USER MANUAL

Supported products

Software	PistonXP version 1.40
PRE-101	Ergospirometer
PDD-301/sh	Spirometer
PDD-301/r	Rhinomanometer
PDD-301/sco	Breath CO monitor and spirometer
PDD-301/rco	Breath CO monitor and rhinomanometer

Piston Ltd.
1033 Budapest, Szőlőkert u. 4/b

CE 1979

Rev.: ERGO-EN-04.00

Date modified: 04/07/2012

VOLUMES INCLUDED

This User Manual includes the following volumes

PC Software — DB

- Installation
- Settings
- Maintenance
- Patient's database
- Common tasks

Spirometry — SR

- Installation
- Use
- Maintenance
- Troubleshooting

Ergospirometry — ES

- Installation
- Use
- Maintenance
- Troubleshooting

Appendix — AX

- Certificates
- Reference tables

DB

PC SOFTWARE

Supported product

PistonXP version 1.40

Piston Ltd.
1033 Budapest, Szőlőkert u. 4/b

CE 1979

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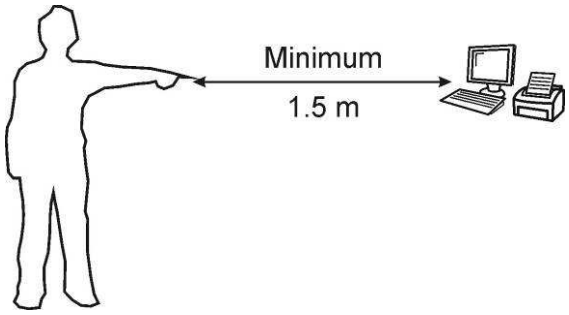
TABLE OF CONTENT

Electric shock protection

The electric shock protection instructions in this section must be followed!

Only Piston Ltd., as manufacturer, or its authorized distributor's personnel, or the distributor's representatives may install the medical device. The above mentioned companies only accept responsibility for systems installed by them.

Before installing the medical devices the personnel must make sure the computer, the monitor and the printer installed as medical electronic devices comply with the standards, for the given country or the user declares concerning this with responsibility.



Information exchange with the computer goes through USB connection. For low leakage current relating to medical devices standards this connection is optically isolated inside the device.

Before shipping we check the device's leakage current. The operator has the opportunity to have the leakage current checked periodically, if he / she finds it necessary.

The system must be installed so the examined person is at least 1.5m away from those devices that are electrically connected to the computer equipment.

Parts of the system (computer, monitor, printer) can only be replaced in case of failure, modification or for any other reason, if the part to be installed has the same electric shock protection conditions as the original one.

The personnel installing the device will train the operator concerning operation electric shock protection. This training includes the contents of this section. The operator verifies the training in official written form.

Minimum PC configuration

The operation of the lung diagnostics system requires a personal computer with the following minimum configuration:

Item	**Minimum***	**Recommended****
Operating system	Windows XP SP3	
Processor (for PDD-301, PDD-401 device family)	800 MHz clock frequency	Intel Pentium 3 / Celeron / Core 2 család AMD Athlon család
Processor (for PDT-111 device family)	1 GHz clock frequency	Intel Celeron / Pentium 4 / Dual Core / Core 2 család AMD Athlon család
Processor (for PRE-101 device family)	1.5 GHz clock frequency	Intel Core 2 család, Core i3 / i5 / i7 AMD Sempron / Phenom / Athlon család
Memory	256 MB	1 GB for Windows XP 2 GB for Windows 7
Memory (for PRE-101 device family)	512 MB	
Hard drive	1.5 GB free space for software system and database management system	4 GB more space for user data
Screen resolution	1024×768	1280×1024
Screen resolution (for PRE-101 device family)	1280×1024, two monitors required	
Printer	Windows compatible	Color for PRE-101 device family
Internet connection		for Software update

* Minimal configuration is the theoretically required minimum for running the operating system and associated services

** Recommended configuration is the required minimum for fluent daily work. Before purchasing a workstation is recommended to consider increasing performance need of later expansion of operating system and other system services.

Compatibility

The medical diagnostic software suite is a PC based Microsoft Windows compatible system that was tested under the following versions of Windows:

32 bit

- Windows XP Home, Professional SP2, SP3
- Windows Vista Home Basic
- Windows Vista Home Premium
- Windows Vista Business
- Windows Vista Enterprise
- Windows Vista Ultimate
- Windows 7 Home Basic
- Windows 7 Home Premium
- Windows 7 Professional SP1
- Windows 7 Enterprise
- Windows 7 Ultimate SP1

64 bit

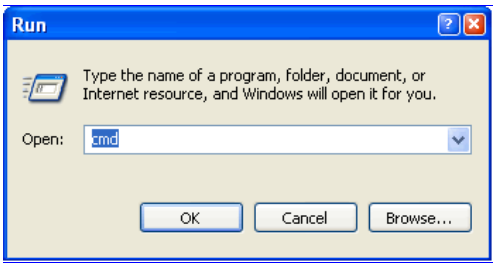
- Windows XP Professional x64 Edition SP2
- Windows Vista Home Basic
- Windows Vista Home Premium
- Windows Vista Business
- Windows Vista Enterprise
- Windows Vista Ultimate
- Windows 7 Home Basic
- Windows 7 Home Premium
- Windows 7 Professional SP1
- Windows 7 Enterprise
- Windows 7 Ultimate SP1
- Windows Server 2008 R2 SP1

Software installation

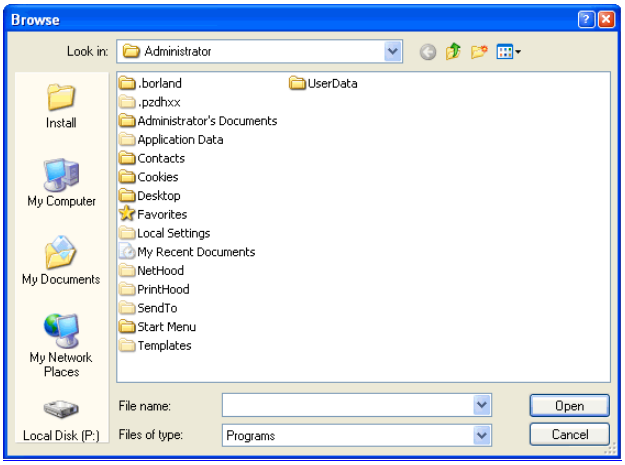
Perform the installation from the included CD.

The most up-to-date version is available from our website:

http://www.pistonmedical.com In the Downloads / Software section.



Click on the **Start** menu and select **Run**

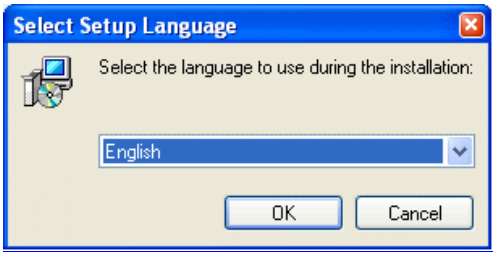


Click on the **Browse** button and select the install program.

When installing from the CD select the CD drive.

Find the pxp_setup.exe file in the Programs folder.

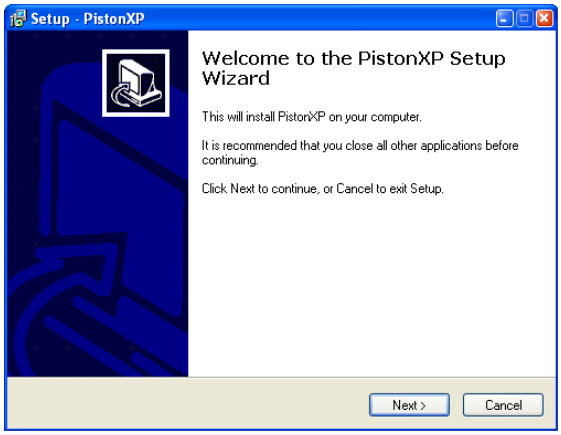
Click **OK**



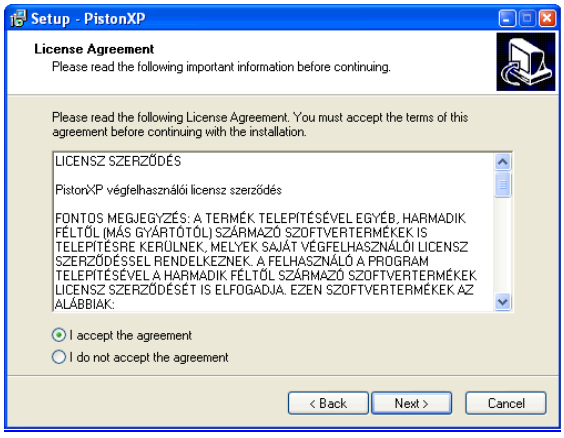
The install program starts

Select the preferred language for the setup and the installed software

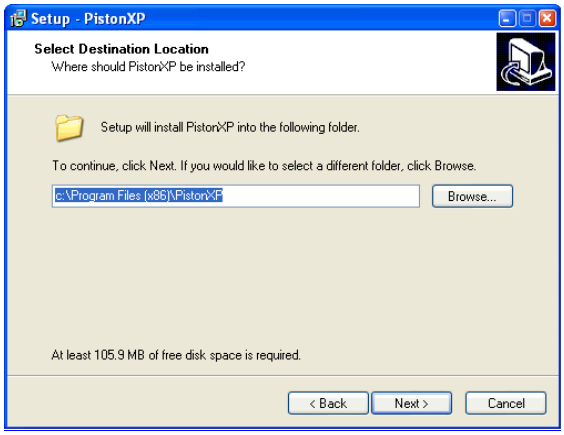
Click **OK**



A welcome screen appears, just click **Next**

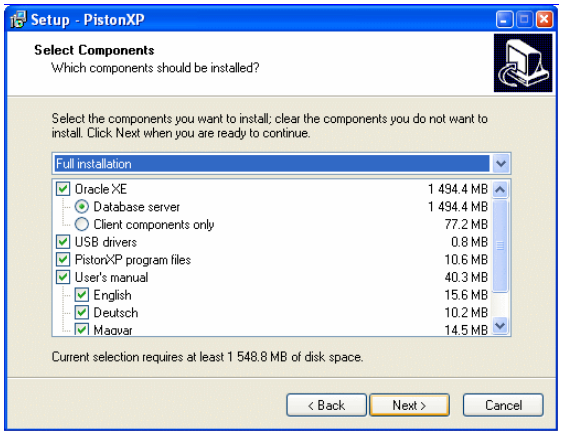


Carefully read the License Agreement, click **I accept the agreement** and click **Next**
If you do not accept the agreement, exit the installation



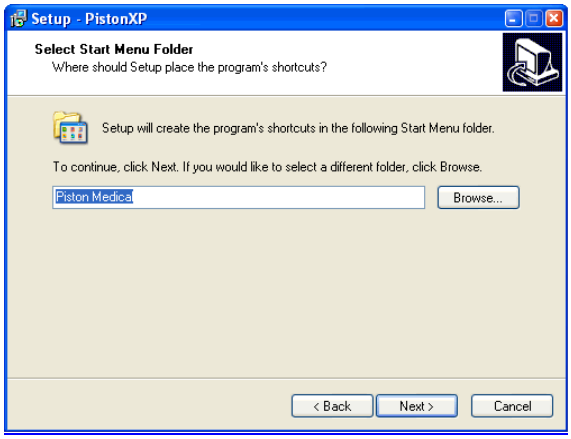
You can specify the install destination.

Click **Next**



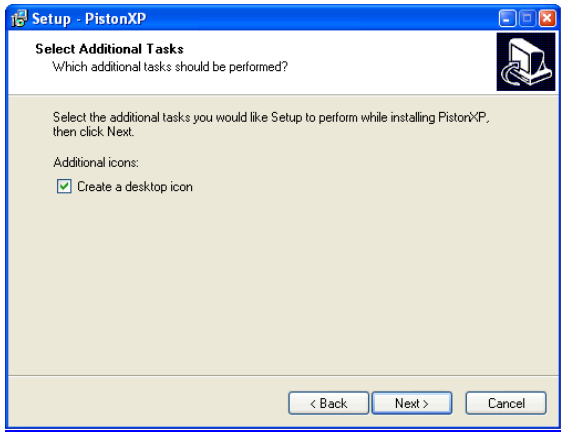
You can select which part of the program to install (experienced users)

Click **Next**



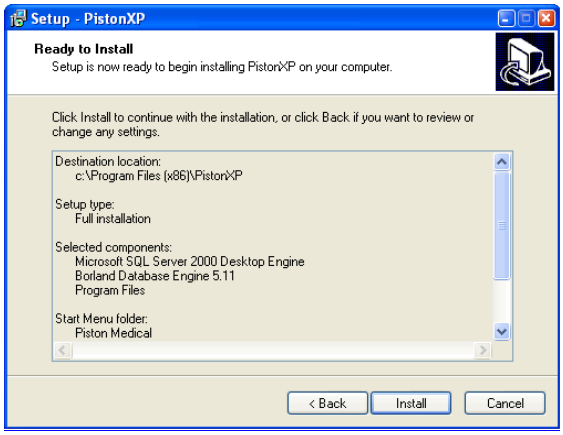
You can enter the name the program appears under in the Start menu (experienced users)

Click **Next**

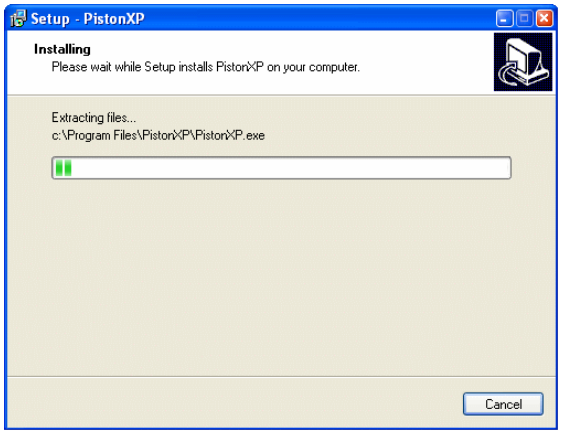


You can select whether a PistonXP icon should be created on the desktop (experienced users)

Click **Next**



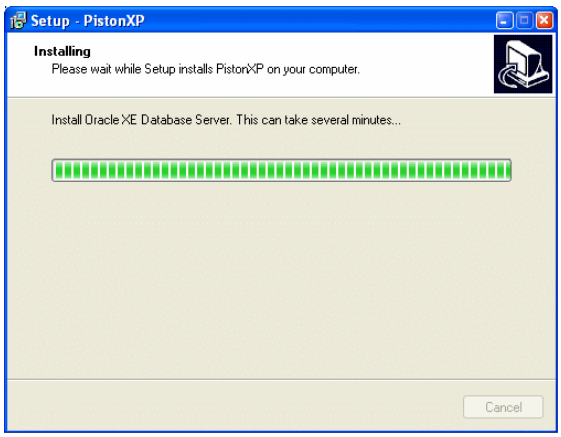
An install summary window appears, and if all settings are acceptable
Click **Install**



The install process begins

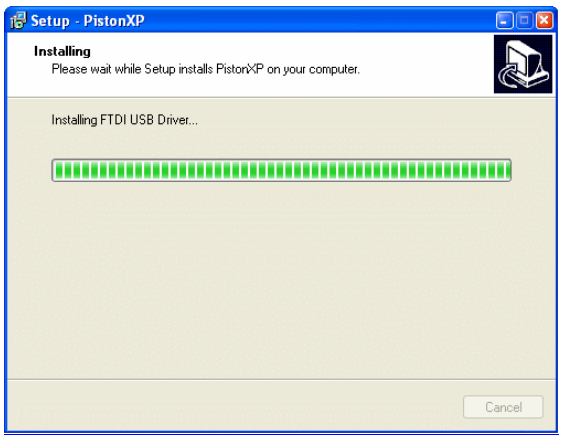
Please wait until it finishes installing the software

After installing the software, external components will be installed also



The installation of the Oracle XE Database Server / Client runs in background and the process can take several minutes

Please wait until it finishes installing the software

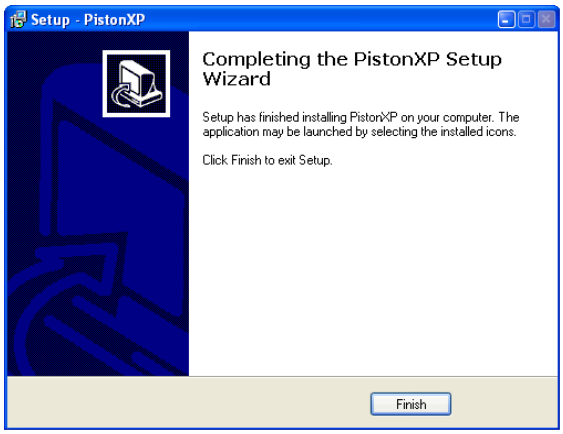


Finally USB Drivers are being installed

Please wait until it finishes installing the software

In case of WindowsXP
If the windows generates a a warning click on the **[Continue Anyway]** button

In case of Windows Vista and 7
If the windows generates a a warning click on the **[Install this driver software anyway]** button



A window indicates the end of the installation

Click **Finish** to close the install wizard

This concludes installation
Start the program
The program automatically detects the connected devices

Icons

Main window


Open patient database


Open expertise editor


Submenu for Hospital information systems


Open report editor and printing


Exit software

Patient database


Clear patient quick search fields


Enter new patient


Modify patient data


Store entered / modified data


Cancel changes


Load all measurements from the selected meeting(s)


Load selected measurements

Settings


Set institute data


Doctor records


Devices' settings connected to the PC


Program operation related settings


Display graphs and other program parts


Maintenance, safety backup related settings


Reference value calculating algorithms


List of parameters to be displayed


Service panels


Enter new doctor


Modify doctor's data


Store entered / modified data


Cancel changes


Accept changes and close Options panel

Report editor


Print preview for lung function tests


Print preview for Compliance test

Print preview for Rhinomanometry

Print preview for Provocation test

Print preview for Ergospirometry

Print preview for Audiometry

Print preview for Calibration

Print selected measurement results

Store a report as PDF document or image

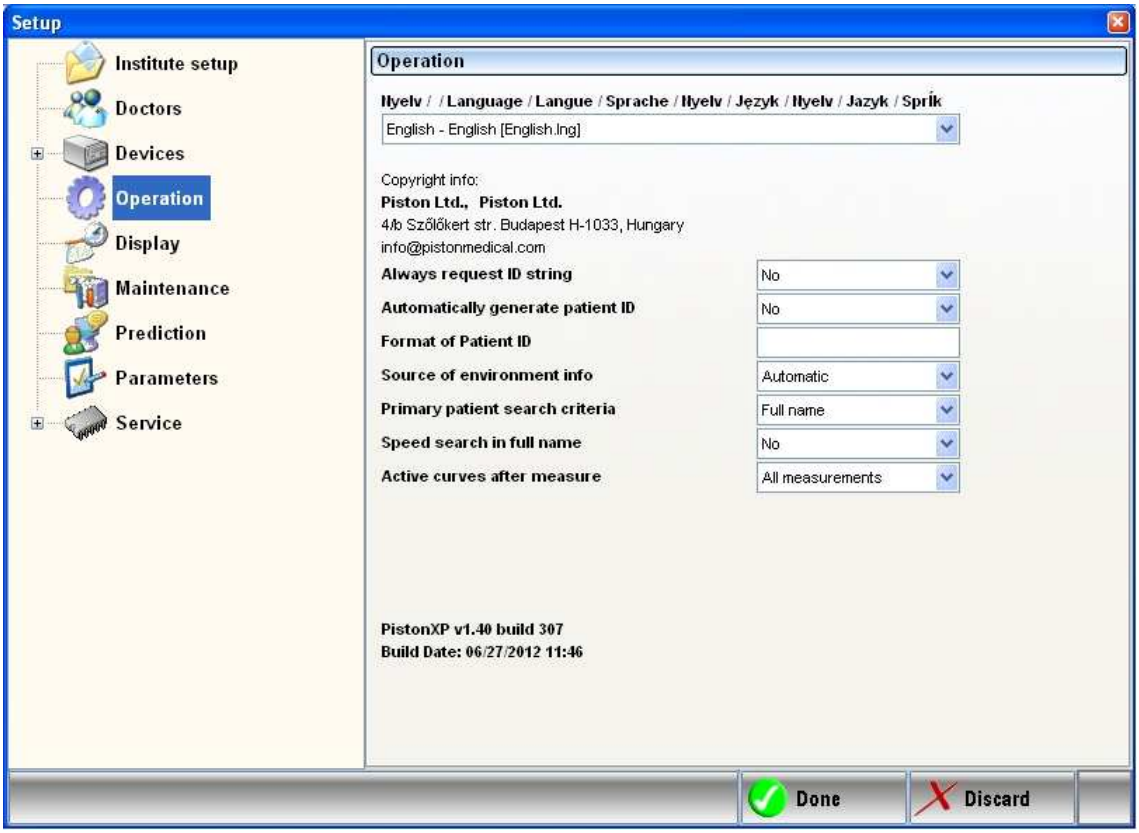
Close Report editor

Settings

The **Setup/Options** menu item allows customization of the system.

Settings that can be changed during measurement are also available in the **Setup** tab of the measurement windows.

Program settings appear grouped on the left side.



Institute data

You can enter the following information at the **Setup/Options/Institute setup** menu item:

Institute name, Site address, Mailing address, Phone number, Fax number, Web page, E-mail address.

This data appears in the header of the printed report.

Doctor's data

The doctor's data can be entered at the **Setup/Options/Doctors** menu item.

New doctor

Press the **[New Doctor]** button to enter data for a new doctor.

Complete the fields.

Make sure that two doctors cannot have the same identifier.

Press the **[Save]** button to store the entered data.

Modify data

Select the doctor from the **[Doctor's** name**]** drop down list whose data you would like to modify.

Click the **[Modify]** button.

Change the desired fields.

When done, press the **[Save]** button.

You will see feedback about the success of the data storage.

If you do not wish to store the entered data, press the **[Discard]** button.

About deleting …

To preserve consistency and for future searches, it is not possible to delete from the database.
All diagnosis has traces in the database.

Language selection

You can select the program's language in the **Setup/Options/Operation** menu item.

All supported languages are displayed in English and in the specific language as well.

Select the language you would like to use.

Patient identification format

You can enter the patient identification format in the **Setup/Options/Operation** menu item.

Format descriptions may be found in the Appendix I. section.

Graph settings

Graph displays may be set in the **Setup/Options/Display** menu item.

Graph scheme

You can select the graph colour settings:

- Dark background, bright lines
- Bright background, dark lines
- Same as printed (white background)

Raster

The grid may be enabled or disabled on the graph

Show curves

It can be selected for several same type measurements:

- The diagrams appear in one coordinate system.
- All the diagrams appear in different coordinate systems.

Visible part of the curve

For easier overview curve sections unrelated to the evaluation can be hidden.

OnFly Analysis

When this function is enabled, the program monitors the patient's breathing during measurement, separates normal breathing from deep exhalations and inhalations.

Active curves after measure

In the **Setup/Options/Operation** menu item those curves can be selected which will be automatically indicated as active ones after each measurement:

- Just the best measure
- First three
- All measurements

Curve magnification

Click on any graph with the right mouse button.

Select the required size from the menu that appears.

The following magnifications are available:

Resistance measurement: 0.5×-, 1×-, 2×-

Other measurements: 0.5×, 1×, 2×, 3×, 5×

Reference values

The desired algorithm may be selected in the **Setup/Options/Prediction** menu item:

- ECCS – European Community for Coal and Steel
- Knudson
- Cotton & Dust
- Crapo-HSU
- Österreichisch

To turn it off, select the **No reference** values option.

Displayed parameters

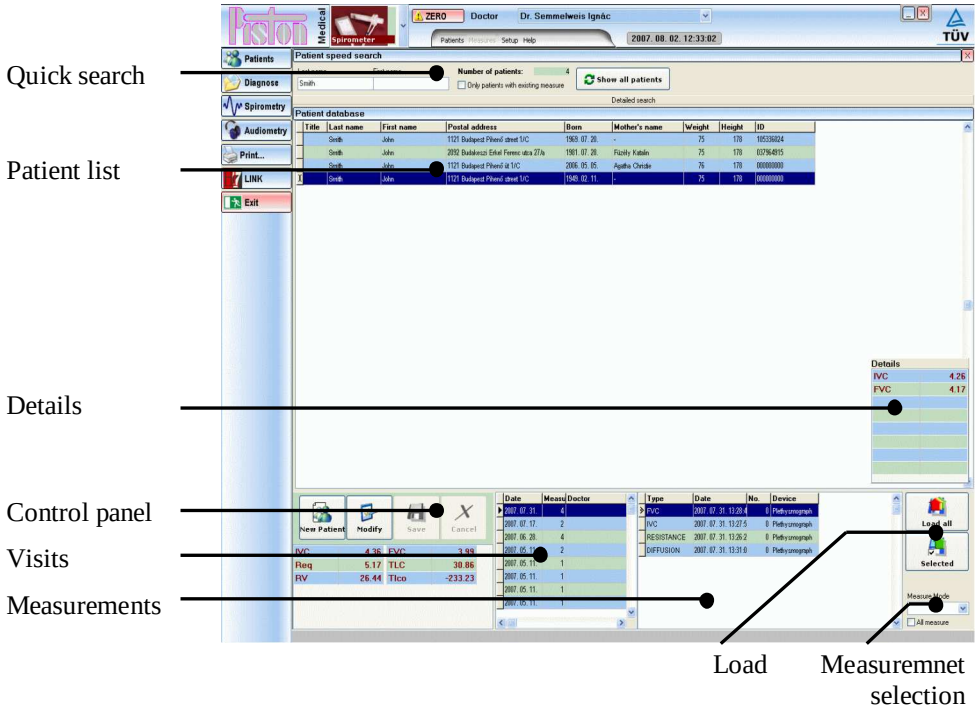
In the **Setup/Options/Parameters** menu you can enter which parameter to display on the screen and which one to print.

Automatic backup

In the **Setup/Options/Maintenance** menu you can select the frequency and the location of automatic backup of the patient database.

User interface overview

Main window



Quick search
Helps find a patient.

Patient list
A list of patients meeting the search criteria.

Details
Displays the selected patient's most important parameters for the selected measurement.

Control panel
Basic database operations: enter new patient, modify patient data, store.

Visits
Dates of previous visits.

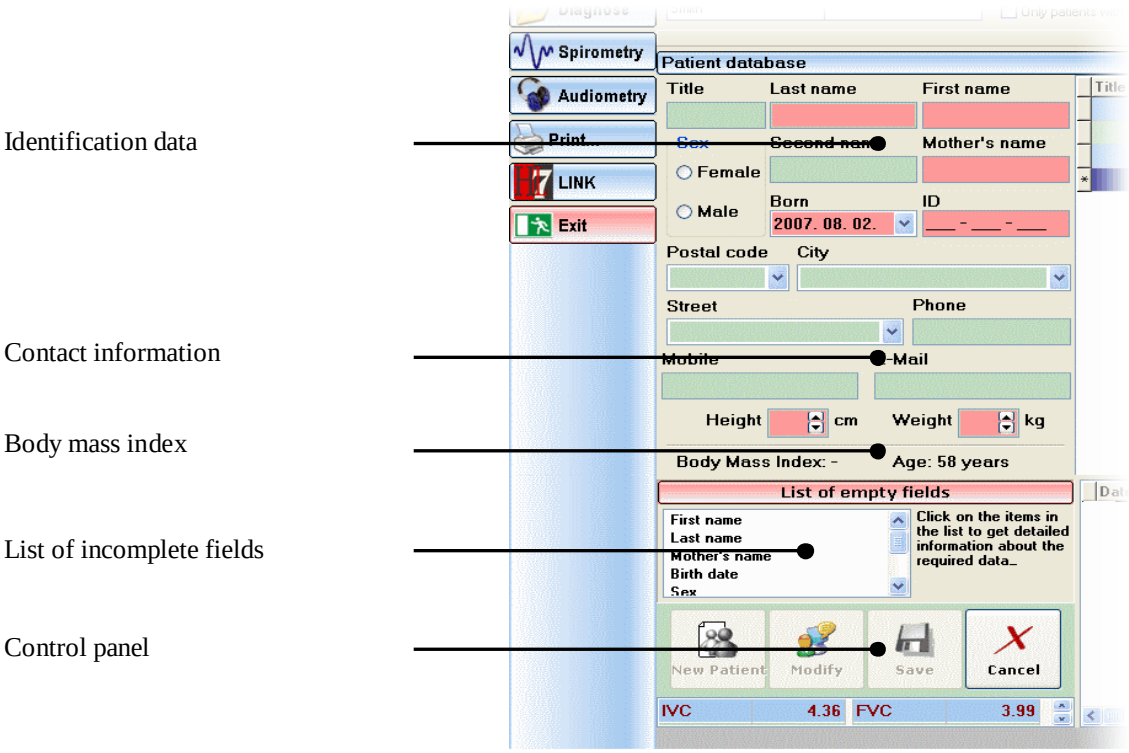
Measurements
A list of measurements for the selected date or measurement type.

