conditions

Temperature	-5°C to +40°C
Humidity	10%rel. to 90% rel. non condensing
Ambient pressure	700hPa to 1200 hPa

Working conditions

Temperature	+18°C to +28°C
Humidity	10%rel. to 90% rel. non condensing
Ambient pressure	700hPa to 1200 hPa

How to dispose the package

We are only using package material that con be recycled. The palette is made from wood and the cover is a sea water resistant cardboard box. Depending on the country, this kind of material can be given for recycling at the public waste collection. In case of any question, ask yor local supplier.

How to dispose the device

Feed the media under the rules applicable to the local waste rules. The equipment, including accessories and empty batteries / batteries do not belong in the garbage, because they are made of quality materials that can be recycled and reused. The European Directive 2002/96/EC (WEEE) required to detect separately the electrical and electronic equipment from unsorted municipal waste, then to feed them to a recycling. The symbol with the crossed out wheeled bin indicates the need for separate collection.

Decommissioning

Special provisions for decommissioning are not to be considered.

ATS and ERS guidelines

Our system fulfills all requirements of ATS and ERS.
All sensors can be calibrated by physical references (box pressure, mouth pressure, and flow).
The criteria for the selection of the best flow/volume curve are FEV1 + FVC.
The FEV1 curve is back extrapolated.
The expiration time of minimum 6 seconds and the flow < 100ml/sec at the end of exhalation are indicated.
The system allows to compare several tests until 3 maximum tests are within 5% variation.
The flow/volume test was tested by the flow wave form calibrator.
Displaying the mouth pressure during CO maneuver to recognize positive or negative pressure caused by the patient during breath holding.

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Device setup

This picture shows the testing device, the patient has to breath through, with shutter and demand valve.

Shutter housing to plug in the flow sensor into the oval shaped connector and the valve piston from the bottom side.

Push the valve piston until stop.

Plug the electromagnet into the valve piston like shown and fix it by a turn until it blocks.

See the completely assembled shutter.

Plug the flow sensor like shown into the oval shaped drilling of the shutter, to avoid the risk of moisture in the tubings, put the tubing connectors into an upright direction. The direction of the flow sensor is correct, if the white tubing connector is located into the shutter direction. The black connector shows away from the shutter.

Take the bacterial filter set out from the plastic bag.

An adapter ring is required to connect the filter to the flow sensor. The adapter ring and the filter are located at the black colored connector side of the flow sensor.

This chart shows the assembled system including the flow sensor, the shutter, the adapter ring, the filter and a mouth piece.

To hold the test device inside the bodybox, a vertical stand with a cross bar and round connector with a lateral drilling is attached to the box.

Plug the round connector with the two blue O-rings into the lateral drilling and adjust it.

Now connect the black and light colored tubes to the correlating connectors of the flow sensor like shown.

Connect the black colored 3-pin connector from the bottom side of the solenoid and fix it by turning the metal screw.

The stand can be adjusted in height with the set screw, shown.

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Device setup in combination with CO-diffusion (option)

The shutter housing has to be substituted by such one with an additional round drilling adapter to connect the demand valve.

The system setup is identical like described in the assembling description in the chapter before. The flow sensor must have three tubing connectors instead of two. There is an additional blue tubing connector to be connected to the yellow tube.

The demand valve has to be plugged into the additional round drilling of the shutter housing

The big transparent tube has to be plugged into the black connector of the demand valve. Please press firmly to make sure, the tube is safely plugged in because this tube is applied with 5,5 bar compressed test gas.

Connect the 4 pole plug to the electrical connector of the demand valve and secure it by turning the metal nut.

Connect the yellow tube to the blue flow sensor nipple.

How to connect the compressed test gas bottle for the CO diffusion test

Before connecting the bottle to the system please check the label of the gas bottle concerning content and expiration date.

Put the gas bottle from top into the gas bottle holder of the table or fix it by a chain on a wall. Take of the safety cap.

Connect the pressure connector by manual turning of the metal nut to the bottle thread and fix it tightly. The pressure regulator has to have a testing certificate for medical use, the secondary pressure may not exceed 5,5 bars.

Now connect the transparent 8 mm gas tube to the connector of the gas regulator by pushing firmly. Check tightness of the connections by opening the gas bottle for a view seconds and closing it again. The displayed pressure shown on the manometer may not trop noticeably after closing the bottle regulator.

Device setup for calibration

Please use for the flow sensor calibration a precise syringe best is a 3 liters one.

A valid calibration certificate of the syringe must be available. If required, sent the syringe to the manufacturer or any other competent institution for recalibration.

To connect the flow sensor to the syringe, an adapter is required. The black tubing connector of the flow sensor must be oriented into the direction of the syringe. (See picture)

Connect flow sensor, adapter and syringe like shown in the right picture. Start the volume calibration program and start calibration procedure. Pump minimum 5 times the full volume by pumping from stop to stop.

System setup for automatic pressure calibration.

On the back of the bodybox, there is a stainless steel pipe with a plastic adapter to connect the oval shaped flow sensor..

To achieve isotherm conditions, the pipe is filled with steel wool.

To perform a box and mouth pressure calibration it is necessary to take the testing device from the stand and connect the flow sensor to the oval adapter drilling of the pipe connector like displayed in the next picture.

Press the device firmly into the connector to avoid leakage.

Close first the right door to activate door magnets before pressing the left door against the bodybox. Wait 20 seconds until the box valve is closed and start the pressure calibration program.

The calibration program starts automatically and ends automatically. If the calibration was o.k. save the results and open doors again by pushing the door open button on the remote control unit.

The remote control for the bodybox device

To control the door locking magnets, the box ventilation valve and the loudspeakers, the bodybox is equipped with a remote control unit.

It was the target to separate the box functionality from the software.

The advantage of this separation is, the door be closed just by pressing the right door agains the bodybox. By doing so, the door touches a sensor and the sensor activates the door magnets. It is important to close the left door immediately after closing the right one before the door ventilation valve is closed. Please make sure that all 4 magnets closed properly.

About 15 seconds after activating the door magnets, the ventilation valve is activated. From this moment on the box is closed tightly. Because of security reasons, the door magnets will be deactivated automatically after 10 minutes continuous closing.

The door magnets can be deactivated all time by pressing the red door open button on the remote control unit.
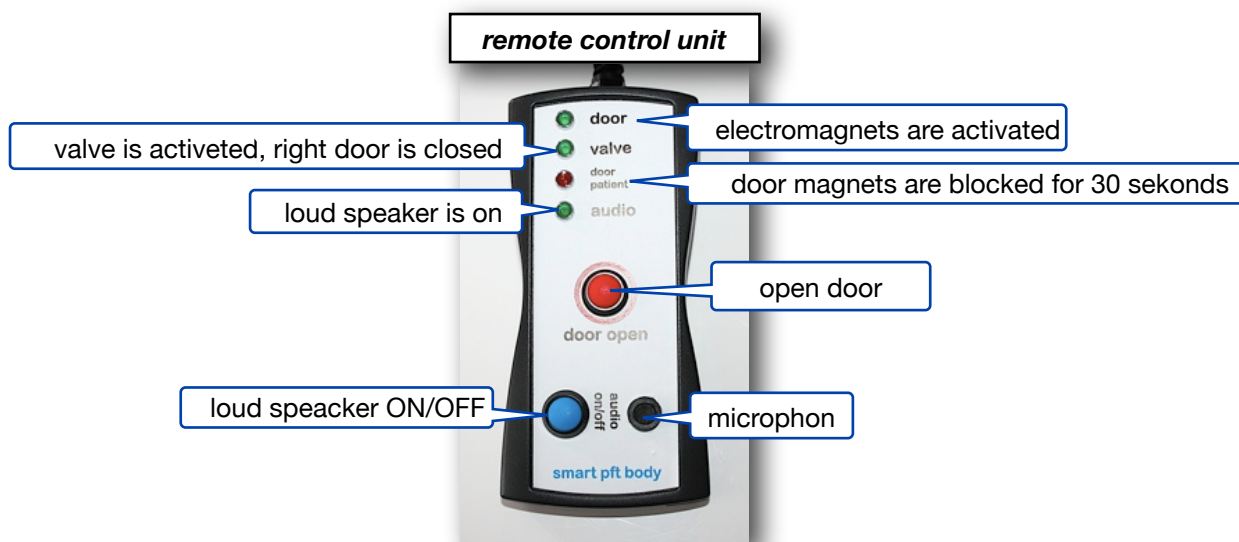
When the door open button was pressed, first the ventilation valve is deactivated and after a short time delay the door magnets too.

The patient captured in the bodybox can deactivate the door magnets any time by pressing the emergency door open button at the rear panel inside the box. In the case of the opening, the ventilation valve is deactivated before the door magnets to secure the pressure transducers. In case of opening the door by the emergency door button, the door magnets stay blocked for approximately 30 seconds. This blockage is assigned by a red lamp on the remote control unit.

By pressing the microphone button, the load speaker inside the bodybox is activated and deactivated. The loudspeaker is automatically deactivated when the door magnets are deactivated.

The activated loudspeaker is indicated by a LED on the remote control.

Also all other control status are displayed by LEDs on the remote control unit.

remote control unit

valve is activeted, right door is closed

electromagnets are activated

door magnets are blocked for 30 sekonds

loud speaker is on

open door

loud speacker ON/OFF

microphon

Important Information

Because of safety reasons, the door magnets are automatically deactivated after 10 minutes of being activated continuously. The red light on the remote control unit indicates, the door magnets are blocked for 30 seconds to be sure the bodybox gets ventilated with fresh air.

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## BTPS conditions: automatically measured or manually entered

Every device includes all necessary sensors to measure the BTPS conditions automatically. These sensors measure temperature, humidity and ambient pressure.

Data acquisition and BTPS sensor module with USB-interface in a stabile aluminum housing in the smartPFT Spirometry.

The yellow point covers the combined temperature and humidity sensor, the atmospheric pressure sensor is located inside the aluminum housing. To get reliable sensor results, the aluminum box may not be placed in front of ventilators and / or heaters that interfere with the ambient conditions. The sensor may also not be touched.
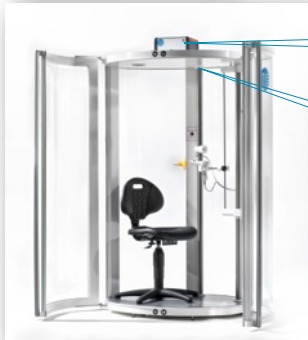
The data acquisition and control unit is located on top of the bodybox. This unit also includes the ambient pressure, flow and gas sensors.

The combined temperature and humidity sensor is located on the top plate inside the bodybox. The sensor is covered and protected by a white plastic housing.

To enter the BTPS conditions values manually, it is necessary to select the **Setup**-ICON in the main menu bar and afterwards the submenu ICON **Common** followed by the ICON **Ambient**.

A window appears that allows to enter the BTPS conditions data manually or to select between automatic measurement and manual BTPS conditions input.

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Important advices to be considered doing a pulmonary function testing.

To obtain reliable results in lung function testing, the patient must perform the breathing maneuvers with maximal compliance. It is recommended to explain the respective respiratory maneuvers before the test and practice where appropriate.

The patient has to put on a nose clip.

The patient also has to enclose tightly the mouth piece of the testing device. Mostly a round or better

an oval shaped mouth piece can be used but in some cases, depending on the patient,

a soft rubber bite mouth piece must be used.

Dentures have to be removed.

The upper picture shows a case of leakage at the mouth angles.

The second picture shows a correct enclose of the mouth piece.

Best test results are achieved if the patient is standing during the flow / volume test.

If the patient sits during the test procedure please adjust the hight position of the testing device in a way,

the patient has to sit straight upright to minimize restriction in thorax movement.
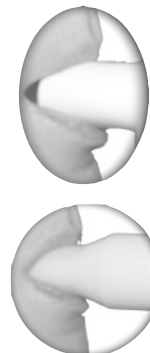
To minimize the risk of cross infections, single use bacterial filters should be used. This filters may be used for only one testing procedure for one patient for one day. Please respect, filters protect not only the patients but also the users and the machine.

Depending on age and hight, total lung size and breathing volume vary significant. The dead space volume of the testing device related the tidal breathing volume of the patient cause more or less a significant carbon dioxide rebreathing of the exhaled CO_2 gas. The relation between dead space and tidal breathing is called dead space ventilation. A too high dead space ventilation can cause a stop of breathing and death of the patient. Especially children have to be observed carefully all time during the test by experienced technicians. The durance of the test should be minimized, if necessary interrupt the test and ask the patient to move away from the device for recovery. In case of significant dead space ventilation, the SpO2 should be monitored during the test. The recommended dead space of the device should not exceed 1ml per kg bodyweight.

The bodybox may only be closed, when an experienced and trained person is present. At the rear spar of the cabin is an emergency button for the patient to open the door in case of an emergency or panic. If the door is closed, there is a potential risk of choking hazard if the bodybox was closed too long.

If you are using a CO diffusion gas please check the following parameter:

CO- and CH4 gas concentration > 0.15% and < 0.3% or > 1500 ppm and < 3000 ppm

Compressed gas bottle has to contain 21% of oxygen? The rest has to be balanced N2!

Check the expiry date of the bottle?

Secure the bottle agains falling?

