

Medikro Spirometer

User Manual



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Introduction



1 Introduction

Medikro Spirometer

User Manual



We all at Medikro Oy wish to thank you for purchasing the Medikro spirometer with Medikro Spirometry Software. We trust it will serve you well. In order to understand better the spirometer system and get the most out of it, we encourage you to study this manual in detail.

This document is intended for clinical professionals performing pulmonary function testing. This manual explains the basics on how the user can properly perform testing procedures using the Medikro spirometer and software.

1.1 About this manual

Note: Some features are only available in certain editions of the Medikro Spirometry Software.

Before testing, users should make sure that they are familiar with the measurements and clinical significance of spirometry test.

Before performing spirometrical studies, the user must know

- how to coach the patient during the measurement procedure
- how to recognize acceptable waveforms from measurements

Hospital staff must have the skills for maintenance and servicing of computer controls/platforms. We recommend that users attend a certified spirometry-training course. This manual is only intended as a guide and should not be used for training purposes.

Before using the spirometer, all users and technicians must read and understand this manual. It is the user's responsibility to follow the safety rules to protect the patients and users. Before using this product, please read all safety warnings provided in this document.

Administrative users should also read Medikro Administration Tool user manual.

If necessary, the electronic version of the user manual can be downloaded from Medikro WWW webpage (eSupport). On user request the user manual can also be delivered in paper form. To be able to download the user manual you must first register to eSupport.

1.2 Terminology, Acronyms and Abbreviations

Table: Terminology, acronyms and abbreviations

Term	Description
ATS	American Thoracic Society
BMI	Body Mass Index
ERS	European Respiratory Society
FIVC	Forced Inspiratory Vital Capacity
FVC	Forced Vital Capacity
FV	Flow Volume
GUI	Graphical User Interface
HIS	Hospital Information System
MVV	Maximum Voluntary Ventilation
Pre	Basal research phase
Post	Bronchodilatation research phase
Representative result	Best result from measurements
RMA	Return Material Authorisation
Phase	Measurement mode (Pre- and Post-phase)
TV	Tidal Volume
SVC	Slow Vital Capacity
VT	Volume Time
Session, study	Medikro Spirometry Software version 4.0 starts to use English term "study" instead of "session".

1.3 Symbols

The following symbols may appear on the spirometer components, on the packaging, on the shipping container, or in this manual.

Shipping, Storing, and Environment symbols:



Single use



Expiration date

	Handle with care
	Temperature limitation
	Keep away from moisture or rain
	Stacking limitation
	This side up
	Keep away from sunlight
	TYPE B APPLIED PART according to EN/IEC 60601-1. APPLIED PART complying with the specified requirements of this standard to provide protection against electric shock, particularly regarding allowable PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT.
	TYPE BF APPLIED PART according to EN/IEC 60601-1. APPLIED PART complying with the specified requirements of this standard to provide a higher degree of protection against electric shock than that provided by TYPE B APPLIED PARTS
IP20	Enclosure Degree of Protection against Foreign Bodies and Moisture. IP20 = Protected against solid foreign objects of 12.5 mm diameter and greater + Not protected against moisture.
	This symbol indicates that this device shall be disposed of according to the European Union Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE). If the device is contaminated, the directive does not apply (FOR EU ONLY).
	Manufacturer
	Date of manufacture
	Global Trade Item Number can be used by a company to uniquely identify all of its trade items.
	Indicates the manufacturer's reference number so that the medical device can be identified.
	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Unique Device Identifier (UDI). UDI is needed in case an incident notification is reported to competent authority. Software UDI can be found from the software About -window.



LOT number



Refer to instruction manual



Operating instructions



Radio frequency (RF)



Humidity limitation



Pressure limitation



Prescription device



Follow instructions for use



Direct current (power supply)



Class II equipment (power supply)

Documentation symbols:

WARNING Indicated situation or practices that, if continued or not corrected immediately, could lead to illness, injury, or death.



CAUTION Indicated situation or practices that, if continued or not corrected immediately, could damage the equipment.

Certification symbols:

This CE marking shows compliance/conformity of this product with Regulation (EU) 2017/745. 0537 indicates manufacturer's notified body under Medical Device Regulation (EU) 2017/745., Eurofins Expert Services, Kivimiehentie 4, FI-02150 Espoo, FINLAND



The CSA mark indicates that the product has been tested and certified to meet applicable standards for medical electrical products. Adjacent indicators 'C' and 'US' indicate that the product has been manufactured to the requirements of both Canadian and U.S. Standards.

1.4 Necessary Computer Skills

The following basic computer skills are required:

- You are capable of using Windows-based applications.
- You are familiar with the basic operations of Windows.

In case you have problems concerning your own PC, contact your local Administrator. In case you have any technical questions or problems concerning the Medikro Spirometry Software, see chapter [Troubleshooting](#) for immediate assistance. Customer service and contact information is listed in chapter [Warranty & Service](#).

1.5 Using the Spirometer Safely

Before using the spirometer, you must read and understand the following safety-related information. For information about contraindications, see chapter [Contraindications](#).

Warnings

A warning statement in this guide identifies a condition or practice which could lead to patient injury, illness, or death. The user shall adhere to warnings in order to ensure a safe and reliable performance of the system.



Data reflecting the patient's physiological condition: Data should not be used as a sole means for determining the patient diagnosis.



Misdiagnosis: It is the physician's responsibility to ensure that spirometry tests are properly administered, evaluated, and interpreted.



Patient is light-headed, dizzy, or faints during a spirometry effort: Monitor the patient closely. If there is any reason for concern, stop the test and take appropriate action.



Cross contamination: Dispose the flow transducer and nose clips after the measurement. Do not clean the flow transducer or nose clip.



Disposable flow transducer change: Use rubber gloves when replacing the flow transducer and washing hands after touching the flow transducer.



It is the user's responsibility to ensure that the system hardware, IT network and IT security provide a necessary level to run the system as intended.



The PC (non-medical electrical equipment): Should be located outside the patient environment (reference IEC 60601-1). If it is necessary for the PC to be located within the patient environment, it is the user's responsibility to ensure that the system provides a level of safety compliant with IEC 60601-1.



Only a 60601-1 approved PC can be used within patient area. The PC shall have an earth leakage current under 100 μ A in normal condition and 500 μ A in single fault condition. If a non-medical PC is used, it shall be used outside the patient environment and it shall have an earth leakage current under 100 μ A in normal condition and 500 μ A in single fault condition.



Safety standard for non-medical electrical equipment: IEC 60950, or its general variants, and the use of an isolation transformer are

recommended.



Appropriate electromagnetic compatibility: The used PC should adhere to the appropriate electromagnetic compatibility (EMC) standard for non-medical electrical equipment (CISPR 32 (EN 55032) /35 (EN 55035) - FCC Part 15 - CE, or related national variants).



Make sure that the patient has followed the spirometry research guidelines before the research begins (some medications and stimulants might affect the spirometry results).



Do not operate in proximity of any equipment that has the potential to generate a sufficiently large electromagnetic field.



The Medikro spirometers needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided (see chapter [Guidance and Manufacture's Declarations](#)).



Portable and mobile radio frequency (RF) communications equipment can affect the Medikro spirometers.



The Medikro spirometer is intended for use by healthcare professionals only. The spirometer may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as re-orienting or relocating the Medikro spirometer or shielding the location.



The Medikro spirometer should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Medikro spirometer should be observed to verify normal operation in the configuration in which it will be used.



No modification of these equipments is allowed.



Do not perform any service activities while device is in use.

Cautions

A caution statement in this guide identifies a condition or practice, which could lead to equipment failure, equipment damage, or data loss.



Pressure tube and sensor cleaning: Do not clean the pressure tubing. Trapped moisture could affect its accuracy or damage the pressure sensor. Replace the pressure tubing when it becomes dirty.



Spirometer storage: Do not immerse any part of the spirometer in a cleaning liquid or sterilise it with hot water, steam, or air. When you put the spirometer away, store its pressure tubing in a basket or drawer or some other place that prevents compression or kinking. Keep the spirometer away from splashing fluids.



Calibration syringe cleaning: To clean the calibration syringe, only wipe its external surfaces with damp cloth. All maintenance and internal cleaning of the calibration syringe is done by Medikro.



Other parts and components: Use only parts and accessories supplied with the device and available through Medikro. The use of accessories other than those specified might degrade the performance of the device.



Adjust ambient settings before calibrating. If the ambient settings are not adjusted before calibration, the device will not be properly calibrated and could give false readings.



Learn the basic operational procedures before start using the device. The user should be familiar with the methods used in spirometry tests with patients. It is recommended that the user is trained in spirometry tests with patients by an association that is certified by a recognised organisation.



It is recommended to make frequent back-up copies of the result database to avoid database corruption or other data loss, in case your computer should suffer a loss of power or an unrecoverable error.



The end of the flow transducer must not be obstructed. Make sure that the patient does not obstruct the flow transducer with his/her fingers. This will cause erroneous measurement results.



Do not ignore software error or information messages. In case you do not understand the message, please take a screen capture of the message, and contact Medikro for more information.

1.6 User Responsibility

This product is designed to perform in compliance with the description contained in this manual and the accompanying labels and inserts, when assembled, operated, maintained, and repaired in accordance with the instructions provided.



The product should not be used if any of its parts are broken, worn, missing, incomplete, distorted, or contaminated. These parts should be replaced immediately.

If repairs or replacements are necessary, we recommend that you contact the Medikro service personnel. The user of the product is responsible for any malfunction resulting from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than Medikro Oy or our authorised service personnel.

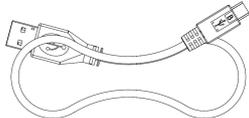
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of your Member State.

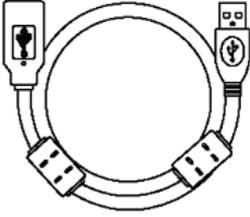
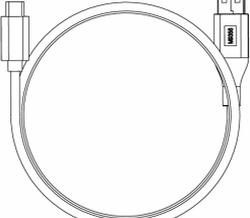
1.7 Product Overview

The components of the Medikro Spirometer:

Product Name	Product Code		Description
Medikro Spirometr	M9831		Medikro spirometers are intended to be

Product Name	Product Code		Description
y Software			used with Medikro Spirometry Software.
Software Upgrade	M9832		Use this product code to order an upgrade from your current Medikro Spirometry Software version to the latest version
Medikro Nose Clip, 100 pcs package.	M9227-100		Highly recommended during testing to avoid air leaks, unless a medical condition makes it uncomfortable or impractical to use. In that case, the clinician should record that the nose clip was not used.
Medikro Calibration Syringe, 3000 ml	M9474		For daily use, to calibrate Medikro Spirometer for accuracy.
Medikro SpiroSafe, 100 pcs or 90 pcs package.	M9256-100 M9256-SP-90		Disposable Flow Transducer. For single patient use only, to minimise the risk of cross contamination.
Medikro Ambi	M911		Mobile Ambient Condition Measuring Unit. Connects to the USB port of your PC. Measures the ambient conditions.
Medikro Nano Spirometer	M913		PC-based mobile spirometer for diagnostic spirometry. Connects to the USB port of your PC.

Product Name	Product Code		Description
Medikro Pro Spirometer	M915		PC-based laboratory spirometer for diagnostic spirometry. Connects to the USB port of your PC. Measures ambient conditions.
Medikro Pressure Tube	M926 4-200		Connects the M9256 flow transducers to the Medikro Pro, Nano and Primo spirometer sensor.
Medikro Primo Spirometer	M914		PC-based office spirometer for diagnostic spirometry. Connects to the USB port of your PC.
Medikro Pressure Tube with grip	M927 4		Connects the M9256 flow transducers to the Medikro Pro, Nano and Primo spirometer sensor. Patient grip for holding the flow transducer.
Medikro Grip, single packed 25 pieces	M912 27-25		Patient grip for holding the flow transducer.
Medikro Duo Spirometer	M920		Hand-held spirometer for screening and serial monitoring spirometry. Connects to your PC via USB cable or Bluetooth. Measures ambient conditions.
USB Cable	M935 4-180W		USB cable for Medikro Pro and Medikro Primo spirometers.

Product Name	Product Code		Description
USB Cable	M9353-50W		USB cable for Medikro Ambi.
USB Cable	M9356-180W		USB cable for Medikro Duo spirometer.

1.8 Warranty & Service

Warranty

All maintenance of products under warranty must be performed or accepted by Medikro Oy. Unauthorised maintenance will void the warranty. In addition, whether or not covered under warranty, any product repair must be performed exclusively by Medikro service personnel.

Service

If the product fails to function properly or if assistance, service, or replacement parts are required, contact Medikro Technical Support.

Contact information:

Medikro Oy
P.O.Box 54
FI-70101 Kuopio, FINLAND

Medikro Oy
Pioneerinkatu 3
FI-70800 Kuopio, FINLAND

 +358 17 283 3000

 www.medikro.com

Before contacting Medikro, it is helpful to attempt to reproduce the problem and to test all accessories to make sure that they are not the reason of the problem. For additional information, please contact us by filling in the technical support request form at www.medikro.com/eSupport and submit a ticket or search for ready-made answers on the Medikro Oy homepage (www.medikro.com).

When contacting Medikro, please provide the following information:

- Medikro Spirometry Software version number.
- Product name, model number, and description of the problem.
- The Product serial number and activation code.

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Medikro Oy

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Home page: www.medikro.com

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medikro@medikro.com

Business ID: 0288691-7

VAT no.: FI02886917

Domicile: Kuopio

-
- Contact information: name, address, and phone number.
 - Out of warranty repairs or parts order.
 - For ordering parts, the spare or replacement part number(s).

1.8.1 Repairs and Maintenance

If your product requires warranty, extended warranty, or non-warranty repair service, please call Medikro Technical Support. An authorised representative will help you solve the problem over web or email.

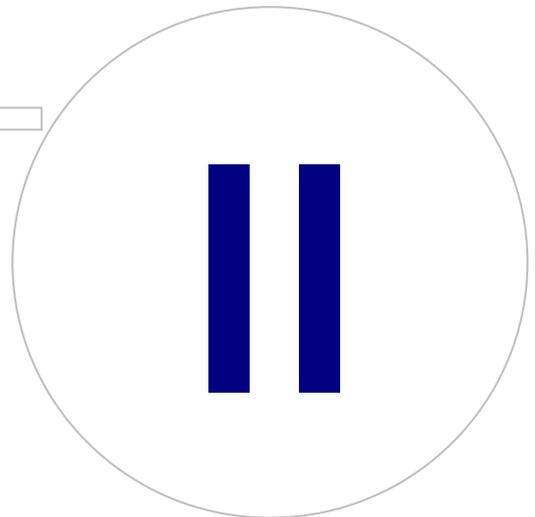
If a return cannot be avoided, the representative will record all necessary information and provide a Return Material Authorisation (RMA) number and return address. A Return Material Authorisation (RMA) number must be obtained before returning the product.

1.8.2 Medikro RMA Policy and Procedure

Before you send the Product to Medikro's service centre for repair, you must obtain a return authorisation number from Medikro to return the Product.

Check the latest RMA Policy and Procedure at www.medikro.com.

General Information



2 General Information

This manual covers the basic use of the Medikro Spirometry Software. The manual gives basic information about the following issues: using the software, programme settings, calibration, person and study management, measurement, analysing results, interpretation, final report and exiting the Medikro Spirometry Software. More technical and detailed information is given in the additional information sections. You can also find interesting tutorials and material at www.medikro.com/eSupport.

Release Information and Recommended System Requirements

You are most likely interested to know what is new in your Medikro Spirometry Software. The release information does not only cover this version but all versions released since the first one.

Click the link below to see

- recommended system requirements for the Medikro Spirometry Software,
- new features,
- enhancements and
- bug fixes.

Trademarks

Windows is a trademark of Microsoft Corporation, Redmond, WA, USA.

Internet Explorer is a trademark of Microsoft Corporation, Redmond, WA, USA.

Disclaimer

Our policy of continuous product improvement makes all Medikro instruments, accessories, brand names, specifications, product documentation and model availability subject to change without notice.

Certificates

Certificates and declaration of conformity are available at <https://medikro.zendesk.com/>

2.1 Getting the Most Out of This Manual

Typically, an operator will require information on new system installation and operation. The installation of the spirometer and related software, as well as the system setup, is described in the Installation Guide provided with the software. Also, the Medikro Administration tool user manual is provided for customising a system to meet your organisation's needs the best. We encourage you to study this User Manual and delivered tutorial material before you put the spirometer into clinical work. In addition, tutorials, manuals, and other material can be downloaded from www.medikro.com/eSupport. This option is only for registered Medikro Spirometry Software users.

2.2 Contraindications

The disposable flow transducers are clean but not sterile. Avoid placing the flow transducer over open wounds that are prone to infection. Other medical contraindications are not known, only the physical limitations of the patient.

Do not perform spirometry test if any of the following reasons apply to the patient. Relative contraindications to performing spirometry:



Hemoptysis of unknown (forced expiratory manoeuvre may aggravate the underlying condition).



Pneumothorax



Unstable cardiovascular status (forced expiratory manoeuvre may worsen angina or cause changes in blood pressure) or recent myocardial infarction or pulmonary embolus.



Recent myocardial infarction or pulmonary embolus.



Thoracic, abdominal, or cerebral aneurysms (danger of rupture because of increased thoracic pressure).



Presence of an acute disease process that might interfere with test performance (e.g., nausea, vomiting)



Recent eye (e.g., cataract), thoracic and abdominal surgery.



Chest and abdominal pain.

2.3 Important Considerations

The lifetime of the spirometry software is limited to the supported operating system versions (See release information). Medikro does not guarantee that the software operates as intended in other operating systems.

The Spirometer should not be used if any part of the equipment or system is known, or assumed to be, defective.

Check the pressure tube and replace it if it is leaking or unclean. It is recommended to change the pressure tube after 300 patients or four times a year.

Make a calibration check carefully with a calibration syringe as described in chapters [Calibration Check](#) (Medikro Duo) and [Calibration and Calibration Check](#) (Medikro Pro, Nano and Primo).

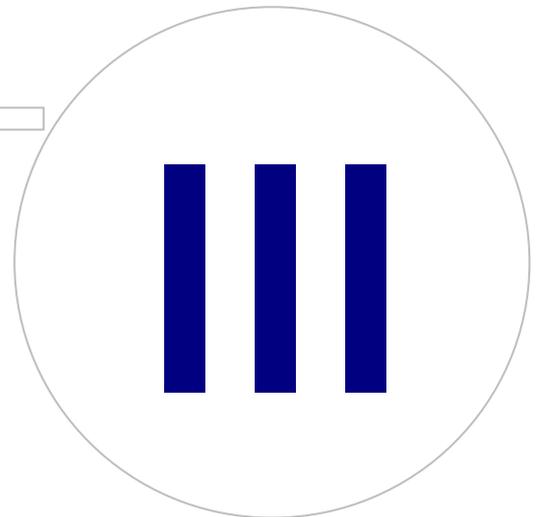
Note that there are no user-serviceable parts inside Medikro spirometers. Only perform routine cleaning and maintenance procedures specifically described in this user manual. Inspection and servicing of internal parts shall only be performed by Medikro service personnel.

2.4 Tutorial

Quick Instructions are provided with every Medikro Spirometry Software package. They contain a description of all procedures required before starting the spirometry measurements. The Quick

Instructions are a short guide for using Medikro spirometer. The instructions in the tutorial are used for explaining the basic steps when performing spirometrical studies. In addition, the guide documents can be downloaded from www.medikro.com/eSupport. This option is only for registered Medikro Spirometry Software users.

SpiroSafe Disposable Flow Transducers



3 SpiroSafe Disposable Flow Transducers

The Medikro spirometers use SpiroSafe disposable flow transducers. **Note:** Use the Calibration Code only with Medikro Spirometry Software.



Figure: M9256 SpiroSafe Disposable Flow Transducer.

Cautions:



Use the M9256 SpiroSafe disposable flow transducer with the following spirometers: Medikro Primo, Medikro Pro, Medikro Nano and Medikro Duo.

SpiroSafe disposable flow transducers are manufactured to high precision, and it is not necessary to calibrate the spirometer system with each flow transducer separately. The lot number is identified at the label of the flow transducer package.

3.1 Flow Transducer Operating and Safety

The SpiroSafe disposable flow transducers manufactured by Medikro use the screen type pneumotach principle. During production, the SpiroSafe disposable flow transducers are subjected to continuous and detailed monitoring to ensure reliable quality and then given a lot number. The SpiroSafe disposable flow transducer performance relies on the flow characteristics of the pneumotach screen.

Each SpiroSafe disposable flow transducer is inspected and measured. The basis of the measurement data assures the quality of the production lot.

Warnings:



The SpiroSafe disposable flow transducer is a Single-Use only product.



Do not wash the SpiroSafe disposable flow transducer. This increases the risk of cross contamination and significantly changes the measurement results. If the SpiroSafe disposable flow transducer is washed, Medikro cannot guarantee the measuring accuracy of the spirometry system.



The SpiroSafe disposable flow transducers are packaged as non-sterile.



Do not mix clean and used the SpiroSafe disposable flow transducers together.



Use a new, clean SpiroSafe disposable flow transducer for each patient.



Cover an opened SpiroSafe disposable flow transducer package.



Check that there are not defects or damage in the product package. Do not use in case package is damaged.

Cautions:



Calibrate the Spirometer according to the instructions in this manual.



Never calibrate the spirometer with a used SpiroSafe disposable flow transducer. This causes a risk of cross contamination through the calibration syringe.



Every time a new package of SpiroSafe disposable flow transducers is opened, check the production lot number or calibration code from the label attached on the outer surface of the package. If this lot number or calibration code differs from the one currently used, a new calibration code must be taken into use before resuming the testing. Using a wrong calibration code may produce inaccurate data.

3.2 Flow Transducer Installation Instruction (Pro, Primo and Nano)

Hold the SpiroSafe flow transducer and pressure tube connector as shown in the picture.



Figure: Disposable Flow Transducer Installation_1

Press the SpiroSafe flow transducer towards the pressure tube connector.



Figure: Disposable Flow Transducer Installation_2

Rotate the pressure tube connector $\frac{1}{4}$ turn clockwise.



Figure: Disposable Flow Transducer Installation_3

The SpiroSafe flow transducer is now ready to use.

3.3 Flow Transducer Installation Instruction (Duo)

Hold the SpiroSafe flow transducer connector towards the pneumatic connector of the device as shown in the picture.



Figure: Disposable Flow Transducer Installation_1

Press the SpiroSafe flow transducer towards the pneumatic connector of the device connector.



Figure: Disposable Flow Transducer Installation_2

Rotate the SpiroSafe flow transducer $\frac{1}{4}$ turn clockwise.



Figure: Disposable Flow Transducer Installation_3

The SpiroSafe flow transducer is now ready to use.

3.4 Disposal Instructions

Dispose of the flow transducer, the internal bag, and the external carton according to national or local laws or according to your facility’s disposal policy. All materials are recyclable or combustible. The product safety sheet is available, upon request, for each material.

GTIN-code: 06420099000554, 06420099000561, 06420099000578, 06420099000585, 06420099000608, 06420099000615

Materials: Flow Transducer: HDPE

Internal Bag: PELD

Single pack film: OPP

External Carton: Cardboard

3.5 Specifications

Specification	Description
Expected Lifetime (shelf life)	4 years from manufacturing date.
Storage and transportation Environment	Temperatures between -20 °C (-4 °F) and +50 °C (122 °F).
Operation Environment	Temperatures between +10 °C (50 °F) and +40 °C (104 °F).

Medikro Pro, Primo and Nano Spirometers



4 Medikro Pro, Primo and Nano Spirometers

Medikro Pro, Medikro Primo and Medikro Nano spirometers are used for performing diagnostic spirometry studies. These spirometers are intended to be used with Medikro Spirometry Software (see [Introduction to Medikro Spirometry Software](#))

4.1 Intended Use

Medikro Spirometer is a device that measures lung air volume and airflow rate for pulmonary disease diagnosis and screening. These measurements provide information about a patient's pulmonary function which may be compared with normal values or the patient's previous values.

The device is designed for

- adult and pediatric patients,
- hospital and clinic use only.

4.2 Connect with Medikro Spirometry Software

Medikro Pro and Medikro Primo

This Medikro spirometer can be connected to the computer via USB cable. USB cable is provided with the spirometer sales package. Plug the smaller connector (Micro USB-B) of the cable to the spirometer USB port, and the wider connector (USB-A) to the computer USB port.

Medikro Nano

Connect the spirometer directly to the computer USB port.

4.3 Calibration Code

Every time a new package of SpiroSafe disposable flow transducers is opened, check the production lot number or calibration code from the label attached on the outer surface of the package. If this lot number or calibration code differs from the one currently used, a new calibration code must be taken into use before resuming the testing. Using a wrong calibration code may produce inaccurate data.

To change the calibration code click the **Calibrate** button (see [Table: Medikro Measurements and Results Basic Buttons](#)) or select:

Device>Settings>Spirometry>Calibration code

Type the calibration code and press OK.

Tip: You can use a bar code reader to read the calibration code from the flow transducer package.

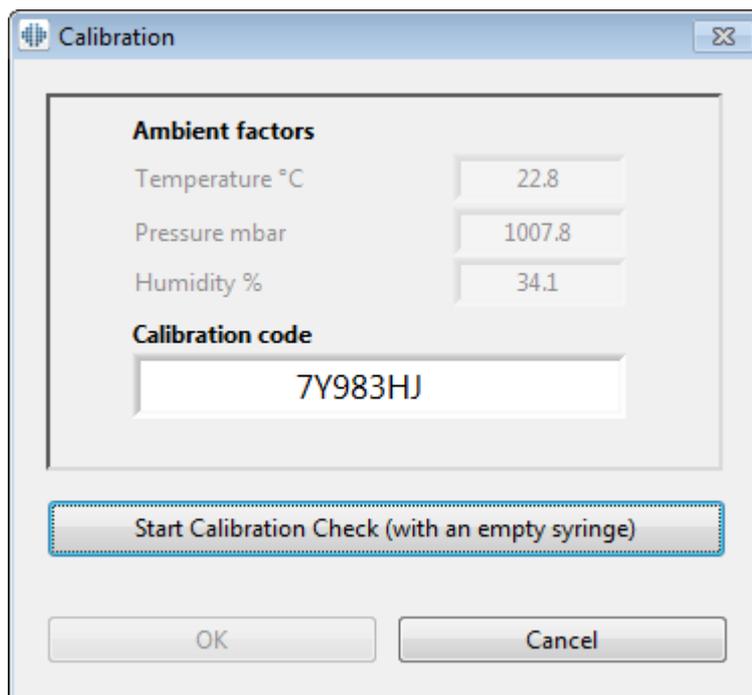


Figure: Calibration window

4.4 Ambient factors

The ambient conditions of the operating environment affect the results measured and calculated by the spirometer. Because of this, the room temperature, atmospheric pressure and relative humidity should be recorded and entered into the programme daily. To change the ambient factors, open the **Calibration** window (see [Figure: Calibration window](#)) by clicking the **Calibrate** button (see [Table: Medikro Measurements and Results Basic Buttons](#)) or select:

Device>Settings>General>Ambient factors

Adjust the ambient factors:

- Daily, and also if the factors change notably during the day.
- Before a calibration takes place.

Note! If the spirometer has built-in ambient unit or you have a separate ambient condition measurement unit, ambient factors are updated automatically and they can't be changed manually.

4.5 Calibration and Calibration Check

Medikro Pro, Medikro Nano and Medikro Primo spirometers use calibration free technology that allows precise and accurate spirometry testing without manual calibration. Calibration of the system is not needed for these devices. However, calibration check is recommended for Medikro Pro, Medikro Nano or Medikro Primo spirometers.

Calibration check forms an essential part of good laboratory practice. The calibration check should be done daily as outlined in the ATS and ERS recommendations. Typically, the calibration check is performed when the spirometer system is switched on.

The calibration check should always be repeated when starting to use a new lot of flow transducers. The calibration code must be given before the performance.

With the calibration check you can test if the system is accurate. The calibration check does not affect to calibration. Intelligence of the software compensates for changes in environment conditions automatically, so the calibration should be unnecessary.

Environment conditions (ambient temperature, pressure and humidity) are measured continuously, if you have Medikro Pro spirometer or Medikro Ambi device. There is no need for a new calibration check, even if environmental conditions change.

If your system has Medikro Nano or Medikro Primo without Medikro Ambi devices, the environment condition values should be updated manually, if there is a notable change in them. However, there is no need for a new calibration check.

▣ Additional information

Calibration log file

Using a calibration log file is recommended and ensures the reliability of your results. You can change the location of this file and other calibration settings as defined in chapter [Spirometry/Additional information](#).

4.5.1 Calibration Check Procedure and Acceptance

A spirometer connected to a PC will start to warm up immediately after Windows is started. This is a normal and general procedure for most high-precision measurement devices.



Before starting the actual measurements or calibration check, it is recommended to allow the spirometer device and calibration syringe to have a brief **warm-up period of a minimum of 5 minutes**, to reach a thermal equilibrium.

To perform a calibration check, click the **Calibrate** button (see [Table: Medikro Measurements and Results Basic Buttons](#)) or select:

Device>Calibrate

A 3000 ml Medikro Calibration Syringe (product code: M9474) is recommended. However, Medikro Spirometry Software allows the user to enter the volume of the calibration syringe leaving you an option to use other volumes for calibration as well.

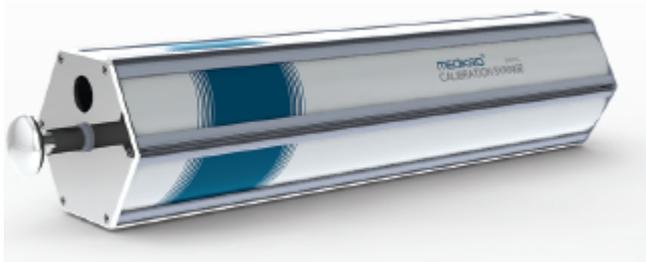


Figure: M9474 Calibration Syringe, 3000 ml.

Attach the spirometer with the flow transducer into your Calibration Syringe. Empty the syringe. Click the **Calibrate** button (see [Table: Medikro Measurements and Results Basic Buttons](#)). The program will instruct as follows:

Start Calibration Check (with an empty syringe).

After starting the calibration, the program will instruct:

Fill the syringe with one stroke.

The program will continue:

Empty the syringe with one stroke.

Perform at least 3 consecutive fill / empty cycles using a flow rate of about 6 L/s and after that click the “**Finish Calibration Check**” button. The program will show the result of calibration check compared to acceptance limit.

If the result is inside the acceptance limit, the compensation performs successfully. If the result is not inside the acceptance limit, redo the calibration check. If the result of the calibration check still fails, perform the calibration (see chapter [Calibration Procedure and Acceptance](#)).

4.5.2 Calibration Procedure and Acceptance

A spirometer connected to a PC will start to warm up immediately after Windows is started. This is a normal and general procedure for most high-precision measurement devices.



Before starting the actual measurements or calibration, it is recommended to allow the spirometer device to have a brief **warm-up period of a minimum of 5 minutes**, to reach a thermal equilibrium.

To calibrate the spirometer, click the **Calibrate** button (see [Table: Medikro Measurements and Results Basic Buttons](#)) or select:

Device>Calibrate

A 3000 ml Medikro Calibration Syringe (product code: M9474) is recommended. However, Medikro Spirometry Software allows the user to enter the volume of the calibration syringe leaving you an option to use other volumes for calibration as well.



Figure: M9474 Calibration Syringe, 3000 ml.

Attach the spirometer with the flow transducer into your Calibration Syringe. Empty the syringe. Click the **Calibrate** button (see [Table: Medikro Measurements and Results Basic Buttons](#)). The program will instruct as follows:

Start Calibration (with an empty syringe).

After starting the calibration, the program will instruct:

Fill the syringe with one stroke.

The program will continue:

Empty the syringe with one stroke.

Perform at least 3 consecutive fill / empty cycles using a flow rate of about 6 L/s and after that click the “Finish Calibration” button. The programme will show the gain before and after the calibration as well as the change in gain from the previous calibration. It will then ask you to accept the new calibration values by pressing OK.

Typically, the gain values during calibration are around 1.00. Should the spirometer system leak, the calibration be performed incorrectly, or should the operator use incorrect calibration files, the absolute gain values after the calibration may lie outside the acceptable gain range. In this case, the programme will instruct:

Gain after calibration is not within the 10 % range. Calibration is not accepted.

The default limit for calibration variation is 10 %, and it determines the acceptable range of gain values (range is calculated as follows: $1.0 \pm 10\% = 0.90 - 1.10$). The limit of calibration variation can be changed as explained in chapter [Spirometry/Additional information](#).

4.6 Specifications

Specification	Description
Measurement manoeuvres	TV, SVC, FVC, FIVC, FVC+FIVC and MVV including basal (PRE) and bronchodilatation (POST) phases
BTPS values	The values are expressed as BTPS values
Sensor Type	Pneumotach
Power Equipment	None, obtained from USB or Serial port
Power Input	(USB port) 5Vdc 100mA
Accuracy	Meets or exceed ATS (1994), ERS (1993) and ATS/ERS (2005)
Time Zero Determination	Backward extrapolation
Correction Factors	BTPS correction according to ambient conditions
Reproducibility	Meets or exceed ATS (1994), ERS (1993) and ATS/ERS (2005)
Flow Range	+ - 14 L/sec
Volume Range	0-14 L
Flow Resolution	1 mL/sec
Volume Resolution	1 mL

Flow Accuracy	± 10% or 0.17 L/sec
Volume Accuracy	± 2.5% or 0.05 L
Resistance	0.08kPa/L/sec at 14 L/sec (~ 0.15kPa/L/sec at 14 L/sec)
Sample Rate	Internal 800 Hz, external 100 Hz
Expected Lifetime	10 years
System requirements	See release information
Predicted values	For Prediction models included, see chapter Prediction Models . Additional prediction models can be added upon customer request.
Variables	102 Measurement variables (see chapter Additional information: Variables)
Quality checks	ATS Acceptability and ATS Reproducibility checks
Storage and transportation Environment	Temperatures between -20 °C (-4 °F) and +50 °C (122 °F). Relative humidity between 10% and 95% (non-condensing). Atmospheric Pressure of 500 hPa (mbar) to 1060 hPa (mbar).
Operation Environment	Temperatures between +10 °C (50 °F) and +40 °C (104 °F), Relative humidity between 15% and 90% (non-condensing), Atmospheric Pressure of 700 hPa (mbar) to 1060 hPa (mbar), Warm up period of 5 minutes.

4.7 Guidance and Manufacture's Declarations



The Medikro spirometers needs special precautions regarding EMC and needs to be installed and put into service according to the following EMC information provided. Portable and mobile RF communications equipment can affect the Medikro spirometers.

Additional information about:

- Electromagnetic emissions

Electromagnetic Emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
The Medikro spirometers are intended for use in the electromagnetic environment specified below. The customer or the user of the Medikro spirometers should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Medikro spirometers 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 Medikro spirometers are suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage 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	

☐ Electromagnetic immunity

Electromagnetic Immunity

Guidance and manufacturer's declaration - electromagnetic immunity			
The Medikro spirometers are intended for use in the electromagnetic environment specified below. The customer or the user of the Medikro spirometer 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 differential mode ±2 kV common mode	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on	<5 % UT (>95 % dip in UT) for 0,5 cycle	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Medikro

power supply input lines IEC 61000-4-11	<p>40 % UT (60 % dip in UT) for 5 cycles</p> <p>70 % UT (30 % dip in UT) for 25 cycles</p> <p><5 % UT (>95 % dip in UT) for 5 sec</p>		spirometers requires continued operation during power mains interruptions, it is recommended that the Medikro spirometers 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 UT is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity

The Medikro spirometers are intended for use in the electromagnetic environment specified below. The customer or the user of the Medikro spirometer 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 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Medikro spirometers, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \cdot \sqrt{P}$ $d = 1.2 \cdot \sqrt{P}$ 80 to 800MHz $d = 2.3 \cdot \sqrt{P}$ 800MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) and d is the
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	

			<p>recommended separation distance in meters (m).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^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 Medikro spirometers are used exceeds the applicable RF compliance level above, the Medikro spirometers should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Medikro spirometers.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Recommended separation distances between portable and mobile RF communications equipment and the Medikro spirometers

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

Rated maximum	Separation distance according to frequency of transmitter
---------------	---

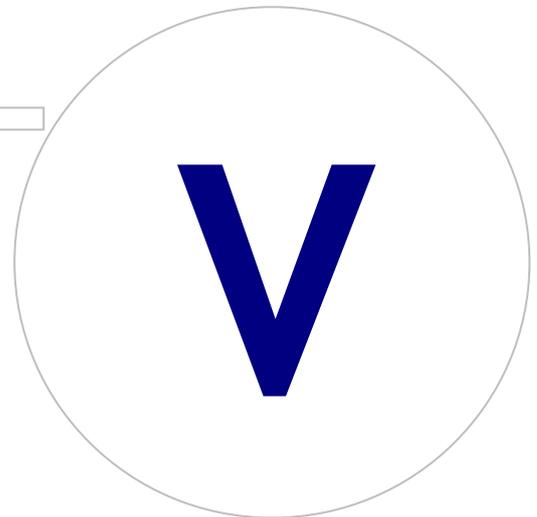
output power of transmitter W	m		
	150 KHz to 80 MHz $d = 1.2 \cdot \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \cdot \sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3 \cdot \sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

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

NOTE 1 At 80 MHz and 800 MHz, the 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.

Medikro Duo Spirometer



5 Medikro Duo Spirometer

Medikro Duo Spirometer is a hand-held device which can be used for screening or monitoring respiratory condition in order to evaluate the need for further diagnostic spirometry study. Medikro Duo is intended to be used with Medikro Spirometry Software (see [Introduction to Medikro Spirometry Software](#))

5.1 Intended Use

Medikro Spirometer is a device that measures lung air volume and airflow rate for pulmonary function testing. These measurements provide information about a patient's pulmonary function which may be compared with normal values or the patient's previous values.

The device is designed for

- adult and pediatric patients,
- hospital and clinic use only.

5.2 Overview of the Medikro Duo Interface



1. **Power button:** Turn the device on (short press) and off (long press). Short press also prevents device from shutting down automatically.
2. **Battery status:** Battery symbol indicates that the device is running out of battery. The arrow inside the battery symbol indicates that the battery is charging.
3. **Bluetooth:** Symbol indicates that the device is connected with PC via Bluetooth.

4. **Quality indicators:** Indicates lazy blow, early termination, cough and hesitation. In case the blow does not have any artifacts, a high peak curve is shown.*
5. **Attention:** Symbol indicates that blow quality problems have occurred.
6. **Reproducibility indicators:** When a breath meets the reproducibility criteria with the most representative breath, a connector is shown on the left of the breath indicator. When connector is missing, the reproducibility criteria are not fulfilled.*
7. **Breath indicators:** The three most representative breaths are represented as circles in ranking order. Check mark indicates that the blow does not have quality problems. Empty circle without check mark indicates that the blow has quality problems.*
8. **Numerical results:** Numerical results for measured variables.
9. **Reset:** Reset the device.
10. **Qi wireless charging area**

Note: Medikro Duo is intended to be used with Medikro Spirometry Software. It is recommended to examine breath quality and measurement results via Medikro Spirometry Software user interface.

* For more information about blow quality criteria see chapter [Blow Quality](#).

5.2.1 Date and Time

Date and time, shown on the device display when the device is powered off, are automatically synchronised to the computer time every time when device connection is established with Medikro Spirometry Software.

5.2.2 Tones

When device is powered on, 1 short beep is produced.

When device is powered off, 1 long beep is produced.

When device has not been operated for 110 seconds, 1 long beep is produced. The device will power off automatically in 10 seconds from the beep, if it is not operated.

When the battery capacity is running low, 1 long beep is produced every 10 minutes. Also, battery symbol appears on the device display.

5.3 Charging

Battery Capacity Indicator

When the device battery capacity is running low, the battery symbol appears on the device display and the device produces a tone.



Figure: Low battery capacity

When the battery is charging, the battery symbol shows a flashing arrow inside.



Figure: Battery charging

When the battery is full, the battery symbol disappears from the device display.

Charging via USB

USB cable is provided with the Medikro device. Plug the smaller connector (USB-C) of the cable to the device's USB port, and the wider connector (USB-A) to the power source's e.g. computer USB port.

Charging wirelessly

The device has an inbuilt interface for wireless charging. If you have a wireless battery charger and wish to charge the Medikro device wirelessly, follow the instructions of your wireless battery charger manufacturer.

Warnings:



Charge the device only with a Qi version 1.1 compatible wireless charger.



Charge the device only with a computer system specified by Medikro.



Use only power supply and USB cable provided by Medikro. Electric shock hazard if inappropriate equipment is used with the spirometer unit.

5.4 Battery Safety

This Medikro spirometer contains a rechargeable lithium polymer battery, which is non-removable by the operator. Leakage of ingredients contained within the battery, or the combustion products of the ingredients, can cause personal injury as well as damage to your Medikro spirometer. If battery leakage occurs, avoid contact with skin. If contact occurs, immediately wash thoroughly with soap and water. If liquid leaking from a battery pack comes into contact with your eyes, immediately flush thoroughly with water and see a doctor.

To avoid battery leakage:

- Do not expose the Medikro spirometer to excessive physical shock, vibration, or liquids.
- Do not disassemble, attempt to repair or deform the Medikro spirometer.

- Do not dispose the Medikro spirometer in a fire.

A dead battery may result if the Medikro spirometer is left uncharged or unused for a long period of a time.

If this occurs, charge the battery by connecting the Medikro spirometer to an external power source.

Warnings:



Electric shock hazard. Do not open the device or attempt repairs.



Do not try remove the battery. This can only be performed by qualified service personnel.

5.5 Cleaning

Recommended frequency of cleaning: Clean the outer surface area of Medikro spirometer after each patient use.

The following agents are compatible with the Medikro spirometer:

- 70 percent isopropyl alcohol
- 10 percent chlorine bleach solution

Note! Disinfect according to your facility's protocols and standards or local regulations.

Warnings:



Change the flow transducer for each patient.



Maintenance procedures must be implemented, or equipment failure and health hazards may result. Only qualified service personnel are allowed to repair the equipment.



Keep the outer surface area of the Medikro spirometer clean. Contaminated areas can spread diseases.

Cautions:



When cleaning the Medikro spirometer, avoid using cloths or solutions that include quaternary ammonium compounds (ammonium chlorides) or glutaraldehyde-based disinfectants.

5.6 Connect with Medikro Spirometry Software

This Medikro spirometer can be connected to the computer either via USB cable or via Bluetooth. Connection from the paired device to the Medikro Spirometry Software is automatically established. When multiple devices are paired with the operating computer, it is possible to select which device to use with Medikro Spirometry Software (See chapter [Select Device](#)).

Via USB

USB cable is provided with the spirometer sales package. Connect the Medikro spirometer with the USB cable to the computer. Plug the smaller connector (USB-C) of the cable to the spirometer USB port, and the wider connector (USB-A) to the computer USB port.

Via Bluetooth

Pair the Medikro spirometer to the operating computer as a Bluetooth device as instructed by your computer system manufacturer. In Windows operating system, pairing is usually done via Start > Settings > Devices > Bluetooth & other devices.

In Windows 10 operating system, the connection with Medikro Spirometry Software can be established without pairing the device.

5.7 Calibration Code

Every time a new package of SpiroSafe disposable flow transducers is opened, check the production lot number or calibration code from the label attached on the outer surface of the package. If this lot number or calibration code differs from the one currently used, a new calibration code must be taken into use before resuming the testing. Using a wrong calibration code may produce inaccurate data.

Note that the calibration code is saved in the device, and therefore has to be entered separately for each Medikro spirometer.

To change the calibration code:

Connect the Medikro spirometer to the operating computer.

Open the Medikro Persons and Studies study view either for a selected person or via Medikro Quick Test shortcut.

Type the new calibration code into the calibration code field.

Incorrect code is indicated with red colour. Accepted code is instantly saved in the device and the device is shown as connected.

Tip: You can use a bar code reader to read the calibration code from the flow transducer package.

5.8 Calibration Check

Medikro spirometers use calibration free technology that allows precise and accurate spirometry testing without manual calibration. However, it is recommended to verify the accuracy of the device on a regular basis.

Using a 3000 ml Medikro Calibration Syringe (product code: M9474) is recommended.



Figure: M9474 Calibration Syringe, 3000 ml.

Check that the spirometer is on FEV6 mode (The measurement mode can be changed in study view. See [Screening Study Data Entry](#)).

Attach the spirometer with the flow transducer into your Calibration Syringe. Turn the spirometer power on. Empty the syringe.

Fill the syringe with one stroke.

Empty the syringe with one stroke.

Emptying the syringe should last a maximum of 6 seconds.

Check the value of FEV6 variable. When 3000 ml Medikro Calibration Syringe is used, the FEV6 value should be between 2.9 and 3.1 (3000ml +/- 3.5%).

If the result is not inside the acceptance limit, repeat the test. Make sure that the flow transducer is intact and securely fastened to the spirometer and to the calibration syringe. If the verification still fails, please contact Medikro Technical Support.