Load
Control buttons to display the selected measurements.

Measurement selection
Measurements may be listed according to measurement type as well.

Data input form

Content of the Data input form can be set in the menu **Setup** / **Options** / **Display** / **Contents of Patient's** Datasheet*



Identification data

Group of data essentially identifying the patient: Name, date of birth, social security number, sex, etc.

Contact information

Patient's accessibility: Address, phone numbers, e-mail address.

Body mass index (calculated value)

The patient's current body weight index: square of the height of the patient in meter divided by body weight

List of incomplete fields

A list of fields those both have to be completed and are still empty, or that have been filled out incorrectly.

Control panel

Basic database operations: new patient, modification, store.

*You have to close and re-open Patient's Database to apply changes

Patient's personal data

The program can store an arbitrary number of patients.

Pink fields indicate fields that have to be completed.

Anthropometrics data

You have to enter the patient's body mass and height

These data are required to calculate reference value

The database stores the body mass and height of the patient for each visit, so changes may be followed in time.

New patient

To enter a new patient, press the **[New Patient]** button. Complete the fields and make sure that two patients cannot have the same identifier.

To store the patient, press the **[Save]** button.

You will receive feedback about the success of data storage.

If you do not wish to save the data, press the **[Cancel]** button.

Modify data

Select the patient to modify

Click on the **[Modify]** button

After modification press the **[Save]** button

You will receive feedback about the success of data storage

If you do not wish to save the modified data, press the **[Cancel]** button

About deleting …

To preserve consistency and for future searches, it is not possible to delete from the database. All diagnosis has traces in the database.

Finding a patient in the database

The top section of the patient database window is the search block.

You can search based on several criteria. When those criteria change, the program automatically lists the patients meeting the updated criteria

Normal search

Search only based on the patient's family and surname.

Enter the patient's name or part of it.

Detailed search

Click the **[Detailed search]** button.

You can refine the search criteria in the window:

- patient‘s sex
- date of birth with interval
- address or part of it
- doctor
- identifier (social security number)

Viewing previous measurements

All previous measurements can be reloaded, so reports can be printed at anytime.

Viewing previous measurements

To reload previous measurements:

- Select the patient
- Select the visit by date
- If you only wish to view the results of certain measurement mode select the one from the list
- Select required measurements

If you wish to see all measurement results of a selected visit, click the **[Open]** button
If only certain measurements are important; click them while holding the CTRL button down
After selection click on the **[Open]** button!

If you wish to include further measurements to the report click the **[Patient database]** button to reopen the Patient database.

Select further measurements and click the **[Add measure]** button to include them to the report.

WARNING:
You can only simultaneously load eight measurements of the same mode.
For this reason, the [Load all] button is not always available.

PRE/POST evaluation

To load the data for all previous visits, check the **[All measurements]** checkbox.

This displays a patient’s all previous measurements sorted according to the following:

- Date
- Measurement mode
- Measurement results quality

Select the results of at least two identical measurement mode, for example two FVC measurements.

Load the data as mentioned earlier.

PRE/POST measurements are detailed in the PRE/POST section.

Comment field for patients

Comments may be entered about the patients even for every visit. All comments are stored separately in the database and may be retrieved individually.

To enter a comment:

- Open the Patient database
- Selected the desired patient
- Click the [Diagnose] button to open the text editor window
- Select the [Patient] operating mode from the list
- Enter the comment
- Press the [Store] button to store the comment

Previous diagnosis

All previous comments about the patient may be retrieved from the **[History]** list.

The currently entered text is not lost when viewing a previous diagnosis.

To display the currently entered text again, select the **[Patient]** option from the list of operating modes again.

Patient selection

Before starting the measurement it is necessary to enter patient data using one of the following methods:

- Enter new patient
- Search for patient already in the database

Preparations

Device

Connection

Make sure that the device you wish to use is connected to the computer.

If not, connect the device as detailed in the Installation section.

Selection

Select the device you wish to use from the **[Device selection]** list, because basic lung function tests (FVC, IVC, MVV) can be performed with any of the devices.

Calibration

Regular calibration ensures maximum accuracy.

Automatic warnings

Warning time interval can be entered for all device types. When this expires the device warns the user to perform calibration again. In this case it is recommended to perform the calibration.

Calibration is detailed in the Calibration section of the Spirometer specific volume.

Measurement

The individual measurement operating modes are detailed in the Measurement Modes section in each device specific volumes.

Enter comment

A separate comment may be entered for all measurement modes.

All comments are stored separately in the database.

- Click on the **[Diagnose]** icon to open Diagnose composer
- Select the measurement mode or the Patient mode from the list to which you would like to add a comment
- Enter the comment
- Press the [Store] button to store the comment in the database attached to the measurement

Previous comments

Previously created comments for the given measurement mode can be viewed anytime in the **[History]** list. The currently entered comment is not lost when viewing a previous or another measurement modes' comments. To display the comment select the measurement mode you would like to edit from the list.

Store

Pulmonary function test and Audiometry

To store curves marked **Visible** and **Questionable**, press the **[Store]** button.

Successful data storage returns a feedback.

Ergospiromety and Resting metabolic test

To stor the actual measurement push the **[Store]** button.

Successful data storage returns a feedback.

Printing

Printable data is divided into several groups:

- Complex report on lung function tests: FCV, IVC, MVV, TGV, DLCO, PMAX
- Compliance
- Rhinomanometer
- Ergospirometry and Resting metabolic test
- Provocation test
- Audiometry

PRE/POST

The system can print two types of reports:

- Normal report: Three measurements' results simultaneously.
- PRE/POST report: Two measurements' results simultaneously and their difference in absolute and percentage format.

Customized reports

The printed report has the following parts:

- Header
- Parameter table
- Graphs
- Comment

The header is the only fixed part of the header, the other three may be turned on and off arbitrarily, only the desired parts make it into the report.

Highlight rows

To highlight odd rows at colour or greyscale printing select the **[Highlight odd rows]** checkbox

Simplified report

To print only the best measurements of all modes select the **[Just the best** measure**]** checkbox

Printing

Before printing measurement results have to be stored so the printed reports can be followed up.

- Click the [Print…] icon in the main menu
- Select the graphs, tables and manual diagnosis you would like to print
- Select the report language
- Select the report type: normal or PRE/POST
- Click on a button in the [Print preview] section to view the print preview
- After making the necessary settings, click the **[Print]** button

During printing graph display is similar to on-screen display:

- Complete curve or only the representative curve section
- One or more graphs

Export report into PDF and other graphical formats

This feature provides export of the printed report into the commonly used graphical formats. Exported reports can be stored and for example sent as an attachment to an e-mail.

Supported formats

- PDF, Adobe Acrobat document
- GIF picture
- JPEG picture
- BMP Windows Bitmap picture
- EMF and WMF vector graphics

Settings

The Export function is in the Report edition window

- Click on the [Print…] button at the main menu

Contents and the format of the exported report are fully identical to the printed version. More information can be found in the chapter Pulmonary function test and Audiometry

To store curves marked **Visible** and **Questionable**, press the **[Store]** button.

Successful data storage returns a feedback.

Ergospiromety and Resting metabolic test

To stor the actual measurement push the **[Store]** button.

Successful data storage returns a feedback.

Printing.

Export procedure

Prior to printing and exporting results of measurements have to be stored in order to provide reliable traceability

- Click on the [Print…] button at the main menu
- Select graphs, tables and text fields to be exported
- Select the language of the report
- Select the type of the report PRE/POST
- For previewing the report click on any button at the [Print preview] section
- After setting click on the [Store] button

Exported graphs are fully identical to the graphs shown on the screen:

- Full curve or only the important part
- One or more graphs

Interface to information systems

Interface to frame systems

Our system provides communication according to the more commonly used protocols:

- Health Level Seven (HL7)
- Geräte Daten Träger (GDT)

These protocols provide exchange of the patient data and measured results between the lung diagnostics equipment and the frame systems. These protocols are predefined by the System administrator consequently can not be modified by the user.

Receiving the request for tests

Click on the [LINK…] button in the main menu and open the Import/Export window

According to your frame system type click one of the **[HL7]** or **[GDT]** buttons in the Import section in order to receive a Request for tests

If a Request for test is available the system automatically acquires it and lists all the requested tests

Exporting

Click on the [LINK…] button in the main menu and open the Import/Export window

According to your frame system type click one of the **[HL7]** or **[GDT]** buttons in the Export section. The system automatically exports the results of the tests.

Filling special forms

The system provides filling customer defined forms. Templates of the forms can be compiled in any ASCII format (HTML, XML, CSV etc.). Compilation of the form is the competence of the System administrator.

Filling a form

User may select a form from the preinstalled templates.

Click on the **[LINK…]** button in the main menu to open the Import/Export window

Click on the **[HTML]** button to open the Custom Report window

Select the desired template from the a **[Templates]** list

Click on the **[Select]** button and the form is automatically filled out

The PRE/POST measurement

The system supports measurement comparison – previous measurements may be compared against measurements made later:

- Select the patient
- Select and load the PRE (or previous) measurements
- Measure the current, POST values with the patient
- Select the two measurement to be compared
- Print the PRE/POST report

Retrieve measurement

Perform the steps described in the Patient Database section:

- Open the database
- Select the patient
- Select one or more measurements
- Load the measurement results

Max. 8 measurements may be displayed simultaneously, so if you loaded 6 measurements, you can perform 2 more measurements.

Notice

The program also makes it possible to print the PRE/POST report from the actually performed measurements.

Printing

Printing is similar to normal report printing:

- Select the PRE/POST option in the report edit window
- Select the parts of the report you would like to print

During printing the graphs are displayed similar to the screen:

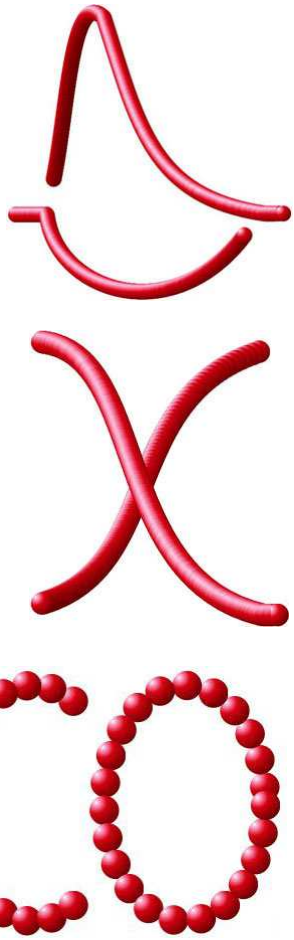
- Complete curve or only the representative curve section
- One or more graphs

Possible problems

Software		
Problem	**Diagnosis**	**Solution**
Cannot find a patient.	Too many search criteria.	Enter less search criteria.
The patient's data cannot be loaded with the [**Selected**] button.	Not a single measurement has been selected.	If there is only one measurement in the list, use the [**Load all**] button.
When making a PRE/POST report, the program only prints previous data loaded from the database.	The new measurement has not been stored.	The measurement must be stored with the [**Store**] button before printing.
Starting up the program the connection to the database server is unsuccessful	After starting up the Windows the database server is not started yet	Wait a few minutes while all the processes of the operational system are fully running
It is impossible to access to the database connected via network	Network connection is interrupted The problem might be caused by the database server	Check the connection with the database server Consult with the system administrator or with the installer
It is impossible to access the local database even after 5 minutes as the Windows started up	The problem might be caused by the database server	Make a cold restart of the PC
It is permanently impossible to access the local database permanently even after re-starting the PC	The problem might be caused by the database server or by the malfunction of the operational system	Consult with the system administrator or with the installer

SR

SPIROMETRY



Supported devices

PDD-301/sh	Spirometer
PDD-301/r	Rhinomanometer
PDD-301/sco	Breath CO monitor and spirometer
PDD-301/rco	Breath CO monitor and rhinomanometer

Piston Ltd.
1033 Budapest, Szőlőkert u. 4/b

CE 1979

Rev.: SR-EN-04.00

Date modified: 04/07/2012

TABLE OF CONTENT

Devices

Piston Ltd.'s respiratory diagnostics product family contains the following members:

PDD-301/s Spirometer

Measurement operating modes

- Forced inspiration and expiration
- Static vital capacity
- Maximum voluntary ventilation

Design

- Flow meter: PPF-18 PinkFlow, symmetric Pitot tube
- USB computer connection
- Portable design

PDD-301/r Rhinomanometer and Spirometer

Measurement operating modes

- Forced inhalation and exhalation
- Static vital capacity
- Maximum voluntary ventilation
- Nasal respiratory resistance measurement with active anterior and posterior methods

Design

- Flow meter: PPF-18 PinkFlow, symmetric Pitot tube
- USB computer connection
- Portable design

PDD-301/sco and PDD-301/rco Breath carbon monoxide monitor

Measurement operating modes

- Forced inhalation and exhalation
- Static vital capacity
- Maximum voluntary ventilation
- Breath carbon monoxide concentration
- Version PDD-301/rco additionally provides nasal respiratory resistance measurement with active anterior and posterior methods

Design

- Flow meter: PPF-18 PinkFlow, symmetric Pitot tube
- Side stream gas analysis for higher accuracy and shorter response time

- USB computer connection
- Portable design

Symbol annotation

The following symbols indicate which descriptions apply to which device.

S	Spirometer
R	Rhinomanometer
C	Breath carbon monoxide monitor

Technical overview

Lung diagnostic device family main parts description:

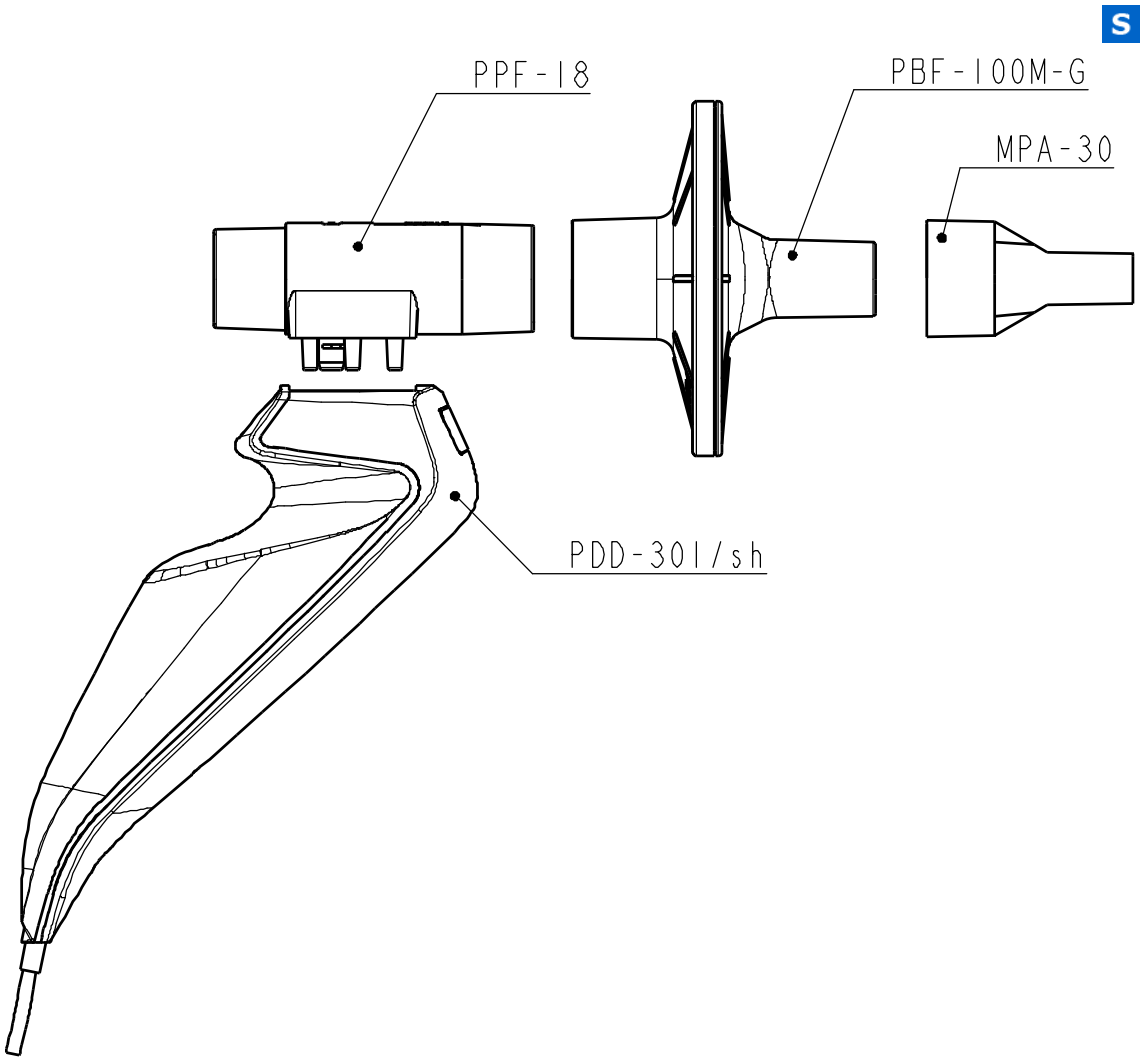
Flow meter PDD-301/s, PDD-301/r PDD-301/sco, PDD-301/rco

S R C

PPF-18 PinkFlow, symmetric Pitot tube flow meter, which provides pressure difference in proportion with the flow speed.

A differentiate pressure sensor converts the pressure difference to electric signal.

PDD 301/s Spirometer installation



Connect the USB cable to the PC

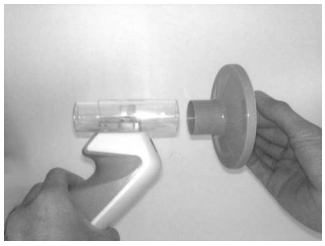
For the connection push the PinkFlow flow meter into the quick connector
For removal push the metal button

To remove the PinkFlow flowmeter push the metal button at the back side of the quick connector and pull off the flowmeter

The PinkFlow flow meter can be used without bacterial filter as well. In this case a clean PinkFlow meter should be installed prior to each patient.

Connect one MPA-30 mouthpiece to bigger diameter end of the PinkFlow flow meter

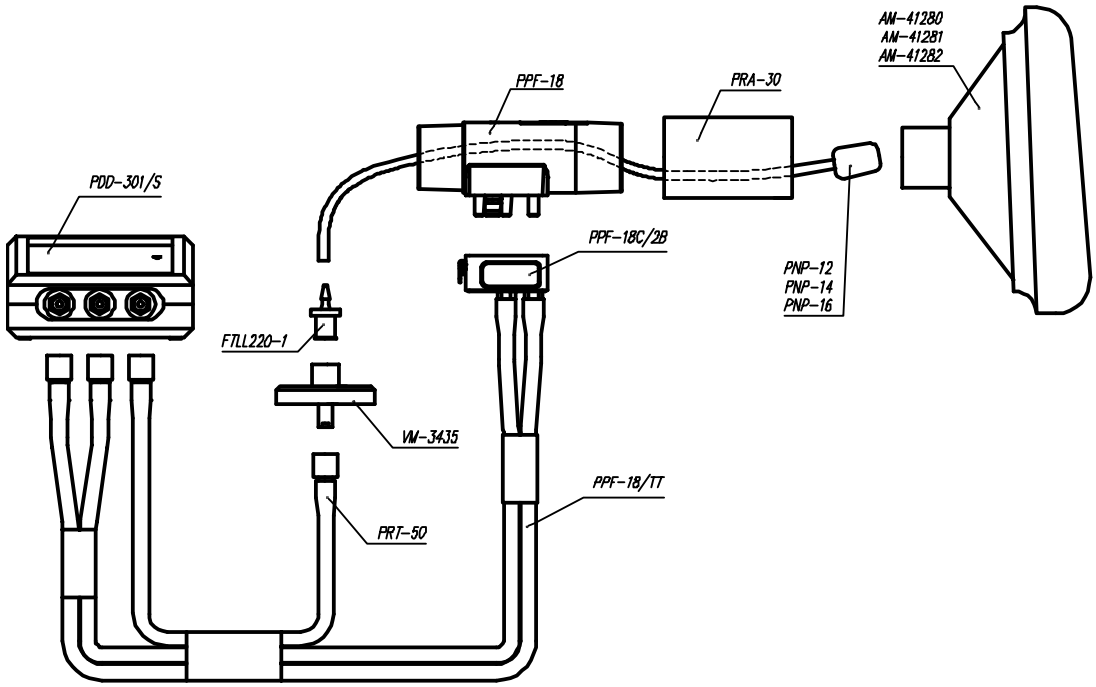
If there is no possibility to provide a clean PinkFlow flow meter prior to each patient you have to use a bacterial and viral filter to avoid cross contamination.
PBF-100MG bacterial and viral filter can be used.



Connect one PBF-100MG bacterial and viral filter to bigger diameter end of the PinkFlow flow meter

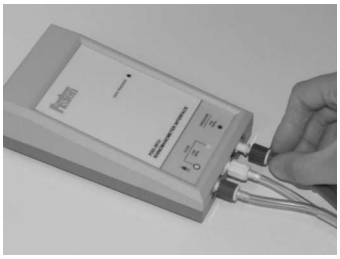
PDD 301/r Rhinomanometer installation

R

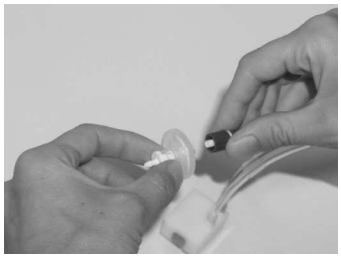


Connect the USB cable to the device and to the PC

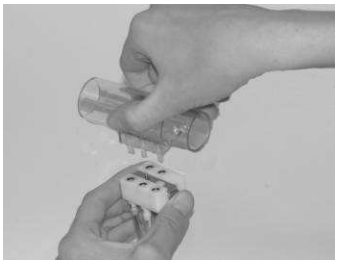
Connect the blue connector of the twin tubing to the blue coded socket indicated with the Flow meter label and the white connector to the white coded socket



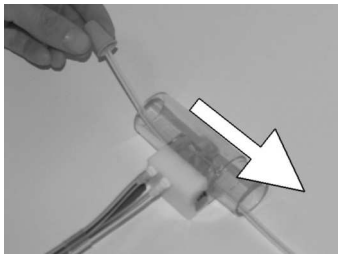
Connect the green connector of the nasal pressure tubing to the green coded socket
For the proper connection the lock should be turned 180 degrees clock wise



The disc filter of the pressure port prevents the device from the contamination
When the disc filter gets dirty it has to be replaced



For the connection push the PinkFlow flow meter into the quick connector
For removal push the metal button



Select a proper size Nasal probe and lace its tubing thru the PinkFlow flow meter. The plug of the Nasal probe has to face the patient side of the flow meter namely it has to be on the opposite side to the release button of the pneumatic quick connector.

Connect the tubing of the Nasal probe to the barbed fitting of the disc bacterial filter

⚠

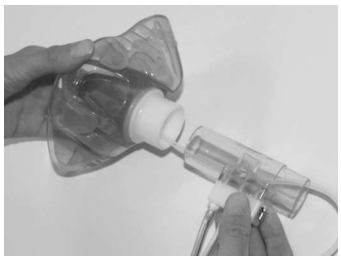
Warning: When a tubing of the Nasal probe is laced thru the PinkFlow flow meter the sensitivity of the flow meter is modified. This modification is automatically corrected in the Rhinomanometer mode.

Do not use the Nasal probe during any other measurement!

Only the Piston made Nasal probes can be used with the device.

⚠

The PinkFlow flow meter can be used only without bacterial and viral filter in Rhinomanometer mode consequently a clean PinkFlow flow meter has to be connected prior to each measurement.



Lace the plug of the Nasal probe thru the adapter of the facial mask and connect the PinkFlow flow meter to the adapter.

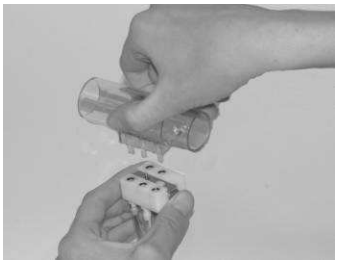
PDD 301/sco and PDD 301/rco Breath CO monitor installation

C

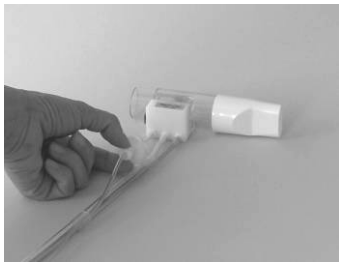
Connect the USB cable to the device and to the PC

Connect the blue connector of the twin tubing to the blue coded socket indicated with the Flow meter label and the white connector to the white coded socket

Connect the yellow connector indicated with the Gas sample label to the yellow coded socket
For the proper connection the lock should be turned 180 degrees clock wise



For the connection push the PinkFlow flow meter into the quick connector
For removal push the metal button



The disc filter of the gas sampling tubing prevents the device from the contamination
When the disc filter gets dirty it has to be replaced

Settings

Part of the parameters are for system data that can seriously effect measurement accuracy.
You can view these parameters through the user interface, but they cannot be modified.
Only professionals can modify these data in the PistonXP.ini file.

Calibration Syrigne

You can set the calibrating pump volume at the **Setup/Options/Devices/Calibration** Syringe menu

Number of calibrating cycles

The number of calibrating cycles with the calibration pump may be set in the **Setup/Options/Devices/Calibration** Syringe menu:

- Minimum: 2
- Maximum: 20
- Recommended: 10

Spirometer

Select the **Spirometer** group in the **Setup/Options/Devices** menu.

The system senses the spirometer connection to the USB port in 2 seconds.

Calibration time interval

You can set how often the device should remind you of the need for calibration

Rhinomanometer

Select the **Rhinomanometer** group in the **Setup/Options/Devices** menu.

The system senses the rhinomanometer connection to the USB port in 2 seconds.

Calibration time interval

You can set how often the device should remind you of the need for calibration.

Icons

Main window – Pulmonary function test

Open calibration measurement window. The checkmark indicates that all connected devices are calibrated.

Open calibration window. The exclamation point indicates that one or more connected device needs to be calibrated.

