User manual

smart pft USB

it is obligatory to read this manual before first use !

CE
0535

Table of content

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, the device may only be used for the specified purpose and only by trained, experienced and authorized persons.
We accept no liability for any damage caused by misuse of the device as well as 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.
Contractual pictures, technical specifications and information contained in this manual are furnished for informational use only and are subject to change at any time without a notice.
Pictures may show options that are not subject of a regular delivery.

Software License Agreement

The use of all our software and / or third party software, delivered in combination with the device is based on license agreements. You have to accept the specific software license agreement of each particular supplier before start using it. 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

Warranties

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

Trademarks

WINDOWS, WINXP, WIN7, WIN8, WIN10 are registered trademarks of Microsoft corporation

smartPFT, is a registered trademark of Medical Equipment Europe GmbH

Important information for the use of this manual

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

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

Important safety advices

Explosion hazard: The device is not suitable for use in hazardous locations

The bodyplethysmograph is a tightly sealed box without any air exchange when the door is closed. It is not allowed to keep persons in the body-box without observation. It is only allowed to close the doors during the required measurement procedures. the door have to be opened immediately after each test.

Persons with very low body weight below 30kg can not be checked. In such a case, the dead space of the system can cause a CO2 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 it is required to use a SpO2 device to check the O2 saturation drop caused by rebreathing, to stop the test in time. Pay attention if persons feel shortness of breath breathing into the system.

Before the daily use, the device itself, the flow sensor, all connectors all visible cables and visible tubes have to be checked. If there is any damage recognizable, the defective parts have to be substituted before using the device again. In case of any questions or uncertainties, a trained and authorized person has to check the device before further use.

At a minimum it is required that the technician knows the guidelines of lung function testing and is experienced in performing tests.

Contraindications for use of the device

Persons with very low body weight below 30 kg can only be checked when the CO2 rebreathing is monitored to avoid dangerous dead space ventilation. 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 CO2 rebreathing it is required to use a SpO2 device to check the O2 saturation drop caused by rebreathing, to stop the test in time. Pay attention if persons feel shortness of breath breathing into the system.

Intended use

SmartPFT USB is a testing device for pulmonary function testing
The test should help to

detect shortness of breath
quantify the severeness of pulmonary limitations
recognize the reason for shortness of breath
Therapy control

The following test procedures are included

Spirometry, is the testing of slow vital capacity in order to monitor lung restrictions.
Flow / Volume test, in order to detect obstructive lung disease like Asthma and COPD as well stenoses.

Indications for testing
Smoker
Dyspnoea (shortness of breath)
Asthma bronchial
Bronchial cancer
Chronicle bronchitis
Chronicle-obstructive lung disease (COPD)
Lung emphysema (irreversible hyperinflation)
Mukoviszidose - cystic fibroses
pleural effusion
Pneumoconiosis
Pneumonia

Contra indications to refuse testing

Insufficient patient collaboration and/or patient does not understand instructions
infection disease (for example. tuberculosis)
Pneumothorax
Aneurysm
Hernien
Angina pectoris oder recent heart attack
Patient had recently an eye surgery , an abdominal or a thoracic surgery

CE marking

Our smart PFT CO transfer unit is declared as a class **IIa** device in relation to directives 93/42/EEC annex I.

The following standards are met.

The device fulfill the standards.

EN 60601-1 part I	for electronic safety
EN 60601-1-2 :	for electromagnetic compatibility

The CE product certification was performed by

BSI Group Deutschland, Eastgate – Hanauer Landstraße 115, D-60314 Frankfurt am Main

N° 0535 / ID 0535

The CE marking includes exclusively the device- and spare- parts listed in the annex.

Magnetic and electric fields can affect function and/or functionality of the device.
When you operate the product, ensure that all third-parties 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.

Manufacturing and service by:

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

Technical data

hand measuring device						
	mechanically					
		dimensions				
			length	163	mm	
			width	65	mm	
			height	40	mm	
			weight	151	g	
		materials	PVC			
			color	white		
		disinfection with	cold gas or liquid or disinfection wipes			

flow sensor						
	mechanically	materials	housing	PVC	color	white & blue
			screen	hostaphan		
		type	pneumotachograph			
		screen type	variable orifice			
		range	0,02l/sec - 20 l/s			
		dimensions	length	80mm		
			width	37mm		
			height	25mm		
			weight	33g		
		effective dead spa	< 35 ml			
		back pressure	< 0,75 kPa/l*s			
		linearity error	< 3 %			
		volume	calculations	numeric integration		
			range	0,02 L to 20 L		
			linearity error	< 3%		
		disinfection:	cold gas & cold liquid			

smartUSB-data cable						
	mechanically	Leitung				
			legt	1600	mm	
			color	white		
			connector	RJ12	USB	
			weight	32	grams	
		materials	PVC			
		disinfection:	disinfection wipes			

e-Sensoren & µ-Controller	mechanically					
		housing	dimensions			
				length	85	mm
				width	35	mm
				height	35	mm
				weight	13	g
			materials	Epoxyd & PVC		
	electrically					
		supply voltage	type			
			voltage	5 V =	via USB	
			current	20 mA	maximal	
			connector	RJ12		
		µ- Processor		MSC 430	low power	
		computer interface		USB 2.0		
		pressure transducer				
			flow			
				type	piezoresisitive	differential
				range	12,7	mbar
				resolution	0,0016	mbar
				long term drift	< 0,15	%FSS
				interface	I2C	
				ADC	14	Bits
				temperaturkompensiert		

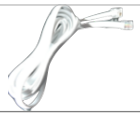
Software	smartSoft MEE					
main program language	C++ / C#					
data base type	SQL					

operating system required	WINDOWS	XP				
		7	32/64 Bits			
		8	32/64 Bits			
		10	32/64 Bits			
		for networking solutions	64 BIT professional obligatory			
minimum computer hardware requirements	µ-processor	minimum Intel Core i3				
	internal memory	minimum 4 GB				
	mass storage	minimum 128 GB	preferably SSD			
	monitor	colour	preferably minimum 22“	HDMI		
	printer	colour				

ISO Symbols

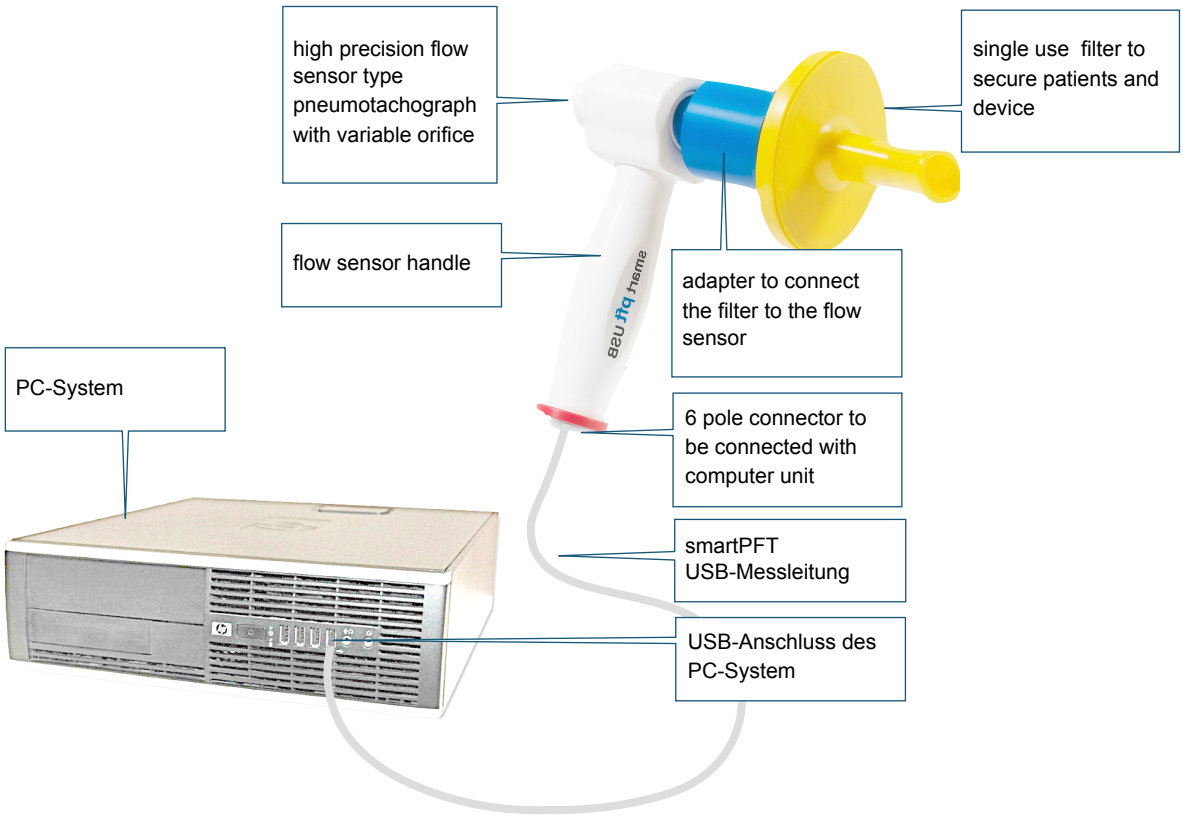
	A product with this label, is part of the application in accordance with DIN EN 60601-1, type BF
	Attention! Accompanying documents!
IPX0	No protection against drops of water!
	Do not dispose in domestic waste!
CE 0535	The so-labeled product is conformed with the guidelines for Medical devices 93/42/EEC 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 BSI Group Deutschland, Eastgate – Hanauer Landstraße 115, D-60314 Frankfurt am Main ID N° 0535 / ID 0535 Correlating documents assigning us to be allowed to label our products by this number can be supplied by us
	Manufacturer of this product: Medical Equipment Europe GmbH Dr. Gerog-Schäfer-Str. 14 97762 Hammelburg Germany

Scope of supply

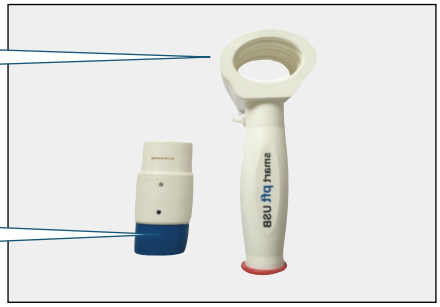
item n°	discription	quantity	picture
1	hand measuring device	1	
2	smartPFT flow sensor V3.0	1	
3	smartPFT USB-cable	1	
4	adapter for filters	1	
5	filter	2	
6	desk stand	1	
7	user manual	1	
8	software - CD or pen drive	1	
9	transport case	1	

Device assembling

The picture below shows the assembled flow measurement device including a single use filter.

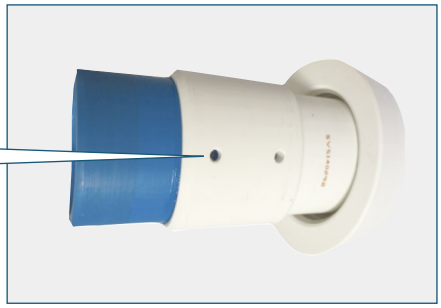


The flow sensor handle includes the sensor and interface electronics.

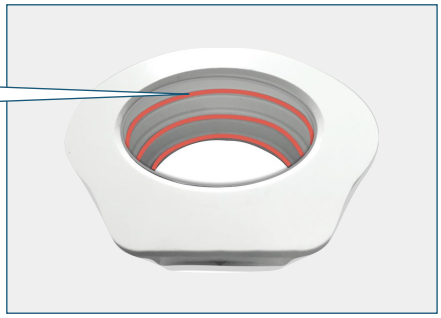


The flow sensor has two drillings. A plastic membrane in the middle of the housing causes a pressure difference. This pressure difference has to be measured in the handle. To connect the flow sensor to the pressure sensor, the flow sensor has to be put into the handle

Please make sure, the two drillings are located upwards when pushing into the handle to avoid moisture blocking the pressure channels. The flow sensor fits only from one side into the handle. The white end of the flow sensor has to be at front when sliding into the handle.