5.9 Spirometer Identifier

In case multiple spirometers are used within same spirometer system, it is useful to have individual, easily recognisable identifiers (friendly name) for the spirometers. The friendly name of the connected device is displayed on the device selection list in Medikro Persons and Studies study view. Enter new friendly name for the device:

Connect the Medikro spirometer to the operating computer.

Open the Medikro Persons and Studies study view either for a selected person or via Medikro Quick Test shortcut.

Select the device from the device selection list.

Click the friendly name button.  **This will open a window for friendly name entry.**

Enter friendly name and click Set button.



Figure: Device selection list and friendly name button

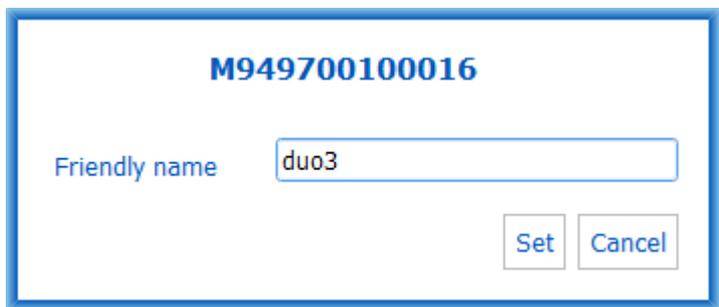


Figure: Device identifier entry window

5.10 Specifications

Specification	Description
Measurement manoeuvres	PEF, FEV6, FVC. See Table: Measurement modes
BTPS values	The values are expressed as BTPS values
Sensor Type	Pneumotach
Power Equipment	Lithium Polymer 3.7V
Accuracy	Meets or exceed ISO 26782, ATS (1994), ERS (1993) and ATS/ERS (2005)
Reproducibility	Meets or exceed ISO 26782, ATS (1994), ERS (1993) and ATS/ERS (2005)
Time Zero Determination	Backward extrapolation
Correction Factors	BTPS correction according to ambient conditions
Flow Range	+ - 14 L/sec
Volume Range	0-14 L
Flow Resolution	1 mL/sec
Volume Resolution	1 mL
Flow Accuracy	± 10% or 0.17 L/sec
Volume Accuracy	± 2.5% or 0.05 L
Resistance	0.08kPa/L/sec at 14 L/sec (~ 0.15kPa/L/sec at 14 L/sec)
Sample Rate	Internal 800 Hz, external 100 Hz
Expected Lifetime	3 years

System requirements	See release information
Predicted values	For predicted models included, see Table: Prediction models
Variables	PEF, FEV1, FEV6, FVC, FEV1/FEV6, FEV1/FVC.
Quality checks	ATS Acceptability and ATS Reproducibility checks
Storage and transportation Environment	Temperatures between -20 °C (-4 °F) and +50 °C (122 °F). Relative humidity between 10% and 95% (non-condensing). Atmospheric pressure of 500 hPa (mbar) to 1060 hPa (mbar).
Operation Environment	Temperatures between +10 °C (50 °F) and +30 °C (86 °F), Relative humidity between 15% and 90% (non-condensing), Atmospheric pressure of 700 hPa (mbar) to 1060 hPa (mbar).
Connectivity	USB-C, BT 4.0
Bluetooth	v. 4.0, single mode compliant Operating Frequency Range (OFR): 2402-2480 GHz Channel separation: 2 MHz Channel bandwidth: 1 MHz Transmission technique: DSSSx Transmission technique: DSSS Modulation: GFSK Effective isotropic radiated power: +1.0 dBm max Antenna gain: 0.5 dBi max Efficiency of the antenna: 30 %
Wireless charger	Qi 1.1 Frequency band of reception: 110 kHz - 205 kHz Bandwidth of the receiving section: 12 kHz
Qi wireless charger	Model: ZESC05B  ZENS Headquarters High Tech Campus 10 5656 AE Eindhoven The Netherlands
Power supply	input: 100-240Vac, 50-60Hz, 0.3A output: 5V, 2A Model: GTM46101-1005-USB  GlobTek, Inc. USA 186 Veterans Drive Northvale, NJ07647 USA
Power Input	(USB port) 5Vdc 500mA

5.11 Guidance and Manufacture's Declarations



The Medikro spirometers needs special precautions regarding EMC and needs to be installed and put into service according to the following EMC information provided. Portable and mobile RF communications equipment can affect the Medikro spirometers.

Additional information about:

- Electromagnetic emissions

Electromagnetic Emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
The Medikro spirometers are intended for use in the electromagnetic environment specified below. The customer or the user of the Medikro spirometers should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Medikro spirometers are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

- Electromagnetic immunity

Electromagnetic Immunity

Guidance and manufacturer's declaration - electromagnetic immunity			
The Medikro spirometers are intended for use in the electromagnetic environment specified below. The customer or the user of the Medikro spirometer should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic	±8 kV contact	±8 kV	Floors should be wood, concrete

discharge (ESD) IEC 61000-4-2	± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	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 100 kHz repetition frequency	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Line-to-line ± 0.5 kV, ± 1 kV Line-to-ground ± 0.5 kV, ± 1 kV, ± 2 kV	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips and interruptions IEC 61000-4-11	Dips 0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° Interruptions 0 % UT; 250/300 cycle	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Medikro spirometers requires continued operation during power mains interruptions, it is recommended that the Medikro spirometers be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity

The Medikro spirometers are intended for use in the electromagnetic environment specified below. The customer or the user of the Medikro spirometer 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 0,15 MHz - 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz - 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	<p>WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Medikro spirometer unit, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2700 MHz	10 V/m 80 MHz to 2700 MHz	
RF wireless communication	9 V/m 710 MHz, 745 MHz, 780 MHz, 5240 MHz, 5500 MHz and 5785 MHz	9 V/m 710 MHz, 745 MHz, 780 MHz, 5240 MHz, 5500 MHz and 5785 MHz	
	27 V/m 385 MHz	27 V/m 385 MHz	
	28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz and 2450 MHz	28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz and 2450 MHz	

5.12 Periodic Maintenance

Periodic maintenance must be performed on the spirometer unit every three (3) years.

This includes technical inspection of the device and replacement of the battery. Periodic maintenance can only be performed by Medikro service personnel.

Introduction to Medikro Spirometry Software



VI

6 Introduction to Medikro Spirometry Software

Medikro Spirometry Software consists of two applications:

- **Medikro Persons and Studies** for person and study management.
- **Medikro Measurements and Results** for viewing and making spirometry measurements.

and additional software components to Medikro Persons and Studies application:

- **Medikro Screener** for pulmonary function screening.
- **Medikro Serial Monitoring** for pulmonary function monitoring.

Your setup may contain one or multiple Medikro applications and software components.

Diagnostic Spirometry

Performing the diagnostic spirometry test with Medikro System requires:

- **Persons and Studies** application
- **Measurements and Results** application
- Medikro Pro, Nano or Primo spirometer

For information about person and study management, see chapter [Person and Study Management](#).
For information about diagnostic spirometry study, see chapter [Diagnostic Spirometry](#).

Screening Spirometry

Performing screening spirometry test with Medikro System requires:

- **Persons and Studies** application with **Medikro Screener** software component.
- Medikro Duo spirometer

For information about person and study management, see chapter [Person and Study Management](#).
For information about screening spirometry study, see chapter [Screening Spirometry](#).

Serial Monitoring Spirometry

Performing serial monitoring spirometry with Medikro System requires

- **Persons and Studies** application with **Medikro Serial Monitoring** software component.

- Medikro Duo spirometer

For information about person and study management, see chapter [Person and Study Management](#).
For information about serial monitoring spirometry study, see chapter [Serial Monitoring Spirometry](#).

6.1 Software Settings

The user can adjust certain settings of Medikro Spirometry Software. For Medikro Measurements and Results settings, see chapter [Measurements and Results Programme Settings](#).

Depending of your Medikro Spirometry Software setup, Persons and Studies settings can be adjusted two ways:

- The administrative user can centrally manage Medikro Persons and Studies settings with the Medikro Administration Tool. For more information, see the Medikro Administration Tool user manual. Or,
- Persons and Studies user can adjust settings on the local workstation. This chapter describes settings available for Persons and Studies user.

6.1.1 General Settings

Language: Language for Persons and Studies.

Date format: Date format used in Persons and Studies. Medikro Measurements and Results uses Windows' date and time format.

Default application size: The size Persons and Studies application window is opened in.

- Saved: Size is the same as when Persons and Studies was closed the last time.
- Standard: Default size that is optimised to use Persons and Studies and Measurements and Results parallel on the screen.
- Full: Full screen.

Enable notification messages: Notifications are shown in bottom right corner, for example, when saving data.

Pre-fill study information: Study information is pre-filled from person's previous study. For spirometry study, *height*, *weight*, *prediction model*, *smoking status*, *smoking info*, *profession*, *illness* and *medication* are prefilled.

Personal ID systems: Only selected systems are available to choose from when entering person information in Persons and Studies.

Default personal ID system: Default personal ID system when creating new persons.

Shown ethnic groups: Only selected ethnic groups are available to choose from when entering person information in Persons and Studies.

Default ethnic group: Default ethnic group when creating new persons.

6.1.2 Import/Export Settings

Import mode: Defines how to save imported persons and studies if they already exist in the database. Note! Import file can specify the import mode, which overrides this setting.

- **Insert:** Data is taken from the database in case of existing persons and studies. New persons and studies are added to database.
- **Update:** The information is updated by imported data.

Import Modes

	Update	Insert
Add persons that are not in the database	X	X
Add studies that are not in the database	X	X
Update information of person existing in the database	X	
Update information of study existing in the database	X	

Identification criteria: Select fields that are used to find a matching person from the database.

Default locations: Directories that are suggested for the user when executing manual import and manual export operations. User can select other locations.

Default file format: File format that is suggested for the user when executing manual import and manual export operations. User can select other format.

- **SpiroXML2 format:** Set default to SpiroXML2 -format defined in SpiroXML2 HIS Interface Document.
- **GDT format:** Set default to GDT 2.0/3.0 -format. Only one person per file can be exported.

Automatic Import/Export

Measurements for persons from external systems can be automatically started with Automatic Import/Export functionality. Automatic import is started in home view of Persons And Studies if a specified input file exists. The person is brought to the system and a new study is created.

When measurement is done and the user goes back to home view, Persons and Studies exports the person with studies to a specified location.

HIS system file format: File format that is used for automatic import and export files. Select None to disable Automatic Import/Export.

Input and output files: Input and output file name and location.

Export options: Selection of whether automatic export occurs manually, automatically or not at all.

- **Autoexport:** Exports the output file automatically without any dialogues.
- **No Autoexport:** Dialogue where user has to select whether to export is shown.
- **No Export:** Export will not happen. No dialogues will be shown.

Export study data: Selection whether automatically exported output file has the data for the current study only or for all studies of the current person.

- **Current Study:** Exports the current study data of the current person.
- **All Studies:** Exports all studies data of the current person.

Proceed into measurement automatically: Select if automatic import proceeds automatically to a point where measurement can be started. Otherwise application will stay at the study view. Automatic import will stop and relevant view will be shown if mandatory information is missing.

6.1.3 Database Settings

Use demo database: Use for demonstration, training or testing purposes only. Demo database containing demo persons and studies is put into use. Your original database settings are automatically put back into use after next application restart.

Offline database location: Path to a folder where offline databases will be created if connection to online databases cannot be established or if system is configured to exclusively use offline databases.

Use offline database exclusively: Local file based databases are used to store person and study data.

Identification criteria: Selected criteria will be used to determine if person already exists in the database when synchronising person and study data from offline databases to online databases.

Shared database location: Path to online databases which can be connected from multiple workstations. If "Use offline database exclusively" is unchecked, shared databases are used to store person and study data.

6.1.4 Person Search Settings

Search results in single row: Person information cells are laid out in single row instead of two rows.

Person search result: Four cells are available to present person information at person search result list. Cell content can be configured to contain any person field information. The leftmost cells are displayed with bold font.

Minimum search characters: Person search is started when given amount of characters is entered to search.

Search parameters: Persons are searched for by matching the search term to information in all of the fields selected here.

6.1.5 Person Information Settings

Standard fields: Select which fields are shown and mandatory in Persons and Studies Person view. Fields that are required by a plugin are always visible, despite of the selection. For example *Birthdate* and *Gender* are mandatory for spirometry study.

- **Mandatory:** Field is shown and mandatory.
- **Visible:** Field is shown but not mandatory.
- **Not visible:** Field is not shown.

Custom fields: Custom fields can be used to introduce new information fields to person data. They are shown in person view below the standard fields in the configured order. Name, visibility and line expanse can be configured as well. Name of the field cannot include reserved special characters: “,” “:” “=” . Removing the custom field does not remove any data from the database.

Order of the full name: Full name is shown in the given order.

Summary fields: Summary of the person information is shown in top area of the Persons and Studies application.

6.1.6 Study Settings

Study information settings for: Study type selection. Spirometry is the only option, unless other study type plugins are installed.

Hidden spirometry prediction models: Prediction models can be hidden from users by selecting them from the list.

Default spirometry prediction model: Prediction model that is selected when new study is created.

Study list fields: Four cells are available to show selected study information when studies are listed. The first field is shown with bold font.

Hidden study field editors: Selected fields are not shown when viewing study. Data cannot be manually entered to hidden fields but may be updated by the measuring application.

6.1.7 Access Control Settings

The following settings can be adjusted from Persons and Studies. Other settings may be available for viewing but can be adjusted only with Medikro Administration Tool.

Access control method:

- **None:** No access control is used and there is no sign in required. User has privileges to all functions in the application. In this case it should be noted that the user cannot be individualised in the Audit Trail.
- **None, simple identification is required:** No access control is used, but the user has to enter a minimum of two characters into Persons and Studies sign in dialog.

6.2 Activating the Measurements and Result Software

Activation Code

Activation Code is needed to activate features of the software. Without the Activation Code the use of software is restricted. All new generation Medikro Spirometers have an embedded Activation Code. As a result of this, users do not need to enter the Activation Code manually.

If the Activation Code has to be entered manually it may be shipped in a separate paper or electrical document.

Activation with the Activation Code

After receiving the Activation Code, it needs to be initialised in the following way:

1. Medikro Spirometry Software must be installed and started.
2. Plug in the spirometer for which you have obtained the Activation Code.

- Open **Help>Software Feature Activation...** ([Figure: Opening Software Feature Activation Window](#)). If a study is opened in the Measurements and Results application, this option is disabled. In that case, close the study.

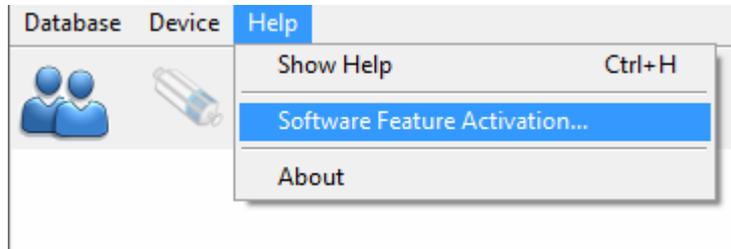


Figure: Opening Software Feature Activation Window

- Software Feature Activation window will open.
- Enter the whole **Activation Code** in the field and press **Activate!** ([Figure: Entering Software Activation Code](#)).

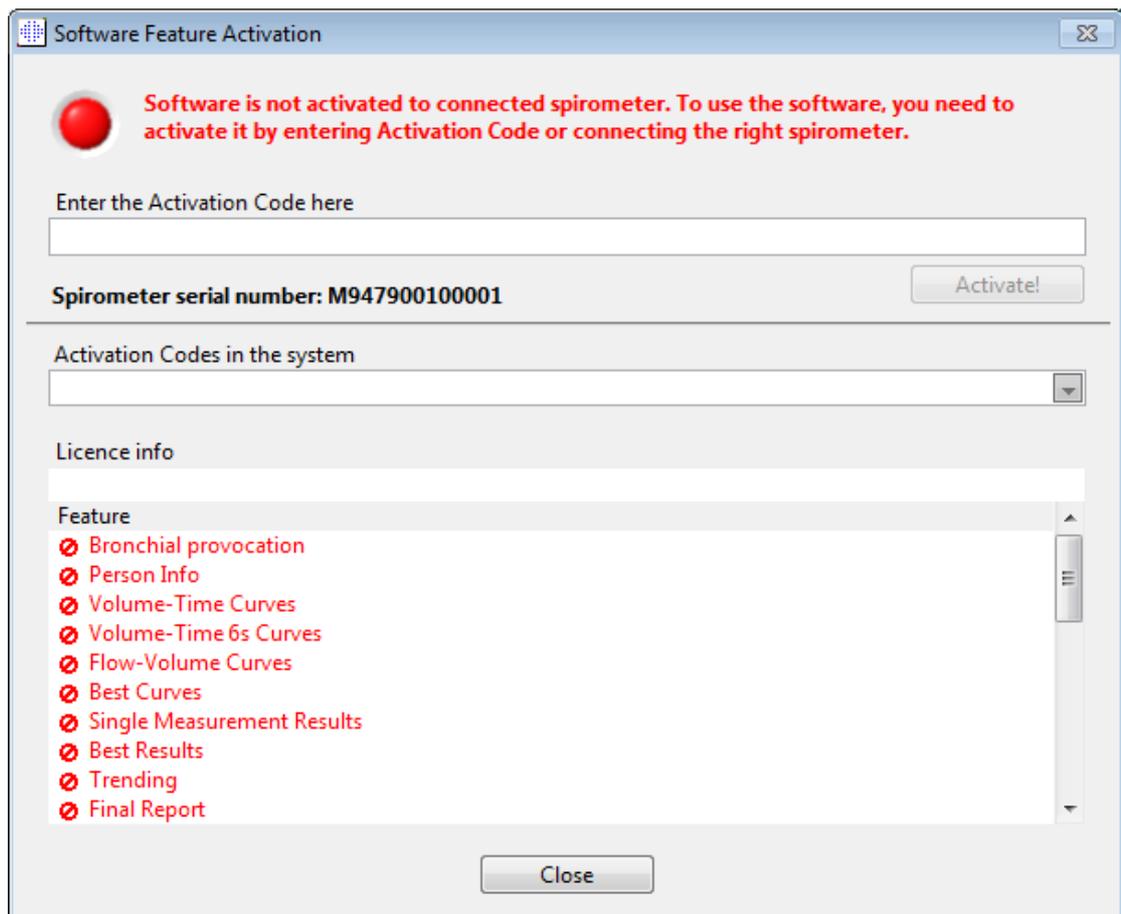


Figure: Entering Software Activation Code

- When a valid **Activation Code** is entered successfully, the software will add it to the system ([Figure: Software Activation Code Added Successfully to the System](#)).

- Spirometer serial number is the serial number of the spirometer currently connected.
- "Activation codes in the system" contains the codes that have been added to the system.
- "Feature table" shows the features enabled or disabled by the Activation Code.
- "Code limitation" shows the limitations of the Activation Code. A limit can be, for example, the spirometer serial number which the code refers to. Here you can check whether the serial number matches with your connected spirometer.

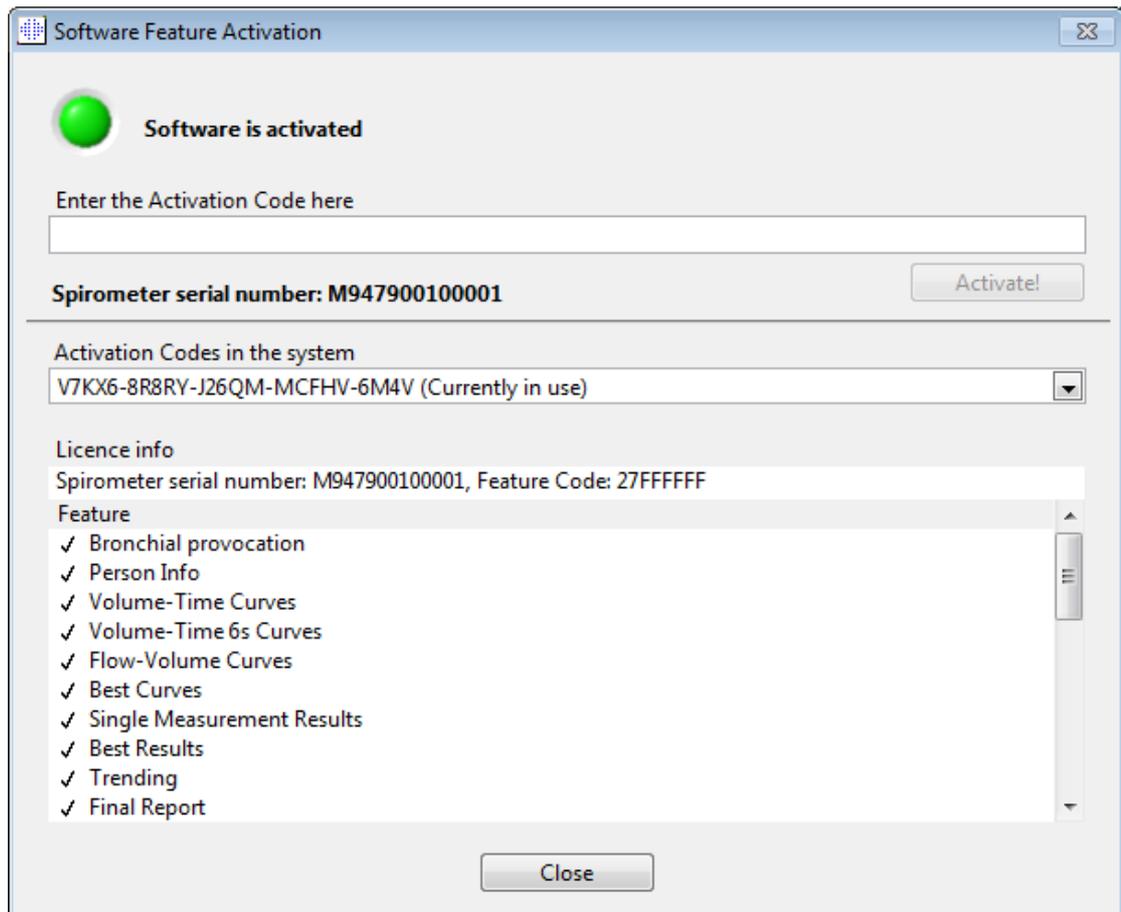


Figure: Software Activation Code Added Successfully to the System

7. Close the **Software Feature Activation** window.

6.3 Sign In and Sign Out

If the system configuration requires user authentication, a single sign in is required to access Medikro Spirometry Software. To sign in, enter correct user name-password combination on Persons and Studies Sign in view. When Medikro Persons and Studies and Medikro Measurements and Results applications are used simultaneously, user is signed in to both applications. Operations of Medikro Measurements and Results are not available if the user is not signed in.

Note: Authentication is configured in the Medikro Administration Tool, and it depends on the system configuration if sign in is required and how the user is authenticated. For more

information on authentication system and access control management, see Medikro Administration tool user manual.

To Sign out, select Settings button on Medikro Persons and Studies, and Sign Out item from the item list. This will sign user out from both Medikro Persons and Medikro Measurements and Results applications, but the applications remain open.

6.4 Help

Displays the Medikro Spirometry Software User Manual. To open the help file, select the **Show Help** button (see [Table: Medikro Measurements and Results Basic Buttons](#) or [Table: Medikro Persons and Studies Buttons](#)).

6.5 Exiting the Medikro Spirometry Software

When you want to stop using the Medikro Spirometry Software, close the application from Persons and Studies Window close button. Measurements and Results application is automatically closed when Medikro Persons and Studies application is closed.

When the session is open in Medikro Measurements and Results, it is possible to close the current session and leave the application open by selecting **Close Session** button (see [Table: Medikro Measurements and Results Basic Buttons](#)).

Person and Study Management



7 Person and Study Management

Persons and studies are managed in the **Persons and Studies** application, which is opened when Medikro Spirometry Software is started.

Person and study management tasks are carried out in dedicated views and the current phase is indicated in the Medikro Persons and Studies application navigation bar ([Figure: Persons and Studies navigation bar](#)):

- *Home view*: Search and select existing person, select to import person from external file, or select to create a new person.
- *Person view*: Enter person information, and select existing study, or select to create a new study for the person.
- *Study view*: Enter study information, and start measurement for the study.
- *Measurement view*: Indicates that the measurement is ongoing.



Figure: Persons and Studies navigation bar

Navigating forward on the views requires that the previous phase is completed. Navigating backward to earlier phases is done by clicking the navigation bar buttons. When Measurement view is active, it is not possible to exit from the view manually. Measurement view closes automatically when measuring is stopped.

There are no Cancel buttons in the views. Instead, confirmation of saving changes is asked if there are unsaved changes when leaving a view. In the confirmation dialogue it is possible to choose to save or discard changes.

Medikro Quick Test

Medikro Quick Test makes an exception for the presented work flow (see [Medikro Quick Test](#)). Quick Test opens directly into the Study view, making it possible to perform screening measurements without saving person information.

7.1 Persons and Studies Software Buttons

Table: Medikro Persons and Studies Buttons:

Button	Function and description
	New person button Opens person view for new person data entry.

Button	Function and description
	Go directly to study button. Opens study view for new study data entry without person data.
	Delete person button. Deletes one (current) person.
	Delete persons button. Deletes selected persons.
	New study button. Opens study view for new study data entry.
	Delete study button. Deletes one (current) study.
	Delete studies button. Deletes selected studies.
	Import button. Opens file explorer for selecting import file.
	Import selected button. Imports persons that are marked to be imported on Import view person list.
	Import all button. Imports all persons on Import view person list.
	Cancel import button. Cancels import.
	Export person button. Opens file explorer for creating external file with current person's or selected persons' data.
	Proceed to measurements and results button. Opens study in Medikro Measurements and Results application for viewing old measurements or for making new measurements.
	Save button. Saves the current person and study information to database.
	Settings button. Opens a menu where user can select to adjust Persons and Studies settings, sign out or see Persons and Studies application's licence information.

7.2 Search Person or Create New

Persons in database can be searched in Home view ([Figure: Home View](#)). Person is searched by typing the search parameters (e.g. personal ID and/or person name) in the search field. Persons matching all given search parameters are listed in the search results. Clicking person on search result list opens person information on Person view.

Note: Search parameters can be configured. For more information, see chapter [Software Settings](#).

To list all persons in the database, type character * (asterisk) or ? (question mark).

To create a new person, click **New person** button (see [Table: Medikro Persons and Studies Buttons](#)) in Home view ([Figure: Home View](#)).

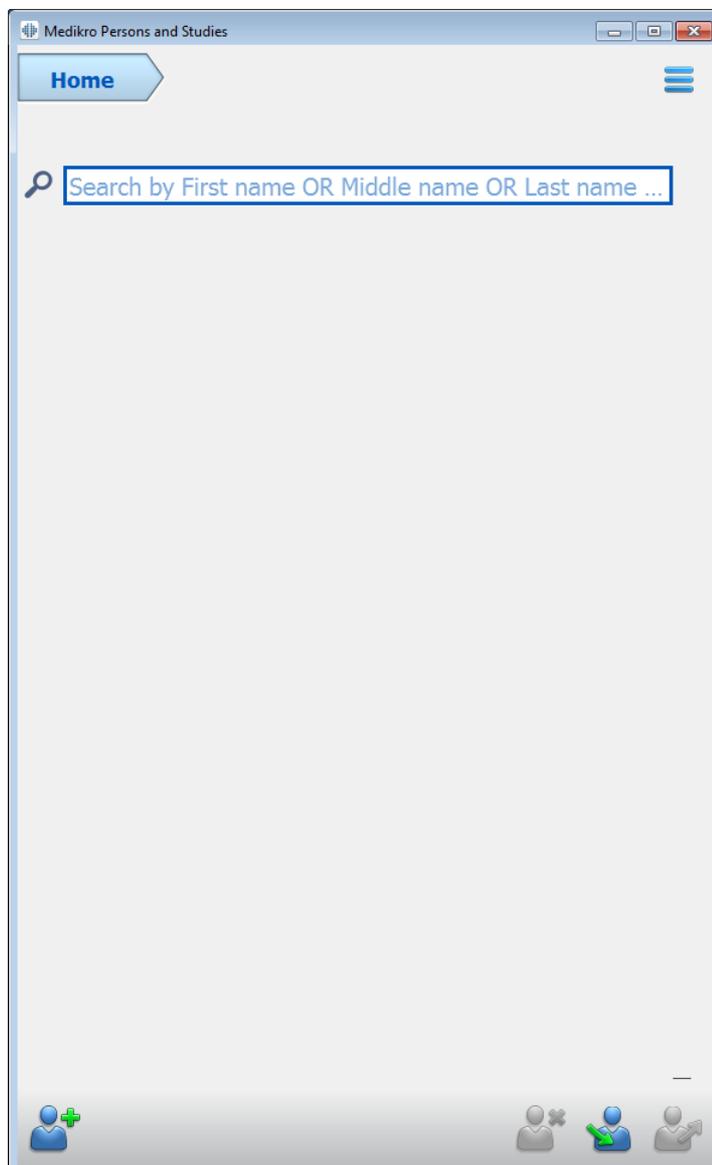


Figure: Home view

7.3 Person Data Entry

Person information is managed in Person view ([Figure: Person View](#)). Mandatory person information fields are indicated with red background colour. It is not possible to save person information if mandatory data is missing.

Note: Person field visibility and mandatory can be configured. For more information, see chapter [Software Settings](#).

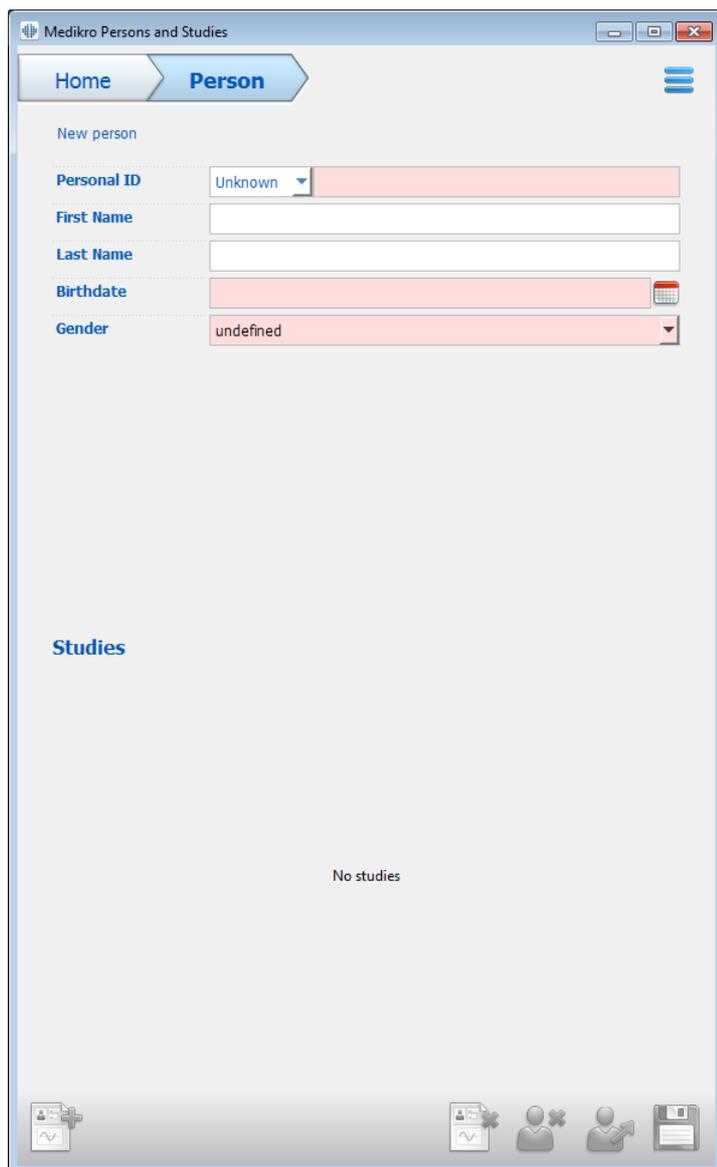


Figure: Person view

Description of fields:

Personal ID: Enter the ID of the patient. In some countries, the social security code is used for this purpose. Personal ID has to be unique (see chapter [Duplicate Personal ID or duplicate Person Code](#)).

Personal ID System: Select from the following options: None/Finnish (ddmmyyy-xxxx)/Swedish (yyyymmdd-xxxx). Personal ID is checked whether it is a valid form according to selected Personal ID System. Depending on the selected Personal ID System, the person's date of birth and gender information are read from the Personal ID, and then there is no need to type them manually.

Last name / First name / Middle name: Name of the person.

Birthdate: Select the birthdate by using the calendar or by typing the date. Date format can be configured. For more information, see chapter [Software Settings](#).

Person Code: Open field for any alphanumeric code used by the establishment / clinic / hospital to identify the patient. Person Code has to be unique (see chapter [Duplicate Personal ID or duplicate Person Code](#)).

Gender: Select from the following options: Male/Female. The "Undefined" option is just for indicating that the selection has not yet been made.

Ethnic Group: Indicates the ethnic origin of the person. Use the drop-down menu for a proper selection. This field is set invisible by default.

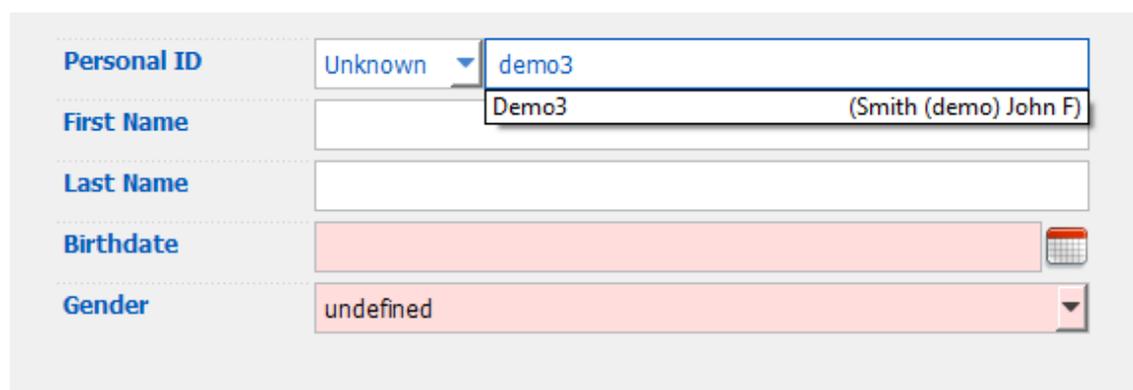
Custom fields: In addition to listed person fields, person view may contain customised person fields. Custom fields can be configured. For more information, see chapter [Software Settings](#).

Duplicate Personal ID or duplicate Person Code

To prevent unintended duplicate persons, the application retrieves matching persons from the database when typing Personal ID or Person Code for a new person ([Figure: Person found with entered ID](#)). User can load existing person from the database by selecting a suggested person from the list, or the user can continue creating a new person by not selecting any suggested persons.

In the latter case, when saving a person with duplicate personal ID or duplicate Person Code, confirmation is shown, where user has to select:

- Load: Existing person is loaded from database on Person view. If multiple matches exist in the database, the user has to select which person is loaded. New person is not created.
- Cancel: Saving person is cancelled. Person view stays open with entered data.



The screenshot shows a form with the following fields:

- Personal ID:** A dropdown menu set to "Unknown" and a text input field containing "demo3". A dropdown menu is open below the input, showing a suggestion: "Demo3 (Smith (demo) John F)".
- First Name:** An empty text input field.
- Last Name:** An empty text input field.
- Birthdate:** A red text input field with a calendar icon on the right.
- Gender:** A red dropdown menu set to "undefined".

Figure: Person found with entered ID

7.4 Select Study or Create New

To select or create new studies, a person must be selected on Person view. Selected person's existing studies are listed ([Figure: Study list](#)) in Person view. Clicking a study on the Study list opens study information on Study view.

To create a new study for the selected person, click **New study** button (see [Table: Medikro Persons and Studies Buttons](#)) on Person view.

It is not possible to create a new study if mandatory person data is missing. However, it is possible to open existing study from Study list when mandatory person data is missing.

Birthdate and gender are mandatory fields for diagnostic spirometry studies and if either of these is missing from person, the diagnostic study is indicated with an exclamation mark (!) in the Study list ([Figure: Study list](#)). This kind of study can be opened in Study view but it is not possible to open the study in the Measurements and Results application. Missing birthdate and gender have to be entered and saved for the person before study can be opened in the Measurements and Results application.

Medikro Persons and Studies

Home Person

John F Smith (demo) 14.11.1987 male

Personal ID Unknown Demo3

First Name John F

Last Name Smith (demo)

Birthdate

Gender Male

Studies

Spirometry	20.01.2012 12:00	<input type="checkbox"/>
Spirometry	15.01.2011 12:00	<input type="checkbox"/>
Spirometry	10.01.2010 12:00	<input type="checkbox"/>
Spirometry	05.01.2009 12:00	<input type="checkbox"/>
Spirometry	01.01.2008 12:00	<input type="checkbox"/>
Spirometry	27.12.2007 12:00	<input type="checkbox"/>
Spirometry	22.12.2006 12:00	<input type="checkbox"/>

Figure: Study list

7.5 Study Data Entry

If your system has multiple measurement software components installed, the study type has to be selected before study data can be entered. If there is only one measurement software component installed, the study type is automatically selected. This chapter explains study data entry for the following study types:

- [Diagnostic Study Data Entry](#)
- [Screening Study Data Entry](#)
- [Serial Monitoring Data Entry](#)

7.5.1 Diagnostic Study Data Entry

Study information is managed in Study view ([Figure: Study View](#)). Mandatory study information fields are indicated with red background colour. It is not possible to save study information or start a measurement if mandatory data is missing.

PersonsAndStudies

Home Person Study

John F Smith (demo) 14.11.1987 fe New study

Study type Diagnostic spirometry

Study date 27.10.2017

Study time 10:36

Height (cm)

Weight (kg)

Prediction model Choose prediction model...

Smoking Choose smoking status...

Smoking Info

Profession

Illness

Medication

Problem

Co-operation Choose co-operation...

Challenge protocol

Severity of ventilatory disturbance

Ventilatory dysfunction type

Result of the bronchodilatation test

Interpretation text

Comments

Figure: Study view

The following fields are mandatory before any measurement can be performed:

- Birthdate (Entered in person view)
- Gender (Entered in person view)
- Prediction model
- Height
- Weight

Note: Person and study field visibility can be configured. For more information, see chapter [Software Settings](#).

When a new study is created and the person has earlier studies, some information might be automatically retrieved from the latest study. It is configurable whether study information is prefilled or not. Prefilled information is indicated with yellow background colour.

Proceeding to measurements and results

If there are unsaved changes in study view when clicking **Proceed to measurements and results** button (see [Table: Medikro Persons and Studies Buttons](#)), unsaved changes are automatically saved.

When measurement is started for the study, Measurement view is opened to indicate that study is open in the Medikro Measurements and Results application. Study information can be entered and modified in Measurement view similarly as in Study view.

Description of fields:

Study type: Select the type of the study you wish to perform. Available study types depend on installed software components (see chapter [Introduction to Medikro Spirometry Software](#)).

Study date and time: Enter date and time of the study using calendar and time components, or by typing the data. Current date and time are used by default.

Prediction model: Select the appropriate prediction model. The model represents the predicted pulmonary function values for the patient. See more information about the prediction models in Additional information.

Height: Enter the height in centimetres, or in feet and inches.

Weight: Enter the weight in kilograms (kg) or in pounds (lb).

Smoking: Select from the following options: Yes / No / No information / Quit.

Smoking info: Enter any additional information related to smoking status.

Profession: Enter the profession of the patient.

Illness: The recording of relevant illnesses of the patient.

Medication: The recording of relevant medication of the patient.

Problem: The recording of any current medical problem.

Co-operation: Select from the following options: Good/Satisfactory/Poor/No information.

Challenge protocol: Shows the challenge protocol used in the study. Challenge protocol is selected in Measurements and Results application.

Severity of ventilatory disturbance: Indicates the severity of ventilatory disturbance. The programme will calculate this after the measurements have been completed.

Ventilatory dysfunction type: Indicates the ventilatory dysfunction type. The programme will calculate this after the measurements have been completed.

Result of Bronchodilation Test: Shows the comparative result of the Pre- and Post-phase tests. The programme will calculate this if the Post-phase measurements have been accomplished.

Interpretation Text: The interpretation of the session results by a consulting doctor. Free text format (**Note:** only the first five rows can be printed in a report). With Sentence editor it is possible to save interpretation texts for later use (see chapter: [Sentence Editor](#))

Comments: Enter any additional observations.

Additional information

Prediction Model

The prediction model represents the predicted pulmonary function values for the patient.

Select the appropriate prediction model from the prediction model drop-down selection. The model includes the predicted values for both sexes and all age groups. There are several choices for the predicted values for different national or ethnic groups.

Table: Prediction models in diagnostic spirometry:

Model	Description (persons under 18 years old are regarded as children)
BergL_Z	Berglund for adults, Zapletal for children
Brazil	Brazilian predicted values
China	Chinese predicted values
Cra_Knu	Crapo for adults, Knudson for children
ECSC_IGiChP	Polish predicted values: European Coal and Steel Community for adults, IGiChP for children
ECSC_P	European Coal and Steel Community for adults, Polgar for children
ECSC_PZ	European Coal and Steel Community for adults, Polgar and partly Zapletal for children
ECSC_Qua	European Coal and Steel Community for adults, Quanjer for children
ECSC_Qua_AT	European Coal and Steel Community for adults, Quanjer for Austrian children
ECSC_Qua_ES	European Coal and Steel Community for adults, Quanjer for Spanish children
ECSC_Qua_GB	European Coal and Steel Community for adults, Quanjer for English

	children
ECSC_Z	European Coal and Steel Community for adults, Zapletal for children
Forche2	Austrian predicted values: Forche for adults and children
Garcia-Rio_Roca_SEP	Spanish predicted values: Garcia-Rio for elderly, Roca for adults, SEPAR for children
GLI2012_African_American	Global Lung Function Initiative predicted values for African American adults and children
GLI2012_Caucasian	Global Lung Function Initiative predicted values for Caucasian adults and children
GLI2012_North_East_Asian	Global Lung Function Initiative predicted values for North East Asian adults and children
GLI2012_Other/mixed	Global Lung Function Initiative predicted values for Other/mixed adults and children
GLI2012_South_East_Asian	Global Lung Function Initiative predicted values for South East Asian adults and children
Gulsvik_Z	Norwegian predicted values: Gulsvik for adults, Zapletal for children
Hedenstrom_Sol	Swedish predicted values: Hedenstrom for adults, Solymar for children
Hedenstrom_Z	Swedish predicted values: Hedenstrom for adults, Zapletal for children
Japan	Japanese predicted values
Jindal	Indian predicted values: Jindal for adults and adolescents
Kainu_Koillinen	Finnish predicted values: Kainu for adults and Koillinen for children
Klement	Russian predicted values: Klement for adults and children
Knudson	Knudson for adults and children
Langhammer_Z	Norwegian predicted values: Langhammer for adults, Zapletal for children
NHANES III_W_African_American	NHANES III (Hankinson) for 8-80-year-olds and Wang for children under 8 years African American ethnics. *)
NHANES III_W_Mexican_American	NHANES III (Hankinson) for 8-80-year-olds and Wang for children under 8 years Mexican American ethnics. *)
NHANES III_W_Other	NHANES III (Hankinson) for 8-80-year-olds and Wang for children under 8 years other ethnics. *)
Pérez-Padilla	Mexican predicted values: Pérez-Padilla for adults and children
SEPAR	Spanish predicted values: SEPAR for adults and children
Udwadia	Indian predicted values: Udwadia for adults and adolescents
Vijayan	Indian predicted values: Vijayan for adults and adolescents

ViL_Koi	Finnish predicted values: Viljanen for adults, Koillinen for children
Viljanen_Kiv	Estonian predicted values: Viljanen for adults, Kivastik for children

*) The ethnic groups mentioned in the references models are related to the ethnic groups used in Medikro Spirometry Software in the following way:

Reference Model	Ethnic group in the reference model	Ethnic group in Medikro Spirometry Software	Name of Ref. Set model
NHANES III	African American	African American, African descent	NHANES III_W_African_American
	Mexican American	Mexican American	NHANES III_W_Mexican_American
	Caucasian	All others	NHANES III_W_Other
Wang	Black	African American, African descent	NHANES III_W_African_American
	White	All others	NHANES III_W_Mexican_American NHANES III_W_Other

7.5.2 Screening Study Data Entry

Study information is managed in Study view.