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List of most important parameters for M.E.E. smart*pft*lab

| parameter	unit	description	ATS criterias
spirometry			
SVC	liter	slow vital capacity	difference < 5% within 3 tests
ERV	liter	exspiratory residual volume	
IRV	liter	inspiratory residual volume	
IC	liter	inspiratory capacity	
TV	liter	tidal volume	
flow / volume			
FVC	liter	forced vital capacity	minimum 6 seconds exhalation time, flow at end of test < 100 ml/s
FEV1	liter	volume exhaled within 1 second after beginning of exhalation	back extrapolation of slope and continuous exhalation, difference < 5% between 3 tests
FEV0,5	liter	volume exhaled within 0,5 seconds after beginning of exhalation	back extrapolation of slope and continuous exhalation, difference < 5% between 3 tests
PEF	liter/second	peak flow during exhalation	
MEF25	liter/second	maximum flow at 25% of exhaled volume	
MEF50	liter/second	maximum flow at 50% of exhaled volume	
MEF75	liter/second	maximum flow at 75% of exhaled volume	
MEF25-75	liter/second	MEF25 minus MEF75	
AEX	l/s*l	area under exhaled flow/volume loop	
PEF@FRC	liter/second	peak flow at FRC level	
PIF	liter/second	peak inspiratory flow	back extrapolation of slope and continuous exhalation, difference < 5% between 3 tests
CO diffusion			
TLCO	mmol/kPa*s	transfer factor CO	
Kco		Krogg factor CO = TLCO/VA	
VA	liter	alveolar volume	
FRC	liter	functional residual capacity	
RV	liter	residual volume	
TLC	liter	total lung capacity	
bodyplethysmography			
sRAW	kPa*s	specific resistance	
RAW	kPa/l*s	total resistance	
sGAW	1/(kPa*s)	specific conductance	
GAW	l/kPa/s	conductance	
RAWex	kPa/l*s	expiratory resistance	
RAWin	kPa/l*s	inspiratory resistance	
TLC	liter	total lung capacity	5% variation between 3 tests
TGV	liter	thoracic gas volume	5% variation between 3 tests
RV	liter	residual volume	5% variation between 3 tests
IC	liter	inspiratory capacity	5% variation between 3 tests
RV/TLC	%		
TGV/TLC	%		
MVV test			
MVV	liter/minute	maximum minute ventilation	breath at 30 breath/minute
BF	1/minute	breathing frequence	30/minute
Rocc			
Rocc	kPa/l*s	occlusion resistance	breath normally

How to do a spirometry test

The quality of lung function testing depends strongly on the quality of the patient instructions. The instructions have to be verbally clear and precise to avoid any kind of miss understanding. The way, how to instruct the patient is defined and published in the guidelines of the American Thoracic Society and European Respiratory Society. The technician must be experienced and well trained to be able to guide patients to do lung function testing with good quality.

Spirometry

A spirometry test determines the static lung volumes that are breathable. The maneuver has to be performed slowly, the most important test result is the slow vital capacity (SVC). The slow vital capacity can be measured most reproducible and without interference by symptoms by a maximum inhalation. A reduced slow vital capacity informs about restrictive lung disease.

The display shows a straight line moving from the left edge of the screen to the right. The coordinate system shows the breathing volume over time. The patient has to put on a nose clip and to enclose the mouthpiece tightly with the lips before starting the test..
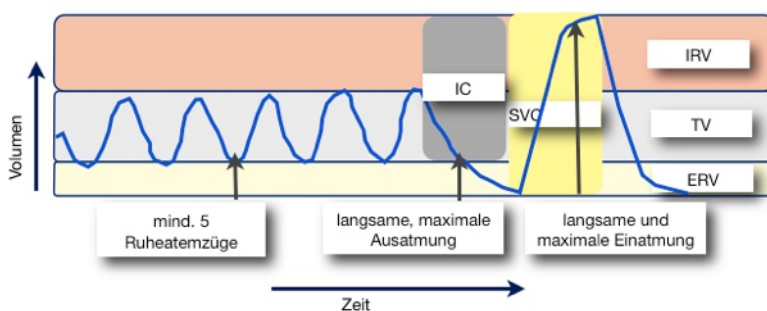
After starting the test program, the patient has to breath minimum 5 times normally to measure the tidal breathing volume and level. In case of a strong varying breathing pattern, the period of normal breathing has to be extended. After this normal breathing period, the patient first has to exhale slowly and deeply as possible. After the deep and maximum exhalation the patient has to inhale slowly and continuously to the possible maximum. After the maximum inhalation he can exhale again.

The patient is not allowed to move away from the mouthpiece during the maneuver and any kind of leakage has to be avoided. The test procedure has to be repeated until the SVC of three tests varies less than 5 % compared to the maximum value.

How to do a flow/volume test
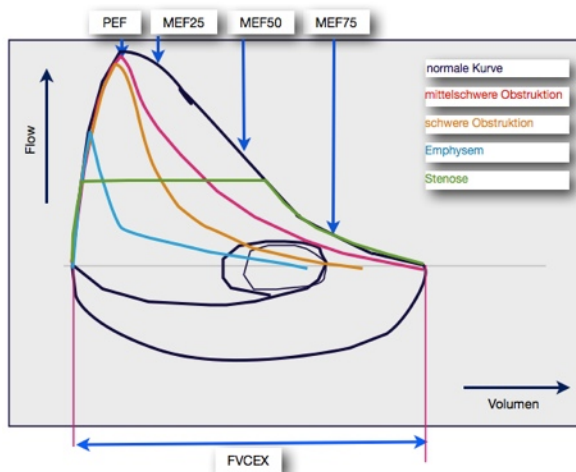
The flow/volume test informs about the dynamics of the lung related to maximum flow rates in order to detect obstructive lung disease. The graphic shows the in/exhaled flow over in/exhaled volume. The shape of the exhaled curve allows to interpret the grade of obstruction.

The test maneuver requires the patient to do a view normal breaths before inhaling slowly to the maximum volume in order to continue with a forced exhalation to a minimum volume before inhaling forced again to the maximum volume. It is very important that the maximum in- and exhalation maneuvers are made with maximum flow speed and volume wise as deep and as long as possible. Good test results require maximum breathing force from the patient.

The picture above shows the shape of typical flow volume tests. Exhalation is shown in the upper part of the graph, inhalation in the lower part. The top of the curve shows the peak flow. A good collaboration is recognizable when the peak is reached before 15% of exhalation volume. This means, the peak has to be as near as possible at the left of the curve and the rising edge of the peak has to be as steep as possible. The volume exhaled within the first second of exhalation is called FEV1. It is recommended to do three tests with a maximum allowed difference of 5%.

It is also obligatory that he patient exhales for minimum 6 seconds. Obstructive persons need a long exhalation time. Please respect, children and fibrosis patient can mostly not exhale for such a long time. There are two bars at the left button part of the test screen to indicate the exhalation time and the flow rate during exhalation. ATS/ERS recommendations require that both bars change from red to green before the patients start inhalation. Again, in some cases patients dot reach these criteria.

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Bodyplethysmography

Since more than 40 years, the bodyplethysmography is accepted as a standard test to measure the airway resistance and static lung volumes especially for obstructive, COPD and emphysema patients.

The test consists of three maneuvers:

1.   Airway resistance test during tidal breathing maneuver with higher breathing frequency (RAW);
2.   Thoracic gas volume by occlusion technique (TGV);
3.   Spirometry maneuver to determine residual volume and total lung capacity.

Compared to the flow/volume test, the resistance test requires no forced breathing maneuver from the patient, the results represent the average resistance of all generations of the lung.
The resistance test measured in the bodybox is more sensitive than any other method, the shape of the curve allows interpretation of emphysema.

There are also other methods to measure residual volume and total lung capacity but only the bodyplethysmograph gives reliable results in case of obstructive lung disease.

To measure RAW and TGV it is necessary to determine the alveolar pressure during the maneuver. To avoid artifacts it is absolutely important that the patient sits without significant movement during the test.

To perform a TGV test, the patient has to sit in the box and the door must be closed. The patient puts on a nose clip and starts breathing normally. From time to time the technician presses the SPACE button on the keyboard to initialize a closing of the shutter. When the valve is closed, the patient must try to continue breathing several times against the blockage to compress and decompress the air in the lung. During this maneuver, box and mouth pressure are registered and displayed continuously. The curve steepness of mouth pressure displayed against box pressure determines the TGV value.
After approximately 3 seconds, the valve opens again. After opening, the patient has to exhale to the minimum followed by inhaling to a maximum like described in the spirometry test in order to determine residual volume and total lung capacity.

To perform a resistance test, the patient has to sit quiet in the closed box and to breath with a breathing frequency of minimum 60 / minute. The breathed tidal volume should be less than 500 ml to achieve best results.

To give you an idea about the pressure differences measured in the box and to understand how sensitive the system is we give you an example. A patient with a normal resistance has an RAW off approximately 0,2kPa/l*s. If he breathes with a speed of 1 l/second, the alveolar pressure is approximately 0,2 kPa. If the volume of the lung is 3 liters, the pressure difference measured in the box is 0,2 kPa / 300 ≈ 0,67 Pa because the ratio box volume / lung volume (900 liters / 3 liters).

This calculation is simplified and does not respects any correction necessary because of adiabatic gas conditions.

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Resistance test (RAW)

block diagram RAW
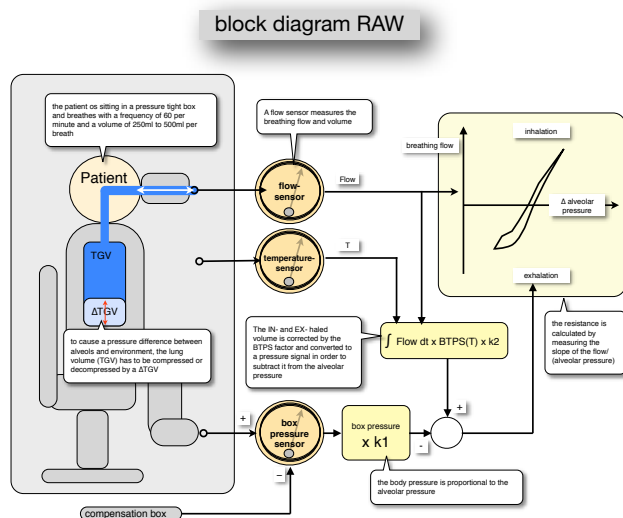
The patient sits in the pressure sealed box, puts on the nose clip and breathes through the flow testing device mounted on an adjustable stand. Switch on the loudspeaker to advice the patient in the box. It is important to sit without physically movement and to breath with a breathing frequency higher than 60 per minute and a breathing volume lower than 500 ml. As bigger as the breathing volume is as higher is the influence of BTPS error, this means, the program takes longer to compensate the displayed curves. The flow rate should be between 1.0 l/s and 1.5 l/s. Small children breath best with a flow rate between 0.5 l/s and 1 l/s. The breathing flow is measured by a pneumotachograph, the bodybox pressure by a difference pressure transducer, measured agains a compensation chamber to reduce ambient pressure artifacts. Box temperature, humidity and ambient pressure are measured to calculate influence of gas changes between ambient and lung during gas exchange.

The airway resistance curves display breathing flow over calculated alveolar pressure, the alveolar pressure is compensated by BTPS. The grade of inclination represents the RAW value. High inclination means low resistance, low inclination means high resistance.

Examples for resistance loops:
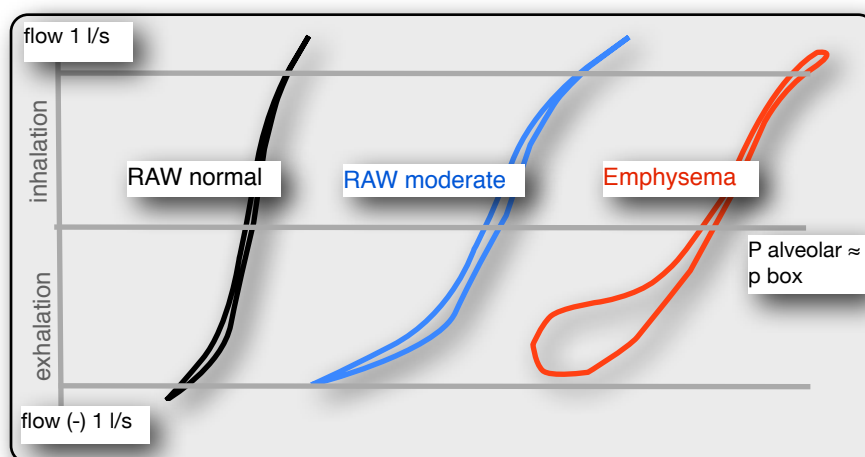
The displayed curves show flow speed over calculated alveolar pressure. To determine the resistance value it is obligatory to know the lung volume (TGV) during the resistance test. We ask to measure TGV before RAW to know the lung volume. There is a sRAW or sGAW used too.
sRAW = RAW * TGV.
sGAW = 1 / sRAW.