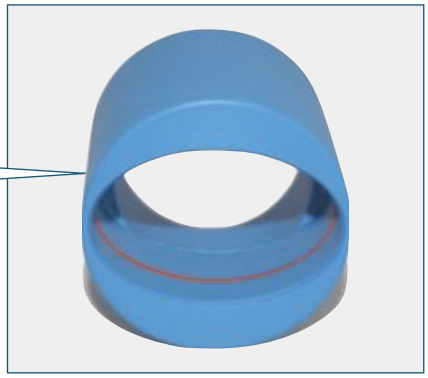


There are tree O-rings inside the oval shaped part of the handle. It is very important to verify, all tree O-rings are well fixed in the grooves. Use vaseline to lubricate the O-rings. Attention: don´t block the two drillings i´between the O-rings.



This picture shows the flow sensor placed into the handle. It is very important to slide in the flow sensor completely. The white middle ring of the flow sensor must be placed fully inside the oval cylinder of the handle. Check the edge between flow sensor and handle at the blue side of the flow sensor.

To connect a filter to the flow sensor an adapter ring is required. please press the oval shaped side of the adapter onto the blue side of the flow sensor.

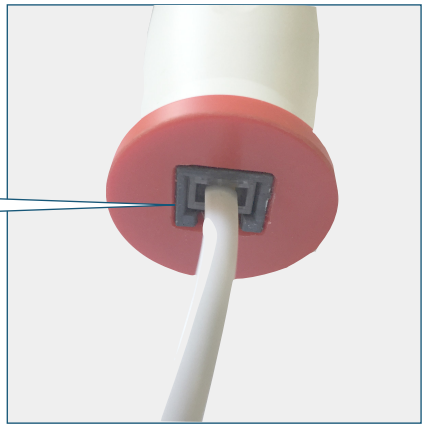


After putting the filter adapter onto the flow sensor, the assembled device looks like this.

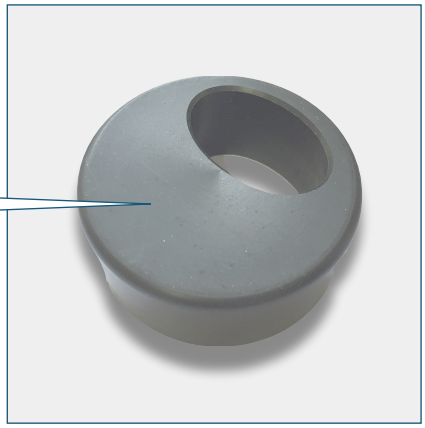
Now, the single use filter must plugged into the round side of the adapter. Depending what kind of filter you are using, a different adapter might be required.

To connect the handle to the computer unit, a cable with two sides RJ45 connectors is required. Before connecting the handle with the computer unit, the latch of the 6 pole plug has to be lifted up to guarantee, the connector can be locked properly.

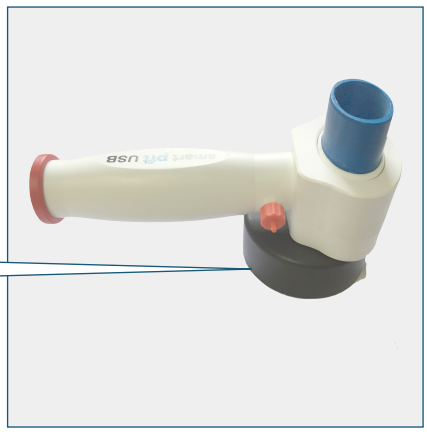
Verify that the cable is locked and connect the other RJ45 connector to the computer unit



Aluminum table holder to place the handle for storage



Place the handle after use onto the black aluminum holder. Eventually it makes sense to fix this holder on the table to avoid the handle can fall and be damaged.



How to place the device

The device should be located in a clean environment, 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.

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.

The patient has to be located in a distance of minimum 1.5 meters from the computer system so he can not touch any computer component connected to the Spirometer. If this distance is not achievable, the computer system the device is connected with via USB should fulfill office regulatory norm like DIN EN 60950 and has to be isolated by safety transformer from power line.

Contraindications for use of the device

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 CO2 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 required : NO

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 can be recycled. Depending on the country, this kind of material can be given for recycling at the public waste collection. In case of any question, ask your 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.

Software installation smartSOFTmee

The User Software ***smartSOFTmee*** is delivered on a CD-ROM.
The software use is based on our license terms, these license terms have to be accepted by the user before the install program can be started.

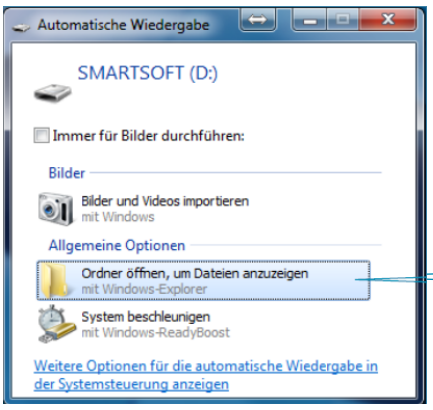
To install the program, the file SETUP.EXE must be executed.

The installation takes about 20 minutes.

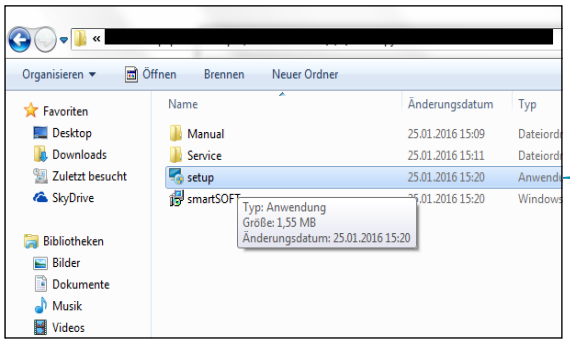
The software can be installed on PC systems using the operating system WIN7® or higher.

For best software performance use a powerful PC-System like I3 processor or higher with minimum 4GB RAM and a SDD HD with minimum 128GB disc space.

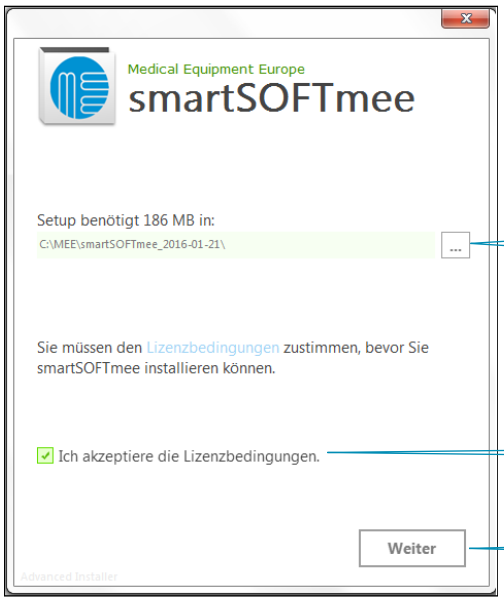
Put install CD into CD-disk drive



When next window pops up, select entry: ***Open folder to display files***



Click on file entry ***Setup*** to start the install program



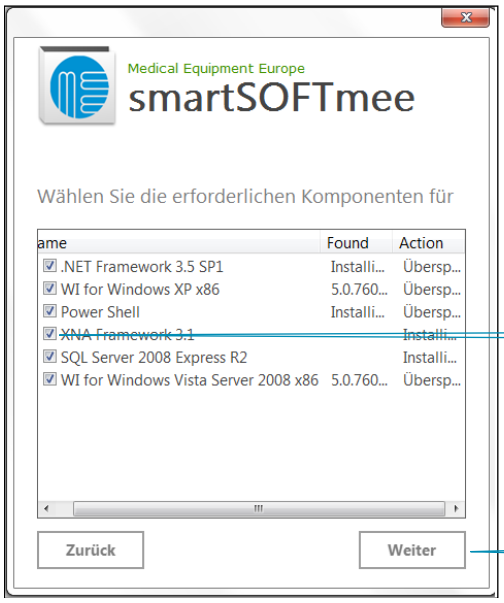
Clicking here allows to change the install path name. It is recommended to make ***NO*** changes.

the software license terms have to be agreed to continue the installation

After agreeing the license terms select the ***Continue ICON*** to go ahead

Select which user group will have access to the program

Click again the ***Continue ICON*** to go forward



The install program checks automatically which programs have to be installed. The √ sign in the ***check boxes*** informs what system program modules still have to be installed.

Click again the ***Continue ICON*** to go forward

Select the ***check boxes*** to define the location of the program symbol to start the software after installation and if ***Autostart*** is required.

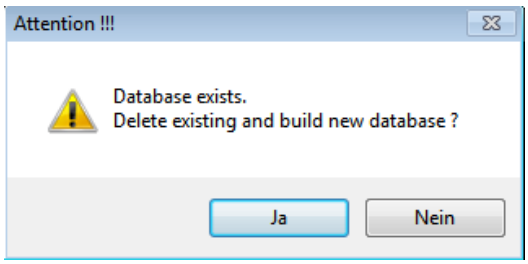
Clicking on ***Install ICON*** starts the program files copying procedure

This green bar informs about % of files already installed.

Clicking this ***Start ICON*** will close the install procedure and opens the smartSOFTmee software immediately.

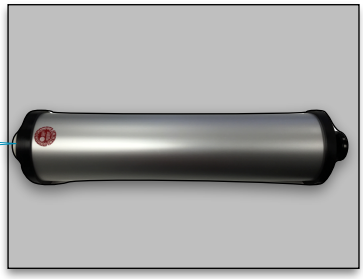
Click on the ***Finish ICON*** to close the installation procedure.

Troubleshooting list for software installation procedure

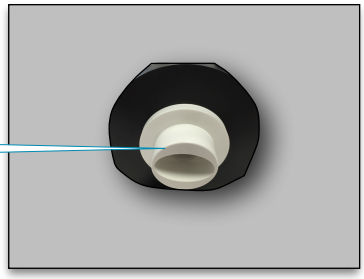
error message	reasons and possible solutions
after installation and running the software the first time, the following window appears: 	The SQL data base could not be startet or installed. Computer name and user name have to be different. Rename computer or user. Call for service support
During installation following window pops up: 	An old data base exists already. The old data base is compatible with the newer one. To keep the old testing data is is important to click the ***No ICON***. By clicking the ***Yes ICON*** all old data get lost, a new data base is created.
The installation program does not go forward anymore.	Move the install message window on the screen, there might be a message window hidden behind this install window.

Device setup for calibration

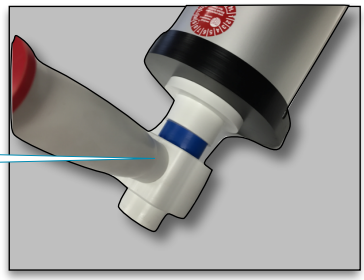
We recommend the use of a 3 liter syringe. Please verify, that the syringe has a valid verification label. Syringes have to be checked by the manufacturer every 2years.



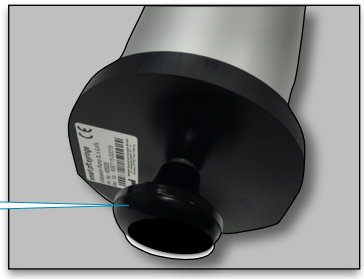
It is important to have the right adapter to connect the flow testing device to the syringe, M.E.E. devices need an oval shaped adapter. Preferably you use a syringe from M.E.E.



To make a volume calibration the flow sensor handle has to be connected to the syringe.



Make sure, the piston of the syringe is fully pushed in before starting the calibration program.



BTPS conditions

To open the mask for entering the BTPS condition values select the ***Setup***-ICON in the main menu bar and afterwards the submenu ICON ***Ambient***.

Optionally, an automatic BTPS measuring device can be connected via USB.

Important advices

This chapter gives you important information to be considered doing a pulmonary function testing.
To obtain reliable results in lung function testing, the patient must perform the breathing maneuver with maximum compliance.
It is recommended to explain the breathing maneuver before starting the test procedure. Each test has to be repeated several times to assure, the test was done with maximum compliance.

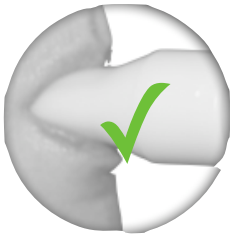
The patient has to put on a nose clip.

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 is required.

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



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 who are in contact with the patient during the testing and / or touching 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 CO2 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.