Forced vital capacity (FVC)

Inspiratory vital capacity (IVC)

Maximal voluntary ventilation (MVV)

Rhinomanometry

Breath carbon monoxide monitoring

Manual

Calibration

Start calibration

Skip specific phase during plethysmograph calibration, continue from the next step

Abort calibration

Store measured results

Print calibration report

Measurement windows – Pulmonary function test

Start measurement in at FVC, IVC, MVV, TGV, TLC measurement

Measure left nostril resistance

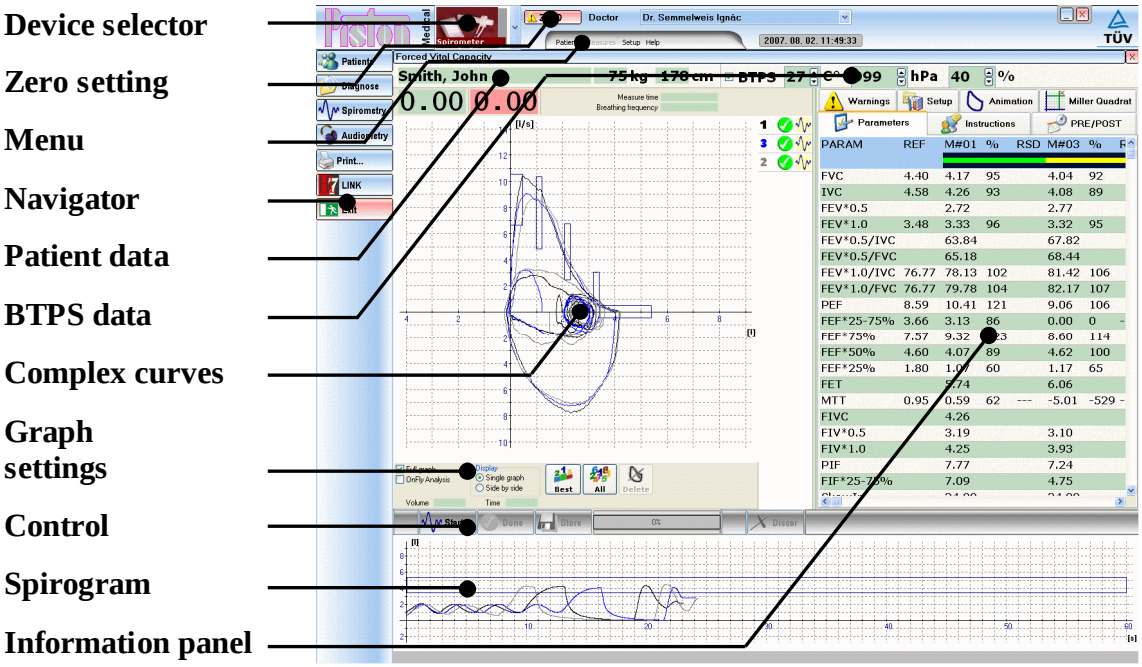
Measure right nostril resistance

Finish measurement (in case of successful measurement)

	Abort measurement (partial results are lost)
	The measurement is technically correct
	The measurement is most likely technically incorrect
	The icon in the summary table indicates the active curves, the specific measurement's curve is also displayed
	Indicates questionable curves The curves appear dashed
	The program does not store curves marked like this and they do not appear on the graph either
	Store active and questionable curves, measurement and their parameters
	Mark all curves as active
	Mark the three best curves as active, hide all other curves
	Effectively delete the selected curve
	List of Lung function Parameters
	Instructions
	PRE/POST
	Warnings
	Setup
	Animation
	Miller Quadrant

User interface general design

The following image shows the general design of the measurement screens. The individual measurement windows may differ from each other but the main controls are identical.



Device selector

Select the device to be used from the drop down list.
This is necessary if, for example, you own a Plethysmograph and a Spirometer, and would like to perform IVC measurement.

Zero setting

Runs manual Zero setting of the selected device
Without manual Zero setting the system automatically sets zero before all measurements

Menu

The program's general main menu, which contains the grouped basic functions.

Navigator

Controls that group the basic phases of daily routine.

Patient data

Contains the most important measurement data for the patient selected from the database.

BTPS data

These are the environment data measured by members of the PDT-111 device family. If you only own the PDD-301 device, this is where you can set the individual values manually.

Complex curves

The more complex curves of the individual measurement operating modes. For example, in case of FVC measurement, the flow-volume loops, in case of Plethysmograph measurement Resistance and TGV loops.

Graph settings

This is where you can set graph display modes. These settings are also available on the Options panel, details may be found in the PC Software volume of this manual.

Control

This filed contains the basic control functions during the measurement. The appropriate Function buttons are shown in square brackets:

- Start measurement [F3]
- Start special measurement section [F4]
- Finish measurement after a successful measurement [F5]
- Stop measurement, abort measurement (for example, in case of malfunction) [ESC]
- Store, print

Spirogram

Volume – time graph, which monitors the patient's breathing during the measurement.

Information panel

This section contains information, settings and functions:

- Current measurement parameter list
- PRE/POST settings and parameters
- Measurement related warnings, error messages
- Measurement instructions

After turning the device on and entering the BTPS data, calibration is recommended for maximum measurement accuracy.

Calibration is recommended when starting a new shift, after flow sensor disinfections or replacement.

IMPORTANT

If work environment conditions (temperature, air pressure, humidity) change significantly, re-calibration is recommended.

Flow meter calibration

The flow meter volume calibration ensures maximum accuracy and is an efficient way to check the proper operation.

It is possible to perform measurements without calibration but at least 5% additional error must be taken into account.

Connecting the flow meter

Connect the patient side, the bigger diameter side of the PinkFlow flow meter of the Spirometer or the Rhinomanometer directly to the calibrating pump.

Calibration process

Spirometry/Calibration

In case of several connected devices, select the one to be calibrated from the **[Device selection]** list.

The calibration should be performed in two steps. At first the peak flow should be at about 1,0 l/s and afterwards at about 5,0 l/s

Press the **[Start]** button to start calibration.

Push the fully drawn out calibrating pump with uniform speed all the way in, then pull it out all the way.

Horizontal lines on the loop curve indicate optimal flow limits. During calibration make sure the calibration curve peaks are within these lines.

The number of calibration cycles may be set as described in the in the PC Software volume of this manual. The number of recommended cycles is 10.

The first part of calibration should be done with the peak flow at about 1,0 l/s (red curves)

The second part of calibration should be done with the peak flow at about 5,0 l/s (green curves)

After the calibration process the system automatically calculates calibration factors for the different flow values.

The following values appear in the calibration result table:

- Param – name of the measured parameter
- Pred – reference value
- Meas – the measured value during calibration
- % – difference of measured value from the reference

Possible error messages

Calibration must contain at least 10 exhalations and inhalations.

Calibration was not performed properly:

- There were less calibration cycles than prescribed
- The flow meter slipped out of the calibrating pump during calibration

Asymmetry error

In this case either calibration was performed incorrectly or an error occurred in the system:

- You did not pull out or push in the calibrating pump all the way
- Check pneumatic connections
- Check flow meter assembly
- Check that the twin tube is not broken or punctured
- Check that there is no liquid in the flow sensor or the twin tube

Flowmeter error out of allowed range

If during calibration the device measures the calibration volume with greater than 20% error, there is a chance for hardware problems.

Checking calibration results

It is recommended to store calibration results as the tendency over time can help draw conclusions concerning device stability and possible aging.

Click the **[Store]** button to store calibration results.

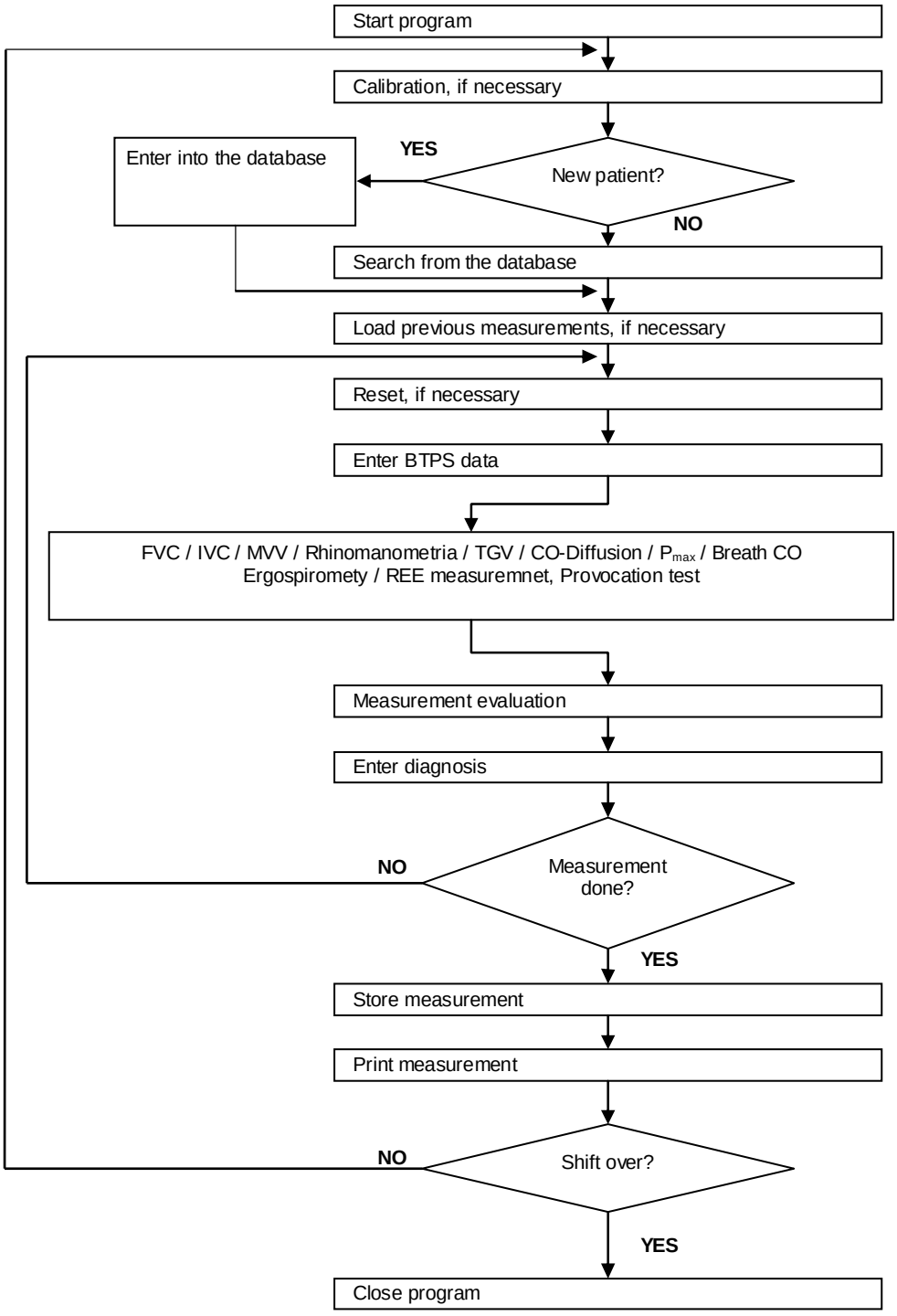
Click the **[Print]** button to print calibration results.

Viewing previous calibration data

Select the **[Result]** tab on the calibration window Information panel.

You can search for previous calibration results from the **[Reload calibration** data**]** time-sorted list.

Daily routine – overview



System overview table

	PDD-301/spf	PDD-301/rpf	PDD-301/sco	PDD-301/o	PDT-111/p	PDT-111/d	PRE-101
	Spirometer	Rhinomanometer	Breath CO me-ter	Oscillometer	Body Plethys-mograph	CO-Diffusion	Ergospirome-ter
PinkFlow* flowmeter	+	+	+	+	+	+	+
Forced Vital Capacity	+	+	+	+	+	+	+
Static Vital Capacity	+	+	+	+	+	+	+
Maximal occlusion pressure	+	+	+	+	+	+	+
Rhinomanometry		+	optional	+	optional		
Breath CO			+				
Impulse oscillometry				+			
Thoracial gas volume					+		
Airways resistance					+		
Légzési munka					+		
Compliance					optional		
CO-Diffusion					optional	+	
Ergospirometry							+
EKG with 12 leads							+
Weight	220 g	220 g	420 g	2,5 kg	200 kg	5,5 kg	4,5 kg
Dimensions	150 * 82 * 45 mm	150 * 82 * 45 mm	190 * 138 * 68 mm	260 * 155 * 160 mm	1680 * 925 * 790 mm	320 * 200 * 240 mm	320 * 200 * 140 mm
Power source	USB port	USB port	USB port	90 – 260 VAC 50/60 Hz	90 – 260 VAC 50/60 Hz	90 – 260 VAC 50/60 Hz	90 – 260 VAC 50/60 Hz

Available examinations

Parallel measurements

The program makes it possible to perform eight different measurements in all measurement modes. All eight measurements' data can be stored and reloaded later.

Forced exhalation and inhalation S R

The most widely applied method for dynamic pulmonary function test. Detailed description may be found in the Measurement modes (page 29) section.
In this operating mode the device measures the following parameters:

FVC **Forced Vital Capacity**

Expired volume after full inspiration at the highest possible flow

FEV*0,5 **Forced Expiratory Volume 0,5 sec**

The amount of air exhaled in the first 0.5s during forced exhalation

FEV*1,0 **Forced Expiratory Volume 1,0 sec**

The amount of air exhaled in the first 1.0s during forced exhalation

FEV*0,5/IVC

The ratio of FEV*0.5 and the static vital capacity

FEV*0,5/FVC

The ratio of FEV*0.5 and the forced vital capacity

FEV*1,0/IVC

The ratio of FEV*1.0 and the static vital capacity

FEV*1,0/FVC

The ratio of FEV*1.0 and the forced vital capacity

PEF **Peak Expiratory Flow rate**

Highest flow during forced exhalation

FEF*25-75% **Forced mid-Expiratory Flow rate**

The average volume-flow speed calculated for the middle half of forced exhalation

MEF*75% **Forced Expiratory Flow at 75% lung volume**

Flow when 75% of the forced vital capacity is still in the lung

MEF*50% **Forced Expiratory Flow at 50% lung volume**

Flow when 50% of the forced vital capacity is still in the lung

MEF*25% **Forced Expiratory Flow at 25% lung volume**

Flow when 25% of the forced vital capacity is still in the lung

FET **Forced Expiratory Time**

The duration of forced exhalation.

MTT **Mean Transit Time**

The average leaving time from the lung of gas molecules during forced expiration

FIVC **Forced Inspiratory Vital Capacity**

Inspired volume after full expiration at the highest possible flow

FIV*0,5 **Forced Inspiratory Volume 0,5 sec**

The amount of air inhaled during the first 0.5 seconds of forced inhalation.

FIV*1,0 **Forced Inspiratory Volume 1,0 sec**

The amount of air inhaled during the first 1.0 seconds of forced inhalation.

PIF **Peak Inspiratory Flow rate**

Highest inhalation flow speed during forced inhalation

FIF*25-75% **Forced mid-Inspiratory Flow rate**

The average flow calculated for the middle half of the forced inhalation.

The following graphs are displayed during measurement:

- Volume/time curve
- Flow/volume loop

Static vital capacity

S R

The most widely used method for the static lung function test.
Detailed description may be found in the Measurement modes (page 29) section

In this operating mode the device measures the following parameters:

IVC **Inspiratory Vital Capacity**

Total inspired volume after a full expiration

IRV **Inspiratory Reserve Volume**

The inspiration reserve volume is volume, what the patient can inhale from the average inhalation endpoints of quiet breathings

ERV **Expiratory Reserve Volume**

The expiration reserve volume is volume, what the patient can exhale from the average exhalation endpoints of quiet breathings

TV **Tidal Volume**

The average volume moved during quiet breathing

SVC **Slow Vital Capacity**

Total expired volume after full inspiration

The following graphs are displayed during measurement:

- Volume/time curve
- Flow/volume loop

Maximal voluntary ventilation

S R

A rarely used dynamic lung function test.
Details may be found in the Measurement modes (page 29) section.
In this operating mode the device measures the following parameters:

MVV **Maximal Voluntary Ventilation**

The maximum respiratory volume measured during voluntary respiration, calculated for one minute

MVV*f **Maximal Voluntary Ventilation Frequency**

The maximum respiratory frequency measured during voluntary respiration, projected for one minute

The following graphs are displayed during measurement:

- Volume/time curve
- Flow/volume loop

Breath CO measurement

C

The device insures the measurement of breath carbon monoxide concentration. It is inevitable in the smoking cessation program.

Details may be found in the Measurement modes (page 29) section.

In this operating mode the device measures the following parameters:

CO ppm **Breath CO concentration**

%COHb **Carboxyhemoglobin %**

SVC **Slow Vital Capacity**

The Slow Vital Capacity is the volume which was exhaled slowly by the patient after a total inspiration.

The following graphs are displayed during measurement:

- Volume/time curve

Rhinomanometry

R

Measuring the nasal airway resistance.
Detailed information may be found in the Measurement modes (page 29) section.

In this operating mode the device measures the following parameters:

Flow (50 Pa)

The flow speed at 50 Pa drive pressure.

Flow (75 Pa)

The flow speed at 75 Pa drive pressure.

Flow (100 Pa)

The flow speed at 100 Pa drive pressure.

Flow (150 Pa)

The flow speed at 150 Pa drive pressure.

Flow (300 Pa)

The flow speed at 300 Pa drive pressure.

The following graphs are displayed during measurement:

- Volume/time curve
- Flow/P_{Ch} Resistance loop

Entering environmental data

S R

Entering exact environmental data is necessary for proper BTPS correction.

If the temperature, humidity or air pressure changes, the data must be re-entered.

BTPS

The top right parts of the individual measurement windows contain the BTPS data panel where you can enter the environmental data.

Automatic BTPS parameter measurement

The following Piston devices provide automatic measurement of ambient temperature, humidity and pressure:

- PDD-301/shm Integrated BTPS module
- PAM-201 Individual BTPS module with USB connection

These devices automatically measure the environmental data and display them in the BTPS panel.

Warning!

Entering incorrect environmental data may cause even 15% inaccuracy

Zero setting

S R

For exact volume measurement the zero setting of flow meter channel must be performed immediately before the measurement.

Preparation

There cannot be any flow through the flow meter during zero setting, so the patient cannot take the connected mouthpiece into the mouth.

Notice P D

In case of Plethysmograph and the Diffusion capacity test pneumatic valves detach the flow meter from the pressure transducer, so zero setting occurs automatically in the background.

Patient may continue breathing thru the flow meter.

Zero setting process

The program automatically starts the zero setting process immediately before each measurement.

The system evaluates the data measured during the zero setting process, and displays an error message and repeats the zero setting process if a zero error is encountered.

Manual zero setting

You can reset the currently selected device anytime with the **[Zero]** button next to the **[Device selection]** list in the program header.

Notice

Zero setting is automatically performed before calibration.

Preparations

Device

Patient circuit

To avoid cross contamination connect a clean PinkFlow flow meter or a new disposable bacterial and viral filter before each patient measurement.

Patient

This chapter describes those general considerations which are necessary to inform the patient and get the patient prepared for the tests

Recommended body position

- Sitting on a chair
- Straight back
- Level head
- Tight clothing or jewels must not prevent free breathing

Directions

Respiratory examination requires patient cooperation so patient preparation and instructions are important for the measurement:

- Let the patient know the measurement process and goal
- Show the patient how to take in the mouthpiece, especially in case of the bite-grip mouthpiece used with Plethysmograph and Diffusion capacity test
- Prepare the patient for any unusual and uncomfortable events, such as shutter closing or breath holding.
- In case of the Diffusion capacity meter it is possible to practice without inhaling the gas mixture.
- The basic pulmonary function test including forced expiration and vital capacity tests may take about 15 minutes
- A complex pulmonary function test including may take about 30 minutes

Connection between the patient and the device

The proper usage of the patient circuit is necessary for the accurate measurement

Nose clip

In order to avoid any nasal breathing during tests apply nose clip. Even at a good cooperation level there can be leakage thru nostrils without nose clip.

Of course at the measurements whit facial mask usage of the nose clip is senseless.

Mouth piece

The leakage free connection between the patient and the device is a key issue for the accurate measurements.

We provide the following options:

- MPA-30 Anatomically shaped mouthpiece, for the basic pulmonary function tests
- PMP-30 Mouthpiece with bite-on grip guarantees the perfect sealing for the most demanding tests like whole body Plethysmograph and diffusion capacity test
- PBF-100M-G Bacterial and viral filter with elliptic patient side

Measurement evaluation – Pulmonary function test

You can simultaneously perform and display max. 8 measurements.

Measurements deemed not appropriate can be deleted and a new one can be performed.

The system selects the best measurements based on different aspects for each measurement operating mode.

Sort order aspects

Forced Vital Capacity
Decreasing order based on **FVC+FEV*1.0** sum

Larger values are better

Inspiratory Vital Capacity
Decreasing order based on **IVC** value

Larger values are better

Hyperventilation
Decreasing order based on **MVV** value

Larger values are better

Rhinomanometry
Increasing order based on **RES [75]** value

Smaller values are better

Pairing

In case of the Rhinomanometer the two nostrils' resistance measurement may differ in time, so before storing them in the database the two sides' measurements must be paired.

The Rhinomanometer's measurement screen has a separate summary table for right and left nostril measurements.

The program automatically pairs the right and left nostril measurement pairs based on quality or measurement time.

Normal mode

In case of a simple measurement it is recommended to sort the measurements based on airway resistance.

PRE/POST

In case of comparison measurement it is recommended to sort the measurements based on measurement time, so the first right side measurement is paired with the first left side measurement.

Measurement selection

Measurement management requires the selection of individual measurements:

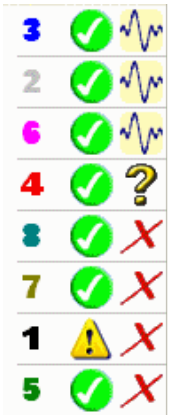
- Click on a single point on a curve with the mouse button

  or

- Click on the line in the summary table belonging to the curve.

The selected curve appears on the graph with a dotted line, the summary table's appropriate line is light blue.

Measurement selection for storage



All measurements are displayed in the measurement summary table

Colour of serial number is identical to the colour of the curve

There are two icons next to their number:

The first icon indicates the measurement's technical quality:

The measurement is technically correct.

The measurement is technically incorrect.

The second icon indicates the given measurement's status:

Visible curve

The measurement appears on the graph with a solid line.
The system can store and print the measurement.

Questionable curve

The measurement appears on the graph with a dashed line.
The system can store and print the measurement.
However, they are easily distinguishable on the graph for the user.

Turned off curve

The system does not store or print this measurement. Unlike when deleted, the curves can be displayed again at anytime.

Changing status:

- Select the measurement and the required curve will be dashed.
- Clicking on the selected line again will rotate the curve status.

Selecting the best measurement

Press the **[Best]** button to have the program automatically display the three best measurements and turn off the rest.

Press the **[All]** button to display all performed measurements.

Click the **[Report]** button to select just one from a couple of measurements. Only the selected curve will be visible all the others will be switched off.

Delete measurement

It is possible to delete measurements not already stored:

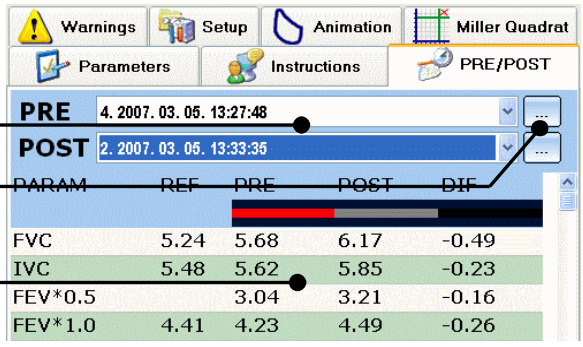
- Select the measurement and the required curve will be dashed.
- Press the **[Delete]** button.

Compilation of PRE/POST reports

Measurement selection

Quick keys

Parameter list



PRE/POST report compilation:

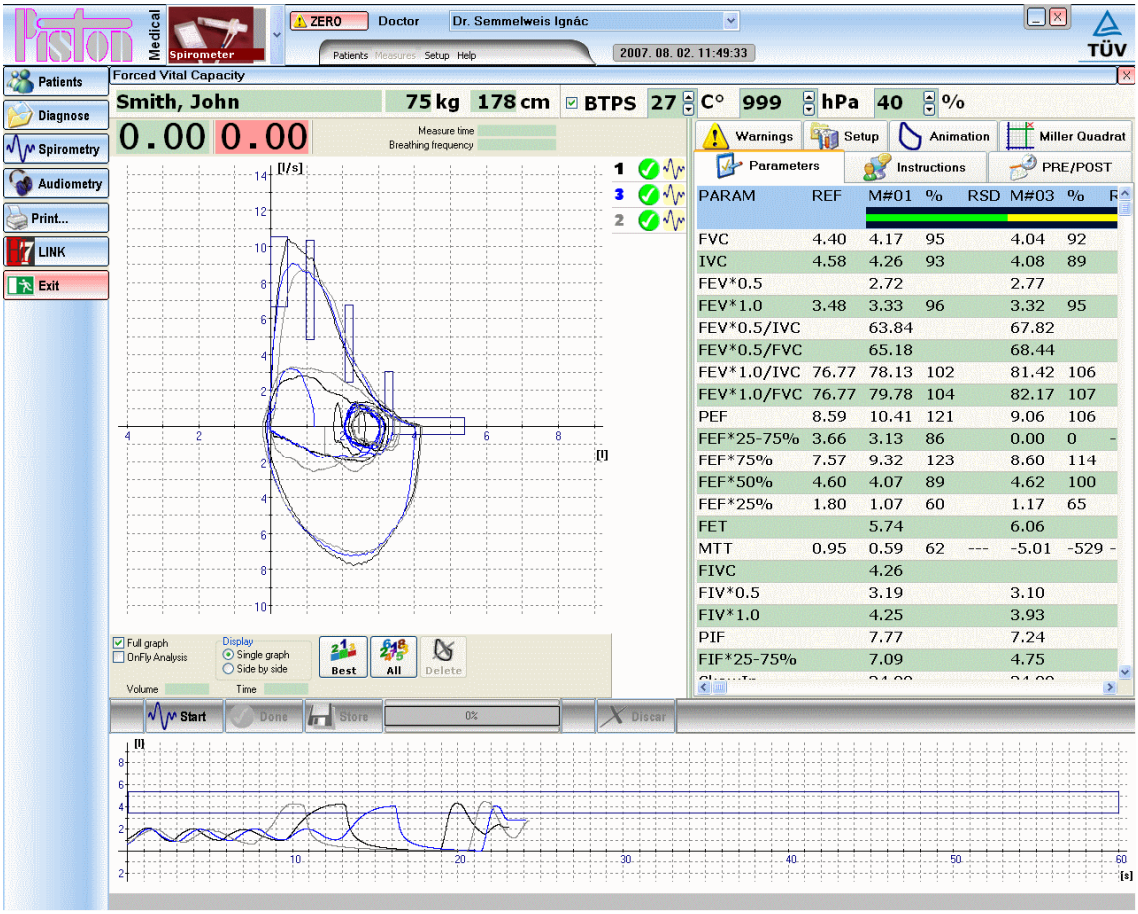
- Select the PRE/POST tab on the measurement window information panel
- Select the two measurements to compare from the measurement selection list
- You can also use the [Quick keys] to select the measurement, use the mouse to select the desired measurement – either from the summary table or directly on the graph
- Selecting the two curves automatically refreshes the parameter table.

Forced Vital Capacity

S R P D E

Measurement goal

The goal of the measurement is to get parameters of the volume forced expiration and inspiration



Measurement process

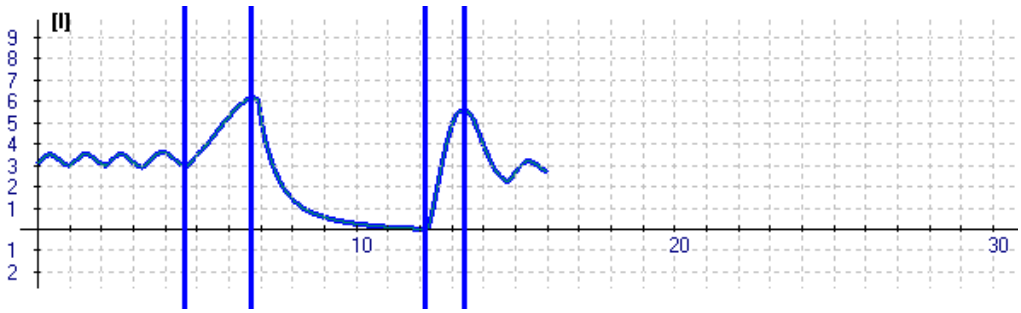
Instruct the patient to perform the following manoeuvres:

- Put on the nasal clip so he / she can only breath through the nose.
- Take at least three quiet breathings
- Take as deep as possible inspiration
- Take as fast and deep as possible expiration
- Take as fast and deep as possible inspiration

The patient has 60 second to perform the FVC manoeuvre

Push the **[Done]** button to stop the measurement.