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TGV test

Block diagram TGV

the patient is sitting in a pressure tight box and tries to continue breathing against a blockage caused by a shutter

Patient

the breathing is blocked with beginning of inhalation by a shutter

p mouth

Δ mouth pressure ≈ Δ lung pressure

TGV

the ratio of mouth pressure and boxpressure represents the TGV

ΔTGV

the breathing maneuver increases and decreases the TGV by a Δ TGV and this change causes a pressure change in the box- and lung pressure, the lung pressure is equal to the mouth pressure

Δ boxpressure

the box pressure changes are measured synchronously to the mouth pressure

p box

To perform a TGV test, the patient has to sit without significant movement in the pressure sealed box like described in RAW test . It is very important to put on the nose clip and to enclose the mouth piece tightly to avoid any leak. We recommend to use flexible bite mouth pieces to be sure the patient seals the mouth tightly. It is necessary to breath normally and to follow the instructions of the technician. After a few breaths, the technician presses the SPACE bar to initialize the blockage of the shutter. After pressing the SPACE bar, the program activates automatically the valve magnet to interrupt the patient breath at begin of the next inhalation. The valve is closed for approximately 3 seconds. During the blockage, the patient continues the breathing maneuver for several cycles. The system requires a significant mouth and box pressure change to determine the TGV. The displayed curves have to be big enough but should not exceed the window screen. Registering and displaying the mouth pressure against box pressure allows to determine the TGV value.

TGV examples

Munddruck

Boxdruck

normales TGV   hohes TGV   Undichtigkeit   zu geringe Anstrengung

Determine the static lung volume RV

To calculate the residual volume (RV) it is necessary, that the patient exhales to the minimum volume after the breath blocking procedure. The volume exhaled after the TGV blockage is called expiratory residual volume (ERV). The volume what is still in the lung after maximum exhalation is called residual volume (RV).

RV=TGV-ERV.

Measure TLC

After exhaling to RV, the patient has to inhale to the maximum. The maximum volume inhaled from RV is called inspiratory vital capacity (IVC). The volume of the lung after inhaling to the maximum is called total lung capacity (TLC).

TLC = RV + IVC.

To achieve reliable results it is necessary to repeat each test minimum 3 times. The program takes always the average of all tests, To exclude tests with artifacts, a particular test has to be deselected.

Single Breath CO- diffusion test

The advantages of a single breath CO diffusion test are:

      Takes less than one minute;

      error consumption is low;

      CO gas absorption for the patient is low;

      reproducibility is high;

      RV and FRC are calculated too.

Disadvantages are:

      The patient has to collaborate well;

      the patient must be able to understand the maneuver;

      the minimum breathing volume has to be more than 1 Liter;

      patients with distribution disease can not be measured properly.

The single breath diffusion test is the method, that is used in more than 90% of all cases for screening.
For this kind of test it is necessary to have fast, selective and linear gas analyzers.

Test gas definition

The required test gas mixture is:

0,2 % to 0,3% CO , 0,2 % to 0,3 % CH4 , 21% O2, rest: N2

Necessary components of the CO testing device

The system consists of the following items:

1	Flow testing sensor with shutter to interrupt the breathing;
1	CH4 Gas analyzer;
1	CO Gas analyzer;
1	Demand valve to supply the test gas;
1	Bottle of compressed test gas;
1	Data sampling and control unit and computer system for display, calculations and storage.

To perform a test, the gas analyzers require a minimum heating up time of 10 minutes. Please switch on the device early enough to stabilize the analyzers. The patient has to use a nose clip and to seal the mouth piece tightly with his lips.

Recommended CO gas concentration is   3000 ppm;

Recommended inert gas concentration is   3000 ppm.

After doing a few quiet breathing cycles, the patient has to exhale until the demand valve for the test gas is activated. After hearing the valve switch, the patient should inhalation the test gas by the demand valve deeply and fast. After inhaling, the patient has to block the breath for 10 seconds and to exhale slowly and deeply after the blockage was released.

With beginning of gas inhalation and during the breath holding period the inertgas is diluted in the lung, the diffusion gas is diluted in the same way but also diffusing. The diffused gas is linked to the hemoglobin in the blood and can not be exhaled anymore. There is a concentration difference between inertgas and diffusion gas. The gas difference allows the determination of the diffusion capacity, it is defined as diffused gas per breath holding period.

TLCO   =   53,6/t * log ((inhaled CO % * exhaled CH4 %) /

                        (exhaled CO% * inhaled CH4 %)) * VA

VA is the alveolar volume and is calculated by the equation total lung capacity during diffusion - anatomic dead space.

KCO   =   TLCO / VA

VA   =   (IVC*inhaled CH4% - V_apparatus*exhaled CH4%) / exhaled CH4% - anatomic_dead_space

                    anatomic_dead_space = 0,0022 * body_weight (assumption)

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How to perform a CO diffusion test

Most gas analyzers are based on the principal of infrared absorption. These kind of gas analyzers require a certain heating up time to reach stable conditions. We recommend to switch on the device 10 minutes before the first test. The program gives you a warning message when the program was started and the heating time is below 10 minutes. This information might be insufficient if the program was restarted. Click on continue to start the test anyhow.

All smart pft devices are equipped with automatic zeroing valves. This means, the patient can be connected to the testing device at any time, also during zeroing.

After starting the test program and zeroing, the system displays the message:

> ### Please breath normally

The patient makes minimum 4 normal breaths, this period allows the program to analyze the average breathing time

After this analysis period the system displays:

> ### exhale continuously and deeply

It is required that the exhalation time is longer than two times the normal breath time. Not the exhaled volume is important but the exhaled time. The next phase is starting when the valve switched and the system displays the next message:

> ### Inhale continuously a maximal

Now, the patient has to inhale fast and deep to reach minimum 90% of his total lung capacity. He should not inhale to the maximum to be able to hold the breath for the following 10 seconds.

After 10 seconds of breath holding, the program displays the last message:

> ### exhales slowly and deeply

It is important that the patients exhales for minimum 3 seconds, better longer. Again, the exhaled volume is less important than a sufficient exhalation time. If possible the patient exhales to (RV) but this is not obligatory.

Training mode for CO diffusion test

It is very important, that the patient understands the test procedure fully. Because the consumption of CO gas should be minimized we recommend to exercise the breathing maneuver before doing a real test. Exercise the maneuver until the patient understands the importance of enclosing the mouth piece tightly at all time of the testing period.
To realize a training mode, You have to activate the button **Training**. If Training mode is on the button displays **Training ON**. If the mode is off, the button displays **Training OFF**. In Training mode ON, the patient can exercise the maneuver again and again without any gas supply. In this mode, the shutter is switched on after gas inhalation during breath holding.

Analyzing mouth pressure during breath holding

If the patient causes a high lung pressure during breath holding the diffusion result can be influenced.
The system displays the mouth pressure during breath holding as a yellow line to recognize and to guide the patient during breath holding.

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the breathing pattern

volume axis

holding breath

calculated diffusion time

tidal breathing

exhale deeply

inhale gas to maximum

50 % of sampling volume

test ends with an normal inhalation

time axis

The diffusion time is calculated by adding the last third of ininhalation volume + blocking time until exhal... me to 50% of exhaled sampling volume

gas concentration curve

Concentration axis

CO
CH4

Phase III

Phase I
Phase II

Phase IV + V

time axis

The sampling volume has to be located fully within Phase III

Evaluation criteria for CO transfer testing

The CO transfer test supplies 2 values to quantify the transfer capacity named TLCO and KCO.

TLCO supplies information about the diffusion capacity related to the lung size. A 50% lung size means 50% diffusion capacity even if the membrane component is normal.

KCO supplies purely information about the membrane component of the diffusion capacity. This value is normal compared to the predicted values even if the lung size is reduced by resection but membrane component is normal.

Severity of the measured TLCO results related to the predicted values in % for diffusion disease.

> 70%	normal
70% - 50%	moderate
< 50%	severe

Please respect, TLCO is also lowered when the lung volume is reduced by surgery, to determine this value it is necessary to inhale nearly to TLC. KCO represents only the pure membrane diffusion. Even this parameter is influenced by perfusion and abnormal hemoglobin blood concentrations.

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Equations to correct Hb interference

If the measured Hb value differs significant from the normals, a correction of the TLCO and KCO factors are required.

Normal value of Hb for men > 15 years	=	14,6 g/dl
For boys < 15 years and women	=	13,4 g/dl

Correction for man > 15 years:
TLCOHb   =   TLCO / (1,7 * Hb / (10,22 + Hb))

Correction for women and children < 15 years
TLCOHb   =   TLCO / (1,7 * Hb / (9,38 + Hb))

Equation to correct TLCO and KCO for altitude changes

TLCO altitude =   TLCO * (1 + 0,0031 * ((P ambient * 0,76 - 47)*0,20942)-150)
P ambient [mbar]

Equation to correct Hb-CO back pressure

TLCO CO Hb   =   TLCO / (102 % - CO Hb %)

Equation for BTPS Correction

VBTPS   = VATPS * (Patm(kPa)-PH2O_T(kPa)) / (Patm(kPa)-6,266)*(273+37)/(273+T)

T   = room temperature
Patm   = atmosphere pressure
PH2O_T   = water vapor saturation pressure at room temperature

Equation for PH2O_T (Magnus-Equation)

PH2O_T   = PH2O(0) * exp. (17,5043*T/(241,2°C+T))
PH2O(0)   = 611(Pa)
T   = room temperature in °C

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How to do a compliance test

Preface:

To do a compliance test, the technician must be trained and experienced in doing such a test. Because of the risk of uncontrolled bleeding caused by injuring of varicose veins, an experienced physician has to be present for the case of an emergency.

The compliance test is an invasive method to determine the elasticity of the lung. As a result of interstitial lung disease caused by inflammation, the thickness of the diffusion membrane is increased. A thicker membrane causes a decrease of the gas diffusion and also decrease of the lung elasticity.

To measure the lung elasticity, an ballon catheter is placed into the esophagus via the nose. It is important to place the catheter correct to measure the right pressure. Fix the correct position of the catheter by a nose clip and advice the patient to enclose the mouth piece tightly.

To measure the static compliance, the patient has to do a very slow inhalation up to the TLC and a maximum exhalation down to RV. The maneuver has to be a slow as possible. The compliance curve displays breathing volume over esophagus pressure. The steepness of the linear part of the curve determines the compliance. The unit is volume/pressure [l/kPa]. Interstitial lung disease causes a decrease of the compliance. Obstructive lung disease may increase the compliance.

The static lung compliance measures the lung elasticity without flow. The dynamic compliance measures the lung elasticity during flow. To do a dynamic compliance test, the patient breathes with normal breathing frequency and tidal volume.

static compliance curve

dynamic compliance curve

The ripple of the curve is caused by the heartbeat. The patient has to breath slowly form RV to TLC. The regression line has to be located in the linear part of the curve.

The patient breathes normally or with a higher frequency but tidal volume. The red line marks point of turn from in- and exhalation
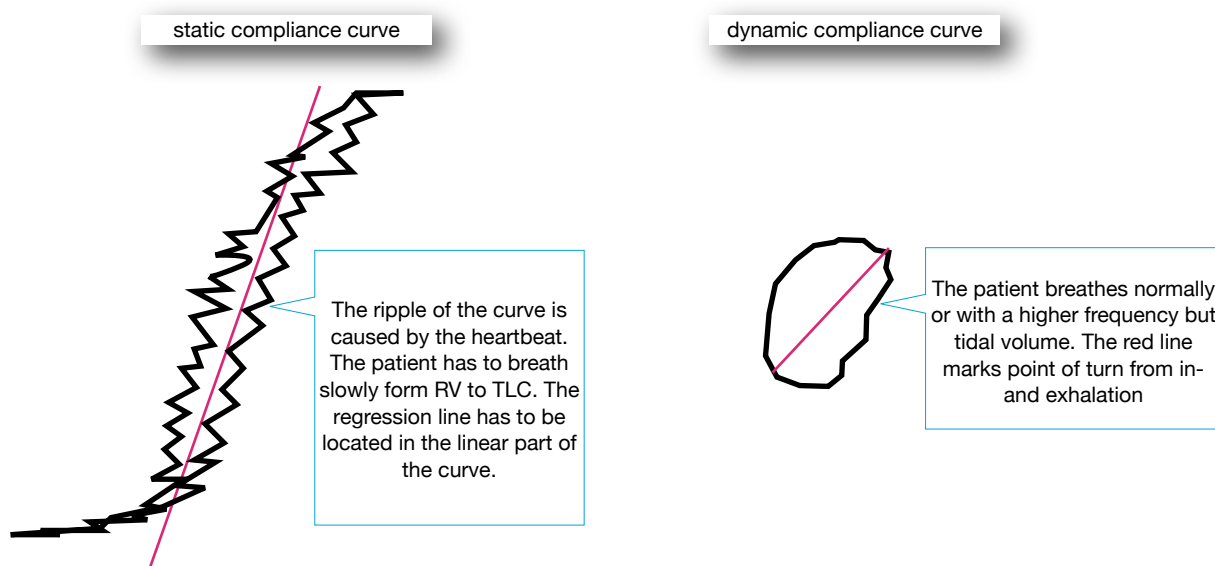
Cleaning and disinfection

To avoid cross-infection, we require the use of disposable filters. The disposable filters not only protect patients from cross infection but also the users and the sensors. The filter must have such a high absorption rate for viruses and bacteria, that a risk of infection can be ruled out.

Nevertheless, all surfaces are treated according to the daily use of the instrument with a spray disinfectant.

The measuring parts, contaminated by the breathing of the patients must be disinfected at least once a week, independent from the use of filters. Certain circumstances may require a complete disinfection immediately after each test.