List of important testing parameters

name	unit	description	ATS criteria
Spirometry			
SVC	litre	slow vital capacity	difference < 5% within 3 tests
ERV	litre	exspiratory residual volume	
IRV	litre	inspiratory residual volume	
IC	litre	inspiratory capacity	
TV	litre	tidal breathing volume	
Flow / Volume test			
FVC	litre	forced exhaled vital capacity	minimum 6 seconds exhalation time, flow at end of test < 100 ml/s
FEV1	litre	maximum volume exhaled within first second of forced exhalation	back extrapolation of slope and continuous exhalation, difference < 5% between 3 tests
FEV0,5	litre	maximum volume exhaled within first 0.5 seconds of forced exhalation	back extrapolation of slope and continuous exhalation, difference < 5% between 3 tests
PEF	l/s	maximum exspiatory flow	
MEF25	l/s	maximum exspiatory flow after 25% of exhalation	
MEF50	l/s	maximum exspiatory flow after 50% of exhalation	
MEF75	l/s	maximum exspiatory flow after 75% of exhalation	
MEF25-75	l/s	MEF25 minus MEF75	
AEX	l/s*l	area under the exspiratory flow/volume loop	
PEF@FRC	l/s	maximum Flow @ FRC	
PIF	l/s	maximum inspiratory Flow	back extrapolation of slope and continuous exhalation, difference < 5% between 3 tests

How to do a spirometry test

The quality of lung function testing depends strongly on the quality how the patient is instructed. The instructions have to be verbally 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.

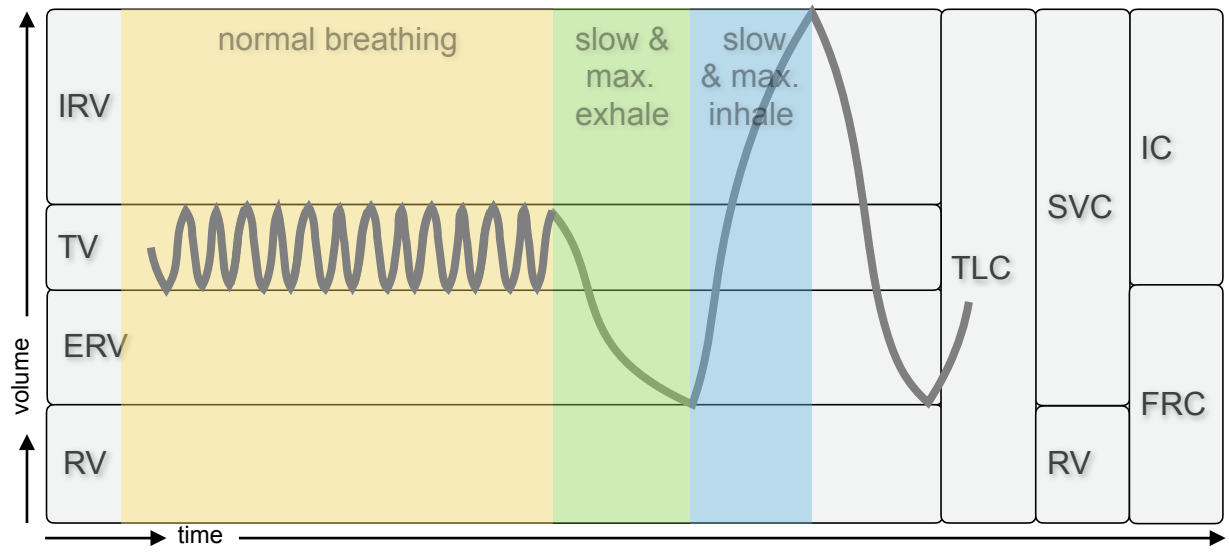
Spirometry

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 doing a maximum inhalation. A reduced slow vital capacity informs about restrictive lung disease.

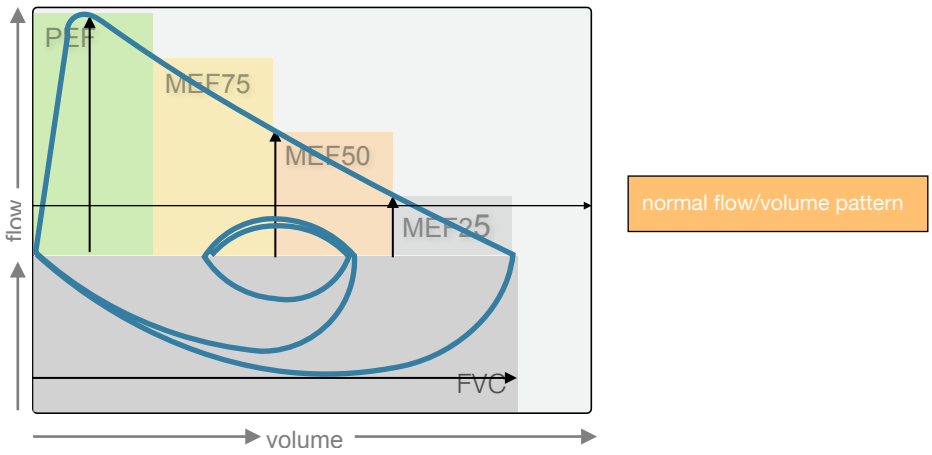
The patient has to put on a nose clip on and to enclose the mouthpiece tightly with the lips before starting the test.

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 should be extended. After this normal breathing period, the patient first should exhale slowly and deeply to a minimum and than inhale slowly and continuously to the possible maximum. After the maximum inhalation he exhales again to the tidal breathing level.

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 flow dynamics of the lung 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 severeness of obstruction.

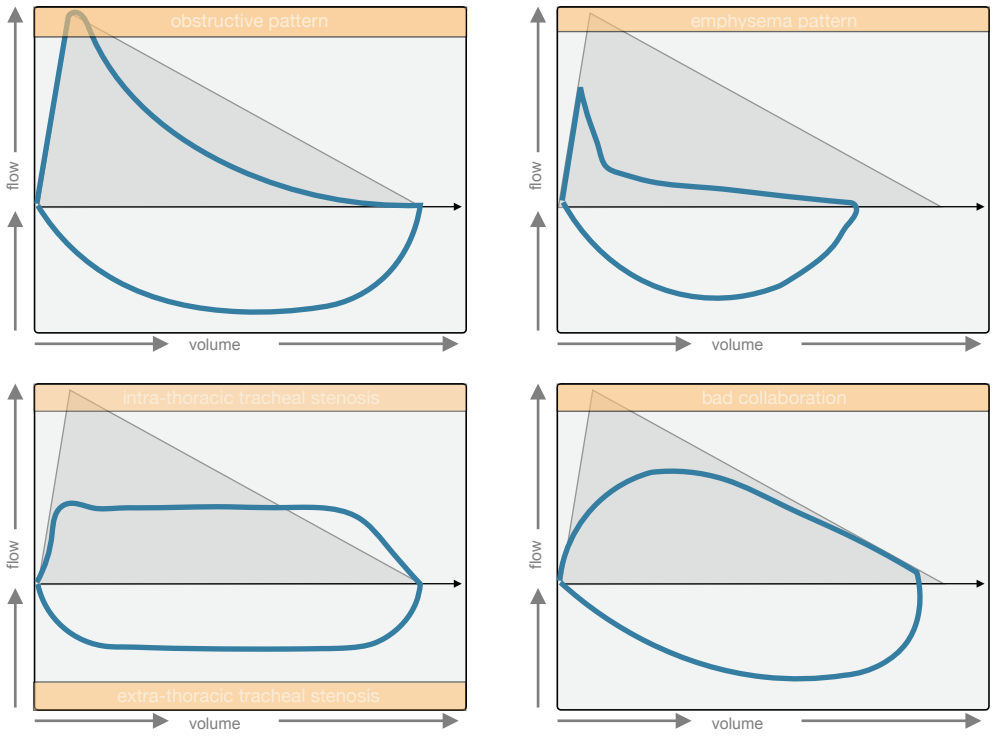
The test maneuver requires the patient to do a view normal breaths before inhaling slowly to the maximum volume followed by an exhalation with maximum flow speed until all volume was exhaled followed again by an inhalation with maximum flow speed until maximum possible inhaled volume. Good test results require maximum breathing force from the patient.

The picture above shows the shape of a typical flow volume test. Exhalation is shown in the upper part of the graph, inhalation in the lower part. The top of the curve shows the peak flow (PEF). A good collaboration is recognizable when the peak is reached before 15% of exhaled volume. The flow peak has to be near to the left edge of the curve and the rising edge of the flow 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 to compare reproducibility. The difference of three test results has to be less than 5% of maximum values.

Patient should exhales for minimum 6 seconds. There are two bars at the right screen bottom 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 patient starts inhalation again.

The upper bar becomes green after 6 seconds of continuous exhalation, the lower bar when flow rates goes below 100ml/sec.



BTPS correction

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

T	=	ambient temperature
P(atm)	=	ambient pressure
PH2O_T	=	vapor saturation pressure at 21°C

Equation PH2O_T (Magnus-Equation)

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

DGHM approved products tested for use on M.E.E. products.

product name	PZN	manufacturer	comments
SAGROTAN® disinfection wipes	4041906	Reckitt Benckiser Deutschland GmbH	
SAGROTAN® medical disinfection spray	3911624	Reckitt Benckiser Deutschland GmbH	
Korsolex extra	963678	Bode Chemie	
Endo Star	1291554	Laboratorium Dr. Deppe GmbH	aldehyde free und phenol free
Mikrobac® Tissues	6968725	Paul Hartmann AG	alcohol free, aldehyde free

Disinfection of particular components

Small articles like adapters, nasal tips, purely mechanical parts can be either disinfected by cold liquid, cold gas, Plasma, autoclaves or microwave sterilizations. In case of using liquids, please use a product from the list above or a product which is equivalent.

It is not allowed to disinfect and/or sterilize single use articles like filters and/or mouth pieces. These articles have to be trashed after each use.

The flow sensor is only allowed to be disinfected by cold liquids and/or cold gas. It is important to dry the sensor properly after any treatment with liquids. The disinfection solution should have a very low concentration of chloride ions.

Valves can be disinfected by cold liquid, cold cold gas, Plasma, autoclaves or microwave sterilizations except the electronic components.

Any electronic parts like shutter magnets are not allowed to put into a disinfection solution. These parts can only be disinfected using disinfection wipes. The electronic components are mostly marked by red color.

If parts show any kind of visible dirtiness, this dirtiness has to be removed before disinfection procedure either mechanically or chemically. Please verify in any case that there is no damage recognizable after such a treatment.

Very sensitive treatments requires the flow sensor. It´s membrane in the inner part can not be cleaned mechanically. If necessary use an ultrasonic device to remove dirtiness. If required, the flow sensor must be substituted by a new one.

Other surfaces of the system are preferably disinfected by disinfection wipes.

To avoid cross infections between patients and/or users, it is obligatory to use single use filters and nose clips. Filters not only protect the patients but also the equipment itself.

The choice of disinfection products and / or disinfection methods depend also on the environment and situations of its use. We only can give recommendations to protect our materials. We don´t take any liability for infections of patients. If you are not sure about the right use and/or selection contact a hygienic adviser.

The recommended disinfection products may not be available in certain countries. In such a case a hygienic expert has to be contacted to find equivalent substitutions.

The use of cleaning and/or disinfection procedures influence the material surfaces and consistence. It is obligatory to verify and/or calibrate the treaded parts.

After the use of any liquids the system should be verified that no liquid traps block drillings and/or tubes. Check all parts visually before restating the machine.

To avoid bad smell after the use of disinfection solution and to accelerate the time period of drying it is recommended to use a bath in alcohol after disinfection.

Please check after each procedure that mechanic and/or electric connectors and/ or O-rings don´t show any damage to avoid leeks and/or electrical connection problems.

The use of chemical products for disinfection and/or cleaning requires safety procedures. Please follow always the safety instruction for the particular product. Use gloves, proper clothes and eye protection.

SmartSoftmee 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, 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 users have 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  .
Exit with ***CANCEL***:	confirm  ICON.
Exit by ***O.K.***:	confirm  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.