Push the **[Discard]** button to delete the measurement.



Correct FVC manoeuvre
Phases: quiet breathing, deep inspiration, forced exhalation, forced inhalation, return to normal breathing.

Miller Quadrant

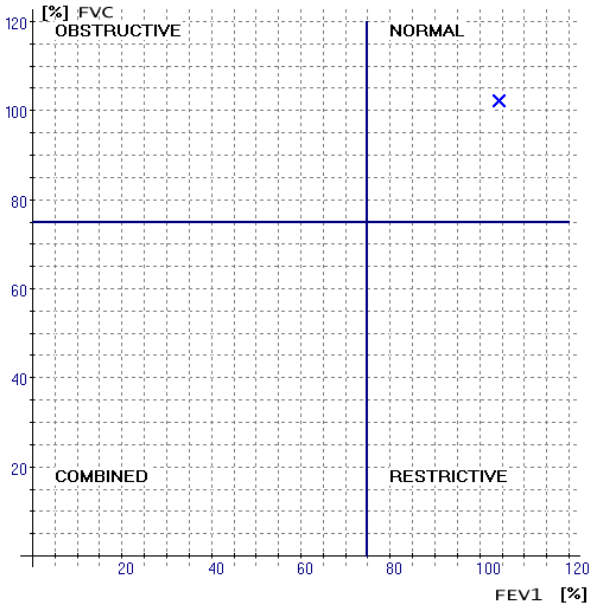
The Miller Quadrant an effective graphical tool which helps making the lung function diagnoses.

The vertical axle shows the ratio of FVC measured value and the reference value

The horizontal axle shows the ratio of FEV*1,0 measured value and the reference value

The diagram is divided into four quadrants:

- Normal
- Restrictive
- Obstructive
- Combined



Animation

Animation with blowing away dandelions helps with motivating children to reach their maximum effort during FVC manoeuvre

Inspiratory Vital Capacity

S R P D E

Measurement goal

The goal of the measurement is to get the parameters of the maximal inspiration.

Measurement process

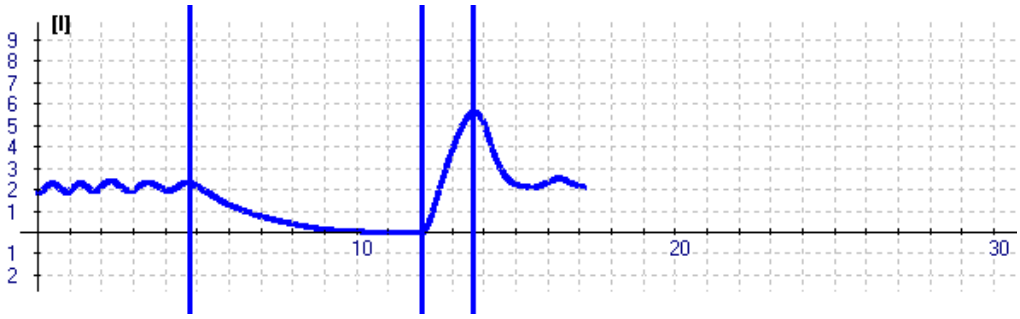
Instruct the patient to perform the following manoeuvres:

- Put on the nasal clip so he / she can only breath through the nose
- At least three quiet breaths
- As deep expiration as possible
- As deep inspiration as possible
- Optionally as deep expiration as possible to get the SVC (Slow Vital Capacity) parameter

The patient has 60 second to perform the IVC manoeuvre

Push the **[Done]** button to stop the measurement.

Push the **[Discard]** button to delete the measurement.



Correct ICV manoeuvre

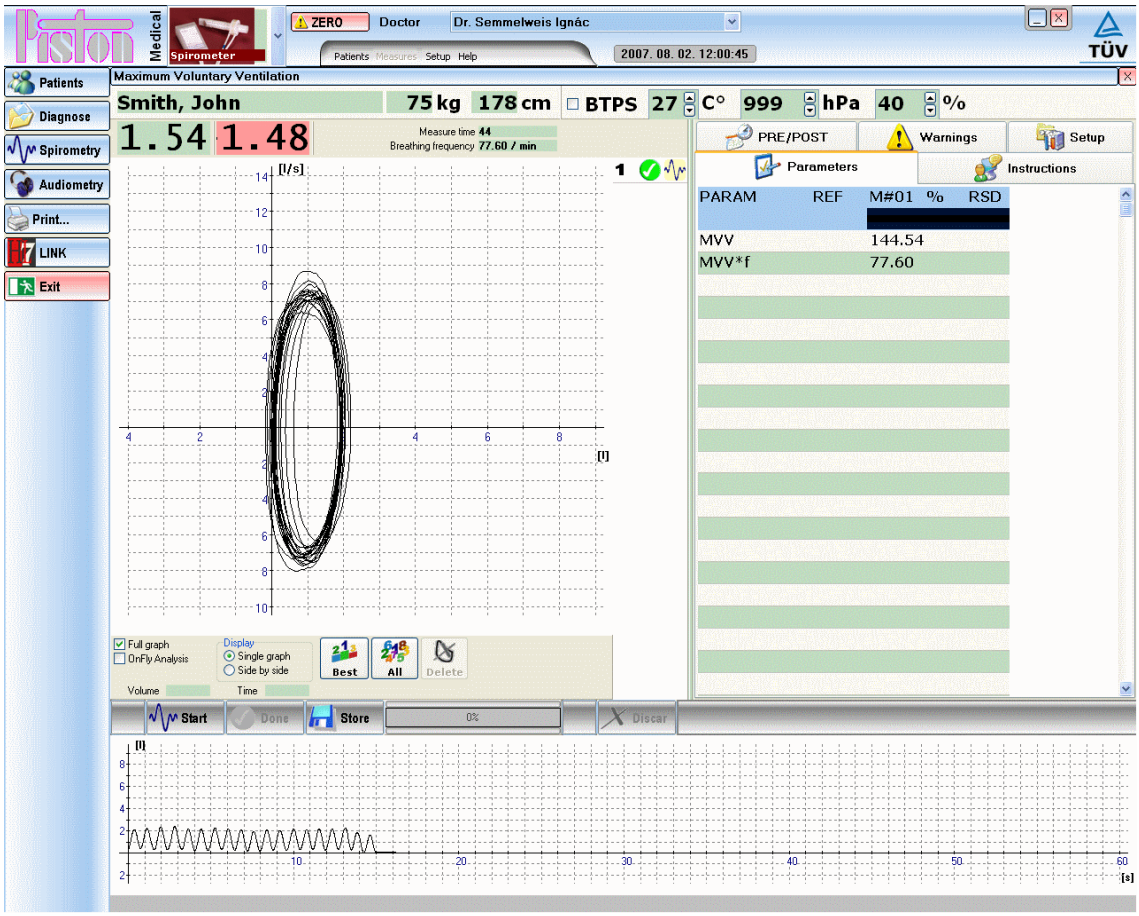
Phases: Quiet breathing, complete deep expiration, complete deep inspiration, return to normal breathing.

Maximal voluntary ventilation

S R P D E

Measurement goal

The goal of the measurement is to get the amount of volume the patient can move in a given time.



Measurement process

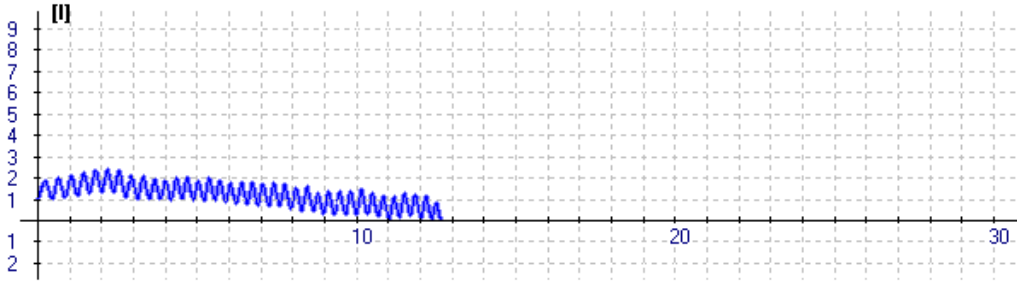
Instruct the patient to perform the following manoeuvres:

- Put on the nose clip so he / she can only breath through the nose.
- Move as much air as possible.
- The patient can choose the breath frequency as convenient
- To prevent hypocapnia it is not recommended to continue this measurement for more than 15 seconds.

The patient has 60 seconds to perform MVV manoeuvre.

Push the **[Done]** button to stop the measurement.

Push the **[Discard]** button to delete the measurement.



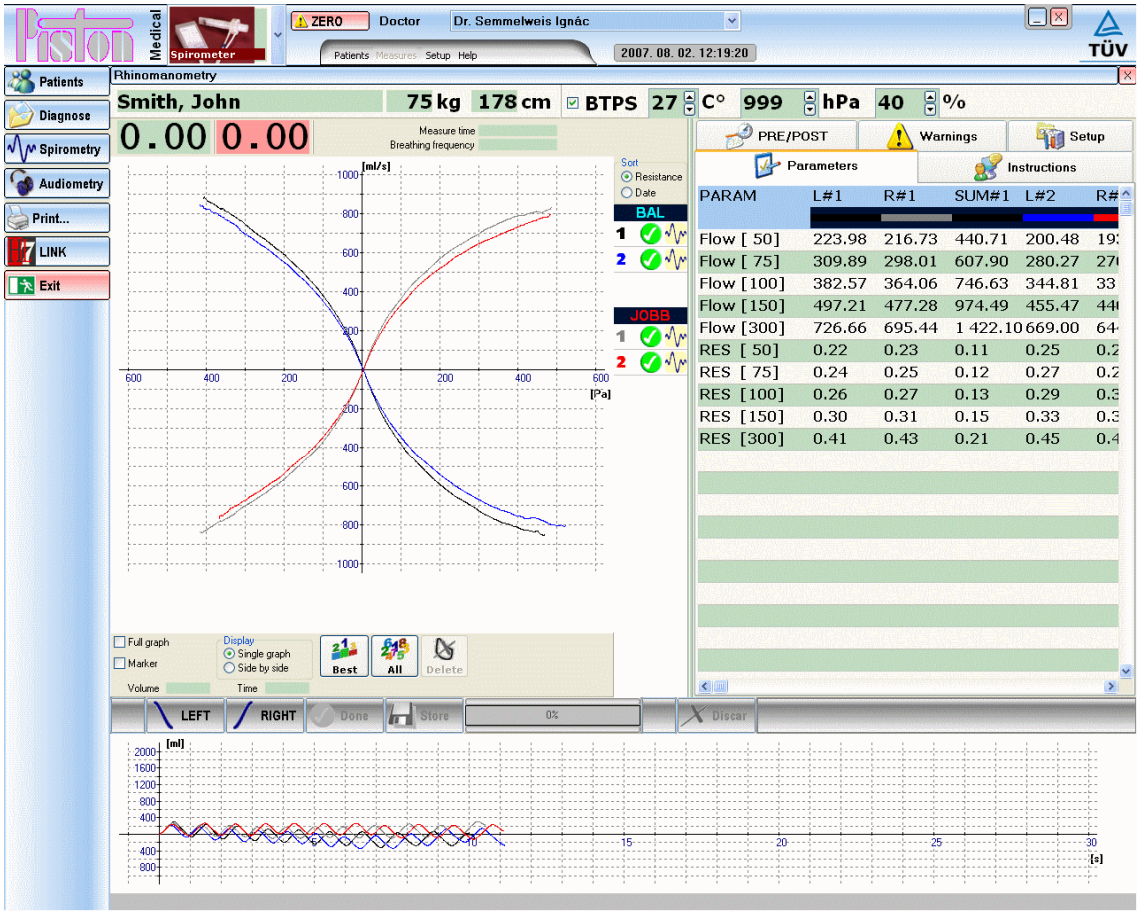
Correct MVV measurement
The patient breaths quickly, evenly during the measurement.

Rhinomanometry

R P D

Measurement goal

The goal of the measurement is to get the patient's nasal airway resistance.



Measurement process

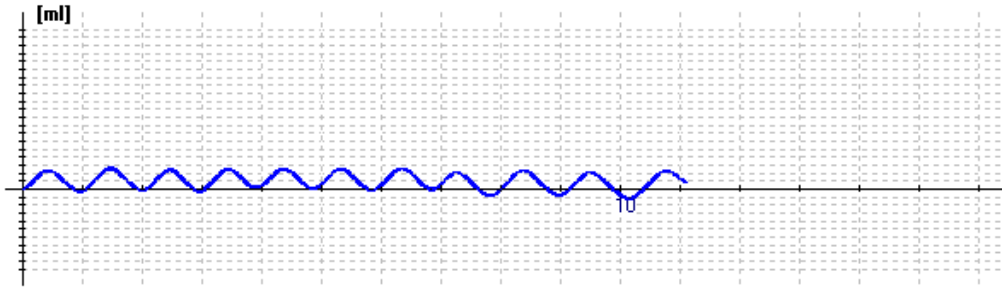
The following series of manoeuvres must be performed:

- The patient must clean the nasal canals
- Place the appropriate size nasal plug into the side opposite the measured one
  So if you would like to measure the resistance of the right nasal canal, place the nasal plug into the left nostril, and vice versa
- Have the patient hold the appropriate size facial mask against his / her face to prevent leaking
- The patient can only breathe through the free nostril, not through the mouth

The patient has 60 second to perform the manoeuvres, but usually a few even respiratory cycles are enough.

Push the **[Done]** button to stop the measurement.

Push the **[Discard]** button to delete the measurement.



Correct Rhinomanometry measurement
The patient breathes relaxed during the measurement.

Selecting the loop curve

The system records several respiratory cycles during the measurement and by default displays their average.
However, you have the option to view the curves one-by-one:

- Select the measurement you would like to modify from the measurement summary table
- Click with the mouse on the spirogram – the marker jumps to the next cycle
- The system automatically recalculates the parameters

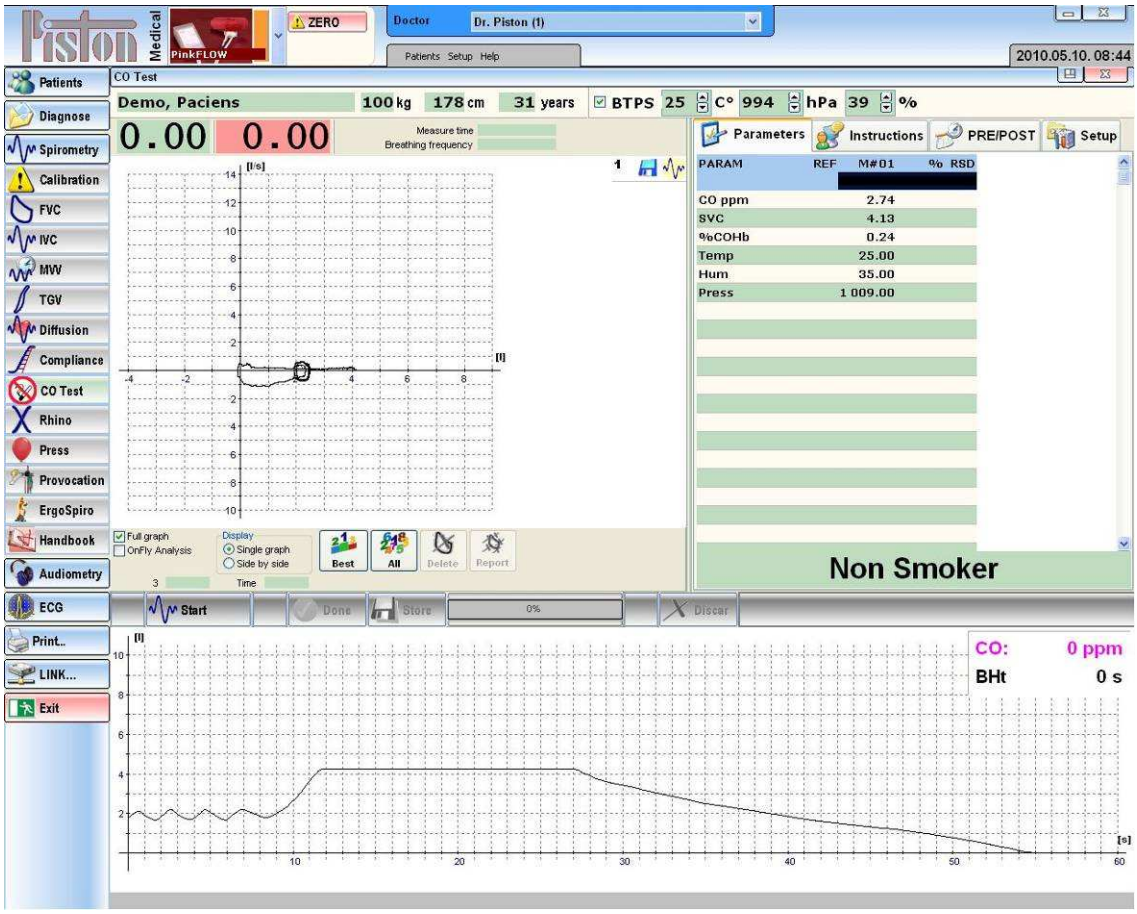
Breath carbon monoxide monitoring

P D

Measurement goal

The goal of the measurement to follow up the smoking habits of the patient and assist the smoking cessation program.

Attention
Avoid measuring patients whose exhalation may content alcohol because the CO sensor of the device may get wrong



Measurement process

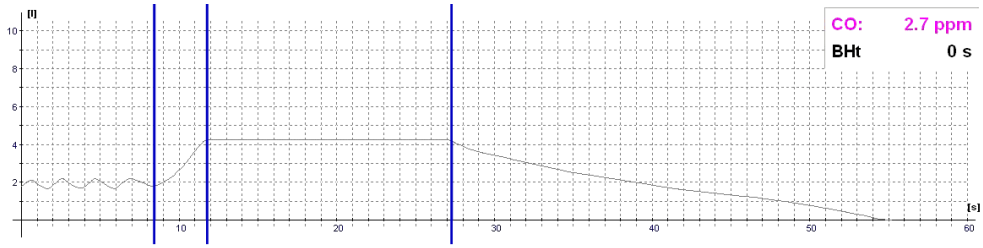
The following series of manoeuvres must be performed:

- Place the Nasal clip to avoid the breathing thru the nostrils
- Perform at least 3 quiet breathings
- Breath hold et least for 10 seconds
- Slow and even full expiration

The patient has 60 second to perform the manoeuvres.

Push the **[Done]** button to stop the measurement.

Push the **[Discard]** button to delete the measurement.



Correct Breath CO measurement
Phases: Quiet breathing, complete deep inspiration, breath holding, complete slow expiration

Evaluation of the results

The following evaluations are given by the system after the measurement:

- Non Smoker
- High value for non-smoker
- Smoker
- Frequent smoker
- Addicted smoker
- Heavily addicted smoker
- Dangerously addicted smoker

Device maintenance

Our lung diagnostics devices do not require special maintenance. For continuous reliable operation take care of the following:

- To prevent device contamination and patient cross-contamination, use a new disposable bacterial and viral filter for all patient measurements
- The flow sensor must be contamination free
- The filter elements must be replaced according to instructions
- The tubes must always be dry and cannot be broken

Flow meter maintenance

The flow meter condition and cleanliness affects measurement accuracy.

Cleaning measurement head main parts

The individual patient circuit type installations are described in section Installation.

The plastic parts may be disinfected with cold water and appropriate chemicals (for example, Sekusept), and may be used after rinsing and drying.

Cleaning the flow meter

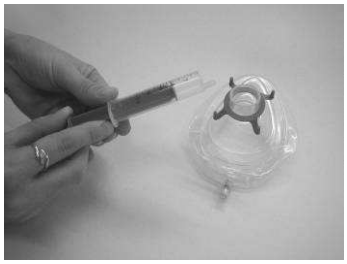
- Disconnect the PinkFlow flow meter from the docker
- Clean the flow meter in a cold disinfecting solvent
- After it is completely dried, reassemble the flow meter

Cleaning the pneumatic twin-tubes

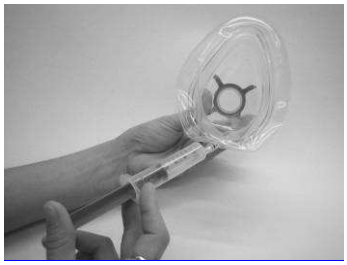
- Disconnect the twin-tube from the device and the flow meter
- Rinse the tube
- After it is completely dried, reconnect the tube

Facial mask maintenance

The facial mask's pneumatic cushion may deflate with time. For appropriate fitting the escaped air must be replaced



Fill a LUER cone-shaped syringe with air



Fit the syringe into the facial mask valve opening, push it in all the way to open the valve. Push the air in

Repeat the previous two steps until the facial mask is properly inflated. Never over inflate as it will not properly fit the face

Breath CO monitor maintenance

The expected life time of the CO sensor is 2 years.

For replacement of CO sensor please contact the local responsible of the Manufacturer!

Single-use parts

It is strictly prohibited to clean and/or reuse the single-use parts

Bacterial and viral filter PBF-100-G and PBF-100M-G

The used bacterial and viral filters are considered to be dangerous waste materials please handle accordingly.

Reusable parts and accessories

The following plastic parts can be cleaned in a cold disinfecting water-based solution (for example: Glutaraldehyde, Sekusept, Cidex e.t.c.)

Type	Description	Material
PPF-18	PinkFlow flow meter	Polystyrol
MPA-30	Mouthpiece	Polypropylene
PMP-30	Mouthpiece with bite-on grip	Thermoplastic elastomer

Some discoloration may occur to the plastic parts after frequent disinfection.

Possible problems

Spirometry		
Problem	**Diagnosis**	**Solution**
During quiet breathing the Volume(time) curve drifts up or down	After several quiet breaths have the patient remove the mouthpiece The program continues to display the curve. Watch the spirogram for at least 10 seconds	Set Zero again and repeat the measurement. Check that liquid did not get into the flow sensor or the twin-tube leading to it.
The measured values deviate from expected to a considerable extent	The device has to be recalibrated Environmental data must be checked	If the situation does not get better even after recalibration, clean the pneumatic twin tubes and check the flow sensor according to Flow meter maintenance (page 39.) section
Rhinomanometer		
The resistance curves are too steep	The pressure meter's or the nasal plug's pneumatic tube is not connected appropriately, it maybe punctured	Check the pressure tubes The nasal plug, the filter, or the pressure release tube is clogged
The resistance curves are too flat	The device measures the drive pressure to be too high	Check the pressure tubes The nasal plug, the filter, or the pressure release tube is clogged

Warranty

The device complies with the effective Technical Specifications.

The manufacturer guarantees the product according to the terms of the Installation/Delivery protocol.

The warranty does not cover post-delivery careless shipping, unprofessional storage, violent damaging, abnormal operation, unprofessional operation, inefficient protection against external effects, natural disasters, or not following the contents of the User Manual.

Check package condition after delivery.
If packaging is damaged, notify the carrier and Piston Ltd., or its representative.

Use of any broken or otherwise damaged products (devices, accessories etc) is dangerous and forbidden!

Limited liability

Piston Ltd. and its carriers, according to the valid laws, do not accept any responsibility for any individual, unforeseeable, direct or indirect damages (including loss of business profit, interruption of business activity, loss of business data, or any other damages due to financial loss), resulting from the use or non-usefulness of the product.

Safety instructions

To avoid possible damages and accidents, please pay attention to the following safety instructions:

- Make sure the mains voltage is the same as that on the product label
- Make sure the connection cable is not damaged
- Take care of your device according to the maintenance section
- Only use the device according to the manual
- Do not use any accessories not recommended for the device
- Store the device in a dry place
- Keep the cable away from heat source, sharp objects, rough surfaces and check the cable's good condition
- Do not expose the device to direct sunlight or strong light (more than 1500 lux)
- Do not use the device in a highly dusty environment
- Do not use the device in a highly vibrating environment
- Take care to ensure the current environmental conditions

The equipment complies with the applicable requirements of laws and standards.

Shipping conditions

Air temperature: ..... -30 °C ÷ +60 °C
Relative humidity: ..... 10% ÷ 100%
Atmospheric pressure: ..... 500 ÷ 1060 mbar

Storage conditions

Air temperature: ..... 0 °C ÷ +50 °C
Relative humidity: ..... 10% ÷ 85%
Atmospheric pressure: ..... 500 ÷ 1060 mbar

Operating conditions

Air temperature: ..... +10 °C ÷ +40 °C
Relative humidity: ..... 30% ÷ 75%
Atmospheric pressure: ..... 700 ÷ 1060 mbar

Informing values

Expected lifetime

Devices ..... 8 years
Measurement head lifetime ..... 2 years

Forced inhalation and exhalation

Measurement duration ..... 60 s
Volume measurement limit ..... 15 l

Vital capacity measurement

Measurement duration ..... 60 s
Volume measurement limit ..... 15 l

Maximal voluntary ventilation

Measurement duration ..... 60 s
Volume measurement limit ..... 250 l/min

Sampling frequency

PDD-301 device family ..... 250 Hz

Other data

Analog-digital converter resolution ..... 16 bit

Electrical data

The connected computer's and printer's electrical data is found in the respective manufacturer provided specifications.

The following values apply only to the Piston Ltd. manufactured devices:

PDD-301/sh – Spirometer

PC connection .....USB 1.1
Power..... Does not require external power

PDD-301/r –Rhinomanometer

PC connection .....USB 1.1
Power..... Does not require external power

PDD-301/sco and PDD-301/rco – Breath CO monitor

PC connection .....USB 1.1
Power..... Does not require external power

Mechanical data

PDD-301/sh – Spirometer

Flow meter ..... PPF-18 PinkFlow
Dimensions..... H 150 * W 82 * D 45 mm
Weight .....255 g

PDD-301/r – Rhinomanometer

Flow meter ..... PPF-18 PinkFlow
Dimensions..... H 150 * W 82 * D 45 mm
Weight .....210 g

PDD-301/sco and PDD-301/rco – Breath CO monitor

Flow meter ..... PPF-18 PinkFlow
Dimensions.....H 185 * W 140 * M 60 mm
Weight .....650 g

Guaranteed values

PPF-18 – PinkFlow flow meter

Type ..... PPF-18 PinkFlow
Principle of operation ..... Symmetric Pitot tube
Flow range.....±18 l/s
Dead space ..... 36 ml
Resistance..... 60 Pa/l/s @ 15 l/s
Weight .....34 g

PDD-301 – Spirometer and Rhinomanometer

Flow meter ..... PPF-18 PinkFlow
Flow measurement range .....±18 l/s
Flow measurement accuracy.....±2% or ±10 ml/s

Flow measurement resolution ..... 10 ml/s
Linearity ..... ±2%
Volume measurement range ..... ±20 l
Volume measurement accuracy ..... ±2% or ±10 ml
Volume measurement resolution ..... 10 ml

PDD-301/r – Rhinomanometer

Flow meter ..... PPF-18 PinkFlow
Pressure measurement range ..... ±2 kPa
Pressure measurement accuracy ..... ±3% or ±15 Pa
Resistance measurement accuracy ..... ±3% or ±30 Pa/l/s

PDD-301/sco – Breath CO monitor and spirometer

Accuracy of CO measurement ..... ±2% or ±2 ppm
All other measurement parameters are the same as of the PDD-301/sh spirometer

PDD-301/rco – Breath CO monitor and Rhinomanometer

Accuracy of CO measurement ..... ±2% or ±2 ppm
All other measurement parameters are the same as of the PDD-301/r rhinomanometer

List of accessories

Included accessories

The current Shipping contract contains the list of accessories included in the purchase price.