Visible contamination of sensors and / or other parts must be removed mechanically or chemically prior to disinfection.

The choice of disinfection mean depends on the needs of that institution. The concentration of the solution and application information of the manufacturer must be observed.

In case of any uncertainty, consult a competent hygiene officer.

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SmartSoftmee 1.1 software

The software was mainly designed using C#, the database is based on a SQL server.

We tried to design the software in a way, that the symbols and program flow are self explaining. To make calculations as simple as possible, statistic methods and advanced compensation algorithm are used to determine particular values. Never less, it is required that the technician or other user has the physiological and technical background to be able to perform valuable test results. In the previous chapters you find the specific information to understand the test procedures. The following chapters inform about the specific software procedures to perform a test.

Common information about the software design

The use of the software requires existing know how in use of windows based programs. The software also requires knowledge in use of a keyboard and / or mouse and / or a touch screen. The available program options, a user can select are displayed as so called ICONS. ICONS are small pictures with or without text, that represent a selectable software option. The option is activated by moving the mouse cursor to this ICON and pressing the left mouse button. In some cases it is required to click the right mouse button to activate additional program options. On Apple PC systems the right mouse click is achieved by pressing the CTRL button on the keyboard in combination with the mouse. In case of touch screens, mostly the right mouse click is achieved by keeping the ICON touched for a view seconds. On Apple track pads with multi touch, klick on the ICON with two fingers instead of one.

Expressions, used in the following chapters

mouse cursor: Small arrow or hand symbol displayed to mark the position of the cursor.

ICON: Small symbol or picture that represents a certain program function.

ICON names are displayed in upper letters in bold and italic. For example **LOGIN , CANCEL**

Select an ICON: Position the mouse cursor on an ICON.

Confirm an ICON: Press left mouse button.

Confirm by **O.K.**:   click on [✔ ICON] .

Exit with **CANCEL**:   confirm [CANCEL] ICON.

Exit by **O.K.**:   confirm [o.k.] ICON.

The menu bars

There are 5 different kind of menu bars used in the program: The main menu bar, the test menu bar, the display menu bar, the data menu bar and the setup menu bar.

The main menu bar is always displayed at the left screen edge and allows selection of patient data and main testing routines as well as setup and program exit.

The test menu bar is always displayed at the right edge of the screen in order to allow interactions during a test.

The display menu bar is located at the right side of the screen and displays possible actions after a test, like repeat and so on.

The data menu bar is located at the upper screen edge and is displayed after main menu ICON **PATIENT** was confirmed.

The setup menu bar is located at the top edge of the screen and shows the selection of different setup routines like print setup, device setup and so on. This bar becomes active when the **SETUP** menu ICON was confirmed before in the main menu bar.

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Software start

To start the program confirm the software ICON on the windows screen by a double click.

Now a Login windows appears on the display, please confirm the **LOGIN** button to start the program.

If Login was correct and if data base could be addressed, the menu screen appears on the display. Depending if manual ambient data input was installed, the ambient data have to be corrected and/or confirmed.
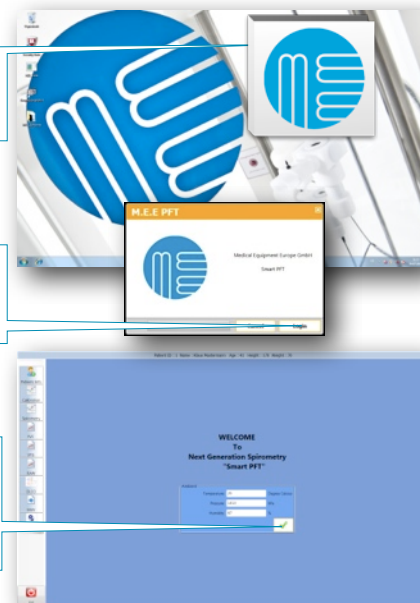
Patient data menu

The left main menu bar displays the possible selections of

Patient data input;
Test selection;
System setup;
Program exit.
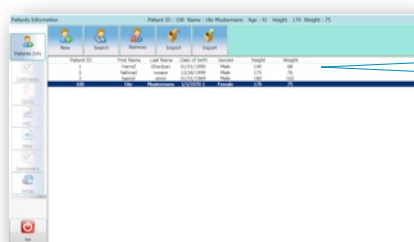
By selecting the upper main menu ICON named **PATIENT DATA**, a list with the last measured patients is displayed. Just by selecting one of the patient rows. New tests can be performed and printed but also stored tests can be reviewed and printed again. A selected patient can be removed from the list by selecting the patient menu bar item **REMOVE**. By double clicking on the patient row the patient data input mask is displayed to make changes.

New patient data can be entered by clicking on the data menu bar the item **NEW**. A new window appears that allows to enter the necessary patient data.
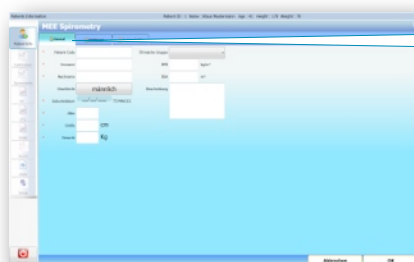
The particular input fields have to be filled in the correct format. If an input is not valid, the program waits for a correct input. Some fields are filled automatically after calculation. Do not forget to save the patient data by clicking on **O.K.**

Additional customized patient data fields are available by selecting the **ADDITIONAL** ICON in the submenu **PATIENT**.
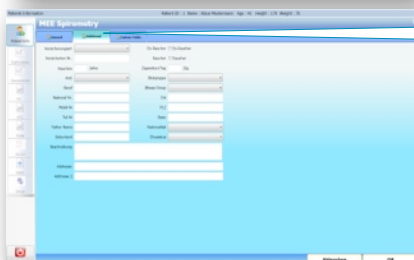
This input option allows the input of customized data fields. Save the input or changes by selecting **O.K.**.

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Sub menu bar **NEW PATIENT**
Customized fields

CUSTOM FIELDS:
Enter or change additional patient data fields.
Don't forget to save the changes.
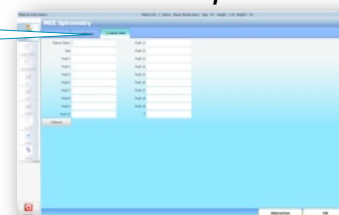
Main menu bar **PATIENT** :
Search patient

SEARCH:
Allows searching and recall of stored patient
data and test results. There is a choice to
search by name or by ID-N°.
RESET deletes the input data.
MORE shows the patient data.
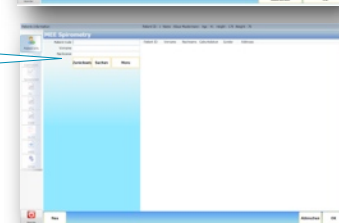
Main menu bar **PATIENT**:
Delete data

This menu item allows to delete patient names
from the list,or to delete test or the whole file
of the selected patient .
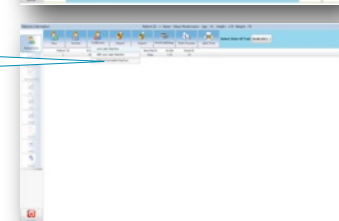
Main menu bar **PATIENT**:
Import data

IMPORT allows to import patient data or tests
from an external source. This function is also
used to a update data base.

Main menu bar **PATIENT**:
Export data

EXPORT allows to store data in an internal or
external storage. This function can also be
used to update a data base.
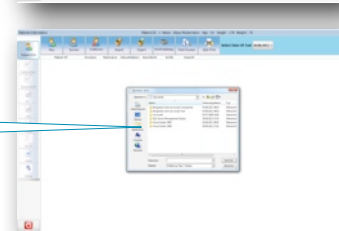
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Define Technician

To define the name of the technician for the next test please select the ICON ***Technician*** in the menu bar.

In the next window that appears, you can enter the name of the technician. Close the procedure by clicking the ***O.K***. button. By selecting O.K. the entered name is stored automatically for a quick selection next time.

If the current technician should be used as a default, select the small square box and deselect in the same way.

Clicking into the square at the right side of the input line, all stored technician names are listed for a quick selection. Select the line with the mouse cursor click and click on the ***O.K***. button for confirmation.

To modify the stored list of Technicians, click on the ***Edit*** button.

The edit window allows you to correct or to delete names of technicians stored before.

Volume calibration

After selecting the **CALIBRATION** ICON in the main menu bar, there is the choice to select between BOX CALIBRATION and FLOW CALIBRATION. After VOLUME CALIBRATION was chosen, the calibration syringe must be connected to the flow sensor. The calibration routine starts by clicking on **PERFORM TEST**.
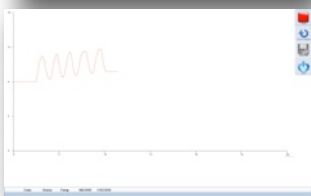
It is required to do minimum 5 complete pump cycles. The pump cycle speed should be approximately 30/minute for a 3 liter syringe and 60/min for a 1 liter syringe. Press the **STOP** ICON to stop calibration and to display the calibration factors.
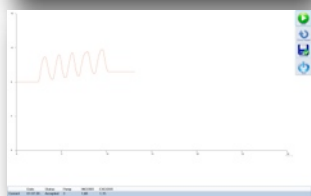
SAVE & EXIT saves the calibration results. The values for exhalation and inhalation should be between 0.7 and 1.3. The symmetry error should be less than 3 %. The factors can be cancelled by pressing **QUIT**.
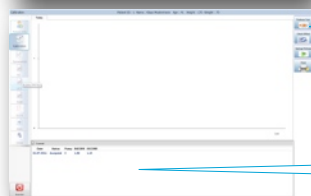
The calibration routine can be repeated by pressing **PERFORM TEST** again.

The lower table displays the calibration factors. The previous factors are also displayed in the row above. Please pay attention if factors vary significant.

Box calibration
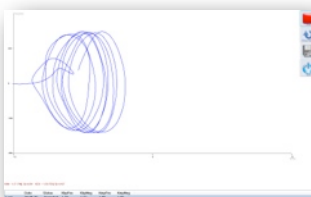
To do a box pressure calibration, connect the test device like explained in the chapter „system setup" for automatic pressure calibration. Close door and wait until box valve is closed .Start the calibration routine by clicking on **PERFORM TEST**. The 50 ml electronic syringe starts automatically, the display shows flow over box pressure. The shape of the curves must be elliptic like displayed in this picture. A drift from left to right is allowed.

The program starts automatically the mouth pressure calibration after closing the shutter. The display shows mouth pressure signal versus time. The calibration program stops automatically at the end of the routine. When the pump stops press the red **STOP** button.
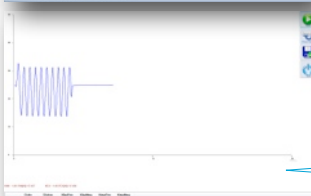
The measured factors are displayed in a result list, the previous factors are displayed above the new ones.

The old and the new calibration factors should not vary significant. In case of significant changes check flow sensor and shutter as well as box sealing and start again. If you are not sure contact a service person.

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Spirometry test

To start a spirometry test select in the main menu toolbar the ICON **SVC.** Ask the patient to put on the nose clip and to enclose tightly the mouth piece with the lips during the test. Start now the test procedure by clicking on the test menu toolbar ICON **PERFORM TEST**.
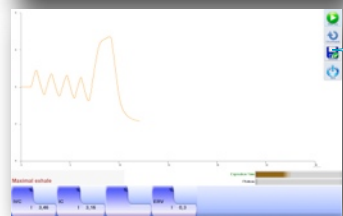
The patient has to follow the instructions of the technician related to the previous chapter Spirometry. The test can be repeated immediately by selecting the **NEW TEST** ICON. All tests are stored in the data base by clicking the **SAVE&EXIT** ICON. If you don't want to save, click **QUIT**.
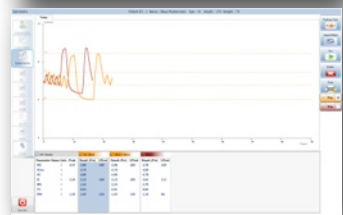
All tests are displayed overlapped. The best test is the test with the highest value for SVC. This test is selected as the best automatically by the software. The best test is marked with an upper **B** letter in the selection toolbar at the right screen edge. The user can make another choice by clicking into the selection toolbar. A manual choice is marked with a lower **b** letter. Tests can be deactivated by clicking into the select toolbar. Attention !!! It is obligatory that a test is declared as best and minimum one test has to be activated.

Flow/Volume test
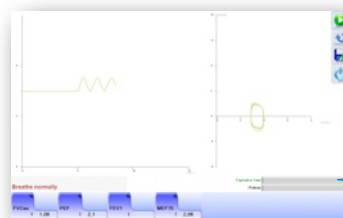
The test procedure is the same like the one for the spirometry. Please follow the guidelines of the previous chapter Flow/Volume test. There are two color bars displayed in addition. This two bars change from red to green if the patient exhaled for more than 6 seconds and if the flow rate is below 100 ml/second at the end of the test maneuver.
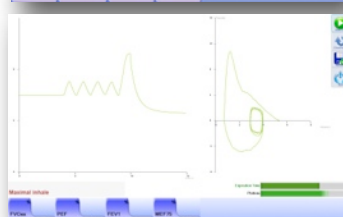
It is recommended to do minimum 3 tests by restarting the test with the ICON **NEW TEST**. All tests are displayed overlapped to recognize reproducibility. Maximum patient compliance is guaranteed if the tests loops have the same size and shape. Save again by clicking **SAVE & EXIT.**
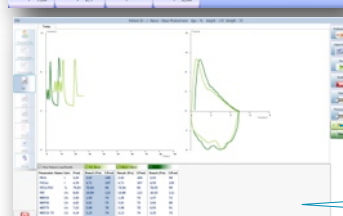
Like in the Spirometry test the best result is selected automatically by the software. If necessary, deactivate particular test by clicking into the correlating toolbar row.