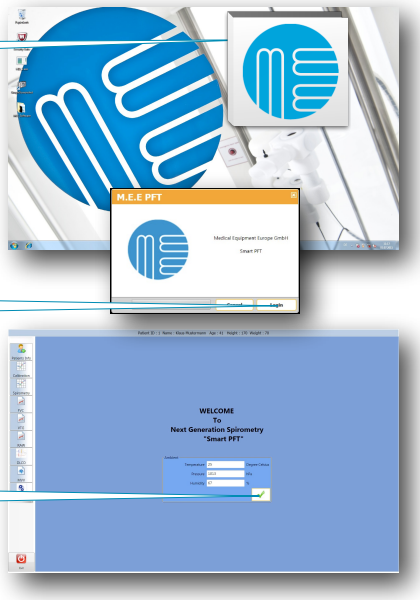
The setup menu bar is located at the top edge of the screen and shows the selection of different setup routines like print setup, device setup and so on. This bar becomes active when the ***SETUP*** menu ICON was confirmed before in the main menu bar.

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.

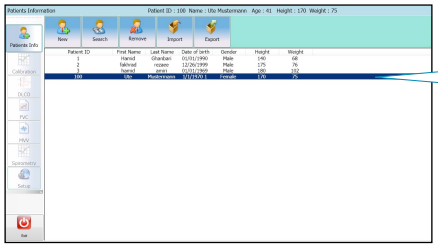
If Login was correct and if data base could be addressed, the menu screen appears on the display. Depending if manual ambient data input was installed, the ambient data have to be corrected and/or confirmed.



Patient data menu

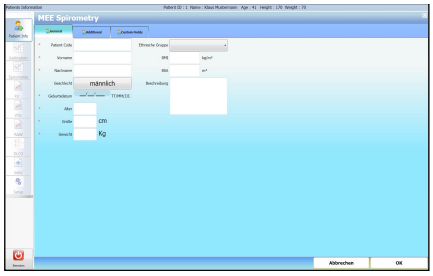
The left main menu bar displays the possible selections of

Patient data input;
Test selection;
System setup;
Program exit.



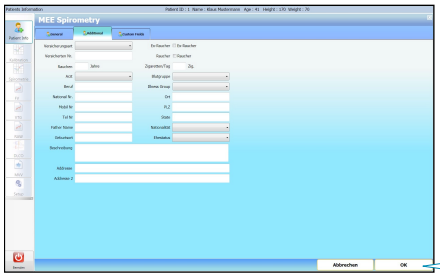
By selecting the upper main menu ICON named ***PATIENT DATA***, a list with the last measured patients is displayed. Just by selecting one of the patient rows. New tests can be performed and printed but also stored tests can be reviewed and printed again. A selected patient can be removed from the list 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.***

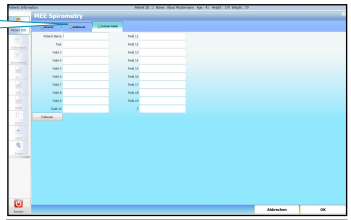
Additional customized patient data fields are available by selecting the ***ADDITIONAL*** ICON in the submenu ***PATIENT***.



This input option allows the input of customized data fields. Save the input or changes by selecting ***O.K.***.

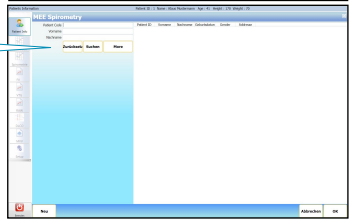
Sub menu bar ***NEW PATIENT***
Customized fields

CUSTOM FIELDS:
Enter or change additional patient data fields. Don‘t forget to save the changes.



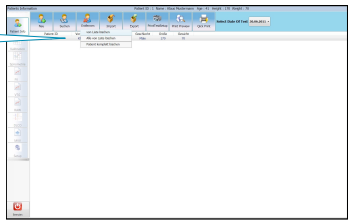
Main menu bar ***PATIENT*** :
Search patient

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.



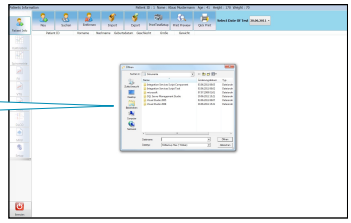
Main menu bar ***PATIENT***:
Delete data

This menu item allows to delete patient names from the list,or to delete test or the whole file of the selected patient .



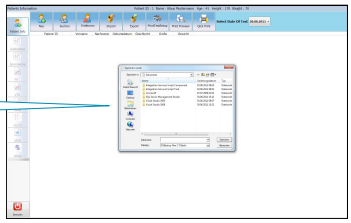
Main menu bar ***PATIENT***:
Import data

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

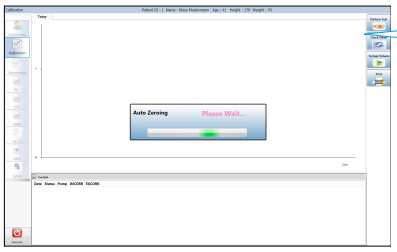


Main menu bar ***PATIENT***:
Export data

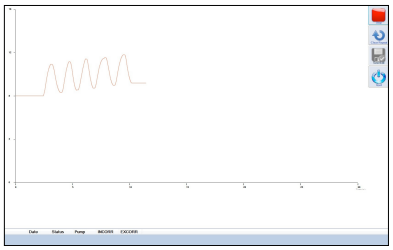
EXPORT allows to store data in an internal or external storage. This function can also be used to update a data base.



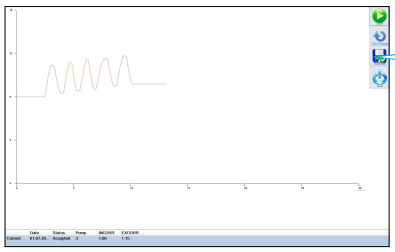
Volume calibration



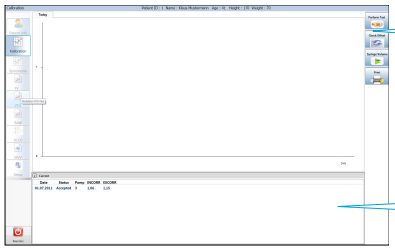
After selecting the ***CALIBRATION*** ICON in the main menu bar, there is the choice to select between BOX CALIBRATION and FLOW CALIBRATION. After VOLUME CALIBRATION was chosen, the calibration syringe must be connected to the flow sensor. The calibration routine starts by clicking on **PERFORM TEST**.



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. The program stops automatically a few seconds after stopping pumping.



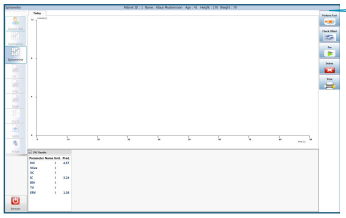
SAVE & EXIT saves the calibration results. The values for exhalation and inhalation should be between 0.7 and 1.3. The symmetry error should be less than 3 %. The factors can be cancelled by pressing ***QUIT***.



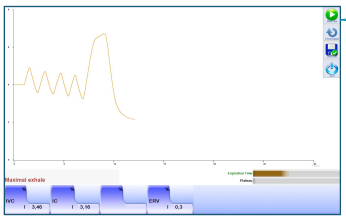
The calibration routine can be repeated by pressing ***PERFORM TEST*** again.

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

Spirometry test

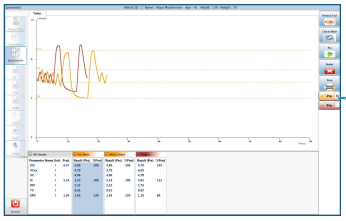


To start a spirometry test select in the main menu toolbar the ICON ***SVC.*** Ask the patient to put on the nose clip and to enclose tightly the mouth piece with the lips during the test. Start now the test procedure by clicking on the test menu toolbar ICON ***PERFORM TEST***.



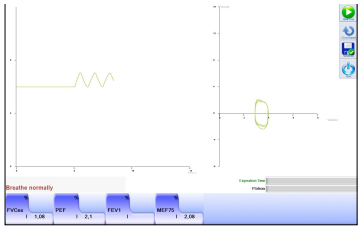
The patient has to follow the instructions of the technician related to the previous chapter Spirometry. A new test can be started immediately by selecting the ***NEW TEST*** ICON.

The test stops automatically when the patient stops breathing for a few seconds. A test can be finished immediately by clicking the ***SAVE&EXIT*** ICON. If you don‘t want to save, click ***QUIT***.

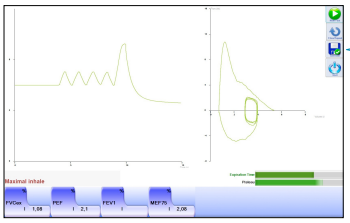


All tests are displayed overlapped. The best test is the test with the highest value for SVC. This test is selected as the best automatically by the software. The best test is marked with an upper ***B*** letter in the selection toolbar at the right screen edge. The user can make another choice by clicking 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 one test is declared as best and minimum one test has to be activated.

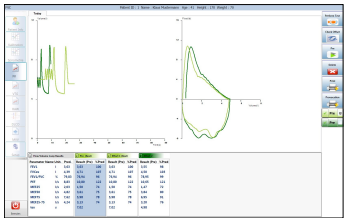
Flow/Volume test



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,*** the test also stops automatically a few seconds after stop of breathing.



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.

Incentive graphs

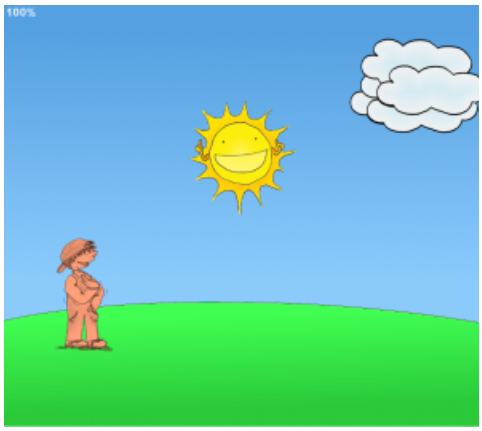
There is an animation program available in order to help small children to understand and to perform a best possible flow/volume test.

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.

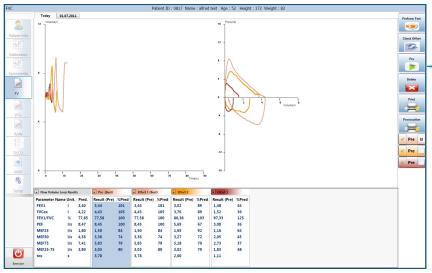
Motivate the child to repeat the test several times.



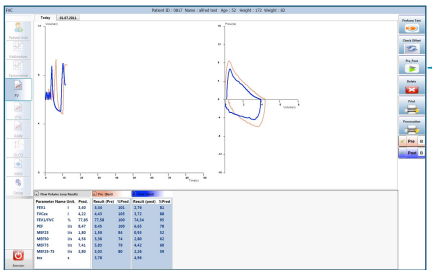
if the child is not able to blow the clouds out of the window, press the ***CURSOR DOWN*** button on the keyboard to decrease the predicted values by 10% each press. By pressing ***CURSOR UP*** you can increase the predicted values by 10% up to maximum 100%.

The test procedures are the same like for flow/volume testing.

PRE & POST



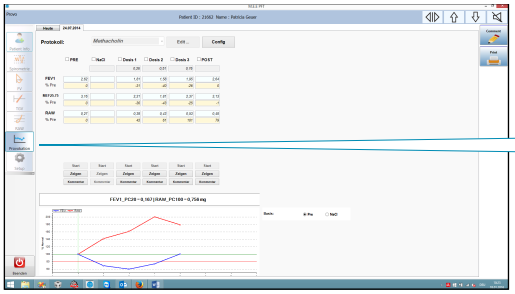
The first test is always a ***PRE*** test. After giving a bronchodilator medication, the next test has to be declared as a ***POST*** test. In the right menu bar you must select the ***PRE*** icon by a mouse click to switch to a ***POST*** test. After the click, the ***PRE*** button changes to ***POST***. 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***.



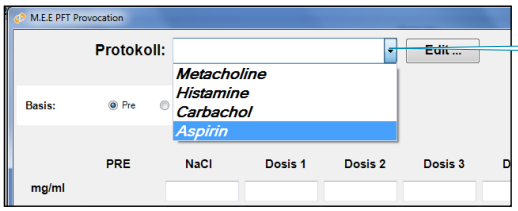
It is only possible to switch to ***POST*** if a ***PRE*** test was made. The ***PRE/POST*** display shows the ***PRE*** and ***POST*** tests graphs and results of the best ***PRE*** test compared to the best ***POST*** test. After doing a ***PRE*** and a ***POST*** test, you can display either a ***PRE*** 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 be selected or deselected in the ***PRE/POST*** display mode. It is important that one ***PRE*** and one ***POST*** test are declared as ***BEST***. If you print a test, the last selection of ***PRE*** or ***POST*** or ***PRE/POST*** is used for the print style.