Optionally purchased accessories

The following information must be provided when ordering accessories and disposables:

- Description
- Type
- Part number
- Device type and serial number for which the accessories are used

EMC GUIDANCE AND MANUFACTURER'S DECLARATION

Guidance and manufacturer's declaration – electromagnetic emissions

The **PDD 301/r** Rhinomanometer (particular implementation **PDD 301/s** Spirometer) is intended for use in the electromagnetic environment specified below. The customer or the user of the **PDD 301/r** Rhinomanometer should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The **PDD 301/r** Rhinomanometer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The **PDD 301/r** Rhinomanometer is suitable for use in all establishments, including domestic establishments and those directly connected to the public lowvoltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity

The **PDD 301/r** Rhinomanometer (particular implementation **PDD 301/s** Spirometer) is intended for use in the electromagnetic environment specified below. The customer or the user of **PDD 301/r** Rhinomanometer should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance Level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	**Not applicable**	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	**Not applicable**	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	**<5 % U_T** (>95 % dip in U_T) for 0,5 cycle **40 % U_T** (60 % dip in U_T) for 5 cycles **70 % U_T** (30 % dip in U_T) for 25 cycles **<5 % U_T** (>95 % dip in U_T) for 5 s	**Not applicable**	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **PDD 301/r** Rhinomanometer requires continued operation during power mains interruptions, it is recommended that the **PDD 301/r** Rhinomanometer be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

Guidance and manufacturer's declaration – electromagnetic immunity

The **PDD 301/r** Rhinomanometer (particular implementation **PDD 301/s** Spirometer) is intended for use in the electromagnetic environment specified below. The customer or the user of the **PDD 301/r** Rhinomanometer should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 V_{rms} 0,15-80 MHz	3 V_{rms} 0,15-80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the **PDD 301/r** Rhinomanometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1{,}17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2,5GHz	3 V/m 80MHz – 2,5GHz	$d = 1{,}17\sqrt{P}$ *80 MHz to 800 MHz* $d = 2{,}33\sqrt{P}$ *800 MHz to 2,5 GHz* where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **PDD 301/r** Rhinomanometer is used exceeds the applicable RF compliance level above, the **PDD 301/r** Rhinomanometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **PDD 301/r** Rhinomanometer.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the PDD 301/r Rhinomanometer

The **PDD 301/r** Rhinomanometer (particular implementation **PDD 301/s** Spirometer)is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of **PDD 301/r** Rhinomanometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **PDD 301/r** Rhinomanometer as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter** **m**		
	150 kHz – 80 MHz $d = 1{,}17\sqrt{P}$	**80 MHz – 800 MHz** $d = 1{,}17\sqrt{P}$	**800 MHz – 2,5 GHz** $d = 2{,}33\sqrt{P}$
0,01	0,12	0,12	0,24
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,7	3,7	7,38
100	11,7	11,7	23,33

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

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

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

e

ES

Ergospirometry

Supported devices

PRE-101 Ergospirometer

Piston Ltd.
1033 Budapest, Szőlőkert u. 4/b

CE 1979

Rev.: ES-EN-04.00

Date modified: 04/07/2012

TABLE OF CONTENT

Devices

PRE-101 Ergospirometer

Measurement operating modes

- Forced inspiration and expiration
- Static vital capacity
- Maximum voluntary ventilation
- Resting ECG
- Ergometry
- Ergospirometry + EKG
- Resting Energy Expenditure (REE)

Design

- Flow meter: PPF-18 PinkFlow, symmetric Pitot tube
- Fast O_2 and CO_2 gas analyzer
- USB computer connection
- PC cart, 2 twin-monitor design
- Isolation transformer (optional)
- Calibration gas mixture: 16% O_2 and 5% CO_2
- Loading devices (optional): bicycle ergometer or treadmill

Technical overview

Lung diagnostic device family main parts description:

Flow meter

PPF-18 PinkFlow, symmetric Pitot tube flow meter, which provides pressure difference in proportion with the flow speed.

A differentiate pressure sensor converts the pressure difference to electric signal.

Patient circuit

The patient circuit provides the connection between the patient and the equipment it consists of the following units:

- PinkFlow flow meter
- Facial mask and headgear

Gas analyzer

The patient's exhaled has mixture must be sampled and analyzed to determine oxygen consumption and CO_2 production.

Elements of the gas calibration line

- High pressure gas cylinder with the calibration gas mixture

- Pressure regulator
- Main valve
- Safety vale with pressure limitation

Elements of the gas analysis:

- Gas sampling capillary
- PermaPure moisture exchange capillary to provide normalized humidity for the gas analyzers
- Gas sampling pump
- O_2 and CO_2 sensors

Oxygen sensor

- Chemical cell ultra fast oxygen sensor
- Paramagnetic (non-depleting) oxygen sensor - optional

Carbon dioxide sensor

- NDIR (Non Dispersive Infra Red) fast gas analyzer

Environment status measurement module PRE-101

BTPS correction requires the measurement of the following environmental data:

- Environment temperature
- Environment relative humidity
- Atmospheric pressure

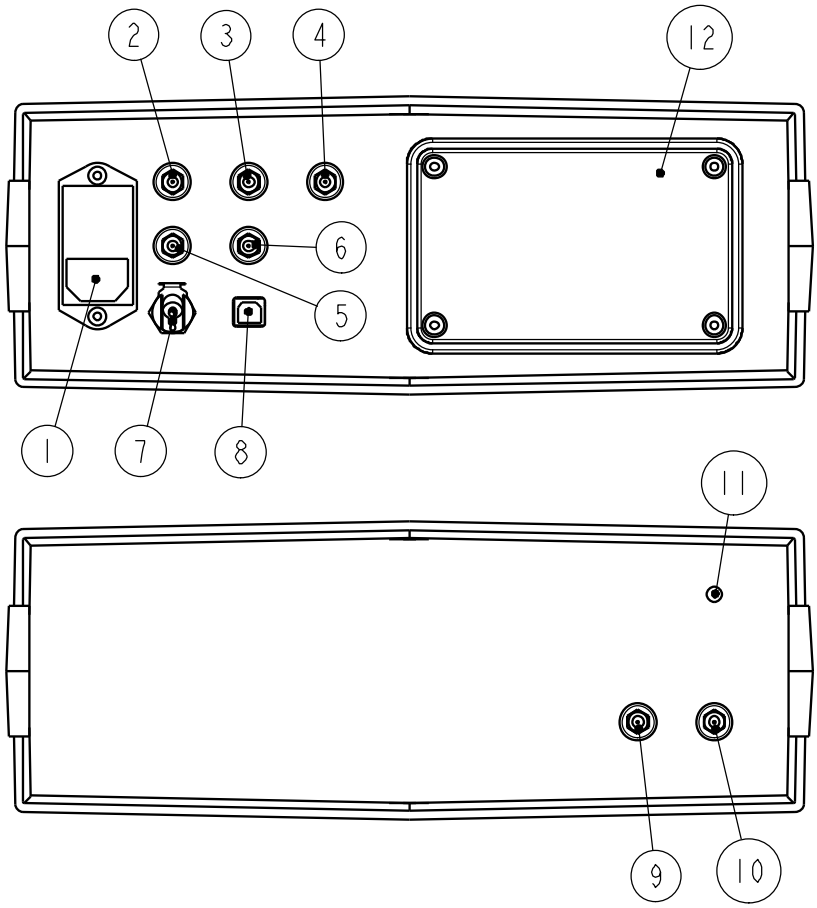
Power supply PRE-101

Medical design switching power supply, which enables operating the device from any mains voltage:

- Mains voltage: 90~264 VAC
- Mains frequency: 50~60 Hz

PRE-101 Ergospirometer installation

E



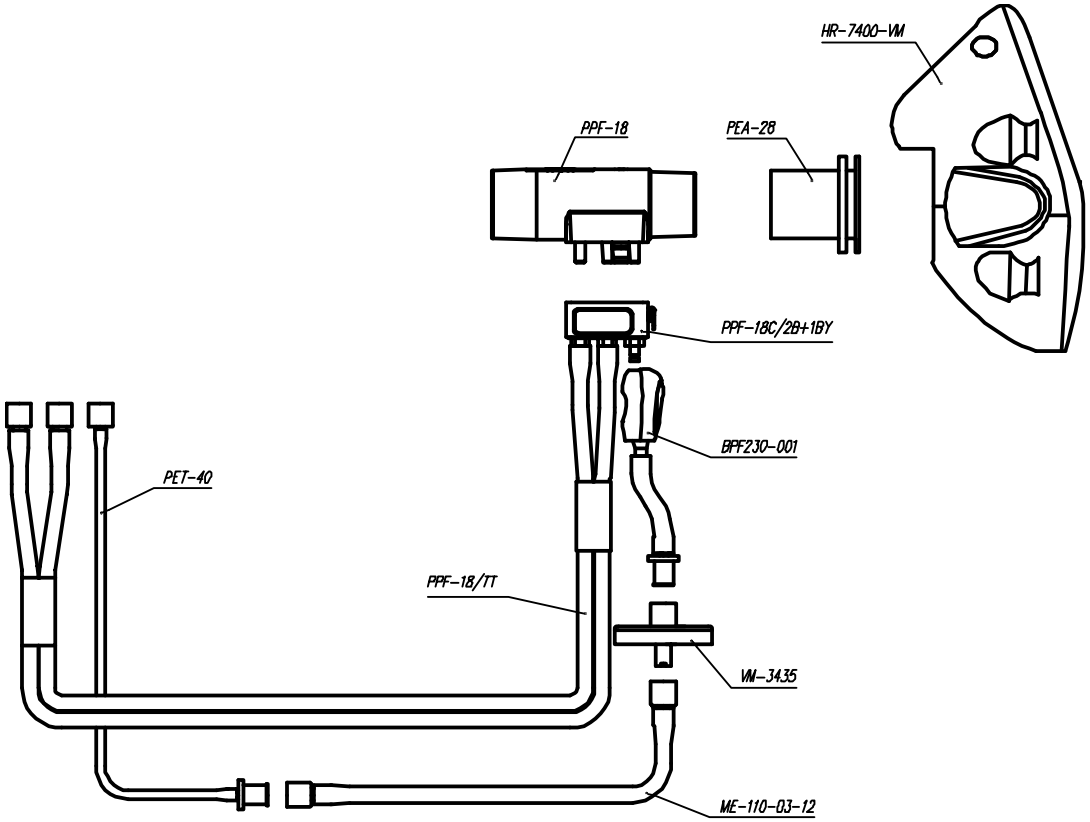
№	Colour	Description	Connection
1.		Mains socket	Mains cable
2.	White	Flow meter	Flow meter docker white connector
3.	Blue	Flow meter	Flow meter docker blue connector
4.	Yellow	Gas sampling port	Flow meter docker yellow connec-tor
5.		Exhaust output of the calibrating gas	Never block!
6.		Exhaust output of the gas sample	Never block!
7.		Quick pneumatic connector of the calibrating gas	High pressure hose from the gas cylinder
8.		USB port of the ergospirometer	USB cable to the PC
9.	(optional*)	USB port of the built-in ECG	USB cable to the PC
10.	(optional*)	USB port of the built-in pulse oxi-meter	Built-in pulse oximeter of the ECG
11.	(optional*)	Patient cable connector of ECG	ECG patient cable

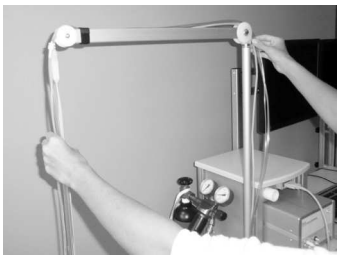
12.	White	Intake port of the ambient air	Never block!
13.	Black	Outlet of the calibrating gas	Quick pneumatic connector of the gas sampling line
14.	Green	LED indicating the data transfer	

Connect the power and data cables and the pneumatic connectors of the patient circuit to the device according to the different connector types and colour codes!

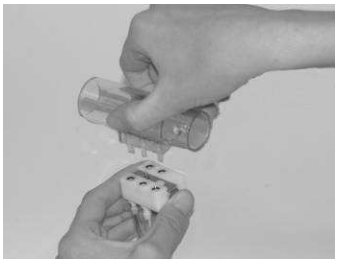
PRE-101 Ergospirometer patient circuit assemble

E

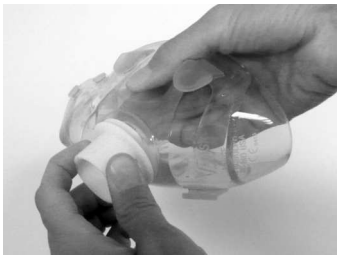




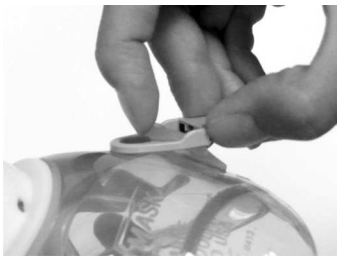
Place the ECG cables and the tubing of the patient circuit on the electrode holder arm.
Adjust the length of the cable and tubing and afterwards fasten it.
Take care about the smooth run of the tubing avoid any sharp bend or break.



Connect the flow meter docker to a clean PinkFlow flow meter.
Push the metal release button to remove the PinkFlow flow meter from the docker.

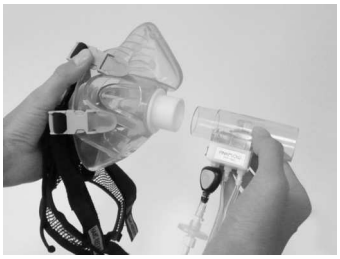


Button the white adapter ring up the facial mask



Button the headgear buckle up the facial mask

Connect facial mask to the headgear



Push the smaller diameter side of the PinkFlow flow meter into the white adapter ring

Ergospirometer placement

E

There are numerous criteria of the ergospirometer placement:

Environmental requirements:

- The equipment can be used only in a well ventilated laboratory.
  If the laboratory has no natural ventilation for example there is no any open able window the equipment can be used only where an air exchanger installed and it guarantees open air quality of the internal air.
  O_2 concentration: 20.93%
  CO_2 maximal concentration: 400 ppm (STPD)
- Avoid one meter proximity of any heat or cold radiating objects, like heating, cooling, window etc.
- Provide stable temperature in the laboratory avoid any fast change of the temperature.

Safety requirements

All conditions of the resuscitation have to be provided both human and material ones:

- Cardiologist and professional assistant
- Defibrillator
- Treatment bed in one meter proximity

Conformity feeling of the patient

- The patient has to be far from the outlet of the air-conditioning avoiding any air drafts since the patient's body overheats because of the exercise and could catch a cold easily.
- Locker and shower
- Relax room

Gas cylinder connection to the Ergospirometer

E

Place the gas cylinder to the PC cart and fasten it with the belt

Regularly change the sealing ring of the gas cylinder
Connect the pressure regulator to the gas cylinder

Connect the high pressure hose to the quick pneumatic connector of the device

Open the main valve of the gas cylinder and set the secondary pressure to 1 bar

Caution!
As the gas calibration is completed always close the main valve of the gas cylinder

Settings

Ergospirometer

E

Select the **Ergospirometer** group in the Setup/Options/Devices menu

Bicycle ergometer
Selection of the bicycle ergometer type if any connected

Treadmill
Selection of the treadmill type if any connected

Blood Pressure monitor
Available options:

- Manual BP measurement
- Ergometer type – if the loading device has a built-in blood pressure meter
- Selection of any other standalone blood pressure meter if any connected

Fitness interpretation
Fitness interpretation evaluation is based on the maximal oxygen consumption. There are two algorithms to select:

- American Heart Association, 1972
- Cooper Institute for Aerobics Research, 1997

BMR prediction
Basal Metabolic Rate.
There are two algorithms for calculation of reference value of the reseting metabolic rate:

- Mifflin - St Jeor Equation, 1990
- Harris - Benedict Equation, 1919

O2 concentration
Oxygen concentration specified in the certificate of the gas refilling company

CO2 concentration
Carbon dioxide concentration specified in the certificate of the gas refilling company

Use filter for VO2 and VCO2Use filter for VO2 and VCO2
Enabling the averaging filters for VO2 and VCO2 calculations. It is advisable to enable these filter during Steady state and Mixing chamber measurements.

FVC loop on main screen
The median value of breathing can be monitored on the FVC panel. This graph can be moved into the main window to substitute the spirogram.

Parameter columns
The number of columns of the displayed parameters during the measurement can be specified.

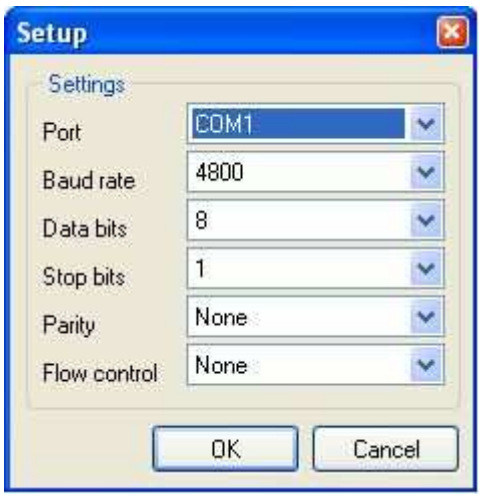
Log time interval
Time interval of the registration into the log file

Mixing Chamber
Select this option if a Mixing chamber is in use

Bicycle Port setup...

Treadmill Port setup...

BP monitor Port setup...
Settings of the communication ports of different connected devices



Select the appropriate PC port where the loading equipment is connected

All the other settings should be set according to the specification of the loading equipment.

Some settings will be automatically overridden according to the selected loading equipment.

Bicycle Ergometer and treadmill protocols
Editing and modifying protocols are possible in the Ergospirometry measuring window. The detailed description can be found in the Ergospirometry chapter.

Icons

Ergospirometry


Settings


Protocol editor


Predicted values and results


Actual test


Breath median


Diary


Test interpretation, Wasserman graphs


Templates – Enter new item


Templates – Edit items


Templates – Store edited item


Templates – Delete selected item
Templates – Abandon modifications

User interface - Ergospirometry

The following image shows the general design of the measurement screen. The individual measurement windows may different from each other but the main controls are identical.

Device selector

Zero setting

Menu

Navigator

Patient data

BTPS data

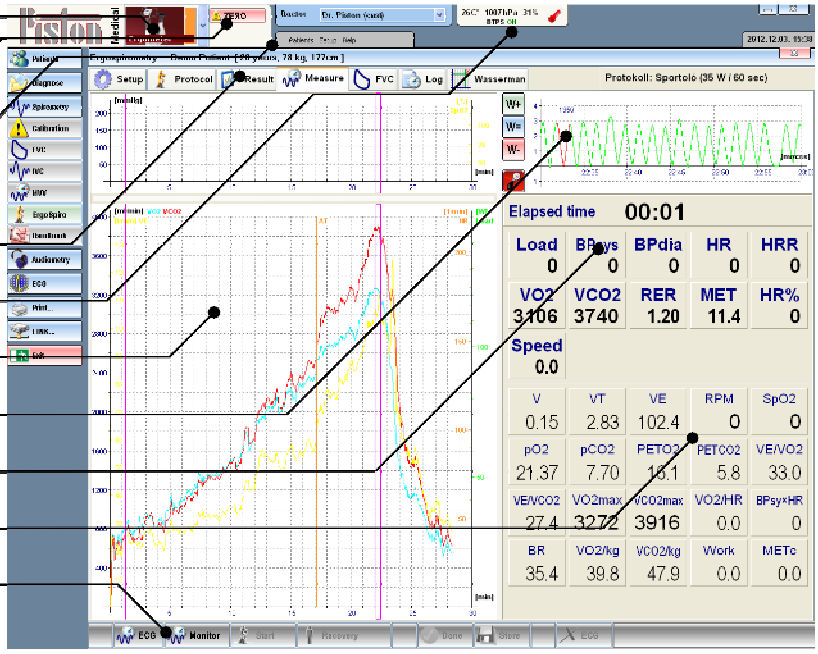
Complex curves

Spirogram

Timer

Parameters

Control



Device selector

Select the device to be used from the drop down list.
This is necessary if, for example, you own a Plethysmograph and a Spirometer, and would like to perform IVC measurement.

Zero setting

Runs manual Zero setting of the selected device
Without manual Zero setting the system automatically sets zero before all measurements

Menu

The program's general main menu, which contains the grouped basic functions.

Navigator

Control buttons which organise the basic phases of daily routine.

Patient data

Contains the most important measurement data for the patient selected from the database.

BTPS data
Usually our ergospirometer is equipped with the ambient module which measures the ambient temperature, humidity and pressure. These ambient data are shown in BTPS fields.

If there is no ambient module connected you may enter the ambient data manually

Overview histrogram
Graphical interpretation of the most iprotant parameters like: VO2, VCO2, VE, Load, Heart rate, Blodd pressure, Saturation

Spirogram
Volume-time graph which monitors the breathing of the patient

Timer
May show the duration of the total test or the duration of the individual load steps or countdowns the time

Control
These control buttons organise basic phases of daily routine as follws:

- Start monitoring **[F3]**
- Start measurement, beginning of the protocol **[F4]**
- Cooling down phase
- End of measurement **[F5]**
- Store and print

After turning the device on and entering the BTPS data, calibration is recommended for maximum measurement accuracy.

Calibration is recommended when starting a new shift, after flow sensor disinfections or replacement.

IMPORTANT

If work environment conditions (temperature, air pressure, humidity) change significantly, re-calibration is recommended.

Flow meter calibration

Please make the calibration of the flow meter according to the "Spirometry" volume of this manual.

Ergospirometer calibration

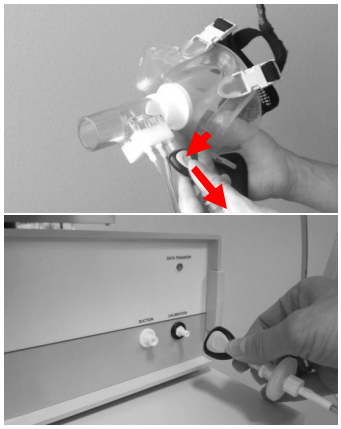
E

Ergospirometer calibration is performed in the Spirometry/Calibration menu.

In case of several connected devices, select **Ergospirometer** from the **[Device selection]** list.

Prior to the calibration of the gas analyzers make the following steps:

- Open the main valve of the gas cylinder
- Check the secondary pressure the nominal value is 1 bar
- Disconnect the gas sampling line from the PinkFlow docker and connect it to the Calibration gas output on the device
  The gas sampling line has a quick action connector.
  For release the grey button has to be pushed and for connection it is enough to push till clicks



The calibration of the gas analyzers is done automatically in the background during the zeroing of the flow channel.

Calibration Error 1: Gas plug not connected!

In this case the connections of gas sampling line has to be checked.

Calibration Error 2: Calibration constant out of range!

Calibration Error 3: Oxygen sensor used up!

If the calibration is not accepted by the system repeat the whole procedure. If the error message appears again contact your local dealer.

Calibration Error 4: Room's air used up. Ventilate it as well as possible!

Thoroughly ventilate the laboratory and repeat the whole calibration procedure.

Available examinations

The ergospirometer system provides the following basic lung function tests:

- Forced exhalation and inhalation
- Static vital capacity
- Hyperventilation

For detailed description please refer to the “Spirometry” volume of this manual.

Ergospirometry

Cardiopulmonary exercise testing provides a global assessment of the integrative exercise responses involving the pulmonary and cardiovascular system.

Detailed information may be found in the Measurement modes chapter.

Safety precautions

- The Ergospirometer can be used only by a trained and authorized personnel
- A cardiologist has to supervise the whole exercise test procedure
- Prior to the exercise test always get know the detailed anamnesis of the patient
- The personal and the material conditions of the resuscitations has to be provided

In this operating mode the device measures the following parameters:

V **Volume**
Actual inspiration volume

VT **Tidal Volume**
Tidal volume during quiet breathing

VE **Minute ventilation**
Total volume of the breathing during one minute

Load **Load**
Actual load setting of the bike ergometer

Calculated load of the treadmill based on the oxygen consumption

RPM **Pedal revolutions**
Actual pedal revolution of the bike ergometer

BPsys, BPdia **Blood pressure**
Last values of the blood pressure

HR **Heart rate**
Actual heart rate

HRR **Residual pulse**
Difference of the maximal predicted heart rate based on the age and the actual heart rate

HR% **Percentage of the heart rate**
Percentage of the actual heart rate to the maximal predicted heart rate based on the age

SpO2 **Saturation**
Oxygen saturation of the blood

pO2 **Momentary O_2 concentration**
Momentary oxygen concentration

pCO2 **Momentary CO_2 concentration**
Momentary carbon dioxide concentration

VO2 **Momentary O_2 consumption**
Momentary oxygen consumption, ml/m

VCO2 **Momentary CO_2 production**
Momentary carbon dioxide production, ml/m

PETO2 **O_2 concentration at the end of expiration**
Oxygen concentration at the end of expiration

PETCO2 **CO_2 concentration at the end of expiration**
Carbon dioxide concentration at the end of expiration

VE/VO2 **Minute ventilation / O_2 consumption**
Ratio of the minute ventilation and the momentary oxygen consumption

VE/VCO2 **Minute ventilation / CO_2 production**
Ratio of the minute ventilation and the momentary carbon dioxide production

VO2max **Maximal O_2 consumption**
Maximal oxygen consumption during the whole test

VCO2max **Maximal CO_2 production**
Maximal carbon dioxide production during the whole test

VO2/HR **Oxygen/pulse**
Oxygen delivery by one heart beat

BPsys×HR **Product of systolic blood pressure and heart rate**
Product of systolic blood pressure and heart rate

BR **Breath rate**
Breath rate, breath / minute

RER **Respiratory Exchange Ratio**
Ration of the CO_2 production and O_2 consumption during exercise

RQ **Respiratory Quotient**
Ration of the CO_2 production and O_2 consumption during resting

VO2/kg **Ratio of momentary O_2 consumption and body weight**
Momentary O_2 consumption / body weight, ml/m/kg

VCO2/kg **Ratio of momentary CO_2 production and body weight**
Momentary CO_2 production / body weight, ml/m/kg

Work **Carried out work**
Total carried out work during the whole exercise, kCal

MET **Metabolic Equivalent**
Energy request of the physical activity. Base unit is the resting energy request of the person being tested. It is a calculated value based on the VO2.

METc **Calculated Metabolic Equivalent**
Energy request of the physical activity. Base unit is the resting energy request of the person being tested. It is a calculated value based on the body weight and load.

Speed **Speed of the treadmill**
If the loading device is a treadmill the speed of the treadmill.

If the loading device is an ergometer bike this parameter is calculated from the oxygen consumption.

Grade **Elevation angle of the treadmill**
If the loading device is a treadmill this parameter is the elevation angle of the treadmill

REE **Resting Energy Expenditure**
Resting energy expenditure in kCal / day.
This parameter is calculated from the O_2 consumption and CO_2 production.

Zero setting

For exact volume measurement the zero setting of flow meter channel must be performed immediately before the measurement.

In case of Ergospirometer pneumatic valves detach the flow meter from the pressure transducer, so zero setting occurs automatically in the background. Patient may continue breathing thru the flow meter.

Zero setting process

The program automatically starts the zero setting process immediately before each measurement.

The system evaluates the data measured during the zero setting process, and displays an error message and repeats the zero setting process if a zero error is encountered.

Manual zero setting

You can reset the currently selected device anytime with the **[Zero]** button next to the **[Device selection]** list in the program header.

Notice

Zero setting is automatically performed before calibration.

Preparations

Device

Patient circuit

To prevent cross contamination a new disposable bacterial and viral filter must be connected before each patient measurement.

Patient

Recommended body position

- Sitting on a chair
- Straight back
- Level head
- Tight clothing or jewels must not prevent free breathing

Directions

Prior to the tests inform the patient about the goal and way of the measurements.

For detailed description please refer to the “Spirometry” volume of this manual.