All test results are displayed in a table, the left column shows the numbers selected as best.

MVV test
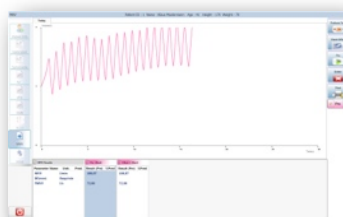
The test procedure is the same like for Spirometry and Flow/Volume test. The patient should breath with a frequency of approximately 30 / minute maximum volume. The test takes 12 seconds, the result is multiplied by 5 to extrapolate to 1 minute. Please pay attention, This test makes the patient feeling bad.

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Incentive graphs

There is an animation program available in order to help small children to understand and to perform a best possible flow/volume test.

The test procedure and instructions are the same like for the standard flow/volume test. The moving graphic should motivate the child to learn the relation between the moving objects on the screen and the breathing.

To start the incentive graphics you have to select the **CHILD GRAPH** button in the right test menu bar after selecting **FLOW/VOLUME** test.

The incentive graphic shows a small boy and some clouds in the middle of the window. It is the target to inhale as deep as possible to exhale as fast and as deep as possible to blow the clouds out of the window. The movement of the clouds are related to the maximum flow rate and the exhaled volume. The clouds disappear when the peek flow and the exhaled volume are more or equal 100% of the predicted values.

Motivate the child to repeat the test several times.
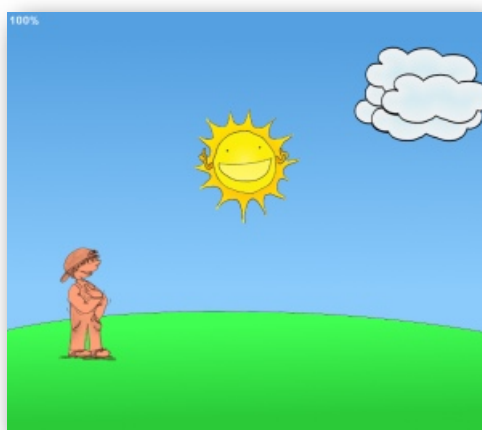
if the child is not able to blow the clouds out of the window, press the **CURSOR DOWN** button on the keyboard to decrease the predicted values by 10% each press. By pressing **CURSOR UP** you can increase the predicted values by 10% up to maximum 100%.

At the end of the test press SAVE&EXIT to save the test. Repeat the test in the usual way of the flow/volume procedure.

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TGV test
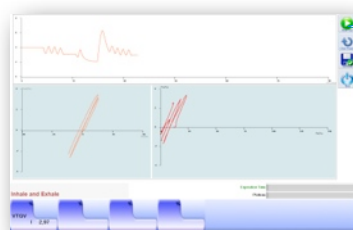
The patient has to sit in the box and to put on the nose clip. Explain the maneuver to the patient and tell him to keep the mouth piece enclosed tightly all the time of the test and to sit quiet all the time too. Close the door by pressing the right door against the box. Close the left door by pressing the door against the box. Make sure all 4 magnets are closed. Wait until the valve of the box is activated, indicated by a lamp on the remote control device. Start test by pressing the **PERFORM TEST** button.
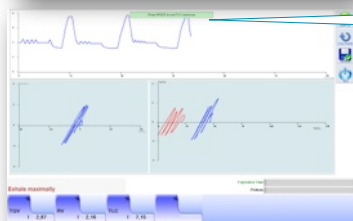
There are three windows displayed on the screen. The upper long window shows the volume / time curve during the whole test. The lower left window displays the mouth pressure over box pressure when TGV maneuver is activated. The lower right window displays all TGV tests made after a maneuver. Tell the patient to breath normally and press the **SPACE BAR** after a view breaths. At the end of the next exhalation, the program activates the shutter to block the breathing. During the blockage the patient has to continue with breathing agains the blockage. After approximately 3 seconds the shutter is deactivated and the patient can continue to breath normally. Tell the patient now to do breath out slowly as deep as possible followed by inhaling slowly as deep as possible. This maneuver is necessary to measure RV and TLC. After the deep inhalation press the **SPACE BAR** again to finish the TGV maneuver. The program moves now the graph of the left window into the right window what shows, the first TGV test is done. Repeat this maneuver minimum 3 time. After 5 times the TGV program ends automatically. You can end the program manually any time by pressing the **SAVE&EXIT** button
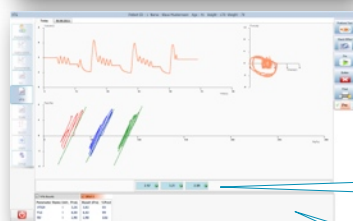
This screen shows the final display of the TGV test. The screen consists of three windows. The upper window displays the volume over time curve for all maneuvers done. The middle windows displays all TGV curves and the lower windows displays the result table.
You can select and deselect particular TGV maneuver by clicking into the small result windows below the TGV curves. The first result correlates with the first TGV curve, the second one with the second curve and so on. Please deselect TGV curves that have artifacts.

The result table shows the averaged values of all activated tests.

Resistance test
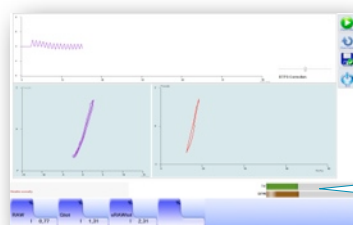
Before a resistance test can be started, a TGV test has to be done. The door of the box has to stay closed and the test gets started by pressing **PERFORM TEST**. The patient has to breath with a higher breathing frequency to achieve good results. Best breathing frequency is minimum 60/minute, best breathing volume is below 500 ml. The flow rate should be between 1l/s and 1,5 l/s. Two color bars indicate best breathing pattern when color changes from red to green. It is important that the patient breathes with constant pattern to adapt BTPS correction factors.
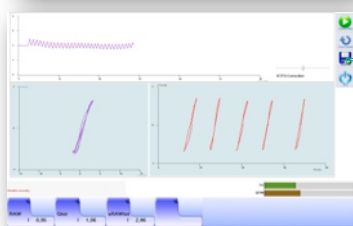
During the test the screen is divided in three windows like for the TGV test. The upper windows displays the volume curve to control the breathing pattern of the patient. The lower left windows displays the online measured resistance curves. Please wait at the beginning until the curves are stabile and compensated. The curves should be as slim as possible. When the curves are stabile click first into the left window to clear the screen. Now wait for minimum 2 breathing cycles before clicking into the right lower window or press **SPACE BAR**. After each click, the left loop is transferred to the right one. After 5 cycles clicked to the right, the test stops automatically. You can repeat the test any time by selecting again the button **PERFORM TEST**.
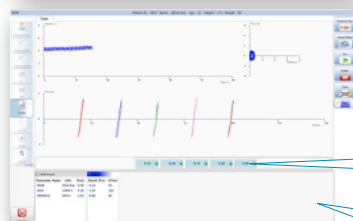
This screen shows the final display of the RAW test. The screen consists of three windows. The upper window displays the volume over time curve for all maneuvers.The middle windows displays all RAW curves and the lower windows displays the result table.
You can select and deselect particular RAW maneuver by clicking into the small result windows below the RAW curves. The first result correlates with the first RAW curve, the second one with the second curve and so on. Please deselect RAW curves that have artifacts.

The result table shows the averaged values of all activated tests.

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Diffusion test

Exercise the diffusion maneuver without gas supply
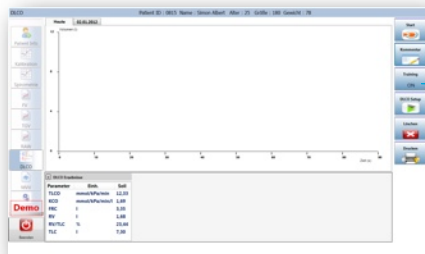
Press the ICON *Training OFF* to switch training mode on and press the ICON *training ON* to switch it off before starting a test by the *PERFORM TEST* button .If Training mode is activated, the patient can exercise the breathing maneuver without gas supply.

Start a diffusion test
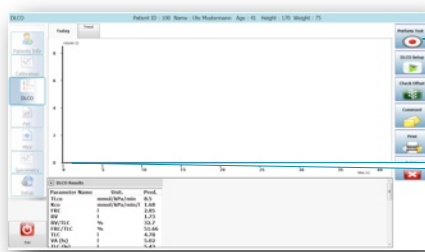
It is very important to explain the test procedure to the patient before starting the test, clicking the *PERFORM TEST* button. It is important that the patient understands the maneuver. Tell him to keep at all time of the test the mouth sealed to the mouth piece. After putting on the nose clip start the test by clicking on *PERFORM TEST*.

Check the mouth pressure line shown as a green colored line on the x-axis. This line indicates a change of mouth pressure to guide the patient stop pressing against the occlusion.
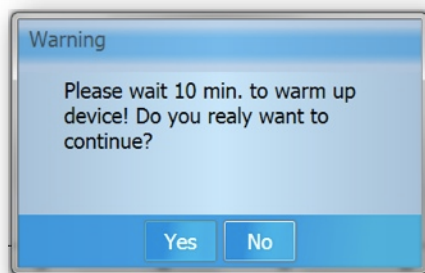
Because the gas analyzer requires a heating time of minimum 10 minutes, the program displays a warning message if the software was started less than 10 minutes ago. This 10 minutes heating time are necessary to stabilize the analyzer. This message depends only on the time since the software was started. If the system hardware is running more than 10 minutes, click *Yes* to continue immediately.

Zeroing the Diffusion gas analyzer
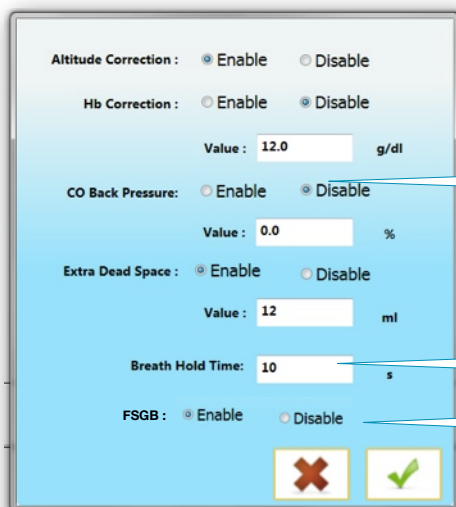
After starting the test by the PERFORM TEST button, the system checks first the CO- and CH4 gas analyzers. If the zero is out of the range, the system proceeds with a hardware zeroing. If zeroing is not necessary, the software starts the test.

If zeroing is necessary, the system displays a message window on the screen to monitor the status of the zeroing procedure. When the question window appears on the screen, you have to select either the *YES* button to start zeroing or the *NO* button to continue without zeroing.

It is recommended to press *YES* to be sure the system gives reliable numbers. Only in the case of testing the gas analyzers it is allowed to continue without zeroing.

After zeroing the system returns to the main menu, you have to start the test again by activating the *PREFORM TEST* ICON in the test menu bar.

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Enter value for Hemoglobin correction and breath holding time

To enter the data for Hb correction of the diffusions results you have to click the **DLCO SETUP** icon before starting the test! In the following window you can enter data for Hb, and CO back pressure.
Enable the Hb Correction and enter the data in the correlating line. Save the data by clicking the green **O.K.** button at the end of the window. The results shown at the end of the test are now Hb corrected.

The breath holding time can be modified by entering the valve blocking time in seconds here. Save the modification by pressing the green **O.K.** Symbol.

Activate FSGB by **Enable** or deactivate by **Disable**.

Fast space gas balancing method FSGB   (optional)

If a patient has distribution disease, the exhaled inert gas line allows to separate between normal distribution, fast spaces distribution disease and slow spaces distribution disease.

In case of fast spaces distribution disease the fast spaces gas balancing technique allows the determination of the correct VA compared to the standard method.

If FSGB is enabled, the VA is calculated using the inert gas extrapolation method of Prof. Brandt, also TLCO is calculated using the corrected VA.
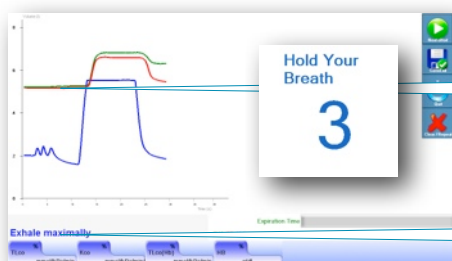
The red and green gas concentration line have to be straight lines during normal breathing. If there is a significant movement in the green line there might be several reasons like, the patient has made a test before and the inhaled gas from previous test is still not washed out or the patient has still blood alcohol what is exhaled or the patient took a mouth refresher spray what contain alcohol. If the red line moves, it is back breathing of CO from smoking. If the green line moves too much you have to wait a certain time until the signal is normal

The text line below the graph displays the information how to instruct the patient. Please follow this instructions because the program synchronizes all steps automatically. At the beginning, the patient has to breath normally. After approximately 4 breathing cycles, the program advices to exhale slowly until the shutter valve is activated, listen to the shutter click. Now the program advices to inhale to nearly the maximum. After inhalation, the patient has to block the breath for 10 seconds. Please see the timer at the right screen edge. After breath holding ,the patient has to exhale slowly for minimum 3 seconds and deeply. The test ends by pressing **SAVE & EXIT**.