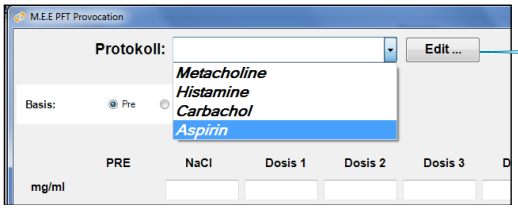
Challenge testing



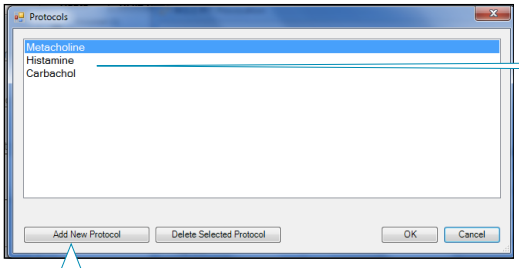
To do a challenge test, the patient has to do a flow/volume test first, he should not have taken a medication like a bronchodilator. The flow/volume test has to show a non obstructive pattern. The FEV1/SVC should be above 80% of predicted. If the first test was normal, the challenge test gets started by clicking onto the ***PROVOCATION*** icon in the left menu bar. The challenge test can also be initialized before the first test, If selected, the display shows the screen for challenge testing.



First you have to select a challenge test protocol. Click into the first line of the screen to list the challenge test protocols. If necessary complete this list by a new protocol.

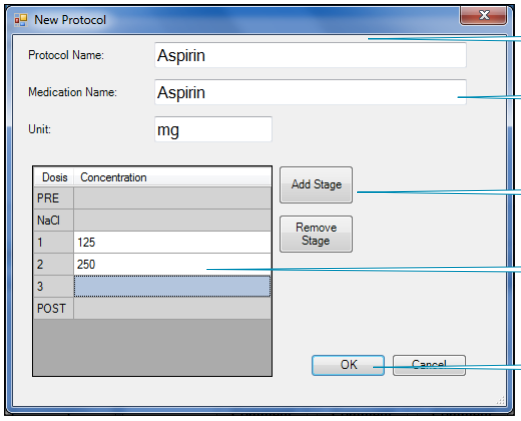


If you want to create a new challenge protocol, click on the Edit ICON



The following window lists all the existing challenge protocols available. It is possible to delete a protocol type by selecting the line and clicking the ICONf ***Delete Selected Protocol***

To define a new medication protocol click at the ICON ***Add New Protocol.***



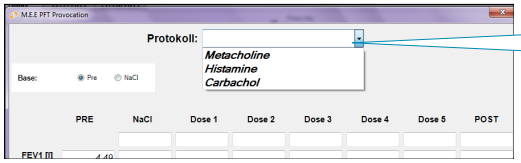
Enter name of new challenge medication protocol, this name appears next time after saving in the list of protocols.

Enter in this line the name of the drug used. Don´t forget to define the ***Unit*** in next line like mg or µg or % or mg/ml…..

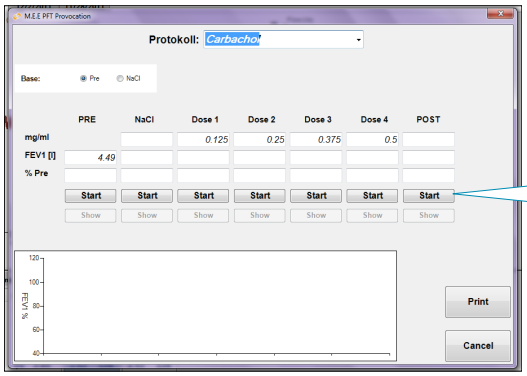
Always click on ***Add Stage*** to generate a new input line for each dose required.

Enter the particular dose or concentration in this lines

Save the new challenge protocol by clicking ***OK***.

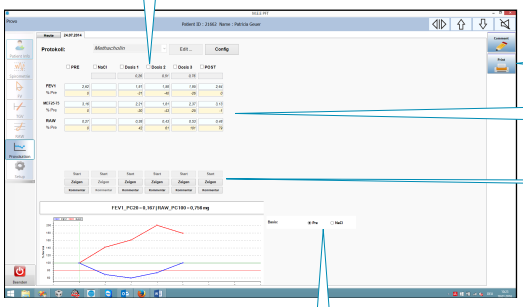


Click again onto this list ICON to list all protocols available including the new one for selection.



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 the test of next step, the previous can not be repeated anymore.

It is possible to compare specific test of the challenge sequence by marking these test in this squares. Put an X in each dose you want to compare.



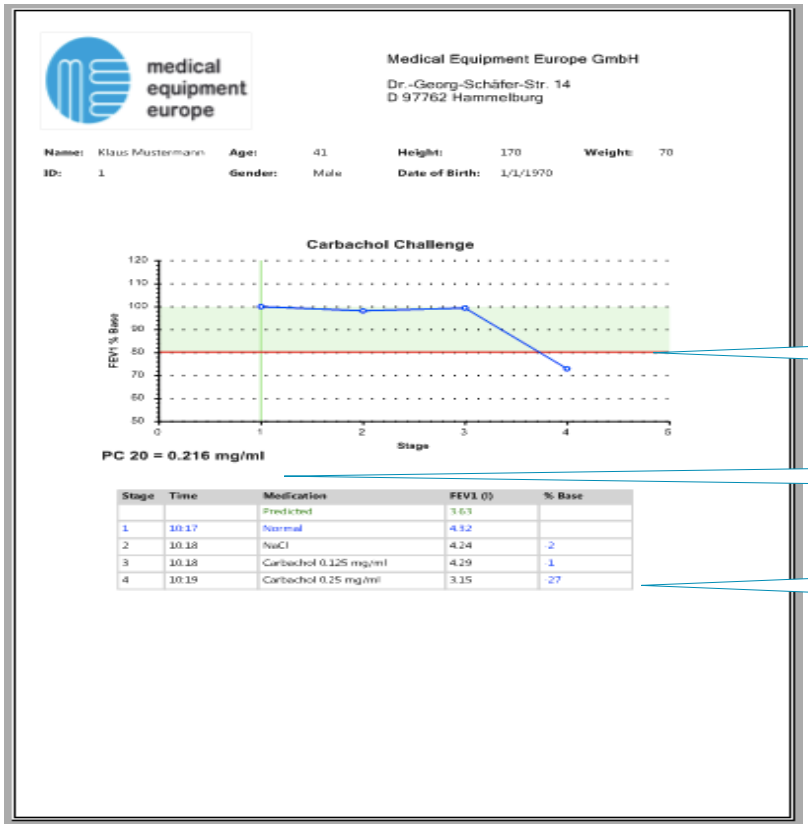
You can print the challenge test by clicking the ***PRINT*** button.

In this window the particular test results are displayed

Click here to start a new test, or display a particular test or to add a comment for this step.

It is possible to compare the test after applying the medication with the ***PRE*** test or the NaCl test by selecting the reference here. A test is positive when the FEV1 drops more than 20% compared to the ***PRE*** or NaCl test. If the program detects a positive reaction after a doing a test, the line above the trend screen flashes red for warning.

Example of a 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.

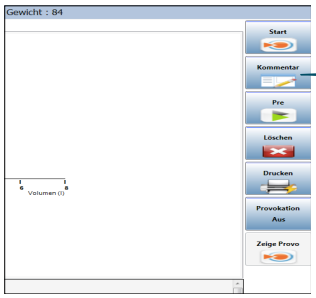
The table shows the results for each step of the provocation.

Comments and Interpretation text

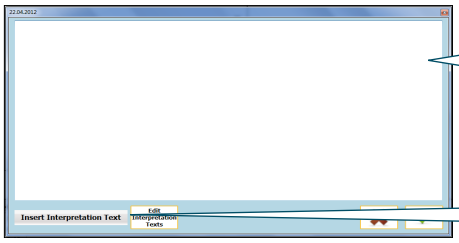
Interpretation text as well as comment text can be entered for tests of the current day as well as for tests made in the past. The text is always assigned to the selected date. For this purpose, the relevant date tab is selected above the measuring screen.

To simplify the work of writing interpretation text there is a possibility to store predefined text blocks in order to merge them to a final interpretation report.
These blocks of text can be edited and supplemented free. New text blocks can also be inserted.

To enter new text objects or to modify existing ones please select the ICON ***Edit Interpretation Text.***

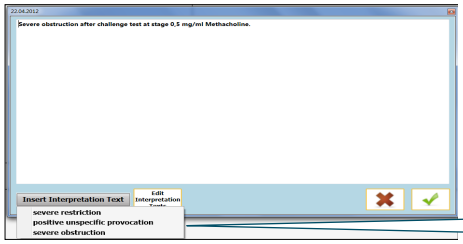


The comment form is started by clicking on the comment icon at the right edge of the measurement screen.

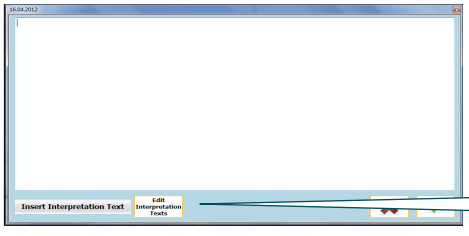


To enter a temporary text, the free text field must be clicked with the mouse. You can enter any text. This text can also be supplemented by text blocks. The entered text is stored by the icon with the green tick or discarded by selecting the red cross

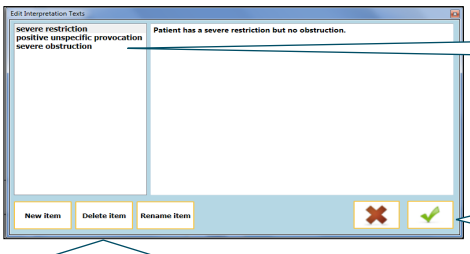
To insert a new text block, click into the ICON field ***Insert Interpretation Text*** .



Now a list of the existing text blocks will be displayed, by selecting one line of the list by the mouse cursor, the correlating text will be displayed in the upper window field. Now you can modify and / or complete this text.



To define new text blocks, or to modify existing the field ***Edit Interpretation Text*** has to be chosen.

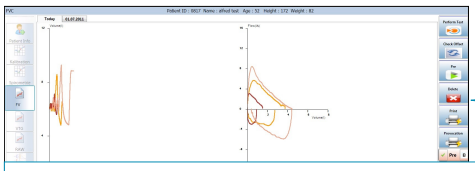


In the left window column, an existing text block can be chosen.

Within this right window part, the text block is displayed correlating to the choice made in the left text column . The text in the right window can be modified or extended. Any change has to be saved by clicking onto the green o.k. button or cancelled by clicking the red cross button.

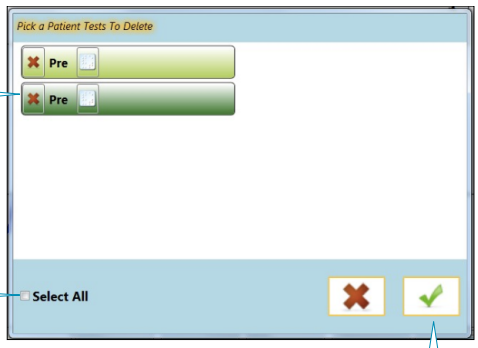
New Item inserts a new line in the left window column, this line has to be renamed. ***Delete Item*** deletes the selected entry of the list. ***Rename Item*** allows to rename an entry.

Delete a test



To delete certain tests, the ICON Delete has to be clicked.

All test of the selected day are displayed in a list box. the X sign assigns, all tests are deselected. To assign a test for deleting, Click on the X field to change the symbol to a ✓ for deleting.



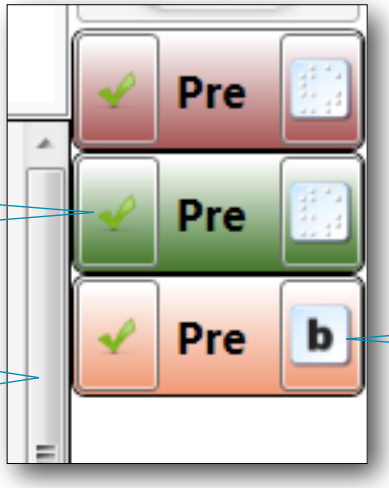
Click on this field to select all measurements for deleting

By clicking on the ✓ ICON, all assigned tests will be deleted. the X sign closes the window without deleting

Chose a test as best or deselect tests

All test made, are preset with a ✓ sign. By clicking on this sign, particular test can be deselected. Deselected test can be reselected by clicking again. Deselected test will be displayed in the graph as thin grey lines. Deselected test are marked with **X**.