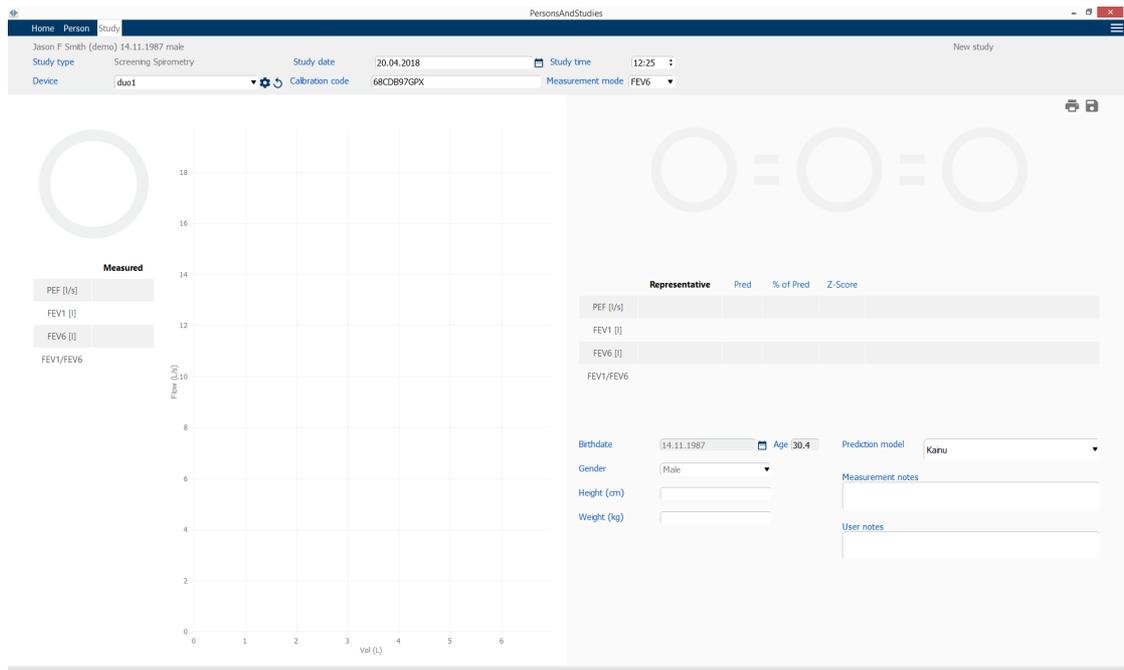


Figure: Study view

The following fields are mandatory before predicted values can be calculated:

- Age
- Gender
- Height
- Prediction model

When a new study is created and the person has earlier studies, some information might be automatically retrieved from the latest study. It is configurable whether study information is prefilled or not. Prefilled information is indicated with yellow background colour.

Description of fields:

Study type: Select the type of the study you wish to perform. Available study types depend on installed software components (see chapter [Introduction to Medikro Spirometry Software](#)).

Study date and time: Enter date and time of the study using calendar and time components, or by typing the data. Current date and time are used by default.

Birthdate: Person information field. Information is automatically retrieved from Person view if available. Otherwise, select the birthdate by using the calendar or by typing the date.

Age: Automatically calculated from birthdate if available. If birthdate is not available, person's age can be entered instead.

Gender: Person information field. Information is automatically retrieved from Person view if available. Otherwise, select from the options: Male/Female/Undefined.

Prediction model: Select the appropriate prediction model (see [Table: Prediction models](#)). The model represents the predicted pulmonary function values for the patient.

Height: Enter the height in centimetres, or in feet and inches.

Weight: Enter the weight in kilogrammes (kg) or in pounds (lb).

Measurement notes: Enter the interpretation or other comments of the results.

User Notes: Enter any additional observations.

Measurement mode: Select the appropriate mode (see [Table: Measurement modes](#)).

Calibration code: Automatically retrieved from the connected Medikro spirometer if available. Check the correctness, and enter the correct code when necessary (see chapter [Calibration Code](#)).

Device: Select the appropriate Medikro spirometer when multiple spirometers are connected (see chapter [Select Device](#)).

Table: Prediction models in screening spirometry

Model	Description
FEV6-mode and FVC-mode	
GLI 2012 African American (3-94)	Global Lung Function Initiative predicted values for African American adults and children
GLI 2012 Caucasian (3-94)	Global Lung Function Initiative predicted values for Caucasian adults and children
GLI 2012 North East Asian (3-94)	Global Lung Function Initiative predicted values for North East Asian adults and children
GLI 2012 Other/mixed (3-94)	Global Lung Function Initiative predicted values for Other/mixed adults and children
GLI 2012 South East Asian (3-94)	Global Lung Function Initiative predicted values for South East Asian adults and children
Kainu 2015 (18-94)	Finnish predicted values: Kainu for adults ($18 \leq \text{age} < 95$)
Koillinen 1998 (6-17)	Finnish predicted values: Koillinen for children ($6 \leq \text{age} < 18$)
PEF-mode	
Eigen (EU) 2001 (3-7) and Cotes (EU) 1973 (8-15)	Eigen in EU scale for children ($3 \leq \text{age} < 8$, height 87-127 cm). Cotes in EU scale for children ($8 \leq \text{age} < 16$)
Koillinen 1998 (EU) (6-17)	Finnish predicted values: Koillinen in EU scale for children ($6 \leq \text{age} < 18$, height 110-170/180 cm)
Nunn & Gregg (EU) 1989 (15-84)	Nunn & Gregg in EU scale for adults ($15 \leq \text{age} < 85$)

Table: Measurement modes

Mode	Calculated variables
PEF	PEF
FEV6	PEF, FEV1, FEV6, FEV1/FEV6 In case the selected prediction model does not provide value for FEV6 but provides value for FVC, FEV6 is substituted by FVC.
FVC	PEF, FEV1, FVC, FEV1/FVC

7.5.2.1 Select Device

When the Study view is opened, system automatically starts searching for Medikro Duo devices.

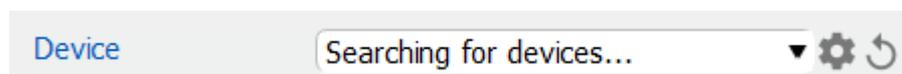


Figure: System is searching for connected devices

The connected Medikro Duo spirometers are displayed on the device selection list. When multiple Medikro Duo spirometers are connected with the operating computer, you have to select from the device selection list, which spirometer to use.

Note: The device identifiers can be edited. See chapter [Spirometer Identifier](#).

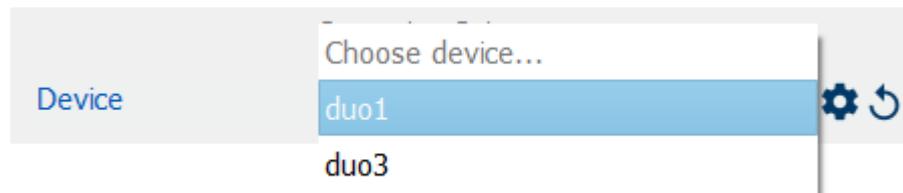


Figure: Select device from connected devices

- If Medikro Duo is connected via USB, there is no need to turn the device power on manually. Medikro Duo switches on automatically.
- If Medikro Duo is connected via Bluetooth, turn the device power on manually from the Medikro Duo power button to establish connection.

System is ready to use when spirometer connection is successfully established. In case the system does not find connected devices, it is possible to handle study information on study view, but it is not possible to perform measurements.

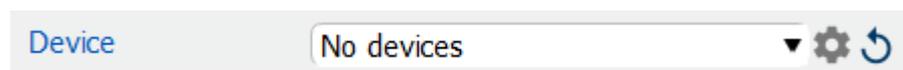


Figure: System cannot find connected devices

Clicking **Refresh device list** button, re-executes a search for connected devices.



Figure: Refresh device list button

7.5.3 Serial Monitoring Data Entry

Study information is managed in Study view. Study information input fields are located in a sidebar

opened with the Study information button



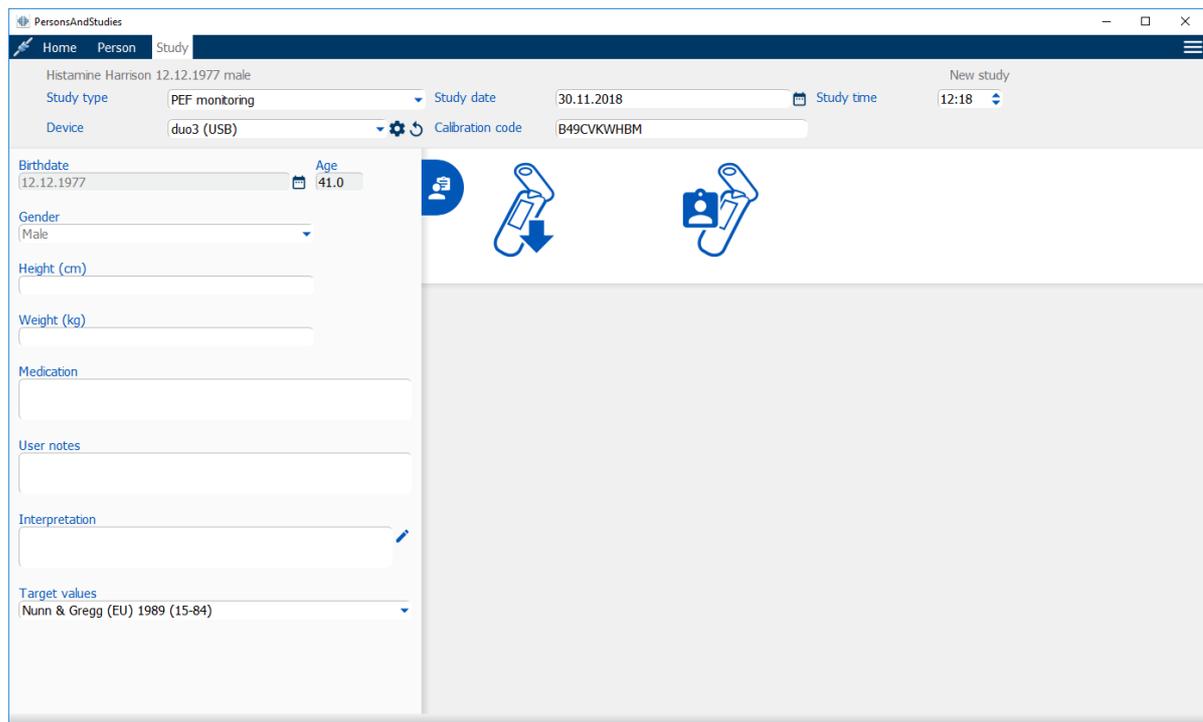


Figure: Study view

The following fields are mandatory before predicted values can be calculated:

- Age
- Gender
- Height
- Prediction Model

When a new study is created and the person has earlier studies, some information might be automatically retrieved from the latest study. It is configurable whether study information is prefilled or not. Prefilled information is indicated with yellow background colour.

Description of fields:

Study type: Select the type of the study you wish to perform. For Serial monitoring, select the study type with appropriate mode (see [Table: Measurement modes](#)). Available study types depend on installed software components (see chapter [Introduction to Medikro Spirometry Software](#)).

Study date and time: Enter date and time of the study using calendar and time components, or by typing the data. Current date and time are used by default.

Birthdate: Person information field. Information is automatically retrieved from Person view if available. Otherwise, select the birthdate by using the calendar or by typing the date.

Age: Automatically calculated from birthdate if available. If birthdate is not available, person's age can be entered instead.

Gender: Person information field. Information is automatically retrieved from Person view if available. Otherwise, select from the options: Male/Female/Undefined.

Target values: Select the appropriate prediction model (see Table: [Prediction models](#)) or select to manually set the values.

Height: Enter the height in centimetres, or in feet and inches.

Weight: Enter the weight in kilogrammes (kg) or in pounds (lb).

User Notes: Enter any additional observations.

Interpretation Text: The interpretation of the session results by a consulting doctor. Free text format (**Note:** only the first five rows can be printed in a report). With Sentence editor it is possible to save interpretation texts for later use (see chapter: [Sentence Editor](#))

Calibration code: Automatically retrieved from the connected Medikro spirometer if available. Check the correctness, and enter the correct code when necessary (see chapter [Calibration Code](#)).

Device: Select the appropriate Medikro spirometer when multiple spirometers are connected (see chapter [Select Device](#)).

Table: Prediction models in serial monitoring spirometry

Model	Description
FEV6-mode	
GLI 2012 African American (3-94)	Global Lung Function Initiative predicted values for African American adults and children
GLI 2012 Caucasian (3-94)	Global Lung Function Initiative predicted values for Caucasian adults and children
GLI 2012 North East Asian (3-94)	Global Lung Function Initiative predicted values for North East Asian adults and children
GLI 2012 Other/mixed (3-94)	Global Lung Function Initiative predicted values for Other/mixed adults and children
GLI 2012 South East Asian (3-94)	Global Lung Function Initiative predicted values for South East Asian adults and children
Kainu 2015 (18-94)	Finnish predicted values: Kainu for adults (18 ≤ age < 95)
Koillinen 1998 (6-17)	Finnish predicted values: Koillinen for children (6 ≤ age < 18)
PEF-mode	
Eigen (EU) 2001 (3-7) and Cotes (EU) 1973 (8-15)	Eigen in EU scale for children (3 ≤ age < 8, height 87-127 cm). Cotes in EU scale for children (8 ≤ age < 16)

Koillinen 1998 (EU) (6-17)	Finnish predicted values: Koillinen in EU scale for children (6 ≤ age < 18, height 110-170/180 cm)
Nunn & Gregg (EU) 1989 (15-84)	Nunn & Gregg in EU scale for adults (15 ≤ age < 85)

Table: Measurement modes

Mode	Calculated variables
PEF	PEF
FEV6	PEF, FEV1, FEV6, FEV1/FEV6 In case the selected prediction model does not provide value for FEV6 but provides value for FVC, FEV6 is substituted by FVC.

7.5.3.1 Select Device

When the Study view is opened, system automatically starts searching for Medikro Duo devices.

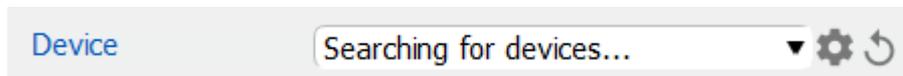


Figure: System is searching for connected devices

The connected Medikro Duo spirometers are displayed on the device selection list. When multiple Medikro Duo spirometers are connected with the operating computer, you have to select from the device selection list, which spirometer to use.

Note: The device identifiers can be edited. See chapter [Spirometer Identifier](#).

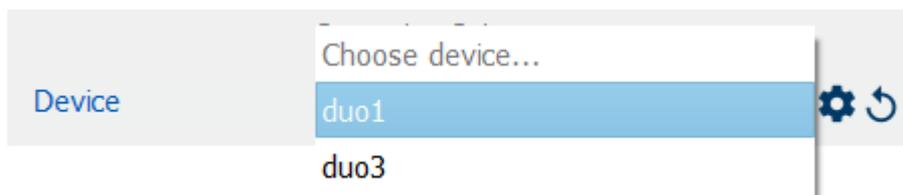


Figure: Select device from connected devices

- If Medikro Duo is connected via USB, there is no need to turn the device power on manually. Medikro Duo switches on automatically.
- If Medikro Duo is connected via Bluetooth, turn the device power on manually from the Medikro Duo power button to establish connection.

System is ready to use when spirometer connection is successfully established. In case the system does not find connected devices, it is possible to handle study information on study view, but it is not possible to perform measurements.

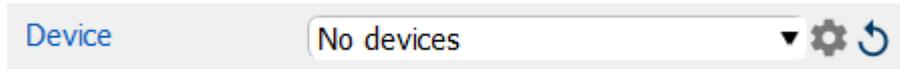


Figure: System cannot find connected devices

Clicking **Refresh device list** button, re-executes a search for connected devices.



Figure: Refresh device list button

7.5.4 Sentence Editor

The interpretation of the session results is written in free text format on the Study view. With Sentence editor it is possible to save interpretation texts for later use. Depending of your Medikro Spirometry Software setup, the sentences are saved locally or they are centrally managed by administrative user. Note that in the latter case you may be able to save sentences but the sentence data is overwritten with centrally managed data when the application is restarted.

To open Sentence editor tool, click the Sentence editor button  on the Study view.

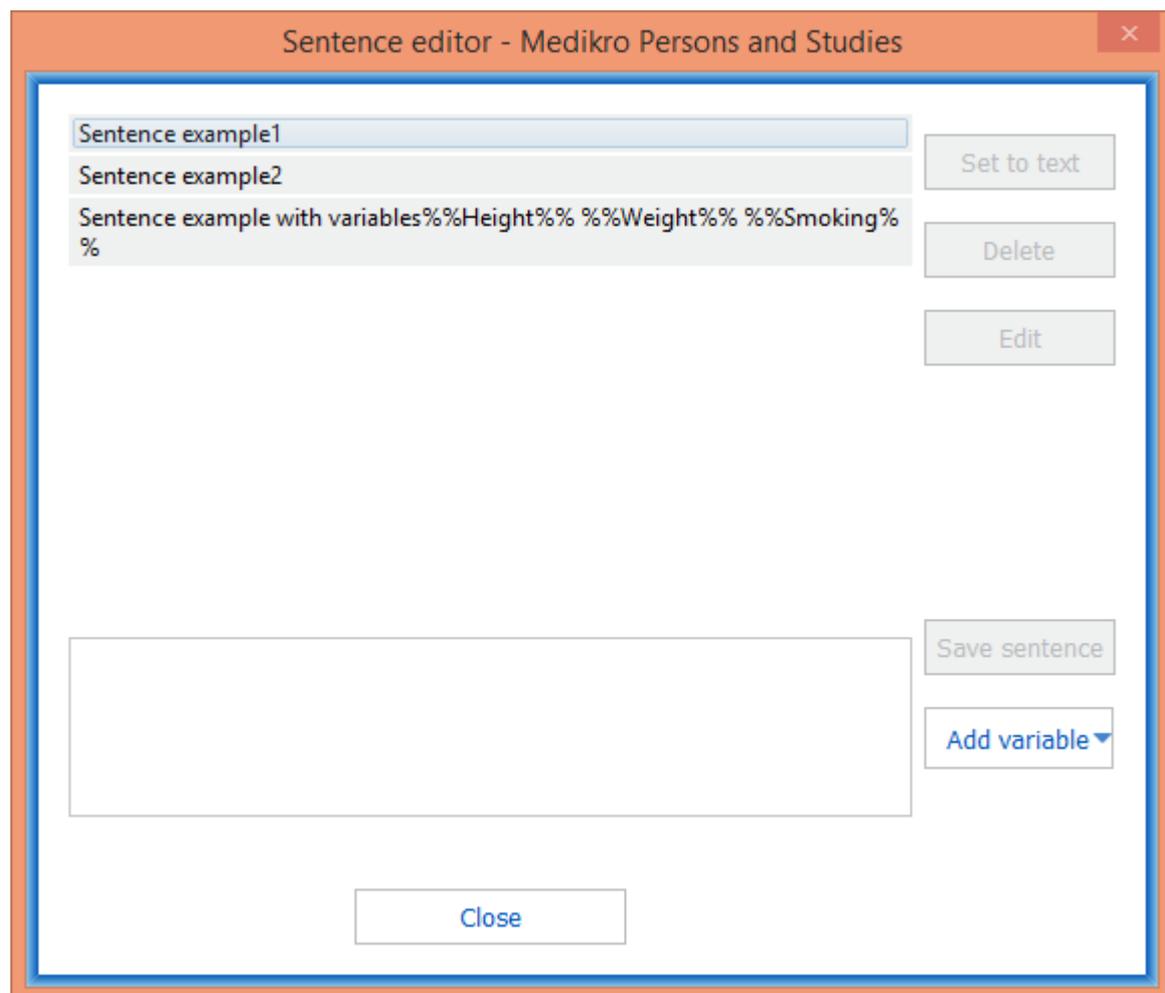


Figure: Sentence editor

Manage Sentences

To create a new sentence, type the text in the text field and select "Save Sentence" button.

To edit saved sentence, select the sentence from the list and select "Edit" button. This will set the selected text into the text field. Modify the text in the text field and select "Save Sentence" button.

To delete saved sentence, select the sentence from the list and select "Delete" button.

It is also possible to save sentences from interpretation text context menu. To save a sentence, select the text you wish to save on the interpretation text field, right-click the mouse over the interpretation field to open the context menu, and select "Interpretation text" - "Save sentence" from the context menu. Figure: Context menu

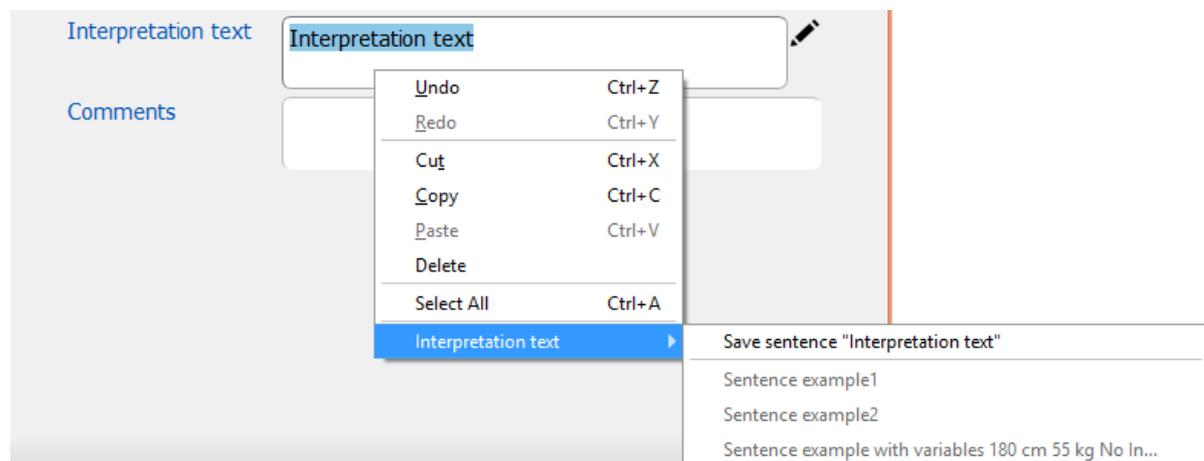


Figure: Context menu

Using Variable Data in Sentences

It is possible to add variable tags into sentences. The tags will be automatically filled in the interpretation text field, if the variable contains data. Note that the latest saved variable value at the time of the interpretation is used in the interpretation. This means that the variable data has to be saved before interpretation is entered, and if the variable data is updated, the variable value in interpretation text field is not updated.

To add variable tag into the sentence use Sentence editor, select "Add variable" button and select the variable from the list.

Add Sentence into Interpretation

There are three ways to insert saved sentence into interpretation text field:

1. To insert a sentence via Sentence Editor, select the sentence from the list and select "Set to text" button.
2. To insert a sentence via context menu, right-click the mouse on top of the interpretation text field on the Study view to open the context menu, and select "Interpretation text" and the sentence from the context menu.

3. To insert a sentence via suggested sentences list, start typing text on the interpretation text field. Saved sentences starting identically are listed. Select sentence from the suggested sentences list.

7.6 Import and Export Persons and Studies

Import and export functions allow for sending and receiving results or an entire flow signal between two Medikro Spirometry Software users or between Medikro Spirometry Software and a Hospital Information System (HIS). Importing and exporting can be done manually (See chapter: [Manual Import and Export](#)) or automatically (See chapter: [Automatic Import and Export](#)).

Note: All settings relating to import and export can be configured. For more information, see chapter [Software Settings](#).

Persons and studies can be imported from and exported to XML or GDT files.

- XML: Multiple persons can be imported and exported inside one XML file.
- GDT: Only one person can be imported and exported inside one GDT file. When exporting multiple person simultaneously, a separate GDT file is created for each person

The table below indicates the data that can be imported and exported.

	XML	GDT2.0	GDT3.0
Person Data			
Import	x	x	x
Export	x	x	x
Diagnostic Study Data			
Import	x	-	-
Export	x	x	x
Screening Study Data			
Import	-	-	-
Export	-	x	x
Serial Monitoring Study Data			
Import	-	-	-
Export	-	-	-

Checking Incoming Person's Identity

Import process checks if imported person is already in database. If imported person is matched with a person in database, Check incoming person's identity dialogue ([Figure: Check Incoming Person's Identity dialogue](#)) allows the user to check that the identity of the imported person matches with the identity of the person found in the database. It is also possible to change identification criteria or edit incoming personal information in order to get the right match. All persons in database that match the identification criteria are shown in the drop down list.

In the person identification dialogue, the user can choose to:

- Accept identification: Incoming person is saved as existing person. Whether the incoming information is updated or rejected in the database depends on the configured "Import mode". (see chapter [Software Settings](#))
- Save as new: Incoming person is saved as new person in database
- Cancel: No persons are imported.

Check incoming person's identity dialogue appears:

- Always on manual and automatic import, when identification criteria (e.g. personal ID) are matched with more than one persons in database
- On manual import, if system configuration requires checking identity when identification criteria (e.g. personal ID) are matched with one person in database. If checking identity of one match is not required, the imported person is automatically identified as the only matching person.

Identification criteria	Incoming Person	
<input checked="" type="checkbox"/> Personal ID	Demo3	Demo3
<input type="checkbox"/> Last name	Smith (demo)	Smith (demo)
<input type="checkbox"/> First name	John F	John F
<input type="checkbox"/> Birthdate (DD.MM.YYYY)	14.11.1987	14.11.1987
Gender	male	male

Accept identification to update information from incoming person to the selected person.
Save as new to save incoming person as a new person.
Cancel to cancel importing of the incoming person.

Figure: Check Incoming Person's Identity Window.

7.6.1 Manual Import and Export

Import Persons

To start import procedure, select **Import** button (see [Table: Medikro Persons and Studies Buttons](#)) on Home view, which opens the file selection dialogue. In file selection dialogue, select correct input file format, locate the input file and select "Open". Persons and Studies Import view is opened ([Figure: Import View](#)) showing list of the persons in input file. To import all persons, select **Import all** button (see [Table: Medikro Persons and Studies Buttons](#)). To import only some of the persons,

tick the checkboxes to mark the persons to be imported, and click **Import selected** button (see [Table: Medikro Persons and Studies Buttons](#)).

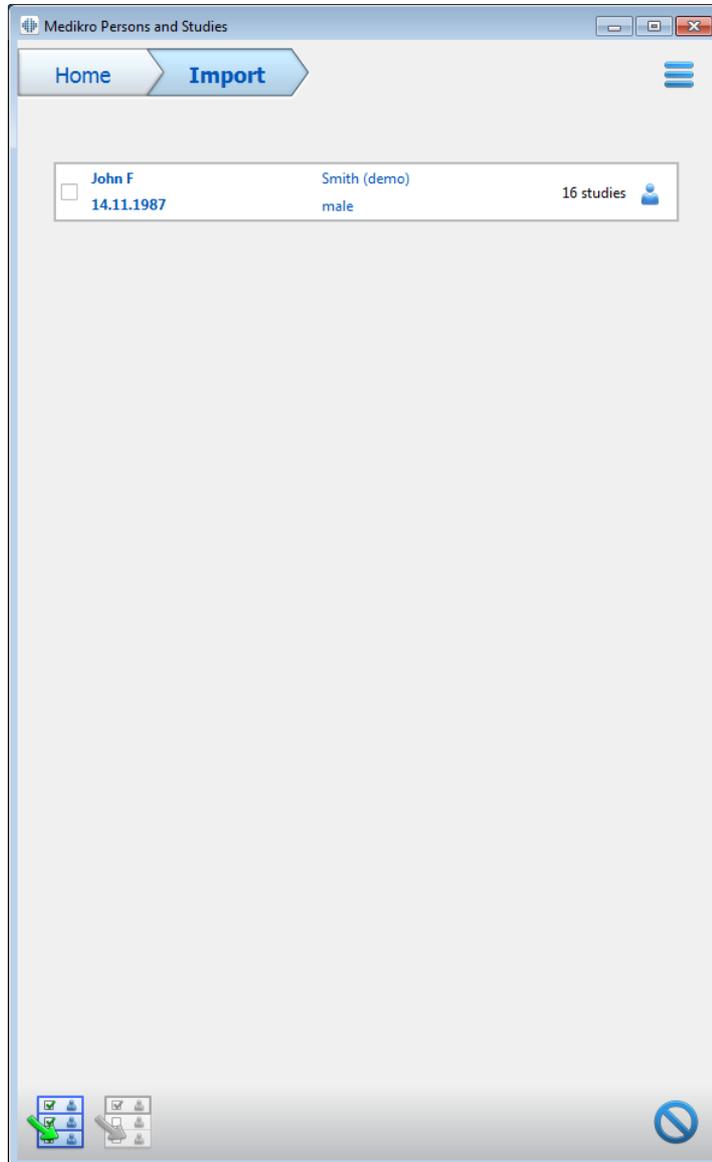


Figure: Import view

If the imported person is not found in the database, the person is imported and saved as a new person in the database. If the imported person is found in the database, Check Incoming Person's identity dialogue appears (see chapter: [Checking Incoming Person's Identity](#))

Export Person

Persons can be exported from Home view or from Person view. On Home view multiple persons can be exported simultaneously. On Person view, currently selected person can be exported, and it is possible to select which of the person's studies are exported.

To export persons on Home view, search the persons to be exported and tick the checkboxes to mark the persons to be exported. Note that when ticking multiple persons, checkboxes get unticked when the search field is emptied. Click **Export persons** button (see [Table: Medikro Persons and Studies Buttons](#)) to export ticked persons. In the opened file selection dialogue, check export file format, name and location, and select "Save". Exporting persons on Home view, exports selected persons and all of the persons' studies.

In Person view, it is possible to select which of the studies are exported. Tick the checkboxes on the person's study list to mark the studies to be exported. Click **Export person** button (see [Table: Medikro Persons and Studies Buttons](#)) to export currently selected person and selected studies. In the opened file selection dialogue, check export file format, name and location, and select "Save". If none of the studies are selected in the study list, the selected person and all of the person's studies are exported.

7.6.2 Automatic Import and Export

The automatic import and export consists of four steps: receiving an input file, checking the imported person's identity, starting a new study for the imported person, and exporting the person.

Note: All settings relating to import and export can be configured. For more information, see chapter [Software Settings](#).

Receiving an input file

Receiving an input file is semiautomatic. The existence of the input file is checked by the software after every log on to Medikro Persons and Studies, and when its Home view is accessed. If it is found, import will start and proceed from the person's identity check-up to the measurement view.

Only one person can be imported automatically. If the input file contains more than one person, or if import fails for any other reason, an error message appears and the import file is moved to the **Incorrect Inputs** folder. Incorrect Inputs location is shown in the error message.

If the input file is imported successfully, the file is automatically deleted.

Checking Import Person's Identity

The following person identification scenarios are possible:

- Incoming person is not found in the database. Person and studies are added to the database.
- Incoming person is found in the database. Person and studies are merged automatically to the person in database. Whether the incoming information is updated or rejected in the database depends on the configured "Import mode". (see chapter [Software Settings](#))
- More than one persons are found in the database matching the incoming person. Check Incoming Person's identity dialogue appears (see chapter: [Checking Incoming Person's Identity](#))

Starting a new study for the person imported to the system

When the person has been identified, automatic import starts a new spirometry study for the person. If the person has earlier studies in database or in input file, the study information is prefilled using data of the latest study. If the system has been configured to automatically proceed

to measurement, the software automatically proceeds to Measurement view and opens the study in Medikro Measurements and Results.

If mandatory spirometry information is missing from the person information, the automatic import process stops in Person view and a new study is not created. If mandatory spirometry information is missing from the study information, the automatic import process stops in Study view and measurement is not started. User has to enter missing mandatory data, and then continue manually.

Export person

When the automatic import process has succeeded, automatic export occurs when user closes imported person (i.e. Medikro Persons and Studies is closed or its Home view is accessed). Depending of the configuration, export may occur automatically or user may have to choose whether to export or not.

7.7 Delete Persons and Studies

Delete persons

Deleting person deletes all person, study and measurement data of the selected person. When persons are being deleted, confirmation of deletion is asked showing information of the person(s) to be deleted. To cancel deletion, select "No" or to accept deletion, select "Yes".

Persons can be deleted from Home view or from Person view. In Person view click **Delete person** button (see [Table: Medikro Persons and Studies Buttons](#)) to delete currently selected person.

On Home view multiple persons can be deleted simultaneously. To delete persons on Home view, search the persons to be deleted and tick the checkboxes to mark the persons to be deleted. Click **Delete persons** button (see [Table: Medikro Persons and Studies Buttons](#)) to delete ticked persons. Note that when ticking multiple persons, checkboxes get unticked when the search is revised (i.e. search field is emptied).

Delete studies

Deleting study deletes all study and measurement data of the selected study. When studies are being deleted, confirmation of deletion is asked showing date and time of the studies to be deleted. To cancel deletion, select "No" or to accept deletion, select "Yes".

Studies can be deleted from Person view or from Study view. In Study view click **Delete study** button (see [Table: Medikro Persons and Studies Buttons](#)) to delete currently selected study.

On Person view multiple studies can be deleted simultaneously. To delete studies on Person view, tick the checkboxes on the study list to mark the studies be deleted. Click **Delete studies** button (see [Table: Medikro Persons and Studies Buttons](#)) to delete ticked studies.

7.8 Database Connection and Synchronization

Depending on the system configuration, the Medikro Software might be connected to a shared online database (multiple workstation environment) or to a local database (single workstation environment). For more information about different environment types and database settings, see Medikro Spirometry Software Installation Guide and Medikro Administration Tool user manual.

Connection to an online database is indicated on Medikro Persons and Studies with a connection indicator as shown in the figures below.



Figure: Disconnected from online database



Figure: Connected to online database

If connection to an online database has been lost, it is not possible to retrieve information from the online database. However, it is possible to continue using Medikro Spirometry Software and create new data. New data is temporarily saved in local database.

Database Synchronisation

If data has been saved to the local database and online database connection is re-established, the data in the local database is automatically transferred to the online database.

The database synchronisation process checks if persons and studies that are transferred already exist in the online database. The following person identification scenarios are possible:

- Incoming person is not found in the database: Person and studies are added to the database.
- Incoming person is found in the database: Person and studies are merged automatically to the person in database. If there are new studies incoming, they are added for the matched person. Existing person and study data are updated by the latest data, with the exception that existing data is not updated by empty data.
- More than one persons are found in the database matching the incoming person: Dialogue is shown, where user has to choose to start or cancel database synchronisation. If user selects "Later" on confirmation dialogue, the synchronisation process is cancelled and the system remains disconnected from the online database. The synchronisation dialogue is shown again when Medikro Persons and Studies is started the next time. If user selects "Yes" on the confirmation dialogue, the Person identification dialogue appears ([Figure: Check Incoming Person's Identity dialogue](#)) where user can choose to:
 - Accept identification: Incoming person and studies are merged to the selected person in database. If there are new studies incoming, they are added for the matched person. Existing person and study data are updated by the latest data, with the exception that existing data is not updated by empty data.
 - Save as new: Incoming person and studies are added to the database.

You are merging data from the offline database to the online database.

Please check the identity of the person from offline database.
You may change the identity information and criteria to find a correct match.

Identification criteria	Person from offline database	Smith (demo) John F
<input checked="" type="checkbox"/> Personal ID	<input type="text" value="Demo3"/>	<input type="text" value="Demo3"/>
<input checked="" type="checkbox"/> Person code	<input type="text"/>	<input type="text"/>
<input checked="" type="checkbox"/> Last name	<input type="text" value="Smith (demo)"/>	<input type="text" value="Smith (demo)"/>
<input type="checkbox"/> Middle name	<input type="text"/>	<input type="text"/>
<input type="checkbox"/> First name	<input type="text" value="John F"/>	<input type="text" value="John F"/>
<input type="checkbox"/> Birthdate (DD.MM.YYYY)	<input type="text" value="14.11.1987"/>	<input type="text" value="14.11.1987"/>
Gender	<input type="text" value="male"/>	<input type="text" value="male"/>

Accept identification to update information from person in the offline database to the selected person.
Save as new to save incoming person as a new person.

Figure: Check Incoming Person's Identity Window.

Diagnostic Spirometry



8 Diagnostic Spirometry

This chapter describes how to perform, analyse and manage measurements using the Medikro Pro, Medikro Nano or Medikro Primo Spirometer together with the Medikro Measurements and Result user interface.

8.1 Using the Measurements and Results Software

After starting and logging ([Figure: Opening View](#)) into Medikro Spirometry Software, the user can:

- create new patients and research sessions,
- adjust programme settings, and
- calibrate the spirometer.

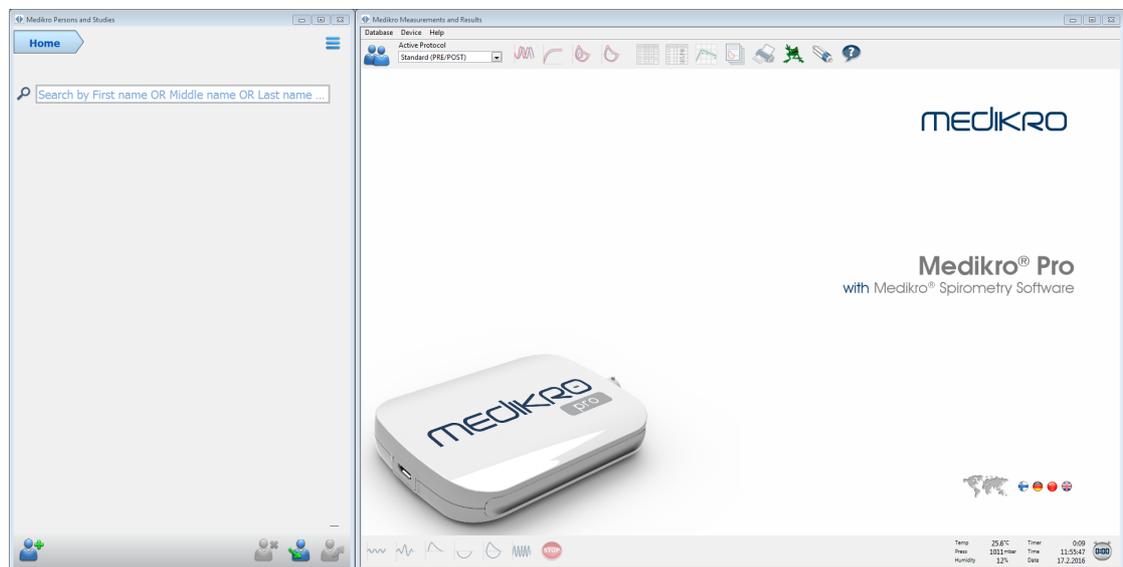


Figure: Opening View

Running a spirometry study is based on the work flow ([Figure: Measurement View](#)):

1. Search or create person (in Medikro Persons and Studies application)
2. Select or create study for the person (in Medikro Persons and Studies application)
3. View measurement results or make new measurements for the study (in Medikro Measurements and Results application)

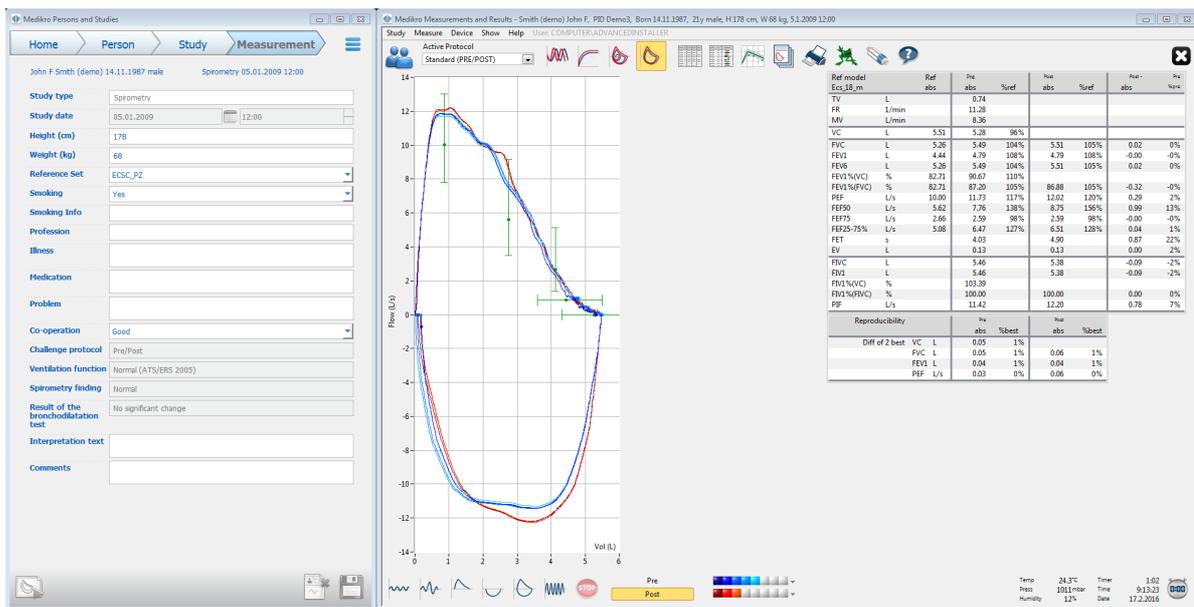


Figure: Measurement view

To create new patients and sessions, see chapter [Person and Study Management](#). To adjust programme settings, see chapter [Programme Settings](#), and to calibrate the spirometer, see chapter [Calibration Check](#). After creating patient information, the user can start measuring the patient (see chapter [Starting the Measurement](#)) and analyse the measurement results (see chapter [Analysing Results](#)). Also, the user can create a final report from the results (see chapter [The Final Report](#)).

Note: User privileges are managed in Medikro Administration Tool. All operations may not be available for all users. For more information on access control management, see Medikro Administration tool user manual.

8.2 Measurements and Results Software Buttons

Table: Medikro Measurements and Results Basic Buttons:

Button	Function and description
	Print button. Prints the contents of the currently shown measurement window
	Calibrate button. Opens the spirometer calibration function.
	Show Help button. Opens the Medikro Spirometry Software User manual.

	Stop button. Stops the measurement.
	Incentive button. Opens the incentive screen.
	Signal table button. Opens the signal table.
	Show NONE/ALL signals of this phase button. This button will activate or inactivate the viewing of all Pre- or Post-phase measurement curves.
	Show Persons and Studies button. Brings Medikro Persons and Studies application on top.
	Close Study button. Closes currently open study in Medikro Measurements and Results application. Application remains open.

Table: Medikro Measurements and Results Measurement Buttons:

Button	Function and description
	TV button. Starts the Tidal Volume (TV) measurement manoeuvre.
	SVC button. Starts the Slow Vital Capacity (SVC) measurement manoeuvre.
	FVC button. Starts the Forced Vital Capacity (FVC) measurement manoeuvre.
	FIVC button. Starts the Forced Inspiratory Vital Capacity (FIVC) measurement manoeuvre.
	FVC+FIVC button. Starts the Forced Expiratory and Inspiratory Vital Capacity measurement manoeuvre.
	MVV button. Starts the Maximum Voluntary Ventilation (MVV) measurement manoeuvre.

Table: Medikro Measurements and Results Show Curves Buttons:

Button	Function and description
	Show Volume-Time Curves button. Displays the Volume/Time curve of the measurement(s).
	Show 6sec Volume-Time Curves button. Displays the 6s Volume/Time curve of the measurements in a separate floating window.
	Show Flow-Volume Curves button. Displays the Flow Volume curve of the measurement(s).

	<p>Show Curves button. Displays the curves of the measurement(s).</p>
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Table: Medikro Measurements and Results Show Results Buttons:

Button	Function and description
	<p>Show Measurement Results button. Displays the results of all measurements in numerical format.</p>
	<p>Show Best Results button. Displays the results of the best measurements both in numerical format and as a histogram</p>
	<p>Show Trend button. Trend allows the inspection of the trend of each individual variable in a graphical and numerical table form. The numerical table can be opened and closed in the trending view.</p>
	<p>Show Report button. Displays the final report.</p>

8.3 Measurements and Results Programme Settings

The user can adjust the general, spirometry, variables, incentive, database, graph scaling and PDF/image export settings of the program. To change the programme settings, select:

Device>Settings

Note: The **Settings** window contains choices that affect the system and spirometry calculations.



WARNING: Changes to programme settings will affect the measurement results.