The yellow line shows the mouth pressure curve during the test procedure


After the test, the results are displayed in the lower window as a table. You can repeat the test any time but please respect to wait for a few minutes before restarting to make sure, the patient exhaled the diluted gas from the previous test. If several test were made, the menu bar on the right side of the screen shows which test is momentarily activated. By clicking into the select box of another line, you can select another test if available.
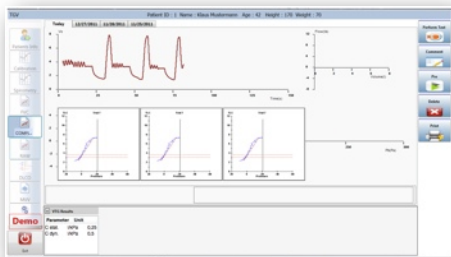
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Compliance test

The patient has to follow the instructions of the technician related to the previous chapter how to do a Compliance test. The test can be repeated immediately by selecting the **NEW TEST** ICON. All tests are stored in the data base by clicking the **SAVE&EXIT** ICON. If you don't want to save, click **QUIT**.

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PRE & POST
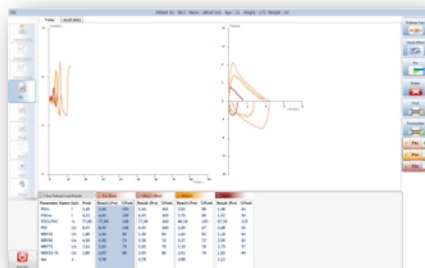
The first test is always a **PRE** test. After giving a brochodilator medication, the next test has to be declared as a **POST** test. In the right menu bar you must select the **PRE** icon by a mouse click to switch to a **POST** test. After the click, the **PRE** button changes to **POST**. If you start now a test by clicking **PERFORM TEST**, the next test is automatically declared as a **POST** test. By another click you switch to **PRE/POST** and after that it returns with another click back to **PRE**.
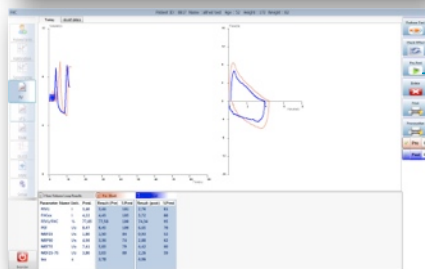
It is only possible to switch to **POST** if a **PRE** test was made. The **PRE/POST** display shows all **PRE** and **POST** tests and the results of the best **PRE** test compared to the best **POST** test. After doing a **PRE** and a **POST** test, you can display either a **PRE** test or a **POST** test or a comparison of **PRE** and **POST** by clicking the icon **PRE** or **POST** or **PRE/POST**.

Single tests of **PRE** or **POST** can not selected or deselected in the **PRE/POST** display mode. It is important that one **PRE** and one **POST** test are declared as **BEST** test. If you print a test, the last selection of **PRE** or **POST** or **PRE/POST** are used for the print style.

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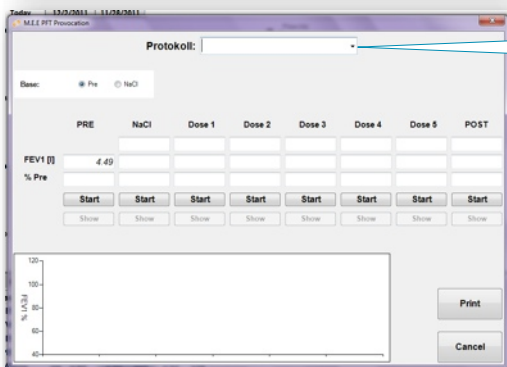
Challenge testing

In the file c:\TTSPIRO\BronchoProvocation.XML the definition for the challenge test medication sequences are defined. See the following example for a Metacholine protocol, this file can be extended easily by new sequences. Metacholine, Histamin and Carbachol exist already as standards.

```
<?xml version="1.0" standalone="yes" ?>
- <Challenge>
- <Sequence>
  <Name>Metacholine</Name>
  <IsCumulative>true</IsCumulative>
- <Stage>
  <Name>Normal</Name>
  <IsAgent>false</IsAgent>
  <Concentration />
  <ConcentrationUnit />
  <Dose />
  <DoseUnit />
  </Stage>
- <Stage>
  <Name>NaCl 0.9 %</Name>
  <IsAgent>false</IsAgent>
  <Concentration>0.9</Concentration>
  <ConcentrationUnit>%</ConcentrationUnit>
  <Dose />
  <DoseUnit />
  </Stage>
- <Stage>
  <Name>Metacholine</Name>
  <IsAgent>true</IsAgent>
  <Concentration>0.01</Concentration>
  <ConcentrationUnit>mg/ml</ConcentrationUnit>
  <Dose />
  <DoseUnit />
  </Stage>
- <Stage>
  <Name>Metacholine</Name>
  <IsAgent>true</IsAgent>
  <Concentration>0.02</Concentration>
  <ConcentrationUnit>mg/ml</ConcentrationUnit>
  <Dose />
  <DoseUnit />
  </Stage>
- <Stage>
  <Name>Metacholine</Name>
  <IsAgent>true</IsAgent>
  <Concentration>2.56</Concentration>
  <ConcentrationUnit>mg/ml</ConcentrationUnit>
  <Dose />
  <DoseUnit />
  </Stage>
- <Stage>
  <Name>Salbutamol</Name>
  <IsAgent>false</IsAgent>
  <Concentration />
  <ConcentrationUnit />
  <Dose />
  <DoseUnit />
  </Stage>
  </Sequence>
```

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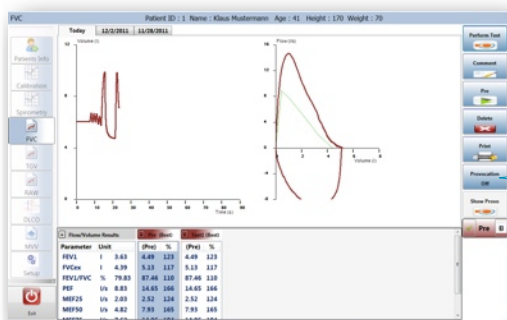
To do a challenge test, the patient has to do a flow/volume test first, he should not have taken a medication like a bronchodilator since a reasonable time to be sure there is no side effect caused by medication. The flow/volume test has to show a non obstructive pattern. The FEV1/SVC should be above 80% of predicted. If the first test was normal, the challenge test gets started by clicking onto the *PROVOCATION OFF* icon in the right menu bar after the first test. The challenge test can also be initialized before the first test, If selected, the *PROVOCATION OFF* icon changes to *PROVOCATION ON*. To start the first test click the *PERFORM TEST* button.Now a selection windows appears on the screen. Please note, Challenge test works only with flow/volume test.
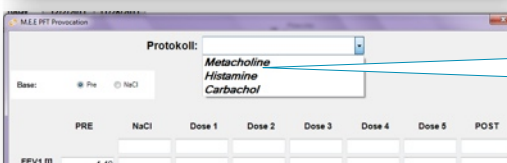
First you have to select a challenge test protocol. Click into the first line of the screen to list the challenge test protocols installed in the file BronchoProvocation.XLM. If necessary complete this file by a new protocol.
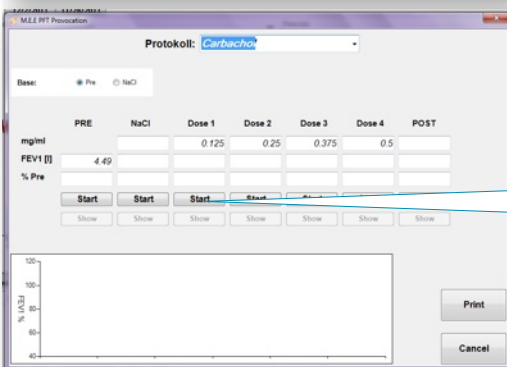
The next window shows the list of challenge test protocols available. Click on the challenge test protocol line you want to use.

The next screen shows the particular steps of the challenge test protocol with the required doses. The first step is always the normal test before any medication. If a normal test was done before selecting the challenge test, The FEV1 of this test is displayed in the first row under *PRE*. You can restart the *PRE* test several times by clicking on *START* below *PRE*. You can start the next step by clicking *START* below *NaCL* dose or by clicking *START* below a *DOSE*. If you did a flow/volume test in a next step, the previous can not be repeated anymore. It is obligatory to supply first the medication by a dosimeter system before starting the correlating test. After finishing a test by *SAVE&EXIT* the FEV1 for this DOSE is displayed below the DOSE. Also a trend graph is displayed.
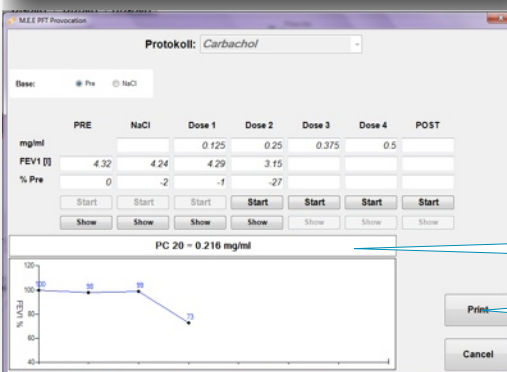
It is possible to compare the test after applying the medication with the *PRE* test or the NaCl test. A test is positive when the FEV1 drops more than 20% compared to the *PRE* or NaCl test. In such a case a red message line is displayed in the text line above the trend graph.

You can print the challenge test by clicking the *PRINT* button.

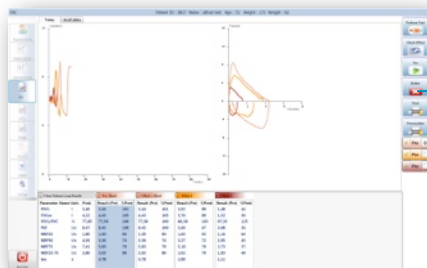smart*pft*lab ™

Challenge test report
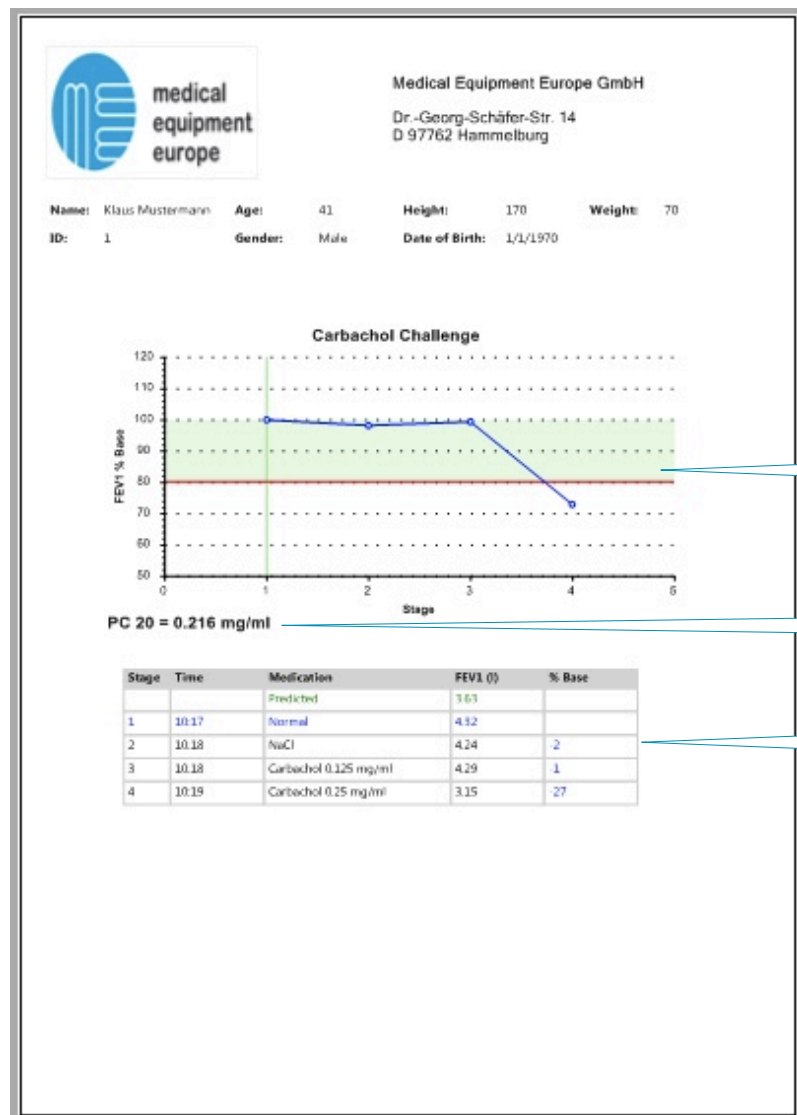
The red line shows the 20% threshold for the FEV1. The 100% line is adjusted to the PRE or NaCl test, depending on your choice.