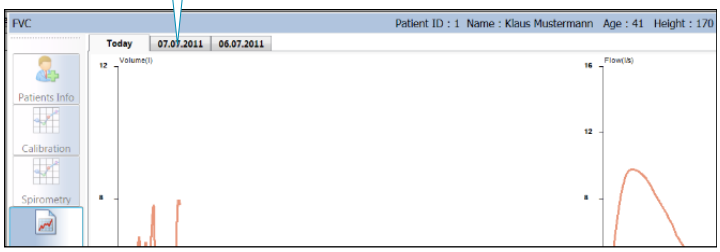
This slider rolls the entry list of tests up and down in case the number of entries don´t fit into the list box.



Below the main test menu bar on the right screen edge is a list box with entries for each test. 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.

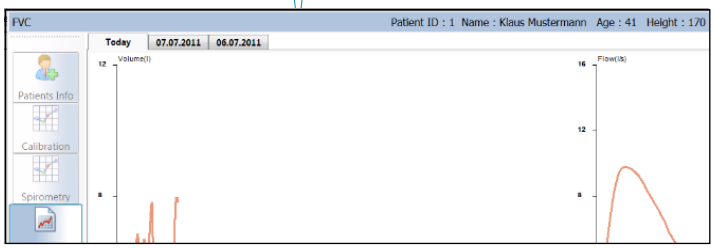
Display tests from archive

Above the measurement graph there is a slider with test dates. Each date displays there was a test made on this particular date. To recall such a test, click on the date field. You can only start a new test sequence when clicking on the ***Today*** slider.

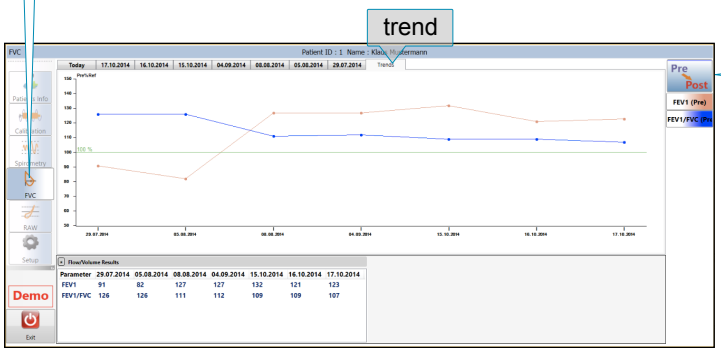


Trend reporting

Above the measurement graph there is a slider with test dates. Each date displays there was a test made on this particular date. The last slider is called Trends.



Depending which type of test was selected, a trend report will be displayed. The parameters for the trend report can be selected in the setup program. It is possible to display up to 4 test parameters within one screen.

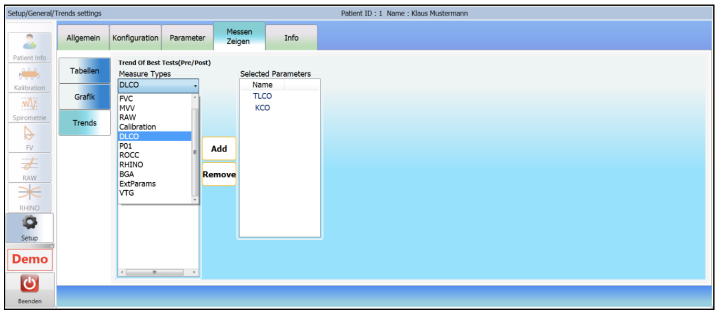


First only ***PRE*** test are displayed, by clicking here, you can change to ***POST*** or ***PRE/POST*** numbers. The numbers display the ***%*** of ***test/predicted***.

Setup trend parameters

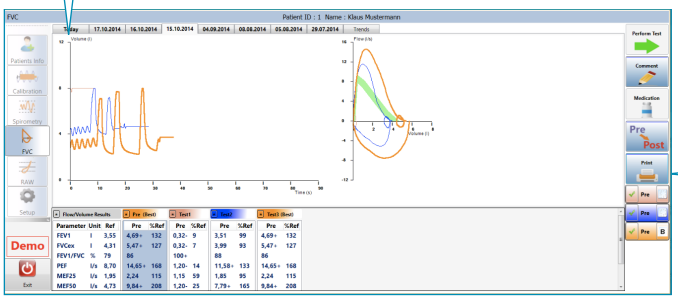
The particular parameters for trend viewing can be selected in the SETP program.

Select first menu item ***Setup***, than ***select TESTIN/VIEWING, followed by menu item TREND and finally the required type of testing.*** By clicking the ***Add*** button, parameters can be added to the list, by clicking ***Remove*** parameters are deleted from the display list.

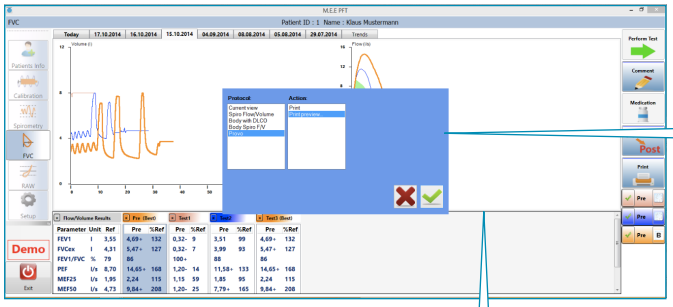


Print test

Test can be print using the ICON ***PRINT*** from the menu bar on the right side of the screen. Please select first the date of the test if you make no choice, today´s test will be displayed.



Choose the ICON ***Print*** to display tests as preview on the screen or to send a report to a printer.

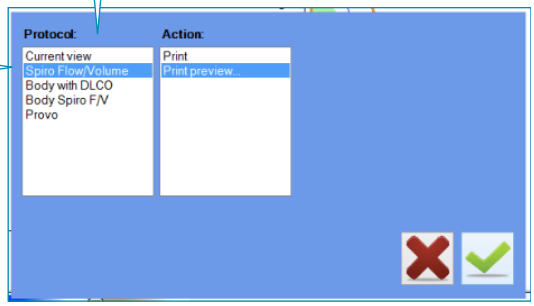


A listbox allows the selection of a certain report format as well as the selection of the report media.

Click onto the ✓ ICON to confirm your choice or ✘ close the window without further action.

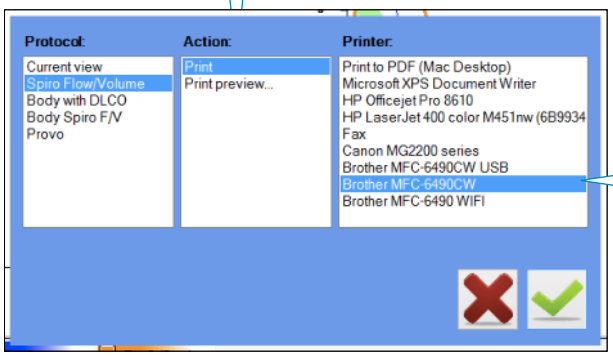
Select the line ***Print*** to print directly on a selected printer. Select line ***Print preview*** to display on the monitor first.

Select from this list your type of report you want to use



Select printer type

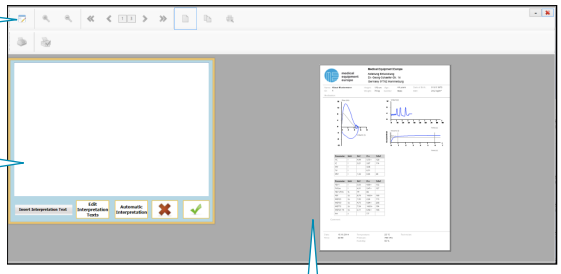
Only if the direct ***Print*** is selected, a printer type can be chosen.



Here a printer has to be selected. All available printer are listed. Please note, if there is no printer installed, select the line Microsoft XPS Document Writer to be able to display tests

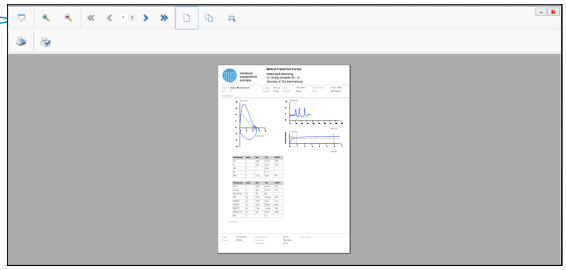
Click here to enter a comment for the report

This window is to type a comment and to display prepared text from the text boxes.



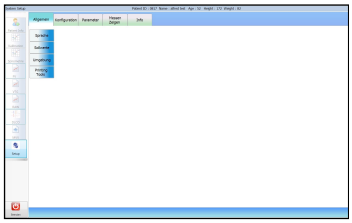
click on the ✓ ICON to save the comment or on the ✘ ICON to leave without saving

After displaying a test in the preview mode the displayed protocol can be printed by clicking on the ***PRINTER ICON***

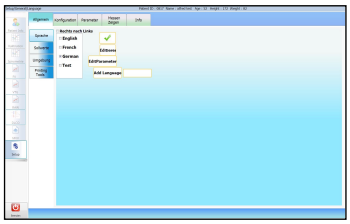


Device and software setup

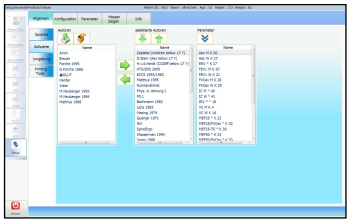
The main window of the SETUP menu



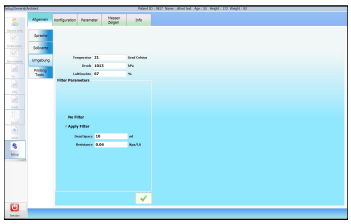
Submenu select language.



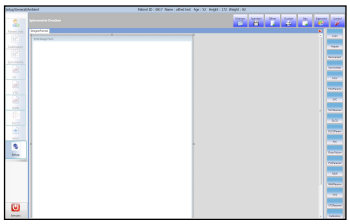
Select authors for predicted values and install priority list.



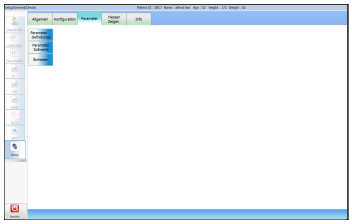
Input BTPS conditions and define data for single use bacterial filter.



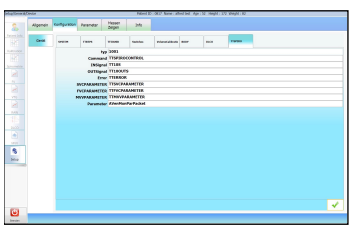
Create print templates.



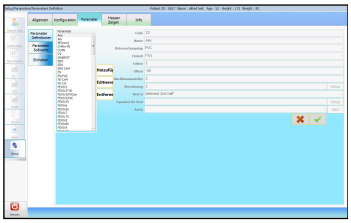
Window to select test parameters.



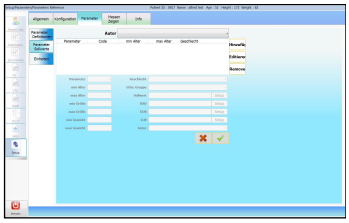
System definitions of the data acquisition system.



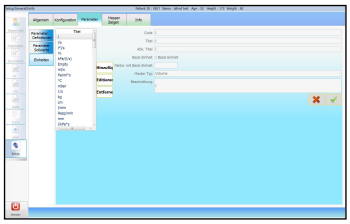
Test parameter definitions.



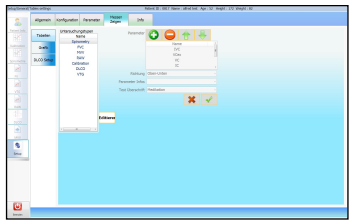
Enter new predected values.



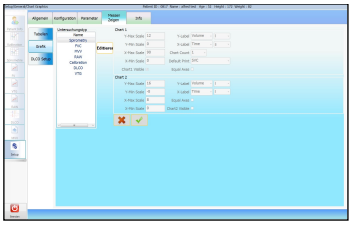
Define parameter units.