Ergospirometry preparations

The cardio-pulmonary exercise test fully differs from the usual pulmonary function tests. It requests not only co-operation but mental and physical abilities from the patient as well.

In order to reach the best results the patient has to be aware of the special aspects of the exercise test in advance.

- The exercise test physically strenuous
- The exercise test has certain level of risk
- Sport dress and shoes are advisable
- The patient has to avoid eating before the exercise test by a few hours
- The patient has to avoid eating heavy and fatty meal before the exercise test by a few days
- The patient has to avoid any heavy physical activity before the exercise test by a few days
- The patient has to avoid smoking before the exercise test by at least 8 hours
- Prior the exercise test a full anamnesis has to be recorded including regular medical treatment, medicines applied especially the cardio pulmonary aspects
- The total duration of a complex exercise test including the preparation, dressing and evaluation is about one and half an hour

Resting metabolic test preparations

The relaxed metabolic test is for analyzing long duration processes therefore the patient has to be aware of the special aspects of the test well before.

- The patient has to avoid any heavy physical activity before the exercise test by a 48 hours
- The patient has to avoid eating and drinking before the exercise test by a 4 hours, of course water drinking is allowed
- The patient has to have a loose and comfortable dress which provide comfortable temperature feeling
- The patient lays down and relaxes for 20 – 30minutes
- The total duration of the test is about one hour

If any of the above listed criteria is not fulfilled there is no sense to make the exercise test

Interaction of the patient and medical devices

The proper usage of the consumable parts is necessary to reach the most correct measurements.

Nose clip

Apply nose clip during all pulmonary function tests expect for the tests done in facial mask in order to avoid false breathing thru the nostrils.

Mouthpieces

The mouthpiece provides the proper connection between the patient and the device.

MPA-30 – Simple mouthpiece

Elliptic mouthpiece is for the basic pulmonary function tests

PMP-30 – Mouthpiece with bite-on grip

For the more demanding pulmonary function tests where the proper sealing is even more important like body plethysmograph or diffusion capacity test

PBF-100-G-M Bacterial and viral filer with elliptic patient side for the basic pulmonary function tests

Facial masks

Applying facial masks makes possible the oral and nasal breathing simultaneously. It provides more comfort and requests less co-operation.

Facial masks are used mostly for ergospirometry and for rhinomanometry.

- Select the best fitting size for the patient the full and proper sealing has to be reached
- Assemble the adapter ring and the headgear

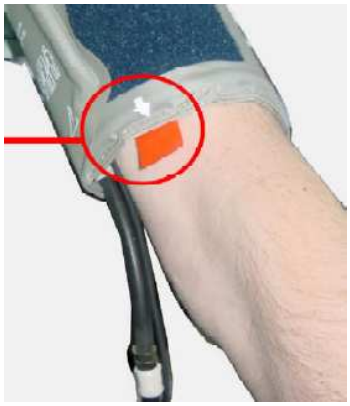
- Place the facial mask to the patient's face as show non the picture
- Adjust the length of the belts of the headgear
- Fasten the headgear with the Velcro tapes
- Never push the facial mask too strong against the patient's face
- To check the proper sealing the patient has to block the orifice of the mask with hand and has to make ex- and inspiration efforts. No leakage is allowed at all!
- If necessary select an other size of the facial masks

If the patient is not fully shaved some leakage may occur.
In this case the facial hair has to be shaved.

Blood pressure meter

A lot of different blood pressure meter can be integrated into the ergospirometer system. Always follow the regulations of the user's manual of the given blood pressure meter.

Take care that the built-in microphone of the handcuff has to be in the position over the Arteria Brachialis!



ECG

A lot of different ECG can be integrated into the ergospirometer system. Always follow the regulations of the user's manual of the given ECG device.

Bicycle ergometer

The body position may influence the maximal working capacity of the patient. Further more the height of the saddle determines which the muscles groups will be used.

In the case of healthy patient
The ideal height of the saddle is when the patient with a stretched leg may reach the pedals with the heel. The patient has to push the pedals with the middle of the sole pads.

Elderly and patient moving with difficultness
Adjust the height of the saddle to reach the most comfortable and the most sense of security for the patient.

Athlete
Athletes are mostly coming for the exercise tests to reach their limits so the usual position is important for them.
Athletes may adjust the bicycle ergometer themselves the height and position of the saddle and the hand bar.

Right position of the foot
The ideal position of the feet is when the middle of the sole pads are on the pedals.

However in the case of elderly and patient pushing the pedals with the full sole is allowed.

Treadmill

Treadmill can be applied for all ambulatory patients but there are a number of safety precautions. Read carefully the user's manual of the treadmill integrated into the system.

- Never allow to use treadmill in a dress which may have loose part like robe belt or too long trousers because these loose part can be cached by the rollers!
- Never touch the moving parts of the treadmill like rollers or the height adjusting mechanism!
- Never stand on the belt barefoot!
- Use always training shoes!
- Use always the safety belt which stops the treadmill immediately as the patient is not able to keep the speed!
- Never try to block or override the safety system of the treadmill!

Evaluation of the cardiopulmonary test

During ergospirometry only one test can be performed in contrary with the basic pulmonary function tests when 8 tests can be performed simultaneously.

Evaluation of the cardiopulmonary test is described in the next chapter.

Ergospirometry

E

WARNING!

The whole ergometer test has to be supervised by a cardiologist

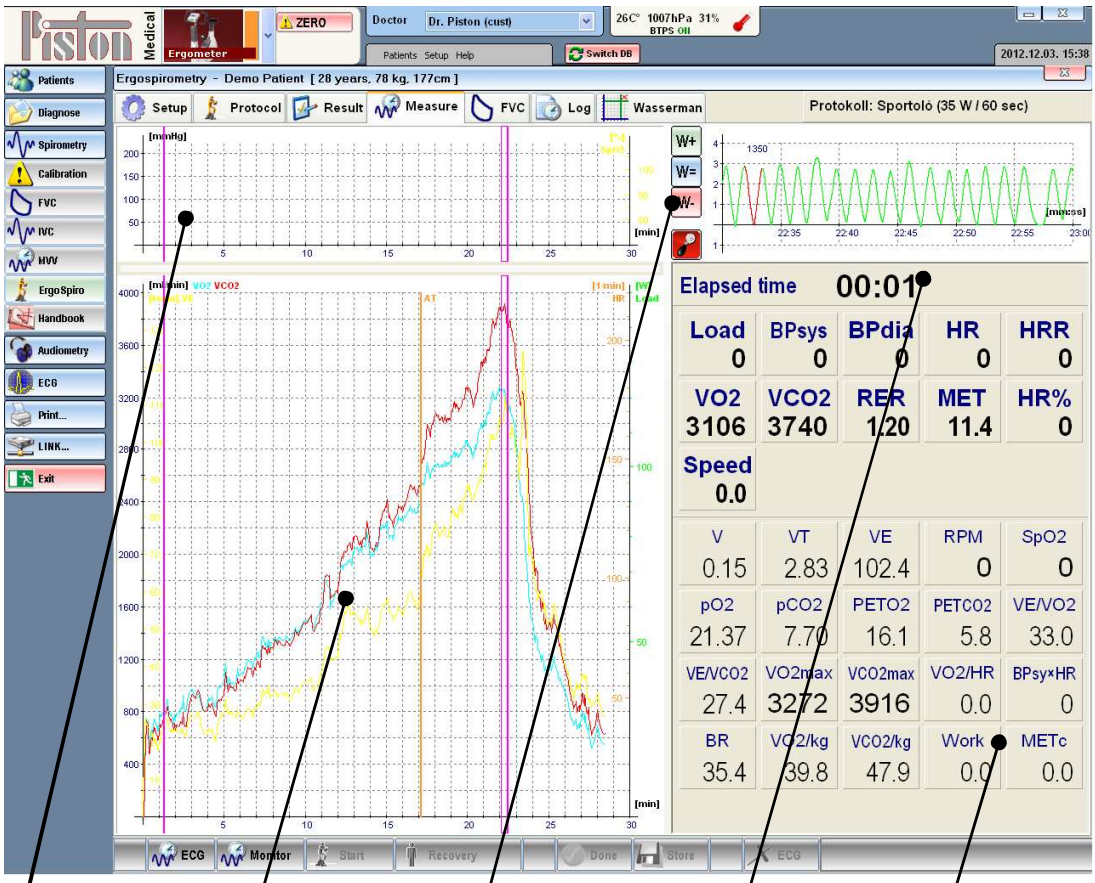
The detailed anamnesis has to be reordered prior to ergospirometer test

The ergospirometer test can be performed if all the conditions of the resuscitation are provided

Goal of the test

Cardiopulmonary exercise testing provides a global assessment of the integrative exercise responses involving the pulmonary and cardiovascular system.

Ergospirometry is increasingly being used in a wide spectrum of clinical applications for the evaluation of undiagnosed exercise intolerance and exercise-related symptoms



HR, BP, SpO2 panel **Main window** **Manual control** **Spirogram** **Parameter table**

The ergospirometer test is a rather complex measurement consequently it requests two monitors. According to the conventions the left monitor is for the ECG and right monitor is for the control and for the monitoring all vital parameters.

Since different models of ECG devices can be integrated into our ergospirometer system this chapter describes the right monitor in majority.

HR, BP, SpO2 panel
The main cardiologic parameters are displayed in this panel during the test

Main window
The main pulmonary and metabolic parameters are displayed during the test: VO2, VCO2, VE

Manual control
The load rate of the bicycle ergometer or the speed and angle of the treadmill can be modified at any time during the whole test

In the case of bicycle ergometer the automatic protocol is not aborted by the manual modification only the actual load rate is increased by the **Increase** value.

In the case of treadmill the automatic protocol is not modified by the manual modification the next load steps equals to value preset in the protocol.

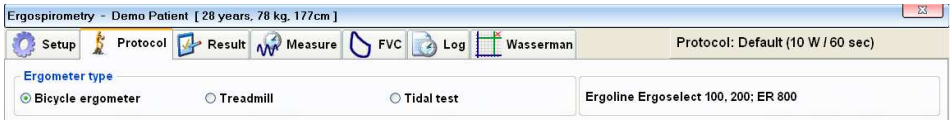
Spirogram
The breathing is monitored in this window the tidal volume, frequency and the median of breathing can be observed.

Parameter table
The values of the main vital parameters are shown during the test.

Load equipment

Press the **[Protocol]** tab and in the **[Ergometer type]** section select the load equipment to use:

- Bicycle ergometer
- Treadmill
- Tidal test



The panel of protocol settings is automatically changes according to the selected load equipment.

The detailed description of the Resting Metabolic Test can be found in the Tidal test az REE – Resting metabolic test chapter (38. page).

Handling templates

Configurations and settings of the exercise tests can be stored in templates in the following groups:

- Bicycle protocols
- Treadmill protocols
- Measurements of blood pressure
- Limits

Creating a new template
Press the „New template" button

- Give a name to the new template
- Enter values in to the fields

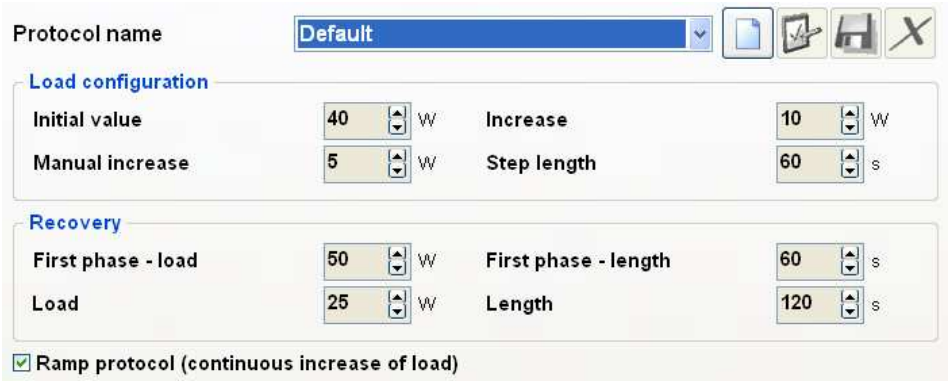
Editing existing template
Press the „Edit template" button

Delete a template
Press the 'Delete template" button

Store
After definition of a new template or modification of an existing template:

- Push the „Store modifications" button to store modifications
- Push the „Abandon modifications" button to cancel modifications

Bicycle ergometer protocols



The loading protocols are increasing the load rate from the basic value by a given step in certain time intervals. Practically the protocol is a Load(Time) function. Afterwards the loading is followed by the cooling down phases.

Load configuration
Initial value: The starting load rate of the test

Increase: Increase of the load between two steps

Manual increase: Step of the manual modification. During the manual control of the load this value will be added to the actual load rate. The

manual modification does not abort the automatic protocols the **Increase** value is always added to the actual load rate.

Step length: The load rate is increased by the specified time interval independently of the manual control

Recovery
First phase - load: The first cooling down phase starts with the specified load rate

First phase - length: Duration of the first cooling down phase

Load: The second cooling down phase starts with the specified load rate

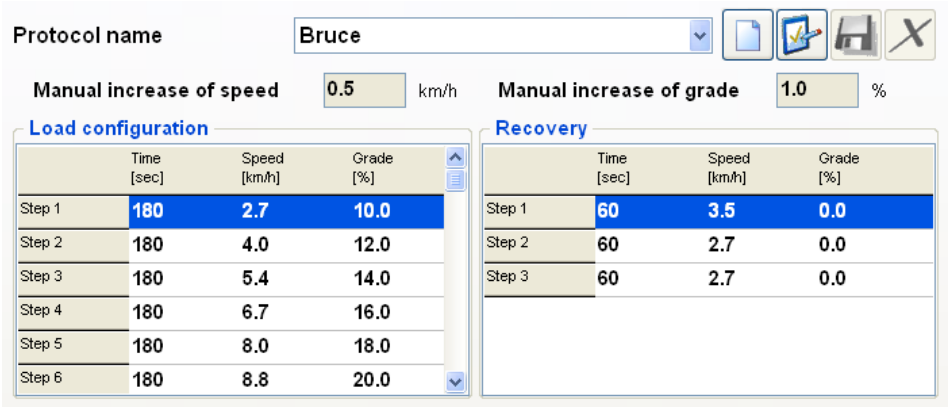
Length: Duration of the second cooling down phase

Ramp protocol (continuous increase of load)
The load rate is increased continuously during the test. The load rate readjusted in every second accordingly to the load rate resolution of the loading equipment.

In this case the load rate is increased by the [**Increase**] value in the every [**Step length**].

Example:
If the **Step length = 60 sec** and the **Increase = 15 Watt** further more the load rate resolution of the bicycle ergometer is 1 Watt it means that the load rate will be increased by 1 Watt in every 4 seconds.

Treadmill protocols



Usually treadmill protocols are defined in tables and the load rate is specified step by step.
The number of protocols is unlimited and there are numerous factory preset protocols to select.

Factory preset protocols

- Bruce
- Bruce Mod
- Blake
- Blake Mod
- Naughton
- Cornell
- ACIP
- Ellestad I. és II.

Manual control
Manual increase of speed: The speed can be increased or decreased by the specified step.

Manual increase of grade: The slope can be increased by the specified step.

The system may override the actual settings according to the resolution of the actual treadmill. For example an 0.1% increase can be rounded to the smallest accepted value as 0.5% or 1%.

Manual modification does not influence the automatic protocol the next load step will be set according to the preset values.

Setting of particular steps
Time: Duration of one step in seconds

Speed: Speed in kilometre per hour

Grade: Slope of the treadmill in percent

(For example 5% slope means 5 meters difference of level in 100 meters)

Blood pressure measurement

Individual blood pressure measuring profile can be defined for each loading equipment and for each loading protocol.

For example if the system is equipped with a bicycle ergometer and with a treadmill as well further more a ramp protocol is used for the bicycle ergometer and the Bruce protocol is used for the treadmill.
While using the bicycle ergometer the blood pressure will be measured by the built-in blood pressure meter of the bicycle automatically in every 2 minutes.
While using the treadmill a warning signal for manual blood pressure measurement will be generated in the 3. minute of the each step of the protocol.

Manual BP measurement: The blood pressure is measured manually the system does not control any automatic blood pressure meter. A warning signal is generated when the blood pressure measurement is necessary.

Blood Pressure measurement is actual

Measuring period

- **Independent interval**: The blood pressure measurements are done in predefined intervals calculated from the beginning of the test. It is independent of the actually running protocol.
- **Relative to** the current step: The blood pressure measurement starts in a predefined time interval calculated from the beginning of the actual load rate step.

Limitations

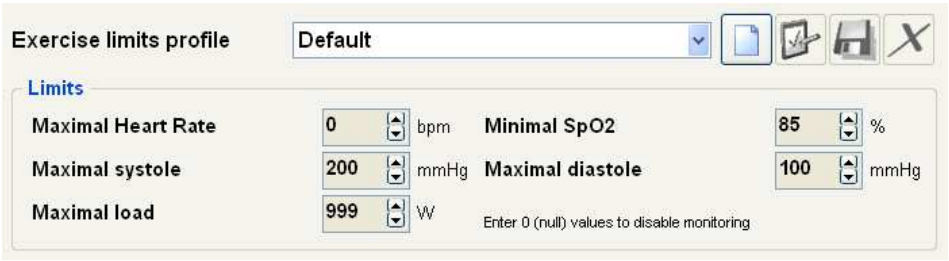
The time interval defined blood pressure measurement can be used at the following conditions:

- This feature is not available for the ramp protocols because there are no definitive start points of the different load rates. In this case the [**Independent interval**] option has to be selected.
- The duration of the load step has to be longer then specified delay time
- The cycle time of a automatic blood pressure measurement has to be taken into consideration (30÷60 sec) when editing a load protocol and a blood pressure measurement profile

Ignore failed measurements

If a blood pressure measurement is unsuccessful only a warning message appears.

Limits



During the exercise test some vital parameters may reach critical limits which could be risky for the patient. These limits are partly published by the international recommendations and partly they are determined individually for each patient.

Obviously these limits are sharply different for a healthy person or for an ill patient (transplanted or with a pacemaker) or for a professional athlete.

If monitoring of a certain parameter is not necessary enter 0 value and monitoring of that parameter will be suspended.

It is impossible to suspend the monitoring of maximal heart rate. If the filed value is empty the maximal heart rate is calculated from the well known equation:

Maximal heart rate = 220 - Age

Contraindications

According to the ATS/ACCP Statement on Cardiopulmonary Exercise Testing (March 1, 2002) making an exercise test is severely contraindicated upon the following circumstances:

Absolute contraindications

- Acute myocardial infarction (3–5 days)
- Unstable angina
- Uncontrolled arrhythmias causing symptoms or hemodynamic compromise)
- Syncope
- Active endocarditis
- Acute myocarditis or pericarditis
- Symptomatic severe aortic stenosis
- Uncontrolled heart failure
- Acute pulmonary embolus or pulmonary infarction
- Thrombosis of lower extremities
- Suspected dissecting aneurysm
- Uncontrolled asthma
- Pulmonary edema
- Room air desaturation at rest < 85%*
- Respiratory failure
- Acute noncardiopulmonary disorder that may affect exercise performance or be aggravated by exercise (i.e. infection, renal failure, thyrotoxicosis)
- Mental impairment leading to inability to cooperate

Relative contraindications

- Left main coronary stenosis or its equivalent
- Moderate stenotic valvular heart disease
- Severe untreated arterial hypertension at rest (>200 mm Hg systolic, >120 mm Hg diastolic)
- Tachyarrhythmias or bradyarrhythmias
- High-degree atrioventricular block
- Hypertrophic cardiomyopathy
- Significant pulmonary hypertension
- Advanced or complicated pregnancy
- Electrolyte abnormalities
- Orthopedic impairment that compromises exercise performance

ATTENTION!

The list of contraindications is only for information purposes the whole responsibility of the exercise test belongs to the supervising physician!

Indications of stopping of an exercise test

It is advisable to stop an exercise test when any of the following symptoms or phenomenon occurs:

Absolute reasons of stopping

- The systolic blood pressure decreases by more than ≥10 Hgmm during increasing load rate and there are other symptoms of the myocardium ischemia.
- Middle or even more serious level of angina pectoris
- Symptoms of central nerves system (ataxia, dizziness, threaten syncope)
- Symptoms of the Hypo perfusion (considerable paleness, cyanosis)
- Sustained tachycardia of chambers (≥30 s)
- ST elevation is ≥1 mm at the lead where is no pathologic Q wave
- The continuous monitoring of ECG and of the blood pressure for any reasons is interrupted
- The patient claims for finishing

Indications of relative stopping

- The systolic blood pressure decreases by more than ≥10 Hgmm during increasing load rate
- Appearance of considerable ST depression (>2 mm horizontal or „down sloping") or a quick change of the QRS axle
- Exhaust, choking, asthmatic breathing, pain in the legs
- Increasing chest pain
- Pathologic response of tension (systolic RR >250 Hgmm, diastolic RR 115 Hgmm)

Attention!

The list of possible reason for abortion is only for information purposes the whole responsibility of the exercise test belongs to supervising physician!

Preparation

It is necessary to inform the patient about the process of the measurement.
Application of different sensors is described in the chapter "Interaction of the patient and medical devices"

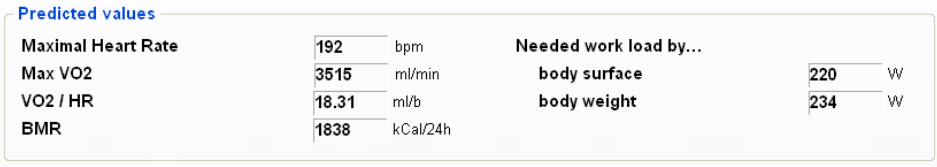
- Make sure that the patient obeyed all the regulations which prescribed during the preliminary information concerning eating, smoking, physical activity
- Go through the anamnesis again
- According to the existing legal regulations ask the patient to sign the declaration of content for the exercise test

- The patient has to change the dress
- In the meanwhile the calibration procedure has to be done
- Make the basic pulmonary function tests (FVC, MVV)
- Attach the self adhesive ECG electrodes to the body of the patient Check out the user's manual of the currently applied ECG equipment as well.
- In the case of an ergometer bicycle ask the patient to seat on the saddle.
- In the case of the treadmill ask the patient to stand on the equipment as all the sensors are attached.
- Connect the cables to the electrodes. Pay attention to the free movement of the patient. Cables should not touch any limbs of the patient during the exercise.
- Attach the hand cuff of the blood pressure meter
- Call attention of the patient that speaking is prohibited during the exercise test because it could influence the measurement
- Teach a simple sign language to the patient, use the Borg scale. Patient may reply with a nodding to the simple questions as: „ Are you all right?" or „Are you able to proceed?" etc.
- Attach the facial mask to the patient with the supplied head gear

Predicted values

The system calculates the following predicted values according to the recommendations of the Karlman Wasserman:

- Maximal hear rate (HR_{max}) = 220 - Age
- Expected load calculated on the base of the body surface and weight
- Maximal oxygen consumption ($VO2_{max}$)
- $(VO2/HR)_{max} = VO2_{max} / HR_{max}$



Measurement process

There is a possibility for monitoring all vital signs of the patient before the exercise test. In the similar way there is a possibility for monitoring all vital signs of the patient after cooling down phases for any duration. All vital parameters are stored and both ECG signals and pulmonary signals can be retrieved and analysed later.

- To start the ECG monitoring push the **[ECG]** button
- To start the pulmonary monitoring push the **[Monitor]** button
- The patient needs about 1-2 minutes to get accustomed to the sensors and to the facial mask. Similarly the systems needs the same period of time to calculate the resting medians of the parameters.
- Usually protocols prescribes 3 minutes of resting monitoring but it can be overridden according to the status of the patient or any other actual needs
- If the manual blood pressure measurement was selected pushing the **[F6]** button will activate the entry fields of blood pressure. As the systolic and diastolic value was entered push the **[Enter]** button
- To start the protocol push the **[Start]** button
- Supervise all the vital parameters of the patient continuously. If there is any sign of disturbance act according the to the Indications of stopping of an exercise test chapter.
- If the patient reached the maximal load rate push the **[Recovery]** button to start the cooling down phase monitoring is still sustained.
- End of the cooling down phase is indicated further more the load of the bicycle ergometer is decreased to the minimal or the treadmill stops.
- The load rate, the speed and the slope still can be modified manually
- If the patient got relaxed and all vital parameters returned close to the normal resting level push the [Done] button to finish monitoring
- Evaluation of the exercise test can be done while the patient is relaxing

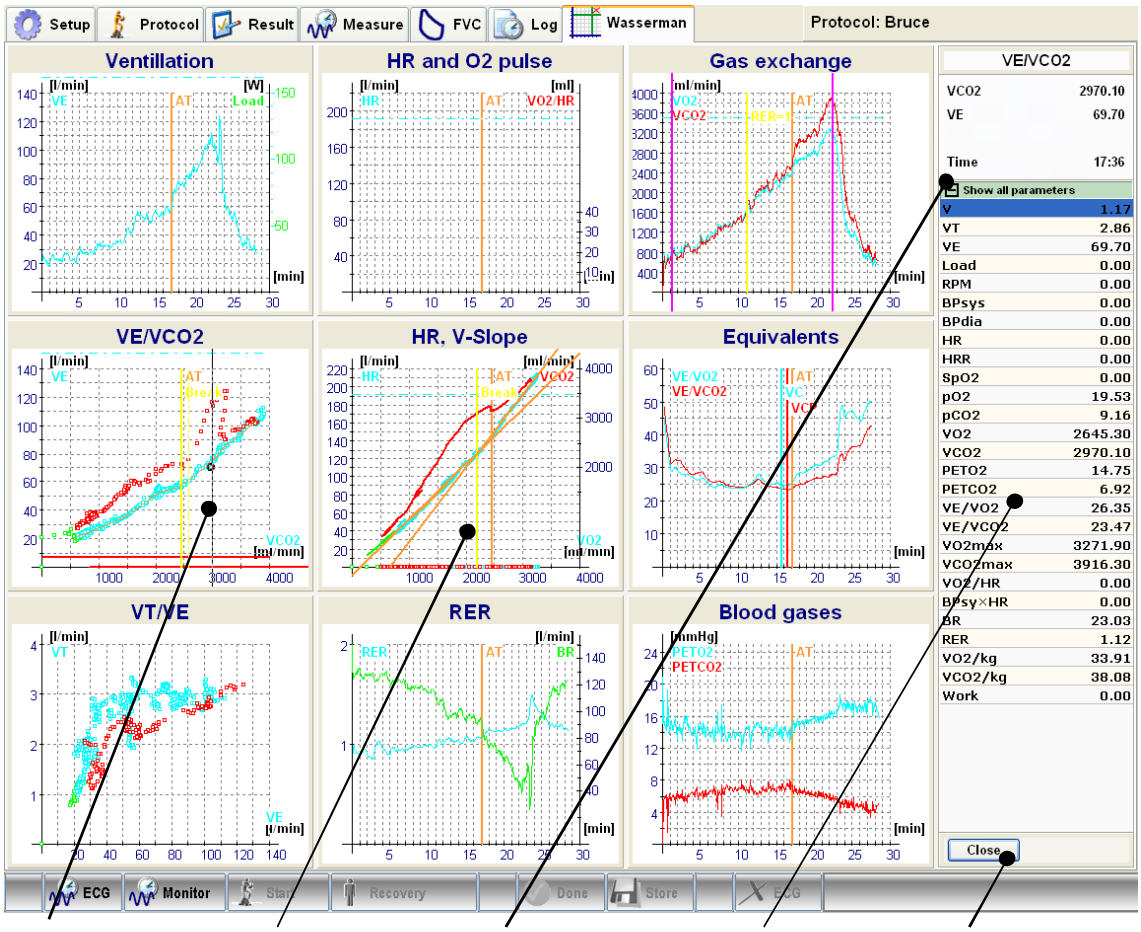
Function buttons during the test

F3	Start monitoring
F4	Start protocol
F5	ECG monitor: ST amplitude on/off
F6	Manual entry of blood pressure values
F8	Swap to the main screen
F9	Swap to the Wasserman panels
ESC	Cooling down phase

Evaluation of the exercise test

Interpretation and evaluation of the exercise test is done according to the recommendations of Karlman Wasserman.