8.3.1 General

To change the general settings, select:

Device>Settings>General

The user can change the following options from the general tab:

- Ambient factors
- Spirometer Detection
- Detection of External Ambi Unit
- Volume unit
- Window size at startup

Additional information:

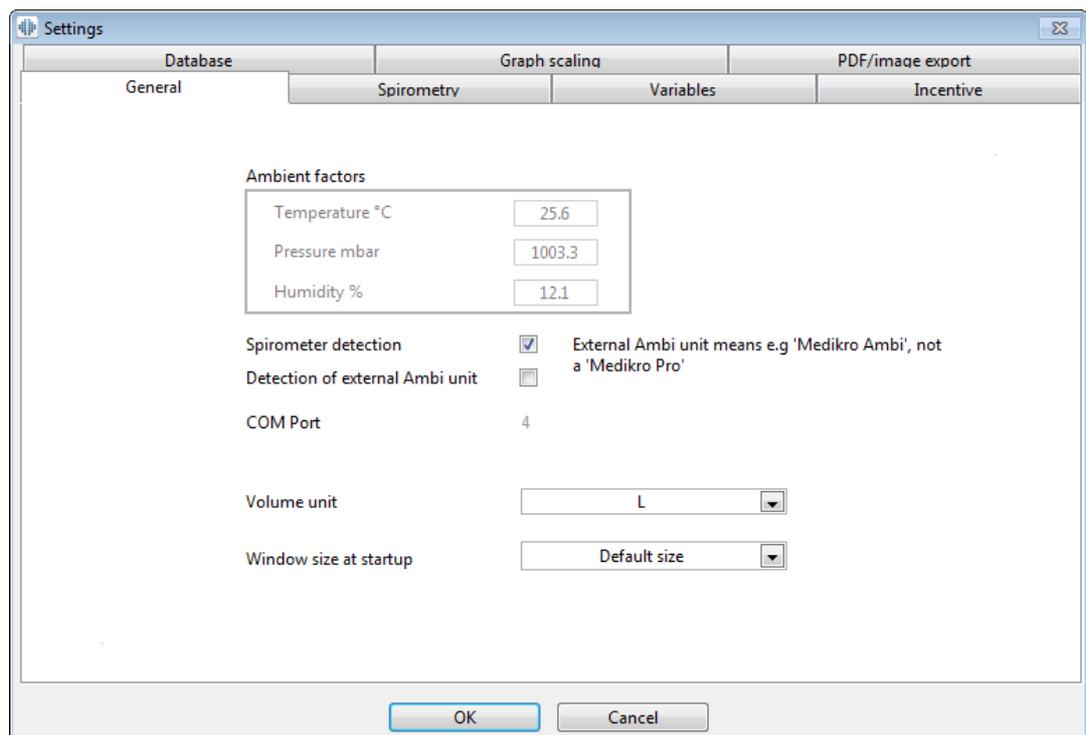


Figure: General settings tab

Ambient factors

The ambient conditions of the operating environment affect the results measured and calculated by the spirometer. Subsequently,

- the room temperature,
- the atmospheric pressure, and
- the relative humidity

should be recorded and entered into the programme daily and, also, if they change notably during the day.

To enter these values, use the following command path:

Device>Settings>General

Note! If the spirometer has built-in ambient unit or you have a separate ambient condition measurement unit, ambient factors are updated automatically and they can't be changed manually.

Spirometer Detection

The default setting of the Medikro Spirometry Software includes an automatic serial port scan for spirometer detection. If you are using the software only for viewing database results and do not have a spirometer connected to your PC, you may want the programme to omit the automatic search. To omit the automatic search use the following command path:

Device>Settings>General>Spirometer Detection

Inactivate/activate the automatic search by clicking the **Spirometer Detection** check box.

Detection of external Ambi unit

External Ambi unit means e.g. Medikro Ambi device. Medikro Pro is not external Ambi unit although it has capability to measure ambient conditions.

Detection of external Ambi unit is disabled by default. When detection is on and external Ambi unit is found, program reads ambient factors from the device and user does not need to enter them manually.

- Enable this setting, if you have any Medikro Spirometer and Medikro Ambi
- Disable this setting, if you have any Medikro Spirometer but no Medikro Ambi

To change this setting, use the following command path:

Device>Settings>General>Detection of external Ambi unit

Volume Unit

You have an option to select between two presentations of litre unit: L or l.

To select between metric and imperial units, see Medikro Administration tool user manual.

To select the units use the following command path:

Device>Settings>General>Volume Unit

8.3.2 Spirometry

To change the spirometry settings, select:

Device>Settings>Spirometry

The user can change the following options from the spirometry tab:

- Calibration Volume
- Max Variation and Logging
- Standard Recommendations
- Exceptions and Choices
- Heading of the Final Report

Additional information

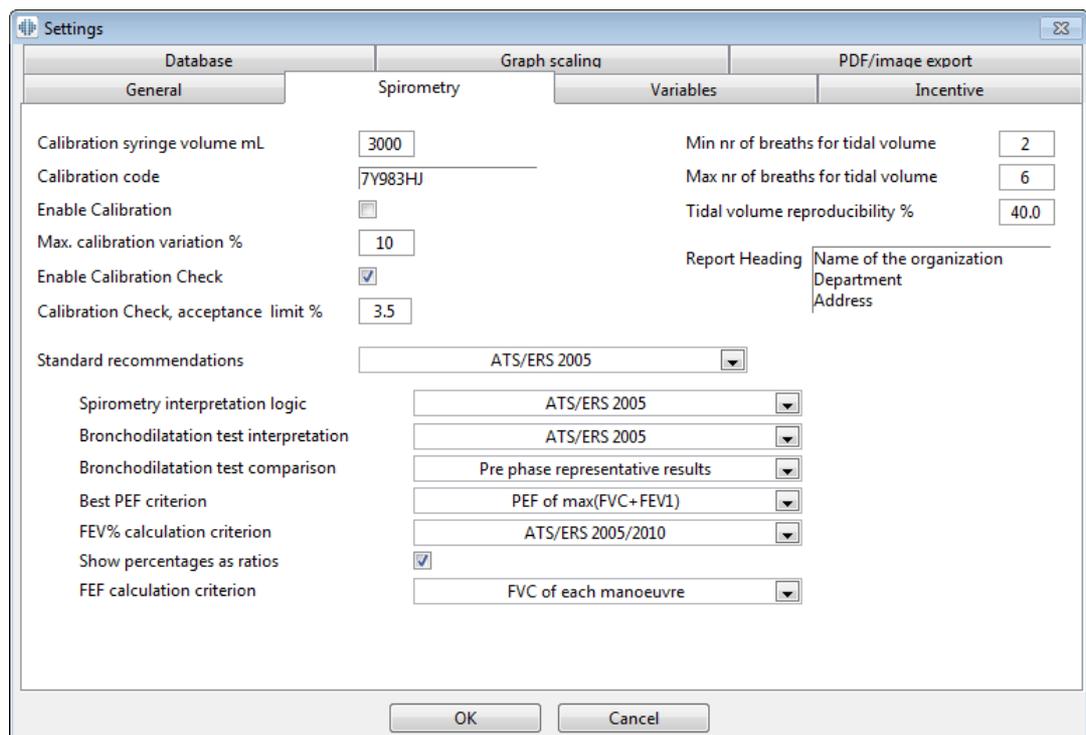


Figure: Spirometry settings tab

Calibration and Calibration Check Settings

Before you run the calibration or calibration check, you should verify that the calibration volume specified in the programme is the same as the volume of the calibration syringe. The default value for calibration syringe volume is 3000 ml. You may also change the maximum variation of the calibration (default value is 10%) and acceptance limit of the calibration check (default value is 3.5%). If you have Medikro Primo, Medikro Nano or Medikro Pro spirometer, calibration is disabled and calibration check is enabled by default (See chapter: [Calibration Check](#)). These settings can be found by using the following command paths:

Device>Settings>Spirometry>Calibration syringe volume ml

Device>Settings>Spirometry>Enable Calibration

Device>Settings>Spirometry>Max. calibration variation %

Device>Settings>Spirometry>Enable Calibration Check

Device>Settings>Spirometry>Calibration Check, acceptance limit %

Min nr of breaths for tidal volume

This value is used when performing tidal volume measurement which precedes IRV, ERV, IC or EC calculations. The value defines the minimum number of breaths that allows transition from TV manoeuvre to SVC manoeuvre. This setting can be found by using the following command paths:

Device>Settings>Spirometry>Min nr of breaths for tidal volume

Max nr of breaths for tidal volume

This value is used when performing tidal volume measurement which precedes IRV, ERV, IC or EC calculations. The value defines how many of the latest breaths are used to calculate tidal breath's minimum and maximum levels and reproducibility of breaths (see chapter Tidal volume reproducibility %). If the actual number of breaths is less than the value, all available breaths are used in calculations. This setting can be found by using the following command paths:

Device>Settings>Spirometry>Max nr of breaths for tidal volume

Tidal volume reproducibility %

This value is used when performing tidal volume measurement which precedes IRV, ERV, IC or EC calculations. Tidal breathing reproducibility is calculated from the latest breaths and its state indicated by a traffic light on SVC-button. If reproducibility is acceptable (it is less or equals the criterion), traffic light is green. If reproducibility is poor, light is red. By changing this criterion you may tighten or ease to get the green light. This setting can be found by using the following command paths:

Device>Settings>Spirometry>Tidal volume reproducibility %

Calibration Code of the Flow Transducer

You can check the calibration code of the flow transducer and change it when needed by using the following command path:

Device>Settings>Spirometry>Calibration code

Calibration code is printed on the side of the flow transducer package. Type the calibration code and press OK. If the code is mistyped, OK button is grayed out.

Tip: You can use a bar code reader to read the calibration code from the flow transducer package.

Standard Recommendations

You may choose which spirometry standard the Medikro Spirometry Software complies with. The options are the ATS 1994, ERS 1993, and ATS/ERS 2005 recommendations. You can change the used standard from the standard recommendations drop-down selection. For the selection use the following command path:

Device>Settings>Spirometry>Standard recommendations

There are generally only minor differences between the American Thoracic Society (ATS) 1994 [1] and the European Respiratory Society (ERS) 1993 [2] recommendations. The views of both the ATS and ERS were joined in 2005 [3-5].

The standard selection affects primarily:

- how the representative values are chosen
- start of test criteria (extrapolated volume)
- end of test criteria (no change in volume, exhalation time)

- repeatability criteria of FVC, FEV1, VC, PEF, and MWV
- bronchodilatation response criteria

Exceptions and Choices

After choosing the standard you may fine tune the spirometry calculations via exceptions and choices. The following options for calculation exceptions and choices are: [Spirometry Interpretation Logic](#), Bronchodilatation Test Interpretation, Bronchodilatation Test Comparison, Best PEF Criterion, FEV% calculation criterion, Show percentages as ratios, FEF calculation criterion.

Spirometry Interpretation Logic

Spirometry interpretation logic combines two interpretation settings, ventilatory dysfunction type (formerly: spirometry finding) and severity of ventilatory disturbance (formerly: ventilation function) together. You can access this setting by using the following command path:

Device>Settings>Spirometry>Spirometry Interpretation Logic

For more information about available options, see chapter [Spirometry Interpretation Logic](#).

Bronchodilatation Test Interpretation

You can select the method to interpret the results of a bronchodilatation test by using the following command path:

Device>Settings>Spirometry>Bronchodilatation test interpretation

There are following options:

ATS/ERS 2005. With this option, the bronchodilatation test is interpreted according to the ATS and ERS 2005 recommendations.

ERS 1993. With this option, the bronchodilatation test is interpreted according to the ERS 1993 recommendations.

Sovijarvi 1994. With this option, the bronchodilatation test is interpreted according to Sovijarvi 1994.

Sovijarvi 2006. With this option, the bronchodilatation test is interpreted according to Sovijarvi 2006.

Moodi 2015. With this option, the bronchodilatation test is interpreted according to Moodi 2015.

None. With this option, the bronchodilatation test is not interpreted and shows an empty value.

For more information about bronchodilation test interpretation, see chapter [Interpretation](#).

Bronchodilatation Test Comparison

You can select the method to compare the results of a bronchodilatation test by using the following command path:

Device>Settings>Spirometry>Bronchodilatation test comparison

There are following options:

Predicted values. With this option, the difference between the Post- and Pre-phase results is calculated in relation to the predicted value and shown as "%of pred". To assess whether the change in the bronchodilatation test is significant, Medikro Spirometry Software compares the relative difference to the predicted value.

Pre-phase representative results. With this option, the difference between the Post- and Pre-phase results is calculated in relation to the Pre-phase representative value and shown as "%pre". To assess whether the change in the bronchodilatation test is significant, Medikro Spirometry Software compares the relative difference to the Pre-phase representative value.

Best PEF Criterion

You can select how the best PEF is chosen by using the following command path:

Device>Settings>Spirometry>Best PEF Criterion

There are following options:

PEF of max(FVC+FEV1). The best PEF is chosen from the manoeuvre with the largest sum of FVC+FEV1.

Largest PEF. The best PEF is the largest PEF of Pre- or Post-phase manoeuvres.

FEV% calculation criterion

You can select how FEV- and FIV-percentages are calculated by using the following command path:

Device>Settings>Spirometry>FEV% calculation criterion

There are following options:

ERS 1993. FEVn%(FVC) is calculated by dividing FEVn by the best FVC of Pre- or Post-phase. n = 0.25, 0.5, 0.75, 1, 2, 3, 4 or 5.

The best FEVn% is calculated by dividing the best FEVn by the best FVC.

The same principle applies to FEVn%(FEV6), FIVn%(FIVC) and FIVn%(FIV6).

ATS/ERS 2005. FEVn%(FVC) is calculated by dividing FEVn by the FVC of each manoeuvre. n = 0.25, 0.5, 0.75, 1, 2, 3, 4 or 5.

The best FEV_n% is chosen from the manoeuvre with the largest sum of FVC+FEV1.

The same principle applies to FEV_n%(FEV6), FIV_n%(FIVC), and FIV_n%(FIV6).

ATS/ERS 2005/2010. FEV_n%(FVC) is calculated by dividing FEV_n by the FVC of each manoeuvre. n = 0.25, 0.5, 0.75, 1, 2, 3, 4 or 5.

The best FEV_n% is calculated by dividing the best FEV_n by the best FVC.

The same principle applies to FEV_n%(FEV6), FIV_n%(FIVC), and FIV_n%(FIV6).

MOUDI 2019. FEV_n%(FVC) is calculated by dividing FEV_n by the FVC of each manoeuvre. n = 0.25, 0.5, 0.75, 1, 2, 3, 4 or 5.

The best FEV_n% is calculated by dividing the best FEV_n by the best FVC.

The same principle applies to FEV_n%(FEV6), FIV_n%(FIVC), and FIV_n%(FIV6).

Show percentages as ratios

Some of the variables are based on division of two variables. If both, the dividend and divider, have equal units the resulting division can be presented as a percentage or as a ratio. By checking this option the division result is shown as a ratio and by unchecking this option a percentage value is shown. This setting can be found by using the following command paths:

Device>Settings>Spirometry>Show percentages as ratios

FEF calculation criterion

You can select how FEF_n, FEF25-75%, FIF_n, and FIF25-75% (n = 25, 50 or 75) are calculated by using the following command path:

Device>Settings>Spirometry>FEF calculation criterion

There are following options:

max FVC of each phase. FEF_n and FEF25-75% are calculated using the best FVC of the Pre- or Post-phase as a reference volume. n = 25, 50 or 75.

The same principle applies to FIF_n and FIF25-75%.

FVC of each manoeuvre. FEF_n and FEF25-75% are calculated using the FVC of each manoeuvre as a reference volume. n = 25, 50 or 75.

The same principle applies to FIF_n and FIF25-75%.

Heading of the Final Report

The header of the report can be modified to include the name of the establishment, clinic, or

institution, as well as the necessary contact information. Use the following command path:

Device>Settings>Spirometry>Report Heading

Enter the necessary information into the free text field, where 3 lines are provided. Individual report formats can be provided on request from Medikro Oy.

8.3.3 Variables

To change the variable settings, select:

Device>Settings>Variables

The user can change the options for variables for display and print in the variable tab.

▣ Additional information:

Variables for display and print

Variables can be individually selected for display or print (there are altogether 102 variables):

 select variable for display

 select variable for print

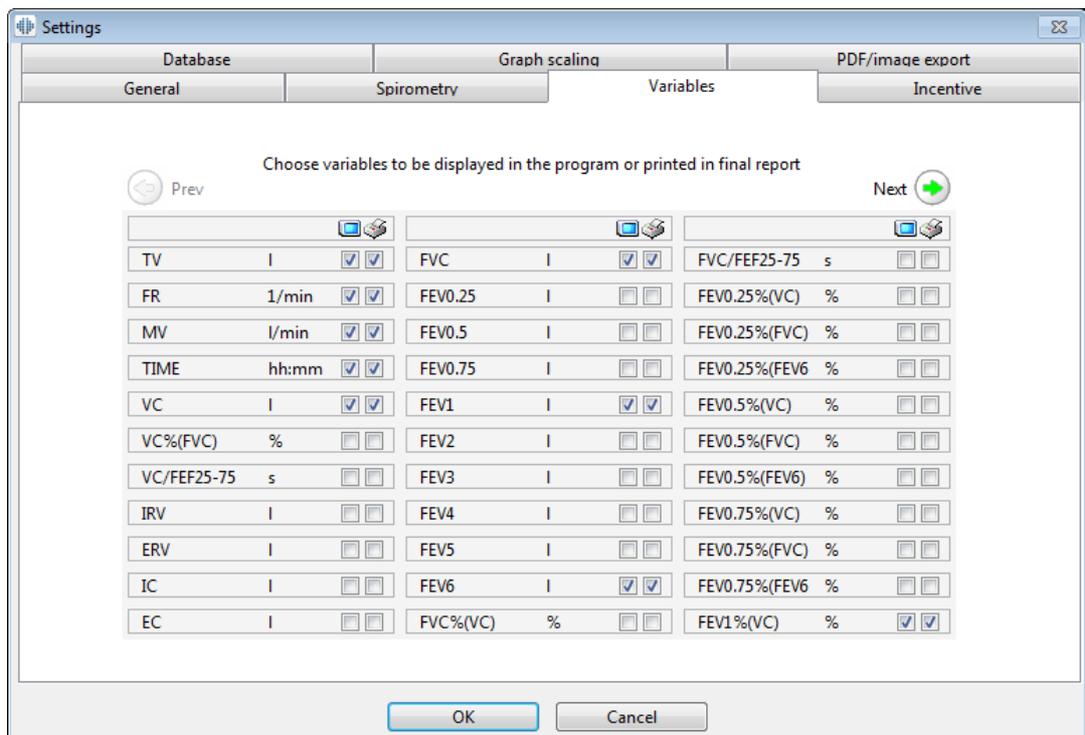


Figure: Variable settings tab

▣ Additional information about variables

	Abbreviation	Name	Unit
1	TV	Tidal volume	L
2	FR	Breathing frequency	1/min
3	MV	Minute ventilation	L/min
4	TIME	Time	hh:mm
5	VC	Vital capacity	L
6	VC%(FVC)	VC / FVC	%
7	VC/FEF25-75	VC / FEF25-75	s
8	IRV	Inspiratory reserve volume	L
9	ERV	Expiratory reserve volume	L
10	IC	Inspiratory capacity	L
11	EC	Expiratory capacity	L
12	FVC	Forced vital capacity	L
13	FEV0.25	Forced expiratory volume at 0.25s	L
14	FEV0.5	Forced expiratory volume at 0.5s	L
15	FEV0.75	Forced expiratory volume at 0.75s	L
16	FEV1	Forced expiratory volume at 1.0s	L
17	FEV2	Forced expiratory volume at 2.0s	L
18	FEV3	Forced expiratory volume at 3.0s	L
19	FEV4	Forced expiratory volume at 4.0s	L
20	FEV5	Forced expiratory volume at 5.0s	L
21	FEV6	Forced expiratory volume at 6.0s	L
22	FVC%(VC)	FVC / VC	%
23	FVC/FEF25-75	FVC / FEF25-75	s
24	FEV0.25%(VC)	FEV0.25 / VC	%
25	FEV0.25%(FVC)	FEV0.25 / FVC	%
26	FEV0.25%(FEV6)	FEV0.25 / FEV6	%
27	FEV0.5%(VC)	FEV0.5 / VC	%
28	FEV0.5%(FVC)	FEV0.5 / FVC	%
29	FEV0.5%(FEV6)	FEV0.5 / FEV6	%
30	FEV0.75%(VC)	FEV0.75 / VC	%

31	FEV0.75%(FVC)	FEV0.75 / FVC	%
32	FEV0.75%(FEV6)	FEV0.75 / FEV6	%
33	FEV1%(VC)	FEV1 / VC	%
34	FEV1%(FVC)	FEV1 / FVC	%
35	FEV1%(FEV6)	FEV1 / FEV6	%
36	FEV1%(FIV1)	FEV1 / FIV1	%
37	FEV1/PEF	FEV1 / PEF	mL/L/min
38	FEV2%(VC)	FEV2 / VC	%
39	FEV2%(FVC)	FEV2 / FVC	%
40	FEV2%(FEV6)	FEV2 / FEV6	%
41	FEV3%(VC)	FEV3 / VC	%
42	FEV3%(FVC)	FEV3 / FVC	%
43	FEV3%(FEV6)	FEV3 / FEV6	%
44	FEV4%(VC)	FEV4 / VC	%
45	FEV4%(FVC)	FEV4 / FVC	%
46	FEV4%(FEV6)	FEV4 / FEV6	%
47	FEV5%(VC)	FEV5 / VC	%
48	FEV5%(FVC)	FEV5 / FVC	%
49	FEV5%(FEV6)	FEV5 / FEV6	%
50	PEF	Peak expiratory flow	L/s
51	PEF	Peak expiratory flow	L/min
52	PEF%(PIF)	PEF / PIF	%
53	RT10-90	Rise time (10-90% of PEF)	ms
54	DT90	Dwell time (90% of PEF)	ms
55	DT95	Dwell time (95% of PEF)	ms
56	PEFT	Time to PEF	ms
57	FEF25	Forced expiratory flow at 25% of FVC [MEF75]	L/s
58	FEF50	Forced expiratory flow at 50% of FVC [MEF50]	L/s
59	FEF75	Forced expiratory flow at 75% of FVC [MEF25]	L/s
60	FEF25-75%	Forced expiratory flow at 25-75% of FVC [MMEF]	L/s
61	FEF50%(FIF50)	FEF50 / FIF50	%

62	FEF25-75/VC	FEF25-75 / VC	1/s
63	FEF25-75/FVC	FEF25-75 / FVC	1/s
64	METT	Mean transit time	s
65	AEFV	Area of expiratory FV curve	L*L/s
66	FET	Forced expiratory time	s
67	EV	Extrapolated volume	L
68	EV%(FVC)	EV / FVC	%
69	LAGE	Lung age	a
70	FIVC	Forced inspiratory vital capacity	L
71	FIV0.5	Forced inspiratory volume at 0.5s	L
72	FIV1	Forced inspiratory volume at 1.0s	L
73	FIV6	Forced inspiratory volume at 6.0s	L
74	FIV0.5%(VC)	FIV0.5 / VC	%
75	FIV0.5%(FIVC)	FIV0.5 / FIVC	%
76	FIV0.5%(FIV6)	FIV0.5 / FIV6	%
77	FIV1%(VC)	FIV1 / VC	%
78	FIV1%(FIVC)	FIV1 / FIVC	%
79	FIV1%(FIV6)	FIV1 / FIV6	%
80	FIV1%(FEV1)	FIV1 / FEV1	%
81	PIF	Peak inspiratory flow	L/s
82	PIF	Peak inspiratory flow	L/min
83	PIF%(PEF)	PIF / PEF	%
84	FIF25	Forced inspiratory flow at 25% of FIVC [MIF75]	L/s
85	FIF50	Forced inspiratory flow at 50% of FIVC [MIF50]	L/s
86	FIF75	Forced inspiratory flow at 75% of FIVC [MIF25]	L/s
87	FIF25-75%	Forced inspiratory flow at 25-75% of FIVC [MMIF]	L/s
88	FIF50%(FEF50)	FIF50 / FEF50	%
89	MITT	Mean inspiratory transit time	s
90	AIFV	Area of inspiratory FV curve	L*L/s
91	FIT	Forced inspiratory time	s
92	IEV	Extrapolated inspiratory volume	L

93	IEV%(FIVC)	IEV / FIVC	%
94	MWV	Max voluntary ventilation	L/min
95	MWFR	MWV frequency	1/min
96	MWVT	MWV time	s
97	VCDIFF	Difference to best VC	L
98	FVCDIFF	Difference to best FVC	L
99	FEV1DIFF	Difference to best FEV1	L
100	PEFDIFF	Difference to best PEF	L/s
101	PEFDIFF	Difference to best PEF	L/min
102	MWVDIFF	Difference to best MWV	L/min

Note: By choosing variables for display, you can also choose which measurement manoeuvre buttons are active. For example, if none of TV manoeuvre variables (TV, FR, or MV) is chosen, the TV manoeuvre button is deactivated (greyed). The same principle also applies to the SVC, FVC, FIVC, FVC+FIVC, and MWV manoeuvres.

8.3.4 Incentive

An incentive screen is a motivator for children (and if need be, for any test subject) to exhale with maximal effort for the spirometry examination. An interactive 3-dimensional animation is displayed during the test, and it operates by responding to the performed exhale.

The setup of the incentive screen has been made into the dialogue sheet 'Incentive'. In most cases, it is enough to check the settings once and start using the incentive without further modifications. All the settings related to the incentive can be found at:

Device>Settings>Incentive

The user can change the following options from the incentive tab:

- Current Incentive
- Targeted FET
- Incentive size
- Data Communication
- Success Criteria

Additional information

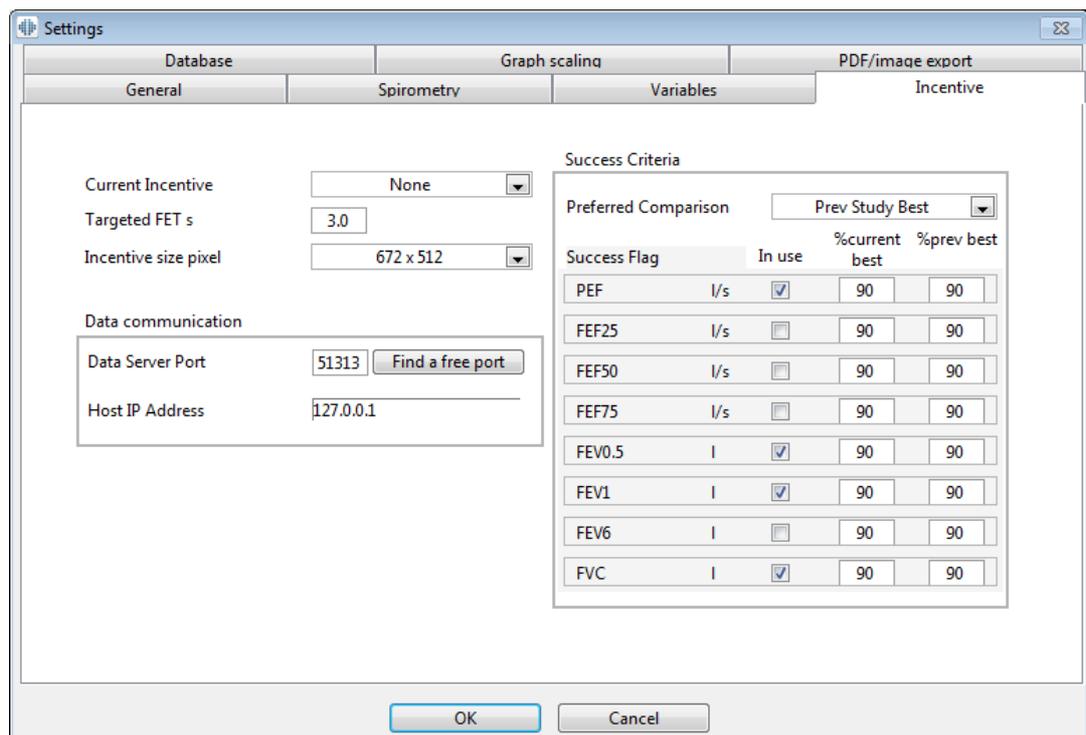


Figure: Incentive settings tab

Current Incentive

This is the main selector from which the incentive is taken into use. The default value is none, which means that the incentive is not in use. Currently, there is one incentive, the “Frog”. Freddie the Frog is an animated frog that spends its time at its favourite pond and waits for strong exhalations that will make it leap to a lily pad on the opposite side of the pond. If the exhalation is not effective enough, Freddie splashes into the water instead.

Targeted FET

A target time of the exhalation (Forced Expiratory Time) in seconds.

Incentive size

Size of the incentive screen in pixels. A default value of 416 x 320 is suitable for most computers, since a larger resolution requires for more performance from the computer.

Data Communication

User can modify the following data communication options: Data Server Port and Host IP Address.

Data Server Port

Port number of the data server. A data server is required for sending data to the Incentive applet. If the port number is reserved, the number is flagged red and an error message will be displayed when exiting Settings (by selecting OK). In that case, a new free data server port can

be found by clicking the **Find a free port** button. It is also possible to edit the port number manually. Incentive can also be viewed in an external workstation. In that case, external workstation should have here the port number of the measurement workstation. Please consult your system administrator.

Host IP Address

If the incentive is displayed in a measurement workstation, this value should be 127.0.0.1. Incentive can also be viewed in an external workstation. In that case, external workstation should have here the IP address of the measurement workstation (e.g. 192.168.64.142). Please consult your system administrator.

Success Criteria

The user can modify the following success criteria options: Preferred comparison and Success Flags.

Preferred comparison

You can choose the preferred comparison to be monitored within the incentive. There are three options to select for the preferred comparison:

Predicted values. With this setting, the selected variables of the exhalation are compared with the lower limit of 95 % of the normal range of the predicted values.

Current session best. With this setting, the selected variables of the exhalation are compared with the best values of the current session. If the current session does not contain any values to compare (e.g. the measurement is the first measurement of the session), the comparison will be made with the best values of the previous session. If the previous session does not contain any values for comparison, the comparison will be made with the lower limit of 95 % of the normal range of their predicted values.

Prev session best. With this setting, selected variables of the exhalation are compared to their best values of the previous session. If the previous session does not contain any values for comparison, the comparison will be done to the best values of the current session. If none exist, the comparison will be made with the lower limit of 95 % of the normal range of the predicted values.

Note that in **Current session best** and **Prev session best**, the comparison limit is determined as a percentage of the current session best or previous session best, respectively. Each selected variable can have an individual percentage.

Also note that the comparison is always phase-related. This means that Post-phase measurements are always compared with Post-phase measurements, and Pre-phase measurements are always compared with Pre-phase measurements.

Success Flags

You can choose the variables from the **in use** selection. The selected variables are monitored within the incentive. The monitored variables are called **success flags**, and they indicate how well the exhalation is performed (see the upper part of the incentive applet screen). For the colour

status of success flags, see chapter [Measurements with the Incentive](#)).

8.3.5 Database

To change the database settings, select:

Device>Settings>Database

The user can change the following options from the database tab:

- Location of Data
- The Final Report Template

▣ Additional information:

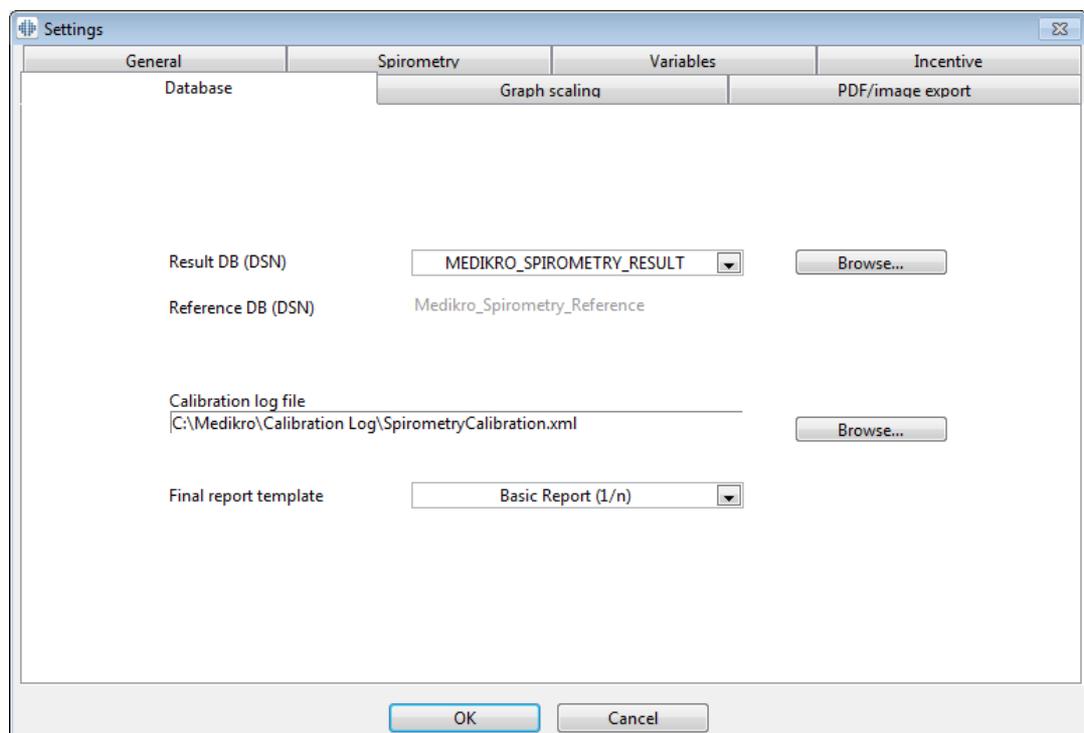


Figure: Database settings tab

Location of Data

The program allows the operator to define databases also in the LAN environment. The operator can define the location of the data generated within a spirometry session. The location of the following data can be established:

Description of data	Default value
Result Database (DSN)	Medikro_Spirometry_Result (This database contains software activation information. Health information and spirometry results are stored in new databases. See the Medikro Administration Tool User manual.)

Reference Database (DSN)	Medikro_Spirometry_Reference (for information only, the location cannot be changed)
Calibration log file	C:\Medikro\Calibration Log\SpirometryCalibration.xml

The Final Report Template

You may choose the default page of the Final Report from the drop-down selection. This page opens first when the final report is selected (see chapter [The Final Report](#)).

8.3.6 Graph Scaling

Graph properties such as scaling, axis minimum and maximum or aspect ratio can be adjusted separately for each graph. Graph settings can be adjusted for the following graphs:

- Flow/Volume graph
- Volume/Time graph
- 6 s Volume/Time graph

To change the graph scale settings, select:

Device>Settings>Graph Scaling

▣ Additional information:

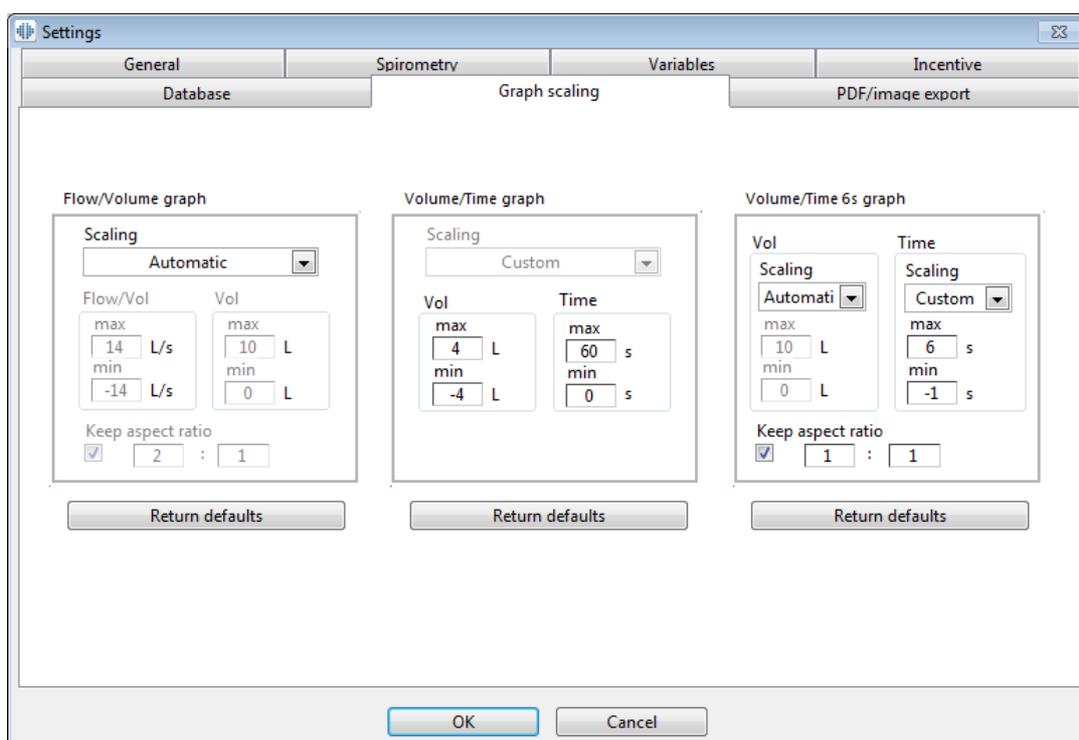


Figure: Graph Scaling tab

Scaling

There are two options:

Automatic. With this option, axes are scaled automatically according to measured curves and predicted values.

Custom. With this option, you can set fixed values for axis maximum and minimum.

Keep aspect ratio

If this check box is selected, graph aspect ratio is kept according to aspect ratio values. Values are represented in order y-axis versus x-axis (y : x). For example aspect ratio 1:1 means that y-axis and x-axis have equal relation.

If this check box is unchecked, aspect ratio is selected automatically so that the graph size is maximized.

Return defaults

Clicking this button returns default scale settings for that graph.

Note: There are some differences between graphs options:

- **Flow/Volume graph:** Aspect ratio can be adjusted only if the custom scaling is selected.
- **Volume/Time graph:** Automatic scaling and aspect ratio are not available for this graph.
- **6 s Volume/Time graph:** Automatic/Custom scaling can be selected separately for both axes.

8.3.7 PDF and image export

PDF export or image export is accessible depending on current feature level of the software.

Via PDF/image export settings tab you can control settings related to PDF/image export such as: when PDF/image files are exported, where they are saved, in which filename format and which report pages are included.

To change the PDF/image export settings, choose:

Device>Settings>PDF/image export

Additional information:

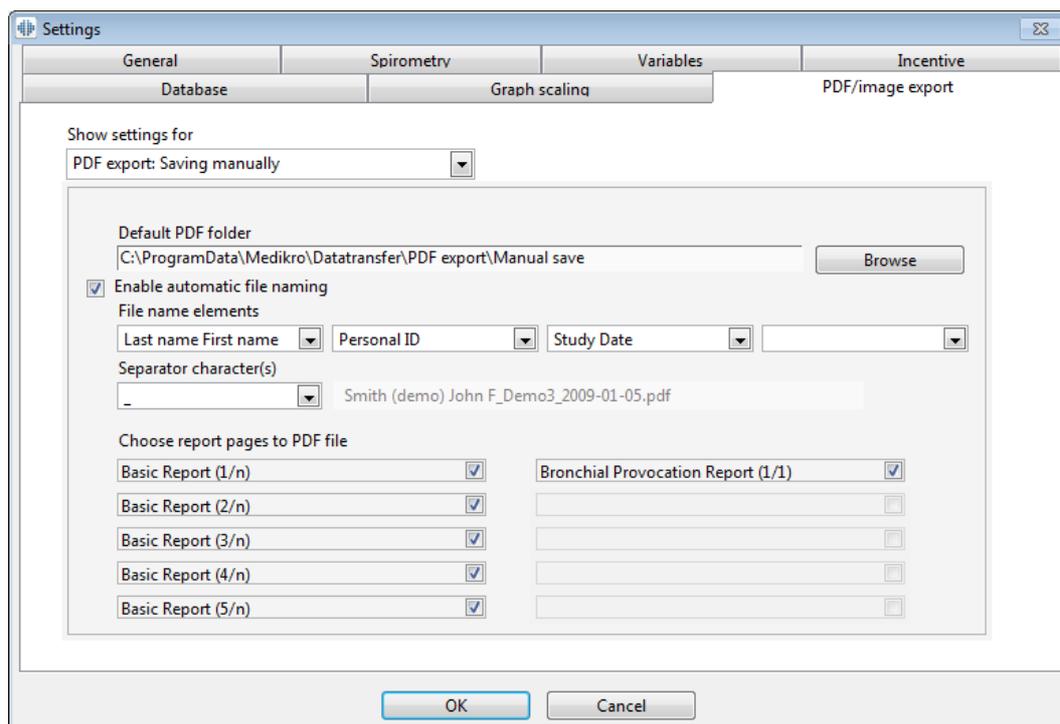


Figure: PDF/image export settings tab

Show settings for

From this drop-down menu you can select which action’s settings you want to edit. You can select from among following actions depending on your software feature level:

PDF export: Saving manually. Final report or any other view can be saved as a PDF file by selecting Study>Save to PDF file from the main window of the spirometry software.

PDF export: Printing a final report. Final report is saved to PDF file automatically when the user selects to print a final report.

PDF export: Exporting a session. Final report is saved to PDF file automatically when person’s session is exported.

PDF export: Saving a session. Final report is saved to PDF file automatically when person’s session is saved to database.

Image export: Saving manually. Final report or any other view can be saved as image files by selecting Study>Save to image file from the main window of the spirometry software.

Image export: Printing a final report. Final report is saved to image files automatically when the user selects to print a final report.

Image export: Exporting a session. Final report is saved to image files automatically

when person's session is exported.

Image export: Saving a session. Final report is saved to image files automatically when person's session is saved to database.

NOTE! You can edit only single action's settings at a time but you can do it for each action separately.

Generate a PDF/image file automatically

By checking this option automatic PDF/image export is taken into use in the selected action.

NOTE! This option is not available for actions:

- PDF export: Saving manually
- Image export: Saving manually

Default PDF/image folder

Default folder where PDF/image files are saved in the selected action. Folder can be changed by clicking Browse button.

Enable automatic file naming

By checking this option automatic file naming is taken into use in the selected action. If this option is unchecked, file name is asked during PDF/image saving.

For a routine use, we recommend using automatic file naming that follows your organization's practice.

File name elements

File name can consist up to four pieces of information, which can be selected and ordered freely. You can select from among these pieces of information: Personal ID, Session Date, Session Date and Time, Patient code, Date, Date and Time, First Names, Last name and finally, a combination of these. Any information field can be set blank or typed freely. We recommend selecting unique information to identify persons and to avoid duplicate file names between persons.

An example file name is shown according to current selections.

Separator character(s)

Separator character between file name elements can be selected from these options: space character, dot, comma or underline character.

Image file format

This option is only available for actions:

- Image export: Saving manually
- Image export: Printing a final report
- Image export: Exporting a session
- Image export: Saving a session

You can select these image formats JPG, PNG and BMP. We recommend using JPG or PNG due to smaller file size.

Choose report pages to PDF file / Choose report pages to be saved as image files

You can select which final report pages are saved as PDF/image files. In case of PDF export, selected report pages are included in a single PDF file. In case of image export, selected report pages are saved as separate image files.

8.4 Measurement

This chapter describes how to perform measurements with the Medikro Spirometry Software.



Before starting the actual measurements or calibration, it is recommended to allow the spirometer device to have a brief **warm-up period of a minimum of 5 minutes** to reach a thermal equilibrium. A spirometer connected to a PC will start to warm up immediately after Windows is started. This is a normal and general procedure for most high-precision measurement devices.

8.4.1 Getting prepared for Measurements

Explain the measurement and prepare the patient for the manoeuvre before the actual measurement. The measurement should also be demonstrated to the patient. Pay attention to correct posture with head elevated, complete inhalation, flow transducer position, and complete exhalation. All manoeuvres should be started and finished with a resting tidal breathing. It is recommended to allow the patient to perform 1-2 sample manoeuvres before the measurement.

The flow transducer should not be removed from the mouth before instructed by the operator. The flow transducer should be kept between the teeth to permit the maximal flow to go through the pneumotach. In addition, the flow transducer should be tightly sealed with the lips to avoid leakage flow. If necessary, any false teeth prostheses are removed before the spirometry session.

It is recommended to use a nose clip during the measurement.

To be able to perform measurements, person and study have to be selected in Medikro Persons and Studies application and **Proceed to measurements and results** button (see [Table: Medikro Persons and Studies Buttons](#)) been clicked. Study is then opened in Medikro Measurements and Results application.

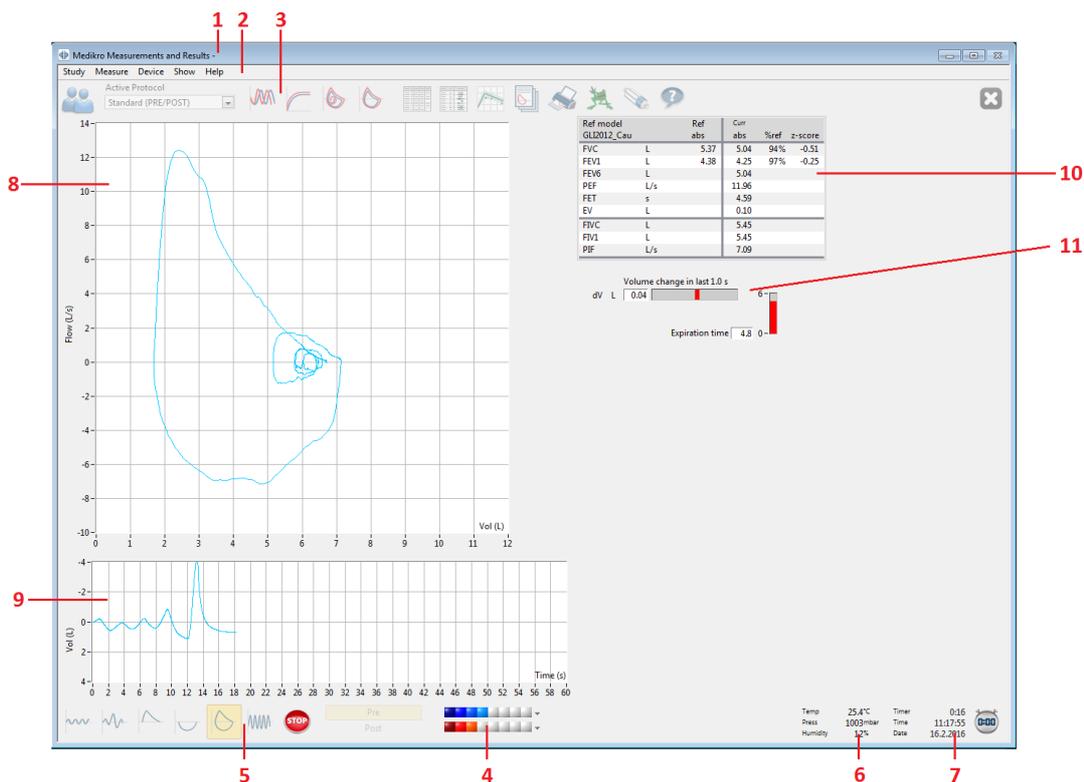


Figure: The Measurement View

The patient data is now displayed on the top of the screen in the Title Bar. All functional buttons are active. The key features of the Measurement Window are:

1. Title Bar with Patient Information
2. Menu Bar with Drop-Down Menus
3. Tool Bar with Functional Buttons
4. Session Status Summary
5. Measurement Manoeuvre Buttons
6. Environmental Conditions
7. Timer / Time of Day / Date
8. Flow and Volume (FV) Graph
9. Volume and Time (VT) Graph
10. Result Table
11. Flow and Duration Indicator

8.4.2 Starting the Measurement

Select the type of measurement manoeuvre to start a measurement (see [Table: Medikro Measurement and Results Measurement Buttons](#)). If you want to start by only monitoring the signal before any of the manoeuvres, you can accomplish it with the menu option **Measure>Start**.