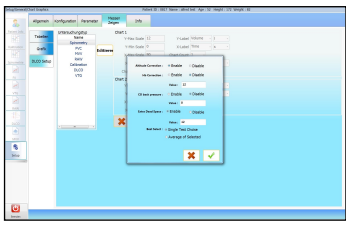
List of parameters for all test procedures.



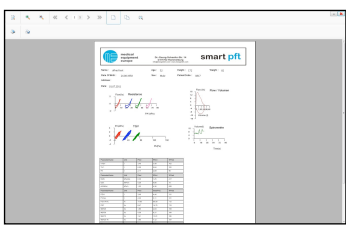
Scale test charts.



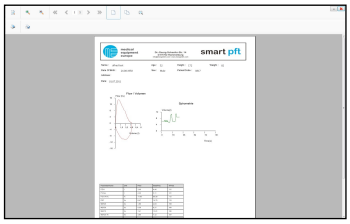
Setup window for diffusion test.



Example of print template for bodyplethysmography.



Example of print template for spirometry.

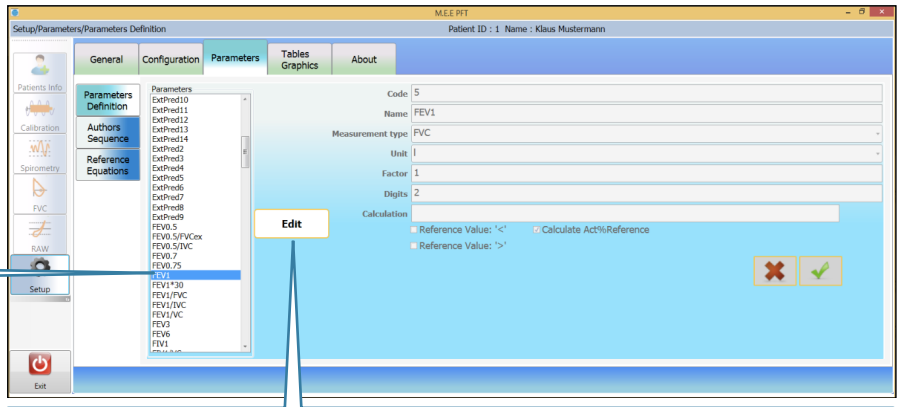


Predicted values

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.

If you make changes of predicted equations it is important to verify the results in particular. This changes are only allowed to be made by experienced and qualified persons.

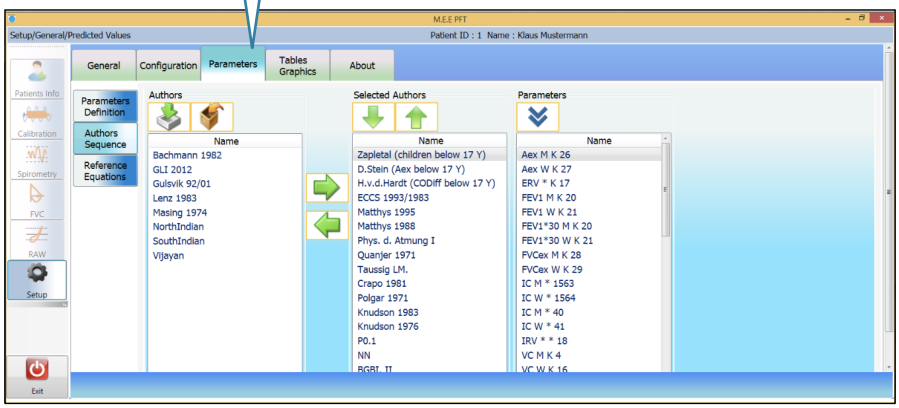
Certain parameters concerning predicted equations for each test parameter can be visualized and/or modified by selecting the main menu item ***Setup followed*** by the menu item ***Parameters***. ***Parameter Definitions.*** From the list displayed, a single parameters con be selected to make definition changes.



Selecting the menu item Edit allows to make changes concerning the selected parameter.

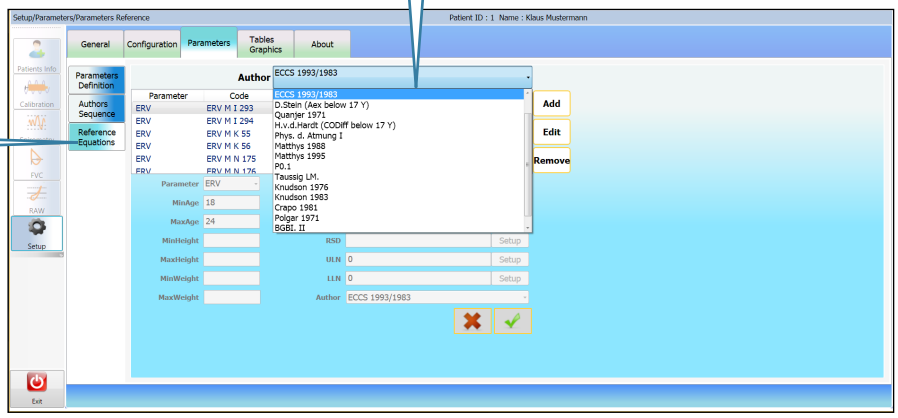
You can chose between several authors by selecting the main menu toolbar item ***Setup***, followed by selecting ***PARAMETERS*** again followed by selecting ***AUTHORS SEQUENCE***. The program displays now three columns. The left column contains the authors available but not selected, The middle column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

You can select and deselect authors 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 name has 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. See details by selecting one of the parameter lines and click onto the blue arrow icon above the column.



By clicking on this line you can select an author you want to display and/or modify,

After clicking on ***REFERENCE EQUATIONS*** you can select a particular author from a list in the upper window 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.

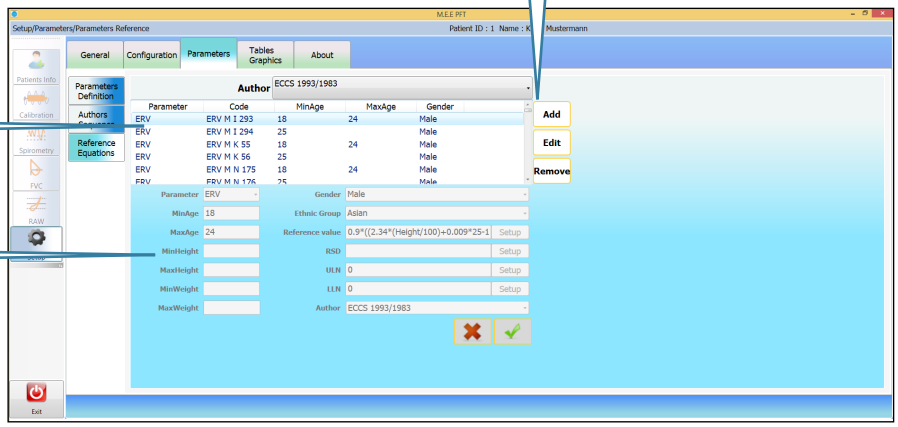


Modify predicted equations

To modify certain equations click in the menu item Edit and save changes by clicking the green √ button. It is also possible to add and to remove equations.

To display an equation concerning a certain test parameter select the parameter from the list.

Any changes have to be made within this definition window

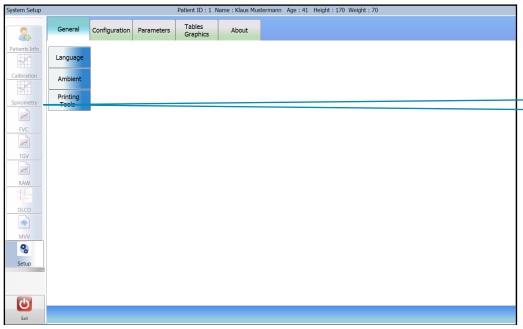


Create and modify print templates

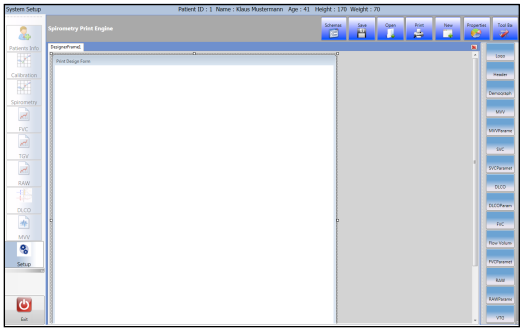
Basics:

smartSoftMEE includes a powerful program module to create new print reports as well as to modify existing templates.

To start the report generator software select the main menu item **SETUP**.

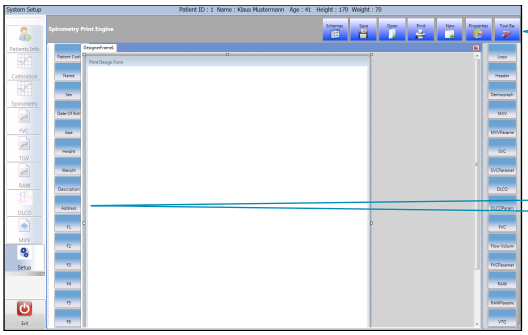


The print report generator is displayed after selecting the submenu item ***Printing Tools***



The top bar of the report generator includes the elements for opening of print templates, create new templates, combine templates with schemes.

The right menu bar includes tools for modifying, complete and re-create templates.



The rightmost selection field of the top menu bar opens when selected another column with tools for editing templates.

The new toolbar menu contains tools for insertion into templates. Above all, these tools include information about the patient himself as: name, date of birth, sex, height, etc.

Schemes opens a window selection with the available print operations (schemes)

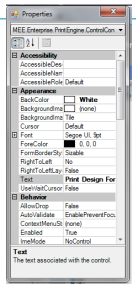
To modify an existing master template the menu item ***Open*** must be clicked.

With ***NEW*** a new print template is created.

To save altered templates the button ***Save*** must be selected by a mouse click.

Print displays a print example to verify the modifications made

If the item ***Properties*** is clicked, the following selection box is displayed.

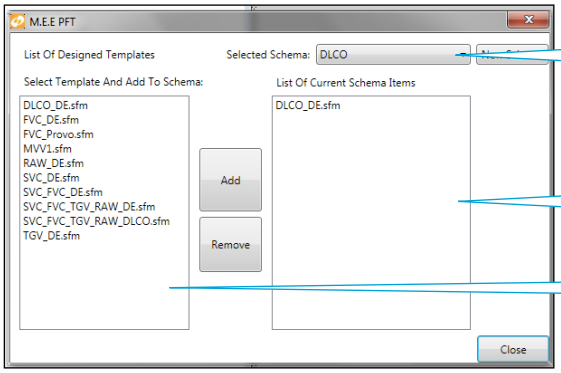


Structure of the report generator

Schemes are permanently combined with the correlating type of measurement. It is possible to combine any print templates with the schemes.

Combine print templates with schema

After the Schema field is selected the following window appears.

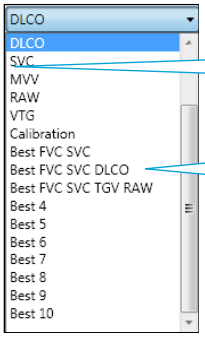


Click in the row labeled Selected Schemes to display all the available schemes. If, for example, the schema DLCO is selected, then its associated templates are listed in the lower right column.

This list in this window shows all the templates combined with the scheme DLCO, in this example it is only one names DLCO_DE.fsm

All print templates from this column can be linked with a scheme. For this, use the Add and Remove Fields.