- Click on the Wasserman tab



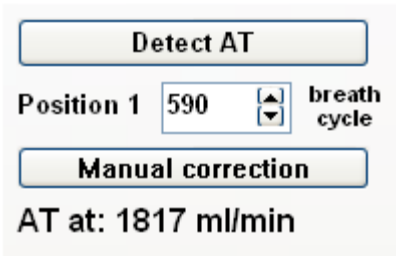
As the exercise test is completed the system determines anaerobe threshold automatically by four different algorithms:

- RER = 1
- V-Slope VCO2/VO2
- VE/VCO2 Equivalent
- VE/VO2 Equivalent

Anaerobe thresholds calculated by the system are only for informational purposes they can be adjusted manually. The final anaerobe thresholds have to be determined in an empiric way by physician.

RER = 1

This algorithm determines the anaerobe threshold at that point where the VCO2 exceeds the VO2 or with other words the ratio of them exceeds the 1.00 value for the first time.



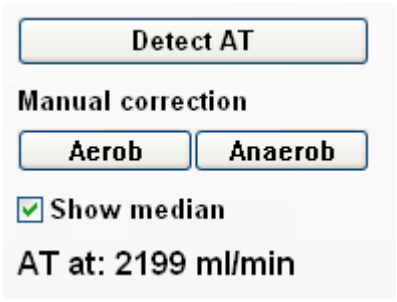
Click on the [Gas Exchange] graph

Modify the counter up/down to reach the desired position

Or push the **[Manual correction]** button and move the cursor on the graph manually

V-Slope

This algorithm determines the anaerobe threshold at the significant breaking point visible on the VCO2(VO2) graph.



Click on the [HR, VCO2/VO2] graph

Push the [**Aerob**] or the [**Anaerob**] button

Match the marker with the selected part of the curve with the help of the mouse

VE/VCO2 equivalent

This algorithm determines the anaerobe threshold at the significant breaking point visible on the VE(VCO2) graph.

Click on the [VE/VCO2 ekvivalens] graph

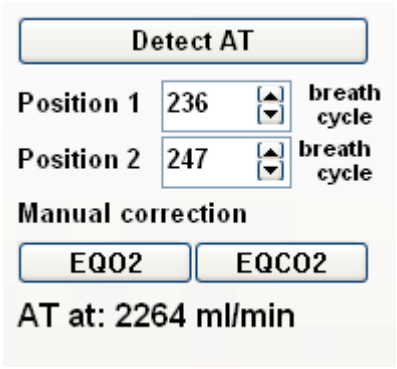
Push the [**Aerob**] or the [**Anaerob**] button

Match the marker with the selected part of the curve with the help of the mouse

VE/VO2 equivalent

This algorithm searches for a point where

- the VE/VO2 started already to increase
- the VE/VCO2 is not increasing yet
- the pCO2 is not decreasing yet



Click on the [Equivalents] graph

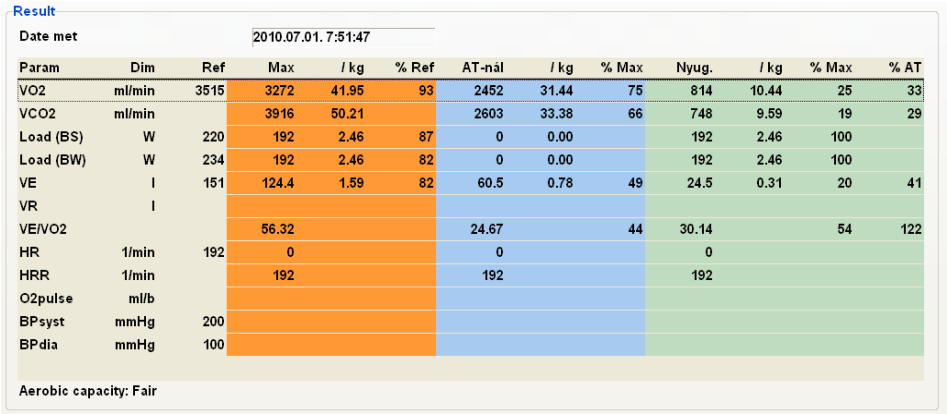
Modify the counter up/down to reach the desired position

Or push on the **[EQO2]** or **[EQO2]** button and move the marker on the graph with the help of the mouse

Result overview

As the AT (anaerobe threshold) is determined already push the [**Result**] tab the overview of the results will be shown in a table divided by the different phases:

- Resting phase
- Anaerobe threshold
- Peak values



Result

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Param	Dim	Ref	Max	/ kg	% Ref	AT-nál	/ kg	% Max	Nyug.	/ kg	% Max	% AT
VO2	ml/min	3515	3272	41.95	93	2452	31.44	75	814	10.44	25	33
VCO2	ml/min		3916	50.21		2603	33.38	66	748	9.59	19	29
Load (BS)	W	220	192	2.46	87	0	0.00		192	2.46	100	
Load (BW)	W	234	192	2.46	82	0	0.00		192	2.46	100	
VE	l	151	124.4	1.59	82	60.5	0.78	49	24.5	0.31	20	41
VR	l											
VE/VO2			56.32			24.67		44	30.14		54	122
HR	1/min	192	0			0			0			
HRR	1/min		192			192			192			
O2pulse	ml/b											
BPsyst	mmHg	200										
BPdia	mmHg	100										

Aerobic capacity: Fair

Values of each parameter are shown in a following sequence:

- Reference (predicted) value
- Maximal value,
  Ratio to the body weight, Ratio to the reference value
- Value at the AT, Ratio of the value at the AT to the body weight,
  Ratio of the value at the AT to the maximal value
- Resting value, Ratio of the resting value to the body weight,
  Ratio of resting value to the maximal value,
  Ratio of the resting value to the value at AT.

Interpretation

The system evaluates the fitness level of the patient taking into consideration the gender and age of the patient and the maximal VO2.

This way of automatic interpretation is most useful in the case healthy and active persons.

Store

If all parameters seem to be correct push the [**Store**] button to store results

The following data will be stored:

- ECG signals for the total duration of the test
- The measured vital parameters (HR, BP, VO2, VCO2 etc.) in time sequence continuously
- Flow and gas concentrations for the total duration of the tests
- The selected AT values and the relevant marker positions

REE – Resting metabolic test

Measurement goal

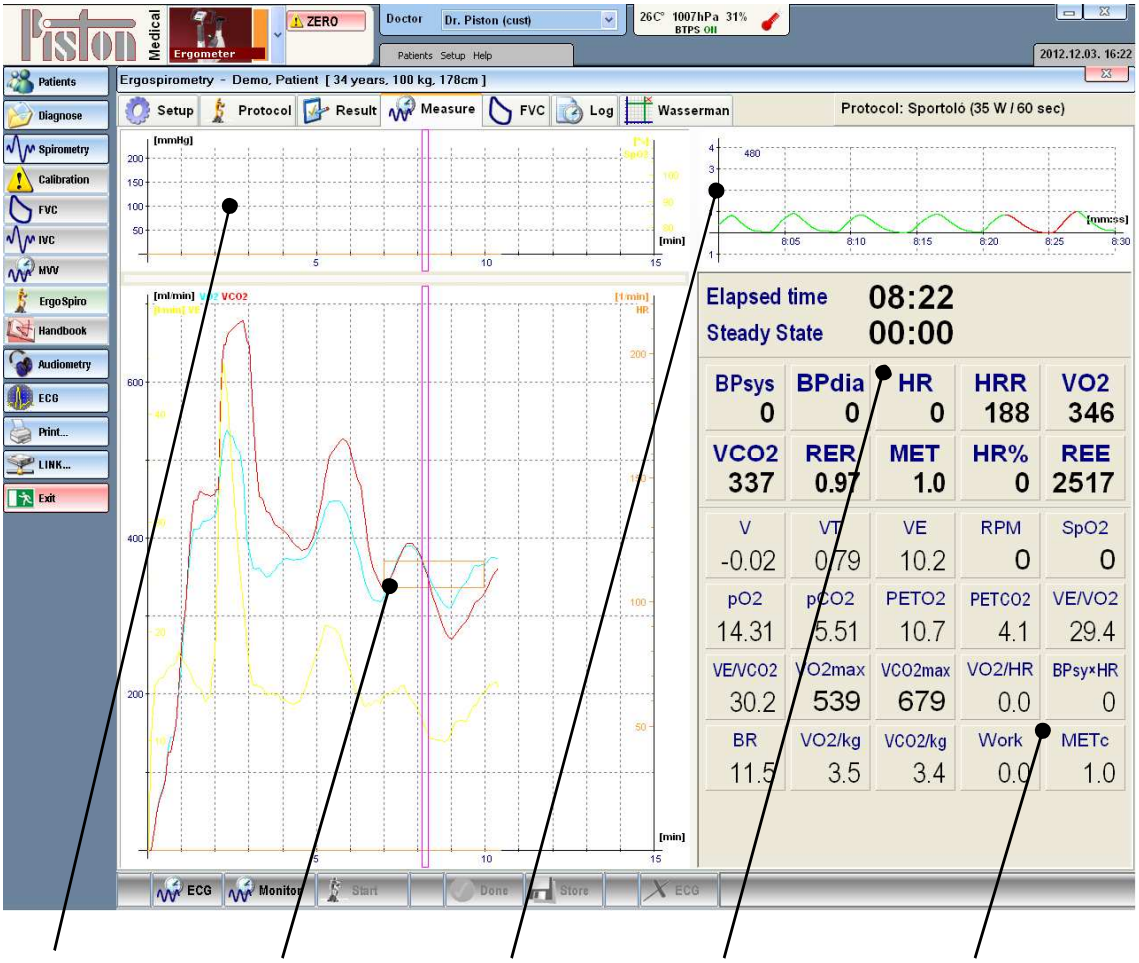
The goal of the test is the determination of the Resting Energy Expenditure (REE).

The Basal Metabolic Rate (BMR) is the energy expenditure which is needed to supply the basic vegetative functions of a resting but awaken person. The Basal Metabolic Rate is estimated by the system and this value is taken as a Reference value.

The values of the REE and of the BMR are very close to each other the difference between them is less than 10%. The main difference between them is the method how to measure them.

The REE is determined after a 20 ÷ 30 minute resting during a 5 minute long period when the oxygen consumption and the carbon dioxide production are nearly constant.

The BMR is measured right away after waking up at severe conditions, exactly on the same way as the REE measurement.



HR, BP, SpO2 panel **Main window** **Spirogram** **Timer** **Parameter table**

HR, BP, SpO2 panel
The basic cardiologic parameters are monitored during the whole test

Main window
The most important metabolic and breathing parameters are monitored: VO2, VCO2, VE

Spirogram
The spirogram shows the breathing, tidal volume, breath rate, and the shifting of the breathing median

Timer
The upper counter shows the total duration of the test and the lower counter shows the duration of the steady state

Parameter table
Values of the vital parameters are shown during the whole test.

Preparation

It is inevitable to inform the patient as described in the in the chapter Preparations.

The following steps should be done:

- Lay the patient down to the examination bed
- The patient has to find a position whish is comfortable enough to lay without any movement for an hour
- While the patient is laying down make the calibration of the system
- Put the facial mask on the patient

Measurement process

- Select under the **[Protocol]** tab in the **[Ergometer type]** section the **[Tidal test]** option
- To start the test push the **[Monitor]** button
- The patient has to refrain from any movement and from speaking as well. Usually 20 ÷ 30 minutes are requested to reach the stable metabolic level.
- Push the **[Start]** button as the VO2, VCO2, VE, RER parameters are getting stable
- The system indicates the stable intervals by frames. The REE value is updated continuously. If all the conditions are met in a 5 minute interval the system indicates it:

Steady state criteria met.

- Push the **[Done]** button
- Results are shown at the **[Result]** tab

Device maintenance

Our lung diagnostics devices do not require special maintenance.

For continuous reliable operation take care of the following:

- To prevent device contamination and patient cross-contamination after each test disinfect the flow meter, the facial mask and the headgear or change the bacterial and viral filter after the basic lung function tests
- The flow sensor must be contamination free
- The filter elements must be replaced according to instructions
- The PermaPure moisture exchange capillary must be replaced according to instructions
- The tubes must always be dry and cannot be broken

Flow meter maintenance

The flow meter condition and cleanliness affects measurement accuracy.

Cleaning measurement head main parts

The individual patient circuit type installations are described in section Installation.

The plastic parts may be disinfected with cold water and appropriate chemicals (for example, Sekusept), and may be used after rinsing and drying.

WARNING!

- **PermaPure moisture exchange capillary must be kept always dry. Do not clean it with water or any alcohol containing cleaning agent.**
- **When the system is turned on never use any alcohol containing cleaning agent because it may penetrate into the gas analyzer line and could endanger the sensitive gas analyzers.**
  The system can be turned on again only after the total drying and ventilaton of the laboratory.

Cleaning the pneumatic twin-tubes

- Disconnect the twin-tube from the device and the flow meter
- Rinse the tube
- Do not clean the gas sampling capillary with any kind of liquid!
- After it is completely dried, reconnect the tube

Ergospirometer maintenance

Oxygen sensor
The expected lifetime of the electrochemical cell is 2 years. As the oxygen sensor is getting older its sensitivity is decreasing. When it reaches the critical limit the next warning appears:

Calibration Error 3: Oxygen sensor used up!

☞ Please contact your local dealer for changing the oxygen sensor

Carbon dioxide sensor
It is advisable to check the linearity of the sensor annually. If it is needed a new linearization has to be done.

☞ Please contact your local dealer for the linearization issue

Load equipment maintenance

Technical maintenance
According to the Users manual the regular maintenance has to be done like cleaning and lubrication.

☞ Please contact your local dealer for the more complex maintenance

Disinfection
Those parts of the bike ergométer and of the treadmills which are in direct contact with the patients (seat, handlebar, and handrail) have to be disinfected regularly.

Please follow the regulations of the manufacturers of the given load equipment.

Single-use parts

The basic lung function tests can be done with the single-use parts as well as described in the “Spirometry” volume of this manual.

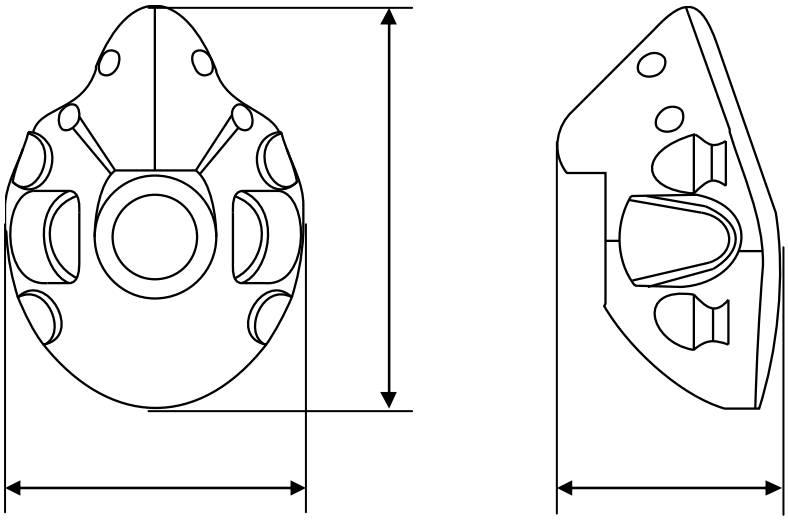
Reusable accessories

Facial mask (AM-41280 series and HR-669170)

The silicone facial masks can be disinfected in a cold disinfecting solvent (Glutaraldehyde, Sekusept, Cidex etc.).
Rinse it carefully and dry fully before use.

The average lifetime of the facial masks guaranteed by the manufacturer 6 months or 25 disinfecting cycles.

Siez / HR-699170 series



Size		L	M	S	XS	Pediatric
A	*[cm]*	15.0	14.0	13.2	12.2	11.7
B	*[cm]*	8.6	7.9	7.1	6.9	6.4
C	*[cm]*	10.7	10.7	10.2	9.9	9.9
Dead space	*[ml]*	290	246	185	157	135
Weight	*[g]*	323	297	274	257	241
Part number		HR-669170	HR-669171	HR-669172	HR-669173	HR-669174

Headgear (HR-201418)

The headgear guarantees the proper sealing of the facial mask.
The lifetime of the headgear guaranteed by the manufacturer is 6 months at an average usage.
The headgear can be disinfected in a cold disinfecting solvent (Glutaraldehyde, Sekusept, Cidex etc.).

Refill of the gas cylinders

General regulations

Gas cylinders and their refill should be provided by the local authorised distributor or dealer.

- **Use always medical grade gas mixtures.**
  Improper quality or concentration of the gas mixture may harm the sensitive parts of the devices.
- **There is a high pressure in the gas cylinder handle it carefully.**
  Only authorized person is allowed to change gas cylinders
- **Always set the exact secondary pressure of the pressure regulator as prescribed in the manual**
  Over pressure may harm the device and on contrary low pressure will not provide adequate quantity of the gas mixture.

- **After each gas cylinder change always enter the actual gas concentration values to the system software.**
  You may find the actual concentration values of the gas mixture on the certificate supplied by the gas filling company.

Diffusion capacity test

Gas mixture

Methane (CH_4) ..... 0.3 %, 1% relative
Carbon monoxide (CO) ..... 0.3 %, 1% relative
Ballast ..... artificial air

Gas cylinder and pressure regulator

Volume ..... 10 litre
Nominal pressure ..... 150 bar
Secondary pressure of the pressure regulator ..... 6 bar

Ergospirometer

Gas mixture

Oxygen (O_2) ..... 16 %, 0.1% relative
Carbon dioxide(CO_2) ..... 5 %, 0.1% relative
Ballast ..... artificial air

Gas cylinder and pressure regulator

Volume ..... 2 litre
Nominal pressure ..... 150 bar
Secondary pressure of the pressure regulator ..... 1 bar

Possible problems

Ergospirometer		
Problem	**Diagnosis**	**Fixing**
Breathing cycles are visible but values of VO2, VCO2 are nearly zero	The gas sampling line is not connected	Connect the gas sampling line
The median line of the breathing is drifting to the unexpected extent	Wrong flow meter calibration	Repeat the flow meter calibration
	The PinkFlow flow meter was not dried completely after disinfection	Install a dry flow meter and repeat the calibration
	The facial mask leaks	Check the facial mask and readjust it
It is impossible to modify the load rate of the bicycle ergometer and the pedal revolution (RPM) is zero	Communication problem	Abort the test Check the connections Turn off and turn on the bicycle ergometer Resume the test

Warranty

The device complies with the effective Technical Specifications.

The manufacturer guarantees the product according to the terms of the Installation/Delivery protocol.

The warranty does not cover post-delivery careless shipping, unprofessional storage, violent damaging, abnormal operation, unprofessional operation, inefficient protection against external effects, natural disasters, or not following the contents of the User Manual.

Check package condition after delivery.
If packaging is damaged, notify the carrier and Piston Ltd., or its representative.

Use of any broken or otherwise damaged products (devices, accessories etc) is dangerous and forbidden!

Limited liability

Piston Ltd. and its carriers, according to the valid laws, do not accept any responsibility for any individual, unforeseeable, direct or indirect damages (including loss of business profit, interruption of business activity, loss of business data, or any other damages due to financial loss), resulting from the use or non-usefulness of the product.

Safety instructions

To avoid possible damages and accidents, please pay attention to the following safety instructions:

- Make sure the mains voltage is the same as that on the product label
- Make sure the connection cable is not damaged
- Take care of your device according to the maintenance section
- Only use the device according to the manual
- Do not use any accessories not recommended for the device
- Store the device in a dry place
- Keep the cable away from heat source, sharp objects, rough surfaces and check the cable's good condition
- Do not expose the device to direct sunlight or strong light (more than 1500 lux)
- Do not use the device in a highly dusty environment
- Do not use the device in a highly vibrating environment
- Take care to ensure the current environmental conditions

The equipment complies with the applicable requirements of laws and standards.

Shipping conditions

Air temperature: ..... -30 °C ÷ +60 °C
Relative humidity: ..... 10% ÷ 100%
Atmospheric pressure: ..... 500 ÷ 1060 mbar

Storage conditions

Air temperature: ..... 0 °C ÷ +50 °C
Relative humidity: ..... 10% ÷ 85%
Atmospheric pressure: ..... 500 ÷ 1060 mbar

Operating conditions

Air temperature: ..... +10 °C ÷ +40 °C
Relative humidity: ..... 30% ÷ 75%
Atmospheric pressure: ..... 700 ÷ 1060 mbar

Informing values

Expected lifetime

Devices ..... 8 years
Measurement head lifetime ..... 2 years

Forced inhalation and exhalation

Measurement duration ..... 60 s
Volume measurement limit ..... 15 l

Vital capacity measurement

Measurement duration ..... 60 s
Volume measurement limit ..... 15 l

Maximal voluntary ventilation

Measurement duration ..... 60 s
Volume measurement limit ..... 250 l/min

Ergospirometry

Duration of a test ..... several hours
Volume measurement limit ..... 500 l/min
O_2 consumption, CO_2 production ..... 10 l/min

Sampling frequency

PRE -101 device family ..... 250 Hz

Other data

Analogue-digital converter resolution ..... 12 bit

Electrical data

The connected computer's and printer's electrical data is found in the respective manufacturer provided specifications.

The following values apply only to the Piston Ltd. manufactured devices:

PRE-101 – Ergospirometer

PC connection ..... USB 2.0 compatible
Mains voltage: ..... 90~260 VAC
Mains frequency: ..... 50~60 Hz
Power consumption (without loading equipment): .... max. 20 VA

Mechanical data

PRE-101 – Ergospirometer

Flow sensor ..... PPF-18 PinkFlow
Gas mixture ..... O_2 16%, CO_2 5%, szintetikus levegő
Gas cylinder ..... 2 litre aluminium
Secondary pressure of the pressure regulator ..... 1 bar
Size (without patient circuit) ..... W 320 * D 295 * H 120 mm
Weight (without patient circuit) ..... 3.17 kg

O_2 analyzer

Principle of operation ..... Electrochemical cell
Range 0-100%
Accuracy 0.05%
Response time T90 ..... 130 ms

CO_2 analyzer

Principle of operation ..... NDIR (Non Dispersive Infrared)
Range 0-10%
Accuracy 0.05%
Response time T90 ..... 130 ms

ECG

The system can be equipped with different types of ECG device. Please refer to the user's manual of the actually applied ECG.

Guaranteed values

PPF-18 – PinkFlow flow meter

Type PPF-18
Principle of operation ..... Symmetric Pitot tube
Flow range ..... ±18 l/s
Dead space ..... 36 ml
Resistance ..... 60 Pa/l/s @ 15 l/s
Weight ..... 34 gramm

PRE-101 – Ergospirometer

Flow sensor ..... PPF-18 PinkFlow
Flow range ..... ±18 l/s
Flow accuracy ..... ±2% or ±50 ml/s
Volume range ..... 500 l/minute
Volume accuracy ..... ±2% or ±50 ml
Range of O_2 consumption ..... 10 l/minute

Range of CO_2 production.....10 l/minute
O_2 consumption accuracy.....±5% or ±100 ml/minute
CO_2 production accuracy .....±5% or ±100 ml/minute

List of accessories

Included accessories

The current Shipping contract contains the list of accessories included in the purchase price.

Optionally purchased accessories

The following information must be provided when ordering accessories and disposables:

- Description
- Type
- Part number
- Device type and serial number for which the accessories are used

Guidance and manufacturer's declaration – electromagnetic emissions

<table>
<tr><td colspan="3">The PRE-101 Ergospirometer is intended for use in the electromagnetic environment specified below. The customer or the user of the PRE-101 Ergospirometer should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions

CISPR 11</td><td>Group 1</td><td>The PRE-101 Ergospirometer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions

CISPR 11</td><td>Class B</td><td rowspan="3">The PRE-101 Ergospirometer is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions

IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions

IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity

The **PRE-101** Ergospirometer is intended for use in the electromagnetic environment specified below. The customer or the user of the **PRE-101** Ergospirometer should assure that it is used in such an environment.

IMMUNITY test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	**<5 % U_T** (>95 % dip in U_T) for 0,5 cycle **40 % U_T** (60 % dip in U_T) for 5 cycles **70 % U_T** (30 % dip in U_T) for 25 cycles **<5 % U_T** (>95 % dip in U_T) for 5 s	**<5 % U_T** (>95 % dip in U_T) for 0,5 cycle **40 % U_T** (60 % dip in U_T) for 5 cycles **70 % U_T** (30 % dip in U_T) for 25 cycles **Not applicable**	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **PRE-101** Ergospirometer requires continued operation during power mains interruptions, it is recommended that the **PRE-101** Ergospirometer be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

Guidance and manufacturer's declaration – electromagnetic immunity

The **PRE-101** Ergospirometer is intended for use in the electromagnetic environment specified below. The customer or the user of the **PRE-101** Ergospirometer should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 V_{rms} 0,15-80 MHz	3 V_{rms} 0,15-80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the **PRE-101** Ergospirometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1{,}17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2,5GHz	3 V/m 80MHz – 2,5GHz	$d = 1{,}17\sqrt{P}$ *80 MHz to 800 MHz* $d = 2{,}33\sqrt{P}$ *800 MHz to 2,5 GHz* where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **PRE-101** Ergospirometer is used exceeds the applicable RF compliance level above, the **PRE-101** Ergospirometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **PRE-101** Ergospirometer.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the PRE-101 Ergospirometer

The **PRE-101** Ergospirometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **PRE-101** Ergospirometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **PRE-101** Ergospirometer as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter** **m**		
	150 kHz – 80 MHz $d = 1{,}17\sqrt{P}$	**80 MHz – 800 MHz** $d = 1{,}17\sqrt{P}$	**800 MHz – 2,5 GHz** $d = 2{,}33\sqrt{P}$
0,01	0,12	0,12	0,24
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,7	3,7	7,38
100	11,7	11,7	23,33

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

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

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

AX

APPENDIX

Piston Ltd.
1033 Budapest, Szőlőkert u. 4/b

CE 1979

Rev.: AX/S-EN-04.00

Date modified: 04/07/2012

TABLE OF CONTENT

CERTIFICATES OF QUALITY MANAGEMENT SYSTEM

Certificate HU11/6220

The management system of

Piston Kft.

Szőlőkert u. 4/b.,
Budapest, 1033, Hungary

has been assessed and certified as meeting the requirements of

MSZ EN ISO 13485:2004

For the following activities

Production and distribution of audiometer and of lung diagnostic equipment and connecting single use mouth-piece and bacterial filter.

Further clarifications regarding the scope of this certificate and the applicability of MSZ EN ISO 13485:2004 requirements may be obtained by consulting the organization

This certificate is valid from 21 December 2011 until 20 December 2014 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 13 December 2014
Issue 1. Certified since 21 December 2011

Authorised by

Tobi András

SGS Hungaria Kft. Systems & Services Certification
1531 Pf. 25. Sirály u. 4. 1124 Budapest Hungary
t +36 1 309 33 40 f +36 1 309 33 33 www.sgs.com

MIR TANÚSÍTÓ
NAT-4-0085/2006

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Certificate HU11/6221

The management system of

Piston Kft.

Szőlőkert u. 4/b.,
Budapest, 1033, Hungary

has been assessed and certified as meeting the requirements of

ISO 9001:2008

For the following activities

Production and distribution of audiometer and of lung diagnostic equipment and connecting single use mouth-piece and bacterial filter.

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2008 requirements may be obtained by consulting the organisation

This certificate is valid from 21 December 2011 until 20 December 2014 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 13 December 2014
Issue 1. Certified since 21 December 2011

Authorised by

SGS United Kingdom Ltd Systems & Services Certification
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

SGS 9001-8 01 0311

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UKAS MANAGEMENT SYSTEMS
005

Format of the patient identification field

The format of the patient identification filed can be any free text or some predefined format according to a special mask.