Note: with this selection, the measurement begins and curves are drawn on the screen, but no results are calculated until you press any of the manoeuvre buttons. This is intended mainly for the MVV manoeuvre to monitor the signal before the start of the manoeuvre.

For quality reasons, the results are calculated from whole breaths. This means that each inspiration and expiration is processed separately to calculate, for example, tidal volume during the TV phase of the measurement, vital capacity during the SVC phase, forced vital capacity, and FEV1 during the FVC phase, and so on.

Start the measurement by pressing the measurement manoeuvre button when the patient is ready. The programme allows the patient to complete the measurement in 60 seconds.

Note: by choosing variables for display, you can also choose which manoeuvre buttons are active. For example, if none of the TV manoeuvre variables (TV, FR or MV) are chosen, the TV manoeuvre button is deactivated (greyed). The same principle is also applied to the SVC, FVC, FIVC, FVC+FIVC, and MVV manoeuvres.

8.4.3 Measurement Manoeuvres

The user can perform the following measurement manoeuvres: TV, tidal volume manoeuvre, SVC, slow vital capacity manoeuvre, FVC, forced expiratory vital capacity manoeuvre, FIVC, forced inspiratory vital capacity manoeuvre, FVC + FIVC, forced expiratory and inspiratory vital capacity manoeuvre, and MVV, maximal voluntary ventilation manoeuvre.

8.4.3.1 TV, tidal volume manoeuvre

TV, tidal volume manoeuvre:

1. Place the flow transducer in the patient's mouth. The patient should breathe in a relaxed/normal rate and frequency through the flow transducer.
2. Start the measurement by selecting the **TV** button.
3. The patient continues to breathe in a relaxed/normal rate and frequency through the flow transducer.
4. Finish the measurement by selecting the **STOP** button.
5. Remove the flow transducer from the patient's mouth.

Please note! If IRV, ERV, IC or EC are wanted to be measured:

To be able to measure IRV, ERV, IC or EC, they need to be selected in program's settings (see chapter [Variables](#)).

Tidal volume measurements are performed normally like in steps 1-3. During the measurement, one should monitor traffic light on **SVC** button. The colour of the traffic light is green if tidal breathing is reproducible and stable. If it is not, the traffic light colour is red.

When the light is green, slow vital capacity measurement (SVC) can be started by clicking its button. It is recommended to move on to **SVC** only when the light is green. Technically it is also possible when the traffic light colour is red.

Tidal breathing reproducibility criterion can be adjusted in program settings, see chapter Tidal volume reproducibility %.

Table: Traffic light on SVC button

Green traffic light	Red traffic light
	

8.4.3.2 SVC, slow vital capacity manoeuvre

SVC, slow vital capacity manoeuvre:

1. Place the flow transducer in the patient's mouth. The patient should breathe in a relaxed/normal rate and frequency through the flow transducer.
2. Start the measurement by selecting the **SVC** button.
3. The patient expires slowly.
4. The patient inspires slowly and long.
5. The patient returns to normal relaxed breathing.
6. Finish the measurement by selecting the **STOP** button.
7. Remove the flow transducer from the patient's mouth.

Please note! If IRV, ERV, IC or EC are wanted to be measured:

To be able to measure IRV, ERV, IC or EC, they need to be selected in program's settings (see chapter [Variables](#)).

1. Place the flow transducer in the patient's mouth. The patient should breathe in a relaxed/normal rate and frequency through the flow transducer.
2. Start the measurement by selecting the **TV** button. Monitor the traffic light colour on the **SVC** button. Select **SVC** button when the colour is green.
3. The patient expires slowly.
4. The patient inspires slowly and long.
5. The patient returns to normal relaxed breathing.
6. Finish the measurement by selecting the **STOP** button.
7. Remove the flow transducer from the patient's mouth.

8.4.3.3 FVC, forced expiratory vital capacity manoeuvre

FVC, forced expiratory vital capacity manoeuvre:

1. Place the flow transducer in the patient's mouth. The patient should breathe in a relaxed/normal rate and frequency through the flow transducer.
2. Start the measurement by selecting the **FVC** button.

3. The patient inspires slowly and long.
4. The patient expires fast and strongly, at least until the indicator changes to green.
5. The patient returns to normal, relaxed breathing.
6. Finish the measurement by selecting the **STOP** button.
7. Remove the flow transducer from the patient's mouth.

8.4.3.4 FIVC, forced inspiratory vital capacity manoeuvre

FIVC, forced inspiratory vital capacity manoeuvre:

1. Place the flow transducer in the patient's mouth. The patient should breathe in a relaxed/normal rate and frequency through the flow transducer.
2. Start the measurement by selecting the **FIVC** button.
3. The patient expires slowly.
4. The patient inspires fast and strongly.
5. The patient returns to normal, relaxed breathing.
6. Finish the measurement by selecting the **STOP** button.
7. Remove the flow transducer from the patient's mouth.

8.4.3.5 FVC+FIVC, forced expiratory and inspiratory vital capacity manoeuvre

FVC+FIVC, forced expiratory and inspiratory vital capacity manoeuvre:

1. Place the flow transducer in the patient's mouth. The patient should breathe in a relaxed/normal rate and frequency through the flow transducer.
2. Start the measurement by selecting the **FVC+FIVC** button.
3. The patient expires slowly.
4. The patient inspires fast and strongly.
5. The patient expires fast and strongly, at least until the indicator changes to green.
6. The patient returns to normal, relaxed breathing.
7. Finish the measurement by selecting the **STOP** button.
8. Remove the flow transducer from the patient's mouth.

8.4.3.6 MVV, maximal voluntary ventilation manoeuvre

MVV, maximal voluntary ventilation manoeuvre:

1. Place the flow transducer in the patient's mouth. The patient should breathe in a relaxed/normal rate and frequency through the flow transducer.

2. The patient inspires in a forced manner fast and strongly then expires in a forced manner fast and strongly. Continue...
3. Start the measurement by selecting the **MVV** button.
4. The patient repeats step no. 2 for a minimum of 12 seconds.
5. Finish the measurement by selecting the **STOP** button.
6. Remove the flow transducer from the patient's mouth.

8.4.4 Stopping the Measurement

When you start the measurement, the **Stop** button ([Table: Medikro Measurement and Results Basic Buttons](#)) will change from a deactivated (greyed) state into an active state. The measurement can be stopped with the **Stop** button before the 60 seconds are finished.

The time of the measurement can be monitored from the volume/time graph on the screen or from the timer. The measurement will be stopped automatically after 60 s if not stopped by the button.

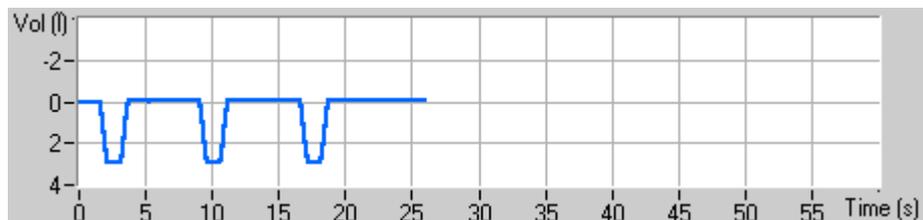


Figure: Volume Time Graph

After stopping the measurement, the programme will instantly show the FIVC or FVC curve (or both), slow VC or MVV curves, as well as the measurement results in the measurement window. This numerical output includes predicted values (Pred), results of the current measurement (Curr), the best results of the session (Best) and the difference between the Current and Best result (Curr - Best).

8.4.5 Acceptance of the Measurement

After performing the measurement, the programme will request an acceptance of the measurement.

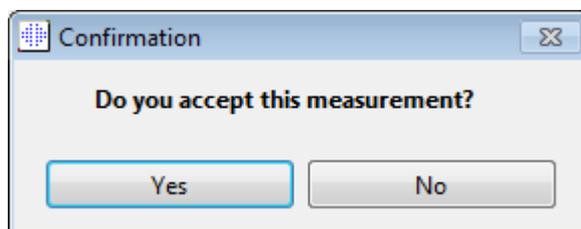


Figure: Accept Measurement

Additional information

You can accept (Yes) the measurement or reject it (No), based on the start of the manoeuvre (extrapolated volume), duration, and possible manoeuvre artefacts (submaximal effort, cough, glottis closure...). The Reproducibility Indicator (see chapter [The Reproducibility Indicator](#)) may be

useful in evaluating the magnitude of the artefacts. For more details of accepting the manoeuvre, see [4].

You can start a new measurement with the same or a new manoeuvre as soon as the patient is ready.

8.4.6 The Flow and Duration Indicator

During measurement, the expiratory and the inspiratory manoeuvres can be monitored using the Flow and Duration Indicator. It indicates the volume change in 1 second (ATS 1994 or ATS/ERS 2005 criteria selected) or in 0.5 seconds (ERS 1993 criteria selected). When there is no horizontal bar to indicate a volume change in a specified time, the “no change” criterion to end or reverse the expiratory/inspiratory manoeuvre is reached.

The time of the last expiration is also shown during the FVC and FVC+FIVC manoeuvres. The expiration should last at least 6 seconds (3 s for children aged < 10 yrs, ATS/ERS 2005).

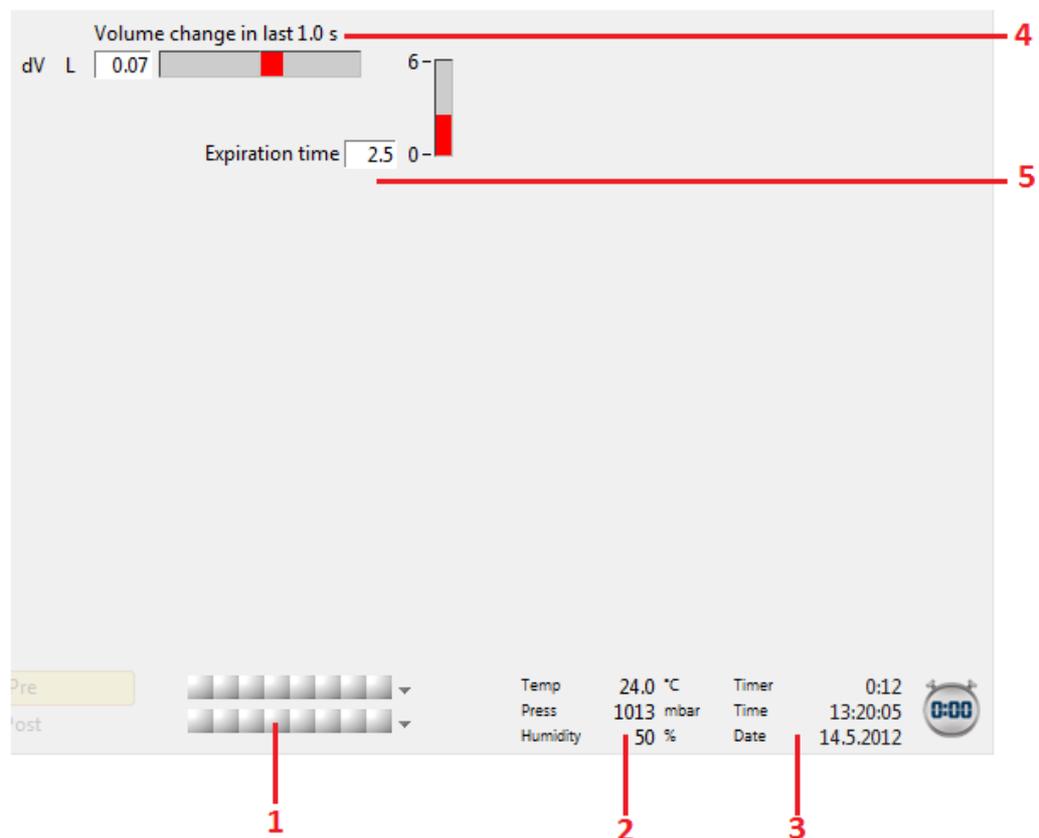


Figure: Flow and Duration indicator

The key features of the Flow and Duration Indicator are:

1. Session Status Summary
2. Environmental Conditions
3. Timer/Time of Day/Date

4. Volume change (Flow and Duration) indicator
5. Expiration Time indicator

8.4.7 The Reproducibility Indicator

After the measurement, the Reproducibility Indicator will tell you if the measurements will meet the reproducibility criteria for the spirometric test.

Reproducibility			Pre		Post	
			abs	%best	abs	%best
Diff of 2 best	VC	L	0.13	2%		
	FVC	L	0.13	2%	0.03	1%
	FEV1	L	0.10	2%	0.02	0%
	PEF	L/s	0.13	1%	0.04	0%

Figure: Reproducibility Indicator

If the criteria are not fulfilled, the programme will flag the results in red.

Medikro Spirometry Software highlights a value in red if its reproducibility criteria are not fulfilled. Reproducibility is determined for both single measurements and session best values. Note that reproducibility is phase-related, which means that Pre- and Post-phase measurements are not compared with each other. For more detailed information, see the ATS 1994 [1], ERS 1993 [2] and ATS/ERS 2005 [3-5] recommendations. After the measurement, the Reproducibility Indicator will tell you if the measurements will meet the reproducibility criteria for the spirometric test.

For more details on reproducibility, see Additional information and [4].

Additional information

VC, FVC and FEV1

Indicating reproducibility for Session Best values: the best value is the largest value for each variable. The best value should not exceed the next highest one by more than the criterion. If the criterion is not fulfilled, the difference between the two largest values is flagged red.

Indicating reproducibility for single measurements: if the VC, FVC, or FEV1 differs from its largest value by more than its criterion, it is flagged red. The respective difference, VCDIFF, FVCDIFF or FEV1DIFF, is also flagged red.

Variable	ERS 1993		ATS 1994		ATS/ERS 2005	
	ml	%best	ml	%best	ml	%best
VC	100	5	200	-	150	
FVC	100	5	200	-	150 *)	
FEV1	100	5	200	-	150 *)	

*) 100 if FVC <= 1 L

FEF75, FEF50, and FEF25 (ERS 1993 only)

Indicating reproducibility for Session Best values: the best value is the largest value for each variable. The chosen flow-volume curves for analyzing FEFs should have a PEF within a criterion of the maximal value. If the criterion is not fulfilled, the maximum difference of all PEF values is flagged red.

Indicating reproducibility for single measurements: if the PEF differs from the maximal value more than a criterion, it is flagged red. The respective difference, PEFDIFF, is also flagged red.

Variable	ERS 1993		ATS 1994		ATS/ERS 2005	
	ml	%best	ml	%best	ml	%best
PEF	-	10	-	-	-	-

(If the ATS 1994 or ATS/ERS 2005 recommendations are selected, the best FEFs are obtained from a forced vital capacity manoeuvre, which has the largest sum of FVC plus FEV1).

FEF25-75% (ERS 1993 only)

Indicating reproducibility for Session Best values: the best value is the largest value. The reported value should be from a forced vital capacity manoeuvre, which differs by less than a criterion from the largest FVC. If the criterion is not fulfilled, the FEF25-75% value is flagged red.

Indicating reproducibility for single measurements: if the best value is chosen from the curve which does not fulfil the criterion, the FEF25-75% of that curve is flagged red.

Variable	ERS 1993		ATS 1994		ATS/ERS 2005	
	ml	%best	ml	%best	ml	%best
FVC	-	5	-	-	-	-

(If the ATS 1994 or ATS/ERS 2005 recommendations are selected, the best FEF25-75% is obtained from a forced vital capacity manoeuvre, which has the largest sum of FVC plus FEV1).

PEF (ATS/ERS 2005 only)

Indicating reproducibility for Session Best values: the best value is 1) the largest PEF or 2) PEF obtained from a forced vital capacity manoeuvre, which has the largest sum of FVC plus FEV1. Whichever the choice, the highest value should not differ from the next highest one by more than the criterion. If the criterion is not fulfilled, the difference between the two largest values is flagged red.

Indicating reproducibility for single measurements: if PEF differs from its largest value by more than its criterion, it is flagged red. The respective difference PEFDIFF is also flagged red.

Variable	ERS 1993		ATS 1994		ATS/ERS 2005	
	L/s	%best	L/s	%best	L/s	%best
PEF	-	-	-	-	0.67	-

MVV (ATS/ERS 2005 only)

Indicating reproducibility for Session Best values: the best value is the largest MVV. No MVV value should differ from the largest value by more than the criterion. If the criterion is not fulfilled, the MVV difference is flagged red.

Indicating reproducibility for single measurements: if the MVV differs from its largest value by more than its criterion, it is flagged red. The respective difference MVVDIFF is also flagged red.

Variable	ERS 1993		ATS 1994		ATS/ERS 2005	
	L/min	%best	L/min	%best	L/min	%best
MVV	-	-	-	-	-	20

8.4.8 Session Status Summary

The programme monitors and reports the number of Pre- and Post-phase measurements performed within one session. The operator can review the session status from the status summary and activate or inactivate the viewing of curves of any measurement within a session from the respective check box, see Figure: Session Status Summary.

Note: this does not affect the calculated results. If the user wants to remove a measured curve from the calculations, it can only be done by deleting it, see chapter [Deleting an Individual Measurement](#).

The colour of the curve is also shown in the session status summary in the lower part of the screen.



Figure: Session Summary Status

Additional information

The programme facilitates up to 8 Pre- and Post-phase measurements as recommended by ATS and ERS.

"Pre" indicates the Basal phase and

"Post" indicates the Bronchodilatation phase.

The "Show NONE signals of this phase / Show ALL signals of this phase" commands will activate or inactivate the viewing of all Pre- or Post-phase measurement curves respectively.

8.4.9 Deleting an Individual Measurement

You can delete signals of the current or reviewed session by selecting the following command path:

Study>Delete signal

In order to delete a signal, select it from the list and press **OK**. To make multiple selections press **CTRL** while choosing signals with a mouse click from the database list.

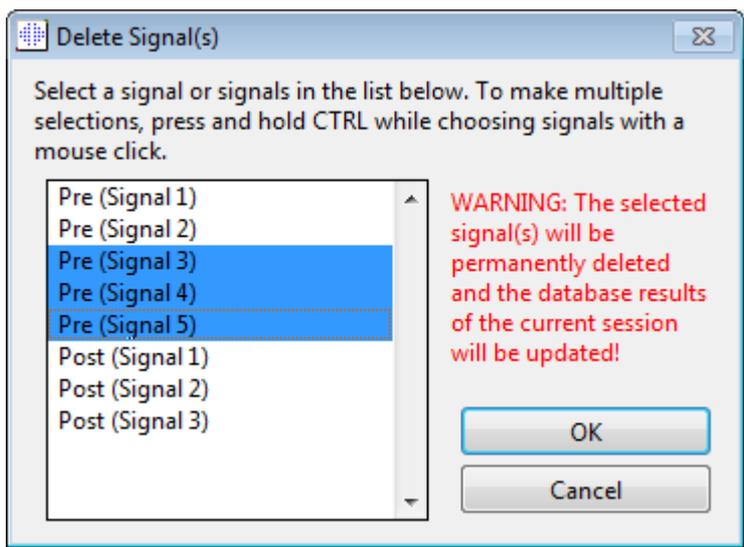


Figure: Session / Delete signal(s)

8.4.10 Measurements with the Incentive

The incentive screen is a motivator for children to perform an acceptable spirometry study. Measurements with incentive are described in the additional information section below.

Additional information

Before the first use of the incentive, it is advisable to read through this chapter, which covers the configuration and setting up of the incentive in details.

This chapter deals with the use of incentive during the measurement. Before the measurement is started, the incentive applet will be rotating the scenery around the frog, see Figure: Incentive applet in an idle state.



Figure: Incentive applet in an idle state.

When the measurement is started (see chapter [Starting the Measurement](#)), the incentive applet will launch in a stand-by state and the frog will be seen from a side view. Now, it is time to start the study (Figure: Incentive applet in a stand-by state).



Figure: Incentive applet in a stand-by state.

During the measurement, the frog will react to the ventilation performance by crouching down on deep inhalation and making a leap on consecutive exhalation. Note that in order to get the frog to crouch and leap, the inhalation must be deep enough, at least 50 % of the current session's Pre-phase best FVC (if the current session does not have FVC, the previous session's Pre-phase best FVC is used instead. Even if that does not exist, the predicted value will still be used). The goal for the jump is the opposite lily pad, which corresponds to a successful FVC (Figure: Incentive applet after a successful exhalation). If the FVC fails, the frog will splash into the water (Figure: Incentive applet after a failed exhalation). Small indicators in the upper part of the screen are called success flags and indicate by colour if the criteria of the variables have been fulfilled.

- An indicator with a white background means that the value has not yet been calculated.
- An indicator with a bright green background means that the measured value fulfils the criterion.
- An indicator with a bright red background means that the measured value does not fulfil the criterion.

Note that the spirometry software makes a prediction for the FVC in the middle part of the exhalation. According to the prediction, the frog will land in the water on the opposite lily pad. However, it is possible that the frog will splash into the water even if the FVC succeeds. This can happen if the exhalation gets better during the latter half of the exhalation.

A clear indicator of a successful FVC is that the frog will jump up and down and raise its hands after the leap (Figure: Incentive applet after a successful exhalation).

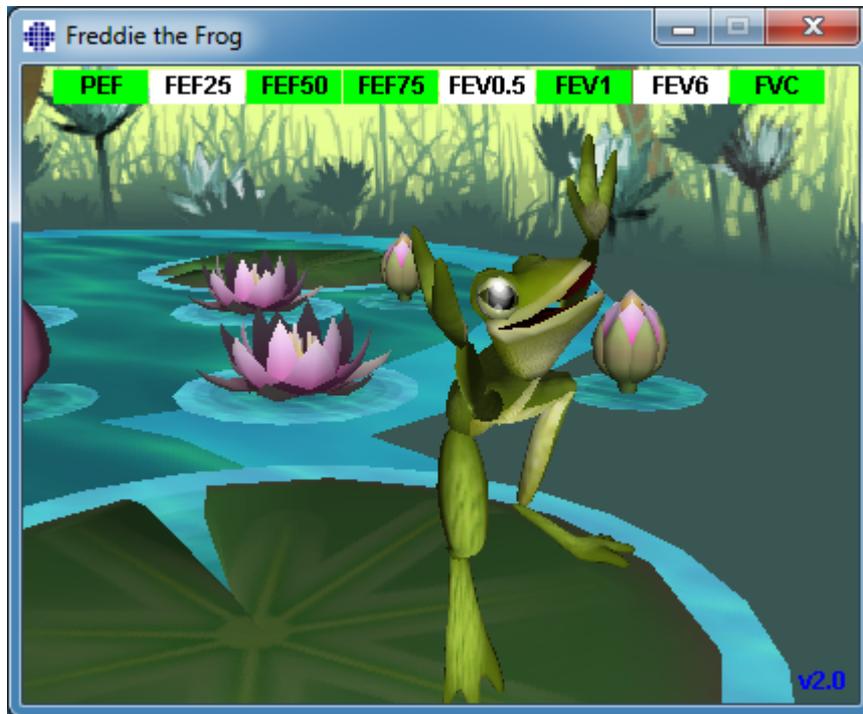


Figure: Incentive applet after a successful exhalation.



Figure: Incentive applet after a failed exhalation.

8.5 Bronchial Provocation

The Bronchial Provocation feature extends the capabilities of Medikro Spirometry Software. “Bronchial Provocation” or “Bronchial Challenge” testing is a method to detect and quantify airway hypersensitivity in clinical practice.

There are many standardised procedures that can be used in bronchial challenge testing. The Bronchial Provocation feature provides the most common procedures, or “protocols” in the software, to be used within the challenge testing. Together with this, the user can freely create new or modify any standard protocols to suit his or her needs in practice.

This User Manual provides technical information on how to use the Bronchial Provocation feature in provocation studies. It does not state how the testing itself should be prepared, performed, or results analysed or interpreted. Nor does it give any information about the precautions to be considered when performing provocation studies.

8.5.1 Basic Use of Bronchial Provocation

General

This chapter describes the main parts of the measurement view.

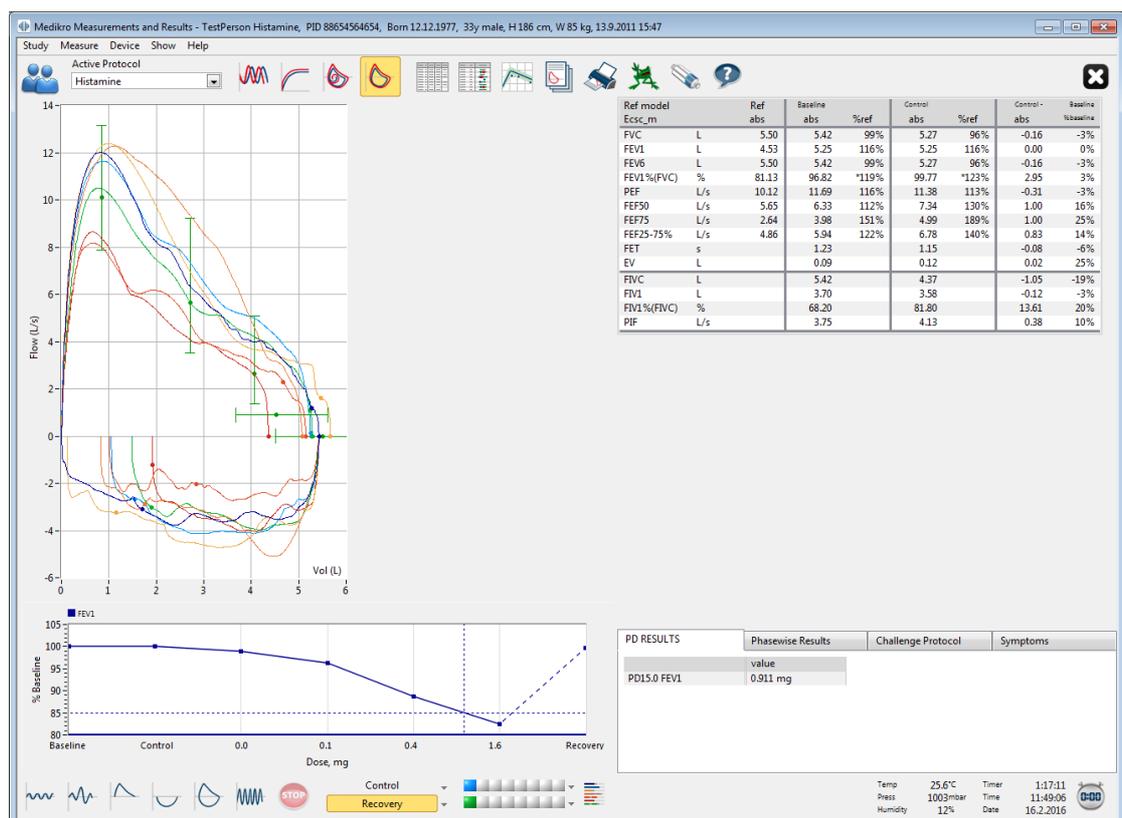


Figure: Measurement View with Provocation Protocol Active

Active Protocol

The active protocol is the currently selected protocol. The protocol can be selected from the drop-down list located between the buttons at top of the window. The protocol list shows the protocols that are installed or imported to the system or created by the user.

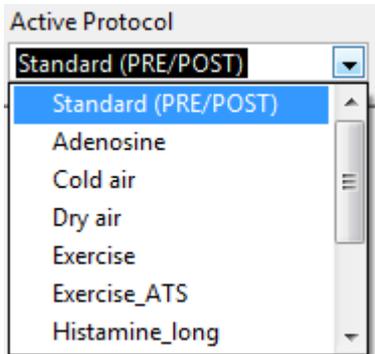


Figure: Selecting Active Protocol

First selection in the list is Standard (Pre/Post), which means a standard bronchodilatation test protocol containing two phases, Pre and Post. Use this selection when performing a standard spirometry test.

Please note: If the Bronchial Provocation feature is not activated via Activation Code, this option is the default protocol and cannot be changed.

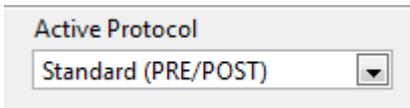


Figure: Standard Bronchodilatation Protocol Selected as Active

Dose-Response Graph

Shows graphically how the values of selected variables (e.g. FEV1) change during the provocation study.

The vertical axis indicates the difference of the selected variable compared to a selected comparison phase (such as baseline or control). The variable to be shown can be selected in the **Protocol Manager** (see chapter [Protocol Manager](#)).

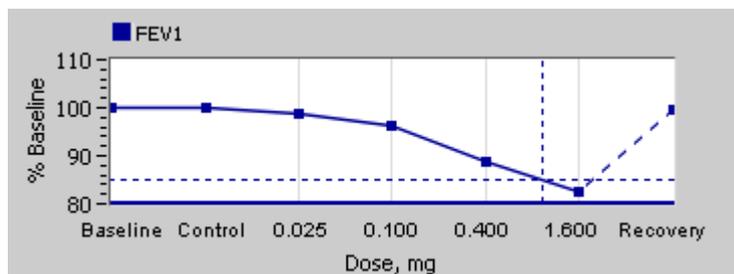


Figure: Dose-Response Graph

The horizontal axis indicates the value of the selected parameter (e.g. Dose) in each phase. The parameter can be selected in the **Protocol Manager** (see chapter [Protocol Manager](#)).

Dashed lines: The crossing point of the dashed lines shows the PD value, see chapter [Provocative Dose](#).

Thick horizontal line: Shows the alarm limit for the variable. If the alarm limit is exceeded, the stimulus caused by provocation is so strong that no more provocations are recommended. This limit can be set in the **Protocol Manager** (see chapter [Protocol Manager](#)).

Challenge Protocol

Shows the challenge protocol table. This table can be used, for example, to check protocol details during testing.

PD RESULTS	Phasewise Results		Challenge Protocol			Symptoms
	Baseline	Control	Challenge1	Challenge2	Challenge3	
Dose, mg	0.000	0.000	0.025	0.100	0.400	
Inhalations, nr	1	1	1	1	4	

Figure: Challenge Protocol Table

If the protocol needs to be modified, perform the task in the **Protocol Manager**. Remember that if a session is opened, modifications to the protocol affect the current session only.

Phasewise Results

Shows the results per measured phase. The following rows are shown:

- Value of the selected variable (e.g. FEV1). If there are multiple measurements in the phase, the highest value is shown.
- Absolute difference of variable to comparison phase (baseline or control).
- Relative difference of variable to comparison phase.
- Value percentage to predicted value.

PD RESULTS	Phasewise Results		Challenge Protocol			Symptoms
	Baseline	Control	Challenge1	Challenge2	Challenge3	
FEV1, L	5.25	5.25	5.20	5.06	4.66	
Diff. to Baseline, L	0.00	0.00	-0.06	-0.19	-0.59	
% Baseline	100%	100%	99%	96%	89%	
% Ref	113%	113%	112%	109%	100%	

Figure: Phasewise Results

PD Results and Interpretation

This table shows the PD values for the selected variables. The interpretation of the PD value is not supported by this version of the software. For more details about PD, see chapter [Provocative Dose](#).

PD RESULTS	Phasewise Results	Challenge Protocol	Symptoms
	value		
PD15.0 FEV1	0.911 mg		

Figure: PD Results and Interpretation

Symptoms

Use this table to type in the symptoms and findings during the test. Information can be recorded for each phase of the protocol.

PD RESULTS	Phasewise Results	Challenge Protocol	Symptoms
	Symptoms and findings in the test		
Baseline			
Control			
Challenge1			
Challenge2			
Challenge3			Wheezing, chest tightness
Challenge4			Coughing, heavy breathing
Recovery			

Figure: Symptoms

Selecting Active Phase

Depending on the provocation protocol, there may be up to 20 phases in the protocol. Each phase can contain a maximum of 8 measurements.

When the provocation testing is going on, the operator of the software selects the actual phase from the drop-down list (button with a downward arrow). The upper drop-down list contains the baseline and control phases, the lower drop-down list contains the remaining protocol phases.

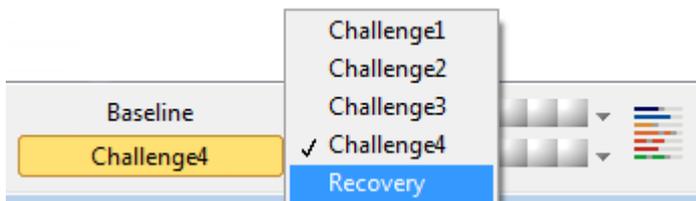


Figure: Selecting Active Phase

When the active phase has been selected, the measurements for that phase can be started.

Please note: It is possible to skip any of the phases and stop the testing during any of the phases.

Signal Indicators

The row of signal indicators shows how many signals have been measured in the phase and which of them have been selected to be shown in the graphs.



Figure: Signal Indicators

If the indicator colour is dark grey, that signal has been measured but not selected to be shown in the graphs.

If the indicator is coloured, that signal is selected.

Please note: Inside each phase, the signal colour is the same for each signal. Each phase has its own colour. The colours are dark blue, light blue, and green for baseline, control, and recovery respectively. The colours from yellow to red are reserved for challenge phases.

Signal Table

This button opens the signal table, which shows the whole list of signals per each phase. This view is especially useful when there are multiple phases in the protocol. Select here which signals you want to show in the graphs.

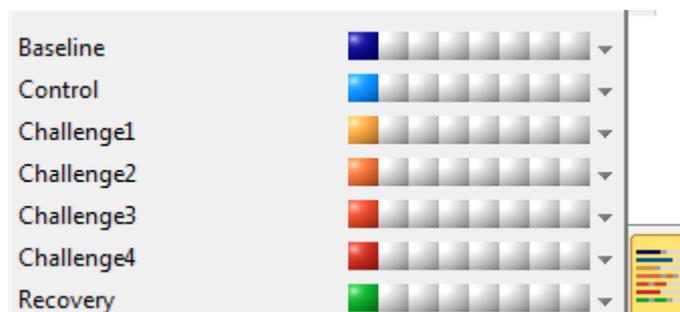


Figure: Signal Table

Clicking the button again closes the signal table.

Timer Reset

This button resets the Timer. You can use the timer, for example, to measure the dose exposure time or to measure the exercise time.

Please note: Starting any measurement manoeuvre resets the timer.



Figure: Timer Reset Button and Timer

Best Results

By clicking the **Show Best Results** button, a table and a histogram are shown. The table shows the best results for the comparison phase (baseline or control) and the phase that has last been measured.

Trending

See details in chapter [Numerical Results and Trend](#). If the person's records contain bronchial provocation sessions, the variable list will contain a PD value to be selected for trending.

Select any PD variable to see how the PD values have developed during the tests.

Please note: The PD variable is dependent on protocol. Sessions that use an equal provocation limit (e.g. 20.0%), equal provocation variable (e.g. FEV1), equal comparison parameter (e.g. concentration), and equal provocation agent (e.g. methacholine) are comparable between sessions. Thus, for example, histamine and methacholine provocation PD results are not comparable. If a person has had both tests done, there will be two different PD variables in the trending.

Final Report

The contents of the final report of the bronchial provocation differ from the standard bronchodilatation report. See details in chapter [The Final Report](#).

8.5.2 Bronchial Challenge Terms

Provocative Dose

Provocative dose (PD), Provocative Concentration (PC), Provocative Temperature (PT) and so on, are outcomes of the provocation test. In this manual, we generally use the terms PD or provocative dose.

Provocation limit (%) defines the change of the selected variable (e.g. FEV1), where the provocative dose is calculated. If the limit is reached between two consecutive provocation phases, the PD value is interpolated between them. Detailed information about the calculation of PD can be found in reference 2, [Appendix: References](#).

In the Medikro Spirometry Software, the PD Value is expressed as

PD15.0 FEV1 (Baseline),

which refers to the provocative dose where the FEV1 difference to baseline has reached 15.0%.

The provocation limit can be set in the **Protocol Manager**.

8.5.3 Protocol Manager

In the protocol manager view, the user can create new protocols and alter existing protocols. In addition, the user can delete, import, and export protocols. The protocol manager is divided into the List of protocols, Active protocol and Protocol settings tabs.

Note: Changes to the protocol "Read-only" affect the current session only.

Note: Self-made protocols that are made with earlier versions than Medikro Spirometry Software 4.0 are not shown in the protocol list, while a new study is opened. To solve this, close the study and export self-made protocols to default location (see Additional information: Protocol Options). Then start a new study and your protocols should be in the protocol list.

Additional information about:

☐ List of Protocols

From the **List of Protocols**, the user can select the protocol used for the current bronchial provocation study.

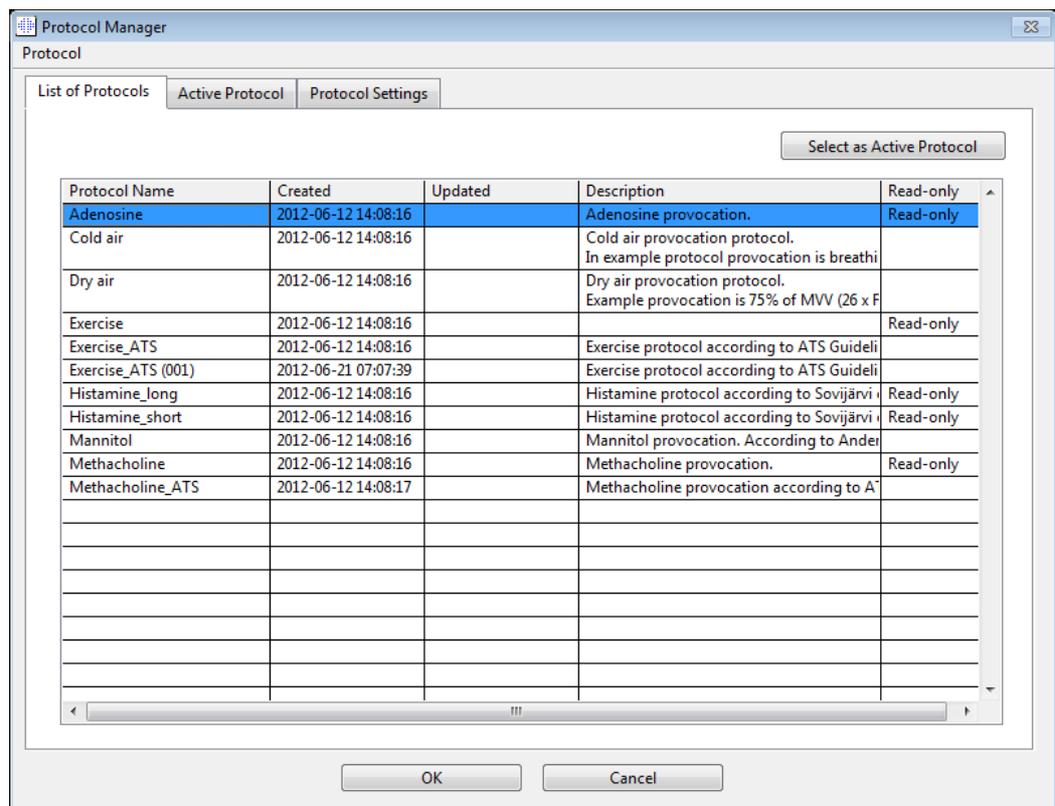


Figure: List of Protocols

☐ Active Protocol

The **Active Protocol** tab has the following options: *Protocol Information*, *Phases*, *Agents*, and *Challenge Parameters*.

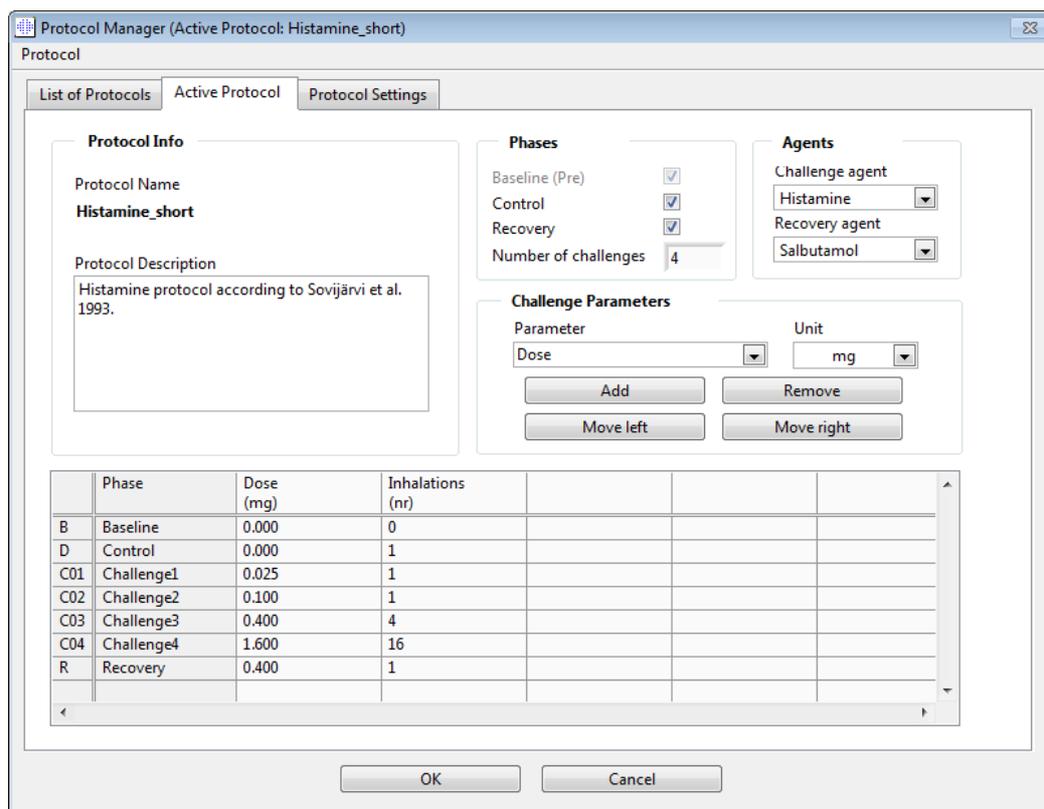


Figure: Active Protocol

Protocol Information

Protocol information is for protocol description. The user can enter the following information about the protocol:

- Protocol Name
- Protocol Description

Phases

The user can select the required phases for the protocol:

- Baseline (optional)
- Control (optional)
- Recovery (optional)
- Number of challenges (1-17 challenge phases)

Agents

Pharmacological agents are used for measuring airway responsiveness in clinical practice as well as in research. These agents are used for producing airways obstruction by smooth muscle contractions (increased microvascular permeability and/or stimulation of (non-)cholinergic activity).

The user can modify the challenge agents and recovery agent. The options for challenge and

recovery agents are: None, Histamine, Methacholine, Adenosine, Mannitol, Saline, Cold Air, Exercise, Distilled Water, Salbutamol, Terbutaline, and Fenoterol.

- *Challenge agent*: Name of the dose drug. This can be selected from the list.
- *Recovery agent*: Name of the recovery drug. This can be selected from the list.

Challenge Parameter

The challenge parameters consist of a parameter and a unit. The options for the parameter are: *Dose, Cumulative Dose, Concentration, Inhalations, Pharmacological Agent, Load, Work, Inclination, Speed, Inhaled Air Temperature, Ventilation Load, Dose Exposure Time, Exercise Time, and Measurement Time*. The options for the unit depend on the selected variable (e.g. Dose: mg, ug, and g).

- *Challenge Parameter*: The user can select which parameters are needed for constructing the dosing sequence. By clicking **Add**, the selected parameter will appear as a column in the dosage table; clicking **Remove** will remove the selected column.
- *Unit*: Dose unit. This can be selected from the drop-down list

Dosage table

- *Dosage Sequence Table*: Interactive table to assist in planning the dosage.