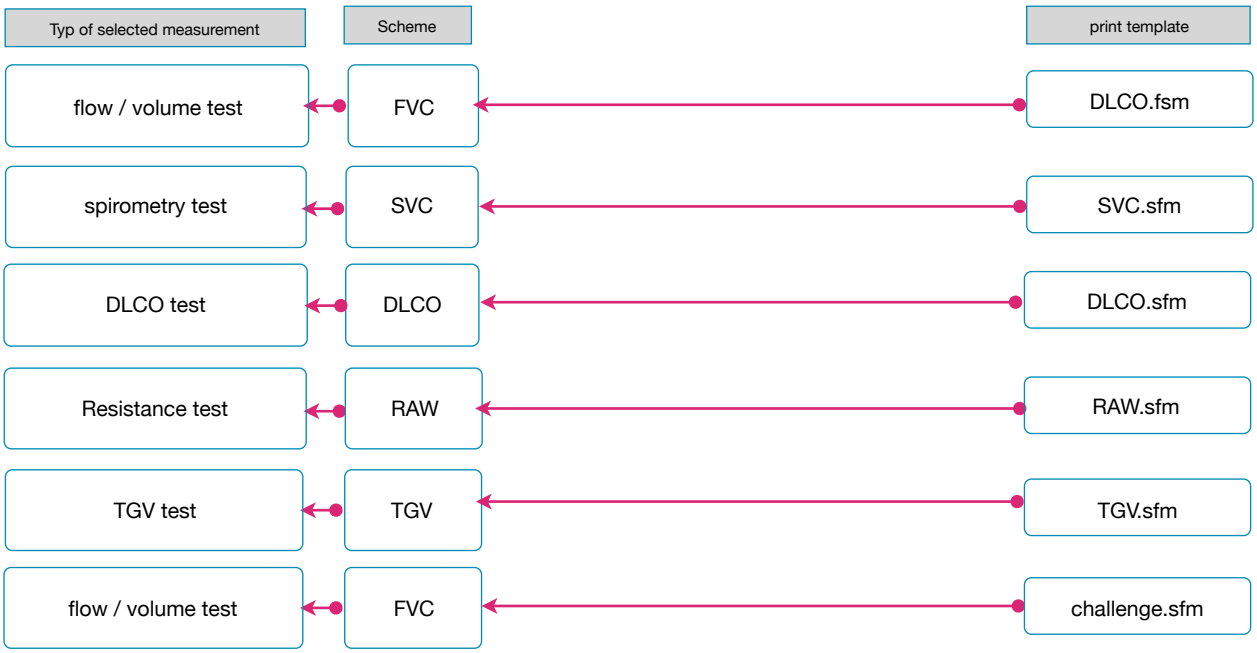
Schemes that combine different types of measurement



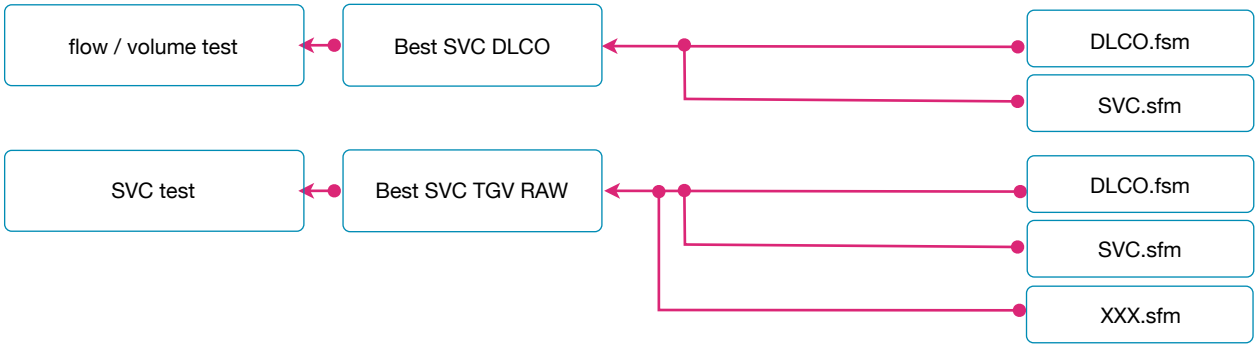
The screen shows an example of the Scheme list .The list shown here includes all the schemes, which are available as standard.

All schemes that begin with the name Best combine templates of different types of measurements. For example, while the scheme DLCO may only contain values of the diffusion measurement the best FVC SVC also contains readings of a diffusion measurement or a resistance measurement.

The structure of a schema with the associated print templates when the left mouse button was pressed.

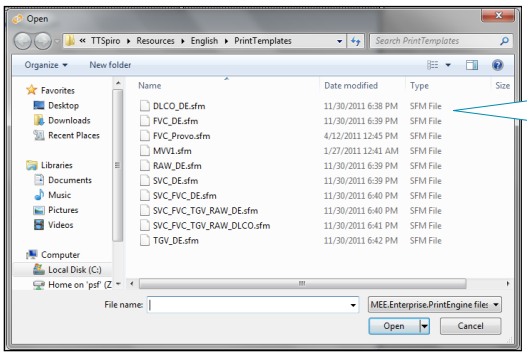


The structure of a schema with the associated print templates (templates) when the right mouse button was pressed.

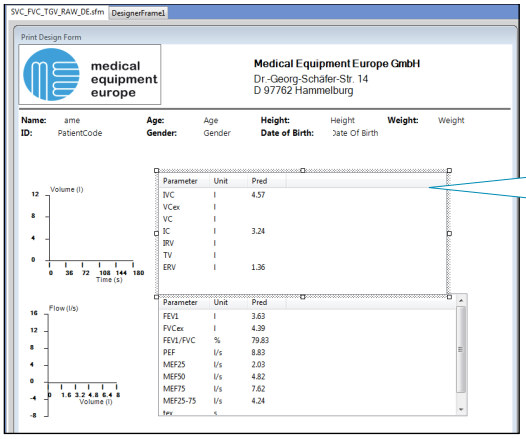


Quick Start Guide as a master copy can be modified.

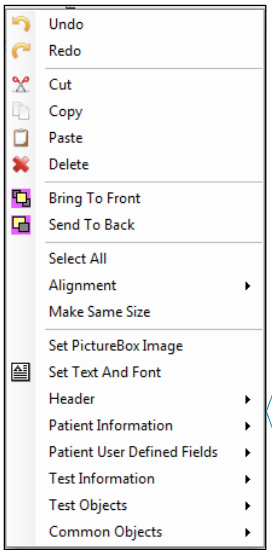
Will open the menu icon is selected, a window opens for selecting predefined print templates.



Select one of the defined print templates with the mouse by a double-click.



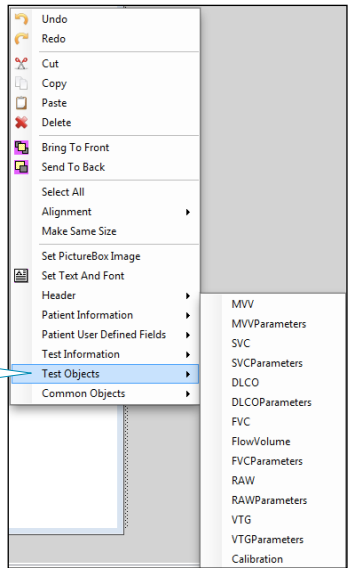
After double-clicking, a window will open with the details of the selected artwork. The artwork consists of multiple entries such as, tables, graphs and the headers with the customer logo. Now click in the entry of the template you want to change. The selected area is highlighted by a frame. This area can now be zoomed with the mouse, reduced, or be repositioned



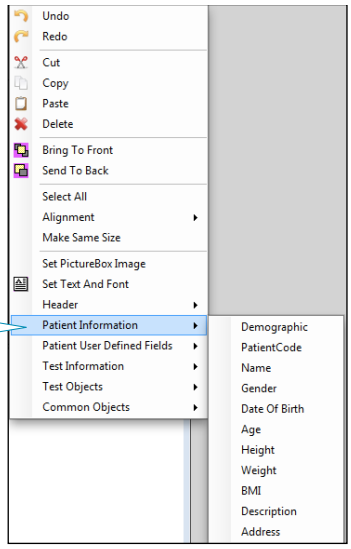
By clicking with the right mouse button into an open template screen or an object like shown above, a list box is opened with tools to make changes related to the selected object.

The entries in the left list box with the names H***eader, Patient Information***, T***est Information*** and ***Test Objects*** include the main elements that make up the template builds.

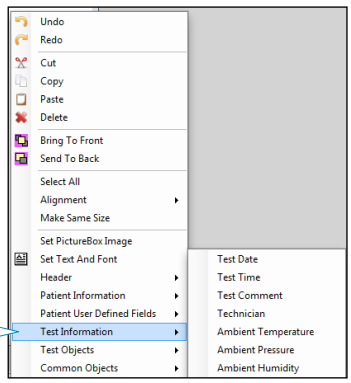
Test Object includes the elements that constitute measurement curves and measurement tables for the respective measurement types. Click SVC with double and a window with an axis system will appear for spirometry. The window must now be scaled and positioned.



Patient information includes the elements that are directly associated with the patient, for example, Age, height, weight.

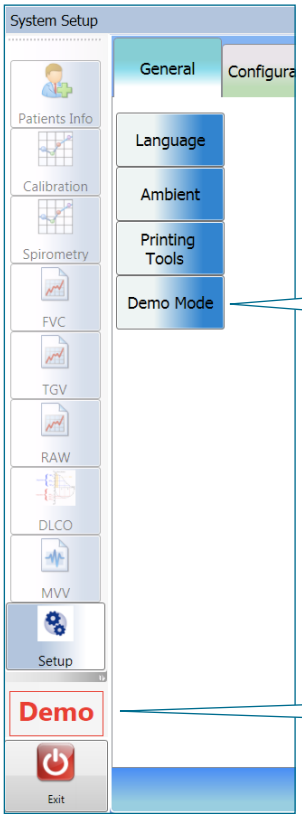


Test Information beinhaltet die Elemente die der Messung zugeordnet sind wie die Umgebungsbedingungen zum Messzeitpunkt, das Datum und die Uhrzeit.



Activate and deactivate Demo mode

Make sure, Demo mode is never active during real testing



To activate Demo mode the main menu item Setup has to be selected. Click now on the menu button Demo Mode to activate or deactivate demo mode.

To assign if demo mode is on, a message is displayed below the main menu bar.

To activate the modification made the program has to be restarted.

Maintenance, STC, MTC

The instrument is very ruggedly constructed, still regularly checks must be carried out to ensure the functionality. The main controls are listed in the following table.

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

maintenance plan smartpft USB					
discription of maintenance	by whom	time table	only recommended	obligatory	with certificate
volume calibration	user	once a day	X		
volume calibration	user	after change of flow sensor		X	
visual check of flow sensor	user	1 x per month		X	
visual check of cables, tubes and connectors	user	1 x per month or after any modification	X		
disinfection of surfaces and components	user	1 x per week or even after each test if required because of patients with infection	X		
STK	certified service	1 x per 2 years		X	X
MTK	certified service	1 x per 1 years		X	X

Trouble shooting

what happens	cause	how to check	how to fix
device does not start	USB cable not connected or error in connection routine	verify USB connector on computer and system unit.	replug USB conector
	no electrical power	check power supply	technician or local service person
	safety transformer switched off	check power supply, connectors and ON/OFF switch of safety transformer	connect cables and switch device on
	safety transformer fuse defect	check cable connectors	change fuse, use only fuses with same characteristics
	power supply cable not connected	check if power switch is lightened	plug in power supply line
	computer switched off	check if computer ON indicator is visible	switch ON computer
test gas supply blocked	gas cylinder empty	check if regulator valve is turned ON and check cylinder pressure. Minimum pressure required is 6 bars	change gas cylinder
	gas regulator closed	check gas pressure on regulator manometer	open regulator valve
	demand valve defect	press on backside of demand valve to open gas supply manually	call service
valve functionality	valve connector	check cable connector	reconnect cable plug
	magnet defect		call service
no volume signal line displayed	USB cable not connected	visual check cable	connect USB cable
	USB error	USB interface error	unplug and replug USB connector
	USB error	USB cable too long	shorten USB cable
	USB error	USB cable defect	replace USB cable
	others		call service

what happens	cause	how to check	how to fix
volume line drift	flow sensor requires recalibration		use a calibrated syringe for recalibration
	flow sensor defect	check sensor optically if there is any damage visible	change flow sensor and recalibrate flow
	patient makes leek at mouth angles	check mouth angles for leakage	instruct patient to avoid leak and/or use bite mouthpiece
	nose clip not used (correctly)	check if nose clip uses or correctly used	put nose clip on
	electrical zero drift	patient removes from mouth piece, if volume line still drifts	patient stays away from mouth piece for 30 seconds until volume line goes straight
	BTPS sensor don´t work correctly (BTPS automatic mode)	go into Setup and verify in BTPS submenu settings for temperature, humidity and ambient pressure	switch off auto BTPS and enter values manually. Call service
	BTPS data input incorrect (BTPS manual mode)	go into Setup and verify in BTPS submenu settings for temperature, humidity and ambient pressure	correct values