If this mask is defined the ID field is compulsory to fill during adding a new patient. Otherwise the field can be left empty.

!	If a ! character appears in the mask, optional characters are represented in the text as leading blanks. If a ! character is not present, optional characters are represented in the text as trailing blanks.
>	If a > character appears in the mask, all characters that follow are in upper-case until the end of the mask or until a < character is encountered.
<	If a < character appears in the mask, all characters that follow are in lower-case until the end of the mask or until a > character is encountered.
<>	If these two characters appear together in a mask, no case checking is done and the data is formatted with the case the user uses to enter the data.
****	The character that follows a \ character is a literal character. Use this character to use any of the mask special characters as a literal in the data.
L	The L character requires an alphabetic character only in this position. For the US, this is A-Z, a-z.
l	The l character permits only an alphabetic character in this position, but doesn't require it.
A	The A character requires an alphanumeric character only in this position. For the US, this is A-Z, a-z, 0-9.
a	The a character permits an alphanumeric character in this position, but doesn't require it.
C	The C character requires an arbitrary character in this position.
c	The c character permits an arbitrary character in this position, but doesn't require it.
0	The 0 character requires a numeric character only in this position.
9	The 9 character permits a numeric character in this position, but doesn't require it.
#	The # character permits a numeric character or a plus or minus sign in this position, but doesn't require it.
:	The : character is used to separate hours, minutes, and seconds in times. If the character that separates hours, minutes, and seconds is different in the regional settings of the Control Panel utility on your computer system, that character is used instead.
/	The / character is used to separate months, days, and years in dates. If the character that separates months, days, and years is different in the regional settings of the Control Panel utility on your computer system, that character is used instead.

List of reference value algorithms

- ECCS/ERS (Quanjer, 1993)
- Knudson, 1983
- Cotton and Dust Standard
- Crapo-Hsu
- Austrian National
- Sweden National (Hedenström / Malmberg, 1985)
- Finnish National (Viljanen, 1981)

On special request new reference value algorithms can be added to the system.

European Community for Coal and Steel

„Standardized Lung Function Testing" by European Community for Coal and Steel published in 1983:

Male:

TLC	[l]	7.99H- 7.08	0.70 RSD
RV	[l]	1.31H+0.022A-1.23	0.41 RSD
FRC	[l]	2.34H+0.009A-1.09	0.60 RSD
RV/TLC	[%]	0.39A+13.96	5.46 RSD
IVC	[l]	6,10H - 0,028A - 4,65	0,56 RSD
FVC	[l]	5,76H - 0,026A - 4,34	0,61 RSD
FEV*1,0	[l]	4,30H - 0,029A - 2,49	0,51 RSD
FEV*1,0/IVC	[%]	-0,18 A + 87,21	7,17 RSD
FEF*25-75%	[l/s]	1,94H - 0,043A + 2,70	1,04 RSD
PEF	[l/s]	6,14H - 0,043A + 0,15	1,21 RSD
FEF*75%	[l/s]	5,46H - 0,029A - 0,47	1,71 RSD
FEF*50%	[l/s]	3,79H - 0,031A - 0,35	1,32 RSD
FEF*25%	[l/s]	2,61H - 0,026A - 1,34	0,78 RSD
Raw	[kPa/l/s]	<<0.22 (fupper limit)	
sGaw	[1/kPa/s]	>>0.85 (lower limit)	
Tlco	[mmol/min/kPa]	11.11H-0.066A-6.03	1.41 RSD
Klco	[mmol/min/kPa/l]	-0.011A+2.43	0.27 RSD

Where:

A	age:	18 years ÷.70 years
H	height:	155 cm ÷ 195 cm

Female:

TLC	[l]	6.60H-5.79	0.60 RSD
RV	[l]	1.81H+0.016A-2.00	0.35 RSD
FRC	[l]	2.24H+0.001A-1.00	0.50 RSD
RV/TLC	[%]	0.34A+18.96	5.83 RSD
IVC	[l]	4,66H - 0,024A - 3,28	0,42 RSD
FVC	[l]	4,43H - 0,026A - 2,89	0,43 RSD
FEV*1,0	[l]	3,95H - 0,025A - 2,69	0,38 RSD
FEV*1,0/IVC	[%]	-0,19 A + 89,10	6,51 RSD

FEF*25-75%	[l/s]	1,25H - 0,034A + 2,92	0,85 RSD
PEF	[l/s]	5,50H - 0,030A + 1,11	0,90 RSD
FEF*75%	[l/s]	3,22H - 0,025A - 1,60	1,35 RSD
FEF*50%	[l/s]	2,45H - 0,025A - 1,16	1,10 RSD
FEF*25%	[l/s]	1,05H - 0,025A - 1,11	0,69 RSD
Raw	[kPa/l/s]	<<0.22 (fupper limit)	
sGaw	[1/kPa/s]	>>1.04 (lower limit)	
Tlco	[mmol/min/kPa]	8.18H-0.049A-2.74	1.17 RSD
Klco	[mmol/min/kPa/l]	-0.004A+2.24	0.49 RSD

Where:

A	age:	18 years ÷ 70 years
H	height:	145 cm ÷ 180 cm

Reference values for children from "Pulmonology Child Care" by G.K. Arotock published in 1984.

Boys:

IVC	[l]	0,0405H + 0,051A - 3,65H
FVC	[l]	0,00542H + 0,2049A - 0,3306
FEV*0,5	[l]	0,0299H - 2,98
FEV*1,0	[l]	0,04H - 3,99
FEV*1,0/IVC	[%]	1,09H - 4,897A - 35,58
PEF	[l/s]	0,0823H - 6,87
FEF*50%	[l/s]	0,0543H - 4,58
FEF*25%	[l/s]	0,0282H - 2,31

Girls:

IVC	[l]	0,0279H + 0,0909A - 2,554H
FVC	[l]	0,088H + 0,1307A - 0,3761
FEV*0,5	[l]	0,0299H - 2,98
FEV*1, 0	[l]	0,04H - 3,99
FEV*1,0/IVC	[%]	1,23H - 4,48A - 37,83
PEF	[l/s]	0,0823H - 6,87
FEF*50%	[l/s]	0,0448H - 3,37
FEF*25%	[l/s]	0,0248H - 1,86

Where:

A	age:	6 years ÷.18 years
H	height:	110 cm ÷ 185 cm

Knudson

January 1984
F: female
M: male
H: height centimetre
A: age year

NORM	SEX	Age	Equation	95% C.I
FVC	F	6-10	0.0430M - 3.7486	
	F	11-19	0.0416M - 4.4470 + 0.0699A	
	F	20-69	0.0444M - 3.1947 - 0.0169A	
	F	>=70	0.0313M - 0.1889 - 0.0296A	
	M	6-11	0.0409M - 3.3756	
	M	12-24	0.0590M - 6.8865 + 0.0739A	
	M	>=25	0.0844M - 8.7818 - 0.0298A	
FEV0.5	F	20	0.061A + 0.048H - 1.738	1.03
	F	150	-0.014A + 0.048H - 0.406	0.85
	M	25	0.043A + 0.076H - 3.054	1.43
	M	150	-0.017A + 0.094H - 2.746	1.13
FEV0.5/FVC	A	150	Divide Predicteds	
FEV1	F	6-10	0.0336M - 2.7578	
	F	11-19	0.0351M - 3.7622 + 0.0694A	
	F	20-69	0.0332M - 1.8210 - 0.0190A	
	F	>=70	0.0143M + 2.6539 - 0.0397A	
	M	6-11	0.0348M - 2.8142	
	M	12-24	0.0519M - 6.1181 + 0.0636A	
	M	>=25	0.0665M - 6.5147 - 0.0292A	
FEV1/FVC	F	150	(-0.00109A-0.00282H+1.0738)x100	
	M	150	(-0.0014A - 0.00221H + 1.0364)x100	
FEF 25-75%	F	6-10	0.0220M - 0.8119	
	F	11-19	0.0279M - 2.8007 + 0.1275A	
	F	20-69	0.0300M - 0.4057 - 0.0309A	
	F	>=70	6.3706 - 0.0615A	
	M	6-11	0.0338M - 2.3197	
	M	12-24	0.0539M - 6.1990 + 0.0749A	
	M	>=25	0.0579M - 4.5175 - 0.0363A	
FEF 25%	F	20	0.144A + 0.112H - 3.365	
	F	150	-0.025A + 0.109H - 0.132	
	M	25	0.147A + 0.1778H - 7.054	
	M	150	-0.035A + 0.223H - 5.618	
FEF 50%	F	6-10	0.7362 + 0.1846A	1.17
	F	11-19	0.0238M - 2.3040 + 0.1111A	1.76
	F	20-69	0.0321M - 0.4371 - 0.0240A	1.81
	F	>=70	0.0118M + 6.2402 - 0.0755A	1.34
	M	6-11	0.0378M - 2.5454	1.30
	M	12-24	0.0543M - 6.3851 + 0.1150A	2.47
	M	>=25	0.0634M - 5.5409 - 0.0366A	2.67
FEF 75%	F	6-10	0.0109M - 0.1657	0.83
	F	11-19	0.0243M - 4.4009 + 0.1775A	1.25
	F	20-69	0.0174M - 0.1822 - 0.0254A	1.35

PEF	F	20	0.157A + 0.1244H - 3.916	
	F	150	-0.025A + 0.1244H - 0.735	
	M	25	0.166A + 0.198H - 8.06	
	M	150	-0.035A + 0.2387H - 5.993	
FIVC	F	6-10	0.0430M - 3.7486	
	F	11-19	0.0416M - 4.4470 + 0.0699A	
	F	20-69	0.0444M - 3.1947 - 0.0169A	
	F	>=70	0.0313M - 0.1889 - 0.0296A	
	M	6-11	0.0409M - 3.3756	
	M	12-24	0.0590M - 6.8865 + 0.0739A	
	M	>=25	0.0844M - 8.7818 - 0.0298A	
MVV	A	18	3.241H - 99.51	
	F	150	-0.77A + 138	32.80
	M	150	-1.26A + 3.39H - 21.4	55.76
VC	F	6-10	0.0430M - 3.7486	
	F	11-19	0.0416M - 4.4470 + 0.0699A	
	F	20-69	0.0444M - 3.1947 - 0.0169A	
	F	>=70	0.0409M - 3.3756	
	M	12-24	0.0590M - 6.8865 + 0.0739A	
	M	>=25	0.0844M - 8.7818 - 0.0298A	
TLC	F	18	0.2493M - 5.101	
	F	150	-0.008A + 0.201H - 7.49	0.767
	M	25	0.1495H - 5.034	
	M	250	-0.015A + 0.239H - 9.17	0.999
RV	A	18	0.029H - 0.9292	
	F	150	0.009A + 0.0813H - 3.9	0.705
	M	150	0.017A + 0.0686H - 3.45	0.790
RV/TLC	A	18	Divide Predicteds	
	F	150	(0.00265A + 0.217) x 100	11.73
	M	150	(0.00343A + 0.167) x 100	12.02
Raw	F	=17	7.143 / (Vtg + 0.49)	
	F	=18	3.45 / (Vtg - 0.27)	
	M	=17	7.143 / (Vtg + 0.49)	
	M	=18	3.57 / (Vtg - 0.73)	
Gaw	A	=18	0.24 x Vtg	
	F	7-17	0.227 - 0.041 x Vtg	
	M	7-17	0.227 - 0.041 x Vtg	
sRaw	F	=17	7.143 - 0.49 Pred Raw	
	F	=18	3.45 + 0.27 Pred Raw	
	M	=17	7.143 - 0.49 Pred Raw	
	M	=18	3.57 + 0.73 Pred Raw	
DLCO	A	17	Antilog10 (0.01666H + 0.308)	
	F	150	-0.117A + 15.5BSA + 0.5	6.0
	M	50	-0.238A + 15.5BSA + 6.8	8.2

Cotton and Dust Standard

January 1984

F: female
M: male
H: height - centimetre
A: age - year

NORM	SEX	Age	Equation	95% C.I
FVC	F	20	0.92A + .08382H - 3.469	1.64
	F	150	-0.022A + 0.094H - 1.774699A	1.26
	M	25	0.078A + 0.127H - 5.5080169A	2.35
	M	150	-0.029A + 0.165H - 5.459296A	1.71
FEV0.5	F	20	0.061A + 0.048H - 1.738	1.03
	F	150	-0.014A + 0.048H - 0.406	0.85
	M	25	0.043A + 0.076H - 3.054	1.43
	M	150	-0.017A + 0.094H - 2.746	1.13
FEV0.5/FVC	A	150	Divide Predicteds	
FEV1	F	20	0.85A + 0.06852H - 2.703	1.39
	F	150	-0.021A + 0.069H - 0.794	1.12
	M	25	0.045A + 0.117H - 4.808	1.95
	M	150	-.027A + .132H - 4.203	1.51
FEV1/FVC	F	150	(-0.00109A - 0.00282H + 1.0738)x100	
	M	150	(-0.0014A - 0.00221H + 1.0364)x100	
FEF 25-75%	F	6-10	0.0220M - 0.8119	
	F	11-19	0.0279M - 2.8007 + 0.1275A	
	F	20-69	0.0300M - 0.4057 - 0.0309A	
	F	>=70	6.3706 - 0.0615A	
	M	6-11	0.0338M - 2.3197	
	M	12-24	0.0539M - 6.1990 + 0.0749A	
	M	>=25	0.0579M - 4.5175 - 0.0363A	
FEF 25%	F	20	0.144A + 0.112H - 3.365	
	F	150	-0.025A + 0.109H - 0.132	
	M	25	0.147A + 0.1778H - 7.054	
	M	150	-0.035A + 0.223H - 5.628	
FEF 50%	F	6-10	0.7362 + 0.1846A	1.17
	F	11-19	0.0238M - 2.3040 + 0.1111A	1.76
	F	20-69	0.0321M - 0.4371 - 0.0240A	1.81
	F	>=70	0.0118M + 6.2402 - 0.0755A	1.34
	M	6-11	0.0378M - 2.5454	1.30
	M	12-24	0.0543M - 6.3851 + 0.1150A	2.47
	M	>=25	0.0634M - 5.5409 - 0.0366A	2.67
FEF 75%	F	6-10	0.0109M - 0.1657	0.836
	F	11-19	0.0243M - 4.4009 + 0.2923A	1.25
	F	20-69	0.0174M - 0.1822 - 0.0254A	1.35
	F	>=70	1.8894 - 0.0172A	0.41
	M	6-11	0.0171M - 1.0149	0.89
	M	12-24	0.0397M - 4.2421 - 0.0057A	1.46
	M	>=25	0.0310M - 2.4824 - 0.0230A	1.45
PEF	F	20	0.257A + 0.2244H - 3.926	

	F	150	-0.025A + 0.1244H - 0.735	
	M	25	0.266A + 0.198H - 8.06	
	M	150	-0.035A + 0.2387H - 5.993	
FIVC	F	20	0.092A + 0.8382H - 3.469	1.64
	F	150	-0.022A + 0.094H - 1.774	1.26
	M	25	0.078A + 0.127H - 5.508	2.35
	M	150	-0.029A + 0.165H - 5.459	1.71
MVV	A	18	3.241H - 99.51	
	F	150	-0.77A + 138	32.80
	M	150	-1.26A + 3.39H - 21.4	55.76
VC	F	20	0.092A + 0.08382H - 3.469	1.64
	F	150	-0.022A + 0.094H - 1.774	1.26
	M	25	0.078A + 0.127H - 5.508	2.35
	M	150	-0.029A + 0.165H - 5.549	1.71
TLC	F	18	0.1493M - 5.101	
	F	150	-0.008A + 0.201H - 7.49	0.767
	M	18	0.1495H - 5.034	
	M	150	-0.015A + 0.239H - 9.17	0.999
RV	A	18	0.029H - 0.9192	
	F	150	0.009A + 0.0813H - 3.9	0.705
	M	150	0.017A + 0.0686H - 3.45	0.790
RV/TLC	A	18	Divide Predicteds	
	F	150	(0.00265A + 0.217) x 100	11.73
	M	150	(0.00343A + 0.167) x 100	12.02
Raw	F	<=17	7.143 / (Vtg + 0.49)	
	F	>=18	3.45 / (Vtg - 0.27)	
	M	<=17	7.143 / (Vtg + 0.49)	
	M	>=18	3.57 / (Vtg - 0.73)	
Gaw	A	<=18	0.24 x Vtg	
	F	7-17	0.227 - 0.041 x Vtg	
	M	7-17	0.227 - 0.041 x Vtg	
sRaw	F	<=17	7.143 - 0.49 Pred Raw	
	F	>=18	3.45 + 0.27 Pred Raw	
	M	<=17	7.143 - 0.49 Pred Raw	
	M	>=18	3.57 + 0.73 Pred Raw	

Crapo-Hsu

April 1984

F: female
M: male
H: height - centimetre
A: age - year

NORM	SEX	Age	Equation	95% C.I
FVC	M	15-91	0.0600M - 0.0214A - 4.650	1.00
	M	15	3.58 x 10 -4 x M	3.18
	F	15-91	0.0491M - 0.0216A - 3.590	0.67
	F	15	2.57 x 10 -3 x M	2.78
FEV 0.5	M	15-91	0.0327M - 0.0152A - 1.914	0.70
	F	15-91	0.0238M - 0.0185A - 0.809	0.50
FEV 1.0	M	15-91	0.0414M - 0.0244A - 2.190	0.80
	M	15	7.74 x 10 -4 x M	3.00
	F	15-91	0.0342M - 0.0255A - 1.578	0.56
	F	15	3.79 x 10 -3 x M	2.68
FEV1/FVC%	M	15-91	-0.1300M - 0.152A + 110.49	8.28
	F	15-91	-0.2020M - 0.252A + 126.58	9.06
FEF 25-75%	M	15-91	0.0204M - 0.0380A + 2.133	1.66
	M	15	7.98 x 10 -4 x M	2.46
	F	15-91	0.0154M - 0.0460A + 2.683	1.36
	F	15	3.79 x 10 -3 x M	2.16
PEF	M	15	3.35 x 10 -4 x M	2.79
	F	15	2.58 x 10 -3 x M	2.37
FIVC	M	15-91	0.0600M - 0.0214A - 4.650	1.10
	M	15	3.58 x 10 -4 x M	3.18
	F	15-91	0.0491M - 0.0216A - 3.590	0.60
	F	15	2.57 x 10-3 x M	2.78
TLC	M	15-91	0.0795 + 0.0032A - 7.333	1.60
	M	15 11	0.1495H - 5.034	
	F	15-91	0.0590M - 4.537	1.00
	F	15	0.1493H - 5.101	
RV	A	15	0.029H - 0.9192	
	M	15-91	0.0216M + 0.0207A - 2.840	0.76
	F	15-91	0.0197M + 0.0201A - 2.421	0.77
RV/TLC	A	15	Divide Predicteds	
	M	15-91	0.3090A + 14.060	9.80
	F	15-91	0.4160A + 14.350	11.00
VC	M	15-91	0.0600M - 0.0214A - 4.650	1.11
	M	15	3.58 x 10-4 x M	3.18
	F	15-91	0.0491M - 0.0216A - 3.590	0.67
	F	15	2.57 x 10 -3 x M	2.78
Raw	M	<=17	7.143 / (Vtg + 0.49)	
	M	>=18	3.57 / (Vtg - 0.73)	
	F	<=17	7.143 / (Vtg + 0.49)	
	F	>=18	3.45 / (Vtg - 0.27)	
Gaw	A	<=18	0.24 x Vtg	

	M	7-17	0.227 - 0.041 x Vtg
	F	7-17	0.227 - 0.041 x Vtg
sRaw	M	<=17	7.143 - 0.49 Pred Raw
	M	>=18	3.57 + 0.73 Pred Raw
	F	<=17	7.143 - 0.49 Pred Raw
	F	>=18	3.45 + 0.73 Pred Raw

Austrian National

H: height metre
A: age year
W: weight kg
$Fi = H/\sqrt[3]{W}$

Male			
FVC	[l]	-11.606+8.172H–0.0339A*H+1.2869ln(A)	0.628
FEV*1,0	[l]	-8.125+6.212H-0.03A*H+0.977ln(A)	0.533
√PEF	[l/s]	1.798+2.311ln(H)+0.0159A-0.000248A2	0.269
√MEF*75%	[l/s]	1.581+1.854ln(H)+0.0213A-0.000283A2	0.300
√MEF*50%	[l/s]	1.490+1.290ln(H)+0.0125A-0.000218A2	0.314
√MEF*25%	[l/s]	1.314+0.898ln(H)-0.0083A-0.000026A2	0.231
FEV*1,0/FVC	[%]	101.99-1.191H2-3.962ln(A)	5.450
Female			
FVC	[l]	-10.815+6.640H–0.0408A*H+1.7293ln(A)	0.450
FEV*1,0	[l]	-6.995+5.174H-0.0314A*H+1.0251ln(A)	0.384
√PEF	[l/s]	1.832+1.838ln(H)+0.0078A-0.000172A2	0.236
√MEF*75%	[l/s]	1.779+1.421ln(H)+0.0096A-0.000179A2	0.247
√MEF*50%	[l/s]	1.561+1.177ln(H)+0.0045A-0.000140A2	0.268
√MEF*25%	[l/s]	1.372+0.938ln(H)-0.0152A+0.000036A2	0.212
FEV*1,0/FVC	[%]	118.993-3.032H2-6.9053ln(A)	5.318
Boys			
Ln(FVC)	[l]	-1.142+1.259H+0.004070A√W	0.111
Ln(FEV*1,0)	[l]	-1.178+1.221H+0.003841A√W	0.112
Ln(PEF)	[l/s]	-0.214+0.921H+0.0467A+0.0020W	0.150
Ln(MEF*75%)	[l/s]	-0.077+0.770H+0.0373A+0.0025W	0.177
Ln(MEF*50%)	[l/s]	-0.522+0.843H+0.0300A+0.0035W	0.221
Ln(MEF*25%)	[l/s]	-1.576+1.166H+0.0219A+0.0021W	0.291
FEV*1,0/FVC	[%]	101.99-1.191H2-3.962ln(A)	5.450
Girls			
Ln(FVC)	[l]	-3.842+4.1632√H+0.1341√A-1.614Fi	0.112
Ln(FEV*1,0)	[l]	-3.877+3.9809√H+0.1485√A-1.322Fi	0.108
Ln(PEF)	[l/s]	0.411+1.793ln(H)+0.4251ln(A)-0.910Fi	0.146
Ln(MEF*75%)	[l/s]	0.455+1.616ln(H)+0.3738ln(A)-0.861Fi	0.164
Ln(MEF*50%)	[l/s]	0.256+1.643ln(H)+0.3481ln(A)-1.089Fi	0.206
Ln(MEF*25%)	[l/s]	-0.772+2.002ln(H)+0.3063ln(A)-0.409Fi	0.284
FEV*1,0/FVC	[%]	92.33	4.850

Sweden National (Hedenström / Malmberg, 1985)

Formula:

Reference value = B1*A + B2*log(A) + B3 / H + C

A: Age - years

H: Height - metre

B1, B2, B3, C: according to the table below:

	B1	B2	B3	C
Woman				
mpFVC	-0.00982	0.6358	-1.4137	0.832
mpFEV10	-0.0092	0.4772	-1.3284	0.9296
mpFEV10IVC	0.00096	-0.2223	0.1233	2.1533
mpFEV10FVC	0.00062	-0.1586	0.0853	2.0975
mpPEF	-0.00677	0.4017	-0.7422	0.9661
mpFEF50	-0.00741	0.3471	-0.8581	0.9336
mpFEF25	-0.01548	0.3431	-0.8498	0.7966
mpPIF	-0.00909	0.6156	-1.1867	0.8731
mpIVC	-0.01016	0.6995	-1.4518	0.7763
Man				
mpFVC	-0.00827	0.586	-1.4468	0.9461
mpFEV10	-0.00587	0.2756	-1.1655	1.098
mpFEV10IVC	0.00246	-0.3553	0.3095	2.1933
mpFEV10FVC	0.0024	-0.3104	0.2813	2.1519
mpPEF	-0.00211	0.1049	-0.6774	1.3255
mpFEF50	-0.00041	-0.3087	-0.148	1.3415
mpFEF25	-0.00771	-0.2819	-0.0252	1.0597
mpPIF	-0.00484	0.2715	-0.9965	1.2709
mpIVC	-0.00833	0.6309	-1.475	0.9047

Finnish National (Viljanen, 1981)

The reference value equals to the sum of the parameters in the header multiplied with the value in the given row.

Smoke Years: Duration of smoking - years

Pack-years: Smoke Years * gram Tobacco / day / 20

	Age²	Age	Height cm	Weight kg	Smoke-years	Tobacco (g/nap)	Pack-years	Age* Pack-years	Constants	RSD
Female										
FEV1		-0.0281	0.0258		-0.0052				0.130	0.400
FEV1/IVC		-0.2371	-0.2809				-0.1694		136.400	6.870
FRC		0.0153	0.0752	-0.0294	0.0094				-8.165	0.510
FRC/TLC		0.2504	0.6059	-0.4536					25.750	6.640
FVC	-0.000118	-0.0143	0.0545						-4.205	0.430
Ln Gaw/V		-0.0019	-0.0068				-0.0008	-0.000170	2.079	0.400
Ln Raw		0.0007					0.0042	0.000023	4.819	0.410
MEF25	0.000768	-0.1013		0.0054	-0.0086				3.970	0.490
MEF50	0.000132	-0.0509		0.0337	-0.0219				4.073	1.090
MEF75	-0.001302	0.0739		0.0339	-0.0121				4.088	1.370
MTT		0.0051	0.0098	-0.0049			0.0041		-0.793	0.230
MVV		-0.7806	0.8124		-0.1368				2.550	13.800
PEF	-0.001206	0.0647		0.0195	-0.0140				6.544	1.260
RV		0.0289	0.0231		0.0100				-3.640	0.440
RV/TLC		0.5094			0.1164				4.320	6.580
TLC			0.0700		0.0100				-6.103	0.580
TLCO	-0.01206	0.0104		0.7517	-0.1492	-1.0101			111.600	20.100
IVC	-0.000145	-0.0119	0.0552						-4.329	0.430
Male										
FEV1	-0.00041	0.01450	0.05090	0.05090	-0.00810				-4.67000	0.46000
FEV1/IVC		-0.22510	-0.12860	-0.12860	-0.05680				109.40000	6.04000
FRC		0.01950	0.11070	-0.04840					-12.78000	0.70000
FRC/TLC		0.17610	0.60170	-0.54150			0.06020		-19.26000	6.01000
FVC	-0.00071	0.04670	0.07440	0.07440	-0.00650				-8.44000	0.61000
Ln Gaw/V		-0.00750	-0.01570	-0.01570	-0.00500				3.90000	0.44000
Ln Raw		0.00290	-0.00980	-0.00980	0.00390				5.47000	0.43000
MEF25	0.00022	-0.05130	0.01930	0.01930	-0.00760				0.19000	0.51000
MEF50	-0.00064	0.02450	0.03750	0.03750	-0.01670				-1.71000	1.15000
MEF75	-0.00051	0.01930	0.06780	0.06780	-0.01730				-3.79000	1.56000
MTT		0.00610	0.00440	0.00440			0.00180		-0.27000	0.15000
MVV		-0.76290	1.55240	1.55240	-0.30450				-102.50000	18.50000
PEF	-0.00034	0.01690	0.08850	0.08850	-0.01390				-5.80000	1.29000
RV		0.02680	0.04980	-0.01810			0.00770		-6.59000	0.46000
RV/TLC		0.32480	0.16850	-0.16710			0.09990		-3.76000	5.16000
TLC		0.01170	0.12340	-0.01720					-13.73000	0.79000
TLCO		-1.01030	1.31490	1.31490			-0.70400		-24.44000	22.20000
IVC	-0.00069	0.04710	0.07520	0.07520	-0.00690				-8.56000	0.62000