	Phase	Dose (mg)	Inhalations (nr)			
B	Baseline	0.000	0			
D	Control	0.000	1			
C01	Challenge1	0.025	1			
C02	Challenge2	0.100	1			
C03	Challenge3	0.400	4			
C04	Challenge4	1.600	16			
R	Recovery	0.400	1			

Figure: Dosage Sequence Table

☐ Protocol Settings

The protocol settings are divided to *Challenge Variables* and *Dose-Response Graph*.

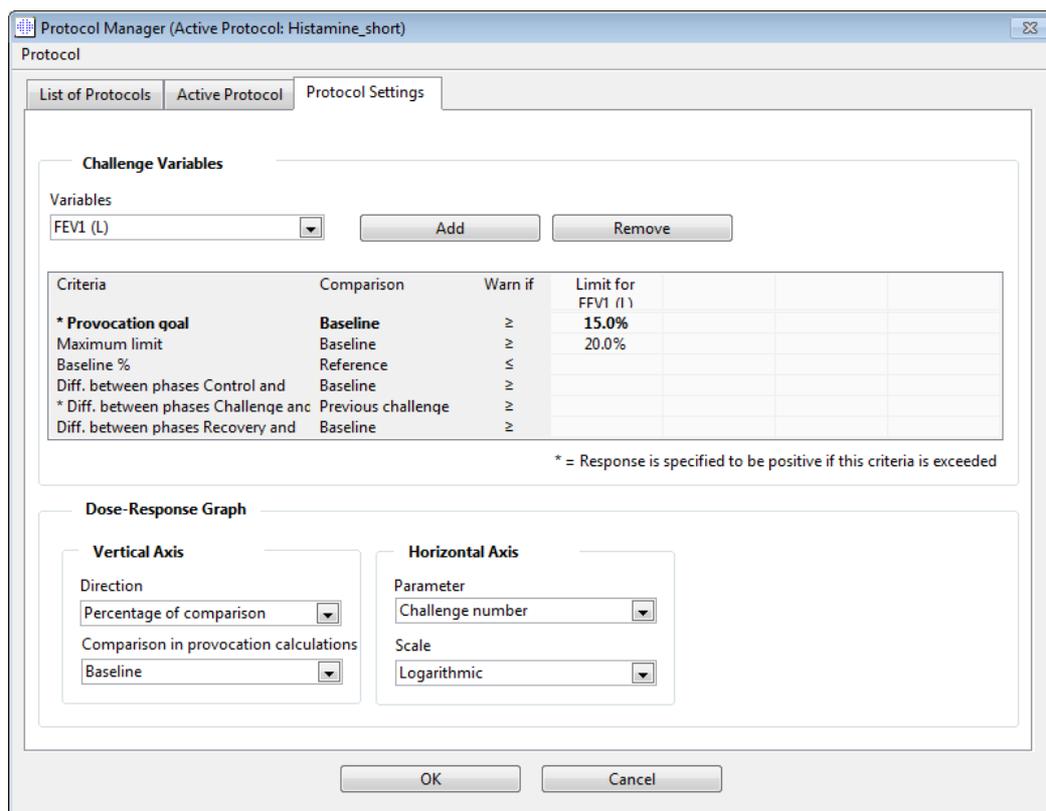


Figure: Protocol Settings

Challenge Variables

In the Challenge Variable section, the user can select the required variables for the current protocol and modify them.

- **Variables:** Drop-down list for selecting variables
- **Add:** Will add the variable to the table of selected variables (maximum number of used challenge variables is four).
- **Remove:** Will remove the selected variable from the table.

In the Variable limits table, the user can alter the variable limits. Variable limit (%) defines the change of the selected variable (e.g. FEV1), where the provocative dose (PD) is calculated.

Dose-Response Graph settings

The user can alter the settings for the horizontal and vertical axis. The vertical axis indicates the difference of the selected *variable* compared to a selected comparison phase (such as baseline or control). The variable can be any variable in the list of variables, except TIME or LAGE. There are two settings for the Vertical axis: *Direction* and *Comparison in provocation calculations*.

Options for *Direction*:

- Percentage of comparison
- Positive difference to comparison

- Negative difference to comparison

Options for *Comparison in provocation calculations*:

- Baseline
- Control
- Reference
- None

The horizontal axis indicates the value of the selected *parameter* (e.g. Dose) in each phase. The parameter is a measurable value and depends on the provocation type. In pharmacological provocation, the parameter could be, for example, *Dose* or *Concentration*. In exercise provocation, the parameter could be, for example, Load or Speed. There are two settings for Horizontal axis: *Parameter* and *Scale*.

Options for *Parameter*:

- Challenge number
- Challenge parameter

Options for *Scale*:

- Linear
- Logarithmic

▣ Protocol Options

The contents of Protocol from the Protocol Manager menu bar: Create New, Save, Delete, Import, and Export.



Figure: Menu bar: Protocol

Create New

Selecting **Protocol>Create New** from the menu bar will start a new protocol construction. Editable fields will be initialised to default values for the selected challenge type.

Save

After a new protocol is created, select **Protocol>Save** from the menu bar. Type a name for the created protocol and select **OK**.

Delete

Select the protocol which needs to be deleted, press the **Select as Active Protocol** button. After

the protocol is active, select **Protocol>Delete** from the menu bar and accept deletion. If the Protocol is marked as "Read-Only", it cannot be modified or deleted.

Import

The user can import new protocols to the programme. Select **Protocol>Import** from the menu bar.

Export

The user can export protocols to the XML file format. To export a protocol, select **Protocol>Export** from the menu bar. The user can export any protocol which is displayed in the **List of Protocols** tab. The exported protocol must be active before exporting.

8.6 Analysing Results

You can analyse the results as graphs or as numeric results, or as a combination of both. To analyse numeric results, select the appropriate button under "Show Results". To analyse graphs, select the appropriate button under "Show Curves".

Note the following details in the representation of figures:

- A '*' mark in front of the predicted value (for example *60%) indicates that the value of the measured variable is below the 95 % of the normal range.
- A '*' mark in front of the Z-score value (for example *-1.70) indicates that the value of the measured variable is below the Z-score normal range +/- 1.65.
- A '*' mark in front of the Post-Pre difference values indicates a significant change in the values of the bronchodilatation test.
- Red font colour of the figure indicates that the reproducibility of the value fails (see chapter [The Reproducibility Indicator](#)).

8.6.1 Curves

The user can choose which curves are displayed in the screen. Medikro Spirometry Software has the following options:

- Volume/Time curve of the measurement(s)

Volume/Time Curves

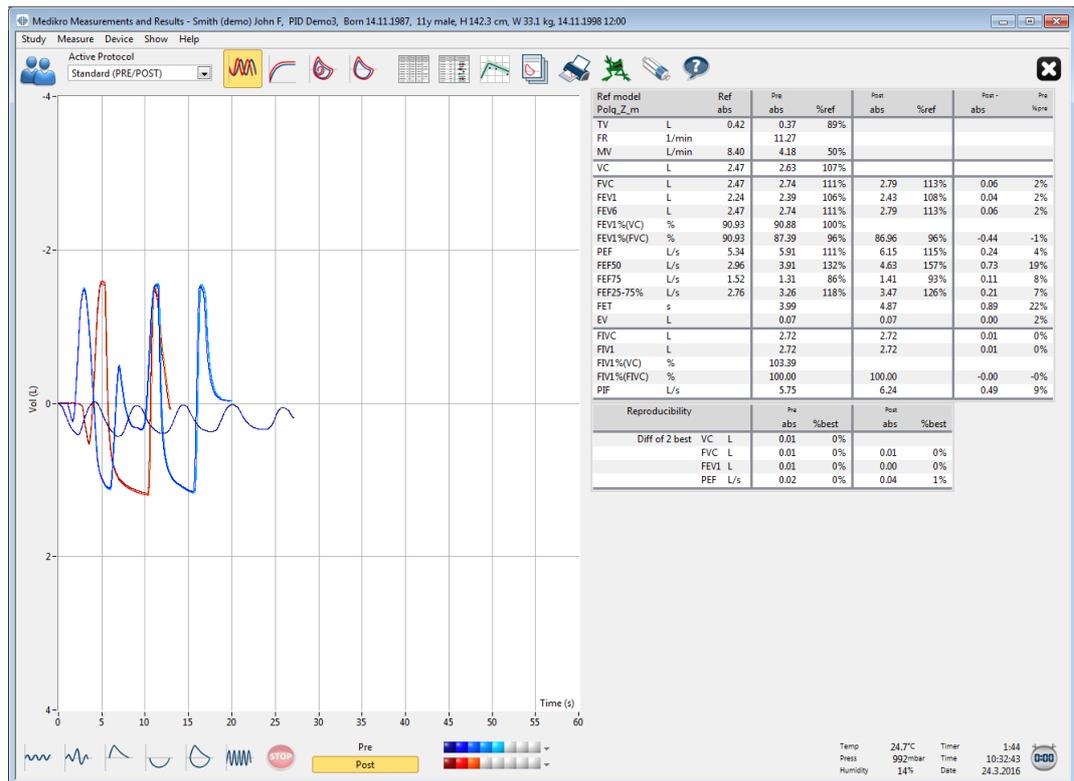


Figure: Show Curves in volume/time curve format.

- Flow/Volume curve of the measurement(s)

FV, Flow/Volume Curves

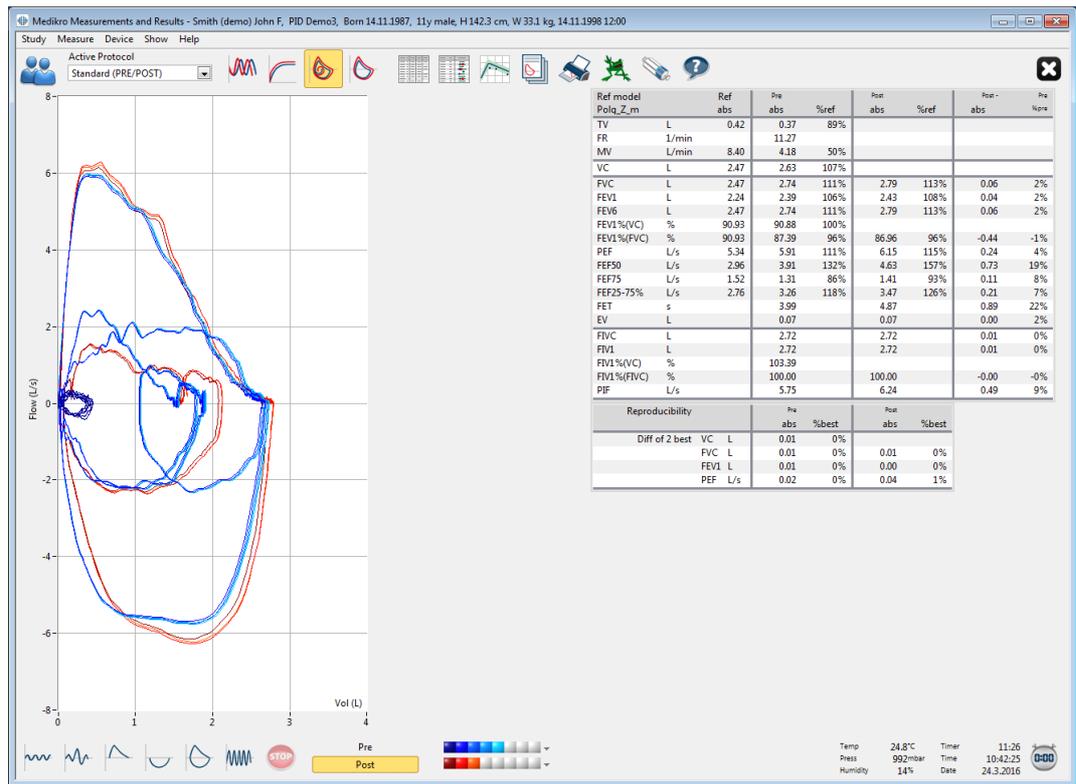


Figure: Show Curves in flow/volume curve format.

Measurement curves

Measurement Curves

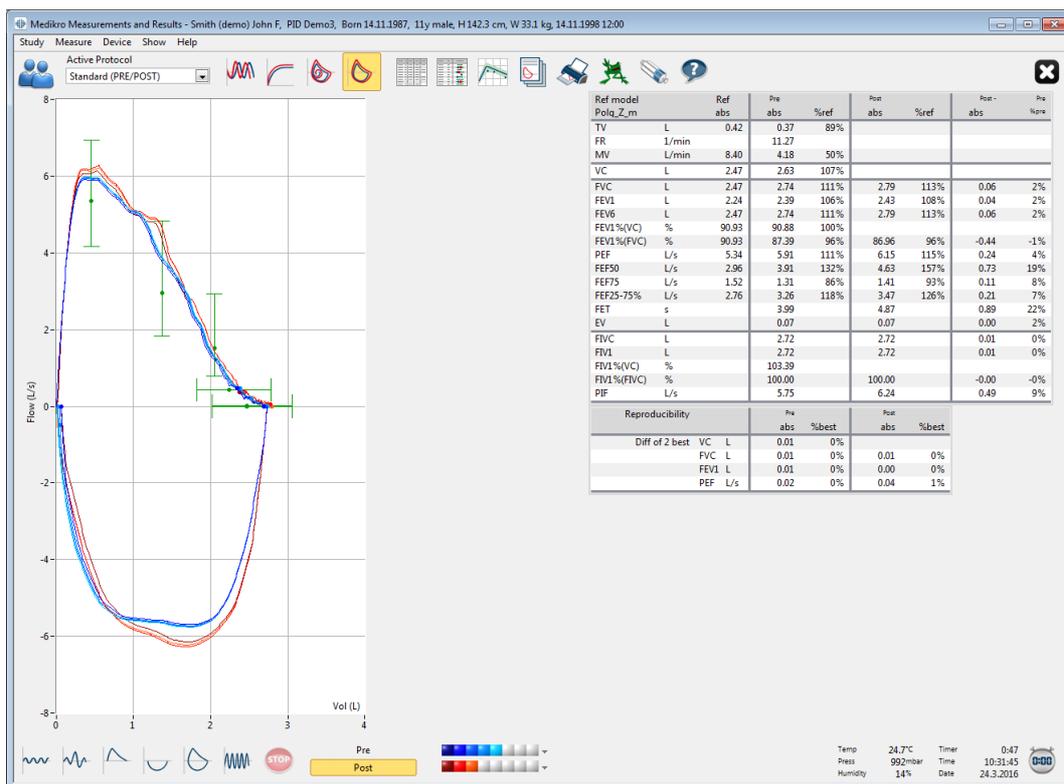


Figure: Show Measurement Curves.

- 6 s Volume/Time curve of the measurement(s)

VT6, 6 s Volume/Time Curves

Pressing the **VT6** button opens a floating window (Figure: Floating VT6 window showing 6s volume/time curves), which shows curves of expiratory 6 s volume/time curves. Clicking the **X** button in the upper right corner will close the **VT6** window.

The **VT6** window can be kept open during the measurements to help monitor the duration (at least 6 seconds or 3 s for children aged < 10 yrs recommended) and performance of the expiratory manoeuvres (FVC, FVC+FIVC).

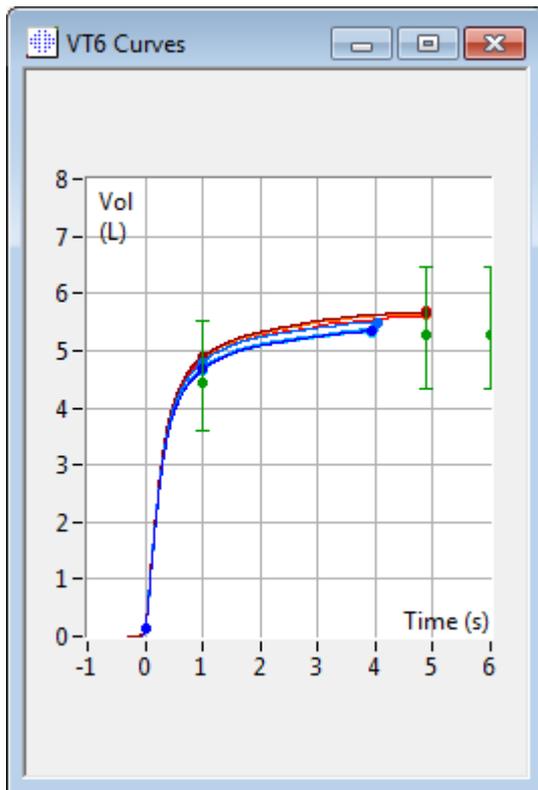


Figure: Floating VT6 window showing 6s volume/time curves.

To analyse curves, select the appropriate button under “Show curves” ([Table: Medikro Measurements and Result Show Curves Buttons](#)) or select:

Show>Volume/time Curve(s)

or

Show>6s. Volume/time Curve(s)

or

Show>Flow/Volume Curve(s)

or

Show>Curve(s)

8.6.2 Magnification of the Curves

The curves can be magnified for more detailed inspection. Select the desired view area of the curve by clicking and dragging from one corner of the area to the opposite corner.

To return to the original graph size, select the **Device / Normalise Graph** command or select the appropriate button under “Show curves”.

Additional information

Magnification of Curves

All curves can be magnified for a more detailed inspection (also applies to VT6 window). Select the desired area of the curve by clicking and dragging from one corner of the area to the opposite corner (Figure: Select the desired area). The selected part of the curve will be magnified. **Note:** the aspect ratio may not remain the same (Figure: After selecting the area, the curve is magnified for a more detailed viewing).

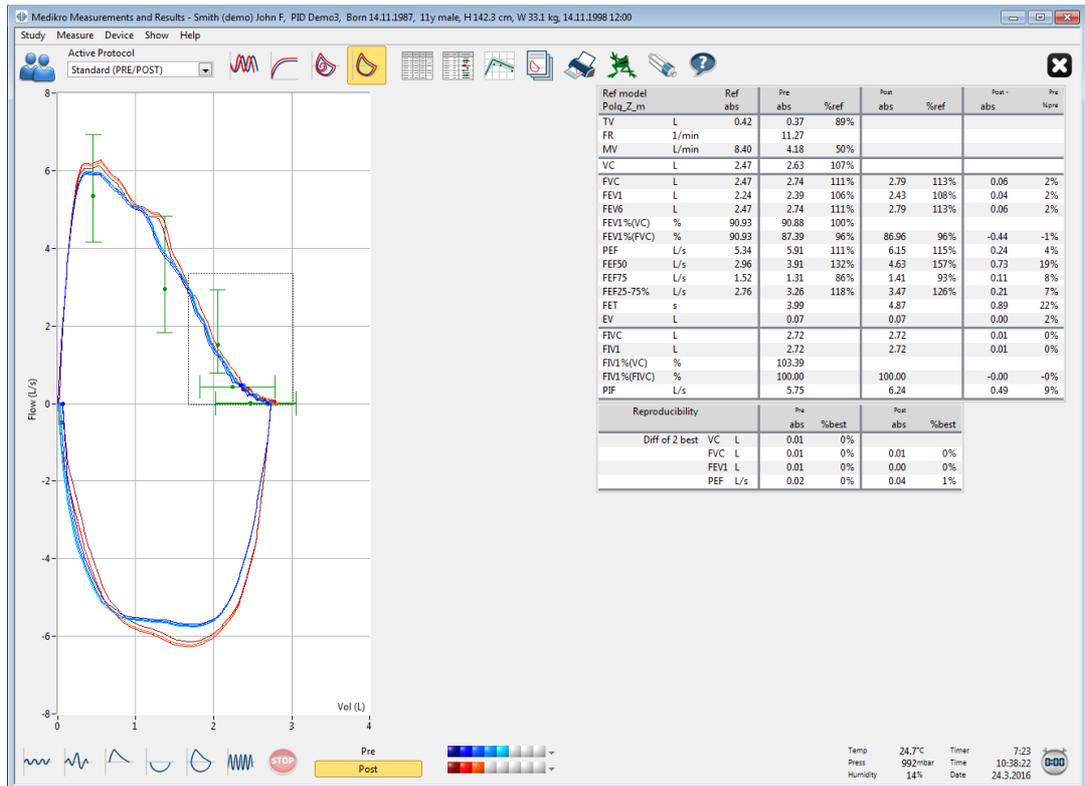


Figure: Select the desired area.

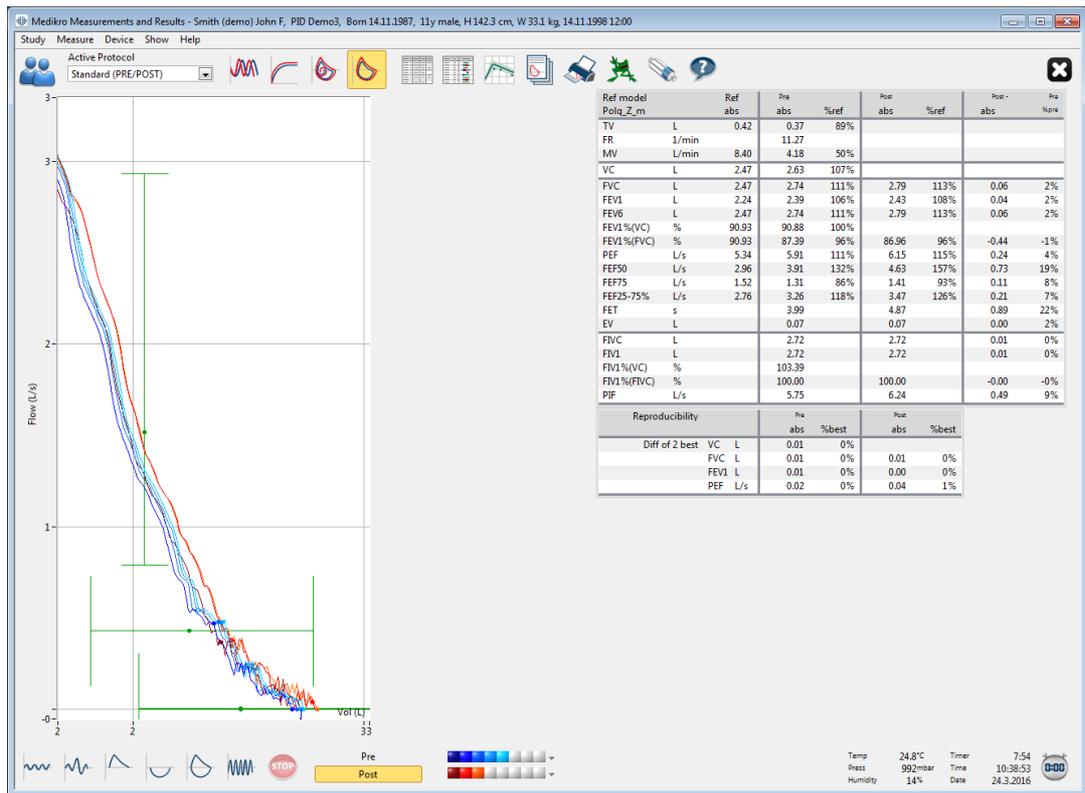


Figure: After selecting the area, the curve is magnified for a more detailed viewing.

To return to the original graph size, select **Device / Normalise Graph** command, or click the **VT**, **VT6**, **FV**, or **Curve(s)** button under **Show Curves**.

8.6.3 Numerical Results and Trend

To analyse results select the buttons “*Show Measurement Results*”, “*Show Best Result*”, or “*Show Trend*” under “*Show Results*” (see [Table: Medikro Measurements and Result Show Results Buttons](#)), or select:

Show>Results of Measurements

or

Show>Representative Results

or

Show>Trend

The following commands will represent the measurement results in numerical formats:

- The results of all measurements.
- The results of the best measurements and a histogram.

The trend allows the inspection of the trend of each individual variable in a graphical and numerical table form.

Additional information about:

▣ Numerical results

The following commands present the measurement results in numerical formats:

- “Show Measurement Results” will show the results of all measurements
- “Show Best Result” will show the representative results

Results of all Measurements

This option will show the results of all measurements in a numerical format (Figure: Numerical Results in tabular format). The list of available variables used in Medikro Spirometry Software is described in chapter [Variables](#).

	Ref abs	Pre		Signal 1		Signal 2		Signal 3		Signal 4		Signal 5		Post		Signal 1		Signal 2		Signal 3		
			abs	%ref	abs	%ref	abs	%ref	abs	%ref	abs	%ref	abs	%ref	abs	%ref	abs	%ref	abs	%ref		
TV	L	0.42		0.37	89%																	
FR	L/min			11.27																		
MV	L/min	8.40		4.18	50%																	
TIME	hh:mm			12:00		12:00		12:00		12:00		12:00		12:00		12:00		12:00		12:00		
VC	L	2.47		2.58	104%	2.60	105%	2.62	106%	2.63	107%											
FVC	L	2.47		2.68	109%	2.71	110%	2.72	110%	2.74	111%	2.73	111%	2.79	113%	2.79	113%	2.79	113%	2.79	113%	
FEV1	L	2.24		2.35	105%	2.37	106%	2.38	106%	2.39	106%	2.38	106%	2.43	108%	2.43	108%	2.43	108%	2.43	108%	
FEV6	L	2.47		2.68	109%	2.71	110%	2.72	110%	2.74	111%	2.73	111%	2.79	113%	2.79	113%	2.79	113%	2.79	113%	
FEV1%(VC)	%	90.93		89.23	98%	90.04	99%	90.47	99%	90.88	100%											
FEV1%(FVC)	%	90.93		85.82	94%	86.59	95%	87.00	96%	87.39	96%	85.11	94%	86.87	96%	86.96	96%	86.96	96%	86.96	96%	
PEF	L/s	5.34		5.84	109%	5.89	110%	5.86	110%	5.91	111%	6.02	113%	6.15	115%	6.11	114%	6.11	114%	6.11	114%	
PEF50	L/s	2.96		3.78	128%	3.85	130%	3.86	131%	3.91	132%	4.36	147%	4.65	157%	4.63	157%	4.63	157%	4.63	157%	
PEF75	L/s	1.52		1.21	80%	1.25	83%	1.28	84%	1.31	86%	1.27	84%	1.41	93%	1.41	93%	1.41	93%	1.41	93%	
PEF25-75%	L/s	2.76		3.06	111%	3.16	115%	3.20	116%	3.26	118%	3.23	117%	3.48	126%	3.47	126%	3.47	126%	3.47	126%	
FET	s			3.95		3.95		4.00		3.99		4.82		4.82		4.82		4.82		4.82		
EV	L			0.06		0.07		0.07		0.07		0.07		0.07		0.07		0.07		0.07		
FVC	L			2.67		2.69		2.71		2.72		2.66		2.72		2.72		2.72		2.72		
FV1	L			2.67		2.69		2.71		2.72		2.66		2.72		2.72		2.72		2.72		
FV1%(VC)	%			101.36		102.27		102.99		103.39		97.75		99.73		100.00		100.00		100.00		
FV1%(FVC)	%			98.04		98.92		99.61		100.00		97.75		99.73		100.00		100.00		100.00		
PIF	L/s			5.68		5.73		5.71		5.75		6.11		6.24		6.19		6.19		6.19		
Reproducibility			abs	%best	abs	%best	abs	%best	abs	%best	abs	%best	abs	%best	abs	%best	abs	%best	abs	%best	abs	%best
VCDIFF	L			-0.05	-2%	-0.03	-1%	-0.01	-0%	-0.00	-0%											
FVCDIFF	L			-0.05	-2%	-0.03	-1%	-0.01	-0%	-0.00	-0%	-0.06	-2%	-0.01	-0%	-0.00	-0%	-0.00	-0%	-0.00	-0%	
FEV1DIFF	L			-0.04	-2%	-0.02	-1%	-0.01	-0%	-0.00	-0%	-0.05	-2%	-0.00	-0%	-0.00	-0%	-0.00	-0%	-0.00	-0%	
PEFDIFF	L/s			-0.07	-1%	-0.02	-0%	-0.04	-1%	-0.00	-0%	-0.13	-2%	-0.00	-0%	-0.04	-1%	-0.04	-1%	-0.04	-1%	

Figure: Numeric results in tabular format.

Up to 8 Pre- and Post-phase measurements are shown. Measurement results include the result of each measured variable as well as a percentage comparison to predicted values. If the selected predicted value is GLI2012, Z-score value is shown for the measured result.

Representative Results

This option will show the results of the best measurements both in a numerical format and as a histogram (Figure: Show Best Results).

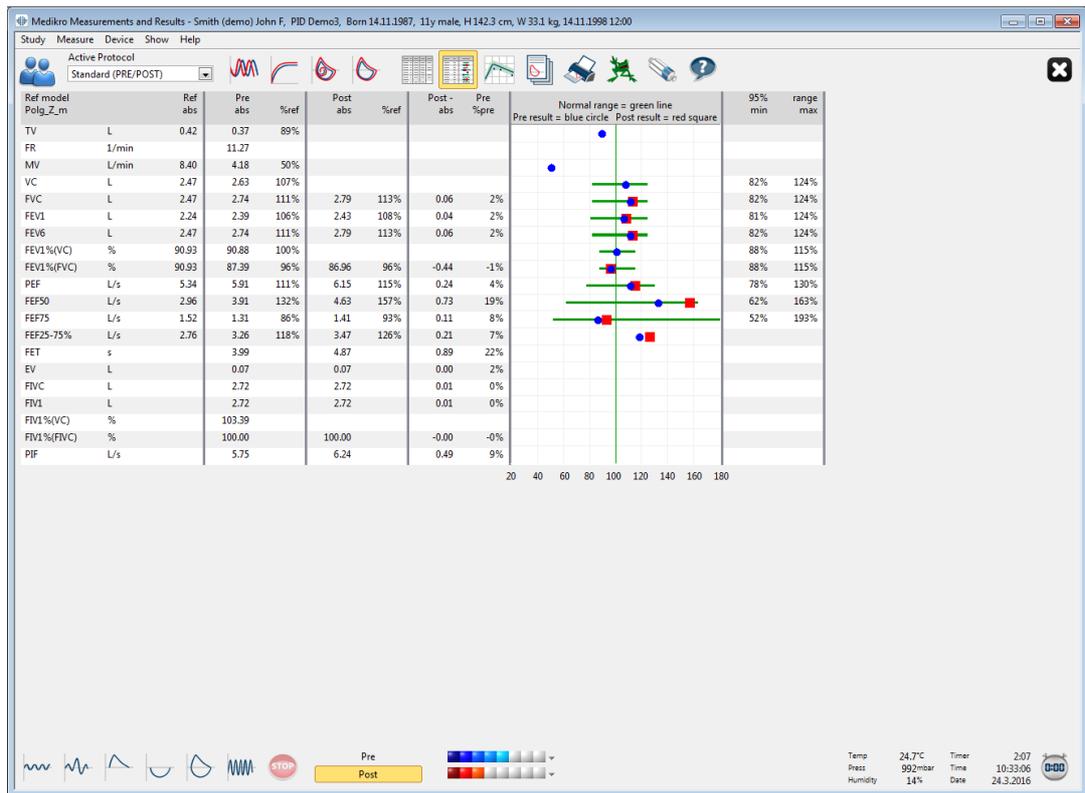


Figure: Show Best Results.

Best results of the Pre- and the Post-phase measurements are compared to predicted values. Also, the Post/Pre difference is shown. If the selected predicted value is GLI2012, Z-score value is shown for the measured result.

The best results are also displayed as a Histogram. It will show 95 % of the normal range for each measured variable as a green bar. The best Pre-phase result is indicated with a blue circle and the best Post-phase result with a red square. The histogram results will give a direct indication on the severity of a limited lung function.

If the selected predicted value is GLI2012, histogram shows z-score value for the measured result and the normal range. Z-score normal range is +/- 1.64 for all measured variables. LLN and ULN indicate lower limit and upper limit of normal range.

[-] Trend

Trend allows the inspection of the trend of each individual variable in a graphical (Figure: Trending in a graphical presentation form) and numeric table (Figure: A separate floating window shows trending in a numeric table presentation) form.

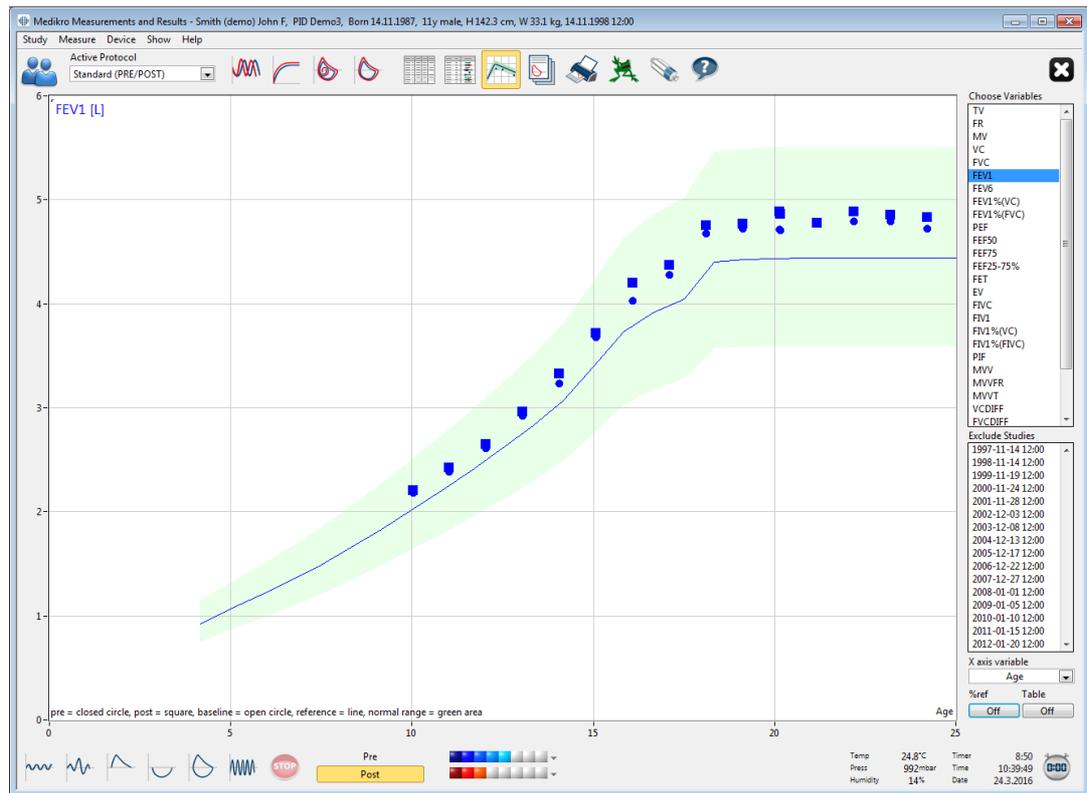


Figure: Trending in a graphical presentation form.

The operator can select one or several variables for the trending inspection from the Choose Variables field (Figure: Trending, interactive elements). The selected variables and their dimensions are shown on the top left hand side of the trend graph. Several variables can be selected by pressing CTRL while making a mouse click.

Choose Variables

- TV
- FR
- MV
- VC
- FVC
- FEV1
- FEV6
- FEV1%(VC)
- FEV1%(FVC)
- PEF
- FEF50
- FEF75
- FEF25-75%
- FET
- EV
- FIVC
- FIV1

Exclude Sessions

- 1984-11-14 12:00
- 1985-11-14 12:00
- 1986-11-19 12:00
- 1987-11-24 12:00
- 1988-11-28 12:00
- 1989-12-03 12:00
- 1990-12-08 12:00
- 1991-12-13 12:00
- 1992-12-17 12:00
- 1993-12-22 12:00
- 1994-12-27 12:00

X axis variable

Age

%ref Table

Off Off

Figure: Trending, interactive elements.

The operator can also select the sessions to be excluded from the trending inspection. The exclusion of the sessions can be selected from the Exclude Sessions field (Figure: Trending, interactive elements). Several sessions can be selected by pressing **CTRL** while making a mouse click. New results are calculated automatically for immediate trending inspection.

X-axis variable can be selected from the appropriate field (Figure: Trending, interactive elements). There are three options:

- Date indicates the date of the session
- Age indicates the age of the person at the time of the measurements
- Session indicates the sequence number of the sessions

The "%of pred" button (Figure: Trending, in relation to predicted values) activates the inspection of the results in relation to predicted values. The results are expressed as a percentage (%) of the predicted value, provided the selected variable has a predicted value.

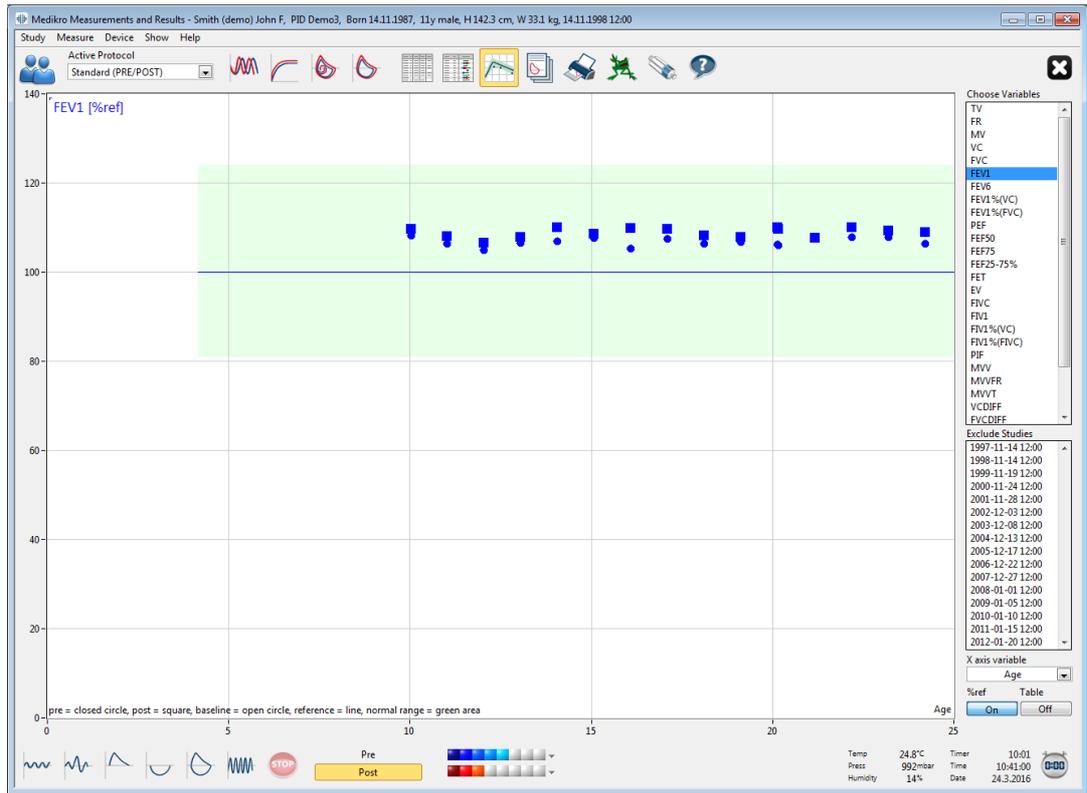


Figure: Trending, in relation to predicted values.

The “Table” button opens a floating window that contains a numeric table of trending data (Figure: A separate floating window shows trending in a numeric table presentation). A drop-down selector “Variables” in the upper left corner of the window shows the list of variables that the operator has chosen from the previous window (Figure: Trending in a graphical presentation form). By using this selection, the operator can choose the variable of which trend data is being studied at a time.

Variables		Reference models: Polg_Z_m, Ecs_18_m, Ecss_m											
Session	Date	Age	Ref abs	Pre abs	%ref	Post abs	%ref	Baseline abs	%ref	Post - abs	Pre %pre	95% min	range max
1	1984-11-14 12:00	10.0	2.02	2.19	108%	2.22	110%			0.03	1%	81%	124%
3	1986-11-19 12:00	12.0	2.49	2.62	105%	2.66	107%			0.04	2%	81%	124%
5	1988-11-28 12:00	14.0	3.03	3.24	107%	3.33	110%			0.10	3%	81%	124%
6	1989-12-03 12:00	15.1	3.42	3.69	108%	3.72	109%			0.04	1%	81%	124%
7	1990-12-08 12:00	16.1	3.83	4.03	105%	4.21	110%			0.18	4%	81%	124%
8	1991-12-13 12:00	17.1	3.99	4.29	108%	4.38	110%			0.09	2%	81%	124%
9	1992-12-17 12:00	18.1	4.40	4.68	106%	4.76	108%			0.08	2%	81%	124%
10	1993-12-22 12:00	19.1	4.42	4.73	107%	4.78	108%			0.05	1%	81%	124%
11	1994-12-27 12:00	20.1	4.44	4.72	106%	4.89	110%			0.17	4%	81%	124%
12	1996-01-01 12:00	21.1	4.44	4.71	106%	4.87	110%			0.16	3%	81%	124%
13	1997-01-05 12:00	22.1	4.44	4.79	108%	4.79	108%			-0.00	-0%	81%	124%
14	1998-01-10 12:00	23.2	4.44	4.80	108%	4.89	110%			0.10	2%	81%	124%
15	1999-01-15 12:00	24.2	4.44	4.80	108%	4.86	109%			0.06	1%	81%	124%
16	2000-01-20 12:00	25.2	4.43	4.73	107%	4.84	109%			0.11	2%	81%	124%

Figure: A separate floating window shows trending in a numeric table presentation.

8.6.4 Printing a Current Window

Whenever you choose the **Print** button, the software will print the contents of the current view in a measurement window. This allows you to select (see the chapter [Session Status Summary](#)) and print any measurement curve individually. The user can also print the current window by selecting:

Study>Print Current Window

8.7 Interpretation

Medikro Spirometry Software has the following interpretation options: Spirometry Interpretation Logic, Bronchodilatation test result and Manual interpretation text.

8.7.1 Spirometry Interpretation Logic

Spirometry interpretation logic combines two interpretation settings, ventilatory dysfunction type (formerly: spirometry finding) and severity of ventilatory disturbance (formerly: ventilation function) together.

You can access this setting by using the following command path:

Device>Settings>Spirometry>Spirometry Interpretation Logic

See the detailed description for available options:

- [Quanjer 2014](#)
- [ATS/ERS 2005](#)
- [Moodi 2019](#)
- [Moodi 2019 without ventilatory dysfunction type classification](#)
- [China \(301\)](#)
- [Custom](#)
- [None](#)

8.7.1.1 Quanjer 2014

When spirometry interpretation logic "Quanjer 2014" is selected, severity of ventilatory disturbance depends on ventilatory dysfunction type.

PLEASE NOTE!

- This interpretation mode can be used with prediction models that support Z-scores.

Ventilatory Dysfunction Type (formerly: Spirometry Finding)

Ventilatory dysfunction type is interpreted according to Quanjer 2014.

Ventilatory dysfunction type	Criteria
Obstruction	FEV1/(F)VC decreased ($z < -1.65$).
No information	FEV1/(F)VC is normal ($z \geq -1.65$).

Severity of Ventilatory Disturbance (formerly: Ventilation Function)

Severity of ventilatory disturbance is interpreted according to Quanjer 2014.

If ventilatory dysfunction is "obstruction", severity of ventilatory disturbance is classified based on the Pre-phase FEV1 Z-score value. Otherwise, value shows "No information".

Severity of ventilatory disturbance	Criteria
Mild	FEV1(z) \geq -2.0
Moderate	-2.5 \leq FEV1(z) $<$ -2.0
Moderately severe	-3.0 \leq FEV1(z) $<$ -2.5
Severe	-4.0 \leq FEV1(z) $<$ -3.0
Very severe	FEV1(z) $<$ -4.0

8.7.1.2 ATS/ERS 2005

Ventilatory Dysfunction Type (formerly: Spirometry Finding)

When this option is selected, ventilatory dysfunction type is interpreted according to ATS/ERS 2005 recommendations.

The interpretation classifies ventilatory dysfunction type based on Pre-phase FEV1 and VC or FVC compared to the predicted value. VC or FVC is selected according to which one is measured. If both are measured, the variable having a greater value is selected.

Ventilatory dysfunction type	Criteria
Restriction	Measured VC or FVC is below of 95 % of the normal range, but FEV1%VC or FEV1%FVC is normal or increased.
Obstruction	VC or FVC is normal or increased, but FEV1%VC or FEV1%FVC is below of 95 % of the normal range.
Mixed reduction	Both VC or FVC and FEV1%VC or FEV1%FVC are below of 95 % of the normal range.
Normal	Both VC or FVC and FEV1%VC or FEV1%FVC are normal or increased.

Severity of Ventilatory Disturbance (formerly: Ventilation Function)

With this option, severity of ventilatory disturbance is interpreted according to the ATS/ERS 2005 recommendations.

The interpretation classifies the spirometry based on the Pre-phase FEV1 compared to the predicted value.

Severity of ventilatory disturbance	FEV1 %Pred
Normal	$x \geq -2 \text{ SD}$
Mild	$70 \leq x < -2 \text{ SD}$
Moderate	$60 \leq x < 70$
Moderately severe	$50 \leq x < 60$
Severe	$35 \leq x < 50$
Very severe	$x < 35$

SD = standard deviation, +- SD = 95 % confidence limit.