This line displays the PC20 value this means, the concentration at the crossing of the red line.
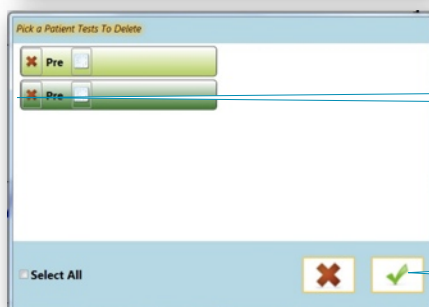
The table shows the results for each step of the provocation.

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Delete tests

Before and after a test it is possible to delete tests of today or of a selected day by clicking to the **DELETE** button in the right displayed menu bar. After selecting this button a new window appears on the screen

By default, all tests are deselected. Select a test for deleting by clicking into the square box with a red X. The X gets substituted by a ✔. Clicking into the select box **Select All**, selects all measurements.

Click on this ✔ button to delete the selected tests.

Select best test, deselect test
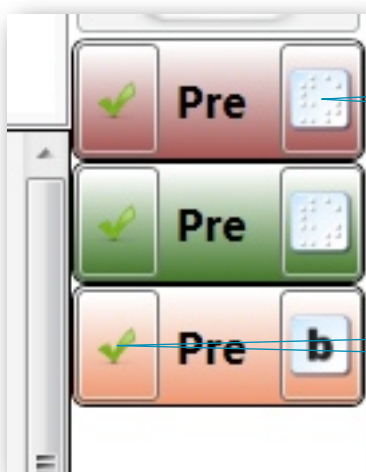
In the right menu bar are square select boxes to declare particular test as **BEST.** The software selects automatically a test as the best, related to the guidelines of ERS and ATS. An automatic selection is marked by an upper **B**. The user can overwrite this selection anytime by clicking into the correlating square. A manual selection is marked with a lower **b.** Please note, it is obligatory that one test is declared as a BEST.

Test can be deselected by clicking into the square box with the ✔ . After deselecting the green ✔ gets substituted by a red **X.** Please ensure, that minimum one test is always selected.

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How to display or print current and archived tests.

the date label displays tests, made on certain days select the label today to display the current tests. The labels located right from today display the date of measurements available.
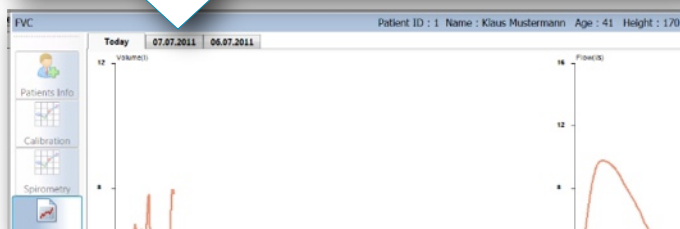
First you have to select the patient from the **PATIENT INFO** list by selecting the name with a mouse click or by the program function **SEARCH**. To display tests made in the past related to the selected patient, you have to select a particular test from the main menu toolbar. If you want to display a resistance test, select the menu ICON **RAW** for example. If archived tests are available, the specific date labels are displayed above the test window. To display a test from a day, select by a mouse click the date label. The archived tests will be displayed on the screen.
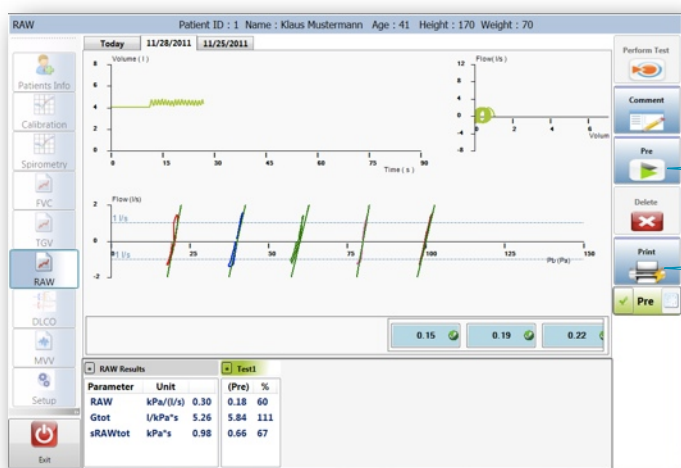
To display tests without any medication, this ICON has to be set to **PRE**. To print only the tests after medication, the icon has to be set to **POST**. To show the comparison between Pre and Post the icon has to be set to **PRE/POST.** To change the status of the icon from PRE to POST or to PRE/POST you have to click into this icon again and again.

To print the test just displayed on the screen click onto the **PRINT** icon with the *left mouse* button. To print or to display complete test reports of the selected day click on the **PRINT ICON** with a *right mouse button*.
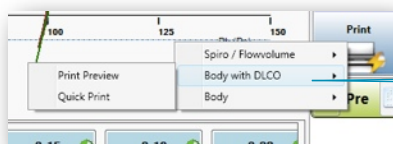
Depending on the print templates available, a list of report types are displayed. By selecting one line of the listed report templates there is a choice to select between screen display and paper print.
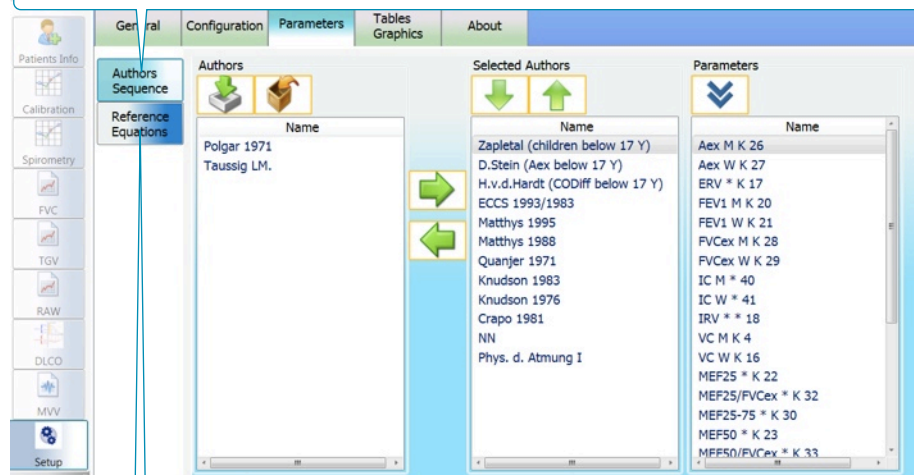
Predicted values

There are several authors for predicted value equations stored as selectable tables.
The author list can be defined with priority levels. The predicted values of the author who is listed on top has the highest priority. The one below has second priority and so on. Priority list means, the program takes first predicted values from the author with highest priority and takes the value from a lower priority level if there is no equation available for a certain value in a higher prior list.

You can chose between several authors by selecting the main menu toolbar item **Setup**, followed by selection of **PARAMETERS** again followed by selection of **AUTHORS SEQUENCE**. The program displays now three columns. The left column contains the authors available but not selected, The middle column shows the authors that are selected. The right column shows the predicted equation of the high lighted author name, selected in the middle column.

You can select and deselect authors by selecting a particular one by a mouse click in the left ore middle column and moving the selected line by clicking one of the green arrows between column left and column middle . In the middle column, the priority is organized in a way that the upper author names have highest priority. To move an author up in the priority level, you have to select the particular one and moving him up and down by clicking one of the green arrows above the middle column. The right column shows the equation belonging to the selected author. Se details by selecting one of the parameter lines and click onto the blue arrow icon above the column.

After clicking on **REFERENCE EQUATIONS** you can select a particular author from a list in the upper windows. In oder to be able to make changes of the predicted values, we recommend to handle this option very carefully to avoid any kind of data mismatch.

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Create and modify reports

General information

Our software includes also a report generator to design customized print templates. To start the generator you have to select the **SETUP** icon in the main menu bar. Please be informed, this chapter gives only common information in the use of the generator. To create or to modify templates it is important to practice the use of this program.
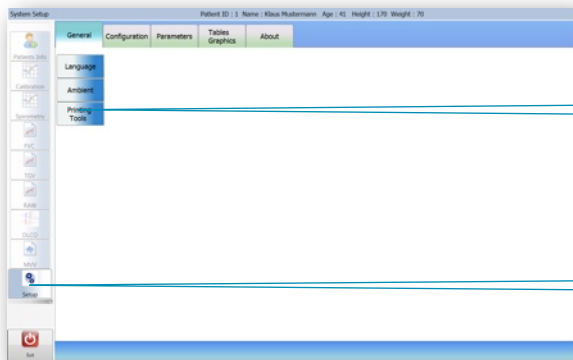

After the setup button was selected, the setup menu bar shows a **PRINTING TOOL** button which has to be selected.

The **SETUP** button in the left main menu bar has to be selected to get to the screen displayed.
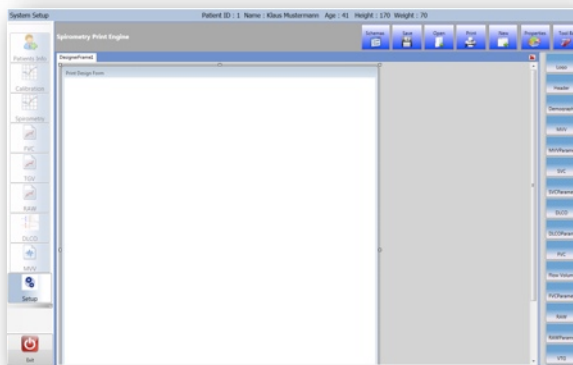
The upper print tool bar contains the control function icons of the report generator. Here you can open and save existing print templates but also create new once. Also the schemes can be opened, saved and modified. The templates can be linked to particular schemas.

The print tools selection bar contains the particular tool list to create, complete or modify templates.
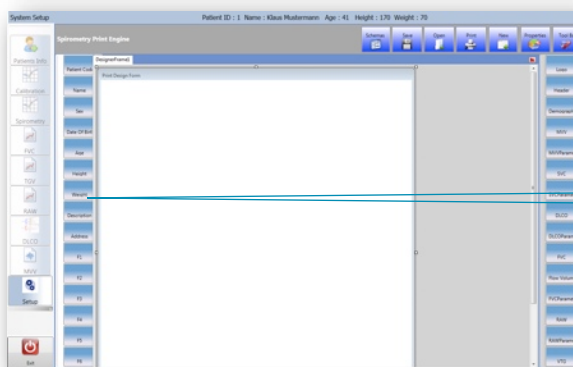
The most right print tool menu bar icon **TOOL BAR** displays additional selections to create print templates

The additional menu **TOOL BAR** menu icons are displayed at the left edge of the report generator window. Here you can select information windows to place for example the name, sex, age, hight of the patient on the template.
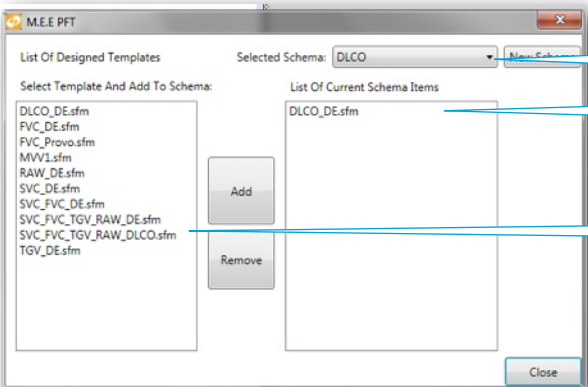
How the report generator is structured

The main menu bar indicates the tests, available in your system. A spirometry system includes the slow vital capacity test and the flow/volume test. A bodyplethysmography includes in addition a RAW and TGV test. If you started the report generator, you can select the icon **SCHEMES**.

The **SCHEMES** are linked to the specific test This link can not be modified but you can connect **TEMPLATES** to the SHEMES and so finally to certain test procedures.

Protocols linked to a specific test

After selecting the ICON **SCHEMES**, the following window will be displayed.
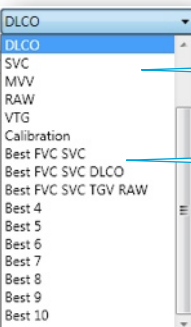
Click into this line **Selected Schemes** to select an existing SCHEME. If you click to the ▼ symbol at the right side of the line, all existing schemes are listed.

This window shows the templates that are connected to the selected **SCHEME**.

You can link any template to the selected scheme from this list by the buttons **Add** or **Remove**. If you selected more than 1 template, all templates are printed in a sequence.
Please be aware that templates have to belong to the kind of test represented by the scheme. You can not link a SVC template to a DLCO scheme.

Protocols, that allow to combine different type of tests

This window shows an example of the list of schemes. The displayed list includes all standard schemes available in the preset system.

All schemes that start with the name **Best**, can combine templates from different test types.
If you click on a **PRINT** icon by pressing the left mouse button, the schemes dedicated to a certain test will be activated, like DLCO, SVC, MVV, RAW, VTG. Here are no combinations allowed.
If you click on a **PRINT** icon by pressing the right mouse button, the **Best** schemes are activated. Here you can print combined tests.