8.7.1.3 Moodi 2019

When spirometry interpretation logic "Moodi 2019" is selected, severity of ventilatory disturbance depends on ventilatory dysfunction type.

PLEASE NOTE!

- This interpretation mode can be used with prediction models that support Z-scores.

Ventilatory Dysfunction Type (formerly: Spirometry Finding)

Ventilatory dysfunction type is interpreted according to Moodi 2019.

If all measured Pre-phase Z-score values (FEV1, VC, FVC, FEV1/VC, FEV1/FVC, PEF, FEF50, FEF25-75%) are within the normal range ($-1.65 \leq z \leq 1.65$), ventilatory dysfunction type gets value "" and severity of ventilatory disturbance gets value "Normal". In other cases there is ventilatory dysfunction, which may have the following types:

Ventilatory dysfunction type	Criteria
Restriction	(F)VC decreased ($z < -1.65$). If both FVC and VC are measured, both have to be decreased for restriction.
Obstruction	FEV1/(F)VC decreased ($z < -1.65$).
Suggesting airway obstruction	Only flow values (PEF, FEF50, FEF25-75%) decreased ($z < -1.65$).
Mixed reduction	Both (F)VC and FEV1/(F)VC decreased ($z < -1.65$).
	Other values are decreased ($z < -1.65$)

Severity of Ventilatory Disturbance (formerly: Ventilation Function)

Severity of ventilatory disturbance is interpreted according to Moodi 2019.

If there is ventilatory dysfunction, severity of ventilatory disturbance is classified based on the Pre-phase FEV1 Z-score value:

Severity of ventilatory disturbance	Criteria
Mild	$FEV1(z) \geq -2.0$
Moderate	$-2.5 \leq FEV1(z) < -2.0$
Moderately severe	$-3.0 \leq FEV1(z) < -2.5$
Severe	$-4.0 \leq FEV1(z) < -3.0$
Very severe	$FEV1(z) < -4.0$

8.7.1.4 Moodi 2019 without ventilatory dysfunction type classification

PLEASE NOTE!

- This interpretation mode can be used with prediction models that support Z-scores.

Ventilatory Dysfunction Type (formerly: Spirometry Finding)

Ventilatory dysfunction type is not determined and shows an empty value.

Severity of Ventilatory Disturbance (formerly: Ventilation Function)

Severity of ventilatory disturbance is interpreted according to Moodi 2019.

If all measured Pre-phase Z-score values (FEV1, VC, FVC, FEV1/VC, FEV1/FVC, PEF, FEF50, FEF25-75%) are within normal range ($-1.65 \leq z \leq 1.65$), severity of ventilatory disturbance gets value "Normal". In other cases there is ventilatory dysfunction and severity of ventilatory disturbance is classified based on the Pre-phase FEV1 Z-score value:

Severity of ventilatory disturbance	Criteria
Mild	$FEV1(z) \geq -2.0$
Moderate	$-2.5 \leq FEV1(z) < -2.0$
Moderately severe	$-3.0 \leq FEV1(z) < -2.5$
Severe	$-4.0 \leq FEV1(z) < -3.0$
Very severe	$FEV1(z) < -4.0$

8.7.1.5 China (301)

Ventilatory Dysfunction Type (formerly: Spirometry Finding)

When this option is selected, ventilatory dysfunction type is interpreted according to China (301) practice. The interpretation classifies the ventilatory dysfunction type based on Pre-phase FEV1 and VC or FVC compared to the predicted value. Additionally, interpretation depends on the value of the severity of ventilatory disturbance. VC or FVC is selected according to which one is measured. If both are measured, the variable having a greater value is selected.

Ventilatory dysfunction type	Severity of ventilatory disturbance	Criteria
Restriction	Not normal	Measured VC or FVC is below of 95 % of the normal range, but FEV1%VC or FEV1%FVC is normal or increased.
Obstruction	Not normal	VC or FVC is normal or increased, but FEV1%VC or FEV1%FVC is below of 95 % of the normal range.
Mixed reduction	Not normal	Both VC or FVC and FEV1%VC or FEV1%FVC are below of 95 % of the normal range.
Normal	Normal	Both VC or FVC and FEV1%VC or FEV1%FVC are normal or increased.

Severity of Ventilatory Disturbance (formerly: Ventilation Function)

With this option, severity of ventilatory disturbance is interpreted according to the ATS/ERS 2005 recommendations.

The interpretation classifies the spirometry based on the Pre-phase FEV1 compared to the predicted value.

Severity of ventilatory disturbance	FEV1 %of Pred
Normal	$x \geq -2 \text{ SD}$
Mild	$70 \leq x < -2 \text{ SD}$
Moderate	$60 \leq x < 70$
Moderately severe	$50 \leq x < 60$
Severe	$35 \leq x < 50$
Very severe	$x < 35$

SD = standard deviation, +/- SD = 95 % confidence limit.

8.7.1.6 Custom

For an interpretation compatibility with former versions, the software automatically selects mode "custom" when a study made with the old software version is opened. In this mode, ventilatory dysfunction type and severity of ventilatory disturbance are interpreted according to the interpretation settings of that study. When the study is closed, the original setting for spirometry interpretation logic is returned.

When an old study is open, user can change the mode from "custom" to any other but cannot change back to "custom" once changed.

Spirometry interpretation logic mode "custom" supports following interpretation methods that have been available in former versions.

Ventilatory Dysfunction Type (formerly: Spirometry Finding)

None. When this option is selected, ventilatory dysfunction type interpretation is disabled and ventilatory dysfunction type fields are empty.

ATS/ERS 2005. When this option is selected, ventilatory dysfunction type is interpreted according to ATS/ERS 2005 recommendations. The interpretation classifies the ventilatory dysfunction type based on Pre-phase FEV1 and VC or FVC compared to the predicted value. VC or FVC is selected according to which one is measured. If both are measured, the variable having a greater value is selected.

Ventilatory dysfunction type	Criteria
Restriction	Measured VC or FVC is below of 95 % of the normal range, but FEV1%VC or FEV1%FVC is normal or increased.
Obstruction	VC or FVC is normal or increased, but FEV1%VC or FEV1%FVC is below of 95 % of the normal range.
Mixed reduction	Both VC or FVC and FEV1%VC or FEV1%FVC are below of 95 % of the normal range.
Normal	Both VC or FVC and FEV1%VC or FEV1%FVC are normal or increased.

China (301). When this option is selected, ventilatory dysfunction type is interpreted according to China (301) practice. The interpretation classifies the ventilatory dysfunction type based on Pre-phase FEV1 and VC or FVC compared to the predicted value. Additionally, interpretation depends on the value of the severity of ventilatory disturbance. VC or FVC is selected according to which one is measured. If both are measured, the variable having a greater value is selected.

Ventilatory dysfunction type	Severity of ventilatory disturbance	Criteria
Restriction	Not normal	Measured VC or FVC is below of 95 % of the normal range, but FEV1%VC or FEV1%FVC is normal or increased.

Obstruction	Not normal	VC or FVC is normal or increased, but FEV1%VC or FEV1%FVC is below of 95 % of the normal range.
Mixed reduction	Not normal	Both VC or FVC and FEV1%VC or FEV1%FVC are below of 95 % of the normal range.
Normal	Normal	Both VC or FVC and FEV1%VC or FEV1%FVC are normal or increased.

Moodi 2015. Ventilatory dysfunction type is interpreted according to Moodi 2015.

PLEASE NOTE!

- This interpretation mode can be used with prediction models that support Z-scores.
- Only those variables that are visible in the final report are used in interpretation.

If all measured Pre-phase Z-score values are within the normal range ($-1.65 \leq z \leq 1.65$), ventilatory dysfunction type gets value "" and severity of ventilatory disturbance gets value "Normal". In other cases there is ventilatory dysfunction, which may have the following types:

Ventilatory dysfunction type	Criteria
Restriction	(F)VC decreased ($z < -1.65$). If both FVC and VC are measured, both have to be decreased for restriction.
Obstruction	FEV1/(F)VC decreased ($z < -1.65$).
Suggesting airway obstruction	Only flow values (PEF, FEF50, FEF25-75%) decreased ($z < -1.65$).
Mixed reduction	Both (F)VC and FEV1/(F)VC decreased ($z < -1.65$).
	Other values are decreased ($z < -1.65$) or no variables visible in final report.

Severity of Ventilatory Disturbance (formerly: Ventilation Function)

ATS/ERS 2005. With this option, severity of ventilatory disturbance is interpreted according to the ATS/ERS 2005 recommendations.

The interpretation classifies the spirometry based on the Pre-phase FEV1 compared to the predicted value.

Severity of ventilatory disturbance	FEV1 %of Pred
Normal	$x \geq -2 \text{ SD}$
Mild	$70 \leq x < -2 \text{ SD}$

Moderate	$60 \leq x < 70$
Moderately severe	$50 \leq x < 60$
Severe	$35 \leq x < 50$
Very severe	$x < 35$

Sovijarvi 1994. With this option, severity of ventilatory disturbance is interpreted according to Sovijarvi 1994.

The interpretation classifies the Pre-phase spirometry results according to the variable that has the lowest value compared to the predicted value. The exceptions are VC and FVC, the classification of which is accomplished according to the variable having a higher value compared to the predicted value.

Severity of ventilatory disturbance	Value compared to the predicted value
Normal	$x \geq -2 \text{ SD}$
Mild	$-3.5 \text{ SD} \leq x < -2 \text{ SD}$
Moderate	$-5.5 \text{ SD} \leq x < -3.5 \text{ SD}$
Severe	$-7.5 \text{ SD} \leq x < -5.5 \text{ SD}$
Critical	$x < -7.5 \text{ SD}$

SD = standard deviation, \pm SD = 95 % confidence limit.

Quanjer 2014. With this option, severity of ventilatory disturbance is interpreted according to Quanjer 2014.

Because interpretation of severity of ventilatory disturbance depends on ventilatory dysfunction in Quanjer 2014, ventilatory dysfunction type is forced to use Quanjer 2014, if severity of ventilatory disturbance uses Quanjer 2014.

Ventilatory dysfunction type is interpreted according to Quanjer 2014.

Ventilatory dysfunction type	Criteria
Obstruction	FEV1/(F)VC decreased ($z < -1.65$).
No information	FEV1/(F)VC is normal ($z \geq -1.65$).

Severity of ventilatory disturbance is interpreted according to Quanjer 2014.

If ventilatory dysfunction is "obstruction", severity of ventilatory disturbance is classified based on the Pre-phase FEV1 Z-score value. Otherwise, value shows "No information".

Severity of ventilatory disturbance	Criteria
Mild	FEV1(z) >= -2.0
Moderate	-2.5 <= FEV1(z) < -2.0
Moderately severe	-3.0 <= FEV1(z) < -2.5
Severe	-4.0 <= FEV1(z) < -3.0
Very severe	FEV1(z) < -4.0

Moodi 2015. Severity of ventilatory disturbance is interpreted according to Moodi 2015.

If there is ventilatory dysfunction, severity of ventilatory disturbance is classified based on the Pre-phase FEV1 Z-score value:

Severity of ventilatory disturbance	Criteria
Mild	FEV1(z) >= -2.0
Moderate	-2.5 <= FEV1(z) < -2.0
Moderately severe	-3.0 <= FEV1(z) < -2.5
Severe	-4.0 <= FEV1(z) < -3.0
Very severe	FEV1(z) < -4.0
	FEV1 not visible in final report

8.7.1.7 None

Ventilatory Dysfunction Type (formerly: Spirometry Finding)

Ventilatory dysfunction type is not determined and shows an empty value.

Severity of Ventilatory Disturbance (formerly: Ventilation Function)

Severity of ventilatory disturbance is not determined and shows an empty value.

8.7.2 Bronchodilatation Test Result

Medikro Spirometry Software interprets the bronchodilatation test result. The result is shown in the Personal Information window and on the first page of the Final Report.

You can select the method to compare the results of a bronchodilatation test by using the following command path:

Device>Settings>Spirometry>Bronchodilatation test comparison

There are two options:

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Predicted values. With this option, the difference between the Post- and Pre-phase results is calculated in relation to the predicted value and shown as "*%of pred*". To assess whether the change in the bronchodilatation test is significant, Medikro Spirometry Software compares the relative difference to the predicted value.

Pre-phase representative results. With this option, the difference between the Post- and Pre-phase results is calculated in relation to the Pre-phase representative value and shown as "*%pre*". To assess whether the change in the bronchodilatation test is significant, Medikro Spirometry Software compares the relative difference to the Pre-phase representative value.

You can select the method to interpret the results of a bronchodilatation test by using the following command path:

Device>Settings>Spirometry>Bronchodilatation test interpretation

The result of bronchodilatation test interpretation is either "*No significant change*" or "*Significant change*". The following interpretation options are available for the bronchodilatation test:

ATS/ERS 2005. With this option, the bronchodilatation test is interpreted according to the ATS and ERS 2005 recommendations. Variables and limits for adults and children are:

	Adults	Children
FVC >=	12% Pre AND 200 ml	12% Pre AND 200 ml
FEV1 >=	12% Pre AND 200 ml	12% Pre AND 200 ml

ERS 1993. With this option, the bronchodilatation test is interpreted according to the ERS 1993 recommendations. Variables and limits for adults and children are:

	Adults	Children
FVC >	12% of Pred AND 200 ml	12% of Pred AND 200 ml
FEV1 >	12% of Pred AND 200 ml	12% of Pred AND 200 ml
PEF >=	1 l/s	-

Sovijarvi 1994. With this option, the bronchodilatation test is interpreted according to Sovijarvi 1994. Variables and limits for adults and children are:

	Adults	Children
FVC >=	15% Pre AND 250 ml	15% Pre
FEV1 >=	15% Pre AND 200 ml	15% Pre
PEF >=	23% Pre AND 1 l/s	23% Pre
FEF25-75 >=	33% Pre AND 0.4 l/s	33% Pre
FEF50 >=	36% Pre AND 0.5 l/s	36% Pre
FEF75 >=	56% Pre AND 0.3 l/s	56% Pre
AEFV >=	25% Pre	25% Pre

FEV0.5 >=	-	20% Pre
-----------	---	---------

Sovijarvi 2006. With this option, the bronchodilatation test is interpreted according to Sovijarvi 2006. Variables and limits for adults and children are:

	Adults	Children
FVC >=	12% Pre AND 200 ml	12% Pre AND 200 ml
FEV1 >=	12% Pre AND 200 ml	12% Pre AND 200 ml
PEF >=	23% Pre AND 1 l/s	-
FEF25-75 >=	33% Pre AND 0.4 l/s	-
FEF50 >=	36% Pre AND 0.5 l/s	-
FEF75 >=	56% Pre AND 0.3 l/s	-
AEFV >=	25% Pre	-

Moodi 2015. With this option, the bronchodilatation test is interpreted according to Moodi 2015.

Please note: Only those variables that are visible in the final report are used in interpretation.

Variables and limits for adults and children are:

	Adults	Children	Bronchodilatation test result
FVC >=	12% Pre AND 200 ml	12% Pre AND 200 ml	Significant increase
FEV1 >=	12% Pre AND 200 ml	12% Pre AND 200 ml	Significant increase
PEF >=	23% Pre AND 1 l/s	23% Pre AND 1 l/s	Suggestive increase
FEF25-75 >=	33% Pre AND 0.4 l/s	33% Pre AND 0.4 l/s	Suggestive increase
FEF50 >=	36% Pre AND 0.5 l/s	36% Pre AND 0.5 l/s	Suggestive increase
AEFV >=	25% Pre	25% Pre	Suggestive increase

None. With this option, the bronchodilatation test is not interpreted and shows an empty value.

8.7.3 Manual Interpretation Text

Interpretation Text is given by a consulting doctor. The text is given in the Medikro Persons and Studies Study view and shown on the first page of the Final Report. Note: only the five first rows of the **interpretation Text** can be printed in the report.

8.8 The Final Report

Standard Final Report

Click the **Show Report** button (see [Table: Medikro Measurements and Result Show Results buttons](#)) to see the printable final report. The Final Report summarises the results and interpretation of the

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current spirometry session. It can also present the summary of the patient's background in a form of graphical and numerical trend data.

Additional information about:

- ☐ Sending and receiving the final report

Sending the Final Report

The report is created in HTML format and can be viewed by any browser, such as Internet Explorer.

When you click the **Show Report** button, a Final Report is generated into the folder C:\Medikro\Temp\Report\. The Final Report contains a minimum of four pages and consists of the following files:

- M8124-3-multi.htm (page 1)
- Best Curves.png (page 1)
- Trend.png (page 1)
- VT6 Curves.png (page 1)

- M8124-5-multi.htm (page 2)
- Pre-phase Curves.png (page 2)
- Post-phase Curves.png (page 2)

- M8124-6-multi.htm (page 3)
- Pre-FlowVolumes.png (page 3)
- Post-FlowVolumes.png (page 3)

- M8124-7_1-multi.htm (page 4) ... M8124-7_n-multi.htm (page n)
- TrendTVar1.png (page 4) ... TrendTVarn.png (n refers to page number)
- Report Logo.gif (all pages)

All of these files are needed to display the full final report, but you can also choose to select files for certain page(s) of the final report. Drag and drop the files to an e-mail message as an attachment and you can send the Final Report in an e-mail to the recipient.

Receiving the Final Report

When you receive a Final Report via e-mail or CD, you can simply double click the file M8124-3-multi.htm and the first page of the Final Report will be opened in the browser screen. You can also print the file from the browser if you want.

The standard final report contains at least five pages: The first page shows the best (representative) results. The results of individual Pre- and Post-phase measurements are shown in the second and third page. Page four shows difference values of trending variables. The difference values are calculated by comparing each selected session trending variable value to its first and its previous session trending variable value. Pages from number five forward show an individual page for each selected trending variable. The number of trending pages depends on how many trending variables the user has selected. The minimum is one variable.

The report pages include the following information in more detail:

- personal information, showing the patient name and ID is selectable (on every page)
- smoking history (page 1)
- clinical information (page 1)
- best results as tables and histogram (pages 1)
- reproducibility of the measurements (pages 1-3), selectable for the first page
- numerical values of the individual Pre- and Post-phase measurements, showing the curves is selectable (pages 2-3)
- difference values of the selected trending variables (page 4)
- numerical values of the selected trending variables (from page 5 forward)
- interpretation (page 1)
- best curves of the individual Pre- and Post-phase measurements (page 2)
- flow-volume curves of the individual Pre- and Post-phase measurements (page 3)

On the first page, the user can select two graphs to display by checking two of the following check boxes (at the upper left corner of the report page):

- best curves,
- trending graph, or
- VT6 curves.

Note the following details in the representation of figures:

- A “*” mark in front of the predicted value (for example *60%) indicates that the value of the measured variable is below the 95 % of the normal range.
- A “*” mark in front of the Z-score value (for example *-1.70) indicates that the value of the measured variable is below the Z-score normal range +/- 1.65.
- A “*” mark in front of the Post-Pre difference values indicates a significant change of values in the bronchodilatation test.
- Red font colour of the figure indicates that the reproducibility of the value fails (see chapter [The Reproducibility Indicator](#)).

Bronchial Provocation Final Report

The contents of the final report of the bronchial provocation differ from the standard bronchodilatation report. The bronchial challenge report consists of the following parts:

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- personal information
- smoking history
- clinical information
- test information, selected protocol and agents
- numerical values for the selected variables per phase
- symptoms and findings table
- dose-response curves of the selected variables
- PD values for the selected variables
- bronchial hyperresponsiveness template to fill in

By checking the check boxes on the top of the page, the user can select whether to display the patient's identification information or, similarly, dose-response curves.

8.8.1 Viewing the Final Report

The final report can be viewed using the **Show Report** button (see [Table: Medikro Measurements and Results Show Results Buttons](#)) or by selecting:

Show>Final report

Additional information

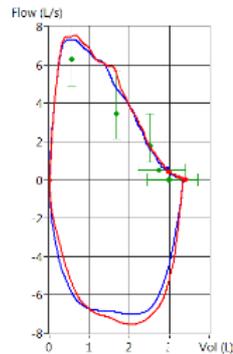
Viewing the Final Report

On the first page, the user can select two graphs to display by checking two of the following check boxes (in the upper left corner of the report page):

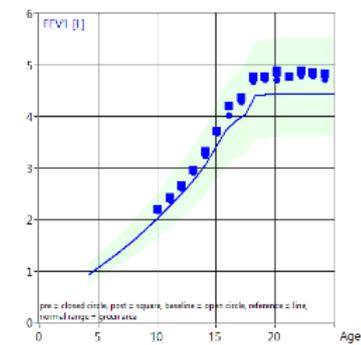
- best curves,
- trending graph, or
- VT6 curves.

Name of the organization		SPIROMETRY		MEDIKRO		
Department		1.1.2008 at 12:00				
Address						
PERSONAL INFORMATION			Date of birth : 14.11.1987	Height : 178 cm		
Last name : Smith (demo)			Age and sex: 20 years old male	Weight : 68.0 kg		
First name : John F			Personal ID : Demo3	BMI : 21.5 kg/m ²		
Profession :			Patient code:	Ethnic group:		
SMOKING Yes						
CLINICAL INFORMATION						
Illness :			Co-operation: Good			
Medication:			Comment :			
Problem :			Operator :			
TEST RESULTS						
Ref value						
----- MEASURED VALUES -----						
Normal range (-----)						
Pre (O) & Post (X) Results						
95% range						
Abbr.	Unit	Ecs_18_m	Pre test abs %ref	Post test abs %ref	Difference abs %pre	20 40 60 80 100 120 140 160 180
TV	L		0.76			-
FR	1/min		10.99			-
MV	L/min		8.31			-
VC	L	5.51	5.19 94			82-124
FVC	L	5.26	5.40 103	5.61 107	0.21 4	82-123
FEV1	L	4.44	4.71 106	4.87 110	0.16 3	81-124
FEV8	L	5.26	5.40 103	5.61 107	0.21 4	82-123
FEV1%(VC)	%	82.71	90.80 110			88-115
FEV1%(FVC)	%	82.71	87.32 106	86.89 105	-0.44 -0	88-115
PEF	L/s	10.00	11.61 116	12.18 122	0.57 5	78-130
FEF50	L/s	5.62	7.68 137	9.48 *169*	1.80 23	62-163
FEF75	L/s	2.66	2.57 97	3.19 120	0.62 24	52-193
FEF25-75%	L/s	5.08	6.40 126	7.22 142	0.82 13	-
FIVC	L		5.37	5.47	0.11 2	-
FIV1	L		5.37	5.47	0.11 2	-
FIV1%(VC)	%		103.40			-
FIV1%(FVC)	%		100.00	100.00	-0.00 -0	-
PIF	L/s		11.31	12.37	1.06 9	-

BEST CURVES



TRENDING



INTERPRETATION

Ventilation function : Normal
Spirometry finding : Normal
Bronchodilatation test: No significant change
Manual interpretation :

M8124-3-4.0-multi.htm

Figure: Standard final report.

8.8.2 Printing the Final Report

When the Final Report window is shown, you can use the **Print** button (see [Table: Medikro Measurements and Result Basic Buttons](#)) to print the Final Report. You can adjust the paper settings for printing by opening the **Page Setup** window. To open Page Setup select:

Database>Page Setup

or, during measurement, select:

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Medikro Oy

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Tel.: +358 17 283 3000

Home page: www.medikro.com

E-mail: medikro@medikro.com

Business ID: 0288691-7

VAT no.: FI02886917

Domicile: Kuopio

Study>Page Setup

8.8.3 Set Report Heading

The header of the report can be modified to include the name of the establishment, clinic, or institution, as well as the necessary contact information. Use the following command path:

Device>Set Report Heading

or

Device>Settings>Spirometry>Report Heading

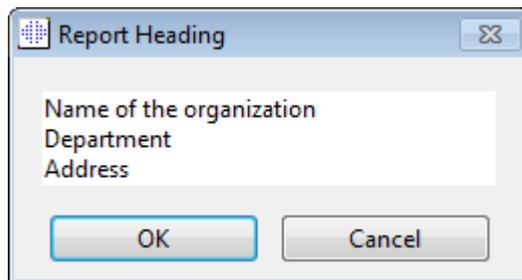


Figure: Set Report Heading Window

Enter the necessary information into the free text field, where 3 lines are provided. Individual report formats can be provided at request from Medikro Oy.

8.9 Help About

Displays a system summary window. The table inside the window contains information about:

- Spirometer hardware and its driver
- Current status of the spirometer
- Information about Calibration details
- System configuration, hardware details, and memory usage
- Operating system, Internet Explorer, and Java Virtual Machine details
- Communication details and status of the incentive
- Information about Database details

The information of the **Help About** window is useful if the user has a problem using the software. Especially, when the Medikro Spirometry Software user needs to contact Medikro Technical Support to solve a problem, it is highly recommended that this information should be sent to technical support.

The whole content of the About window can be saved in a separate report file by selecting **Save to file...** button. To open the Help About window, select:

Help>About

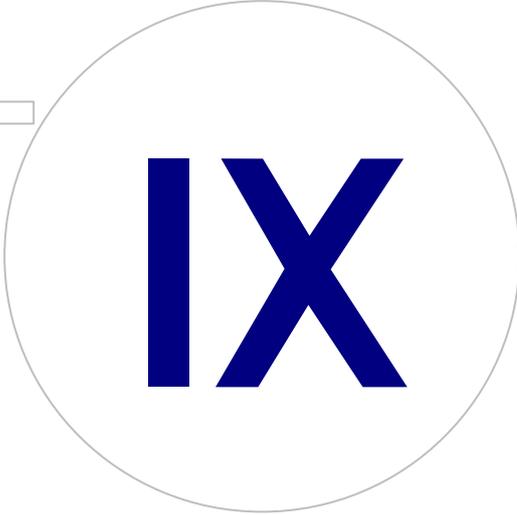
8.10 Keyboard Shortcuts

Keyboard shortcuts are for advanced Medikro Spirometry Software users.

The current keyboard shortcuts used in Medikro Spirometry Software are presented in the following table:

Keyboard Shortcut	Function in Medikro Spirometry Software
Ctrl+Shift+C	Start Calibration
Ctrl+I	Open Personal Information
F5	Start/Finish TV manoeuvre
F6	Start/Finish SVC manoeuvre
F7	Start/Finish FVC manoeuvre
F8	Start/Finish FIVC manoeuvre
F9	Start/Finish FVC+FIVC manoeuvre
F10	Start/Finish MVV manoeuvre
Ctrl+M	Start Measurement
Ctrl+V	Show Volume/Time Curve(s)
Ctrl+6	Show 6s Volume/Time Curve(s)
Ctrl+F	Show Flow/Volume Curve(s)
Ctrl+E	Show Curve(s)
Ctrl+A	Show Results of Measurements
Ctrl+B	Show Representative Results
Ctrl+T	Show Trend
Ctrl+R	Show Final Report
Ctrl+P	Print Current Window
Ctrl+H	Show Help
Ctrl+X	Exit
Enter	Positive response - Log On, OK, Yes etc., if a dialogue window is open
Esc	1) Negative response - Cancel, Close, Exit, No etc., if a dialogue window is open 2) Stop Measurement, if a measurement is going on 3) Exit

Screening Spirometry



IX

9 Screening Spirometry

This chapter describes how to perform, analyse and manage measurements using the Medikro Duo Spirometer together with the Medikro Spirometry Software user interface.

9.1 Variables

Abbreviation	Name	Unit
FEV1	Forced expiratory volume at 1.0s	L
FEV6	Forced expiratory volume at 6.0s In case the selected prediction model does not provide value for FEV6 but provides value for FVC, FEV6 is substituted by FVC.	L
FVC	Forced vital capacity.	L
FEV1/FEV6	FEV1 / FEV6	
FEV1/FVC	FEV1/FVC	
PEF	Peak expiratory flow	L/min or L/s

9.2 Screening Work Flows

Medikro Screener allows two ways to perform measurements: basic screening work flow and Medikro Quick Test work flow.

Note: User privileges are managed in Medikro Administration Tool. All operations may not be available for all users. For more information on access control management, see Medikro Administration tool user manual.

Basic screening

Perform screening for a selected person:

1. Search or create person (see chapter [Person and Study Management](#)).
2. Create study for the person (see chapter [Person and Study Management](#)).
3. Perform new measurements for the study (see chapter [Performing Measurement](#)).

Medikro Quick Test

Perform screening without person data:

1. Start Medikro software from the **Medikro Quick Test** application shortcut or from the **Go directly to study** button on Home View (see chapter [Persons and Studies Software Buttons](#))
2. Make new measurements for the study (see chapter [Performing Measurement](#)).

3. Enter study data (see chapter [Study Data Entry](#)).

It is not possible to save Quick Test study without person data. If you wish to save Quick Test study:

4. Go to Person view and save person data for the study (see chapter [Person Data Entry](#)). Note that the system automatically fills person's last name field with "Anonymous". Replace this text with person's correct name.

9.3 Screener Software Buttons

Table: Medikro Screener Buttons:

Button	Function and description
	Print Report button. Prints the contents of the currently shown measurement window
	Save Report button. Saves the contents of the currently shown measurement in pdf file.
	Friendly name button. Opens window where device name can be saved into the connected device.
	Refresh device list button. Executes a search for connected devices.

9.4 Measurement Manoeuvres

Explain the measurement and prepare the patient for the manoeuvre before the actual measurement. The measurement should also be demonstrated to the patient applying local recommendations. Pay attention to correct posture with head elevated, complete inhalation, flow transducer position, and complete exhalation. It is recommended to allow the patient to perform 1-2 sample manoeuvres before the measurement.

The flow transducer should be kept between the teeth to permit the maximal flow to go through the pneumotach. In addition, the flow transducer should be tightly sealed with the lips to avoid leakage flow. If necessary, any false teeth prostheses are removed before the spirometry session.

It is recommended to use a nose clip during the measurement.

9.4.1 FEV6 manoeuvre

FEV6 manoeuvre with closed circuit technique:

1. Place the flow transducer in the patient's mouth. The patient should breathe in a relaxed/normal rate and frequency through the flow transducer.
2. The patient inspires deep.
3. The patient expires fast and strongly. The expiration should last at least 6 seconds (assisted by incentive).
4. Remove the flow transducer from the patient's mouth.

FEV6 manoeuvre with open circuit technique:

1. The patient inspires deep.
2. The patient holds breath while placing the flow transducer in the mouth.
3. The patient expires fast and strongly. The expiration should last at least 6 seconds (assisted by incentive).
4. Remove the flow transducer from the patient's mouth.

9.4.2 PEF manoeuvre

PEF manoeuvre with closed circuit technique:

1. Place the flow transducer in the patient's mouth. The patient should breathe in a relaxed/normal rate and frequency through the flow transducer.
2. The patient inspires deep.
3. The patient expires in a forced manner fast and strongly.
4. Remove the flow transducer from the patient's mouth.

PEF manoeuvre with open circuit technique:

1. The patient inspires deep.
2. The patient holds breath while placing the flow transducer in the mouth.
3. The patient expires in a forced manner fast and strongly.
4. Remove the flow transducer from the patient's mouth.

9.4.3 FVC manoeuvre

FVC manoeuvre with closed circuit technique:

1. Place the flow transducer in the patient's mouth. The patient should breathe in a relaxed/normal rate and frequency through the flow transducer.
2. The patient inspires deep.
3. The patient expires fast and strongly. The expiration should last at least 6 seconds and until plateau (volume change <25mL in the last 1 s of expiration) has been achieved.
4. Remove the flow transducer from the patient's mouth.

FVC manoeuvre with open circuit technique:

1. The patient inspires deep.
2. The patient holds breath while placing the flow transducer in the mouth.
3. The patient expires fast and strongly. The expiration should last at least 6 seconds and until plateau (volume change <25mL in the last 1 s of expiration) has been achieved.
4. Remove the flow transducer from the patient's mouth.

9.5 Performing Measurement

To perform screening measurements, the study view has to be opened for Screening Spirometry study type, and Medikro Duo device has to be connected with the Medikro software.

- If Medikro spirometer is connected via USB, there is no need to turn the device power on manually. Medikro spirometer switches on automatically.
- If Medikro spirometer is connected via Bluetooth, turn the device power on manually from the Medikro spirometer power button to establish connection.

The study information can be entered any time on the study view, before or after measurements (see chapter [Study Data Entry](#)).

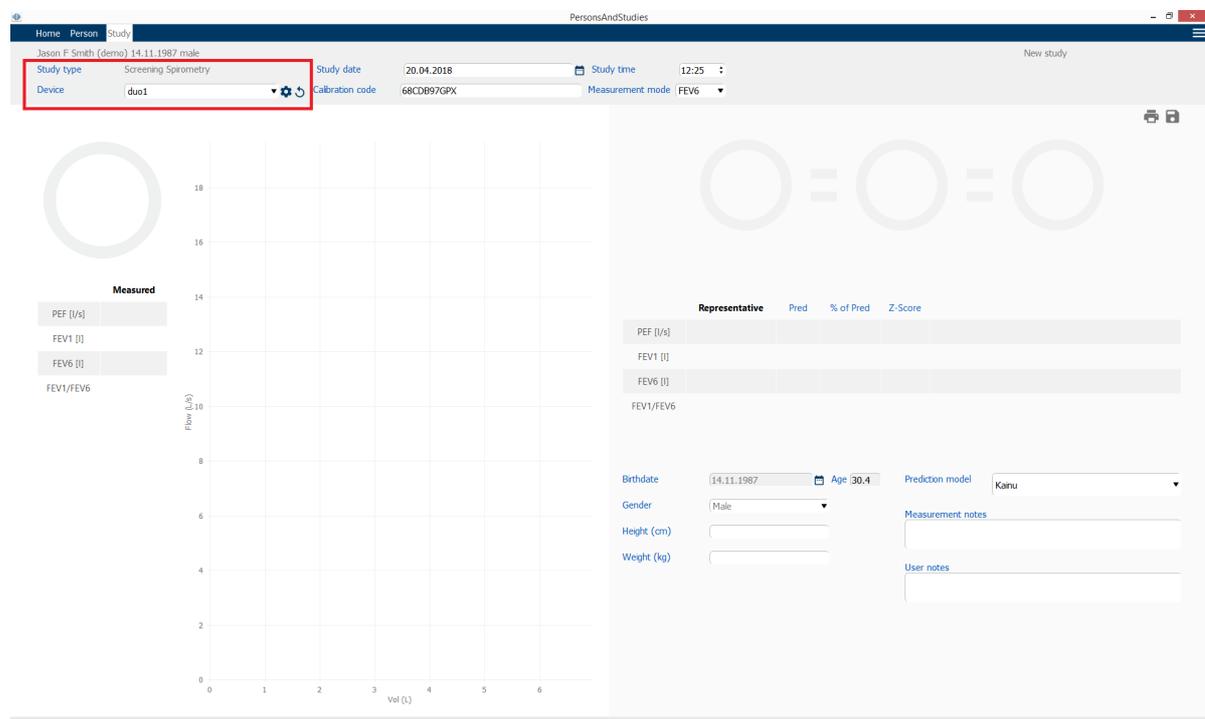


Figure: Ready for screening

9.5.1 Starting and Stopping Measurements

After the device is selected, performing measurements can be started. User does not need to manually start or stop the measurements. Measuring is started automatically when Medikro spirometer starts receiving breaths, and measuring is stopped automatically when performing breaths is stopped.

New breaths for the selected study can be performed until you exit the Study view. It is not possible to perform new breaths for studies that have previous measurements.

9.5.2 Saving Measurements

User does not need to manually save measurements. Measurements are automatically saved with the study when basic test is performed (See Chapter [Screening Work Flows](#)). In case study information

has been modified, confirmation dialogue for saving changes is shown.

9.5.3 Exit Measurement

Screening study is closed when navigating back to Person view or Home view, or when closing the Medikro Persons and Studies application completely. After this, it is only possible to select the study for viewing measurements. It is not possible to perform new measurements for the same study.

The spirometer turns off automatically in 20 seconds after the study is closed.

9.5.4 Deleting Measurements

It is not possible to delete individual measurements. The whole study can be deleted as instructed in chapter [Delete Persons and Studies](#).

9.6 Monitoring Blows

As the blows are performed, the programme shows:

1. **Flow-volume curve:** Shape of the air flows for active breath and representative breath.
2. **Measured values:** Measured values for current breath.
3. **Incentive:** Breath duration indicator.
4. **Quality indicators:** Indicates lazy blow, early termination, cough and hesitation, as well as successful breath for three most representative breaths.
5. **Reproducibility indicators:** Indicates whether a breath fulfills reproducibility criteria with the most representative breath.
6. **Representative results table:** Representative results. Measured, predicted and z-score values, and graphical presentation of the results.

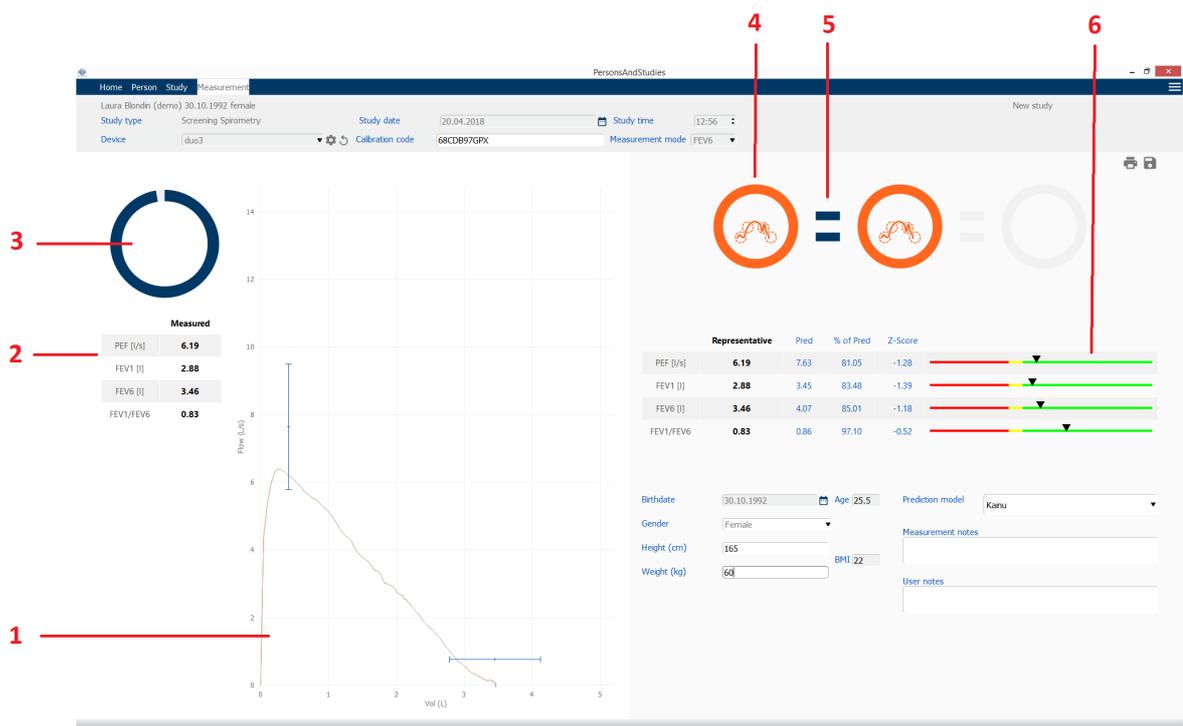


Figure: Measurement ongoing

9.6.1 Incentive

The incentive indicates the duration of the expiration.

- FEV6: The 6 seconds target time is reached when the incentive has drawn a full circle.
- FVC: 6 seconds and plateau are reached when the incentive has drawn a full circle.

When expiration is stopped, the incentive shows symbol for blow quality (see chapter [Blow Quality](#)).

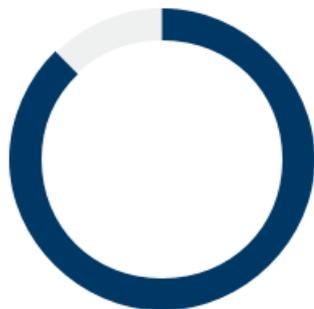


Figure: Incentive: duration of expiration



Figure: Incentive: blow quality

9.6.2 Measured values

The measured values are shown for the current breath only. As new breaths are performed, the values in the table are updated.

Measured	
PEF [l/s]	6.19
FEV1 [l]	2.88
FEV6 [l]	3.46
FEV1/FEV6	0.83

Figure: Measured values table

9.6.3 Blow Quality

Each performed breath is evaluated for quality and reproducibility. The breaths are represented as circles.

The three most representative breaths are placed in ranking order. When more than three blows are performed, only the three most representative breaths are shown.

Representative criteria in different measurement modes:

- FVC: FEV1+FVC
- FEV6: FEV1+FEV6
- PEF: PEF

Reproducibility

When a breath meets the reproducibility criteria with the most representative breath, a connector (=) is shown on the left of the breath indicator.



Reproducibility criteria in different measurement modes:

- **FVC:** The difference between two FEV1 values and between two FVC values is maximum of 150mL (if FVC <= 1L, maximum is 100 mL)
- **FEV6:** The difference between two FEV1 values and between two FEV6 values is a maximum of 150mL (if FEV6 <= 1 L, maximum is 100mL)
- **PEF:** The difference between the two PEF values is maximum of 20L/min

Quality Indicators

Indicator	Description
	<p>Successful Blow</p> <p>In case the blow does not have any artifacts, the success symbol is shown.</p>
	<p>Hesitation</p> <p>The hesitation symbol is shown when the start of the expiration is not fast and strong enough at the start of the effort.*</p>
	<p>Lazy Blow</p> <p>The lazy blow symbol is shown when the start of the expiration is not fast and strong enough. The expiratory peak is not high and sharp on the curve.*</p>
	<p>Cough</p> <p>The cough symbol is shown when coughing occurs during the first second of the expiration.*</p>
	<p>Early Termination</p> <p>The early termination symbol is shown when the expiration is not long enough. The criteria for acceptable expiration time is 6 seconds.*</p>

* Manoeuvre acceptability criterion defined by Enright et al. (1991) is applied.

9.6.4 Curve

The flow-volume curve is drawn for each breath during the breath. Also the curve for the representative breath of the current measurement is shown. The current breath curve is light blue and the representative breath curve is dark blue.

The line segments illustrate normal range and predicted value for measured variables. Line segment is drawn only if selected prediction model provides predicted value for the variable, and all required study data has been entered (see chapter [Study Data Entry](#)).

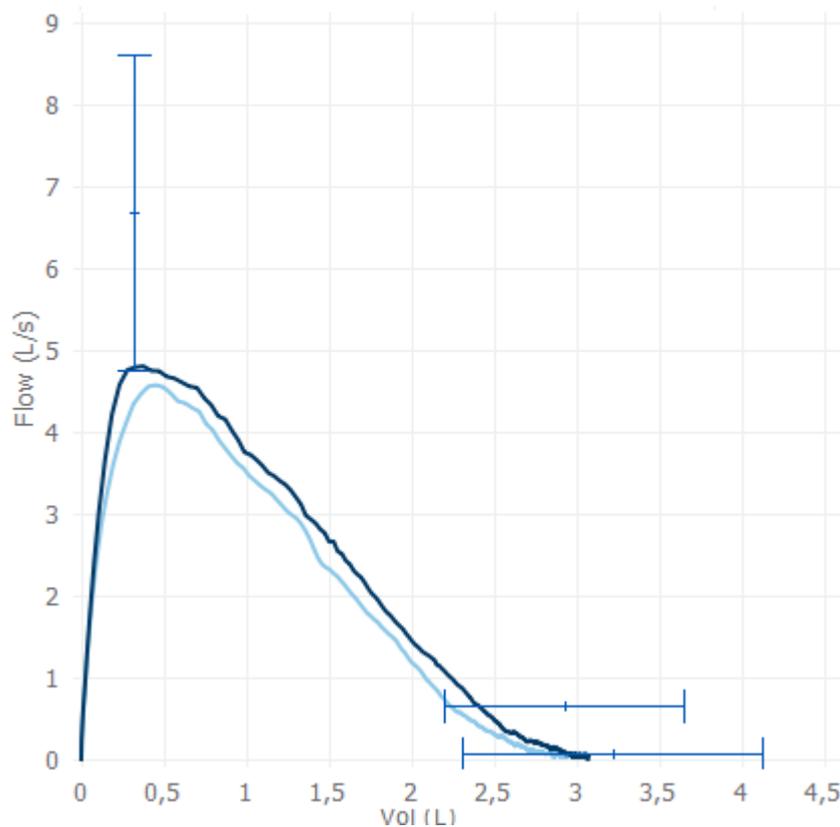


Figure: Flow-Volume Curve

9.7 Analyzing the Representative Results

Only the representative results of the measurements are saved for the study and are available for later viewing. The representative results can be viewed from the results table and curve.

Results table

Results table presents representative results for the measurement, as well as predicted values and z-score values if all required study data has been entered (see chapter [Study Data Entry](#)).

When z-score is available, graphical presentation indicates the z-value in respect of the normal range (± 1.645). The green area indicates that the z-value is within or above the normal range ($z \geq -1.645$). The yellow area indicates mild decrease ($-2.0 \leq z < -1.645$). The red area indicates more severe decrease ($z < -2.0$).

	Representative	Pred	% of Pred	Z-Score	
PEF [l/s]	6.64	7.62	87	-0.90	
FEV1 [l]	3.20	3.18	100	0.04	
FEV6 [l]	4.15	3.84	108	0.65	
FEV1/FEV6	0.77	0.82	94	-1.23	

Figure: Representative Results Table with z-score

When z-score is not available, graphical presentation indicates the measured values in relation to the predicted value (% of Pred). 100% scales in the middle of the scale. The green area indicates that the value is within or above the normal range.

	Representative	Pred	% of Pred	Z-Score	
PEF [l/min]	354	393	90		

Figure: Representative Results Table with % of pred

Flow-volume curve

The representative blow is drawn as flow-volume curve. The line segments illustrate normal range and predicted value for measured variables. Line segment is drawn only if selected prediction model provides predicted value for the variable, and all required study data has been entered (see chapter [Study Data Entry](#)).

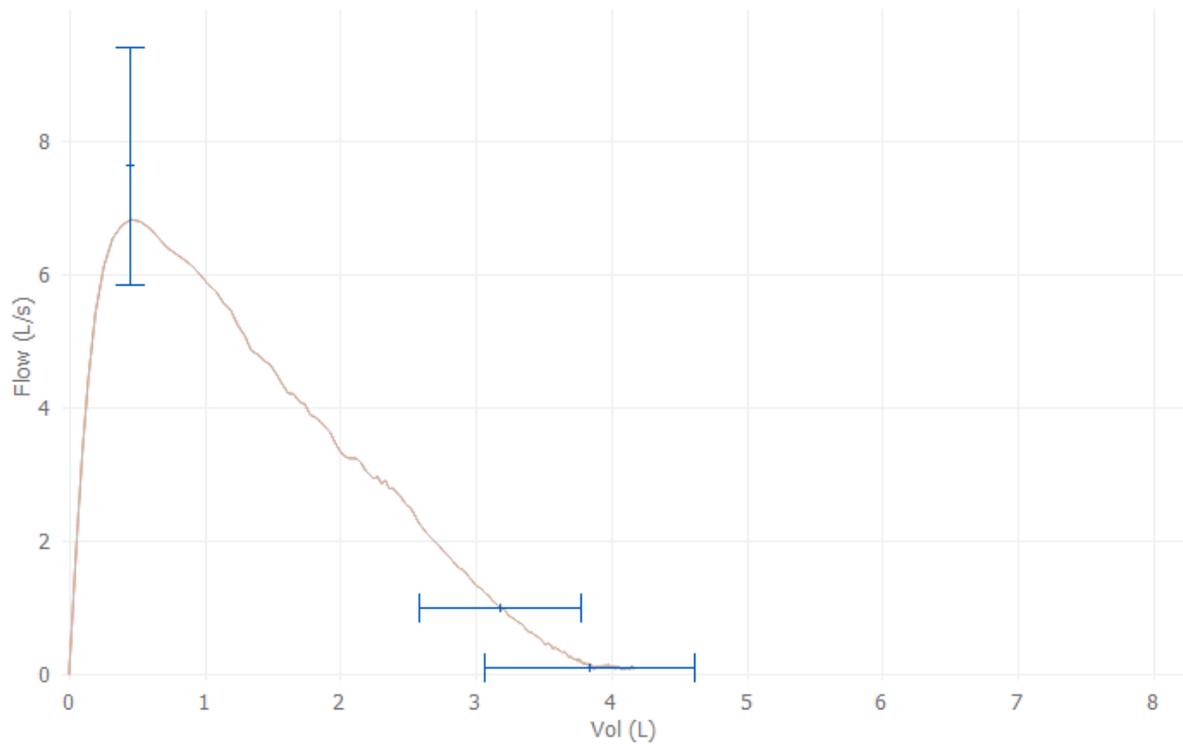


Figure: Curve

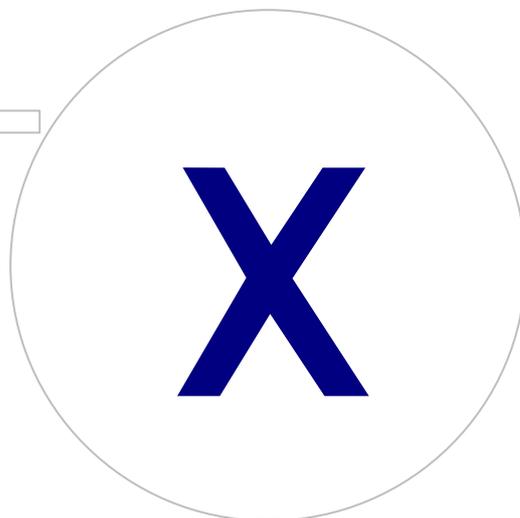
9.8 Report

On the study view, click the **Print Report** button to print the report, or click **Save Report** button to save the report as pdf-file.



Figure: Print Report and Save Report buttons

Serial Monitoring Spirometry



10 Serial Monitoring Spirometry

This chapter describes how to perform, analyse and manage measurements using the Medikro Duo Spirometer together with the Medikro Spirometry Software user interface.

10.1 Variables

Abbreviation	Name	Unit
FEV1	Forced expiratory volume at 1.0s	L
FEV6	Forced expiratory volume at 6.0s In case the selected prediction model does not provide value for FEV6 but provides value for FVC, FEV6 is substituted by FVC.	L
FVC	Forced vital capacity.	L
FEV1/FEV6	FEV1 / FEV6	
PEF	Peak expiratory flow	L/min or L/s

10.2 Serial Monitoring Software Buttons

Table: Medikro Serial Monitoring Buttons:

Button	Function and Description
	Friendly name button. Opens window where device name can be saved into the connected device and option to show or hide numerical display of the connected device.
	Refresh device list button. Executes a search for connected devices.
	Study information button. Opens study information window allowing to change study information.
	Download measurements button. Downloads measurements from the connected device to a study.
	Designate device button. Designate the connected device to person and study.
	Print Report button. Prints result contents of the currently shown study.
	Save Report button. Saves result contents of the currently shown study.
	Enable Comparison button. Enable or disable comparison to target value.
	Show Quality Indication button. Show or hide quality indication in trend.

	Enable PEF Variable button. Enable or disable PEF breath variable in the study results.
	Enable FEV1 Variable button. Enable or disable FEV1 breath variable in the study results.
	Enable FEV6 Variable button. Enable or disable FEV6 breath variable in the study results.
	Enable FEV1/FEV6 Variable button. Enable or disable FEV1/FEV6 breath variable in the study results.

10.3 Measurement Manoeuvres

Explain the measurement and prepare the patient for the manoeuvre before the actual measurement. The measurement should also be demonstrated to the patient applying local recommendations. Pay attention to correct posture with head elevated, complete inhalation, flow transducer position, and complete exhalation. It is recommended to allow the patient to perform 1-2 sample manoeuvres before the measurement.

The flow transducer should be kept between the teeth to permit the maximal flow to go through the pneumotach. In addition, the flow transducer should be tightly sealed with the lips to avoid leakage flow. If necessary, any false teeth prostheses are removed before the spirometry session.

It is recommended to use a nose clip during the measurement.

10.3.1 FEV6 manoeuvre

FEV6 manoeuvre with closed circuit technique:

1. Place the flow transducer in the patient's mouth. The patient should breathe in a relaxed/normal rate and frequency through the flow transducer.
2. The patient inspires deep.
3. The patient expires fast and strongly. The expiration should last at least 6 seconds.
4. Remove the flow transducer from the patient's mouth.

FEV6 manoeuvre with open circuit technique:

1. The patient inspires deep.
2. The patient holds breath while placing the flow transducer in the mouth.
3. The patient expires fast and strongly. The expiration should last at least 6 seconds.
4. Remove the flow transducer from the patient's mouth.

10.3.2 PEF manoeuvre

PEF manoeuvre with closed circuit technique:

1. Place the flow transducer in the patient's mouth. The patient should breathe in a relaxed/normal rate and frequency through the flow transducer.
2. The patient inspires deep.

3. The patient expires in a forced manner fast and strongly.
4. Remove the flow transducer from the patient's mouth.

PEF manoeuvre with open circuit technique:

1. The patient inspires deep.
2. The patient holds breath while placing the flow transducer in the mouth.
3. The patient expires in a forced manner fast and strongly.
4. Remove the flow transducer from the patient's mouth.

10.4 Serial Monitoring Measurement Modes

Serial monitoring can be done with the modes supported by Medikro Duo Spirometer (see Table: [Measurement modes](#)). The appropriate mode can be selected by selecting the corresponding serial monitoring study type.

- Select PEF monitoring study type for PEF mode serial monitoring.
- Select FEV monitoring study type for FEV mode serial monitoring.

Note: Measurements performed with a certain mode cannot be later converted to another mode!

10.5 Serial Monitoring Work Flows

Medikro Serial Monitoring allows you to create a study and to designate a device for the selected person before the monitoring period. The measurements from the device can then be saved directly to the created study without selecting the person.

Measurements from the device can also be downloaded by selecting a person first and then saving the measurements to the person.

Prepare a serial monitoring study for a selected person:

1. Search or create person (see chapter [Person and Study Management](#)).
2. Create study for the person (see chapter [Person and Study Management](#)).
3. Designate a device for the person (see chapter [Designate Device](#)).

Import designated serial monitoring measurements to the software:

1. Go straight to study from Home View (see chapter [Persons and Studies Software Buttons](#)).
2. Download measurements from device (see chapter [Download Measurements from Device](#)).

Import designated serial monitoring measurements to designated study:

1. Search person (see chapter [Person and Study Management](#)).
2. Select designated study (see chapter [Person and Study Management](#)).
3. Download measurements from device (see chapter [Download Measurements from Device](#)).

Import undesignated serial monitoring measurements to the software:

1. Search or create person (see chapter [Person and Study Management](#)).
2. Create study for the person (see chapter [Person and Study Management](#)).
3. Download measurements from device (see chapter [Download Measurements from Device](#)).

The study information can be entered any time on the study view, before or after measurements (see chapter [Study Data Entry](#)). Note that if target values are wanted to be set to the device, then prerequisite information needs to be entered before the designation (see chapter [Study Data Entry](#)).

10.6 Designate Device

The device is set automatically to correct mode when being designated. Target values will also be set to the device with the designation if they are available. It is not compulsory to designate the device for a person, but then it must be made sure that the device is in correct mode and the previously set target values are correct or empty.

To designate a device, the study view has to be opened for appropriate Serial Monitoring Spirometry study type, and Medikro Duo device has to be connected with the Medikro software.

- If Medikro spirometer is connected via USB, there is no need to turn the device power on manually. Medikro spirometer switches on automatically
- If Medikro spirometer is connected via Bluetooth, turn the device power on manually from the Medikro spirometer power button to establish connection



To designate the device, click the Designate device button

10.7 Download Measurements from Device

Measurements are removed from the device when they are transferred from the device to a database. Target values are cleared from the device when corresponding measurements are removed.

To download measurements from a device, the study view has to be opened for same Serial Monitoring Spirometry study type as the measurements, and Medikro Duo device has to be connected with the Medikro software.



To start a download, click Download measurements button . A dialog showing the designations and measurements contained in the device is shown. Note that if study view is entered straight from the home view and only one device is connected, the dialog opens automatically.

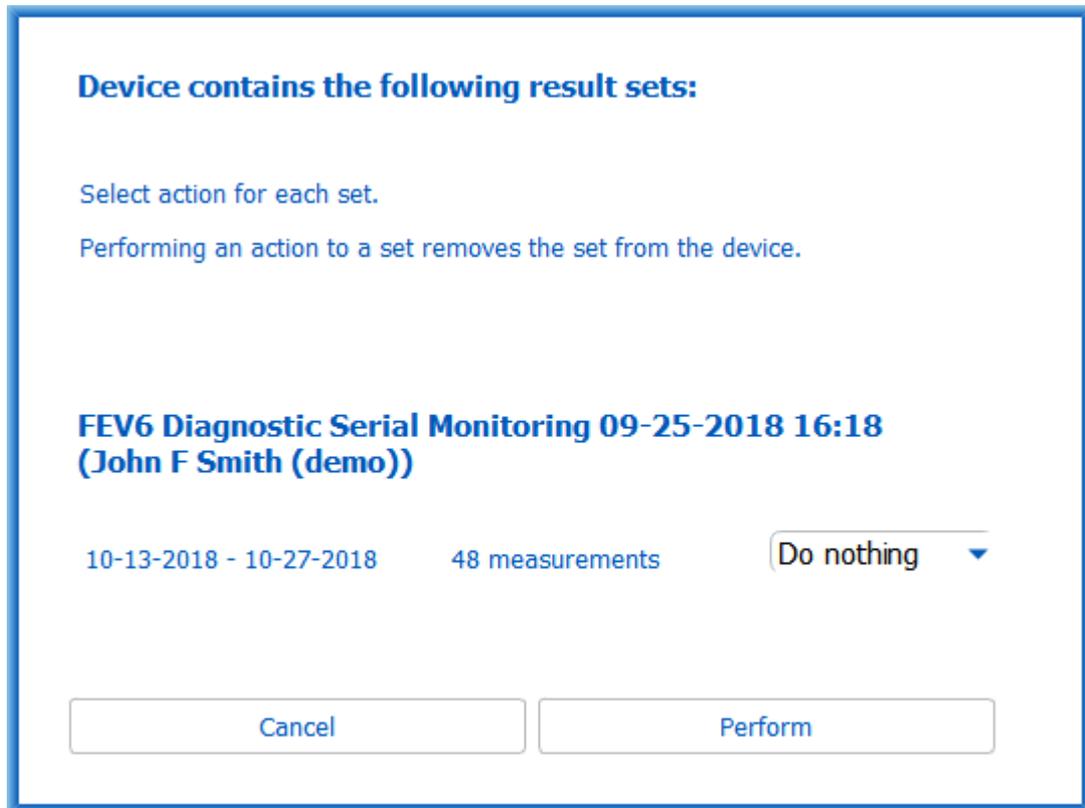


Figure: Serial monitoring download dialog

Measurements from a device can be downloaded and shown on the study view or they can be directly stored to a designated study without viewing them.

Open to View

Select Open to view option for the measurements that you want to download and then click Perform button.

Save Directly from Device

Select Store to option for the measurements that you want to download and then click Perform button.

Do nothing

Do nothing to the measurements.

Delete

Select Delete option for the measurements that you want to delete and then click Perform button.

10.8 Analyzing the Results

After measurements are downloaded to a study or existing Serial Monitoring study is opened results can be analyzed from study view. Result contents will update automatically if study content is manipulated by the operator.

Blow Quality

Summary of the recording quality contains following items:

- Calendar icon with number of measurement days. Hovering cursor over the icon shows start and finish date of the study as a tooltip.
- Successful blow icon with number of measurements having two reproducible breaths without quality errors in three of the most representative breaths of total number of measurements.
- Failed icon with number of unsuccessful measurements of total number of measurements.
- Unequal icon with number of measurements not having two reproducible breaths in three of the most representative breaths of total number of measurements.
- Hesitation icon with number of measurements having hesitation in top three breaths of total number of measurements.
- Lazy blow icon with number of measurements having lazy blow in top three breaths of total number of measurements.
- Cough icon with number of measurements having cough in top three breaths of total number of measurements.
- Early termination icon with number of measurements having early termination in top three breaths of total number of measurements.

Hovering cursor over the items shows description of the item as a tooltip.

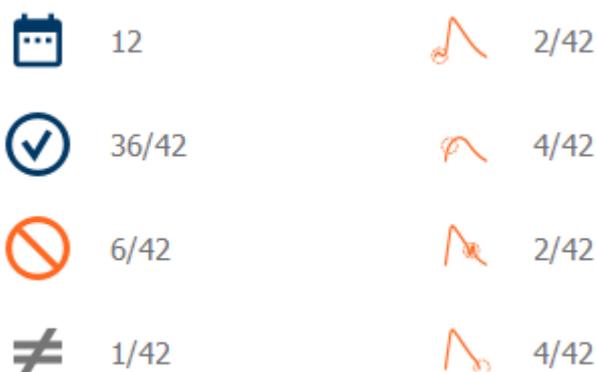


Figure: Summary of the recording quality

Results Figure

Results figure contains figures with average results for each breath variable available for the study. The results figure has options to choose which breath variable figure is visible or option to show all breath variable figures side by side.

Each breath variable figure has a fixed scale so that just by looking the figure results a possible respiratory problem can be detected.

Figure shows average measurement PRE values for morning and evening separately (Figure, 1.). If there is variation between morning and evening averages, it can be seen in the figure (Figure, 2.). Average PRE value for study is also shown in the figure (Figure, 3.).

If daily measurements were performed only in the morning or evening, only average is shown.

After medication average measurement POST values (Figure, 4.) and responses to medication (Figure, 5.) are shown in the figures if phases after medication were performed.

Values can be seen as a tooltips by hovering cursor over the graphical items in the figure (Figure, 6.).

It is possible to emphasize response to medication and the daily variation in the figure by pressing down the zoom button in the results figure. (Figure, 7.)

Comparison to target values is shown in the figure if required study information is set and comparison is enabled in the study. (Figure, 8.)



Figure: Results figure

Summary Table

Summary table shows average measurement values of the study. Averages are compared to comparison target values if required study information is set and enabled. Daily variation of measurements is shown with percentage and number of significant variations. Average bronchodilation response after medication is shown with percentage and number of significant responses.

Table contents in PEF monitoring study:

Average before bronchodilatation medication	Average of morning measurement values before medication	Percentage of the morning average to comparison target value	Average of evening measurement values before medication	Percentage of the evening average to comparison target value
Daily Variation	Average variation of daily measurement values before medication	Average percentage of the daily variation	Number of times when daily variation is significant (variation is equal or greater than 20%) [1]	
Bronchodilatation response	Average response to medication	Average percentage of the response to medication	Number of times when bronchodilatation response is significant (response is equal or greater than 15% and additionally over 60L/min for adults) [2]	

1. When number of significant daily variations is equal or greater than three, table cell border becomes red indicating significant daily variation in the study.
2. When number of significant responses is equal or greater than three, table cell background becomes red indicating significant bronchodilatation response in the study.

Table contents in FEV monitoring study for each breath variable:

Average before bronchodilatation medication	Average of morning measurement values before medication	Percentage of the morning average to comparison target value	Average of evening measurement values before medication	Percentage of the evening average to comparison target value
Daily Variation	Average variation of daily measurement values before medication	Average percentage of the daily variation		

Bronchodilatation response	Average response to medication	Average percentage of the response to medication		
----------------------------	--------------------------------	--	--	--

Trend

Trend has a slider with two handles to control day range of the trend (Figure, 1.) and a chart for each breath variable available for the study (Figure, 2.). First and last day with selected day count of total count of study days is shown over the slider.

Each handle of the slider (Figure, 3.) can be used to change the range of measurement days which are presented in the chart(s). Slider is always reset to first and last measurement day of the study when study is opened.

Each chart has a vertical scale for measurement values. Scale limits are automatically set with the measurements included in the selected day range (Figure, 4.). Horizontal axis of the scale contains all days of the selected day range (Figure, 5.).

Each day in the chart is divided to morning 00:00 - 11:59 (Figure, 6.) and evening 12:00 - 23:59 sections (Figure, 7.). If there is significant bronchodilation response, a background of the section is shown as red (Figure, 8.). If there is significant daily variation, a red border is shown around the morning and evening section (Figure, 9.).

Measurements of the study are divided to PRE and POST phases automatically. Individual measurements in both phases are shown as dots connected with lines (Figure, 10.). Failed measurements are shown with failed icon (Figure, 11.).

Hovering cursor over the measurement dot shows numerical value of the measurement's representative result as a tooltip (Figure, 12.). Clicking the measurement dots pins the numerical tooltip to stay visible (Figure, 13.). Clicking pinned measurement again hides the pinned tooltip. Right clicking the chart opens an option to hide all pinned tooltips at once.

Right clicking the measurement dot opens a menu with option to exclude measurement or option to change phase of the measurement. If measurement is excluded, it is shown with exclusion icon in the chart (Figure, 14.) and all result contents are updated ignoring the excluded measurement. Result contents will also change if the measurement phase is changed.

Comparison to target values is shown in the chart if required study information is set and comparison is enabled in the study. (Figure, 15.)

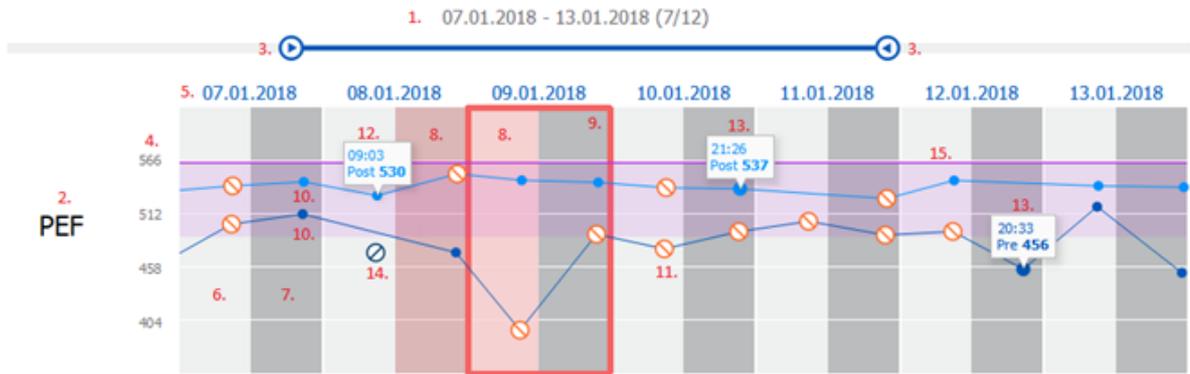


Figure: Trend

10.9 Report

On the study view, click the **Print Report** button to print the report, or click **Save Report** button to save the report as pdf-file.



Figure: Print Report and Save Report buttons

10.10 Saving Study

User does not need to manually save measurements. Measurements are automatically saved with the study when measurements are downloaded from a device (See Chapter [Serial Monitoring Work Flows](#)). In case study information has been modified, confirmation dialogue for saving changes is shown.

10.11 Exit Study

Serial monitoring study is closed when navigating back to Person view or Home view, or when closing the Medikro Persons and Studies application completely. After this, it is only possible to select the study for viewing measurements. It is not possible to append new measurements for the same study.

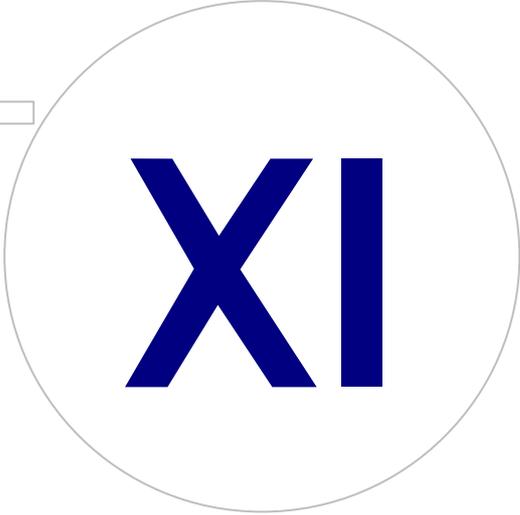
The spirometer turns off automatically in 20 seconds after the study is closed.

10.12 Deleting Measurements

It is not possible to delete individual measurements. The whole study can be deleted as instructed in chapter [Delete Persons and Studies](#).

Measurements can be excluded from result calculations by excluding them from trend chart (See Chapter [Trend](#)).

Troubleshooting



XI

11 Troubleshooting

Problems with spirometry measurements are related to instrument failures and erroneous manoeuvres.

Instrument failures are typically either mechanical or software related. Typically problems are related to:

- spirometer and computer connection
- operating environment
- software
- spirometer search
- leaks

Typical problems

- The Spirometer connection to the computer may be loose. Make sure the connector is in place.
- The minimum system requirements should be fulfilled to guarantee that the software functions properly. The minimum requirements can be found in the release information .
- Software related problems are system-dependent. Memory allocation, processor speed, operating system, other devices and applications play a significant role. The user is advised to contact Medikro Technical Support or to search for ready-made answers on the Medikro Oy homepage (www.medikro.com/eSupport).
- The Spirometer can sometimes experience air leakage. Leaks may occur if pressure tubing is damaged or if any connection between the flow transducer, pressure tube and spirometer is not properly fastened.

Medikro Primo, Nano and Pro spirometers: Leaks can be detected by daily calibration of the spirometer. If the gain value after calibration is not in the acceptable gain range, the software will inform the user with the "Calibration, Not Accepted" message. Make sure that the pressure tube is properly fastened to the transducer and to the spirometer unit. Check the pressure tube and replace it if it is leaking or unclean. It is recommended to change the pressure tube after 300 patients or four times a year.

Medikro Duo spirometers: Make sure that the flow transducer is properly fastened to the spirometer unit.

- Incorrect calibration code. The calibration code is not changed when the use of a new flow transducer lot is started. This might lead to inaccurate calibration or calibration check.

Messages Associated with Error Situations



XII

12 Messages Associated with Error Situations

Error Messages Associated with Signing in

An error message is displayed if password is missing

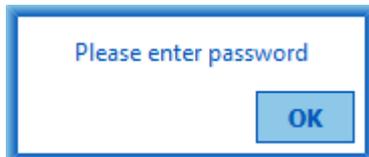


Figure: Missing password

An error message is displayed if internal user authentication fails

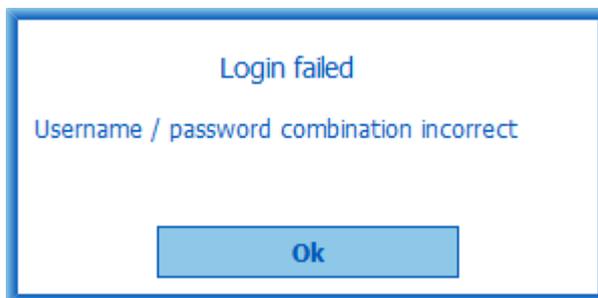


Figure: Incorrect username-password combination

An error message is displayed if Windows user authentication fails

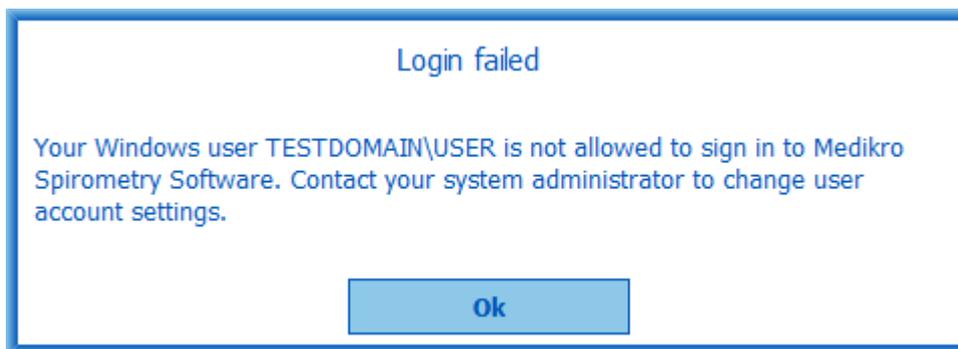


Figure: User not authorised

Error Messages Associated with Person and Study Management

An error message is displayed when leaving Person view with unsaved changes and mandatory person data is missing.

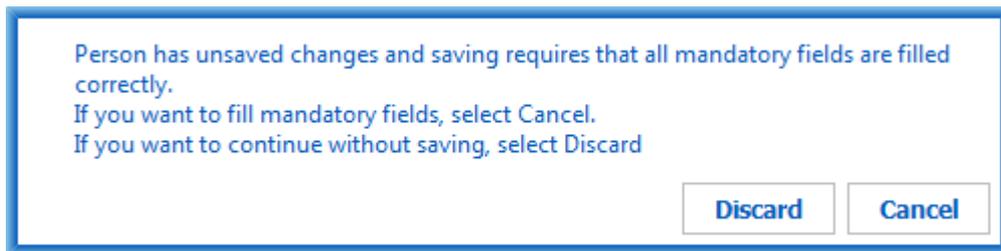


Figure: Mandatory person data missing

An error message is displayed when opening existing study but mandatory person data is missing.

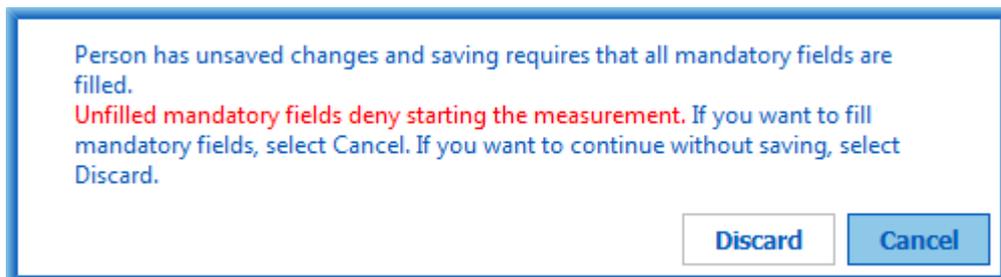


Figure: Mandatory person data missing for old study

An error message is displayed when leaving Study view with unsaved changes and mandatory study data is missing.

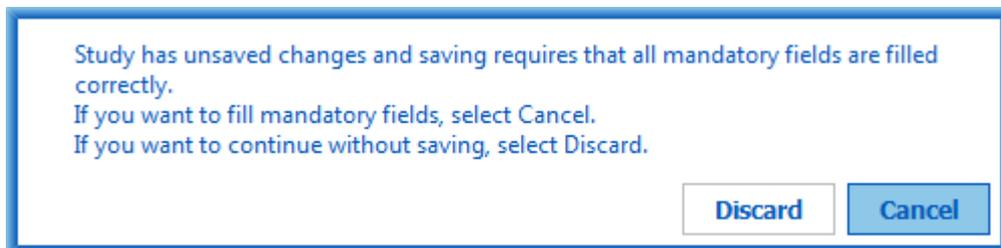


Figure: Mandatory study data missing

Error Messages Associated with Import

An error message is displayed when manually selected import file cannot be imported.



Figure: Cannot import selected file

An error message is displayed when automatic import file cannot be imported.

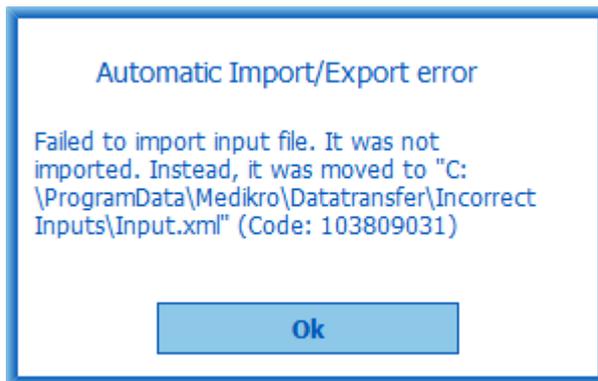


Figure: Cannot import input file

An error message is displayed when automatic import file contains multiple persons.



Figure: Cannot import multiple persons

An error message is displayed when automatic import tries to proceed to measurement but mandatory study data is missing.

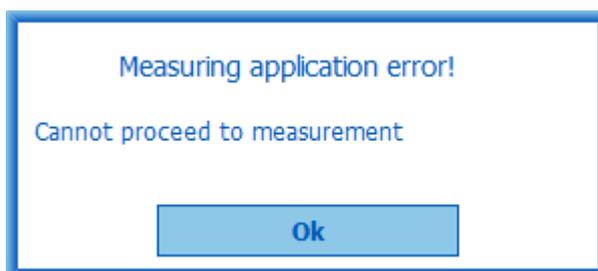


Figure: Cannot proceed to measurement

An error message is displayed when automatic import is triggered but user does not have privilege to import.

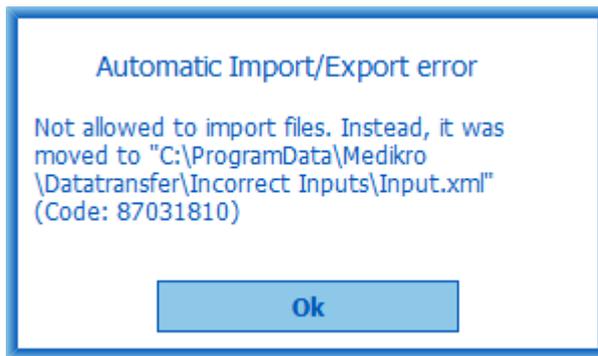


Figure: No import permission

An error message is displayed when automatic export is triggered but user does not have privilege to export.

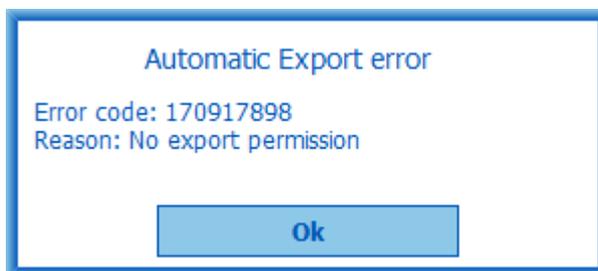


Figure: No export permission

Error Messages Associated with Database connection

An error message is displayed if client is connected to online server and connection is interrupted

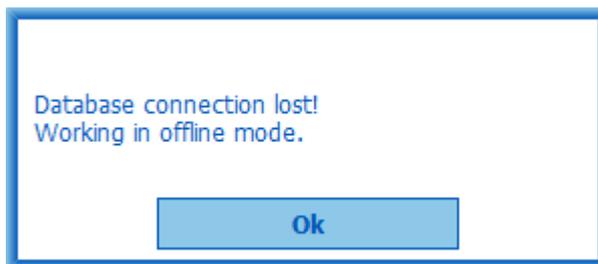


Figure: Connection lost

An error message is displayed if data synchronisation fails.

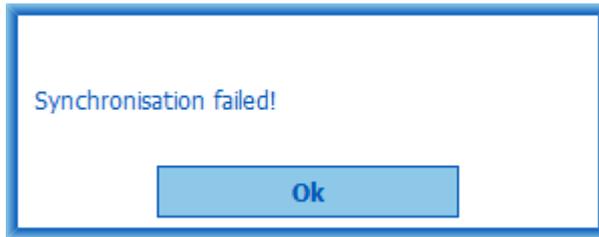


Figure: Synchronisation failed

Error Messages Associated with open Measurement

An error message is displayed if study is open in Measurements and Results and trying to exit software or study view

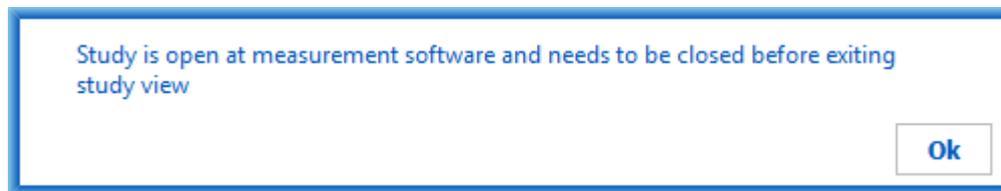


Figure: Measurement open

12.1 Measurements and Results Error messages

Error Message Associated with the Calibration Code

An error message is displayed if calibration code has not been entered. Measurements cannot be performed with Measurements and Results before calibration code is entered.

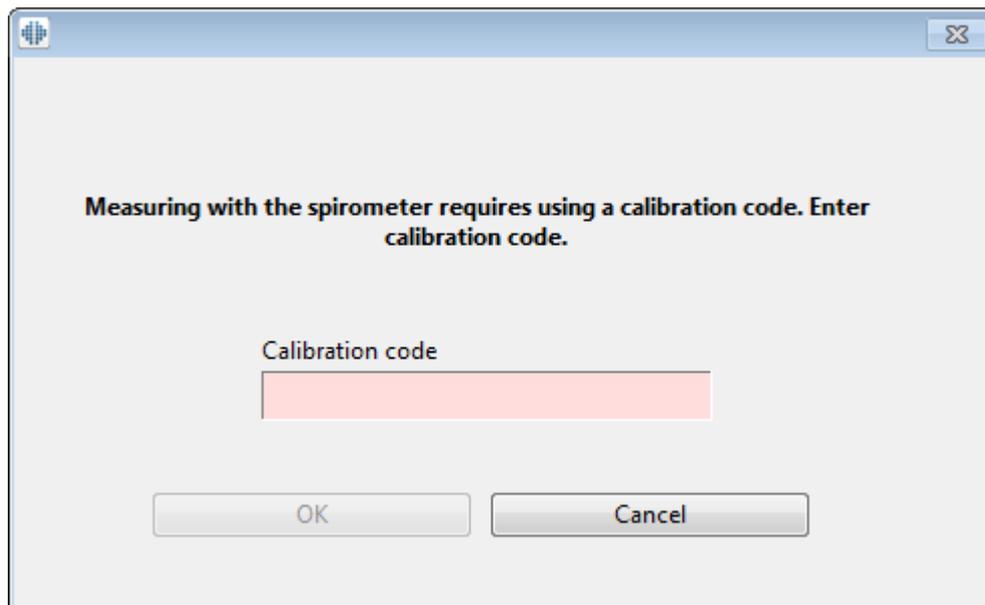


Figure: Calibration code missing

Error Message Associated with Performing Measurements

An error message is displayed if you are trying to do more than 8 measurements in one phase. If more measurements are required you need to delete measurements from this phase. More information about how to delete the measurement can be from chapter [Deleting an Individual Measurement](#).

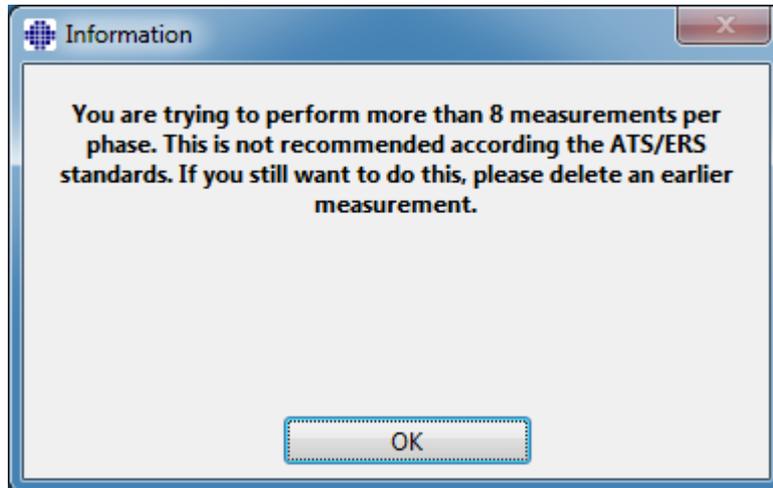


Figure: 8 measurements in one phase

Error Messages Associated with the Spirometer and External Ambi Unit

An error message is displayed if spirometer and/or external Ambi unit is not connected to the computer. Check that the devices are properly connected to the computer. If automatic detection is selected the software will automatically detect the devices.

More information about how to change the device detection settings can be found from chapter Detection of external Ambi unit.

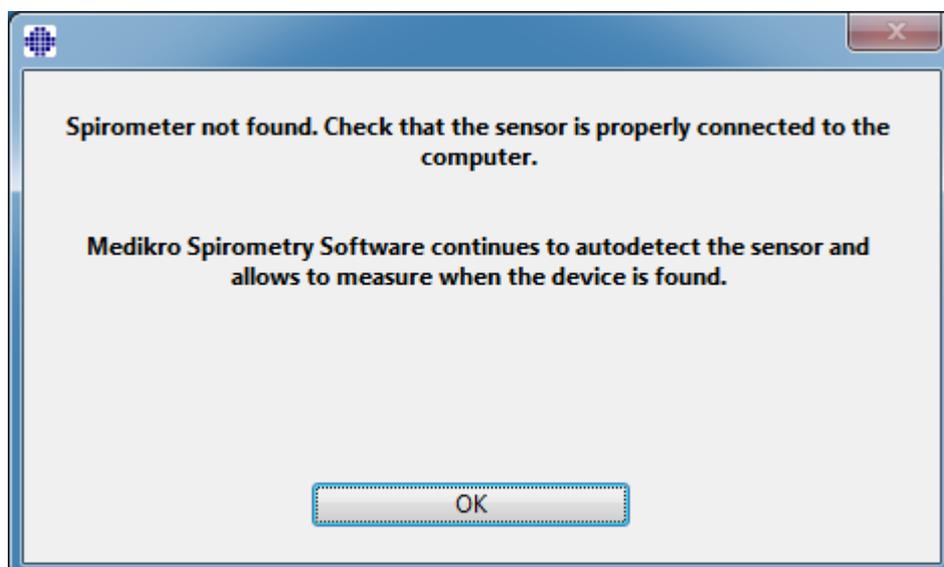


Figure: Spirometer not found message

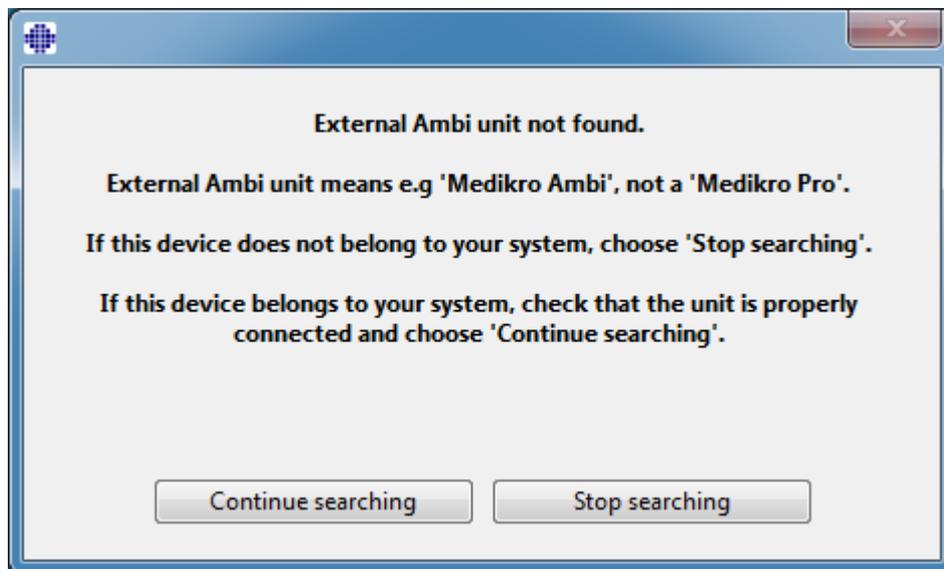


Figure: Ambient condition unit not found message

12.2 Screener Error Messages

An error message is displayed if device connection is lost

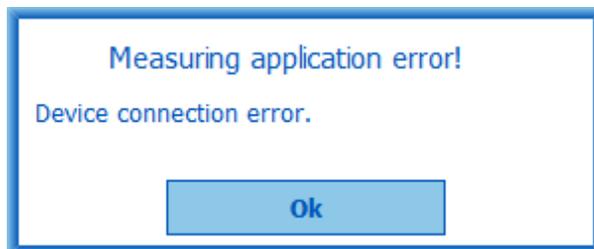


Figure: Device Connection Error

12.3 Serial Monitoring Error Messages

An error message is displayed if device connection is lost



Figure: Device Connection Error

An error message is displayed if device designation fails

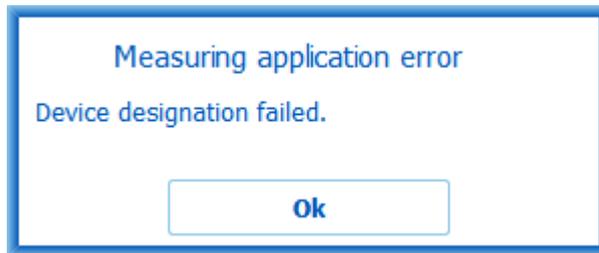


Figure: Device Designation Error

An error message is displayed if device firmware version is not compatible

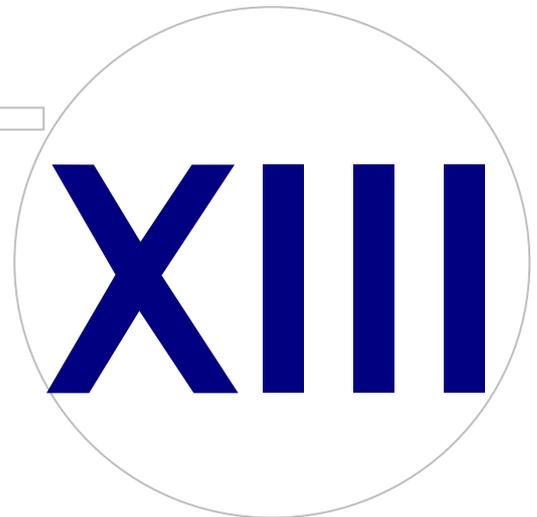


Figure: Device Firmware Version Error

12.4 Medikro Device Error Messages

Error Code	Description	Solution
ER0001	SD card error	Reset the device (see chapter Overview of the Medikro Duo Device Interface). If the error persists, send the product to Medikro's service centre for repair (see chapter Warranty & Service).

Appendix: References



13 Appendix: References

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