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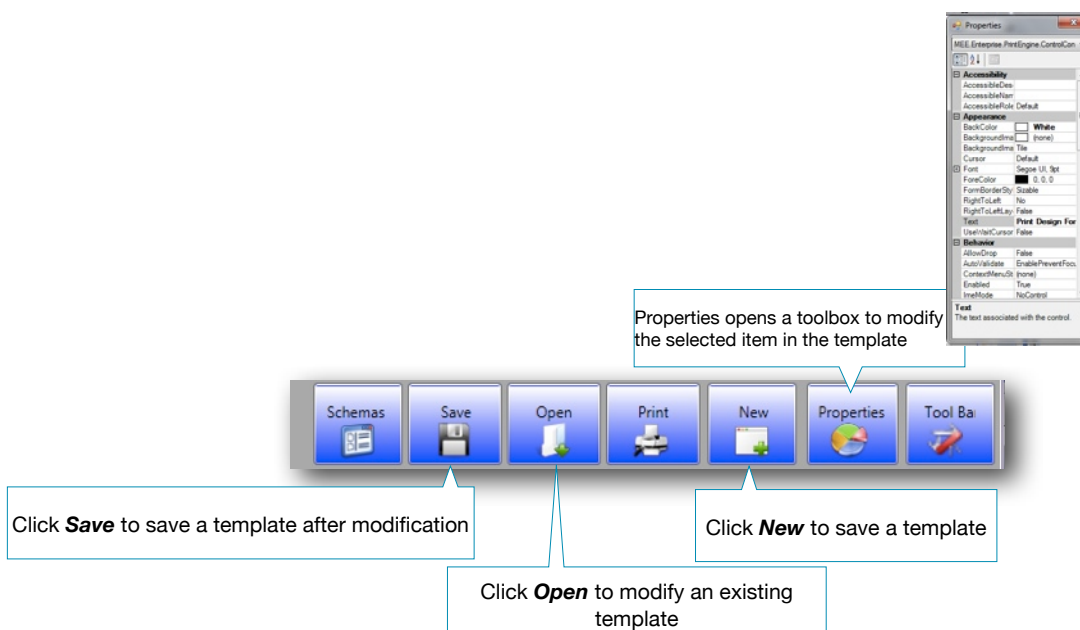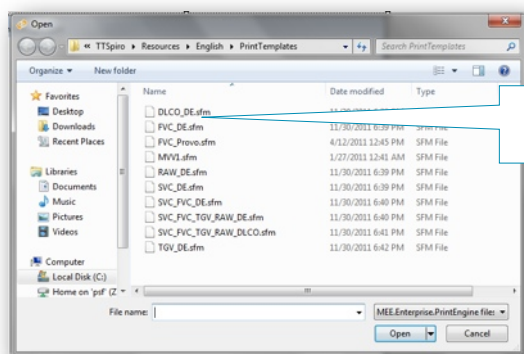Structure of schemes for dedicated tests selected by a **left** mouse click.

kind of selected test	Scheme	predefined templates
flow / volume test	FVC	DLCO.fsm
spirometry test	SVC	SVC.sfm
DLCO test	DLCO	DLCO.sfm
Resistance test	RAW	RAW.sfm
TGV test	TGV	TGV.sfm
flow / volume test	FVC	challenge.sfm
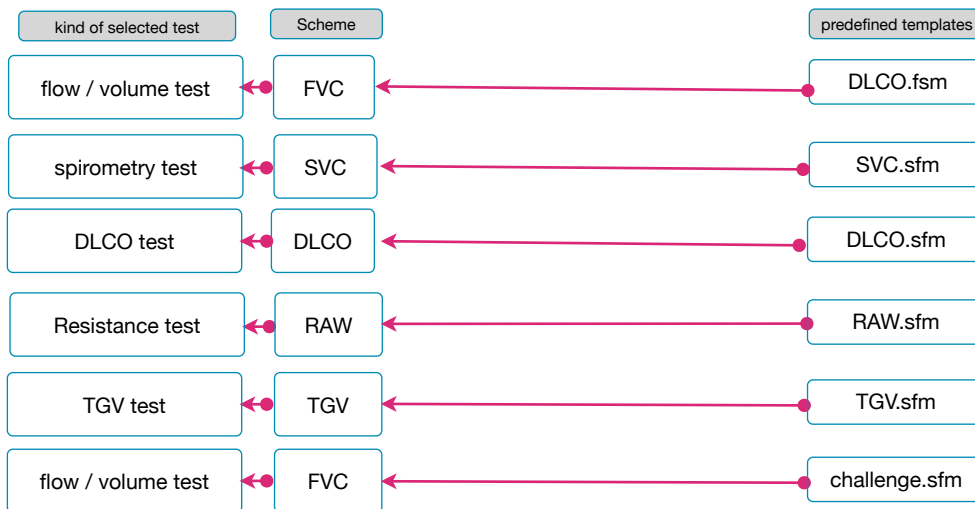
Example of the structure of schemes for combined tests selected by a **right** mouse click.

flow / volume test	Best SVC DLCO	DLCO.fsm
		SVC.sfm
SVC test	Best SVC TGV RAW	DLCO.fsm
		SVC.sfm
		XXX.sfm
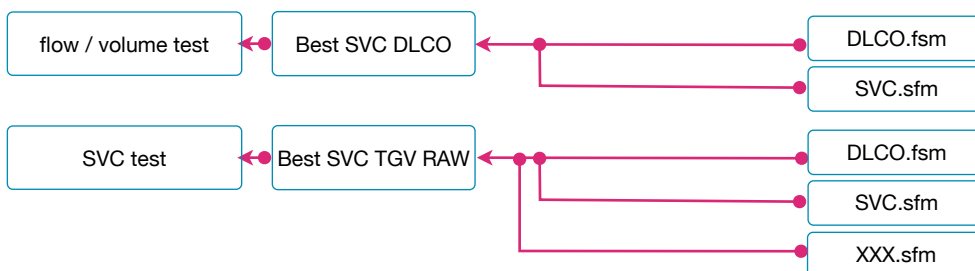
Quick guide how to modify a template

If you clicked on **Open**, a window opens, displaying the templates available.

Properties opens a toolbox to modify the selected item in the template

Schemas   Save   Open   Print   New   Properties   Tool Ba

Click **Save** to save a template after modification

Click **Open** to modify an existing template

Click **New** to save a template

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Select one of the existing templates you want to modify by a mouse click
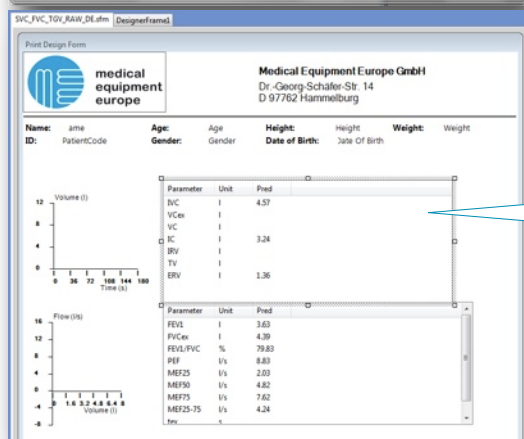
To modify any item of the template you have to click with the mouse into the item. A selected item is displayed with a frame. A selected item can be replaced or resized or removed from the template.
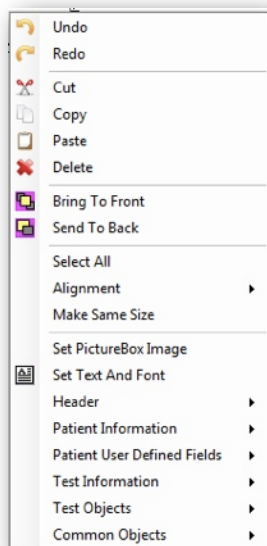
If you click into an item with the right mouse button, a tool bar opens with all tools available to modify the selected one or to import new items.

Header imports a Logo or a text field to enter customer headlines.
Patient

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Activate demo mode
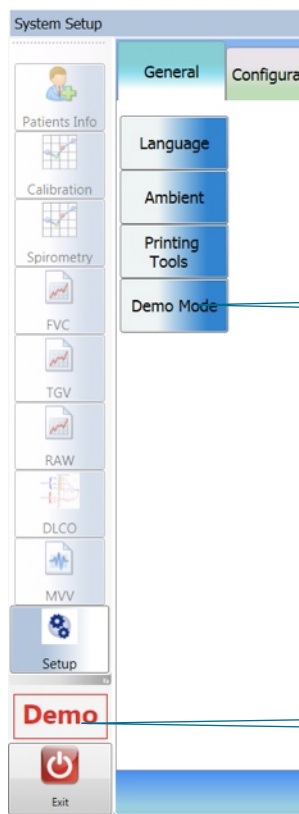
All test can be exercised in a demo mode. To initialize the demo mode you have to go to the **SETUP** menu and click on the bottom **DemoMode.** Do the same procedure to deactivate demo.

To recognize if Demo Mode is active, a red colored Window with the writing **Demo** is displayed all time during active DEMO mode.

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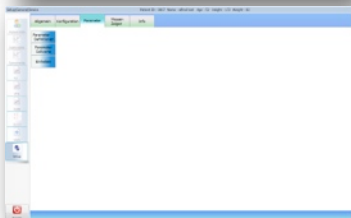# *Device and software setup*
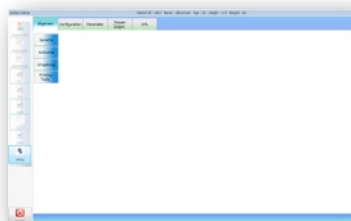
The main window of the SETUP menu.
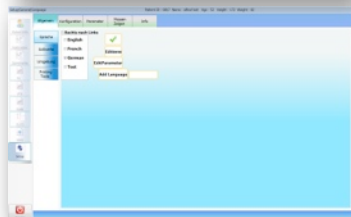
Submenu select language.
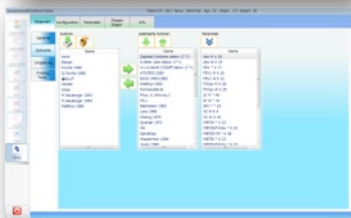
Select authors for predicted values and install priority list.

Input BTPS conditions and define data for single use bacterial filter.
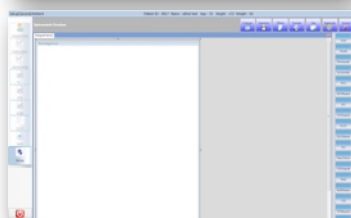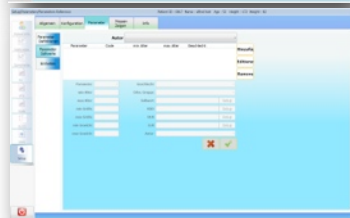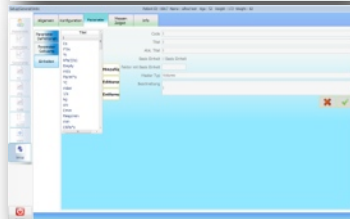
Create print templates.

Window to select test parameters.
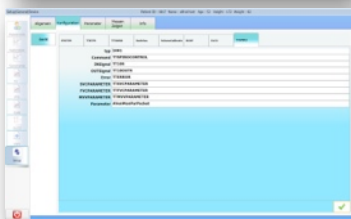
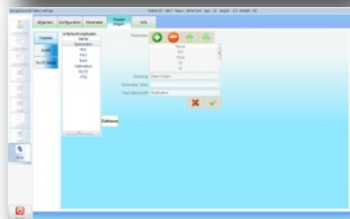System definitions of the data acquisition system.

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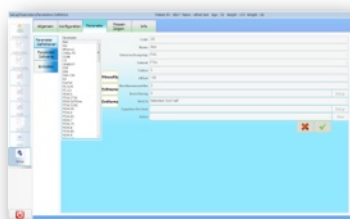
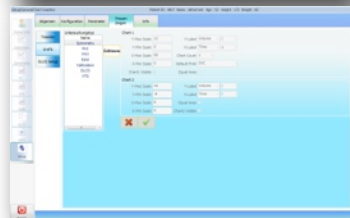Test parameter definitions.

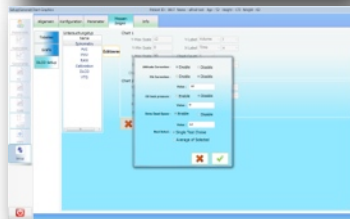Enter new predected values.

Define parameter units.

List of parameters for all test procedures.

Scale test charts.

Setup window for diffusion test.

Print template for bodyplethysmography.

Print template for spirometry.

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Maintenance, STK, MTK

Maintenance plan for smart*pft*lab					
Subject of service	carried out by	at intervals of	recommended	obligatory	certificate required
Volume calibration	the user	daily or after sensor change	✓		
Box calibration	the user	daily	✓		
Volume calibration	the user	1x per week		✓	
Box calibration	the user	1x per week		✓	
	the user				
Optical control of flow sensor	the user	1x per month or if results are not reliable		✓	
Optical control of door sealing	the user	1x per week	✓		
	the user				
Optical control of tubes	the user	1x per month	✓		
Surface disinfection of device and box	the user	1x per week	✓		
STK	qualified service	1x per year		✓	✓
MTK	qualified service	1x per year		✓	✓
Change membrane of demand valve	manufacturer or qualified service person	1x per year		✓	✓
Change pressure tube of gas supply	manufacturer or qualified service person	1x per 2 years		✓	✓

The unit is built very sturdy, but regular checks are required to ensure the functionality. The most important checks are listed in the table below.

The best maintenance is performed by a service of the manufacturer or its licensed sales and customer service partners.